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

Version K

Manufacturer Contact Details:

GABI SMARTCARE® SA

Rue Emile Francqui, 6

1435 Mont-Saint-Guibert (Belgium)

Table of Contents

1. WELCOME TO GABI™ 5

2. ABOUT PEDIARITY™ SYSTEM 6

2.1 DEVICE INDICATIONS FOR USE 6
2.2 PRODUCT DESCRIPTION 6
2.3 CONTRAINDICATIONS 7

3. GENERAL WARNINGS AND CAUTIONS 8

3.1 WARNINGS 8
3.2 CAUTIONS 8
3.3 PRECAUTIONS 8

4. YOUR GABI™ ANALYTICS – REGISTRATION AND LOGIN ON THE PLATFORM 10

4.1 ACCOUNT CREATION 10
4.2 PASSWORD DEFINITION 14
4.3 LOGIN ON 16
4.4 PASSWORD RESET 16

5. YOUR GABI™ ANALYTICS – PATIENTS MANAGEMENT 18

5.1 PATIENTS LIST 18
5.1.1 ACTIVE PATIENTS LIST 18
5.1.2 INACTIVE PATIENTS LIST 21
5.1.3 ALL PATIENTS LIST 22
5.2 PATIENT CREATION 22
5.2.1 CHILD'S INFORMATION 22
5.2.2 HEALTH CONDITION 24
5.2.3 EVENT CONFIGURATION 24
5.2.4 CAREGIVER INFORMATION 25
5.2.5 PRESCRIBER 25
5.2.6 ACCESS GROUP 26
5.2.7 ONBOARDING 26
5.3 PATIENT UPDATE 26
5.4 QR CODE GENERATION 27
5.5 PATIENT DELETION 28

6. YOUR GABI™ ANALYTICS – PATIENT BIOMETRICS REVIEW 30

6.1 PATIENT HEALTH REPORT 30
6.1.1 PATIENT HEALTH REPORT – LAST AVAILABLE NIGHT 30
6.1.2 PATIENT HEALTH REPORT – LAST 7 NIGHTS 33
6.1.3 PATIENT HEALTH REPORT – LAST 30 NIGHTS 33
6.1.4 PATIENT HEALTH REPORT – TRENDS 90 NIGHTS 34
6.1.5 EVENTS CONFIGURATION 34
6.2 PATIENT DAILY BIOMETRICS 35
6.2.1 NIGHT SELECTION 35
6.2.2 SCROLLBAR AND SLIDING WINDOW 36
6.2.3 DETAILED BIOMETRICS 37

7. YOUR GABI™ ANALYTICS – USER PROFILE AND GROUPS MANAGEMENT 40

7.1 LOGOUT FROM GABI™ ANALYTICS 40
7.2 USER PROFILE 40
7.2.1 PROFILE SHEET 41
7.2.1 CONFIGURATION 41
7.2.2 GROUPS SHEET 41
7.2.3 EMAIL ADDRESS SHEET 42
7.2.4 PASSWORD SHEET 43
7.3 GROUPS MANAGEMENT 44
7.3.1 CREATE A NEW GROUP 45
7.3.2 ADD A USER TO A GROUP 45
7.3.3 REMOVE A USER FROM AN EXISTING GROUP 47
7.3.4 ADMINISTRATOR ROLE UPDATE 47
7.3.5 RENAME AN EXISTING GROUP 47
7.3.6 DELETE AN EXISTING GROUP 47

8. YOUR GABI™ ANALYTICS – NEW FEATURES AND ADDITIONAL INFORMATION 48

8.1 DEMO PATIENT 48
8.2 GUIDED TOUR 49
8.3 NEW FEATURES LIST AND CHANGE LOG 50
8.4 ACCESS TO INSTRUCTIONS FOR USE 50
8.5 CONTACT INFORMATION 50
8.6 LEGAL MENTION 50
8.7 POLICIES 50

9. TECHNICAL SPECIFICATIONS 51

9.1 OPERATIONAL SPECIFICATIONS 51
9.2 EQUIPMENT SPECIFICATIONS 51
9.2.1 DATA RANGE DISPLAY 51
9.2.2 PULSE RATE ACCURACY 51
9.2.1 SpO_2 ACCURACY 52
9.2.2 USED PEAK WAVELENGTHS 54

9.3 LIFETIME 54
9.4 PRODUCT COMPLIANCE 54

10. TROUBLESHOOTING 55

10.1 I CANNOT FIND MY PATIENT 55
10.2 HOW CAN I SHARE A PATIENT REPORT WITH OTHER HEALTHCARE PROFESSIONAL(S)? 55
10.3 I CANNOT FIND GUIDED TOUR / DEMO PATIENT 55
10.4 MY PATIENT'S BIOMETRICS ARE NOT AVAILABLE 55
10.5 MY PATIENT'S BIOMETRICS ARE PARTIALLY AVAILABLE 56
10.6 CAREGIVER HAS LOST HIS QR CODE, WHERE CAN I FIND IT? 57
10.7 GABI™ ANALYTICS IS NOT ACCESSIBLE DUE TO SCREEN RESOLUTION 57
10.8 GABI™ ANALYTICS IS NOT ACCESSIBLE DUE TO BROWSER VERSION 57

11. SYMBOLS ON PRODUCT OR PACKAGE LABELLING 58

12. ADDITIONAL INFORMATION 59

12.1 CLINICAL STUDIES 59
12.2 DISEASE AND SELF-CARE INFORMATION 59
12.3 ADVERSE EVENTS 59

13. USER ASSISTANCE INFORMATION 60

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 60).

2. About Pediarity™ System

The Pediarity™ system is a non-invasive, innovative, and advanced solution that allows to measure wirelessly several physiological parameters (SpO_2 and Pulse Rate) of 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 for spot-checking and/or continuous recording of pulse rate (PR) and 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.

2.2 Product Description

The Pediarity™ system is composed of

- the Gabi™ system used by the patient's caregiver, including the Gabi™ Band and Gabi™ Monitor.

- 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.

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.

⚠ Movement levels are provided for information purposes only. They should not be relied upon to inform patient care.

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.

To ensure the safety of your network, it is important to take necessary precautions. We strongly recommend that you follow the following guidelines:

1- Keep your network infrastructure up to date: Regularly upgrade your network devices, including home routers, to the latest versions available. This ensures that you have the most secure and stable software running on your devices.
2- Avoid default usernames and passwords: Change the default login credentials provided by your network devices. Default usernames and passwords are widely known and can make your network vulnerable to unauthorized access. Choose unique and strong combinations for enhanced security.
3- Use strong passwords for all user accounts: It is crucial to set strong passwords for all user accounts associated with your network. A strong password consists of a combination of uppercase and lowercase letters, numbers, and special characters. This makes it harder for attackers to guess or crack your passwords.

4- Change the router's default IP address: Modifying the default IP address of your router adds an extra layer of protection. Attackers often target routers using default IP addresses, so changing it reduces the chances of unauthorized access.
5- Disable remote access features: To minimize the risk of external manipulation of your network infrastructure, it is advisable to disable remote access features on your router. Remote access allows individuals outside your network to access and potentially compromise your network. Disabling this feature ensures that only authorized users within your network can make changes.

By following these recommendations, you can significantly enhance the security of your network and protect it from potential threats.

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 v80
- Safari higher than or equal to v13
- Firefox higher than or equal to v80
- Opera higher than or equal to v70
- 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.

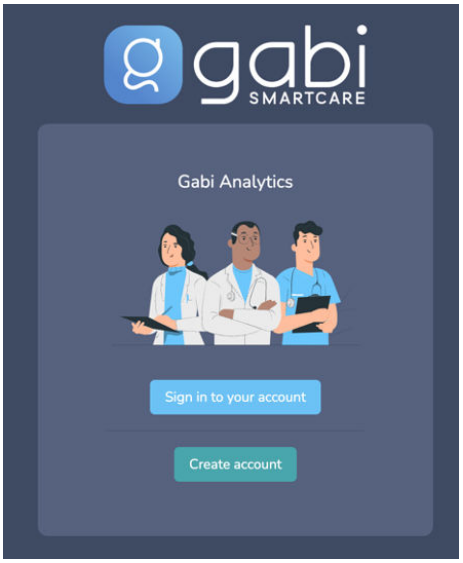

Figure 2: Gabi Analytics login page

The self-registration page opens.

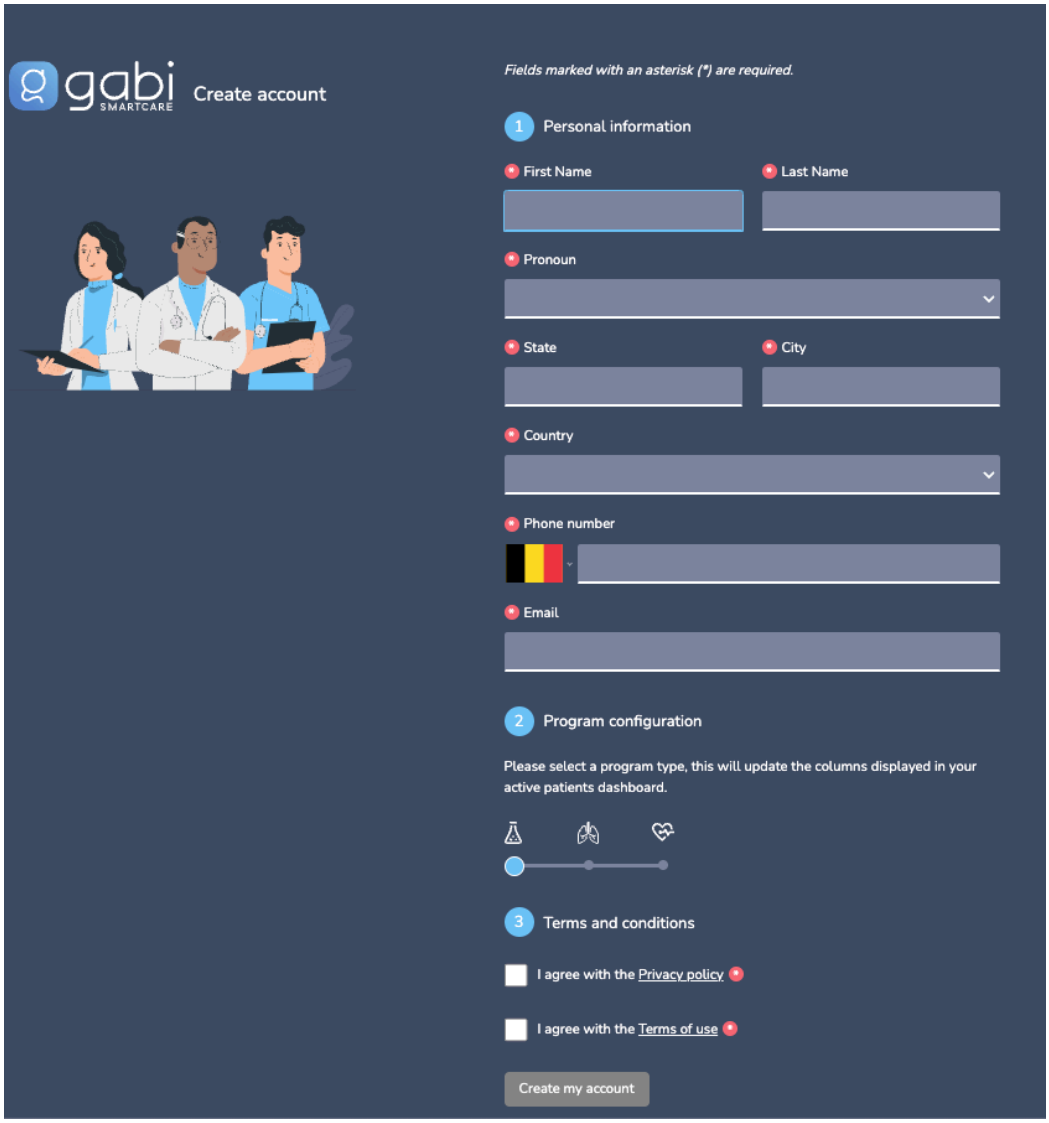

Figure 3: self-registration page

Please fill the mandatory fields:

- Your first name
- Your last name
- Your pronouns
- 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

Select a program type, this will update the columns displayed in your active patients dashboard.

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

Press the “Create my account” button.

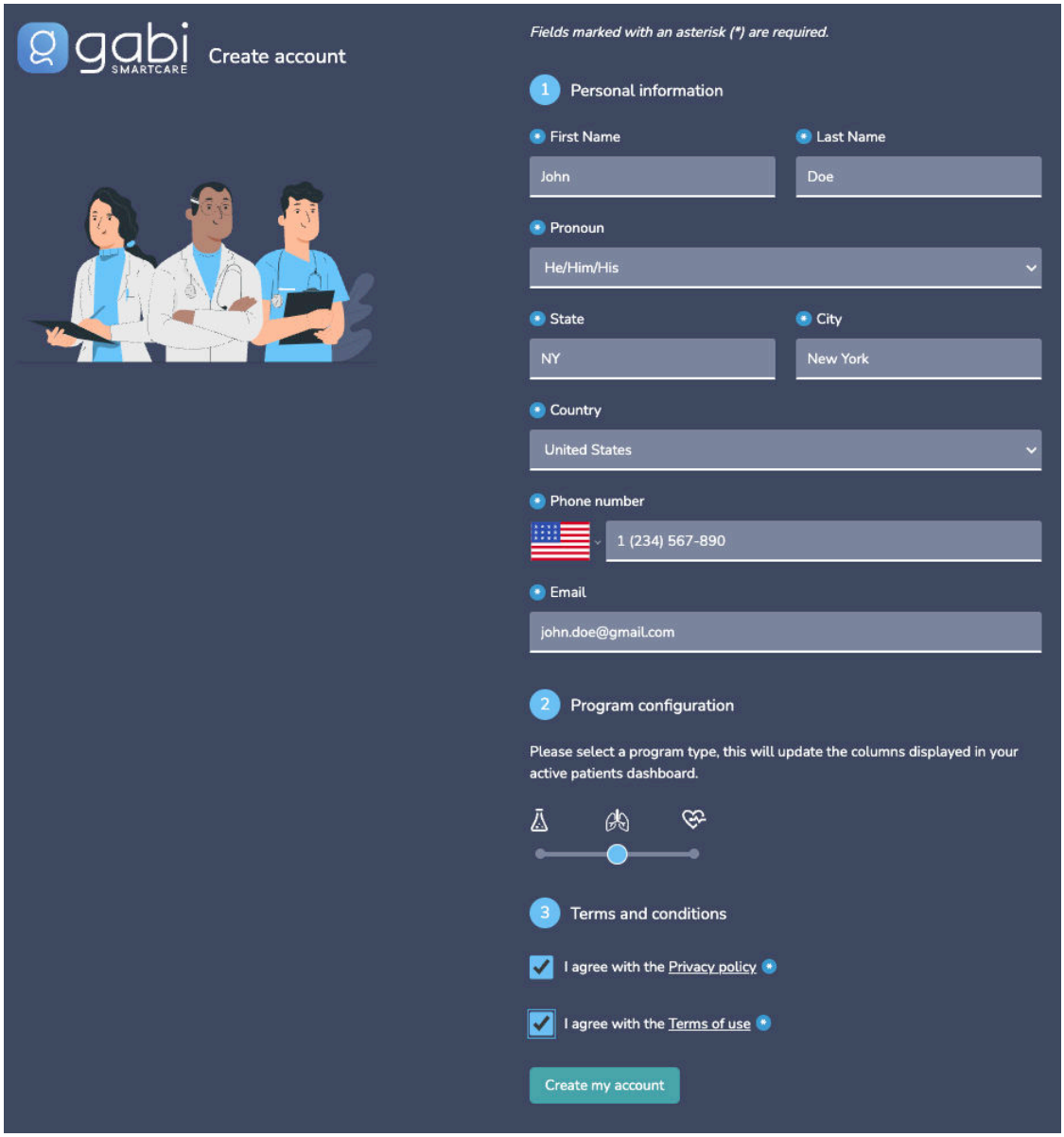

Figure 4: Example of filled self-registration page

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

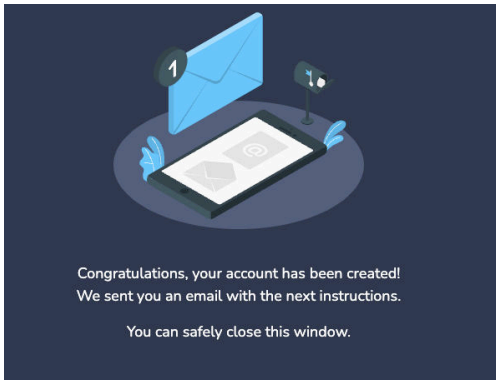

Figure 5: account creation confirmation message

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.

