BAYOOCARE

LEGAL MANUFACTURER

PreFree

Instructions for Use – EN

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1. SYMBOLS AND ABBREVIATIONS

1.1. Symbols for Identification

Symbol	Meaning
	Manufacturer
	Medical device
	Unique product identification
	Distributor
	Product name
 Hinweis auf eIFU	Refer to electronic instructions for use (PDF). Download: bayoocare.com
	Information / informal note
	Action required, work step

Table 1: Symbols for Identification

1.2. Symbols Used in the Software

Symbol	Meaning
	Instructions for use
	Help function / information about the software
	Specification: input field for email
	Specification: input field for date
	Specification: input field with drop-down menu
	Log in (to the application)
	Log out (from the application)
	Display user profile
	Display current organization profile (organization name, clinicians, terms and conditions, etc.)
	Display patient overview
	Create new patient
	Display all available details of the corresponding entry
	Search function to filter patients
	Cancel

Symbol	Meaning
	Save
	Delete function to remove a patient
	Edit
	Invite function to invite a patient to use PreFree
	Send invitation
	Input field for email to invite a patient
	Data entry
	Data entry
	Patient master data
	Patient medical history
	Patient medical history
	Patient examinations
	Archive a pregnancy (create pregnancy outcome)
	Back
*	Mandatory field required to save entered patient data

Symbol	Meaning
**	Mandatory field required to perform a risk prediction
	Confirm execution of an action
	Indication of a risk prediction in the green range
	Indication of a risk prediction in the orange range
	Indication of a risk prediction in the red range
	Logo
	Display of recorded entries
	Data entry
	Edit
	Profile and settings

Table 2: Symbols Used in the Software

2. DEFINITIONS OF TERMS AND ABBREVIATIONS

2.1. Definitions of Terms

This section defines basic terms used throughout this document.

Term	Explanation
Risk prediction	Prediction of the risk or probability that a patient will reach a specific condition during pregnancy. In PreFree, two types of risk predictions are distinguished: 1. The probability of delivery within a defined period. 2. The probability of preeclampsia-associated severe adverse events in the mother or child.
Patient / pregnant woman	Terms used equivalently in this document. As the application exclusively concerns pregnancies, the term "patient" always refers to the female sex.
Physicians	Used synonymously with medical professionals, who represent the main user group of the PreFree software. For readability, the generic masculine form is used but includes all genders.
Software / application / PreFree	Refers to the software solution described in this instructions for use. Only the physician-facing component (Physician-Facing Interface), including the risk prediction algorithms, is part of the certified medical device. The patient-facing component serves exclusively for optional data entry and is not part of the medical device.

Table 3: Definition of terms

2.2. Used Abbreviations

Abbreviation	Explanation
DGGG	German Society for Gynecology and Obstetrics
SSW	Gestational week
GA	Gestational age
SS	Pregnancy
sFlt-1	Soluble fms-like tyrosine kinase-1
PlGF	Placental growth factor
PE	Preeclampsia
SAE	PE-associated serious adverse events
HELLP	Hemolysis, elevated liver enzymes, and low platelet count
ML	Machine learning
KIS	Hospital information system

PA	Physician-Facing Interface (physician-side user interface; certified medical device)
HA	Health App or Patient-Facing Interface (optional, non-certified component for data entry)

Table 4: Used abbreviations

3. INTENDED PURPOSE

PreFree is a Software as a Medical Device (SaMD) designed to support qualified healthcare professionals by providing AI-based risk predictions and clinical visualizations for pregnant women at increased risk for preeclampsia and associated complications. The software provides individualized risk predictions for:

- The occurrence of severe maternal or fetal adverse outcomes associated with hypertensive disorders in pregnancy
- The likelihood of delivery within 14 days before 34 weeks' gestation

PreFree is intended to support, but not replace, clinical judgment. The software does not alter the standard of care and is not intended to be used as a standalone diagnostic tool.

Note: The optional inclusion of self-reported patient data (e.g., blood pressure, urine sample, weight, and symptoms) serves only as supplementary information displayed in the physician interface and is not part of the certified medical device.

3.1. Expected Clinical Performance

1. **Prediction of the probability of preeclampsia-associated severe adverse events (PSAE)**

PSAE risk prediction is available within the following validated operating conditions:

- Gestational age from 20+0 weeks to 34+0 weeks, and
- 34+0 weeks to < 37+0 weeks, if all of the following conditions are met:
    - sFlt-1/PlGF ratio 110
    - systolic blood pressure 160 mmHg
    - diastolicblood pressure 110 mmHg

Validated performance characteristics:

- AUROC: 0.879
- Threshold-dependent performance metrics:

Threshold of predicted probability	Sensitivity	Specificity	PPV	NPV
≥ 12%	88.5 %	62.5 %	41.0 %	94.9 %
≥ 43%	72.3 %	93.7 %	77.2 %	92.0 %

2. **Prediction of the probability of delivery within 14 days**

Prediction of the probability of delivery within 14 days for women presenting before 34+0 weeks gestational age.

Validated performance characteristics:

- AUROC: 0.877
- Threshold-dependent performance metrics:

Threshold of predicted probability	Sensitivity	Specificity	PPV	NPV
≥ 25%	90.3 %	57.1 %	44.3 %	94.0 %
≥ 60%	65.4 %	92.4 %	76.6 %	87.6 %

3.2. Indication

PreFree is indicated as an adjunctive decision support tool for the monitoring and management of pregnant patients at increased risk of preeclampsia or preeclampsia-associated complications.

Typical medical conditions include:

- **O10.*:** Pre-existing hypertension in pregnancy, childbirth, or the puerperium
- **O11:** Chronic hypertension with superimposed preeclampsia
- **O13:** Gestational hypertension without significant proteinuria
- **O14.0:** Mild to moderate preeclampsia
- **O14.9:** Unspecified preeclampsia (e.g., suspected diagnosis)
- **O16:** Unspecified maternal hypertension

3.3. Contraindication

PreFree is not intended for stand-alone use as a diagnostic or decision-making tool. Use requires standard clinical supervision by qualified healthcare professionals.

Use is contraindicated in the following cases:

- **O35.0:** Suspected fetal malformations or aneuploidy
- **D69.3:** Thrombotic thrombocytopenic purpura
- **D59.3:** Hemolytic-uremic syndrome
- **O26.6:** Acute fatty liver of pregnancy
- **O14.1:** Severe preeclampsia
- **O14.2:** HELLP syndrome
- **O15:** Eclampsia
- **O30:** Multiple pregnancy

In these cases, the software must not be used or must be discontinued. Additionally, use is not permitted if no valid patient consent for data processing exists or if consent has been withdrawn.

3.4. Users

PreFree is intended for use by qualified healthcare professionals. Use by supporting personnel or patients is limited to defined roles and must occur under medical supervision.

Healthcare professionals (licensed)

Primary user group with full access to all functions. Responsible for assessing and interpreting risk predictions.
Examples: specialists in gynecology, obstetrics, or perinatal medicine.

Supporting healthcare personnel

Use the application to enter medical data. No independent clinical decision-making. Use occurs under supervision of healthcare professionals.
Examples: midwives, nursing staff.

Patients

Use a non-medical user interface to enter self-measured data (e.g., blood pressure, weight, symptoms). They do not have access to risk predictions or clinical evaluations. Data entry is optional and occurs only under medical guidance.

3.5. Target Population

PreFree is intended for use in pregnant patients:

- Aged 18 to 45 years
- With a singleton pregnancy

- With a gestational age between 20+0 and 40+6 weeks
- Classified by healthcare professionals as being at risk for preeclampsia or preeclampsia-associated complications.

4. SAFETY INFORMATION

4.1.Classification of Safety Notices

The safety and important usage notes in this document are classified based on risk.

- Familiarize yourself with the meaning of these classifications before using the certified software components.

NOTE!

Indicates a potentially harmful situation.

If not avoided, it may lead to data loss or compromise of information.

4.2. Safe Use

For safe use of PreFree, please observe the following instructions:

- Read these instructions for use carefully and keep them for reference.

	The instructions for use are integrated into PreFree (physician-facing interface) and can be accessed at any time.
	If you require a printed version, please contact BAYOOCARE GmbH via the help function in the software or the contact details provided in Chapter 13. A printed copy will be provided as soon as possible.

