



Accuro®

Pocket-sized ultrasound device for spinal and epidural anesthesia guidance.

USER'S MANUAL

RIVANNA®

Accuro®

CAUTION: In the United States, federal law restricts this device to use by, or on the order of, a physician.

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 **RIVANNA®**
Contact Information:
Rivanna Medical, Inc.
2400 Hunters Way
Charlottesville, VA 22911 USA
T: 800-645-7508
www.rivannamedical.com
info@rivannamedical.com

EC	REP
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MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

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Accuro® USER'S MANUAL

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Important Information

Product description

The Accuro is a pocket-sized and battery operated ultrasound instrument. The device is a single self-contained unit consisting of an ultrasound system, ultrasound probe, and rotatable touchscreen display. The instrument provides LUMBAR and THORACIC presets to facilitate epidural and spinal anesthesia imaging guidance with real-time 3D navigation of the lumbar or thoracic spine. The LUMBAR and THORACIC presets use proprietary technology, called SpineNav3D, to automate spinal bone landmark detection and depth measurements and to assess real-time scan plane orientation in 3D.

Accuro ultrasound scans and measurements can be saved in an examination file on the device and exported to a computer for storage or printing.

Principles of operation

Medical ultrasound imaging uses an ultrasound transducer, which transmits and receives high frequency mechanical waves. The transmitted ultrasound waves reflect off of structures in the body that exhibit changes in acoustic impedance. A portion of the reflected ultrasound energy returns to the ultrasound transducer and is converted back into an electrical signal, which is then amplified, digitized, and processed through a series of filters. The digital signal is transformed into an image that can be saved in memory and displayed to the display screen in real-time.

The SpineNav3D feature has only been clinically validated in the lumbar and thoracic spine analysis of obese and non-obese patients and not in any other areas of the spine or in case of spinal deformities, significant spinal degeneration, previous spinal surgeries, etc.

The Accuro LUMBAR and THORACIC presets use ultrasonic reflections acquired from multiple scan planes to obtain 3D volume scans of the lumbar and thoracic spine. The SpineNav3D technology facilitates image interpretation of individual 2D lumbar and thoracic spine scans by automating spinal bone landmark detection and depth measurements and providing a real-time assessment of scan plane orientation in 3D. SpineNav3D technology makes image interpretation and measurements of the lumbar and thoracic spine anatomy simple, quick, and easy. A sonographer is not required to use the LUMBAR or THORACIC presets.

Real-time 2D scans from either LUMBAR, THORACIC, or BONE presets are formed using proprietary BoneEnhance technology. The BoneEnhance technology provides images of bone anatomy at greater bone-to-tissue contrast compared with conventional ultrasound image reconstructions.

Indications for use

The Accuro ultrasound scanner is intended for diagnostic ultrasound imaging of the human body in the following clinical applications:

USA only

- Abdominal
- Cardiac
- Musculoskeletal (Conventional)
- Musculoskeletal (Superficial)
- Pediatric
- Small Organ
- Peripheral vessel

Non-USA only

- Abdominal
- Cardiac
- Musculoskeletal (Conventional)
- Musculoskeletal (Superficial)
- Peripheral vessel

Essential performance

The essential performance of the Accuro consists of ultrasonic image display of the dimension and location of spinal anatomy, display of ultrasound indexes pertaining to safety related indications, and prevention of unintended or excessive ultrasound output and transducer assembly surface temperature.

Contraindications

The Accuro ultrasound instrument is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

Statement of prescription

United States law restricts this device to sale or use by, or on the order of, a physician.

Warnings and cautions

The Accuro should only be used by trained individuals who have been authorized by a physician. All users must read the entire User's Manual prior to using the Accuro. To prevent damage of the equipment or injury to yourself or others, carefully read the following warnings and cautions before using the Accuro. Rivanna Medical, Inc. disclaims all responsibility and liability for the operating safety, reliability, and performance of the Accuro if the warnings and cautions disclosed in this User's Manual are disregarded in any way.

The Accuro has not been evaluated for use with high frequency (HF) surgical equipment.

A typical examination using the Accuro is guidance of neuraxial anesthesia.

Important Information

WARNINGS

WARNING! Risk of explosion, fire, or serious injury

If you use the Accuro in the presence of flammable anesthetics, the hazard of potential explosion exists.

Do not place the Accuro near a heat source or expose it to direct flame. Such exposure may lead to corrosive liquid leakage, electrical shock, or fire.

Stop using the Accuro if the casing is damaged. Failure to do so may result in electrical shock or fire.

Electrical shock may result from using damaged USB cables with the Accuro or if modifications are made to the Accuro by anyone other than personnel authorized by RIVANNA. Only use RIVANNA approved cables with the Accuro.

Avoid dropping or subjecting the Accuro to severe impacts. This could result in electrical shock, corrosive liquid leakage, and injury.

If battery leakage is present, wear protective gloves and discard the Accuro immediately following applicable regulations.

WARNING! Potential patient hazard

Do not use the Accuro instrument for ophthalmic indications. Ophthalmic use may cause patient injury.

CAUTIONS

CAUTION: Potential patient hazard from acoustic exposure

To date, exposure to diagnostic medical ultrasound has not been shown to produce adverse health effects. However, medical professionals should use ultrasound only when clinically indicated. Medical professionals should use the lowest exposure times possible. The ultrasound output of the Accuro is not user-adjustable and is limited to the minimum level necessary for effective performance.

CAUTION: Hazardous materials present. Assure proper disposal.

The Accuro may contain mineral oils, batteries, and other environmentally hazardous materials. When the Accuro has reached the end of its useful service, follow your local protocols for hazardous waste disposal.

CAUTION: Assure proper distance from patient

When transmitting data to or from your computer, make sure that the Accuro, accessories, and the computer are outside of the patient vicinity (more than six feet from the patient).

