User manual for the MELD Score

MELD 1.0
MELD Na
MELD 3.0
reMELD-Na

Version 9, October 2025, 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 MELD Score, (which covers the MELD 1.0, MELD Na, MELD 3.0, and reMELD-Na). The User Manual can also be referred to as the Instructions For Use (IFU).

Throughout this manual CE-marked content, the term medical device, and medical device software (MDSW) are used interchangeably.

2. Disclaimer

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⚠ 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, 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 MELD Score

The MELD Score can be used to estimate the 3-month mortality risk or 90-day survival probability of patients with end-stage liver disease.

The MELD Score consists of four different algorithms that largely overlap in their required input variables and presented outcomes and which can all be used independently. This singular term is used for clarity and brevity when a statement applies to all four algorithms. Differences between the separate devices will be mentioned when applicable.

The MELD 1.0 was originally developed to predict patient survival and identify those patients whose liver-related mortality post-TIPS (Trans jugular intrahepatic portosystemic shunts) would be 3 months or less. Subsequent research showed the applicability of this prediction algorithm to a wider patient group, predicting the 3-month risk of patients with end-stage liver disease.

With the aim of improving the accuracy of these predictions, the variable Serum Sodium was supplemented and recalibrating existing equation coefficients, resulting in the MELD Na, mostly used in the USA.

Relatively recently in 2021, the MELD 3.0 was introduced, adding the variable of patients Sex while removing the act of regular hemodialysis. The outcome of the MELD 3.0 is also different compared to the other algorithms, now calculating the 90-day survival. In part due to its novelty MELD 3.0 has yet to reach the wide scale adoption and integration into clinical guidelines compared to the MELD 1.0.

In 2021, Goudsmit et al. refitted the UNOS-MELD score to improve the suitability for the Eurotransplant region, as the UNOS-MELD was developed in a cohort in the United States. The reMELD-Na consists of new boundaries and coefficients tailored to the European population.

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.

4.1. Lifetime, residual risks and side effects

The MELD Score 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 MELD Score is a low-risk device, there are no noticeable risks involved outside of possible mis-estimation of a patient's 3-month mortality risk or 90–day survival probability, and all residual risks are accepted.

Most identified 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 inaccessibility 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.* It should be noted that the use of Evidencio's Medical Device Software is itself a risk mitigation measure, as Evidencio's certified Quality Management System ensures and monitors the reliability of the calculations performed with its certified medical devices.

The MELD Score does not have any direct side effects relevant for the patient.

5. Electronic Label

The electronic label of this device contains the following information:

CE 2797	**Name of the device**	MELD score (reMELD-Na, MELD 3.0, MELD Na, and MELD 1.0)
	**Manufacturer information**	Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands
LOT	**LOT number**	V4.0-10085.25.10.31 V-3.0-10085.25.10.31 V-2.0-10085.25.10.31 V-1.2-10085.25.10.31
UDI	**UDI number**	**reMELD-Na** (01)08720938015380(8012)v4.0(4326)251031(240)10085 **MELD 3.0** (01)08720938015236(8012)v3.0(4326)251031(240)10085 **MELD Na** (01)08720938015229(8012)v2.0(4326)251031(240)10085 **MELD 1.0** (01)08720938015212(8012)v1.2(4326)251031(240)10085
MD	**MD indication**	Medical device

The electronic label can be found on the Evidencio website, see also **section I** and **Figure 5**.

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 indicated 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 is an international tool that helps users identify and find information on products. Evidencio's UDIs 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 three sub-algorithms. Version 1.2 for the MELD 1.0, version 2.0 for the MELD Na, version 3.0 for the MELD 3.0, and version 4.0 for the reMELD-Na.

6. Intended Purpose

6.1. Intended Medical Use

The MELD Score is intended to be used by professional users who are capable of operating the device and interpreting its results. It can be used to estimate the 3-month mortality risk or 90-day survival probability.

The MELD Score consists of four different algorithms that largely overlap in their required input variables and presented outcomes.

The MELD 1.0 combines the following inputs:

- Serum bilirubin
- Serum creatinine
- International Normalised Ratio (INR)

to predict the 3-month mortality risk.

The MELD Na and reMELD-Na require the same input variables as the MELD 1.0, with the addition of serum sodium as a risk factor input:

- Serum bilirubin
- International Normalised Ratio (INR)
- Serum creatinine
- Serum sodium

to predict the 3-month (or 90-day) mortality risk. The MELD 3.0 further added sex and serum albumin values as risk factors to predict the 90-day survival probability.

The device is intended to be used for patients with end-stage liver disease. The result of the MELD Score is intended to be reviewed and interpreted by qualified healthcare professionals only. The device is not intended for use by patients on their own.

The MELD Score is not intended to replace clinical decision-making, it can only provide information to the user on the 3-month mortality risk or 90-day survival probability. The user can use this information to support clinical decision-making regarding the prognosis and treatment of the patient. In practice, this typically entails the decisions involving palliative care or liver transplantation.

6.2. Clinical Benefit

Correct functioning of the MELD Score can result in the following clinical benefit:

- The MELD Score provides accurate information on the 3-month mortality risk or 90-day survival probability of patients with end-stage liver disease to the user to assist in clinical decisionmaking.

6.3. Indented target population and exclusion

The MELD Score is intended to be used only for a specific group of patients, corresponding to the below indications and contra-indications.

