Exhibit E - Infringement of U.S. Patent No. 11,129,591 (the ’591 Patent)

Pursuant to Patent L.R. 3-1, this chart sets forth where and how in the Accused Products each element of claims 1-20 of U.S. Patent No. 11,129,591 (the ’591 Patent) is found. The Accused Products include, but are not limited to, Defendants’ Voluson family of ultrasound systems, which Defendants list as the Voluson SWIFT, Expert Series, and Signature Series products. *See generally* https://www.gehealthcare.com/products/ultrasound/voluson/ (describing the Accused Products).

Defendants’ Voluson products incorporate SonoLyst AI software, which is based on Intelligent Ultrasound’s ScanNav AI proprietary ultrasound image analysis technology. *See* https://www.gehealthcare.com/about/newsroom/press-releases/ge-healthcare-unveils-voluson-swift-ai-enhanced-womens-health-ultrasound-with (“*SonoLyst incorporates the AI technology of Intelligent Ultrasound”); https://polaris.brighterir.com/public/intelligent_ultrasound/news/rns/story/xq64o7r (“Intelligent Ultrasound (AIM: MED), the artificial intelligence (AI) based ultrasound software and simulation company, announces that GE Healthcare's Voluson SWIFT ultrasound machine that incorporates GE Healthcare's SonoLyst software with Intelligent Ultrasound’s ScanNav Assist AI technology, has received 510(k) clearance from the FDA for sale in the USA.”). On information and belief, the SonoLyst suite of AI tools contains the same neural network architecture and algorithms as ScanNav AI.

Because of the structural similarities in the hardware of the Accused Products and their collective use of SonoLyst AI software, the analysis against any one of Defendants’ Voluson ultrasound systems has been provided as representative of all the Accused Products. This chart is also representative of any reasonably similar product that incorporates the neural network-based functionality of the Accused Products, which UBC also accuses of infringement.

Defendants further indirectly infringe by inducing others to infringe with knowledge of their infringement. For example, Defendants sell the Accused Products to their customers and/or other end users and instruct them to practice all claims of the ’591 Patent by using the Accused Products. Defendants also actively contribute to infringement by selling the Accused Products to their customers and/or other end users knowing they have no substantial noninfringing use.

UBC reserves the right to identify additional products and claims and identify further representative products. UBC reserves the right to amend, supplement, expand, modify, or narrow its identifications in the Accused Products as it develops facts during discovery, based on the Court’s claim constructions, or for any other allowable purpose in this action. UBC reserves the right to amend, supplement, expand, modify, or narrow its identifications in the source code based on additional code review.

’591 Claim 1	Voluson Family Products
1[pre]: A computer-implemented system for facilitating echocardiographic image analysis, the system comprising at least one processor configured to:	The Voluson family products disclose *“[a] computer-implemented system for facilitating echocardiographic image analysis.”* The Voluson family products are *computer-implemented systems* because they include a console with a display monitor and HDMI interface, WiFi connectivity, a Bluetooth-to-wireless ultrasound probe, and are configured with various hardware, firmware, and software components including, but not limited to, 2x 8GB of memory and a Microsoft Windows 10 lot Enterprise 64 bit operating system. The computer-implemented system comprises *at least one processor* because it uses a frontend processor (e.g., DMA logic, FPGA) and a backend processor (e.g., GPU, CPU). Additionally, ScanNav AI, on which the SonoLyst AI algorithm of the Voluson family products is based, was trained on a PC with an RTX4000 GPU, which necessarily requires a processor. The Voluson family products facilitate echocardiographic image analysis because they acquire images of a fetal echocardiogram and can automatically identify fetal anatomy for standard views while enhancing efficiency by adding annotations and measurements. The Voluson family products achieve automated image quality assessment in fetal cardiac ultrasound by leveraging deep learning at multiple levels: image recognition to identify the standard view, image analysis to score the view’s quality continuously, and intelligent control logic to provide feedback or automation. For example, see the following passages and/or figures, as well as all related disclosures: SonoLyst AI, powered by Intelligent Ultrasound’s ScanNav AI software, is available on the Voluson Expert, Signature and SWIFT ranges of ultrasound machines. *See* https://polaris.brighterir.com/public/intelligent_ultrasound/news/rns/story/xopgg1r. SonoLystX, one of several tools in the SonoLyst AI suite, “compares the image or view acquired to standard criteria accepted by experts to ensure it meets clinical standards.” *See* https://www.gehealthcare.com/products/ultrasound/voluson/sonolyst. Voluson™ Product Family, https://configure-my-voluson.com/en/voluson/system-overview.

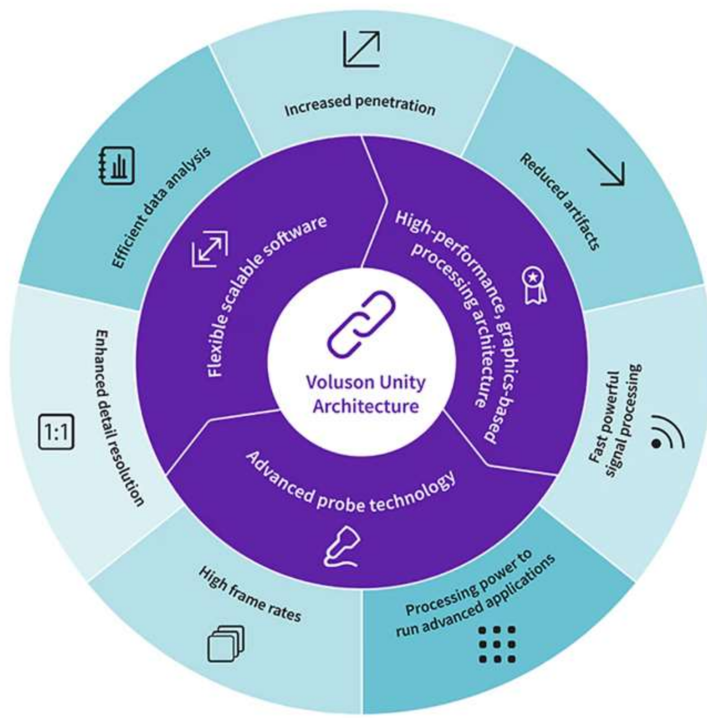
	 Voluson™ Family product page, https://gehealthcare-ultrasound.com/en/voluson-family/: “Continuous innovation is at the heart of our Voluson family of women's ultrasounds. Every day, we strive to further improve the quality of ultrasound images and develop specialized clinical tools that allow you to see more anatomical details with greater confidence.” Voluson SWIFT Brochure JB83443XXt (Sep 2020) at 6: This is **EFFICIENCY** Let's face it – you're busy. Voluson SWIFT is designed to help remove some of the obstacles that consistently slow you down. By leveraging the power of artificial intelligence, Voluson SWIFT allows you to save valuable time on acquisition, analysis, and reporting for both routine and detailed exams. Scan quickly and easily with SonoLyst,* a suite of image recognition tools that automatically identify fetal anatomy seen on standard views.

Voluson Signature 20 Product Page,
https://www.gehealthcare.com/products/ultrasound/voluson/voluson-signature20

Voluson Unity Architecture

Get great images fast.

Advanced beamforming capabilities work in harmony with expert-level probes to deliver faster processing speeds and frame rates for enhanced detail and contrast resolution, greater color quality and sensitivity, and exceptional 3D/4D.



Voluson Expert 22 Product Page, https://www.gehealthcare.ca/en-ca/products/ultrasound/voluson/voluson-expert22/workflow-efficiency

SonoLyst

Your Onboard Assistant

SonoLyst is your virtual on-board expert utilizing AI to automatically identify fetal anatomy seen on standard views while enhancing efficiency by adding annotations and measurements. For quality assurance, SonoLyst can also be used to compare the image or view acquired to standard criteria ensuring exam quality and consistency.

	Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2. All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload. Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 3-3,

	 *Figure 3-1 System description* 1. Monitor 2. Additional USB-C port 3. USB ports 4. Speakers 5. Gel warmer holder 6. DVD player (optional) 7. Drawer (optional) 8. Touch panel 9. Probe holder 10. User interface (Operator/ Control Panel/ Console) adjustment buttons 11. User interface (Operator/ Control Panel/ Console) 12. Probe (connector) ports 13. Foot rest 14. Caster brakes • Front: Swivel and brake lock • Rear 1: Swivel, swivel lock or steer and brake lock • Rear 2: unlock brake Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 13-43.

13.12.3 Drives

DVD/CD + RW Drive: (optional)	Read Speed:	• 16x DVD-ROM • 40x CD-ROM
	Write Speed:	• DVD+R: 16x • DVD+RW: 8x • CD-R: 40x • CD-RW: 32x
	Supported Media:	DVD-ROM, DVD+R, DVD+RW, CD-ROM, CD-R, CD-RW
Hard disk:	Integrated HDD/SSD	Expert 22: 1x 2000 GB (2TB) HDD or 1x 1TB SSD (optional) 1x greater or equal 60 GB SSD or M.2 SSD (2TB) Expert 18 and Expert 20: 1x 1000 GB (1TB) HDD or 1x 1TB SSD (optional) 1x greater or equal 60 GB SSD or M.2 SSD (1TB)

Voluson Expert Series Service Manual Rev 6 (Aug 2024) at 5-4:

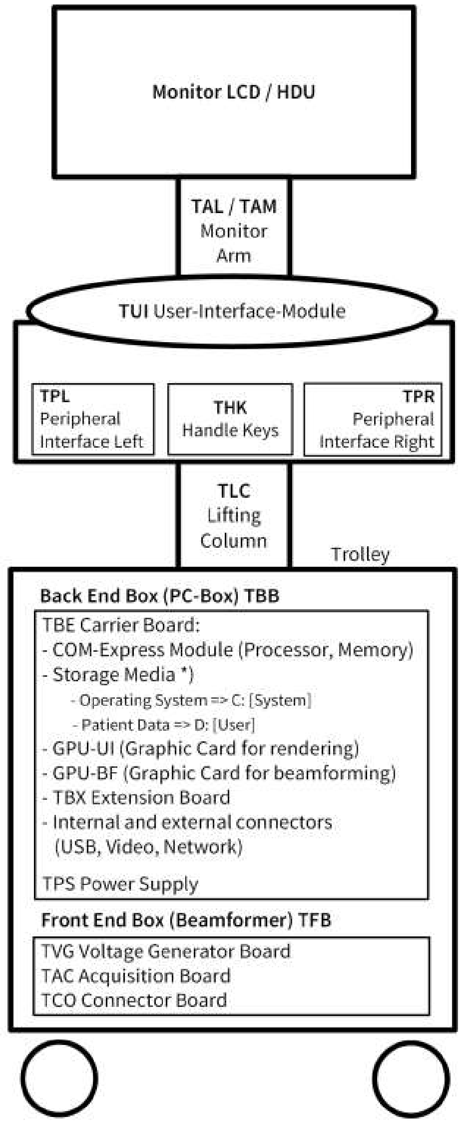
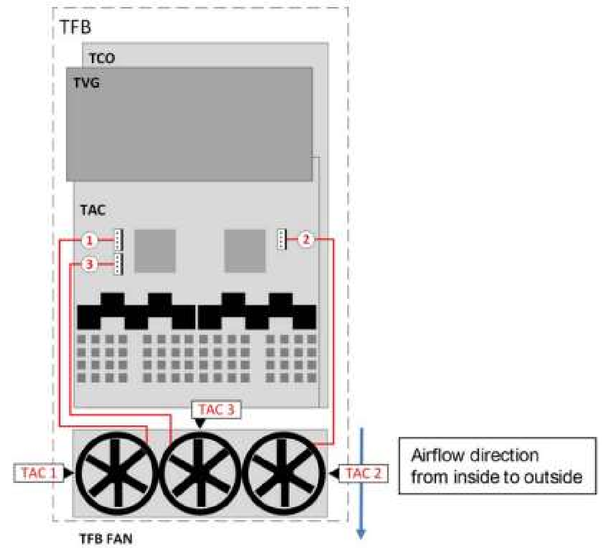


Figure 5-2: Basic Block diagram of Voluson Expert Series

	Voluson Expert Series Service Manual Rev 6 (Aug 2024) at 5-21 to 5-22: **5.2 FrontEnd Processor**  Figure 5-4: FrontEnd - Block diagram

	5.2.1 TCO - Connector Board Switches the Probe Connectors and recognizes Probes • 4 Probe Connectors 408pin • Probe Select Relays • Probe Recognition **5.2.2 TAC - Acquisition Board** The FrontEnd Acquisition Board supports Tx/Rx for 192 channels[10] / 256 channels[11]. **5.2.2.1 TAC Board - Interface Tasks** 1. DMA logic 2. Beamformer Interface 3. TAC Control Interface 4. TAC FPGA Control Interface **5.2.2.2 TAC Board - Processing Tasks** 1. Ultrasound Data Pre-Processing 2. System Control 3. Motor Control **5.2.3 TVG - Voltage Generator Board** The voltage generator board generates the ultrasound system specific voltages. Voluson Expert Series Service Manual Rev 6 (Aug 2024) at 5-23 to 5-25:

5.3 BackEnd Processor

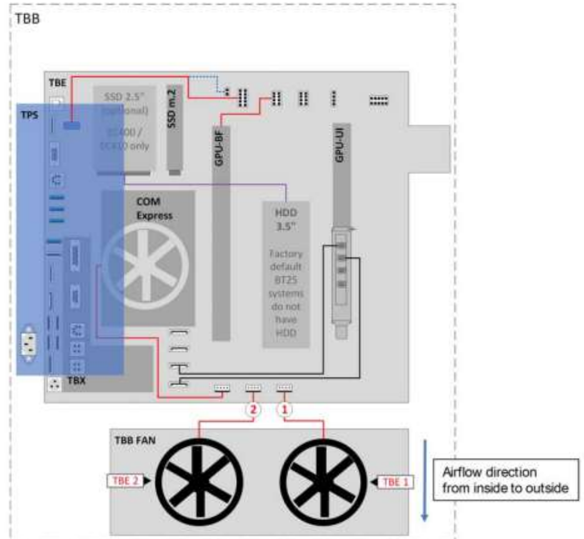


Figure 5-5: BackEnd - Block diagram

Content in this chapter

	5.3.1 TBE - Backend Carrier Board (Base Board) Built in or external Components: • COM-Express (Computer on Module with CPU, Memory, Audio and USB-Root Hub) • Graphic cards (GPU-BF and GPU-UI) • PCIe Switch • EC400, EC410 (BT24) and systems that were upgraded to EC420 (BT25): - M.2 NVMe SSD for operating system - HDD for patient data • EC420 (BT25): - M.2 NVMe SSD for operating system + patient data, no additional HDD • Audio-Amplifier • Video splitter and scaler • MCU for monitoring and bootup sequence Cores Major Tasks: • System Control • Connections to User Interface, Frontend, Peripherals and external connectivity **5.3.2 TBX - Extension Board** Built in or external Components: • Electronic switch and fuse for User Interface (TUI) • Electronic switch and fuse for Lift (TLC) • Electronic switch and fuse for Peripherals such as Printer and Trolley Lighting Unit (TLU) Cores Major Tasks: • Power distribution and monitoring **5.3.3 COM Express Module** Built in or external Components: • LAN • USB 2.0 • USB 3.0 • CPU: 2.5GHz (max. 4.2GHz) • Memory (2x 8GB) • Active cooling Cores Major Tasks: • System Control **5.3.6 Graphic Card** The Voluson E-Series system has two Graphic Cards installed. Their scope of application is different. **Graphic Card GPU-BF** Provides processing capacity to perform software-beamforming. **Graphic Card GPU-UI** Renders 2D, 3D and 4D images as well as the complete user interface for all displays (Touchscreen, Main Monitor and external outputs).

	T.G. Day et. al., *Video Clip Extraction From Fetal Ultrasound Scans Using Artificial Intelligence to Allow Remote Second Expert Review for Congenital Heart Disease*, Prenatal Diagnosis, 2025, 45:531-538, at 532-33 (Aug. 7, 2024) ("During the AI-assisted scan, the novel AI tool was used. This takes as input every frame of the ultrasound scan video obtained by the sonographer, and automatically classified each frame into one of 13 standard image plane labels, or background. This included five cardiac planes (abdominal situs view, four-chamber view (4CH), left ventricular outflow tract view (LVOT), right ventricular outflow tract view (RVOT), and three vessel tracheal views (3VT)). This step was performed by the SonoNEXT model and is fully described in a separate publication [9], but briefly this model is a type of convolutional neural network, taking as input a single ultrasound image frame, and producing a prediction of the most likely standard image plane label. Each image was also automatically assigned a quality score. Again, full information on the quality scoring model is available in our previous publication [9], but briefly this is also a convolutional neural network, taking as input a single image and producing an output that is a predicted quality score on a continuous scale, also taking into account image diversity (to avoid multiple very similar images being selected as the best quality). Details of the development and performance of the AI models are described in the previous publication [9]. The AI models were run in real time during the scans on a computer equipped with a graphical processing unit (Boxer-8641AI, Aaeon Technology Inc., Taipei, Taiwan), which was connected to the ultrasound machine via a high-definition multimedia interface (HDMI) connection. Information on AI model output was displayed to the sonographer via a tablet (iPad Air Fifth Generation, Apple Inc. Cupertino, United States of America). The tablet was connected to the computer via a Wi-Fi connection.").
1[a]: receive signals representing a first at least one echocardiographic image;	The Voluson family products disclose a computer-implemented system for facilitating echocardiographic image analysis configured to *"receive signals representing a first at least one echocardiographic image."* The user moves the ultrasound probe (transducer) along the patient's body to capture diagnostic fetal echocardiographic images. When the ultrasound probe of the Voluson family products is in use, the SonoLyst AI algorithm continuously receives new echocardiographic image data, one of which can be a first echocardiographic image, as the ultrasound probe is moved around. When the AI recognizes a desired view and the quality score for that frame crosses a certain threshold, SonoLyst*live* can trigger an automatic image capture and store it, without the user having to freeze or press save. For example, see the following passages and/or figures, as well as all related disclosures:

See discussion with respect to **1[pre]** above.

Voluson SWIFT Brochure JB83443XXt (Sep 2020) at 3, 6:

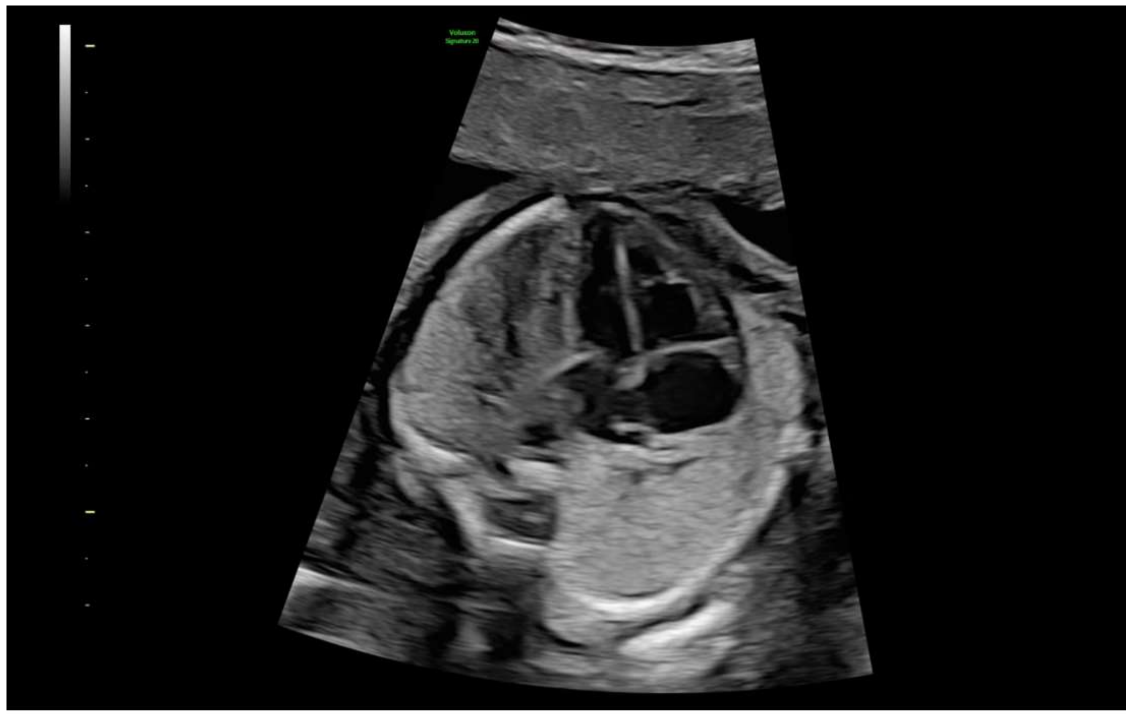
This is **SIMPLICITY**

Tap. Swipe. Pinch. With touchscreen operation and a select group of most frequently used hard keys, the Voluson SWIFT ultrasound system is easy to learn because it incorporates the same intuitive functionalities as the devices we use every day.

- Capture exceptional images effortlessly
- Move from standard 2D views to rendered 3D planes in just a few simple steps

Let's face it – you're busy. Voluson SWIFT is designed to help remove some of the obstacles that consistently slow you down. By leveraging the power of artificial intelligence, Voluson SWIFT allows you to save valuable time on acquisition, analysis, and reporting for both routine and detailed exams. Scan quickly and easily with SonoLyst;* a suite of image recognition tools that automatically identify fetal anatomy seen on standard views.

Voluson Signature 20 Product Page, https://www.gehealthcare.com/products/ultrasound/voluson/voluson-signature20

	Voluson Unity Architecture ## Get great images fast. Advanced beamforming capabilities work in harmony with expert-level probes to deliver faster processing speeds and frame rates for enhanced detail and contrast resolution, greater color quality and sensitivity, and exceptional 3D/4D.  22-week fetal heart Voluson Expert 22 Datasheet DOC2668404_JB19599XX (2022) at 2:

Product description
The Voluson Expert 22 is a premium imaging platform that combines extraordinary image quality with our superb volume ultrasound technology.

Voluson Expert 22 Product Page, https://www.gehealthcare.ca/en-ca/products/ultrasound/voluson/voluson-expert22/workflow-efficiency

Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 1-4:

1.1 About this system

Intended use

This system is intended for use by a qualified physician or sonographer for ultrasound evaluation in the following clinical application: Image acquisition for diagnostic purposes including measurements on acquired image.

Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 4-6:

Using the *Freeze* button

1. Press ***Freeze*** to freeze the image.
2. Pay attention to new functions available in Freeze Mode, such as new trackball functions.
3. Press ***Freeze*** again to continue live image data acquisition.

Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 4-8 to 4-9:

Cine

Cine images are constantly being stored by the system and are available for playback or manual review via cine. Cine can be viewed as a continuous loop via Cine Loop or manually frame by frame via the trackball.

1. Press **Freeze** to activate Cine.
2. Press **Img.** or **Cine** (lower trackball button) to switch between Image mode and Cine mode.
3. The Cine display (located at the lower right corner of the monitor) indicates which frame you are viewing of the whole loop, as well as the total acquired time of the loop. On the left side of the cine bar the programmed cine storage time for the P-key is shown.

Cine gaps: If a data-interruption occurred during scanning, this icon appears in the left upper corner when the cine cursor is 0.5sec before or after the marked cine gap (missing frames). However, in case that also a time-trace (e.g. PW-trace) is displayed, the cine gap (missing frames) is additionally indicated in the time-trace.

Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 5-50:

Vscan Air™ probe types	
Curved Linear probe	Sector Linear probe
	

Table 5-6 Vscan Air™ probe types

Vscan Air consists of a dual-headed probe (Vscan Air CL or Vscan Air SL), a wireless charging pad and a mobile app. The Vscan Air probe acquires and forms the ultrasound image, while the Vscan Air mobile app contains the software needed to use a mobile device as the display and the user interface control unit.

The Vscan Air probe acquires and forms the ultrasound image, sends the image data in real time through Wi-Fi to the ultrasound system, and the console displays the image. The ultrasound system provides the needed software to use the console as the display and the UI control unit.

Note *You need a WLan-Stick with BT to connect the probe to the Ultrasound system.*

Note *When Wifi is set as default and a Vscan Air probe is connected, the DICOM Spooler is on hold. DICOM Store images are kept in the Spooler and Worklist queries do not work until the Vscan Air probe is disconnected. After disconnection the DICOM Spooler is lifted shortly and the images are sent. Querying the Worklist then works again.*

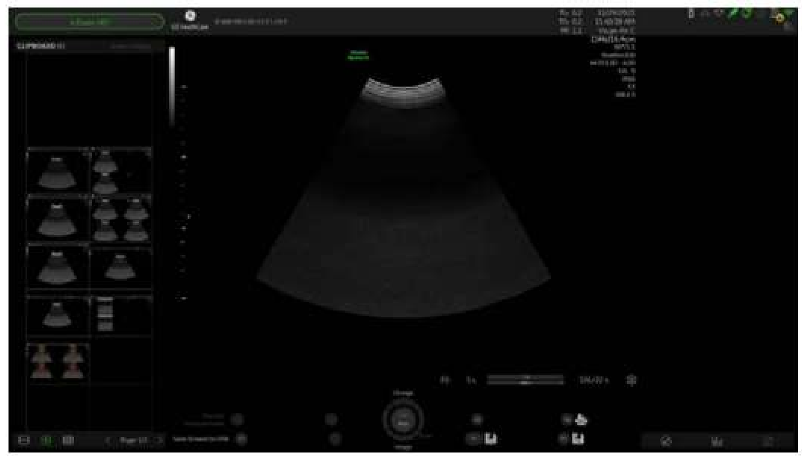
Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 5-53 to 5-54:

To begin scanning with the Vscan Air:

1. Select the Vscan Air probe icon on the touch panel

2. Select the Curved or Linear button on the touch panel.

3. Select an application and preset on the touch panel. The Vscan Air probe begins scanning and the system displays the images.



Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-8:

	Summary Opens the SonoLyst*live* 1st or 2nd Trimester worksheet. A green checkmark indicates that the capture count is reached. If the count is not reached or no view stored, no checkmark appears. Detailed criteria for available views are displayed. ***Auto Capture*** Switches between following levels: • green: only good views are captured • yellow: good views and middle views are captured • Manual: no ***Auto Capture*** active; manual action required • Background **Note** *This control is available in certain modes when the* ***Protocols*** *menu is closed. When a new exam is started, the selections are reset to the values defined in the system setup.* Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-13: The ***Auto Capture*** function for Scan Assistant depends on the system setup settings for SonoLyst*live*. If ***Auto Capture*** is enabled and a view o a Scan Assistant item is captured with SonoLyst*live* configured, it is possible to select between ***Accept*** (saves the image to the clipboard, the Scan Assistant item is checked automatically and configured annotations are inserted automatically) or ***Discard*** (the corresponding item is unchecked and deleted from the clipboard) on the trackball. With ***Auto Capture*** it is possible to switch between the levels: • green: only good views are captured • yellow: good views and middle views are captured • Manual: no ***Auto Capture*** active; manual action required • Background
1[b]: associate the first at least one echocardiographic image with a first view category of a plurality of predetermined echocardiographic image view categories;	The Voluson family products disclose a computer-implemented system for facilitating echocardiographic image analysis configured to *"associate the first at least one echocardiographic image with a first view category of a plurality of predetermined echocardiographic image view categories."* The Voluson family products use a Deep Convolutional Neural Network (DCNN) called SonoLyst AI to acquire fetal echocardiographic images then sort each image to its correct pre-defined standard view

	and grade the image for quality. The SonoLyst AI DCNN was trained with over 40,000 test images to a minimum acceptable algorithmic performance of 80% accuracy for grading and sorting. When the ultrasound probe of the Voluson family products is in use, the SonoLyst AI Algorithm continuously receives new echocardiographic image data as the ultrasound probe is moved around. The SonoLyst AI algorithm repeatedly evaluates and displays information indicating quality of the current image with respect to a specific view as new images are received. When an assessment is performed of an echocardiographic image that is displayed on the Voluson family product user interface, the Voluson family products associate the echocardiographic image with a view category (pre-defined standard view). For example, the SonoLyst AI algorithm outputs a quality assessment value for each input echocardiographic image in the form of a traffic light quality status indicator that is displayed beneath the output image with respect to the pre-defined standard view. This dynamic visualization guides the sonologist: if the circle is gray, the DCNN has not yet detected all required cardiac anatomy, prompting the user to adjust the probe; yellow indicates partial improvement; and a green light means the target view is optimized and can be accepted or automatically captured. Importantly, the continuous feedback loop helps the operator understand how to get to a better image: if the quality indicator is not improving, the sonologist knows to adjust the probe angle or location (since the system may be signaling missing anatomy), or to alter a setting like gain (if the anatomy is present but image is too dim/bright). We understand that the target view can either be selected by the user or automatically selected by the SonoLyst AI algorithm, such as when the assessment moves on to the next target view within a predetermined sequence of views (e.g., Scan Assistant). In either case, the SonoLyst AI algorithm knows the target view under which the current image is being assessed and continuously and automatically detects whether the image is close to the target view. For example, SonoLystIR is part of the suite of AI tools and has an image recognition algorithm that determines whether an item linked to a SonoLyst image has an associated view (i.e., "a depending plane") then displays the "view depending criteria" on the user interface. Because the SonoLyst AI algorithm knows to perform image assessment and displays information with respect to a target view, the Voluson family products "associate the first at least one echocardiographic image with a first view category of a plurality of predetermined echocardiographic image view categories." For example, see the following passages and/or figures, as well as all related disclosures:

	See discussion with respect to **1[a]** above. FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K220358) at 7-8: "SonoLyst: Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance • For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images. • The number of individual patients images were collected from: 5000+ exams • The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops. … Information about equipment and protocols used to collect images. • Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection. Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): 1. The images were curated (sorted and graded) by a single Sonographer 2. The images were sorted and graded by SonoLyst. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system.

	Description of how independence of test data from training data was ensured: • The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two." FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K231965) at 10-11: "Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. • Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population. • The verification for the SonoLyst 2nd Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features. • The verification of the SonoLystLive 2nd Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality. • The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher. … <u>Quantitative evaluation</u>: For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation … Information about the reference standard and dataset ("truthing process"): To ensure the quality of the curated data for verification, the following strategy is employed: 1. The images were curated (sorted and graded) by a single sonographer. 2. The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel.

	4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system." Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6: All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

<table>
<tr>
<td></td>
<td>
The output image of the SonoLystlive feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:

As SonoLystIR and SonoLystX are deeply integrated in the Scan Assistant workflow, please refer to ' Scan Assistant ' on page 7-10 for more details about the usage and setup.
All SonoLyst features use the following predefined standard views and depending criteria for the 1st Trimester:
</td>
</tr>
</table>

Pre-defined standard view	Criteria
Sagittal Fetus	Magnification Mid-sagittal Neutral position and orientation Crown visible Rump visible
Axial Head	Magnification Symmetrical hemispheres Full head circumference visible Choroid plexus visible Midline falx
Transthalamic Plane	Magnification Symmetrical hemispheres Two separate thalami Midline falx
Axial Orbits	Magnification Both orbits visible
Coronal Orbits	Magnification Both orbits visible Nose visible Both ears visible
Coronal Palate	Magnification Nasal bone Supermaxilla
Coronal Lips	Magnification Nasal tip Upper lip
4CH/Thorax	Magnification 4 chambers clearly visible
Cord Insertion	Magnification Cord inserted into abdominal wall
Axial Abdomen	Magnification Full abdominal circumference visible Stomach visible
Axial Kidneys	Magnification Both kidneys visible
Axial Bladder	Magnification Bladder visible
Coronal Kidneys	Magnification Both kidneys visible
Sagittal Spine	Magnification Vertebrae are aligned Skin edge
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible

Pre-defined standard view	Criteria
Hand	Magnification Hand visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible
Sagittal Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Sagittal Profile	Magnification Mid-sagittal Neutral position and orientation Nasal tip
Sagittal Brain	Magnification Brainstem Fourth ventricle Cisterna magna

All SonoLyst features use the following predefined standard views and depending criteria for the 2nd Trimester:

Pre-defined standard view	Criteria
Transventricular Plane	Magnification Brain symmetry Midline falx Lateral cerebral ventricles Choroid Plexus Cavum septum pellucidum No Cerebellum
Transthalamic Plane	Magnification Brain symmetry Midline falx Thalamus Cavum septum pellucidum No Cerebellum
Transcerebellar Plane	Magnification Brain symmetry Midline falx Cavum septum pellucidum Cerebellum Cisterna Magna
Profile	Magnification Nasal tip Forehead bone visible

Pre-defined standard view	Criteria
Orbits	Magnification Both orbits visible Symmetrical orbits
Nose/Lips	Magnification Nasal tip Nostrils Upper lip
4CH/Thorax	Magnification 4 Chambers visible Ventricular Septum Valves visible
LVOT	Continuity Ventricular Septum Magnification
RVOT	Vessel Bifurcation Magnification
3VV/3VT	3 Vessels Magnification
Abdomen (AC)	Magnification Stomach Umbilical vein Rib visible Circular/Shape No Kidney visible
Abdomen - Cord Insertion	Magnification Cord visible
Transverse Kidneys	Magnification Both kidneys visible
Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Femur	Magnification Angle of insonation Clear Diaphysis
Plantar Foot	Magnification Full foot visible
Hand	Magnification Clear hand visible
TA Cervix	Magnification Endocervical Canal Internal Os External Os
Spine Sacrum	Lumbar - alignment Lumbar - Skin line Magnification

Pre-defined standard view	Criteria
Spine Lumbar	Lumbar - alignment Lumbar - Skin line Magnification
Spine Thoracic	Thoracic - alignment Thoracic - Skin line Magnification
Spine Cervical	Cervical - alignment Cervical - Skin line Magnification
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible

Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-10 to 7-13:

7.2 Scan Assistant

The Scan Assistant is a tool with guidelines for sonographers. It offers specific factory checklists containing the anatomical structures or organs to be examined in certain examinations and so prevents from missing important items. It is possible to customize these checklists and also to set up new lists. Additionally the Scan Assistant can be used to activate a specific measurement for an exam item as well as annotate, save or send the image for documentation purposes.


SONOLYSTIR MID-TRIM
0 / 32 items completed
SonoLystIR: found
General
Head
Face
Lateral Ventricle
Cerebellum/ CM
DESCRIPTION
Measure cerebellum and cisterna magna
MEASUREMENTS
Cereb.:
CM:
FETAL ANATOMY
Cerebellum: visualized
Cisterna magna:
SONOLYSTX
Transcerebellar Plane
Brain symmetry
Cavum septum pellucidum
Cerebellum
Cisterna Magna
Midline falx
Magnification
0 / 32

Following sections/items are displayed:

- list name
- progress viewer / Pause

Note *If Scan Assistant is active, the progress symbol of Scan Assistant is shown in the tab area of the Flexible Display area. It is possible to display and hide the Flexible Display area by pressing on the progress symbol. The left number is the number of images which reached the capture count, the right number is the number of possible views.*

- selected group (if available)
- selected item
- description area
- measurement result area
- Fetal Anatomy (OB) / Findings (GYN) area
- SonoLystX area (only visible when a SonoLystX item was found and SonoLystX view is activated on the touch panel)

Following icons are displayed:

1. is displayed at the measurement header when a measurement is required.
2. is displayed at the description header when the current item is an optional item.
3. is displayed at the ***Fetal Anatomy (OB) / Findings (GYN)*** header when a fetal anatomy item (OB) / finding (GYN) is required.
4. is displayed if an SonoLyst linked item is active.

	Using the Scan Assistant 1. Start the exam by scanning the first item of the first category. 2. When the item is scanned, freeze the image and press the P-Button configured for confirming. **Note** *It is also possible to check/uncheck an item manually by tapping at the check area (circle).* 3. The item is checked and the next item turns green. 4. Scan all items of the category and move to the next category. If the items cannot be scanned in the predefined order, use the arrow keys on the keyboard or on the touch panel to change between items and/or categories. 5. Press ***End Exam*** to finish. A summary of the Scan Assistant is displayed on the screen showing all (not) examined categories and items.

Figure 7-5 Scan Assistant with SonoLyst (example)

If an item is linked to a SonoLyst image and the system finds a depending plane, this item is displayed on the touch panel.

The items linked to SonoLyst are labeled accordingly with a badge (only available when the option is set). SonoLystX shows the corresponding pictogram and criteria.

It is also possible to switch the SonoLystIR image recognition algorithm on and off. When the image is zoomed in or out or another image is selected from the cine buffer, the SonoLyst algorithm is restarted (if switched on).

Instead of the group area all SonoLystIR view depending criteria are displayed. It is possible to set a criterion to found/not found manually by tapping onto the circle.

	Starting/selecting Scan Assistant lists can also be done by pressing ***Protocols*** on the touch panel. Three different states are available: 1. No Scan Assistant or Assessment Tool is started: Select the desired tool or list and press ***Start***. The menu closes automatically. 2. Already ongoing Scan Assistant list or Assessment Tool: • The ongoing Assessment tool list is paused. Press ***Continue*** to go on. Press ***None*** to deactivate the currently ongoing Scan Assistant list without losing data. • Select a Scan Assistant list and press ***Start***. The menu closes automatically. • Press ***Discard*** to clear the currently selected list or tool. Confirm the clearing of data (***Yes***) or decline (***No***). 3. No exam started: A message appears together with the ***Start Exam*** button. Press the button to open the Patient Information Dialog. The ***Auto Capture*** function for Scan Assistant depends on the system setup settings for SonoLyst*live*. If ***Auto Capture*** is enabled and a view o a Scan Assistant item is captured with SonoLyst*live* configured, it is possible to select between ***Accept*** (saves the image to the clipboard, the Scan Assistant item is checked automatically and configured annotations are inserted automatically) or ***Discard*** (the corresponding item is unchecked and deleted from the clipboard) on the trackball. With ***Auto Capture*** it is possible to switch between the levels: • green: only good views are captured • yellow: good views and middle views are captured • Manual: no ***Auto Capture*** active; manual action required • Background Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 13-45 to 13-47:

13.13 Deep Learning Based Features

Note *Some of these deep learning based features are not available in all countries:*

- SonoLystIR
- SonoLystIR 1st Trimester
- SonoLystX
- SonoLystX 1st Trimester
- SonoLyst*live*
- SonoLyst*live* 1st Trimester
- Sono*Biometry* CRL
- SonoPelvicFloor
- SonoCNS
- Sono*Biometry* Cereb, Vp, CM
- FetalHS
- SonoAVC™*follicle* 2.0
- SonoAVC™*follicle* Auto Caliper
- Fibroid Mapping
- AutoSpine
- SonoPF2D
- AnalSphincter

The application of deep learning based features requires caution by the user and an informed decision on the usage of the specific feature. Therefore, all caution information and performance testing for each feature are summarized in this chapter.

