pacmed critical

Instructions for Use

English version

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1. Introduction

1.1. About Pacmed Critical

Pacmed Critical supports qualified intensive care unit medical professionals (e.g, intensivists, medical specialists) who are responsible for the care of patients and discharge processes with decision-making related to patient discharge.

The decision-support software specifically predicts the seven-day combined risk of patient readmission and mortality, at the moment of discharge to the regular ward, using historical patient data and a machine learning model. It has been developed and manufactured by Pacmed.

1.2. About these Instructions for Use

The Instructions for Use (IFU) is intended to assist users in the safe and effective use of the Pacmed Critical software product. Before attempting to use the software, users must read the IFU thoroughly, paying particular attention to all safety information, including all WARNINGS, it contains.

All users must also have received the Pacmed validated training provided by a representative allowed to give the training before using the software.

The IFU can be viewed and downloaded via [the Download Handleiding]-button on the user interface of the software. The IFU is also available on the webpage https://pacmed.ai/ifu/ .

1.2.1. Updates to these Instructions for Use

A downloaded or hardcopy version of the IFU can become outdated. If a new software version is released, the corresponding version of the IFU will be indicated. All versions of the IFU are available via Pacmed, with the corresponding software version number and publication date.

1.2.2. Paper format

Upon written request, a printed version of this IFU can be delivered at no additional cost and within 7 calendar days by sending a written request via email at support@pacmed.nl .

1.3. About this Publication

Neither Pacmed nor anyone else involved in the development, production or delivery of the documentation can be held liable for any special, incidental or consequential damages, whether on the basis of breach of warranty, breach of contract, negligence, strict liability based on unlawful deed, or any other legal basis.

1.4. Use of the software

The software is intended to be installed and used only in accordance with the safety procedures and instructions given in this IFU and for the purpose for which it was designed. Users will at all times remain responsible for sound clinical judgement and best clinical procedure, regardless of what is stated in this IFU.

Use of this software is subject to the law in the jurisdiction of The Netherlands, the country in which it is being used. Users must only use the software product in such ways as do not conflict with applicable laws, or regulations which have the force of law.

In addition, use of the software product for purposes other than those intended and expressly stated by Pacmed, as well as incorrect use, may relieve Pacmed from all or some responsibility for resultant non-compliance, damage or injury.

1.5. Compatibility

Changes and/or additions to the software product should only be carried out by Pacmed. Such changes and/or additions must comply with all applicable laws and regulations which have the force of law within the jurisdictions concerned, and with best engineering practice.

1.6 Compliance

This software complies with relevant international and national standards, regulations and laws. Information on compliance will be supplied on request by your Pacmed representative.

1.7. Symbols Glossary

The following symbols may appear in the IFU and/or in the user interface:

Symbol	Symbol name	Symbol description
	Manufacturer	Indicates the name and address of the manufacturer of the software.
	Date of manufacture	Indicates the date that the version of the software was released.
	Batch code	Indicates the version number of the software.
	Consult Instructions for Use	Indicates when the user must consult the Instructions for Use.
	Warning	Warnings are directions which when not followed could cause injury to the user, patient or other user, or could lead to clinical misdiagnosis. The presence of the symbol in the user interface indicates that the user must consult the IFU for an important warning related to the use of the software which cannot be displayed in the user interface itself.
	CE-mark	Pacmed Critical is CE certified under the European Medical Device Regulation (MDR)

MD	Medical Device (MD)	Indicates that it is a Medical Device
UDI	Unique Device Identifier (UDI)	The UDI is a globally harmonized, unique (alpha) numeric code used to identify the medical device. The UDI consists of a UDI-DI (Device Identifier) and a UDI-PI (Product identifier). The UDI-PI corresponds to the software version number.

1.8. Contact Information

▲	Pacmed Critical has been developed and produced by Pacmed B.V., Stadhouderskade 55 1072 AB, Amsterdam, Netherlands. For further information, please contact Pacmed: Website: https://pacmed.ai/ Email: support@pacmed.nl

Users can also contact the support desk by using the 'Feedback' button.

2. Safety

Before using this software, you must have read and understood the instructions for use and have followed the training to ensure safe and correct use of Pacmed Critical.

2.1. Important Safety Warnings

⚠️	**1. WARNING:** The software product is not intended for the discharge of patients from the Intensive Care Unit to the Medium Care Unit.
⚠️	**2. WARNING:** The software tool presents a seven-day readmission/mortality risk, displayed as a percentage. This represents a combined probability and must be interpreted as such.
⚠️	**3. WARNING:** Pacmed Critical should only be used as a complementary tool for clinical decision making. The software is not intended to replace medical expertise, hospital protocols, and any other relevant process.
⚠️	**4. WARNING:** The software tool is an extra source of information in the decision-making process for discharge of a patient to a step-down unit (e.g. general ward). It is not intended to be used for discharges of a patient from the ICU to the medium care unit. The software must never be used without consideration of all clinical, operational and any other patient information.
⚠️	**5. WARNING:** The software shall not be used for treating and improving only one single feature that has a big impact on the prediction, with the sole purpose of decreasing the prediction probability.
⚠️	**6. WARNING:** The machine-learning model is trained on historical data and thus it depends on the patient population and hospital practices at the time of model training. Be aware that significant changes in the patient population and/or hospital practice may affect the performance of Pacmed Critical.
⚠️	**7. WARNING:** The software must only be used for patients who are eligible for discharge. The predictions are unreliable for patients who, because of dependency on certain ICU-specific support or treatment cannot be discharged.
⚠️	**8. WARNING**: Risk of readmission and/or death might be displayed for patients that do not meet the eligibility criteria according to the hospital's specific discharge protocol. The user is responsible to verify whether the patient is eligible for discharge.
⚠️	**9. WARNING:** The readmission/mortality risk is a prediction made by a statistical model based on patient, laboratory and monitoring device data. Since this is a prediction, it is not 100%

