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Size: 668790
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Pages: 9

Signatories:

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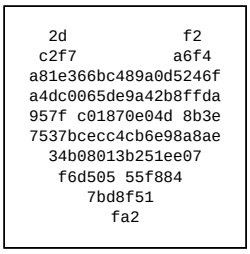
Time: 2024-04-02 14:26:20 (543825)
ip: 192.168.1.22



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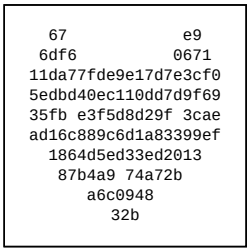

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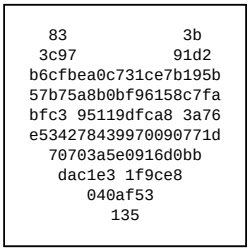

User manual

for

FIB-4 Index

Version 1, April 2024, in English

1. The Evidencio platform

The Evidencio platform facilitates the creation, use, validation and implementation of medical prediction models and clinical decision support tools. This user manual specifically relates to the FIB-4 Index. The User Manual can also be referred to as the Instructions For Use (IFU).

Throughout this manual CE-marked content and the term medical device are used interchangeably.

2. Disclaimer

Evidencio provides information, models, calculators, equations, and algorithms (tools) intended for use by healthcare professionals. Some of these tools have been certified as CE-medical devices. For such CE-marked content the 'Official Legal Disclaimer for CE-marked content' applies. All other content and tools provided by Evidencio are explicitly only covered by the 'Official Legal Disclaimer for non CE-marked content' both are available here: https://www.evidencio.com/disclaimer

3. Warnings

1. Warnings for CE-marked content

Calculations alone should never dictate patient care, and are no substitute for professional judgement. This tool is only to be used by physicians in a clinical setting, and is not for patient use.

Always read the intended use before using this tool.

Before reading the result, double check the filled in values to prevent errors.

Results that concern risk percentages, do not guarantee certain outcomes. When there is a risk present, do not expect an event to not occur at all, even if the risk is very small.

This model is only intended for use in settings where the usage and result of a model are never immediately needed.

4. Model landing page

The medical device model on the Evidencio platform is shown in Figure 1. The model landing page contains the following sections, that are indicated in Figure 1.

