User manual
for the
Wells' Criteria for Pulmonary Embolism (PE)

Version 3.0, August 2025, 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 Wells' Criteria for Pulmonary Embolism (PE). 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, 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.
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 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.

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 Wells' Criteria for Pulmonary Embolism (PE)

The Wells' Criteria for Pulmonary Embolism (PE) is intended to objectively assess the pretest probability of Pulmonary Embolism (PE) in patients with suspected PE. The physician can then choose what further testing is required for the diagnosis or exclusion of pulmonary embolism. The algorithm consists of a point score. The Wells' Criteria for PE are currently the State of the Art regarding patients with a suspicion of pulmonary embolism.

The Wells' Criteria for PE can be used with either 3 tiers (low, moderate, high) or 2 tiers (unlikely, likely), which are both endorsed by multiple guidelines.

It risk stratifies patients for pulmonary embolism (PE), and has been validated in both inpatient and emergency department settings. There must first be a clinical suspicion for PE in the patient (the criteria should not be applied to all patients with chest pain or shortness of breath, for example).

It is not meant to diagnose PE but to guide workup by predicting pre-test probability of PE and appropriate testing to rule out the diagnosis.

Its score is often used in conjunction with d-dimer testing to evaluate for PE. **The criteria should not be determined after the results of a d-dimer assay are known.**

4.1. Lifetime, residual risks and side effects

The Wells' Criteria for Pulmonary Embolism (PE) 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 Wells' Criteria for Pulmonary Embolism (PE) is a low-risk device, there are no noticeable risks involved outside of possible mis-estimation of patient risk, 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 Wells' Criteria for Pulmonary Embolism (PE) does not have any direct side effects relevant for the patient.

5. Electronic label

The electronic label of this device contains the following information:

CE 2797	**Name of the device**	Wells' Criteria for Pulmonary Embolism (PE)
	**Manufacturer information**	Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands
LOT	**LOT number**	V-1.5-154.25.08.20
UDI	**UDI number**	(01)08720938015328(8012)v1.5(4326)250820(240)154
MD	**MD indication**	Medical device

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 number

Stands for Unique Device Identifier Production Identifier (UDI) number is an international tool that helps users identify and find information on products. Evidencio's UDIs 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 Wells' Criteria for PE is intended to be used for patients with suspected PE after a clinical history check and physical examination as a pre-test prediction algorithm.

The Wells' Criteria for PE combines showing clinical signs and symptoms of DVT, whether PE is the most likely diagnosis (or equally likely), heart rate, recent immobilization or surgery, a previous, objectively diagnosed PE or DVT, suffering from hemoptysis and a recent malignancy or being palliative to provide an estimate on the probability of pulmonary embolism in patients with suspected PE.

The result of the Wells' Criteria for PE is intended to be reviewed and interpreted by qualified medical specialists who are capable of operating the device and interpreting its results only. The device is not intended for use by patients on their own.

The Wells' Criteria for PE is not intended to replace clinical decision-making, it can only provide information to the user on the estimation of the probability of a PE. In practice, it is encouraged to perform a D-dimer assay, and/or the Pulmonary Embolism Rule-out Criteria (PERC rule) after the Wells' Criteria for PE. The user can use this information to support clinical decision-making regarding diagnosis of the patient. This typically entails the decision to rule-out the risk of PE or to continue with other diagnostics to confirm or rule-out PE.

6.1.1. Additional remarks on the intended use

As mentioned above, the Wells' Criteria for PE is usually discussed in the context of being a pre-test prediction algorithm prior to a D-dimer assay, and/or a subsequent PERC rule. The guidelines that were identified in a preliminary literature search all mentioned the Wells' Criteria for PE alongside a D-dimer assay.

Moreover, the Wells' Criteria for PE, as discussed in the original development paper from Wells *et al*. (2000), uses both a two-tier and three-tier result interpretation, i.e. "PE unlikely" or "PE likely", and "low", "moderate" and "high risk", the latter accompanied by a risk percentage. There is no consensus on which is preferred. Both the two- and three-tier systems are recommended in different guidelines, with the majority of them including both systems.

6.2. Clinical benefit

In accordance with its intended use, correct functioning of the Wells' Criteria for PE can result in these clinical benefits:

- The Wells' Criteria for PE can be used to accurately estimate the pre-test probability of PE.
- The Wells' Criteria for PE can assist in pre-test risk assessment for PE in patients with suspected PE to help optimize further testing decisions.
- Pre-test risk assessment can reduce the burden of unnecessary (invasive, costly or time-intensive) imaging procedures such as CTPA in patients at low risk of PE, freeing up these (scarce) resources for patients at high risk.
- Use of an online calculator reduces the number of errors made in the calculation of the result for the Wells' Criteria for PE algorithm
- Digital implementation of the algorithm underlying the Wells' Criteria for PE as a medical device can improve the speed and reliability of calculation.

