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

March 25, 2021

Re: K203273
Trade/Device Name: FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, and 630)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: March 2, 2021
Received: March 4, 2021

Dear Dr. 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K203273

Device Name
FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, and 630)

Indications for Use *(Describe)*
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.
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

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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K203273

510(K) Summary
Echosens' FibroScan® System

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

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Date Prepared: January 29, 2021

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name: FibroScan® Family of Products
(Models: 502 Touch, 530 Compact, 430 Mini+, 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
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Establishment Registration Number: 3010258456

Predicate Device

This submission claims substantial equivalence to:

1. Primary Predicate Device: Echosens's FibroScan® Family of Products (Models: 502 Touch, 530 Compact, and 430 Mini+), cleared on July 9, 2018 (#K181547)
2. Reference Device: Echosens's FibroScan® 630, cleared in on July 16, 2020 (#K200655)

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 an updated version of FibroScan software (CLPC 4.1) for all previously cleared FibroScan® Family of Products. The software version CLPC 4.1 involves the following changes:

- Streamlined software platform across between all devices
- Simplified user interface
- Functional enhancements:
    - Continuous CAP (Controlled Attenuation Parameter) measurement (CAPc)
    - CAPc applied to S+ probe
    - SmartDepth adjustment of measurement depth to patient anatomy
    - Improved probe localization step

FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, and 630) has the same intended use as the previously cleared FibroScan models. The submission expands the indications for use of the system to include use of the S+ probe for estimation of CAP.

Comparison of Technological Characteristics

All systems in the FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, 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) #K181547 and #K200655. 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 3.5 MHz.

The CAPc and SmartDepth options are enabled on CLPC 4.1 with the 'SmartExam' capability. The SmartDepth option automatically adapts the depth of the liver stiffness measurement (LSM), based on the anatomy of the patient. The LSM calculated with the SmartDepth capability uses the same LSM algorithm as the predicate and reference systems. The continuous CAP (CAPc) option improves the standard CAP measurements by extending the time window for data acquisition. The CAPc and SmartDepth do not impact the spleen examination (available on FibroScan® 630 Expert).

By allowing the system to automatically adjust to the recommended measurement depth, the FibroScan system with the SmartDepth capability is able to measure deeper and more accurate liver measurements, with the M+ and XL+ probes. Specifically, with SmartDepth, the measurement depths may be automatically adjusted to either 25-65 mm (M1) or 30-70 mm (M2) using the M+ probe, and to either 35-75 mm (XL1), 40-80 mm (XL2) or 45-85 mm (XL3) using the XL+ probe. In comparison, FibroScan without SmartDepth capability includes fixed depth measurements that correspond to the M1 and XL1 range only, for the M+ and XL+ probes, respectively.

The CAPc option was developed to improve the intra-measurements variability of the standard CAP measurements by increasing the collected data used to compute the final CAP value. Specifically, CAPc method estimates CAP based on U/S attenuation measurements captured during the imaging phase over a longer period of time. The CAPc uses the same algorithm to calculate CAP as in the standard CAP method, however, since there are more data points, CAPc is calculated as a mean value rather than the median value as in the standard CAP.

Moreover, the inclusion of the CAPc on the S+ probe allows extending the applicability of CAP for patients with anatomies consistent with the S+ probe. Therefore, this submission is expanding the indications for use of the system in accordance with the new applicability of the CAP on the S+ probe. Notably, CAP examination in pediatric population was cleared using the M+ probe in the predicate devices (#K200655 and #K181547). Therefore, the candidate and predicate and reference devices are substantially equivalent.

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; First Edition 2006-05, Equivalent to IEC 62304: 2006/A1:2016.
- ISO 14971 Second: Medical Devices - Application Of Risk Management To Medical Devices; Edition 2007-03-01.

Intended Use / Indications for Use

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.

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*

Performance Data

The FibroScan CLPC 4.1 effectiveness was evaluated in terms of its bias and precision in measuring liver shear wave speed (m/s), standard CAP, SmartDepth and CAPc, using the S+, M+ and XL+ probes. Direct comparison of the measurement accuracy between the proposed and cleared systems were performed on the same sample of phantoms.

