



User manual for the Feverkidstool

Version 2, 25 April 2025, English

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1. The FeverKidsTool

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 FeverKidsTool. The User Manual can also be referred to as the Instructions For Use (IFU).

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

2. Disclaimer

Evidencio provides certain CE-marked information, calculators, equations, and algorithms (tools) on any of its websites, applications, apps, or services. These tools may only be used in accordance with the intended use / intended purpose that has been published with the respective CE-marked tool.

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

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Your use of the websites, applications, apps, or services provided by Evidencio is subject to our Terms & Conditions, which can be found here: <https://www.evidencio.com/terms-conditions>.

3. Warnings for CE-marked content



Calculations alone should never dictate patient care, and are no substitute for professional judgement. See our full disclaimer on: <https://www.evidencio.com/disclaimer>. This tool is only to be used by healthcare professionals in a clinical setting, and is not for patient use.

Always read the intended use before using this tool.

Always make sure the patient complies with the clinical indications and clinical contra-indications as stated on the Evidencio website, and in **Chapter 7** of this user manual.

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. Electronic label

The electronic label of this device contains the following information:

 2797	Name of the device	Feverkidstool
	Manufacturer information	Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands
	LOT number	V-2.2-3322.25.04.25
	UDI number	(01)08720938015021(8012)v2.2(4326)250425(240)3322
	MD indication	Medical device

4.1 LOT number

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

4.2 UDI number

Stands for Unique Device Identifier (UDI) number, which is an international tool that helps users identify and find information on products. Evidencio's UDI's 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>.

5. Device description Feverkidstool

The Feverkids tool is Medical Device Software (MDSW). Since the calculator is an MDSW algorithm, it is not a physical product and does not consist of materials. The calculator does not have, for example, packaging, sterilization, or contact with the human body. The Feverkids tool is intended to support clinical decision making by informing clinical management on the predicted risk of the presence of pneumonia or other serious bacterial infections (SBIs) in children with fever at the emergency department.

6. 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, the Feverkidstool requires a stable internet connection and runs on the following devices:

- Personal computers or laptops using the following browsers:
 - Safari (version 18.3.1 and higher)
 - Chrome (version 135.0.7049.96 and higher)
 - Firefox (version 137.0.2 and higher)
 - Edge (version 135.0.3179.73 and higher)
- Tablets or smartphones running on the next operating systems:
 - IOS (version 18.3.1 and higher)
 - Android ((version 14 and higher)

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.

The FeverKidsTool 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 algorithm is only intended for use in settings where the usage and result of an algorithm are never urgently needed.

7. Intended use

The Feverkids tool is intended to support clinical decision making by informing clinical management on the predicted risk of presence of pneumonia or other serious bacterial infections (SBIs) in children with fever at the emergency department. With the risk prediction, the Feverkids tool supports clinical decisions regarding antibiotic prescriptions for febrile children presenting at the emergency ward.

The Feverkids tool combines the following variables to predict the presence of pneumonia or SBIs: Age, gender, duration of fever, body temperature, respiratory rate, heart rate, oxygen saturation, capillary refill time, Chest wall retractions, ill appearance, and CRP.

The device is intended to be used by physicians in the emergency department, 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 regarding further therapeutic or diagnostic activities.

Benefit/risk profile

Correct functioning of the Feverkidstool does not directly result in a clinical benefit, but can be used to support the decision making process and therefore indirectly contribute to the following clinical benefit:

Use of the algorithm positively impacts patient management by optimizing clinical decision making in febrile children presenting at the emergency department, and informing clinical management on further diagnostic and therapeutic options.

The calculator can be used for febrile children at the emergency department if an acute infection is suspected by the parents, the referring clinician, or the triage nurse.

The calculator is not suitable for patients with the following characteristics:

- Children >15 years;
- Fever duration > 6 days.

User profile

The Feverkidstool 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.

