User manual for the ADNEX model

Version 2.0, August 2025, in English

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1. The Evidencio platform

The Evidencio platform facilitates the creation, use, validation and implementation of medical prediction algorithms and clinical decision support tools. This User Manual specifically relates to the ADNEX 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 for CE-marked content

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

In general, and unless explicitly stated otherwise, CE-marked tools on Evidencio are only to be used by physicians in a clinical setting and are not for patient use.

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

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

Always read the intended use before using this tool.

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

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

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

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

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

3.1. Notice to the user

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

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

4. Device description ADNEX model

The ADNEX model is Medical Device Software (MDSW), that is hosted on the Evidencio platform. As an MDSW algorithm, the calculator is not a physical product and contains no tangible materials. The calculator does not involve, for example, packaging, sterilisation, or direct contact with the human body.

The ADNEX model is intended to support clinical decision making by estimating the risk of an adnexal mass being benign or malignant, as well as by estimating the risk of a malignant tumour being classified as borderline, stage I cancer, stage II-IV cancer, or as secondary metastatic ovarian tumour.

The ADNEX model was developed in a cohort that consisted of 3506 patients in a multicentre prospective population. A total of 51 studies validated the ADNEX model. Of those 51 studies, 27 studies were performed in Europe, 20 in Asia, two in the United States, and two in South America.

The MDSW's underlying mathematical formula are logistic regressions. The ADNEX model was developed to predict risk of ovarian cancer.

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

4.1. Lifetime, residual risks and side effects

The ADNEX 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 ADNEX model is a low-risk device, there are no noticeable risks involved outside of possible mis-estimation of a tumour being benign or malignant, as well as the risk of it being classified as borderline, stage I cancer, stage II-IV cancer, or as a secondary metastatic ovarian tumour, and all residual risks are accepted.

Most risks can be defined into two main groups, depending on their outcome.

a) The risk calculation was wrong or;
b) The MDSW prediction algorithm is inaccessible.

A wrong risk calculation can be the result of erroneous input values or an error in the mathematical calculation. Technical risks, including the erroneous calculations or the inaccessibly due to a technical error, have been mitigated when possible. These measures focussed on reducing the risks' probability and severity. Concluding that the risks could not be mitigated further, the residual risks were classified as *low-level and acceptable.* It should be noted that the use of Evidencio's Medical Device Software is itself a risk mitigation measure, as Evidencio's certified Quality Management System ensures and monitors the reliability of the calculations performed with its certified medical devices.

The ADNEX 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**	ADNEX model
	Manufacturer information	Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands
LOT	**LOT number**	V-2.0-945.25.08.08
UDI	**UDI number**	(01)08720938015311(8012)v2.0(4326)250808(240)945
MD	**MD indication**	Medical device

The electronic label can be found on the Evidencio website, see also section **I** and **Figure 5** in **Chapter 10**.

The electronic label on the website further contains the option to download the **User Manual** and **Declaration of conformity** (DoC).

5.1. LOT number

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

5.2. UDI number

Stands for Unique Device Identifier (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 ADNEX model is intended to be used by healthcare professionals who are capable of operating the device and interpreting its results. It can be used to estimate the risk of an adnexal mass being benign or malignant, as well as estimating the risk of a malignant tumour being classified as borderline, stage I cancer, stage II-IV cancer, or as a secondary metastatic ovarian tumour.

The ADNEX model combines Age, Oncology center, Maximal diameter of the lesion, Maximal diameter of the largest solid part, Cyst locules, Number of papillations, Acoustic shadow present, Ascites present, and Serum CA-125 to estimate the risk of a tumour being benign or malignant in women with an adnexal mass, as well as estimating the risk of a malignant tumour being classified as borderline, stage I cancer, stage II-IV cancer, or as a secondary metastatic ovarian tumour. Of the inputs, the level of serum CA-125 is optional, though the ability to distinguish between malignant tumour types is reduced without serum CA-125.

The device is intended to be used for women presenting to secondary care with an adnexal mass. The result of the ADNEX model is intended to be reviewed and interpreted by qualified medical specialists only. The device is not intended for use by patients on their own.

The ADNEX model is not intended to replace clinical decision-making. It provides users with estimated risks of an adnexal mass being benign or malignant and further categorizes malignant tumours into borderline, stage I cancer, stage II-IV cancer, or secondary metastatic. The user can use this information to support clinical decision-making regarding the diagnosis of the adnexal mass of the patient. In practice, this typically entails decisions surrounding optional surgical dissection or selecting and prioritising diagnostic tests.

6.2. Clinical benefit

The ADNEX model is intended to assist healthcare professionals with patients that have relevant and specified clinical outcome parameters. Concretely, this is achieved by estimating a risk to support clinical decision-making aimed at women with an ovarian mass, to support clinical decision-making regarding patient prognosis. Correct functioning of the ADNEX model can result in these clinical benefits:

- The ADNEX model 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.
- Digital implementation of the algorithm underlying the ADNEX model 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.

6.3. Indented target population and exclusion

The ADNEX model is intended to be used only for a specific group of patients, corresponding to the clinical indications and clinical contra-indications stated below.

6.3.1. Clinical indications

The ADNEX model should be used for patients who meet the following inclusion criteria:

- Patients with at least one adnexal mass judged not to be a physiological cyst.
- Patients aged 18 years or older.
- Patients who have been examined with transvaginal ultrasound.

