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# Fusion Bx 2.0

v. 2.4

## USER MANUAL



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

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Product specifications are subject to change without notice. The information in this manual is intended for informational use only, is subject to change without notice, and should not be construed as a commitment by Focal Healthcare. Focal Healthcare assumes no responsibility or liability for any error or inaccuracies that may appear in this publication. In addition, it is the sole responsibility of the user to ensure he or she is receiving the most up-to-date information.

**Disclaimer:** This is a professional version. Users must have a working knowledge of English and be a physician, or medical specialist familiar with the biopsy planning and biopsy sample extraction process. It is essential that all data entered are correct and that all results are verified.

**For any assistance, contact your Focal Healthcare representative.**

**Installation by anyone other than authorized Focal personnel or delegated representative could void your warranty for this device.**

**⚠ WARNING:** This user manual contains information on the safe use and operation of this device. Please read this entire manual and all safety information before installation, operation, maintenance, or repair of this device. Always follow the recommended use and operation.

If, in relation to the use of this device, a death or a serious deterioration of health has occurred, this should be reported to the Focal Healthcare and the competent authority of the county in which the user and/or patient is established. When in doubt, please consult with a advisor on regulatory affairs.



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# 1 CONFORMITY WITH STANDARDS

Fusion Bx conforms to the following electrical safety and imaging standards:

- AAMI/ANSI ES 60601-1:2005/(R)2012 Medical Electrical Equipment, Part 1—General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2 Edition 4.0: 2014 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements And Tests
- IEC 60529: 1989+A1:1999—The device has an IPX0 protection level as per this standard.
- DICOM—Image data imported to and exported from Fusion Bx is DICOM compliant.

# 2 SAFETY FEATURES

Fusion Bx has been designed with a number of safety features in place to ensure the device is used as safely and effectively as possible during procedures.

The main safety features include:

- Fully locking casters to prevent cart movement during a procedure
- Multiple brakes along the hardware arm, including the swing arm and tracker, for ease of setup and targeting
- Labelling on the hardware to indicate locking mechanisms and potential hazards
- On-screen software error messages to indicate when something is wrong (e.g. tracking is poor, invalid DICOM images)

# 3 INTENDED USE

Fusion Bx is intended for use by physicians for enhanced visualization of ultrasound imaging of the prostate in clinic and hospital settings. It provides 2D and 3D image visualization including review, manipulation, and analysis tools. Additional features include patient data management, image measurement, multiplanar reconstruction, 3D image registration, segmentation, image annotation, and to record the locations where the biopsies were acquired during the procedure.

# 4 GENERAL CAUTIONS AND WARNINGS

This manual serves as a reference guide only. The contents are not intended to supersede the healthcare professional’s instructions regarding the use of the device. Individuals using this equipment should read all cautions, precautions, contraindications, and warning labels provided in this manual. They must be fully trained by Focal-qualified personnel on how to use the device prior to operation. To see the list of warning labels found on Fusion Bx, see Appendix B. Labels.

## 4.1 CAUTIONS

### GENERAL



- U.S. federal law restricts the sale of this device to, or on the order of, a physician.
- Fusion Bx is intended for use by healthcare professionals only.
- Do not operate the device in a manner not specified in this manual.

### INTRA-PROCEDURE

- The stepper is designed to provide enough range of motion to clear the patient table and to image/biopsy the entire prostate. In addition, it will restrict excessive movement that could contact and/or adversely impact the patient.
- Prior to performing a fusion biopsy, ensure the base of the probe is pressed firmly against the stepper cradle, as shown in Figure 3. If the probe base is not flush with the stepper cradle, tracking accuracy may be impacted. This may increase the likelihood of diagnosis and/or treatment errors.
- Lag between the probe movement and on-screen video capture may occur. If this happens, immobilize the probe and wait a few seconds until the on-screen display catches up.
- Only the following ultrasound settings may be changed during the procedure: Flip L/R, depth, and gain.
- If unintended ultrasound setting changes take place, do not proceed with the workflow until all correct ultrasound settings are restored, and all warnings are cleared.
- It is standard of care to follow fusion procedure up with a systematic biopsy.
- Cables should not be unplugged at any time during the procedure.
- Do not unplug the ultrasound machine or transrectal ultrasound (TRUS) probe while 3D ultrasound reconstruction is processing.

### SECURITY

- Always logout of the Fusion Bx software when leaving the system unattended. For details regarding correct system start-up and shutdown, see Sections 6.3 and 6.14.
- For added security, the system times out after 30 minutes of inactivity to reduce the risk of unauthorized access.
- Fusion Bx is not intended to be used as a storage device. Data on Fusion Bx should be backed up regularly to a secure location.
- Only encrypted USB flash drives should be used for patient data transfer to and from Fusion Bx.
- Fusion Bx should only be connected to a secure and trusted network.

- If the Fusion Bx hardware is connected to a network, internet connectivity can be manually enabled or disabled. Focal Healthcare recommends that internet connectivity is disabled unless it is being used for remote support.

## INSTALLATION AND MAINTENANCE

- Installation by anyone other than authorized Focal personnel or delegated representative could void your warranty for this device.
- No unauthorized modification of this equipment is allowed.
- The use of accessories and cables other than those supplied by the manufacturer may result in increased electromagnetic emissions or decreased electromagnetic immunity and may cause the system to be non-compliant with the requirements of IEC 60601-1-2:2014 Edition 4.
- Fusion Bx has been tested for electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in Appendix H. Safety Specifications.
- Follow your local guidelines for the proper disposal of electrical medical devices, or contact Focal for disposal instructions.

## ENVIRONMENTAL HAZARDS

- Fusion Bx must only be used in an environment which satisfies the requirements stipulated in Section 6.1.
- This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the equipment or shielding the location.
- Portable and mobile radiofrequency (RF) communications equipment and Magnetic Resonance (MR) environment can affect the device.

## MECHANICAL SAFETY

- Fusion Bx should only be handled in the way specified in this manual.
- Do not force movement of the tracker while the tracker brakes are engaged.

### 4.2 PRECAUTIONS

- All users must undergo training from a training representative prior to initial use of Fusion Bx. An overview of user training can be seen in Appendix I. Training Overview.
- Ensure your product license is up-to-date; this is required to operate Fusion Bx. For more information on licenses, see Section 7.2.
- Ensure that all cables are plugged into their proper place.
- Ensure that the commercially-available TRUS probe fits tightly in its customized cradle and the retaining latch is secure.

- Ensure that the device components such as the hardware arm, cart, and monitor are cleaned per cleaning procedure in Section 8.
- Do not position the device in a way that would make it difficult to disconnect the device from the power main.
- Users should be comfortable navigating the probe/needle guide to all regions of the prostate.
- Avoid distractions while using Fusion Bx. If significant distractions cannot be mitigated, consider re-scheduling or moving the system to a quieter location.
- This device holds sensitive patient data. Keep it in a restricted-access area at all times.
- Fusion Bx should only be used with approved products listed Appendix D. Compatible Products.

### 4.3 WARNINGS

- It is the user's responsibility to monitor the health status of the patient throughout this procedure.
- Fusion Bx is not intended to touch the patient at any point during the procedure.
- All plugs and sockets must be kept dry at all times.
- If the biopsy needle touches a non-sterile surface, it must be replaced with a clean needle.
- If the patient experiences abnormal discomfort, remove the probe from the patient's rectal canal.
- To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- Do not operate Fusion Bx near unshielded blasting caps or in an explosive environment. The computer should be switched off when in any area with a potentially explosive atmosphere and all signs and instructions must be obeyed.
- In the event of malfunction of the device or changes in its performance that may affect safety, remove the probe from the patient's rectum and stop using the device until it has been properly serviced by Focal Healthcare personnel.
- Only qualified personnel, such as representatives of Focal Healthcare, may carry out installation, servicing, and repair of Fusion Bx and its connection to other equipment.
- This device weighs approximately 265 lbs (120 kg). Do not attempt to lift or move without assistance.
- Fusion Bx should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- Follow the facility warnings and guidelines of a conventional biopsy procedure.
- Follow the manufacturer warnings and guidelines of the ultrasound system, TRUS probe, biopsy gun, and needle used in any biopsy procedure.

#### 4.4 CONTRAINDICATIONS

Fusion Bx should not be used for planning or in conjunction with any procedure other than workflow enhancement of a TRUS prostate scan or biopsy. The acquired 3D image and the image processing methods may not be used to plan or perform any other type of procedure.

#### 4.5 ABOUT THIS USER MANUAL

This user manual is a reference guide intended for physicians using Fusion Bx Model 2.0, running software version 2.4 to perform fusion and tracked systematic prostate biopsies. It includes information on operating the device safely and effectively, navigating the graphical user interface, cleaning and maintenance of the included hardware, and troubleshooting.

## 5 GENERAL INFORMATION ON FUSION BX

### 5.1 SYSTEM DESCRIPTION

Fusion Bx is a navigation system for prostate biopsy procedures with 2D and 3D imaging capabilities. It is designed to incorporate MR data for enhanced visualization and targeting of the prostate gland under TRUS guidance (i.e. fusion biopsies) but can also be used without MR data to track biopsy sample locations in tracked systematic biopsies. This device will assist clinicians in planning and performing image-guided interventional procedures such as biopsies and placing instruments in the prostate. The device is intended for adult men with suspected prostate cancer. The system will integrate into existing workflows by connecting to standard ultrasound equipment. This system will not prevent the clinician from using the standard ultrasound equipment.

To use Fusion Bx, a third-party ultrasound with an end-fire, bi-plane, or tri-plane transrectal probe must be connected to the frame grabber component. Fusion Bx supports 3D TRUS volume reconstruction, which can be fused to MR segmentation data using an advanced surface-based algorithm. Imaging capabilities allow the probe position to be visualized relative to the fused volume for precise targeting of regions of interest (ROIs), and mark-up tools are provided to record the location of biopsy samples. Additional software features include patient data management, multi-planar reconstruction, segmentation, image measurements and 3D image registration.

Fusion Bx supports DICOM and real-time 2D TRUS imaging formats. DICOM-compliant images can be received through USB flash drive, DVD, local area network, or PACS and are saved in their original format. Data from the procedure, such as annotations, images, and screenshots, are also saved in DICOM format.

Fusion Bx is comprised of a monitor and computer with pre-installed software and a hardware assembly. The included hardware consists of a keyboard, mouse, frame grabber, motorized lift column, isolation transformer, hardware arm (comprising of a swing arm, counterbalance, tracker, and stepper), and cart. See Figure 1 for a diagram of each component.

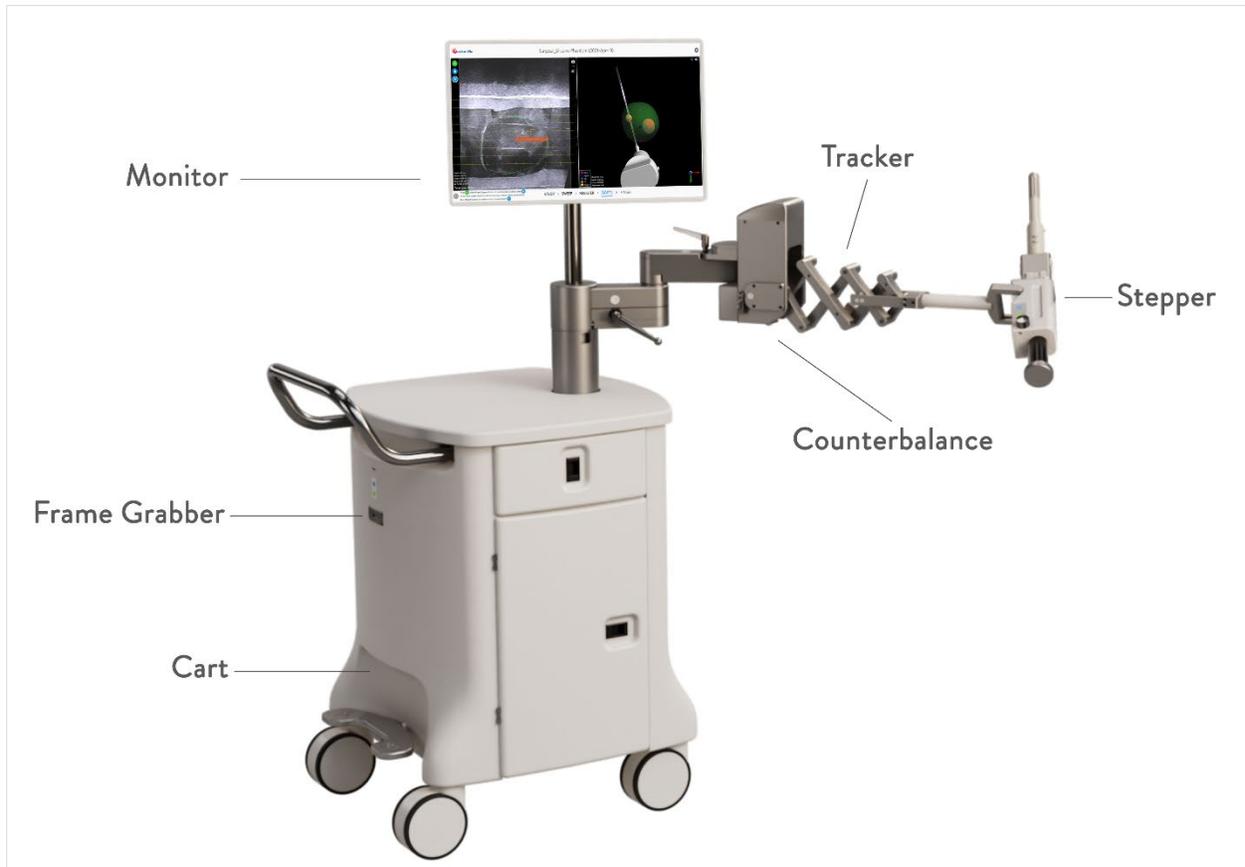


Figure 1: Fusion Bx and its components

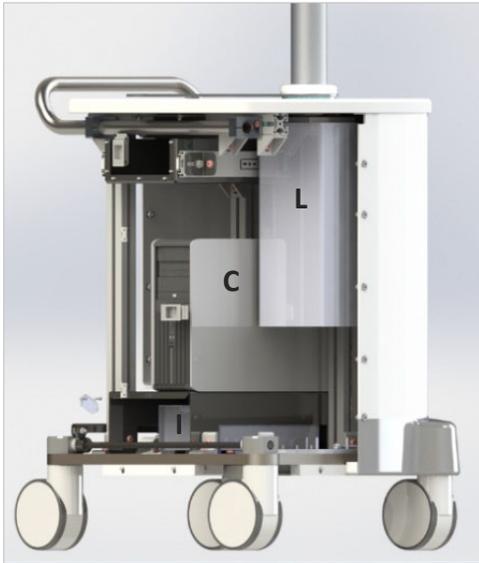
## 5.2 CART

The cart supports the entire system and allows it to be easily transported. The casters are controlled by a master foot lock and must remain locked throughout the entire procedure after gross adjustments are made. Attached to the cart is a large handle to improve the ease of transport. Housed within the cart are an isolation transformer, a computer, a motorized lift column, and all the necessary cables required for the procedure. The frame grabber is secured to the rear of the cart, with the DVI connection exposed. A drawer is also provided for storage of small items.

The **wheel foot pedal (W)** is the master foot pedal which controls all four wheels. Press the side of the lever with a picture of a locked lock (🔒) down until it clicks to lock the cart.

*Note: Refer to the label above the foot pedal for the locked and unlocked positions. When the pedal is horizontal, it is locked.*





The **motorized lift column (L)** moves the swing arm vertically (up/down). There are controls located on the rear of the cart above the frame grabber, that control this. Press the blue button to move the swing arm upwards and press the green button to move the swing arm downwards.

The **isolation transformer (I)** transfers alternating current (AC) power to the Fusion Bx computer, monitor, and motorized lift column while isolating the powered device from the power source.

The **computer (C)** runs the Fusion Bx software and is housed within the cart.

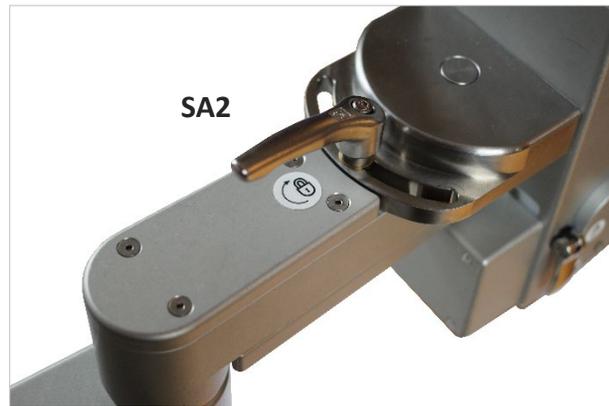
### 5.3 MONITOR AND KEYBOARD

The monitor is affixed to the cart via a locking mechanism, which allows it to rotate, swivel, and be moved up or down. The computer and monitor will be connected via a DisplayPort connection. The keyboard and mouse will be situated on top of the cart, which will allow the user to type in any necessary data and control the Fusion Bx software. Alternatively, the user can use the cart drawer with a mousepad to operate the software.

*Note: Both the keyboard and mouse are wireless and will require charging from time to time. The keyboard is charged by connecting it to a USB port using the supplied USB-to-micro USB cable. The mouse is charged by placing it into the supplied cradle and plugging the cradle into a USB port. Both the keyboard and mouse have corresponding USB dongles connected to the underside of the monitor.*

### 5.4 SWING ARM AND ENCODER CONVERTER

The swing arm affords gross adjustment of the probe position so the procedure can be carried out comfortably in a variety of different arrangements. Up and down motion of the swing arm is carried out by the motorized lift column, while other movements are carried out manually by unlocking the locks situated on the hardware. Since there are no motion encoders on the swing arm, it must be locked and stationary throughout the procedure. The encoder converter is located inside the swing arm. It transmits probe position information from the tracker and stepper to the Fusion Bx software.



The first **swing arm lever (SA1)** locks the relative position between the cart stand and the 2 swing arms. Turn clockwise to lock.

The second **swing arm lever (SA2)** locks the relative position between the swing arm and tracker. Twist clockwise to lock.

## 5.5 COUNTERBALANCE

The counterbalance supports the weight of the tracker, stepper, and probe; holding them steady in any position, acting as a third arm throughout the procedure. This also allows for probe manipulation that has comparable feel to freehand.

## 5.6 STEPPER



The stepper holds the TRUS probe and allows for the probe to be inserted into and removed from the patient's rectum, as well as rotational motion up to 360°. There is a small silver knob on the stepper which allows for fine-tuned adjustments in the in-out direction. The stepper also contains two buttons that allow the user to navigate through the Fusion Bx procedure. Instructions on when to use the Stepper buttons will be found throughout Section 6.

*Note: The color of the stepper buttons correspond to the color of the icons displayed in each step of the workflow.*

## 5.7 TRACKER



The tracker is responsible for tracking motion in the lateral (left/right) and vertical (up/down) direction of the probe (with respect to the user). At the connection to the stepper, there is a joint allowing rotational motion of the probe in the pitch and yaw directions. Together, the tracker and stepper combined provide 6 degrees of freedom of motion. The tracker is best handled gently. Do not pull or yank. **Note that motion in-out of the patient is accomplished at the stepper. The tracker**

**should not be forced towards, or away from, the patient.** The tracker should not be moved while the brakes are engaged.

The **tracker lever (T1)** locks the relative position between the counterbalance and the tracker and locks the compression/extension of the tracker. Push down to lock.

## 5.8 ENCODERS

Encoders track the motion of the probe. There is a total of six encoders in the arm, all located within the tracker and stepper. For this reason, only the tracker and the stepper should be moved during the procedure.

## 6 USING FUSION BX

**⚠ CAUTION:** All users must undergo training from a training representative prior to using Fusion Bx for the first time.

In this section, you will find information on proper setup, data transfer, and use of the Fusion Bx software to perform fusion and tracked systematic prostate biopsy procedures. Fusion biopsies use previously-acquired images (e.g. MRI) to identify suspicious areas in the prostate. Fusion Bx fuses these images to the real-time TRUS feed, allowing you to target these suspicious regions for biopsy. Tracked systematic biopsies do not use any previous imaging. In this type of procedure, only TRUS imaging is used to locate the prostate and biopsy samples are taken systematically throughout the prostate. Fusion Bx can record biopsy locations for fusion and tracked systematic biopsies. For fusion biopsies, it is standard of care to finish with a systematic biopsy.

In general, the fusion and tracked systematic biopsy workflows are very similar. If you are performing a tracked systematic biopsy, look for green boxes like this one which provide alternative instructions.

The Fusion Bx software workflow consists of 4 main steps: STUDY, SWEEP, REGISTER, and BIOPSY. Each step has its own dedicated software page, with its own set of instructions. Each step must be performed in consecutive order and must be fully completed in order to proceed to the next one. For a general flowchart of the overall procedure, see Appendix F. Workflows.

### 6.1 REQUIREMENTS FOR OPERATION

You must ensure that the following requirements are satisfied before operating Fusion Bx:

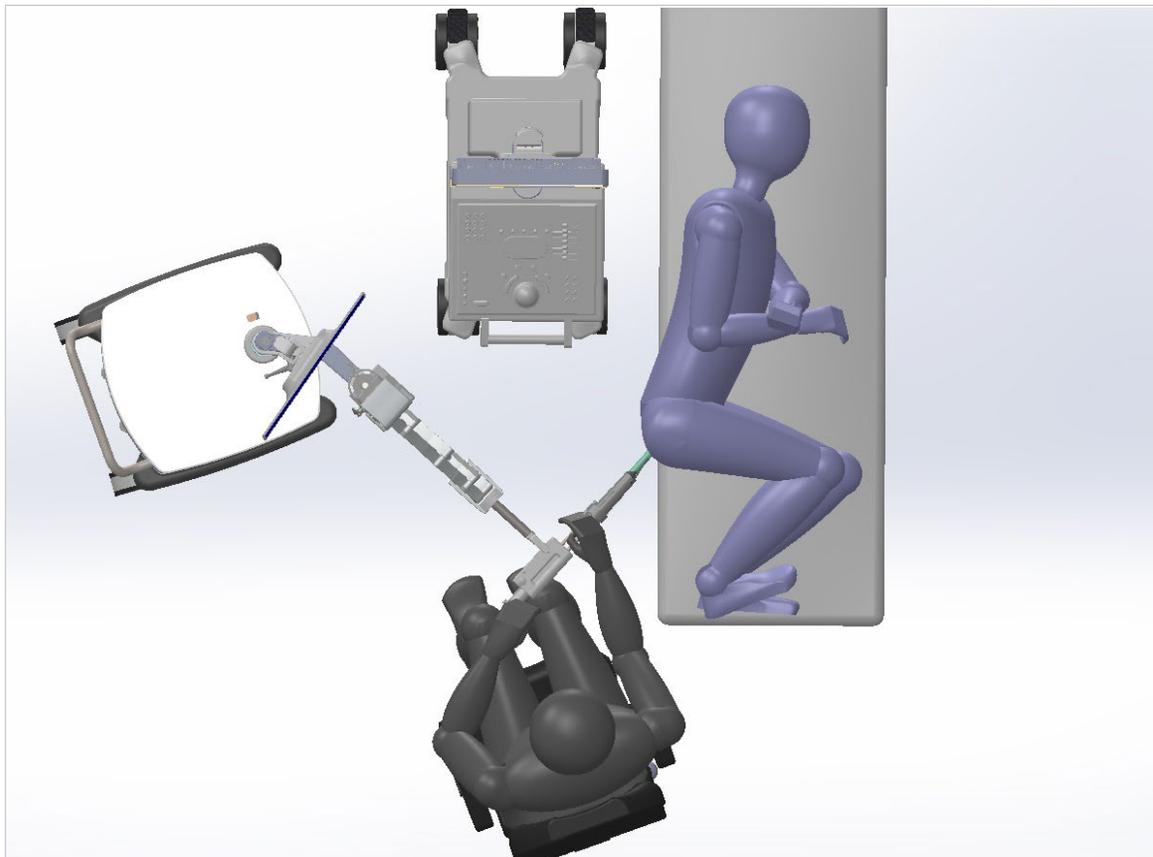
- All users have been adequately trained on the safe and effective operation of Fusion Bx. See Appendix I. Training Overview.
- For security purposes, Fusion Bx must be kept in a restricted-access area at all times to prevent any unauthorized access to sensitive patient data.
- The environment is well-lit, sanitary and free from distractions.
- The operating temperature range is between 50-86 °F (10-30 °C).
- The operating humidity is between 10-95% (non-condensing).
- The operating atmospheric pressure is between 14-16 psi (97 – 110 kPa).
- At least one other person is present to assist with the procedure.
- The floor on which Fusion Bx stands is level. This is necessary for proper tracking.
- At least two electrical outlets (maximum power supply wattage 400 W) are available for the ultrasound machine and the isolation transformer.