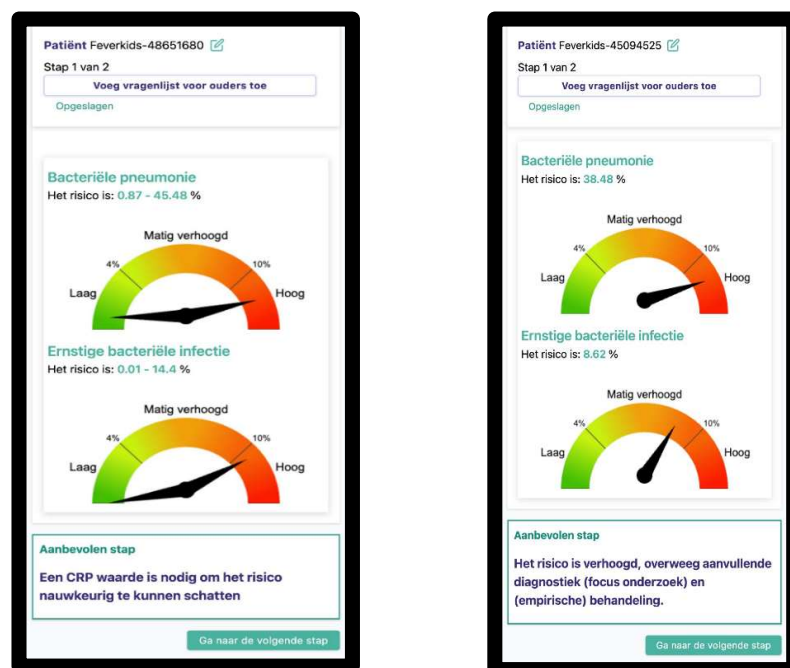
Functioning, physical principle

The Feverkids tool is implemented as a sequential algorithm on the Evidencio platform. The underlying mathematical formula of the Feverkids tool is a polytomous logistic regression algorithm. For the Feverkids tool, the probability of pneumonia and (other) serious bacterial infection can be calculated. For the implementation, the outcomes of the Feverkids tool are calculated with the use of an R-script.

8. Result interpretation

Primary result

The result of the MDSW is the probability of pneumonia or (other) serious infections for a patient. The primary result is displayed as;



Figuur 9. Example of a result display.

9. Additional information

9.1 Details

Author of the algorithm	T. A. Hueting
Root algorithm ID	3322
Version	2.2
Revision date	25-APR-2025
Specialty	Unspecified
Algorithm type	Sequential Algorithm
MeSH terms	No MeSH classifications added

9.2 Input variables

To perform the calculations successfully, the Feverkidstool requires the input variables as listed in Table 1.

Table 1. Variables used as input for the Feverkidstool.

Name	Variable	Option/range (value)
Date of arrival	Age calculated as: ((date of arrival) – (date of birth))/365.25	In years
Date of birth		
Gender	Sex	Boy (0), Girl (1)
Temperature	Temperature	36-45°C
Fever duration in days	Duration of fever	0-6 days
Respiratory rate	Presence of tachypnoea	0 - 100 breaths per minute
Heart rate	Presence of tachycardia	1 - 230 beats per minute
Oxygen saturation	Oxygen saturation <94% Calculated out of the filled in saturation of 70-100%. Saturation <94% = value 1 Saturation ≥94% = value 0	70 - 100 %
Capillary refill time	Capillary refill time (>3s)	≤3 seconds (0) >3 seconds (1)
Chest wall retractions	Presence of chest wall retractions	Absent (0) Present (1)
Ill appearance	Ill appearance	No (0), Yes (1)
CRP	CRP	0-200 mg/L Unknown

10. Algorithm landing page

The medical device algorithm on the Feverkids platform is shown in Figure 1,2 & 3. The algorithm landing page contains the following sections, that are indicated in Figure 1,2 & 3.

