



cSound Architecture

Ultrasound for today, platform for tomorrow

The breadth of clinical scenarios in general imaging ultrasound places significant demands on the ultrasound device. A patient who cannot hold her breath while a renal Doppler is performed. A patient whose tendon tear requires sub millimeter resolution. An obese patient needing a liver biopsy. A brain scan of a neonate in an incubator. A liver fibrosis assessment that depends on detecting a shear wave signal thinner than a human hair. In today's demanding clinical environment, the ultrasound machine is a partner in helping the clinician meet every challenge.

GE Healthcare has designed its advanced cSound™ Architecture to put the latest ultrasound technology in the hands of clinicians. It combines the power of XDclear™ probes with a new cSound Imageformer to enable confident diagnoses, provide comprehensive tools, and support concise workflow.

cSound Imageformer

The cSound Imageformer is the data acquisition and processing engine of the new architecture. At its core are cutting-edge NVIDIA® GPUs, the same graphics processing technology that is advancing the driverless car industry and the next generation of video gaming. This technology gives GE ultrasound engineers access to 48 times the data throughput and 10 times the processing power of our previous systems.* This opens up new opportunities, allowing the cSound Imageformer to collect and use more data to create every ultrasound image.



Traditional Beamforming

To understand cSound Imageforming, it helps to review how traditional beamforming works. As shown in Figure 1, traditional beamforming is performed in customized hardware and only the resulting beam or vector data is provided to the flexible, software-based processor that creates the ultrasound images.

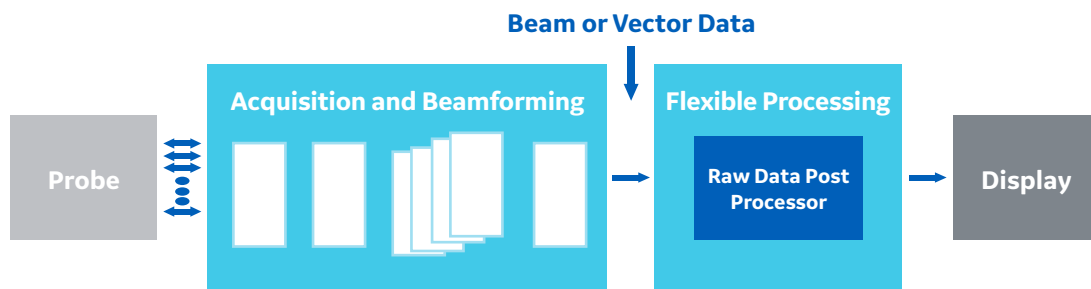
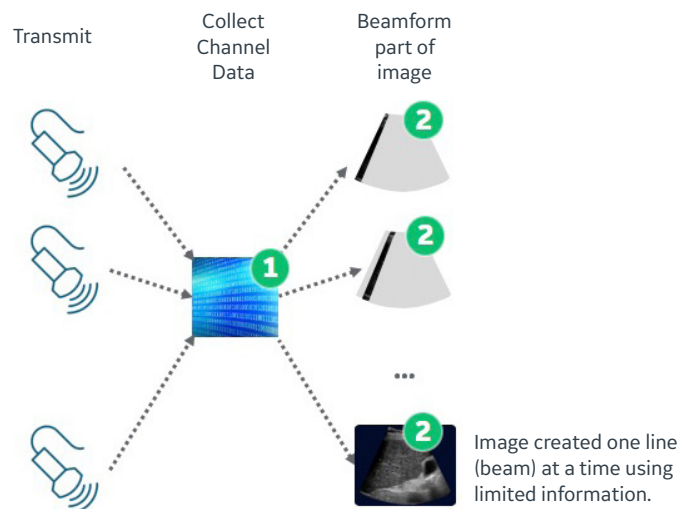


Figure 1. A traditional beamforming architecture.

Traditional Beamforming Steps

1. A transmit event is performed. The return ultrasound data is dynamically received and collected in a single instance of channel memory.
2. The collected channel data is processed to create a particular portion of the image often referred to as one or more vectors or beams.
Note: If multiple focal depths are desired, steps 1 and 2 are also repeated with a transmit event focused at a different depth.
3. Steps 1-2 are repeated for another portion of the image until the entire image has been created.

Traditional Beamformer



The channel data processed in step 2 and then overwritten still has useful information. However, a traditional beamformer has no means to extract this additional value before the channel data associated with the next transmit event overwrites it.

cSound Imageforming – Methodology

As shown in Figure 2, cSound Imageforming is performed using flexible, GPU-based processing. In contrast to traditional beamforming, the cSound Architecture moves raw channel data at high speeds from the acquisition system to components that perform flexible, software-based processing, including the cSound Imageformer. This channel data can be retained in memory even as channel data from subsequent transmit events is acquired and transferred to the cSound Imageformer.

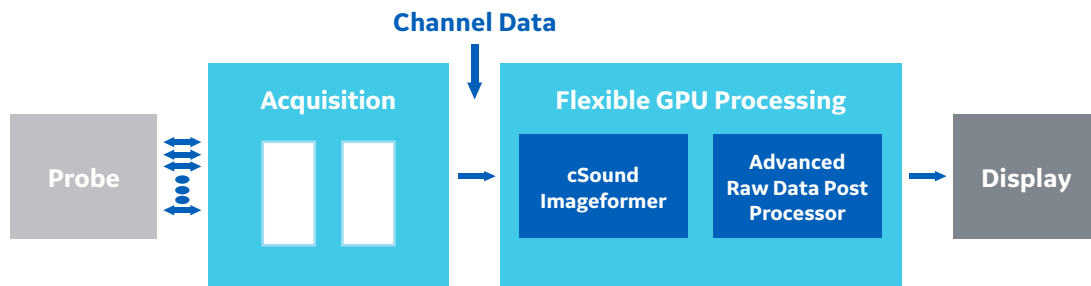
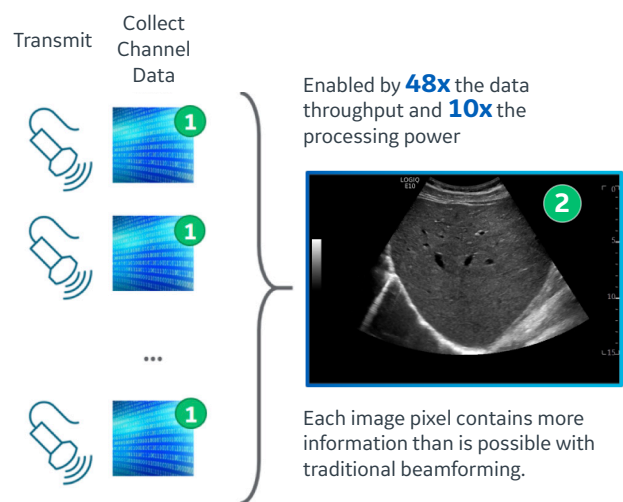


Figure 2. cSound Architecture.

cSound Imageforming Phases

1. Acquisition – A series of transmit events are performed with the return ultrasound data being dynamically received and transferred to memory.
2. Reconstruction – The channel data from all of the transmits is combined to form the image.

New cSound Imageformer



Similar to CT and MRI, cSound Imageforming has a distinct acquisition phase followed by a reconstruction phase. This requires the cSound Architecture to acquire, move and store large amounts of channel data and, once collected, the cSound Imageformer must be able to process the data at high speeds to enable real-time image reconstruction. The image formation process leverages channel data that would have been discarded in traditional beamforming. This additional data provides numerous samples for every point in the image. The image formation process combines these samples to achieve transmit focus for each point in the image, enhance contrast resolution and deliver fine spatial resolution.

cSound Imageformer – Retrospective Transmit Focus

In traditional beamforming, each transmit event has a transmit focus that is created by adjusting the time delays of individual transducer elements. This generates a curved wave front that converges until reaching a particular depth (the focus depth) and then diverges as it continues to propagate beyond the focus depth. The focus is the location that is insonified from multiple directions.

For each transmit event, the cSound Imageformer collects and saves the receive ultrasound data for each element. This is referred to as channel data. *Even when a new transmit event occurs, the channel data associated with previous transmit events is retained and not overwritten.*

Individual transmit events are spatially and/or angularly offset from one another creating significant overlap. As a result, for any point in the image, there are multiple transmit events that have insonified the point, each from a different direction. Knowing the spatial locations of a particular point in the image relative to a given transmit event, the cSound Imageformer can retrospectively process the channel data of each intersecting transmit event, and then coherently

combine the results to achieve retrospective transmit focus at that point. It is worth noting that noise associated with each transmit beam is independent and therefore sums incoherently while the signal itself sums coherently. This increases the signal-to-noise ratio, further improving contrast resolution throughout the image.

This approach to focusing at each point in an image is possible for all types of transmit events providing there is overlap.

- **Converging waves** – Sound from multiple elements converges at a finite depth relative to the transducer face
- **Plane waves** – Sound from multiple elements is unfocused or essentially focused at an infinite depth
- **Diverging waves** – Sound from multiple elements diverges as if the focus was behind the transducer face

The cSound Imageformer is capable of all types of transmit events, giving engineers the flexibility to optimize the system uniquely depending on the needs of each clinical application.

cSound Imageformer – Retrospective Transmit Focus, an Example

For illustrative purposes consider a simplified scenario, as shown in Figure 3.

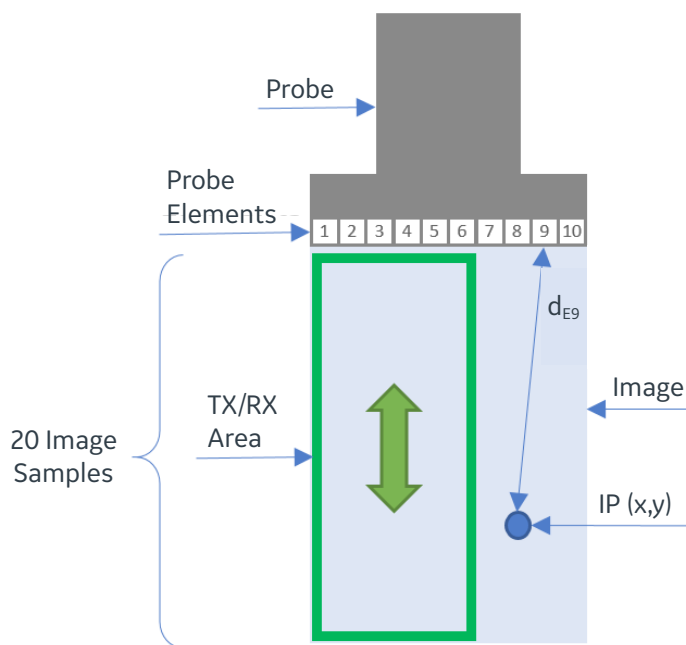


Figure 3. A simplified imaging scenario for illustrating retrospective transmit focus.

- Linear transducer with just 10 elements (E1 – E10)
- Each transmit event uses just six elements for transmitting and receiving. In this case, the first transmit event uses elements 1 through 6 (1-6) and then subsequent transmit events shift by a single element to use elements 2-7, 3-8, 4-9, and 5-10 for a total of 5 transmit events to create the image
- All transmit events are unfocused
- The receive signal is sampled so that 20 samples cover the depth of the image
- Each point in the image can be represented by IP (x,y) where x is the lateral direction and is restricted to the width of the image (which equals the width of the probe) and y is the axial direction and is restricted to the depth of the image
- The distance between IP (x,y) and a particular probe element is defined as d_{EN} where N is the element number 1-10

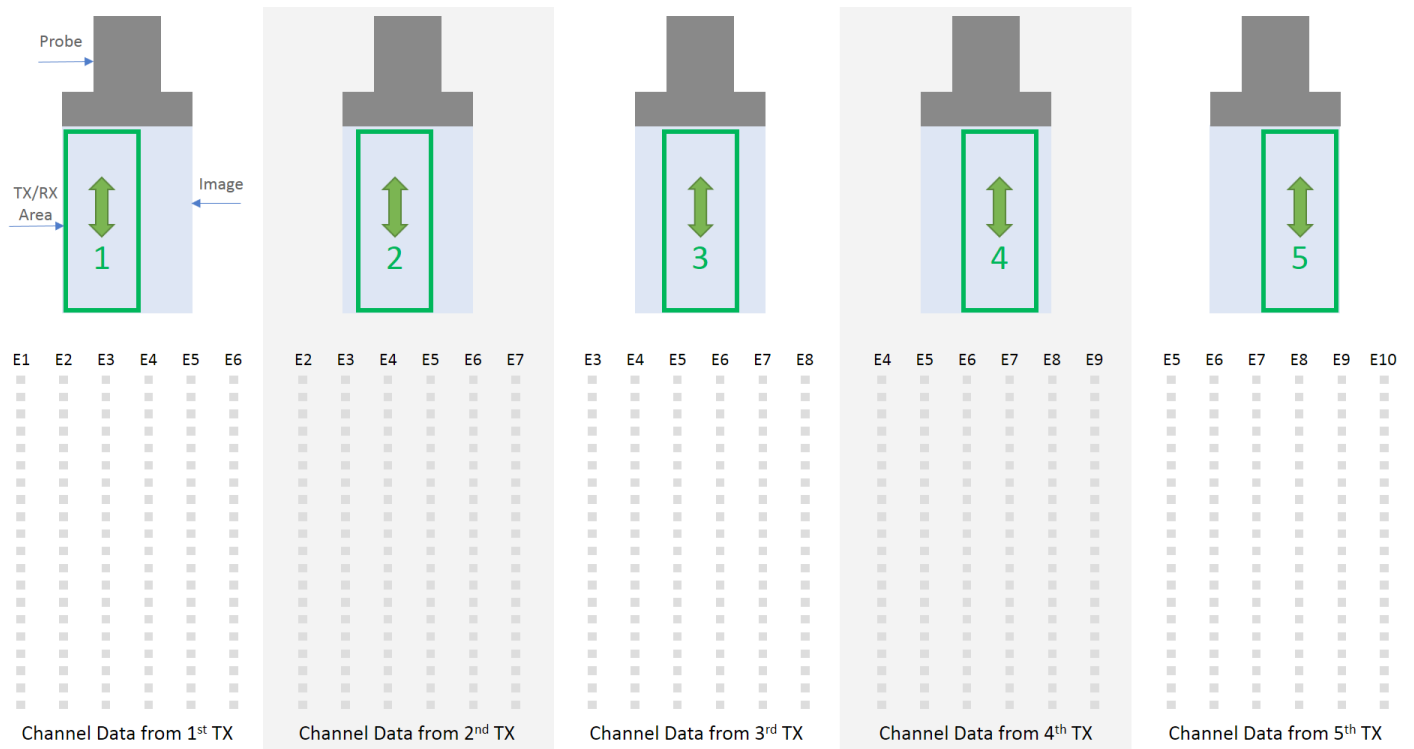


Figure 4. The first transmit (1) occurs and channel data is collected and stored. This is repeated for subsequent transmits (2 through 5) which are each offset from the previous.

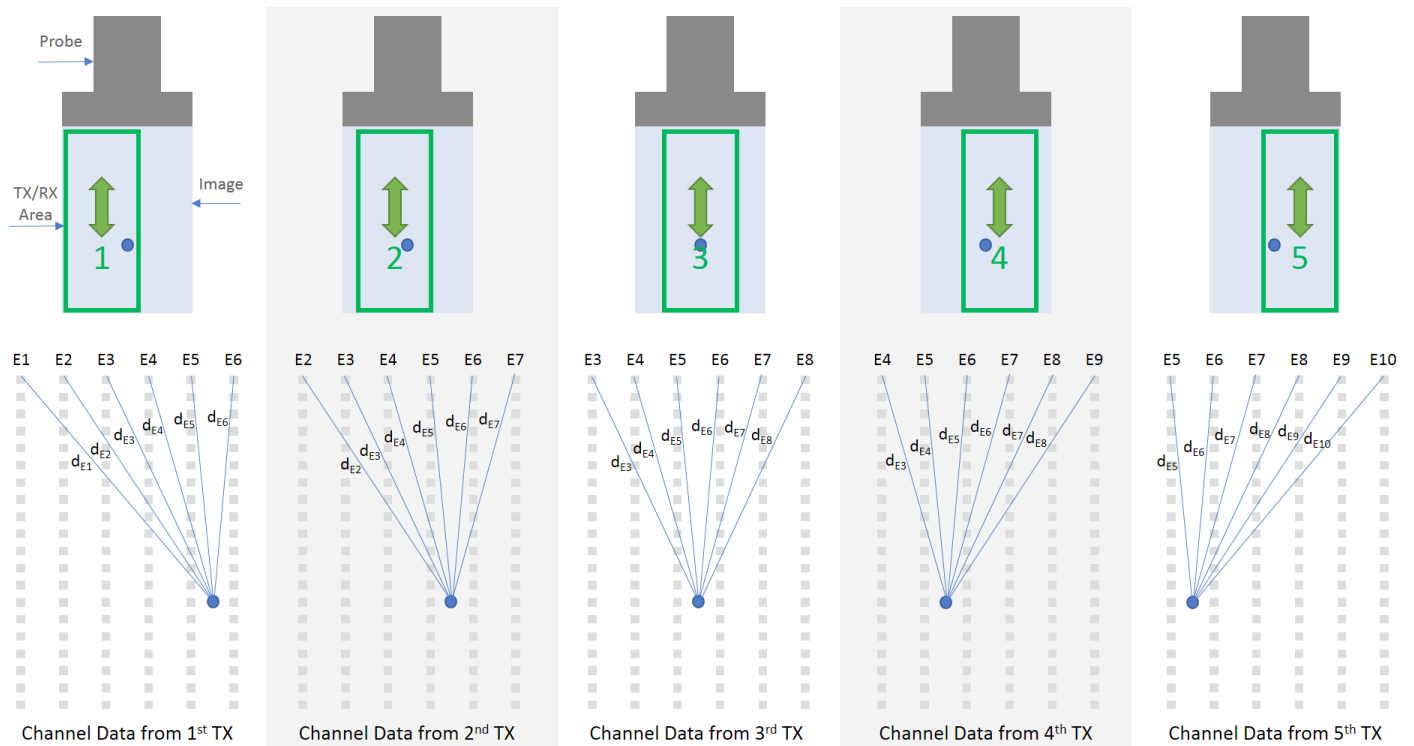


Figure 5. For each set of relevant channel data, the distance between the deep image point (represented by the circle) and each probe element is computed.

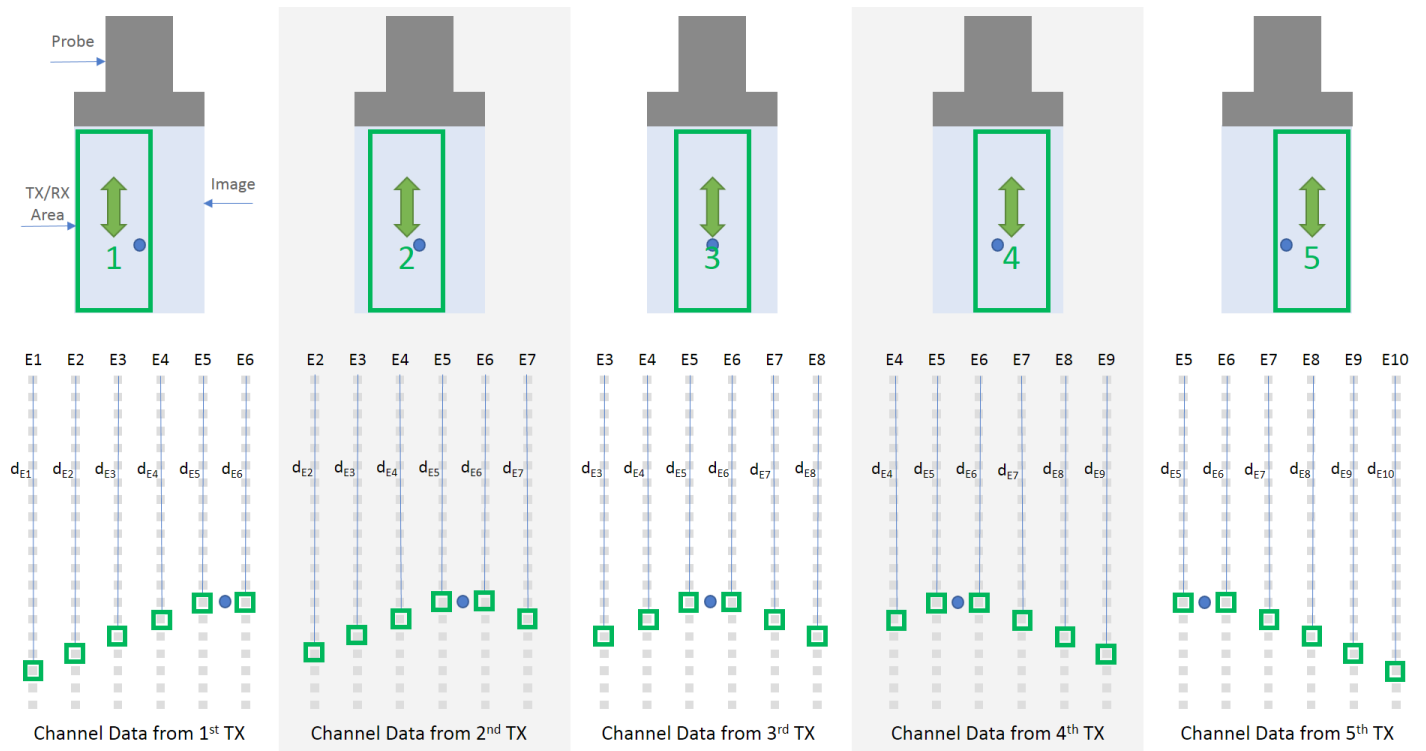


Figure 6. The computed distances between the image point and each element are used to access the channel data that focuses on the image point. The selected channel data from each transmit is coherently summed to determine the signal associated with the image point.

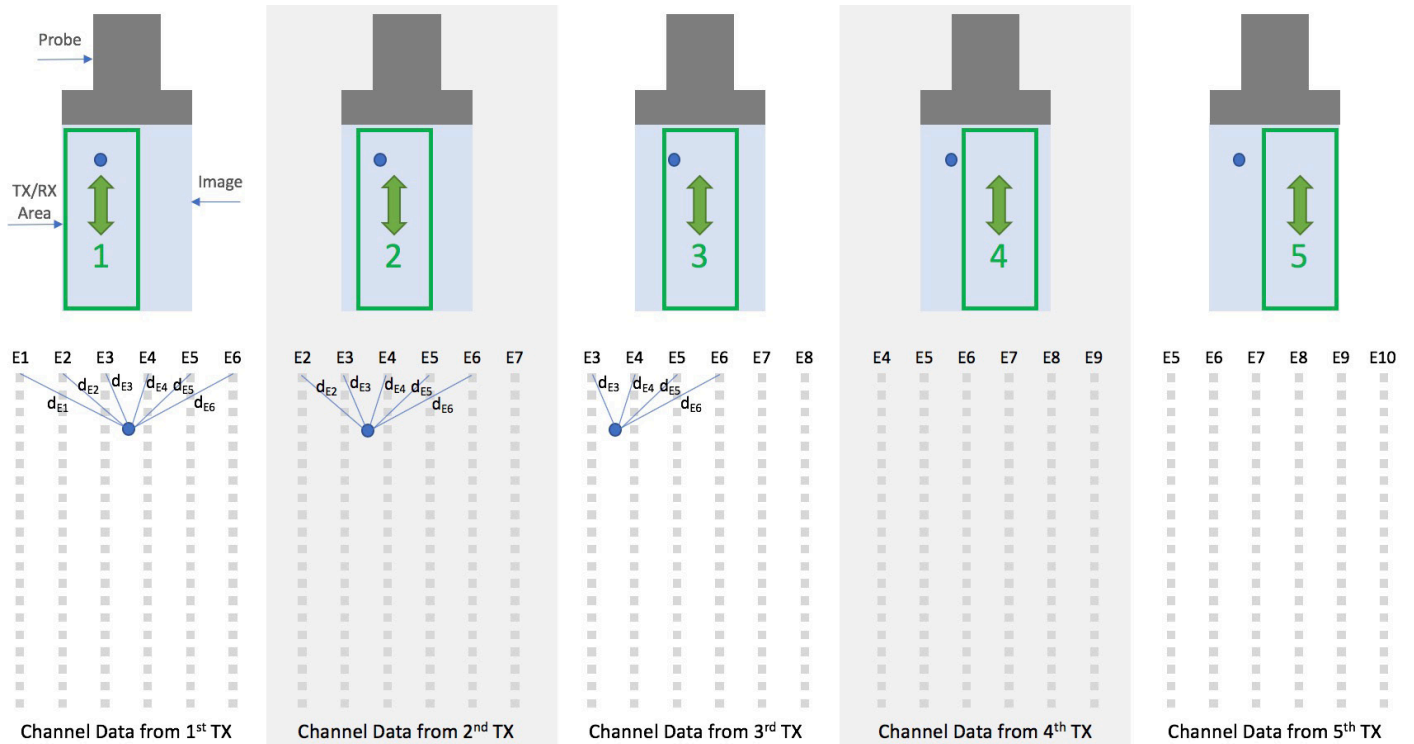


Figure 7. For each set of relevant channel data, the distance between the shallow image point (represented by the circle) and each probe element is computed. Note that transmits 4 and 5 do not overlap with the image point. Further note that some elements, such as E7 and E8 on transmit 3, are not included because of their steep angle relative to the image point.

