

SuperSonic Imagine
“The Innovative Ultrasound Company”

introduces the **Aixplorer® V11** release featuring

Advanced Breast Imaging Solutions

Clinical Innovations including

“TriVu” Real-Time Simultaneous B-mode, SWE™
and Color+ mode,

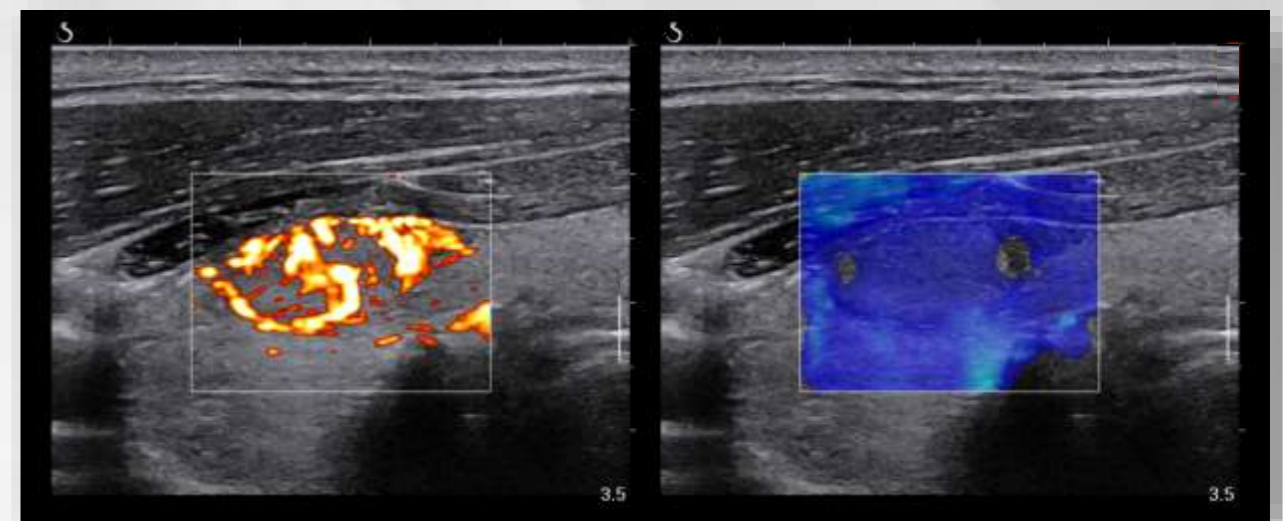
Angio PL.U.S. PLanewave UltraSensitive™ Imaging
on the XC6-1

&

Fusion, Volume Navigation and
Needle Guidance Solutions

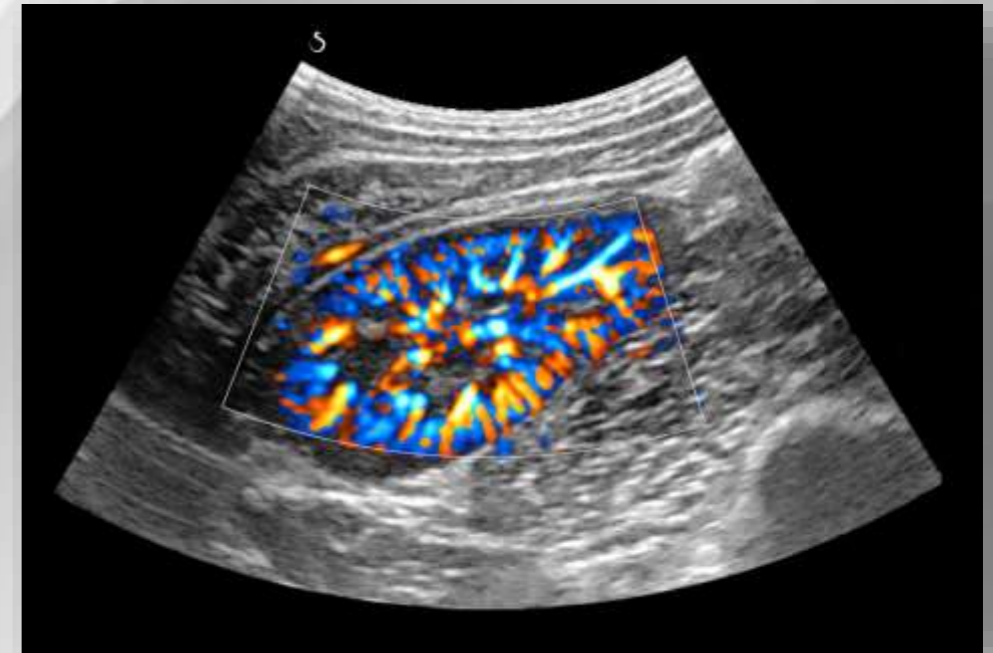


- Comprehensive and Confident Breast imaging
 - A complete line of probes for breast imaging including the new all-purpose SL18-5
 - A new compact linear array SLH20-6 for high resolution imaging
 - Outstanding vascular color sensitivity with Angio PL.U.S. and the new TriVu* simultaneous mode
 - Real-time SWE on all breast probes, 3D breast imaging, and more!
- TriVu real-time simultaneous imaging
 - Combines B-mode, Color+ and SWE™ into a powerful real-time simultaneous mode
 - Setting a new bar for innovation and workflow leveraging UltraFast imaging
 - Allows simultaneous visualization of anatomy, flow and tissue stiffness



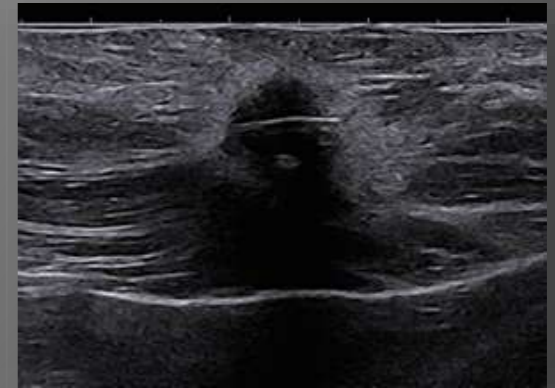
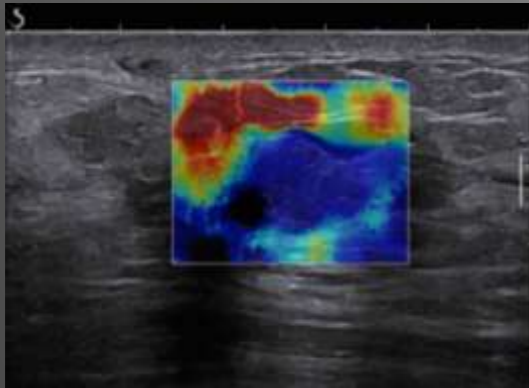
*Pending FDA 510k clearance

- Angio PL.U.S. PLanewave UltraSensitive™ imaging
 - A new solution for microvascular visualization, now available on the XC6-1 Abdominal transducer
 - Real-time and exquisite High Definition imaging
- Fusion, Navigation & Needle Guidance
 - Synthesizing cross-modality diagnostic information for complete diagnostic imaging confidence
- Solution Evolution
 - New capabilities and enhancements in Imaging, Connectivity, Reporting, Workflow and Research
 - Wireless DICOM*
 - Improved Reporting*
 - SonicResearch capability to capture raw SWE data



*Pending FDA 510k clearance

AIXPLOTORER[®] V11 COMPREHENSIVE AND CONFIDENT BREAST IMAGING



Breast Imaging

Comprehensive Suite of Breast Optimized Transducers



SL18-5

A high resolution ultra-wide bandwidth probe covering all routine needs with:

- Excellent resolution
- Outstanding conspicuity
- Improved anatomic feature discrimination
- Real-time SWE™
 - Angio PL.U.S.
 - TriVu

SLV16-5

The only 3D Real-time ShearWave™ Elastography transducer capable of imaging coronal views of the breast

- Multi-slice and multi-plane views
- Fast Real-time SWE™ acquisition
- Retrospective SWE analysis

SL10-2

A mid-frequency linear array probe offering extra penetration for imaging deep or dense structures

- Smaller footprint for axillary access
- Ideal for lymph nodes
- Real-time SWE™
 - Angio PL.U.S.
 - TriVu

SLH20-6

A high resolution compact array transducer for imaging detailed structures such as superficial lesions and lymph nodes

