



User manual for the ELAN-HF Score

Version 2.0, October 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 ELAN-HF Score. The User Manual can also be referred to as the Instructions For Use (IFU).

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

2. Disclaimer

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

In general, and unless explicitly stated otherwise, CE-marked tools on Evidencio are only to be used by healthcare professionals and are not for patient use.

The CE-marked content on the platform is to be regarded as a specific set of tools, apart from the general platform content. Any available content, on any of the websites, applications, apps, or services provided by Evidencio that is not clearly labelled as a CE-marked tool is explicitly not covered by this disclaimer for CE-marked content, the general Evidencio Disclaimer for non-CE-marked content applies.

CE-marked tools may provide limited professional advice to the intended user(s). However, the intended user must exercise their clinical judgment as to the information these tools provide.

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

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

Your use of the websites, applications, apps, or services provided by Evidencio is subject to our Terms & Conditions, which can be found here: <https://www.evidencio.com/terms-conditions>.



3. Warnings for CE-marked content

Calculations alone should never dictate patient care, and are no substitute for professional judgement. See our full disclaimer on: <https://www.evidencio.com/disclaimer>. This tool is only to be used by healthcare professionals, and is not for patient use.

Always read the intended use before using this tool.

Always make sure the patient complies with the clinical indications and clinical contra-indications as stated on the Evidencio website, and in **paragraphs 6.3.1** and **6.3.2** of this user manual respectively.

Before reading the result, double check the filled in values to prevent errors.

Results that concern risk percentages, do not guarantee certain outcomes. When there is a risk present, do not expect an event to not occur at all, even if the risk is very small. Conversely, a high risk does not guarantee that an event will occur.

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

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

3.1. Notice to the user

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the country in which you, the reader, are established. A competent authority is the institute that governs all issues related to medical devices in a country.

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

4. Device Description ELAN-HF Score

The ELAN-HF is a linear algorithm that predicts 180-day all-cause mortality after discharge in patients hospitalised for Acute Decompensated Heart Failure (ADHF), using demographics, clinical parameters, sodium, serum urea, and NT-proBNP measurement, including reduction in NT-proBNP.

4.1. Lifetime, residual risks and side effects

The ELAN-HF Score 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 ELAN-HF Score is a low-risk device, there are no noticeable risks involved outside of possible mis-estimation of the risk of patient all-cause mortality within 180 days of hospital discharge, 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 inaccessibility 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 ELAN-HF Score does not have any direct side effects.

5. Electronic Label

The electronic label of this device contains the following information:

	Name of the device	ELAN-HF Score
	Manufacturer information	Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands
	LOT number	V-2.0-9969.25.10.01
	UDI number	(01)08720938015304(8012)v2.0(4326)251001(240)9969
	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 (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 Medical Use

The ELAN-HF Score is intended to be used by healthcare professionals to estimate the probability of 180-day all-cause mortality in patients with Acute Decompensated Heart Failure (ADHF), about to be discharged.

The device combines Admission and discharge NT-proBNP measurements, Age at admission, Peripheral Oedema status, SBP at admission, Hyponatremia at admission, Serum Urea at discharge, and New York Heart Association Class at discharge to predict 6-month all-cause mortality.

The device is intended to be used for patients with ADHF, at discharge, by healthcare professionals. The device is not intended for use by patients on their own. Healthcare professionals do not require additional training prior to the use of the medical device

The ELAN-HF Score is not intended to replace clinical decision-making, it can only provide information to the user on the probability of 180-day all-cause mortality. The healthcare professional can use this information to support clinical decision-making regarding follow-up measures regarding ADHF patients about to be discharged.

6.2. Clinical benefit

The ELAN-HF Score is intended to assist healthcare professionals with patients that have relevant and specified clinical outcome parameters. Concretely, this is achieved by estimating a risk in order to support clinical decision-making aimed at patients with ADHF, in order to support clinical decision-making regarding patient prognosis.

Correct functioning of the ELAN-HF Score can result in the following clinical benefit:

- The ELAN-HF Score can assist in risk stratification for patients.
- Risk stratification can reduce the unnecessary consumption of (scarce) medical resources, decreasing costs and increasing their availability for high-risk patients.
- Digital implementation of the algorithm underlying the ELAN-HF Score as a medical device can improve the speed and reliability of calculation. This would further increase the accuracy of the prognosis and by extent increase the chance for the above-mentioned benefits.
- Use of the algorithm positively impacts patient management by optimising the risk-based post-discharge care for patients with ADHF and informing clinical management on further *prognostic/therapeutic* options.

