



The Gabi™ System

Caregiver Instructions for Use



	Pediarity™ Caregiver IFU – EN Version	Version G
		26-MAY-2023

All rights reserved ©2022 Gabi SmartCare® S.A. All content in these Instructions for Use, including the texts, trademarks, service marks, logos, illustrations, photos, graphics, design, etc., are the property of Gabi SmartCare® S.A. Gabi SmartCare® S.A. owns all rights with respect to any trademarks, service marks, logos, and copyrights appearing in these Instructions for Use.

Bluetooth is a trademark of Bluetooth SIG Inc. Android is a trademark of Google Inc.



Manufacturer Contact Details:

GABI SMARTCARE® SA
Rue Emile Francqui, 6
1435 Mont-Saint-Guibert
Belgium

Table of Contents

1. WELCOME TO GABI™	8
2. ABOUT YOUR GABI™ SYSTEM	9
2.1 DEVICE INDICATIONS FOR USE	9
2.2 PRODUCT DESCRIPTION	9
2.3 CONTRAINDICATIONS	9
3. GENERAL WARNINGS AND CAUTIONS	11
3.1 WARNINGS	11
3.2 CAUTIONS.....	12
3.3 PRECAUTIONS.....	12
3.3.1 DEVICE USE AND STORAGE.....	12
3.3.2 WATER AND HUMIDITY	13
3.3.3 DEVICE CHARGING.....	13
3.3.4 CLEANING THE GABI™ BAND	13
4. YOUR GABI™ SYSTEM – OPERATING INFORMATION	14
4.1 GABI™ KIT CONTENT.....	14
4.2 THE GABI™ SYSTEM COMPONENTS	14
4.2.1 THE GABI™ BAND	14
4.2.2 GABI™ MONITOR TABLET	15
4.2.3 THE GABI™ MONITOR APP	15
4.3 USE YOUR GABI™ SYSTEM – SETUP INSTRUCTIONS	18
4.3.1 SETUP THE GABI™ BAND	18
4.3.2 SETUP THE TABLET	19
4.3.3 SETUP THE GABI™ MONITOR APP	20
4.4 USING YOUR GABI™ SYSTEM – OPERATING INSTRUCTIONS.....	26
4.4.1 BEFORE STARTING A RECORDING	26
4.4.2 AT THE END OF THE RECORDING PERIOD.....	28
4.5 CLEANING INSTRUCTIONS	30
4.5.1 CLEANING THE GABI™ BAND	30
4.5.2 CLEANING THE GABI™ MONITOR TABLET	31
4.6 STORAGE INSTRUCTIONS	31
4.7 MAINTENANCE	31
5. USE OF GABI™ MONITOR APP – ADDITIONAL FEATURES	32
5.1 ACCESS AND MODIFY YOUR PERSONAL DATA OR DELETE YOUR ACCOUNT.....	33

5.1.1 CHILD INFORMATION..... 34

5.1.2 CAREGIVER INFORMATION..... 35

5.1.3 DELETE YOUR ACCOUNT..... 35

5.2 SOFTWARE UPDATE.....36

5.2.1 GABI™ MONITOR APP UPDATE..... 36

5.2.2 GABI™ BAND FIRMWARE UPDATE..... 38

5.3 USE A NEW WI-FI NETWORK.....39

5.4 CHANGE YOUR PIN FOR UNLOCKING THE GABI™ MONITOR TABLET39

5.5 RESET APPLICATION SETTINGS39

6. END OF USE – DISPOSAL OF YOUR GABI™ SYSTEM40

7. TECHNICAL SPECIFICATIONS41

7.1 OPERATIONAL SPECIFICATIONS41

7.2 EQUIPMENT SPECIFICATIONS.....41

7.2.1 BIOMETRICS RANGE AND ACCURACY..... 41

7.2.2 USED PEAK WAVELENGTHS 42

7.2.3 RECEPTION AND TRANSMISSION SPECIFICATIONS 42

7.2.4 DISPLAY 42

7.3 ELECTRICAL42

7.3.1 POWER..... 42

7.3.2 BATTERY 43

7.4 PHYSICAL CHARACTERISTICS.....43

7.5 LIFETIME.....43

7.6 PRODUCT COMPLIANCE43

7.7 MANUFACTURER’S DECLARATION44

7.7.1 ELECTROMAGNETIC COMPATIBILITY (EMC)..... 44

8. TROUBLESHOOTING50

8.1 TROUBLESHOOTING SPECIFIC TO THE GABI™ BAND50

8.1.1 THE WHITE LIGHT OF THE GABI™ BAND DID NOT BLINK UPON CONNECTION TO THE CHARGER 50

8.1.2 THE GREEN AND RED LIGHTS ON THE BOTTOM OF THE GABI™ BAND SENSOR DID NOT BLINK UPON DISCONNECTION FROM THE CHARGER..... 50

8.1.3 A YELLOW LIGHT IS ON, ON THE TOP PART OF THE GABI™ BAND..... 51

8.1.4 A PURPLE LIGHT IS BLINKING ON THE TOP PART OF THE GABI™ BAND 51

8.1.5 I AM NOT SURE I PLACED THE GABI™ BAND CORRECTLY 51

8.2 TROUBLESHOOTING SPECIFIC TO THE GABI™ MONITOR APP52

8.2.1 I CANNOT START THE RECORDING AND THE “CONNECTION WITH GABI BAND” ICON IS LOADING 52

8.2.2 I CANNOT START THE RECORDING AND THE “BATTERY” ICON IS RED 53

8.2.3 I CAN START THE RECORDING BUT THE “BATTERY” ICON IS ORANGE 54

8.2.4 THE GABI CLOUD ICON TURNED RED 54

8.2.5 THE GABI™ MONITOR APP IS LOADING ENDLESSLY WHEN ATTEMPTING TO OPEN IT 56

8.3 TROUBLESHOOTING SPECIFIC TO THE TABLET.....57

8.3.1 THE TABLET DOES NOT POWER ON 57

9. GABI™ BAND LIGHT INDICATIONS58

10. SYMBOLS ON PRODUCT OR PACKAGE LABELING60

10.1 CERTIFICATION AND SAFETY-RELATED SYMBOLS60

11. ADDITIONAL INFORMATION.....62

11.1 CLINICAL STUDIES62

11.2 DISEASE AND SELF-CARE INFORMATION62

11.3 ADVERSE EVENTS62

11.4 WARRANTY62

11.5 RETURN PROCEDURE62

11.6 TRAVEL OR INTERNATIONAL USE62

12. USER ASSISTANCE INFORMATION64

1. Welcome to Gabi™

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

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

If your questions are not addressed in these instructions for use, please contact our customer service (see contact details on page 64).

2. About your Gabi™ System

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

Be aware that you need to access Wi-Fi (2,4GHz only, 5GHz is not supported) with an internet connection to configure the Gabi™ system and to be able to share the recorded data with your physician.

The Gabi™ system is part of the PEDIARITY™ product.

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.

2.2 Product Description

The Gabi™ system is a non-invasive, innovative, and advanced solution that allows you to wirelessly measure several physiological parameters of your child in non-motion conditions. These data are shared with your physician through your internet connection.

The Gabi™ system is a reusable device, which is composed of:

- a smart bracelet – called the Gabi™ Band (version GSC2) – placed around the child's upper arm
- a mobile application – called the Gabi™ Monitor App – installed on a dedicated tablet

The Gabi™ Band includes sensors that allow measurement of pulse rate (measurement of the heart rate, i.e. the number of times the heart beats per minute), functional oxygen saturation (i.e., the level of oxygen in blood), respiratory rate (i.e. the number of breaths per minute) and movements of your child while sleeping. The Gabi™ Band is connected via Bluetooth to the Gabi™ Monitor Tablet, on which the Gabi™ Monitor App is running, providing the ability to start/stop the recording, review the data measured by the Gabi™ system and send the collected data to your physician via Wi-Fi. Thanks to the Gabi™ system, your child's doctor is able to continuously access and review your child's physiological parameters remotely.

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

2.3 Contraindications

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

Gabi™ system **does not provide physiological alarms.**

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



The Gabi™ system is contraindicated for children older than 12 years and infants and children weighing less than 2.5 kg (5.5 lbs).

3. General Warnings and Cautions

The following terms are used to alert the user to the potential consequences of not following the instructions and to encourage the safe and proper use of the device.

A "**WARNING**" typically refers to a situation where there is a serious risk of harm or death if the device is not used correctly, and immediate corrective action is required.

A "**CAUTION**" refers to a situation where there is a lower level of potential harm, but the user should still take care to follow the instructions carefully to avoid any adverse events.

3.1 Warnings



Do not charge the Gabi™ Band while being worn or positioned close to your child.



Do not use the Gabi™ Band while in charge because the cord can pose a strangulation hazard.



Do not use the Gabi™ system if it appears to be damaged.



Do not repair, open, disassemble, or modify. Damage to the device may result in degraded performance and/or child injury.



To avoid electric shock, do not attempt to replace or remove the battery from Gabi™ Band.



Do not place the tablet in any position that might cause it to fall on the child.



Do not tighten too much the Gabi™ Band on the child's arm, it may induce tourniquet injuries.



The Gabi™ Band 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 Gabi™ system as a diagnosis tool.



Do not use the Gabi™ system if your doctor recommends the use of a hospital pulse oximeter.



Do not use the Gabi™ system if your doctor recommends the use of a hospital apnea monitor.



Do not use the Gabi™ system as an excuse for unsafe sleeping habits.

 Avoid using the Gabi™ system adjacent to or stacked with other equipment because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

 Do not use any power cable or power adapter other than the one provided with the Gabi™ system as it may negatively affect the electrical safety and/or the electromagnetic compatibility.

 Do not short-circuit the Gabi™ Band charging cable connector pins.

 Do not touch the power cable and the child at the same time.

 Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the Gabi™ system, including power cables provided with the Gabi™ system.

 In case the Gabi™ system does not behave as expected, consider the possibility that electromagnetic disturbances affect the device. Relocate the equipment or switch-off the equipment that is the source of the disturbance.

 If you do not use the Gabi Band on a regular basis, charge it at least every 3 months.

3.2 Cautions

 Do not use Gabi™ Band with any monitoring tool other than Gabi™ Monitor App.

 Do not use the Gabi™ Band for more than 18 hours at a single site on the child.

 Be aware that child motion reduces the biometrics accuracy.

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

 Do not use caustic or abrasive cleaning agents.

3.3 Precautions

3.3.1 Device Use and Storage

The Gabi™ Band and the tablet are not toys. You shall ensure to keep the Gabi™ Band (while not in use) and the tablet out of reach of children.

The tablet has been configured in kiosk mode, which means that it can be used for the sole purpose of monitoring the child's biometrics measured by the Gabi™ Band. To avoid technical problems with the Gabi™ Monitor App, you shall not provide the password of the tablet to your children or to anyone not involved in the use of the Gabi™ system.

3.3.2 Water and Humidity

You are advised to keep your Gabi™ system away from extremely humid areas and sources of water. Water and humidity can result in device malfunctions.

3.3.3 Device Charging

Your Gabi™ Band must be charged when not in use so as to be fully charged for the next recording. Your Gabi™ Monitor Tablet can be used when powered from its internal battery. However, to ensure uninterrupted recording, we recommend that the Gabi™ Monitor Tablet remains connected to the charging adapter during use. Make sure to follow the safety instructions and keep the Gabi™ Monitor Tablet, the charging cable, and the power adapter away from the child.

3.3.4 Cleaning the Gabi™ Band

Please carefully follow the instructions from chapter 4.5 Cleaning Instructions (see page 30).

4. Your Gabi™ system – Operating Information

4.1 Gabi™ Kit Content

The enclosed Gabi™ Kit contains this user manual, a quick setup guide and the following components:



(1) A Gabi™ Band sensor unit



(2) 4 bracelets of different size (S, M, L, XL)



(3) A power adapter and charging cable¹ to charge the Gabi™ Band



(4) The Gabi™ Monitor App installed on a dedicated tablet and its power adapter and micro-USB charging cable

4.2 The Gabi™ System Components

4.2.1 The Gabi™ Band

The **Gabi™ Band** is a wearable recording device positioned around the child's upper arm. It is composed of a textile bracelet of adjustable size and of a hard housing that includes 2 main sensors, a rechargeable battery, and Bluetooth Low Energy (BLE) capabilities (the sensor unit). It continuously measures the level of oxygen in the blood, the pulse rate and respiratory rate using a light-based technology, called Photoplethysmography (PPG), like in a smart watch. It also includes an accelerometer to measure the child's movements.

The Gabi™ Band must be used in non-motion condition, i.e., while the child asleep, to ensure the quality of the recorded data.

See below the main components of the Gabi™ Band:

- A. Bracelet size (S / M / L / XL)
- B. Status Light (see section 9 for details on Light Indications)
- C. Pins for battery charging
- D. Stretch bracelet closure
- E. Light sensor (PPG)

¹ This is a dedicated cable, to be used with Gabi™ Band only. Do not use any other USB-cables with Gabi™ Band, and do not use this cable with other devices.

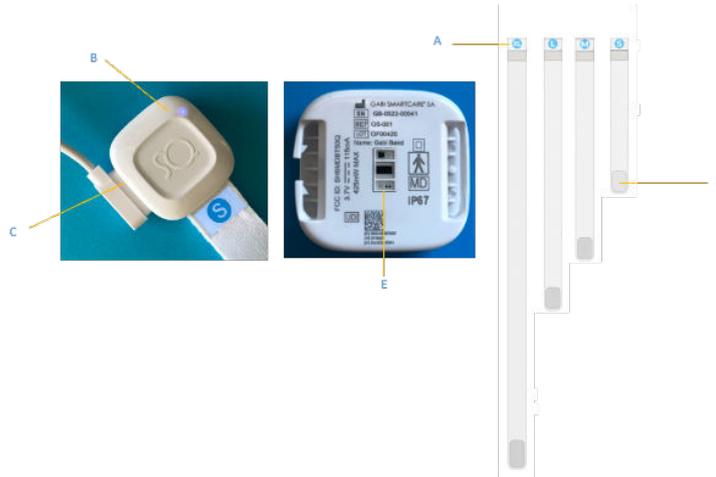


Figure 1: Gabi Band main components

4.2.2 Gabi™ Monitor Tablet

The Gabi™ Monitor Tablet includes a touch screen (see D on the figure below), on which you will interact with the Gabi™ Monitor App.