- Highest resolution
- Smallest footprint
- Real-time SWE™

Breast Imaging

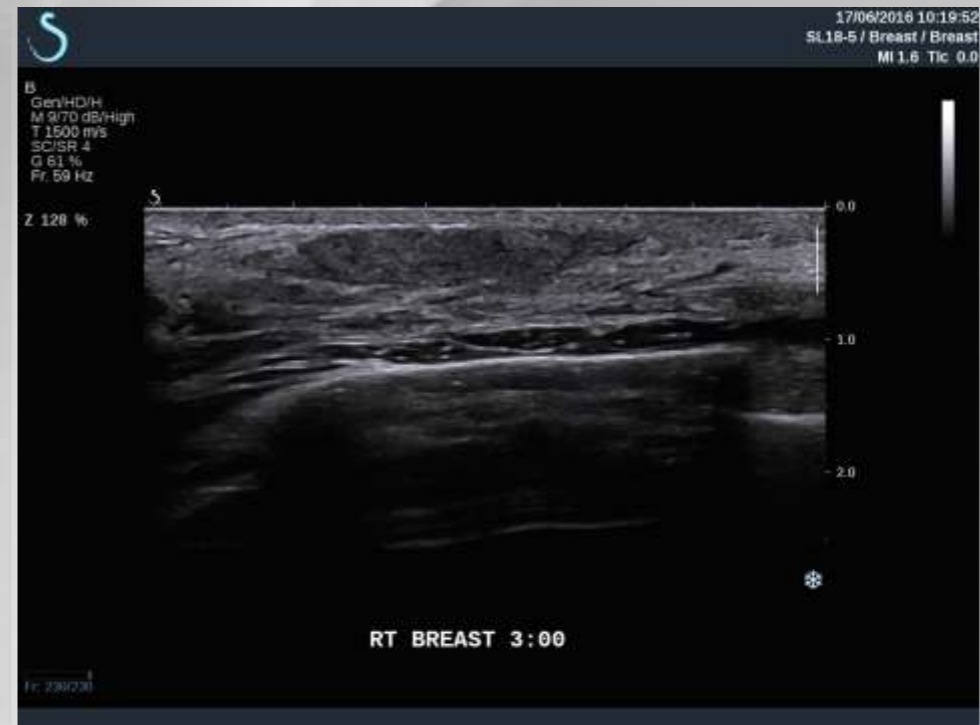
Outstanding B-mode Image Quality



Complex Cyst



Fibro-adenoma



Posterior Nipple



Cyst



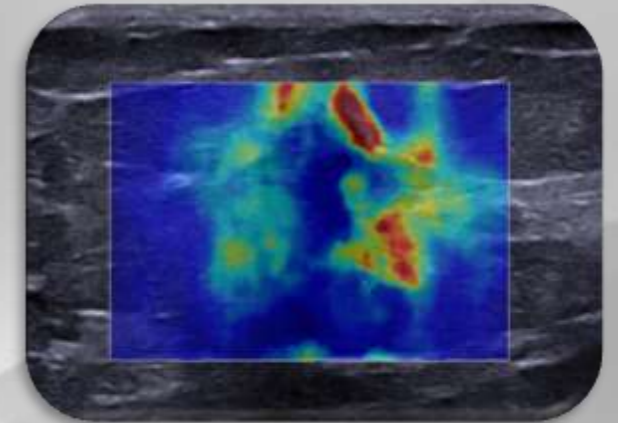
Breast Imaging

Clinically Realized Innovation



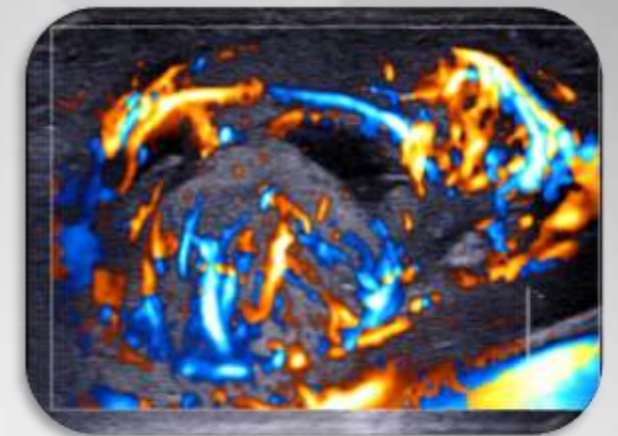
- ShearWave Elastography

- In both 2D and 3D, SWE™ allows physicians to visualize and analyze the stiffness of tissue in a real-time, reliable, and reproducible manner.
- SWE is an important parameter in diagnosing potentially malignant or other diseased breast tissue.



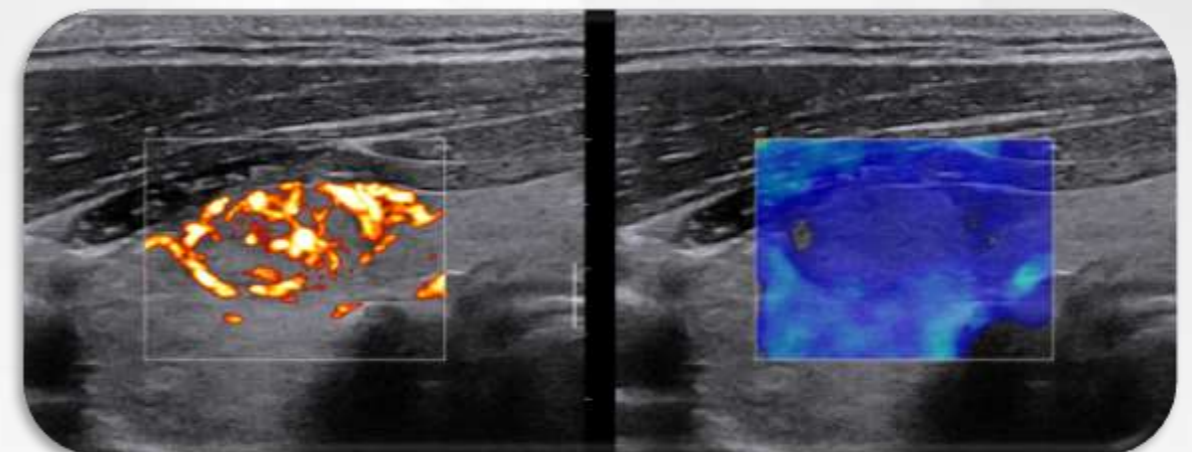
- Angio PL.U.S. - PLanewave UltraSensitive™ imaging

- Angio PL.U.S. provides a new level of microvascular imaging through significantly improved color sensitivity and spatial resolution.



- NEW: TriVu*

- B-mode, SWE™ and Color+ real-time simultaneous imaging
- Cutting edge simultaneous imaging allowing physicians to concurrently visualize anatomy, tissue stiffness, and blood flow in breast tissue in real-time.



*Pending FDA 510k clearance

Breast Imaging

Clinical Advantages



- “Best in class” high frequency, ultra-wide bandwidth SL18-5, SLH20-6 and SL10-2 probes
 - Excellent lesion conspicuity and high frame rates to survey suspect areas
 - Best in-class spatial resolution to resolve anatomic detail in fundamental and harmonic modes
 - Deep tissue penetration with the lower frequency SL10-2 for challenging cases
 - Sensitive Color Flow imaging in CFI, CPA and dCPI modes
- Angio PL.U.S. PLanewave UltraSensitive™ imaging is available on the SL18-5 and SL10-2 breast presets to examine microvascular flow patterns
- Real-time SWE™ for faster and more diagnostically complete BI-RADS lesion assessment
 - Real-time SWE™ is available on all probes/presets in the Breast Application. With over 100 peer-reviewed publications, SWE is the most studied shear-wave based elastography technology for breast cancer management
- Aixplorer’s SLV16-5 is the only probe offering 3D SWE™ for coronal plane lesion evaluation
- “TriVu” B, SWE, and COL+ is a unique real-time simultaneous mode which allows complex questions of anatomy, flow and tissue stiffness to be answered with precise correlation of imaging planes
- Biopsy steering enhances needle visualization during freehand procedures

AIXPLORER® V11
INNOVATION:
TRIVU & ANGIO PL.U.S.

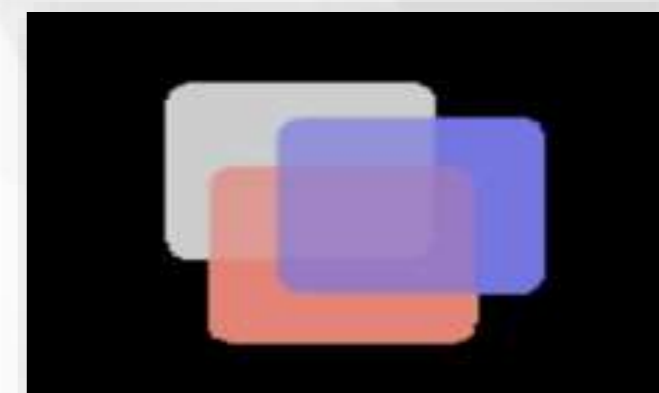
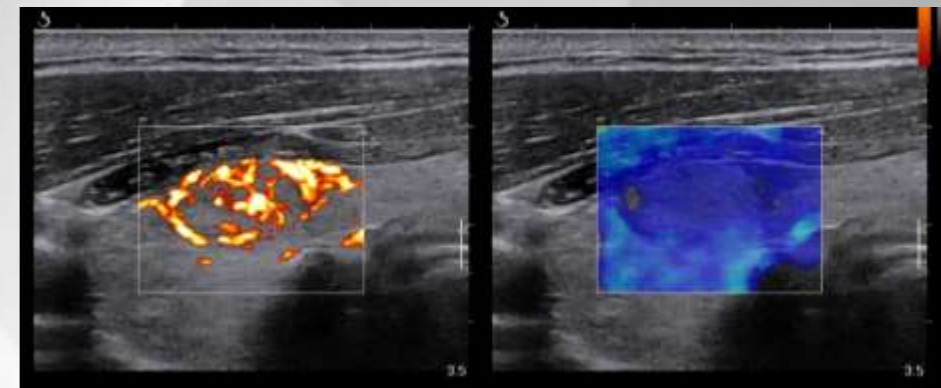
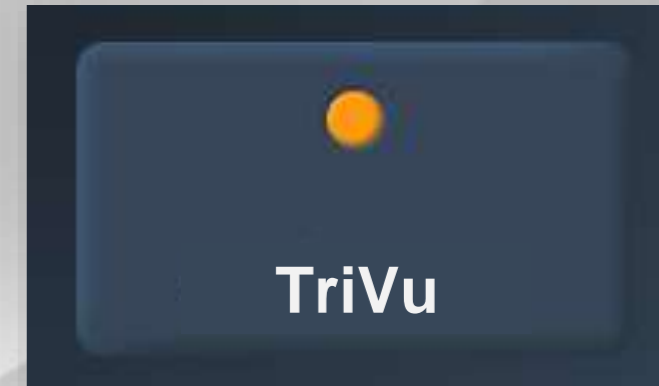


TriVu*

B, SWE and Col+ Real-time imaging



- TriVu, is the first of its kind imaging mode that merges B-mode, SWE™ and enhanced Color+ imaging, setting a new bar for both innovation and workflow.
- TriVu leverages the speed and power of UltraFast™ plane wave imaging to capture BOTH shear wave propagation and blood flow simultaneously.
- When combined with Aixplorer's high resolution B-mode, this unique combination allows physicians to visualize anatomy, tissue stiffness and blood flow from precisely the same imaging plane, simultaneously and in real-time.

