User manual for the PORTRET Tool

Version 1.0, January 2026, 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 PORTRET Tool. 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 certain CE-marked information, 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 healthcare professionals 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.
CE-marked tools may provide limited professional advice to the intended user(s). However, the intended user must exercise their clinical judgment as to the information these tools provide.

Evidencio does not assume any liability or responsibility for damage or injury (including death) to you, other persons, or property arising from any misuse of any product, information, idea, or instruction contained in the tools provided to you.

The disclaimer for non-CE-marked content is available on the Evidencio website: https://www.evidencio.com/disclaimer.

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 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, 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.

3.1. Notice to the user

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.

4. Device description PORTRET Tool

The PORTRET Tool is Medical Device Software (MDSW), that is hosted on the Evidencio platform. The PORTRET Tool is developed to support clinical decision making by informing clinical management on the estimated 5-year risks of mortality related to breast cancer, other-cause mortality, survival through adjuvant therapy, and survival without adjuvant therapy. The device combines Age, Tumour size, Tumour grade, Nodal status, ER/PR status, HER2 status, Ki-67 status, Mode of detection, Number of comorbidities, Polypharmacy, Difficulty walking, Dementia/ cognitive impairment, Sensory handicap to calculate the mortality and survival risks for elderly patients with breast cancer.

The MDSW's underlying mathematical formula is based on cause-specific Cox proportional hazard models. The treatment effects —used to calculate the expected adjuvant therapy benefits— were derived from the Early Breast Cancer Trialists' Collaborative Group (EBCTCG, 2005) and are fixed. The estimates of expected benefits of adjuvant therapies are calculated by combining the treatment effects with risk functions for all outcomes.

The calculation of the algorithm is performed by communication with the Evidencio platform, hosted at www.evidencio.com. The algorithm is also accessible by 3rd party applications through the API and iFrame implementation. The Evidencio platform is managed under Evidencio's certified quality management system that ensures the correctness of calculations and availability of its services.

4.1. Lifetime, residual risks and side effects

The PORTRET Tool 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 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 PORTRET Tool is a low-risk device, there are no noticeable risks involved outside of possible mis-estimation of patient 5-year risks of mortality related to breast cancer, other-cause mortality, survival through adjuvant therapy, and survival without adjuvant therapy, 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 PORTRET Tool does not have any direct side effects.

5. Electronic label

The electronic label of this device contains the following information:

CE 2797	**Name of the device**	PORTRET Tool
	Manufacturer information	Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands
LOT	**LOT number**	V-2.8-2917.26.01.28 V-2.9-2917.26.01.28
UDI	**UDI number**	(01)08720938015366(8012)v2.8(4326)260128(240)2917 (01)08720938015366(8012)v2.9(4326)260128(240)2917
MD	**MD indication**	Medical device

The electronic label can be found on the Evidencio website, see also section **I** and 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 indicates the algorithm version, the algorithm identifier, and the algorithm publication date. Publication date is indicated as YY.MM.DD.

5.2. UDI number

Stands for Unique Device Identifier (UDI) number, which is an international tool that helps users identify and find information on products. Evidencio's UDI's 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 use

The PORTRET tool is an algorithm intended to estimate the 5-year risks of mortality related to breast cancer, other-cause mortality, survival through adjuvant therapy, and survival without adjuvant therapy in elderly patients with early breast cancer, in order to support healthcare professionals with decisions surrounding treatment strategies.

The PORTRET Tool is not intended to replace clinical decision-making. The intended user, the healthcare professional, can use this information to support clinical decision-making regarding treatment of the patient. In practice, this typically entails the decision to undergo adjuvant treatment or not.

6.2. Clinical benefit

Correct functioning of the PORTRET Tool can result in the following clinical benefit:

- The PORTRET Tool provides accurate prognostic information regarding mortality related to breast cancer, mortality from a cause not related to breast cancer, survival without adjuvant therapy, and survival through adjuvant therapy, in older patients with breast cancer.

6.3. Indented target population and exclusion

The PORTRET Tool is intended to be used only for a specific group of patients, corresponding to the clinical indications and contra-indications mentioned below.

6.3.1. Clinical indications

- Women diagnosed with early breast cancer.
- Patients aged 65 years or older.

6.3.2. Clinical contra-indications

There are currently no known contra-indications.

6.4. Intended users

The intended users are healthcare professionals. Results shall always be reviewed and interpreted by healthcare professionals, 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. The MDSW can also be used through Evidencio's iFrame representation as an embedded view. 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.

7. Additional information

7.1. Details

Algorithm author	T.A. Hueting
Root algorithm ID	2917
Versions	2.8 PORTRET Tool 2.9 PORTRET API
Revision date	2026-01-29
Speciality	Oncology
Algorithm type	R-Script algorithm
MeSH terms	• No MeSH classifications added

7.2. Input variables

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

Table 1. Variables used as input for the PORTRET Tool.

