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Exploring the utility of assistive artificial intelligence for ultrasound scanning in regional anesthesia

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ABSTRACT

Introduction Ultrasound-guided regional anesthesia (UGRA) involves the acquisition and interpretation of ultrasound images to delineate sonoanatomy. This study explores the utility of a novel artificial intelligence (AI) device designed to assist in this task (ScanNav Anatomy Peripheral Nerve Block; ScanNav), which applies a color overlay on real-time ultrasound to highlight key anatomical structures.

Methods Thirty anesthesiologists, 15 non-experts and 15 experts in UGRA, performed 240 ultrasound scans across nine peripheral nerve block regions. Half were performed with ScanNav. After scanning each block region, participants completed a questionnaire on the utility of the device in relation to training, teaching, and clinical practice in ultrasound scanning for UGRA. Ultrasound and color overlay output were recorded from scans performed with ScanNav. Experts present during the scans (real-time experts) were asked to assess potential for increased risk associated with use of the device (eg, needle trauma to safety structures). This was compared with experts who viewed the AI scans remotely.

Results Non-experts were more likely to provide positive and less likely to provide negative feedback than experts ($p=0.001$). Positive feedback was provided most frequently by non-experts on the potential role for training (37/60, 61.7%); for experts, it was for its utility in teaching (30/60, 50%). Real-time and remote experts reported a potentially increased risk in 12/254 (4.7%) vs 8/254 (3.1%, $p=0.362$) scans, respectively.

Discussion ScanNav shows potential to support non-experts in training and clinical practice, and experts in teaching UGRA. Such technology may aid the uptake and generalizability of UGRA.

Trial registration number NCT04918693.

INTRODUCTION

The performance of ultrasound-guided regional anesthesia (UGRA) relies on the optimal acquisition and interpretation of ultrasound images.^{1–3} This skill is underpinned by knowledge of the underlying anatomy.^{4–5} However, even experienced anesthesiologists can find this challenging, particularly in the context of anatomical variation or other difficulties in scanning (eg, obesity).^{6–7} Furthermore, sonographic image interpretation is variable, even among experts.^{8–10} In the authors' experience, though ultrasound technology yields ever-greater image resolution, acumen in ultrasound image acquisition and interpretation has not demonstrated an equal

improvement since the introduction of ultrasound guidance in regional anesthesia in 1989.¹¹

The implementation of artificial intelligence (AI) in clinical practice continues to grow and regional anesthesia has potential to embrace this technology for patient benefit, such as supporting UGRA training and practice to increase patient access to these techniques, as well as improve patient safety.¹² Broadly speaking, AI includes any technique that enables computers to undertake tasks associated with human intelligence.¹² Common techniques in this field include machine learning (ML) and deep learning (DL). ML uses algorithms, rule-based problem-solving instructions implemented by the computer,¹² to learn: training data are analyzed to identify patterns (statistical correlations) in this information. If the algorithm is informed of the desired endpoints (eg, by labeling the images during the training stage) and then looks for correlations between the raw input data and the endpoints, this is called supervised ML. In unsupervised ML, the algorithm is given no instruction as to what endpoints are desired but looks for clusters of similarity in the dataset. Semisupervised ML uses a mixture of these two approaches. DL is a method of implementing ML. The algorithm encodes a network of artificial neurons (mathematical functions) which are arranged in layers. Successive layers of the network operate on the data as it is passed through the system, extracting progressively more information. DL is a common technique used in computer vision—a branch of AI which allows computers to interact with the visual world—a field that is readily applicable to medical image analysis.

ScanNav Anatomy Peripheral Nerve Block (ScanNav, formerly known as AnatomyGuide; Intelligent Ultrasound, Cardiff, UK) is an AI-based device that uses DL to apply a color overlay to real-time B-mode ultrasound.¹³ It highlights relevant anatomical structures on the ultrasound image, aiming to assist ultrasound image interpretation (see online supplemental files A–D). Expert evaluation of ultrasound videos have previously considered the color overlay to be helpful in identifying specific structures and confirming an appropriate block view in over 99% of cases.¹⁴ Similar systems include Nerveblox (Smart Alfa Teknoloji San. Ve Tic AS, Ankara, Turkey), which also applies a color overlay of anatomical structures on ultrasound in regions commonly scanned for UGRA,¹⁵ and NerveTrack (Samsung Medison, Seoul, South Korea), which applies a bounding box around the median and ulnar nerves when scanning the forearm.¹⁶



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Though highlighting accuracy data have been published for ScanNav and Nerveblox,^{14 15} there are limited data from real-world use of these systems—particularly on their utility for operators. We therefore aimed to assess the subjective utility of ScanNav as an aid to identifying relevant structures, teaching/learning UGRA scanning, and increasing operator confidence. We also assessed UGRA experts' perception of potential risks associated with the use of ScanNav, including increased risk of block failure or unwanted needle trauma to important safety structures (eg, nerves, arteries, and pleura/peritoneum).

METHODS

The study was registered with www.clinicaltrials.gov.

Non-expert participants (ultrasound scanners)

Fifteen non-experts in UGRA were recruited; US postgraduate year 2–4 medical doctors enrolled in the anesthesiology residency training program at OHSU.

Expert participants (ultrasound scanners/real-time assessors)

Fifteen experts in UGRA were recruited: US board-certified anesthesiologists and current or former anesthesiology faculty at OHSU. All were competent to perform UGRA independently and met at least two of the following three characteristics: completed fellowship training in UGRA, regularly delivered direct clinical care using UGRA (including for 'awake' surgery), and regularly taught UGRA in the course of their clinical work (including advanced techniques).

Remote expert assessors

Three remote experts were recruited to subsequently review ultrasound videos recorded when a subject was scanned using ScanNav (unmodified videos presented with videos to which the AI color overlay was applied). One was a UK-based consultant anesthetist and two were US-based attending anesthesiologists. All met the criteria defined previously (with the exception that one was a pediatric anesthesiologist, thus their conduct of 'awake' surgery is limited by their patient population). With the exception of one participant (GW, who is an author of this article and was not remunerated for work in this study), participants and remote expert assessors did not form part of the investigator group and were compensated for their time.

Subjects

Two healthy volunteers for ultrasound scanning were recruited from a professional modeling agency and compensated for their services. Half of the scans were performed on each subject. The only exclusion criterion was pathology of the areas to be scanned.

Equipment

Ultrasound scanning was performed using the X-Porte or PX SonoSite ultrasound machines (Fujifilm SonoSite, Bothell, Washington, USA). Participants were free to choose from a selection of compatible probes for each machine; X-Porte with HFL50xp/L38xp linear or C60xp curvilinear probe, or PX with L15-5/L12-3 linear or C5-1 curvilinear probe.

ScanNav (US V.1.0) was connected to the main ultrasound machine high-definition multimedia interface (HDMI) output. It displayed the same ultrasound image, with color overlay, on a secondary monitor (see [figure 1](#)). It is important to note that this device is not intended to replace clinician judgment and has been submitted to the US Food and Drug Administration for

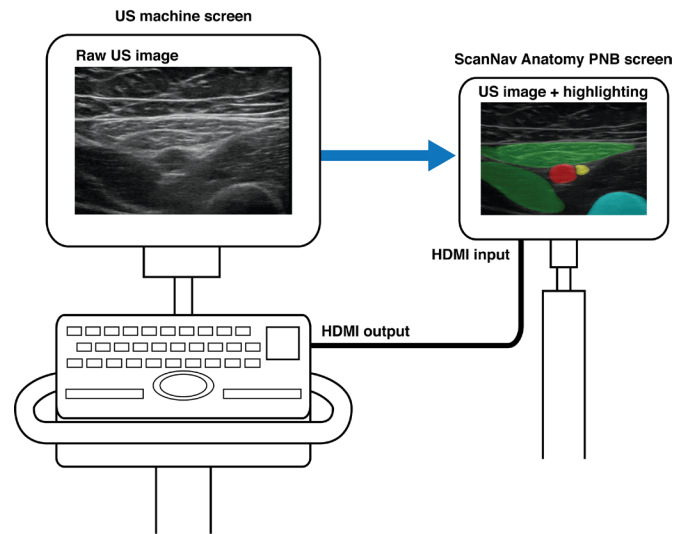


Figure 1 Schematic of ScanNav connected to an ultrasound machine, displaying the same ultrasound image with a color overlay. US, ultrasound.

regulatory approval as a scanning-only device (for use prior to needle insertion or local anesthetic injection).

Scanning protocol

After gaining informed consent (both scanners and subjects), ultrasound assessment was performed at the typical locations for nine peripheral nerve blocks. The upper limb included the interscalene-level, upper trunk-level, supraclavicular-level and axillary-level brachial plexus regions. The trunk included the erector spinae plane and rectus sheath plane block regions. Lower limb scanning included regions for the suprainguinal-level fascia iliaca plane, adductor canal and popliteal-level sciatic nerve blocks.

Participants were free to set the depth and gain settings deemed appropriate for each scan and use the scanning technique they would in their normal clinical practice. The first scan was performed by an expert and performed on both sides, once with the use of ScanNav and once without. Eight participants performed the first scan with the use of ScanNav and seven without (order alternating between participants). Subsequently, a non-expert participant entered the room and was asked to scan for the same block in the same subject, under the supervision of the expert. The expert taught and/or supported the non-expert, as necessary, to achieve an optimal block view. As before, both sides were scanned, once with the use of the AI color overlay and once without (order alternating as above). This same process of four scans was then repeated on the same subject, scanning for a different block. The expert/non-expert pair then repeated the scanning protocol on a second subject (the scanning sequence is summarized in online supplemental file E).

This process of 16 scans (8 by the expert and 8 by the non-expert) was performed by 15 expert/non-expert pairs (total 240 scans). All AI-assisted scans (n=120) were recorded for later analysis by remote experts.

Utility: experts versus non-experts

After scanning for each block, the participants were asked to complete a questionnaire evaluating the AI color overlay for the images acquired (n=120, half by non-experts and half by experts; questionnaires available in online supplemental file E).

