User manual for the Lille Model

Version 2, March 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 Lille Model. 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.

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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 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 Lille Model

The Lille Model as provided by Evidencio allows for the calculation of the probability of 6-month mortality and likelihood of corticosteroid response in patients with severe Alcoholic Hepatitis treated with corticosteroids. For this use, the Lille Model can be regarded as the state of the art. The algorithm is able to improve risk stratification of patients into complete, partial and null responders to corticosteroid to classify the patient's response to corticosteroid treatment.

Using the Lille Model is recommended by multiple clinical guidelines, often at day 7 of treatment, especially in combination with algorithms identifying severe alcoholic hepatitis such as the Model for end-stage liver disease (MELD) Score, which are often consulted earlier during treatment.

The Lille Model is an algorithm intended to use Age, Albumin, Bilirubin at day 0, Bilirubin at day 7, renal insufficiency status, and Prothrombin time or INR to estimate the mortality and corticosteroid response in patients with severe Alcoholic Hepatitis in order to support healthcare professionals with decisions surrounding patients with severe Alcoholic Hepatitis. It is intended for patients with a clinical diagnosis of severe Alcoholic Hepatitis who are undergoing Corticosteroid therapy for seven days and not for use in patients younger than 18 years old.

The MDSW's underlying mathematical formula is logistic regression. The Lille Model was developed to predict mortality risk of Severe Alcoholic Hepatitis patients. The Lille Model can assist in risk stratification for patients and in identifying corticosteroid therapy responders and non-responders.

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.

The Summary of Safety and Performance for this device will be made available via EUDAMED once the relevant module is fully operational. In the meantime, the Summary of Safety and Performance can be requested from the manufacturer and will be provided without undue delay.

4.1. Lifetime, residual risks and side effects

The Lille Model 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 Lille Model is a low and medium risk device, there are no noticeable risks involved outside of possible mis-estimation of a patient's mortality 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-medium level and acceptable*.

The Lille Model 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**	Lille Model
	Manufacturer information	Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands
LOT	**LOT number**	V-1.0-10279.26.03.02
UDI	**UDI number**	(01)08720938015106(8012)v1.0(4326)260302(240)10279
IVD	**IVD indication**	*In vitro* diagnostic medical device

The electronic label can be found on the Evidencio website, see also section **I** and **Figure 6** 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 Lille Model is intended to be used by professional users who are capable of operating the device and interpreting its results. It can be used to estimate the probability of 6-month mortality and likelihood of corticosteroid response in patients with severe Alcoholic Hepatitis.

The Lille model is medical device software that automates the calculation of the formula. It requires quantitative and qualitative inputs to provide a semi-quantitative output. Albumin, Bilirubin, Renal insufficiency (Serum Creatinine/Creatinine clearance), Clotting time measurement (Prothrombin time/International Normalized Ratio (INR)) have to be determined using a serum/plasma sample and the whole blood sample, respectively, from the same blood draw/sample collection.

The Lille Model is not intended to replace clinical decision-making, it can only provide information to the user on the estimation of the 6-month mortality and corticosteroid response. The user can use this information to support clinical decision-making regarding prognosis and treatment of the patient. In practice, this typically entails the decision to continue or stop the corticosteroid treatment.

6.2. Clinical benefit

The benefits and risks associated with the use of the Lille model for the patient are indirect. The benefits arise from clinical decisions made using the Lille model in combination with other clinical and patient-specific factors. Correct functioning of the Lille Model can result in these clinical benefits:

- The Lille Model can assist in risk stratification for patients;
- The Lille Model can assist in identifying corticosteroid therapy responders and non-responders.

6.3. Intended target population and exclusion

The Lille Model should be used only for a specific group of patients, corresponding to the below indications and clinical contra-indications.

6.3.1. Clinical indications

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

- Patients with a clinical diagnosis of severe Alcoholic Hepatitis (mDF ≥32 or GAHS ≥9);
- Patients undergoing Corticosteroid therapy for seven days.

6.3.2. Clinical contra-indications

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

- Patients younger than 18 years old.

6.4. User profile

The result of the Lille Model is intended to be reviewed and interpreted by 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. Users can manually enter the required input data through the user interface. In addition, the MDSW is available as an embedded view via Evidencio's iFrame representation. 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. The device is not intended to be used at the bedside of the patient.

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. History/ versions of the algorithm

The version of the Lille Model concerns the initial version of MDSW of which Evidencio is the manufacturer.

6.8. Functioning, physical principle

The MDSW's underlying mathematical formula is logistic regression. 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 Lille Model are provided in the instructions for use. Entering the details for an individual in the MDSW initiates the estimation of 6-month mortality and corticosteroid response.

7. Additional information

7.1. Details

Algorithm author	Evidencio
Root algorithm ID	10279
Version	1.0
Revision date	2026-03-02
Speciality	Hepatology
Algorithm type	R-Script algorithm
MeSH terms	• Alcoholic Hepatitis

7.2. Input variables

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

Table 1. Variables used as input for the Lille Model.