- Adequate space is available for the Fusion Bx device, an ultrasound machine, a patient bed, a medical cart, the user, an assistant, and any other equipment necessary for the procedure. For Fusion Bx dimensions, see Appendix A. Specifications.

In order to operate Fusion Bx, the system must be setup properly prior to the procedure. This includes the setup of Fusion Bx components, connection to a third-party ultrasound device, and patient positioning. Failure to do this could result in delays, suboptimal registration, and may even require restarting the procedure. Below is the suggested configuration of Fusion Bx, patient, user, and ultrasound in a typical biopsy procedure. For a general description of each hardware component, see Section 5.1.

## 6.2 RECOMMENDED SETUP

**⚠ CAUTION:** It is strongly recommended that you become acquainted with the Fusion Bx hardware on a prostate phantom to familiarize yourself with the maneuverability and range of motion of the probe before attempting a procedure. For more information, see Section 6.7.



*Figure 2: Illustration of Fusion Bx system with suggested configuration into clinical workspace*

## THIRD-PARTY DEVICES

A compatible ultrasound system and probe must be connected to Fusion Bx during operation.

The ultrasound machine must be:

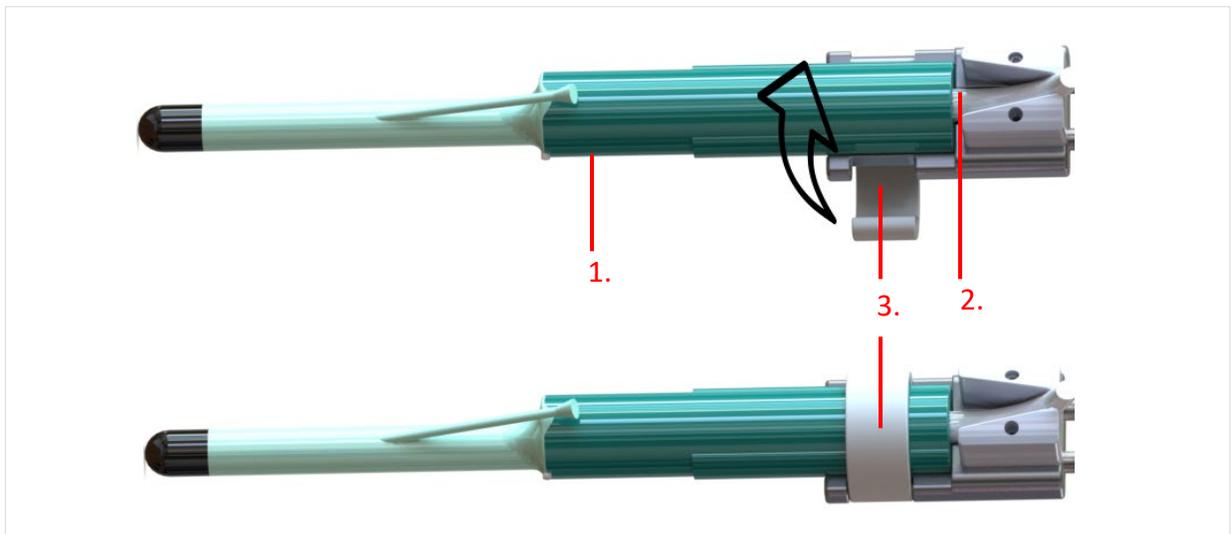
- ✓ plugged into a wall power outlet
- ✓ powered on
- ✓ connected to the frame grabber via DVI cable
- ✓ set to the appropriate settings

The TRUS probe must be:

- ✓ plugged into the ultrasound machine
- ✓ set to side-fire or end-fire mode
- ✓ properly fastened into the stepper

To fasten the probe (see below):

1. Insert the probe, so that the imaging crystal is at the same height as the dove tail of the stepper cradle.
2. Slide the probe towards the stepper block until the base of the probe is pressed firmly against the stepper cradle, position number 2 in Figure 3.
3. Secure the probe by locking the clip into place, item number 3 in Figure 3.
4. To remove the probe, simply reverse these steps.



*Figure 3: Illustration of how probe is fastened to the stepper*

*Note: Depending on the installation, your stepper cradle may differ slightly from the one shown above.*

For a list of compatible third-party products, refer to Appendix D. Compatible Products.

## COMPONENTS

In order to operate Fusion Bx, the following items must be properly connected and functioning: the isolation transformer, frame grabber, and compatible ultrasound system.

**⚠ CAUTION:** Before plugging the Fusion Bx into an outlet, ensure that the device is properly configured for the electrical requirements of the region or country that the Fusion Bx is being used. Refer to the label adjacent to the power outlet to confirm.

**⚠ CAUTION:** Do not unplug the Fusion Bx at any time. Shut down Fusion Bx using the procedure found in Section 6.14 before unplugging it from the power outlet.

The isolation transformer powers the Fusion Bx software and hardware, and must be:

- ✓ plugged into a power outlet with protective earth (ground)

The frame grabber must be:

- ✓ connected to the ultrasound machine via DVI cable

The ultrasound system must be:

- ✓ plugged into a power outlet with protective earth (ground)

## 6.3 STARTUP

Once the setup is complete, you are ready to start using Fusion Bx.

1. Press the **power** button on the computer and monitor to turn them on.
2. **Log into your account.** After login, the Fusion Bx software application will be launched automatically.

*Note: For more information on managing user accounts, contact your Focal Healthcare representative.*

## 6.4 TRANSFERRING DATA TO FUSION BX

Before a fusion biopsy can begin, patient DICOM files (e.g. MRI images) must first be transferred to Fusion Bx. This transfer can be done via **encrypted USB flash drive, DVD, local area network (LAN), or PACS** and is recommended to be done **the day before a scheduled procedure**. Note that, by default, Wi-Fi is disconnected for security purposes.

*Note: A partially damaged DVD may cause Fusion Bx to stall while importing DICOM files. If the displayed DVD import message remains static for a number of minutes, the DVD may have been*

physically damaged. Please cancel the DVD transfer. Re-import data to a non-damaged DVD and repeat the import process.

**⚠ CAUTION:** This data contains confidential patient information. Ensure you are exporting it to an encrypted USB flash drive, encrypted CD/DVD or to a password-protected network location.

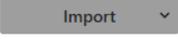
For tracked systematic biopsies: Skip this step.

## USB FLASH DRIVE

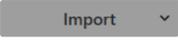
1. Plug the USB flash drive into the USB port on the PC or monitor.
2. Click the drop-down arrow beside **Import**  , then click **Import from USB** and select the appropriate flash drive. The Windows Explorer directory will be displayed showing you the flash drive contents. Select the appropriate folders. Fusion Bx will import the selected files and display them in the patient list.
3. When the transfer is complete, unplug the USB from the device port.

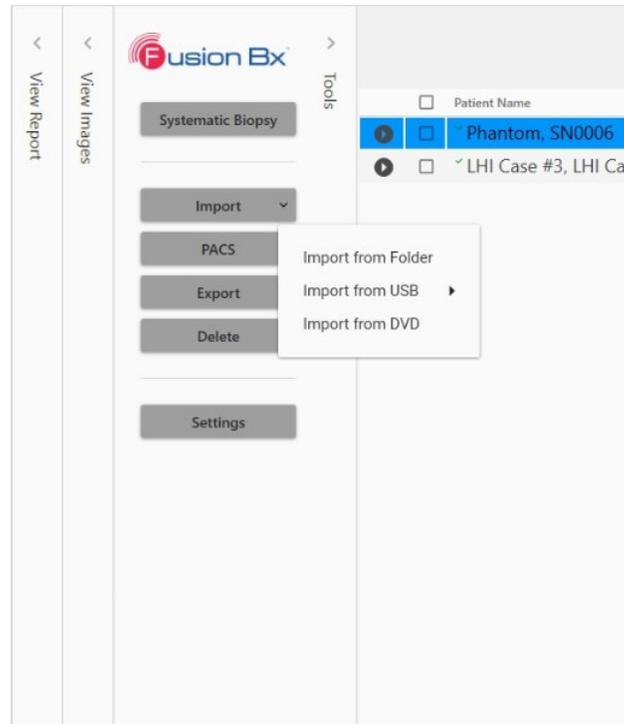
*Note: Unplugging the USB before the transfer is complete can result in corrupted data.*

## DVD

1. Insert the DVD into the computer. (*Note: you will have to open the cart door to access the DVD drive*)
2. Click the drop-down arrow beside **Import**  , then click **Import from DVD**. The Windows Explorer directory will be displayed showing you the DVD contents. Select the appropriate folders. Fusion Bx will import the selected files and display them in the patient list.
3. When the transfer is complete, remove the DVD from the computer.

## LOCAL AREA NETWORK

1. Connect the Fusion Bx computer to a local area network via Ethernet cable or Wi-Fi (see Section 9.1 for network configuration).
2. Click the drop-down arrow beside **Import**  , then click **Import from Folder**. The Windows Explorer directory will be displayed allowing you to access data from a connected network.
3. Navigate to the directory which contains your desired files. Click **Select Folder**.
4. Fusion Bx will import all the files contained within the given folder and display them in the patient list.



Available Import options

## PACS

*Note: Fusion Bx will need to be connected to a PACS server and be properly configured as a DICOM node for successful import of studies. See Section PACS Settings for instructions on setting up a PACS.*

1. Connect the Fusion Bx computer to a local area network via Ethernet cable or Wi-Fi.
2. On the Study page, select **PACS** .
3. Select **Query**  to view all studies contained within the configured PACS server.
4. To narrow your search, fill in at least one of the following fields: Patient ID, Patient Name, Study ID, Accession Number, Referring Physician, Query Level, or Dates. Select **Query** .
5. In the Results section, select your desired patient(s) by selecting the box beside their name. Select **Retrieve** , a progress bar will pop up to indicate the progress of study retrieval. Retrieval is complete when the progress bar is completely full.
6. Select **Close**  or click outside of the PACS window to close the viewer. The selected study(s) should now appear in the study list.

Querying from: ONEPACS - (pz\_0 <-> ONEPACS-VM@192.168.10.111:4104)

Patient ID

Patient Name

Study ID

Accession Number

Referring Physician

Query level

Study

Dates

All dates

Results

<input type="checkbox"/>	Progress	Study Date	Patient ID	Patient Name	Study ID	Series Description	Accession
<input type="checkbox"/>	-----	20170919	SamfordSample002	SamfordSample002	537766486		
<input checked="" type="checkbox"/>	-----	20180612	12345	Patient^ Test			56789
<input type="checkbox"/>	-----	00010101	OP-3670932681	FHC006			42280886
<input type="checkbox"/>	-----	20180611	666	Kramers^Matt			
<input type="checkbox"/>	-----	20140220	666	Kramers^Matt	999		333
<input type="checkbox"/>	-----	20141219	OP-3670932644	FHC005			15832066
<input type="checkbox"/>	-----	20120901	OP-3429048015	FHCtest-2016-03-09			11716441
<input type="checkbox"/>	-----	20160120	2211060/1	COEN^KENNETH^L	1		161738-1
<input type="checkbox"/>	-----	20180703	258987	Leavitt 001			
<input type="checkbox"/>	-----	20180511	666	Kramers^Matt			
<input type="checkbox"/>	-----	20170713	Dylan002_RC	Dylan002_RC	4783951		NOTFOUN
<input type="checkbox"/>	-----	20180705	1234	Smith^John	5678		6789
<input type="checkbox"/>	-----	20160521	LHI Case #3	LHI Case #3^LHI Case #3	12481		LHICase3
<input type="checkbox"/>	-----	20180717	OP-3670932607	FHC004			
<input type="checkbox"/>	-----	20180712	666	Kramers^Matt			
<input type="checkbox"/>	-----	20180725	OP-2790178881	UTC-04			

*Pulling a study from PACS*

**⚠ WARNING:** In rare circumstances a system crash may occur if only importing the annotation file of a given patient. To avoid this, always import the entire study for a given patient (i.e. MRI images and annotation file).

**⚠ CAUTION:** When importing duplicate data, the software may display the incorrect number of existing files. This will have no impact on successful study import.

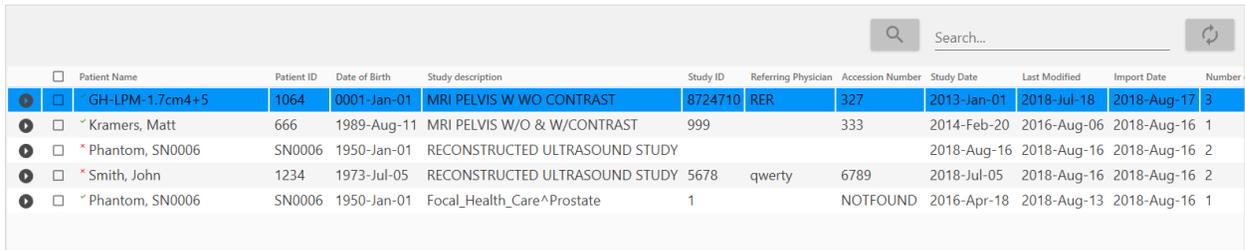
## 6.5 STUDY: SELECTING A PATIENT

The first step of the procedure is to select your patient from the patient list. Data from the procedure will later be saved to the patient's file on Fusion Bx. If you are performing a fusion biopsy procedure, the patient must have a pre-existing file containing his DICOM MR images and annotations (see Section 6.4). If you are performing a tracked systematic biopsy, you can create a new file for your patient at this point.

### LOADING A PRE-EXISTING PATIENT FILE

If the patient's MRI files have been uploaded onto the system, his file can be found in the patient list.

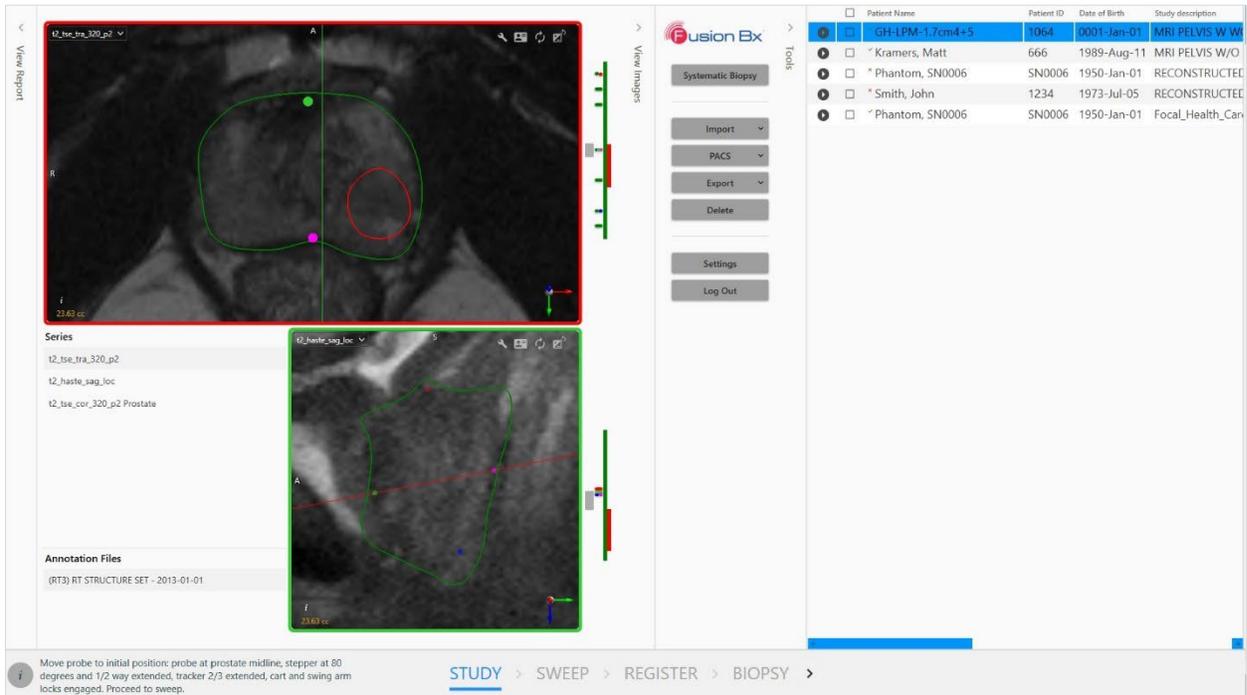
1. If the patient's file cannot be easily found in the list, **enter a keyword** (e.g. last name, first name, referring physician) into the **search bar** at the top of the page. Select **Search**  or press the 'Enter' key, and all files containing the keyword will be listed. Click on the desired **patient**.



<input type="checkbox"/>	Patient Name	Patient ID	Date of Birth	Study description	Study ID	Referring Physician	Accession Number	Study Date	Last Modified	Import Date	Number
<input checked="" type="checkbox"/>	GH-LPM-1.7cm4+5	1064	0001-Jan-01	MRI PELVIS W WO CONTRAST	8724710	RER	327	2013-Jan-01	2018-Jul-18	2018-Aug-17	3
<input type="checkbox"/>	✓ Kramers, Matt	666	1989-Aug-11	MRI PELVIS W/O & W/CONTRAST	999		333	2014-Feb-20	2016-Aug-06	2018-Aug-16	1
<input type="checkbox"/>	* Phantom, SN0006	SN0006	1950-Jan-01	RECONSTRUCTED ULTRASOUND STUDY				2018-Aug-16	2018-Aug-16	2018-Aug-16	2
<input type="checkbox"/>	* Smith, John	1234	1973-Jul-05	RECONSTRUCTED ULTRASOUND STUDY	5678	qwerty	6789	2018-Jul-05	2018-Aug-16	2018-Aug-16	2
<input type="checkbox"/>	✓ Phantom, SN0006	SN0006	1950-Jan-01	Focal_Health_Care^Prostate	1		NOTFOUND	2016-Apr-18	2018-Aug-13	2018-Aug-16	1

*Study page showing patient list and search bar*

2. Review the patient's MRI images and annotation files (prostate contour, landmarks and targets / ROIs) either by clicking the **View Images** tab or double-clicking the patient's file. If multiple annotation files are available, they will be displayed under the **Annotation Files** heading. Ensure you choose your preferred file. Scroll through the images to ensure that all the data has been uploaded correctly. There are 2 image viewers shown. The top (primary) viewer is defaulted to display the contoured axial T2 MR image, if available. The bottom (secondary) viewer is defaulted to display the contoured sagittal T2 MR image, if available. Click the drop-down menu in the top left-hand corner of the image viewer to select and view other available series.



Study page showing preview of MRI images (left) and patient list (right)

- To change the display of a given window, select **Tools**  in the top right-hand corner. The following items can be used: **Zoom** , **Pan** , **Brightness/Contrast** , **Auto Brightness/Contrast** , and **Point Scrolling** . Select **Reset**  to clear any zoom or pan changes and select **Reset Brightness/Contrast**  to reset any brightness or contrast changes.

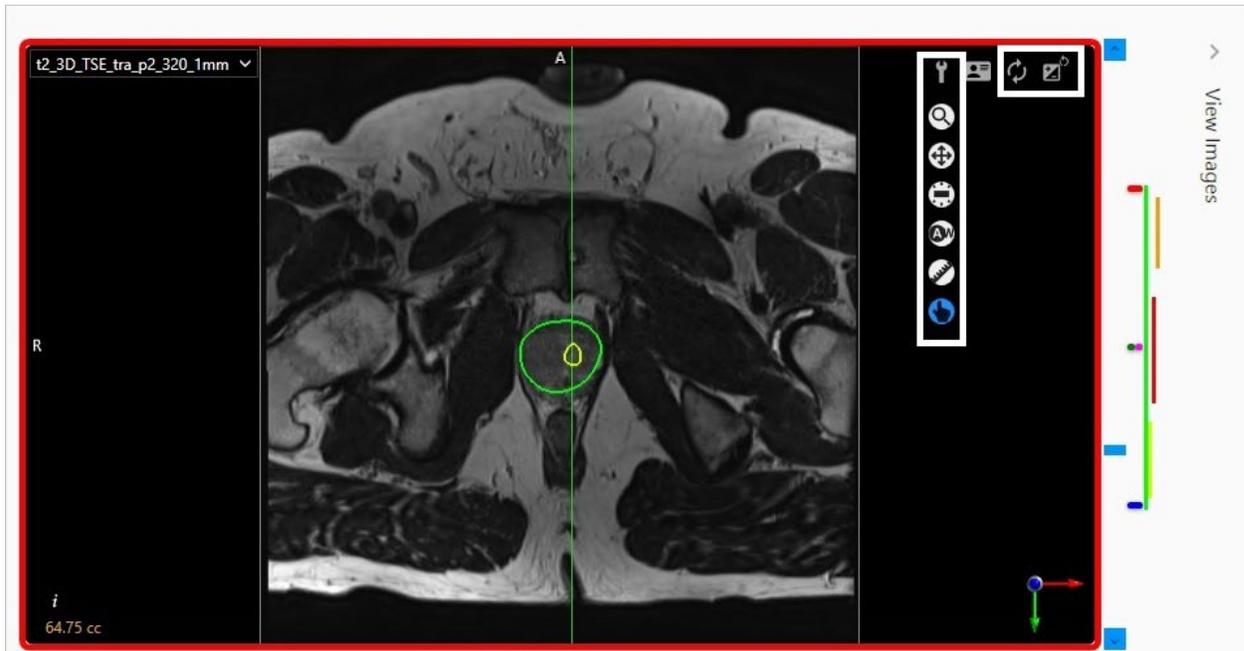
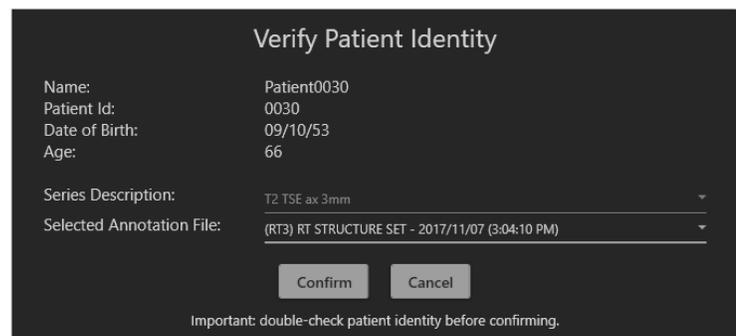


Image viewer showing list of available tools to change the display of the image

4. Click **SWEEP** to proceed to the Sweep page. A dialog box will ask you to verify the patient's information. If multiple annotation files are available for the patient, use the **Select annotation file** drop-down menu to select your desired annotation file,



and press **Continue** **Continue** . Press **Cancel** **Cancel** if you do not wish to continue. Annotation files are timestamped and can be used to determine the desired file.

## ADDITIONAL FEATURES

- Click on the respective column headers to sort the list by patient name, patient ID, date of birth, study description, study ID, referring physician, accession number, study date, last modified, import date, number of series, number of files, or patient age.
  - By default, studies will be organized according to Import Date, this way the most recent studies will be displayed at the top of the list.
- Studies with a compatible MRI annotation file will be displayed with a **green** checkmark. The **green** checkmark confirms that a fusion biopsy can be performed.

Studies with no compatible MRI annotation file will be displayed with a red "X". The red "X" indicates that a fusion biopsy cannot be carried out.

<input type="checkbox"/>	Patient Name	Patient ID
<input checked="" type="checkbox"/>	Kramers, Matt	666
<input checked="" type="checkbox"/>	✗ Phantom, SN0006	SN0006
<input checked="" type="checkbox"/>	Ⓜ Smith, John	1234
<input checked="" type="checkbox"/>	✓ Phantom, SN0006	SN0006
<input checked="" type="checkbox"/>	✓ GH-LPM-1.7cm4+5	1064

- When a fusion biopsy procedure is completed, a separate reconstructed ultrasound study will be created under the same patient name. This is identified by the icon Ⓜ. You cannot complete a biopsy procedure with the reconstructed ultrasound data. This study simply serves as a reference of the completed procedure and houses the patient report.
- Fusion Bx will save all data from an aborted or interrupted procedure.
- To delete patient studies, select the checkbox on the left of the patient entries and click **Delete** Delete.
- Click **Settings** Settings to display the settings window. The following information is available: PACS Settings, About, Service and Support Tools, License, Initial Device Set-Up, Needle Settings, Visualization and Tracking. For more information on settings, see Section 7.1.