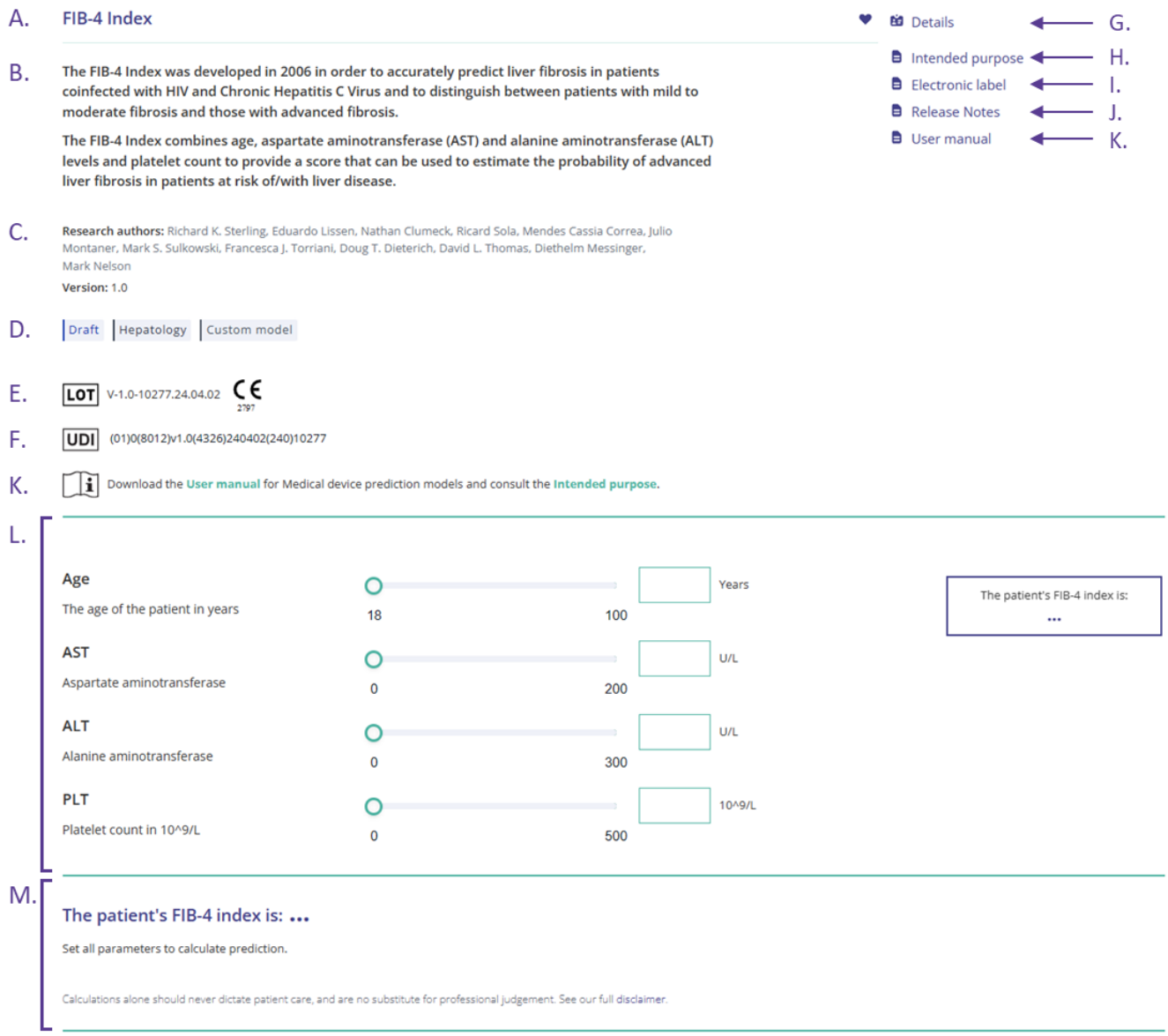

Figure 1. An example of a model landing page.

A. Model title

This is the title and name of the model.

B. Model description

This is a short description of the model.

C. Research authors

These are the research authors of the paper that originally published the model.

D. Model tags

These are the tags that are assigned to the model. Evidencio has the following status tags: “Draft”, “Public”, “Private”, “Under review”. Evidencio has the following model type tags: “Composite model”, “Sequential model”, “API model”. Evidencio has the

following calculation method tags: “Linear model”, “Logistic regression”, “Cox regression”, “RScript” and “Custom model”. Next to this, there are tags that indicate the specialty e.g. “Cardiology”.

E. LOT number

The LOT number indicated the model version, the model identifier, and the model publication date. Publication date is indicated as YY.MM.DD.

Additionally, the CE mark is displayed next to the LOT number. This way, medical devices can be easily recognized.

F. UDI number

The UDI number is an international tool that helps users identify and find information on products. UDI stands for Unique Device Identifier. Evidencio’s UDIs have the following format:

(01)UDI-DI number(8012)versionnumber(4326)releasedate(240)identificationnumber

The UDI-DI number is a unique numeric code. For each medical device of Evidencio, a unique UDI-DI is ascribed. This UDI-DI is used as an “access key” for information stored in a unique device identification database (UDID). Information on Evidencio’s medical devices can be found by searching for the UDI-DI number in the following data base: https://gepir.gs1.org/index.php/search-by-gtin

G. Details button

On the top right of the model page, several clickable buttons are displayed that show a pop-up when clicked. The first button opens a pop-up concerning additional information about the model. This pop-up has three sections: Details, Study characteristics and Supporting publications & related files.

Details

The first part of the additional information concerns the details of the model as shown in Figure 2.

Figure 2. The model details.

Study characteristics

Below the ‘Details section’ the section labeled ‘Study characteristics’ provides information on the characteristics of the patient data used to derive and validate the model. Additional information is provided on the methods used to develop and/or validate the model.

An important part of the Study characteristics is the information on Supporting publications and related files. These sections can be found at the bottom of the Details-pop-up as shown in Figure 3.

Figure 3. An example of Supporting publications & related files.

H. Intended use button

Intended medical use
The FIB-4 Index is intended to be used by professional users who are capable of operating the device and interpreting its results. The result of the FIB-4 Index can be used to estimate the risk of advanced fibrosis.

The FIB-4 Index combines age, aspartate aminotransferase (AST) and alanine aminotransferase (ALT) levels and platelet count to provide a score that can be used to estimate the probability of advanced liver fibrosis in patients at risk of/with liver disease.

The device is intended to be used for patients at risk of/with liver disease who are at risk of advanced fibrosis. The result of the FIB-4 Index is intended to be reviewed and interpreted by qualified medical specialists only. The device is not intended for use by patients on their own.