CAUTION: Assure proper computer system and/or printer configuration

When using the Accuro with an external computer system and/or printer unit, the computer system and/or printer unit or a charger, the computer system and/or printer unit or charger must be minimally certified to EN/IEC 60601-1 system standard.

CAUTION: Damage to the instrument may occur

Only apply commercially available ultrasonic couplant, which has been specifically formulated for use in medical applications, to the acoustic window (or face) of the probe. Failure to do so may cause damage to the Accuro instrument.

CAUTION: Damage to the instrument may occur

Do not attempt to sterilize the Accuro instrument. Damage to the Accuro instrument may occur.

CAUTION: Damage to the instrument may occur

Hot water in excess of 113°F or 45°C may damage the instrument.

CAUTION: Damage to the instrument may occur

Do not immerse the instrument in disinfectant solution.

CAUTION: Images and calculations are not to be used as the sole basis for clinical diagnosis

The images and calculations provided by the Accuro instrument are intended for use by competent users, as a diagnostic tool. They are explicitly not to be used as the sole, irrefutable basis for clinical diagnosis. Users are encouraged to account for the clinical utility of the Accuro and make their own professional conclusions.

CAUTION: Risk of inaccurate measurements

The images and calculations provided by the Accuro instrument are intended for use by competent users, as a diagnostic tool. The user should be aware of the instrument specifications, accuracy, and limitations. These limitations must be considered before making any decision based on images and quantitative values.

Incorrect image settings, equipment malfunction, or failure to correctly operate the Accuro can result in measurement errors or failure to detect certain details in the image. The user must be thoroughly familiar with the operation of the Accuro in order to optimize its performance and to recognize possible malfunctions and limitations. Application training is available through the sales representative.

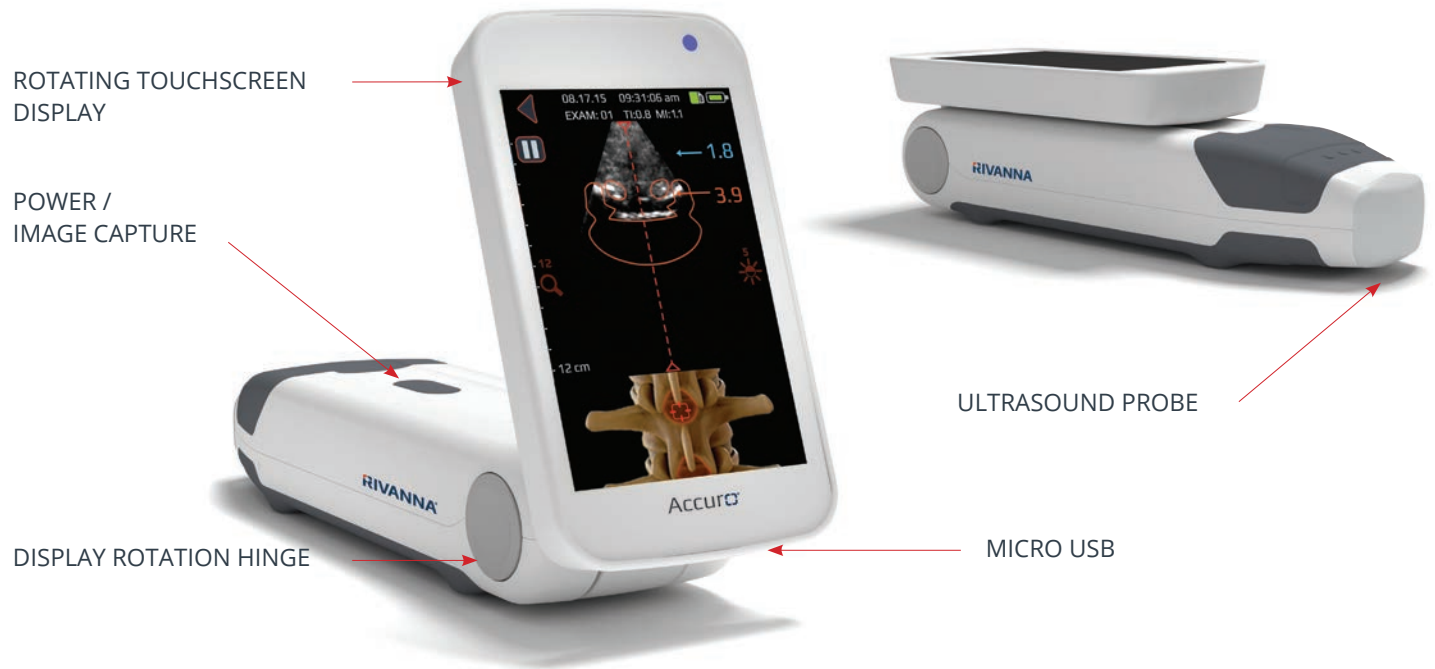
CAUTION: Ensure security of protected health information

Protected health Information (PHI) such as personal identifiers can be manually entered on Accuro to associate with image data. To best secure PHI during storage and transfer, it is recommended to always use password protection and maintain anonymous image files. Both can be configured from the SETTINGS screen.

If Accuro needs to be transported for repair, ensure that all patient data is backed up and confirm that backup was successful. All patient data must be erased from internal memory of Accuro before shipment.

Introducing the Accuro

Instrument parts and features



Components

Battery charger components

PART NAME	DESCRIPTION
USB wall charger	Charges the battery inside the Accuro.
Micro-USB to USB cable (charging cable)	Connects the USB wall charger to the Accuro.
Micro-USB to USB cable (screen mirror)	Connects the Accuro to external display screen (10ft) Allows screen mirror functionality.

