

platform 24

User Manual - Smart Care Plans - Monitoring

CLINIC, SMART CARE PLANS MEDICAL DEVICE VERSION 2

Manual version 8.0 2025-03-27



Copyright © 2025 Platform24 Healthcare AB







UDI-DI: 7350127221035



Consult instructions for use: eIFU provided from within the product and via manufacturers web-



2025-04-01



Platform24 Healthcare AB

Söder Mälarstrand 57, SE-118 25 Stockholm

Any serious incidents that have occurred in relation to the medical device should be reported to Platform24 and to the competent authority of the Member State in which the user and/or patient is established.

Paligo publication ID 13080 (UUID-7225d02e-d968-9f9a-715a-ef58a2d283ea)

Paligo internal publication version 10.0

Table of Contents

1. Introduction	
1.1. About Smart Care Plans - Monitoring	
1.2. About this manual	
1.3. Hardware and software specifications	6
2. Contact details	7
2.1. Manufacturer	
2.2. Support	
2.2.1. End user support	
2.2.2. Superuser support	
2.3. Feedback and questions regarding the User Manual	
2.3.1. Request printed version of the Instructions for Use	
3. Definition of symbols and precautions	
3.1. Symbols definition	
3.2. Precautions definition	
4. Safety precautions	
5. Smart Care Plans - Intended use	
5.1. Product name	
5.2. Intended use	
5.3. Intended user profile	
5.3.1. Target client	
5.3.2. Intended users	
5.4. Intended operational environment	
5.5. Intended target conditions	
5.6. Intended patient population	
5.7. Intended clinical benefits	
5.8. Performance characteristics	
5.9. Contraindications	
5.10. Residual risks	. 14
5.11. Foreseeable misuse	. 15
6. Log in and log out	. 16
6.1. Log in to Clinic	. 16
6.2. Log out of Clinic	. 16
7. Remote monitoring of patients in Clinic	. 17
7.1. The Remote Monitoring view	
7.2. Patient list	
7.3. Enroll patient to remote monitoring plan	
7.4. Search patient	
7.4.1. Search for a patient	
7.4.2. Register a new patient	
7.5. Patient's health data	
7.5.1. Graph view and parameter details	
7.6. Add monitored activities	
7.7. Attestation priorities and interpretations	
7.7.1. Attestation priorities (for practitioners)	
7.7.2. Interpretations (presented to patients and practitioners)	
7.7.3. Edit thresholds for attestation priorities and interpretations	
7.7.4. Add thresholds for weight and spirometry	
7.7.4. Add thresholds for weight and sphotherly	
7.9. Patient details	
7.10. Attestations	
7.10.1. Incoming attestations	
7.10.2. Attestations created by me	
7.10.3. Attestations attested by me	. 44

7.10.4. Components in the Attestations view	44
7.10.5. Attest an attestation	
7.10.6. Assign the attestation to a colleague	
7.11. Conclude monitored activities	
8. Smart Care Plans in the Patient app	51
8.1. Dynamic menu item and introduction page for patients	51
9. Terms and definitions	
10. User Manual versions	53

1. Introduction

1.1. About Smart Care Plans - Monitoring

Smart Care Plans - Monitoring is a product offered by Platform24 that enables healthcare practitioners to remotely monitor patients' medical parameters.

Smart Care Plans - Monitoring helps patients manage their diseases remotely. It analyzes the patient's reported data to provide insights about the patient's current state and progress in order to better meet the treatment goals. Smart Care Plans - Monitoring includes the functionality where values outside the limits of acceptance trigger automated responses and alerts in *Clinic*. For more information, see Attestation priorities and interpretations [32].

Smart Care Plans - Monitoring automatically prioritizes patients with the biggest need, in order to achieve an effective workflow for the practitioner.

Smart Care Plans - Monitoring is a variant of Smart Care Plans that is used for monitoring care flows. Smart Care Plans is the overarching name of the product supporting care plans both for monitoring and episodic care flows. This manual describes the monitoring care flows, and in the rest of the manual Smart Care Plans is used to reference the product. For more information about episodic care flows, refer to the Smart Care Plans - Episodic User Manual.

1.2. About this manual

This is the User Manual for Smart Care Plans.



NOTE

The User Manual might not always be fully up to date regarding all User Interface (UI) elements. For example, smaller UI elements, such as updated names for buttons, fields etc. might not in themselves produce a new version of the User Manual. All UI changes will, however, be communicated in the Release Notes at the time of the update. All warnings will always be up to date in the User Manual, and, in addition, new warnings will be communicated in the Release Notes.

1.3. Hardware and software specifications

- Hardware Computer with SITHS-card reader (only required when practitioner authenticates with SITHS-card) - Sweden only
 - Computer with Windows OS
 - 8 GB RAM
 - Bandwidth > 600 kb/s per stream for calls
 - Camera (required for video calls)
 - Microphone (required for video calls)
 - Speakers or headphones (required for video calls)
 - Screen resolution 1366x768 or above
 - Mouse with scroll wheel (required for stationary computers)

Software

- 2 latest versions of Microsoft Edge (Chromium)
- · Latest version of Chrome

2. Contact details

2.1. Manufacturer

Address Platform24 Healthcare AB

Söder Mälarstrand 57

SE-118 25 Stockholm

Website https://platform24.com

2.2. Support

2.2.1. End user support

Platform24 does not offer direct access to end user support. For questions, the first line of support is your on site *superusers* and trainers.

For information about the superusers in your organization, refer to your internal routines and procedures.

2.2.2. Superuser support

A *superuser* is an end user with increased knowledge and responsibility about the platform on each unit.

The superuser acts as the first-line support for the end users on the device and is the one who turns to Platform24 for further support, if necessary.

For information about the superusers in your organization, refer to your internal routines and procedures.

Urgent cases

For urgent support cases superusers should call the Platform24 support phone number below.

Phone: +46 (0) 10-140 23 21

Non urgent cases

For all non urgent support cases superusers should email the support email below.

E-mail: <support@platform24.com>

For questions regarding additional services or modules your organization may want to buy or activate, superusers should contact their *Customer Success Manager*, (*CSM*) at Platform24.

2.3. Feedback and questions regarding the User Manual

For feedback and questions regarding the User Manual, email the user documentation support email below.

E-mail: <support@platform24.com>

2.3.1. Request printed version of the Instructions for Use

The Instructions for Use (IFU) information is included in the User Manual for each product and available in digital format in the user interface.

If you require a paper version of the User Manual, contact Platform24 via:

E-mail: <support@platform24.com>

A paper version will be provided at the latest within 7 calendar days of receiving a request from the user, or at the time of delivery of the device if so requested at the time of order.

3. Definition of symbols and precautions

3.1. Symbols definition



CE marking



Consult instructions for use



Consult the instructions for use for important information such as warnings and cautions.



Date of manufacture



Manufacturer



Medical Device



Unique Device Identifier

3.2. Precautions definition

This section describes the different types of precautions that are used in the User Manuals.



WARNING

A warning indicates a hazardous situation that, if not avoided, could result in death or serious injury.



CAUTION

A caution indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.



IMPORTANT

An important precaution indicates information that is important for the user to take note of.



NOTE

A note indicates information that the user should to take note of.



TIP

A tip indicates recommendations for the user.

4. Safety precautions

All the safety precautions relevant for Smart Care Plans are summarized in this chapter.



WARNING

Values that fall within the interval where you have defined that no attestation will be created, will NOT be sent as an attestation to practitioners. The values will be visible in the graphs, but no-one will be informed that the patient has sent in new values.

In the case that the patient does NOT send in their value in time, an attestation WILL be sent to the practitioner.

The purpose of this is to reduce the workload for practitioners, as only values outside the set thresholds for attestation will need attestation. However, use it with caution and always make an individual risk/benefit assessment.



WARNING

For the parameters weight and spirometry (PEF, FEV1, FVC, FEV1/FVC), thresholds must be set for the individual patient as what is considered within target varies between individuals.

If thresholds have not been set for these parameters, no attestation will be sent to practitioners.



CAUTION

Clinic lacks support to be used via Citrix VPN. If your computer is connected to the Internet via Citrix VPN, for example to allow you to remotely access your regular medical record system, you need to ensure that you log in and work in Clinic in a separate web browser window outside the current Citrix VPN session. Please note that all communication and data in Clinic is always handled in a secure and legally compliant manner.

