

User Manual

CGM CARE MAP Mobile

Multi-platform



Contents

Introduction	3
Identification data	3
Precautions for use.....	3
General.....	3
Warnings	5
Checks before use	6
Checks during use	6
Information about the app	7
FIRST START-UP	8
Permissions	8
Android.....	8
iOS.....	9
HOME SCREEN	9
MAIN SCREEN.....	12
AGENDA SCREEN	14
CHAT SCREEN	18
MEASUREMENTS SCREEN.....	19
GRAPH SCREENS	21
DOCUMENTS SCREEN	22
NOTIFICATIONS SCREEN	24
Push notifications:.....	25
MENU SCREENS	26
DEVICES	34
UC352BLE - AND Scale	34
UA651BLE - AND Blood Pressure Monitor	34
GD40 DELTA - Bruno Glucometer	35
Connect 6 - FORA Glucose Meter	36
OnCallSure - Glucose Meter	36
Spirobank/SmartOne - MIR Spirometers.....	37
IR21b - FORA Thermometer.....	37
IR42b - FORA Thermometer.....	38
POD-1W - Pulse Oximeter	39
B2BH4 - CGM HI 3 LEADS ECG	40
FitBit	45
Setup	45
Enabling and configuring the FitBit service	46
Using the Fitbit service	48
Disabling the FitBit service	48
General information and references.....	50
Intended use.....	50
Classification.....	50
Intended users.....	50
Patients, indications and contraindications.....	50
Technical specifications	52

Introduction

This document describes the features of the CGM CARE MAP Mobile application, so that users can utilise them easily.

This document outlines the features available in the multi-platform version of the product, which can be used on mobile devices running the Android or iOS operating systems; the screenshots shown are for the Android version; the iOS version may differ in some graphical details due to the different operating system, but these differences are not significant for the purposes of understanding and using the product.

Where such differences are significant, screenshots of both versions will be provided.

At the end of the document, the main evidence of compliance with Regulation (EU) 2017/745 is provided, such as the manufacturer's details, the device classification (Class IIa), the technical characteristics of the devices that can be used, the intended use, and any instructions and warnings for use.

The device consists of several modules, only some of which fall within the definition of a medical device. The modules with medical functions, which are subject to assessment by the notified body (IMQ) and therefore bear the CE marking with code 0051, are as follows:

- CGM CARE MAP:
 - Reporting
 - Alarms
- **CGM CARE MAP Mobile:**
 - **Data acquisition from device**
- CGM POINT OF CARE:
 - Measurement acquisition from device

All other modules are essential for the correct functioning of the device, but do not contain medical functions. These modules are not subject to assessment by the notified body.

Identification data

The CGM CARE MAP Mobile module is part of the medical device:

Trade name	CGM CARE MAP
Model	CGM CARE MAP
Brand	CGM TELEMEDICINE
Software version	4.0.0.0

Precautions for use

This chapter provides the user with the information necessary to use the CGM CARE MAP Mobile application correctly and safely.

General

- Please read the user manual carefully in its entirety before using CGM CARE MAP Mobile.

- The manufacturer guarantees the safety, reliability and performance of CGM CARE MAP Mobile only if it is used in accordance with the instructions for use contained in this document.
- The manufacturer's liability and warranty shall lapse in the event of the user's failure to comply with the contents of this document.
- The CGM CARE MAP Mobile app requires a mobile/Wi-Fi connection to the central server to function correctly. Ensure that the app is used in an area with adequate coverage.
- CGM CARE MAP Mobile uses the device's mobile data connection; therefore, the minimum distance for patients with pacemakers must not be less than 1m.
- Report any serious incident occurring in relation to the device to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.
- Contact the Manufacturer using the contact details provided at the end of this document to obtain the product's Technical Description document.

Warnings

- Use the application only with medical devices supplied and authorised by the Manufacturer:

Manufacturer	Model	Description
Beurer	BF720	Diagnostic scales with BMI calculation
Omron	Viva (Android only)	Weight and body composition monitor
Fora	IR121b	Ear thermometer
Fora	IR42b	Forehead thermometer
Viatom	CheckMe Pro	The CheckMe Pro health monitor is intended for use in measuring, displaying, reviewing and storing multiple physiological parameters, including ECG, oxygen saturation (SpO2), pulse rate and temperature, in the home or in healthcare settings
CGM Telemedicine	Hi	Wearable 3-lead Holter ECG
FitBit	various models (Fitbit Inspire 2, 3)	Fitness smartwatch
Bruno Farmaceutici	GD40	Bluetooth blood glucose monitor
FORA	FORA 6 Connect	Bluetooth blood glucose meter
GIMA	P15 - On Call Sure Synch	Bluetooth blood glucose meter
A&D	UA-651BLE	Blood pressure monitor
Gima	LS808-BS	Blood pressure monitor
Roche	CoaguChek INRange	The CoaguChek® INRange system, comprising the CoaguChek INRange measuring device and the CoaguChek XS® PT Test PST test strip, is intended for the determination of prothrombin time (PT) in fresh capillary blood
Shenzhen Creative Industry	POD-1W	Pulse oximeter
MIR	SmartOne	Spirometer
MIR	Spirobank Smart	Spirometer
A&D	UC-352BLE	Personal scales

- The app is compatible with the Android and iOS operating system versions listed in the “Technical Specifications” section at the end of this document; please check the version of your operating system before installing the app.
- Consult a doctor or other healthcare professional if you have any doubts about the validity of the measurements taken or, in general, on any medical matter.
- Only data from CE-marked medical measuring devices is used by the medical modules for the medical purposes described in the intended use. Data from other types of non-medical devices (e.g. FitBit) is not processed by the medical modules and is not used for medical purposes; it is therefore excluded from the scope of the device’s marking. Alarms generated from measurements not originating from medical devices must not be used to make diagnostic and/or therapeutic decisions.

Checks before use









- Check that a data or Wi-Fi connection is available. If not, move to an area where there is sufficient signal strength to connect to the server.
- Check that the battery level is above 50%; if not, fully charge the device before using the application.

Checks during use









- Ensure that the name displayed on the CGM CARE MAP Mobile screen always matches the patient's name. If not, contact customer support.
- The Bluetooth connection works effectively if the distance between the devices and the smartphone is within a few metres, depending on battery charge levels and the presence of any interference. If the connection is lost or malfunctions, ensure the battery is charged and move the devices closer together until a reliable connection is restored.

Information about the app

At any time, by clicking on the Settings > About menu, you can access the screen displaying the version summary and manufacturer details (CGM CARE MAP Mobile is part of the CGM CARE MAP medical device).

	CGM TELEMEDICINE S.r.l. Sede legale: Foro Buonaparte, 70 – 20121 – Milano (MI) - Italia Sede operativa: Via Emilia Parmense, 204 – 29122 – Piacenza (PC) - Italia	
	CGM CARE MAP	
CGM TELEMEDICINE		
Ver. 4.0.0.0		
Modulo Mobile		
	(01)00086000573683(8012)v.4.0.0.0	
	[aaaa/mm/gg]	
		
	Le istruzioni per l'uso sono disponibili in formato elettronico PDF all'interno della sezione 'Formazione' della schermata Documenti. Per la visualizzazione è sufficiente un qualunque programma che supporti tale formato (Acrobat Reader o similari). E' possibile richiederne una copia cartacea inviando una mail all'indirizzo <mail configurata>, che sarà inviata gratuitamente entro 7 giorni.	

Explanation of symbols:

	Manufacturer identification
	Device model
	Release date
	Refer to the user manual
	Symbol indicating that the IFU is available in electronic format
	UDI vector
	Medical device
	Compliant with Regulation (EU) 2017/745, Class IIa medical device. The 4-digit code indicates the device's certification notified body.

FIRST START-UP

Permissions

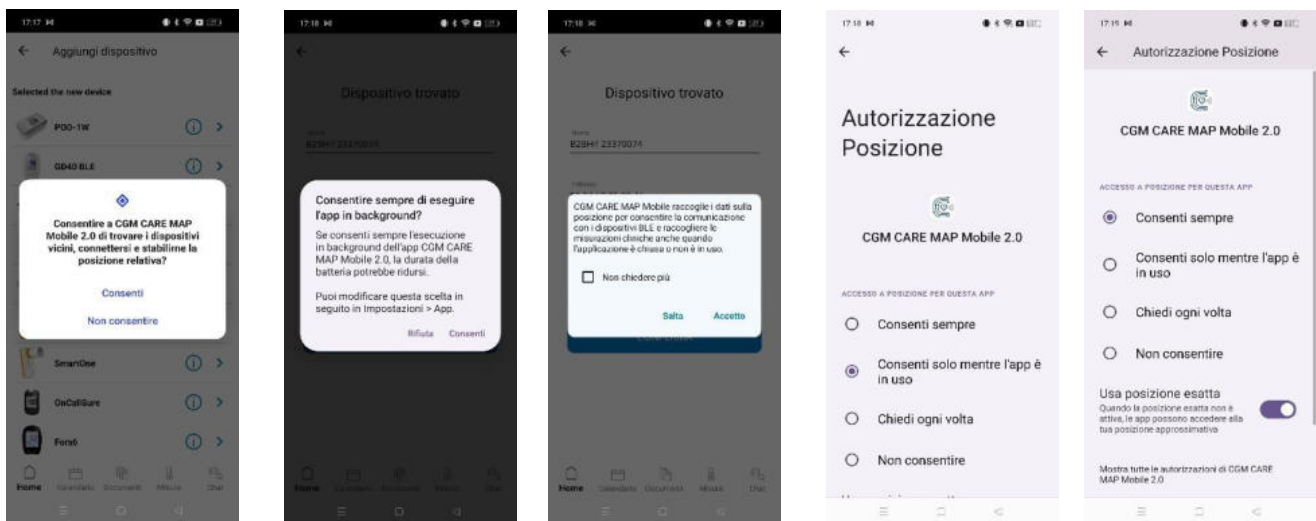
When you first launch the app after installation, it may request certain permissions necessary for it to function correctly, such as sending notifications; accept these requests to be able to use all the app's features.

Bluetooth connectivity is required to use the measuring devices, so the relevant permissions will be requested, depending on whether the operating system is Android or iOS.

Android

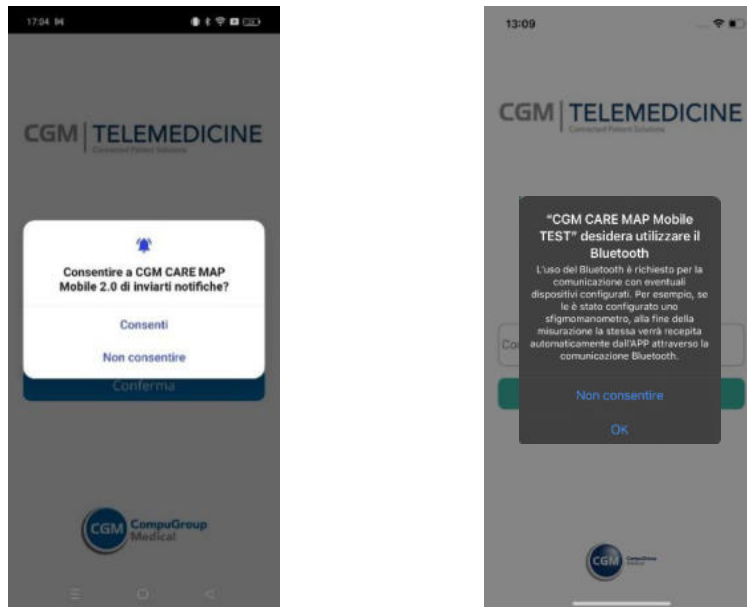
On Android, the Bluetooth permission is included within the geolocation permissions, so both must be granted to enable communication with the devices, even if the app does not use the device's location.

For some measurement devices that require continuous communication with the app, such as the HI 3 LEADS ECG, permission must be granted not only when the app is in use but also when it is not visible (app running in the background), so as not to interrupt the acquisition of measurements. To do this, you must ensure that "Always allow" is selected in the Geolocation permissions management page within your smartphone's settings, rather than "Allow only whilst using the app". If permission for background use is not initially granted, the App will prompt the user to select it with a message; by selecting OK, you will be directed to the Settings page where you can select "Permissions" -> "Location" and finally set the permission to "Always Allow":



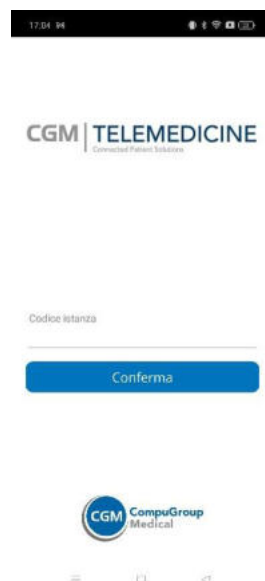
ios

Permission for Bluetooth is requested via a pop-up, which indicates that Bluetooth communication is required; select OK:



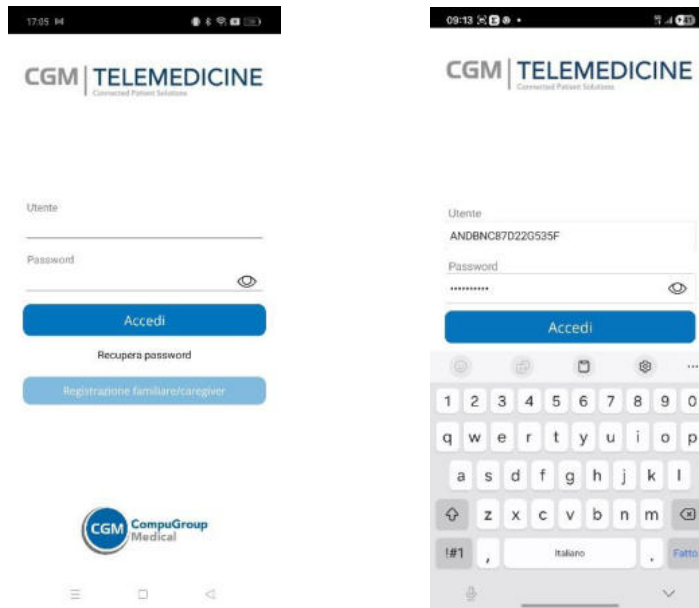
HOME SCREEN

When the app is launched for the first time, an instance code may be requested to identify the platform to connect to. Enter the code provided to you during user registration:



On subsequent launches, if the device has not already been registered and linked to a patient, the first screen displayed is the "Login" screen, where you are asked to enter your Username and Password to authenticate and download data.