6.3. Intended target population and exclusion

The ELAN-HF Score is intended to be used only for a specific group of patients, corresponding to the below indications and contra-indications.

6.3.1. Clinical indications

The ELAN-HF Score should be used for patients who meet the following inclusion criteria:

- Admitted for clinically validated ADHF.
- About to be discharged from the hospital.
- 18 years or older.

6.3.2. Clinical contra-indications

No clinical contra-indications have been found for the ELAN-HF Score.

6.4. User profile

The ELAN-HF Score is intended to be used by healthcare professionals or automatically calculated 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 version of the ELAN-HF Score concerns the initial version of MDSW of which Evidencio is the manufacturer.

6.8. Functioning, physical principle

The ELAN-HF Score's underlying algorithm concerns a custom algorithm with a linear point equation. The acquisition and processing of the data, the analyses to assemble the relevant criteria for the ELAN-HF Score as well as the setup and refinement of the ELAN-HF Score are described in the original study from Salah *et al.* (2013) Entering the details of an individual in the web-application and pressing the Calculate button initiates the calculation of the risk category of the patient.

7. Result interpretation

The primary output of this device is given as a number of points, with an associated risk percentage per risk category, based on these points, shown alongside the outcome.

Conditional information

Several pieces of conditional information are shown for the ELAN-HF Score, dependent on the precise input. First, estimated risk percentages based on the ELAN-HF Score of the patient are provided, including risk categories as defined in the original derivation study by Salah et al.:

- ELAN-HF Score ≤ 2 : Low risk category, corresponding to a 3.6% risk of 180-day all-cause mortality post-discharge in the derivation cohort and 2.2% in the external validation cohort.
- ELAN-HF Score 3-4: Intermediate risk category, corresponding to a 9.2% risk of 180-day all-cause mortality post-discharge in the derivation cohort and 8.2% in the external validation cohort.
- ELAN-HF Score 5-7: High risk category, corresponding to a 23.5% risk of 180-day all-cause mortality post-discharge in the derivation cohort and 22.9% in the external validation cohort.
- ELAN-HF Score ≥ 8 : Very high risk category, corresponding to a 51.1% risk of 180-day all-cause mortality post-discharge in the derivation cohort and 53.6% in the external validation cohort.

Additionally, there are several possible statements regarding the point score conditional on the entered admission and discharge values of NT-proBNP, and the calculated reduction in NT-proBNP. (**[reductionpercentage]** shows the reduction in NT-proBNP when comparing between admission and discharge as a percentage):

- The reduction in NT-proBNP is **[reductionpercentage]%** which is higher than the cutoff value at 30% and adds 0 points to the result of the ELAN-HF Score.
- The reduction in NT-proBNP is **[reductionpercentage]%** which is lower than the cutoff value at 30% and adds 1 point to the result of the ELAN-HF Score.
- There was no reduction in NT-proBNP during hospitalisation, which adds 1 point to the result of the ELAN-HF Score.
- The NT-proBNP value at patient discharge is below 1500, which adds 0 points to the result of the ELAN-HF Score.
- The NT-proBNP value at patient discharge is between 1500 and 5000, which adds 1 point to the result of the ELAN-HF Score.
- The NT-proBNP value at patient discharge is between 5001 and 15000, which adds 3 points to the result of the ELAN-HF Score.
- The NT-proBNP value at patient discharge is above 15000, which adds 4 points to the result of the ELAN-HF Score.

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	9969
Version	ELAN-HF Score
Revision date	01-OCT-2025
Speciality	Cardiology
Algorithm type	Custom algorithm (Conditional)
MeSH terms	<ul style="list-style-type: none"> Heart failure

8.2. Input variables

To perform the calculations successfully, the ELAN-HF Score requires the input variables as listed in **Table 1**. Additionally, the last two variables are filled in indirectly, calculated from previously provided input.

Table 1. Variables used as input for the ELAN-HF Score.

