# Voluson **Expert 22** Gynecology

You Set the Limits

Symptoms such as pelvic pain, post-menopausal bleeding, genitourinary dysfunction, and infertility can be confusing and concerning for your patients. The Voluson™ Expert 22, with advanced analysis tools and easy 3D technologies, can help you gain greater insights into pelvic anatomy and pathology, thus detecting and diagnosing gynecological conditions sooner. Be confident you have the vital information needed to plan treatment or explore interventional options to help your patients lead a healthier life.
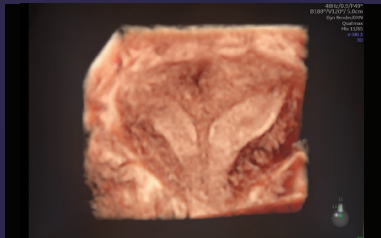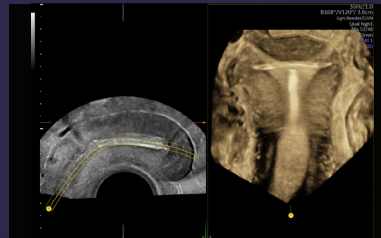
SIMPLIFYING DIAGNOSES TO FIND ANSWERS

Every pelvic exam brings the opportunity to help ensure the future health of your patients.
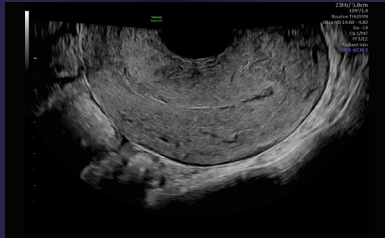
**2D Imaging** enhanced clarity and detail with minimal fine-tuning

3D Imaging provides views not possible with 2D scanning for a more complete evaluation


Advanced VCI with OmniView improves contrast resolution and visualization of anatomy in any image plane, even irregularly shaped structures
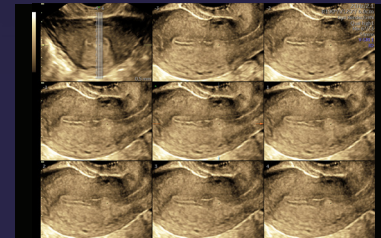

Tomographic Ultrasound Imaging (TUI) helps view gynecology volumes in parallel slices for a comprehensive view through anatomy and/or pathology
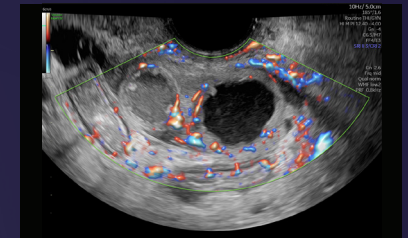
Slow*flow*HD and **Radiant*flow*™** expand the range of visible blood flow with excellent sensitivity
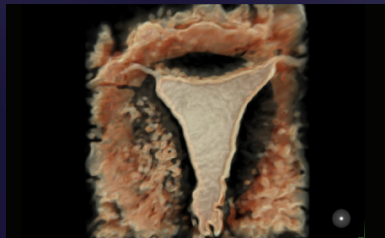
3D Hysterosalpingo-Foam Sonography (HyFoSy) and HyCoSy (Hysterosalpingo Contrast Sonography) – Non-ionizing procedure for tubal patency assessment with 3D display of fallopian tubes*
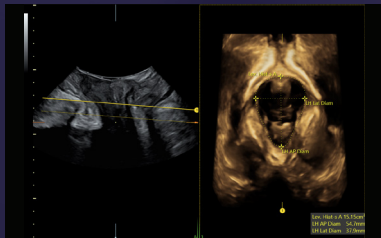
SonoPelvicFloor – an AI-based technology that automates plane alignment, measurements, and offers a guided workflow for pelvic floor assessment thereby eliminating exam uncertainty and improving efficiency**

Uterine Classifications based on ESHRE, ESGE, and ASRM guidelines*** help simplify identification and reporting of uterine malformations

Document ovarian cancer risk estimate based on **IOTA (International Ovarian Tumor Analysis)** Simple Rules, IOTA LR2, and IOTA ADNEX

Evaluate risk and assign classification of the endometrial lining based on **IETA (International Endometrial Tumor Analysis). Utilize the onboard IDEA (International Deep Endometriosis Analysis)** protocol for thorough and comprehensive step by step analysis

*HyCoSy/HyFoSy not approved in all countries.

**Not available in all countries.

***ESHRE – European Society of Human Reproduction and Embryology.
ESGE – European Society of Gastrointestinal Endoscopy
ASRM – American Society of Reproductive Medicine.

Voluson **Expert 22**
Electronic 4D Technology
You Set the Limits

As you guide the way to higher standards, utilize the *e*M6C technology – the world's first commercially available curved matrix electronic 4D probe designed specifically for women's health. This revolutionary probe with the Voluson™ Expert 22 opens new possibilities for exceptional care with ultra-fast volume rates, flexible imaging formats, and excellent resolution in routine women's health exams to complex fetal echocardiography.

The *e*M6C probe partners with the Lyric Architecture to extract the maximum amount of data to achieve high volume rates and exceptionally detailed image quality, helping you achieve more every day while setting new benchmarks in imaging performance to obtain patient answers faster.

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MORE DETAIL, MORE CLARITY IN LESS TIME

The *e*M6C probe offers unique rendering tools to help achieve more clinical information, faster.
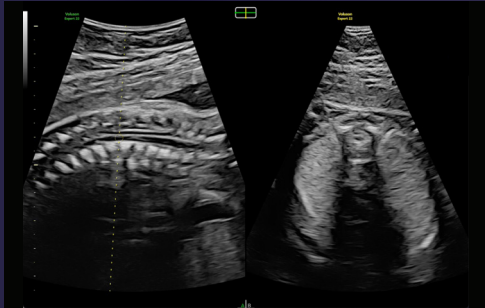

Bi-Plane imaging – Provides simultaneous display of high resolution, high frame rate images in two perpendicular planes. Technology available in 2D and color Doppler modes


Real-Time 4D – Achieve exceptional volume rates in 4D for real-time display of motion