Non-experts were asked to compare their experience of scanning with versus without ScanNav using the following metrics:

- ▶ Confidence in scanning (0–10: 0, low confidence; 10, confident).
- ▶ Identifying relevant anatomical structures on ultrasound (assisted, no difference, hindered).
- ▶ Identifying the correct view for the block (easier, no difference, harder).
- ▶ Learning scanning for the block (easier to learn, no difference, harder to learn)
- ▶ Facilitating training (beneficial, no difference, detrimental).
- ▶ Modify level of support required from your supervisor (less support required, no change, more support required)

Experts were similarly asked to compare their experience of scanning with versus without ScanNav:

- ▶ Confidence in their own scanning (0–10: 0, low confidence; 10, confident).
- ▶ Identifying relevant anatomical structures on ultrasound (assisted, no difference, hindered).
- ▶ Teaching scanning for the block (easier to teach, no difference, harder to teach).
- ▶ Supervising scanning for the block (beneficial, no difference, detrimental).
- ▶ Reduce the frequency of intervention during supervision of the non-expert (yes, no difference, no).
- ▶ Confidence in the non-expert's scanning ability (0–10: 0, low confidence; 10, confident).

Potential risks: real-time expert users versus remote experts

For each scan performed with ScanNav (n=120), experts were asked to report potential for increased risk of block failure or unwanted needle trauma to 'safety critical' structures as relevant to each block (eg, nerves, arteries, pleura, and peritoneum; see online supplemental file E). The risk of complications related to each structure included:

- ▶ Nerve injury/postoperative neurological symptoms (PONS, nerves).
- ▶ Local anesthetic systemic toxicity (LAST, arteries).
- ▶ Pneumothorax (pleura).
- ▶ Peritoneal violation (peritoneum).
- ▶ Block failure (overall).

The real-time expert assessment was compared with that of the panel of remote experts, who viewed the recorded ultrasound with the unmodified video presented adjacent to the AI-color overlay video. Three remote experts viewed each ultrasound video and a majority view for each question was taken. In cases where no majority was reached, this was classified as 'no consensus'.

Data analysis

Data were reported descriptively and, where appropriate, statistical evaluation (using R software V.4.1.1) was used to assess the relationship between variables. A χ^2 test was used to compare feedback (expert vs non-expert, real-time user vs remote expert, and subject 1 vs subject 2) except for participant confidence, which used a Mann-Whitney U test to compare ordinal data. Statistical significance was deemed as a p value of <0.05.

RESULTS

In total, 240 ultrasound scans were performed, 120 with ScanNav and 120 without. Of the 120 scans performed with the ScanNav, 60 were performed by non-experts in UGRA (under the supervision of experts) and 60 by experts. Both scan subjects were adult men; one was 34 years old with a body mass index

Table 1 Non-expert feedback on benefits (n=60 scans with ScanNav)

	Positive	Neutral	Negative
Identifying structures	31 (51.7%)	27 (45.0%)	2 (3.3%)
Acquisition of correct view	22 (36.7%)	37 (61.7%)	1 (1.7%)
Learning scan	36 (60.0%)	23 (38.3%)	1 (1.7%)
Helped training	37 (61.7%)	23 (38.3%)	0 (0%)
Supervisor support	8 (13.3%)	51 (85.0%)	1 (1.7%)
Confidence	31 (51.7%)	25 (41.7%)	4 (6.7%)
Overall (/360)	165 (45.8%)	186 (51.7%)	9 (2.5%)

(BMI) of 37.2 kg/m² and the other was 41 years old with a BMI of 28.9 kg/m². The data are summarized in tables 1–3 and a full breakdown is in online supplemental file E.

Utility: non-experts versus experts

Non-experts provided positive feedback more frequently and provided negative feedback less frequently than experts (p=0.001). The most frequent positive feedback provided by non-experts was on ScanNav's role in their training (37/60, 61.7%); for experts, it was for ScanNav's use in teaching (30/60, 50%). Overall, 70% of participants reported that ScanNav aided in the identification of key anatomical structures for a peripheral nerve block, and 63% believed that it assisted in confirming the correct ultrasound view during scanning. Non-experts' most frequent negative feedback was that it may decrease their confidence in scanning (4/60, 6.7%); for experts, it was that ScanNav may increase the frequency of supervisor intervention (10/60, 16.7%). Non-expert median confidence in their own scanning was 6 (IQR 5–8) without ScanNav and 7 (IQR 5.75–9) with ScanNav (p=0.07). Experts reported median confidence of 10 (IQR 8–10) vs 10 (IQR 8–10) respectively (p=0.57). When supervising a non-expert scanning, their median confidence in the non-expert's scanning was 7 (IQR 4.75–8) without ScanNav and 8 (IQR 4–9) with ScanNav (p=0.23). Overall, there was no difference in the reporting between subjects scanned (p=0.562).

Potential risks: real-time user expert versus remote expert

Of the 120 scans performed with ScanNav, real-time expert user data were collected on 103 scans (17 lost), and remote expert assessment was thus compared for the same 103 scans. Real-time and remote expert reported a potential increase in risk: 12/254 (4.7%) vs 8/254 (3.1%), respectively (p=0.362, table 3).

DISCUSSION

This study explores the potential role of assistive AI in the acquisition and interpretation of ultrasound scans for UGRA, with real-world users in a simulation setting. Positive sentiment

Table 2 Expert feedback on benefits (n=60 scans with ScanNav)

	Positive	Neutral	Negative
Identifying structures	15 (25.0%)	42 (70.0%)	3 (5.0%)
Teaching	30 (50.0%)	29 (48.3%)	1 (1.7%)
Supervising	27 (45.0%)	29 (48.3%)	4 (6.7%)
Frequency of intervention	16 (26.7%)	34 (56.7%)	10 (16.7%)
Confidence (own scanning)	(Increase) 14 (23.3%)	(No difference) 44 (73.3%)	(Decrease) 2 (3.3%)
Confidence (supervising non-expert)	(Increase) 29 (48.3%)	(No difference) 24 (40.0%)	(Decrease) 7 (11.7%)
Overall (/360)	131 (36.4%)	202 (56.1%)	27 (7.5%)

Table 3 Reported potential risks: real-time expert versus remote expert assessor (max n=103)

	Real-time expert	Remote expert
Nerve injury/PONS (/67)	5 (7.5%)	0 (0%)
LAST (/71)	3 (4.2%)	0 (0%)
Pneumothorax (/16)	0 (0%)	0 (0%)
Peritoneum violation (/8)	0 (0%)	0 (0%)
Block failure (/92)	4 (4.3%)	8 (8.7%)*
Total (/254)	12 (4.7%)	8 (3.1%)*

N.B. Despite 103 block feedback sheets return, not all feedback elements were completed by participants for all blocks (hence, n<103 for block failure).

*8/92 of all block views considered (7/8 of these views considered 'inadequate' by expert panel).

LAST, local anesthetic systemic toxicity; PONS, postoperative neurological symptoms.

(36.4%–45.8%) about ScanNav was reported by users more commonly than negative sentiment (2.5%–7.5%), while the majority (63%–70%) reported that it aided in the identification of key anatomical structures on ultrasound and in confirmation of the correct ultrasound view. Non-experts derived most benefit from ScanNav; $\geq 50\%$ reported it to aid in the identification of sonoanatomical structures, learning the scanning for a block, benefits to training and improving their confidence in scanning. These data suggest a role for ScanNav in the training of non-experts in UGRA. Training can be in the form of non-patient-facing activities such as formal teaching and educational courses. However, teaching during clinical practice plays a fundamental role in medical training. Thus, although it requires additional financial resources, ScanNav may be used for educational purposes in both settings, supporting widespread adoption of UGRA¹⁷ and patient access to these techniques.¹⁸

The areas receiving the highest frequency of negative feedback (frequency of supervisor intervention and decreasing confidence of performing/supervising ultrasound scanning) are perhaps unsurprising. This is a new medical device, based on AI technology with which many clinicians are unfamiliar, and the participants in this study had not used it prior to participating in this study. Initial use of any new technology may be associated with more frequent intervention and lower confidence, which may improve with time and increased familiarity with the device.

There was a low perception of increased risk associated with AI highlighting by ScanNav (3.1%–4.7%), though potential complications considered may be clinically important (eg, nerve injury/PONS and LAST). Potential causes of error include those related to device performance, such as incorrect highlighting, which may cause anesthesiologists to misinterpret the ultrasound image(s). Block failure or unwanted needle trauma to safety critical structures may therefore be more likely if the anesthesiologist is falsely reassured by the presence or absence of color on the screen. Others may be associated with use of the device, such as correct highlighting causing distraction by drawing focus away from other relevant structures. The current technology therefore provides additional information for the anesthesiologist rather than a decision-making system on ultrasound image interpretation (much as is the case for other image augmentation systems, eg, color Doppler). Furthermore, correct structure/block view identification alone does not ensure safe or effective UGRA nor does the device guide needle placement. It is therefore the practitioner's responsibility to identify hazards and undertake safe practice. The data show a more critical view of real-time users as compared with those viewing the video remotely. Real-time users have a richer source of information as they performed the dynamic scan; however,

they had to subsequently give their assessment from their memory of the preceding few minutes. Remote users had the benefit of scrolling back and forth through the video to carefully scrutinize the unmodified ultrasound video. In addition, three remote experts assessed each video compared with one real-time user expert. It is not possible to determine, with these limited data, whether one cohort or another is correct—but to be aware of the range of opinion and that more work must be done to explore this facet of the data. Nevertheless, a more cautious view adopted by real-time users is perhaps a welcome inadvertent safety feature, showing a desire to maintain the use of clinical judgment which has been developed over years of training.

This study has limitations. These data are subjective, based on a limited use of the device, and may not necessarily reflect clinical practice. Over time, clinical data may support or refute the conclusions drawn here and could include studies in other settings (eg, UGRA in the emergency department or prehospital emergency care). Outcome data, including patient outcomes and resource-use metrics, will be crucial in validating the clinical utility of ScanNav. This study included only 2 scan subjects and 30 anesthesiologist participants; these data may need to be replicated with a larger number of participants and subjects with different demographics, such as body habitus, comorbid status or anatomical abnormalities. Also, all participants were from a single institution, while UGRA practices and experiences may vary between institutions, regions or countries. In addition, a three-point scale was given for participants to provide their assessment, whereas a five-point scale may have allowed greater discrimination of subjective assessment. Finally, only two ultrasound machines were assessed; further work is required to ensure generalizability of these data.