5. Smart Care Plans - Intended use

5.1. Product name

Smart Care Plans

5.2. Intended use

Smart Care Plans is a software used in an outpatient setting where medical parameters are reported by patients asynchronously through external services, connected hardware or manual entry. Smart Care Plans is intended to be used to monitor received medical parameters, or the results of medical questionnaires, compare them to limits of acceptance and inform clinical management through the following functionalities:

- 1. Alerts to the treating practitioner with varying priority levels.
- 2. Presentation of configured messages, prompts and requests for action to the patient.
- 3. Representation of values, or the trends in values, in relation to the limits of acceptance over time using visualizations and written messages.

Smart Care Plans is suitable for any clinical condition that benefits from planned actions based on collection of relevant medical parameters. Its configurability makes it adaptable to a spectrum of clinical conditions.

5.3. Intended user profile

5.3.1. Target client

Healthcare providers

5.3.2. Intended users

- Healthcare practitioners
- Patients
- Medical content developers

Healthcare practitioners

Create and adjust care plans and act on triggered actions.

Details

Type of user Professional
Age >20 years old

<u>Level of instructions</u> • Licensed practitioner, e.g., medical doctor, nurse, psychologist

• Level *C1-C2* in the language supported in the product for the relevant market.

User manual

Interface Clinic (web)

Patients

Patients input data and act on triggered actions.

Details

<u>Type of user</u> Layman

Age • System default: 0-120 years

• The system allows patients to seek care for themselves from the age they can digitally identify themselves. The exact age is however defined by the healthcare provider.

 The system also allows users to seek care for their child up to the age of 18 years old.

<u>Level of instructions</u> • Level <u>B1-B2</u> in the language supported in the product for the rele-

vant market.

<u>Interface</u> Patient (app/web)

Medical content developers

Create templates for care plans.

Details

<u>Type of user</u> Professional <u>Age</u> >20 years old

<u>Level of instructions</u> • Undergone education and training

• Level C1-C2 in the language supported in the product for the rele-

vant market.

User manual

<u>Interface</u> Manage (web)

5.4. Intended operational environment

Smart Care Plans is intended to be used by healthcare providers and healthcare systems in countries where the population has access to the internet through smartphones or computers.

5.5. Intended target conditions

Smart Care Plans is intended to be used for well-known and predictable health conditions, investigations, or care episodes where a smart digital care plan is feasible and would be of benefit for the patient without requiring any continuous health data streams.

5.6. Intended patient population

Smart Care Plans shall be used by the patients as determined by their treating practitioners, in order to provide accurate medical information to inform clinical management. The target treatment group includes patients in the need of a smart digital care plan for instance to monitor their chronic disease or handle an elective care episode.

5.7. Intended clinical benefits

The clinical benefit of Smart Care Plans lies in more effective patient management. This is done by increasing the relevance of the information presented to practitioners by utilizing rule-based actions, which enables clinicians to focus more on patients in need of their attention, and possibly also managing more patients, without reducing safety. Due to the rule-based actions, decisions and/or actions on the reported medical parameters are also virtually immediate, meaning that patients will get an assessment on their medical parameters faster.

Other indirect clinical benefits include giving patients accurate and timely feedback on their reported medical parameters, by allowing practitioners to automate rule-based communication with the

patient and present this in a user-friendly way. Another benefit lies in the possibility of Smart Care Plans to adapt to the patient's current health, which increases both relevance and safety to the individual patients, as well as relevance to practitioners.

The Smart Care Plans product has the following claims:

- The use of smart events increases the relevance of the information presented to the practitioners
- The use of smart events enables the practitioners to handle more patients
- Smart Care Plans enables relevant and individualized care plans
- The use of Smart Care Plans does not entail any increased risk compared to standard remote patient monitoring care

5.8. Performance characteristics

By allowing individualized thresholds and actions for medical parameters, Smart Care Plans minimizes unnecessary attestations by making sure that practitioners only receive clinically relevant information, enhancing patient management efficiency.

5.9. Contraindications

Certain patients shall not use the product:

- 1. Patients with life-threatening symptoms that require immediate medical attention, i.e., are expected to need acute hospitalization within 24 hours. In cases where these symptoms are discovered during the use of Smart Care Plans, the use of the device should stop.
- 2. Patients who are not well-informed about their health condition, including but not limited to, recognizing signs of deterioration of their health condition and knowing when, where and how to seek emergency care if needed.
- 3. Patients with severe cognitive issues (including but not limited to dementia or severe intellectual disability).
- 4. Patients for which access to the required medical data for use of a smart digital care plan is restricted.
- 5. Smart Care Plans is not intended to provide information which is used to take decisions with diagnosis or therapeutic purposes where such decisions have an impact that may cause death, irreversible deterioration of a person's state of health, serious deterioration of a person's state of health or a surgical intervention.

5.10. Residual risks

Despite the implementation of risk control measures, certain residual risks remain and cannot be completely eliminated:

- Incorrect treatment decisions may occur due to incorrect or misleading information.
- Delayed or absent treatment may result from reliance on connectivity and availability of the software.
- Inaccurate user input may lead to incorrect or misleading output that in turn can lead to impacts on performance and clinical benefit.
- Software errors may cause unexpected behavior that could impact performance and clinical benefit.
- Even though due care has been taken to validate all care plan templates, configuration of care plan templates can result in unsuitable care plans based on the patient's ability and condition.
- User errors, including misinterpretation of the interface, may affect proper use and affect clinical benefit.

Users shall follow the instructions carefully and apply clinical judgment when interpreting results.

5.11. Foreseeable misuse

Certain behaviors are technically possible by the product but outside of the intended use:

- 1. Smart Care Plans is not intended to be used to automate decisions on critically ill patients.
- 2. Smart Care Plans is not intended for monitoring of patients in an inpatient setting.
- 3. Smart Care Plans is not intended to be used to replace any process which is intended to reduce the risk of suicide or self harm for a patient. It is however within the intended use of the product to enhance the work to reduce the risk of suicide or self harm for a patient.
- 4. Smart Care Plans is not intended for continuous synchronous monitoring.
- 5. Smart Care Plans is not intended for independently determining patient management in a closed loop system, without the involvement of a practitioner.
- 6. Smart Care Plans shall not be initiated via an integration from an external system if the care plan can cause harm if applied to the wrong patient.

6. Log in and log out

6.1. Log in to Clinic

Open the browser and enter the URL https://clinic.platform24.se.
 The recommended web browsers are Google Chrome or Microsoft Edge.



NOTE

Some customers might have a unique environment link. Talk to your superuser if the link does not work.

2. Log in using your selected authentication method.



NOTE

The selected authentication method is customer-specific. Talk to your superuser if you are unsure about the login process at your clinic.

6.2. Log out of Clinic

1. Click **Log out** in the lower left corner.

7. Remote monitoring of patients in Clinic

The patient care in Smart Care Plans is organized by enrolling the patient in a remote monitoring plan where applicable parameters can be monitored in Clinic. Once enrolled in a remote monitoring plan, patients can report their values in the Patient application.

When a new patient is enrolled to a remote monitoring plan, the responsible practitioners are assigned to the patient's remote monitoring plan. The responsible practitioners' roles are preconfigured for the remote monitoring plan, but the specific practitioners are set for the individual patient.

Patients that have been added to a remote monitoring plan can be listed, sorted and filtered within that remote monitoring plan.

7.1. The Remote Monitoring view

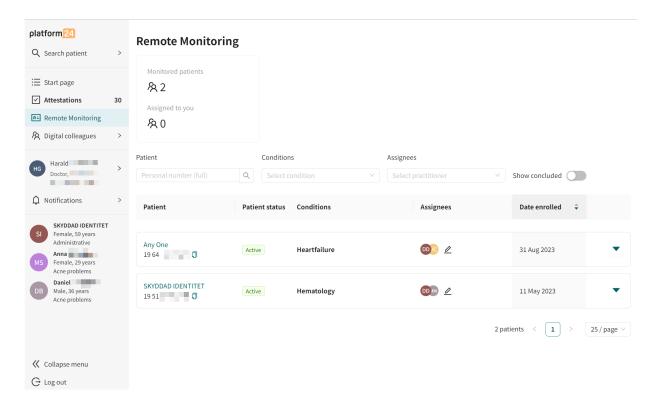
The patients that are remotely monitored are listed in the **Remote Monitoring** view. A patient can have one or more conditions that are being monitored, and all conditions are summarized in this view.



NOTE

The **Remote Monitoring** view is only visible and accessible for users that have the Care planner role.

To reach the **Remote Monitoring** view, click **Remote Monitoring** in the main menu.



The **Remote Monitoring** view consists of:

Statistics Information about the number of **Monitored patients** and how many patients

that are **Assigned to you**.

