SmartA

INSTRUCTIONS FOR USE

nerveblox

Rx Only

nerveblox

Version: V2.0.3

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00	Initial version	ZU
01	Updated for Venue Ultrasound Implementation EU and USA Region	CVD
02	Updated UI	ZU

IMPORTANT INFORMATION

! CAUTION: DO NOT use Nerveblox in the presence of a needle. The software is intended for pre-injection guidance only and has not been validated for use in combination with needles.

! CAUTION: DO NOT use Nerveblox for arterial or venous line insertions.

⚠ WARNING: The information provided in these instructions for use does not lessen the operator's responsibility to use informed clinical judgment and best clinical procedure.

⚠ WARNING: Always use your clinical judgment when viewing Nerveblox outputs. Nerveblox is an artificial intelligence based assistive tool that may produce errors and should not be solely relied upon for clinical decisions.

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DEFINITIONS AND SYMBOLS

Refer to the definitions below for abbreviations, technical terms, and specialized language used throughout this document.

Term	Definition
AI	Artificial Intelligence
Audit log	A record of events and changes to the system
Block region	A shortened term for Peripheral Nerve Block
BMI	Body Mass Index, where BMI = kg/m^2 and kg is the patient's weight in kilograms and m is the patient's height in meters.
B-mode	Brightness mode, ultrasound imaging mode
Highlighting	Overlay of color mask over an original ultrasound image
Interventional Procedure	Any procedure used for diagnosis or treatment that involves incision, puncture, entry into a body cavity, or the use of ionizing, electromagnetic, or acoustic energy.
Probe	Ultrasound probe, also known as an ultrasound transducer
MHz	Megahertz

This document uses the following symbols:

Symbol	Definition
⚠ WARNING:	Warnings alert the user to the possibility of serious effects associated with product misuse.
! CAUTION:	Cautions alert the user to situations that, if not avoided, could result in minor injury or damage to equipment.
NOTE:	Notes provide additional information.

1. DEVICE DESCRIPTION

1.1. INTENDED USE

Nerveblox software is intended to assist qualified healthcare professionals in the identification and highlighting of anatomical structures in ultrasound images to support ultrasound-guided regional anesthesia procedures.

! CAUTION: DO NOT use Nerveblox in the presence of a needle. The software is intended for pre-injection guidance only and has not been validated for use in combination with needles.

1.2. INTENDED USERS

Nerveblox is intended for use by qualified healthcare professionals who are licensed to perform ultrasound-guided regional anesthesia procedures and have received training in the use of the software.

⚠ WARNING: Outputs generated by Nerveblox must not be interpreted by anyone other than the intended users.

1.3. INDICATIONS FOR USE

Nerveblox is indicated for use in the supported block regions and is intended exclusively for adult patients, 18 years of age or older. It is only designed for use prior to needle insertion during ultrasound-guided regional anesthesia procedures and is not intended for use in combination with needles or during needle insertion.

Nerveblox supports users in the following anatomical regions:

- Interscalene Brachial Plexus
- Supraclavicular Brachial Plexus
- Infraclavicular Brachial Plexus
- Cervical Plexus
- Axillary Brachial Plexus
- PECS I & II
- Transversus Abdominis Plane (TAP)
- Rectus Sheath
- Femoral Nerve
- Adductor Canal
- Popliteal Sciatic
- Erector Spinae Plane (ESP)

⚠ WARNING: Use Nerveblox only for the anatomical regions specified in the Indications for Use section.

1.4. CONTRAINDICATIONS

There are no known contraindications for the use of Nerveblox when applied in accordance with its intended use by the intended user.

1.5. INTENDED USE ENVIRONMENT

Nerveblox is intended for use in professional healthcare settings where ultrasound-guided interventional procedures such as regional anesthesia are conducted.

1.6. TRAINING

Please review this 'Instructions for Use' document to ensure the safe use of Nerveblox. Additionally, before using this information and the Nerveblox product, operators must also be familiar with the Venue ultrasound system family and general ultrasound techniques.
If additional hands-on training is required, please contact your sales representative.

1.7. KEY FEATURES

Nerveblox has the following assistive features:

- It supports 12 ultrasound-guided regional anesthesia regions. See **APPENDIX A.**
- It provides real-time feedback on ultrasound view quality, displayed as a 'Quality Meter' bar.
- It highlights clinically relevant anatomical structures in real time with color and name labels (only when the Quality Meter indicates 'Quality Score 2' or higher).
- It provides reference probe orientation and anatomical view images as additional schematic guidance. See **APPENDIX A.**

Nerveblox software operates locally and does not require access to external or remote resources or an internet connection. Nerveblox does not collect, process, or require any sensitive information, including personal data, for its operation. Additionally, it does not save, store, or reuse any data generated during its use, including ultrasound images, ensuring complete data privacy and security. Nerveblox cannot provide feedback on single ultrasound image frames.

2. SAFETY INFORMATION

⚠ **WARNING: Read all instructions, including warnings and cautions, before using Nerveblox.**

⚠ **WARNING: The information provided in these instructions for use does not lessen the operator's responsibility to use clinical judgment and best clinical procedure.**

⚠ **WARNING: Nerveblox must only be used by healthcare professionals who are licensed to perform ultrasound-guided regional anesthesia procedures and who have been trained in its use.**

This product must be operated by a qualified healthcare professional. The instructions for use are intended for healthcare professionals who operate Nerveblox.
Before using this information and Nerveblox, operators must be familiar with ultrasound techniques. Sonography training and clinical procedures are not described here.

! CAUTION: Do not use or operate the software if it is in a defective, incomplete, or improper condition. Nerveblox software must only be used in a manner that does not conflict with applicable laws or regulations. Neither the manufacturer nor its representatives shall be liable for any incompatibility, damage, or injury resulting from misuse of the product or operation of the product for purposes other than those intended and expressly stated by the manufacturer.

3. VISUAL GUIDANCE COMPONENTS

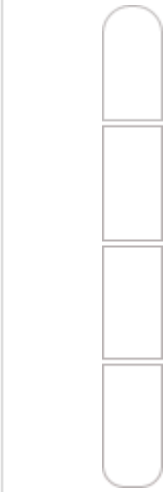
3.1. QUALITY METER

The quality meter provides visual feedback by assigning a quality score to the ultrasound image based on anatomical structure visibility by coloring a bar at varying levels.
The below criteria collectively influence the overall quality score, ensuring a standardized assessment of image quality:

- The relevance of the acquired image to the selected block region.
- The extent to which all supported anatomical structures are visible in the image.
- The relevance of the acquired image to the selected probe orientation.

Descriptions of the levels of the quality meter are provided in **Table 1**.

Table 1. Quality Score Descriptions

				
Color overlays are not provided		**Color overlays are provided**		
Quality Score 0: Image does not correspond to the selected block region	**Quality Score 1:** Image corresponds to the selected block region but has	**Quality Score 2:** Minimal anatomical structures are visible	**Quality Score 3:** Majority of the anatomical structures are visible	**Quality Score 4:** All anatomical structures are visible

	insufficient diagnostic visibility			

📝 **Note:** If the probe is not correctly aligned (e.g., lateral or medial) relative to the selected probe orientation, the quality score will be low. To achieve a high-quality score, you must ensure proper probe alignment using the schematic guidance.

📝 **Note:** If the quality score remains consistently low, adjust your probe position to improve the view and ensure that the 'Gain' parameter is not set to an excessive level, as this may lead to a lower score.

3.2. COLOR OVERLAYS

! CAUTION: Avoid using the device if you have a color vision deficiency, as it may impair your ability to interpret the color overlays effectively.

Nerveblox can detect and highlight key anatomical landmarks in the supported block regions. These landmarks are single or multiple instances of nerves, muscles, arteries, veins, ribs, transverse processes, fascia, tendons, the pleura and the peritoneal cavity. For the full list of anatomical structures that Nerveblox is able to identify and highlight, refer to **APPENDIX B**.

The highlighting is applied by using semi-transparent color overlays on the detected anatomical structures.

⚠️ **WARNING: Color overlays and name labels are not provided when the Quality Score is 0 or 1.**

Within a given block region, all instances of the same type of anatomical structure are consistently overlaid with the same assigned color.

