

User Manual for myFibroScan V2.1

E604M004.2 – myFibroScan v2.1.0 – 27/01/2020

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 myFibroScan application.

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.

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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

Indication for use

myFibroScan 2 is an application intended to be used by physicians to give access to medical device tools associated with FibroScan results (E and CAP).

It also provides a proven source of information for scientific publications related to liver diseases.

Patient Population

Patient population for myFibroScan are patients with chronic liver diseases.

User Profile

myFibroScan users are healthcare professionals experienced in dealing with liver diseases acting for medical purposes.

Operational Conditions

myFibroScan is downloaded from iTunes App Store or Google Play Store and installed locally on user mobile or tablet.

Once done, myFibroScan runs locally and connects to an Echosens Cloud platform for authentication and score computation only.

3. Technical recommendations for FibroScan® procedure

The measurement of liver stiffness (E) and controlled attenuation parameter (CAP) shall be done 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.

Patient should be fasting since at least 3 hours as specified in the publication entitled "Food intake increases liver stiffness in patients with chronic or resolved hepatitis C virus infection" by Mederacke I, Wursthorn K, Kirschner J, Rifai K, Manns MP, Wedemeyer H and Bahr MJ in Liver International in 2009 volume 29(10) page 1500-1506.

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, Lebaill 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.

4. myFibroScan use cases

3.1. 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 download, anyone can launch the application but he 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 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.

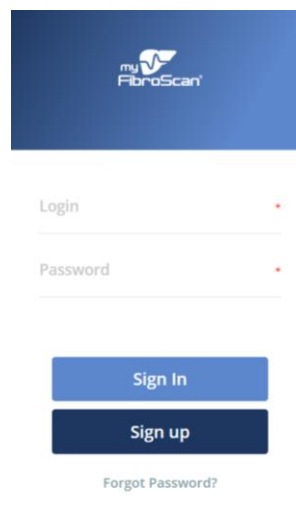


Figure 1: Sign In screen

3.2. Forgot password

If the user forgot his/her password, he/she can click on “Forgot Password?” link. The user has to enter his/her email address and click on “Submit”. By clicking on the link contained in the automatic email sent to this address, the user will be able to reset his password.

3.3. Registration

As described in 4.1 paragraph, to use myFibroScan, 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: Account creation on Echosens Cloud Services

Any field with a star is required. Language, specialty, type of institution and country are to be chosen in a picklist. Password shall fit the following rules to be acceptable:

- composed of alphanumeric characters
- contain at least 8 characters
- contain at least one digit
- contain at least one uppercase
- contain at least one lowercase

All conditions have to be acknowledged by checking the checkbox except the last one before the user can confirm his/her registration.

General Conditions for Use are available on Echosens website and are accessible by clicking on the link.

Then, the user can sign up. If all mandatory fields are correctly filled, a message will confirm his/her account creation and display the next instructions. Otherwise, an error message will appear to guide the user.

An automatic message will be sent to the user mailbox to confirm his/her email address. The user has to click on the confirmation link before being able to login into the application (account activation).

3.4. Home page

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

He/She can see the various services offered to him/her:

- available scores
- interpretation guide module
- contact platform
- miscellaneous information
- settings

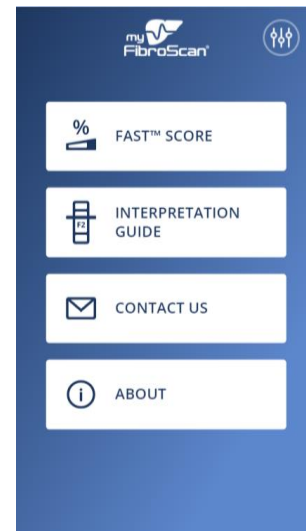


Figure 3: Home page

3.5. Scores

By now, only FAST score computation is available.

All specific indications, intended use, target population and precautions for use are described in the user manual dedicated to FAST score product (ref. E505M001).

3.5.1. Inputs screen

By clicking on the “FAST score” block, the user accesses to the FAST input screen (figure 4).

The user can fill CAP (Controlled Attenuation Parameter) and E (Stiffness) values manually or by scanning a QR code printed on a FibroScan examination report. AST (ASAT parameter) value can only be filled manually.

Invalid values will be notified to the user. He will not be able to submit its computation with erroneous values.

The user has to confirm that:

- No more than 6 months separates VCTE examination and blood sampling
- the physician is aware of precautions for use related to FAST score computation

The user can access to:

- FAST 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.


Figure 4: FAST score inputs

3.5.2. Results screen

After submission, the user accesses to the results screen. 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  pictogram.

Again, the user can access to:

- FAST 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.

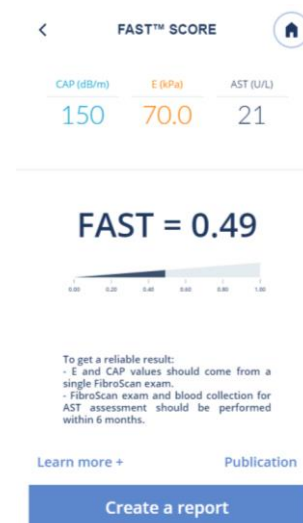


Figure 5: FAST score results

3.5.3. Report creation

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

- If E and CAP values have been scanned from a FibroScan examination report, then the corresponding patient information are automatically filled and the user only needs to confirm the statement: the patient is aware of data processing before being able to generate the report
- If not, 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.