The characters entered in the Password field are replaced by "*" to protect their confidentiality; if you need to check the password you have entered, simply click on the eye icon on the right and the text will be displayed normally. Clicking again returns you to the protected view.



Once you have logged in successfully, if this is your first time logging in, you will be presented with a series of screens allowing you to configure the necessary account settings, such as authentication methods and your height.

If you choose to enable authentication at every login, you will be asked to select the method you wish to use for subsequent logins. There are three possible options, though some may not be available depending on your current settings (you can later change your selection within the app via the Settings section):

- Open access: no authentication
- Username and password
- Phone authentication (the method you use to unlock your phone)



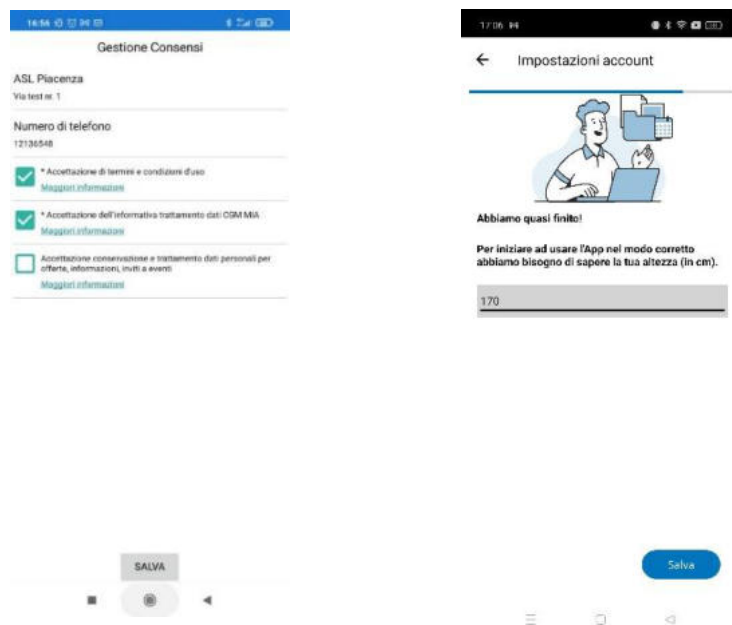
Biometric authentication uses the features already present on the phone and does not collect any information beyond what is already provided during the phone's setup.

Once authenticated, you will be directed to the "Terms and Conditions" screen.

On first use, after you have been asked for your credentials, the "Consent Management" window will appear:

The patient's organisation and telephone number will be displayed.

The "Save" button will become active once at least the mandatory consents, marked with an asterisk (*), have been selected.



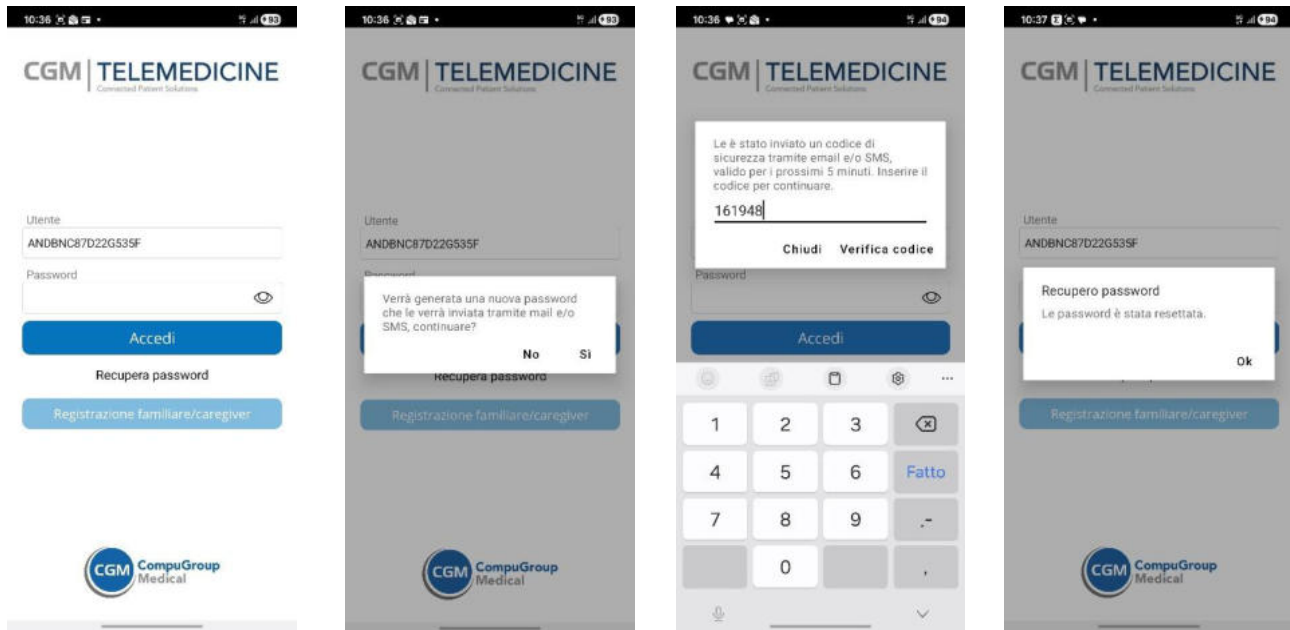
By accepting, you will proceed to check the patient's details and, once accepted, the appointment book screen will be displayed.

If height has not been entered, please enter it before viewing the calendar. Pressing "OK" will open the main "CALENDAR" screen.

Password recovery

You can recover your password from the main login screen by entering your username. A code will be sent to the patient via SMS or email to reset the password.

Subsequently, once the code has been entered, the patient will receive an email with the new password.



MAIN SCREEN

When the app launches, the main screen appears, with certain information always displayed at the top:

- Name of the patient associated with the phone
- User icon: only if the multi-patient option is enabled; this allows you to select the current patient.



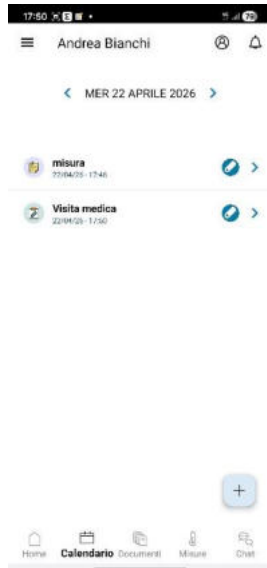
- Notifications icon: may show the number of unread messages.
- Navigation bar for navigating between sections. If the chat function is enabled, the message icon is displayed, with a red dot indicating unread notifications.

In the central section, there is a welcome message or information on the progress of the monitoring process, the icon of the relevant organisation with a brief text, and a summary of upcoming activities scheduled in the calendar/agenda, which can be accessed by clicking on the text 'Calendar>'.





At the bottom, there are two buttons to access the Documents page and the 'About Us' section of the app directly (see later in the manual for details).

AGENDA SCREEN

The app's agenda screen displays the current day of the calendar, where the patient can view the day's activities and add any notes or reminders. Clicking on the day opens the calendar, allowing you to select a different day to navigate to more quickly.

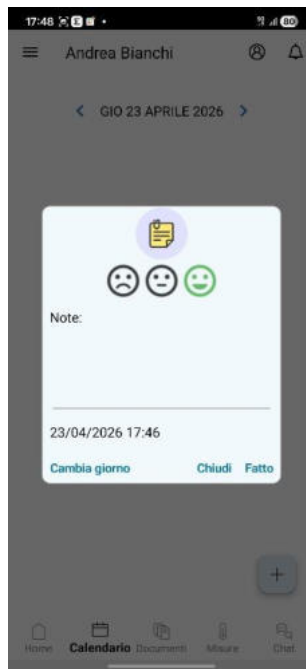
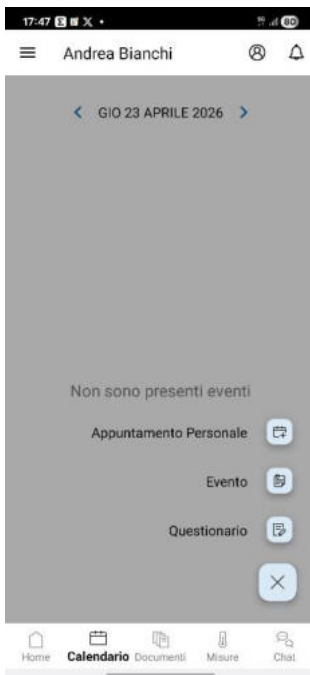


Activities may be displayed with the following icons:

-  : indicates that the activity has yet to be completed.
-  : indicates that the activity has been completed
-  : indicates that the activity has not been completed on time (overdue).
-  : indicates that the activity was created by the patient and can be edited or deleted by the patient.

Adding reminders and notes:

Using the '+' icon, the patient can add activities to their calendar (the types of activities that can be added depend on the application's configuration):



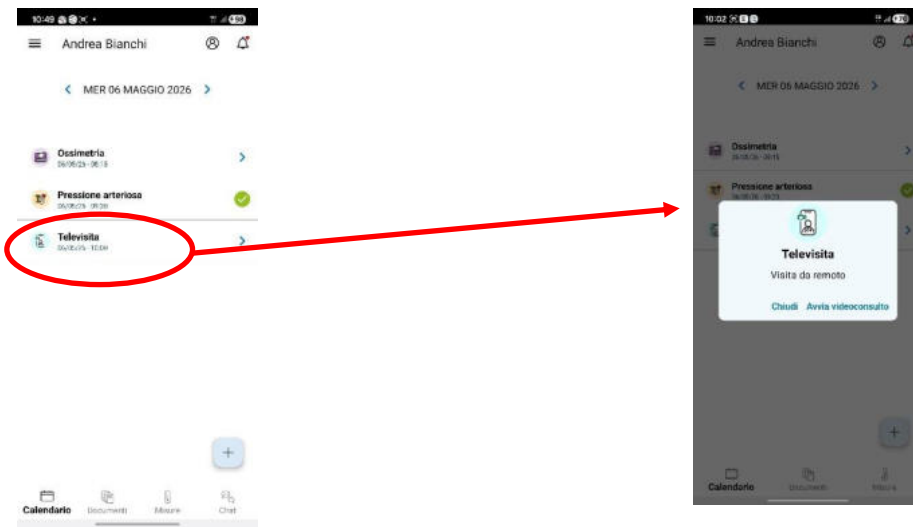
To edit or delete the activity, click on the text corresponding to its creation:

- Change day: change the date and time of the activity
- Close: to exit without saving changes
- Done: to save the changes made.
- Delete: to delete the activity. The patient will be asked to confirm.



Video consultation activity:

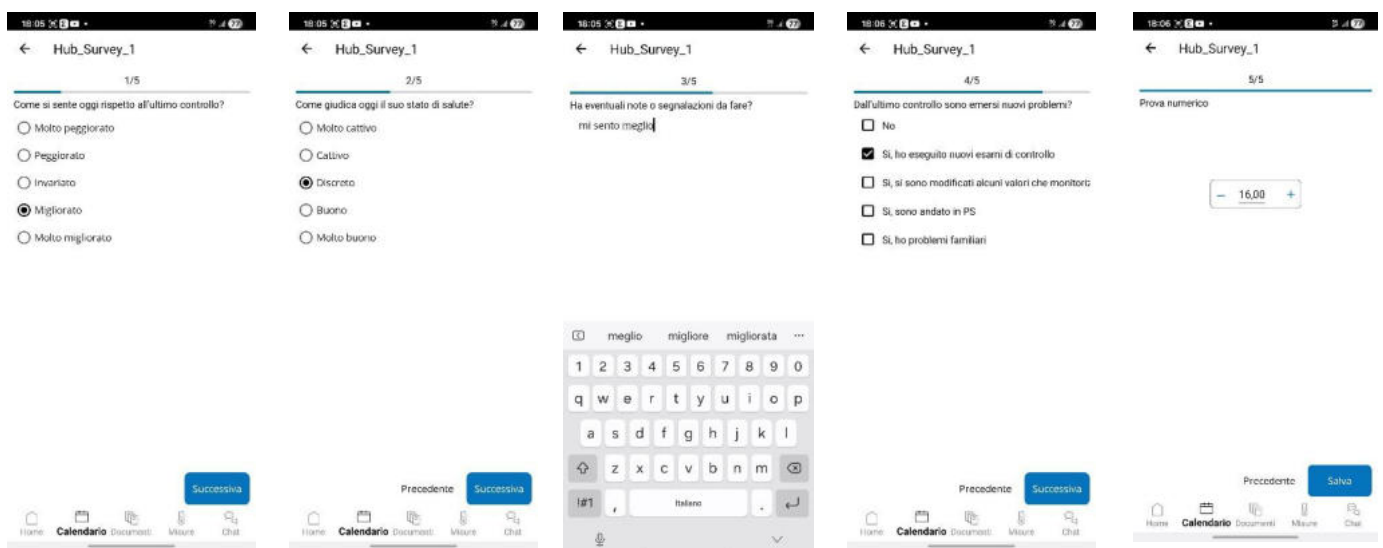
The video consultation activity allows you to make a video call by tapping on the activity to view its details and then tapping on the camera icon



Questionnaires:

This activity involves completing predefined questionnaires, consisting of several questions with both closed and open-ended answers. When the questionnaire is opened for completion, a screen may appear displaying a description of the questionnaire.

