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Size: 590947
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Pages: 7

Signatories:

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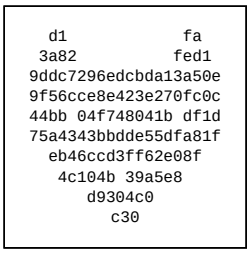
Time: 2024-05-23 12:06:41 (798080)
ip: 192.168.1.54



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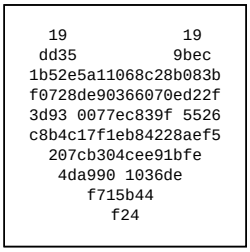

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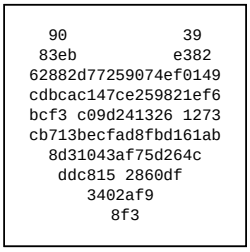
ip: 192.168.1.28



User manual

for

OSAsense

Version 1, May 2024, 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 OSAsense algorithm. 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. Interface for the results

The interface for the results on the OSAsense platform is shown in Figure 1. The interface for the results contains the following sections, that are indicated in Figure 1.

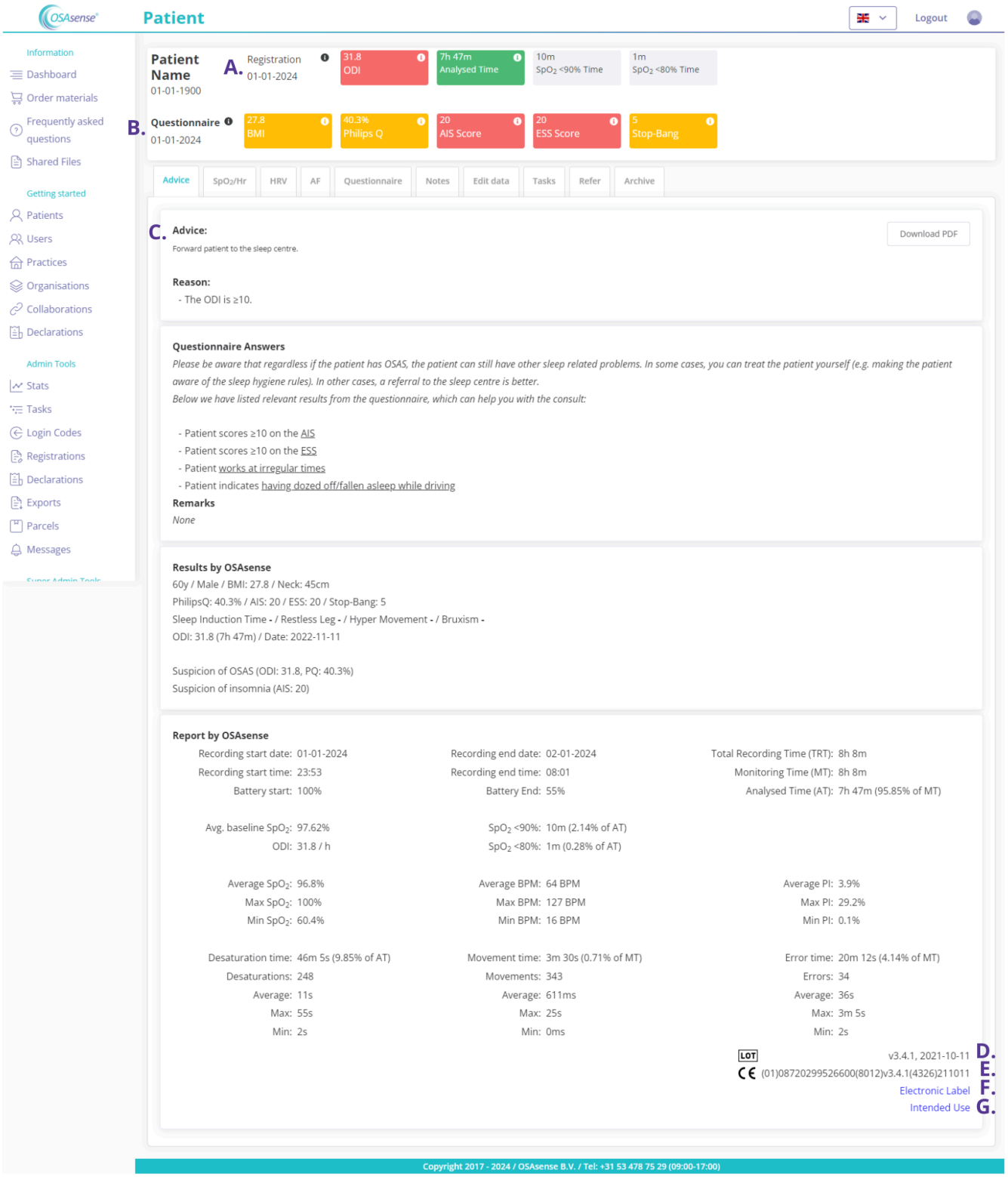


Figure 1. Interface for the results on the OSAsense platform.

A. Registration outcome

These are the results for the registration. There is a 'stoplight' system, red means not good, yellow means intermediate and green means good. Clicking on the top right corner of the colored space, a pop up comes up and gives more information about the result and the belonging cut-off values.

B. Questionnaire outcome

These are the results for the questionnaire. There is a 'stoplight' system, red means not good, yellow means intermediate and green means good. Clicking on the top right corner of the colored space, a pop up comes up and gives more information about the result and the belonging cut-off values.