6.3.2. Clinical contra-indications

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

- Patients who are pregnant.

6.4. User profile

The ADNEX model is intended to be used in three ways; by healthcare professionals using the algorithm interface on the Evidencio website or an image of the algorithm hosted by a distributor, or by using an automatic calculation through Evidencio's API. Results shall always be reviewed and interpreted by qualified healthcare professionals only, in the context of the patient's clinical history and other diagnostic test results. Healthcare professionals do not require additional training prior to the use of the medical device. The device is not intended for use by patients on their own.

6.5. Intended use environment

The MDSW can be used as made available on the Evidencio platform in any actively supported web-browser on personal computers, mobile devices, or tablet PCs. The MDSW can also be used through Evidencio's iFrame representation as an embedded view, provided that the specific Evidencio guidelines for iFrame implementations of this MDSW are adhered to. Automated calculation of the device is enabled through Evidencio's API. The device is only intended for use in healthcare settings where the immediate application and outcomes of the device are not required.

6.6. Physical interaction

The MDSW is stand-alone software and does not come into contact with any bodily or other material of the patient, user or otherwise.

6.7. Versions of the MDSW

The version of the ADNEX 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 a multinomial 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 ADNEX model are provided in the instructions for use. Entering the details for an individual in the MDSW initiates the risk estimation of an adnexal mass being benign or malignant, as well as estimating the risk of a malignant tumour being classified as borderline, stage I cancer, stage II-IV cancer, or as a secondary metastatic ovarian tumour.

7. Result interpretation

The outcome of the MDSW is a polytomous risk that distinguishes between six types of adnexal masses (benign, malignant, borderline, stage I invasive, stage II-IV invasive, and secondary metastatic cancer).

The primary output of the device is given as a bar chart consisting of a bar that presents the risk of adnexal mass being benign or malignant, as well as a bar that presents the risk of the adnexal mass being classified as Borderline, Stage I, Stage II-IV and Secondary metastatic.

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	T. A. Hueting
Root algorithm ID	945
Version	2.0
Revision date	08 AUG 2025
Speciality	Gynaecology, Oncology
Algorithm type	R-script
MeSH terms	• Gynecology • Surgical Oncology • Ovarian Cancer

8.2. Input variables

To perform the calculations successfully, the ADNEX model requires the input variables as listed in **Table 1**

Table 1. Variables used as input for the ADNEX model.

Name	Description	Type	Range (step size)	Units
Age	The age of the patient.	Continuous	18-100 (1)	Year
Oncology center	Is the center in question a tertiary referral center with a specific gynecological unit?	Categorical	No Yes	-
Maximal diameter of the lesion	Largest of the diameters measured in three perpendicular planes.	Continuous	8-400 (1)	mm
Maximal diameter of the largest solid part	The maximal diameter of largest solid part.	Continuous	0-400 (1)	mm
Cyst locules	Is the lesion multilocular or multilocular-solid with more than 10 cystic locules that are separated by septa?	Categorical	0-10 >10	-
Number of papillations	(papillary projections) papillations must be at least 3 mm.	Categorical	None 1 2 3 >3	-
Acoustic shadow present	Presence of acoustic shadows is defined as loss of an acoustic echo behind a sound-absorbing structure.	Categorical	No Yes	-
Ascites present	Is there fluid outside the pelvis present?	Categorical	No Yes	-
Serum CA-125	The Serum CA-125 level of the patient.	Continuous	1-30000 (1)	U/mL

Formula

Table 2. The formulas for the ADNEX model.

P (Benign)	$\frac{\mathbf{1}}{\mathbf{1}+\mathbf{exp}(z\mathbf{1})+\mathbf{exp}(z\mathbf{2})+\mathbf{exp}(z\mathbf{3})+\mathbf{exp}\,(z\mathbf{4})}$
P (Borderline)	$\frac{\exp\,(z1)}{1+\exp(z1)+\exp(z2)+\exp(z3)+\exp\,(z4)}$
P (Stage I cancer)	$\frac{\exp\,(z2)}{1+\exp(z1)+\exp(z2)+\exp(z3)+\exp\,(z4)}$
P (Stage II-IV cancer)	$\frac{\exp\,(z3)}{1+\exp(z1)+\exp(z2)+\exp(z3)+\exp\,(z4)}$
P (Metastatic cancer)	$\frac{\exp\,(z4)}{1+\exp(z1)+\exp(z2)+\exp(z3)+\exp\,(z4)}$

In the above-mentioned formulas z1, z2, z3 and z4 refer to the linear predictors in the logistic regression. The linear predictors contain model coefficients for each predictor: the prediction of borderline vs. benign tumours (z1), stage I cancer vs. benign tumours (z2), stage II-IV cancer vs. benign tumours (z3), and secondary metastatic cancer vs. benign tumours (z4). The overall risk of a malignant ovarian tumour is calculated through simple addition of the risk of the four subcategories of malignant tumours.

