SUPERSONIC® MACH® 30

V4.2

UltraFast® Intelligence

SUPERSONIC imagine™

SuperSonic® MACH® 30

Addressing Your Expectations with UltraFast® Innovations

Created in 2005 in Aix en Provence, SuperSonic Imagine® was born from a collaboration with the Onde et Acousitque laboratory at ESPCI Paris and the CNRS (Head of French National Scientific Research organization). This collaboration led to the introduction of the innovative technology – **Real-time ShearWave® Elastography.**

SuperSonic Imagine® developed an ultrasound platform that marked the technological and clinical breakthrough changing the landscape of ultrasound and setting new standards for imaging across multiple clinical applications. These clinically validated innovations continue to be unrivaled.

The SuperSonic® MACH® 30 ultrasound system leverages more than 15 years of clinical expertise to help you handle a wide range of exams, from routine to comprehensive, with **ease and confidence**.

By analyzing your exam workflow, SuperSonic® MACH® 30 was designed to **maximize comfort and drive efficiency** in a busy practice thanks to its ease of use and streamlined ergonomics.

Deep inside is a powerful processor running on our exclusive UltraFast® technology, the design for which was inspired by the video gaming industry. The intelligent signal processing **with image capture capacity of up to 20,000 frames per second**[1] brings unlimited possibilities into ultrasound imaging, including excellent image quality, innovative imaging modes and upcoming AI integration.

The image quality of the SuperSonic® MACH® 30 combined with access to advanced capabilities delivers the level of **premium performance** you expect, and patients deserve.

Supporting User Comfort

For Improved Experience and Workflow

1. Widescreen 23” full HD monitor

Enhanced image uniformity, deeper blacks and refined detail

2. Large 15” full HD touch display

More flexibility to define your workflow

6. Automated Protocols

Increase workflow efficiency and maintain exam consistency

3. Intuitive control panel with revolutionary SonicPad®

Improved user experience and workflow

4. Low noise level, optimized cooling fan architecture

Reduced noise for all environments

5. Reduced footprint

Suitable for any practice

SONICPAD®

Being able to “focus on what you see, and not on what you do,” helping reduce user’s movements and examination time to improve workflow.