Accessories

PART NAME	DESCRIPTION
Acoustic coupling gel	Travel sized ultrasound coupling gel.
Carrying case	Transports Accuro and accessories.

Displays, Controls, and Indicators

Console display and functions








The Accuro console consists of an LCD touchscreen display and a single power button. The LCD display presents a combination of user information, scan displays, and prompts, which vary depending on the current device function.

The power button has the function of either powering on/off the device, putting the device in sleep mode, or saving images. The functionality depends on the state of the device, such as the current screen, and the length of the button hold.

Home screen

The HOME screen appears when the Accuro is first powered on. The HOME screen serves as a starting point for all the main functions of the Accuro.

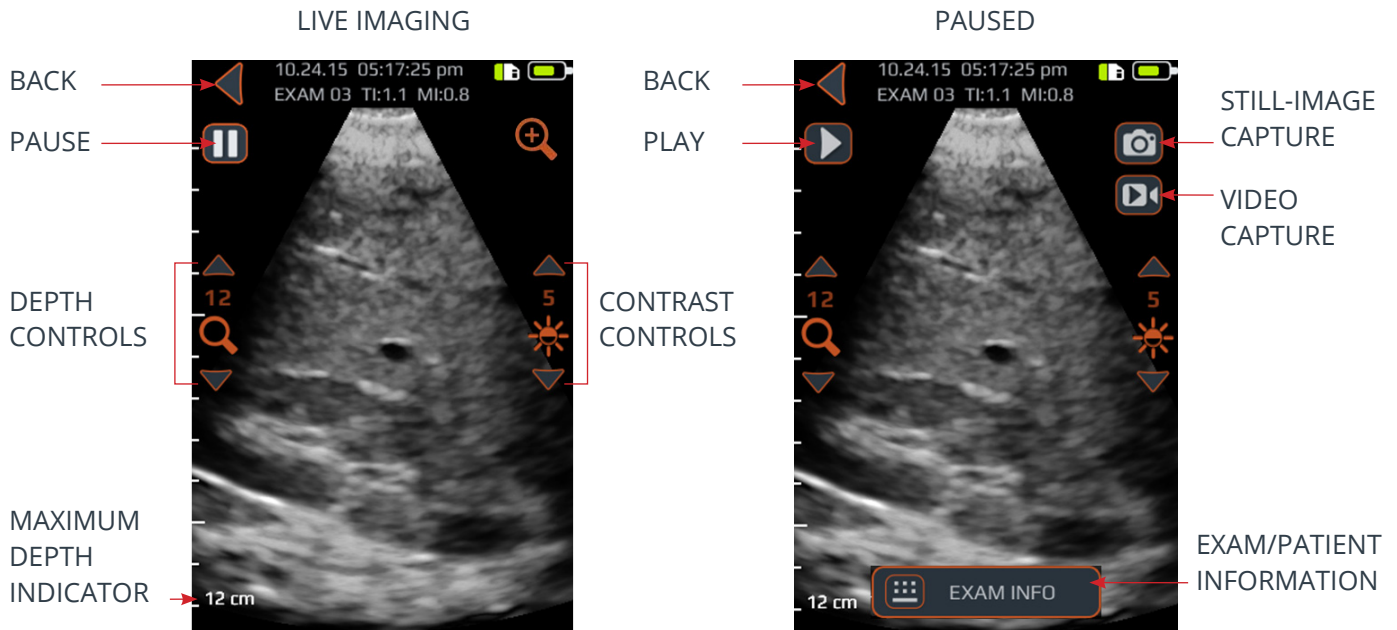


BUTTON OR INDICATOR	FUNCTION
	Press to go to LUMBAR imaging preset using SpineNav3D automation.
	Press to go to THORACIC imaging preset using SpineNav3D automation.
	Press to go to BONE or TISSUE imaging presets.
	Press to go to the GALLERY main menu screen.
	Press to access the Accuro HELP screen.
	Press to power off the device.
	Press to go to the SETTINGS screen.
	Indicates the current battery charge.
	Indicates the available mmc storage space.
	Blue LED indicates power on.
	Orange LED indicates battery is charging.

Displays, Controls, and Indicators

BONE and TISSUE preset scanning screen

The BONE or TISSUE scanning screen appears after you press the BONE or TISSUE button from the HOME screen.

