USER MANUAL

MODEL CPC12S

Created by “Checkpoint R&D Ltd.”

Read carefully before use!

In this manual, you will learn how to use the Multiple Physiological Parameter Ambulatory Telemonitoring System Model CPC12S and how to connect it to a patient. Please follow the instructions, as they will assist you in getting the best possible results with the product. If you have any further questions, remarks for the supplier, or if you need more assistance, please contact the manufacturer or your local representative.

Contents

CE 2195

Product Name: Multiple Physiological Parameter Ambulatory Telemonitoring System Model

Company Name	Check Point R & D Ltd.
Authorized Person / Appellation	Ventseslav Kolev
Company Address	37 Osvobojdenie Str, 6100 Kazanlak / Bulgaria
Production Address	37 Osvobojdenie Str, 6100 Kazanlak / Bulgaria1
Contact Number	+359888920108
Official Website / E-mail	https://www.checkpointcardio.com / info@checkpointcardio.com
Basic UDI -DI	3800945CPCC3

Medical device model CPC12S is a Multiple Physiological Parameter Ambulatory Telemonitoring System designed to monitor patients' vital physiological parameters.2

It measures the following vital physiological parameters:

ECG — 2 Leads (250 Hz)

ECG — 3 Leads (250 Hz)

ECG — 12 Leads (250 Hz)

Pulse rate 30 — 250 bpm

SpO2 (oxygen saturation) - Automatic signal scaling- Photoplethysmogram on the finger Infrared: 910 nanometers 1.2mW maximum average Red: 660 nanometers 0.8 mW maximum average Measurement Accuracy: SpO2: 70%~ 99% ±3%; ≤69% unspecified with updated time less than 10 seconds. The SpO2 oximeter is not designed to work under conditions of low perfusion. Values measured during motion are not guaranteed.

Respiratory rate: 6 - 50 breaths/min

Body temperature - precision 0.05 °C;

Non-invasive Blood Pressure

Body position and activity

It records the collected signals and values in its internal memory for 36 hours with one battery set and transfers them to the file server for further analyses. The communication device (mobile phone) is part of the system and connects medical device model CPC12S to the file server through the Internet.

Multiple Physiological Parameter Ambulatory Telemonitoring System Model CPC12S consists of a Main Box, Two Battery Packs, ECG Electrodes (12 / 2 / 3 Lead), Pulse Oximeter finger sensor, Thermometer probe and a Communication Device (Mobile Phone).

Images of Components of Medical device CPC12S

Main Box

Battery pack

2 lead ECG patch for CPC12S

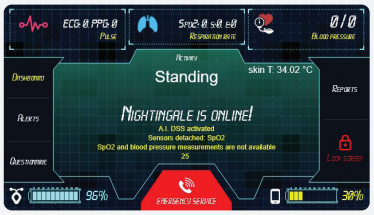
3 lead ECG patch for CPC12S

12 lead ECG patch for CPC12S

SpO2 Ear Clips Sensor

SpO2 ring sensor (adjustable size)

Thermometer probe



Communication Device

Pic 1

Intended Use and Usage Area

Medical device model CPC12S is used to monitor vital physiological parameters (Electrocardiography, SpO2 (Oxygen Saturation), Non-invasive Blood Pressure, Respiratory rate, Body position and Activity) of the human body by continuous remote observation in real time and helps the physician to diagnose the patient by examining the vital physiological parameters. **Medical device model CPC12S** cannot replace medical examinations and consultations!

The device is designed for the observation of vital physiological parameters in real time. It is used for preventative follow-up, hospital follow-up, and after a hospital stay.

Tracking indicators — Use cases:

- Conducting intermittent patient follow-up monitoring
- Diagnosing life-threatening conditions
- Early detection of life-threatening conditions during hospital stays
- Early detection of post-surgical or post-interventional complications requiring emergency responses
- Early diagnosis of pathological medical conditions and diseases across all medical specialties
- Early prediction of potential complications during the post-hospitalization period
- Managing patient conditions until physiological parameters stabilize and rehabilitation processes are completed
- Monitoring adherence to prescribed medication and rehabilitation regimens
- Monitoring patients in hard-to-reach areas lacking regular medical care
- Monitoring physiological parameters in military and law enforcement personnel
- Monitoring physiological parameters in pediatric patients
- Monitoring physiological states of individuals in high-stress occupations or extreme environments
- Prediction of life-threatening conditions based on physiological parameters, laboratory data, imaging diagnostics, and patient comorbidities
- Providing early recommendations for adjustments to prescribed medication and rehabilitation regimens
- Tracking physiological parameters of athletes engaged in extreme sports
- Tracking physiological states of individuals with high-responsibility roles involving public safety or critical services (e.g., flight attendants, control-center operators, drivers)

User Group

The product is designed for patients of all sexes weighing over 10 kg, suitable for both sick patients and healthy individuals wishing to monitor their physiological status. The device is intended for diagnosis, early detection, and prediction of diseases and life-threatening conditions across all medical specialties. With the provided data, physicians can promptly adjust medication regimens and rehabilitation plans for various patient groups—including children and elderly patients—in both hospital and outpatient settings.

Contraindications:

- The device is not waterproof. Do not use the device in wet environments, such as in rain, bathrooms, showers, or other areas where the device could come into contact with water. However, normal operation is maintained for patients who perspire.
- The device is not defibrillator protected. Do not use it with external (non-implanted) defibrillators. For safety, always remove electrodes, patient lead wires, and the device from the patient before defibrillation.
- The device is not intended for use in infants weighing less than 10 kg.

Side Effects:

- No known side effects have been reported.

Complications:

Prolonged use of ECG electrodes—which are not included as part of the CPC12S medical device—may lead to allergic skin reactions. To minimize this risk, electrodes should be replaced and repositioned on a different area of skin every two days.

Product life

The life expectancy of the Multiple Physiological Parameter Ambulatory Telemonitoring System Model CPC12S unit is five (5) years.

Device Operating Instructions

The Multiple Physiological Parameter Ambulatory Telemonitoring System Model CPC12S is compatible with standard ECG adhesive electrodes. However, we strongly recommend using high-quality electrodes, as electrode quality significantly impacts measurement accuracy. Poor electrode-skin contact, or low-quality electrodes will result in unacceptable signal quality. We recommend using **3M Red Dot Electrodes (type 2560)**. The manufacturer specifies a maximum application time of up to 5 days. Electrodes that have been stored improperly—such as being exposed to extreme temperatures, open air for extended periods, or beyond their expiration date—should not be used.

⚠ **NOTE:** *If the electrodes are old or the patient's skin is excessively dry, the device may indicate that electrodes are detached. In such cases, place a drop of water onto the electrode gel before attachment.*

Electrodes are not provided with the CPC12S system; however, **3M Red Dot Electrodes** are recommended for use with the device.

If the device remains attached for an extended period, the patch location should be moved by approximately 60 mm, and new electrodes must be attached at the new site.

1. Patient Preparation

- If the patient's skin is dry or rough, gently abrade (lightly sand) the area where electrodes will be attached to improve skin contact.
- Remove body hair from the electrode placement area if present. Clean the area thoroughly with an alcohol-soaked cotton swab or alcohol wipe before attaching the medical device patch.

2. Device Installation

- Connect the medical device (see Pic. 1) to the appropriate ECG patch (2-lead, 3-lead, or 12-lead).
- Check the battery charge level by attaching the battery to the charging station. If all three indicator lights display a steady green light, the battery is fully charged and ready to be attached to the patch.
- Confirm proper connection by observing a blinking green indicator light on the medical device.

After completing the patient preparation and ensuring the electrode placement sites are ready, remove the electrodes from their packaging and apply them according to the procedure outlined below.

ECG Electrode Patch Application Procedure

- Connect the electrodes securely to the reusable patch.
- Remove the adhesive backing from each electrode at the pre-cut separation (located on the back side of the electrode, near the gel area).
- Apply the electrodes carefully to the prepared skin sites, aligning them according to the shape of the reusable patch.

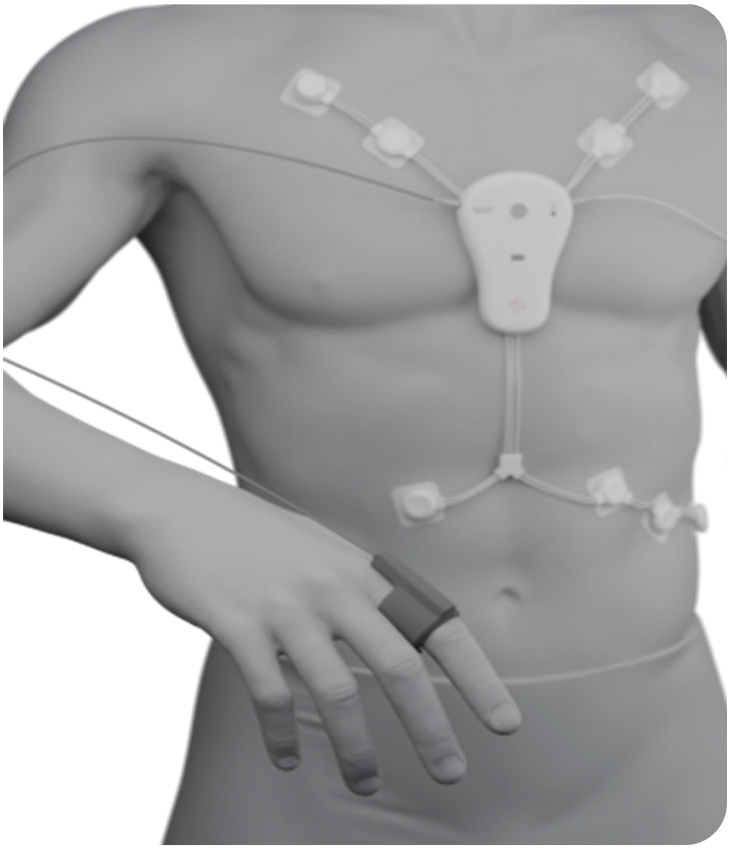
⚠ Important Notes:

- Do not tighten or stretch the electrode cables. Ensure that the patient remains seated and relaxed during electrode attachment.
- Smooth each adhesive electrode from the center outward, pressing firmly around the edges to ensure proper adhesion to the skin.
- Do not press directly on the center of the electrode, as doing so can displace the conductive gel and reduce signal quality.
- For female patients with larger breasts, electrodes may be placed directly on the breasts (potentially resulting in reduced ECG amplitude) or directly below the breasts (to minimize signal artifacts due to sweating or pressure).
- If electrodes are old, or if the patient's skin is excessively dry, the device may display an electrode detachment message. In this case, place a small drop of water onto the electrode gel to enhance skin contact before attachment.
- Electrodes are not included with the device. However, we recommend using 3M Red Dot Electrodes for optimal performance.

ECG Patch Configurations Available:

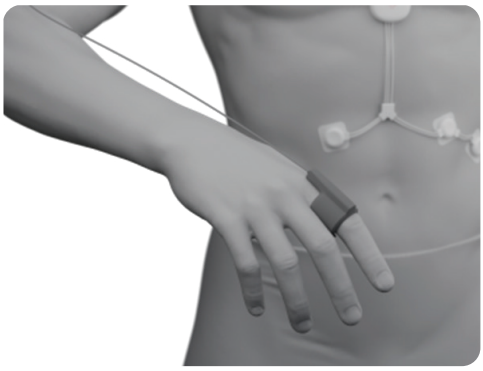
- **2-lead ECG:** Requires 3 electrodes
- **3-Lead ECG (Wilson + 3 Modified):** Requires 5 electrodes
- **12-Lead ECG (Wilson):** Requires 10 electrodes

The patch is magnetically attached to the device.



SpO2 Sensor Attachment

This device uses a Ring SpO2 Sensor. See the picture below for installation instructions:



If you suspect the SpO2 measurements are inaccurate, verify them using an iM12 vital signs monitor or another clinically validated monitor with a CE 0123 mark. The device requires no special calibrations for body temperatures above 41°C.

Blood Pressure Calibration & Re calibration for the CPC Cuffless Algorithm (PPG/ECG PW(T)T)

This section describes how clinicians calibrate and re calibrate the CPC wearable's cuffless blood pressure (BP) algorithm so that continuous/trended cuffless BP values align with a validated reference (cuff based or invasive). These instructions apply to adult in patients (ICU/ward) and out patients monitored in clinical settings.

⚠ **Important:** The CPC cuffless BP function complements standard BP measurement. **It is not intended to diagnose or manage hypertension withoiut calibration**, consistent with European Society of Hypertension (ESH) guidance. Always use validated cuff devices or invasive arterial pressure for calibration and verification.

Definitions:

- **Cuffless BP:** BP values estimated from physiological surrogates (PPG/ECG and PW(T)T) that **must be calibrated** to a cuff or invasive reference.
- **Reference method:** (a) **Upper arm oscillometric cuff** validated per ISO 81060 2; or (b) **Invasive arterial line** (IABP) using a leveled, zeroed transducer when present.

When to calibrate or recalibrate (triggers)

Use the following mandatory **triggers**. These reflect ESH statements on cuffless devices and good clinical practice; they are written as manufacturer instructions per MDR 23.4.

Trigger	Action	Reference method
At admission / start of monitoring	Perform **baseline calibration**	Validated oscillometric cuff
After any major haemodynamic change (e.g., start/stop vasopressors or inotropes; fluid resuscitation; new/worsening arrhythmia; fever/sepsis; rapid change in sedation/analgesia; significant posture change to a new steady state)	**Re-calibrate immediately**	Cuff; or **invasive arterial line** if available and reliable
Cuffless vs reference discrepancy (persistent difference >10 mmHg in SBP or DBP on repeated paired checks)	Re-calibrate immediately	Cuff
ICU/unstable patients	**At least once daily**, irrespective of changes	Cuff
Ward/stable out patients/home use under clinical supervision	**At least weekly** or sooner if any trigger occurs	Cuff

Rationale for the 10-mmHg discrepancy trigger and periodicity: this is a **manufacturer set safety threshold** and schedule to control residual risk from drift and physiological variability, consistent with ESH's requirement for **individual calibration and re-calibration** and with variability seen in clinical BP measurement.

Step by step calibration procedure (cuff reference)

Follow these steps exactly; they derive from ESH best practice for office/clinical BP measurement adapted to calibration.

Preparation

1. Explain the procedure; confirm the patient is **resting** and has **avoided caffeine, nicotine, exercise** for ≥30 min where feasible.
2. Position: patient **seated or semi recumbent, back supported, feet flat/uncrossed, arm supported at heart level** on the side used for the cuff **and** wearing the CPC wearable; **no talking**.
3. Select **correct cuff size** and place on **upper arm** (same limb side as the wearable if possible).
4. Fit CPC wearable per device instructions; verify **signal quality indicator = Good** (green).

Acquiring the reference

1. Rest **5 minutes**.
2. Take **3 consecutive cuff readings, 1 minute apart; discard the first and average the last two** for SBP and DBP (standard ESH technique).

Capturing the calibration

1. Ensure the patient's **posture and conditions do not change** while transferring the average reference values into the CPC calibration screen.
2. Start the CPC calibration capture; maintain motionless position until the system confirms **Calibration OK**.

Acceptance / redo rules

1. The CPC system checks internal fit; **if Calibration Failed** or if an immediate paired check shows **>10 mmHg** difference versus a fresh cuff reading, **repeat** steps 5—8 (check cuff size/placement and wearable position).
2. **Save** the calibration; confirm **date/time/user ID** and **reference device ID** are recorded.

Step by step calibration (invasive arterial line available)
Use only if the arterial line is **functioning and reliable**.

1. Confirm **transducer leveled at phlebostatic axis** and **zeroed**, perform a **fast flush test** per local policy.
2. Ensure patient is **stable** for ≥30 s (no arterial damping or artefact).
3. Record **simultaneous** arterial **SBP/DBP** (or **MAP** if your software requires) and start CPC calibration capture.
4. If the paired check after calibration shows **>10 mmHg** gap (SBP or DBP) vs current arterial values under stable conditions, **repeat** after troubleshooting line damping/leveling and wearable placement.

Ongoing verification (spot checks)

- In the ward, perform **paired spot checks** (cuff or art line) at least **once per shift**, or any time the nurse doubts the reading (artefacts, low perfusion, movement).
- If two consecutive paired checks show **>10 mmHg** gaps, apply the **re-calibration** procedure immediately.

Limitations, contraindications & warnings

Use with caution or obtain reference BP by cuff/arterial line and **treat according to the reference** if any of the following are present:

- **Significant arrhythmias** (e.g., atrial fibrillation with variable R R), frequent ectopy.
- **Poor peripheral perfusion** / severe vasoconstriction (shock, hypothermia), severe peripheral oedema, pronounced tremor.
- **Active movement** during measurement, or inability to position arm at heart level.

- **Changes in sensor placement** or **long sensor off time** (>24 h) since last calibration.
- **Clinical decision rule:** When cuffless and reference values disagree in a clinically meaningful way, **trust the validated reference** (cuff or invasive) and **re-calibrate** the cuffless system.

Documentation and User Responsibility

All calibration and recalibration events should be logged in the CPC12S system

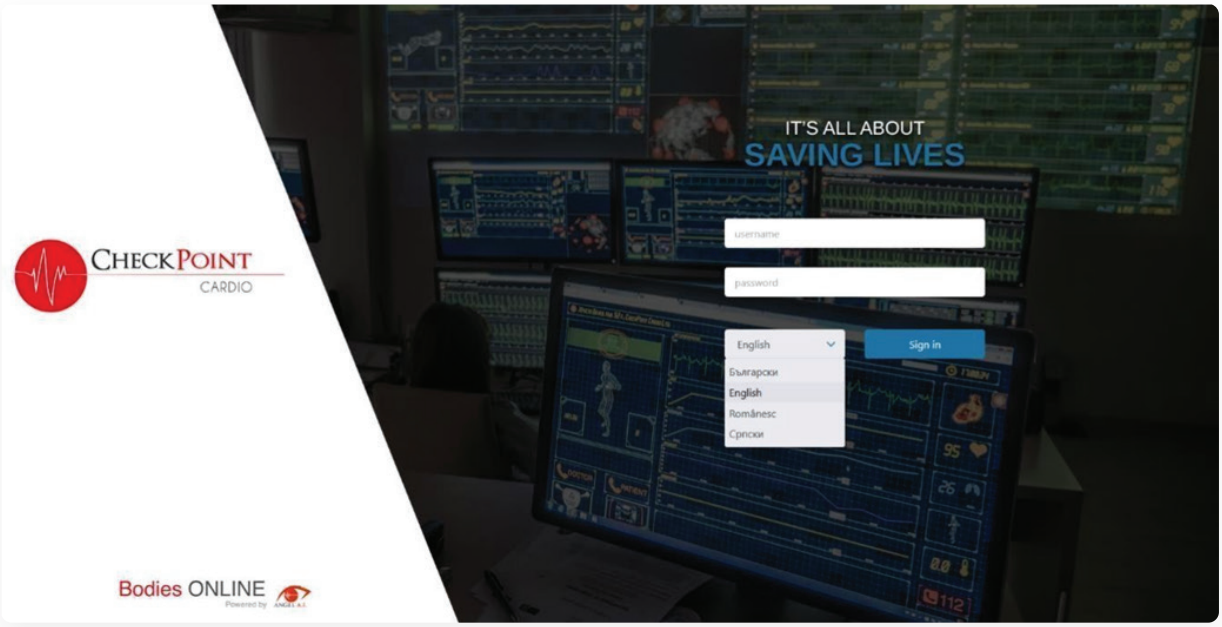
⚠ Only healthcare professionals trained in clinical BP measurement should perform calibration procedures.

Logging into the “Check Point Cardio” telemonitoring system

Enter the access address for the “Check Point Cardio” telemonitoring system in your “Google Chrome” browser’s address line on your personal computer.

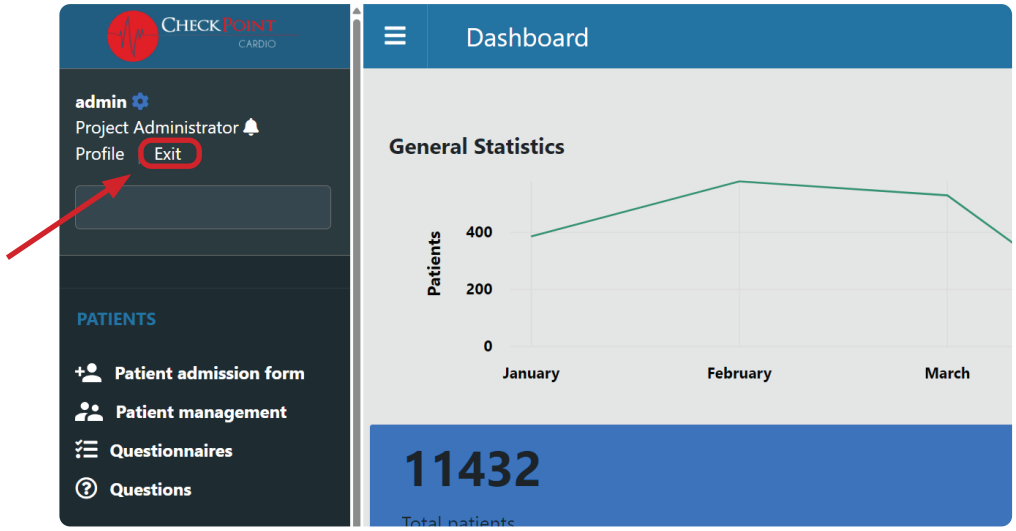
Choose the interface language for the “Check Point Cardio” telemonitoring system from the drop-down menu.

Enter your “Username” and “Password” to access the system. Select “Enter”.



Exiting the “Check Point Cardio” telemonitoring system

To exit the system, select the “Exit” button.

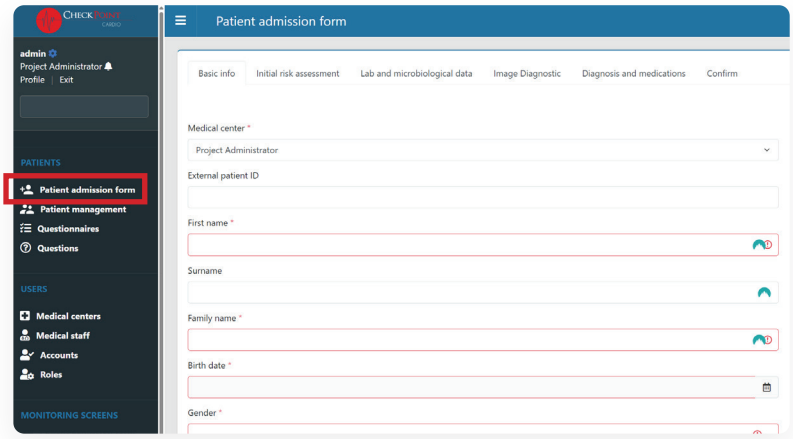


Choosing a medical center

By choosing a medical center, the observer selects which patients from which medical center will be under observation. From the drop-down list choose the medical monitoring center.

Adding a new patient to the telemonitoring system

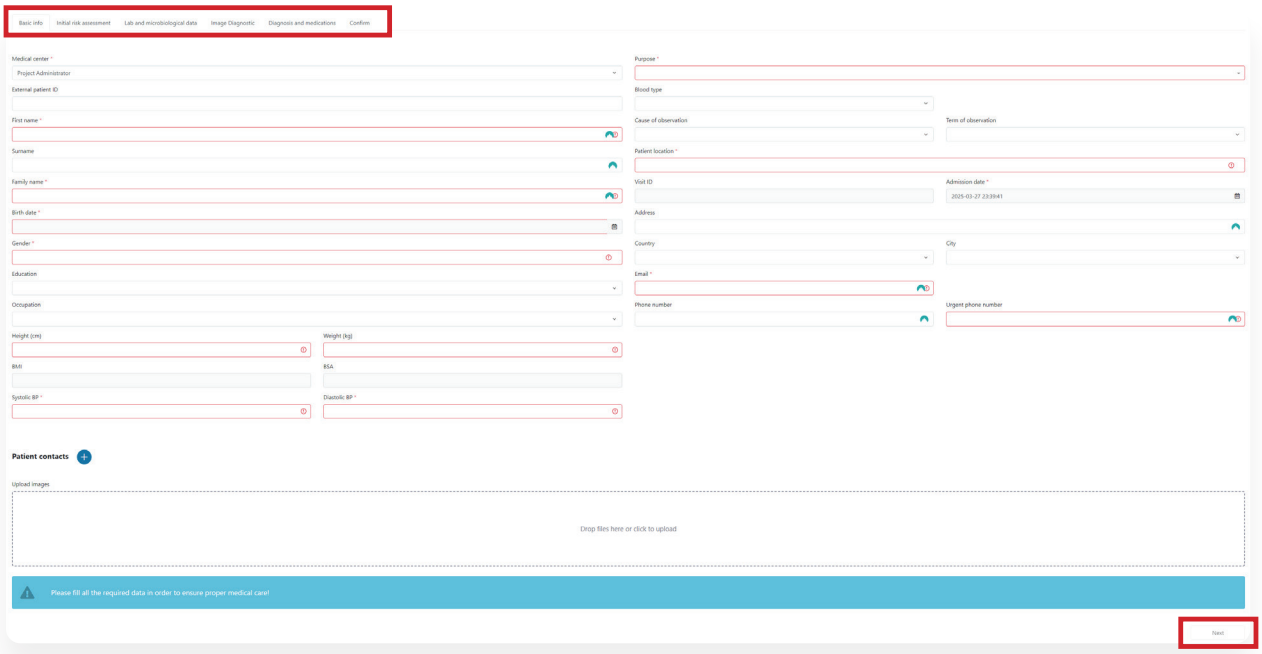
Select „Patient Admission Form ".



Fill in all the required data in the appropriate tabs ("Basic info", "Initial risk assessment", "Lab and microbiological data", "Image Diagnostic", "Diagnosis and medications", "Confirm"). Navigate by pressing the "Next" or "Previous" button on each of the tabs or select the appropriate tab directly.

The patient session cannot be added to the system if:

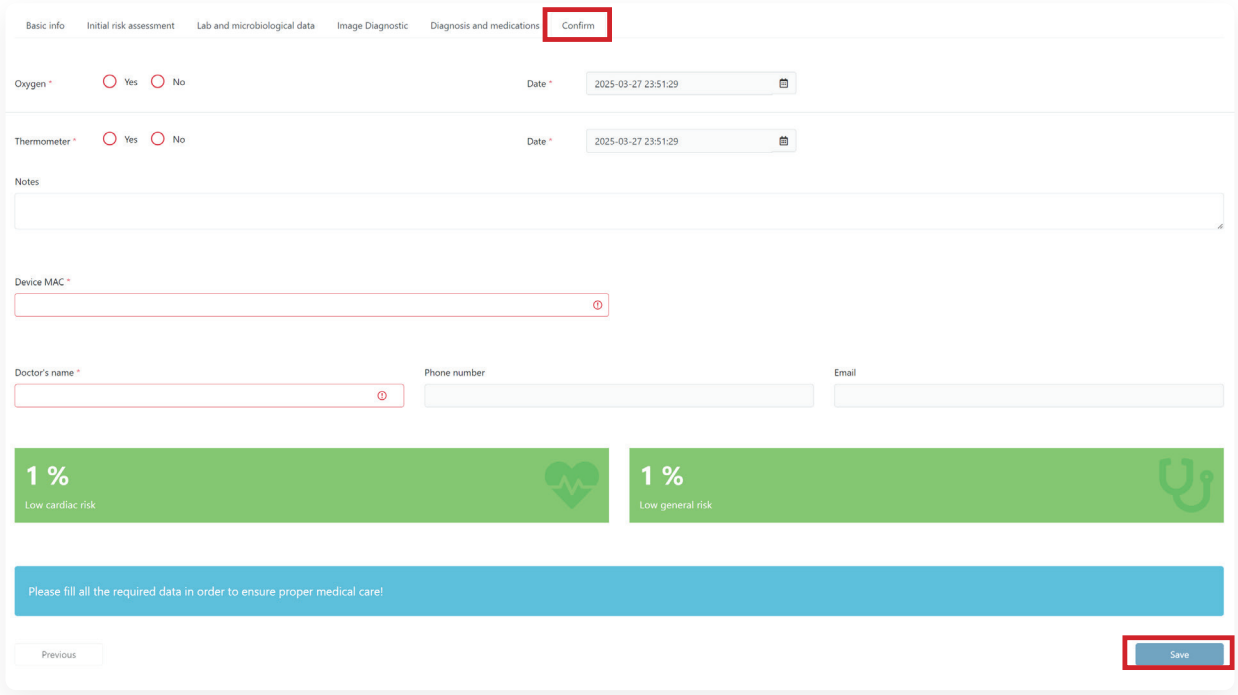
- Any field marked with a "*" sign and red outline is not filled in.
- One or more of the fields marked with a "*" sign contains invalid data.

