User manual for the PIPRA

Version 2, November 2024, in English

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1. The Evidencio platform

The Evidencio platform facilitates the creation, use, validation and implementation of medical prediction algorithms and clinical decision support tools. This User Manual specifically relates to the PIPRA. 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 for CE-marked content

Evidencio provides certain CE-marked information, algorithms, calculators, equations, and algorithms (tools) on any of its websites, applications, apps, or services. These tools may only be used in accordance with the intended use / intended purpose that has been published with the respective CE-marked tool.

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.

The CE-marked content on the platform is to be regarded as a specific set of tools, apart from the general platform content. Any available content, on any of the websites, applications, apps, or services provided by Evidencio that is not clearly labelled as a CE-marked tool is explicitly not covered by this disclaimer for CE-marked content, the general Evidencio Disclaimer for non-CE-marked content applies.
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Your use of the websites, applications, apps, or services provided by Evidencio is subject to our Terms & Conditions, which can be found here: https://www.evidencio.com/terms-conditions.

3. Warnings

⚠ 3.1. Warnings for CE-marked content

Calculations alone should never dictate patient care, and are no substitute for professional judgement. See our full disclaimer on: https://www.evidencio.com/disclaimer. This tool is only to be used by healthcare professionals 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 6.3.1** and **6.3.2** 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 algorithm is only intended for use in settings where the usage and result of an algorithm are never immediately needed.

The data used to perform the calculations is stored by Evidencio to enhance algorithm function and allow issues to be traceable for further improvements. For details, see the privacy policy on our website at: https://www.evidencio.com/privacy-policy.

4. Device Description PIPRA

PIPRA calculates an individual pre-surgical risk score of presenting postoperative delirium (POD).

4.1. Lifetime, residual risks and side effects

The PIPRA 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.

No steps are required to be undertaken by the user to decommission a product when it is taken off the market. If the lifetime is not extended, a notice will be placed on the algorithm's page on the platform. When a device is taken off the market, users may be informed about this (e.g. through e-mail).

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

The PIPRA is a low-risk device, there are no noticeable risks involved outside of possible mis-estimation of patient's pre-surgical risk for presenting POD, and all residual risks are accepted.

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

a) The risk calculation was wrong or;
b) The MDSW prediction algorithm 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 inaccessibly 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 PIPRA does not have any direct side effects.

5. Electronic Label

The electronic label of this device contains the following information:

Name of the device	PIPRA
Manufacturer information	Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands
LOT number	2461
UDI-PI number	08720299526457
Swiss representative	Decomplix AG, Freiburgstrasse 3, 3010 Bern, Switzerland

The electronic label can be found on the Evidencio website, see also section **I** and **Figure 5** in **Chapter 10**.

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 algorithm version, the algorithm identifier, and the algorithm 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 PIPRA is intended to be used by professional users who are capable of operating the device and interpreting its results. It can be used to preoperatively estimate the risk of developing postoperative delirium (POD) in patients at risk for POD. The device combines age, height & weight or BMI, ASA status, history of delirium, cognitive impairment, number of medications, preoperative CRP (optional), surgical risk and laparotomy/thoracotomy surgery to predict the risk of developing POD.

The device is intended to be used for patients who will undergo surgery and are at risk of POD. The result of the PIPRA 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 PIPRA is not intended to replace clinical decision-making, it can only provide information to the user on the estimation of the risk of POD. The user can use this information to support clinical decision-making regarding the care of the patient after surgery. In practice, this typically entails the decision to provide extra care measures to prevent or limit POD.

6.2. Clinical benefit

The PIPRA is intended to assist patients with relevant and specified clinical outcome parameters. Concretely, this is achieved by estimating a risk in order to support clinical decision-making aimed at patients who will undergo surgery at risk for POD, in order to support clinical decision-making regarding patient prognosis. Correct functioning of the PIPRA can result in these clinical benefits:

- The PIPRA can assist in risk stratification of patients
- Risk stratification can reduce the burden of medical procedures such as postoperative care 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 PIPRA as a medical device can improve the speed and reliability of calculation.

6.3. Indented target population and exclusion

The PIPRA Algorithm is intended to be used with older patients who are planned to undergo surgery and who are at risk of developing POD. As such, the PIPRA is intended to be used only for a specific group of patients, corresponding to the below indications and contra-indications.

6.3.1. Clinical indications

The PIPRA should be used for patients who meet the following inclusion criteria:

- Patients of 60 years and older.
- Patients scheduled for a surgery.

6.3.2. Clinical contra-indications

The PIPRA should not be used for patients who meet one or more of the following exclusion criteria:

- The clinical intervention planned for the patient is a cardiac surgery.
- The clinical intervention planned for the patient is an intracranial surgery.

6.4. User profile

The PIPRA is intended to be used by Healthcare Professionals or automatically calculated through Evidencio's API (Application Programming Interface). 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.

6.5. 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.

6.6. 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.

6.7. Versions of the MDSW

The PIPRA has previously been available as an MDD certified medical device on the Evidencio platform, of which Evidencio is the manufacturer. The underlying function and algorithm of the MDSW discussed in this clinical evaluation, of which Evidencio is the manufacturer, will be equivalent to those previously certified under the MDD.