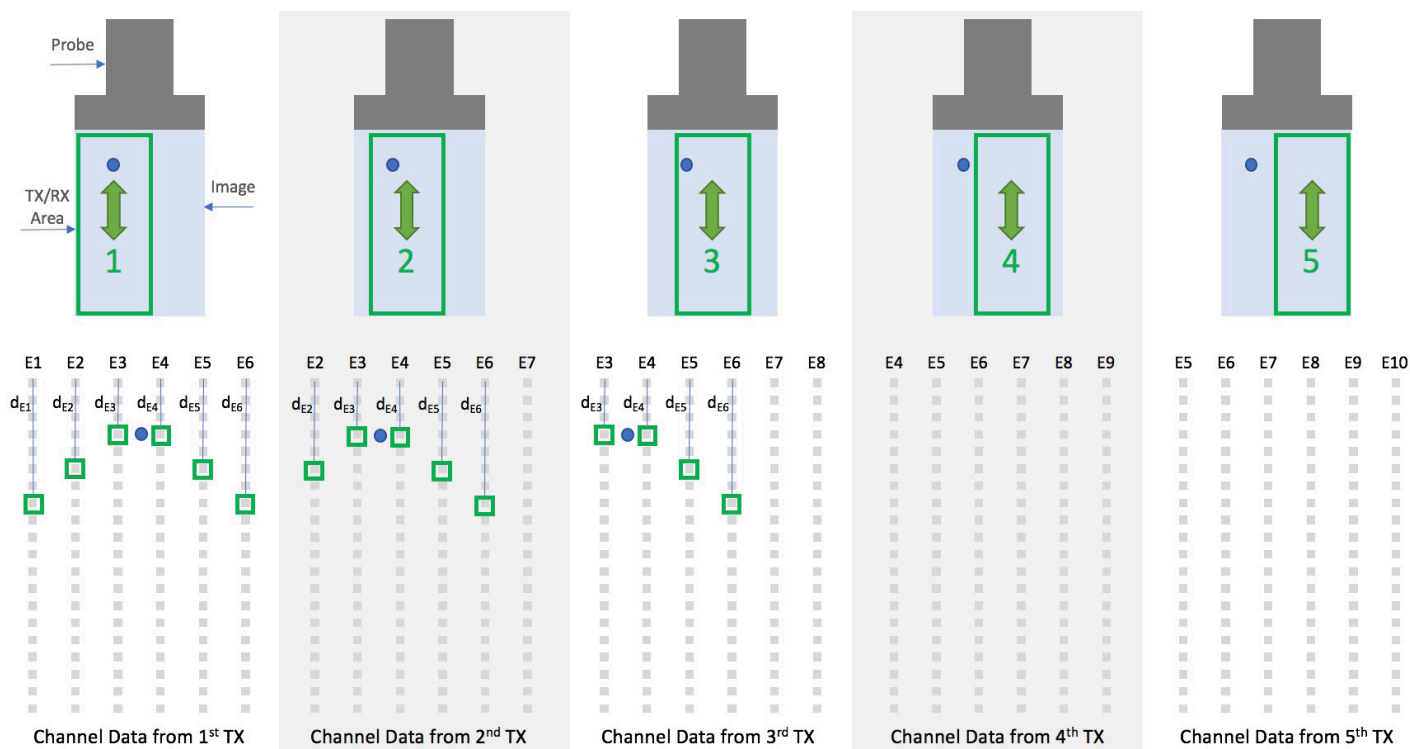


Figure 8. The computed distances between the image point and each element are used to access the channel data that focuses on the image point. The selected channel data from each transmit is coherently summed to determine the signal associated with the image point.

When extending this simplified scenario to the cSound Imageformer, there are additional complexities to consider. For example, the geometry of the transducer and the delay profile of the transmit event impact the computation of the image point to probe element distance and therefore the offset needed to reference the correct channel data. In another difference, the received elements are often larger than the number of transmit elements. Most notably, the sheer volume of data puts extensive demands on the system:

- The large quantity of collected channel data must be reliably and quickly streamed to the channel data memory before additional channel data is collected from the next transmit
- A massive amount of channel memory is required to store the channel data collected from many transmit events
- The retrospective processing of each relevant set of channel data for each point in the image requires intensive, ultra-high-speed, parallel computations to be performed to achieve real-time imaging at very high frame and volume rates

In a less powerful system, the real-time nature of imageforming could be achieved by restricting the amount of data collected by each transmit; speed would come at the expense of image quality. The cSound Architecture, in contrast, is able to keep up without restricting the data, even in radiology's most challenging applications. To put the cSound Architecture's performance in context, it can move the equivalent of multiple DVDs worth of data in one second.

cSound Imageformer – Benefits

Imagine an ultrasound department where no image is acquired with the focal zone in the wrong position. With each point in the image in focus, the user doesn't need to select multiple focal zones or to move the focus position. Additionally, there are no trade-offs between near- and far-field image quality. Deep liver imaging provides detailed data from the capsule to the diaphragm. When biopsying a deep lesion, there is no compromise to needle visualization as it enters the image area. When surveying breast tissue, a clinician is able to see small lesions present from the skin line to the chest wall – all without the user having to make any adjustments.

While greater focal range in ultrasound has traditionally meant lower frame rates, cSound Imageforming actually increases frame rates. It requires a smaller collection of transmit events, a direct result of efficiently using the data collected from each individual transmit event. To understand this efficiency, consider that an ultrasound transmit event can be focused, but the sound energy still travels in many directions; it acts like a flashlight rather than a laser.

Though a flashlight generates maximum light energy in the center of its beam, there is still useful visual information in the light outside of the central beam. Similarly, there is much useful ultrasound image data in the sound that propagates outside the focused direction and the cSound Imageformer is designed to take full advantage of this data.

cSound Imageformer – A Platform for Growth

cSound Imageforming runs on high performance NVIDIA GPUs, but the imageforming algorithms are software based. This affords significant flexibility; the algorithms can be adjusted for specific applications and evolve over time without impacting the underlying hardware architecture. In addition to forming the image, current algorithms can incorporate Adaptive Contrast Enhancement (ACE) and other GE proprietary techniques to boost the real image signal and suppress artifact. And with advances in GPU technology, there is potential to incorporate newer GPUs into the platform, enabling even more sophisticated algorithms.

Advanced Raw Data Post Processor

The improved images resulting from the cSound Imageformer flow into the Advanced Raw Data Post Processor where additional enhancement is performed by spatial compounding, frame averaging, advanced speckle reduction imaging (Advanced SRI), and other functions. The post-processed image data is then mapped to gray scale levels and the scan is converted for display to the operator.

While speckle reduction imaging has been a feature of ultrasound systems for many years, Advanced SRI is GE's most sophisticated algorithm to date, and requires the expanded computational power of the cSound architecture to achieve real-time results. It employs proprietary processing steps at different resolutions of the raw image data to smooth speckle-based artifacts while simultaneously enhancing structures of all sizes within the image. The level of smoothing and enhancement is adjustable by the user.

The "Raw Data" aspect of the Advanced Raw Data Post Processor refers to the fact that image data is saved prior to the processing steps. This allows the user to continue to adjust the processing long after the images have been saved.

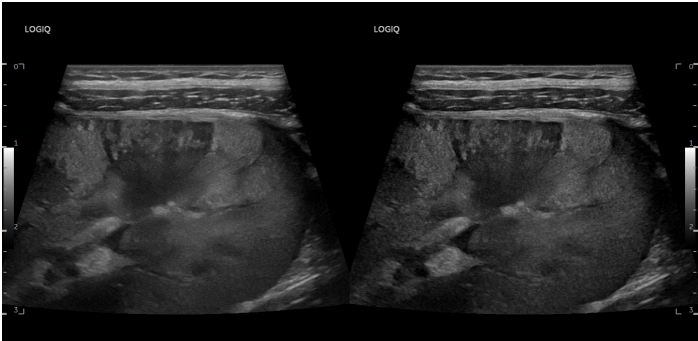
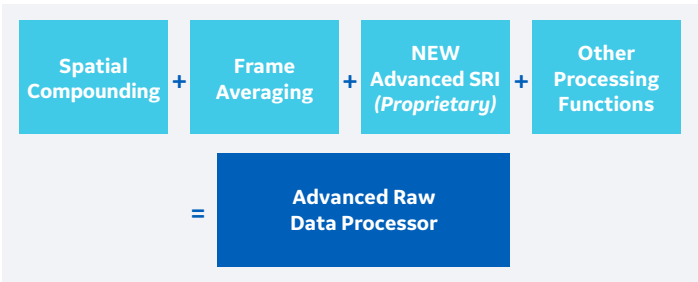


Figure 9. Advanced SRI (right) takes advantage of the increased computational power of the cSound Architecture to identify and enhance structures of all sizes while reducing speckle-based artifacts.



XDclear Probes

While cSound Imageforming provides numerous benefits over traditional beamforming, the quality of the acoustic data coming into the system is still of utmost importance. In combination with the cSound Architecture’s state-of-the-art transmit and receive electronics, XDclear transducers help deliver a more powerful, pure, and efficient sound wave with wider bandwidth than traditional GE transducer technology. This results in impressive deep penetration and high resolution, enabling ultrasound to be used effectively on a broad range of patients.



Figure 10. XDclear probes: Derive their superior performance from three key technologies: Single Crystal, Cool Stack, and Acoustic Amplifier.

XDclear transducers are a proprietary combination of advanced materials and innovative design. The XDclear design incorporates an enhanced piezoelectric material, Single Crystal, to generate a high quality acoustic signal. The quality of that signal is preserved through an innovative Acoustic Amplifier design coupled with GE’s Cool Stack technology to help optimize energy management. The ability to effectively and efficiently combine these technologies is what makes XDclear extraordinary.

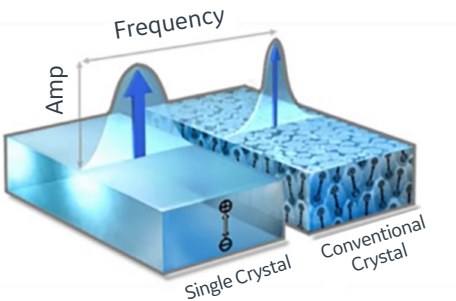


Figure 11. *Single Crystal*: Advanced piezoelectric material that delivers high quality acoustic signal with a wider bandwidth than conventional piezoelectric material.

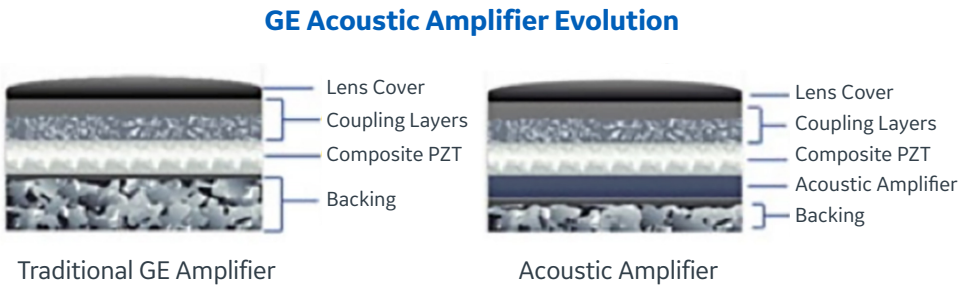


Figure 12. *Acoustic Amplifier*: Preserves the acoustic signal through an innovative design that captures and redirects the unused energy that passes through the crystal to enhance sensitivity, axial resolution, and penetration.

XDclear transducers enable deep penetration and resolution. One objective measure of transducer performance is bandwidth: the range of frequencies that the transducer can transmit and receive. Increased bandwidth allows a transducer to cover a broader frequency range, which makes it possible to achieve deep penetration and high resolution, as well as enhanced performance in harmonic imaging.

With sufficient bandwidth, one transducer can cover the range of acoustic frequencies that previously required separate transducers. XDclear transducers with Single Crystal materials have measurably enhanced bandwidth, achieving a -6 dB fractional bandwidth that can exceed 100 percent compared with 70 to 80 percent for traditional GE transducers. The result is a new level of penetration, resolution, and sensitivity in GE transducer performance.

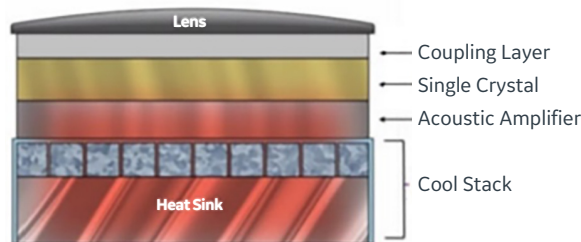


Figure 13. *Cool Stack*: Optimizes energy usage via patented technology integrated into the transducer's internal architecture; it relieves inherent heat generation that can otherwise reduce sensitivity and penetration.

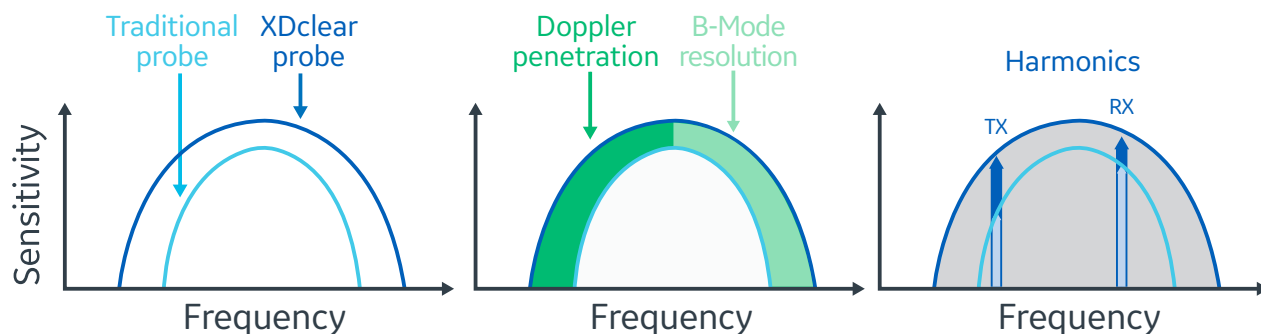


Figure 14. XDclear probe performance benefits are derived from improved sensitivity and wider bandwidth.

cSound Architecture Summary

The cSound Architecture leverages next-generation data rates and processing power that were previously unavailable, allowing significantly more data to be collected and used to create every image. This additional data is used to achieve focus at every point and to increase contrast and spatial resolution—all while significantly improving frame rates. Combined with the performance advantages of XDclear probes and the Advanced Raw Data Post Processor, these advancements make the cSound Architecture an excellent imaging system for today and its flexible design makes it a powerful imaging platform for tomorrow.



*As compared to the LOGIQ™ E9.

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March 2022
JB19417XX





EC DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745

Following the directive 2011/65/EU, directive 2014/53/EU

We

Manufacturer and manufacturing site	EU Authorized Representative
GE Ultrasound Korea, Ltd. 9, Sunhwan-ro 214beon-gil, Jungwon-gu, Seongnam-si Gyeonggi-do 13204, Republic of Korea SRN: KR-MF-000001860	GE Medical Systems SCS 283 rue de la Minière 78530 BUC, France SRN: FR-AR-000000344

Declare under our sole responsibility that the device:

LOGIQ Fortis

Basic UDI-DI: **8406821BUG00214GZ**

Identification number:

REF Catalog	H-Catalog Number	UDI-DI
LOGIQ Fortis HDU	H43302LA	00195278405326
LOGIQ Fortis LCD	H43302LB	00195278405333

Intended Purpose: The LOGIQ Fortis is a general-purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid.

EMDN Code: **Z110401**

EMDN Description: Ultrasound Scanners

GMDN Code: **40761**

GMDN Description: General-purpose ultrasound imaging system

UMDNS Code: **15-976**

Classification: **Ila**

Classification rule (Annex VIII): **Rule 10, Class: Ila**

To which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 that apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) and the directive 2014/53/EU on the radio equipment (RED).



This conformity is based on the following elements:

- Technical Documentation reference: DOC2379389, of the product to which this declaration relates.
- EC certificate No. HZ 2004702-01:
 - Conformity assessment procedure followed: Annex IX of the medical device regulation 2017/745
 - Delivered by TUV Rheinland LGA Products GmbH (Notified Body n° 0197)

This EC declaration of conformity is the initial release.

SIGNATURE:

Date of issue: 13-12-2021
Place of issue: China
Name: Qingmeng Chen
Function: Regulatory Affairs Program Manager
Signature:

Qingmeng Chen



ADDENDUM TO THE EC DECLARATION OF CONFORMITY
LOGIQ Fortis including accessories and components
dated 13-12-2021

Product Description	H-Catalog Number ¹
Ultrasound Console	
LOGIQ Fortis HDU Console	H43302LA / 6602000
LOGIQ Fortis LCD Console	H43302LB / 6601000
Probe Options²	
IC5-9-D	H40442LK
ML6-15-D	H40452LG
L8-18i-D	H40452LL
C2-9-D (XDClear)	H40462LN
C1-6-D (XDClear)	H40472LT
C1-6VN-D (XDClear)	H40472LW
C2-9VN-D (XDClear)	H40472LY
C3-10-D (XDClear)	H40482LB
M5Sc-D (XDClear)	H44901AE
L2-9-D	H44901AI
L2-9VN-D	H44901AJ
6Tc-RS	H45551ZE
C2-7-D	H46422LM
C2-7VN-D	H46422LN
P2D	H4830JE
RIC5-9-D	H48651MS
RAB6-D	H48681MG
P6D	H4830JG
BE9CS-D	H40482LE
L3-12-D	H48062AA
6S-D	H45021RR
L6-24-D Probe	H4920HF
TEE Probe Accessories²	
TEE RS-DLP Adapter	H46352LK
Adult TEE Clip-on Bite Guard	H45511EE
Adult TEE Clip-on Bite Guard Opr.	H45521CB
Adult TEE Scanhead Protection Cover	H45521CK
Adult TEE Conventional Bite Guard	H45521JH
BITE HOLE INDICATOR	H45531HS
TEE STORAGE RACK	H45551NM
Software Options	
Advanced Security	H46622LL
Coded Contrast	H43332LA
Parametric Imaging	H43332LB
Cardiac AFI	H46622LN
LOGIQ Exx DVR	H4918DR
Report Writer	H46622LR
Stress Echo	H46622LS
Tricefy	H46622LT
LOGIQ Apps	H46622LW
KOIOS SW	H46622LY
LOGIQ Exx KOIOS Thyroid	H4920KT
LOGIQ E10 KOIOS INSTALL	H4919KI



Product Description	H-Catalog Number ¹
KOIOS 3.x INSTALL	H4921KY
Scan Assistant	H46622LZ
Advanced Probes	H46612LS
AUTO IMT	H46612LT
B Steer+	H46612LW
B-FLOW	H46612LY
Compare Assistant	H46612LZ
DICOM	H46622LA
FLOW QA	H46622LB
Measure Assist Breast	H46622LC
Measure Assist OB	H46622LD
Elastography	H43332LC
Elasto QA	H43332LD
Shear Wave Elastgraphy	H46622LE
LOGIQ Exx SRI HD Type2	H4920SR
UGAP	H46622LH
SonoNT SonoIT	H46622LJ
LOGIQ Exx VNAV Image	H4920VR
Hepatic Assistant - SWE-UGAP	H43332LE
Omni View	H43332LF
STIC	H43332LG
TUI	H43332LH
VCI-Static	H43332LJ
VOCAL_II	H43332LK
Thyroid Productivity	H43332LL
Breast Productivity	H43332LM
Vita on Demand	H43332LN
Hardware Options²	
CW Doppler	H43342LA
Realtime 4D	H43342LB
ECG Option	H43342LC
Scan on battery option kit	H43342LD
Power Assistant	H43342LE
Volume Navigation	H43342LF
Volume Navigation for V-Nav Inside T1	H43372LK
Wireless Option	H43342LG
S-Video Option	H43342LH
Pencil CW	H43342LJ
Peripheral Options²	
USB FOOTSWITCH 3 BUTTON	H46732LF
SONY UPD25MD COLOR PRINTR	H4911JT
BW Printer Installation Kit T1	H43342LK
LOGIQ Exx Protective Cover	H4918DC
LOGIQ Exx Inkjet Printer	H4918RP
LOGIQ Fortis High Cabinet	H43342LL
LOGIQ Fortis Low Cabinet	H43342LM
LOGIQ Fortis Side Cabinet	H43342LN
Sinch bay Option	H43342LP
An Keyboard Assembly	
AN Keyboard ENGLISH	H43342LR
AN Keyboard GERMAN	H43342LS
AN Keyboard FRENCH	H43342LT
AN Keyboard GREEK	H43342LW
AN keyboard NORWEGIAN	H43342LY



Product Description	H-Catalog Number ¹
AN Keyboard SWEDISH	H43352LA
Accessories²	
Ethernet protection Cable	H43272LJ
FC389,ECG CABLE SET	H45521AL
VNav Stand (Offboard)	H4908NS
ECG CABLE - AHA STYLE	H4910EC
VNav NEEDLE TRACKING	H4910NT
VNav VirtuTRAX Starter Kit	H4910NY
ECG Cables IEC Style	H4911JC
VNav Virtual Tracker	H4911NG
VNav Active Tracker kit	H4913AT
VNav Needle Tracking storage insert	H4913NS
VNav Needle Tracking Kit - 18/20g or less	H4913NT
VNav ETRAX 12 14G ST KT	H4913NU
VNav ETRAX 14 16G ST KT	H4913NV
VNav Probe sensors	H4913PS
VNav MR Active Tracker	H4915MT
Small Probe Holder	H43352LC
VERTICAL TV PROBE HOLDER	H43352LD
TVTR Probe Holder	H43352LE
PROBE CABLE HANGER	H44412LA
OPTION TRAY BOX	H43372LF
OPTION TRAY Bracket	H43372LG
Power Cords Destination Sets	
Power Cord 220V for EU	H46342LZ
Power Cord DK STD C13 GRY	H46692LK
DESTINATION SET UK	H46712LM
DESTINATION SET SWISS	H46712LS
DESTINATION SET DENMARK	H46712LT
DESTINATION SET ITALY	H46722LD
V-nav Options²	
ML6-15 M_BPSY_TRU3D_SKIT	H40432LK
C3-10 VNav Holder Starter Kit	H40482LF
IC5-9 V NAV BRACKET	H4908NF
L8-18I V NAV BRACKET	H4908NH
M5S V NAV BRACKET	H4908NM
Biopsy Kits²	
E721 STARTER KIT	E8385MJ
IC5-9-D Reusable Biopsy Guide	H40412LN
ML6-15 M_BIOPSY_SKIT	H40432LJ
C2-7 Biopsy Kit	H40482LK
C2-7 Biopsy Kit Stainless	H40482LL
L2-9 Needle Guide Starter Kit	H44901AM
M5Sc-D Biopsy Bracket	H45561FC
RAB BIOPSY STARTER KIT	H46701AE
RIC5-9-D Biopsy Guide	H46721R
C2-9 Biopsy Starter Kit	H4913BA
C1-6-D Verza Biopsy Starter Kit	H4917VB
C1-6-D Biopsy Starter Kit	H4913BB
L3-12-D Biopsy Kit	H48302AA
RAB6-D BIOPSY STARTER KIT	H48681ML
BE9CS Biopsy Kit 742-401	H42742LJ



Notes:

[1] *H-Catalog number identifies the device(s) in the manufacturer's catalog and is usually included on commercial documents like sales contract, order processing documents and shipping documents.*

[2] *Probes and accessories may carry the CE-mark and when applicable, the Notified Body number corresponding to the EC Declaration under which the products are CE-marked by their manufacturer. GE Ultrasound Korea Ltd. has verified the mutual compatibility of the devices in combination with LOGIQ Fortis and included relevant information to users with the LOGIQ Fortis instructions for use.*

End of Document

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

GE ULTRASOUND KOREA, Ltd.