Figure 2: Gabi Monitor Tablet

- A. Camera
- B. Volume buttons
- C. Power ON/OFF button
- D. Touch screen

4.2.3 The Gabi™ Monitor App

The data collected by the Gabi™ Band are wirelessly transmitted via Bluetooth to a dedicated tablet (the Gabi™ Monitor Tablet), on which the Gabi™ Monitor App is installed, allowing to start and stop the recording of the Gabi™ Band and to view the measured data. To ensure proper data recording, the dedicated **tablet must be left within 7 meters (23 feet) from the child while the Gabi™ Band is recording.**

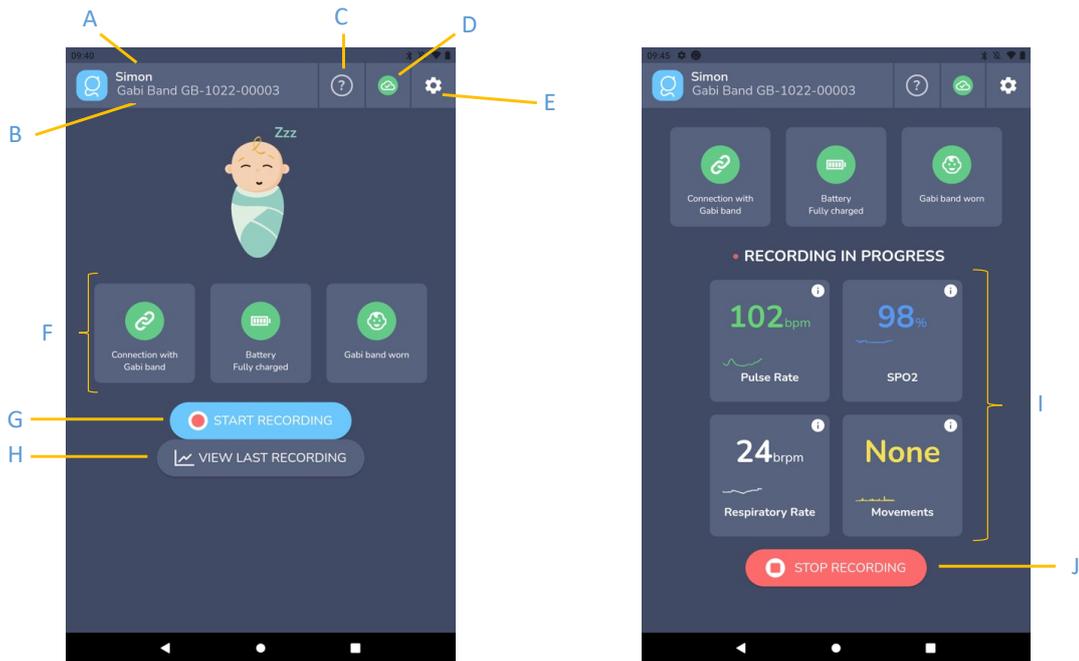


Figure 3: main screens of Gabi Monitor Application

See below the main features of the Gabi™ Monitor App:

- A. Child's first name
- B. Gabi™ Band Serial Number: serial number (format GB-XXXX-XXXXX) of the Gabi™ Band that is connected to the App.
- C. Link to Gabi Monitor user guide
- D. Status of the internet connection and of data sharing with your physician:
 - “” the Gabi™ Monitor App is connected to internet, or the data upload is successful
 - “” the Gabi™ Monitor App is not connected to internet
 - “” the data upload has failed
 - “” the data upload is in progress
- E. Application Settings (see details below).
- F. Gabi™ Band statuses:
 - Connection with Gabi™ Band: status of the connection between the Gabi™ Band and the tablet.
 - Battery: battery level of the Gabi™ Band.
 - Gabi Band Worn: indication of whether the Gabi™ Band is being worn or not.
Be careful, this status is not an indication that it is correctly placed on the child's arm.
- G. Start recording button.
- H. “View Last Recording” button, allowing you to get an overview of the last recording.
- I. Data measured by the Gabi™ system in real time, during a recording, namely:
 - The **Pulse Rate (PR)**: The pulse rate is the rate at which the heart beats. The Pulse rate is measured in beats per minute (bpm). It varies widely across adults, depending on the general health, body size, activity levels and medical conditions. The pulse rate is lower

when you are resting or sleeping than when you are awake or exercising/moving. Infants and young children's pulse rates vary as well but are inherently higher than adults' pulse rates. A '--' indicates that the signal quality is too low to provide correct accuracy.

- The **Oxygen Saturation (SpO₂)**: The oxygen saturation (SpO₂) indicates the amount of oxygen traveling through your body with your 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. A '--' indicates that the signal quality is too low to provide correct accuracy.
- The **Respiratory Rate (RR)**: The respiratory rate is the number of breaths taken per minute (brpm), or the number of respiratory cycles completed in 1 min, where a respiratory cycle consists of one inhalation followed by one exhalation. A '--' indicates that the signal quality is too low to provide correct accuracy.
- **Movements**: Magnitude of movements detected i.e., "None", "Low", "Medium" or "High". It is important to note that movements may impact the accuracy of the pulse rate, oxygen saturation and respiratory rate measurements.

J. Stop recording button.

4.3 Use your Gabi™ system – Setup Instructions

4.3.1 Setup the Gabi™ Band

- (1) Take the Gabi™ Band out of the box. You can keep the box to easily travel with your Gabi™ system.
- (2) Select the bracelet of the right size based on the upper arm circumference of your child (if known) or on their weight.



Figure 4: Gabi Band

Band size	S	M	L	XL
Child's upper arm circumference	<160mm (<6.3")	150mm – 200mm (5.9" – 7.9")	190mm – 260mm (7.5" – 10.2")	>250mm (>9.8")
Child's weight	< 15kg (< 33lbs)	9kg – 30kg (20lbs – 66lbs)	22kg – 45kg (49lbs – 99lbs)	> 40kg (>88lbs)

- (3) Hold the Gabi™ Band in one hand, with the sensors facing up and in the other hand, hold the bracelet, with the size label facing down.

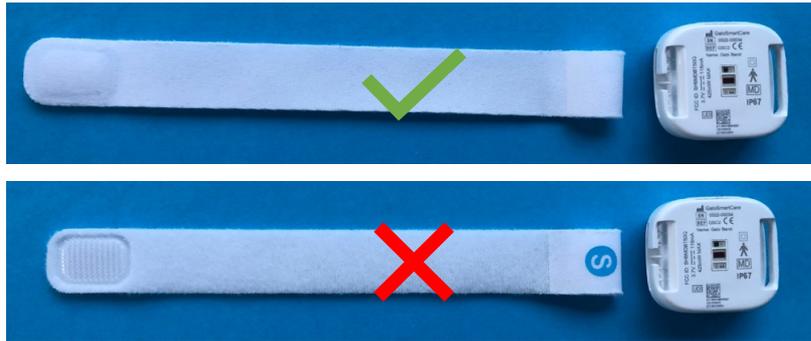


Figure 5: Strap orientation

- (4) Attach the loop part of the bracelet to the small protrusions found on one side of the Gabi™ Band sensor. These protrusions serve as the attachment points for the bracelet and allow you to change the bracelet when necessary. If you need to dismount the bracelet, be extremely gentle during the operation to avoid breaking the sensors unit protrusions.

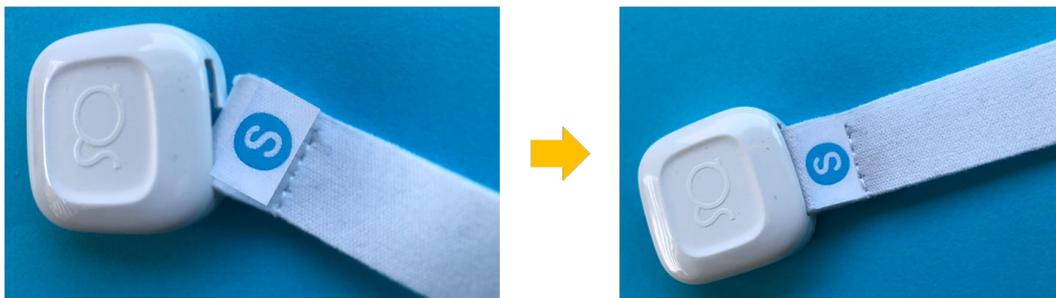


Figure 6: Gabi band assembly

- (5) Connect the supplied Gabi™ Band charging cable to the supplied power adapter. Then connect the Gabi™ Band charging cable to the Gabi™ Band charging port.
- (6) Connect the power charger to a power outlet (not accessible to children). A white light should start blinking on the Gabi™ Band, indicating charging.

 Do not charge the Gabi™ Band while being worn or when positioned close to your child.



Figure 7: Gabi Band charging (step 5)

4.3.2 Setup the tablet

- (1) Connect the provided Gabi™ Monitor Tablet to its power adapter using the supplied micro-USB charging cable.
- (2) Connect the power adapter to a power outlet (not accessible to children).



Figure 8: Gabi Monitor Tablet charging

4.3.3 Setup the Gabi™ Monitor App

To be able to complete this setup, a Wi-Fi network (2,4 GHz only, 5GHz is not supported) with internet connection is required.

- (1) Power ON the Gabi™ Monitor Tablet (see button C of Figure 2 on page 15)
- (2) If not launched yet, launch the Gabi™ Monitor App
- (3) Choose your language and press the ‘START’ button

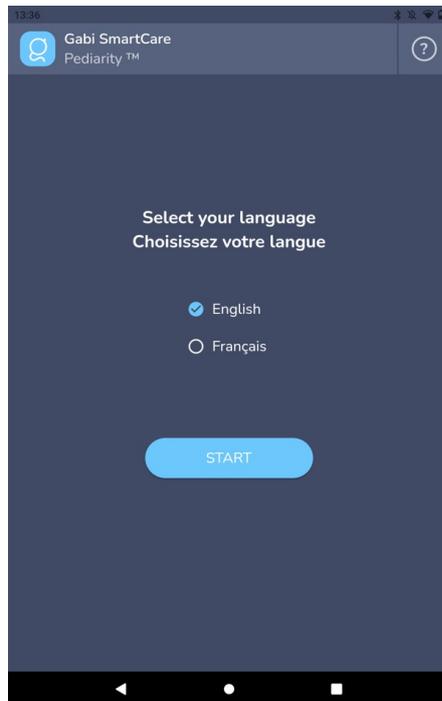


Figure 9: Gabi Monitor Application setup process - Language selection

A welcome screen is displayed. Press the ‘START’ button when you are ready to configure the Gabi™ Monitor App.

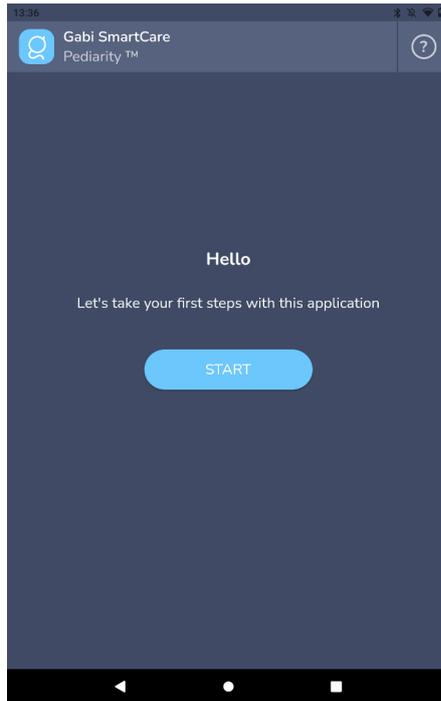


Figure 10: Gabi Monitor Application setup process - welcome screen

- (4) Configure your Wi-Fi network, by pressing on the ‘WI-FI SETTINGS’ button. In the detected Wi-Fi list, select the correct network and enter the required password. When the Gabi™ Monitor Tablet is connected to internet, press the back button of the tablet (triangle on the bottom of the screen). The Gabi™ Monitor App displays that the connection to internet has correctly been established. Be aware that the Gabi™ Monitor Tablet can only connect to **2,4GHZ** Wi-Fi networks. 5GHz Wi-Fi networks are not supported!

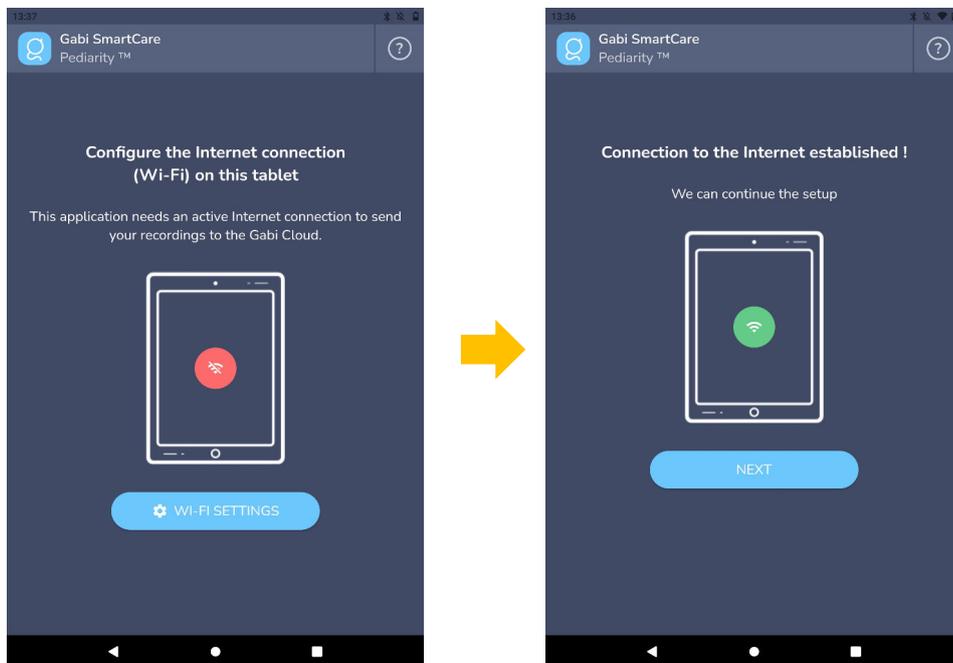


Figure 11: Gabi Monitor Application setup process - internet connection screens

- (5) If not done yet, connect your Gabi™ Band to the supplied power adapter using the charging cable. Press on the ‘NEXT’ button.

