March 2, 2023

Echosens
% Zvi Ladin
Principal
Boston MedTech Advisors Inc.
990 Washington Street, Suite #204
DEDHAM MA 02026

Re: K223902
Trade/Device Name: FibroScan® device (Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: December 21, 2022
Received: December 28, 2022

Dear Zvi Ladin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223902

Device Name
FibroScan® device (Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630)

Indications for Use *(Describe)*
The FibroScan® device (Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630) is intended to measure liver stiffness (E) using Vibration Controlled Transient Elastography™ (VCTE™) at 50 Hz shear wave frequency and liver ultrasound attenuation coefficient (CAP™)* at 3.5 MHz. FibroScan® 630 Expert is also intended to measure spleen stiffness using VCTE™ at 100 Hz shear wave frequency.

FibroScan liver stiffness measurements (LSM) by VCTE™ may aid the physician in determining the likelihood of cirrhosis and may be used, taken in context with other clinical and laboratory data, as an aid in the assessment of liver fibrosis. FibroScan CAP™ measurements may be used, taken in context with other clinical and laboratory data, as an aid in the assessment of hepatic steatosis.

FibroScan® is indicated as a non-invasive aid for the clinical management, diagnosis, and monitoring of adult and pediatric patients with confirmed or suspected liver disease, as part of an overall assessment of the liver. Results in the pediatric population should be interpreted while considering the clinical condition and the overall patient profile.

The FibroScan® device is intended for use by healthcare professionals in hospitals, clinics or any facility where healthcare is provided.

*CAP™ refers to ultrasound attenuation coefficient (originally defined as Controlled Attenuation Parameter). CAP™ on S+ probe is only available with SmartExam capability.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K223902

510(K) Summary
Echosens' FibroScan® System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Manufacturer: Echosens
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Date Prepared: February 23, 2023

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name: FibroScan® device
(Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630)

Common Name: Diagnostic Ultrasound System and Accessories

Classifications:

Classification Name	Regulation	Product Code
Ultrasonic Pulsed Echo Imaging System	21 CFR §892.1560	IYO
Diagnostic Ultrasonic Transducer	21 CFR §892.1570	ITX

Manufacturing Facility: Echosens
6 rue Ferrus, Paris, France, 75014
Telephone: +33 1 44 82 78 56
Fax: +33 1 44 82 78 60

Establishment Registration Number: 3010258456

Predicate Device

This submission claims substantial equivalence to the following predicate and reference devices:

1. Primary Predicate Device: Echosens's FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, and 630), cleared on March 25, 2021 (#K203273)
2. Reference Device: Echosens's FibroScan® 230, cleared in on July 30, 2021 (#K212035)

Device Description

FibroScan® System consists of a system unit and a hand-held probe. It is based on Vibration-Controlled Transient Elastography (VCTE™) technology and is designed to perform non-invasive measurements of liver/spleen shear wave speed and estimate tissue stiffness. The probe, containing a mechanical vibrator, produces low-amplitude elastic waves that travel through the skin and intercostal space into the liver/spleen. Ultrasound is used to track the shear (elastic) wave, measure its speed and provide estimated stiffness. The results are displayed on the system unit.

The focus of this submission is the clearance of the FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630) with a streamlined IFU and updated labelling materials. FibroScan® has the same intended use as the predicate and reference FibroScan systems. However, this submission is expanding the indications for use of the system, to be used with other clinical and laboratory data, as an aid in determining the likelihood of cirrhosis, in the assessment of liver fibrosis and in the assessment of hepatic steatosis. Additionally, the IFU is expanding its indications to patients with confirmed or suspected liver disease. The contraindications of the system for patients with pregnancy and/or active implants were removed. Instead, a warning statement was included in the device labeling regarding the lack of extensive studies of such populations and the resulting possible impact on patient risk and measurement reliability. These changes, among others, are based on comprehensive clinical literature and practice guideline support.

Although there have been no significant changes to the software, this clearance includes an updated version of the FibroScan® software for all models.

Comparison of Technological Characteristics

All systems in the FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630) have the same fundamental scientific technology, basic design, operating principles, general user interface, and basic software specifications. There are no differences in the device hardware and probes compared to its predicate and reference FibroScan systems.

