User manual for the ROMA™

ROMA™ (for postmenopausal patients)
ROMA™ (for premenopausal patients)

Version 1, March 2026, in English

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1. The Evidencio platform

The Evidencio platform facilitates the creation, use, validation and implementation of medical prediction algorithms and clinical decision support tools. This User Manual specifically relates to the ROMA™, which covers the ROMA™ (for postmenopausal patients) and the ROMA™ (for premenopausal patients). The User Manual can also be referred to as the Instructions For Use (IFU). The ROMA™ meets the requirements laid down in: Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. Compliance with the applicable regulations is provided by means of declaration of conformity.

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 ROMA™

The ROMA™ is a collective name used here to refer to two related medical devices, which can be used independent. Both the ROMA™ (for premenopausal patients) and the ROMA™ (for postmenopausal patients) can be used to estimate the risk of ovarian malignancy in premenopausal and postmenopausal patients who present with an ovarian adnexal mass. The algorithm combines a patient's serum concentration of Elecsys HE4 assay, Elecsys CA125 II assay and menopausal status to calculate the risk of ovarian malignancy.

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

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

4.1. Lifetime, residual risks and side effects

The ROMA™ 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 ROMA™ is a low-risk device, there are no noticeable risks involved outside of possible mis-estimation of patient risk for an ovarian malignancy, 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.*

The ROMA™ 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**	ROMA™
	Manufacturer information	Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands
LOT	**LOT number**	V-1.31-9927.26.03.17 V-1.32-9927.26.03.17
UDI	**UDI number**	(01)08720938015151(8012)v1.31(4326)260317(240)9927 (01)08720938015168(8012)v1.32(4326)260317(240)9927
IVD	**IVD indication**	*In vitro* diagnostic 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 indicates the algorithm version, the algorithm identifier, and the algorithm publication date. Publication date is indicated as YY.MM.DD.

5.2. UDI number

Stands for Unique Device Identifier (UDI) number, which is an international tool that helps users identify and find information on products. Evidencio's UDI's have the following format:

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

The UDI-DI (Device Identifier) number is a unique numeric code. For each medical device of Evidencio, a unique UDI-DI is ascribed. This UDI-DI is used as an "access key" for information stored in a unique device identification database (UDID). Information on Evidencio's medical devices can be found by searching for the UDI-DI number in the following data base: https://gepir.gs1.org/index.php/search-by-gtin.

The version number, also part of the UDI, is linked to one of the 2 device sub-models. Version 1.31 for ROMA™ (for premenopausal patients) and Version 1.32 for the ROMA™ (for postmenopausal patients).

6. Intended purpose

6.1. Intended use

The ROMA™ is an algorithm intended to use HE4 and CA-125 values obtained from an Elecsys HE4 assay and an Elecsys CA 125 II assay, respectively, to estimate the risk of malignancy in patients presenting with an ovarian adnexal mass, in order to support healthcare professionals with decisions surrounding optimal clinical management of the patient.

The ROMA™ is medical device software that automates the calculation of the formula. It requires quantitative inputs to provide a quantitative output (a risk percentage).

The ROMA™ is not intended to replace clinical decision-making; it can only provide information to the healthcare professional on the estimation of the risk of ovarian malignancy. The healthcare professional can use this information to support clinical decision-making regarding optimal clinical management of the patient presenting with an ovarian adnexal mass for whom a surgical intervention is planned. In practice, this typically entails the decision to triage high risk patients to surgeons in centers of excellence that are experienced in the management of patients with this disease resulting in a decreased morbidity and mortality.

6.2. Clinical benefit

The benefits and risks associated with the use of the ROMA™ for the patient are indirect. The benefits arise from clinical decisions made using the ROMA™ in combination with other clinical and patient-specific factors.

Correct functioning of the ROMA™ can result in the following clinical benefit:

- It can assist in risk stratification for patients who present with an ovarian adnexal mass.

6.3. Intended target population and exclusion

The ROMA™ is intended to be used for patients who fit the clinical indications and contra-indications listed below.

6.3.1. Clinical indications

The ROMA™ should be used for patients who meet the following inclusion criteria:

- Patients of 18 years or older.
- Patients whose menopausal status corresponds to that of the version of the algorithm, who present with an ovarian adnexal mass for which surgery is planned.
- Patients who are not yet referred to an oncologist.

6.3.2. Contra-indications

The ROMA™ should not be used for patients who meet the following exclusion criteria:

- Patients who are pregnant.
- Patients who have had a prior bilateral oophorectomy.