Name	Description	Type	Range (step size)	Units	Points
Admission					
NT-proBNP value (Admission)	NT-proBNP value at admission (pg/mL).	Continuous	0-30000 (1)	pg/mL	-
Age	The age of the patient in years.	Categorical	<75 years ≥75 years	-	0 1
Peripheral oedema	Peripheral oedema status at admission.	Categorical	No Yes	-	0 1
Hyponatremia	Hyponatremia at admission, defined as sodium <135 mmol/L.	Categorical	≥135 mmol/L sodium <135 mmol/L sodium	-	0 1
Systolic blood pressure	Systolic blood pressure in mm Hg at admission.	Categorical	>115 mm Hg ≤115 mm Hg	-	0 1
Discharge					
NT-proBNP value (Discharge)	NT-proBNP value at discharge (pg/mL).	Continuous	0-30000 (1)	pg/mL	-
Serum urea	Serum urea at discharge in mmol/L.	Categorical	<15 mmol/L ≥15 mmol/L	-	0 1
NYHA Class	New York Heart Association Class at discharge.	Categorical	Class I / Class II Class III / Class IV	-	0 1
Indirect calculations					
NT-proBNP value (discharge) (points)	Point score related to discharge NT-proBNP	Categorical	< 1 500 (pg/mL) ≥ 1 500 (pg/mL) AND ≤5 000 (pg/mL) > 5 000 (pg/mL) AND ≤15 000 (pg/mL) >15 000 (pg/mL)	-	0 1 3 4
NT-proBNP reduction	Percentage of reduction in NT-proBNP during hospital stay	Categorical	> 30% ≤ 30%	-	0 1

Formula

The formula for the ELAN-HF Score is:	Age + Peripheral oedema + Hyponatremia + Systolic blood pressure + Serum urea + NYHA Class + NT-proBNP value (discharge) (points) + NT-proBNP value (reduction)
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8.3. Study characteristics

The derivation study used a combined cohort from 7 different studies with a total of 1301 patients for Cox regression and subsequently derived a linear scoring tool. A validation cohort of 325 patients was used to validate the scoring tool. Different in- and exclusion criteria were used in the different studies included in the development of the ELAN-HF. As such, not all patient groups were equally represented. Therefore, it should be noted that many (but not all) studies used for the development of the ELAN-HF Score excluded patients with ACS, or patients with a certain degree of renal dysfunction or dialysis.

Salah *et al.* (2019) identified AUC's for the ELAN-HF Score of 0.78 (95% CI: 0.74-0.82) and 0.77 (95% CI: 0.69-0.84) in the ELAN-HF and PRIMA II cohorts respectively.

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

Table 2. Information on the patient group data used to derive the algorithm.

Name	Mean/Median	Mean/Median Value	Q1	Q3	SD	Unit
Age	median	74	64	80	-	Years
SBP at admission	mean	133	-	-	31.9	mm Hg
DBP at admission	mean	81	-	-	20.3	mm Hg
Heart rate at admission	mean	93	-	-	24.8	bpm
Haemoglobin at admission	mean	126.4	-	-	20.5	g/L
Haemoglobin at discharge	mean	128	-	-	19.9	g/L
Serum urea at admission	mean	12.6	-	-	7.8	mmol/L
Serum urea at discharge	mean	13.7	-	-	8.1	mmol/L
eGFR at admission*	mean	56.9	-	-	32.8	mL/min/1.73 m ²
eGFR at discharge*	mean	56.9	-	-	42	mL/min/1.73 m ²
NT-proBNP at admission	median	6447	3057	12632	-	pg/mL
NT-proBNP at discharge	median	3252	1419	7291	-	pg/mL
cTnT at admission	median	0.03	0.01	0.1	-	µg/L
Admission duration	median	9	6	14	-	Days

*calculated with Modification of Diet in Renal Disease (MDRD) equation.

Table 3. Categorical characteristics on the patient group data used to derive the algorithm.

Name	Subset / Group	Number of patients
Age	≥ 75	607
History	DM	422
	COPD	209
	Hypertension	661
Admission Variables	JVP Distended at admission	635
	Pulmonary rales at admission	821
	peripheral oedema at admission	674
	Atrial fibrillation at admission	513
LVEF	Preserved (≥45%)	327
	Mild-moderate (25–44%)	514
	Severe (<25%)	324
NYHA class at discharge	III	212
	IV	4
Discharge medication	Diuretics	1156
	ACE-inhibitor	806
	β-blocker	685

8.4. Supporting publication & Related files

Several relevant studies, such as the original derivation study by Salah *et al.* (2013) 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.