CONCLUSION

The few studies conducted in this field so far report little in the way of contemporaneous feedback by users or evaluation of the clinical utility of AI devices to support ultrasound scanning in UGRA. We have demonstrated that ScanNav may support non-experts in their training and clinical practice, and experts in their teaching of UGRA. It may help by drawing attentional focus to the area of interest to aid in confirmation of the correct ultrasound view and the identification of sonoanatomical structures on that view. We believe that AI-augmented ultrasound scanning, through devices such as ScanNav, may support the uptake and generalizability of ultrasound-guided techniques in the future.

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Competing interests JSB is a Senior Clinical Advisor for Intelligent Ultrasound, receiving research funding and honoraria. KEB is an Editor for Anaesthesia and has received research, honoraria and educational funding from Fisher and Paykel Healthcare Ltd, GE Healthcare and Ambu. DBSL is a Clinical Advisor for Intelligent Ultrasound, receiving honoraria. JAN is a Senior Scientific Advisor for Intelligent Ultrasound.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and ethical approval was granted by the Oregon Health & Science University Institutional Review Board

(STUDY00022920). Participants gave informed consent to participate in the study before taking part.

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REFERENCES

- Woodworth GE, Carney PA, Cohen JM, *et al.* Development and validation of an assessment of regional anesthesia ultrasound interpretation skills. *Reg Anesth Pain Med* 2015;40:306–14.
- Sites BD, Chan VW, Neal JM, *et al.* The American Society of regional anesthesia and pain medicine and the European Society of regional anaesthesia and pain therapy joint Committee recommendations for education and training in ultrasound-guided regional anesthesia. *Reg Anesth Pain Med* 2009;34:40–6.
- Henderson M, Dolan J. Challenges, solutions, and advances in ultrasound-guided regional anaesthesia. *BJA Educ* 2016;16:374–80.
- Bowness J, Taylor A. Ultrasound-Guided regional anaesthesia: visualising the nerve and needle. *Adv Exp Med Biol* 2020;1235:19–34.
- Mariano ER, Marshall ZJ, Urman RD, *et al.* Ultrasound and its evolution in perioperative regional anesthesia and analgesia. *Best Pract Res Clin Anaesthesiol* 2014;28:29–39.
- Tremlett M. Final Fellowship of the Royal College of Anaesthetists (FRCA) Examination Chairman's Report (Academic Year September 2013 - July 2014): Review of the RCoA Final Exam 2013 - 2014;2014.
- Bowness J, Turnbull K, Taylor A, *et al.* Identifying the emergence of the superficial peroneal nerve through deep fascia on ultrasound and by dissection: implications for regional anesthesia in foot and ankle surgery. *Clin Anat* 2019;32:390–5.
- Williams L, Carrigan A, Auffermann W, *et al.* The invisible breast cancer: experience does not protect against inattention blindness to clinically relevant findings in radiology. *Psychon Bull Rev* 2021;28:503–11.
- Drew T, Vö ML-H, Wolfe JM. The invisible gorilla strikes again: sustained inattention blindness in expert observers. *Psychol Sci* 2013;24:1848–53.
- Bowness J, Turnbull K, Taylor A, *et al.* Identifying variant anatomy during ultrasound-guided regional anaesthesia: opportunities for clinical improvement. *Br J Anaesth* 2019;122:e75–7.
- Ting PL, Sivagnanaratnam V. Ultrasonographic study of the spread of local anaesthetic during axillary brachial plexus block. *Br J Anaesth* 1989;63:326–9.
- Bowness J, El-Boghdady K, Burckett-St Laurent D. Artificial intelligence for image interpretation in ultrasound-guided regional anaesthesia. *Anaesthesia* 2021;76:602–7.
- Bowness J, Macfarlane AJR, Noble JA. Anaesthesia, nerve blocks and artificial intelligence. *Anaesthesia News* 2021;408:4–6.
- Bowness J, Varsou O, Turbitt L, *et al.* Identifying anatomical structures on ultrasound: assistive artificial intelligence in ultrasound-guided regional anaesthesia. *Clin Anat* 2021;34): :802–9.
- Gungor I, Gunaydin B, Oktar SO, *et al.* A real-time anatomy identification via tool based on artificial intelligence for ultrasound-guided peripheral nerve block procedures: an accuracy study. *J Anesth* 2021;35:591–4.
- Soulton Brief. Available: <https://www.intel.com/content/dam/www/public/us/en/documents/solution-briefs/samsung-nervetrack-solution-brief.pdf> [Accessed 25 Dec 2021].
- Turbitt LR, Mariano ER, El-Boghdady K. Future directions in regional anaesthesia: not just for the cognoscenti. *Anaesthesia* 2020;75:293–7.
- Mudumbai SC, Auyong DB, Memtsoudis SG, *et al.* A pragmatic approach to evaluating new techniques in regional anesthesia and acute pain medicine. *Pain Manag* 2018;8:475–85.

Supplemental File

1 SCANNING TASKS, BLOCK ALLOCATION & STRUCTURES CONSIDERED

1.1 SCANNING TASKS PERFORMED

Scanning tasks were performed as per the table below (the order of scanning with/without ScanNav Anatomy PNB was alternated between participants).

BMI	Block	Task	Side	ScanNav Anatomy PNB	
Subject 1	Block 1	Expert	L	Yes	
			R		
		Expert + Non-expert	L	Yes	
			R		
	Block questionnaire				
	Block 2	Expert	L	Yes	
			R		
		Expert + Non-expert	L	Yes	
			R		
	Block questionnaire				
Subject 2	Block 1	Expert	L	Yes	
			R		
		Expert + Non-expert	L	Yes	
			R		
	Block questionnaire				
	Block 2	Expert	L	Yes	
			R		
		Expert + Non-expert	L	Yes	
			R		
	Block questionnaire				

1.2 BLOCK ALLOCATION

ScanNav Anatomy PNB supports anatomical structure identification for nine UGRA blocks. Study participant pairs (expert + non-expert) were assigned two blocks each in a pseudo-random manner, to provide coverage of supported blocks from the upper limb, trunk and lower limb.

Participant ID	Block 1	Block 2
E1/N1	Rectus sheath plane	Popliteal level sciatic nerve
E2/N2	Erector spinae plane	Sub-sartorial femoral triangle / Adductor canal
E3/N3	Superior trunk of brachial plexus	Sub-sartorial femoral triangle / Adductor canal
E4/N4	Rectus sheath plane	Sub-sartorial femoral triangle / Adductor canal
E5/N5	Popliteal level sciatic nerve	Axillary level brachial plexus
E6/N6	Suprainguinal fascia iliaca plane	Popliteal level sciatic nerve
E7/N6	Popliteal level sciatic nerve	Supraclavicular level brachial plexus
E8/N8	Interscalene level brachial plexus	Rectus sheath plane
E9/N9	Erector spinae plane	Axillary level brachial plexus
E10/N10	Popliteal level sciatic nerve	Suprainguinal fascia iliaca plane
E11/N11	Suprainguinal fascia iliaca plane	Sub-sartorial femoral triangle / Adductor canal
E12/N12	Erector spinae plane	Popliteal level sciatic nerve
E13/N13	Suprainguinal fascia iliaca plane	Sub-sartorial femoral triangle / Adductor canal
E14/N14	Interscalene level brachial plexus	Popliteal level sciatic nerve
E15/N15	Superior trunk of brachial plexus	Sub-sartorial femoral triangle / Adductor canal

A summary of ultrasound scans performed (by participant, with/without ScanNav Anatomy PNB, subject BMI and ultrasound machine) us shown below

Number of Ultrasound scans		Low BMI ($<30\text{kg/m}^2$)	High BMI ($\geq 30\text{kg/m}^2$)	SonoSite PX	SonoSite X-Porte
with ScanNav Anatomy PNB	120	60	60	60	60
captured by experts	60	30	30	30	30
captured by trainees	60	30	30	30	30
without ScanNav Anatomy PNB	120	60	60	60	60
captured by experts	60	30	30	30	30
captured by trainees	60	30	30	30	30
Total	240	120	120	120	120

1.3 SAFETY CRITICAL STRUCTURES

Following structures were considered as safety critical structures for each block:

Item	Anatomical Region	Safety critical anatomical structures
1)	Brachial plexus in the neck: -Interscalene -Superior trunk -Supraclavicular	<ul style="list-style-type: none"> • Brachial plexus nerves (roots, trunks, divisions) • Subclavian or carotid artery • Pleura
2)	Axillary level brachial plexus	<ul style="list-style-type: none"> • Radial, ulnar, median, and musculocutaneous nerves • Axillary artery
3)	Erector spinae plane	<ul style="list-style-type: none"> • Pleura • Transverse processes
4)	Rectus sheath plane	<ul style="list-style-type: none"> • Peritoneum • Fascial plane
5)	Suprainguinal fascia iliaca	<ul style="list-style-type: none"> • Deep circumflex iliac artery • Fascial plane
6)	Sub-sartorial femoral triangle / Adductor canal	<ul style="list-style-type: none"> • Femoral artery • Saphenous nerve
7)	Popliteal level sciatic nerve	<ul style="list-style-type: none"> • Sciatic nerve (or peroneal/fibular and tibial nerve components) • Popliteal artery



Expert questionnaire results are presented below:

