User manual

for

ESC 0-1 Hour Algorithm

Version 4, MAY 2025, in English

1. The Evidencio platform

The Evidencio platform facilitates the creation, use, validation and implementation of medical prediction models and clinical decision support tools. This user manual specifically relates to the ESC 0-1 Hour Algorithm. The User Manual can also be referred to as the Instructions For Use (IFU).

Throughout this manual CE-marked content and the term medical device are used interchangeably.

2. Disclaimer

Evidencio provides information, models, calculators, equations, and algorithms (tools) intended for use by healthcare professionals. Some of these tools have been certified as CE-medical devices. For such CE-marked content the 'Official Legal Disclaimer for CE-marked content' applies. All other content and tools provided by Evidencio are explicitly only covered by the 'Official Legal Disclaimer for non CE-marked content' both are available here: https://www.evidencio.com/disclaimer

3. Warnings

1. Warnings for CE-marked content

Calculations alone should never dictate patient care, and are no substitute for professional judgement. This tool is only to be used by physicians in a clinical setting, and is not for patient use.

Always read the intended use before using this tool.

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.

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

4. Model landing page

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

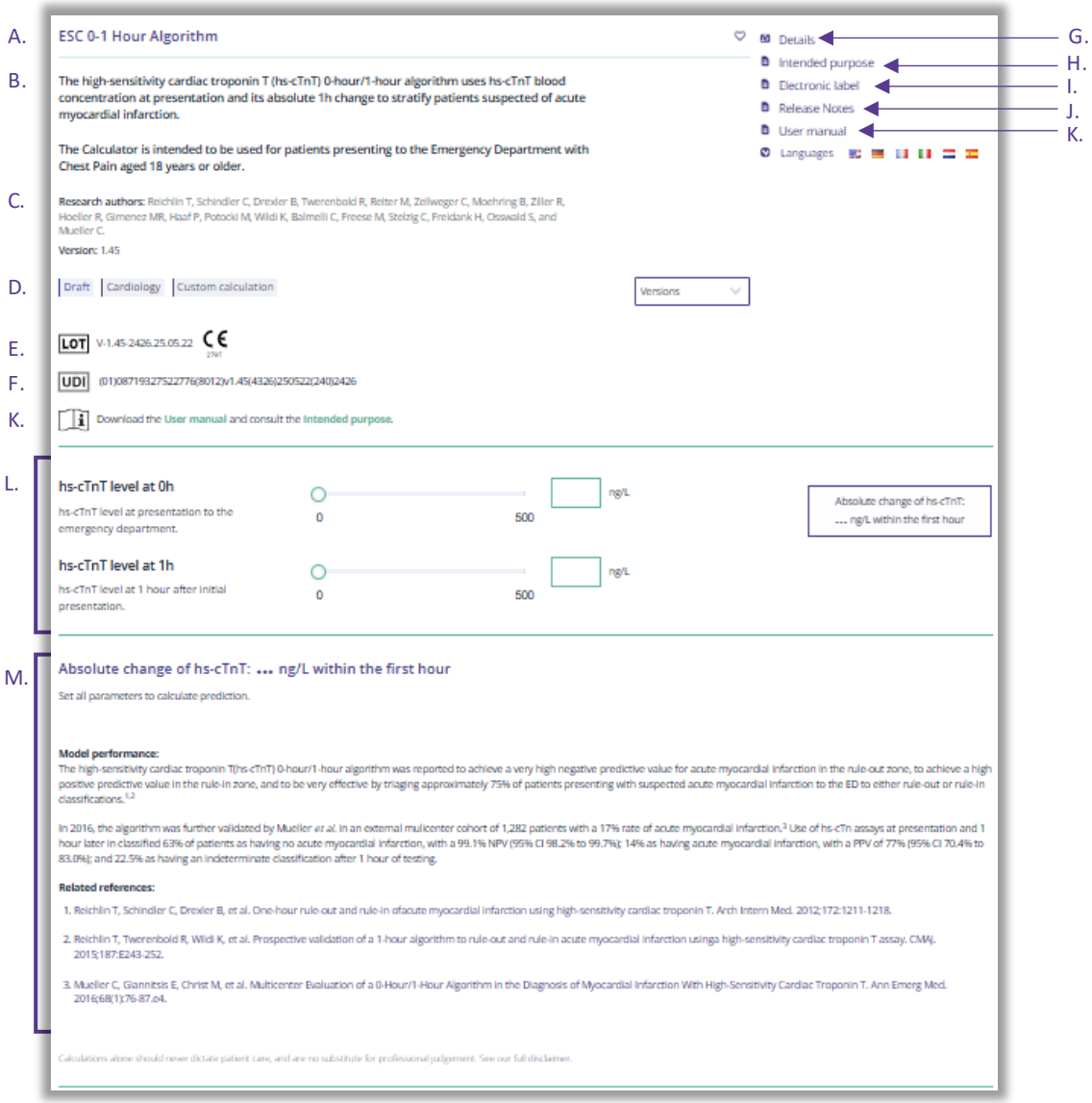

Figure 1. An example of a model landing page.

A. Model title

This is the title and name of the model.

B. Model description

This is a short description of the model.

C. Research authors

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