Name	Description	Type	Range (step size) [units]	Prerequisite
Age	Age at the time of breast cancer diagnosis.	Continuous	65-105 (1) [Years]	N/A
Tumour size	Size of the tumour in millimetres. If there are multiple tumours, enter the size of the largest tumour.	Continuous	0-200 (1) [mm]	N/A
Tumour grade	Degree (or differentiation), as indicated in the pathology report.	Categorical	1 2 3	N/A
Nodal status	The presence of positive lymph nodes, as indicated in the pathology report.	Categorical	Negative Positive	N/A
ER/PR status	Positive if oestrogen and/or progesterone receptor positive with ≥10% positivity, as indicated in the pathology report.	Categorical	Negative Positive	N/A
HER2-status	Positive if HER2 is 2+ or 3+ on immunohistochemical examination, or negative if HER2 is 0-1.	Categorical	Negative Positive	N/A
Ki-67 status	Positive if Ki-67 is present immunohistochemically in ≥10% of tumour cells, or negative if Ki-67 is present in <10% of tumour cells.	Categorical	Negative Positive Unknown	N/A
Mode of detection	Breast cancer has been diagnosed after screening (for example, as part of population screening), or by presence of symptoms.	Categorical	By screening By symptoms	N/A
Number of comorbidities	All comorbidities with a potential impact on life expectancy are included in the count. These include comorbidities that require medication intake, or that, according to clinical judgment, may have an impact on the patient's life expectancy. To see the list of comorbidities, click on "Details" at the top right of the screen.	Continuous	0-20 (1)	N/A
Polypharmacy	Define as 'yes' if the patient takes 5 or more types of medication per day. Excluding over-the-counter drugs.	Categorical	No Yes	N/A
Difficulty walking	Define as 'yes' when the patient indicates difficulty walking, or when the patient uses a cane, walker or wheelchair.	Categorical	No Yes	N/A

Dementia/ cognitive impairment	Define as 'yes' if a diagnosis of dementia has been established, or if there is clinical evidence of cognitive decline.	Categorical	No Yes	N/A
Sensory handicap	Define as 'yes' if the patient uses a hearing aid, if there are hearing complaints and/or if there are vision complaints despite the use of glasses/lenses.	Categorical	No Yes	N/A
Variables in the result section				
Display results		Categorical	Bar chart Waffle chart Table Text	N/A
Hormone therapy	Hormone therapy, also called endocrine therapy, inhibits the growth of tumour cells stimulated by the hormone oestrogen. Some commonly used drugs include tamoxifen (Nolvadex, Istabul, Valodex and Soltamox) and aromatase inhibitors, such as anastrozole (Arimidex), exemestane (Aromasin) and letrozole (Femara).	Categorical	No Yes	ER/PR status: Positive
Chemotherapy	Chemotherapy uses drugs to weaken or eliminate cancer cells throughout the body. Combinations of drugs are often used to optimise effectiveness. The options in this web tool are the same as in the PREDICT tool: No chemotherapy Second generation (standard-dose, anthracycline-based chemotherapy regimens, such as FEC (fluorouracil, epirubicin and cyclophosphamide)) Third generation (High-dose, anthracycline- or taxane-based chemotherapy regimens containing taxanes, such as paclitaxel (Taxol) and docetaxel (Taxotere))	Categorical	No chemotherapy Second generation Third generation	N/A
Trastuzumab	Trastuzumab (Herceptin) specifically targets HER2-positive tumours.	Categorical	No Yes	HER2 status: Positive

7.3. Formula

The PORTRET Tool consists of a combination of cause-specific cox proportional hazard models. The two cause-specific models (cancer related mortality and other-cause mortality) are fitted based on data from the FOCUS cohort. The survival is estimated by taking the competing risks into account. The treatment effects, used to calculate the expected adjuvant therapy benefits, were derived from the Early Breast Cancer Trialists' Collaborative Group (EBCTCG, 2005) and are fixed. The estimates of expected benefits of adjuvant therapies are calculated by combining the treatment effects with risk functions for all outcomes.

7.4. Result interpretation

Primary outcome

The output of the PORTRET Tool consists of multiple different calculated risks, namely:

- Mortality from a cause not related to breast cancer
- Mortality related to breast cancer
- Survival without adjuvant therapy
- Survival through chemotherapy
- Survival through radiotherapy
- Survival through trastuzumab

The 5-year risks of mortality related to breast cancer, mortality from a cause not related to breast cancer, and survival without adjuvant therapy are provided. If selected, the survival predictions through chemotherapy, hormone therapy, and trastuzumab are given. The predictions are given in percentages with zero decimals.

For better visualisation the result can be displayed in a bar chart, waffle chart, table, or text (see **Figures 1- 4**).