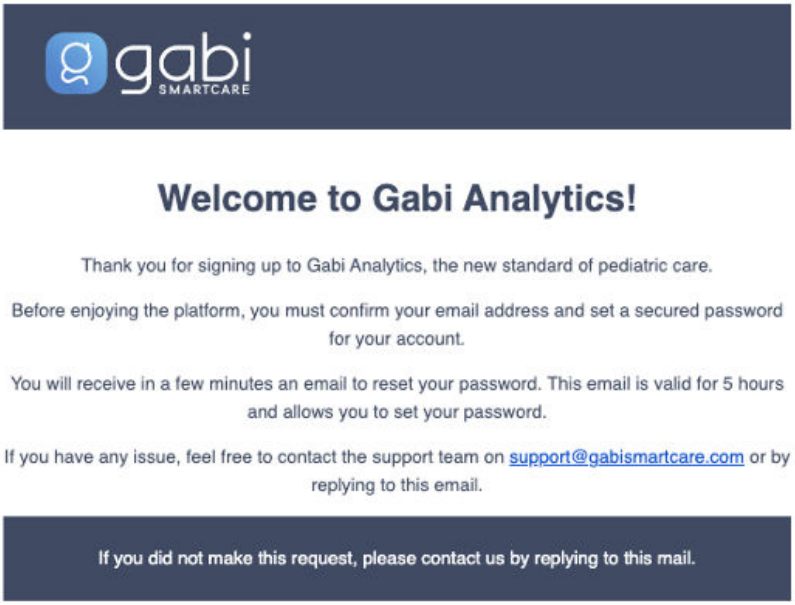

Figure 6: Welcome email content

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.

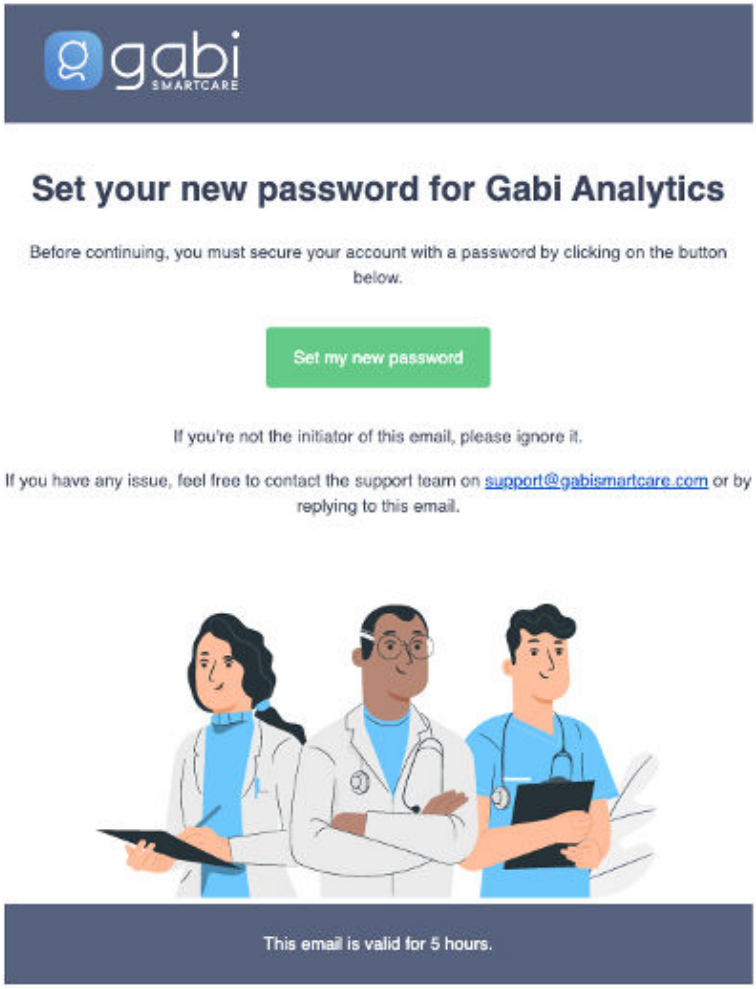

Figure 7: Set password email content

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 16).

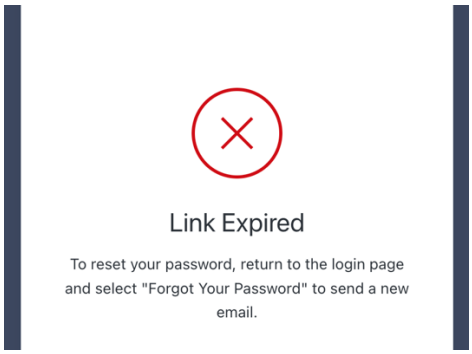

Figure 8: Set password expired link

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.

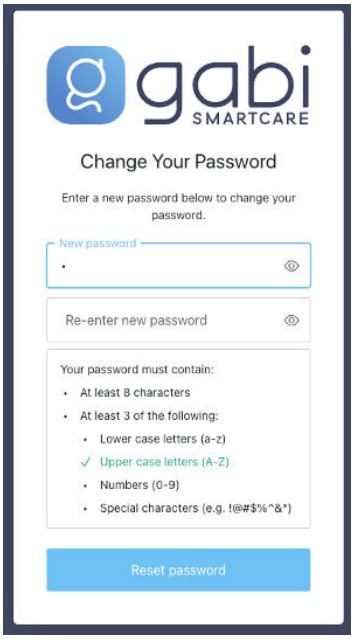

Figure 10: Password rules display

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.

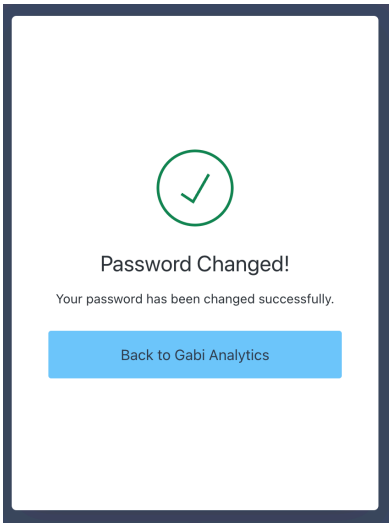

Figure 11: Password definition confirmation page

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.

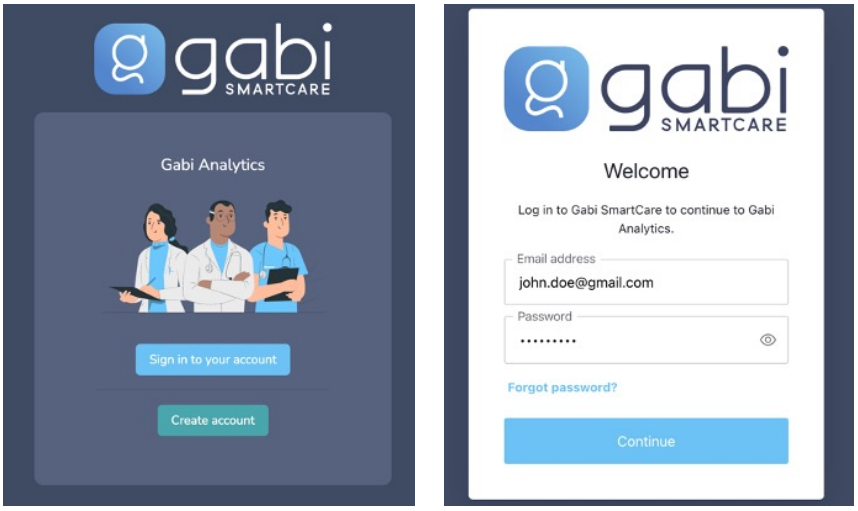

Figure 12: Login page and form

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.

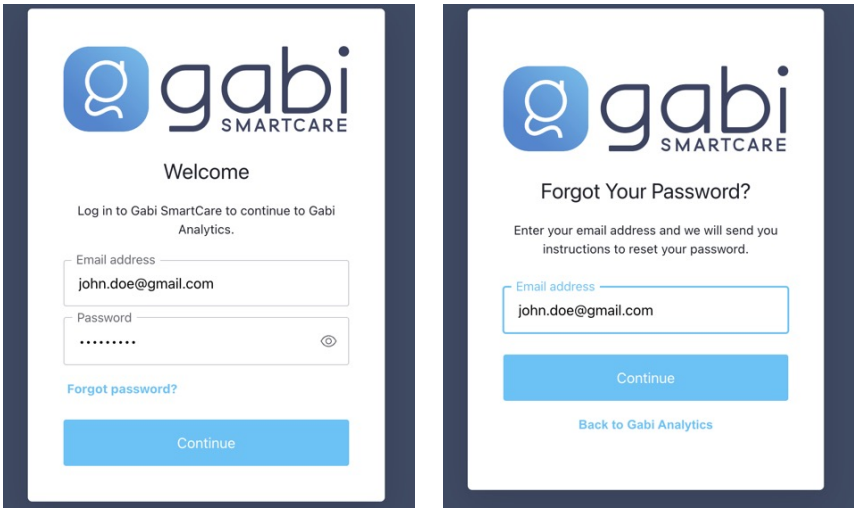

Figure 13: Forgot password page

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 14.

5. Your Gabi™ Analytics – Patients Management

When you log in Gabi™ Analytics, your list of active patients is displayed.

5.1 Patients list

5.1.1 Active patients list

You can find in this list all the patients created by you or shared with you, who performed a recording within the last 7 nights. You can also find the demo patient, which allows you to get some explanations on the different features of the platform.

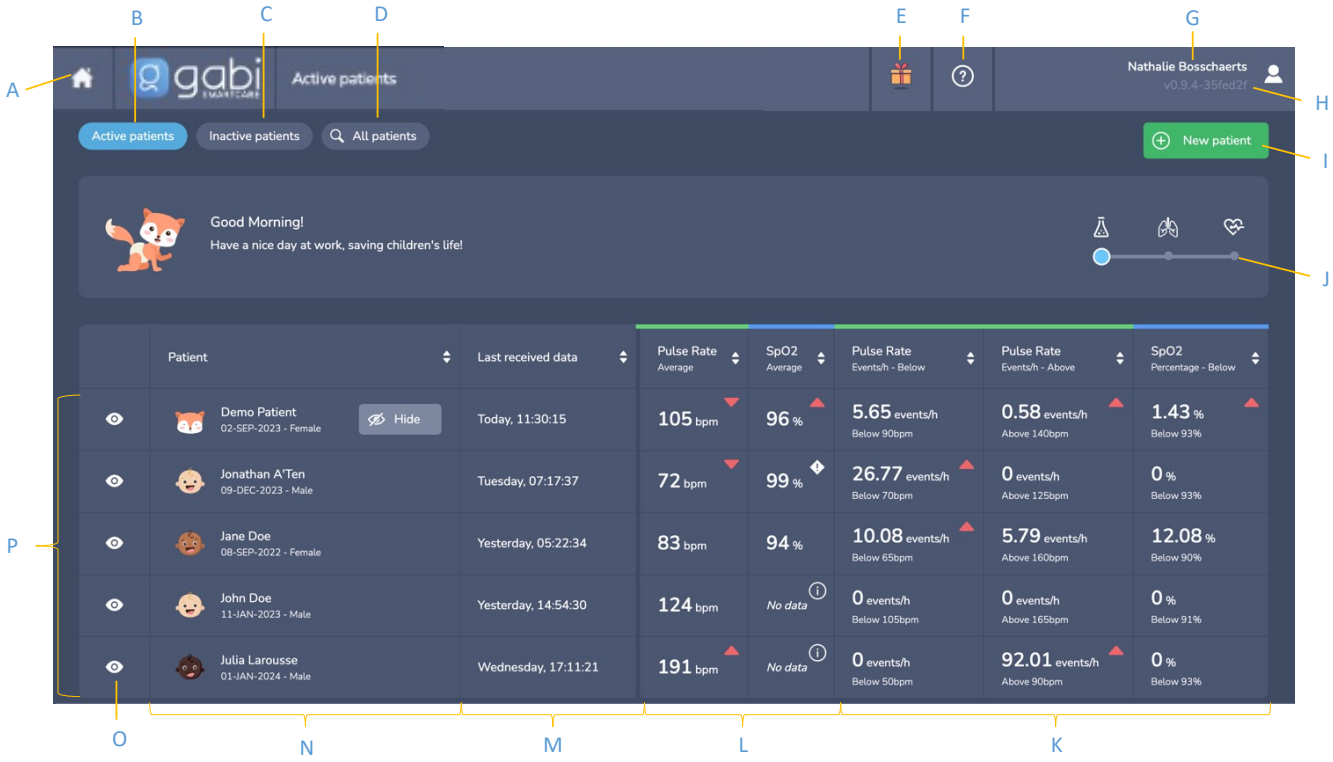

Figure 14: List of patients page

A. Home page button
B. List of active patients (with recent recordings)
C. List of inactive patients (with recordings older than 7 nights but younger than 90 nights)
D. All patients list, including the search function
E. List of the new features (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. New patient creation button
J. Program selector (laboratory (all events displayed), respiratory (SpO2 events displayed), cardiology (PR events displayed)
K. Summary of last recording events
L. Summary of last recording average and trends
M. Time of last recording end
N. Patient personal information

O. Access to patient's health report
P. List of patients

5.1.1.1 Patient information

This part (see N on Figure 14) includes the personal data of the patient.