Performance Testing for SonoLyst:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystIR	80% accuracy	41936

Performance Testing for SonoLystIR 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystIR 1st Trimester	80% accuracy	5271

Performance Testing for SonoLystX:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystX	80%	9998

Performance Testing for SonoLystX 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystX 1st Trimester	80%	2400

Performance Testing for SonoLyst*live*:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLyst*live*	80% accuracy	5623

Performance Testing for SonoLyst*live* 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLyst*live* 1st Trimester	80%	6000

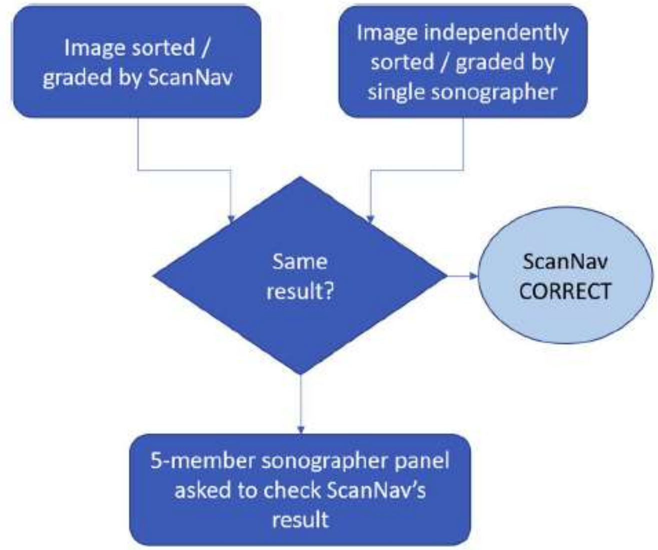
Further, Defendants' SonoLyst AI software incorporates Intelligent Ultrasound's ScanNav AI technology, and thus is based on ScanNav's DCNN architecture and associated algorithms. *See*

	https://polaris.brighterir.com/public/intelligent_ultrasound/news/rns/story/xq64o7r ("Intelligent Ultrasound (AIM: MED), the artificial intelligence (AI) based ultrasound software and simulation company, announces that GE Healthcare's Voluson SWIFT ultrasound machine that incorporates GE Healthcare's SonoLyst software with Intelligent Ultrasound's ScanNav Assist AI technology, has received 510(k) clearance from the FDA for sale in the USA."). The ScanNav AI DCNN was developed using 479,322 images obtained from 48,161 routine mid-trimester scans. To train the system, experienced sonologists manually determined whether a subset of images was correct (high quality) for each of the 19 required fetal views (i.e., pre-defined standard views). The resulting algorithm was then assessed using a separate set of 38,840 test images obtained from 4,284 scans, where the image was scored as correct if 2 or more (out of 5) independent sonologists agreed with the image quality. ScanNav AI achieved a 92.2% standard deviation on image quality as compared to sonologists. Based on this training, the Voluson family products "associate the first at least one echocardiographic image with a first view category of a plurality of predetermined echocardiographic image view categories." For example, see the following passages and/or figures, as well as all related disclosures: Yangdi Xu et al., *Simulating realistic fetal neurosonography images with appearance and growth change using cycle-consistent adversarial networks and an evaluation*, Journal of Medical Imaging (Sep⁄Oct 2020), Vol. 7(5) at 4: "ScanNav® (Intelligent Ultrasound Ltd., Milton Park, Abingdon, United Kingdom) is a pre-commercial deep learning-based automatic image analysis software application that assesses the quality of second-trimester scans according to the UK FASP guidelines. It is able to accurately detect different structures of a standard plane in large scale. It had been designed and trained by analzsing thousands of clinical second-trimester ultrasound images to label and grade images. Details of the underpinning algorithms and data used to build the quality assessment model are proprietary. However, we assume that the quality of software-derived annotation labels is at the same level as a typical experienced sonographer. This assumption is confirmed to be valid for our data later in this article. Under this assumption, ScanNav® is treated as equivalent to an experienced sonographer in ultrasound image classifications. It can assess and compare hundreds of real and simulated second-trimester scans efficiently and quickly (which is something that is tedious and costly to achieve if the task is performed by human experts)."

	E.H. Bradburn et al., *OC10.05 An artificial intelligence system that can correctly identify fetal ultrasound imaging planes throughout gestational age*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28-29. **Methods:** Anonymised fetal ultrasound images, acquired at 15 to 40 weeks of gestation, from a large image database were analysed in this study. This included images of head circumference (HC), abdominal circumference (AC), femur length (FL), amniotic fluid index (AFI) and miscellaneous images. An AI algorithm (ScanNav, trained primarily on routine anatomy scans from 18-24 weeks), was applied to each image and categorised it into one of five categories: HC, AC, FL, AFI and others. A random ten percent per view of all images were manually reviewed by one experienced clinician to determine the accuracy of this classification. The performance of the AI algorithm, according to the gestational age at the time of the scan, was assessed. **Results:** Over 450,000 images were assessed by ScanNav, and a random 10% (45,036 images) underwent clinical review. The accuracy of the AI algorithm in categorising the images into standard biometry planes (HC, AC, FL and AFI) was 99.1%. This was 99.6%, 99.1%, 97.9% and 99.9% for HC, AC, FL and AFI, respectively. Across all categories the algorithm performed best between 20+0 and 35+6 weeks, with an accuracy that remained stable throughout that gestational age range (97%). There was a slight drop in accuracy below 20 weeks and above 36 weeks, to 94% and 96% respectively. **Conclusions:** Although trained primarily on routine anatomy scans from 18-24 weeks, the ScanNav AI algorithm is 99.1% accurate in image categorisation of basic biometry planes. Accuracy was maintained over a very broad range of gestational ages. This may reflect that clinically these standard planes remain consistent in appearance throughout gestation. Improvement at the extremes of GA may be possible by further algorithm training.

	E.H. Bradburn et al., *OC10.04 Estimating fetal gestational age based on ultrasound image characteristics using artificial intelligence*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28. **Methods:** Quality assessed ultrasound images of head circumference (HC) and abdominal circumference (AC) were used from a multicentre study database of women with known GA (CRL performed < 14 weeks) who underwent serial ultrasound examinations from 15 to 40 weeks. We split data randomly into 67.5% training, 7.5% validation and 25% testing sets. We developed and tested an artificial intelligence (AI) algorithm using a regression neural network to estimate the GA, based on image characteristics only without measurement information. Mohammad Yaqub et al., *491 ScanNav® audit: an AI-powered screening assistant for fetal anatomical ultrasound*, American Journal of Obstetrics & Gynecology, Supplement to February 2021, at S312.

		OBJECTIVE: To develop and evaluate a real-time Artificial Intelligence (AI) based system to automatically keep track of acquired images; and check that the images conform to imaging protocol standards, in essence, replacing a human peer reviewer. **STUDY DESIGN:** We developed an AI system (ScanNav) which automatically (1) checks the completeness of the imaging record during fetal anomaly screening, ensuring all 19 required fetal views are recorded; and (2) assesses the quality of these images (in this case according to the guidelines of ISUOG). First, AI algorithms were trained on images manually evaluated by a pool of experienced sonologists and using state-of-the-art deep learning technology. The resulting algorithm was then assessed on a separate testing set; it was deemed correct if 2 or more (from a panel of 5) independent sonologists agreed with its decision. Due to the lack of expert agreement for "marginal" images, it was deemed appropriate to include as agreement such a 2:3 panel split. **RESULTS:** The system was developed on 479,322 anonymised images from 48,161 routine mid-trimester scans. Agreement between ScanNav and the sonologist panel was performed on an independent set of 38,840 images (4,284 scans). For scan completeness the mean (standard deviation) of agreement between ScanNav and the sonologists was 93.5% (±5.6%); for image quality it was 92.2% (±4.7%). The system processes 11 frames per second on a PC with an RTX4000 GPU.



# Sonographers agree with ScanNav	ScanNav
0	INCORRECT
1	INCORRECT
2	CORRECT
3	CORRECT
4	CORRECT
5	CORRECT

T.G. Day et al., *Artificial Intelligence to Assist in the Screening Fetal Anomaly Ultrasound Scan (PROMETHEUS): A Randomized Controlled Trial*, medRxiv, at 41-42 (2024) ("Therefore, we devised a method to automatically regress a quality score for each image of each standard plane and presented the image with the highest predicted quality. We trained a CNN to predict the clinical quality of images classified as valid standard plane. This method could then be incorporated into the clustering step for future versions of the AI tool.

	T.G. Day et al., *Artificial Intelligence to Assist in the Screening Fetal Anomaly Ultrasound Scan (PROMETHEUS): A Randomized Controlled Trial*, medRxiv, at 41-42 (2024) ("Standard plane classification We used the data and annotations described above to train an AI model to classify for fetal standard planes. We used the SonoNEXT architecture as previously described and trained it on the training labels described above, as well as 'background' frames corresponding to no standard plane. This classifier obtained >90% top-1 classification accuracy in the iFIND test dataset (taken from scans with trailing digit 8-9). We named this model SonoNEXT.")
1[c]: determine, based on the first at least one echocardiographic image and the first view category, a first quality assessment value representing a view category specific quality assessment of the first at least one echocardiographic image;	The Voluson family products disclose a computer-implemented system for facilitating echocardiographic image analysis configured to *"determine, based on the first at least one echocardiographic image and the first view category, a first quality assessment value representing a view category specific quality assessment of the first at least one echocardiographic image."* The Voluson family products determine a view category-specific "first quality assessment value" by the SonoLyst AI algorithm that is trained with ideal echocardiographic images, for each cardiac view including the first view category, that have been associated with transducer position and labeled by expert sonologists for image quality and correctness. As described above for 1[b], each received image is assessed with respect to a target view. Based on a received image and the target view, the SonoLyst AI algorithm uses a neural network trained with quality related labels to compare the current image to the ideal image for the view category of the target view. The SonoLyst AI algorithm then outputs a quality assessment value for each input echocardiographic image in the form of a traffic light quality status indicator that is displayed beneath the output image with respect to the pre-defined standard view. SonoLyst AI defines its training process as a method for sorting and grading ultrasound images, where (i) sorting means categorizing an image into (i.e., predicting) the correct standard view and (ii) grading means scoring an image based on its correctness (accuracy of standard view prediction) and image quality. As discussed in 1[b] above, the SonoLyst AI algorithm was trained to automatically assess the quality of acquired ultrasound images by checking whether they adhere to the imaging protocols for pre-defined standard views. Per the '591 Patent, to determine a quality assessment value based on an image (and its view category) means to compute a quantitative measure of that image's quality or adequacy for its particular view. *See* '591 Patent, 14:58-15:7. For example, one grading criteria for the SonoLyst AI algorithm includes whether certain anatomical structures are present and visible for the image in

	each view. The SonoLyst DCNN training images were used for quantitative evaluation which, in combination with the concepts of grading and scoring, indicate determining a quality assessment value that is used to display a traffic light quality status indicator (gray, yellow, or green) beneath the output image. A green status indicator communicates to the user that the detected view in the output image fully adheres to the protocol criteria for that pre-defined standard view. This is consistent with the '591 Patent, where a high quality assessment value denotes good positioning of the transducer and optimal image capture parameters. *See* '591 Patent, 5:38-45 ("The operator may make such adjustments until a high quality assessment value is provided on the display 15, for example, at which point the operator may be confident that the echocardiographic images captured are suitable for subsequent quantified clinical measurement of anatomical features and/or to assist in diagnosing a medical condition or a characteristic of the heart."). For example, see the following passages and/or figures, as well as all related disclosures: *See* discussion with respect to **1[a]** and **1[b]** above. FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K220358) at 7-8: "<u>SonoLyst</u>: Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance • For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images. • The number of individual patients images were collected from: 5000+ exams • The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops. … Information about equipment and protocols used to collect images. • Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection.

	Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): 1. The images were curated (sorted and graded) by a single Sonographer 2. The images were sorted and graded by SonoLyst. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system. Description of how independence of test data from training data was ensured: • The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two." FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K231965) at 10-11: "Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. • Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population. • The verification for the SonoLyst 2nd Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features. • The verification of the SonoLystLive 2nd Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality. • The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher. …

	Quantitative evaluation: For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation … Information about the reference standard and dataset ("truthing process"): To ensure the quality of the curated data for verification, the following strategy is employed: 1. The images were curated (sorted and graded) by a single sonographer. 2. The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system." Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6:

All SonoLyst features are workflow supporting features and are all based on Deep Learning technology:

- SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views.

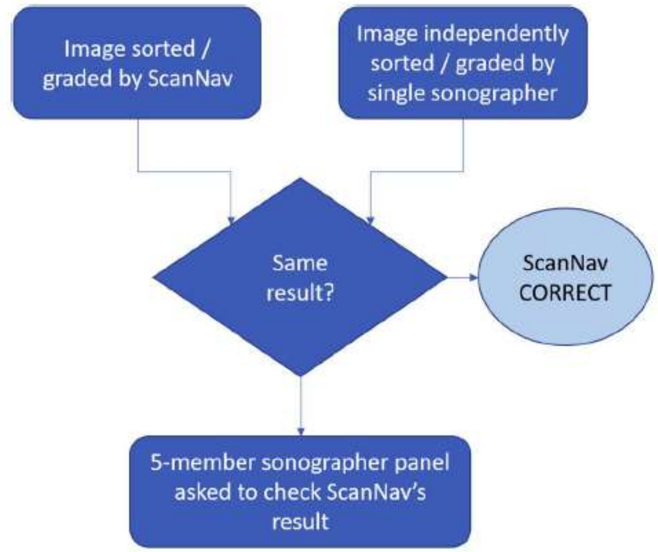
- SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria).

- SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

  The output image of the SonoLyst*live* feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:

	Yangdi Xu et al., *Simulating realistic fetal neurosonography images with appearance and growth change using cycle-consistent adversarial networks and an evaluation*, Journal of Medical Imaging (Sep⁄Oct 2020), Vol. 7(5) at 4: "ScanNav® (Intelligent Ultrasound Ltd., Milton Park, Abingdon, United Kingdom) is a pre-commercial deep learning-based automatic image analysis software application that assesses the quality of second-trimester scans according to the UK FASP guidelines. It is able to accurately detect different structures of a standard plane in large scale. It had been designed and trained by analzsing thousands of clinical second-trimester ultrasound images to label and grade images. Details of the underpinning algorithms and data used to build the quality assessment model are proprietary. However, we assume that the quality of software-derived annotation labels is at the same level as a typical experienced sonographer. This assumption is confirmed to be valid for our data later in this article. Under this assumption, ScanNav® is treated as equivalent to an experienced sonographer in ultrasound image classifications. It can assess and compare hundreds of real and simulated second-trimester scans efficiently and quickly (which is something that is tedious and costly to achieve if the task is performed by human experts)." *491 ScanNav® audit: an AI-powered screening assistant for fetal anatomical ultrasound*, Mohammad Yaqub et al., American Journal of Obstetrics & Gynecology, Supplement to February 2021, at S312.

		OBJECTIVE: To develop and evaluate a real-time Artificial Intelligence (AI) based system to automatically keep track of acquired images; and check that the images conform to imaging protocol standards, in essence, replacing a human peer reviewer. **STUDY DESIGN:** We developed an AI system (ScanNav) which automatically (1) checks the completeness of the imaging record during fetal anomaly screening, ensuring all 19 required fetal views are recorded; and (2) assesses the quality of these images (in this case according to the guidelines of ISUOG). First, AI algorithms were trained on images manually evaluated by a pool of experienced sonologists and using state-of-the-art deep learning technology. The resulting algorithm was then assessed on a separate testing set; it was deemed correct if 2 or more (from a panel of 5) independent sonologists agreed with its decision. Due to the lack of expert agreement for "marginal" images, it was deemed appropriate to include as agreement such a 2:3 panel split. **RESULTS:** The system was developed on 479,322 anonymised images from 48,161 routine mid-trimester scans. Agreement between ScanNav and the sonologist panel was performed on an independent set of 38,840 images (4,284 scans). For scan completeness the mean (standard deviation) of agreement between ScanNav and the sonologists was 93.5% (±5.6%); for image quality it was 92.2% (±4.7%). The system processes 11 frames per second on a PC with an RTX4000 GPU.



# Sonographers agree with ScanNav	ScanNav
0	INCORRECT
1	INCORRECT
2	CORRECT
3	CORRECT
4	CORRECT
5	CORRECT

The grading criteria or values derived based on grading criteria (e.g., quantitative evaluation) can indicate quality. Answer ¶¶ 38-41. The ’591 Patent discloses that quality assessment values, used to train the neural network, can be derived from “features such as centering, depth, gain, axis, focus, frequency or another parameter optimization feature or image capture parameter.” ’591 Patent, 14:58-15:1.

UBC contends that the accused system literally satisfies this element but, to the extent Defendants do not literally infringe this claim element requiring determining a “quality assessment value,” Defendants

	infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. The function of determining a quality assessment value is to inform the operator when the probe is at an ideal position for capturing images for a given view and/or to have the system automatically capture images when the probe is in that position. The traffic light quality status indicator performs the same function because it turns green to inform the operator when the right view is detected and the image fully adheres to the required protocol. Further, it performs it in the same way—by determining whether the probe is at the ideal position for capturing an image for the relevant view category. Finally, the result is the same—the system guides the user to position the probe at the ideal position for capturing an image of that view and/or the system automatically captures an image at that position. Since the traffic light quality status indicator indicates the quality of the assessed ultrasound image, Defendants infringe any claim element including a "quality assessment value" under the doctrine of equivalents. For example, see the following passages and/or figures, as well as all related disclosures: See discussion with respect to **1[a], 1[b], and 1[c]** above. Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-6 to 7-9:

Figure 7-1 SonoLystlive monitor display (example)

If configured, the last captured image is displayed on the monitor together with the detected view name. A message appears when an image is captured and the following symbols (detected view status) are displayed:

Indicator	Description
	View detected
	View detected, partially protocol adherent
	View detected, fully protocol adherent

In the Flexible Display area all selected views for detection are displayed. Views deactivated in the system setup are disabled. The view icon contains a capture counter. As soon as the capture count is reached, the counter gets a checkmark and the view icon is dimmed. Furthermore in ***Freeze*** mode a SonoLystX section is visible displaying the view (if detected) depending on SonoLystX criteria.

Flat list: all selected views for detection are displayed. Views deactivated in the system setup are disabled. Each view contains a capture counter. As soon as the capture count is reached, the counter gets a checkmark.

If SonoLyst*live* is active, the progress symbol of SonoLyst*live* is shown in the tab area of the Flexible Display area. It is possible to display and hide the Flexible Display area by pressing on the progress symbol. The left number is the number of images which reached the capture count, the right number is the number of possible views.

Note *If more than one Spine or Extremity view is detected, all of the views are displayed next to the hexagon.*

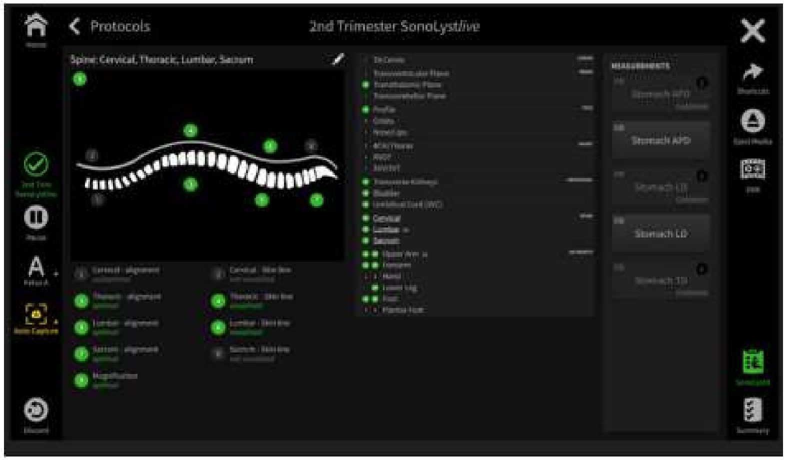


Figure 7-2 SonoLystlive Protocol touch menu (example)

The touch menu is opened by pressing ***1st Trimester SonoLystlive*** or ***2nd Trimester SonoLystlive***. It contains SonoLystX (can be switched on/off by selecting the corresponding button) and measurements (if configured).

Summary

Opens the SonoLyst*live* 1st or 2nd Trimester worksheet. A green checkmark indicates that the capture count is reached. If the count is not reached or no view stored, no checkmark appears. Detailed criteria for available views are displayed.

Auto Capture

Switches between following levels:

- green: only good views are captured
- yellow: good views and middle views are captured
- Manual: no ***Auto Capture*** active; manual action required
- Background

Note *This control is available in certain modes when the **Protocols** menu is closed. When a new exam is started, the selections are reset to the values defined in the system setup.*

Pause / ***Continue***

Pause / ***Continue*** switches between live mode and pause state. When SonoLyst*live* is paused, a blue infobox is displayed on the main screen and within the ***Protocols*** menu on the touch panel.

Fetus

If more than one fetus is available, it is possible to switch between the fetuses. All captured views (except Cervix) belong to the selected fetus, capture counts are updated automatically.

Discard

Discard enables to delete images. Depending on whether unaccepted images are available or not, a message appears asking for confirmation. Select ***Yes*** to discard the images and close the dialog or ***No*** to continue without deleting.

Edit

A press onto ***Edit*** (pencil icon) opens a new window in which it is possible to change views configured in the system setup and/or detected criteria. All editable criteria can be changed by tapping onto them. If configured, a ***Left*** / ***Right*** selection is possible. Press ***Set*** to save the changes made and to close the window or ***Cancel*** to leave the menu without saving changes.

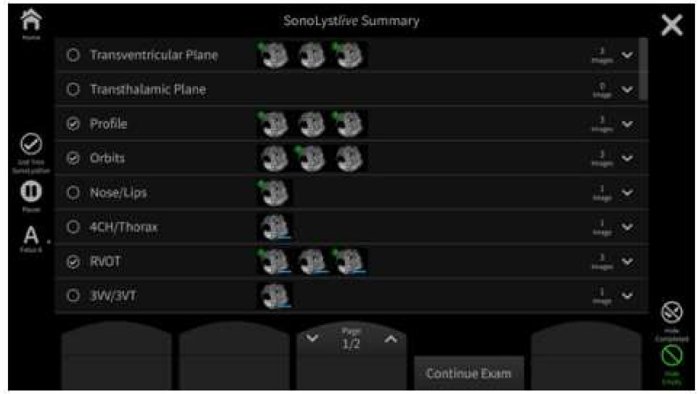


Figure 7-3 SonoLystlive Summary (example)

A tap onto a row displays the depending images of that view, a tap onto an image displays the depending SonoLystX menu. A circle with a checkmark indicates that the capture count is reached. As most of the controls are the same as in SonoLystX, only the summary page specific controls are described here:

Continue Exam	Closes the dialog and goes back to the exam.
Review Images	Opens the ***Exam Review*** to review and / or delete images.

	Accept & End Exam All images are accepted, the dialog and the exam are closed. ***Hide Completed*** When selected all completed views are hidden. ***Hide Empty*** When selected all empty views are hidden. ***Hide Accepted*** When selected all accepted images are hidden. Trackball buttons: ***SonoLystlive / Pause*** Toggles between SonoLyst*live* and ***Pause***. ***Discard*** Deletes the image from the clipboard. ***Accept*** Accepts the image. ***Left/Right/Both*** A left/right view is detected. Accepts the image by selecting the correct side/both sides and adds it to the configured annotation .The corresponding icon in the Flexible Display area increases the capture count. ***Measure*** Saves and reloads the image. The first measurement of the next incomplete measurement is started automatically. It is possible to perform all configured measurements for the auto-captured view. **Note** *Only available when* ***Auto capture views with measurement*** *is selected in the system setup.* Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-13: The ***Auto Capture*** function for Scan Assistant depends on the system setup settings for SonoLyst*live*. If ***Auto Capture*** is enabled and a view o a Scan Assistant item is captured with SonoLyst*live* configured, it is possible to select between ***Accept*** (saves the image to the clipboard, the Scan Assistant item is checked automatically and configured annotations are inserted automatically) or ***Discard*** (the corresponding item is unchecked and deleted from the clipboard) on the trackball. With ***Auto Capture*** it is possible to switch between the levels: • green: only good views are captured • yellow: good views and middle views are captured • Manual: no ***Auto Capture*** active; manual action required • Background

	T.G. Day et al., *Artificial Intelligence to Assist in the Screening Fetal Anomaly Ultrasound Scan (PROMETHEUS): A Randomized Controlled Trial*, medRxiv, at 41-42 (2024) ("Therefore, we devised a method to automatically regress a quality score for each image of each standard plane and presented the image with the highest predicted quality. We trained a CNN to predict the clinical quality of images classified as valid standard plane. This method could then be incorporated into the clustering step for future versions of the AI tool. Quality dataset labelling We generated training datasets for each of our models from the outputs of the SonoNEXT standard-plane detection model. We randomly selected a single image for each standard plane from the test set of the SonoNEXT model (n=1457 subjects). There was no pre-selection step: the random selection intentionally included SonoNEXT misclassifications and poor-quality views to be representative of the images that would be passed to the quality models during scanning. A set of objective clinical criteria were devised to evaluate the quality of each standard plane, decided by a committee of clinical experts. In addition to these criteria, we also asked labellers whether each image was overall "clinically acceptable". We also asked them to rate the subjective quality of each image on a scale of 1-10. Quality model training We trained models using the same SonoNEXT architecture that we used for plane-classification to evaluate the quality of images. We modified the output layer to predict each feature that had been labelled for this standard plane, turning the network into a multitask classification network. We used cross-entropy as the loss function in training.") T.G. Day et al., *Artificial Intelligence to Assist in the Screening Fetal Anomaly Ultrasound Scan (PROMETHEUS): A Randomized Controlled Trial*, medRxiv, at 42-43 (2024) ("Image scoring and presentation After each image for a standard plane was processed through our quality models, we selected 9 images to present to the sonographer to make a manual selection of the best one. To select the images to

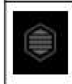
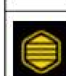
	present, we calculated two scores for each image, which we called the quality score and the diversity score. The quality score is a single score using a composite measure derived from the output vector for each image. Not all of the features labelled and predicted by the network are equally important: some should be given a higher weight when determining an image's quality. To quantify the importance of each feature, we calculated a multivariate logistic regression to predict whether each image was rated "clinically acceptable" based on all the other labelled features. This had a predictive accuracy of >95% for all standard planes. The quality score was therefore a weighted sum of the predicted features, weighted by the regressed weights associated with that plane. Each image had a quality score calculated in this way. In a single scan, the images with the highest quality score are usually visually very similar to each other and are often consecutive frames acquired very close to each other. Presenting the images with the highest quality score for the sonographer to select from would only offer a very restricted choice. To address this, we added a diversity score, designed to be higher for images that are more different from those already presented…") T.G. Day et al., *Artificial Intelligence to Assist in the Screening Fetal Anomaly Ultrasound Scan (PROMETHEUS): A Randomized Controlled Trial*, medRxiv, at 41-42 (2024) ("Standard plane classification We used the data and annotations described above to train an AI model to classify for fetal standard planes. We used the SonoNEXT architecture as previously described and trained it on the training labels described above, as well as 'background' frames corresponding to no standard plane. This classifier obtained >90% top-1 classification accuracy in the iFIND test dataset (taken from scans with trailing digit 8-9). We named this model SonoNEXT.")
1[d]: produce signals representing the first quality assessment value for causing the first quality assessment value to be associated with the first at least one echocardiographic image;	The Voluson family products disclose a computer-implemented system for facilitating echocardiographic image analysis configured to *"produce signals representing the first quality assessment value for causing the first quality assessment value to be associated with the first at least one echocardiographic image."* The Voluson family products' first quality assessment value, as discussed in claim **1[c]** above, is represented on the user interface of the LCD monitor as a quality status indicator. The status indicator is a traffic light-style icon showing the quality of the current echocardiographic image (based on

	grading criteria) relative to a known view category (i.e., pre-defined standard views). When the SonoLyst AI algorithm detects a diagnostic quality image, the status indicator turns green. For example, see the following passages and/or figures, as well as all related disclosures: See discussion with respect to **1[a]**, **1[b]**, and **1[c]** above. Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2: All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

	The output image of the SonoLyst*live* feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:  Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-6 to 7-9:

Figure 7-1 SonoLystlive monitor display (example)

If configured, the last captured image is displayed on the monitor together with the detected view name. A message appears when an image is captured and the following symbols (detected view status) are displayed:

Indicator	Description
	View detected
	View detected, partially protocol adherent
	View detected, fully protocol adherent

In the Flexible Display area all selected views for detection are displayed. Views deactivated in the system setup are disabled. The view icon contains a capture counter. As soon as the capture count is reached, the counter gets a checkmark and the view icon is dimmed. Furthermore in ***Freeze*** mode a SonoLystX section is visible displaying the view (if detected) depending on SonoLystX criteria.

Flat list: all selected views for detection are displayed. Views deactivated in the system setup are disabled. Each view contains a capture counter. As soon as the capture count is reached, the counter gets a checkmark.

If SonoLyst*live* is active, the progress symbol of SonoLyst*live* is shown in the tab area of the Flexible Display area. It is possible to display and hide the Flexible Display area by pressing on the progress symbol. The left number is the number of images which reached the capture count, the right number is the number of possible views.

Note *If more than one Spine or Extremity view is detected, all of the views are displayed next to the hexagon.*

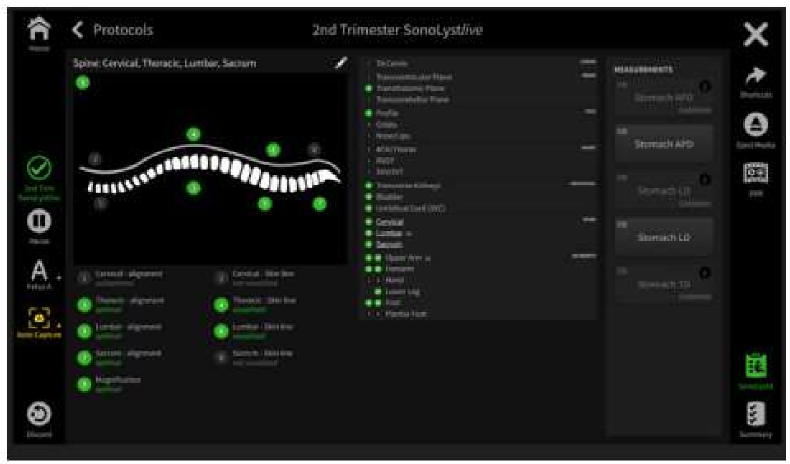


Figure 7-2 SonoLystlive Protocol touch menu (example)

The touch menu is opened by pressing ***1st Trimester SonoLystlive*** or ***2nd Trimester SonoLystlive***. It contains SonoLystX (can be switched on/off by selecting the corresponding button) and measurements (if configured).

Summary	Opens the SonoLyst*live* 1st or 2nd Trimester worksheet. A green checkmark indicates that the capture count is reached. If the count is not reached or no view stored, no checkmark appears. Detailed criteria for available views are displayed.
Auto Capture	Switches between following levels: • green: only good views are captured • yellow: good views and middle views are captured • Manual: no ***Auto Capture*** active; manual action required • Background **Note** *This control is available in certain modes when the **Protocols** menu is closed. When a new exam is started, the selections are reset to the values defined in the system setup.*
Pause / ***Continue***	***Pause*** / ***Continue*** switches between live mode and pause state. When SonoLyst*live* is paused, a blue infobox is displayed on the main screen and within the ***Protocols*** menu on the touch panel.
Fetus	If more than one fetus is available, it is possible to switch between the fetuses. All captured views (except Cervix) belong to the selected fetus, capture counts are updated automatically.
Discard	***Discard*** enables to delete images. Depending on whether unaccepted images are available or not, a message appears asking for confirmation. Select ***Yes*** to discard the images and close the dialog or ***No*** to continue without deleting.
Edit	A press onto ***Edit*** (pencil icon) opens a new window in which it is possible to change views configured in the system setup and/or detected criteria. All editable criteria can be changed by tapping onto them. If configured, a ***Left*** / ***Right*** selection is possible. Press ***Set*** to save the changes made and to close the window or ***Cancel*** to leave the menu without saving changes.

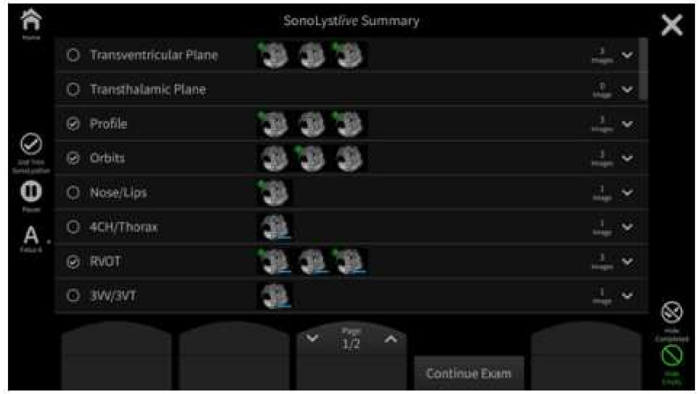


Figure 7-3 SonoLystlive Summary (example)

A tap onto a row displays the depending images of that view, a tap onto an image displays the depending SonoLystX menu. A circle with a checkmark indicates that the capture count is reached. As most of the controls are the same as in SonoLystX, only the summary page specific controls are described here:

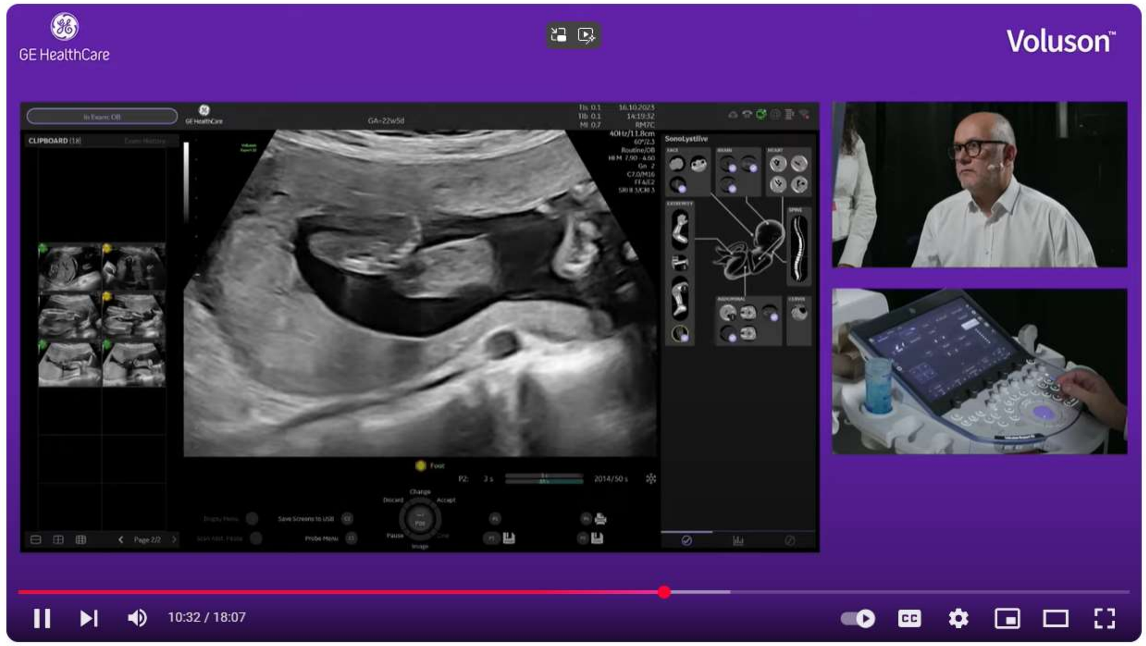
Continue Exam	Closes the dialog and goes back to the exam.
Review Images	Opens the ***Exam Review*** to review and / or delete images.

	<table><tr><td>***Accept & End Exam***</td><td>All images are accepted, the dialog and the exam are closed.</td></tr><tr><td>***Hide Completed***</td><td>When selected all completed views are hidden.</td></tr><tr><td>***Hide Empty***</td><td>When selected all empty views are hidden.</td></tr><tr><td>***Hide Accepted***</td><td>When selected all accepted images are hidden.</td></tr></table> Trackball buttons: <table><tr><td>***SonoLystlive* / *Pause***</td><td>Toggles between SonoLyst*live* and ***Pause***.</td></tr><tr><td>***Discard***</td><td>Deletes the image from the clipboard.</td></tr><tr><td>***Accept***</td><td>Accepts the image.</td></tr><tr><td>***Left*/*Right*/*Both***</td><td>A left/right view is detected. Accepts the image by selecting the correct side/both sides and adds it to the configured annotation .The corresponding icon in the Flexible Display area increases the capture count.</td></tr><tr><td>***Measure***</td><td>Saves and reloads the image. The first measurement of the next incomplete measurement is started automatically. It is possible to perform all configured measurements for the auto-captured view. **Note** *Only available when **Auto capture views with measurement** is selected in the system setup.*</td></tr></table> GE Healthcare, *The Future is Now. How AI can Change the Practice of Obstetric Ultrasound.* (Sep 5, 2024), https://www.youtube.com/watch?v=6kFi6RNjqnE (demonstrating SonoLyst*live* functionality)

	GE HealthCare GA=22w5d CLIPBOARD (32) SonoLystlive Save Screens to USB Probe Menu Change Discard Accept Pause Page 3/3 GE HealthCare GA=22w5d CLIPBOARD (32) SonoLystlive 4CH/Thorax Save Screens to USB Probe Menu Change Discard Accept Pause Page 3/3

	 T.G. Day et. al., *Video Clip Extraction From Fetal Ultrasound Scans Using Artificial Intelligence to Allow Remote Second Expert Review for Congenital Heart Disease*, Prenatal Diagnosis, 2025, 45:531-538, at 532-33 (Aug. 7, 2024) ("During the AI-assisted scan, the novel AI tool was used. This takes as input every frame of the ultrasound scan video obtained by the sonographer, and automatically classified each frame into one of 13 standard image plane labels, or background. This included five cardiac planes (abdominal situs view, four-chamber view (4CH), left ventricular outflow tract view (LVOT), right ventricular outflow tract view (RVOT), and three vessel tracheal views (3VT)). This step was performed by the SonoNEXT model and is fully described in a separate publication [9], but briefly this model is a type of convolutional neural network, taking as input a single ultrasound image frame, and producing a prediction of the most likely standard image plane label. Each image was also automatically assigned a quality score. Again, full information on the quality scoring model is available in our previous publication [9], but briefly this is also a convolutional neural network, taking as input a single image and producing an output that is a predicted quality score on a continuous scale, also taking into account image diversity (to avoid multiple very similar images being selected as the best quality). Details of the development and performance of the AI models are described in the previous

	publication [9]. The AI models were run in real time during the scans on a computer equipped with a graphical processing unit (Boxer-8641AI, Aaeon Technology Inc., Taipei, Taiwan), which was connected to the ultrasound machine via a high-definition multimedia interface (HDMI) connection. Information on AI model output was displayed to the sonographer via a tablet (iPad Air Fifth Generation, Apple Inc. Cupertino, United States of America). The tablet was connected to the computer via a Wi-Fi connection.")
1[e]: receive signals representing a second at least one echocardiographic image;	The Voluson family products disclose a computer-implemented system for facilitating echocardiographic image analysis configured to *"receive signals representing a second at least one echocardiographic image."* As described with respect to 1[b], when the ultrasound probe of the Voluson family products is in use, the SonoLyst AI algorithm continuously receives new echocardiographic image data as the ultrasound probe is moved around. The step described in 1[a] can thus be repeated for a second echocardiographic image. For example, see the following passages and/or figures, as well as all related disclosures: See discussion with respect to **1[a]**, **1[b]**, **1[c]**, and **1[d]** above. GE Healthcare, *The Future is Now. How AI can Change the Practice of Obstetric Ultrasound.* (Sep 5, 2024), https://www.youtube.com/watch?v=6kFi6RNjqnE (demonstrating SonoLyst*live* functionality)



Excerpt from video transcript (9:58-10:34): "You do have the ability to set it to capture any number of images over here so you can see at the moment this system is set up to capture, I don't know how many, um up to three up but you can set it to capture just a single image or five depending on your hospital protocol. … For example, for the biometry measurements, it might ask for a number which is often three."

Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at

Cine

Cine images are constantly being stored by the system and are available for playback or manual review via cine. Cine can be viewed as a continuous loop via Cine Loop or manually frame by frame via the trackball.

7.4 Cine Mode

While scanning a certain number of frames (2D images of the last examination sequence) are stored in the cine memory automatically. This is indicated by the green bar. By pressing the ***Freeze*** button or the defined ***P***x button, the cine memory is stored as a sequence. This sequence can be reviewed in loop mode or image by image. After the cine clip is stored the cine memory is deleted. Move the trackball horizontally to display the 2D images of the stored sequence, one by one.

Cine Mode Monitor Display

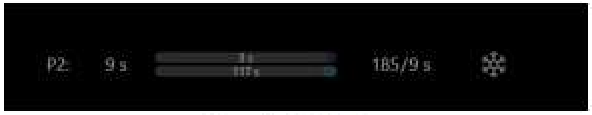


Figure 7-10 Cine Run

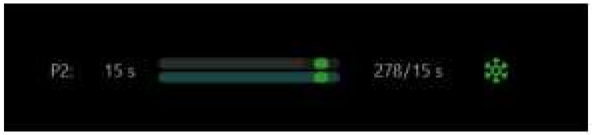


Figure 7-11 Cine Freeze

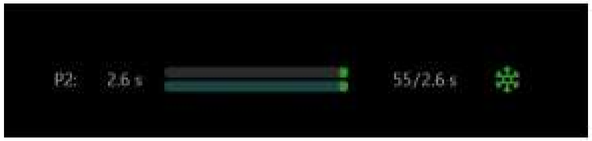


Figure 7-12 Edit Cine

Figure 7-13 Save Cine

<table>
<tr>
<td></td>
<td>
<table>
<tr><td>Px</td><td>Programmed Px button</td></tr>
<tr><td>xx s</td><td>Default clip length in seconds programmed under a Px button</td></tr>
<tr><td>upper bar</td><td>Save clip (corresponding to the activated Px button)</td></tr>
<tr><td>lower bar</td><td>Acquisition clip (original clip)</td></tr>
<tr><td>xx/yy s</td><td>Alphanumeric display of the currently captured cine length in frames (xx) and seconds (yy).</td></tr>
<tr><td></td><td>Freeze (green) and Run (grey) icon</td></tr>
<tr><td>Cine image marker</td><td>Green marker on the upper/lower bar (only present in Freeze mode). The position corresponds to the image (clip frame) on the screen.
The marker can be moved using the trackball. The marker is green as long it is inside the “save clip” section. Outside of the “save clip” section it turns red.</td></tr>
<tr><td>Calculating</td><td>Displayed during the Save process.</td></tr>
</table>
<u>Remarks</u>:

The number of stored images depends on the number of scan lines, scan depth and magnification. In Freeze mode the length of the sequence is indicated on the status bar.
Starting the Cine mode erases measuring marks and measuring displays.
The Cine Function (operation and storage) is identical in 2D mode and CFM mode.

</td>
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<tr>
<td>1[f]: associate the second at least one echocardiographic image with a second view category of the plurality of predetermined echocardiographic image view categories, said second view category being different from the first view category;</td>
<td>The Voluson family products disclose a computer-implemented system for facilitating echocardiographic image analysis configured to “associate the second at least one echocardiographic image with a second view category of the plurality of predetermined echocardiographic image view categories, said second view category being different from the first view category.”

The Voluson family products are configured to acquire a series of images (any one of which could be considered a “second” image) and associate them with different views (e.g., calculates the grading criteria for multiple view categories), any one of which could be considered a “second view category.” The system is also configured to allow the user to specify a different target view and, in that situation, will associate the second image with that view. In other words, the associating process step of claim 1[b] is repeated for a newly acquired image with respect to a different second view category (e.g., a second target view). As described above for claim 1[b], because the SonoLyst AI algorithm knows to</td>
</tr>
</table>

perform image assessment and display information with respect to a target view, the Voluson family products “associate the second at least one echocardiographic image with a second view category of the plurality of predetermined echocardiographic image view categories, said second view category being different from the first view category.”

For example, see the following passages and/or figures, as well as all related disclosures:

See discussion with respect to **1[a]**, **1[b]**, **1[c]**, **1[d]**, and **1[e]** above.

Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6:

> All SonoLyst features are workflow supporting features and are all based on Deep Learning technology:
>
> - SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views.
> - SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria).
> - SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

	The output image of the SonoLyst*live* feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:  As SonoLystIR and SonoLystX are deeply integrated in the Scan Assistant workflow, please refer to ' Scan Assistant ' *on page 7-10* for more details about the usage and setup. Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-10 to 7-13: "The Scan Assistant is a tool with guidelines for sonographers. It offers specific factory checklists containing the anatomical structures or organs to be examined in certain examinations and so prevents from missing important items. It is possible to customize these checklists and also to set up new lists. Additionally the Scan Assistant can be used to activate a specific measurement for an exam item as well as annotate, save or send the image for documentation purposes."


SONOLYSTIR MID-TRIM
0 / 32 items completed
SonoLystIR: found
Head
Cerebellum/
CM
DESCRIPTION
Measure cerebellum and cisterna magna
MEASUREMENTS
Cereb.:
CM:
FETAL ANATOMY
Cerebellum: visualized
Cisterna magna:
SONOLYSTX
Transcerebellar Plane
Brain symmetry
Cavum septum pellucidum
Cerebellum
Cisterna Magna
Midline falx
Magnification
0 / 32

	Following sections/items are displayed: • list name • progress viewer / Pause **Note** *If Scan Assistant is active, the progress symbol of Scan Assistant is shown in the tab area of the Flexible Display area. It is possible to display and hide the Flexible Display area by pressing on the progress symbol. The left number is the number of images which reached the capture count, the right number is the number of possible views.* • selected group (if available) • selected item • description area • measurement result area • Fetal Anatomy (OB) / Findings (GYN) area • SonoLystX area (only visible when a SonoLystX item was found and SonoLystX view is activated on the touch panel) Following icons are displayed: 1. is displayed at the measurement header when a measurement is required. 2. is displayed at the description header when the current item is an optional item. 3. is displayed at the ***Fetal Anatomy (OB) / Findings (GYN)*** header when a fetal anatomy item (OB) / finding (GYN) is required. 4. is displayed if an SonoLyst linked item is active.

	Using the Scan Assistant 1. Start the exam by scanning the first item of the first category. 2. When the item is scanned, freeze the image and press the P-Button configured for confirming. **Note** *It is also possible to check/uncheck an item manually by tapping at the check area (circle).* 3. The item is checked and the next item turns green. 4. Scan all items of the category and move to the next category. If the items cannot be scanned in the predefined order, use the arrow keys on the keyboard or on the touch panel to change between items and/or categories. 5. Press ***End Exam*** to finish. A summary of the Scan Assistant is displayed on the screen showing all (not) examined categories and items.

Figure 7-5 Scan Assistant with SonoLyst (example)

If an item is linked to a SonoLyst image and the system finds a depending plane, this item is displayed on the touch panel.

The items linked to SonoLyst are labeled accordingly with a badge (only available when the option is set). SonoLystX shows the corresponding pictogram and criteria.

It is also possible to switch the SonoLystIR image recognition algorithm on and off. When the image is zoomed in or out or another image is selected from the cine buffer, the SonoLyst algorithm is restarted (if switched on).

Instead of the group area all SonoLystIR view depending criteria are displayed. It is possible to set a criterion to found/not found manually by tapping onto the circle.

<table>
<tr>
<td></td>
<td>
Starting/selecting Scan Assistant lists can also be done by pressing Protocols on the touch panel. Three different states are available:

1. No Scan Assistant or Assessment Tool is started: Select the desired tool or list and press Start. The menu closes automatically.

2. Already ongoing Scan Assistant list or Assessment Tool:
• The ongoing Assessment tool list is paused. Press Continue to go on. Press None to deactivate the currently ongoing Scan Assistant list without losing data.
• Select a Scan Assistant list and press Start. The menu closes automatically.
• Press Discard to clear the currently selected list or tool. Confirm the clearing of data (Yes) or decline (No).

3. No exam started: A message appears together with the Start Exam button. Press the button to open the Patient Information Dialog.

The Auto Capture function for Scan Assistant depends on the system setup settings for SonoLystlive. If Auto Capture is enabled and a view o a Scan Assistant item is captured with SonoLystlive configured, it is possible to select between Accept (saves the image to the clipboard, the Scan Assistant item is checked automatically and configured annotations are inserted automatically) or Discard (the corresponding item is unchecked and deleted from the clipboard) on the trackball.

With Auto Capture it is possible to switch between the levels:
• green: only good views are captured
• yellow: good views and middle views are captured
• Manual: no Auto Capture active; manual action required
• Background
</td>
</tr>
<tr>
<td>1[g]: determine, based on the second at least one echocardiographic image and the second view category, a second quality assessment value representing a view</td>
<td>The Voluson family products disclose a computer-implemented system for facilitating echocardiographic image analysis configured to “determine, based on the second at least one echocardiographic image and the second view category, a second quality assessment value representing a view category specific quality assessment of the second at least one echocardiographic image.”</td>
</tr>
</table>

category specific quality assessment of the second at least one echocardiographic image; and	The Voluson family products are configured to determine grading criteria for all images captured. As discussed above, these values are "quality assessment" values for specific views. In other words, the determining step of claim 1[c] can be repeated for a newly acquired image with respect to a second view category. The plurality of possible second echocardiographic images is discussed above in limitations 1[e] and 1[f]. UBC contends that the accused system literally satisfies this element but, to the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result for the same reasons discussed above for 1[c]. For example, since the traffic light quality status indicator indicates the quality of the assessed ultrasound image by turning green when the probe is at an ideal position for capturing protocol adherent images for a given pre-defined standard view, Defendants infringe any claim element including a "quality assessment value" under the doctrine of equivalents. See claim 1[c].
1[h]: produce signals representing the second quality assessment value for causing the second quality assessment value to be associated with the second at least one echocardiographic image;	The Voluson family products disclose a computer-implemented system for facilitating echocardiographic image analysis configured to *"produce signals representing the second quality assessment value for causing the second quality assessment value to be associated with the second at least one echocardiographic image."* The Voluson family products are configured to acquire a series of images of various view categories and produce associated signals that are represented on the user interface of the LCD monitor as a traffic light quality status indicator. The deep neural network (SonoLyst AI algorithm) can, therefore, repeat the producing process discussed above in claim 1[d] for each acquired image. For example, see the following passages and/or figures, as well as all related disclosures: See discussion with respect to **1[a]**, **1[b]**, **1[c]**, **1[d]**, **1[e]**, **1[f],** and **1[g]** above.
1[i]: wherein each of the plurality of predetermined echocardiographic image view categories is	The Voluson family products disclose that *"each of the plurality of predetermined echocardiographic image view categories is associated with a respective set of assessment parameters, each of the sets of assessment parameters being a set of neural network parameters that define a neural network having*

associated with a respective set of assessment parameters, each of the sets of assessment parameters being a set of neural network parameters that define a neural network having a plurality of layers including an input layer configured to receive one or more echocardiographic images and an output layer configured to output one or more quality assessment values, and	*a plurality of layers including an input layer configured to receive one or more echocardiographic images and an output layer configured to output one or more quality assessment values."* The deep neural network (SonoLyst AI algorithm) has a plurality of predetermined echocardiographic image view categories, each of which are associated with a set of assessment parameters. Each of the sets of assessment parameters are associated with a view category and are neural network parameters that define a neural network (e.g., a neural network within a neural network) for that view. For example, the SonoLyst AI algorithm was trained on ideal (e.g., high quality) images for the view category of each target view, as identified by expert sonologists. The resulting SonoLyst AI algorithm uses a neural network trained with quality related labels to compare the current image to the ideal image. Thus, the SonoLyst AI algorithm involves sets of assessment parameters, each associated with a different fetal heart view category (e.g., 4CH/Thorax, LVOT, RVOT, and 3VV). The SonoLyst AI algorithm is a deep neural network having a plurality of layers including an input layer configured to receive echocardiographic images and an output layer configured to output quality assessment values (grading criteria). For example, see the following passages and/or figures, as well as all related disclosures: See discussion with respect to **1[a]**, **1[b]**, **1[c]**, **1[d]**, **1[e]**, **1[f], 1[g], 1[h]** above. FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K220358) at 7-8: "SonoLyst: Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance • For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images. • The number of individual patients images were collected from: 5000+ exams • The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops.

	… Information about equipment and protocols used to collect images. • Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection. Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): 1. The images were curated (sorted and graded) by a single Sonographer 2. The images were sorted and graded by SonoLyst. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system. Description of how independence of test data from training data was ensured: • The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two." FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K231965) at 10-11: "Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. • Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population. • The verification for the SonoLyst 2nd Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features.

	• The verification of the SonoLystLive 2nd Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality. • The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher. … Quantitative evaluation: For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation … Information about the reference standard and dataset ("truthing process"): To ensure the quality of the curated data for verification, the following strategy is employed: 1. The images were curated (sorted and graded) by a single sonographer. 2. The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system." Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6:

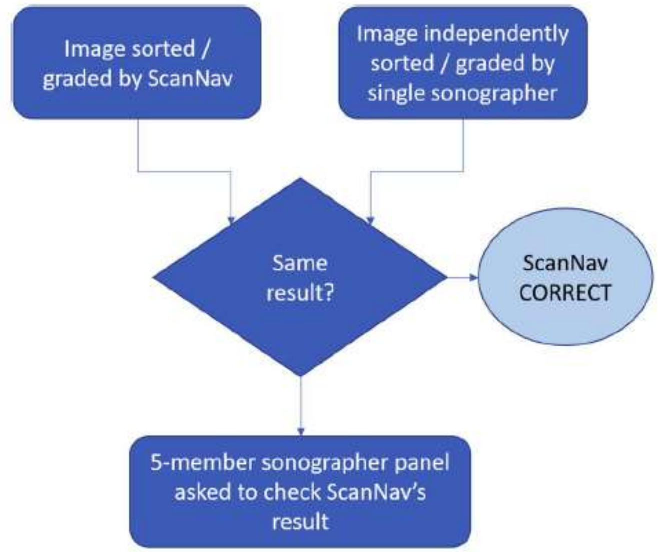
	All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload. Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 13-45 to 13-47:

	13.13 Deep Learning Based Features **Note** *Some of these deep learning based features are not available in all countries:* • SonoLystIR • SonoLystIR 1st Trimester • SonoLystX • SonoLystX 1st Trimester • SonoLyst*live* • SonoLyst*live* 1st Trimester • Sono*Biometry* CRL • SonoPelvicFloor • SonoCNS • Sono*Biometry* Cereb, Vp, CM • FetalHS • SonoAVC™*follicle* 2.0 • SonoAVC™*follicle* Auto Caliper • Fibroid Mapping • AutoSpine • SonoPF2D • AnalSphincter The application of deep learning based features requires caution by the user and an informed decision on the usage of the specific feature. Therefore, all caution information and performance testing for each feature are summarized in this chapter. E.H. Bradburn et al., *OC10.05 An artificial intelligence system that can correctly identify fetal ultrasound imaging planes throughout gestational age*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28-29.

	Methods: Anonymised fetal ultrasound images, acquired at 15 to 40 weeks of gestation, from a large image database were analysed in this study. This included images of head circumference (HC), abdominal circumference (AC), femur length (FL), amniotic fluid index (AFI) and miscellaneous images. An AI algorithm (ScanNav, trained primarily on routine anatomy scans from 18-24 weeks), was applied to each image and categorised it into one of five categories: HC, AC, FL, AFI and others. A random ten percent per view of all images were manually reviewed by one experienced clinician to determine the accuracy of this classification. The performance of the AI algorithm, according to the gestational age at the time of the scan, was assessed. **Results:** Over 450,000 images were assessed by ScanNav, and a random 10% (45,036 images) underwent clinical review. The accuracy of the AI algorithm in categorising the images into standard biometry planes (HC, AC, FL and AFI) was 99.1%. This was 99.6%, 99.1%, 97.9% and 99.9% for HC, AC, FL and AFI, respectively. Across all categories the algorithm performed best between 20+0 and 35+6 weeks, with an accuracy that remained stable throughout that gestational age range (97%). There was a slight drop in accuracy below 20 weeks and above 36 weeks, to 94% and 96% respectively. **Conclusions:** Although trained primarily on routine anatomy scans from 18-24 weeks, the ScanNav AI algorithm is 99.1% accurate in image categorisation of basic biometry planes. Accuracy was maintained over a very broad range of gestational ages. This may reflect that clinically these standard planes remain consistent in appearance throughout gestation. Improvement at the extremes of GA may be possible by further algorithm training. E.H. Bradburn et al., *OC10.04 Estimating fetal gestational age based on ultrasound image characteristics using artificial intelligence*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28.

	Methods: Quality assessed ultrasound images of head circumference (HC) and abdominal circumference (AC) were used from a multicentre study database of women with known GA (CRL performed < 14 weeks) who underwent serial ultrasound examinations from 15 to 40 weeks. We split data randomly into 67.5% training, 7.5% validation and 25% testing sets. We developed and tested an artificial intelligence (AI) algorithm using a regression neural network to estimate the GA, based on image characteristics only without measurement information. Mohammad Yaqub et al., *491 ScanNav® audit: an AI-powered screening assistant for fetal anatomical ultrasound*, American Journal of Obstetrics & Gynecology, Supplement to February 2021, at S312.

		OBJECTIVE: To develop and evaluate a real-time Artificial Intelligence (AI) based system to automatically keep track of acquired images; and check that the images conform to imaging protocol standards, in essence, replacing a human peer reviewer. **STUDY DESIGN:** We developed an AI system (ScanNav) which automatically (1) checks the completeness of the imaging record during fetal anomaly screening, ensuring all 19 required fetal views are recorded; and (2) assesses the quality of these images (in this case according to the guidelines of ISUOG). First, AI algorithms were trained on images manually evaluated by a pool of experienced sonologists and using state-of-the-art deep learning technology. The resulting algorithm was then assessed on a separate testing set; it was deemed correct if 2 or more (from a panel of 5) independent sonologists agreed with its decision. Due to the lack of expert agreement for "marginal" images, it was deemed appropriate to include as agreement such a 2:3 panel split. **RESULTS:** The system was developed on 479,322 anonymised images from 48,161 routine mid-trimester scans. Agreement between ScanNav and the sonologist panel was performed on an independent set of 38,840 images (4,284 scans). For scan completeness the mean (standard deviation) of agreement between ScanNav and the sonologists was 93.5% (±5.6%); for image quality it was 92.2% (±4.7%). The system processes 11 frames per second on a PC with an RTX4000 GPU.



# Sonographers agree with ScanNav	ScanNav
0	INCORRECT
1	INCORRECT
2	CORRECT
3	CORRECT
4	CORRECT
5	CORRECT

T.G. Day et al., *Artificial Intelligence to Assist in the Screening Fetal Anomaly Ultrasound Scan (PROMETHEUS): A Randomized Controlled Trial*, medRxiv, at 41-42 (2024) ("Therefore, we devised a method to automatically regress a quality score for each image of each standard plane and presented the image with the highest predicted quality. We trained a CNN to predict the clinical quality of images classified as valid standard plane. This method could then be incorporated into the clustering step for future versions of the AI tool.")

UBC contends that the accused system literally satisfies this element but, to the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe

	this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result for the same reasons discussed above for 1[c]. For example, the function of determining a quality assessment value is to inform the operator when the probe is at an ideal position for capturing images for a given view and/or to have the system automatically capture images when the probe is in that position. The traffic light quality status indicator performs the same function because it turns green to inform the operator when the right view is detected and the image fully adheres to the required protocol. Further, it performs it in the same way—by determining whether the probe is at the ideal position for capturing an image for the relevant view category. Finally, the result is the same—the system guides the user to position the probe at the ideal position for capturing an image of that view and/or the system automatically captures an image at that position. Since the traffic light quality status indicator indicates the quality of the assessed ultrasound image,, Defendants infringe any claim element including a "quality assessment value" under the doctrine of equivalents. *See* claim 1[c]. Additionally, UBC contends that the accused system literally satisfies this element but, to the extent Defendants do not literally infringe this claim element requiring "each of the sets of assessment parameters being a set of neural network parameters that define a neural network," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. The function of each of the sets of assessment parameters is to assess the quality of echocardiographic images with respect to a specific view category based on a trained neural network-based model. All parameters used to assess echocardiographic images with respect to a specific view category, including those from any layer involving a linear regression, perform the same function. Further, they perform the same function in the same way—by assessing an echocardiographic image based on parameters and providing intermediary values that lead to a grading criteria value. In this regard, all of the parameters used to assess echocardiographic images with respect to a specific view category are neural network parameters that define a neural network for assessing the image quality with respect to a specific view category. Finally, the result is the same—echocardiographic images assessed using a set of assessment parameters associated with a view category results in a grading criteria value indicating the quality of an image with respect to that view category. Since all of the parameters used to assess echocardiographic images with respect to a specific view category provide parameters for a neural network-based model that outputs a grading criteria value, Defendants infringe this claim limitation literally or at least under the doctrine of equivalents.

1[j]: wherein the at least one processor is configured to determine the first quality assessment value by: determining that a first set of assessment parameters of the sets of assessment parameters is associated with the first view category; and in response to determining that the first set of assessment parameters is associated with the first view category, inputting the first at least one echocardiographic image into the neural network defined by the first set of assessment parameters; and	The Voluson family products disclose that *"at least one processor is configured to determine the first quality assessment value by: (i) determining that a first set of assessment parameters of the sets of assessment parameters is associated with the first view category; and (ii) in response to determining that the first set of assessment parameters is associated with the first view category, inputting the first at least one echocardiographic image into the neural network defined by the first set of assessment parameters."* The Voluson family products contain at least one processor configured to determine the first quality assessment value. See 1[pre]. The Voluson family products determine that a first set of assessment parameters is associated with the first view category. As described for claim 1[i], the SonoLyst AI algorithm includes sets of assessment parameters, each associated with a different view category. When determining the first quality assessment value with respect to the first view category (e.g., a target view to be displayed on the Voluson family products' user interface, as described above for 1[b]), the Voluson family products identify and thus determine the set of assessment parameters associated with the first view category. In response, the Voluson family products input the first echocardiographic image into the neural network that is defined by that set of assessment parameters associated with the first view category. Additionally and alternatively, during the training phase, the SonoLyst AI algorithm learns and determines sets of assessment parameters each associated with a view category, including a first set of assessment parameters associated with a first view category. In response to this determination, the SonoLyst AI algorithm inputs the first echocardiographic image into the neural network that is defined by the first set of assessment parameters associated with the first view category. For example, see the following passages and/or figures, as well as all related disclosures: See discussion with respect to **1[a]**, **1[b]**, **1[c]**, **1[d]**, **1[e]**, **1[f], 1[g]**, **1[h]**, and **1[i]** above. Voluson Expert Series Service Manual Rev 6 (Aug 2024) at 5-4:

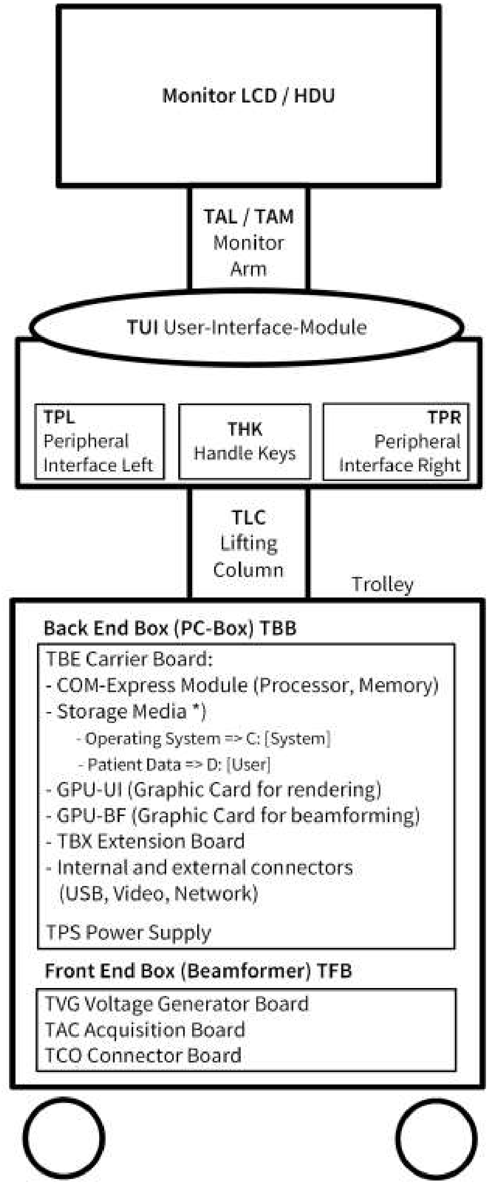
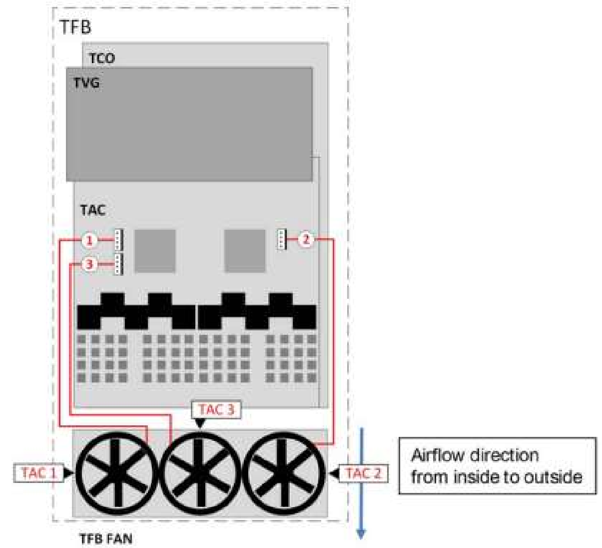


Figure 5-2: Basic Block diagram of Voluson Expert Series

	Voluson Expert Series Service Manual Rev 6 (Aug 2024) at 5-21 to 5-22: **5.2 FrontEnd Processor**  *Figure 5-4: FrontEnd - Block diagram*

	5.2.1 TCO - Connector Board Switches the Probe Connectors and recognizes Probes • 4 Probe Connectors 408pin • Probe Select Relays • Probe Recognition **5.2.2 TAC - Acquisition Board** The FrontEnd Acquisition Board supports Tx/Rx for 192 channels[10] / 256 channels[11]. **5.2.2.1 TAC Board - Interface Tasks** 1. DMA logic 2. Beamformer Interface 3. TAC Control Interface 4. TAC FPGA Control Interface **5.2.2.2 TAC Board - Processing Tasks** 1. Ultrasound Data Pre-Processing 2. System Control 3. Motor Control **5.2.3 TVG - Voltage Generator Board** The voltage generator board generates the ultrasound system specific voltages. Voluson Expert Series Service Manual Rev 6 (Aug 2024) at 5-23 to 5-25:

5.3 BackEnd Processor

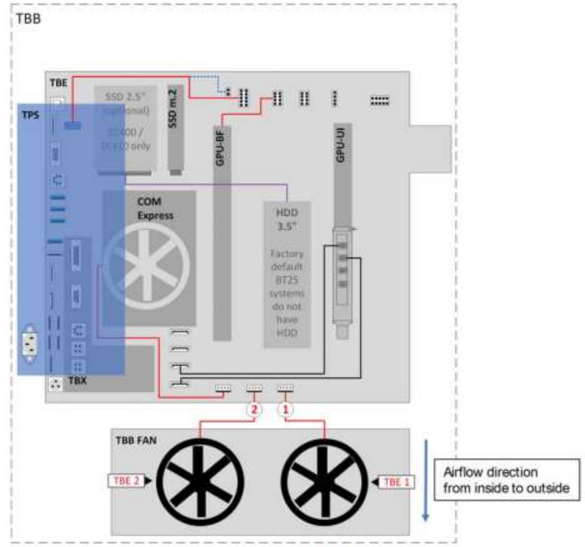


Figure 5-5: BackEnd - Block diagram

Content in this chapter

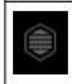
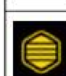
	5.3.1 TBE - Backend Carrier Board (Base Board) Built in or external Components: • COM-Express (Computer on Module with CPU, Memory, Audio and USB-Root Hub) • Graphic cards (GPU-BF and GPU-UI) • PCIe Switch • EC400, EC410 (BT24) and systems that were upgraded to EC420 (BT25): - M.2 NVMe SSD for operating system - HDD for patient data • EC420 (BT25): - M.2 NVMe SSD for operating system + patient data, no additional HDD • Audio-Amplifier • Video splitter and scaler • MCU for monitoring and bootup sequence Cores Major Tasks: • System Control • Connections to User Interface, Frontend, Peripherals and external connectivity **5.3.2 TBX - Extension Board** Built in or external Components: • Electronic switch and fuse for User Interface (TUI) • Electronic switch and fuse for Lift (TLC) • Electronic switch and fuse for Peripherals such as Printer and Trolley Lighting Unit (TLU) Cores Major Tasks: • Power distribution and monitoring **5.3.3 COM Express Module** Built in or external Components: • LAN • USB 2.0 • USB 3.0 • CPU: 2.5GHz (max. 4.2GHz) • Memory (2x 8GB) • Active cooling Cores Major Tasks: • System Control **5.3.6 Graphic Card** The Voluson E-Series system has two Graphic Cards installed. Their scope of application is different. **Graphic Card GPU-BF** Provides processing capacity to perform software-beamforming. **Graphic Card GPU-UI** Renders 2D, 3D and 4D images as well as the complete user interface for all displays (Touchscreen, Main Monitor and external outputs).

	Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6: All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

	The output image of the SonoLyst*live* feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:  Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-6 to 7-9:

Figure 7-1 SonoLystlive monitor display (example)

If configured, the last captured image is displayed on the monitor together with the detected view name. A message appears when an image is captured and the following symbols (detected view status) are displayed:

Indicator	Description
	View detected
	View detected, partially protocol adherent
	View detected, fully protocol adherent

In the Flexible Display area all selected views for detection are displayed. Views deactivated in the system setup are disabled. The view icon contains a capture counter. As soon as the capture count is reached, the counter gets a checkmark and the view icon is dimmed. Furthermore in ***Freeze*** mode a SonoLystX section is visible displaying the view (if detected) depending on SonoLystX criteria.

Flat list: all selected views for detection are displayed. Views deactivated in the system setup are disabled. Each view contains a capture counter. As soon as the capture count is reached, the counter gets a checkmark.

If SonoLyst*live* is active, the progress symbol of SonoLyst*live* is shown in the tab area of the Flexible Display area. It is possible to display and hide the Flexible Display area by pressing on the progress symbol. The left number is the number of images which reached the capture count, the right number is the number of possible views.

Note *If more than one Spine or Extremity view is detected, all of the views are displayed next to the hexagon.*

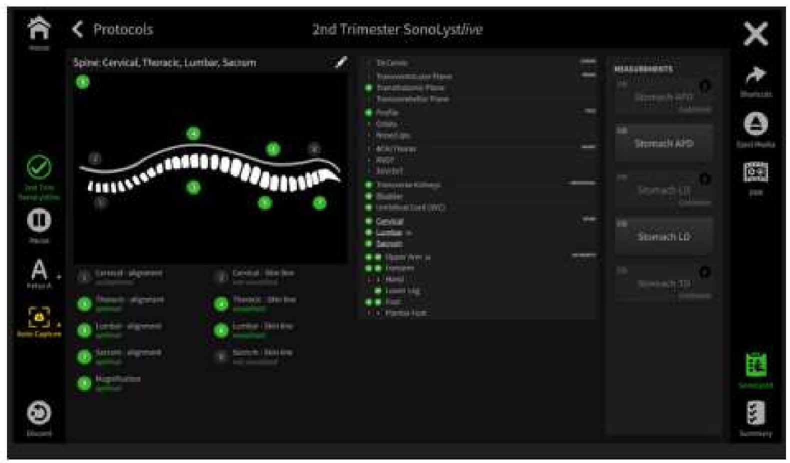


Figure 7-2 SonoLystlive Protocol touch menu (example)

The touch menu is opened by pressing ***1st Trimester SonoLystlive*** or ***2nd Trimester SonoLystlive***. It contains SonoLystX (can be switched on/off by selecting the corresponding button) and measurements (if configured).

Summary	Opens the SonoLyst*live* 1st or 2nd Trimester worksheet. A green checkmark indicates that the capture count is reached. If the count is not reached or no view stored, no checkmark appears. Detailed criteria for available views are displayed.
Auto Capture	Switches between following levels: • green: only good views are captured • yellow: good views and middle views are captured • Manual: no ***Auto Capture*** active; manual action required • Background **Note** *This control is available in certain modes when the* ***Protocols*** *menu is closed. When a new exam is started, the selections are reset to the values defined in the system setup.*
Pause / ***Continue***	***Pause*** / ***Continue*** switches between live mode and pause state. When SonoLyst*live* is paused, a blue infobox is displayed on the main screen and within the ***Protocols*** menu on the touch panel.
Fetus	If more than one fetus is available, it is possible to switch between the fetuses. All captured views (except Cervix) belong to the selected fetus, capture counts are updated automatically.
Discard	***Discard*** enables to delete images. Depending on whether unaccepted images are available or not, a message appears asking for confirmation. Select ***Yes*** to discard the images and close the dialog or ***No*** to continue without deleting.
Edit	A press onto ***Edit*** (pencil icon) opens a new window in which it is possible to change views configured in the system setup and/or detected criteria. All editable criteria can be changed by tapping onto them. If configured, a ***Left*** / ***Right*** selection is possible. Press ***Set*** to save the changes made and to close the window or ***Cancel*** to leave the menu without saving changes.

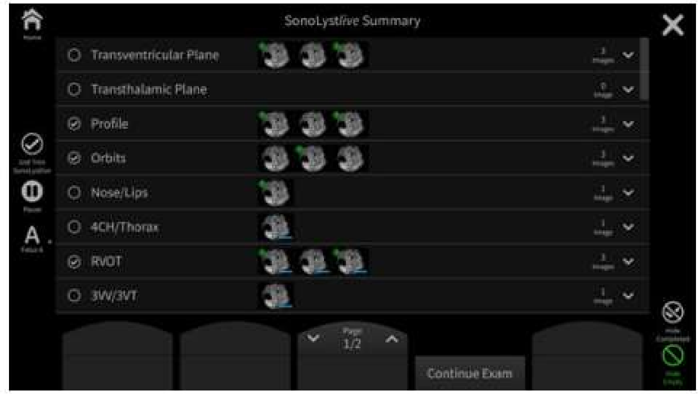


Figure 7-3 SonoLystlive Summary (example)

A tap onto a row displays the depending images of that view, a tap onto an image displays the depending SonoLystX menu. A circle with a checkmark indicates that the capture count is reached. As most of the controls are the same as in SonoLystX, only the summary page specific controls are described here:

Continue Exam	Closes the dialog and goes back to the exam.
Review Images	Opens the ***Exam Review*** to review and / or delete images.

	Accept & End Exam All images are accepted, the dialog and the exam are closed. ***Hide Completed*** When selected all completed views are hidden. ***Hide Empty*** When selected all empty views are hidden. ***Hide Accepted*** When selected all accepted images are hidden. Trackball buttons: ***SonoLystlive / Pause*** Toggles between SonoLyst*live* and ***Pause***. ***Discard*** Deletes the image from the clipboard. ***Accept*** Accepts the image. ***Left/Right/Both*** A left/right view is detected. Accepts the image by selecting the correct side/both sides and adds it to the configured annotation .The corresponding icon in the Flexible Display area increases the capture count. ***Measure*** Saves and reloads the image. The first measurement of the next incomplete measurement is started automatically. It is possible to perform all configured measurements for the auto-captured view. **Note** *Only available when* ***Auto capture views with measurement*** *is selected in the system setup.* Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-10 to 7-13: **7.2 Scan Assistant** The Scan Assistant is a tool with guidelines for sonographers. It offers specific factory checklists containing the anatomical structures or organs to be examined in certain examinations and so prevents from missing important items. It is possible to customize these checklists and also to set up new lists. Additionally the Scan Assistant can be used to activate a specific measurement for an exam item as well as annotate, save or send the image for documentation purposes.


SONOLYSTIR MID-TRIM
0 / 32 items completed
SonoLystIR: found
General
Head
Face
Lateral Ventricle
Cerebellum/ CM
DESCRIPTION
Measure cerebellum and cisterna magna
MEASUREMENTS
Cereb.:
CM:
FETAL ANATOMY
Cerebellum: visualized
Cisterna magna:
SONOLYSTX
Transcerebellar Plane
Brain symmetry
Cavum septum pellucidum
Cerebellum
Cisterna Magna
Midline falx
Magnification
0 / 32

Following sections/items are displayed:

- list name
- progress viewer / Pause

Note *If Scan Assistant is active, the progress symbol of Scan Assistant is shown in the tab area of the Flexible Display area. It is possible to display and hide the Flexible Display area by pressing on the progress symbol. The left number is the number of images which reached the capture count, the right number is the number of possible views.*

- selected group (if available)
- selected item
- description area
- measurement result area
- Fetal Anatomy (OB) / Findings (GYN) area
- SonoLystX area (only visible when a SonoLystX item was found and SonoLystX view is activated on the touch panel)

Following icons are displayed:

1.  is displayed at the measurement header when a measurement is required.
2.  is displayed at the description header when the current item is an optional item.
3.  is displayed at the ***Fetal Anatomy (OB) / Findings (GYN)*** header when a fetal anatomy item (OB) / finding (GYN) is required.
4.  is displayed if an SonoLyst linked item is active.

	Using the Scan Assistant 1. Start the exam by scanning the first item of the first category. 2. When the item is scanned, freeze the image and press the P-Button configured for confirming. **Note** *It is also possible to check/uncheck an item manually by tapping at the check area (circle).* 3. The item is checked and the next item turns green. 4. Scan all items of the category and move to the next category. If the items cannot be scanned in the predefined order, use the arrow keys on the keyboard or on the touch panel to change between items and/or categories. 5. Press ***End Exam*** to finish. A summary of the Scan Assistant is displayed on the screen showing all (not) examined categories and items.