***e*STIC (electronic Spatio-Temporal Image Correlation)** – Enhance fetal cardiac exams with improved resolution and up to 75% reduction in acquisition time over traditional STIC[1]
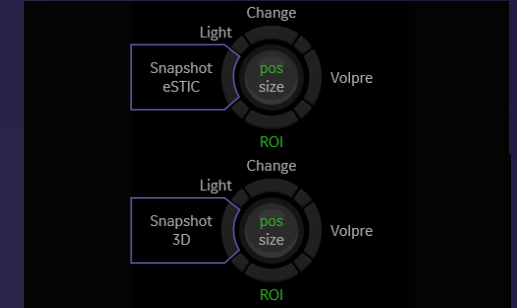
***e*4D SnapShot** – Optimizes exam time with one button access from Real-Time 4D to acquire high resolution 3D volume or *e*STIC data sets
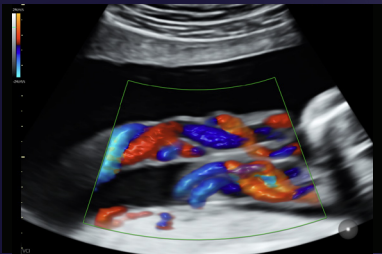
VCI-A (Volume Contrast Imaging) – Delivers excellent contrast resolution through thick slice volume imaging of grey scale and color Doppler images
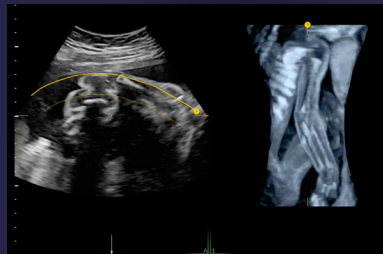
Exceptional visualization of long bones of the arm at 24 weeks with Advanced VCI with OmniView
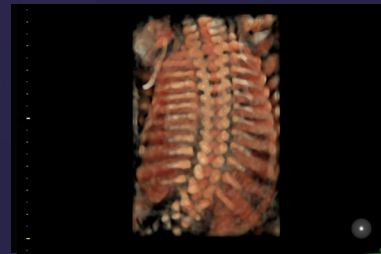
23-week fetal spine with HD*live*™ Studio+

Aortic Arch with 4D VCI-A mode and HD-Flow™

Stunning *e*STIC with HD*live* Studio+

1. As compared to volume rates on e4D vs mechanical probes (RAB6) on Voluson E10 BT20

Voluson **Expert 22** Fetal Heart

You Set the Limits

Congenital heart defects are one of the most common and most difficult fetal anomalies to detect. Identifying fetal cardiac abnormalities earlier means you can intervene sooner, plan for delivery and potentially improve outcomes. The Voluson™ Expert 22 provides a comprehensive solution of imaging and evaluation tools to help distinguish the tiniest structures with stunning clarity and to help simplify assessment and monitoring of the fetal heart – allowing you to focus on early identification rather than late diagnosis.

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DETECTION

Assess the fetal heart from the earliest development stages with high detail, high resolution 2D, 3D, and 4D imaging. Utilize easy automation to help obtain and visualize the recommended fetal heart for a complete exam.

fetalHS helps determine if a fetal heart is normal by guiding you through a step-by-step instruction to identify Fetal Situs, 4-Chamber, 3-Vessels and Trachea View, and Cardiac Axis

Radiant offers clear border definition to aid in detail visibility. Change the levels of elevation for a greater 3D-like appearance of your 2D image
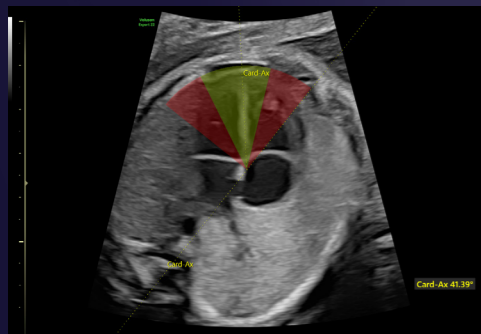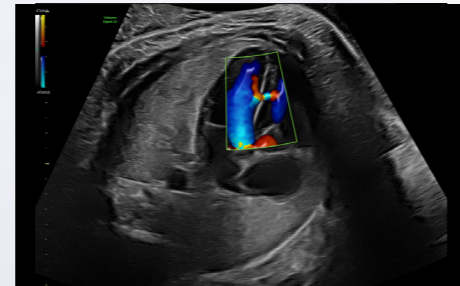

Cardiac Axis is an automated measurement to help quickly identify the potential for a congenital heart defect


RIC6-12 high resolution endovaginal probe helps detect fetal abnormalities earlier in the first trimester

DIAGNOSIS

Find answers to your challenging exams with cutting edge tools that help provide more clarity, more speed, and more flexibility.

Radiant*flow*™ delivers easy, fast visualization of blood flow using the amplitude of the Color Doppler signal to enhance the robustness and create a 3D-like appearance
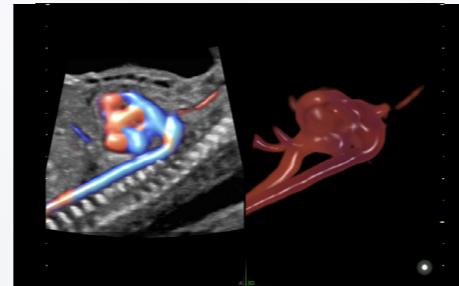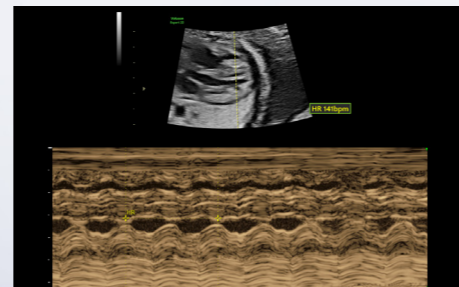

HD*live*™ Flow – Clearly display vascular structures and orientation with greater dimension and illumination

HD*live* Flow Silhouette – Visualize blood vessels and fetal heart flow to provide greater insight transparently through vascular anatomy

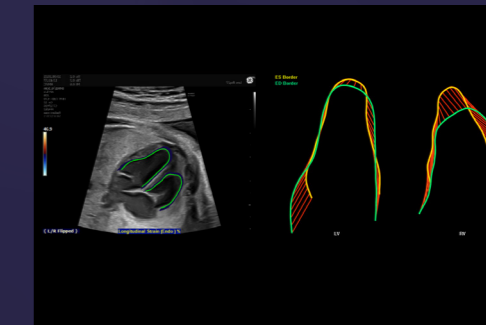**Slow*flow*HD** expands the range of visible blood flow to include low velocities vessels

SonoFHR places calipers on the M-mode or PW trace to automate Fetal Heart Rate calculation

Ensure complete fetal heart assessment through the help of **Scan Assistant** – a flexible, and customizable exam protocol tool that helps increase exam consistency and productivity while documenting for quality assurance purposes

SonoLyst – Automatically identifying fetal anatomy seen on standard views to select all applicable annotations to enhance efficiency – compare acquired image/view to standard criteria for quality assurance ensuring image quality and consistency