6.8. Functioning, physical principle

The MDSW's underlying mathematical formula is a custom model based on an R-script. 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 PIPRA are provided in the instructions for use. Entering the details for an individual in the MDSW initiates the pre-operative estimation of the risk of POD up to 7 days after surgery.

7. Result interpretation

The primary output of this device is given as a percentage representing the risk for a postoperative delirium.

In addition to this, two charts are generated. To better visualize the impact of each individual risk factor on the predicted risk, a bar chart is generated which shows if they have a positive or negative contribution together with their significance.

Secondly, a waffle chart is generated to aid visualization how many COP cases are expected out of a hundred patients with the same input characteristics.

These charts are automatically provided on the site and the information contained in them is also part of the API response.

Conditional information

Based on the calculated risk the patients are stratified into four risk categories; Low risk (0% - 10%), medium risk (10.1% - 20%), high risk (21.1% - 35%), and very high risk (35.1% - 100%).

The result predicts the risk (in percentage) of a patient developing POD after surgery.
Recommended actions for patients at risk can be found in the following guidelines:

- European Society of Anaesthesiology evidence-based and consensus-based guideline on postoperative delirium; https://pubmed.ncbi.nlm.nih.gov/2818705.
- American Society for Enhanced Recovery and Perioperative Quality Initiative Joint Consensus Statement on Postoperative Delirium Prevention; https://pubmed.ncbi.nlm.nih.gov/32022748.
- American Geriatrics Society Expert Panel on Postoperative Delirium in Older Adults. American Geriatrics Society abstracted clinical practice guideline for postoperative delirium in older adults; https://pubmed.ncbi.nlm.nih.gov/25495432.

Non-exhaustive summary of recommended preventive measures extracted from the above-mentioned guidelines

- Patient identified as high-risk patients should be informed of their risk.
- Hospitals and health systems should develop a process to assess postoperative delirium in older high-risk patients.
- Older high-risk patients should get multicomponent, non-pharmacologic interventions for the prevention of postoperative delirium.
- Minimize medications known to be associated with an increased risk of postoperative delirium in older high-risk surgical patients.
- Optimize intra- and post-operative pain control.
- Implement fast track surgery.
- Monitor depth of anaesthesia using processed EEG monitoring.

Further information & resources; https://www.pipra.ch/tool.

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:	T. A. Hueting
Root model ID	2461
Version	2.10
Revision date	05-JUN-2024
Specialities	Anaesthesiology, Geriatrics, Surgery
Model type	R-Script model
MeSH terms	• Postoperative Complications • Delirium, Dementia, Amnestic, Cognitive Disorders

8.2. Input variables

To perform the calculations successfully, the PIPRA requires the input variables as listed in **Table 1**.

Table 1. Variables used as input for the PIPRA.

Name	Description	Type	Range (step size)	Units
Age in years	The risk of POD increases with age	Continuous	60 – 100 (1)	Years
Height & Weight or BMI	Would you like to enter BMI directly, or enter the height and weight of the patient?	Categorical	Height & Weight	-
			BMI	-
Height	Only visible when "Height & Weight" is selected	Continuous	50 – 250 (1)	cm
Weight	Only visible when "Height & Weight" is selected	Continuous	30 – 300 (1)	kg
BMI	Only visible when "BMI" is selected	Continuous	15 – 40 (0.1)	Kg/m^2
American society of Anesthesiologist (ASA) Status	ASA Physical classification system	Continuous	1 – 5 (1)	-
History of delirium	Has the patient previously suffered from delirium	Categorical	No	-
			Yes	-
Cognitive impairment	The cognitive assessment of the patient can be done by MMSE[1], MoCA[2] or another reliable score.	Categorical	No	-
			Yes	-
Medications	Number of medications taken by the patient before the operation	Continuous	0 – 16 (1)	-
C-reactive protein	Do you have a CRP value	Continuous	No	-
			Yes	-
Preoperative CRP	Only visible when "C-reactive protein" is set to "Yes" C-reactive protein measured within the last 24h	Continuous	0.1 – 500 (1)	mg/L
Surgical risk	The risk of POD depends on the type of surgery. Enter the surgical risk according to the ESA[3] classification of cardiac risk for non-cardiac surgery[4].	Continuous	1 – 3 (1)	-
Laparotomy/thoracotomy	Is the surgery a laparotomy/ thoracotomy? The type of surgery influences the risk of POD and open surgery has a particularly high risk.	Categorical	No	-
			Yes	-

[1]Mini-Mental status Exam. [2]Montreal Cognitive Assessment. European Society of Anaesthesiology.

[4]Table 3 in the 2014 ESC/ESA Guidelines on non-cardiac surgery:

1 = Low risk, e.g. minor orthopaedic/gynaecology, urological surgery, thyroid surgery, superficial surgery.

2 = Intermediate risk, e.g. intraperitoneal, endovascular, non-major intrathoracic, major orthopaedic/ gynaecology/urological.

3 = High risk, e.g. aortic and major vascular, liver surgery, pneumonectomy, repair of perforated bowel.