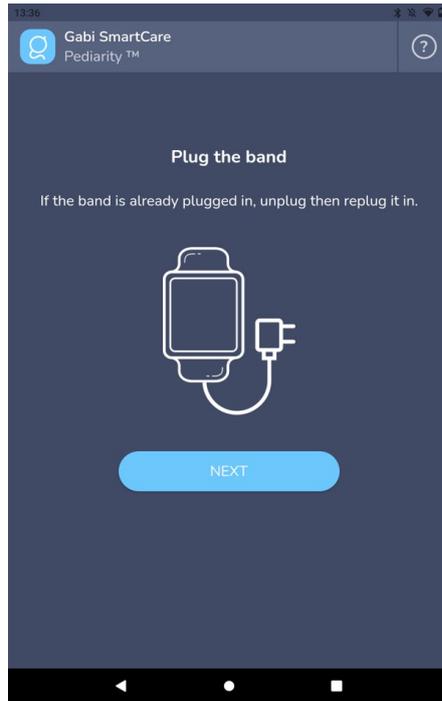


Figure 12: Gabi Monitor Application setup process - plug the band screen

- (6) Pair the Gabi™ Band with the Gabi™ Monitor Tablet. The Gabi™ Monitor App is scanning the Bluetooth communication to find the Gabi™ Band. Check your Gabi™ Band ID number on the back side of your Gabi™ Band sensor unit or on the packaging box. This ID is composed of “GB-XXXX-XXXX”. When your Gabi™ Band ID is listed, select it by tapping on the ID listed on the screen. The pairing is on-going. Be aware that your Gabi™ Band is accessible for pairing only during the first 5 minutes after connecting the Gabi™ Band to the power. If your Gabi Band is not listed, please unplug the power, and plug it again.

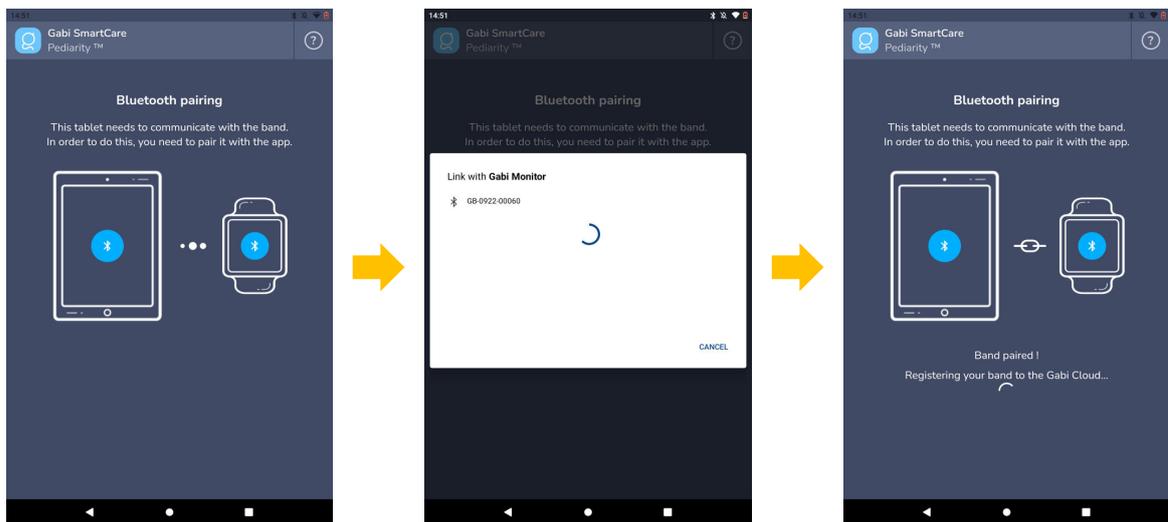


Figure 13: Gabi Monitor Application setup process - pairing screens

- (7) Press on the ‘NEXT’ button. To link your Gabi™ system to the child created by your physician, you need to scan the QR code you received from him. Prepare the QR-code on your computer or on a paper and scan it using the built-in camera of the Gabi™ Monitor Tablet (see A of Figure 2 on page 15).

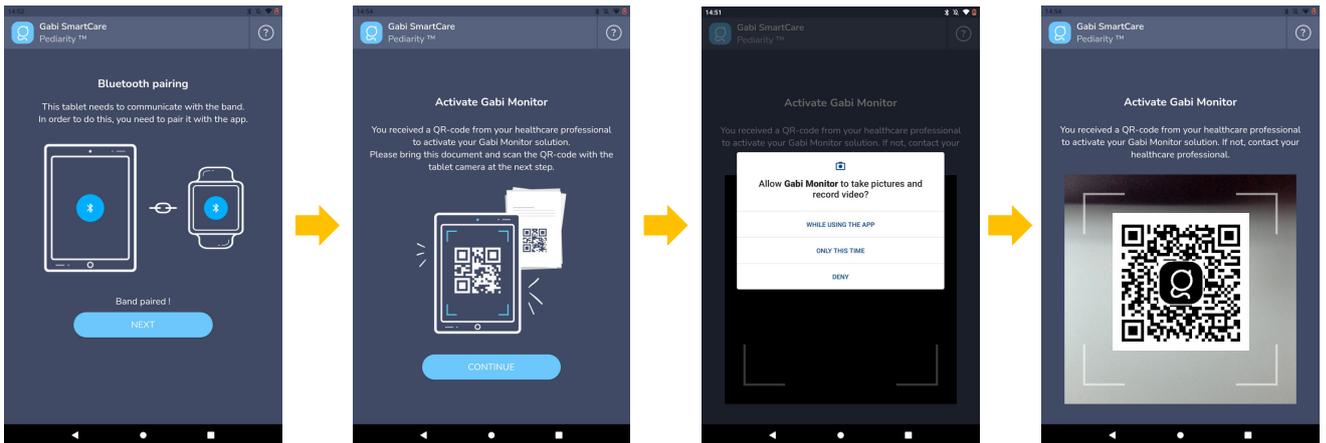


Figure 14: Gabi Monitor Application setup process - QR code

(8) The Gabi™ Monitor App requests you to confirm your child’s first name.

If it is your child’s first name, press the ‘YES’ button and when the account has been created, press the ‘NEXT’ button.

If it is not your child’s first name, press the ‘NO’ button and contact your physician.

If you pressed the ‘NO’ button by error, you will need to restart the setup process from step 2.

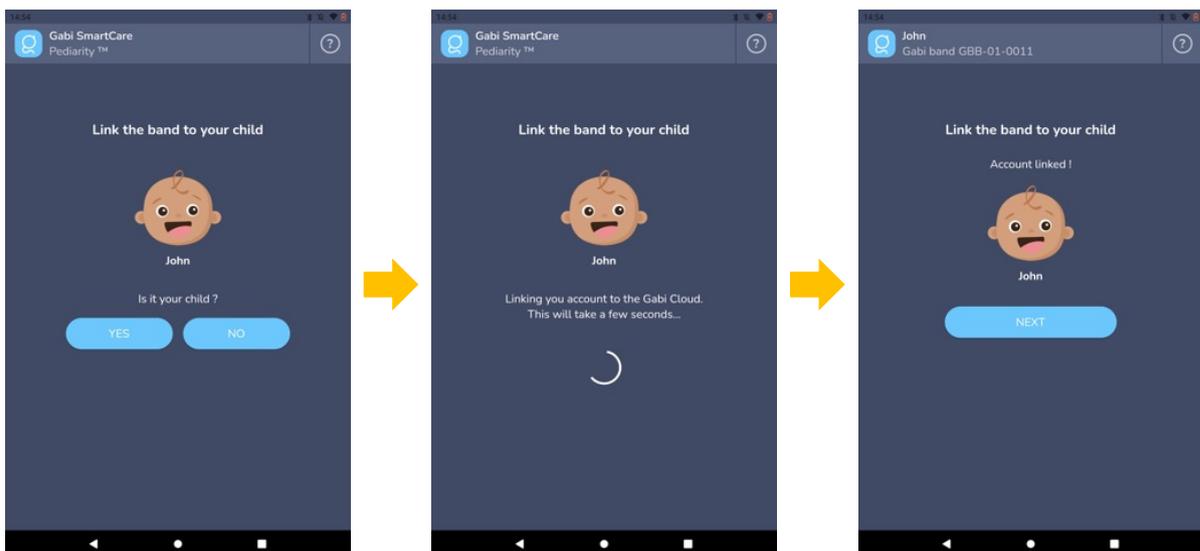


Figure 15: Gabi Monitor Application setup process - link to the child

(9) The Gabi™ Monitor App requests you to confirm the current date and time.

If the displayed date and time are the current ones, press the ‘YES’ button.

If the displayed date and time are not the current ones, press the ‘NO, OPEN SETTINGS’ button. You are redirected to the Gabi™ Monitor Tablet’s time settings page. Define your time settings and come back to the Gabi™ Monitor App.

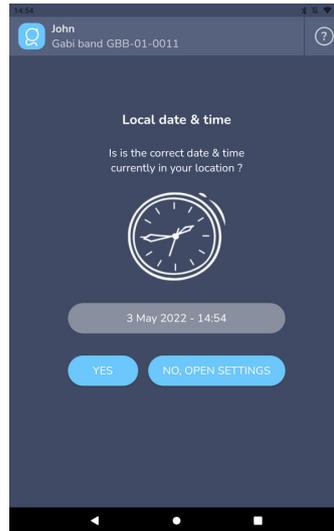


Figure 16: Gabi Monitor Application setup process - date & time check

- (10) The Gabi™ Monitor App requests you to secure the access to the Gabi™ Monitor Tablet by defining a pin code or a pattern to unlock it. Press the ‘Security settings’ button, you will be redirected to the Gabi™ Monitor Tablet’ security settings. Define your security settings and come back to the Gabi™ Monitor App.

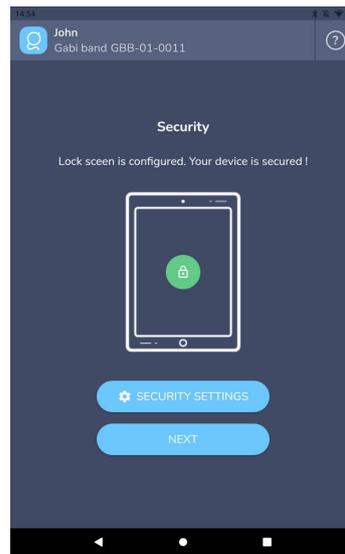


Figure 17: Gabi Monitor Application setup process - security settings

- (11) The Gabi™ Monitor App explains how to correctly place the Gabi™ Band on your child’s arm, including pictures of correct and bad installations. After you have read the directions carefully, acknowledge the explanation.
- (12) The setup is complete. Press the ‘DONE’ button to start using the Gabi™ system.

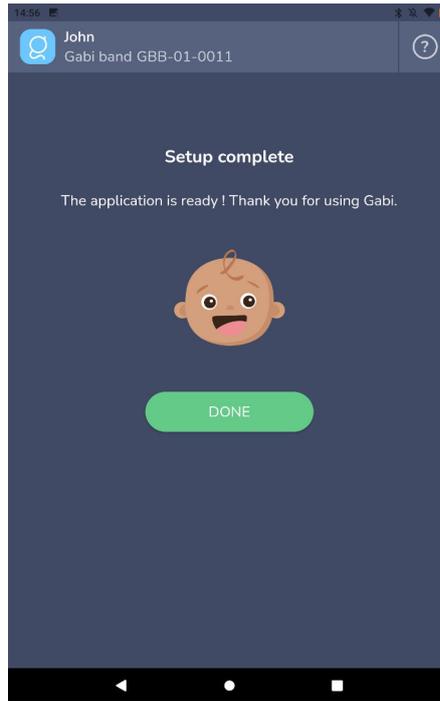


Figure 18: Gabi Monitor Application setup process - end of process

If you face any issue during the setup, feel free to contact our customer support (see contact details on page 64).

4.4 Using your Gabi™ system – Operating Instructions

4.4.1 Before starting a recording

Each time you plan a recording (i.e., when your child is about to go to sleep/nap), follow the steps below:

- (1) Disconnect the Gabi™ Band from its charging cable.



Figure 19: Gabi Band and its charging cable

- (2) Verify that the sensor unit's green and red lights on the bottom of the sensor are blinking, thereby indicating that the Gabi™ Band is ready to be attached on the child's arm.

The green and red lights will blink once every 5 seconds until the Gabi™ Band is put in contact with the child's skin.

A summary of the Gabi™ Band light indications is available in chapter 9 (Gabi™ Band Light indications).



Figure 20: Green and red LEDs blinking

- (3) Within 5 minutes following charger disconnection, place the Gabi™ Band on the upper arm of your child **in contact with the skin, halfway between the shoulder and the elbow.**



The Gabi™ Band needs to be placed in direct contact with the child's skin, not on top of any clothes.