D. Model tags

These are the tags that are assigned to the model. Evidencio has the following status tags: “Draft”, “Public”, “Private”, “Under review”. Evidencio has the following model type tags: “Composite model”, “Sequential model”, “API model”. Evidencio has the following calculation method tags: “Linear model”, “Logistic regression”, “Cox regression”, “RScript” and “Custom model”. Next to this, there are tags that indicate the specialty e.g. “Cardiology”.

E. LOT number

The LOT number indicated the model version, the model identifier, and the model publication date. Publication date is indicated as YY.MM.DD.

Additionally, the CE mark is displayed next to the LOT number. This way, medical devices can be easily recognized.

F. UDI number

The UDI number is an international tool that helps users identify and find information on products. UDI stands for Unique Device Identifier. Evidencio’s UDIs have the following format:

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

The UDI-DI number is a unique numeric code. For each medical device of Evidencio, a unique UDI-DI is ascribed. 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

G. Details button

On the top right of the model page, several clickable buttons are displayed that show a pop-up when clicked. The first button opens a pop-up concerning additional information about the model. This pop-up has three sections: Details, Study characteristics and Supporting publications & related files.

Details

The first part of the additional information concerns the details of the model as shown in Figure 2.

Additional information on the rating of a model can be found by hovering over the 'i' icon, next to the stars.

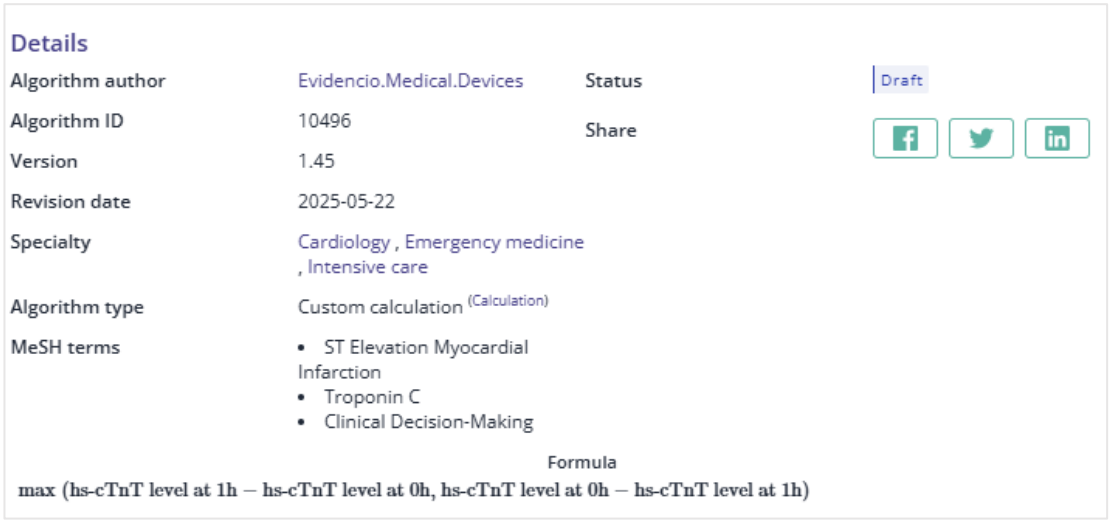

Figure 2. The model details.