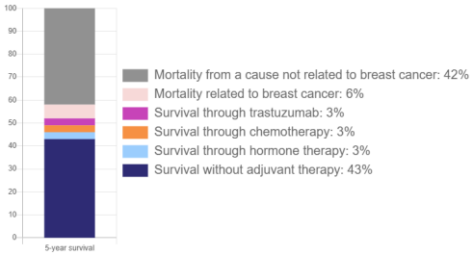

Figure 1. The results visualized in a bar chart

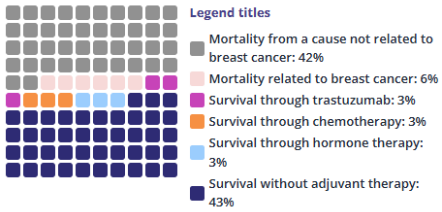

Figure 2. The results visualized in a waffle chart

	% Additional benefit as part of the treatment combination	% Survival for those following the treatment combination
Surgery only	-	43
+ Hormone therapy	3	46
+ Chemotherapy	3	49
+ Trastuzumab	3	52

Figure 3. The results visualized in a table

This view shows what we would expect for women who had surgery and then received the combination of treatments you selected, after 5 years.

Survival without adjuvant therapy: 43%
Survival through hormone therapy: 3%
Survival through chemotherapy: 3%
Survival through trastuzumab: 3%
Mortality related to breast cancer: 6%
Mortality from a cause not related to breast cancer: 42%

Figure 4. The result visualized as text

Conditional information

These results show what we would expect for 100 women who underwent surgery and then received your selected combination of treatments, after 5 years.

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.

7.5. Study characteristics

To develop the PORTRET Tool, 2744 female patients were included in the development cohort and 13631 female patients in the validation cohort. The median age was 74,8 years (range 65 - 98) in the development cohort and 76,0 years (70 - 101) in the validation cohort. The 5-year follow-up was complete for more than 99% of all patients. We observed 343 and 1462 recurrences, and 831 and 3594 deaths, of which 586 and 2565 were without recurrence, in the development and validation cohorts, respectively. The area under the receiver-operating-characteristic curve after 5 years in the external dataset was 0,76 (95% CI 0,75 - 0,76) for overall mortality, 0,76 (0,76 – 0,77) for recurrence, and 0,75 (0,74 – 0,75) for mortality from other causes.

Table 2. Patient characteristics

	Development cohort	Validation cohort	
Name	**Median (range)**	**Median (range)**	**Unit**
Age	74.8 (65-98)	76.0 (70-101)	Years
Tumour size	2.0 (1.4-3.0)	1.9 (1.3-2.6)	cm
Number of comorbidities	2.0 (0.0-3.0)	1.0 (0.0-2.0)	

Table 3. Categorical patient characteristics

	Development cohort		Validation cohort	
Name	**Subset / Group**	**Number of patients**	**Subset / Group**	**Number of patients**
TNM stage	I	1001	I	6043
	II	1346	II	5947
	III	281	III	1615
	Not known	116	Not known	26
Grade	I	383	I	3263
	II	1067	II	6479
	III	641	III	3438
	Not known	653	Not known	451
Nodal status	Negative	1685	Negative	9215
	Positive	956	Positive	4345
	Not known	103	Not known	71
ER/PR status	ER/PR negative	444	ER/PR negative	1886
	ER and/ or PR positive	1905	ER and/ or PR positive	11552
	Not known	395	Not known	193
HER2-status	Negative	1243	Negative	11109
	Positive	342	Positive	1201
	Not known	1159	Not known	1321
Ki-67 status	Negative	1359	Negative	NA
	Positive	127	Positive	NA
	Not known	1258	Not known	NA
Mode of action	Symptomatic	1461	Symptomatic	NA
	Screen-detected	704	Screen-detected	NA
	Not known	579	Not known	NA
Number of comorbidities	0-1	1329	0-1	4027
	2-4	1143	2-4	2473
	5 or more	272	5 or more	112
	Not known	0	Not known	7019
Sensory handicap	No	2222	No	NA
	Yes	522	Yes	NA
Difficulty walking	No	2464	No	NA
	Yes	280	Yes	NA
Dementia or cognitive impairment	No	2637	No	NA
	Yes	107	Yes	NA
Polypharmacy	No	2369	No	NA
	Yes	375	Yes	NA
Adjuvant chemotherapy	No	2599	No	13402
	Yes	145	Yes	229
Adjuvant endocrine therapy	No	1589	No	7168
	Yes	1155	Yes	6463
Adjuvant radiotherapy	No	1472	No	6982
	Yes	1272	Yes	6649

7.6. Supporting publication & Related files

Table 4 contains an overview of relevant papers. 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 the PORTRET tool to predict recurrence, overall survival, and other-cause mortality in older patients with breast cancer in the Netherlands: a population-based study** (2021) *van der Plas-Krijgsman WG, Giardiello D, Putter H, Steyerberg EW, Bastiaannet E, Stiggelbout AM, Mooijaart SP, Kroep JR, Portielje JEA, Liefers GJ, de Glas NA* DOI: 10.1016/S2666-7568(21)00229-4
Information on topic	**Effects of chemotherapy and hormonal therapy for early breast cancer on recurrence and 15-year survival: an overview of the randomised trials** *Early Breast Cancer Trialists' Collaborative Group (EBCTCG)* DOI: 10.1016/S0140-6736(05)66544-0

7.7. Release notes

The release notes for each publicly available version of the device can be found on the Evidencio website page for the PORTRET Tool: https://www.evidencio.com/models/show/2917, selecting the correct device (version), 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.