6.3.1. Clinical Indications

The MELD Score should be used for patients who meet the following inclusion criteria:

- Patients should be at least 18 years or older *
- Having end-stage liver disease

**The authors of the MELD Score suggest that it can be used for patients of 12 years or older. However, this is not universally accepted, e.g. the OPTN policy acknowledges three groups: less than 12 years, 12 or older and 18 or older. In contrast, Eurotransplant uses an age limit of 18 years or older, below which the PELD is recommended. Because of this lack of consensus, the age for the use of the MELD Score is set to 18 years or older.*

6.3.2. Clinical contra-indications

The following conditions are acknowledged as MELD Exceptions in different liver allocation and transplantation programs, and thus the use of the MELD Score for patients with these conditions should be performed with caution and the MELD Score results should be interpreted within the context of the condition:

Generally acknowledged MELD Exceptions:

- Hepatopulmonary syndrome (HPS)
- Portopulmonary hypertension (PPH)
- Primary hyperoxaluria
- Cystic fibrosis (CF)
- Cholangiocarcinoma (CCA)
- Hepatocellular carcinoma (HCC) (often together with Milan criteria to determine if HCC patients are eligible/suitable for transplantation)

Additionally, the ELITA acknowledges the following exceptions:

- Cholangitis (Primary sclerosing cholangitis and biliary sepsis/secondary sclerosing cholangitis)
- Neuroendocrine tumours
- Polycystic liver disease (PLD)Hepatic artery thrombosis (HAT)
- Persistent hepatic dysfunction (incl. small-for-size syndrome)
- Hereditary hemorrhagic telangiectasia (Rendu-Osler-Weber-Syndrome)
- Biliary atresia
- Non-metastatic hepatoblastoma
- Urea-cycle disorder/organic acidemia
- Hepatic hemangioendothelioma

Moreover, the following exceptions are mentioned in other literature:

- Familial amyloid polyneuropathy (FAP)
- (Unusual) metabolic disease
- Hepatorenal syndrome (HRS) (Eurotransplant region)
- Amyloidosis

Acknowledged by the 2006 MELD Exception Study Group and Conference (MESSAGE):

- Unusual tumour
- Unusual metabolic disease
- Ascites
- Hepatic encephalopathy
- Gastrointestinal bleeding
- Budd-Chiari Syndrome (BCS)
- Pruritus

Moreover, in an OPTN proposal for addition of serum sodium, it is stated that the serum sodium values for patients with hyperglycemia should be corrected via an additional formula. Thus, caution is also necessary if the MELD Score is used for these patients.

6.4. User profile

The MELD Score is intended to be used by healthcare professionals or automatically calculated through Evidencio's API. Results shall always be reviewed and interpreted by qualified healthcare professionals 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.

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. 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.

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. Version of the MDSW

The version of the MELD Score concerns the initial version of MDSW of which Evidencio is the manufacturer.

6.8. Functioning, physical principle

The MDSW's underlying mathematical formula concerns a combination of a risk score model and a Cox regression model. The risk score model results in a specific number of points that correspond to a mortality or survival risk. 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 MELD Score are provided in the instructions for use. Entering the details for an individual in the MDSW initiates the estimation of short term mortality/survival risk.

7. Result interpretation

The MELD 1.0 and MELD Na provide the same 2 output statements;

- **MELD score (MELD 1.0, MELD Na, MELD 3.0, and reMELD-Na scores)**

This score is the outcome of the formula for which the patients' values are the input combined with the derived coefficient rounded to the nearest whole integer.

- **MELD (estimate 3-month mortality) (MELD 1.0, MELD Na, reMELD-Na scores)**

From this MELD score a mortality risk is determined when using the MELD 1.0, MELD Na, and reMELD-Na scores. The MELD 1.0 and MELD Na link certain ranges of the MELD scores to specific risk percentages.

Different from the MELD 1.0, MELD Na, and reMELD-Na, the MELD 3.0 provide beside a MELD score the;

- **MELD (estimated 90-day survival) (MELD 3.0 score)**

The MELD 3.0 provides a MELD Score and an estimated 90-day survival chance, provided in a percentage. This is equated from the calculated MELD score using a single formula. This allows for a more precise and continuous relationship between the MELD score and chance for survival.

The MELD Scores are not intended to replace clinical decision-making, it can only provide information to the user on the 3-month mortality risk or 90-day survival chance. The user can use this information to support clinical decision-making regarding the prognosis and treatment of the patient.

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 Community	
Algorithm ID	10085	
	Version number	**Revision date**
MELD 1.0	1.2	31 October 2025
MELD Na	2.0	31 October 2025
MELD 3.0	3.0	31 October 2025
reMELD-Na	4.0	31 October 2025
Speciality	Hepatology	
Algorithm type	R-Script algorithm	

MeSH terms

- Risk
- Hepatology
- Creatinine
- Sodium
- INR
- Hepatology
- Bilirubin
- End Stage Liver Disease
- Mortality
- Liver
- Dialysis

8.2. Input variables

To perform the calculations successfully, the devices comprising the MELD Score requires the input of all input variables. Which input variables are part of the equation differs between the devices, an overview of which is given in **Table 1**, **Table 2**, **Table *3***, and **Table 4** for the MELD 1.0, MELD Na, MELD 3.0, and reMELD-Na respectively**.**

Table 1. Variables used as input for the MELD 1.0. For some variables, the units can be switched.

Name	Description	Type	Range (step size)	Units
Serum Bilirubin	Values below 17.1 µmol/L (1.0 mg/dL) are set to 17.1 µmol/L (1.0 mg/dL)	Continuous	1.5 – 850 (0.1)	*µmol/L*
			0.1 – 45 (0.1)	*mg/dL*
INR	International Normalized Ratio, Values below 1.0 are set to 1.0	Continuous	0.5 – 20 (0.1)	-
Serum Creatinine	Values below 88.42 µmol/L (1.0 mg/dL) are set to 88.42 µmol/L (1.0 mg/dL)	Continuous	10 – 850 (1)	*µmol/L*
			0.2 – 9 (0.01)	*mg/dL*
			Input options	
Hemodialysis	Dialysis at least twice in the past week. If yes, serum creatinine will be set to 4.0	Categorical	Yes	No

Table 2. Variables used as input for the MELD Na. For some variables, the units can be switched.