C. OSAsense advice

The outcome of the MDSW is an advice that there is no indication for OSAS or an advice to refer the patient to a sleep center or hospital for further diagnostic tests. This advice is based on the ODI and the outcome of the Philips Q.

D. 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.

E. 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

F. 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 2.

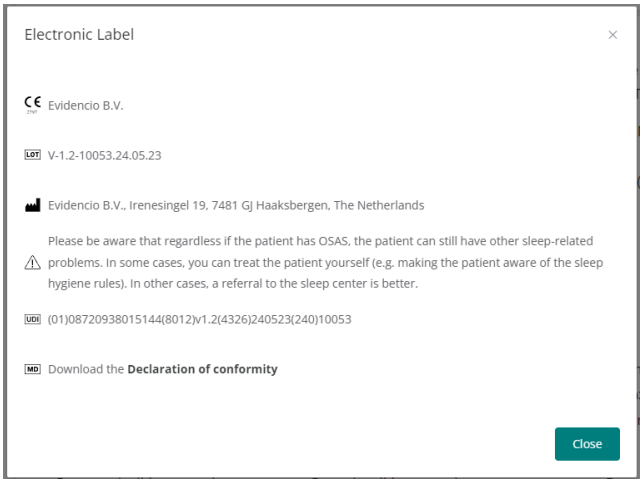


Figure 2. Example of the electronic label

G. Intended use button

Intended medical use
The OSAsense is intended to be used by professional users who are capable of operating the device and interpreting its results. It can be used to rule out the presence of obstructive sleep apnea in patients with signs and symptoms indicative of sleep apnea.

The OSAsense combines and analyzes photoplethysmographic data with patient reported questionnaire data to estimate the chance a patient has obstructive sleep apnea.

The device is intended to be used for patients with signs and symptoms related to sleep apnea. The result of the OSAsense is intended to be reviewed and interpreted by qualified medical specialists only. The device is not intended for use by patients on their own.

The OSAsense is not intended to replace clinical decision-making, it can only provide information to the user on the likelihood of sleep apnea. The user can use this information to support clinical decision-making regarding diagnosis and treatment options of the patient. In practice, this typically entails the decision to refer the patient to second-line or specialized care.

