< EviSign >

File information:

Name: 1002-DOC-43 rev1.0 User manual HOSPITAL Score.pdf
Size: 603032
Hash: 67FD9065FBFE76728F4E084A1D30C8DF18A6081ACB65723F4BDAB3DFCE4CDA3A
Pages: 9

Signatories:

Role: author
Name: W.R. (Wouter) van Dijk (id: 16)
Time: 2023-06-01 07:23:17 (863198)
ip: 192.168.1.61

```
    67          8e
  180e          b631
 7f9a2524a560c0e55a38
 2de6cdf2a4820337b981
 2652 9bcc4e73b5 2c8e
 08cad46704921c59d24a
   7d885ea8cfa16e2d
    42104d 0ff684
       b4309a0
         e5f
```

Role: reviewer
Name: D.S. (Ditte) Moejes (id: 6)
Time: 2023-06-01 07:31:05 (847625)
ip: 192.168.1.65

```
    76          d5
  3e46          5429
 5911b5a19aca1b2c329c
 af947e63f94160ec6e43
 9cf7 1dada349f6 d81d
 e814fd8a5fafb7621fd7
   9a3351b83a964413
    c05c60 779844
       8a1dd9a
         ca1
```

Role: approver
Name: T.A. (Tom) Hueting (id: 3)
Time: 2023-06-01 08:28:34 (230702)
ip: 192.168.1.53

```
    f6          fe
  1229          1270
 3f09b1e8be8e6b48a407
 25e014eb2692dca06b26
 7f68 862fa4582f b802
 c4041e9c1bfe5c13e074
   44c4d5d95517851f
    bebe5d b2cd7d
       95fc76e
         f0c
```

User manual

for

HOSPITAL Score

Version 1, March 2023, 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 HOSPITAL Score. The User Manual can also be referred to as the Instructions For Use (IFU).

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

2. Disclaimer

Evidencio provides 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

⚠️ **1.** **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.

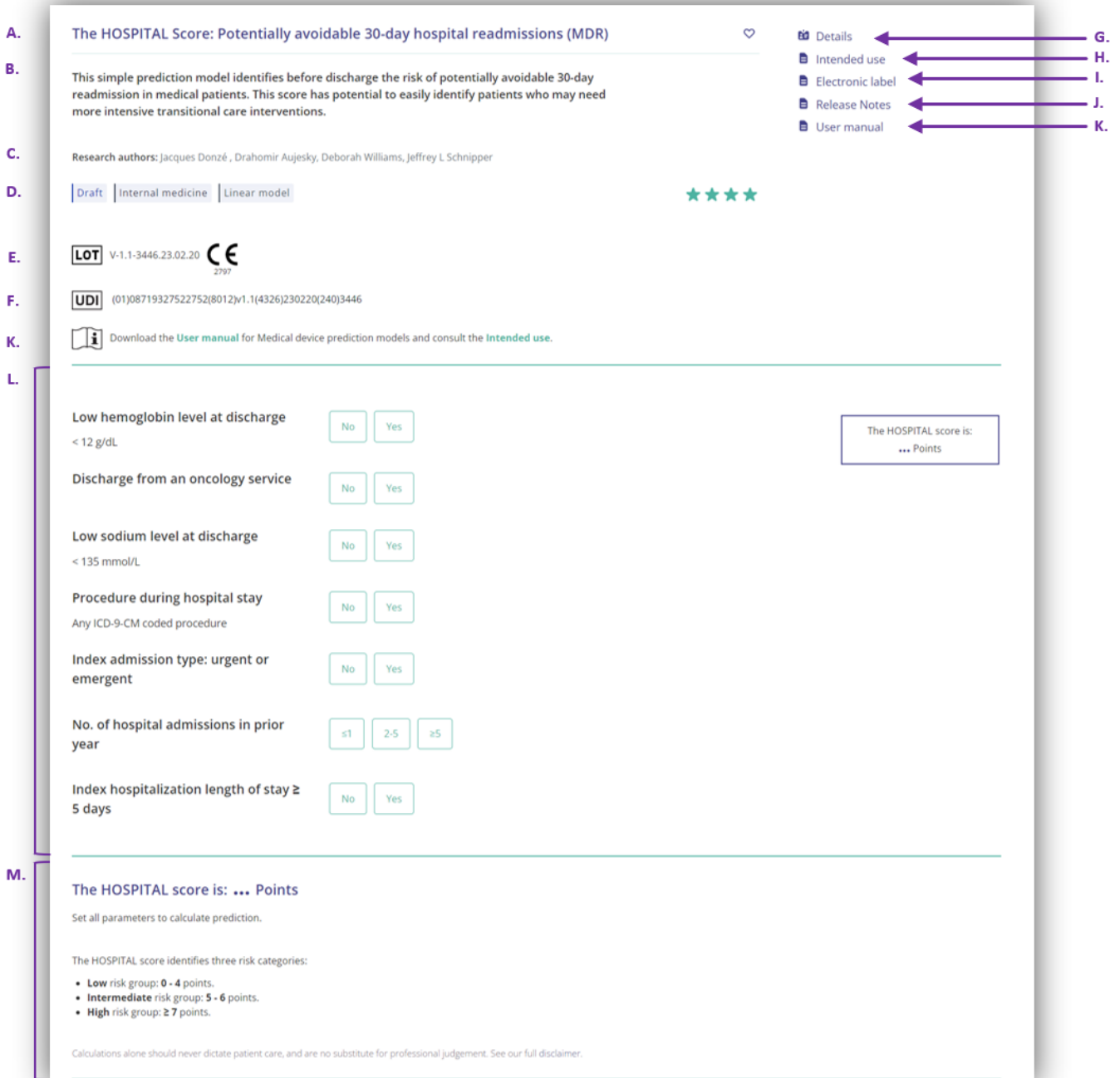Always read the intended use before using this tool.