Name	Description	Type	Range (step size)	Units
Serum Bilirubin	Values below 17.1 µmol/L (1.0 mg/dL) are set to 17.1 µmol/L (1.0 mg/dL)	Continuous	1.5 – 850 (0.1	*µmol/L*
			0.1 – 45 (0.1)	*mg/dL*
INR	International Normalized Ratio, Values below 1.0 are set to 1.0	Continuous	0.5 – 20 (0.1)	-
Serum Creatinine	Values below 88.42 µmol/L (1.0 mg/dL) are set to 88.42 µmol/L (1.0 mg/dL)	Continuous	10 – 850 (1)	*µmol/L*
			0.2 – 9 (0.01)	*mg/dL*
The variable Serum Sodium is included if the MELD 1.0 score > 11.				
Serum Sodium	Sodium is limited to a range of 125-137 mmol/L. If outside these bounds, is set to the nearest limit.	Continuous	110 – 150 (1)	*mmol/L*
			110 – 150 (1)	*mEq/L*
			Input options	
Hemodialysis	Dialysis at least twice in the past week. If yes, serum creatinine will be set to 4.0	Categorical	Yes	No

Table 3. Variables used as input for the MELD 3.0. For some variables, the units can be switched.

Name	Description	Type	Range (step size)	Units
Serum Bilirubin	Values below 17.1 µmol/L (1.0 mg/dL) are set to 17.1 µmol/L (1.0 mg/dL)	Continuous	1.5 – 850 (0.1	*µmol/L*
			0.1 – 45 (0.1)	*mg/dL*
INR	International Normalized Ratio, Values below 1.0 are set to 1.0	Continuous	0.5 – 20 (0.1)	-
Serum Creatinine	Values below 88.42 µmol/L (1.0 mg/dL) are set to 88.42 µmol/L (1.0 mg/dL)	Continuous	10 – 850 (1)	*µmol/L*
			0.2 – 9 (0.01)	*mg/dL*
Serum Sodium	Sodium is limited to a range of 125-137 mmol/L. If outside these bounds, is set to the nearest limit.	Continuous	110 – 150 (1)	*mmol/L*
			110 – 150 (1)	*mEq/L*
Serum Albumin	Limited to a range 15-35 g/L (1.5 – 3.5 g/dL). Values outside this range are set to the nearest limit.	Continuous	*0 – 50 (1)*	*g/L*
			0 – 5 (0.1)	*g/dL*
			Input options	
Sex	Sex of the patient	Categorical	Female	Male

Table 4. Variables used as input for the reMELD-Na. For some variables, the units can be switched.

Name	Description	Type	Range (step size)	Units
Serum Bilirubin	Values below 5.13 µmol/L (0.3 mg/dL) are set to 5.13 µmol/L (0.3 mg/dL) Values above 461.7 µmol/L (27 mg/dL) are set to 461.7 µmol/L (27 mg/dL)	Continuous	1.5 – 850 (0.1)	*µmol/L*
			0.1 – 45 (0.1)	*mg/dL*
INR	International Normalized Ratio (INR) Values above 2.6 are set to 2.6	Continuous	0.5 – 20 (0.1)	-
Serum Creatinine	Values below 61.9 µmol/L (0.7 mg/dL) are set to 61.9 µmol/L (0.7 mg/dL) Values above 221.1 µmol/L (2.5 mg/dL) are set to 221.1 µmol/L (2.5 mg/dL)	Continuous	10 – 850 (1)	*µmol/L*
			0.2 – 9 (0.01)	*mg/dL*
Serum Sodium	Values below 120 mmol/L (120 mEq/L) are set to 120 mmol/L (120 mEq/L) Values above 138.6 mmol/L (138.6 mEq/L) are set to 138.6 mmol/L (138.6 mEq/L)	Continuous	110 – 150 (1)	*mmol/L*
			110 – 150 (1)	*mEq/L*
			Input options	
Hemodialysis	Dialysis at least twice in the past week. If yes, serum creatinine will be set to 2.5	Categorical	Yes	No

Algorithm

Each of the algorithms adds the given points for every imputed variable to provide both a summed total of points as well as a risk percentage that accompanies the points.

MELD 1.0

The algorithm for the MELD 1.0 is defined as follows:

$$MELD\ score = (0.378 * Ln\left(Bilirubin\left[\frac{mg}{dL}\right]\right) + 1.120 * Ln(INR) + 0.957 * Ln\left(Creatinine\left[\frac{mg}{dL}\right]\right) + 0.643) * 10 \quad (1)$$

MELD Na

The MELD Na is the same as the MELD 1.0 as described above, but adds an additional calculation for MELD score results above 11. As such, the algorithm for the MELD Na can be defined as follows:

If the result is ≤ 11:

$$MELD\ score = MELD\ 1.0$$

If the result is > 11:

$$MELD\ score = (MELD\ 1.0) + 1.32 * \left(137 - Na\left[\frac{mmol}{L}\right]\right) - (0.033 * (MELD\ 1.0) * \left(137 - Na\left[\frac{mmol}{L}\right]\right)) \quad (2)$$

MELD 3.0

The algorithm for the MELD 3.0 is defined as follows:

$$MELD\ score = (1.33\ if\ female) + 4.56 * Ln\left(Bilirubin\left[\frac{mg}{dL}\right]\right) + 9.09 * Ln(INR) + 11.14 * Ln\left(Creatinine\left[\frac{mg}{dL}\right]\right) + 0.82 * \left(137 - Na\left[\frac{mmol}{L}\right]\right) - 0.24 * \left(137 - Na\left[\frac{mmol}{L}\right]\right) * Ln\left(Bilirubin\left[\frac{mg}{dL}\right]\right) + 1.85 * \left(3.5 - Albumin\left[\frac{g}{dL}\right]\right) - 1.83 * \left(3.5 - Albumin\left[\frac{g}{dL}\right]\right) * Ln\left(Creatinine\left[\frac{mg}{dL}\right]\right) + 6 \quad (3)$$

reMELD-Na

The algorithm for the reMELD-Na is defined as follows:

$$\text{Re-MELD-Na} = 7.85 + 9.03 * ln\,(creatinine) + 2.97 * ln\,(bilirubin) + 9.52 * ln\,(INR) + 0.392 * (138.6 - Na) - 0.351 * (138.6 - Na) * ln\,(creatinine) \quad (4)$$

Corresponding risk percentages

MELD 1.0 and MELD Na

Table 5 shows the conversion from points to mortality risk percentages for the MELD 1.0 and MELD Na.

