



The PEDIARITY™
HealthCare Professionals (HCP)
Instructions for Use (IFU)



	Pediarity™	Version D
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Manufacturer Contact Details:
GABI SMARTCARE® SA
Rue Emile Francqui, 6
1435 Mont-Saint-Guibert (Belgium)

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1. Welcome to Gabi™

Thank you for joining us and our Gabi™ community! Thank you also for your trust in our product. For an optimal use and to ensure product safety, we strongly recommend you read the following instructions before starting to use Gabi™ Analytics.

This manual includes information for the proper use of the Gabi™ Analytics. It also provides features, operations and safety recommendations.

If your questions are not addressed in these instructions for use, please contact our customer service (see contact details on page 58).

2. About Pediarity™ System

The Pediarity™ system is a non-invasive, innovative, and advanced solution that allows to measure wirelessly several physiological parameters (SpO₂, Pulse Rate, Respiratory Rate) of neonates¹, infants, and children up to 12 years old in non-motion condition.

The Pediarity™ system is composed of:

- a) A **Gabi™ Band**, a non-invasive, wearable, wireless measuring device positioned around the patient’s upper arm.
- b) **Gabi™ Monitor**, made of:
 - **Gabi Monitor App**: a mobile application dedicated to caregivers, allowing to start and stop a recording of physiological parameters measured by the Gabi Band, displays measuring information and transfers collected data to the Gabi Cloud via Wi-Fi.
 - **Gabi Monitor Tablet**: a tablet provided to the caregiver inside the solution package, on which the Gabi Monitor App is pre-installed.
- c) A **Gabi™ Cloud**, an online service that stores and manages the collected data and shares them with Gabi Analytics.
- d) **Gabi™ Analytics**, a web interface allowing you to access and review remotely the physiological parameters of the patient.

The Pediarity™ system is illustrated in Figure 1 below.



Figure 1: Pediarity™ system components

2.1 Device Indications for Use

The Pediarity™ system is intended for use in the home setting to measure and record pulse rate (PR), respiratory rate (RR) and movement of well-perfused neonates, infants, and children in non-motion conditions. The system also measures and records functional oxygen saturation of arterial hemoglobin (SpO₂) of well perfused infants and children in non-motion conditions.

The Pediarity™ system is not a monitoring device and does not provide physiological alarms during use.

Measurements are sent to a web server for remote review by a physician.

¹ The SpO₂ measurements on neonates is still under validation. It is not currently included in Pediarity™

2.2 Product Description

The Pediarity™ system is composed of

- the Gabi™ system used by the patient’s caregiver, including the Gabi™ Band and the Gabi™ Monitor Tablet with Gabi™ Monitor, made of:
- **Gabi Monitor App.**
- Gabi™ Analytics used by you, the physician.

The Gabi™ system is to be used on the order of a physician.

Be aware that Gabi™ system does not replace parental supervision.

2.3 Contraindications

Only use the Pediarity™ system on intact skin (no injuries, no tattoo, no bruises, etc).

Pediarity™ system **does not provide physiological alarms-**

Pediarity™ system is not intended for use as an apnea monitoring system.

The Pediarity™ system is contraindicated for children older than 12 years and infants and children weighing less than 2.5 kg.

3. General Warnings and Cautions

3.1 Warnings

 The Pediarity™ system does not:

- Diagnose, cure, lessen, monitor, treat or prevent disease or injury,
- Affect body functions/structures,
- Achieve primary intended purposes through chemical action,
- Prevent Sudden Infant Death Syndrome (SIDS).

As safety information, please:

 Do not use the Pediarity™ system as a diagnosis tool.

3.2 Cautions

 Be aware that patient motion reduces the biometrics accuracy.

 Be aware that inappropriate positioning of the Gabi™ Band influences the biometrics accuracy.

3.3 Precautions

Gabi™ Analytics can only be used by healthcare professionals and authorized personnel. Once you have registered on the platform, you will define a password to access your Gabi™ Analytics account. Please do not share the password of your Gabi™ Analytics account with anyone.

4. Your Gabi™ Analytics – Registration and Login on the Platform

Before to use Gabi™ Analytics, you need to create an account on the platform and to define your password.

To perform the following steps, you need to have access to internet and to your email address.

Please note that Gabi™ Analytics is working on the following browsers:

- Chrome higher than or equal to v66
- Safari higher than or equal to v11
- Firefox higher than or equal to v70
- Opera higher than or equal to v60
- Edge higher than or equal to v80

4.1 Account Creation

Open the following URL <https://analytics.gabismartcare.com/> and press the “Create account” button.

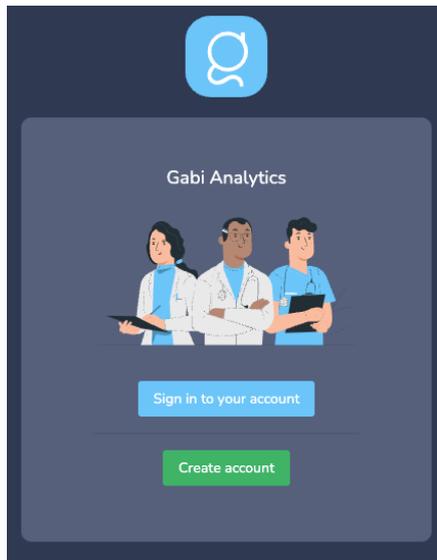


Figure 2: Gabi Analytics login page

The self-registration page opens.

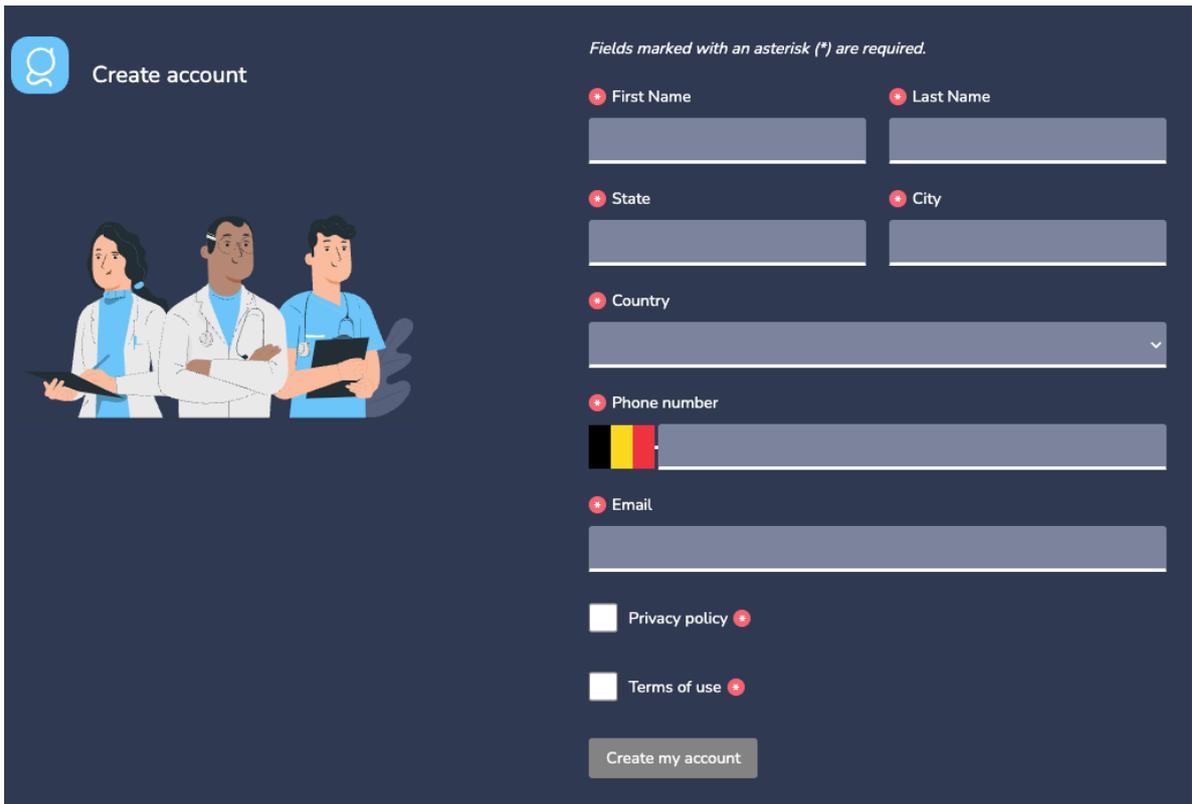


Figure 3: self-registration page

Please fill the mandatory fields:

- Your first name
- Your last name
- Your state (if not applicable in your country, simply fill with "/")
- Your city
- Your country, to be selected from a drop-down list
- Your phone number
- Your email address

Carefully read the privacy policy and the Terms of use. Check the two if you agree with them.

Press the “Create my account” button.

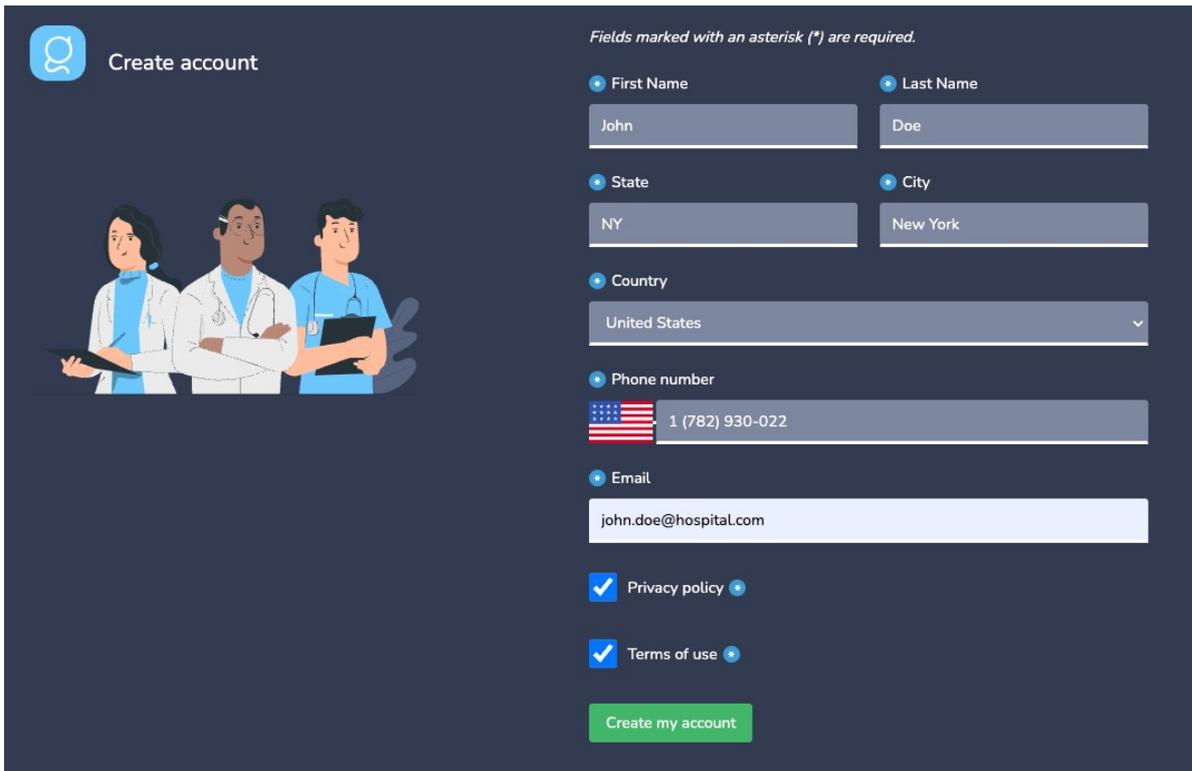


Figure 4: Example of filled self-registration page

When the account creation is confirmed, a message is displayed on your screen.

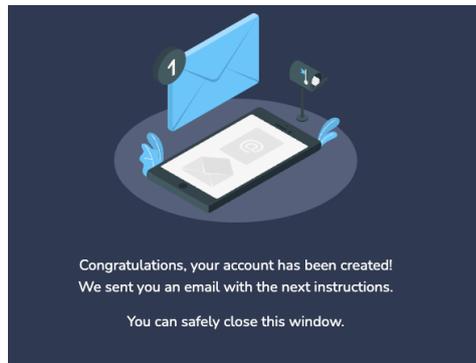


Figure 5: account creation confirmation message

You will receive two emails from support@gabismartcare.com. If you don't receive them within 5 minutes, please check that:

- You are connected to the internet
- The emails may be in another folder (as SPAM)

The first email is a welcome email. No action is required from this email.

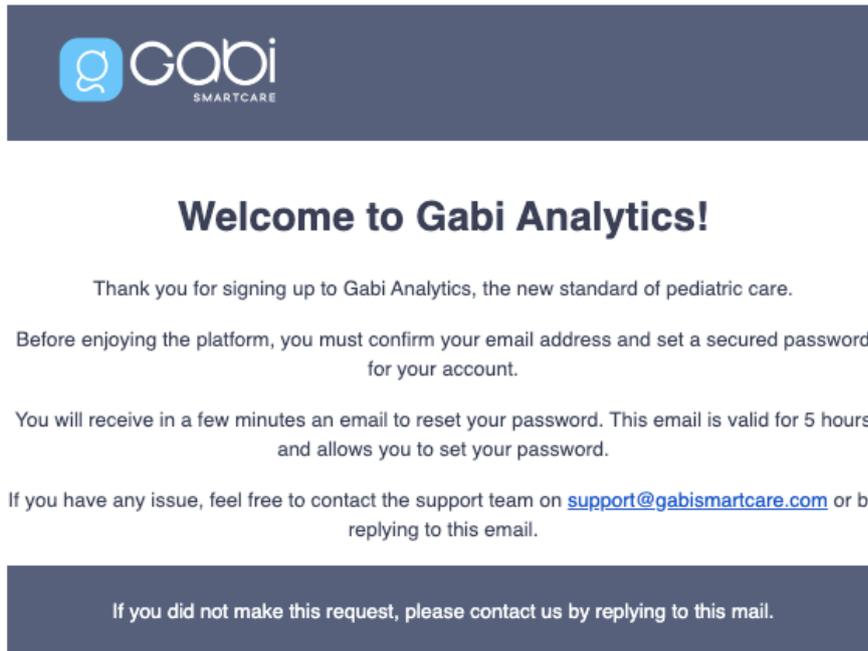


Figure 6: Welcome email content

With the second email, you will be able to finalize your account configuration, by defining your password. Click on the button “Set my new password” included in the email.