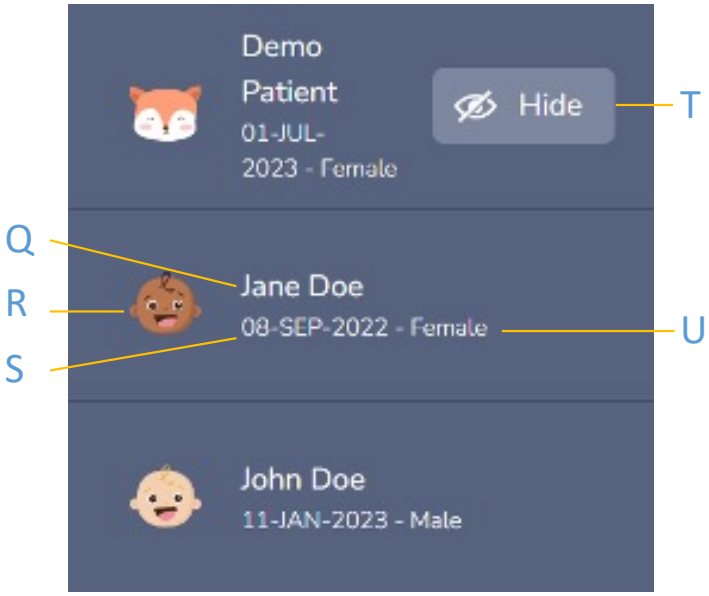

Figure 15: patient information

Q. Patient's first and last names
R. Patient's logo, including their skin color using Fitzpatrick scale[1]
S. Patient's birthdate
T. Specific to demo patient: option to hide from your patient's list (see §8.1 on page 48)
U. Patient' sex

5.1.1.2 Last recording averages and trends

This part (see L on Figure 14) includes the average of patient's biometrics (PR and SpO_2) from the last recording.

A trend sign (or) is displayed if this last recording average is outside the average of the previous 14 nights +/- 1 standard deviation.

[1] 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.

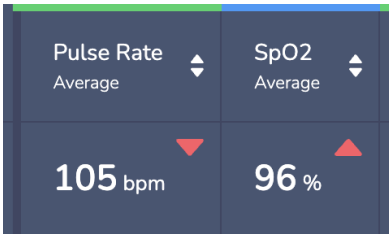

Figure 16: Trend signs

In the Figure 16 above, the pulse rate average is lower than the PR average of the previous 14 nights - 1 standard deviation and the SpO_2 average is upper than the SpO_2 average of the previous 14 nights + 1 standard deviation.

By moving the cursor of your mouse on the trend sign, you can display a graph (see Figure 17 below) with, for each nights of the 'previous 14 nights' period:

V. the duration of the recording for which the biometric is reliable (displayed as a grey bar)
W. the average of the biometric of reliable data (displayed as a point on the graph)
X. the minimal value of the biometric (displayed as a lighter area)
Y. the maximal value of the biometric (displayed as a lighter area)

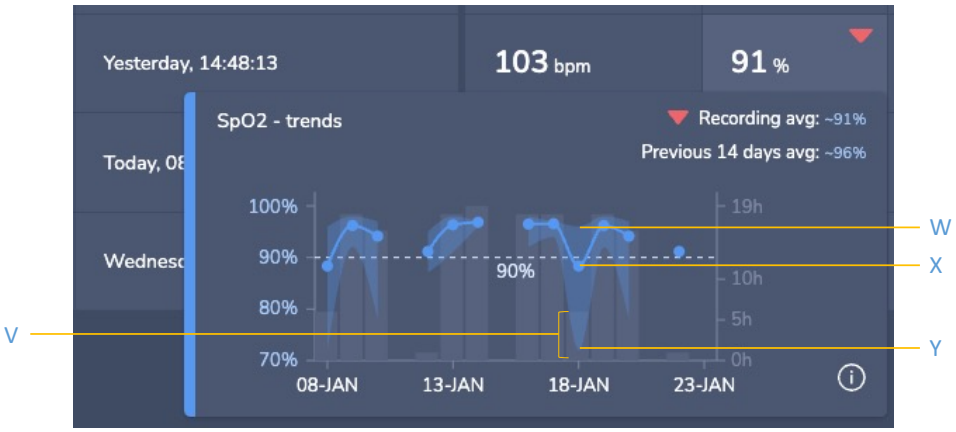

Figure 17: Average per night during period

If no data are available in the previous 14 nights, this comparison cannot be done. In this case, the average of the last recording will be displayed with a white warning sign, as shown in Figure 18 below.

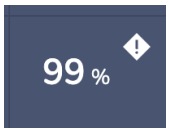

Figure 18: Warning sign

If no data are reliable for the whole last recording, "no data" is displayed.

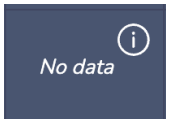

Figure 19: "No data" information

5.1.1.3 Last recording events

This part (see K on Figure 14) shows a summary of the events from the last recording.

For the pulse rate, this is summarized in number of events per hour.

For the SpO2, this is summarized by the percentage of time that the patient's SpO2 was under the threshold during the last recording.

As for the average part, trends signs are used:

- if this last recording event summary is below the average of the previous 14 nights +/- 1 standard deviation.
- if this last recording event summary is above the average of the previous 14 nights +/- 1 standard deviation.
- if no data are available for the previous 14 nights, making the comparison impossible

5.1.2 Inactive patients list

In this list, you can find the patients with last recording older than 7 nights but more recent than 90 nights or patients without recording and created in the last 90 nights, sorted by alphabetical order.

Figure 20: Inactive patients list

Z. Patient's status: this can be one of these four states:
- "Patient information are incomplete" when the QR code for the onboarding of the caregiver system is not available due to missing data for the patient In this case, you need to fill the missing data, by updating the patient via the CC button. The missing data are either the caregiver data or events configuration.
- "The caregiver did not complete the onboarding" when the caregiver has received the QR code for the onboarding of their system but that they didn't complete the link of their system yet.
- "The caregiver is ready to start recording" when the Gabi system linked to the patient is ready but that no recording has been performed yet.
- "No recording for xxx nights" when at least one recording has been performed, and that this last recording is older than 7 nights but more recent than 90 nights

AA. Caregiver data (first name, last name, phone number and email address)

BB. Access to onboarding information

CC. Update action: you will be able to update the patient data as described in §5.3 on page 26.

DD. Possibility to delete the patient (see §5.5 on page 28). This functionality is available as long as the caregiver didn't complete the onboarding of their system. After that, the patient cannot be deleted anymore.

5.1.3 All patients list

In this list, you can find all your patients: those included in the active patients list, those included in the inactive patients list, as well as those created before the last 90 nights and those having performed their last recording prior to the last 90 nights. In this view, you can also perform a search on the patient first name or last name via the search bar (see EE in Figure 21 below).

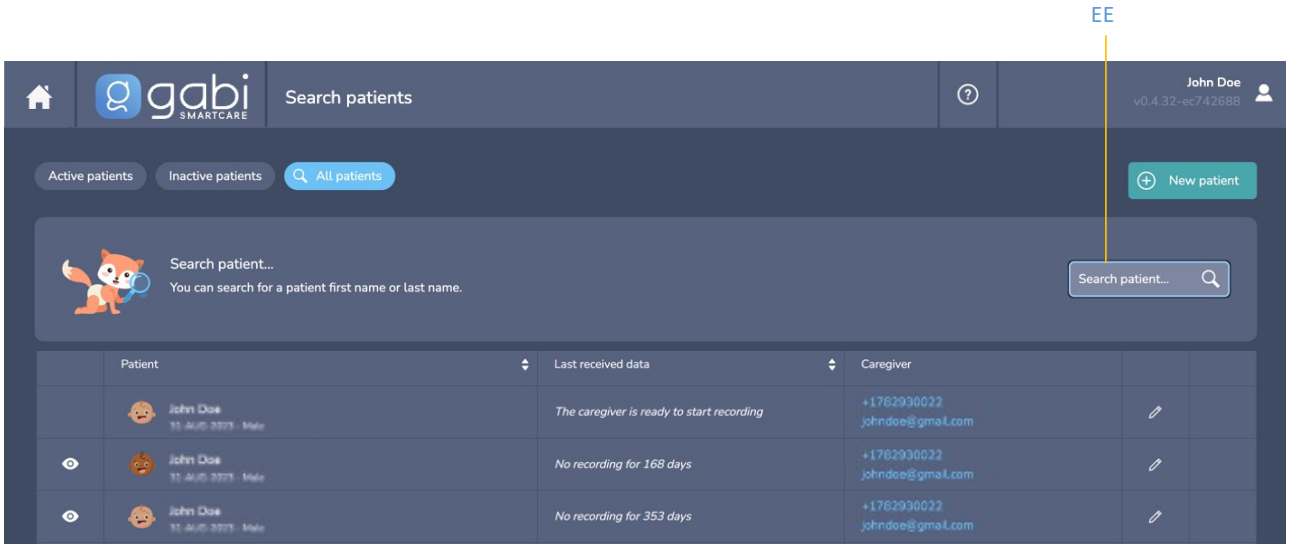

Figure 21: All patients list

5.2 Patient Creation

You can create a new patient by pressing the "new patient" button. Be aware that there are several 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 §5.3 Patient Update on page 26).

5.2.1 Child's information

You first need to fill in the child information.

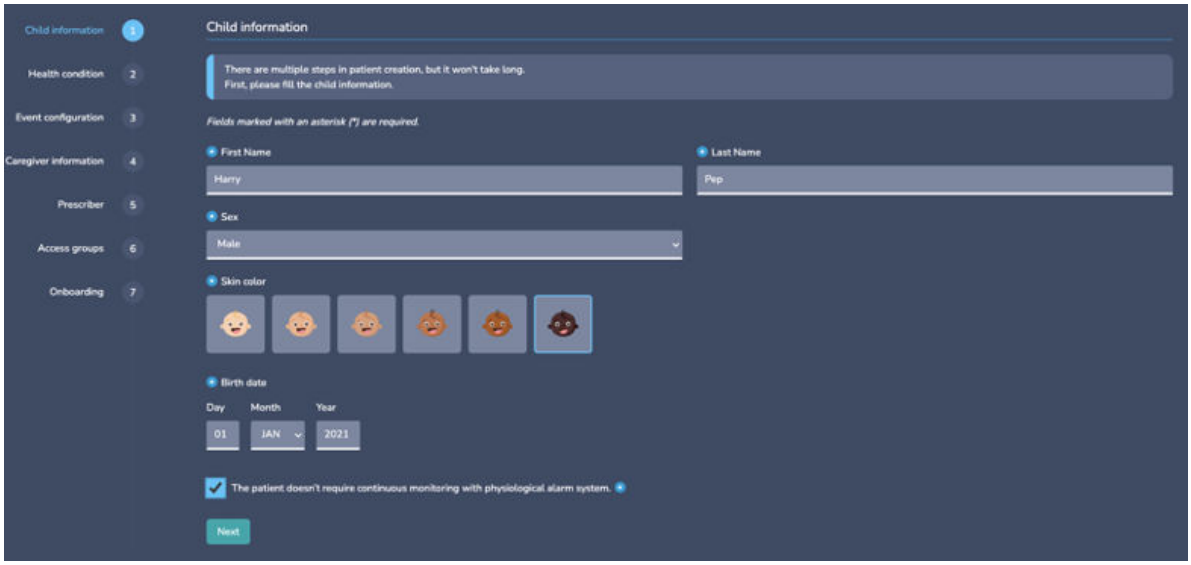

Figure 22: Patient creation form - child information

- Child's first name *(text field)*
- Child's last name *(text field)*
- Child' sex *(dropdown)*
- Child' skin color using Fitzpatrick scale[2] *(dropdown)*
- Child's birthdate *(numbers field)*
- 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 or older than 12 years old) *(checkbox)*

  ⚠ The Pediarity™ system is intended for use on infants and children up to and including 12 years of age.

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 §5.3 Patient Update on page 26).

5.2.2 Health condition

The second step is related to the patient's health condition.

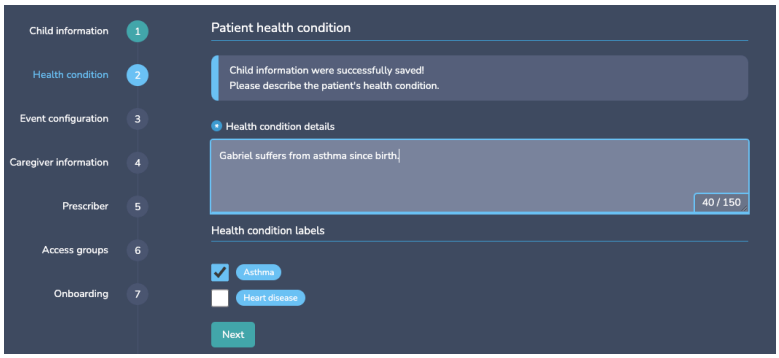

Figure 23: Patient creation form - health condition

- Health condition details
- Selectable health condition labels

5.2.3 Event configuration

The third step is related to the patient's event configuration.

A biometric measurement point is considered as an **event** when the biometric is outside the range defined by the thresholds for this biometric, during a predefined duration defined by the sensitivity.

For the pulse rate, you can define an upper and a lower threshold. Depending on patient age, default thresholds are proposed (see Table 1 below). You can also define a sensitivity (time that the pulse rate is outside the threshold before considering it as an event). By default, it is fixed at 5 seconds. You can adapt the two thresholds and the sensitivity by moving left or right the corresponding cursor.

For the SpO2, you can define a lower threshold. By default, it is defined at 93%. You can adapt it by moving left or right the cursor.

Patient age	HR [bpm[3]]	SpO2 [%]
1-3 months	[100 ;150]	[93 ; 100]
4-6 months	[90 ;140]	
7-11 months	[80 ;140]	
1-2 years	[70 ;130]	
3-5 years	[65 ;120]	
6-12 years	[60 ;110]	

Table 1: Default thresholds per patient age

[3] **bpm** (beat per minute)

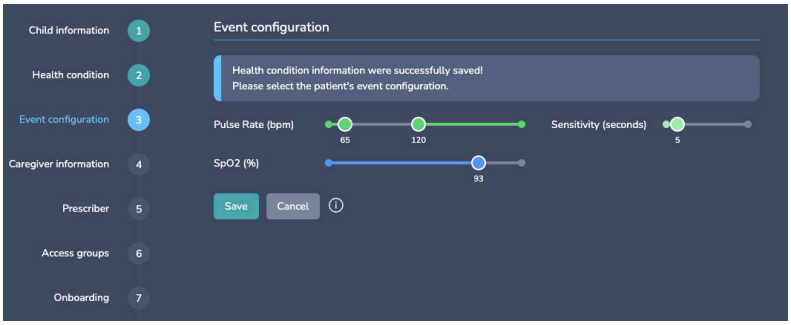

Figure 24: Patient creation form - event configuration

5.2.4 Caregiver information

The fourth step is related to the caregiver information.

