

File information:

Name: 2464-DOC-43 rev2.0 User manual SaMD - CHA2DS2-VASC Stroke Risk Calculator.pdf
Size: 604347
Hash: CE9C6542CAFA7234E2F671473AF35C5ECB7DBD6FF6B0B7053154FA7F44B67646
Pages: 10

Signatories:

Role: author
Name: D.S. (Ditte) Moejes (id: 6)
Time: 2022-07-27 09:46:02 (739342)
ip: 192.168.1.50

```
b1          e6
250c       7ec5
22bcb4f828dce6a46d7c
6e26afa2569b82791813
3e24 a0e48ad7db 9f36
e0438a2fd54682d217dc
b80b895504db911f
cc033e 3b2743
e8bd2b3
d4c
```

Role: reviewer
Name: E.M. (Emma) Knijn (id: 5)
Time: 2022-07-27 09:52:45 (797688)
ip: 192.168.1.49

```
7e          53
9b05       e4cd
4cb740fc40937a6860f8
582008913a40e34d6146
2f53 7eece3932b 121a
6a905901a727f9a5d5d1
73a002e34adad972
21be22 1d06f4
c588610
3de
```

Role: approver
Name: R.J. (Rob) Mentink (id: 2)
Time: 2022-07-27 09:53:38 (300810)
ip: 192.168.1.37

```
4e          eb
d09d       8114
4137f78a07f5d56047b1
cebd713f163207150953
5346 f1cdef449 2162
23286c31dde9a2672e84
ca12640bb5c5f72c
f5ffc3 134a6e
1e47047
8c8
```



User manual
for
the CHA2DS2-VASC Stroke Risk Calculator

Version 1, 27th of July, 2022, in English

1. The Evidencio platform

The Evidencio platform facilitates the creation, use, validation and implementation of medical prediction models and clinical decision support tools. This user manual specifically relates to the 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 information, models, calculators, equations and algorithms (tools) intended for use by healthcare professionals. Some of these tools have been certified as CE-medical devices. For such CE-marked content the 'Official Legal Disclaimer for CE-marked content' applies. All other content and tools provided by Evidencio are explicitly only covered by the 'Official Legal Disclaimer for non CE-marked content' both are available here:

<https://www.evidencio.com/disclaimer>

3. Warnings



Warnings for CE-marked content

Calculations alone should never dictate patient care, and are no substitute for professional judgement.

This tool is only to be used by physicians in a clinical setting, and is not for patient use.

Always read the intended use before using this tool.


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

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

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

4. Model landing page

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



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. Crijns

D. Draft | Cardiology | Linear model

E. ★★★★★

F. LOT V-1.5-2666.22.03.01 CE 2797

G. UDI (01)08720299526419(8012)v1.5(4326)220301(240)2666

L. Download the [User Manual](#) for Medical device prediction models and consult the [Intended use](#).

M.

Age: 18 to 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)

N. Calculated CHA2DS2-VASc risk score: ... points

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.

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

H. Details

I. Intended use

J. Electronic label

K. Release Notes

L. User Manual

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. Model rating

Evidencio can award up to 5 stars to each model, these stars are awarded when:

1. All model details are provided;
2. A TRIPOD form is added to the supporting publications;
3. An internal review is added to the supporting publications;
4. An external review is added to the supporting publications; and
5. A peer review is added to the supporting publications.

Under the "Details button", indicated by H, details are given to which of these stars are awarded for which reason. The CHA2DS2-VASC Stroke Risk Calculator has 5 stars.

F. 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.

G. 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>

H. Details button

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

Details

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

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

Details

Model author	T. A. Hueting	Rating	★ ★ ★ ★ ⓘ
Model ID	2464	Status	Private
Version	1.15	Share	f t in
Revision date	2021-06-28		
Specialty	Cardiology		
Model type	Linear model <small>(Calculation)</small>		
MeSH terms	<ul style="list-style-type: none"> • Atrial Fibrillation • Clinical Prediction Rule • Stroke 		

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	<ul style="list-style-type: none"> Paper Internal validation Peer review
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	<ul style="list-style-type: none"> Paper External validation Peer review
ESC Clinical Practice Guidelines (2020 Guidelines for Management of Atrial Fibrillation)	<ul style="list-style-type: none"> Information on topic
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	<ul style="list-style-type: none"> Information on topic
NICE guideline [NG196] (Atrial fibrillation: diagnosis and management)	<ul style="list-style-type: none"> Information on topic

Figure 3. An example of Supporting publications.