- Use PreFree exclusively in accordance with its intended purpose (see Chapter 3).
- Healthcare professionals are responsible for the proper and complete entry of clinical data.
- Supporting users and patients may enter data only under the supervision or instruction of healthcare professionals.
- Perform the function test as described in Chapter 10 to verify correct operation of the certified software.
- The optional patient-side data entry is performed via a non-medical supplementary module. This may be provided by the manufacturer or replaced in the future by externally connected patient apps. Although it is not part of the certified medical device, its functionality is described in this instructions for use to ensure safe and consistent operation. Integration is optional and not required for the core functionality of PreFree.

4.3. Predictable Misuse

NOTE!

Use of the risk assessment as the sole basis for therapeutic decisions

- Do not use the risks calculated by PreFree as the sole basis for therapeutic decisions.

- The software serves only as decision support and does not replace clinical assessment or diagnosis.

Misinterpretation of software outputs or unauthorized interference with system functionality may result in incorrect assessments and potentially harmful clinical decisions.

4.4. General Warnings

In the event of technical problems, unexpected behavior, or other safety-relevant incidents related to the use of the certified PreFree software, please observe the following instructions:

4.4.1. Incidents

- Report any incident associated with the use of PreFree in accordance with the applicable national regulations to the competent authority and to BAYOOCARE GmbH.
- Use the integrated form in the help section of PreFree to report to BAYOOCARE GmbH.

4.4.2. Malfunctions

- Report any malfunction or unexpected behavior of the software immediately to BAYOOCARE GmbH.
- Use the form provided in the help section of PreFree.
- Discontinue use of PreFree if the software does not function properly or produces unexpected results.

4.5. Residual Risks

All residual risks are acceptable. There is no significant accumulation of risks approaching the limit of unacceptability that could, in total, shift the overall residual risk into an intolerable range. No risks with unusually high severity have been identified that would be atypical for this type of medical device.

The overall benefit clearly outweighs the residual risk.

5. SPECIFICATIONS AND FUNCTIONALITY

5.1. Technical Minimum Requirements

PreFree is a web-based software application accessed via current internet browsers. It provides different functions for various user groups, and display or input options may vary depending on the device.

ℹ	For healthcare professionals: use via desktop PCs (access to the certified software component).
ℹ	For patients: use of the optional data entry function via mobile devices or desktop; not part of the certified medical device.

Please note that controls and display may differ depending on the device used.

Requirements for desktop PCs *(healthcare professionals)*

- PC with keyboard/mouse
- Internet connection: minimum 1 Mbit/s recommended
- Current internet browser (Chrome, Edge, Firefox), not older than 6 months
- Processor: 2 GHz
- RAM: 4 GB
- Resolution: 1920 x 1080 pixels

Requirements for mobile devices *(patients only / optional data entry component)*

- Screen size: 4,7 inches
- Resolution: 1080 x 1920 pixels (DPR 3)
- Internet connection: minimum 1 Mbit/s recommended
- Browser: Chrome, Edge, Firefox, Safari – current version (less than 6 months old)
- Operating system: iOS 15 or higher, Android 9 or higher
- Processor: 2 GHz
- RAM: 2 GB

5.2. Medical Minimum Requirements

For PreFree to perform a risk prediction, all required medical parameters must be completely documented by a physician. Only complete and valid clinical datasets will result in a prediction.

ℹ	Data provided by patients through the optional input component are used solely for physician documentation and are not included in the risk calculation.

5.2.1. Required Information – Medical History

Parameter	Acceptance criteria

Estimated due date	Date (mm/dd/yyyy); for gestational age calculation
Chronic hypertension	Yes / No
Height	In cm
Weight before pregnancy	In kg

Table 5: Minimum requirements and acceptance criteria for medical history data entry in the context of risk prediction

5.2.2. Required Information – Examination

Parameter	Acceptance criteria
Examination date	Date + time
Systolic blood pressure	80 – 200 mmHg
Diastolic blood pressure	40 – 130 mmHg
Proteinuria (urine dipstick)	Negative to 4+
Hypertension	Yes / No
Thrombocytopenia	Yes / No
Elevated liver enzymes	Yes / No
sFlt-1	In pg/ml
PlGF	In pg/ml

Table 6: Required clinical examination parameters and accepted value ranges for performing a risk prediction with PreFree

Validity of Examination Data

- Ensure that all examination parameters are collected during the same examination.

NOTE!

Entry of examination parameters from different time points

- Combining examination parameters from different time points may lead to incorrect risk calculations.
  Only complete and time-synchronous datasets are processed.

Incomplete datasets

If the medical history or examination data (according to Table 5 and Table 6) are incomplete, no risk prediction will be generated.

- Ensure that all examination parameters are collected during the same examination.

6. USE OF PREFREE

NOTE!

Data compromise due to unauthorized access

Unauthorized access to PreFree may result in loss or manipulation of sensitive patient data and inaccurate risk predictions!

- Change your initial password after the first login.
- Use a secure, non-guessable password known only to you. Change your password immediately if it may have become known to another person.
- Enter your password manually each time you log in and do not save it in the browser.
- Log out of PreFree after each session, especially when using shared devices.
- Ensure that only authorized medical personnel have access to professional functions.

6.1. PreFree – Functions for Different User Groups

After launching the PreFree software, you will be directed to the home page. From there, functions for different user groups are available:

- Functions for healthcare professionals (including supporting personnel)
- Functions for patients (non-medical component)

Functions for Healthcare Professionals

The functionality for healthcare professionals includes the certified medical decision support and provides, among others:

- Management and monitoring of patients
- Visualization of medical examinations and optionally entered patient data
- Display of predictive risk values
- Graphical display of blood pressure trends and the sFlt-1/PlGF ratio
- Archiving and access to archived pregnancy courses

NOTE!

Interpretation of risk predictions

Only healthcare professionals may interpret risk predictions and derive actions from them.

The term "*function for patients*" continues to appear in the user interface but refers exclusively to a non-medical supplementary module without prediction or evaluation functionality.

Functions for Patients

The function for patients is not part of the certified medical device and serves solely for the optional entry of health data by the patient.
Only the data entered by the patient (e.g., blood pressure, weight, symptoms) are displayed. No risk predictions, trend data, or clinical analyses are shown.

6.2. PreFree Operation Modes

The available operating modes in PreFree differ depending on the function used and the device type. Functionality remains consistent, while the user interface adapts to screen size and input device.

6.2.1. Modes for Patients

The function for patients (non-medical) provides two display modes for different devices:

- The standard mode is optimized for use on desktop PCs and tablets.
- The compact mode is optimized for display and operation on mobile devices (e.g., smartphones).

Input functions remain identical. No medical evaluation takes place within this module.

> On mobile devices and tablets, users can switch between the desktop version (standard mode) and the mobile version (compact mode) via browser settings.

6.2.2. Modes for Healthcare Professionals

The function for healthcare professionals is available only in standard mode and optimized for use on desktop PCs and tablets. Use on mobile devices is not intended, as the functionality and layout are optimized for larger screens and professional environments.

6.3. Login Without Hospital Information System (HIS) Integration

> PreFree is currently available only as a standalone web application. Integration with a hospital information system (HIS) is not yet supported.

6.3.1. User Group Selection

After opening the home page, select your user group:

- **Clinician** (healthcare professional)
- **Pregnant** (patient)

This selection determines which functionality of the product will be loaded (→ see Chapter 6.1).



Figure 1: Selection of your user group

6.3.2. Login as Healthcare Professional

> The initial login credentials are provided by BAYOOCARE GmbH.

After selecting the option “Clinician,” the login window appears.
To access the system, you need the following information:

- **Email address**
- **Password**

▶ Enter your credentials and click “**Log in**.”

▶ If you have forgotten your password, you can request a new one via the “**Forgot password?**” link (→ see Chapter 6.5).

6.3.3. Invitation and Registration of Patients

Healthcare professionals invite patients to use the non-medical data entry module.

After successful registration of a patient, an invitation to use the patient function can be sent via email:

▶ Click “**Invite patient.**”

▶ The patient receives an email with a registration code (invitation code) and a link to the login page.