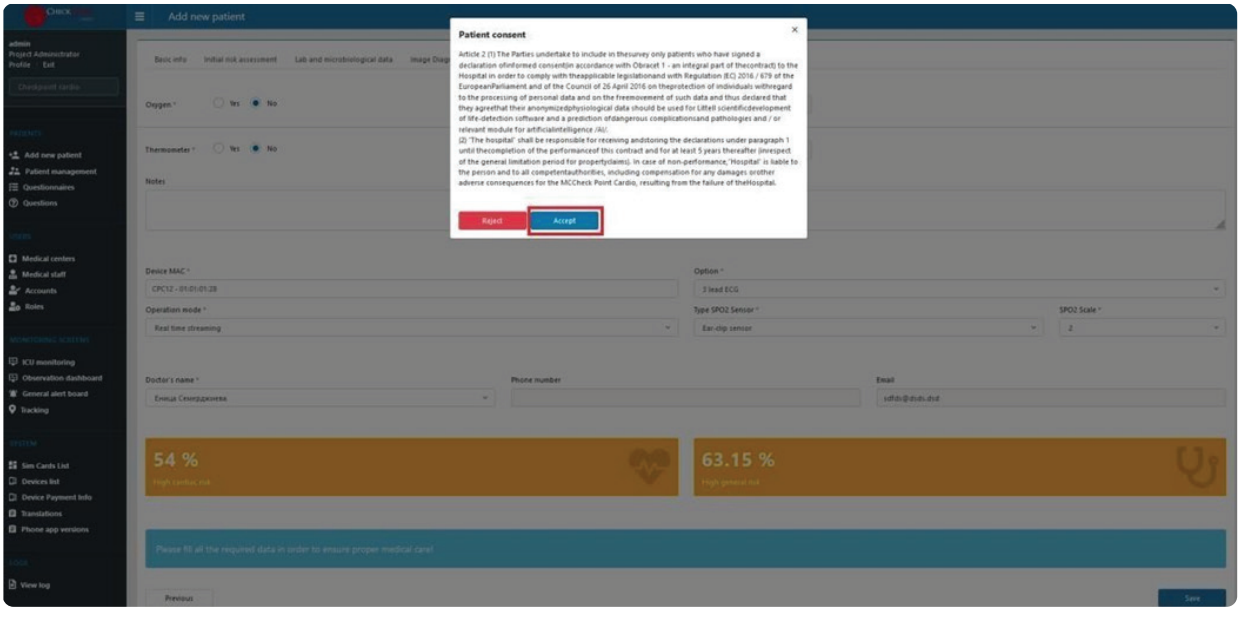


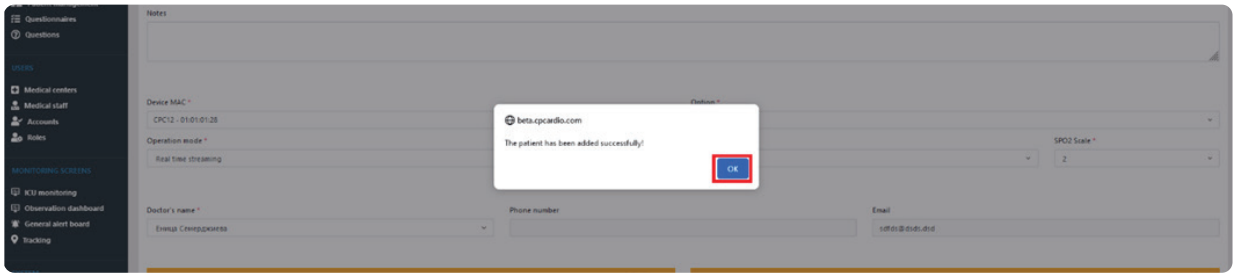
When you've filled in all the mandatory fields, the "Save" button in the "Confirm" tab will become active.

Click the "Save" button to add the patient session to the system and agree to the GDPR declaration by clicking the "Accept" button.

If you do not accept the GDPR declaration, the patient cannot be added to the system.



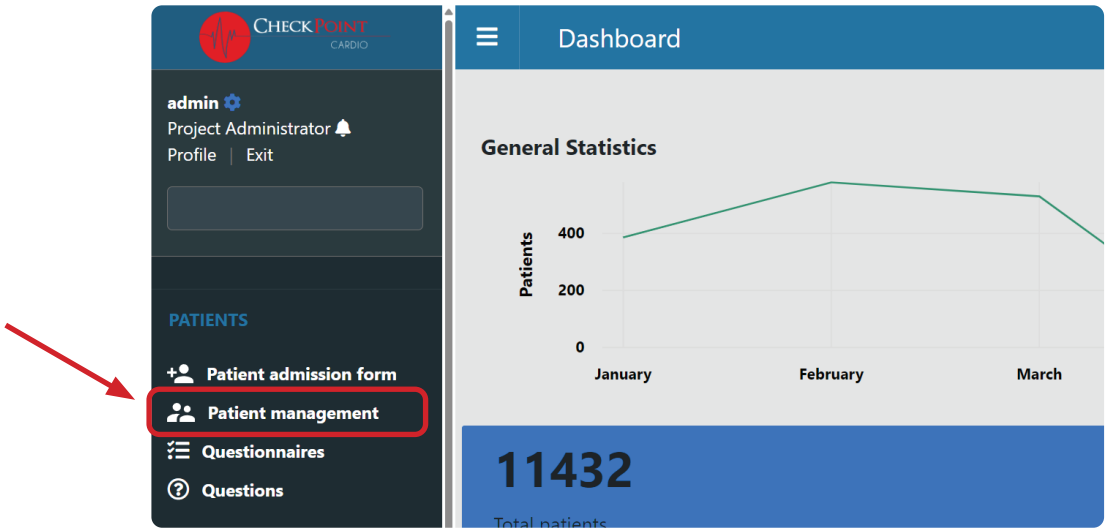




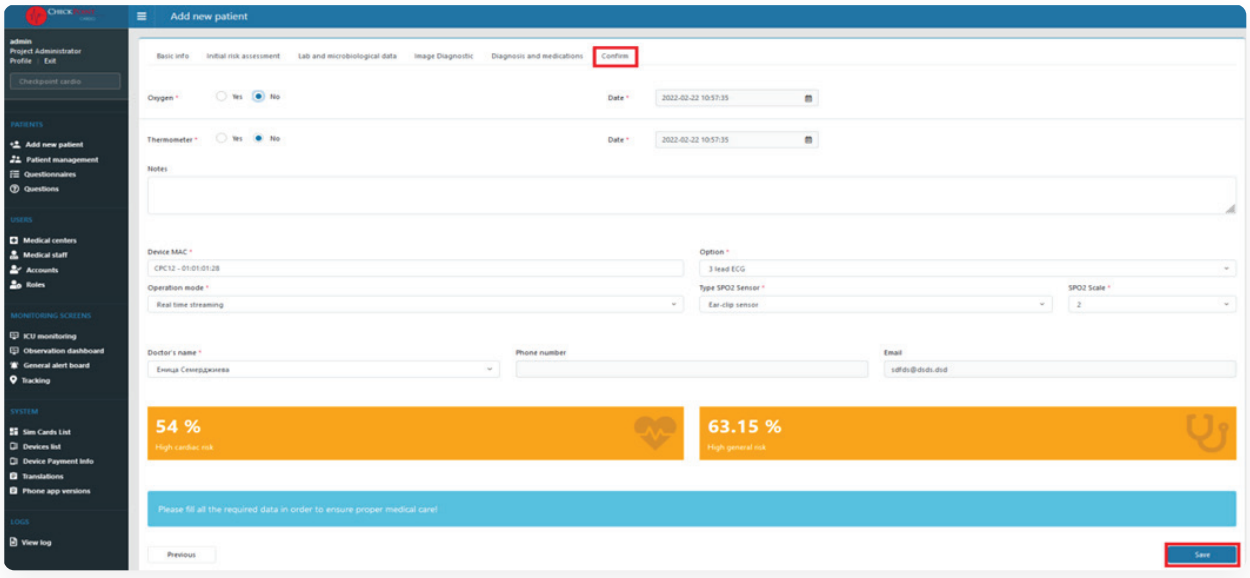
Adding a new visit to an existing patient in the telemonitoring system

If additional patient observation is required (for patients who have already been added to the system once), a new visit should be created.

To do this, navigate to the previous patient session in the “Patient management” menu (the provided filters can be used for easier searching) and press the red “+” button (next to “Patient ID”)



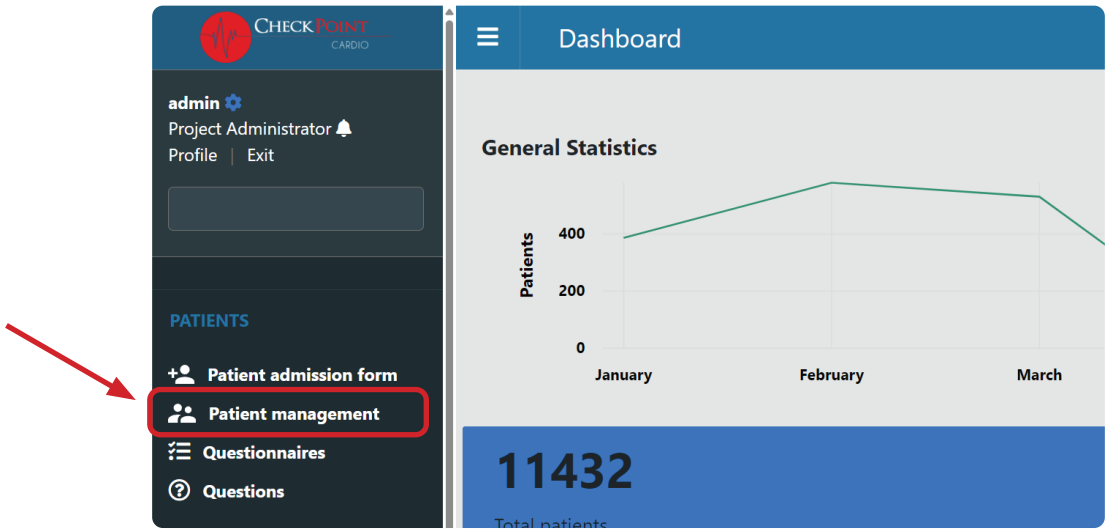
To finish adding the new visit to the existing patient, the user needs to fill in all the required fields once more and click the “Save” button (in the “Confirm” tab).



Patient management

This menu contains patients that are currently under observation, as well as patients that are no longer being monitored.

To access it, select “Patient Management” from the sidebar menu.



In this menu, you can look for a patient manually or by applying one or more filters to narrow down your search. You can apply these filters by making your selection in the relevant box and pressing the “Apply Filters” button.

To see a list of all patients, active and inactive, press the “Show all” button.

To see a list of patients that are currently under observation, check the “Observed” checkbox and press the “Apply Filters” button.

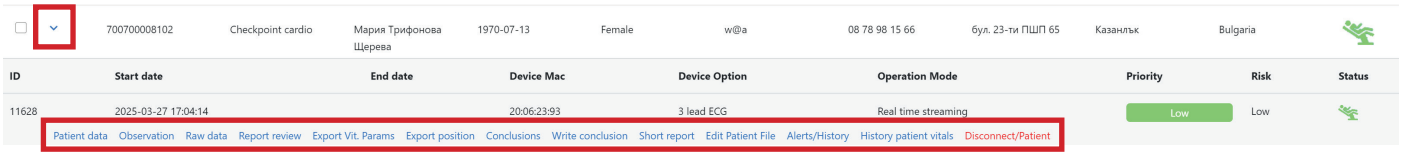
For each patient, the following information is shown: “Patient ID” (generated automatically by the system), “Patient’s name”, “Birth date”, “Gender”, “Email”, “Phone”, “Address”, “City”, “Country”.

Status – This field shows whether a given patient is under observation

The patient is under observation. The color is determined by the system based on the calculations of the patient’s general and cardiac risk. Patients with a **low** general and cardiac risk will have their status denoted in **green**, patients with a **medium** general and/or cardiac risk will have their status denoted in **yellow** and patients with a **high** general and/or cardiac risk will have their status denoted in **red**.

The patient is currently not under observation.

To see additional options and information related to a specific patient, click on the blue arrow next to the patient.



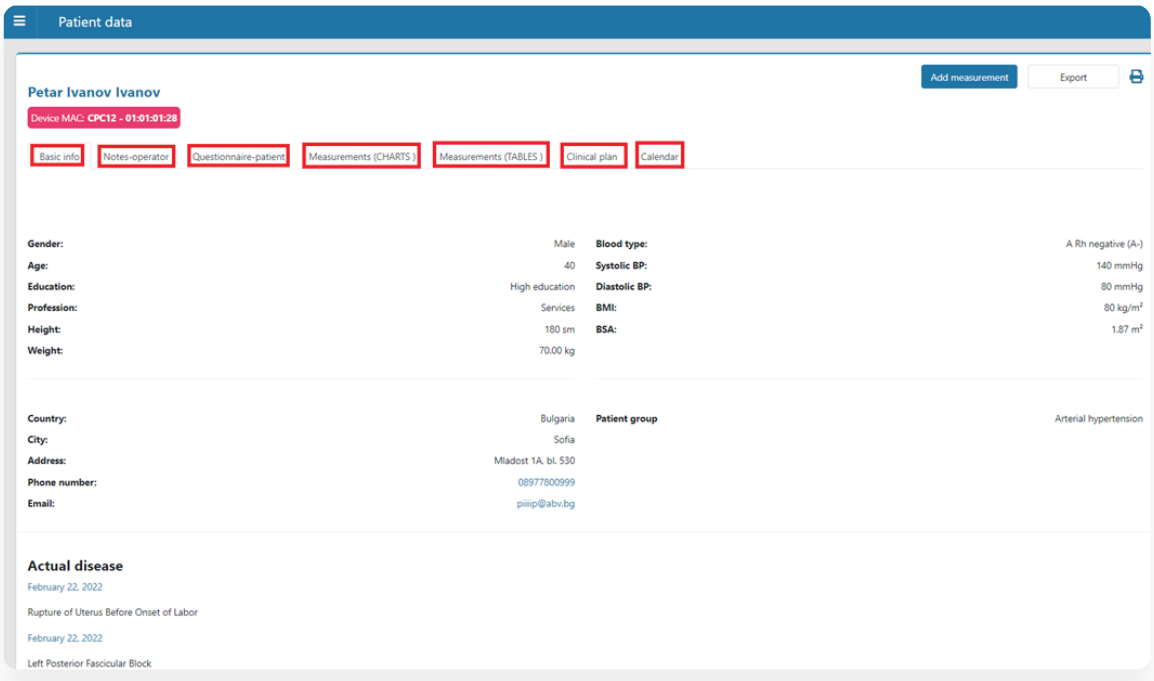
Additional patient information includes:

- **ID** – Session number.
- **Start date** – The date and time when patient monitoring began.
- **End date** – The date and time when patient monitoring ended.
- **Device Mac** – The serial number of the device attached to the patient.
- **Device option** – The number of ECG leads (depends on the equipment used by the patient)
- **Operation Mode** – Tells you if the device is set to transmit in real-time or every two minutes (depends on the choice made by the user when registering the patient session)
- **Priority** – Automatically determined by the system, based on the patient's general and cardiac risk
- **Risk** – Automatically determined by the system, based on the overall health status of the patient at the time of admission
- **Status** – Shows whether the monitoring session is active or inactive.

Monitoring session options

Patient data

By choosing the "Patient data" option you will be taken to the following screen.



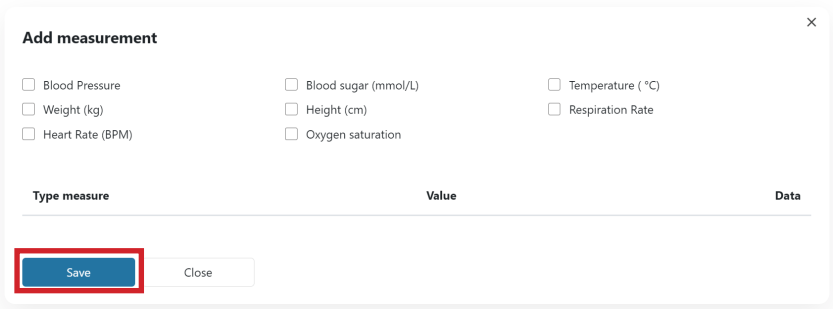
Using the tabs shown you can view the summarized basic information of the patient after they have been placed under observation and from here you can also assign a new: diet, medicinal therapy, activities and questions for the patient to receive, answer and perform.

- **Basic Info** tab – Here the user can view a summary of the patient's information as it was entered into the system during registration, as well as view all additional activities that have been assigned and whether the patient has completed these.
- **Notes-Operator** tab – Here the user (or operator) can add notes that can be seen by himself, as well as other op-

erators who have access to the system and this patient. Each note can be individually defined by the operator that creates it as “visible to others” or not.

- **Questionnaire-patient** – Here the user can check the questions assigned to the patient and the patient’s answer to these questions and if the patient has answered at all.
- **Measurements (CHARTS)** – Here the user can see a graphical representation of the added measurements.
- **Measurements (TABLES**) – Here the user can see all added measurements in a table format.
- **Clinical Plan** – Here the user can use the options provided in this tab to add or modify the patient’s: “Medication”, “Diet”, “Additional medical procedures”, “Activities” and “Questionnaires”
- **Calendar** – Here the user can view a broader image of the patient’s clinical plan in the form of a personalized calendar. Clicking on each calendar date will provide detailed information about the patient’s duties pertaining to the clinical plan for that specific timeframe.

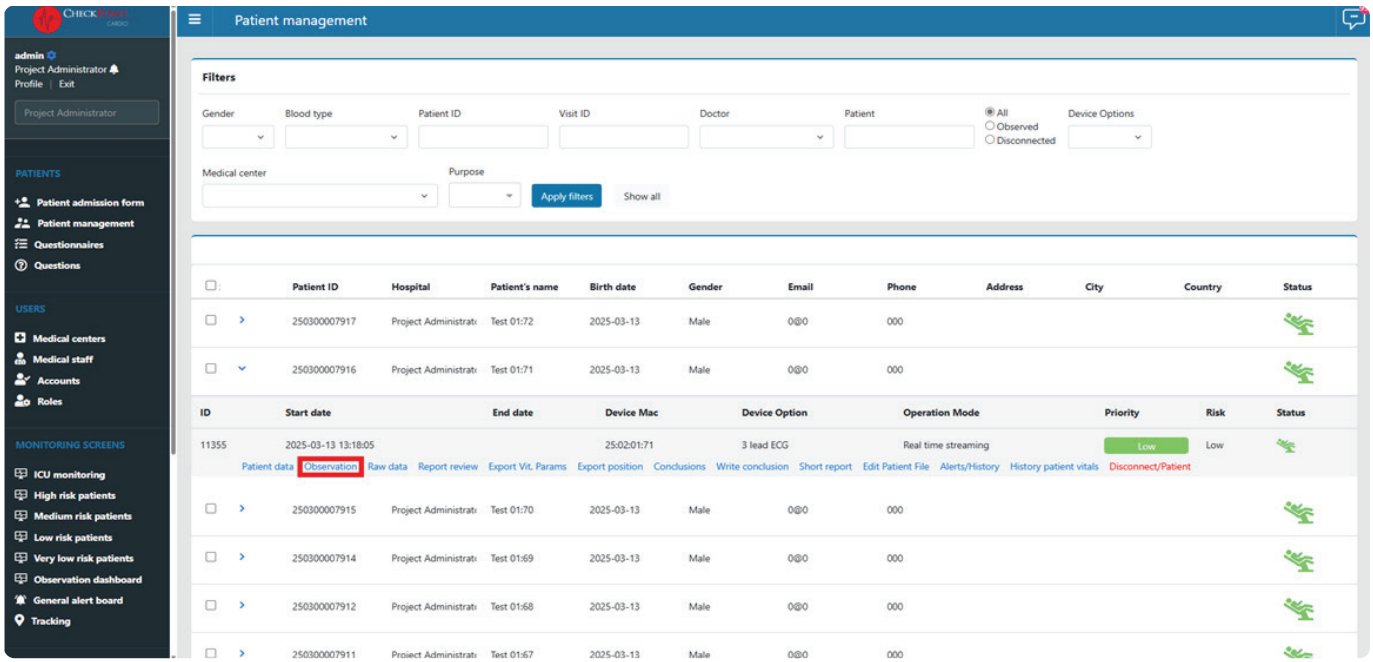
To add measurements to the patient file the user can press the “Add measurement” button, select the desired measurement and fill in the required information. After this, the user must click on the “Save” button to finalize the process.



To export any of this data, simply select the “Export” button or select the print icon.

Observation

The “Observation” option leads to the “ICU monitoring” screen of the patient.



Raw Data

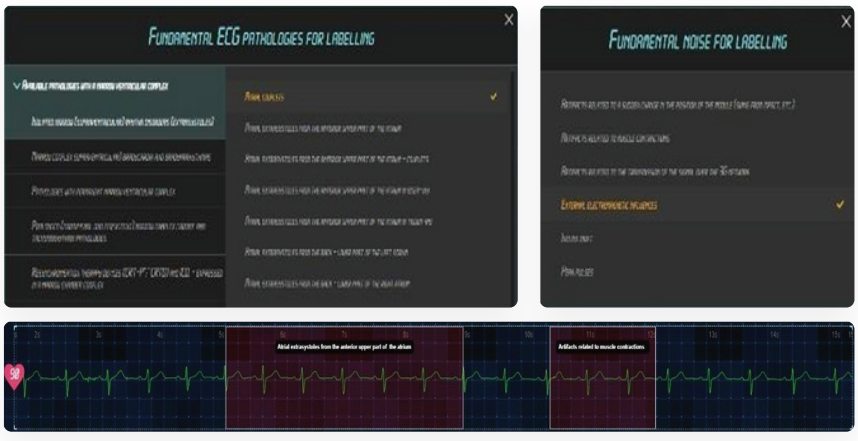
By selecting the “Raw data” option, the user will be taken to a new menu where they can track the history of the patient’s vital parameters and ECG strips.

Alternatively, you can navigate to the raw data menu by pressing the icon in the “ICU monitoring” screen of an individual patient.

To navigate through the recorded data, you can set the date, time and the temporal range of the observation interval (15 or 60 minutes). To go forwards or backwards through the recorded data by your selected interval, use the corresponding arrows next to the “Range” option. To navigate using your set parameters, press the “Load” button.

Use the  buttons to label noise or pathologies.

From the list that appears after pressing the corresponding button, select the pathology or noise.



Use your mouse to scroll through the ECG graph and specify the start and end point of the pathology. Each ECG strip can be labelled with multiple pathologies or noises. If you'd like to delete an already labeled pathology or noise, select it with your mouse and press the "Delete" or "Backspace" key on your keyboard.

To add points, intervals or show vital parameter values on the ECG strips, use one or more of the following buttons:

To view additional ECG strip information, select the "Show All" button.

To save the ECG strip press the  button. This saves the ECG strip to the patient's conclusion. When this operation has been completed successfully, the button color will change: 

To export the data for the corresponding ECG strip (in .xlsx format) or print the selected ECG strip, use one or both of the following buttons: 

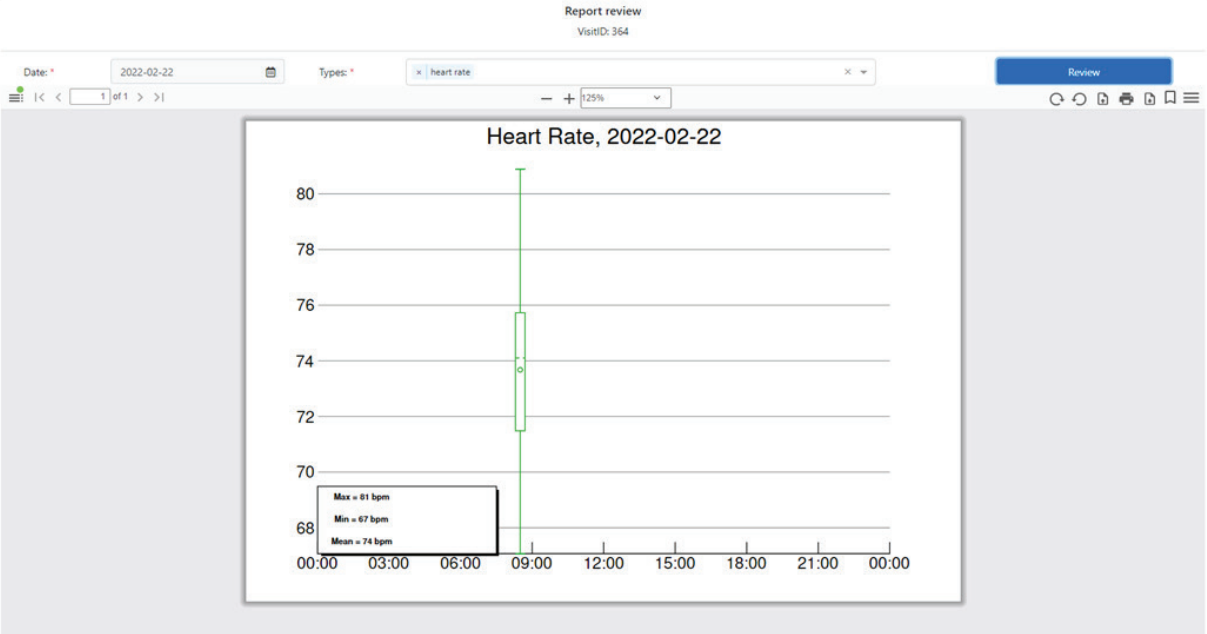
To make more detailed analyses or leave a comment on an ECG strip, use the corresponding tools from the following menu:

Report review

The "Report Review" option allows the user to generate a graphical representation of the monitored vital parameters (in a .pdf format).

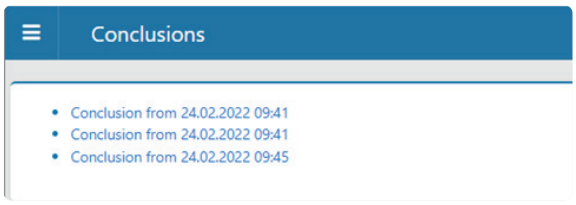
From the "Date" drop-down menu, select the date of interest for which you would like to receive a graphical representation of the patient's vital parameters. Afterwards, from the "Types" drop down menu, select one, several or all the vital parameters which of interest to you and finally press the "Review" button to generate the report.

You can use the built-in .pdf instruments to zoom in and out of the report, rotate the graph(s), save the graph(s) in a .pdf format to your PC or print the graph(s).



Conclusions

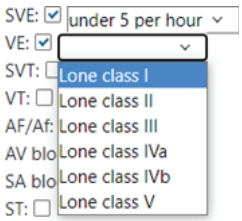
The "Conclusions" option allows you to view all the patient's created conclusions. Conclusions are presented in a .pdf format. To open a conclusion, simply select it from the menu.



Write conclusion

This option allows you to generate a conclusion for the period during which the patient was monitored.

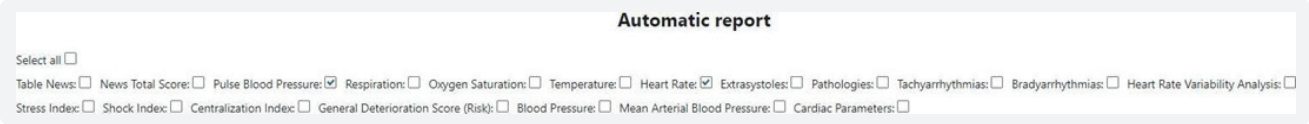
- Diagnoses — This is where patient diagnoses are shown. The field is automatically filled with diagnoses that were specified when the patient was originally being added to the system for monitoring (patient admission) and can also be expanded on by the user if needed.
- Medication — This is where the current medication that the patient is taking is shown. Please note that this field is automatically filled with the medication that was specified when the patient was originally added to the system for monitoring (patient admission) and can also be expanded on by the user if needed.
- Use the provided checkboxes to specify which parameters you'd like to be included in the conclusion. Some of the parameters need to be manually selected from a drop-down menu.



- Pathology — Select one or more pathologies from the drop-down menu, to be added to the conclusion. These selections will then be added to the "Conclusion" field.
- Conclusion - Write down the patient's conclusion in this field.
- Recommendations — Any recommendations for the patient should be written here.

All recorded pathologies and ECG strips from the "Raw data" menu that were saved are then graphically represented in the conclusion. If you wish to remove one or more of them, select the trashcan icon in the upper right corner of the ECG strip.

A graphical presentation of one or more of the vital parameters can be added to the conclusion by selecting the checkbox of the vital parameter which the user wishes to add to the conclusion.



To finish creating your conclusion, press the "Create Conclusion" button.

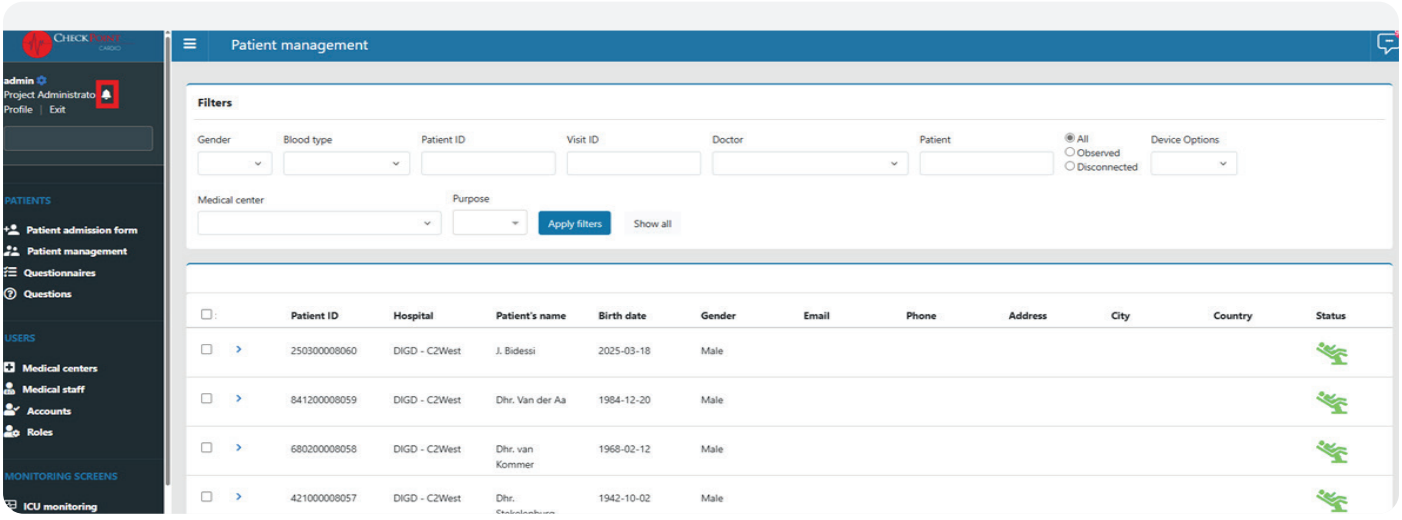
Edit Patient File

This option allows you to change or update any information related to the patient after they have already been added to the system for monitoring.

