



User manual for the Child-Pugh Score

Version 2, AUGUST 2024, in English

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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 Child-Pugh Score. 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 on the Evidencio website:

<https://www.evidencio.com/disclaimer>.

3. Warnings



3.1. 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.

Always make sure the patient complies with the clinical indications and clinical contra-indications as stated on the Evidencio website, and in **paragraphs 6.4.1** and **6.4.2** of this user manual respectively.

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. Conversely, a high risk does not guarantee that an event will occur.

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

Calculations alone should never dictate patient care, and are no substitute for professional judgement. See our full disclaimer on: <https://www.evidencio.com/disclaimer>.

No security or privacy-sensitive personal and health-related data is stored after the use of CE-certified Medical Device Software (MDSW) models provided by Evidencio. When using the online platform, any new input, the closing of the browser tab and the refreshing of the page will remove the previously provided input. Only user data regarding which devices are used when and by whom are logged.

4. Device Description Child-Pugh Score

The Child-Pugh Score is intended to support clinical decision making by estimating the severity of liver disease in patients with liver dysfunction. The device combines Bilirubin, Albumin, Prothrombin time or INR, Encephalopathy grade and Ascites severity to estimate severity of liver dysfunction, by classifying it as Child-Pugh class A, B or C.

The Child-Pugh score was originally developed in 1973. It was then developed to predict mortality during surgery, but is nowadays often used to determine prognosis in patients suffering from chronic liver disease (mostly cirrhosis).

The Child-Pugh score is also known as the Child-Turcotte-Pugh score or the Child score.

If the continuous values (i.e. bilirubin, albumin & INR) of the patients are higher or lower than the minimum/maximum allowed value to enter, please enter the maximum or the minimum of the slider. It does not influence the score any further.

5. Electronic Label

The electronic label of this device contains the following information:

Name of the device	Child-Pugh Score
Manufacture information	Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands
LOT number	V-2.0-253.24.08.08
UDI-PI number	(01)08720938015090(8012)v2.0(4326)240808(240)253

The electronic label can be found on the Evidencio website, see also section **H** and **Figure 5**.

The electronic label on the website further contains the option to download the **User Manual** and **Declaration of conformity** (DoC).

5.1. 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.

5.2. UDI-PI number

Stands for Unique Device Identifier Production Identifier (UDI-PI) number is an international tool that helps users identify and find information on products. Evidencio's UDI-PIs have the following format:

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

The UDI-DI (Device Identifier) 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>.

6. Intended Purpose

6.1. Intended Medical Use

The Child-Pugh Score is intended to be used by professional users who are capable of operating the device and interpreting its results. It can be used to estimate the severity of liver disease in patients with liver dysfunction.

The Child-Pugh Score combines Bilirubin, Albumin, INR, Encephalopathy grade and Ascites severity to estimate severity of liver dysfunction.

The device is intended to be used for patients with liver dysfunction. The result of the device 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 Child-Pugh Score is not intended to replace clinical decision-making, it can only provide information to the user on the severity of liver dysfunction. The user can use this information to support clinical decision making regarding prognostic/therapeutic options. In practice, the Child-Pugh Score is used in a wide variety of specific contexts.

6.2. Input variables

To perform the calculations successfully, the Child-Pugh Score requires the input variables as listed in **Table 1**.

Table 1. Variables used as input for the Child-Pugh Score.

Name	Description	Type	Range (step size)	Units
Encephalopathy	Presence of encephalopathy	Categorical	None Grade I-II Grade III-IV	-
Bilirubin	Bilirubin level in $\mu\text{mol/L}$ or mg/dL	Continuous	1.5-850 (0.1)	$\mu\text{mol/L}$
			0.1-45 (0.1)	mg/dL
Albumin	Albumin level in g/L or g/dL	Continuous	0-50 (1)	g/L
			0-5 (0.1)	g/dL
INR	International normalized ratio	Continuous	0.5-20 (0.1)	-
Ascites	Presence of ascites	Categorical	None Mild Moderate to Severe	-

6.3. Clinical benefit

The Child-Pugh Score is intended to assist professionals with patients that have relevant and specified clinical outcome parameters. Concretely, this is achieved by estimating a level of liver dysfunction in order to support clinical decision-making aimed at patients with liver dysfunction, in order to support clinical decision-making regarding patient prognosis. Correct functioning of the Child-Pugh Score can result in these clinical benefits:

- Use of the algorithm allows pharmaceutical dosage to be adapted to patient liver function as described in the guidance from the U.S. Food and Drug administration (FDA) and the European Medicines Agency (EMA).
- Use of the algorithm positively impacts patient management by optimising the assessment of the severity of liver dysfunction of patients with liver disease and informing clinical management on further prognostic/therapeutic options.
- Digital implementation of the algorithm underlying the Child-Pugh Score 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.