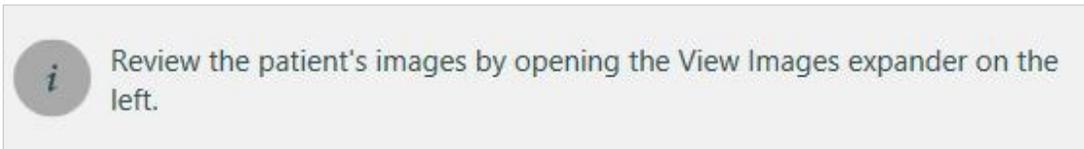
For tracked systematic biopsies:

ADDING A NEW PATIENT

1. Click **Systematic Biopsy** Systematic Biopsy
2. Enter the patient's first name, last name, ID, referring physician, accession number and birth date in the appropriate fields.
3. Click **Proceed to Sweep** Proceed to Sweep
4. The software will automatically progress to the Sweep page.

## 6.6 INTERACTIVE HINTS

Throughout the procedure, you will notice interactive hints displayed in the bottom left-hand corner. These hints are intended to guide the user through the procedure and are automatically updated as the user progresses through the workflow. These Interactive Hints can be toggled on or off by selecting the  in the bottom left-hand corner. Additionally, the interactive hints are customizable. If you want custom hints to better suit your needs, contact your Focal Healthcare representative and they can provide this.



## 6.7 HARDWARE SETUP

It is very important that the hardware arm is set up properly before starting a procedure. This will ensure the encoders are properly set to a known location and allows for optimal maneuverability of the probe during the procedure.

### HARDWARE SETUP

*Note: Before proceeding any further, the hardware **must** be set up properly to ensure optimal maneuverability of the probe during the procedure. Set-up for side-fire and end-fire will be slightly different.*

#### SIDE-FIRE

1. Ensure the ultrasound probe is held in a position such that the image displayed is the prostate at mid-gland, centred in the imaging field of view.
2. Position the cart such that the keyboard and mouse will be easily accessible during biopsy and ensure the monitor is easily visible when the cart is positioned in this manner.
3. Position the tracker and stepper in their **starting positions** (see **Figure 4**):
  - a. Extend the tracker approximately 2/3 of its full extent (white dot aligns with the "S" sticker). Ensure the tracker is parallel to the floor by adjusting the height of the arm using the motorized lift column.

*Note: Targets in anterior apical regions of larger prostates can be challenging to reach. In this case, it may be necessary to orient the probe at a large angle with respect to the prostate. To facilitate this, conduct the initial setup and sweep with the tracker extended further than usual (e.g. 3/4 of the way extended instead of 2/3 extended).*

- b. Position the stepper such that it is about 80-90° to the tracker and parallel to the floor.
4. Position the stepper halfway between fully inserted/retracted. **Unlock** the swing arm and cart wheel brakes.
  5. With the probe inside the patient, move the cart such that the probe can be clipped into the cradle.

*Note: The tracker and stepper should be horizontal with the probe inserted into the patient's rectum. If you need to adjust the height of the hardware arm, use the*

motorized lift column to raise or lower the arm. **Do not** adjust the hardware arm height when the device is connected to the patient.

Alternatively, the probe can be removed from the patient, attached to the stepper and then reinserted into the patient. It will be important to maintain the starting position described above when following this method.

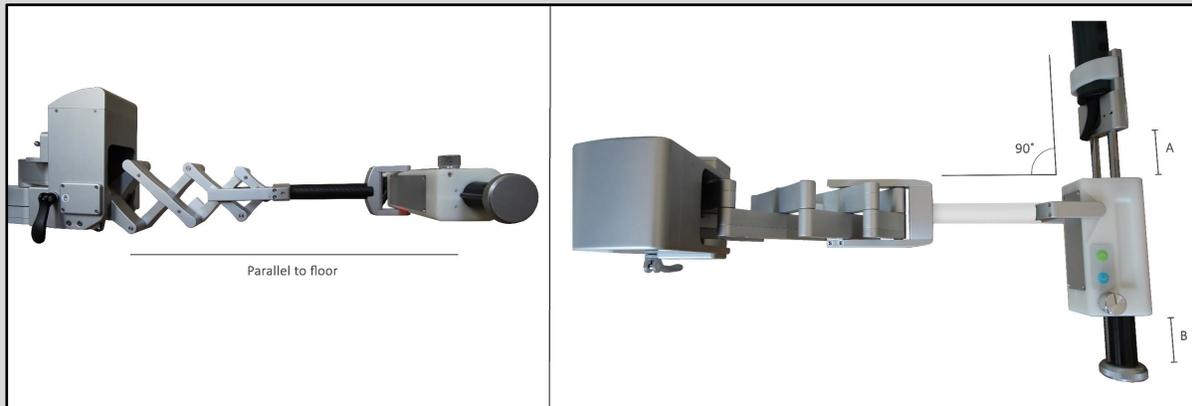


Figure 4: Starting position for side-fire from side-view (left) and top-view (right). Both the tracker and stepper should be approximately 90° to one another and parallel to the floor. The swing arm should be unlocked. Lengths A and B should be approximately equal.

6. **Rotate** the stepper and **adjust** the swing arm until the prostate is approximately mid-gland and reasonably centered in the imaging field of view.
7. **Lock** both swing arm brakes and the cart wheels.

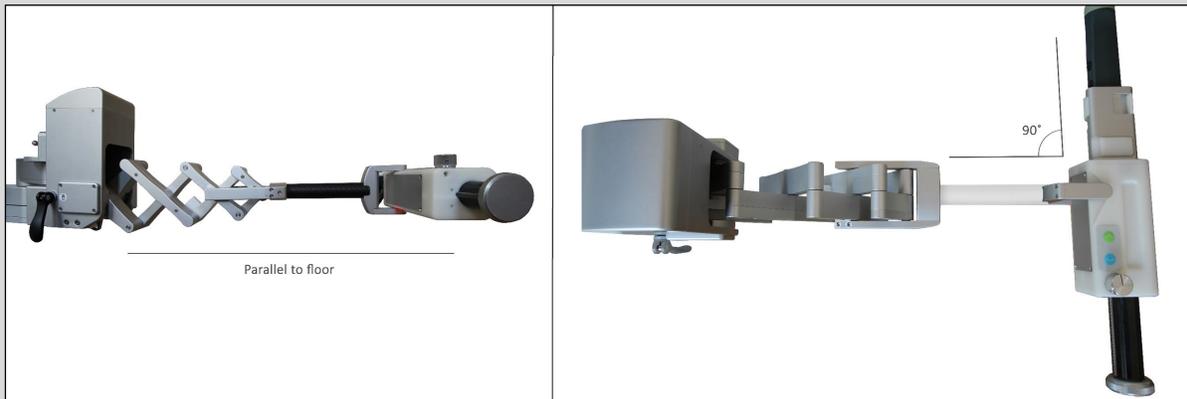
## END-FIRE

1. Ensure the ultrasound probe is held in a position such that the image displayed is the axial view of the prostate at mid-gland, centred in the imaging field of view.
2. Position the cart such that the keyboard and mouse will be easily accessible during biopsy and ensure the monitor is easily visible when the cart is positioned in this manner.
3. Position the tracker and stepper in their **starting positions** (see **Figure 5**):
  - a. Extend the tracker approximately 1/2 of its full extent (white dot aligns with the “E” sticker). Ensure the tracker is parallel to the floor by adjusting the height of the arm using the motorized lift column.
  - b. Position the stepper such that it is about 80-90° to the tracker and parallel to the floor.
4. Position the stepper so it is butted against the stepper block. **Unlock** the swing arm and cart wheel brakes.

5. With the probe inside the patient, move the cart such that the probe can be clipped into the cradle.

*Note: The tracker and stepper should be horizontal with the probe inserted into the patient's rectum. If you need to adjust the height of the hardware arm, use the motorized lift column to raise or lower the arm. **Do not** adjust the hardware arm height when the device is connected to the patient.*

*Alternatively, the probe can be removed from the patient, attached to the stepper and then reinserted into the patient. It will be important to maintain the starting position described above when following this method*



*Figure 5: Starting position for end-fire from side-view (left) and top-view (right). Both the tracker and stepper should be approximately 90° to one another and parallel to the floor. The swing arm should be unlocked.*

6. **Rotate** the stepper and **adjust** the swing arm until the prostate is in an axial orientation at mid-gland and reasonably centered in the imaging field of view.
7. **Lock** both swing arm brakes and the cart wheels.

**⚠ WARNING:** At this point, the following brakes must be fully locked for proper tracking:

- The cart wheels
- The two swing arm locks

For more information on brakes, see Section 5.

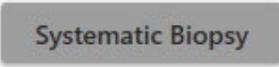
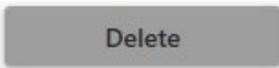
Recommendation: before starting the sweep, secure the tracker lever, T1, on the tracker.

*Note: The location for each lock is shown in Section 5.6 and 5.7 respectively. When using auto-motion compensation (Section Motion Compensation for more information), it is essential that these locks are properly secured prior to performing the sweep.*

Once proper setup is achieved, click **Sweep**  to proceed to the Sweep portion of the fusion biopsy procedure. Alternatively, setup can also be completed while the user is on the Sweep page. If multiple annotation files are available, you will be asked to choose which one you wish to use.

*Note: The user can progress through the Fusion Bx workflow using Stepper buttons. Situations where a stepper button can be used will be mentioned along with the option of using the mouse to complete a given function.*

Button Table:

Name	Button	Action
Systematic Biopsy		Opens systematic biopsy window
Import		Allows files to be imported from USB, DVD, or local directory
PACS		Opens the PACS window
Export		Allows files to be exported to USB, DVD, or local directory
Delete		Deletes selected studies from the study list
Settings		Opens the Settings menu
Logout		Closes Fusion Bx software
Search		Searches for a given field within the study list.

## 6.8 SWEEP: 3D RECONSTRUCTION

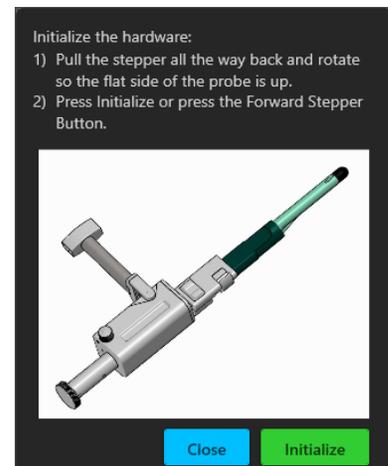
On the Sweep page, you will perform a sweep by manually scanning through the prostate using the TRUS transducer. It is very important that the hardware arm is set up properly before the sweep begins. Depending on your biopsy approach (side-fire or end-fire), your sweep approach will be slightly different.

**⚠ CAUTION:** If the imaging field of view to the left is black, grey or does not update when the probe is rotated then do not proceed with the sweep. Check the connection to the ultrasound as well as the settings specific to the ultrasound to ensure that they are correct. Refer to the Troubleshooting section for more information.

### INITIALIZING THE HARDWARE

Before carrying out a fusion biopsy procedure, the hardware must be “Initialized”. This process needs to be completed for each procedure. If hardware cables become disconnected this process must be repeated.

1. Before a sweep can be started, you must initialize the hardware.
2. Click **Home**  or press the **Blue** stepper button.
3. A pop-up window will appear prompting you to “Initialize the hardware”.
4. Follow the instructions in the pop-up window. “1) Pull the stepper all the way back and rotate so the flat side of the probe cradle is up.”
5. Click **Initialize**  or press the **Green** Stepper Button.
6. You can now move the probe freely.



**⚠ WARNING:** Full retraction and rotation so the flat side of the probe cradle is facing up is necessary for calibration and proper tracking. Failure to do so will result in image misalignment.

**⚠ CAUTION:** In the unlikely scenario where the encoder converter cable becomes disconnected during a procedure, users will need to repeat the “Initialize the Hardware” process. The user will be blocked from initializing the hardware until the encoder cable is re-connected.

## SWEEP INDICATOR

While performing a sweep, it is important to monitor the sweep indicator that appears below the reconstructed ultrasound window.

The indicator changes color depending on the speed at which the probe is being rotated. Green indicates the ideal speed, while yellow is a warning, and red indicates that the sweep is being performed too quickly. Rotating the probe too quickly can result in images being missed. Missed images will produce a reconstructed ultrasound of lower quality and may make it more difficult to identify landmarks or delineate the prostate.

Ensure that the sweep indicator is green throughout the entire sweep. If the sweep indicator shows red at any point during the sweep or if black gaps appear in the reconstructed ultrasound, then reperform the sweep.

## SIDE-FIRE SWEEP

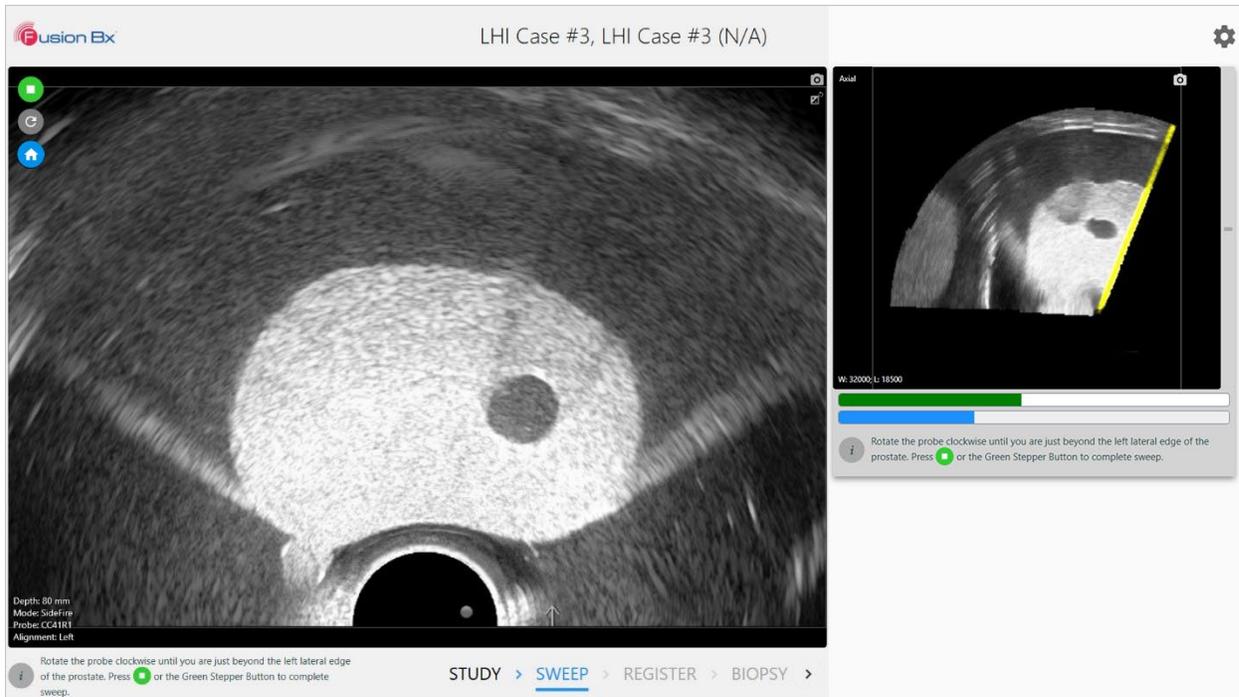
1. With the prostate positioned at mid-gland, centred in the imaging field of view, follow the displayed animated image: Rotate the probe counter-clockwise until you are just beyond the right lateral edge of the prostate.



2. Select **Play**  or press the **Green** stepper button. Rotate the probe clockwise until the entire prostate is captured. It is recommended that you rotate the probe at a consistent speed using the speed indicator as a feedback and limit any movements outside of rotation. As you are rotating the probe through the prostate, the reconstructed ultrasound view will be displayed simultaneously in the adjacent

window. Additionally, a blue bar will be displayed informing the user that the sweep is in progress. Ensure large sections of the reconstruction are not being missed as you rotate the probe through the prostate.

- If you notice you missed a large section of the prostate while performing the sweep. Select **Reset sweep** . Re-position the probe to the proper starting position and select **Start** or press the **Green** stepper button to re-do the sweep.



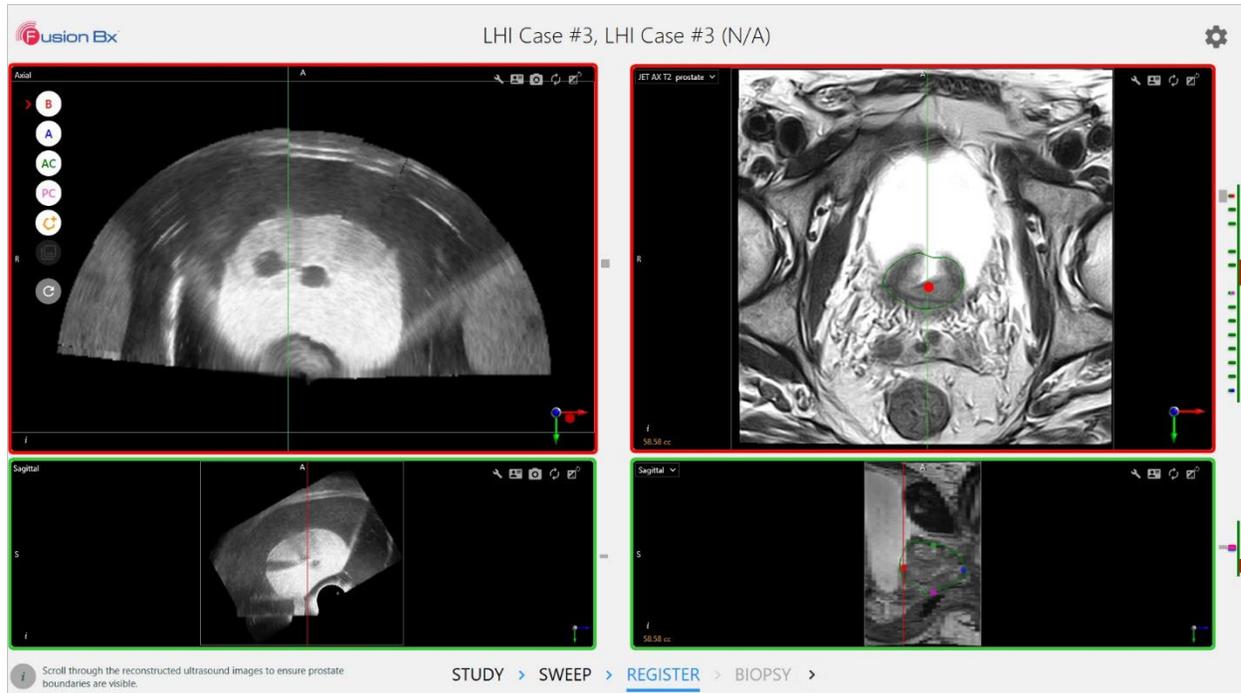
3. Once you have captured the entire prostate, select **Stop** or press the **Green** stepper button. The software will automatically progress to the Register page.
4. Before continuing with the registration process, review the reconstructed ultrasound volume generated in the two left windows.
  - By default, the top left window will be the axial view and the bottom left window will be the sagittal view.
  - Scroll through each image viewer to ensure the entire prostate was captured and that no areas of the prostate have been poorly reconstructed. These areas will be indicated as large black sections missing in the prostate. If these areas are present, select **Sweep** to redo the sweep. A pop-up

window will appear to verify you want to leave the Register page, select **Yes**



→ Use **Tools**  to change the display of a given image.

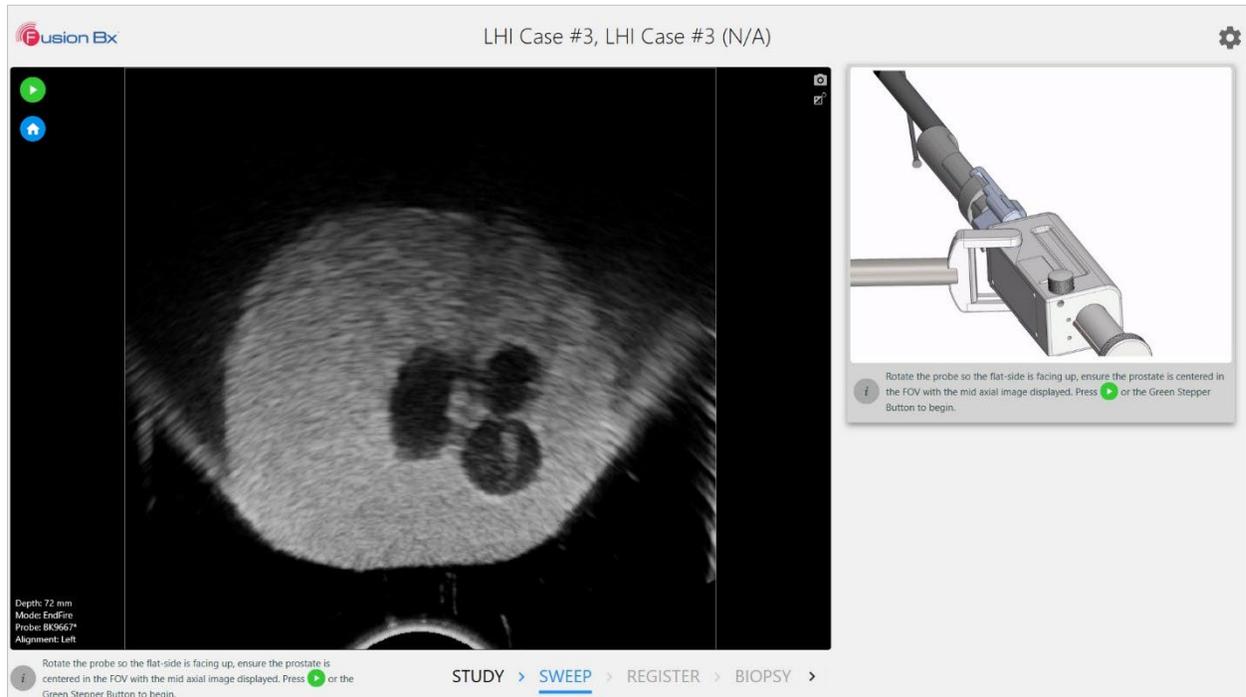
→ Use **Reset**  to reset the image back to its default state



5. If you are satisfied with the reconstruction, proceed with the **Register** process.

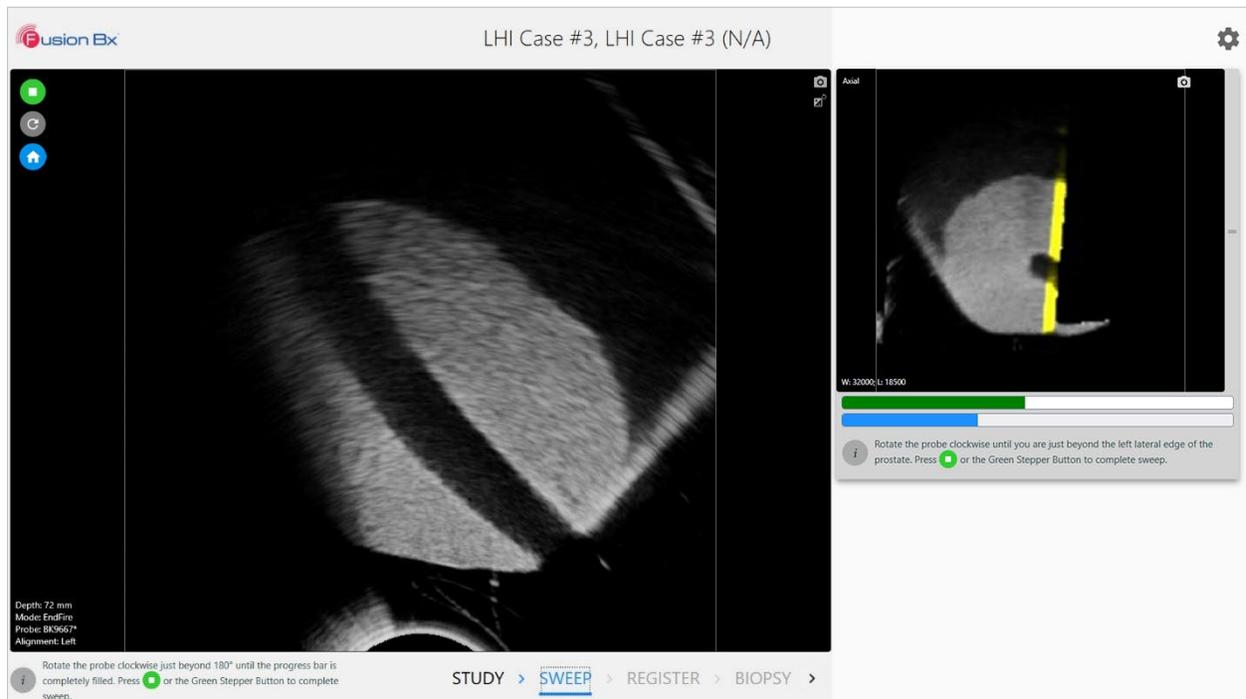
## END-FIRE SWEEP

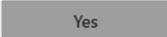
1. Following the displayed animated image, rotate the probe so the flat-side of the probe is facing up, and ensure the prostate is centred in the imaging field of view with the mid axial image displayed.