Participant ID	Block	Model ID	BMI	BP-1	BP-2	BP-3	BP-4	BP-5	BP-6	BP-7	BP-8
E1	Pop	2	High	10	10	B	B	B	B	5	3
E1	Pop	3	Low	10	10	B	B	C	C	6	4
E1	RS	2	High	10	10	B	B	B	C	10	4
E1	RS	3	Low	10	10	B	B	B	C	10	10
E2	Add	2	High	10	10	B	C	C	B	2	2
E2	Add	3	Low	10	10	B	B	B	B	2	2
E2	ESP	2	High	10	10	B	A	A	B	2	2
E2	ESP	3	Low	10	10	B	B	B	B	1	1
E3	Add	2	High	10	10	B	B	B	B	10	10
E3	Add	3	Low	10	10	B	B	B	B	10	10
E3	ST	2	High	8	8	A	A	A	B	3	4
E3	ST	3	Low	5	5	B	B	B	B	5	5
E4	Add	2	High	10	10	B	B	B	B	8	8
E4	Add	3	Low	10	10	B	B	B	B	9	9
E4	RS	2	High	10	10	B	B	B	B	8	8
E4	RS	3	Low	10	10	B	B	B	B	9	9
E5	Ax	2	High	10	8	C	B	C	B	8	7
E5	Ax	3	Low	10	10	C	B	C	C	9	8
E5	Pop	2	High	10	8	C	B	B	C	9	8
E5	Pop	3	Low	10	10	A	A	A	C	9	9
E6	Pop	2	High	10	10	B	B	B	C	10	10
E6	Pop	3	Low	9	9	B	B	B	B	8	6
E6	SFIC	2	High	10	10	B	A	A	B	8	8
E6	SFIC	3	Low	7	10	B	B	B	B	4	7
E7	Pop	2	High	10	10	B	A	A	B	8	10
E7	Pop	3	Low	10	10	B	B	B	B	9	10
E7	SC	2	High	10	10	B	A	B	B	10	10
E7	SC	3	Low	10	10	B	A	A	C	8	9
E8	IS	2	High	8	8	B	B	B	C	2	2
E8	IS	3	Low	7	7	B	B	A	B	2	4
E8	RS	2	High	6	6	B	A	B	A	2	4
E8	RS	3	Low	7	8	A	A	A	C	4	4
E9	Ax	3	Low	9	9	B	A	A	A	7	9
E9	Ax	2	High	9	9	B	A	A	B	6	8
E9	ESP	2	High	3	4	B	B	B	B	3	3
E9	ESP	3	Low	9	10	A	A	A	A	8	9
E10	Pop	2	High	9	9	B	B	B	B	9	9
E10	Pop	3	Low	9	9	B	B	A	B	8	8
E10	SFIC	2	High	7	8	A	A	A	B	7	8
E10	SFIC	3	Low	8	9	A	A	B	A	8	9



Participant ID	Block	Model ID	BMI	BP-1	BP-2	BP-3	BP-4	BP-5	BP-6	BP-7	BP-8
E11	Add	2	High	7	8	A	A	B	A	6	8
E11	Add	3	Low	6	8	A	A	B	A	6	8
E11	SFIC	2	High	7	8	A	A	A	B	6	8
E11	SFIC	3	Low	7	8	A	A	A	A	6	8
E13	Add	2	High	10	10	B	A	A	A	7	8
E13	Add	3	Low	10	10	B	B	B	B	7	7
E12	ESP	2	High	6	7	A	A	A	A	5	6
E12	ESP	3	Low	7	9	A	A	A	A	6	8
E12	Pop	2	High	9	10	A	A	A	A	8	9
E12	Pop	3	Low	9	10	A	A	A	A	9	10
E13	SFIC	2	High	8	8	B	A	A	A	8	8
E13	SFIC	3	Low	10	10	B	B	B	B	7	7
E14	IS	2	High	10	10	B	A	A	B	6	8
E14	IS	3	Low	10	10	B	B	A	A	7	8
E14	Pop	2	High	10	10	B	A	A	A	7	8
E14	Pop	3	Low	10	10	B	B	A	A	7	8
E15	Add	2	High	10	10	B	A	A	B	1	4
E15	Add	3	Low	10	10	B	A	B	B	2	4
E15	ST	2	High	10	10	A	A	A	B	1	2
E15	ST	3	Low	10	10	B	A	B	B	1	2

Benefit	Study Questions		Results	
			Positive or Neutral Response	Negative response
Improving in operator confidence to achieve optimum view	BP-1 On a scale of 0 to 10 for this block, how would you rate your scanning confidence on this subject WITHOUT ScanNav Anatomy PNB BP-2 On a scale of 0 to 10 for this block, how would you rate your scanning confidence on this subject WITH ScanNav Anatomy PNB	0-10 scale, 0 being no confidence, 10 being totally confident. Change in confidence is calculated as a difference between two confidence scores with and without device.	In 97% (n=58) cases device either increased or did not change participant confidence levels	In 3% (n=2) cases device decreased participant confidence levels
identification of anatomical structures obtaining the correct ultrasound view of the anatomy prior to needle insertion	BP-3 When identifying the relevant anatomical structures for this block on ultrasound, ScanNav Anatomy PNB	A. Assisted/helped you B. Made no difference C. Hindered you/made it harder	In 95% (n=57) cases device either assisted or made no difference to user	In 5% (n=3) cases device hindered the user
supervision and training in anatomical structure identification for UGRA scanning	BP-4 When teaching the scanning for this block, ScanNav Anatomy PNB made it	A. Easier to teach B. No difference C. Harder to teach	In 98% (n=59) cases device made it either easier or made no difference in teaching blocks	In 2% (n=1) cases device hindered teaching
supervision and training in anatomical structure identification for UGRA scanning	BP-5 When supervising the trainee on this block, ScanNav Anatomy PNB	A. Was beneficial to you B. Made no difference C. Was detrimental to/hindered your teaching	In 93% (n=56) cases device was beneficial or made no difference when supervising trainee	In 7% (n=4) cases device did not assist when supervising trainee
supervision and training in anatomical structure identification for UGRA scanning	BP-6 ScanNav Anatomy PNB reduced the frequency of interventions you needed to supervise the trainee effectively	A. Yes B. No difference C. No	In 83% (n=50) cases device either reduced or made no difference in frequency of interventions	In 17% (n=10) device did not reduce the frequency of interventions
Improving in operator confidence to achieve optimum view (Trainee scanning) supervision and training in anatomical structure identification for UGRA scanning	BP-7 On a scale of 0 to 10, how confident were you in the trainee's scanning ability WITHOUT ScanNav Anatomy PNB BP-8 On a scale of 0 to 10, how confident were you in the trainee's scanning ability WITH ScanNav Anatomy PNB	0-10 scale, 0 being no confidence, 10 being totally confident. Change in confidence is calculated as a difference between two confidence scores with and without device.	In 88% (n=53) cases device either increased or did not change confidence levels in trainees	In 12% (n=7) cases device decreased confidence levels in trainees

1.4.1 Change in expert confidence (Question BP-1 and BP-2)

Mean confidence in expert scanning without using ScanNav Anatomy PNB was 8.93/10 compared to 9.17/10 when using ScanNav Anatomy PNB.

23% (n=14) of responses to the User Confidence question indicated that block scanning confidence increased when scanning with ScanNav Anatomy PNB. Most participants reported a 1-point improvement, with 1 participant reporting a 3-point improvement (from 7 to 10) when scanning with Anatomy PNB for the SIFIB block. The other 73% (n=44) of responses reported no difference in confidence. In over half of the responses (58%, n=35), participants identified their scanning confidence without device as "10" (the maximum) for the assigned block, making further improvement impossible.

3% (n=2) of responses reported decrease in confidence by 2 points. These responses came from the same participant (E5) for Axillary and Popliteal block, reporting a 2-point decrease in confidence from 10 to 8 points on a high BMI model.

1.4.2 Identification of structures (Question BP-3)

25% (n=15) of responses indicated that the device assisted or helped the participant when identifying the relevant anatomical structures for the block, while 70% (n=42) reported that device made no difference when identifying structures.

5% (n=3) of responses reported that the device hindered or made it harder to identify anatomical structures.

1.4.3 Teaching scanning for UGRA (Question BP-4)

50% (n=30) of responses indicated that the device made it easier to teach scanning for the given block, while 48% (n=29) reported that the device assistance made no difference.

1 participant (E2) reported that they found it harder to teach. This was in high BMI model (adductor block). Participant E2 reported that the device made no difference in teaching for the adductor or ESP blocks in the low BMI model, but that it did assist in teaching for the ESP in the high BMI model.

1.4.4 Supervision of UGRA procedures (Question BP-5)

45% (n=27) of responses indicated that when supervising the trainee, the device was beneficial to the participant, while 48% (n=29) reported that the device assistance made no difference.

7% (n=4) of responses indicated that the device was either detrimental or hindered their supervision of trainee for the given block. One response was obtained from participant E1 on the low BMI model (popliteal block), and participant E2 on the high BMI model (adductor block). The other 2 negative responses were obtained from the same participant E5, on both low and high BMI models (axillary blocks).

1.4.5 Frequency of interventions by supervisor (Question BP-6)

27% (n=16) of responses indicated that device reduced the frequency of interventions when supervising the trainee. 57% (n=34) reported that the device made no difference, and 17% (n=10) reported that ScanNav Anatomy PNB did not reduce the frequency of interventions.

Out of 10 responses that reported the device did not reduce the frequency of interventions, both participants E1 and E5 responded in this manner 3 times each. Remaining responses were from E6, E7 and twice from E8. Four of responses were for each popliteal and rectus blocks.



1.4.6 Change of expert confidence in (when supervising) trainee (Question BP-7 and BP-8)

The mean score of expert confidence in trainee scanning was 6.32/10 without the use of ScanNav Anatomy PNB and 6.82 with.

48% (n=29) of responses indicated that their confidence in the trainee increased when the trainee was scanning with the device. Most of these participants reported a 1 to 2-point improvement in confidence, while 2 of the 29 reported a 3-point improvement (adductor and SFIC blocks). 40% (n=24) of participant responses indicated that device did not affect trainee confidence.

12% (n=7) of responses indicated a decrease in trainee confidence. Participant E1 made 3 observations that their trainee's confidence was decreased (rectus sheath and popliteal blocks). Participant E5 made 3 observations that their trainee's confidence was decreased (axillary and popliteal blocks). Participant E6 made one observation that their trainee's confidence reduced when using the device (popliteal block). In 6 of these instances, the decrease in confidence was 1-2 points. In one instance, participant E1 reported a 6-point reduction in trainee confidence (from 10 to 4) when scanning for the rectus sheath block on the high BMI model.

1.4.7 Analysis of positive responses to questionnaire

A total of 360 expert responses to the Benefit Questionnaire were analysed. 36.4% (131/360) of responses were positive. 92.5% (333/360) of responses were either positive or neutral.