Name	Description	Type	Range (step size)	Units
Age	Age of the patient	Continuous	18 – 100 (1.0)	Years
Bilirubin day 0	Bilirubin levels at day 0	Continuous	1.5 - 850 (0.1)	µmol/L
			0.1 - 45 (0.1)	mg/dL
Bilirubin day 7	Bilirubin levels at day 7	Continuous	1.5 - 850 (0.1)	µmol/L
			0.1 - 45 (0.1)	mg/dL
Albumin day 0	Blood Albumin level	Continuous	10 - 70 (0.1)	g/L
			1 - 7 (0.01)	g/dL
Renal insufficiency	Serum creatinine above 115 µM (1.3 mg/dL) or creatinine clearance of less than 40 mL/min	Categorical	Serum Creatinine	-
			Creatinine clearance	-
When selecting **Serum Creatinine** in the variable **Renal insufficiency**				
Serum Creatinine	Renal insufficiency is defined as Serum Creatinine above 115 µmol/L (1.3 mg/dL)	Continuous	10-1000 (1)	µmol/L
			0.1-25 (0.1)	mg/dL
When selecting **Creatinine clearance** in the variable **Renal insufficiency**				
Creatinine clearance	Renal insufficiency is defined as creatinine clearance less than 40 ml/min	Continuous	0.1-150 (0.1)	ml/min
Clotting time measurement	Select which type of clotting times data is available or preferred	Categorical	Prothrombin time	-
			International Normalized Ratio (INR)	
When selecting **Prothrombin time** in the variable **Clotting time measurement**				
Prothrombin time		Continuous	0 - 100	*Seconds*
When selecting **International Normalized Ratio (INR)** in the variable **Clotting time measurement**				
INR	International Normalized Ratio	Continuous	0 – 20 (0.1)	-

7.3. Algorithm

The Lille Model is composed of a logistic regression model. The equations can also be found in the original document provided by Louvet *et al.* (2007).

$$risk(R) = \frac{e^{-R}}{1+e^{-R}} \quad (1)$$

$$R = 3.19 - 0.101 * (age) + 0.147 * (albumin\ day\ 0) + 0.0165 * (Bilirubin\ change) - 0.206 * (renal\ insufficiency) - 0.0065 * (bilirubin\ day\ 0) - 0.0096 * (prothrombin\ time\ OR\ INR) \quad (2)$$

Equation 1 refers to the linear predictor *R* in the logistic regression model. The linear predictor *R* is described in equation 2. The algorithm has almost identical performance compared to either using prothrombin time or INR as input, when the same coefficients are used. The algorithm as implemented on Evidencio uses either Serum Creatinine (above 115 µmol/L or 1.3 mg/dL) or Creatinine clearance (less than 40 ml/min) to determine whether the (Boolean) value for renal insufficiency is 0 or 1.

7.4. Result interpretation

Primary outcome

The primary output of this device is given as a Lille Score that relates to the 6-month mortality. Furthermore, the Lille Model provides a likelihood of corticosteroid response in patients with severe alcoholic hepatitis treated with corticosteroids on day 7 of corticosteroid treatment.

Conditional information

Based on this outcome patients can be stratified into different groups depending on their risk percentage combined with threshold values, which are set in the derivation paper by Louvet *et al.* (2007) and a later paper from the same group by Mathurin *et al.* (2010). Stratification is based on the notion that patients can respond to corticosteroids differently, with a low response signalling alternative patient management.

According to the study by Louvet *et al.* (2007) a Lille score **< 0.45** is classified as a **Responder** and **Low-risk** and a Lille score **≥ 0.45** as a **Non-responder** and **High-risk**.

According to the study by Mathurin *et al.* (2010), aimed to update Lille Model, a Lille score of **≤ 0.16** is classified as a **complete responder**, a Lille score **< 0.16** and **≤ 0.56** is classified as a **Partial responder**, and a Lille score **> 0.56** as a **Null responder**.

The algorithm's accuracy was shown to be high. The derivation study found an AUC of 0.85 ± 0.04 for the Lille Model based on a prospective validation cohort of 118 patients.

Table 2. Conditional information for the Lille Model.

Condition	Information
Lille Score < 0.45	According to the original 2007 derivation study by Louvet *et al*. this patient is classified as low risk, according to the Lille Score <0.45, and this patient is likely to respond to corticosteroid therapy based on this category ("**responder**"). Patients in this group had a 6-month survival of 85% ±2.5%.
Lille Score ≥ 0.45	According to the original 2007 derivation study by Louvet *et al*. this patient is classified as high risk, according to the Lille Score ≥0.45, and this patient is unlikely to respond to corticosteroid therapy based on this category ("**non-responder**"). Patients in this group had a 6-month survival of 25% ±3.8%
Lille Score ≤ 0.16	According to the 2010 meta-analysis by Mathurin *et al*. (2010) this patient is classified as a "**complete responder**" for corticosteroid treatment due to having a Lille Score ≤0.16. Patients in this group had a 28-day survival of 91.1% ±2.7%
Lille Score > 0.16 AND Lille Score ≤ 0.56	According to the 2010 meta-analysis by Mathurin *et al*. (2010) this patient is classified as a "**partial responder**" for corticosteroid treatment due to having a Lille Score >0.16 and ≤0.56. Patients in this group had a 28-day survival of 79.4% ±3.8%

Lille Score > 0.56	According to the 2010 meta-analysis by Mathurin *et al*. (2010) this patient is classified as a "**null responder**" for corticosteroid treatment due to having a Lille Score >0.56. Patients in this group had a 28-day survival of 53.3% ±5.1%

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7.5. Study characteristics

The derivation paper from Louvet *et al*. (2007) describes the development of the model. They described their methods as follows;

"**Inclusion Criteria and Corticosteroid Protocol**
All patients with a DF ≥ 32 or encephalopathy at admission were treated by corticosteroids if they fulfilled the following criteria: (1) a history of alcoholism; (2) liver chemistry suggestive of AH; (3) the absence of uncontrolled infection or recent gastrointestinal hemorrhage (<15 days); (4) transjugular liver biopsy, which was carried out for all patients. Histological diagnosis of AH was based on the presence of hepatocellular necrosis and infiltration of polymorphonuclear leukocytes. We excluded patients with active peptic ulcers, neoplasms, positive test for hepatitis B surface antigen, and human immunodeficiency virus antibodies. Patients were treated in all centers using the same treatment protocol. Prednisolone was given in a single dose of 40 mg each morning for 28 days. Patients unable to take oral medication received intravenous infusions of 32 mg methylprednisolone. In the validating cohort, only patients with a DF ≥ 32 were treated.