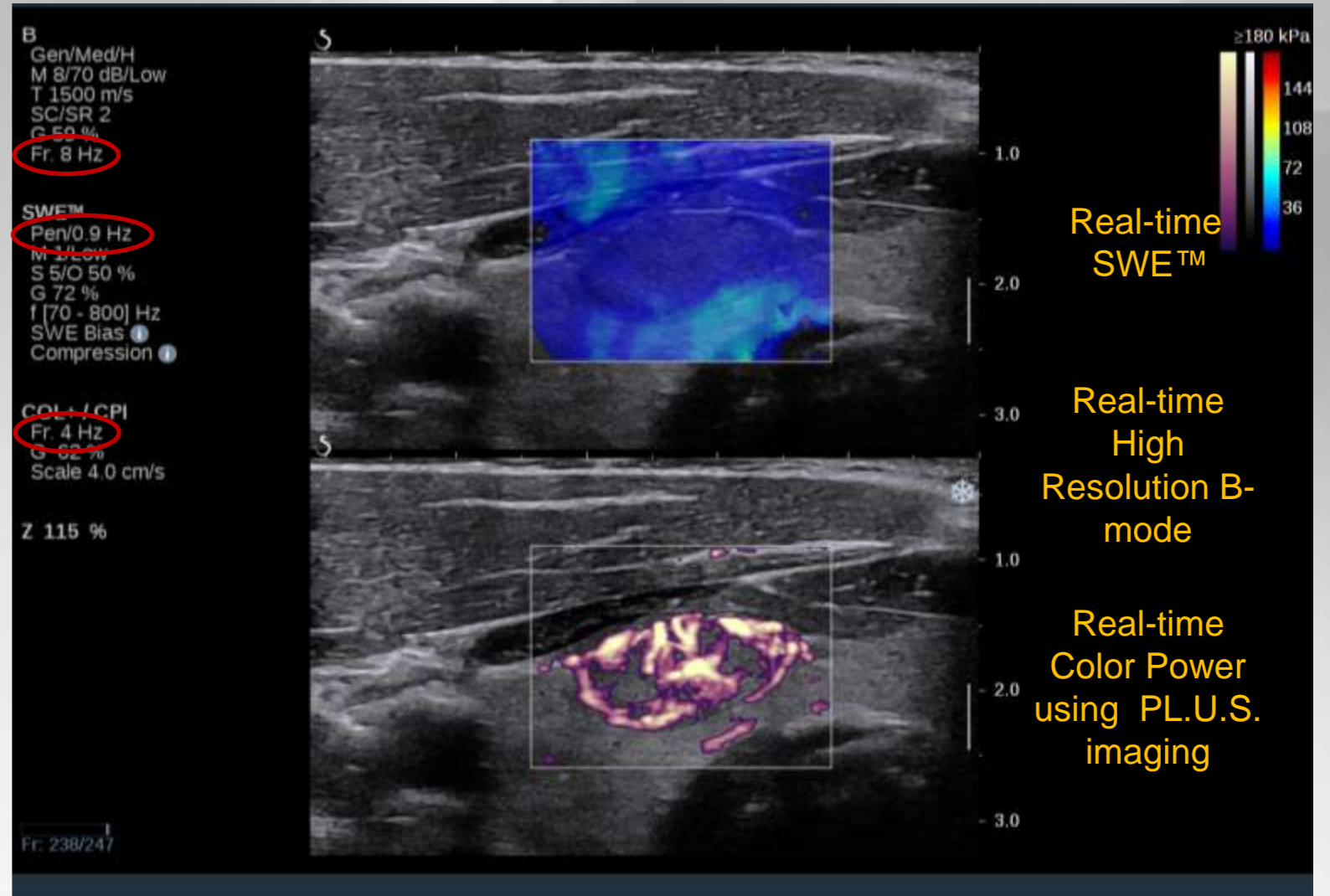


TriVu*

B, SWE and Col+ Real-time imaging



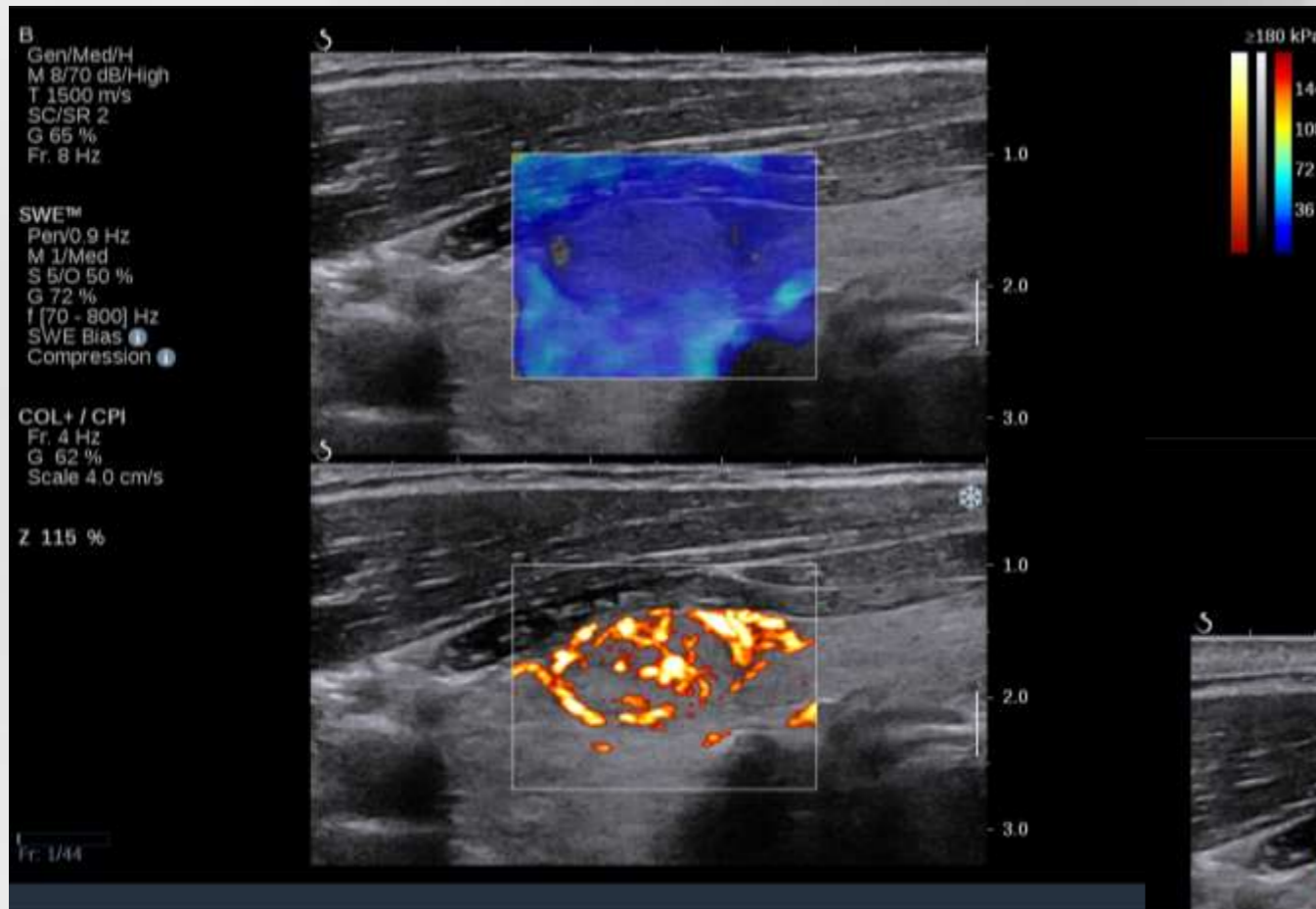
- High quality focused B-mode
- Maintains SWE™ quality and performance
- COL+ plane wave imaging enhances low flow visualization in small vessels
- Real-time B-mode and Color frame rates
- Available on the: SL18-5, SL10-2 and SL15-4 in Breast & Thyroid presets