Participant ID	Number of positive responses						Total
	BP-3	BP-4	BP-5	BP-6	Participant confidence	Trainee confidence	
E1	0	0	0	0	0	0	0
E2	0	1	1	0	0	0	2
E3	1	1	1	0	0	1	4
E4	0	0	0	0	0	0	0
E5	1	1	1	0	0	0	3
E6	0	1	1	0	1	1	4
E7	0	3	2	0	0	3	8
E8	1	2	2	1	1	2	9
E9	1	3	3	2	2	3	14
E10	2	2	2	1	2	2	11
E11	4	4	2	3	4	4	21
E12	4	4	4	4	4	4	24
E13	0	2	2	2	0	1	7
E14	0	2	4	3	0	4	13
E15	1	4	2	0	0	4	11
Total	15	30	27	16	14	29	131

Experts



The majority of expert participants (13/15) contributed to the positive feedback about the device. Participant E12 provided maximum number of possible positive responses (24/24), while on average each participant providing positive feedback provided approximately 10 responses out of 24 possible opportunities (on average 40%).

BMI

Of the 131 positive responses (out of 360), 48% (63/131) positive responses were related to scans taken on a high BMI model and 52% (68/131) responses were related to scans taken on a low BMI model.

Block

Most positive responses were related to the Axillary and Interscalene blocks (approximately 20% of positive responses each), followed by the Popliteal (16%, 21/131 positive responses) and Adductor blocks (14.5%, 19/131 positive responses).

BLOCK	COUNT OF POSITIVE RESPONSES	PERCENT
INTERSCALENE	28	21.4%
AXILLARY	27	20.6%
POPLITEAL	21	16.0%
ADDUCTOR	19	14.5%
SUPRACLAVICULAR	10	7.6%
RECTUS SHEATH	8	6.1%
ESP	7	5.3%
SFIC	7	5.3%
SUPERIOR TRUNK	4	3.1%
TOTAL	131	

1.4.8 Analysis of negative responses to benefit questionnaire

A total of 360 participant responses to Benefit Questionnaire were analysed. 7.5% (27/360 responses) were negative.

Participant ID	Number of negative responses						Total
	BP-3	BP-4	BP-5	BP-6	Participant confidence	Trainee confidence	
E1	0	0	1	3	0	3	7
E2	0	1	1	0	0	0	2
E3	0	0	0	0	0	0	0
E4	0	0	0	0	0	0	0
E5	3	0	2	3	3	2	13
E6	0	0	0	1	0	1	2
E7	0	0	0	1	0	0	1
E8	0	0	0	2	0	0	2
E9	0	0	0	0	0	0	0
E10	0	0	0	0	0	0	0
E11	0	0	0	0	0	0	0



E12	0	0	0	0	0	0	0
E13	0	0	0	0	0	0	0
E14	0	0	0	0	0	0	0
E15	0	0	0	0	0	0	0
Total	3	1	4	10	3	6	27

Experts

Six experts (6/15) contributed to the negative feedback. Almost half (48%, n=13) of negative responses were provided by single participant E5, while approximately quarter (26%, n=7) of negative responses were provided by participant E1. The remaining quarter (26% n=7) of issues were reported by another 4 different participants.

BMI

16 negative responses were related to scans taken on a High BMI model and 11 responses were related to scan taken on a Low BMI model.

Block

41% (n=11) of negative responses were related to the popliteal block and 30% (n=8) responses were related to the axillary block. The remaining 8 negative responses were related to either rectus sheath, adductor, interscalene or supraclavicular blocks. The popliteal block was assigned to both E1 and E5 participants who contributed to most of the negative feedback collected. All the negative feedback regarding the axillary block was received from participant E5.

BLOCK	COUNT OF NEGATIVE RESPONSES	PERCENT
POPLITEAL	11	40.7
AXILLARY	8	29.6
RECTUS SHEATH	4	14.8
ADDUCTOR	2	7.4
INTERSCALENE	1	3.7
SUPRACLAVICULAR	1	3.7



Participant ID	Block	Model ID	BMI	BP-9	BP-10	BP-11	BP-12	BP-13	BP-14	BP-15	BP-16
T1	Pop	2	High	0	5	5	B	B	B	B	B
T1	Pop	3	Low	10-20	5	5	A	B	B	B	B
T1	RS	2	High	0	1	4	A	A	A	A	B
T1	RS	3	Low	0	5	5	A	B	A	A	B
T2	Add	2	High	10	7	6	A	C	A	B	A
T2	Add	3	Low	10	7	7	A	B	B	A	B
T2	Esp	2	High	0	7	9	A	A	B	A	A
T2	Esp	3	Low	0	6	6	B	A	B	A	B
T3	Add	2	High	2	3	2	C	B	B	B	B
T3	Add	3	Low	2	4	3	C	B	C	B	B
T3	ST	2	High	0	2	2	B	B	B	B	B
T3	ST	3	Low	2	2	2	B	B	B	B	B
T4	Add	2	High	50	10	10	B	B	A	A	B
T4	Add	3	Low	50	10	10	B	B	A	B	B
T4	RS	2	High	<10	10	10	B	B	B	B	B
T4	RS	3	Low	<10	9	10	B	B	A	A	B
T5	AX	2	High	5	6	6	B	B	A	A	B
T5	AX	3	Low	5	6	6	B	B	A	A	B
T5	Pop	2	High	20	7	7	B	B	A	B	B
T5	Pop	3	Low	20	6	8	A	A	A	A	C
T6	Pop	2	High	>30	10	10	B	B	B	B	B
T6	Pop	3	Low	>30	8	8	B	B	B	B	B
T6	SFIC	2	High	0	3	5	A	A	A	A	B
T6	SFIC	3	Low	0	1	2	B	B	B	B	B
T7	Pop	2	High	0	6	7	A	B	A	A	B
T7	Pop	3	Low	1	6	7	A	B	A	A	B
T7	SC	2	High	0	6	7	A	A	A	A	B
T7	SC	3	Low	0	6	7	A	B	A	A	B
T8	IS	2	High	0	3	7	B	A	A	A	B
T8	IS	3	Low	0	4	8	A	A	A	A	A
T8	RS	2	High	0	8	9	B	B	A	A	A
T8	RS	3	Low	0	7	9	A	A	A	A	A
T9	Ax	2	High	5	7	8	A	A	A	A	B
T9	AX	3	Low	5	7	8	A	A	A	A	B
T9	Esp	2	High	0	2	3	A	A	A	A	B
T9	Esp	3	Low	0	5	8	A	A	A	A	B
T10	Pop	2	High	20-30	7	7	B	B	B	B	B
T10	Pop	3	Low	20-30	9	9	A	A	B	B	B
T10	SFIC	2	High	3-4	5	6	A	A	A	A	B
T10	SFIC	3	Low	3-4	7	8	A	A	A	A	B
T11	Add	2	High	50	10	10	B	B	B	A	A



Participant ID	Block	Model ID	BMI	BP-9	BP-10	BP-11	BP-12	BP-13	BP-14	BP-15	BP-16
T11	Add	3	Low	50	10	10	B	B	B	B	B
T11	SFIC	2	High	5	8	9	A	A	A	A	A
T11	SFIC	3	Low	5	10	10	B	B	A	A	A
T12	Esp	2	High	2	6	5	B	B	B	B	B
T12	Esp	3	Low	3	9	9	B	B	B	B	B
T12	Pop	2	High	15	8	8	A	A	B	A	B
T12	Pop	3	Low	15	9	9	B	B	B	B	B
T13	Add	2	High	2	4	6	A	B	A	A	B
T13	Add	3	Low	2	5	6	A	A	A	A	B
T13	SFIC	2	High	0	2	3	B	B	B	B	B
T13	SFIC	3	Low	0	3	4	B	B	B	B	B
T14	IS	2	High	10	5	7	A	B	A	A	B
T14	IS	3	Low	10	7	9	A	A	A	A	B
T14	Pop	2	High	15	8	9	A	B	A	A	B
T14	Pop	3	Low	15	8	9	B	B	A	B	B
T15	Add	2	High	0	5	7	A	A	A	A	B
T15	Add	3	Low	0	8	8	B	B	A	B	B
T15	ST	2	High	0	5	5	A	B	A	A	B
T15	ST	3	Low	0	5	6	A	A	B	A	B

Benefit	Study Questions		Results	
			Positive or Neutral Response	Negative response
Improving in operator confidence to achieve optimum view	BP-10 On a scale of 0 to 10 for this block, how would you rate your scanning confidence on this subject WITHOUT ScanNav Anatomy PNB BP-11 On a scale of 0 to 10 for this block, how would you rate your scanning confidence on this subject WITH ScanNav Anatomy PNB	0-10 scale, 0 being no confidence, 10 being totally confident. Change in confidence is calculated as a difference between two confidence scores with and without device.	In 93% (n=56) cases device either increased or did not change trainee confidence levels	In 7% (n=4) cases device decreased trainee confidence levels
Identification of anatomical structures Obtaining the correct ultrasound view of the anatomy prior to needle insertion	BP-12 When identifying the relevant anatomical structures for this block on ultrasound, ScanNav Anatomy PNB:	A. Assisted/helped you B. Made no difference C. Hindered you/made it harder	In 97% (n=58) cases device either assisted or made no difference to trainee	In 3% (n=2) cases device hindered the trainee
Obtaining the correct ultrasound view of the anatomy prior to needle insertion	BP-13 When acquiring the correct ultrasound view for this block, did ScanNav Anatomy PNB:	A. Assisted/helped you B. Made no difference C. Hindered you/made it harder	In 98% (n=59) cases device made it either easier or made no difference in finding the correct view	In 2% (n=1) cases device hindered finding the correct view
Supervision and training in anatomical structure identification for UGRA scanning	BP-14 When learning scanning for this block, ScanNav Anatomy PNB made it:	A. Easier to learn B. No difference C. Harder to learn	In 98% (n=59) cases device was beneficial or made no difference when learning how to scan	In 2% (n=1) cases device made it harder when learning how to scan
Supervision and training in anatomical structure identification for UGRA scanning	BP-15 When scanning for this block, ScanNav Anatomy PNB:	A. Was beneficial for/helped your training B. Made no difference to your training C. Was detrimental to/hindered your training	In 100% (n=60) cases device was either beneficial or made no difference in trainees training to scan	In no cases did the device hindered trainees training
Supervision and training in anatomical structure identification for UGRA scanning	BP-16 While using ScanNav Anatomy PNB for this block I required:	A. Less support from my supervisor B. The same amount of support from my supervisor C. More support from my supervisor	In 98% (n=59) cases device either increased or did not change confidence levels in trainees	In 2% (n=1) cases device decreased confidence levels in trainees

Table 1: Summary of benefit questionnaire results (trainees)

1.5.1 Trainee prior experience in scanning blocks (Question BP-9)

38% (n=23) of trainee responses indicated that they have never performed their assigned block before. All other trainees who participated in this study have previously performed the assigned block between 1 and 50 times.