9, Sunhwan-ro 214beon-gil, Jungwon-gu,

SEONGNAM-SI, GYEONGGI-DO, REPUBLIC OF KOREA

Catégorie du(des) dispositif(s) / Device(s) category

Dispositif ou système de diagnostic par ultrasons

Ultrasound diagnostic device or system

Voir document complémentaire GMED / See GMED additional document

n° 36988

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P183396, P601203, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

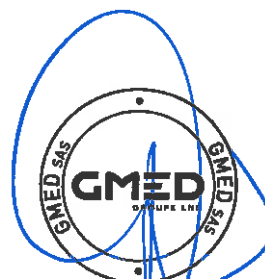
GMED certifies that, on the basis of the results contained in the file referenced P183396, P601203, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : September 14th, 2020 (included)

Valable jusqu'au / Expiry date : May 26th, 2024 (included)



Lionel DREUX
Certification Director

Ce document complémentaire GMED n° 36988 rev. 0 atteste de la validité du certificat CE n° 7697 rev. 18 au regard des informations listées ci-dessous.

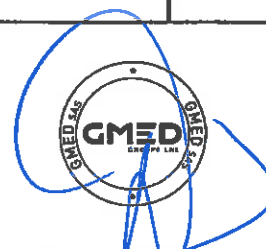
This GMED additional document N° 36988 rev. 0 attests to the validity of CE certificate n° 7697 rev. 18 with regard to the information listed below.

Fabricant / Manufacturer:

GE ULTRASOUND KOREA, Ltd.
9, Sunhwan-ro 214beon-gil, Jungwon-gu,
SEONGNAM-SI, GYEONGGI-DO, REPUBLIC OF KOREA

Identification des dispositifs / Identification of devices

Désignation du dispositif / Accessoires marqués CE <i>Device designation / CE marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM MD class
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ P7	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ P8	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ P9	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ P10	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON S6	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON S8	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON S8t	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON S10	Ila



Lionel DREUX
Certification Director

Désignation du dispositif / Accessoires marqués CE <i>Device designation / CE marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM MD class
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON S10 Expert	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON P6	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON P8	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON SWIFT	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON SWIFT+	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ S8	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ S7 Expert	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ S7 Pro	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ S7 XDclear2.0	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ E10s	Ila

Site couvert et Activités / Locations and Activities

Site / Location	Activités / Activities
GE ULTRASOUND KOREA, Ltd. 9, Sunhwan-ro 214beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, REPUBLIC OF KOREA équivalent à equivalent to GE ULTRASOUND KOREA, Ltd. 65-1, Sangdaewon-dong, Jungwon-gu, Seongnam-si, Gyeonggi-do - 462-120 REPUBLIC OF KOREA	Conception, fabrication et contrôle final Design, manufacture and final control



Lionel DREUX

Certification Director

GMED - 36988 rev. 0

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720 GMED 0901-4 rev 0 du 31/08/2020



Certificate

No. Q5 075707 0058 Rev. 02

Holder of Certificate: **GE Healthcare Austria GmbH & Co OG**
Tiefenbach 15
4871 Zipf
AUSTRIA

Facility(ies): GE Healthcare Austria GmbH & Co OG
Tiefenbach 15, 4871 Zipf, AUSTRIA

Design and Development, Production
and Distribution of Diagnostic Ultrasound
Systems, Probes and Standalone Software
for Ultrasound-Image Processing

Certification Mark:



Scope of Certificate: **Design and Development, Production
and Distribution of Diagnostic Ultrasound
Systems, Probes and Standalone Software
for Ultrasound-Image Processing**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 075707 0058 Rev. 02

Report No.: 713202497

Valid from: 2021-11-20

Valid until: 2024-04-23

Date, 2021-11-11

Christoph Dicks
Head of Certification/Notified Body



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LOGIQ Fortis™

Powerful | Streamlined | Multi-purpose
Always ready. Always by your side.

[gehealthcare.com](https://www.gehealthcare.com)





Powerfully streamlined

New GE LOGIQ Fortis

LOGIQ Fortis is the affordable, all-in-one solution for your ultrasound imaging needs. Powerfully streamlined and equipped with the most advanced technology, it helps users deliver on the promise of confident care in multiple clinical settings.

- **Exceeding your expectations** ... with next-generation imaging technologies for a wide range of patients and clinical applications—head to toe, obese to thin, neonate to geriatric
- **Optimizing your productivity** ... with user-friendly apps and AI-based productivity tools, and the ability to scan on battery
- **Maximizing your investment** ... with a future-focused digital platform, robust cybersecurity protection, and value-added lifecycle solutions

LOGIQ Fortis.
Your trusted companion for every body.

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MULTI-PURPOSE/ RADIOLOGY

The high-performing LOGIQ Fortis enables a full spectrum of ultrasound exams and procedures on any body type.

- Exceptional image quality with cSound™ Architecture—now including advanced Speckle Reduction Imaging (SRI)
- Whole body imaging with versatile XDclear™ probes
- Advanced quantification and productivity tools, including 2D Shear Wave Elastography, Ultrasound-Guided Attenuation Parameter (UGAP), CEUS, and Volume Navigation

[+ CLINICAL IMAGES](#)[LOGIQ Fortis Overview](#)

LOGIQ Fortis



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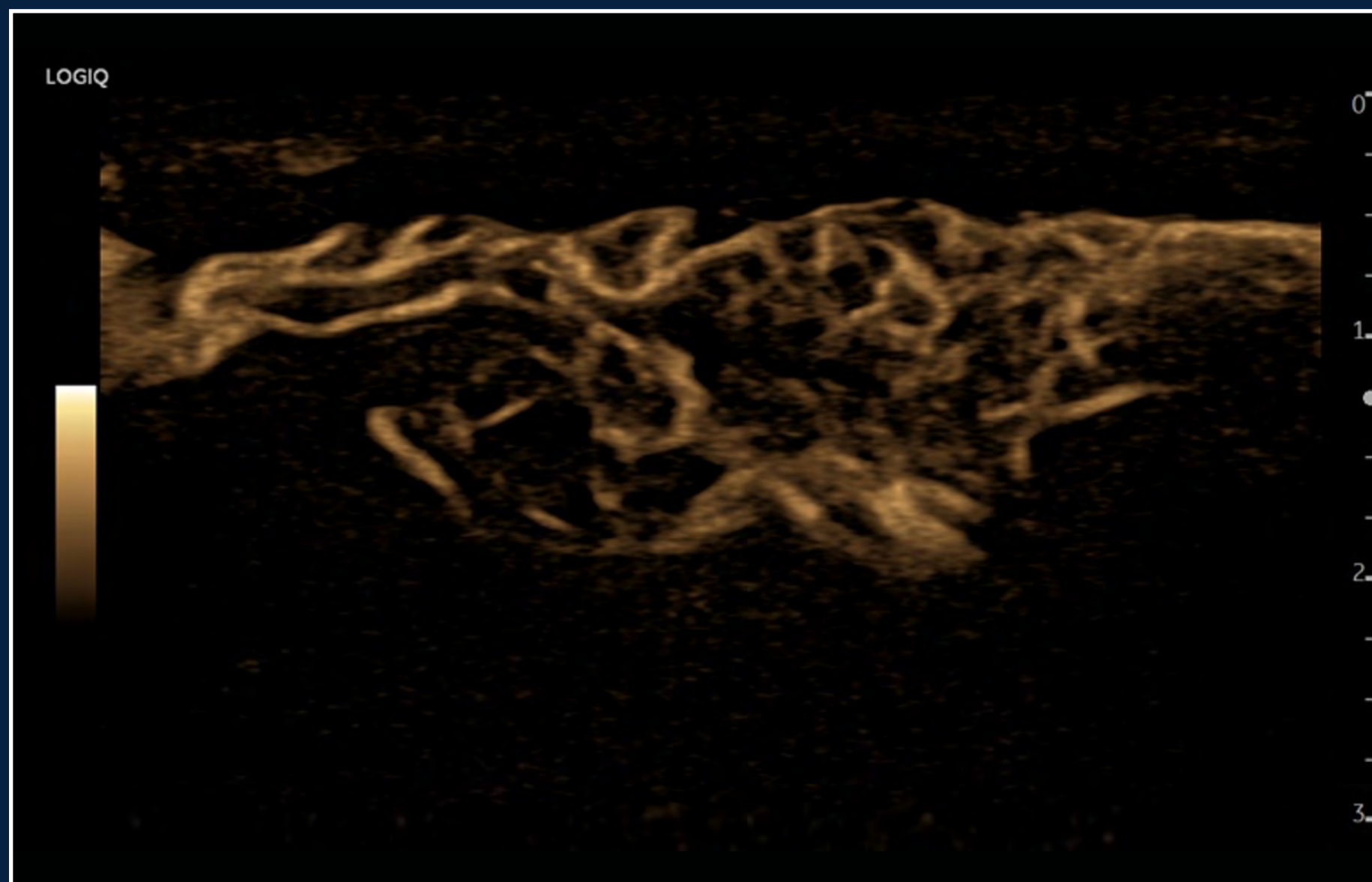
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Exceeding your expectations: whole body imaging



Flow Visualization, B-Flow in Thyroid, ML6-15-D





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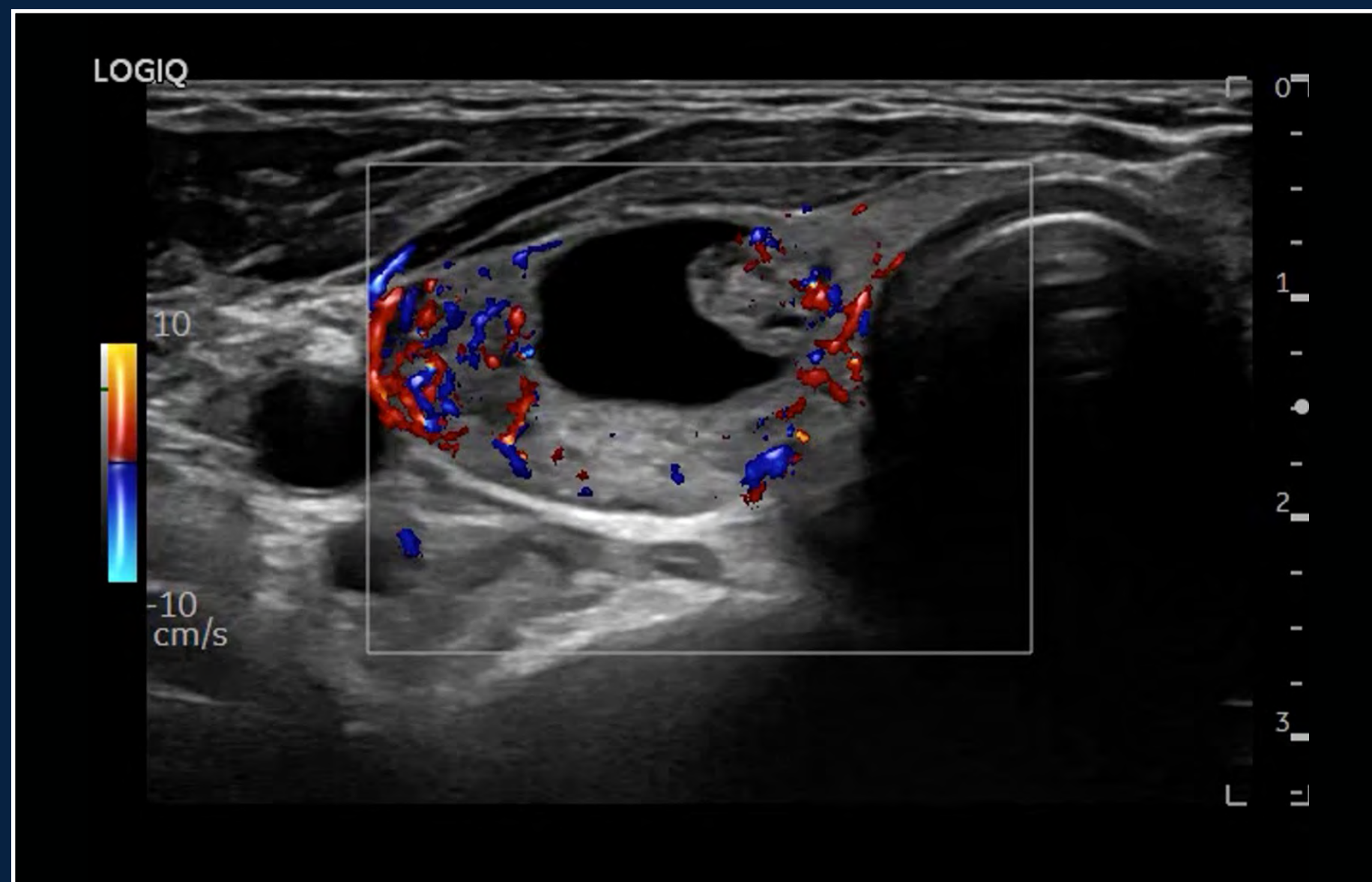
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Radiantflow™ Color Flow in Thyroid, ML6-15-D





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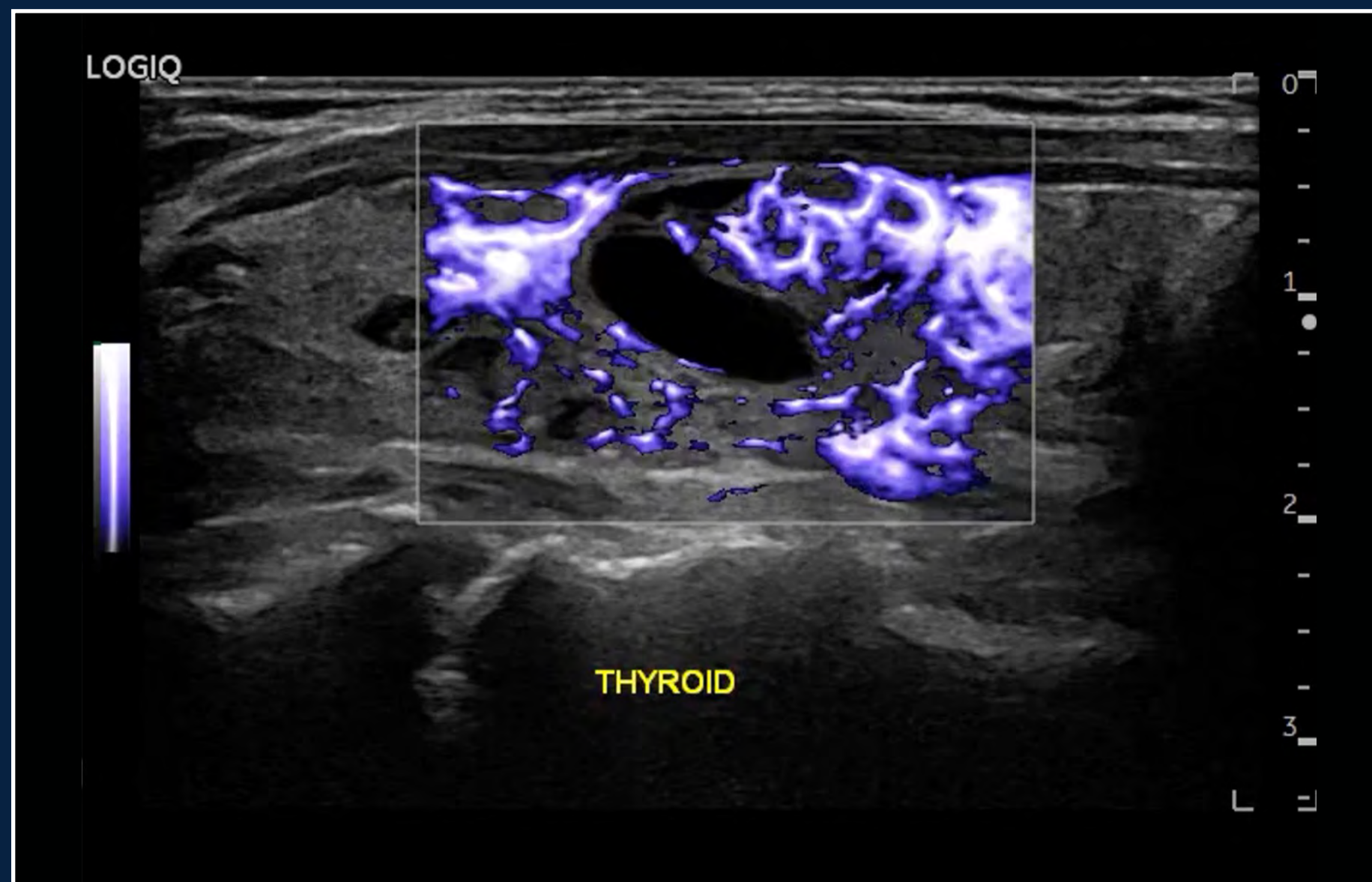
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MVI with Radiantflow in Thyroid, ML6-15-D





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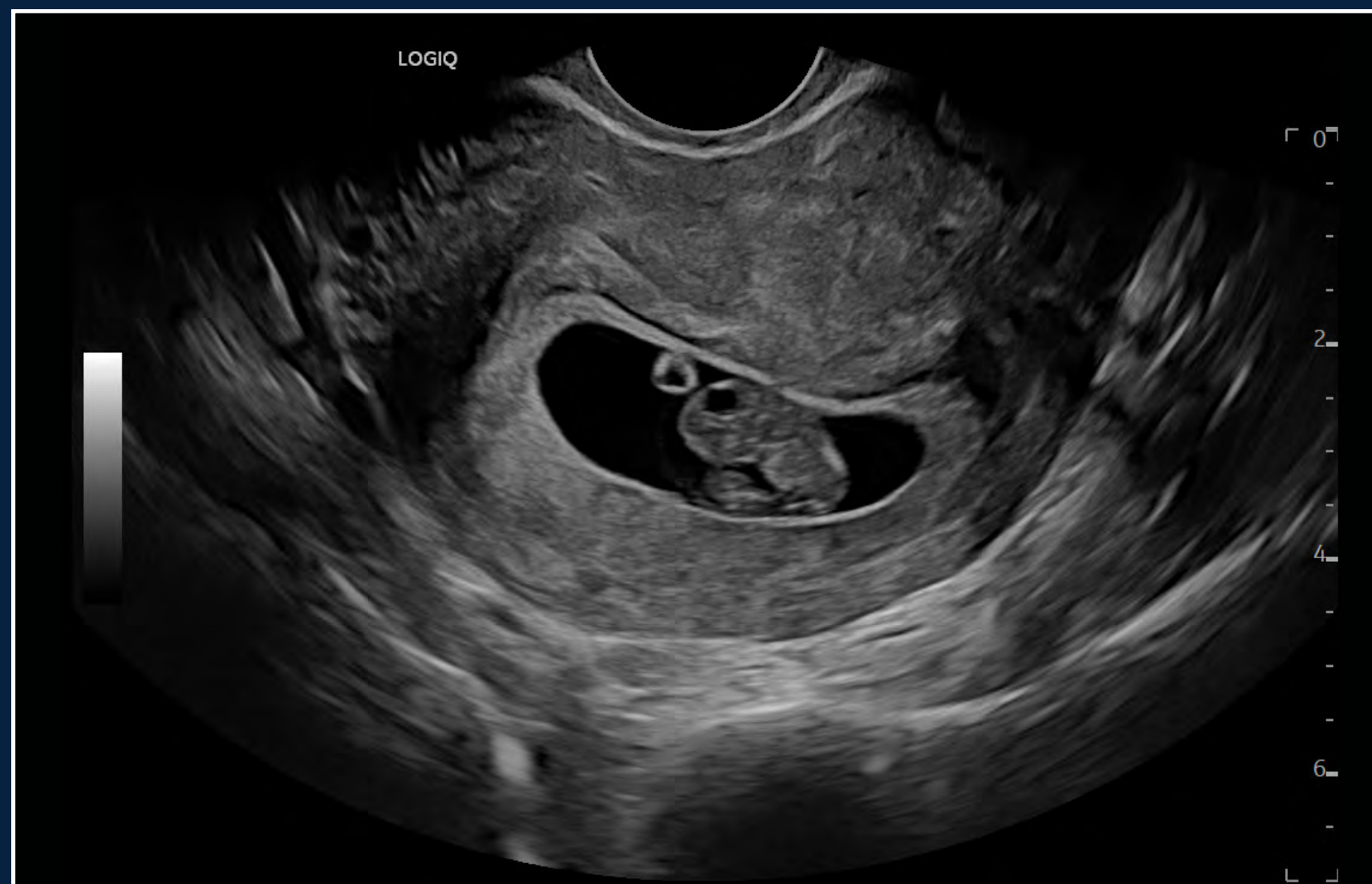
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B-Mode with Advanced SRI Early Fetus and Yolk Sac, IC5-9-D





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PDI with Radiantflow in Umbilical Cord, C1-6-D





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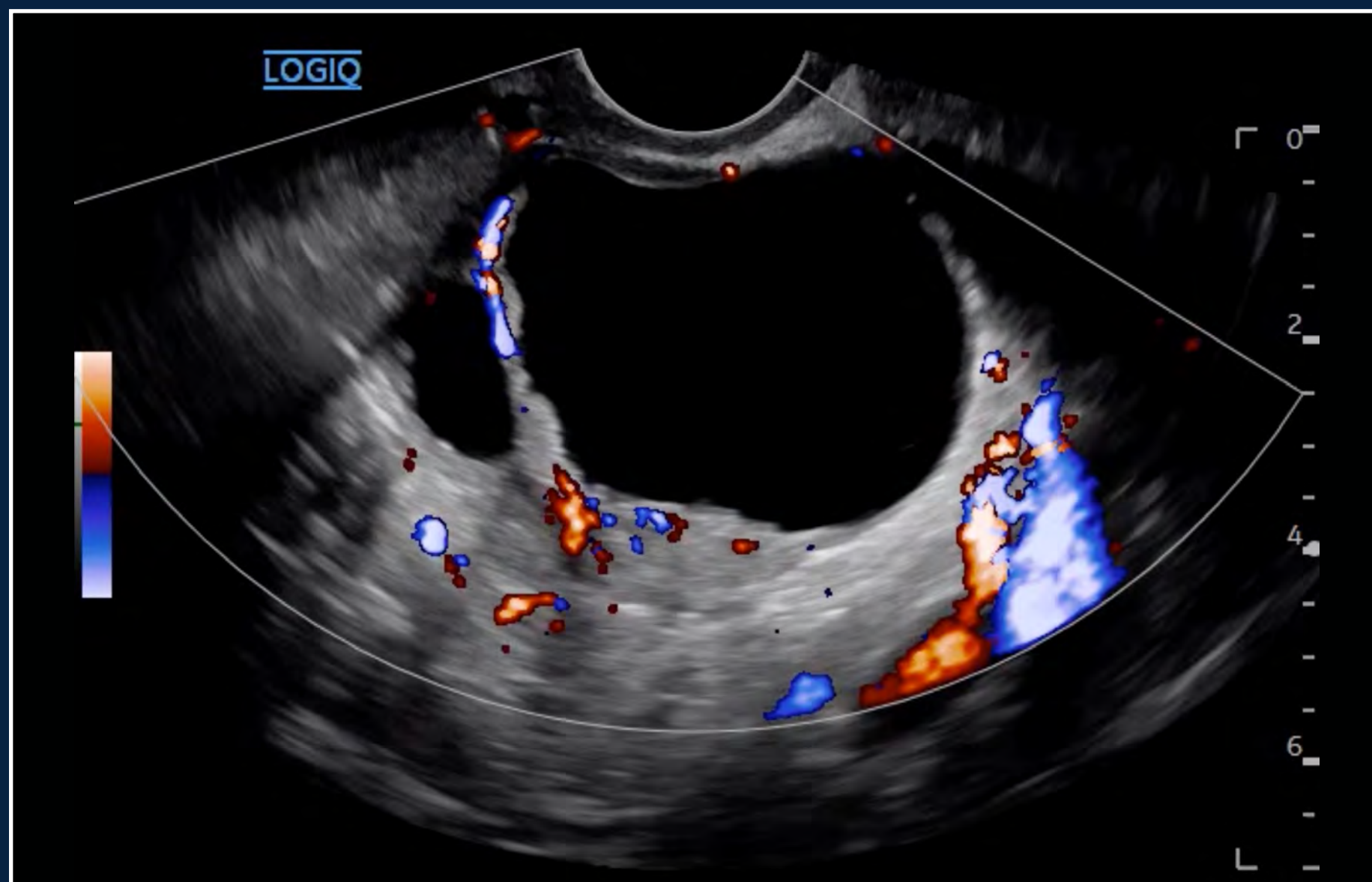
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PDI of Ovary, IC5-9-D