8.3. Study characteristics

To summarize the methods used to develop the algorithm: A total of 9 different datasets were combined to develop and validate the algorithm. Three different statistical approaches to develop the algorithm were compared head-to-head by 10-fold-cross validation. The three approaches concerned Logistic regression, Random Forest, and XGBoost. The Logistic regression algorithm was selected as the best performing algorithm with an apparent C-index of 0.83, and a cross-validated C-index of 0.81. As pre-operative CRP is not available for all patients, a second algorithm without CRP as risk factor was developed. The cross-validated C-index of the non-CRP algorithm is 0.8.

In **Table 2** and **Table 3** information on the characteristics of the patient data used to derive and validate the algorithm is provided.

Table 2. This table contains information on the patient group data used to derivate the algorithm.

Name	Q1	Median	Q3	Unit
BMI	21.3	23.7	26.4	Kg/m^2
Total number of medications (pre-operation)	1		xx.x	-
Pre-operative CRP	0.1	0.21	1.21	mg/dL

Table 3. This table contains categorical characteristics on the patient group data used to derive the algorithm.

Name	Subset / Group	Number of patients
History of delirium	Yes	66
Cognitive impairment	Yes	176
Laparotomy/thoracotomy	Yes	255
Age	60 - 69	720
Age	70 - 79	920
Age	80+	610
ASA Status	1	189
ASA Status	2	1069
ASA Status	3	627
ASA Status	4	61
ASA Status	5	1
Surgery severity	1	52
Surgery severity	2	1885
Surgery severity	3	297

8.4. Supporting publication & Related files

Several relevant studies, such as the original derivation study by Dodsworth *et al*. (2023) are contained in **Table 4**. These publications have tags to identify their link with the algorithm. 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 4. Overview of selection of supporting publications & Related files.

Derivation paper	**Development and validation of an international preoperative risk assessment model for postoperative delirium** (2023) *Benjamin T. Dodsworth, Kelly Reeve, Lisa Falco, Tom Hueting4, Behnam Sadeghirad, Lawrence Mbuagbaw, Nicolai Goettel, Nayeli Schmutz Gelsomino* DOI: 10.1093/ageing/afad086
Parameter selection	**Preoperative prognostic factors associated with postoperative delirium in older people undergoing surgery: protocol for a systematic review and individual patient data meta-analysis** (2020) *Tayler A. Buchan, Behnam Sadeghirad, Nayeli Schmutz, Nicolai Goettel, Farid Foroutan, Rachel Couban, Lawrence Mbuagbaw & Benjamin T. Dodsworth* DOI: 10.1186/s13643-020-01518-z
Dataset	**Clock-Drawing Test as a Bedside Assessment of Post-operative Delirium Risk in Elderly Patients with Accidental Hip Fracture** (2017) *Claudia C. Vasilian, Simona C. Tamasan, Diana Lungeanu, Dan V. Poenaru* DOI: 10.1007/s00268-017-4294-y
Dataset	**Slow Gait Speed and Rapid Renal Function Decline Are Risk Factors for Postoperative Delirium after Urological Surgery** (2016) *Tendo Sato, Shingo Hatakeyama, Teppei Okamoto, Hayato Yamamoto, Shogo Hosogoe, Yuki Tobisawa, Tohru Yoneyama, Eiji Hashiba, Takahiro Yoneyama, Yasuhiro Hashimoto, Takuya Koie, Kazuyoshi Hirota, Chikara Ohyama* DOI: 10.1371/journal.pone.0153961
Dataset	**DELirium Prediction Based on Hospital Information (Delphi) in General Surgery Patients** (2016) *Kim, Min Young; Park, Ui Jun; Kim, Hyoung Tae; Cho, Won Hyun* DOI: 10.1097/MD.0000000000003072
Dataset	**Low skeletal muscle mass as a risk factor for postoperative delirium in elderly patients undergoing colorectal cancer surgery** (2018) *Mosk CA, van Vugt JLA, de Jonge H, Witjes CDM, Buettner S, Ijzermans JNM, van der Laan L* DOI: 10.2147/CIA.S175945
Dataset	**Postoperative delirium after colorectal surgery in older patients** (2011) *Linda Thomson Mangnall; Robyn Gallagher; Jane Stein-Parbury* DOI: 10.4037/ajcc2010902
Dataset	**Is preoperative state anxiety a risk factor for postoperative delirium among elderly hip fracture patients?** (2015) *Bastiaan Van Grootven, Elke Detroyer, Els Devriendt, An Sermon, Mieke Deschodt, Johan Flamaing, Christophe Dubois, Koen Milisen* DOI: 10.1111/ggi.12581
Dataset	**The effect of a multidisciplinary care bundle on the incidence of delirium after hip fracture surgery: a quality improvement study** (2019) *A. Chuan, L. Zhao, N. Tillekeratne, S. Alani, P. M. Middleton, I. A. Harris, L. McEvoy, D. Ní Chróinín* DOI: 10.1111/anae.14840
Dataset	**The effect of a pre- and postoperative orthogeriatric service on cognitive function in patients with hip fracture: randomized controlled trial (Oslo Orthogeriatric Trial)** (2014) *Leiv Otto Watne, Anne Cathrine Torbergsen, Simon Conroy, Knut Engedal, Frede Frihagen, Geir Aasmund Hjorthaug, Vibeke Juliebo, Johan Raeder, Ingvild Saltvedt, Eva Skovlund & Torgeir Bruun Wyller* DOI: 10.1186/1741-7015-12-63

8.5. Release notes

The release notes for each publicly available version of the device can be found on the Evidencio website page for the PIPRA: https://www.evidencio.com/models/show/2461, 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 algorithm version is selected.