*Pending FDA 510k clearance

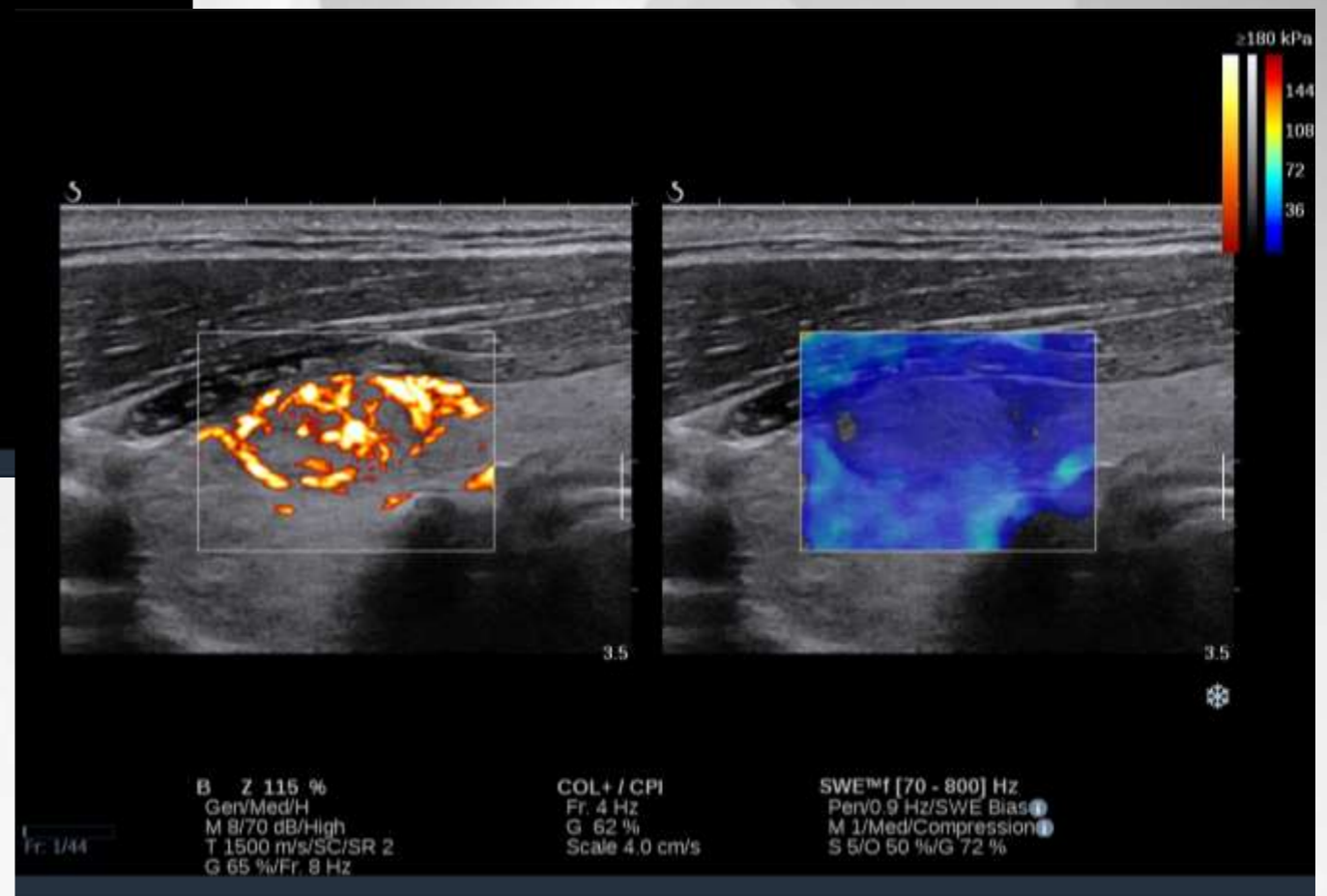
TriVu

Presentation Options



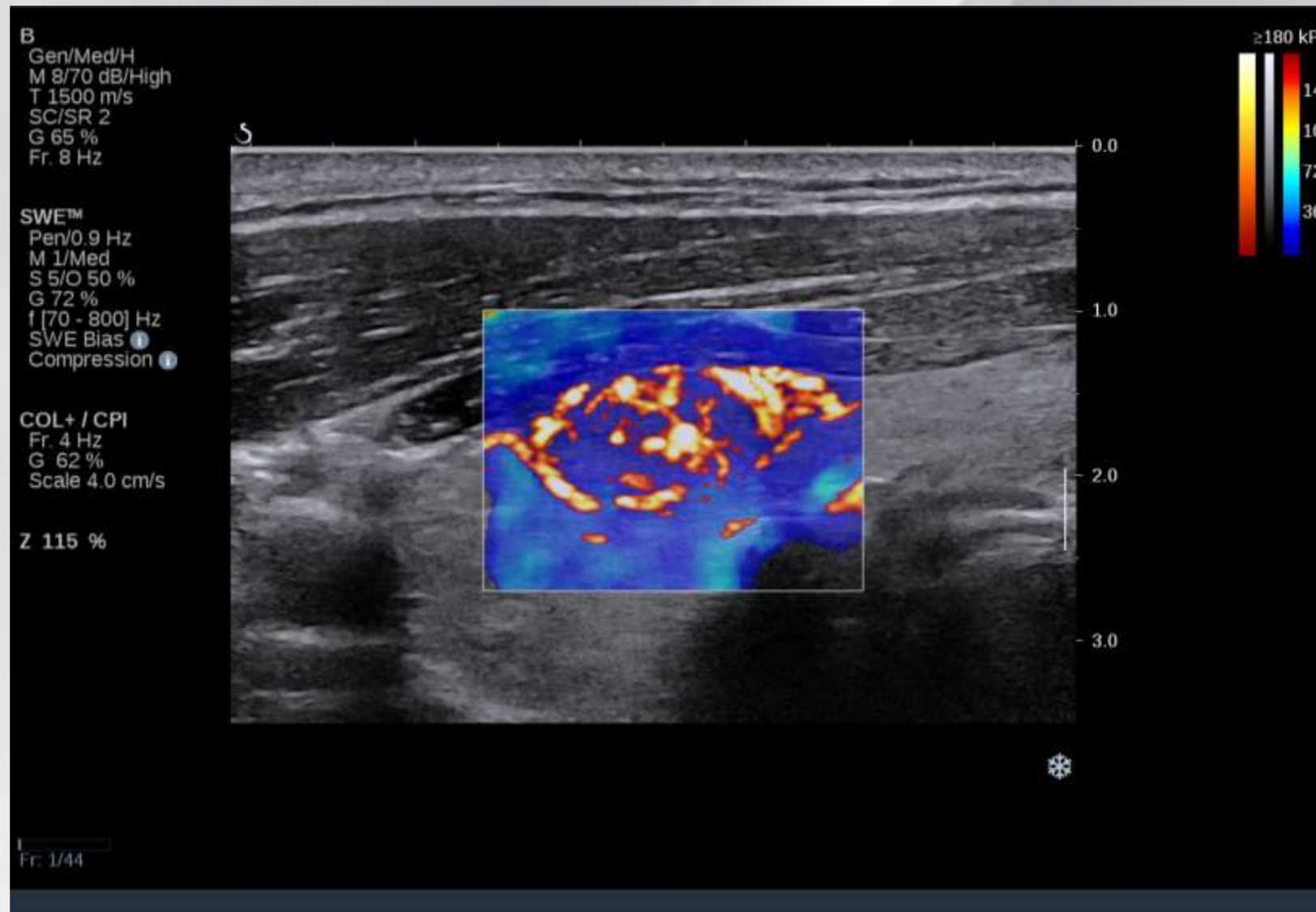
Top/Bottom
SWE™ / COL+

Side-by-Side
SWE™ / COL+



TriVu

Presentation Options



Full Screen with Opacity Control

A New Solution for Microvascular Imaging

Challenge:

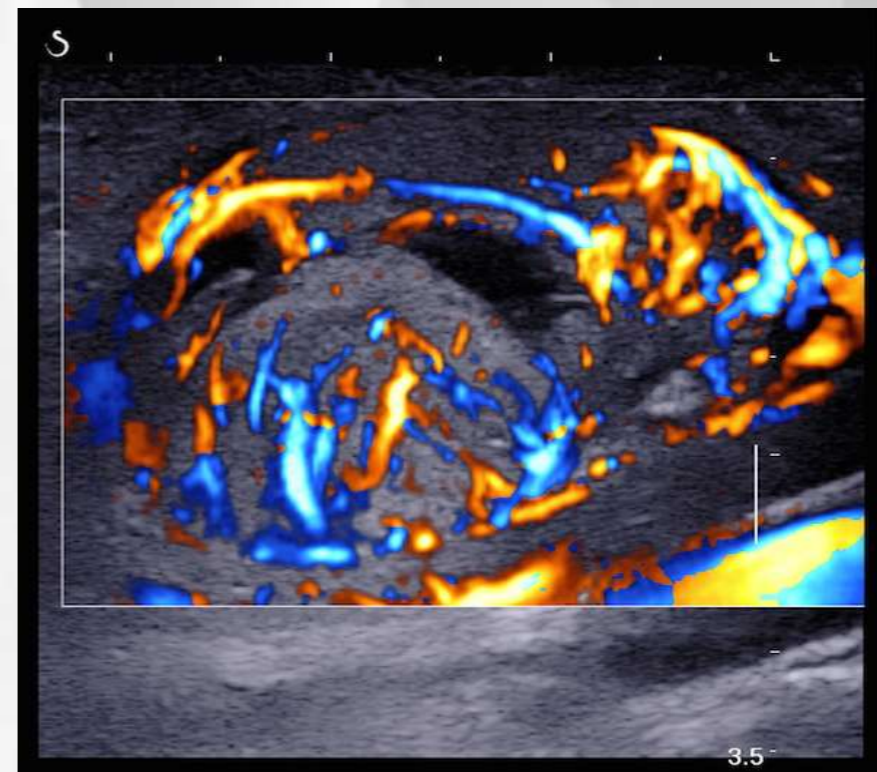
Conventional color Doppler is limited in its ability to visualize microvascular flow



Conventional Color Doppler

Solution:

Angio PL.U.S. increased sensitivity and spatial resolution results in greater flow detail



Angio PL.U.S.

Angio PL.U.S.