6.3.4. Login or Registration by Patient

After selecting the option “Pregnant,” the patient sees two buttons:

- **Registration** (for first-time access)
- **Login** (for already registered users)

Registration

▶ The patient enters her email address and the 8-digit invitation code from the invitation email.

▶ She then sets her own password, thereby activating access.

Login

▶ On subsequent visits, the patient logs in using her email address and password via the known login screen.

> This registration applies exclusively to the non-certified data entry function for patients.

6.4. Change Password

The password can be changed at any time via the personal profile settings. This applies to both healthcare professionals and patients, provided the user is already logged in.

NOTE!

Password security

Choose a secure password that is at least 8 characters long and contains uppercase and lowercase letters as well as at least one number.

Never share your password with third parties, as this compromises data security.

6.4.1. Password Change Process for Healthcare Professionals

- Select "**Profile**" from the top menu.
- Click the "**Change password**" button.
- Enter the following information in the form:
  - Your current password
  - A new password
  - Confirmation of the new password
- Save the change by clicking "**Save.**"

6.4.2. Password Change Process for Patients

- Click "**Settings**" in the menu at the bottom of the screen.
- Tap the edit icon (pencil) next to the name.
- In the "**Edit password**" section, enter the following information:
  - Your current password
  - The new desired password
  - Confirmation of the new password
- Click "**Save**" to apply the change.

6.5. Reset Password

If you have forgotten your password, you can reset it using the password recovery function. This is available to both patients and healthcare professionals.

6.5.1. Procedure for Password Recovery

- Open the PreFree home page and select your user group ("**Clinician**" or "**Pregnant**").
- Click the "**Forgot password?**" link.
- Enter the email address you used during registration.
- Submit the request.

You will receive an email with a link to set a new password.

- Check the inbox of your registered email account.
- Follow the instructions in the email to create a new password.
- After successful change, you can log in with your new password.

> If you do not receive an email, please also check your spam folder. If problems persist, contact your responsible healthcare professional or the BAYOOCARE GmbH technical support.

6.6. Log Out of PreFree

After using PreFree, it is recommended to log out actively, especially on shared devices. Logging out ends the session and protects data from unauthorized access.

6.6.1. Logout for Healthcare Professionals

- Click "**Log out**" in the top menu (icon with arrow and door symbol).
- The session will end immediately, and you will return to the home page.



Figure 2: User logout for healthcare professionals in the healthcare professional function.

6.6.2. Logout for Patients

- Tap "**Settings**" at the bottom of the screen.
- Then click the "**Log out**" button.
- The session will end, and you will return to the selection page (Login / Registration).

6.7. Language Settings

The PreFree user interface is currently available in German and English. The language can be changed via the header bar.

Additional language versions are planned for future releases.

7. DATA ENTRY FOR HEALTHCARE PROFESSIONALS

ℹ	For data entry by **patients**, see Chapter 9.
ℹ	**Mandatory** fields are marked with a red asterisk (*).

7.1. Manage Organizations and Profile

Healthcare professionals can be assigned to one or more organizations within PreFree. The organization defines, among other things, access to patient data and the working environment within the healthcare professional function.

In your profile, you can view all organizations to which you are assigned or have been invited. Additional functions are also available here to adjust your profile (→ see Chapter 7.1.4).

7.1.1. Aktive Organisation anzeigen

The currently active organization is displayed in the upper navigation area (e.g., "**Sample Clinic**").



Figure 3: Display of the currently active organization in the upper navigation area

7.1.2. Join Organization

If you are invited to join a new organization, you will receive an invitation email containing a link and further information.

Procedure

- Click the link in the invitation email.
- You will be redirected to the "Join Organization" confirmation page.
- Enter your name and choose a secure password (please refer to the password requirements in Chapter 6.4)

After successful confirmation, you become a member of the organization and can access its patients and functions according to your assigned permissions.

7.1.3. Switch Organization

To switch to another organization:

- Click "Info" in the top menu.
- Select the "Switch organization" button.
- You will be redirected to the profile section.
- There you will find an overview of all organizations to which you are assigned.
- Click the name of an organization to switch to it.

ℹ	You will only see patients and data belonging to the organization that is currently

	active.
	Changes to organizational settings (e.g., adding new organizations or changing roles) are managed centrally by the manufacturer's system administration team or by an administrator of the respective organization.

7.1.4. Functions in the Profile Section

In the profile section, you can also:

- View and edit your user data (name, email)
- Change your password (→ see Chapter 6.4)
- Update your email address
- View the date of registration and email verification
- Check your organization status (admin / non-admin)

7.2. Manage Patients

NOTE!

Data loss

▶ Save all entered data and values before exiting the software.

7.2.1. Create Patient

To register a new patient in PreFree, use the "Create new patient" function within the healthcare professional interface. This provides access to an input form for personal and organizational master data.

Procedure:

▶ Navigate to the "Patients" tab in the top menu bar.

▶ Click the "Create new patient" button.

▶ Fill in all relevant fields in the dialog window that opens.

	Mandatory fields are marked with a red asterisk (*).

▶ Click "**Create patient**" to save the entry.



Figure 4: Input fields for creating new patients

After successful creation, a confirmation message appears, and you are redirected directly to the patient's profile.

Further Actions

In the patient profile, the following functions are available:

- **Edit master data:**
  Edit the entered information
- **Enter medical data:**
  Start entering medical history or examination data (→ Chapter 7.3)
- **Invite patient (*):**
  Send an email invitation with an access code for the patient function
- **Delete patient:**
  Remove the patient from the system (→ Chapter 7.2.3)

> (*)The invitation to use the patient function is not sent automatically. Use the "Invite patient" button once the patient should be actively involved.

7.2.2. View and Edit Patient Data

After creating a patient or selecting an existing one from the patient overview (menu item "Patients"), you are directed to the patient detail view. This view opens by default in the "Master data" tab.

Overview of Patient Data

In the "Master data" tab, the following sections are displayed:

- **Personal data:** Last name, first name, date of birth, ethnicity
- **Contact data:** Phone number, email address (once the patient is registered)

Editing Functions

The following functions are available in the upper area of the detail view:

- **Edit:** Edit master data by clicking the pencil icon
- **Invite patient:** Send an invitation for patient registration
- **Delete patient:** Remove the patient from the system (→ see Chapter 7.2.3)

> If a patient has not yet been invited or registered, her email address is displayed as "*None (patient not yet registered or deleted).*"

Additional Medical Functions

Once medical data have been entered (i.e., medical history has been recorded), additional functions and tabs are unlocked:

- "**Medical history**" tab (appears after entering medical data)
- "**Examinations**" tab (also visible only after medical history entry)
- **Buttons**:
  - **„Archive pregnancy "**
  - **„Create examination"**

These functions are available only for active pregnancies and represent the further clinical course.

> The additional tabs and functions remain hidden until medical data (medical history) are available.

7.2.3. Delete Patient

If a patient needs to be removed from the system, she can be deleted via the detail view.

Procedure

- ▶ Navigate to the patient detail view under the "Master data" tab (→ Chapter 7.2.1).
- ▶ Click the "Delete patient" button in the upper right corner.
- ▶ A security prompt appears with the message:
  „Do you really want to delete this patient? All stored patient-specific data will be lost."
- ▶ To confirm deletion, click "Confirm."
- ▶ Click "Cancel" to abort the process.

NOTE!

Permanent deletion of a patient

Deleting a patient permanently and irreversibly removes all associated data. Recovery by the user is not possible—verify the action carefully, especially if medical entries exist.

7.2.4. Patient Overview

The patient overview lists all patients recorded in the currently active organization. It serves as the central management and access interface for detail views and further editing.

Table Structure

For each patient, the following information is displayed:

- **Name**: Patient's last and first name (linked to the detail view)
- **Date of birth:** Displayed in the format day.month.year
- **Patient number:** Internal patient number assigned by the user
- **Active pregnancy?:** Indicates whether a current pregnancy is documented
- **Current gestational age:** Based on the calculated due date, shown as weeks + days (e.g., 39+2 weeks)

Filter and Search Functions

At the top of the overview, the following filter options are available:

- **Search field:** Filter by name, date of birth, or patient number
- **Switch "Show inactive pregnancies?":**
  - **„No " (default)**: Displays only patients with active pregnancies
  - **„Yes"**: Also shows archived cases (completed pregnancies)

> Patients with archived pregnancies can still be viewed but not edited. A new pregnancy must be created separately if needed.