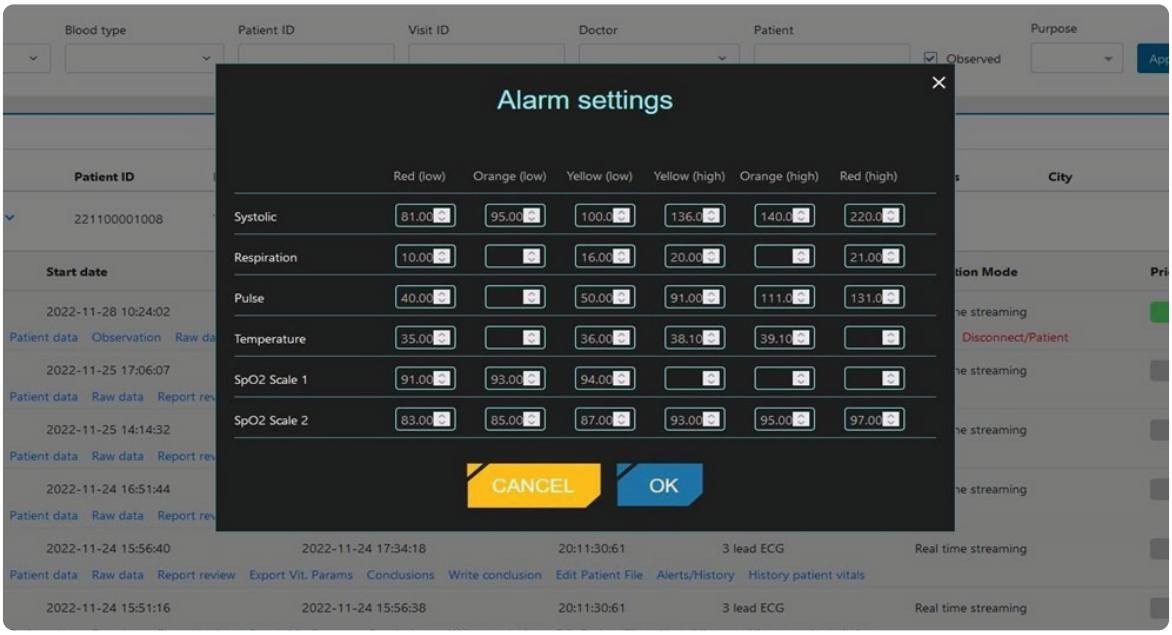
Alarm settings

This option allows you to change and set custom alert settings for each of the measured vital parameters (Respiration rate, Heart rate, SpO2, Blood Pressure, Temperature) for your medical center.

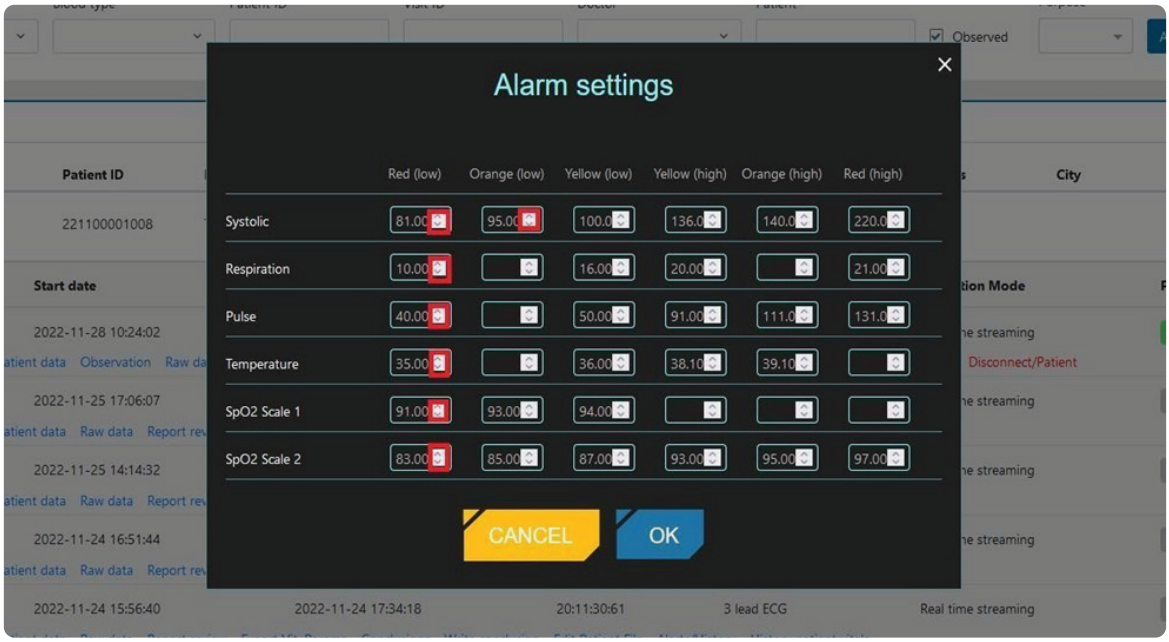
To access the alarm settings screen, you must first select the blue bell, which is visible next to the name of your medical center:



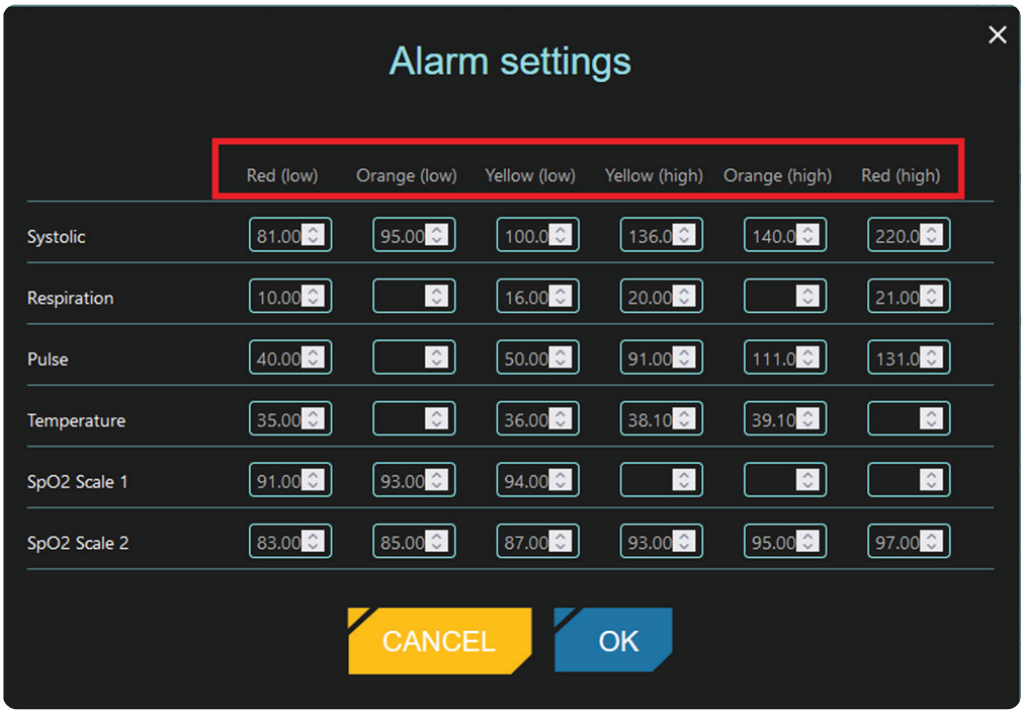
Once you have selected the blue bell you will see the following screen, which will allow you to begin making changes to the general values of the measured vital parameters for the whole medical center. These settings will apply to all patients registered to your medical center:



Clicking on either the up or down arrows will allow you to raise and lower the value, at which the specific alarm will appear:

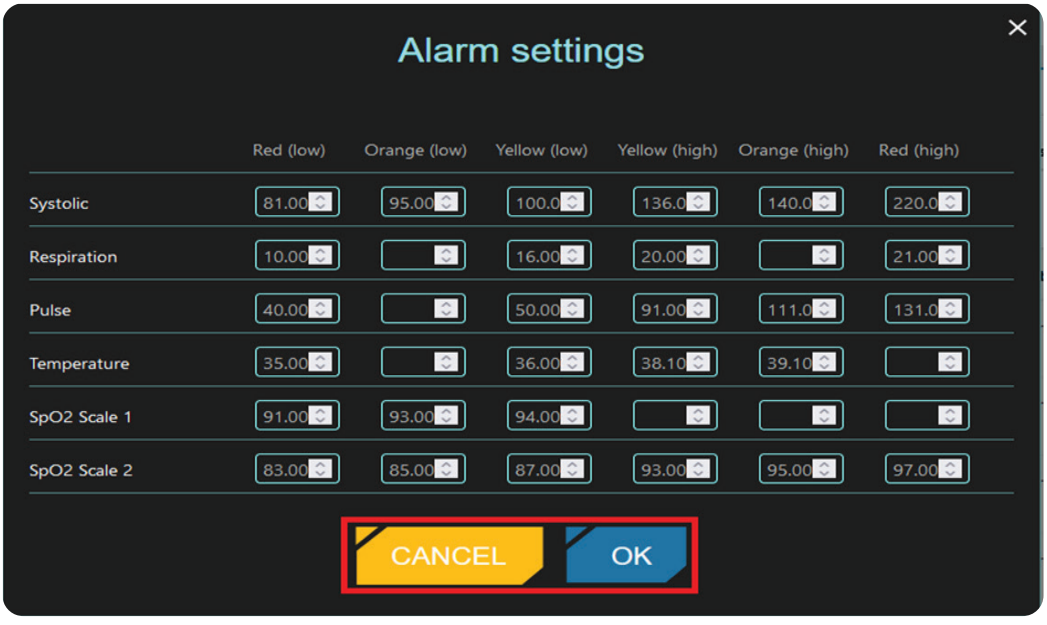


Above each of the measured parameters you will notice un-editable text that says either “Red, Orange or Yellow” followed by either “low” or “high”:

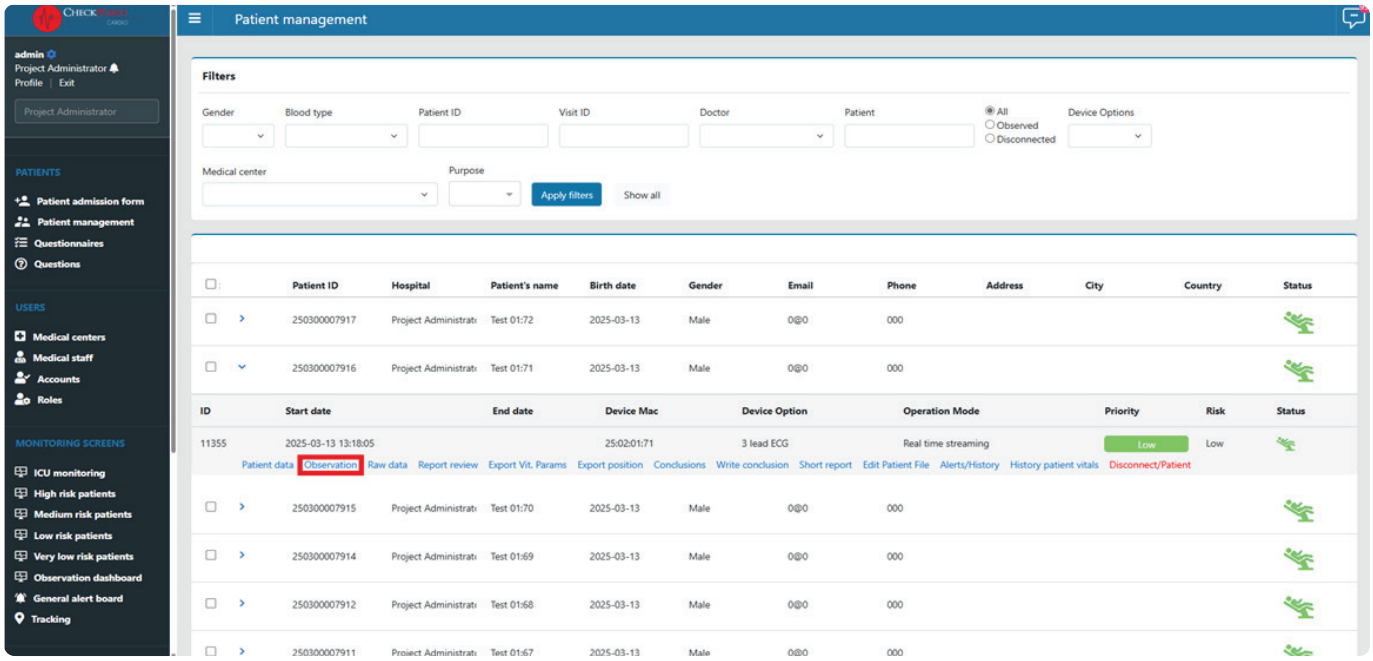


Red, Orange or Yellow signify the urgency of the alert, with the red color denoting the highest urgency, whilst yellow denotes the lowest urgency, with orange being the middle ground. Low and high respectively address whether the parameter is lower than what is considered normal (e.g red low SpO2 91) or higher (e.g red high pulse 131).

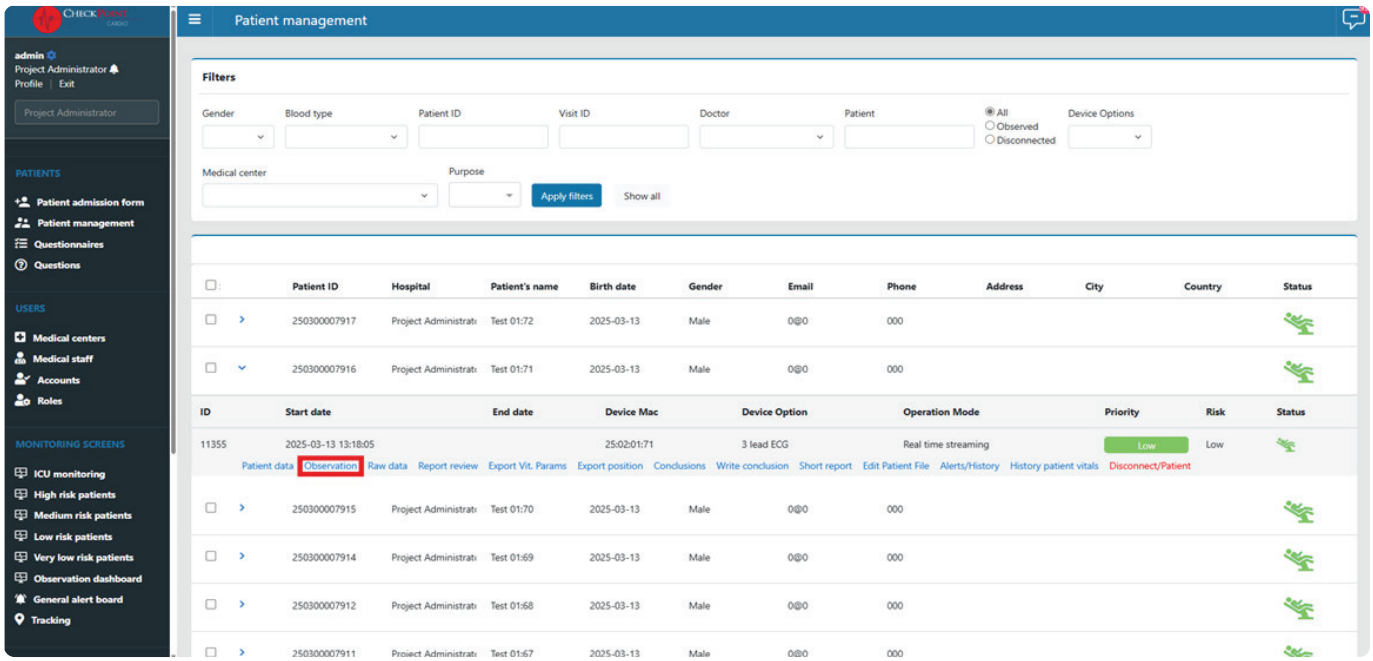
If you’re happy with the changes you’ve made, select “OK”, otherwise select either “Cancel” or the “X” in the top-right corner:



If you'd like to edit the personal settings for a specific patient to accommodate for differences in their vital parameters that are either considered normal or need to be watched more closely, you can access that patient's personal alarm settings by first going to "Patient Management":



From here select "Observation"

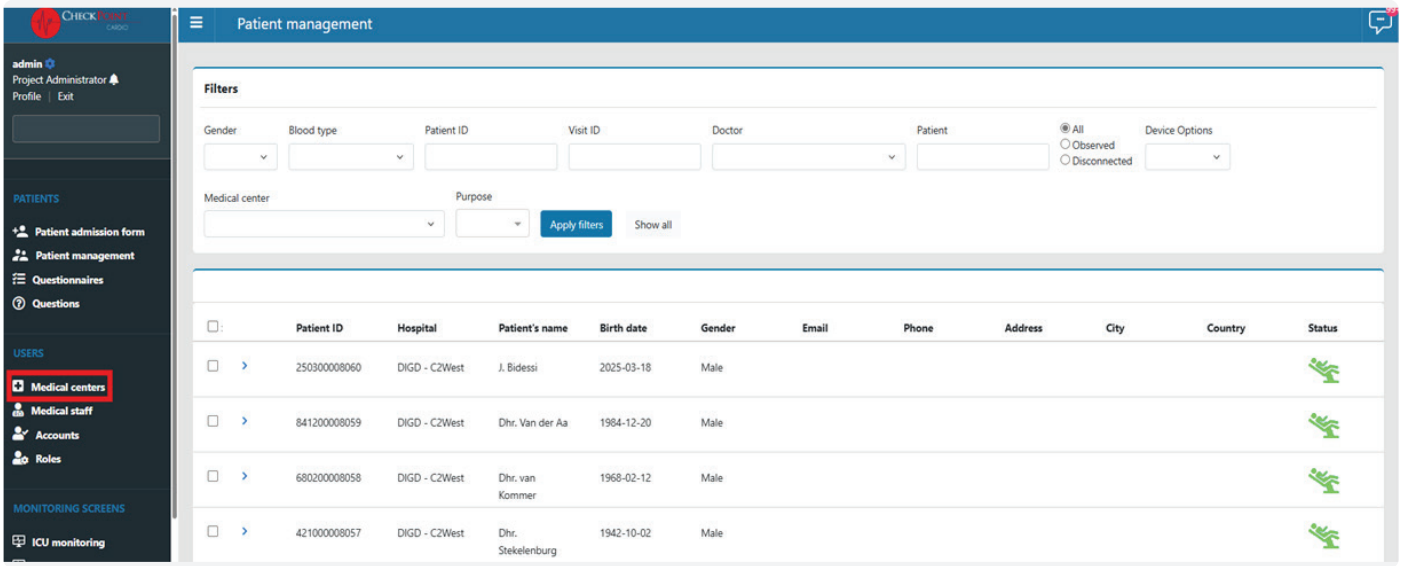


Once you've entered the "Observation" screen, select the blue button with the cogwheel on it to access the patient's personal alarm settings:

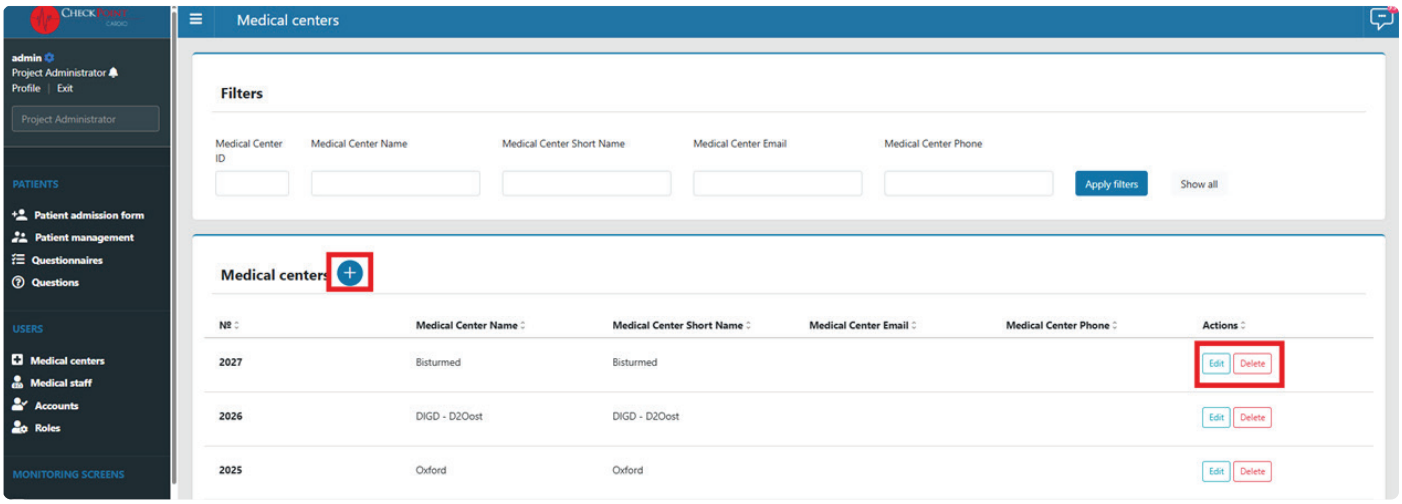
Selecting the blue cogwheel button will open the same alarm settings menu as the general medical center alarm menu. Editing the vital parameters there is done using the same process as in the medical center alarm settings.

Medical Centers

The system has the option to add, remove and edit any additional medical centers. To access the "Medical Center" menu, follow these steps:



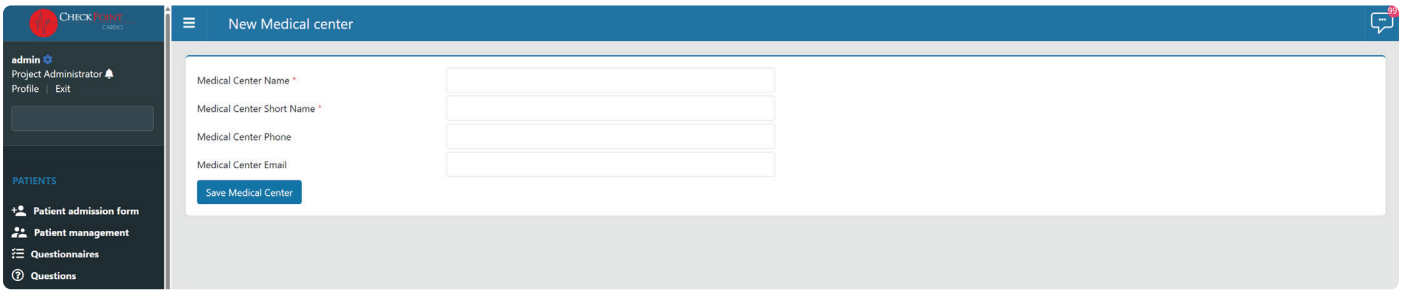
Select the "Medical Centers" option from the main dashboard. Once you've done this, you will be taken to the following screen:



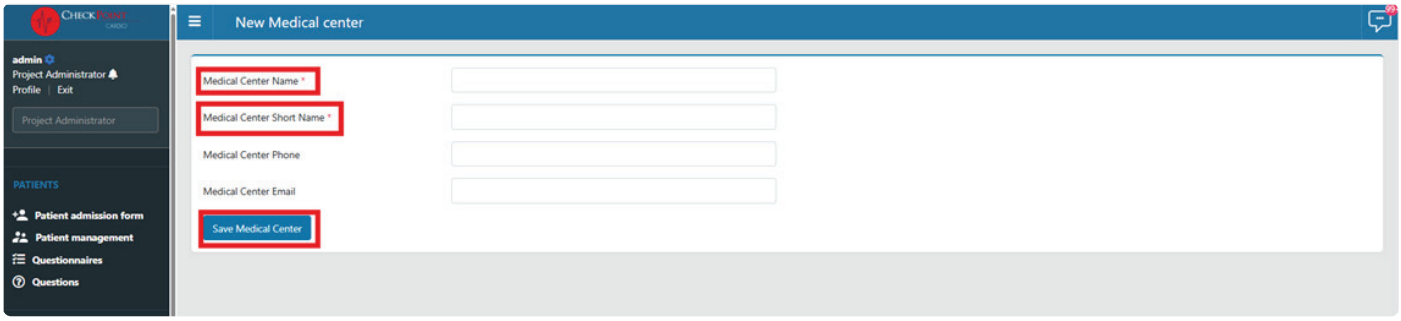
From this screen, you can take the following actions:

- You can add a new medical center by pressing on the blue "+" icon
- You can edit an already existing medical center by selecting "Edit" under the "Actions" tab
- You can remove an already existing medical center by pressing on "Delete" under the "Actions" tab

If you choose to add a new medical center, you will be taken to the following screen

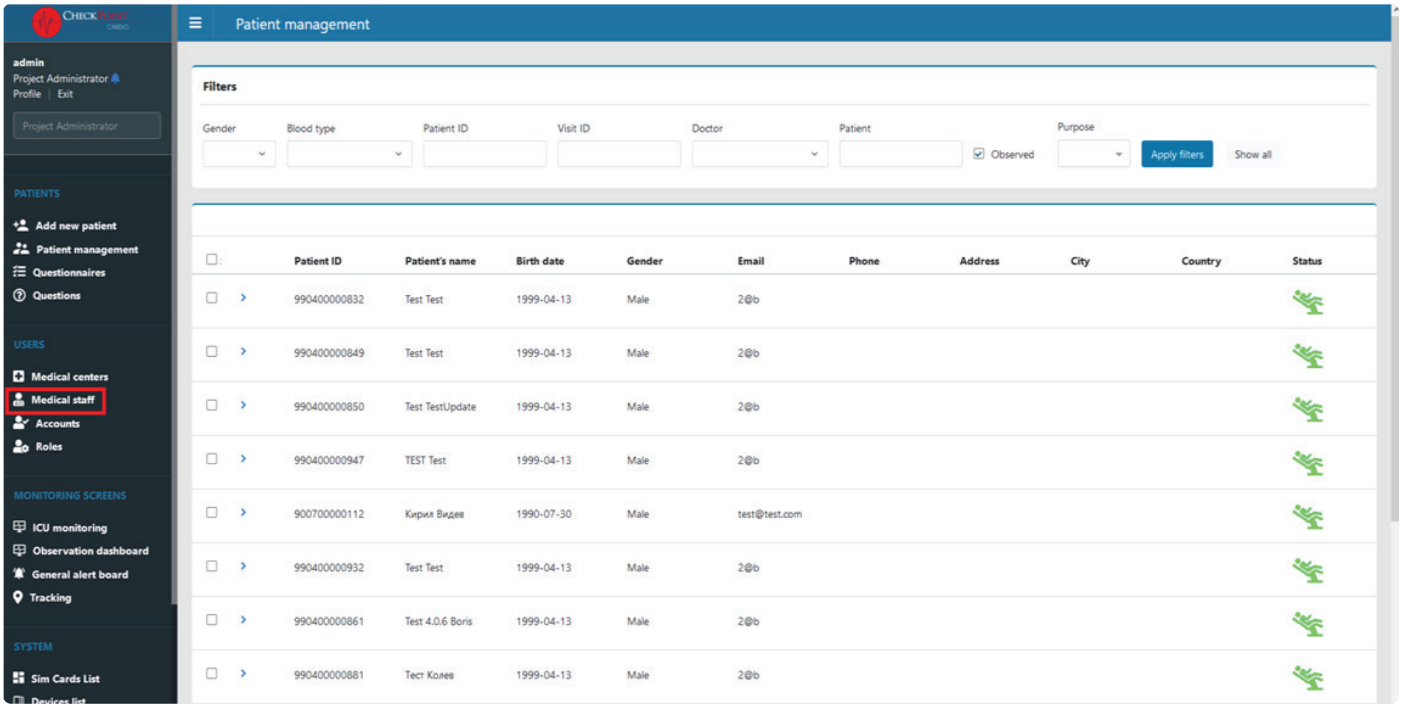


In this menu you need to fill in at least the two mandatory fields marked by a red *. Afterwards, when you're happy with the information you've put in, press "Save Medical Center" to create the new medical center.