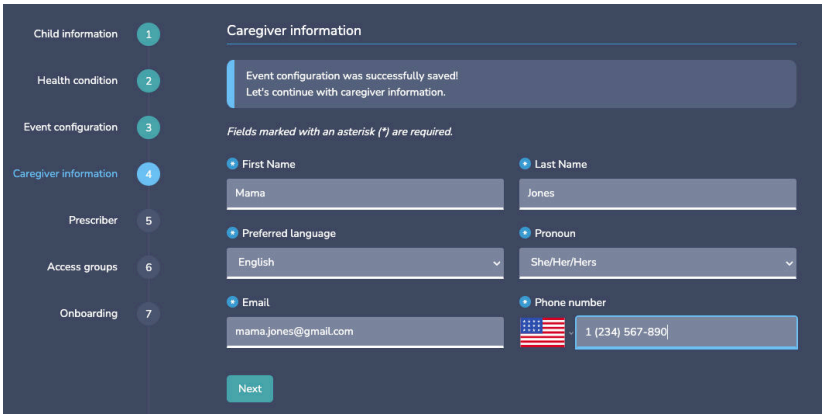

Figure 25: Patient creation form - caregiver information

- Caregiver's first name *(text field)*
- Caregiver's last name *(text field)*
- Caregiver's preferred language *(dropdown)*: the language defined here will be used in the emails sent to the caregiver.
- Caregiver's pronoun *(dropdown)*
- Caregiver's email address *(text field)*: this email address is used to send the QR code to the caregiver (see §5.2.7 Onboarding on page 26)
- 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.

5.2.5 Prescriber

The fifth 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 44).

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

5.2.6 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.

5.2.7 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.

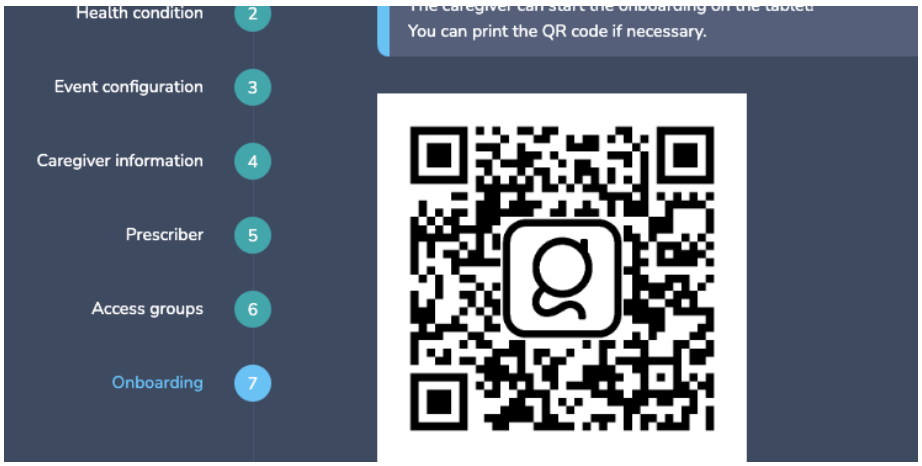

Figure 26: Patient creation form - QR code for caregiver

5.3 Patient Update

You can update a patient either from the inactive/all patients list (via button BB from Figure 20 on page 21) or from the patient health report.

To update a patient from the health report, follow the following steps:

1. Open the patient health report of your patient.
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.

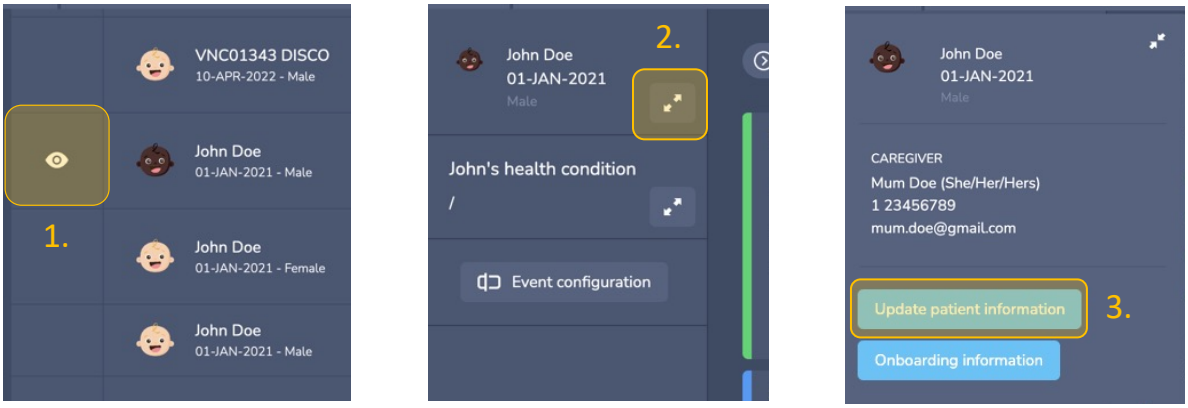

Figure 27: Patient update – steps

On the patient update page (see Figure 28 below), 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).

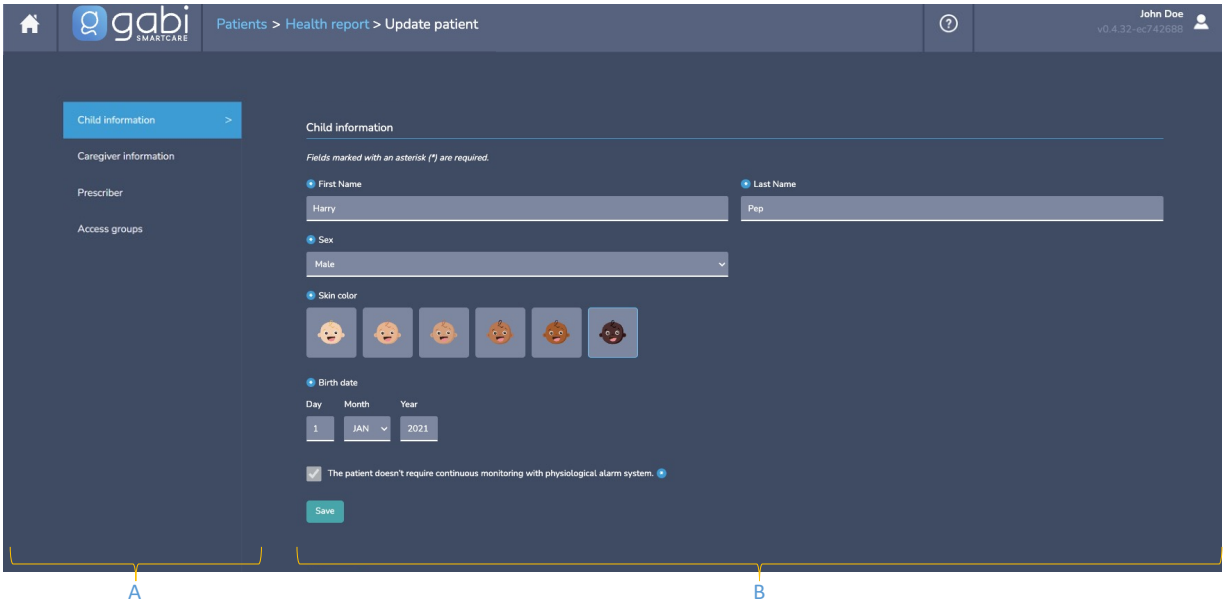

Figure 28: Patient update page

5.4 QR code generation

If the caregiver has lost the QR code generated during the patient creation (see §5.2.7 Onboarding on page 26), you can display the current QR code, or print it, by following these steps:

1. Open your patient’s health report.
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 ‘Onboarding information’ button.

The QR code is displayed. You can print it in pdf by pressing the blue button “print QR code”.

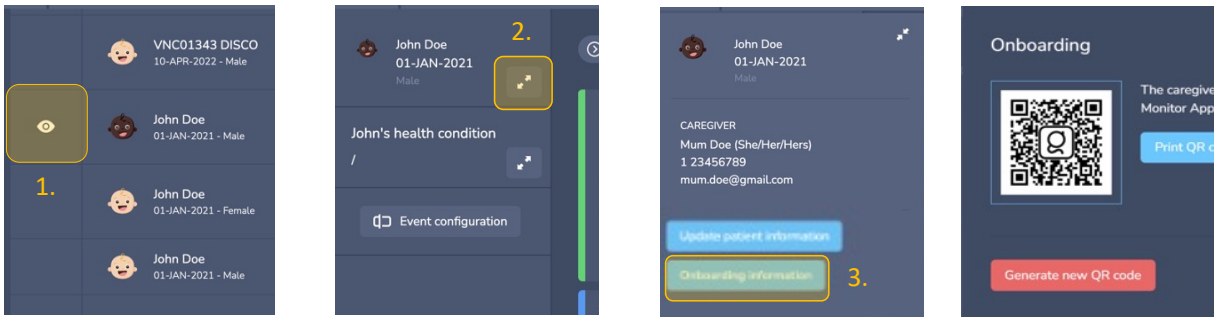

Figure 29: Display of current QR code

You can also generate a new QR code. This is required if the patient needs to use a new Gabi system. Proceed to the same steps as to display the QR code (see Figure 29) and then:

4. On the downside of the onboarding information, press the 'Generate new QR code' button.
5. Write GENERATE in the field and
6. Press the 'Generate new QR code' button.

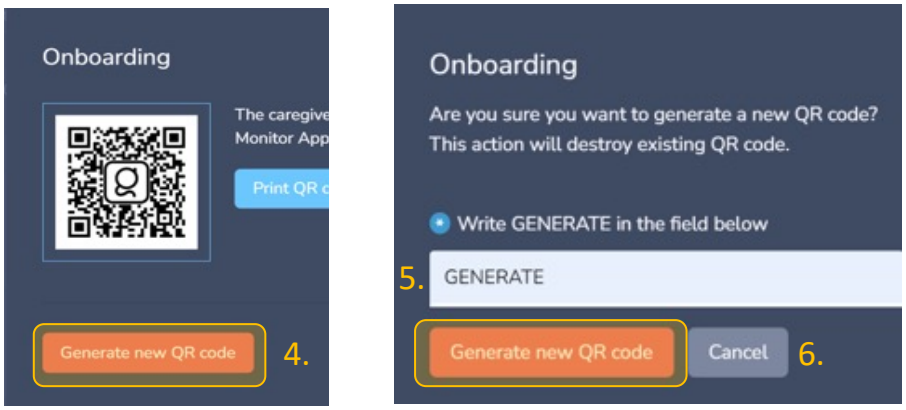

Figure 30: new QR code generation

5.5 Patient Deletion

You can only delete the patients created but not yet linked to a Gabi™ system, via the button CC from Figure 20 on page 21).

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

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.

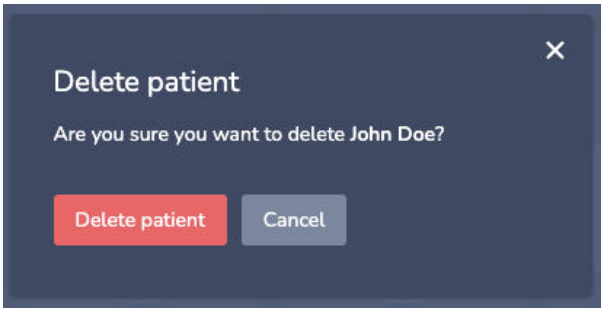

Figure 31: Patient deletion confirmation message

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

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 button O of Figure 14 on page 18. The patient health report opens.

6.1 Patient Health Report

The patient health report shows an overview of the patient current and previous biometrics.

There are 4 different views in the patient's health report:

- Last recording night overview
- Last 7 nights overview
- Last 30 nights overview
- Trends on last 90 nights

6.1.1 Patient Health Report – Last available night

The patient health report is composed of:

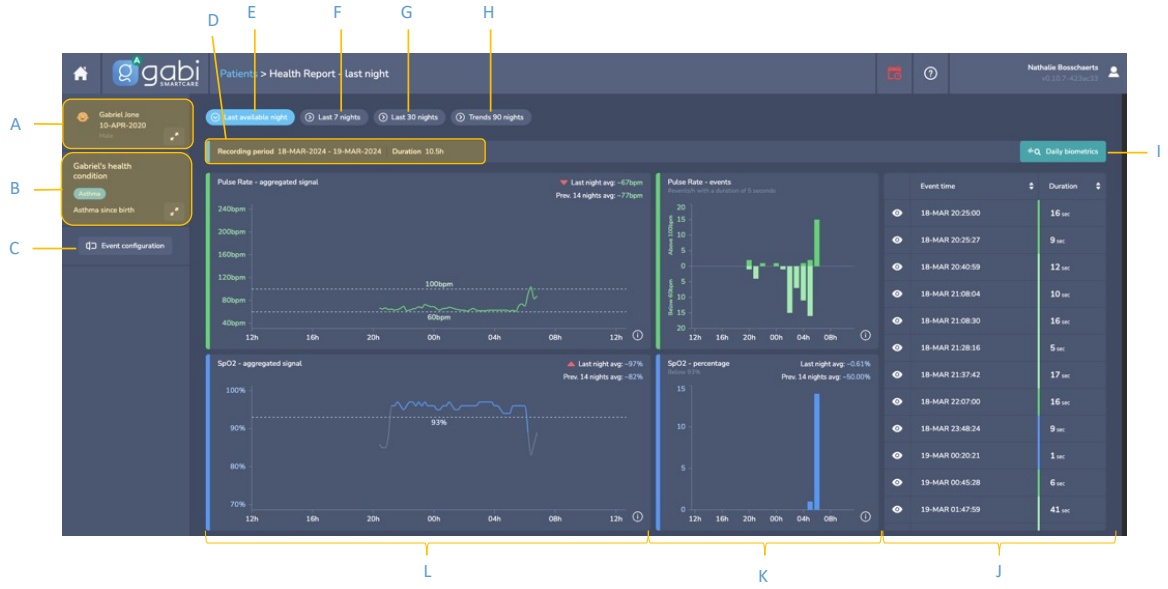

Figure 32: Patient Health Report composition

A. Patient's personal data, including patient's names, patient's birthdate, and patient' sex
B. Patient's health condition
C. Event configuration button (see §6.1.5 on page 34)
D. Recording timing (see §6.1.1.1 on page 31)
E. Last available night overview access
F. Last 7 nights overview access (see §6.1.2 on page 33)
G. Last 30 nights overview access (see §6.1.3 on page 33)
H. Last 90 nights trends access (see §6.1.4 on page 34)
I. Daily biometrics access (see §6.2.3 on page 37)
J. Events list (see §6.1.1.4 on page 32)
K. Number of events for each hour over the period (see §6.1.1.3 on page 31)

L. Aggregated signal for the period (see §6.1.1.2 on page 31)

6.1.1.1 Recording timing

You can find the dates of the considered period. As recording should be done in non-motion conditions, it is mainly done during the night. For this reason, the considered period is from 12:00 noon until 12:00 noon the next day.

You can also find the duration, which is the total length of recording during the considered period, including the potential moments with non-reliable data.

If the recording is older than 7 nights, a warning sign ( ) is displayed.