- (4) Wrap the bracelet around the child's arm.
- (5) Place the free end of the Gabi™ Band bracelet in the Gabi™ Band's attachment loop.
- (6) Fold the free end of the bracelet around the attachment loop and gently pull on the end until reaching the appropriate bracelet size.



The Gabi™ Band bracelet size needs to be adjusted in a way that it will not move, without being too tight either.

- (7) Attach the hook part of the bracelet to the fabric part of the bracelet to fasten it. The Gabi™ Band needs to be firmly attached to the arm. When fastened properly, the sensor cannot turn around on the arm or slide up and down on the arm either. You can check chapter 8.1.5 “I am not sure I placed the Gabi™ Band correctly” on page 51 for more details.

 Do not tighten the bracelet too much and be careful not to pinch your child’s skin. Your child’s blood needs to circulate normally.

 If your child is wearing long-sleeved clothes, make sure to choose one that is not too tight in order to keep room for the Gabi™ Band under the sleeve with direct skin contact.



Figure 21: steps 4 to 7 of Gabi Band installation

- (8) Unlock the tablet using the defined password.
- (9) If not yet done, open the Gabi™ Monitor App on the tablet.
- (10) Verify that the 3 Gabi™ Band statuses are green and press “Start recording”.
If one of the statuses is red or orange, please refer to section 8.2.
Once the recording starts, the status changes to “Recording in progress” and the measured physiological parameters will be displayed.

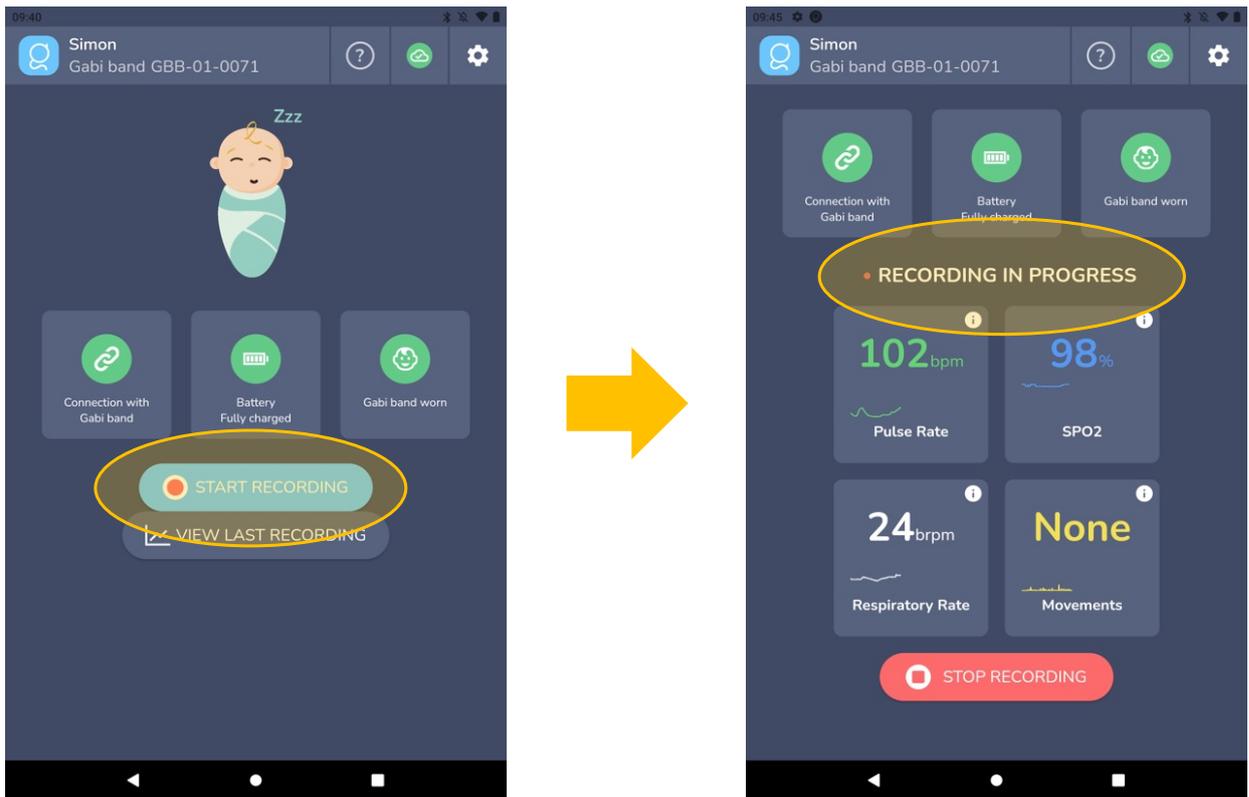


Figure 22: Start of recording

- (11) Leave the tablet **within 7 meters (23 feet) from the child** and keep it out of reach of all children during the recording to ensure the proper data collection.



Do not place the tablet in any position that might cause it to fall on the child.

- (12) Leave the **tablet connected to power** during the recording.

4.4.2 At the end of the recording period

When you want to end the recording (i.e., when your child wakes up), follow the steps below:

- (1) Unlock the tablet using the defined password.
- (2) If not already open, open the Gabi™ Monitor App.
- (3) Press on “Stop recording”.

Once the recording is stopped, the “Gabi Cloud” icon turns “☁️”, indicating that the recorded Gabi data are being sent to the Gabi Cloud to allow your physician to visualize them remotely. Once sent, the “Gabi Cloud” icon turns “☁️”.

If the Gabi Cloud icon turns red “🚫”, please refer to section 8.2.4.

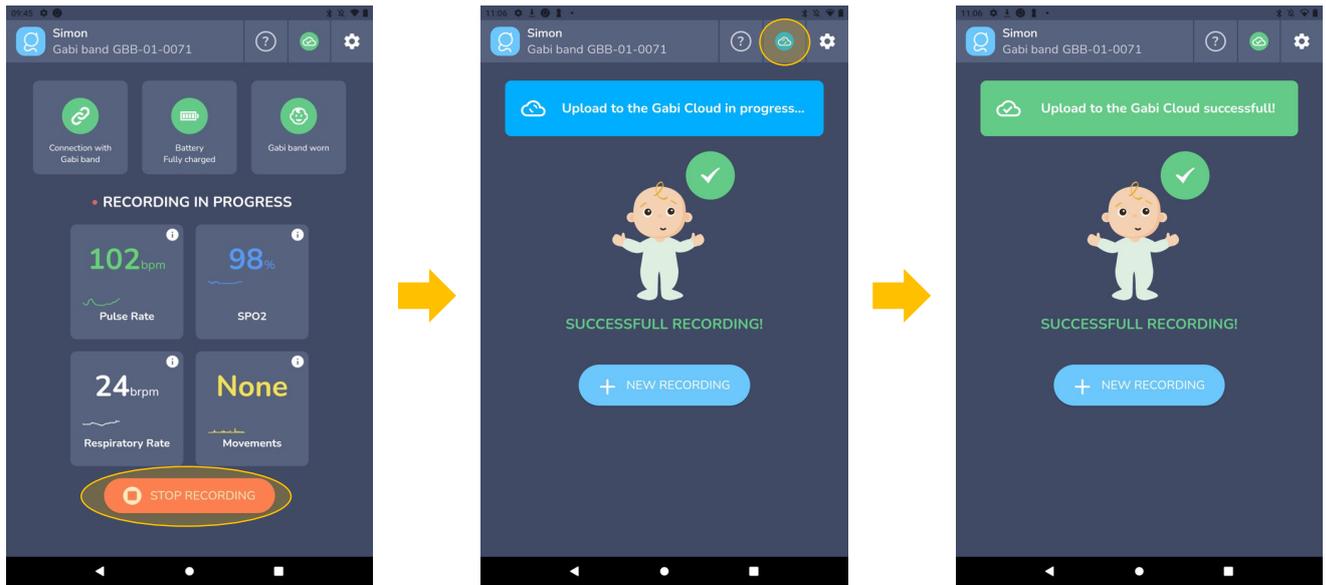


Figure 23: Stop recording and upload data

- (4) Remove the Gabi™ Band from the child’s arm. Be aware that light, temporary marks may appear after wearing the Gabi™ Band for several hours. They should disappear within approximately 10 minutes after removal of the device.
- (5) If the Gabi™ Band bracelet is not clean, you can remove it from the Gabi™ Band sensor and proceed to clean it (see on page 30, 4.5.1 “Cleaning the Gabi™ Band”).
- (6) Connect the Gabi™ Band to its charger and place it out of reach of children.
Once connected to the charger, the battery icon switches to ‘Battery charging’. Once fully charged, the battery icon switched to ‘Battery fully charged’.
Even when fully charged, you are strongly advised to leave the Gabi™ Band connected to power while not in use to ensure it will be sufficiently charged for the next recording.

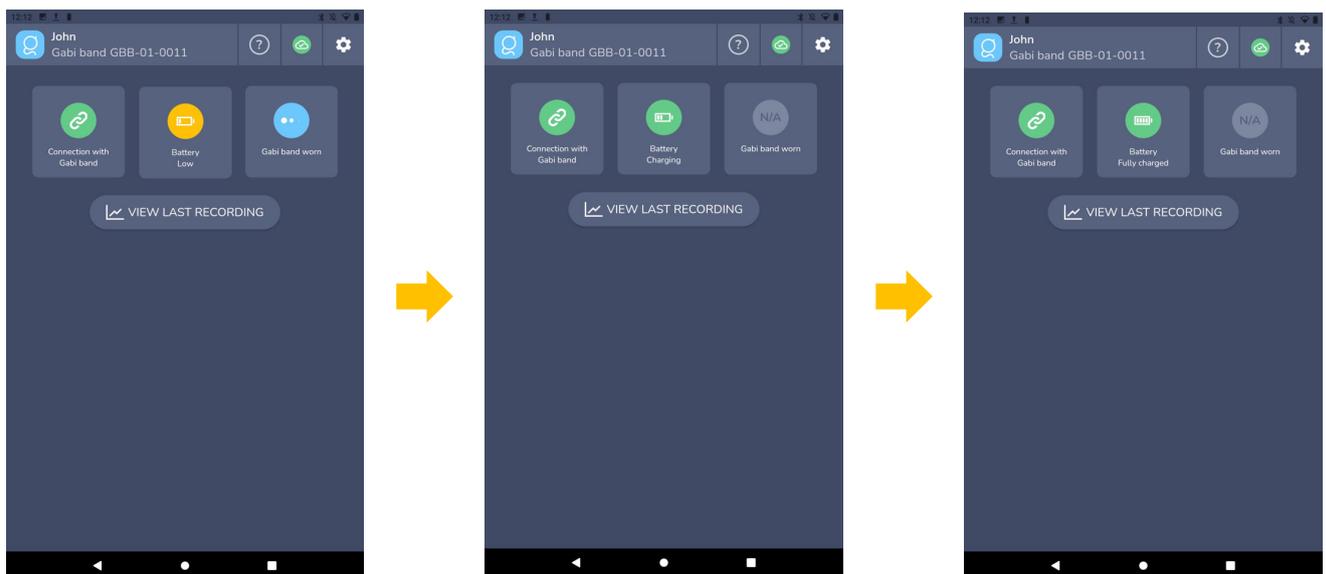


Figure 24: Battery status display

When no recording is on-going, you can click on “View Last Recording” to see an overview of the last recording. When finished, you can go back to the previous screen by clicking on the back arrow in the top bar.

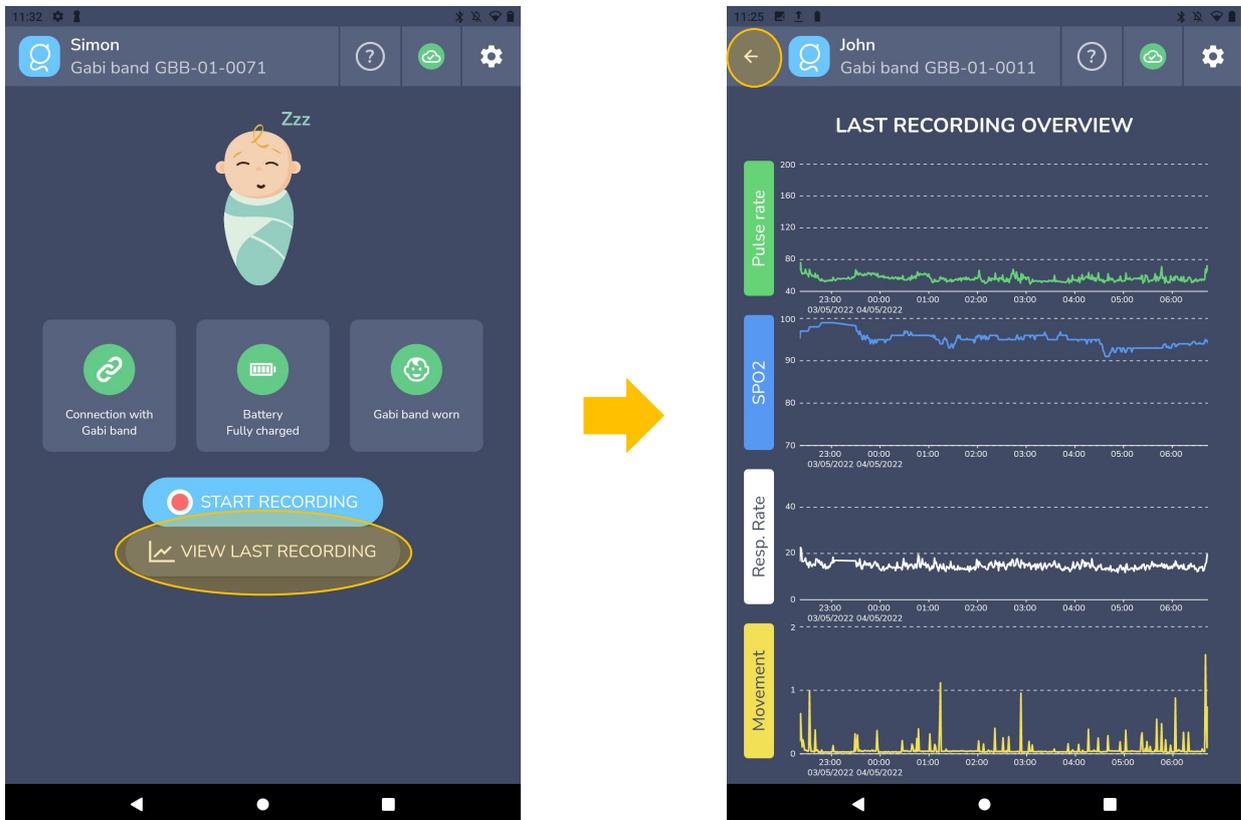


Figure 25: Last recording overview

4.5 Cleaning Instructions

You should clean the device on a regular basis. The frequency of cleaning is at your own discretion.