FibroScan® Family of Products is substantially equivalent to the FibroScan® systems cleared by 510(k) #K203273 and #K212035. Table 1 provides a detailed comparison of the candidate, predicate, and reference devices. All systems provide 50Hz shear wave speed measurements and estimates of tissue stiffness in the liver using the S+, M+, and XL+ transducers. Additionally, all systems provide CAP, designed to estimate the ultrasound attenuation at the frequency of 3.5MHz.

The technological characteristics of the FibroScan® Family of Products in this submission are substantially equivalent to the predicate and reference devices.

Recognized Consensus Standards Used

Non-clinical testing to assure compliance with acoustic output, biocompatibility, cleaning, and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety were performed and have been found to conform to applicable standards. The system complies with the following standards:

- IEC 60601-2-37: Medical Electrical Equipment - Part 2-37: Particular Requirements for The Basic Safety And Essential Performance Of Ultrasonic Medical Diagnostic And Monitoring Equipment; Edition 2.1 2015.
- NEMA UD: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3; 2-2004 (R2009).
- IEC 62127-1: Ultrasonics -- Hydrophones -- Part 1: Measurement and Characterization of Medical Ultrasonic Fields Up To 40 Mhz; Edition 1.1 2013-02.
- IEC 62127-2: Ultrasonics -- Hydrophones -- Part 2: Calibration for Ultrasonic Fields Up To 40 Mhz; Edition 1.1 2013-02.
- IEC 62127-03: Ultrasonics -- Hydrophones -- Part 3: Properties of Hydrophones for Ultrasonic Fields Up To 40 Mhz; Edition 1.1 2013-05.
- IEC 61161: Ultrasonics -- Power Measurement -- Radiation Force Balances and Performance Requirements; Edition 3.0 2013-01.
- AAMI / ANSI ES60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, Mod); 2005/(R) 2012.
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests; Edition 4: 2014-02.
- IEC 60601-1-6: Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability; Edition 3.1 2013-10
- IEC 62366-1 Edition 1.0 2015-02: Medical Devices - Application Of Usability Engineering To Medical Devices.
- IEC 62304: Medical Device Software - Software Life Cycle Processes; Edition 1.1 2015-06 CONSOLIDATED VERSION.
- ISO 14971 Second: Medical Devices - Application of Risk Management To Medical Devices; Third Edition 2019-12.

Intended Use / Indications for Use

The FibroScan® device (Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630) is intended to measure liver stiffness (E) using Vibration Controlled Transient Elastography™ (VCTE™) at 50 Hz shear wave frequency and liver ultrasound attenuation coefficient (CAP™) at 3.5 MHz. FibroScan® 630 Expert is also intended to measure spleen stiffness using VCTE™ at 100 Hz shear wave frequency.*

FibroScan liver stiffness measurements (LSM) by VCTE™ may aid the physician in determining the likelihood of cirrhosis and may be used, taken in context with other clinical and laboratory data, as an aid in the assessment of liver fibrosis. FibroScan CAP™ measurements may be used,

taken in context with other clinical and laboratory data, as an aid in the assessment of hepatic steatosis.

FibroScan® is indicated as a non-invasive aid for the clinical management, diagnosis, and monitoring of adult and pediatric patients with confirmed or suspected liver disease, as part of an overall assessment of the liver. Results in the pediatric population should be interpreted while considering the clinical condition and the overall patient profile.

The FibroScan® device is intended for use by healthcare professionals in hospitals, clinics or any facility where healthcare is provided.

**CAP™ refers to ultrasound attenuation coefficient (originally defined as Controlled Attenuation Parameter). CAP™ on S+ probe is only available with SmartExam capability.*

Performance Data

No new hardware elements were included in the submission, and the new software version does not impact device performance. Therefore, no new performance data were required in support of the submission. The changes in the indications for use and labeling included in this submission are supported by a comprehensive clinical literature of approximately 100 published clinical literature articles and 20 supporting published professional guidelines. Papers used in support of the changes were focused on studies in which FibroScan® results are compared to the ground truth of liver biopsy.