	accurate and therefore a decision must never be made solely based on the readmission/mortality risk displayed.
⚠	**10. WARNING:** The software uses patient, laboratory, medication and equipment data. It does not currently use any information on radiology diagnostic test results, surgery details and patient data from prior to admission.
⚠	**11. WARNING:** For each patient's prediction, the software shows both the contribution of the organ system, and the relative contribution of each predictive feature associated with that organ system. These factors are calculated for the most recent prediction of this patient. During the patient's admission, the relative importance will change constantly as the patient status evolves.
⚠	**12. WARNING:** The Software is using information from the EHR, and is dependent on that information. Inaccurate registration in the source system leads to inaccurate predictions in the software.
⚠	**13.WARNING**: The software should not be used remotely and without the consultation of a qualified physician present in the ICU.
⚠	**14.WARNING**: The software product is not intended for use on mobile devices (tablets or mobile phones).

2.2. Information provided on Residual risks

Pacmed Critical is a software medical device which is intended to support clinical decision making related to patients whose treatment includes intensive monitoring or organ support. Pacmed Critical should only be used as a complementary tool for clinical decision. The software is not intended to replace medical expertise, hospital protocols, and any other relevant process. The intended user needs to take the information generated by the device and place it in a medical context (i.e. to determine if they think the percentage risk is high or low for that patient) in order to translate the prediction into a clinical decision. In line with its intended use, the risk prediction of readmission and/or mortality is intended only as supportive information.

Misuse or off-label use of the device (i.e. use of the device by untrained personnel, the user solely relies on the device output, incorrect assumption between the model features and the model outcome) might lead to hazardous situations leading to patient harm. Only trained and qualified medical personnel are authorised to use the device. If you have any questions regarding the residual risks, please contact Pacmed support team (support@pacmed.nl).

3. Device Description

Pacmed Critical is a software medical device that provides a probability of the patient's readmission (and/or their mortality) to the department where they are receiving intensive monitoring or organ support. The risk prediction is based on historical clinical data that represents the intended patient population where the software is used. The software is a standalone software product that is integrated with the Electronic Health Records (EHR) system of a hospital. This integration entails receiving clinical data from the EHR that is used by the software to produce a risk prediction. The risk prediction is shown as part of a user interface (UI).

3.1. Intended Use

Pacmed Critical is intended to support clinical decision making related to patients whose treatment includes intensive monitoring or organ support[NOTE]. The tool predicts the probability of the patient's readmission to the department where they are receiving intensive monitoring or organ support and/or unexpected death. The predictions are intended as supplementary information that can support a user's clinical decision making and estimations about the optimal duration of intensive monitoring or organ support for a given patient.

[NOTE] These are patients who are typically found on the Intensive Care Unit (ICU) or Medium Care Unit (MCU). A need for intensive monitoring is defined as a need for recording of vital signs > 6 times /day. Patients on organ supportive therapy can be defined as those on: mechanical ventilation, high flow oxygen therapy, regular tracheobronchial toilet, inotropics, vasopression, extracorporeal membrane oxygenation, renal replacement therapy or sedation / anaesthetics.

3.2. Indications for Use

Pacmed Critical is intended to be used for patients admitted to the Intensive Care Unit (ICU) or Medium Care Unit (MCU) and whose treatment includes intensive monitoring or organ support. The user needs to take the predicted probability into account in clinical decision making by using the prediction into medical context. This means for example to:

- compare the probability with the average probability of readmission or mortality within the ICU where the tool is used;

- place the probability into context of other risks the user deems acceptable for the type of patient, and;

- do an assessment of the likelihood that future developments substantially change the probability.

Pacmed Critical should only be used as a complementary tool for clinical decision. The software is not intended to replace medical expertise, hospital protocols, and any other relevant process.

3.3. Intended User

The intended users are qualified medical professionals (e.g. intensivists, nurses or other medical specialists) who are responsible for the care of patients who need intensive monitoring or organ support.

3.4. Intended Patient Population

Patients aged 18 years or older whose treatment has included intensive monitoring or organ support.

3.5. Intended Environment

Pacmed Critical shall be used in the hospital clinical settings where patients need intensive monitoring or organ support, this is typically the ICU.

3.6. Operating Principles

The software is trained on that dataset (historical patient data) which include a set of validated clinical features. Finally, the model is tested on the most recent data collected for that hospital (hold-out dataset). The resulting tested model is implemented on live data for validation and acceptance, and deployed in the same hospital which has been trained on.

The software generates a risk prediction of readmission and/or mortality based on historical patient data that is retrieved from the Electronic Health Records (EHR) system of a hospital.

3.7. Contraindications

Pacmed Critical is not intended to be used for patients under 18 years. The device is not intended for patients admitted within less than 12 hours in the ICU, for patients who are not deemed eligible for discharge, and for discharge to medium care.
The device should not be used for palliative care patients, patients that have a do-not-return code or patients transferred to another hospital.