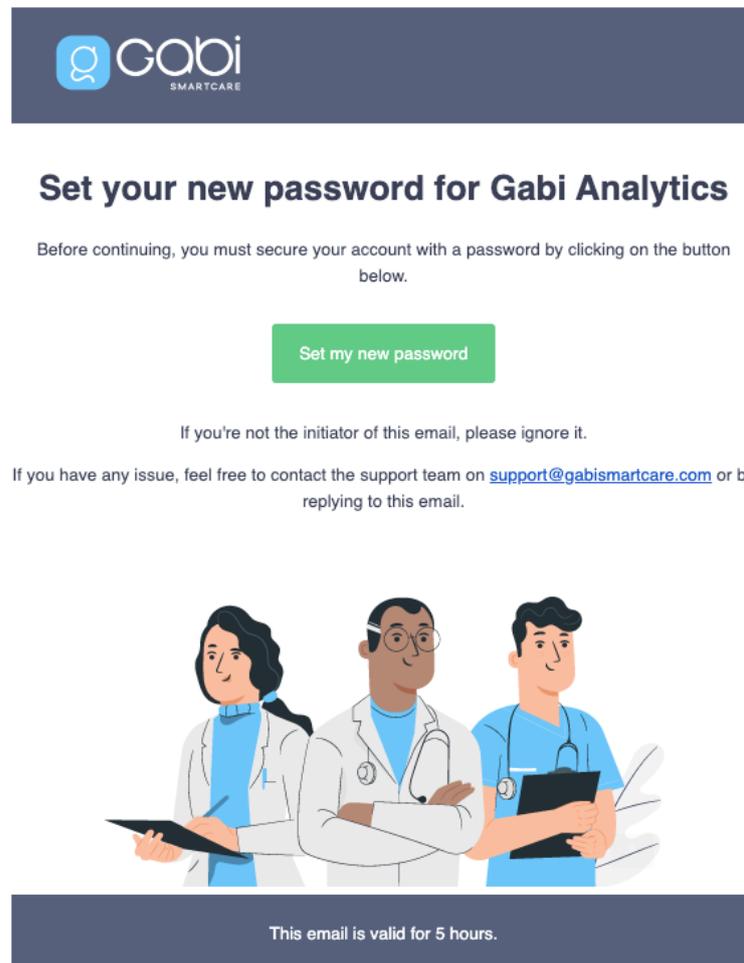


Figure 7: Set password email content

Be aware that this link is only **valid for the next 5 hours** from the account creation. If you don't define your password within this timeframe, you will need to ask for a reset password on the Gabi™ Analytics login page, to receive a new link (see §4.4 Password reset on page 17).

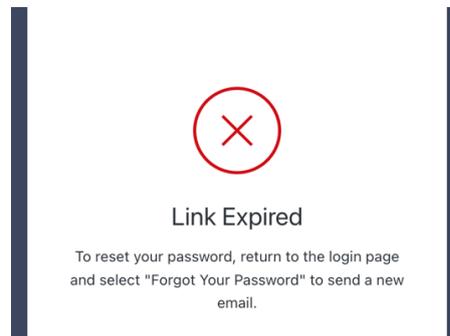


Figure 8: Set password expired link

4.2 Password definition

Once you click on the button “Set my password” included in the email, the password definition page opens.

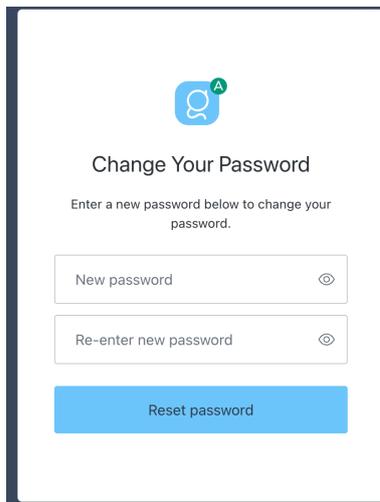


Figure 9: Password definition page

Your password must contain:

- At least 8 characters
- At least 3 out of the 4 following:
 - Lower case letters (a-z)
 - Upper case letters (A-Z)
 - Numbers (0-9)
 - Special characters (e.g. !@#\$%^&*)

The rules already followed by the password you are typing are highlighted in green.

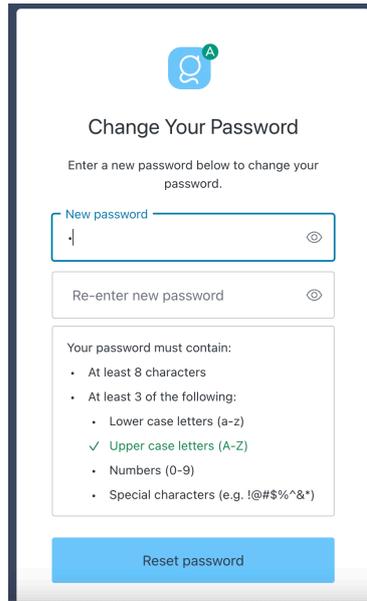


Figure 10: Password rules display

You need to write your password in the first field and then write it again in the second field to confirm it, before being able to save it. When saved, a confirmation page opens. You can now go back to Gabi™ Analytics login page, by pressing the ‘Back to Gabi Analytics’ button.

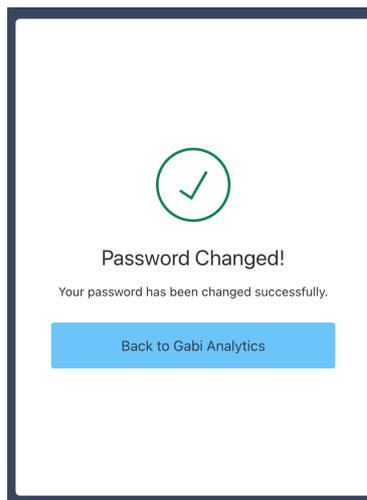


Figure 11: Password definition confirmation page

4.3 Login on

Once your account is created and your password defined, you can log on Gabi™ Analytics. Open the following URL <https://analytics.gabismartcare.com/> and press the “Sign in to your account” button. Fill in the two fields (email address used to create your account and password just defined), and press the “continue” button.

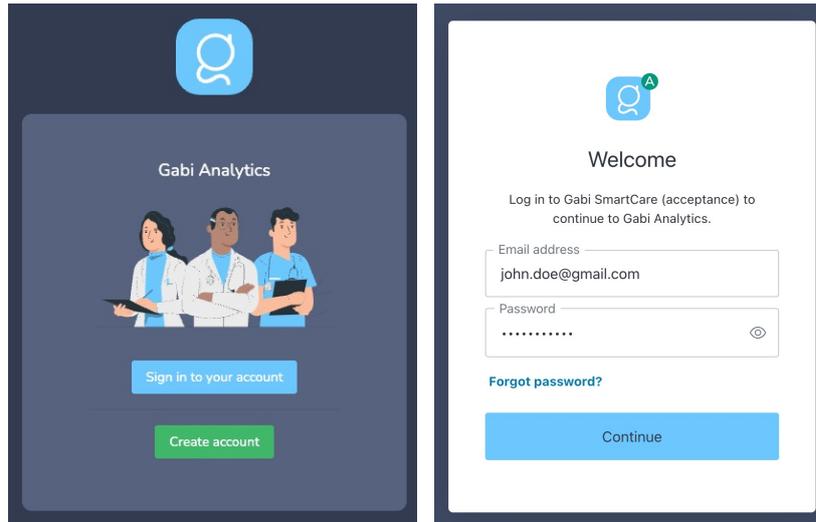


Figure 12: Login page and form

4.4 Password reset

If you have forgotten your password, you can reset it by clicking on the “Forgot password?” button of the login page. You need to enter your email address and press the “Continue” button.

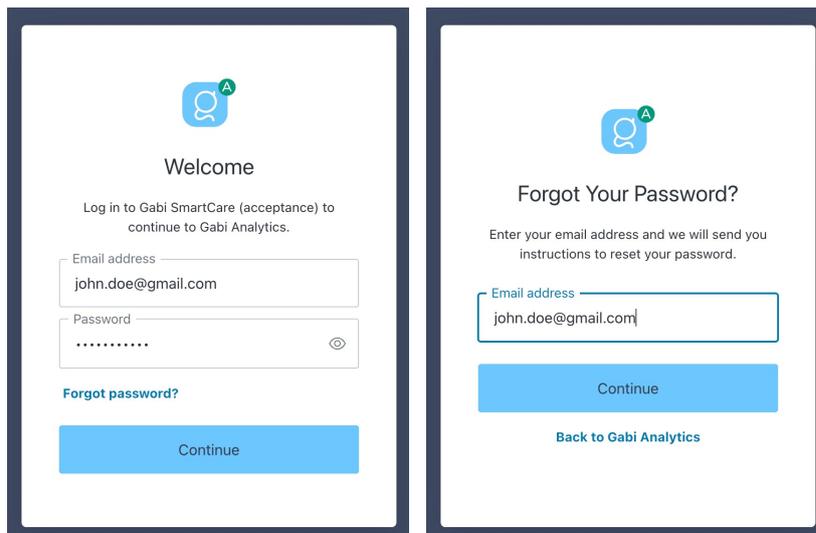


Figure 13: Forgot password page

You will receive the same mail as defined in Figure 7: Set password email content.

To define your new password, you can now proceed to the steps defined in §4.2 Password definition on page 15.

5. Your Gabi™ Analytics – Patients Management

When you log on Gabi™ Analytics, your list of patients is displayed. You can find in this list all the patients created by you or shared with you. You can also find the demo patient, which allows you to get some explanations on the different features of the platform.

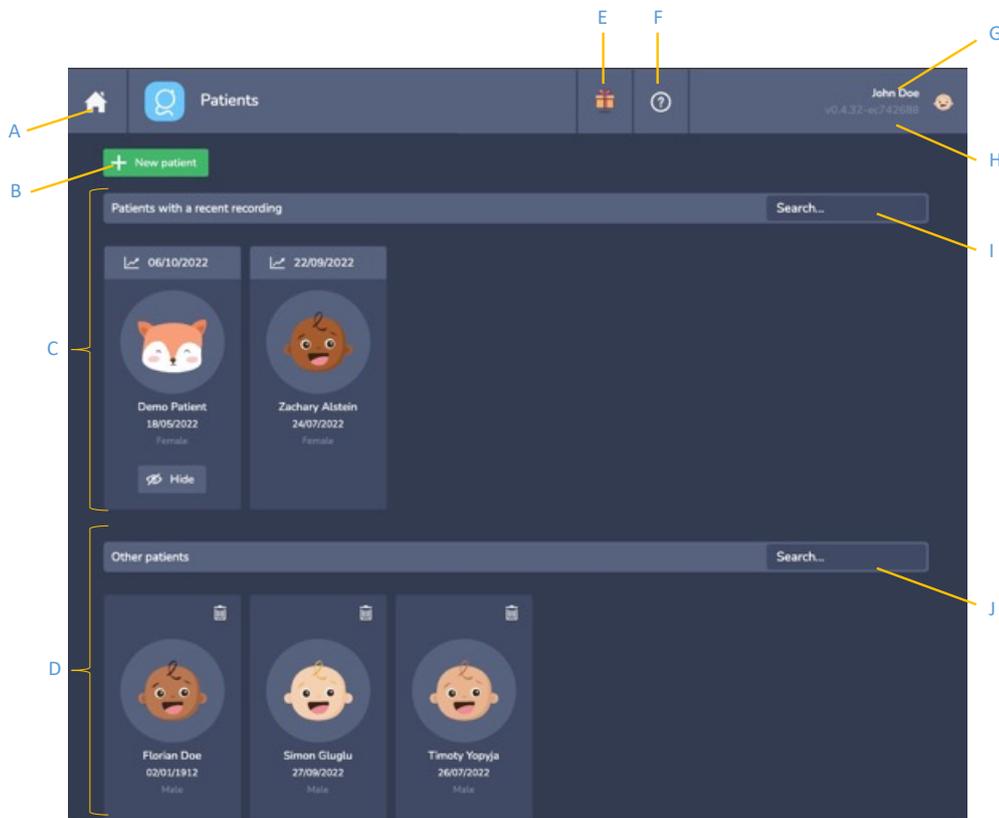


Figure 14: List of patients page

- A. Home page button
- B. New patient creation button
- C. List of patients with recent recordings
- D. List of patients without recent recordings
- E. New features list button (see chapter 8 on page 48)
- F. Information button (see chapter 8 on page 48)
- G. Current user first name and last name (see chapter 7 on page 40)
- H. Gabi™ Analytics current version
- I. Search field for patients with recent recordings
- J. Search field for patients without recent recordings

Each patient from the list of patients is represented by a tile, including different pieces of information.

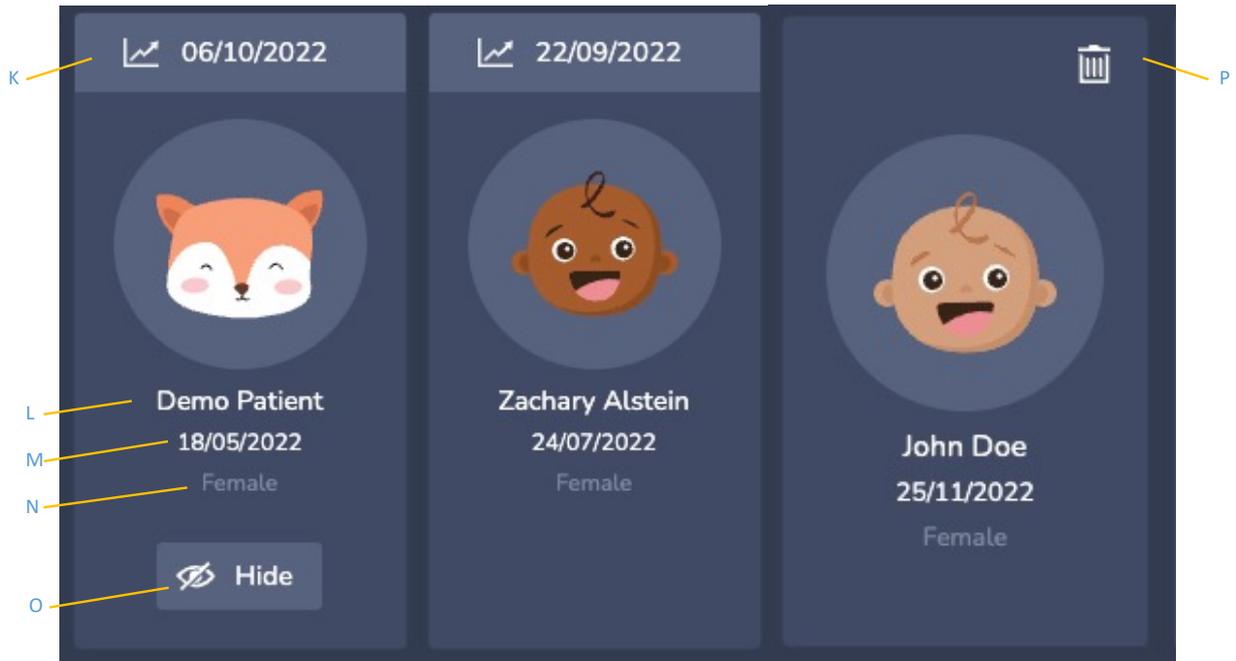


Figure 15: patient tile

- K. Last recording date
- L. Patient’s first name and last name
- M. Patient’s birthdate
- N. Patient’ sex
- O. Specific to demo patient: option to hide from your patient’s list (see §8.1 on page 48)
- P. Possibility to delete the patient (if available, see §5.4 Patient Deletion on page 24)

5.1 Patient Creation

You can create a new patient by pressing the “new patient” button. Be aware that there are five steps in the patient creation form! Once you have validated one step, you will not be able to come back to it during the patient creation process but you will be able to update all the data by updating the patient after its creation (see §5.2 Patient Update on page 22).