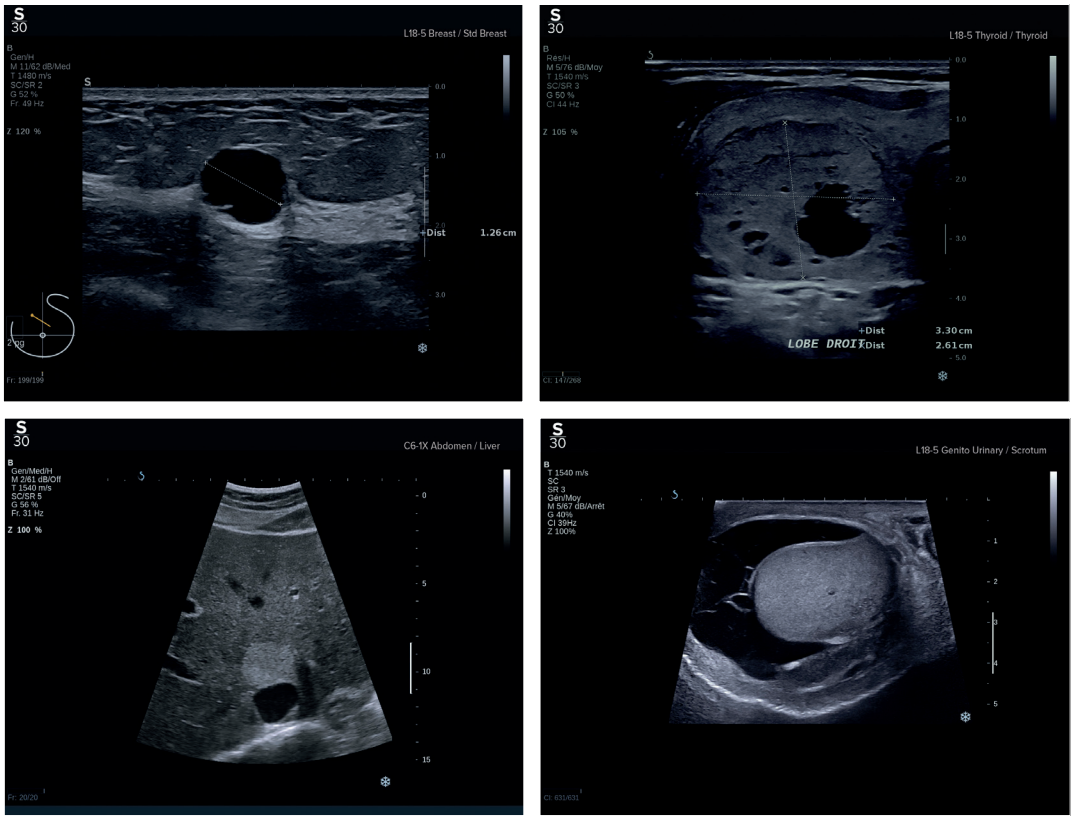
Exceptional B-mode Imaging

Incredible Definition in Fundamental and Harmonic Imaging Modes

The innovative transducer design and powerful capabilities of software-based architecture are optimizing signal-to-noise ratio at each step of signal processing, offering you **an incredible definition in both fundamental and harmonic imaging modes.**[2, 3, 4]

A set of advanced features is available to simplify and speed up the image acquisition process. These include:

- Optimized penetration settings: for visualizing structures at variable depths and in dense breast.
- SuperCompound: fast compounding designed for smooth images with reduced speckle.
- SuperRes: delineation of structures to help improve lesion conspicuity.
- TissueTuner: clear images obtained by matching the speed of sound to tissue density.
- AutoTGC: designed for optimization of the gain for the entire image.



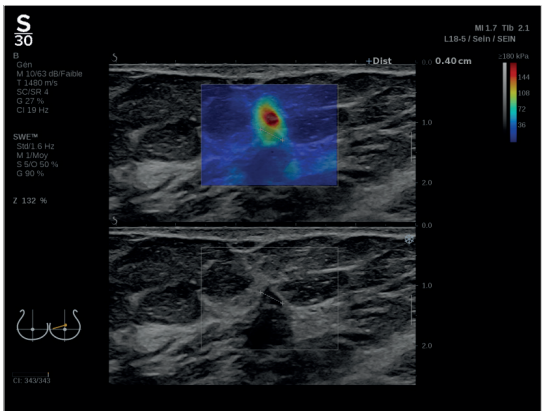
ShearWave® PLUS Elastography

A New Kind of Elastography Experience

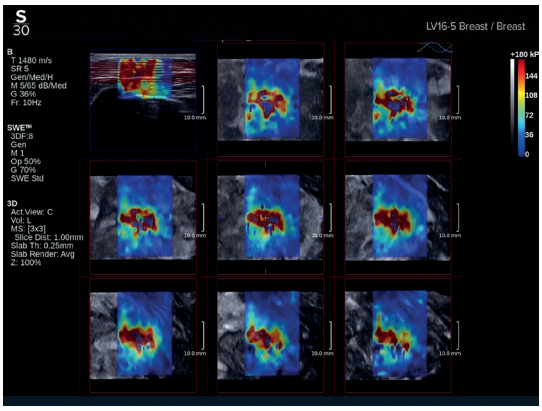
ShearWave® PLUS elastography (SWE PLUS™ 3.0) is **the only technique capable of visualizing, analyzing and quantifying tissue stiffness in real time, on all transducers**. This non-invasive approach remains reliable and highly reproducible in 2D and 3D.[5, 6, 7]

Breast

With over 225 publications[8] in peer-reviewed medical journals, SWE PLUS™ has been proven to be a complementary tool for: breast lesion diagnosis and characterization[9]; biopsy planning[10] and treatment; and therapy monitoring[11] and prognosis.