📝 **Note:** In some instances, the same colors are used to denote unrelated anatomical structures. These structures will never be present in the same anatomical area.
The intensity of the color overlays can be adjusted as described in **SECTION 4.6.1.**

⚠️ **WARNING: Nerveblox does not make any recommendations about where the needle should be placed nor where the anesthetic should be injected.**

3.3. NAME LABELS

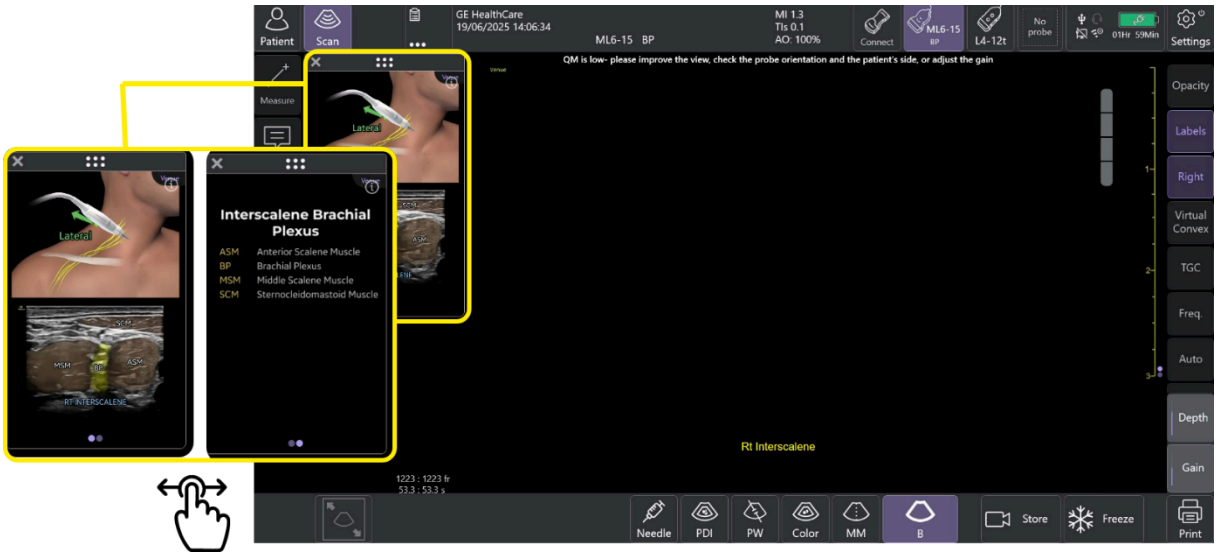
Name labels, which are typically yellow and in the form of two- to five-letter acronyms or abbreviations, are added within the boundaries of anatomical structures on the ultrasound image.
The name labels can be toggled on and off as described in **SECTION 4.6.2**.

⚠️ **WARNING: Color overlays and name labels are not provided when the Quality Score is 0 or 1.**

3.4. SCHEMATIC GUIDE

Schematic representations of the ideal probe positions and the corresponding anatomy are displayed as schematic guides. The complete set of schematic guide images are provided in **APPENDIX A**.

Note: To see the full names of the abbreviated name labels, swipe the schematic guidance to the left (*See Figure 1*)



- **Note**: Tapping the schematic guide icon displayed on the screen will maximize the schematic guide when it is minimized *(see Figure 2)*.

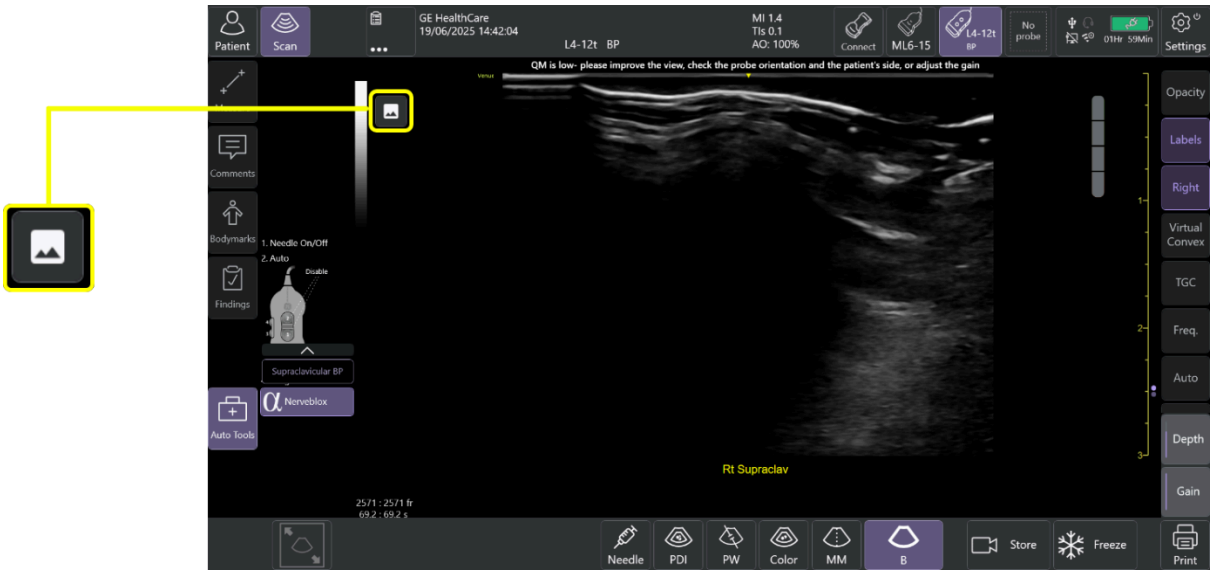


Figure 2. Schematic Guide Icon

4. OPERATING STEPS

⚠ **WARNING: Always follow your facility's safety protocols for ultrasound-guided regional anesthesia.**

Note: The operating steps and instructions use the term 'tap/tapping', which refers to the action of select/selecting or click/clicking a menu item or button on the touchscreen of the ultrasound system. Refer to the ultrasound system's user manual for detailed instructions on system operation.

4.1. STARTING NERVEBLOX

Nerveblox is only accessible when one of the 'Nerve' presets for the active probe is selected (see Figure 3). Refer to the preset selection section of your ultrasound system user manual for guidance or assistance.

STEP 1: Select the appropriate preset from the list of 'Nerve' presets.

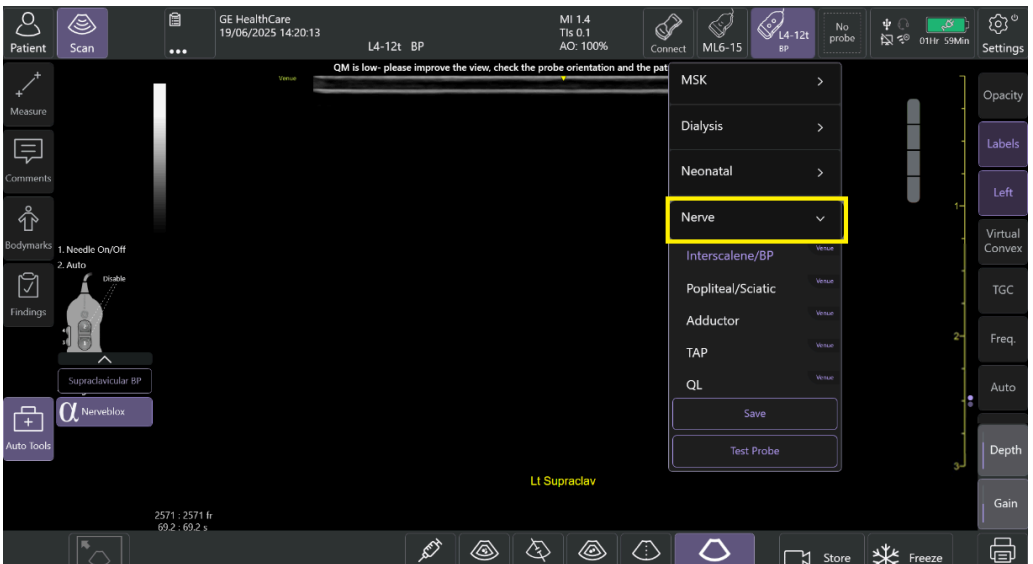


Figure 3. 'Nerve' Presets

! CAUTION: Nerveblox requires optimized ultrasound images to achieve the best performance. Ensure the ultrasound image preset is set to the appropriate 'Nerve' preset.

STEP 2: When a nerve preset is selected, tap the **'Auto Tools'** menu in the lower-left corner of the ultrasound screen (*see Figure 4)* and then tap the Nerveblox button *(see Figure 5*).