5.1.1 Child’s information

You first need to fill in the child information.

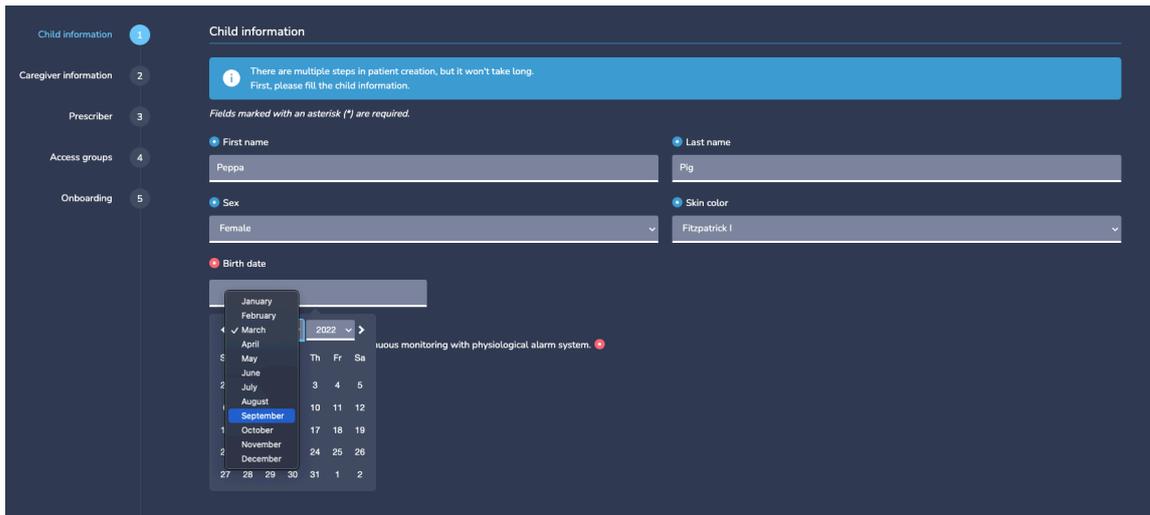


Figure 16: Patient creation form - child information

- Child’s first name (*text field*)
 - Child’s last name (*text field*)
 - Child’ sex (*dropdown*)
 - Child’ skin color using Fitzpatrick scale² (*dropdown*)
 - Child’s birthdate (*calendar selection*): select first the year and month, then on the calendar, you can select the day.
 - Confirmation that the patient doesn’t require continuous monitoring with physiological alarm systems (*checkbox*)
- ⚠ The Pediarity™ system does not include any physiological alarm. You cannot use Pediarity™ system for a patient requiring continuous monitoring with alarms! You may use it in addition of a device with alarms.
- If required, confirmation that you will use the device under your own responsibility as using it outside the intended use (for children younger than 28 days old for SpO2 or older than 12 years old) (*checkbox*)
- ⚠ The Pediarity™ system is intended for use on neonates, infants, and children up to and including 12 years of age. The SpO2 measurement may not be accurate for neonates.

When you have filled all the fields in, the ‘next’ button switches to green. You can press it to move to next step.

Be aware that if you leave the form before having press on the ‘next’ button, the already filled data will be lost.

² Type I - Always burns, never tans. These individuals have pale white skin, blond or red hair, blue eyes, and freckles.
 Type II - Usually burns, tans poorly. These individuals have white skin, blond or red hair, and blue or green eyes.
 Type III - Tans after initial burn, then tans well. Creamy skin tone and blue, green or brown eyes.
 Type IV - Tans well. Light brown skin tone, usually brown eyes.
 Type V - Rarely burns. Has dark brown skin tone and brown eyes.
 Type VI - Never burns. Is deeply pigmented with the darkest skin tone.

Be also aware that if you leave the form after having press on the ‘next’ button, the patient will be created but data from all next steps will be missing. You can still find it in your list of patients and update the patient from there (see §5.2 Patient Update on page 22).

5.1.2 Caregiver information

The second step is related to the caregiver information.

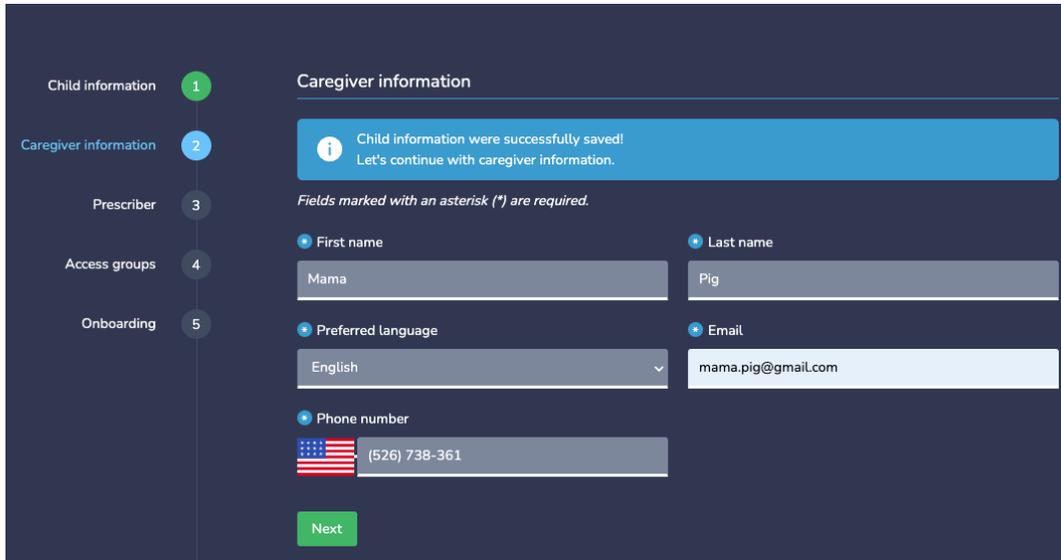


Figure 17: Patient creation form - caregiver information

- Caregiver’s first name (*text field*)
- Caregiver’s last name (*text field*)
- Caregiver’s preferred language (*dropdown*): the language defined here will be used for the user interface of the Gabi™ system used by the caregiver.
- Caregiver’s email address (*text field*): this email address is used to send the QR code to the caregiver (see §5.1.5 Onboarding on page 22)
- Caregiver’s phone number (*dropdown for the country and number field*): you can define the caregiver’s country by clicking on flag and then type his phone number

When you have filled all the fields, the ‘next’ button switches to green. You can press it to move to next step.

5.1.3 Prescriber

The third step is related to the prescriber. The prescriber is most of the time the physician of the child and is considered as the owner of the patient in the system.

By default, the prescriber is defined as you (the current user creating the patient). You can choose another prescriber from the proposed dropdown list. In this list, you will find any other healthcare professionals with whom you have a link through an access group (see §7 Your Gabi™ Analytics – User Profile and Groups Management on page 40). By choosing another prescriber, you will not be able to update this prescriber afterwards. The chosen prescriber will be the owner of the patient and is the only one being able to update this prescriber afterwards.

If you do not find the healthcare professional you want to select, this means either that this person does not use Gabi™ Analytics yet or that this person is not included in any of your access group.

To add this healthcare professional to your list, you need to add him to one of your access groups. You can either add him to an existing group or create a new group and include him (see §7.3 Groups Management on page 43).

When you have selected your prescriber, you can press the ‘next’ button to move to next step.

5.1.4 Access Group

The fourth step is the selection of access groups. The persons included in the group(s) that you select here will have access in read and write to the patient’s data.

You can select no group at all, only one group or several groups.

When you have selected the access group(s), you can press the ‘next’ button to move to next step.

5.1.5 Onboarding

The fifth and last step is the QR code that the caregiver will need to link its Gabi™ system to the patient you just created.

The caregiver will receive this QR code on the email address you define in step 2. If you want to print this QR code, you can press the ‘Print QR code’ button.

The patient has now been created with all required data. You can either go back to the patient dashboard by pressing the ‘patients dashboard’ button or leave the page.

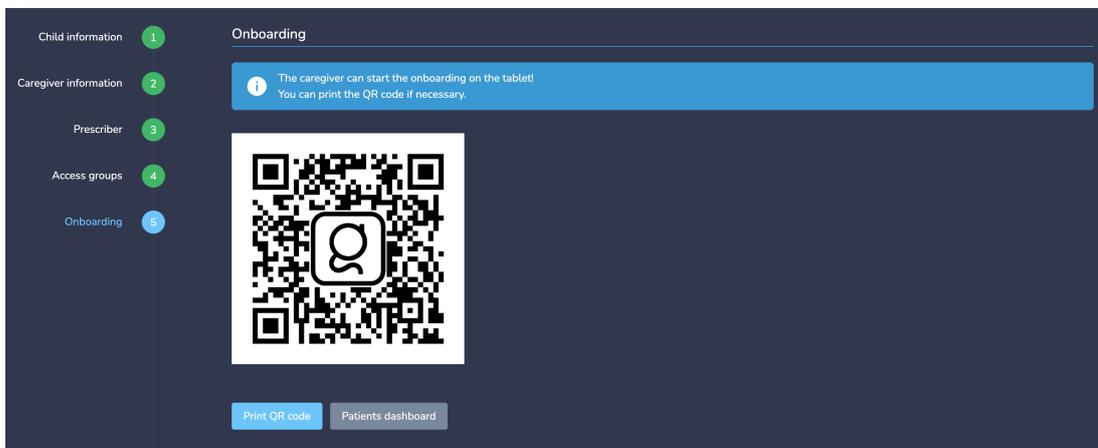


Figure 18: Patient creation form - QR code for caregiver

5.2 Patient Update

To update a patient, follow the following steps:

1. Find it in your list of patients and press on the patient tile. The patient health report opens.
2. On the left bar, press on the two arrows present next to the patient personal data. The patient details open.
3. On the downside of the patient details, press on the ‘update patient information’ button. The patient update page opens.

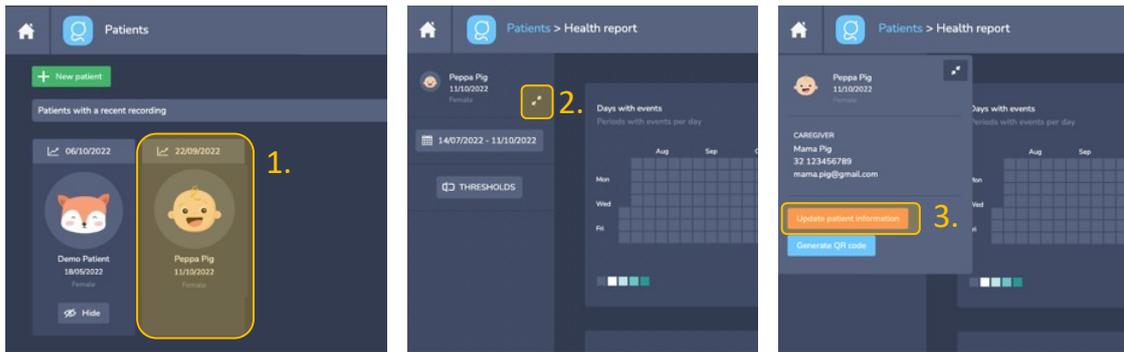


Figure 19: Patient update – steps

On the patient update page, you have four sheets (A): child information, caregiver information, prescriber, and access groups. You can navigate through these four sheets through the left bar of the page.

On each sheet, you can update the information filled during the patient creation (B).

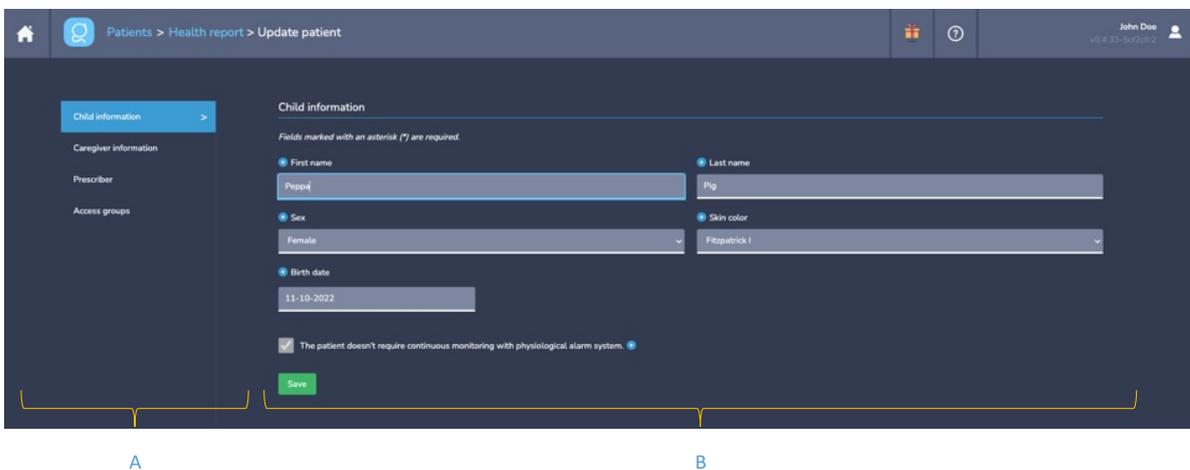


Figure 20: Patient update page

5.3 QR code generation

If the caregiver has lost the QR code generated during the patient creation (see §5.1.5 Onboarding on page 22), you can generate it again.

Follow the following steps:

1. Find the patient in your list of patients and press on the patient tile. The patient health report opens.
2. On the left bar, press on the two arrows present next to the patient personal data. The patient details open.
3. On the downside of the patient details, press on the ‘generate QR code’ button.



Figure 21: QR code generation

If the patient is already linked to a Gabi™ system, an error message is displayed and the QR code generation is not allowed.

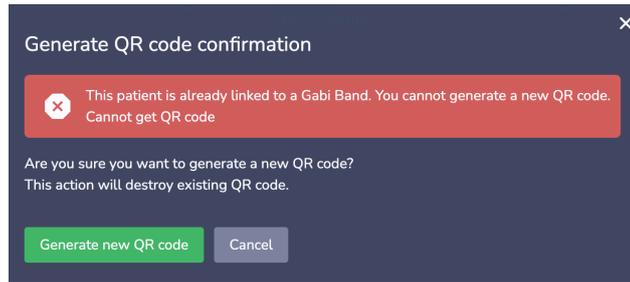


Figure 22: QR code generation error message

If the button from step 3 (‘QR code generation’) is not present, this means that some important data of the patient is not filled in. Proceed first to a patient update to fill these data in, then you will be able to generate the QR code.