1.5.2 Change in trainee confidence (Question BP-10 and BP-11)

Mean confidence in trainees scanning without using ScanNav Anatomy PNB was 6.17/10 compared to 6.92/10 when using ScanNav Anatomy PNB.

52% (n=31) of responses indicated that the trainees self-perceived confidence increased when scanning with the device for the block. Most trainees reported a 1-point improvement, whilst 1 trainee reported a 4-point improvement when scanning for interscalene block with the device (on both low and high BMI models). The remaining responses (42%, n=25) reported no difference in confidence.

7% (n=4) of responses reported a decrease in confidence by 1 point. Two of the responses were from trainee T3 scanning an adductor block on both low and high BMI model. The other two responses were recorded from trainees T2 and T12 who scanned ESP and adductor models on the high BMI model.

1.5.3 Identification of structures (Question BP-12)

52% (n=31) of responses indicated that the device assisted or helped the trainee when identifying the relevant anatomical structures for the block, while 45% (n=27) reported that device made no difference.

3% (n=2) responses reported that device hindered or made it harder to identify anatomical structures. All such responses were obtained from trainee T3, while scanning low and high BMI model for the adductor block.

1.5.4 Finding correct view (Question BP-13)

37% (n=22) of responses indicated that the device assisted the trainee to find the correct ultrasound view for the assigned block, while 62% (n=37) of responses reported that the device assistance made no difference.

1 trainee (T2) reported that they found the device hindered them when finding the correct view, during an adductor block scan on High BMI model.

1.5.5 Learning to scan for the block (Question BP-14)

60% (n=36) of trainee responses indicated that the device made it easier to learn how to scan for the given block, while 38% (n=23) reported that the device assistance made no difference.

2% (n=1) responses indicated that the device made it harder to learn how to scan for the given block. This response was obtained from participant T3 for the Adductor block on the low BMI model.

1.5.6 Helped training (Question BP-15)

62% (n=37) of trainee responses indicated that device was beneficial or helped their training, while 38% (n=23) reported that the device made no difference.

No participants reported that device was detrimental or hindered their training.

1.5.7 Supervisor support (Question BP-16)

A majority of trainees responses (85%, n=51) indicated that they required the same amount of support from their supervisor while using the device. Some trainees (13%, n=8) indicated that they required less



support and one trainee T5 responded that they required more support from their supervisor when scanning the Popliteal block on low BMI model with the device.

1.5.8 Analysis of positive response to Benefit Questionnaire

A total of 360 participant responses to the Benefit Questionnaire were analysed. 45.8% (165/360) of responses were positive. 97.5% (351/360) of responses were either positive or neutral.

Participant ID	Number of positive responses						Trainee confidence	Total
	BP-12	BP-13	BP-14	BP-15	BP-16			
T1	3	1	2	2	0	1	9	
T2	3	2	1	3	2	1	12	
T3	0	0	0	0	0	0	0	
T4	0	0	3	2	0	1	6	
T5	1	1	4	3	0	1	10	
T6	1	1	1	1	0	2	6	
T7	4	1	4	4	0	4	17	
T8	2	3	4	4	3	4	20	
T9	4	4	4	4	0	4	20	
T10	3	3	2	2	0	2	12	
T11	1	1	2	3	3	1	11	
T12	1	1	0	1	0	0	3	
T13	2	1	2	2	0	4	11	
T14	3	1	4	3	0	4	15	
T15	3	2	3	3	0	2	13	
Total	31	22	36	37	8	31	165	

Non-experts

Fourteen (of 15) non-expert participants contributed positive feedback. Participants T8 and T9 provided most positive responses (20/24), while on average each participant who did provide positive feedback provided approximately 12 positive responses out of 24 (on average 50%).

BMI

Of the 165 positive responses (out of 360), 53% (87/165) positive responses were related to scans taken on a High BMI model and 47% (78/165) responses were related to scans taken on a Low BMI model.

Block

Most positive responses were equally split between SFIC, Popliteal and Adductor blocks (approx. 16% of positive responses each).

BLOCK	COUNT OF POSITIVE RESPONSES	PERCENT
SFIC	27	16.4%
POPLITEAL	26	15.8%
ADDUCTOR	25	15.2%



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RECTUS SHEATH	21	12.7%
INTERSCALENE	19	11.5%
ESP	17	10.3%
AXILLARY	14	8.5%
SUPRACLAVICULAR	9	5.5%
SUPERIOR TRUNK	7	4.2%
TOTAL	165	

1.5.9 Analysis of negative responses to Benefit Questionnaire

A total of 360 trainee responses to the Benefit Questionnaire were analysed. 2.5% (9/360 responses) were negative.



Trainee ID	Number of negative responses					Trainee confidence	Total
	BP-12	BP-13	BP-14	BP-15	BP-16		
T1	0	0	0	0	0	0	0
T2	0	1	0	0	0	1	2
T3	2	0	1	0	0	2	5
T4	0	0	0	0	0	0	0
T5	0	0	0	0	1	0	1
T6	0	0	0	0	0	0	0
T7	0	0	0	0	0	0	0
T8	0	0	0	0	0	0	0
T9	0	0	0	0	0	0	0
T10	0	0	0	0	0	0	0
T11	0	0	0	0	0	0	0
T12	0	0	0	0	0	1	1
T13	0	0	0	0	0	0	0
T14	0	0	0	0	0	0	0
T15	0	0	0	0	0	0	0
Total	2	1	1	0	1	4	9

Non-experts

Four participants (4/15) contributed to the negative feedback. Over half (n=5) negative issues were reported by a single trainee T3, while the remaining issues (n=4) were reported by different 3 trainees.

TRAINEE ID	COUNT	PERCENT
T3	5	56%
T2	2	22%
T12	1	11%
T5	1	11%
TOTAL	9	100%

BMI

4 negative responses were related to High BMI and 5 responses were related to Low BMI. There does not seem to be an effect or relationship between negative feedback and BMI. The upper bound of BMI from the volunteer models that took part in the study is 40 kg/m².



Block

78.5% (n=7) negative responses were related to the adductor block while the remaining 2 responses related to the ESP and popliteal blocks.

The adductor block was assigned to both T2 and T3 who contributed to most of negative feedback in this questionnaire.

BLOCK	NO. OF NEGATIVE COMMENTS	PERCENT
ADDUCTOR	7	77.8%
AXILLARY	0	0%
ESP	1	11.1%
INTERSCALENE	0	0%
POPLITEAL	1	11.1%
RECTUS SHEATH	0	0%
SFIC	0	0%
SUPRACLAVICULAR	0	0%
SUPERIOR TRUNK	0	0%
TOTAL	9	100%



1.6 SAFETY PERFORMANCE EVALUATION BY EXPERTS (REAL-TIME USERS VS REMOTE EXPERTS)

1.6.1 Safety

A summary of device effect on safety and effectiveness of block is presented below:

	<i>Answer/ Risk</i>	<i>Yes</i>	<i>No</i>	<i>*N/A</i>	<i>No-consensus</i>
<i>PONS real-time</i>		5	62	36	n/a
<i>PONS remote experts</i>		0	67	36	0
<i>Pneumothorax real-time</i>		0	16	87	n/a
<i>Pneumothorax remote experts</i>		0	16	87	0
<i>LAST real-time</i>		3	68	32	n/a
<i>LAST remote experts</i>		0	71	32	0
<i>Peritoneum violation real-time</i>		0	8	95	n/a
<i>Peritoneum violation remote experts</i>		0	8	95	0
<i>Block failure real-time</i>		4	88	11	n/a
<i>Block failure remote experts</i>		8**	82	11	2

*Data not on data sheet returned by real-time expert or structure/complication not relevant to block

**In 7/8 cases where remote experts reported increased risk of block failure, they also reported the view acquired was not adequate

1.6.4 Raw data (real-time user)

The experts using ScanNav Anatomy PNB in real time (or supervising a trainee) answered the following questions:

Based on the scan just performed, does the highlighting increase the risk of:

- Nerve injury/post-operative neurological symptoms (PONS)
- Pneumothorax
- Local anaesthetic systemic toxicity
- Peritoneum violation
- Block failure

The raw data in answer to these questions are presented below:

#	Model BMI	Scanner ID	Scanner type	PONS	Pneumothorax	LAST	Peritoneum Violation	Block Failure	Missing
1	High	E1	Expert						Y
2	Low	E1	Expert						Y
3	High	T1	Trainee						Y
4	Low	T1	Trainee						Y
5	High	E1	Expert						Y
6	Low	E1	Expert						Y
7	High	T1	Trainee						Y
8	Low	T1	Trainee						Y
9	High	E2	Expert	N	N/A	N	N/A	N	N
10	Low	E2	Expert	N	N/A	N	N/A	N	N
11	High	T2	Trainee	N	N/A	N	N/A	Y	N
12	Low	T2	Trainee	N	N/A	N	N/A	N	N
13	Low	E2	Expert	N/A	N	N	N/A	N	N
14	High	E2	Expert	N/A	N	N	N/A	N	N
15	Low	T2	Trainee	N/A	N	N	N/A	N	N
16	High	T2	Trainee	N/A	N	N	N/A	N	N
17	High	E3	Expert						Y
18	Low	E3	Expert						Y
19	High	T3	Trainee						Y
20	Low	T3	Trainee						Y
21	High	E3	Expert						Y
22	Low	E3	Expert						Y
23	High	T3	Trainee						Y
24	Low	T3	Trainee						Y