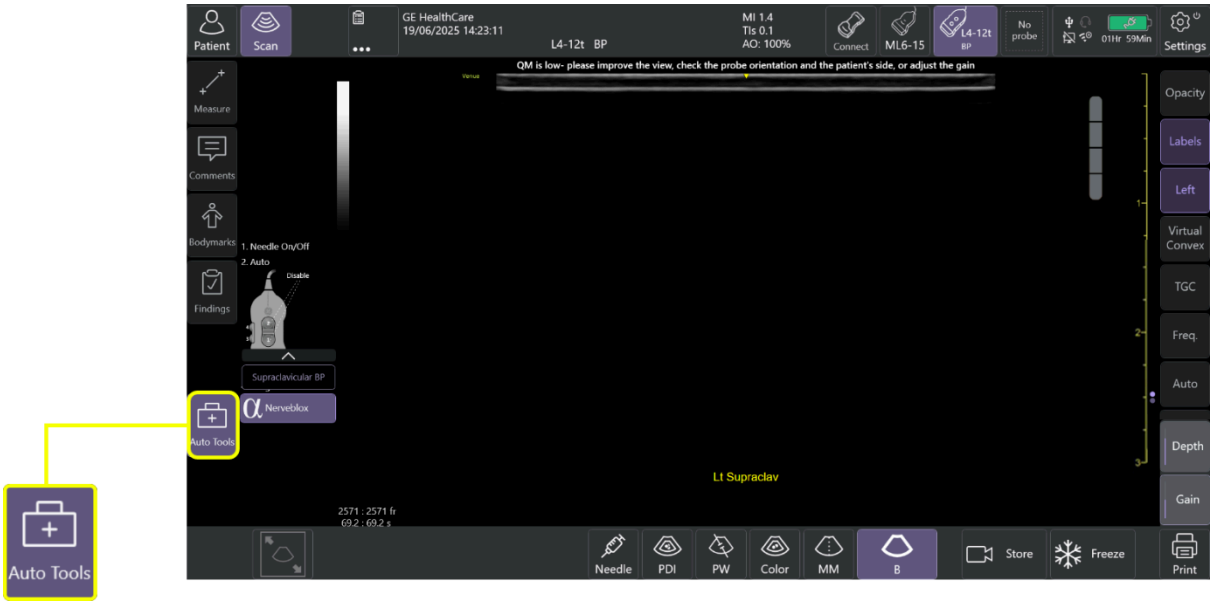


Figure 4. Auto Tools Button

Figure 5. Nerveblox Button

4.2. BEFORE SCANNING

Nerveblox supports 12 ultrasound-guided regional anesthesia procedures. Select the appropriate block region and align the probe with the on-screen schematic guidance for optimal visualization.
STEP 1: Select a block region from the list of supported block regions displayed after tapping the 'Nerveblox' button.

Note: The name of the selected block region is displayed above the Nerveblox button. You can change it by expanding the full list of block regions by tapping on the name of the selected block region.

Note: Depending on the type of selected 'Nerve' preset, if a matching block region is supported by Nerveblox, it will be automatically selected by default.

STEP 2: Refer to the schematic guidance on the left upper side of the screen for information about probe orientation and expected output *(see Figure 6).*

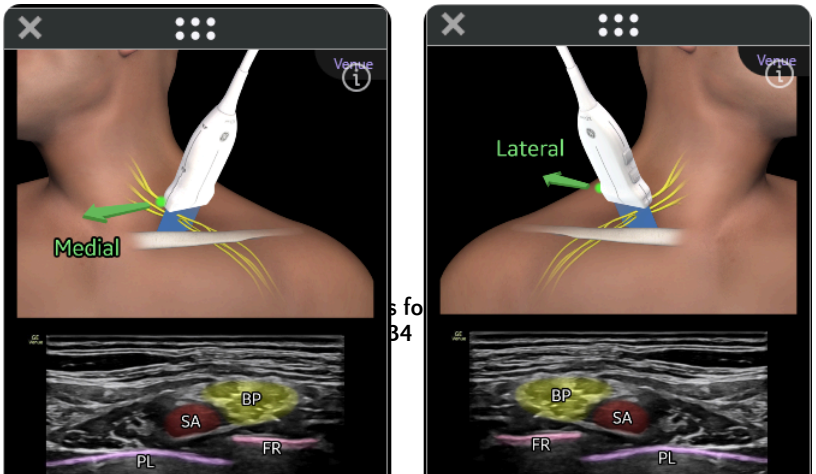


Figure 6. Schematic Guidance for Probe Orientation

STEP 3: You can adjust the probe orientation by tapping the orientation button in the scan controls area, depending on whether you are scanning the right or left side of the patient or based on your usual practice. This adjustment is necessary if the selected orientation in Nerveblox, as indicated on the schematic guide, does not match your actual probe orientation *(see Figure 7).*

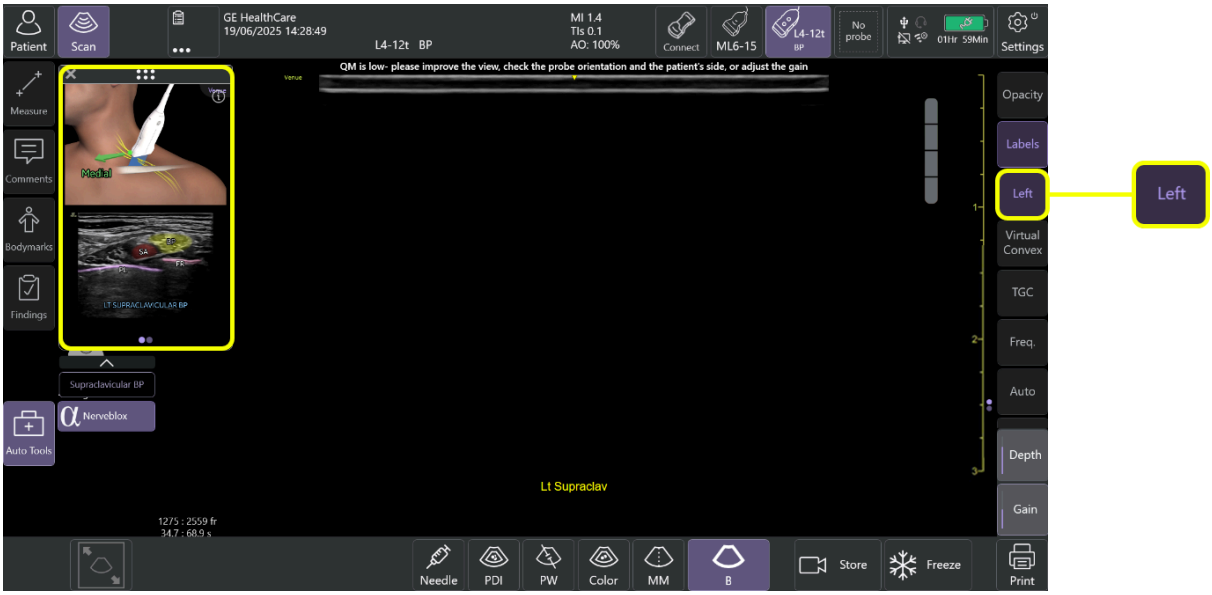


Figure 7. Adjusting Probe Orientation

Note: To determine the orientation of the ultrasound probe, refer to the Schematic Guide. For a different orientation, you can use the orientation button (Right/Left). Each tap on the Orientation button flips the orientation in which Nerveblox processes the image. The original image seen on the screen is not affected.

Note: Probe orientation adjustment does not affect the original image seen on the ultrasound display, only the Nerveblox software is informed of your actual probe orientation.

! CAUTION: To ensure correct outputs from Nerveblox, you must align the ultrasound probe orientation exactly as shown in the schematic guide. Any deviation can result in incorrect outputs.

4.3. SCANNING

⚠ WARNING: Do not use Nerveblox for any procedures other than those indicated.

⚠ WARNING: Do not use Nerveblox for arterial or venous line insertions.

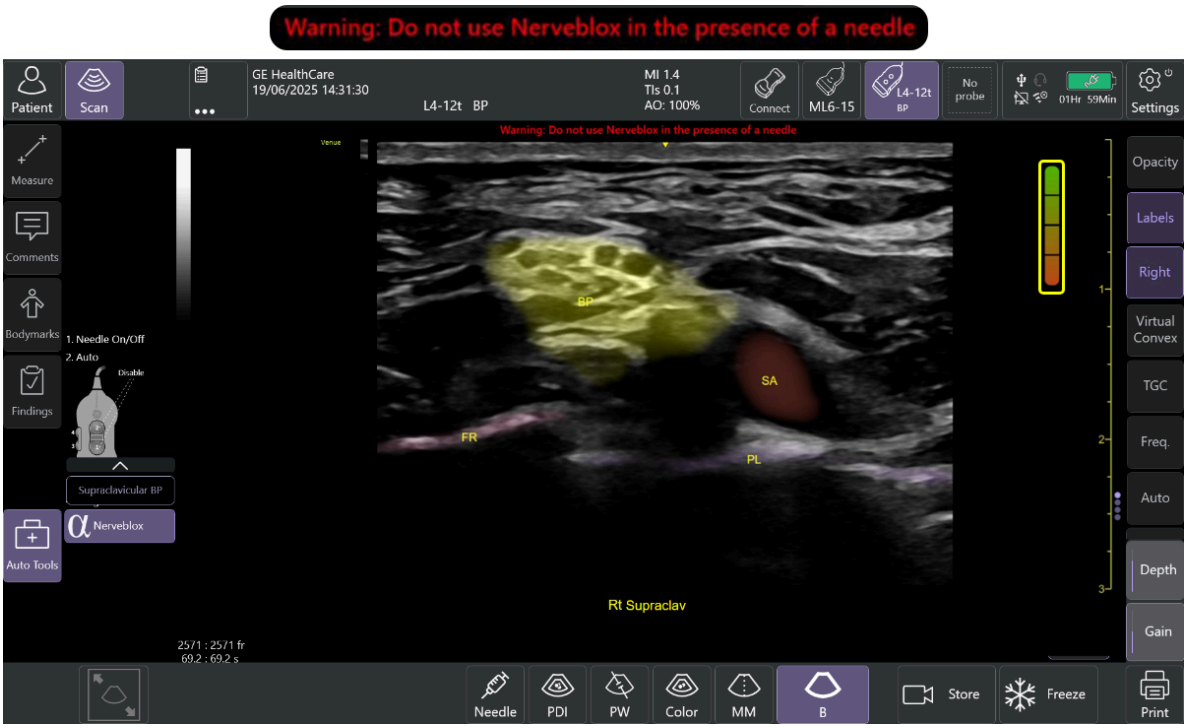
STEP 1: Start scanning after selecting the nerve block region from the list of supported block regions and aligning the probe orientation as shown in the schematic guide.