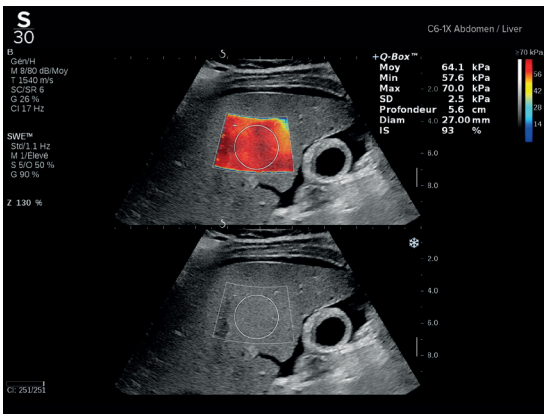


Enhance breast lesion assessment with access to **3D ShearWave® PLUS** elastography volume in a single acquisition.
Breast tissue can be visualized in any plane of 3D volume and this large color-coded map provides information on the elasticity distribution inside and around the lesion.



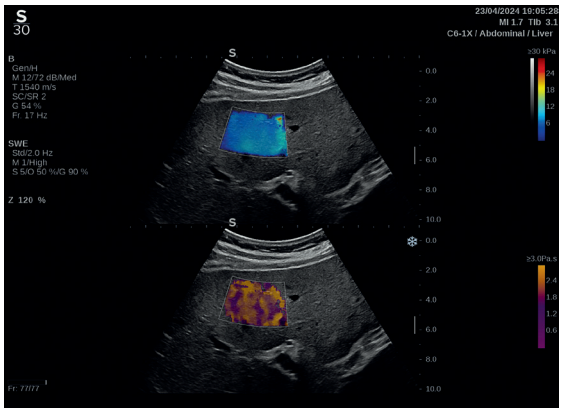
Liver

The utility of SWE PLUS™ in the management of patients with chronic liver disease has been demonstrated in more than 225 clinical publications[12] for evaluation[13] and diagnosis[14] of hepatic fibrosis and follow-up and monitoring of patients.



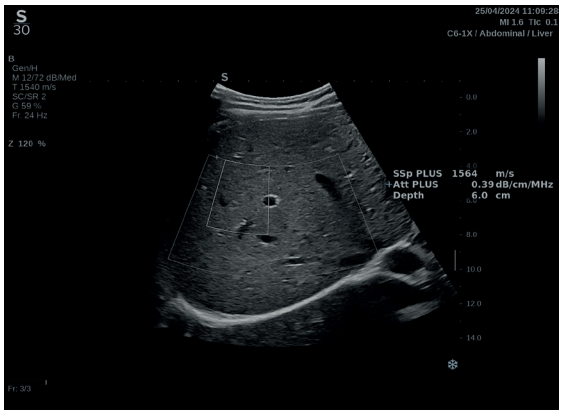
Innovative Imaging Modes

Features Designed to Improve Diagnostic Accuracy

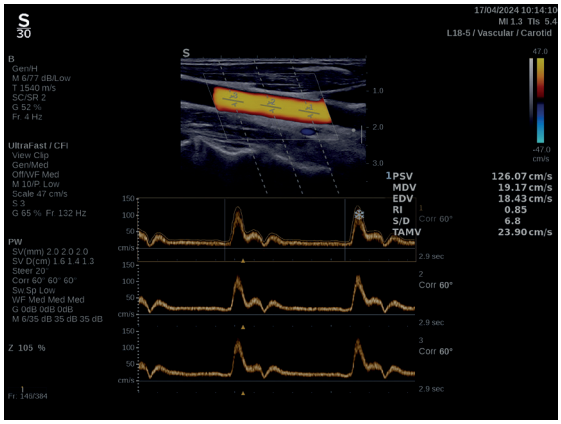


Liver Ultrasound Markers

Introducing unprecedented tools for non-invasive assessment of liver disease severity: SWE PLUS™ for liver stiffness assessment and Viscosity (Vi PL.U.S™) to quantify the viscous proprieties of the liver.