Monitored patients Assigned to you

条3 条0

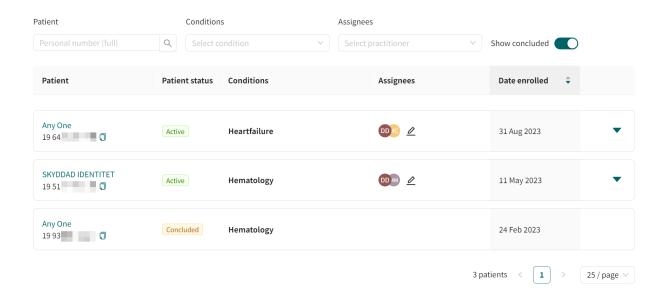
Patient list

The patient list contains patients all patients that are being monitored remotely.

For more information about the patient list, see Patient list [19].

7.2. Patient list

The patient list in the **Remote Monitoring** view contains all patients that are being monitored remotely.



It is possible to search for a patient in the list by using the *unique personal identifier*. The patient list can also be filtered by using the **Conditions** and **Assignees** drop-down lists, where it is possible to select multiple options.

Use the **Show concluded** slider to also show concluded remote monitoring plans that are no longer active.



The patient list contains the following components:

Patient The name and unique personal identifier of the patient.

Patient status The **Active** status means that at least one condition for the patient is currently

being monitored. The **Inactive** status means that no conditions are currently

being monitored for the patient.

Conditions The conditions that are being monitored or have been monitored.

Assignees The assigned practitioners. The assigned practitioners can be edited by click-

ing on the pen ∠ symbol.

Date enrolled The date the patient was enrolled in the remote monitoring plan. Click the

arrows to sort the list according to this field.

Click on a patient row in the list to display the patient's latest measurements (i.e., the latest measured value for each parameter).



Click on the patient name in the list to go to the patient's **Health data** tab where all the reported parameters and values are presented. For more information about the **Health data** tab, see Patient's health data [24].

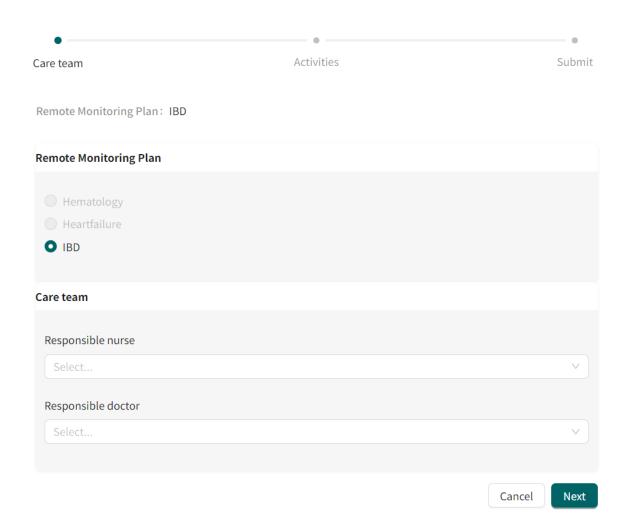
7.3. Enroll patient to remote monitoring plan

- 1. Go to the **Health data** tab (Patient's health data [24]).
- 2. Click the **Enroll to Remote Monitoring Plan** button.

Enroll to Remote Monitoring Plan

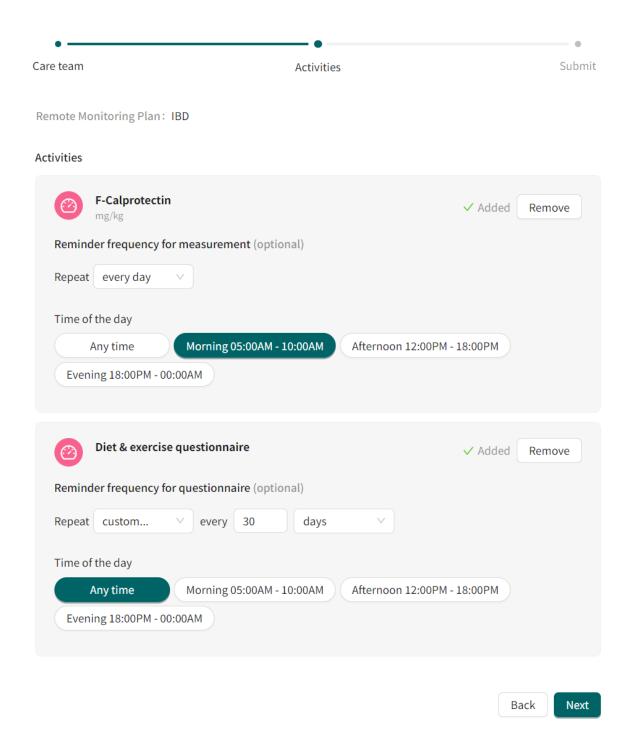
 Select the Remote Monitoring Plan and the Care team (responsible practitioners) and click Next. Note that you have to select the remote monitoring plan first before the care team part of the dialog is available.

New Remote Monitoring Plan



Select reminder frequency for the activities.
 By default, a preselected list of activities is included in the remote monitoring plan. To remove an activity, click the **Remove** button in the top right corner of that activity.

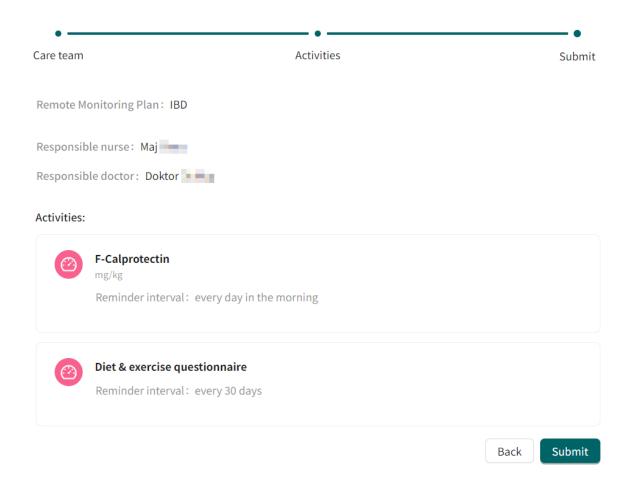
New Remote Monitoring Plan



5. Click Next.

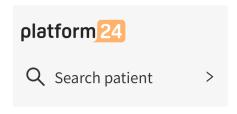
6. Review the summary and click **Submit** to enroll the patient to the remote monitoring plan.

New Remote Monitoring Plan



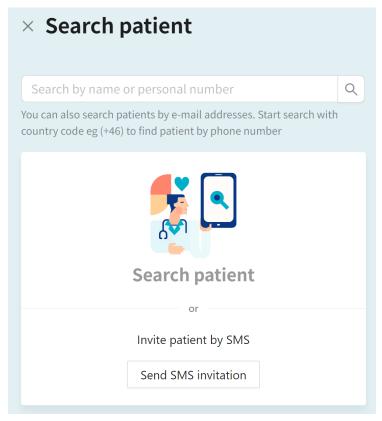
7.4. Search patient

When clicking on **Search patient** in the main menu, you can search for a patient, register a new patient and send a text message with a link to the Patient app.



7.4.1. Search for a patient

To search for a patient, enter a name, unique personal identifier or a phone number (including the country code) and press *Enter*. Click on the patient's profile to, for example, access previous appointments, book the patient for a new consultation or send an asynchronous message.



Note that the image only is an example. The Search patient option will look different depending on customer configuration.

If you want to send your web app link to a patient, click **Send SMS invitation**. This function is useful if, for instance, during a physical meeting or phone call, you inform the patient that you can be reached online, and recommend that the patient, for example, uses this channel to contact you in future.

7.4.2. Register a new patient

If you searched for a patient that was not found in the system, the **Create patient** option is displayed. Click there and follow the steps to register a new patient.

How to create a patient in Clinic is customer-specific and depends on if integrations are in plate to fetch patient information such as name, contact information and guardian. Talk to your superuser or internal support if you have questions about this.

7.5. Patient's health data

To access a patient's health data, click on the patient name in the **Remote Monitoring** view. It is also possible to go to this view by first clicking on a patient's name in the **Attestations** list or via **Search patient**, and then selecting the **Health data** tab.

Figure 1. Patient health data in a remote monitoring plan



1. Patient summary (e.g., name, age, unique personal identifier, height, BMI).

2. Patient Details

Contains the patient's details such as, for example, e-mail, phone number, health profile, internal notes and dependents (see Patient details [41]).

3. Tickets

Patient's tickets.

4. Health data tab

Shows all current and historic data being collected, including activities that are part of a remote monitoring plan. The health data that is currently being monitored has a green "Active" label to distinguish it from historic data.