Probe & Preset Availability



SL18-5



XC6-1



SL10-2

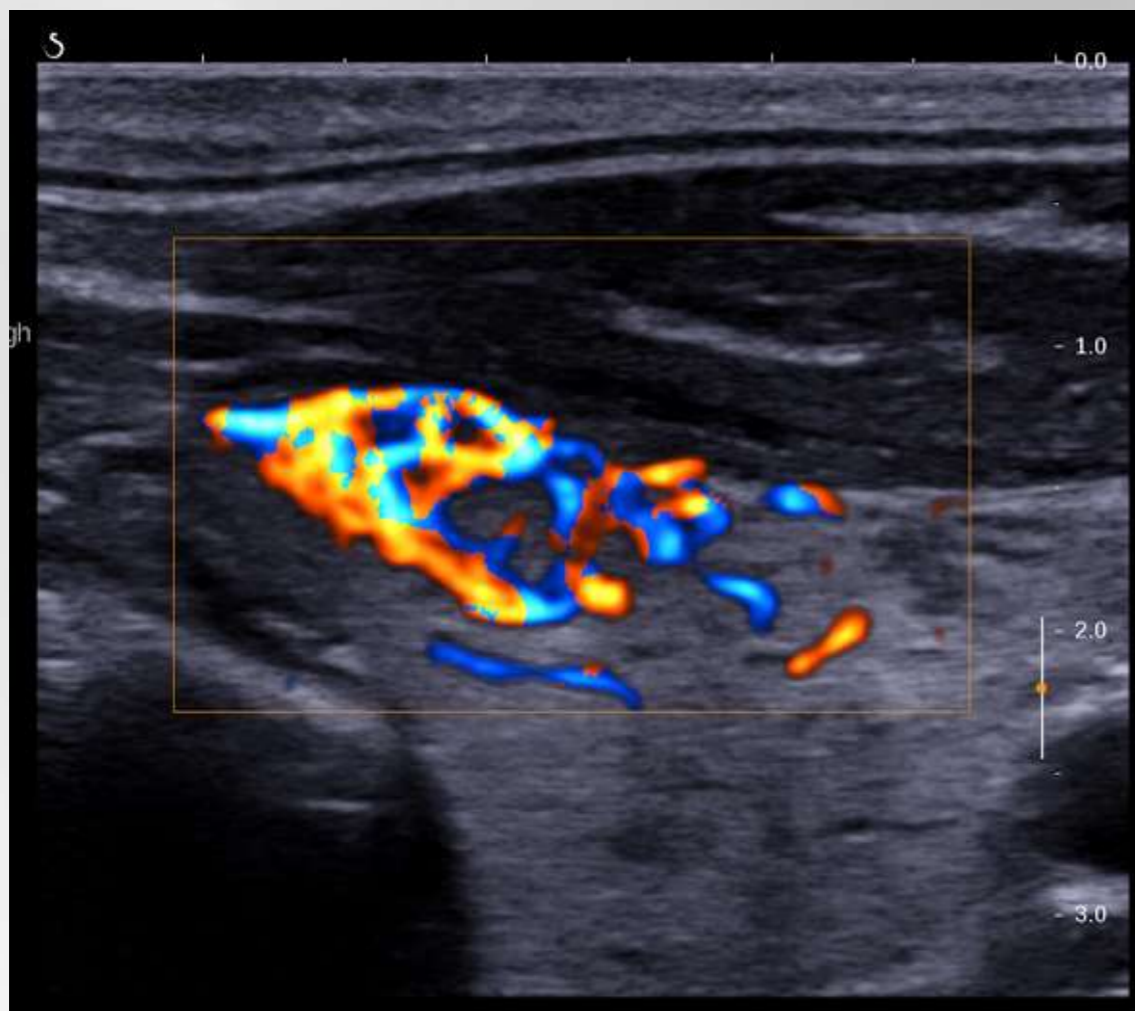


SL15-4

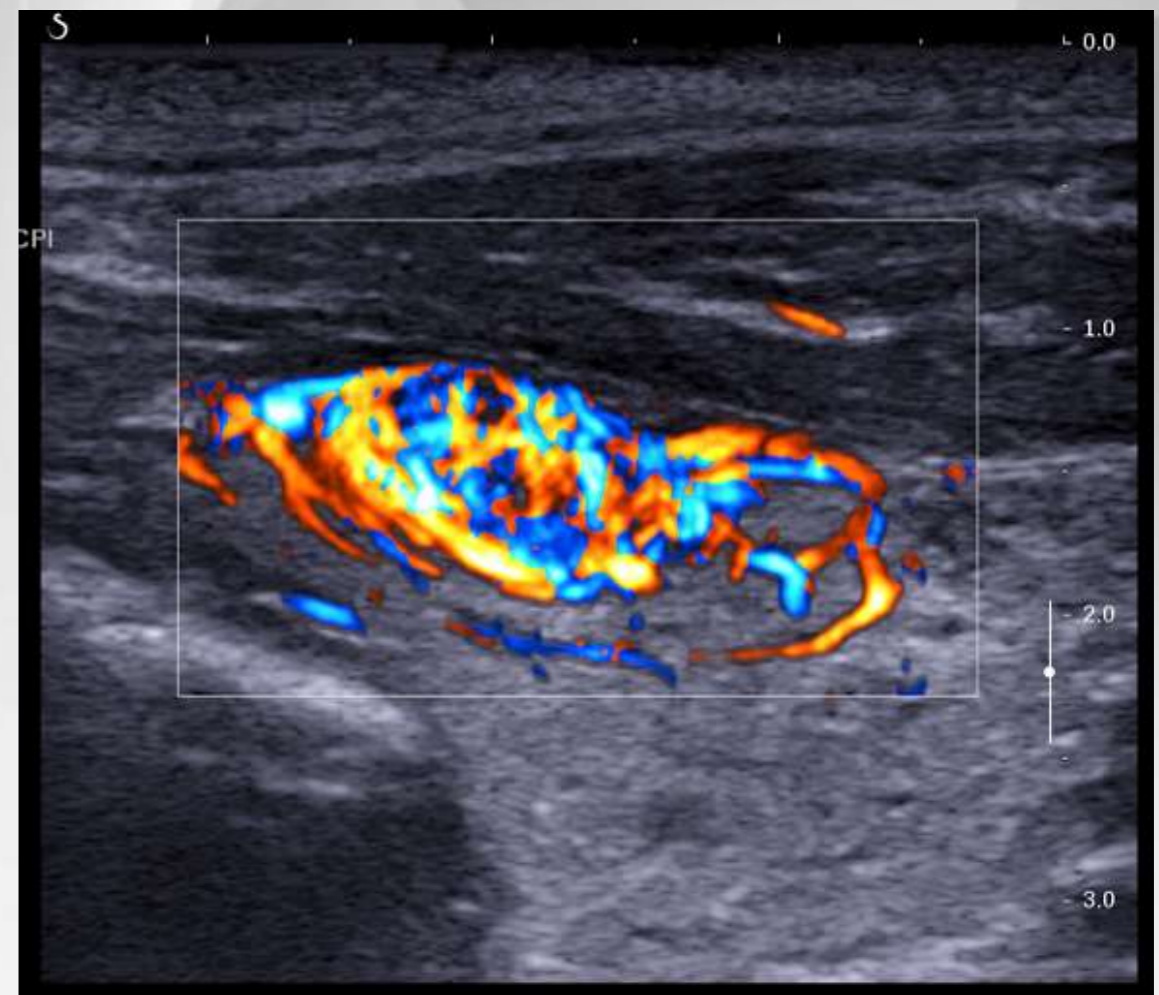


Applications: Breast, Thyroid, Abdominal,
MSK, Vascular, Gyn

Conventional Color Doppler

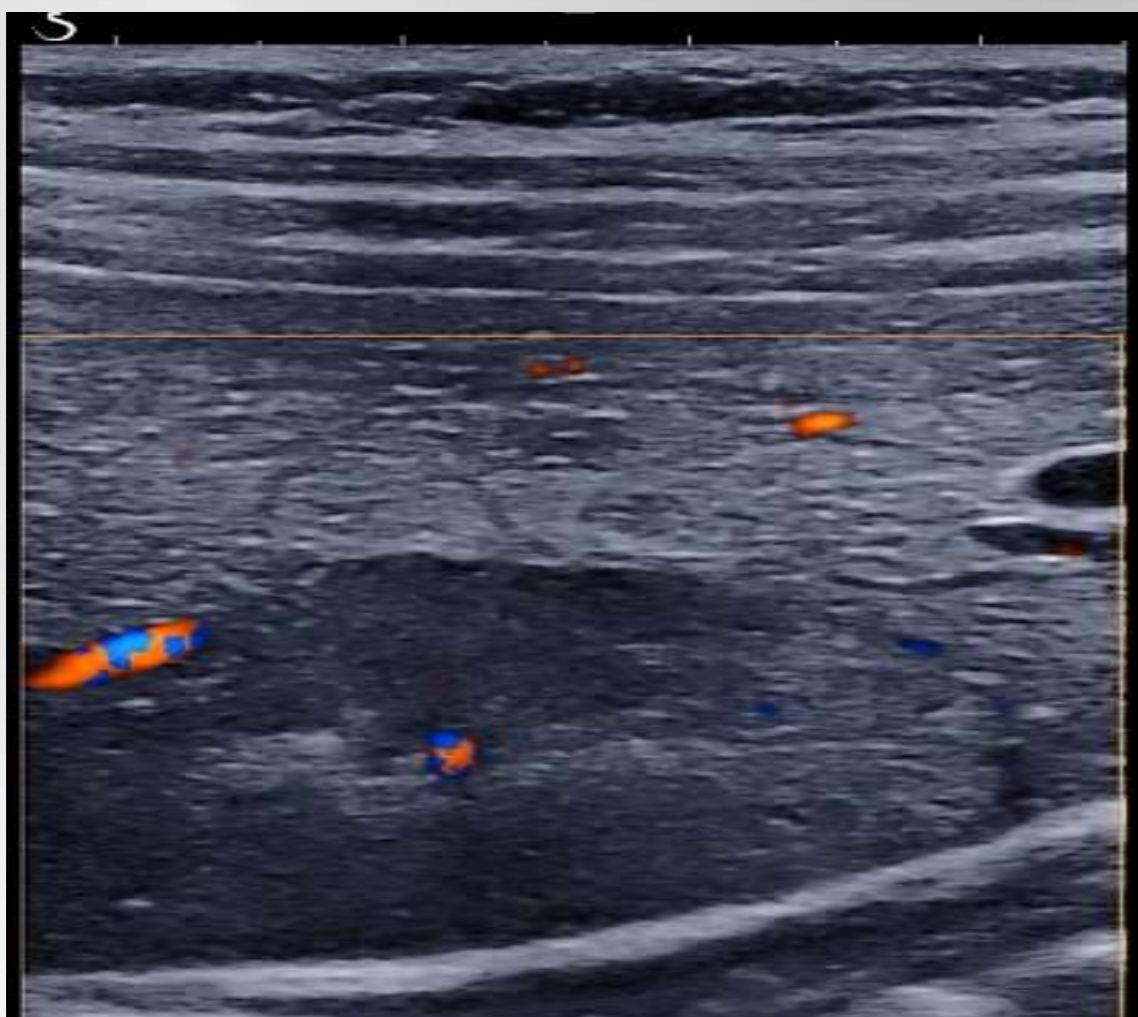


Angio PL.U.S. HD Imaging

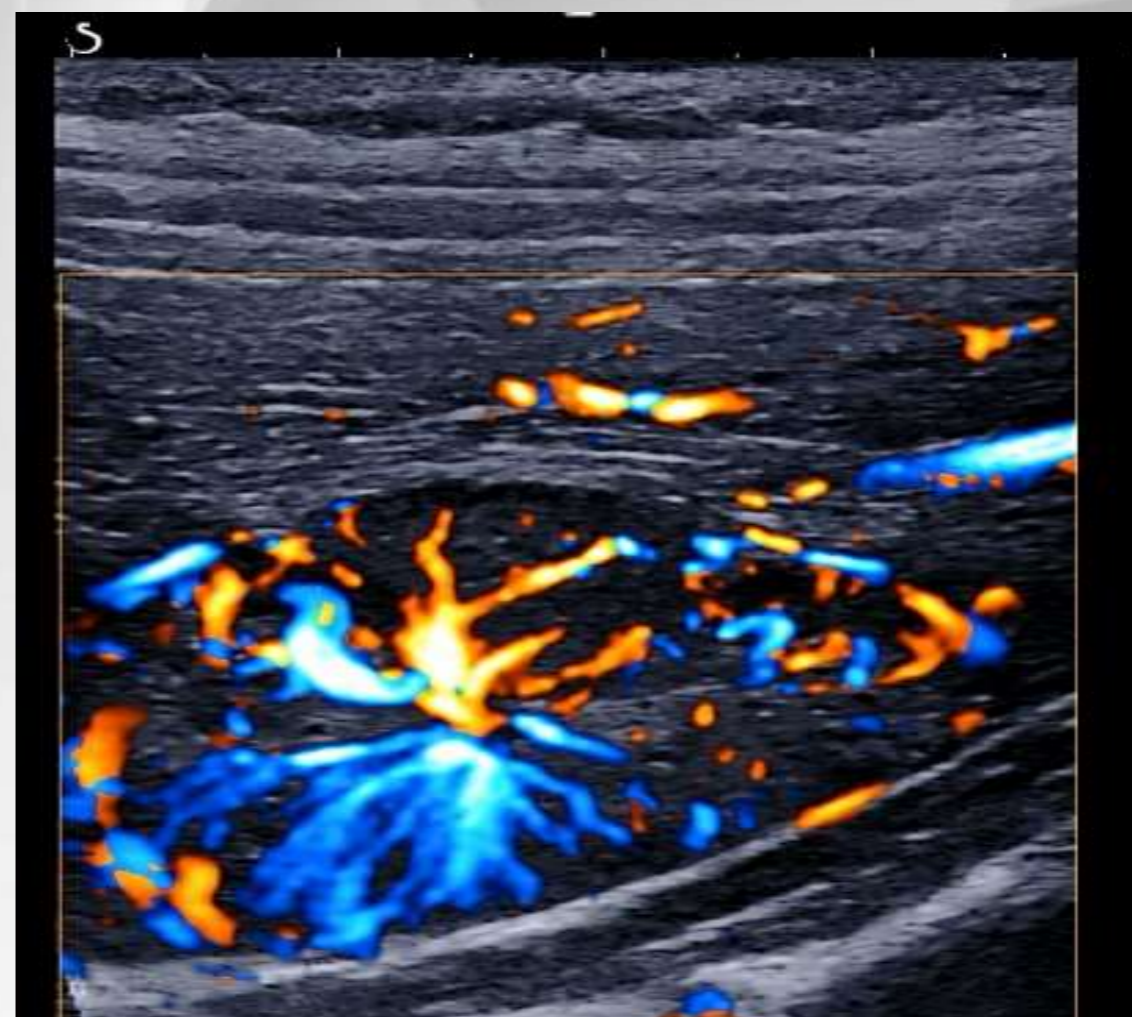