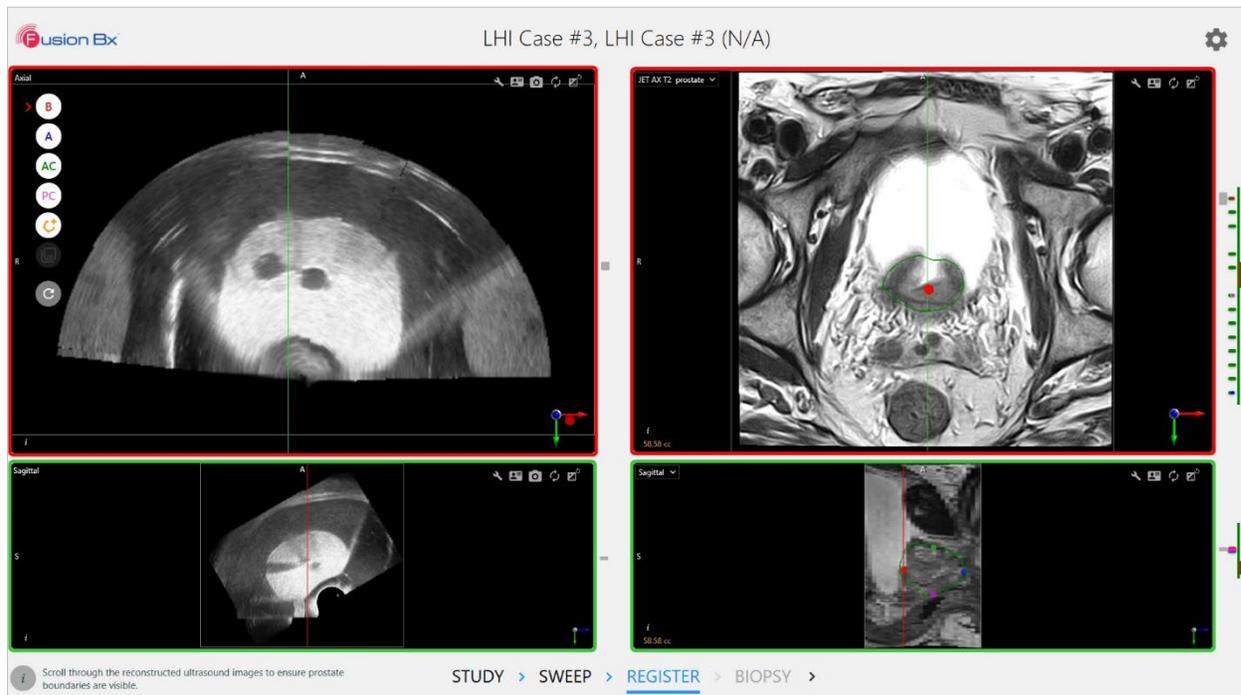


2. Select **Play**  or press the **Green** stepper button. Rotate the probe clockwise approximately 200° until the entire prostate is captured. It is recommended that you rotate the probe at a consistent speed using the speed indicator as a feedback and limit any motion outside of rotation. As you are rotating the probe through the prostate, the reconstructed ultrasound view will be displayed simultaneously in the adjacent window. Additionally, a blue progress bar will fill as the probe is rotated. Once the probe is rotated to approximately 200°, the bar will be full and will display a message of “Done!”. Do not sweep beyond this point. Ensure large sections of the reconstruction are not being missed as you rotate the probe through the prostate.

→ If you notice you missed a large section of the prostate while performing the sweep. Select **Reset sweep** . Re-position the probe to the proper starting position and select **Start**  or press the **Green** stepper button to re-do the sweep.



3. Once you have captured the entire prostate, select **Stop**  or press the **Green** stepper button. The software will automatically progress to the Register page.
4. Before continuing with the registration process, review the reconstructed ultrasound volume generated in the two left windows.
  - By default, the top left window will be the axial view and the bottom left window will be the sagittal view.
  - Scroll through each image viewer to ensure the entire prostate was captured and that no areas of the prostate have been poorly reconstructed. These areas will be indicated as large black sections missing in the prostate. If these areas are present, select **Sweep**  to redo the sweep. A pop-up window will appear to verify you want to leave the Register page, select **Yes** .
  - Use **Tools**  to change the display of a given image.
  - Use **Reset**  to reset the image back to its default state



5. If you are satisfied with the reconstruction, proceed with the **Register** process.

## WINDOW LEVELING

If you find the live ultrasound image on the Sweep page unclear then there are controls available to adjust the brightness and contrast. These controls should only be used once all appropriate controls on the ultrasound machine have been adjusted and there is a difference between the image on the ultrasound machine and the one shown on the Sweep page.

- **Brightness** is adjusted by holding the ALT button on the keyboard and the left mouse button, and dragging the mouse left and right over the viewer.
- **Contrast** is adjusted by holding the ALT button on the keyboard and the left mouse button, and dragging the mouse up and down over the viewer.

Window levels can be saved, reset and reloaded by clicking on **Brightness/Contrast** . These settings affect the live ultrasound image on the Sweep and Biopsy pages. They do not affect the reconstructed ultrasound images on the Register page.

### Stepper Shortcuts:

Key	Action
	Start and Stop Sweep
	Start Initialize Hardware

### Button Table:

Name	Button	Action
Home		Start the Initialize Hardware process
Play		Starts Sweep recording
Stop		Stops Sweep recording and brings you to Register page
Re-do Sweep		Erases the current Sweep and allows you to perform a new one.
Screenshot		Acquires a screenshot
Brightness/Contrast		Adjust the brightness/contrast of the view
Settings		Opens the Settings menu

## 6.9 REGISTER: CONTOURING AND REGISTRATION

Once the sweep is complete, the Register page allows you to contour the reconstructed TRUS image and co-register (i.e. fuse) the previously-acquired DICOM (MRI) to the TRUS image. If you are performing a tracked systematic biopsy, you will contour but not co-register.

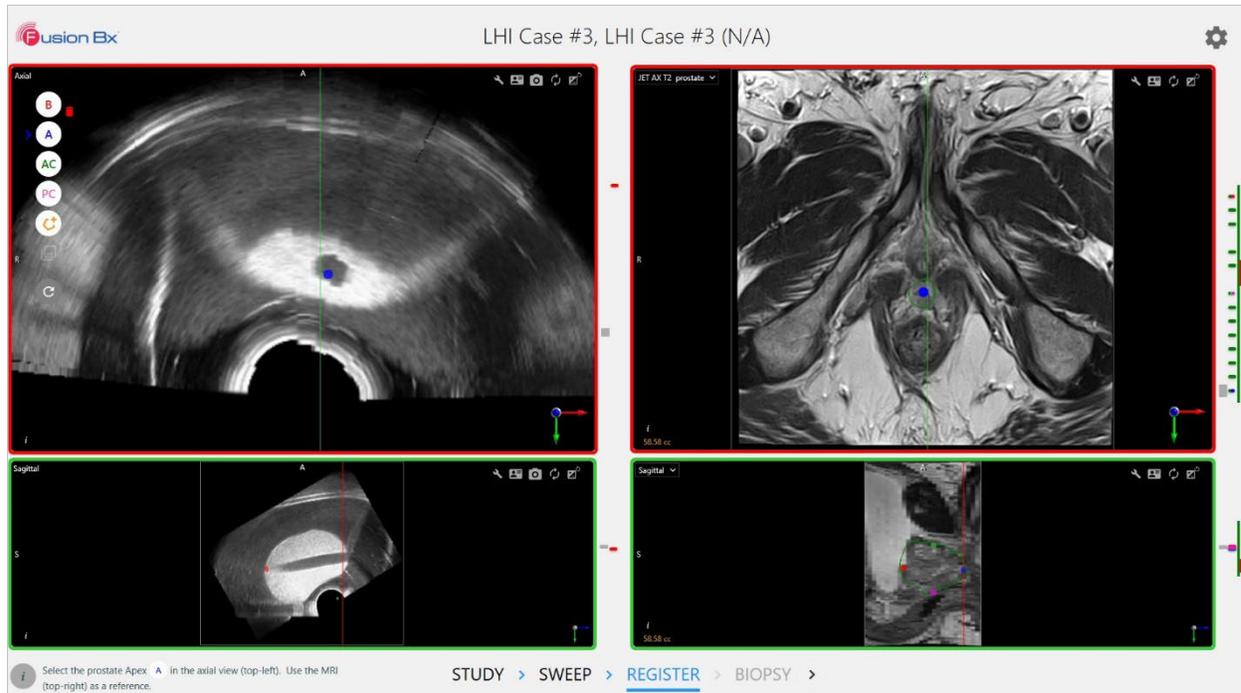
### LANDMARKING

The registration process begins with the selection of four prostate landmarks (base, apex, anterior capsule, and posterior capsule) in the axial view (primary viewer) of the 3D reconstructed ultrasound image. Below the axial view, in a separate window (secondary viewer), the sagittal view of the reconstructed ultrasound volume is provided to help with the selection of these landmarks. The sagittal view is used for both the selection of landmarks and for scrolling and guidance (i.e. clicking on a point will take you to the corresponding axial slice). To fuse MRI to TRUS, these points will be aligned with the landmarks previously chosen by the radiologist on MRI. Therefore, it is of utmost importance that the locations of these points match. Refer to the right MRI window to see where the landmarks were picked on MRI.

1. **Base**  : Use the sagittal ultrasound view to select a point near the base of the prostate. Using the axial view, make fine adjustments by scrolling with the scroll bar (or mouse scroll wheel). Select the point in the base of the prostate that most closely matches the base chosen by the radiologist (refer to the MRI on the right). Once you've selected the base, the software will automatically progress to **Apex** selection.

*Note: you may click on any of the buttons to bypass auto-progression and select that landmark.*

2. **Apex**  : Use the sagittal view to select a point near the apex of the prostate. Similar to base selection, use the axial view for fine adjustments. Select the apex point that most closely matches the apex chosen by the radiologist (refer to the MRI on the right). Once you've selected the Apex, the program will automatically progress to **Anterior Capsule** selection.



Marking the Apex on the Register page.

3. **Anterior capsule** AC : You will be taken to a slice midway between the selected base and apex landmarks. Select the anterior capsule point to match the radiologist’s selection (refer to the MRI on the right). The program will automatically progress to **Posterior capsule** selection.
4. **Posterior capsule** PC : Select the posterior capsule point to match the radiologist’s selection (refer to the MRI on the right). The program will automatically progress to **Contour** mode.

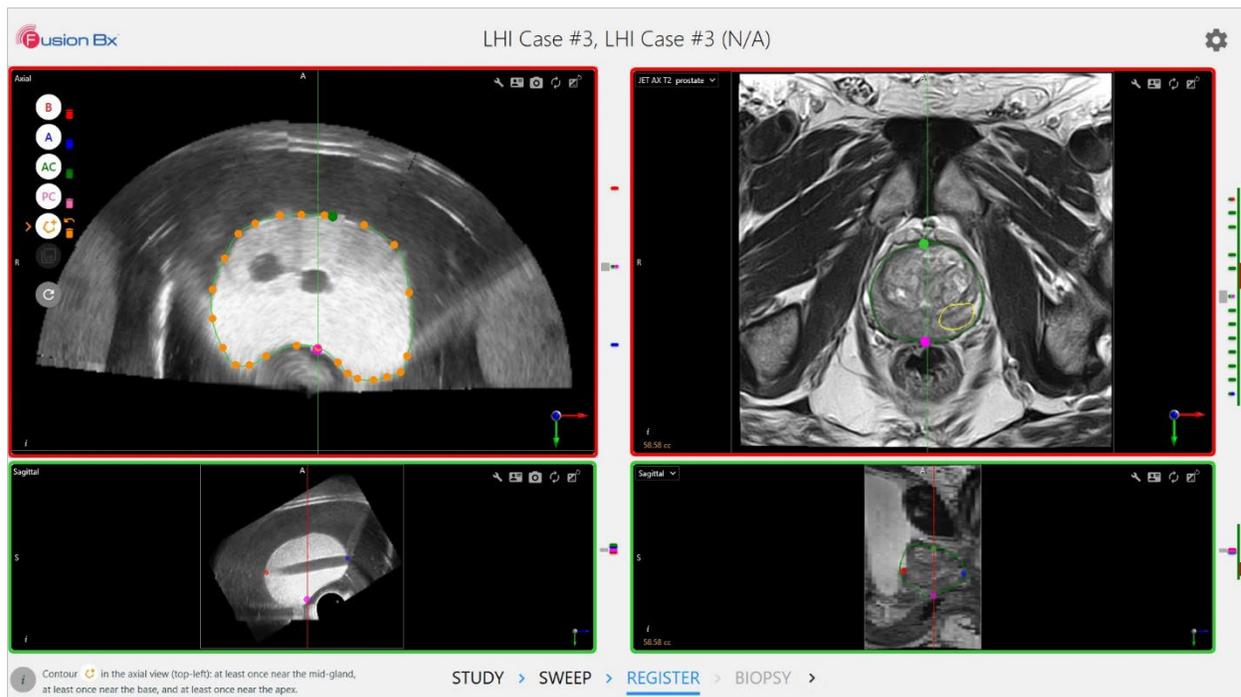
*Note: You can edit landmarks by clicking on their respective buttons along the left side of the viewer. Selecting a landmark will take you to the location of this respective landmark. To change landmark location, select the trash-can beside a given landmark and place it in your desired location. These can be edited or deleted at any point before **Register** is selected. When re-selecting a landmark, the software will automatically progress to the next unfinished step.*

## CONTOURING

The contouring step allows you to outline the prostate gland on the reconstructed TRUS image. Contouring is crucial to accurate non-rigid registration (“fusion”) of segmentation on previously-acquired MRI to the new segmentation on the reconstructed 3D ultrasound. In turn, the ROIs from MRI are fused to the ultrasound.

1. After selection of landmarks, you will automatically progress to the contouring function . Contour the prostate surface on the TRUS axial view. Begin outlining a slice at mid-gland where the gland is clearly visible (i.e. the slice where the Anterior and Posterior capsule landmarks were selected).
2. **Select points along the outline of the prostate** until you've generated a contour. A minimum of three points are required. Click back on the original point to close the shape.

*Note: Consult the previously-acquired MRI in the right window to make sure that your contours on TRUS correspond to those that were contoured on MRI.*



*Contouring the prostate on the Register page.*

3. Once the mid-gland contour is closed, the software will automatically bring you to the ultrasound slice with the base landmark. Note, that contouring on the auto-scroll slice may not give you the best results. Scroll down 2-3 slices and select a slice where the prostate boundaries are clearly discernible.

Contour the gland in the axial view. Avoid contouring adjacent slices, as this can result in a jagged 3D surface.

4. Once the base contour is closed, the software will automatically bring you to the ultrasound slice with the apex landmark. Note, that contouring on the auto-scroll slice may not give you the best results. Scroll up 2-3 slices and select a slice where

the prostate boundaries are clearly discernible.

Contour the gland in the axial view. Avoid contouring adjacent slices, as this can result in a jagged 3D surface.

*Note: To improve the accuracy of the registration, space the contours apart as much as possible. We recommend contouring one slice near the base, middle, and apex of the prostate.*

5. After contouring three slices, the software creates a full 3D surface by interpolating between the slices that you have contoured. This interpolation minimizes the number of slices that you need to contour. Slices that you have created or edited will show up as green markers along the status bar to the right of the viewer, as they are considered correct. They will not change unless you modify them. Interpolated slices will not have any bookmarks associated with them. These are updated (re-interpolated) every time you make a change. The software shows the results of this interpolation in both the axial and sagittal TRUS views. **Review the segmentation** in both the axial and sagittal view. Contours can only be adjusted on the axial image in the primary viewer, but you can use the sagittal view as a guide to correct for any areas that have not been segmented appropriately. Clicking on a sagittal slice will bring you to the corresponding axial slice.

*Note: The volume measurement of the segmented prostate will appear in the bottom left corner of the axial TRUS window. Additionally, a percentage versus MRI volume will be displayed, this will give an indication of how close the TRUS volume is compared to the MRI volume. Before proceeding, take note of the volumes and ensure they are similar between TRUS and MRI.*

*For tracked systematic biopsies:*

Since you will not be co-registering MRI to TRUS, at this point you can move to the next step by clicking **Biopsy**.

6. When you are satisfied with the segmentation click **Register**  to perform MRI to TRUS fusion. You also have the option of editing or adding more contours.

## EDITING THE SEGMENTATION

After three slices have been manually contoured, Fusion Bx will automatically segment the rest of the prostate. The segmentation can be verified by scrolling through the images in the axial and sagittal views. Contours are only editable from the axial view. You can continue to re-contour or edit slices at any time. To edit contours:

1. **Scroll** to the image slice you wish to edit. This can be accomplished by selecting a desired point in the sagittal view or scrolling through the axial view.
2. To edit a slice that has not been manually contoured (i.e. an interpolated slice), you have three options:
  - I. To make small edits to the contour, hover the mouse cursor over the portion of the contour you want to modify then click and drag it to the desired position. As soon as an interpolated contour is clicked, vertices will automatically appear below the mouse cursor and along the rest of the contour. The contour will now be treated as a manually drawn contour. Editing this contour will follow the same sequence of steps outlined in step 3 below.
  - II. To re-contour the entire slice, simply begin selecting points along the boundaries of the prostate to generate a new contour.
  - III. If re-contouring an entire slice that is close to the existing contour, select the trash-can beside **Contour**  first.

To re-select the last placed vertex at anytime, select the undo arrow beside

**Contour** . For completed/closed contours, the undo action can only be done until there are a minimum of three vertices visible.

3. To edit a manually drawn contour, two options are available:
  - I. To edit a portion of the contour, simply drag the vertices around the contour to the desired position.
  - II. To re-do an entire contour, select the trash-can beside **Contour** . As implied, this will clear the entire contour from the current slice. Begin selecting points along the boundaries of the prostate to generate a new contour. To re-do the entire contour you have drawn, select the trash-can beside **Contour** . To re-select the last placed vertex at anytime, select the undo arrow beside **Contour** .

*Note: While Fusion Bx will automatically update the entire interpolated segmentation after each edit occurs, user-placed points and contours will never be changed.*

4. When you are satisfied with the segmentation, select **Register** .

*Note: Fusion Bx will automatically guide you through a pre-determined workflow of selecting landmarks first and then contouring. However, you can deviate from this workflow at anytime. For example, contouring can be completed before selecting landmarks if desired.*

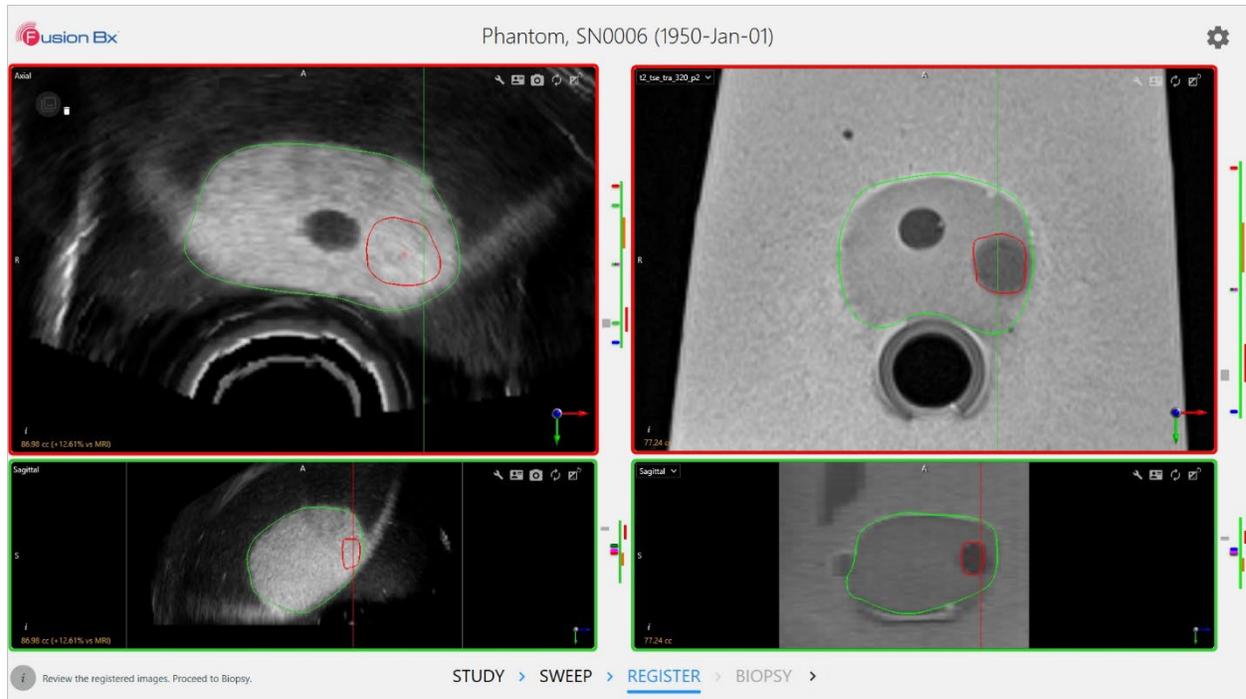
**WARNING:** While contouring the prostate do not select the Contour button, as this will result in a freezing of the contouring process. If this action is performed accidentally, select the trash-can or scroll to another slice to resume the contouring process.

**WARNING:** If any of the tools in the tool tab are selected during the contouring process then the vertices of the contour may not be visible. To restore the vertices, simply click on the Contour button.

**⚠ CAUTION:** It may be difficult to place landmarks at locations in close proximity to active contour vertices. The contour tool is activated when the user's cursor is in close proximity to a vertex. The landmark tool is temporarily inactive under this condition, and therefore, may create difficulties placing a landmark near an active vertex. Temporarily adjust the contour, place the landmark, and then correct the contour accordingly if presented with this situation.

## REVIEWING THE REGISTRATION

After the registration is complete, the fused volume will appear in the left window. When you are finished reviewing, click **Biopsy**  to proceed.



*Register page displayed after MR-TRUS fusion*

- Use the **Tools tab**  to complete any of the following actions: zoom, pan, adjust contrast/brightness, auto adjust contrast/brightness, measure
- **Zoom** can also be performed by right-clicking and dragging.
- **Pan** can also be performed by middle-clicking and dragging.
- The opacity of various items can be edited by selecting **Settings** . This includes Prostate, ROI, Landmarks, Needle Guide, Biopsy Cores, and Bulls Eye. Turn the opacity up or down by moving the respective toggle right or left.
- Auto Scroll Slices can be turned on or off by selecting **Settings** . By default, this will remain on. To turn off, simply switch the toggle to the left.
- View the results of the rigid registration by switching the toggle to the right in the **Settings**  menu.

**WARNING:** In rare occurrences the segmentation may appear “twisted”. Ensure to always review the segmentation in detail, and adjust as necessary before proceeding to the Biopsy page.

## ADDITIONAL FEATURES

- Reset the view of the reconstruction and the MRI by clicking **Reset View** 
- To delete the registration and return to contour mode, click the trash-can beside **Register**  .
- To restart from the beginning of landmark selection, click **Reset all landmarks**  .  
A warning message will pop-up to confirm you want to reset registration, contours, and landmarks.
- To take a screenshot, click **Screen Capture**  .