5.4 Patient Deletion

You can only delete the patients created but not yet linked to a Gabi™ system.

As soon as the caregiver has made the link with his Gabi™ system, the possibility to delete the patient is removed from Gabi™ Analytics.

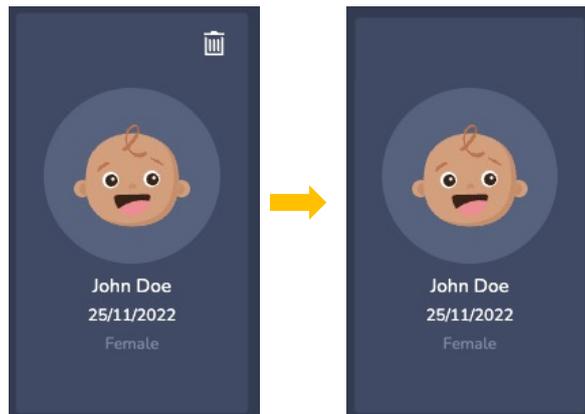


Figure 23: Patient tile: delete option

To delete a patient, press the bin button. A pop-up message is displayed, asking you to confirm you want to delete this patient. If you want to confirm the deletion, press the ‘delete’ button. In the other case, press the ‘cancel’ button.

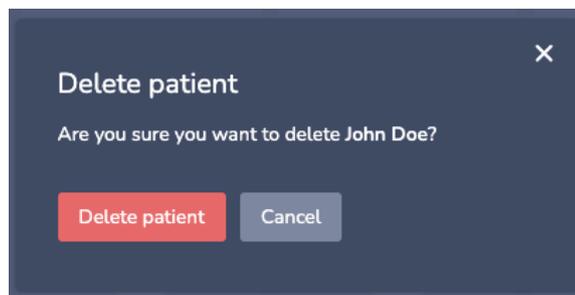


Figure 24: Patient deletion confirmation message

Be aware that a patient can request the deletion of his personal data. In this case, the patient will be deleted, including all recordings and notes.

6. Your Gabi™ Analytics – Patient Biometrics Review

In this section, you will find the instructions to display the recordings performed by your patients.

You need first to select the patient you want to review. Find it in your list of patients and press on the patient tile. The patient health report opens.

6.1 Patient Health Report

The patient health report shows the evolution of the number of events occurring for the patient’s recordings, based on the selected period and defined thresholds. A measurement point is considered as an **event** when the biometric is outside the range defined by the thresholds for this biometric.

It is to be noted that as the recording should be done in non-motion conditions, it is mainly done during the night. For this reason, the recording is from 12:00 noon until 12:00 noon the next day. The date displayed in the graphs is the start date of the recording.

The patient health report is composed of:

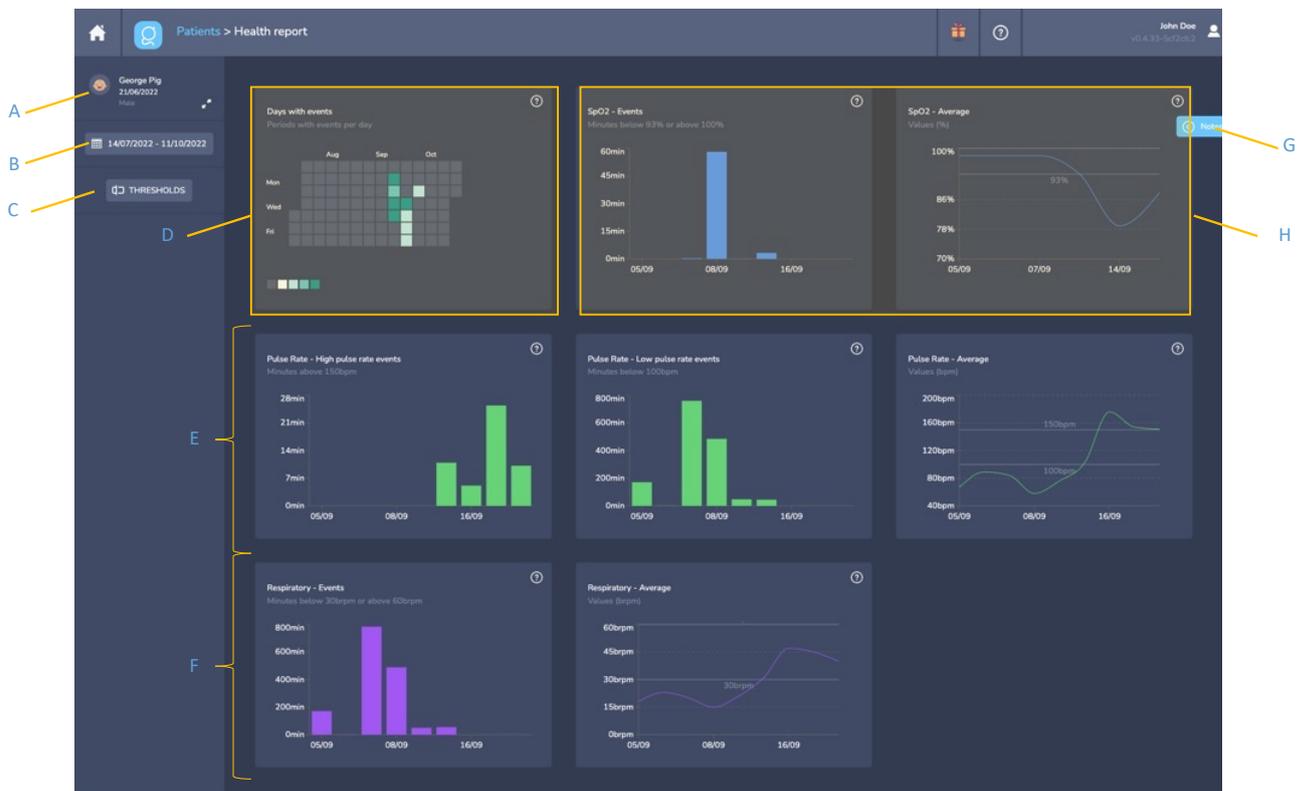


Figure 25: Patient Health Report composition

- A. Patient personal data, including patient’s names, patient’s birthdate, and patient’ sex
- B. Period selection
- C. Thresholds selection
- D. One tile with the calendar showing the heatmap of events
- E. Three tiles with pulse rate related events
- F. Two tiles with respiratory rate related events
- G. Patient notes (see §6.3 Patient Note on page 37)

H. Two tiles with SpO2 related events

On the upper right corner of each tile, a ⓘ icon is available. When clicking on it, you have access to an explanation of the tile content.

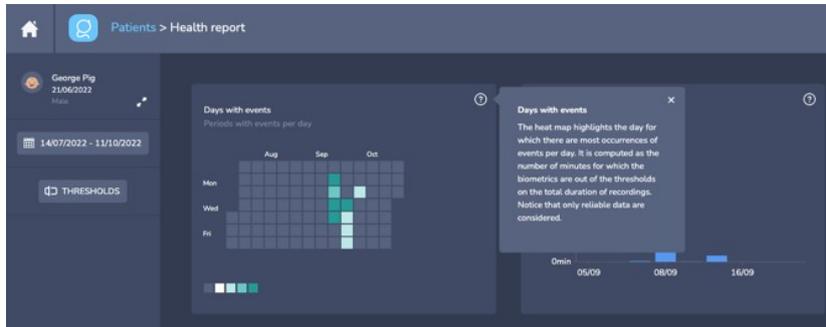


Figure 26: Information on tile content

6.1.1 Period Selection

To select a period, press on the related button (B in Figure 25: Patient Health Report composition).

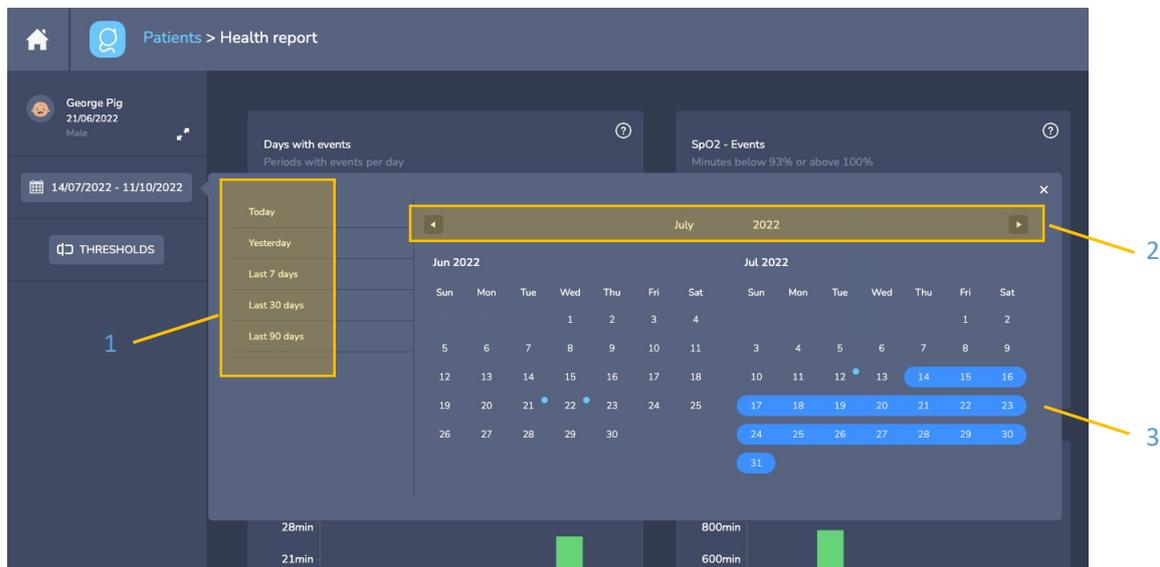


Figure 27: Period selection window

The time selection window opens, composed of:

1. Predefined periods
2. Navigation part
3. Selected period highlighted in blue

In the calendar, you can also see the days with a recording. They are identified with blue dots.

You can either select a predefined period among the five available, or manually select it by clicking on the first day of the period and clicking on the last day of the period. The selected period is highlighted in blue in the calendar.

To change the displayed months, you can either use the left and right arrows or directly select the month and the year by clicking respectively on it in the navigation part (B).

6.1.2 Thresholds Selection

At patient creation, default thresholds are defined for the patient depending on his age.

These default thresholds are explained in the table below:

Patient age	HR [bpm ³]	RR [brpm ⁴]	SpO2 [%]
< 1 month	[120 ; 160]	[35 ; 60]	/
1-3 months	[100 ;150]	[30 ; 60]	[93 ; 100]
4-6 months	[90 ;140]	[30 ; 50]	
7-11 months	[80 ;140]	[25 ; 45]	
1-2 years	[70 ;130]	[20 ; 30]	
3-5 years	[65 ;120]	[20 ; 25]	
6-12 years	[60 ;110]	[14 ; 22]	

Table 1: Default thresholds per patient age

To update the thresholds, press on the related button (C in Figure 25: Patient Health Report composition).

The thresholds definition window opens. For each biometric, a lower and an upper value are defined. You can update these values by moving left or right the cursor. Do not forget to apply your updates by pressing the “apply” button. If you do not want to apply your changes, press the “cancel” button.

³ bpm (beat per minute)

⁴ brpm (breath per minute) is equivalent to cpm (respiratory cycle per minute) or to rpm (respiration per minute)



Figure 28: Health report - thresholds definition

The thresholds are defined for a specific patient, only on your own user account. If another Gabi™ Analytics user has access to the same patient, he can define his own thresholds for this patient.

6.1.3 Tile with Calendar showing Events Heatmap

The calendar displays the selected period and a status for each day of this period.

- means that there is no recording for this day
- means that there is a recording but no event
- means that less than 25% of the recording are events
- means that between 25% and 50% of the recording are events
- means that more than 50% of the recording are events

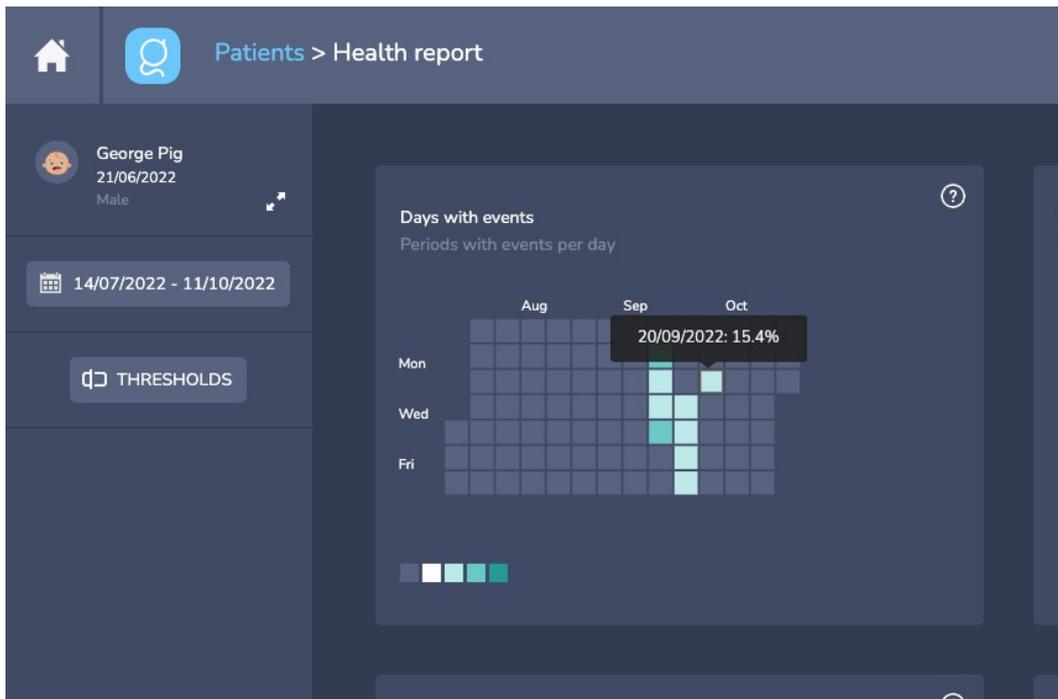


Figure 29: Heatmap of events

You can move your mouse on the day to see the exact percentage of events for the day.

Please note that

- only reliable data are considered for this computation
- all the recordings of the day are considered

6.1.4 Tiles with Biometrics Related Events

For each biometric, the system displays two types of tiles:

- Tile showing the number of minutes with events for each day
- Tile showing the evolution of the average biometric value over time



Figure 30: Tile with biometrics related events

You can move your mouse on the day to see the exact value for the day.

Please note that

- only reliable data are considered for this computation
- all the recordings of the day are considered

6.2 Patient Daily Biometrics

You can have access to the detailed biometrics by clicking on the corresponding day, in any tiles of the Health Report.