Figure 7-5 Scan Assistant with SonoLyst (example)

If an item is linked to a SonoLyst image and the system finds a depending plane, this item is displayed on the touch panel.

The items linked to SonoLyst are labeled accordingly with a badge (only available when the option is set). SonoLystX shows the corresponding pictogram and criteria.

It is also possible to switch the SonoLystIR image recognition algorithm on and off. When the image is zoomed in or out or another image is selected from the cine buffer, the SonoLyst algorithm is restarted (if switched on).

Instead of the group area all SonoLystIR view depending criteria are displayed. It is possible to set a criterion to found/not found manually by tapping onto the circle.

	Starting/selecting Scan Assistant lists can also be done by pressing ***Protocols*** on the touch panel. Three different states are available: 1. No Scan Assistant or Assessment Tool is started: Select the desired tool or list and press ***Start***. The menu closes automatically. 2. Already ongoing Scan Assistant list or Assessment Tool: • The ongoing Assessment tool list is paused. Press ***Continue*** to go on. Press ***None*** to deactivate the currently ongoing Scan Assistant list without losing data. • Select a Scan Assistant list and press ***Start***. The menu closes automatically. • Press ***Discard*** to clear the currently selected list or tool. Confirm the clearing of data (***Yes***) or decline (***No***). 3. No exam started: A message appears together with the ***Start Exam*** button. Press the button to open the Patient Information Dialog. The ***Auto Capture*** function for Scan Assistant depends on the system setup settings for SonoLyst*live*. If ***Auto Capture*** is enabled and a view o a Scan Assistant item is captured with SonoLyst*live* configured, it is possible to select between ***Accept*** (saves the image to the clipboard, the Scan Assistant item is checked automatically and configured annotations are inserted automatically) or ***Discard*** (the corresponding item is unchecked and deleted from the clipboard) on the trackball. With ***Auto Capture*** it is possible to switch between the levels: • green: only good views are captured • yellow: good views and middle views are captured • Manual: no ***Auto Capture*** active; manual action required • Background UBC contends that the accused system literally satisfies this element but, to the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result for the same reasons discussed above for 1[c]. For example, since the traffic light quality status indicator indicates the quality of the assessed ultrasound image by turning green when the probe is at an ideal position for capturing protocol adherent images for a given pre-defined standard view,

	Defendants infringe any claim element including a "quality assessment value" under the doctrine of equivalents. *See* claim 1[c].
1[k]: wherein the at least one processor is configured to determine the second quality assessment value by: (i) determining that a second set of assessment parameters of the sets of assessment parameters is associated with the second view category; and (ii) in response to determining that the second set of assessment parameters is associated with the second view category, inputting the second at least one echocardiographic image into the neural network defined by the second set of assessment parameters.	The Voluson family products disclose that *"at least one processor is configured to determine the second quality assessment value by: (i) determining that a second set of assessment parameters of the sets of assessment parameters is associated with the second view category; and (ii) in response to determining that the second set of assessment parameters is associated with the second view category, inputting the second at least one echocardiographic image into the neural network defined by the second set of assessment parameters."* The Voluson family products are configured to acquire a series of images of various view categories. The determining and inputting process steps of claim 1[j] can be repeated for a newly acquired image with respect to a second view category. The Voluson family products contain at least one processor configured to determine the first quality assessment value. See 1[pre]. The Voluson family products determine that a second set of assessment parameters is associated with the second view category. As described for claim 1[i], the SonoLyst AI algorithm includes sets of assessment parameters, each associated with a different view category. When determining the second quality assessment value, the Voluson family products identify and thus determine the set of assessment parameters associated with the second view category. In response, the Voluson family products input the second echocardiographic image into the neural network that is defined by the second set of assessment parameters associated with the second view category. The plurality of possible second echocardiographic images and assessment parameters sets is discussed above in limitations 1[e], 1[f], 1[i], and 1[j]. For example, see the following passages and/or figures, as well as all related disclosures: See discussion with respect to **1[a]**, **1[b]**, **1[c]**, **1[d]**, **1[e]**, **1[f]**, **1[g]**, **1[h]**, **1[i]**, and **1[j]** above. UBC contends that the accused system literally satisfies this element but, to the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result for the same reasons discussed above for 1[c]. For example, since the traffic light quality status indicator indicates the quality of the assessed ultrasound image by turning green when the probe is at

	an ideal position for capturing protocol adherent images for a given pre-defined standard view, Defendants infringe any claim element including a "quality assessment value" under the doctrine of equivalents. *See* claim 1[c].
'591 Claim 2	**Voluson Family Products**
2: The system of claim 1 wherein the first quality assessment value represents an assessment of suitability of the first at least one echocardiographic image for quantified clinical measurement of anatomical features and wherein the second quality assessment value represents an assessment of suitability of the second at least one echocardiographic image for quantified measurement of anatomical features.	The Voluson family products disclose that *"the first quality assessment value represents an assessment of suitability of the first at least one echocardiographic image for quantified clinical measurement of anatomical features and wherein the second quality assessment value represents an assessment of suitability of the second at least one echocardiographic image for quantified measurement of anatomical features."* As described in 1[c] and 1[i], the SonoLyst AI algorithm is trained with expert input based on training images and ideal probe position for each cardiac view. For any view, the trained SonoLyst AI algorithm outputs a grading criteria that indicates how far the current probe position is from the ideal probe position, and thus whether the assessed echocardiographic image is high quality for that view. The SonoLyst AI algorithm is configured to receive a series of images of various view categories, and thus each quality assessment value output by the SonoLyst AI algorithm represents an assessment of suitability of the first at least one echocardiographic image for quantified clinical measurement of anatomical features. *See* 1[c]. For example, see the following passages and/or figures, as well as all related disclosures: *See* discussion with respect to claim **1[c]** above. SonoLyst product page, https://www.gehealthcare.com/products/ultrasound/voluson/sonolyst

AI tool helps automatically identify fetal anatomy

- **SonoLyst**: Save up to 40%* on routine 2nd trimester exams with SonoLyst.
- **SonoLystlive**: No freezing, no annotating, no storing. SonoLystlive takes image recognition to the next level by capturing images as you scan, in real-time.
- **SonoLystIR**: Simply scan, then freeze and SonoLystIR (Image Recognition) does the rest.
- **SonoLystX**: Build and refine your skills with SonoLystX. Using AI, the system compares the image or view acquired to standard criteria accepted by experts to ensure it meets clinical standards.

SonoLyst product page, https://www.gehealthcare.com/products/ultrasound/voluson/sonolyst (showing Measurements functionality on upper righthand side and diagnostic clinical standard criteria for the view category at bottom right)

	Voluson Expert 22 Product Page, https://www.gehealthcare.ca/en-ca/products/ultrasound/voluson/voluson-expert22/workflow-efficiency **SonoLyst** **Your Onboard Assistant** SonoLyst is your virtual on-board expert utilizing AI to automatically identify fetal anatomy seen on standard views while enhancing efficiency by adding annotations and measurements. For quality assurance, SonoLyst can also be used to compare the image or view acquired to standard criteria ensuring exam quality and consistency. Voluson Expert 18 Brochure (Aug 2023) at 5: **SonoLystX:** Build and refine your skills with SonoLystX. Using AI, the system compares the image or view acquired to standard criteria accepted by experts to ensure it meets clinical standards. SonoLystX can help enhance accuracy and quality with anatomy diagrams plus the ability to insert image examples. Ideal for teaching and training, progress can be monitored for quality assurance to ensure the highest quality imaging standards and consistency. SonoLyst Second & Third Trimester product page, https://womens-health.net/clinical-specialty/second-third-trimester/sonolyst

	The real power of AI in women's health SonoLystIR automatically detects anatomy and applies applicable annotations and measurements. All you do is confirm, and data is entered into the Scan Assistant checklist and report— enhancing workflow and reducing variability between operators for improved consistency. Another aspect of SonoLyst is the ability to build and refine skills of less experienced users. SonoLystX is your virtual, on-board ultrasound expert. Acting like a personal scanning assistant, it compares the image or view acquired to standardized expert image criteria to ensure it contains the required anatomy for the imaging plane. SonoLystX is ideal for teaching and training. Progress can be monitored for quality assurance to ensure the highest quality imaging standards and consistency. Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 1-4

	## 1.1 About this system **Intended use** This system is intended for use by a qualified physician or sonographer for ultrasound evaluation in the following clinical application: Image acquisition for diagnostic purposes including measurements on acquired image. **Clinical benefit** The clinical benefit of a diagnostic ultrasound device is to help healthcare professionals provide an accurate diagnostic information (visualize human tissue/internal structure) that enhances the diagnostic and treatment care pathways of the patient for a variety of diseases and conditions. **Clinical applications** • Abdomen • Obstetrics (incl. Fetal Cardio) • Gynecology • Cardiology • Transrectal • Vascular • Cephalic • Pediatrics • MSK • Small Parts (incl. Breast) Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 5-23 ## 5.3 Probes ### 5.3.1 Intended use, contraindications and patient population **Intended use** Image Acquisition for diagnostic purposes including measurements on acquired image. Extracting tissue samples with guided and freehand biopsy.

	Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6: All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

The output image of the SonoLyst*live* feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:

As SonoLystIR and SonoLystX are deeply integrated in the Scan Assistant workflow, please refer to ' Scan Assistant ' *on page 7-10* for more details about the usage and setup.

All SonoLyst features use the following predefined standard views and depending criteria for the 1st Trimester:

Pre-defined standard view	Criteria
Sagittal Fetus	Magnification Mid-sagittal Neutral position and orientation Crown visible Rump visible
Axial Head	Magnification Symmetrical hemispheres Full head circumference visible Choroid plexus visible Midline falx
Transthalamic Plane	Magnification Symmetrical hemispheres Two separate thalami Midline falx
Axial Orbits	Magnification Both orbits visible
Coronal Orbits	Magnification Both orbits visible Nose visible Both ears visible
Coronal Palate	Magnification Nasal bone Supermaxilla
Coronal Lips	Magnification Nasal tip Upper lip
4CH/Thorax	Magnification 4 chambers clearly visible
Cord Insertion	Magnification Cord inserted into abdominal wall
Axial Abdomen	Magnification Full abdominal circumference visible Stomach visible
Axial Kidneys	Magnification Both kidneys visible
Axial Bladder	Magnification Bladder visible
Coronal Kidneys	Magnification Both kidneys visible
Sagittal Spine	Magnification Vertebrae are aligned Skin edge
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible

Pre-defined standard view	Criteria
Hand	Magnification Hand visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible
Sagittal Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Sagittal Profile	Magnification Mid-sagittal Neutral position and orientation Nasal tip
Sagittal Brain	Magnification Brainstem Fourth ventricle Cisterna magna

All SonoLyst features use the following predefined standard views and depending criteria for the 2nd Trimester:

Pre-defined standard view	Criteria
Transventricular Plane	Magnification Brain symmetry Midline falx Lateral cerebral ventricles Choroid Plexus Cavum septum pellucidum No Cerebellum
Transthalamic Plane	Magnification Brain symmetry Midline falx Thalamus Cavum septum pellucidum No Cerebellum
Transcerebellar Plane	Magnification Brain symmetry Midline falx Cavum septum pellucidum Cerebellum Cisterna Magna
Profile	Magnification Nasal tip Forehead bone visible

Pre-defined standard view	Criteria
Orbits	Magnification Both orbits visible Symmetrical orbits
Nose/Lips	Magnification Nasal tip Nostrils Upper lip
4CH/Thorax	Magnification 4 Chambers visible Ventricular Septum Valves visible
LVOT	Continuity Ventricular Septum Magnification
RVOT	Vessel Bifurcation Magnification
3VV/3VT	3 Vessels Magnification
Abdomen (AC)	Magnification Stomach Umbilical vein Rib visible Circular/Shape No Kidney visible
Abdomen - Cord Insertion	Magnification Cord visible
Transverse Kidneys	Magnification Both kidneys visible
Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Femur	Magnification Angle of insonation Clear Diaphysis
Plantar Foot	Magnification Full foot visible
Hand	Magnification Clear hand visible
TA Cervix	Magnification Endocervical Canal Internal Os External Os
Spine Sacrum	Lumbar - alignment Lumbar - Skin line Magnification

Pre-defined standard view	Criteria
Spine Lumbar	Lumbar - alignment Lumbar - Skin line Magnification
Spine Thoracic	Thoracic - alignment Thoracic - Skin line Magnification
Spine Cervical	Cervical - alignment Cervical - Skin line Magnification
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible

To the extent Defendants do not literally infringe this claim element requiring a “quality assessment value,” Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. For example, since the traffic light quality status indicator indicates the quality of the assessed ultrasound image by turning green when the probe is at an ideal position for capturing protocol adherent images for a given pre-defined standard view, Defendants infringe any claim element including a “quality assessment value” under the doctrine of equivalents. *See* claim 1[c].

’591 Claim 3	Voluson Family Products
3: The system of claim 1 wherein the at least one processor is configured to: produce signals for causing a representation of the first quality assessment value to be transmitted to at least one display for causing the at least one display to	The Voluson family products disclose a processor configured to *“produce signals for causing a representation of the first quality assessment value to be transmitted to at least one display for causing the at least one display to display the first quality assessment value in association with the first at least one echocardiographic image, to assist one or more operators of an echocardiographic device in capturing at least one subsequent echocardiographic image”* and *“produce signals for causing a representation of the second quality assessment value to be transmitted to the at least one display for causing the at least one display to display the second quality assessment value in association with the second at least one echocardiographic image, to assist the one or more operators in capturing at least one subsequent echocardiographic image.”*

display the first quality assessment value in association with the first at least one echocardiographic image, to assist one or more operators of an echocardiographic device in capturing at least one subsequent echocardiographic image; and	The Voluson family products include at least one processor. *See* claim 1[pre]. *See* 1[d] and 1[h]. The Voluson family products' *first quality assessment value* is represented on the user interface of the LCD monitor as a traffic light quality status indicator. The status indicator is a traffic light-style icon showing the quality of the current echocardiographic image (based on grading criteria) relative to a known view category (i.e., pre-defined standard views). When the operator scans the first view and the SonoLyst AI algorithm detects a diagnostic quality image, the status indicator turns green. This directly assists the operator in capturing subsequent images. For example, if the first view is unsatisfactory (i.e., the status indicator is gray or yellow), the operator knows to keep adjusting the probe before moving on. Once the image is acceptable, SonoLyst*live* captures it and the operator moves to the next view, guided again by the quality display for the second view.
produce signals for causing a representation of the second quality assessment value to be transmitted to the at least one display for causing the at least one display to display the second quality assessment value in association with the second at least one echocardiographic image, to assist the one or more operators in capturing at least one subsequent echocardiographic image.	The Voluson family products are configured to acquire a series of images of various view categories and thus the producing process step of claim 1[d] can be repeated for a newly acquired image. For example, see the following passages and/or figures, as well as all related disclosures: Voluson Expert Series Service Manual Rev 6 (Aug 2024) at 5-4:

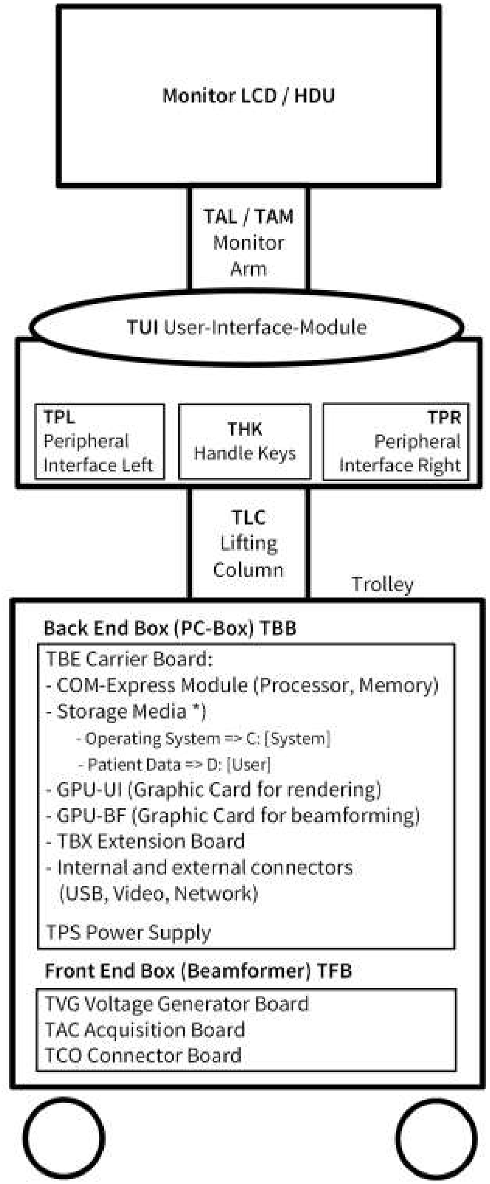
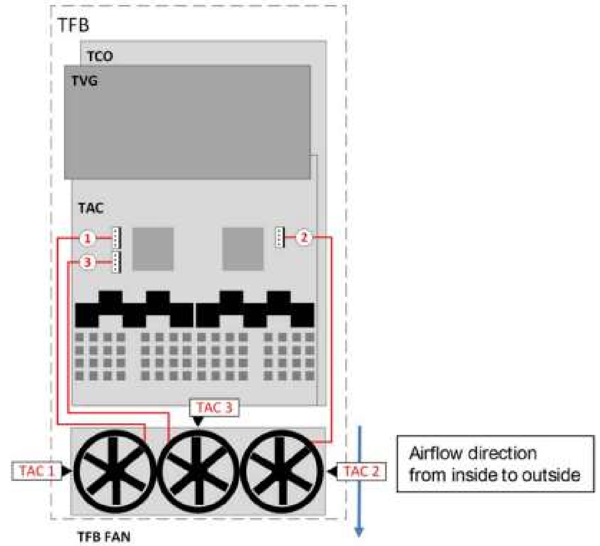


Figure 5-2: Basic Block diagram of Voluson Expert Series

	Voluson Expert Series Service Manual Rev 6 (Aug 2024) at 5-21 to 5-22: **5.2 FrontEnd Processor**  Figure 5-4: FrontEnd - Block diagram

5.2.1 TCO - Connector Board

Switches the Probe Connectors and recognizes Probes

- 4 Probe Connectors 408pin
- Probe Select Relays
- Probe Recognition

5.2.2 TAC - Acquisition Board

The FrontEnd Acquisition Board supports Tx/Rx for 192 channels[10] / 256 channels[11].

5.2.2.1 TAC Board - Interface Tasks

1. DMA logic
2. Beamformer Interface
3. TAC Control Interface
4. TAC FPGA Control Interface

5.2.2.2 TAC Board - Processing Tasks

1. Ultrasound Data Pre-Processing
2. System Control
3. Motor Control

5.2.3 TVG - Voltage Generator Board

The voltage generator board generates the ultrasound system specific voltages.

Voluson Expert Series Service Manual Rev 6 (Aug 2024) at 5-23 to 5-25:

5.3 BackEnd Processor

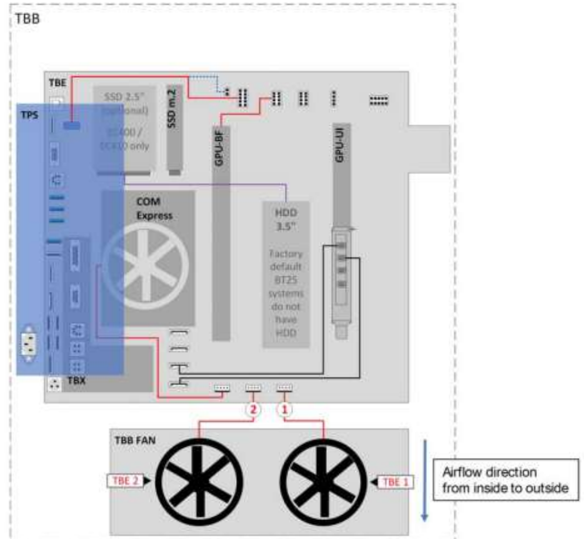


Figure 5-5: BackEnd - Block diagram

Content in this chapter

	5.3.1 TBE - Backend Carrier Board (Base Board) Built in or external Components: • COM-Express (Computer on Module with CPU, Memory, Audio and USB-Root Hub) • Graphic cards (GPU-BF and GPU-UI) • PCIe Switch • EC400, EC410 (BT24) and systems that were upgraded to EC420 (BT25): - M.2 NVMe SSD for operating system - HDD for patient data • EC420 (BT25): - M.2 NVMe SSD for operating system + patient data, no additional HDD • Audio-Amplifier • Video splitter and scaler • MCU for monitoring and bootup sequence Cores Major Tasks: • System Control • Connections to User Interface, Frontend, Peripherals and external connectivity **5.3.2 TBX - Extension Board** Built in or external Components: • Electronic switch and fuse for User Interface (TUI) • Electronic switch and fuse for Lift (TLC) • Electronic switch and fuse for Peripherals such as Printer and Trolley Lighting Unit (TLU) Cores Major Tasks: • Power distribution and monitoring **5.3.3 COM Express Module** Built in or external Components: • LAN • USB 2.0 • USB 3.0 • CPU: 2.5GHz (max. 4.2GHz) • Memory (2x 8GB) • Active cooling Cores Major Tasks: • System Control **5.3.6 Graphic Card** The Voluson E-Series system has two Graphic Cards installed. Their scope of application is different. **Graphic Card GPU-BF** Provides processing capacity to perform software-beamforming. **Graphic Card GPU-UI** Renders 2D, 3D and 4D images as well as the complete user interface for all displays (Touchscreen, Main Monitor and external outputs).

	Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2: All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

	The output image of the SonoLyst*live* feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:  Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-6 to 7-9:

Figure 7-1 SonoLystlive monitor display (example)

If configured, the last captured image is displayed on the monitor together with the detected view name. A message appears when an image is captured and the following symbols (detected view status) are displayed:

Indicator	Description
	View detected
	View detected, partially protocol adherent
	View detected, fully protocol adherent

In the Flexible Display area all selected views for detection are displayed. Views deactivated in the system setup are disabled. The view icon contains a capture counter. As soon as the capture count is reached, the counter gets a checkmark and the view icon is dimmed. Furthermore in ***Freeze*** mode a SonoLystX section is visible displaying the view (if detected) depending on SonoLystX criteria.

Flat list: all selected views for detection are displayed. Views deactivated in the system setup are disabled. Each view contains a capture counter. As soon as the capture count is reached, the counter gets a checkmark.

If SonoLyst*live* is active, the progress symbol of SonoLyst*live* is shown in the tab area of the Flexible Display area. It is possible to display and hide the Flexible Display area by pressing on the progress symbol. The left number is the number of images which reached the capture count, the right number is the number of possible views.

Note *If more than one Spine or Extremity view is detected, all of the views are displayed next to the hexagon.*

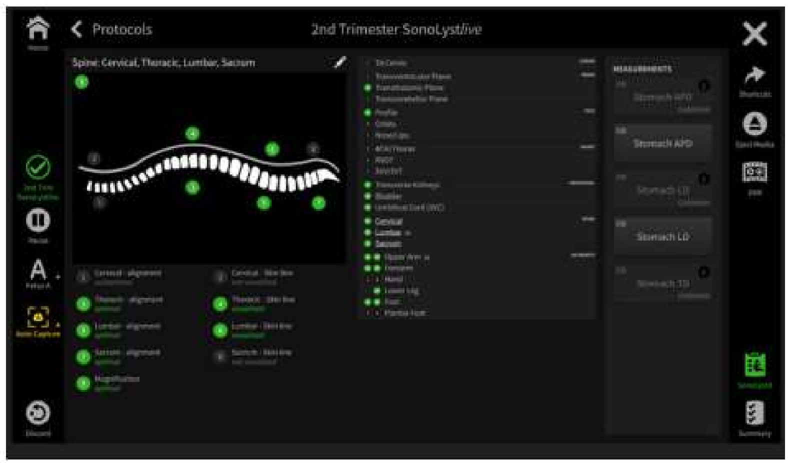


Figure 7-2 SonoLystlive Protocol touch menu (example)

The touch menu is opened by pressing ***1st Trimester SonoLystlive*** or ***2nd Trimester SonoLystlive***. It contains SonoLystX (can be switched on/off by selecting the corresponding button) and measurements (if configured).

Summary	Opens the SonoLyst*live* 1st or 2nd Trimester worksheet. A green checkmark indicates that the capture count is reached. If the count is not reached or no view stored, no checkmark appears. Detailed criteria for available views are displayed.
Auto Capture	Switches between following levels: • green: only good views are captured • yellow: good views and middle views are captured • Manual: no ***Auto Capture*** active; manual action required • Background **Note** *This control is available in certain modes when the **Protocols** menu is closed. When a new exam is started, the selections are reset to the values defined in the system setup.*
Pause / ***Continue***	***Pause*** / ***Continue*** switches between live mode and pause state. When SonoLyst*live* is paused, a blue infobox is displayed on the main screen and within the ***Protocols*** menu on the touch panel.
Fetus	If more than one fetus is available, it is possible to switch between the fetuses. All captured views (except Cervix) belong to the selected fetus, capture counts are updated automatically.
Discard	***Discard*** enables to delete images. Depending on whether unaccepted images are available or not, a message appears asking for confirmation. Select ***Yes*** to discard the images and close the dialog or ***No*** to continue without deleting.
Edit	A press onto ***Edit*** (pencil icon) opens a new window in which it is possible to change views configured in the system setup and/or detected criteria. All editable criteria can be changed by tapping onto them. If configured, a ***Left*** / ***Right*** selection is possible. Press ***Set*** to save the changes made and to close the window or ***Cancel*** to leave the menu without saving changes.

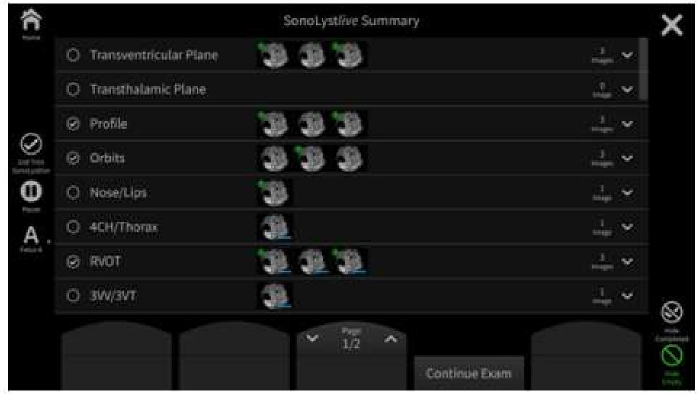


Figure 7-3 SonoLystlive Summary (example)

A tap onto a row displays the depending images of that view, a tap onto an image displays the depending SonoLystX menu. A circle with a checkmark indicates that the capture count is reached. As most of the controls are the same as in SonoLystX, only the summary page specific controls are described here:

Continue Exam Closes the dialog and goes back to the exam.

Review Images Opens the ***Exam Review*** to review and / or delete images.

	Accept & End Exam All images are accepted, the dialog and the exam are closed. ***Hide Completed*** When selected all completed views are hidden. ***Hide Empty*** When selected all empty views are hidden. ***Hide Accepted*** When selected all accepted images are hidden. Trackball buttons: ***SonoLystlive*** / ***Pause*** Toggles between SonoLyst*live* and ***Pause***. ***Discard*** Deletes the image from the clipboard. ***Accept*** Accepts the image. ***Left/Right/Both*** A left/right view is detected. Accepts the image by selecting the correct side/both sides and adds it to the configured annotation .The corresponding icon in the Flexible Display area increases the capture count. ***Measure*** Saves and reloads the image. The first measurement of the next incomplete measurement is started automatically. It is possible to perform all configured measurements for the auto-captured view. **Note** *Only available when* ***Auto capture views with measurement*** *is selected in the system setup.* GE Healthcare, *The Future is Now. How AI can Change the Practice of Obstetric Ultrasound.* (Sep 5, 2024), https://www.youtube.com/watch?v=6kFi6RNjqnE (demonstrating SonoLyst*live* functionality)

		 CLIPBOARD (32) SonoLystlive GA=22w5d 16.10.2023 Page 3/3  CLIPBOARD (32) SonoLystlive GA=22w5d 16.10.2023 4CH/Thorax Page 3/3

	 To the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. For example, since the traffic light quality status indicator indicates the quality of the assessed ultrasound image by turning green when the probe is at an ideal position for capturing protocol adherent images for a given pre-defined standard view, Defendants infringe any claim element including a "quality assessment value" under the doctrine of equivalents. *See* claim 1[c].
'591 Claim 4	**Voluson Family Products**
4: The system of claim 1 wherein the at least one processor is configured to: apply one or more view categorization functions to the first at least one	The Voluson family products discloses that the processor is configured to *"apply one or more view categorization functions to the first at least one echocardiographic image to determine that the first at least one echocardiographic image falls within the first view category"* and *"apply one or more view categorization functions to the second at least one echocardiographic image to determine that the second at least one echocardiographic image falls within the second view category."*

echocardiographic image to determine that the first at least one echocardiographic image falls within the first view category; and apply one or more view categorization functions to the second at least one echocardiographic image to determine that the second at least one echocardiographic image falls within the second view category.	The Voluson family products apply *view categorization functions* (i.e., algorithms or AI models) to the acquired images to determine whether the detected features in the image fall within the current view category. Specifically, SonoLyst AI uses a trained classification neural network on the image frames. As described above for 1[b], the SonoLyst AI algorithm repeatedly evaluates and displays information indicating quality of the current image with respect to a specific view as new images are received. For example, the Voluson family user interface displays a traffic light quality status indicator (based on grading criteria) with respect to a target view that can be detected automatically. This process can be repeated for multiple views (e.g., the first and second view categories). For example, see the following passages and/or figures, as well as all related disclosures: FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K220358) at 7-8: "SonoLyst: Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance • For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images. • The number of individual patients images were collected from: 5000+ exams • The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops. … Information about equipment and protocols used to collect images. • Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection. Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): 1. The images were curated (sorted and graded) by a single Sonographer

	2. The images were sorted and graded by SonoLyst. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system. Description of how independence of test data from training data was ensured: • The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two.” FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K231965) at 10-11: “Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. • Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population. • The verification for the SonoLyst 2nd Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features. • The verification of the SonoLystLive 2nd Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality. • The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher. … <u>Quantitative evaluation</u>: For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation

	… Information about the reference standard and dataset ("truthing process"): To ensure the quality of the curated data for verification, the following strategy is employed: 1. The images were curated (sorted and graded) by a single sonographer. 2. The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system." Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6: All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

The output image of the SonoLyst*live* feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:

As SonoLystIR and SonoLystX are deeply integrated in the Scan Assistant workflow, please refer to ' Scan Assistant ' *on page 7-10* for more details about the usage and setup.

Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-10 to 7-13:

7.2 Scan Assistant

The Scan Assistant is a tool with guidelines for sonographers. It offers specific factory checklists containing the anatomical structures or organs to be examined in certain examinations and so prevents from missing important items. It is possible to customize these checklists and also to set up new lists. Additionally the Scan Assistant can be used to activate a specific measurement for an exam item as well as annotate, save or send the image for documentation purposes.


SONOLYSTIR MID-TRIM
0 / 32 items completed
SonoLystIR: found
General
Head
Face
Lateral Ventricle
Cerebellum/ CM
DESCRIPTION
Measure cerebellum and cisterna magna
MEASUREMENTS
Cereb.:
CM:
FETAL ANATOMY
Cerebellum: visualized
Cisterna magna:
SONOLYSTX
Transcerebellar Plane
Brain symmetry
Cavum septum pellucidum
Cerebellum
Cisterna Magna
Midline falx
Magnification
0 / 32

Following sections/items are displayed:

- list name
- progress viewer / Pause

Note *If Scan Assistant is active, the progress symbol of Scan Assistant is shown in the tab area of the Flexible Display area. It is possible to display and hide the Flexible Display area by pressing on the progress symbol. The left number is the number of images which reached the capture count, the right number is the number of possible views.*

- selected group (if available)
- selected item
- description area
- measurement result area
- Fetal Anatomy (OB) / Findings (GYN) area
- SonoLystX area (only visible when a SonoLystX item was found and SonoLystX view is activated on the touch panel)

Following icons are displayed:

1. is displayed at the measurement header when a measurement is required.
2. is displayed at the description header when the current item is an optional item.
3. is displayed at the ***Fetal Anatomy (OB) / Findings (GYN)*** header when a fetal anatomy item (OB) / finding (GYN) is required.
4. is displayed if an SonoLyst linked item is active.

	Using the Scan Assistant 1. Start the exam by scanning the first item of the first category. 2. When the item is scanned, freeze the image and press the P-Button configured for confirming. **Note** *It is also possible to check/uncheck an item manually by tapping at the check area (circle).* 3. The item is checked and the next item turns green. 4. Scan all items of the category and move to the next category. If the items cannot be scanned in the predefined order, use the arrow keys on the keyboard or on the touch panel to change between items and/or categories. 5. Press ***End Exam*** to finish. A summary of the Scan Assistant is displayed on the screen showing all (not) examined categories and items.

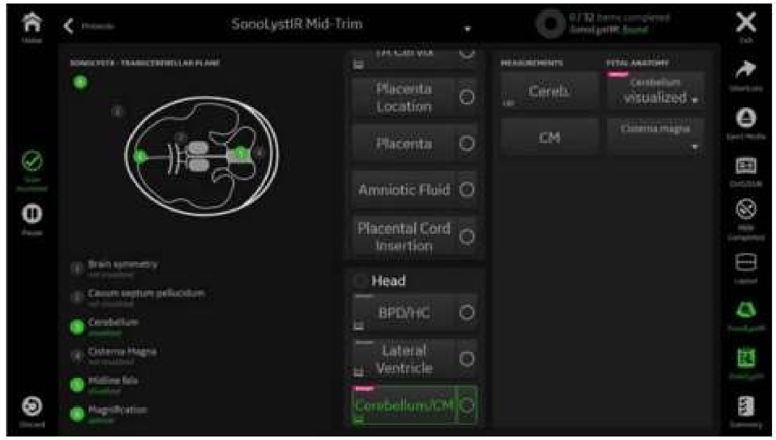


Figure 7-5 Scan Assistant with SonoLyst (example)

If an item is linked to a SonoLyst image and the system finds a depending plane, this item is displayed on the touch panel.

The items linked to SonoLyst are labeled accordingly with a badge (only available when the option is set). SonoLystX shows the corresponding pictogram and criteria.

It is also possible to switch the SonoLystIR image recognition algorithm on and off. When the image is zoomed in or out or another image is selected from the cine buffer, the SonoLyst algorithm is restarted (if switched on).

Instead of the group area all SonoLystIR view depending criteria are displayed. It is possible to set a criterion to found/not found manually by tapping onto the circle.

	Starting/selecting Scan Assistant lists can also be done by pressing ***Protocols*** on the touch panel. Three different states are available: 1. No Scan Assistant or Assessment Tool is started: Select the desired tool or list and press ***Start***. The menu closes automatically. 2. Already ongoing Scan Assistant list or Assessment Tool: • The ongoing Assessment tool list is paused. Press ***Continue*** to go on. Press ***None*** to deactivate the currently ongoing Scan Assistant list without losing data. • Select a Scan Assistant list and press ***Start***. The menu closes automatically. • Press ***Discard*** to clear the currently selected list or tool. Confirm the clearing of data (***Yes***) or decline (***No***). 3. No exam started: A message appears together with the ***Start Exam*** button. Press the button to open the Patient Information Dialog. The ***Auto Capture*** function for Scan Assistant depends on the system setup settings for SonoLyst*live*. If ***Auto Capture*** is enabled and a view o a Scan Assistant item is captured with SonoLyst*live* configured, it is possible to select between ***Accept*** (saves the image to the clipboard, the Scan Assistant item is checked automatically and configured annotations are inserted automatically) or ***Discard*** (the corresponding item is unchecked and deleted from the clipboard) on the trackball. With ***Auto Capture*** it is possible to switch between the levels: • green: only good views are captured • yellow: good views and middle views are captured • Manual: no ***Auto Capture*** active; manual action required • Background Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 13-45 to 13-47:

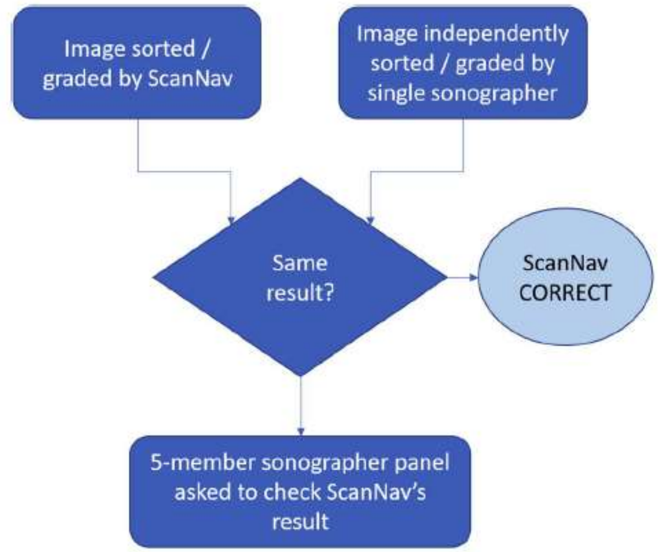
	13.13 Deep Learning Based Features **Note** *Some of these deep learning based features are not available in all countries:* • SonoLystIR • SonoLystIR 1st Trimester • SonoLystX • SonoLystX 1st Trimester • SonoLyst*live* • SonoLyst*live* 1st Trimester • Sono*Biometry* CRL • SonoPelvicFloor • SonoCNS • Sono*Biometry* Cereb, Vp, CM • FetalHS • SonoAVC™*follicle* 2.0 • SonoAVC™*follicle* Auto Caliper • Fibroid Mapping • AutoSpine • SonoPF2D • AnalSphincter The application of deep learning based features requires caution by the user and an informed decision on the usage of the specific feature. Therefore, all caution information and performance testing for each feature are summarized in this chapter. Yangdi Xu et al., *Simulating realistic fetal neurosonography images with appearance and growth change using cycle-consistent adversarial networks and an evaluation*, Journal of Medical Imaging (Sep/Oct 2020), Vol. 7(5) at 4: "ScanNav® (Intelligent Ultrasound Ltd., Milton Park, Abingdon, United Kingdom) is a pre-commercial deep learning-based automatic image analysis software application that assesses the quality of second-trimester scans according to the UK FASP guidelines. It is able to accurately detect different structures of a standard plane in large scale. It had been designed and trained by analzsing thousands of clinical second-trimester ultrasound images to label and grade

	images. Details of the underpinning algorithms and data used to build the quality assessment model are proprietary. However, we assume that the quality of software-derived annotation labels is at the same level as a typical experienced sonographer. This assumption is confirmed to be valid for our data later in this article. Under this assumption, ScanNav® is treated as equivalent to an experienced sonographer in ultrasound image classifications. It can assess and compare hundreds of real and simulated second-trimester scans efficiently and quickly (which is something that is tedious and costly to achieve if the task is performed by human experts)." E.H. Bradburn et al., *OC10.05 An artificial intelligence system that can correctly identify fetal ultrasound imaging planes throughout gestational age*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28-29.