9. Implementation of the algorithm through an API

The PIPRA can be used through Evidencio's API to allow for (automated) calculation of the risk for postoperative delirium (POD) In the case of use of the MDSW through the API, the user should take into account the different inputs for the algorithm, in order to properly interpret the results.

Instructions 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 algorithm on the Evidencio website

Using the tool on the Evidencio website requires a stable internet connection. The tool was developed to work on the latest versions, as of the making of this manual, of the four most commonly used internet browsers; Google Chrome, Mozilla Firefox, Microsoft Edge, and Apple Safari.

The tool can also be accessed on mobile devices running the most recent versions of the Android and iOS operating systems.

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 algorithm 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 algorithm are adhered to.

The Evidencio MDSW algorithm 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 algorithm is only intended for use in settings where the usage and result of a algorithm are never immediately needed.

10.1. General algorithm landing page

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

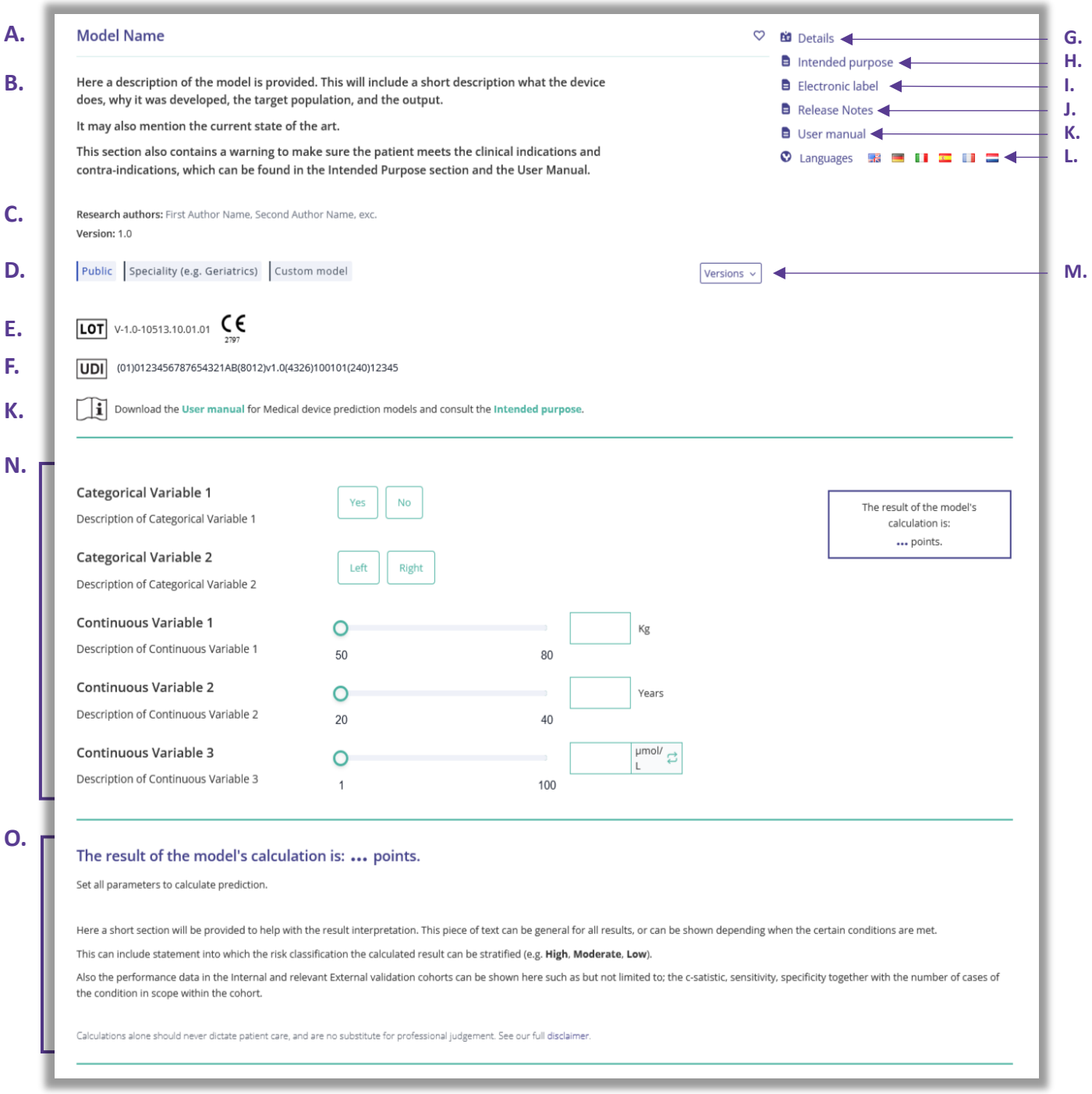


Figure 1. Example of a model landing page on the Evidencio website.