STEP 2: Follow the **'Quality Meter'** to obtain feedback on the quality of the ultrasound view.

⚠ WARNING: Always use your clinical judgment when viewing Nerveblox outputs.

STEP 3: When you are ready to proceed to the needle procedure, you must exit the Nerveblox software and continue the procedure by manually examining the ultrasound image.

⚠ WARNING: Do not use Nerveblox in the presence of a needle. The software is intended for pre-injection guidance only and has not been validated for use in combination with needles.



! CAUTION: Highlighting may appear intermittent when the probe is moving or if the quality score is low.

! CAUTION: The boundaries of highlighted regions may not correspond exactly to the boundaries of the underlying anatomical structures.

! CAUTION: Nerveblox may not highlight well on low-quality ultrasound views, such as those obtained from patients with a BMI above 35 kg/m^2.

Note: The highlighting may appear flickery or intermittent if the correct view is not obtained or if the ultrasound image is poor.

4.4. EXIT NERVEBLOX

STEP 1: Tap the '**Nerveblox**' button to exit Nerveblox.

4.5. CONSIDERATIONS FOR SPECIFIC BLOCK REGIONS

4.5.1. Supraclavicular Brachial Plexus

When scanning the supraclavicular brachial plexus block region, pleura is only highlighted at the points along the line where it is visible. Please use your own judgment to complete the pleura line at points where it is not highlighted.

4.5.2. Erector Spinae Plane (ESP)

When scanning the ESP block region, choose an appropriate anatomical region for your clinical needs, as the anatomical appearance of the region is similar at different levels. The schematic images provided are for information purposes only.
Pleura is only highlighted at the points along the line where it is visible. Please use your own judgment to complete the pleura line at points where it is not highlighted.
Multiple transverse process structures may be visible in the ESP block region, but not all of them may necessarily be highlighted at the same time in the image. Please use your own judgment to recognize the full anatomical structure.

4.5.3. PECS I & II

When scanning the PECS I & II block, choose an appropriate anatomical region for your clinical needs, as the anatomical appearance of the region is similar. The schematic images provided in Nerveblox are for information purposes only.
Pleura is only highlighted at the points along the line where it is visible. Please use your own judgment to complete the pleura line at points where it is not highlighted.
Multiple rib structures may be visible in the PECS block region, but not all of them may necessarily be highlighted at the same time in the image. Please use your own judgment to recognize the full anatomical structure.

4.5.4. Popliteal Sciatic

Despite its high accuracy, Nerveblox has a higher false positive rate for color highlighting in the popliteal sciatic block region compared to other block types, sometimes leading to incorrect or unnecessary highlights on the ultrasound image. Users are advised to verify highlights against their own anatomical knowledge and ultrasound interpretation, particularly in cases where visualization is challenging.

4.5.5. Regions With Veins

During scanning, veins may collapse due to excessive probe pressure and might become invisible. Ensure optimal probe pressure to prevent a complete vein collapse while maintaining a clear ultrasound view. If the veins collapse, Nerveblox may not detect them, and the Quality Meter might not reach optimal levels.

4.6. ADJUSTING VISUAL COMPONENTS

Nerveblox allows the following adjustments to its visual feedback elements:

- Adjusting intensity of color overlays
- Showing or hiding name labels

4.6.1. Adjusting Intensity of Color Overlays

Nerveblox allows adjustment of color overlay intensity, which affects the visibility of anatomical structures on the underlying ultrasound image.

STEP 1: Tap the '**Opacity**' button on the scan controls area *(see Figure 9)*.

STEP 2: Set the color intensity level by using the displayed '**Opacity Slider**'

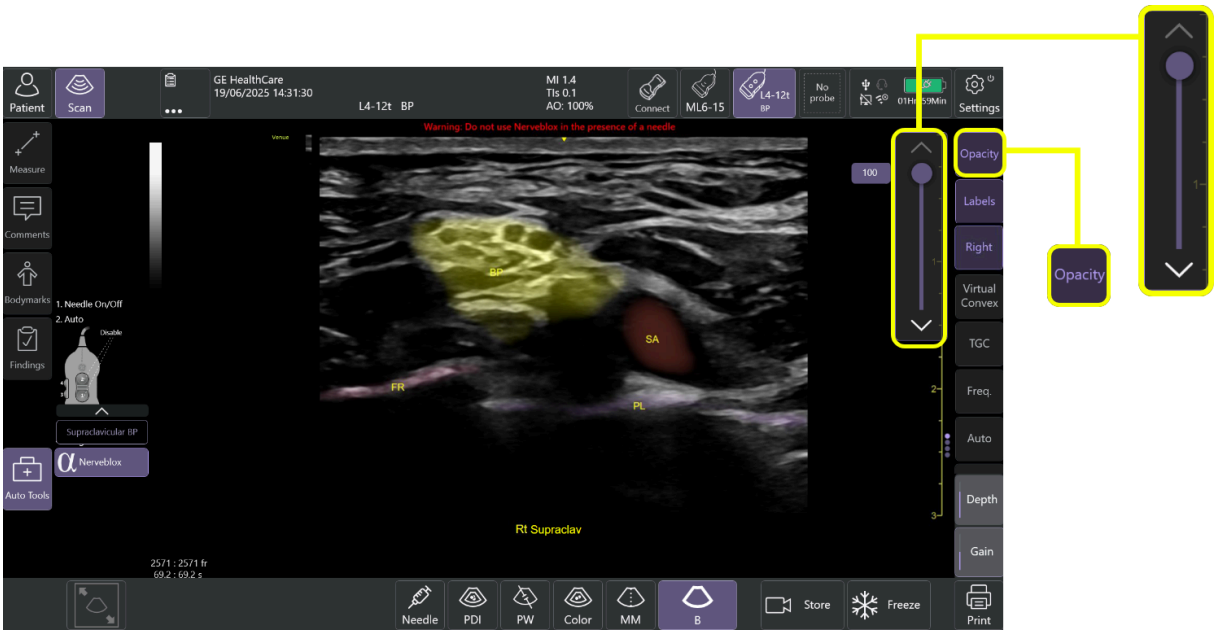


Figure 9. Opacity Button and Opacity Slider

- **Note:** When the opacity level is set to the minimum, the color overlays fade out and become invisible. However, if the name labels are disabled, the color overlays will remain partially visible even at the minimum opacity level for reasons of safety.

When the opacity level is set to the maximum, the color overlays still remain semi-transparent and do not become fully opaque. This ensures that the underlying ultrasound image remains visible for accurate interpretation.

4.6.2. Showing/Hiding Name Labels

Nerveblox allows showing/hiding of name labels for the anatomical structures.
STEP 1: Tap the '**Labels**' button on the scan controls area *(see Figure 10)*.