Faster volume rates, flexible imaging formats, and brilliant resolution provided by the latest electronic 4D probe technology, **eM6C**. Probe technology offers unique tools to help with comprehensive fetal echo exams[*]

eSTIC (electronic Spatio-Temporal Image Correlation) – Enhances fetal cardiac exams with up to 75% reduction in acquisition time over traditional STIC and delivers improved resolution in the B and C planes[**]
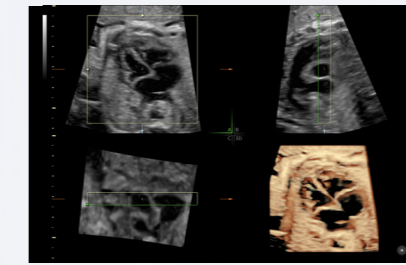
Bi-Plane Imaging – Provides simultaneous display of high resolution, high frame rate images in two perpendicular planes. Technology may be used in 2D and color Doppler modes

e4D SnapShot – Optimizes exam time with one button access from real-time 4D to acquire an eSTIC data set
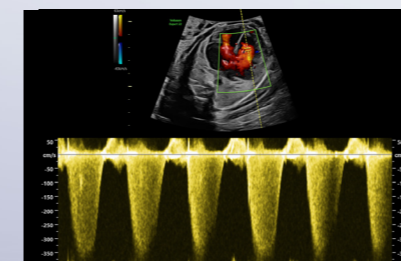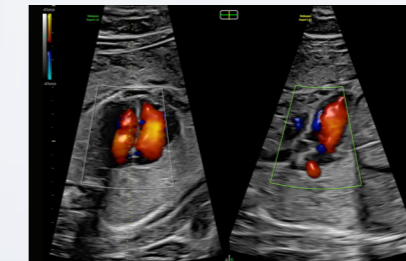
Pulsed Wave Doppler assessment offers unprecedented sensitivity and clarity
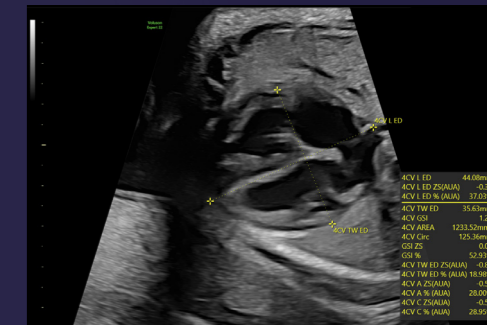
MONITORING

Not only anomalies can impact fetal heart. Monitoring the Size, Shape and Contractility of the fetal heart can provide additional data to help you make more informed decisions about maternal/fetal well-being and delivery planning.

fetalHQ – Conduct an easy and comprehensive evaluation of the size, shape and contractility of the fetal heart from the 4-chamber view using measurements based on 2D imaging and speckle tracking. fetalHQ contains an in-depth report including Z-scores and percentiles for each of the cardiac measurements. AutoFlip and Quiver features help simplify the fetal heart orientation, border identification and endocardial border
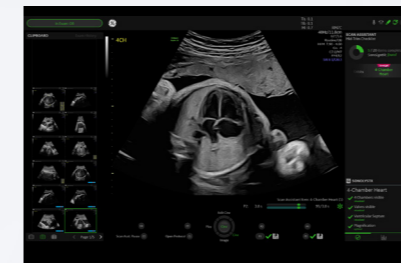

Fetal heart contractility outlined in an in-depth report

Global Sphericity Index (GSI) helps assess size and shape of fetal heart

Integrated **TAPSE/MAPSE** and other published measurement data allow for expanded reporting and diagnostic support

Explore **3D Printing** for rapid clinical prototyping and research with full mesh exports directly from the Voluson ultrasound system – export files can be generated from color, inversion, and glass body data sets

*As compared to volume rates on e4D vs mechanical probes (RAB6) on BT20

**Compared to conventional mechanical probe technology with STIC.

Voluson™ **Expert 22**
Sono-Automation
You Set the Limits

Patient demands and time pressures are high. To succeed, your practice requires exceptional and efficient imaging – helping you to provide answers for your patients while managing your busy practice. With easy-to-use automation tools, you can streamline your workflow and decrease exam complexity while increasing consistency. Voluson's Sono-Automation technologies help improve reproducibility of obstetric and gynecologic exams while documenting for quality assurance purposes, helping you accomplish more each day while empowering you to deliver the best care to your patients.

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ACHIEVE THE UNACHIEVABLE

Easy-to-use tools to help reduce keystrokes and enhance patient care.
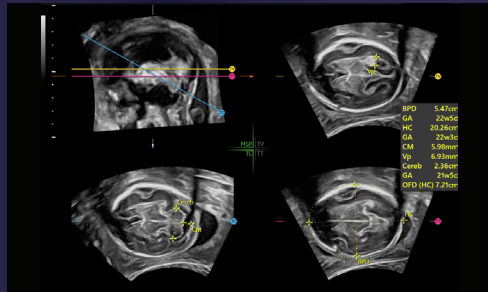
SonoCNS – Artificial Intelligence tool that supports consistent measurements and helps drive workflow efficiency by helping align and display recommended views and measurements of the fetal brain from a 3D volume
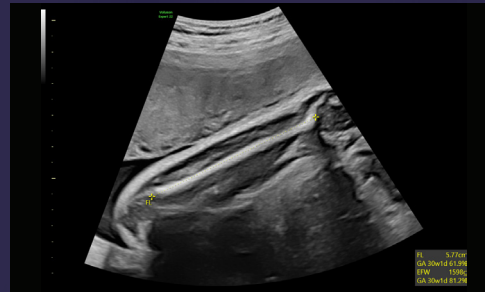
SonoBiometry – Helps reduce keystrokes and improves exam time with automatic caliper placement and fetal measurements of bi-parietal diameter (BPD), cisterna magna (CM), lateral ventricle (Vp), cerebellum, head circumference (HC), abdominal circumference (AC), femur length (FL), and humerus length (HL)
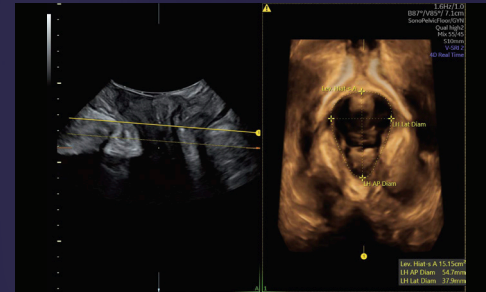
Analysis of the pelvic floor anatomy can be complicated. Through AI, **SonoPelvicFloor** simplifies the exam process by automating plane alignment, measurements, and workflow guidance to eliminate uncertainty while improving efficiency
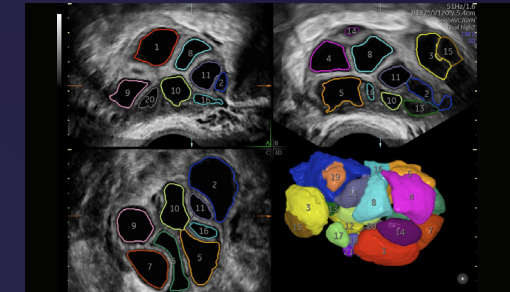
SonoAVC™ *follicle* – (Sonography-based Automated Volume Count follicle) – Automatically calculates the number, dimensions, and volume of hypoechoic structures in a volume sweep to help monitor patient follicles faster

SonoNT™/SonoIT – (Sonography-based Nuchal /Intracranial Translucency) – semi-automatic, standardized measurements of nuchal and intracranial translucencies
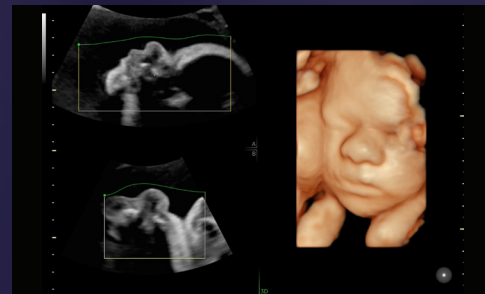
SonoRender*live* – Simplifies volume rendering by automating render-line placement in 3D and 4D imaging
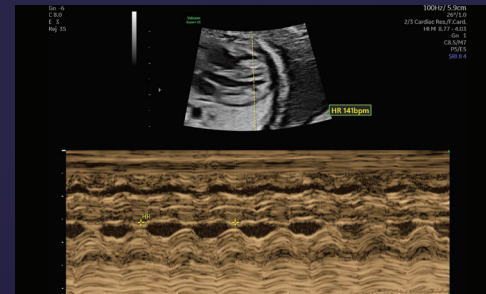
SonoFHR – Automation tool that automatically places calipers in M-Mode or pulsed wave Doppler to quickly obtain the fetal heart rate