6.3. Indented target population and exclusion

The Wells' Criteria for PE should be used for patients who are suspected of a PE after a physician has performed a clinical history check and physical examination. Furthermore, it is intended for patients who have not received a D-dimer assay assessment or other imaging procedures (yet).

6.3.1. Clinical indications

The Wells' Criteria for PE should be used for patients who meet the following inclusion criteria:

- The Wells' Criteria for PE is intended for patients who, after receiving a clinical history check and physical examination by a physician, are suspected of a PE.
- Patients should be 18 years or older.

6.3.2. Clinical contra-indications

The Wells' Criteria for PE should not be used for patients who meet the following exclusion criteria:

- The criteria should not be used for patients with chest pain, shortness of breath, or leg pain or swelling without the suspicion of having a PE.
- Patients for whom the result of a D-dimer assay is already known to the physician, since the D-dimer assay results may influence the subjective component of the Wells' Criteria, and thus their result.
- Patients hospitalized with trauma.

In certain populations (e.g. the elderly, pregnant patients, patients with renal insufficiency) the Wells' Criteria for PE is able to estimate pretest probability, but D-dimer level testing is unreliable and/or CTPA is advised against. While D-dimer assays are not a part of the Wells' Criteria for PE, most guidelines rely on the combination of a reliable result of both. Clinical decision support according to guidelines, i.e. based on the combination of the Wells' Criteria for PE and a D-dimer test, may be hampered in these patients.

6.4. User profile

The Wells' Criteria for PE is intended for physicians and qualified medical personnel in a clinical setting. It should not be used by patients alone. Health care professionals do not require additional training prior to the use of the medical device.

The Wells' Criteria for PE is intended to be used in two ways; by healthcare professionals using the algorithm interface on the Evidencio website or an image of the algorithm hosted by a distributor, or by using an automatic calculation through Evidencio's API. Results shall always be reviewed and interpreted by qualified healthcare professionals 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. 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 original version of the Wells' Criteria for PE was developed in 2000 by Wells *et al*. and is the version concerned in this document.

7. Result interpretation

The primary output of this device is given as a point score. Furthermore, information for interpretation is given within the conditional information, including the risk category and an associated pooled prevalence within that risk group. Extra information for the interpretation of the result is also presented on the platform. This information can be found in **section 4** of this document.

Conditional information

Table 1. Conditional information for the Wells' Criteria for PE

Condition	Conditional Information
Result < 2	According to the three-tier categorization system of Wells *et al.*, **a point score of <2 is considered low risk.** A 2010 meta-analysis by Ceriani *et al.* found **a pooled prevalence of 5.7% PE** on average in this category.
2 ≤ Result ≤ 6	According to the three-tier categorization system of Wells *et al.*, **a point score of ≥ 2 and ≤ 6 is considered as moderate risk.** A 2010 meta-analysis by Ceriani *et al.* found **a pooled prevalence of 23.2% PE** on average in this category.
Result > 6	According to the three-tier categorization system of Wells *et al.*, **a point score of > 6 is considered high risk.** A 2010 meta-analysis by Ceriani *et al.* found **a pooled prevalence of 49.3% PE** on average in this category.
Result ≤ 4	According to the two-tier categorization system of Wells *et al.*, **a point score of ≤ 4 is considered as 'PE Unlikely'.** A 2010 meta-analysis by Ceriani *et al.* found **a pooled prevalence of 8.4% PE** on average in this category.
Result > 4	According to the two-tier categorization system of Wells *et al.*, **a point score of > 4 is considered as 'PE Likely'.** A 2010 meta-analysis by Ceriani *et al.* found **a pooled prevalence of 34.4% PE** on average in this category.

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

Algorithm author	Evidencio
Root algorithm ID	154
Version	1.5
Revision date	2025-08-20
Speciality	Pulmonology
Algorithm type	Linear regression
MeSH terms	• Pulmonary Embolism

8.2. Input variables

To perform the calculations successfully, the Wells' Criteria for Pulmonary Embolism (PE) requires the input variables as listed in **Table 2**.

Table 2. Variables used as input for the Wells' Criteria for Pulmonary Embolism (PE).