#	Model BMI	Scanner ID	Scanner type	PONS	Pneumothorax	LAST	Peritoneum Violation	Block Failure	Missing
25	High	E4	Expert	Y	N/A	N	N/A	Y	N
26	Low	E4	Expert	N	N/A	N	N/A	N	N
27	Low	T4	Trainee	Y	N/A	N	N/A	Y	N
28	High	T4	Trainee	Y	N/A	N	N/A	Y	N
29	Low	E4	Expert	N/A	N/A	N	N	N	N
30	High	E4	Expert	N/A	N/A	N	N	N	N
31	Low	T4	Trainee	N/A	N/A	N	N	N	N
32	High	T4	Trainee	N/A	N/A	N	N	N	N
33	Low	E5	Expert	N	N/A	N	N/A	N	N
34	High	E5	Expert	Y	N/A	Y	N/A	N/A	N
35	Low	T5	Trainee	N	N/A	Y	N/A	N	N
36	High	T5	Trainee	Y	N/A	Y	N/A	N/A	N
37	Low	E5	Expert	N	N/A	N	N/A	N	N
38	High	E5	Expert	N	N/A	N	N/A	N	N
39	Low	T5	Trainee	N	N/A	N	N/A	N	N
40	High	T5	Trainee	N	N/A	N	N/A	N	N
41	High	E6	Expert	N	N/A	N	N/A	N	N
42	Low	E6	Expert	N	N/A	N	N/A	N	N
43	High	T6	Trainee	N	N/A	N	N/A	N	N
44	Low	T6	Trainee	N	N/A	N	N/A	N	N
45	Low	E6	Expert	N/A	N/A	N	N/A	N	N
46	High	E6	Expert	N/A	N/A	N	N/A	N	N
47	High	T6	Trainee	N/A	N/A	N	N/A	N	N
48	Low	T6	Trainee	N/A	N/A	N	N/A	N	N
49	High	E7	Expert	N	N/A	N	N/A	N	N
50	Low	E7	Expert	N	N/A	N	N/A	N	N
51	High	T7	Trainee	N	N/A	N	N/A	N	N
52	Low	T7	Trainee	N	N/A	N	N/A	N	N
53	High	E7	Expert	N	N	N	N/A	N	N
54	Low	E7	Expert	N	N	N	N/A	N	N
55	Low	T7	Trainee	N	N	N	N/A	N	N
56	High	T7	Trainee	N	N	N	N/A	N	N
57	Low	E8	Expert	N	N/A	N	N/A	N	N
58	High	E8	Expert	N	N/A	N	N/A	N	N
59	Low	T8	Trainee	N	N/A	N	N/A	N	N
60	High	T8	Trainee	N	N/A	N	N/A	N	N
61	High	E8	Expert	N/A	N/A	N	N	N	N
62	Low	E8	Expert	N/A	N/A	N	N	N	N



#	Model BMI	Scanner ID	Scanner type	PONS	Pneumothorax	LAST	Peritoneum Violation	Block Failure	Missing
63	High	T8	Trainee	N/A	N/A	N	N	N	N
64	Low	T8	Trainee	N/A	N/A	N	N	N	N
65	High	E9	Expert	N	N/A	N	N/A	N	N
66	Low	E9	Expert	N	N/A	N	N/A	N	N
67	High	T9	Trainee	N	N/A	N	N/A	N	N
68	Low	T9	Trainee	N	N/A	N	N/A	N	N
69	Low	E9	Expert	N/A	N	N	N/A	N	N
70	High	E9	Expert	N/A	N	N	N/A	N	N
71	Low	T9	Trainee	N/A	N	N	N/A	N	N
72	High	T9	Trainee	N/A	N	N	N/A	N	N
73	High	E10	Expert	N	N/A	N	N/A	N	N
74	Low	E10	Expert						Y
75	Low	T10	Trainee	N	N/A	N	N/A	N	N
76	High	T10	Trainee	N	N/A	N	N/A	N	N
77	High	E10	Expert	N/A	N/A	N	N/A	N	N
78	Low	E10	Expert	N/A	N/A	N	N/A	N	N
79	High	T10	Trainee	N/A	N/A	N	N/A	N	N
80	Low	T10	Trainee	N/A	N/A	N	N/A	N	N
81	Low	E11	Expert	N	N/A	N	N/A	N	N
82	High	E11	Expert	N	N/A	N	N/A	N	N
83	Low	T11	Trainee	N	N/A	N	N/A	N	N
84	High	T11	Trainee	N	N/A	N	N/A	N	N
85	Low	E11	Expert	N/A	N/A	N	N/A	N	N
86	High	E11	Expert	N/A	N/A	N	N/A	N	N
87	Low	T11	Trainee	N/A	N/A	N	N/A	N	N
88	High	T11	Trainee	N/A	N/A	N	N/A	N	N
89	High	E12	Expert	N/A	N	N	N/A	N	N
90	Low	E12	Expert	N/A	N	N	N/A	N	N
91	High	T12	Trainee	N/A	N	N	N/A	N	N
92	Low	T12	Trainee	N/A	N	N	N/A	N	N
93	High	E12	Expert	N	N/A	N	N/A	N	N
94	Low	E12	Expert	N	N/A	N	N/A	N	N
95	High	T12	Trainee	N	N/A	N	N/A	N	N
96	Low	T12	Trainee	N	N/A	N	N/A	N	N
97	Low	E13	Expert	N	N/A	N	N/A	N	N
98	High	E13	Expert	N	N/A	N	N/A	N/A	N
99	High	T13	Trainee	N	N/A	N	N/A	N	N
100	Low	T13	Trainee	N	N/A	N	N/A	N	N



#	Model BMI	Scanner ID	Scanner type	PONS	Pneumothorax	LAST	Peritoneum Violation	Block Failure	Missing
101	Low	E13	Expert	N/A	N/A	N	N/A	N	N
102	High	E13	Expert	N/A	N/A	N	N/A	N	N
103	Low	T13	Trainee	N/A	N/A	N	N/A	N	N
104	High	T13	Trainee	N/A	N/A	N	N/A	N	N
105	Low	E14	Expert	N	N/A	N	N/A	N	N
106	High	E14	Expert	N	N/A	N	N/A	N	N
107	Low	T14	Trainee	N	N/A	N	N/A	N	N
108	High	T14	Trainee	N	N/A	N	N/A	N	N
109	High	E14	Expert	N	N/A	N	N/A	N	N
110	Low	E14	Expert	N	N/A	N	N/A	N	N
111	High	T14	Trainee	N	N/A	N	N/A	N	N
112	Low	T14	Trainee	N	N/A	N	N/A	N	N
113	Low	E15	Expert	N	N/A	N	N/A	N/A	N
114	High	E15	Expert	N	N/A	N	N/A	N/A	N
115	Low	T15	Trainee	N	N/A	N	N/A	N/A	N
116	High	T15	Trainee	N	N/A	N	N/A	N/A	N
117	Low	E15	Expert	N	N/A	N	N/A	N/A	N
118	High	E15	Expert	N	N/A	N	N/A	N/A	N
119	Low	T15	Trainee	N	N/A	N	N/A	N/A	N
120	High	T15	Trainee	N	N/A	N	N/A	N/A	N

Specific adverse events

PONS

An assessment whether highlighting increases a risk of PONS was made for total of 67 scans, over six block regions (adductor, axillary, interscalene, popliteal, supraclavicular and superior trunk):

Risk of PONS	Number of scans	Rate
No	62	0.925
Yes	5	0.0746
Total	67	

Scan ID	Block	BMI	Scanner type	Scanner ID	Risk of PONS
25	Add	High	Expert	E4	Yes
27	Add	Low	Trainee	T4	Yes
28	Add	High	Trainee	T4	Yes
34	Ax	High	Expert	E5	Yes
36	Ax	High	Trainee	T5	Yes

**LAST**

An assessment whether highlighting increases a risk of LAST was made for total of 103 scans, over all 9 supported blocks.

Risk of LAST	Number of scans	Rate
No	68	0.958
Yes	3	0.042
Total	103	

Scan ID	Block	BMI	Scanner type	Scanner ID	Risk of LAST
34	Ax	High	Expert	E5	Yes
35	Ax	Low	Trainee	T5	Yes
36	Ax	High	Trainee	T5	Yes

BLOCK FAILURE

An assessment was made for total of 92 scans, over all 9 supported blocks.

Risk of Block Failure	Number of scans	Rate
No	88	0.956
Yes	4	0.043
Not applicable	11	n/a
Total	103	

Scan ID	Block	US machine	BMI	Scanner type	Scanner ID	Nerve	Artery	Risk of Block failure
11	Add	SonoSite PX	High	Trainee	T2	FP	TP	Yes
25	Add	SonoSite PX	High	Expert	E4	FP	TP	Yes
27	Add	SonoSite Xporte	Low	Trainee	T4	FP	TP	Yes
28	Add	SonoSite PX	High	Trainee	T4	FP	TP	Yes



1.6.5 Raw Data (Remote Expert)

A panel of 3 independent experts viewed the ultrasound videos remotely (with unmodified and highlighted videos presented one above the other), to score the 103 scans collected with ScanNav Anatomy PNB during this study (for which real-time data was available). The experts scored clips independently and were unaware of each other's answers. The majority view of the experts was established afterwards to arrive to a single majority decision.

The majority views of the experts are presented below. In some instances, it was not possible to arrive to a majority decision, so those instances are marked as "undetermined" and were excluded from analysis. Entries marked as "N/A" represent entries that are not applicable for the assigned block (e.g., accuracy scores for the Peritoneum are marked as "N/A" for the Popliteal block, as there is no possibility of encountering the peritoneum in this location).