Study characteristics

Below the 'Details section' the section labeled 'Study characteristics' provides information on the characteristics of the patient data used to derive and validate the model. Additional information is provided on the methods used to develop and/or validate the model.

An important part of the Study characteristics is the information on Supporting publications and related files. These sections can be found at the bottom of the Details-pop-up as shown in Figure 3.

Tags are attached to the different files to identify their link with the model. Examples of relevant tags are a.o.; "Peer review", "Internal validation", "External validation", and "TRIPOD". Publications that have the tags: "Internal validation" or "External validation", contain the performance characteristics of the device.

These tags are considered important, because the availability of particular information covered by the above mentioned tasks provide insight into the quality of the model development process and the model itself. As a completeness of information and quality indicator a model receives a certain number of stars when these labels can be assigned to relevant files or references.

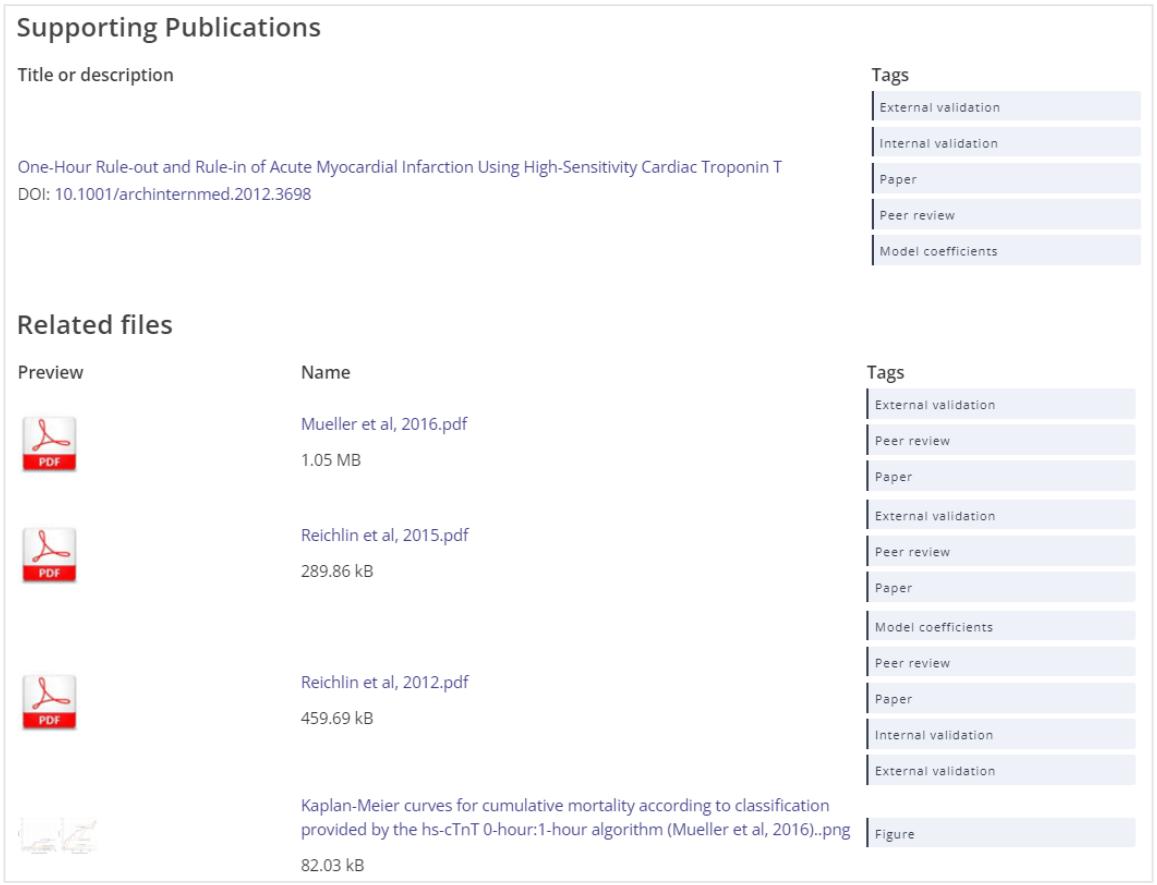

Figure 3. An example of Supporting publications & related files.

H. Intended use button

The intended use and (medical) purpose of the model can be found under the button: 'Intended use'. Among other things, the intended use indicates inclusion criteria of the medical device. Furthermore, the intended use comments on the appropriate use of the model regarding the intended use environment, intended users, and intended patient population (in- and exclusion criteria). For the ESC 0-1 Hour Algorithm the following intended use is described:

Intended use
The device is intended to be used by physicians to estimate the risk of 30-day acute myocardial infarction (AMI) in patients presenting with chest pain at the emergency department.

The device uses results of a Troponin T measurement at presentation and its absolute 1h change to calculate the risk of AMI within 30 days. The device is meant for use with the Elecsys® Troponin T high sensitivity assay from Roche diagnostics, different assays may have different applicable cutoff values for risk prediction.

The device is intended to be used for patients reporting to the emergency department with chest pain, by physicians and qualified medical specialists in a clinical setting. The device is not intended for use by patients on their own.