Name	Description	Type	Options (points)
Clinical signs & symptoms of DVT	Whether the patient exhibits clinical signs and symptoms of DVT.	Categorical	No (0) Yes (+3)
PE is the most likely diagnosis (or equally likely)	Whether PE is considered the number one most likely diagnosis, or equally likely as another diagnosis that is also considered the most likely.	Categorical	No (0) Yes +(3)
Heart rate > 100 beats/min	Whether the patient suffers from tachycardia, i.e. a heart rate above 100 beats per minute.	Categorical	No (0) Yes (+1.5)
Recent immobilization or surgery	Whether the patient was immobilized at least 3 days, or had surgery in the last 4 weeks.	Categorical	No (0) Yes (+1.5)
Previously diagnosed PE or DVT	Whether the patient suffered a previous, objectively diagnosed PE or DVT.	Categorical	No (0) Yes (+1.5)
Hemoptysis	Whether the patient exhibits hemoptysis, i.e. coughing up blood.	Categorical	No (0) Yes (+1)
Malignancy	Whether the patient has a malignancy for which the patients had treatment within the last 6 months, or is palliative.	Categorical	No (0) Yes (+1)

8.3. Study characteristics

Wells *et al*. developed a prediction tool in 1998 to identify patients for whom PE can be safely excluded without the need of diagnostic techniques.

However, the 1998 tool was quite complex and required extensive screening methods, limiting its clinical utility. They developed an easier to use prediction tool in 2000, i.e. the Wells' Criteria for Pulmonary Embolism (PE). The intent of the Wells' Criteria was to use this tool together with a D-dimer assay with the intention that of the patients categorized as 'PE unlikely' and with a negative D-dimer assay, that only around 2% would still present PE. This is the equation presented here.

As such, they performed a logistic regression analysis including 40 clinical variables, which led to the Wells' Criteria for PE, which comprises the seven most relevant variables from the analysis. These variables do not comprise any lab values. As such, a D-dimer assay is often used in conjunction with the criteria. They used both a two-tier (i.e. PE unlikely and PE likely) and three-tier (low, moderate and high risk) risk categorization. The target population included over 1,200 consecutive inpatients and outpatients with suspected PE.

In 2001, Wells *et al*. validated the Wells' Criteria for PE in an emergency department with patients with suspected PE to determine the safety of the tool for managing the patients when combined with D-dimer assay results.

Since then, the Wells' Criteria for PE has been validated and evaluated in meta-analysis multiple times. Moreover, it is also adopted in multiple clinical guidelines as part of the state of the art.

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

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

Name	Subset / Group	Number of patients
Previous deep-vein thrombosis or PE	Yes	160
Normal perfusion scans	Yes	354
Nonhigh probability	Yes	737
High probability of VQ scans	Yes	169
Events in the three-month follow-up	Normal perfusion scan group	4
Events in the three-month follow-up	Nonhigh probability VQ scan group	64
Events in the three-month follow-up	High probability VQ scan group	154

8.4. Supporting publication & Related files

Several relevant studies, such as the original derivation study by Wells *et al*. (2000) 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 study Original calculator Risk factors	**Derivation of a Simple Clinical Model to Categorize Patients Probability of Pulmonary Embolism: Increasing the Models Utility with the SimpliRED D-dimer** (2000) *Philip S. Wells, David R. Anderson, Marc Rodger, Jeffrey S. Ginsberg, Clive Kearon, Michael Gent, Alexander G.G. Turpie, Janis Bormanis, Jeffrey Weitz, Michael Chamberlain, Dennis Bowie, David Barnes, Jack Hirsh* DOI: 10.1055/s-0037-1613830
External validation	**Excluding pulmonary embolism at the bedside without diagnostic imaging: management of patients with suspected pulmonary embolism presenting to the emergency department by using a simple clinical model and d-dimer** (2001) *P S Wells, D R Anderson, M Rodger, I Stiell, J F Dreyer, D Barnes, M Forgie, G Kovacs, J Ward, M J Kovacs* DOI: 10.7326/0003-4819-135-2-200107170-00010
Systematic review and meta-analysis	**Clinical prediction rules for pulmonary embolism: a systematic review and meta-analysis** (2010) *Ceriani E, Combescure C, Le Gal G, Nendaz M, Perneger T, Bounameaux H, Perrier A, Righini M.* DOI: 10.1111/j.1538-7836.2010.03801.x

8.5. Release notes

If available, the release notes for each publicly available version of the device can be found on the Evidencio website page for the Wells' Criteria for Pulmonary Embolism (PE): https://www.evidencio.com/models/show/154?v=1.5, 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 Wells' Criteria for Pulmonary Embolism (PE) can be used through Evidencio's API to allow for (automated) calculation of the Wells' Score, which is an indicator of the risk for pulmonary embolism. 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 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.