Each question is displayed on its own screen, along with the possible answers. For closed-ended questions, you must select one answer (or more, if multiple selections are permitted), whilst for open-ended questions, you can type your answer into the appropriate fields.



At the top of the screen, the number of the current question is always displayed, along with the total number of questions and arrows to move forwards and backwards through the questionnaire. Once you reach the last question, you must confirm your responses by clicking the Save button to send them to the web portal.

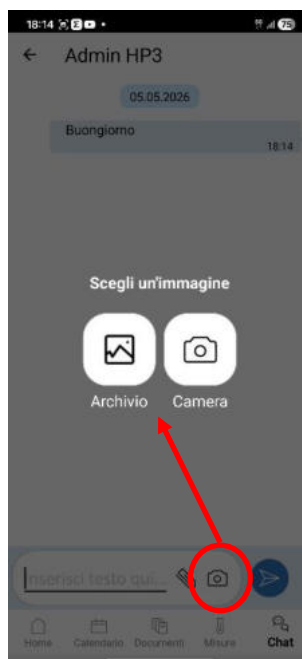
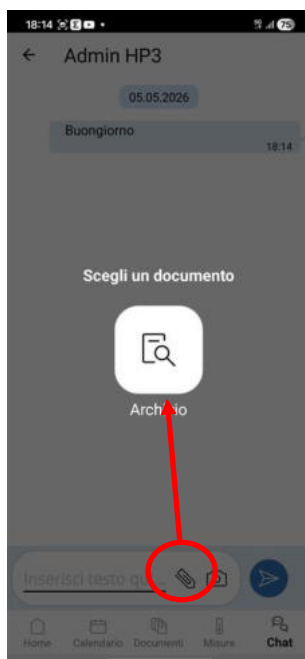
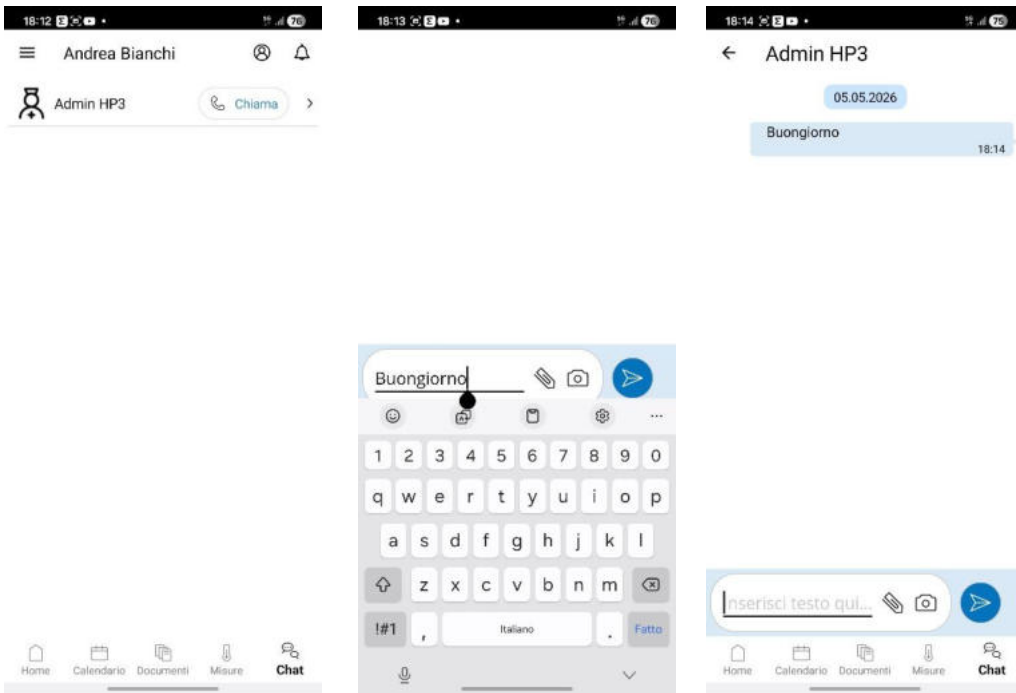
Once the questionnaire has been submitted, it will still be visible under 'Activities'; the answers provided will be visible but cannot be edited.

CHAT SCREEN

If the chat section is enabled (the message icon is visible), you can access the list of open conversations via the dedicated icon in the toolbar.

The central section displays the chats available for the specific patient, including therapy groups. For each chat, you can see whether it is possible to call, message, or both.

The icons in the top right-hand corner allow you to send documents (PDFs) and images.

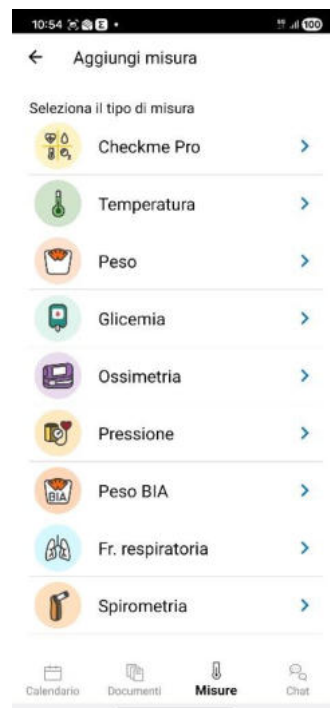


MEASUREMENTS SCREEN

The measurements screen displays a panel showing the most recent measurement recorded for each type. If the patient has the device connected to medical devices, measurements can be automatically recorded by the app and the status of any scheduled measurement activities will be updated automatically.

If the patient's device is not connected to medical devices, the app allows the value to be entered manually by opening the specific screen for that type of measurement.

By pressing the "+" in the bottom right-hand corner, you can enter a measurement manually. The available manual measurements are: Respiratory rate, temperature, blood glucose, oximetry, blood pressure, weight and spirometry.



Adding the various measurements:

10:54

Aggiungi misura

Effettua la misura richiesta e digita i valori che appaiono sullo schermo del dispositivo

Fr. respiratoria

06/05/2026 10:54

Fr. respiratoria

10:54

Aggiungi misura

Effettua la misura richiesta e digita i valori che appaiono sullo schermo del dispositivo

Temperatura

06/05/2026 10:54

Temperatura

10:55

Aggiungi misura

Effettua la misura richiesta e digita i valori che appaiono sullo schermo del dispositivo

Glicemia

06/05/2026 10:55

Glicemia

11:01

Aggiungi misura

Effettua la misura richiesta e digita i valori che appaiono sullo schermo del dispositivo

Ossimetria

06/05/2026 11:01

Saturazione SpO2

Pulsazioni

10:55

Aggiungi misura

Effettua la misura richiesta e digita i valori che appaiono sullo schermo del dispositivo

Pressione

06/05/2026 10:55

Sistolica

Diastolica

Pulsazioni

10:56

Aggiungi misura

Effettua la misura richiesta e digita i valori che appaiono sullo schermo del dispositivo

Peso

06/05/2026 10:56

Peso

10:56

Aggiungi misura

Effettua la misura richiesta e digita i valori che appaiono sullo schermo del dispositivo

Peso BIA

06/05/2026 10:56

Peso

Percentuale massa ossea

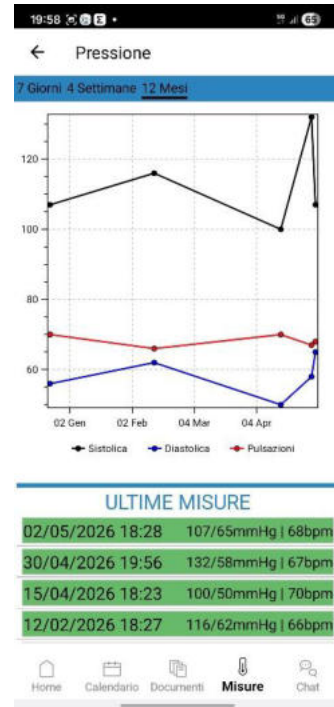
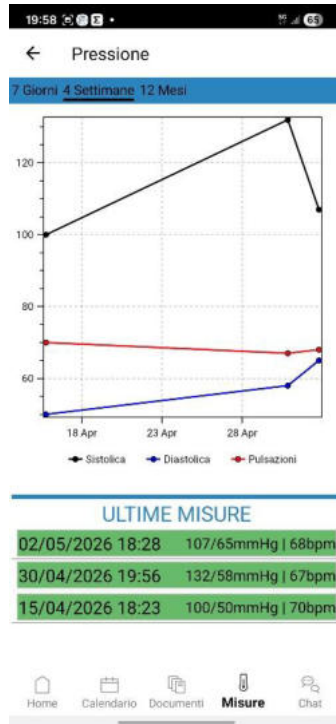
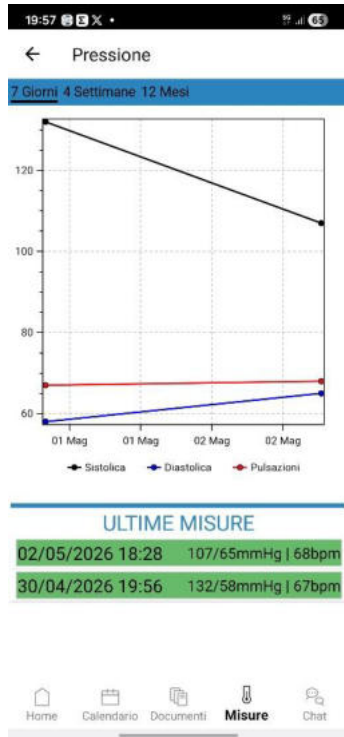
Percentuale massa muscolare

Percentuale acqua corporea

Percentuale massa grassa

GRAPH SCREENS

Each measurement box can be selected; tapping it opens a screen displaying a graph of the values recorded over the last 7 days for the selected measurement. Below the graph, the date and value of the measurements are shown, sorted from most recent to oldest:



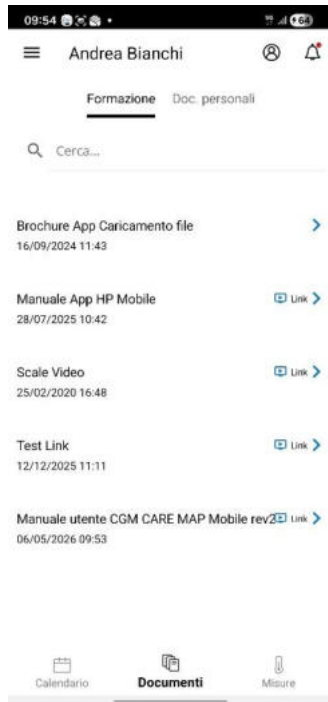
Tapping “4 Weeks” opens the graph showing measurements taken over the last 4 weeks, with the most recent measurements listed below.

Pressing “12 Months” opens a graph showing the averages (12, one per month) of the measurements taken over the last 12 months, with the most recent months listed below in descending order.

DOCUMENTS SCREEN

Clicking on the documents icon takes you to the screen containing training documents, including documents, websites, videos and links available to the patient in the 'TRAINING' tab, and the patient's personal documents in the 'PERSONAL DOCS' tab.

When you tap on a document in the 'Training' section, the app redirects the patient to the relevant website for that specific document or opens the attached PDF.