The ESC 0-1 Hour Algorithm is not intended to replace clinical decision-making, it can only inform the physician, and only provides a risk category for 30-day AMI. No direct instructions for further diagnostics, treatment, or otherwise, are given.

Clinical benefit
The 0/1-Hour Algorithm is intended to assist patients with relevant and specified clinical outcome parameters. Concretely, this is achieved by estimating a risk in order to support clinical decision making aimed at patients presenting to the emergency department with chest pain, in order to support clinical decision making regarding patient triage. Correct functioning of the 0/1-Hour Algorithm can result in these clinical benefits:

- The 0/1-Hour Algorithm can assist in risk stratification for patients.

- Risk stratification can reduce the burden of (invasive and intensive) medical procedures such as tests on patients with low risks, reducing, shortening or avoiding stays in hospitals or other care facilities.
- Risk stratification can reduce the unnecessary consumption of (scarce) medical resources, decreasing costs and increasing their availability for high risk patients.

Intended target population and exclusion

The ESC 0-1 Hour Algorithm is intended to be used only for a specific group of patients, corresponding to the below indications and contra-indications. The target population of the model is patients presenting to the emergency department with chest pain, provided that they fit the listed indications and contra-indications.

Clinical indication

- Patients presenting to the Emergency Department with Chest Pain/Suspected ACS
- Patients aged 18 years or older.

Contra-indications

- Patients on dialysis and patients with chronic renal failure

User profile

Since Acute Myocardial Infarction is regarded as a 'critical healthcare situation or condition', the use of the SaMD is intended for specialised trained users. Health care professionals do not require additional training prior to the use of the medical device. Thus, the SaMD may be used by physicians and qualified medical specialists in a clinical setting. The SaMD should not be used by patients.

Intended Use Environment

The SaMD can be used as made available on the Evidencio platform in any actively supported web-browser on personal computers, mobile devices, or tablet PCs, and on the mobile app provided by Evidencio. Furthermore, the SaMD can be used through the Evidencio iFrame representation of the SaMD, as an embedded view, provided that the specific Evidencio guidelines for iFrame implementations of this SaMD are adhered to. The model is only intended for use in settings where the usage and result of a model are never immediately needed.