The use of probes based on patient morphology rather than age is supported by 41 papers with ~8,570 patients. Of the 41 studies, the safe and effective use of the S+ probe on patients older than 18 was evaluated in 3 studies (n = 250 patients including healthy controls, patients with liver disease, and patients with cystic fibrosis); the safe and effective use of the M+ probe on patients younger than 14 was evaluated in 29 studies (n = 5,950 patients including healthy controls, Nonalcoholic fatty liver disease (NAFLD), Non-alcoholic steatohepatitis (NASH), with fibrosis and/or steatosis, cystic fibrosis, obese, obese without liver disease, chronic liver disease, intestinal failure, Hepatitis C, and liver transplant patients); and the safe and effective use of the XL+ Probe on patients younger than 18 was evaluated in 9 studies (n = 2,369 patients including healthy controls, NAFLD, with fibrosis, Hepatitis C, and NASH). Use of probes on patients outside their indicated age limits, as documented in the numerous clinical publications, showed no adverse events related to probe use, supporting the safety of such use, as well as supported the effectiveness based on LSM, CAP, or both.

The use of FibroScan® as an aid to diagnosis and monitoring of pediatric patients is supported by 24 papers (n = 6,573) supporting the effectiveness of FibroScan® as an aid to diagnosis in pediatric population, and six additional papers (n = 293) supporting FibroScan® as an aid to monitoring in pediatric population. No adverse events related to performing FibroScan® examinations were recorded.

The effectiveness of the FibroScan® system in patients suspected of liver disease is supported by ten studies (n= 5,650 patients) assessing suspected patients (following their initial screening) using transient elastography (TE) as part of an overall assessment of the liver. The use of TE in

patients suspected of liver disease is also supported by clinical guidelines. Similarly, the revision of the labeling for FibroScan® output interpretation by physicians “with appropriate training” is intended to reflect the current recommendations from clinical guidelines on the use of FibroScan® as an essential component of clinical care, following initial screening of suspected liver disease patients in a primary care clinical environment, followed by further assessment by physicians experienced in the management of liver diseases as necessary.

The added clinical claims in the IFU include the aid in assessment of liver fibrosis and hepatic steatosis, when taken in context with other clinical and laboratory data. Additionally, the claims include the aid in determining the likelihood of cirrhosis. The addition of the clinical claims to the IFU is supported by peer reviewed literature demonstrating the consistent and robust correlation between LSM and fibrosis and LSM as an indicator of cirrhosis (3 longitudinal studies (290 patients) and 18 meta-analyses totaling 369 studies (>40,000 patients)) as well as between CAP™ and steatosis (6 meta-analysis publications, tallying 138 studies with ~12,900 patients). The clinical utility is also strongly supported by professional society clinical guidelines.

The removal of the contraindication of the device for active implants and for pregnant women is supported by technical considerations addressing the acoustic and mechanical output of the electrodynamic actuator and ultrasound probe. In addition, removal of contraindications for active implants is supported by 2 studies with 141 patients and removal of contraindications for pregnant women is supported by 3 studies with 611 pregnant women. These studies showed the device performs effectively on these patient populations, with no adverse events. Moreover, a warning statement was included in the device labeling regarding the lack of extensive studies of such populations and the resulting possible impact on patient risk and measurement reliability.

The clinical literature review demonstrates that the FibroScan® Family of Products with updated labelling and indications for use are safe, effective, and substantially equivalent to the predicate and reference FibroScan® devices.

Substantial Equivalence Discussion

The FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630) uses the same operating principle and materials, incorporates the same basic design, emits the same energy, acquires the same information, and has the same intended use as the predicate and reference FibroScan® devices (#K203273 and #K212035). The updated indications for use and labeling, do not raise new or different questions of safety or efficacy. The updated software version was verified and validated.

In summary, the conclusions drawn from the clinical review provided in this submission demonstrate that FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630) raises no new or different issues of safety or effectiveness and is substantially equivalent to its primary predicate device.

Table 1. Predicate and Reference Device Comparison for FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630)