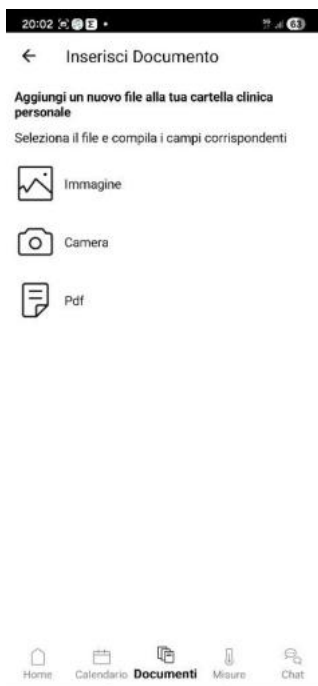
In the 'Training' section, documents are organised by section, which can be configured via the web, and it is possible to search by keywords, which can also be configured via the web:



In the 'PERSONAL DOCS' section, documents are also divided into sections; in this case, they cannot be configured via the web but are predefined and currently include:

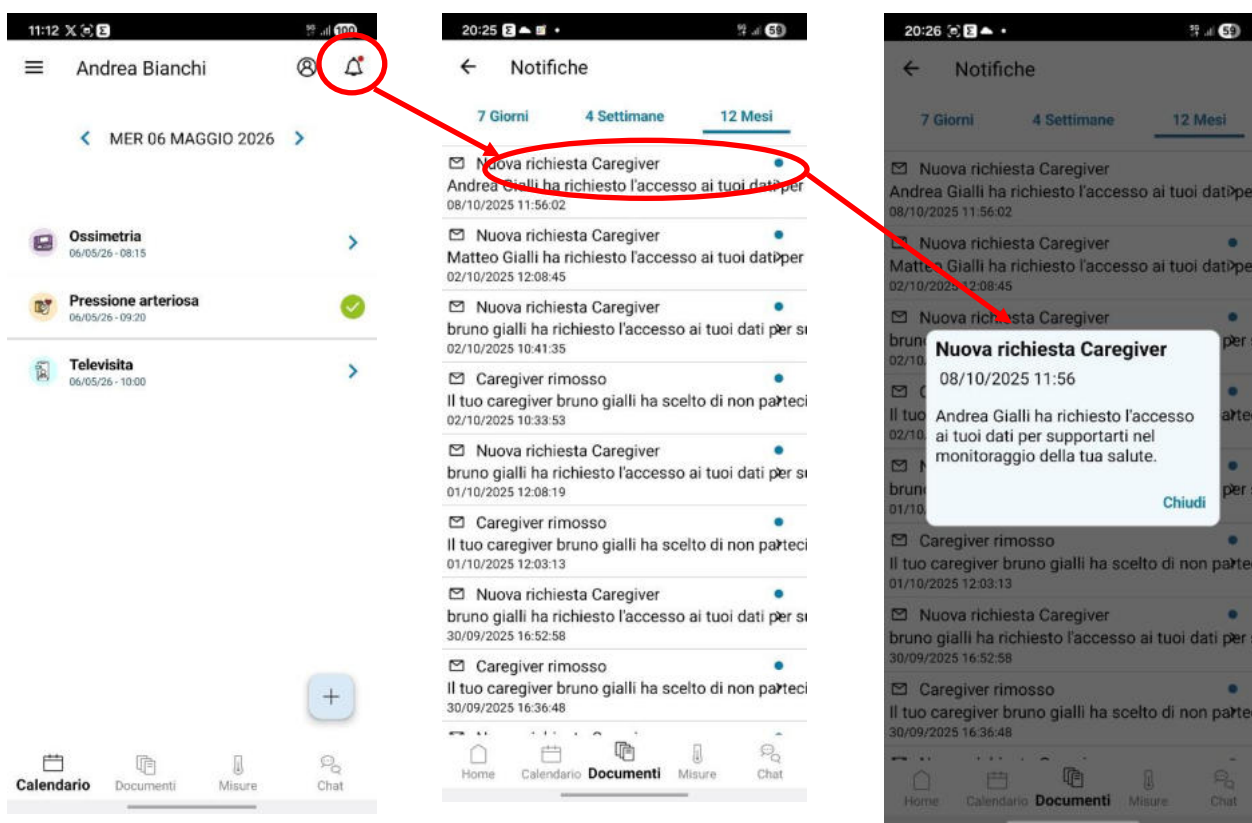
- Report
- Health check-up
- Certificate
- Prescription
- Symptom assessment
- Other

You can add a new document (image, photo or PDF) using the '+' icon at the bottom right, choose the section where you want to upload the document, and then save.



NOTIFICATIONS SCREEN

In the top right-hand corner, tapping the bell icon (the red number indicates the number of unread notifications) opens the notifications page with a time filter showing notifications received in the last 7 days:



When you open and confirm a notification, it is displayed and the dot (and the corresponding number) disappears.

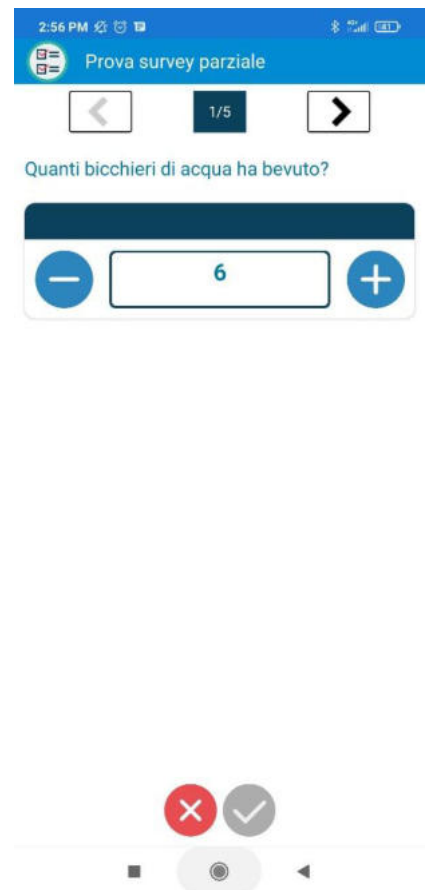
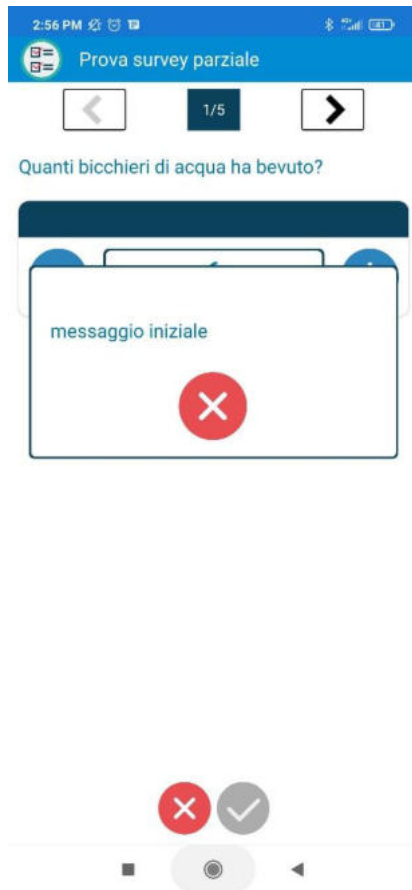
If the notification is linked to a task in the calendar, an icon will also appear so that you can quickly access the event and carry it out.

Tapping "4 Weeks" loads notifications received in the last 4 weeks.

Tapping "12 Months" loads notifications received in the last 12 months.

Push notifications:

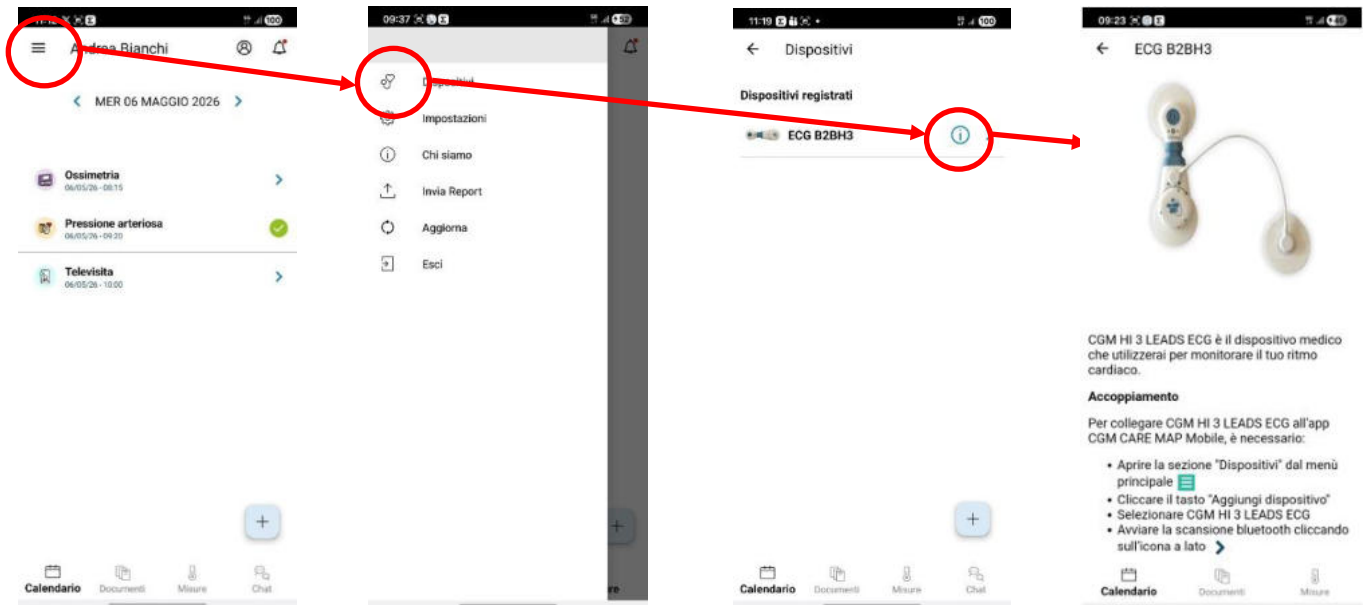
Once you have received a push notification – the instant notification that appears when your phone is locked, reminding you of a calendar event – you can access the event directly by opening the notification you have just received.



MENU SCREENS

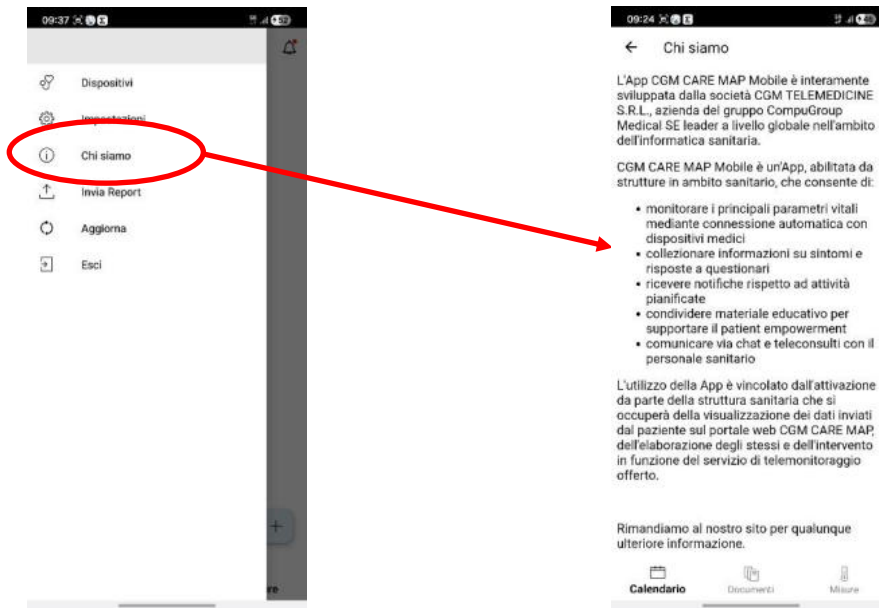
“UPDATE” updates the connected devices and the status of measurements, notes, reminders and events.

Tapping “DEVICES” opens the list of devices linked to the app, along with their respective tutorials. Each device, if managed, will have its own tutorial page explaining how it works, which can be viewed by tapping the ‘?’ icon next to the device name.



All other features open their respective pages:

“ABOUT US” opens the screen with a description of CGM TELEMEDICINE and the product.



“SETTINGS” contains all settings that can be modified by the user:

← Impostazioni

[Ruler] Unità di misura >

[Tongue] Cambia Lingua >
Italiano

[Lock] Informazioni >

[Gear] >

Livello di log

[LOG] >

Errore

[LOG] >

Avviso

[Key] >

Informazione

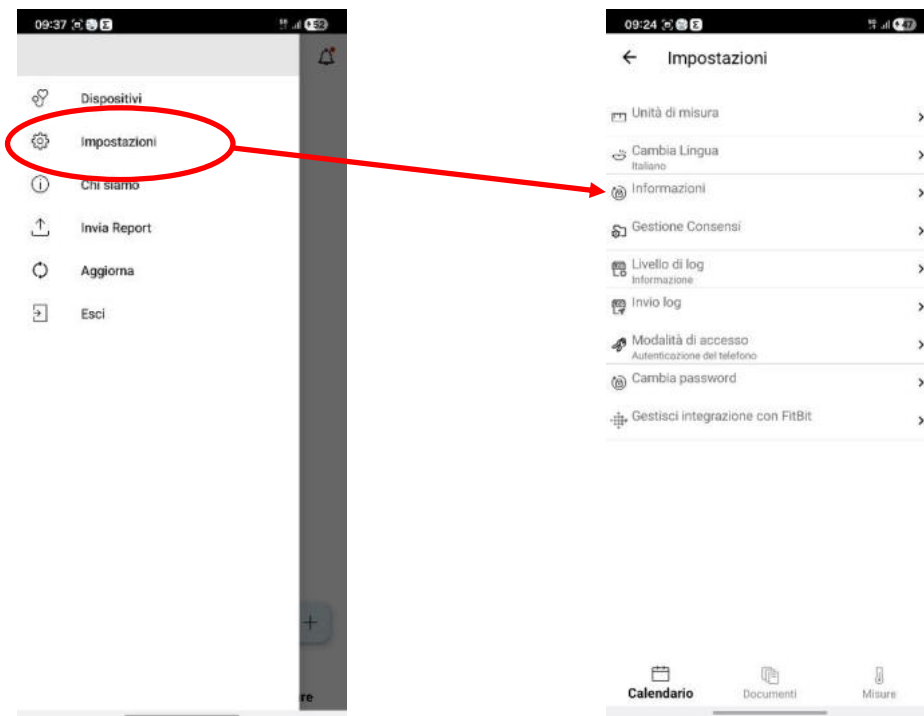
[Lock] >

Debug

[Grid] >

Verboso

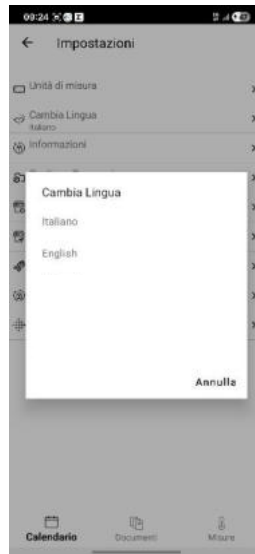
Annulla











“Units of measurement” allows you to change some of the units of measurement used to display parameters; it opens a pop-up with the measurement types that have multiple units of measurement available, so you can select the one to use for displaying measurements in the app:



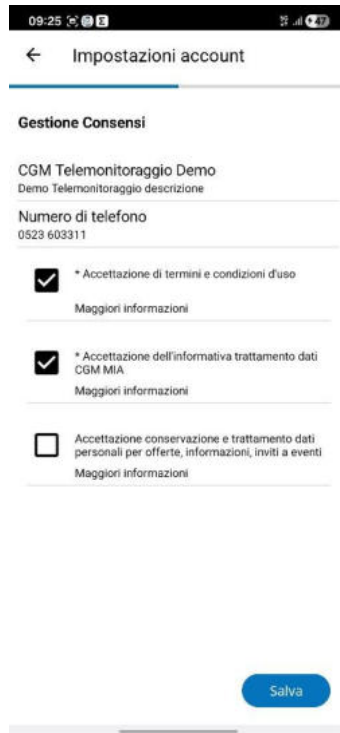
“Change Language” opens a pop-up menu with a list of languages to choose from



The “Information” menu opens a screen with information about the manufacturer.