Stepper Shortcuts:

Key	Action
NOT APPLICABLE	

Button Table:

Name	Button	Action
Base		Go to Pick Base mode
Apex		Go to Pick Apex mode
Anterior Capsule		Go to Pick Anterior Capsule mode
Posterior Capsule		Go to Pick Posterior Capsule mode
Contour		Enable Contour mode
Contour (Selected)		Enables the user to delete the entire contour or delete the last placed vertex.
Co-register		Register MR to TRUS image
Reset		Resets all landmarking and contouring
Settings		Opens the Settings window
Screenshot		Acquire a screenshot
Tools		Activates image editing tools

Patient Information		Opens patient information
Reset View		Resets the image back to default state
Reset Brightness/Contrast		Resets the contrast/brightness of the image

## 6.10 BIOPSY: ACQUIRING TARGETED SAMPLES

The Biopsy page is where you can begin to take biopsy samples from the patient. It contains two viewing windows: the window on the right shows the ultrasound image plane with respect to the 3D rendering of the prostate, the registered ROIs, and the probe. The window on the left shows the live TRUS image with the prostate segmentation and ROIs overlaid. A markup tool is provided to record the location of biopsy samples for future reference. The motion compensation feature allows manual adjustment of the location of the fused image in relation to the live TRUS feed if they become visibly misaligned. Misalignment can be identified when the prostate segmentation does not line up with the prostate seen on the live TRUS image.

### MOVING THE TRACKER AND STEPPER

The following tables help to identify how the tracker and/or stepper should be moved or positioned to target a specific region in the prostate. Table 1 summarizes tracker arm position using a side-fire biopsy approach and Table 2 summarizes tracker arm position using an end-fire biopsy approach. The patient is positioned in left lateral decubitus for both biopsy approaches.

**Table 1- Side-fire Biopsy:** Summarizes the tracker arm position and how it relates to a position within the prostate using a side-fire biopsy approach. The tracker arm position is relative to the user's position while using Fusion Bx, whereas the region of the prostate follows proper anatomical conventions.

Target/Prostate Region	Tracker Arm Position
MID-GLAND	STARTING POSITION
Anterior	Tracker arm compressed
Posterior	Tracker arm extended
Right side	Rotate stepper counter clockwise (CCW)
Left side	Rotate stepper clockwise (CW)
Base	Insert probe (CCW on stepper dial)
Apex	Retract probe (CW on stepper dial)
Anterior base	Tracker arm compressed + insert probe
Posterior base	Tracker arm extended + insert probe
Anterior apex	Tracker arm compressed + retract probe (dial on stepper)
Posterior apex	Tracker arm extended + retract probe (dial on stepper)
Right side	Tracker arm pushed down
Left side	Tracker arm pushed up

**Table 2- End-fire Biopsy:** Summarizes the tracker arm position and how it relates to a position within the prostate using an end-fire biopsy approach. The tracker arm position is relative to the user's position while using Fusion Bx, whereas the region of the prostate follows proper anatomical conventions. During an end-fire biopsy, using an axial view of the prostate is recommended. To accommodate this the probe will need to be positioned with the needle guide at 6 o'clock, or the needle guide at 12 o'clock. To avoid penetrating the urethra, the following is recommended: when targeting the left side of the prostate, the needle guide should be positioned at 6 o'clock (i.e. positioned at the bottom of the probe); when targeting the right side of the prostate, the needle guide should be positioned at 12 o'clock (i.e. positioned at the top of the probe). In most cases, when the needle guide is at 12 o'clock (i.e. top of the probe), the left side of the prostate is on the left side of ultrasound screen. When the needle guide is at 6 o'clock (i.e. bottom of the probe), the right side of the prostate is on the left side of the ultrasound screen. You can adjust R/L ultrasound settings to achieve your desired orientation of the prostate. **Once in your mid-axial starting position, inserting and retracting the probe is not recommended as this may change the shape of the prostate.**

Targeting the Left Side of the Prostate (Needle guide at 6 o'clock - bottom of probe)	
Target/Prostate Region	Tracker Arm Position
MID-AXIAL	STARTING POSITION
Apex	Tracker Arm Compressed
Base	Tracker Arm Extended
Towards midline (Right side)	Tracker Arm Pushed Down
Towards lateral edge (Left side)	Tracker Arm Pushed Up
Targeting the Right Side of the Prostate (Needle guide at 12 o'clock - top of probe)	
Target/Prostate Region	Tracker Arm Position
MID-AXIAL	STARTING POSITION
Apex	Tracker Arm Compressed
Base	Tracker Arm Extended
Towards lateral edge (Right side)	Tracker Arm Pushed Down
Towards midline (Left side)	Tracker Arm Pushed Up

## TAKING BIOPSY SAMPLES AND RECORDING THEIR LOCATION

*Note: It is recommended that the registration at both lateral edges of the prostate are checked at the start of each biopsy to ensure proper registration. If misalignment is detected, use the motion compensation feature described in the next section.*

### 1. **Acquire your biopsy sample** and eject the core.

*Note: Targets in anterior apical regions of larger prostates can be challenging to reach using the side-fire biopsy approach. In this case, it may be necessary to orient the probe at a large angle with respect to the prostate. To facilitate this, conduct the initial setup and sweep with the tracker extended further than usual (e.g. 3/4 of the way extended instead of 2/3 extended).*

### 2. **Record the location of the biopsy sample** in one of three ways:

- a. Click **Add Biopsy Core** . A core marker (orange cylinder) will appear along the needle guide.
- b. Press the **Green** stepper button. A core marker (orange cylinder) will appear along the needle guide.
- c. Double-click any location in the left window where the tip of the sample was taken. A core marker (orange cylinder) will appear below your click-point.

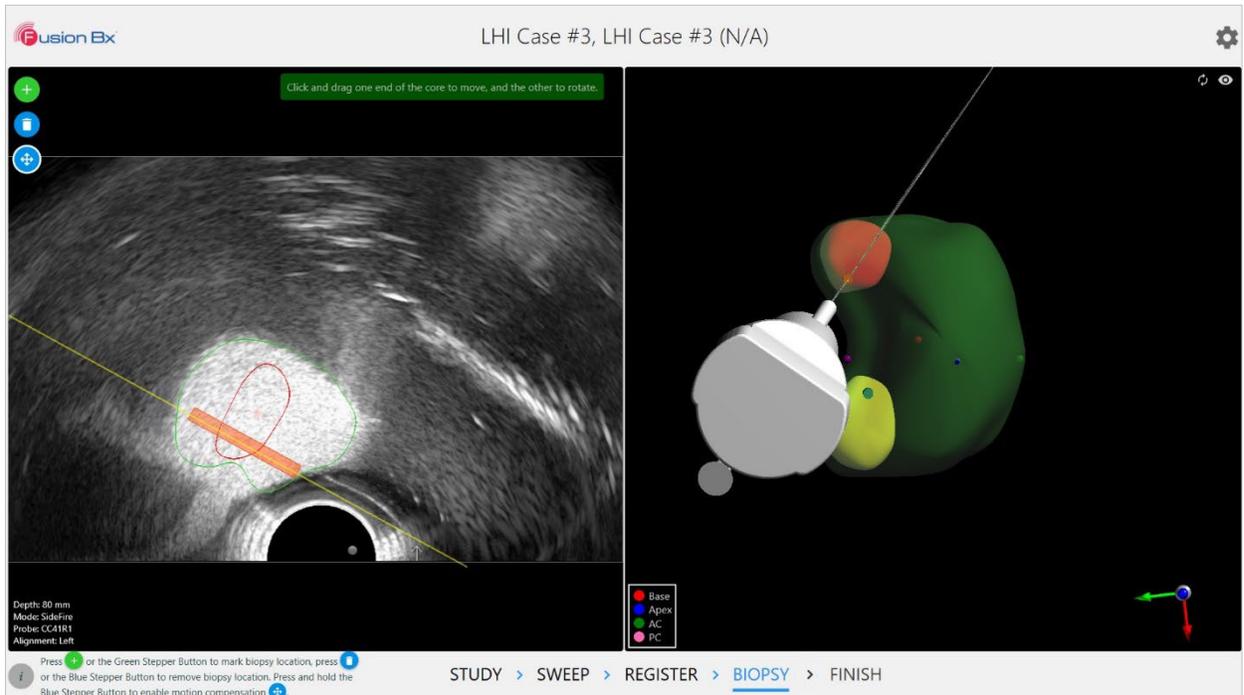
### 3. **Adjust the core marker location and angle.**

- To move the core marker, hover the mouse cursor over the top half of the core (a pan icon will appear), and left click and drag the cylinder.
- To change the angle, hover the mouse cursor over the bottom half of the core (a rotate icon will appear), and left click and drag the cylinder.

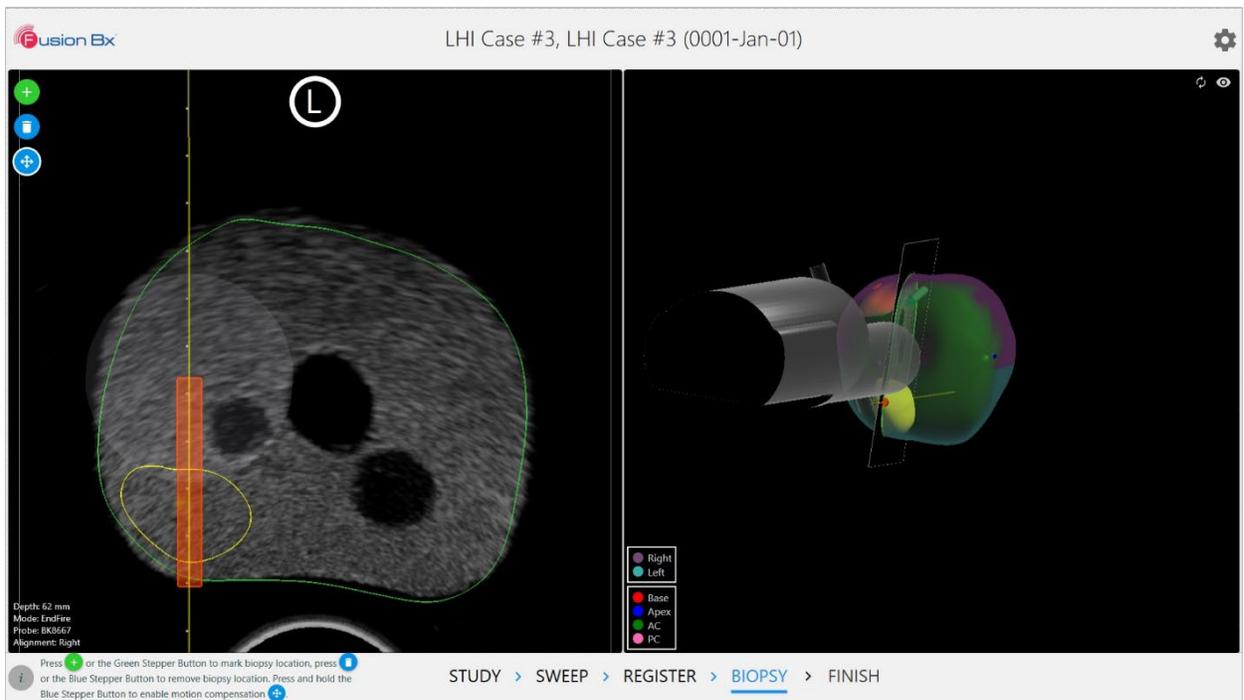
### 4. **Repeat steps 1-4** for each fusion and systematic biopsy sample taken.

### 5. If you ever add a core accidentally, simply press **Remove Biopsy Core** or the **Blue** stepper button to remove it.

### 6. When you are finished with the procedure, remove the probe from the patient's rectum and click **Finish** .



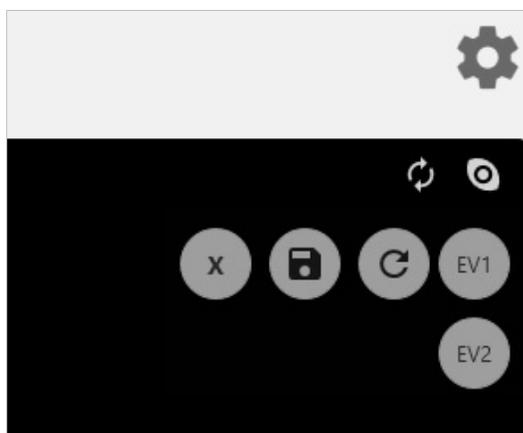
*Biopsy page in Add a Core mode*



*Biopsy page in Add a Core mode: End-fire*

## ADDITIONAL FEATURES

- The yellow line is the needle guide. This is the estimated trajectory of the needle calculated by the software and should closely approximate the actual needle track on the TRUS feed. If it does not, contact your Focal Healthcare representative.
- Each ROI will have a bullseye indicating the center of the ROI.
- Core features can be changed by clicking **Settings**  and selecting **Add New Core** . Set Needle Gauge and Core Length and describe core as desired.
- To change various visual properties, click **Settings**  and select the **Visualization** tab. Visualizations can be changed on the Live Ultrasound and the 3D Mesh. For Live Ultrasound the opacity of the following can be changed from 0 to 100% by dragging their respective toggles from left to right: **Prostate, ROI, Landmarks, Needle Guide, Biopsy Cores, Bullseye**. For 3D Mesh the opacity of the following can be changed from 0 to 100% by dragging their respective toggles from left to right: **Prostate, ROI, Landmarks, Needle Guide**.
- The ultrasound imaging plane and ultrasound probe on the 3D Mesh can be toggled on and off through the **Settings**  menu.
- In the event of lag between the movement of the probe and on-screen video capture, wait a couple of seconds until the video catches up. This can sometimes happen if the probe is moved too quickly.
- The 3D model is oriented differently for side vs. end-fire biopsy. Two options are given for each biopsy approach, select the **Eye**  in the top-right corner of the 3D model window to choose your desired view. This model can be zoomed, panned, and rotated to best suit user needs. Right-clicking on a view button will give you the option to **Reset to Default** , **Save Current Position** , or **Exit** . Selecting **Return to Last Saved View**  will orient the 3D model in the position it was last saved in.



Right-click on a View button (i.e. EV1) to access additional options

## ADDITIONAL FEATURES: ENDFIRE ENHANCE

The following features are only available during an end-fire biopsy approach. When using an end-fire ultrasound probe, the right and left sides of the prostate are switched on the live ultrasound depending on how the probe is rotated. These features are intended to help the user easily identify which side of the prostate they are targeting, and can be toggled on or off to best suit the user's needs:

- By default, the 3D model of the prostate is divided in half by different colors. The right side of the prostate is represented by a purple shading, and the left side of the prostate is represented by a blue shading. To turn this setting off, select **Settings**  and select the **Endfire Enhance** tab. Navigate to the toggle bar beside **Prostate Color** and switch it to the off position (tab on the left side).
- By default, when the needle guide is intersecting the left side of the prostate, a large “L” will be displayed on the live ultrasound view. Conversely, when the needle guide is intersecting the right side of the prostate, a large “R” will be displayed on the live ultrasound view. To turn this setting off, select **Settings**  and select the **Endfire Enhance** tab. Navigate to the toggle bar beside **Probe View Display** and switch it to the off position (tab on the left side).
- By default, the probe rendering is displayed as a translucent model to avoid the probe impeding on the 3D model. To turn this setting off, select **Settings**  and select the **Endfire Enhance** tab. Navigate to the toggle bar beside **Glass Probe** and switch it to the off position (tab on the left side). The probe will be displayed as white and opaque.
- By default, the opacity of the 3D model remains the same when targeting any area of the prostate. To turn this setting off, select **Settings**  and select the **Endfire Enhance** tab. Navigate to the toggle bar beside **Prostate Opacity** and switch it to the off position (tab on the left side). When the needle guide is intersecting a given side of the prostate, that side will be displayed as more translucent.

## MOTION COMPENSATION

The motion compensation feature provides the ability to automatically and manually adjust the location of the fused image in relation to the live TRUS image. If they become misaligned, this could lead to suboptimal targeting if left uncorrected. Misalignment can occur through pressure applied by the probe and the needle, patient movement (including respiration), and prostate motion. In addition, inaccurate segmentation can be mistaken for misalignment. Misalignment due to motion can be accounted for in two ways, automatically and manually.

### Automatic Motion Compensation

Automatic motion compensation is switched on by default but can be toggled on and off in Settings. Fusion Bx's automatic motion compensation will only account for movement in the pitch and/or yaw stepper directions. For optimal use of this feature it is necessary to engage the tracker lock prior to performing the sweep (see Section 5.7). This will help isolate the patient movement and more accurately compensate for it. Any movement outside of stepper pitch/yaw will automatically disable this feature. Excessive patient movement, movements outside of pitch and/or yaw, and applying various forces on the probe may not be corrected using automatic motion compensation.

### Manual Motion Compensation

For scenarios where patient movement cannot be addressed with automatic motion compensation, manual motion compensation can be used instead.

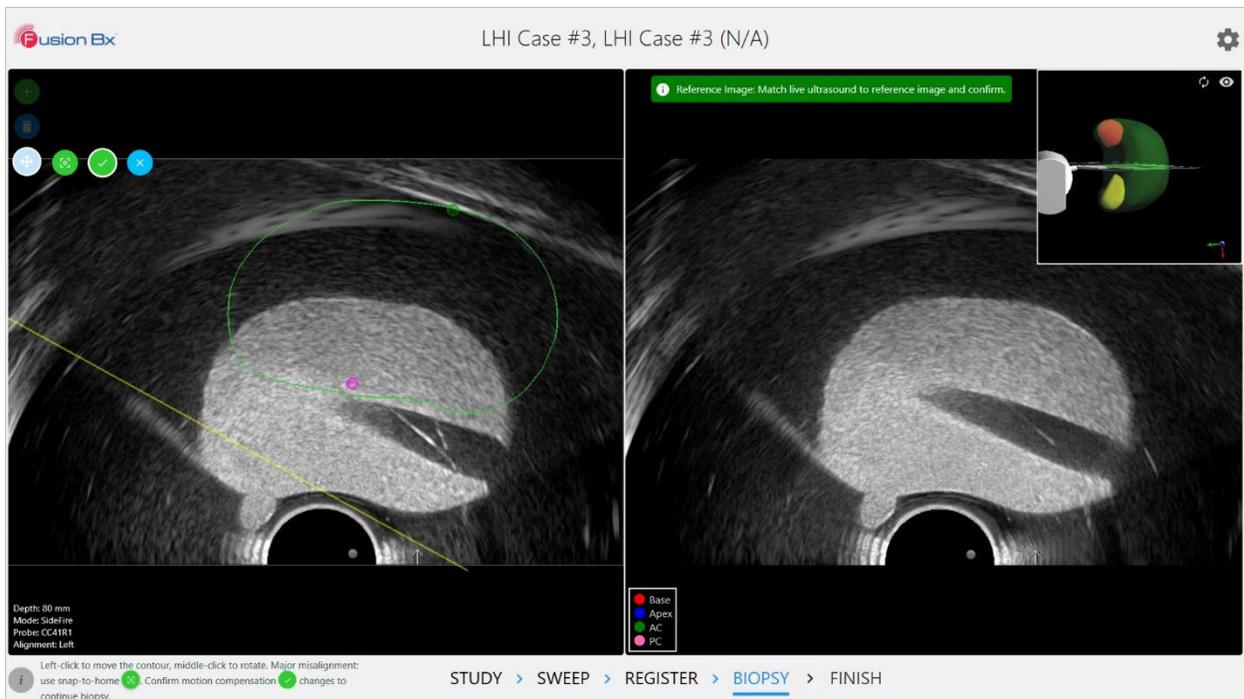
1. Click **Motion Compensation**  or press and hold the **Blue** stepper button. This unlocks the contour and allows for manual adjustments.
2. **Adjust the prostate contour** (green) until it overlaps with the TRUS feed.
  - Move the contour: position the mouse cursor within the boundaries of the contour (a pan tool will be displayed), left-click and drag mouse.
  - Rotate the contour: position the mouse cursor outside the boundaries of the contour (a rotation tool will be displayed), left-click and drag mouse.

*Note: After using these methods, check alignment by rotating the probe to each lateral edge of the prostate.*
3. Click **Confirm Motion Compensation**  to accept changes or **Cancel Motion Compensation**  to discard changes. Alternatively, press and hold the **Green** stepper button to accept changes or press the **Blue** stepper button to discard changes.

In cases of significant patient motion and substantial misalignment:

1. Click **Motion Compensation**  or press and hold the **Blue** stepper button.
2. The **Snap-to-Home**  feature option now displayed is used to readjust for significant patient motion.
3. This **Snap-to-Home**  feature is available, only in the same R/L flip setting the 3D sweep reconstruction (section 6.8) was obtained in. Hence, if the snap to home feature is disabled , the R/L flip orientation on the ultrasound should be changed to enable it.

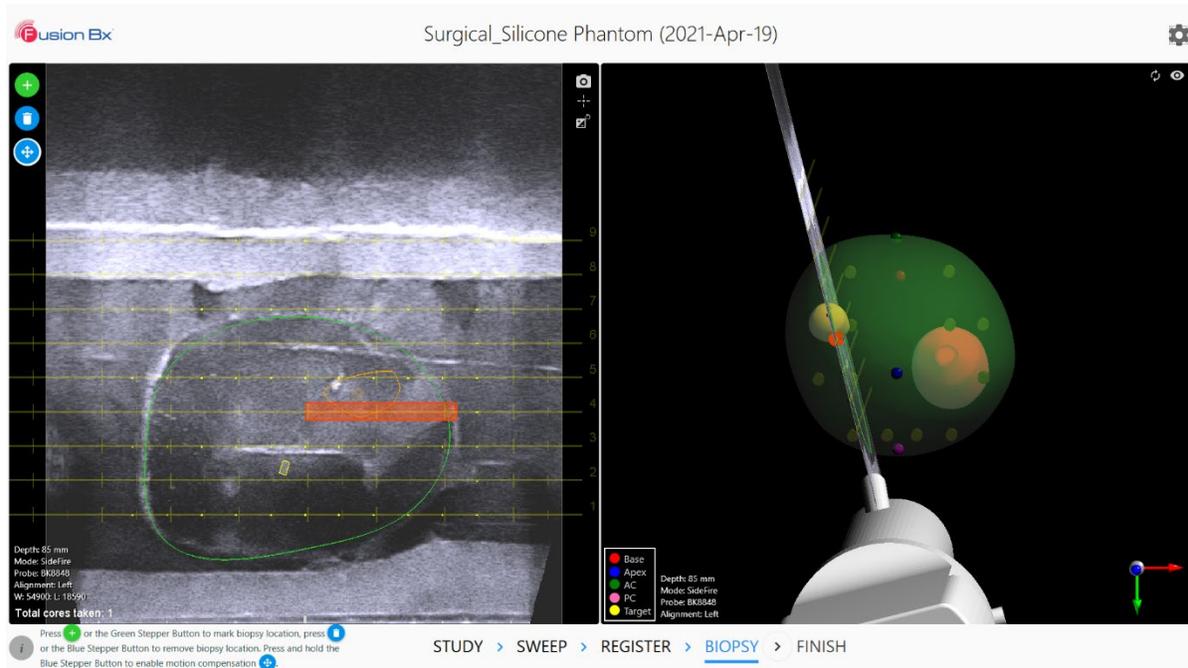
4. An ultrasound view of the prostate where the **Anterior Capsule** was selected appears on the lower right-hand side of the screen under the 3D rendering of the prostate.
  - In Sidefire, this will roughly correspond to a mid gland sagittal image of the prostate.
  - In Endfire, this will roughly correspond to the image at 90 degrees clockwise from where the sweep was started.
5. Adjust the live ultrasound image to correspond to the image displayed on the lower right-hand side of the screen.
6. Once the live ultrasound image is realigned, select **Snap-to-Home**  or press the **Green** stepper button. This will bring the contour back into alignment.
7. Minor in-plane adjustments can be made if necessary. Confirm alignment by rotating the probe to each lateral edge of the prostate.
8. Click **Confirm Motion Compensation**  to accept changes or **Cancel Motion Compensation**  to discard changes. Alternatively, press and hold the **Green** stepper button to accept changes or press the **Blue** stepper button to discard changes.