Functioning, physical principle

The SaMD's underlying mathematical formula is a decision rule based on subtraction of the measured values of Troponin Tat 0 and 1 hours after presentation. The acquisition and processing of the data, the analyses to assemble the relevant criteria for the SaMD as well as the setup and refinement of the 0/1-Hour Algorithm are described in the original study from Reichlin et al. Entering the details of an individual in the Evidencio SaMD initiates the calculation of the risk of 30-day AMI and shows the absolute change of troponin T and the associated risk category, i.e. rule-in, observe or rule-out for the risk of 30-day AMI.

I. Electronic label button

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 4.

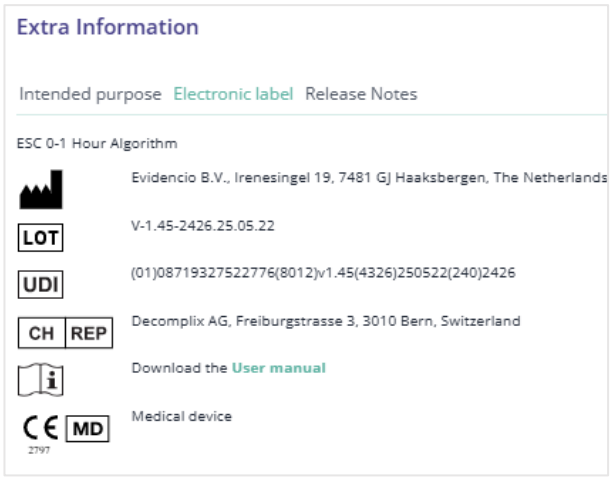

Figure 4. Example of the electronic label

J. Release notes

The 'Release Notes' button opens a pop-up with the latest release notes of the model. Here you can find what has changed over the last versions of the model. Additionally, if there are any known residual anomalies the user should be aware of, they are listed here.

K. User Manual

This user manual can be found in three places: 1) under the short description, 2) on the right of the model page, and 3) in the electronic label. 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 5. The user manual page is shown in Figure 6.

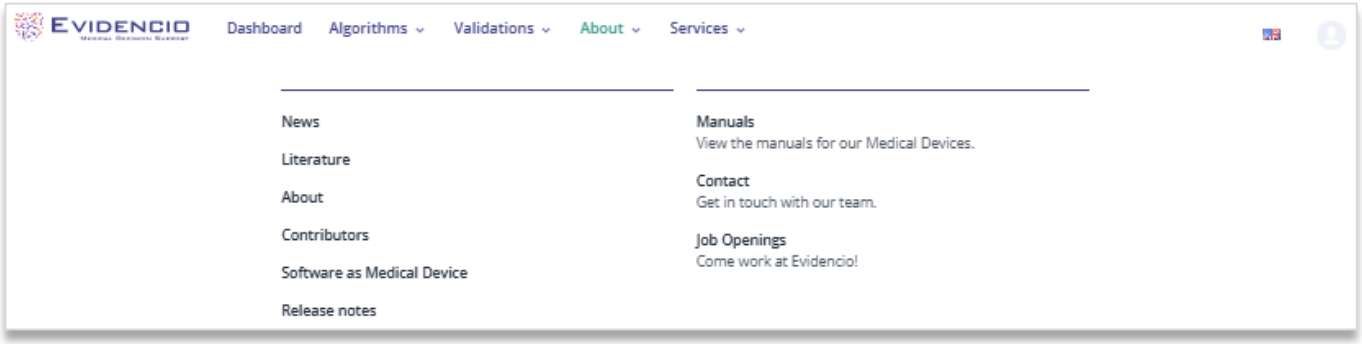

Figure 5. The drop-down menu where the user manual page can be found.