The shear wave speed bias measurement and the precision measurement was evaluated and compared to the corresponding value reported for the predicate device.

Results show that, for liver examination, the bias and precision measurements of the candidate FibroScan® system and the predicate FibroScan® system documented similar performance. Specifically, the ranges of the bias values documented for the candidate are substantially equivalent to the ranges of the bias values documented for the predicate device (0.5% – 12.6% for the candidate and 2.6% – 8.0% for the predicate) and the precision values documented for the candidate are very similar to the ranges of the precision values documented for the predicate device.

The range of CAP bias and precision values were also measured for the candidate and predicate FibroScan® system, using different configurations (i.e., static testing with single spot measurements, static testing with multiple spot measurements, and continuous dynamic testing with multiple spot measurements on a large surface).

Results of the standard CAP measurement with static single-spot measurements documented similar performance for the liver measurements for the candidate and predicate systems. Specifically, the range of CAP bias values for the predicate device were 17.1% for the M+ probe and 12.9% for the XL+ probe while the corresponding values for the candidate device were 15.3% and 14.1%. The range of CAP precision values for the predicate device were 0.5% for the M+ probe and 1% for the XL+ probe while the corresponding values for the candidate device were 0.5% and 0.7%.

Similarly, results of the standard CAP measurement with static multiple measurements, using a rotating turntable, documented similar performance for the liver measurements. Specifically, the range of CAP bias values for the predicate device were 0.8% for the M+ probe and 16.2% for the XL+ probe while the corresponding values for the candidate device were 0.8% and 12.2%. The range of CAP precision values for the predicate device were 3.2% for the M+ probe and 2.8% for the XL+ probe while the corresponding values for the candidate device were 0.5% and 1.7%.

Results of CAPc using dynamic testing (>200 measurements) on multiple spots demonstrated the range and mean values of CAPc bias were substantially equivalent to the bias of the standard CAP in the candidate device, both as a static single spot measurement and at multiple measurements spots (range of 6.9% – 12.2% for the candidate CAPc dynamic testing vs. 0.8% – 12.2% for the candidate standard CAP static multi-spot vs. 14.1% – 15.3% for the candidate standard CAP single spot). The range and mean values of CAPc precision values were also equivalent to the precision of the Standard CAP in the candidate device, both at a static single spot measurement and at multiple measurements spots (range of 0.3% – 2.1% for the candidate CAPc dynamic testing vs. 0.5% – 1.7% for the candidate standard CAP static multi-spot vs. 0.5% – 0.7% for the candidate standard CAP single spot).

The range and mean values of CAPc precision values were equivalent to the precision of the Standard CAP in the candidate device, both as a static single spot measurement and at multiple measurements spots. Moreover, the precision results of the CAPc with the S+ probe (both the S1 and S2 exam) were equivalent to the precision results when using the M+ and XL+ probes.

The bias values for the shear wave speed and standard CAP/CAPc were shown to be comparable (under 5% difference) between all FibroScan systems (FibroScan® 502 Touch, FibroScan® 530 Compact, FibroScan® 430 Mini+ and FibroScan® 630). Therefore, the proposed systems have substantially equivalent effectiveness in measuring shear wave speed and CAP/CAPc bias. In addition, the stiffness and CAP measurement ranges, as for the predicate devices, have been verified on applicable products of the FibroScan family, embedded with the currently submitted software version CLPC 4.1.

As the shear wave speed and stiffness for spleen is only available on FibroScan® 630 Expert and the changes introduced by CLPC 4.1 do not affect the shear wave speed and stiffness for spleen, the bias of the candidate FibroScan® 630 Expert embedded with the current software version CLPC 4.1 were compared to the FibroScan® 630 Expert reference device configuration system (#K200655). Results showed comparable values (under 5% differences). Therefore, the proposed systems have the same effectiveness in measuring spleen shear wave speed bias.