	CGM TELEMEDICINE S.r.l. Sede legale: Foro Buonaparte, 70 – 20121 – Milano (MI) - Italia Sede operativa: Via Emilia Parmense, 204 – 29122 – Piacenza (PC) - Italia	
	CGM CARE MAP	
Ver. 4.0.0.0		
Modulo Mobile		
	(01)00086000573683(8012)v.4.0.0.0	
	[aaaa/mm/gg]	
		
	Le istruzioni per l'uso sono disponibili in formato elettronico PDF all'interno della sezione 'Formazione' della schermata Documenti. Per la visualizzazione è sufficiente un qualunque programma che supporti tale formato (Acrobat Reader o similari). È possibile richiederne una copia cartacea inviando una mail all'indirizzo <mail configurata>, che sarà inviata gratuitamente entro 7 giorni.	

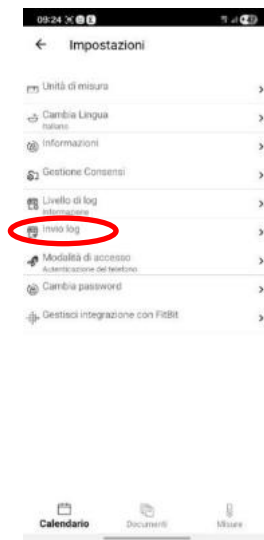
The “Consent Management” menu opens a screen displaying the accepted terms and conditions.



“Log Level” opens a pop-up with selectable logs, used only upon request by support:



The “Send logs” menu sends the logs recorded so far but not yet sent to the server; these are used only upon request by support:



The “Login Method” menu allows you to change the authentication method previously chosen to access the app:

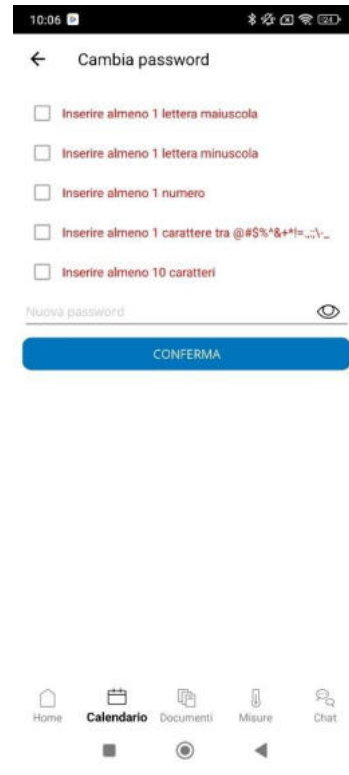
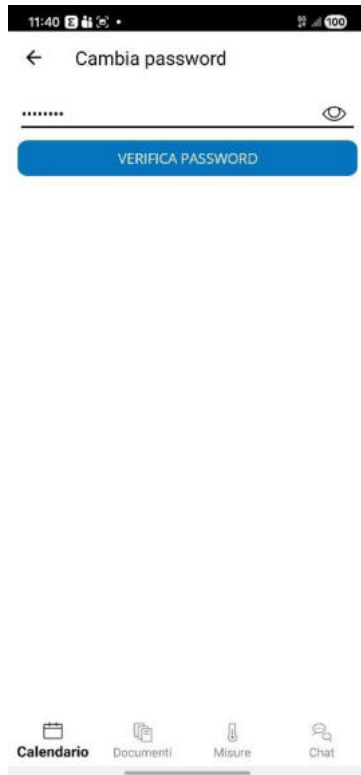


The “Change password” menu allows you to change the patient’s password.

You must ensure you have network coverage as the app needs to communicate with the server to complete the change. To protect password security, all relevant fields have their content hidden by replacing the actual characters with an asterisk; if you wish to view the content, simply press the eye-like symbol at the far right of the field.

You will first be asked to enter your current password to verify your identity. After pressing “Verify password”, if the password is correct, you will be asked to enter the new password.

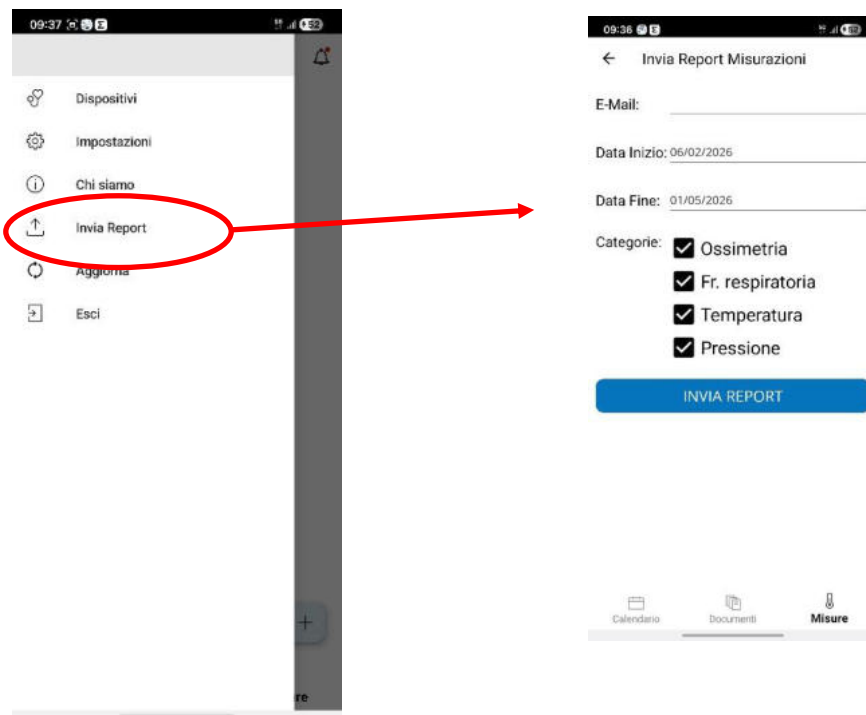
At the top of the screen, you will see the criteria that must be met for the new password to be considered sufficiently secure, such as the inclusion of uppercase letters, numbers and special characters, as well as a minimum length:



As you enter the characters of the new password, whenever a criterion is met, the corresponding checkbox is ticked and coloured green; once all criteria are met, a new text box appears in which to re-enter the password for confirmation. Subsequently, if the two passwords match, the “Confirm” button is enabled; pressing it sends the password change request to the server to complete the change.



“SEND REPORT” allows you to generate a report that will be sent by email, containing the measurements (type selectable by the user) collected over a specific period (specified by the patient), specifying the recipient’s email address:



DEVICES

UC352BLE - AND Scale

Pairing

Before taking any measurements, you must pair the scales with your phone. To pair the scales, press and hold the “Set” button on the back of the scales until “Pr” appears on the display, then release the button. After a few seconds, “End” will appear on the display to indicate that the procedure has been successful. If an error occurs, an error code (e.g. "E-10") will appear: in this case, you must repeat the procedure.

Recommendations

It is recommended to weigh yourself weekly; this allows you to calculate your BMI.

The BMI (Body Mass Index) calculation indicates an adult’s weight status and is also based on the ratio of weight to height.

Please note: this is only an indicative result! There are, in fact, several factors: body type, age, gender, muscle mass or body shape can all influence body weight.

UA651BLE – AND Blood Pressure Monitor

Pairing

Before taking any measurements, you must pair the blood pressure monitor with your phone. To pair the devices, press and hold the "START" button on the blood pressure monitor until "Pr" appears on the display, then release the button. After a few seconds, "End" will appear on the blood pressure monitor’s display to

indicate that the procedure was successful. If an error occurs, an error code (e.g. "E-10") will appear: in this case, you must repeat the procedure.

Recommendations

Throughout the blood pressure measurement and until the cuff has deflated completely, please bear in mind the following simple recommendations:

- The patient should be relaxed, sitting comfortably in a quiet environment at a comfortable temperature for at least five minutes.
- You should not have consumed any caffeinated drinks in the previous hour, nor smoked for at least fifteen minutes (in fact, you should never smoke!).
- The arm must be supported and the cuff must be at heart level. It does not matter which arm is used for the measurement, but it should be remembered that there are sometimes significant differences in the readings taken from the two arms. In such cases, the arm with the higher blood pressure should be used for the measurement.

The size of the rubber cuff must be adjusted to fit the patient's arm. For children or very slim adults, smaller-than-standard cuffs must be used, whilst for very large or obese patients, the cuff should be longer.

GD40 DELTA - Bruno Glucometer

By following these simple instructions, you will be able to use the blood glucose meter and take accurate blood glucose readings.

Recommendations

- Wash your hands and dry them thoroughly
- Do not use any disinfectant
- Massage your finger for about 20 seconds at the point where you will prick it
- Always use a new test strip and a new lancing device for each measurement

Instructions for using the blood glucose meter

- Insert a new test strip into the slot at the bottom of the meter: the meter will switch on automatically
- Place the lancing device on the outer side of the chosen finger: blood flow is better in this area
- Wipe away the first drop of blood with a cotton wool ball or sterile gauze
- Place the test strip on the drop of blood and wait for the beep
- Wait for the countdown to complete to measure your blood glucose level
- Eject the test strip by pressing the dedicated button on the top of the meter or by pulling the strip out with your fingers
- The reading will appear on your mobile device automatically. If this does not happen, press down the dedicated button on the left-hand side of the meter
- The blood glucose reading you have just taken will be visible on your mobile device in the "Measurements" section (this may take a few seconds)

To view all previous blood glucose readings, use your mobile device and check the "Measurements" section.

Connect 6 - FORA Glucose Meter



By following these simple instructions, you will be able to use the blood glucose meter and take accurate blood glucose readings.

Recommendations

- Wash your hands and dry them thoroughly
- Do not use any disinfectant
- Massage your finger for about 20 seconds at the point where you will prick it
- Always use a new test strip and a new lancing device for each measurement

Instructions for using the blood glucose meter

- Insert a new test strip into the slot at the top of the meter: the meter will switch on automatically
- Place the lancing device on the outer side of the chosen finger: blood flow is better in this area
- Wipe away the first drop of blood with a cotton wool ball or sterile gauze
- Place the test strip on the drop of blood and wait for the sensor to emit a soft beep
- Wait for the countdown to complete to measure your blood glucose level
- Eject the test strip by pressing the dedicated button on the left side of the meter or by pulling the strip out with your fingers
- The reading will appear on your mobile device automatically. If this does not happen, allow the meter to switch off, then press the M button
- The blood glucose reading you have just taken will be visible on your mobile device in the "Measurements" section (this may take a few seconds)

To view all previous blood glucose readings, use your mobile device and check the "Measurements" section.

OnCallSure - Glucose Meter



By following these simple instructions, you will be able to use the blood glucose meter and measure your blood glucose levels accurately.

[Instructions for use](#)

- If a PIN is requested during the initial pairing of the device, use the last 6 characters of the blood glucose meter's serial number.
- During the setup process when switching on the device, ensure that 'AUTO' mode is enabled to send readings once the test is complete.
- Press the 'OK' button on the blood glucose meter.
- Insert the blood glucose test strip into the designated slot at the top of the device.
- Place the top of the strip in contact with blood.
- Wait for the meter to display the reading and slide the side button to eject the used test strip.
- Press both arrow buttons on the meter simultaneously to download the readings to the app if the reading was not saved to the app at the time of testing.

You can view all previous blood glucose readings on your mobile device on the 'Readings' screen.

Spirobank/SmartOne – MIR Spirometers



By following these simple instructions, you will be able to use the spirometer and take an accurate measurement.

Instructions for use

Enter your weight and ethnicity

Once you have found the spirometer, take a deep breath and breathe out as quickly as possible into the turbine

Wait for the measurement result

To view all previous spirometry readings, use your mobile device and go to the "Measurements" section.