5. Previous appointments

The patient's previous appointments.

6. **Consents and video tests** performed by the patient.

7. New

Here you can communicate with the patient, for example by creating a new asynchronous message.

Health data

Displays how many remote monitoring plans the patient is enrolled in. Here you can enroll a patient in a remote monitoring plan (Enroll patient to remote monitoring plan [20]), add activities (Add monitored activities [28]) and conclude activities (Conclude monitored activities [49]). If you conclude all activities connected to a remote monitoring plan, you will conclude the remote monitoring plan as well. When a remote monitoring plan is concluded, data related to the patient is kept and can be retrieved if needed.



NOTE

When the remote monitoring plan is concluded, the patient can no longer report their activities, but can view their previously reported values.

9. **Graph thumbnails** of the patient's health data (monitored parameters).

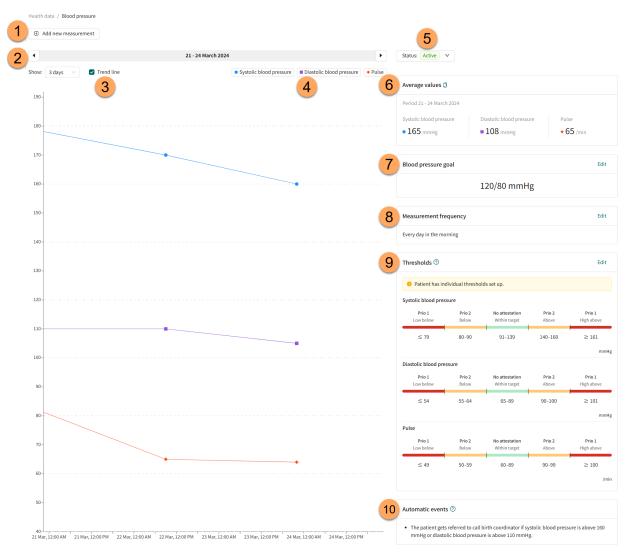
The graph thumbnails show the latest reported measurement and its corresponding threshold interpretation (if applicable). The **Active** status indicates that this parameter is currently being monitored. Click the graph thumbnails to access the parameter details and graph for the reported parameter (see Graph view and parameter details [26]).

For blood pressure, both systolic and diastolic values will be displayed, but only the most severe threshold level will be mentioned in the thumbnail (e.g., if the systolic value is high but the diastolic value is normal, only high will be mentioned in the text above the graph).

7.5.1. Graph view and parameter details

Click on the graph thumbnails in the **Health data** tab to reach the graph view and parameter details.

Figure 2. Graph view and parameter details for blood pressure



This example shows the blood pressure graph for hypertension. The parameter details of the reported parameter can vary depending on the parameter.

1. Add new measurement

Click the **Add new measurement** button to manually add a new measurement for the patient.

Timeline

Select time unit in the graph in the **Show** drop-down list (e.g., day, week, month). Use the arrows to shift the displayed timeline back and forth. If for example "week" has been selected in the **Show** field, the arrows will shift one week back and forth.

3. Trend line

Select the **Trend line** checkbox to display a line in the graph that connects each measured value.

4. Graph legend

Click on a parameter in the graph legend to display the threshold guide colors for the parameter in the graph (see Figure 8 [36]). Note that only one parameter at a time can be selected for the threshold guide colors to be visible.

If an activity has many parameters, only a few may be visible by default. To view more parameters in the graph, click on the parameters in the graph legend.

5. Status

Indicates the **Active** status of the activity. Here it is also possible to conclude the activity by using the drop-down button and selecting **Conclude activity...**.

Note that if all activities in a remote monitoring plan are concluded, the remote monitoring plan will also be concluded. For more information, see Conclude monitored activities [49].



6. Average values

Shows the average measurement values of the selected time period.

7. Blood pressure goal

Displays the blood pressure goal for the selected patient.

The blood pressure goal can be updated by clicking the **Edit** button.

8. Measurement frequency

Displays the measurement frequency of the activity for the selected patient. For information on how to edit the measurement frequency, see Edit measurement frequency of an activity in the graph view [40].

9. Thresholds

Displays the attestation priorities and interpretations for the selected patient. For information on how to edit the attestation priorities and thresholds, see Attestation priorities and interpretations [32].

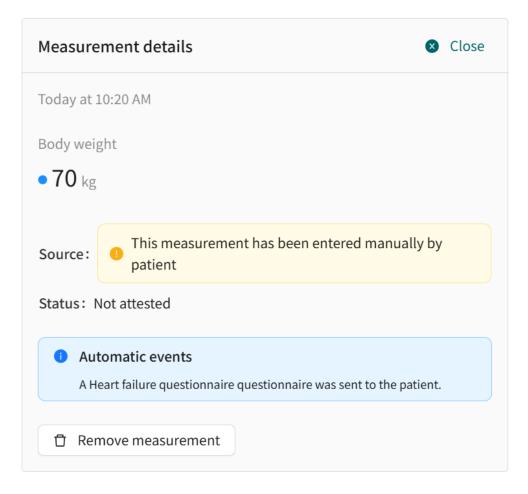
10. Automatic events

Displays the activated automatic events for the patient. For example, that a questionnaire should be sent if a measured value goes over or under a certain level. Automatic events are set on the care plan level and applied to each patient enrolled in the care plan.

Measurement details

Click on a value in the graph to display the **Measurement details** for that particular value. In this view it is also possible to remove the selected measurement by clicking the **Remove measurement** button.

If an automatic event has been triggered, information about this will be shown in the **Measure-ment details** section.



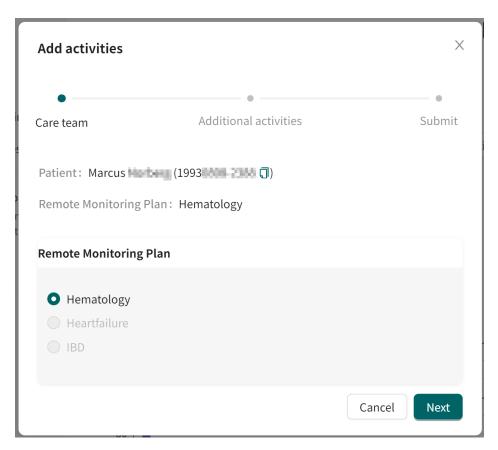
7.6. Add monitored activities

To add one or more patient activities to be monitored for a patient:

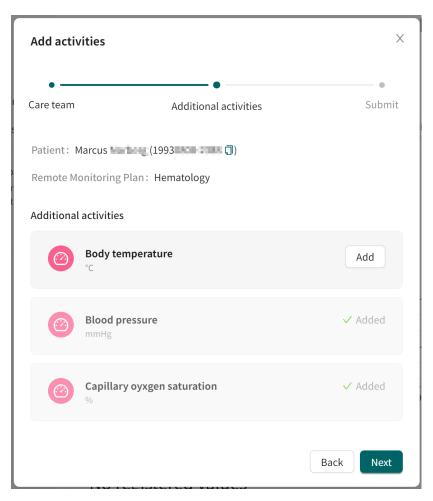
- 1. Go to the **Health data** tab (Patient's health data [24]).
- 2. Click the Add activities button.

Add activities

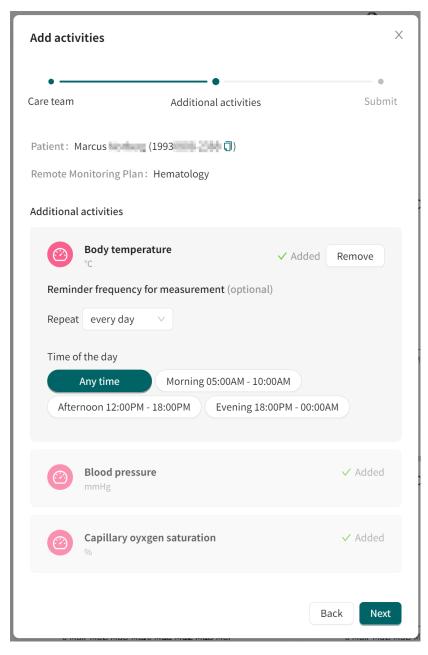
3. Select the remote monitoring plan to add activities from and click **Next**.