In addition, validation studies were performed on tissue-mimicking calibrated phantoms and on a heterogeneous phantom, in order to estimate the bias, precision, and reproducibility performances of the CAPc and compare its results to standard CAP. Results demonstrated that there was no significant bias between standard CAP and CAPc on phantoms, that the CAPc measurements on the S+ probe are highly correlated with the values measured by the M+ and XL+ probes and within the range of the M+ and XL+ probes, and that there is no significant difference between the CAPc measurements in different depths. Validation testing on heterogeneous phantom demonstrated the CAPc capability to select homogenous tissue, yielding more precise and less varied data.

In summary, the bias and the precision of the shear wave speed and the CAP/CAPc measured by the FibroScan® Family of Products with software version CLPC 4.1 with the SmartExam capability are within the same range as those of the predicate FibroScan® devices and, therefore, are substantially equivalent to the predicate FibroScan® devices cleared in #K200655 and #K181547.

Clinical Data

Clinical data was submitted to provide validation of the CAPc and SmartDepth capabilities with CLPC 4.1. Specifically, retrospective in-vivo validations of the CAPc in comparison to standard CAP and of LSM using SmartDepth calculation in comparison to the standard fixed depth calculation were performed on data from five studies (two used for CAPc validation and three used for SmartDepth validation). There have been no adverse events nor complications reported for all studies.

The retrospective in-vivo performance of CAPc for steatosis assessment, compared with MRI-PDFF as a reference, was conducted on a total of 195 participants (from two studies). Of total participants, 58% were healthy participants, 50% males and females, age (mean +/- SD for study B085) was 56 (+/- 8). BMI distribution included 1% ≤18.5, 27% 18.5<BMI≤25, 36% 25<BMI≤30, 21% 30<BMI≤35, and 15% >35. Results showed that CAPc is substantially equivalent to the performance of standard CAP. In addition, there was no significant bias between standard CAP

and CAPc but CAPc showed better precision (lower variability) and better robustness. Based on the data comparing the bias, precision and repeatability of CAPc as measured by all three probes, it is therefore concluded that the CAPc can be assessed as reliably with the S+ probe as with the other FibroScan probes.

The retrospective in-vivo performance testing to validate LSM using SmartDepth calculation in comparison to the standard fixed depth calculation, and in comparison to biopsy as a reference, was conducted on a total of 566 participants (from three studies). Of total participants, 32% were healthy participants, 54% males and 46% females, age (mean +/- SD) was 53 (+/- 12). BMI distribution included 4% 18.5<BMI≤25, 21% 25<BMI≤30, 27% 30<BMI≤35, and 48% >35. Results showed that LSM with SmartDepth were substantially equivalent to the LSM without SmartDepth. Using SmartDepth, the applicability, success rates, consistency, and examination durations showed improvement in comparison to the standard fixed depth.

Substantial Equivalence Discussion

The FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, and 630) uses the same operating principle and materials, incorporates the same basic design, emits the same energy and acquires the same information as the predicate FibroScan® device (K181547). The updated new software version CLPC 4.1, with SmartExam capability, as well as the use of the CAPc with the S+ probe, do not raise new or different questions of safety or efficacy.

The updated new software version CLPC 4.1, with SmartExam capability, was demonstrated to be substantially equivalent to its predicate device FibroScan® 530 (K181547) based on the aforementioned verification and validation studies. A comparison of the performance of the CAPc with the S+ probe with the M+ and XL+ probes demonstrated the device's safety and effectiveness in measuring CAP for pediatric patients with liver disease.

Conclusion

The conclusions drawn from the clinical and nonclinical information provided in this submission demonstrate that FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, and 630) with the updated software (CLPC 4.1) is as safe, as effective, and performs as well as or better than the legally marketed device predicate. The FibroScan® Family of Products raises no new or different issues of safety or effectiveness and is substantially equivalent to its predicate and reference devices.