A. Algorithm title

This is the title and name of the algorithm.

B. Algorithm description

This is a short description of the algorithm.

C. Research authors

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

D. Algorithm tags

These are the tags that are assigned to the algorithm. 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 algorithm version, the algorithm identifier, and the algorithm 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

For information on the UDI-PI Number see **Section 5.2** on **page 5** of this user manual.

G. Details button

On the top right of the algorithm’s 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 algorithm. 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 algorithm 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.

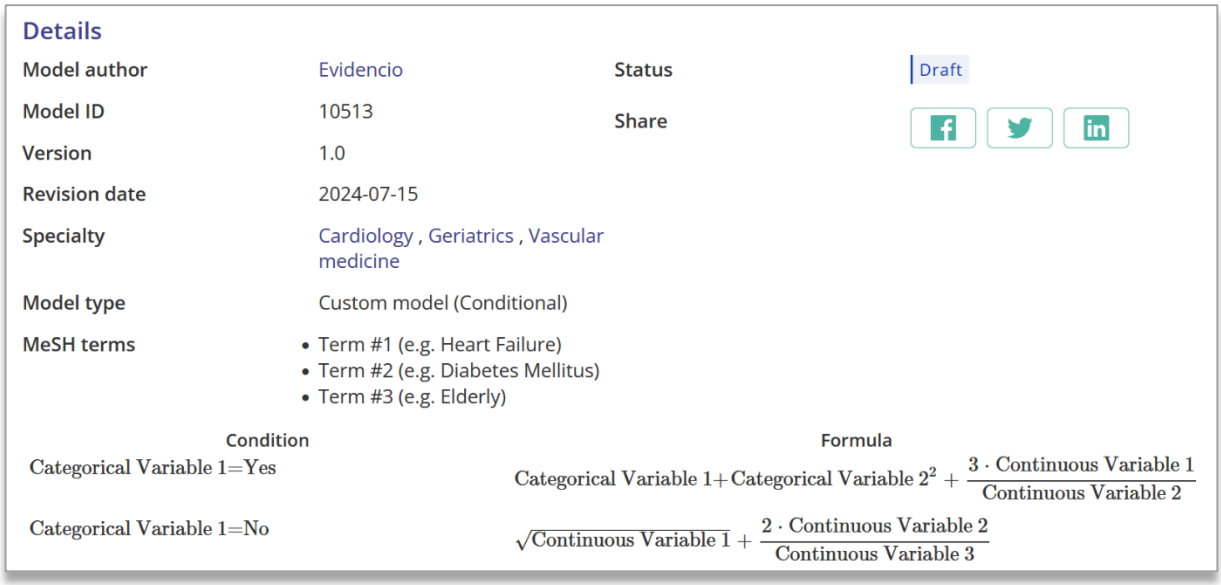
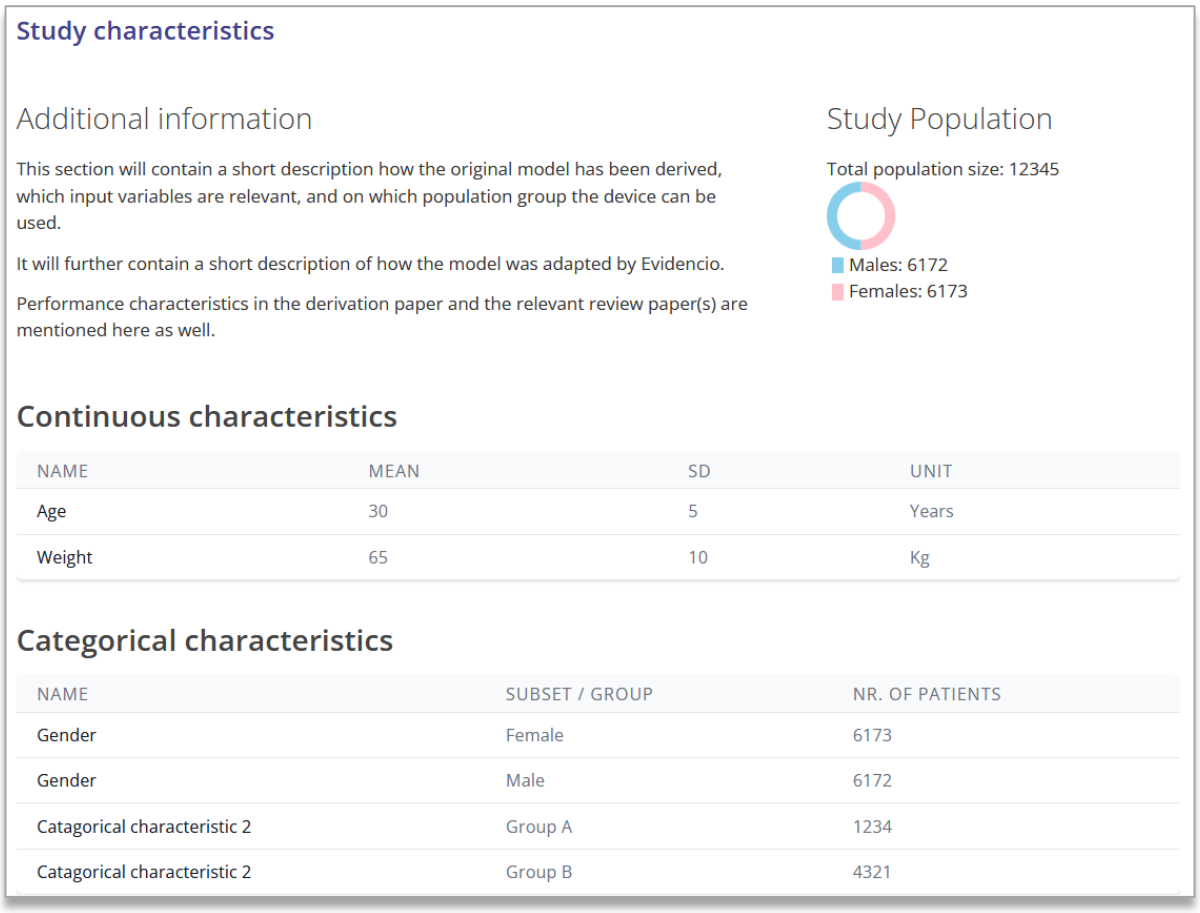