Figure 31: Daily Biometrics view

- A. Patient personal data, including patient’s names, patient’s birthdate, and patient’ sex
- B. Day selection
- C. Thresholds selection (see §6.1.2 Thresholds Selection on page 27)
- D. Recording in a nutshell
- E. Time gridline selection
- F. Scrollbar and sliding window
- G. Patient notes (see §6.3 Patient Note on page 37)
- H. Detailed biometrics and movements

6.2.1 Day selection

Depending on your screen resolution, the calendar can be fully displayed in the main screen, or only the selected date can be displayed. In the second case, you need first to click on the selected date to open the full calendar.

The calendar displays the selected day with a blue background and the days with a recording with a blue dot. You can navigate through the different months via the arrows on both sides of the current month. Click on the date you wish to visualize. For the low-resolution screen, you can then close the full calendar by clicking on the top-right cross.

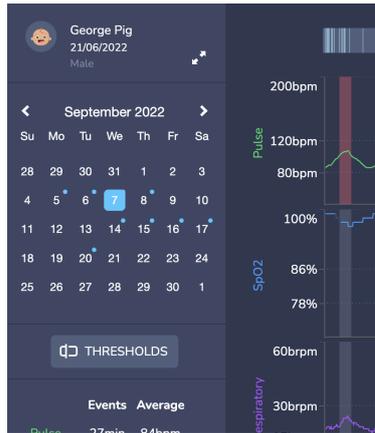


Figure 32: Day selection big resolution display - full calendar

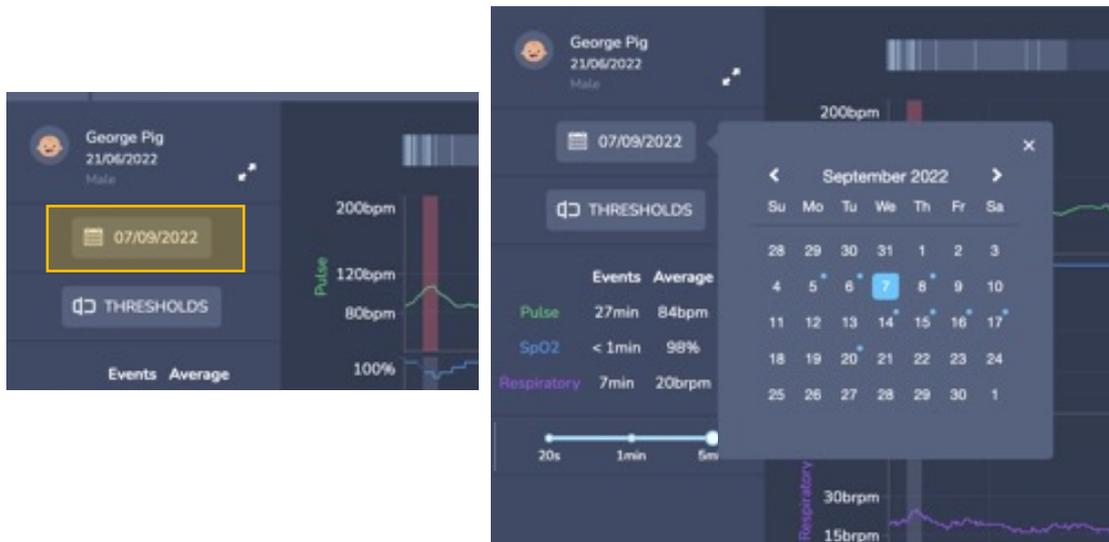


Figure 33: Day selection low resolution display - selected date

6.2.2 Recording in a nutshell

The main data of the recording are displayed in a nutshell in the left bar. For the three biometrics, the following data are available:

- 1- The number of minutes considered as events (outside the defined thresholds)
- 2- The average of the biometrics

Please note that

- only reliable data are considered for this computation
- all the recordings of the day are considered

	Events	Average
Pulse	27min	84bpm
SpO2	< 1min	98%
Respiratory	7min	20brpm

Figure 34: daily biometrics in a nutshell

6.2.3 Time gridline selection

By selecting 20s, 1m or 5m, you can change the gridline used for the X-axis (time). The gridline will use respectively a scale of 20 seconds, 1 minute or 5 minutes to display the recording.



Figure 35: gridline selection

Here are examples of the same recording using each gridline:

A gridline of 5 minutes means a longer period is displayed with less zoom on the data.



Figure 36: example of 5m gridline



Figure 37: example of 1 minute gridline

A gridline of 20 seconds means a smaller period is displayed with more zoom on the data.



Figure 38: example of 20 seconds gridline

6.2.4 Scrollbar and sliding window

On the top on the four graphs, a scroll bar represents the full recording time-axis. The blue sliding window represents the currently displayed period of time. In this scroll bar, the events are displayed in light blue.

To scroll through the timeline, you need to use the blue sliding window and to translate it along the scrollbar until the period of interest.

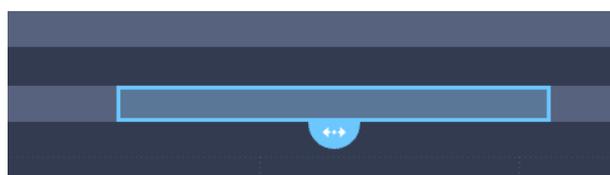


Figure 39: sliding window on the scroll bar

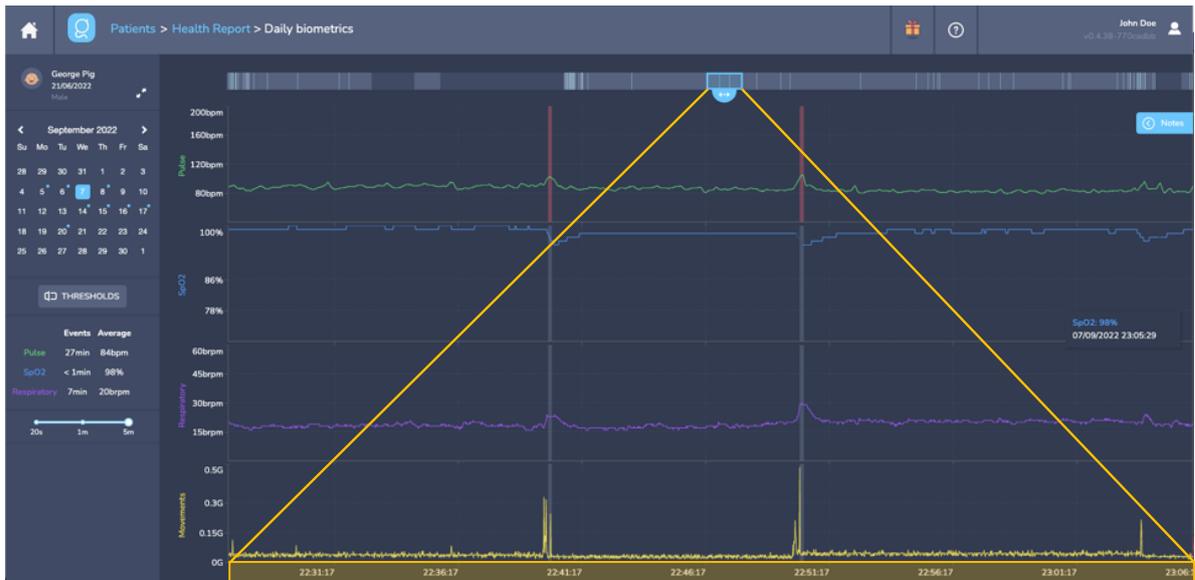


Figure 40: Sliding window represents displayed time-axis

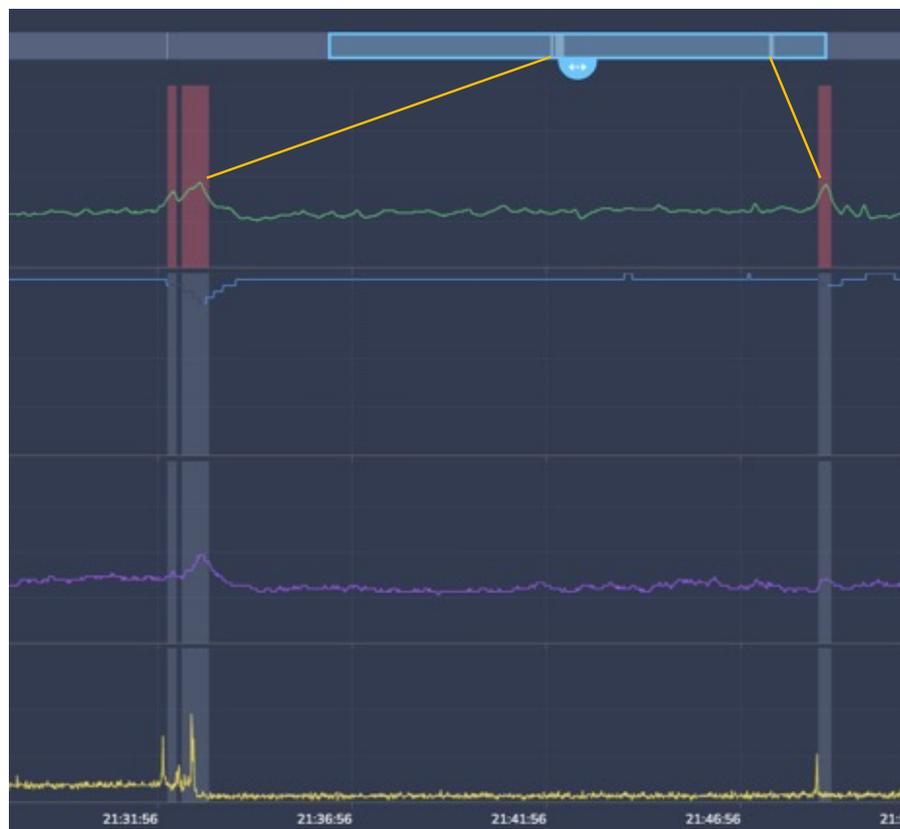


Figure 41: Events displayed in scrollbar

6.2.5 Detailed biometrics

Four graphs are displayed, sharing the same time axis.

In green, you can find the **pulse rate**. The pulse rate is the rate at which your heart beats. It is measured in beats per minute (bpm). It varies widely across patients, depending on the general health, body size, activity levels and medical conditions. The pulse rate is lower at rest or while sleeping than when you are awake or exercising/moving.

In blue, you can find the **oxygen saturation** (SpO2). It indicates the amount of oxygen traveling through the body with the red blood cells. The blood oxygen level is measured as a percentage (%). A lower-than-normal level of oxygen in the blood is defined as hypoxemia.

In purple, you can find the **respiratory rate**. It is the number of breaths you take per minute (brpm), or the number of respirations per minute (rpm), or the number of respiratory cycles completed in 1 min (cpm), where a respiratory cycle consists of one inhalation followed by one exhalation.

In yellow, you can find the amount of **movements** detected. It indicates the acceleration of the patient’s arm minus the gravity and is displayed in g (equivalent to 9.8 m/s²).

 It is important to note that movements may impact the accuracy of the pulse rate, oxygen saturation and respiratory rate measurements.

Moving your mouse on the graph will display a tracker showing you the value of the biometric and the time of measurement.



Figure 42: Biometrics graph with tracker

Events display

A measurement point is considered as an **event** when the biometric is outside the range defined by the thresholds for this biometric. The events are highlighted in the graphs with a red background (see for example the PR graph in Figure 43 below). The biometrics that are not outside their thresholds during an event are highlighted with a grey background. If two biometrics are outside their thresholds at the same time, both are displayed with the red background (see for example the graphs on the right in Figure 43 below).



Figure 43: Events examples – on the left: only PR outside its thresholds; on the right: PR and SpO2 outside their thresholds

Not reliable data

The data for which the quality index is too low are displayed in grey. The biometric value may not be reliable.

This can be due to different causes, as for example:

- Movement of the patient
- Bad placement of the sensor on the patient skin
- Sensor not placed on the patient
- Calibration of the sensor on-going
- Etc.

Zoom feature

To zoom on a specific part of one biometric graph, click on the starting point and only release at the ending point. A modal (window) opens with the selected time frame (starting point to ending point) in X-axis. On Y-axis, the scale will adapt to the values of the biometric selected by you. To close the zoom modal, you can click on the right-top cross or click anywhere outside the zoom window.

The tracker is also available in the zoom modal: moving your mouse on the graph will display a tracker showing you the value of the biometric and the time of measurement.



Figure 44: Zoom modal

6.3 Patient Note

You can add some notes to your patient. These notes are available from the patient’s health report and from the patient’s daily biometric view. To open the notes, click on the G button from Figure 25 or from Figure 31. The notes open on the right part of your window.

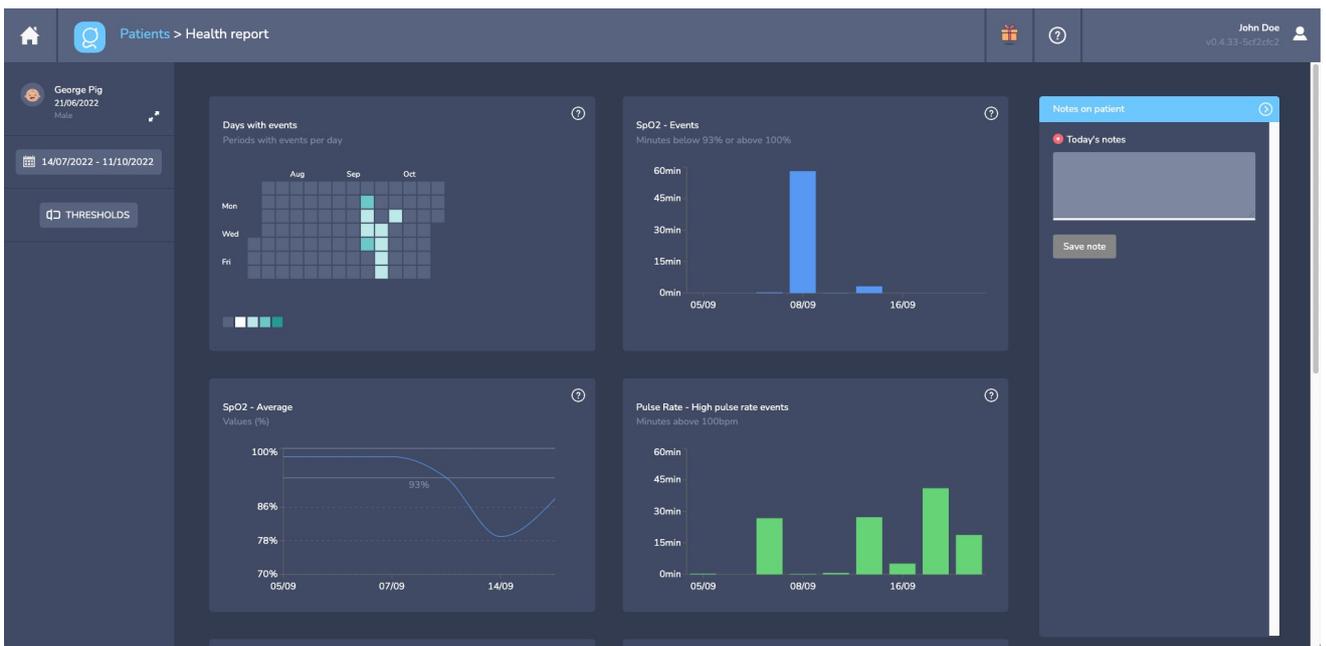


Figure 45: Patient's notes in the Health Report

The existing notes are listed with the oldest on the bottom part. Each note is displayed with its date of creation and its content.

