



FibroScan ^{touch} **502**
POWERED BY **VCTE™**

INNOVATION in liver disease management

Discover FibroScan[®], the state of the art technology that will improve your liver diagnosis.

This unique, accurate and efficient device brings you extra clinical confidence to support your patient management.

FibroScan touch **502**



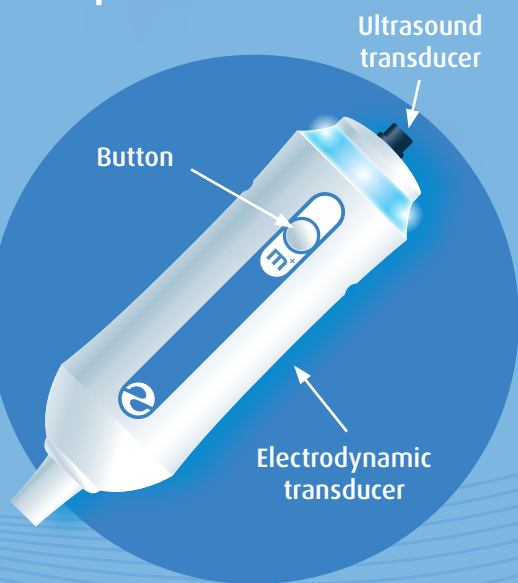
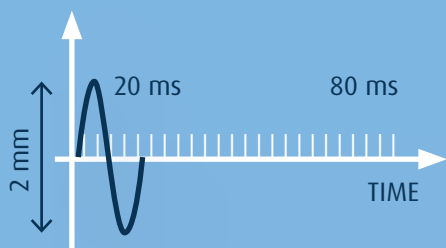


Sharing INNOVATIVE technology

Based on patented Vibration-Controlled Transient Elastography (VCTE™), FibroScan® 502 Touch provides multiple controls for reliable, accurate and reproducible assessment of liver tissue stiffness: CONTROLLED VIBRATION, CONTROLLED ENERGY, CONTROLLED ALGORITHM.

POWERED BY **VCTE™**

CONTROLLED VIBRATION



- This custom-designed ergonomic transducer generates a controlled vibration which induces a mechanical shear wave with consistent frequency and energy
- Static force is monitored in real time to prevent wave distortions
- Shear wave center frequency is 50Hz

CONTROLLED ENERGY

- Propagation of the mechanical shear wave through the skin and liver tissues is measured using low energy 3.5 MHz ultrasound
- Large explored volume of 3 cm³ (at least 100 times more than a biopsy)
- Depth of measurement from 15 to 75 mm depending on probe



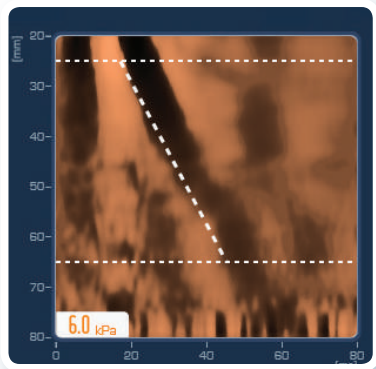
25 mm

CONTROLLED ALGORITHM

IGR	CAP (dB/m)	E (kPa)	IGR
IGR/med.	MEDIAN	MEDIAN	IGR/med.
41	177	8.1	1.8
23 %			22 %

- VCTE™ guidance process ensures the operator obtains measurements of the liver
- A sophisticated algorithm computes liver stiffness and ultrasound attenuation
- A quality controlled calculation is performed automatically, the algorithm selects the valid measurements

Stiffness (E)



- Stiffness is computed from the **ELASTOGRAM**
- The Elastogram is a **GRAPHIC REPRESENTATION** of the shear wave propagation as a function of time and depth
- The Young's Modulus (E) is expressed in **KILOPASCAL (kPa)**

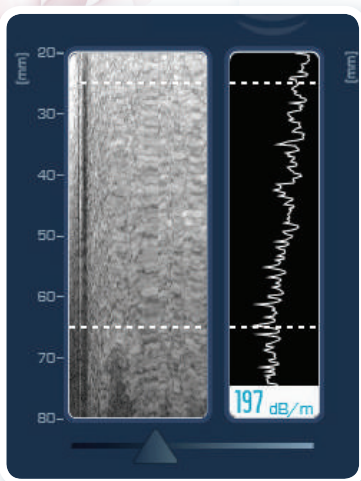
FIBROSIS⁽¹⁻²²⁾

Explored volume with **m⁺** Probe

3 CM³

- **At least 100 TIMES LARGER** than with a liver biopsy
- **Both stiffness and CAP™ are simultaneously measured IN THE SAME LIVER VOLUME**
- **Stiffness & CAP™ results are the MEDIAN of 10 valid measurements**