Figure 2. Example of first part of detail section.

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 algorithm. Additional information is provided on the methods used to develop and/or validate the algorithm. An example of the Study characteristics section can be seen in **Figure 3**.



Study characteristics

Additional information

This section will contain a short description how the original model has been derived, which input variables are relevant, and on which population group the device can be used.

It will further contain a short description of how the model was adapted by Evidencio.

Performance characteristics in the derivation paper and the relevant review paper(s) are mentioned here as well.

Study Population

Total population size: 12345

Males: 6172
Females: 6173

Continuous characteristics

NAME	MEAN	SD	UNIT
Age	30	5	Years
Weight	65	10	Kg

Categorical characteristics

NAME	SUBSET / GROUP	NR. OF PATIENTS
Gender	Female	6173
Gender	Male	6172
Catagorical characteristic 2	Group A	1234
Catagorical characteristic 2	Group B	4321

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**.

Supporting Publications

Title or description
Title Derivation Paper
DOI: DOI: 10.1234/ABCD.1234.5678

Title External Validation
DOI: DOI: 10.1234/ABCD.1234.5678
Title Peer Review Paper
DOI: DOI: 10.1234/ABCD.1234.5678

Tags
Original calculator
Internal validation
External validation
Peer review

Related files

Preview | Name | Tags

Derivation Paper.pdf
24.93 KB
Original calculator
Internal validation

External Validation.pdf
24.93 KB
External validation

Peer Review Paper.pdf
24.93 KB
Peer review

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

Tags are attached to the different files to identify their link with the algorithm. 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.

H. Intended purpose

Under this tab, the intended purpose can be found, containing a lot of information regarding the algorithm, 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**.