6.4. Indented target population and exclusion

The Child-Pugh Score is intended to be used only for a specific group of patients, corresponding to the below indications and contra-indications. The target population of the model is patients with liver dysfunction, provided that they fit the listed indications and contra-indications.

6.4.1. Clinical indications

The Child-Pugh Score should be used for patients who meet the following inclusion criteria:

- Patients should be at least 18 years or older
- Patients must have a confirmed diagnosis of liver disease leading to cirrhosis.

6.4.2. Clinical contra-indications

The Child-Pugh Score should not be used for patients who meet one or more of the following exclusion criteria:

- Patients younger than 18 years.

The Child-Pugh Score should not be seen as directly interchangeable with other hepatic function assessment systems such as the NCIc classification.

The Child-Pugh score is designed for chronic liver disease. Its utility in acute liver failure and liver dysfunction primarily due to advanced liver metastases or primary liver malignancies is limited. Other scoring systems may be more appropriate in acute settings.

6.5. Lifetime, residual risks and side effects

The Child-Pugh Score is software, and does not expire. The lifetime is initially set at 5 years from certification, if the state of the art does not change in such a way as to negatively affect the benefit-risk of the device, the lifetime can be extended.

Evidencio has identified a series of risks associated with the use of this model.

The Child-Pugh Score is a low-risk device, there are no noticeable risks involved outside of possible mis-estimation of patient liver functioning, and all residual risks are accepted.

Most identified risks can be defined into two main groups, depending on their outcome.

- a) The risk calculation was wrong or;
- b) The MDSW prediction model is inaccessible.

A wrong risk calculation can be the result of erroneous input values or an error in the mathematical calculation. Technical risks, including the erroneous calculations or the inaccessibility due to a technical error, have been mitigated when possible. These measures focussed on reducing the risks' probability and severity. Concluding that the risks could not be mitigated further, the residual risks were classified as low-level and acceptable. It should be noted that the use of Evidencio's Medical Device Software is itself a risk mitigation measure, as Evidencio's certified Quality Management System ensures and monitors the reliability of the calculations performed with its certified medical devices.

The Child-Pugh Score does not have any direct side effects relevant for the patient.

6.6. User profile

The Child-Pugh Score 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.

6.7. 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.

6.8. 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.

6.9. Versions of the MDSW

The version of the Child-Pugh score concerns the initial version of MDSW of which Evidencio is the manufacturer.

6.10. Functioning, physical principle

The MDSW's underlying mathematical formula is a custom model. 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 Child-Pugh Score are provided in the instructions for use. Entering the details for an individual in the MDSW initiates the estimation of severity of liver dysfunction.

7. Result interpretation

The primary output of this device is given as a number of points between 5 and 15, with an associated Child-Pugh Class of A, B or C.

The outcome of the Child-Pugh Score can be used to stratify patients according to liver functioning and prognosis. However, the effectiveness of the Child-Pugh Score and the associated risk percentages can differ between different Cirrhosis etiology and patient conditions.

Conditional information

The algorithm provides conditional information to the user, presenting the Child-Pugh letter grade associated with their point score:

Result interval 5 to 6 Child-Pugh class A

Result interval 7 to 9 Child-Pugh class B

Result interval 10 to 15 Child-Pugh class C

Calculations alone should never dictate patient care, and are no substitute for professional judgement. See the Evidencio website for the full disclaimer; <https://www.evidencio.com/disclaimer>.

8. Additional information

8.1. Details

Model author:	FleurBoone
Model ID	253
Version	2.0
Revision date	2024-08-08
Speciality	Gastroenterology
Model type	Custom model
MeSH terms	<ul style="list-style-type: none"> • Liver Cirrhosis • Chronic Liver Failure • Liver Disease

Formula

The formula for the Child-Pugh Score is:	Encephalopathy + Bilirubin + Albumin + INR + Ascites
--	--

8.2. Study characteristics

The Child-Pugh was originally derived in a series of 38 patients seen between January 1966 and July 1972 admitted as an emergency with bleeding oesophageal varices, in which ligation of the oesophageal varices via the transthoracic approach was performed after controlling the haemorrhage for 24 hours by other means.