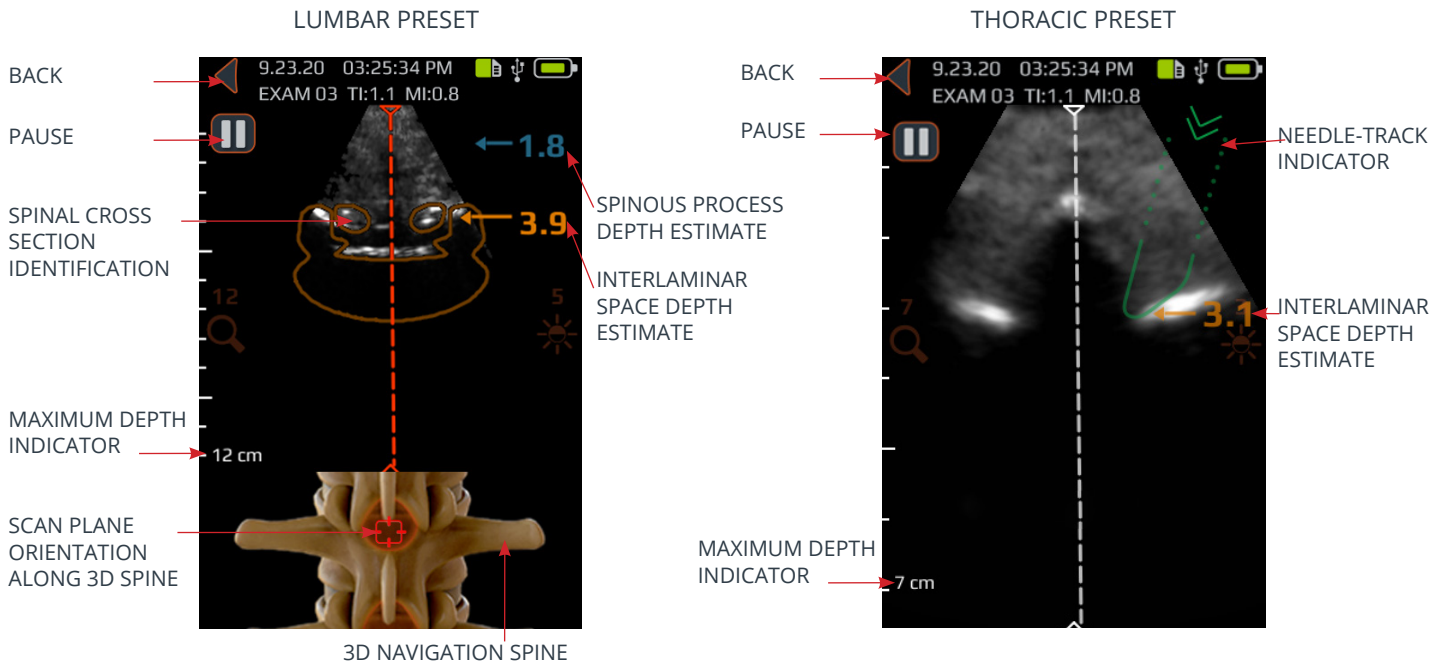


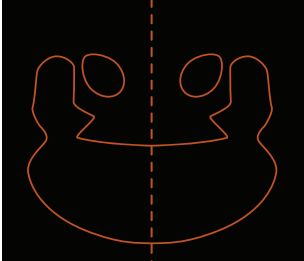
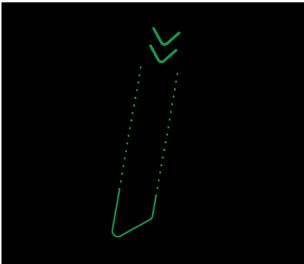
BUTTON OR INDICATOR	FUNCTION
	Press to go back to HOME screen.
	Press to pause current imaging session.
	Press to resume imaging session. This button replaces pause button after pause button is pressed.
	Press to toggle quick zoom. Quick zoom will increase resolution and decrease imaging depth.
	Press up or down arrow to increase or decrease imaging depth.
	Press up or down arrow to increase or decrease image brightness. In the BONE imaging preset, brightness controls are used to increase or decrease the tissue signal brightness only.
	Press to save the current image on the screen. The saved image will be stored in the GALLERY and associated with the current exam. This button is present after the pause button is pressed.
	Press to save a video of the previous 4 seconds. The saved video will be stored in the GALLERY and associated with the current exam. This button is present after the pause button is pressed.
	Press to go to the exam information page to enter patient and exam information.
	Press the physical device button to save the current image to the current exam during live imaging. This button can save either still-image or video capture depending on the user's settings.

Displays, Controls, and Indicators

LUMBAR and THORACIC preset scanning screen

The LUMBAR or THORACIC screen appears after you press the LUMBAR or THORACIC button from the HOME screen.



BUTTON OR INDICATOR	FUNCTION
	<p>Indicator in the top panel of the LUMBAR preset screen that automatically identifies the presence and location of either interlaminar space or spinous process cross-sections within the 2D scan.</p> <p>The cross-section overlay is orange when interlaminar space is identified and blue when spinous process is identified.</p> <p>The cross-section overlay possesses a transparency that indicates algorithmic confidence of correct interlaminar space or spinous process identification. A less transparent overlay indicates high confidence in anatomy detection while more transparency indicates less confidence. The transparency of the overlay matches that of the 3D navigation spine in the bottom image panel.</p>
	<p>Indicator in the top panel of the THORACIC preset screen that identifies a prescribed needle path based on the Accuro Locator needle guide (sold separately).</p> <p>The indicator is present when the paramedian needle path intersects a location adjacent to the spinous process but within the width of the interlaminar space, and at the depth of the interlaminar space.</p> <p>Transparency indicates algorithmic confidence of correct spinous process and interlaminar depth identifications.</p>

