



User manual for the CHA2DS2-VASC Stroke Risk Calculator

Version 4, May 2025, in English

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1. The Evidencio platform

The Evidencio platform facilitates the creation, use, validation and implementation of medical prediction models and clinical decision support tools. This user manual specifically relates to the CHA2DS2-VASC Stroke Risk Calculator. 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 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.

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 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 **Chapter 6** 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>.

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. Model landing page

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



A. CHA2DS2-VASc stroke risk score

B. The CHA2DS2-VASc stroke risk score calculates stroke risk for patients with atrial fibrillation. This model is intended to be used for patients who have been diagnosed with atrial fibrillation or atrial flutter.

C. Research authors: Gregory Y.H. Lip, Robby Nieuwlaat, Ron Pisters, Deirdre A. Lane, Harry J.G.M. Crjns
Version: 1.24

D. Draft | Cardiology | Linear regression | Versions

E. LOT V-1.24-2464.25.03.27 CE

F. UDI (01)08720299526419(8012)v1.24(4326)250327(240)2464

K. Download the [User manual](#) and consult the [Intended purpose](#).

L.

Age 18 100 years

Sex Male Female

Diabetes mellitus No Yes
Fasting glucose >125 mg/dL (7 mmol/L) or treatment with oral hypoglycaemic agent and/or insulin

Hypertension No Yes
Resting blood pressure >140/90 mmHg on at least two occasions or current antihypertensive treatment

Congestive Heart Failure No Yes
Clinical Heart Failure, or objective evidence of moderate to severe Left Ventricular dysfunction, or Hypertrophic Cardiomyopathy

Thromboembolism No Yes
Previous stroke, transient ischaemic attack, or thromboembolism

Vascular disease No Yes
Angiographically significant coronary artery disease, previous myocardial infarction, peripheral artery disease, or aortic plaque

Calculated CHA2DS2-VASc risk score: ... points

M. Set all parameters to calculate prediction.

The CHA₂DS₂-VASc score is recommended to be used for stroke risk assessment in patients with atrial fibrillation by different international clinical practice guidelines (such as the ESC guideline, AHA guideline, and the NICE guideline). The CHA₂DS₂-VASc score was developed as an improved score compared to the CHAD₂.

Even though the CHA₂DS₂-VASc score shows a moderate to good performance in terms of discrimination (C-index ranges between 0.6 - 0.71) in validation studies. The model should be used to identify patients at truly low risk.

Calculators alone should never dictate patient care, and are no substitute for professional judgement. See our full disclaimer.

Figure 1. An example of a model landing page.

A. Model title

This is the title and name of the model.

B. Model description

This is a short description of the model.

C. Research authors

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

D. Model tags

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

E. LOT number

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

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

F. UDI number

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

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

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

<https://gepir.gs1.org/index.php/search-by-gtin>

G. Details button

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

Details

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

Details




Algorithm author	Evidencio.Medical.Devices	Status	<div>Draft</div>	
Algorithm ID	10534	Share	<div><div></div><div></div><div></div></div>	
Version	1.24			
Revision date	2025-03-27			
Specialty	Cardiology			
Algorithm type	Linear regression <small>(Calculation)</small>			
MeSH terms	<div><div></div><div><div>Atrial Fibrillation</div><div>Clinical Prediction Rule</div><div>Stroke</div></div></div>			

Figure 2. The model details.

Study characteristics

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

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

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

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

Supporting Publications

Title or description	Tags
Refining clinical risk stratification for predicting stroke and thromboembolism in atrial fibrillation using a novel risk factor-based approach: the euro heart survey on atrial fibrillation DOI: 10.1378/chest.09-1584	Paper
Evaluation of risk stratification schemes for ischaemic stroke and bleeding in 182 678 patients with atrial fibrillation: the Swedish Atrial Fibrillation cohort study DOI: 10.1093/eurheartj/ehr488	Internal validation
ESC Clinical Practice Guidelines (2020 Guidelines for Management of Atrial Fibrillation)	Peer review
2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society in Collaboration With the Society of Thoracic Surgeons DOI: 10.1161/CIR.0000000000000665	Paper
NICE guideline [NG196] (Atrial fibrillation: diagnosis and management)	External validation
	Peer review
	Information on topic
	Information on topic
	Information on topic

Figure 3. An example of Supporting publications.