Clinical Benefit
The OSAsense is intended to assist patients with relevant and specified clinical outcome parameters. Concretely, this is achieved by ruling out patients in order to support clinical decision-making aimed at patients with signs and symptoms indicative of sleep apnea, in order to support clinical decision-making regarding patient prognosis. Correct functioning of the OSAsense can result in these clinical benefits:

- The OSAsense can assist in ruling out patients with signs and symptoms indicative of sleep apnea
- Ruling out can reduce the burden of (invasive and intensive) medical procedures such as tests on patients with low risks, reducing, shortening or avoiding stays in hospitals or other care facilities.
- Ruling out can reduce the unnecessary consumption of (scarce) medical resources, decreasing costs and increasing their availability for high risk patients.
- Digital implementation of the algorithm underlying the OSAsense as a medical device can improve the speed and reliability of calculation. This would further increase the accuracy of the prognosis and by extent increase the chance for the above-mentioned benefits.

Intended target population and exclusion
The OSAsense is intended to be used only for a specific group of patients, corresponding to the below indications and contra-indications.

Clinical indication
The OSAsense should be used for patients who meet the following inclusion criteria:

- Patients showing signs and symptoms indicative of sleep apnea
- Patients who are capable of providing the answers to the questionnaire

Contra-indications
The OSAsense should not be used for patients who meet one or more of the following exclusion criteria:

- Patients aged <18
- Patients actively receiving treatment affecting blood oxygen levels (i.e. Continuous Positive Airway Pressure (CPAP), mechanical ventilation).

User profile
The OSAsense is intended to be used by Healthcare Professionals or automatically calculated through Evidencio's API. Results shall always be reviewed and interpreted by qualified medical specialists only, in the context of the patient's clinical history and other diagnostic test results. Healthcare professionals do not require additional training prior to the use of the medical device. The device is not intended for use by patients on their own.

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, and on the mobile app provided by Evidencio. The MDSW can also be used through Evidencio's iFrame representation as an embedded view, provided that the specific Evidencio guidelines for iFrame implementations of this MDSW are adhered to. Automated calculation of the device is enabled through Evidencio's API. The device is only intended for use in healthcare settings where the immediate application and outcomes of the device are not required.

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.

Versions of the MDSW
The version of the OSAsense concerns the initial version of MDSW of which Evidencio is the manufacturer.

Functioning, physical principle
The acquisition and processing of the data, the analyses to assemble the relevant criteria for the MDSW as well as the setup and refinement of the OSAsense algorithm are provided in the instructions for use. Entering the details for an individual in the web-application initiates the calculation of the risk category of the patient.

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 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

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Hash:	AD6073A699A1BB701BCA4D70318E6A4E87C61249BD205FC4E39D7F3B8C8D06A6
Pages:	7
Date format:	DD - MM - YYYY

Document history:

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File downloaded	**23 - 05 - 2024** 12:06:29 UTC	Viewed by A.F. (Fleur) Boone (id: 15) IP: 192.168.1.54
File signed	**23 - 05 - 2024** 12:06:41 UTC	Signed by A.F. (Fleur) Boone (id: 15) IP: 192.168.1.54
File signatories	**23 - 05 - 2024** 12:06:43 UTC	**Signatories:** Author: A.F. (Fleur) Boone (id: 15) Reviewer: W.R. (Wouter) van Dijk (id: 16) Approver: T.A. (Tom) Hueting (id: 3)
File downloaded	**23 - 05 - 2024** 12:45:26 UTC	Viewed by W.R. (Wouter) van Dijk (id: 16) IP: 192.168.1.73
File signed	**23 - 05 - 2024** 12:46:09 UTC	Signed by W.R. (Wouter) van Dijk (id: 16) IP: 192.168.1.73
File downloaded	**23 - 05 - 2024** 12:47:38 UTC	Viewed by T.A. (Tom) Hueting (id: 3) IP: 192.168.1.28
File signed	**23 - 05 - 2024** 12:48:07 UTC	Signed by T.A. (Tom) Hueting (id: 3) IP: 192.168.1.28
File completed	**23 - 05 - 2024** 12:48:07 UTC	The document has been completed.