<p>Derivation Study ELAN-HF Score</p> <p>Internal validation, Patient characteristics, External validation, Peer review, Algorithm formula.</p>	<p>A novel discharge risk model for patients hospitalised for acute decompensated heart failure incorporating N-terminal pro-B-type natriuretic peptide levels: a European coLLaboration on Acute decompensated Heart Failure: ÉLAN-HF Score</p> <p><i>Salah K, Kok WE, Eurlings LW, Bettencourt P, Pimenta JM, Metra M, Bayes-Genis A, Verdiani V, Bettari L, Lazzarini V, Damman P, Tijssen JG, Pinto YM.</i></p> <p>https://doi.org/10.1136/heartjnl-2013-303632</p>
<p>Validation Study ELAN-HF Score</p> <p>External validation, Peer review, Kaplan Meier plot.</p>	<p>External Validation of the ELAN-HF Score, Predicting 6-Month All-Cause Mortality in Patients Hospitalized for Acute Decompensated Heart Failure</p> <p><i>Salah K, Stienen S, Moons AHM, Bakx ALM, van Pol PE, Kortz RAM, Ferreira JP, Marques I, Schroeder-Tanka JM, Keijer JT, Bayes-Genis A, Pinto YM, Tijssen JG, Kok WE.</i></p> <p>https://doi.org/10.1161/JAHA.118.010309</p>
	<p>Validation of the ELAN-HF Score and self-care behaviour on the nurse-led heart failure clinic after admission for heart failure</p> <p><i>Vinck TAM, Deneer R, Verstappen C, Kok WE, Salah K, Scharnhorst V, Otterspoor LC.</i></p> <p>https://doi.org/10.1186/s12912-022-00914-1</p>

8.5. Release notes

The release notes for each publicly available version of the device can be found on the Evidencio website page for the ELAN-HF Score: <https://www.evidencio.com/models/show/9969>, 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 ELAN-HF Score can be used through Evidencio's API to allow for (automated) calculation of the risk of 180-day post-discharge all-cause mortality. 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.

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.