3.8. Device Limitations

The device is not intended to be used autonomously. The trained and qualified hospital personnel must not solely rely on the risk prediction of the software. The users should carefully and independently assess the patient's health condition before any discharge decision is made.

3.9 Variants/accessories

There are no accessories or variants applicable to this device.

3.10. Clinical benefit

Pacmed Critical aims to improve patient outcomes by supporting clinicians to decide on the optimal timing of discharge for patients whose treatment includes intensive monitoring or organ support. Specifically it provides decision support to help clinicians either reduce the length of stay, or reduce patient readmission or mortality after discharge.

Pacmed Critical also improves clinicians' workflows by providing them with an effective overview of patients on the ICU.

4. Model description

4.1. Model Introduction

Pacmed Critical is a software system that supports the decision to discharge patients from the Intensive Care Unit (ICU) to the general ward at the right time.

The method has been developed by a team of intensivists from Amsterdam UMC, location VUMC in collaboration with statisticians and machine-learning experts from Pacmed.[1]

The model is trained on historical hospital data. After its definition, when it is meant to be used on a single patient, the model does not require further analysis on historical hospital data, only the data gathered about the patient under consideration is needed.

The model employed in a version of Pacmed Critical used in a specific hospital is developed only with data of that specific hospital. No model is trained on a combination of data from multiple hospitals. Periodic retraining of the model is done on the available dataset of that hospital. See **Summary of model performance - section 'Input data'** for all inputs used for the model.

The software predicts the probability of readmission to the ICU or death of an ICU patient within seven days after discharge to the general ward, would this patient have been discharged at this moment. The software also presents the historical evolution of *this* probability during the patient's admission at the ICU (up to a maximum of 30 days) and shows the patient attributes ('predictors' or 'features') which are most important for the prediction according to the model. The predictors are grouped by organ system to improve the explainability of the model. Pacmed Critical shows both the contribution per organ system to the risk prediction, and the contribution of the individual predictors per organ system. A small number of predictors (e.g. last pH in the past 24 hours) are assigned to an organ system based on a simple decision rule. These predictors and the corresponding decision rules can be found in the **Summary of model performance - section 'input data'**

The software runs in the Cloud, and its predictions are continuously - at least every 60 minutes - updated. The model can provide the first prediction for an individual patient as soon as the patient has been admitted for at least 12 hours at the ICU. In certain conditions the model cannot provide a reliable prediction. When this happens, the software does not show a prediction. The model does not show a prediction when (a) a patient was admitted less than 12 hours ago, (b) a patient is dependent on certain ICU-specific support or treatment (e.g. mechanical ventilation or renal replacement therapy (c) the patient's data is considered unreliable and (d) the patient's data is considered too different from patients in the training data.

4.2. Device output: Readmission/Mortality Risk prediction

Since in literature readmission and mortality are both clearly defined as undesirable outcomes of a discharge[2], a negative outcome of the discharge is defined as:

- ICU readmission within seven days after ICU discharge, which is defined as a transfer from the ICU to the general ward and back to the ICU or MCU during the same hospital stay, OR

- Death within seven days after ICU discharge.

Similarly, a **positive** outcome of the discharge is defined as no readmission or death within seven days after discharge to the general ward.

The model predicts the probability of a negative outcome if a patient would have been discharged right now. In consultation with medical experts, the choice has been made to not separately show the risk of readmission and the risk of mortality, but only the probability of the combination of both negative events happening. This is done to prevent an overload of information for the intensivist. Presenting a single risk of the combined negative outcome is hypothesised to improve comprehension, interpretability and thus added value for decision-making. Last, separately modelling the readmission risk from the mortality risk did not increase predictive performance of the model.

4.2.1. Input data

In order to generate a prediction, the model uses data stored in the EPD. The software uses the following types of information:

- Patient information
- Admission information
- Laboratory test results
- Vital signs and device data
- Clinical Observations
- Medication

Inter-hospital variability may cause slight changes when certain inputs are not available or when additional relevant input is available within these categories.

Refer to **Summary of model performance - section 'Feature list'** for all features used for the model.

4.2.2. Inclusion/exclusion criteria

The following categories of patients have been excluded from the data:

- Under 18 years of age;
- Death during the ICU admission;
- Discharges to the medium care;
- Transfers to another hospital;
- Palliative care;
- Admissions with a length of stay less than 12 hours;
- Do-not-return code.

The risk prediction is not displayed for patients that do not meet the eligibility criteria. See Summary of model performance - section 'Eligibility criteria'.

4.2.3. Validated Data

In order to generate a risk prediction, the software only uses measurements that have been validated. Measurements that are not yet validated will not be used in the prediction. However, after validation, predictions can be retrospectively updated with the data just validated. For example:

- A pH value is measured at 10:45h and not yet validated.

- At 11:00 the model makes a prediction for timestamp 11:00h using all validated data measured before 11:00h. The pH value of 10:45h will not be used at that point because it is not validated. However, any pH measurement measured and validated earlier that morning will be used.

- At 11:30h, the pH value measured at 10:45h is validated.

- Now the model will update the prediction of timestamp 11:00h, since now that prediction is allowed to use the pH value measured at 10:45h.

Because of this reason, predictions of Pacmed Critical are sometimes changed a couple of percentages in retrospect when earlier data points are validated. For the user this means that the shown prediction might be different compared to an earlier moment. Therefore, when recently measured lab values or vital signs are about to be validated with values being substantially different from previously validated values, the user should consider reevaluating the decision by reinspecting the prediction at a later point.