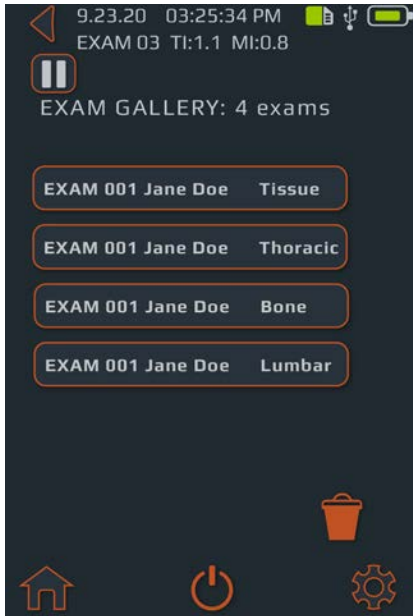
Displays, Controls, and Indicators








BUTTON OR INDICATOR	FUNCTION
	<p>Indicator in the bottom panel of the LUMBAR preset screen that illustrates the position and orientation of the current 2D scan plane along a 3D spine reconstruction.</p> <p>The 3D spine possesses a transparency that indicates algorithmic confidence of correct spinal position detection. A less transparent 3D spine indicates high confidence in position and scan plane orientation while more transparency indicates less confidence. The transparency of the 3D navigation spine overlay matches that of the cross-section overlay in the top image panel.</p>
	<p>Indicator along the right of the display that automatically detects the depths of the interlaminar space and spinous process depths. Interlaminar space is indicated with orange text while spinous process is indicated with blue text.</p> <p>The depth indicator possesses a transparency that indicates algorithmic confidence of correct interlaminar space or spinous process position detection.</p>
	<p>Press to go back to HOME screen.</p>
	<p>Press to pause current imaging session.</p>
	<p>Press to resume imaging session. This button replaces the pause button after pause button is pressed.</p>
	<p>Press up or down arrow to increase or decrease imaging depth.</p>
	<p>Press up or down arrow to increase or decrease image brightness. The brightness control is used to increase or decrease the tissue signal brightness only.</p>
	<p>Press to save the current image on the screen. The saved image will be stored in the GALLERY and associated with the current exam. This button is present after the pause button is pressed.</p>
	<p>Press to save a video of the last 4 seconds before the imaging session was paused. The saved video will be stored in the GALLERY and associated with the current exam. This button is present after the pause button is pressed.</p>
	<p>Press to go to the exam information page where patient information and exam information is entered.</p>
	<p>Press the physical device button to save the current image to the current Exam. This button can save either still-image or video capture depending on user's preference. To toggle between still-image and video capture go to HOME->SETTINGS->Physical Button.</p>

Displays, Controls, and Indicators

Gallery main screen

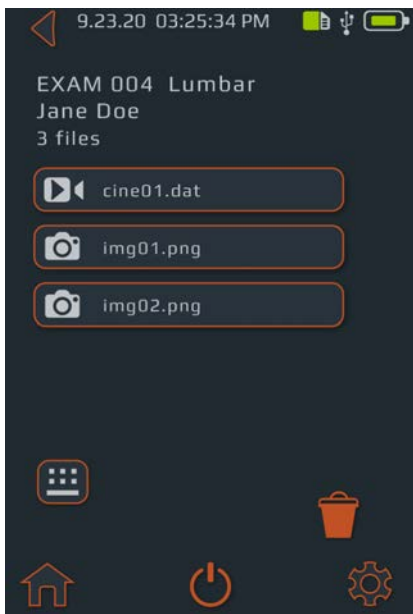
The GALLERY screen appears after you press the VIEW EXAM GALLERY icon from the HOME screen.











BUTTON OR INDICATOR	FUNCTION
	Press to go to HOME screen.
	Press to go to HOME screen.
	Press to power off the device.
	Press to go to the SETTINGS screen.
	Press to select exam(s) for deletion.
	Indicates the current battery charge.
	Indicates the available mmc storage space.

Gallery image selection screen

The GALLERY image selection screen appears after you press the VIEW IMAGE GALLERY icon from the HOME screen and then select an Exam from the GALLERY main screen.

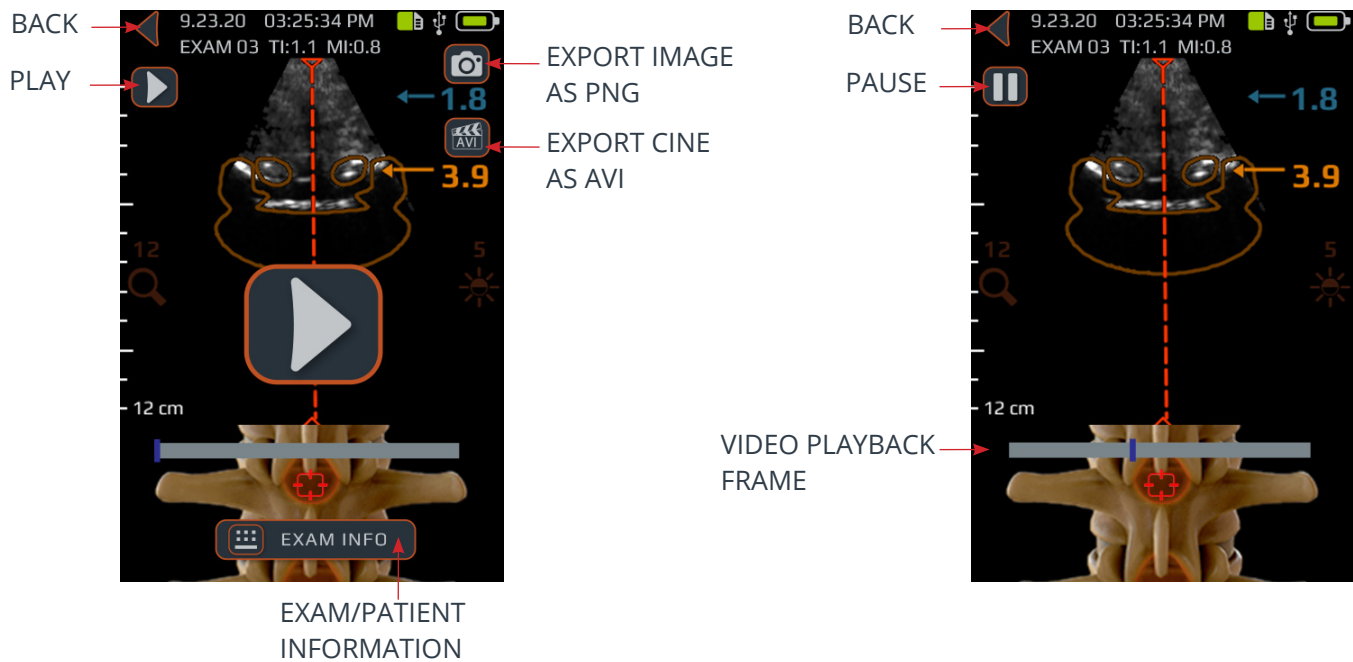


BUTTON OR INDICATOR	FUNCTION
	Press to go to HOME screen.
	Press to go to HOME screen.
	Press to power off the device.
	Press to go to the SETTINGS screen.
	Press to select exam(s) for deletion.
	Indicates the current battery charge.
	Indicates the available mmc storage space.
	Press to go to the exam info page where patient information and exam

Displays, Controls, and Indicators

Gallery video playback screen

The gallery video playback screen appears after you press the GALLERY icon from the HOME screen, then select an Exam from the GALLERY main screen, and select a file with a 'cine' prefix.