Table 5. Conversion of MELD 1.0 and MELD Na points to risk percentages (Wiesner *et al.* (2003)).

MELD score	3-month mortality probability
≤ 9	1.9%
10-19	6.0%
20-29	19.6%
30-39	52.6%
40	71.3%

MELD 3.0

To convert the accumulated points for the MELD 3.0 to a survival percentage, the following Cox proportional-hazards regression model is used (Kim *et al.* (2021)).

$$estimated\ 90\ day\ survival\ (\%) = 0.946^{\exp(0.17698*(MELD\ 3.0)-3.56)} * 100 \quad (5)$$

reMELD-Na

To convert the points for the reMELD to a mortality percentage, the table below is used. The score to risk conversion is based on MELD mortality rates dating from 2006.

Table 6. Conversion of reMELD-Na points to risk percentages

MELD score	3-mo mortality equivalent
20	10%
22	15%
24	20%
25	25%
26	30%
28	35%
29	40%
29	45%
30	50%
31	55%
32	60%
33	65%
33	70%
34	75%
35	80%
36	85%
37	90%
39	95%
40	100%

8.3. Study characteristics

The performance of the MELD 1.0, MELD Na, MELD 3.0, and reMELD-Na of the MELD score were assessed with data from at least 269,942, 340,378, 41,083, and 6890 different patients respectively.

In terms of discrimination, the MELD 1.0, MELD Na, MELD 3.0, and reMELD-Na performed well. Their discriminatory performance was similar to each other. The C-statistics of the MELD 1.0, the MELD Na, MELD 3.0, and reMELD-Na were 0.80 (95% CI: 0.74 – 0.85). 0.78 (95% CI: 0.63 – 0.89), 0.79 (95% CI: 0.62 – 0.90), and 0.869 respectively.

8.4. Supporting publication & Related files

The equation used by the MELD 1.0 was derived in a paper by Malinchoc *et al*. (2000) and later refined by Kamath *et al*. (2001). This was followed by an update on the interpretation of the outcome by Wiesner *et al*. (2003), which is adopted in most guidelines as well as by Evidencio.

For the MELD Na an adjusted version which added Serum Sodium levels to the variables was developed by Biggins *at al*. (2006), and was proposed to be adopted by the United Network for Organ Sharing (UNOS), and the Organ Procurement & Transplantation Network (OPTN) in the US in 2014 and 2013 respectively.

The development of the MELD 3.0 was described by Kim *et al*. (2021), who aimed to optimize the MELD 1.0 further by integrating additional variables (Sex and Serum Albumin), removing Hemodialysis as and variable, and updating the coefficients of existing variables.

The derivation of reMELD-Na is described by Goudsmit et al. in 2021. This study refitted the MELD for the European population.

The most relevant studies are contained in **Table 7**. 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 7. Overview of selection of supporting publications & Related files.

Development paper MELD 1.0	**A model to predict poor survival in patients undergoing transjugular intrahepatic portosystemic shunts** (2000) *M Malinchoc, P S Kamath, F D Gordon, C J Peine, J Rank, P C ter Borg* DOI: 10.1053/he.2000.5852
Development paper MELD 1.0	**A model to predict survival in patients with end-stage liver disease** (2001) *P S Kamath, R H Wiesner, M Malinchoc, W Kremers, T M Therneau, C L Kosberg, G D'Amico, E R Dickson, W R Kim* DOI: 10.1053/jhep.2001.22172
Development paper MELD 1.0	**Model for end-stage liver disease (MELD) and allocation of donor livers** (2003) *Russell Wiesner, Erick Edwards, Richard Freeman, Ann Harper, Ray Kim, Patrick Kamath, Walter Kremers, John Lake, Todd Howard, Robert M Merion, Robert A Wolfe, Ruud Krom* DOI: 10.1053/gast.2003.50016
Development paper MELD Na	**Evidence-based incorporation of serium sodium concentration into MELD** (2006) *Scott W Biggins, W Ray Kim, Norah A Terrault, Sammy Saab, Vijay Balan, Thomas Schiano, Joanne Benson, Terry Therneau, Walter Kremers, Russell Wiesner, Patrick Kamath, Goran Klintmalm* DOI: 10.1053/j.gastro.2006.02.010
Development paper MELD 3.0	**MELD 3.0: The Model for End-stage Liver Disease Updated for the Modern Era** (2021) *W. Ray Kim, Ajitha Mannalithara, Julie K. Heimbach, Patrick S. Kamath, Sumeet K. Asrani, Scott W. Biggins, Nicholas L. Wood, Sommer E. Gentry, Allison J. Kwong* DOI: 10.1053/j.gastro.2021.08.050

Development paper reMELD-Na	**Refitting the Model for End-Stage Liver Disease for the Eurotransplant Region** *Ben F.J. Goudsmit, Hein putter, Maarten E. Tushuizen, Serge Vogelaar, Jacques Pirenne, Ian P.J. Alwayn, Bart van Hoek, and Andries E. Braat* DOI: 10.1002/hep.31677
Guidelines recommending MELD Na for the USA.	**Proposal to add Serum Sodium to the MELD Score** (2013) *Organ Procurement & Transplantation Network (OPTN), USA*
	Changes to OPTN bylaws and policies form June 2014 board meeting (2014) *United Network for Organ Sharing (UNOS), USA*
Guideline recommending reMELD-Na for the European population	**ET Liver Allocation System (ELAS) Chapter 5** (2025) Eurotransplant manual

8.5. Release notes

The release notes for each publicly available version of the device can be found on the Evidencio website page by going to the MELD Score: https://www.evidencio.com/models/show/10085, selecting the correct device, 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.

9. Implementation of the algorithm through an API

The MELD Score can be used through Evidencio's API to allow for (automated) estimation of the 3-month mortality risk or 90-day survival probability of patients with end-stage liver disease. 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.