4.2.4. Selection and computation of the Predictive Features

Patient data (e.g. lab values, vital signals and clinical observations) are usually measured and/or registered multiple times during the stay. These values are transformed into predictive features by creating so-called summary statistics. Per each feature, a set of summary statistics, which were deemed clinically relevant, are selected together with medical experts. The summary statistics are the average (or minimum or maximum) value over the last 24 hours, or the last measured value.

The model will impute the missing values with a parameter-specific, clinically sensible, value (e.g. the mean from the whole population or the last measured value). The full list of features is shown in **Summary of model performance - section 'Feature list'** . Per feature, the summary statistics that are calculated and the imputation technique used are shown

The selection and imputation of the predictive features result in a list of predictive features validated by medical experts. The predictive features are used by the model to generate the risk of readmission or mortality within 7 days of discharge.

4.3. Creating the Prediction Model

The best predictive model for this application is a frequently used method in Machine Learning applications; a Gradient Boosted Trees model. This is a technique based on the creation of decision trees, which classifies patients according to their characteristics into high- or low-risk groups. In Figure 1 a simplified example of such a decision tree is shown. Note that the numbers shown in the example are fictitious.

The difference with traditional decision trees is that with Gradient Boosting, after every decision tree the patients that are predicted incorrectly by the model are modelled again in separate decision trees. As a consequence, more subtle (non-linear) effects can be modelled than with traditional methods like Logistic Regression or Proportional Hazard models. Gradient Boosting models therefore tend to outperform traditional techniques in terms of accuracy.
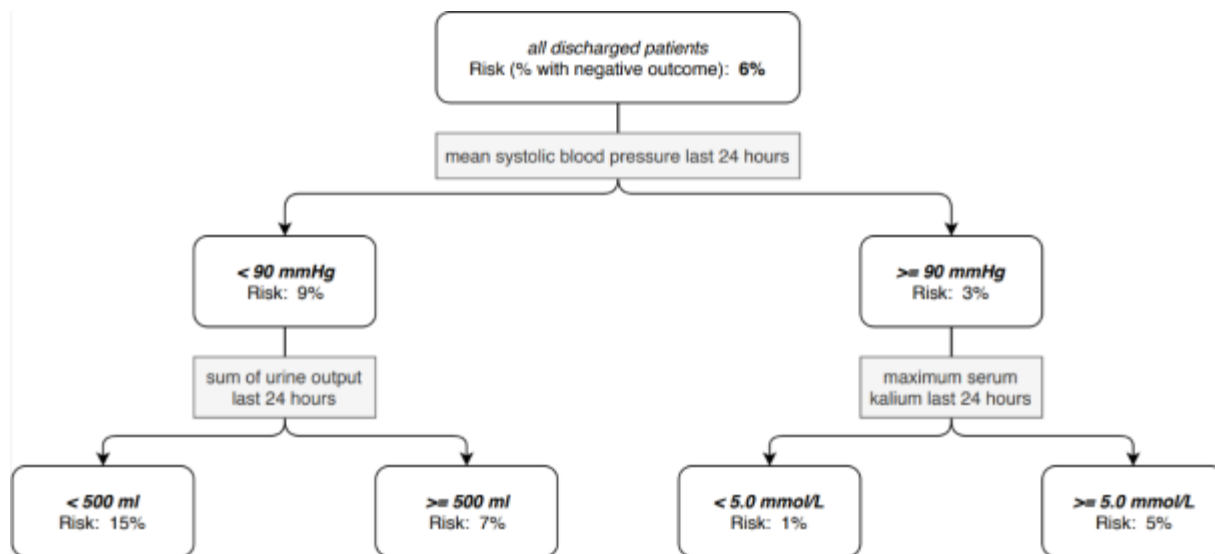
Figure 1: Simplified example of a decision-tree model

4.4. Model Performance

The performance of the model (i.e. how good the model is in discriminating successful ICU discharges by those followed by adverse events) is determined by cross-validation. This means that the model is trained iteratively on a subset of patients and then tested on the data from the remaining patients that the model has not yet 'seen'. This is done multiple times so that each patient is part of the test set once.

4.4.1. Area under the ROC-curve (AUC)

The model typically predicts a probability of readmission and/or mortality within 7 days of discharge between 0% and 50%. A readmission/mortality probability of 8% signifies that the model expects that out of 100 patients with a similar profile who are discharged from the ICU, eight of them will be re-admitted or will die within seven days. It almost never happens that the model indicates a probability of adverse outcome higher than 50%. The user should remember that the average readmission/mortality probabilities are between 5% and 10%,% so that values do not need to be close to 100% to indicate high risk. Compared to the average readmission/mortality probability of 6%, a prediction of 12% already indicates an increased risk of negative outcome.

Refer to **Summary of model performance - section 'Model performance'** for the model accuracy.

4.5. Calculating the relative contribution of each feature to the prediction

Besides displaying the risk of a patient's readmission or mortality, the software also displays the extent to which each organ system contributes to the prediction. There are 8 organ systems displayed in the software, and these are based on ABCDE mnemonic that is commonly used in acute care:

1. Respiratory (A and B)
2. Circulatory (C)
3. Neurology (D)
4. Infection & Inflammation (E)
5. Renal & Metabolic (E)

6. Gastro-intestinal (E)

7. Hematology & Coagulation (E)

8. Patient and admission (category containing immutable attributes of the patient and admission, such as age).

The software determines the respective contribution of each organ system to the overall risk prediction by:

- Working out how much each individual feature contributes to the overall risk prediction

- Summing the respective contributions of the features within a specific organ system to calculate how much that organ system contributes to the overall risk.