I. 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 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 ESC 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.

Inclusion criteria

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

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.

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, and on Evidencio's mobile App. 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. The model is only intended for use in settings where the usage and result of a model are never urgently needed.

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.

J. Electronic label button

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

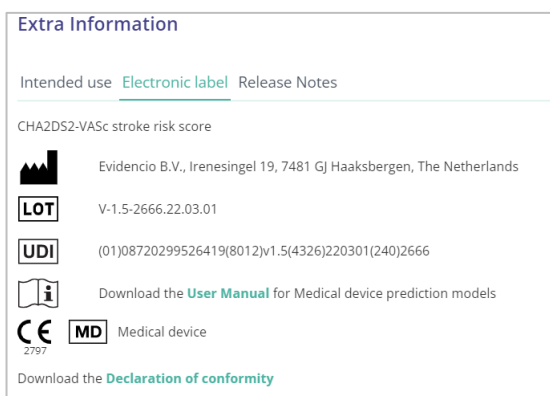


Figure 4. Example of the electronic label

K. 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.

L. 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.

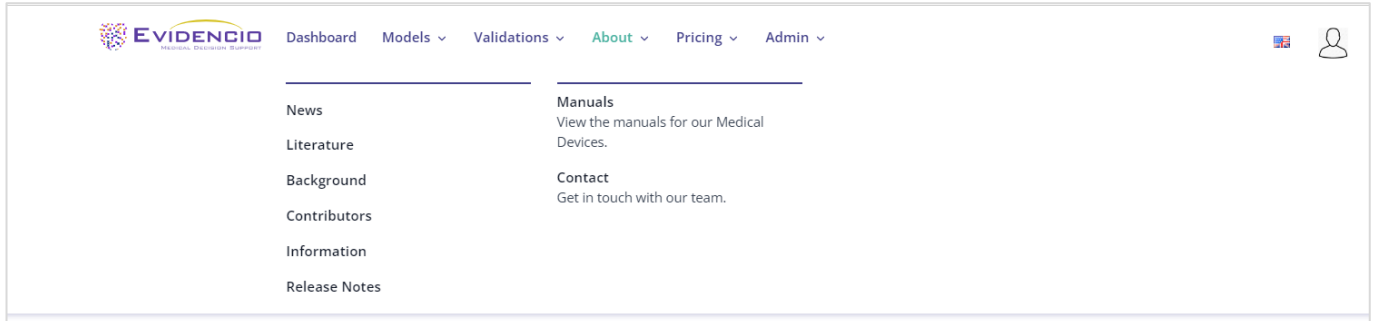


Figure 5. The drop-down menu where the user manual page can be found.

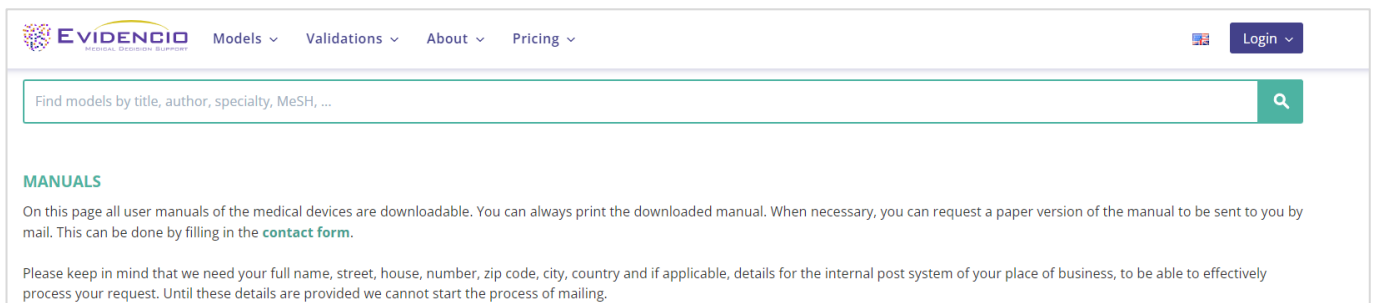


Figure 5. The user manual page for all user manuals.