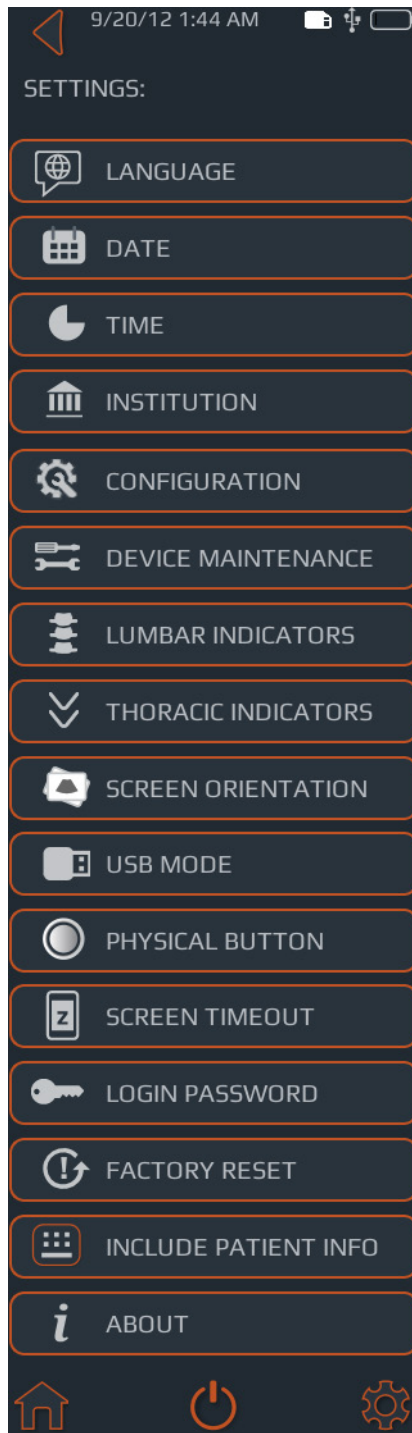





BUTTON OR INDICATOR	FUNCTION
	Press to go back to GALLERY image selection screen.
	Press to export current image as '.png' file.
	Press to go to the exam info page where patient information and exam information is entered.
	Press to start/resume video playback.
	Press to pause video playback.
	Press to export current cine as '.avi' file.
	Video playback progression indicator.

Displays, Controls, and Indicators

Settings screen

The SETTINGS screen appears after you press the SETTINGS icon from the HOME screen.



BUTTON/ INDICATOR	FUNCTION
	Press to go to HOME screen.
	Press to power off the device.
	Press to go to the settings main menu.

Swipe up or down to display more settings items.

Displays, Controls, and Indicators

BUTTON/ INDICATOR	FUNCTION
	Press to set language.
	Press to set the date.
	Press to set the time.
	Press to set the institution name.
	Press to enter code provided by RIVANNA to unlock features.
	Press for further options to perform system diagnosis and repair.
	Toggle control to customize lumbar display.
	Press to customize thoracic needle track indicator display.
	Press to select desired screen orientation.
	Press to choose USB connection functionality.
	Press to choose between video or still-image action for physical button quick press.
	Press to set time before device automatically goes to sleep.
	Press to toggle device password protection on/off and set password.
	Press for option to perform a factory reset. Factory reset will restore device to default conditions.
	Press to toggle whether or not patient information will be included on saved image.
	Press for more information about Accuro.

Using the Accuro

Using SpineNav3D to guide epidural and spinal anesthesia

The Accuro LUMBAR and THORACIC presets use ultrasonic reflections acquired from multiple scan planes to obtain 3D volume scans of the lumbar and thoracic spine. The SpineNav3D technology facilitates image interpretation of individual 2D lumbar and thoracic spine scans by automating spinal bone landmark detection and depth measurements and providing a real-time assessment of scan plane orientation in 3D. SpineNav3D technology makes image interpretation and measurements of the lumbar and thoracic spine anatomy simple, quick, and easy. A sonographer is not required to use the LUMBAR or THORACIC presets.

To perform a clinical lumbar or thoracic epidural or related spinal anesthesia procedure:



1. Turn on the Accuro by pressing the power on/off button.

2. Place the Accuro in a sterile cover and administer the Accuro Locator needle guide (sold separately).

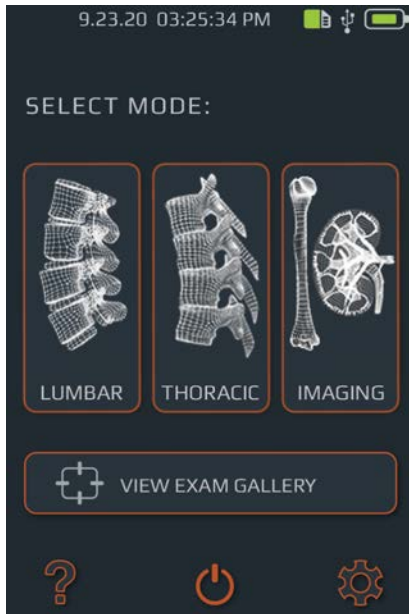
3. Select the LUMBAR or THORACIC imaging preset for neuraxial anesthesia guidance with SpineNav3D.