The relative contribution of each individual feature to the prediction is calculated using SHAP (Shapley Additive Explanations) values. The SHAP value calculation shows what contribution each feature makes to the prediction by calculating what would happen if the patient would have a different value for that feature. The higher the SHAP value, the more that feature increases the readmission/mortality probability, and vice versa. This calculation means it is possible to identify the features that are most predictive because they correspond to the ones with the higher SHAP values.

To calculate how much each organ system contributes to the overall prediction, each of the model's features are assigned to one of the organ systems listed above. For example the feature 'mean heart rate in the last 24 hours' is assigned to the 'Circulatory' organ system. By summing the SHAP values of the features assigned to a specific organ system, it's possible to see the overall contribution that organ system makes to the prediction. Note, in some instances, whether a feature is assigned to a certain organ system depends on the value of that specific feature or of related features. For example, for patients with high Lactate values, bicarbonate is associated with Circulation. For patients with low Lactate values, bicarbonate is associated with the Renal system. For more details of how the predictive features are assigned to each organ system, please see **Summary of model performance - section 'feature list'**.

5. User instructions

5.1. Getting Started

In order to start using the software, the user needs to login to the hospital-specific network/domain. Most hospitals will require the use of a Microsoft account to do so. Once logged in, the trained user can visit a web page (URL) generated by the hospital's ICT department to start using the software. This URL is domain-specific and cannot be used by other people outside of the hospital's virtual environment.

Some hospitals may support remote access to the hospital's network, for example by means of a VPN connection. However, The software should not be used remotely and without the consultation of a qualified physician present in the ICU.

Hospitals may choose to embed Pacmed Critical in the EHR system, either enabling opening of PC within the EHR or from the EHR. Additionally, authentication can be arranged using Single Sign-On, allowing the user to no longer separately log-in to Pacmed Critical.

When logged in to the hospitals' network, the user should lock their device(s) at all times when leaving it unattended. Unauthorized users may get access to sensitive data if they fail to do so.

5.2. Interface screens

The interface consists of the screens outlined below. A full explanation of the user interface can be found in section 6 'User Interface'.

5.2.1 Department Monitor

The Department Monitor shows an overview of all patients currently in the Intensive Care Unit (ICU), alongside the prediction of Readmission/Mortality.

5.2.2 Patient Detail screen

The Patient Detail Screen contains a graph of how the prediction of Readmission/Mortality changes over time, and a chart showing how much the features associated with each organ system contribute to the overall risk of Readmission/Mortality.

5.2.3 Feature View (per organ system)

The feature view displays all the features associated with that specific organ system sorted by the extent to which they increase the risk.

5.3. Navigation

When navigating around the interface, the cursor will change from a standard pointer to a gloved hand to indicate that that element is clickable. Additional information may also be displayed when hovering the cursor over other elements.

5.4. Login Screen

In case the login information is forgotten, depending on the hospital configuration, a new login can be requested.

Example of the login screen

5.5. Error Message

Preventing patient mix-ups
Error message: "*To prevent possible mix-ups between patients, it is only possible to open Pacmed Critical in 1 tab at the same time.*"
This error message is displayed when Pacmed Critical is opened in two different tabs or on two different web pages. To resolve the error message, close Pacmed Critical from the other screens. Pacmed Critical can then be refreshed.

No predictions
Error message: "*Unfortunately, we cannot show predictions at this time. Please wait and refresh the screen in 15 minutes. If predictions are still not displayed after 15 minutes, please contact functional application management or send an e-mail to support@pacmed.nl.*"

This error message is displayed when Pacmed Critical cannot display predictions. This can have several causes. Often this will involve a technical problem with the source data. The user is advised to refresh the user interface, after waiting a few minutes, to see if the problem has been resolved in the meantime.

If an error message persists, please contact the functional administrator of the EHR/PDMS, or contact Pacmed for support (see 1.8 for Contact details).