The linear predictors for are ADNEX model with CA-125 are defined as follows:

$$z1 = -7.577663 + 0.004506*A + 0.111642*Log2(B) + 0.372046*Log2(C) + 6.967853*(D/C) - 5.65588*(D/C)^2 + 1.375079*E + 0.604238*F - 2.04157*G + 0.971061*H + 0.953043*I$$

$$z2 = -12.276041 + 0.017260*A + 0.197249*Log2(B) + 0.873530*Log2(C) + 9.583053*(D/C) - 5 .83319*(D/C)^2 + 0.791873*E + 0.400369*F - 1.87763*G + 0.452731*H + 0.452484*I$$

$$z3 = -14.915830 + 0.051239*A + 0.765456*Log2(B) + 0.430477*Log2(C) + 10.37696*(D/C) - 5.70975*(D/C)^2 + 0.273692*E + 0.389874*F - 2.35516*G + 1.348408*H + 0.459021*I$$

$$z4 = -11.909267 + 0.033601*A + 0.276166*Log2(B) + 0.449025*Log2(C) + 6.644939*(D/C) - 2.30330*(D/C)^2 + 0.899980*E + 0.215645*F - 2.49845*G + 1.636407*H + 0.808887*I$$

The linear predictors for the ADNEX model without CA-125 are defined as follows:

$$Z1 = -7.412534 + 0.003489*A + 0.430701*log2(C) + 7.117925*(D/C) - 5.74135*(D/C)^2 + 1.343699*E + 0.607211*F - 2.11885*G + 1.167767*H + 0.983227*I$$

$$z2 = -12.201607 + 0.017607*A + 0.98728*log2(C) + 10.07145*(D/C) - 6.17742*(D/C)^2 + 0.763081*E + 0.410449*F - 1.98073*G + 0.77054*H + 0.543677*I$$

$$z3 = -12.826207 + 0.045172*A + 0.759002*log2(C) + 11.83296*(D/C) - 6.64336*(D/C)^2 + 0.316444*E + 0.390959*F - 2.94082*G + 2.691276*H + 0.929483*I$$

$$z4 = -11.424379 + 0.033407*A + 0.560396*log2(C) + 7.264105*(D/C) - 2.77392*(D/C)^2 + 0.983394*E + 0.199164*F - 2.63702*G + 2.185574*H + 0.906249*I$$

[A]= patients age (years), [B]= serum CA-125 (U/mL), [C]= maximal diameter of lesion (mm), [D]= maximal diameter of largest solid component (mm), [E]= more than 10 cyst locules (1 or 0), [F]= number of papillary structures (0, 1, 2, 3, 4, with 4 indicating more than three), [G]= acoustic shadows (1 or 0), [H]= ascites (1 or 0), [I]= examination at oncology centre (1 or 0).

Note: The ADNEX model can be used with and without serum CA-125, though the ability to distinguish between malignant tumour types is reduced without serum CA-125.

8.3. Study characteristics

Van Calster et al. who presented the ADNEX model in their 2014 paper, described the derivation as follows;

"We developed a prediction model using data from the women included in IOTA phases 1, 1b, and 2 (n=3506) and validated the model on data from the women included in phase 3 (n=2403). To acknowledge variability between centres we used multinomial logistic regression with random centre intercepts to construct the polytomous model. We multiplied the predictor coefficients with uniform "shrinkage factors" to avoid exaggerated model coefficients. We trained the model on each of the 100 completed datasets following multiple imputation. Probabilities were derived by averaging linear predictors (without the random effects) and odds ratios by averaging model coefficients. We included nine variables in the Assessment of Different NEoplasias in the adneXa (ADNEX) model: age, serum CA-125 level (log transformed), type of centre, maximum diameter of the lesion (log transformed), proportion of solid tissue (with quadratic term), number of papillary projections, more than 10 cyst locules, acoustic shadows, and ascites. Family history of ovarian cancer was dropped by the variable selection analysis."

In the tables, **Table 3** and **Table 4** information on the characteristics of the patient data used to derive and validate the algorithm is provided.

Table 3. This table contains information on the patient group data used to derive and validate the ADNEX model.

Name	Benign	Borderline	Stage I	Stage II-V	Metastatic
Median age (IQR)	42 (32-54)	49 (36-62)	54 (44-64)	59 (50-67)	57 (47-68)
Median serum CA-125 (U/ml)	18 (11-39)	30 (16-86)	51 (20-195)	442 (145-1238)	91 (29-271)
Family history of ovarian cancer (%)	79 (2.0)	10 (3.0)	13 (3.7)	57 (5.8)	5 (2.0)
Median (IQR) maximal diameter of lesion (mm)	63 (45-87)	86 (51-150)	106 (71-153)	85 (56-123)	86 (56-124)
Solid tissue:					
Presence of solid tissue (%)	1322 (33.2)	267 (78.8)	328 (92.1)	968 (98.0)	234 (95.1)
Median (IQR) proportion of solid tissue if present (%)	42 (20-100)	37 (24-59)	61 (38-100)	100 (56-100)	100 (64-100)
No of papillary projections %:					
0	3424 (86.0)	135 (39.8)	227 (63.8)	772 (78.1)	213 (86.6)
1	333 (8.4)	69 (20.4)	25 (7.0)	56 (5.7)	12 (4.9)
2	80 (2.0)	21 (6.2)	17 (5.8)	30 (3.0)	0 (0)
3	66 (1.7)	24 (7.1)	17 (4.8)	28 (2.8)	2 (0.8)
>3	77 (1.9)	90 (26.5)	70 (19.7)	102 (10.3)	19 (7.7)
>10 cyst locules (%)	199 (5.0)	74 (21.8)	69 (19.4)	93 (9.4)	36 (14.6)
Acoustic shadows (%)	676 (17.0)	8 (2.4)	18 (5.1)	30 (3.0)	10 (4.1)
Ascites (%)	64 (1.6)	28 (8.3)	65 (18.3)	473 (47.9)	90 (36.6)
Missing values for CA-125 (%)	1447 (36.4)	62 (18.3)	71 (19.9)	163 (16.5)	62 (25.2)

Table 4. This table contains categorical characteristics on the patient group data used to derive and validate the ADNEX model.