 Do not use caustic or abrasive cleaning agents.

 Do not immerse the Gabi™ Band sensor unit in any liquid solution.

 Do not sterilize the Gabi™ system by irradiation, steam, or autoclave.

4.5.1 Cleaning the Gabi™ Band

You shall ensure the Gabi™ Band is kept in a clean environment.

To clean the Gabi™ Band, disconnect it from the power and ensure it is not applied to the child.

The Gabi™ Band shall be cleaned gently with a damp and clean cloth.

If the bracelet of Gabi™ Band is dirty, dismount it from the Gabi™ Band sensor unit. Proceed to the cleaning of the textile: you can wash it in a washing machine at a maximum temperature of 30°C (86°F) and a maximum spin speed of 800rpm. Do not tumble dry it!

When fully dry, attach back gently the loop end of the bracelet to the two protrusions of the Gabi™ Band sensor unit (see chapter 4.3.1 “Setup the Gabi™ Band” on page 18).

4.5.2 Cleaning the Gabi™ Monitor Tablet

You shall ensure the Gabi™ Monitor Tablet is kept in a clean environment.

If necessary, the Gabi™ Monitor Tablet can be cleaned gently with a dry and clean cloth.

4.6 Storage Instructions

Store the Gabi™ system out of reach of children.

Do not store in direct sunlight.

The following storage conditions should be followed:

- Temperature range: -20°C to 45°C (-4°F to 113°F)
- Humidity range: 15% to 90%
- Atmospheric pressure: 700hPa to 1060hPa

For an extended storage (more than three months without usage), we recommend you follow these restricted conditions:

- Temperature range: 10°C to 30°C (50°F to 86°F)

After a very long storage (more than one year without charging), the battery capacity might be reduced.

4.7 Maintenance

No specific maintenance is required for your Gabi™ system.

5. Use of Gabi™ Monitor App – Additional features

The settings tab (⚙️ see button E in Figure 3 on page 16) allows you to access some data and provides technical information about the paired Gabi™ Band and the Gabi™ Monitor App version.

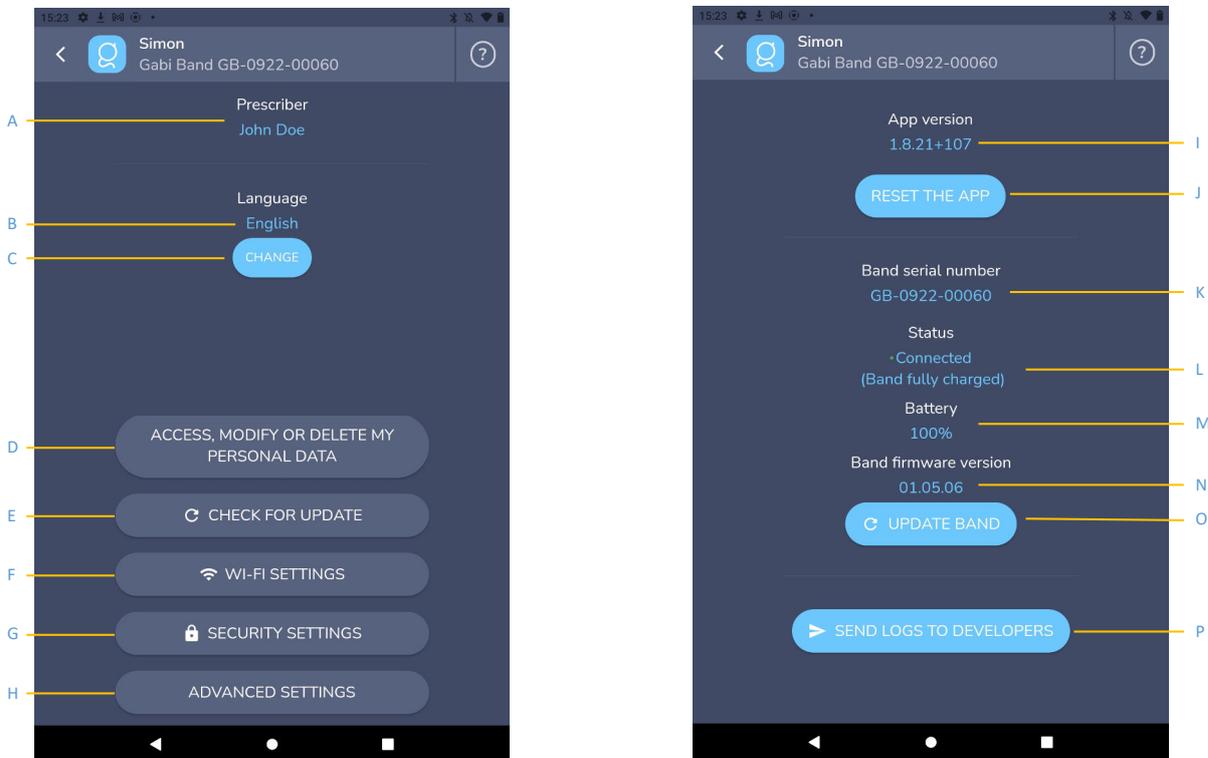


Figure 26: Settings screen of Gabi Monitor Application

- A. The name of the physician who prescribed you the Gabi™ system
- B. Your current preferred language
- C. Choose another language for your interface. Click on the “change” button and select the new language. The Gabi™ Monitor App is automatically switched to this new language.
- D. Access, modify or delete your personal data. You can press this button if you want to access or modify your personal data (see §5.1 Access and modify your personal data on page 33) or if you want to delete your account (see §5.1.3 Delete your account on page 35).
- E. Check for update of the Gabi™ Monitor App (see 5.2.1 Gabi™ Monitor App update on page 36)
- F. Access the Wi-Fi settings (see §5.3 Use a new Wi-Fi network on page 39)
- G. Access the lock screen settings (see §5.4 Change your pin for unlocking the Gabi™ Monitor Tablet on page 39)
- H. Access the advanced settings menu, allows you to access to items I to P
- I. Gabi™ Monitor App current version
- J. Reset the Gabi™ Monitor App (see §5.5 Reset Application settings on page 39)
- K. Gabi™ Band serial number
- L. Gabi™ Band status
 - Connected worn
 - Connected standby

- Connected charging
- Connected Band fully charged
- Not connected

M. Gabi™ Band battery level

N. Gabi™ Band current firmware version

O. Force the firmware update on the Gabi™ Band (see §5.2.2 Gabi™ Band firmware update on page 38)

P. Send logs to Gabi SmartCare (can be helpful during troubleshooting or when contacting customer support for assistance)

5.1 Access and modify your personal data or delete your account

If you want to verify or update your personal data or delete your account, press the “access, modify or delete my personal data” button (see D in Figure 26 on page 32). You will receive an email including a link to access to your personal data (email title is “Gabi: access to personal data”). On the confirmation screen, you can check the email address on which you will receive the link.

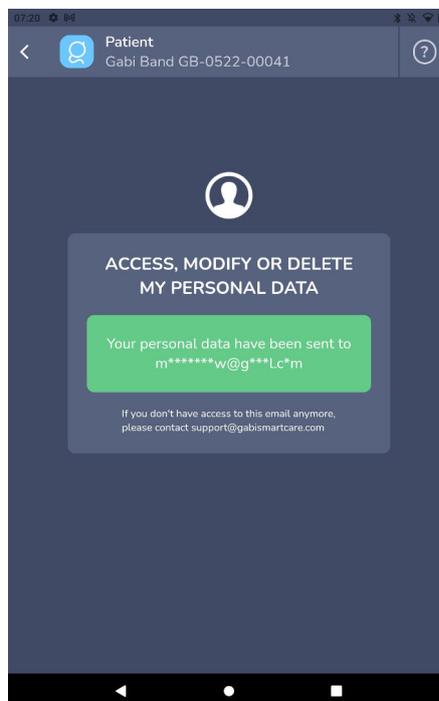


Figure 27: access to personal data - email confirmation

Open your email and click on the included link (which is something like <https://privacy.gabismartcare.com/xxx>).

This opens the Privacy page in your web browser.

Be aware that some browsers may not be supported. If you encountered some difficulties to view the page, check your browser version. The supported browsers and versions are:

- Chrome higher than or equal to v64
- 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

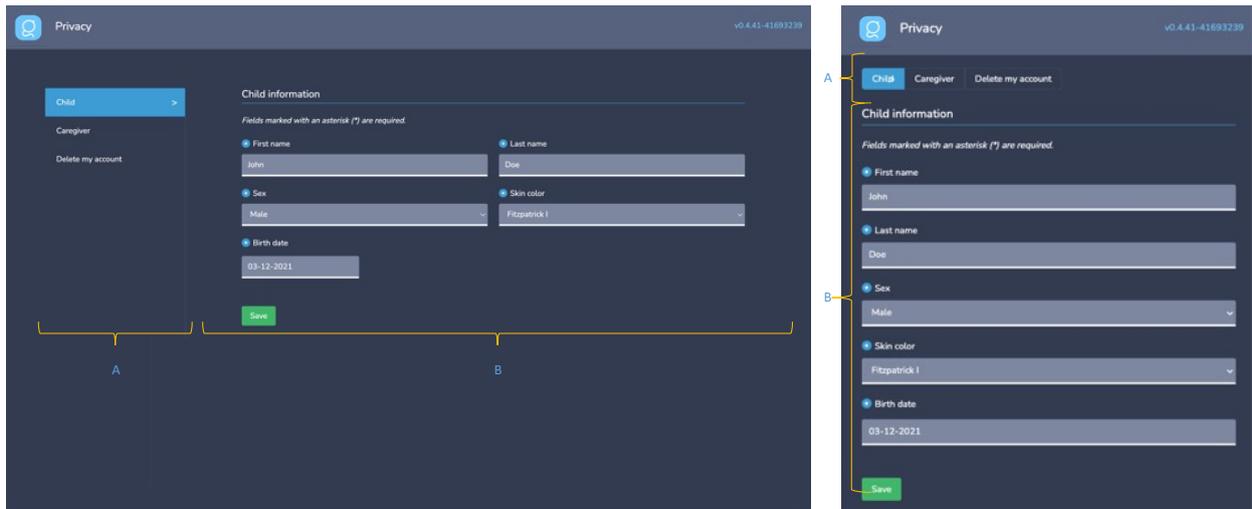


Figure 28: Privacy page on different screen types

On the privacy page, you have three tabs (A): child information, caregiver information and delete my account action. You can navigate through these three sheets through the left bar of the page.

On each sheet, you can update the information or take actions (B).

5.1.1 Child information

In the child information sheet, you can update the different fields:

- Child's first name (*text field*)
- Child's last name (*text field*)
- Child's sex (*dropdown*)
- Child's 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.
- If required, confirmation that you will use the device under your own responsibility when using it outside the intended use (e.g. for children older than 12 years old or younger than 28 days old) (*checkbox*)



The Gabi™ 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.

Be aware that if you leave the form before pressing the 'save' button, then the already updated 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.

5.1.2 Caregiver information

In the caregiver information sheet, you can update the different fields:

- 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 Gabi™ Monitor App.
- Caregiver's email address (*text field*): this email address is used to send the QR code to the caregiver and to get access to the personal data
- 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

Be aware that if you leave the form before pressing the 'next' button, then the already updated data will be lost.

5.1.3 Delete your account

By deleting your account, you will lose your access to Gabi™ Monitor App. All your personal data will be deleted, meaning that your physician will lose access to your biometrics recordings. This is an irreversible action! Once done, the previous recordings are lost and cannot be recovered. If you want to use your Gabi™ system after the deletion, you will need to ask your physician to create a new account for you. Your previous history will not be available.

If you want to proceed, open the 'delete my account' page. Write 'DELETE' (in capital letters) in the corresponding field. Once done, a field appears where you can enter the reason for deleting your account (i.e. offboarding). You can now press the "delete my account" button. A confirmation pop-up message will ask you to definitively confirm your choice.