Figure 6: Patient information and patient list

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

Even if the time elapsed between these two dates is longer than 6 months, the report will be generated. However, the FAST score result will not be displayed as it does not meet the specific indications agreed by the user to use the FAST computation module.

Once done, the user can click on Submit button. The report is generated, downloaded on the phone and can be open by any PDF reader available on the device. He/She can go back to the home page by clicking on the

 pictogram.

Report file is detailed in the user guide dedicated to FAST score (ref. E505M001).

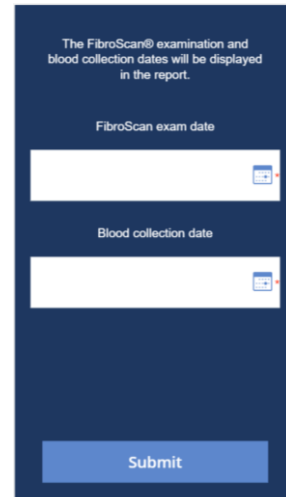


Figure 7: Examinations dates

3.6. Interpretation guide

All specific indications, intended use, target population and precautions for use are described in the user manual dedicated to Interpretation guide product (ref. E504M001).


3.6.1. Inputs screen

By clicking on the “Intepretation Guide” block, the user access to the screen aside.

The user can fill CAP (Controlled Attenuation Parameter) and/or E (Stiffness) values manually or by scanning the QR code printed on a FibroScan examination report. Then he selects an etiology from the dropdown list (figure 8).

Invalid values will be notified to the user. The user will not be able to submit its parameters with erroneous values.

The user can access to Interpretation Guide user manual by clicking on “Learn more”

Then, the user can submit his/her request or go back to the home page by clicking on the  pictogram.

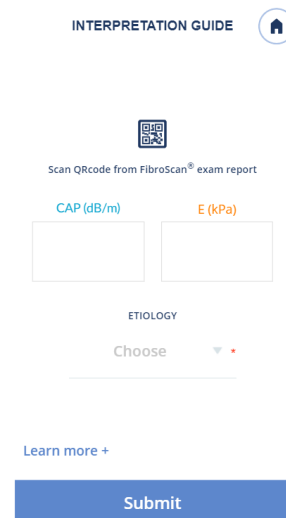




Figure 8: Interpretation guide inputs

3.6.2. Results screen

After submission, the user accesses to the corresponding results screen (figure 9). He/She can consult the input 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  pictogram.

According to the input parameters, the user can visualize steatosis and/or fibrosis stage. Interpretation is detailed into the user guide dedicated to this feature (ref. E504M001) and available by clicking on “Learn more +”.

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.

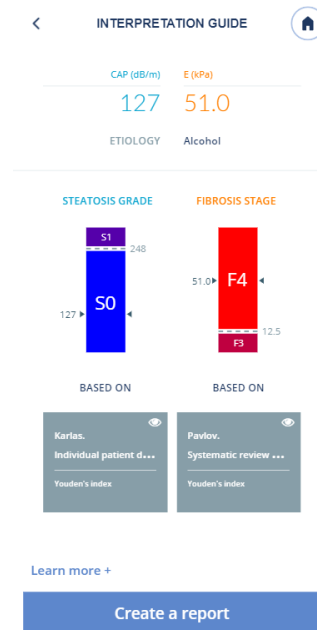
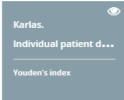





Figure 9: Interpretation Guide results



3.6.3. List of publications and change of default publication

From the screen displayed in Figure 9, the user can consult the publication details related to the cut-offs taken into

account in the computation, by clicking on the publication information square: .

He/She accesses to the list of available publications filtered by the input parameters such as the selected criteria: fibrosis or steatosis and the etiology. The user can then consult publication cut-offs details by opening the arrow .

The selected publication from which current results are based is identified with a blue toggle: . The user can change the publication used for computation by playing with any grey toggle . A confirmation screen will ask the user to validate his choice (Figure 10). This choice will be memorized for the next request.

From here, the user can come back to the graphs screen by clicking on the  pictogram or go back to the home page by clicking on the  pictogram.

