

Instruction for Use

KITMed Version 2.1

for Medical Professionals

Version 3.0 | 2022-07-25

Doc-ID: KITM-3681



Manufacturer:
AIT Austrian Institute of Technology GmbH Giefinggasse 4,
1210 Wien, Austria
Date of manufacture: 2022



Serial number:
KITMed 2.1.0



Use-by date:
2026-10



Notified Body:
mdc medical device certification GmbH, Kriegerstrasse 6,
70191 Stuttgart, Germany

KITMed is a medical device.



(01)09120109830139



Caution: Please read paragraphs marked with this symbol
carefully as they contain important safety information.

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1 For whom is this document intended?

This document is intended for medical personnel (doctors, nurses) who have knowledge of **KITMed**. It is intended to teach them the safe handling and functionality of **KITMed**.

2 What is *KITMed*?

KITMed is a software service (medical product) for the automated analysis of vital data from electronic diaries in relation to individual limit values. **KITMed** can be used in combination with a data management system (DMS).

3 Who is allowed to use *KITMed*?

KITMed is intended to be used by qualified physicians and nursing staff.

The Intended User must meet the following requirements:

- At least 18 years old or under supervision of trained personnel
- Physical and mental ability to handle a PC and its standard function

4 What can *KITMed* be used for?

KITMed provides therapy support for chronic diseases through automated analysis of vital data, in particular blood sugar, blood pressure, heart rate, body weight, International Normalized Range (INR) and subjective well-being. **KITMed** enables an automated comparison of chronologically ordered vital data in relation to user-defined limit values using predefined rules. **KITMed**, serves as an independent service which can be used as an add-on module for a data management system (DMS). As result of the systematic analysis, **KITMed** provides a report with information on data values that exceed or fall below the limit values.

5 How long is the lifetime of *KITMed*?

The life span of this version of **KITMed** ends on support time of the operating system and the supported Python Version approved for this version on 2026-10 (October 2026). As of these dates, no more error corrections will be performed for **KITMed** and this version of **KITMed** may no longer be used.

6 For which patients can *KITMed* be used?

KITMed can be used for adults from the age of 18 if an electronic diary of vital data for compliance and therapy monitoring is kept by the professional user. Possible "exemplary" application examples are the analysis of blood sugar data for diabetes mellitus, the analysis of blood pressure, heart rate and body



Patients with indication for intensive medicinal treatment are excluded from the use of *KITMed*.

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weight data for cardiac diseases (cardiac insufficiency or hypertension) or the analysis of coagulation data in relation to individual limit values for patients with a cardiac support system. There are no gender restrictions.

7 What are the restrictions on use?

The software service **KITMed** for the automatic analysis of vital parameters cannot replace the evaluation by the physician. As with any automatic procedure, analysis with **KITMed** may result in analysis blur. The detection rate of abnormalities depends on the individual limit values defined by the treating physician and the vital parameters recorded by the patient. The gender of the patient has no effect on the application of the defined rules. A 100% detection rate cannot be guaranteed. For the evaluation of the overall health picture of the patient, more comprehensive information must therefore be used. **KITMed** does not give any diagnoses, diagnostic recommendations or prognoses about the condition of the patient. It remains the physician's responsibility to decide on diagnoses and treatment.



KITMed is not intended for use in emergency medical care.



The patient must be informed that in the event of an emergency the family doctor or the local rescue or emergency medical service must be contacted directly.



KITMed does not give any diagnoses, diagnostic recommendations or prognoses about the condition of the patient. It remains the physician's responsibility to decide on diagnoses and treatment.



Patients with indications for intensive medical treatment are excluded from the use of KITMed.



The automatic analysis of vital parameters, performed by KITMed, cannot replace the evaluation by the physician.



The gender of the patient has no effect on the application of the defined rules.

8 What are the prerequisites for using KITMed?

8.1 Working environment

For the use of KITMed, a computer with an Internet connection must be available (a "medical PC" with IP65 degree of protection and EN60601-1 and EN60601-1-2 certification is not required). A supported Internet browser (see Chapter 16) must be installed on the personal computer (PC, operating system-independent) with which content from the Internet and a document in Portable Document Format (PDF) can be visualized.