H. Intended use button

The intended use and (medical) purpose of the model can be found under the button: 'Intended use'. Among other things, the intended use indicates the inclusion criteria of the of a medical device. Furthermore, the intended use comments on the appropriate use of the model regarding the intended use environment, intended users, and intended patient population (inclusion criteria). For the CHA2DS2-VASc Stroke Risk Calculator the following intended use is described:

Intended use

The CHA2DS2-VASc Stroke Risk Calculator is intended to support clinical decision-making by informing clinical management on the estimated risk that an individual patient diagnosed with atrial fibrillation or atrial flutter may suffer a stroke or systemic embolism (also referred to as a thromboembolic event).

The calculator combines patient data (age & sex) with clinical data (diabetes mellitus, hypertension, heart failure, thromboembolism, and vascular disease) to calculate the estimated risk.

The calculator is intended to be used by physicians in a clinical setting, in combination with other information related to the patient (such as clinical history, appearance, comorbidities, other scores, patient preferences, etc.) used in the context of the physician's decision to prescribe anticoagulant medication or to change an existing prescription. In addition, the calculator can be used repeatedly at patient follow-ups to assess the risk over time.

The CHA2DS2-VASc Score on Evidencio does **not** provide any recommendations regarding the type or dose of anticoagulant treatment, and does **not** provide recommendations regarding contra-indications for specific anticoagulant treatment options.

Clinical benefit

The CHA2DS2-VASc Score indicates whether the physician should consider the administration of anticoagulation. CHA2DS2-VASc is recommended in the guideline for the stratification between low and high risk patients. Prescribing anticoagulant treatment in patients with a CHA2DS2-VASc score >0 (in men), and >1 (in women) resulted in net clinical benefit.

Clinical indication

The calculator is intended to be used for patients who have been diagnosed with atrial fibrillation or atrial flutter.

Contra-indication

The calculator should not be used for atrial fibrillation patients who have been diagnosed with hypertrophic cardiomyopathy.

- Caution should be used for patients with active cancer, as this algorithm does not take patient cancer characteristics into account, and active cancer may increase both bleeding and stroke risks

User profile

The calculator should not be used by patients.

The calculator may be used by physicians and qualified medical specialists in a clinical setting. Healthcare professionals do not require additional training prior to the use of the medical device.

Intended use environment

The calculator can be used as made available on the Evidencio platform in any actively supported web-browser on personal computers, mobile devices, or tablet PCs. Furthermore, the calculator can be used through the Evidencio iFrame representation of the calculator, as an embedded view, provided that the specific Evidencio guidelines for iFrame implementations of this model 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.

Functioning, physical principle

The calculator's underlying mathematical formula is a logistic regression that has been transformed into an easy to use risk score. The specifications and equations of the model are described in the document published by Lip et al.

Additional information to consider

The CHA2DS2-VASc Score has been developed in 2010, and has since been validated many times. The score has been recommended to be used for stroke risk assessment in AF patients for many years by international clinical guidelines. Still, a high score does not mean that the patient will suffer from a thromboembolic event. Additionally, patients with the lowest score may still suffer from thromboembolic events, regardless of anticoagulant treatment.

The CHA2DS2-VASc Score is easy to use, and easy to interpret due to the use of a risk score. However, the translation of a risk score from model coefficients may cause a reduction in the model's performance to stratify between high and low risk patients. Other, similar tools have been developed using coefficients or using additional risk factors to improve stroke risk prediction. Several of these tools are the ABC stroke risk score or the ATRIA stroke risk score. The CHA2DS2-VASc Score is still recommended by multiple international guidelines, but the similar tools may be used concomitant to further stratify between patients at high or low risk for thromboembolic events.

It is recommended to use this calculator together with a risk assessment tool intended to be used for the risk of major bleeding in patients undergoing anticoagulant treatment. Advised risk assessment tools for bleeding risk assessment are the HAS-BLED score, the ORBIT score, the ATRIA bleeding risk score, or the ABC bleeding risk score.

The use of the CHA2DS2-VA is recommended by the ESC guidelines for patients with AF. The CHA2DS2-VA essentially functions the same as the CHA2DS2-VASc, except for the exclusion of the variable sex. However, the CHADS2-VASc for men can be used regardless of the variable sex, due to the omission of the additional point for the female sex, both for the variable and threshold while thresholds for risk stratification are also 1 point higher than the male equivalents, essentially making the whole sex variable obsolete. Thus, the CHA2-DS2-VA does not make functional difference in practice.

I. Electronic label button

The electronic label button opens a pop-up with the location and address of Evidencio, the LOT number, the UDI number, the CE-mark, the medical device logo and a download link for the declaration of conformity of the medical device. The example of the electronic label is shown in Figure 4.