Exploratory Cohort of Severe AH
For development of the model, 320 patients were included from July 1990 to October 2001 in Beaujon, Beclere, and Saint-Antoine Hospitals and from October 2001 to October 2003 in the Lille Hospital.

Validating Cohort of Severe AH
We validated the performance of the Lille model in an independent prospective cohort of patients hospitalized in Lille and Bethune Hospitals for severe AH treated by corticosteroids. Validation and comparison of models were performed prospectively from November 2003 to April 2005 in all patients (n =118) admitted. International normalized ratio (INR) was measured in this validating cohort to compare the Lille model with the MELD score calculated using the formula described by Dunn *et al*."

The algorithm was adapted by Evidencio by following the equations as described in the derivation paper followed by an internal verification of its performance.

Information on the characteristics of the patient data used to derive and validate the algorithm is provided in **Table 3** and

Table 4.

Table 3. Patient characteristics on the derivation and validation cohort.

Name	Lower Limit	Median	Upper Limit	Unit
Age	28.2	49.7	78	*years*
Bilirubin	32	210	877	*µmol/L*
Prothrombin time	13.5	19.5	32	*seconds*
Albumin	11	27	49	*g/L*
Serum creatinine	0.32	0.8	6.7	*mg/dL*
AST	15	95	504	*IU/L*
white blood cells	2200	10800	64000	*no/mm^3*
Daily Alcohol intake	30	120	400	*g/day*
Evolution of Bilirubin between day 0 and day 7	355	32.2	403	*µmol/L*
Child-Pugh Score	7	10	15	*points*
Maddrey Function	23.2	47.5	144.6	-

Table 4. Categorical patient characteristics on the derivation and validation cohort.

Name	Subset / Group	Nr. of patients
Presence of ascites	Yes	203
Presence of ascites	No	55
Presence of ascites	Unknown	37
Encephalopathy	Yes	78
Encephalopathy	No	217

Additionally, the individual patient data meta-analysis of Mathurin et al. identified the difference in response to corticosteroid treatment in patients from different risk categories based on the Lille Model, clearly showing a statistically significant increased survival from corticosteroid treatment in the low risk (responder) group but similar survival in the high-risk group.

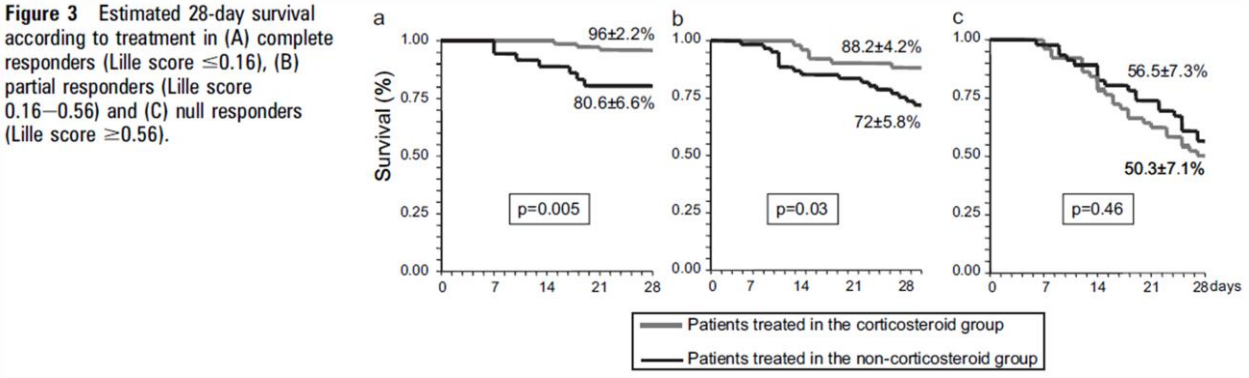

Figure 1. Figure from Mathurin et al. showing corticosteroid treatment effect according to Lille Model risk categories.

7.6. Supporting publication & Related files

Several relevant studies, such as the original derivation study by Louvet *et al.* (2007) contained in **Table 5**. 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 5. Overview of selection of supporting publications & Related files.

Derivation study Original calculator	**The Lille Model: A new tool for therapeutic strategy in patients with severe alcoholic hepatitis treated with steroids** (2007) *Alexandre Louvet, Sylvie Naveau, Marcelle Abdelnour, Marie-José Ramond, Emmanuel Diaz, Laetitia Fartoux, Sébastien Dharancy, Frédéric Texier, Antoine Hollebecque, Lawrence Serfaty, Emmanuel Boleslawski, Pierre Deltenre, Valérie Canva, François-René ruvot, Philippe Mathurin* DOI: 10.1002/hep.21607
Model updating	**Corticosteroids improve short-term survival in patients with severe alcoholic hepatitis: meta-analysis of individual patient data** (2010) *Philippe Mathurin , John O'Grady, Robert L Carithers, Martin Phillips, Alexandre Louvet, Charles L Mendenhall, Marie-José Ramond, Sylvie Naveau, Willis C Maddrey, Timothy R Morgan* DOI: 10.1136/gut.2010.224097

7.7. Analytical performance characteristics

To demonstrate the analytical performance of the Lille Model, evidence was collected based on four requirements. This led to the following results:

- A code review and functional test showed that the calculation of the online tool provides the exact same results as described in the paper by Louvet *et al*. (2007).
- Monthly uptime reports show that the device is available online with an uptime of at least 99%.
- The calculation time is within 2 minutes, otherwise an error is given to the manufacturer, this is analysed each 6 months in the analysis of quality data.
- Absence of unacceptable cybersecurity vulnerabilities.