Name	Number of patients
Total	5909
Benign	3980
Borderline	339
Stage I	356
Stage II-IV	988
Metastatic	246

8.4. Supporting publication & Related files

Several relevant studies, such as the original derivation study by Van Calster *et al*. (2014) are 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 + supplementary material	**Evaluating the risk of ovarian cancer before surgery using the ADNEX model to differentiate between benign, borderline, early and advanced stage invasive, and secondary metastatic tumours: prospective multicentre diagnostic study** *Van Calster et al. (2014)* https://www.bmj.com/content/349/bmj.g5920.long **DOI:** 10.1136/bmj.g5920
Validation study + supplementary material	**Benign descriptors and ADNEX in two-step strategy to estimate risk of malignancy in ovarian tumors: retrospective validation in IOTA5 multicenter cohort** *Landolfo et al. (2023)* https://pubmed.ncbi.nlm.nih.gov/36178788/ **DOI:** 10.1002/uog.26080
Practical guidance	**Practical guidance for applying the ADNEX model** *Van Calster et al. (2015)* *https://pubmed.ncbi.nlm.nih.gov/25897370/*
Validation study	**Validation of models to diagnose ovarian cancer in patients managed surgically or conservatively: multicentre cohort study** *Van Calster et al. (2020)* https://pubmed.ncbi.nlm.nih.gov/32732303/ **DOI:** 10.1136/bmj.m2614

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 ADNEX model: https://www.evidencio.com/models/show/945?v=2.0, 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 ADNEX model can be used through Evidencio's API to allow for (automated) calculation of the risk of a tumour being benign or malignant, as well as the risk of a malignant tumour being classified as borderline, stage I cancer, stage II-IV cancer, or as a secondary metastatic ovarian tumour. In the case of use of the MDSW through the API, the user should take into account the different inputs for the algorithm, in order to properly interpret the results.

Instructions on how to implement the API within a system are included in a separate document that is made available to the party performing the technical implementation.

When using the MDSW through the API, the warnings and descriptions given in this document all apply, as does the additional information. The information for use included in this document regards both use through the website as well as use through the API, as long as the API is properly implemented. The API is only intended for authorized users.

10. Using the algorithm on the Evidencio website

Using the tool on the Evidencio website requires a stable internet connection. The tool was developed to work on the four most commonly used internet browsers; Google Chrome (version 135.0.7049.115 and higher), Mozilla Firefox (version 137.0.2 and higher), Microsoft Edge (version 135.0.3179.98 and higher), and Apple Safari (version 18.4 and higher). The medical device cannot be used in combination with Internet Explorer.

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

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

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

Furthermore, the algorithm may be used through the Evidencio iFrame representation of the calculator, as an embedded view, provided that the specific Evidencio guidelines for iFrame implementations of that algorithm are adhered to.

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

The MDSW is intended for authorised users only, and should not be used by unauthorised personnel.