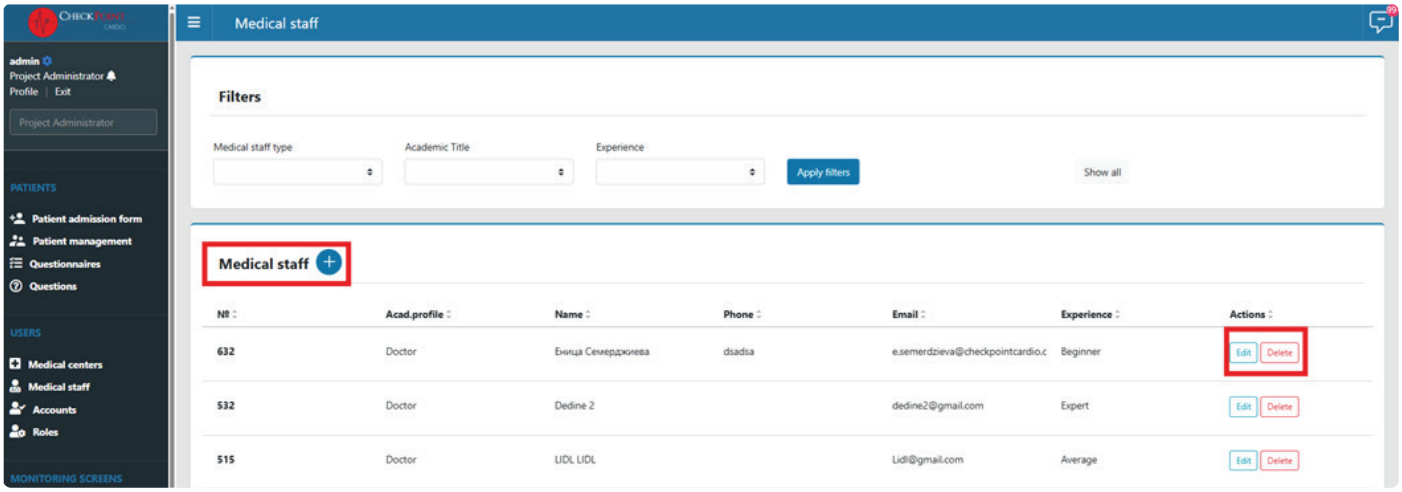


Medical Staff

The system has the option to add a list of medical staff to your medical center. To do so, select the “Medical Staff” option from the main dashboard:



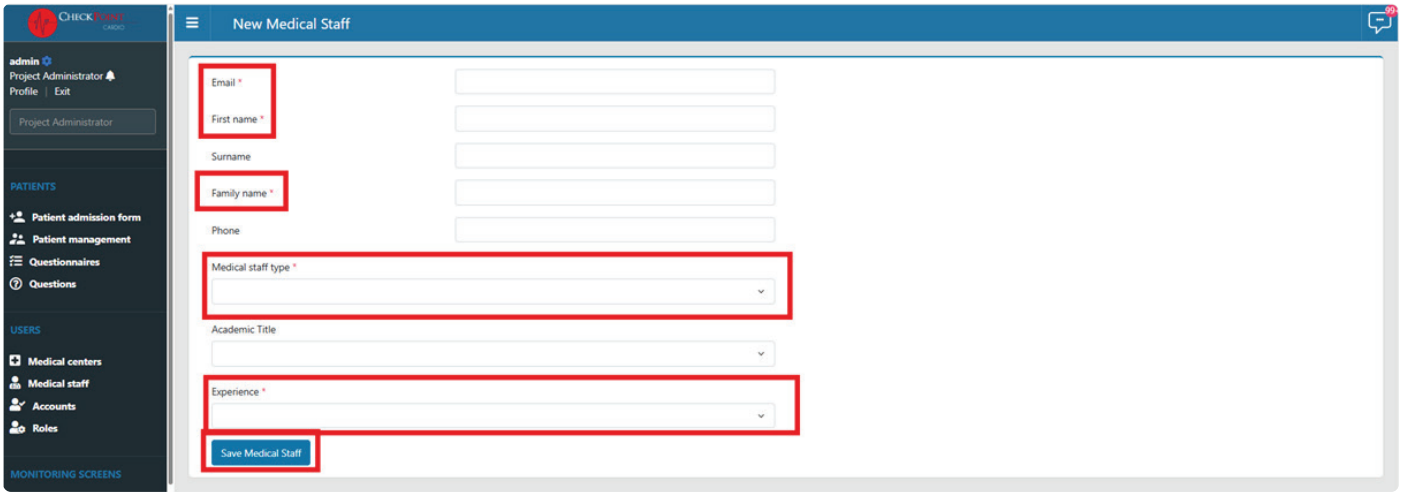
After you’ve selected “Medical Staff” you will see the following screen:



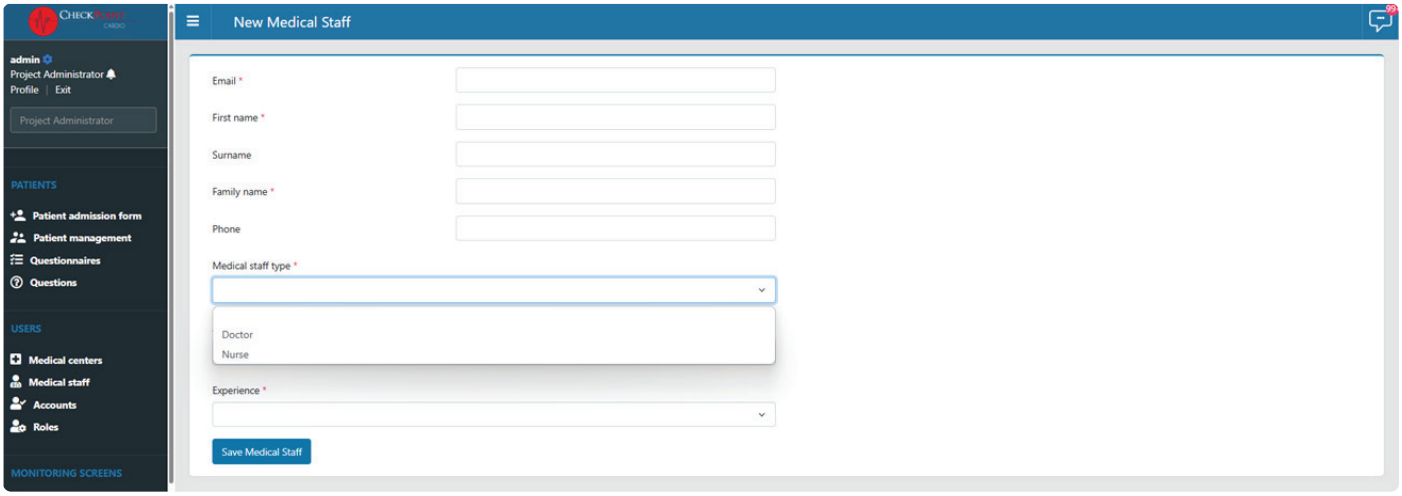
From this screen you can:

- See already existing medical staff for your medical center.
- Add new medical staff using the blue + button.
- Edit an already existing medical staff member using the “Edit” button under the “Actions” tab.
- Delete an already existing medical staff member using the ‘Delete” button under the “Actions” tab.

If you choose to add a new medical staff member by selecting the blue + button, you will see the following screen:



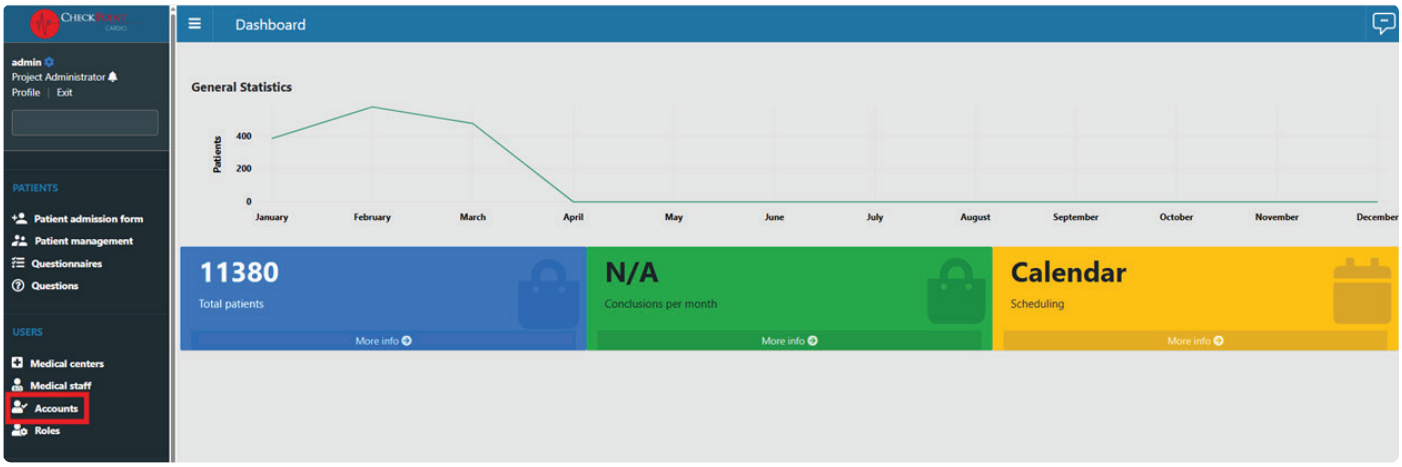
From here you need to fill in all the mandatory fields marked by a red *, as well as select an option from the mandatory drop-down menus:



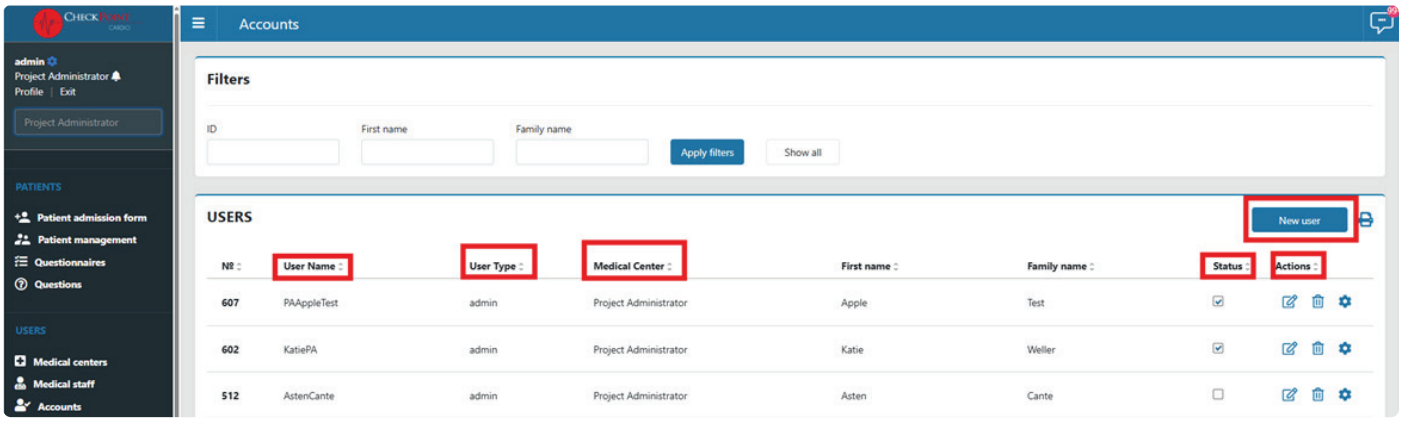
Once you have filled all the mandatory fields, select the blue “Save Medical Staff” button to save your new staff member.

Accounts

The new system allows the creation of multiple accounts able to access the same medical center/s. To view, edit and create new accounts for your medical center, select the "Accounts" option from the main dashboard:



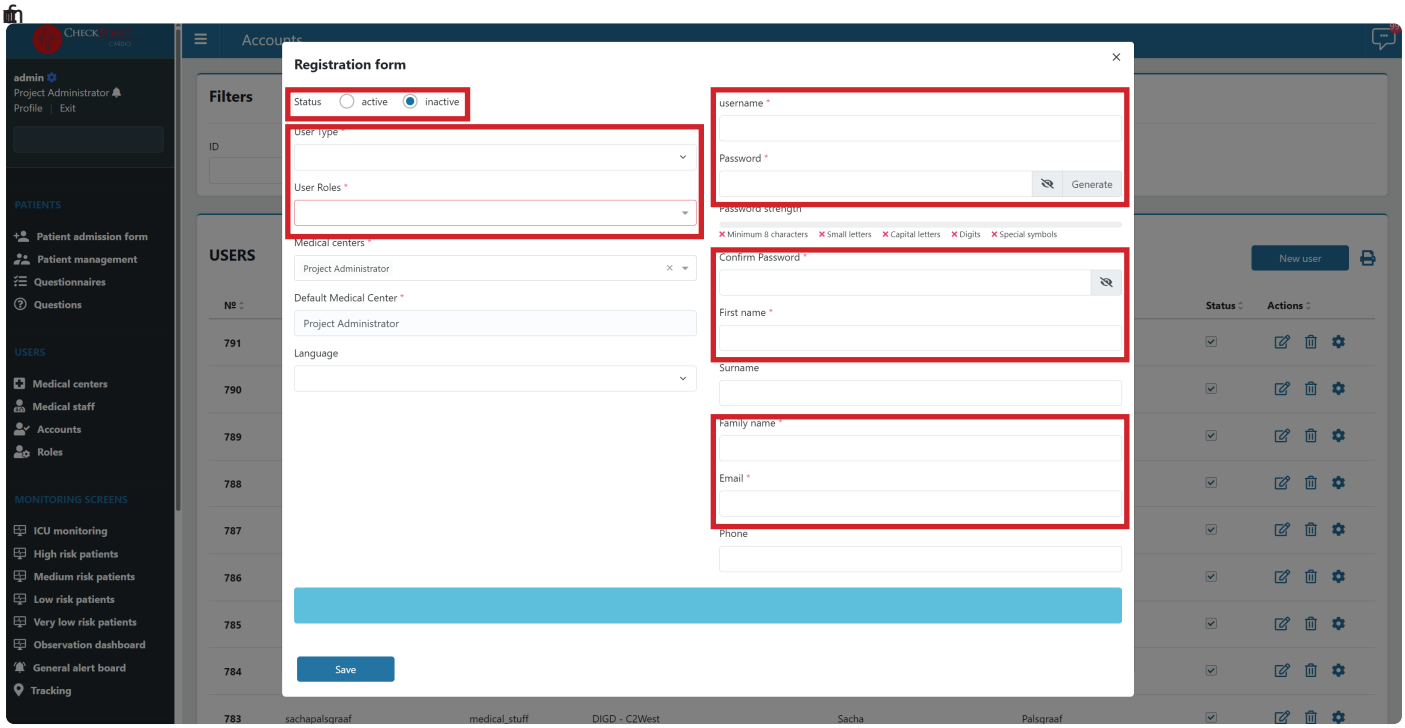
Once you've selected the "Accounts" tab you will see the following screen:



From this screen you can:

- View already existing users, their username, the type of user, the medical center they are registered to, their status, which can be either active or inactive (marked with a blue checkmark for active and an empty box for inactive).
- Edit an already existing user by pressing on the blue paper and pen button to the right of the user you'd like to edit under the "Actions" tab.
- Delete an already existing user by pressing on the blue trashcan button to the right of the you'd like to delete under the "Actions" tab.
- Add a new user by pressing on the blue "New User" button.

If you choose to add a new user, you will be taken to the following registration



In this registration form you need to perform the following steps to successfully create a new user:

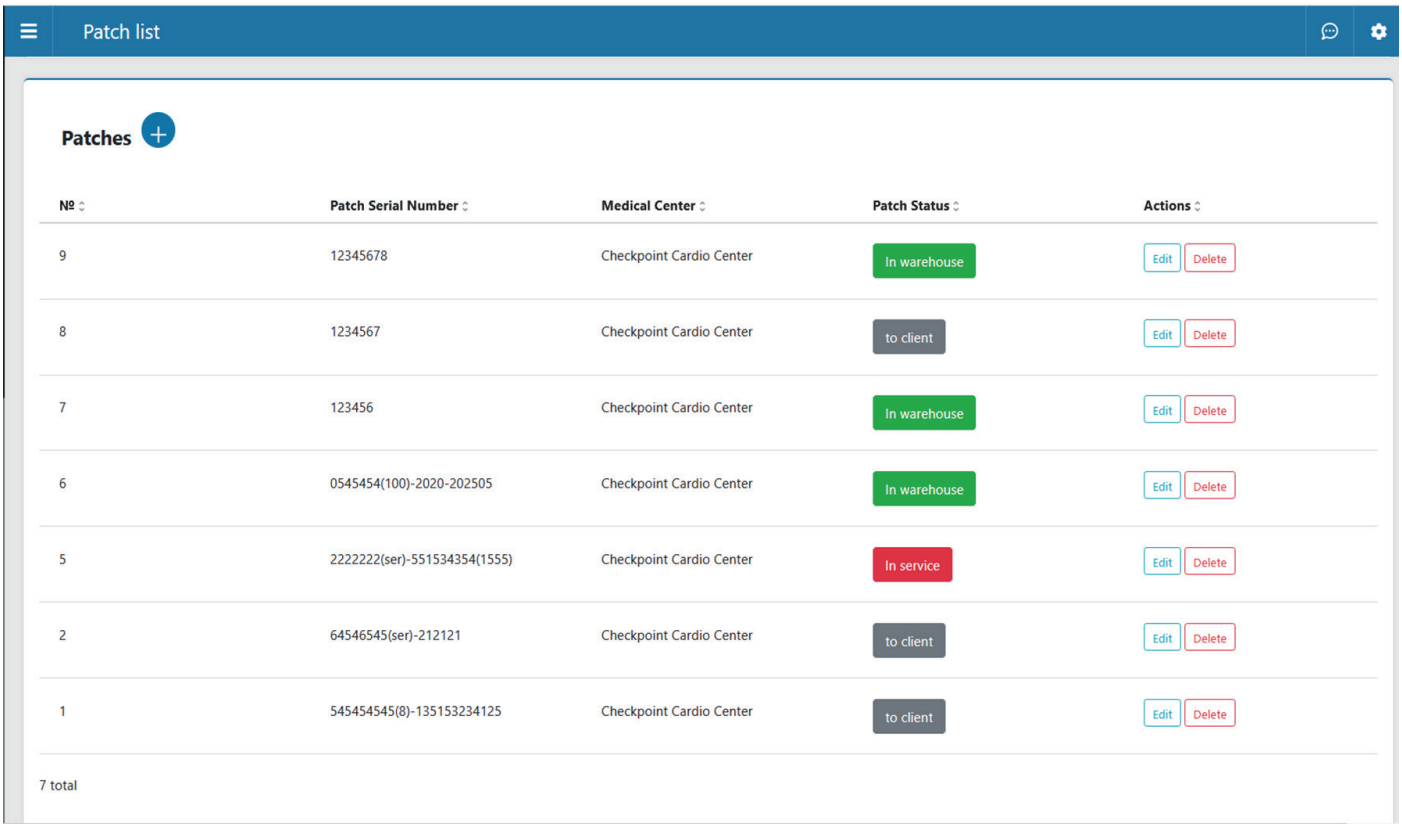
- Set the status of the user to “Active”
- Select the user type from the drop-down menu (It is recommended you create an admin account before you create a medical staff account).
- Choose the roles you would like this user to have. These roles are best described as the rights to certain menus and features that the user you are creating will have (e.g. adding/removing patients, accessing the “Accounts” tab, etc.)
- Select the medical centers you would like this user to be able to view.
- Choose and enter a username for the new user.
- Choose and enter a password for the new user, which complies with the requirements listed below the password field. If you’d like the system to generate a conformed and secure password for you, click on the grey “Generate” button next to the passwords field.
- Confirm the password that was generated or chosen.
- Enter the user’s first name.
- Enter the user’s surname (optional).
- Enter the user’s family name.
- Enter the user’s email address.
- Enter the user’s phone number (optional).

Once you’ve completed all the above steps correctly, click on the blue “Save” button and your user will be created.

Patches list

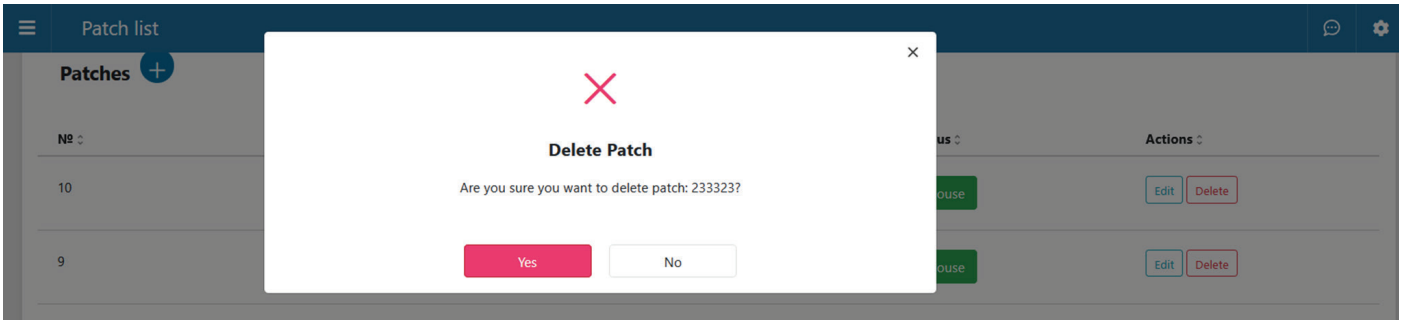
To access the barcode/patches menu, select the “Patches list” option from the leftmost sidebar:

In this menu you can view, add, remove and edit new or existing patches that are added or can be added to an existing/new medical device:

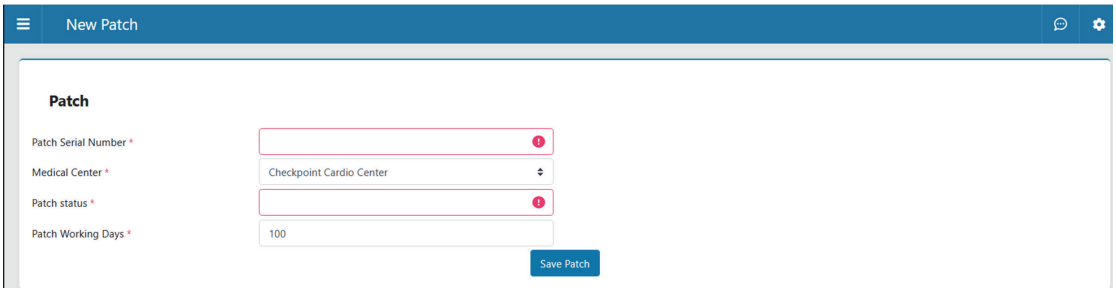


The patch status signifies whether a patch is available for use (In warehouse), is currently being used (To client) or has exceeded the 100 days working period/been sent back for maintenance (In service).

Use the “Delete” button to remove patches from the available list and use the “Edit” button to make changes to already existing patches.



To add a new patch to the list, press the blue + button to start the enrollment process:

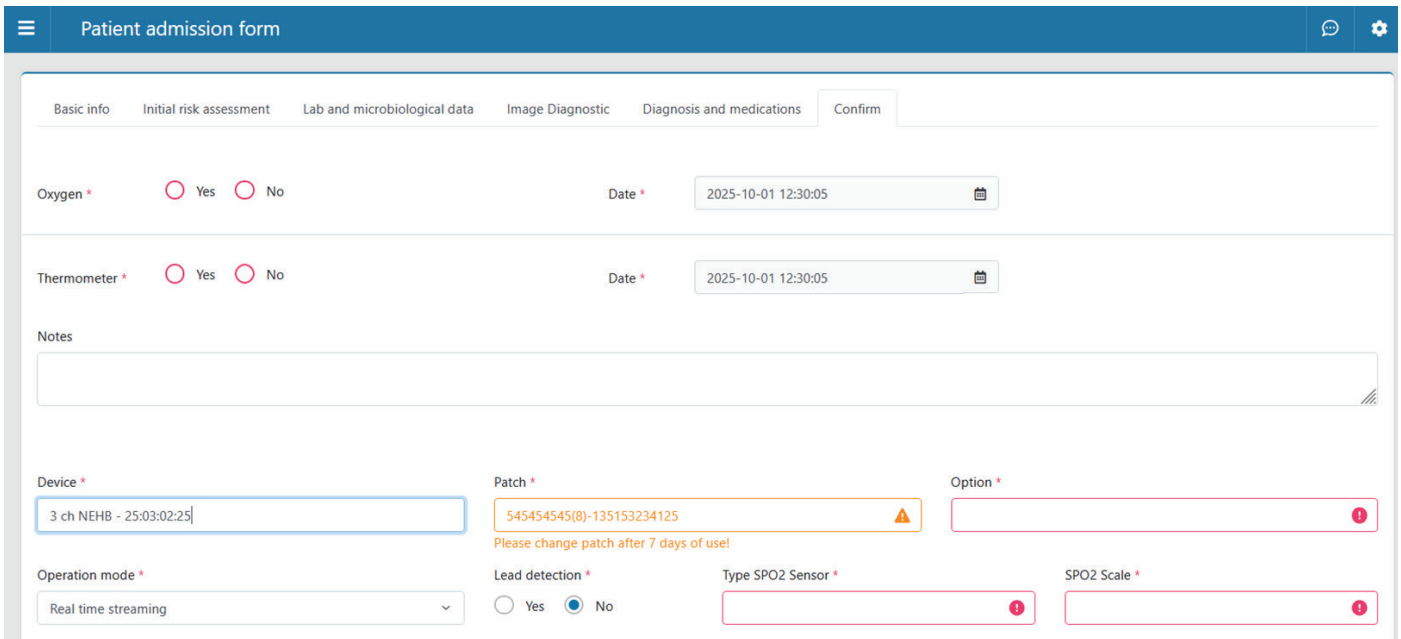


To register a new patch after pressing the blue + button, all 4 mandatory fields must be filled-in with the relevant information.

- Patch serial number: Enter the serial number of the patch which can be found physically inscribed/taped to the back of it.
- Medical Center: By default this field will be filled with the medical center you are currently logged into. If your account has been granted access to more than one medical center, you can select which medical center you'd like to add the patch to from the drop-down menu, by clicking on the two black arrow on the right-hand side of the field.
- Patch status: Select whether the patch is currently available (In warehouse), in use on a patient/testing (To client) or if it has exceeded it's working days/is currently sent for maintenance to the manufacturer (In service)
- Patch working days: By default this field is filled-in with "100". **Do not change the number of days unless otherwise specified by the manufacturer in official communication or the "Warranty" section of your CPC device model's purchase order documentation.**

Once you've filled-in all the fields with the correct information, press the "Save Patch" button at the bottom of the page.

If the patch is saved correctly and added to a device via the "Devices" menu, when you select the device serial number during patient registration the patch should automatically appear next to the device serial number:



If the device working days are close to expiration, the system will alert you with an orange warning symbol and a system message that will remind you to change the patch 1 week beforehand. Once the patch working days period expires, the patch will automatically be toggled by the system to "In service".

General Alert Board

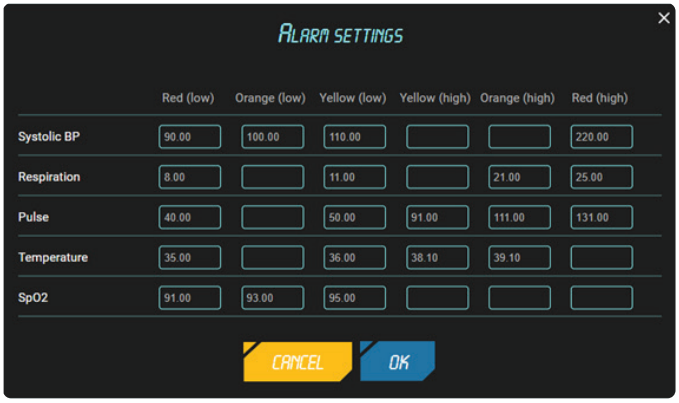
This option allows the user to observe all alerts generated by the system, in real-time, for their selected patient or all active patients.

Both “NEWS alerts” and “Cardiac alerts” are displayed for the current user.

Alerts in the “NEWS alerts” section are raised when some of the monitored parameters exceed preset limits.

To specify the limit for when the alert will be generated for one or more parameters press the ⚙ button.

You can also divide alerts by color based on the preset NEWS 2 limit.



Please note that alerts related to problems with patient measuring equipment are also raised in this section.

Alerts in the “Cardiac alerts” section are sent when a pathology is labeled in the “Raw data” screen of the current patient. Based on the type of pathology, the alert is marked with a different color.

When the alert is sent (in both sections) it is expected that the user will evaluate the alert and take necessary action. These are predefined in the "Follow-up action" drop-down menu.

The date and time when the follow-up action is taken is recorded in the "Resp. time" section. Please note that when a "Follow-up action" is taken for specific alert, that alert is deleted from the "General alert board".

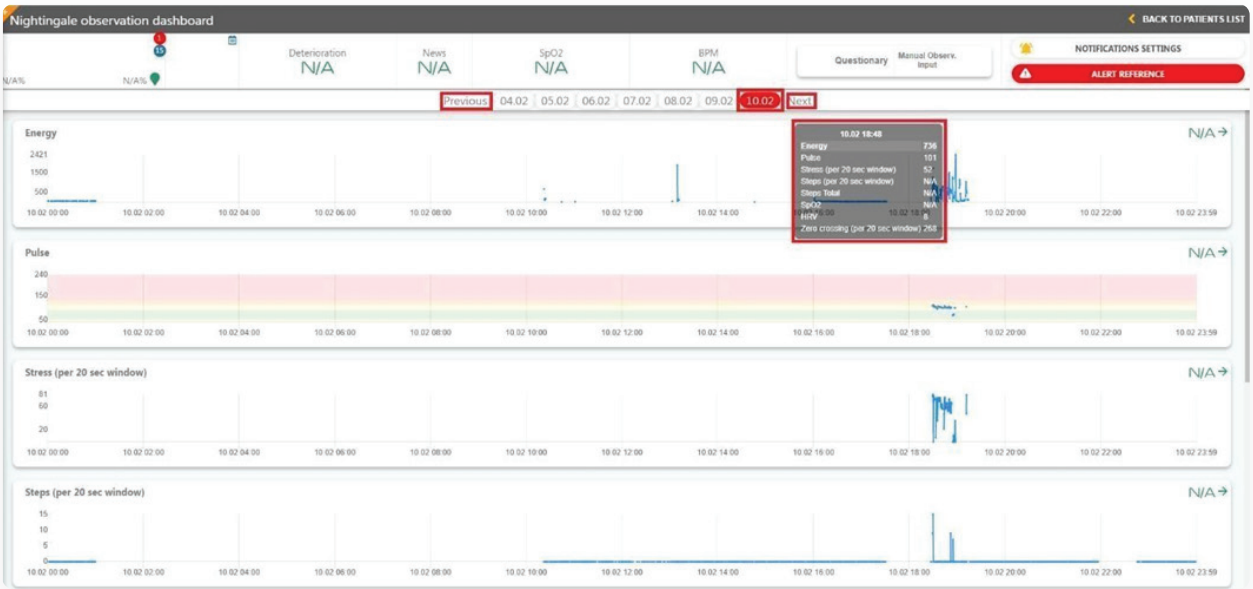
By using the button, the user can see all rejected alerts.