7.8. Clinical performance characteristics

The performance of the Lille model was assessed using data from 11 different studies with a total of 3499 patients with Severe Alcoholic Hepatitis. In all studies, the Lille model was able to discriminate between high-risk and low-risk patients with an Area Under the Receiver Operating Characteristic curve of 0.65 or higher. In the original derivation study, the C-statistic was 0.85 (95% CI 0.76 - 0.91)

7.9. Release notes

The release notes for each publicly available version of the device can be found on the Evidencio website page for the Lille Model: https://www.evidencio.com/models/show/10279, 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. 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.

8.1. General algorithm landing page

An example of a medical device algorithm interface on the Evidencio platform is shown in **Figure 2**. The different sections indicated are explained in this chapter.

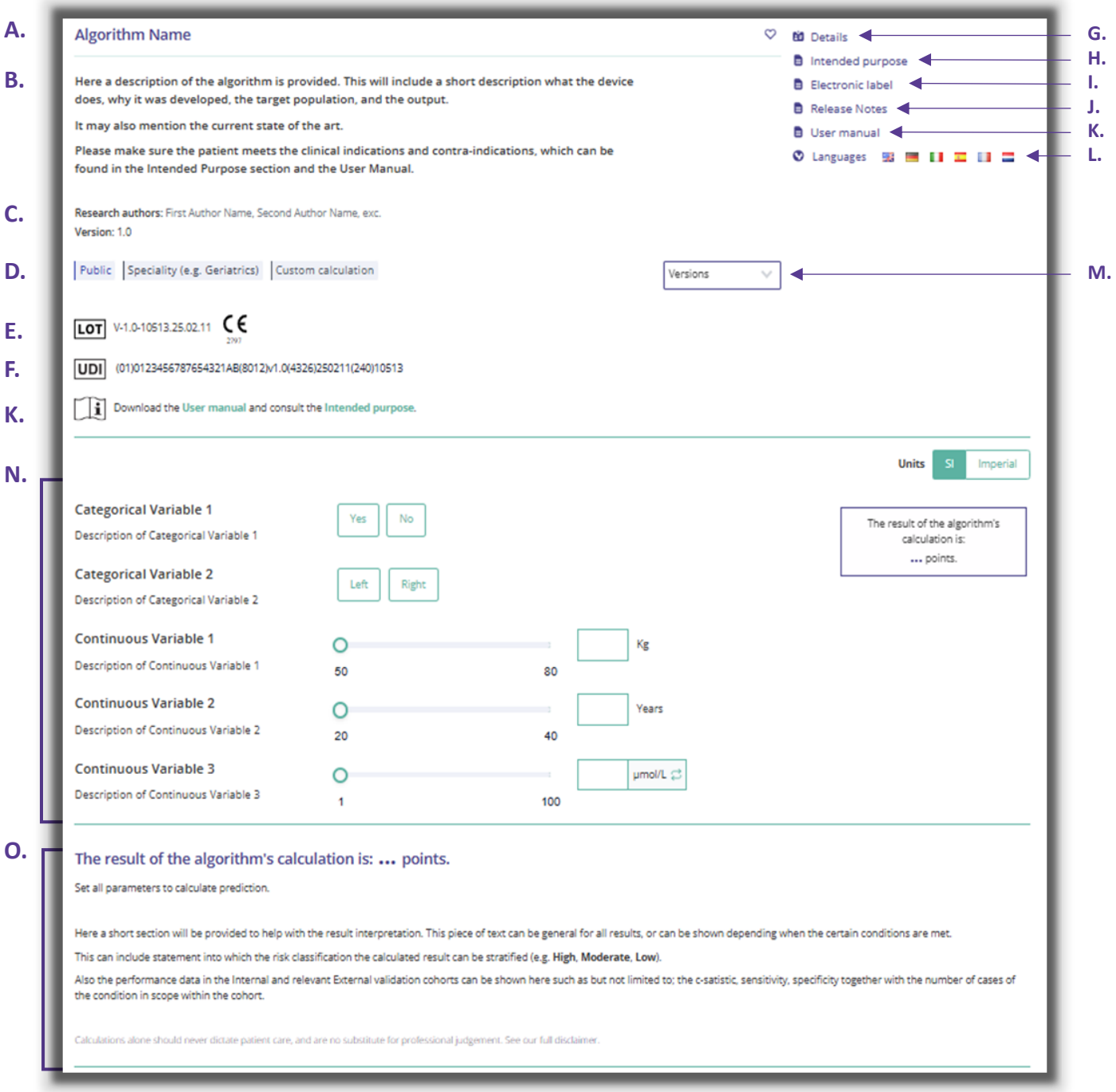

Figure 2. Example of an algorithm landing page on the Evidencio website.

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 Algorithm” 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 3**. 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.