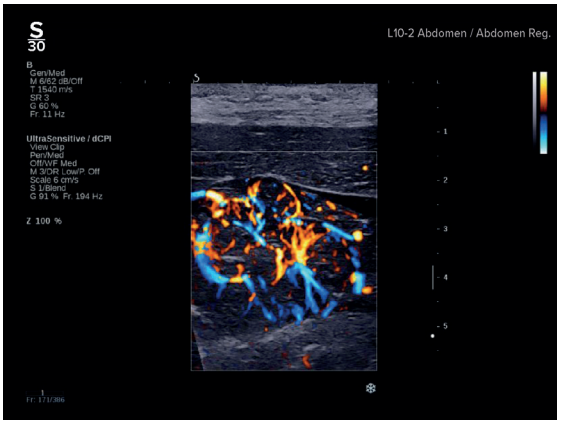


Att PL.U.S™ and Ssp PL.U.S™ to measure Intrahepatic
Fat content for the detection of liver steatosis[15].



UltraFast® Doppler

Offers higher frame rates on the SuperSonic® MACH® 30 system[16] and the same spectrogram quality as conventional PW to simultaneously capture all of the PW Doppler signals at different locations in a single acquisition.
This allows them to be compared during the same cardiac cycle.

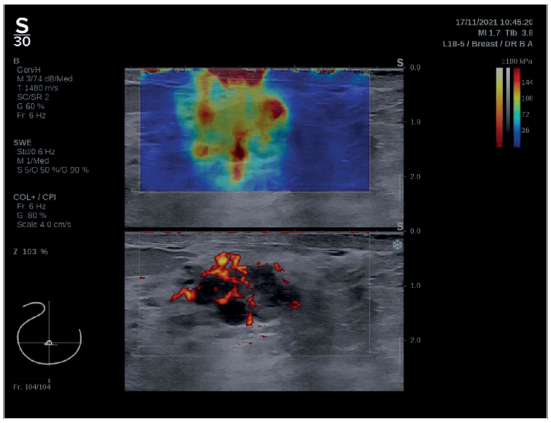


Angio PL.U.S™

This mode allows you to assess microvasculature with incredible spatial resolution and high-frame rate, all without compromising the B-mode.

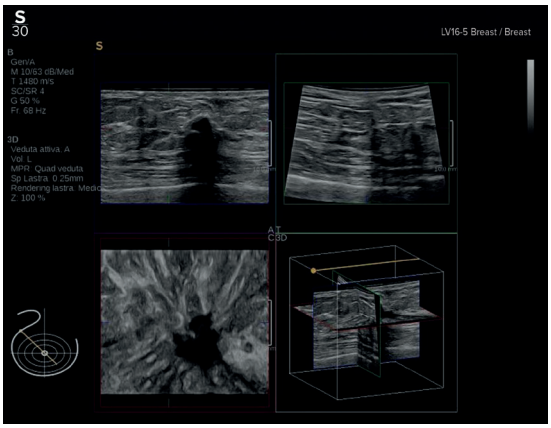
TRIVU™

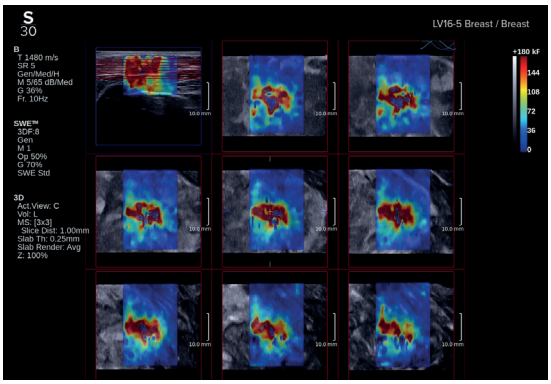
This unique feature enables you to visualize in real-time simultaneously B-mode (anatomy), ShearWave® PLUS (function-tissue stiffness) and Angio PL.U.S™ (micro blood flow) on the same image at the same time.