6. User Interface

6.1. Department monitor
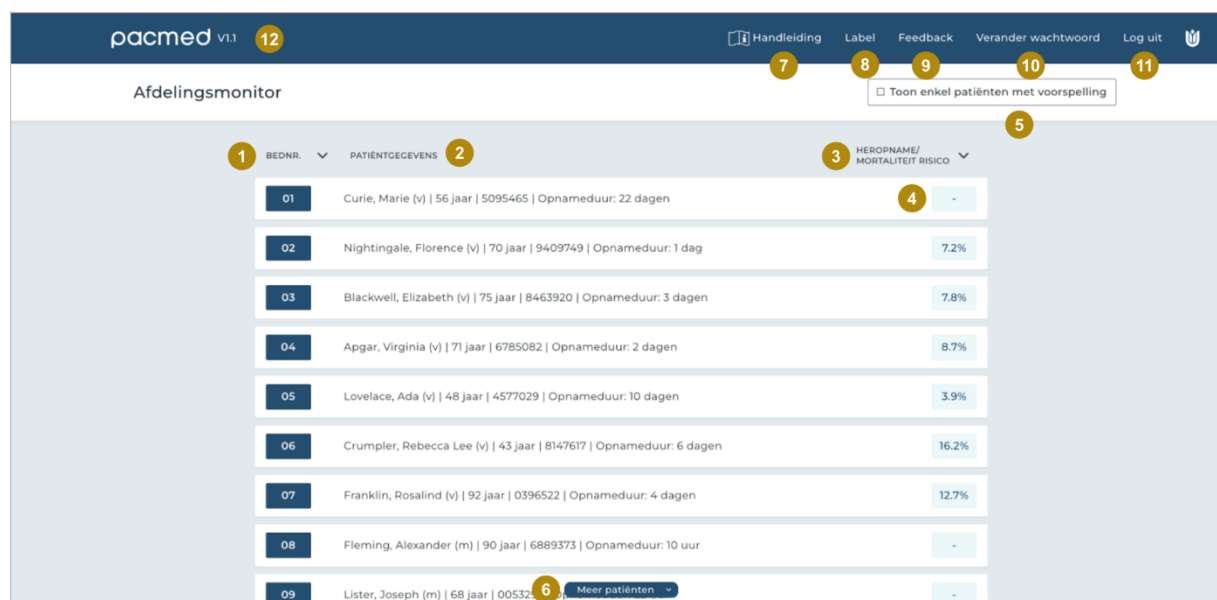
The software shows the following information from the EPD per patient (e.g. bed number, name, patient number, date of birth, admission specialty) and is dependent on this information from the EPD.

1. **Bed number ('bednr.')**
   The patient's bed number is shown here. The patients can be sorted by bed number by clicking on 'bednr.' or the arrow next to 'bednr.'.

2. **Patient data**
   Here the identifying patient data is displayed. Specifically name, gender, age, MRN number and the admission duration.

3. **Readmission/mortality risk**
   Here the probability of readmission or mortality within 7 days is shown if the patient were to be discharged to the ward right now. Patients can be sorted by risk by clicking on 'heropname/mortaliteitsrisico' or the arrow next to 'heropname/mortaliteitsrisico'.

4. **No prediction**
   When a patient is not considered ready for discharge, due to specific support, or when the patient's data appears unreliable, no prediction is shown (displayed with "-"). When exactly this exactly happens is specified in appendix A.

5. **Show only patients with prediction**
   If this checkbox is selected, only the patients with a prediction are displayed.

6. **More Patients**

   If not all patients are visible, this button can be clicked to display the other patients.

7. **Instructions for use**

   The instructions for use can be downloaded as a PDF by clicking on 'handleiding'.

8. **Label**

   The product label can be shown by clicking 'Label'

9. **Feedback**

   Feedback on the use of the software, complaints, problems, questions, suggestions for improvements and compliments, can be given to Pacmed by filling in the feedback form.

10. **Change password**

    The password can be changed by clicking on 'Verander wachtwoord'.
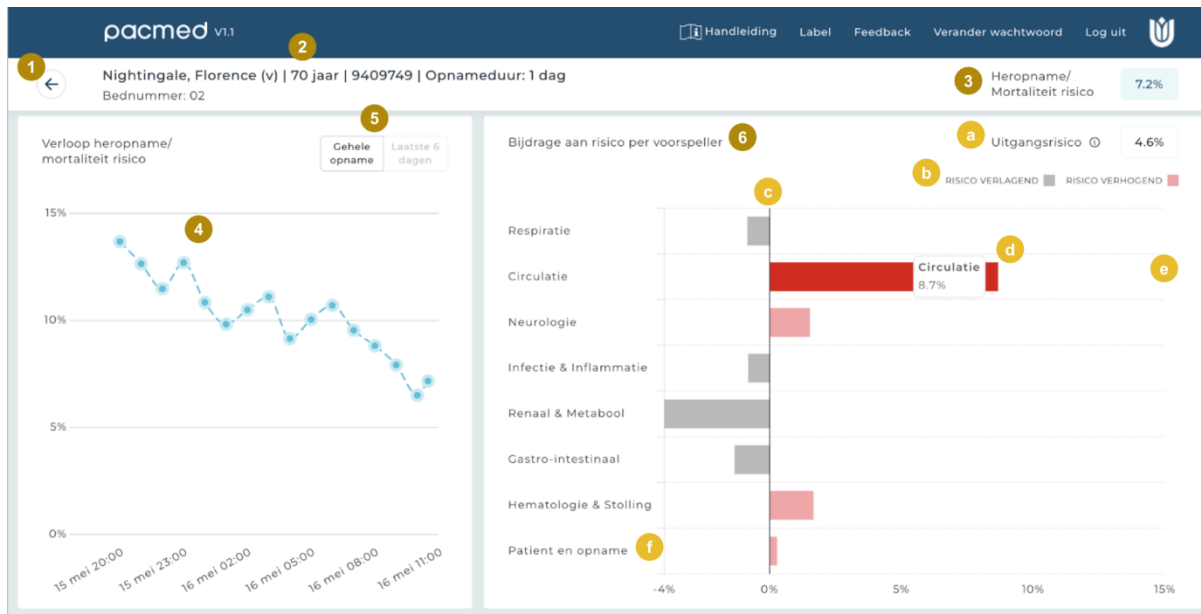

11. **Log out**

    The user can log out by clicking on 'Log uit'.

12. **Version number**

    The version number of the software is visible on the top left part of the screen.

