

Fast™

User manual for Fast score CE

E505M001 – Version 4 –10/05/2021

(software version 1.3)

en

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1. PURPOSE OF THE USER MANUAL


The present User Manual has no contractual value whatsoever and under no circumstances may Echosens be held responsible on the basis of the information contained in the present manual.

The present User Manual details the information required for the use of Fast computation.

Echosens publishes this manual "as is", without guarantees of any nature, whether explicit or implicit, including, but not limited to, implicit guarantees concerning merchantability or fitness for a particular use, for the purpose of providing simple and accurate information. Consequently, Echosens cannot accept any responsibility for any incorrect interpretation of the manual. Though all efforts have been made to offer a manual that is as accurate as possible, the manual may nevertheless contain some technical inaccuracies and/or typographical errors.

Echosens cannot, under any circumstances, be held responsible for any loss of profit, loss of business, data loss, business interruption, or for any indirect, specific, accidental or consecutive damages of any type.

Any information or modification requests pertaining to this manual should be sent to: Echosens, 6 rue Ferrus, 75014 PARIS, France or support-it@echosens.com.

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2. INDICATIONS

2.1. INTENDED USE

Fast™ is an algorithm using liver stiffness measurement, controlled attenuation parameter and aspartate amino transferase intended to compute a score between 0 and 1.

2.2. INDICATION FOR USE

Fast™ calculator is a tool for clinicians, computed from LSM and CAP (obtained from FibroScan device) and AST blood parameter measurement, to aid in the identification of patients with suspicion of NAFLD as being at risk for active fibrotic NASH (NASH+NAS \geq 4+F \geq 2).

Fast™ is presented as an educational service intended for licensed healthcare professionals. While this score is about specific medical and healthcare issues, it is not a substitute for or replacement of personalized medical advice and is not intended to be used as the sole basis for making individualized medical or health-related decisions.



2.3. PRECAUTIONS FOR USE

The following circumstances may affect the results obtained and therefore may affect the interpretation of Fast result:

- Pregnancy
- Patients under 18 years of age
- Other chronic or acute liver disease than NAFLD
- Liver transplant patients
- Cardiac failure and/or significant vascular disease
- Confirmed diagnosis of active malignancy or other terminal disease
- Use of treatment inducing liver injury

To get a reliable result:

- LSM and CAP should come from a single FibroScan exam
- FibroScan exam and blood collection for AST assessment should be performed within 6 months.

2.4. TARGET POPULATION

Fast is indicated for adult patients with suspicion of NAFLD.

2.5. INTENDED USER

The device is intended for use by healthcare professionals.

The results obtained from the device are intended to be interpreted by a physician experienced in the management of liver diseases.

2.6. INTENDED ENVIRONMENT

Fast is accessible through devices connected to the internet using dedicated services. Users shall authenticate and confirm his/her status and abilities to use Fast.

3. CLASSIFICATION

Fast is an in vitro diagnostic medical device according to directive 98/79/EC and a non-device Clinical Decision Support (FDA).

4. CLINICAL PERFORMANCES

Population	Derivation	USA	France	Malaysia	China (1)	China (2)	Turkey	Bariatric	Pooled
Patients (N)	350	242	182	176	104	83	129	110	1026
Prevalence of NASH + NAS \geq 4 + F \geq 2 (%)	50%	12%	43%	20%	9%	43%	57%	15%	27%
AUC	0.80	0.86	0.80	0.85	0.84	0.85	0.74	0.95	0.85

Formula and performances are available in Newsome et al., Lancet Gastroenterol Hepatol. 2020 Apr;5(4):362-373

5. OPERATING PROCEDURE

5.1. TECHNICAL RECOMMENDATION FOR FIBROSCAN PROCEDURE

The measurement of liver stiffness (E or LSM) and controlled attenuation parameter (CAP) shall be done on a FibroScan device by an operator trained and certified by Echosens or its local representative according to the recommendations of Echosens with a probe fitted to the morphology of the patients as described in the FibroScan user guide.

The FibroScan examination results should fulfill reliability criteria defined in the publication entitled "Determination of reliability criteria for liver stiffness evaluation by transient elastography" by Boursier J, Zarski JP, de Ledinghen V, Rousselet MC, Sturm N, Lebail B, Fouchard-Hubert I, Gallois Y, Oberti F, Bertrais S, Cales P and the Multicentric Group from ANRS/HC/EP23 FIBROSTAR St published in Hepatology in 2013 volume 57(3) page 1182-1191.