History of patient vitals

This observation screen allows the user to track the values of the patient's vital parameters in real-time, as well as simultaneously view the history of their vital parameters for a specific date and time.

The measured or displayed parameters depend on the type of CPC device the patient is currently wearing.

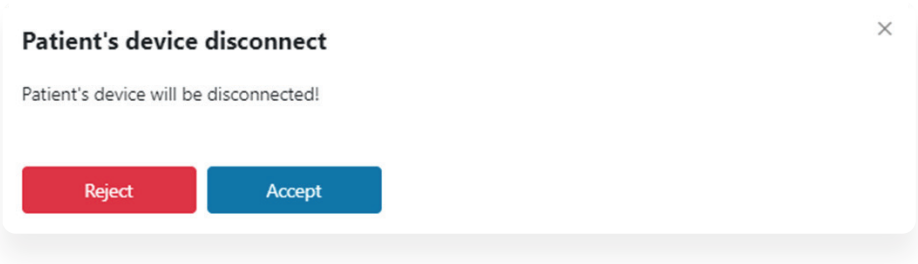
To see the recorded values of the measured parameters, select the date from the list. Use the "Previous" or "Next" buttons to change the date. For a more detailed digital representation of the measured parameters, highlight one of the graphs with your mouse cursor and use the mouse to further navigate in the graph.



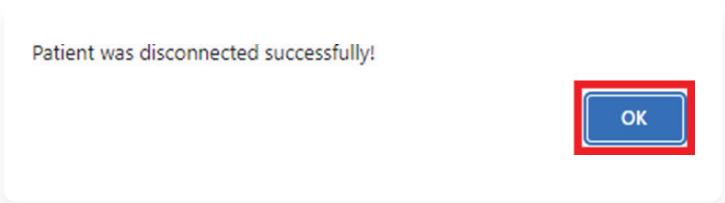
Disconnect

This option allows the user to disconnect the patient's session from the system, when the patient is no longer during observation.

To do this, select the "Disconnect" option. Afterwards, select the "Accept" button to confirm you wish to disconnect the patient from the monitoring system or "Reject" if you wish to cancel the disconnection process.



Finally, close the information window by pressing "OK".

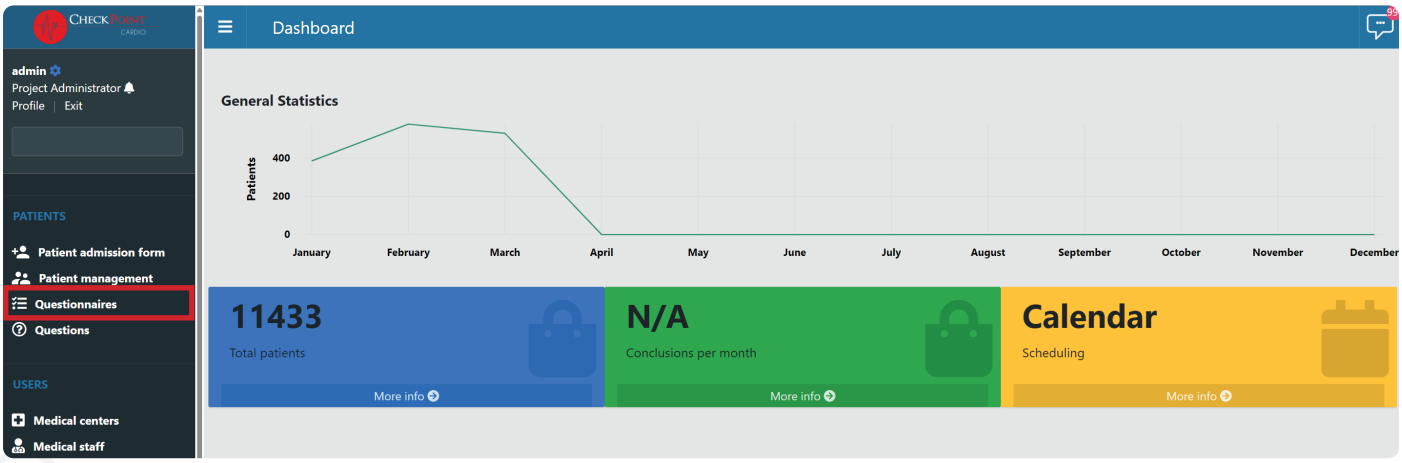


Disconnected patients can only be re-added to the system by creating a new patient session.

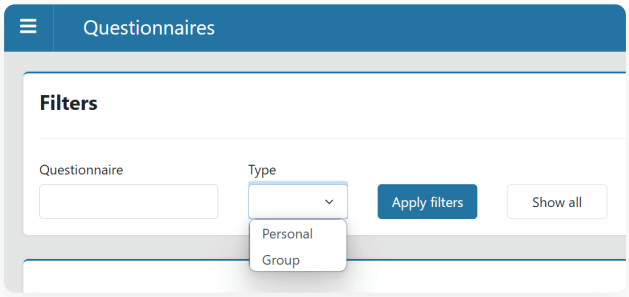
Questionnaires

This option allows the user to create custom questionnaires or use preset ones, which can then be assigned to individual patients or a group of patients.

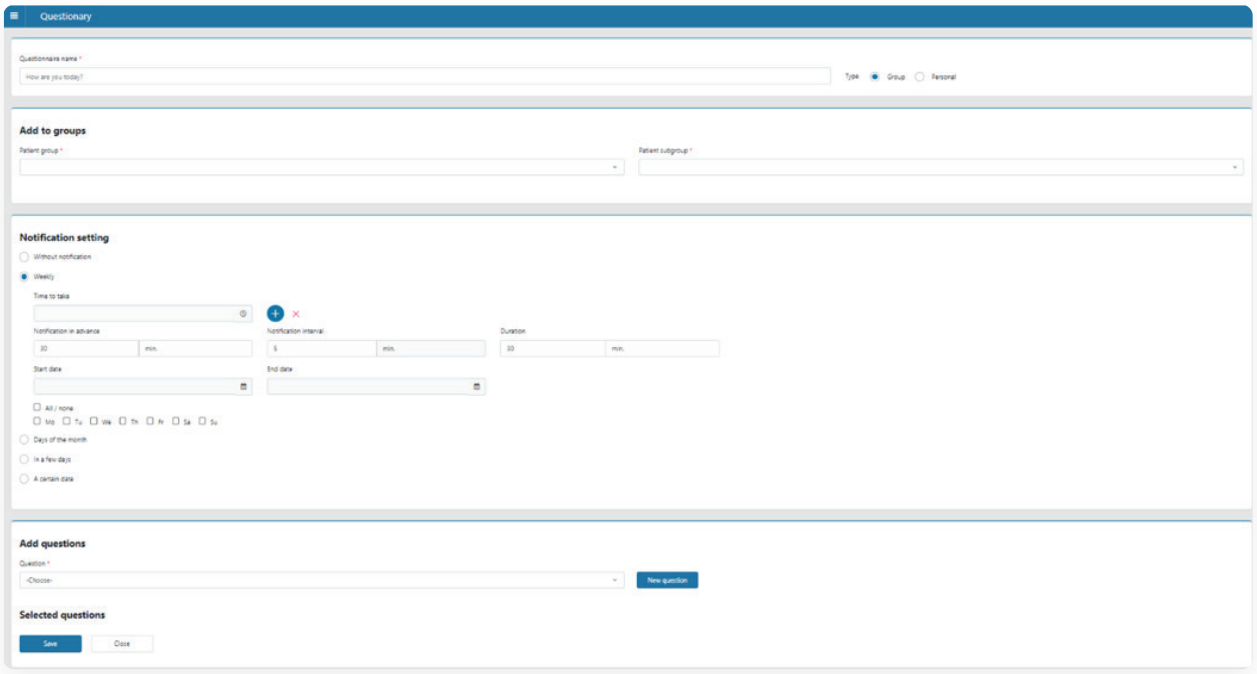
From the main dashboard, select "Questionnaires".



The user can use the options provided to filter through the list of already created questionnaires. Use the “Show All” button to display all the available questionnaires.



To create a new questionnaire, select the New questionnaire button.



- **Questionnaire name** – Assign a name to your questionnaire.
- **Type** – Specifies the questionnaire type: “Group” or “Personal”.

Group questionnaires will be assigned to all patients who belong to a predefined disease specified in the “Patient group” and “Patient subgroup” drop down lists in the “Diagnosis and medications” tab when the patient was originally being added to the system.

Personal questionnaires will only be assigned to individual patients whose name or anonymized callsign can be selected via a drop-down menu.

- **Notification settings** – This allows for notification intervals and settings to be adjusted further by the user. The following options are available: “No notification”, “Weekly”, “Days of the month” (chosen by the user), “In a few days” and “A certain date”. Please note that if notifications are enabled, the patient will be notified of each questionnaire on their mobile device.
- **Add questions** – Here the user can add questions to the questionnaire by selecting them from a drop-down menu or they can create new questions using the “New Question” button.

Questions created through the “New Question” button are saved and can be viewed in the “Questions” menu.

To save a newly created questionnaire, select the “Save” button.

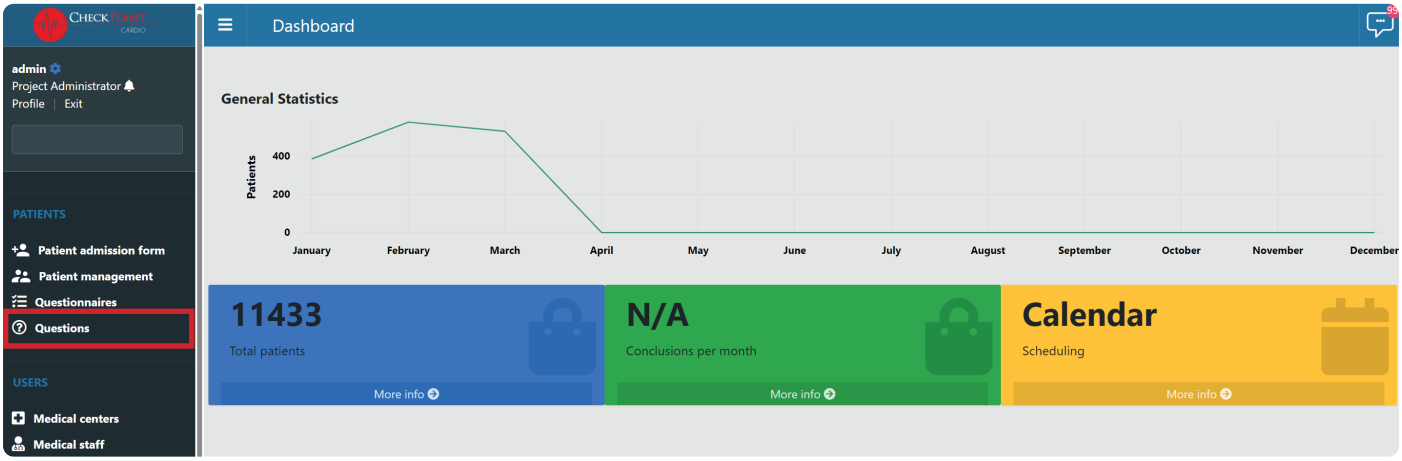
To edit an already existing questionnaire, use the button.

To delete an already existing questionnaire, use the button.

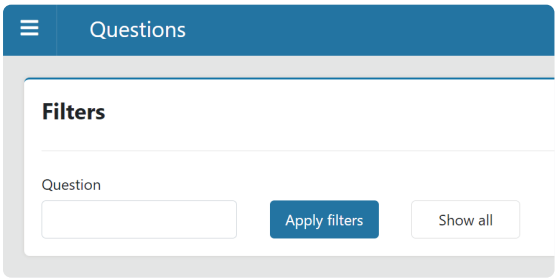
Questions

This option is used to create individual questions which can then be added to a questionnaire.

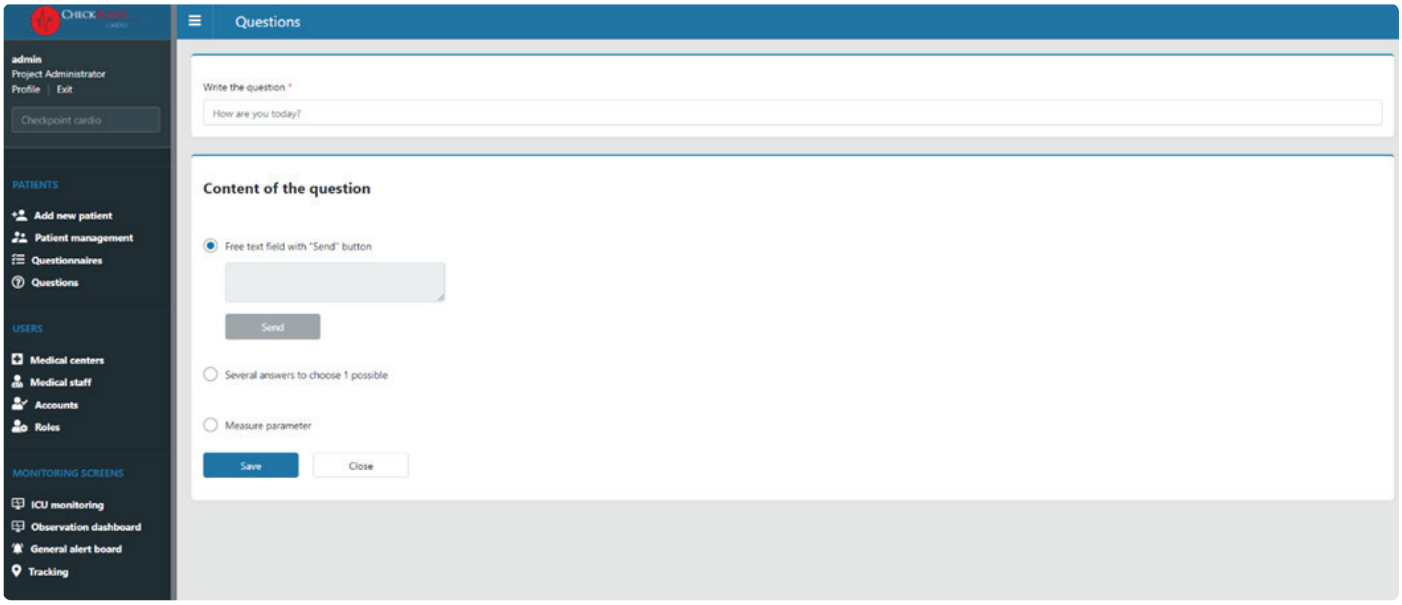
From the main dashboard, select “Questions”.



The user can use the options provided to filter through the list of already created questions. Use the “Show All” button to display all the available questions.



To create a new question, select the New question button.



- **Write the question** – In this field you must write down the question. When the question is assigned to the patient or patient group through "questionnaires", it will be sent to the patient. The action that the patient must take to answer the question is dependent on the question's content or type.
- **Content of the question** – From here you must select the content of the question:
- **Free text field** – The patient will have to answer the question using free text, before sending their answer back using the "Send" button.
- **Several answers to choose** – This option allows for several multiple-choice questions and answers to be created. For each created choice the "Type of answer" needs to be specified. The following types of answers are available: "Positive", "Negative" and ''Undefined'.

The patient receiving this type of question will have to choose one of the available answers to send back.

- **Measure parameter** – When the patient receives this type of question, they are expected to measure the specified vital parameter using the appropriate measuring equipment and then fill in the value of their measurement before sending the answer back to the system.

Patient answers can be seen in the "Questionnaire-patient" tab.

To save newly created questions, select the "Save" button.

To edit already existing questions, press the following button

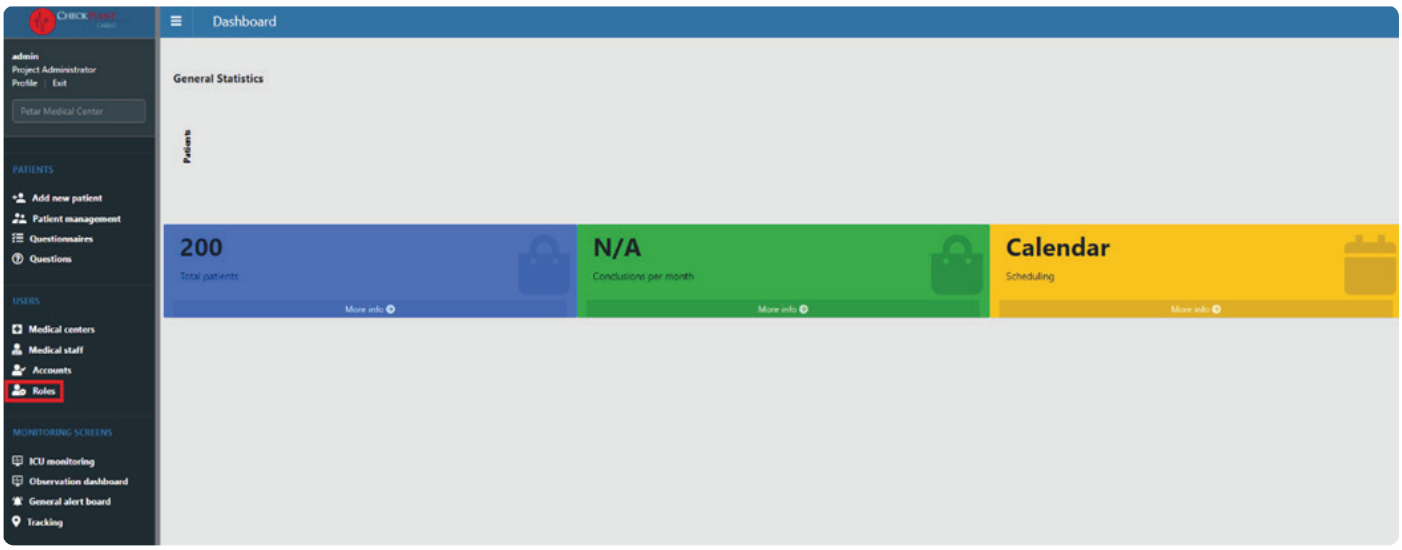
To delete already existing questions, press the following button

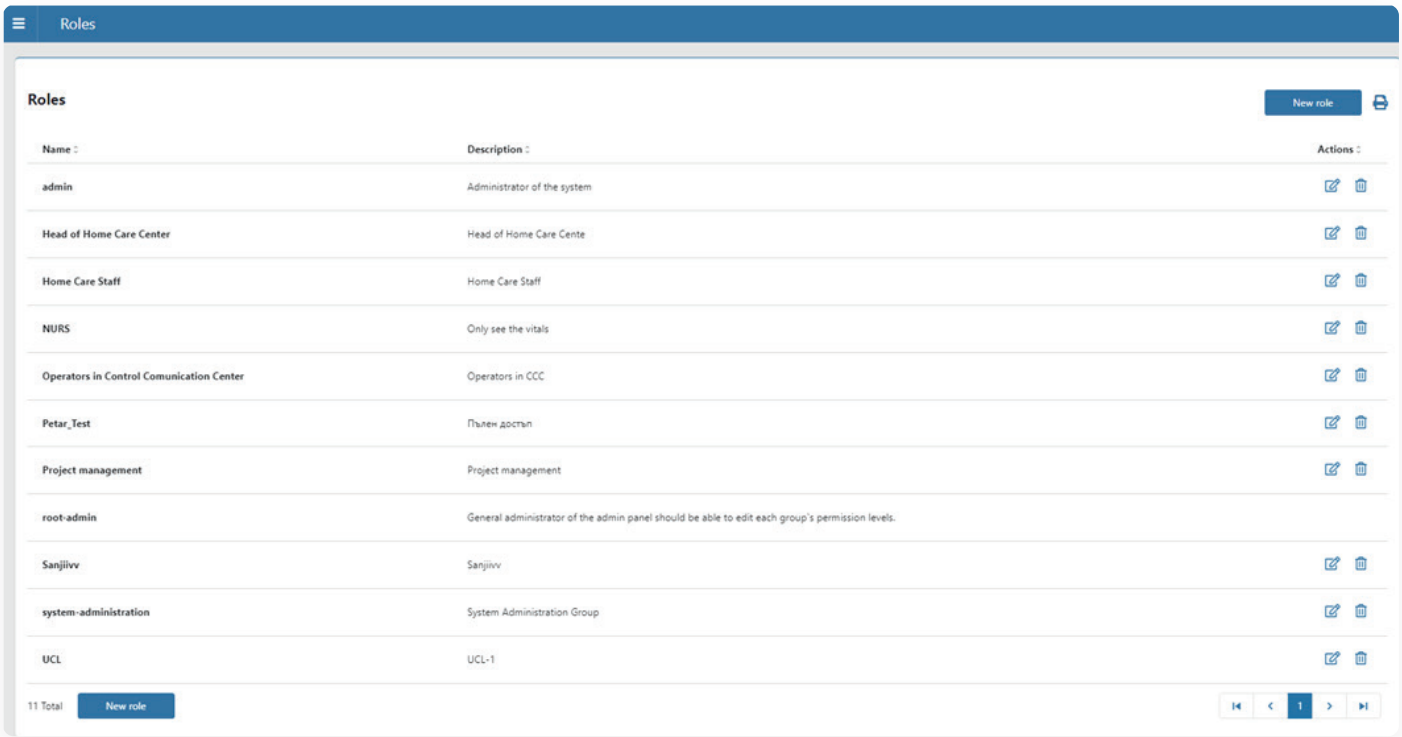
Roles

This option is used to manage account roles, which allow or do not allow the user to perform specific actions within their assigned medical center.

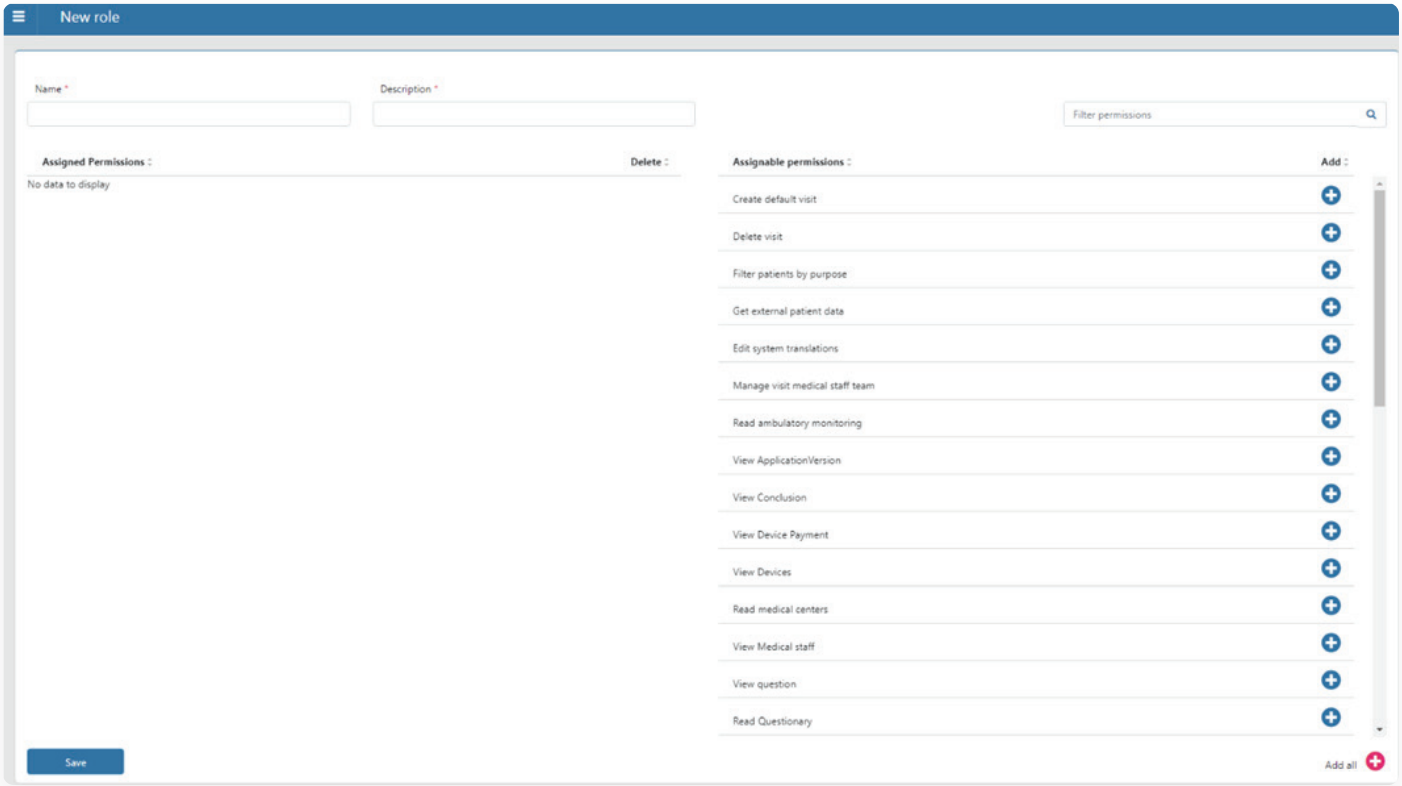
Each account or "user" in the system has one or more roles attached to them. In turn, each role has permissions assigned to it. These permissions determine the amount of access the user is allowed to have within the system.

Select "Roles" from the dashboard to access the "Roles" menu.





To create new role, select the “New role” button.



- Name – This field requires that you assign a name to your new role.
- Description – This field allows you to attach a short description the role you are creating.
- Assigned Permissions – All available role permissions are listed here. To add these permissions to your role, press the ⊕ button. To remove any permissions, press the × button.

To finish creating the role, select the “Save” button.

To edit an already existing role, press the button.

To delete an already existing role press the button.

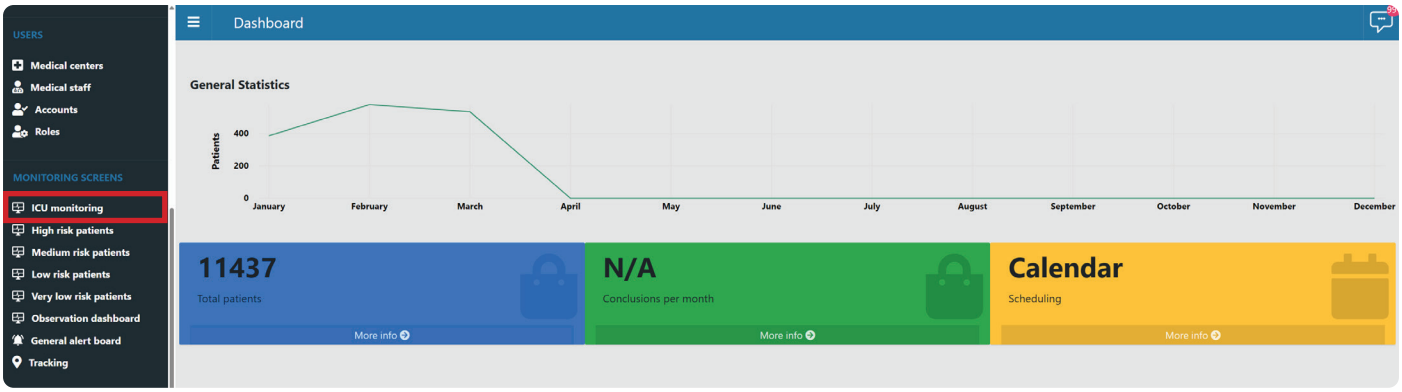
MONITORING SCREENS

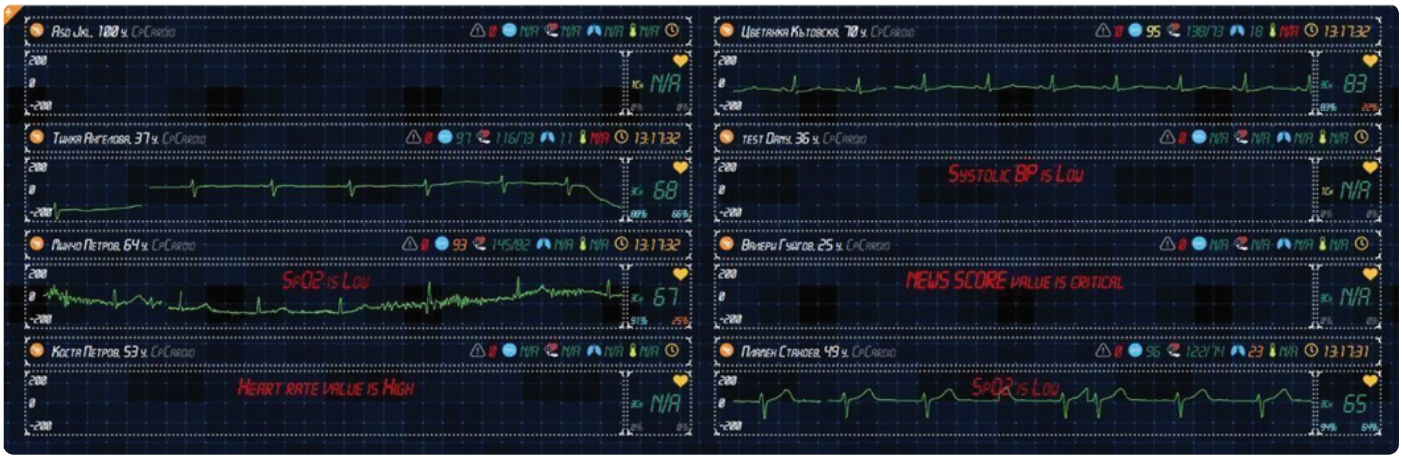
The “Check Point Cardio” monitoring system offers different screen layouts for patient monitoring. Each one of the monitoring screens offers a different form of presentation of the monitored parameters. The user can choose whether to monitor multiple patients or see a more detailed view of an individual patient.