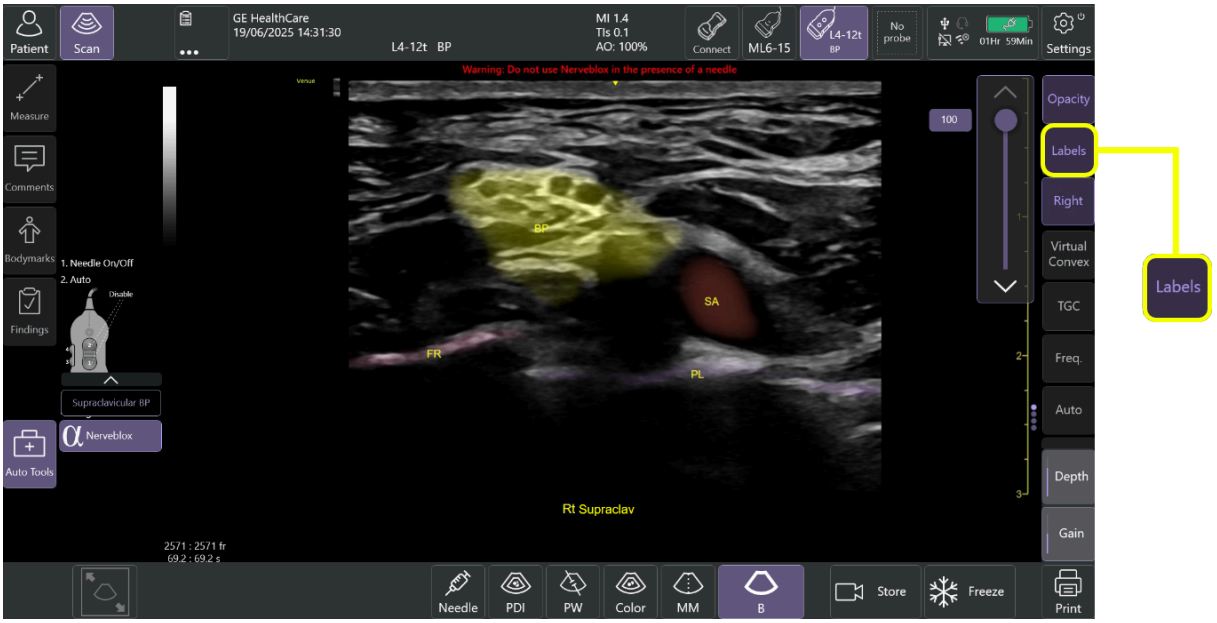


Figure 10. Labels Button

Note: Either the color overlays can be made fully transparent, or the name labels can be hidden, but not both at the same time.

4.7. ADJUSTING SCAN PARAMETERS

When Nerveblox is running, the ultrasound system allows adjustments to the following scan parameters only:

- Gain

- Depth
- Virtual Convex
- TGC
- Frequency
- Auto
- Gray Maps
- Thermal Index

Any image parameters not listed above will remain set to their default values.

5. SYSTEM SETTINGS

5.1. ACCESSING THE AUDIT LOG

Audit logs for Nerveblox can be accessed through your ultrasound system's interface. Please follow the procedures outlined in your ultrasound system's user manual or consult your ultrasound system administrator for assistance in retrieving and managing audit logs.

5.2. UPDATING THE SYSTEM

Nerveblox can be updated following your ultrasound system's update procedures. For detailed instructions, refer to the documentation provided by your ultrasound manufacturer.

6. TECHNICAL SPECIFICATIONS

6.1. TECHNOLOGY OVERVIEW

Nerveblox is a software as a medical device which is integrated into compatible ultrasound systems.

Nerveblox's image interpretation functionality is achieved through a combination of Artificial Intelligence (AI) and Computer Vision technologies. The core AI technology of Nerveblox is based on deep learning, which involves extensive training of neural network models prior to market release. These neural network models are 'locked,' meaning that they do not continue to learn or adapt during use. No scan data is collected or utilized during operation, ensuring patient privacy and data security.

It is important to note that AI technology can make mistakes. While robust safety and security controls are in place to minimize risks, users must exercise their own clinical judgment at every step when using the system to ensure safe and effective patient care. Nerveblox functions as a second opinion, enhancing anatomical visualization to support qualified healthcare professionals.

6.2. SUMMARY OF ESSENTIAL PERFORMANCE EXPECTATION

Nerveblox is designed to function safely within its intended clinical environment. Its performance has been tested against applicable industry standards to ensure accuracy under expected conditions and evaluated for its intended users and patient population to confirm compliance with essential performance requirements.

The performance of Nerveblox in detecting and color-highlighting anatomical structures has been clinically validated. Additionally, the quality score functionality has been validated, demonstrating agreement with expert assessments, where a quality score of 0 indicates an image that does not correspond to the selected block region, a score of 1 indicates an image that corresponds to the selected block region but does not meet the minimum diagnostic

criteria, and scores above 1 indicate an image that corresponds to the selected block region and meets the minimum diagnostic criteria.

However, Nerveblox is an assistive device that supports trained clinicians and is not intended to replace the user's own clinical judgment.

6.3. CLINICAL EVIDENCE AND TESTING

Based on preclinical validation and clinical performance evaluations, it is concluded that Nerveblox meets clinical accuracy needs and the overall residual risk of using Nerveblox is low, acceptable and outweighed by the clinical benefits of the device.

A prospective clinical validation study was conducted to evaluate the performance of Nerveblox, which involved 80 distinct ultrasound scans from 40 healthy volunteers, with ultrasound scans performed by anesthesiologists. The study population included participants with a mean age of 37.9 years, ranging from 18 to 66 years. In terms of body mass index (BMI), 52.5% of participants had a BMI below 30, while 47.5% had a BMI above 30, with a mean BMI of 29.13 (±4.76).

The scans were later processed by the AI, and the results were evaluated by expert U.S. board-certified anesthesiologists. The primary objective was to assess the accuracy of Nerveblox in detecting and highlighting key anatomical structures on ultrasound images. Secondary objectives included evaluating the consistency of the AI's image quality grading against predefined criteria and identifying potential risks in AI-assisted interpretation.

The study measured the software's accuracy in anatomical landmark highlighting by comparing AI-generated results with expert evaluations. The software demonstrated a high accuracy rate of 97%, with a true positive rate of 98% and a true negative rate of 90%. The false-positive rate (FPr) was 10.4%, while false-negative rate (FNr) was 2%. Expert assessments indicated that AI-assisted highlighting reduced the perceived risk of adverse events in 61.67% of cases and reduced the risk of block failure in 66.36%. The AI also contributed to procedural efficiency while maintaining safety concerning risks such as pneumothorax, local anesthetic systemic toxicity, peritoneum violation, and nerve injury.

The AI-generated image quality scores were compared with expert evaluations using Cohen's Kappa test to measure agreement. The agreement between Nerveblox and experts was found to be substantial, with a mean Kappa score of 0.70 which indicates a substantial agreement. Agreement varied by region, ranging from 0.31 (fair agreement) for popliteal sciatic block to 1.0 (perfect agreement) for supraclavicular brachial plexus block. The overall accuracy of the AI in assessing whether images met minimum diagnostic criteria (Quality Score above 1) was 95.3%, with an error rate of 4.7%. Accuracy varied by region, ranging from 86.3% for popliteal sciatic block to 100% for supraclavicular brachial plexus block.

The study concluded that Nerveblox provides accurate anatomical structure detection and consistent image quality classification, showing strong agreement with expert evaluations. AI-based highlighting was considered safe, with the potential to reduce procedural risks and improve clinical outcomes in ultrasound-guided regional anesthesia.

6.4. PATIENT SAFETY

Nerveblox is intended to assist qualified healthcare professionals in the identification of anatomical structures for ultrasound-guided interventional procedures.

Should any part of Nerveblox fail to provide the indicated functionality, the clinician should continue the procedure by exiting the Nerveblox software. Nerveblox is an assistive device only.

To avoid any potential hazard to patients, always read and follow the instructions for use supplied with the ultrasound system and perform procedures as specified in these instructions for use.

6.5. CLINICAL SAFETY

Follow Standard Precautions[1] or Managing Medical Devices guidance[2] when maintaining medical devices for interventional procedures.

Ultrasound-guided interventional procedures require appropriate training as dictated by current relevant medical practices, as well as training in the proper operation of the ultrasound system. Nerveblox must only be used by healthcare professionals who are licensed to perform ultrasound-guided regional anesthesia procedures, as outlined in **SECTION 1.2.**

6.6. COMPATIBLE ULTRASOUND SYSTEMS

⚠ **WARNING: For specific functional and safety information related to the ultrasound system, follow the system manufacturer's instructions.**

Nerveblox software is compatible with the ultrasound systems and probes listed in **Table 2**.

Table 2. Compatible Ultrasound Systems

Manufacturer	Product name	Probe types
GE HealthCare	Venue Venue Go Venue Sprint Venue Fit	4.2-13MHz linear probe (L4-12t-RS) 3-20MHz linear probe (L4-20t-RS) 5-13MHz linear probe (12L-RS) 3.5-10MHz linear probe (9L-RS) 4-15MHz linear probe (ML6-15-RS) Vscan Air CL linear array (3-12MHz) Vscan Air SL linear array (3-12MHz)

6.7. DATA HANDLING

6.7.1. Data Storage and Protection

Nerveblox does not record or store any patient- or user-identifiable data, nor does it store or record ultrasound images.

The software generates audit logs that record runtime events, including technical issues such as errors or failures that may occur during use, to assist in diagnosing any issues. These audit logs do not contain any medical or personal information and are stored by the ultrasound system.

6.7.2. Data Transfer and Disposal

Nerveblox does not support data transfer. Nerveblox does not record or store any patient- or user-identifiable data, nor does it store or record ultrasound images.

6.8. CYBERSECURITY

Nerveblox is integrated into the ultrasound system and operates only within its environment. It does not support general interoperability beyond this designated integration.

