

SCANNAVTM

ANATOMY Peripheral Nerve Block

Version: 1.0

OVERVIEW

ScanNav Anatomy: Peripheral Nerve Block (Anatomy PNB) is a software medical device which assists anaesthetists and other appropriately qualified healthcare professionals in the identification of anatomical structures for ultrasound-guided regional anaesthesia procedures. The software is supplied installed on a panel PC with an integrated touchscreen display.

The device reads the ultrasound scan video in real-time from a compatible general-purpose ultrasound system. It processes the images from video frames using image processing and deep learning artificial intelligence algorithms to highlight relevant anatomical structures, producing a composite output image for display on the panel PC.



Before using the system, we recommend reading all of the instructions for use.

INTENDED PURPOSE OF USE

ScanNav Anatomy: Peripheral Nerve Block is intended to assist qualified healthcare professionals in the identification of anatomical structures for ultrasound-guided interventional procedures.

INTENDED USERS

ScanNav Anatomy: Peripheral Nerve Block is intended for use by anaesthetists and other appropriately qualified healthcare professionals who are licensed to perform ultrasound-guided regional anaesthesia procedures.

INDICATIONS FOR USE

ScanNav Anatomy: Peripheral Nerve Block is indicated to assist qualified healthcare professionals in the identification of anatomical structures for ultrasound-guided regional anaesthesia (UGRA) procedures in patients 18 years of age or older.

ScanNav Anatomy: Peripheral Nerve Block is an accessory to compatible general purpose diagnostic ultrasound systems.

The highlighting of structures in the following anatomical regions is supported:

- Axillary
- Erector spinae plane
- Interscalene
- Popliteal
- Rectus Sheath

- Sub-sartorial femoral triangle / Adductor canal
- Superior trunk
- Supraclavicular
- Suprainguinal fascia iliaca

The device performs the highlighting using deep learning artificial intelligence technology that has been trained to recognise the anatomical features of interest.

CLINICAL BENEFITS

The clinical benefits of Anatomy PNB are as follows:

- Support the performance of healthcare professionals who are suitably qualified but who perform ultrasound-guided procedures on an infrequent basis.
- Enhance the accuracy and standardization of ultrasound image interpretation by making it easier to identify key anatomical structures.

CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

- The device should not be used on patients under 18 years of age or for any procedures other than those listed in the Indications for use.
- All users must be qualified and licensed to perform ultrasound-guided regional anaesthesia. Standard clinical procedures, safety protocols and risk-mitigation protocols for ultrasound-guided regional anaesthesia must be followed.
- The device may not highlight well on low-quality ultrasound views, such as those obtained from patients with a BMI greater than 35.
- Standard clinical guidelines for regional anaesthesia should be followed when using the device. The device does not make any recommendations about where the needle should be placed, nor where the anaesthetic should be injected.
- The ultrasound machine and the hardware platform used with Anatomy PNB must meet the compatibility requirements in the instructions for use.



INTELLIGENT ULTRASOUND LIMITED
Floor 6A, Hodge House, 114-116 St Mary Street,
Cardiff, CF10 1DY, United Kingdom



ADVENA LTD. Tower Business Centre, 2nd Flr., Tower
Street, Swatar, BKR 4013 Malta