	Methods: Anonymised fetal ultrasound images, acquired at 15 to 40 weeks of gestation, from a large image database were analysed in this study. This included images of head circumference (HC), abdominal circumference (AC), femur length (FL), amniotic fluid index (AFI) and miscellaneous images. An AI algorithm (ScanNav, trained primarily on routine anatomy scans from 18-24 weeks), was applied to each image and categorised it into one of five categories: HC, AC, FL, AFI and others. A random ten percent per view of all images were manually reviewed by one experienced clinician to determine the accuracy of this classification. The performance of the AI algorithm, according to the gestational age at the time of the scan, was assessed. **Results:** Over 450,000 images were assessed by ScanNav, and a random 10% (45,036 images) underwent clinical review. The accuracy of the AI algorithm in categorising the images into standard biometry planes (HC, AC, FL and AFI) was 99.1%. This was 99.6%, 99.1%, 97.9% and 99.9% for HC, AC, FL and AFI, respectively. Across all categories the algorithm performed best between 20+0 and 35+6 weeks, with an accuracy that remained stable throughout that gestational age range (97%). There was a slight drop in accuracy below 20 weeks and above 36 weeks, to 94% and 96% respectively. **Conclusions:** Although trained primarily on routine anatomy scans from 18-24 weeks, the ScanNav AI algorithm is 99.1% accurate in image categorisation of basic biometry planes. Accuracy was maintained over a very broad range of gestational ages. This may reflect that clinically these standard planes remain consistent in appearance throughout gestation. Improvement at the extremes of GA may be possible by further algorithm training. E.H. Bradburn et al., *OC10.04 Estimating fetal gestational age based on ultrasound image characteristics using artificial intelligence*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28.

	Methods: Quality assessed ultrasound images of head circumference (HC) and abdominal circumference (AC) were used from a multicentre study database of women with known GA (CRL performed < 14 weeks) who underwent serial ultrasound examinations from 15 to 40 weeks. We split data randomly into 67.5% training, 7.5% validation and 25% testing sets. We developed and tested an artificial intelligence (AI) algorithm using a regression neural network to estimate the GA, based on image characteristics only without measurement information. Mohammad Yaqub et al., *491 ScanNav® audit: an AI-powered screening assistant for fetal anatomical ultrasound*, American Journal of Obstetrics & Gynecology, Supplement to February 2021, at S312.

		OBJECTIVE: To develop and evaluate a real-time Artificial Intelligence (AI) based system to automatically keep track of acquired images; and check that the images conform to imaging protocol standards, in essence, replacing a human peer reviewer. **STUDY DESIGN:** We developed an AI system (ScanNav) which automatically (1) checks the completeness of the imaging record during fetal anomaly screening, ensuring all 19 required fetal views are recorded; and (2) assesses the quality of these images (in this case according to the guidelines of ISUOG). First, AI algorithms were trained on images manually evaluated by a pool of experienced sonologists and using state-of-the-art deep learning technology. The resulting algorithm was then assessed on a separate testing set; it was deemed correct if 2 or more (from a panel of 5) independent sonologists agreed with its decision. Due to the lack of expert agreement for "marginal" images, it was deemed appropriate to include as agreement such a 2:3 panel split. **RESULTS:** The system was developed on 479,322 anonymised images from 48,161 routine mid-trimester scans. Agreement between ScanNav and the sonologist panel was performed on an independent set of 38,840 images (4,284 scans). For scan completeness the mean (standard deviation) of agreement between ScanNav and the sonologists was 93.5% (±5.6%); for image quality it was 92.2% (±4.7%). The system processes 11 frames per second on a PC with an RTX4000 GPU.



# Sonographers agree with ScanNav	ScanNav
0	INCORRECT
1	INCORRECT
2	CORRECT
3	CORRECT
4	CORRECT
5	CORRECT

GE Healthcare, *The Future is Now. How AI can Change the Practice of Obstetric Ultrasound.* (Sep 5, 2024), https://www.youtube.com/watch?v=6kFi6RNjqnE (demonstrating SonoLyst*live* functionality)

		GE HealthCare GA=22w5d CLIPBOARD (32) SonoLystlive Page 3/3 GE HealthCare GA=22w5d CLIPBOARD (32) SonoLystlive 4CH/Thorax Page 3/3

	
’591 Claim 5	**Voluson Family Products**
5: The system of claim 1 wherein the first at least one echocardiographic image comprises a plurality of echocardiographic images and wherein the at least one processor is configured to determine the first quality assessment value by determining a single quality assessment value representing a view	The Voluson family products disclose a computer-implemented system *“wherein the first at least one echocardiographic image comprises a plurality of echocardiographic images and wherein the at least one processor is configured to determine the first quality assessment value by determining a single quality assessment value representing a view category specific assessment of the plurality of echocardiographic images.”* *See* also claim 1[pre] and 1[j] regarding the Voluson family products’ at least one processor. *See* claim 1 generally regarding a plurality of echocardiographic images. *See* claim 1[c] regarding determining a view category specific quality assessment value.

category specific assessment of the plurality of echocardiographic images.	The Voluson family products are configured to acquire a series of images of various view categories and can also obtain video clips, which are a sequence of images (e.g., frames). As described for 1[c], the SonoLyst AI algorithm can determine a first quality assessment value for an echocardiographic image. Similarly, the SonoLyst AI algorithm can determine a first quality assessment value based on multiple images, such as a short cine loop or multiple frames. For example, see the following passages and/or figures, as well as all related disclosures: GE Healthcare, *The Future is Now. How AI can Change the Practice of Obstetric Ultrasound.* (Sep 5, 2024), https://www.youtube.com/watch?v=6kFi6RNjqnE (demonstrating SonoLyst*live* functionality)  <u>Excerpt from video transcript</u> (9:58-10:34): "You do have the ability to set it to capture any number of images over here so you can see at the moment this system is set up to capture, I don't know how many, um up to three up but you can set it to capture just a single image or

	five depending on your hospital protocol. … For example, for the biometry measurements, it might ask for a number which is often three." Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at **Cine** Cine images are constantly being stored by the system and are available for playback or manual review via cine. Cine can be viewed as a continuous loop via Cine Loop or manually frame by frame via the trackball. **7.4 Cine Mode** While scanning a certain number of frames (2D images of the last examination sequence) are stored in the cine memory automatically. This is indicated by the green bar. By pressing the ***Freeze*** button or the defined ***P***x button, the cine memory is stored as a sequence. This sequence can be reviewed in loop mode or image by image. After the cine clip is stored the cine memory is deleted. Move the trackball horizontally to display the 2D images of the stored sequence, one by one.

Cine Mode Monitor Display

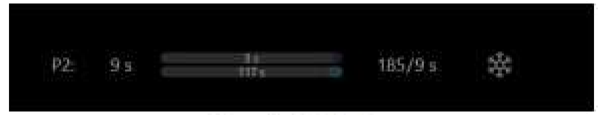


Figure 7-10 Cine Run

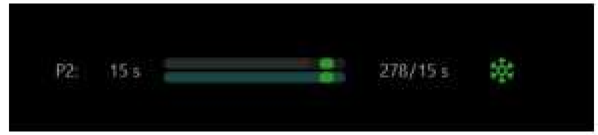


Figure 7-11 Cine Freeze

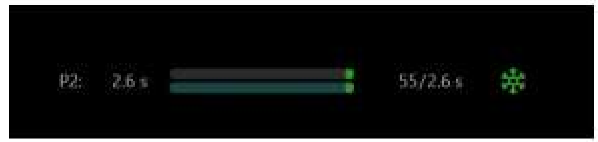


Figure 7-12 Edit Cine

Figure 7-13 Save Cine

Px	Programmed ***Px*** button
xx s	Default clip length in seconds programmed under a ***Px*** button
upper bar	Save clip (corresponding to the activated ***Px*** button)
lower bar	Acquisition clip (original clip)
xx/yy s	Alphanumeric display of the currently captured cine length in frames (xx) and seconds (yy).
	***Freeze*** (green) and ***Run*** (grey) icon
Cine image marker	Green marker on the upper/lower bar (only present in ***Freeze*** mode). The position corresponds to the image (clip frame) on the screen. The marker can be moved using the trackball. The marker is green as long it is inside the "save clip" section. Outside of the "save clip" section it turns red.
Calculating	Displayed during the ***Save*** process.

Remarks:

- The number of stored images depends on the number of scan lines, scan depth and magnification. In ***Freeze*** mode the length of the sequence is indicated on the status bar.
- Starting the Cine mode erases measuring marks and measuring displays.
- The Cine Function (operation and storage) is identical in 2D mode and CFM mode.

FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K220358) at 7-8:

"SonoLyst: Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance

- For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images.
- The number of individual patients images were collected from: 5000+ exams
- The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops.

	… Information about equipment and protocols used to collect images. • Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection. Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): 1. The images were curated (sorted and graded) by a single Sonographer 2. The images were sorted and graded by SonoLyst. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system. Description of how independence of test data from training data was ensured: • The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two." FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K231965) at 10-11: "Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. • Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population. • The verification for the SonoLyst 2nd Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features.

	- The verification of the SonoLystLive 2nd Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality. - The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher. … <u>Quantitative evaluation</u>: For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation … Information about the reference standard and dataset ("truthing process"): To ensure the quality of the curated data for verification, the following strategy is employed: - The images were curated (sorted and graded) by a single sonographer. - The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting. - Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. - Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system." Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6:

All SonoLyst features are workflow supporting features and are all based on Deep Learning technology:

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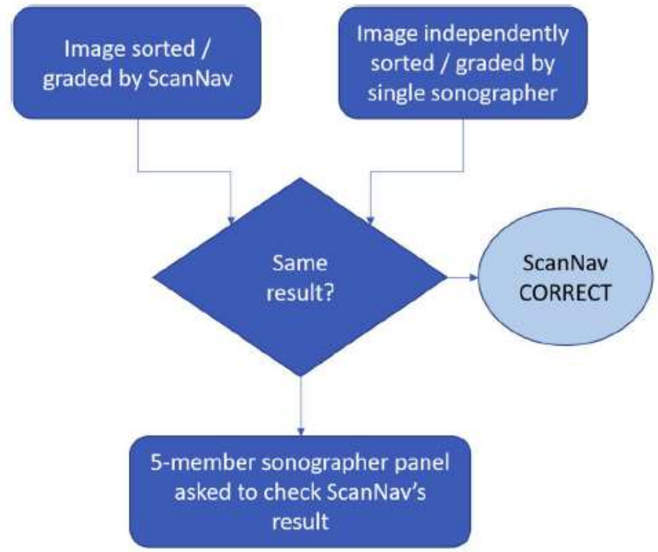
- SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

  The output image of the SonoLyst*live* feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:

	Yangdi Xu et al., *Simulating realistic fetal neurosonography images with appearance and growth change using cycle-consistent adversarial networks and an evaluation*, Journal of Medical Imaging (Sep/Oct 2020), Vol. 7(5) at 4: "ScanNav® (Intelligent Ultrasound Ltd., Milton Park, Abingdon, United Kingdom) is a pre-commercial deep learning-based automatic image analysis software application that assesses the quality of second-trimester scans according to the UK FASP guidelines. It is able to accurately detect different structures of a standard plane in large scale. It had been designed and trained by analzsing thousands of clinical second-trimester ultrasound images to label and grade images. Details of the underpinning algorithms and data used to build the quality assessment model are proprietary. However, we assume that the quality of software-derived annotation labels is at the same level as a typical experienced sonographer. This assumption is confirmed to be valid for our data later in this article. Under this assumption, ScanNav® is treated as equivalent to an experienced sonographer in ultrasound image classifications. It can assess and compare hundreds of real and simulated second-trimester scans efficiently and quickly (which is something that is tedious and costly to achieve if the task is performed by human experts)." *491 ScanNav® audit: an AI-powered screening assistant for fetal anatomical ultrasound*, Mohammad Yaqub et al., American Journal of Obstetrics & Gynecology, Supplement to February 2021, at S312.

		OBJECTIVE: To develop and evaluate a real-time Artificial Intelligence (AI) based system to automatically keep track of acquired images; and check that the images conform to imaging protocol standards, in essence, replacing a human peer reviewer. **STUDY DESIGN:** We developed an AI system (ScanNav) which automatically (1) checks the completeness of the imaging record during fetal anomaly screening, ensuring all 19 required fetal views are recorded; and (2) assesses the quality of these images (in this case according to the guidelines of ISUOG). First, AI algorithms were trained on images manually evaluated by a pool of experienced sonologists and using state-of-the-art deep learning technology. The resulting algorithm was then assessed on a separate testing set; it was deemed correct if 2 or more (from a panel of 5) independent sonologists agreed with its decision. Due to the lack of expert agreement for "marginal" images, it was deemed appropriate to include as agreement such a 2:3 panel split. **RESULTS:** The system was developed on 479,322 anonymised images from 48,161 routine mid-trimester scans. Agreement between ScanNav and the sonologist panel was performed on an independent set of 38,840 images (4,284 scans). For scan completeness the mean (standard deviation) of agreement between ScanNav and the sonologists was 93.5% (±5.6%); for image quality it was 92.2% (±4.7%). The system processes 11 frames per second on a PC with an RTX4000 GPU.



# Sonographers agree with ScanNav	ScanNav
0	INCORRECT
1	INCORRECT
2	CORRECT
3	CORRECT
4	CORRECT
5	CORRECT

To the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. For example, since the traffic light quality status indicator indicates the quality of the assessed ultrasound image by turning green when the probe is at an ideal position for capturing protocol adherent images for a given pre-defined standard view, Defendants infringe any claim element including a "quality assessment value" under the doctrine of equivalents. *See* claim 1[c].

’591 Claim 6	Voluson Family Products
6: The system of claim 1 wherein each of the sets of assessment parameters includes: a set of common assessment parameters, which are common to each of the sets of assessment parameters; and a set of view category specific assessment parameters, which are unique to the set of assessment parameters.	The Voluson family products disclose a computer-implemented system “*wherein each of the sets of assessment parameters includes: a set of common assessment parameters, which are common to each of the sets of assessment parameters; and a set of view category specific assessment parameters, which are unique to the set of assessment parameters*.” The SonoLyst AI algorithm involves common assessment parameters corresponding to non-view category specific layers, and view category specific assessment parameters corresponding to view category specific layers. Each neural network defined by one of the sets of assessment parameters (e.g., a neural network within a neural network) thus includes a set of the common assessment parameters and a set of view category specific parameters of the SonoLyst AI algorithm. See claim 1[i] regarding the Voluson family products view category specific assessment parameters, which are unique to the set of assessment parameters. SonoLyst AI knows the present view and applies the appropriate assessment parameters for that view. For example, once SonoLystIR identifies that it is in a 4CH view, SonoLystX will use the 4CH quality model or parameters to score the image. If the next image is a 3VV view, the system will use the 3VV quality model or parameters. For example, see the following passages and/or figures, as well as all related disclosures: FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K220358) at 7-8: “SonoLyst: Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance • For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images. • The number of individual patients images were collected from: 5000+ exams • The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops. …

	Information about equipment and protocols used to collect images. • Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection. Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): 1. The images were curated (sorted and graded) by a single Sonographer 2. The images were sorted and graded by SonoLyst. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system. Description of how independence of test data from training data was ensured: • The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two." FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K231965) at 10-11: "Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. • Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population. • The verification for the SonoLyst 2nd Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features.

	• The verification of the SonoLystLive 2nd Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality. • The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher. … <u>Quantitative evaluation</u>: For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation … Information about the reference standard and dataset ("truthing process"): To ensure the quality of the curated data for verification, the following strategy is employed: 1. The images were curated (sorted and graded) by a single sonographer. 2. The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system." Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6:

	All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload. Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 13-45 to 13-47:

13.13 Deep Learning Based Features

Note *Some of these deep learning based features are not available in all countries:*

- SonoLystIR
- SonoLystIR 1st Trimester
- SonoLystX
- SonoLystX 1st Trimester
- SonoLyst*live*
- SonoLyst*live* 1st Trimester
- Sono*Biometry* CRL
- SonoPelvicFloor
- SonoCNS
- Sono*Biometry* Cereb, Vp, CM
- FetalHS
- SonoAVC™*follicle* 2.0
- SonoAVC™*follicle* Auto Caliper
- Fibroid Mapping
- AutoSpine
- SonoPF2D
- AnalSphincter

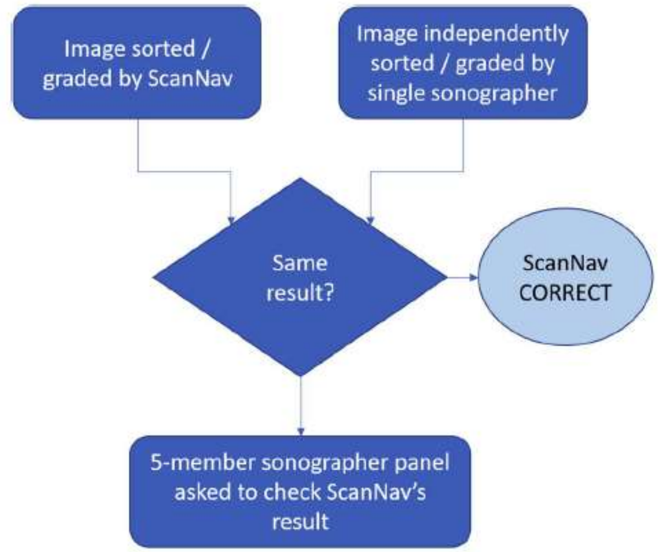
The application of deep learning based features requires caution by the user and an informed decision on the usage of the specific feature. Therefore, all caution information and performance testing for each feature are summarized in this chapter.

E.H. Bradburn et al., *OC10.05 An artificial intelligence system that can correctly identify fetal ultrasound imaging planes throughout gestational age*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28-29.

	Methods: Anonymised fetal ultrasound images, acquired at 15 to 40 weeks of gestation, from a large image database were analysed in this study. This included images of head circumference (HC), abdominal circumference (AC), femur length (FL), amniotic fluid index (AFI) and miscellaneous images. An AI algorithm (ScanNav, trained primarily on routine anatomy scans from 18-24 weeks), was applied to each image and categorised it into one of five categories: HC, AC, FL, AFI and others. A random ten percent per view of all images were manually reviewed by one experienced clinician to determine the accuracy of this classification. The performance of the AI algorithm, according to the gestational age at the time of the scan, was assessed. **Results:** Over 450,000 images were assessed by ScanNav, and a random 10% (45,036 images) underwent clinical review. The accuracy of the AI algorithm in categorising the images into standard biometry planes (HC, AC, FL and AFI) was 99.1%. This was 99.6%, 99.1%, 97.9% and 99.9% for HC, AC, FL and AFI, respectively. Across all categories the algorithm performed best between 20+0 and 35+6 weeks, with an accuracy that remained stable throughout that gestational age range (97%). There was a slight drop in accuracy below 20 weeks and above 36 weeks, to 94% and 96% respectively. **Conclusions:** Although trained primarily on routine anatomy scans from 18-24 weeks, the ScanNav AI algorithm is 99.1% accurate in image categorisation of basic biometry planes. Accuracy was maintained over a very broad range of gestational ages. This may reflect that clinically these standard planes remain consistent in appearance throughout gestation. Improvement at the extremes of GA may be possible by further algorithm training. E.H. Bradburn et al., *OC10.04 Estimating fetal gestational age based on ultrasound image characteristics using artificial intelligence*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28.

	Methods: Quality assessed ultrasound images of head circumference (HC) and abdominal circumference (AC) were used from a multicentre study database of women with known GA (CRL performed < 14 weeks) who underwent serial ultrasound examinations from 15 to 40 weeks. We split data randomly into 67.5% training, 7.5% validation and 25% testing sets. We developed and tested an artificial intelligence (AI) algorithm using a regression neural network to estimate the GA, based on image characteristics only without measurement information. Mohammad Yaqub et al., *491 ScanNav® audit: an AI-powered screening assistant for fetal anatomical ultrasound*, American Journal of Obstetrics & Gynecology, Supplement to February 2021, at S312.

		OBJECTIVE: To develop and evaluate a real-time Artificial Intelligence (AI) based system to automatically keep track of acquired images; and check that the images conform to imaging protocol standards, in essence, replacing a human peer reviewer. **STUDY DESIGN:** We developed an AI system (ScanNav) which automatically (1) checks the completeness of the imaging record during fetal anomaly screening, ensuring all 19 required fetal views are recorded; and (2) assesses the quality of these images (in this case according to the guidelines of ISUOG). First, AI algorithms were trained on images manually evaluated by a pool of experienced sonologists and using state-of-the-art deep learning technology. The resulting algorithm was then assessed on a separate testing set; it was deemed correct if 2 or more (from a panel of 5) independent sonologists agreed with its decision. Due to the lack of expert agreement for "marginal" images, it was deemed appropriate to include as agreement such a 2:3 panel split. **RESULTS:** The system was developed on 479,322 anonymised images from 48,161 routine mid-trimester scans. Agreement between ScanNav and the sonologist panel was performed on an independent set of 38,840 images (4,284 scans). For scan completeness the mean (standard deviation) of agreement between ScanNav and the sonologists was 93.5% (±5.6%); for image quality it was 92.2% (±4.7%). The system processes 11 frames per second on a PC with an RTX4000 GPU.



# Sonographers agree with ScanNav	ScanNav
0	INCORRECT
1	INCORRECT
2	CORRECT
3	CORRECT
4	CORRECT
5	CORRECT

’591 Claim 7	Voluson Family Products
7: The system of claim 1 wherein the at least one processor is configured to train the neural networks by:	The Voluson family products disclose a computer-implemented system “*wherein the at least one processor is configured to train the neural networks by: receiving signals representing a plurality of echocardiographic training images, each of the plurality of echocardiographic training images associated with one of the plurality of predetermined echocardiographic image view categories; receiving signals representing respective expert quality assessment values representing view category specific quality assessments of the plurality of echocardiographic training images, each of*

receiving signals representing a plurality of echocardiographic training images, each of the plurality of echocardiographic training images associated with one of the plurality of predetermined echocardiographic image view categories; receiving signals representing respective expert quality assessment values representing view category specific quality assessments of the plurality of echocardiographic training images, each of the expert quality assessment values provided by an expert echocardiographer and associated with one of the plurality of echocardiographic training images; and training the neural networks using the plurality of echocardiographic training images as inputs and the associated expert quality assessment values as desired outputs to determine the sets of neural network	*the expert quality assessment values provided by an expert echocardiographer and associated with one of the plurality of echocardiographic training images; and training the neural networks using the plurality of echocardiographic training images as inputs and the associated expert quality assessment values as desired outputs to determine the sets of neural network parameters defining the neural networks*." *See* claims 1[pre] and 1[j], which show that the Voluson family products include at least one processor. *See* claim 1[c] and 1[i] regarding the deep neural network training process. The Voluson family products train the SonoLyst AI algorithm with ideal echocardiographic images that have been associated with transducer position and labeled by expert sonologists for image quality and correctness. The SonoLyst AI algorithm is also trained to estimate the four (4) diagnostic view categories of the fetal heart (e.g., 4CH/Thorax, LVOT, RVOT, and 3VV). Therefore, each echocardiographic training image is associated with a predetermined image view category. The deep neural network (SonoLyst AI algorithm) has a plurality of layers including an input layer configured to receive echocardiographic images and an output layer configured to output quality assessment values. Because the images are labeled and annotated with associated expert quality assessment values during the training process, the associated expert quality assessment values (i.e., ideal probe position) are the desired outputs. *See* claim 1[i]. For example, see the following passages and/or figures, as well as all related disclosures: FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K220358) at 7-8: "SonoLyst: Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance • For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images. • The number of individual patients images were collected from: 5000+ exams

parameters defining the neural networks.	• The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops. … Information about equipment and protocols used to collect images. • Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection. Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): 1. The images were curated (sorted and graded) by a single Sonographer 2. The images were sorted and graded by SonoLyst. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system. Description of how independence of test data from training data was ensured: • The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two." FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K231965) at 10-11: "Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. • Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population.

	• The verification for the SonoLyst 2nd Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features. • The verification of the SonoLystLive 2nd Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality. • The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher. … <u>Quantitative evaluation</u>: For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation … Information about the reference standard and dataset ("truthing process"): To ensure the quality of the curated data for verification, the following strategy is employed: 1. The images were curated (sorted and graded) by a single sonographer. 2. The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system." Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6:

	All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

	The output image of the SonoLyst*live* feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:  As SonoLystIR and SonoLystX are deeply integrated in the Scan Assistant workflow, please refer to ' Scan Assistant ' *on page 7-10* for more details about the usage and setup. All SonoLyst features use the following predefined standard views and depending criteria for the 1st Trimester:

Pre-defined standard view	Criteria
Sagittal Fetus	Magnification Mid-sagittal Neutral position and orientation Crown visible Rump visible
Axial Head	Magnification Symmetrical hemispheres Full head circumference visible Choroid plexus visible Midline falx
Transthalamic Plane	Magnification Symmetrical hemispheres Two separate thalami Midline falx
Axial Orbits	Magnification Both orbits visible
Coronal Orbits	Magnification Both orbits visible Nose visible Both ears visible
Coronal Palate	Magnification Nasal bone Supermaxilla
Coronal Lips	Magnification Nasal tip Upper lip
4CH/Thorax	Magnification 4 chambers clearly visible
Cord Insertion	Magnification Cord inserted into abdominal wall
Axial Abdomen	Magnification Full abdominal circumference visible Stomach visible
Axial Kidneys	Magnification Both kidneys visible
Axial Bladder	Magnification Bladder visible
Coronal Kidneys	Magnification Both kidneys visible
Sagittal Spine	Magnification Vertebrae are aligned Skin edge
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible

Pre-defined standard view	Criteria
Hand	Magnification Hand visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible
Sagittal Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Sagittal Profile	Magnification Mid-sagittal Neutral position and orientation Nasal tip
Sagittal Brain	Magnification Brainstem Fourth ventricle Cisterna magna

All SonoLyst features use the following predefined standard views and depending criteria for the 2nd Trimester:

Pre-defined standard view	Criteria
Transventricular Plane	Magnification Brain symmetry Midline falx Lateral cerebral ventricles Choroid Plexus Cavum septum pellucidum No Cerebellum
Transthalamic Plane	Magnification Brain symmetry Midline falx Thalamus Cavum septum pellucidum No Cerebellum
Transcerebellar Plane	Magnification Brain symmetry Midline falx Cavum septum pellucidum Cerebellum Cisterna Magna
Profile	Magnification Nasal tip Forehead bone visible

Pre-defined standard view	Criteria
Orbits	Magnification Both orbits visible Symmetrical orbits
Nose/Lips	Magnification Nasal tip Nostrils Upper lip
4CH/Thorax	Magnification 4 Chambers visible Ventricular Septum Valves visible
LVOT	Continuity Ventricular Septum Magnification
RVOT	Vessel Bifurcation Magnification
3VV/3VT	3 Vessels Magnification
Abdomen (AC)	Magnification Stomach Umbilical vein Rib visible Circular/Shape No Kidney visible
Abdomen - Cord Insertion	Magnification Cord visible
Transverse Kidneys	Magnification Both kidneys visible
Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Femur	Magnification Angle of insonation Clear Diaphysis
Plantar Foot	Magnification Full foot visible
Hand	Magnification Clear hand visible
TA Cervix	Magnification Endocervical Canal Internal Os External Os
Spine Sacrum	Lumbar - alignment Lumbar - Skin line Magnification

	(table below)

Pre-defined standard view	Criteria
Spine Lumbar	Lumbar - alignment Lumbar - Skin line Magnification
Spine Thoracic	Thoracic - alignment Thoracic - Skin line Magnification
Spine Cervical	Cervical - alignment Cervical - Skin line Magnification
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible

Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 13-45 to 13-47:

13.13 Deep Learning Based Features

Note *Some of these deep learning based features are not available in all countries:*

- SonoLystIR
- SonoLystIR 1st Trimester
- SonoLystX
- SonoLystX 1st Trimester
- SonoLyst*live*
- SonoLyst*live* 1st Trimester
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- SonoAVC™*follicle* 2.0
- SonoAVC™*follicle* Auto Caliper
- Fibroid Mapping
- AutoSpine
- SonoPF2D
- AnalSphincter

The application of deep learning based features requires caution by the user and an informed decision on the usage of the specific feature. Therefore, all caution information and performance testing for each feature are summarized in this chapter.

Performance Testing for SonoLyst:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystIR	80% accuracy	41936

	Performance Testing for SonoLystIR 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystIR 1st Trimester	80% accuracy	5271

Performance Testing for SonoLystX:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystX	80%	9998

Performance Testing for SonoLystX 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystX 1st Trimester	80%	2400

Performance Testing for SonoLyst*live*:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLyst*live*	80% accuracy	5623

Performance Testing for SonoLyst*live* 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLyst*live* 1st Trimester	80%	6000

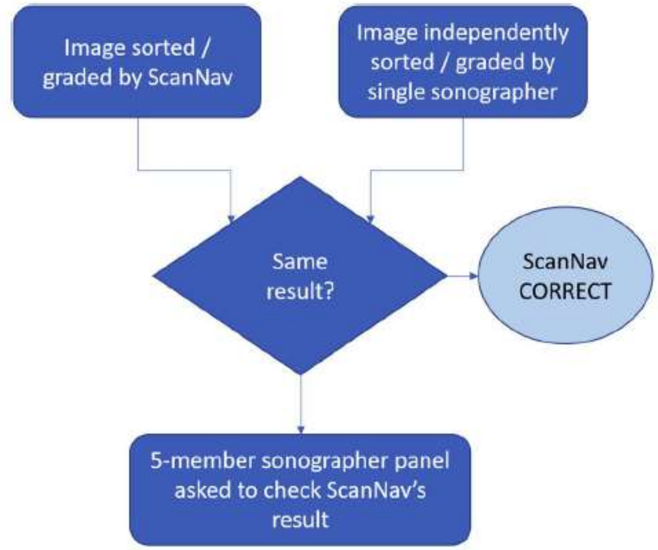
Yangdi Xu et al., *Simulating realistic fetal neurosonography images with appearance and growth change using cycle-consistent adversarial networks and an evaluation*, Journal of Medical Imaging

	(Sep/Oct 2020), Vol. 7(5) at 4: "ScanNav® (Intelligent Ultrasound Ltd., Milton Park, Abingdon, United Kingdom) is a pre-commercial deep learning-based automatic image analysis software application that assesses the quality of second-trimester scans according to the UK FASP guidelines. It is able to accurately detect different structures of a standard plane in large scale. It had been designed and trained by analzsing thousands of clinical second-trimester ultrasound images to label and grade images. Details of the underpinning algorithms and data used to build the quality assessment model are proprietary. However, we assume that the quality of software-derived annotation labels is at the same level as a typical experienced sonographer. This assumption is confirmed to be valid for our data later in this article. Under this assumption, ScanNav® is treated as equivalent to an experienced sonographer in ultrasound image classifications. It can assess and compare hundreds of real and simulated second-trimester scans efficiently and quickly (which is something that is tedious and costly to achieve if the task is performed by human experts)." E.H. Bradburn et al., *OC10.05 An artificial intelligence system that can correctly identify fetal ultrasound imaging planes throughout gestational age*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28-29.

	Methods: Anonymised fetal ultrasound images, acquired at 15 to 40 weeks of gestation, from a large image database were analysed in this study. This included images of head circumference (HC), abdominal circumference (AC), femur length (FL), amniotic fluid index (AFI) and miscellaneous images. An AI algorithm (ScanNav, trained primarily on routine anatomy scans from 18-24 weeks), was applied to each image and categorised it into one of five categories: HC, AC, FL, AFI and others. A random ten percent per view of all images were manually reviewed by one experienced clinician to determine the accuracy of this classification. The performance of the AI algorithm, according to the gestational age at the time of the scan, was assessed. **Results:** Over 450,000 images were assessed by ScanNav, and a random 10% (45,036 images) underwent clinical review. The accuracy of the AI algorithm in categorising the images into standard biometry planes (HC, AC, FL and AFI) was 99.1%. This was 99.6%, 99.1%, 97.9% and 99.9% for HC, AC, FL and AFI, respectively. Across all categories the algorithm performed best between 20+0 and 35+6 weeks, with an accuracy that remained stable throughout that gestational age range (97%). There was a slight drop in accuracy below 20 weeks and above 36 weeks, to 94% and 96% respectively. **Conclusions:** Although trained primarily on routine anatomy scans from 18-24 weeks, the ScanNav AI algorithm is 99.1% accurate in image categorisation of basic biometry planes. Accuracy was maintained over a very broad range of gestational ages. This may reflect that clinically these standard planes remain consistent in appearance throughout gestation. Improvement at the extremes of GA may be possible by further algorithm training. E.H. Bradburn et al., *OC10.04 Estimating fetal gestational age based on ultrasound image characteristics using artificial intelligence*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28.

	Methods: Quality assessed ultrasound images of head circumference (HC) and abdominal circumference (AC) were used from a multicentre study database of women with known GA (CRL performed < 14 weeks) who underwent serial ultrasound examinations from 15 to 40 weeks. We split data randomly into 67.5% training, 7.5% validation and 25% testing sets. We developed and tested an artificial intelligence (AI) algorithm using a regression neural network to estimate the GA, based on image characteristics only without measurement information. Mohammad Yaqub et al., *491 ScanNav® audit: an AI-powered screening assistant for fetal anatomical ultrasound*, American Journal of Obstetrics & Gynecology, Supplement to February 2021, at S312.

		OBJECTIVE: To develop and evaluate a real-time Artificial Intelligence (AI) based system to automatically keep track of acquired images; and check that the images conform to imaging protocol standards, in essence, replacing a human peer reviewer. **STUDY DESIGN:** We developed an AI system (ScanNav) which automatically (1) checks the completeness of the imaging record during fetal anomaly screening, ensuring all 19 required fetal views are recorded; and (2) assesses the quality of these images (in this case according to the guidelines of ISUOG). First, AI algorithms were trained on images manually evaluated by a pool of experienced sonologists and using state-of-the-art deep learning technology. The resulting algorithm was then assessed on a separate testing set; it was deemed correct if 2 or more (from a panel of 5) independent sonologists agreed with its decision. Due to the lack of expert agreement for "marginal" images, it was deemed appropriate to include as agreement such a 2:3 panel split. **RESULTS:** The system was developed on 479,322 anonymised images from 48,161 routine mid-trimester scans. Agreement between ScanNav and the sonologist panel was performed on an independent set of 38,840 images (4,284 scans). For scan completeness the mean (standard deviation) of agreement between ScanNav and the sonologists was 93.5% (±5.6%); for image quality it was 92.2% (±4.7%). The system processes 11 frames per second on a PC with an RTX4000 GPU.

<table>
<tr><td></td><td>

<table>
<tr><th># Sonographers agree with ScanNav</th><th>ScanNav</th></tr>
<tr><td>0</td><td>INCORRECT</td></tr>
<tr><td>1</td><td>INCORRECT</td></tr>
<tr><td>2</td><td>CORRECT</td></tr>
<tr><td>3</td><td>CORRECT</td></tr>
<tr><td>4</td><td>CORRECT</td></tr>
<tr><td>5</td><td>CORRECT</td></tr>
</table></td></tr>
<tr><th>’591 Claim 8</th><th>Voluson Family Products</th></tr>
<tr><td>8: The system of claim 7 wherein each of the expert quality assessment values represents an assessment of suitability of the associated echocardiographic image</td><td>The Voluson family products discloses a computer-implemented system “wherein each of the expert quality assessment values represents an assessment of suitability of the associated echocardiographic image for quantified clinical measurement of anatomical features.”</td></tr>
</table>

for quantified clinical measurement of anatomical features.	*See* claims 1[i] and 7 regarding the deep neural network training process using expert quality assessment values. As shown above for claims 1[i] and 7, the expert quality assessment values indicate anatomically correct images for specific views and higher diagnostic quality. *See* claim 2 regarding suitability for quantified clinical measurement of anatomical features. For example, see the following passages and/or figures, as well as all related disclosures: Voluson Expert 22 Product Page, https://www.gehealthcare.ca/en-ca/products/ultrasound/voluson/voluson-expert22/workflow-efficiency > **SonoLyst** > Your Onboard Assistant > SonoLyst is your virtual on-board expert utilizing AI to automatically identify fetal anatomy seen on standard views while enhancing efficiency by adding annotations and measurements. For quality assurance, SonoLyst can also be used to compare the image or view acquired to standard criteria ensuring exam quality and consistency. Voluson Expert 18 Brochure (Aug 2023) at 5: > **SonoLystX:** Build and refine your skills with SonoLystX. Using AI, the system compares the image or view acquired to standard criteria accepted by experts to ensure it meets clinical standards. SonoLystX can help enhance accuracy and quality with anatomy diagrams plus the ability to insert image examples. Ideal for teaching and training, progress can be monitored for quality assurance to ensure the highest quality imaging standards and consistency.

	SonoLyst Second & Third Trimester product page, https://womens-health.net/clinical-specialty/second-third-trimester/sonolyst **The real power of AI in women's health** SonoLystIR automatically detects anatomy and applies applicable annotations and measurements. All you do is confirm, and data is entered into the Scan Assistant checklist and report— enhancing workflow and reducing variability between operators for improved consistency. Another aspect of SonoLyst is the ability to build and refine skills of less experienced users. SonoLystX is your virtual, on-board ultrasound expert. Acting like a personal scanning assistant, it compares the image or view acquired to standardized expert image criteria to ensure it contains the required anatomy for the imaging plane. SonoLystX is ideal for teaching and training. Progress can be monitored for quality assurance to ensure the highest quality imaging standards and consistency. Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 1-4

	1.1 About this system **Intended use** This system is intended for use by a qualified physician or sonographer for ultrasound evaluation in the following clinical application: Image acquisition for diagnostic purposes including measurements on acquired image. **Clinical benefit** The clinical benefit of a diagnostic ultrasound device is to help healthcare professionals provide an accurate diagnostic information (visualize human tissue/internal structure) that enhances the diagnostic and treatment care pathways of the patient for a variety of diseases and conditions. **Clinical applications** • Abdomen • Obstetrics (incl. Fetal Cardio) • Gynecology • Cardiology • Transrectal • Vascular • Cephalic • Pediatrics • MSK • Small Parts (incl. Breast) Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 5-23 **5.3 Probes** **5.3.1 Intended use, contraindications and patient population** **Intended use** Image Acquisition for diagnostic purposes including measurements on acquired image. Extracting tissue samples with guided and freehand biopsy.

	Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6: All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

	The output image of the SonoLyst*live* feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:  As SonoLystIR and SonoLystX are deeply integrated in the Scan Assistant workflow, please refer to ' Scan Assistant ' *on page 7-10* for more details about the usage and setup. All SonoLyst features use the following predefined standard views and depending criteria for the 1st Trimester:

Pre-defined standard view	Criteria
Sagittal Fetus	Magnification Mid-sagittal Neutral position and orientation Crown visible Rump visible
Axial Head	Magnification Symmetrical hemispheres Full head circumference visible Choroid plexus visible Midline falx
Transthalamic Plane	Magnification Symmetrical hemispheres Two separate thalami Midline falx
Axial Orbits	Magnification Both orbits visible
Coronal Orbits	Magnification Both orbits visible Nose visible Both ears visible
Coronal Palate	Magnification Nasal bone Supermaxilla
Coronal Lips	Magnification Nasal tip Upper lip
4CH/Thorax	Magnification 4 chambers clearly visible
Cord Insertion	Magnification Cord inserted into abdominal wall
Axial Abdomen	Magnification Full abdominal circumference visible Stomach visible
Axial Kidneys	Magnification Both kidneys visible
Axial Bladder	Magnification Bladder visible
Coronal Kidneys	Magnification Both kidneys visible
Sagittal Spine	Magnification Vertebrae are aligned Skin edge
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible

Pre-defined standard view	Criteria
Hand	Magnification Hand visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible
Sagittal Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Sagittal Profile	Magnification Mid-sagittal Neutral position and orientation Nasal tip
Sagittal Brain	Magnification Brainstem Fourth ventricle Cisterna magna

All SonoLyst features use the following predefined standard views and depending criteria for the 2nd Trimester:

Pre-defined standard view	Criteria
Transventricular Plane	Magnification Brain symmetry Midline falx Lateral cerebral ventricles Choroid Plexus Cavum septum pellucidum No Cerebellum
Transthalamic Plane	Magnification Brain symmetry Midline falx Thalamus Cavum septum pellucidum No Cerebellum
Transcerebellar Plane	Magnification Brain symmetry Midline falx Cavum septum pellucidum Cerebellum Cisterna Magna
Profile	Magnification Nasal tip Forehead bone visible

Pre-defined standard view	Criteria
Orbits	Magnification Both orbits visible Symmetrical orbits
Nose/Lips	Magnification Nasal tip Nostrils Upper lip
4CH/Thorax	Magnification 4 Chambers visible Ventricular Septum Valves visible
LVOT	Continuity Ventricular Septum Magnification
RVOT	Vessel Bifurcation Magnification
3VV/3VT	3 Vessels Magnification
Abdomen (AC)	Magnification Stomach Umbilical vein Rib visible Circular/Shape No Kidney visible
Abdomen - Cord Insertion	Magnification Cord visible
Transverse Kidneys	Magnification Both kidneys visible
Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Femur	Magnification Angle of insonation Clear Diaphysis
Plantar Foot	Magnification Full foot visible
Hand	Magnification Clear hand visible
TA Cervix	Magnification Endocervical Canal Internal Os External Os
Spine Sacrum	Lumbar - alignment Lumbar - Skin line Magnification

Pre-defined standard view	Criteria
Spine Lumbar	Lumbar - alignment Lumbar - Skin line Magnification
Spine Thoracic	Thoracic - alignment Thoracic - Skin line Magnification
Spine Cervical	Cervical - alignment Cervical - Skin line Magnification
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible

SonoLyst product page, https://www.gehealthcare.com/products/ultrasound/voluson/sonolyst

AI tool helps automatically identify fetal anatomy

- **SonoLyst**: Save up to 40%* on routine 2nd trimester exams with SonoLyst.
- **SonoLystlive**: No freezing, no annotating, no storing. SonoLystlive takes image recognition to the next level by capturing images as you scan, in real-time.
- **SonoLystIR**: Simply scan, then freeze and SonoLystIR (Image Recognition) does the rest.
- **SonoLystX**: Build and refine your skills with SonoLystX. Using AI, the system compares the image or view acquired to standard criteria accepted by experts to ensure it meets clinical standards.

SonoLyst product page, https://www.gehealthcare.com/products/ultrasound/voluson/sonolyst (showing Measurements functionality on upper righthand side and diagnostic clinical standard criteria for the view category at bottom right)

<table>
<tr><td></td><td>
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<tr><th>’591 Claim 9</th><th>Voluson Family Products</th></tr>
<tr><td>9: The system of claim 7 wherein the at least one processor is configured to derive each of the expert quality assessment values at least in part from a clinical plane assessment value representing an expert opinion whether the associated echocardiographic training image was taken in an</td><td>The Voluson family products disclose a computer-implemented system “wherein the at least one processor is configured to derive each of the expert quality assessment values at least in part from a clinical plane assessment value representing an expert opinion whether the associated echocardiographic training image was taken in an anatomical plane suitable for quantified clinical measurement of anatomical features.”

See claims 1[i] and 7 regarding the deep neural network training process using expert quality assessment values.

See claim 2 regarding suitability for quantified clinical measurement of anatomical features.</td></tr>
</table>

anatomical plane suitable for quantified clinical measurement of anatomical features.	An echocardiogram involves imaging along a variety of 2D anatomical planes of the heart. '591 Patent, 9:1-12. Since the SonoLyst AI algorithm is trained based on the ideal probe position for the standard diagnostic views as shown above for claim 1[i], the expert quality assessment values are derived at least in part from an expert opinion about whether the associated echocardiographic training image was taken in an anatomical plane suitable for quantified clinical measurement of anatomical features. For example, see the following passages and/or figures, as well as all related disclosures: FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K220358) at 7-8: "SonoLyst: Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance • For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images. • The number of individual patients images were collected from: 5000+ exams • The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops. … Information about equipment and protocols used to collect images. • Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection. Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): 1. The images were curated (sorted and graded) by a single Sonographer 2. The images were sorted and graded by SonoLyst. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the

	system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system. Description of how independence of test data from training data was ensured: • The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two." FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K231965) at 10-11: "Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. • Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population. • The verification for the SonoLyst 2nd Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features. • The verification of the SonoLystLive 2nd Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality. • The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher. … <u>Quantitative evaluation</u>: For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation … Information about the reference standard and dataset ("truthing process"): To ensure the quality of the curated data for verification, the following strategy is employed: 1. The images were curated (sorted and graded) by a single sonographer.

	2. The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system." Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6: All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

	The output image of the SonoLyst*live* feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:  As SonoLystIR and SonoLystX are deeply integrated in the Scan Assistant workflow, please refer to ' Scan Assistant ' *on page 7-10* for more details about the usage and setup. All SonoLyst features use the following predefined standard views and depending criteria for the 1st Trimester:

Pre-defined standard view	Criteria
Sagittal Fetus	Magnification Mid-sagittal Neutral position and orientation Crown visible Rump visible
Axial Head	Magnification Symmetrical hemispheres Full head circumference visible Choroid plexus visible Midline falx
Transthalamic Plane	Magnification Symmetrical hemispheres Two separate thalami Midline falx
Axial Orbits	Magnification Both orbits visible
Coronal Orbits	Magnification Both orbits visible Nose visible Both ears visible
Coronal Palate	Magnification Nasal bone Supermaxilla
Coronal Lips	Magnification Nasal tip Upper lip
4CH/Thorax	Magnification 4 chambers clearly visible
Cord Insertion	Magnification Cord inserted into abdominal wall
Axial Abdomen	Magnification Full abdominal circumference visible Stomach visible
Axial Kidneys	Magnification Both kidneys visible
Axial Bladder	Magnification Bladder visible
Coronal Kidneys	Magnification Both kidneys visible
Sagittal Spine	Magnification Vertebrae are aligned Skin edge
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible

	(table below)

Pre-defined standard view	Criteria
Hand	Magnification Hand visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible
Sagittal Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Sagittal Profile	Magnification Mid-sagittal Neutral position and orientation Nasal tip
Sagittal Brain	Magnification Brainstem Fourth ventricle Cisterna magna

All SonoLyst features use the following predefined standard views and depending criteria for the 2nd Trimester:

Pre-defined standard view	Criteria
Transventricular Plane	Magnification Brain symmetry Midline falx Lateral cerebral ventricles Choroid Plexus Cavum septum pellucidum No Cerebellum
Transthalamic Plane	Magnification Brain symmetry Midline falx Thalamus Cavum septum pellucidum No Cerebellum
Transcerebellar Plane	Magnification Brain symmetry Midline falx Cavum septum pellucidum Cerebellum Cisterna Magna
Profile	Magnification Nasal tip Forehead bone visible

Pre-defined standard view	Criteria
Orbits	Magnification Both orbits visible Symmetrical orbits
Nose/Lips	Magnification Nasal tip Nostrils Upper lip
4CH/Thorax	Magnification 4 Chambers visible Ventricular Septum Valves visible
LVOT	Continuity Ventricular Septum Magnification
RVOT	Vessel Bifurcation Magnification
3VV/3VT	3 Vessels Magnification
Abdomen (AC)	Magnification Stomach Umbilical vein Rib visible Circular/Shape No Kidney visible
Abdomen - Cord Insertion	Magnification Cord visible
Transverse Kidneys	Magnification Both kidneys visible
Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Femur	Magnification Angle of insonation Clear Diaphysis
Plantar Foot	Magnification Full foot visible
Hand	Magnification Clear hand visible
TA Cervix	Magnification Endocervical Canal Internal Os External Os
Spine Sacrum	Lumbar - alignment Lumbar - Skin line Magnification

Pre-defined standard view	Criteria
Spine Lumbar	Lumbar - alignment Lumbar - Skin line Magnification
Spine Thoracic	Thoracic - alignment Thoracic - Skin line Magnification
Spine Cervical	Cervical - alignment Cervical - Skin line Magnification
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible

Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 13-45 to 13-47:

13.13 Deep Learning Based Features

Note *Some of these deep learning based features are not available in all countries:*

- SonoLystIR
- SonoLystIR 1st Trimester
- SonoLystX
- SonoLystX 1st Trimester
- SonoLyst*live*
- SonoLyst*live* 1st Trimester
- Sono*Biometry* CRL
- SonoPelvicFloor
- SonoCNS
- Sono*Biometry* Cereb, Vp, CM
- FetalHS
- SonoAVC™*follicle* 2.0
- SonoAVC™*follicle* Auto Caliper
- Fibroid Mapping
- AutoSpine
- SonoPF2D
- AnalSphincter

The application of deep learning based features requires caution by the user and an informed decision on the usage of the specific feature. Therefore, all caution information and performance testing for each feature are summarized in this chapter.

Performance Testing for SonoLyst:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystIR	80% accuracy	41936

Performance Testing for SonoLystIR 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystIR 1st Trimester	80% accuracy	5271

Performance Testing for SonoLystX:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystX	80%	9998

Performance Testing for SonoLystX 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystX 1st Trimester	80%	2400

Performance Testing for SonoLyst*live*:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLyst*live*	80% accuracy	5623

Performance Testing for SonoLyst*live* 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLyst*live* 1st Trimester	80%	6000

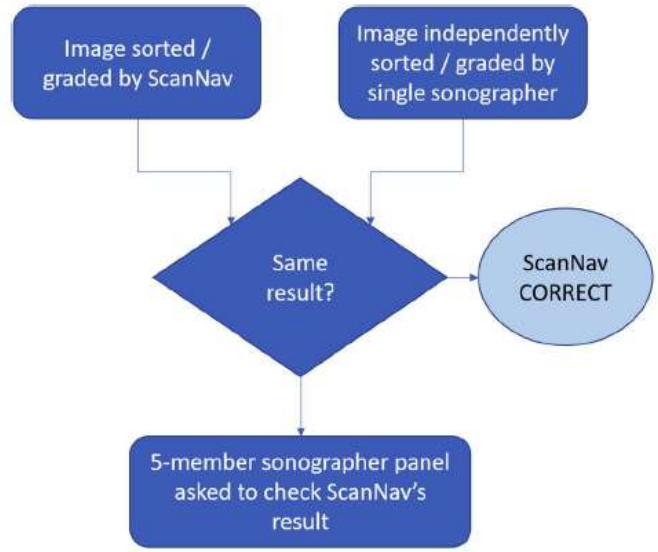
Yangdi Xu et al., *Simulating realistic fetal neurosonography images with appearance and growth change using cycle-consistent adversarial networks and an evaluation*, Journal of Medical Imaging

	(Sep/Oct 2020), Vol. 7(5) at 4: "ScanNav® (Intelligent Ultrasound Ltd., Milton Park, Abingdon, United Kingdom) is a pre-commercial deep learning-based automatic image analysis software application that assesses the quality of second-trimester scans according to the UK FASP guidelines. It is able to accurately detect different structures of a standard plane in large scale. It had been designed and trained by analzsing thousands of clinical second-trimester ultrasound images to label and grade images. Details of the underpinning algorithms and data used to build the quality assessment model are proprietary. However, we assume that the quality of software-derived annotation labels is at the same level as a typical experienced sonographer. This assumption is confirmed to be valid for our data later in this article. Under this assumption, ScanNav® is treated as equivalent to an experienced sonographer in ultrasound image classifications. It can assess and compare hundreds of real and simulated second-trimester scans efficiently and quickly (which is something that is tedious and costly to achieve if the task is performed by human experts)." E.H. Bradburn et al., *OC10.05 An artificial intelligence system that can correctly identify fetal ultrasound imaging planes throughout gestational age*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28-29.

	Methods: Anonymised fetal ultrasound images, acquired at 15 to 40 weeks of gestation, from a large image database were analysed in this study. This included images of head circumference (HC), abdominal circumference (AC), femur length (FL), amniotic fluid index (AFI) and miscellaneous images. An AI algorithm (ScanNav, trained primarily on routine anatomy scans from 18-24 weeks), was applied to each image and categorised it into one of five categories: HC, AC, FL, AFI and others. A random ten percent per view of all images were manually reviewed by one experienced clinician to determine the accuracy of this classification. The performance of the AI algorithm, according to the gestational age at the time of the scan, was assessed. **Results:** Over 450,000 images were assessed by ScanNav, and a random 10% (45,036 images) underwent clinical review. The accuracy of the AI algorithm in categorising the images into standard biometry planes (HC, AC, FL and AFI) was 99.1%. This was 99.6%, 99.1%, 97.9% and 99.9% for HC, AC, FL and AFI, respectively. Across all categories the algorithm performed best between 20+0 and 35+6 weeks, with an accuracy that remained stable throughout that gestational age range (97%). There was a slight drop in accuracy below 20 weeks and above 36 weeks, to 94% and 96% respectively. **Conclusions:** Although trained primarily on routine anatomy scans from 18-24 weeks, the ScanNav AI algorithm is 99.1% accurate in image categorisation of basic biometry planes. Accuracy was maintained over a very broad range of gestational ages. This may reflect that clinically these standard planes remain consistent in appearance throughout gestation. Improvement at the extremes of GA may be possible by further algorithm training. E.H. Bradburn et al., *OC10.04 Estimating fetal gestational age based on ultrasound image characteristics using artificial intelligence*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28.

	Methods: Quality assessed ultrasound images of head circumference (HC) and abdominal circumference (AC) were used from a multicentre study database of women with known GA (CRL performed < 14 weeks) who underwent serial ultrasound examinations from 15 to 40 weeks. We split data randomly into 67.5% training, 7.5% validation and 25% testing sets. We developed and tested an artificial intelligence (AI) algorithm using a regression neural network to estimate the GA, based on image characteristics only without measurement information. Mohammad Yaqub et al., *491 ScanNav® audit: an AI-powered screening assistant for fetal anatomical ultrasound*, American Journal of Obstetrics & Gynecology, Supplement to February 2021, at S312.

		OBJECTIVE: To develop and evaluate a real-time Artificial Intelligence (AI) based system to automatically keep track of acquired images; and check that the images conform to imaging protocol standards, in essence, replacing a human peer reviewer. **STUDY DESIGN:** We developed an AI system (ScanNav) which automatically (1) checks the completeness of the imaging record during fetal anomaly screening, ensuring all 19 required fetal views are recorded; and (2) assesses the quality of these images (in this case according to the guidelines of ISUOG). First, AI algorithms were trained on images manually evaluated by a pool of experienced sonologists and using state-of-the-art deep learning technology. The resulting algorithm was then assessed on a separate testing set; it was deemed correct if 2 or more (from a panel of 5) independent sonologists agreed with its decision. Due to the lack of expert agreement for "marginal" images, it was deemed appropriate to include as agreement such a 2:3 panel split. **RESULTS:** The system was developed on 479,322 anonymised images from 48,161 routine mid-trimester scans. Agreement between ScanNav and the sonologist panel was performed on an independent set of 38,840 images (4,284 scans). For scan completeness the mean (standard deviation) of agreement between ScanNav and the sonologists was 93.5% (±5.6%); for image quality it was 92.2% (±4.7%). The system processes 11 frames per second on a PC with an RTX4000 GPU.



# Sonographers agree with ScanNav	ScanNav
0	INCORRECT
1	INCORRECT
2	CORRECT
3	CORRECT
4	CORRECT
5	CORRECT

'591 Claim 10	**Voluson Family Products**
10: The system of claim 7 wherein each of the sets of neural network parameters includes: (i) a set of common neural network parameters, which	The Voluson family products disclose a computer-implemented system "*wherein each of the sets of neural network parameters includes: (i) a set of common neural network parameters, which are common to each of the sets of neural network parameters; and (i) a set of view category specific neural network parameters, which are unique to the set of neural network parameters; and (iii) wherein the at least one processor is configured to, for each echocardiographic training image: (a) select one of the sets of view category specific neural network parameters based on the predetermined*

are common to each of the sets of neural network parameters; and (i) a set of view category specific neural network parameters, which are unique to the set of neural network parameters; and (iii) wherein the at least one processor is configured to, for each echocardiographic training image: (a) select one of the sets of view category specific neural network parameters based on the predetermined echocardiographic image view category associated with the echocardiographic training image; and (b) using the echocardiographic training image as an input and the associated expert quality assessment values as a desired output, train a neural network defined by the set of common neural network parameters and the selected one of the sets of view category specific neural network parameters to update the set of common	*echocardiographic image view category associated with the echocardiographic training image; and (b) using the echocardiographic training image as an input and the associated expert quality assessment values as a desired output, train a neural network defined by the set of common neural network parameters and the selected one of the sets of view category specific neural network parameters to update the set of common neural network parameters and the selected one of the sets of view category specific neural network parameters*." *See* claims 1[pre] and 1[j], which show that the Voluson family products include at least one processor. *See* claim 1[i] and 6 regarding the disclosure of the sets of assessment parameters that are neural network parameters, common assessment parameters that are common neural network parameters, and view category specific assessment parameters that are neural network parameters, which are unique to the sets of neural network parameters. *See* claim 1[c] regarding the deep neural network training process. The Voluson family products train the SonoLyst AI algorithm with ideal echocardiographic images, for each cardiac view, that have been associated with transducer position and labeled by expert sonologists for image quality and correctness. The SonoLyst AI algorithm is also trained to estimate the four (4) diagnostic view categories of the fetal heart (e.g., 4CH/Thorax, LVOT, RVOT, and 3VV). Therefore, each echocardiographic training image is associated with a predetermined image view category. The deep neural network (SonoLyst AI algorithm) has a plurality of layers including an input layer configured to receive echocardiographic images and an output layer configured to output quality assessment values. Because the training images are labeled and annotated with associated expert quality assessment values during the training process, the associated expert quality assessment values (i.e., grading criteria) are the desired outputs. As the SonoLyst AI algorithm is trained with the expert-labelled training images, the neural network parameters are iteratively refined and updated to better predict how to acquire high-quality image for specific views. For example, see the following passages and/or figures, as well as all related disclosures: FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K220358) at 7-8:

neural network parameters and the selected one of the sets of view category specific neural network parameters.	"SonoLyst: Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance • For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images. • The number of individual patients images were collected from: 5000+ exams • The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops. … Information about equipment and protocols used to collect images. • Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection. Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): 1. The images were curated (sorted and graded) by a single Sonographer 2. The images were sorted and graded by SonoLyst. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system. Description of how independence of test data from training data was ensured: • The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two."

	FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K231965) at 10-11: "Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. • Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population. • The verification for the SonoLyst 2nd Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features. • The verification of the SonoLystLive 2nd Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality. • The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher. … <u>Quantitative evaluation</u>: For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation … Information about the reference standard and dataset ("truthing process"): To ensure the quality of the curated data for verification, the following strategy is employed: 1. The images were curated (sorted and graded) by a single sonographer. 2. The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system."

	Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6: All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

The output image of the SonoLyst*live* feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:

As SonoLystIR and SonoLystX are deeply integrated in the Scan Assistant workflow, please refer to ' Scan Assistant ' *on page 7-10* for more details about the usage and setup.

All SonoLyst features use the following predefined standard views and depending criteria for the 1st Trimester:

Pre-defined standard view	Criteria
Sagittal Fetus	Magnification Mid-sagittal Neutral position and orientation Crown visible Rump visible
Axial Head	Magnification Symmetrical hemispheres Full head circumference visible Choroid plexus visible Midline falx
Transthalamic Plane	Magnification Symmetrical hemispheres Two separate thalami Midline falx
Axial Orbits	Magnification Both orbits visible
Coronal Orbits	Magnification Both orbits visible Nose visible Both ears visible
Coronal Palate	Magnification Nasal bone Supermaxilla
Coronal Lips	Magnification Nasal tip Upper lip
4CH/Thorax	Magnification 4 chambers clearly visible
Cord Insertion	Magnification Cord inserted into abdominal wall
Axial Abdomen	Magnification Full abdominal circumference visible Stomach visible
Axial Kidneys	Magnification Both kidneys visible
Axial Bladder	Magnification Bladder visible
Coronal Kidneys	Magnification Both kidneys visible
Sagittal Spine	Magnification Vertebrae are aligned Skin edge
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible

Pre-defined standard view	Criteria
Hand	Magnification Hand visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible
Sagittal Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Sagittal Profile	Magnification Mid-sagittal Neutral position and orientation Nasal tip
Sagittal Brain	Magnification Brainstem Fourth ventricle Cisterna magna

All SonoLyst features use the following predefined standard views and depending criteria for the 2nd Trimester:

Pre-defined standard view	Criteria
Transventricular Plane	Magnification Brain symmetry Midline falx Lateral cerebral ventricles Choroid Plexus Cavum septum pellucidum No Cerebellum
Transthalamic Plane	Magnification Brain symmetry Midline falx Thalamus Cavum septum pellucidum No Cerebellum
Transcerebellar Plane	Magnification Brain symmetry Midline falx Cavum septum pellucidum Cerebellum Cisterna Magna
Profile	Magnification Nasal tip Forehead bone visible

Pre-defined standard view	Criteria
Orbits	Magnification Both orbits visible Symmetrical orbits
Nose/Lips	Magnification Nasal tip Nostrils Upper lip
4CH/Thorax	Magnification 4 Chambers visible Ventricular Septum Valves visible
LVOT	Continuity Ventricular Septum Magnification
RVOT	Vessel Bifurcation Magnification
3VV/3VT	3 Vessels Magnification
Abdomen (AC)	Magnification Stomach Umbilical vein Rib visible Circular/Shape No Kidney visible
Abdomen - Cord Insertion	Magnification Cord visible
Transverse Kidneys	Magnification Both kidneys visible
Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Femur	Magnification Angle of insonation Clear Diaphysis
Plantar Foot	Magnification Full foot visible
Hand	Magnification Clear hand visible
TA Cervix	Magnification Endocervical Canal Internal Os External Os
Spine Sacrum	Lumbar - alignment Lumbar - Skin line Magnification

Pre-defined standard view	Criteria
Spine Lumbar	Lumbar - alignment Lumbar - Skin line Magnification
Spine Thoracic	Thoracic - alignment Thoracic - Skin line Magnification
Spine Cervical	Cervical - alignment Cervical - Skin line Magnification
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible

Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 13-45 to 13-47:

13.13 Deep Learning Based Features

Note *Some of these deep learning based features are not available in all countries:*

- SonoLystIR
- SonoLystIR 1st Trimester
- SonoLystX
- SonoLystX 1st Trimester
- SonoLyst*live*
- SonoLyst*live* 1st Trimester
- Sono*Biometry* CRL
- SonoPelvicFloor
- SonoCNS
- Sono*Biometry* Cereb, Vp, CM
- FetalHS
- SonoAVC™*follicle* 2.0
- SonoAVC™*follicle* Auto Caliper
- Fibroid Mapping
- AutoSpine
- SonoPF2D
- AnalSphincter

The application of deep learning based features requires caution by the user and an informed decision on the usage of the specific feature. Therefore, all caution information and performance testing for each feature are summarized in this chapter.

Performance Testing for SonoLyst:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystIR	80% accuracy	41936

	Performance Testing for SonoLystIR 1st Trimester: | Sub-Feature | Minimum Acceptable Algorithmic Performance | Number of Test Images | | SonoLystIR 1st Trimester | 80% accuracy | 5271 | Performance Testing for SonoLystX: | Sub-Feature | Minimum Acceptable Algorithmic Performance | Number of Test Images | | SonoLystX | 80% | 9998 | Performance Testing for SonoLystX 1st Trimester: | Sub-Feature | Minimum Acceptable Algorithmic Performance | Number of Test Images | | SonoLystX 1st Trimester | 80% | 2400 | Performance Testing for SonoLyst*live*: | Sub-Feature | Minimum Acceptable Algorithmic Performance | Number of Test Images | | SonoLyst*live* | 80% accuracy | 5623 | Performance Testing for SonoLyst*live* 1st Trimester: | Sub-Feature | Minimum Acceptable Algorithmic Performance | Number of Test Images | | SonoLyst*live* 1st Trimester | 80% | 6000 | Yangdi Xu et al., *Simulating realistic fetal neurosonography images with appearance and growth change using cycle-consistent adversarial networks and an evaluation*, Journal of Medical Imaging

Performance Testing for SonoLystIR 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystIR 1st Trimester	80% accuracy	5271

Performance Testing for SonoLystX:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystX	80%	9998

Performance Testing for SonoLystX 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystX 1st Trimester	80%	2400

Performance Testing for SonoLyst*live*:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLyst*live*	80% accuracy	5623

Performance Testing for SonoLyst*live* 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLyst*live* 1st Trimester	80%	6000

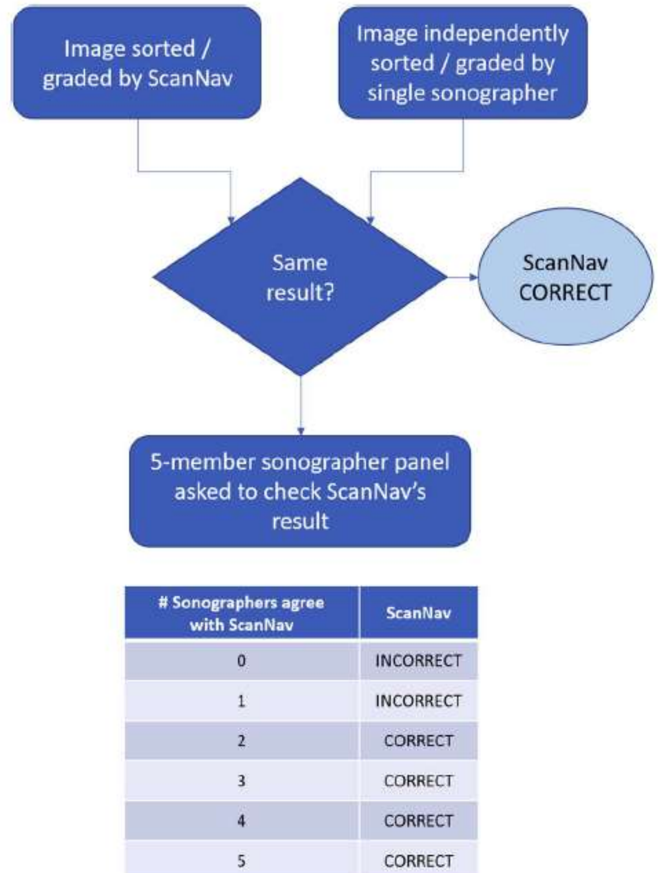
Yangdi Xu et al., *Simulating realistic fetal neurosonography images with appearance and growth change using cycle-consistent adversarial networks and an evaluation*, Journal of Medical Imaging

	(Sep/Oct 2020), Vol. 7(5) at 4: "ScanNav® (Intelligent Ultrasound Ltd., Milton Park, Abingdon, United Kingdom) is a pre-commercial deep learning-based automatic image analysis software application that assesses the quality of second-trimester scans according to the UK FASP guidelines. It is able to accurately detect different structures of a standard plane in large scale. It had been designed and trained by analzsing thousands of clinical second-trimester ultrasound images to label and grade images. Details of the underpinning algorithms and data used to build the quality assessment model are proprietary. However, we assume that the quality of software-derived annotation labels is at the same level as a typical experienced sonographer. This assumption is confirmed to be valid for our data later in this article. Under this assumption, ScanNav® is treated as equivalent to an experienced sonographer in ultrasound image classifications. It can assess and compare hundreds of real and simulated second-trimester scans efficiently and quickly (which is something that is tedious and costly to achieve if the task is performed by human experts)." E.H. Bradburn et al., *OC10.05 An artificial intelligence system that can correctly identify fetal ultrasound imaging planes throughout gestational age*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28-29.

	Methods: Anonymised fetal ultrasound images, acquired at 15 to 40 weeks of gestation, from a large image database were analysed in this study. This included images of head circumference (HC), abdominal circumference (AC), femur length (FL), amniotic fluid index (AFI) and miscellaneous images. An AI algorithm (ScanNav, trained primarily on routine anatomy scans from 18-24 weeks), was applied to each image and categorised it into one of five categories: HC, AC, FL, AFI and others. A random ten percent per view of all images were manually reviewed by one experienced clinician to determine the accuracy of this classification. The performance of the AI algorithm, according to the gestational age at the time of the scan, was assessed. **Results:** Over 450,000 images were assessed by ScanNav, and a random 10% (45,036 images) underwent clinical review. The accuracy of the AI algorithm in categorising the images into standard biometry planes (HC, AC, FL and AFI) was 99.1%. This was 99.6%, 99.1%, 97.9% and 99.9% for HC, AC, FL and AFI, respectively. Across all categories the algorithm performed best between 20+0 and 35+6 weeks, with an accuracy that remained stable throughout that gestational age range (97%). There was a slight drop in accuracy below 20 weeks and above 36 weeks, to 94% and 96% respectively. **Conclusions:** Although trained primarily on routine anatomy scans from 18-24 weeks, the ScanNav AI algorithm is 99.1% accurate in image categorisation of basic biometry planes. Accuracy was maintained over a very broad range of gestational ages. This may reflect that clinically these standard planes remain consistent in appearance throughout gestation. Improvement at the extremes of GA may be possible by further algorithm training. E.H. Bradburn et al., *OC10.04 Estimating fetal gestational age based on ultrasound image characteristics using artificial intelligence*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28.

	Methods: Quality assessed ultrasound images of head circumference (HC) and abdominal circumference (AC) were used from a multicentre study database of women with known GA (CRL performed < 14 weeks) who underwent serial ultrasound examinations from 15 to 40 weeks. We split data randomly into 67.5% training, 7.5% validation and 25% testing sets. We developed and tested an artificial intelligence (AI) algorithm using a regression neural network to estimate the GA, based on image characteristics only without measurement information. Mohammad Yaqub et al., *491 ScanNav® audit: an AI-powered screening assistant for fetal anatomical ultrasound*, American Journal of Obstetrics & Gynecology, Supplement to February 2021, at S312.

		OBJECTIVE: To develop and evaluate a real-time Artificial Intelligence (AI) based system to automatically keep track of acquired images; and check that the images conform to imaging protocol standards, in essence, replacing a human peer reviewer. **STUDY DESIGN:** We developed an AI system (ScanNav) which automatically (1) checks the completeness of the imaging record during fetal anomaly screening, ensuring all 19 required fetal views are recorded; and (2) assesses the quality of these images (in this case according to the guidelines of ISUOG). First, AI algorithms were trained on images manually evaluated by a pool of experienced sonologists and using state-of-the-art deep learning technology. The resulting algorithm was then assessed on a separate testing set; it was deemed correct if 2 or more (from a panel of 5) independent sonologists agreed with its decision. Due to the lack of expert agreement for "marginal" images, it was deemed appropriate to include as agreement such a 2:3 panel split. **RESULTS:** The system was developed on 479,322 anonymised images from 48,161 routine mid-trimester scans. Agreement between ScanNav and the sonologist panel was performed on an independent set of 38,840 images (4,284 scans). For scan completeness the mean (standard deviation) of agreement between ScanNav and the sonologists was 93.5% (±5.6%); for image quality it was 92.2% (±4.7%). The system processes 11 frames per second on a PC with an RTX4000 GPU.



# Sonographers agree with ScanNav	ScanNav
0	INCORRECT
1	INCORRECT
2	CORRECT
3	CORRECT
4	CORRECT
5	CORRECT

To the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. For example, since the traffic light quality status indicator indicates the quality of the assessed ultrasound image by turning green when the probe is at an ideal position for capturing protocol adherent images for a given pre-defined standard view, Defendants infringe any claim element including a "quality assessment value" under the doctrine of equivalents. *See* claim 1[c].

’591 Claim 11	Voluson Family Products
11[pre]: A computer-implemented system for training neural networks to facilitate echocardiographic image analysis, the system comprising at least one processor configured to:	The Voluson family products discloses “*[a] computer-implemented system for training neural networks to facilitate echocardiographic image analysis, the system comprising at least one processor*.” *See* claim 1[pre] regarding how the Voluson family products are computer-implemented and include at least one processor. *See* claim 1[c] and 1[i] regarding how the Voluson family products are a system for training neural networks to facilitate echocardiographic image analysis. For example, see the following passages and/or figures, as well as all related disclosures: FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K220358) at 7-8: “SonoLyst: Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance • For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images. • The number of individual patients images were collected from: 5000+ exams • The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops. … Information about equipment and protocols used to collect images. • Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection.

	Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): 1. The images were curated (sorted and graded) by a single Sonographer 2. The images were sorted and graded by SonoLyst. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system. Description of how independence of test data from training data was ensured: • The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two." FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K231965) at 10-11: "Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. • Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population. • The verification for the SonoLyst 2nd Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features. • The verification of the SonoLystLive 2nd Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality. • The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher. … <u>Quantitative evaluation</u>:

	For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation … Information about the reference standard and dataset ("truthing process"): To ensure the quality of the curated data for verification, the following strategy is employed: 1. The images were curated (sorted and graded) by a single sonographer. 2. The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system." Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6:

	All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

	The output image of the SonoLyst*live* feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:  As SonoLystIR and SonoLystX are deeply integrated in the Scan Assistant workflow, please refer to ' Scan Assistant ' *on page 7-10* for more details about the usage and setup. All SonoLyst features use the following predefined standard views and depending criteria for the 1st Trimester:

	<table><tr><th>Pre-defined standard view</th><th>Criteria</th></tr><tr><td>Sagittal Fetus</td><td>Magnification Mid-sagittal Neutral position and orientation Crown visible Rump visible</td></tr><tr><td>Axial Head</td><td>Magnification Symmetrical hemispheres Full head circumference visible Choroid plexus visible Midline falx</td></tr><tr><td>Transthalamic Plane</td><td>Magnification Symmetrical hemispheres Two separate thalami Midline falx</td></tr><tr><td>Axial Orbits</td><td>Magnification Both orbits visible</td></tr><tr><td>Coronal Orbits</td><td>Magnification Both orbits visible Nose visible Both ears visible</td></tr><tr><td>Coronal Palate</td><td>Magnification Nasal bone Supermaxilla</td></tr><tr><td>Coronal Lips</td><td>Magnification Nasal tip Upper lip</td></tr><tr><td>4CH/Thorax</td><td>Magnification 4 chambers clearly visible</td></tr><tr><td>Cord Insertion</td><td>Magnification Cord inserted into abdominal wall</td></tr><tr><td>Axial Abdomen</td><td>Magnification Full abdominal circumference visible Stomach visible</td></tr><tr><td>Axial Kidneys</td><td>Magnification Both kidneys visible</td></tr><tr><td>Axial Bladder</td><td>Magnification Bladder visible</td></tr><tr><td>Coronal Kidneys</td><td>Magnification Both kidneys visible</td></tr><tr><td>Sagittal Spine</td><td>Magnification Vertebrae are aligned Skin edge</td></tr><tr><td>Upper Arm</td><td>Magnification Upper Arm visible</td></tr><tr><td>Forearm</td><td>Magnification Forearm visible</td></tr></table>

Pre-defined standard view	Criteria
Hand	Magnification Hand visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible
Sagittal Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Sagittal Profile	Magnification Mid-sagittal Neutral position and orientation Nasal tip
Sagittal Brain	Magnification Brainstem Fourth ventricle Cisterna magna

All SonoLyst features use the following predefined standard views and depending criteria for the 2nd Trimester:

Pre-defined standard view	Criteria
Transventricular Plane	Magnification Brain symmetry Midline falx Lateral cerebral ventricles Choroid Plexus Cavum septum pellucidum No Cerebellum
Transthalamic Plane	Magnification Brain symmetry Midline falx Thalamus Cavum septum pellucidum No Cerebellum
Transcerebellar Plane	Magnification Brain symmetry Midline falx Cavum septum pellucidum Cerebellum Cisterna Magna
Profile	Magnification Nasal tip Forehead bone visible

Pre-defined standard view	Criteria
Orbits	Magnification Both orbits visible Symmetrical orbits
Nose/Lips	Magnification Nasal tip Nostrils Upper lip
4CH/Thorax	Magnification 4 Chambers visible Ventricular Septum Valves visible
LVOT	Continuity Ventricular Septum Magnification
RVOT	Vessel Bifurcation Magnification
3VV/3VT	3 Vessels Magnification
Abdomen (AC)	Magnification Stomach Umbilical vein Rib visible Circular/Shape No Kidney visible
Abdomen - Cord Insertion	Magnification Cord visible
Transverse Kidneys	Magnification Both kidneys visible
Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Femur	Magnification Angle of insonation Clear Diaphysis
Plantar Foot	Magnification Full foot visible
Hand	Magnification Clear hand visible
TA Cervix	Magnification Endocervical Canal Internal Os External Os
Spine Sacrum	Lumbar - alignment Lumbar - Skin line Magnification

Pre-defined standard view	Criteria
Spine Lumbar	Lumbar - alignment Lumbar - Skin line Magnification
Spine Thoracic	Thoracic - alignment Thoracic - Skin line Magnification
Spine Cervical	Cervical - alignment Cervical - Skin line Magnification
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible

Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 13-45 to 13-47:

13.13 Deep Learning Based Features

Note *Some of these deep learning based features are not available in all countries:*

- SonoLystIR
- SonoLystIR 1st Trimester
- SonoLystX
- SonoLystX 1st Trimester
- SonoLyst*live*
- SonoLyst*live* 1st Trimester
- Sono*Biometry* CRL
- SonoPelvicFloor
- SonoCNS
- Sono*Biometry* Cereb, Vp, CM
- FetalHS
- SonoAVC™*follicle* 2.0
- SonoAVC™*follicle* Auto Caliper
- Fibroid Mapping
- AutoSpine
- SonoPF2D
- AnalSphincter

The application of deep learning based features requires caution by the user and an informed decision on the usage of the specific feature. Therefore, all caution information and performance testing for each feature are summarized in this chapter.