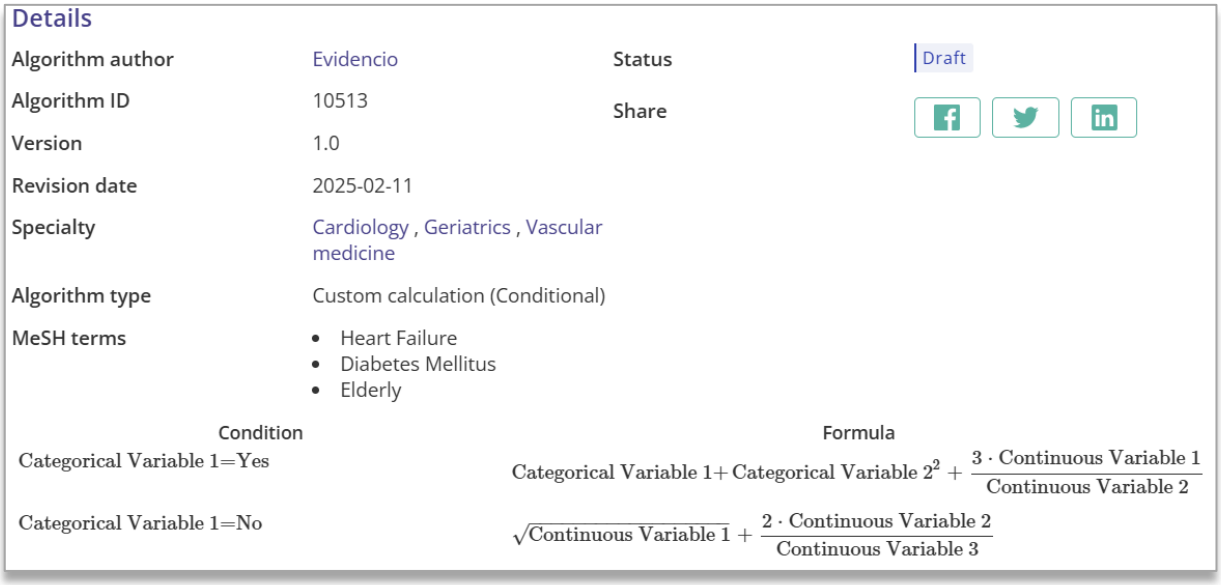

Figure 3. Example of first part of Details section.

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 4**.

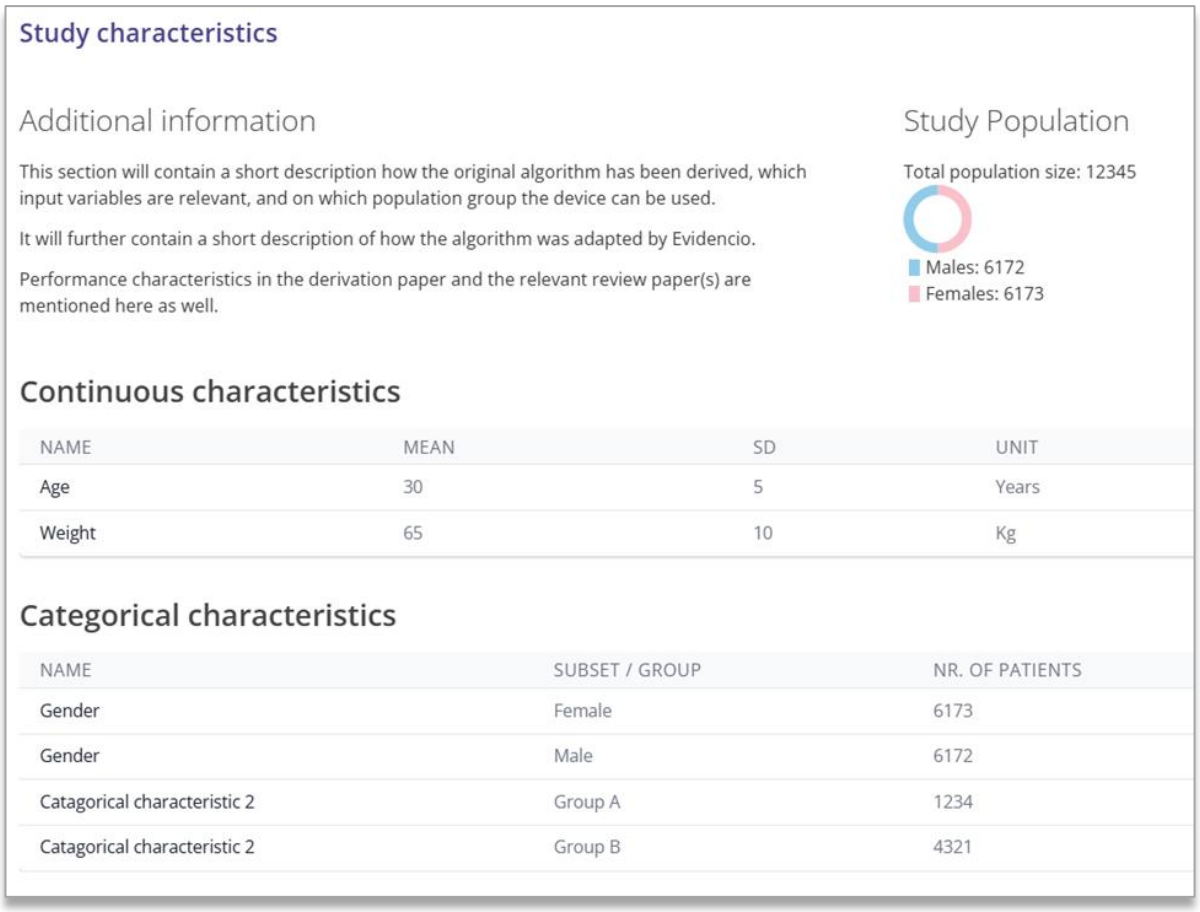

Figure 4. Example of the study characteristics section under the Details tab.