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 immediately needed.

4. Model landing page

The 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.

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.

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

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 validate the model. Additional information is provided on the methods used to develop and/or validate the model.

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, because 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
Original article: Potentially avoidable 30-day hospital readmissions in medical patients: derivation and validation of a prediction model. DOI: 10.1001/jamainternmed.2013.3023	Internal validation / Paper / Peer review / Model coefficients
Validation: The HOSPITAL Score Predicts Potentially Preventable 30-Day Readmissions in Conditions Targeted by the Hospital Readmissions Reduction Program. DOI: 10.1097/MLR.0000000000000665	External validation / Paper
Validation: International Validity of the "HOSPITAL" Score to Predict 30-day Potentially Avoidable Readmissions in Medical Patients DOI: 10.1001/jamainternmed.2015.8462	External validation / Paper

Related files

No related files available

Figure 3. An example of Supporting publications & related files.

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 inclusion criteria of the 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 (in- and exclusion criteria). For the HOSPITAL Score the following intended use is described:

Intended use
The device is intended to be used by hospital staff to estimate the risk of potentially avoidable 30-day readmission, in patients that are about to be discharged, especially for cardiac patients.

The device combines hemoglobin at discharge, discharge from oncology service, sodium level at discharge, procedure during index admission, index type of admission, number of admissions in the past 12 months and length of stay to calculate the estimated risk of preventable 30-day readmission.

The device is intended to be used for patients about to be discharged from the hospital by physicians and qualified medical specialists in a clinical setting. The device is not intended for use by patients on their own.

The HOSPITAL score is not intended to replace clinical decision-making, it can only **inform** the physician, and only provides a probability of avoidable 30-day readmission. No direct instructions for further diagnostics, treatment, or otherwise, are given.

Clinical benefit
The HOSPITAL Score is intended to assist patients with relevant and specified clinical outcome parameters. Concretely, this is achieved by estimating risk in order to support clinical decision making aimed at whether or not to discharge a patient. Correct functioning of the HOSPITAL Score can result in these clinical benefits:

- Reduce the amount of avoidable hospital readmissions.
- Reduce the risk of (irreversible and/or severe) complications/consequences, inappropriate interventions, and readmissions by providing appropriate post-hospital care or prolonging the hospital stay.
- Help reduce unnecessary (intensive or even risky) healthcare, e.g. (intensive) post-hospital care or a prolonged hospital stay.
- Potentially increase availability of (scarce) medical resources for patients with high risks, potentially accelerating healthcare for these patients.

Intended target population and exclusion

The HOSPITAL Score is intended to be used only for a specific group of patients, corresponding to the below indications and contra-indications. Additionally, for the use of the HOSPITAL Score on Evidencio, the patient's age should be at least 18 years.

Clinical indication

The HOSPITAL Score is intended for:

- hospitalized patients about to be discharged from hospital.

Contra-indications

The HOSPITAL Score is not intended for:
- use outside of medical services;
- for patients who are hospitalized for observational stays.