*Biopsy page with motion compensation enabled*

## SYSTEMATIC BIOPSY TEMPLATE

When enabled, a systematic biopsy template can be used to guide users to take biopsy samples from specific areas defined by the template. The template is enabled or disabled by clicking **Show Biopsy Grid**  in the top corner of the live ultrasound viewer. Enabling the systematic template will place small yellow cylinders throughout the 3D mesh and the live ultrasound view. The locations of the yellow cylinders are determined by the configured biopsy grid layout and the volume of the 3D mesh. Information regarding the configuration of systematic biopsy templates can be found in Section 7.1.



*Systematic Biopsy Template*

### Stepper Shortcuts:

Key	Action
	Add Biopsy core (single-press)
	Remove Biopsy core (single-press)
	Activate Motion compensation (press-and-hold)
Motion Compensation State:	
	Snap-to-home (single-press)
	Confirm changes (press-and-hold)
	Discard changes (single-press)

Button Table:

Action	Button	Function
Add a Core		Record the location of your biopsy sample
Delete Last Core		Delete the last added core reconstruction
Motion Compensation		Activates Motion Compensation
Reset View		Reset 3D model to default view
View Pop-ups		Opens 3D model view options
Show Biopsy Grid		Enables systematic biopsy template
Reset to Default		Resets 3D model back to factory pre-set
Save Current Position		Saves the 3D model in its current position
Exit		Closes the View Pop-ups tab
Snap-to-Home		Activates Snap-to-Home
Confirm Motion Compensation		Confirms motion compensation changes
Discard Motion Compensation		Discard motion compensation changes
Settings		Opens Settings menu

## 6.11 INTERRUPTED OR ABORTED PROCEDURE

There is a possibility that a procedure is interrupted or needs to be aborted, resulting in an incomplete procedure. Fusion Bx will automatically save all completed portions of the procedure before the interruption occurred. This includes reconstructed ultrasound data from the Sweep page, contoured ultrasound data from the Register page, biopsy core locations from the Biopsy page, and any screenshots taken throughout the procedure.

## 6.12 REPORT: REVIEW PROCEDURE

The Report is accessed through the Study page and allows you to add notes and measurements, review the procedure (including biopsy samples and screenshots), and add pathology results. After completing the Biopsy step and selecting **Finish** **FINISH** the View Report tab will automatically be displayed. To access the Report at any other time, select the drop-down beside the patient's name, and click the View Report tab. The information on this page will automatically be saved to the patient's file and can be exported at your convenience. The Report can be edited by selecting **Edit Report** **Edit Report** in the bottom right-hand corner of the viewer. Three different pages are available for editing and review:

- 1) Notes
- 2) Images
- 3) Pathology Results

**Fusion Bx**

Patient Name: Phantom, SN0006  
Patient ID: SN0006  
Study ID: N/A  
Study Date/Time: 8/15/2018 2:03:40 PM

### 1. Patient Information

Patient Name	Phantom, SN0006
Patient Date of Birth	1/1/1950
Patient ID	SN0006

### 2. Ultrasound Summary

Prostate Volume (cc)	69.15
----------------------	-------

### 3. Procedure Summary

Procedure Date/Time	8/15/2018 2:03:40 PM
---------------------	----------------------

View Report

View Images

Reconstructed Sweep (8/15/2018 2:04:22 PM)

Series  
Reconstructed Sweep (8/15/2018 2:04:22 PM)

Annotation Files  
ISSRG01 Axial - 2018/08/15

69.15 cc

69.15 cc

Move probe to initial position; probe at prostate midline, stepper at 90 degrees and 1/2 way extended, tracker 2/3 extended, cart and swing arm locks engaged. Proceed to sweep.

[STUDY](#) > [SWEEP](#) > [REGISTER](#) > [BIOPSY](#) >

Edit Report

## NOTES

The **Notes** page allows you to add any relevant notes related to the patient and the procedure. Click within a dialogue box and begin typing to add notes.

Notes Images Pathology Results

View Report

### Patient Information

Patient Name: LHI Case #3, LHI Case #3  
Date of Birth: 1/1/0001  
Patient ID: LHI Case #3

### Diagnosis

Elevated PSA:   
Abnormal Exam:   
PSA (ng/ml): \_\_\_\_\_

### Ultrasound Summary

PSA Density (ng/ml/cc): \_\_\_\_\_  
Prostate Volume (cc): 96.46

### Study Description

Study Description: \_\_\_\_\_

### Procedure Summary

Study ID: \_\_\_\_\_

Date/Time: 8/15/2018  
Performing Physician: \_\_\_\_\_  
Location: \_\_\_\_\_

### Study Description

Study Description: \_\_\_\_\_

### Physician Notes

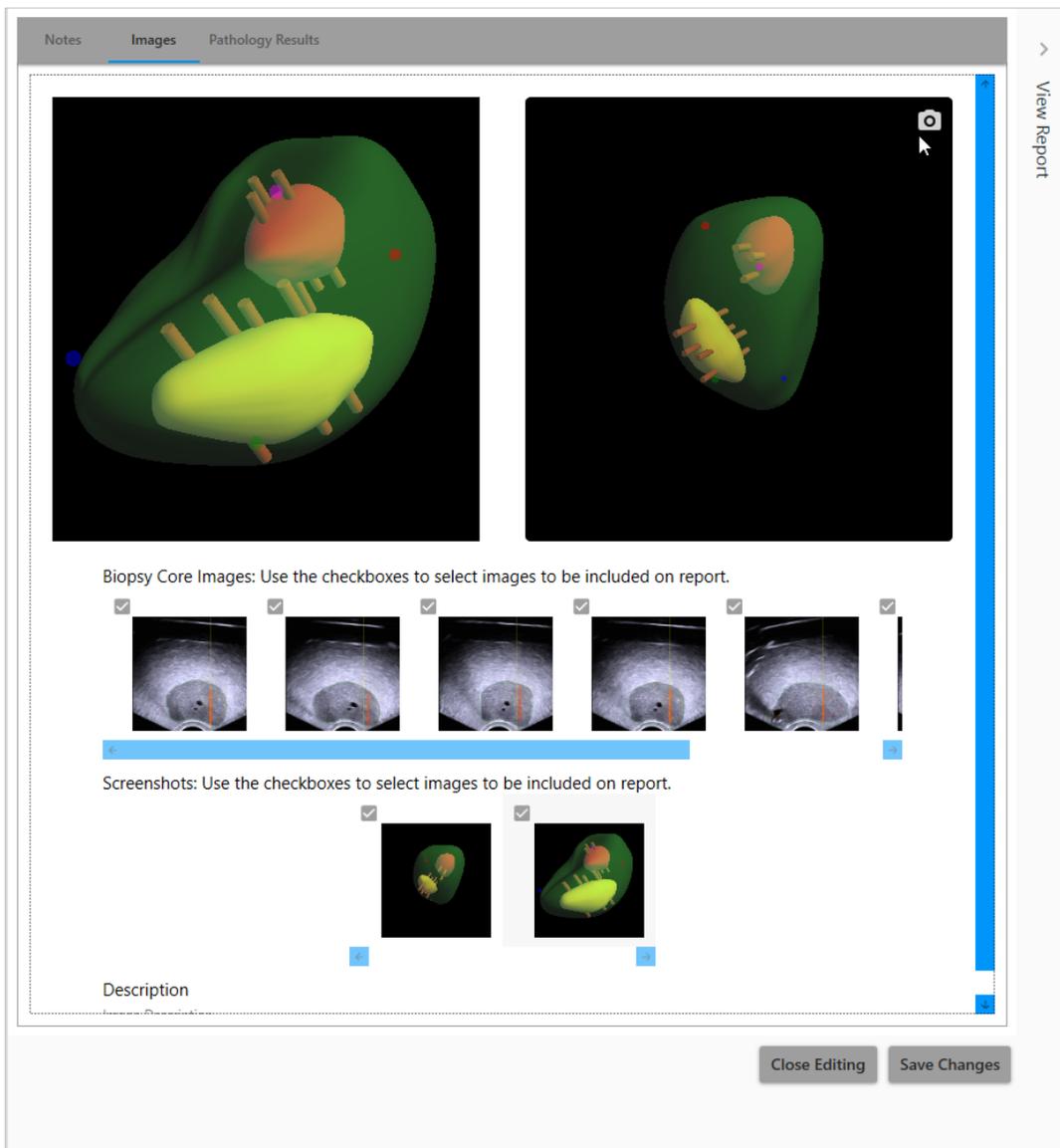
Physician Notes: \_\_\_\_\_

Close Editing Save Changes

## IMAGES

The **Images** page allows you to review the cores taken throughout the procedure. Every core placed throughout the procedure will have a screenshot associated with it. Click on a screenshot to enlarge it. Additionally, any screen captures taken throughout the procedure will be displayed here. By default, all images will be displayed in the report. If you do not want to include an image, simply uncheck the box in the top-left hand corner.

The 3D model that was generated during the procedure will also be available with all ROIs and cores shown. This is a live model that can be rotated (hold left mouse button and drag) and zoomed (hold right mouse button and drag) to share with patients. To take a screenshot of the 3D model and save it in the PDF report, click **Screen Capture**  .



The screenshot displays the 'Images' tab of a medical software interface. At the top, there are tabs for 'Notes', 'Images', and 'Pathology Results'. The main area shows two 3D models of a prostate gland with biopsy cores. Below the models, there are two sections for selecting images to be included in the report:

- Biopsy Core Images:** Use the checkboxes to select images to be included on report. This section shows a row of six grayscale images of biopsy cores, each with a checked checkbox.
- Screenshots:** Use the checkboxes to select images to be included on report. This section shows two 3D model screenshots, each with a checked checkbox.

At the bottom of the interface, there is a 'Description' field and two buttons: 'Close Editing' and 'Save Changes'. A vertical blue bar on the right side of the interface is labeled 'View Report'.

## PATHOLOGY RESULTS

The **Pathology Results** page displays a table that can be filled out according to the pathologist's report. By default, the 12 systematic biopsy locations and any available ROI's will automatically be populated in the Location column. You can add the following information: PIRADS, Region Volume, Core Length, Gleason Score, % Involved, and Description. Additionally, the following checkboxes are available for quick entry: Prostate Adenocarcinoma (PCa), Benign, Proliferative Inflammatory Atrophy (PIA), Atypical Small Acinar Proliferation (ASAP), Prostatic Intraepithelial Neoplasia (PIN). This page provides you with the ability to store pathology results in an organized fashion and can be used in the repeat biopsy (i.e. active surveillance) setting.

Notes
Images
Pathology Results

Location	PIRADS	Region Volume	Core Length	Gleason Score	% Involved	PCa	Benign	PIA	ASAP	PIN	Description
ROI #1	5	1.1cc	20mm	4+5	87	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
ROI #2	3	0.8cc	18mm	3+4	61	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RBL						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RBM						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
LBL						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
LBM						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RML						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RMM						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
LML						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
LMM						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RAL						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RAM						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
LAL						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
LAM						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Close Editing
Save Changes

> View Report

## REPORT FORMAT

The Report can be viewed in PDF format and can be saved to a local directory. Additionally, the Report can be pushed to PACS as a DICOM encapsulated PDF.

## RECONSTRUCTED ULTRASOUND DATA

In addition to report generation, the reconstructed ultrasound data collected during the procedure can be viewed. This data set can be saved as a DICOM and exported to a desired location.

*Note: The box-window level tool and pixel value indicator have no effect on the reconstructed images.*

## 6.13 TRANSFERRING DATA FROM FUSION BX

Once the procedure is complete, the data from the procedure (which can be viewed on the Study page) can be transferred to an electronic repository (e.g. urologist's computer) via encrypted USB flash drive, CD/DVD, LAN, or PACS. While transferring data from Fusion Bx does not automatically delete the data, we recommend that data which has been transferred be cleared periodically from Fusion Bx for optimal software performance (for instructions on how to delete patient files refer to Section 6.5).

**⚠ CAUTION:** This data contains confidential patient information. Ensure you are exporting it to an encrypted USB flash drive or to a password-protected network location.

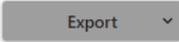
## USB FLASH DRIVE

1. Plug the USB flash drive into the USB port on the PC or monitor.
2. On the Study page, click on the checkbox next to the patient files you wish to transfer.
3. Click the drop-down arrow beside **Export** , then click **Export to USB** and select the appropriate flash drive. The Windows Explorer directory will be displayed showing you the flash drive contents. Select your desired export location. All selected contents will be exported to the USB flash drive.
4. When the transfer is complete, unplug the USB from the device port.
5. Transfer the data from USB to your computer.

*Note: Unplugging the USB before the transfer is complete can result in corrupted data.*

## DVD

1. Insert the DVD into the computer. (*Note: You will have to open the cart door to access the DVD drive.*)

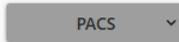
2. On the Study page, click on the checkbox next to the patient files you wish to transfer.
3. Click the drop-down arrow beside **Export** , then click **Export to DVD**. The Windows Explorer directory will be displayed showing you the DVD contents. Select your desired export location. All selected contents will be exported to the DVD.
4. When the transfer is complete, remove the DVD from the computer.
5. Transfer the data from DVD to your computer.

## LOCAL AREA NETWORK

1. Connect the Fusion Bx computer to a local area network via Ethernet cable or Wi-Fi (see Section 10.1 Remote Support for network configuration).
2. Click the drop-down arrow beside **Export** , then click **Export to a Folder**. The Windows Explorer directory will be displayed allowing you to access data from a connected network.
3. Navigate to the directory which contains your desired files. Click **Select Folder**.
4. Fusion Bx will import all the files contained within the given folder and display them in the patient list.

## EXPORT TO PACS

*Note: To export to PACS, Fusion Bx will need to be connected to a PACS server. See Section 7.1 for instructions on setting up PACS.*

1. On the Study page, click on the checkbox next to the patient files you wish to transfer.
2. Click the drop-down arrow beside **PACS** , then click **Export to PACS**. A progress bar will appear indicating the progress of the export. When the progress bar is filled completely Fusion Bx will automatically push the selected files into the connected PACS server.
3. To verify studies have been successfully exported to PACS, select **PACS** . Enter the appropriate data into one of the displayed fields and select **Query** . The previously selected files should be displayed.

## EXPORTING ANONYMIZED DATA

There may be instances in which data must be anonymized before exporting. Fusion Bx has a built-in anonymizer that automatically anonymizes patient data.

1. On the Study page, click on the checkbox next to the patient files you wish to transfer.

2. Click the drop-down arrow beside **Export Studies**  , then click **Export Anonymized**. A Windows Explorer dialogue box will open, prompting you to save the files in a local directory. Select your desired location and Fusion Bx will automatically anonymize the data and copy the selected files in your specified directory.
3. To verify studies have been anonymized, navigate to the above directory. The folder will be saved as a random assortment of characters, making patient data completely anonymous.

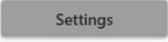
## 6.14 LOGOUT, SHUTDOWN, SLEEP, AND RESTART

Log out of Fusion Bx by clicking **Logout**  on the Study page. Logging out will take you to the login page; from here, you can choose to switch users, or log back in at a later time. To shut down, restart or put the computer to sleep, click the **Power** icon in the lower-right corner of the login screen.

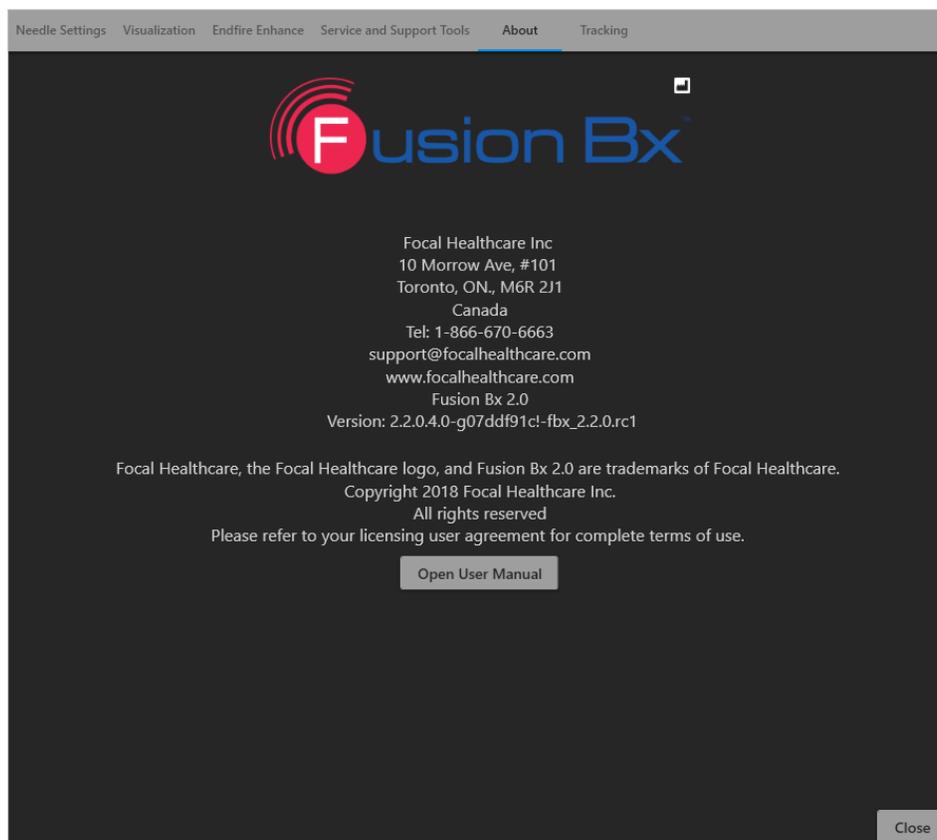
**⚠WARNING:** If the Fusion Bx screen appears blank then it may be a result of the application being minimized. To maximize the application, simply press the Windows key () and the up-arrow key on the keyboard at the same time.

## 7 ADVANCED SOFTWARE USE

### 7.1 SETTINGS

The **Settings** menu is available from all pages during the Fusion Bx procedure; however, the menu is custom-tailored to each step of the procedure. To access the exhaustive list of Fusion Bx settings, click **Settings**  on the Study page. The Settings menu will display the following tabs:

1. PACS Settings
2. About
3. Service and Support Tools
4. License
5. Initial Device Set-Up
6. Needle Settings
7. Visualization
8. Tracking
9. Systematic Biopsy



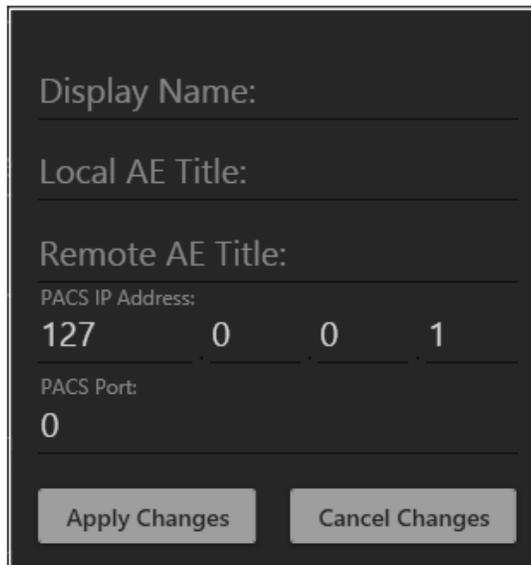
*Settings menu*

## PACS SETTINGS

The first tab displayed following the selection of the Settings button is the **PACS Settings** tab (displayed above). To configure PACS, follow the below instructions.

### Add a PACS Server

1. From the Study page, Select **Settings** .
2. From the Settings window, select the PACS Settings tab and select **Add PACS** under Remote DICOM Nodes.
3. Enter the:
  - a. Display Name: for identification when selecting between different PACS connections  
*Note: This is required in order to enable the import/export option on the Study page.*
  - b. Local AE Title: title of current workstation, this is configured on the PACS server
  - c. Remote AE Title: title of the PACS server
  - d. PACS IP Address: IP Address of PACS server
  - e. PACS Port: Port on which to communicate with PACS server
4. Click **Apply Changes**.



Display Name:

Local AE Title:

Remote AE Title:

PACS IP Address:  
127 . 0 . 0 . 1

PACS Port:  
0

Apply Changes Cancel Changes

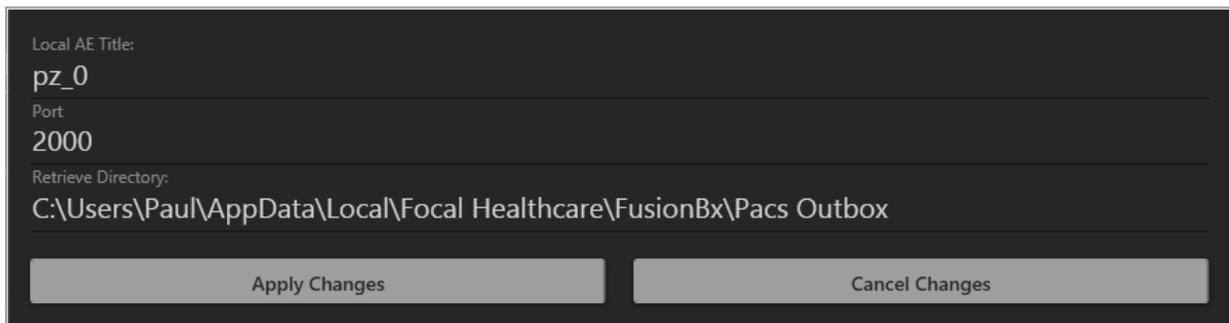
Settings up a PACS server

**⚠ WARNING:** After making any changes to PACS settings, select the Settings button again, then close the pop-up window, to enable the drop-down arrow beside the PACS button.

### Set up PACS Service (DICOM Node)

When PACS service is running, the Fusion Bx workstation can receive DICOM'S pushed to it, as a DICOM node. Once a PACS server has been set up, configure the DICOM node.

1. In the PACS Settings tab, click on **Edit**  under Local Destination for Retrieve.
2. Input the same Local AE title used for PACS setup.
3. Enter the port number provided by your PACS administrator.
4. The Retrieve Directory can be changed, but the default location is recommended.
5. Save the changes by clicking **Apply Changes**.



Local AE Title:  
pz\_0

Port  
2000

Retrieve Directory:  
C:\Users\Paul\AppData\Local\Focal Healthcare\FusionBx\Pacs Outbox

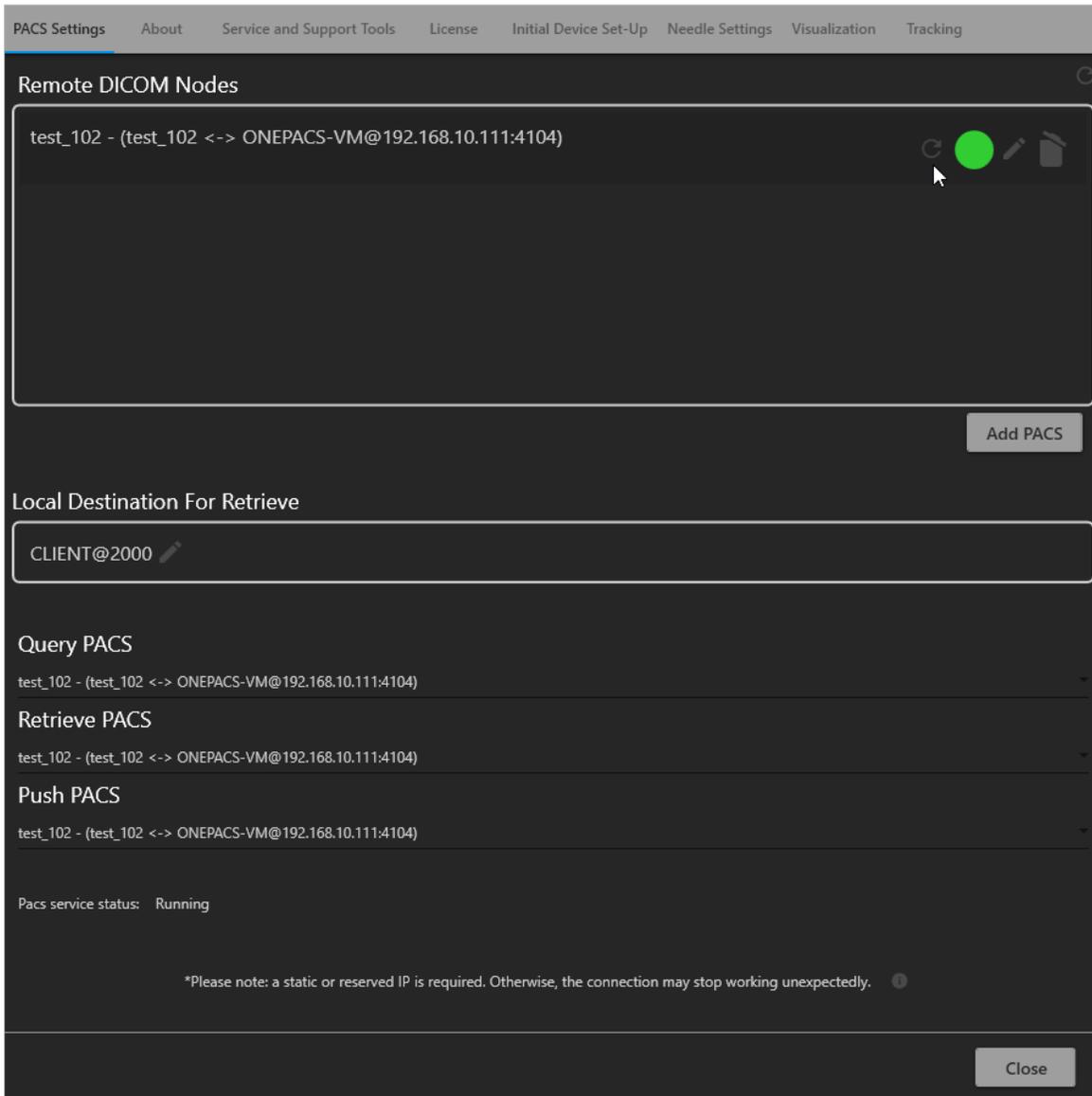
Apply Changes Cancel Changes

#### Editing the DICOM Node

### Select a PACS Server

In some instances, you may have multiple PACS servers configured on your workstation. Fusion Bx allows you to select the appropriate PACS server for query, retrieve and push.