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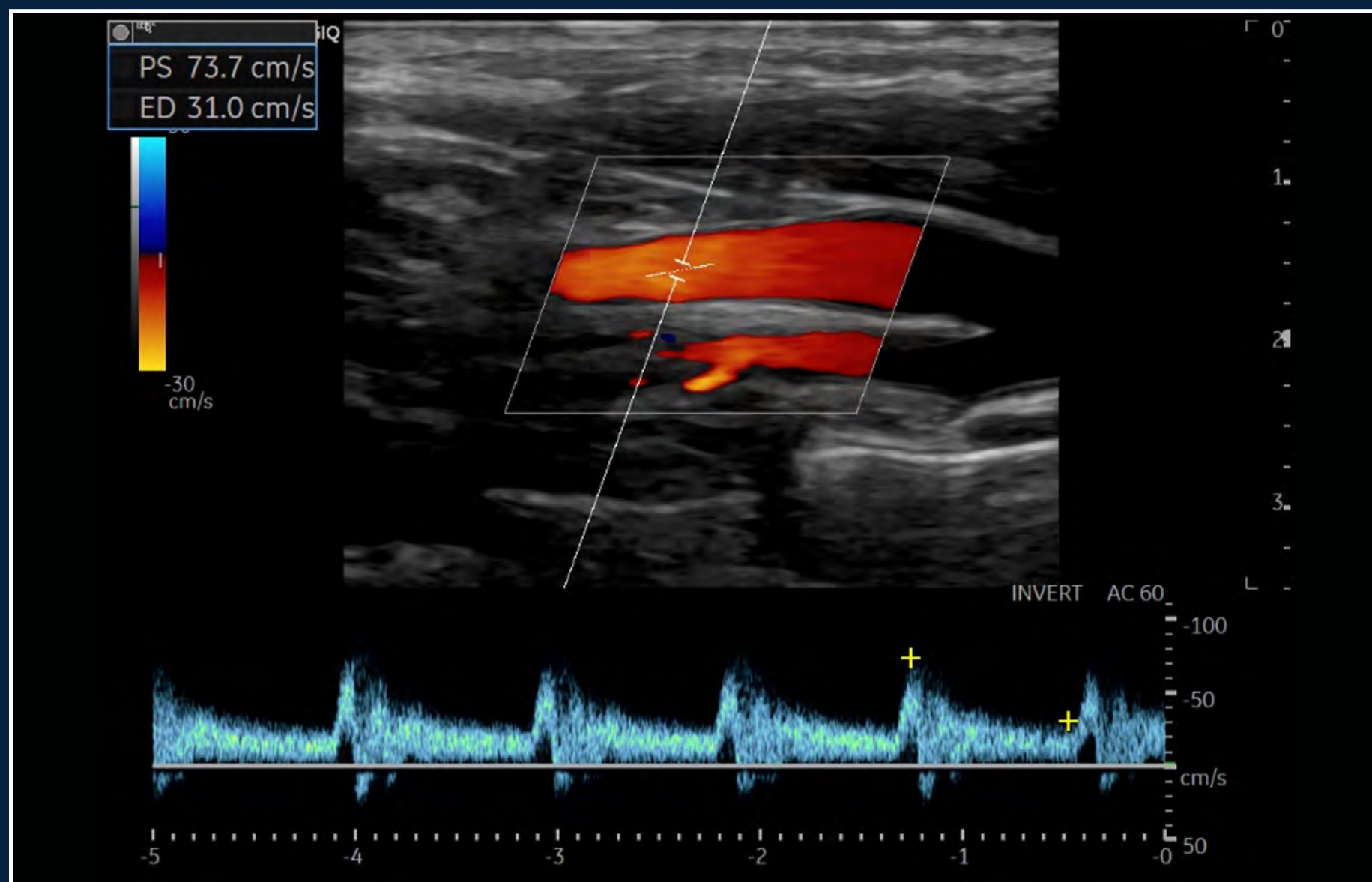
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Exceeding your expectations: whole body imaging



Color Flow and PW Doppler in Internal Carotid Artery, L2-9-D





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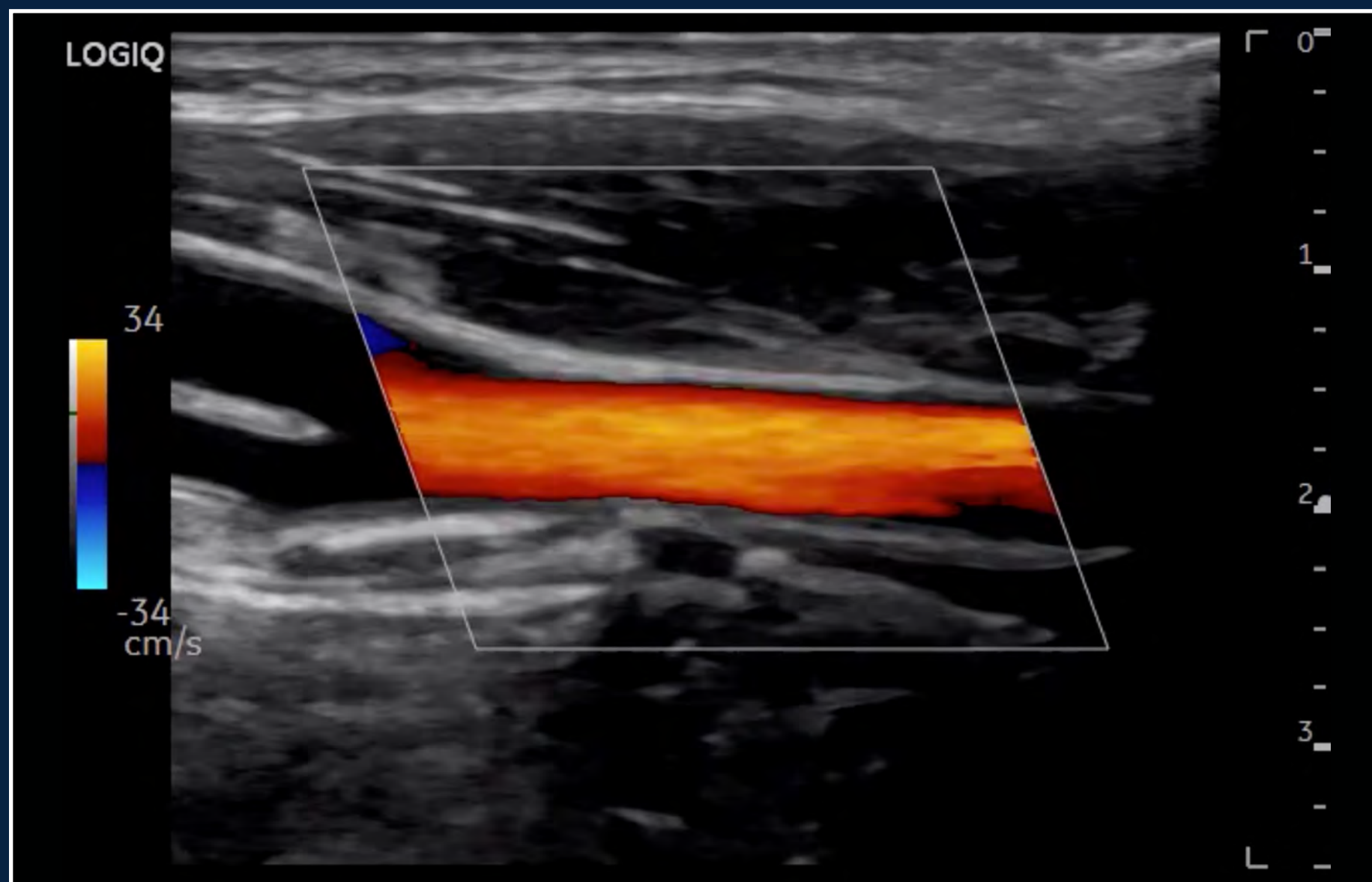
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Color Flow Carotid, L2-9-D





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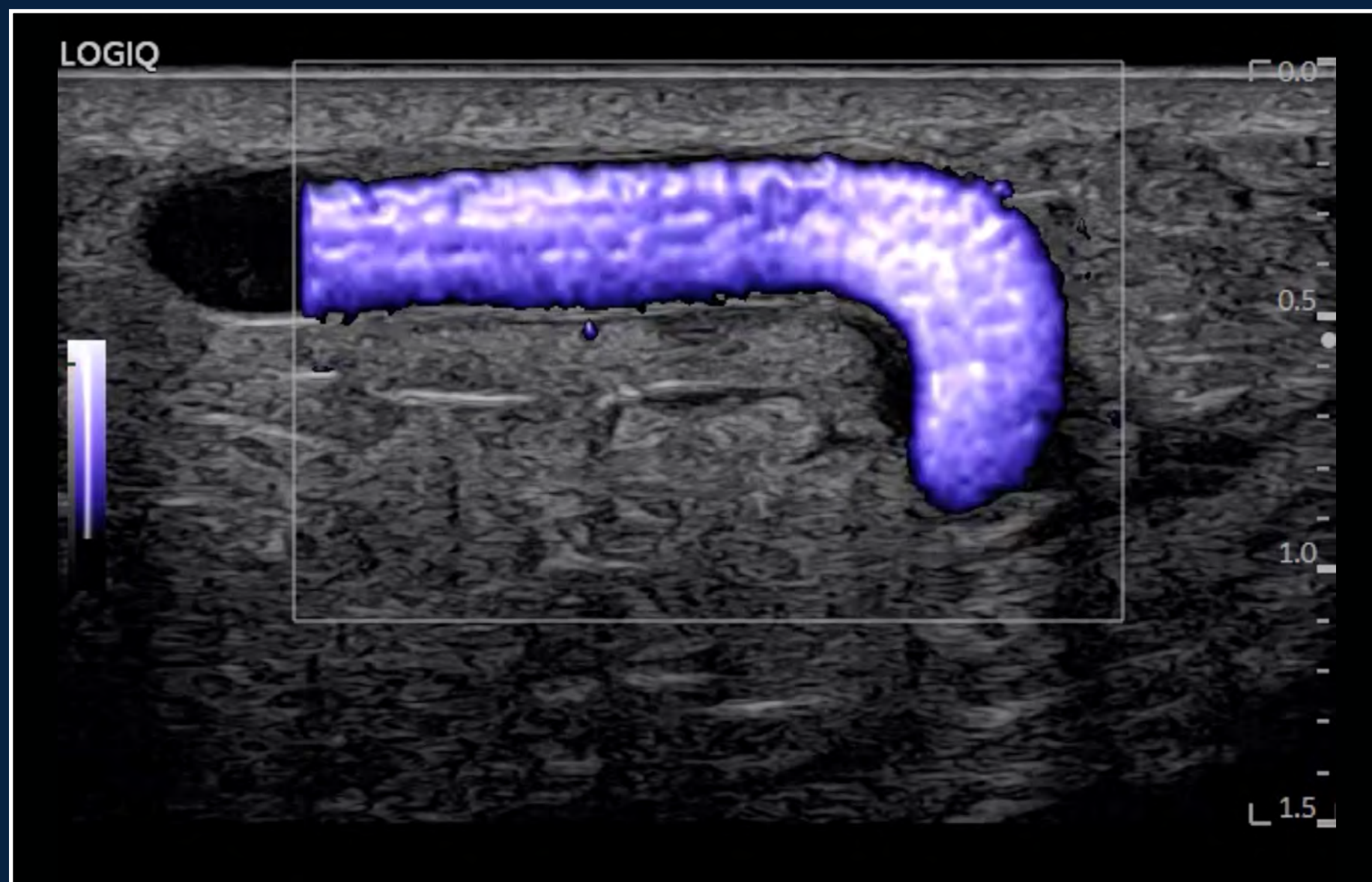
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MVI Superficial Vein, L6-24-D





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B-Mode with Advanced SRI Liver with TIPS, C1-6-D





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Liver B-Flow Cine Capture, C2-9-D





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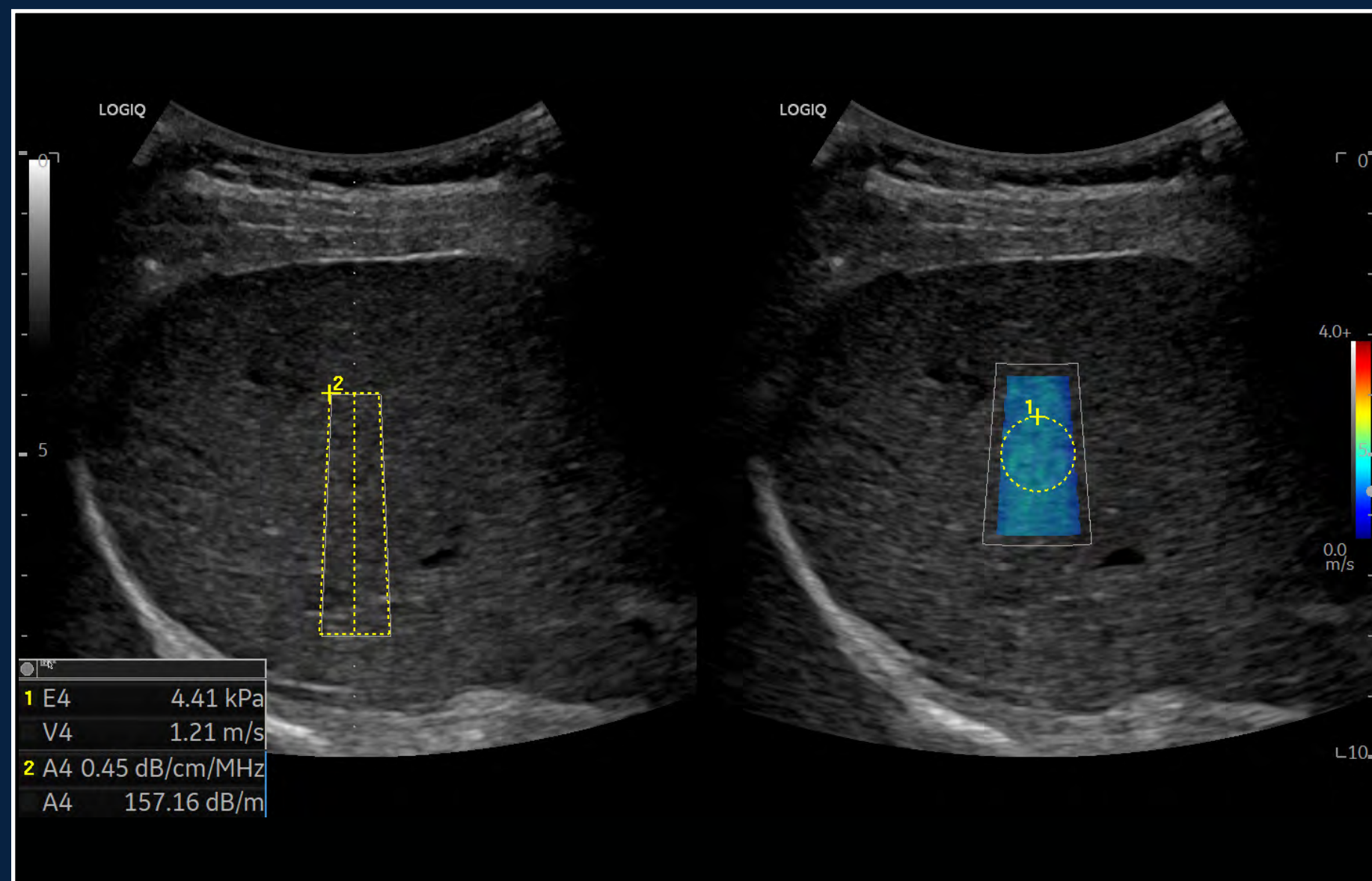
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Hepatic Assistant UGAP and Shear Wave, C1-6-D





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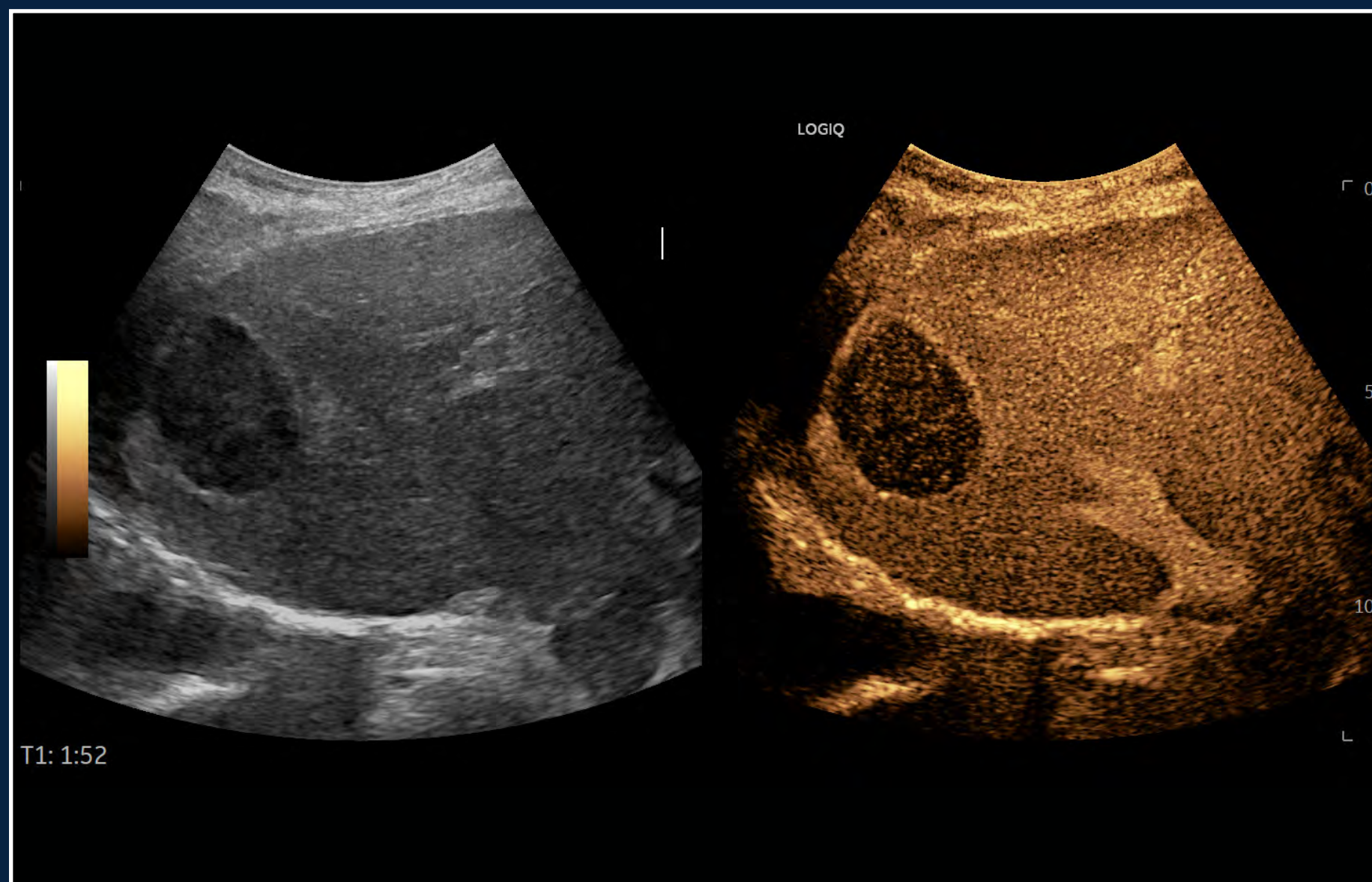
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Liver Lesion CEUS, C1-6-D





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B-Mode with Advanced SRI Spleen, C2-9-D





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Color Flow with Radiantflow, C2-9-D





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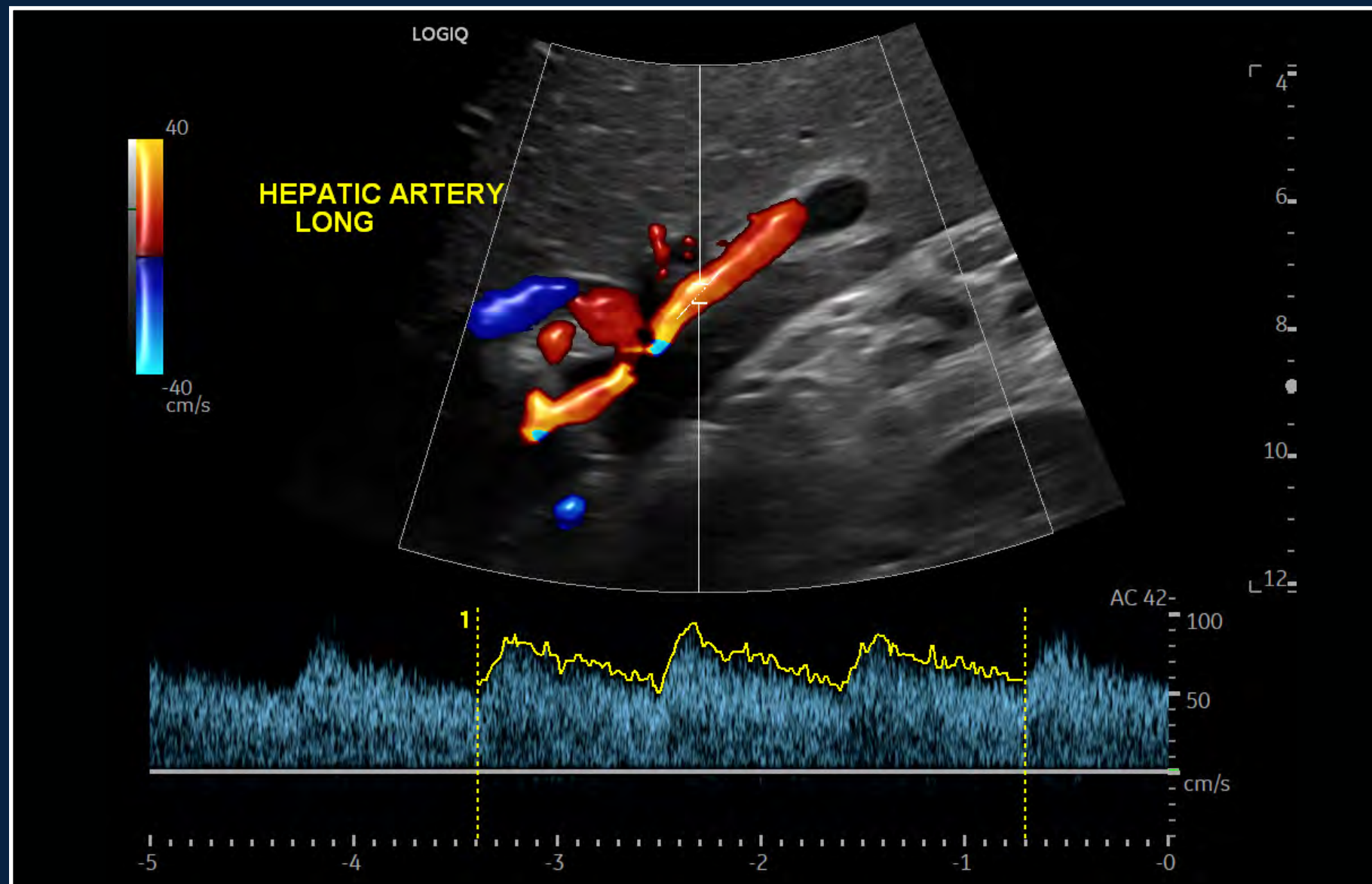
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cSound B-Mode CF with Radiantflow and PW Doppler, C1-6-D