Information displayed on the monitoring screens depends on the used patient measuring equipment (device).

ICU monitoring

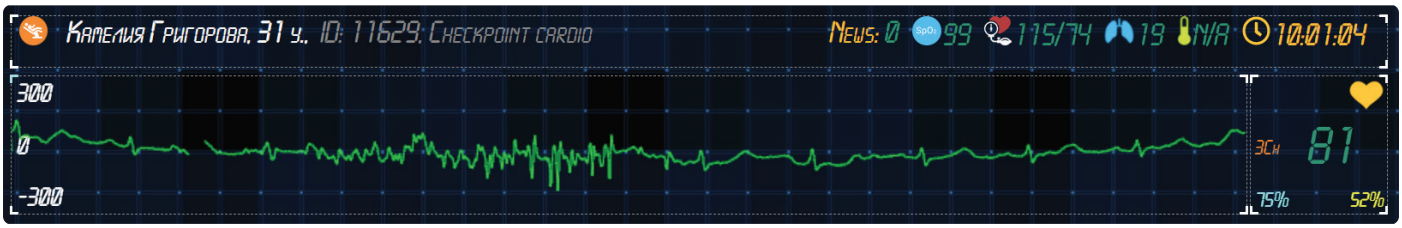
To access “ICU monitoring”, select the “ICU monitoring” option in the dashboard. This will display all currently active patients.



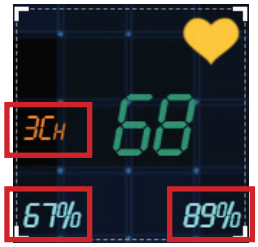


The following information for all observed patients is displayed:

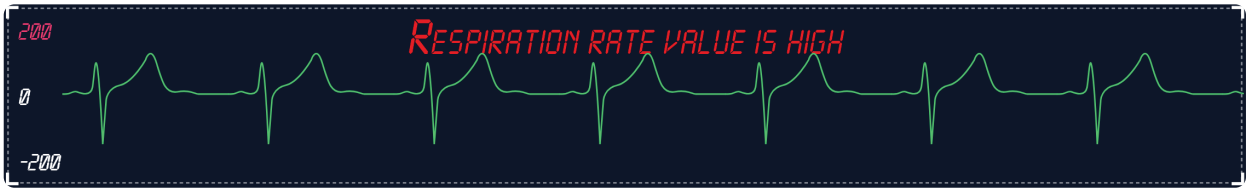
- Name and age of the patient.
- The medical center to which the patient belongs to.
- Values of the vital parameters measured in real time (SpO2, blood pressure, respiration, temperature, pulse).



- Number of ECG Leads (based on the monitoring device capabilities) and the remaining battery charge of the monitoring and the communication devices.

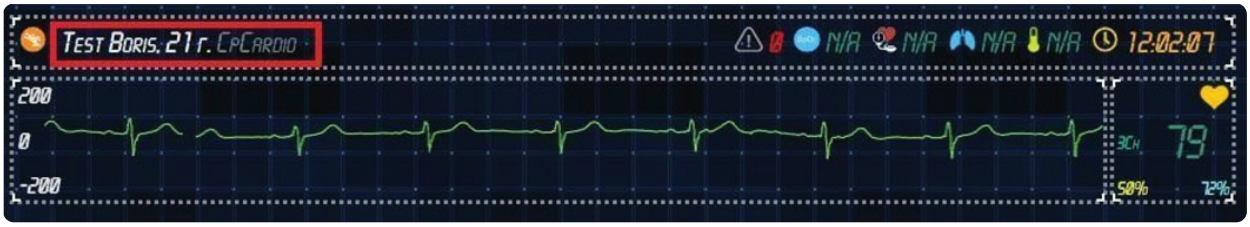


- Alerts for: when some of the vital parameters exceed predefined limits;when pathology is labelled in Raw data screen; problems with the communication device.



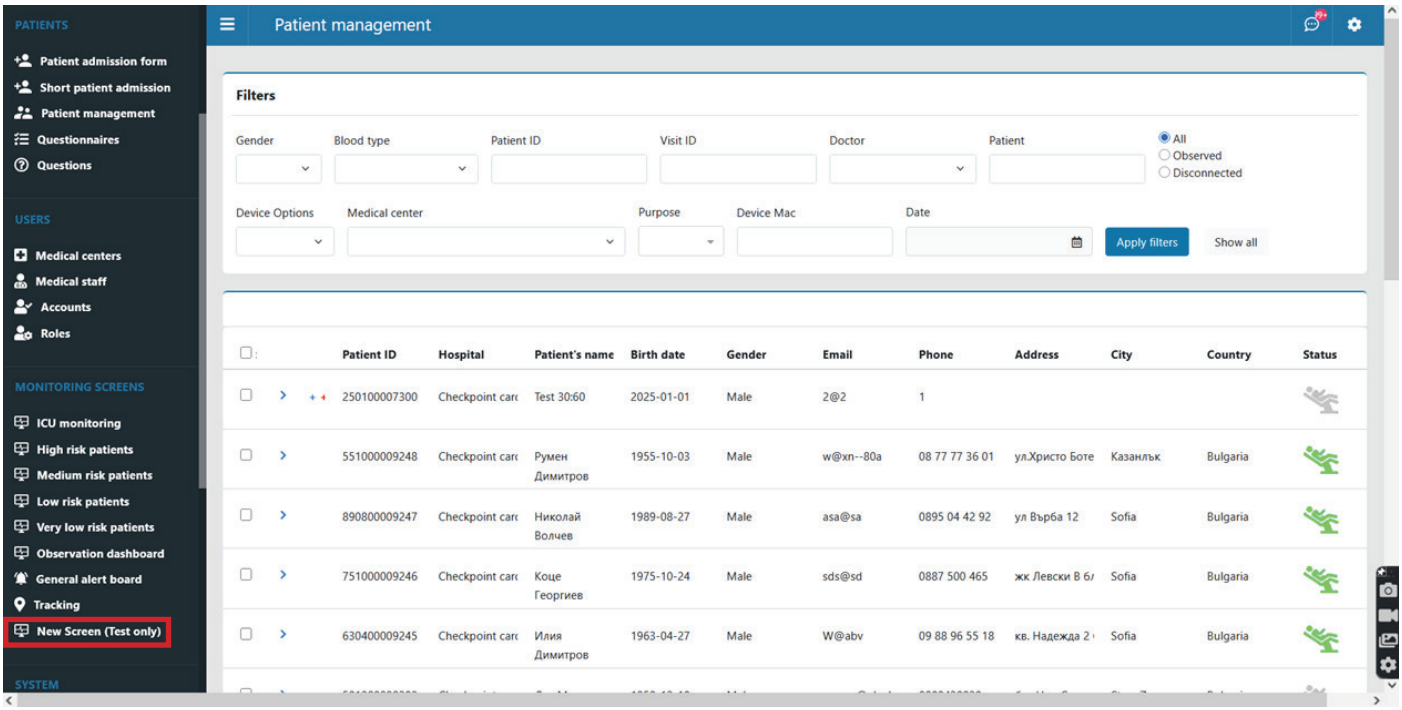
ICU monitoring screen for an individual patient

To display the ICU monitoring screen for an individual patient, click on the patient's name.



New ICU Screen

To access the new ICU screen, press on the “New Screen” button in the leftmost toolbar:

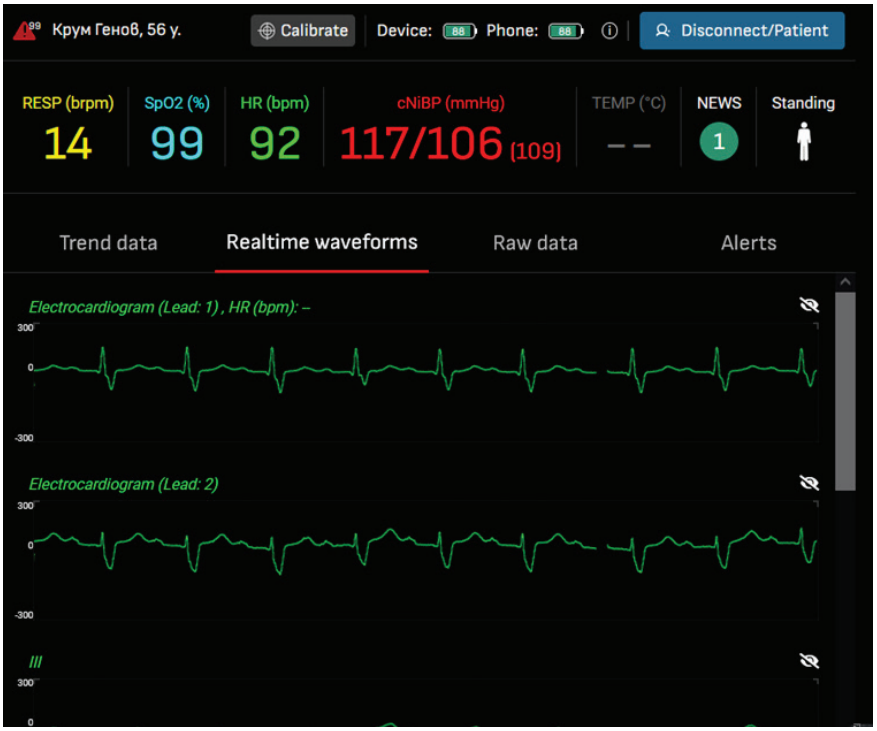


Pressing on “New Screen” allows you to access the updated ICU view, from which you can observe active patients, expand their observation for more information, add new patients and switch through medical patients:

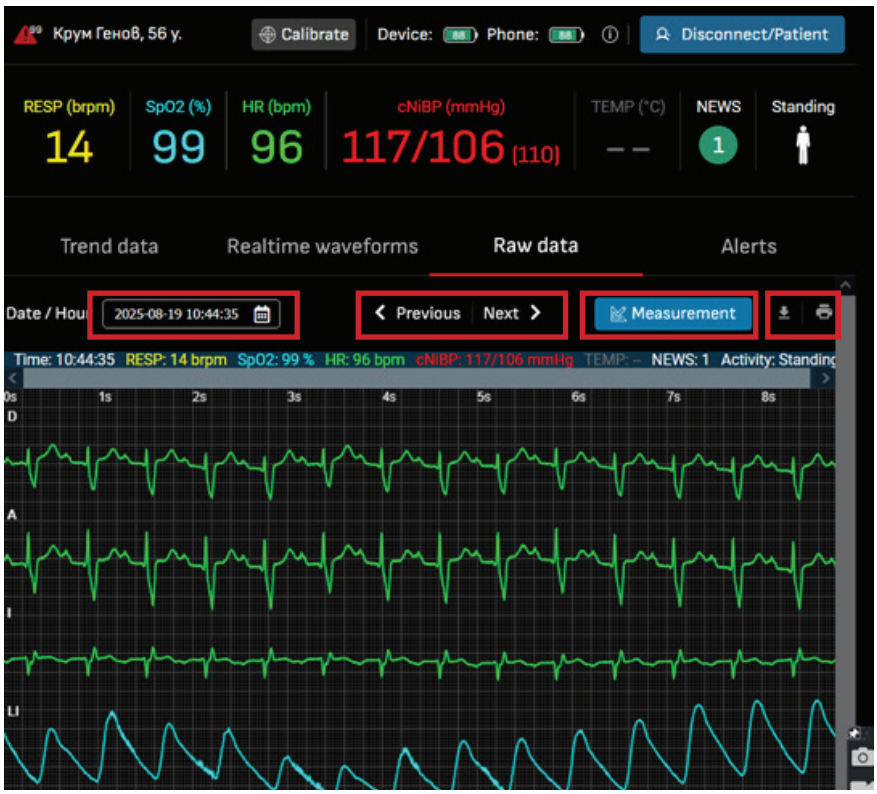
To expand the patient view simply press on the patient you'd like to observe from the list to get a more detailed view of their trends, vital parameters, live ECG waveforms and more:

From this expanded patient view you can see the patient's live vital parameters, body position, NEWS score and their trend, raw, live and alert data and also technical information like the battery level of the communication device and the medical device. To switch through these various menus simply click on them. Furthermore, you can also scroll through the days during which the patient was under observation by selecting the appropriate date (dd-mm format) and review their past data.

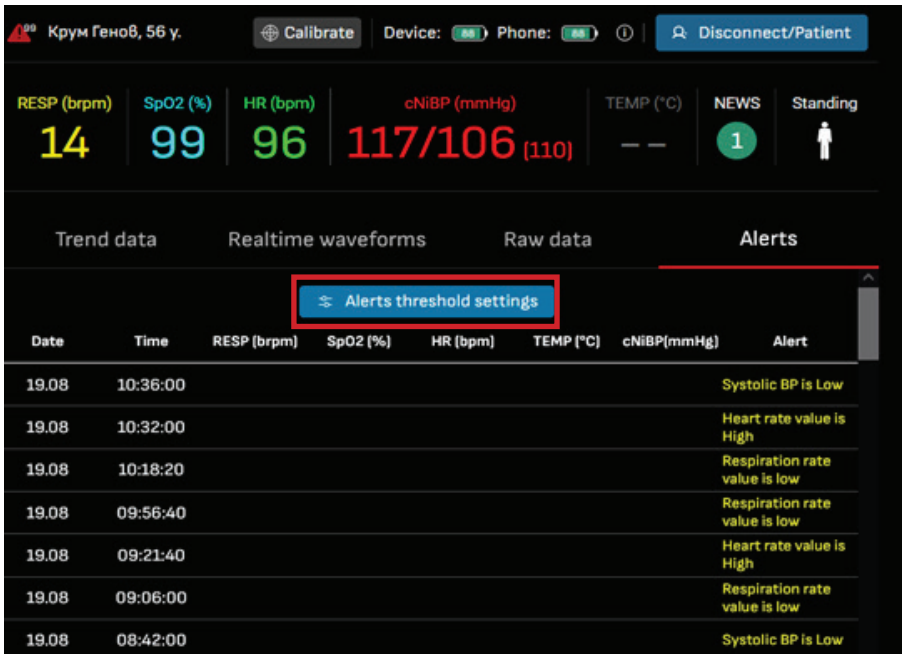
By accessing the “Realtime Waveforms” tab you can see the live ECG data of the patient. Depending on the type of device the patient is wearing, the number of ECG boxes changes.



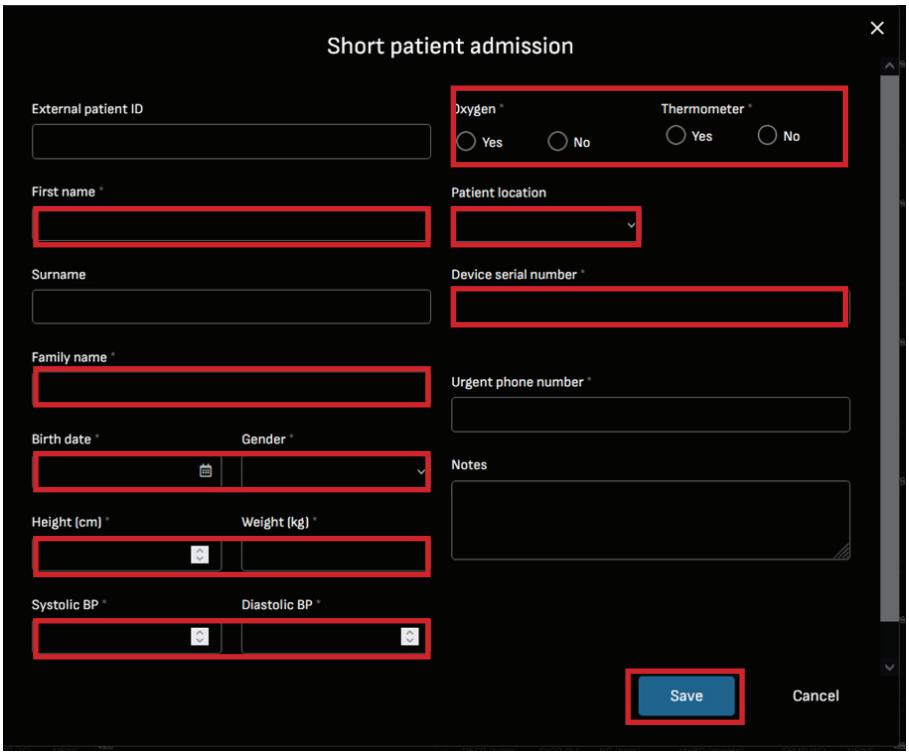
From the “Raw Data” tab, you can access the raw data of the patient. In this tab, you can scroll through the raw data using the “next” and “previous” buttons or through the “Date” drop-down menu. Additionally, using the “Measurement” button, you can make take any necessary measurements of the patient’s ECG data directly in this tab. From here you can also download important ECG strips or print them out using the “Print” and “Download” button accordingly.



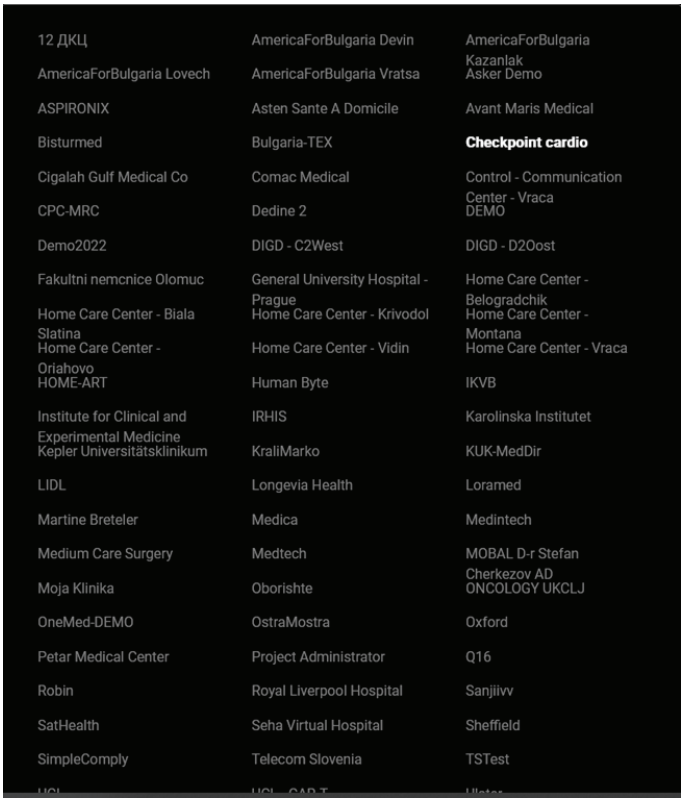
Through the "Alerts" tab you can view all automatic and manual alerts that are generated for this particular patient session with their appropriate timestamps. From here you can also set the personal alert threshold of a patient using the "Alerts Threshold Settings" button.



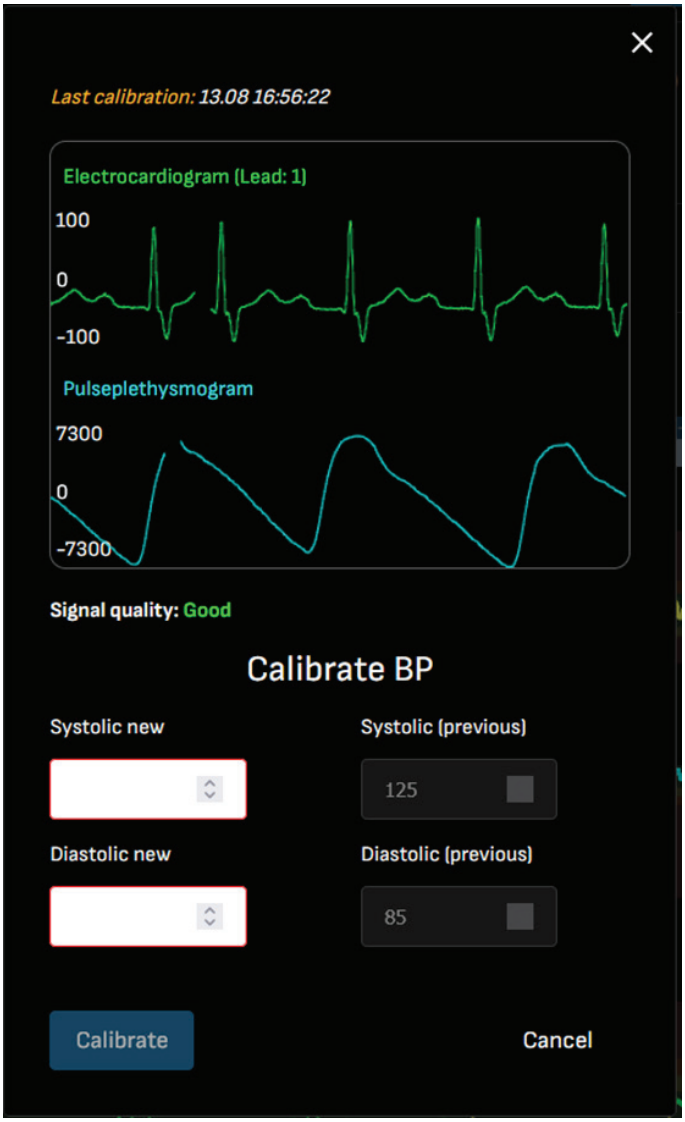
Clicking on the "Add New Patient" button will open the short patient admission form where you can enter the data of a new patient and register them through the New ICU screen directly. To add the patient simply fill-in all the mandatory fields with the patient's information and press "Save".



If your account has been given access to more than one medical center, you can scroll through the available options by clicking the white arrow next to the current medical center you are on and select the medical center you'd like to switch to from the drop-down menu.



By clicking on the "Calibrate" button when you are in the expanded patient menu you can adjust the initial BP value entered during patient registration by simply entering the new value in the Systolic and Diastolic BP fields and pressing "Save".



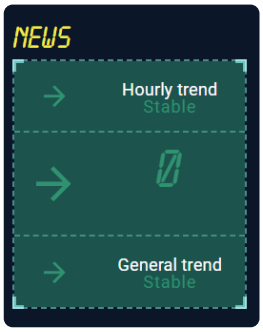
Observed parameters

The following detailed information is displayed in the individual patient's screen:

- Numerical and graphical presentations of the "NEWS" score.

The color depends on how critical the level of the observed parameter is.

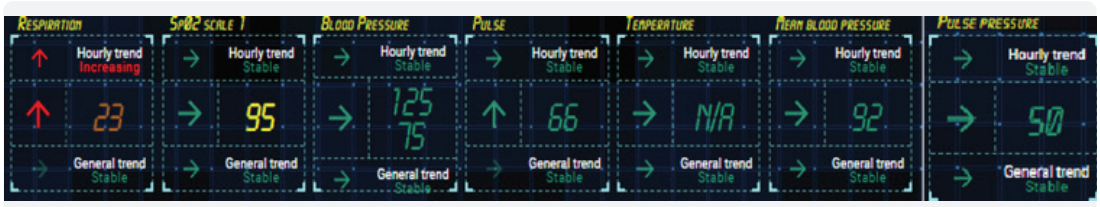
Move the mouse over the graph to see more detailed information about the values through different time intervals.



- Numeric and graphical presentation of the "Deterioration risk" – based on the vital parameters and evaluated by the system risk.

- Numerical values of the vital parameters, as well as their trends.

The values of the parameters as well as the arrows showing their trend are colored depending on their critical levels.



When a certain indicator is missing data (the corresponding sensor is either detached or missing), the following indication is displayed and the value is marked as “N/A”.

- Numeric and graphic representation of the patient’s blood pressure trends.

You can check the values of the blood pressure through the different hours of the day, by moving through the graph using your mouse.

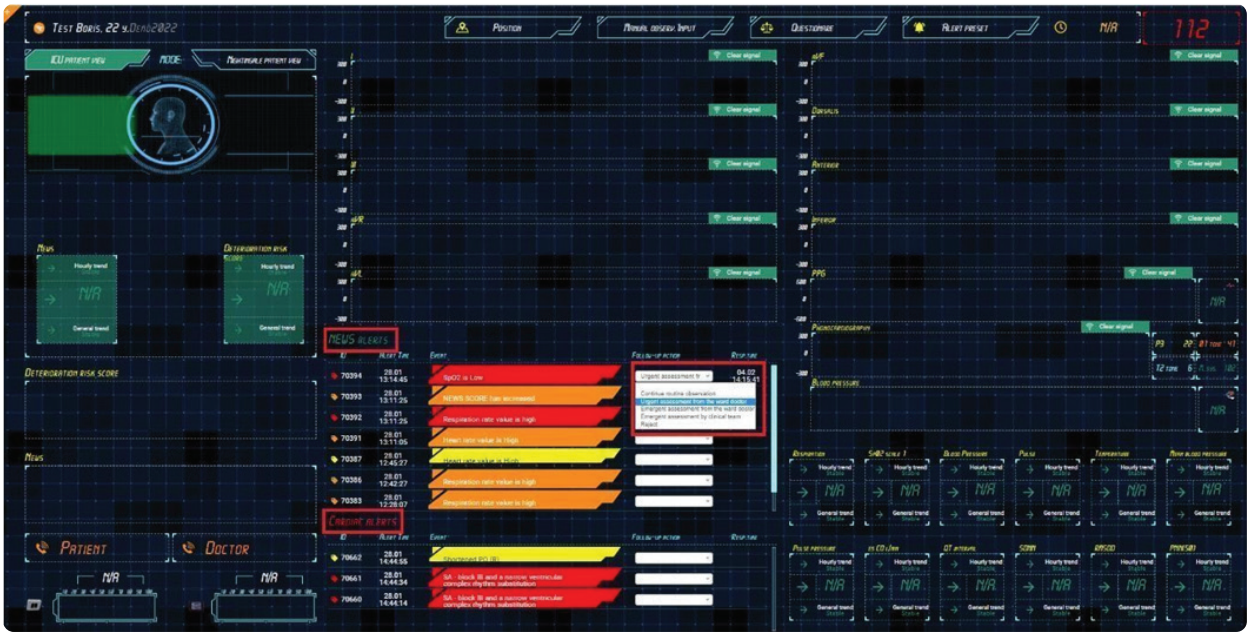
Alerts

Two types of alerts are generated by the system:

- **NEWS alerts**– Based on predefined values of the vital parameters.
- **Cardiac alerts** — Based on labelled ECG pathologies in the “Raw data” screen.

For both types of notifications, it is expected that the user will evaluate the risk and, if needed, will take necessary action.

These actions are predefined and are selected from the drop-down menu.



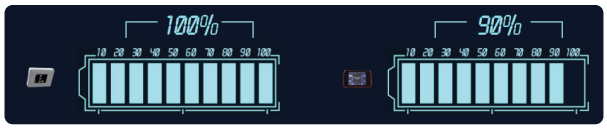
Other Possibilities

From the ICU screen, the user can directly access the “Raw data” screen by pressing this button:

By using these buttons:

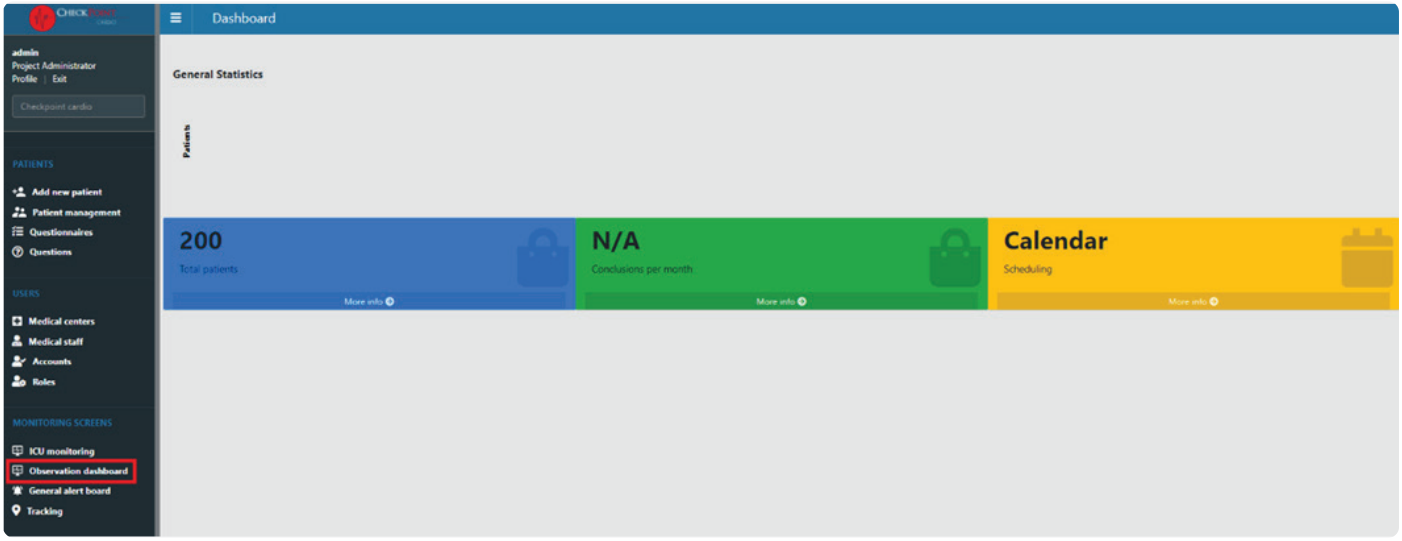
The user can contact the patient, the on-duty physician or the national emergency services line (these buttons work only when the phone is connected and configured to work with the system) if needed.