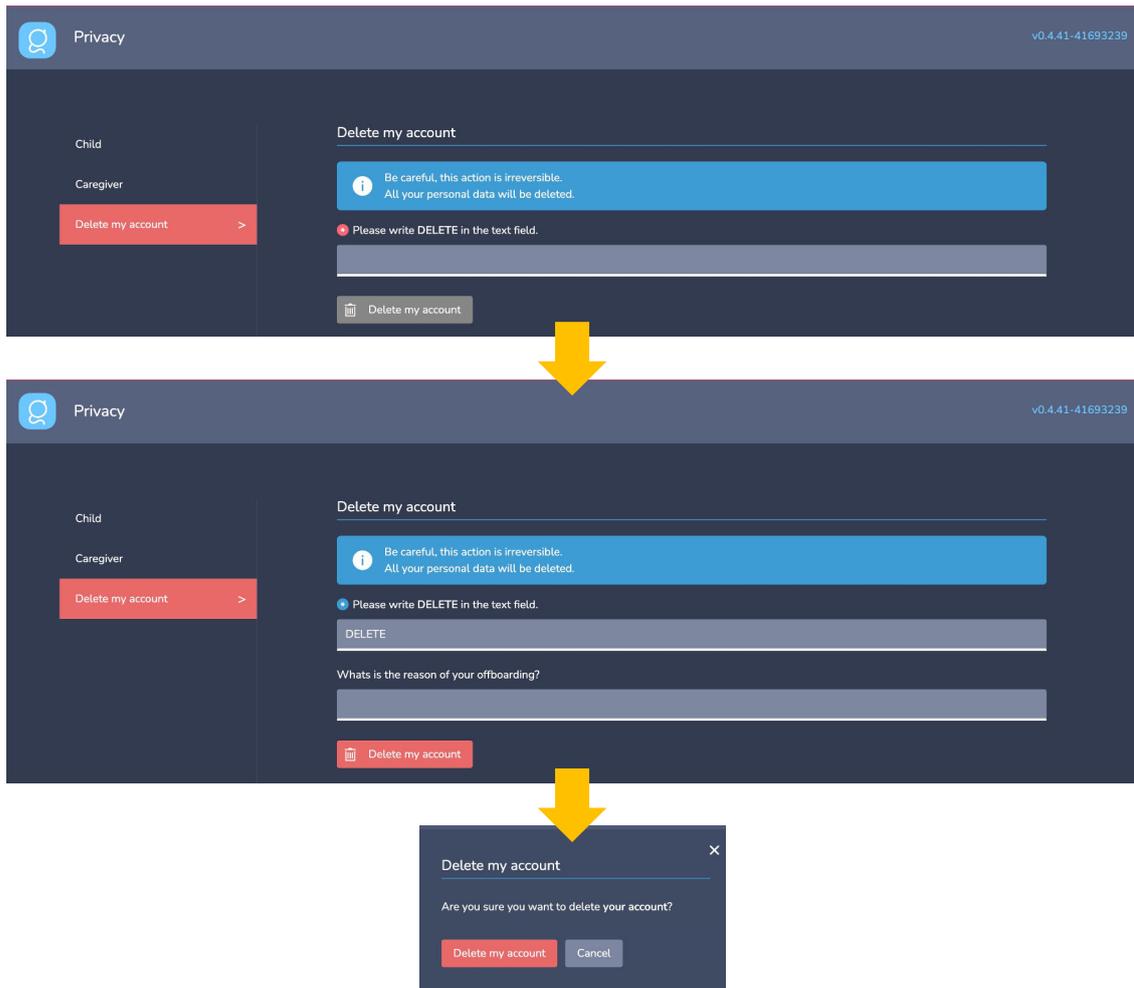


Figure 29: Account deletion – steps

5.2 Software update

5.2.1 Gabi™ Monitor App update

New versions of Gabi™ Monitor App are issued on a regular basis by Gabi SmartCare.

If the new version solves a major issue, this new version must be installed on your device. You will not be able to start a new recording without this new version. Press the button “update now” to continue.

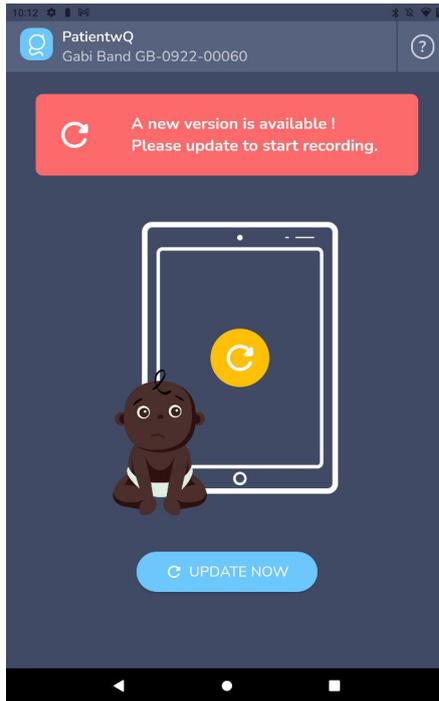


Figure 30: New version - mandatory update of the application

In other cases, the new version can be installed on your device but there is no obligation. To install a new version, press the “check for updates” button from the settings screen (see E in Figure 26 on page 32). The system will check if a new version is available and, in this case, it will propose you to proceed to the version update. Press the “update” button to continue.

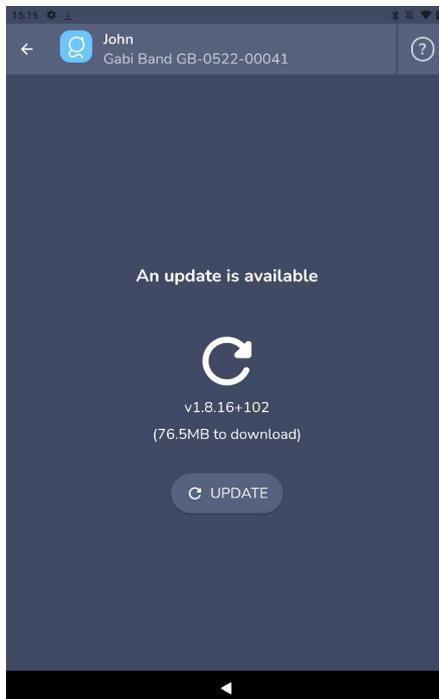


Figure 31: New version availability

If the update is optional or mandatory, the new version will be downloaded. When this download is finished, press the “install” button. When the installation is finished, you can open the new version by pressing the “open” button.

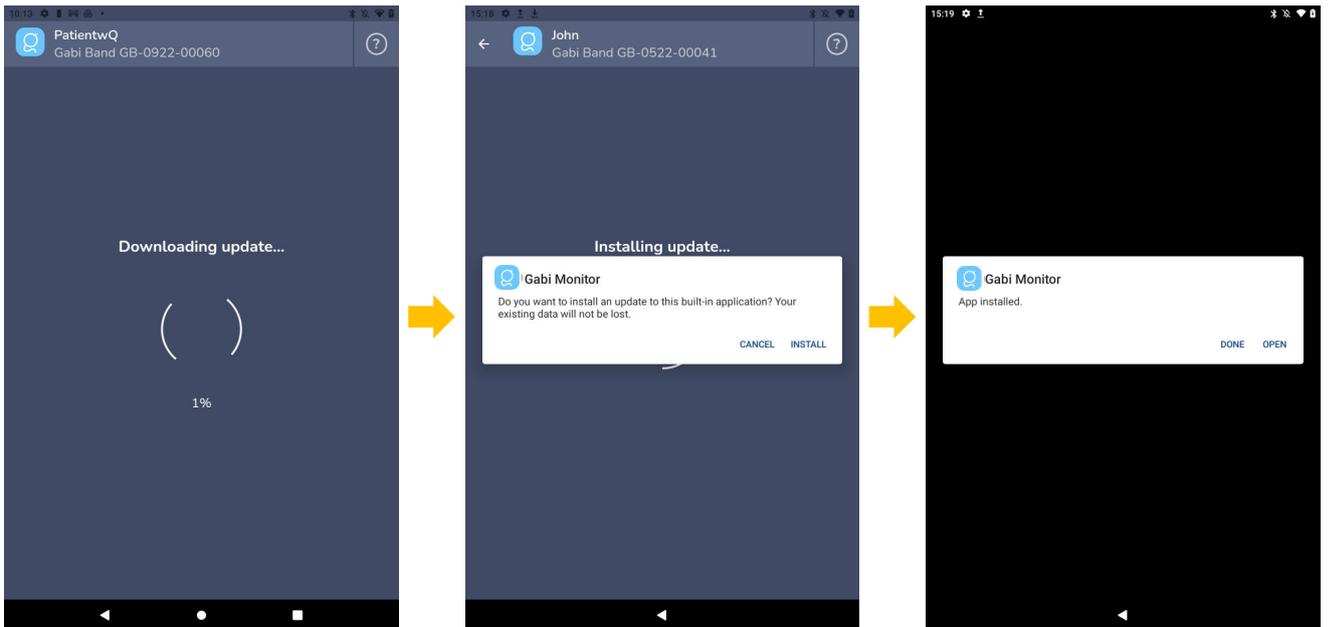


Figure 32: New version download and installation steps

5.2.2 Gabi™ Band firmware update

When a new version of Gabi™ Monitor App is installed, it sometimes includes a new version of the firmware present in your Gabi™ Band. In this case, you will not be able to start a new recording without this new version.

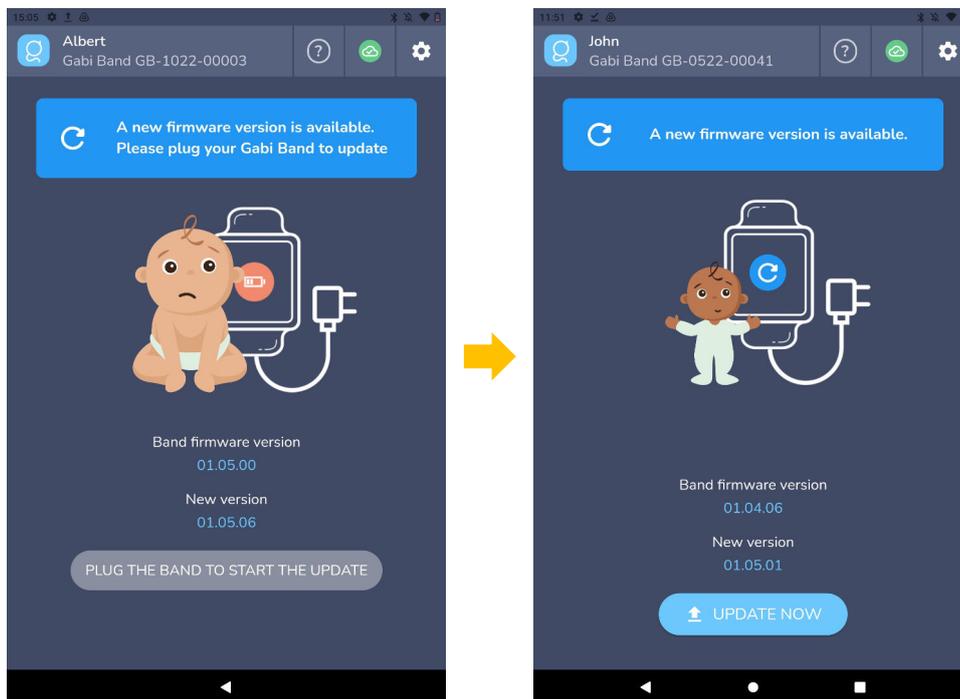


Figure 33: Firmware update – steps

To update the firmware, first connect the Gabi™ Band to its power adapter, then press the “update now” button. During the update, please:

- do not switch off your tablet
- keep the tablet near the Gabi™ Band

- keep the Gabi™ Band connected to power

Once the update is done, acknowledge the installation. You will now be able to use your Gabi™ system as before.

5.3 Use a new Wi-Fi network

If you want to use another Wi-Fi network or if you updated your Wi-Fi password, press the “Wi-Fi settings” button of the settings screen (see E in Figure 26 on page 32).

5.4 Change your pin for unlocking the Gabi™ Monitor Tablet

If you change the pin used to lock your Gabi™ Monitor Tablet screen, press the “Security settings” button of the settings screen (see G in Figure 26 on page 32). You will need to first enter your current pin and then you will be able to enter your new pin.

5.5 Reset Application settings

Resetting the Gabi™ Monitor App to its initial settings means that the pairing between the Gabi™ Band and the Gabi™ Monitor Tablet will be erased, and that the link between your child and the Gabi™ Monitor App will be lost. The recordings previously done will still be available for your physician. If you want to use your Gabi™ system after the reset, you will need to ask your physician to create a new QR code for you.

If you want to proceed, press the “Reset the App” button of the settings screen (see J in Figure 26 on page 32).

Be aware that the Wi-Fi settings and the screen lock settings will not be affected by this operation.

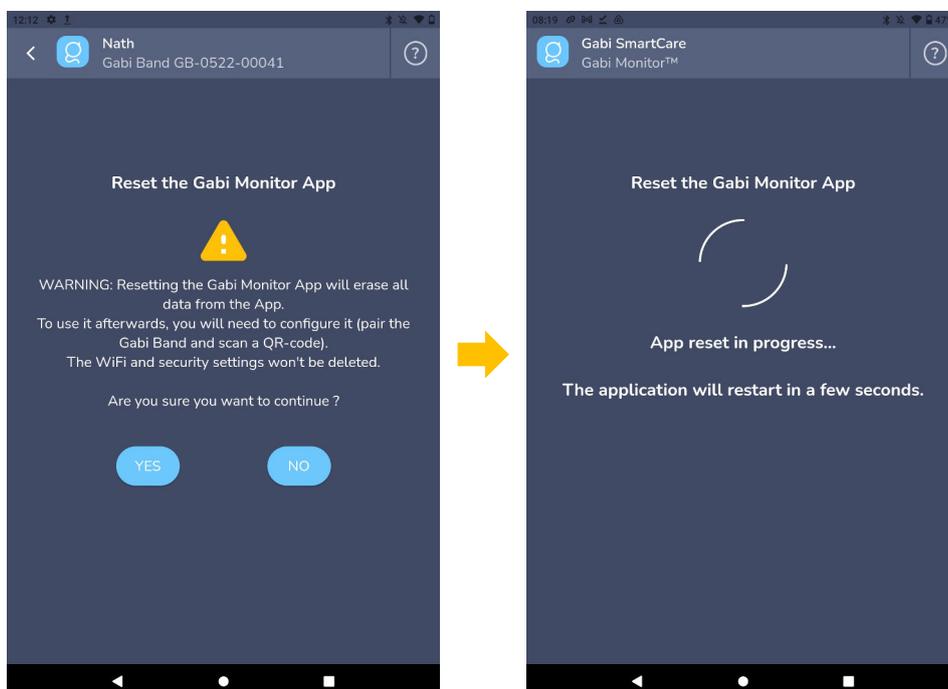


Figure 34: Reset Application to factory settings

6. End of use – Disposal of your Gabi™ system

The Gabi™ Band and Gabi™ Monitor Tablet both contain an internal battery. Dispose of the devices according to country or regional requirements.