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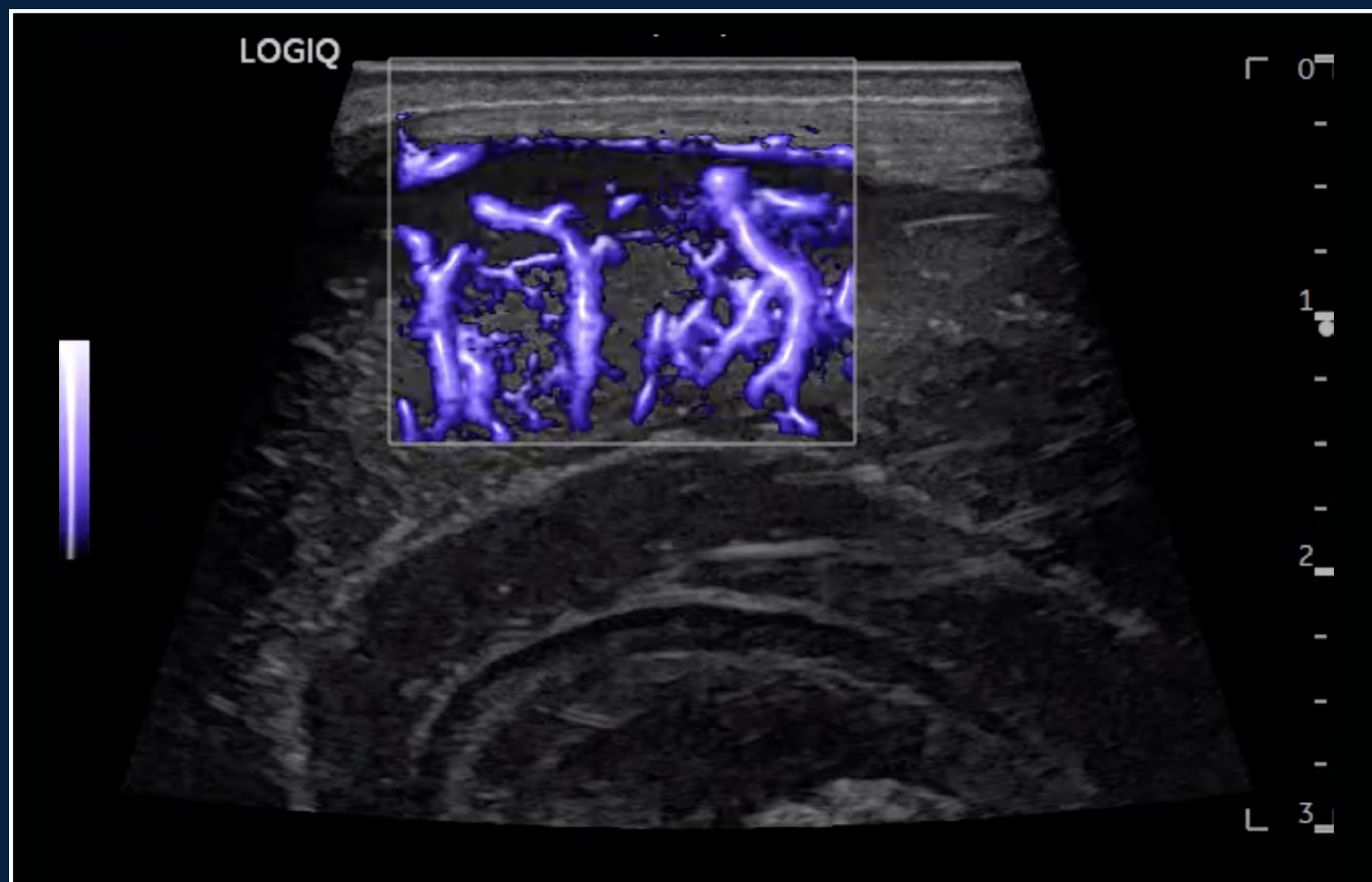
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MVI with Radiant*flow* neonatal brain, L6-24-D





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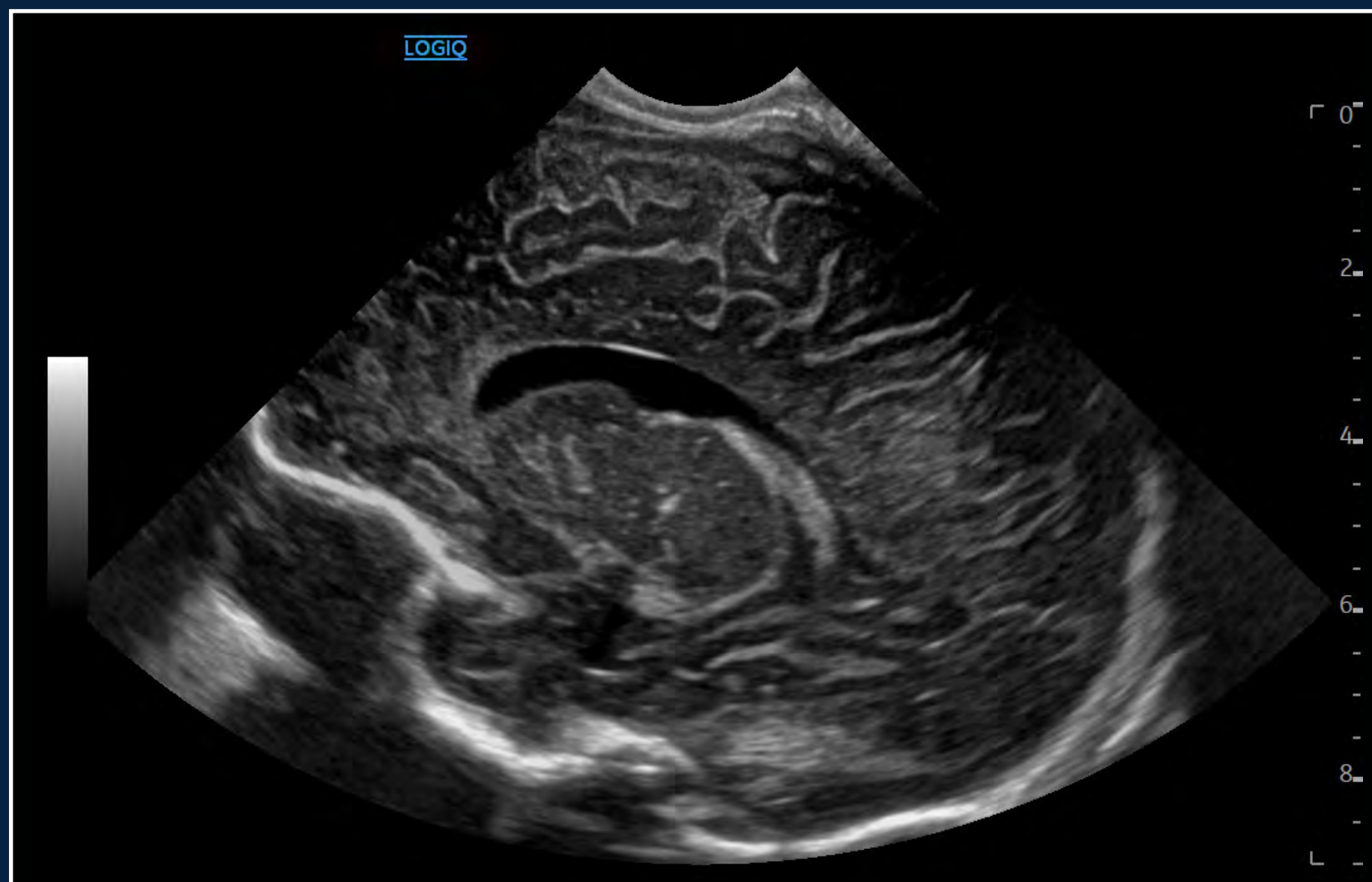
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Neonatal head, C3-10-D





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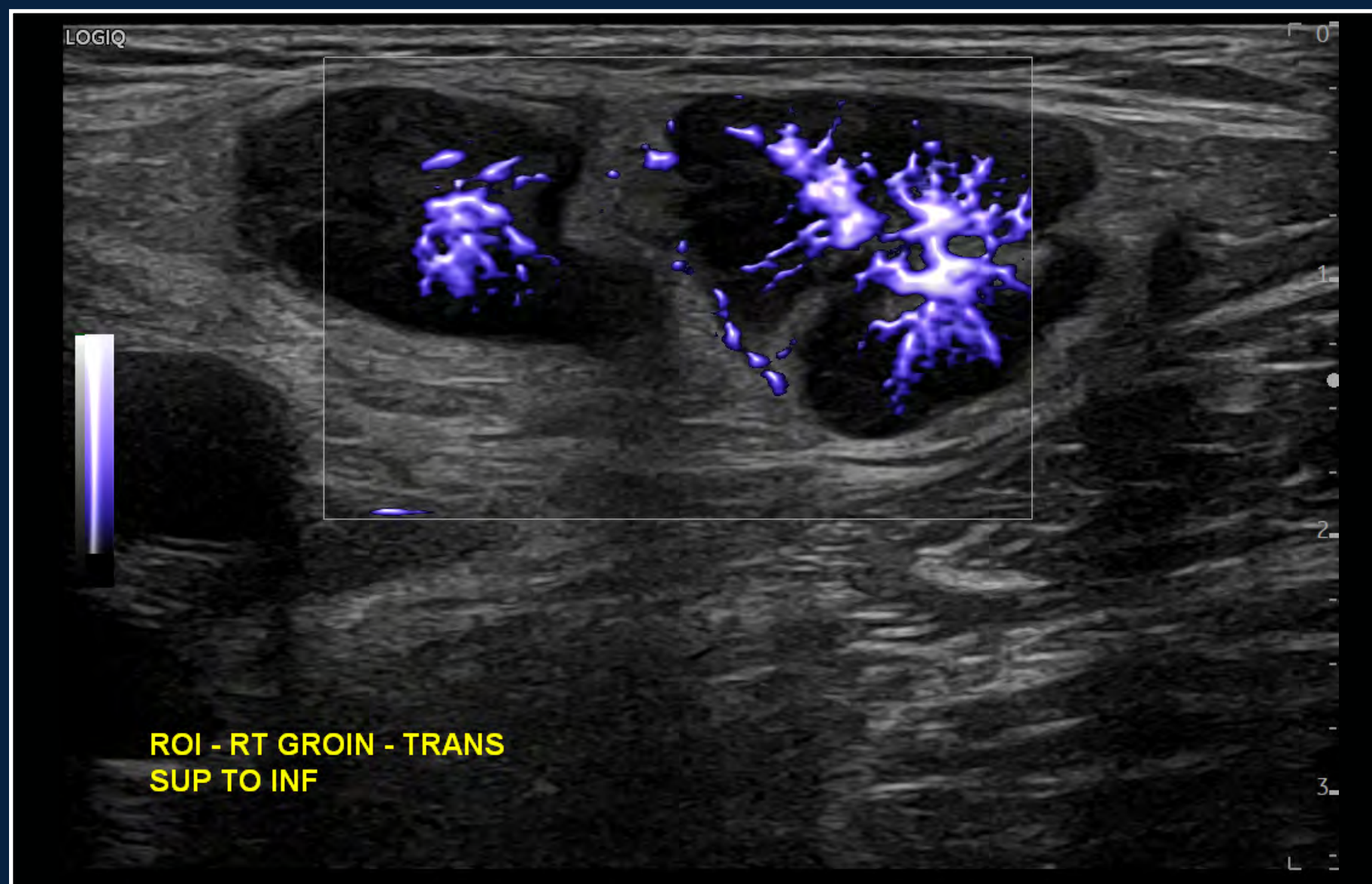
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MVI with Radiantflow groin lymph node, ML6-15-D





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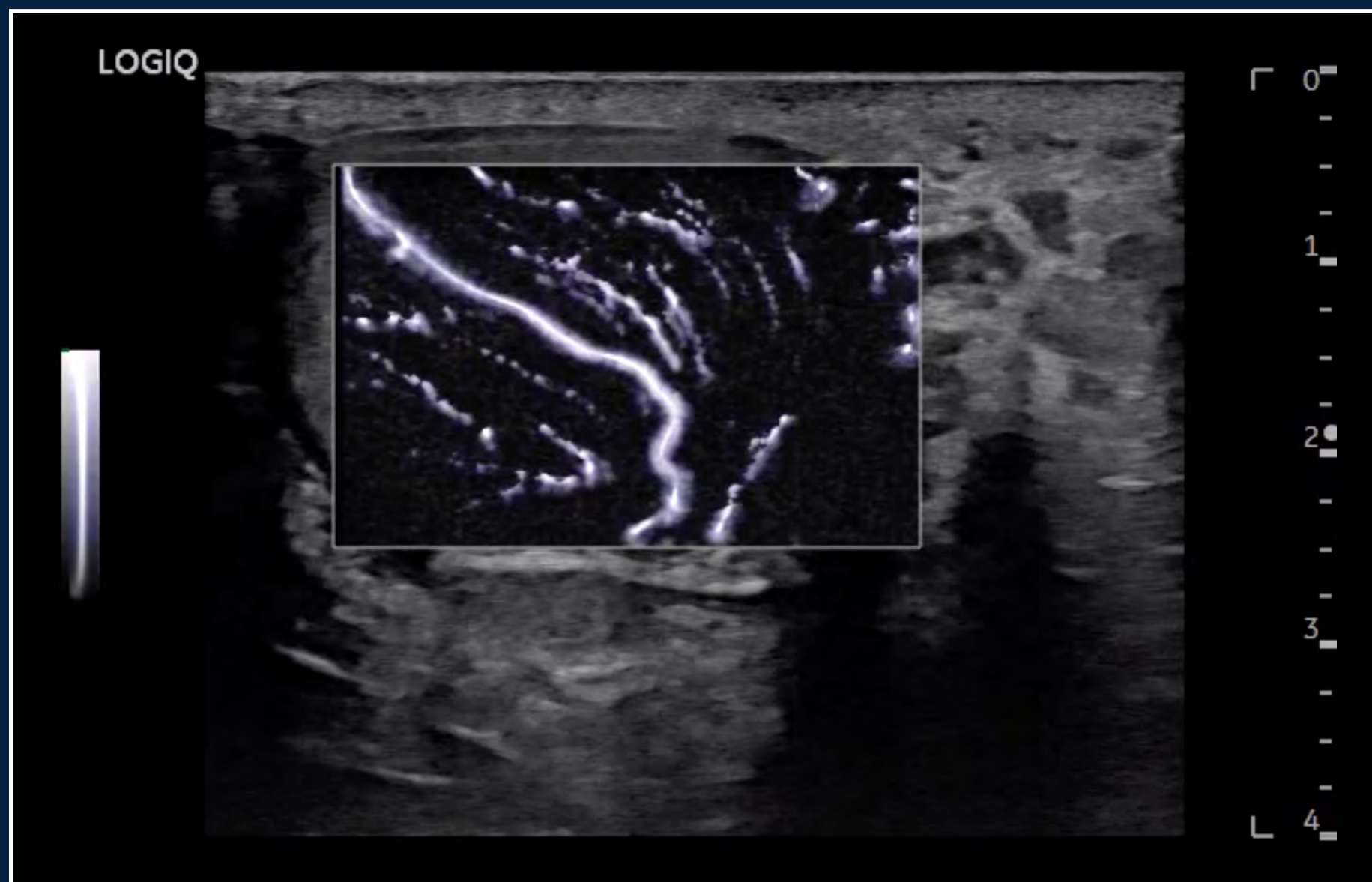
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MVI with Radiantflow in scrotal, L3-12-D

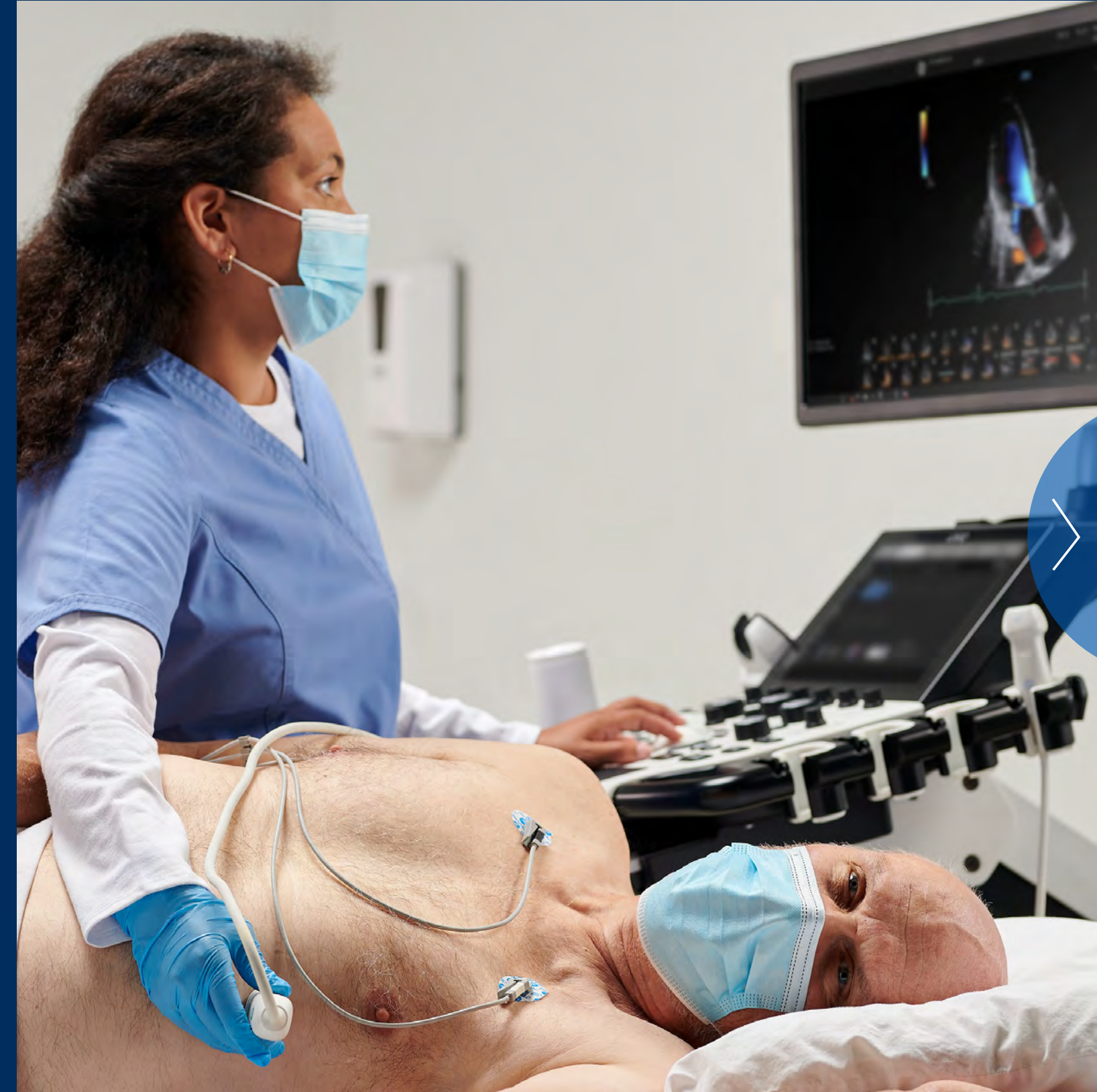


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CARDIOLOGY

LOGIQ Fortis delivers superb image quality within fast scan times across a wide range of cardiac exams.