The screenshot shows the algorithm landing page for Feverkids. It includes a header with a menu icon (A), the title 'Feverkids new' (B), and patient information 'Patiënt Feverkids-6340716' with an edit icon (C). Below this is a button 'Voeg vragenlijst voor ouders toe' (D) and a status 'Opgeslagen'. A paragraph (E) describes the algorithm's purpose. A link 'Klik hier voor aanvullende informatie.' (F) is highlighted. A form section (G) titled '1 Vul patiëntgegevens in' contains fields for 'Geboortedatum' (24-04-2022), 'Geslacht' (Meisje selected), 'Bezoekdatum' (12-04-2023), and 'Koortsduur in dagen' (4 days).

Figure 1. An example of an algorithm landing page.

G.

Zieke indruk 🤒

Nee

Ja

Intercostale intrekkingen

Afwezig

Aanwezig

Hartslagfrequentie ❤️

1 - 230 per minuut

Ademfrequentie 🫁

0 - 100 per minuut

Zuurstofsaturatie ⓘ O₂

70 - 100 %

Capillaire refill

≤3 seconden

>3 seconden

Temperatuur ⓘ 🌡️

36 - 45 Celsius


CRP ⓘ 🧪

0.1 - 200 mg/L

H.

Bacteriële pneumonie

Het risico is: 16.59 %



Ernstige bacteriële infectie

Het risico is: 17.5 %




Figure 2. An example of an algorithm landing page.

I. **Aanbevolen stap**

Bij een hoog risico wordt antibiotica aanbevolen

J. **PROTOCOL AFGEROND** Kopieer

Het resultaat kan gekopieerd worden voor invoer in het EPD

C. Registratie: Feverkids-6340716
Datum: 14-04-2023

K. Voeg zelf nog opmerkingen toe

B *I* U ☰ ↶ ↷

+ Voeg toe

L. **CONSULT AFRONDEN** Afronden

De gegevens van de patiënt worden opgeslagen.

M. Dit model wordt verstrekt voor informatieve doeleinden ter optimalisering en implementatie van de Feverkidstool. Het mag niet worden gebruikt ter ondersteuning van medische besluitvorming, of om medische of diagnostische diensten te verlenen. Lees onze [volledige disclaimer](#).

N. Feverkidstool is ontwikkeld onder het NEN7510 & ISO27001 gecertificeerde managementsysteem voor informatiebeveiliging. Lees onze [volledige privacy policy](#).

Figure 3. An example of an algorithm landing page.

A. Menu

By clicking on this icon a menu will show as seen in Figure 4. It is possible to see the patient overview, the patient archive and background information.



Figure 4. Menu of the Feverkidstool.

B. Algorithm title

This is the title and name of the algorithm.

C. Patient information

This is the specific patient code.

D. Parents questionnaire

By clicking on 'Voeg vragenlijst voor ouders toe' a pop-up is shown with a link to the questionnaire and a login code. The questionnaire aimed to be used by parents is still under development is to be used for research and personal purposes only.

E. Algorithm description

This is a short description of the algorithm.

F. Supplementary information

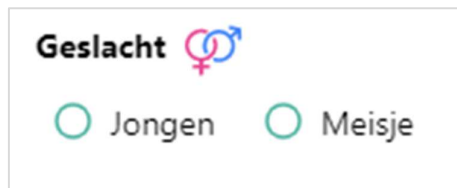
Clicking on this link opens a new tab where supplementary information is given such as; details, disclaimer and the project group.

G. Input section

The Feverkidstool allows two types of input; categorical, and numerical variables.

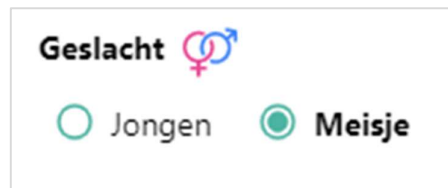
Categorical variables

In the example shown in Figure 5 and 6, the **Gender** 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 7.