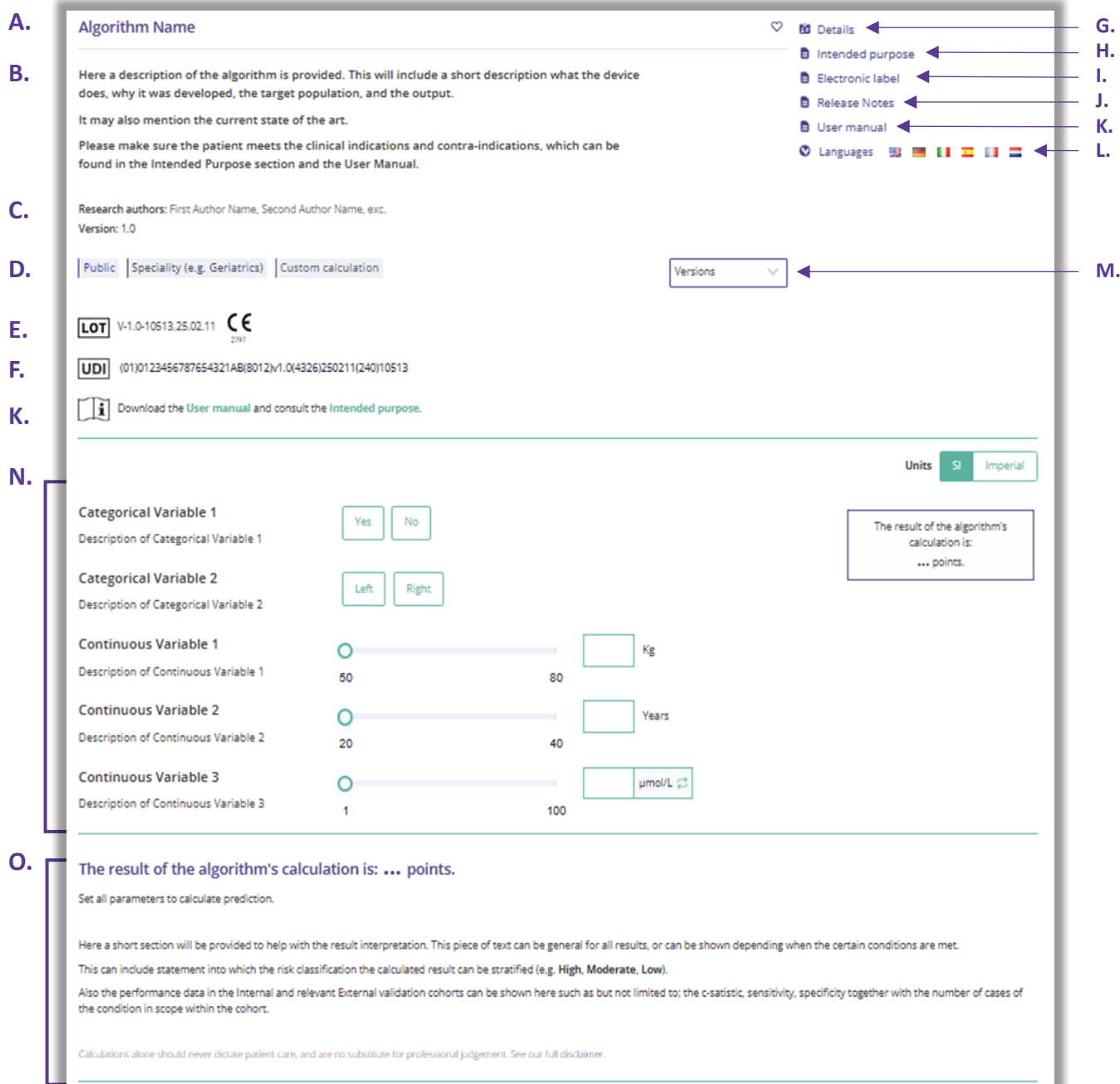


Figure 1. Example of an algorithm landing page on the Evidencio website.

This is the title and name of the algorithm.

This is a short description of the algorithm.

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-PI Number

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

G. Details button

On the top right of the algorithm 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.




Details		
Algorithm author	Evidencio	Status Draft
Algorithm ID	10513	Share   
Version	1.0	
Revision date	2025-02-11	
Specialty	Cardiology , Geriatrics , Vascular medicine	
Algorithm type	Custom calculation (Conditional)	
MeSH terms	<ul style="list-style-type: none"> Heart Failure Diabetes Mellitus Elderly 	
Condition		Formula
Categorical Variable 1=Yes		$\text{Categorical Variable 1} + \text{Categorical Variable 2}^2 + \frac{3 \cdot \text{Continuous Variable 1}}{\text{Continuous Variable 2}}$
Categorical Variable 1=No		$\sqrt{\text{Continuous Variable 1}} + \frac{2 \cdot \text{Continuous Variable 2}}{\text{Continuous Variable 3}}$

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**.