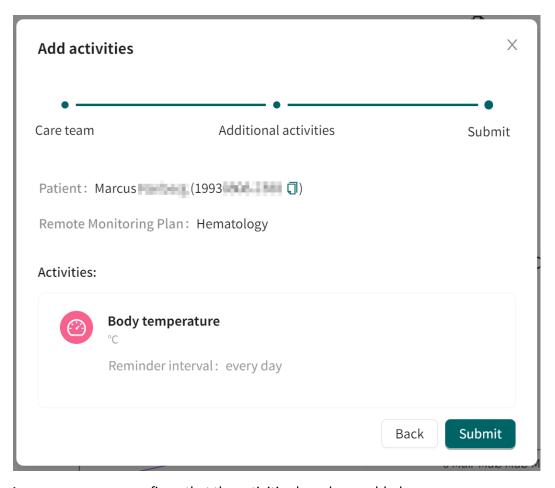
4. Click the **Add** button in the **Additional activities** list for each activity you want to add.



5. Enter the reminder frequency for the added activities and click **Next**.



6. Review the summary of the added activities and click **Submit**.



7. A pop-up message confirms that the activities have been added.

7.7. Attestation priorities and interpretations

7.7.1. Attestation priorities (for practitioners)

For most monitored parameters, thresholds are defined for when a measured value should result in a sent attestation and which attestation priority it should have. For these parameters, the attestation priority thresholds are predefined in the system, but the responsible practitioner can also within limits adjust the thresholds for an individual patient. To edit the predefined thresholds, see Edit thresholds for attestation priorities and interpretations [36].

Exceptions to this are the two parameters weight and spirometry. For these parameters, thresholds need to be set for the individual patient as these parameters vary between individuals. If thresholds have not been set for these parameters, no attestation will be sent to practitioners. To add thresholds for weight and spirometry, see Add thresholds for weight and spirometry [39].



IMPORTANT

When changing the thresholds for one interval, it also affects the thresholds for the adjacent intervals. For example, if changing the lower threshold of the "No attestation/Within target" interval, this will also affect the upper threshold of the "Prio 2/Below" interval.

Example:

Figure 3. Before changing thresholds



Figure 4. After changing thresholds



After changing the lower threshold of the "No attestation/Within target" interval from 91 to 89 mmHg, the upper threshold of the "Prio 2/Below" interval is also changed from 90 to 88 mmHg.



WARNING

Values that fall within the interval where you have defined that no attestation will be created, will NOT be sent as an attestation to practitioners. The values will be visible in the graphs, but no-one will be informed that the patient has sent in new values.

In the case that the patient does NOT send in their value in time, an attestation WILL be sent to the practitioner.

The purpose of this is to reduce the workload for practitioners, as only values outside the set thresholds for attestation will need attestation. However, use it with caution and always make an individual risk/benefit assessment.



WARNING

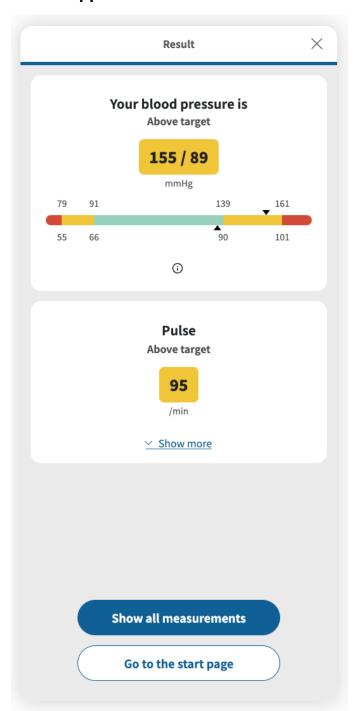
For the parameters weight and spirometry (PEF, FEV1, FVC, FEV1/FVC), thresholds must be set for the individual patient as what is considered within target varies between individuals.

If thresholds have not been set for these parameters, no attestation will be sent to practitioners.

7.7.2. Interpretations (presented to patients and practitioners)

For some monitored parameters, interpretations of measured values in the Patient app are defined to guide the patient. The interpretation thresholds are set in Clinic and reflected in the Patient application (and in Clinic).

Figure 5. Interpretations for blood pressure as presented to the patient in the Patient application



For blood pressure shown in this example, the following interpretation levels exist in the Patient application: Low below target = red, Below target = yellow, Within target = green, Above target = yellow, High above target = red. For blood pressure, both systolic and diastolic values will be displayed, but only the most severe interpretation will be mentioned in the text (e.g., if the

systolic value is "Above target" but the diastolic value is "Within target", only "Above target" will be mentioned in the text on the result page).

Default interpretations, for parameters where this is applicable, are predefined in the system but their suitability needs be evaluated for each patient before implementation. The responsible practitioner can also within limits adjust the interpretations for an individual patient. Patient-specific interpretations will be reflected in the Patient application and in the graph in Clinic.

Figure 6. Interpretations for blood pressure in Clinic



The interpretation guide colors are shown in the graph when clicking on a parameter in the graph legend above the graph.

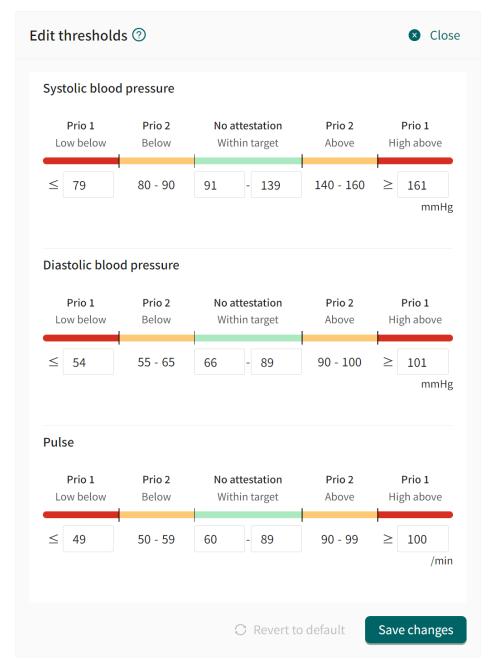
7.7.3. Edit thresholds for attestation priorities and interpretations

The attestation priorities and interpretations for measurements are connected and adjusted simultaneously. For questionnaires the interpretations are already predefined and therefore only the attestation priorities can be adjusted.

If the default thresholds set by the care unit do not suit a patient's specific needs, individual thresholds must be set for the patient.

To edit patient-specific thresholds:

Click the Edit button in the parameter details (Graph view and parameter details [26]).
 This opens the Edit thresholds view.



For blood pressure shown in this example, the following interpretation levels exist: **Low below** = red, **Below** = yellow, **Within target** = green, **Above** = yellow, **High above** = red.

- 2. Enter the desired values for the thresholds. This determines:
 - What attestation priority a measured value shall have.
 - How the patient's measurements should be interpreted in the Patient application. The interpretation will also be reflected in Clinic.



IMPORTANT

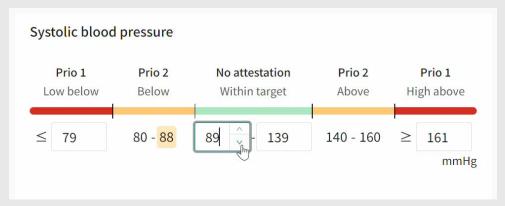
When changing the thresholds for one interval, it also affects the thresholds for the adjacent intervals. For example, if changing the lower threshold of the "No attestation/Within target" interval, this will also affect the upper threshold of the "Prio 2/Below" interval.

Example:

Figure 7. Before changing thresholds



Figure 8. After changing thresholds



After changing the lower threshold of the "No attestation/Within target" interval from 91 to 89 mmHg, the upper threshold of the "Prio 2/Below" interval is also changed from 90 to 88 mmHg.



WARNING

Values that fall within the interval where you have defined that no attestation will be created, will NOT be sent as an attestation to practitioners. The values will be visible in the graphs, but no-one will be informed that the patient has sent in new values.

In the case that the patient does NOT send in their value in time, an attestation WILL be sent to the practitioner.

The purpose of this is to reduce the workload for practitioners, as only values outside the set thresholds for attestation will need attestation. However, use it with caution and always make an individual risk/benefit assessment.

- 3. To revert to the default settings, click the **Revert to default** button.
- 4. Click the **Save changes** button to save any changes, or click **Close** in the upper right corner to cancel.

7.7.4. Add thresholds for weight and spirometry

As weight and spirometry vary a lot for individual patients, there are no predefined thresholds in the system and the thresholds must be set for the individual patient.



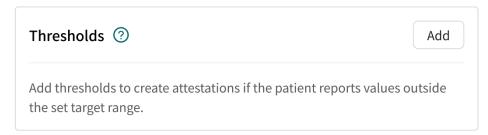
WARNING

For the parameters weight and spirometry (PEF, FEV1, FVC, FEV1/FVC), thresholds must be set for the individual patient as what is considered within target varies between individuals.