8. Implementation of the algorithm through an API

The PORTRET Tool can be used through Evidencio's API to allow for (automated) calculation of the 5-year risks of mortality related to breast cancer, other-cause mortality, survival through adjuvant therapy, and survival without adjuvant therapy.

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.

9. 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 four most commonly used internet browsers; Google Chrome (version 135.0.7049.115 and higher), Mozilla Firefox (version 137.0.2 and higher), Microsoft Edge (version 135.0.3179.98 and higher), and Apple Safari (version 18.4 and higher). The medical device cannot be used in combination with Internet Explorer.

The tool can also be accessed on mobile devices running the most recent versions of the Android (version 15 and higher) and iOS (version 18.4.1 and higher) operating systems.

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

The personal computers, laptops, tablets or smartphones used should at least be able to have an internet connection and use the browsers mentioned above.

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 algorithms 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 minimal screen 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 an algorithm are never immediately needed.

9.1. General algorithm landing page

An example of a medical device algorithm interface on the Evidencio platform is shown in **Figure 5**. The different sections indicated are explained in this chapter.

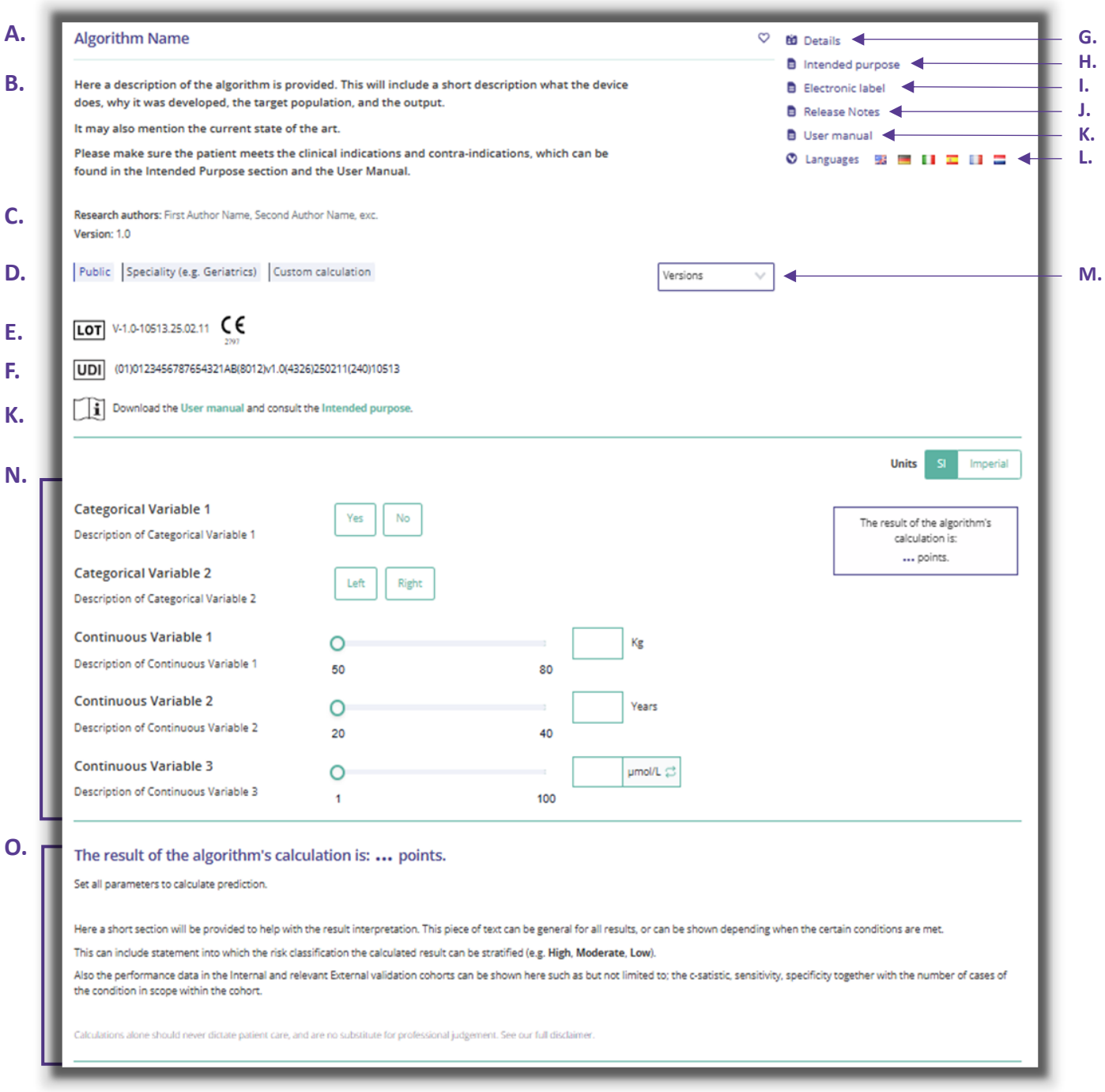

Figure 5. Example of an algorithm landing page on the Evidencio website.