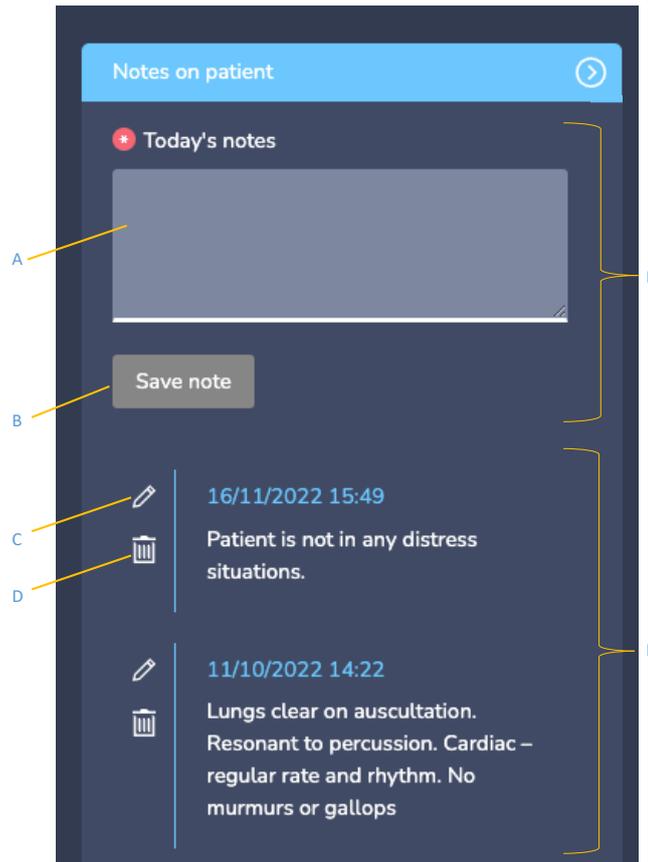


Figure 46: Patient's notes parts

- A. Text field for new note
- B. Saving button for new note
- C. Edition button for existing note
- D. Deletion button for existing note
- E. New note
- F. Existing notes

6.3.1 Create a new note

To create a new note, type your text in the “Today’s note” text field (see part A in Figure 46 above). When done, click on the green “save note” button (see button B in Figure 46 above).

The note is created and included in the existing notes list. It can be edited or deleted afterwards.

6.3.2 Update an existing note

At any time, you can edit an existing note that you created. If you are not the creator of the note, the edition of the note is not possible. You can still create new note for the same patient.

To edit an existing note, click on the pen button (see button C in Figure 46 above) next to the note you want to edit. A modal opens with the note. Proceed to the edition of the note, then save the changes by pressing the “save note” button.

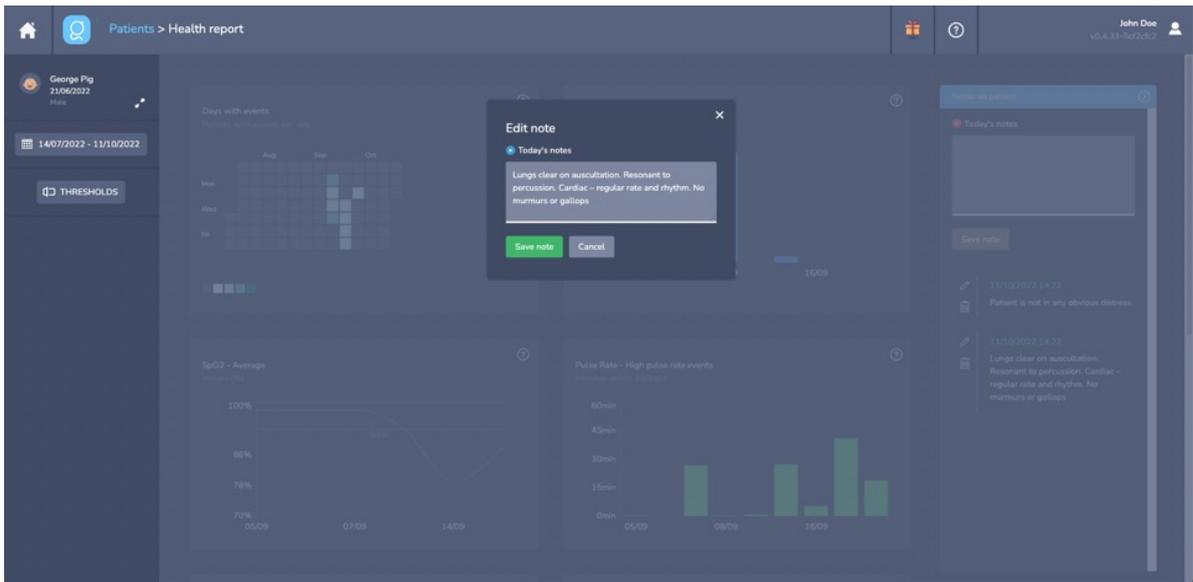


Figure 47: Patient's note edition

6.3.3 Delete an existing note

At any time, you can delete an existing note that you created. If you are not the creator of the note, the deletion of the note is not possible. You can still create new note for the same patient.

To delete a note, click on the bin button (see button D in Figure 46 above) next to the note you want to delete. A modal opens with a confirmation button. If you are sure you want to delete the note, press the 'delete note' button. Otherwise, press the 'cancel' button or the up-right cross. Be aware that once deleted, a note cannot be retrieved.

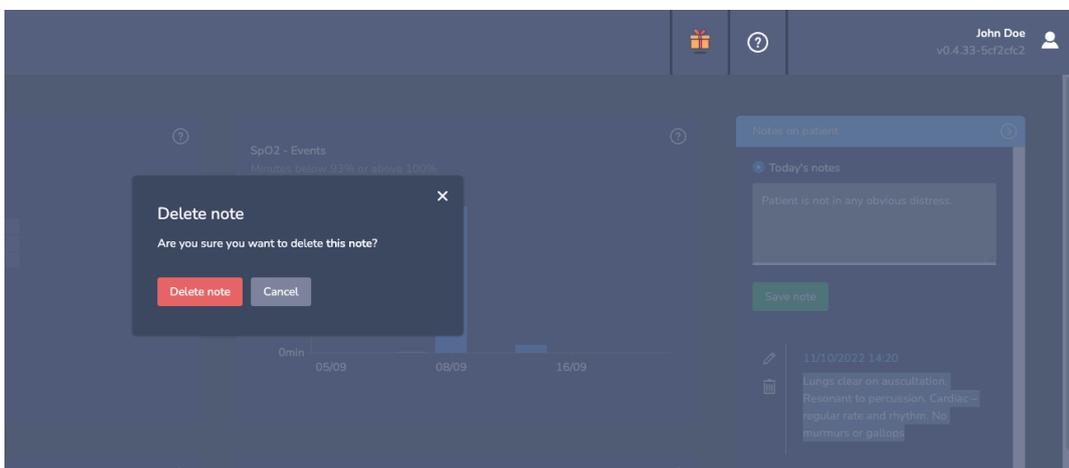


Figure 48: Patient's note deletion confirmation message

7. Your Gabi™ Analytics – User Profile and Groups Management

To manage your profile and group, click on the top right part of Gabi™ Analytics (see zone A in Figure 49 below).

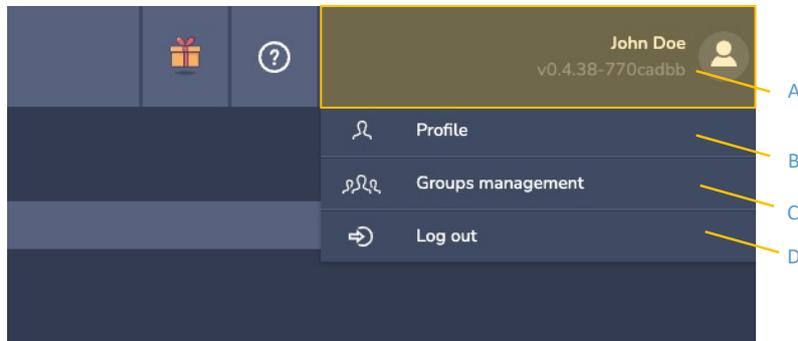


Figure 49: Profile and Groups Management access

- A. Zone to access to user profile and groups management
- B. User profile access button
- C. Groups managements access button
- D. Log out button

7.1 Logout from Gabi™ Analytics

If you want to log out, press on the button “log out” (see button D in Figure 49 above). You will be redirected to the login page.

Please note that after 15 minutes of inactivity, you are automatically logged out for security reasons.

7.2 User Profile

You can access to your user profile by pressing the button B in Figure 49 above.

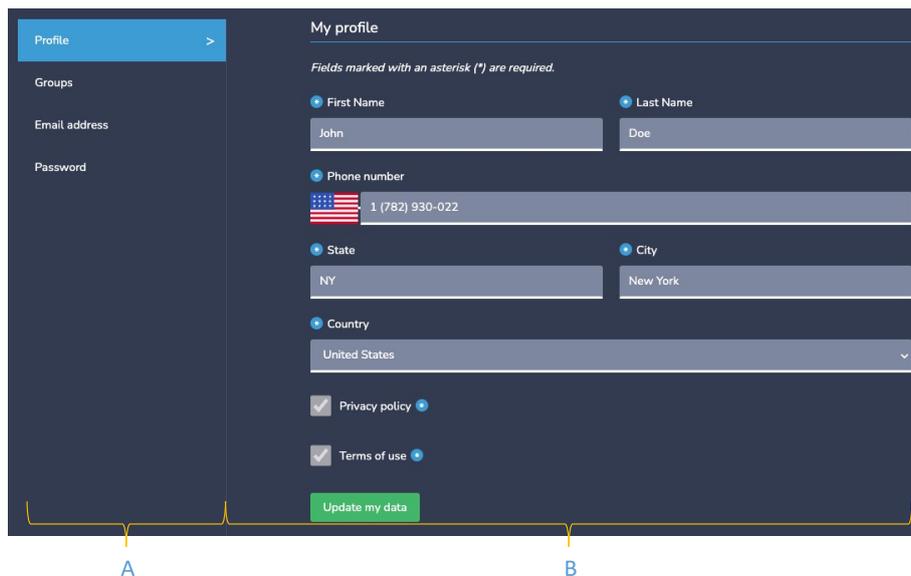


Figure 50: User profile – Composition and Profile sheet

On the user profile page, you have four sheets (A): profile, groups, email address, and password. You can navigate through these four sheets through the left bar of the page.

On each sheet, you can update the related information (B).

7.2.1 Profile sheet

The profile sheet contains most of the data you filled during your self-registration (see 4.1 Account Creation on page 11):

- Your first name
- Your last name
- Your phone number
- Your state
- Your city
- Your country

Once you have edited one or more fields, press the ‘update my data’ button.

If you leave the sheet without saving, your modifications will be lost.

7.2.2 Groups sheet

The group sheet lists the different groups you are included in. From this page, you can choose to leave a group except if you are the only administrator of this group (see 7.3 Groups Management on page 43 for more information).

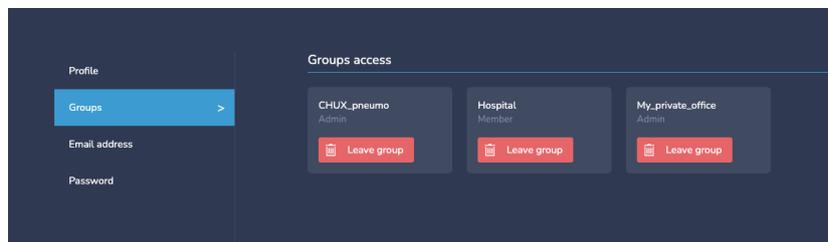


Figure 51: User profile - Groups sheet

To leave a group, press the “leave a group” button related to the group you want to leave. A modal is displayed asking you to confirm you want to leave the group. Confirm by pressing the “leave group” button.

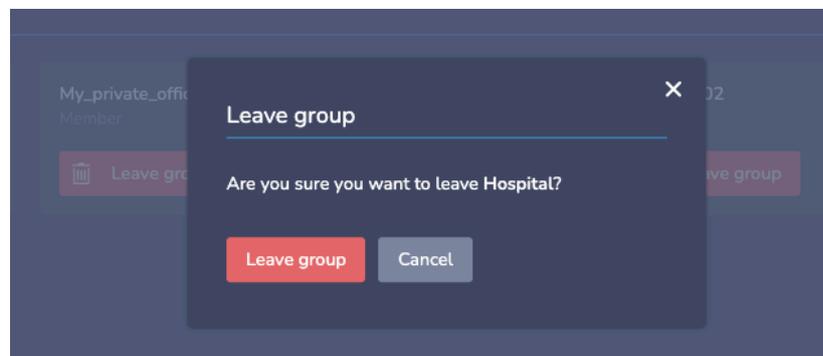


Figure 52: Leave group confirmation message

If you are the only administrator of the group, you will not be able to leave it. You first need to update the group by defining a new administrator and then you will be able to proceed.

7.2.3 Email address sheet

The email address sheet allows you to update your email address. The email address is used as login and received the different notifications from the platform.

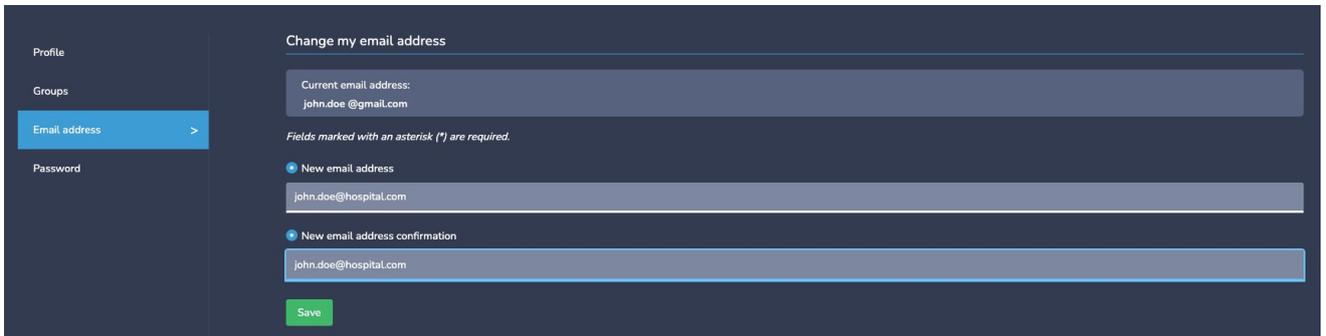


Figure 53: User profile - Email address sheet

The email address currently defined for your account is displayed under “current email address”. If you want to update it, enter the new email address in the two dedicated fields (“new email address” and “new email address confirmation”) and press the save button. If the email addresses you just typed are identical, the system will save your modifications and display a confirmation message.