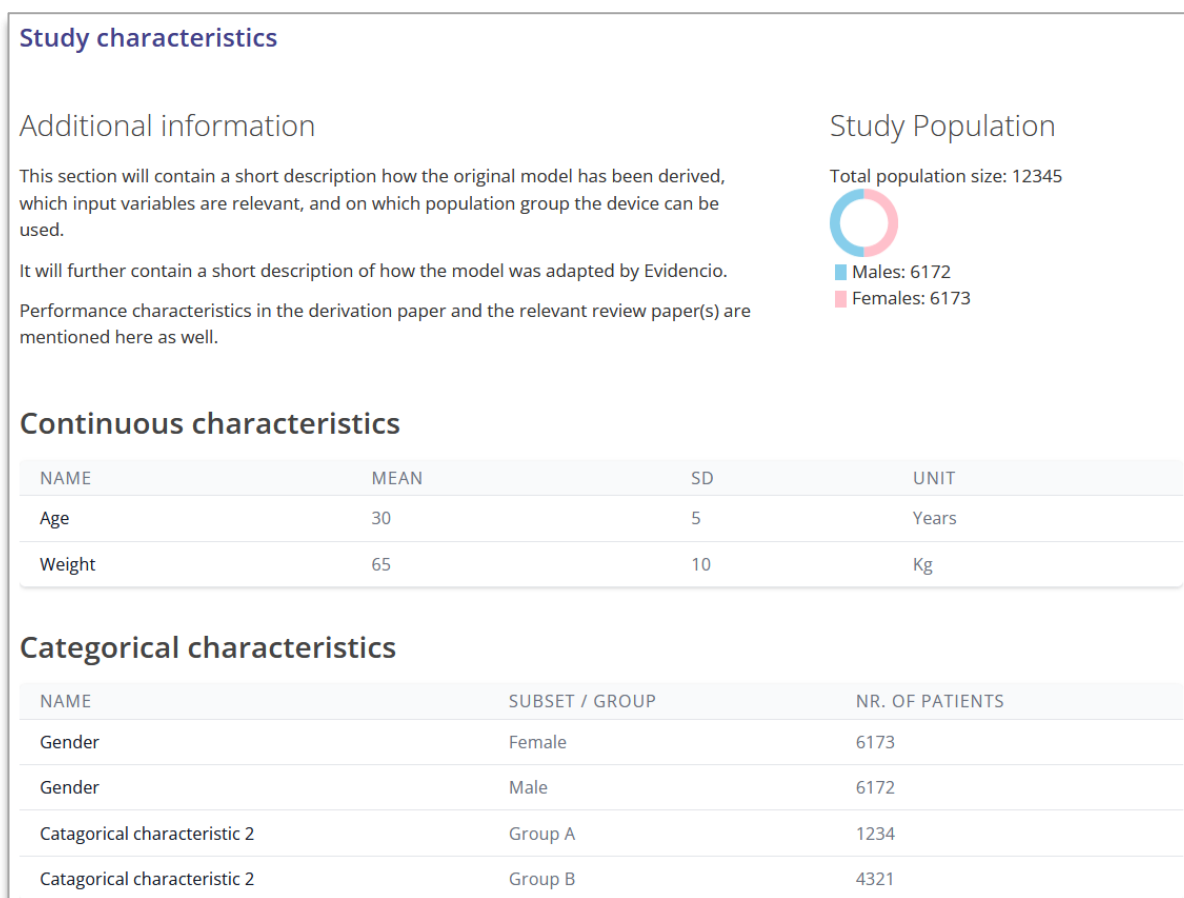


Figure 3. Example of the study characteristics section under the Details tab.

Supporting publications & Related files

An important part of the Study characteristics is the information on Supporting publications and related files. 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.

Tags are attached to the different files to identify their link with the algorithm. Examples of relevant tags are a.o.; “Peer review”, “Internal validation”, “External validation”, and “TRIPOD”. Publications that have the tags: “Internal validation” or “External validation”, contain the performance characteristics of the device. Figures and tables which help to interpreted the results may also be provided here.

H. Intended purpose

Under this tab, the intended purpose can be found, containing a lot of information regarding the algorithm, its user, target population, clinical benefit, etc. This information is also provided in this manual and can be found in **Chapter 6** on **page 5**.

I. Electronic label

The electronic label button opens a pop-up with the location and address of Evidencio, the LOT number, the UDI number, the CE-mark, the medical device logo and a download link for the declaration of conformity of the medical device. The example of the electronic label is shown in **Figure 5**.