6.1.1.2 Aggregated signal for the period

This graph shows an aggregated view of the biometric over the period (from noon on day 1 to noon on day 2). It is computed by averaging the biometric values over a 12-minutes period. On this 12-minutes period, if more than 20% of the points are not reliable, the average is considered as not reliable and displayed in grey on the graph.

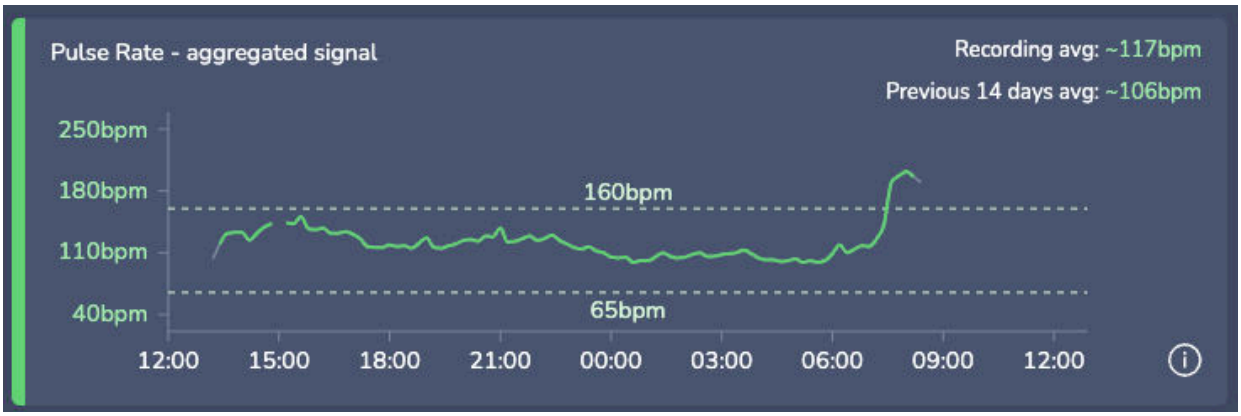

Figure 33: Aggregated signal

On the top right of the graph, the average of the recording and the average of the previous 14 nights are displayed.

A trend sign (or) is displayed next to the recording average if this last recording average is outside the average of the previous 14 nights +/- 1 standard deviation.

If no data are available in the previous 14 nights, this comparison cannot be done. In this case, the average of the last recording will be displayed with a white warning sign ( ).

6.1.1.3 Number of events for each hour over the period

You can find the event definition in §5.2.3 on page 24.

For the pulse rate biometric, this graph displays the number of events per hour.

Be aware that:

1- The graph for the pulse rate includes event for crossing the lower and the upper thresholds.

2- If the pulse rate was below the lower threshold for 20 minutes from 10h to 11h, one event will be reported for 10h.
3- If the pulse rate was below the lower threshold for 1 minute (with a sensitivity smaller than 1 minute), 7 times from 10h to 11h, 7 events will be reported for 10h.
4- If the pulse rate was below the lower threshold for 20 minutes from 10h to 11h, but that the data were not reliable or not available during 30 minutes from 10h to 11h, two events will be reported for 10h: as one event is reported out of 30 reliable minutes, it corresponds to 2 events on 60 minutes.

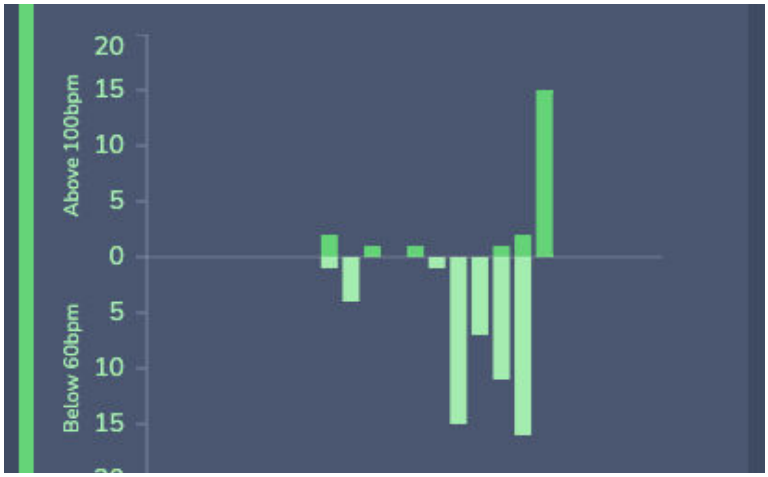

Figure 34: Events per hour

For the SpO2 biometric, this graph displays the percentage of time that the SpO2 was under the threshold for each hour of the period.

Be aware that if the SpO2 was below the threshold for 20 minutes from 10h to 11h, but that the data were not reliable or not available during 20 minutes from 10h to 11h, 50% will be reported for 10h: as 20 minutes is reported out of 40 reliable minutes, it corresponds to 50% of the time on the full hour.

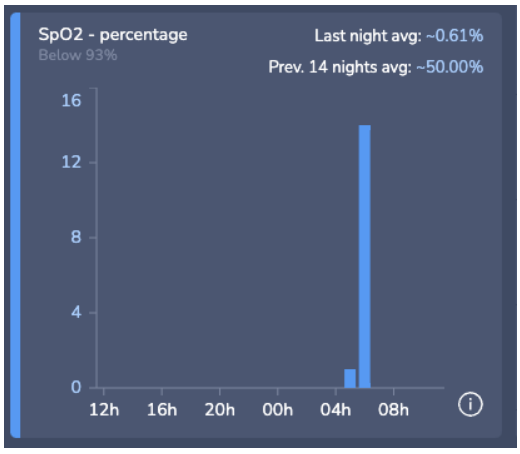

Figure 35: SpO2 events per hour in percentage

6.1.1.4 Events list

The event list displays all events that occurred during the period. For each event, the table displays:

- the type of event, depending on the colour (green for pulse rate, blue for SpO2),
- the event time and

- the event duration.

Figure 36: Tile with event time list

6.1.2 Patient Health Report – Last 7 nights

For each biometric, the system displays two graphs, for the last 7 nights:

- the average biometric value per night
- the daily average of the events/h (pulse rate) or percentage per night (SpO2)

On the top right, the average of the biometric on the last 7 nights is available.

Figure 37: Tiles with biometrics related events – last 7 nights health report

6.1.3 Patient Health Report – Last 30 nights

For each biometric, two graphs are displayed, showing, for the last 30 nights:

- the average biometric value per night
- the daily average of the events/h (pulse rate) or percentage per night (SpO2)

On the top right, the average of the biometric on the last 30 nights is available.

Figure 38: Tiles with biometrics related events – last 30 nights health report

6.1.4 Patient Health Report – Trends 90 nights

For each biometric, the system displays the average biometric value per night.

On the top right, the average of the biometric on the last 90 nights is available.

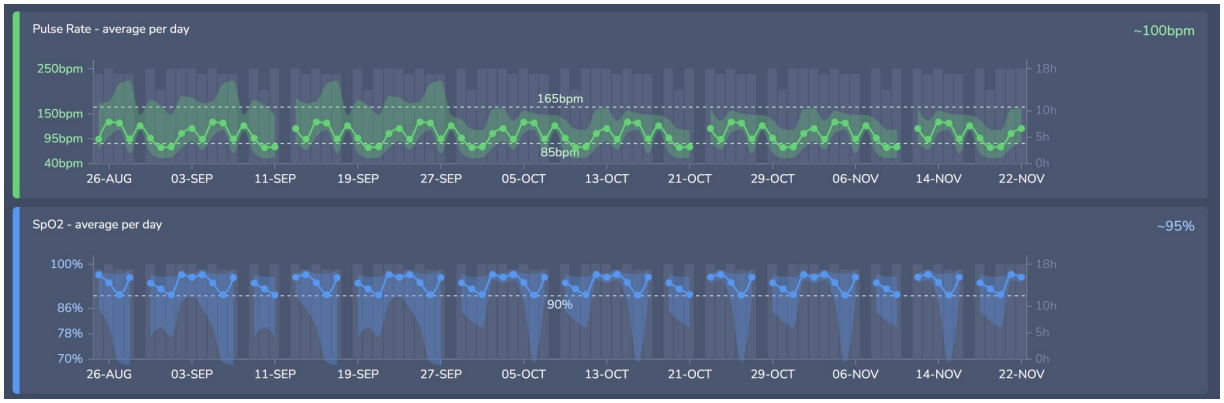

Figure 39: Tiles with biometrics related events – trends 90 nights health report

6.1.5 Events configuration

To update the thresholds defined at patient creation, press on the related button (C in Figure 32).

For the pulse rate, you can define an upper and a lower threshold. You can also define a sensitivity (time that the pulse rate is outside the threshold before considering it as an event). You can adapt the two thresholds and the sensitivity by moving left or right the corresponding cursor.

For the SpO2, you can define a lower threshold. You can adapt it 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.

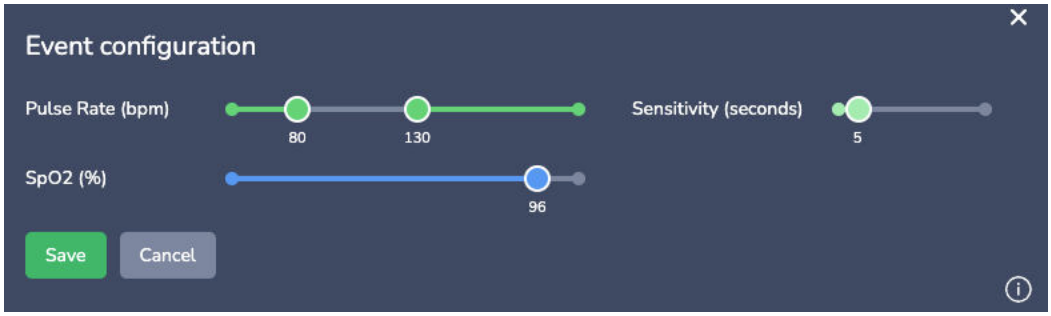

Figure 40: Health report - thresholds definition

The thresholds are defined for a specific patient, for any HCP having access to this patient. If another Gabi™ Analytics user has access to the same patient, your update will impact the thresholds used for this patient for the other user.

6.2 Patient Daily Biometrics

You can have access to the detailed biometrics by clicking on the daily biometrics button (see button I in Figure 32 on page 30) or on the corresponding time or night, in any tiles of the Health Report.

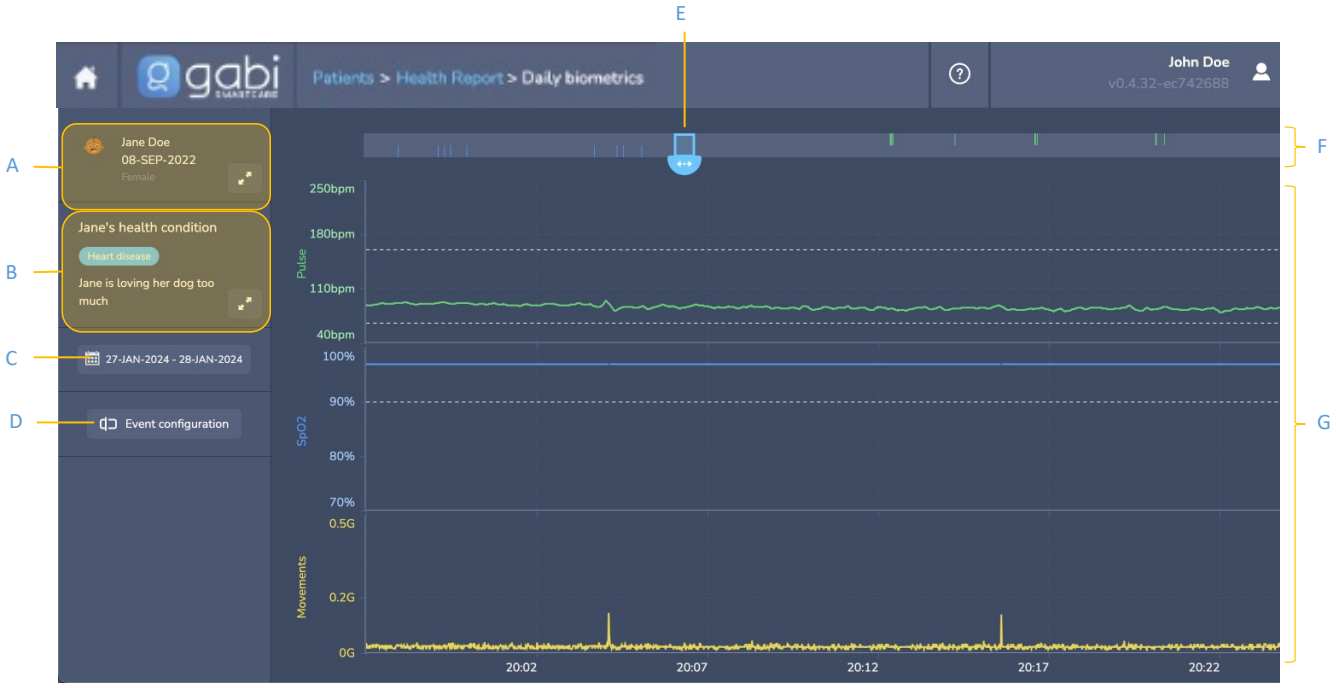

Figure 41: Daily Biometrics view

A. Patient personal data, including patient's names, patient's birthdate, and patient's sex
B. Patient's health condition
C. Night selection button
D. Event configuration button (see §6.1.5 on page 34)
E. Sliding window
F. Night overview of events
G. Detailed biometrics and movements

6.2.1 Night selection

The selected night is displayed in the button (example 27 JAN 2024 – 28 JAN 2024 which means that the period displayed in the daily biometrics view starts on 27 JAN 2024 noon and ends on 28

JAN 2024 noon). To select another night, click on the button. A calendar opens, it displays the selected night with a blue background and the nights 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. Once date is selected, you can close the calendar by clicking on the top-right cross.

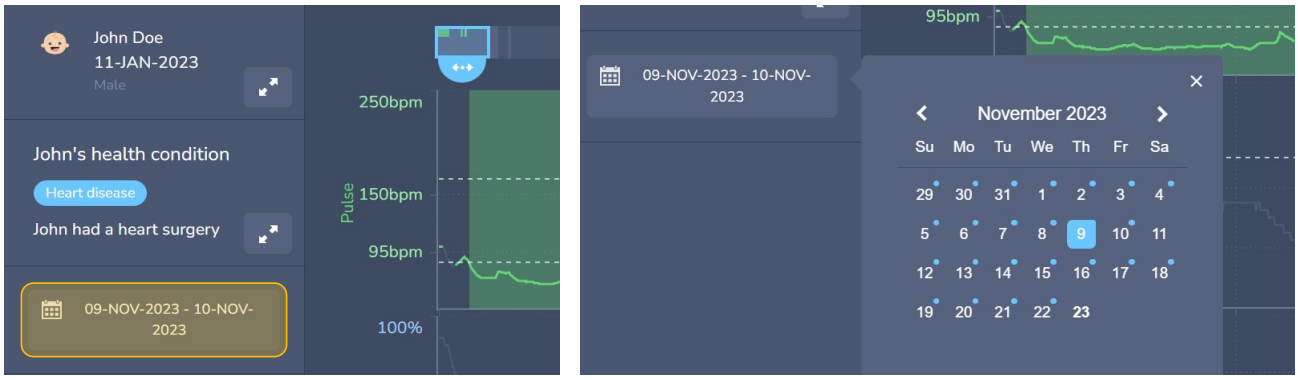

Figure 42: Night selection display - selected date

6.2.2 Scrollbar and sliding window

On the top on the graphs, a scroll bar represents the full recording time-axis. The blue sliding window represents the currently displayed period of time.