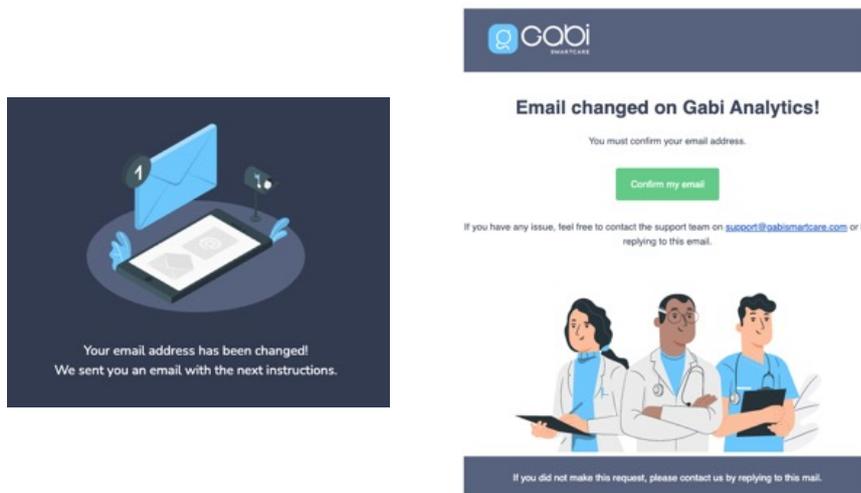


Figure 54: email updated confirmation message and email

You will receive an email from support@gabismartcare.com. If you don't receive it within the minutes following your email update, please check that:

- You are connected to the internet
- The email may be in another folders (as SPAM)

With this email, you will be able to finalize your new email configuration, by confirming it. Click on the button “Confirm my email” included in the email.

Once confirmed, please log out from the platform and login with your new email address with the same password as previously set.

7.2.4 Password sheet

The password sheet allows you to change your password.

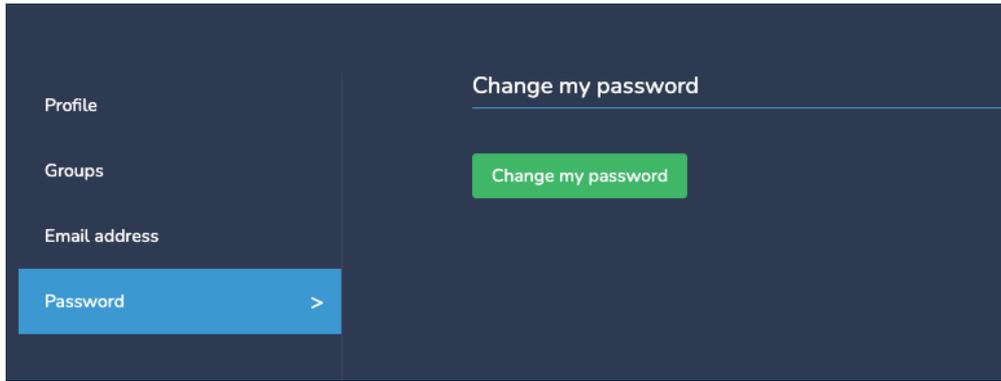


Figure 55: User profile - Password sheet

Press on the “change my password” button. A new page opens, allowing you to define a new password. Enter twice the new password and press on the “reset password” button. If the two passwords are identical and comply with the complexity rules (see §4.2 Password definition on page 15), the modification is saved, and a confirmation message is displayed.

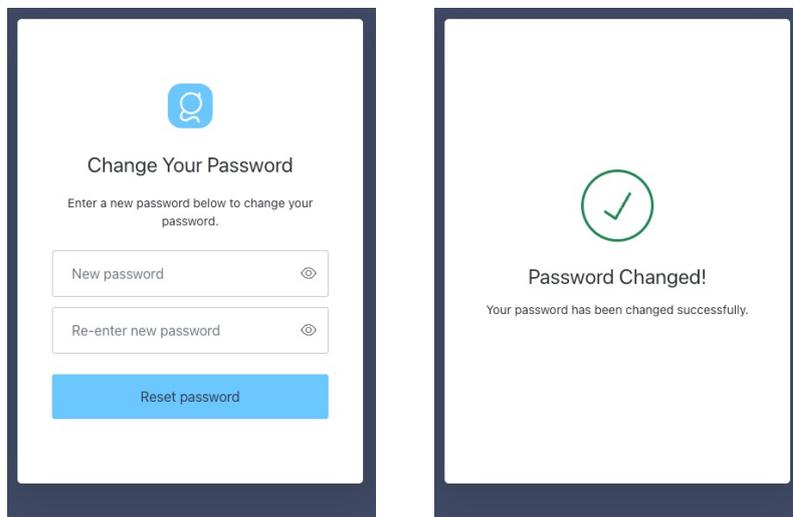


Figure 56: Change password page and confirmation message

7.3 Groups Management

Gabi™ Analytics offers you the possibility to create and manage groups. A group includes several users of the platform. When a group is added to a patient, this patient will be available in the patients’ list of all the users from the group. This allows you to easily share a patient to a group of users.

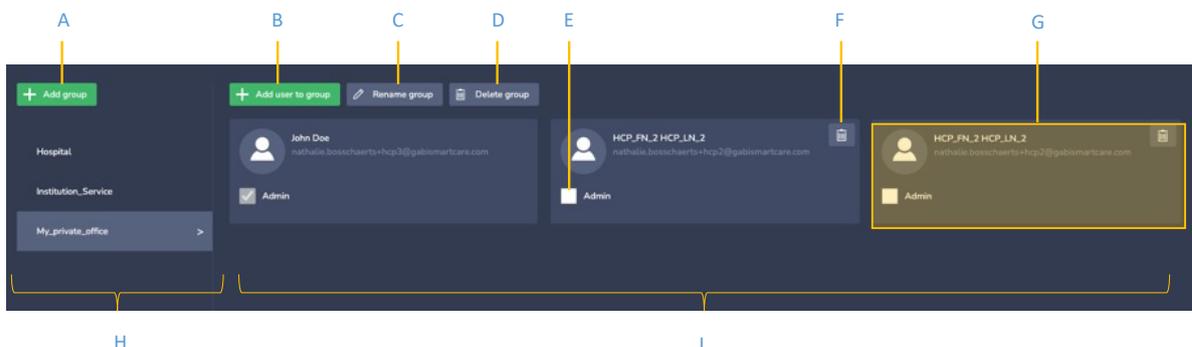


Figure 57: Groups management page

- A. Add group button
- B. Add user to group button
- C. Rename group button
- D. Delete group button
- E. Set/unset admin role to a user
- F. Remove a user from the group
- G. User information
- H. Groups list
- I. Users in the selected group

On the groups management page, you have your groups list on the left (H). When you select a group in this list, the users included in the selected group are displayed on the right (I). Each user is displayed with his first name, last name and email address (G).

Each group has at least one administrator, who can manage the group: add or remove user and rename or delete the group.

7.3.1 Create a New Group

To create a new group, press the “add group” button (button A in Figure 57 above).

A modal opens, where you can type the name of the group you want to create. To help you, you can press the magic wand button. Answer to the two questions and the platform suggest you a group name. When you have decided your group name, click on the ‘create group’ button.



Figure 58: Group creation modal

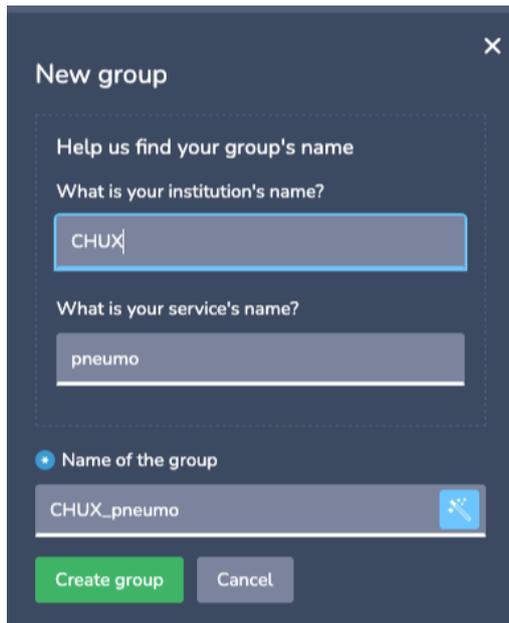


Figure 59: Help for naming of group

The group is created and added to your groups list on the left. You can now add user to your group (see 7.3.2 Add a user to a group).

7.3.2 Add a user to a group

If you are administrator of the group, you can add a user by clicking on the “add user to group” button (see button B in Figure 57 above). A modal opens, where you can type the complete email address of the user you want to add.

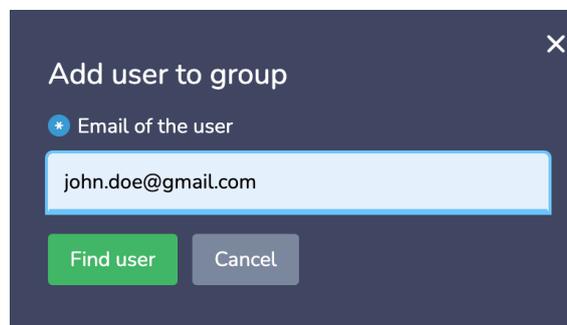


Figure 60: Add user to group modal

If the email address is known in Gabi™ Analytics, you can define if you want to add him as administrator of the group, by checking the checkbox “Admin”. You can add him to your group by clicking on the “add user to group” button.

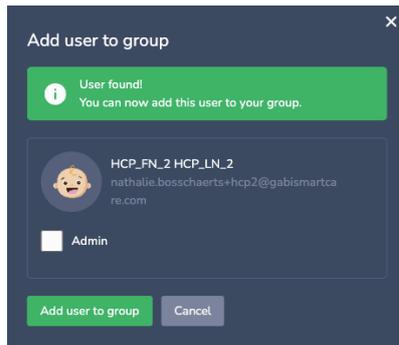


Figure 61: Add user to group confirmation

If the email address is not known in Gabi™ Analytics, the platform suggests you to invite the healthcare professional to join the platform. If you want to invite this user, click on the “invite user to group” button. A confirmation message is displayed. You can close it to access to your group. The user will receive a notification to inform him that he has been invited to join Gabi™ Analytics by you.

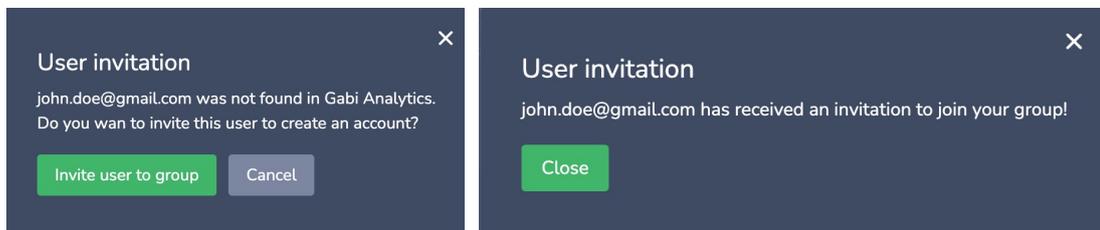


Figure 62: User invitation and confirmation

The invited user is in a category “Pending invitation” as long as he has not registered on the platform.

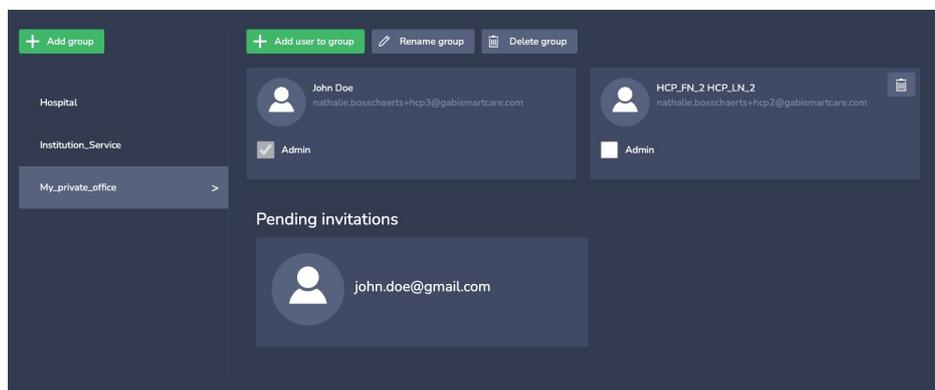


Figure 63: Pending invitations category

7.3.3 Remove a user from an existing group

If you are administrator of the group, you can add a user by clicking on the bin button (see button **F** in Figure 57 above). A modal opens asking you to confirm that you want to delete the user from the group. If you are sure, click on the “remove user” button. The user will receive a notification to inform him that he has been removed from the group by you.

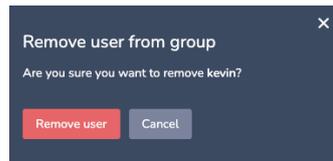


Figure 64: Confirmation of user removal from a group

7.3.4 Administrator role update

If you are administrator of the group, you can add or remove the administrator rights to/from a user of the group (see button E in Figure 57 above). The user will receive a notification to inform him that he has been granted the administrator rights by you or that these rights have been removed by you. Be aware that a group must have at least one administrator.

7.3.5 Rename an existing Group

If you are administrator of the group, you can rename it by clicking on the “rename group” button (see button C in Figure 57 above). A modal opens where you can update the current group name. Save your modifications by clicking on “rename group” button of the modal.

7.3.6 Delete an Existing Group

To delete a group, select it. If you are administrator of the group, click on the “delete group” button (see button D in Figure 57 above). Be aware that by this action, you can lose access to patients shared with you by this group.

8. Your Gabi™ Analytics – New Features and Additional Information

There are other features and information that you can find on the Gabi™ Analytics platform.