IR21b – FORA Thermometer



By following these simple instructions, you will be able to use the thermometer and take an accurate body temperature reading.

Recommendations

- You can take a temperature reading from either the forehead or the ear.
- There must be at least one minute between taking one measurement and the next; otherwise, the second measurement will not be accepted

Instructions for use

- To switch on the thermometer, press the button below the display
- Place the thermometer on the forehead or insert it into the ear
- To take a reading, press the button on the back of the thermometer
- Wait a few seconds for the body temperature reading to be transmitted to the app

To view all previous temperature readings, use your mobile device and go to the "Measurements" section.

IR42b – FORA Thermometer



By following these simple instructions, you will be able to use the thermometer and take an accurate body temperature reading.

Recommendations

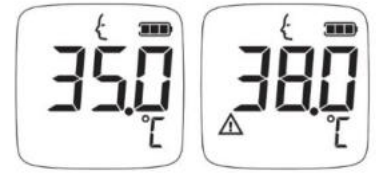
- You can take a temperature reading at the centre of the forehead, holding the thermometer at a distance of between 3 and 7 cm from the skin's surface.
- There must be at least one minute between taking one measurement and the next; otherwise, the second measurement will not be accepted.

Instructions for use

- Remove the protective cap. The forehead should be free of hair and sweat.
- Aim at the centre of the forehead at a distance of between 3 and 7 cm from the skin's surface. Ensure the thermometer is perpendicular to the skin's surface.



- Press the power button once to take a measurement. A double beep indicates that the measurement has been taken and is shown on the device's display.
- If the temperature is higher than 38.0°C, a warning symbol with a red background appears on the display.
- Wait a few seconds for the body temperature reading to be transmitted to the app.



To view all previous temperature readings, use your mobile device and go to the "Measurements" section.

POD-1W - Pulse Oximeter



Recommendations

By following these simple instructions, you will be able to use the pulse oximeter and take accurate oximetry measurements.

- Do not use the pulse oximeter if you are wearing nail varnish
- Rest your arm on a support and keep your finger still
- Do not wear clothing that may restrict blood circulation

Instructions for use

- Insert your index finger into the device with your fingernail facing upwards
- Ensure your finger reaches the end of the guide without applying too much pressure
- Wait for the oximetry and pulse readings to appear on the display
- Wait for about 15 seconds without moving your finger so that the pulse oximeter can take an accurate reading
- The oximetry reading just taken will be visible on your mobile device in the "Measurements" section
- Remove your finger from the pulse oximeter

To view all previous oximetry readings, use your mobile device and go to the "Measurements" section.

B2BH4 - CGM HI 3 LEADS ECG

This is a wearable device which, when placed on the chest, allows you to record an electrocardiogram (ECG) and other physiological parameters.



Pairing

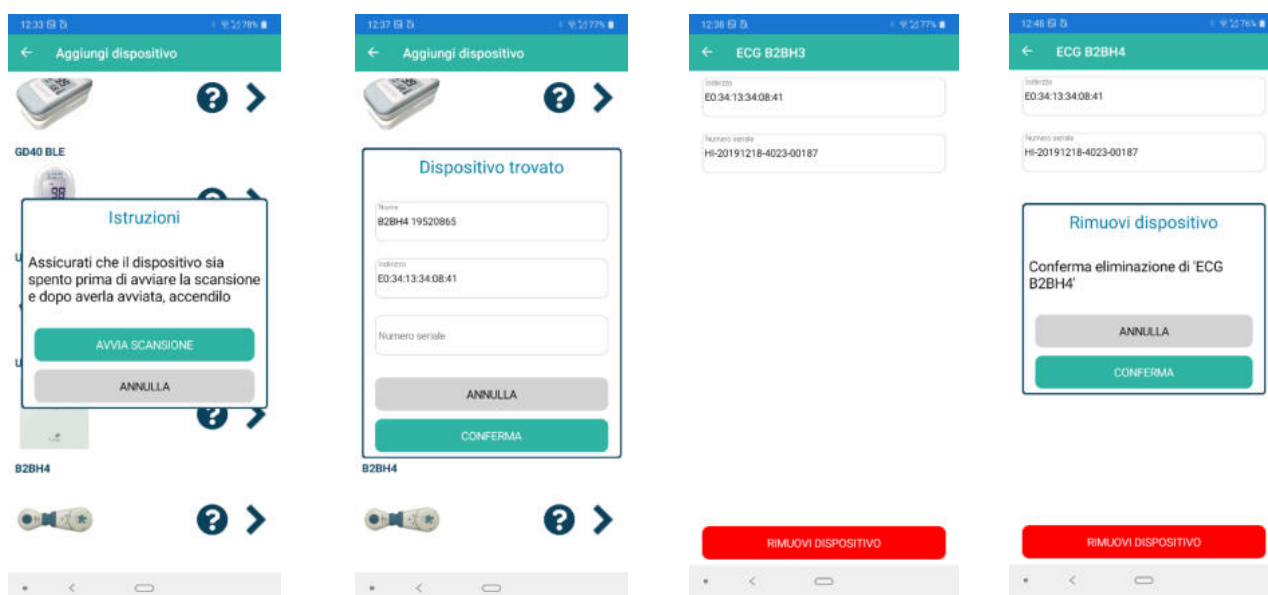
Before taking any measurements, you must pair the Hi device with your phone. To pair the devices, select the main menu and then 'Devices'; a list of currently registered devices will appear.

Press the "ADD DEVICE" button at the bottom of the screen. In the window that appears, scroll through the list of devices and select the ">" symbol to the right of the image next to the name "B2BH4". A screen will appear allowing you to start scanning for the device, in the following order:

- Switch off the device if it is switched on
- Start the scan by pressing the "START SCAN" button
- Switch on the Hi device.

If a request for authorisation to use Geolocation appears (which is actually required for Bluetooth communication), accept the request (refer to the 'Authorisations' section at the beginning of this document)

Once the app has found the device, a screen displaying its identification details will appear; press the "CONFIRM" button to complete the pairing procedure.



You can check the pairing with the device by going to the Devices menu and verifying that the list of registered devices includes an entry for "ECG B2BH4".

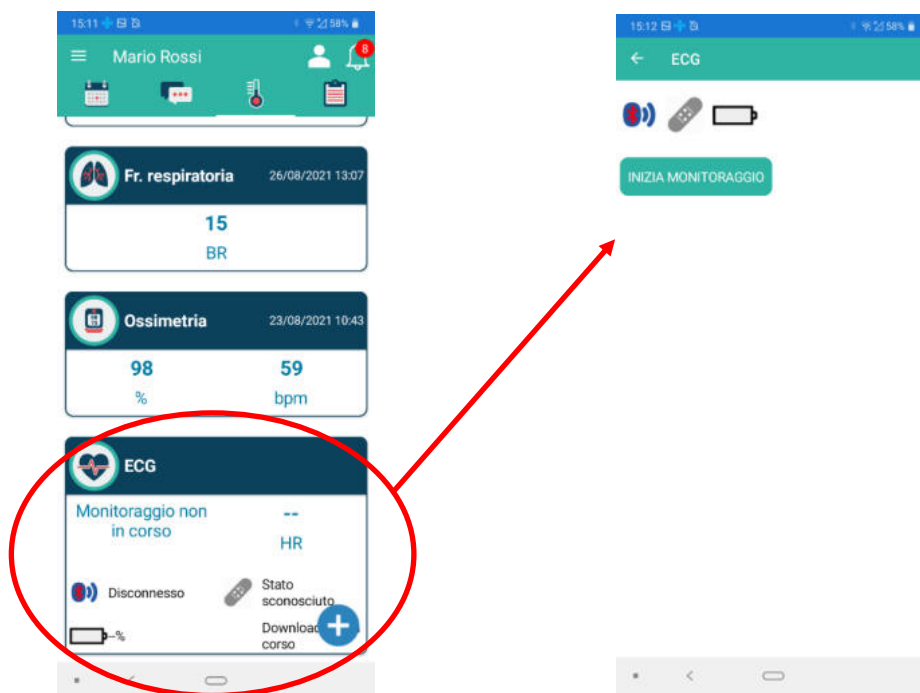
Clicking on the device name displays some information about it, and at the bottom of the screen there is a "REMOVE DEVICE" button to unpair the device; pressing it prompts you to confirm that you wish to unpair the

device; pressing the “CONFIRM” button removes the pairing. If you wish to use the device again, you must pair it once more.

Instructions for using the ECG

To record an ECG trace, you must start a monitoring session, during which the app reads data from the device via Bluetooth and sends it to the web portal.

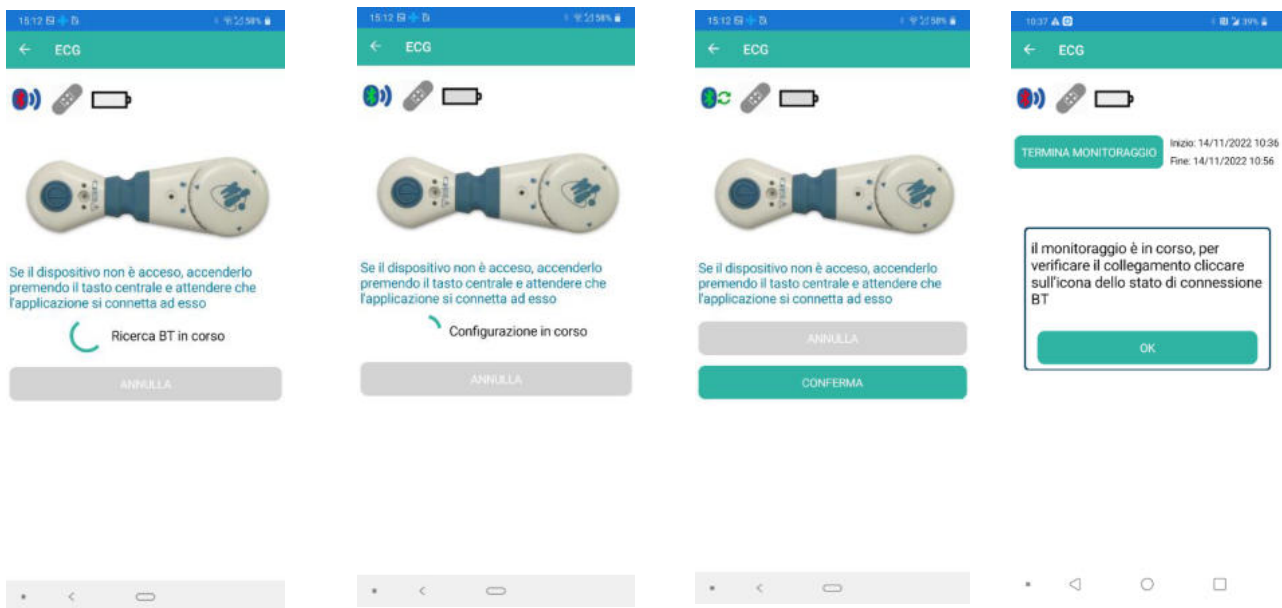
After correctly fitting the Hi device and switching it on, following the instructions in the relevant manual, you must go to the measurements section and check that there is an ECG panel displaying information on the device’s current status (monitoring session status, heart rate, Bluetooth connection status, electrode status, battery level, data download in progress).



Tapping inside the ECG box displays the Monitoring screen, where you can start and stop monitoring and check the data acquisition status and any anomaly alerts during the session, such as the disconnection of one or more electrodes.

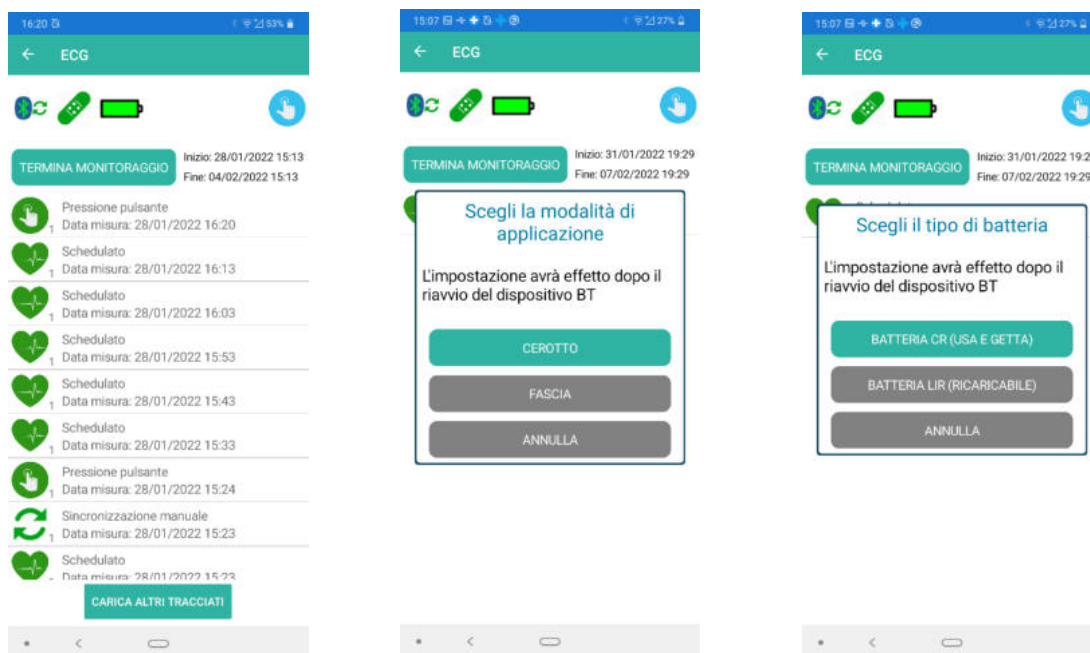
If a session has already been started, the date and time at which it ended are also displayed.