In the table **Table 2** information on the characteristics of the patient data used to derive and validate the model is provided.

Table 2. This table contains categorical characteristics on the patient group data used to derive the model.

Name	Subset / Group	Nr. of patients
Child-Pugh Grade	Grade A	7
Child-Pugh Grade	Grade B	13
Child-Pugh Grade	Grade C	18
Hepatic Encephalopathy	Yes	19
Hepatic Encephalopathy	No	19
Jaundice	Yes	19
Jaundice	No	19
Ascites	Yes	17
Ascites	No	21
Mortality	In-hospital death	21
Mortality	Death within 6 months	5
Mortality	survived for 1 year	9

8.3. Supporting publication & Related files

Several relevant studies, such as the original derivation study by *Pugh et al.* (1973) are contained in **Table 3**. These publication have tags to identify their link with the model. Examples of relevant tags are; "Peer review", "Internal validation", "External validation", and "TRIPOD". Publications that have the tags: "Internal validation" or "External validation", contain data on the performance characteristics of the device.

Table 3. Overview of selection of supporting publications & Related files.

Derivation study	Transection of the oesophagus for bleeding oesophageal varices <i>R N Pugh, I M Murray-Lyon, J L Dawson, M C Pietroni, R Williams</i> https://academic.oup.com/bjs/article-abstract/60/8/646/6188292 https://doi.org/10.1002/bjs.1800600817
Validation study	Systematic review: the model for end-stage liver disease – should it replace Child-Pugh's classification for assessing prognosis in cirrhosis? <i>Cholongitas, E., Papatheodoridis, G. V., Vangeli, M., Terreni, N., Patch, D., & Burroughs, A. K.</i> https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2036.2005.02691.x https://doi.org/10.1111/j.1365-2036.2005.02691.x

8.4. Release notes

The release notes for each publicly available version of the device can be found on the Evidencio website page for the Child-Pugh Score, selecting the correct device, and clicking on Release Notes. It is recommended to read these notes after a version update to see if these changes are relevant to you. Please make sure the correct model version is selected.

9. Implementation of the model through an API

The Child-Pugh Score can be used through Evidencio's API to allow for (automated) calculation of the Child-Pugh Score and class. In the case of use of the MDSW through the API, the user should take into account the different inputs for the model, in order to properly interpret the results. Furthermore, the information contained within this user manual, specifically chapters 3-8, should be read and understood by the user.

Instruction on how to implement the API within a system are included in a separate document that is made available to the party performing the technical implementation.

When using the MDSW through the API, the warnings and descriptions given in this document all apply, as does the additional information. The information for use included in this document regards both use through the website as well as use through the API, as long as the API is properly implemented. The API is only intended for authorized users.

10. Using the model on the Evidencio website

Using the tool on the Evidencio website, requires a stable internet connection. The tool was tested on the following browsers and will run on these versions and higher;

- Personal computers or laptops using the following browsers:
 - Safari (version 17.5 and higher)
 - Chrome (version 126.0.6478.127 and higher)
 - Firefox (version 128.0 and higher)
 - Edge (version 126.0.2592.102 and higher)
- Tablets or smartphones running on the next operating systems:
 - IOS (version 17.5.1 and higher)
 - Android (version 13 and higher)

Correct functioning of the tool with earlier versions of these browsers cannot be guaranteed.

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.