	Subject Device: FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630)	**Primary Predicate Device: FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, 630)**	**Reference Device: FibroScan® 230**
510(k) # (Clearance)	**K223902**	**K203273**	**K212035**
Manufacturer	Echosens	Echosens	Echosens
Indications for Use	The FibroScan® device (Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630) is intended to measure liver stiffness (E) using Vibration Controlled Transient Elastography™ (VCTE™) at 50 Hz shear wave frequency and liver ultrasound attenuation coefficient (CAP™)* at 3.5 MHz. FibroScan® 630 Expert is also intended to measure spleen stiffness using VCTE™ at 100 Hz shear wave frequency. FibroScan liver stiffness measurements (LSM) by VCTE™ may aid the physician in determining the likelihood of cirrhosis and may be used, taken in context with other clinical and laboratory data, as an aid in the assessment of liver fibrosis. FibroScan CAP™ measurements may be used, taken in context with other clinical and laboratory data, as an aid in the assessment of hepatic steatosis. FibroScan® is indicated as a non-invasive aid for the clinical management, diagnosis, and monitoring of adult and pediatric patients with confirmed or suspected liver disease, as part of an overall assessment of the liver. Results in the pediatric population should be interpreted while considering the clinical condition and the overall patient profile.	The FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, and 630) is intended to provide shear wave speed measurements and estimates of tissue stiffness as well as ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter) in internal structures of the body. The Shear wave speed and stiffness measurements may be used as an aid to clinical management of adult patients with liver disease. The FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, and 630) is indicated for non-invasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as determining a 3.5 MHz ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter). The shear wave speed and stiffness, and CAP may be used as an aid to diagnosis and monitoring of adult patients with liver disease, as part of an overall assessment of the liver.	The FibroScan® is intended to provide shear wave speed measurements and estimates of tissue stiffness as well as ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter) in internal structures of the body. The Shear wave speed and stiffness measurements may be used as an aid to clinical management of adult patients with liver disease. The FibroScan® is indicated for non-invasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as determining a 3.5 MHz ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter). The shear wave speed and stiffness, and CAP may be used as an aid to diagnosis and monitoring of adult patients with liver disease, as part of an overall assessment of the liver. Shear wave speed and stiffness, and CAP may be used as an aid in the clinical management of

	The FibroScan® device is intended for use by healthcare professionals in hospitals, clinics or any facility where healthcare is provided. * CAP™ refers to ultrasound attenuation coefficient (originally defined as Controlled Attenuation Parameter). CAP™ on S+ probe is only available with SmartExam capability.	Shear wave speed and stiffness, and CAP* may be used as an aid in the clinical management of pediatric patients with liver disease. FibroScan® 630 (Expert) is also indicated for noninvasive measurement in the spleen of 100 Hz shear wave speed and estimates of stiffness that may be used as an aid to diagnosis, monitoring and clinical management of adult patients with liver disease, as part of an overall assessment of the liver. *CAP for pediatric patients with liver disease is only available with SmartExam capability on FibroScan® Models: 530 Compact, 430 Mini+, and 630	pediatric patients with liver disease.
Application	Abdominal	Abdominal	Abdominal
Imaging Modes	A-mode / M-mode Transient Elastography/ Shear Wave / (CAP™)	A-mode / M-mode Transient Elastography/ Shear Wave / (CAP™)	A-mode / M-mode Transient Elastography/ Shear Wave / (CAP™)
Ultrasound	Piezoelectric ultrasound source	Piezoelectric ultrasound source	Piezoelectric ultrasound source
Probes	M+-probe (3.5 MHz) XL+ probe (2.5 MHz) S+ probe (5 MHz) (single element ultrasound transducer)	M+-probe (3.5 MHz) XL+ probe (2.5 MHz) S+ probe (5 MHz) (single element ultrasound transducer)	M+-probe (3.5 MHz) XL+ probe (2.5 MHz) S+ probe (5 MHz) (single element ultrasound transducer)
Fixed Depth Method	S1 exam : 15-40 mm S2 exam : 20-50 mm M exam: 25-65 mm XL exam: 35-75 mm	S1 exam : 15-40 mm S2 exam : 20-50 mm M exam: 25-65 mm XL exam: 35-75 mm	S1 exam : 15-40 mm S2 exam : 20-50 mm