Highly vascular benign thyroid nodule

Conventional Color Doppler

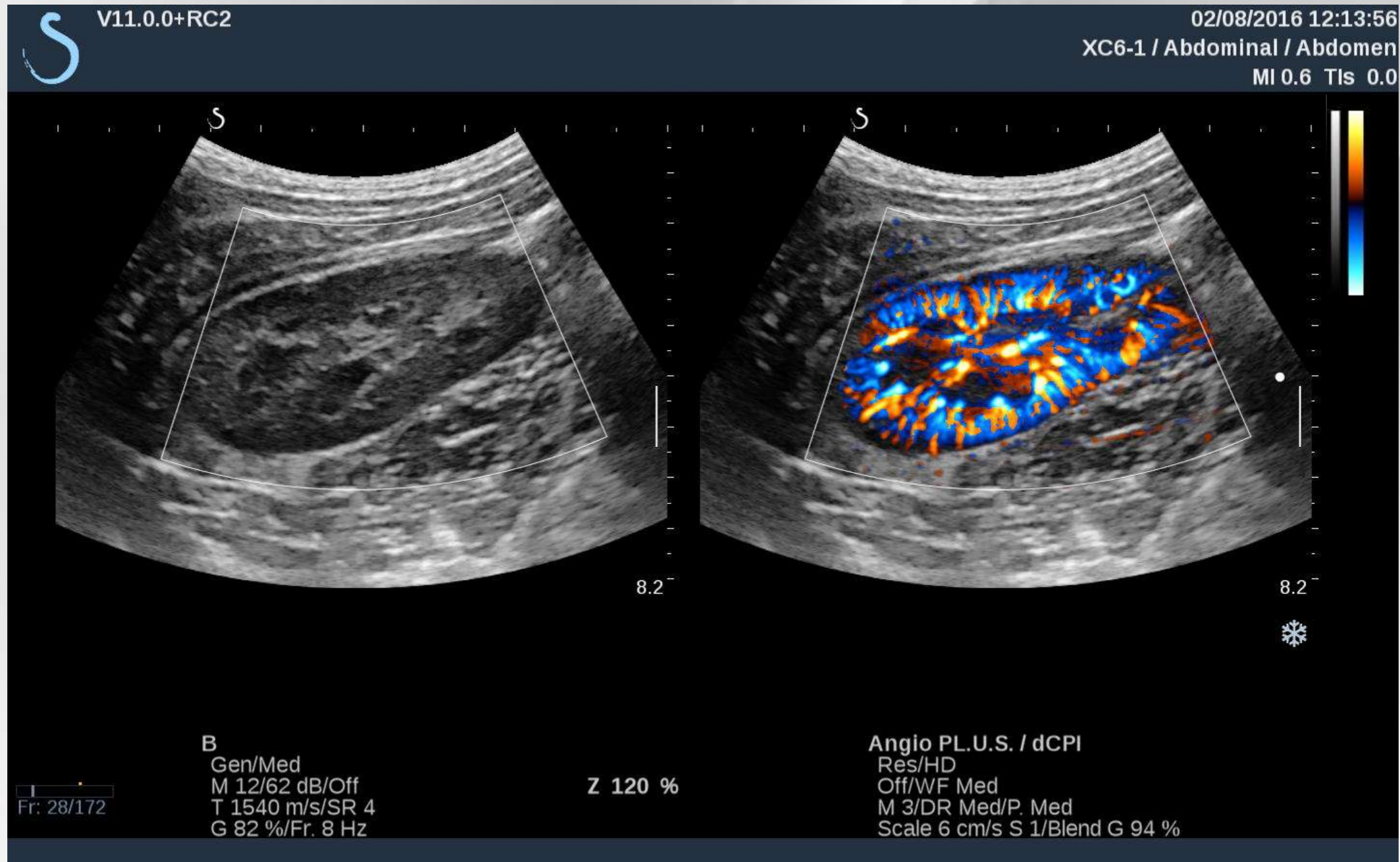


Angio PL.U.S. HD Imaging



Focal Nodular Hyperplasia (FNH) in the Liver

Angio PL.U.S. XC6-1 Transducer



Angio PL.U.S. with dCPI in the Kidney

Angio PL.U.S. XC6-1 Transducer



Monochrome map demonstrating excellent vascular sensitivity in liver vessels.