6.4. User profile

The result of the ROMA™ is intended to be reviewed and interpreted by healthcare professionals. Results shall always be reviewed and interpreted by healthcare professionals, in the context of the patient's clinical history and other diagnostic test results. Healthcare professionals do not require additional training prior to the use of the medical device. The device is not intended for use by patients on their own.

6.5. Intended use environment

The MDSW can be used as made available on the Evidencio platform in any actively supported web-browser on personal computers, mobile devices, or tablet PCs. Users can manually enter the required input data through the user interface. In addition, the MDSW is available as an embedded view via Evidencio's iFrame representation. Automated calculation of the device is enabled through Evidencio's API. The device is only intended for use in healthcare settings where the immediate application and outcomes of the device are not required. The device is not intended to be used at the bedside of the patient.

6.6. Physical interaction

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

6.7. History/versions of the MDSW

The current version of the MDSW concerns the ROMA™ (for premenopausal patients) and ROMA™ (for postmenopausal patients) of which Evidencio is the manufacturer.

7. Result interpretation

Primary outcome

The primary output of this device is given as a percentage of the estimated risk of ovarian malignancy.

This percentage allows risk stratification into **Low Risk** and **High Risk**. Evidencio uses a cutoff value based on a specificity of 75%.

For the ROMA™ (for premenopausal patients) patients are classified as **Low Risk** at **<11.4%** and **High Risk** at **≥11.4%**.

For the ROMA™ (for postmenopausal patients) patients are classified as **Low Risk** at **<29.9%** and **High Risk** at **≥29.9%**.

Conditional information

These cutoff values are based on a specificity of 75%, which is dependent on the assay used to determine the concentration of biomarkers in the patient's blood. Assays other than the Elecsys™ assays provided by Roche will have other specificities, requiring different cutoff values, and thus should not be used as input in the ROMA™ as implemented by Evidencio.

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	9227	
	Version	**Revision date**
ROMA™ (premenopausal patients)	V1.31	2026-03-17
ROMA™ (postmenopausal patients)	V1.32	2026-03-17
Speciality	Gynaecology, Oncology	
Algorithm type	Custom calculation	
MeSH terms	• Ovarian cancer • Gynecology • Surgical oncology	

8.2. Input variables

To perform the calculations successfully, both sub-models comprising the ROMA™ requires the input variables as listed in **Table 1.**

Table 1. Variables used as input for both sub-models of the ROMA™.

Name	Description	Type	Range (step size)	Units
Elecsys HE4 assay result	Concentration of human epididymis protein 4 in patient's blood measured with the Elecsys HE4 assay (including 1:20 dilution)	Continuous	15-30000 (0.1)	*pM*
Elecsys CA 125 II assay result	Concentration of carbohydrate antigen 125 in patient's blood measured with the Elecsys CA125 II assay (including 1:5 dilution)	Continuous	2-15000 (0.1)	*IU/mL*

8.3. Algorithm

The algorithms of the ROMA™ consist of logistic regressions as shown in equation 1, 2 and 3. The estimated probability for ovarian malignancy is calculated as described in equation 1 for premenopausal and as in equation 2 for postmenopausal patients.

For premenopausal patients the predictive Index (PI) is calculated by the following formula:

$$PI = \left(-12 + 2.38 \times ln(\boldsymbol{Elecsys\ HE4\ assay\ result}) + 0.0626 \times ln(\boldsymbol{Elecsys\ CA\ 125\ II\ assay\ result})\right) \quad (1)$$

For postmenopausal patients the predictive Index (PI) is calculated by the following formula:

$$PI = \left(-8.09 + 1.04 \times ln(\boldsymbol{Elecsys\ HE4\ assay\ result}) + 0.732 \times ln(\boldsymbol{Elecsys\ CA\ 125\ II\ assay\ result})\right) \quad (2)$$

The ROMA™ is calculated as follows:

$$ROMA^{TM} = \frac{e^{PI}}{1+e^{PI}} \cdot 100\%.$$

The equations above as described by Moore *et al.* (2009) were adapted for the implementation of Evidencio to a maximum predictive index of 7.5 to prevent ROMA™ outcomes of 100%, as a 100% certainty is not justifiable. Therefore, the second part of the calculation was adapted to equation 3.