To be able to visualize the PDF or rather open it, the professional user requires a software which is capable of reading PDFs of version 1.5 and above (e.g. Adobe Reader 6.0 or higher).

Further information can also be found in chapter 17 *In which application environments can KITMed be used?*

8.2 Plausibility check

In the data management system (DMS), medically plausible limit values for the vital parameters must be set for the respective patient. Depending on the physician's requirements, patients must regularly enter vital data. If no vital parameter data or no limit values are provided for analysis by KITMed, this is noted in the results report with a corresponding symbol (--). If data is classified as "not plausible" during the automatic plausibility check, the values are crossed out and marked with the symbol (#) in the comment.

For the following vital parameters, the typical measuring ranges of commercially available measuring instruments for home use are used.

- **Blood sugar [mg/dl]**
 - Upper plausibility value: 600 mg/dl
 - Lower plausibility value: 20 mg/dl
 - Unit: mg/dl
 - **Reference for plausibility values:** *Measurement range of Roche AccuChek Guide (Roche Diabetes Care Austria GmbH, Austria)*

In addition, for the analysis of blood glucose readings, it is defined that only those values shall be used for the analysis which are marked 'fasting' or 'before meals'. All other values (without or with a different annotation) are crossed out in the result report and marked with (#) in the comment.

(see chapter 14 Which symbols are used in the KITMed results report?, page 10)

- **Systolic blood pressure [mmHg]**
 - Upper plausibility value: 279 mmHg
 - Lower plausibility value: 60 mmHg
 - Unit: mmHg
 - **Reference for plausibility values:** *Measurement range of bosso medicus systems (bosso Bosch + Sohn GmbH Deutschland)*
- **Diastolic blood pressure [mmHg]**
 - Upper plausibility value: 200 mmHg

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- Lower plausibility value: 40 mmHg
- Unit: mmHg
- **Reference for plausibility values:** Measurement range of bosco medicus systems (bosco Bosch + Sohn GmbH Deutschland)

- **Heart rate [1/min]**
 - Upper plausibility value: 180 1/min
 - Lower plausibility value: 40 1/min
 - Einheit: 1/min (Herzschläge pro Minute)
 - **Reference for plausibility values:** Measurement range of bosco medicus systems (bosco Bosch + Sohn GmbH Deutschland)

- **Body weight [kg]**
 - Upper plausibility value: 200 kg
 - Lower plausibility value: 30 kg
 - Unit: kg
 - **Reference for plausibility values:** Measurement range of A&D Medical (A&D Instruments Limited, UK)

- **Coagulation factor (INR)**
 - Upper plausibility value: 8,0
 - Lower plausibility value: 0,8
 - No unit, because of „Ratio“
 - **Reference for plausibility values:** Measurement range of CoaguCheck INRange System (Roche Deutschland Holding GmbH)

The plausibility check for the vital parameter well-being:

For well-being it is defined that only values with the contents "good", "medium" and "bad" are used for the analysis. If the values transferred to **KITMed** for analysis do not correspond to one of these terms, the term is crossed out and the symbol (#) is noted in the comment.

(see Chapter 14 Which symbols are used in the KITMed results report?, page 10)

8.3 Routine check

Regardless of the results of KITMed, the user must ensure that vital data and the set limits are routinely checked within an appropriate period of time for the respective indication (e.g. weekly).

9 How does KITMed make the analysis results available?

KITMed presents the analysis results in a report in Portable Document Format (PDF/X-3 version ≥ 1.5). The result report can be opened and viewed on the PC with any common PDF reading software. In addition, **KITMed** offers an interface for the corresponding data management system, which makes the analysis results available electronically in structured form for visualization. This function is not part of this instruction manual and is described in the installation manual of **KITMed** for commissioning by an IT technician.