I. 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**.

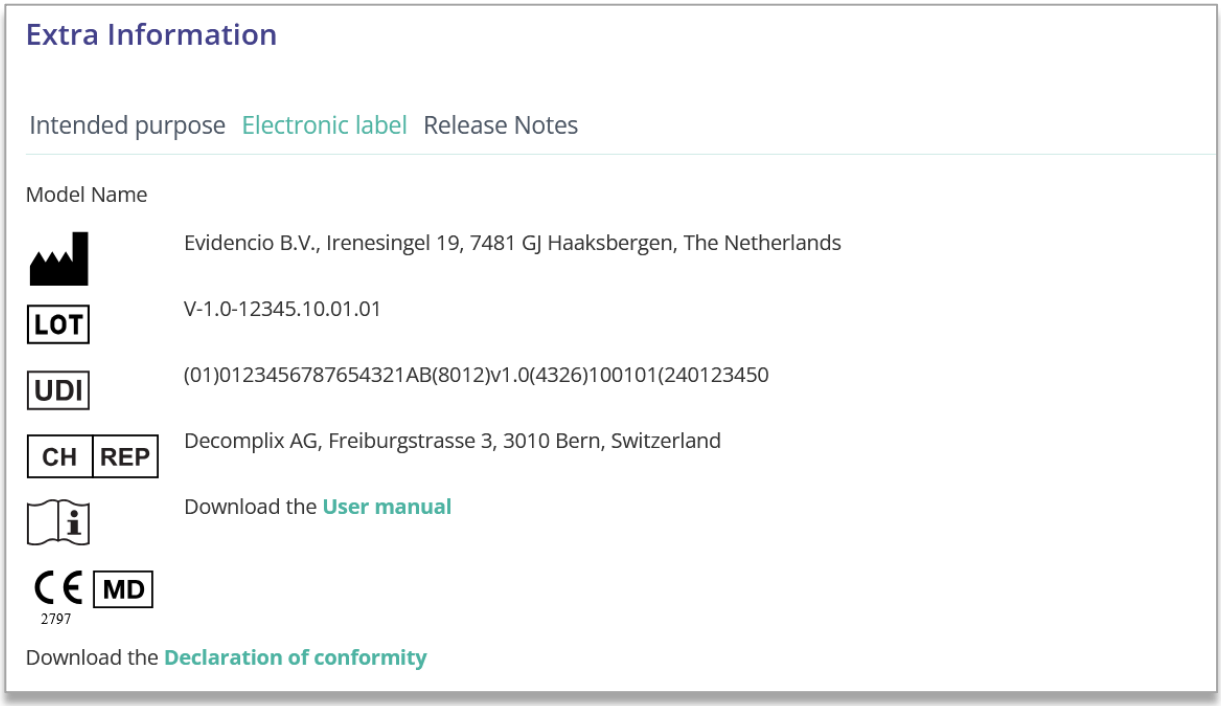


Figure 5. Example of an electronic label under the Electronic Label tab.

J. Release notes

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

The ‘Release Notes’ button opens a pop-up with the latest release notes of the algorithm. Here you can find a list of the most significant changes over the different versions of the algorithm. 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 algorithm on the Evidencio algorithm’s page, 2) on the right of the algorithm’s 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 **Chapter 11** of this user manual.

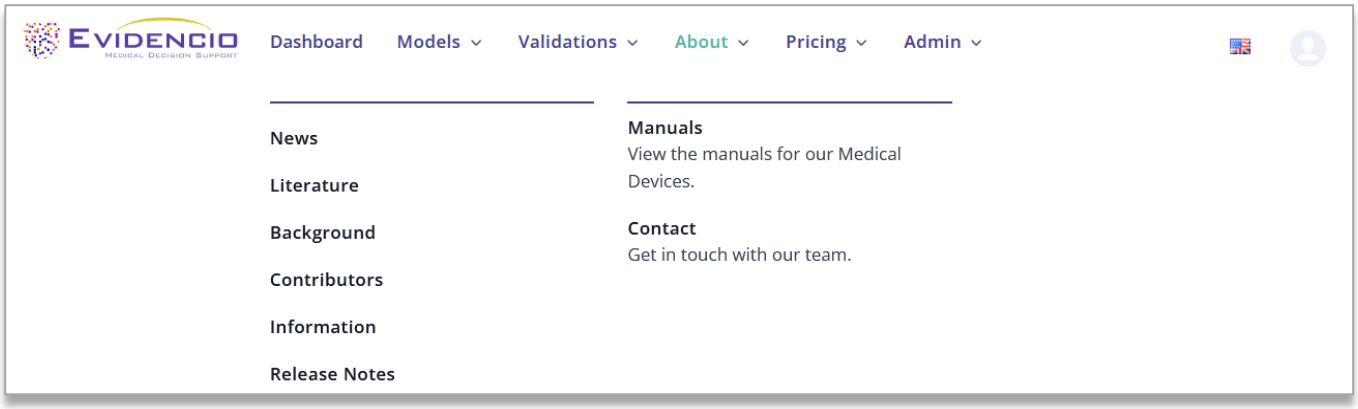


Figure 6. The drop-down menu where the user manual page can be found.

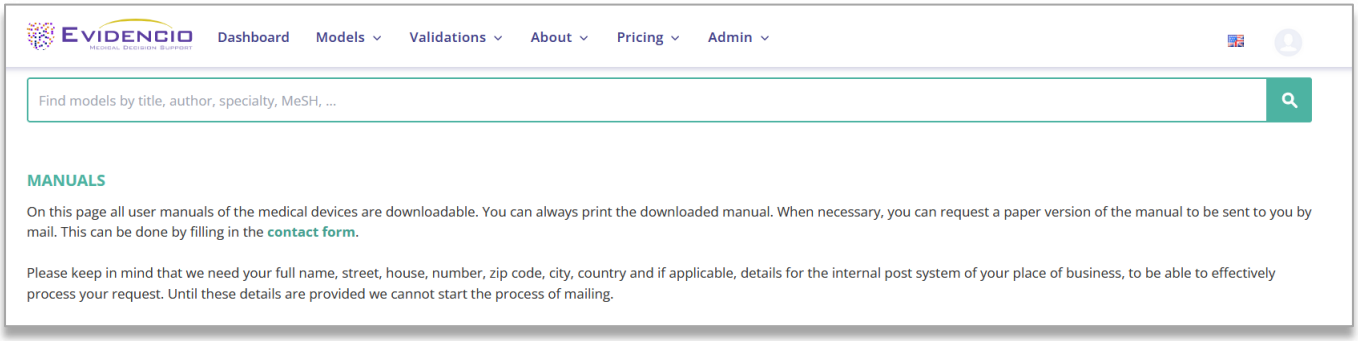


Figure 7. The user manual page for all user manuals.

L. Languages

Here an overview of languages in which the PIPRA is available is provided, any of which can be selected by clicking on the corresponding flag icon. The standard language on the Evidencio website is English. When other languages are available, these can be selected here.