*fetal*HS – An AI-based guided workflow with step-by-step instructions to help identify normal anatomy with a focus on fetal situs, 4-chamber heart, 3-vessels and trachea view, and cardiac axis

Voluson™ **Expert 22**

*fetal*HQ

You Set the Limits

Maternal Fetal Medicine specialists face complicated pregnancies every day. Detecting and diagnosing fetal heart anomalies is one of the most difficult evaluations. However, foreseeing outcomes for compromised fetuses may prove more challenging. Congenital heart defects, Intrauterine Growth Restriction (IUGR), and Twin to Twin Transfusion Syndrome (TTTS) are just a few things that can impact the function of the fetal heart. How do you stay ahead of potential changes?

GE Healthcare's dedication, coupled with collaboration with fetal echocardiography experts, has led to the development of *fetal*HQ. By monitoring the size, shape, and contractility of the fetal heart, you have access to additional data to make more informed decisions about maternal/fetal well-being and delivery planning.

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SIGNIFICANCE OF SIZE AND SHAPE

Changes in size and shape of the fetal heart can be an early warning to cardiac dysfunction. Besides anomalies, common conditions including fetal anemia, IUGR, TTTS, and maternal diabetes can cause alterations to the fetal heart.

- Size: compensates by growing in size and/or becoming hypertrophic
- Shape: becomes more rounded/'globular' in shape as it compensates for lack of oxygen
- Contractility: can pump harder distributing more oxygen to the body, or conversely, can pump less due to fluid overload, causing contractility changes

With the Voluson Expert 22 and *fetal*HQ, we aim to help you improve patient care through innovative technologies to allow you to focus on early detection rather than late diagnosis.

Measuring the Global Sphericity Index (GSI) can help identify changes in the heart shape over time. Measured in end diastole, the GSI is calculated using the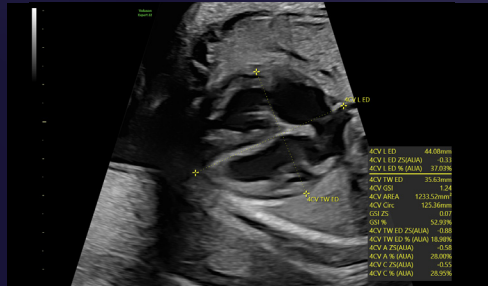 Basal-Apical Length and the Transverse Width. With 2 easy measurements, you can gather vital information on the size and shape of the fetal heart.

Normal GSI
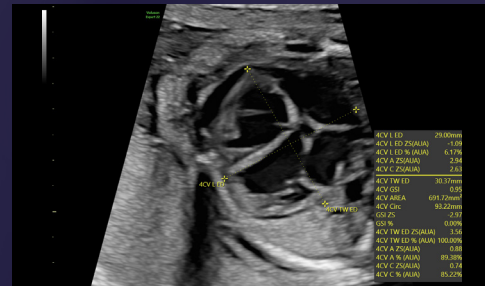
Abnormal GSI – Aortic Stenosis

Comparative nomograms and Z-scores are available onboard the Voluson for convenient analysis.

EFFORTLESS VENTRICULAR SHAPE AND CONTRACTILITY

Evaluation of cardiac function is a crucial component to fetal echocardiography. The ventricles may need to remodel their shape or pump harder to compensate for various conditions. Identifying signs of possible fetal distress earlier can help plan for early delivery, change in delivery location, and in extreme cases, prompt surgical intervention. With *fetal*HQ, you can easily determine the ventricular shape and contractility to make better decisions faster.

The *fetal*HQ contractility assessment is based on endocardial speckle tracking since the endocardium is more sensitive to hypoxic changes than the myocardium in the fetus. Simply indicate the apex and septal and lateral wall insertions of the valve, and the tool will automatically trace the endocardium. Aiding in the placement of the trace line, Quiver introduces fine movements of the ventricles for improved visualization of the endocardium versus a still image. Additionally, Auto Flip will automatically orient the fetal heart for consistent display. By tracing the endocardium in End Systole and End Diastole, *fetal*HQ tracks the speckle movement (deformation) for calculation and assessment of the shape and contractility of the ventricles.
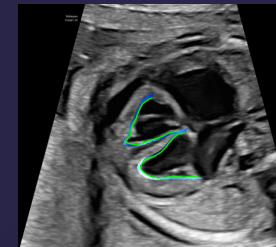
These calculations will result in multiple measurements based on published data which are integrated on the Voluson.

The *fetal*HQ report includes Z-scores and percentiles for each of the cardiac measurements along with nomograms embedded directly on the Voluson Expert 22. Whether you want a qualitative or quantitative view of the data, you can customize the information included in a report. You can use this information for delivery planning and collaboration with other fetal/pediatric cardiologist colleagues.

Voluson **Expert 22**
First Trimester

You Set the Limits

Patients' expectations on early diagnosis continues to grow. Through advances in imaging technology, the first trimester assessment presents the opportunity to identify potential complications earlier than ever before. Identifying small anatomy and exposing anomalies requires clear, high-resolution imaging. The unparalleled image quality of the Voluson™ Expert 22, with the high frequency RIC6-12 probe and unique assessment tools, grants you the opportunity to uncover critical answers in the first trimester for better decision making.

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SMALL ANATOMY, FINE DETAILS, TIMELY DIAGNOSIS

The unique capabilities of the Lyric Architecture allow you to observe greater details earlier in pregnancy than ever before. More uniformity throughout the image with increased spatial and contrast resolution showcases anatomical development more clearly and more completely. Having detailed visualization provides insights into fetal development and the ability to detect and diagnose earlier.
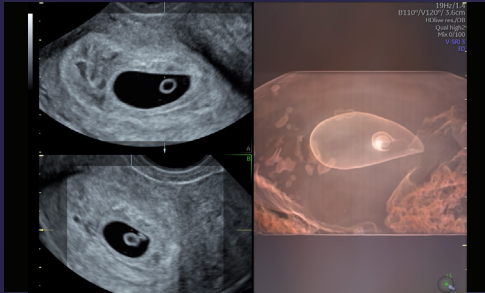
Confidently explore fetal images in the earliest stages with the **RIC6-12** high frequency probe

Increased axial and lateral resolution with **UltraHD** reveals highly detailed anatomy for increased visualization