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 algorithm type tags: “Composite algorithm”, “Sequential algorithm”, “API algorithm”. Evidencio has the following calculation method tags: “Linear regression”, “Logistic regression”, “Cox regression”, “RScript” and “Custom calculation”. 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 Number

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

G. Details button

On the top right of the algorithm 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 6**. 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.

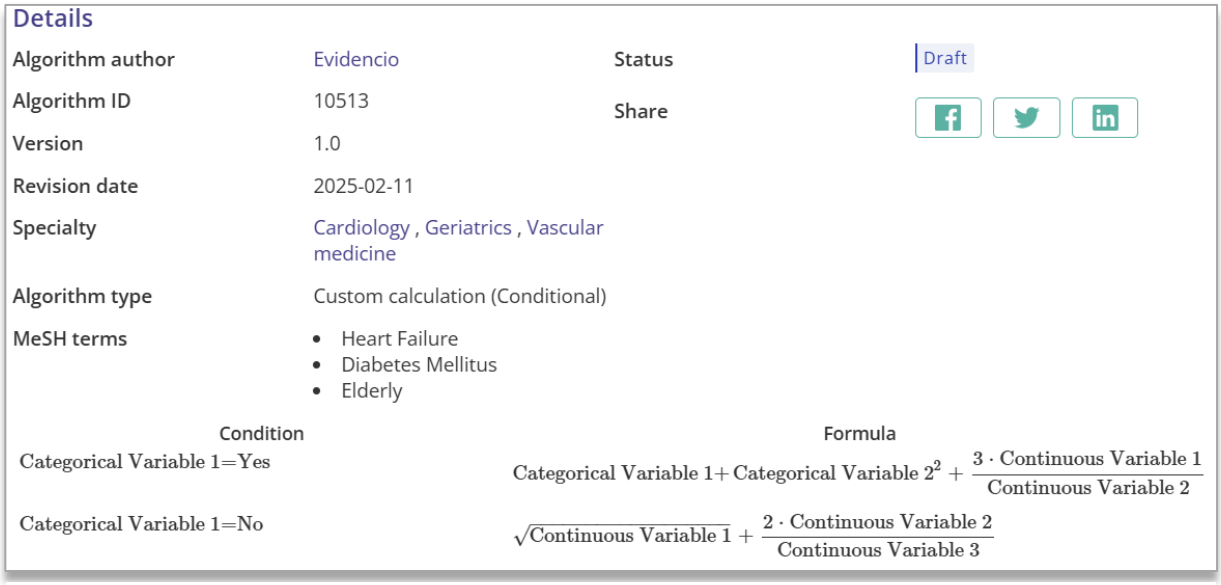

Figure 6. Example of first part of Details section

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 7**.