10.1. General algorithm landing page

An example of a medical device algorithm interface on the Evidencio platform is shown in **Figure 1.** The different sections indicated are explained in this chapter.

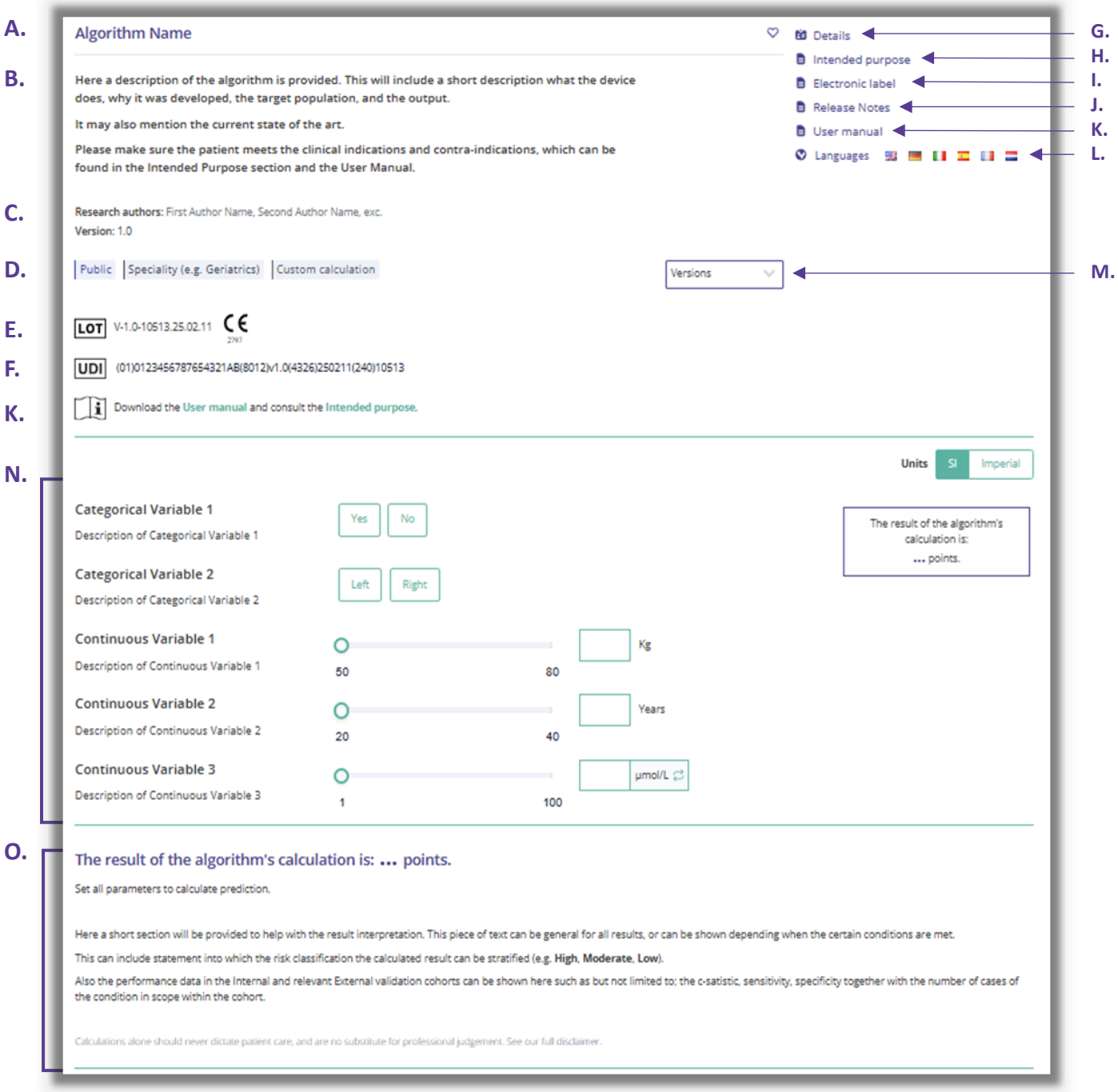

Figure 1. Example of an algorithm landing page on the Evidencio website.

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 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.