Figure 5: Example filter by the name "Mara." The overview displays all patients matching this search criterion.

7.3. Record and Edit Medical History

Recording the medical history forms the medical starting point in PreFree. Only after entering the medical history do additional functions, such as creating examinations or archiving the pregnancy, become available.

NOTE!

Data loss

▶ Save all entered data and values before exiting the software.

7.3.1. Record Medical History

Procedure

- Open the detail view of the desired patient.
- After clicking “Enter medical data,” the input form for medical history opens. This form is divided into three sections:

Field	Description	Required for prediction?
Pregnancy details		
Estimated due date (calculated)	Expected date of delivery (e.g., by ultrasound)	✅
Pre-pregnancy weight	Body weight before conception in kilograms	✅
Conception	Type of conception (e.g., spontaneous, IVF, unknown)	
Personal information		
Blood group	Patient’s blood group	
Height	Body height in centimeters	✅
Gravidity	Number of previous pregnancies	
Parity	Number of completed pregnancies	
Risk factors		
Chronic hypertension	Presence of pre-existing hypertension? (Yes / No / Unknown)	✅
Antiphospholipid syndrome (APS)	Diagnosed APS?	
Systemic lupus erythematosus (SLE)	Diagnosed SLE?	
Pre-existing diabetes mellitus	Known diabetes before pregnancy?	
Pre-existing kidney disease	Diagnosed kidney disease before pregnancy?	
History of IUGR	Previous intrauterine growth restriction	
Previous preeclampsia	Occurred in a previous pregnancy	
Previous preterm birth	Birth before 37+0 weeks in a prior pregnancy	

- Complete the entry by clicking **„Save“**.

After successful saving, a confirmation message appears, and you are redirected directly to the patient’s “Medical history” tab.

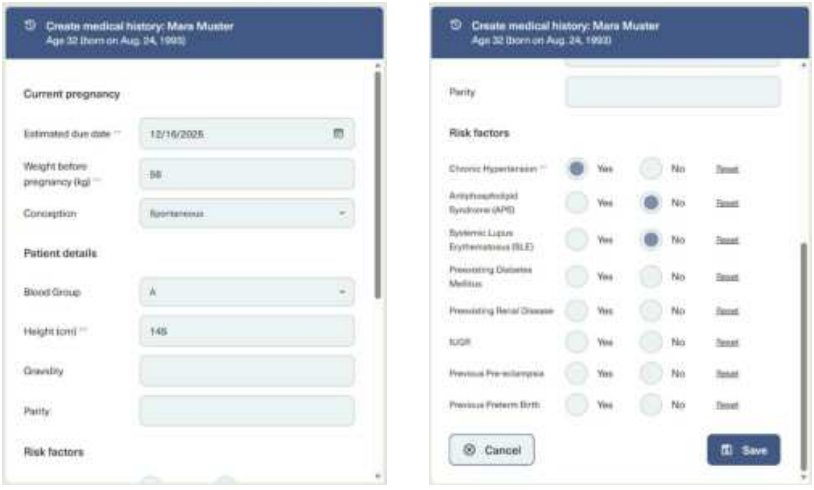


Figure 6: Medical history input form with pregnancy data, personal information, and risk factors, partially completed as an example.

7.3.2. View and Edit Medical History

After successful saving, the “Medical history” tab is automatically activated in the patient view. Here, all entered data are clearly grouped:

- Schwangerschaftsdaten (Geburtstermin, Gewicht, Konzeption
- Personal information
- Risk factors with selected status (Yes, No, Unknown)

ℹ	Changes to the medical history can be made at any time by clicking the pencil icon.

7.4. Record and Edit Examinations

After completing the medical history, physician-performed examinations can be documented. Recording current parameters is the basis for automatic risk prediction.

NOTE!

Data loss

▶ Save all entered data and values before exiting the software.

7.4.1. Record a New Examination

Procedure

▶ Open the “Medical history” or “Examinations” tab within the patient view.

▶ Click the “Create examination” button.

▶ The following input form opens, divided into several sections:

Field	Description	Required for prediction?
Personal data		

Date of examination		✅
Weight	Current weight at the time of examination	
BMI	Automatically calculated	
Blood pressure measurement		
Systolic blood pressure	mmHg	✅
Diastolic blood pressure	mmHg	✅
Proteinuria		
Proteinuria measurement	Scale from negative to 4+	✅
Laboratory values		
ALT	U/l	
AST	U/l	
sFlt-1	ng/l	✅
PlGF	ng/l	✅
sFlt-1 : PlGF ratio	Automatically calculated	
Symptoms at presentation		
Hypertension		✅
Thrombocytopenia		✅
Elevated liver enzymes		✅
Visual disturbances		
Headache		
Severe edema		
Upper abdominal pain		

▶ Click “Save” to complete the examination.

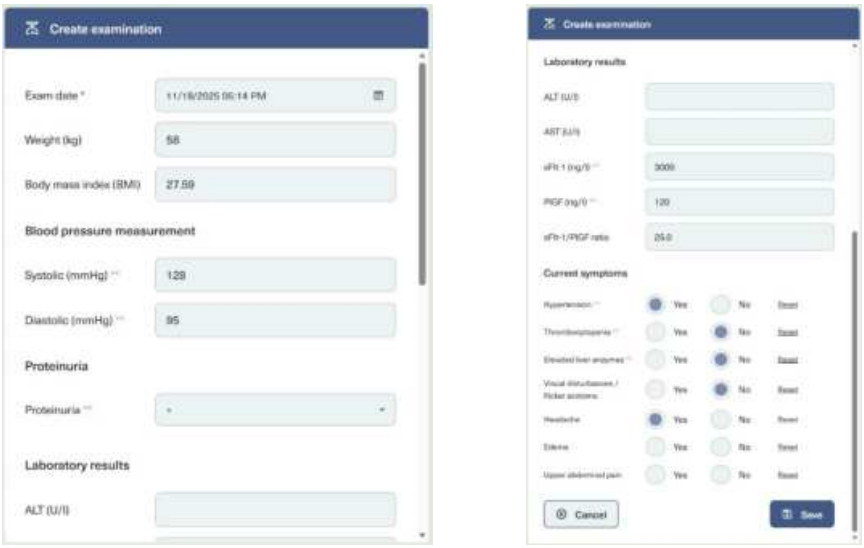


Figure 7: Examination input form, partially completed as an example.

7.4.2. View and Edit Results

After successful saving, the examination appears:

- In the “Examinations” tab
- With a complete display of all entered values
- In the tabular overview of all examinations

Risk Predictions and Trend Charts

Based on the examination, PreFree automatically calculates risk-based predictions and displays them together with graphical trends of relevant parameters.

ℹ	An overview of the displayed risk parameters, the conditions for prediction, and guidance for interpreting the visualizations can be found in **Chapter 8**.
ℹ	The risk predictions are based exclusively on clinical data collected and entered by healthcare professionals. Patient-entered values are not included in the calculation.

NOTE!

Missing PSAE risk prediction

▶ The risk prediction for preeclampsia-associated serious adverse events (PSAE) is only calculated at a gestational age ≥34+0 weeks if the sFlt-1/PlGF ratio is < 110. Otherwise, no prediction is generated. This does not represent a system failure but follows the medically validated logic of the algorithm.

7.5. Archive Pregnancy

Pregnancy archiving is performed by documenting the pregnancy outcome. Once this entry is completed, the pregnancy is considered closed, and the patient is no longer listed as actively pregnant.

7.5.1. Record Pregnancy Outcome

Procedure

▶ Open the patient view in the “Master data,” “Medical history,” or “Examinations” tab.

▶ Click the “Archive pregnancy” button.

▶ Fill in the following delivery-related fields in the dialog:

- Date of delivery (mandatory field)
- Mode of delivery (mandatory field, e.g., spontaneous, cesarean section, induction)
- Preeclampsia diagnosed
- Preeclampsia-related adverse events
- Newborn admitted to hospital
- Intrauterine growth restriction

▶ Click “Save” to complete the pregnancy outcome entry.