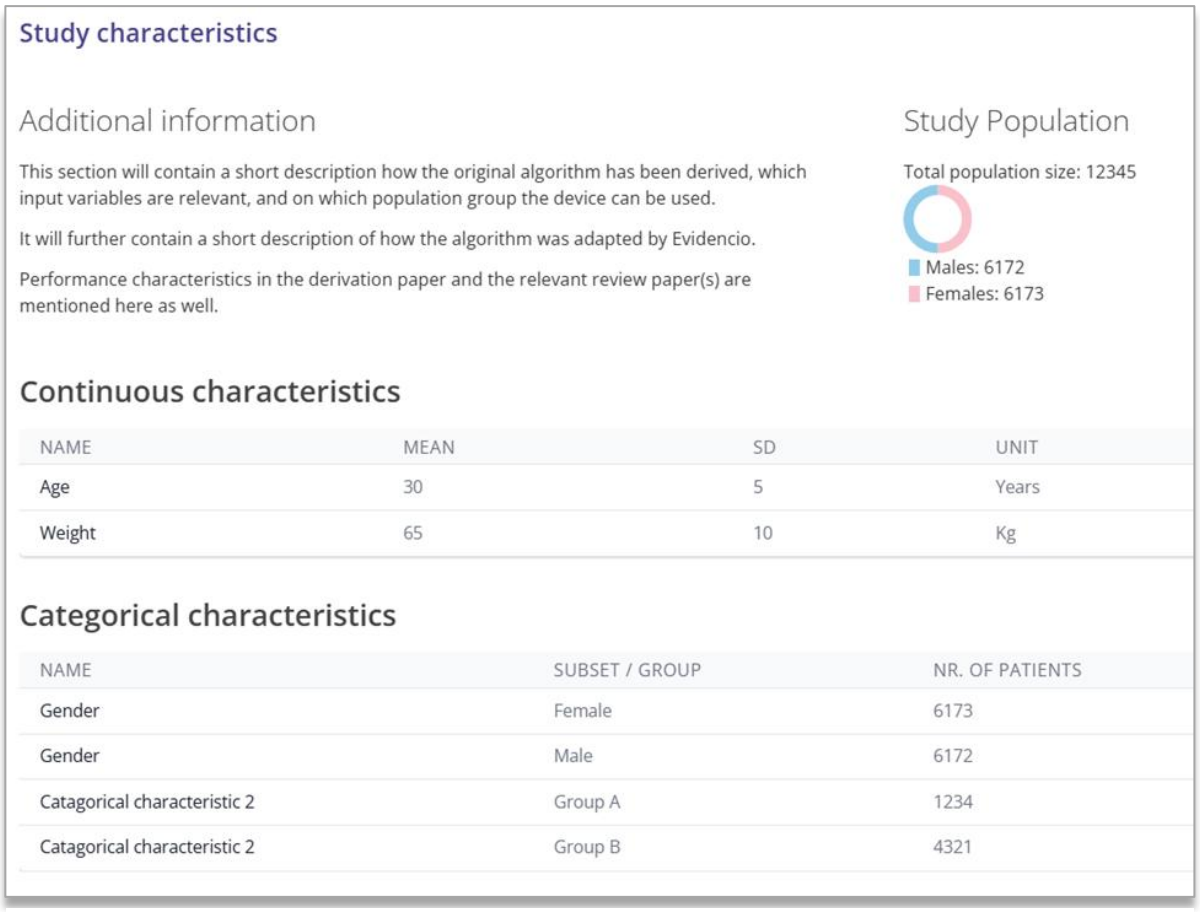

Figure 7. Example of the study characteristics section under the Details tab.

Supporting publications & Related files

An important part of the Study characteristics is the information on Supporting publications and related files. The list of related files and relevant tags can also be found in **Paragraph 7.6**. These sections can be found at the bottom of the Details-pop-up as shown in **Figure 8**.

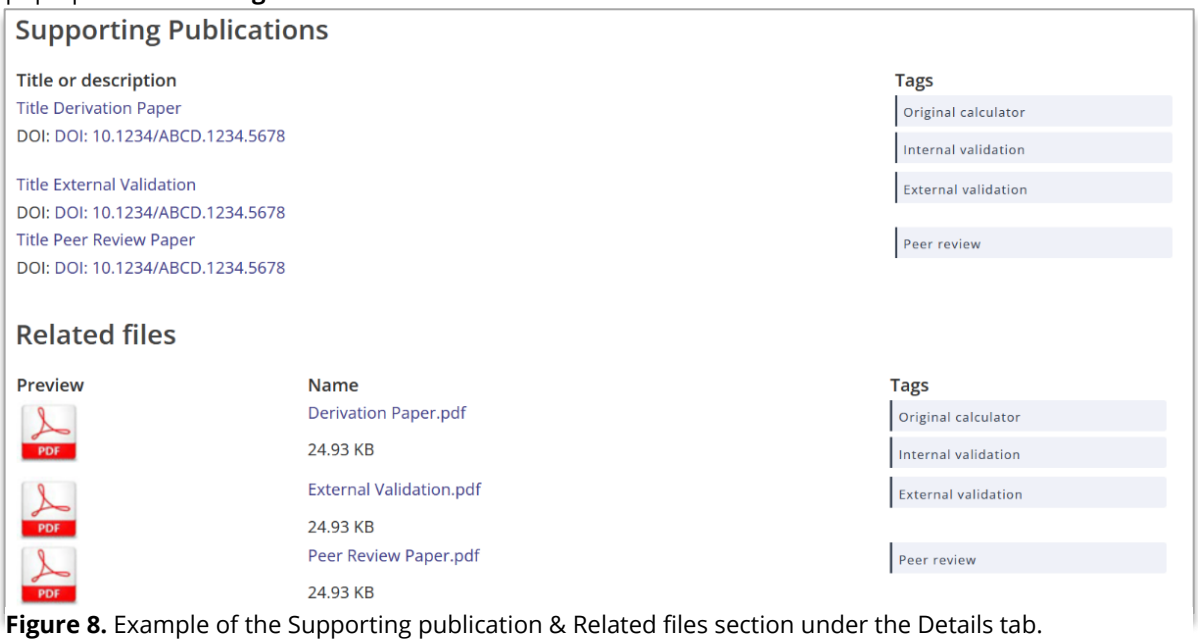

Figure 8. Example of the Supporting publication & Related files section under the Details tab.

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 9**.