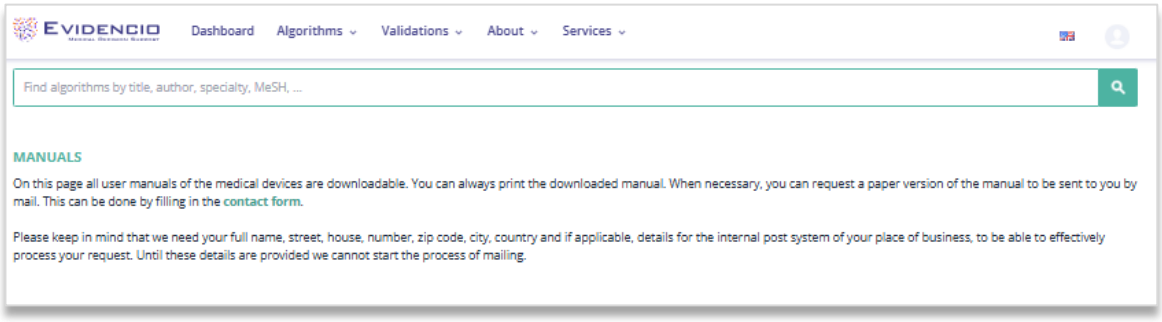

Figure 6. The user manual page for all user manuals.

You (The user) can always print this downloaded manual. When necessary, you can request a paper version of the manual to be sent to you by mail. Evidencio's contact details are listed in Chapter 6 of this user manual.

L. Input section

The Evidencio platform allows two separate input variables; categorical, and continuous variables. For the ESC 0-1 Hour Algorithm, only the continuous variables are used.

Continuous variables

In the example shown in Figure 7, the **hs-cTnT level at 0h** variable, exemplifies a continuous variable.

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 200 is entered for **hs-cTnT level at 0h**).

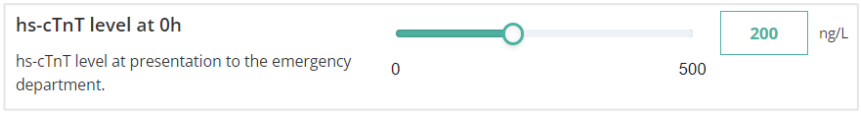

Figure 7. The variable for age, where "65" has been entered.

Details on variable measurements

Directly underneath the name for each variable, additional details can be provided on the methods required to enter the correct value for each variable. In Figure 8, the details below **hs-cTnT level at 0h** explain what the risk factors are.

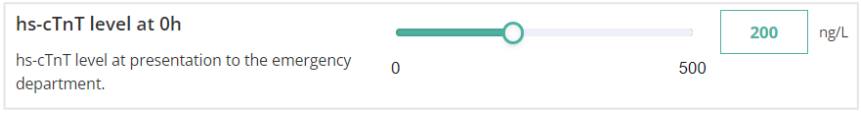

Figure 8. An example on how additional information can be provided for a variable.

M. Result section

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

Result calculation

When all variables are filled in, a result will be calculated. No risk is displayed until all variables are filled in. The result section indicates *"Set all parameters to calculate prediction."*

Result interpretation

In the result interpretation, a risk stratification is given based on the risk score. Furthermore, some explanation about the model is given. An example of the information is shown In Figure 9.