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

10.1. General algorithm landing page

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

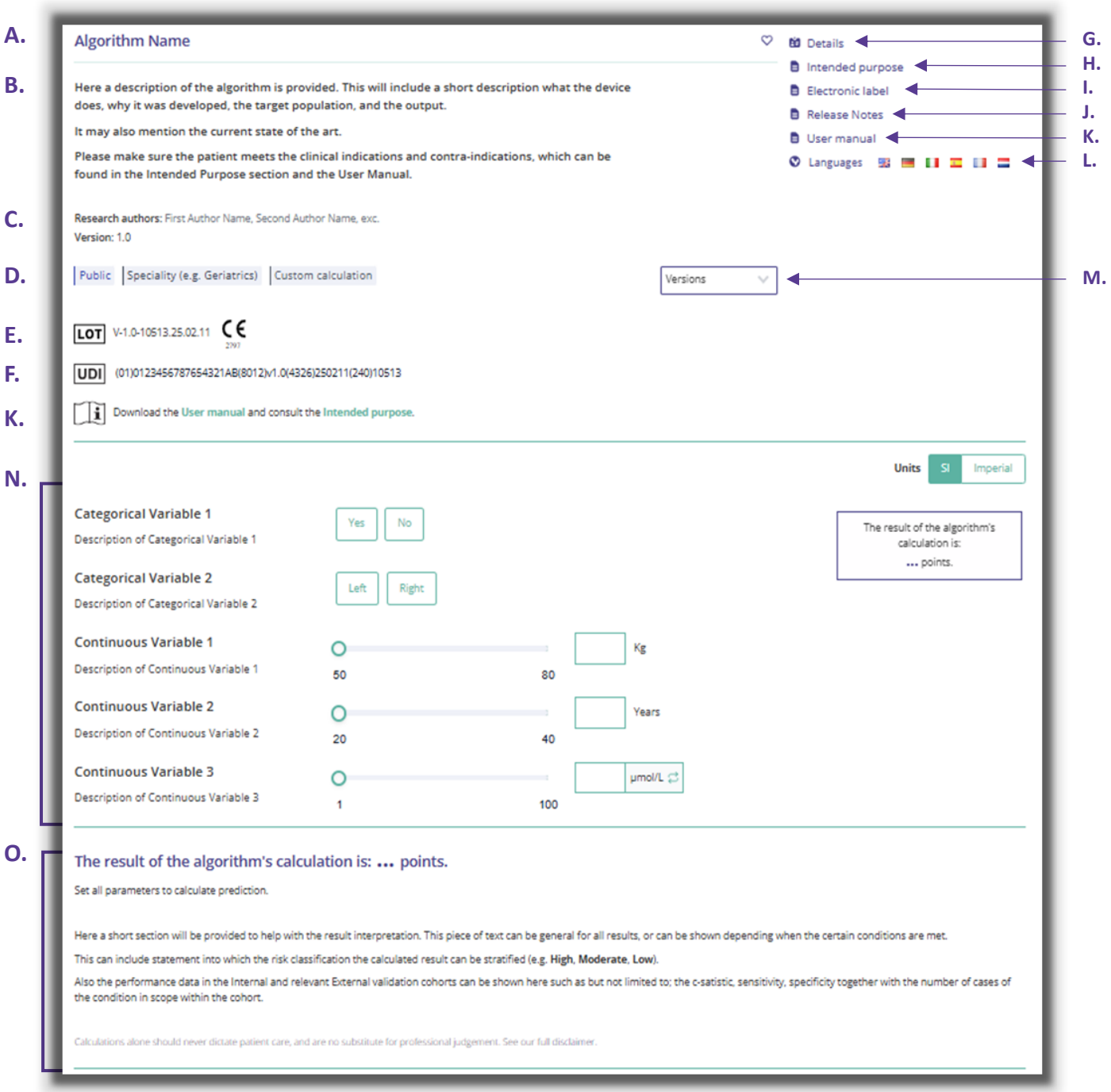


Figure 1. Example of an algorithm landing page on the Evidencio website.

A. Algorithm title

This is the title and name of the algorithm.

B. Algorithm description

This is a short description of the algorithm.

C. Research authors

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

D. Algorithm tags

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

E. LOT number

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

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

F. UDI-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.

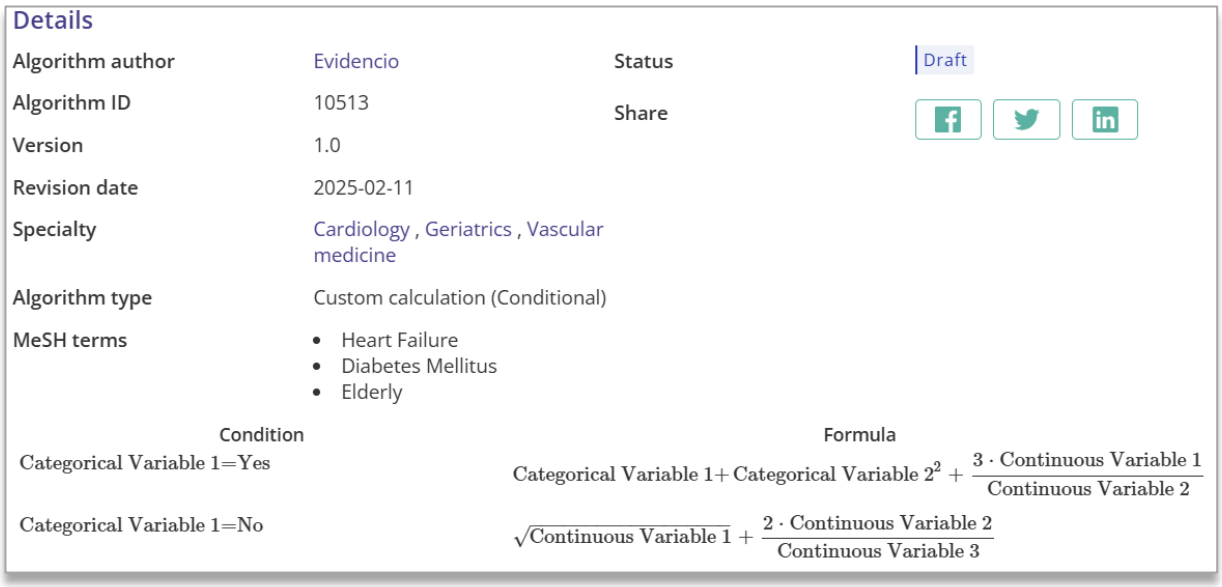
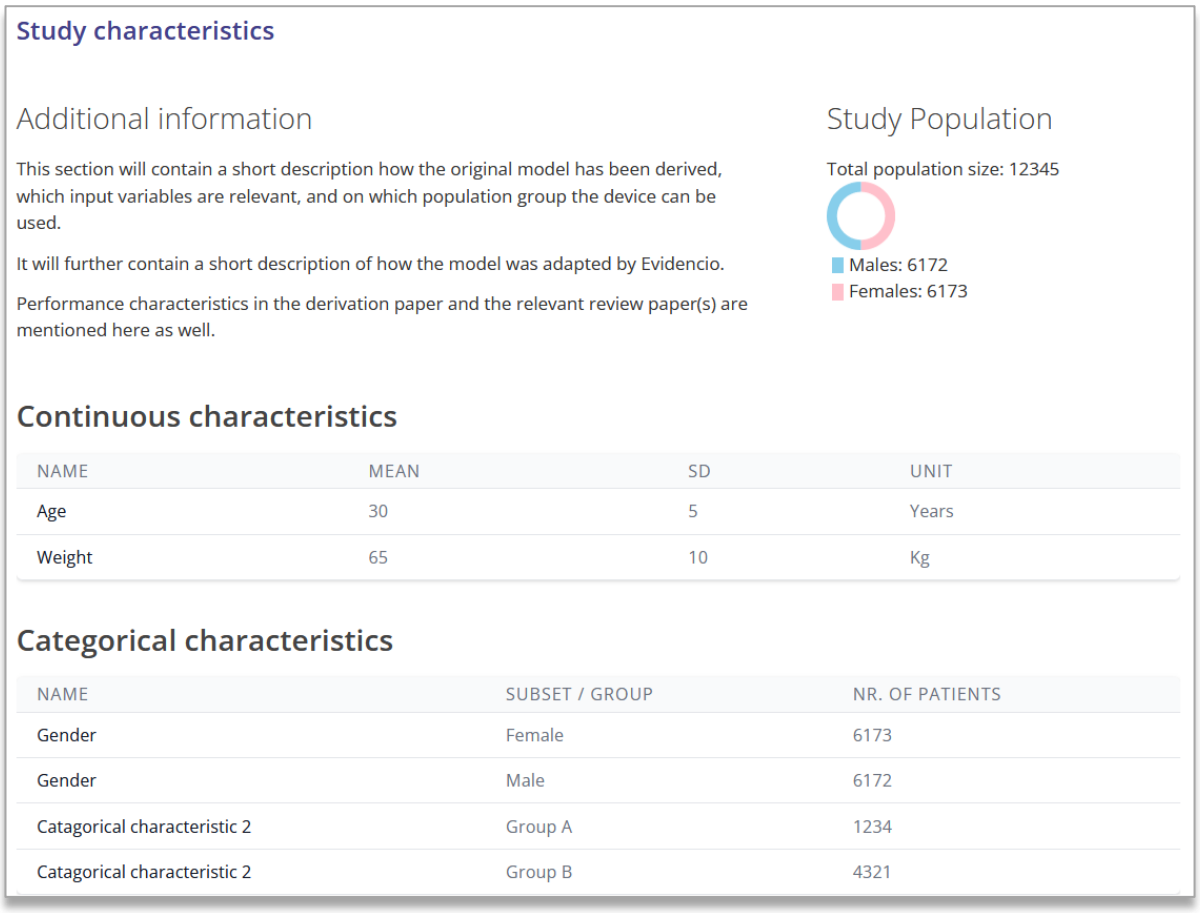