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

	FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, and 630)	**#K200655 : FibroScan® 630**	**#K181547 : FibroScan® Family of Products (Models: 502 Touch, 530 Compact, And 430 Mini+)**
Manufacturer	Echosens	Echosens	Echosens
510(k) # (Clearance)	N/A	July 16, 2020	July 8, 2018
Software Version	CLPC 4.1.2	CLPC 4.0.5	CLPC 3.2.5 (for FibroScan® 530 and 430) CLPC 3.2.2 (for FibroScan® 502T)
Indications for Use	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® 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. FibroScan® 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® Family of Products (Models: 502 Touch, 530 Compact, and 430 Mini+) is intended to provide 50 Hz shear wave speed measurements and estimates of tissue stiffness as well as 3.5 MHz ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter) in internal structures of the body. FibroScan® Family of Products (Models: 502 Touch, 530 Compact, and 430 Mini+) is indicated for noninvasive 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

	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**	Shear wave speed and stiffness 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.	liver disease, as part of an overall assessment of the liver. Shear wave speed and stiffness may be used as an aid to clinical management of 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)
Depth Analysis Method	Fixed Depth: S1 exam : 15-40 mm S2 exam : 20-50 mm M exam: 25-65 mm XL exam: 35-75 mm **With SmartDepth (Adaptative Depth):** **M exam: 25-65 mm / 30-70 mm**	Fixed Depth: S1 exam : 15-40 mm S2 exam : 20-50 mm M exam: 25-65 mm XL exam: 35-75 mm	Fixed Depth: S1 exam : 15-40 mm S2 exam : 20-50 mm M exam: 25-65 mm XL exam: 35-75 mm

	XL exam: 35-75 mm/ 40-80 mm/ 45-85 mm		
B-Mode Ultrasound Localization Probe	ES-C5-2R60S-3 (for FibroScan® 630 Expert)	ES-C5-2R60S-3 (for FibroScan® 630 Expert)	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 Interquartile range (IQR) and IQR/median ratio
VCTE™ Display (Spleen)	For FibroScan® 630 : Shear wave speed and stiffness medians and Interquartile range (IQR)	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	First generation CAP: Elastography 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:** **CAP mean and standard deviation**	First generation CAP: CAP median and interquartile range (IQR)	First generation CAP: CAP median and interquartile range (IQR)
Attenuation Display – Probes compatibility	First generation CAP: M+ Probe XL Probe **Second generation CAP:** **M+ Probe** **XL+ Probe** **S+ Probe (model 10 only)**	First generation CAP: M+ Probe XL Probe	First generation CAP: M+ Probe XL Probe
Size and Weight	FibroScan® 502T :1350 mm x 680 mm x 610 mm (H x W x D)	1365mm x 642mm x 584mm (H x W x D)	FibroScan® 502T :1350 mm x 680 mm x 610 mm (H x W x D)

	41kg with accessories FibroScan® 530 : 460 mm x 360 mm x 250 mm (H x W x D) 10kg with accessories FibroScan® 430 : 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	46kg with accessories	41kg with accessories FibroScan® 530 : 460 mm x 360 mm x 250 mm (H x W x D) 10kg with accessories FibroScan® 430 : 275mm x 400mm x 95mm (H x W x D) 6kg with accessories
Power supply	100-240 V ~ 50–60 Hz	100-240 V ~ 50–60 Hz	100-240 V ~ 50–60 Hz
Elastography engine	FibriScan 502T : Analog front end High frequency (US): PV2 ; Analog front end Low frequency (servo control): PV2 FibroScan® 530, 430 and 630 : Analog front end High frequency (US): PV3 ; Analog front end Low frequency (servo control): PV3	Analog front end High frequency (US): PV3 Analog front end Low frequency (servo control): PV3	FibriScan 502T : Analog front end High frequency (US): PV2 ; Analog front end Low frequency (servo control): PV2 FibroScan® 530, and 430: 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® 502T: 19-inch. FibroScan® 530: 15-inch. FibroScan® 430: 12.1-inch. FibroScan® 630: 19-inch.	Color LCD touch screen: 19-inch.	Color LCD touch screen FibroScan® 502T: 19-inch. FibroScan® 530: 15-inch. FibroScan® 430: 12.1-inch.
Wi-Fi Option	N/A	N/A	N/A
Battery	FibroScan® 502T and 630 : N/A FibroScan® 530 and 430 : ARTS Energy (ref. 4 INR19/66-2) Part number 806957 / M300002	N/A	FibroScan® 502T: N/A FibroScan® 530 and 430 : ARTS Energy (ref. 4 INR19/66-2) Part number 806957 / M300002