Utilize **Radiant** for greater border visibility and sharpness. Change the levels to enhance the 3D like elevation
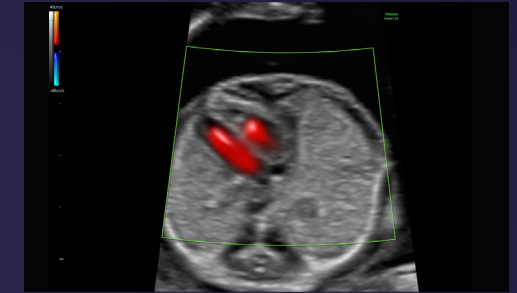
Achieve effortless and robust blood flow imaging with **Radiant*flow*™** – demonstrating a 3D-like appearance to color Doppler
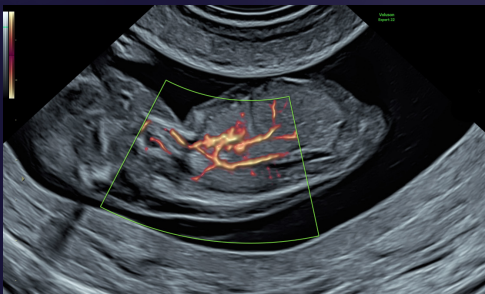
Extend your color capabilities by assessing blood perfusion, even in low velocity vessels, with **Slow*flow*HD** and **Slow*flow*3D**
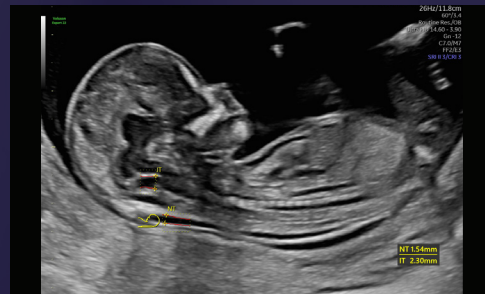
Measure nuchal and intracranial translucencies with the automation tool **SonoNT™/SonoIT** – (Sonography-based Nuchal/Intracranial Translucency)

Easily obtain volume images with unprecedented depth and clarity using **HD*live*™ Studio+** – an essential problem solving technology for a deeper understanding of relational anatomy and developing structures

Explore **3D Printing** for rapid clinical prototyping, research, and parent bonding. Export files directly from the Voluson ultrasound system to instantly 3D print projected and full mesh data sets

Voluson **Expert 22** Security & Privacy

You Set the Limits

With the advancement of digital capabilities including wireless technology and software in healthcare, the possibility that a practice will face cyber threats and/or data breaches is imminent. Being a computer-based system, ultrasound devices can be vulnerable to security threats which could impact safety, effectiveness, and data security of the device.

At GE Healthcare, your safety and the data privacy of your patients are a top priority. We work diligently to ensure Voluson™ ultrasound systems rely on the latest and most advanced security policies and technologies with the flexibility needed to efficiently manage your practice.

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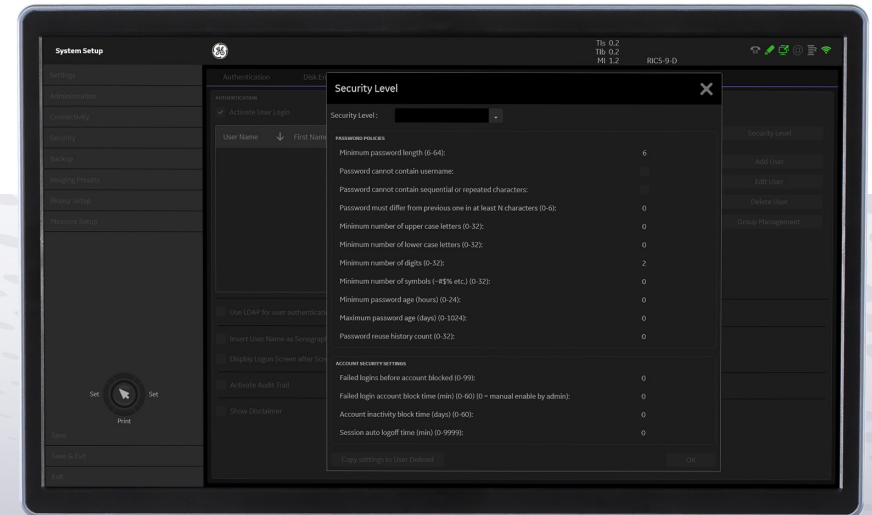
CYBERSECURITY IS MORE THAN ANTI-VIRUS PROTECTION

Designing the Most Secure Ultrasound

GE Healthcare has created a strategic framework called Design Engineering for Privacy and Security (DEPS) which is utilized in our product development. It begins by assessing the privacy and security risk and providing guidance to the ultrasound system design team. The Voluson ultrasound systems contain the following design elements to protect you out of the box.

- Windows® 10 IoT Enterprise operating system and ability to update with the latest security patches when Microsoft® makes them available. This update can happen after engineering evaluation and testing for system compatibility
- The main software components of Voluson ultrasound systems, including Microsoft's Windows 10 IoT Enterprise operating system, are configured using guidance from standards including Defense Information Systems Agenda (DISA), Standard Technical Implementation Guides (STIGs), National Institute of Standards and Technology (NIST) Cybersecurity Framework, and Center for Internet Security (CIS) best practices
- Software services embedded in the operating system which are not required to run on an ultrasound system are removed or disabled
- Network ports not required for data communication are disabled to minimize the risk of threat invasion
- Protection against USB-borne attacks by disabling any auto-run functionality and by scanning the USB stick for security threats immediately when connected
- Prevent import/export of data on ultrasound system by deactivating storage devices on USB ports
- For means of anti-virus protection, we apply whitelisting – limiting software programs that can run on a system to those identified and approved in advance. Unknown, potentially malicious software will not be executed to protect the ultrasound system
- An advantage of a big company like GE is that it has a strong central security team that constantly monitors for new security threats and communicates with Voluson engineers to design and implement additional security updates as needed

Maintaining patient privacy and security

Protecting the systems against malware or other cyber attacks is one aspect of system security, but it is also important to protect locally stored information against theft or corruption. This is where data protection measures come into play.

Secure sharing

- Locally stored patient information can be protected with Hard Drive (HD) encryption – AES Encryption with 256-bit key
- Voluson ultrasound systems use encrypted DICOM® Communication Capability (TLS) – TLS is a cryptographic protocol which provides communication security. It ensures that data being passed across your networks cannot be intercepted, read, and modified during transmission to ViewPoint,™ PACS, HIS, etc.*
- Now users can securely share and retrieve ultrasound information via the cloud with Tricefy™**

User management

- Easily manage ultrasound system access for multiple users with individual log on credentials – define adjustable access levels to system functionality based on user need
- User access credentials can be managed remotely by means of a Lightweight Directory Access Protocol (LDAP) interface, particularly targeted towards the use in larger institutions
- Voluson can monitor and record any security-related activities including user management actions, system inactivity and logins/logouts events, and data handling and configuration changes, generating an audit trail and usage log
- Instead of passwords, already existing clinical RFID badges can be integrated for user logon for unified access.

* Check PACS and HIS system for TLS encryption availability.