1. Select the **Query PACS** configuration corresponding to the PACS you wish to use from the drop-down list.
2. Select the **Retrieve PACS** configuration corresponding to the PACS you wish to use from the drop-down list.
3. Select the **Push PACS** configuration corresponding to the PACS you wish to use from the drop-down list.
4. Under Remote DICOM Nodes, you will see a grey circle beside the PACS server. Click **Echo** . If the circle turns green, then it indicates that the PACS has been properly configured and is communicating with Fusion Bx.
5. If you are having difficulties communicating with PACS, contact your Focal Healthcare representative.



*Selecting your PACS server*

### *Edit PACS Server Settings*

1. From the PACS Settings tab, select the PACS server you wish to edit and click **Edit**  .
2. Edit the desired fields, as shown in Add a PACS Server. Consult with your PACS Admin if any changes to the Display Name, Local AE Title, Remote AE Title, PACS IP Address, PACS Port are necessary.
3. Click **Apply Changes**. Confirm the changes were successful by clicking **Echo**  and verifying the respective PACS Item has a green circle beside it.

4. To delete a PACS connection, select the appropriate server from the list and click **Delete**  .

### *PACS and Network Set-up*

1. The local PACS server must be configured to:
  - a. Allow association with Fusion Bx with the AE Titles and ports that are listed under “PACS Items” on this dialogue.
  - b. RT Structure Set must be set as an allowable SOP Class UID.
  - c. Fusion Bx cannot accept Grayscale Presentation State DICOMs.
2. The Fusion Bx configuration:
  - a. May need a static IP address to act as a DICOM node.
  - b. May need to change Windows Firewall settings to receive DICOM images over a specific port.

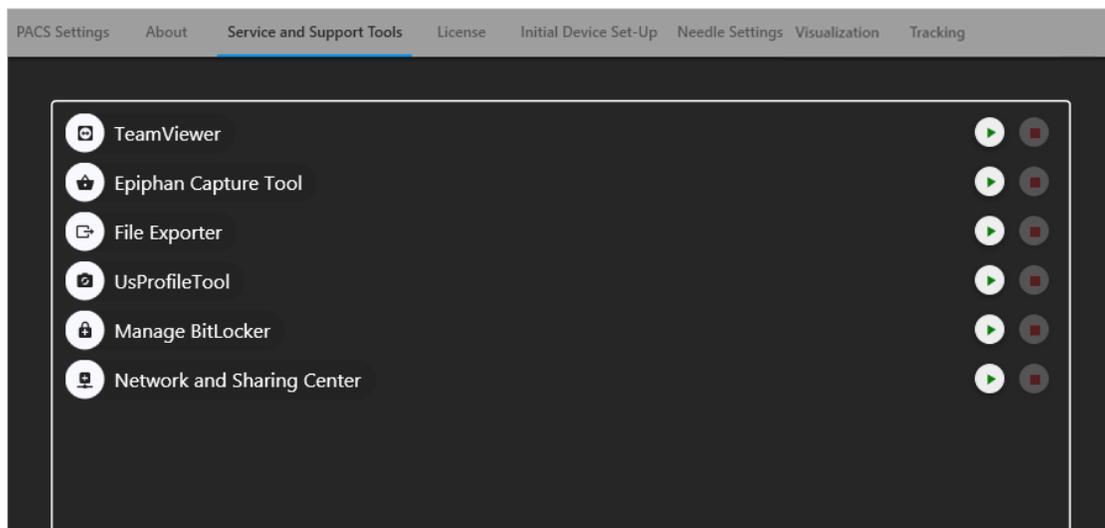
*Note: To access PACS through a VPN, additional network equipment may need configuration (e.g. Network router).*

## ABOUT

The **About** tab displays information about Focal Healthcare along with the software version number and a link to the user manual.

## SERVICE AND SUPPORT TOOLS

The **Service and Support Tools** tab allows the user access to a variety of troubleshooting tools. This includes connecting to Focal service personnel for remote support through TeamViewer.



*Service and Support Tools*

For a description of each tool, refer to the below table:

Action	Button	Function
TeamViewer		<p>Connects the user to Focal Healthcare service personnel for remote support. To receive remote support, complete the following steps:</p> <ol style="list-style-type: none"> <li>1. Contact Focal Healthcare at <a href="tel:866-670-6663">1-866-670-6663</a></li> <li>2. Select the TeamViewer tab.</li> <li>3. Communicate your TeamViewer ID and password to your Focal Healthcare representative.</li> <li>4. A Focal representative can provide remote support.</li> </ol>
Epiphan Capture Tool		<p>Launches the Epiphan Capture Tool. This provides a live screenshot of the video output from the ultrasound machine.</p>
File Exporter		<p>Provides users the ability to export EPHI logs, Windows Audit logs, Application Logs, and Application Configuration Files</p>
USProfileTool		<p>Launches the Ultrasound Profile Tool. <i>Warning: This tool is only to be used by Focal service personnel, an authorized 3<sup>rd</sup> party representative, or under the guidance of Focal service personnel.</i></p>
Manage BitLocker		<p>Manages device encryption settings.</p>
Network and Sharing Center		<p>Provides users the ability to connect/disconnect to a network.</p>

## LICENSE

The **License** tab allows you to see your software license information, and provides information on how to obtain and/or renew your license. For complete instructions on how to obtain an updated license, refer to Section 7.2.

## INITIAL DEVICE SET-UP

The **Initial Device Set-up** tab gives the user the required information to properly set up Fusion Bx, the patient, and the ultrasound system. Lastly, it gives the user a pre-sweep checklist to adhere to for optimal results of the fusion biopsy procedure.

## NEEDLE SETTINGS

The **Needle Settings** tab allows you to change needle gauge, core length, and type in a description of your biopsy needle.

## VISUALIZATION

The **Visualization** tab allows users to change the opacity settings of various components of the live ultrasound and the 3D mesh. These changes can also be viewed on the Register and Biopsy page; therefore, it is recommended to change these settings when the aforementioned pages are active.

Additionally, the **Visualization** tab contains the following controls:

- **Image Plane:** Enables/disables the ultrasound image that appears in the 3D model.
- **Ultrasound Probe:** Enables/disables the ultrasound probe that appears along with the 3D model.
- **Auto Scroll Slices:** Enables/disables automatic scrolling of the axial view to the base, apex and mid-gland when contouring.
- **Rigid Registration:** Enables/disables the appearance of the rigid-only registration on the Registration page. Selecting this does not disable elastic registration. It only shows the differences between the two registration methods.
- **Biopsy Approach:** Determines the orientation of the reconstruction of the axial view on the Sweep page along with the default view of the 3D mesh. Transrectal assumes that the patient is in left decubitus position, while Transperineal assumes the patient is in lithotomy position.

## TRACKING

The **Tracking** tab allows users to enable and disable automatic motion compensation.

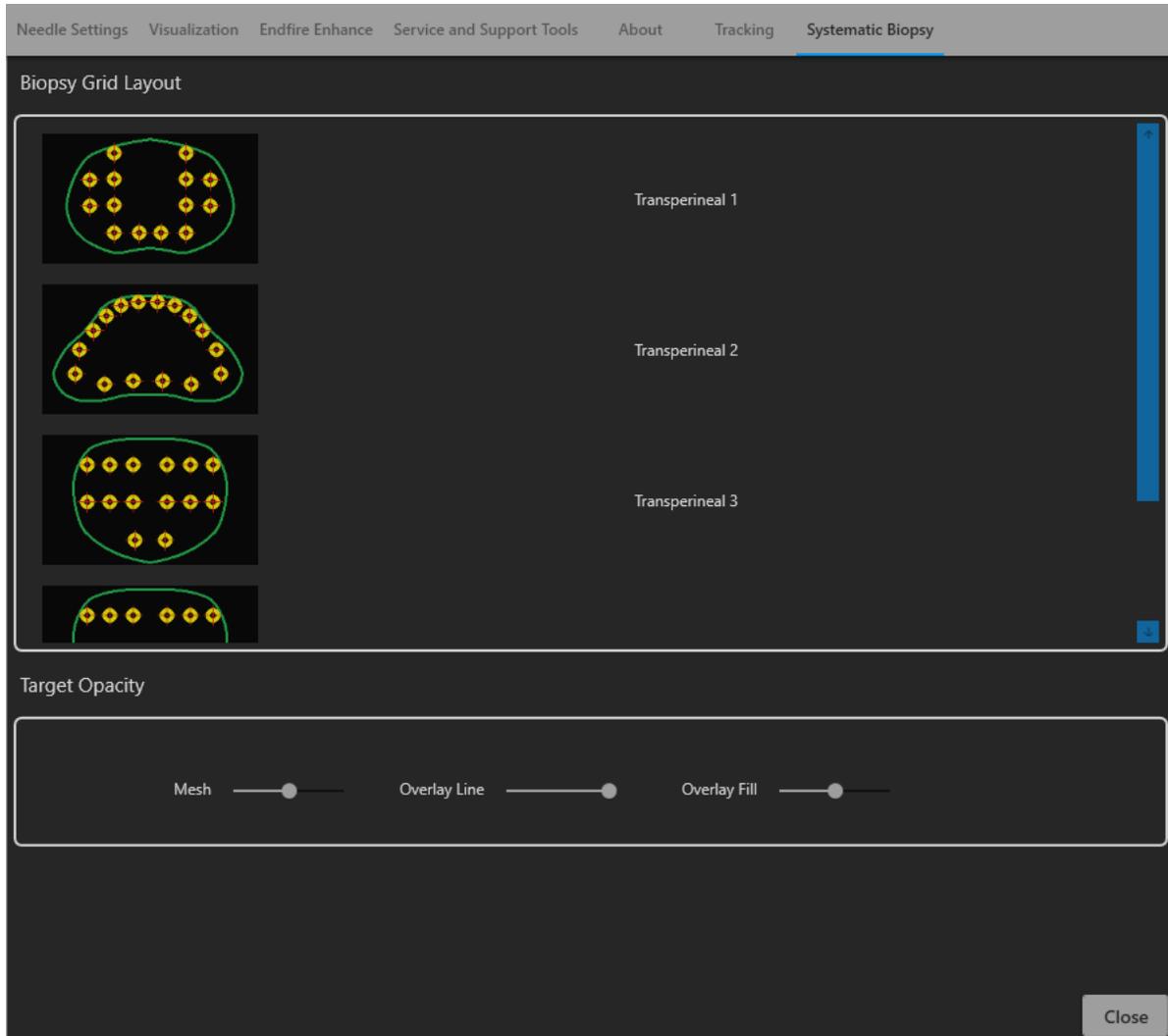
## SYSTEMATIC BIOPSY

The **Systematic Biopsy** tab allows users to configure systematic biopsy templates that are used to provide a layout of targets for performing systematic biopsies. The templates are configurable and will use the 3D mesh of the prostate to determine the optimal placement of the targets to achieve a distributed sampling of the prostate.

- **Biopsy Grid Layout:** The selected layout determines where systematic biopsy targets will be placed throughout the 3D mesh and the live ultrasound views. The available

layouts can be customized and require the support of a Focal Healthcare service specialist.

- **Mesh:** Controls the opacity of the systematic biopsy targets in the 3D mesh.
- **Overlay Line:** Controls the opacity of the outline of systematic biopsy targets in the live ultrasound view.
- **Overlay Fill:** Controls the opacity of the systematic biopsy targets in the live ultrasound view.

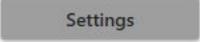
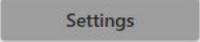
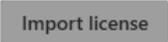


*Systematic Biopsy Settings*

## 7.2 OBTAINING AN UPDATED LICENSE

Once your license has expired, you can obtain an updated one by following the steps below. Note, that Fusion Bx will allow a grace period and extra sessions for emergency use after

your license has expired. The length of your grace period and number of extra sessions available vary from license to license.

1. Click **Settings**  from the Study page.
2. Click the **License** tab.
3. Click **Copy** to copy the unique ID used to generate the license.
4. Paste the unique ID into an email and send it to your Focal Healthcare representative or to [license@focalhealthcare.com](mailto:license@focalhealthcare.com).
5. Once your unique ID has been received, you will be sent an invoice which needs to be paid before a new device license is issued via email.
6. Download your new license and save it to a USB, DVD, or local area network.
7. Click **Settings**  from the Study page.
8. Click the **License** tab.
9. Click **Import License** 
10. A Windows Explorer dialogue box will open. Navigate to the location of the License File in the directory and select the License File for import.

## 7.3 DATA MANAGEMENT

Fusion Bx can hold up to 200 GB of data. Since the device holds sensitive patient data, it is not intended to be used as a long-term storage system in case of theft or unauthorized intrusion. Data should be periodically transferred to a safe digital repository (e.g. urologist's computer) that is backed up, where it can be managed and stored on a secure, password-protected network (e.g. PACS server).

### TRANSFERRING DATA TO FUSION BX

Instructions for transferring data to Fusion Bx are discussed in Section 6.4.

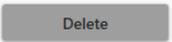
### TRANSFERRING DATA FROM FUSION BX

Instructions for transferring data from Fusion Bx are discussed in Section 6.4.

### REMOVING DATA FROM FUSION BX

Removing a patient's data from Fusion Bx is done on the Study page.

#### *DELETING PATIENT STUDIES:*

1. Check the box(es) of the patient study/studies you wish to delete.
2. Click **Delete**  .

*Note: If there is less than 10 GB of space available left on Fusion Bx, a warning will appear on the Study page.*

## 7.4 IMAGE FILE REQUIREMENTS

Please refer to Appendix G. DICOM Conformance Statement.

## 8 CLEANING, STORAGE, MAINTENANCE, AND TRANSPORTATION

**⚠ WARNING:** It is the user's responsibility to ensure that Fusion Bx is cleaned and disinfected before use and to adhere to the guidelines and regulations specific to the jurisdiction in which they use Fusion Bx. Only the user may decide if the below listed cleaning and disinfection processes are sufficient. Focal Healthcare is not responsible for the materials used, or the process followed, in cleaning and disinfection. None of the hardware components of Fusion Bx are intended to come into direct contact with the patient. However, there is still a risk of contamination with patient materials by discharged fluids, and from handling by users. Every patient must be regarded as a potential source of infection and appropriate precautions should be taken to prevent cross-contamination. It is the user's responsibility to decide if the cleaning, disinfection, and sterilization processes are sufficient.

### 8.1 CLEANING

Every procedure should include:

- Washing of hands both before and after direct patient contact
- Use of personal protective equipment where appropriate
- Maintenance of clean and/or disinfected patient equipment, as required
- Maintenance of a clean working environment
- Correct disposal of waste

Cleaning should be done immediately after each use before fluids are allowed to dry.

We recommend using cleaning products that kill potentially infectious substances of human origin (i.e. blood- and fecal-borne pathogens).

*Note: The following cleaning procedures must be completed prior to the arrival of Focal servicing personnel when performing any servicing on the device (including troubleshooting, installation of replacement parts, or preventative maintenance activities) or prior to the shipment of the device and/or parts for service or return.*

#### CLEANING NON-CRITICAL EQUIPMENT

Before servicing, maintenance and/or repair of Focal non-critical equipment, the device shall be cleaned and decontaminated by the customer using a low-level disinfectant in a spray bottle.

##### *No Visible Soil Disinfecting*

1. Wash hands.
2. Put on gloves.
3. Prior to cleaning the system, disconnect the power cord.

4. Clean the monitor using a dry, soft, lint-free cloth, preferably the micro-fiber cleaning cloth and a glass cleaning solution.
  - a. Apply the glass cleaner to the cloth and gently clean the monitor screen. A solution of mild soap and water can also be used.
5. Clean the keyboard in one of four ways:
  - a. Use Hospital Grade Disinfectant Spray (Best Practice): Thoroughly spray all surface areas and between keys.
  - b. Use Disinfectant Wipes: Thoroughly wipe all surface area with disinfectant wipes.
  - c. Hand wash with soap and water: Soak in warm water using dish soap or other cleaning agent. Vigorously wash and rinse keyboard to ensure thorough cleaning.
  - d. Machine Wash in Dishwasher: Place keyboard on top rack of dishwasher. Wash in dishwasher using dishwasher detergent and standard wash cycle. Disable “Heated Drying”.

*Note: The keyboard comes with a silicone cover. The silicone cover is optional; however, it provides a fast and easy way to wipe the keyboard clean.*

6. Clean the mouse in one of four ways:
  - a. Use Hospital Grade Disinfectant Spray (Best Practice): Thoroughly spray all surface areas and between mouse buttons.
  - b. Use Disinfectant Wipes: Thoroughly wipe all surface area with disinfectant wipes.
  - c. Hand wash with soap and water: Soak in warm water using dish soap or other cleaning agent. Vigorously wash and rinse mouse to ensure thorough cleaning.
  - d. Machine Wash in Dishwasher: Place mouse on top rack of dishwasher. Wash in dishwasher using dishwasher detergent and standard wash cycle. Disable “Heated Drying”.
7. Wipe down the cart with a soft cloth and ethyl or isopropyl alcohol (70-95%).
8. Cleaning and Low-level Disinfection of the Rest of the System:

The rest of the system includes the tracker, stepper, frame grabber, and counterbalance.

  - a. Manually clean the tracker, stepper, frame grabber, and counterbalance using a soft brush and an ethyl or isopropyl alcohol (70-95%) spray. Take care to get into all lumens with the brush.
  - b. Chlorine-based cleaning agents should not be used on the device as regular contact with these agents may accelerate corrosion.
  - c. Leave surface wet for a contact time of at least 1 minute.
  - d. Allow to air dry or blow dry with an air gun.

- e. Visually inspect under adequate lighting that the device appears visually clean.
- f. If the device appears visually clean, proceed with the disinfection steps.

### *Visible Soil Cleaning*

Non-critical medical devices shall be cleaned and disinfected using a low-level disinfectant if they become contaminated with blood or bodily fluids or if they have been exposed to a patient with an infectious organism.

1. Wash hands.
2. Put on gloves.
3. Wear appropriate personal protective equipment.
4. Assess risk of splashing and spraying of body fluids during cleaning process. Consider use of masks, eye protection, and gown.
5. Prior to cleaning the system, disconnect the power cord.
6. Clean the monitor using a dry, soft, lint-free cloth, preferably the micro-fiber cleaning cloth and a glass cleaning solution.
7. Apply the glass cleaner to the cloth and gently clean the monitor screen. A solution of mild soap and water can also be used.
8. Clean the keyboard in one of four ways:
  - a. Use Hospital Grade Disinfectant Spray (Best Practice): Thoroughly spray all surface areas and between keys.
  - b. Use Disinfectant Wipes: Thoroughly wipe all surface area with disinfectant wipes.
  - c. Hand wash with soap and water: Soak in warm water using dish soap or other cleaning agent. Vigorously wash and rinse keyboard to ensure thorough cleaning.
  - d. Machine Wash in Dishwasher: Place keyboard on top rack of dishwasher. Wash in dishwasher using dishwasher detergent and standard wash cycle. Disable "Heated Drying".

*Note: The keyboard comes with a silicone cover. The silicone cover is optional; however, it provides a fast and easy way to wipe the keyboard clean.*

9. Clean the mouse in one of four ways:
  - a. Use Hospital Grade Disinfectant Spray (Best Practice): Thoroughly spray all surface areas and between mouse buttons.
  - b. Use Disinfectant Wipes: Thoroughly wipe all surface area with disinfectant wipes.
  - c. Hand wash with soap and water: Soak in warm water using dish soap or other cleaning agent. Vigorously wash and rinse mouse to ensure thorough cleaning.

- d. Machine Wash in Dishwasher: Place mouse on top rack of dishwasher. Wash in dishwasher using dishwasher detergent and standard wash cycle. Disable “Heated Drying”.
10. Wipe down the cart with a soft cloth and ethyl or isopropyl alcohol (70-95%).
11. **Manually clean the system using a soft brush and an ethyl or isopropyl alcohol (70-95%) spray until any visible debris, blood, or any bodily fluids have been scrubbed off.** The system includes the tracker, stepper, frame grabber, and counterbalance.
12. Leave surface wet for a contact time of at least 1 minute to ensure disinfection.
13. Allow to air dry or blow dry with an air gun.
14. Visually inspect under adequate lighting that the device appears visually clean.
15. If the device is not visually clean, repeat step 11.
16. Low-level disinfection of the rest of the system:
  - a. Repeat Manual cleaning of the system using a soft brush and an ethyl or isopropyl alcohol (70-95%) spray until any visible debris, blood, or any bodily fluids have been scrubbed off.
  - b. Leave surface wet for a contact time of at least 1 minute to ensure disinfection.
  - c. Remove gloves.
  - d. Remove any Personal Protective Equipment
  - e. Wash hands.
  - f. Medical device is now ready for servicing personnel.

## 8.2 STORAGE AND TRANSPORTATION

Fusion Bx must be stored in a secure environment with the following requirements:

- Storage temperature range: 32- 113 °F (0-45 °C)
- Storage and transportation atmospheric pressure range: 8- 16 psi (55 – 110 kPa)
- Storage humidity: 10% - 95% (non-condensing)

When storing and transporting Fusion Bx from room-to-room, the device should be placed in a position such that:

- The swing arm and tracker are close to parallel with one another
- Swing arm is rotated so there is the least amount of overhang over the cart
- The tracker is fully compressed
- The stepper hangs vertically (can either point up or down)
- Wheels locked if being stored, unlocked if being transported

## 8.3 PREVENTIVE MAINTENANCE

Focal promises to ensure the safety, reliability, and performance of Fusion Bx by performing regular preventive maintenance on commissioned devices. The frequency of the preventive

maintenance will be determined by authorized Focal Personnel or delegated representative. Please contact your Focal representative for further information.

## 9 TROUBLESHOOTING

The following table outlines troubleshooting tips in the event TRUS probe tracking is not functioning as expected.