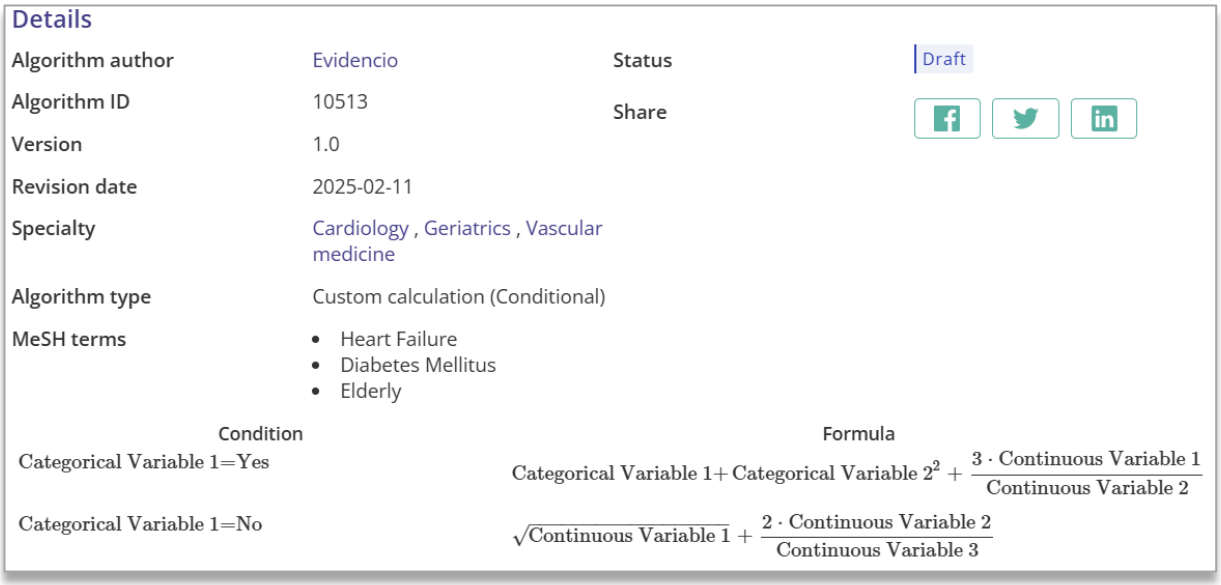

Figure 2. Example of first part of detail section.

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**.