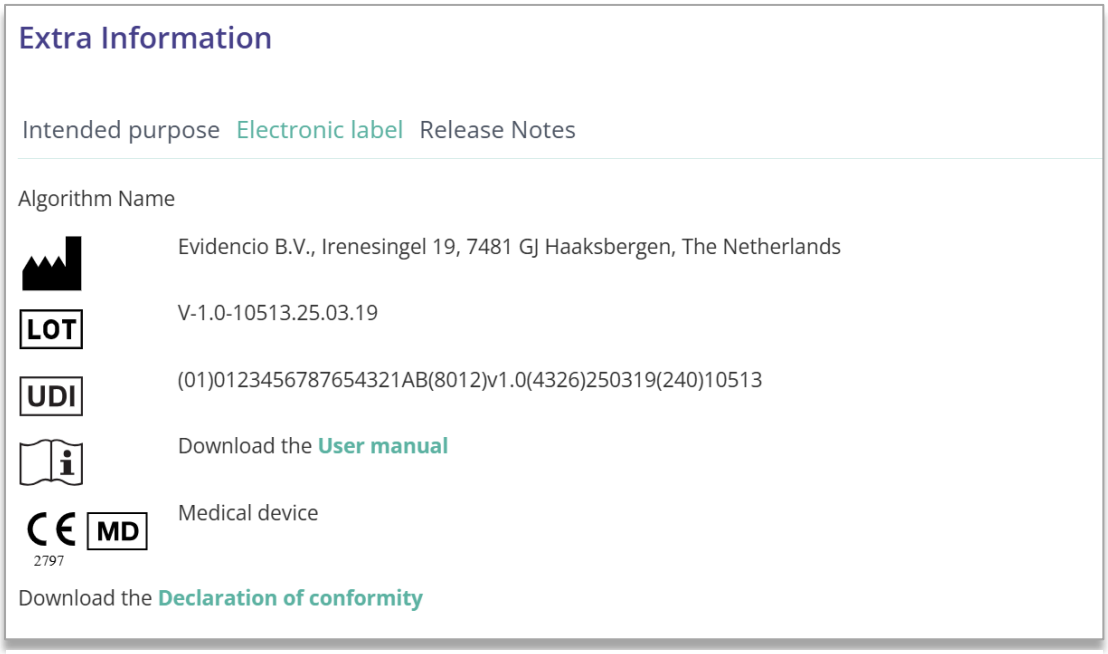

Figure 9. Example of an electronic label under the Electronic Label tab.

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 page, 2) on the right of the algorithm 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 10**. The user manual page is shown in **Figure 11.** 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.

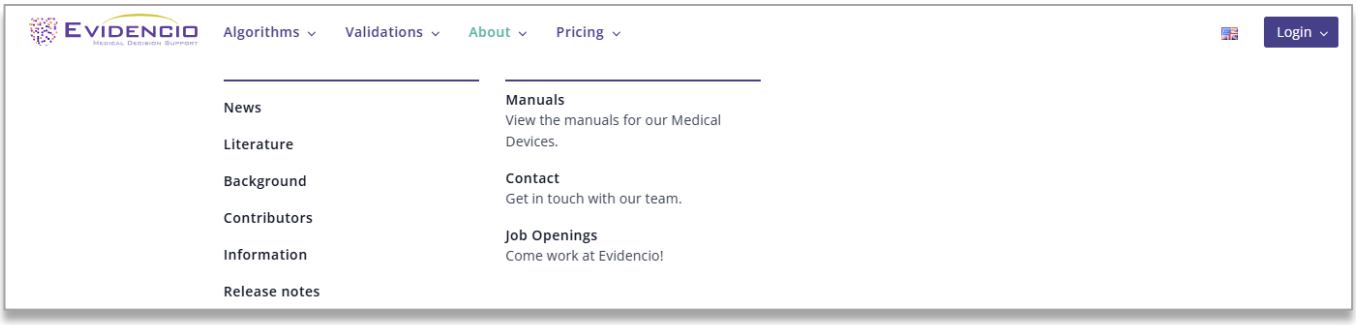

Figure 10. The drop-down menu where the user manual page can be found.

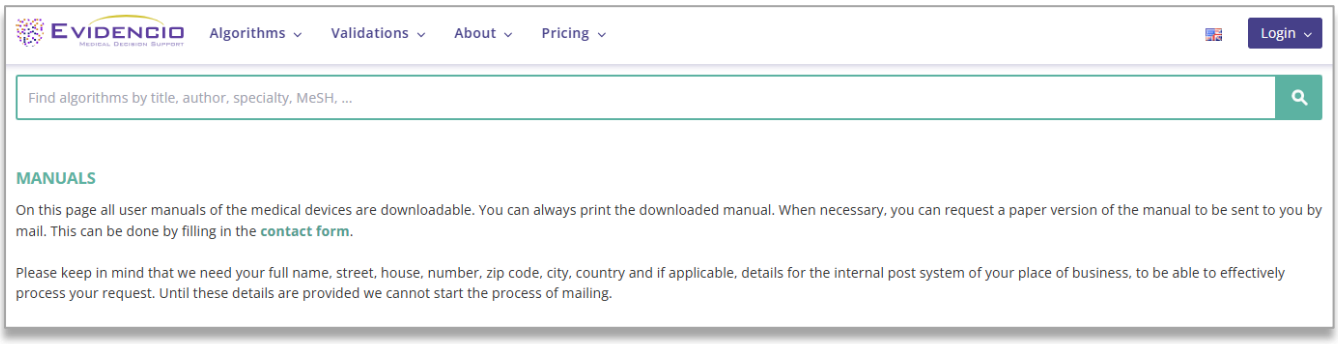

Figure 11. The user manual page for all user manuals.