10 How is the KITMed Result Report structured?

10.1 Document information

- **Headline of the KITMed Results Report**
 - Identification data of the patient: [Patient ID]
 - Name of the corresponding system: [Called by]
 - Date and time of report creation: [DD/MM/YYYY at hh:mm (tz)] – date, time and timezone is dependent on the server running KITMed
 - Page number and number of pages
- **Patient Information of the KITMed Results Report**
 - Patient
 - Identification data of the patient: [Patient ID]
 - First name and surname (optional)
 - Date of birth (optional)
 - Analysis period:
 - From: [dd/mm/yyyy 00:00] am
 - To: [dd/mm/yyyy hh:mm] pm
- **Footer of the KITMed Results Report**
 - Report ID [unique code number of the report]
 - KITMed 2.1.0
 - Serial number: [Software Version], [language]
 - Manufacturer information
 - AIT Austrian Institute of Technology GmbH, Giefinggasse 4, 1210 Vienna, Austria
 - E-mail address for inquiries: kitmed@ait.ac.at
 - CE mark with number of Notified Body (0483)
 - KITMed provides an electronic instruction for use. Printed instructions for use available from manufacturer.

10.2 Explanation of symbols and terms

- The first page of the results report contains a table explaining all symbols and terms used in the results report.
- *See also chapter 14 Which symbols are used in the KITMed results report? (page 10)*

10.3 Results overview (page 2)

- In the results overview, the summary of the analysis results from the detailed results is displayed for each vital parameter in order to provide an overview of the **KITMed** analysis.
- Exceeding limit values of vital data and their amount are highlighted in the results overview (written in bold and highlighted in colour).

10.4 Detailed results

- In the detailed results, the measured values and limit values transmitted for analysis with date and time of measurement are displayed for each vital parameter.
- For each vital parameter, the rules applied are explained in a text area at the beginning of the results tables.

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- For traceability, measured values that are not used for the analysis are displayed crossed out. Reasons for this can be:
 - The measured value lies outside the plausibility limits of a vital parameter.
 - The measurement is repeated. A measurement repetition is defined as up to 3 consecutive measurement values with a time delay of less than 10 minutes only the last measurement value is used for analysis. Repeated measurements are not taken into account for blood glucose readings and well-being.
- Missing limit values are indicated by the symbol "~".
- In a separate column, the irregularities (exceeding or shortfalls) and explanatory comments are displayed.
- In the lower part of the table of a vital parameter, the summary of the analysis are displayed with the number of irregularities (rule violations in the analysis period).

11 Which vital parameters are evaluated with KITMed?

The following vital parameters are analysed by KITMed, which are transferred from the corresponding DMS to KITMed. The unit of the vital parameter is given in square brackets.

- Blood Glucose [mg/dl]
- Systolic blood pressure [mmHg]
- Diastolic blood pressure [mmHg]
- Heart rate (pulse) [1/min]
- Body weight [kg]
- Change in body weight [kg/time range]
- Coagulation factor (INR)
- Well-being [good/medium/bad]

12 Which analysis period is evaluated with KITMed?

All vital parameters of different types are processed by the corresponding data management system (DMS) (see chapter 11 page 8) in the period from the day and time of the service call back to 6 days 00:00 hrs to **KITMed** for analysis. This results in the following analysis period as an example:

- from 29/04/2019 08:30 am (Date and time of service call)
- to 23/04/2019 00:00 pm (minus 6 days at 00:00)

13 Which rules are applied with KITMed?

13.1 Rule for repeated values

Repeat values are vital parameters of the same type that have been measured or transmitted several times within a period of less than 10 minutes. A maximum of 3 repetition values in series are considered and the last value of this series is used for analysis and evaluation. Thus the 3rd value in series (within a maximum of 20 min) is used for the analysis, the two immediately preceding data values are marked as repetition values (crossed out, e.g. 123) and are not used for the analysis. If other values follow on the same day, they are checked again for repetition values.

13.2 Rule for missing limit values

If no corresponding limit values are transferred to **KITMed** for a vital parameter, **KITMed** cannot analyse this vital parameter. In the result report, the symbol „~“ indicates this and the comment "missing limit value" appears.