AIXPLORER® V11

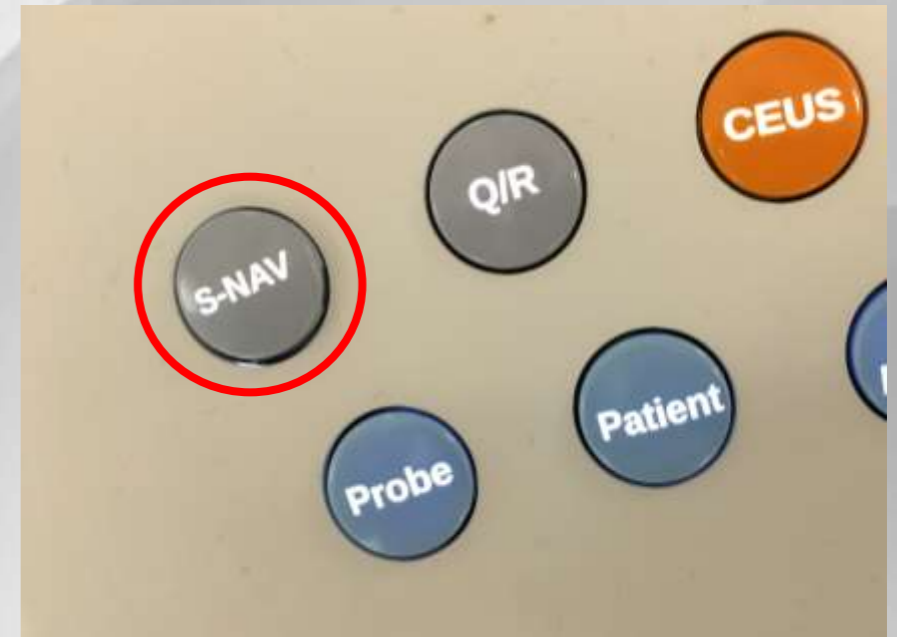
FUSION, NAVIGATION & NEEDLE GUIDANCE SOLUTIONS



Fusion, Navigation & Needle Guidance On Aixplorer*

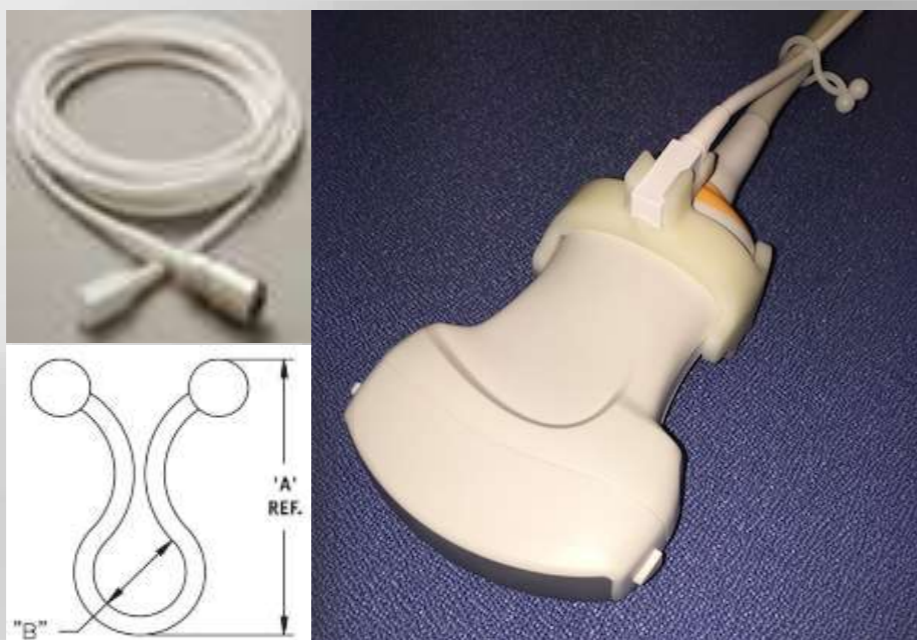


- Flexible package options for multi-modality imaging:
 - Fusion Imaging
 - Volume Navigation & Needle Guidance
 - Fusion, Volume Navigation & Needle Guidance
- Easily accessible through the “S-NAV” hard key*
- Available for XC6-1, SL10-2, SE12-3 & SEV12-3
 - All applications and presets on these probes are supported
 - Same hardware is required for Fusion, Volume Navigation & Needle Guidance options
- All imaging modes available in Fusion:
 - B, Color, real-time SWE, CEUS, Angio PL.U.S. & TriVu
 - Unique differentiator for guiding RFA/Biopsy, etc...



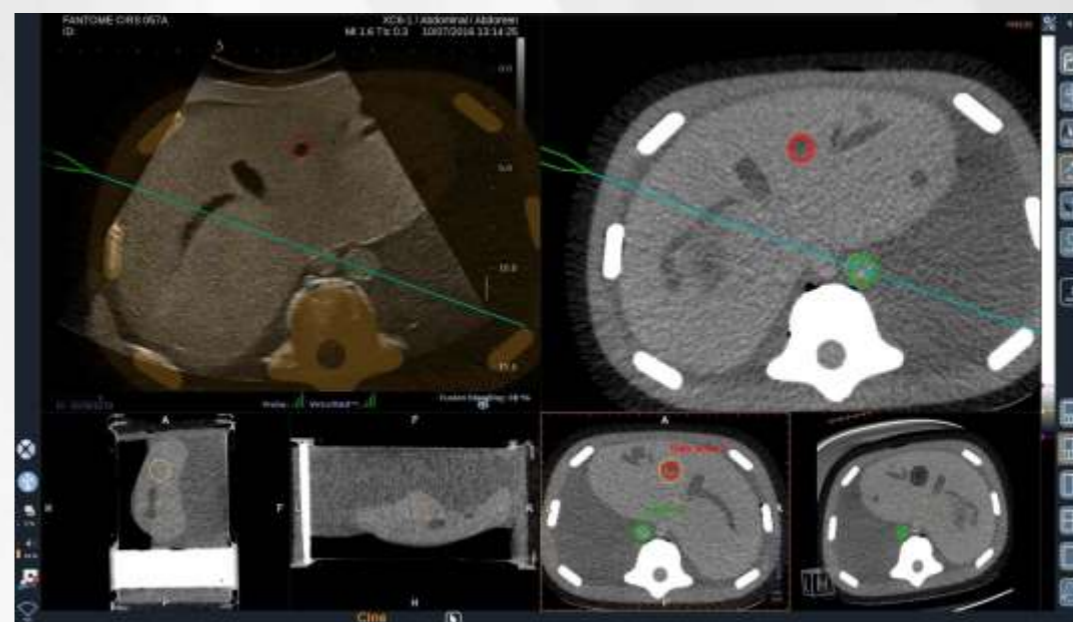
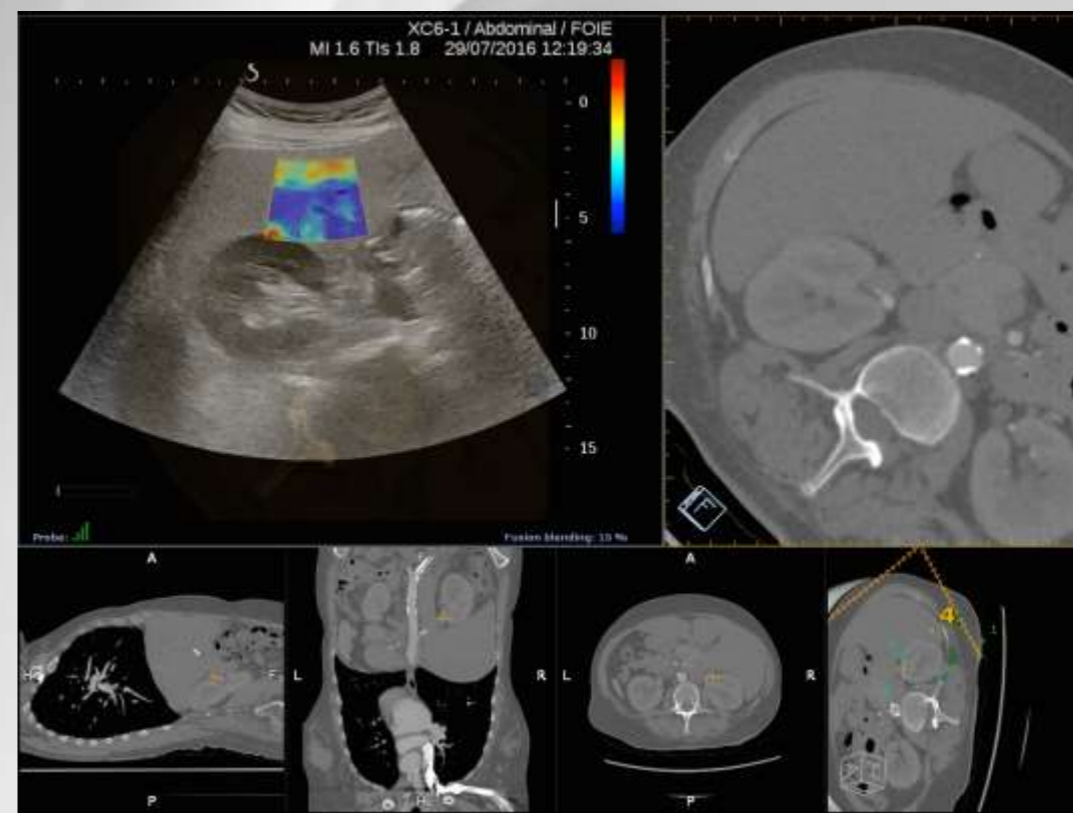
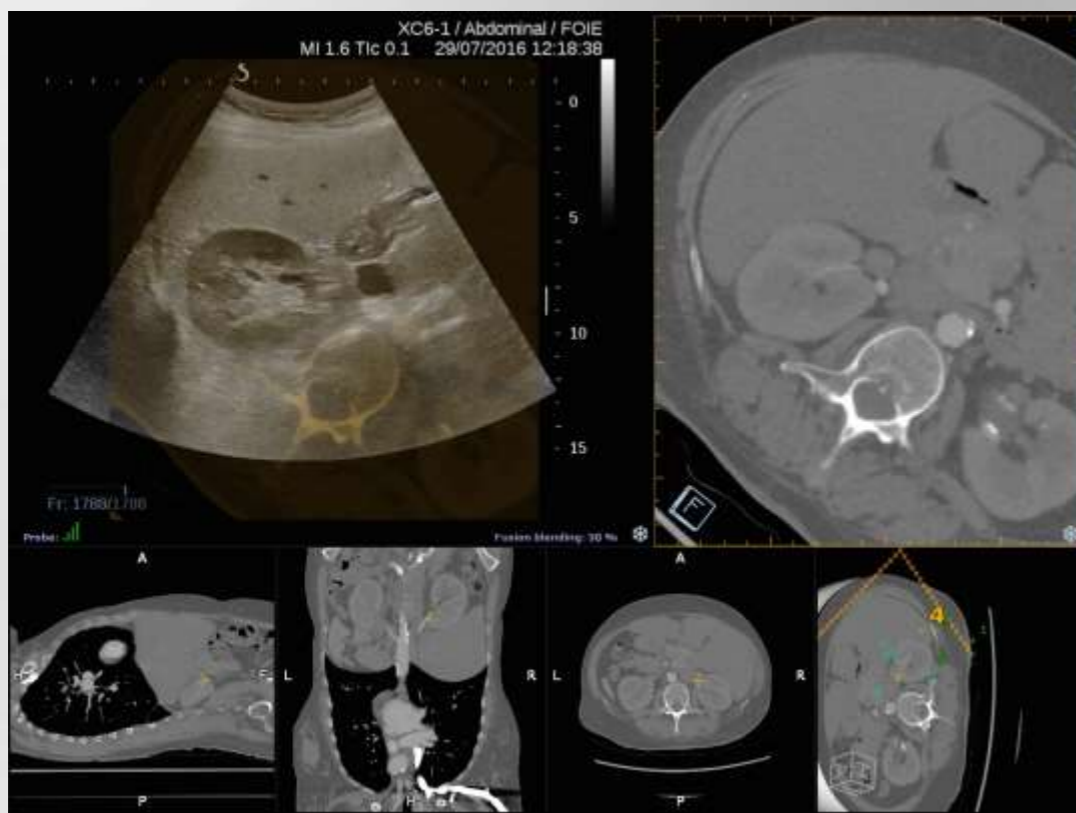
*Pending FDA 510k clearance