Controlled Attenuation Parameter (CAP™)



- CAP™ is computed from the **ULTRASOUND** acquired for stiffness measurement
- CAP™ **IS ONLY CALCULATED** if the stiffness acquisition is **VALID**
- CAP™ is expressed in **DECIBEL PER METER (dB/m)**

STEATOSIS⁽²³⁻²⁷⁾

Sharing INNOVATIVE features:



NON INVASIVE ASSESSMENT AND QUANTIFICATION OF LIVER STEATOSIS

CAP™ is a measure of the ultrasound attenuation which corresponds to the decrease in amplitude of ultrasound waves as they propagate through the liver.

CAP™ is powered by a sophisticated guidance process based on VCTE™:

- CAP™ and liver stiffness are simultaneously measured in the same liver volume
- CAP™ is calculated only if liver stiffness measurement is valid

- Gain (ultrasound amplitude)
- Ultrasound frequency
- Region of measurement

ARE CONTROLLED AND PREDEFINED

- CAP™ is measured with the M probe at 3.5 MHz at depth between 25 and 65 mm
- CAP™ is expressed in decibel per meter (dB/m)

CAP™ measurement

Like liver stiffness measurement with the FibroScan® 502 Touch, CAP™ measurement:

- IS NON INVASIVE
- IS IMMEDIATE: does not lengthen the FibroScan® examination
- benefits from an established examination procedure: the final CAP™ result IS THE MEDIAN OF 10 VALID CAP™ MEASUREMENTS
- can be performed by an operator without any ultrasound imaging skills

CAP™ is a tool for non invasive assessment and QUANTIFICATION OF STEATOSIS enhancing the spectrum of non invasive methods for the examination and follow-up of patients with liver disease.



*CAP™ is a new non invasive
physical quantitative parameter
AVAILABLE with the*

FibroScan touch **502**



Sharing CLINICAL DATA

LITERATURE OVERVIEW

FibroScan® procedures are easy to put into routine practice for all chronic liver diseases.

- **To date, more than 760 peer reviewed original articles have demonstrated the usefulness of liver stiffness measurement with the FibroScan®**
- **As a stand-alone tool or as an adjunct to liver biopsy, FibroScan® allows accurate decisions as part of your patient management strategy**
- **From mass screening to follow-up of post transplanted patients and prognostic value, liver stiffness measured by FibroScan® has a wide range of use**

Liver stiffness

FIBROSCAN® HAS BEEN STUDIED IN DIFFERENT CLINICAL SETTINGS

- Tertiary units
- Mass screening [18]
- Street-based outreach for drug users [19]
- Paediatrics [20, 21]
- Tropical medicine [22]

CHRONIC HEPATITIS C (HCV)

In chronic viral hepatitis C, the diagnosis accuracy of liver stiffness measurement is good to excellent. According to the first pivotal study [1], the AUROC* were:

- **0.79 for the diagnosis of significant fibrosis**
- **0.91 for the diagnosis of advanced fibrosis**
- **0.97 for the diagnosis of cirrhosis**

Overall, the diagnosis accuracy depends on the quality of the liver biopsies used as the reference and the distribution of patients into the different stages of fibrosis.

CHRONIC HEPATITIS B (HBV)

The diagnosis accuracy of FibroScan® to assess fibrosis has been shown to be similar in patients

with chronic hepatitis B compared to patients with chronic hepatitis C [2]. However, necro-inflammatory activity has also been shown to significantly affect liver stiffness in this etiology [3].

HIV-HCV CO-INFECTION

The presence of HIV co-infection with HCV, does not impair the diagnosis accuracy of FibroScan® [4].

ALCOHOLIC LIVER DISEASE (ALD)

Liver stiffness measured by FibroScan® can be used to assess liver fibrosis in patients with alcoholic liver disease with diagnosis accuracies similar to those obtained in chronic viral hepatitis [5].

Moreover, the FibroScan® procedure is very well accepted by patients with alcohol dependence or abuse and therefore appears as a first choice tool to detect advance fibrosis or cirrhosis at-risk population with a better accuracy than simple biological evidence [6].

NON ALCOHOLIC FATTY LIVER DISEASE (NALFD)

A recent meta-analysis [7] based on 6 different studies has shown that liver stiffness measured with FibroScan® is good to detect :

- significant liver fibrosis with a **mean AUROC* of 0.84 (95% CI** : 0.79-0.90)**
- excellent to detect cirrhosis with a **mean AUROC of 0.94 (0.86-0.99).**

* AUROC: area under Receiver Operator Characteristics curve
** 95% CI : 95% confidence interval

Moreover, the availability of the new XL probe dedicated to overweight patients with a skin-to-liver capsula distance greater than 2.5 cm will allow assessment of a large portion of the patients that could not previously benefit from the FibroScan® procedure [8].