Nerveblox does not store any data and operates exclusively as a host-specific software module within the ultrasound system. All data exchange occurs internally within the Venue system, and Nerveblox does not communicate with or integrate into external medical devices, PACS, or IT networks. The software does not establish connections with network devices and does not use or require cloud or network storage.

All software cybersecurity controls are implemented in compliance with industry standards to ensure secure operation. For further details on cybersecurity controls, please refer to the 'Privacy and Security Manual' of your ultrasound system.

If you identify or suspect any cybersecurity incident, please report it promptly by contacting your ultrasound system's manufacturer through their designated technical support channels for initial troubleshooting and further assistance.

7. LICENSE

Nerveblox software is licensed for use under the terms and conditions specified in the Nerveblox End User License Agreement (EULA). Please refer to your sales documentation or consult your sales representative to review the license terms. For information about third-party software licenses, see the 'Nerveblox' page in the 'About' section of your ultrasound system. Refer to the ultrasound system's user manual for instructions on accessing the 'About' section.

8. CONTACT INFORMATION

8.1. MANUFACTURER

Please contact Nerveblox's manufacturer to report safety incidents.

Smart Alfa Teknoloji San. ve Tic. A.S.

Address: Universiteler Mah. Ihsan Dogramaci Blv. 17/1 No.109, 06800 Ankara, Türkiye
E-Mail Address: info@smartalpha.ai
Phone: +90 (312) 557 18 83

8.2. SUPPORT

For any support requests or issues, including unauthorized access, data breach, malware activity, or any unusual behavior related to the Nerveblox software, please contact your ultrasound system's manufacturer through designated support channels.

9. PRODUCT LABEL

9.1. LABEL

Figure 11. Product Label

9.2. SYMBOL DEFINITIONS

Table 3. Nerveblox Label Symbols

SYMBOL	DEFINITION
	Manufacturer
	Date of manufacture
	Consult Instructions for Use

SYMBOL	DEFINITION
	Medical Device
	Catalog Number
	Unique Device Identifier
	LOT Number
	CE Mark
	There are specific warnings or precautions associated with the medical device, which are not otherwise found on the label.
	Prescription use only

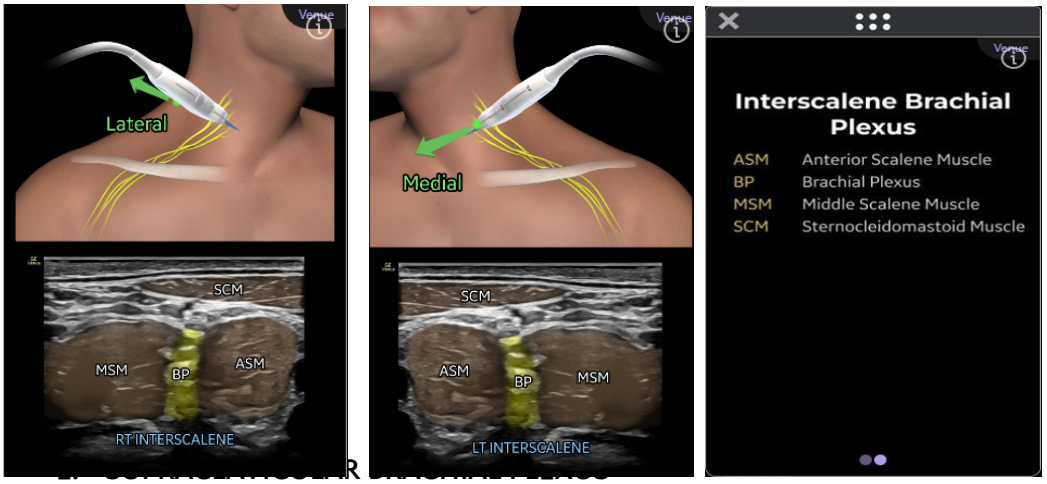
10. REFERENCES

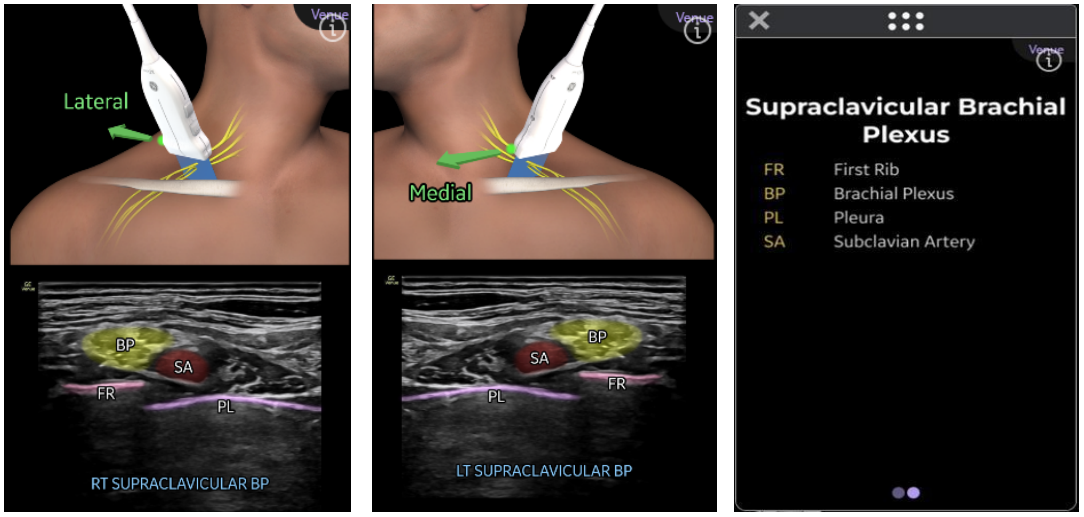
[1] "Standard Precautions for All Patient Care", The Centers for Disease Control and Prevention of the United States., January 2016.
[2] "Managing Medical Devices, Guidance for healthcare and social services organizations", Medicines & Healthcare products Regulatory Agency (MHRA). April 2015.

APPENDIX A – SUPPORTED REGIONS

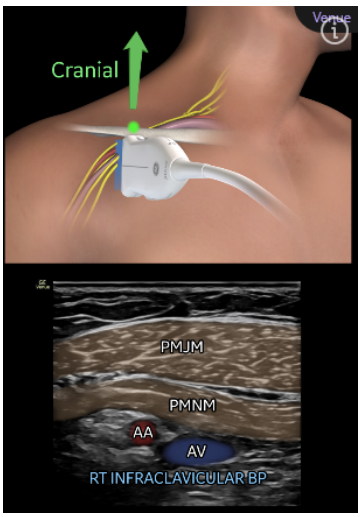
The below peripheral nerve block regions are supported by Nerveblox.
The associated schematic and textual guidance for probe positions, reference anatomical views, and the legend for name labels corresponding to each peripheral nerve block region is provided below as a reference, obtained from the Venue Go (GE HealthCare Technologies, Inc., Chicago, Illinois) ultrasound system.