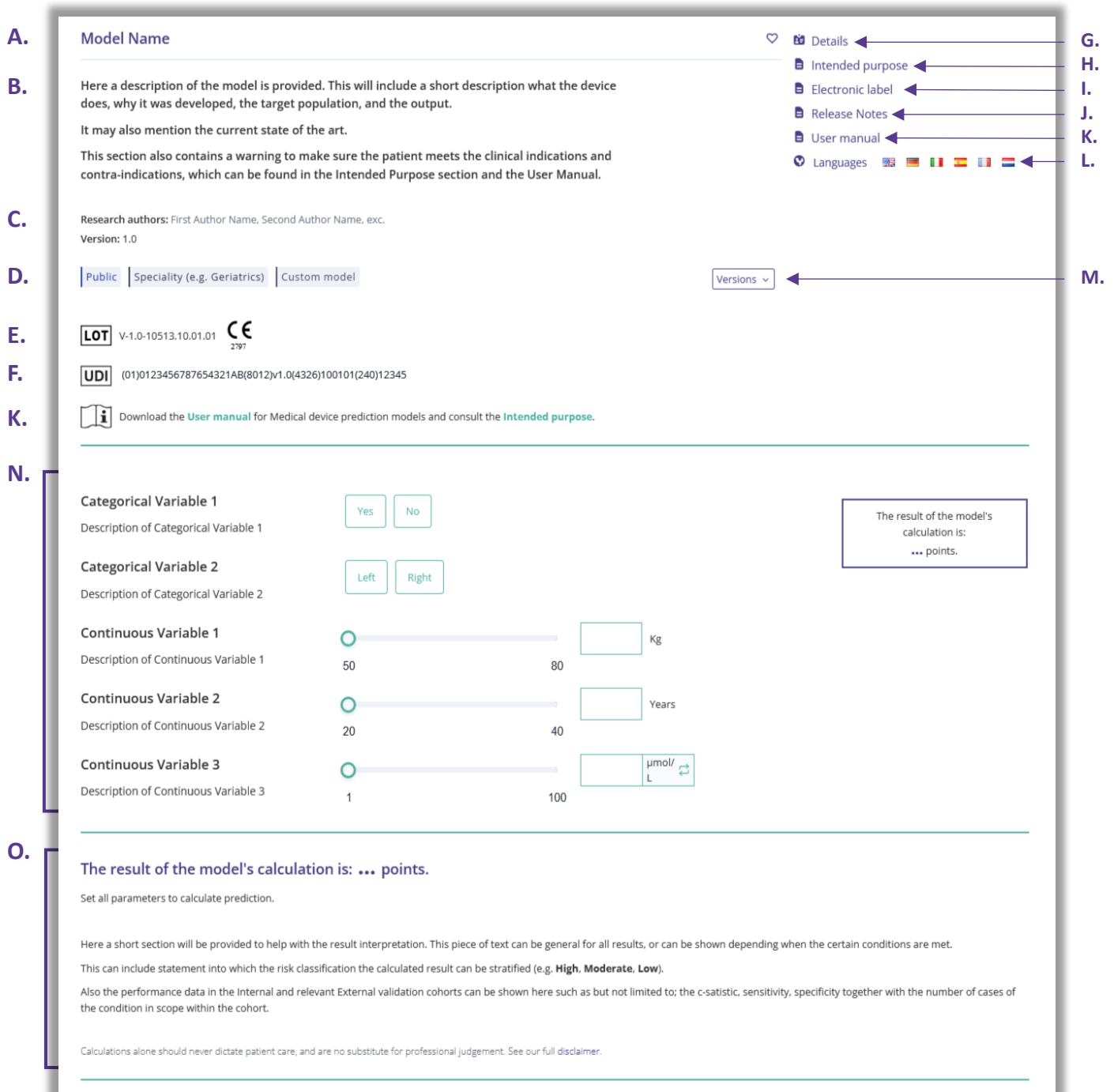
The Evidencio MDSW models can be used with any browser settings that don't distort the regular display of websites, with a 50% to 500% zoom rate, and at a display resolution starting from 800x600. However, factory recommended browser settings, 100% zoom rate and regular display resolution are recommended.

The MDSW is intended for authorised users only, and should not be used by unauthorised personnel.

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

10.1. General modelling 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**.



A. Model Name

B. Here a description of the model is provided. This will include a short description what the device does, why it was developed, the target population, and the output.
It may also mention the current state of the art.
This section also contains a warning to make sure the patient meets the clinical indications and contra-indications, which can be found in the Intended Purpose section and the User Manual.

C. Research authors: First Author Name, Second Author Name, exc.
Version: 1.0

D. **Public** | Speciality (e.g. Geriatrics) | Custom model

E. **LOT** V-1.0-10513.10.01.01 **CE** 2197

F. **UDI** (01)0123456787654321AB(8012)1.0(4326)100101(240)12345

K. Download the [User manual](#) for Medical device prediction models and consult the [Intended purpose](#).

N.

O.