BILIARY DISEASE

Liver stiffness has also been shown to be of clinical use to detect fibrosis and cirrhosis in patients with primary biliary cirrhosis and primary sclerosing cholangitis [9].

Controlled Attenuation Parameter (CAP™)

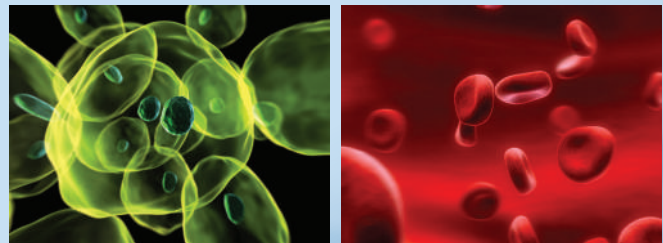
In addition to measuring liver stiffness, FibroScan® 502 Touch now allows you to also assess the Controlled Attenuation Parameter (CAP™) which has been developed for the detection of liver steatosis. Several publications and communications support this new feature of the FibroScan® 502 Touch.

→ A proof of concept publication on the CAP™ technology [23]

→ In a cohort of 115 patients with various chronic liver diseases, the AUROC[®] of CAP™ to assess steatosis were:

- 0.91 for steatosis superior or equal to 11%
- 0.94 for steatosis superior or equal to 34%
- 0.89 for steatosis superior or equal to 67%

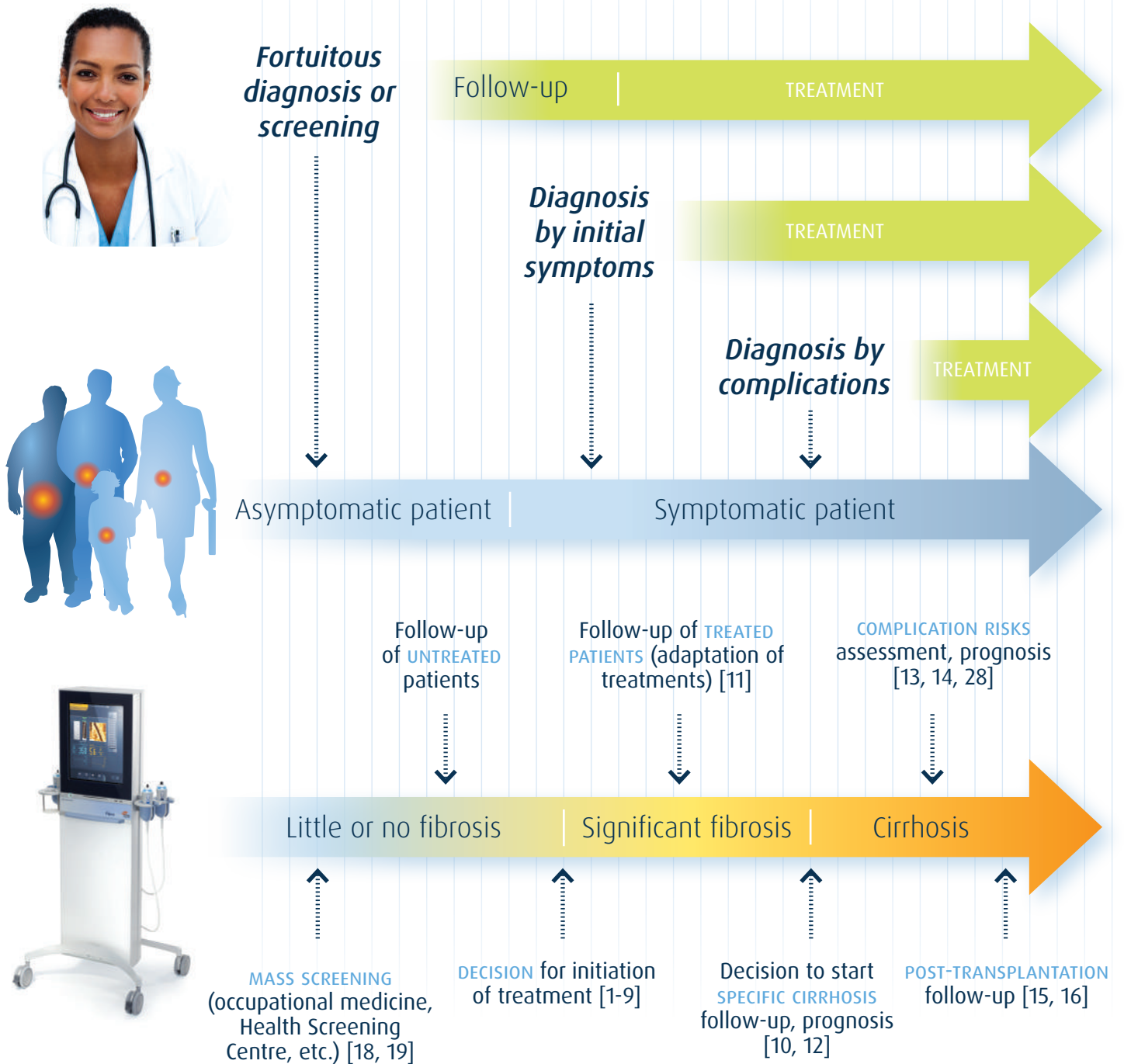
→ Several communications in international hepatology meetings (AASLD, EASL, APASL) [24-27]