6.2. Patient Detail Screen

1. **Arrow to return to Department Monitor**
   If the arrow is clicked, it returns to the Department Monitor.

2. **Patient data**
   Here the identifying patient data is displayed, namely name, gender, age, MRN number and admission duration.

3. **Readmission/mortality risk**
   Shown here is the probability of readmission or mortality within 7 days if the patient were to be discharged to the nursing unit now.

4. **Graph showing readmission/mortality risk over time**
   The graph shows the course of the patient's readmission/mortality risk over time during admission. No prediction is shown for times when the patient did not appear ready for discharge. The x-axis shows the date and time, the y-axis shows the predicted risk. If the mouse is hovered over a bullet, the exact percentage and time of prediction is displayed. To the right of the graph, the time of the last prediction is displayed.

5. **Display all / last 6 days**
   By default, the graph does not show predictions made more than 6 days ago. The user can see predictions for the entire intake if 'Entire intake' is clicked.

6. **Risk contribution**
   A bar graph that shows how much the features associated with each organ system contribute to the overall risk of readmission/mortality. Hovering over each bar graph displays the specific percentage that the features of that organ system contribute to the overall prediction. Clicking on any of the organ systems navigates to the Feature View where a list of the features that are associated with that particular organ system can be seen in detail, along with the risk that each feature contributes.

a. Baseline risk
   The baseline risk is the average risk for all patients in the hospital's ICU.

b. Legend

   The red bars indicate that the total contribution of an organ system is risk-increasing. The gray bars indicate that the total contribution of an organ system is risk-reducing.

c. Bar charts

   The bar graphs on the right side of the screen show how much the predictors within each organ system together contribute to the prediction.

d. Hovering

   When the mouse is hovered over a bar in the bar graph, the percentage that the predictors within an organ system together contribute to the overall readmission/mortality risk is shown.

e. Clicking

By clicking on one of the organ systems, a more detailed view of the predictors within the organ system follows.

f. Patient and admission

Overall refers to the extent to which static factors, such as age, contribute to overall risk.

6.3. Feature View
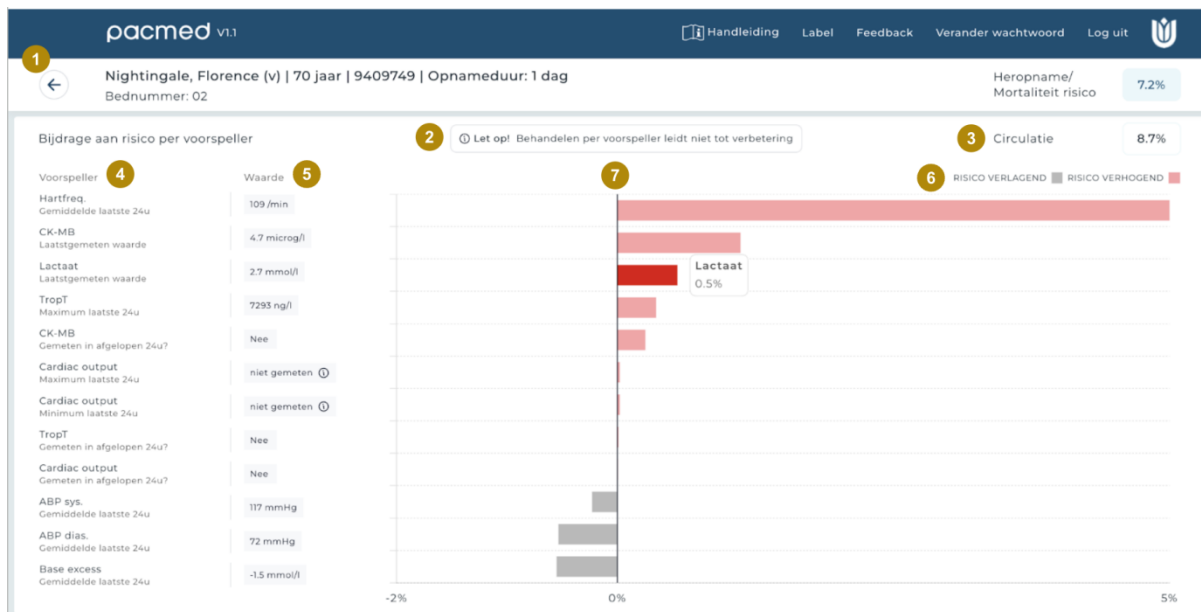
When an organ system on the patient detail screen is clicked, it navigates to a further screen which shows all the features associated with that specific organ system. The features are ordered by how risk increasing they are, with the most risk increasing features at the top.

Given this order is based on the latest data available for that patient, it's likely that the order and relative contribution of the features will change over time. Note also that these feature contributions are an estimate so may not be 100% accurate.

1. **Back arrow**
   Arrow to return to Patient Detail screen. If the arrow is clicked, it returns to the patient detail screen.

2. **Warning**
   The text warns that medical intervention to improve the values of the specific predictors will not necessarily reduce the risk of readmission or mortality.

3. **Organ system risk contribution**
   This indicates how much the organ system contributes to the overall risk of readmission/mortality for this patient.

4. **Predictor**
   The predictors associated with the organ system (e.g., heart rate: average past 24 hours) are shown.

5. **Value of patient**
   The exact value of the predictor used in the most recent prediction for this patient.

6. **Legend**
   The red bars indicate that the contribution of the predictor is risk-increasing. The gray bars indicate that the predictor's contribution is risk-reducing.