*Table 2: Troubleshooting tracking errors*

Symptom	Potential Cause	Page(s) Seen On	Resolution
The ultrasound probe and image plane appear to “bounce” or oscillate in the 3D image space (right image pane). This may or may not be observed in the live ultrasound (left) image pane as well.	This may be caused by a faulty encoder.	Biopsy	Please contact a Focal Healthcare service specialist for assistance.
When navigating to a target, the prostate contour (left image pane) “jumps” in and out of view or changes rapidly with minimal tracker movement. This type of motion is also visible in the 3D image space (right image pane).	<p>This may be caused by an encoder that isn’t properly connected or a damaged cable.</p> <p>It is possible the hardware was not properly “initialized” prior to beginning the procedure.</p>	Biopsy	<p>Return to the Sweep page, press the “Initialize Hardware” button and ensure to follow instructions to “Initialize” the probe.</p> <p>If the problem persists, please contact a Focal Healthcare service specialist for assistance.</p>

Symptom	Potential Cause	Page(s) Seen On	Resolution
When navigating to a target, the prostate contour does not update to match the live ultrasound. Additionally, movement in the 3D image space does not match, manual movement of the hardware.	This may be caused by an encoder that isn't properly connected or a damaged cable.  It is possible the hardware was not properly "initialized" prior to beginning the procedure.	Biopsy	Return to the Sweep page, press the "Initialize Hardware" button and ensure to follow instructions to "Initialize" the probe.  If the problem persists, please contact a Focal Healthcare service specialist for assistance.

The table below lists some of the possible errors you may encounter, along with their fixes.

*Table 3: Troubleshooting error messages*

Error Message	Possible Fixes	Page(s) Seen On
Hardware Error: Encoder board is disconnected.	Please contact a Focal Healthcare service specialist for assistance.	Study, Sweep, Biopsy
Hardware Error: Frame grabber is disconnected from computer	Unplug the blue USB cable connecting the frame grabber to the front of the computer and reinsert it. Note: In some systems the cable may be connected to the back of the computer. In this case, try unplugging the cable from the frame grabber end.	Study, Sweep, Biopsy
Hardware Error: Ultrasound is disconnected from frame grabber	Please check the ultrasound to frame grabber connection. The DVI cable should be connected from the ultrasound machine to the frame grabber. Note: the frame grabber is located at the rear of the cart.	Study, Sweep, Biopsy

Error Message	Possible Fixes	Page(s) Seen On
<p>Ultrasound profile not recognized.</p>	<p>Fusion Bx does not recognize the configured ultrasound profiles.</p> <p>Fusion Bx may not have an ultrasound profile configured for the given ultrasound unit, Fusion Bx may not support the current depth setting, or the TGC sliders may be occluding the depth setting on the ultrasound machine. Change the depth setting to see if the message disappears and push the TGC sliders to the left to ensure the depth setting is not occluded. Lastly, Up/Down flip is not supported.</p> <p>If the problem persists, contact your Focal Healthcare service specialist for assistance.</p>	<p>Sweep, Biopsy</p>
<p>Invalid ultrasound settings</p>	<p>Fusion Bx may not support the current ultrasound settings.</p> <p>Fusion Bx only supports sagittal and end-fire ultrasound views with or without L/R flip. Up/Down flip is not supported. Exam type should be set to Uro Prostate: Focal Healthcare.</p> <p>If the problem persists, contact your Focal Healthcare service specialist for assistance,</p>	<p>Sweep, Biopsy</p>
<p>Hardware disconnected. Unable to home probe.</p>	<p>Ensure all cables are connected, and ultrasound has been previously used with system. If a new ultrasound is being used then a new ultrasound profile will need to be created. Contact your Focal Healthcare service specialist for assistance,</p>	<p>Study, Sweep</p>

Error Message	Possible Fixes	Page(s) Seen On
You can't proceed while your hard drive is almost full.	This occurs when trying to export to a location with full memory. Select a different location or delete files to continue.	Study
Unable to proceed with US reconstructed study	Attempting to proceed to the Sweep page with a reconstructed ultrasound study. Select a patient with a compatible annotation file or press "Systematic Biopsy" to continue to Sweep page.	Study
Selected study contains no valid series.	The selected study does not have an MRI study or annotation structures.	Study
The sweep has failed.	The sweep has been reset. Ultrasound settings/hardware configuration was changed while the sweep was in progress. Position the probe back to the original starting position and press Play to re-do the sweep.	Sweep
Unable to sweep. Hardware disconnected.	Ensure all cables are connected.	Sweep
Annotation/Registration incomplete.	Attempting to proceed to the Biopsy page without fusing MRI to TRUS. Select the Register button to initiate registration and select Biopsy when completed.	Contour
Registration failed.	Unable to complete non-rigid registration: The centre of the MRI segmentation is outside of the ultrasound segmentation after rigid registration likely due to oddly shaped segmentation.  Recommendation: re-sweep and double-check landmarks and contours.	Contour

Error Message	Possible Fixes	Page(s) Seen On
Error: unable to add core. Please ensure you have a valid needle guide.	This may occur if there is no configured needle guide. Contact your Focal Healthcare Service Specialist for assistance.	Biopsy
Some studies/series failed to retrieve  All studies/series failed to retrieve	Failed to retrieve some or all the selected studies from PACS. Ensure PACS is properly configured. Contact your Focal Healthcare service specialist or local IT administrator for assistance.	PACS
No valid software license found. Follow the instructions to obtain a valid license.	See Section 7.2 on how to obtain a valid license.	Study
Failed to Save Bx Report.	Modify the report and try saving again. If the problem persists, please contact your Focal Healthcare service specialist for assistance.	Report
No studies are selected to delete.	Ensure a study is selected.	Study
Free space error	Delete studies that are no longer needed.	Study

For issues with the frame grabber, refer to the LED color indications table below. If the internal cable has been replaced or reinserted, note that a USB 3.0 cable is required but that it must be plugged into a USB 2.0 port on the computer.

*Table 4: Frame grabber LED color indications*

<b>LED Color</b>	<b>Message</b>
Flashing blue	Firmware is loaded, device is idle.
Flashing green	Video mode detection in progress.
Solid Red	Frame grabber is powered on, however, it is not functional. The driver is either not installed or failed to load.
Flashing red	Frame grabber signature validation has failed. On-board EEPROM failure or incorrect initialization at the factory. Frame grabber needs to be replaced.
Solid yellow	Image capture or data transfer is in progress.

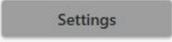
If your problem is still not resolved, please contact a Focal Healthcare service specialist for further assistance.

## 9.1 REMOTE SUPPORT

Focal Healthcare is committed to offering our customers unparalleled service by offering remote service and troubleshooting via the internet. In order to facilitate this, users must first enable internet connection by either Wi-Fi or hardware LAN connection. User accounts must have administrative privileges to enable internet connectivity.

### WI-FI

To enable Wi-Fi, one of two methods can be used:

1. Fusion Bx Settings Menu:
  - a. From the Fusion Bx software, click **Settings** .
  - b. Navigate to the **Service and Support Tools** tab and select the Network and Sharing Center tool.
  - c. A Windows Explorer dialogue box will open prompting you to setup a new connection or network.
  - d. Follow your facility protocols to establish a secure connection.
2. Network and Sharing Centre:
  - a. Log out of the Fusion Bx software to get to the Windows sign-in screen.
  - b. In the bottom left of the screen, click on (  ) and then enable Wi-Fi. The wireless connection should automatically be established once Wi-Fi is turned on.
  - c. Follow your facility protocols to establish a secure connection.
  - d. Log back into Fusion Bx using your login information.

Once a secure connection is established, complete the following steps to receive remote support:

1. From the Study page, click Settings > Service and Support Tools > Team Viewer
2. Provide the Team Viewer ID and password (if required) to the Focal Healthcare representative to start sharing your session.
3. Upon closing the remote support session, disable Wi-Fi by following methods 1 or 2 above.

*Note: To minimize the risk of any cyber security threats, users must have Wi-Fi disabled unless remote support is required.*

### LAN

1. Connect Ethernet cable from your Ethernet jack to the Fusion Bx computer.
2. Follow your facility protocol to establish a secure connection.
3. Follow steps 1-3 on receiving remote support above.

## 9.2 CONTACT US

FOCAL HEALTHCARE INC.  
10 Morrow Avenue, Unit 101  
Toronto, Ontario  
M6R 2J1, Canada

**Toll-free number:** 866-670-6663 (toll-free)

**Phone:** +1 (647) 479-9603

**Info:** [info@focalhealthcare.com](mailto:info@focalhealthcare.com)

**Support:** [support@focalhealthcare.com](mailto:support@focalhealthcare.com)

**Website:** [www.focalhealthcare.com](http://www.focalhealthcare.com)

# APPENDIX

## A. SPECIFICATIONS

### General

- Group 1, Class A Equipment
- Mode of operation: Continuous
- The unit has no patient-applied parts
- IPX0 rating

### Dimensions

- Base: 24" x 24"
- Height: 54.5 – 62.5"
- Span (fully extended): 50"

### Operating System

- 64-bit Windows IOT LTSC

### CPU, System Memory and Storage

- Intel® Core i7-7700
- 16 GB, DDR4 RAM
- 250 GB SSD storage
- 1000 GB HDD
- Nvidia Quadro P1000

### Display and Image Acquisition

- 21.5" Full HD (1920 x 1080) 16:9

### Power Supply

- Input 100-240V~, 50-60Hz, 3A (North America and Taiwan)
- Input: 240VAC, 50-60Hz, 1.5 A (Europe)
- The system will use a maximum of 300 W power

### Environment

- Storage temperature range: 32- 113 °F (0-45 °C)
- Storage and transportation atmospheric pressure range: 8- 16 psi (55 – 110 kPa)
- Storage humidity: 10% - 95% (non-condensing)
- Operating temperature range: 50- 86 °F (10-30 °C)
- Operating atmospheric pressure range: 14- 16 psi (97 – 110 kPa)
- Operating humidity: 10% - 95% at 104 °F (40 °C) (non-condensing)
- Operating ground elevation: 0°
- Shock resistance: 10G peak acceleration (11ms duration)

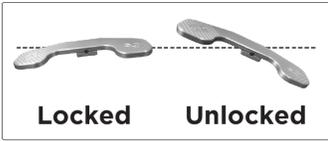
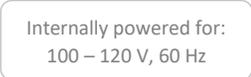
## Materials

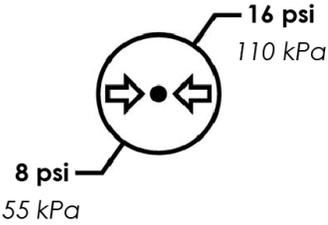
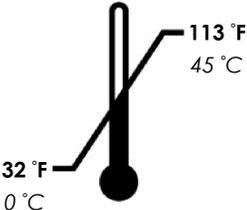
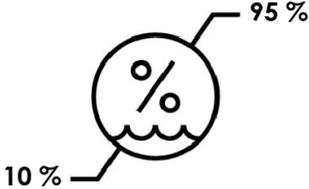
- Fusion Bx has no materials accessible to the patient or user that could constitute an unacceptable risk

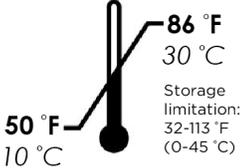
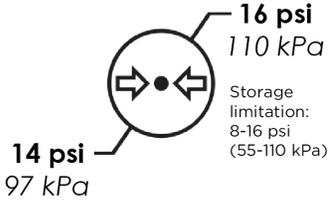
## B. LABELS

There are labels on Fusion Bx to warn the user of possible injury to themselves, the patient, the environment or the equipment. All warning labels must be obeyed for safe handling, operation, transportation and storage of the device. The following table explains the meaning of each label.

Table 5: Labels

Title of Symbol	Symbol	Function/Description	Location
Initial position		Line up these dots on the tracker to ensure you are in the 'initial position'. For side-fire, line up the white dot on the tracker with the dot labelled 'S'. For end-fire, line up the white dot on the tracker with the dot labelled 'E'.	Tracker
Twist to lock		Turn the swing arm brake (SA1 and SA2) clockwise to lock. This brake must be locked during a procedure.	Swing arm
Lock		Tracker brake should be locked during a sweep. Only unlock when compression or extension of the arm is required during the biopsy.	Tracker
Caster lock		Locked and unlocked positions of caster foot pedal.	Cart
Power outlet		To indicate the internally configured power specifications. Power specifications will vary depending on region or country device was shipped.	Cart
Fragile (handle with care)		To indicate that the transport package should be handled with care.  Shock resistance up to 10G peak acceleration (11ms duration).	Packaging

Title of Symbol	Symbol	Function/Description	Location
Keep dry		Protect from moisture. To indicate that the transport package shall be kept away from rain and in dry conditions.	Packaging
Transport pressure		Recommended storage pressure range: 8-16 psi (55-110 kPa)	Packaging
Transport temperature		Recommended storage temperature range: 32-113 °F (0-45 °C)	Packaging
Transport relative humidity		Recommended relative humidity range: 10-95% (non-condensing)	Packaging
Use by prescription only		Only patients who have been advised by a healthcare professional should undergo the procedure.	Device label
Manufacturer		Manufacturer identifier	Device label
Catalogue number		Fusion Bx model 2.0.	Device label
Caution		General caution sign.	Device label

Title of Symbol	Symbol	Function/Description	Location
Accompanying documents must be consulted.		The user manual must be consulted during each use for instructions on how to operate the device.	Device label
Temperature limit		<p>Operating temperature range: 50-86 °F (10-30 °C).</p> <p>Storage temperature range: 32-113 °F (0-45 °C).</p>	Device label
Atmospheric pressure limitation		<p>Recommended pressure range:</p> <p>Operating: 14- 16 psi (97- 110 kPa)</p> <p>Storage: 8- 16 psi (55- 110 kPa)</p>	Device label

## C. SYSTEM COMPONENTS

The Fusion Bx package includes the following components:

- Fusion Bx (including: pre-installed hardware arm and Acer VX4650G computer)
- 21.5" HD monitor
- 1 washable wireless optical mouse
- 1 encrypted USB flash drive
- 1 wireless waterproof keyboard
- 1 DVI cable (10' long, single-link ferrited, shielded)

## D. COMPATIBLE PRODUCTS

Fusion Bx is compatible with the following ultrasound scanners and TRUS transducers:

Ultrasound scanner:

- BK Medical 1202 ultrasound (Flex Focus 400)
- BK 5000
- Hitachi Ascendus
- Philips IU22

TRUS transducers:

- BK Medical Prostate Triplane 8818
- BK Medical Prostate Biplane 8808e
- Hitachi EUP-V53W
- Philips IU22 C9-5ec

Please contact your Focal Healthcare provider for further information on product compatibility.

## E. DATA SECURITY

When transferring patient data to/from Fusion Bx, users must do so in a secure manner.

When using an encrypted USB flash drive, Fusion Bx supports two options:

1. Hardware-based encryption
2. Windows Bitlocker

To decrypt a USB drive with patient data using Windows Bitlocker, perform the following:

1. Insert the encrypted USB flash drive into the PC or monitor.
2. From the Study Page, click Settings > Service and Support Tools > Manage Bitlocker.
3. Locate the USB drive in the list of available drives and select, “Unlock Drive” and enter the appropriate password.

*Note: If you are using the **Import** button to import studies before unlocking the encrypted USB drive, it will not be displayed as an option. After unlocking the encrypted drive, it will be available from the **Import** menu.*

## F. WORKFLOWS

### Pre-Procedure:

<b>Device Setup</b>	Connect all cables to Fusion Bx and ultrasound machine
	Turn on Fusion Bx
<b>Study Page</b>	Load all patient MRI data (network, USB, CD, PACS) <sup>1</sup>
	Create new patient entry (as needed)
	Position patient
	Review MRI
	Select tracked systematic or fusion-targeted biopsy
	Confirm patient information matches person on the table

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<sup>1</sup> It is strongly recommended that users load patient MRIs well in advance of any scheduled procedures, e.g. the day before.

Procedure:

<b>Device Setup</b>	Clinician to review prostate volume measurements and administer local/general anaesthesia
	Position device and connect to probe
	Lock casters
<b>Sweep Page</b>	Initialize hardware
	Confirm that the entire prostate will be visible in a single sweep
	Secure swing arm and tracker locks
<b>Register Page</b>	Probe sweep (create 3D ultrasound volume)
	Pick landmarks as identified by the radiologist
<b>Biopsy Page</b>	Contour prostate, review in sagittal view and use MRI as reference
	Perform fusion-guided biopsy
	Acquire biopsy cores for each target
	Save location of each sample
<b>Biopsy Page</b>	Perform tracked systematic biopsy

Post-Procedure:

<b>Report Page</b>	Add relevant patient notes and measurements
	Review screenshots
	Enter pathology results
	Export/print case report and data
<b>Cleaning, Storage, and Transportation</b>	Wipe/disinfect all surfaces of Fusion Bx
	Backup all patient data to local hard drive
	Store device in a safe place - refer to Section 8.2 for proper transport and storage "position"

## G. DICOM CONFORMANCE STATEMENT

*Table 6: SOP Classes for Application Entity (AE) Storage*

SOP Class Name	SOP Class UID	SCU	SCP
MR Image Storage	1.2.840.10008.5.1.4.1.1.4	Yes	No
Ultrasound Multiframe Image Storage	1.2.840.10008.5.1.4.1.1.3.1	No	Yes
RT Structure Set Storage	1.2.840.10008.5.1.4.1.1.481.3	Yes	Yes
Encapsulated PDF Storage	1.2.840.10008.5.1.4.1.1.104.1	Yes	Yes
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	Yes	Yes
US Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	Yes	Yes

*Table 7: IODs, SOP Classes and Transfer Syntaxes for Offline Media*

Information Object Definition	SOP Class UID	Transfer Syntax	Transfer Syntax UID
Media Storage Directory Storage	1.2.840.10008.1.3.10	Explicit VR Little Endian	1.2.840.10008.1.2.1
MR Image Storage	1.2.840.10008.5.1.4.1.1.4	Explicit VR Little Endian	1.2.840.10008.1.2.1
Ultrasound Multiframe Image Storage	1.2.840.10008.5.1.4.1.1.3.1	Explicit VR Little Endian	1.2.840.10008.1.2.1
RT Structure Set Storage	1.2.840.10008.5.1.4.1.1.481.3	Explicit VR Little Endian	1.2.840.10008.1.2.1
Encapsulated PDF Storage	1.2.840.10008.5.1.4.1.1.104.1	Explicit VR Little Endian	1.2.840.10008.1.2.1
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	Explicit VR Little Endian	1.2.840.10008.1.2.1
US Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	Explicit VR Little Endian	1.2.840.10008.1.2.1

## H. SAFETY SPECIFICATIONS

Fusion Bx is intended for use in the electromagnetic environment specified in tables below. The user should ensure that it is used in such an environment.

*Table 8: IEC 60601-1-2 Edition 3:2007 Table 1 Requirements*

<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic Environment - Guidance</b>
RF Emissions CISPR 11	Group 1	Fusion Bx 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	Fusion Bx is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:  Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating Fusion Bx or shielding the location.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

*Table 9: IEC 60601-1-2 Edition 4:2014 Table 2 Requirements*

<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment - Guidance</b>
Electrostatic Discharge (ESD) IEC 61000-4-2	38 kV Contact 316 kV Air	38 kV Contact 316 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	32 kV for power supply lines	32 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	31 kV line(s) to line(s) 32 kV line(s) to earth	31 kV line(s) to line(s) 32 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage Dips, short interruptions and voltage variations on power supply input lines  IEC 61000-4-11	$<0\% U_T$ (0 % dip in $U_T$ ) for 0,5 cycle  $0\% U_T$ (0% dip in $U_T$ ) for 1 cycle  $70\% U_T$ (70% dip in $U_T$ ) for 30 cycles  $<0\% U_T$ (0% dip in $U_T$ ) for 300 cycles	$<0\% U_T$ (0 % dip in $U_T$ ) for 0,5 cycle  $0\% U_T$ (0% dip in $U_T$ ) for 1 cycle  $70\% U_T$ (70% dip in $U_T$ ) for 30 cycles  $<0\% U_T$ (0% dip in $U_T$ ) for 300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of Fusion Bx requires continued operation during power mains interruptions, it is recommended that Fusion Bx be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field (50/60 Hz)  IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.			

Table 10: IEC 60601-1-2 Edition 3:2007 Table 4 Requirements

Immunity Test	Immunity Test	Compliance Level	Electromagnetic Environment - Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of Fusion Bx including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance: <math>d = 1.2\sqrt{P}</math></p> <p><math>d = 1.2\sqrt{P}</math> 80 MHz to 800 MHz</p> <p><math>d = 2.3\sqrt{P}</math> 800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup> should be less than the compliance level in each frequency range<sup>b</sup>.</p> <p>Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>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 Fusion Bx is used exceeds the applicable RF compliance level above, Fusion Bx should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Fusion Bx.</p> <p>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Fusion Bx is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of Fusion Bx can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Fusion Bx as recommended below, according to the maximum output power of the communications equipment.

*Table 11: IEC 60601-1-2 Edition 3:2007 Table 6 Requirements (Recommended separation distances between portable and mobile RF communications equipment and Fusion Bx)*

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## I. TRAINING OVERVIEW

Staff training may include a combination of remote, in-class, and hands-on sessions that review the following topics:

- Fundamentals of Fusion
- Hands-on Phantom Training
- Best Practices

User training is required for all first-time users and may also be required from time-to-time if/when there are product upgrades. Additional user training is available upon request.

Total training times can range from 15 minutes for product upgrades to two hours for first-time users.

For more details on training requirements, content, and materials please contact your Focal Healthcare representative.

## J. GLOSSARY

**axial (adj.)-** of, relating to the horizontal plane that divides the standing body into superior and inferior parts.

**biopsy location (n.)-** the location at which a tissue sample is taken.

**biopsy procedure (n.)-** a medical procedure involving the sampling of tissues for microscopic examination.

**biopsy sample (n.)-** a piece of tissue that is suspected to have cancer taken from the body using a hollow needle.

**clinician (n.)-** a healthcare professional qualified in patient care, as distinguished from one engaged in research.

**contour (n.)-** a drawn outline, either of the prostate boundary or a lesion, on a 2D image.

**contour (v.)-** to draw a closed outline, either of the prostate or a lesion, on a 2D medical image.

**core (n.)-** (see 'biopsy sample')

**DICOM (Digital Imaging and Communications in Medicine) (n.)-** a standard for handling, storing, printing, and transmitting information in medical imaging. It includes a file format definition and a network communications protocol.

**fiducial (n.)-** a point or object that is taken as a standard of reference for comparison purposes.

**frame grabber (n.)-** an electronic device that captures digital still frames from an analog video signal or a digital video stream and stores them as images or video clips.

**fusion biopsy (n.)-** an ultrasound-guided biopsy procedure utilizing information from pre-acquired MRI images; also known as **targeted biopsy**.

**gauge (n.)-** the thickness of a needle.

**landmark (n.)-** an anatomical point that can be unambiguously defined and repeatedly located with a high degree of accuracy and precision.

**lesion (n.)-** any localized abnormality in the tissue of an organism, including tumours, ulcers, sores and wounds.

**magnetic resonance imaging (MRI) (n.)**- a technique that uses a magnetic field and radio waves to create detailed images of the organs and tissues of the body.

**PACS (Picture Archiving and Communication System) (n.)**- a medical imaging technology which provides storage of and convenient access to images from multiple modalities.

**physician (n.)**- a person who is legally qualified to practice medicine.

**probe (n.)**- a blunt-ended surgical instrument used for exploring the body.

**prostate (n.)**- a gland of the male reproductive system which surrounds the urethra at the base of the bladder.

**prostate cancer (n.)**- a malignant tumor in the prostate gland created by an abnormal and uncontrolled growth of cells.

**radiologist (n.)**- a medical doctor who specializes in diagnosing and treating disease and injuries using medical imaging techniques, such as x-rays, computed tomography (CT), and magnetic resonance imaging (MRI).

**reconstruction (n.)**- the creation of a 2D or 3D image from a set of images.

**region of interest (ROI) (n.)**- a lesion that is suspected of cancer that has been contoured by a radiologist.

**registration (n.)**- transformation of two or more different sets of data into one coordinate system.

**sagittal (adj.)**- of, relating to the vertical plane passing through the standing body from front to back.

**segment (v.)**- to create a 3D outline of the prostate gland.

**slice (n.)**- a 2D medical image, especially one which is used to reconstruct a 3D medical image.

**sweep (n.)**- a stack of 2D TRUS images obtained by rotating a transducer a certain angle.

**sweep (v.)**- to rotate a transducer through a certain angle (around 180 degrees), while obtaining a 2D TRUS image at discrete intervals to produce a stack of 2D TRUS images.

**systematic biopsy (n.)**- a medical procedure involving the random sampling of tissues throughout the gland for microscopic examination.

**transducer (n.)**- an electronic device which generates acoustic signals that bounce off body tissues and detects returned signals.

**urologist (n.)**- a physician who specializes in diseases of the male and female urinary tract and the male reproductive organs.