Figure 2. Example of first part of detail section.

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**.



Study characteristics

Additional information

This section will contain a short description how the original model has been derived, which input variables are relevant, and on which population group the device can be used.

It will further contain a short description of how the model was adapted by Evidencio.

Performance characteristics in the derivation paper and the relevant review paper(s) are mentioned here as well.

Study Population

Total population size: 12345

Males: 6172
Females: 6173

Continuous characteristics

NAME	MEAN	SD	UNIT
Age	30	5	Years
Weight	65	10	Kg

Categorical characteristics

NAME	SUBSET / GROUP	NR. OF PATIENTS
Gender	Female	6173
Gender	Male	6172
Catagorical characteristic 2	Group A	1234
Catagorical characteristic 2	Group B	4321

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**.

Supporting Publications

Title or description
Title Derivation Paper
DOI: DOI: 10.1234/ABCD.1234.5678

Title External Validation
DOI: DOI: 10.1234/ABCD.1234.5678
Title Peer Review Paper
DOI: DOI: 10.1234/ABCD.1234.5678

Tags
Original calculator
Internal validation
External validation
Peer review

Related files

Preview | Name | Tags

Derivation Paper.pdf
24.93 KB
Original calculator
Internal validation

External Validation.pdf
24.93 KB
External validation

Peer Review Paper.pdf
24.93 KB
Peer review

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 6**.

I. Electronic label

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

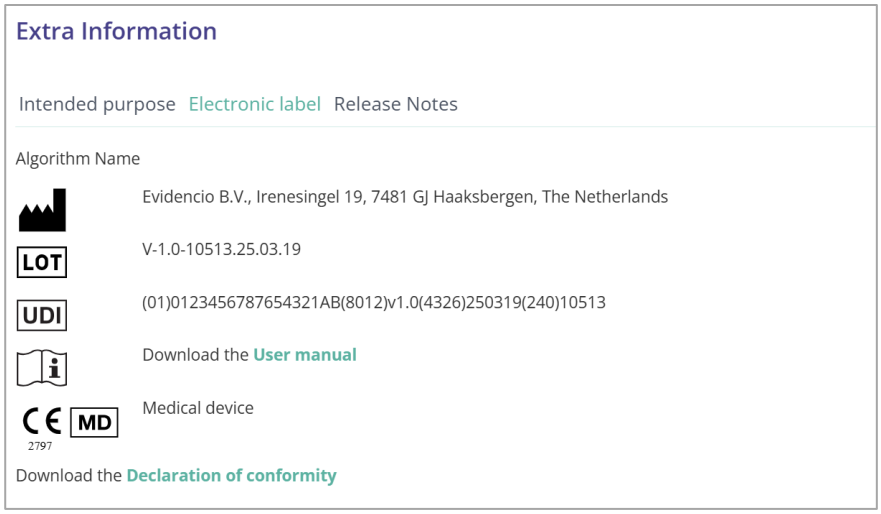


Figure 5. Example of an electronic label under the Electronic Label tab.