5.2. TECHNICAL RECOMMENDATION FOR BLOOD SAMPLING

It is essential to comply with the requirements of the ISO 15189 international standard concerning the performance of quality controls (internal quality control, external evaluation including the mandatory national quality control), and with the regulations in force in the country where the laboratory is located.

Blood collection should be performed in fasting conditions. The patient should not have made recent physical effort to avoid hemolysis.

5.3. ADDITIONAL RECOMMENDATION



The delay between the FibroScan examination and the blood collection shall be less than 6 months.

5.4. USER REGISTRATION ON MyFIBROSCAN

Downloading and sign in

myFibroScan application can be used on iOS and Android platforms. It is available on both Apple store and Google play store. Once it has been downloaded, anyone can launch the application but he/she has to be registered to access Echosens services.

The screen aside appears. The application is available both in French and English. However, by default, this page language is based on the phone language.

If the user is already registered, he/she can connect himself/herself by entering his/her login and password and clicking on “Sign In” button. If not, the user should create an account by clicking on “Sign Up” button.

Once signed-in, unless he/she specifically logs out from the application, the user will be automatically logged-in and will not have to enter his credentials again.

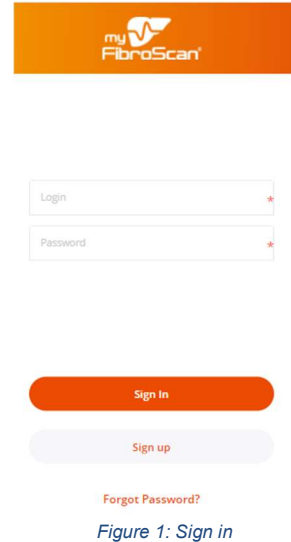


Figure 1: Sign in

Registration

To access Fast, any user has to create an account on Echosens Cloud services by clicking on “Sign Up”. He/she then accesses to the following screens:

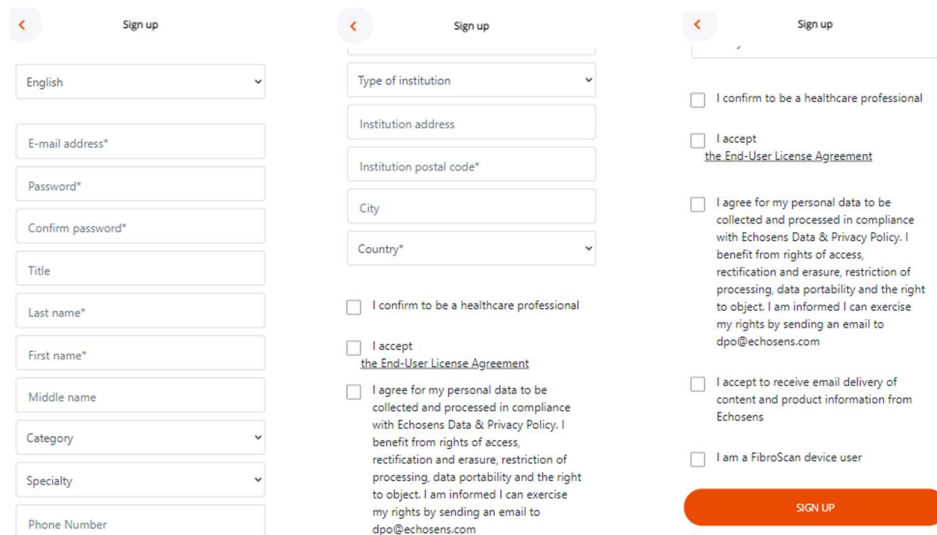


Figure 2 : Sign up

5.5. Fast COMPUTATION FROM myFIBROSCAN ACCESSORY

Home page

Once logged-in, the user accesses to the home page screen (figure 3).