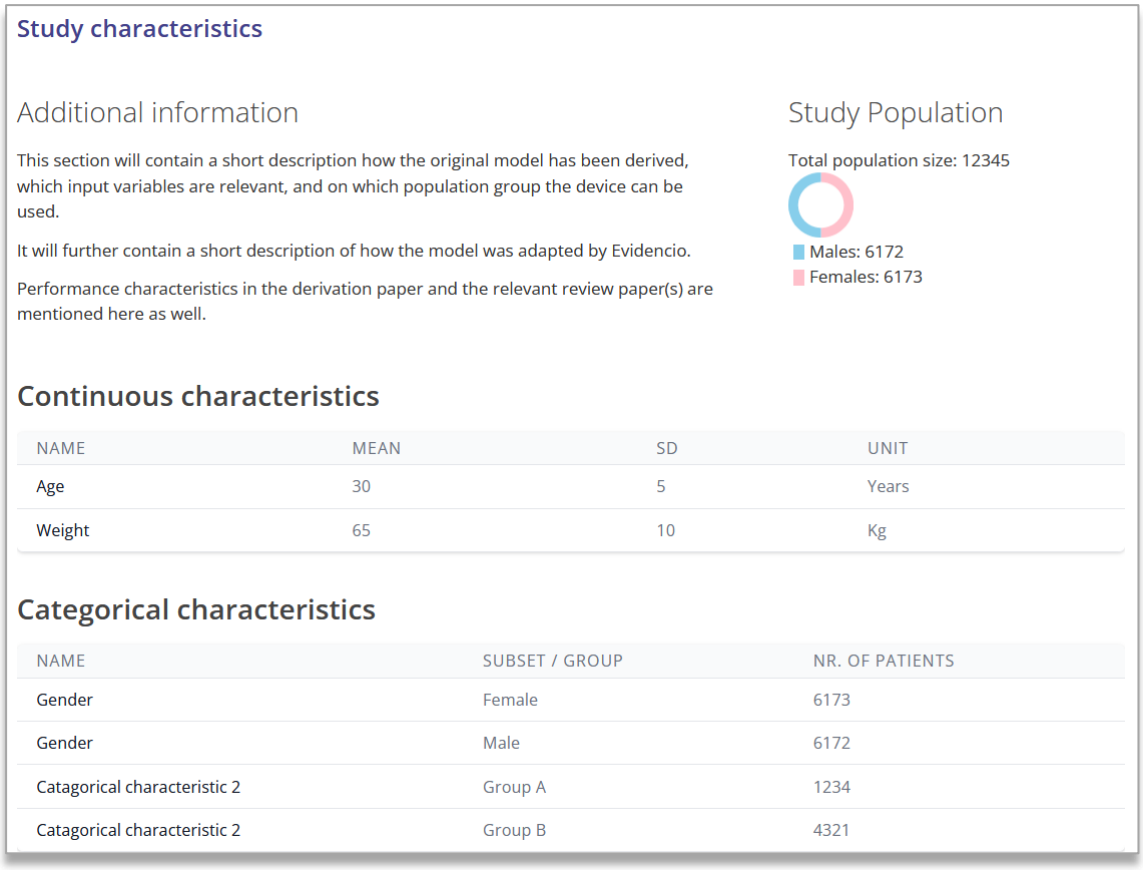

Figure 3. Example of the study characteristics section under the Details tab.

Supporting publications & Related files

An important part of the Study characteristics is the information on Supporting publications and related files. The list of related files and relevant tags can also be found in **Paragraph 8.4.** These sections can be found at the bottom of the Details-pop-up as shown in **Figure 4**.

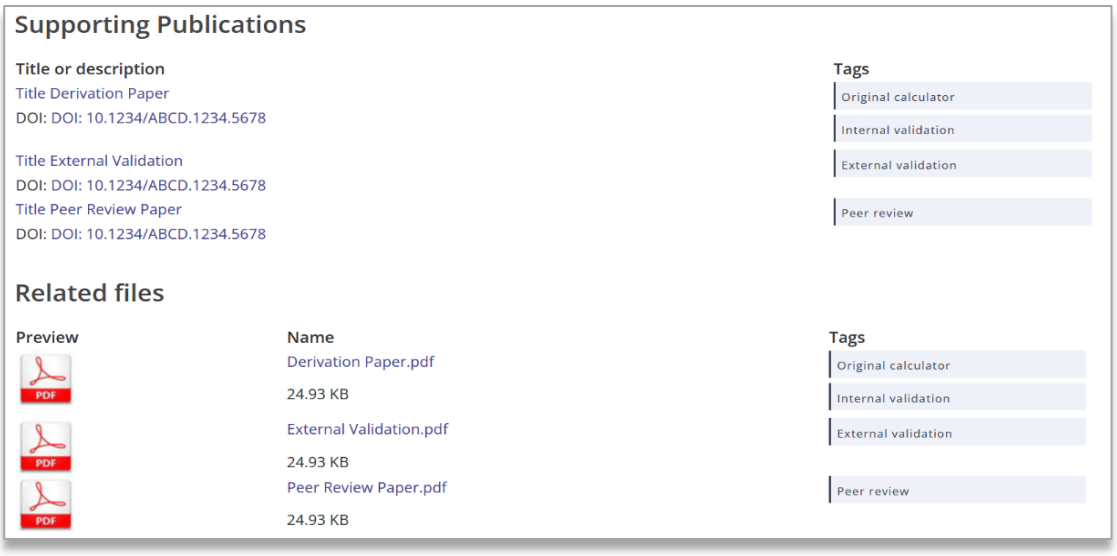

Figure 4. Example of the Supporting publication & Related files section under the Details tab.

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 6**.

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**.

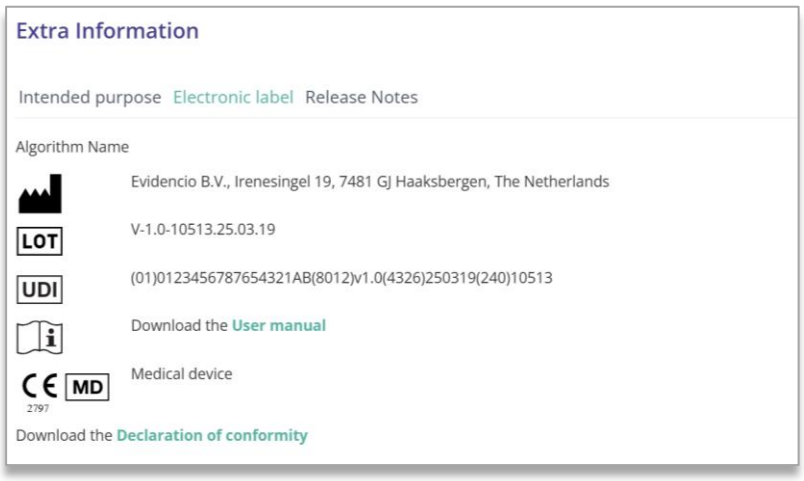

Figure 5. Example of an electronic label under the Electronic Label tab.