7. Technical Specifications

7.1 Operational Specifications

The Gabi™ Band can safely operate in the following environment:

- Operating temperature range: 5°C to 35°C (41°F to 95°F)
- Humidity range: 15% to 90%
- Atmospheric pressure: 700hPa to 1060hPa

After 500 battery charge and discharge cycles, the battery performance might be reduced.

7.2 Equipment Specifications

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

- Pulse Rate indication
- SpO2 indication

In case of electromagnetic (EM) disturbances to the BLE communication between the Gabi™ Band and the Gabi™ Monitor Tablet, the Gabi™ Monitor App may stop displaying any values to the operator. EM disturbances will not cause erroneous values to be displayed by the Gabi™ Monitor App. During the EM disturbance, the Gabi™ Band will continue to record the physiological parameters from the child. After the EM disturbance stops, the Gabi™ Monitor App will automatically reconnect to the Gabi™ Band and continue with normal operation.

7.2.1 Biometrics range and accuracy

Table 1: 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	250 bpm	0.65 bpm
Respiratory Rate	4 brpm	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.

The 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 clinical study complies with ISO 14155:2011.

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 \pm Arms of the value measured by the reference equipment in the clinical study.

 A functional tester cannot be used to assess the accuracy of the Gabi™ system.

7.2.2 Used peak wavelengths

Infrared LED: 950nm

Red LED: 660nm

Green LED: 526nm

7.2.3 Reception and transmission specifications

Gabi™ Band wireless interface (BLE mode)

Frequency: 2402MHz - 2480MHz

Modulation: GFSK

Peak Effective Isotropic Radiated Power (EIRP): 8.44 dBm

Gabi™ Monitor Tablet Wi-Fi frequency: 2.4 GHz - 802.11b/g/n: 2412-2472 MHz

Gabi™ Monitor Tablet Bluetooth frequency: 2402-2480 MHz

Peak output power: -0.956 dBm

7.2.4 Display

Display Update Rate: 1 second

7.3 Electrical

7.3.1 Power

Power supply for Gabi™ Monitor Tablet

AC power adapter input: 100-240V, 50-60Hz, 0.4A

AC power adapter output: 5V, 2A

Note: only use the supplied Gabi™ Monitor Tablet AC/DC power adapter

- For use in North America, the power adapter model number is FX2U-050200U
- For use in European Union, the power adapter model number is WRP2E-050200U

Power supply for Gabi™ Band

AC power adapter input: 100-240V, 50-60Hz, 0.2A

Note: only use the Gabi™ Band power adapter

- For use in North America, the power adapter model number is SK12G-0500100U
- For use in European Union, the power adapter model number is SK12G-0500100V

7.3.2 Battery

Battery of Gabi™ Monitor Tablet

Type: rechargeable Lithium-Ion battery

Capacity: 3000mAh

Charging time: < 2 hours (time to reach 80% capacity at 25°C / 77°F)

Discharging time: > 18 hours in typical continuous usage

Battery of Gabi™ Band

Type: rechargeable Lithium-Ion battery

Capacity: 115mAh

Charging time: < 2 hours (time to reach 80% capacity at 25°C / 77°F)

Discharging time: > 18 hours in typical continuous usage

7.4 Physical Characteristics

Gabi™ Monitor Tablet

Dimensions: 185mm x 110mm x 9mm (7.3" x 4.3" x 0.35")

Weight: 240g (1.63lbs)

Display characteristics: LCD 1920 x 1200

Gabi™ Band

Dimensions: 32 mm x 30 mm x 11.7 mm (1.3" x 1.2" x 0.5")

Weight: 9g (0.02lbs)

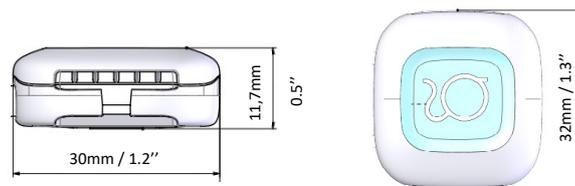


Figure 35: Gabi Band dimensions

7.5 Lifetime

The expected usable lifetime of the Gabi™ system is 3 years.

7.6 Product Compliance

Standards Compliance

- IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
- IEC 60601-1-2:2014, IEC60601-1-2:2014/AMD1:2020
- ISO 80601-2-61:2017
- IEC 60601-1-6:2010/AMD1:2013 & IEC 62366-1:2007/AMD1:2014
- IEC 60601-1-11:2015

- IEC 62304:2006/AMD1:2015

Equipment Classification

- Type of Protection against electric shock: Class II (AC power) / Internally powered (Battery power)
- Degree of Protection of electrical shock: Defibrillation proof Type BF-Applied Part
- Mode of Operation: Continuous Operation
- Electromagnetic class: Class B
- Electromagnetic group: Group 1
- Protection against harm from solid and liquid ingress: IP67 for the Gabi Band

7.7 Manufacturer's Declaration

WARNING:

This ME Equipment may cause radio interference or may disrupt the operation of nearby equipment, regardless of whether it is CISPR compliant or not. It may be necessary to take mitigation measures, such as reorienting or relocating the ME Equipment or shielding the location.

WARNING:

The use of accessories, sensors, and cables other than those specified may result in inaccurate readings of the ME Equipment and increased EMI emission or decreased electromagnetic immunity of the ME Equipment.

WARNING:

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME Equipment, including cables specified by the manufacturer. Otherwise, degradation of ME Equipment performance may result.

WARNING:

The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Caution:

When operating ME Equipment, special precautions related to electromagnetic compatibility (EMC) are required. Install the ME Equipment according to the EMC information included in this manual.

7.7.1 Electromagnetic Compatibility (EMC)

The Gabi™ system is suitable for use only in the specified electromagnetic environments, in accordance with the IEC 60601-1-2:2014, IEC60601-1-2:2014/AMD1:2020 standard. The Gabi™

system requires special precautions during installation and operation for electromagnetic compatibility. In particular, the use of nearby mobile or portable communications equipment may influence the Gabi™ system performance.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Any changes or modifications to this equipment not expressly approved by Gabi SmartCare may cause harmful radio frequency interference and void your authority to operate this equipment.

The emissions characteristics of this equipment make it suitable for use in a residential environment (for which CISPR 11 class B is normally required). This equipment might not offer adequate protection to radiofrequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

NOTE: “Harmful interference” is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

Guidance and manufacturer’s declaration—Electromagnetic Emissions (IEC/EN 60601-1-2)		
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1, Class B	ME Equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC/EN 61000-3-2	Class A	Suitable for use in all establishments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations and flicker IEC 61000-3-3	Complies	

Guidance and manufacturer’s declaration—Electromagnetic Immunity (IEC/EN 60601-1-2)		
--	--	--

The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601-1-2 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	+/-8 kV (Contact) +/-15 kV (Air)	+/-8 kV (Contact) +/-15 kV (Air)	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric fast transient/burst IEC/EN 61000-4-4	+/- 2 kV for power lines		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	+/-1 kV differential mode +/-2 kV common mode		Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply IEC/EN 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles. Single phase: at 0° 0 % UT; 250/300 cycle		Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a

			typical hospital environment.
--	--	--	----------------------------------

Guidance and manufacturer’s declaration—Electromagnetic Immunity
(IEC/EN 60601-1-2)

The ME Equipment is intended for use in the electromagnetic environment specified below.
The customer or the user of the ME Equipment should assure that it is used in such an environment.

Immunity test	IEC/EN 60601-1-2 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 V and 6 V 150 kHz to 80 MHz	3 V and 6 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the ME Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><u>Recommended Separation Distance</u></p> $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	30 V/m 80 MHz to 2.5 GHz	28 V/m	$d = 1.2\sqrt{P}$ <p>80 MHz to 800 MHz</p>
	10 V/m 6 GHz	9 V/m	$d = 2.3\sqrt{P}$ <p>800 MHz to 2.7 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site</p>

			<p>survey^a, should be less than the compliance level in each frequency range^b. Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			
<p>^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ME Equipment is used exceeds the applicable RF compliance level above, the monitoring system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME Equipment.</p> <p>^bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

8. Troubleshooting

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

8.1 Troubleshooting specific to the Gabi™ Band

A summary of the Gabi™ Band light indications is available in section 9.

8.1.1 The white light of the Gabi™ Band did not blink upon connection to the charger

If the white light of the Gabi™ Band did not blink upon connection to the charger, follow these steps:

1. Make sure the Gabi™ Band's charging cable is properly attached to the charging port and properly inserted in the USB receptacle of the power adapter. Make sure the power adapter is plugged into a wall outlet.
2. Disconnect the charging cable from the Gabi™ Band and connect it again.
3. If the white light still does not start blinking and no light appears on the Gabi™ Band after 10 seconds, please contact the customer support at your earliest convenience.



Figure 36: White light on Gabi Band

8.1.2 The green and red lights on the bottom of the Gabi™ Band sensor did not blink upon disconnection from the charger

If the green and red lights on the bottom of the Gabi™ Band sensor did not blink upon disconnection from the charger, follow these steps:

1. Disconnect the Gabi™ Band power adapter from the wall outlet.
2. Make sure the Gabi™ Band is properly connected to its charging cable and power adapter.
3. Connect the Gabi™ Band power adapter to a wall outlet and wait 10 seconds until the white light of the Gabi™ Band blinks. Then disconnect the charging cable from the Gabi™ Band.
4. If the green and red lights on the bottom of the sensor still do not start blinking, check if there is a purple blinking light on top part the Gabi™ Band:
 - a. If yes, it means the Gabi™ Band battery is depleted and that the Gabi™ Band should be charged before use (see section 8.1.4 for more detailed information).
5. If the problem persists, please contact the customer support at your earliest convenience.



Figure 37: Green and red lights at the bottom of the sensor

8.1.3 A yellow light is on, on the top part of the Gabi™ Band

If the yellow light is steady on the Gabi™ Band, it means the software of the Gabi™ Band is being updated. Please do not disconnect the Gabi™ Band from its charger until the yellow light turns off and the light turns white (blinking or steady).



Figure 38: Gabi Band yellow light

8.1.4 A purple light is blinking on the top part of the Gabi™ Band

If the purple light is blinking on the top part of the Gabi™ Band, it means the Gabi™ Band battery is low and it should be charged before use. If it happens, follow the steps below:

1. Connect the Gabi™ Band to its charger.
2. Make sure the charger is connected to a wall outlet.
3. Make sure that a white light is blinking on the top part of the Gabi™ Band, indicating charging.
4. Once fully charged, a steady white light will be displayed.



Figure 39: Gabi Band purple light

8.1.5 I am not sure I placed the Gabi™ Band correctly

If you are not sure you placed the Gabi™ Band correctly, refer to section 4.4.1 for optimal placement and perform the checks below:

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

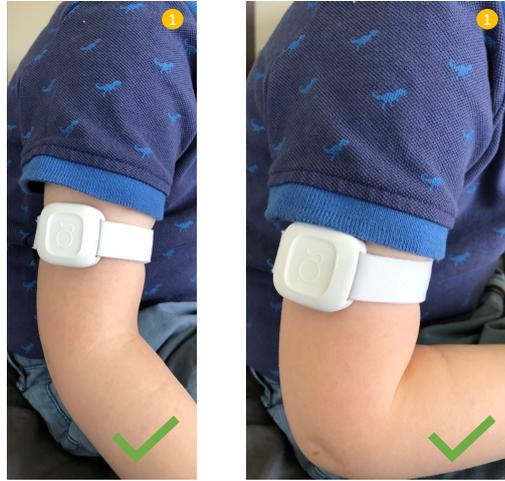


Figure 40: Gabi Band correct positioning



Figure 41: Gabi Band wrong positionings

8.2 Troubleshooting specific to the Gabi™ Monitor App

8.2.1 I cannot start the recording and the “Connection with Gabi Band” icon is loading

If the “Connection with Gabi Band” status is indefinitely on-going, follow the steps below:

1. Verify that the Gabi™ Band is in range, i.e. within 7 meters (23 feet) of the tablet.
2. Close the Gabi™ Monitor App and reopen it.
3. If the problem persists, connect the Gabi™ Band to its charger, once plugged in, the “Connection with Gabi Band” icon should turn green indicating the Gabi™ Band is connected.