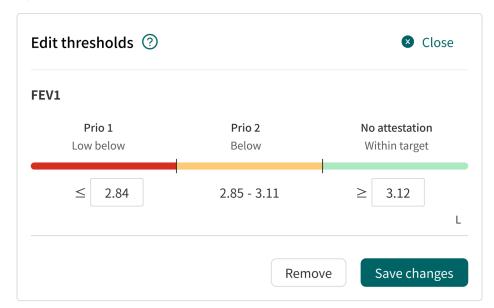
If thresholds have not been set for these parameters, no attestation will be sent to practitioners.

To set thresholds for weight and spirometry:

1. Click the **Add** button in the parameter details (Graph view and parameter details [26]).



- 2. Enter the desired values for the thresholds. This determines:
 - What attestation priority a measured value shall have.
 - How the patient's measurements should be interpreted in the Patient application. The interpretation will also be reflected in Clinic.





WARNING

Values that fall within the interval where you have defined that no attestation will be created, will NOT be sent as an attestation to practitioners. The values will be visible in the graphs, but no-one will be informed that the patient has sent in new values.

In the case that the patient does NOT send in their value in time, an attestation WILL be sent to the practitioner.

The purpose of this is to reduce the workload for practitioners, as only values outside the set thresholds for attestation will need attestation. However, use it with caution and always make an individual risk/benefit assessment.

If needed, the **Remove** button can be used to delete the thresholds.

3. Click the **Save changes** button to save any changes, or click **Close** in the upper right corner to cancel.

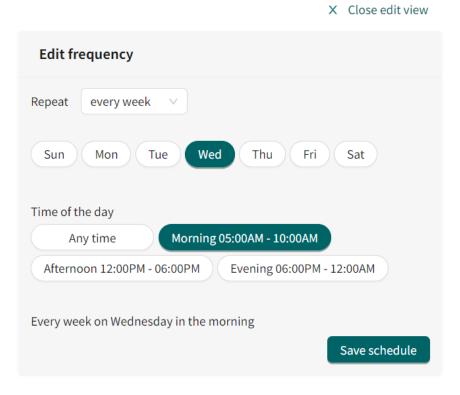
7.8. Edit measurement frequency of an activity in the graph view

To edit the measurement frequency of an activity:

- 1. Go to the parameter details the graph view (Graph view and parameter details [26]).
- 2. In the **Measurement frequency** area, click the **Edit** button.

Measurement frequency	Edit
Every week on Monday and Thursday in the morning	

This opens the **Edit frequency** options.



- 3. Select how often the activity should take place in the **Repeat** field. The options are: every day, every week, or a custom option (e.g., every 2 days or every 3 weeks).
- 4. Select the desired week day for the activity. Multi-select is available.
- 5. Enter the desired **Time of the day** for the activity. **Any time** = during the whole day, **Morning** = Between 05:00am to 10:00am, **Afternoon** = Between 12:00pm to 06:00pm, **Evening** = Between 06:00pm to 12:00am.
- 6. Click the Save schedule button.

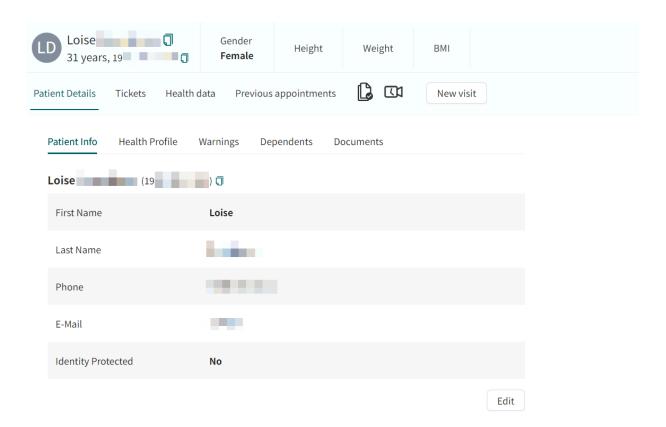
Save schedule

7.9. Patient details

The **Patient Details** tab contains the following information:

- · Patient info
- Health profile
- Warnings
- **Dependents** (children connected to this patient)
- Documents

In the **Patient info** tab, it is possible to edit the phone number, e-mail and if the patient has a protected identity or not.

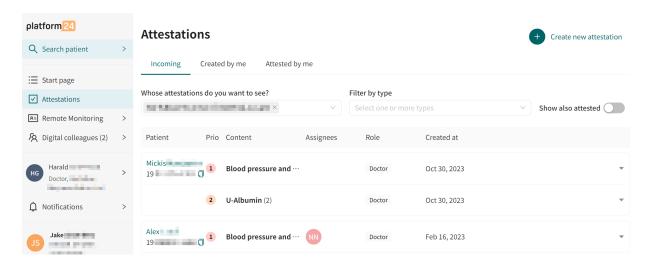


7.10. Attestations

When the patient has sent in a reported value for a monitored parameter or ordered lab referrals, an attestation will be created if the reported measurement is configured to create an attestation.

All incoming, created and attested attestations are listed the **Attestations** view. The attestations are grouped per patient and activity, and the list is sorted by priority.

To reach the **Attestations** view, click **Attestations** in the main menu.

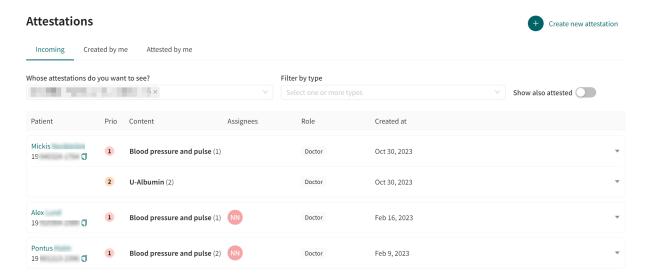


The responsible practitioner has the following options:

- Attest the attestation. This will remove the attestation from the list after the page has been reloaded. For instructions, see Attest an attestation [44].
- Assign the attestation to a colleague. For instructions, see Assign the attestation to a colleague [47].

7.10.1. Incoming attestations

All incoming attestations are listed in the **Incoming** tab in the **Attestations** view.



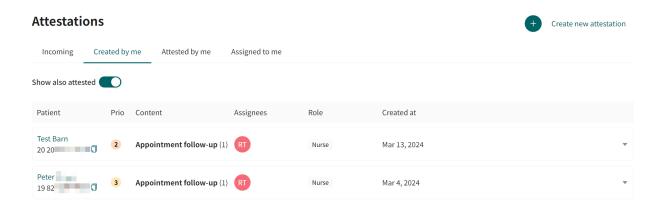
The attestations in the **Incoming** tab can be filtered by care unit and practitioner, as well as by attestation type. Use the drop-down lists to apply these filters. It is possible to select multiple options in the drop-down lists.

Use the **Show also attested** slider to also show the already attested attestations.

Show also attested

7.10.2. Attestations created by me

The **Created by me** tab in the **Attestations** view lists attestations created by the logged in practitioner.

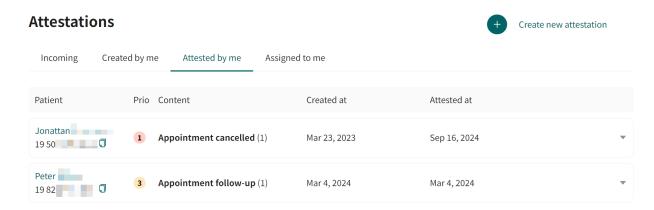


Use the **Show also attested** slider to also show the already attested attestations.

Show also attested

7.10.3. Attestations attested by me

The **Attested by me** tab in the **Attestations** view lists attestations attested by the logged in practitioner.



7.10.4. Components in the Attestations view

The **Attestations** view with its tabs contains the following components:

Patient The name and unique personal identifier of the patient.

Prio The priority for the attestation.

Content The attestation activity (e.g., blood pressure, questionnaire finished).

Assignees The practitioners assigned to the attestation.

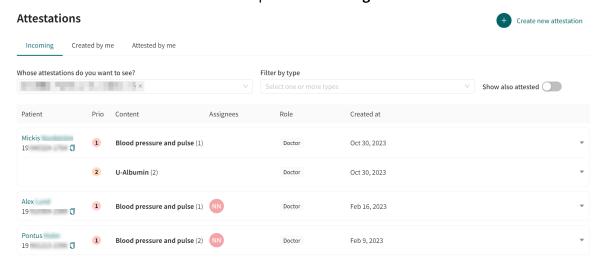
Role The responsible practitioner's role.

Created at The date the attestation was created.