After successful entry, the pregnancy is archived. The patient will no longer appear in the default view of active pregnancies.



Figure 8: Input form for recording the pregnancy outcome.

7.6. Simultaneous Data Editing by Multiple Users

If multiple users work on the same patient record simultaneously, conflicts may occur.

When a user saves changes to a record, PreFree automatically checks whether the same data have been modified by another user in the meantime. If this is the case:

- A warning message appears indicating that the data have been changed,
- The user's own entries are not saved,
- The most recent data from the database are reloaded,
- **All locally made changes are lost.**

This mechanism protects against accidental overwriting of already updated information.

8. INTERPRETATION AND VISUALIZATION OF CLINICAL RESULTS

8.1. Requirements for Risk Calculation

The calculation of risk predictions in PreFree is based on a trained, medically validated AI model. The prediction relies exclusively on complete examination data entered by healthcare professionals. Data submitted by patients themselves are not included in the risk calculation. To generate a prediction, both information from the initial medical history and complete values from a single examination must be available. Without these complete inputs, no risk prediction will be displayed.

The PSAE risk prediction is only generated within the validated operating limits: from 20+0 to ≤ 34+0 weeks of gestation and from > 34+0 to < 37+0 weeks of gestation, provided that the sFlt-1/PlGF ratio is < 110 and systolic and diastolic blood pressure values are < 160 mmHg and < 110 mmHg, respectively. If these conditions are not met, the PSAE prediction is automatically suppressed.

> All parameters required for a risk prediction are marked with the following symbol: **

Required Parameters from the Medical History

The following information must be entered once as part of the medical history:

Parameter	Description
Pre-pregnancy weight	In kilograms
Height	In centimeters
Estimated due date (calculated)	e.g., by ultrasound
Presence of chronic hypertension?	Yes / No

Table 7: Data to be recorded as part of the medical history to enable a risk prediction

> The medical history forms the static basis for prediction. If any of these details are missing, no risk predictions will be calculated for the patient, regardless of the number or completeness of subsequent examinations.

Required Parameters from the Current Examination

For each examination in which a risk prediction is to be generated, all of the following inputs must be available:

Parameter	Description
Systolic blood pressure (RR SYS)	In mmHg
Diastolic blood pressure (RR DIA)	In mmHg
sFlt-1	In ng/l
PlGF	In ng/l

Urine dipstick (proteinuria)	Category from neg. to ++++
Hypertension?	Yes / No
Elevated liver enzymes?	Yes / No
Thrombocytopenia?	Yes / No

Table 8: Data to be recorded during each clinical examination to enable a risk prediction

Laboratory-based raw values such as ALT (GPT) or AST (GOT) are not required, as the model calculation relies on the physician's assessment "Elevated liver enzymes: Yes/No."

Notice for Incomplete Data

If one or more of the required inputs are missing, no prediction will be calculated for the corresponding entry. Instead, a clear message appears in the interface listing the specific missing inputs.



Figure 9: Example display when the risk calculation could not be performed due to missing data

Note: In certain cases, no risk prediction is displayed despite complete data entry. For more information, see Chapter 8.5.

8.2. Visualization and Interpretation of Risk Predictions

NOTE!

Interpretation of displayed risk predictions

- The interpretation of risk predictions and any resulting medical decisions may only be performed by appropriately qualified physicians.

Once all required data (→ Chapter 8.1) are available, PreFree automatically calculates various risk predictions for each valid examination. These are clearly visualized in the "Examinations" tab.

Types of risk predictions

Prediction	Description	Applies from	Scale
PE-associated adverse events	Probability of severe preeclampsia-associated complications (SAE)	GA 20+0 ≤ 34+0 weeks; GA > 34+0 to < 37+0 weeks[1]	0.0 bis 1.0

Delivery within 14 days	Probability of delivery ≤ 14 days after examination	Only for GA 34+0 weeks	0.0 bis 1.0

Table 9: Overview of the risk predictions calculated in PreFree; shows the two predictive probabilities, including their application conditions and scale values.
*[1]**Exception:** PSAE prediction is only generated within the validated operating limits: GA 20+0 to ≤ 34+0 weeks and GA > 34+0 to < 37+0 weeks, provided that sFlt-1/PlGF < 110 and blood pressure is < 160/110 mmHg. Outside these limits, the PSAE prediction is suppressed.*

Display in the Interface

- The risk predictions appear in the upper left section of the "Examinations" tab.
- The corresponding examination is marked by a vertical black line in the trend chart.
- The risk prediction values are visualized as color-coded semicircular gauges (gauge visualization).



Figure 10: Trend chart with vertical marker for the selected examination and corresponding risk predictions

Interpretation of Colors

Each prediction is displayed as a numeric value (0.0 to 1.0) and a color-coded semicircular gauge. The classification is based on medically defined thresholds:

Symbol	Color	Meaning	Clinical interpretation
	Green	Low risk	No immediate action required
	Yellow/Orange	Moderate risk	Close monitoring recommended
	Red	High risk	Consider inpatient observation

Table 10: Color scale and clinical interpretation of risk predictions; meaning of color-coded risk levels for quick clinical assessment and action guidance.

These recommendations are based on model calibration and are not diagnoses but intended as decision support. The color-coded risk categories are based on validated, model-specific thresholds and do not correspond to the sFlt-1/PlGF ratio thresholds used in clinical guidelines.

Interactive Details: Thresholds and Metrics

When hovering over a risk diagram, a detail view appears showing model performance metrics, including:

- Cutoff values (thresholds for risk categorization)
- Sensitivity and specificity
- Positive and negative predictive values (PPV/NPV)

These values are based on validated test data and support evidence-based interpretation of classifications. The displayed thresholds and performance metrics correspond to the validated performance characteristics described in the Intended Purpose and apply only within the defined operating limits of the model. The displayed metrics apply exclusively to examinations documented by healthcare professionals. No risk predictions are calculated for patient-entered measurements.



Figure 11: Tooltip examples for predictions with different cutoffs and performance metrics

Dynamic Navigation

- In the overview table on the right, different entries (clinical examinations or patient submissions from home) can be selected.
- When clicked, the vertical line in the trend chart automatically moves to the corresponding time point.
- If an examination with complete data is selected, the displayed risk predictions are automatically updated for that examination.

8.3. Trend Charts for Temporal Assessment

To support time-oriented clinical decision-making, PreFree displays all relevant measurements from both physician examinations and patient submissions in an interactive trend chart. This enables an immediate visual assessment of the progression of potentially critical parameters.

Displayable Parameters

The trend chart displays the following parameters by default:

Parameter	Beschreibung
Blood pressure (SYS / DIA)	Systolic and diastolic values in mmHg
sFlt-1/PlGF ratio	Ratio of growth and angiogenic factors in ng/l

The ratio is calculated automatically based on the recorded individual values. Both axes (left for blood pressure, right for the ratio) are dynamically scaled.

Simple Navigation and Interaction

- A vertical black line always marks the currently selected examination or submission.
- This marker is automatically updated when an entry in the table on the right is clicked.
- The associated risk prediction appears in the upper left area (→ Chapter 8.2).

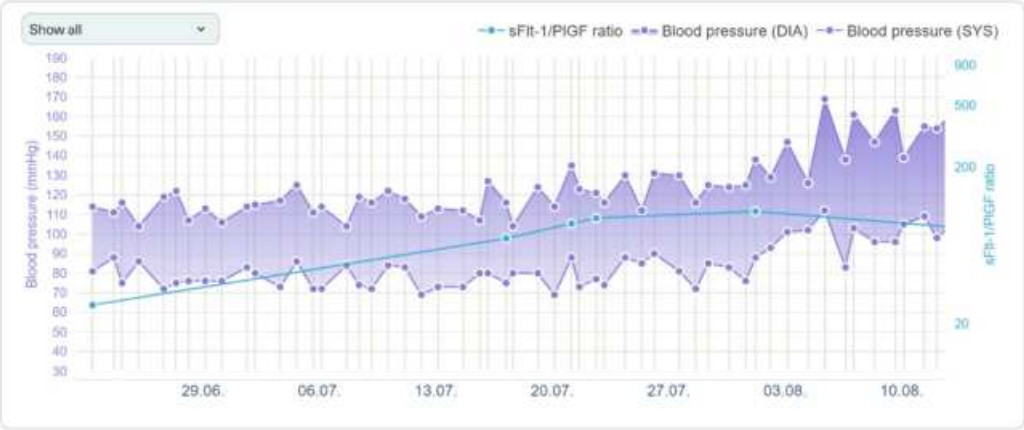


Figure 12: Trend chart with vertical marker for the selected measurement time

Adjusting the Time Axis in the Trend Chart

To adjust the time axis in the trend chart, you can interact directly within the diagram using your mouse:

- **Scrolling** with the mouse wheel **zooms** in or out on the visible time range (X-axis).
- **Clicking and dragging** with the mouse button held down **shifts** the displayed time range left or right.