Extra Information

Intended purpose [Electronic label](#) [Release Notes](#)

CHA2DS2-VASc stroke risk score



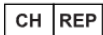
Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands



V-1.24-2464.25.03.27



(01)08720299526419(8012)v1.24(4326)250327(240)2464



Decomplic AG, Freiburgstrasse 3, 3010 Bern, Switzerland



Download the [User manual](#)



Medical device

Download the [Declaration of conformity](#)

Figure 4. Example of the electronic label

J. Release notes

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

K. User Manual

This user manual can be found in three places: 1) under the short description, 2) on the right of the model page, and 3) in the electronic label. Additionally, all versions of the user manual can be found in the general page for all user manuals for medical devices. The page can be found under the 'About' drop-down menu button as shown in Figure 5. The user manual page is shown in Figure 6.

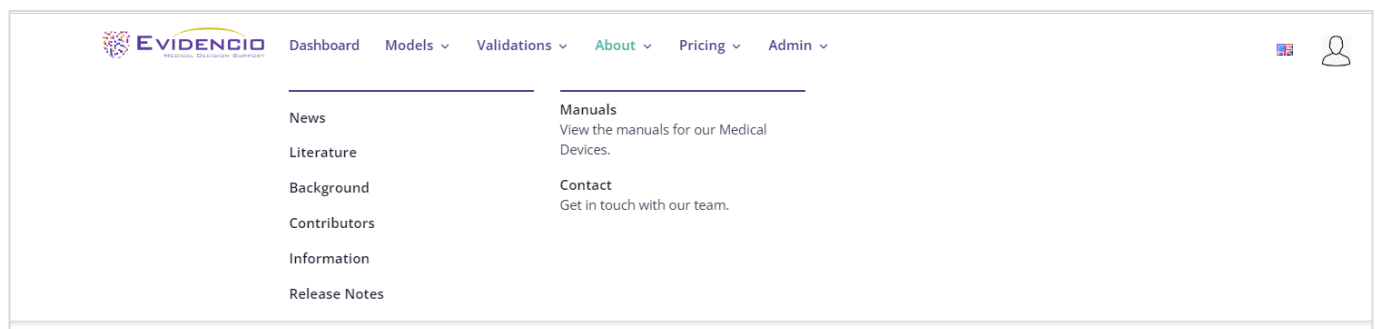


Figure 5. The drop-down menu where the user manual page can be found.

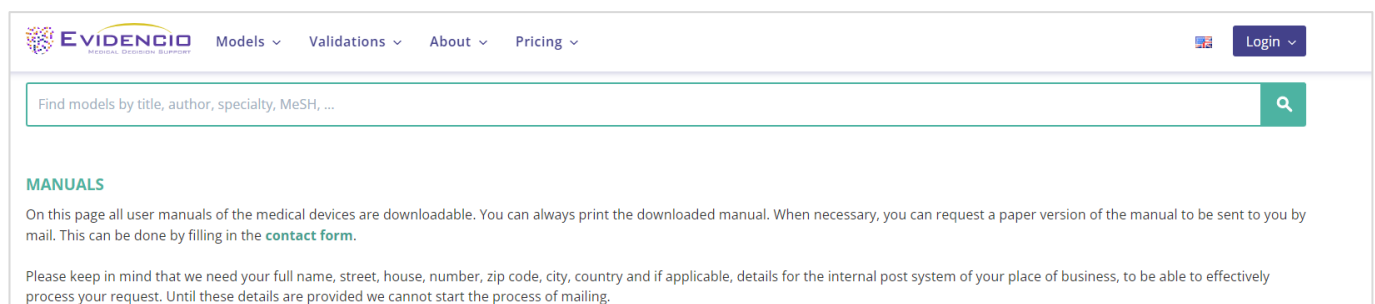


Figure 6. The user manual page for all user manuals.

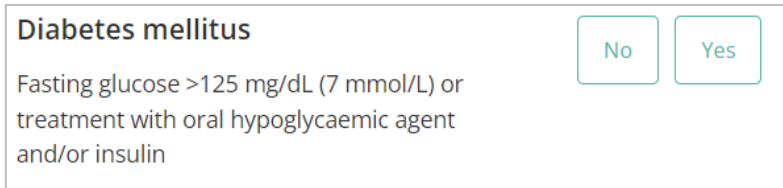
You (The user) can always print this downloaded manual. When necessary, you can request a paper version of the manual to be sent to you by mail. Evidencio's contact details are listed in Chapter 6 of this user manual.

L. Input section

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

Categorical variables

In the example shown in Figure 7 and 8, the **Diabetes mellitus** variable concerns a categorical variable. The patient status can be entered by clicking on either button. The selected button changes to green, as seen in Figure 8.