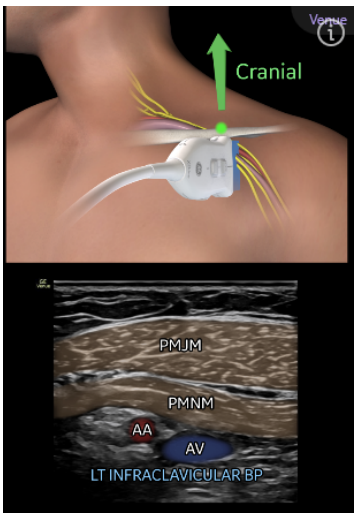
1. INTERSCALENE BRACHIAL PLEXUS

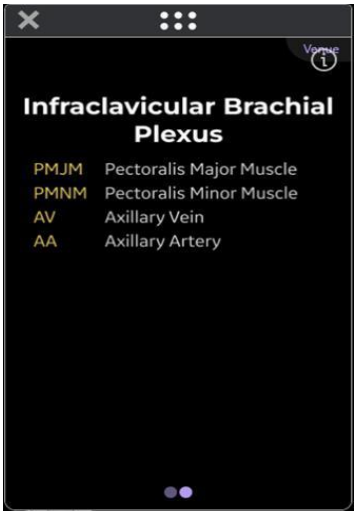


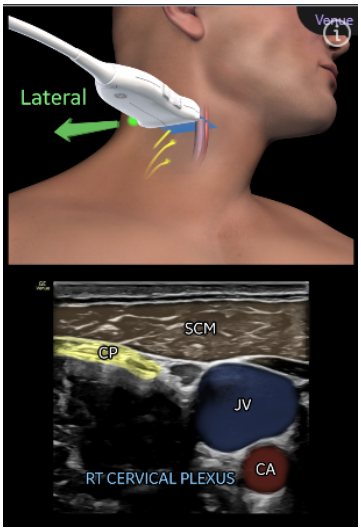


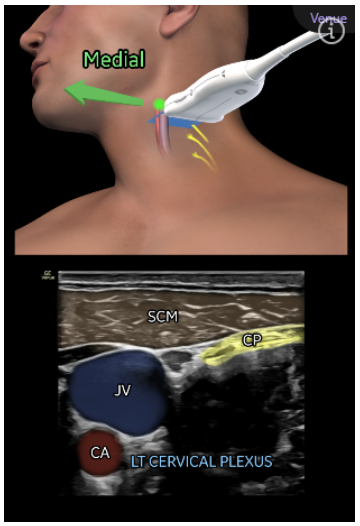
3. INFRACLAVICULAR BRACHIAL PLEXUS

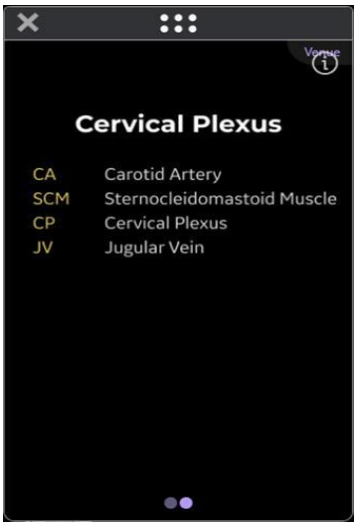




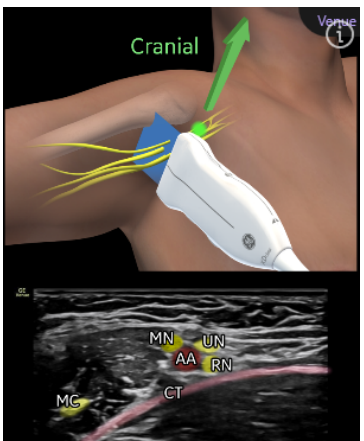


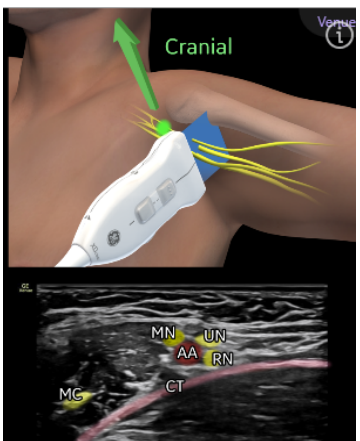


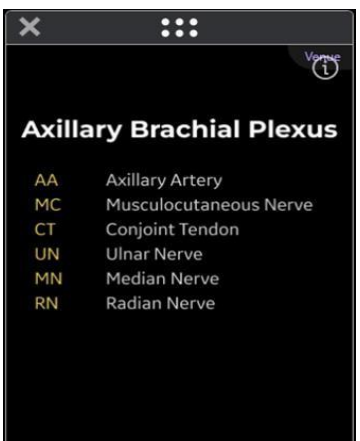




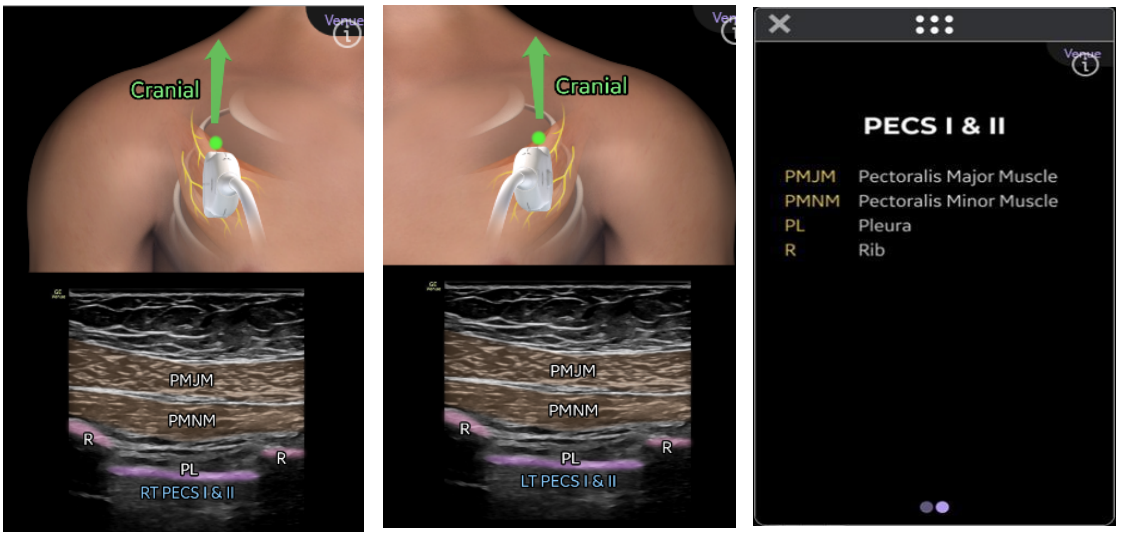
5. AXILLARY BRACHIAL PLEXUS



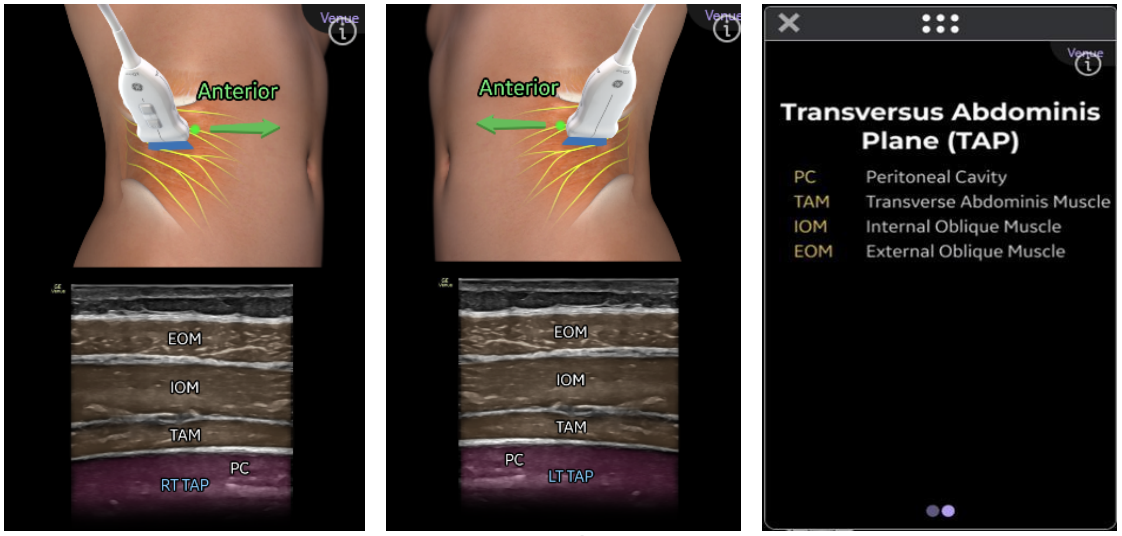




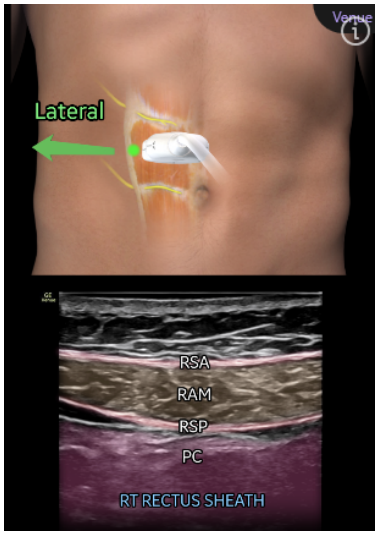
6. PECS I & II

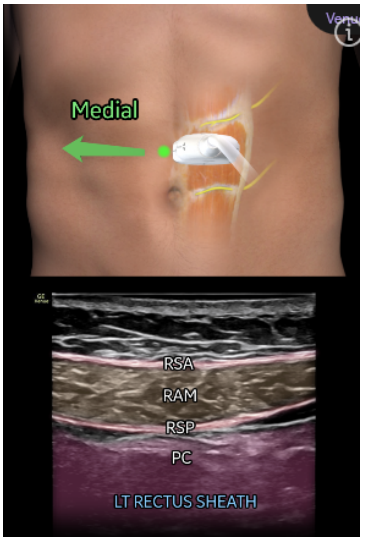


7. TRANSVERSUS ABDOMINIS PLANE (TAP)

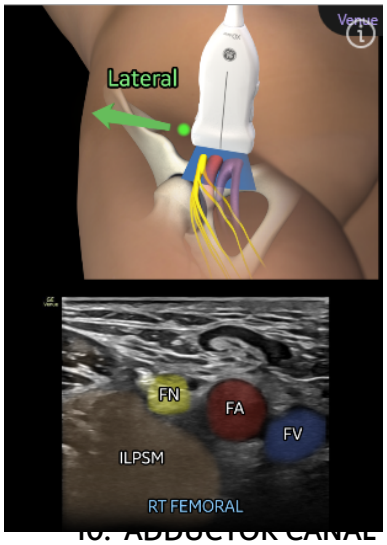


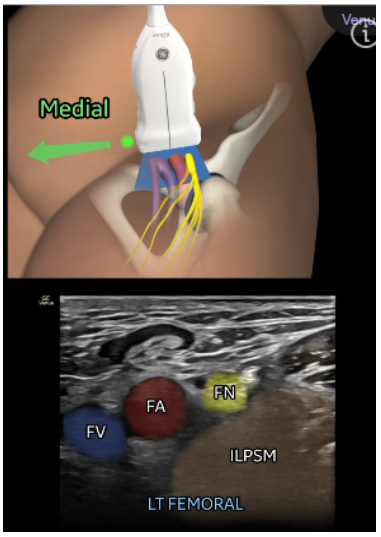
8. RECTUS SHEATH

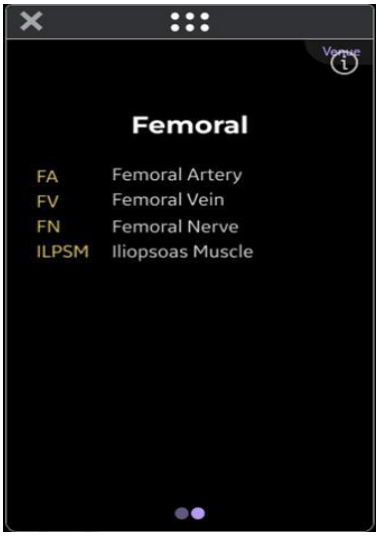




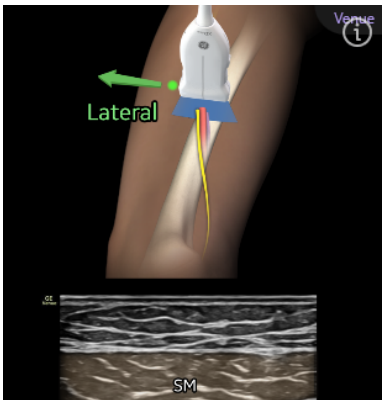
9. FEMORAL

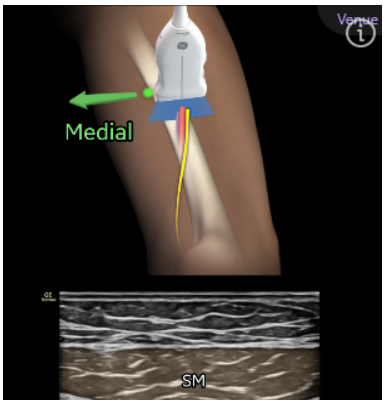




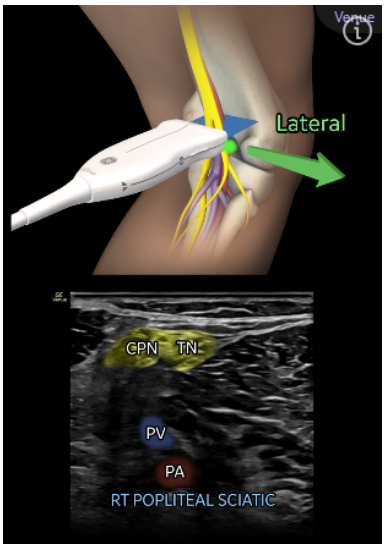


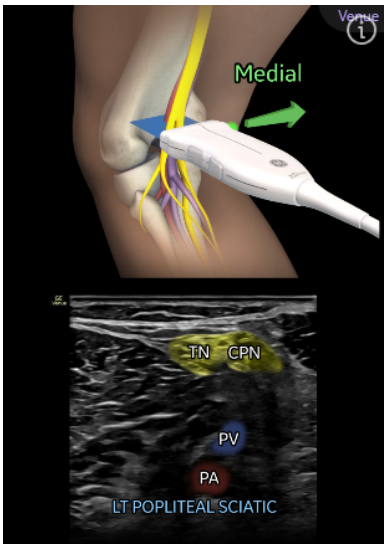
10. ADDUCTOR CANAL

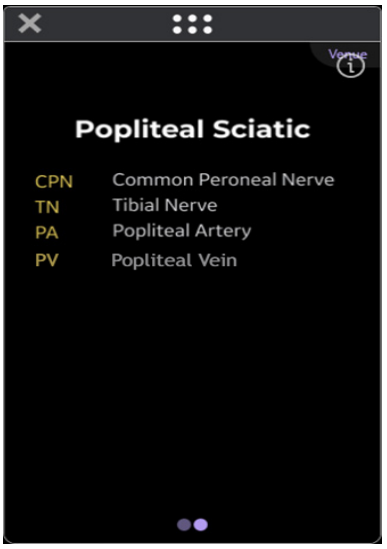




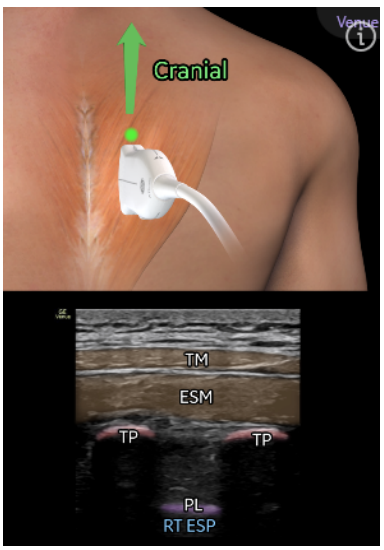
11. POPLITEAL SCIATIC

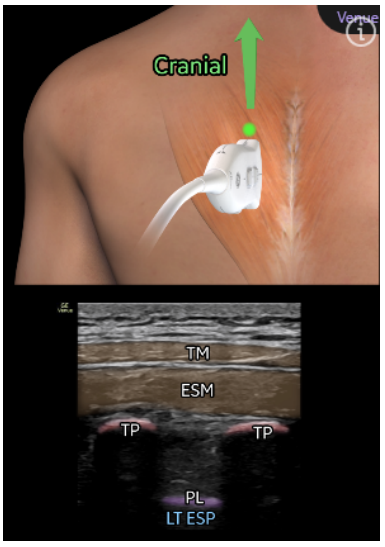






12. ERECTOR SPINAE PLANE (ESP)





APPENDIX B – SUPPORTED STRUCTURES

Ultrasound-Guided Regional Anesthesia Regions	Anatomical Structure	Anatomical Structure Acronym/Abbreviation