G. Details

H. Intended purpose

I. Electronic label

J. Release Notes

K. User manual

L. Languages

M. Versions

Categorical Variable 1
Description of Categorical Variable 1

Categorical Variable 2
Description of Categorical Variable 2

Continuous Variable 1
Description of Continuous Variable 1
50 80 Kg

Continuous Variable 2
Description of Continuous Variable 2
20 40 Years

Continuous Variable 3
Description of Continuous Variable 3
1 100 $\mu\text{mol/L}$

The result of the model's calculation is: ... points.

The result of the model's calculation is: ... points.

Set all parameters to calculate prediction.

Here a short section will be provided to help with the result interpretation. This piece of text can be general for all results, or can be shown depending when the certain conditions are met.
This can include statement into which the risk classification the calculated result can be stratified (e.g. **High**, **Moderate**, **Low**).
Also the performance data in the Internal and relevant External validation cohorts can be shown here such as but not limited to; the c-statistic, sensitivity, specificity together with the number of cases of the condition in scope within the cohort.

Calculations alone should never dictate patient care, and are no substitute for professional judgement. See our full disclaimer.

Figure 1. Example of a model landing page on the Evidencio website.

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-PI number

The UDI-PI number is an international tool that helps users identify and find information on products. UDI stands for Unique Device Identifier and PI stands for Production 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. It 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**. This section may show the calculation if it is built as a mathematical formula and, if applicable, shows the conditions at which certain formulas are used.




Details		
Model author	Evidencio	Status Draft
Model ID	10513	Share   
Version	1.0	
Revision date	2024-07-15	
Specialty	Cardiology , Geriatrics , Vascular medicine	
Model type	Custom model (Conditional)	
MeSH terms	<ul style="list-style-type: none"> • Term #1 (e.g. Heart Failure) • Term #2 (e.g. Diabetes Mellitus) • Term #3 (e.g. Elderly) 	
Condition	Formula	
Categorical Variable 1=Yes	$\text{Categorical Variable 1} + \text{Categorical Variable 2}^2 + \frac{3 \cdot \text{Continuous Variable 1}}{\text{Continuous Variable 2}}$	
Categorical Variable 1=No	$\sqrt{\text{Continuous Variable 1}} + \frac{2 \cdot \text{Continuous Variable 2}}{\text{Continuous Variable 3}}$	

Figure 2. Example of first part of detail section.

Study Characteristics

Below the 'Details section' the section labelled '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 example of the Study characteristics section can be seen in **Figure 3**.