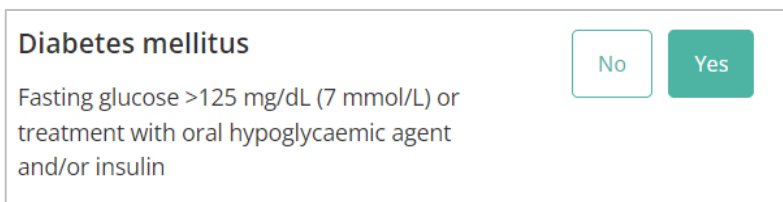


Diabetes mellitus

Fasting glucose >125 mg/dL (7 mmol/L) or treatment with oral hypoglycaemic agent and/or insulin

No Yes

Figure 7. The variable for Diabetes mellitus, where no button has been clicked, and thus no input has been provided by the user.



Diabetes mellitus

Fasting glucose >125 mg/dL (7 mmol/L) or treatment with oral hypoglycaemic agent and/or insulin

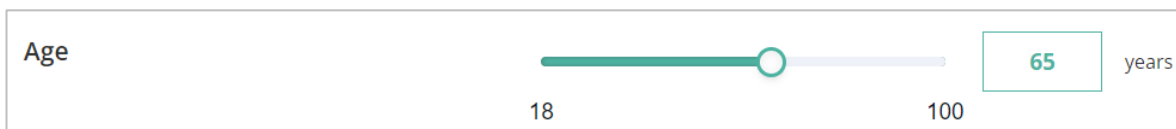
No Yes

Figure 8. The variable for Diabetes mellitus, where the "Yes" button has been clicked.

Continuous variables

In the example shown in Figure 9, the **Age** variable, exemplifies a continuous variable. The plausible ranges for the variables are defined by the model author. For example, the model is not suitable for patients younger than 22, or older than 95. Thus, the model only allows input of ages for patients between the ages of 22 to 95.

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 65 is entered for **Age**).



Age

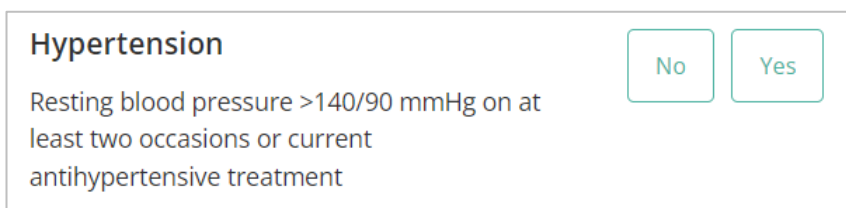
18 100

65 years

Figure 9. The variable for age, where "65" has been entered.

Details on variable measurements

Directly underneath the name for each variable, additional details can be provided on the methods required to enter the correct value for each variable. In Figure 10, the details below **Hypertension** explain how hypertension is defined for this model.



Hypertension

Resting blood pressure >140/90 mmHg on at least two occasions or current antihypertensive treatment

No Yes

Figure 10. An example of how additional information can be provided for a variable.

M. Result section

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

Result calculation

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

Result interpretation

In the result interpretation, a risk stratification is given based on the risk score. The patient is classified as high risk, medium risk or low risk. Furthermore, some explanation about the model is given including the c-index of the external validation. An example of the information for a patient with a risk score of 3 points is stated here:

The study by Friberg et al. reports the absolute risk percentages associated with each of the possible CHA₂DS₂-VASC Scores.

CHA₂DS₂-VASC score = 3

Ischaemic stroke risk = 3.2%

Stroke/TIA/peripheral emboli risk = 4.6%

The CHA₂DS₂-VASC score is recommended to be used for stroke risk assessment in patients with atrial fibrillation by different international clinical practice guidelines (such as the ESC guideline, AHA guideline, and the NICE guideline). The CHA₂DS₂-VASC score was developed as an improved score compared to the CHADS₂.

Even though the CHA₂DS₂-VASC score shows a moderate to good performance in terms of discrimination (C-index ranges between 0.6 - 0.71) in validation studies. The model should be used to identify patients at truly low risk.

Relevant information for correct use of the model

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

5. Implementation of the model through an API

The CHA₂DS₂-VASC Stroke Risk Calculator can be used through Evidencio's API to allow for (automated) calculation of the stroke risk assessment. In the case of use of the MDSW through the API, the user should take into account the different inputs for the model, 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.

6. Use of the Medical device 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.

7. Manufacturer details

Contact details of Evidencio:



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