J. Release notes

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

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

K. User manual

This user manual can be found in three places: 1) under the short description of the algorithm on the Evidencio algorithm page, 2) on the right of the algorithm page, and 3) as a tab in the electronic label screen. Additionally, all versions of the user manual can be found in the general page for all user manuals for medical devices. The page can be found under the ‘About’ drop-down menu button as shown in **Figure 6**. The user manual page is shown in **Figure 7**. This version of the manual can be printed if required. If necessary, a paper version of the manual can be requested to be sent to you by mail. Evidencio’s contact details are listed in **Chapter 12** of this user manual.

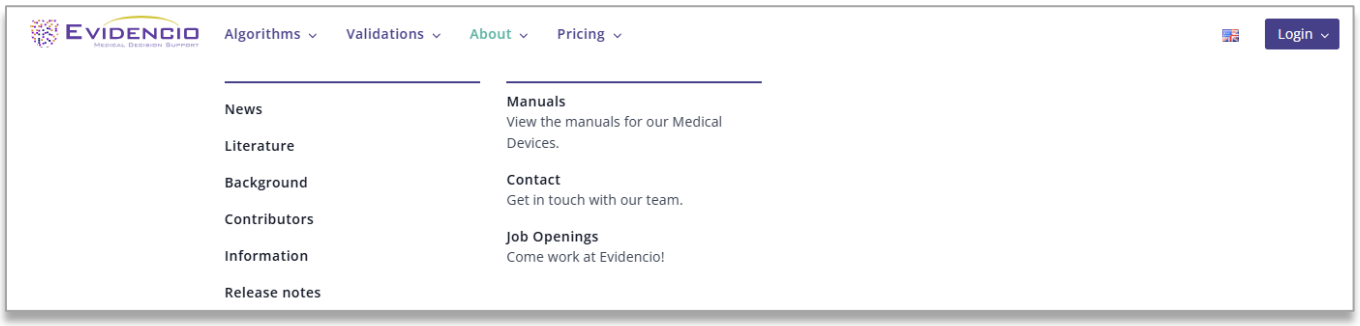


Figure 6. The drop-down menu where the user manual page can be found.

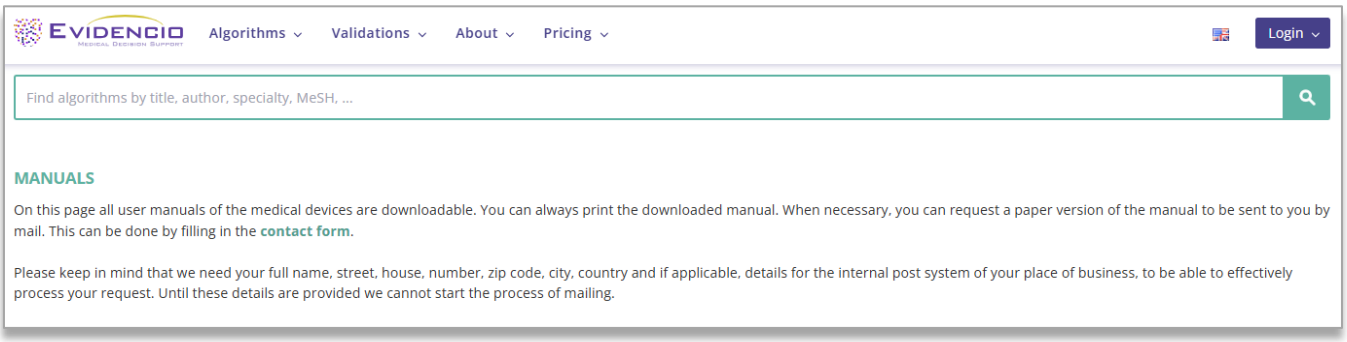


Figure 7. The user manual page for all user manuals.

L. Languages

Here an overview of languages in which the ADNEX 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 ADNEX model from a list as displayed in **Figure 8.** Please note that the algorithm currently selected is not presented in the dropdown menu.

Figure 8. Example of version selection tab.

N. Input section

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

Categorical variables

In the example shown in **Figure 9** and **Figure 10**, the example **Categorical Variable 1** concerns a categorical variable. The input that is wished to be used can be entered by clicking on either button. The selected button changes to green, as seen in **Figure 10**.

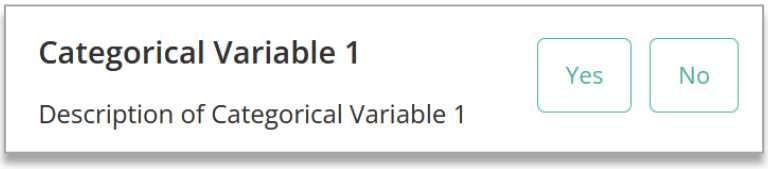


Figure 9. Example of a categorical variable, no button has been clicked and thus no input has been provided by the user.