3D Breast Imaging

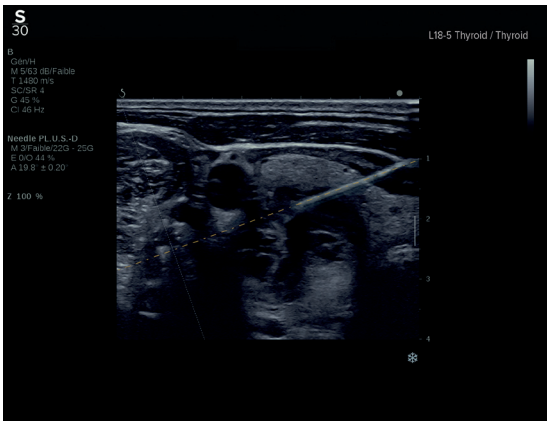
3D ultrasound imaging opens the door as an additional application in breast lesion diagnostics and may support in accurate interpretation. SuperSonic® MACH® provide access to high-resolution B-mode and ShearWave® PLUS 3.0 elastography 3D volumes.





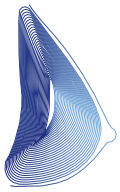
Needle PL.U.S™

This real-time imaging mode allows you to perform biopsies with precision and confidence, without loss of B-mode information. It enhances the visualization of the needle and predicts its trajectory.



General Imaging

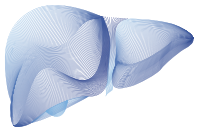
Turning Technological Innovation into Clinical Value



Breast

Offering exclusive features designed to facilitate everyday productivity and improve patient management and outcomes.

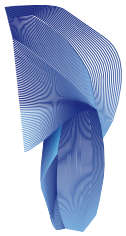
- Enhance breast lesion diagnosis and characterization, including breast 3D assessment as well as on-cart BI-RADS classification.
- Improve clinical decision-making for biopsy and treatment.
- Access prognostic information.
- Query/Retrieve function to access Mammography images of same patient to perform side by side comparison.



Liver

Meeting the needs of liver experts focused on patients with chronic and focal liver disease; allows the user to follow patients throughout the continuum of care.

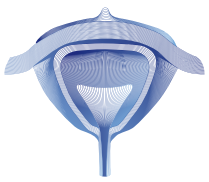
- Quickly and reliably assess liver fibrosis and liver steatosis.
- Non-invasively follow up and monitor patients over time.
- Screen and characterize focal liver lesions.



Muscles, Tendons, Joints & Nerves

Enhancing overall diagnostic capabilities for the musculoskeletal systems.

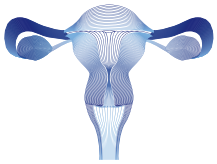
- Screen and assess musculoskeletal injuries.
- Explore both inflammatory and mechanical disorders.
- Obtain precise characterization of the musculoskeletal unit for a more confident diagnosis.



Masculine Health

A multi-parametric modality for masculine health.

- Screen for prostate cancer and characterize lesions.
- Conduct multiparametric prostate assessments and therapy monitoring.
- Perform targeted prostate biopsies.



Obstetrics & Gynecology

Visualizing clearly fine morphological structural details of the ovaries, adnexa and endometrium.[17, 18]

- Detect and characterize gynecological pathologies.
- Choose a comprehensive fetal imaging and reporting solution.
- Add real-time stiffness assessment and measurement of the tissues.

Thyroid

Delivering accurate exam information critical to your thyroid diagnostic challenges.

- Simultaneously assess thyroid morphology, microvascularization and stiffness in real time with TRIVU™.
- Perform multiparametric nodule characterization and TI-RADS classification.
- Take advantage of ShearWave® elastography, which renders a real-time, quantitative (kPa) color-coded assessment, to characterize both thyroid nodules and cervical lymph nodes and guide biopsies.

Pediatric

Dedicated optimized presets to meet all imaging needs.

- Gain key information (morphology, stiffness and microvascularization) with real-time multiparametric assessments to enhance diagnostic efficiency and patient monitoring.
- Leverage new ultrasound biomarkers to optimize and guide patient management at an early stage.
- Tailor it to your requirements; a family of pediatric transducers and application-specific presets.

Vascular

Expanded capabilities thanks to a unique software based technology.

- Perform stenosis staging in 3 different locations simultaneously and in a single acquisition during the same cardiac cycle with UltraFast® Doppler.
- Conduct ultrasensitive blood flow analysis without compromise with Angio PL.U.S™
- Improve patient management and monitoring with advanced vascular analysis.