- cSound Architecture with advanced SRI for precise details
- Cardiac Strain assists in early identification of underlying cardiac disease
- Contrast agent imaging with high contrast sensitivity
- TVI/TVD to help assess tissue velocities

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LOGIQ Fortis



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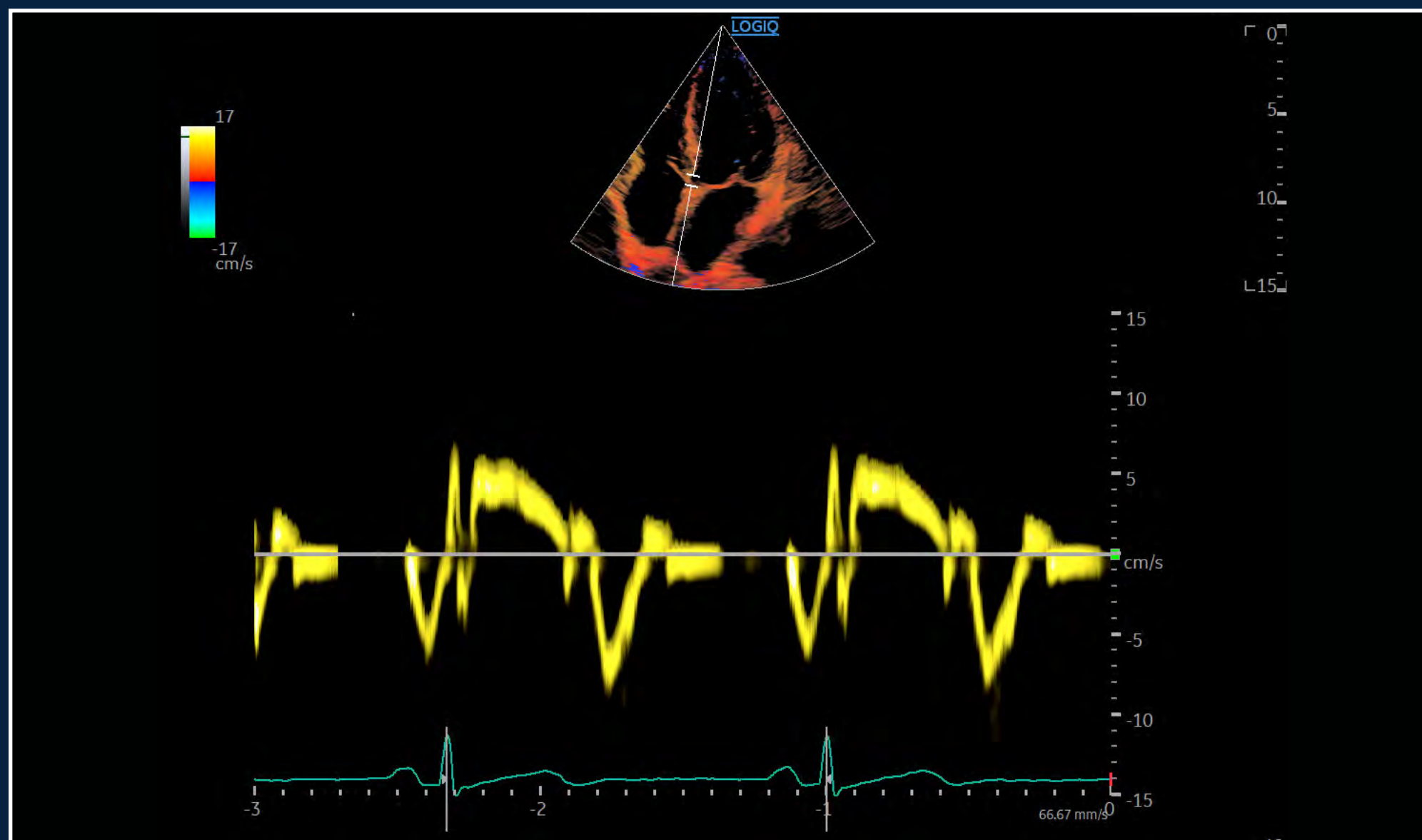
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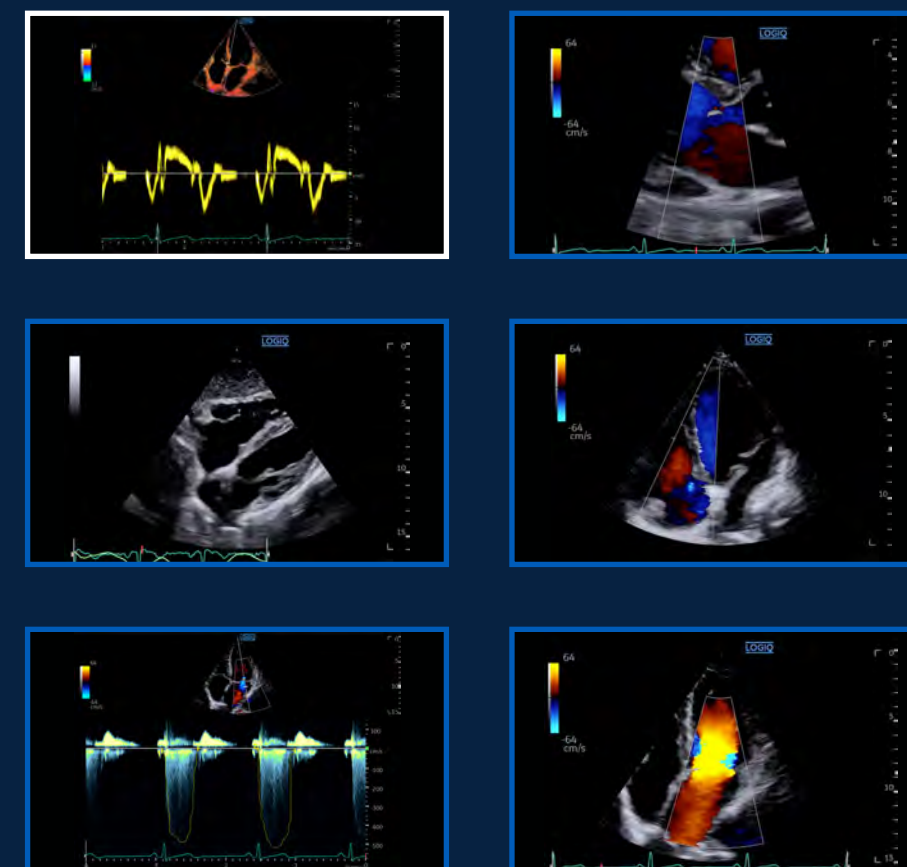
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CLINICAL IMAGES | Cardiology

Acquire highly detailed cardiac images within efficient exam times, even in challenging cases



TVI and TVD Apical 4 Chamber View, M5Sc-D





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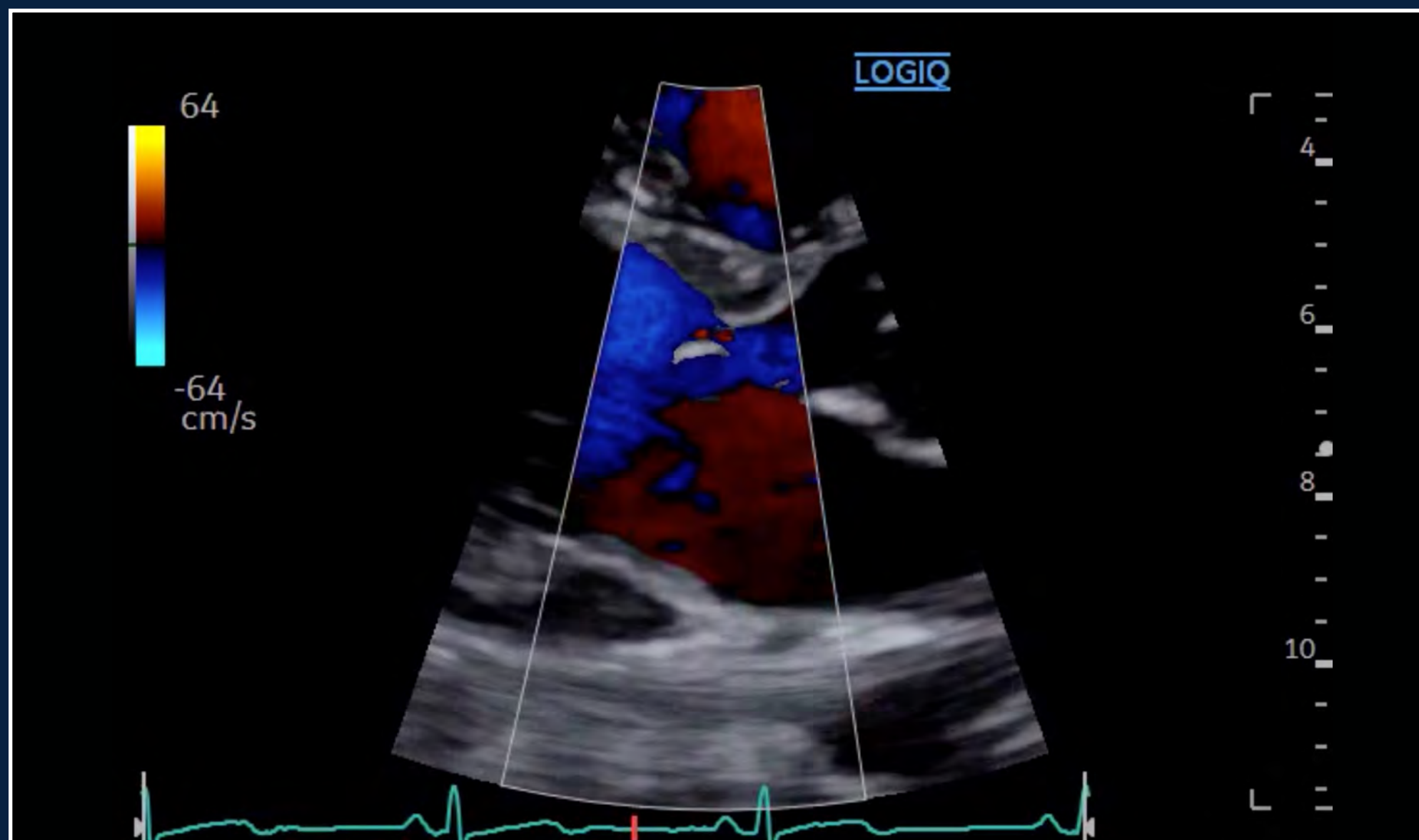
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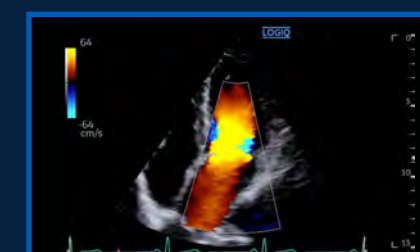
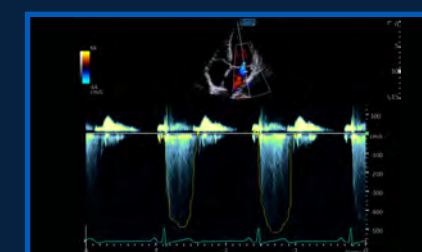
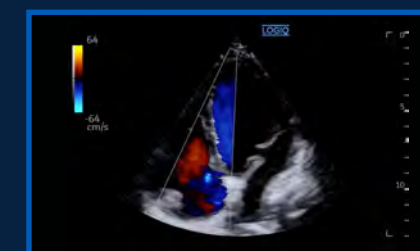
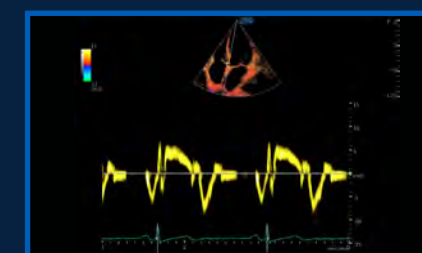
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Color Flow in Cardiac Parasternal Long Axis View, M5Sc-D





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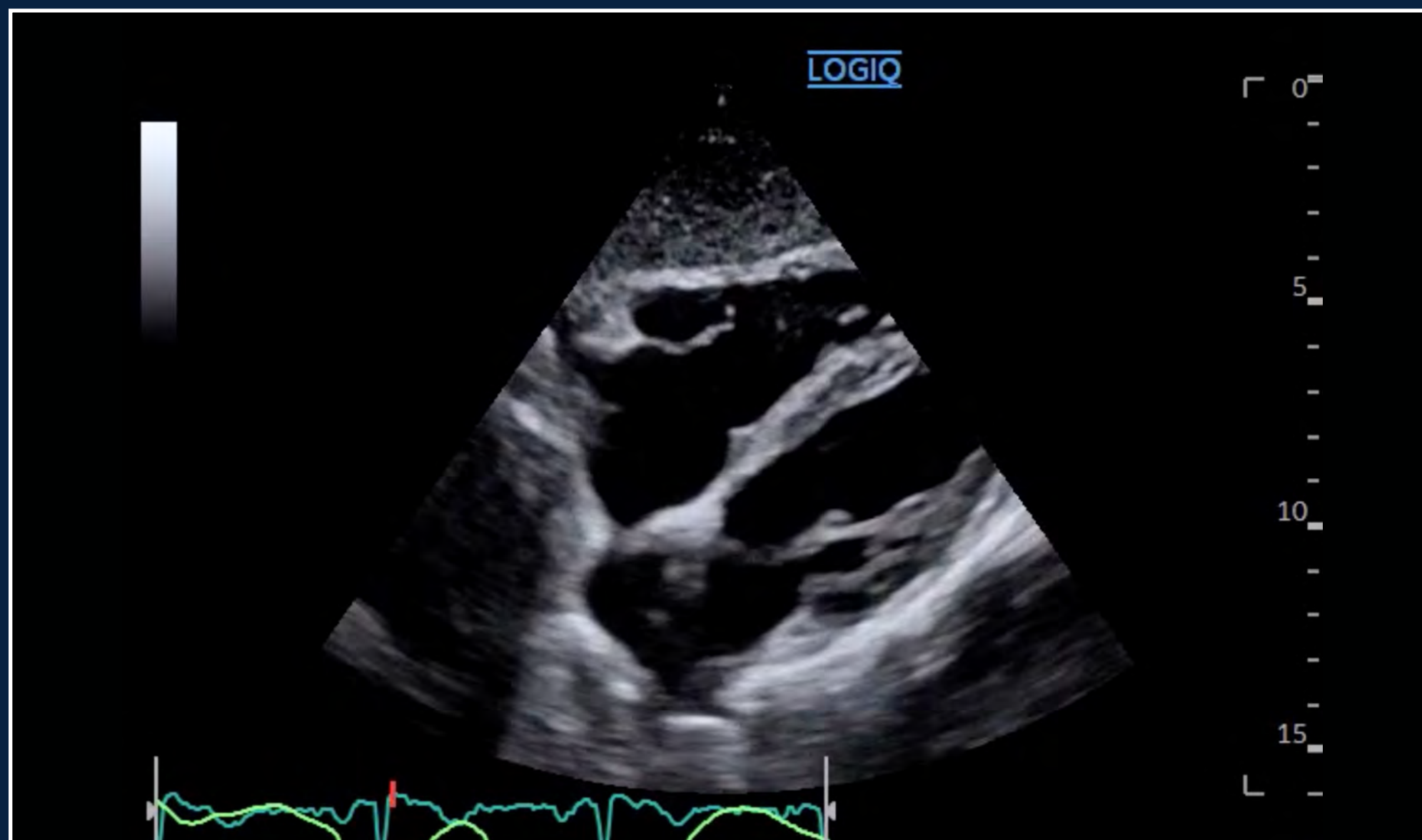
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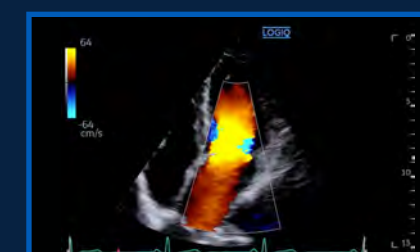
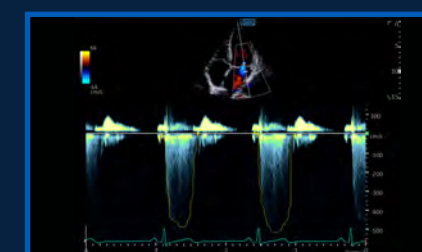
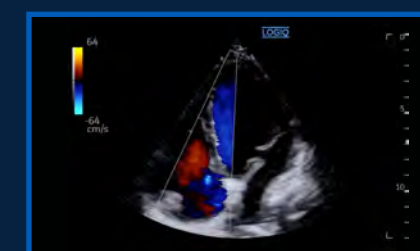
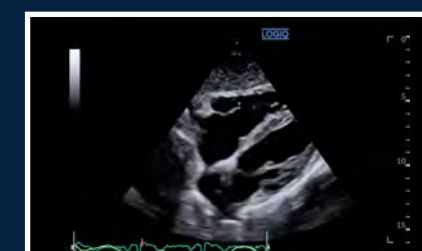
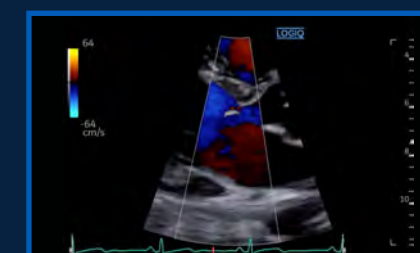
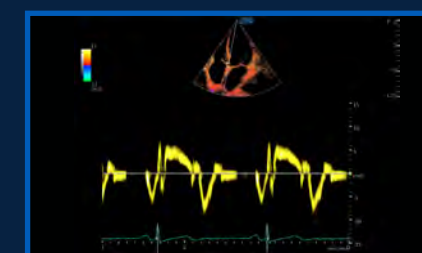
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CLINICAL IMAGES | Cardiology

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B-Mode with Advanced SRI ECG and Respirometer Display, M5Sc-D





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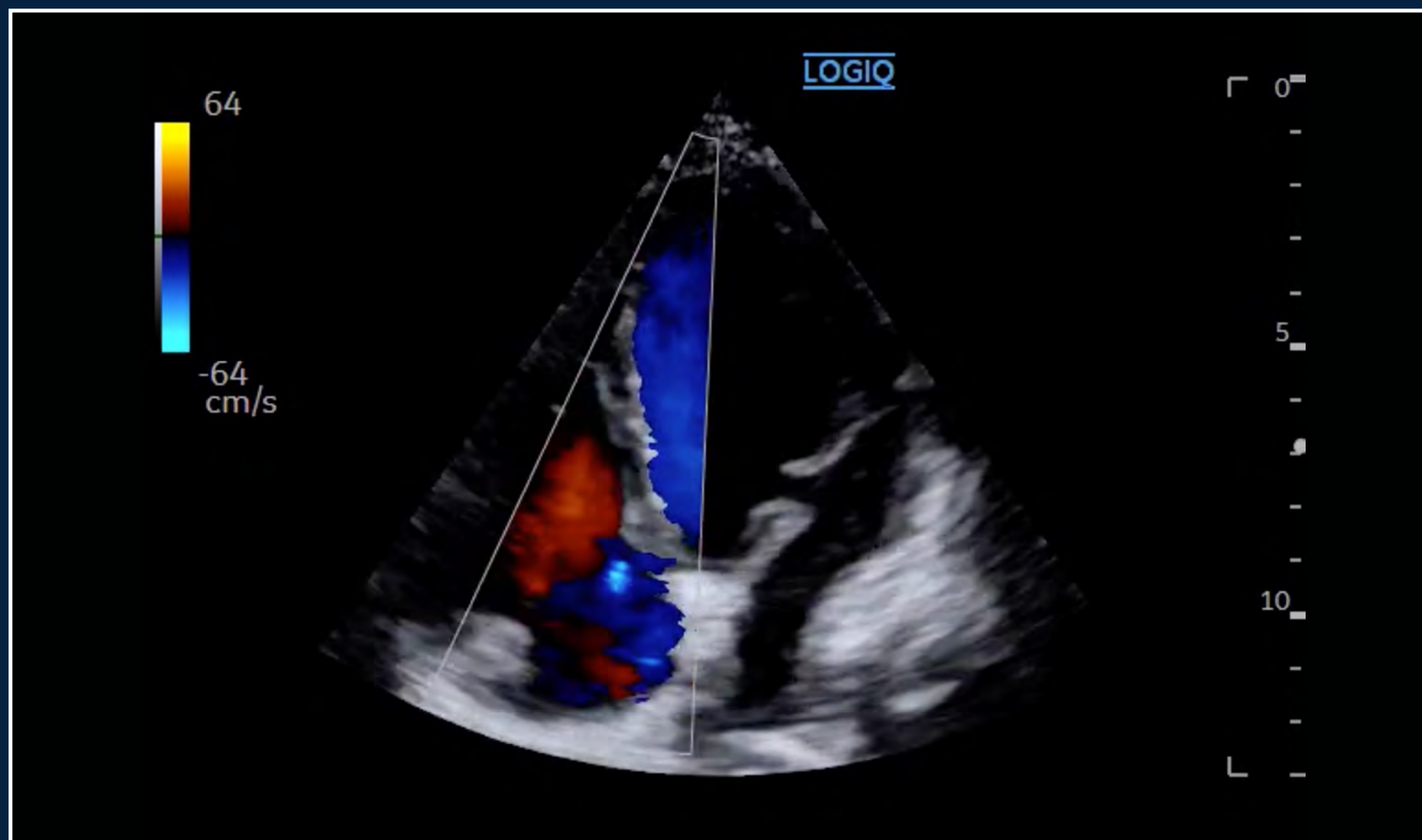
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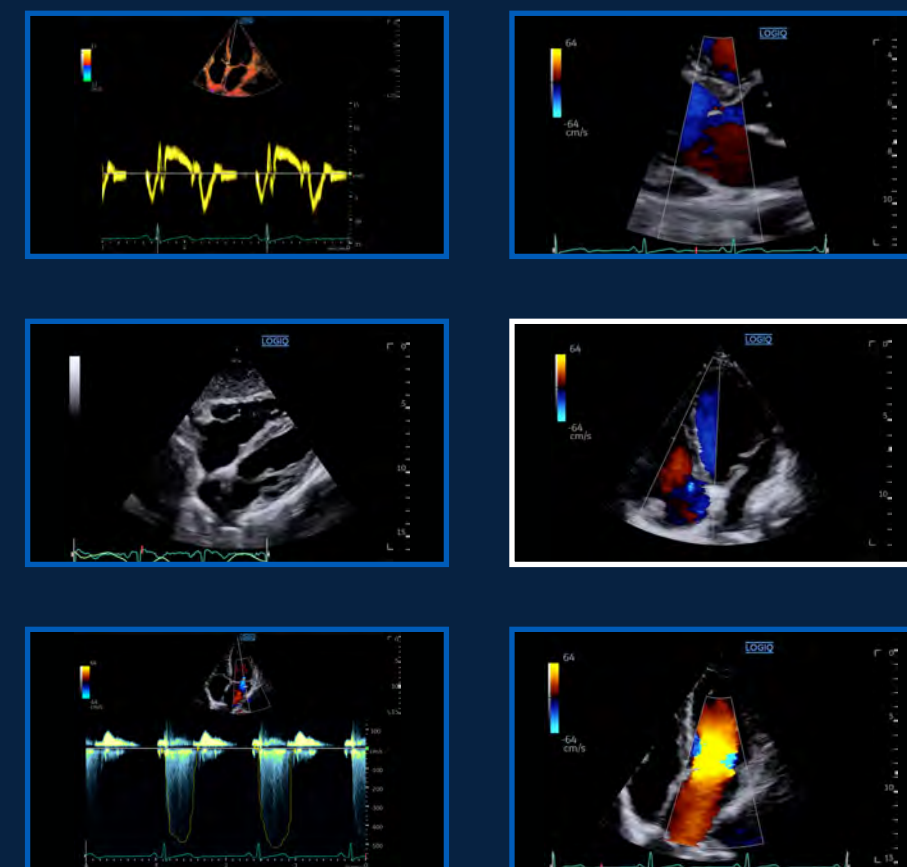
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Acquire highly detailed cardiac images within efficient exam times, even in challenging cases