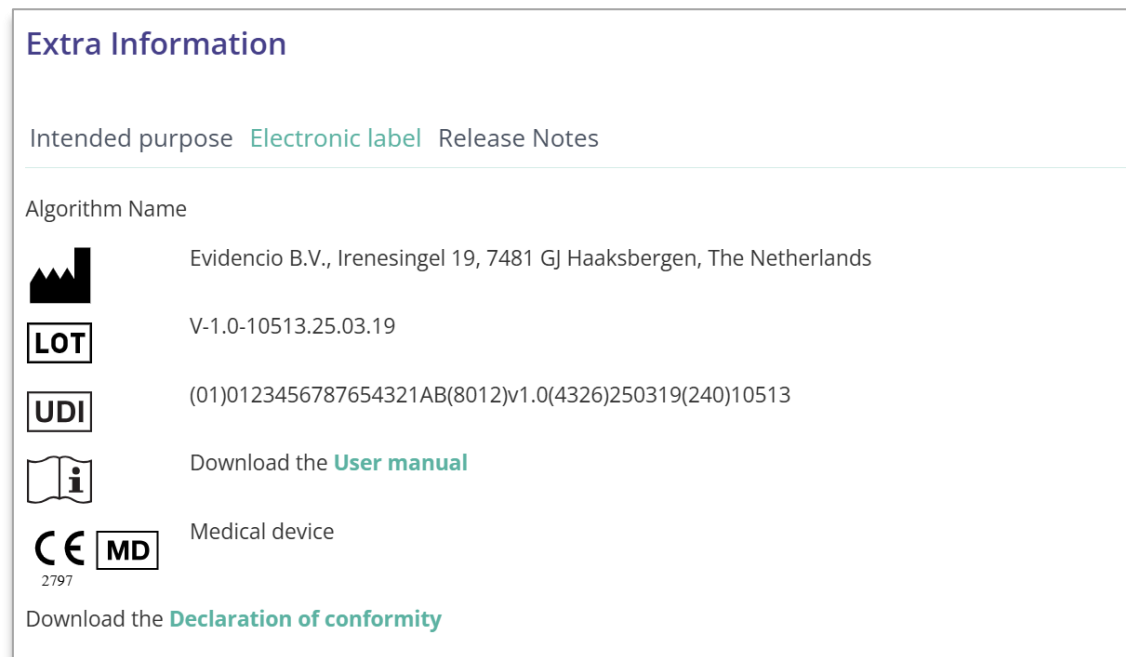


Figure 5. Example of an electronic label under the Electronic Label tab.

J. Release notes

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

The ‘Release Notes’ button opens a pop-up with the latest release notes of the algorithm. Here you can find a list of the most significant changes over the different versions of the algorithm. Additionally, if there are any known residual anomalies the user should be aware of, they are listed here. It is recommended to read these notes after a version update to see if these changes are relevant to you.

K. User manual

This user manual can be found in three places: 1) under the short description of the algorithm on the Evidencio algorithm 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.

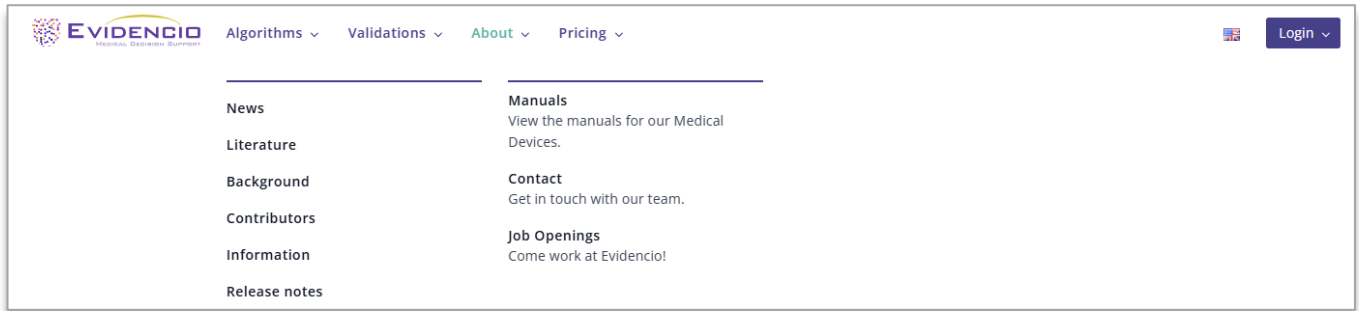


Figure 6. The drop-down menu where the user manual page can be found.

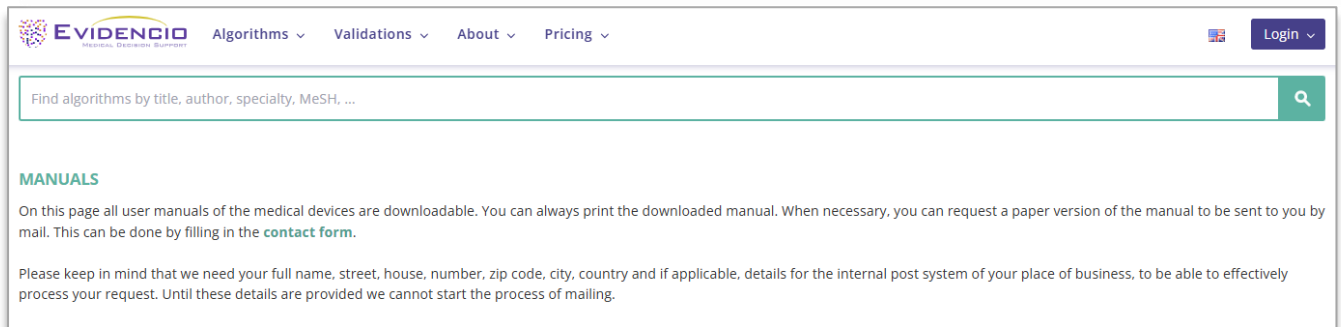


Figure 7. The user manual page for all user manuals.