Power at Your Fingertips

SuperSonic® MACH® 30's transducer portfolio leverages and combines:

- Unique SuperSonic Imagine® 100% software beamforming
- UltraFast® Imaging
- Single crystal technology
- Next generation pinless connector for easy handling
- Re-designed housing facilitating one hand manipulation

C6-1X SINGLE CRYSTAL CURVILINEAR

Single crystal element
192

Bandwidth
1-6 MHz

Clinical Applications

- Abdominal
- Pelvis
- OB-GYN
- Pediatric
- Thyroid
- Vascular

C9-2X SINGLE CRYSTAL CURVILINEAR

The perfect solution for narrow intercostal spaces without compromise on penetration.

Single crystal element
192

Bandwidth
2-9 MHz

Clinical Applications

- Abdominal
- Breast
- OB-GYN
- Pediatric
- Thyroid

L18-5 LINEAR

Composite elements
256

Bandwidth
5-18 MHz

Clinical Applications

- Abdominal
- Breast
- Musculo-skeletal
- Pediatric
- Thyroid
- Vascular
- Small parts

L10-2 LINEAR

Composite elements
192

Bandwidth
2-10 MHz

Clinical Applications

- Abdominal
- Breast
- Musculo-skeletal
- Pediatric
- Thyroid
- Vascular
- Small parts

E12-3 ENDOCAVITARY

Composite elements
192

Bandwidth
3-12 MHz

Clinical Applications

- OB-GYN
- Prostate

P5-1X SINGLE CRYSTAL PHASED ARRAY

Single crystal element
96

Bandwidth
1-5 MHz

Clinical Applications

- Vascular abdominal
- TCD
- Cardiac

MC12-3 MICRO-CONVEX

Composite elements
192

Bandwidth
3-12 MHz

Clinical Applications

- Pediatric
- Vascular

LV16-5 LINEAR VOLUMETRIC (3D)

Composite elements
192

Bandwidth
5-16 MHz

Clinical Applications

- Breast

LH20-6 LINEAR

Composite elements
192

Bandwidth
6-20 MHz

Clinical Applications

- Musculo-skeletal
- Vascular
- Breast
- Pediatric
- Small parts

Connected Experience

SuperSonic® MACH® 30 facilitates exchanges and ensures that information is always available in the right place at the right time.

- Disk encryption at installation to protect patient's personal data.
- Password requiring login to ensure security and that user preferences are preserved.
- DICOM compatibility and multiple connection ports for greater flexibility.

Accessories

Wi-Fi

- Capability for wireless DICOM modalities and network connections
- Linksys AE3000 External Wi-Fi Dongle compliant with 802.11 b/g/n standard
- Wi-Fi device FCC/IC/CE certified

High-End Barcode Reader

- Hand held ergonomic scanner to read bar codes
- Factory programmed to be operational with SuperSonic® MACH® 30

Black and White Thermal Printer

- Sony Model UP-D898DC (A6 format) integrated into SuperSonic® MACH® 30

Two or Three Function Footswitches Available

- Easily connects to any USB port
- Programmable from a set of frequently used operations

Integrated Gel Warmer

- Automatic management of heating up to 37°C

Biopsy Accessories and Kits Available

- CIVCO ,Protek and InnoFine for various transducers: L18-5, L10-2, C6-1X, E12-3, MC12-3, C9-2X

Flex Transducer Cable Stand

An Eco-designed Product

SuperSonic Imagine® is certified ISO 14001. This certification confirms that the company has voluntarily implemented an environmental management policy, demonstrating a strong commitment to minimize environmental impact throughout the product's life cycle.

References:

1/ Tozaki M, Fukuma E. Pattern classification of ShearWave™ Elastography images for differential diagnosis between benign and malignant solid breast masses. Acta Radiol. 2011;52(10):1069-1075. doi: 10.1258/ar.2011.110276.