FibroScan® 502 Touch, with its dedicated probes, is a diagnostic aid measuring liver stiffness and Controlled Attenuation Parameter.

These values must be interpreted by a medical doctor specialized in liver disease taking into account the complete medical record of the patient, presence of identified confounding factors and the quality of the measurement procedure (number of valid measurements, dispersion,...).

FibroScan® is of use THROUGHOUT THE COURSE of chronic liver disease



*Your patients will be asking you:
"Can I have a FibroScan® exam?"*



Sharing POWERFUL practice

AN INNOVATIVE DESIGN WHICH IMPROVES PRODUCTIVITY

To date **2,000 FibroScan®** devices have been installed worldwide. FibroScan® is used to aid diagnosis in 1.5 million men, women and children every year.



New Software

TACTILE INTERFACE WITH A NEW DESIGN

- Optimized ergonomomy & data workflow
- User-friendly interface
- Easy to use

PATIENT DATA MANAGEMENT

- Organized by patients
- Multi-criteria search (last name, first name, date...)

NETWORK CONNECTION

- Easy data export
- Push data to shared network directories



Smart Tools

AUTOMATED PROBE SELECTION

- An indicator to recommend the probe best suited to the patient's morphology

FIBROSCAN® REPORTS

- Generate and edit multilingual reports
- Personalize reports with hospital logo, address...
- Print examination history



FibroScan® 502 Touch expert tools

Non invasive liver stiffness measurement
Innovative steatosis quantification

Hardware

17" TOUCH SCREEN

- Optimal comfort & image quality in all situation
- High contrast & brightness
- Wide viewing angle

ADVANCED CONNECTIVITY OPTIONS

- Save & export data to removable drive (USB key...) or network

2 PROBE CONNECTORS

- Connect two probes simultaneously

FRONT AND REAR HANDLES

- Easy to move and manipulate

ADVANCED ELECTRONIC FOR FAST AND EFFECTIVE EXAMINATION

- High speed elastometry engine





Probes

THREE DIFFERENT ERGONOMIC PROBES ENABLE YOU TO ADDRESS A FULL RANGE OF CLINICAL AND MORPHOLOGICAL NEEDS

Each patient is different. Echosens has designed its probes to ensure efficient diagnosis in all circumstances.



PAEDIATRIC PROBE

- Transducer specifically designed for being placed into narrow intercostal space
- A higher ultrasound frequency, 5 MHz, enabling measurements adapted for chest perimeter from 45 to 75 cm
- Depth of measurement are adapted from 15 to 50 mm depending on children's morphology



ADULT PROBE

- The M probe is designed for the general population. It is used for the majority of adults with a thoracic perimeter of more than 75 cm
- Ultrasound frequency is 3.5 MHz
- Liver stiffness measurements take place between 25 and 65 mm under the skin



PROBE FOR OVERWEIGHT PATIENTS

- A more sensitive ultrasound sensor at the frequency of 2.5 MHz has been designed to enhance deeper signal penetration through tissues over a 35 to 75 mm depth
- XL probe must be used on patient with a Skin Capsule Distance (SCD) greater than 2.5 cm. Automated probe selection will recommend the probe best suited to the patient's morphology

RECOMMENDATIONS FOR USE

- Training: Echosens™ or its representative must certify the operator to ensure the proper use of the device and all its features
- Examination procedures provide better reproducibility and accuracy with 10 valid stiffness measurements at the same measurement point

PRECAUTIONS FOR USE

- FibroScan® should not be used on pregnant women, patient with active implantable medical device and person with ascites
- Presence of ascites may prevent from obtaining valid measurements



Sharing SERVICE solutions

DISTRIBUTION, TRAINING AND AFTER-SALES SERVICE

Distribution

OUR DISTRIBUTOR NETWORK IN YOUR COUNTRY IS YOUR DIRECT CONTACT

Echosens™ has an exclusive distribution network that provides sales, training and after-sales support.