L. Languages

Here an overview of languages in which the PORTRET Tool 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.

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 PORTRET Tool from a list as displayed in **Figure 12**. Please note that the algorithm currently selected is not presented in the dropdown menu.

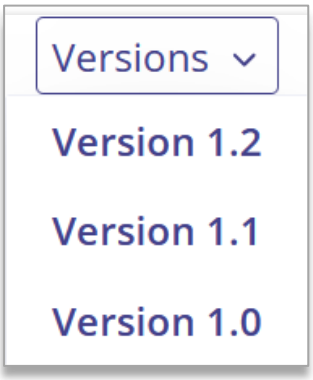

Figure 12. Example of version selection tab.

N. Input section

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

Categorical variables

In the example shown in **Figure 13** and **Figure 14,** 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 14.**

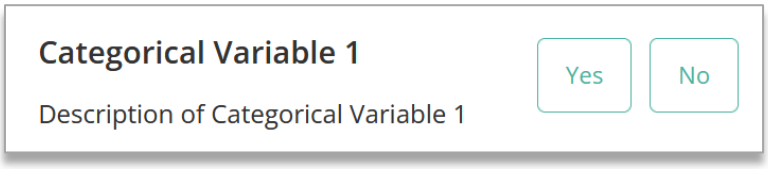

Figure 13. Example of a categorical variable, no button has been clicked and thus no input has been provided by the user.

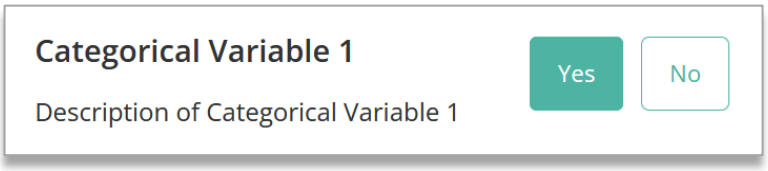

Figure 14. Example of a categorical variable, where the "Yes" button has been clicked.

Continuous variables

In the example shown in **Figure 15**, 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**).

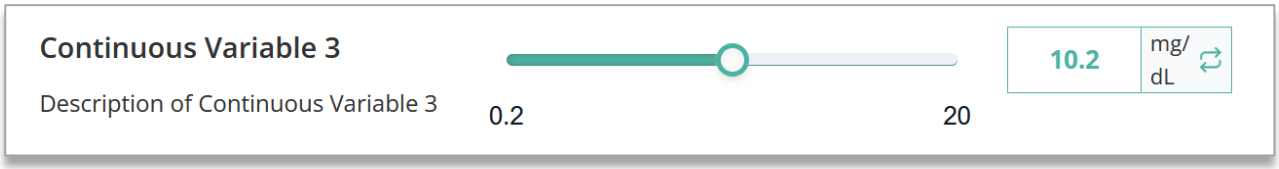

Figure 15. Example of a continuous variable, where "10.2 mg/dL" has been entered.

Unit conversion

Sometimes it is possible to use a unit conversion, by clicking on the unit when the green arrows are present. See **Figure 16** below where the unit has been clicked and switched.

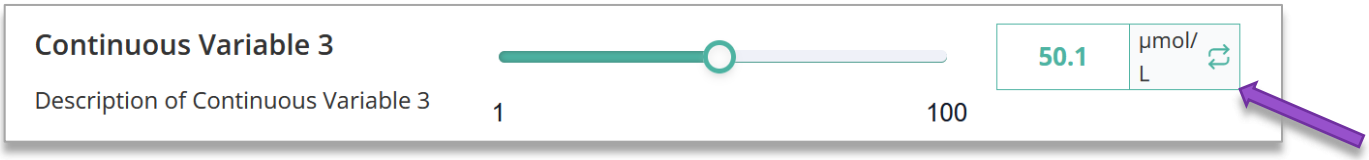

Figure 16. Example of a continuous variable where "50.1 $\mu mol/L$" has been entered.

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 (cut-off values).

O. Result section

At the bottom of the algorithm landing 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 can 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. **Chapter 7.4** shows examples of the different result visualization options.

10. User manual revision history

Version	Revision notes
V1.0 JAN-2026	Original version

11. Manufacturer details

Contact details of Evidencio:

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