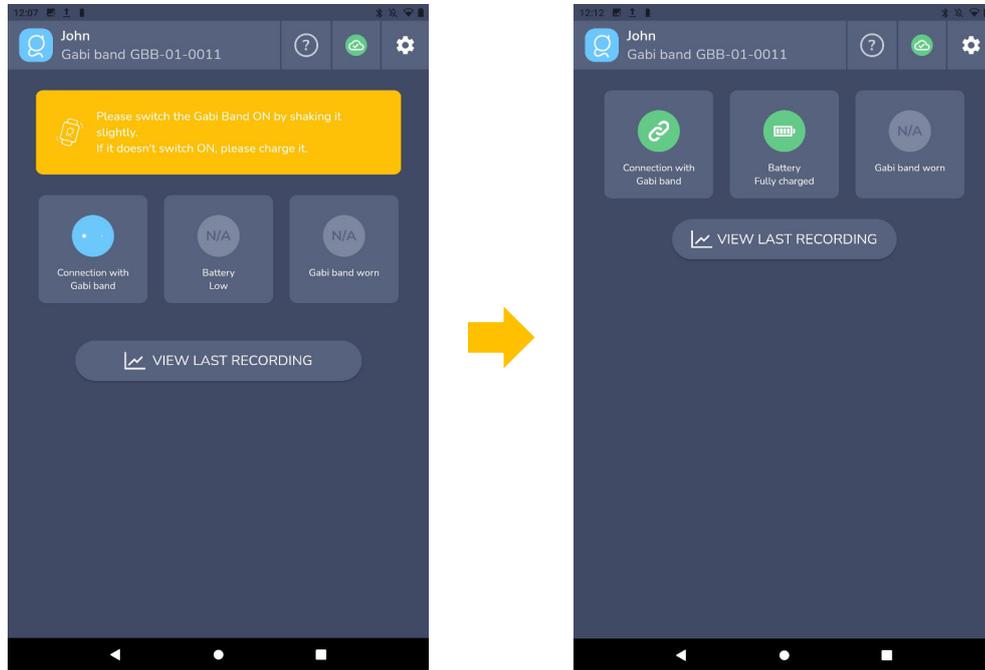


Figure 42: connection with Gabi Band issue

4. If the icon turns blue again, verify that the Bluetooth symbol appears on the top of the screen.
5. Restart the Gabi™ Monitor Tablet by holding the power button until it shuts down. Then press the power button again to turn the Gabi™ Monitor Tablet back on.

8.2.2 I cannot start the recording and the “Battery” icon is red

If you cannot start the recording and the battery status is red, it means the battery of the Gabi™ Band is not sufficiently charged to perform a recording. Please charge the Gabi™ Band before proceeding to the next recording.

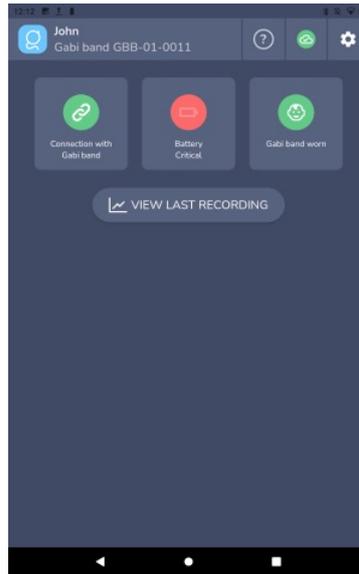


Figure 43: Battery level is critical (icon is red)

8.2.3 I can start the recording but the “Battery” icon is orange

The battery icon turns orange when the charge state of the Gabi™ Band battery is less than 50% capacity. However, recordings will still be permitted if the battery level remains between 15% and 50%.

You are strongly advised to connect the Gabi™ Band to its charger when not in use to ensure sufficient battery capacity for the next recording.

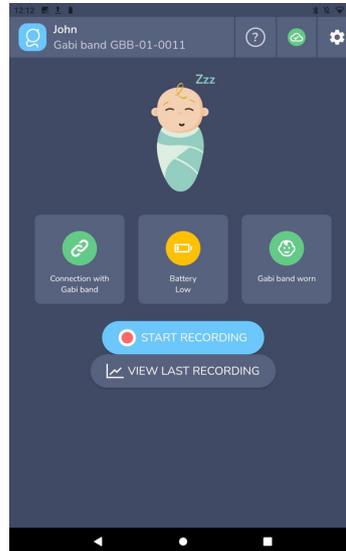


Figure 44: Battery level is low (icon is orange)

8.2.4 The Gabi Cloud Icon turned red

If the Gabi Cloud icon turned red at the end of the recording, it means that the data collected by the Gabi™ Band during the last recording(s) could not be uploaded to the Gabi Cloud and therefore, could not be sent to your physician. This happens when the tablet is not connected to Wi-Fi when you press “Stop recording”.

To send the pending Gabi recordings, follow the steps below:

1. Click on the red Gabi Cloud icon 
2. If the Gabi™ Monitor Tablet is not connected to Wi-Fi, connect it to Wi-Fi by moving it nearer to your Wi-Fi access point.
3. Click on “Upload data”. The list of “data pending upload” should be cleared, and the Gabi Cloud icon should turn green .

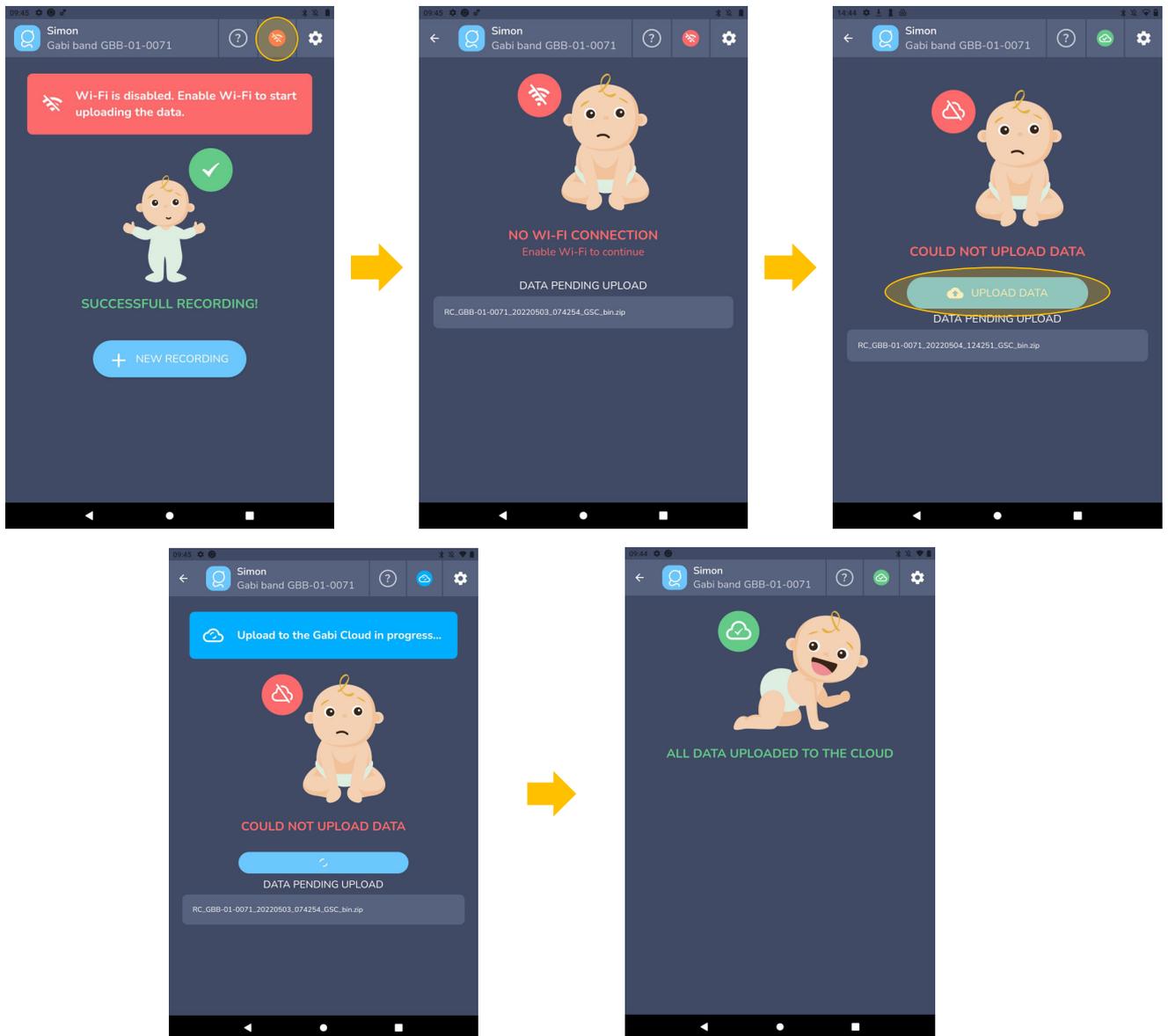


Figure 45: Upload of data on Gabi Cloud

4. If the upload failed again, verify that the tablet is connected to Wi-Fi:
 - a. Go to “Settings” page.
 - b. Then click “Wi-Fi settings”.
 - c. Verify Wi-Fi is ON and if not, turn it ON and select the appropriate Wi-Fi network name.
5. Once done, go back to the Gabi™ Monitor App, and repeat steps 1 to 3 above.
6. If the problem persists, restart the tablet by holding the power button until it shuts down. Then press the power button again to turn on the tablet. Repeat steps 1, 2 and 3 above.
7. If the problem persists, contact the customer support at your earliest convenience.

8.2.5 The Gabi™ Monitor App is loading endlessly when attempting to open it

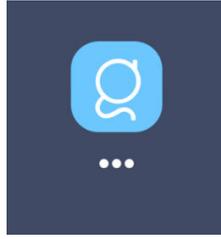


Figure 46: Gabi Monitor Application loading screen

If the Gabi™ Monitor App is loading endlessly when attempting to open it, follow the steps below:

1. Restart the tablet by holding the power button (see button C of Figure 2 on page 15) until the tablet shuts down. Then press the power button again to turn on the tablet.
2. Try opening the Gabi™ Monitor App again. If the problem persists, contact the customer support at your earliest convenience.

8.3 Troubleshooting specific to the Tablet

8.3.1 The tablet does not power on

If the tablet does not power on, connect it to its charger and wait a few minutes then hold the power button (see button C of Figure 2 on page 15) until the tablet turns on. A battery symbol could appear, which means that the battery of the tablet was fully depleted.

If the tablet still does not power on, make sure the micro-USB charging cable is properly inserted in the tablet and the other end of the charging cable is properly connected to the USB receptacle of the power adapter. Make sure the power adapter is connected to a functioning wall outlet.

If it still does not solve the issue, please contact the customer support at your earliest convenience.

9. Gabi™ Band Light indications

A summary of the Gabi™ Band light indications and their meaning is provided in the table below.

Color	State	Meaning
White light 	Blinking every second	The Gabi™ Band is connected to the power adapter and the battery is charging.
	Steady	The Gabi™ Band is connected to the power adapter and the battery is fully charged.
Green light 	Steady	The Gabi™ Band is in contact with the skin and is ready for recording.
Purple light 	Blinking every second	The Gabi™ Band battery charge status is very low and it should be charged before use. Please follow the instructions to charge the Gabi™ Band.
Blue light 	Steady	The pairing between the Gabi™ Band and the Gabi™ Monitor Tablet is on-going.

<p>Yellow light</p> 	<p>Steady</p>	<p>The Gabi™ Band is connected to the charger and an update of the software is in progress.</p> <p>⚠ Do not disconnect the Gabi™ Band from its charger during this operation.</p>
<p>Red light</p> 	<p>Steady</p>	<p>An error occurred on your Gabi™ Band. Please try to update the firmware. If the problem persists, contact the customer support at your earliest convenience.</p>
<p>Green and red sensor unit lights</p> 	<p>Blinking every 5 seconds</p>	<p>The Gabi™ Band is ready to be put in contact with the skin and is checking every 5 seconds if it is being worn or not.</p>

10. Symbols on Product or Package Labeling

10.1 Certification and safety-related symbols

	Medical Device
	Manufacturer
	Date of manufacturing
	Unique Device Identifier
	Model Number
	Serial Number
	Mark of conformity to European Medical Device Regulation 2017/745
	Separate Collection for electrical and electronic equipment (WEEE)
	Restriction of Hazardous Substances
	Federal Communications Commission (FCC) licensing
	Consult Instruction for Use
	Keep dry
	Caution: Federal Law (USA) restricts this device for sale by or on the order of a physician
	Lot code
	Storage temperature range
	Storage humidity range

	<p>Storage atmospheric pressure range</p>
	<p>Electric class II (powered by an external source without reliable protective earth)</p>
	<p>Applied Part Type BF</p>
<p>IP67</p>	<p>Ingress Protection 67</p>
	<p>Continuous current (DC power supply)</p>
	<p>The instruction manual/booklet must be read</p>
	<p>The device is non-sterile</p>
	<p>No SpO2 alarms included</p>

11. Additional Information

11.1 Clinical Studies

See 7.2.1 Biometrics range and accuracy on page 41.

11.2 Disease and self-care information

The Gabi™ system does not replace parental supervision.

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

Telemonitoring does not replace regular check-ups with your doctor. Consult your doctor in case of severe and persistent symptoms.

11.3 Adverse events

For adverse events or if you encounter a technical problem, please:

- Record the serial number of the device.
- Contact Gabi SmartCare® S.A (see contact information in chapter 12 User Assistance Information on page 64) 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.

11.4 Warranty

Gabi SmartCare® S.A's Standard Terms and Conditions of Sale effective at the time shall apply. Agreements diverging from these Standard Terms and Conditions do not restrict the legal rights of the buyer. Any warranty exceeding the above provisions shall require a contractual form and shall exclude component-related vandalism and consumables. Under this warranty, Gabi SmartCare® S.A will remedy free of charge any defects due to faulty workmanship or the use of faulty materials, either through our Customer Service or directly at the factory. The warranty for the unit is not extended by this.

11.5 Return procedure

Before returning a Gabi™ system component for service, contact Gabi SmartCare® S.A or your distributor, quote your device's serial number, and ask for a return number. Include this number when you ship the device.

11.6 Travel or International Use

If you want to use the Gabi™ system in foreign countries, you will need a power adapter with an appropriate plug. The power adapters provided with the Gabi™ Band and Gabi™ Monitor Tablet support a universal input voltage, i.e. 100-240V, 50-60Hz. Therefore, you may need a converter for different plug types but you will not need an additional power convertor.

The Gabi™ Band and Gabi™ Monitor Tablet both include Li-ion batteries. Therefore, when flying with the Gabi™ system you may be required to place the devices in your carryon luggage instead of

your checked luggage. Make sure to check the rules and regulations for your specific airline carrier.

12. 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 healthcare agency: _____

Physician: _____

Referral for disposal of the device: _____