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 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 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 12** of this user manual.

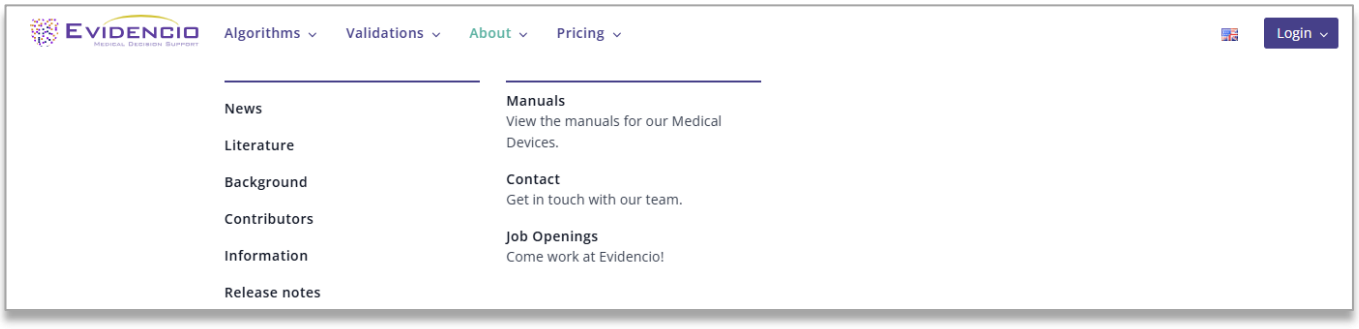

Figure 6. The drop-down menu where the user manual page can be found.

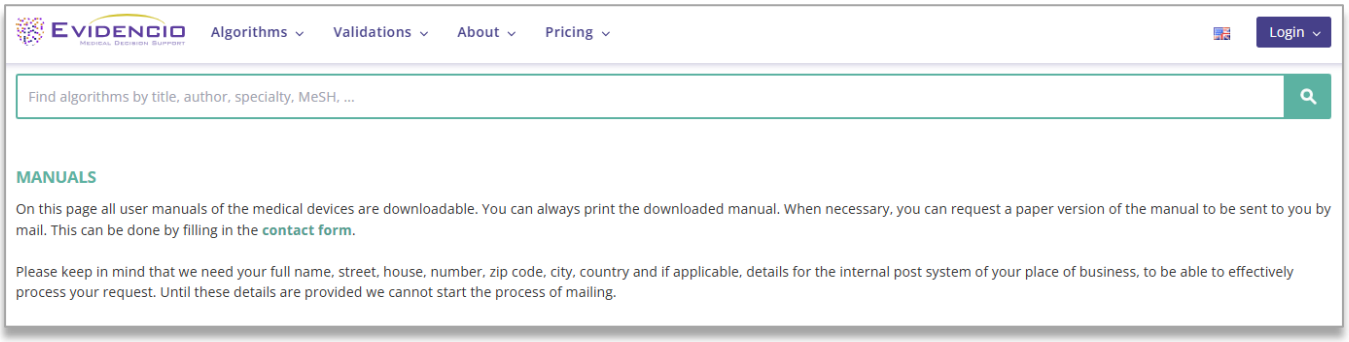

Figure 7. The user manual page for all user manuals.

L. Languages

Here an overview of languages in which the Wells' Criteria for Pulmonary Embolism (PE) 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 Wells' Criteria for Pulmonary Embolism (PE) from a list as displayed in **Figure 8**. 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**.

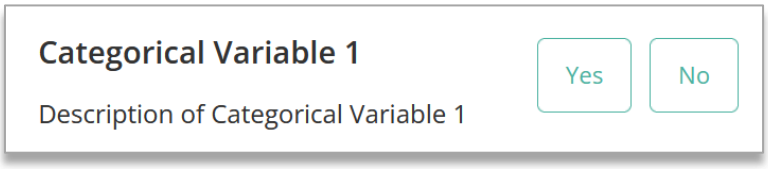

Figure 9. Example of a categorical variable, no button has been clicked and thus no input has been provided by the user.