4. The micro-USB port is used for charging and image export to a computer.

5. Power off the Accuro by pressing the power icon from the Accuro HOME screen.

CAUTION: For accurate imaging results, SpineNav3D must be performed in the lumbar or thoracic region with a transverse scan plane orientation.

Using the Accuro



Generate exam reports and/or save exam images to an external computer

To annotate, generate exam reports, or save exam images to an external computer:

1. For best results, shut down Accuro and connect the Accuro to an external computer using the micro-USB cable provided with Accuro
2. Restart Accuro while connected
3. Find the ATLAS drive on the external computer and run the AccuroATLAS application to enable image annotation, generation of exam reports, and/or saving of exam images.

Check for software upgrades

To check for software upgrades:

Visit our website
www.rivannamedical.com/upgrade/



Using screen mirror

To use screen mirror function:

1. Go to SETTINGS -> USB Mode, select SCREEN MIRROR
2. Connect Accuro to an external computer.
3. Start the camera application on the external computer.

Minimum system requirements

Note: Connection to an external computer should occur outside of the patient environment unless computer equipment is certified to IEC 60601-1

Computer operating system – Microsoft Windows® 10

Minimum processor – 1 GHz

Minimum RAM - 1 GB

Minimum display – 1024 x 768

CAUTION: Assure proper distance from patient.

When transmitting data to or from your computer, make sure that the Accuro, accessories, and the computer are outside of the patient vicinity (more than six feet from the patient).

Accuro Maintenance

Instrument care and maintenance inspection

The Accuro should be inspected for physical damage and cracks prior to every use of the instrument. Stop using the Accuro if damage is noted. Failure to do so may result in electrical shock or fire.

Other than the routine inspection and cleaning described in this User's Manual, there is no periodic or preventive maintenance required for Accuro. There are no components that require periodic testing or calibration for performance assurance.

Cleaning and disinfection

Cleaning procedure

The Accuro instrument should be cleaned between patient uses. To clean the Accuro probes, follow these instructions:

Turn off the Accuro system.

Dampen a nonabrasive cloth with isopropyl alcohol and wipe the probe until thoroughly cleaned.

Gently wipe the dampened cloth over exterior surfaces requiring cleaning.

Wipe with a dry cloth.

Disinfecting procedures

If the instrument needs to be disinfected, use a dampened nonabrasive cloth with an approved disinfecting agent or wipe. The instrument should be wiped until thoroughly cleaned.

Contact RIVANNA for a list of approved disinfectants and disinfecting wipes.

CAUTION: Damage to the instrument may occur

Do not immerse the instrument in disinfectant solution.

Use cleaning and disinfecting procedures as described above.

Electromagnetic Compatibility (EMC)

The Accuro has been designed and tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to the EN/ IEC 60601-1-2 standard for EMC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

WARNING: Use of the Accuro adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers and cables other than those specified or provided by RIVANNA could result in increased

electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

CAUTION: Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable or mobile RF communications equipment or other strong or nearby radio-frequency sources, could result in performance disruption of the ultrasound system. Evidence of disruption may include image degradation or distortion, erratic readings, self-reset, equipment ceasing to operate, unexpected shutdown, or other incorrect functioning.

If this occurs, survey the site to determine the source of disruption, and take the following actions to eliminate the source(s):

- Turn on the Accuro by pressing the power on/off button and verify that Accuro operates as intended.
- Turn equipment in the vicinity off and on to isolate the source.
- Relocate or re-orient the interfering source.
- Increase distance between source and the ultrasound unit.
- Educate clinical staff to recognize potential EMI-related problems.
- Restrict use of cell phones, etc. near the ultrasound unit.

Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions

The Accuro is intended for use in the electromagnetic environment specified below. The customer or the user of the Accuro should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment — Guidance
RF Emissions CISPR 11	Group 1	The Accuro 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. However, a separation distance of 1.5 m shall be maintained.
RF Emissions CISPR 11	Class A	The Accuro is suitable for any professional healthcare environment.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions	Complies	

Electromagnetic Compatibility (EMC)

Electromagnetic Immunity

The Accuro is intended for use in the electromagnetic environment specified below. The customer or the user of the Accuro should assure that it is used in such an environment.		
Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV ±4 kV ±8 kV ±15 kV air	In compliance
Electrical fast transient/burst IEC 6100-4-4	±2 kV 100 kHz repetition frequency	In compliance
Surge IEC 61000-4-5	±0.5 kV ±1 kV Line-to-line ±0.5 kV ±1 kV ±2 kV Line-to- earth	In compliance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % U_T ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycles Single phase: at 0° Voltage interruptions: 0 % U_T ; 250/300 cycle	Immunity
Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	In compliance
Conducted RF IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m

Electromagnetic Compatibility (EMC)

Electromagnetic Emissions

Recommended separation distances between portable and mobile RF communications equipment and Accuro.

The Accuro is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Accuro can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Accuro as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz 1.2	80 MHz to 800 MHz 1.2	800 MHz to 2.5 GHz 2.3
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (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 structure, objects, and people.

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.

ALARA Principle

ALARA is the guiding principle for the safe use of diagnostic ultrasound. Sonographers and other qualified ultrasound users, using good judgment and insight, determine the acoustic exposure that is “as low as reasonably achievable.” There are no set rules to determine the correct acoustic exposure for every clinical situation. The qualified ultrasound use determines the most appropriate way to keep exposure low and bio-effects to a minimum, while obtaining a clinically efficacious study.

A thorough knowledge of the imaging modes, transducer capability, system setup, and scanning techniques is essential. The imaging mode determines the nature of the ultrasound beam. A stationary beam (non-scanning mode) results in a more concentrated exposure than a scanned beam (imaging mode), which spreads the acoustic exposure over the scanned area. The transducer capability depends upon the frequency, penetration, resolution, and field of view. The default system presets are set at the start of each new patient. It is the scanning technique of the qualified ultrasound user along with patient body habitus variability that determines the system setting during the examination.