8.3.1. Filter Options

A dropdown menu above the chart allows filtering of the data source for displayed values:

- Clinical examinations by healthcare professionals
- Measurements recorded by the patient

- Display all values

Source Filtering

A dropdown menu above the chart allows selection of the data source for the trend display:

Selection option	Content
Clinical examinations only	Display of physician-recorded parameters only
Patient measurements only	Display of values documented by the patient only
Display all values	Integrated display of all available measurements

This feature enables differentiated analysis, for example, comparing trends between clinical visits and patient home measurements.

Clinical Interpretation

The trend chart enables:

- Early detection of critical developments (e.g., rising blood pressure, steep increase in ratio),
- Correlation with risk prediction based on the currently active entry,
- Objective trend analysis over longer periods – even with limited patient presence in clinical settings.

8.4. Data Overview and Table View

All measurements – both physician-documented examinations (Type: Clinical) and patient-submitted values (Type: Home) – are listed chronologically in the table on the right side of the examination area. The table serves as a central overview for individual data entries, navigation within the trend chart, and targeted detail views.

8.4.1. Structure and Content of the Table

Each row in the table represents one entry and contains the following information:

- Time: Date of measurement
- Herkunft: *Klinik* (ärztlich) oder *Zuhause* (Patientin)
- Weight: At the time of measurement
- Sys / Dia: Systolischer und Diastolischer Blutdruck
- Proteinuria measurement

The “Source” column allows quick distinction between physician-recorded values and patient-entered data.

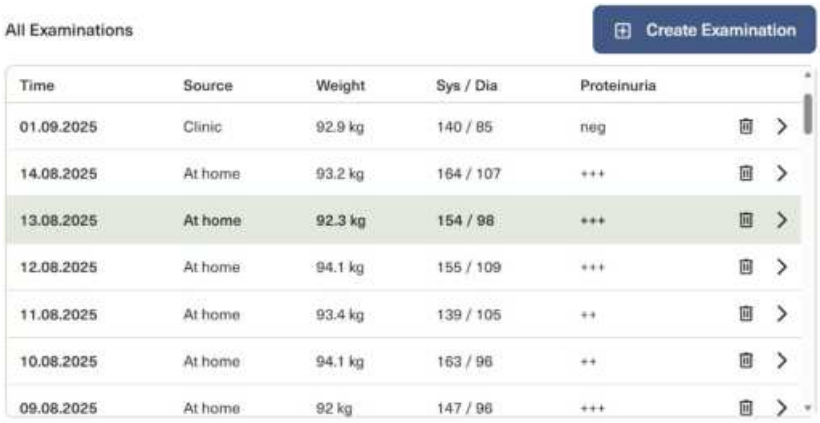


Figure 13: Overview table with entries from clinical examinations and home measurements

8.4.2. Detailed View of Individual Entries

By clicking the “>” symbol (see Figure 13) in the last column of an entry in the table on the right, the detailed view of a submitted patient entry or examination can be opened.

- The detail view of patient submissions is read-only and cannot be edited by healthcare professionals.
- If an entry is clearly incorrect or invalid, it can be deleted by healthcare professionals (trash can icon, see Figure 13).
- The detail view of examinations is editable, allowing modifications as needed.

> Changes to the content (e.g., blood pressure values, symptoms) must always be made by the patient herself, ensuring data integrity and traceability.

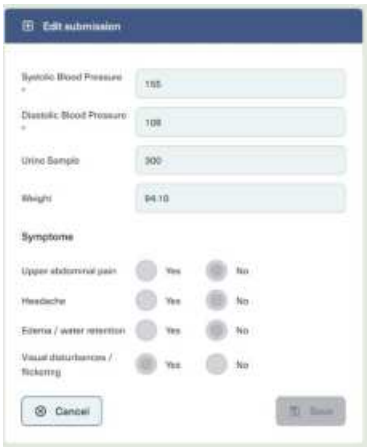


Figure 14: Detail view of a submission showing blood pressure, weight, urine value, and symptoms as an example

Risk predictions are calculated exclusively for examinations documented by healthcare professionals. Patient submissions are visually integrated but not included in predictive analysis.

8.4.3. Linking with the Trend Chart and Display Filter Options

Linking

When clicking on an entry:

- The vertical marker in the trend chart automatically moves to the corresponding time point,
- And the related risk predictions are displayed (if it is a complete physician-documented examination).

Submissions do not generate a risk prediction but can contribute to clinical trend assessment.

Filter Options

The filtering options in the graphical display (→ Chapter 8.3.1) also apply to the table:

- Selecting “Examinations only” or “Submissions only” allows targeted restriction of the table view.
- Selecting “Show all” lists all available entries.



Figure 15: Trend chart with filter options for displaying measurements

8.5. Notes on Missing Risk Predictions

There are several reasons why a risk prediction may not be displayed:

- **Incomplete data:** At least one required parameter is missing (→ Chapter 8.1)
- **Model-based suppression:** Model-based suppression: The PSAE prediction is suppressed when the examination falls outside the validated operating limits, for example at GA ≥ 34+0 weeks with sFlt-1/PlGF ≥ 110, or when systolic blood pressure is ≥ 160 mmHg or diastolic blood pressure is ≥ 110 mmHg. PSAE prediction is generated only between GA 20+0 and ≤ 34+0 weeks, and between > 34+0 and < 37+0 weeks if all operating limits are met. Outside these ranges, no PSAE prediction is displayed. This behavior supports medically validated interpretation and does not represent a software error. The following message is displayed:
    - German: „Ab 34+0 SSW wird die PSAE-Vorhersage nicht angezeigt, wenn relevante klinische Grenzwerte überschritten werden.“
    - English: „ From 34+0 weeks GA onward, the PSAE prediction cannot be displayed if any relevant clinical thresholds are exceeded.“

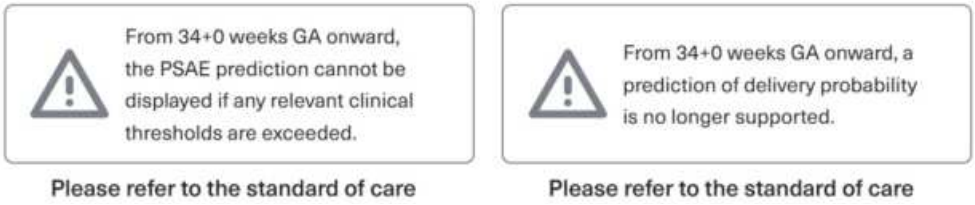


Figure 16: System message indicating model-based suppression of PSAE prediction for elevated sFlt-1/PlGF values from 34+0 weeks GA onward

- Gestational age ≥ 34+0 weeks: From 34+0 weeks of pregnancy, no prediction of delivery probability is made. Prediction of delivery within 14 days is only supported for a gestational age < 34+0 weeks. Instead, the following message is displayed:
    - German: „Ab 34+0 SSW wird die Vorhersage der Wahrscheinlichkeit einer Entbindung nicht mehr unterstützt."
    - English: „ From 34+0 weeks GA onward, a prediction of delivery probability is no longer supported."



Figure 17: Message displayed when the delivery prediction is suppressed from 34+0 weeks GA onward

- **Gestational age ≥ 37+0 weeks:** From 37+0 weeks of pregnancy, no algorithmic predictions are displayed. In this advanced stage, clinical management according to current obstetric guidelines takes precedence. Furthermore, algorithmic predictions are not sufficiently reliable due to limited case numbers and highly individual pregnancy courses.