Figure 43: Sliding window represents displayed time-axis

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.

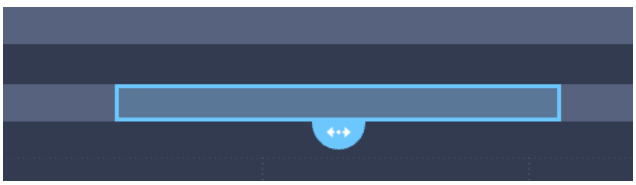

Figure 44: sliding window on the scroll bar

In the scroll bar, the events are displayed by vertical lines in the colour of the related biometrics.

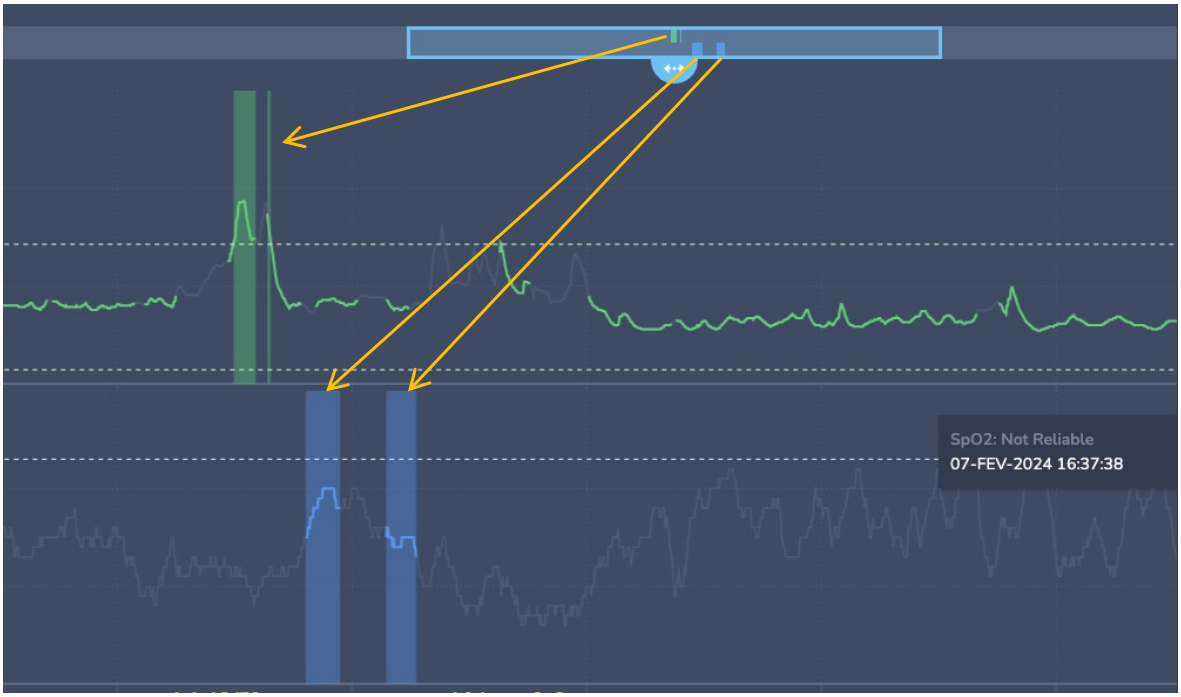

Figure 45: Events displayed in scrollbar

In the scroll bar, the periods with reliable biometric are displayed by horizontal lines, also in the colour of the related biometrics and the periods without recording are displayed with a darker grey background. In the Figure 46 below, the PR is reliable during the whole period A and the SpO_2 is mostly reliable during the period B.

Figure 46: Reliable data and recording displayed in scrollbar

A. Horizontal line representing the periods where PR is reliable
B. Horizontal line representing the periods where SpO_2 is reliable
C. Switch from period with recording on the left (light grey) to a period without recording on the right (darker grey)

6.2.3 Detailed biometrics

Three 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** (SpO_2). 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 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/s^2).

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

⚠ Movement levels are provided for information purposes only. They should not be relied upon to inform patient care.

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

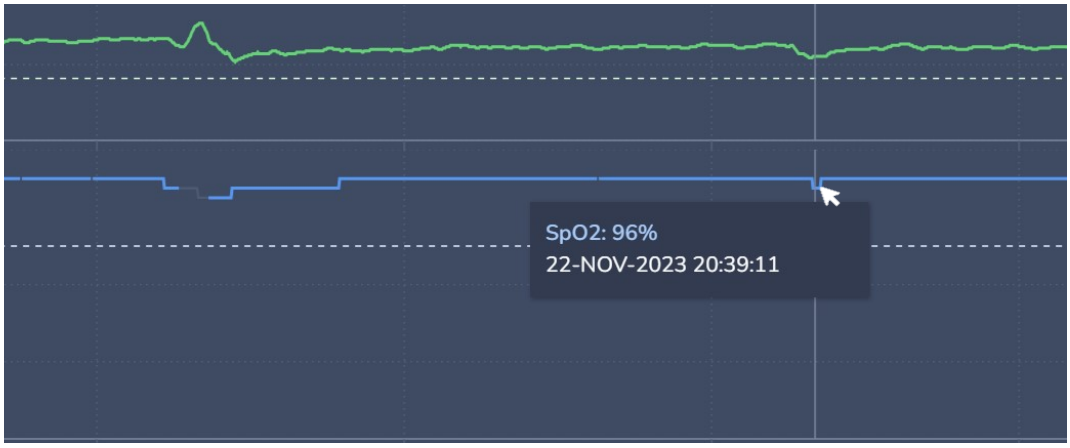

Figure 47: Biometrics graph with tracker

6.2.3.1 Events display

A biometric measurement point is considered as an **event** when the biometric is outside the range defined by the thresholds for this biometric, during a predefined duration defined by the sensitivity.

The events are highlighted in the graphs (see for example for both biometrics in Figure 48 below).

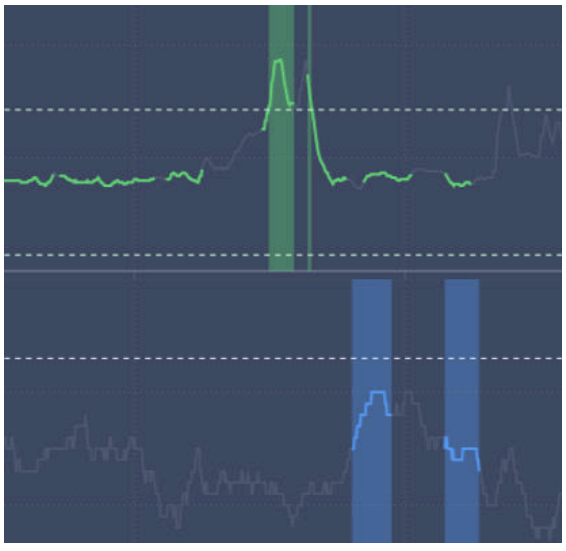

Figure 48: Events example

6.2.3.2 Not reliable data

The data for which the quality 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

If many data from a night are not reliable, it can be due to the Gabi Band being wrongly placed.

We advise you to contact the caregiver and check with them how they are using the product. You can refer to section 10.5 on page 56 for more information on the subject.

6.2.3.3 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 selected biometric. 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 49: Zoom modal

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 50 below).

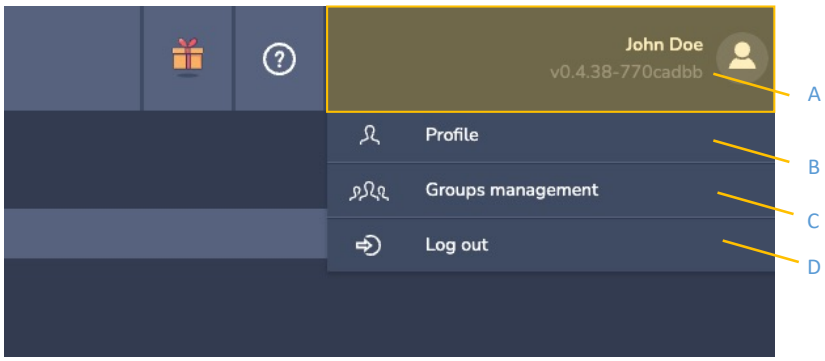

Figure 50: Profile and Groups Management access

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 50 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 50 above.

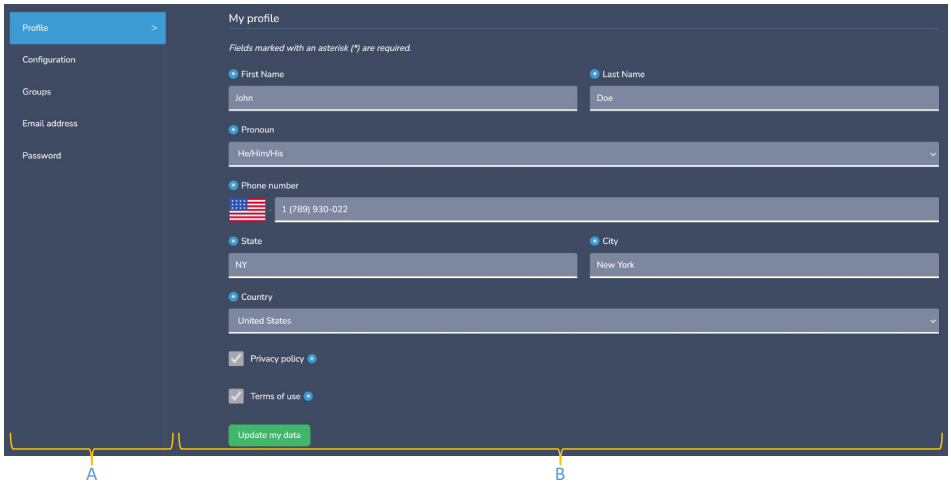

Figure 51: User profile – Composition and Profile sheet

On the user profile page, you have five sheets (A): profile, configuration, groups, email address, and password. You can navigate through these five 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 10):

- Your first name
- Your last name
- Your pronoun
- 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.

7.2.1 Configuration

The configuration sheet allows you to change your program type:

- laboratory (all events displayed),
- respiratory (SpO2 events displayed),
- cardiology (PR events displayed)

The program selected here will be used by default when you open your patients list. You can change this selection in the active patients list for the current display of your patients list but it will be reset to what is selected here for the next display.

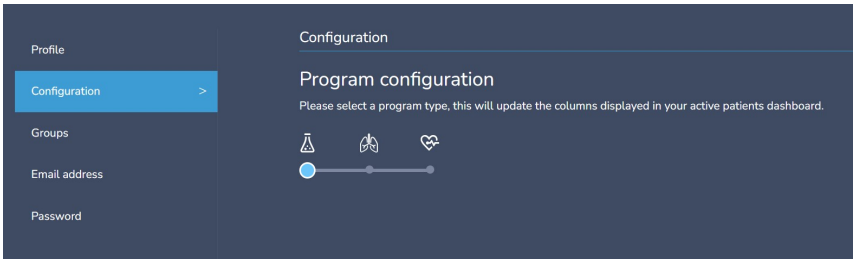

Figure 52: User profile - Configuration

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 44 for more information).

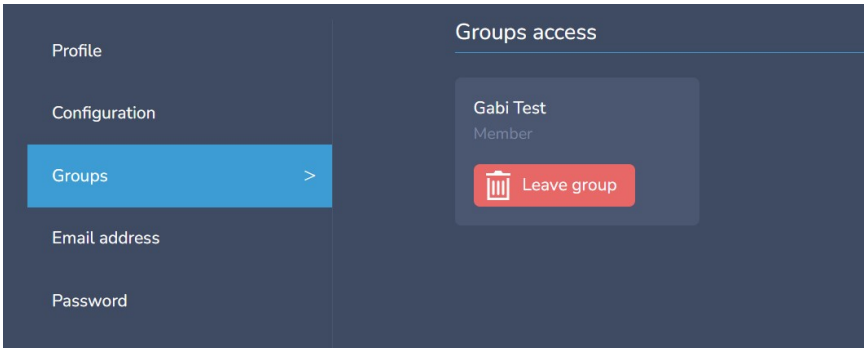

Figure 53: User profile - Groups sheet

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.

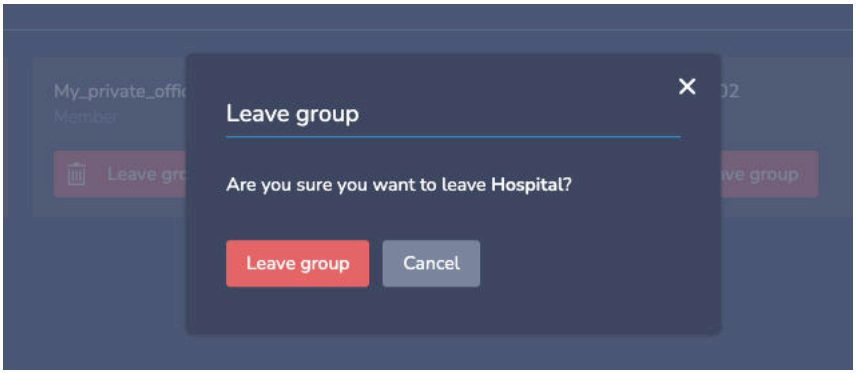

Figure 54: Leave group confirmation message

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.

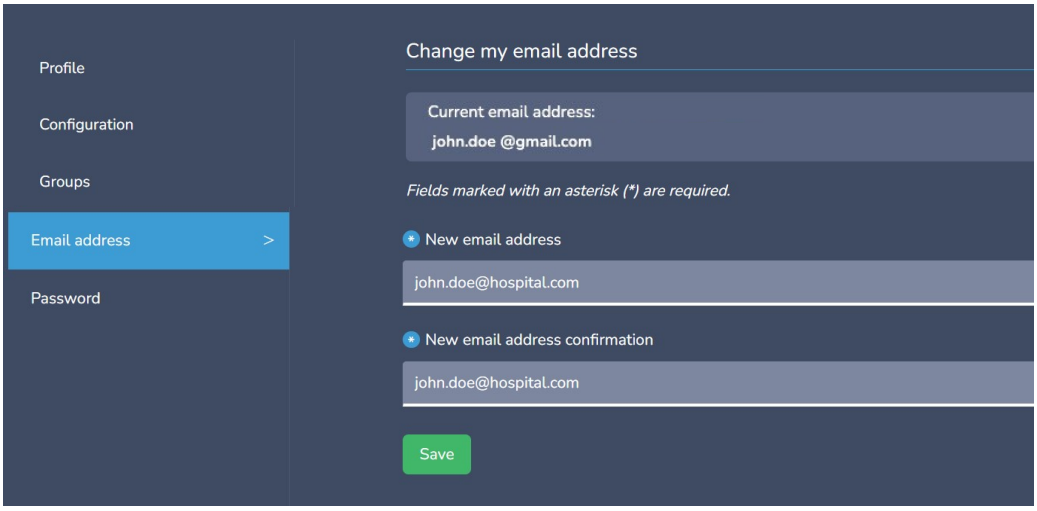

Figure 55: User profile - Email address sheet

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.