L. Languages

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

Please note that, if a language is selected, only the user interface of the specific algorithm will be translated, other general features and information on the site might still be set to one of our primary languages English, German, and Dutch.

When you find mistranslations, irregularities, confusing or ambiguous use of language in English or any other language on the Evidencio website or in one of our manuals, please do not hesitate to contact us using the contact information provided at the end of this manual.

M. Version selection

If available, clicking on the Version-tab allows the user to select a different version of the ELAN-HF Score from a list as displayed in **Figure 8**. Please note that the algorithm version currently selected is not presented in the dropdown menu.



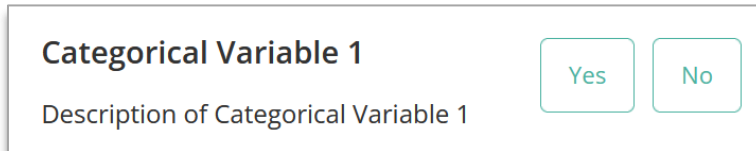
Figure 8. Example of version selection tab.

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**.

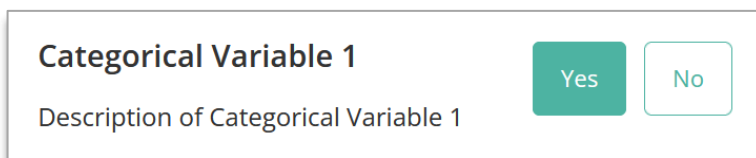


Categorical Variable 1

Description of Categorical Variable 1

Yes No

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



Categorical Variable 1

Description of Categorical Variable 1

Yes No

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

Continuous variables

In the example shown in **Figure 11**, the **Continuous Variable 3**, exemplifies a continuous variable. The plausible ranges for which the algorithm is tested and deemed valid are used.

The details for a patient can be entered by sliding the button to the correct value, or by entering the correct value in the box on the right-hand side (i.e., where the 10.2 mg/dL is entered for the **Continuous Variable 3**).



Continuous Variable 3

Description of Continuous Variable 3

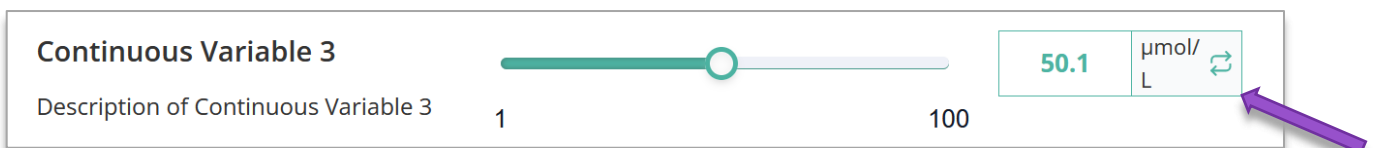
0.2 20

10.2 mg/dL

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.



Continuous Variable 3

Description of Continuous Variable 3

1 100

50.1 μmol/L

Figure 12. Example of a continuous variable where "50.1 μmol/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**.

The result of the algorithm's calculation is: ... points.

Set all parameters to calculate prediction.

Here a short section will be provided to help with the result interpretation. This piece of text can be general for all results, or can be shown depending when the certain conditions are met.

This can include statement into which the risk classification the calculated result can be stratified (e.g. **High, Moderate, Low**).

Also the performance data in the Internal and relevant External validation cohorts can be shown here such as but not limited to; the c-satistic, sensitivity, specificity together with the number of cases of the condition in scope within the cohort.

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

11. User manual revision history

Version	Revision notes
V1.0 JUL-2025	Original version
V2.0 OCT-2025	Updated conditional information in Ch. 7

12. Manufacturer details

Contact details of Evidencio:



Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands
www.evidencio.com
 tel: +31 53 85195 08
 e-mail: info@evidencio.com