The FIB-4 Index is not intended to replace clinical decision-making, it can only provide information to the user on the estimation of the risk of advanced fibrosis. The user can use this information to support clinical decision-making regarding prognosis or diagnosis of the patient. In practice, this typically entails the decision to exclude advanced fibrosis for low-risk patients or further diagnostics for those with intermediate or high risk of advanced fibrosis, for example through liver elastography.

Clinical Benefit
The FIB-4 Index is intended to assist patients with relevant and specified clinical outcome parameters. Concretely, this is achieved by calculating a score that can be used to estimate a risk in order to support clinical decision-making aimed at patients with (potential) liver disease who are suspected or at risk of having advanced liver fibrosis, in order to support clinical decision-making regarding patient prognosis and diagnosis. Correct functioning of the FIB-4 Index can result in these clinical benefits:

- Use of the algorithm positively impacts patient management by optimizing the diagnosis and/or treatment of patients with/at risk of liver fibrosis and informing clinical management on further diagnostic/prognostic options.
- The FIB-4 Index can assist in risk stratification for patients
- Risk stratification can reduce the burden of (invasive and intensive) medical procedures such as tests on patients with low risks, reducing, shortening or avoiding stays in hospitals or other care facilities.
- Risk stratification can reduce the unnecessary consumption of (scarce) medical resources, decreasing costs and increasing their availability for high risk patients.
- Digital implementation of the algorithm underlying the FIB-4 Index as a medical device can improve the speed and reliability of calculation. This would further increase the accuracy of the prognosis and by extent increase the chance for the above-mentioned benefits.

Intended target population and exclusion
The FIB-4 Index should be used for patients with (potential) liver disease who are at risk of fibrosis. The FIB-4 Index is intended to be used only for a specific group of patients, corresponding to the below indications and contra-indications.

Clinical indication
The FIB-4 Index should be used for patients who meet the following inclusion criteria:

- Patients with liver disease or an increased risk of liver disease
- Patients above 18 years old

Contra-indications
The FIB-4 Index should not be used for patients who meet one or more of the following exclusion criteria:

- Patients that do not have an increased risk of advanced fibrosis

User profile
The FIB-4 Index is intended to be used by healthcare professionals or automatically calculated through Evidencio's API. Results shall always be reviewed and interpreted by qualified medical specialists only, in the context of the patient's clinical history and other diagnostic test results. Healthcare professionals do not require additional training prior to the use of the medical device. The device is not intended for use by patients on their own.

Intended use environment
The MDSW can be used as made available on the Evidencio platform in any actively supported web-browser on personal computers, mobile devices, or tablet PCs, and on the mobile app provided by Evidencio. The MDSW can also be used through Evidencio's iFrame representation as an embedded view, provided that the specific Evidencio guidelines for iFrame implementations of this MDSW are adhered to. Automated calculation of the device is enabled through Evidencio's API. The device is only intended for use in healthcare settings where the immediate application and outcomes of the device are not required.

Physical interaction
The MDSW is stand-alone software and does not come into contact with any bodily or other material of the patient, user or otherwise.

Versions of the MDSW
The version of the FIB-4 Index concerns the initial version of MDSW of which Evidencio is the manufacturer.

Functioning, physical principle
The MDSW's underlying mathematical formula is a custom formula entailing the patient's age multiplied by their AST, divided by the product of their platelet count and their ALT. The acquisition and processing of the data, the analyses to assemble the relevant criteria for the MDSW as well as the setup and refinement of the FIB-4 Index are provided in the instructions for use. Entering the details for an individual in the MDSW initiates the calculation of a score that can be used to estimate the risk of advanced liver fibrosis.

I. Electronic label button

The electronic label button opens a pop-up with the location and address of Evidencio, the LOT number, the UDI number, the CE-mark, the medical device logo and a download link for the declaration of conformity of the medical device. The example of the electronic label is shown in Figure 4.