** Not available in all countries.

SonoDefense:

ADVANCED CYBERSECURITY AND DATA PRIVACY PROTECTION

Healthcare institutions are under the growing threat of cyber attack – and the impact is staggering. In 2021, an average of 59 data breaches were reported each month and a total of 712 healthcare data breaches were reported between January 1 and December 31, 2021. That sets a new record for healthcare data breaches, exceeding last year's total by 70 – a 10.9% increase from 2020.[1]

Protecting against these threats and safeguarding your patients and your institution requires more than anti-virus protection. SonoDefense is GE Healthcare's multi-layer strategic approach to cybersecurity and patient data privacy for ultrasound.

SonoDefense is designed to:

- Keep the ultrasound machine safe and functional in the face of cyberthreats
- Protect patient data on the machine from unauthorized access
- Enable you to successfully implement HIPAA and security policies, while still managing productive daily workflows

Defense-in-Depth Strategy

SonoDefense is designed for maximum security protection with multiple layers of security to protect our systems from attack.

Blocks unused communication channels

Disables unneeded services in the Windows® 10 operating system

} Reduces potential points of attack

Seamlessly integrates into your facility's security ecosystem

Facility Ecosystem
Network Firewall
Windows® 10 Hardening
Malware Threat Protection
Local/Remote Access Management
PHI Encryption

Limits applications that can be run on the ultrasound system

- Customizable, role-based access
- Federated identity management
- Session management
- Auditing
- Secure remote access

Customizable patient data encryption at rest and in transit

The SonoDefense defense-in-depth strategy consists of six layers, with each layer enhancing the overall security of the system and helping to protect patient data.

LAYER 1
Facility Ecosystem

SonoDefense is designed to fit seamlessly into your facility's existing security ecosystem.

LAYER 2
Network Firewall

A malicious cyber attack requires a point of entry. The strict firewall layer reduces the potential points of attack by disabling all unused ports and the DICOM® firewall limits DICOM connections to defined devices.

LAYER 3
Windows 10 Hardening

Windows 10 IoT is a version of Windows 10 specifically made for embedded systems with an extended support model. Its applications are vast compared to the needs of the SonoDefense-enabled scanner. Accordingly, we have configured the system so that all software services embedded in the operating system that are not explicitly needed to run the medical applications are removed or disabled. This "hardening" minimizes the parts of the system that are exposed to threats, helping to reduce the potential for attack. The Windows 10 IoT configuration, including security profiles, is set using guidance from standards including Defense Information Systems Agenda (DISA) Standard Technical Implementation Guides (STIGs), National Institute of Standards and Technology (NIST) Cybersecurity Framework, and Center for Internet Security (CIS) best practices.

LAYER 4
Malware Threat Protection

The Windows 10 security features provide the foundation for SonoDefense's malware protection, enforcing restrictions on applications that can be run on the ultrasound scanner.

- Whitelisting only permits trusted applications that meet secure implementation guidelines to run on the ultrasound system
- Kiosk mode disables the user's access to the internet and the Windows desktop, which are common malware vectors for spreading viruses through email services, web browsers, and other applications
- Media auto-run is disabled and BIOS access is password protected
- Security tools actively monitor for malware behavior

LAYER 5
Local/Remote Access Management

SonoDefense provides cyberdefense for the real world of patient care. Its extensive, customizable, role-based user access enables users to successfully implement HIPAA and security policies, while still ensuring efficient and productive daily workflows.

- *User roles* – Custom creation of user roles and assignment rights for roles puts the institution in control
- *User management* – Individual users are created and assigned customizable roles, dictating their allowable access to and manipulation of patient data and system configuration
- *Password policies* – Configurable across all attributes including length, content, reuse, and expiration for local and remote users
- *Federated identity management* – Lightweight Directory Access Protocol (LDAP), or single sign-on, can be used to manage users consistently across your enterprise
- *Session management* – System access can be restricted after a configurable period of inactivity
- *Audit report* – An extensive list of events, including patient data and system access, are recorded in an audit log to facilitate an incident investigation
- *Remote service access* – Remote service is only allowed if authorized by local user on device
- *Local service access* – Protected by a two-factor authentication scheme

LAYER 6
PHI Encryption

The encryption layer of SonoDefense security software is designed to protect data privacy and assist your organization in complying with HIPAA/HITECH regulations. Safeguards include:

- Data on the system's customer data volumes can be encrypted to provide protection in the event of a stolen device or hard drive[3]
- Patient data can be deleted from the hard drive in a way that is cryptographically unreadable and unrecoverable
- DICOM Transport Layer Security (TLS) encrypts both wired and wireless DICOM communications[4]
- Wireless network communication can be encrypted including enterprise level protocols[4]
- All remote service sessions are encrypted by default using the TLS cryptographic protocol

Security-related features for Voluson™ ultrasound scanners[2]

All features are standard unless otherwise noted

Firewall policy blocks all unnecessary ports and limits DICOM communications to only defined devices

OS – Windows 10 IoT	
OS hardening	• Configuration settings use guidance from DISA STIGs, NIST Cybersecurity Framework, and CIS best practices • Disables unnecessary services and protocols
Media export security	• Provides the ability to disable export of patient data to removable media. Configurable at individual user level
Malware protection	• Whitelisting* • Disables auto-run for removable media • Kiosk mode • Provides the ability to de-activate storage devices on USB ports * *Whitelisting is an optional feature in Voluson products*

Access and access level
(Requires administrator rights)

Ability to create user groups

Ability to assign patient data access rights to each group	• Archive • Export • Email • Delete • Edit Settings
Ability to assign access rights to system setup settings	• Settings • Administration • Connectivity • Backup • Imaging Presets • Measure Setup • Security

Create users and assign to groups

Emergency mode with only minimal operational functions needed for scanning is enabled

Passwords	• Password Policies – Pre-configured templates for different security levels – User-configurable for individual requirements • Password length and reuse – Minimum password length (6-64 characters) – Password cannot contain user name (on/off) sequences or repeated characters (on/off) – Password must differ from previous ones in at least N characters (0-18)

Access and access level *continued*
(Requires administrator rights)

Passwords	• Password complexity – Minimum number of upper case characters (0-32) – Minimum number of lowercase characters (0-32) – Minimum number of digits (0-32) – Minimum number of symbols (0-32) • Password lifespan – Minimum password age (0-24 hours) – Maximum password age (0-1024 days) – Password reuse history (0-32)
RFID*	• Existing clinical RFID badges can be used as alternative logon method • Automatic RFID Tag Type Recognition * *RFID connectivity is an optional system feature*
Session management	• Account lockout policies – Failed logins before account blocked (off, 0-99) – Failed login account block time (0-60 minutes) – Account inactivity block time (0-60 minutes) • Auto logoff timeout – automatically logs off a user after the specified period of inactivity (disabled, 1-60 minutes)

Local user management policy
(Requires administrator rights to configure)

User management restricted to administrator rights

Local user management

User display ID can be unique from login ID

Ability to force a password reset

Support for multiple unique user accounts

Ability to temporarily disable a user

Support for multiple unique administrator accounts

Can be used in parallel to remote user management

Security-related features, *continued*
All features are standard

Remote user management policy
(Requires administrator rights to configure)