Performance Testing for SonoLyst:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystIR	80% accuracy	41936

	Performance Testing for SonoLystIR 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystIR 1st Trimester	80% accuracy	5271

Performance Testing for SonoLystX:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystX	80%	9998

Performance Testing for SonoLystX 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystX 1st Trimester	80%	2400

Performance Testing for SonoLyst*live*:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLyst*live*	80% accuracy	5623

Performance Testing for SonoLyst*live* 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLyst*live* 1st Trimester	80%	6000

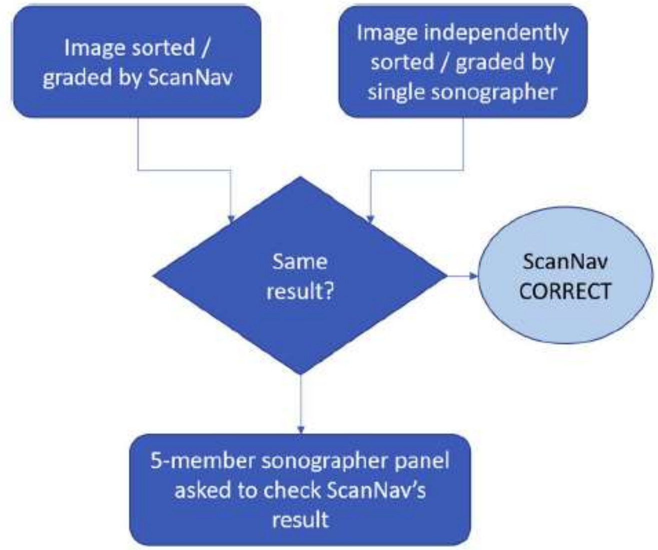
Yangdi Xu et al., *Simulating realistic fetal neurosonography images with appearance and growth change using cycle-consistent adversarial networks and an evaluation*, Journal of Medical Imaging

	(Sep⁄Oct 2020), Vol. 7(5) at 4: “ScanNav® (Intelligent Ultrasound Ltd., Milton Park, Abingdon, United Kingdom) is a pre-commercial deep learning-based automatic image analysis software application that assesses the quality of second-trimester scans according to the UK FASP guidelines. It is able to accurately detect different structures of a standard plane in large scale. It had been designed and trained by analzsing thousands of clinical second-trimester ultrasound images to label and grade images. Details of the underpinning algorithms and data used to build the quality assessment model are proprietary. However, we assume that the quality of software-derived annotation labels is at the same level as a typical experienced sonographer. This assumption is confirmed to be valid for our data later in this article. Under this assumption, ScanNav® is treated as equivalent to an experienced sonographer in ultrasound image classifications. It can assess and compare hundreds of real and simulated second-trimester scans efficiently and quickly (which is something that is tedious and costly to achieve if the task is performed by human experts).” E.H. Bradburn et al., *OC10.05 An artificial intelligence system that can correctly identify fetal ultrasound imaging planes throughout gestational age*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28-29.

	Methods: Anonymised fetal ultrasound images, acquired at 15 to 40 weeks of gestation, from a large image database were analysed in this study. This included images of head circumference (HC), abdominal circumference (AC), femur length (FL), amniotic fluid index (AFI) and miscellaneous images. An AI algorithm (ScanNav, trained primarily on routine anatomy scans from 18-24 weeks), was applied to each image and categorised it into one of five categories: HC, AC, FL, AFI and others. A random ten percent per view of all images were manually reviewed by one experienced clinician to determine the accuracy of this classification. The performance of the AI algorithm, according to the gestational age at the time of the scan, was assessed. **Results:** Over 450,000 images were assessed by ScanNav, and a random 10% (45,036 images) underwent clinical review. The accuracy of the AI algorithm in categorising the images into standard biometry planes (HC, AC, FL and AFI) was 99.1%. This was 99.6%, 99.1%, 97.9% and 99.9% for HC, AC, FL and AFI, respectively. Across all categories the algorithm performed best between 20+0 and 35+6 weeks, with an accuracy that remained stable throughout that gestational age range (97%). There was a slight drop in accuracy below 20 weeks and above 36 weeks, to 94% and 96% respectively. **Conclusions:** Although trained primarily on routine anatomy scans from 18-24 weeks, the ScanNav AI algorithm is 99.1% accurate in image categorisation of basic biometry planes. Accuracy was maintained over a very broad range of gestational ages. This may reflect that clinically these standard planes remain consistent in appearance throughout gestation. Improvement at the extremes of GA may be possible by further algorithm training. E.H. Bradburn et al., *OC10.04 Estimating fetal gestational age based on ultrasound image characteristics using artificial intelligence*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28.

	Methods: Quality assessed ultrasound images of head circumference (HC) and abdominal circumference (AC) were used from a multicentre study database of women with known GA (CRL performed < 14 weeks) who underwent serial ultrasound examinations from 15 to 40 weeks. We split data randomly into 67.5% training, 7.5% validation and 25% testing sets. We developed and tested an artificial intelligence (AI) algorithm using a regression neural network to estimate the GA, based on image characteristics only without measurement information. Mohammad Yaqub et al., *491 ScanNav® audit: an AI-powered screening assistant for fetal anatomical ultrasound*, American Journal of Obstetrics & Gynecology, Supplement to February 2021, at S312.

		OBJECTIVE: To develop and evaluate a real-time Artificial Intelligence (AI) based system to automatically keep track of acquired images; and check that the images conform to imaging protocol standards, in essence, replacing a human peer reviewer. **STUDY DESIGN:** We developed an AI system (ScanNav) which automatically (1) checks the completeness of the imaging record during fetal anomaly screening, ensuring all 19 required fetal views are recorded; and (2) assesses the quality of these images (in this case according to the guidelines of ISUOG). First, AI algorithms were trained on images manually evaluated by a pool of experienced sonologists and using state-of-the-art deep learning technology. The resulting algorithm was then assessed on a separate testing set; it was deemed correct if 2 or more (from a panel of 5) independent sonologists agreed with its decision. Due to the lack of expert agreement for "marginal" images, it was deemed appropriate to include as agreement such a 2:3 panel split. **RESULTS:** The system was developed on 479,322 anonymised images from 48,161 routine mid-trimester scans. Agreement between ScanNav and the sonologist panel was performed on an independent set of 38,840 images (4,284 scans). For scan completeness the mean (standard deviation) of agreement between ScanNav and the sonologists was 93.5% (±5.6%); for image quality it was 92.2% (±4.7%). The system processes 11 frames per second on a PC with an RTX4000 GPU.



# Sonographers agree with ScanNav	ScanNav
0	INCORRECT
1	INCORRECT
2	CORRECT
3	CORRECT
4	CORRECT
5	CORRECT

Voluson Expert Series Service Manual Rev 6 (Aug 2024) at 5-4:

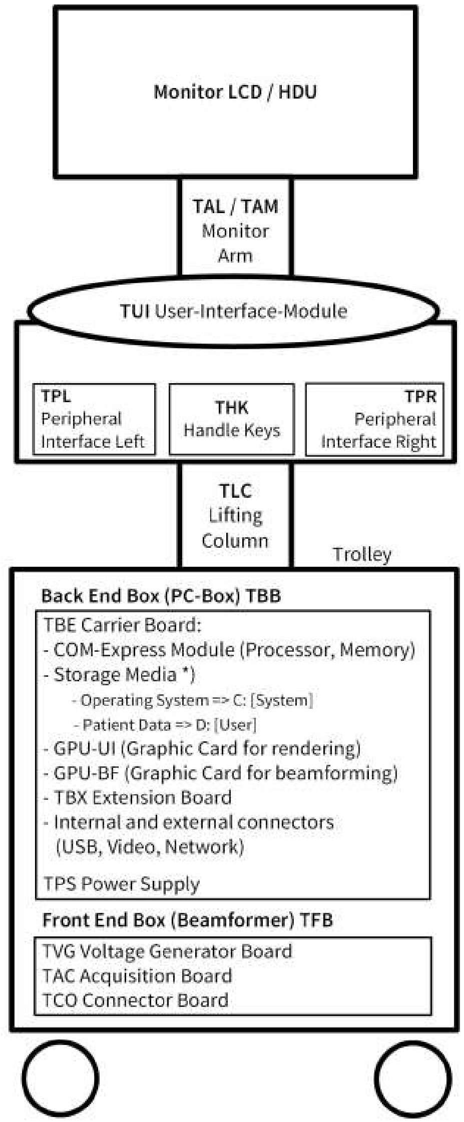
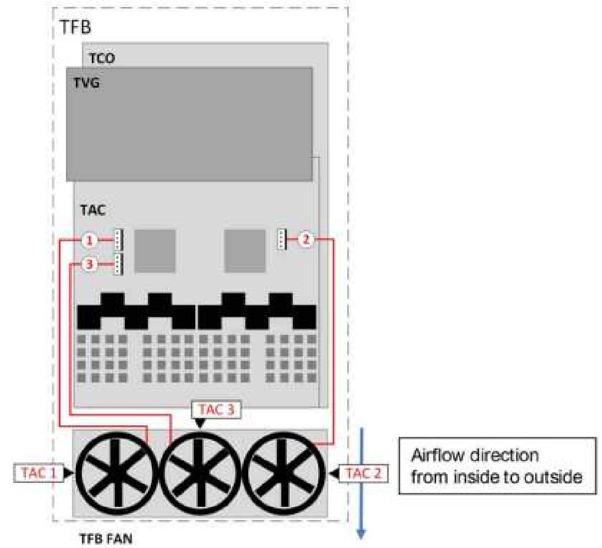
	

Figure 5-2: Basic Block diagram of Voluson Expert Series

	Voluson Expert Series Service Manual Rev 6 (Aug 2024) at 5-21 to 5-22: **5.2 FrontEnd Processor**  Figure 5-4: FrontEnd - Block diagram

5.2.1 TCO - Connector Board

Switches the Probe Connectors and recognizes Probes

- 4 Probe Connectors 408pin
- Probe Select Relays
- Probe Recognition

5.2.2 TAC - Acquisition Board

The FrontEnd Acquisition Board supports Tx/Rx for 192 channels[10] / 256 channels[11].

5.2.2.1 TAC Board - Interface Tasks

1. DMA logic
2. Beamformer Interface
3. TAC Control Interface
4. TAC FPGA Control Interface

5.2.2.2 TAC Board - Processing Tasks

1. Ultrasound Data Pre-Processing
2. System Control
3. Motor Control

5.2.3 TVG - Voltage Generator Board

The voltage generator board generates the ultrasound system specific voltages.

Voluson Expert Series Service Manual Rev 6 (Aug 2024) at 5-23 to 5-25:

5.3 BackEnd Processor

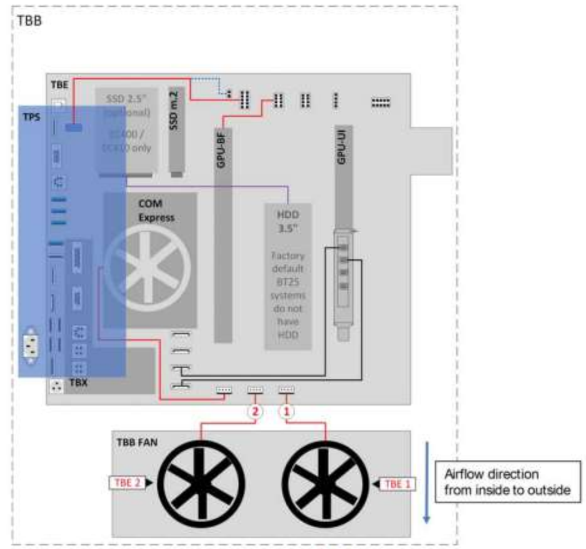


Figure 5-5: BackEnd - Block diagram

Content in this chapter

5.3.1 TBE - Backend Carrier Board (Base Board)

Built in or external Components:

- COM-Express (Computer on Module with CPU, Memory, Audio and USB-Root Hub)
- Graphic cards (GPU-BF and GPU-UI)
- PCIe Switch
- EC400, EC410 (BT24) and systems that were upgraded to EC420 (BT25):
  - M.2 NVMe SSD for operating system
  - HDD for patient data
- EC420 (BT25):
  - M.2 NVMe SSD for operating system + patient data, no additional HDD
- Audio-Amplifier
- Video splitter and scaler
- MCU for monitoring and bootup sequence

Cores Major Tasks:

- System Control
- Connections to User Interface, Frontend, Peripherals and external connectivity

5.3.2 TBX - Extension Board

Built in or external Components:

- Electronic switch and fuse for User Interface (TUI)
- Electronic switch and fuse for Lift (TLC)
- Electronic switch and fuse for Peripherals such as Printer and Trolley Lighting Unit (TLU)

Cores Major Tasks:

- Power distribution and monitoring

5.3.3 COM Express Module

Built in or external Components:

- LAN
- USB 2.0
- USB 3.0
- CPU: 2.5GHz (max. 4.2GHz)
- Memory (2x 8GB)
- Active cooling

Cores Major Tasks:

- System Control

5.3.6 Graphic Card

The Voluson E-Series system has two Graphic Cards installed. Their scope of application is different.

Graphic Card GPU-BF

Provides processing capacity to perform software-beamforming.

Graphic Card GPU-UI

Renders 2D, 3D and 4D images as well as the complete user interface for all displays (Touchscreen, Main Monitor and external outputs).

11[a]: receive signals representing a plurality of echocardiographic training images, each of the plurality of echocardiographic training images associated with one of a plurality of predetermined echocardiographic image view categories;	The Voluson family products disclose a computer-implemented system comprising at least one processor that "*receive[s] signals representing a plurality of echocardiographic training images, each of the plurality of echocardiographic training images associated with one of a plurality of predetermined echocardiographic image view categories*." *See* claim 1[pre] regarding how the Voluson family products are computer-implemented and include at least one processor. *See* claims 1[a] and 1[b] regarding the receiving and associating process steps. *See also* claim 1[c] regarding the deep neural network training process. The Voluson family products train the SonoLyst AI algorithm with ideal echocardiographic images that have been associated with transducer position and labeled by expert sonologists for image quality and correctness, per each cardiac view. The SonoLyst AI algorithm is also trained to estimate the four (4) diagnostic view categories of the fetal heart (e.g., 4CH/Thorax, LVOT, RVOT, and 3VV). Therefore, each echocardiographic training image is associated with a predetermined image view category. For example, see the following passages and/or figures, as well as all related disclosures: FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K220358) at 7-8: "<u>SonoLyst</u>: Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance • For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images. • The number of individual patients images were collected from: 5000+ exams • The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops. … Information about equipment and protocols used to collect images.

	• Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection. Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): 1. The images were curated (sorted and graded) by a single Sonographer 2. The images were sorted and graded by SonoLyst. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system. Description of how independence of test data from training data was ensured: • The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two." FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K231965) at 10-11: "Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. • Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population. • The verification for the SonoLyst 2nd Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features. • The verification of the SonoLystLive 2nd Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality.

	• The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher. … <u>Quantitative evaluation</u>: For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation … Information about the reference standard and dataset ("truthing process"): To ensure the quality of the curated data for verification, the following strategy is employed: 1. The images were curated (sorted and graded) by a single sonographer. 2. The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system." Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6:

	All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

	The output image of the SonoLyst*live* feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:  As SonoLystIR and SonoLystX are deeply integrated in the Scan Assistant workflow, please refer to ' Scan Assistant ' *on page 7-10* for more details about the usage and setup. All SonoLyst features use the following predefined standard views and depending criteria for the 1st Trimester:

Pre-defined standard view	Criteria
Sagittal Fetus	Magnification Mid-sagittal Neutral position and orientation Crown visible Rump visible
Axial Head	Magnification Symmetrical hemispheres Full head circumference visible Choroid plexus visible Midline falx
Transthalamic Plane	Magnification Symmetrical hemispheres Two separate thalami Midline falx
Axial Orbits	Magnification Both orbits visible
Coronal Orbits	Magnification Both orbits visible Nose visible Both ears visible
Coronal Palate	Magnification Nasal bone Supermaxilla
Coronal Lips	Magnification Nasal tip Upper lip
4CH/Thorax	Magnification 4 chambers clearly visible
Cord Insertion	Magnification Cord inserted into abdominal wall
Axial Abdomen	Magnification Full abdominal circumference visible Stomach visible
Axial Kidneys	Magnification Both kidneys visible
Axial Bladder	Magnification Bladder visible
Coronal Kidneys	Magnification Both kidneys visible
Sagittal Spine	Magnification Vertebrae are aligned Skin edge
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible

Pre-defined standard view	Criteria
Hand	Magnification Hand visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible
Sagittal Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Sagittal Profile	Magnification Mid-sagittal Neutral position and orientation Nasal tip
Sagittal Brain	Magnification Brainstem Fourth ventricle Cisterna magna

All SonoLyst features use the following predefined standard views and depending criteria for the 2nd Trimester:

Pre-defined standard view	Criteria
Transventricular Plane	Magnification Brain symmetry Midline falx Lateral cerebral ventricles Choroid Plexus Cavum septum pellucidum No Cerebellum
Transthalamic Plane	Magnification Brain symmetry Midline falx Thalamus Cavum septum pellucidum No Cerebellum
Transcerebellar Plane	Magnification Brain symmetry Midline falx Cavum septum pellucidum Cerebellum Cisterna Magna
Profile	Magnification Nasal tip Forehead bone visible

Pre-defined standard view	Criteria
Orbits	Magnification Both orbits visible Symmetrical orbits
Nose/Lips	Magnification Nasal tip Nostrils Upper lip
4CH/Thorax	Magnification 4 Chambers visible Ventricular Septum Valves visible
LVOT	Continuity Ventricular Septum Magnification
RVOT	Vessel Bifurcation Magnification
3VV/3VT	3 Vessels Magnification
Abdomen (AC)	Magnification Stomach Umbilical vein Rib visible Circular/Shape No Kidney visible
Abdomen - Cord Insertion	Magnification Cord visible
Transverse Kidneys	Magnification Both kidneys visible
Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Femur	Magnification Angle of insonation Clear Diaphysis
Plantar Foot	Magnification Full foot visible
Hand	Magnification Clear hand visible
TA Cervix	Magnification Endocervical Canal Internal Os External Os
Spine Sacrum	Lumbar - alignment Lumbar - Skin line Magnification

Pre-defined standard view	Criteria
Spine Lumbar	Lumbar - alignment Lumbar - Skin line Magnification
Spine Thoracic	Thoracic - alignment Thoracic - Skin line Magnification
Spine Cervical	Cervical - alignment Cervical - Skin line Magnification
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible

Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 13-45 to 13-47:

13.13 Deep Learning Based Features

Note *Some of these deep learning based features are not available in all countries:*

- SonoLystIR
- SonoLystIR 1st Trimester
- SonoLystX
- SonoLystX 1st Trimester
- SonoLyst*live*
- SonoLyst*live* 1st Trimester
- Sono*Biometry* CRL
- SonoPelvicFloor
- SonoCNS
- Sono*Biometry* Cereb, Vp, CM
- FetalHS
- SonoAVC™*follicle* 2.0
- SonoAVC™*follicle* Auto Caliper
- Fibroid Mapping
- AutoSpine
- SonoPF2D
- AnalSphincter

The application of deep learning based features requires caution by the user and an informed decision on the usage of the specific feature. Therefore, all caution information and performance testing for each feature are summarized in this chapter.

Performance Testing for SonoLyst:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystIR	80% accuracy	41936

	Performance Testing for SonoLystIR 1st Trimester: Sub-Feature / Minimum Acceptable Algorithmic Performance / Number of Test Images: SonoLystIR 1st Trimester / 80% accuracy / 5271

Performance Testing for SonoLystIR 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystIR 1st Trimester	80% accuracy	5271

Performance Testing for SonoLystX:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystX	80%	9998

Performance Testing for SonoLystX 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystX 1st Trimester	80%	2400

Performance Testing for SonoLyst*live*:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLyst*live*	80% accuracy	5623

Performance Testing for SonoLyst*live* 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLyst*live* 1st Trimester	80%	6000

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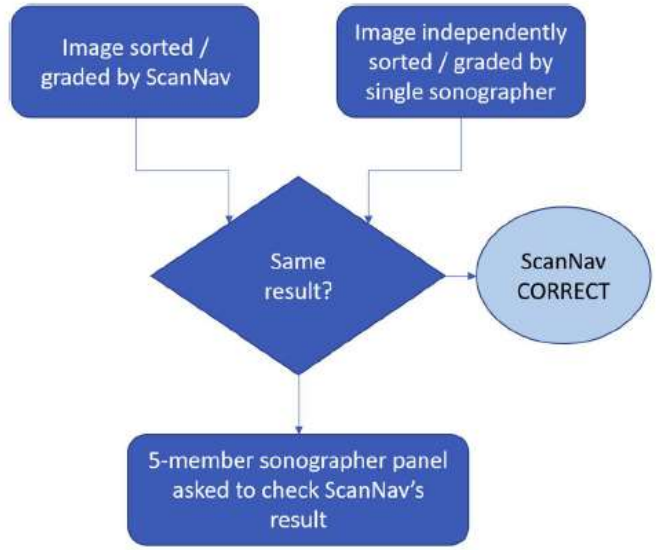

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0	INCORRECT
1	INCORRECT
2	CORRECT
3	CORRECT
4	CORRECT
5	CORRECT

11[b]: receive signals representing expert quality assessment values representing view category specific quality assessments of the plurality of echocardiographic training images, each of the expert	The Voluson family products disclose a computer-implemented system comprising at least one processor that "*receive[s] signals representing expert quality assessment values representing view category specific quality assessments of the plurality of echocardiographic training images, each of the expert quality assessment values provided by an expert echocardiographer and associated with one of the plurality of echocardiographic training images.*" *See* claim 1[pre] regarding how the Voluson family products are computer-implemented and include at least one processor.

quality assessment values provided by an expert echocardiographer and associated with one of the plurality of echocardiographic training images; and	*See* discussion with respect to 11[a] above regarding the receiving and associating process steps. *See also* claim 1[c] regarding how view category specific quality assessments are provided by expert echocardiographers as part of the deep neural network training process. For example, see the following passages and/or figures, as well as all related disclosures: FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K220358) at 7-8: "<u>SonoLyst</u>: Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance • For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images. • The number of individual patients images were collected from: 5000+ exams • The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops. … Information about equipment and protocols used to collect images. • Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection. Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): 1. The images were curated (sorted and graded) by a single Sonographer 2. The images were sorted and graded by SonoLyst. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the

	system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system. Description of how independence of test data from training data was ensured: • The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two." FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K231965) at 10-11: "Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. • Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population. • The verification for the SonoLyst 2nd Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features. • The verification of the SonoLystLive 2nd Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality. • The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher. … <u>Quantitative evaluation</u>: For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation … Information about the reference standard and dataset ("truthing process"): To ensure the quality of the curated data for verification, the following strategy is employed: 1. The images were curated (sorted and graded) by a single sonographer.

	2. The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system." Yangdi Xu et al., *Simulating realistic fetal neurosonography images with appearance and growth change using cycle-consistent adversarial networks and an evaluation*, Journal of Medical Imaging (Sep⁄Oct 2020), Vol. 7(5) at 4: "ScanNav® (Intelligent Ultrasound Ltd., Milton Park, Abingdon, United Kingdom) is a pre-commercial deep learning-based automatic image analysis software application that assesses the quality of second-trimester scans according to the UK FASP guidelines. It is able to accurately detect different structures of a standard plane in large scale. It had been designed and trained by analzsing thousands of clinical second-trimester ultrasound images to label and grade images. Details of the underpinning algorithms and data used to build the quality assessment model are proprietary. However, we assume that the quality of software-derived annotation labels is at the same level as a typical experienced sonographer. This assumption is confirmed to be valid for our data later in this article. Under this assumption, ScanNav® is treated as equivalent to an experienced sonographer in ultrasound image classifications. It can assess and compare hundreds of real and simulated second-trimester scans efficiently and quickly (which is something that is tedious and costly to achieve if the task is performed by human experts)." E.H. Bradburn et al., *OC10.05 An artificial intelligence system that can correctly identify fetal ultrasound imaging planes throughout gestational age*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28-29.

	Methods: Anonymised fetal ultrasound images, acquired at 15 to 40 weeks of gestation, from a large image database were analysed in this study. This included images of head circumference (HC), abdominal circumference (AC), femur length (FL), amniotic fluid index (AFI) and miscellaneous images. An AI algorithm (ScanNav, trained primarily on routine anatomy scans from 18-24 weeks), was applied to each image and categorised it into one of five categories: HC, AC, FL, AFI and others. A random ten percent per view of all images were manually reviewed by one experienced clinician to determine the accuracy of this classification. The performance of the AI algorithm, according to the gestational age at the time of the scan, was assessed. **Results:** Over 450,000 images were assessed by ScanNav, and a random 10% (45,036 images) underwent clinical review. The accuracy of the AI algorithm in categorising the images into standard biometry planes (HC, AC, FL and AFI) was 99.1%. This was 99.6%, 99.1%, 97.9% and 99.9% for HC, AC, FL and AFI, respectively. Across all categories the algorithm performed best between 20+0 and 35+6 weeks, with an accuracy that remained stable throughout that gestational age range (97%). There was a slight drop in accuracy below 20 weeks and above 36 weeks, to 94% and 96% respectively. **Conclusions:** Although trained primarily on routine anatomy scans from 18-24 weeks, the ScanNav AI algorithm is 99.1% accurate in image categorisation of basic biometry planes. Accuracy was maintained over a very broad range of gestational ages. This may reflect that clinically these standard planes remain consistent in appearance throughout gestation. Improvement at the extremes of GA may be possible by further algorithm training. Mohammad Yaqub et al., *491 ScanNav® audit: an AI-powered screening assistant for fetal anatomical ultrasound*, American Journal of Obstetrics & Gynecology, Supplement to February 2021, at S312.

		OBJECTIVE: To develop and evaluate a real-time Artificial Intelligence (AI) based system to automatically keep track of acquired images; and check that the images conform to imaging protocol standards, in essence, replacing a human peer reviewer. **STUDY DESIGN:** We developed an AI system (ScanNav) which automatically (1) checks the completeness of the imaging record during fetal anomaly screening, ensuring all 19 required fetal views are recorded; and (2) assesses the quality of these images (in this case according to the guidelines of ISUOG). First, AI algorithms were trained on images manually evaluated by a pool of experienced sonologists and using state-of-the-art deep learning technology. The resulting algorithm was then assessed on a separate testing set; it was deemed correct if 2 or more (from a panel of 5) independent sonologists agreed with its decision. Due to the lack of expert agreement for "marginal" images, it was deemed appropriate to include as agreement such a 2:3 panel split. **RESULTS:** The system was developed on 479,322 anonymised images from 48,161 routine mid-trimester scans. Agreement between ScanNav and the sonologist panel was performed on an independent set of 38,840 images (4,284 scans). For scan completeness the mean (standard deviation) of agreement between ScanNav and the sonologists was 93.5% (±5.6%); for image quality it was 92.2% (±4.7%). The system processes 11 frames per second on a PC with an RTX4000 GPU.

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<tr>
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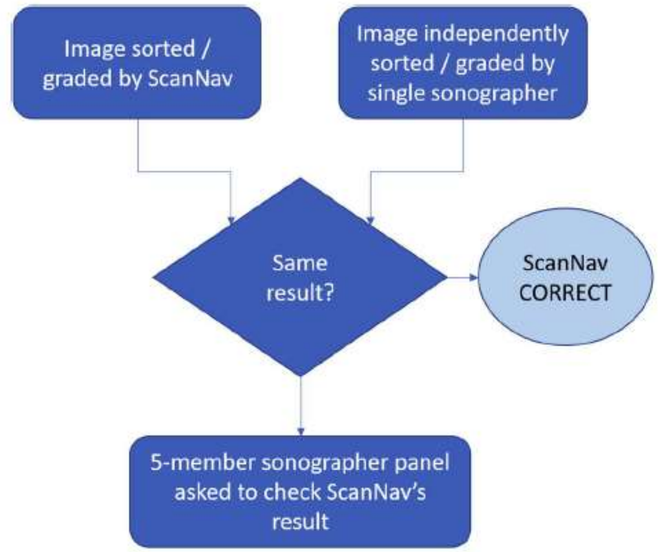

<table>
<tr><th># Sonographers agree with ScanNav</th><th>ScanNav</th></tr>
<tr><td>0</td><td>INCORRECT</td></tr>
<tr><td>1</td><td>INCORRECT</td></tr>
<tr><td>2</td><td>CORRECT</td></tr>
<tr><td>3</td><td>CORRECT</td></tr>
<tr><td>4</td><td>CORRECT</td></tr>
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<tr>
<td>11[c]: train the neural networks using the plurality of echocardiographic training images and the associated expert quality assessment values to determine sets of neural network parameters</td>
<td>The Voluson family products disclose a computer-implemented system that comprises at least one processor that “train[s] the neural networks using the plurality of echocardiographic training images and the associated expert quality assessment values to determine sets of neural network parameters defining the neural networks, at least a portion of each of said neural networks associated with one of the plurality of predetermined echocardiographic image view categories.”

See claim 1[pre] regarding how the Voluson family products are computer-implemented and include at least one processor.</td>
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</table>

defining the neural networks, at least a portion of each of said neural networks associated with one of the plurality of predetermined echocardiographic image view categories;	*See* claim 1[c] and 1[i] regarding training of the SonoLyst AI algorithm and how view category specific quality assessments are provided by expert echocardiographers as part of the deep neural network training process. Training of the SonoLyst AI algorithm results in determination of sets of neural network parameters defining the neural networks (e.g., neural networks within a neural network). As discussed above for claim [i], each of the neural networks include view category specific neural network parameters, and thus at least a portion of each of the neural networks are associated with a view category from the ten standard views used for training the SonoLyst AI algorithm. For example, see the following passages and/or figures, as well as all related disclosures: FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K220358) at 7-8: "SonoLyst: Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance • For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images. • The number of individual patients images were collected from: 5000+ exams • The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops. … Information about equipment and protocols used to collect images. • Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection. Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): 1. The images were curated (sorted and graded) by a single Sonographer

	2. The images were sorted and graded by SonoLyst. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system. Description of how independence of test data from training data was ensured: • The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two.” FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K231965) at 10-11: “Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. • Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population. • The verification for the SonoLyst 2nd Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features. • The verification of the SonoLystLive 2nd Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality. • The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher. … <u>Quantitative evaluation</u>: For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation

…
Information about the reference standard and dataset ("truthing process"):
To ensure the quality of the curated data for verification, the following strategy is employed:

1. The images were curated (sorted and graded) by a single sonographer.
2. The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting.
3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel.
4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system."

Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6:

All SonoLyst features are workflow supporting features and are all based on Deep Learning technology:

- SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views.
- SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria).
- SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload.

	The output image of the SonoLyst*live* feature is shown below as an example, displaying the detected 4 Chamber Heart view and the green status indicator:  As SonoLystIR and SonoLystX are deeply integrated in the Scan Assistant workflow, please refer to ' Scan Assistant ' *on page 7-10* for more details about the usage and setup. All SonoLyst features use the following predefined standard views and depending criteria for the 1st Trimester:

	(table below)

Pre-defined standard view	Criteria
Sagittal Fetus	Magnification Mid-sagittal Neutral position and orientation Crown visible Rump visible
Axial Head	Magnification Symmetrical hemispheres Full head circumference visible Choroid plexus visible Midline falx
Transthalamic Plane	Magnification Symmetrical hemispheres Two separate thalami Midline falx
Axial Orbits	Magnification Both orbits visible
Coronal Orbits	Magnification Both orbits visible Nose visible Both ears visible
Coronal Palate	Magnification Nasal bone Supermaxilla
Coronal Lips	Magnification Nasal tip Upper lip
4CH/Thorax	Magnification 4 chambers clearly visible
Cord Insertion	Magnification Cord inserted into abdominal wall
Axial Abdomen	Magnification Full abdominal circumference visible Stomach visible
Axial Kidneys	Magnification Both kidneys visible
Axial Bladder	Magnification Bladder visible
Coronal Kidneys	Magnification Both kidneys visible
Sagittal Spine	Magnification Vertebrae are aligned Skin edge
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible

Pre-defined standard view	Criteria
Hand	Magnification Hand visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible
Sagittal Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Sagittal Profile	Magnification Mid-sagittal Neutral position and orientation Nasal tip
Sagittal Brain	Magnification Brainstem Fourth ventricle Cisterna magna

All SonoLyst features use the following predefined standard views and depending criteria for the 2nd Trimester:

Pre-defined standard view	Criteria
Transventricular Plane	Magnification Brain symmetry Midline falx Lateral cerebral ventricles Choroid Plexus Cavum septum pellucidum No Cerebellum
Transthalamic Plane	Magnification Brain symmetry Midline falx Thalamus Cavum septum pellucidum No Cerebellum
Transcerebellar Plane	Magnification Brain symmetry Midline falx Cavum septum pellucidum Cerebellum Cisterna Magna
Profile	Magnification Nasal tip Forehead bone visible

Pre-defined standard view	Criteria
Orbits	Magnification Both orbits visible Symmetrical orbits
Nose/Lips	Magnification Nasal tip Nostrils Upper lip
4CH/Thorax	Magnification 4 Chambers visible Ventricular Septum Valves visible
LVOT	Continuity Ventricular Septum Magnification
RVOT	Vessel Bifurcation Magnification
3VV/3VT	3 Vessels Magnification
Abdomen (AC)	Magnification Stomach Umbilical vein Rib visible Circular/Shape No Kidney visible
Abdomen - Cord Insertion	Magnification Cord visible
Transverse Kidneys	Magnification Both kidneys visible
Bladder	Magnification Bladder visible
Umbilical Cord (3VC)	Magnification Bladder visible
Femur	Magnification Angle of insonation Clear Diaphysis
Plantar Foot	Magnification Full foot visible
Hand	Magnification Clear hand visible
TA Cervix	Magnification Endocervical Canal Internal Os External Os
Spine Sacrum	Lumbar - alignment Lumbar - Skin line Magnification

	(inner table below) Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 13-45 to 13-47:

Pre-defined standard view	Criteria
Spine Lumbar	Lumbar - alignment Lumbar - Skin line Magnification
Spine Thoracic	Thoracic - alignment Thoracic - Skin line Magnification
Spine Cervical	Cervical - alignment Cervical - Skin line Magnification
Upper Arm	Magnification Upper Arm visible
Forearm	Magnification Forearm visible
Upper Leg	Magnification Upper Leg visible
Lower Leg	Magnification Lower Leg visible
Foot	Magnification Foot visible

Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 13-45 to 13-47:

13.13 Deep Learning Based Features

Note *Some of these deep learning based features are not available in all countries:*

- SonoLystIR
- SonoLystIR 1st Trimester
- SonoLystX
- SonoLystX 1st Trimester
- SonoLyst*live*
- SonoLyst*live* 1st Trimester
- Sono*Biometry* CRL
- SonoPelvicFloor
- SonoCNS
- Sono*Biometry* Cereb, Vp, CM
- FetalHS
- SonoAVC™*follicle* 2.0
- SonoAVC™*follicle* Auto Caliper
- Fibroid Mapping
- AutoSpine
- SonoPF2D
- AnalSphincter

The application of deep learning based features requires caution by the user and an informed decision on the usage of the specific feature. Therefore, all caution information and performance testing for each feature are summarized in this chapter.

Performance Testing for SonoLyst:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystIR	80% accuracy	41936

Performance Testing for SonoLystIR 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystIR 1st Trimester	80% accuracy	5271

Performance Testing for SonoLystX:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystX	80%	9998

Performance Testing for SonoLystX 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLystX 1st Trimester	80%	2400

Performance Testing for SonoLyst*live*:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLyst*live*	80% accuracy	5623

Performance Testing for SonoLyst*live* 1st Trimester:

Sub-Feature	Minimum Acceptable Algorithmic Performance	Number of Test Images
SonoLyst*live* 1st Trimester	80%	6000

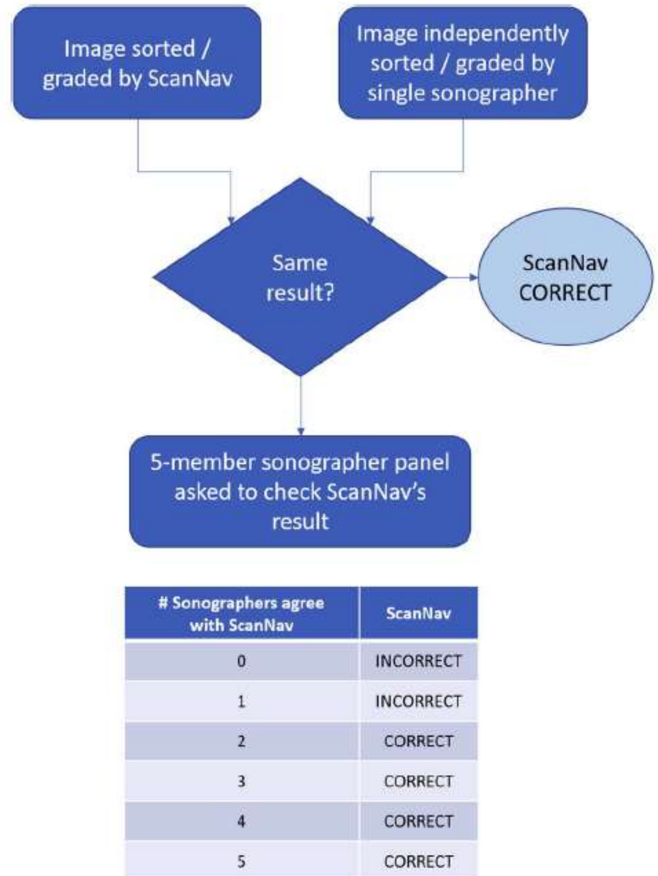
Yangdi Xu et al., *Simulating realistic fetal neurosonography images with appearance and growth change using cycle-consistent adversarial networks and an evaluation*, Journal of Medical Imaging

	(Sep/Oct 2020), Vol. 7(5) at 4: "ScanNav® (Intelligent Ultrasound Ltd., Milton Park, Abingdon, United Kingdom) is a pre-commercial deep learning-based automatic image analysis software application that assesses the quality of second-trimester scans according to the UK FASP guidelines. It is able to accurately detect different structures of a standard plane in large scale. It had been designed and trained by analzsing thousands of clinical second-trimester ultrasound images to label and grade images. Details of the underpinning algorithms and data used to build the quality assessment model are proprietary. However, we assume that the quality of software-derived annotation labels is at the same level as a typical experienced sonographer. This assumption is confirmed to be valid for our data later in this article. Under this assumption, ScanNav® is treated as equivalent to an experienced sonographer in ultrasound image classifications. It can assess and compare hundreds of real and simulated second-trimester scans efficiently and quickly (which is something that is tedious and costly to achieve if the task is performed by human experts)." E.H. Bradburn et al., *OC10.05 An artificial intelligence system that can correctly identify fetal ultrasound imaging planes throughout gestational age*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28-29.