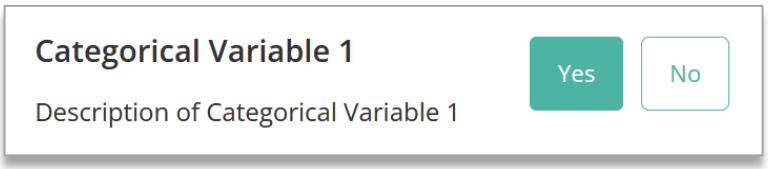

Figure 10. Example of a categorical variable, where the "Yes" button has been clicked.

Continuous variables

In the example shown **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**).

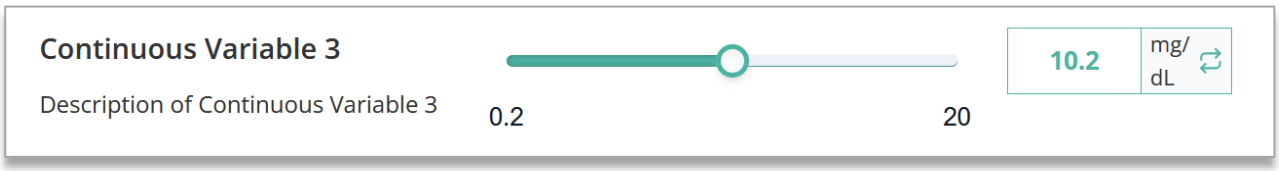

Figure 11. Example of a continuous variable, where "10.2 mg/dL" has been entered.

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.

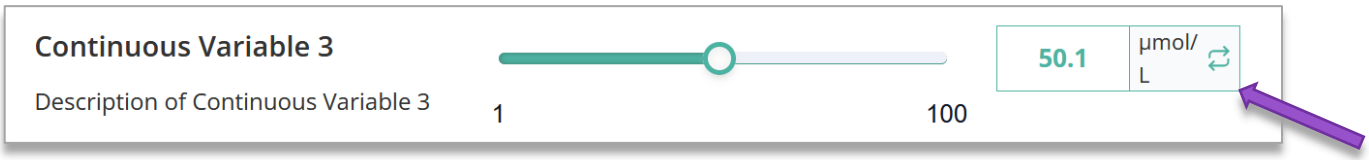

Figure 12. Example of a continuous variable where "50.1 $\mu mol/L$" has been entered.

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**.

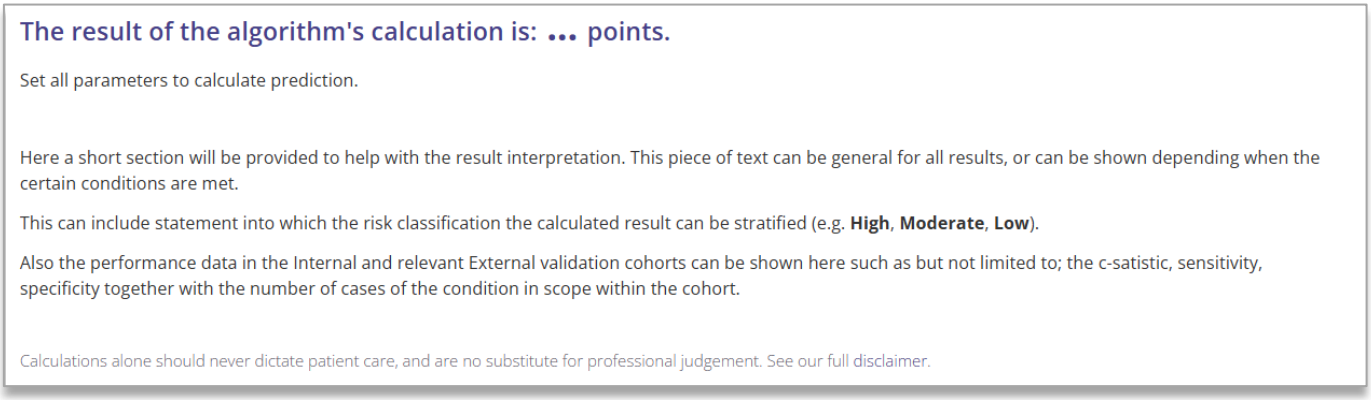

Figure 13. Example of the result display and information section.

11. User manual revision history

Version	Revision notes
V1.0 FEB-2025	Original version
V2.0 JUL-2025	Replaced 'model' with 'algorithm'.
V3.0 AUG-2025	Minor updates.

12. Manufacturer details

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