Supports active directory authentication utilizing LDAP

Support for individual accounts and AD groups for users and administrators

May utilize LDAP or secure LDAP

Customer may configure the system to perform authenticated binding

Can be used in parallel to local user management

Customizable mapping to local groups for rights management

Remote service access

TLS protocol enabled by default

Remote control is only allowed if authorized by local user on device

No open ports required

Additional features

Local service access	• Secure Service Access (SSA) or 2F authentication (HW dongle and rotating password)* * *Beginning with EC400, only SSA dongle is supported*
Hard drive encryption[3]	• AES-256 • Automatic unlock tied to USB key or manual pre boot password entry

Auditing	• Audit log creation including the following type of events:
	  – System startup and shutdown
	  – User login and logout from the system
	  – Transfer of DICOM instances
	  – Data Import/Export
	  – Display, modification, and deletion of images and patient information
	  – User management events*
	  – Network, security, and system configuration changes*
	
	  * *User management and configuration changes events are audited only on Voluson products from EC350 software version*

Additional features *continued*

Wireless security protocols[4]	• WPA2-Personal • WPA2-Enterprise • 802.1x
Internet protocol address standard	• IPv4
Secure delete to render deleted patient data unreadable and unrecoverable	
DICOM TLS	
Software security updates	• Customer can download and install digitally signed software security updates on the system* * *This feature is only available on Voluson products from EC350 software version*

References:

1. https://www.hipaajournal.com/december-2021-healthcare-data-breach-report/ HIPAA Journal, Dec 2021.

2. Unless otherwise noted, the SonoDefense feature set described in this document applies to Voluson products from EC330 and SPC330 software versions.

3. Disk encryption is an optional feature in Voluson products. Only available on the patient data drive.

4. Wireless connectivity is an optional system feature.

Voluson Expert 22

PROBE GUIDE

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	Description	Applications	FOV	Bandwidth
ABDOMINAL – 2D				
C1-6-D H40472LT	XDclear™ Wide Band Convex Probe	Abdomen, Obstetrics, Gynecology, Fetal Echo	113°	2 – 5 MHz
C2-9-D H40462LN	XDclear Wide Band Convex Probe	Abdomen, Obstetrics, Gynecology, Pediatrics, Fetal Echo	100°	3 – 9 MHz
ABDOMINAL – REAL-TIME 4D				
eM6C G3 H48711KW	Wide Band Convex Volume Probe with Active Full Electronic Matrix Array Technology	Abdomen, Obstetrics, Gynecology, Fetal Echo	85°, V 85° x 90°	2 – 7 MHz
RM7C H44901AR	XDclear Wide Band Convex Volume Probe with Active Matrix Array Technology	Abdomen, Obstetrics, Gynecology, Pediatrics, Fetal Echo	90°, V 90° x 85°	2 – 8 MHz
RAB6-D H48681MG	Wide Band Convex Ultra-light Volume Probe	Abdomen, Obstetrics, Gynecology, Pediatrics	90°, V 90° x 85°	2 – 8 MHz
ENDOCAVITY – 2D				
IC 5-9-D H40442LK	Wide Band Micro Convex Endocavitary Probe	Obstetrics, Gynecology, Transrectal	189°	4 – 9 MHz
ENDOCAVITY – REAL-TIME 4D				
RIC5-9-D H48651MS	Wide Band Micro Convex Endocavitary Volume Probe	Obstetrics, Gynecology, Transrectal	189°, V 189° x 120°	4 – 9 MHz
RIC6-12-D H48651NA	Wide Band Micro Convex Endocavitary Volume Probe	Obstetrics, Gynecology, Transrectal	190°, V 190° x 120°	5 – 13 MHz

Description	Applications	FOV	Bandwidth
LINEAR – 2D			
Wide Band Linear Probe 9L-D H40442LM	Small Parts, Peripheral Vascular, Pediatrics, Obstetrics, Musculoskeletal	44 mm	3 – 8 MHz
Wide Band Linear Probe 11L-D H40432LN	Small Parts, Breast Peripheral Vascular, Pediatrics, Musculoskeletal	38 mm	4 – 10 MHz
Wide Band Linear Probe with Active Matrix Array Technology ML6-15-D H40452LG	Small Parts, Breast Peripheral Vascular, Pediatrics, Musculoskeletal	50 mm	4 – 13 MHz
Wide Band Linear Probe L8-18I-D H40452LL	Small Parts, Musculoskeletal, Pediatrics	25 mm	5 – 14 MHz
LINEAR – REAL-TIME 4D			
Wide Band Linear Volume Probe RSP6-16-D H48651MR*	Small Parts, Breast, Peripheral Vascular, Pediatrics, Musculoskeletal	38 mm V 38 mm x 29°	6 – 18 MHz
PHASED ARRAY – 2D			
Wide Band Phased Array Probe 6S-D H45021RR	Small Parts, Cardiology, Pediatrics	90°	2 – 7 MHz
XDclear Wide Band Phased Array Probe M5Sc-D H44901AE	Abdominal, Cardiology, Obstetrics, Fetal Echo, Pediatrics, Cephalic	90°	1.5 – 4.5 MHz

*Not available in all countries.

Voluson **Expert 22**
Probe Check FAQ

1. What is Probe Check?

Probe Check on the Voluson™ Expert 22 allows any user to quickly assess the probe health of any probe on your system. This simple test measures the signal strength of each probe element and provides a Pass or Fail result for the selected probe. Further information can be found in the Instructions for Use (see "Probe Check").

2. How do I perform the Probe Check test?

Before beginning, inspect the probe for gel or debris. If there is nothing visible, clean the probe surface with a wet cloth. Ensure the probe is dry before starting the test. Place the probe on a stable surface, such as the probe holder, and ensure the probe is not in contact with other objects. Activate the probe, select Probe Check from the probe menu, then select "Start Probe Test." Do not touch the probe surface during the test. After the test is completed, disinfect the probe before patient use as per your site's approved procedures.

*Note: If there is significant build-up of gel or debris on the probe, soak the probe in water to the allowable immersion level. Use a soft cloth to remove water and debris.

3. What do the results of the Probe Check mean?

Probe Check can detect many probe defects, but not all possible defects. A passed result shows that relevant parameters are working within probe dependent acceptance levels. If artifacts are visible in the image or a visible defect is detected on the probe, the probe should not be used for scanning even if the test is passed. If Probe Check results in a failure, ensure the probe is clean and repeat the test. Please contact your Service representative in case of visible defects, a failed Probe Check report, or image artifacts. Contact your Clinical Applications Specialist regarding any image quality issues or concerns. If the failure persists, please contact your Service representative.

4. How long does Probe Check take?

The test takes 30 to 120 seconds.

5. How often should I perform a Probe Check?

It is recommended that Probe Check be done on a regular basis or as specified by your site's quality assurance program. You should also perform the test after specific events which might have damaged the probe (e.g. probe drop).

6. Am I required to record or report the results from Probe Check?

Please follow your local quality assurance procedures for reporting of the test results. Contact your Service representative if you have any questions.

7. Does Probe Check contain any user or patient information?

No. The test does not use or store any patient specific data nor information about the user.