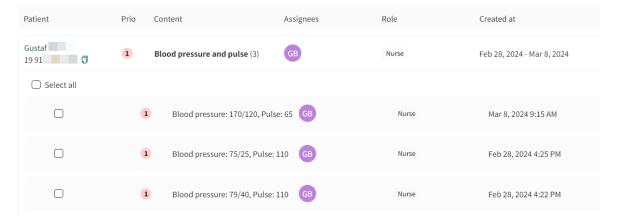
Attested at The date the attestation was attested.

7.10.5. Attest an attestation

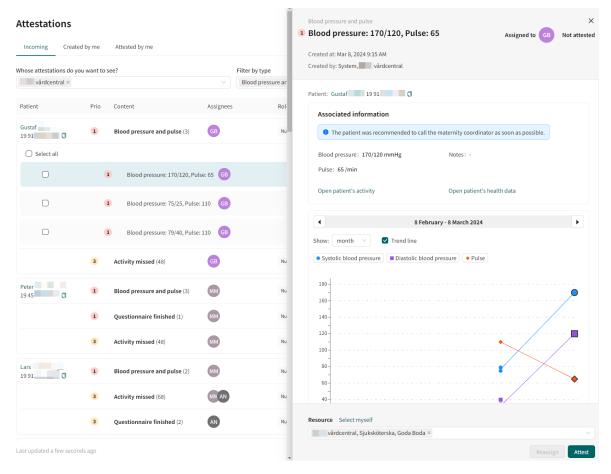
1. Click **Attestations** in the main menu to open the **Incoming** tab in the **Attestations** view.



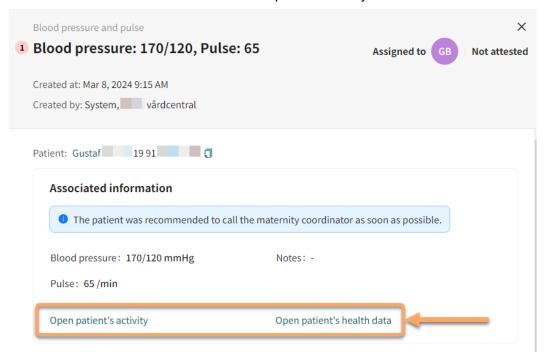
2. Click on a parameter row in the attestation list to expand the row and to make the attestations selectable.



3. If desired, click on an attestation to show more details about the attestation (e.g., historical measurements).

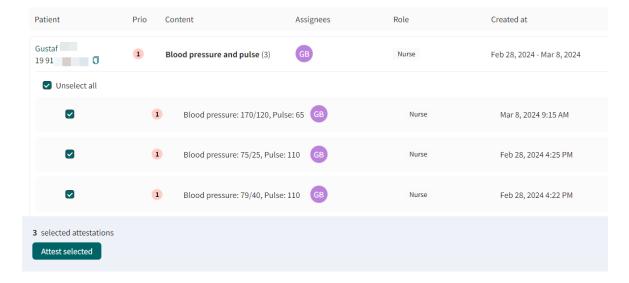


The detailed view also contains links to the patient activity and to the **Health data** tab.



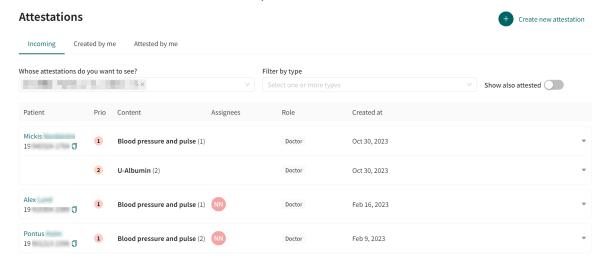
- 4. Select one or more attestations in the attestation list.
- 5. Click the **Attest** button, either in the detailed view or in the attestation list.

 The **Attest** button is always visible in the detailed view, but in the attestations list it will appear at the bottom of the list when one or more attestations are selected.



7.10.6. Assign the attestation to a colleague

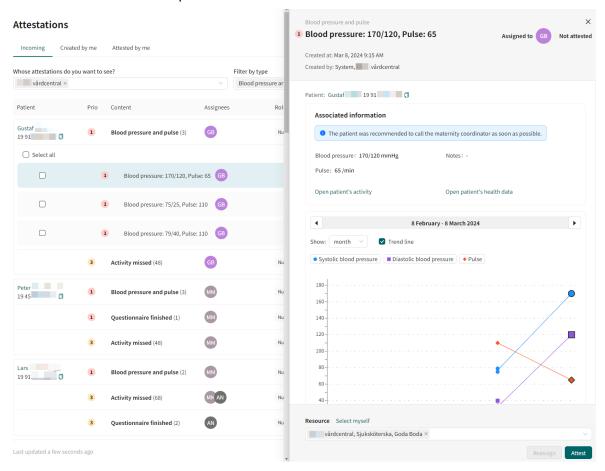
1. Click **Attestations** in the main menu to open the **Attestations** view.



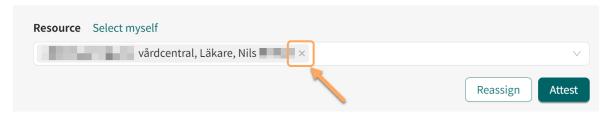
2. Click on a parameter row in the attestation list to expand the row and to make the attestations selectable.



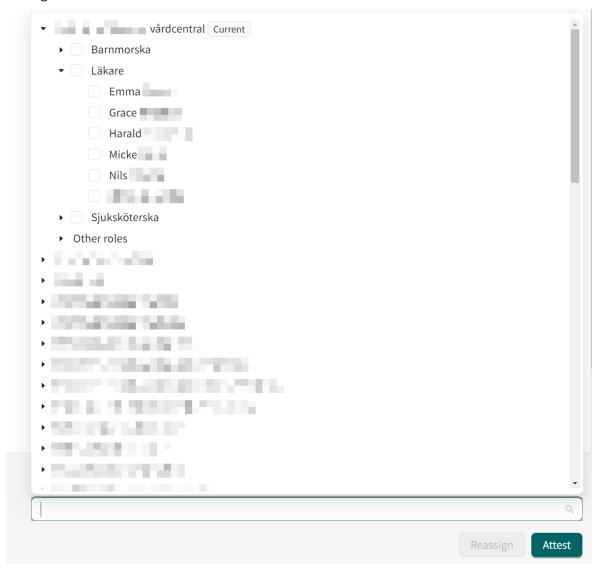
3. Click on an attestation to expand it.



- 4. Scroll to the bottom of the expanded list of details to the right.
- 5. Click the "x" to remove the currently selected resource from the **Resource** field.



6. Click somewhere in the **Resource** field to expand the resource selection view and add the new colleague or resource.



7. Click the **Reassign** button.



7.11. Conclude monitored activities

If all activities in a remote monitoring plan are concluded, the remote monitoring plan will also be concluded. When a remote monitoring plan is concluded, data related to the patient is kept and can be retrieved if needed.

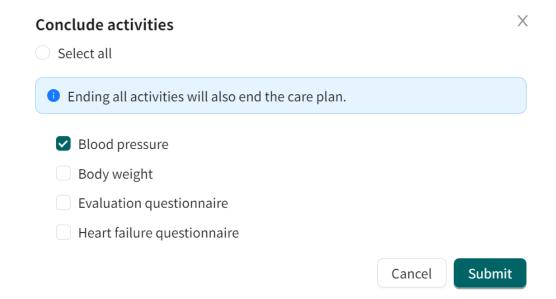


NOTE

When the remote monitoring plan is concluded, the patient can no longer report their activities or order lab referrals, but can view their previously reported values.

To conclude one or more monitored patient activities:

- 1. Go to the **Health data** tab (Patient's health data [24]).
- 2. Click the **Conclude activities** button.
 - ☐ Conclude activities
- 3. Select the activities you want to conclude and click **Submit**.



- 4. Confirm by clicking **Conclude activities**, or cancel by clicking **Cancel**.
 - Are you sure you want to end selected activities for this patient?

 Confirming will end activities and the patient will not need to take any measurements for it again.

 Cancel Conclude activities

8. Smart Care Plans in the Patient app

Note that this chapter is not an instruction to the Patient application, but an informative chapter to give practitioners an overview of what the patient can see when using a remote monitoring plan.