For both models the Predictive Probability (PP) in percentages can be calculated by; $\frac{e^{\min((PI),7.5)}}{1+e^{\min((PI),7.5)}} \cdot 100\%$ (3)

8.4. Study characteristics

In the development paper by Moore *et al.* (2009) the derivation of the ROMA™ is described. In summation; total of 566 patients were enrolled from 12 different geographic sites across the United States. Of the 566 patients enrolled onto the trial, 531 patients were evaluable, with 283 postmenopausal women and 248 premenopausal women. A total of 54 women had menopausal status determined by plasma FSH levels, 47 of which had a prior hysterectomy with preservation of at least one ovary. The mean age of the evaluable study cohort was 54 years old (range: 18 to 87), with a mean age for postmenopausal women of 65 years old (range: 42 to 87) and for premenopausal 41 years old (range: 18 to 59). There were 352 women with benign disease (150 postmenopausal and 202 premenopausal) and 179 women with a malignancy diagnosed in the study group.

For the implementation of the ROMA™ on the Evidencio website, its performance was assessed with data from a total of 22.599 patients gathered through literature research.

8.5. Supporting publication & Related files

Several relevant studies, such as the original derivation study by Moore et al. (2009) are contained in **Table 3**. 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 *3*. Overview of selection of supporting publications & Related files.

Derivation study ROMA™	**A novel multiple marker bioassay utilizing HE4 and CA125 for the prediction of ovarian cancer in patients with a pelvic mass** (2009) *Richard G. Moore, D. Scott McMeekin, Amy K. Brown, Paul DiSilvestro, M. Craig Miller, W. Jeffrey Allard, Walter Gajewski, Robert Kurman, Robert C. Bast, Jr, and Steven J. Skatesh* DOI: *10.1016/j.ygyno.2008.08.031*
Validation study	**Validation of the Cut-points Recommended for ROMA Using the Roche Elecsys CA125 and HE4 Assays** (2018) *Kendall W Cradic, Michael A Lasho, and Alicia Algeciras-Schimnich* PMID: 29531002

8.6. Analytical performance characteristics

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

- A code review and functional test showed that the calculation of the online tool provides the exact same results as described in the paper by Moore *et al*. (2009).
- Monthly uptime reports show that the device is available online with an uptime of at least 99%.
- The calculation time is within 2 minutes, otherwise an error is given to the manufacturer, this is analysed each 6 months in the analysis of quality data.
- Absence of unacceptable cybersecurity vulnerabilities.

8.7. Clinical performance characteristics

A meta-analysis performed during the performance evaluation showed a C-statistic of 0.83 (95%CI: 0.78 - 0.87) for ROMA™ premenopausal patients and a C-statistic of 0.89 (95%CI: 0.79 - 0.94) for ROMA™ postmenopausal patients.

The ROMA™ achieved a specificity of at least 75.0% in almost all studies.

8.8. Release notes

The release notes for each publicly available version of the device can be found on the Evidencio website page for the ROMA™: https://www.evidencio.com/models/show/9927 selecting the correct device (version), and clicking on Release Notes. It is recommended to read these notes after a version update to see if these changes are relevant to you. Please make sure the correct algorithm version is selected.

9. 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.