The variable which affect the way the qualified user implements the ALARA principle include: patient body size, location of the bone relative to the focal point, attenuation in the body, and ultrasound exposure time. Exposure time is an especially

useful variable because the qualified user can, for the most part, control it. The ability to limit exposure over time supports the ALARA principle.

Applying ALARA

The system imaging mode selected by the user is determined by the diagnostic information required. B-mode imaging provides anatomical information and Tissue Harmonic Imaging, which uses higher received frequencies, provides less image clutter, artifact, and improves the overall resolution of the B-mode image. Understanding the nature of the various operational modes allows the qualified user to most effectively apply the ALARA principle.

Prudent use of ultrasound requires that patient exposure to ultrasound be limited to the lowest acoustic output for the shortest time necessary to achieve acceptable diagnostic results. Decisions that support prudent use are based on the type of patient, exam type, patient history, ease or difficulty in obtaining diagnostically useful information, and potential localized heating of the patient due to transducer surface temperatures.

The user uses the system controls to adjust image quality and limit ultrasound acoustic output. The system controls are divided into three categories relative to acoustic output: controls that directly affect output, controls that indirectly affect output, and receiver controls.

Direct controls

The Accuro system does not contain any controls that directly affect output.

Indirect controls

The Accuro system does not contain any controls that indirectly affect output.

Receiver controls

The receiver controls are the gain controls. Receiver controls do not affect acoustic output. They should be used, if possible, to improve image quality before using controls that directly or indirectly affect output.

Other Technical Specifications

Instrument specifications

Item	Specification
Maximum dimensions	5.1 cm x 6.5 cm x 16.5 cm
Weight	0.31 kg (0.7 lb)
Display type	48.96 mm x 73.44 mm (480 pixels x 320 pixels, 166 dpi)

Operating and storage conditions

The Accuro is designed to function under the following operating and storage conditions:

Condition	Description
Storage temperature	-10°C - 50°C
Storage humidity range	20% - 80% non-condensing
Operating temperature	10°C - 35°C
Operating humidity range	20% - 80% non-condensing

Probe specifications

Item	Description
Diameter	12 mm
Frequency	5 MHz
Sector size	60°
Max scan depth	12.5 cm

Acoustic output specifications

See summary of acoustic quantities on the following page.

Battery specifications

The Accuro contains a Lithium Ion battery that is permanently enclosed in the instrument unit. The battery is not replaceable. A battery icon is located on the instrument upper right display and indicates the current charge level and when recharging is required. The battery meets the following specifications:

Item	Description
Battery type	Lithium ion
Battery life	Up to 90 minutes of continuous imaging
Charge time	< 4 hours from an empty battery to full charge

Battery is charged by plugging the device into the provided USB cable and the USB cable into the provided USB wall charge.

Accuracy statement

The measurement accuracy of linear distances and SpineNav3D landmark depth estimates are validated on images of tissue-equivalent ultrasound phantoms. Both phantoms possessed speeds of sound 1540 +/- 10 m/s. In in-vivo use, the accuracy may be greater due to variations in speed of sound.

Specification	Accuracy
Linear distance measurement accuracy (vertical and horizontal)	< 10%
SpineNav3D accuracy	< 3 mm

Acoustic measurement uncertainties

The following acoustic uncertainties are an assessment of both random and systemic uncertainties:

Mechanical Index (MI): +/-3.9%
Thermal Index (TI): +/-7.8%

Other Technical Specifications

Summary of acoustic quantities

Transducer Model: **Accuro**

Operating Mode: B-Mode

Index Label		MI	TIS			TIB	TIC	
			Scan	Non-scan		Non-scan		
				$A_{aprt} \leq 1 \text{ cm}^2$	$A_{aprt} > 1 \text{ cm}^2$			
Maximum index value		1.05	0.822	-	-	-	#	
Associated acoustic parameter	$p_{r,3}$ (MPa)	1.67						
	W_0 (mW)		69.2	-		-	#	
	min of $[W_{.3}(z_1), I_{TA,3}(z_1)]$ (mW)				-			
	z_1 (cm)				-			
	z_{bp} (cm)				-			
	z_{sp} (cm)	3.30				-		
	$d_{eq}(z_{sp})$ (cm)					-		
	f_c (MHz)	2.50	2.50	-	-	-	#	
	Dim of A_{aprt}	X (cm)		1.20	-	-	-	#
Y (cm)			1.20	-	-	-	#	
Other Information	PD (μsec)	1.47						
	PRF (Hz)	1280						
	$p_r @ PII_{max}$ (MPa)	2.21						
	$d_{eq} @ PII_{max}$ (cm)					-		
	Focal Length	FL_x (cm)		6.0	-	-		
		FL_y (cm)		6.0	-	-		
$I_{PA,3} @ MI_{max}$ (W/cm^2)	220							
Operating Control Conditions	Sector scan 4 pulse mode 128 lines over 60 degrees							

Note 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

Note 2: Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.









Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed.

No data reported.

Safety

Symbols

SYMBOL	DEFINITION
	Type BF applied part
	Manufacture date
	Manufacturer of product
	Follow Instructions For Use (IFU)
	Serial number
	Degree of protection against harmful ingress of water
	Dispose of product in accordance with Directive 2012/19/EU
	TUV Rheinland Nationally Recognized Testing Laboratory (NRTL) certification

Accuro® USER'S MANUAL

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Contact Information:
Rivanna Medical, Inc.
2400 Hunters Way
Charlottesville, VA 22911 USA
T: 800-645-7508
www.rivannamedical.com
info@rivannamedical.com