Pressing the “START MONITORING” button opens the monitoring screen, with icons showing the monitoring status (Bluetooth connection, electrode status and battery level) at the top; the app then searches for the previously paired Hi device and, once found, asks for confirmation to start the session. Pressing the “CONFIRM” button starts the session and the app begins receiving data and any notifications based on the session configuration; the device’s central LED changes from a steady light to flashing every 10 seconds, whilst pressing “CANCEL” prevents the session from starting and returns you to the previous page.




During the session, the scheduled start and end dates of the session are displayed, along with an “END MONITORING” button which can be used to terminate the session early.




In the centre of the screen is a list of recent events received during the session, such as ECG data reception and electrode disconnection events. As events are collected, older events are hidden to prevent the list from becoming excessively long; if there are events available that are not displayed, the “LOAD MORE TRACKS” button appears, allowing you to include them in the list.



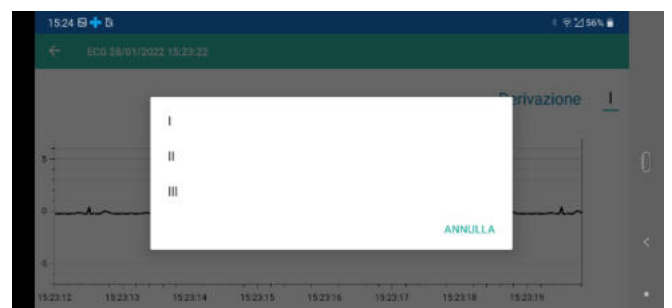
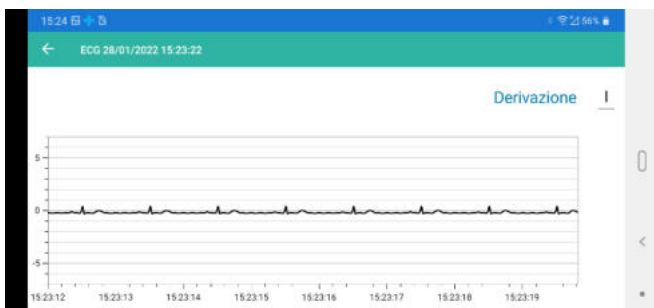
At the top of the screen, the status icons are displayed:

-  Bluetooth: indicates the status of the Bluetooth connection between the smartphone and Hi; green if the connection is active and red if it is inactive. The app automatically restores the connection in the event of interruptions, caused for example by excessive distance between the smartphone and the device or by Hi being switched off. By tapping the icon, you can start recording a short ECG trace from the device, which is added to the events list and can be viewed by tapping the relevant row and

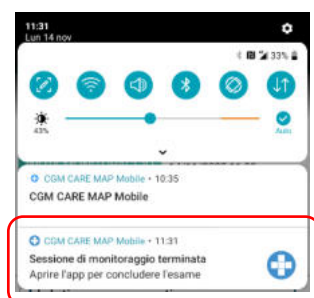
opening a dedicated screen displaying the trace; You can view individual leads by selecting them using the indicator in the top right-hand corner (I, II, III).

-  Electrodes: the plaster-shaped icon changes colour depending on the actual contact status of the three Hi electrodes with the skin: green if all electrodes are correctly connected, grey if the status cannot currently be determined (typically the first time a session is started), red if at least one of the electrodes is not connected or contact with the skin is insufficient to obtain a good signal. In this case, you must check that the electrodes are correctly connected; the app will alert the user with periodic notifications. By tapping the icon, you can select the electrode application mode: PATCH (the configuration normally used) or BAND.
-  Battery: Indicates the battery level: green = fully charged, yellow = medium charge, orange = low battery, red = flat battery; replace immediately. By tapping the icon, you can select the type of battery used: disposable or rechargeable.
-  Manual event: by pressing the button, you can enter a manual event, such as feeling unwell or a cardiac event deemed abnormal, so that it can be taken into account by the medical staff analysing the recording. The effect is the same as pressing the physical button on the device.

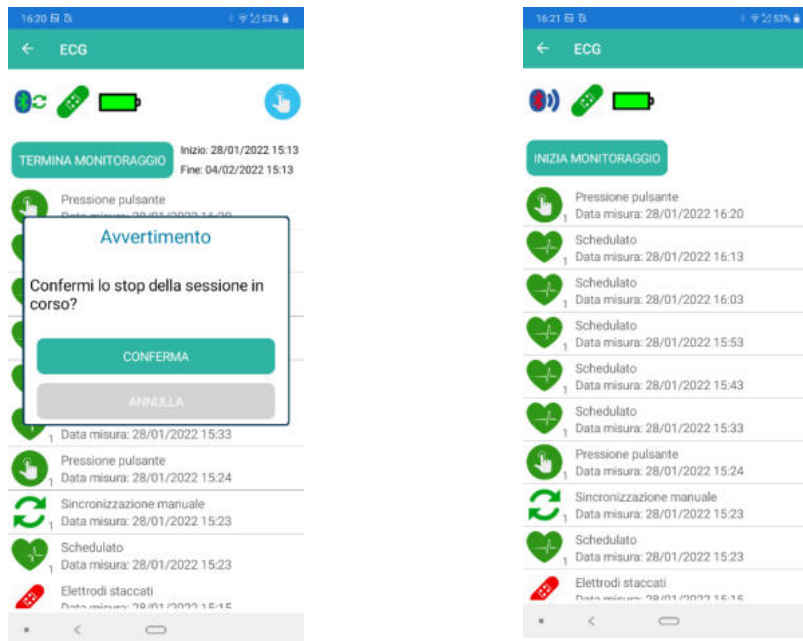
During monitoring, if enabled, you can view the collected ECG tracings by tapping the corresponding row in the list; a screen will open where you can view the signal graph for the three leads. You can scroll forwards and backwards through the graph by tapping and holding it and swiping left and right; to choose which lead to view, select its number in the top right-hand corner.



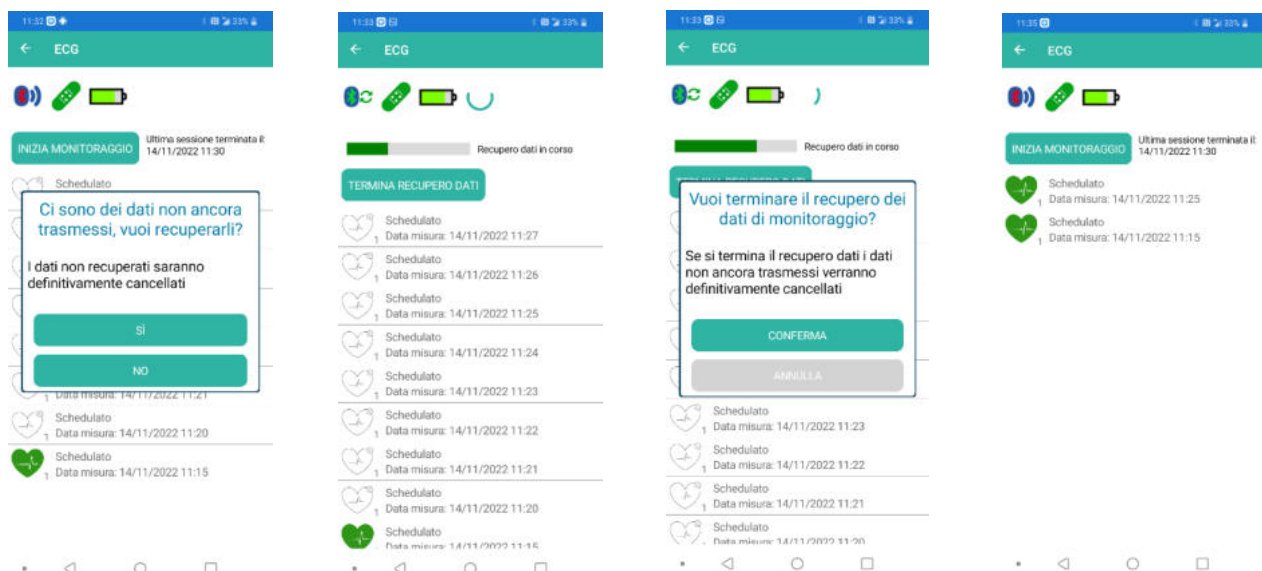
The monitoring session ends once the end time set at the start has been reached, and the connection with the Hi device is closed after the latest available data has been retrieved. You will receive a notification to indicate the end of the session and, if necessary, to request that it be completed by initiating the retrieval of any data not yet acquired.



If you wish to end the session early, you can do so by pressing the “END MONITORING” button; a confirmation message will appear and, by pressing the “CONFIRM” button, the session will be ended.



If the session is terminated early, some data may not yet have been retrieved by the app; a screen will appear asking whether you wish to start retrieving the missing data or terminate the session without data retrieval.



Pressing ‘Yes’ starts the retrieval of missing data; progress is shown by a grey horizontal bar that turns green upon completion, and the session closes once finished. If you wish to stop the data retrieval early, press ‘END DATA RETRIEVAL’; the app will ask for confirmation, and if you press ‘CONFIRM’, the session will end without retrieving any further data.

WARNING: if you interrupt the recovery process, any data not yet collected will be deleted from the device and cannot be recovered.

FitBit

If you have a FitBit device (smartwatch or tracker), you can share the collected data so that it is uploaded to your personal folder within the CGM CARE MAP web portal and is therefore available to healthcare staff for consultation.

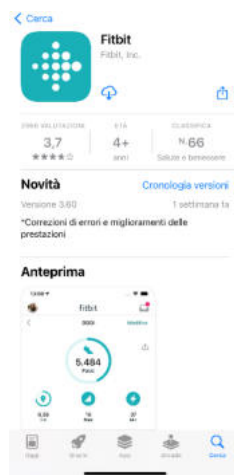
The data will be collected and sent to the server via the FitBit app normally used by the user, which must therefore be installed on the smartphone and correctly configured by creating a FitBit profile; CGM CARE MAP Mobile does not establish any Bluetooth connection with the FitBit device.

Setup

In order to enable integration with FitBit, the user must have:


- installed the FitBit app on their smartphone (not necessarily the one on which the CGM CARE MAP Mobile app is installed, as the latter does not interface with the FitBit device)
- created a FitBit profile
- linked the FitBit device to the smartphone and to their FitBit profile.

The app must be installed via the app store corresponding to the smartphone's operating system (Google Play for Android and the App Store for iOS), ensuring that the smartphone's specifications are compatible with the FitBit app:



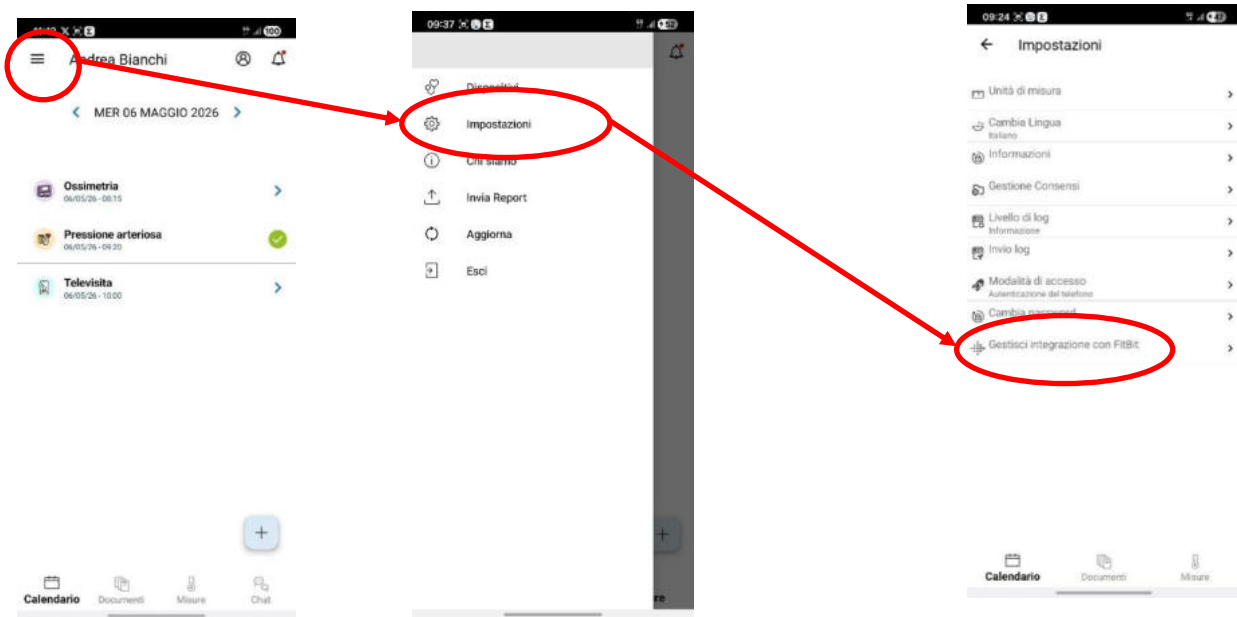
Once the app has been installed and launched, if you do not have a Fitbit account, you must create one by clicking on "Sign up for Fitbit" and following the instructions displayed by the app. To create a Fitbit account, you will be asked to enter your date of birth, height, weight and gender to calculate your stride length and estimate your distance, basal metabolic rate and calories burned.