	Methods: Anonymised fetal ultrasound images, acquired at 15 to 40 weeks of gestation, from a large image database were analysed in this study. This included images of head circumference (HC), abdominal circumference (AC), femur length (FL), amniotic fluid index (AFI) and miscellaneous images. An AI algorithm (ScanNav, trained primarily on routine anatomy scans from 18-24 weeks), was applied to each image and categorised it into one of five categories: HC, AC, FL, AFI and others. A random ten percent per view of all images were manually reviewed by one experienced clinician to determine the accuracy of this classification. The performance of the AI algorithm, according to the gestational age at the time of the scan, was assessed. **Results:** Over 450,000 images were assessed by ScanNav, and a random 10% (45,036 images) underwent clinical review. The accuracy of the AI algorithm in categorising the images into standard biometry planes (HC, AC, FL and AFI) was 99.1%. This was 99.6%, 99.1%, 97.9% and 99.9% for HC, AC, FL and AFI, respectively. Across all categories the algorithm performed best between 20+0 and 35+6 weeks, with an accuracy that remained stable throughout that gestational age range (97%). There was a slight drop in accuracy below 20 weeks and above 36 weeks, to 94% and 96% respectively. **Conclusions:** Although trained primarily on routine anatomy scans from 18-24 weeks, the ScanNav AI algorithm is 99.1% accurate in image categorisation of basic biometry planes. Accuracy was maintained over a very broad range of gestational ages. This may reflect that clinically these standard planes remain consistent in appearance throughout gestation. Improvement at the extremes of GA may be possible by further algorithm training. E.H. Bradburn et al., *OC10.04 Estimating fetal gestational age based on ultrasound image characteristics using artificial intelligence*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28.

	Methods: Quality assessed ultrasound images of head circumference (HC) and abdominal circumference (AC) were used from a multicentre study database of women with known GA (CRL performed < 14 weeks) who underwent serial ultrasound examinations from 15 to 40 weeks. We split data randomly into 67.5% training, 7.5% validation and 25% testing sets. We developed and tested an artificial intelligence (AI) algorithm using a regression neural network to estimate the GA, based on image characteristics only without measurement information. Mohammad Yaqub et al., *491 ScanNav® audit: an AI-powered screening assistant for fetal anatomical ultrasound*, American Journal of Obstetrics & Gynecology, Supplement to February 2021, at S312.

		OBJECTIVE: To develop and evaluate a real-time Artificial Intelligence (AI) based system to automatically keep track of acquired images; and check that the images conform to imaging protocol standards, in essence, replacing a human peer reviewer. **STUDY DESIGN:** We developed an AI system (ScanNav) which automatically (1) checks the completeness of the imaging record during fetal anomaly screening, ensuring all 19 required fetal views are recorded; and (2) assesses the quality of these images (in this case according to the guidelines of ISUOG). First, AI algorithms were trained on images manually evaluated by a pool of experienced sonologists and using state-of-the-art deep learning technology. The resulting algorithm was then assessed on a separate testing set; it was deemed correct if 2 or more (from a panel of 5) independent sonologists agreed with its decision. Due to the lack of expert agreement for "marginal" images, it was deemed appropriate to include as agreement such a 2:3 panel split. **RESULTS:** The system was developed on 479,322 anonymised images from 48,161 routine mid-trimester scans. Agreement between ScanNav and the sonologist panel was performed on an independent set of 38,840 images (4,284 scans). For scan completeness the mean (standard deviation) of agreement between ScanNav and the sonologists was 93.5% (±5.6%); for image quality it was 92.2% (±4.7%). The system processes 11 frames per second on a PC with an RTX4000 GPU.

<table>
<tr><td></td><td>
</td></tr>
<tr><td>11[d]: wherein the at least one processor is further configured to, once the neural networks are trained:
receive signals representing a first at least one</td><td>The Voluson family products disclose a computer-implemented system "wherein the at least one processor is further configured to, once the neural networks are trained: receive signals representing a first at least one echocardiographic image."

See claim 1[pre], 1[a], and 11[pre].</td></tr>
</table>

echocardiographic image;	
11[e]: associate the first at least one echocardiographic image with a first view category of a plurality of predetermined echocardiographic image view categories;	The Voluson family products disclose a computer-implemented system "*wherein the at least one processor is further configured to, once the neural networks are trained…associate the first at least one echocardiographic image with a first view category of a plurality of predetermined echocardiographic image view categories*." *See* claim 1[b].
11[f]: determine, based on the first at least one echocardiographic image and the first view category, a first quality assessment value representing a view category specific quality assessment of the first at least one echocardiographic image;	The Voluson family products disclose a computer-implemented system "*wherein the at least one processor is further configured to, once the neural networks are trained…determine, based on the first at least one echocardiographic image and the first view category, a first quality assessment value representing a view category specific quality assessment of the first at least one echocardiographic image*." *See* claim 1[c]. To the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. *See* claim 1[c].
11[g]: produce signals representing the first quality assessment value for causing the first quality assessment value to be associated with the first at least one echocardiographic image;	The Voluson family products disclose a computer-implemented system "*wherein the at least one processor is further configured to, once the neural networks are trained…produce[s] signals representing the first quality assessment value for causing the first quality assessment value to be associated with the first at least one echocardiographic image*." *See* claim 1[d].
11[h]: receive signals representing a second at least one echocardiographic image;	The Voluson family products disclose a computer-implemented system "*wherein the at least one processor is further configured to, once the neural networks are trained…receive signals representing a second at least one echocardiographic image*."

	See claim 1[e].
11[i]: associate the second at least one echocardiographic image with a second view category of the plurality of predetermined echocardiographic image view categories, said second view category being different from the first view category;	The Voluson family products disclose a computer-implemented system "*wherein the at least one processor is further configured to, once the neural networks are trained…associate the second at least one echocardiographic image with a second view category of the plurality of predetermined echocardiographic image view categories, said second view category being different from the first view category*." *See* claim 1[f].
11[j]: determine, based on the second at least one echocardiographic image and the second view category, a second quality assessment value representing a view category specific quality assessment of the second at least one echocardiographic image; and	The Voluson family products disclose a computer-implemented system "*wherein the at least one processor is further configured to, once the neural networks are trained…determine, based on the second at least one echocardiographic image and the second view category, a second quality assessment value representing a view category specific quality assessment of the second at least one echocardiographic image*." *See* claim 1[g]. To the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. *See* claim 1[c].
11[k]: produce signals representing the second quality assessment value for causing the second quality	The Voluson family products disclose a computer-implemented system "*wherein the at least one processor is further configured to, once the neural networks are trained…produce signals representing the second quality assessment value for causing the second quality assessment value to be associated with the second at least one echocardiographic image*."

assessment value to be associated with the second at least one echocardiographic image;	*See* claim 1[h].
11[l]: wherein each of the plurality of predetermined echocardiographic image view categories is associated with a respective set of assessment parameters, each of the sets of assessment parameters being a set of neural network parameters that define a neural network having a plurality of layers including an input layer configured to receive one or more echocardiographic images and an output layer configured to output one or more quality assessment values, and	The Voluson family products disclose a computer-implemented system "*wherein each of the plurality of predetermined echocardiographic image view categories is associated with a respective set of assessment parameters, each of the sets of assessment parameters being a set of neural network parameters that define a neural network having a plurality of layers including an input layer configured to receive one or more echocardiographic images and an output layer configured to output one or more quality assessment values*." *See* claim 1[i]. To the extent Defendants do not literally infringe this claim element requiring a "quality assessment value" and "each of the sets of assessment parameters being a set of neural network parameters that define a neural network," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. *See* claim 1[c] and 1[i].
11[m]: wherein the at least one processor is configured to determine the first quality assessment value by: (i) determining that a first set of assessment parameters of the sets of assessment parameters is associated with the first view category; and	The Voluson family products disclose a computer-implemented system "*wherein the at least one processor is configured to determine the first quality assessment value by: (i) determining that a first set of assessment parameters of the sets of assessment parameters is associated with the first view category; and (ii) in response to determining that the first set of assessment parameters is associated with the first view category, inputting the first at least one echocardiographic image into the neural network defined by the first set of assessment parameters*." *See* claim 1[j].

(ii) in response to determining that the first set of assessment parameters is associated with the first view category, inputting the first at least one echocardiographic image into the neural network defined by the first set of assessment parameters; and	To the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. *See* claim 1[c].
11[n]: wherein the at least one processor is configured to determine the second quality assessment value by: (i) determining that a second set of assessment parameters of the sets of assessment parameters is associated with the second view category; and (ii) in response to determining that the second set of assessment parameters is associated with the second view category, inputting the second at least one echocardiographic image into the neural network defined by the	The Voluson family products disclose a computer-implemented system "*wherein the at least one processor is configured to determine the second quality assessment value by: (i) determining that a second set of assessment parameters of the sets of assessment parameters is associated with the second view category; and (ii) in response to determining that the second set of assessment parameters is associated with the second view category, inputting the second at least one echocardiographic image into the neural network defined by the second set of assessment parameters*." *See* claim 1[k]. To the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. *See* claim 1[c].

second set of assessment parameters.	
’591 Claim 12	**Voluson Family Products**
12: The system of claim 11 wherein each of the expert quality assessment values represents an assessment of suitability of the associated echocardiographic image for quantified clinical measurement of anatomical features.	The Voluson family products disclose a computer-implemented system “*wherein each of the expert quality assessment values represents an assessment of suitability of the associated echocardiographic image for quantified clinical measurement of anatomical features.*” *See* claims 1[c], 1[i], and 7 regarding the deep neural network training process using expert quality assessment values. *See* claim 2 regarding suitability for quantified clinical measurement of anatomical features.
’591 Claim 13	**Voluson Family Products**
13: The system of claim 11 wherein the at least one processor is configured to derive each of the expert quality assessment values at least in part from a clinical plane assessment value representing an expert opinion whether the associated echocardiographic training image was taken in an anatomical plane suitable for a quantified clinical measurement of anatomical features.	The Voluson family products disclose a computer-implemented system “*wherein the at least one processor is configured to derive each of the expert quality assessment values at least in part from a clinical plane assessment value representing an expert opinion whether the associated echocardiographic training image was taken in an anatomical plane suitable for a quantified clinical measurement of anatomical features.*” *See* claim 2 regarding suitability for quantified clinical measurement of anatomical features. An echocardiogram involves imaging along a variety of 2D anatomical planes of the heart. ’591 Patent, 9:1-12. Since the SonoLyst AI algorithm is trained based on the ideal probe position for the standard diagnostic views as shown above for claim 1[i], the expert quality assessment values are derived at least in part from an expert opinion about whether the associated echocardiographic training image was taken in an anatomical plane suitable for quantified clinical measurement of anatomical features. *See* claim 9.
’591 Claim 14	**Voluson Family Products**

14: The system of claim 11 wherein each of the sets of neural network parameters includes: a set of common neural network parameters, which are common to each of the sets of neural network parameters; and a set of view category specific neural network parameters, which are unique to the set of neural network parameters; and wherein the at least one processor is configured to, for each echocardiographic training image: select one of the sets of view category specific neural network parameters based on the predetermined echocardiographic image view category associated with the echocardiographic training image; and using the echocardiographic training image as an input and the associated expert quality assessment value as a desired output, train a neural network defined by the set of common neural	The Voluson family products disclose a computer-implemented system "*wherein each of the sets of neural network parameters includes: a set of common neural network parameters, which are common to each of the sets of neural network parameters; and a set of view category specific neural network parameters, which are unique to the set of neural network parameters; and wherein the at least one processor is configured to, for each echocardiographic training image: select one of the sets of view category specific neural network parameters based on the predetermined echocardiographic image view category associated with the echocardiographic training image; and using the echocardiographic training image as an input and the associated expert quality assessment value as a desired output, train a neural network defined by the set of common neural network parameters and the selected one of the sets of view category specific neural network parameters to update the set of common neural network parameters and the selected one of the sets of view category specific neural network parameters*." *See* claim 1[i] and 6 regarding the disclosure of the sets of assessment parameters that are neural network parameters, common assessment parameters that are common neural network parameters, and view category specific assessment parameters that are neural network parameters, which are unique to the sets of neural network parameters. *See* claim 1[c] regarding the deep neural network training process. The Voluson family products train the SonoLyst AI algorithm with ideal echocardiographic images that have been associated with transducer position and labeled by expert sonologists for image quality and correctness. The SonoLyst AI algorithm is also trained to estimate the four (4) diagnostic view categories of the fetal heart (e.g., 4CH/Thorax, LVOT, RVOT, and 3VV). Therefore, each echocardiographic training image is associated with a predetermined image view category. The deep neural network (SonoLyst AI algorithm) has a plurality of layers including an input layer configured to receive echocardiographic images and an output layer configured to output quality assessment values. Because the training images are labeled and annotated with associated expert quality assessment values during the training process, the associated expert quality assessment values (grading criteria) are the desired outputs. As the SonoLyst AI algorithm is trained with the expert-labelled training images, the neural network parameters are iteratively refined and updated to better predict how to acquire high-quality image for specific views.

network parameters and the selected one of the sets of view category specific neural network parameters to update the set of common neural network parameters and the selected one of the sets of view category specific neural network parameters.	For example, see the following passages and/or figures, as well as all related disclosures: FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K220358) at 7-8: "SonoLyst: Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance • For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images. • The number of individual patients images were collected from: 5000+ exams • The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops. … Information about equipment and protocols used to collect images. • Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection. Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): 1. The images were curated (sorted and graded) by a single Sonographer 2. The images were sorted and graded by SonoLyst. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system.

	Description of how independence of test data from training data was ensured: • The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two." FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K231965) at 10-11: "Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. • Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population. • The verification for the SonoLyst 2nd Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features. • The verification of the SonoLystLive 2nd Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality. • The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher. … <u>Quantitative evaluation</u>: For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation … Information about the reference standard and dataset ("truthing process"): To ensure the quality of the curated data for verification, the following strategy is employed: 1. The images were curated (sorted and graded) by a single sonographer. 2. The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel.

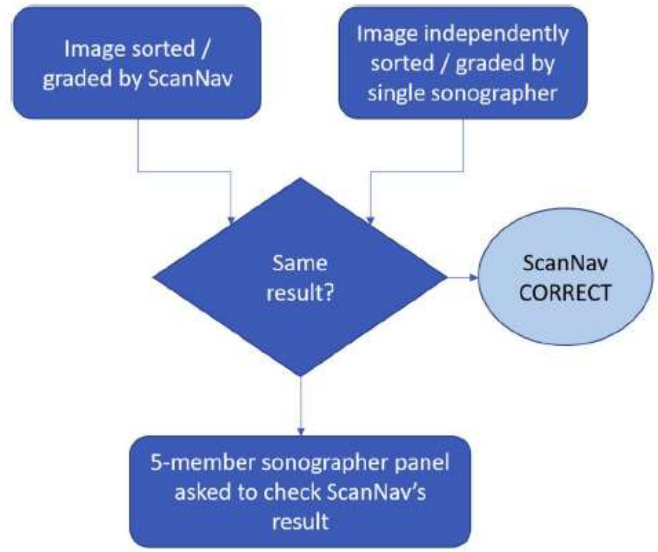
	4. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system." Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6: All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload. Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 13-45 to 13-47:

	13.13 Deep Learning Based Features **Note** *Some of these deep learning based features are not available in all countries:* • SonoLystIR • SonoLystIR 1st Trimester • SonoLystX • SonoLystX 1st Trimester • SonoLyst*live* • SonoLyst*live* 1st Trimester • Sono*Biometry* CRL • SonoPelvicFloor • SonoCNS • Sono*Biometry* Cereb, Vp, CM • FetalHS • SonoAVC™*follicle* 2.0 • SonoAVC™*follicle* Auto Caliper • Fibroid Mapping • AutoSpine • SonoPF2D • AnalSphincter The application of deep learning based features requires caution by the user and an informed decision on the usage of the specific feature. Therefore, all caution information and performance testing for each feature are summarized in this chapter. E.H. Bradburn et al., *OC10.05 An artificial intelligence system that can correctly identify fetal ultrasound imaging planes throughout gestational age*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28-29.

	Methods: Anonymised fetal ultrasound images, acquired at 15 to 40 weeks of gestation, from a large image database were analysed in this study. This included images of head circumference (HC), abdominal circumference (AC), femur length (FL), amniotic fluid index (AFI) and miscellaneous images. An AI algorithm (ScanNav, trained primarily on routine anatomy scans from 18-24 weeks), was applied to each image and categorised it into one of five categories: HC, AC, FL, AFI and others. A random ten percent per view of all images were manually reviewed by one experienced clinician to determine the accuracy of this classification. The performance of the AI algorithm, according to the gestational age at the time of the scan, was assessed. **Results:** Over 450,000 images were assessed by ScanNav, and a random 10% (45,036 images) underwent clinical review. The accuracy of the AI algorithm in categorising the images into standard biometry planes (HC, AC, FL and AFI) was 99.1%. This was 99.6%, 99.1%, 97.9% and 99.9% for HC, AC, FL and AFI, respectively. Across all categories the algorithm performed best between 20+0 and 35+6 weeks, with an accuracy that remained stable throughout that gestational age range (97%). There was a slight drop in accuracy below 20 weeks and above 36 weeks, to 94% and 96% respectively. **Conclusions:** Although trained primarily on routine anatomy scans from 18-24 weeks, the ScanNav AI algorithm is 99.1% accurate in image categorisation of basic biometry planes. Accuracy was maintained over a very broad range of gestational ages. This may reflect that clinically these standard planes remain consistent in appearance throughout gestation. Improvement at the extremes of GA may be possible by further algorithm training. E.H. Bradburn et al., *OC10.04 Estimating fetal gestational age based on ultrasound image characteristics using artificial intelligence*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28.

	Methods: Quality assessed ultrasound images of head circumference (HC) and abdominal circumference (AC) were used from a multicentre study database of women with known GA (CRL performed < 14 weeks) who underwent serial ultrasound examinations from 15 to 40 weeks. We split data randomly into 67.5% training, 7.5% validation and 25% testing sets. We developed and tested an artificial intelligence (AI) algorithm using a regression neural network to estimate the GA, based on image characteristics only without measurement information. Mohammad Yaqub et al., *491 ScanNav® audit: an AI-powered screening assistant for fetal anatomical ultrasound*, American Journal of Obstetrics & Gynecology, Supplement to February 2021, at S312.

		OBJECTIVE: To develop and evaluate a real-time Artificial Intelligence (AI) based system to automatically keep track of acquired images; and check that the images conform to imaging protocol standards, in essence, replacing a human peer reviewer. **STUDY DESIGN:** We developed an AI system (ScanNav) which automatically (1) checks the completeness of the imaging record during fetal anomaly screening, ensuring all 19 required fetal views are recorded; and (2) assesses the quality of these images (in this case according to the guidelines of ISUOG). First, AI algorithms were trained on images manually evaluated by a pool of experienced sonologists and using state-of-the-art deep learning technology. The resulting algorithm was then assessed on a separate testing set; it was deemed correct if 2 or more (from a panel of 5) independent sonologists agreed with its decision. Due to the lack of expert agreement for "marginal" images, it was deemed appropriate to include as agreement such a 2:3 panel split. **RESULTS:** The system was developed on 479,322 anonymised images from 48,161 routine mid-trimester scans. Agreement between ScanNav and the sonologist panel was performed on an independent set of 38,840 images (4,284 scans). For scan completeness the mean (standard deviation) of agreement between ScanNav and the sonologists was 93.5% (±5.6%); for image quality it was 92.2% (±4.7%). The system processes 11 frames per second on a PC with an RTX4000 GPU.



# Sonographers agree with ScanNav	ScanNav
0	INCORRECT
1	INCORRECT
2	CORRECT
3	CORRECT
4	CORRECT
5	CORRECT

’591 Claim 15	**Voluson Family Products**
15[pre]: A computer-implemented method of facilitating echocardiographic image analysis, the method comprising:	The Voluson family products disclose “*[a] computer-implemented method of facilitating echocardiographic image analysis*.” *See* claim 1[pre].

15[a]: receiving signals representing a first at least one echocardiographic image;	The Voluson family products disclose a computer-implemented method comprising "*receiving signals representing a first at least one echocardiographic image.*" *See* claim 1[a].
15[b]: associating the first at least one echocardiographic image with a first view category of a plurality of predetermined echocardiographic image view categories;	The Voluson family products disclose a computer-implemented method comprising "*associating the first at least one echocardiographic image with a first view category of a plurality of predetermined echocardiographic image view categories.*" *See* claim 1[b].
15[c]: determining, based on the first at least one echocardiographic image and the first view category, a first quality assessment value representing a view category specific quality assessment of the first at least one echocardiographic image;	The Voluson family products disclose a computer-implemented method comprising "*determining, based on the first at least one echocardiographic image and the first view category, a first quality assessment value representing a view category specific quality assessment of the first at least one echocardiographic image.*" *See* claim 1[c]. To the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. *See* claim 1[c].
15[d]: producing signals representing the first quality assessment value for causing the first quality assessment value to be associated with the first at least one echocardiographic image;	The Voluson family products disclose a computer-implemented method comprising "*producing signals representing the first quality assessment value for causing the first quality assessment value to be associated with the first at least one echocardiographic image.*" *See* claim 1[d]. To the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. *See* claim 1[c].

15[e]: receiving signals representing a second at least one echocardiographic image;	The Voluson family products disclose a computer-implemented method comprising "*receiving signals representing a second at least one echocardiographic image.*" *See* claim 1[e].
15[f]: associating the second at least one echocardiographic image with a second view category of the plurality of predetermined echocardiographic image view categories, said second view category being different from the first view category;	The Voluson family products disclose a computer-implemented method comprising "*associating the second at least one echocardiographic image with a second view category of the plurality of predetermined echocardiographic image view categories, said second view category being different from the first view category.*" *See* claim 1[f].
15[g]: determining, based on the second at least one echocardiographic image and the second view category, a second quality assessment value representing a view category specific quality assessment of the second at least one echocardiographic image; and	The Voluson family products disclose a computer-implemented method comprising "*determining, based on the second at least one echocardiographic image and the second view category, a second quality assessment value representing a view category specific quality assessment of the second at least one echocardiographic image.*" *See* claim 1[g]. To the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. *See* claim 1[c].
15[h]: producing signals representing the second quality assessment value for causing the second quality assessment value to be	The Voluson family products disclose a computer-implemented method comprising "*producing signals representing the second quality assessment value for causing the second quality assessment value to be associated with the second at least one echocardiographic image.*" *See* claim 1[h].

associated with the second at least one echocardiographic image;	
15[i]: wherein each of the plurality of predetermined echocardiographic image view categories is associated with a respective set of assessment parameters, each of the sets of assessment parameters being a set of neural network parameters that defines a neural network having a plurality of layers including an input layer configured to receive one or more echocardiographic images and an output layer configured to output one or more quality assessment values and	The Voluson family products disclose a computer-implemented method "*wherein each of the plurality of predetermined echocardiographic image view categories is associated with a respective set of assessment parameters, each of the sets of assessment parameters being a set of neural network parameters that defines a neural network having a plurality of layers including an input layer configured to receive one or more echocardiographic images and an output layer configured to output one or more quality assessment values*." *See* claim 1[i]. To the extent Defendants do not literally infringe this claim element requiring a "quality assessment value" and "each of the sets of assessment parameters being a set of neural network parameters that defines a neural network," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. *See* claim 1[c] and 1[i].
15[j]: wherein: determining the first quality assessment value comprises: determining that a first set of assessment parameters of the sets of assessment parameters is associated with the first view category; and	The Voluson family products disclose a computer-implemented method "*wherein: determining the first quality assessment value comprises: determining that a first set of assessment parameters of the sets of assessment parameters is associated with the first view category; and in response to determining that the first set of assessment parameters is associated with the first view category, inputting the first at least one echocardiographic image into the neural network defined by the first set of assessment parameters applying a first function based on the first set of assessment parameters to the first at least one echocardiographic image*." *See* claim 1[j].

in response to determining that the first set of assessment parameters is associated with the first view category, inputting the first at least one echocardiographic image into the neural network defined by the first set of assessment parameters applying a first function based on the first set of assessment parameters to the first at least one echocardiographic image; and	To the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. *See* claim 1[c].
15[k]: determining the second quality assessment value comprises: determining that a second set of assessment parameters of the sets of assessment parameters is associated with the second view category; and in response to determining that the second set of assessment parameters is associated	The Voluson family products disclose a computer-implemented method wherein "*determining the second quality assessment value comprises: determining that a second set of assessment parameters of the sets of assessment parameters is associated with the second view category; and in response to determining that the second set of assessment parameters is associated with the second view category, inputting the second at least one echocardiographic image into the neural network defined by the second set of assessment parameters*." *See* claim 1[k]. To the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. *See* claim 1[c].

with the second view category, inputting the second at least one echocardiographic image into the neural network defined by the second set of assessment parameters.	
’591 Claim 16	**Voluson Family Products**
16: The method of claim 15 wherein the first quality assessment value represents an assessment of suitability of the first at least one echocardiographic image for quantified clinical measurement of anatomical features and wherein the second quality assessment value represents an assessment of suitability of the second at least one echocardiographic image for quantified measurement of anatomical features.	The Voluson family products disclose a computer-implemented method “*wherein the first quality assessment value represents an assessment of suitability of the first at least one echocardiographic image for quantified clinical measurement of anatomical features and wherein the second quality assessment value represents an assessment of suitability of the second at least one echocardiographic image for quantified measurement of anatomical features*.” *See* claim 2 regarding assessment of suitability for quantified clinical measurement of anatomical features. The Voluson family products are configured to acquire a series of images of various view categories and thus the assessment process step can be repeated for a newly acquired image. *See* claim 2. To the extent Defendants do not literally infringe this claim element requiring a “quality assessment value,” Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. *See* claim 1[c].
’591 Claim 17	**Voluson Family Products**
17. The method of claim 15 wherein: producing the signals representing the first quality assessment value comprises producing signals for	The Voluson family products disclose a computer-implemented method “*wherein: producing the signals representing the first quality assessment value comprises producing signals for causing a representation of the first quality assessment value to be transmitted to at least one display for causing the at least one display to display the first quality assessment value in association with the first at least one echocardiographic image, to assist one or more operators of an echocardiographic device in capturing at least one subsequent echocardiographic image; and producing the signals representing*

causing a representation of the first quality assessment value to be transmitted to at least one display for causing the at least one display to display the first quality assessment value in association with the first at least one echocardiographic image, to assist one or more operators of an echocardiographic device in capturing at least one subsequent echocardiographic image; and producing the signals representing the second quality assessment value comprises producing signals for causing a representation of the second quality assessment value to be transmitted to the at least one display for causing the at least one display to display the second quality assessment value in association with the second at least one echocardiographic image, to assist the one or more operators in capturing at	*the second quality assessment value comprises producing signals for causing a representation of the second quality assessment value to be transmitted to the at least one display for causing the at least one display to display the second quality assessment value in association with the second at least one echocardiographic image, to assist the one or more operators in capturing at least one subsequent echocardiographic image*." *See* claim 3 for discussion of how the Voluson family products transmit a representation of the first quality assessment value to the display to assist the user in capturing at least one subsequent echocardiographic image. The Voluson family products are configured to acquire a series of images of various view categories and thus the producing process step can be repeated for a newly acquired image. *See* claim 3.

least one subsequent echocardiographic image.	
’591 Claim 18	**Voluson Family Products**
18. The method of claim 15 wherein: associating the first at least one echocardiographic image with the first view category comprises applying one or more view categorization functions to the first at least one echocardiographic image to determine that the first at least one echocardiographic image falls within the first view category; and associating the second at least one echocardiographic image with the second view category comprises applying one or more view categorization functions to the second at least one echocardiographic image to determine that the second at least one echocardiographic image falls within the second view category.	The Voluson family products disclose a computer-implemented method “*wherein: associating the first at least one echocardiographic image with the first view category comprises applying one or more view categorization functions to the first at least one echocardiographic image to determine that the first at least one echocardiographic image falls within the first view category; and associating the second at least one echocardiographic image with the second view category comprises applying one or more view categorization functions to the second at least one echocardiographic image to determine that the second at least one echocardiographic image falls within the second view category.*” *See* claim 4 for discussion of how the Voluson family products apply one or more view categorization functions to an echocardiographic image to determine whether it falls within a view category. Since the Voluson family products is configured to acquire a series of images of various view categories, the application of one or more view categorization functions can be repeated for different echocardiographic images, each associated with a different view category (e.g., first and second view categories). *See* claim 4. The Voluson family products are configured to acquire a series of images of various view categories and thus the associating process step can be repeated for a newly acquired image. *See* 15[b] and 15[f].
’591 Claim 19	**Voluson Family Products**
19. The method of claim 15 wherein the first at least one	The Voluson family products disclose a computer-implemented method “*wherein the first at least one echocardiographic image comprises a plurality of echocardiographic images and wherein*

echocardiographic image comprises a plurality of echocardiographic images and wherein determining the first quality assessment value comprises determining a single quality assessment value representing a view category specific assessment of the plurality of echocardiographic images.	*determining the first quality assessment value comprises determining a single quality assessment value representing a view category specific assessment of the plurality of echocardiographic images.*" *See* claim 1[c] and 5. The Voluson family products are configured to acquire a series of images of various view categories and can also obtain video clips, which are a sequence of images (e.g., frames). As described for 1[c], the SonoLyst AI algorithm can determine a first quality assessment value for an echocardiographic image. Similarly, the SonoLyst AI algorithm can determine a first quality assessment value based on multiple images, such as a video. To the extent Defendants do not literally infringe this claim element requiring a "quality assessment value," Defendants infringe this claim element under the doctrine of equivalents because the accused structure performs substantially the same function in substantially the same way to achieve substantially the same result. *See* claim 1[c].
'591 Claim 20	**Voluson Family Products**
20. The method of claim 15 wherein each of the sets of assessment parameters includes: a set of common assessment parameters, which are common to each of the sets of assessment parameters; and a set of view category specific assessment parameters, which are unique to the set of assessment parameters.	The Voluson family products disclose a computer-implemented method "*wherein each of the sets of assessment parameters includes: a set of common assessment parameters, which are common to each of the sets of assessment parameters; and a set of view category specific assessment parameters, which are unique to the set of assessment parameters*." *See* claim 1[i] and 6. The SonoLyst AI algorithm involves common assessment parameters corresponding to non-view category specific layers, and view category specific assessment parameters corresponding to view category specific layers. Each neural network defined by one of the sets of assessment parameters (e.g., a neural network within a neural network) thus includes a set of the common assessment parameters and a set of the view category specific parameters of the SonoLyst AI algorithm. *See* claim 1[i] regarding the Voluson family products view category specific assessment parameters, which are unique to the set of assessment parameters. For example, see the following passages and/or figures, as well as all related disclosures: FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K220358) at 7-8:

	"SonoLyst: Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance • For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images. • The number of individual patients images were collected from: 5000+ exams • The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops. … Information about equipment and protocols used to collect images. • Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection. Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): 5. The images were curated (sorted and graded) by a single Sonographer 6. The images were sorted and graded by SonoLyst. This process resulted in some images being reclassified during sorting. 7. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 8. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system. Description of how independence of test data from training data was ensured: • The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two."

	FDA 510(k) Premarket Notification Submission for Voluson Expert Series (K231965) at 10-11: "Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. • Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population. • The verification for the SonoLyst 2nd Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features. • The verification of the SonoLystLive 2nd Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality. • The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher. … <u>Quantitative evaluation</u>: For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation … Information about the reference standard and dataset ("truthing process"): To ensure the quality of the curated data for verification, the following strategy is employed: 5. The images were curated (sorted and graded) by a single sonographer. 6. The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting. 7. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 8. Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system."

	Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 7-2 to 7-6: All SonoLyst features are workflow supporting features and are all based on Deep Learning technology: • SonoLystIR – analyzes a frozen ultrasound image and determines whether the image contains one of the pre-defined standard views or not (see list of pre-defined standard views below). SonoLystIR can only be used in conjunction with the Scan Assistant. It adds the capability to the Scan Assistant to select Scan Assistant List items linked with one of the pre-defined standard views. • SonoLystX – works in conjunction with SonoLystIR described above. In addition, if a pre-defined standard view is found by SonoLystIR, the fulfillment of criteria is assessed - for example the presence of certain anatomical structures in this plane. The assessment of this analysis is displayed for the user (pre-defined standard view and depending criteria). • SonoLyst*live* – works similar to SonoLystIR without Scan Assistant and can be enabled in the System Setup. This means SonoLyst*live* performs an assessment with respect to pre-defined standard views. The assessed standard view is displayed for the user in the live and in the frozen image. Additionally an indicator is shown which reflects the quality of the detected view based on detected criteria (see SonoLystX) in the assessed standard view. SonoLyst*live* is enabled when an OB exam is started and available in live mode, freeze and in reload. Voluson Expert 18/20/22 Instructions for Use, Rev 5 (Jan 2025) at 13-45 to 13-47:

13.13 Deep Learning Based Features

Note *Some of these deep learning based features are not available in all countries:*

- SonoLystIR
- SonoLystIR 1st Trimester
- SonoLystX
- SonoLystX 1st Trimester
- SonoLyst*live*
- SonoLyst*live* 1st Trimester
- Sono*Biometry* CRL
- SonoPelvicFloor
- SonoCNS
- Sono*Biometry* Cereb, Vp, CM
- FetalHS
- SonoAVC™*follicle* 2.0
- SonoAVC™*follicle* Auto Caliper
- Fibroid Mapping
- AutoSpine
- SonoPF2D
- AnalSphincter

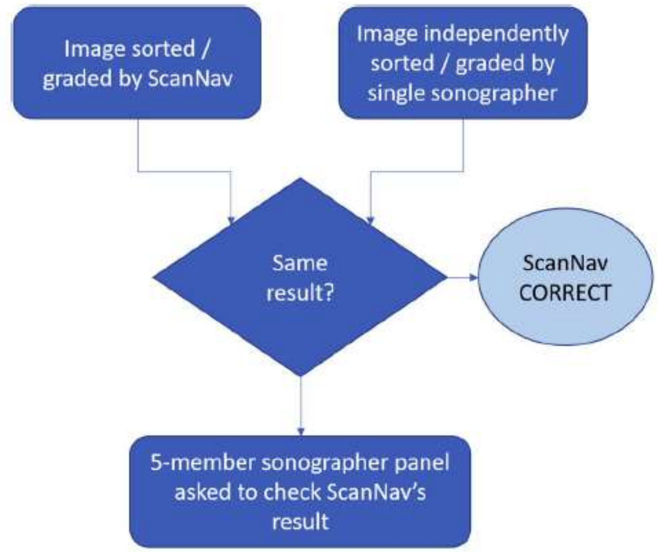
The application of deep learning based features requires caution by the user and an informed decision on the usage of the specific feature. Therefore, all caution information and performance testing for each feature are summarized in this chapter.

E.H. Bradburn et al., *OC10.05 An artificial intelligence system that can correctly identify fetal ultrasound imaging planes throughout gestational age*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28-29.

	Methods: Anonymised fetal ultrasound images, acquired at 15 to 40 weeks of gestation, from a large image database were analysed in this study. This included images of head circumference (HC), abdominal circumference (AC), femur length (FL), amniotic fluid index (AFI) and miscellaneous images. An AI algorithm (ScanNav, trained primarily on routine anatomy scans from 18-24 weeks), was applied to each image and categorised it into one of five categories: HC, AC, FL, AFI and others. A random ten percent per view of all images were manually reviewed by one experienced clinician to determine the accuracy of this classification. The performance of the AI algorithm, according to the gestational age at the time of the scan, was assessed. **Results:** Over 450,000 images were assessed by ScanNav, and a random 10% (45,036 images) underwent clinical review. The accuracy of the AI algorithm in categorising the images into standard biometry planes (HC, AC, FL and AFI) was 99.1%. This was 99.6%, 99.1%, 97.9% and 99.9% for HC, AC, FL and AFI, respectively. Across all categories the algorithm performed best between 20+0 and 35+6 weeks, with an accuracy that remained stable throughout that gestational age range (97%). There was a slight drop in accuracy below 20 weeks and above 36 weeks, to 94% and 96% respectively. **Conclusions:** Although trained primarily on routine anatomy scans from 18-24 weeks, the ScanNav AI algorithm is 99.1% accurate in image categorisation of basic biometry planes. Accuracy was maintained over a very broad range of gestational ages. This may reflect that clinically these standard planes remain consistent in appearance throughout gestation. Improvement at the extremes of GA may be possible by further algorithm training. E.H. Bradburn et al., *OC10.04 Estimating fetal gestational age based on ultrasound image characteristics using artificial intelligence*, Ultrasound in Obstetrics & Gynecology 2020; 56 (Suppl. 1) (16-18 October 2020), at 28.

	Methods: Quality assessed ultrasound images of head circumference (HC) and abdominal circumference (AC) were used from a multicentre study database of women with known GA (CRL performed < 14 weeks) who underwent serial ultrasound examinations from 15 to 40 weeks. We split data randomly into 67.5% training, 7.5% validation and 25% testing sets. We developed and tested an artificial intelligence (AI) algorithm using a regression neural network to estimate the GA, based on image characteristics only without measurement information. Mohammad Yaqub et al., *491 ScanNav® audit: an AI-powered screening assistant for fetal anatomical ultrasound*, American Journal of Obstetrics & Gynecology, Supplement to February 2021, at S312.

		OBJECTIVE: To develop and evaluate a real-time Artificial Intelligence (AI) based system to automatically keep track of acquired images; and check that the images conform to imaging protocol standards, in essence, replacing a human peer reviewer. **STUDY DESIGN:** We developed an AI system (ScanNav) which automatically (1) checks the completeness of the imaging record during fetal anomaly screening, ensuring all 19 required fetal views are recorded; and (2) assesses the quality of these images (in this case according to the guidelines of ISUOG). First, AI algorithms were trained on images manually evaluated by a pool of experienced sonologists and using state-of-the-art deep learning technology. The resulting algorithm was then assessed on a separate testing set; it was deemed correct if 2 or more (from a panel of 5) independent sonologists agreed with its decision. Due to the lack of expert agreement for "marginal" images, it was deemed appropriate to include as agreement such a 2:3 panel split. **RESULTS:** The system was developed on 479,322 anonymised images from 48,161 routine mid-trimester scans. Agreement between ScanNav and the sonologist panel was performed on an independent set of 38,840 images (4,284 scans). For scan completeness the mean (standard deviation) of agreement between ScanNav and the sonologists was 93.5% (±5.6%); for image quality it was 92.2% (±4.7%). The system processes 11 frames per second on a PC with an RTX4000 GPU.



# Sonographers agree with ScanNav	ScanNav
0	INCORRECT
1	INCORRECT
2	CORRECT
3	CORRECT
4	CORRECT
5	CORRECT