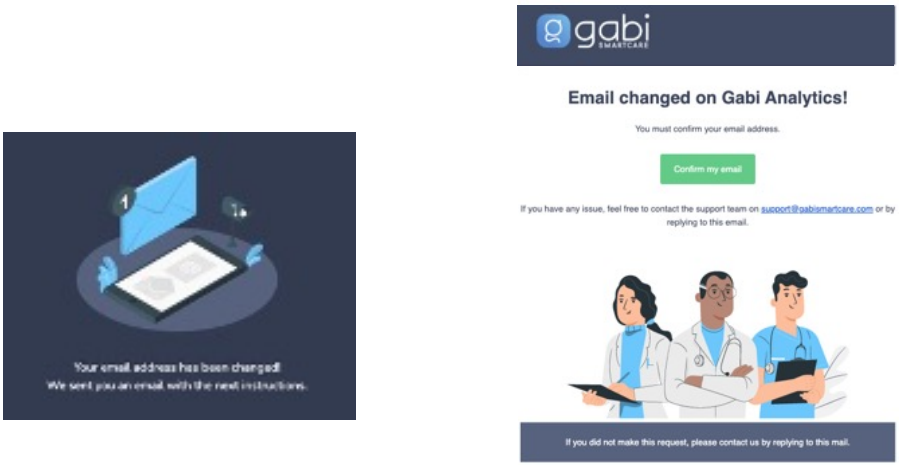

Figure 56: email updated confirmation message and email

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.

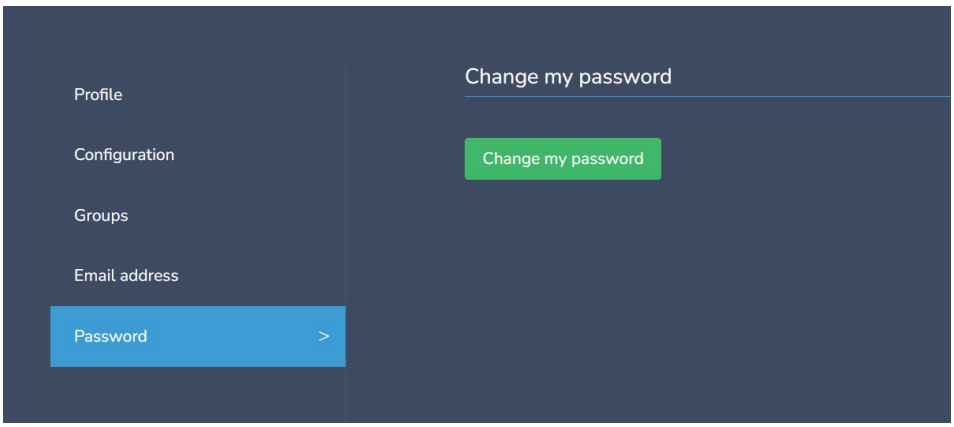

Figure 57: User profile - Password sheet

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 14), the modification is saved, and a confirmation message is displayed.

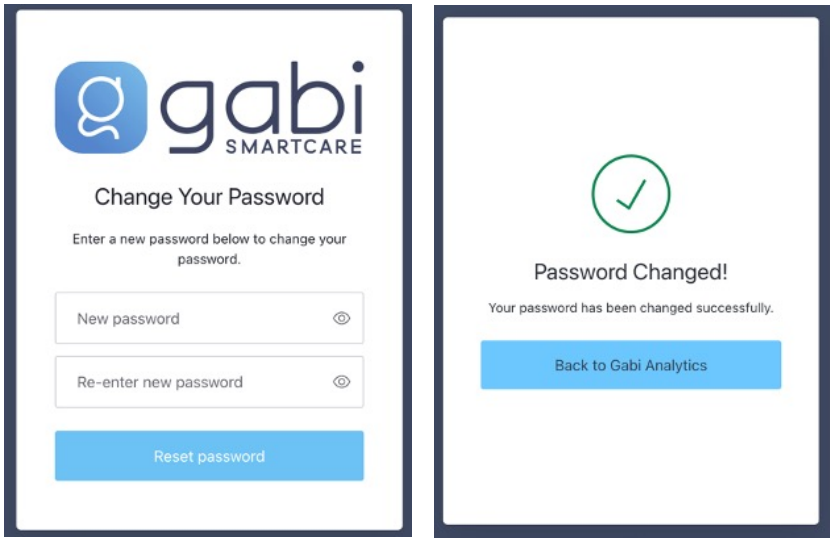

Figure 58: Change password page and confirmation message

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 59: 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 59 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.

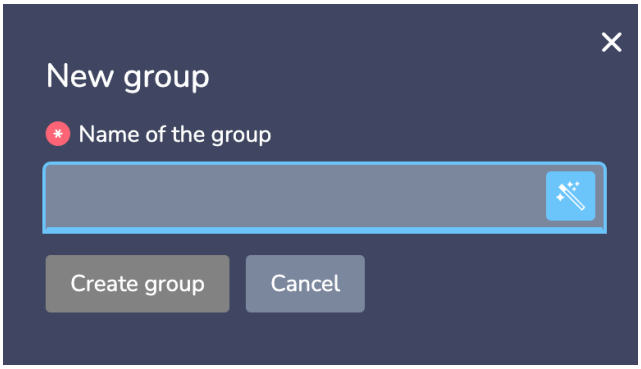

Figure 60: Group creation modal

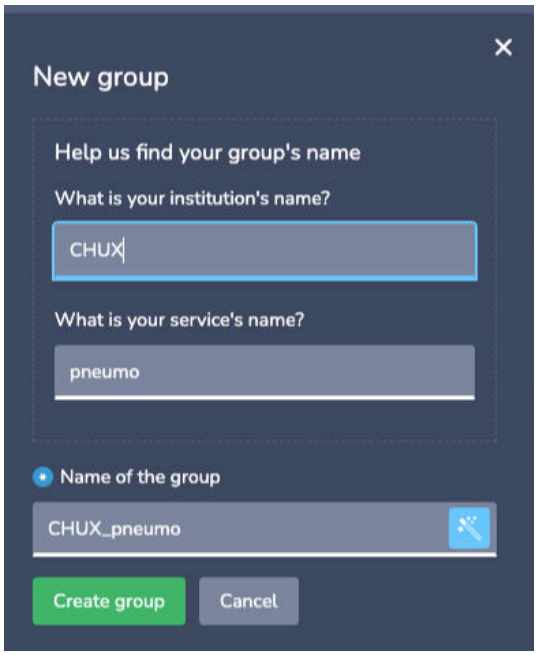

Figure 61: Help for naming of group

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 59 above). A modal opens, where you can type the complete email address of the user you want to add.

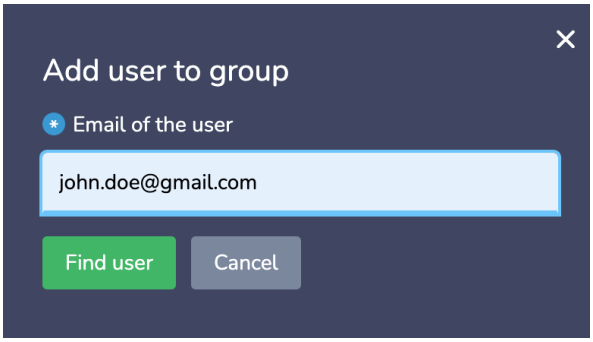

Figure 62: Add user to group modal

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.

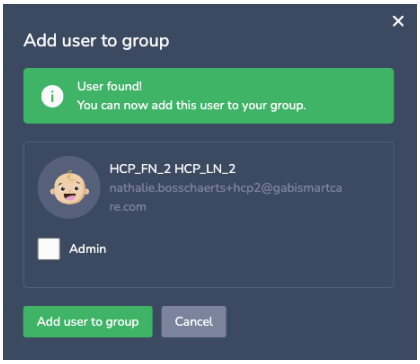

Figure 63: Add user to group confirmation

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.

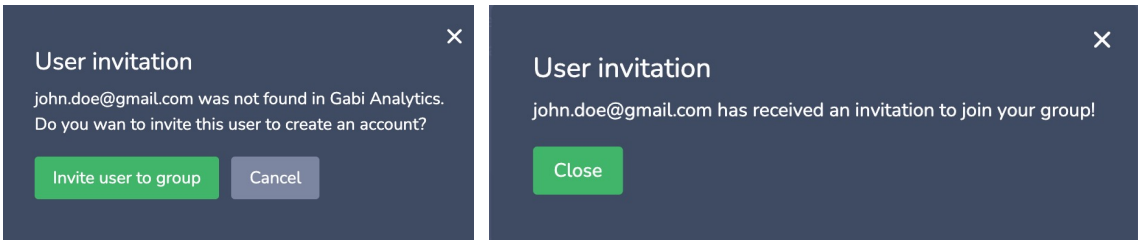

Figure 64: User invitation and confirmation

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

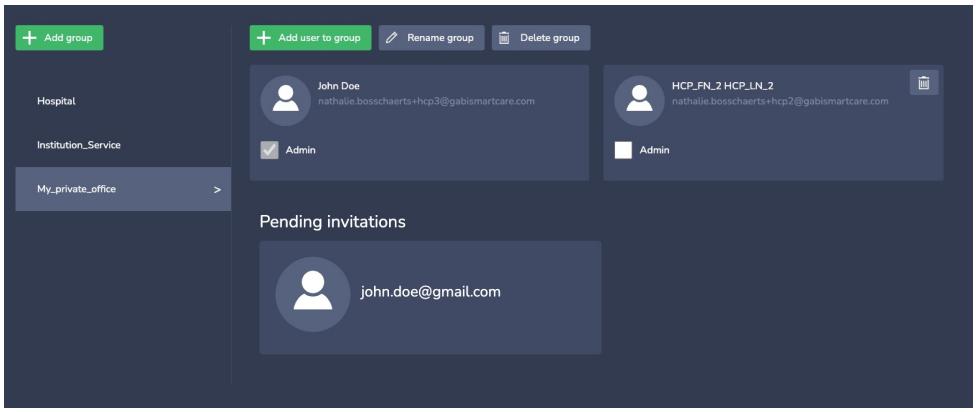

Figure 65: Pending invitations category

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 59 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.

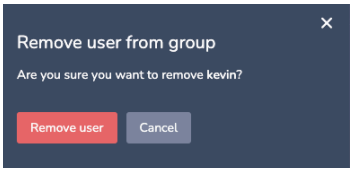

Figure 66: Confirmation of user removal from a group

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 59 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 59 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 59 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.

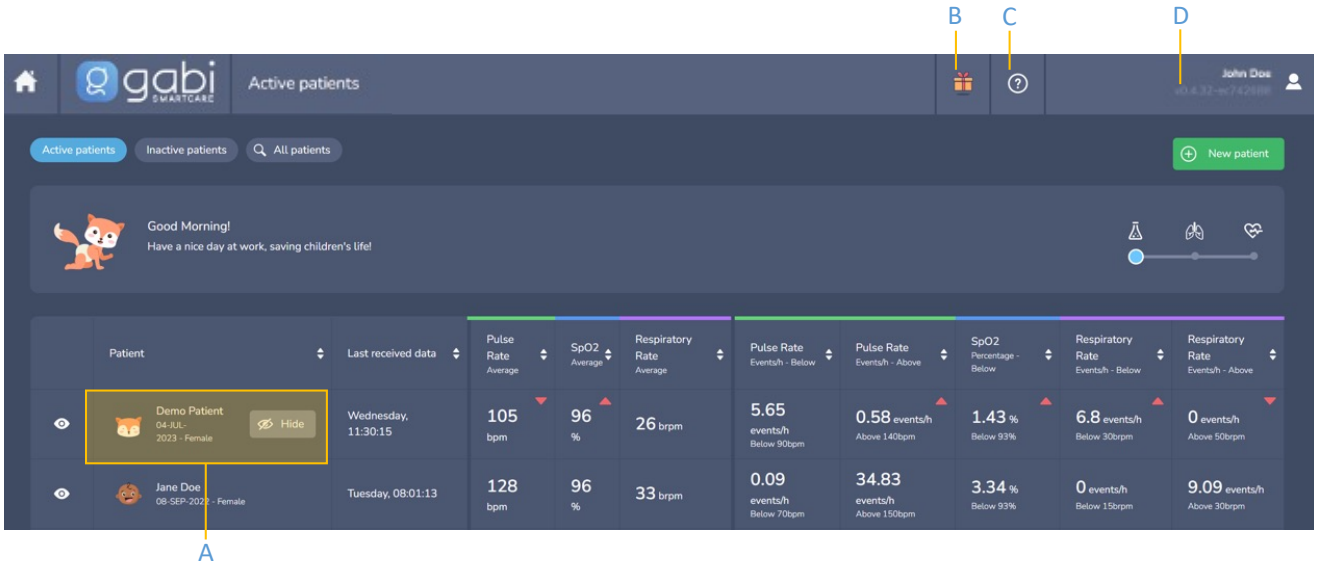

Figure 67: Additional features and Information

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 67 above).

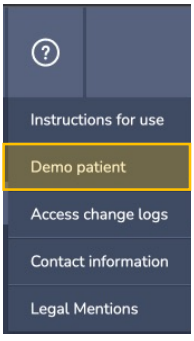

Figure 68: Access to Demo patient when hidden in list of patients

To open the Demo patient, click on its tile. The health report of the Demo patient opens.

8.2 Guided Tour

The guided tour is open by default when you first log on the platform, through a modal on the bottom right of the screen (see A in *Figure 69* below).