9.1. General algorithm landing page

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

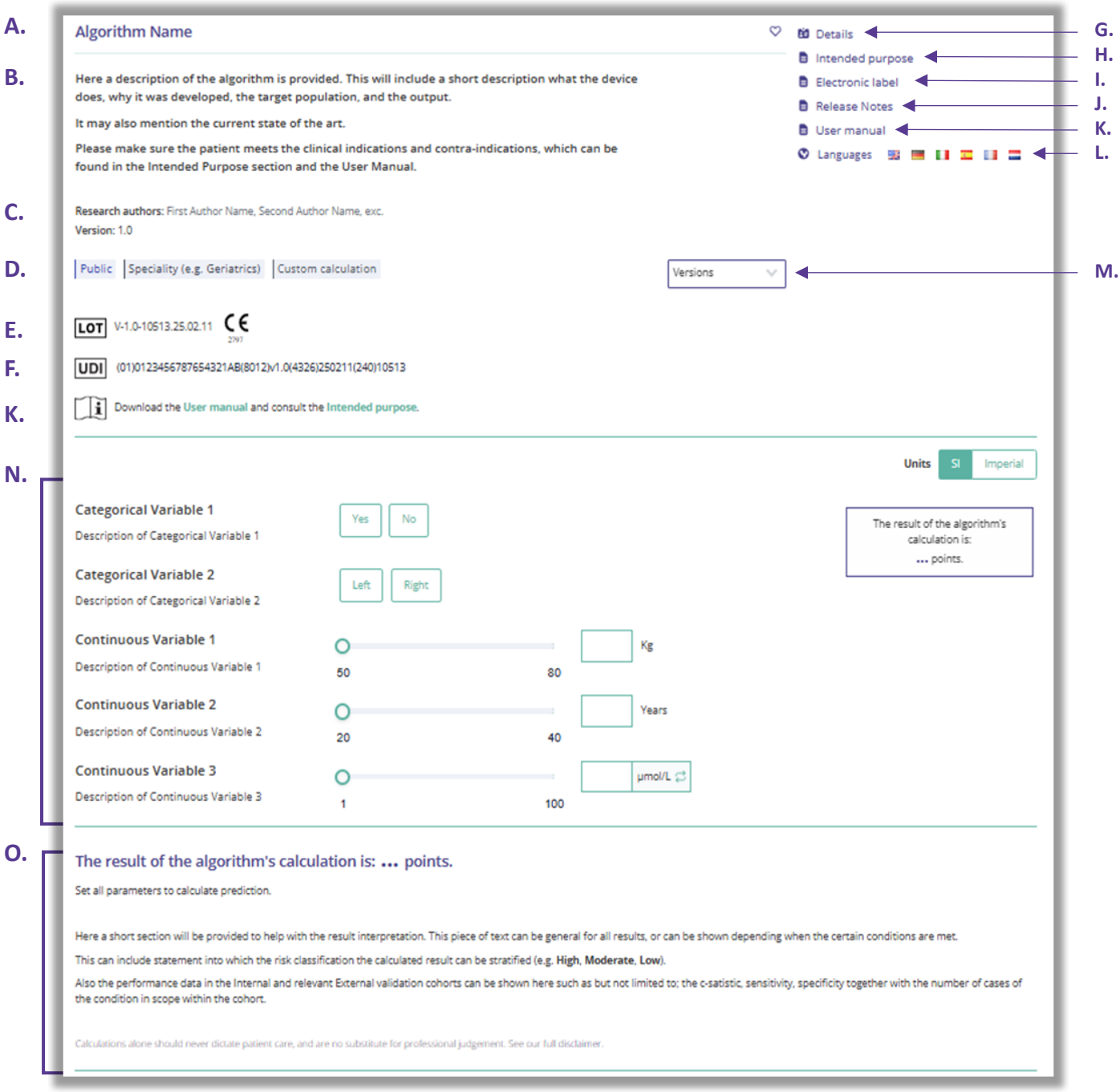

Figure 1. Example of an algorithm landing page on the Evidencio website.

A. Algorithm title

This is the title and name of the algorithm.

B. Algorithm description

This is a short description of the algorithm.

C. Research authors

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

D. Algorithm tags

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

E. LOT number

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

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

F. UDI Number

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

G. Details button

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

Details

The first part of the additional information concerns the details of the algorithm as shown in **Figure 2**. This section may show the calculation if it is built as a mathematical formula and, if applicable, shows the conditions at which certain formulas are used.