Adaptive Depth Method (SmartDepth)	M exam: 25-65 mm / 30-70 mm XL exam: 35-75 mm/ 40-80 mm/ 45-85 mm	M exam: 25-65 mm / 30-70 mm XL exam: 35-75 mm/ 40-80 mm/ 45-85 mm	M exam: 25-65 / 30-70 mm XL exam: 35-75 mm/ 40-80 mm/ 45-85 mm
B-Mode Ultrasound Localization Probe	For FibroScan® 630 Expert: ES-C5-2R60S-3	For FibroScan® 630 Expert: ES-C5-2R60S-3	N/A
VCTE™ Mode	Shear wave speed measurements and tissue stiffness	Shear wave speed measurements and tissue stiffness	Shear wave speed measurements and tissue stiffness
VCTE™ Range (Liver)	Shear wave speed (0.8-5.0 m/s) Stiffness (2.0-75 kPa)	Shear wave speed (0.8-5.0 m/s) Stiffness (2.0-75 kPa)	Shear wave speed (0.8-5.0 m/s) Stiffness (2.0-75 kPa)
VCTE™ Range (Spleen)	For FibroScan® 630 Expert: Shear wave speed (1.4-5.8 m/s) Stiffness (6.0-100 kPa)	For FibroScan® 630 Expert: Shear wave speed (1.4-5.8 m/s) Stiffness (6.0-100 kPa)	N/A
VCTE™ Display (Liver)	Shear wave speed and stiffness medians and Interquartile range (IQR) and IQR/median ratio	Shear wave speed and stiffness medians and Interquartile range (IQR) and IQR/median ratio	Shear wave speed and stiffness medians and IQR/median ratio
VCTE™ Display (Spleen)	For FibroScan® 630 Expert: Shear wave speed and stiffness medians and Interquartile range (IQR)	For FibroScan® 630 Expert: Shear wave speed and stiffness medians and Interquartile range (IQR)	N/A
Mode of U/S signals acquisition	First generation CAP: Elastography mode Second generation CAP: Imaging mode	First generation CAP: Elastography mode Second generation CAP: Imaging mode	First generation CAP: Elastography mode Second generation CAP: Imaging mode
Attenuation Range	CAP value (100-400 dB/m)	CAP value (100-400 dB/m)	CAP value (100-400 dB/m)
Attenuation Display	First generation CAP: CAP median and interquartile range (IQR) Second generation CAP and FibroScan® 230: CAP mean and standard deviation	First generation CAP: CAP median and interquartile range (IQR) Second generation CAP: CAP mean and standard deviation	CAP mean and standard deviation
Attenuation Display – Probes compatibility	S+ Probe (second generation, model 10) M+ Probe XL+ Probe	S+ Probe (second generation, model 10) M+ Probe XL+ Probe	S+ Probe M+ Probe XL Probe

Size and Weight	FibroScan® 502 Touch: 1350 mm x 680 mm x 610 mm (H x W x D) 41kg with accessories FibroScan® 530 Compact: 460 mm x 360 mm x 250 mm (H x W x D) 10kg with accessories FibroScan® 430 Mini+: 275mm x 400mm x 95mm (H x W x D) 6kg with accessories FibroScan® 630: 1365mm x 642mm x 584mm (H x W x D) 46kg with accessories FibroScan® 230: 265.5mm x 157mm x 200mm (H x W x D) 4.4kg with accessories	FibroScan® 502 Touch:1350 mm x 680 mm x 610 mm (H x W x D) 41kg with accessories FibroScan® 530 Compact: 460 mm x 360 mm x 250 mm (H x W x D) 10kg with accessories FibroScan® 430 Mini+: 275mm x 400mm x 95mm (H x W x D) 6kg with accessories FibroScan® 630: 1365mm x 642mm x 584mm (H x W x D) 46kg with accessories	FibroScan® 230: 265.5mm x 157mm x 200mm (H x W x D) 4.4kg with accessories
Power supply	100-240 V ~ 50–60 Hz	100-240 V ~ 50–60 Hz	100-240 V ~ 50–60 Hz
Elastography engine	FibroScan 502 Touch: Analog front end High frequency (US): PV2; Analog front end Low frequency (servo control): PV2 FibroScan® 530 Compact, 430 Mini+, 630, and 230: Analog front end High frequency (US): PV3; Analog front end Low frequency (servo control): PV3	FibroScan 502 Touch: Analog front end High frequency (US): PV2; Analog front end Low frequency (servo control): PV2 FibroScan® 530 Compact, 430 Mini+, and 630: Analog front end High frequency (US): PV3; Analog front end Low frequency (servo control): PV3	FibroScan® 230: Analog front end High frequency (US): PV3 Analog front end Low frequency (servo control): PV3
Operating system	Windows Embedded	Windows Embedded	Windows Embedded
Screen	Color LCD touch screen FibroScan® 502 Touch: 19 inches. FibroScan® 530 Compact: 15 inches. FibroScan® 430 Mini+: 12.1 inches. FibroScan® 630: 19 inches. FibroScan® 230: User’s computer (Screen resolution req: 1024 x 768)	Color LCD touch screen FibroScan® 502 Touch: 19 inches. FibroScan® 530 Compact: 15 inches. FibroScan® 430 Mini+: 12.1 inches. FibroScan® 630: 19 inches.	User’s computer (Screen resolution req: 1024 x 768)