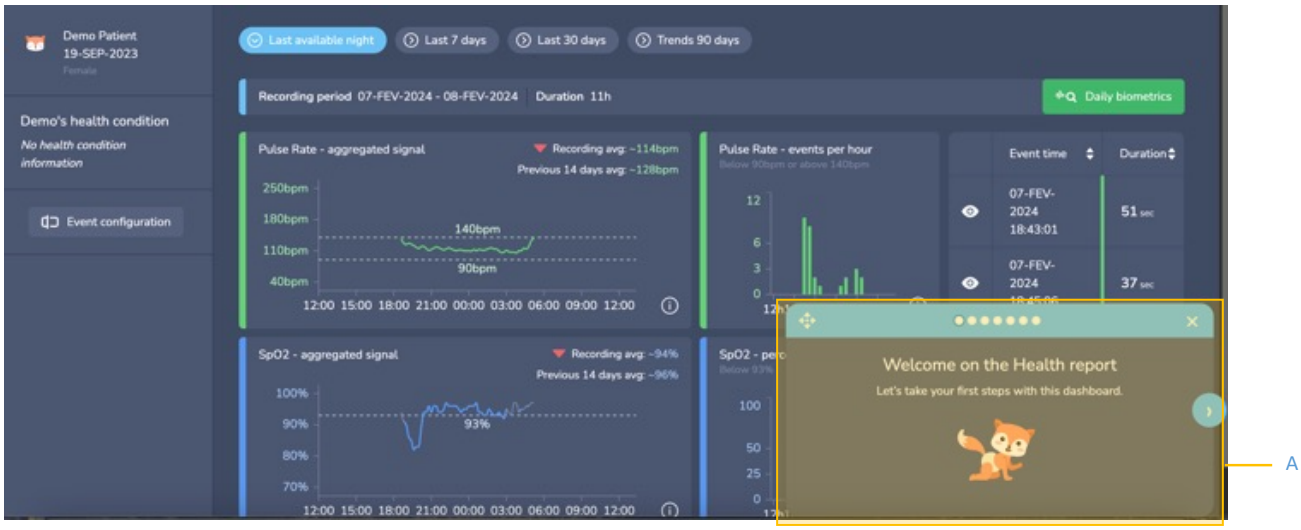

Figure 69: Health report of Demo patient

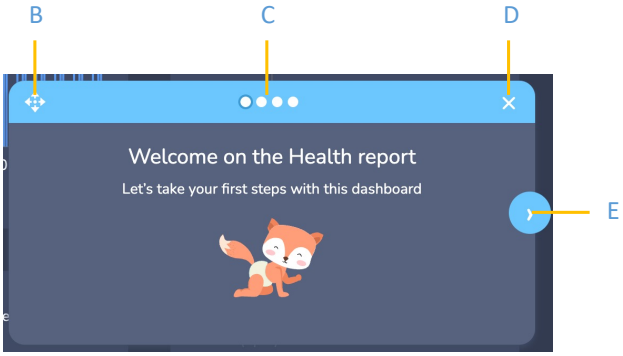

Figure 70: Guided Tour

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 70 above) or via the bullets on the top bar of the guided tour (see C in Figure 70 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 70 above) or close it by pressing the cross on top right of the guided tour (see D in Figure 70 above).

When closed, you can still reopen it through the '?' button on the top bar of the platform (see C in Figure 67 on page 48).

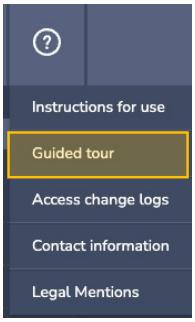

Figure 71: Access to guided tour when modal is closed

8.3 New Features List and change log

When a new version of Gabi™ Analytics is deployed, the version number is updated (see D in Figure 67 above) and a gift is displayed on the top bar (see B in Figure 67 above).

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

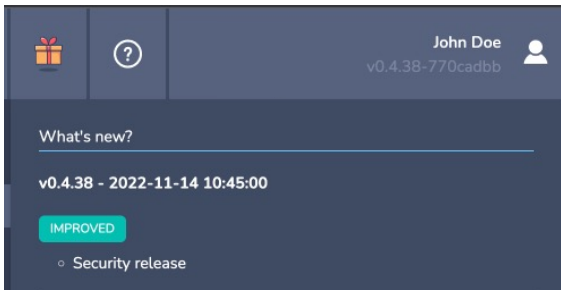

Figure 72: New features list

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 67 above) and selecting "access change log".

8.4 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 67 above) and selecting "Instructions for use". You will have access to this document in pdf format.

8.5 Contact Information

By clicking on the '?' button on the top bar of the platform (see C in Figure 67 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.

8.6 Legal Mention

By clicking on the '?' button on the top bar of the platform (see C in Figure 67 above) and selecting "Legal Mention", you have a direct access to the legal mentions of Gabi™ Analytics

8.7 Policies

By clicking on the '?' button on the top bar of the platform (see C in Figure 67 above) and selecting "Policies", you are redirected to the help center of Gabi™ Analytics (https://help.gabismartcare.com/#hcp-documents), with access to the different policies: the privacy policy, the cookies policy and the software terms of use.

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 v80
- Safari higher than or equal to v13
- Firefox higher than or equal to v80
- Opera higher than or equal to v70
- Edge higher than or equal to v80

9.2 Equipment Specifications

Per IEC 60601-1:2005/AMD2:2020 and ISO 80601-2-61:2017, the Pediarity™ system 's essential performance attributes include:

- Pulse Rate indication
- SpO2 indication

9.2.1 Data range display

Table 2: Data range

Parameter	Min value	Max value
SpO_2	50%	100%
Pulse Rate	25 bpm[4]	250 bpm
Movements	'None'	'High'

9.2.2 Pulse rate accuracy

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.

Table 3: Detailed ARMS per PR range

Range PR	25-100	100-175	175-250	**Total**
ARMS (bpm)	0.33	0.79	0.71	0.65

[4] **bpm** (beat per minute)

9.2.1 SpO_2 accuracy

Gabi™ system SpO_2 measurement has been validated for SpO_2 accuracy for the range of 50% - 100% in bench testing against a Whaleteq AECG100 with PPG-2R-940 simulator.

Gabi™ system SpO_2 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.

Table 4: Detailed ARMS per SpO2 range (Gabi Band #1)

Range SpO2 ARMS (%)[5]	70-80	80-90	90-100	70-100
All subjects	2.42	2.62	2.77	2.61
Female	2.61	1.74	2.09	1.99
Male	3.32	3.57	3.50	3.46
Medium pigmentation	3.17	2.74	3.11	3.00
Dark pigmentation	1.91	1.68	2.45	2.06

Table 5: Detailed ARMS per SpO2 range (Gabi Band #2)

Range SpO2 ARMS (%)[6]	70-80	80-90	90-100	70-100
All subjects	2.60	1.74	3.15	2.59
Female	2.65	1.51	3.24	2.55
Male	2.54	2.23	3.01	2.66
Medium pigmentation	2.93	1.32	2.75	2.41
Dark pigmentation	1.62	2.12	3.76	2.60

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

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

[5,5] ARMS = Average Root Mean Square error. This value has been computed by removing two significantly low perfusion index subjects displaying outliers. The Pediarity™ system is intended for well perfused patients.

Here are the graphical plots of all sampled data points for SpO2 clinical study, including the subjects 8 and 12 who have been removed from the tables 4 and 5 due to too low perfusion index:

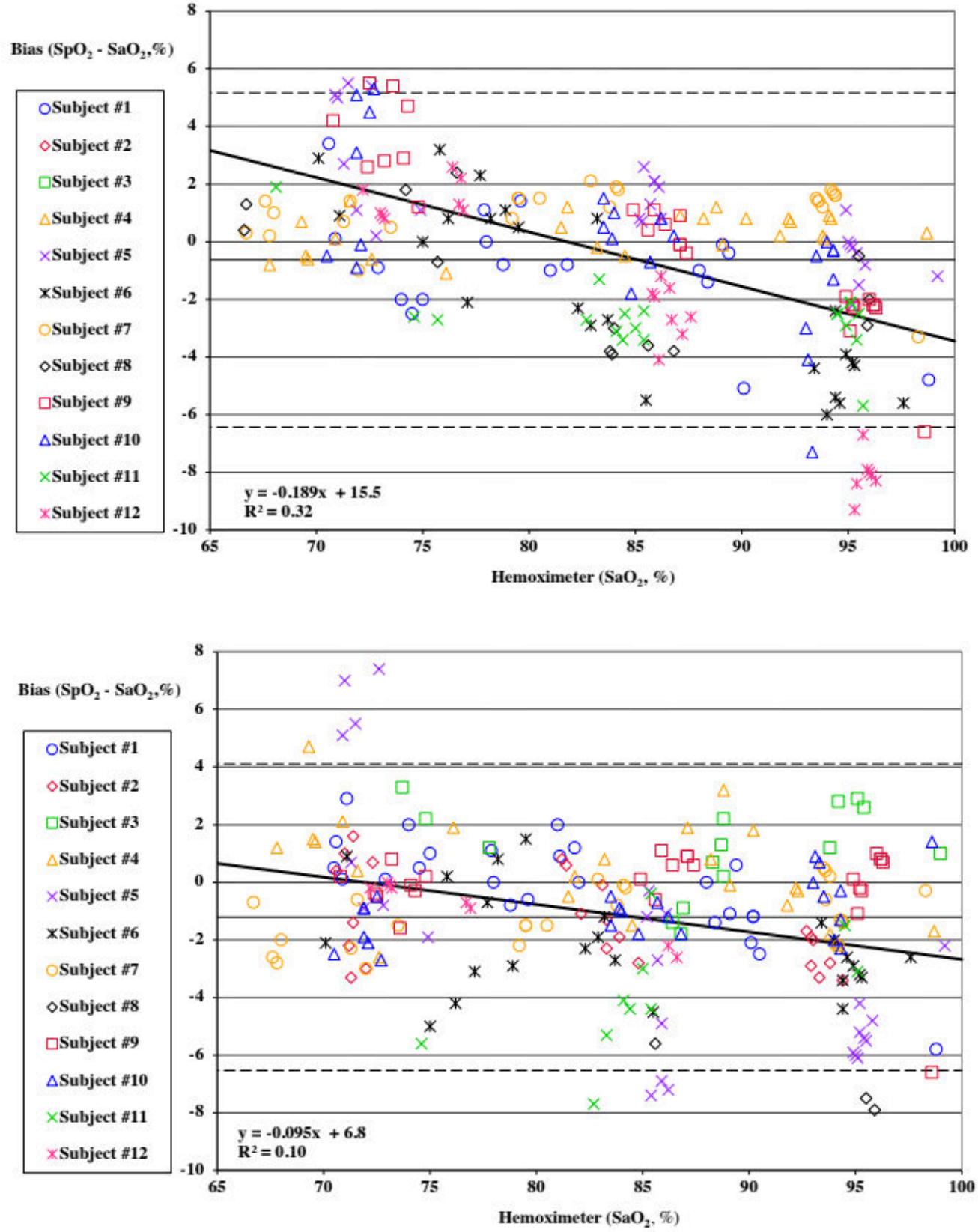

Figure 73: Sampled data points during SpO2 study

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 in the "all patients" list, be sure that no filter is applied (no entry in the search field)
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 45) 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 45)
- Add this group to the patient you want to share (see §5.3 Patient Update on page 26 – 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 67 on page 48). Refer to Figure 68 on page 48 and to Figure 69 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 date?

1- Check the time of the supposed monitoring. If the monitoring occurred before noon, you need to look for it on the day before, as a night start on noon.
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 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).

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 many data are not reliable (greyed) in the daily biometrics of your patient, it may be due to a bad positioning of the Gabi™ Band on the patient's arm. We strongly advise you to check the Gabi™ Band placement with the patient's caregiver.

Here are the steps to be followed:

Figure 74: steps 4 to 7 of Gabi™ Band installation

- The Gabi™ Band is positioned halfway between the shoulder and the elbow.
- The Gabi™ Band is in direct contact with the child's skin.
- The bracelet is tightened enough to prevent the Gabi™ Band from moving/rotating.
- The bracelet is not too tight, to allow blood to circulate normally.

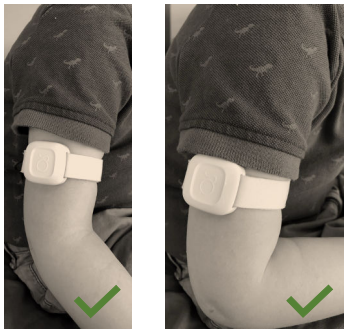

Figure 75: Gabi™ Band correct positioning

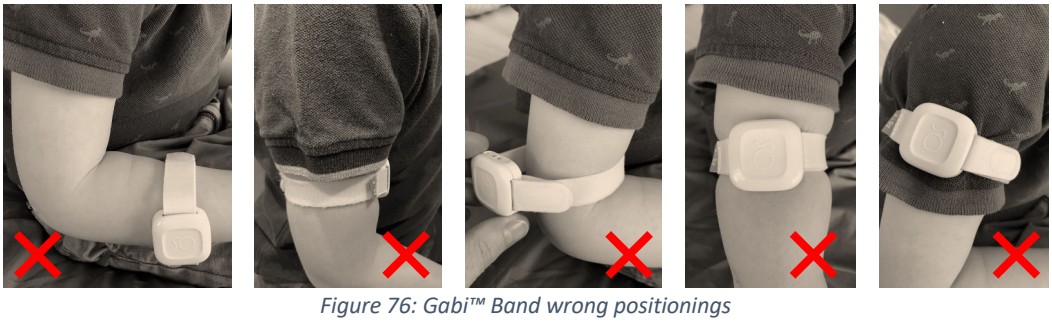

Figure 76: Gabi™ Band wrong positionings

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

If the caregiver lost 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 §5.4 QR code generation on page 27.

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.

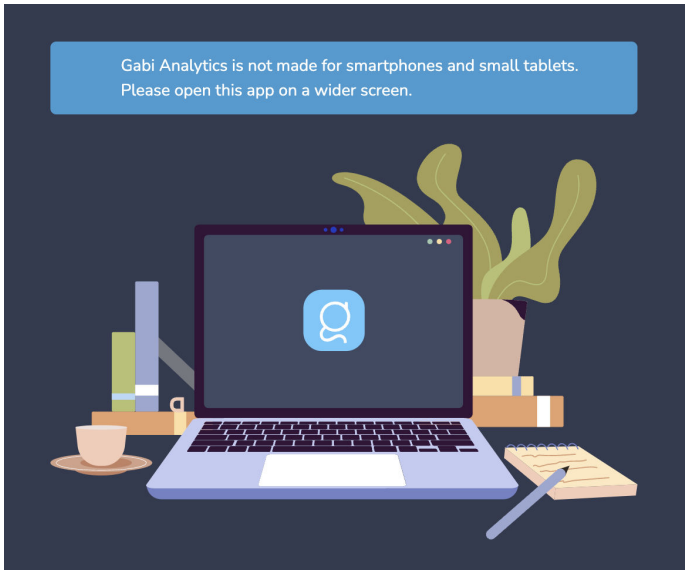

Figure 77: Too low resolution message

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.

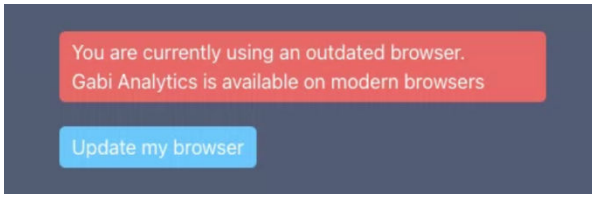

Figure 78: Outdated browser message

11. Symbols on Product or Package Labelling

Table 6: Labels meaning

MD	Medical Device
	Manufacturer
UDI	Unique Device Identifier
	The instruction manual/booklet must be read
LOT	Lot code

12. Additional Information

12.1 Clinical Studies

See 9.2.1 SpO_2 accuracy on page 52.

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 60) 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-231

To contact our customer support:

Email: support@gabismartcare.com