Instruction 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.

10. 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.

10.1. General algorithm landing page

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

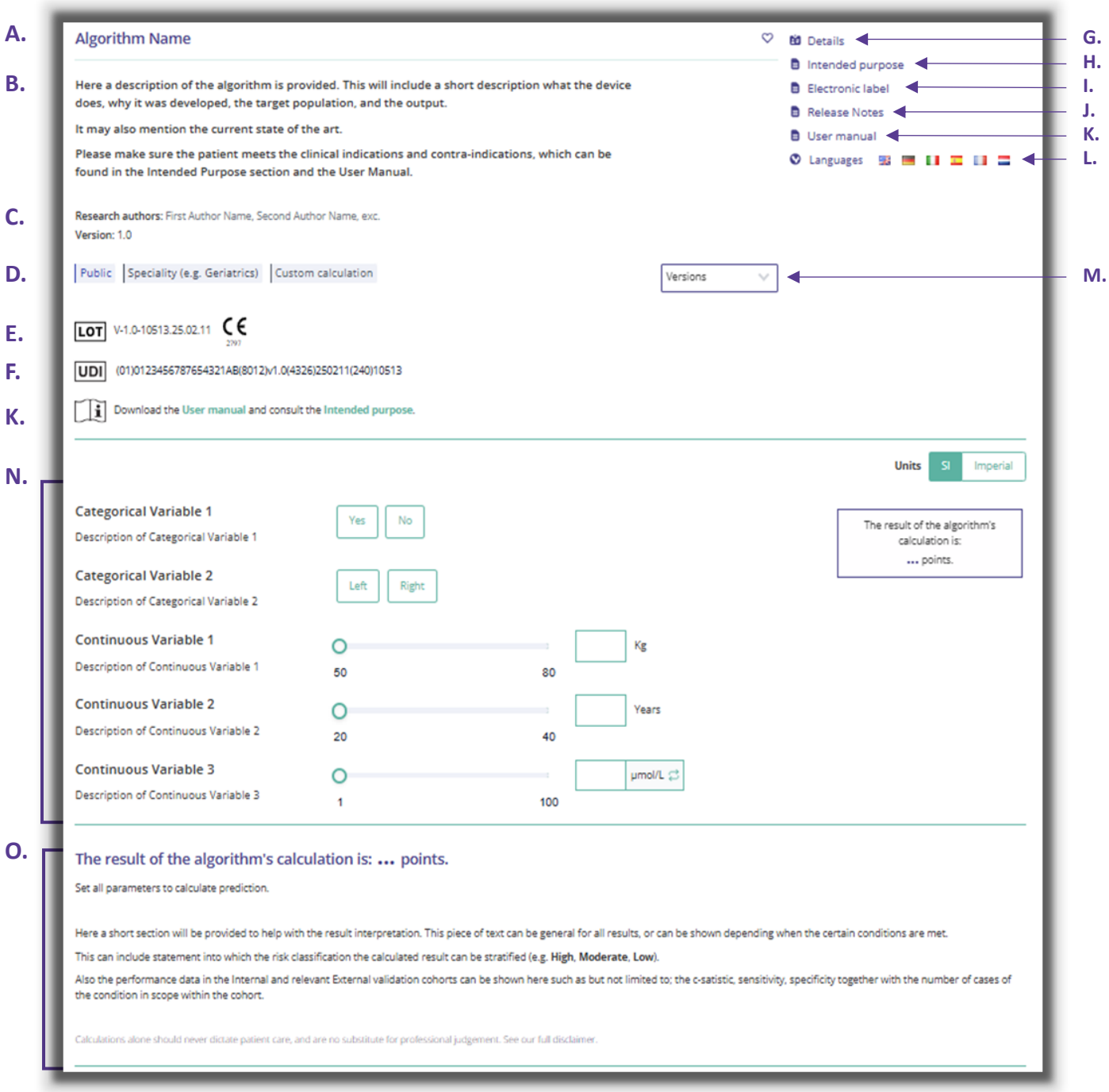

Figure 1. Example of an algorithm landing page on the Evidencio website.

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-PI number

For a description of the UDI-PI number; see **section 5.2** on **page 5** of this 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.

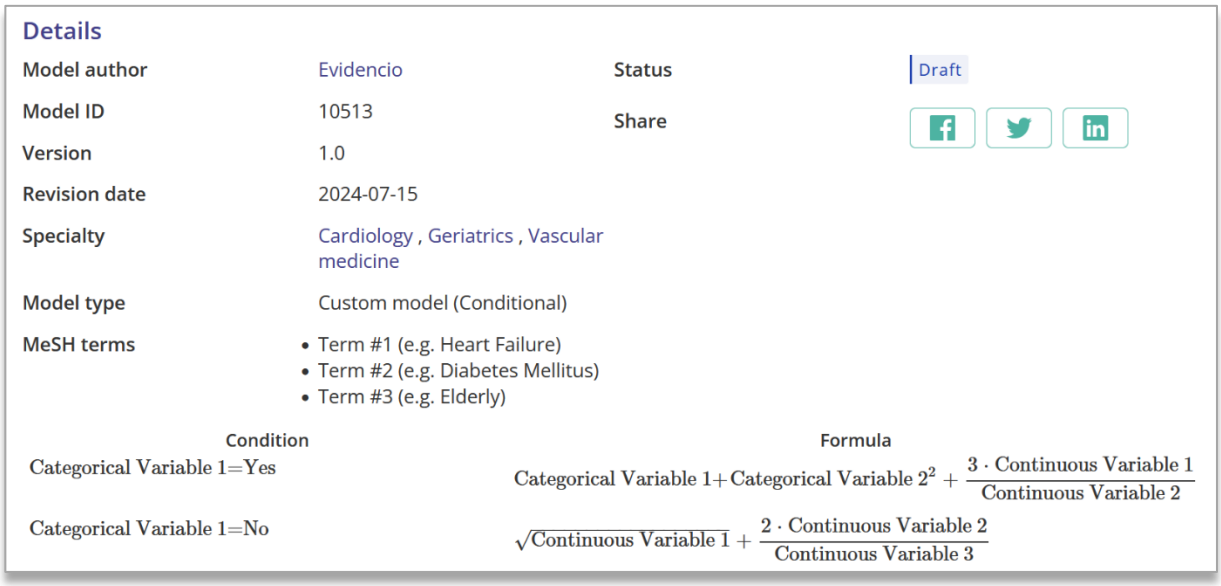

Figure 2. Example of first part of detail section.