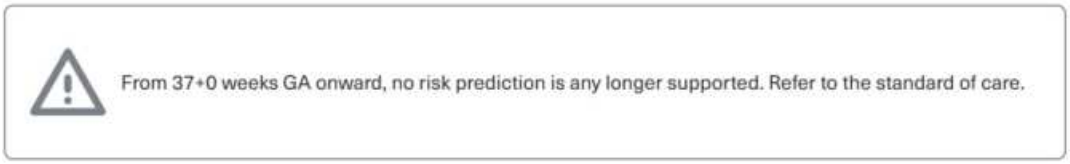


Figure 18: Message displayed when all risk predictions are fully suppressed from 37+0 weeks GA onward

9. DATA ENTRY IN THE PATIENT FUNCTION

ℹ	For data entry in the healthcare professional function, see Chapter 7.
ℹ	The patient function described in this chapter is a non-medical supplementary component provided by the manufacturer. It is an optional input module and not part of the certified medical device. In the future, other connected external patient apps may also be used for data entry, provided they have been approved by the manufacturer and are integrated into the system via a specified interface (API). Technical compatibility and approval of these external modules are managed exclusively by the manufacturer's team as part of the medical device's technical documentation.

9.1. Overview of the Input Interface

After successful login to the patient function, the patient is directed to a clear home screen. There, previously entered records are displayed in a table, sorted by date. Each entry shows blood pressure, urine status, weight, and any recorded symptoms.

At the bottom of the screen, a navigation bar provides access to three main sections:

- **Entries:** Displays all previously recorded daily values with time and symptoms
- "+" (New entry): Opens the step-by-step entry process (→ see Chapter 9.2)
- **Settings:** User profile, language settings, logout, and account deletion

The interface is optimized for mobile devices and designed for intuitive use. The most important recorded measurements are displayed in large, easily readable tiles.



Figure 19: Home screen of the patient function with current entries

This function serves exclusively for supportive documentation. No medical evaluation or risk prediction is performed within this user interface.

9.2. Recordable Parameters

In the patient function, patients can independently record medically relevant values on a daily basis. Data entry follows a guided step-by-step process consisting of four consecutive input screens. These are clearly structured and include instructions for proper measurement.

Overview of Recordable Parameters

Category	Parameter	Details / Notes
1. Blood pressure	Systolic blood pressure (mmHg)	Manual entry after measurement with a home device
	Diastolic blood pressure (mmHg)	A reminder to rest before measurement is displayed
2. Urine test	Proteinuria (urine status)	Selection based on reference color chart: *neg.*, *trace*, *+*, *++*, *+++*, *++++*
3. Weight	Body weight (kg)	Entry of current value, with a note on the time of day for measurement
4. Symptoms	Visual disturbances / visual field loss	Option to indicate worsening of symptoms within the last 24 hours
	Headache	
	Swelling (edema)	
	Upper abdominal pain	

Table 11: Overview of parameters that can be documented by the patient, structured by input steps and supplemented with recording notes.

All entries are voluntary but should be made regularly to enable continuous monitoring by healthcare professionals.

The recorded values are reviewed by healthcare professionals and used for trend assessment but do not influence risk prediction. Risk predictions are based exclusively on clinically collected data.

Important: At the end of each entry, the patient receives an automatically generated message, for example in the case of abnormal blood pressure values. These messages are based on recognized clinical guidelines and serve as guidance only—they do not replace professional medical advice.

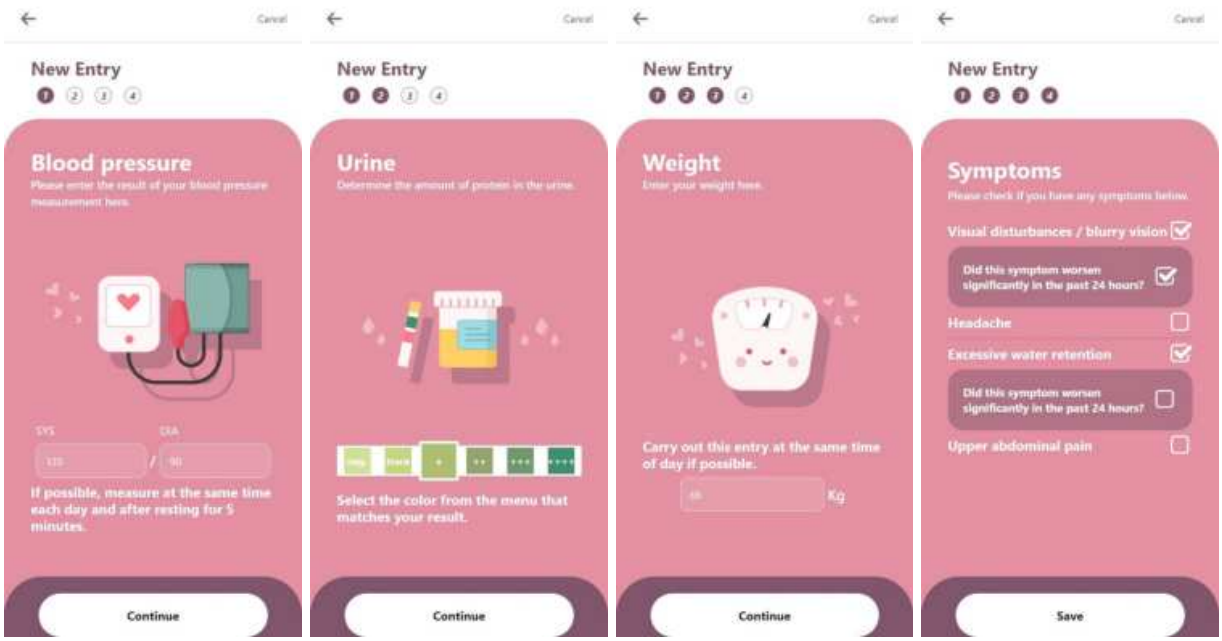


Figure 20: All steps for data entry (see next chapter for notes on data processing)

NOTE!

Display of messages in the app

- Important: The automated messages provided are based on generally accepted threshold values, not on personalized risk calculations by the underlying ML model. Medical consultation is always required.

9.3. Data Transmission Notes

The values entered by the patient are transmitted almost in real time after final saving to the same database in which the data collected by healthcare professionals are stored. This constitutes a shared, centralized data repository.

Transmission Details

- **Time of transmission:** Immediately after saving a complete entry
- **Transmitted data:** All inputs from the step-by-step process (blood pressure, urine status, weight, symptoms including timestamp)
- **Encryption:** In accordance with applicable data protection and security standards
- **Offline recording:** When no active internet connection is available, data entry is currently not possible. Ensure that an active internet connection is established.

> The patient does not have direct access to the calculated risk values—the data serve solely for documentation and monitoring by the attending healthcare professionals.

The patient has no access to the clinical evaluation of her data. All entries serve only as supplementary information for healthcare professionals and are not part of the certified medical device.

9.4. Data Visibility in the Healthcare Professional Function

All data entered by the patient in the patient function are displayed in the healthcare professional function after transmission to the system (→ see Chapter 7.2.2). These data appear in the table within the “Examinations” section and are labeled as “Submission.”

The data are displayed in the patient’s examination view as follows:

- **Tabular view:** In the lower right table view, all patient entries are listed chronologically. For each entry, the timestamp, type (e.g., “Submission”), weight, blood pressure (SYS/DIA), and urine protein status are displayed.
- **Detailed view:** By clicking an entry in the table, all recorded details can be viewed, e.g., symptoms such as headache or upper abdominal pain.
- **Graphical trend view:** In the graphical display (on the left), users can toggle between all entries, physician-documented examinations only, or patient measurements only. This allows visual assessment of blood pressure or sFlt-1/PlGF ratio trends over time.

> ⚠ **Note:** Patient measurements are not included in the risk prediction but are essential for longitudinal monitoring.