Interscalene Brachial Plexus	Brachial Plexus	BP
	Anterior Scalene Muscle	ASM
	Middle Scalene Muscle	MSM
	Sternocleidomastoid Muscle	SCM
Supraclavicular Brachial Plexus	First Rib	FR
	Pleura	PL
	Subclavian Artery	SA
	Brachial Plexus	BP
Infraclavicular Brachial Plexus	Pectoralis Major Muscle	PMJM
	Pectoralis Minor Muscle	PMNM
	Axillary Artery	AA
	Axillary Vein	AV
Cervical Plexus	Carotid Artery	CA
	Sternocleidomastoid Muscle	SCM
	Cervical Plexus	CP
	Jugular Vein	JV
Axillary Brachial Plexus	Axillary Artery	AA
	Musculocutaneous Nerve	MC
	Conjoint Tendon	CT
	Ulnar Nerve	UN
	Median Nerve	MN
	Radial Nerve	RN
PECS I & II	Pectoralis Major Muscle	PMJM
	Pectoralis Minor Muscle	PMNM
	Pleura	PL
	Rib	R
Transversus Abdominis Plane (TAP)	Transverse Abdominis Muscle	TAM
	Internal Oblique Muscle	IOM
	External Oblique Muscle	EOM

	Peritoneal Cavity	PC
Rectus Sheath	Rectus Abdominis Muscle	RAM
	Peritoneal Cavity	PC
	Rectus Sheath (Anterior Aspect)	RSA
	Rectus Sheath (Posterior Aspect)	RSP
Femoral	Femoral Vein	FV
	Femoral Nerve	FN
	Femoral Artery	FA
	Iliopsoas Muscle	ILPSM
Adductor Canal	Femoral Artery	FA
	Sartorius Muscle	SM
	Vastus Medialis Muscle	VMM
	Saphenous Nerve	SN
Popliteal Sciatic	Common Peroneal Nerve	CPN
	Tibial Nerve	TN
	Popliteal Artery	PA
	Popliteal Vein	PV
Erector Spinae Plane (ESP)	Trapezius Muscle	TM
	Erector Spinae Muscle	ESM
	Transverse Process	TP
	Pleura	PL