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**.

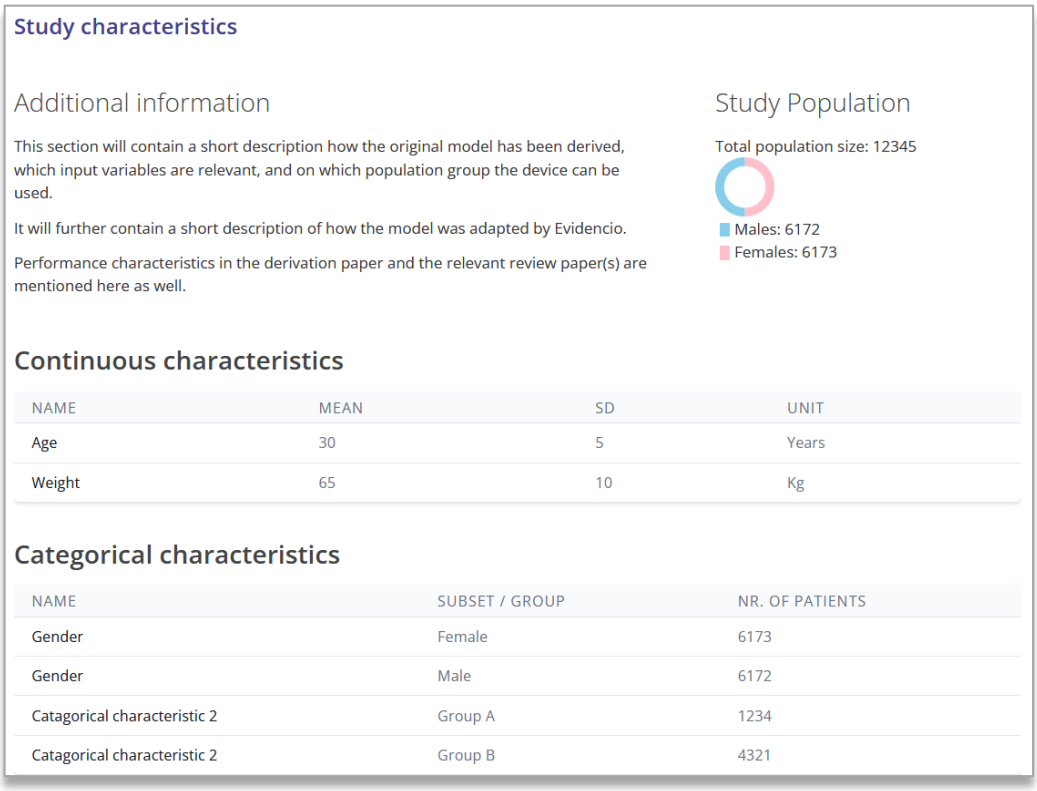

Figure 3. Example of the study characteristics section under the Details tab.

Supporting publications & Related files

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

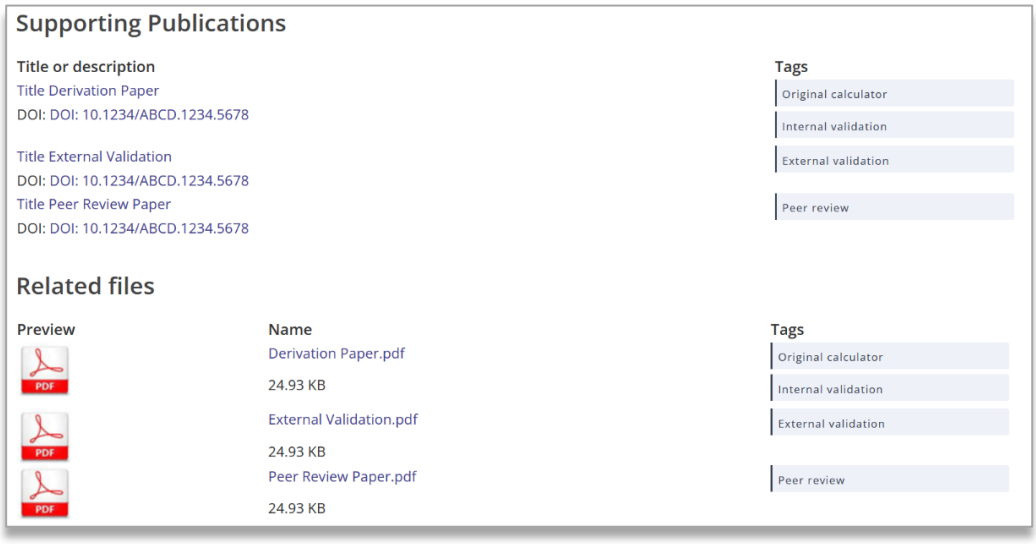

Figure 4. Example of the Supporting publication & Related files section under the Details tab.

Tags are attached to the different files to identify their link with the algorithm. 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. Figures and tables which help to interpreted the results may also be provided here.

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 0** on **page 6**.

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 MELD Score.