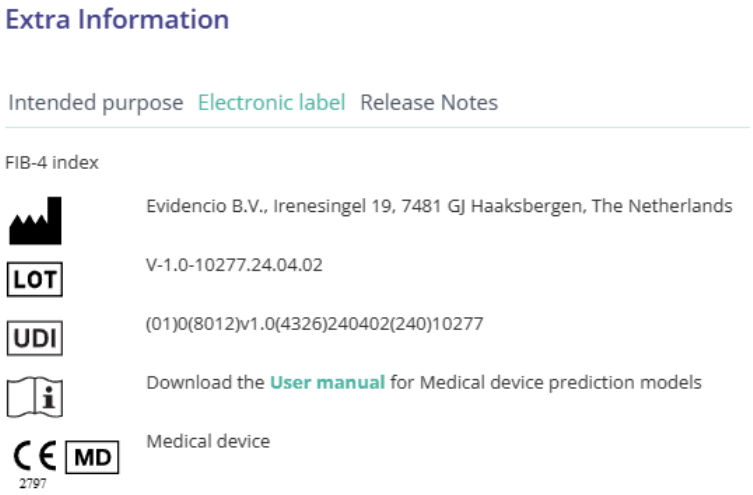

Figure 4. Example of the electronic label

J. Release notes

The 'Release Notes' button opens a pop-up with the latest release notes of the model. Here you can find what has changed over the last versions of the model. Additionally, if there are any known residual anomalies the user should be aware of, they are listed here.

K. User Manual

This user manual can be found in three places: 1) under the short description, 2) on the right of the model page, and 3) in the electronic label. Additionally, all versions of the user manual can be found in the general page for all user manuals for medical devices. The page can be found under the 'About' drop-down menu button as shown in Figure 5. The user manual page is shown in Figure 6.

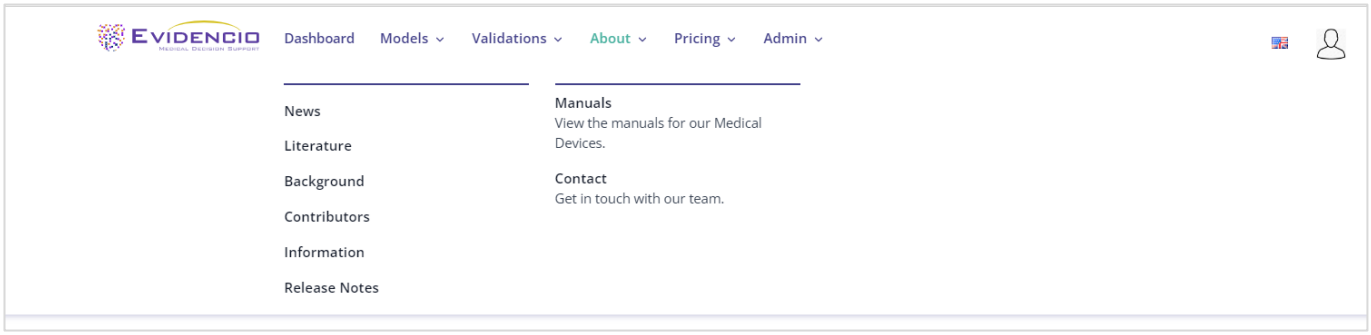

Figure 5. The drop-down menu where the user manual page can be found.

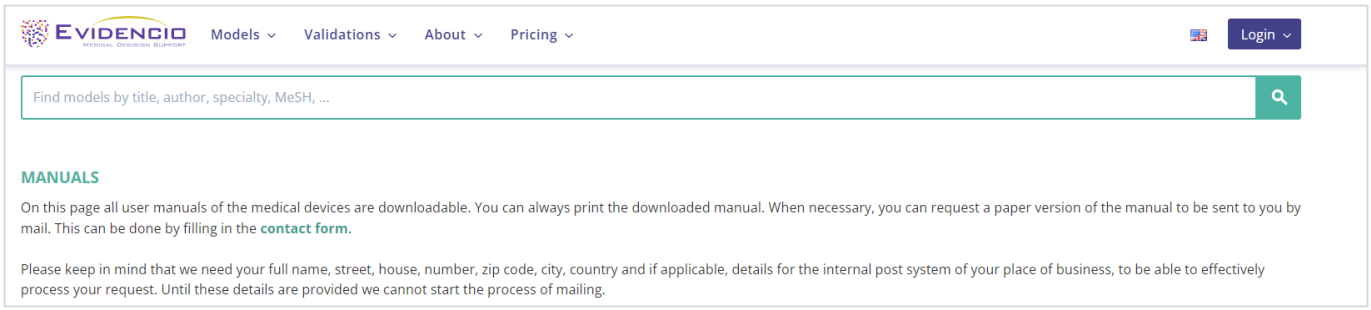

Figure 6. The user manual page for all user manuals.

You (The user) can always print this downloaded manual. When necessary, you can request a paper version of the manual to be sent to you by mail. Evidencio's contact details are listed in Chapter 6 of this user manual.

L. Input section

The Evidencio platform allows two separate input variables; categorical, and continuous variables.

Continuous variables

In the example shown in Figure 7, the **Age** variable, exemplifies a continuous variable. The plausible ranges for the variables are used for the model.