Scan ID	block	BMI category	Scanner ID	Scanner type	Majority view				
					PONS	Pneumothorax	LAST	Peritoneum violation	Block failure
1	POP	High	E01	Expert					
2	POP	Low	E01	Expert					
3	POP	High	T01	Trainee					
4	POP	Low	T01	Trainee					
5	RS	High	E01	Expert					
6	RS	Low	E01	Expert					
7	RS	High	T01	Trainee					
8	RS	Low	T01	Trainee					
9	ADD	High	E02	Expert	N	#N/A	N	#N/A	N
10	ADD	Low	E02	Expert	N	#N/A	N	#N/A	N
11	ADD	High	T02	Trainee	N	#N/A	N	#N/A	N
12	ADD	Low	T02	Trainee	N	#N/A	N	#N/A	N
13	ESP	Low	E02	Expert	#N/A	N	N	#N/A	Y
14	ESP	High	E02	Expert	#N/A	N	N	#N/A	N
15	ESP	Low	T02	Trainee	#N/A	N	N	#N/A	undetermined
16	ESP	High	T02	Trainee	#N/A	N	N	#N/A	N
17	ADD	High	E03	Expert					
18	ADD	Low	E03	Expert					
19	ADD	High	T03	Trainee					
20	ADD	Low	T03	Trainee					
21	ST	High	E03	Expert					
22	ST	Low	E03	Expert					
23	ST	High	T03	Trainee					
24	ST	Low	T03	Trainee					



Scan ID	block	BMI category	Scanner ID	Scanner type	Majority view				
					PONS	Pneumothorax	LAST	Peritoneum violation	Block failure
25	ADD	High	E04	Expert	N	#N/A	N	#N/A	N
26	ADD	Low	E04	Expert	N	#N/A	N	#N/A	N
27	ADD	Low	T04	Trainee	N	#N/A	N	#N/A	N
28	ADD	High	T04	Trainee	N	#N/A	N	#N/A	N
29	RS	Low	E04	Expert	N	#N/A	N	N	N
30	RS	High	E04	Expert	N	#N/A	N	N	N
31	RS	Low	T04	Trainee	N	#N/A	N	N	N
32	RS	High	T04	Trainee	N	#N/A	N	N	N
33	AX	Low	E05	Expert	N	#N/A	N	#N/A	N
34	AX	High	E05	Expert	N	#N/A	N	#N/A	N
35	AX	Low	T05	Trainee	N	#N/A	N	#N/A	N
36	AX	High	T05	Trainee	N	#N/A	N	#N/A	N
37	POP	Low	E05	Expert	N	#N/A	N	#N/A	N
38	POP	High	E05	Expert	N	#N/A	N	#N/A	N
39	POP	Low	T05	Trainee	N	#N/A	N	#N/A	Y
40	POP	High	T05	Trainee	N	#N/A	N	#N/A	N
41	POP	High	E06	Expert	N	#N/A	N	#N/A	N
42	POP	Low	E06	Expert	N	#N/A	N	#N/A	N
43	POP	High	T06	Trainee	N	#N/A	N	#N/A	N
44	POP	Low	T06	Trainee	N	#N/A	N	#N/A	N
45	SFIC	Low	E06	Expert	N	#N/A	N	#N/A	undetermined
46	SFIC	High	E06	Expert	N	#N/A	N	#N/A	N
47	SFIC	High	T06	Trainee	N	#N/A	N	#N/A	N
48	SFIC	Low	T06	Trainee	N	#N/A	N	#N/A	Y
49	POP	High	E07	Expert	N	#N/A	N	#N/A	N
50	POP	Low	E07	Expert	N	#N/A	N	#N/A	N
51	POP	High	T07	Trainee	N	#N/A	N	#N/A	N

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Scan ID	block	BMI category	Scanner ID	Scanner type	Majority view				
					PONS	Pneumothorax	LAST	Peritoneum violation	Block failure
52	POP	Low	T07	Trainee	N	#N/A	N	#N/A	N
53	SC	High	E07	Expert	N	N	N	#N/A	N
54	SC	Low	E07	Expert	N	N	N	#N/A	N
55	SC	Low	T07	Trainee	N	N	N	#N/A	N
56	SC	High	T07	Trainee	N	N	N	#N/A	N
57	IS	Low	E08	Expert	N	N	N	#N/A	N
58	IS	High	E08	Expert	N	N	N	#N/A	N
59	IS	Low	T08	Trainee	N	N	N	#N/A	N
60	IS	High	T08	Trainee	N	N	N	#N/A	N
61	RS	High	E08	Expert	N	#N/A	N	N	N
62	RS	Low	E08	Expert	N	#N/A	N	N	N
63	RS	High	T08	Trainee	N	#N/A	N	N	N
64	RS	Low	T08	Trainee	N	#N/A	N	N	N
65	AX	High	E09	Expert	N	#N/A	N	#N/A	N
66	AX	Low	E09	Expert	N	#N/A	N	#N/A	N
67	AX	High	T09	Trainee	N	#N/A	N	#N/A	N
68	AX	Low	T09	Trainee	N	#N/A	N	#N/A	N
69	ESP	Low	E09	Expert	#N/A	N	N	#N/A	N
70	ESP	High	E09	Expert	#N/A	N	N	#N/A	Y
71	ESP	Low	T09	Trainee	#N/A	N	N	#N/A	N
72	ESP	High	T09	Trainee	#N/A	N	undetermined	#N/A	Y
73	POP	High	E10	Expert	N	#N/A	N	#N/A	N
74	POP	Low	E10	Expert					
75	POP	Low	T10	Trainee	N	#N/A	N	#N/A	N
76	POP	High	T10	Trainee	N	#N/A	N	#N/A	N
77	SFIC	High	E10	Expert	N	#N/A	N	#N/A	N
78	SFIC	Low	E10	Expert	N	#N/A	N	#N/A	N

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Scan ID	block	BMI category	Scanner ID	Scanner type	Majority view				
					PONS	Pneumothorax	LAST	Peritoneum violation	Block failure
79	SFIC	High	T10	Trainee	N	#N/A	N	#N/A	N
80	SFIC	Low	T10	Trainee	N	#N/A	N	#N/A	N
81	ADD	Low	E11	Expert	N	#N/A	N	#N/A	N
82	ADD	High	E11	Expert	N	#N/A	N	#N/A	N
83	ADD	Low	T11	Trainee	N	#N/A	N	#N/A	N
84	ADD	High	T11	Trainee	N	#N/A	N	#N/A	N
85	SFIC	Low	E11	Expert	N	#N/A	N	#N/A	Y
86	SFIC	High	E11	Expert	N	#N/A	N	#N/A	N
87	SFIC	Low	T11	Trainee	N	#N/A	N	#N/A	N
88	SFIC	High	T11	Trainee	N	#N/A	N	#N/A	N
89	ESP	High	E12	Expert	#N/A	N	N	#N/A	Y
90	ESP	Low	E12	Expert	#N/A	N	N	#N/A	N
91	ESP	High	T12	Trainee	#N/A	N	N	#N/A	Y
92	ESP	Low	T12	Trainee	#N/A	N	N	#N/A	N
93	POP	High	E12	Expert	N	#N/A	N	#N/A	N
94	POP	Low	E12	Expert	N	#N/A	N	#N/A	N
95	POP	High	T12	Trainee	N	#N/A	N	#N/A	N
96	POP	Low	T12	Trainee	N	#N/A	N	#N/A	N
97	ADD	Low	E13	Expert	N	#N/A	N	#N/A	N
98	ADD	High	E13	Expert	N	#N/A	N	#N/A	N
99	ADD	High	T13	Trainee	N	#N/A	N	#N/A	N
100	ADD	Low	T13	Trainee	N	#N/A	N	#N/A	N
101	SFIC	Low	E13	Expert	N	#N/A	N	#N/A	N
102	SFIC	High	E13	Expert	N	#N/A	N	#N/A	N
103	SFIC	Low	T13	Trainee	N	#N/A	N	#N/A	N
104	SFIC	High	T13	Trainee	N	#N/A	N	#N/A	N
105	IS	Low	E14	Expert	N	N	N	#N/A	N

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					PONS	Pneumothorax	LAST	Peritoneum violation	Block failure
106	IS	High	E14	Expert	N	N	N	#N/A	N
107	IS	Low	T14	Trainee	N	N	N	#N/A	N
108	IS	High	T14	Trainee	N	N	N	#N/A	N
109	POP	High	E14	Expert	N	#N/A	N	#N/A	N
110	POP	Low	E14	Expert	N	#N/A	N	#N/A	N
111	POP	High	T14	Trainee	N	#N/A	N	#N/A	N
112	POP	Low	T14	Trainee	N	#N/A	N	#N/A	N
113	ADD	Low	E15	Expert	N	#N/A	N	#N/A	N
114	ADD	High	E15	Expert	N	#N/A	N	#N/A	N
115	ADD	Low	T15	Trainee	N	#N/A	N	#N/A	N
116	ADD	High	T15	Trainee	N	#N/A	N	#N/A	N
117	ST	Low	E15	Expert	N	N	N	#N/A	N
118	ST	High	E15	Expert	N	N	N	#N/A	N
119	ST	Low	T15	Trainee	N	N	N	#N/A	N
120	ST	High	T15	Trainee	N	N	N	#N/A	N

Specific adverse events**BLOCK FAILURE**

An assessment was made for total of 92 scans (11 of the 103 returned data sets incomplete), over all 9 supported blocks.

Risk of Block Failure	Number of scans	Rate
No	82	0.919
Yes	8	0.087
undetermined	2	0.021
Total	92	

Scan ID	Block	BMI	Scanner type	Scanner ID	Correct view	Risk of Block failure	Nerve	Artery	Pleura
13	ESP	Low	Expert	E02	No, incorrect gain	Y	n/a	n/a	TP
15	ESP	Low	Trainee	T02	No, incorrect structures	undetermined	n/a	n/a	TP
39	POP	Low	Trainee	T05	Y	Y	FP	TP	n/a
45	SFIC	Low	Expert	E06	No, incorrect structures	undetermined	n/a	undetermined	n/a
48	SFIC	Low	Trainee	T06	No, incorrect structures	Y	n/a	undetermined	n/a
70	ESP	High	Expert	E09	undetermined	Y	n/a	n/a	TP
72	ESP	High	Trainee	T09	undetermined	Y	n/a	n/a	TP
85	SFIC	Low	Expert	E11	No, incorrect structures	Y	n/a	TN	n/a
89	ESP	High	Expert	E12	undetermined	Y	n/a	n/a	undetermined
91	ESP	High	Trainee	T12	No, artifact	Y	n/a	n/a	TN