The values of the remaining battery charge of the medical device and the communication device:

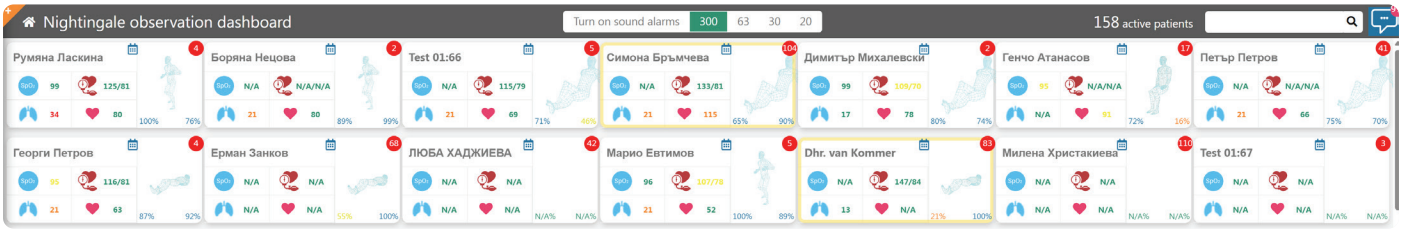


Observation dashboard

To access the “Observation Dashboard”, select the “Observation Dashboard” option from the main dashboard.



Once you access this menu, you can see all currently observed patients in the medical center.



For each patient, the following information is displayed:

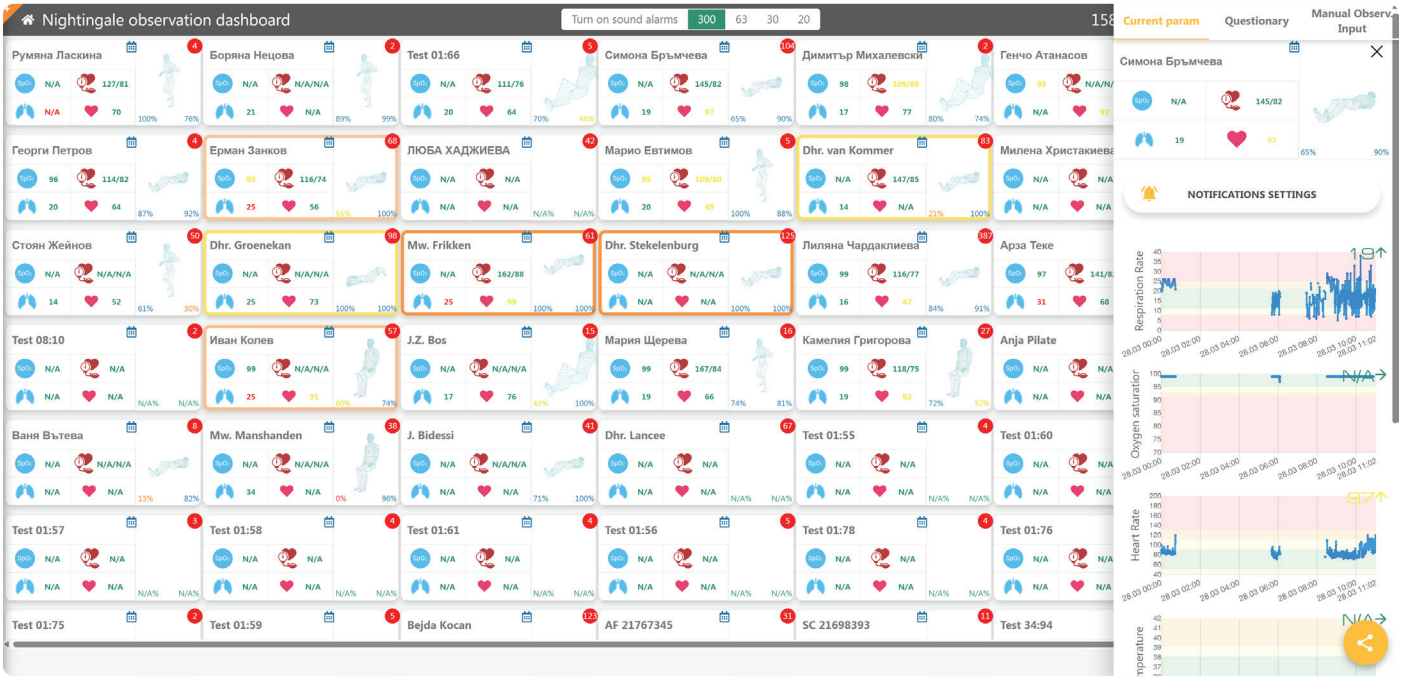
- **Patient's name**.
- **NEWS**— Standardized scale which represents the patient's general condition based on the monitored parameters.
- **Deterioration risk**- Represents the probability of the patient's health to deteriorate, based on the change of the vital parameters.
- **Patient activity** — Represents the patient's position and body activity.
- **SpO2** — Patient's real-time SpO2 value.
- **Pulse** — Patient's real-time pulse value.
- **The patient's communication and medical device battery level**.

Please note that displayed parameters depend on the measuring equipment currently placed on the patient.

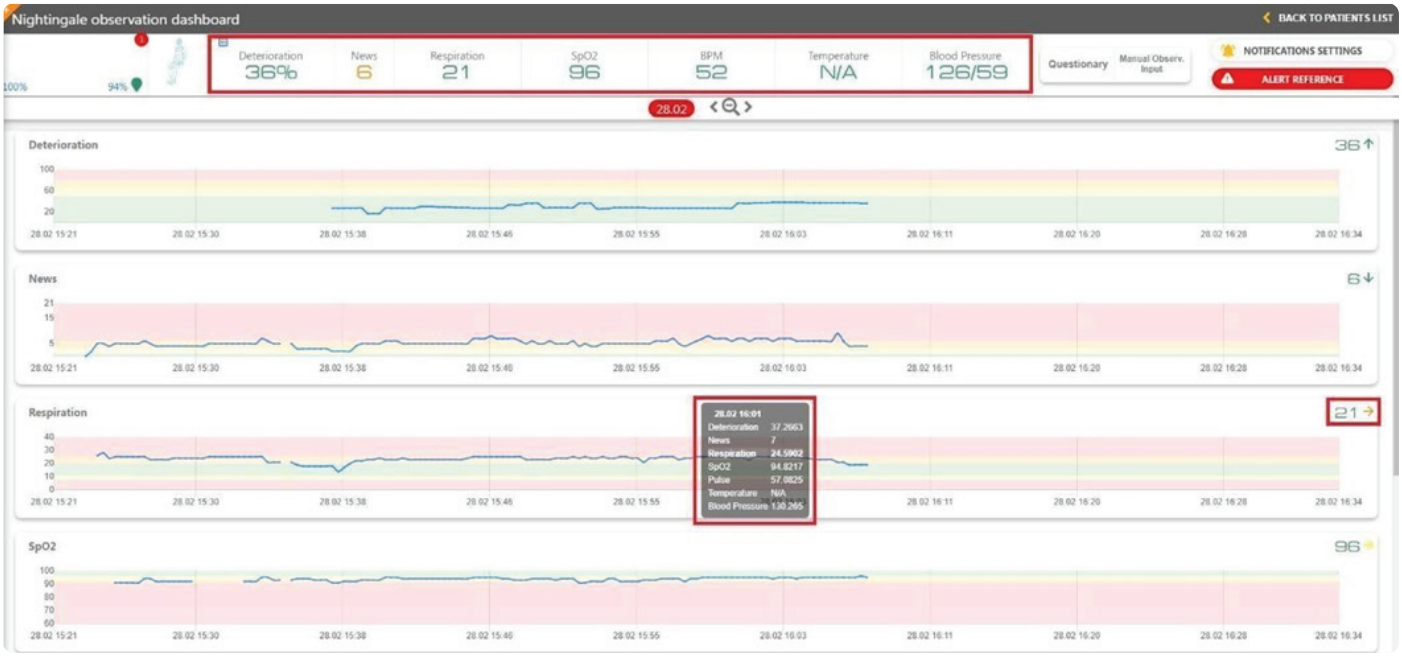
Depending on how critical the values of the measured parameters are, the patient will be highlighted accordingly:

Individual patient observation

To observe the numerical and graphical representation of the monitored vital parameters click on the patient's name.



To observe an individual patient, click on one of the graphs with your mouse (to return to the list containing all patients, press the “BACK TO PATIENTS LIST” button).

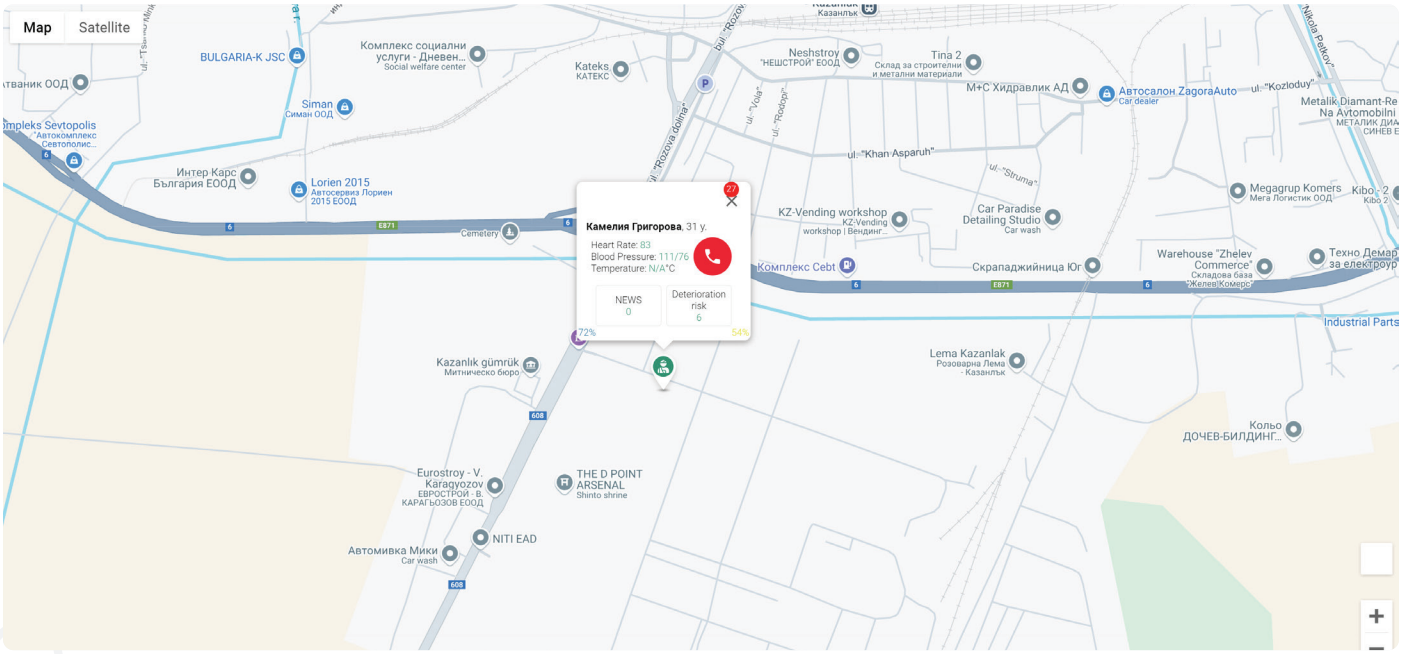


In the upper part of the screen, a real time numerical representation of the observed vital parameters is displayed. The colors of the parameters are related to their critical level.

The history of the vital parameters is represented in a graphical format. The colors of the graphics are related to the critical level of the measured parameter. Move your mouse along the graphics to see a numerical representation of the parameter during the corresponding time interval.

In the upper right corner of each graphic, the real time value of the observed parameter is shown. The arrows represent the development trend.

To see the patient’s physical location on the map click on the following icon:

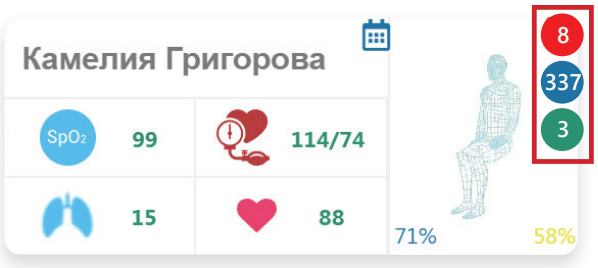


To receive additional information regarding the patient and their position, press the following button:

Please note that this feature availability depends on the patient's measuring equipment!

Alerts – Observation Dashboard

Alerts are displayed in the upper right corner of the patient window and are divided into three types:



- **Red notifications** – These notifications are related to the patient's deterioration score based on the predefined values of the measured parameters and to the cardiac alerts labeled in the patient's "Raw data" screen. Alerts related to the patient's measuring and communication equipment are also presented here.
- **Blue notifications** – These notifications are related to the tasks set in the patient's clinical plan. When tasks are not completed or confirmed for a certain period (30 minutes), an alert is generated.
- **Green notifications** – These notifications are related to the completion status of the patient's daily tasks.

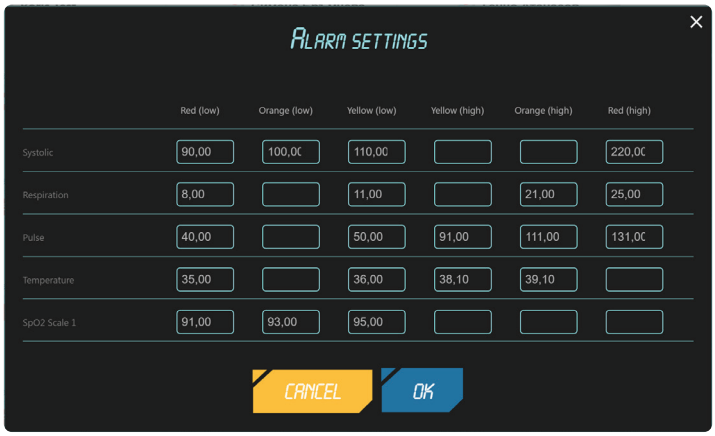
Additional "Observation Dashboard" options

ALERT REFEERNCE

This button will take the user to that specific patient's alert board where "NEWS alerts" and "Cardiac alerts" can be viewed, and follow-up actions can be taken.

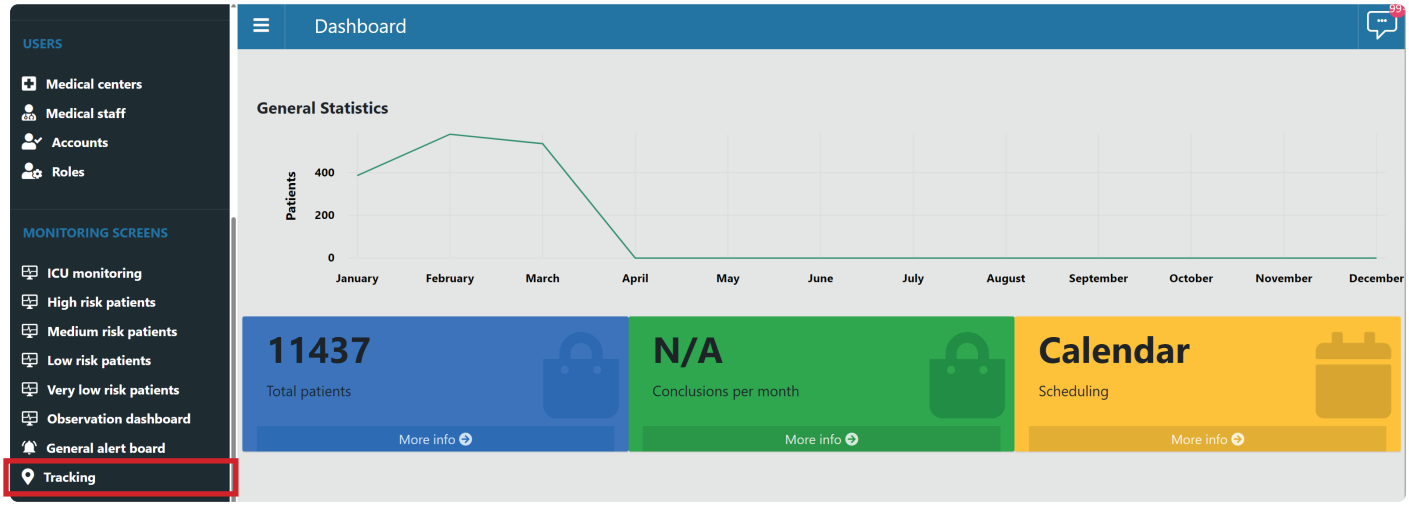
NOTIFICATIONS SETTINGS

The user can tune the alerts (sound or vibration) of the patient when any of the monitored parameters go outside of the predefined limits.

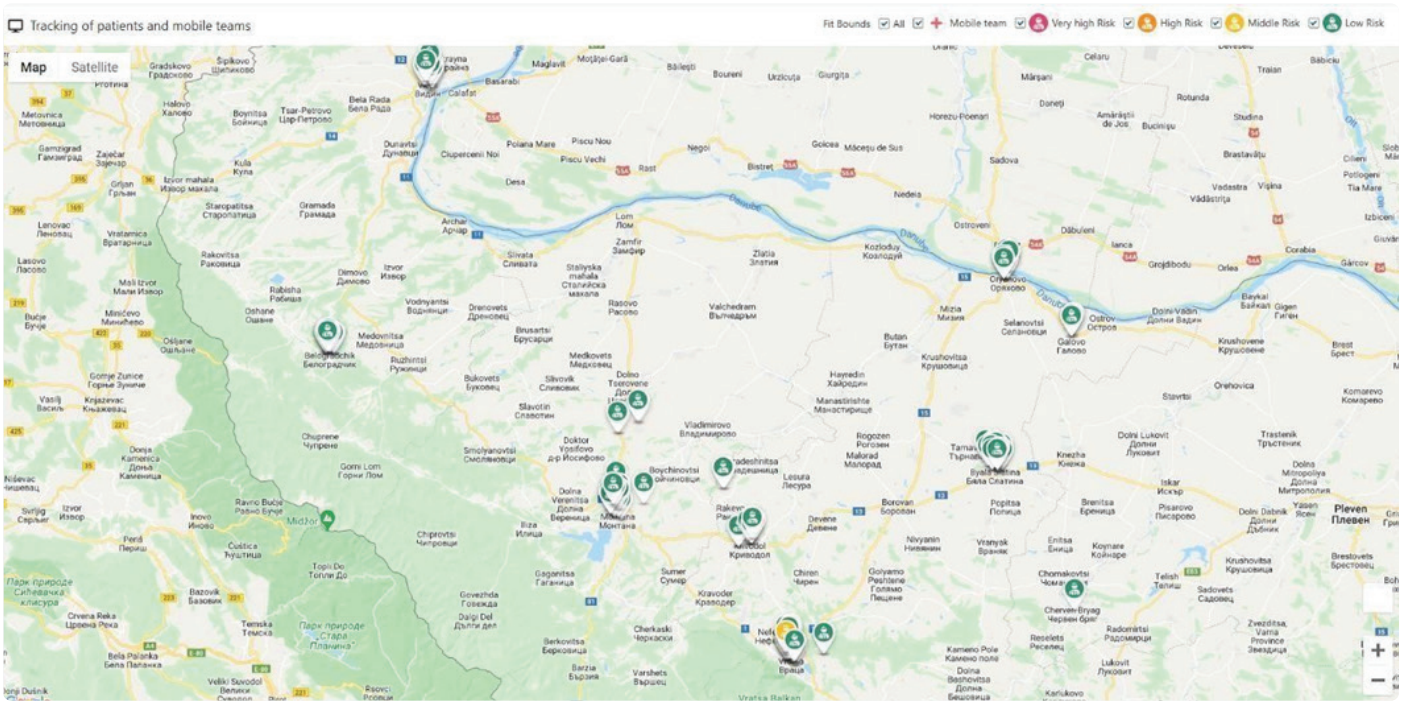


Tracking

This menu is used to monitor the physical position of all currently active patients on “Google Maps”.

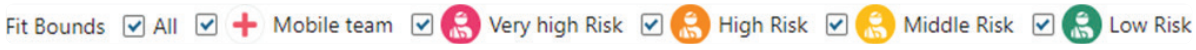


To access this menu, select “Tracking” in the main dashboard.

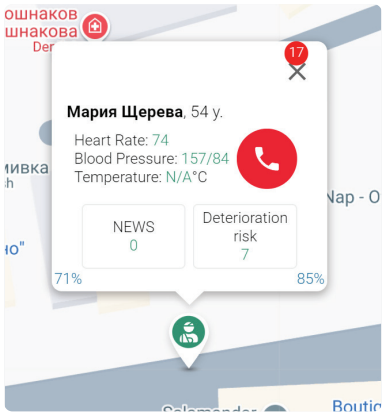


Based on the patients’ health risk, each positional marker is presented in the according color.

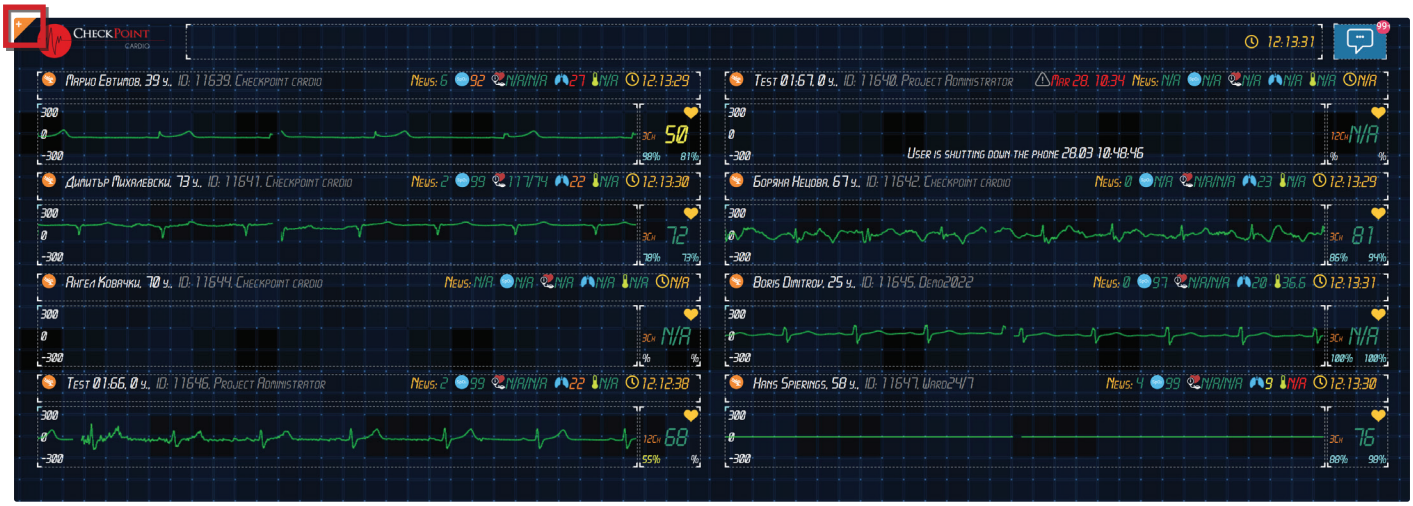
Use the provided menu (in the upper right corner) to filter the patients based on their health risk. Only the options that are checked will be displayed on the map.



To receive additional information about the patient, click on their position marker.



Use this icon (in the upper left corner) to quickly switch between the following screens: “ICU monitoring”, “Observation dashboard”, “General alert board” and “Tracking”



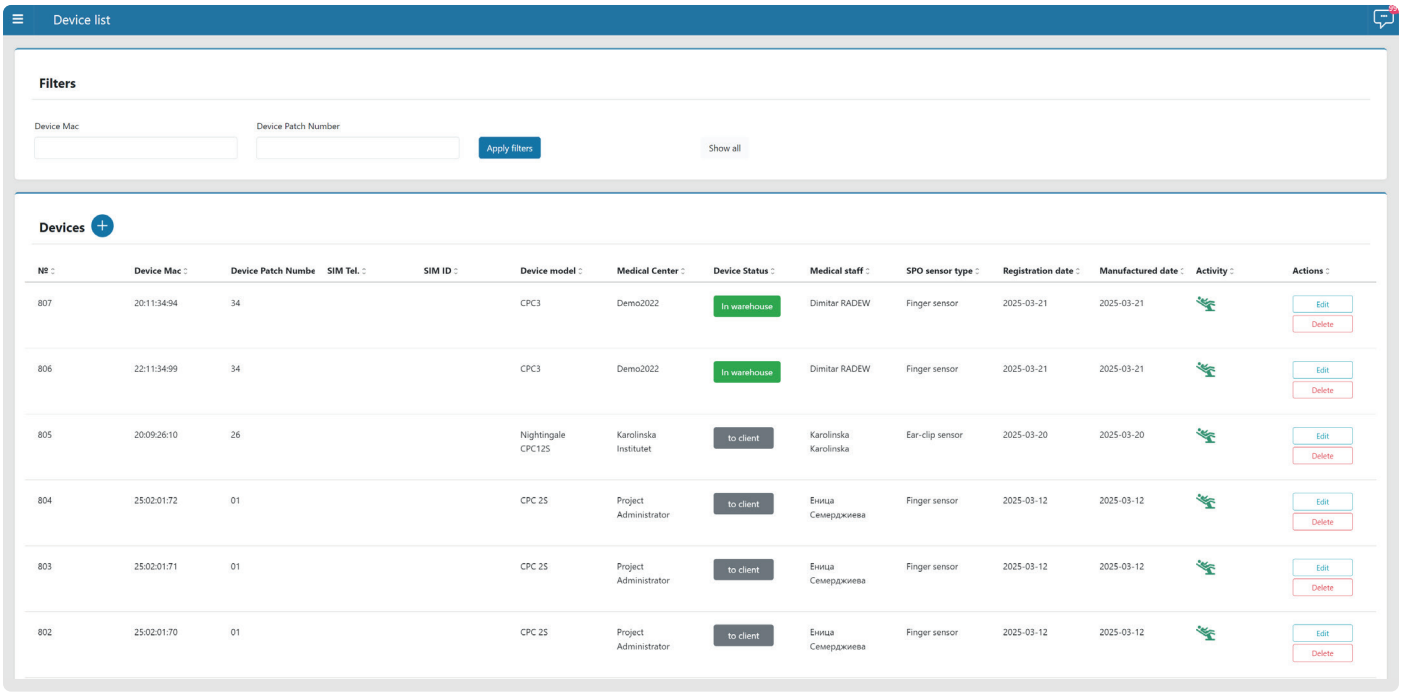
SYSTEM

Devices list

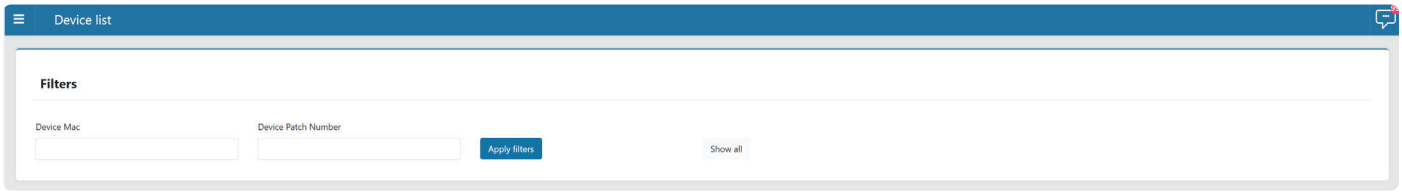
This menu is used to check which medical devices are assigned to a medical center.

To access this menu, select “Device List” from the main dashboard.

When first accessing the menu, you will see all the currently available devices for your medical center.

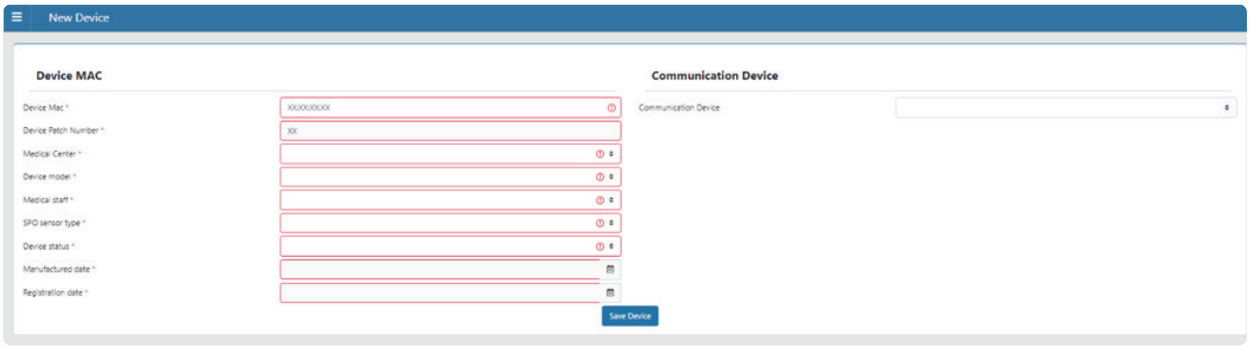


To search for specific devices, use the provided filter options. To see all devices registered to the medical center, select the “Show all” button.



To add a new device to your medical center, select the blue “+” button.

After selecting the blue “+” button you need to follow these steps to finish adding the new device to your medical center



- **Device Mac** – Enter the serial number of the device. The serial number or “MAC” is the unique physical address of a device. Please follow the specified MAC address format when filling in the field.
- **Device Batch Number** – The field is related to the device batch number and is filled-in automatically by the system, based on the MAC address of the device.
- **Medical Center** – Select the name of the medical center that the device will be assigned to from the drop-down.
- **Device model** – Select the device model from the drop-down menu.
- **Medical staff**– Select the medical personnel that will have the device assigned to them from the drop-down menu.
- **SpO2 sensor type** – Select the type of SpO2 sensor that will be used with this device.
- **Device Status** – Select the status of the device:

  – **to client** – This status indicates that the device is currently in use by a patient. Devices that have this status attached to them cannot be selected from the “Device” drop-down menu in the patient admission form.
  – **in warehouse** – This status indicates that the device is currently not in use and can be selected from the “Device” drop-down menu in the patient admission form.
  – **in service** – This status indicates that the device is currently not available because it is undergoing maintenance at our service center. It will not be available for selection in the “Device” drop-down menu in the patient admission form.