Color Flow Apical 4 Chamber View, M5Sc-D





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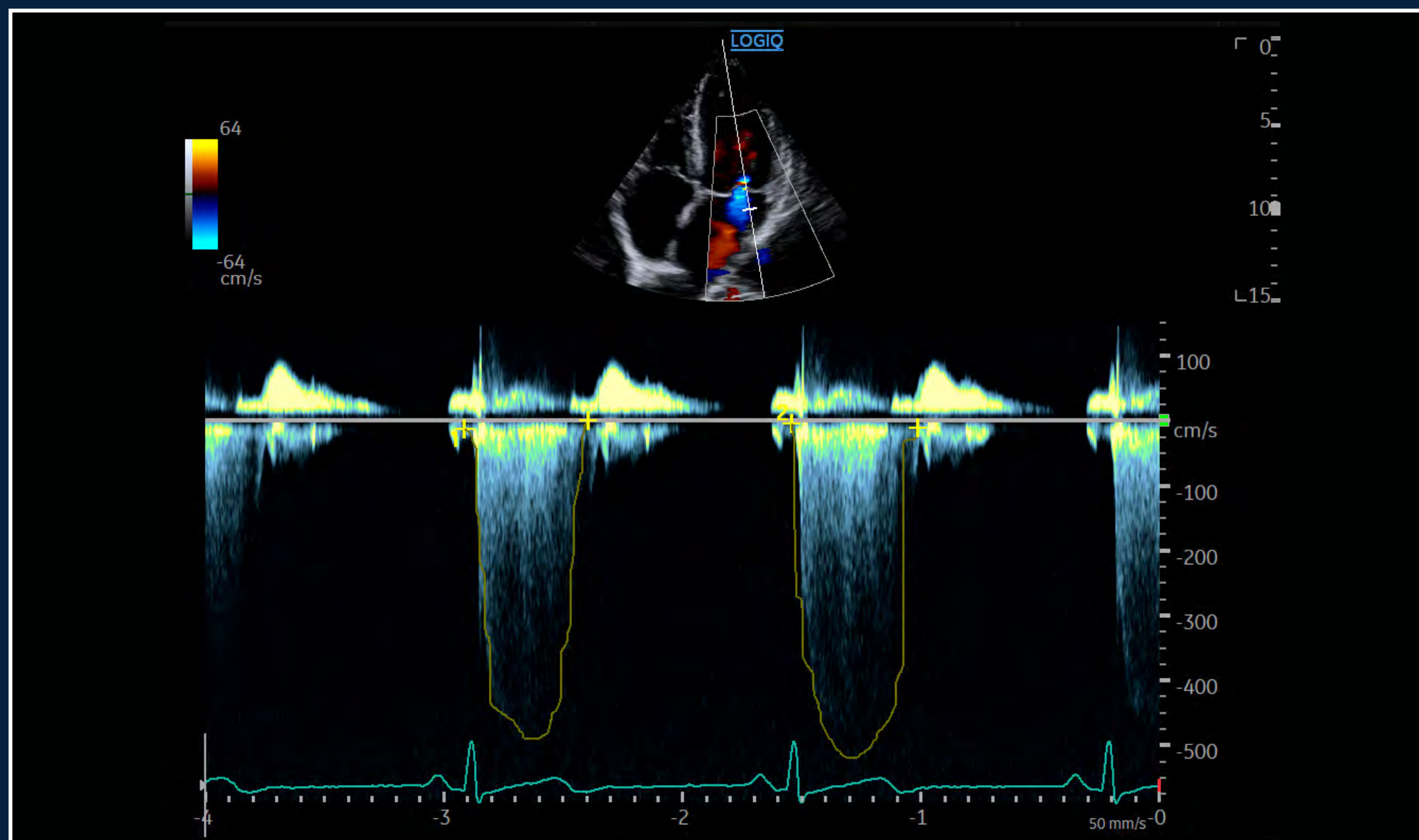
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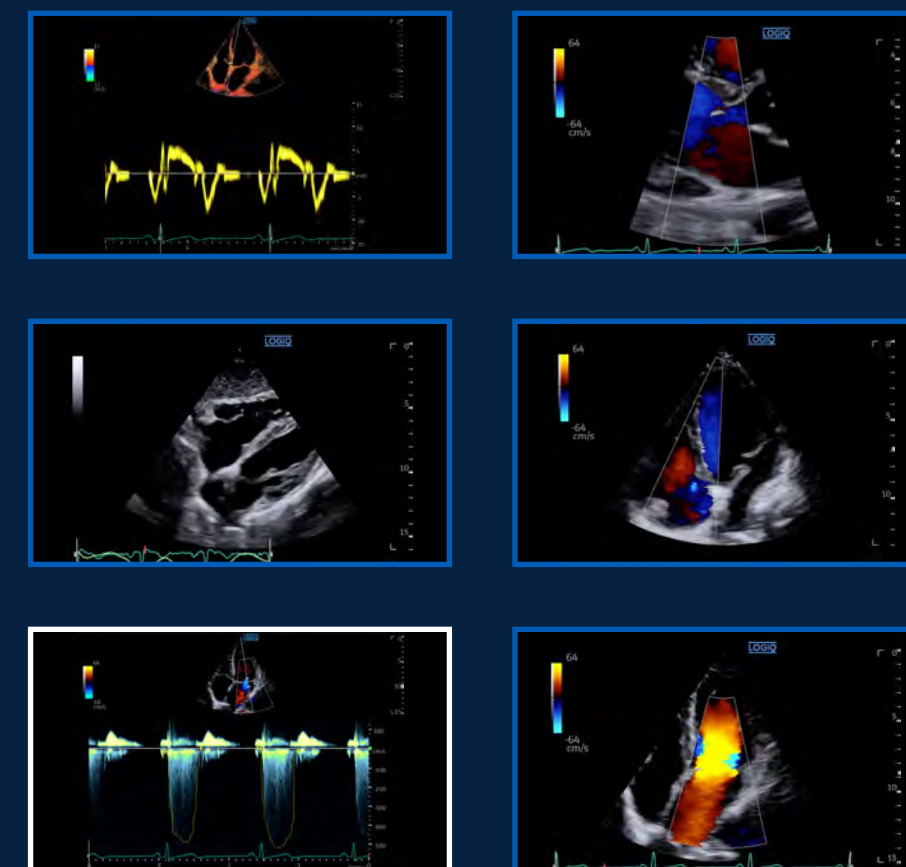
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Acquire highly detailed cardiac images within efficient exam times, even in challenging cases



Color Flow and CW Doppler Mitral Valve, M5Sc-D





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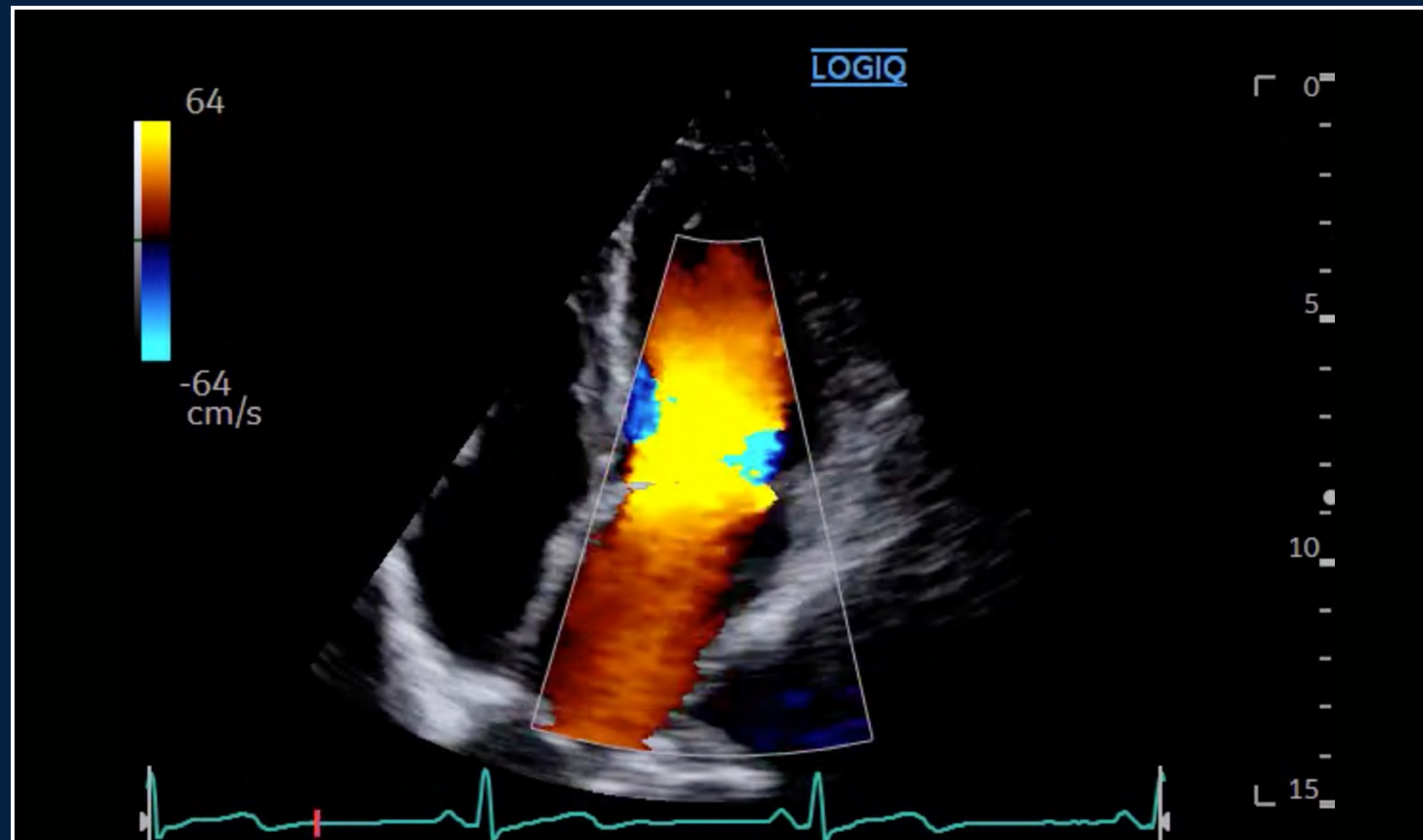
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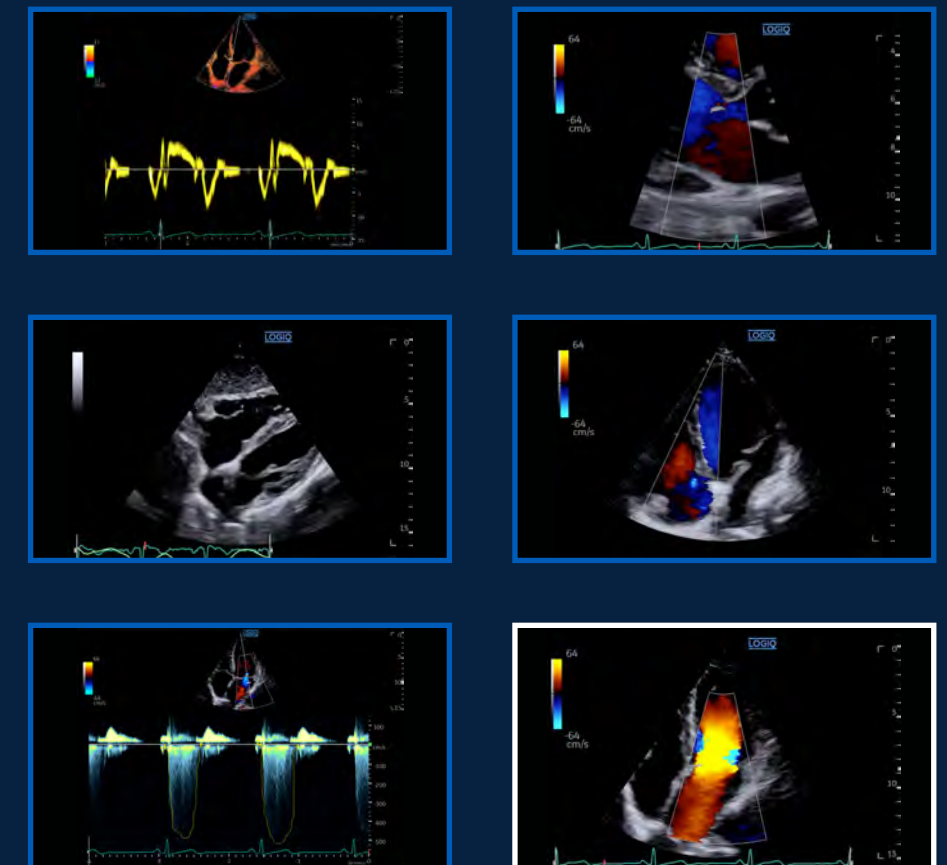
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Acquire highly detailed cardiac images within efficient exam times, even in challenging cases



Color Flow Apical 4 Chamber View Mitral Valve, M5Sc-D



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MUSCULOSKELETAL

With precise, efficient imaging, LOGIQ Fortis assists clinicians in managing a wide range of musculoskeletal conditions and a high volume of patients.

- Micro Vascular Imaging (MVI) and Radiantflow combine to enable near-3D visualization of tiny, slow-flow vessels
- 2D Shear Wave Elastography available on multiple probes
- Photo Assistant App lets you acquire and send photos of relevant anatomy from an Android™ device

[+ CLINICAL IMAGES](#)

LOGIQ Fortis



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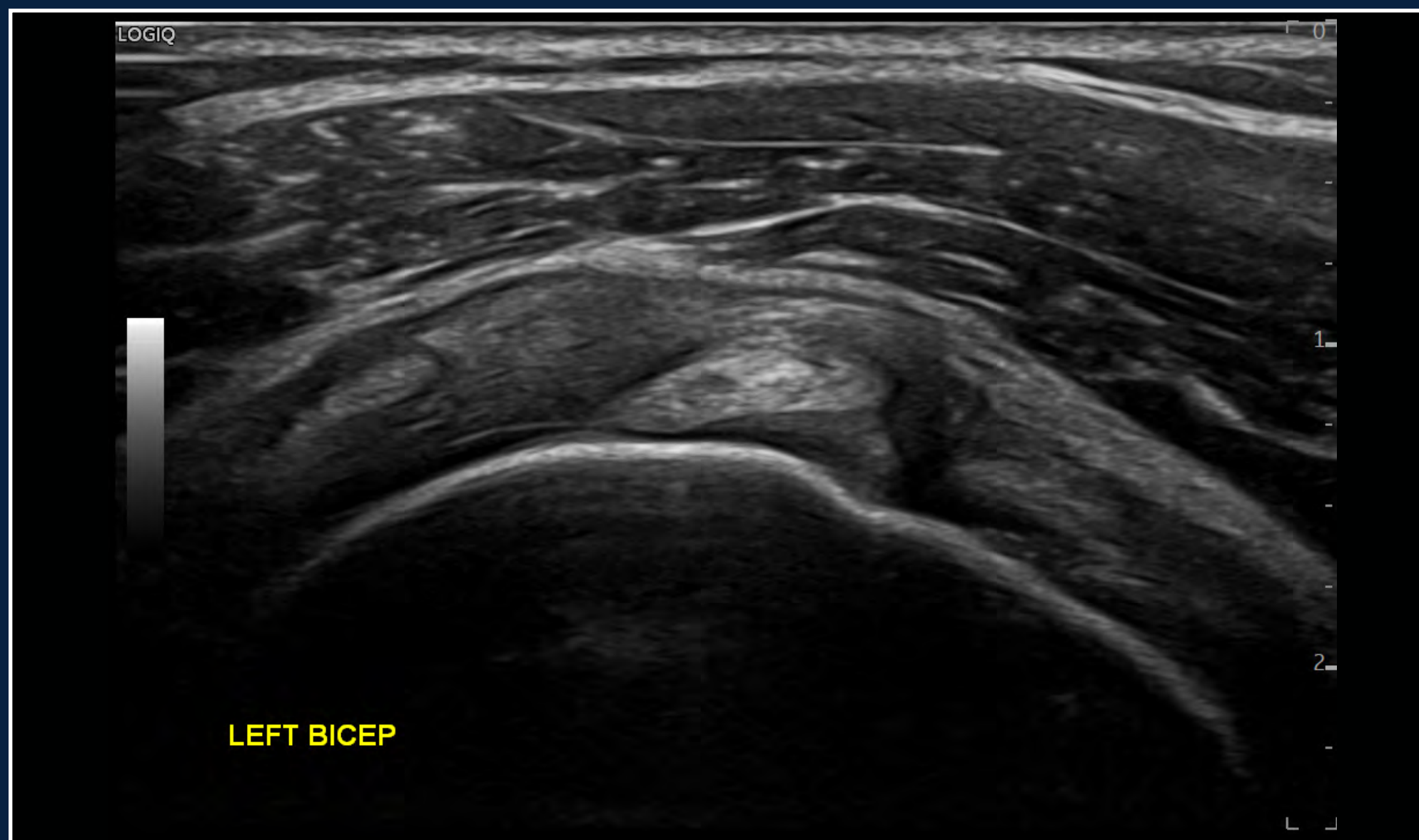
INVESTMENT

CONTACT

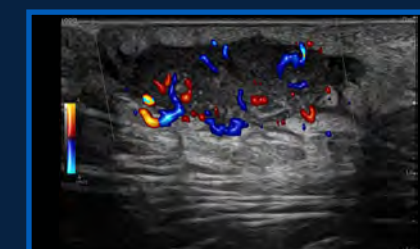
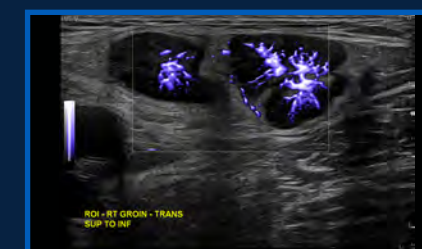
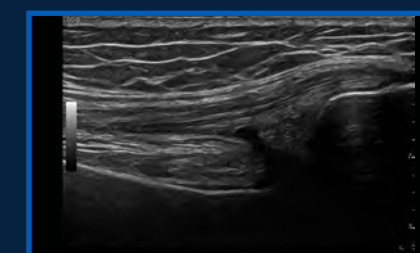
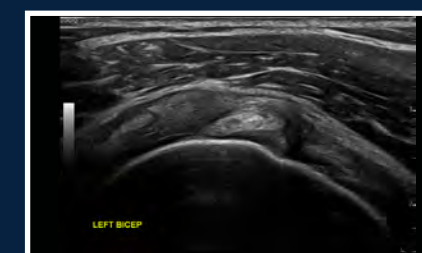
CLINICAL IMAGES | Musculoskeletal



Excellent detail and contrast resolution to support in-depth understanding of tissue, pathology, blood flow, and inflammation



B-Mode with Advanced SRI Shoulder, ML6-15-D





OVERVIEW

MULTI-PURPOSE/
RADIOLOGY

CARDIOLOGY

MUSCULOSKELETAL

BREAST

PRODUCTIVITY

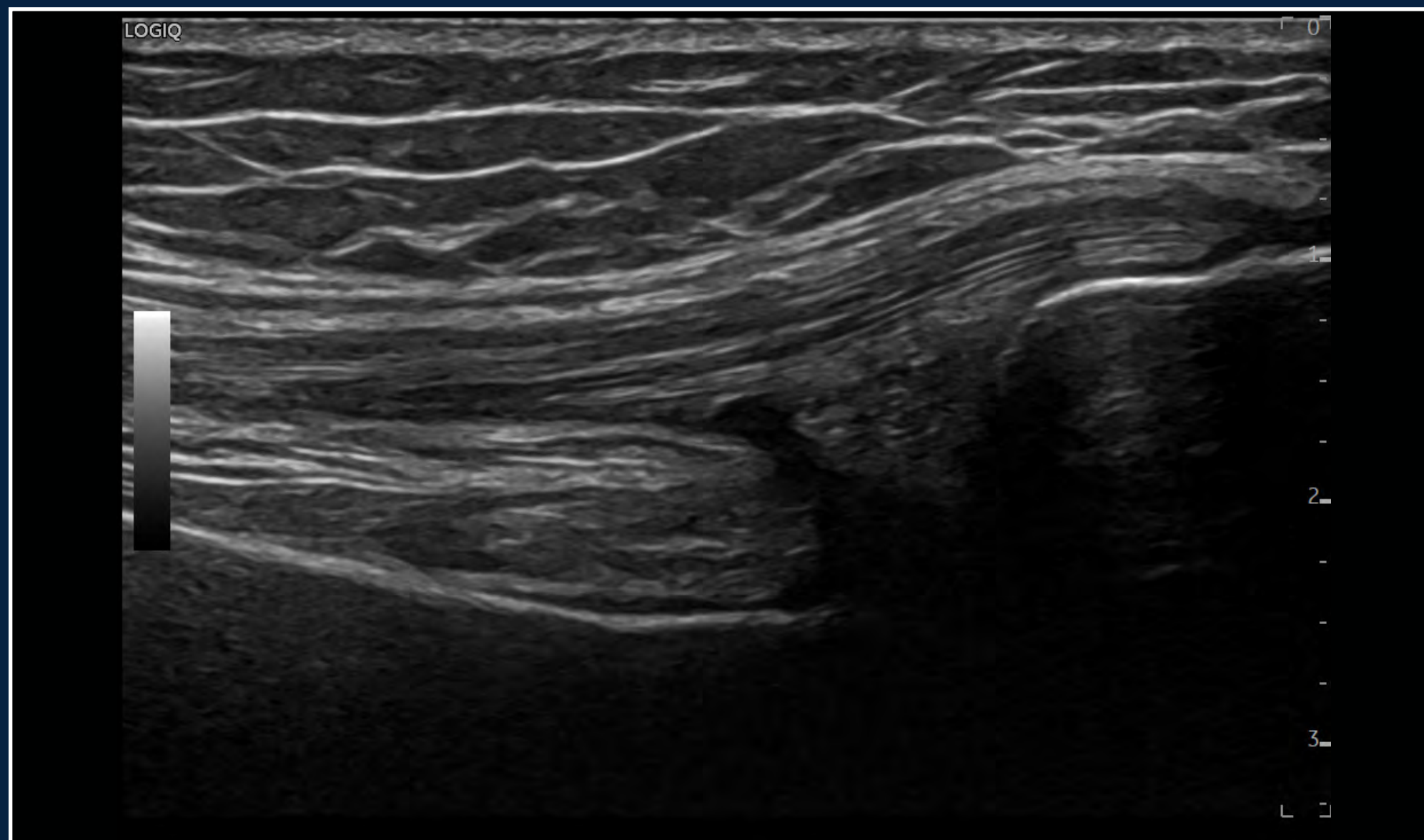
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CONTACT

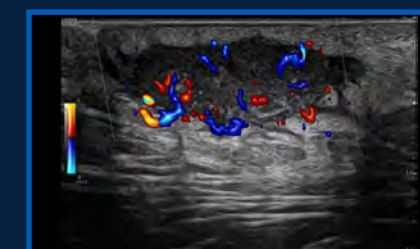
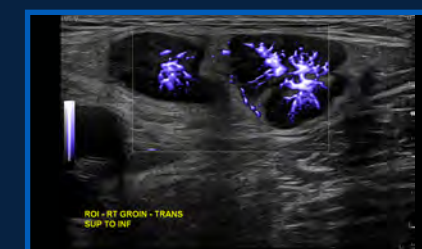
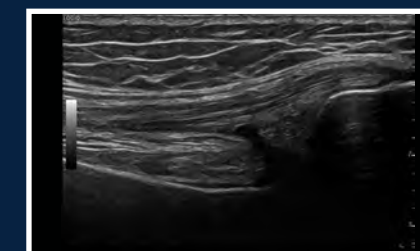
CLINICAL IMAGES | Musculoskeletal



Excellent detail and contrast resolution to support in-depth understanding of tissue, pathology, blood flow, and inflammation



B-Mode with Advanced SRI Knee Tendon, ML6-15-D





OVERVIEW

MULTI-PURPOSE/
RADIOLOGY

CARDIOLOGY

MUSCULOSKELETAL

BREAST

PRODUCTIVITY

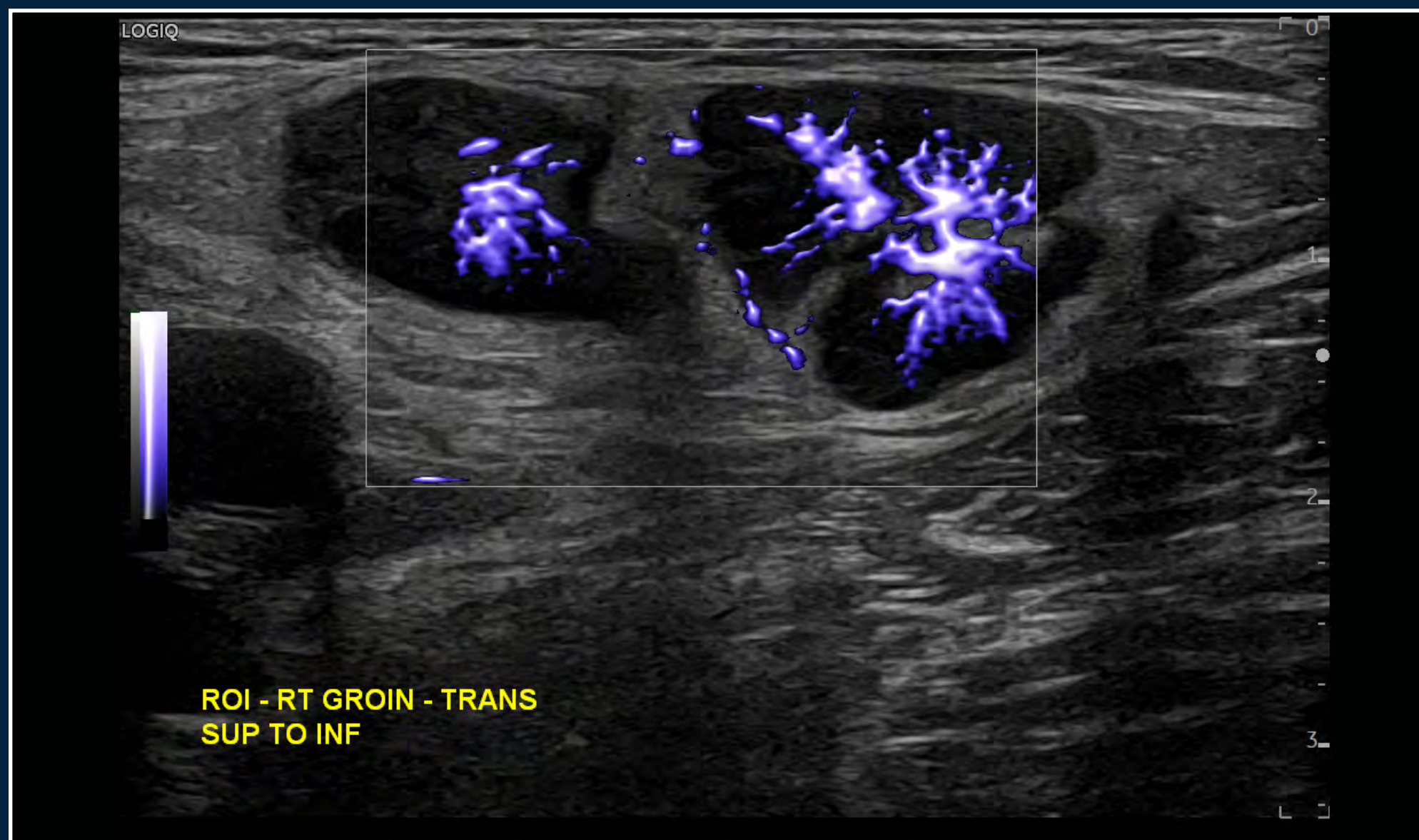
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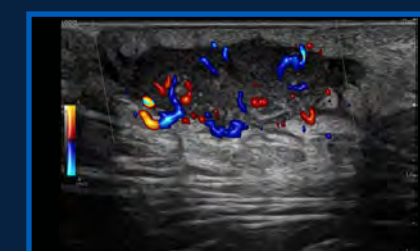
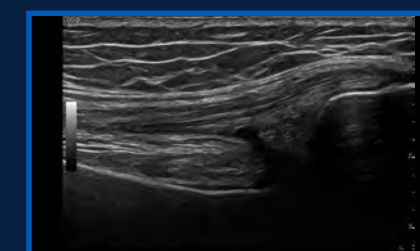
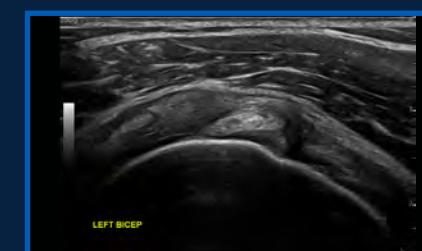
CLINICAL IMAGES | Musculoskeletal