13.3 Rules for exceeding and falling short of limit values

If a vital parameter exceeds the upper limit values valid at the time of measurement, this is indicated in the result report with the symbol „↑“.

If a vital parameter falls below the lower limit values valid at the time of the measurement, this is indicated in the result report with the symbol „↓“.

13.4 Rules for detecting weight changes in time intervals

The following rules are used to analyse weight changes:

Rule (A): 2 kg in 2 days gradient on reporting day

- Compares the first body weight value on the report day with the first body weight value 2 days earlier.

Rule (B): 2 kg in 2 days gradient in analysis period

- Compares the first body weight value on each day from report day to 5 days back to the first body weight value 2 days earlier.

Rule (C): 3 kg in 6 days gradient on reporting day

- Compares the first body weight value on the report day with the first body weight value on the first day of the analysis period (6 days earlier).

If the limit value (+2kg for rule A and B or +3kg for rule C) is exceeded in the case of a body weight increase, this is noted in the result report with the symbol „↗“.



If the limit value (-2kg for rule A and B or -3kg for rule C) is undershot for a drop in body weight, this is indicated in the results report with the symbol „↘“.

13.5 Rule for irregularities in well-being

The rule checks whether the well-being was noted as "bad" at least once a day. If the well-being is identified as "bad", the „↑“ symbol is displayed in the results report.

13.6 Rules for exceeding or falling below blood sugar limits

Only values that have been annotated with "fasting" or "before eating" are examined.

| | |
|---|--|
|  | Blood glucose reading with annotation "fasting" (symbol: contour of an apple) |
|  | Blood glucose reading with annotation "before eating" (symbol: apple filled out) |

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All other measured values with no or another note are not used for the analysis, are crossed out and marked with the symbol (#) in the comment.





The blood glucose rule checks whether the readings are below or above the limit.

Blood glucose values marked "fasting" or "before eating" exceed the upper limits applicable at the time of measurement and are marked with the symbol „↑“ in the result report.

Blood glucose values marked "fasting" or "before eating" below the lower limits valid at the time of the measurement are marked with the symbol „↓“ in the result report.

For the analysis period, it is also checked whether more than 25% of all values marked "fasting" or "before eating" are above the upper limit value or below the lower limit value.

14 Which symbols are used in the KITMed results report?

| Symbol/Term | Meaning |
|---|---|
| 1 | <i>This value or result was marked as "suspicious" (printed in bold).</i> |
|  | <i>This value or result was marked as "suspicious" (square)</i> |
| Period of analysis | <i>Period from day and time of the call of KITMed to 6 days back 00:00. Example: KITMed Call, Analysis Period</i> <ul style="list-style-type: none"> <i>from 28/04/2019 08:30 am (date time KITMed call)</i> <i>until 22/04/2019 00:00 pm (minus 6 days, 00:00)</i> |
| ↑ | <i>The upper limit of the vital parameter has been exceeded.</i> |
| ↓ | <i>The lower limit of the vital parameter has been undershot.</i> |
| ↗ | <i>The upper gradient of the vital parameter was above the upper threshold limit.</i> |
| ↘ | <i>The gradient of the vital parameter was below the lower threshold limit.</i> |
| ~ | <i>There are no limit values available in the analysis period to perform an analysis.</i> |
| -- | <i>No vital parameter values available in the analysis period to perform an analysis.</i> |
| xx | <i>No vital parameter values available to calculate gradient.</i> |
| 123 Repeat values | <i>Repeat values: these are up to 2 successively measured values, each repeated within 10 minutes; these values are not considered for the analysis.</i> |
|  | <i>Blood glucose reading with annotation "fasting" (symbol: contour of an apple)</i> |
|  | <i>Blood glucose reading with annotation "before meal" (symbol: apple filled)</i> |
|  | <i>Blood glucose reading with annotation "after meal" (symbol: bitten apple)</i> |
| 123 (*) | <i>This blood glucose value is ignored for analysis because it has not the context "fasting" or "before meal".</i> |
| 12345 ... (#) | <i>Value not plausible or unit not supported. A maximum of 5 characters of the transmitted value are displayed.</i> |
| (...) | <i>There are more than 70 values for a vital parameter. The analysis was limited to the first 10 values per day.</i> |

The displayed symbols were consciously chosen to be easy and understandable.