The details for a patient can be entered by sliding the button to the correct value, or by entering the correct value in the box on the right-hand side (i.e., where the 54 is entered for **Age**).

Figure 7. The variable for Age, where "54" has been entered

Details on variable measurements

Directly underneath the name for each variable, additional details can be provided on the methods required to enter the correct value for each variable. In Figure 8, the details below **AST** explain what the abbreviation AST stands for.

Figure 8. An example on how additional information can be provided for a variable.

M. Result section

At the bottom of the page, the results of the model are shown.

Result calculation

When all variables are filled in, a result will be calculated. No risk is displayed until all variables are filled in. The result section indicates *"Set all parameters to calculate prediction."*

Result interpretation

In the result interpretation, a risk stratification is given based on the risk score. An example of the information is shown In Figure 9.

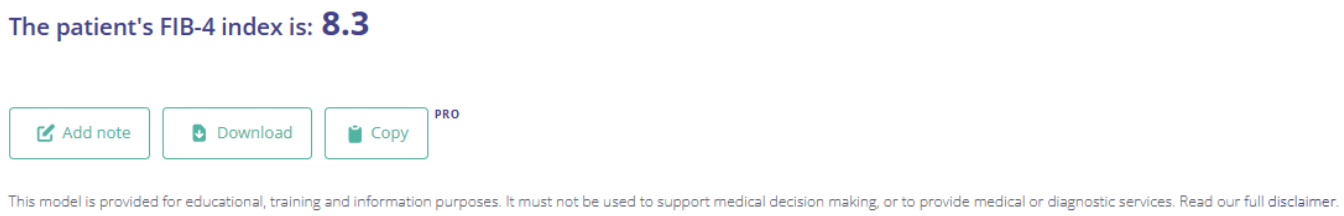

Figure 9. The result information

Relevant information for correct use of the model

At the bottom of the page, there is a link to Evidencio's terms and conditions of use, the privacy policy, and the disclaimer.

5. Use of Medical devices

In general, and unless explicitly stated otherwise, CE-marked tools on Evidencio are only to be used by physicians in a clinical setting, and are not for patient use.

To use the tool, Evidencio requires a stable internet connection and runs on the following devices:

- Personal computers or laptops using the following browsers:
  - Safari (the latest three versions)
  - Chrome (the latest three versions)
  - Firefox (the latest three versions)
  - Edge (the latest three versions)
- Tablets or smartphones running on the next operating systems:
  - IOS (the latest three versions)
  - Android (the latest three versions)

The medical device cannot be used in combination with Internet Explorer. The personal computers, laptops, tablets or smartphones used should at least be able to have an internet connection and use the browsers mentioned above. The minimal screen resolution should be 800x600.
Furthermore, the model may be used through the Evidencio iFrame representation of the calculator, as an embedded view, provided that the specific Evidencio guidelines for iFrame implementations of that model are adhered to.

The Evidencio SaMD models can be used with any browser settings that don't distort the regular display of websites, with a 50% to 500% zoom rate, and at a display resolution starting from 800x600. However, factory recommended browser settings, 100% zoom rate and regular display resolution are recommended.

This model is only intended for use in settings where the usage and result of a model are never immediately needed.

6. Manufacturer details

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the country in which you, the reader, are established. A competent authority is the institute that governs all issues related to medical devices in a country.
Contact details of your competent authority can be found here: https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human

Please contact Evidencio when you suspect any malfunction or changes in the performance of a medical device. Do not use the device, until Evidencio replies to your message that it is safe to start using it again.

Contact details of Evidencio:

Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands
www.evidencio.com
tel: +31 53 85195 08
e-mail: info@evidencio.com

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Name:	10277-DOC-43 rev1.0 User manual FIB-4 Index.pdf
Size:	668790
Hash:	BD9932B9033E1E1A15FB4FD232E7683A5E3998B25CFD8CB92DFB2B3DE33CD16E
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Document history:

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File downloaded	**02 - 04 - 2024** 14:11:16 UTC	Viewed by T. (Thijs) Pasman (id: 13) IP: 192.168.1.22
File downloaded	**02 - 04 - 2024** 14:12:30 UTC	Viewed by T. (Thijs) Pasman (id: 13) IP: 192.168.1.22
File signatories	**02 - 04 - 2024** 14:13:40 UTC	**Signatories:** Author: T. (Thijs) Pasman (id: 13) Reviewer: W.R. (Wouter) van Dijk (id: 16) Approver: R.C. (Romé) Oonk (id: 23)
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