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 5**.

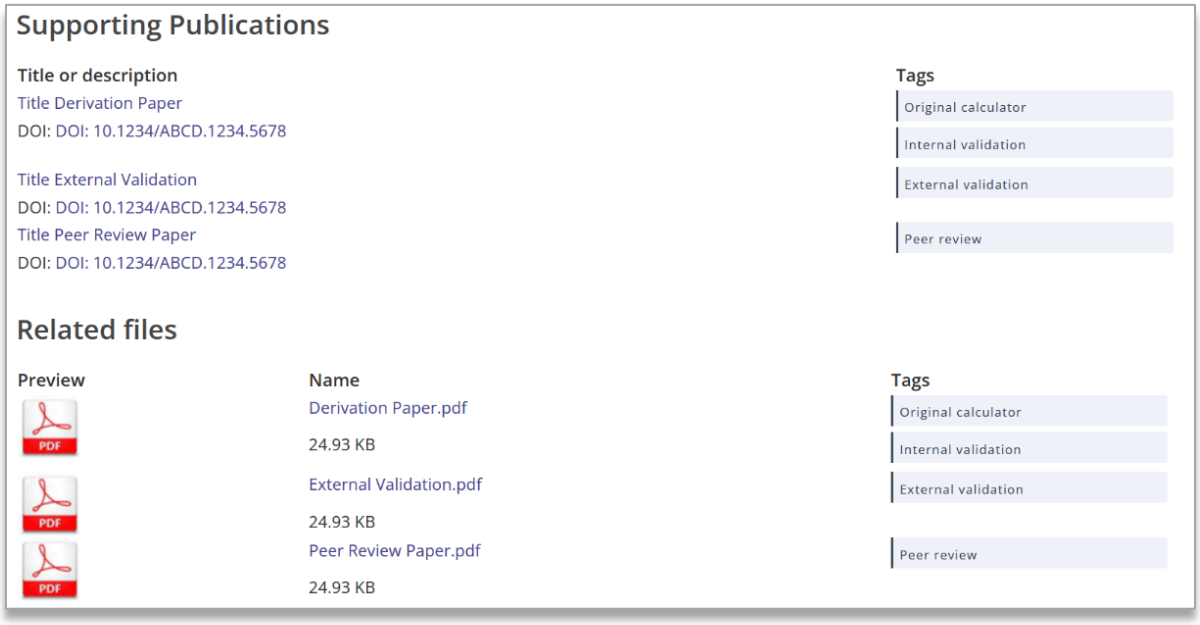

Figure 5. Example of the Supporting publication & Related files section under the Details tab.

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 6**.

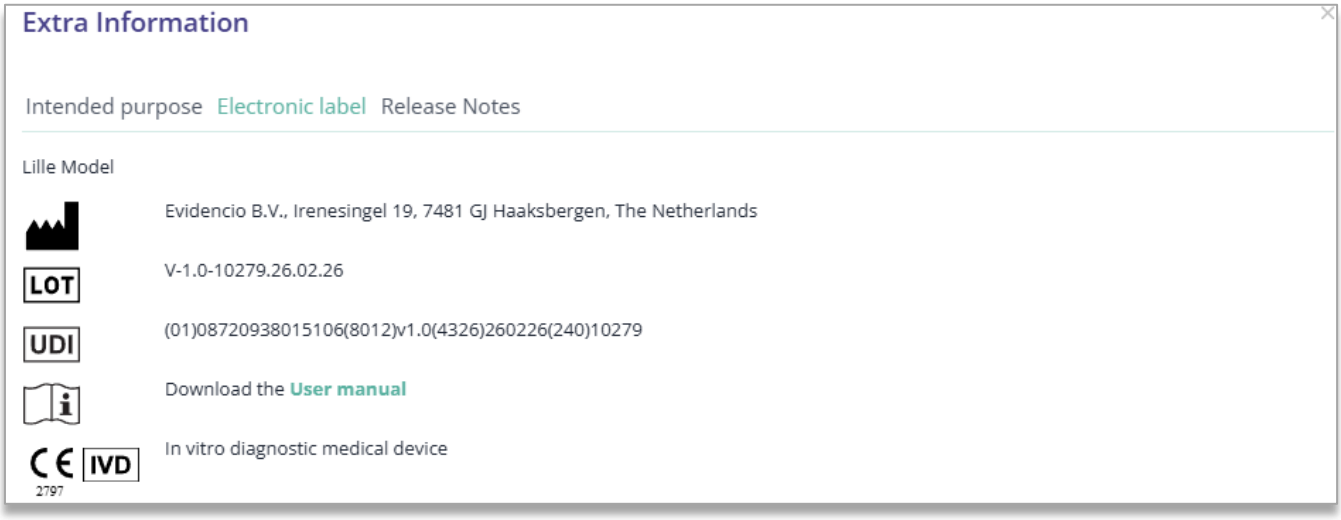

Figure 6. Example of an electronic label under the Electronic Label tab.

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 7**. The user manual page is shown in **Figure 8.** 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.