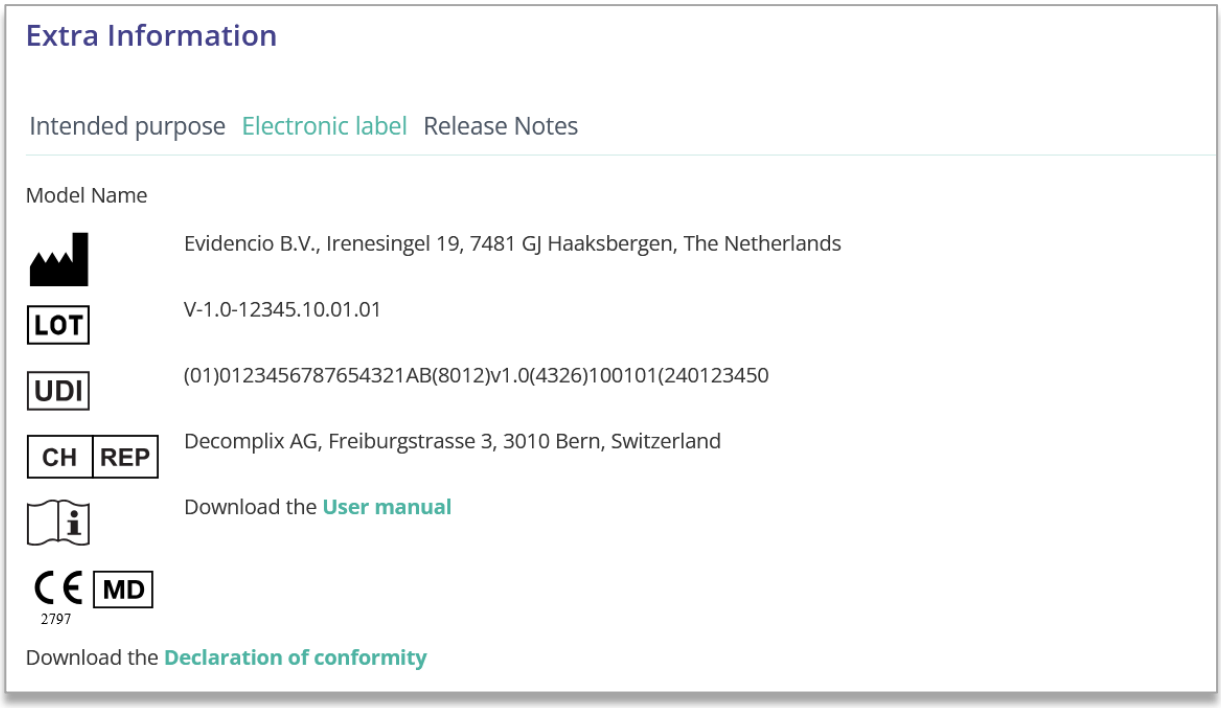

Figure 5. Example of an electronic label under the Electronic Label tab.

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.

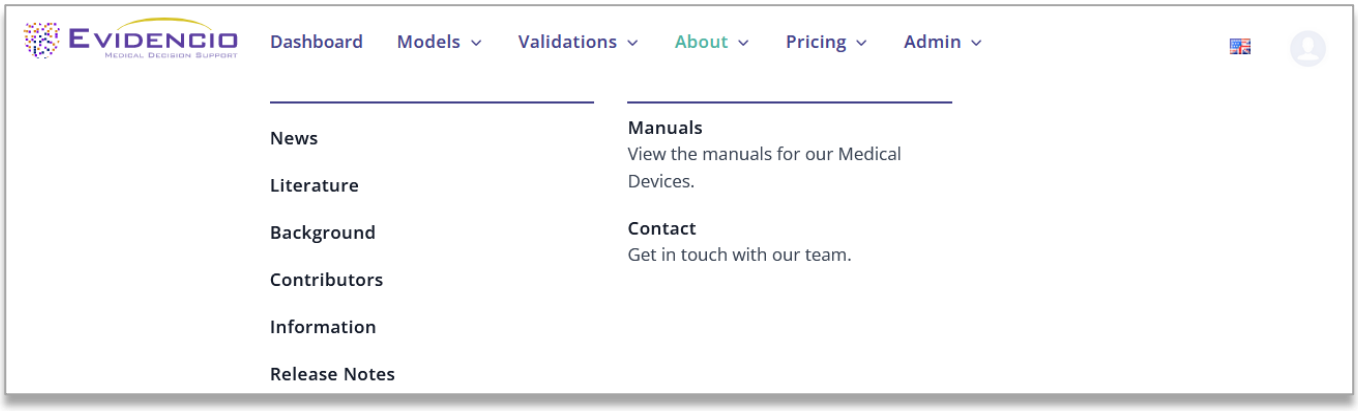

Figure 6. The drop-down menu where the user manual page can be found.

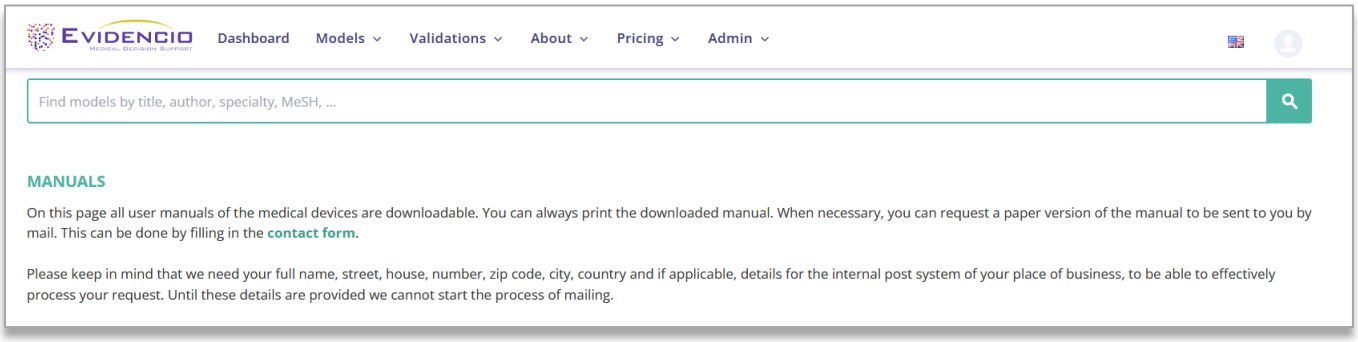

Figure 7. The user manual page for all user manuals.