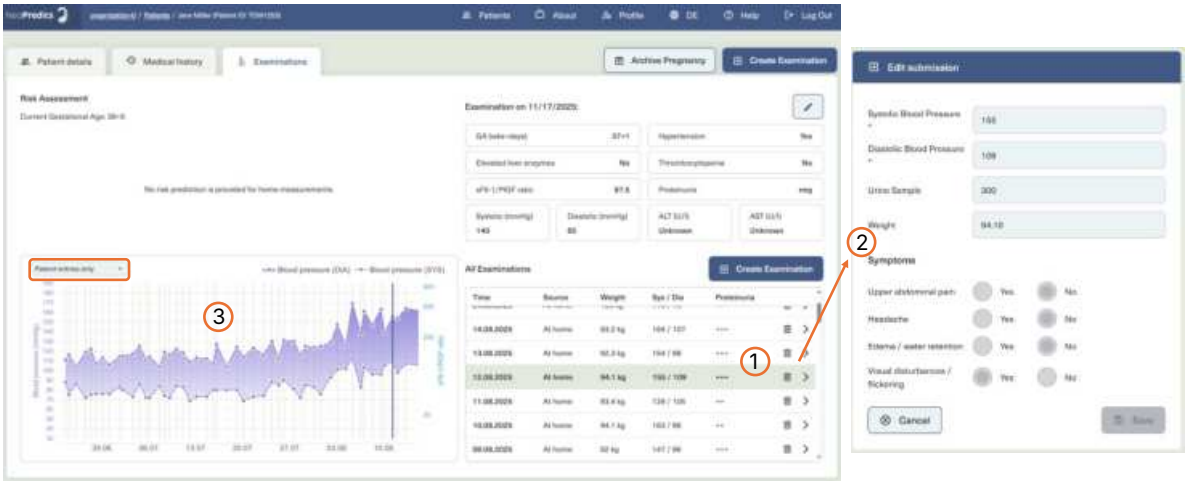


Figure 21: Display of patient-entered data in the healthcare professional function.
① All submissions appear in the table with date, weight, blood pressure, and urine status.
② Clicking on an entry opens the complete details for review and editing.
③ In the trend chart, patient measurements can optionally be displayed separately.

10. FUNCTION TEST

NOTE!

Use of PreFree with functional error(s)

Using PreFree software that is not functioning properly may result in incorrect predictions due to faulty data entry.

- ▶ Do not use the software if it is not functioning correctly.
- ▶ Report any malfunctions to BAYOOCARE GmbH.
- ▶ Use the form in the software's help function to do so.

To verify proper functionality of the PreFree software, you can perform a function test.

- ▶ Enter the following data for a test patient:

Register new patient

Parameter	Input value
Patient ID	00112233
Last name	Muster
Patient's date of birth	e.g., 15.06.1990

Table 12: Test data for function test – patient registration

Record medical history (enter medical data)

Parameter	Input value
Estimated due date (calculated)	Today 7 weeks, 10:30 AM
Pre-pregnancy weight	58 kg
Conception	Spontaneous
Blood group	A
Height	169 cm
Chronic hypertension	No
Antiphospholipid syndrome (APS)	No
Systemic lupus erythematosus	No

Table 13: Test data for function test – medical history

Examinations

Record examination – 1st examination

Parameter	Input value

Date & time	Today – 2 weeks, 10:30 AM
Weight	68 kg
Systolic BP	135 mmHg
Diastolic BP	97 mmHg
Urine dipstick (proteinuria)	negative
sFlt-1	1900
PlGF	60
Hypertension	Yes
Thrombocytopenia	No
Elevated liver enzymes	No

Table 14: Test data for function test – examination no. 1

Record examination – 2nd examination

Parameter	Input value
Date & time	Today 10:30 AM
Weight	69 kg
Systolic BP	147 mmHg
Diastolic BP	80 mmHg
Urine dipstick (proteinuria)	+
sFlt-1	5632
PlGF	12
Hypertension	Yes
Thrombocytopenia	No
Elevated liver enzymes	Yes

Table 15: Test data for function test – examination no. 2

The calculated risk predictions and graphical parameter displays should match Figure Figure 22.

If the comparison does not match:

- ▶ Do not continue using the software for performing risk predictions.
- ▶ Report the issue immediately to BAYOOCARE GmbH.

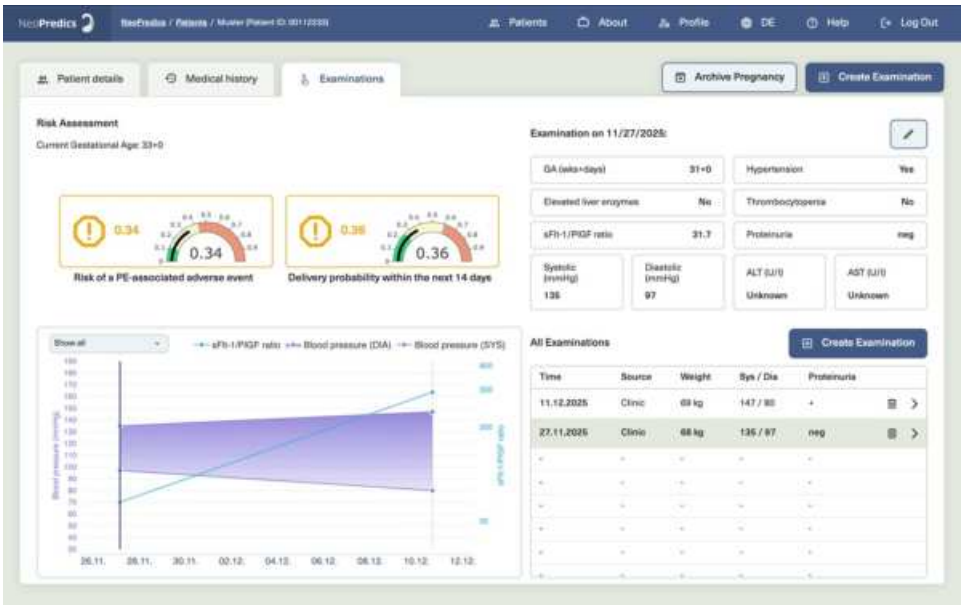


Figure 22: Expected result of the function test

11.CYBERSECURITY

The use of PreFree requires a secure environment outside the software system. The operator is responsible for ensuring compliance with security standards within the operating environment (e.g., network, device access, operating system).

> No specific training or skills related to cybersecurity are required for the use of the software.

Operator responsibilities:

- Ensure that the required security levels for the operating environment, including the necessary infrastructure, are maintained (e.g., latest browser version, secure network, physical access control, up-to-date malware protection software; see also Kapitel 5.1).
- Apply best-practice security standards.
- Ensure that personnel are properly trained and available to respond to security issues
- Ensure that the system is used in accordance with the manufacturer's policies and security requirements, including:
  - No physical access by unauthorized users.
  - Definition of access rights through user roles.
  - Compliance with password policies by users (see also Chapter 6).
  - Deactivation of unused features or applications that do not contribute to security (also relevant outside the software system, e.g., in the runtime environment).
  - No use of mobile devices when operating the software.
- Ensure that health and personal data are protected outside the software system as well (e.g., exported files or printed reports).
- Ensure that mandatory maintenance is carried out as required, including the acceptance and installation of security updates/patches provided by the manufacturer
- Inform the manufacturer and the competent authority of the member state in which the user and/or patient is established without delay of any suspected security incident.

12. HELP

For questions or troubleshooting, use the help function in the software to obtain support. It can be accessed from the application’s header bar.

13. CONTACT INFORMATION

	**BAYOOCARE GmbH** Europaplatz 5 64293 Darmstadt, Germany Phone: +49 6151 8618-0 Email: info@bayoocare.com bayoocare.com

APPENDIX I – PATIENT ID ASSIGNMENT

The **patient ID** must meet the following requirements:

- Must be unique for each patient.
- Do not use the special or control characters ".", "\" or Unicode characters U+007F–U+009F.
- Allowed special characters include:

Character	Name
;	Semicolon
,	Comma
/	Slash
?	Question mark
:	Colon

Character	Name
@	At sign
&	Ampersand
=	Equals sign
+	Plus sign
$	Dollar sign

Table 16: Permitted special characters for the patient ID