Excellent detail and contrast resolution to support in-depth understanding of tissue, pathology, blood flow, and inflammation



MVI with Radiantflow Groin Lymph Node, ML6-15-D





OVERVIEW

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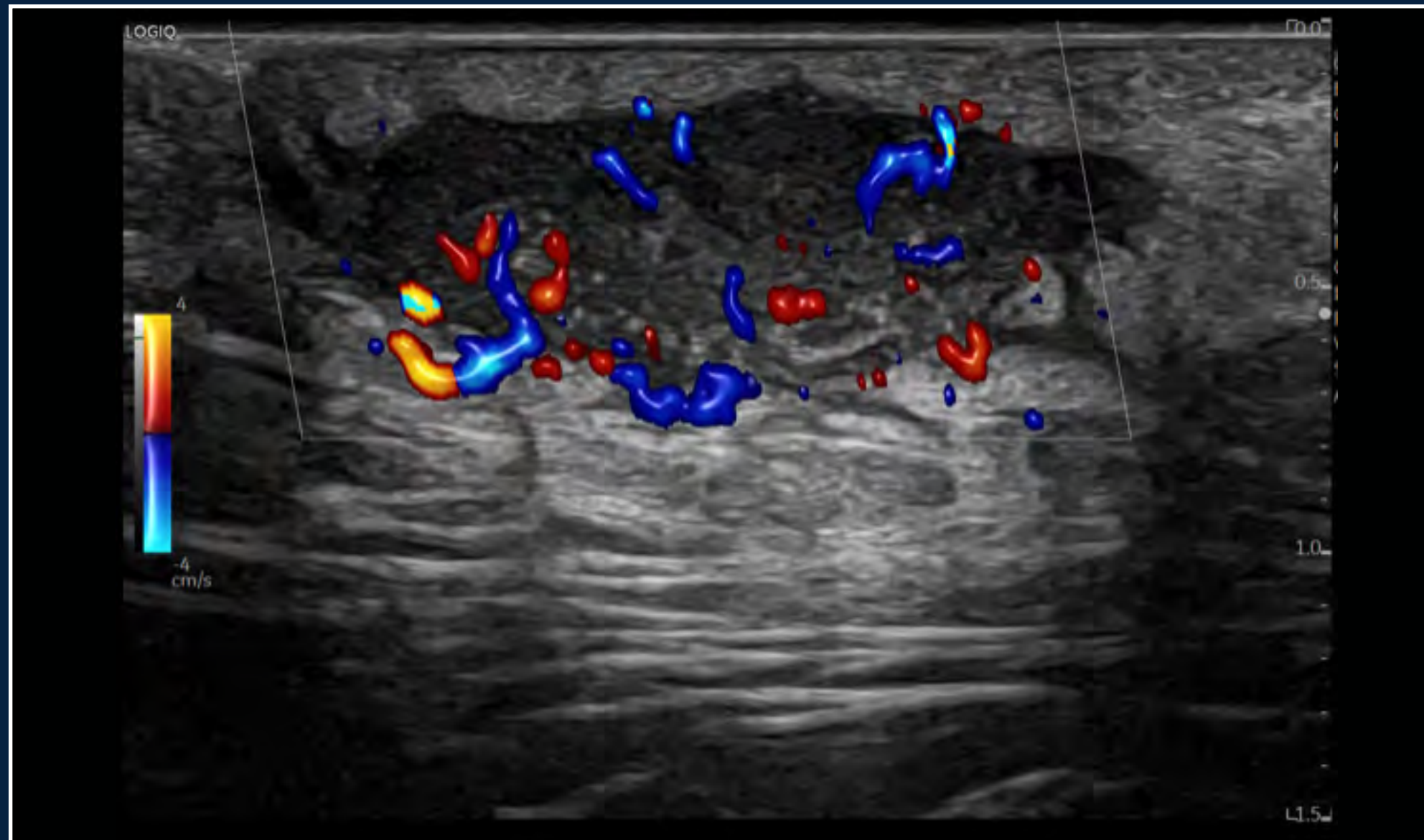
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CONTACT

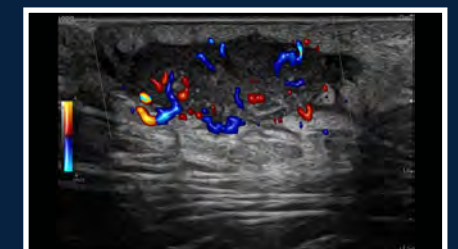
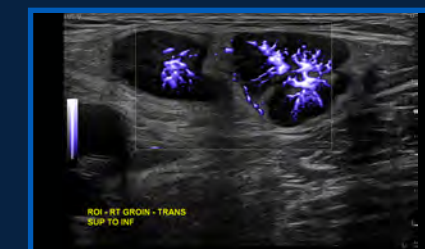
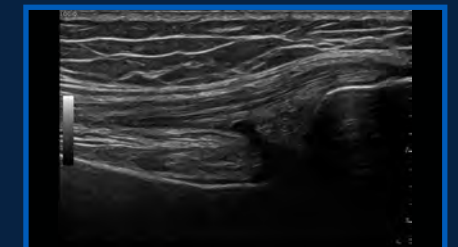
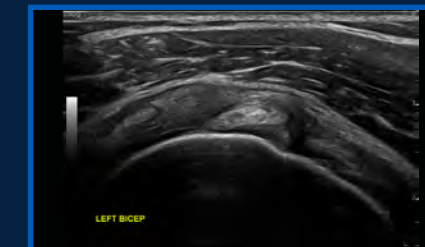
CLINICAL IMAGES | Musculoskeletal



Excellent detail and contrast resolution to support in-depth understanding of tissue, pathology, blood flow, and inflammation



Leg Mass with Color Flow and Radiantflow, L6-24-D



[OVERVIEW](#)[MULTI-PURPOSE/
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BREAST

LOGIQ Fortis provides high-quality images and robust tools to help clinicians detect and characterize breast disease as efficiently as possible.

- 2D Shear Wave Elastography with Quality Indicator
- Automated workflow tools, including Measure Assistant and Compare Assistant
- Breast Assistant, powered by Koios DS™, an AI-based decision support tool providing quantitative risk assessment aligned to a BI-RADS® category*

[+ CLINICAL IMAGES](#)

LOGIQ Fortis



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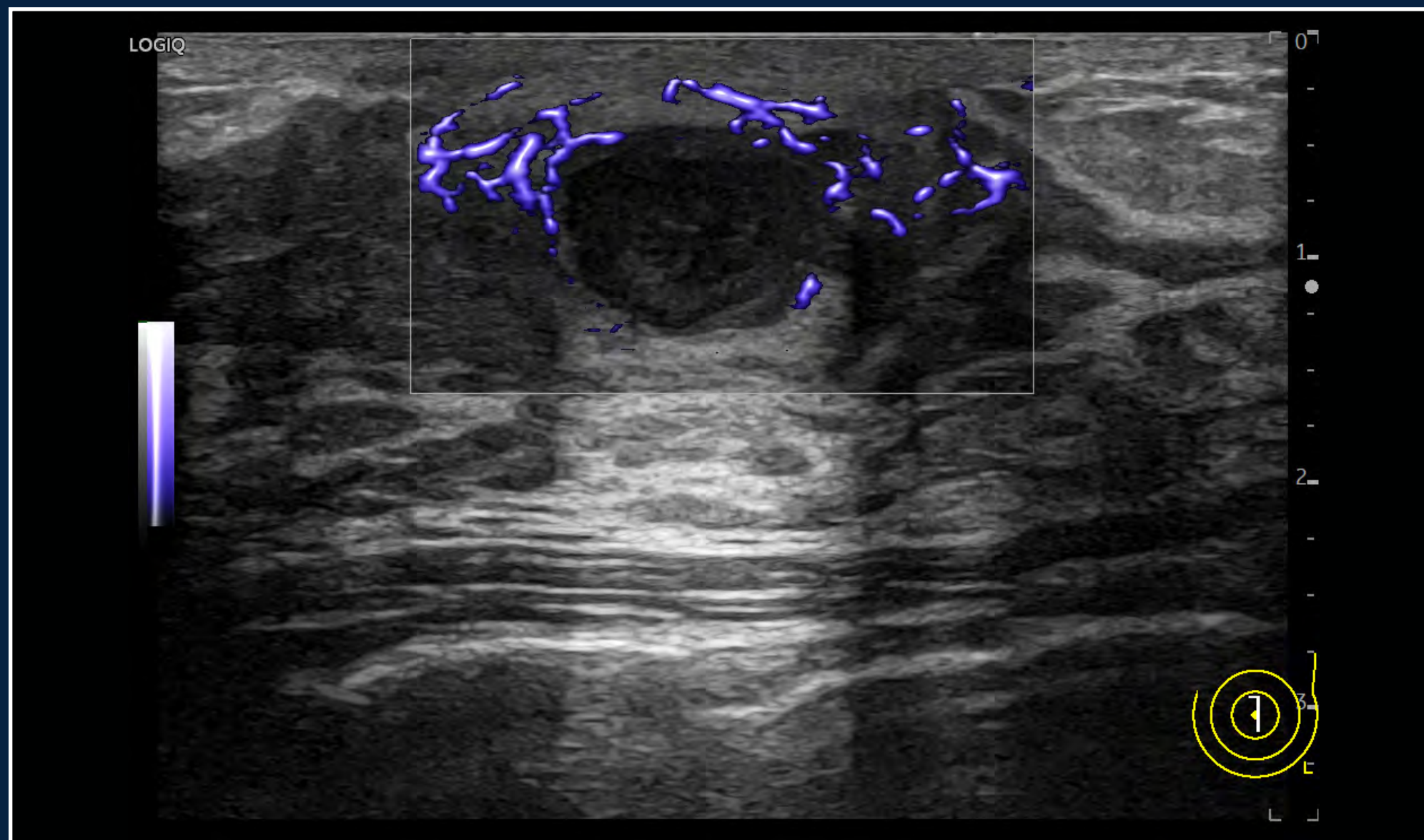
PRODUCTIVITY

INVESTMENT

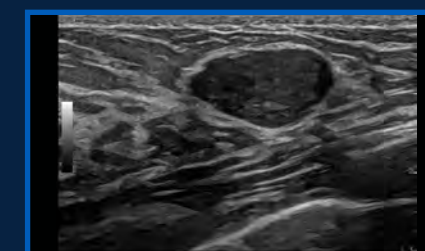
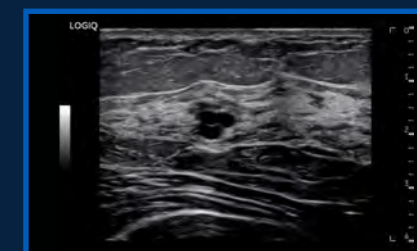
CONTACT

CLINICAL IMAGES | Breast

Highly detailed images to detect and characterize breast disease efficiently



MVI Breast, ML6-15-D





OVERVIEW

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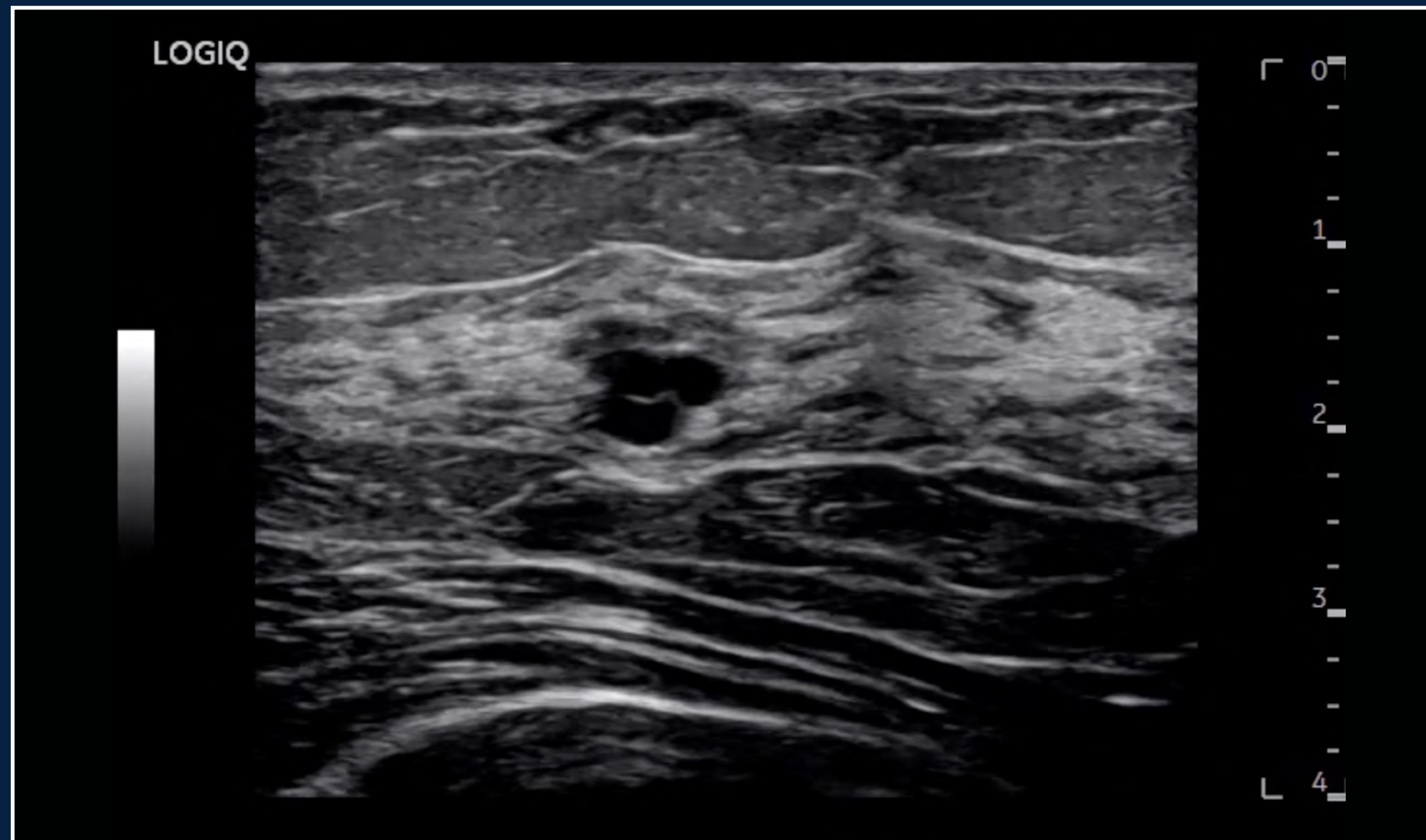
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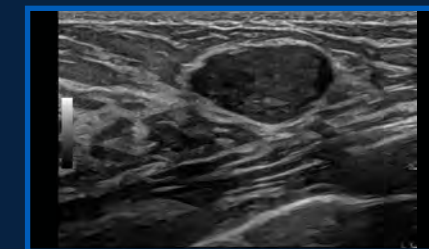
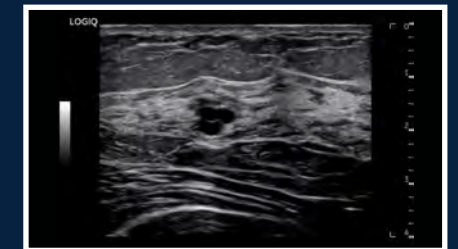
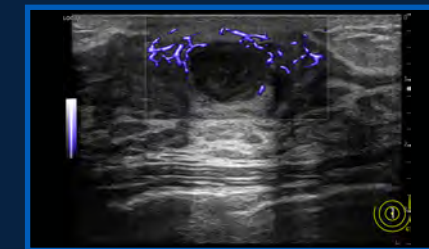
CONTACT

CLINICAL IMAGES | Breast

Highly detailed images to detect and characterize breast disease efficiently



B-Mode with Advanced SRI in Breast, L3-12-D





OVERVIEW

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CARDIOLOGY

MUSCULOSKELETAL

BREAST

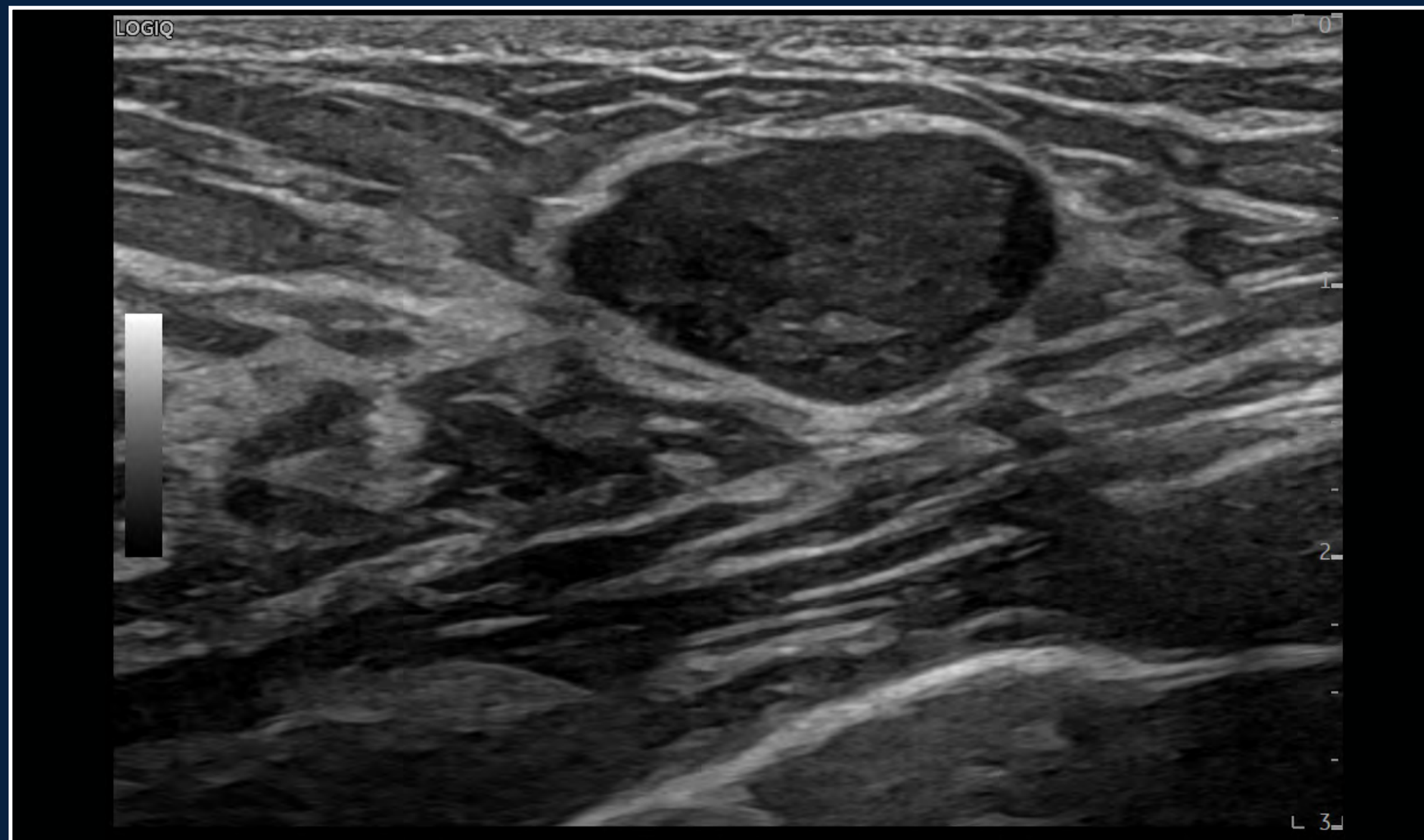
PRODUCTIVITY

INVESTMENT

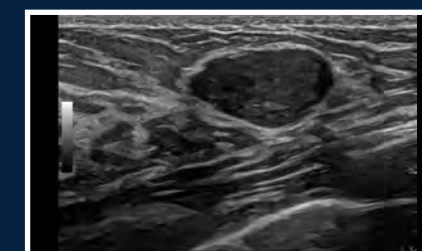
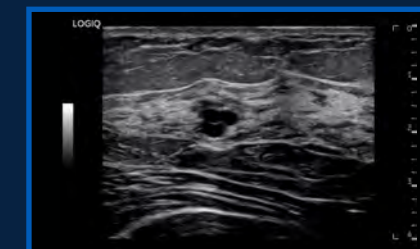
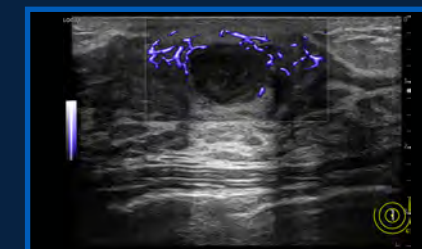
CONTACT

CLINICAL IMAGES | Breast

Highly detailed images to detect and characterize breast disease efficiently



B-Mode with Advanced SRI in Breast, ML6-15-D



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OPTIMIZING YOUR PRODUCTIVITY

LOGIQ Fortis is powerfully streamlined to help clinicians optimize workflow, ensure accurate results, and enhance clinical confidence.

- New EZ Imaging with customizable probe presets, simplified touch panel to reduce operator interactions, and quick patient set-up
- AI-based and automated tools to speed up workflow
- Easy system maneuverability with Scan on Battery

[COVID-19 Support](#)[Systems Cleaning Compatibility](#)[Transducers Cleaning Compatibility](#)[LOGIQ Club](#)

LOGIQ Fortis

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MAXIMIZING YOUR INVESTMENT

From radiology to cardiology, the multi-purpose LOGIQ Fortis is easily scaled to your needs, so you can avoid acquiring multiple ultrasound systems for different requirements.

- A to A digital platform lets you add next-generation capabilities to stay at the forefront of ultrasound
- Lifecycle solutions—from InSite™ remote support to iCenter™ performance analytics—help optimize asset performance and utilization
- SonoDefense multi-layer cybersecurity and data privacy protection guards your investment 24/7



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LOGIQ Fortis

A powerful, streamlined ultrasound solution that's always ready, always by your side.

For more information, visit the [LOGIQ Digital Experience](#).

* Not all products or features are available in all geographies.
Check with your local GE Healthcare representative for availability in your country.

Product may not be available in all countries and regions. Full product technical specification is available upon request. Contact a GE Healthcare Representative for more information. Please visit www.gehealthcare.com/promotional-locations.

Data subject to change.

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January 2022
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