User profile

Since unplanned hospital readmission is regarded as a 'critical healthcare situation or condition', the use of the SaMD is intended for specialised trained users. Healthcare professionals do not require additional training prior to the use of the medical device. Thus, the SaMD may be used by physicians and qualified medical specialists in a clinical setting. The SaMD should **not** be used by patients.

Intended Use Environment

The SaMD 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 the mobile app provided by Evidencio. Furthermore, the SaMD can be used through the Evidencio iFrame representation of the SaMD, as an embedded view, provided that the specific Evidencio guidelines for iFrame implementations of this SaMD are adhered to. The model is only intended for use in settings where the usage and result of a model are never immediately needed.

Functioning, physical principle

The SaMD's underlying mathematical formula is a linear model. The acquisition and processing of the data, the analyses to assemble the relevant criteria for the SaMD as well as the setup and refinement of the HOSPITAL score are described in the original study/studies from Donzé et al. Entering the details of an individual in the Evidencio SaMD initiates the calculation of the cumulative score of the patient, and it's associated risk category.

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.

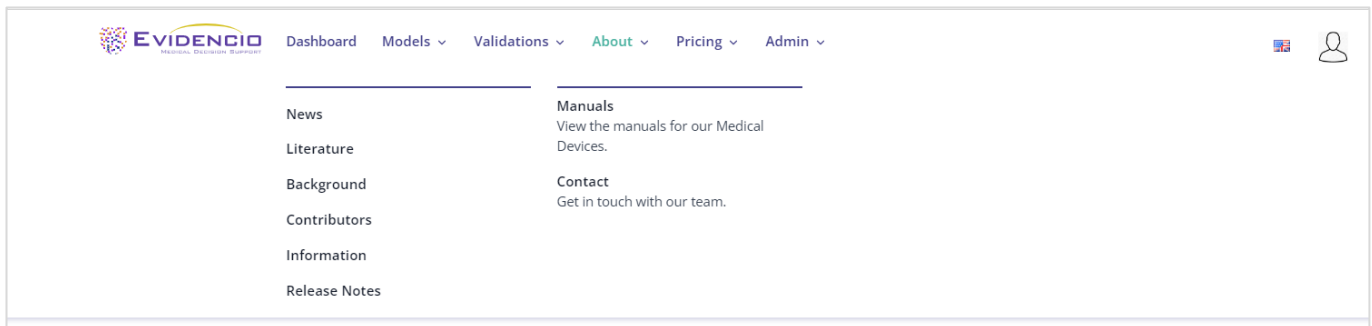*Figure 4. Example of the electronic label*

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.
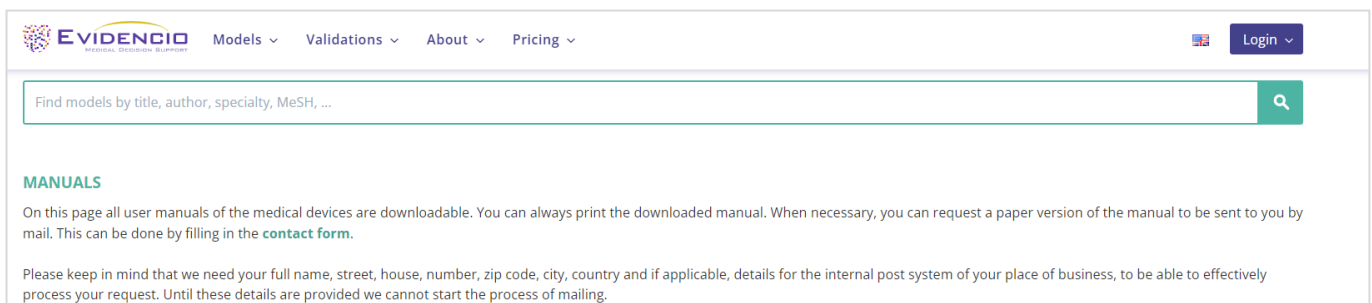
K.   User Manual

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. For the HOSPITAL Score, only the categorical variables are used.

Categorical variables

In the example shown in Figures 7 and 8, the **"Low hemoglobin level at discharge"** 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.
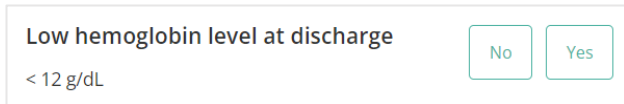

Figure 7. The variable for "Low hemoglobin level at discharge", where no button has been clicked, and thus no input has been provided by the user.
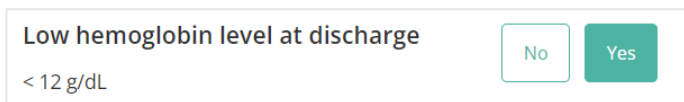

Figure 8. The variable for "Low hemoglobin level at discharge", where the "Yes" button has been clicked.