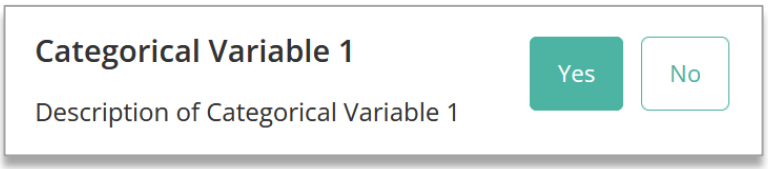


Figure *10*. Example of a categorical variable, where the "Yes" button has been clicked.

Continuous variables

In the example shown 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**).

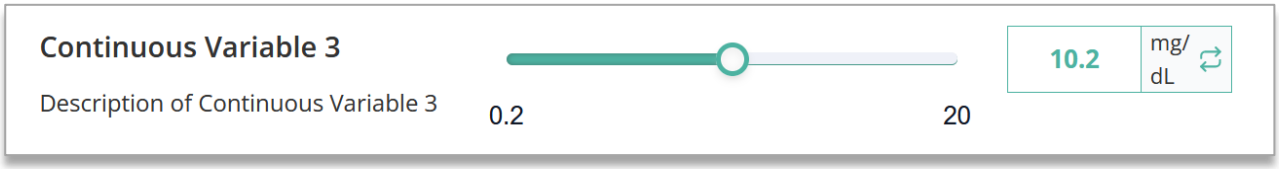


Figure *11*. Example of a continuous variable, where "10.2 mg/dL" has been entered.

Unit conversion

Sometimes it is possible to use a unit conversion, by clicking on the unit when the green arrows are present. See **Figure 12** below where the unit has been clicked and switched.

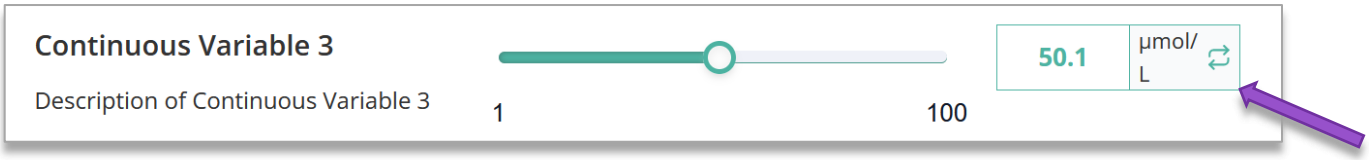


Figure *12*. Example of a continuous variable where "50.1 $\mu mol/L$" has been entered.

Details on variable measurements

Directly underneath the name for each variable, additional details can be provided on, for example, the methods required to enter the correct value for each variable. Details may include but are not limited to; more detailed explanation of the variable, the ranges of the variables (for healthy individuals), or a description when a continuous variable should be true or false.

O. Result section

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

Calculations alone should never dictate patient care and are no substitute for professional judgement. See our full disclaimer on: https://www.evidencio.com/disclaimer.

Result calculation

When all variables are filled in, and the user presses calculate, a result will be calculated. No result is displayed until all variables are filled in and the result section will indicate; *"Set all parameters to calculate prediction."*

Result interpretation

In the result interpretation, a stratification may be provided based on the calculated results. Additional information about this stratification and the classification as found in the derivation and important validation cohorts may also be provided. An example of the information is shown in **Figure 13**.

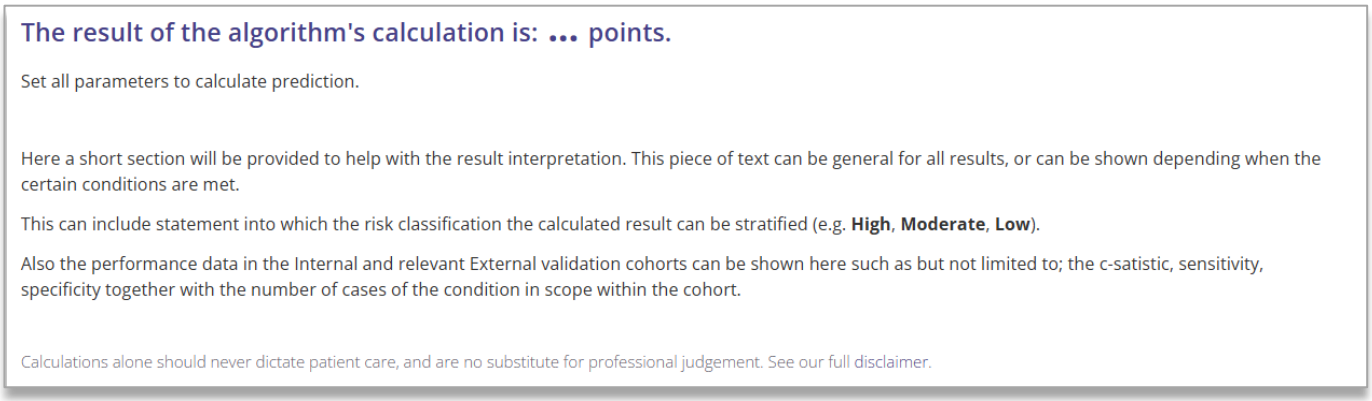


Figure 13. Example of the result display and information section.

11. User manual revision history

Version	Revision notes
V1.0 JUL-2025	Original version
V2.0 AUG-2025	Updated chapter 4 device description

12. Manufacturer details

Contact details of Evidencio:

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