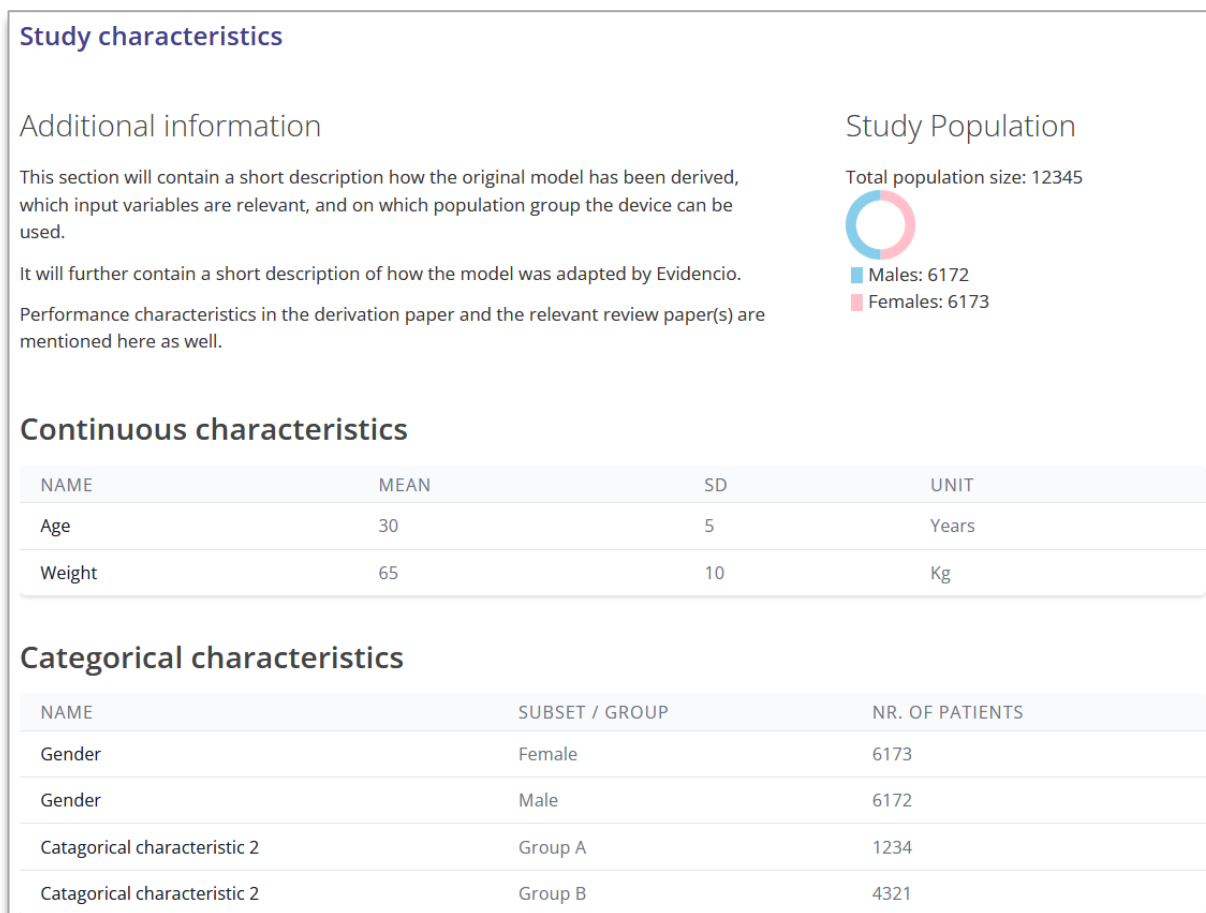


Figure 3. Example of the study characteristics section under the Details tab.

Supporting publications & Related files

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 4**. Tags are attached to the different files to identify their link with the model. Examples of relevant tags are a.o.; “Peer review”, “Internal validation”, “External validation”, and “TRIPOD”. Publications that have the tags: “Internal validation” or “External validation”, contain the performance characteristics of the device. Figures and tables which help to interpreted the results may also be provided here.

Supporting Publications

Title or description	Tags
Title Derivation Paper DOI: DOI: 10.1234/ABCD.1234.5678	Original calculator
Title External Validation DOI: DOI: 10.1234/ABCD.1234.5678	Internal validation
Title Peer Review Paper DOI: DOI: 10.1234/ABCD.1234.5678	External validation
	Peer review

Related files

Preview	Name	Tags
	Derivation Paper.pdf 24.93 KB	Original calculator
	External Validation.pdf 24.93 KB	Internal validation
	Peer Review Paper.pdf 24.93 KB	External validation
		Peer review

Figure 4. Example of the Supporting publication & Related files section under the Details tab.


H. Electronic label


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 5**.


Extra Information


Intended purpose [Electronic label](#) [Release Notes](#)


Model Name


 Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands


 V-1.0-12345.10.01.01


 (01)0123456787654321AB(8012)v1.0(4326)100101(240123450


 Decomplix AG, Freiburgstrasse 3, 3010 Bern, Switzerland


 Download the [User manual](#)



 Download the [Declaration of conformity](#)

Figure 5. Example of an electronic label under the Electronic Label tab.

I. Intended purpose

Under this tab, the intended purpose can be found, containing a lot of information regarding the model, its user, target population, clinical benefit, etc. This information is also provided in this manual and can be found in **Chapter 6** on **page 5**.

J. Release notes

Under this tab the most recent release notes can be found, noting the most significant changes between the versions of the model found on the Evidencio website.

The 'Release Notes' button opens a pop-up with the latest release notes of the model. Here you can find a list of the most significant changes over the different versions of the model. Additionally, if there are any known residual anomalies the user should be aware of, they are listed here. It is recommended to read these notes after a version update to see if these changes are relevant to you.

K. User manual

This user manual can be found in three places: 1) under the short description of the model on the Evidencio model page, 2) on the right of the model page, and 3) as a tab in the electronic label screen. 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 6**. The user manual page is shown in **Figure 7**.

This version of the manual can be printed if required. If necessary, a paper version of the manual can be requested to be sent to you by mail. Evidencio's contact details are listed in **Section 11** of this user manual.