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 9, the details below **Low sodium level at discharge** explain what the exact meaning of the variable is.
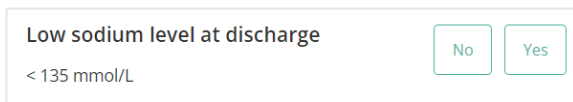
Figure 9. An example on how additional information can be provided for a variable.

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, moderate risk, or low risk. Furthermore, some explanation about the model is given. An example of the information is shown In Figure 10.

Figure 10. The result information

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.
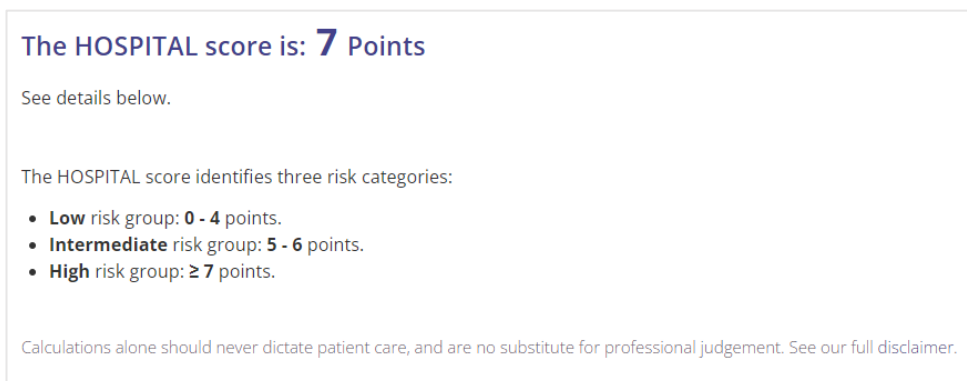
To use the tool, Evidencio requires a stable internet connection and runs on the following devices:
- Personal computers or laptops using the following browsers:
  - o Safari (the latest three versions)
  - o Chrome (the latest three versions)
  - o Firefox (the latest three versions)
  - o Edge (the latest three versions)
- Tablets or smartphones running on the next operating systems:
  - o IOS (the latest three versions)
  - o 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 immediately 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

< EviSign >

File information:

Name: 1002-DOC-43 rev1.0 User manual HOSPITAL Score.pdf
Size: 603032
Hash: 67FD9065FBFE76728F4E084A1D30C8DF18A6081ACB65723F4BDAB3DFCE4CDA3A
Pages: 9
Date format: DD - MM - YYYY

Document history:

File created	**31 - 05 - 2023** 15:15:48 UTC	Created by W.R. (Wouter) van Dijk (id: 16) IP: 192.168.1.61
File downloaded	**31 - 05 - 2023** 15:15:48 UTC	Viewed by W.R. (Wouter) van Dijk (id: 16) IP: 192.168.1.61
File signatories	**31 - 05 - 2023** 15:16:01 UTC	**Signatories:** Author: W.R. (Wouter) van Dijk (id: 16) Reviewer: D.S. (Ditte) Moejes (id: 6) Approver: T.A. (Tom) Hueting (id: 3)
File downloaded	**01 - 06 - 2023** 07:23:05 UTC	Viewed by W.R. (Wouter) van Dijk (id: 16) IP: 192.168.1.61
File signed	**01 - 06 - 2023** 07:23:17 UTC	Signed by W.R. (Wouter) van Dijk (id: 16) IP: 192.168.1.61
File downloaded	**01 - 06 - 2023** 07:31:02 UTC	Viewed by D.S. (Ditte) Moejes (id: 6) IP: 192.168.1.65
File signed	**01 - 06 - 2023** 07:31:05 UTC	Signed by D.S. (Ditte) Moejes (id: 6) IP: 192.168.1.65
File downloaded	**01 - 06 - 2023** 08:28:30 UTC	Viewed by T.A. (Tom) Hueting (id: 3) IP: 192.168.1.53
File signed	**01 - 06 - 2023** 08:28:34 UTC	Signed by T.A. (Tom) Hueting (id: 3) IP: 192.168.1.53
File completed	**01 - 06 - 2023** 08:28:34 UTC	The document has been completed.