L. Languages

Here an overview of languages in which the MELD Score 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. When other languages are available, these can be selected here.

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. Algorithm & Version selection

Clicking on the Version tab allows the user to select a different algorithm and algorithm version of the MELD Score for a list as displayed in **Figure 8**. Please note that the algorithm currently selected is not presented in the dropdown menu.

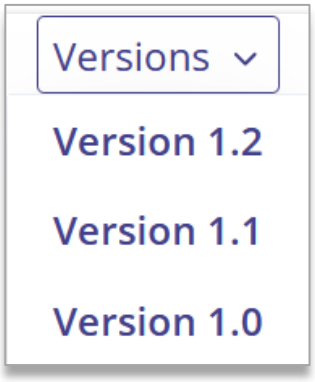

Figure 8. Example of the algorithm selection tab.

N. Input section

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

Categorical variables

In the example shown in 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**.

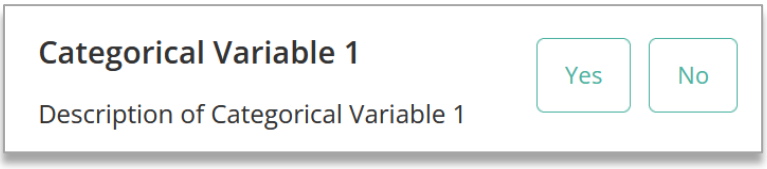

Figure 9. Example of a categorical variable, no button has been clicked and thus no input has been provided by the user.

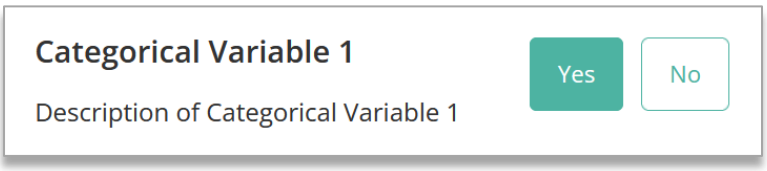

Figure 10. Example of a categorical variable, where the "Yes" button has been clicked.

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**).

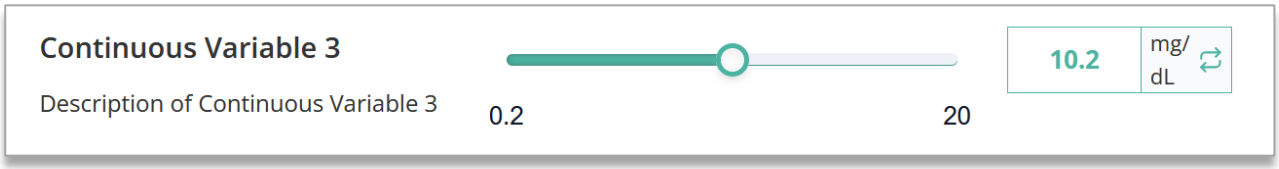

Figure 11. Example of a continuous variable, where "10.2 mg/dL" has been entered.

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.

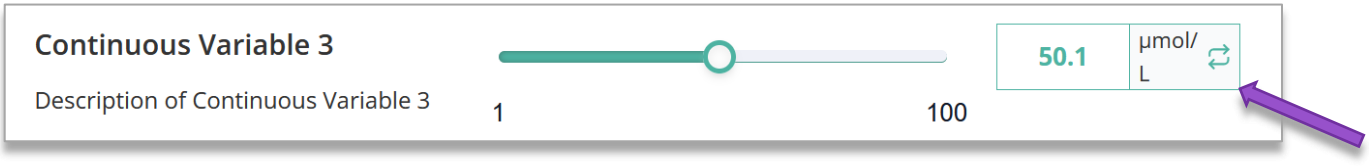

Figure 12. Example of a continuous variable where "50.1 $\mu mol/L$" has been entered.

Details on variable measurements

Directly underneath the name for each variable, additional details can be provided on 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.

O. Result section

At the bottom of the 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 will 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 risk stratification is provided based on the calculated result. 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**.

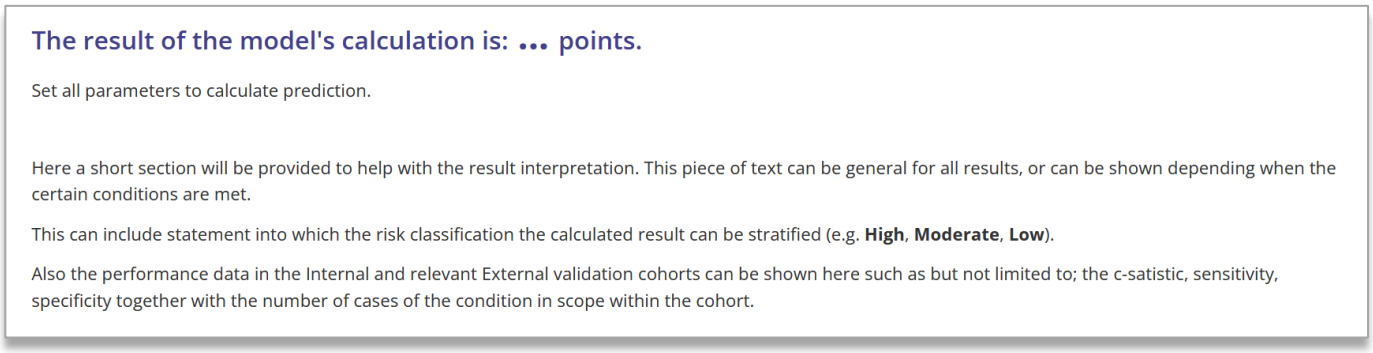

Figure 13. Example of the result display and information section.

11. User manual revision history

Version	Revision notes
V1.0 to V7.0 2024	Development versions
V8.0 AUG-2025	First public version
V9.0 OCT-2025	- Added the reMELD-Na version - Updated the intended use

12. Manufacturer details

Contact details of Evidencio:

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e-mail: info@evidencio.com