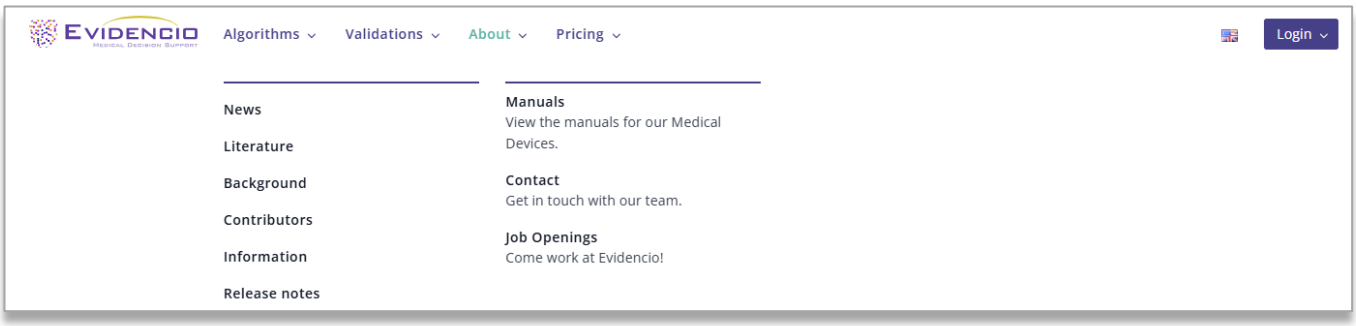

Figure 7. The drop-down menu where the user manual page can be found.

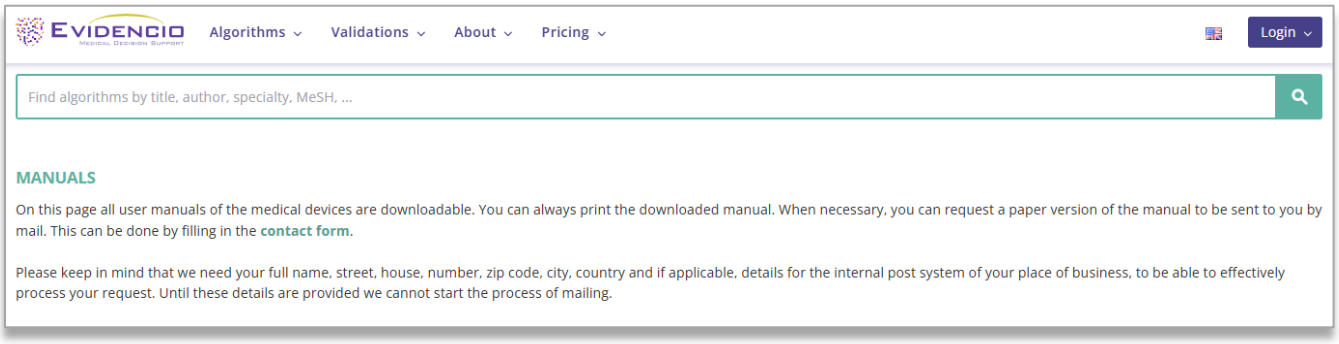

Figure 8. The user manual page for all user manuals.

L. Languages

Here an overview of languages in which the Lille Model 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 Lille Model from a list as displayed in **Figure 9**. Please note that the algorithm currently selected is not presented in the dropdown menu.

Figure 9. 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 10** and **Figure 11**, 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 11**.

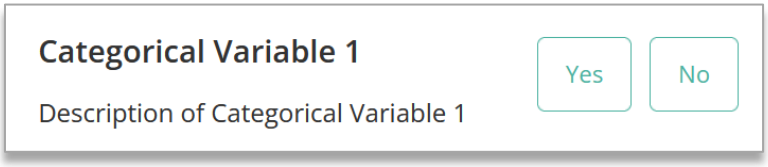

Figure 10. Example of a categorical variable, no button has been clicked and thus no input has been provided by the user.

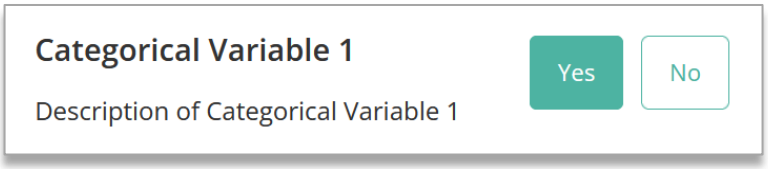

Figure 11. Example of a categorical variable, where the "Yes" button has been clicked.

Continuous variables

In the example shown in Figure 12, 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**).

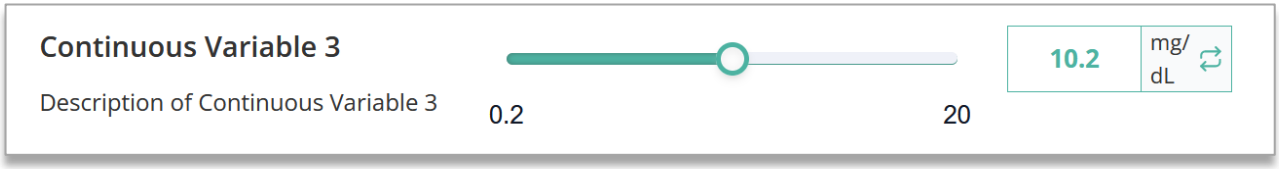

Figure 12. Example of a continuous variable, where "10.2 mg/dL" has been entered.

Unit conversion

Sometimes it is possible to use a unit conversion, by clicking on the unit when the green arrows are present. See **Figure 13** below where the unit has been clicked and switched.

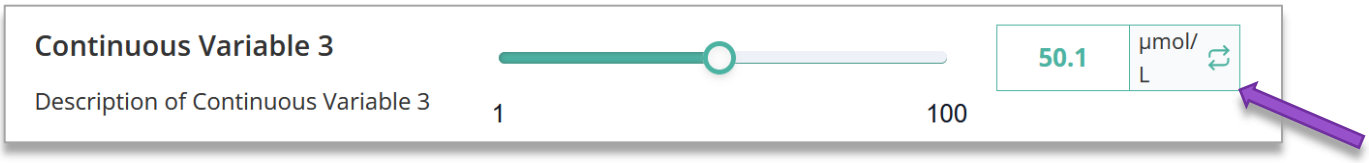

Figure 13. Example of a continuous variable where "50.1 $\mu mol/L$" has been entered.