Fusion, Navigation & Needle Guidance On Aixplorer*



*Pending FDA 510k clearance

Fusion, Navigation & Needle Guidance On Aixplorer*



*Pending FDA 510k clearance

- Compare:
 - Aixplorer's solution* is very similar to Virtual Navigator by Esaote, PercuNav by Philips, Volume Navigation & Needle Tracking on the GE Logiq E9
 - Leverages industry standard hardware:
 - NDI Drivebay, CIVCO eTrax, virtuTrax, omniTrax, etc.
 - Sensors are attached with custom probe brackets
 - User Interface is customized for Aixplorer
- Advantages:
 - Perform real-time guidance with Aixplorer's unique SWE™, Angio PL.U.S. RT, and TriVu real-time imaging modes

Multi-modality imaging + Innovative real-time imaging modes
=
More diagnostic power and confidence!

*Pending FDA 510k clearance

AIXPLORER® V11 EVOLUTION: WORKFLOW & MORE...



Hardware Evolution

Expanded Connectivity and Storage



Aixplorer now features expanded Connectivity and Storage:

- **Dual Band WiFi***
 - 2.4GHz – 5GHz; 802.11b/g/n compliant
 - External USB Dongle
 - Adds wireless capability to all DICOM modalities
 - Print to a WIFI capable printer
- **Larger Hard Drives**
 - 1 Tb Total (2 x 500Gb)
 - Required for Navigation & Fusion



*Pending FDA 510k clearance

Reporting Evolution

OB and Liver Reporting



- New OB Tables have been added including ISOUG, and several CRL authors
- Custom OB tables can be added to Aixplorer upon request
- Liver Report*
 - Reference articles with data using Aixplorer in clinical research studies can be selected and displayed in the Liver Report
 - Data is presented as a table with fibrosis cut-off values
 - Papers cover various etiologies (HCV, HBV, NASH, etc.)

Report Builder

Patient Data | Images | Measurements | Worksheet | Conclusion

OB-GYN

Fetal Information: Fetus A

Fetus: Fetus A Gestational age: Average Ultrasound Age: 32w6d
 LMP: 20/11/2015 GA by LMP: 32w 5d Estimated Date Delivery by AUA: 24/08/2016
 DOC: 04/12/2015 EDD from LMP: 26/08/2016 Date of Conception by AUA: 02/12/2015
 EDD: 26/08/2016

Placenta: Location: Previa: Yes No Presentation: Vertex Breech Transverse Shoulder
 Grade: 0 1 2 3

Biophysical Profile:

Fetal movements: /8 Amniotic Fluid Volume: /10
 Fetal breathing movements: /2 Non-Stress Test: /2
 Fetal tone: /2

Biometry: Fetus A

Gestational Age measurements
 Femur length (FL): 6.36 cm GA: 32w6d (Hadlock, 1984) 42 th % -0.20

Anatomy: Fetus A

Fetal Cranium: seen not seen / not
 Cavum septi pellucidi:
 Midline falx:
 Thalami:

Gestational Age measurements

Femur length (FL): 6.36 cm GA: 32w6d (Hadlock, 1984) 42 th % -0.20

Report Builder

Patient Data | Images | Measurements | Worksheet | Conclusion

Abdominal

Liver

Published Papers

Cassinotto C, Hepatology 2016; NAFLD/NASH patients

Fibrosis METAVIR stage	Median (IQR)	AUROC (95% CI)	Youden Cut-off value (kPa)	Rule-out cut-off value (kPa)	Rule-in cut-off value (kPa)
F0-F1	6.0 (2.7)				
F2	8.0 (3.4)	0.86 (0.79-0.90)	8.9	6.3	8.7
F3	12.0 (5.0)	0.89 (0.83-0.92)	9.3	8.3	10.7
F4	17.0 (13.6)	0.88 (0.82-0.92)	10.0	10.5	14.4

Concl

Signa

Signature

Published Papers

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F4	17.0 (13.6)	0.88 (0.82-0.92)	10.0	10.5	14.4

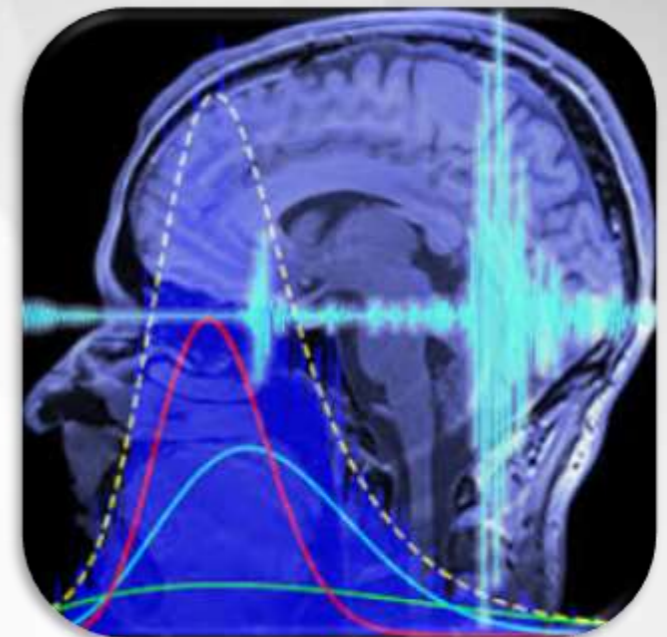
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CEUS and Sonic Research Evolution

Available on Aixplorer systems in the USA*



- CEUS has been FDA approved in the USA for evaluation of liver lesions in Adult and Pediatric applications
- “Lumason” (SonoVue) optimizations available on:
 - XC6-1/Abdominal/Abdomen & Liver presets
 - XC6-1/Pediatric/Abdomen preset
 - SL10-2/Abdominal/Abdomen preset
 - SL10-2/Pediatric/Abdomen preset
- The SonicResearch package includes SWE data acquisition:
 - SWE raw data acquisition and processing
 - Downloadable custom acquisition sequences for B-mode and SWE
 - B-mode and UltraFast™ data acquisition also available as in previous releases.
 - Simplified NDA process



*Pending FDA 510k clearance on Aixplorer

*CEUS quantification package is not available as Bracco's VueBox is not FDA approved in the United States

Workflow & Quality Improvements

Quality, Workflow and User Feedback



- **Presets & Patient Info**
 - Custom settings not saved when creating new preset has been fixed
 - Applications staff may Hide/Show factory presets
 - Image zoom set back to 100% after preset selection
 - Patient name order & upper/lowercase issues corrected
- **Imaging Workflow**
 - Screen flashes while changing depth + imaging modes transition has been eliminated
 - Black touchscreen or image from other exams has been corrected
 - Depth & Focus graphics are now outside of the image area
 - Loop wrapping available when scrolling clips
 - Panoramic imaging issues on the SL15-4 Superficial Breast preset has been corrected
 - Reset to default zoom control now available
- **Measurements**
 - Multi Q-Box workflow ending after AutoTGC has been corrected
 - Prox/Mid/Dist or None modifier available for ICA/CCA vascular labeled measurements
 - Manual selection of PW goalposts
 - Dissociated Traces on TS has been corrected
- **Reporting**
 - Capability to select the order of images to be sent or printed from Review
- **Customization**
 - Custom rotation of Depth & Focus controls now available to the user
- **Options Management**
 - Capability to unlock an options file for a pre-determined period of time to enhance Sales demos

AIXPLORER® V11

DIAGNOSTIC EXCELLENCE & INNOVATION



V11 Diagnostic Excellence & Innovation

Summary



- Comprehensive and Confident Breast imaging
 - With a complete line of probes and innovative features, including the new SL18-5, Angio PL.U.S. and TriVu*
- TriVu real-time simultaneous plane wave technology
 - Setting a new bar for innovation and workflow by combining B-mode, SWE™ and Color+ and into a powerful combined mode
- Angio PL.U.S. PLanewave UltraSensitive™ imaging
 - A new solution for microvascular visualization
- Fusion, Navigation & Needle Guidance*
 - Synthesizing cross-modality diagnostic information for complete diagnostic imaging confidence
- Solution Evolution
 - New capabilities and enhancements in Imaging, Connectivity, Reporting, Workflow and Research



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