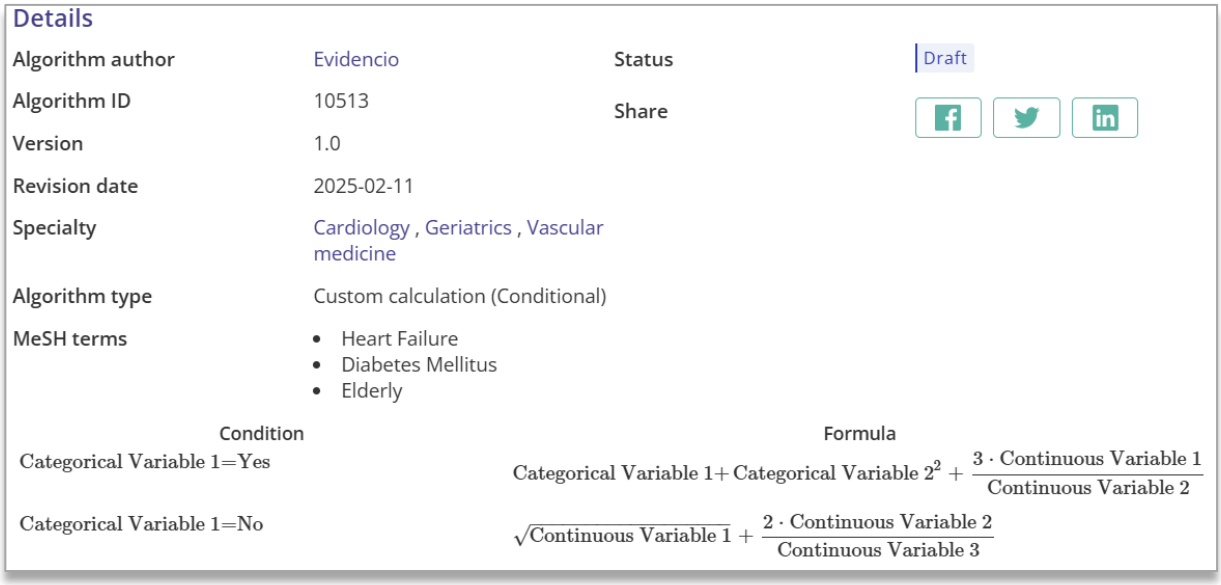

Figure 2. Example of first part of Details section.

Study Characteristics

Below the 'Details section' the section labelled "Study characteristics" provides information on the characteristics of the patient data used to derive and validate the algorithm. Additional information is provided on the methods used to develop and/or validate the algorithm. An example of the Study characteristics section can be seen in **Figure 3**.

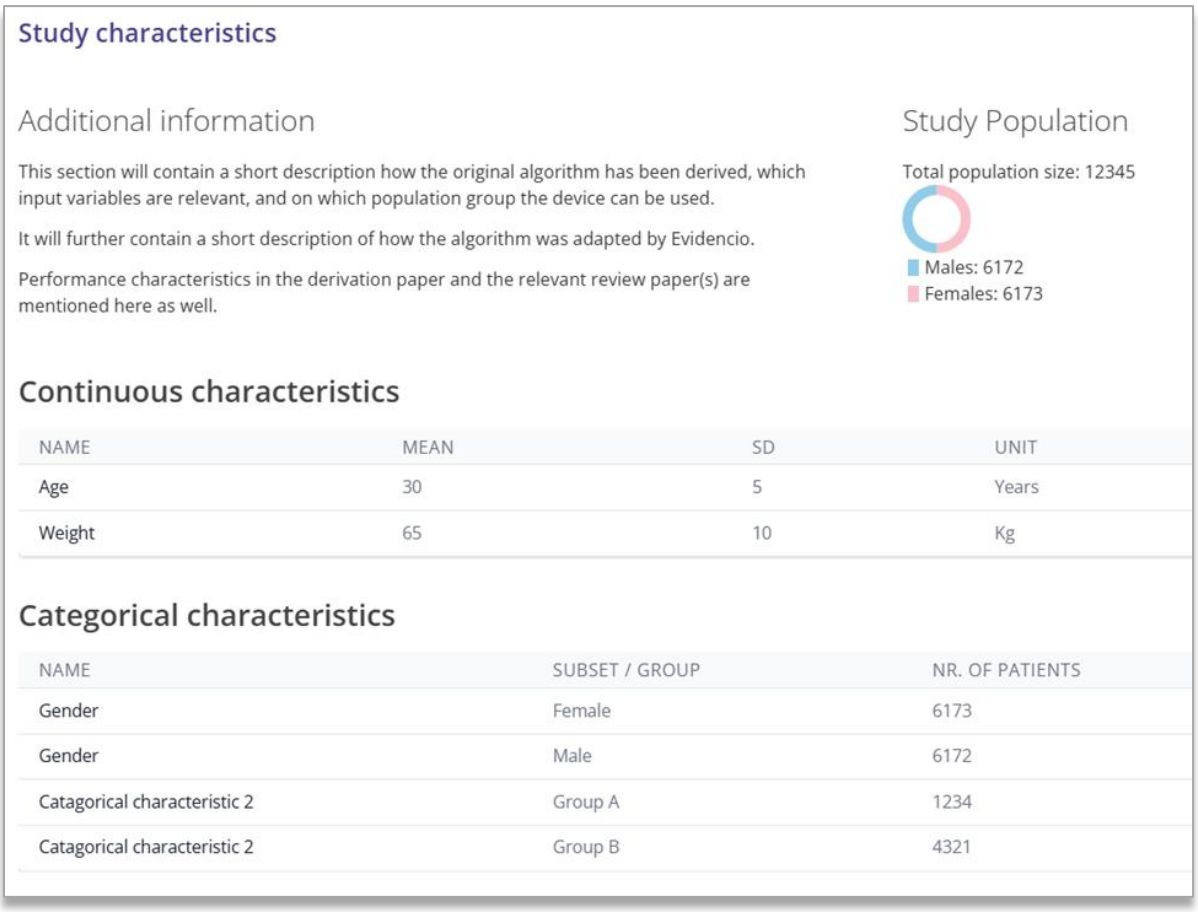

Figure 3. Example of the study characteristics section under the Details tab.