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Voluson™ **Expert 22**
SW Update FAQ

1. Why do I need automatic software updates for my Voluson system?

Automatic SW updates allow us to ensure each Voluson Expert 22 system has the latest security updates and clinical performance enhancements, letting you spend more time on your patients and business, and less time worrying about your equipment.

2. What do I need to do to activate automatic Software Updates on my Voluson system?

Your system comes ready for this functionality and just needs to be connected to the GE InSite™ network. Just ask the GE personnel installing your system to activate InSite and SW Updates using eDelivery during warranty. Please note that site-specific network details will be needed from the IT or network administration teams.

3. Will my Voluson Expert 22 system be secure when it is connected to the GE network?

Yes, the GE InSite connectivity used across our equipment portfolio is designed with security in mind. The GE InSite connectivity uses Transport Layer Outbound TLS/HTTPS connections with TLS version 1.2 and AES 256 bit. Additionally, we enforce a 2048 bit RSA Certificate Key, have a SHA256 Signature Algorithm with RSA, and ensure encryption in transit and encryption at rest.

4. Is my patient data and machine data secure?

Yes. Only the minimum necessary data is sent to the GE network to monitor the system performance in compliance with HIPAA, GDPR and internal GE standards. Patient identifiable data is not used or transferred when InSite and automatic SW Updates are used. Additionally, customers can secure data using our SonoDefense suite of offerings which includes hard disk encryption, network port blocking and whitelisting.

5. I would like to connect my Voluson Expert 22 for direct to device SW Updates and InSite connectivity. What technical information do I need from the IT or network administration team to activate these capabilities?

The GE Healthcare serviced medical device must reach the GE Healthcare servers using the internet. Your site team will need to share details required to add devices to your network depending on your site security and firewall configuration. Your security network environment (e.g. firewall) configuration will need to whitelist our GE Healthcare Server URLs.

6. Can I use wired and wireless networks for automatic SW Updates and InSite on my Voluson Expert 22?

While your Voluson system supports wired and wireless networks, a wired network is recommended during the SW Update download and installation. Please note that WPA Enterprise and WPA2 Enterprise security protocols used for wireless networks are not compatible with the SW Update feature on Voluson Expert systems.

7. Can I manually download and install the SW updates myself on my Voluson Expert 22?

Customers do not have the ability to manually download from a Portal and install the SW updates themselves on the Voluson Expert 22 products. This functionality may be available on other GE Ultrasound systems.

8. Will SW updates for my ultrasound be available during warranty? Will I be able to get SW Updates after my system warranty ends?

Voluson Expert 22 customers will receive SW Updates during the warranty period (which is typically 1 year). After the warranty period lapses, the SW Update functionality is available as part of a service contract.

9. How long will the SW Update take?

The complete SW Update process including the software download and installation of the new software will take approximately 45 to 60 minutes to complete when using a network speed of 10 MBs.

10. Can I continue scanning during the SW Update?

The download can be paused to allow scanning and other functions and resumed when scanning is completed. The installation cannot be paused, so it is recommended to perform the download and installation at the end of the work day.

11. Why do SW Updates need an eDelivery contact name and email address during the order process?

We need an eDelivery contact name and e-mail address to set up your customer account and keep you informed of SW releases in the future. The contact name and email address can be changed as needed.

12. Which users are allowed to initiate the SW download and installation?

All Voluson user profiles can initiate the SW download and installation.

13. Can I indefinitely postpone or ignore the procedure?

The on-screen SW Update icons will appear when a SW update is available. If a SW Update is declined the procedures can be restored from the Service Desktop.

14. Will a physical form of digital media still be available?

Yes, a physical form of digital media will be shipped with each system. The latest version can still be ordered for installation by authorized personnel.

Voluson™ Expert 22
QUICK CARD

1	Power On/Off	**11**	2D mode and gain control	**21**	3D & 4D keys
2	New Patient	**12**	Push/Turn – HD/Pan Zoom Up/Down – Depth Control	**22**	Auto Optimize/Auto TGC
3	Archive/Exam Review Key			**23**	Print, Store, and Save Keys
4	Report Key	**13**	Turn – Sector Width Up/Down – Focal Position	**24**	Freeze/Run
5	End Exam	**14**	Custom Keys	**25**	Trackball and Trackball Keys
6	Multi-function control knobs with corresponding touch footer controls	**15**	Body Marker Key	**26**	Touch Footer
		16	Menu Exit Key	**27**	Shortcuts
7	PW mode and gain control/X axis*	**17**	Arrow Key	**28**	Eject Media
8	M mode and gain control/Y axis*	**18**	Annotation/Abc Key	**29**	DVR Menu
9	PD mode and gain control/Z axis*	**19**	Clear key	**30**	XL Format
10	CF mode and gain control/ Parallel Shift*	**20**	Measure/Calc key	**31**	Home

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*3D Control

Voluson **Expert 22**
QUICK CARD

Entering patient data
1. Press the "New Patient" key (2).
2. Enter patient information. Patient ID is required to store images. Growth chart information will only be displayed if LMP, EDD or GA is input.
3. Select "Start" from the "Top trackball" key (25), touch panel or monitor menu.
4. To End exam, select "End Exam" key (5).

Calculation measurements
1. Press the "Measure/Calc" key (20). The calculation package for the active application (e.g. OB) will appear on the touch panel.
2. Select the desired calculation.
3. The calipers can be set by "Right or Left trackball" key (25).
4. For patient report, press "Report" key (4).

Generic measurements
1. Press the "Measure/Calc" key twice for generic measurements (20).
2. Select the desired measurement from the touch panel (e.g. generic dist). Entering and setting of calipers is done with the "Right or Left trackball" key (25) Endpoints can be adjusted with "Top trackball" key; calipers are set with "Right or Left trackball" key.

3D/4D mode
1. Press the "3D or 4D" key (21).
2. If choosing 4D, select the desired 4D mode on the top of the touch panel.
   The "Right trackball" key (25) or "Freeze" key (24) will begin the acquisition.

CF mode (Color Doppler mode)
1. Press the "CF mode" key (10).
2. The CFM box appears in the active 2D image.
3. The "Top trackball" key (25) switches between CF box position and size.
The "CF mode" key (10) is also the color mode gain control.
Activate Power Doppler or HD-Flow™ in the same way with the "PD mode" key (9).
To switch between PD and HD-Flow, use touch panel control.

PW mode (Pulsed Wave Doppler mode)
1. Press the "PW mode" key (7).
2. Adjust the PW cursor position and gate size with the trackball on the 2D image. The "Top trackball" key (25) switches between gate position and gate width.
3. Press the "Left trackball" key (25) to start the spectral Doppler.
4. The "PW mode" key (7) is also the PW spectrum gain control.

Note:
To deactivate all modes, press the "2D mode" key (11).

Important note:
An Electronic Instruction for Use (IfU) is integrated on the Voluson Expert 22. Press Home (31) to access the IfU.*

Touch Footer
Functions found on "Multi-function control knobs" (6) can also be controlled via the "Touch Footer" (26) with tap or slide action.

*First-time selection of the IfU requires the documentation DVD or USB to be inserted.