Once the account has been created, you need to pair your Fitbit device with your smartphone so that the Fitbit device and the smartphone can communicate with each other and synchronise the relevant data. If the FitBit

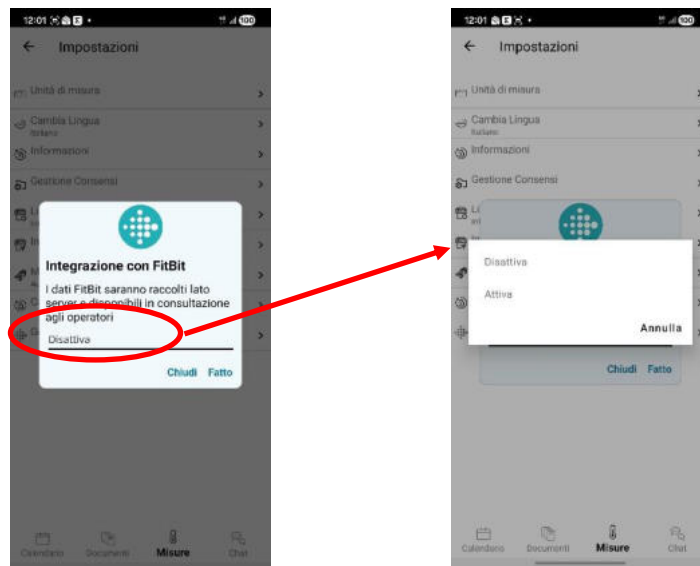
app does not automatically suggest pairing, tap the "Today" tab , tap your profile picture and then tap "Set up a device", selecting your device from the list displayed.

Enabling and configuring the FitBit service

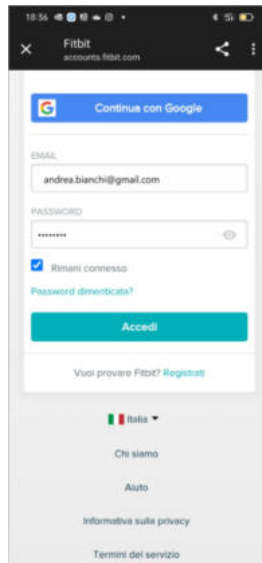
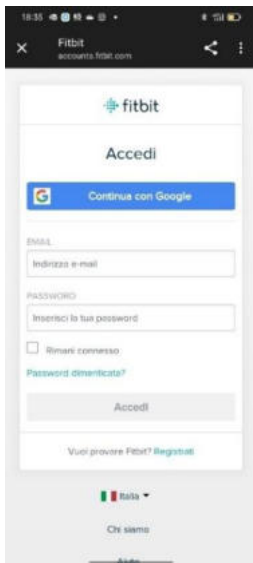
To enable the receipt of data collected by the Fitbit device, you need to access the SETTINGS menu and tap on "Manage Fitbit integration":



A screen will appear showing the current status of the integration service, which is initially set to 'Off'. Click on 'Off', then select 'On' from the list that appears, and finally click on the green tick to proceed. Please ensure you have an active internet connection, as communication with the server is required.

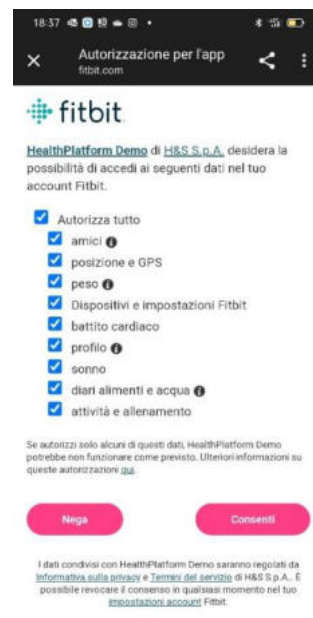


A window will open where you must enter your FitBit account credentials (email and password) so that FitBit can record your authorisation to share data with the CGM CARE MAP portal.



Once you have entered your credentials, press 'Log in' to continue. If two-factor authentication is enabled on your FitBit account, a further window will appear in which you must enter the code received via SMS and press 'Confirm'.

In the next window, you will be asked to select the types of data that may be accessed by the CGM CARE MAP portal. You can select 'Authorise all' or select only certain items, but in the latter case, some data will not be collected by CGM CARE MAP and the service may not function as intended.



You can view the Privacy Policy and Terms of Service by clicking on the links at the bottom of the screen

Click on 'Allow' to authorise access to your data and continue. A registration completion window will appear, confirming that your FitBit profile has been linked to your account on the CGM CARE MAP portal, which will then retrieve the data recorded by your Fitbit device on a daily basis.



Using the Fitbit service

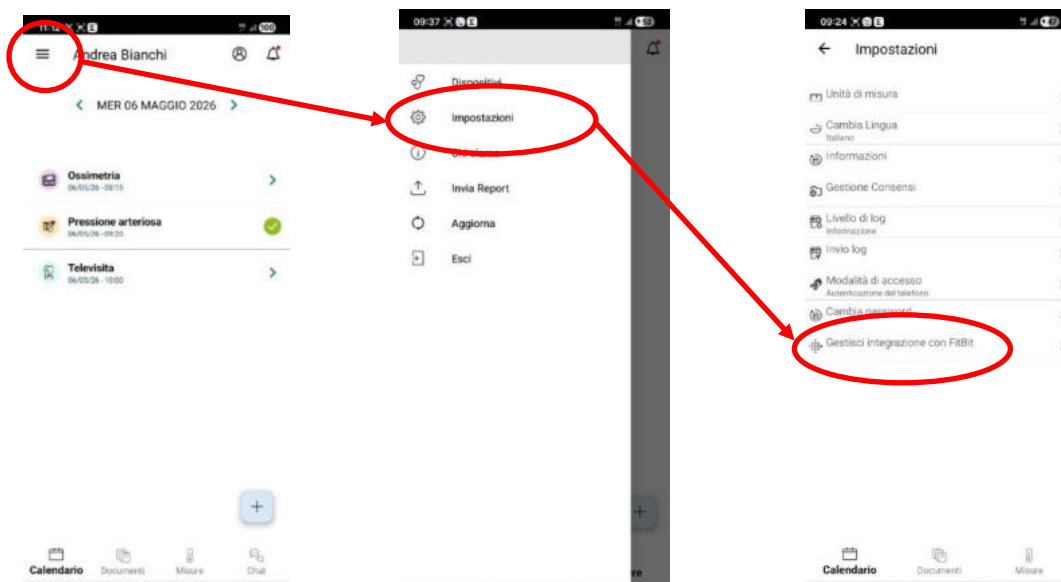
Use your FitBit device as normal, according to your needs, wearing it regularly so that it can continuously collect data.

For data collection to continue normally, the FitBit app must communicate regularly with the device and send data to the FitBit server, so that the CGM CARE MAP portal can read it.

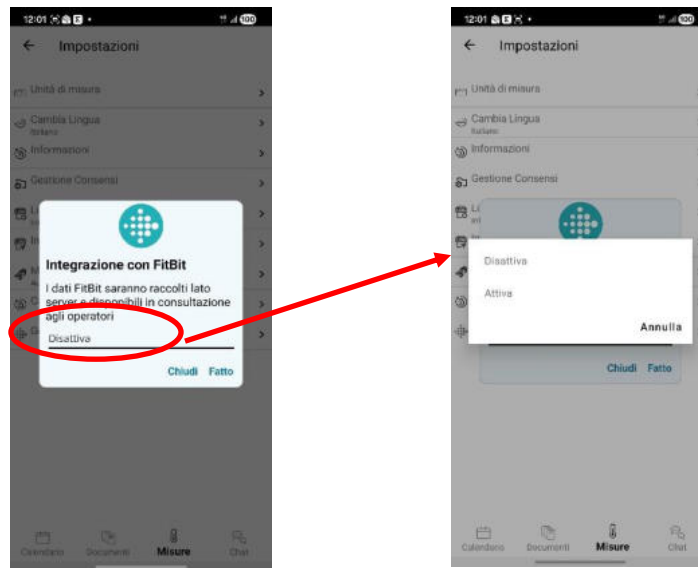
On certain occasions, the authorisation granted may expire. In this case, the portal will send a notification to the CGM CARE MAP Mobile App alerting the user that they cannot access the data and asking them to repeat the authorisation procedure described in the previous section, so as not to interrupt data collection.

Disabling the FitBit service

If you wish to stop the FitBit service, as with activation, you must go to the SETTINGS menu and click on "Manage FitBit integration":



In the service management screen, where the current integration status is displayed, click on 'Active' and, in the list that appears, select 'Deactivate', then click on the green tick to confirm.



General information and references

Intended use

CGM CARE MAP can receive the following broad categories of parameters from medical measurement devices: Vital signs, Blood chemistry, Cardiac, Anthropometric, Spirometry, Urine, Risk indices, Physical activity, Environmental parameters. This input data is used to:

- create graphs showing the temporal trends of the monitored vital signs; allow the doctor to set various types of customised thresholds and the resulting prioritisation and management of the generated alarms;
- display ECG tracings, use rulers to measure the tracing and apply filters (LowPass, HighPass);
- in the case of blood pressure Holter monitoring, calculate mean values and standard deviation of blood pressure and heart rate, systolic/diastolic range, compare with the set thresholds to identify rejected measurements and calculate the percentage above threshold
- in the case of spirometry, display the received curves, calculate the theoretical value for various parameters (FVC, FEV1, etc.) and the ratio between the actual value and the theoretical value (% Theoretical).
- in the case of continuous pulse oximetry, display the trace and calculate the minimum, maximum and average values for oxygen saturation and pulse rate, as well as indicating the time intervals during which the value was below a series of predefined reference values (e.g. 90%, 88%, 80%, 70%, 60%).

This enables remote monitoring of patients' health status with the aim of providing information used by the doctor to make decisions for diagnostic and therapeutic purposes. CGM CARE MAP must not be used in settings or on patients where the nature of the variations in vital signs is such that it could pose an immediate danger to the patient (e.g. intensive care units or patients connected to life support systems).

Classification

Classification in accordance with Regulation (EU) 2017/745, Article 51 – Annex VIII, Rule 11, Class IIa.

The product is classified as a medical device in accordance with the decision tree set out in MDGC 2019-11, which allows software to be classified as a medical device software (MDSW).

Intended users

Each module of the device is intended for use by different users with different roles:

- CGM CARE MAP: used by healthcare professionals (doctors, nursing staff)
- CGM CARE MAP Mobile: used by patients themselves or with the assistance of carers
- CGM POINT OF CARE: used by healthcare professionals (doctors, nursing staff, pharmacists)

Patients, indications and contraindications

The device is used for patients requiring continuous remote monitoring; these are usually patients with chronic conditions, for whom it is important to monitor various clinical parameters and keep their health status under control. Use is excluded in settings and for patients where the nature of changes in vital signs is such that it could pose an immediate danger to the patient (e.g., intensive care units or patients connected to life-support systems). No further specific restrictions on use or contraindications have been identified for the use of the

software, in terms of patients' age or characteristics; it may also be used for patients with reduced cognitive and motor abilities, as they are usually assisted by family members or carers, who can help them use the device.

Manufacturer

CGM CARE MAP Mobile (part of the CGM CARE MAP medical device) is manufactured by:

CGM TELEMEDICINE S.R.L.

Registered office: Foro Buonaparte, 70 - 20121 – Milan

Operational headquarters: Via Emilia Parmense, 204 - 29122 Piacenza

Tel. +39 0523 603311

Fax +39 0523 603364

at the operational headquarters in Piacenza.

Technical specifications

The app is designed for use on Android and iOS devices, provided they meet the following minimum requirements for operating systems and hardware:

Minimum hardware requirements:

- RAM: min 2GB
- Internal storage: min. 32GB
- Connectivity: Wi-Fi and/or 4G-5G, Bluetooth
- Screen size of at least 4.7"
- Camera

Operating system:

- Android:
 - Version: Android 11, 12, 13, 14
 - Bluetooth: min 5.0
- iOS:
 - Version: iOS 17, 18
 - Bluetooth: 5.0 (does not work in Classic mode)

You must download and install the app from the store corresponding to your operating system, which is the only secure source available. Avoid installing applications from unofficial stores or by directly uploading the setup file to your device. We accept no liability for any damage or malfunctions resulting from installations not carried out via official stores.

Interface features:

The app features a graphical interface designed specifically for use on mobile devices and is intuitive, to facilitate immediate understanding of the information and data collected.

Network requirements:

To use the App, a connection to the CGM CARE MAP server is required in order to authenticate the user, download configurations and send the acquired data. Either a 4G/5G mobile connection or Wi-Fi, if available, can be used for the connection.

Some features are also available offline, such as taking measurements; data will then be transferred as soon as a network connection is available.

IT security measures, including protection against unauthorised access:

For the first login, credentials are required (and a connection to the server for validation); thereafter, the phone's authentication method can be used.

Data is stored in encrypted form in a dedicated section of the smartphone's memory and deleted after a configured period of time.

All communications take place via secure protocols (HTTPS, TLS 1.2).

Specific requirements for the mobile processing platform or other devices or equipment necessary to run the software as intended:

To download the app from the Android/iOS stores, you must have a valid account for access.

MANUFACTURER

CGM TELEMEDICINE S.R.L.

a CompuGroup Medical company



WEBSITE