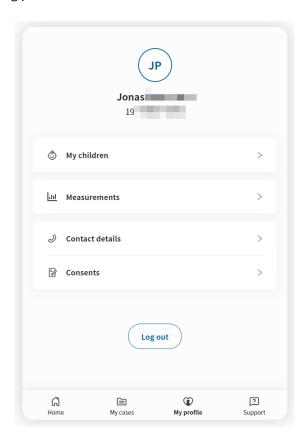
8.1. Dynamic menu item and introduction page for patients

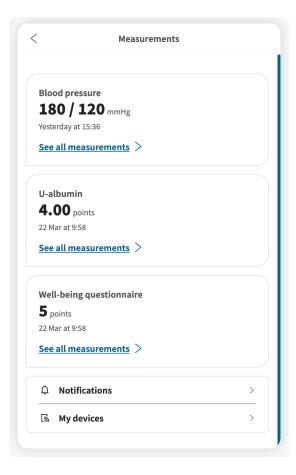
A patient which is added to one or more remote monitoring plans, e.g., hypertension, at a care unit can see relevant measurements for the remote monitoring plans through the Patient application.

The measurements can be found by clicking on **My profile** in the app, and then on the **Measurements** button. The **Measurements** button is only visible for patients that have been enrolled to one or more remote monitoring plans.

In the **Measurements** view, the patient will see the latest measurement for each enrolled remote monitoring plan and a notifications menu.

By clicking on **Overview** in the latest measurement of a remote monitoring plan, the patient can see more details as well all historic measurements of parameters relevant to the remote monitoring plan.





The My profile view and the Measurements view respectively in the Patient application.

9. Terms and definitions

B1-B2 B1-B2 in the Common European Framework of Reference (CEFR)

self-assessment scale. e.g. Independent user of the language.

C1-C2 in the Common European Framework of Reference (CEFR)

self-assessment scale. e.g. Proficient user of the language.

Clinic The healthcare practitioner's platform, where you receive and com-

municate with the patient.

Customer Success Manag-

er (CSM)

A CSM (Customer Success Manager) is the customer's main strategic advisor. The CSM is also the customer's main contact person for any contractual, commercial questions/issues. The CSM is the first point

of escalation for any unsolved questions/requests/issues

superuser A superuser is an end user with increased knowledge and responsi-

bility around the platform at each care unit.

The superuser acts as the first-line support for the end users on the device and is the one who turns to Platform24 for further support, if

necessary.

unique personal identifier For practitioners: can be for example e-mail, HSA-ID

For patients: can be for example e-mail, personal identity number,

insurance number, BSN

10. User Manual versions

#	Date	Description
1.0	2022-12-05	1st version
2.0 2023-05-05	2023-05-05	Clinic24 changed to Clinic.
		 Images of the Clinic user interface replaced with new Platform24 logo- type.
		 Information about how to report serious incidents added to page 2.
		 Clarifying note regarding updates in the manuals added to the Intro- duction chapter in a new section called About this manual. Text from Abstract on page 2 was moved to the new About this manual section.
		Note about login link added in Chapter 6.
		Structural improvements in Chapter 7. Some sections were moved and previous chapter 9 was moved into chapter 7.
		 Images updated in the "Add patient to remote monitoring plan group" section.
		 Sections "Patient profile" and "RPM24 automated responses and edit thresholds" updated with new images and updated text to reflect updates in the UI.
		New feature frequency added.
3.0	2023-08-23	General: Updated images and text to reflect UI changes.
		"Patient lists" in the main menu renamed to "Remote Monitoring".
		 Updated section 7.5. Patient profile to reflect changes in the UI (e.g., remote monitoring plan tab name changed to health data).
		 Added functionality in section 7.6 Edit attestation priorities and thresholds. It is now possible to set individual threshold values that affect the interpretation of the measurement in both the patient app and in Clinic.
		 Information added in section 7.7 Edit measurement frequency of an activity in the graph view about the possibility to predefine the fre- quency of activities.
		• Section 7.8 Patient details renamed and re-written.
		• Clarifications made in sections 7.10. Attestations and 7.11. Filter, sort and search for a patient in a remote monitoring plan group.
3.1	2024-02-23	Contraindication about inner block added in section <i>5.3.2. Contraindications</i> .

#	Date	Description
4.0	2024-04-30	Main updates are:
		The support email for User Manuals has been updated in Section 2.3.
		 New IMPORTANT precaution added about when changing the thresh- olds for one interval it affects the adjacent intervals.
		 Chapter 3 Definition of symbols and precautions has been renamed and updated to also contain a definition of the precautions in the User Manuals. It was also clarified in the section titles that this chap- ter contains definitions.
		• Chapter 4 Warnings has been renamed to Safety precautions.
		• Waist circumference added as a supported parameter in Section 5.4.
		 Chapter 7 Remote monitoring of patients in Clinic has been renamed and updated.
		 Section 7.1 Remote Monitoring view has been renamed and updated. One of the updates is that the Remote Monitoring view is now accessed directly in the main menu instead of via the Patient lists pop-up menu.
		 Section 7.2 Patient list has been updated to reflect updates in the UI with new descriptions and filtering options. The patient's latest measurements can now be shown when clicking on a patient in the patient list.
		 Section 7.3 Enroll patient to remote monitoring plan has been updated to reflect updates in the UI. The patient is now enrolled in a remote monitoring plan via the Health data tab.
		• Section 7.4. Register a new patient in Clinic has been updated.
		 Section 7.5 Patient's health data has been renamed and updated to reflect changes in the UI. A sub-section 7.5.1 has been added for clarity.
		 Clarification in Section 7.7.2 added about that the suitability of the default interpretations, for parameters where this is applicable, needs to be evaluated for each patient before implementation.
		 Section 7.7.3 Edit thresholds for attestation priorities and interpretations has been updated to reflect changes in the UI. For measurements, the attestation thresholds and interpretations are connected and adjusted simultaneously. Clarification added that if the default thresholds do not suit a patient's specific needs, individual thresholds must be set for the patient.
		• Section 7.8 Edit measurement frequency of an activity in the graph view has been updated.
		• Section 7.10. Attestations has been updated to reflect changes in the UI.
		 General: The Remote Monitoring Plans view has been renamed to the Remote Monitoring view.
		 General: Clarified terminology for interpretations of measured values in the Patient app (previously referred to as thresholds instead of interpretations).
		• New sections: 7.6 Add monitored activities, 7.10.3 Attestations attested by me, 7.10.5. Attest an attestation, 7.10.6. Assign the attestation to a colleague, 7.11 Conclude monitored activities

#	Date	Description
5.0	2024-05-28	Clinic version added on the first page.
		• Date of manufacture symbol has been added on page 2 and in <i>Section 3.1 Symbols definition</i> .
		 Information added in Section 2.3.1 about that a paper version of the user manual will be provided at the latest within 7 calendar days of receiving a request from the user.
		 In Section 3.1. Symbols definition, the previous warning symbol has been replaced with a caution symbol indicating to the users to con- sult the instructions for use for relevant warnings and cautions.
		 In Chapter 5 RPM24 - Intended use the RPM24 - Intended clinical benefits was updated, a new section Performance was added and the IMPORTANT note in the Contraindications section was updated.
6.0	2024-09-19	 New warning added in Chapter 4, Section 7.7.1 and Section 7.7.4. The warning highlights that thresholds for weight and spirometry must be added manually.
		 Section 7.7.1. Attestation priorities (for practitioners) updated to describe that thresholds for weight and spirometry has to be added manually.
		New section: 7.7.4. Add thresholds for weight and spirometry.
7.0	2025-02-03	 Wording in the manual changed to be applicable for all markets. For example, the term "unique personal identifier" is used instead of "personal number".
		Updates on regulatory information on page 2. MD icon added.
		 Address to manufacturer updated on page 2 and in section 2.1 Manufacturer.
		Chapter 6. Log in to Clinic has been updated to be more generic and renamed to "Log in and out".
		 Section 7.4. Register a new patient in Clinic has been renamed and updated to be more generic. Information about how to search for a patient added.
		 Section 7.5.1. Graph view and parameter details updated to also describe automatic events in the graph view and parameter details. Information also added that parameters can be selected and deselected in the graph legend.
		New chapter: 9. Terms and definitions added.
8.0	2025-03-27	 General: RPM24 renamed to Smart Care Plans. In the manual title and the introduction section, Smart Care Plans - Monitoring is used to clarify that this manual describes monitoring care flows.
		 Section 1.1. About RPM24 renamed and updated to also include a description on how Smart Care Plans - Monitoring relates to Smart Care Plans.
		Section 1.3 Hardware and software specifications added.
		 Medical Device Version on the front page updated to contain Smart Care Plans instead of RPM24 and revised to number 2.
		UDI-DI number and Date of manufacture updated on page 2.
		Chapter 5. RPM24 - Intended use replaced with 5. Smart Care Plans Intended use.