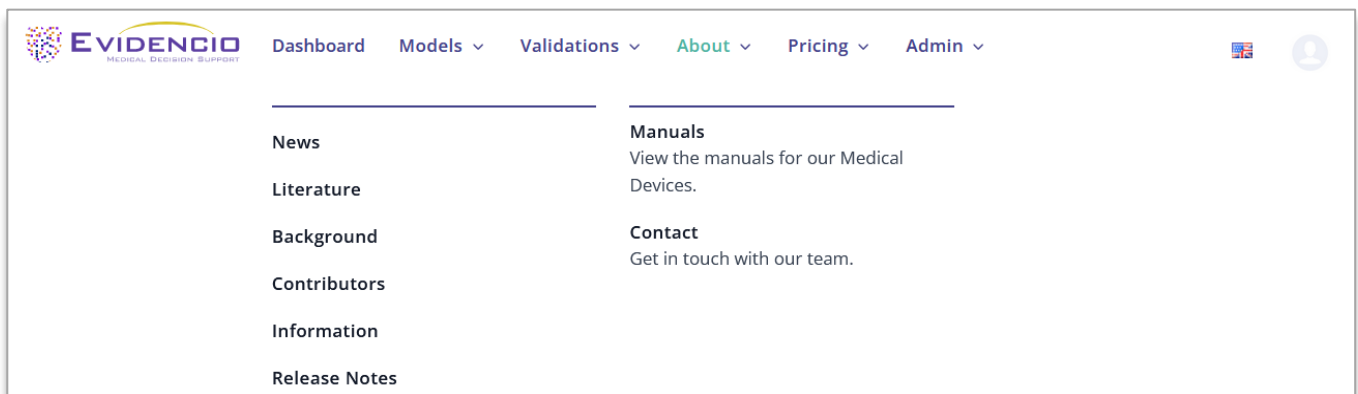


Figure 6. The drop-down menu where the user manual page can be found.

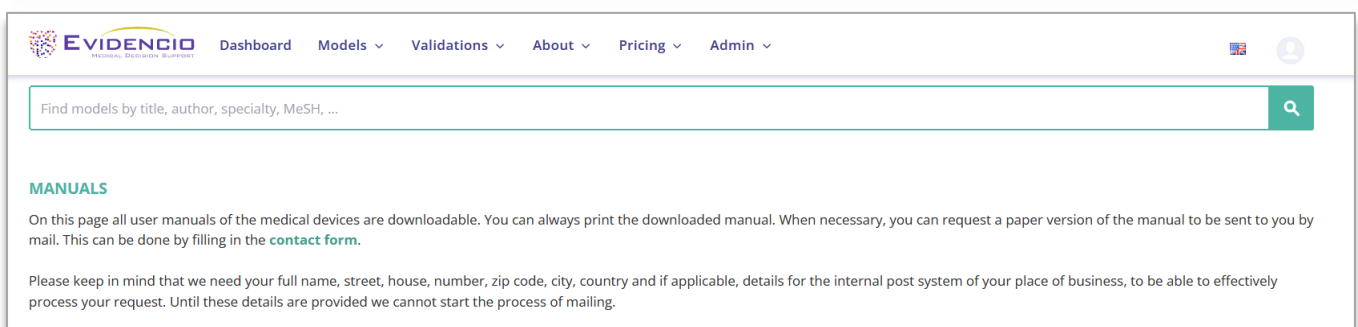


Figure 7. The user manual page for all user manuals.

L. Languages

The standard language on the Evidencio website is English. When other languages are available, these can be selected here. The list of languages may be different between models and may change when in time more languages will become available. Currently the Child-Pugh Score and its user manual are available in English.

Please note that, if a language is selected, only the user interface of the specific model will be translated, other general features and information on the site might still be set to one of our primary languages: English, German, and Dutch.

When you find mistranslations, irregularities, or confusing or ambiguous use of language in English or any other language on the Evidencio website or in one of our manuals, please do not hesitate to contact us using the contact information provided at the end of this manual.

M. Version / Model selection

Clicking on the Version tab allows the user to select a different version of the Briganti Nomogram for a list as displayed in **Figure 8**. Please note that the model currently selected is not presented in the dropdown menu.