Please note that, if a language is selected, only the user interface of the specific algorithm 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, 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 selection

If available, clicking on the Version tab allows the user to select a different version of the PIPRA for a list as displayed in **Figure 8** Error! Reference source not found.. Please note that the algorithm 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**.

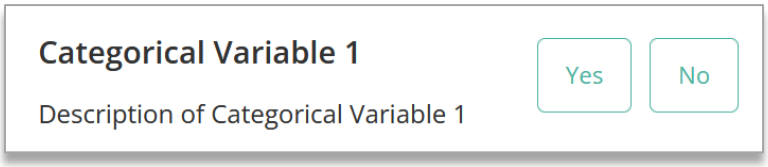


Figure 9. Example of a categorical variable, no button has been clicked and thus no input has been provided by the user.

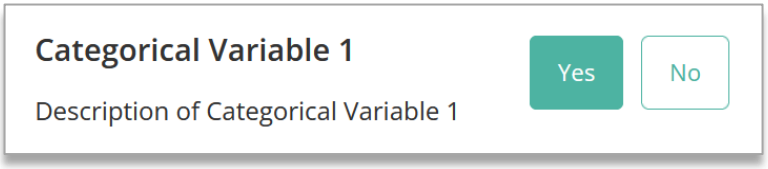


Figure 10. Example of a categorical variable, where the "Yes" button has been clicked.

Continuous variables

In the example shown in **Figure 11**, the **Continuous Variable 3**, exemplifies a continuous variable. The plausible ranges for which the algorithm 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**).

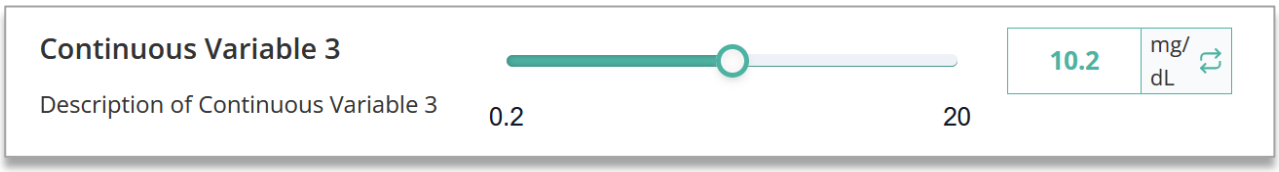


Figure 11. Example of a continuous variable, where "10.2 mg/dL" has been entered.

Unit conversion

Sometimes it is possible to use a 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.

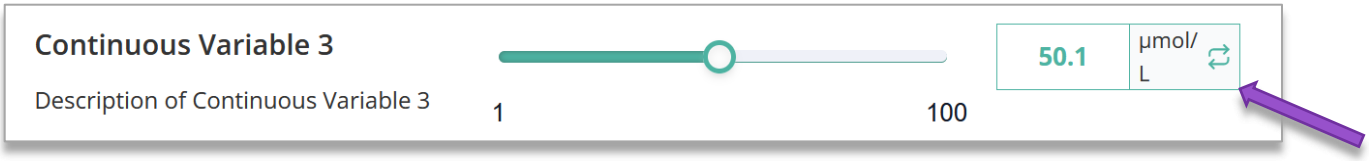


Figure 12. Example of a continuous variable where "50.1 $\mu mol/L$" has been entered.

Details on variable measurements

Directly underneath the name for each variable, additional details can be provided on, for example, 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 algorithm 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, and the user presses calculate, a result will be calculated. No result 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 stratification may be provided based on the calculated results. 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**.

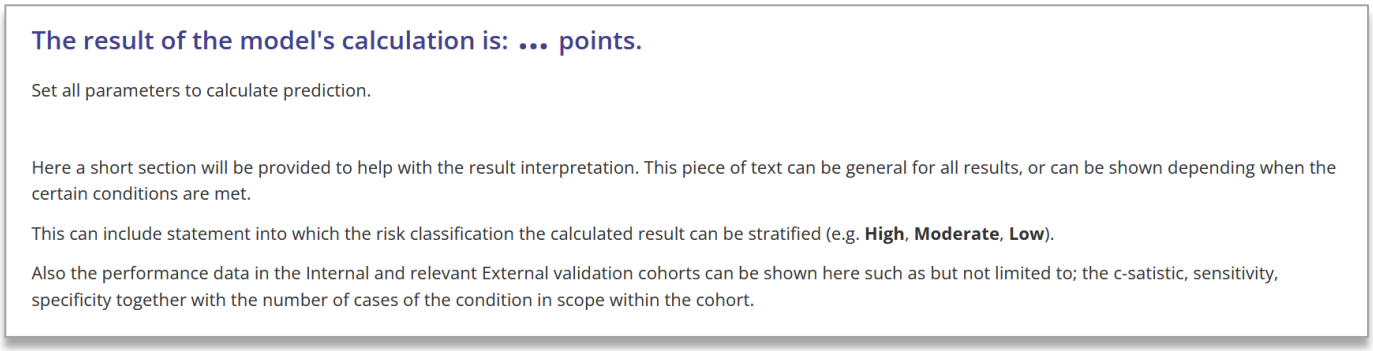


Figure 13. Example of the result display and information section.

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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