Fast is available under the “Scores” menu (figure 4)

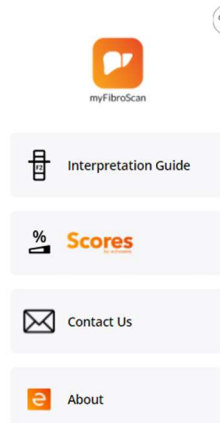


Figure 3: myFibroScan Home page

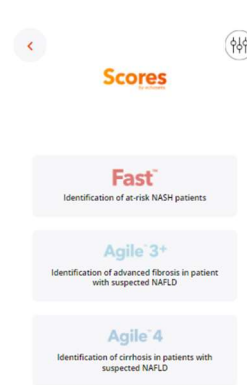


Figure 4: myFibroScan - Scores menu

Inputs screen

By clicking on the “Fast ” block, the user accesses

Fast input screen to fill the input parameters: LSM by VCTE (E), CAP and AST (SGOT). (figure 5).

Invalid values will be notified to the user. He will not be able to submit its computation with out of range values of bad/missing units.

The user has to confirm that:

- He/ She has read precautions for use, including that patient is suspected of NAFLD,
- VCTE liver examination and blood collection for AST assessment are performed within 6 months



Figure 5 : Fast input parameters

The user can access:

- This user guide by clicking on “Learn more”
- Fast formula by clicking on publication

Then, the user can submit his/her computation or go back to the home page

by clicking on the  pictogram.

Results screen

After submission, the user accesses the results screen (figure 6). He/She can consult the input parameters he/she submitted and the associated result. If he/she wants to update one of these values, the user can come back to the inputs screen by clicking on the “back” pictogram.

Again, the user can access:

- This user guide by clicking on “Learn more”
- Fast formula by clicking on publication


From here, he can generate the corresponding report by clicking on “Create a report” or go back to the home page by clicking on the  pictogram.




Figure 6: Fast Results screen

Report creation

To generate a report, the user has to enter personal patient data. Several options are possible:

- The user can re-use data previously entered by selecting a patient from the patient list and confirm the statement.
- Or he/she can create a new patient file. It will be locally stored on the phone and will be visible in the patient list for future use. Fields with a red star are mandatory.

Once done, the user can submit the data or go back to the home page by clicking on the  pictogram.

Once submitted, the user has to fill or select FibroScan examination date and blood collection date (figure 7).

Even if the time elapsed between these two dates is longer than the threshold mentioned in the Fast input recommendations, the report will be generated. However, the Fast result will not be displayed since it does not meet the specific indications agreed by the user to use the Fast computation.

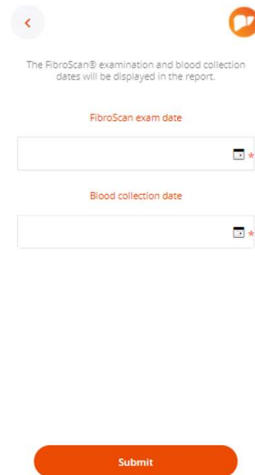



Figure 7: Examination dates

Once done, the user can click on Submit button. The report is generated, downloaded on the phone and can be read by any PDF reader.

He/She can go back to the home page by clicking on the  pictogram.

Results and PDF reports are not stored in myFibroScan application. PDF report can be stored in the phone under the responsibility of the user.

5.6. Fast COMPUTATION FROM Echosens API

For specific purposes, users can contact Echosens to implement direct API calls without using myFibroScan interface to perform Fast computations.

6. SYMBOLS ON THE DEVICE

The logo for the Fast device, featuring the word "Fast" in a bold, red, sans-serif font with a trademark symbol (TM) to the upper right.

Fast device



CE marking affixed by Echosens
04th November 2019



In vitro diagnostic Medical Device



Manufacturer

7. CONTACT US

The user can contact Echosens by clicking on the "Contact us" block available on myFibroScan home page.



Contact Us

It will redirect him/her towards the support platform in which he/she will be able to fill a request form.

8. ABOUT

By clicking on the "About" block available on myFibroScan home page, the user can consult general information regarding Echosens, myFibroScan, trademarks and patents.



About

9. GLOSSARY

Name	Definition
AST / SGOT	Aspartate Aminotransferase / Serum Glutamic Oxaloacetic Transaminase
CAP	Controlled Attenuation Parameter
myFS	myFibroScan
LSM / E	Liver Stiffness measurement
NAFLD	Non-alcoholic fatty liver disease
NASH	Non-alcoholic Steatohepatitis

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