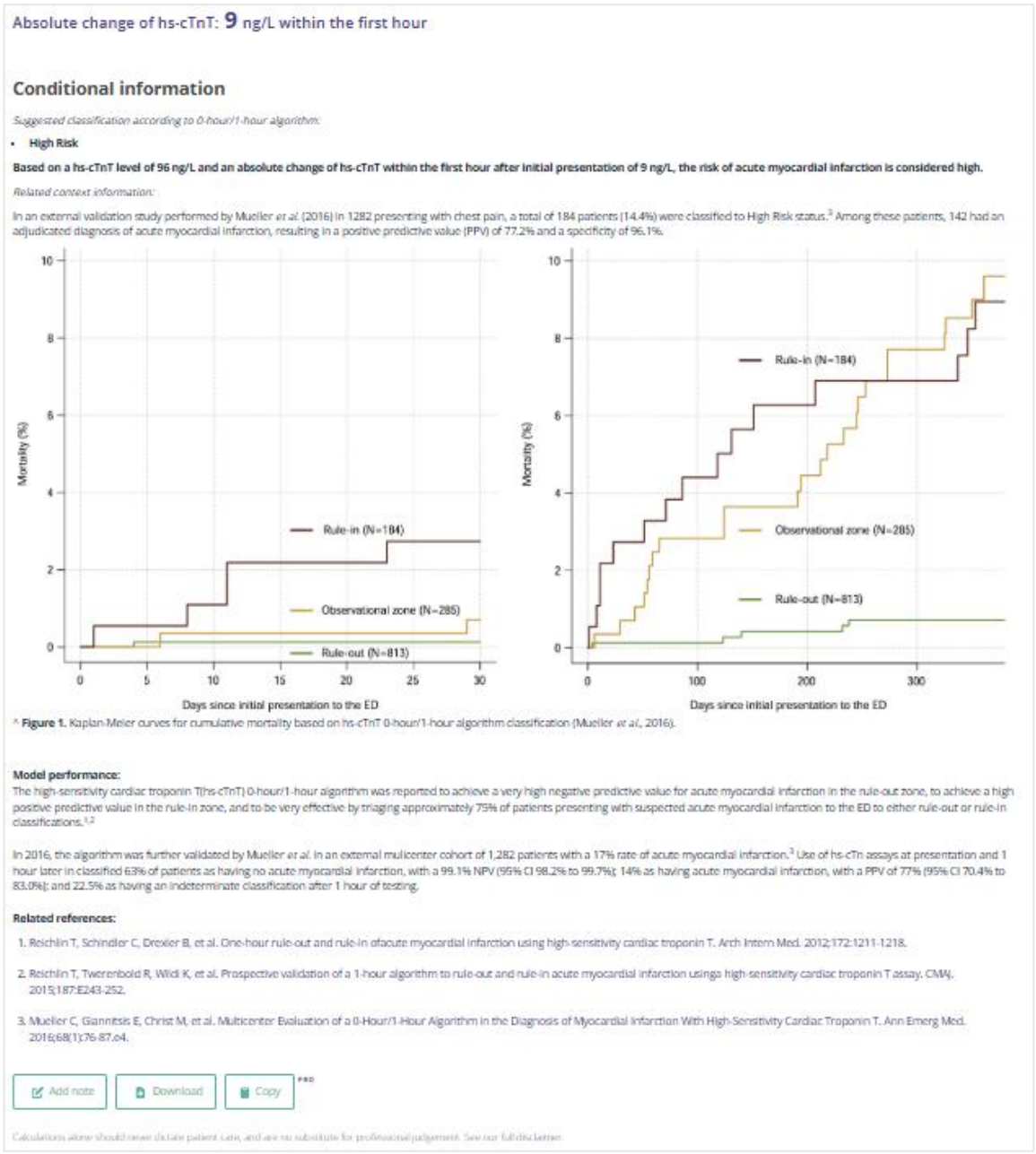

Figure 9. The result information

Relevant information for correct use of the model

At the bottom of the page, there is a link to Evidencio's terms and conditions of use, the privacy policy, and the disclaimer.

5. Use of Medical devices

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.

To use the tool, Evidencio requires a stable internet connection and runs on the following devices:

- Personal computers or laptops using the following browsers:
  - Safari (the latest three versions)
  - Chrome (the latest three versions)
  - Firefox (the latest three versions)
  - Edge (the latest three versions)
- Tablets or smartphones running on the next operating systems:
  - IOS (the latest three versions)
  - Android (the latest three versions)

The medical device cannot be used in combination with Internet Explorer. The personal computers, laptops, tablets or smartphones used should at least be able to have an internet connection and use the browsers mentioned above. The minimal screen resolution should be 800x600.
Furthermore, the model may be used through the Evidencio iFrame representation of the calculator, as an embedded view, provided that the specific Evidencio guidelines for iFrame implementations of that model are adhered to.

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

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

6. Manufacturer details

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the country in which you, the reader, are established. A competent authority is the institute that governs all issues related to medical devices in a country.
Contact details of your competent authority can be found here: https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human

Please contact Evidencio when you suspect any malfunction or changes in the performance of a medical device. Do not use the device, until Evidencio replies to your message that it is safe to start using it again.

Contact details of Evidencio:

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e-mail: info@evidencio.com