We will also provide direct support in countries we serve directly.

For more information, contact our sales team:
distribution@echosens.com or your local distributor

Training

HOW TO ACHIEVE BEST PRACTICE

After on site training, you will be certified to use FibroScan®. The training is mandatory in order to obtain accurate and reliable measurements. Nurses can use the equipment but only physicians can interpret the results in light of the patient's history.

Dedicated training includes:

- A custom-designed theory session aimed at understanding indications and criteria for use of the device and individual probes
- A practical session to teach in good examination practice

For more information, contact our training team:
training@echosens.com





Accessing technology know-how after you acquire your FibroScan®

After-sales service

LOCAL SUPPORT IS AVAILABLE

Distributors are in charge of ensuring the after-sales service of all Echosens™ products. Our specially trained and certified engineers will take care of your device. We ensure fast and efficient answers that will keep your device up and running*.

ACCESSORIES AND SUPPLIES

To enhance your productivity, the Echosens Service Centre or your local distributor will support you with calibration, repairs, parts and maintenance services.

→ ***FibroScan® probes need to be calibrated every six months to maintain proper performance.***

SERVICE CONTRACT

Service contracts with local support.

It can range from probe maintenance alone to an all-inclusive contract. You're free to choose.

For more information, contact our team after-sales service:
service@echosens.com

* After acceptance of an estimate or under a service contract

Sharing EXPERTISE & INNOVATION

ABOUT ECHOSENS™

Echosens™ is actively expanding its global presence. We are supported by a team of medical experts who have helped to transform our core technology*, VCTE™, into the first commercially available product with Transient Elastography: FibroScan®.

OUR MISSION

Offer to our customers technological and ergonomic solutions in hepatology to improve patient quality of life based on:

- A robust portfolio of patents
- A totally non-invasive solution

OUR PARTNERS

Echosens™ establishes many medical and scientific partnerships around the world (Germany, China, USA, United Kingdom...).

In France, we develop strong links with the universities as:

- Université Rabelais de Tours
- Centre d'Investigation Clinique – Innovation Technologie, CHRU de Tours, Hôpital Bretonneau
- Institut Pierre et Marie Curie, Paris
- Telecom ParisTech
- INSERM

OUR COMMITMENT

Our commitment to quality is shown by:

- ISO 13485 certification since 2005
- CE mark since 2003



* Echosens owns 13 patents in the domain of transient elastography.

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FS502T112013 - Revision date [20/11/13] - FibroScan® is a class IIa medical device according to Directive EC/93/42 and is manufactured by Echosens. Assessment of its conformity with the essential requirements of the Directive EC/93/42 is certified by LNE-G-MED (France). FibroScan® is indicated for the non invasive measurement of liver stiffness (E) and controlled attenuation parameter (CAP) in human beings.

It is expressly recommended to closely read the instruction within the Use' Guide and the labeling of the device. FibroScan® examinations must only be performed by operators certified by the manufacturer or its accredited local representative. FibroScan® must not be used in the following situation: other organs but liver, patients with active implantable medical devices (such as pacemakers, defibrillators, pumps, etc.), wounds at the measurement point, pregnant women. Presence of ascites can compromise obtaining valid measurements. The values obtained with FibroScan® must be interpreted by a physician experienced in dealing with liver disease, taking into account the complete medical record of the patient.

In France, liver stiffness measurement by FibroScan® is included on the list of acts and services covered by the national Social Security medical insurance under the code HLQM002 and the following conditions. Indications: (i) assessment of chronic untreated hepatitis C adult patients with no comorbidities except obvious diagnosis of cirrhosis or (ii) assessment of chronic untreated hepatitis C adult patients with HIV co-infection except obvious diagnosis of cirrhosis. Invoicing note: Limit of one examination per year except in case of risk factors of rapid evolution toward cirrhosis, provided further examination is expected to have an impact on the therapeutic management of the patient. In case of chronic hepatitis C: (i) as first line test as an alternative to blood tests (ii) as second line test (in case of non agreement between the first line test and the clinical context or in case of non-interpretable first line test) as an alternative to liver biopsy. In case of HIV-HCV co-infection: as first line test to evaluate the presence of cirrhosis. Background: consultation specialized in the management of patients with HCV, in collaboration with a centre specialized in the management of HIV infection as second indication.



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