Supporting publications & Related files

An important part of the Study characteristics is the information on Supporting publications and related files. The list of related files and relevant tags can also be found in **Paragraph 8.5**. These sections can be found at the bottom of the Details-pop-up as shown in **Figure 4**.

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

H. Intended purpose

Under this tab, the intended purpose can be found, containing a lot of information regarding the algorithm, its user, target population, clinical benefit, etc. This information is also provided in this manual and can be found in **Chapter 6** on **page 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**. The electronic label is unique for each algorithm comprising the ROMA™.

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.

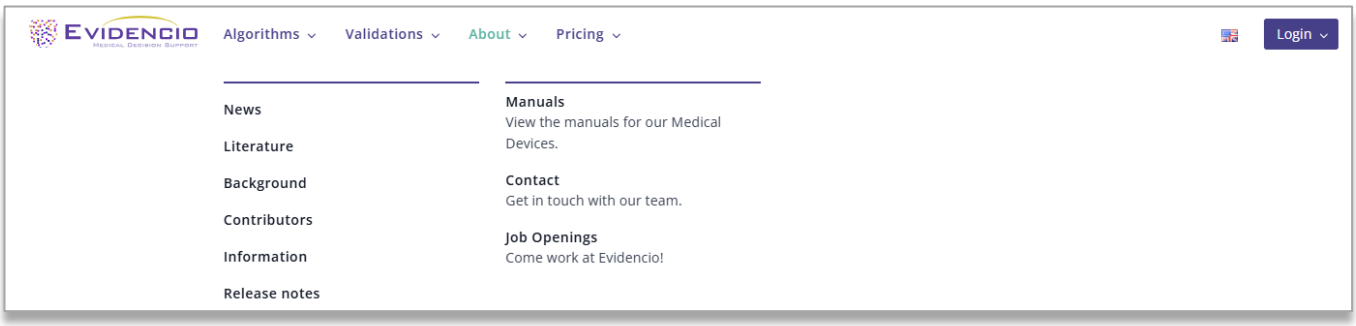

Figure 6. The drop-down menu where the user manual page can be found.

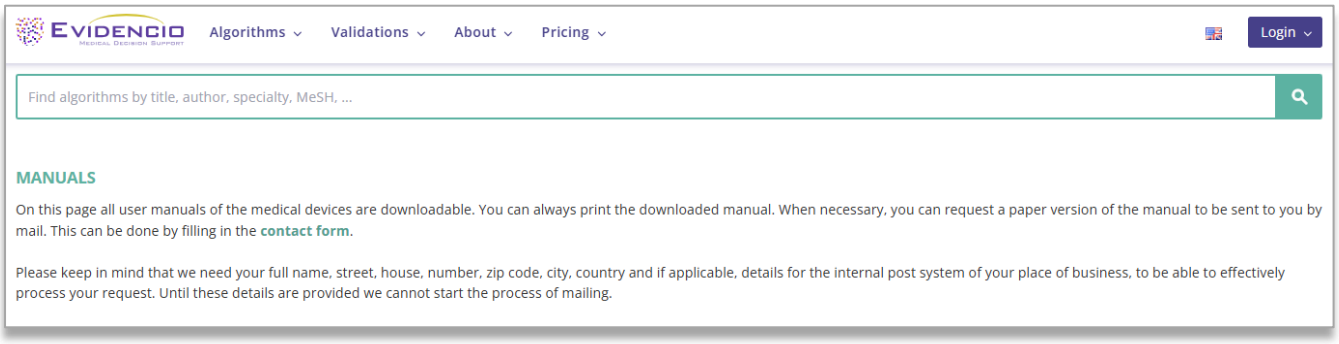

Figure 7. The user manual page for all user manuals.

L. Languages

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

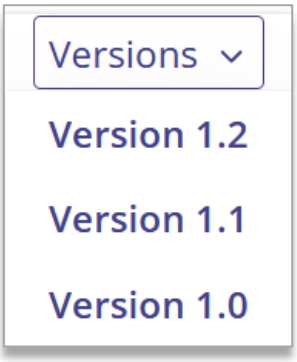

Figure 8. Example of version selection tab.

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**.