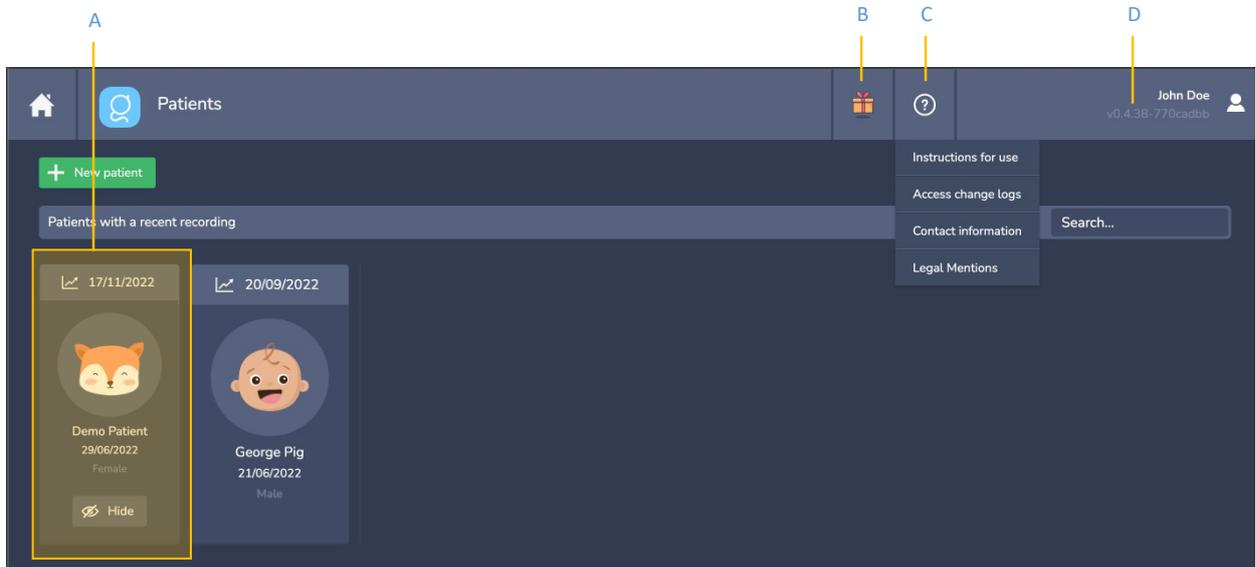


Figure 65: Additional features and Information

- A. Demo patient
- B. New features list
- C. Help button
- D. Current version of Gabi™ Analytics

8.1 Demo patient

The demo patient is recognizable by its specific logo. With this patient, you can navigate through the different screens and get a guided tour for each of them.

If you don't want to see the Demo patient in your list of patients, simply press the 'hide' button of the Demo patient. When it is hidden, you can still access it through the '?' button on the top bar of the platform (see C in Figure 65 above).

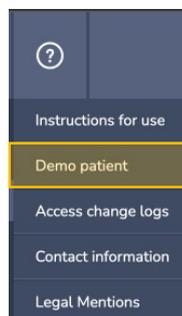


Figure 66: Access to Demo patient when hidden in list of patients

To open the Demo patient, click on its tile. The health report of the Demo patient opens, with the guided tour modal on the bottom right of the screen (see A in Figure 67 below).

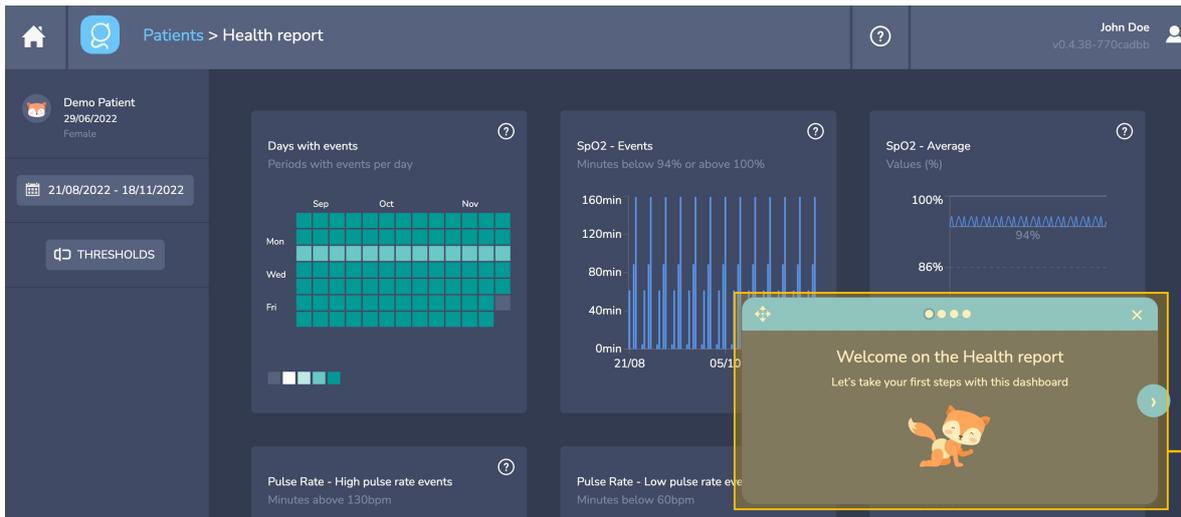


Figure 67: Health report of Demo patient



Figure 68: Guided Tour

- A. Guided tour modal
- B. Move the modal
- C. Swipe between explanations
- D. Close the guided tour modal
- E. Next explanation

The guided tour contains several explanations on the current screen features. You can swipe between the different explanations by either using the arrow on the right side of the guided tour (see E in Figure 68 above) or via the bullets on the top bar of the guided tour (see C in Figure 68 above).

You can move the modal to another location of the screen using the multidirectional arrows on the top left of the guided tour (see B in Figure 68 above) or close it by pressing the cross on top right of the guided tour (see D in Figure 68 above).

When closed, you can still reopen it through the '?' button on the top bar of the platform (see C in Figure 65 on page 48).

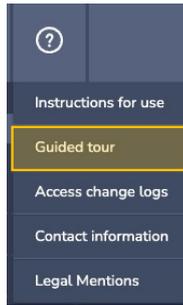


Figure 69: Access to guided tour when modal is closed

8.2 New Features List and change log

When a new version of Gabi™ Analytics is deployed, the version number is updated (see D in Figure 65 above) and a gift is displayed on the top bar (see B in Figure 65 above).

When clicking on the gift button, a list of the modifications with the previous version is displayed.

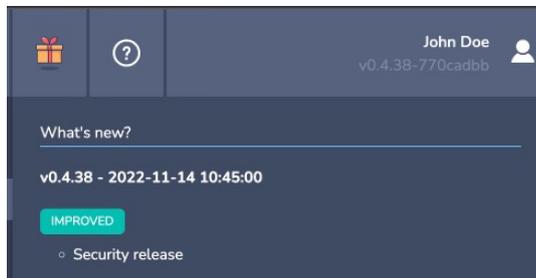


Figure 70: New features list

You can access the list of all versions and their changes through the ‘?’ button on the top bar of the platform (see C in Figure 65 above) and selecting “access change log”.

8.3 Access to Instructions for Use

You can easily access the latest instructions for use version through the ‘?’ button on the top bar of the platform (see C in Figure 65 above) and selecting “Instructions for use”. You will have access to this document in pdf format.

8.4 Contact Information

By clicking on the ‘?’ button on the top bar of the platform (see C in Figure 65 above) and selecting “Contact information”, Gabi™ Analytics will open your mail manager and open a new mail to support@gabismartcare.com. Feel free to contact us via this channel.

8.5 Legal Mention

By clicking on the ‘?’ button on the top bar of the platform (see C in Figure 65 above) and selecting “Legal Mention”, you have a direct access to the legal mentions of Gabi™ Analytics

9. Technical Specifications

Here you can find some technical specifications of the Gabi™ system that you prescribe to your patients.

9.1 Operational Specifications

Gabi™ Analytics is working on the following browsers:

- Chrome higher than or equal to v66
- Safari higher than or equal to v11
- Firefox higher than or equal to v70
- Opera higher than or equal to v60
- Edge higher than or equal to v80

9.2 Equipment Specifications

Per IEC 60601-1 and ISO 80601-2-61, the Pediarity™ system’s essential performance attributes include:

- Pulse Rate indication
- SpO2 indication

9.2.1 Biometrics range and accuracy

Table 2: Biometrics range and accuracy

<u>Parameter</u>	<u>Min value</u>	<u>Max value</u>	<u>Accuracy (Arms)</u>
SpO₂	70%	100%	2.95%
Pulse Rate	25 bpm ⁵	250 bpm	0.65 bpm
Respiratory Rate	4 brpm ⁶	70 brpm	2.9 brpm
Movements	‘None’	‘High’	/

Gabi™ system PR measurement has been validated for pulse rate accuracy for the range of 25-250 bpm in bench testing against a Whaleteq AECG100 with PPG-1R-525 simulator.

Gabi™ system SpO2 measurement has been validated on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter.

The data averaging time for the SpO2 parameter is 20 seconds.

⁵ bpm (beat per minute)

⁶ brpm (breath per minute) is equivalent to cpm (respiratory cycle per minute) or to rpm (respiration per minute)

 Because SpO₂ equipment measurements are statistically distributed, only about two-thirds of equipment measurements can be expected to fall within \pm Arms of the value measured by the reference equipment in the clinical study.

9.2.2 Used peak wavelengths

Infrared LED: 950nm

Red LED: 660nm

Green LED: 526nm

9.3 Lifetime

3 years

9.4 Product Compliance

Standards Compliance

- IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
- ISO 80601-2-61:2017
- IEC 60601-1-6:2010/AMD1:2013 & IEC 62366-1:2007/AMD1:2014
- IEC 62304:2006/AMD1:2015

10. Troubleshooting

This section details troubleshooting for Gabi™ Analytics. If your question or problem is not addressed in the following, please contact the customer support.

10.1 I cannot find my patient

You created your patient, but you do not find it in your list of patients?

- 1- The list of patients is ordered alphabetically on the last name of your patients.
- 2- If you are using the search tool, be sure you didn't make a spelling mistake. The tool is not case sensitive, but the spelling must be the correct one.
- 3- If you are not using the search tool, be sure no remaining entry is present in the tool.
- 4- If you were not the prescriber of the patient, be sure you are still in one of the groups attached to the patient.

10.2 How can I share a patient report with other healthcare professional(s)?

If your patient is included in a group, the healthcare professionals of this group have access to the patient report.

Proceed to the following steps:

- If not yet existing, create a group (see §7.3.1 Create a New Group on page 44) and include the healthcare professional(s) you want to share the patient with in the group (see §7.3.2 Add a user to a group on page 4544)
- Add this group to the patient you want to share (see §5.2 Patient Update on page 22 – Access group tab)

10.3 I cannot find guided tour / demo patient

If you closed the guided tour or the demo patient by mistake, you can reopen them via the help menu (see C in Figure 65 on page 48). Refer to Figure 66 on page 48 and to Figure 67 on page 49 for more details.

10.4 My patient's biometrics are not available

Your patient has been monitored, but no data are available in his daily biometrics on the corresponding day?

- 1- Check the time of the supposed monitoring. If the monitoring occurred before noon, you need to look for it on the day before
- 2- Check with the patient's caregiver if he has connected the Gabi™ system to Wi-Fi and if all the pending files have been sent.
- 3- Check the supposed length of the recording. A recording shorter than 20 minutes is considered as irrelevant by the system and is not available in Gabi™ Analytics.

If none of the points solves your issue, you can contact the customer service. Be sure to have the following information ready:

- Gabi™ Band serial number
- Start date and time of the recording

10.5 My patient’s biometrics are partially available

Your patient has been monitored, but the data available in his daily biometrics present some holes? If the data are greyed, it means that the quality index of the signal was too low and that the biometrics value may not be accurate.

If no data are available during a period of time, it means that the connection between the Gabi™ Band and the Gabi™ Monitor App has been lost during a certain period of time and that the recovery process of the missing data has not been completed till the end. The connection can be lost if the distance between the two devices is too high (more than around 7 meters).

10.6 Caregiver has lost his QR code, where can I find it?

If the caregiver lists his QR code, you can generate a new QR code, to allow him to link his Gabi™ system to the patient you created for him. Refer to §5.3 QR code generation on page 23.

10.7 Gabi™ Analytics is not accessible due to screen resolution

You try to open Gabi™ Analytics but a message explains you that the screen is too small? You may be using a smartphone, a small tablet or a browser window with small size. You need to increase the window size. If you are already using the maximum size, please use another tablet or computer.

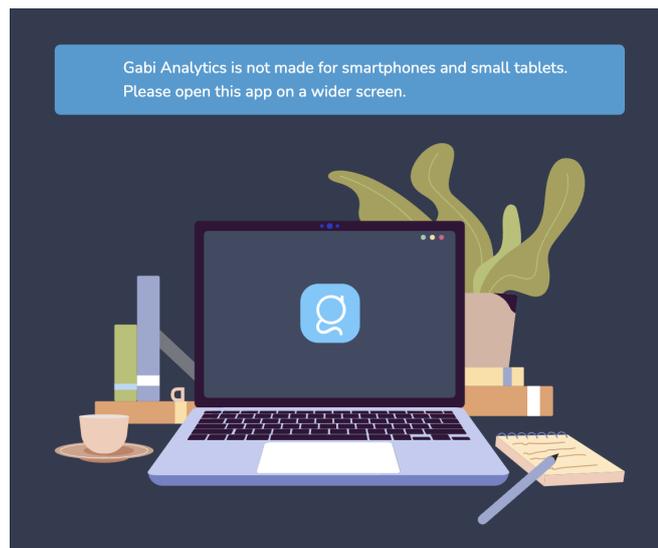


Figure 71: Too low resolution message

10.8 Gabi™ Analytics is not accessible due to browser version

You try to open Gabi™ Analytics but a message explains you that the current version of your browser is outdated? You have two solutions. Either use another browser already installed on your computer; or update your browser to a more recent version. You can do this by pressing the “update my browser” button. This will redirect you to an external site, listing the very latest version of the most common browsers.

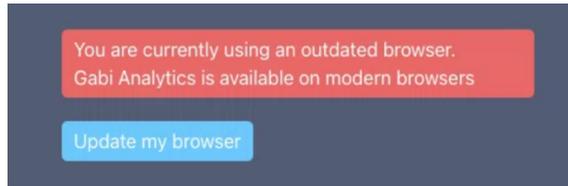


Figure 72: Outdated browser message

11. Symbols on Product or Package Labelling

Table 3: Labels meaning

	Medical Device
	Manufacturer
	Unique Device Identifier
	Mark of conformity to European Medical Device Regulation 2017/745
	The instruction manual/booklet must be read
	Lot code

12. Additional Information

12.1 Clinical Studies

See 9.2.1 Biometrics range and accuracy on page 51.

12.2 Disease and self-care information

The Pediarity™ system does not replace parental supervision.

The Pediarity™ system is not intended to replace the care of a healthcare professional, including prescription, diagnosis or treatment.

12.3 Adverse events

For adverse events or if you encounter a technical problem, please contact Gabi SmartCare® S.A (see contact information in chapter 13 User Assistance Information on page 58) or your local distributor.

Any serious incident that has occurred in relation to the device should also be reported to your Competent Authority with respect to your local regulation.

13. User Assistance Information

GABI SMARTCARE® SA

Rue Emile Francqui, 6

1435 Mont-Saint-Guibert (Belgium)

Device name: Pediarity

Model number: GSK-201

To contact our customer support:

Email: support@gabismartcare.com

Notes:

Medical equipment supplier: _____

home health care agency: _____

Physician: _____

Referral for disposal of the device: _____