2/ MACH 30 V1 Evaluation Report Hôpital privé Jean Mermoz july, 5th & 6th 2018. PM.TP/TR.092

3/ MACH 30 V1 Evaluation Report CHRU Jean Minjoz - Besançon – France. PM.TP/TR.093

4/ MACH 30 V1 SSI in-house. PM.TP/TR.094

5/ Cosgrove D, Berg W, Doré J et al. Shear wave elastography for breast masses is highly reproducible. European Radiology. 2012 May; 22(5): 1023–1032.

6/ Hudson J, Milot L, Parry C et al. Inter-and intra-operator reliability and repeatability of shear wave elastography in the liver: a study in healthy volunteers. Ultrasound Med Biol. 2013 Jun;39(6):950-5

7/ Garcovich M, Veraldi S, Di Stasio E et al. Liver Stiffness in Pediatric Patients with Fatty Liver Disease: Diagnostic Accuracy and Reproducibility of Shear-Wave Elastography. Radiology. 2017 Jun; 283(3):820-827.

8/ Publications List for Breast Health, MISC-06500 Rev 002

9/ Berg WA, Cosgrove DO, Doré CJ, et al. Shear-wave elastography improves the specificity of breast US: the BE1 multinational study of 939 masses. Radiology. 2012 Feb;262(2):435-49.

10/ Mullen R, Thompson JM, Moussa O et al. Shear-wave elastography contributes to accurate tumour size estimation when assessing small breast cancers. Clin Radiol. 2014;69(12):1259–1263.

11/ Peer Reviewed Articles ShearWave™ Elastography for Liver and Abdominal Imaging, MKG.EC.337,

12/ Lee SH, Chang JM, Han W, et al. Shear-Wave Elastography for the Detection of Residual Breast Cancer After Neoadjuvant Chemotherapy. Ann Surg Oncol. 2015;22 Suppl 3: S376–S384.

13/ Gao Y, Zheng J, Liang P, et al. Liver Fibrosis with Two-dimensional US Shear-Wave Elastography in Participants with Chronic Hepatitis B: A Prospective Multicenter Study. Radiology. 2018 Nov;289(2):407-415.

14/ Garcovich M, Veraldi S, Di Stasio E, et al. Liver Stiffness in Pediatric Patients with Fatty Liver Disease: Diagnostic Accuracy and Reproducibility of Shear-Wave Elastography. Radiology. 2017;283(3):820–827.

15/ Fujiwara et al., The B-mode image-guided ultrasound attenuation parameter accurately detects hepatic steatosis in chronic liver disease, Ultrasound in Med. & Biol. 2018

16 / In comparison with Aixplorer® MultiWave™ systems

17/ Engineering Clinical Evaluation (Ece) V10 Endocavity Probes Evaluation in Gynecology Dr Shojai Aix En Provence; PM.TP/TR.034

18/ V10 CMR Validation – Institut de Radiologie de Paris – Gynecology; PM.TP/TR.036

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Indications for Use: The SuperSonic Imagine® - SuperSonic® MACH® range ultrasound diagnostic systems and transducers are intended for general purpose pulse echo ultrasound imaging, soft tissue viscoelasticity imaging and Doppler fluid flow analysis of the human body. The SuperSonic® MACH® ultrasound diagnostic systems are indicated for use in the following applications, for imaging and measurement of anatomical structures: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, Intraoperative, OB-GYN, Pelvic, Pediatric, Transrectal, Transvaginal, Urology, Neonatal/Adult Cephalic and Non-invasive Cardiac. In addition, the SuperSonic Imagine® - SuperSonic® MACH® ultrasound diagnostic systems and associated transducers are intended for: measurements of abdominal anatomical structures; measurements of broadband shear wave speed, and tissue stiffness in internal structures of the liver and the spleen; measurements of brightness ratio between liver and kidney; visualization of abdominal vascularization, microvascularization and perfusion; quantification of abdominal vascularization and perfusion. The shearwave speed, beam attenuation, viscosity and stiffness measurements, the brightness ratio, the visualization of vascularization, microvascularization and perfusion, the quantification of vascularization and perfusion may be used as an aid to clinical management of adult and pediatric patients with liver disease. It is intended for use by licensed personnel qualified to direct the use of the medical ultrasound devices. CE certificate no. 26415, FDA cleared K180572.

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