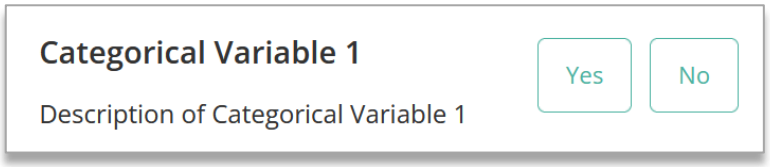

Figure 9. Example of a categorical variable, no button has been clicked and thus no input has been provided by the user.

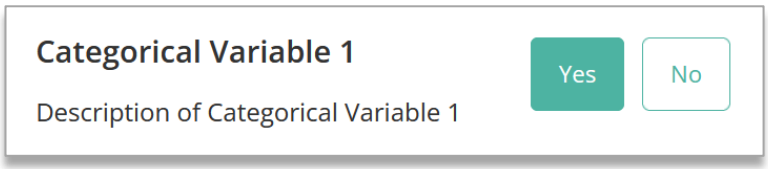

Figure 10. Example of a categorical variable, where the "Yes" button has been clicked.

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**).

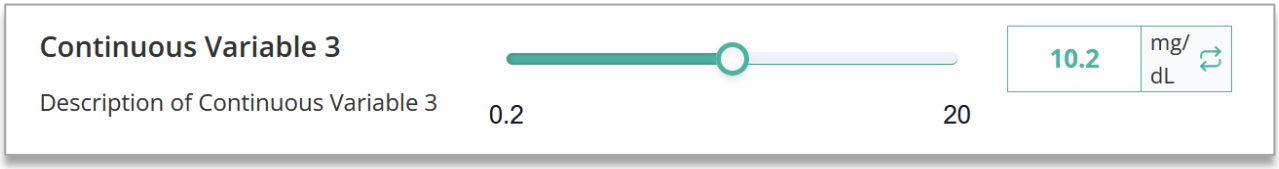

Figure 11. Example of a continuous variable, where "10.2 mg/dL" has been entered.

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.

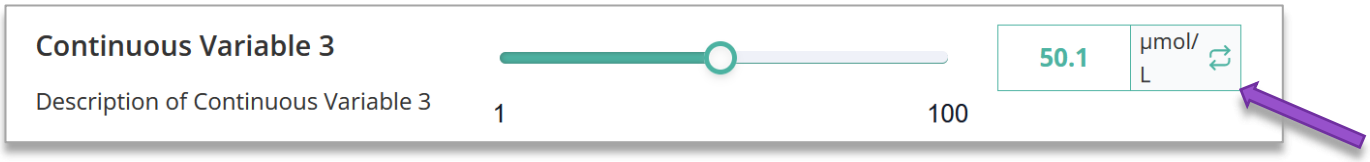

Figure 12. Example of a continuous variable where "50.1 $\mu mol/L$" has been entered.

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 (cut-off values).

O. Result section

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

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

Result calculation

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

Result interpretation

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

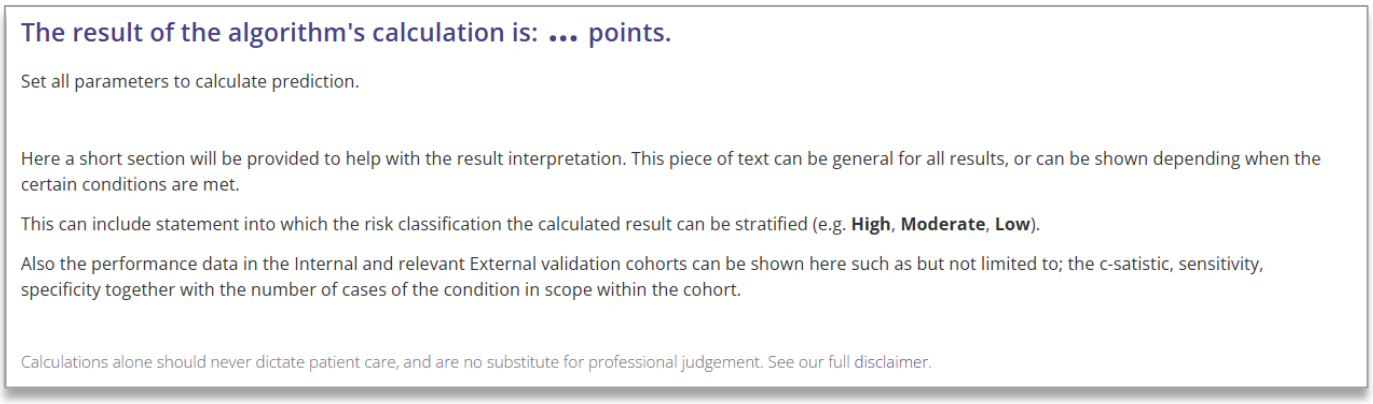

Figure 13. Example of the result display and information section.