The screenshot shows a form titled "Geslacht" with a gender symbol icon. Below the title are two radio buttons: "Jongen" and "Meisje". Both buttons are currently unselected, indicated by empty circles.


Figure 5. The variable for gender, where no button has been clicked.



The screenshot shows the same "Geslacht" form. The "Meisje" radio button is now selected, indicated by a filled green circle. The "Jongen" button remains unselected.

Figure 6. The variable for gender, where "Meisje" has been clicked.

Continuous variable (date)

In the example shown in Figure 7, the **date of birth** variable exemplifies a date as a continuous variable. The quickest way to enter the date of birth is to click on the  icon, then on the month and year and then on the year, as seen in Figure 8.

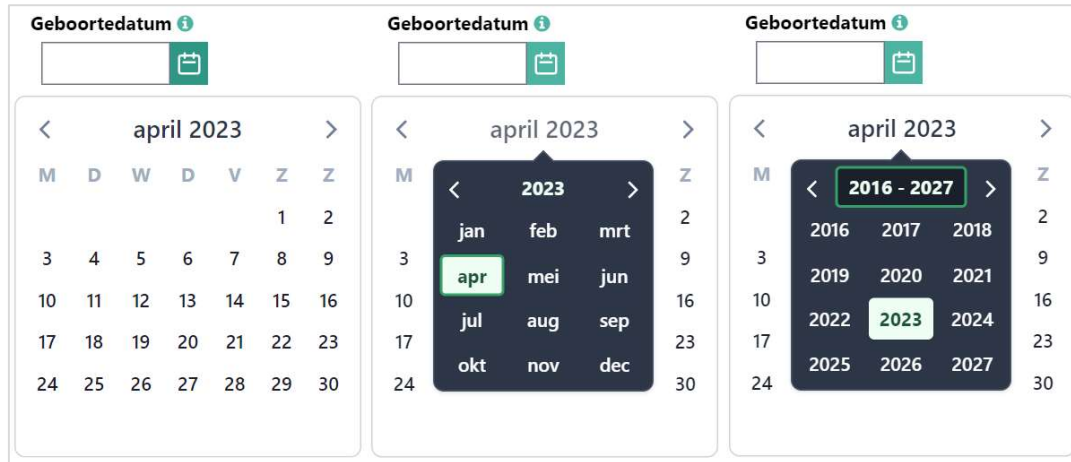


Figure 7. Example to enter a date in the Feverkidstool.

Numerical variable

In the example shown in Figure 9, the **heartbeat** variable exemplifies a numerical variable. The plausible ranges for the variables are defined by the algorithm developer. For example, the tool is not suitable for patients with a heartbeat under 1 beat per minute, or faster than 230 beats per minute. Thus, the algorithm only allows input of ages for patients between the range of 1 to 230 beats per minute.



Figure 8. The variable for heartbeat, where "120" has been entered.

H. Result calculation and visualization

At the bottom of the page, the results of the algorithm are shown. When all variables are filled in, a result will be calculated. No risk is displayed until all variables are filled in. A risk percentage is given and a figure shows the risk categorization.

I. Result Interpretation

Depending on the calculation a recommended next step is given.

J. Copy the results

This is the end of the Feverkidstool, it is possible to copy the result and put it in the patient file. Additional made comments are copied with it.

K. Comment option

Here the attending physician can add additional comments for this specific patient.

L. Finish and save the consult

The consult can be finished and saved if the consult is completed.

M. Disclaimer

This is the disclaimer of the algorithm, the link to the entire disclaimer is added.

N. Privacy policy

This is the privacy policy of the algorithm, the link to the entire privacy policy is added.

11. User manual revision history

Version	Revision notes
V1.0 JUN-2024	Original version
V2.0 APR-2025	Included option for unknown CRP value

12. Manufacturer details

Contact details of Evidencio:

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