15 Is there additional help for KITMed?

Requests for additional help can be sent to the Helpdesk via the e-mail address available on the DMS website or directly at kitmed@ait.ac.at.

16 Which commissioning, maintenance and repair measures are mandatory?

KITMed requires no special maintenance. However, the manufacturer may issue updates at irregular intervals. The manufacturer or distributor will inform the user about these updates. It is recommended that updates from the Internet browser manufacturer are installed promptly. The user must ensure that the Internet browsers used meet the minimum requirements defined below: Internet Explorer (at least version 11), Firefox (at least version 43), Chrome (at least version 47).

Furthermore, the use of PDF reading software such as Adobe Acrobat Reader is recommended. Adobe Acrobat Reader can be downloaded free of charge from the Internet and is often supplied by software manufacturers together with the documentation of their programs. The requirements for **KITMed** concerning the installation environment of the system operator are listed in the provided document **KITMed – Installation Guide and operation Manual**.

17 In which application environments can KITMed be used?

KITMed can only be used in combination with a DMS (Data Management System) that provides **KITMed** with the vital parameters transferred by the patient and the parameter limits set by the professional user (limit values). Furthermore, it must be ensured that the result report can be opened and visualized as a PDF document. The results can optionally be displayed via a technical interface directly in the DMS, whereby this does NOT replace the result report, but may be used additionally. For further information please contact kitmed@ait.ac.at.

18 What information must I observe according to the basic data protection regulation?

If the information in the results report is obviously related to a patient, the report must be kept confidential.



Please make sure that you store the result report only on trustworthy media. You as the media owner are responsible for the basic data protection regulation.

19 How can feedback and problems be reported?

The user can report feedback and problems with **KITMed** to the distributor where the software was purchased or directly to the manufacturer using the email address kitmed@ait.ac.at.

Any serious incidents that occur in relation to the device should be reported directly to the manufacturer using the email address kitmed@ait.ac.at and the competent authority of the member state in which the user and/or patient is established.

20 Where can I get a printed version of this User Manual?







A printed version of this leaflet is available directly from the manufacturer.

21 Where can I get information about KITMed?

Each result report includes version information, manufacturer address, contact information,




certification, and the date and time the report was generated.

22 Explanation of the symbols in this user manual

| Symbol | Meaning | Description |
|---|--------------------------|---|
|  | Special attention | This symbol refers to special instructions in the instructions for use. |
|  | Manufacturer | This symbol refers to the manufacturer's address |
|  | Serial number | This symbol indicates the serial number of the software to which this instruction manual applies |
|  | CE mark | This symbol indicates conformity with Regulation (EU) 2017/745 with the number of the Notified Body (0483- mdc medical device certification GmbH, Kriegerstrasse 6, 70191 Stuttgart, Germany) |
|  | Unique Device Identifier | Indicates a carrier that contains unique device identifier information. |
|  | Use-by date | This symbol indicates the date after which the medical device may no longer be used. |

Errors and omissions excepted

23 Local information about distribution and authorized representatives

| <i>Authorized Representative with Country Code</i> | <i>Contact information</i> |
|---|---|
|  | <p>CH-Representative Arazy Group Swiss GmbH Bruderholzallee 53 4059 Basel, Switzerland</p> <p>swiss.ar@arazygroup.com</p> |
|  | <p>TR-Representative Siemens Healthcare Sağlık A.Ş. Yakacık Cad. No:111 34870 Kartal, İstanbul, Türkiye Çağrı Merkezi: 444 0 633</p> |
| <div style="display: flex; align-items: flex-start;"> <div style="margin-right: 20px;">  </div> <div> <p>Importeur Siemens Healthineers International AG Hinterbergstr. 14 Switzerland</p> <p>Sponsor for Australia Siemens Healthcare PTY Ltd. Level 3, 141 Camberwell Rd Hawthorn East, VIC 3123 Australia</p> </div> </div> | |