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. An example of the information is shown in **Figure 14**.

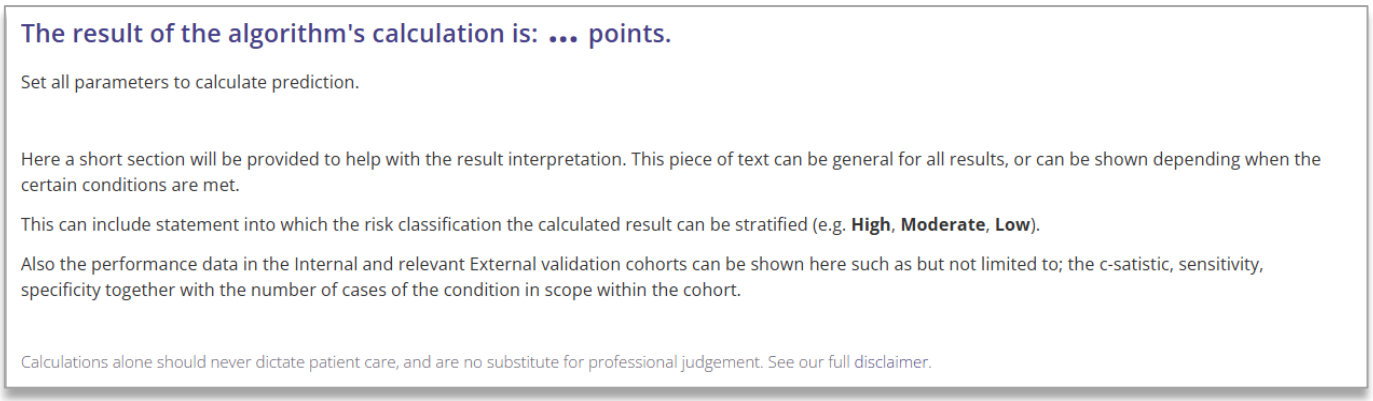

Figure 14. Example of the result display and information section.

9. Implementation of the algorithm through an API

The Lille Model can be used through Evidencio's API to allow for (automated) calculation of the 6-month mortality and likelihood of corticosteroid response, which can be used to stratify patients with severe alcoholic hepatitis treated with corticosteroids on day 7 of corticosteroid treatment. 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.

The information provided over the API is the same as the information that is displayed in the graphical user interface on the web application provided by Evidencio. In **Box 1** below, an example of a result from the Lille Model over the API is shown. The result concerns a JSON formatted text. The API for the Lille Model leverages the generic API that is provided for the Evidencio platform and therefore contains information that may be applicable for different software algorithms and devices. This means that not all of the details provided over the API may be relevant for the Lille Model.


```
{
  "CIPercentage": 0,
  "id": 10279,
  "author": "Evidencio",
  "title": "Lille Model",
  "variables": {
    "5080704907": 70,
    "6756571437": 240,
    "5724022389": 150,
    "7010767653": 30,
    "3066814874": 0,
    "4799503227": 45,
    "8819464112": 150,
    "8930647257": 0,
    "1209764258": 10,
    "6292843747": 0
  },
  "min": 0.41,
  "max": 0.41,
  "additionalResultSet": [],
  "mintxt": "0.41",
  "maxtxt": "0.41",
  "result": "0.41",
  "resultText": "The Lille Score is",
  "postresultText": "",
  "formulaSegments": [],
  "conditionalResultArray": [
    "<p><p>According to the original 2007 derivation study by Louvet et al. this patient is classified as low risk, according to the Lille Score lower than 0.45, and this patient is likely to respond to corticosteroid therapy based on this category (\"responder\"). Patients in this group had a 6-month survival of 85% ±2.5%.</p></p>",
    "<p><p>According to the 2010 meta-analysis by Mathurin et al. (2010) this patient is classified as a \"partial responder\" for corticosteroid treatment due to having a Lille Score greater than 0.16. Patients in this group had a 28-day survival of 79.4% ±3.8%</p></p>"
  ],
  "conditionalResultText": "<p><p>According to the original 2007 derivation study by Louvet et al. this patient is classified as low risk, according to the Lille Score lower than 0.45, and this patient is likely to respond to corticosteroid therapy based on this category (\"responder\"). Patients in this group had a 6-month survival of 85% ±2.5%.</p></p><p><p>According to the 2010 meta-analysis by Mathurin et al. (2010) this patient is classified as a \"partial responder\" for corticosteroid treatment due to having a Lille Score greater than 0.16. Patients in this group had a 28-day survival of 79.4% ±3.8%</p></p>",
  "UDI": "(01)08720938015106(8012)v1.0(4326)260226(240)10279",
  "medicalDevice": "This is an in vitro diagnostic medical device. The electronic label is available at: https://www.evidencio.com/models/show/10279?v=1.0",
  "userManual": "Always refer to the user manual for correct use of the in vitro diagnostic medical device. The user manual can be found at: https://www.evidencio.com/manuals"

}
```

10. User manual revision history

Version	Revision notes
V1.0 February 2026	Original version
V2.0 March 2026	Updated the intended purpose

11. Manufacturer details

Contact details of Evidencio:

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e-mail: info@evidencio.com