Please note that the “Device status” is automatically changed from “in warehouse” to “to client” when the device is being used by a patient. When the patient is disconnected, the device status will automatically change from “to client” to “in warehouse”.

- **Manufactured date** – Specify the manufacturing date of the device in this field.
- **Registration date** – Specify the date that the device was added to the system for the first time.

To edit already existing device information, select the Edit button. After you’re finished editing, select the “Save” button.

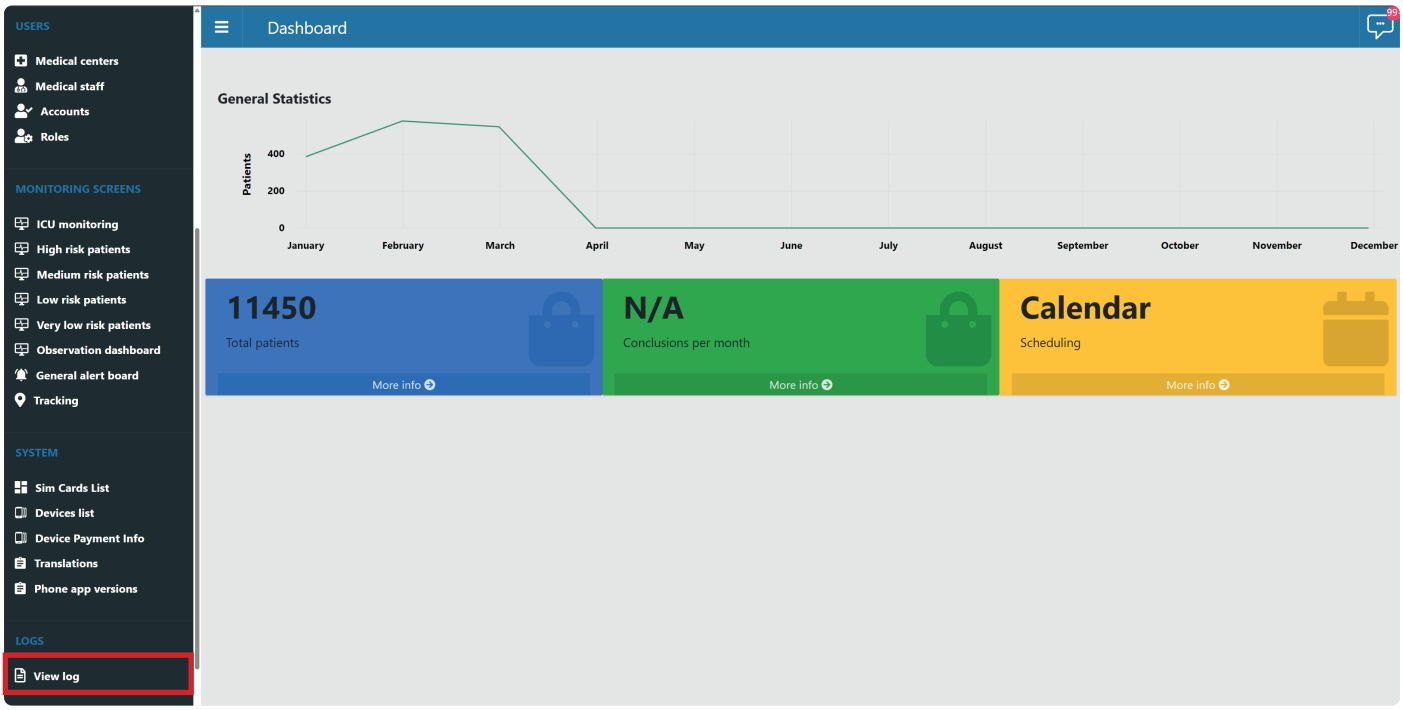
To remove a device from the medical center, select the Delete button.

AUDIT LOGS

View log

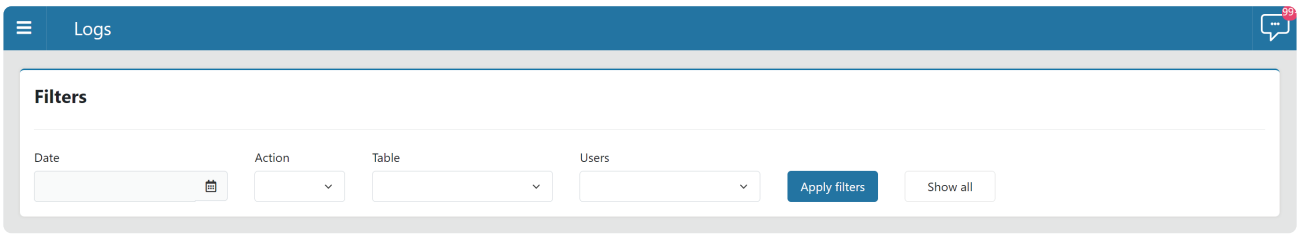
The “View Logs” menu is used to track user activity in the system for a specific medical center.

To access it, select the “View Logs” option from the main dashboard.



All the system information is stored in different database tables. Any action which the user takes regarding patient information such as adding, deleting or updating it anywhere in the system, is tracked.

You can use the provided filters to refine your search results.

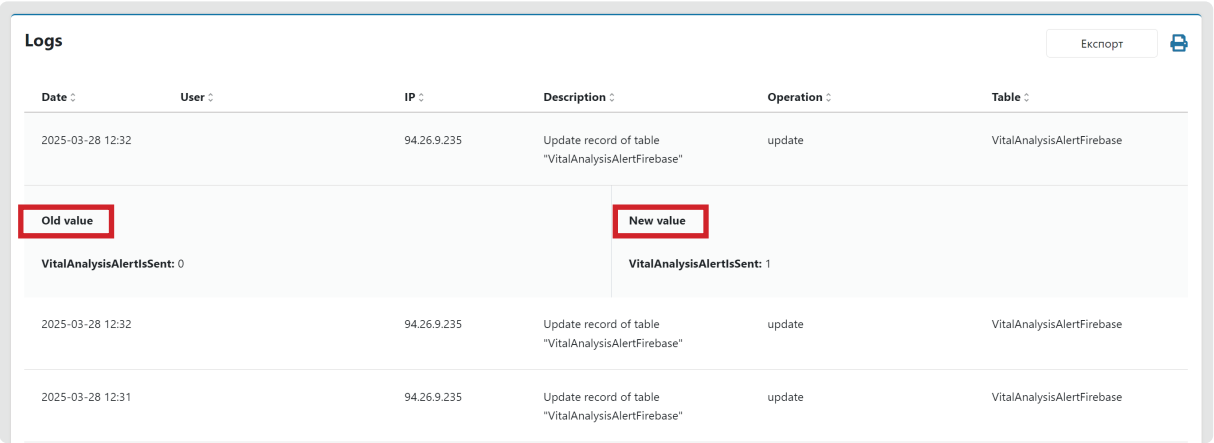


- **Date** – Set the date you are interested in from the drop-down menu.
- **Action** – Set the type of actions you are interested in from the drop-down menu. The following user interactions can be tracked:

  – **insert** – These types of actions are related to inserting information in database tables.
  – **update**- These types of actions are related to updating any existing information in specific database tables.
  – **delete** - These types of actions are related to deleting existing information in specific database tables.
  – **Table** – Select the table for which you want to track changes in the drop-down menu.
  – **Users** – Select a specific user or users whose actions you wish to track from the drop-down menu.

Once you’re done with your filter selection, select the “Apply Filters” option to apply them.

To receive more detailed information regarding an action, select it. Information for the “Old value” and “New value” change is then displayed.



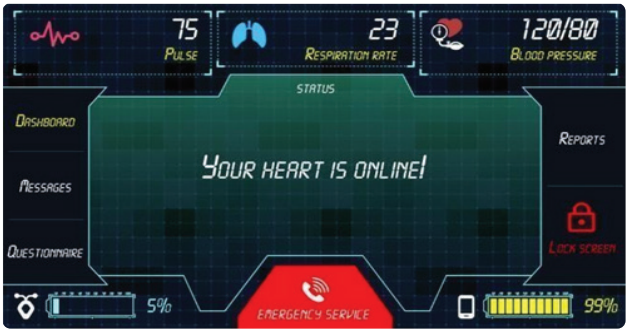
The following information is available for each log:

- **Date** – Date and time when the parameter was changed.
- **User** –System user who made the change.
- **IP** – The IP address from which the user has accessed the system and made the change.
- **Description** – Specifies which table and what kind of action was executed.
- **Operation** – Specifies what kind of action was executed on the parameter by the user.
- **Table** – Specifies which tables were affected by the change.

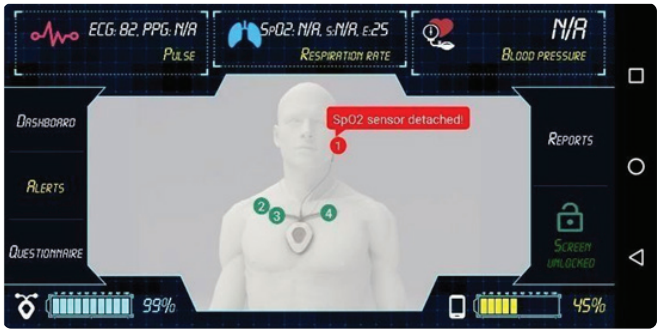
To export or print the information in this log, select the “Export” or “Print” button respectively.

Activating the Communication Device

Switch the communication device on by holding down its power button. The communication device will then start, and you will be taken to the following screen.

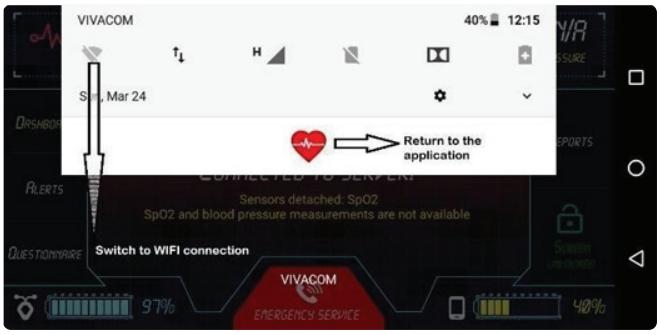


This message confirms that the device has successfully connected to the server.

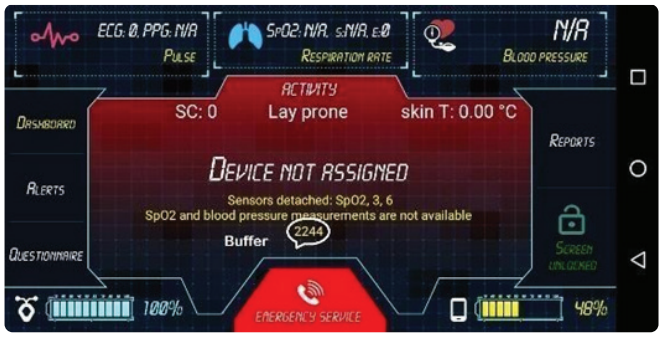


If yellow alert messages appear on the main screen, press the **Alert** button to view details about the issue.

If the device cannot connect to the server, swipe down on the screen and verify the WiFi or 3G connection status, as shown in the image above.



The communication device can switch between WiFi and 3G networks as needed.



The device temporarily stores data packets in a local database. The buffer value indicates how many data packets have not yet been sent to the server. Once the connection to the server is restored, the buffer value will reset to zero.

THE MESSAGES SHOWN ON THE COMMUNICATION DEVICE	
“Device is not assigned”	The device is not receiving acknowledgment signals confirming that the data has been successfully delivered to the file server.
“SpO2 sensor is detached”	The SpO2 sensor is not properly attached to the ear, or the sensor cable is damaged.
“ECG sensor is detached”	The ECG signals are of unacceptable quality. Possible reasons include de-tached sensors or expired electrodes.
“Device is detached”	The device is not attached to the patient. It may be placed on a table or in a box. In this case, vital sign values will not be displayed on the screen.
“Low quality SpO2 signal “	The SpO2 sensor is attached, but the device cannot determine the SpO_2 value. Possible causes include low perfusion at the measurement site or excessive patient movement.
“Please charge the communication device”	The battery level of the communication device is below 15%.
“Please charge the medical device”	The battery level of the medical device is below 15%
“Connecting to server”	The device is transmitting data packets to the server, but acknowledgment signals confirming receipt have not been received.
“Connected to server”	The device has received acknowledgment signals from the server, con-firming that the transmitted data packets have been successfully accept-ed.
“Device is not connected”	There is no connection between the medical device and communication device. A problem with Bluetooth pairing is possible. Press the lock/unlock button 10 times to check
“Device connecting”	The communication device is attempting to establish a connection with the medical device.
“Low quality Bluetooth signal”	The distance between the medical device and the communication device is too large, preventing the normal transfer of both historical (buffered) data and real-time data streams.
“Your heart is online !”	If this message appears, the device is correctly installed, and communica-tion has been successfully established.

Patient Monitoring

The medical device transmits data to the communication device via a Bluetooth Low Energy (BLE) connection. Real-time values of vital parameters are displayed on the 5.8-inch screen, along with statistical information over selected time periods. Raw data from all measured signals is transferred to the file server, where it is stored, displayed, and available for further analysis.

After placing the patch and connecting the device, open the **ICU Monitoring** page to verify that all ECG leads are correctly attached and functioning properly. Once proper connectivity is confirmed, the communication device will display the message: “**Your heart is online**.” To monitor all vital parameters, navigate to the main menu and select the patient’s name.

All valid ECG Leads are used to detect the patient's **heart rate**. QRS complexes and their corresponding R-wave peaks (Rmax), along with the timestamps of maximum QRS amplitudes, are identified using a specialized velocity method. This approach involves generating a special velocity (SV) signal for QRS slope detection and employing a set of adaptive beat-detection thresholds.

The Hilbert Transform method has a unique property of producing zero-crossings at peak-value locations. Using these zero-crossing points, corresponding R-peak locations are identified to detect pauses **(Pause Detection)**.

The medical device model **CPC12S** supports the detection of **ST elevation**. The device does not measure atrial fibrillation **(AF)** or ventricular fibrillation **(VF)**

Automatic Alert and Patient Physiological Parameter Reporting System

The system integrated into the CPC desktop application for monitoring physiological parameters is based exclusively on the standardized early warning decision support framework known as **NEWS2** (National Early Warning Score 2).

NEWS2 is the latest version of the National Early Warning Score (**NEWS**), initially released in 2012 and updated in December 2017. It provides a standardized approach for assessing and responding to acute clinical deterioration.

NEWS2 has received formal endorsement from NHS England and NHS Improvement, establishing it as the primary early-warning system for identifying acutely ill patients—including those with sepsis—in hospitals across England.

5.1. The NEWS Clinical Observation Chart

To ensure a standardized and consistent approach to recording vital signs data, a color-coded clinical chart (**NEWS Chart**) has been developed and widely implemented across the NHS. This chart is designed for recording routine clinical observations and monitoring a patient's clinical condition. The primary objective of this chart is to promptly alert clinical teams to any significant clinical deterioration and to facilitate effective monitoring of patient recovery. The NEWS score assists in determining the urgency and scale of the clinical response required.

5.2 NEWS 2 Observation screen layout:

Chart 1: The NEWS scoring system

Physiological parameter	Score 3	2	1	0	1	2	3
Respiration rate (per minute)	≤8		9–11	12–20		21–24	≥25
SpO_2 Scale 1 (%)	≤91	92–93	94–95	≥96			
SpO_2 Scale 2 (%)	≤83	84–85	86–87	88–92 ≥93 on air	93–94 on oxygen	95–96 on oxygen	≥97 on oxygen
Air or oxygen?		Oxygen		Air			
Systolic blood pressure (mmHg)	≤90	91–100	101–110	111–219			≥220
Pulse (per minute)	≤40		41–50	51–90	91–110	111–130	≥131
Consciousness				Alert			CVPU
Temperature (°C)	≤35.0		35.1–36.0	36.1–38.0	38.1–39.0	≥39.1	

5.3. Definition of alerts and thresholds:

A score is assigned to each measured parameter, with the magnitude of the score corresponding to the degree of deviation from the normal range. These individual scores are then aggregated into a total score. For patients requiring supplemental oxygen to maintain recommended oxygen saturation levels, the total score is increased by 2 points. Alerts and their corresponding values are displayed according to the NEWS standard in green (NEWS 0), yellow (NEWS 1), orange (NEWS 2), and red (NEWS 3 or higher).

See the figure below for details:

Chart 2: NEWS thresholds and triggers

NEW score	Clinical risk	Response
Aggregate score 0–4	Low	Ward-based response
Red score Score of 3 in any individual parameter	Low–medium	Urgent ward-based response*
Aggregate score 5–6	Medium	Key threshold for urgent response*
Aggregate score 7 or more	High	Urgent or emergency response**

* Response by a clinician or team with competence in the assessment and treatment of acutely ill patients and in recognising when the escalation of care to a critical care team is appropriate.

**The response team must also include staff with critical care skills, including airway management.

Alerts for Clinical Response According to the NEWS2 Standard:

Chart 4: Clinical response to the NEWS trigger thresholds

NEW score	Frequency of monitoring	Clinical response
0	Minimum 12 hourly	• Continue routine NEWS monitoring
Total 1–4	Minimum 4–6 hourly	• Inform registered nurse, who must assess the patient • Registered nurse decides whether increased frequency of monitoring and/or escalation of care is required
3 in single parameter	Minimum 1 hourly	• Registered nurse to inform medical team caring for the patient, who will review and decide whether escalation of care is necessary
Total 5 or more Urgent response threshold	Minimum 1 hourly	• Registered nurse to immediately inform the medical team caring for the patient • Registered nurse to request urgent assessment by a clinician or team with core competencies in the care of acutely ill patients • Provide clinical care in an environment with monitoring facilities
Total 7 or more Emergency response threshold	Continuous monitoring of vital signs	• Registered nurse to immediately inform the medical team caring for the patient – this should be at least at specialist registrar level • Emergency assessment by a team with critical care competencies, including practitioner(s) with advanced airway management skills • Consider transfer of care to a level 2 or 3 clinical care facility, ie higher-dependency unit or ICU • Clinical care in an environment with monitoring facilities

1. Physical Device Removal

To remove the patch from the patient, first disconnect the electrodes from the patient's body. Then remove each electrode from the patch by holding the electrode knob with one hand and gently pulling the electrode with the other.

⚠ **Important**: Do not pull directly on the patch, as this can significantly shorten its lifespan.

2. Charging the Device

The CPC12S medical device is powered by a rechargeable LiPo battery housed within the battery pack. The battery capacity is 1000 mAh at 3.7 V, and it carries a valid CE certificate.

To charge the battery pack:

- Connect the battery pack to the docking station.
- Use the provided adapter (110—250 V compatible) connected via a standard USB-A cable on both ends.
- Ensure the charger used is CE-marked.

The LED indicators will begin flashing slowly from one LED, progressively lighting up until all LEDs are steadily illuminated, indicating the battery is fully charged.

3. Device Maintenance and Cleaning

It is recommended to clean the device and patch before each patient examination:

- Use a soft cotton cloth dampened with 70% alcohol solution.
- Wipe gently without applying excessive pressure, giving particular attention to any embossed or raised areas.
- When cleaning the device's side panel, ensure liquids do not enter the cable or connector outlet.

The ECG patch and SpO_2 sensor cable may be cleaned using either hydrogen peroxide (3%) or isopropyl alcohol (70%).

⚠ **Important:** Never place the oximeter sensor into a high-pressure container and never immerse the sensor directly into any liquid.

4. Proper Disposal of the Product

This refers to the disposal of electrical and electronic equipment. It is applicable in the EU and other European countries which collect waste separately. This symbol on the product or in the accompanying literature indicates that the product should not be disposed of in daily waste. Medical device model CPC12S must be recycled to avoid possible damage to the environment or human health from uncontrolled waste disposal and to promote the reuse of materials and resources. It is your responsibility to dispose of the device separately from general household waste when it is unusable. For this purpose, return the medical device to the manufacturer by sending it to the address indicated below.

5. Troubleshooting

If the communication device displays the message "**Device disconnected**" and the green LED on the medical device is blinking, verify proper pairing:

- Press the **Lock/Unlock** button **10 times** consecutively.
- A list of nearby Bluetooth devices will appear. The paired medical device will be indicated with a star (★) next to its name.

6. Product storage and Operational Conditions

- Environmental Conditions:
- Operating Temperature: 5°C~40°C Storage Temperature: -20°C~55°C
- Humidity: ≤80%, no condensation in operation
- ≤93%, no condensation in storage

Device Specifications

MEDICAL DEVICE MODEL CPC12S	
Dimensions	67mm x 101mm x 12mm
Weight:	0.080 kg
Operation time:	30 h
Power:	From battery pack 1000 mAh.
Power consumption:	0.1 W
Storage memory	7 days
Charger:	Auto switching 110 -240 VAC (external adaptor)
Power:	Internal battery 3.7 V
Power check button:	Yes
ECG	
Leads (Three patches)	2 lead, 3 Lead, 12 Lead
ECG Cable	Reusable patch
Sample Rate	250 Hz
Lead Detection	Yes
Respiration rate	Yes
SPO2	
Range:	70 to 100 %
Sensor:	Finger probe
Alarm:	No
Temperature	
Range:	34 – 43 Deg C
Sensor:	Skin Temperature – patch
Blood pressure	
Systolic:	60 – 250
Diastolic	40 – 150
Pulse Rate	
Range	30 – 260 Beat per minute

Warnings and Precautions

⚠	Model CPC12S is a device for monitoring the vital parameters of the human body. Its main purpose is to help medical specialists to monitor their patients. The CPC12S medical device cannot replace medical examinations and consultations!
⚠	The device is not classified as waterproof. Do not use the device in wet environments such as: rain, bathrooms, showers, and other areas where water could reach the device. The device works normally with perspired patients.
⚠	The Device is not defibrillator-protected, do not use with not-implanted defibrillator. For safety reasons — Remove the electrodes, patient lead wires, and main box from the patient before defibrillation.
⚠	The device is not intended for infants weighing less than 10 kg
⚠	Do not let your medical device model CPC12S get wet — liquids could cause serious damage.
⚠	Do not store medical device model CPC12S in a dirty or dusty place to prevent damage.
⚠	Avoid dropping, throwing, or crashing your device into other objects.
⚠	The device could be damaged if it is exposed to magnetic fields.
⚠	Do not expose your device to high or low temperatures. This could shorten the life of the battery or melt some plastic elements. When the environment in which the device is located has rapidly changing temperatures, it can get wet and could damage the electronic circuit boards.
⚠	Do not use corrosive materials or cleaners to clean the device.
⚠	Do not paint the device.
⚠	Do not open the device on your own and do not let unqualified people do so. The device contains small parts that could be broken, as well as the device itself.
⚠	Always carry medical device model CPC12S in its bag to ensure proper functioning. The bag is designed to provide the best protection for your device.
⚠	There are no user-serviceable components inside the system. Authorized service personnel should do all internal troubleshooting and repair or replacement using only parts and accessories approved by Check Point R&D.
⚠	Periodically check all connector cables for damage. Do not operate the equipment if the integrity of these components is questioned.
⚠	Only people who are qualified, competent, and have the right knowledge about laws regarding telemedicine should operate this device.
⚠	The device is not intended to be used with HF surgical equipment
⚠	The Bluetooth® transmission may be influenced in different environments by materials such as walls, metallic doors, steel wire netting and an MRI or a CT environment.
⚠	Never place the battery packs of the CPC12S in heating devices such microwaves and ovens or electric heaters. Batteries can explode if heated. Do not break the integrity of the battery pack. Be careful not to expose the battery to external pressure - this could cause short circuiting and overheating.
⚠	The battery pack may heat while charging.
⚠	Proximity to magnets, metal detectors, high-voltage electrical wires, and electrical appliances such as shavers, toothbrushes, and hair dryers may have an influence on the signal quality.
⚠	Excessive perspiration may cause the electrodes to loosen or detach completely.
⚠	Inaccurate SpO2 measurements and readings may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquids.
⚠	Intravascular dyes such as indocyanine green or methylene blue may cause inaccurate SpO2 readings.
⚠	SpO2 measurements may be adversely affected in the presence of higher ambient light.
⚠	Excessive patient movement may cause inaccurate SpO2 readings.
⚠	The reusable patch is designed for 100 examinations. After this period, a possible degradation or malfunctions can occur.
⚠	The device cannot be attached by disabled persons. Care-givers should perform the installation instead.

Liability Notice

Failure to comply with the instructions outlined in this manual shall absolve Check Point R&D of any responsibility regarding the safety, reliability, and performance of this equipment. All operators must thoroughly read this manual before operating the system. Only authorized personnel may perform assembly, modification, or repairs. Electrical wiring must meet local regulatory standards. Use the equipment strictly in accordance with its intended use.

Terms of Warranty

Check Point R&D will, at its sole discretion, either repair or replace any part of its products found to be defective due to improper workmanship or materials. Repaired or replacement parts or products will be provided by Check Point R&D on an exchange basis. This warranty does not cover damage resulting from accidents, abuse or misuse, natural disasters or personal catastrophes, or unauthorized disassembly, modification, or repairs. CPC12S medical devices sold by Check Point R&D carry a warranty of 12 months from the date of purchase; all associated accessories, supplies, and disposable components carry a warranty period of 30 days from the date of purchase. This warranty is strictly limited to the repair or replacement of defective Check Point R&D products as described above. Check Point R&D shall not be liable for, and explicitly excludes from warranty coverage, any costs associated with patient care, servicing, or product installation. Check Point R&D commits to continued product support and will not discontinue or obsolete its products as long as necessary components and materials remain commercially available and reasonable customer demand persists.

Incident Reporting

In the event of an incident or adverse event related to the use of the CPC12S medical device, please notify the manufacturer immediately:

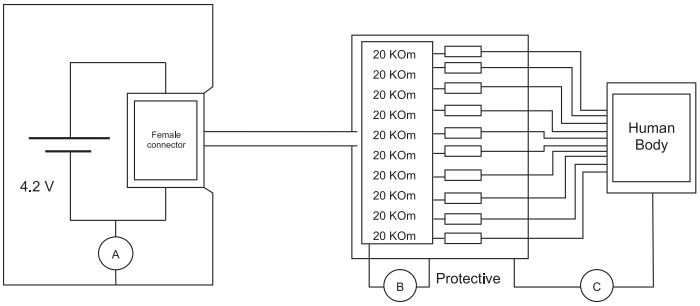
Check Point R&D Ltd.
Address: 37 Osvobojdenie Str, 6100 Kazanlak, Bulgaria
Phone: +359888920108
E-mail: info@checkpointcardio.com
Website: www.checkpointcardio.com

When reporting an incident, please provide the following information:

- The serial number of the device;
- A detailed description of the incident or adverse event;
- The date and location of the incident;
- Patient information (if applicable, without personal data);
- Name and contact details of the person reporting the incident.

The manufacturer will promptly conduct an investigation, take the necessary corrective actions, and, if required, notify the competent regulatory authorities in accordance with the requirements of Regulation (EU) 2017/745.

Device Insulation Diagram



Manufacturer's EMC Declaration

Guidance and manufacturer's declaration — electromagnetic emissions		
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should be sure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment — guidance**
RF emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration — electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment — guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+ 6 kV contact (ECG Data) + 8 kV air (ECG Data)	+ 6 kV contact (ECG Data) + 8 kV air (ECG Data)	The floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic discharge (ESD) IEC 61000-4-2	+ 8 kV contact SpO2, Temp + 15 kV air SpO2 , Temp	+ 8 kV contact SpO2, Temp + 15 kV air SpO2, Temp	The floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m, 50Hz ECG	3 A/m, 50Hz ECG	If image distortion occurs, it may be necessary to position this device further from sources of power frequency, magnetic fields, or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to ensure that it is sufficiently low.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50Hz SpO2 Temp	30 A/m, 50Hz SpO2 Temp	
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity

This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device must assure that it is used in such an electromagnetic environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Conducted RF IEC 61000-4-6	150kHz-80MHz, 3V rms, 80% AM (1kHz) (6Vrms for ISM bands)	1 V_{active}	Portable and mobile RF communications equipment should be used no closer to any part of This device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter **Recommended separation distance** $d=1.16\sqrt{P}$ $d=1.2\sqrt{P}$ 0,15 MHz to 80 MHz $d=2.3\sqrt{P}$ 80 MHz to 2.7 GHz where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and ***d*** is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	80MHz - 2700MHz, 3V/m, 80% AM (1kHz)	10 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

b) The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the this device is used exceeds the applicable RF compliance level above, then this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this device.

d) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Symbols and Meanings in the Label Prepared in Accordance with EN 15223-1 Standard

Guidance and manufacturer's declaration — electromagnetic immunity			
CHECK POINT CARE	Company Logo	**Multiple Physiological Parameter Ambulatory Telemonitoring System Model CPC12S**	Product Name
CE 2195	Notified Body Number	SN	Serial Number
	Refer to instruction manual / booklet		Date of Manufacture
	Manufacturer		Keep Dry
	Barcode Number		Type BF Applied Part
	Protective earth (ground)		Class II equipment
	Caution	IP22	IP Declaration
LATEX	Latex Free	PVC	PVC Free
	Bluetooth Wireless Communi-cation Technology Not ionizing radiation — Device including Blue-tooth based RF transmitter.		Power Supply
	Humidity limitation		Temperature limit

CHECK POINT
R&D

37 Osvobojdenie str.
Kazanlak Bulgaria

info@checkpointcardio.com

0700 10 282