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 0 of this user manual.

M. 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

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

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**).

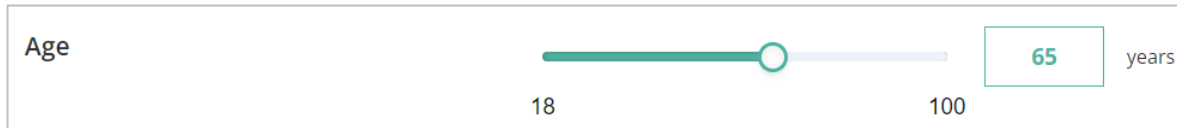


Figure 9. The variable for age, where “65” has been entered.

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.

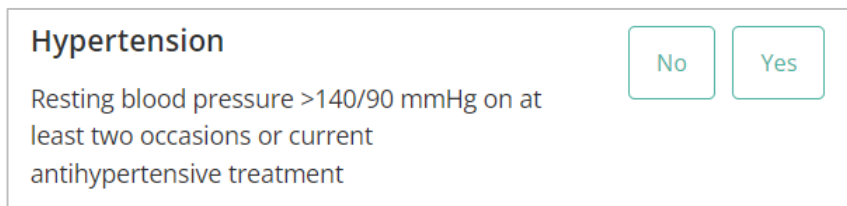


Figure 10. An example of how additional information can be provided for a variable.

N. 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. Use of Medical devices

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

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

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

The medical device cannot be used in combination with Internet Explorer. The personal computers, laptops, tablets or smartphones used should at least be able to have an internet connection and use the browsers mentioned above. The minimal screen resolution should be 800x600.

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

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

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

6. Manufacturer details

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

Contact details of your competent authority can be found here: <https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human>

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

Contact details of Evidencio:



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

File information:

Name: 2464-DOC-43 rev2.0 User manual SaMD - CHA2DS2-VASC Stroke Risk Calculator.pdf
Size: 604347
Hash: CE9C6542CAFA7234E2F671473AF35C5ECB7DBD6FF6B0B7053154FA7F44B67646
Pages: 10
Date format: DD - MM - YYYY

Document history:

File created	27 - 07 - 2022 09:35:06 UTC	Created by D.S. (Ditte) Moejes (id: 6) IP: 192.168.1.50
File downloaded	27 - 07 - 2022 09:35:06 UTC	Viewed by D.S. (Ditte) Moejes (id: 6) IP: 192.168.1.50
File signatories	27 - 07 - 2022 09:35:15 UTC	Signatories: Author: D.S. (Ditte) Moejes (id: 6) Reviewer: E.M. (Emma) Knijn (id: 5) Approver: R.J. (Rob) Mentink (id: 2)
File downloaded	27 - 07 - 2022 09:40:42 UTC	Viewed by D.S. (Ditte) Moejes (id: 6) IP: 192.168.1.50
File downloaded	27 - 07 - 2022 09:45:58 UTC	Viewed by D.S. (Ditte) Moejes (id: 6) IP: 192.168.1.50
File signed	27 - 07 - 2022 09:46:02 UTC	Signed by D.S. (Ditte) Moejes (id: 6) IP: 192.168.1.50
File downloaded	27 - 07 - 2022 09:48:04 UTC	Viewed by E.M. (Emma) Knijn (id: 5) IP: 192.168.1.49
File signed	27 - 07 - 2022 09:52:45 UTC	Signed by E.M. (Emma) Knijn (id: 5) IP: 192.168.1.49
File downloaded	27 - 07 - 2022 09:53:10 UTC	Viewed by R.J. (Rob) Mentink (id: 2) IP: 192.168.1.37
File signed	27 - 07 - 2022 09:53:38 UTC	Signed by R.J. (Rob) Mentink (id: 2) IP: 192.168.1.37
File completed	27 - 07 - 2022 09:53:38 UTC	The document has been completed.