10. Implementation of the algorithm through an API

The ROMA™ can be used through Evidencio's API to allow for (automated) calculation of the risk of ovarian malignancy. In the case of use of the MDSW through the API, the user should take into account the different inputs for the algorithm, in order to properly interpret the results.

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


```
{
  "CIPercentage": 0,
  "id": 9927,
  "author": "Evidencio",
  "title": "ROMA™ (for premenopausal patients)",
  "variables": {
    "4931998973": 71,
    "6654202163": 89
  },
  "min": 17.2,
  "max": 17.2,
  "additionalResultSet": [],
  "mintxt": "17.2",
  "maxtxt": "17.2",
  "result": "17.2",
  "resultText": "Risk of ovarian malignancy",
  "postresultText": "%",
  "formulaSegments": {
    "Premenopausal": -1.5738332558964383
  },
  "conditionalResultArray": [
    "<p><p>High risk identified due to a risk equal to or higher than 11.4% in premenopausal patients (ROMA™ ≥ 11.4%)</p></p>",
    "<p><p>ROMA™ is a registered trademark of Fujirebio Diagnostics, Inc.</p></p>"
  ],
  "conditionalResultText": "<p><p>High risk identified due to a risk equal to or higher than 11.4% in premenopausal patients (ROMA™ ≥ 11.4%)</p></p><p><p>ROMA™ is a registered trademark of Fujirebio Diagnostics, Inc.</p></p>",
  "UDI": "(01)08720938015151(8012)v1.31(4326)260317(240)9927",
  "medicalDevice": "This is an in vitro diagnostic medical device. The electronic label is available at: https://www.evidencio.com/models/show/9927?v=1.31",
  "userManual": "Always refer to the user manual for correct use of the in vitro diagnostic medical device. The user manual can be found at: https://www.evidencio.com/manuals"
}
```


Box 1: Example of an API output for the ROMA™.

Table 6 shows a match between the separately listed items in the API output with the items listed on the graphical user interface on the Evidencio website (elaborated in **Chapter 9**).

Table 6. API and GUI items for the ROMA™.

API Item	GUI item	Comment
CIPercentage	N/A	Not applicable for the ROMA™ as this feature is not used for the ROMA™.
id	Algorithm ID under 'details' Id used in the URL (www.evidencio.com/models/show/9927)	The ID is the Evidencio specific identification number of the algorithm.
author	Algorithm author under 'details'	Name of the Evidencio user who created the algorithm on the Evidencio platform.
title	Title of the algorithm (part A of figure 1).	-
variables	Input variables and their entered value. (part N. of figure 1)	The API displays the variables as unique IDs.
min	N/A	Depicts the lowest value when the result of the algorithm is a range. Since the ROMA™ always displays a single value as a result, this value is the same as the 'result'.
max	N/A	Depicts the highest value when the result of the algorithm is a range. Since the ROMA™ always displays a single value as a result, this value is the same as the 'result'.
additionalResultSet	N/A	N/A
mintxt	N/A	Same as 'min', but as a string.
maxtxt	N/A	Same as 'max', but as a string.
result	The main result of the algorithm, the ROMA™.	-
resultText	The text displayed in front of the main result	e.g. "Risk of ovarian malignancy".
postresultText	The text displayed behind the main result	"%".
formulaSegments	N/A	The formula segment (premenopausal/postmenopausal) is used as a component within a larger formula.
conditionalResultArray	Result interpretation displayed beneath "Conditional Information" (section O. in figure 1).	The API result shows the raw HTML text that is rendered by the software used for the graphical user interface.
conditionalResultText	Result interpretation displayed beneath "Conditional Information" (section O. in figure 1).	This section is the same as *'conditionalResultArray',* but displayed as a single string.
UDI	Same as the UDI displayed in the GUI (section F. in figure 1).	-
medicalDevice	The electronic label (section I. in figure 1).	The API refers to the electronic label on the graphical user interface.
userManual	The user manual (section K. in figure 1).	The API refers to the location of the user manual at the user interface & Evidencio website).

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. The party performing the integration of the ROMA™ using the API should adhere to the requirements outlined in **9927-DOC-45 Instructions for API integration ROMA™.**

11. User manual revision history

Version	Revision notes
V1.0 March 2026	Original version

12. Manufacturer details

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