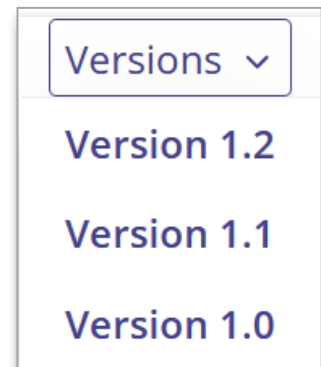


Figure 8. Example of version selection tab.

N. Input section

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

Categorical variables

In the example shown in shown in **Figure 9** and **Figure 10**, the example **Categorical Variable 1** concerns a categorical variable. The input that is wished to be used can be entered by clicking on either button. The selected button changes to green, as seen in **Figure 10**.

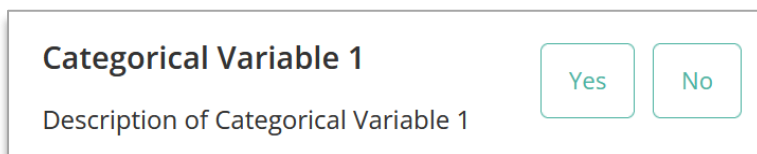


Figure 9. Example of a categorical variable, no button has been clicked and thus no input has been provided by the user.

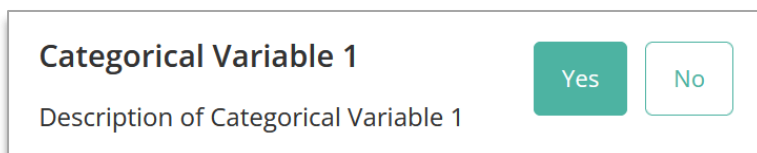


Figure 10. Example of a categorical variable, where the "Yes" button has been clicked.

Continuous variables

In the example shown in **Figure 11**, the **Continuous Variable 3**, exemplifies a continuous variable. The plausible ranges for which the model is tested and deemed valid are used.

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 10.2 *mg/dL* is entered for the **Continuous Variable 3**).



Figure 11. Example of a continuous variable, where “10.2 *mg/dL*” has been entered.

Unit conversion

Sometimes it is possible to use an unit conversion, by clicking on the unit when the green arrows are present. See **Figure 12** below where the unit has been clicked and switched.

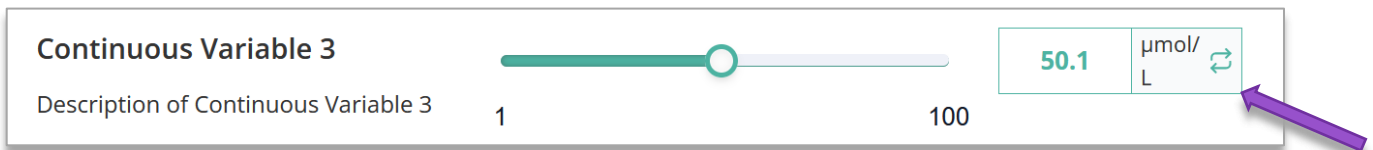


Figure 12. Example of a continuous variable where “50.1 *μmol/L*” has been entered.

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. Details may include but are not limited to; more detailed explanation of the variable, the ranges of the variables (for healthy individuals), or a description when a continuous variable should be true or false.

O. Result section

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

Calculations alone should never dictate patient care, and are no substitute for professional judgement. See our full disclaimer on: <https://www.evidencio.com/disclaimer>.

Result calculation

When all variables are filled in, a result will be calculated. No risk is displayed until all variables are filled in and the result section will indicate; “*Set all parameters to calculate prediction.*”

Result interpretation

In the result interpretation, a risk stratification is provided based on the risk score. Additional information about this stratification and the classification as found in the derivation and important validation cohorts may also be provided. An example of the information is shown in **Figure 13**.

The result of the model's calculation is: ... points.

Set all parameters to calculate prediction.

Here a short section will be provided to help with the result interpretation. This piece of text can be general for all results, or can be shown depending when the certain conditions are met.

This can include statement into which the risk classification the calculated result can be stratified (e.g. **High, Moderate, Low**).

Also the performance data in the Internal and relevant External validation cohorts can be shown here such as but not limited to; the c-statistic, sensitivity, specificity together with the number of cases of the condition in scope within the cohort.

Figure 13. Example of the result display and information section.

11. 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.

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:



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