7. **Order**
   The predictors are ordered from most risk-increasing (top) to least risk-increasing (bottom).

7. Technical Specifications, Maintenance and Support

7.1. Software Installation and decommissioning

Pacmed is in charge of the installation, maintenance and decommissioning of the software. In case you decide to no longer use this software, please contact Pacmed support team (support@pacmed.nl) who will arrange the uninstallation and decommissioning. Personal and health-related data (e.g. patient data and confidential patient information) will be processed and stored in line with the terms and conditions laid out in the DPA which has been previously signed in agreement with the hospital.

7.2. Technical Specifications

Supported browsers and minimal screen resolution are required for proper display of the device:

- Pacmed Critical has been developed to be used on screens with resolutions greater than 1440 x 900 (WXGA+);

- Pacmed Critical shall not be used on mobile devices (tablets and mobile phones);

- Pacmed Critical can be used in the following browsers:

    - Microsoft Edge, all versions

    - Google Chrome, all versions

    - Mozilla Firefox, all versions

The hospital shall ensure that the workstations have sufficient resources to run a web browser. The software should be running only on systems that adhere to these minimum IT requirements.

7.3. Hardware and IT requirements

The requirements for the virtual hardware of the application are validated by Pacmed during the installation of the software.

Note: This IFU is not meant to describe the IT requirements of the system or equipment on which the Pacmed product is installed.

7.4. Software Updates

Software updates are essential to keep the product operating safely, effectively, and reliably. Software updates can include security patches, updates of the model and general improvements.

The process around delivery and installation of software updates is described in the Service Level Agreement.

When a software update is available, the hospital will be notified by Pacmed following a process agreed upon by Pacmed and the hospital. These agreements are generally made with the hospital project lead, key-user, and/or functional application administrators of the EHR/PDMS. In case of changes to the product that could affect its use in clinical practice a hospital contact person will be contacted and trained by a representative of Pacmed.

7.5. Starting the Software

The device implements state of the art token-based access control. User management is performed by Pacmed. Only trained personnel will be able to access the device. Only authorised Pacmed users are granted admin access to the device.

7.6. Closing the Software

The Software can be closed by closing the web page using the cross on the top right side of the browser. Alternatively, the [Log off] button in the software can be chosen. Finally - depending on the chosen EPD/PDMS integration - Pacmed Critical will automatically close when a different patient is selected in the EPD/PDMS than the one open in Pacmed Critical, to prevent patient switching.

7.7. Monitoring system

The device has been integrated with the hospital IT systems to:

- Enable easy access to the device. Optionally hospitals integrated the device in their EHR/PDMS systems. If such an integration has been set up, it has been validated during the installation by means of an acceptance test.

- Ensure the availability of recent clinical data. Pacmed has implemented monitoring systems to monitor the validity of the source data. The correctness of the source data in the hospital's data systems remains the responsibility of the hospital.

7.8. Troubleshooting & Support

Contact the Pacmed support desk to report any problems encountered with the software. You can contact Pacmed directly from the 'Feedback' button or the contact information provided in section 1.8.

7.9. Serious incident reporting

In the unlikely case of any serious incident related to the use of the software tool, Pacmed will take all necessary follow-up actions as required by law. Any serious incident that has occurred in relation to Pacmed Critical should be reported to Pacmed and the Ministry of Health, wellbeing and sports (medicaldevices@minvws.nl).

7.10. Network Safety, Data and Information Security

The hospital network and Pacmed's cloud environment are connected by means of a secure site-to-site VPN. The hospital IT department will set up this VPN connection together with Pacmed.

The data that is used in the software system is stored in a database that is running within the ICT environment of the hospital.

Patient data used for Pacmed Critical is stored in the Cloud. Pacmed does not keep a backup copy of the data. In case of failure, the data will be extracted again from the hospital's data source.

Pacmed Critical is solely to be used within the internal hospital network. The software is not intended for remote access and access from the public internet. If a user is allowed to login from a remote location

using VPN, then that user can use the software from outside the hospital but only in collaboration with another qualified physician actually present in the ICU at the moment of use. The risks of using the device outside the hospital environment include, but are not limited to:

- Information security risks: making Pacmed Critical available to the public internet exposes it to additional cybersecurity threats.

- Misuse of the device: lowering the barrier for access to the device increases the risk that untrained personnel access the device

- Data privacy: lowering the barrier for access to the device increases the risk that unauthorized people access the device (for instance when it is left unguarded in a public space).

The software does not provide any protection against viruses. It is therefore recommended that the system on which the software is used is running antivirus software.

8. References

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Document History

Document version	Change description	Author	Change date
01	initial release - IFU VUmc	Brian Tielrooij	2024/01/03
02	Updated to resolve Technical Questions - MDR 774346 (added section 2.2, updated section 5.1 and Indications for use)	Tamara Petetta	2024-03-01
03	Updated in line with changes related to Maasstad product release (refer to CIA version 2.4.0). The warning list has been revised and listed in priority order.	Tamara Petetta	2024-04-24

Signatures

Signature Meaning	Name	Title	Date	Signature
Author	Tamara Petetta	Regulatory Affairs Manager		
Contributor	Brian Tielrooij	Implementation Manager		
Reviewer	Daan De Bruin	Head of Data & AI		
Reviewer	Kieron Kirkland	Head of Product Discovery		
Approver	Arjen Mol	Medical Data Specialist		