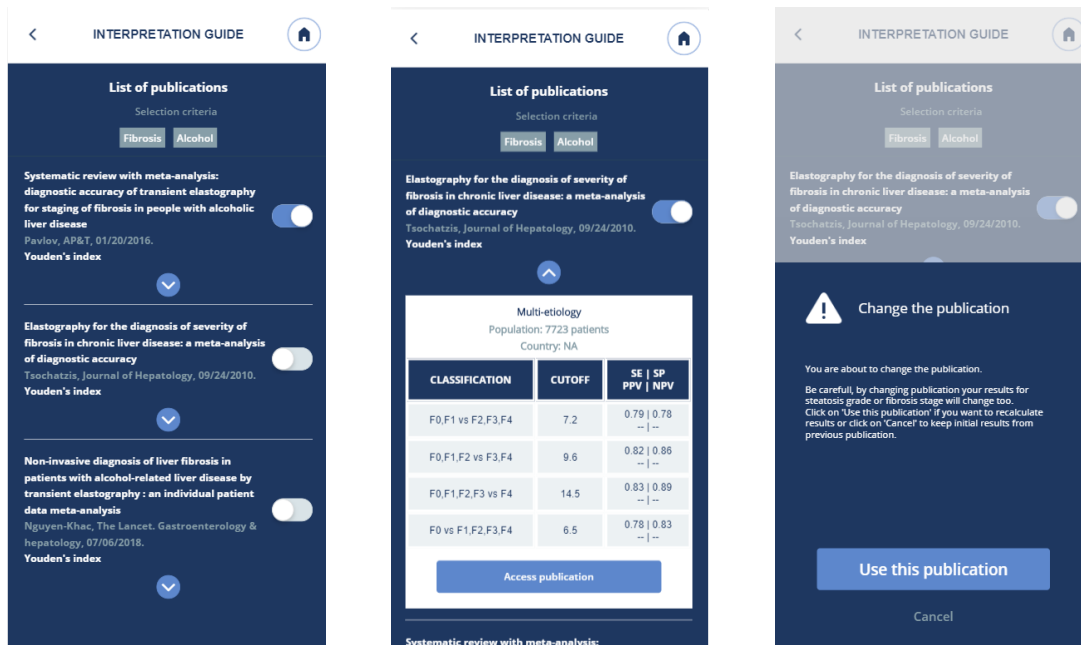


Figure 10: List of publications, cut-offs and change


3.6.4. Report creation


From screen displayed in Figure 9, the user can generate a report. He/She has to enter personal patient data (figure 11). Several options are possible:

- If E and CAP values have been scanned from a FibroScan examination report, then the corresponding patient information are automatically filled and the user has only to confirm that the patient is aware of data processing before being able to generate the report
- If not, 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.

Figure 11: Patient information and patient list

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 VCTE examination date (figure 12). Then, the user can click on Submit button. The report is generated, downloaded on the phone and can be open by the PDF reader available on the device. He/She can go back to the home page by clicking on the  pictogram.

Report file is detailed in the user guide dedicated to interpretation guide score (ref. E504M001).





Figure 12: Examination date

3.7. Settings

Settings are accessible by clicking on the following pictogram: 

In this feature, the user will be able to:

- Update his/her profile
- Change his/her password
- Consult general conditions for use
- Logout

3.7.1. Profile update

MyFibroScan application is available both in French and English. In this screen, the user can switch to another language than the one already selected.

He/She can also update his/her personal data. All fields with a red star are mandatory. However, the email address cannot be changed since it is the user's identifier.

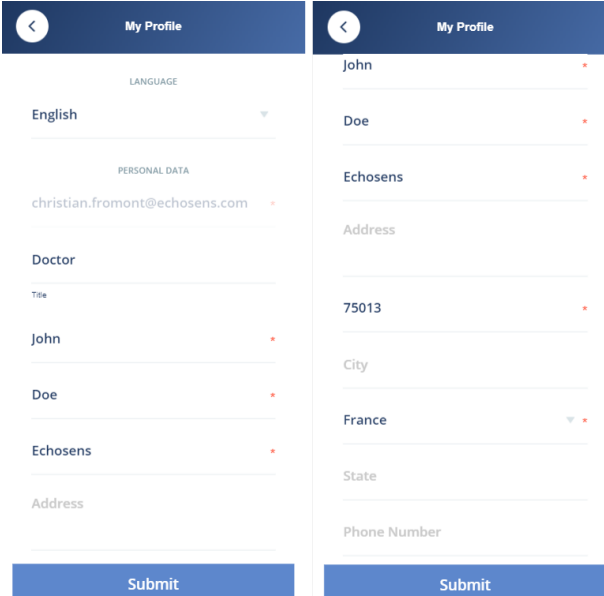


Figure 13: Profile update

3.7.2. Password update

The user can change his current password and replace it with a new one (figure 14). He/She has to confirm it before being able to submit it to the server.

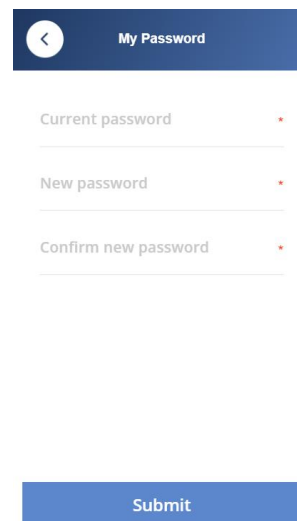


Figure 14: Password update

3.8. Contact us

The user can contact Echosens by clicking on the Contact us pictogram. It will redirect him/her towards the support platform in which he/she will be able to fill a request form.

3.9. About

By clicking on the About pictogram, the user can consult general information regarding Echosens, myFibroScan, trademarks and patents.

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