

User's Manual

CGM CARE MAP Mobile

Multiplatform



Content

Introduction	3
Precautions for use.....	4
General.....	4
Warnings.....	4
Checks before use	5
Checks during use	5
About the application.....	6
FIRST START	8
Permissions	8
Android.....	8
Android 9.....	8
Android 10 or higher	8
iOS.....	9
HOME SCREEN	10
MAIN SCREEN.....	13
AGENDA SCREEN	14
CHAT SCREEN.	18
SCREEN MEASURES.....	20
GRAPHIC SCREENS	22
DOCUMENT SCREENS	23
NOTIFICATION SCREEN	26
Push notifications:.....	27
MENU SCREENS	28
DEVICES.....	34
UC352BLE - AND Scales.....	34
UA651BLE - AND Pressure Meter.....	34
GD40 DELTA - Bruno Glucometer	35
Connect 6 - FORA Glucometer	36
OnCallSure - Glucometer.....	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
Predisposition	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
Manufacturer	51
Technical characteristics	51

Introduction

This document describes the functionality of the CGM CARE MAP Mobile application so that it can be easily used by the user.

The document illustrates the features provided for the multiplatform version of the product, which can be used on mobile devices with the Android or iOS operating system; the screenshots shown are for the Android version; the iOS version may differ in some graphic details due to the different operating system, but these differences are not significant for understanding and using the product.

In case these differences are significant, screenshots of both versions will be shown.

At the end of the document are the main evidences of compliance with Regulation (EU) 2017/745, such as the indication of the manufacturer, the classification of the device (Class IIa), the technical characteristics of the devices that can be used, the intended use, and any indications and warnings for use.

The device is made up of various modules, only some of which fall within the definition of a medical device. The modules with medical functionality, subject to evaluation by the notified body (IMQ) and which therefore present the CE marking with code 0051, are the following:

- CGM CARE MAP:
 - Reporting
 - Alarms
- CGM CARE MAP Mobile:
 - Acquisition of measurements from devices
- CGM POINT OF CARE:
 - Acquisition of measurements from devices

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

Identifying data

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

Trade name	CGM CARE MAP
Model	CGM CARE MAP
Brand	CGM TELEMEDICINE
SW Version	4.0.0.0

Usage precautions

The chapter provides the user with the necessary information in order 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 warrants the safety, reliability, and performance of CGM CARE MAP Mobile only if it is used in accordance with the operating instructions contained herein.
- All liability of the manufacturer and the warranty shall lapse if the user fails to comply with the contents of this document.
- The CGM CARE MAP Mobile application needs to communicate with the central server via cellular/wi-fi connection to function properly. Make sure the application is used in an area where the necessary coverage is available.
- CGM CARE MAP Mobile uses the device's mobile data connection; therefore, the minimum distance for pacemaker patients should not be less than 1m.
- Report any serious incidents occurring in relation to the device to the manufacturer and the competent authority of the member state in which the user and/or patient is established
- Contact the Manufacturer at the contacts provided at the end of the document to obtain the Technical Description document of the product.

Warnings

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

Fabbricante	Modello	Descrizione
Beurer	BF720	Diagnostic scale 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 to be used for measuring, viewing, reviewing and storing multiple physiological parameters including ECG, oxygen saturation (SpO2), pulse rate and temperature, in the home environment or health facilities
CGM Telemedicine	Hi	3-lead wearable Holter ECG
FitBit	diversi modelli (fitbit inspire 2,3)	Smartwatch for fitness

Bruno Farmaceutici	GD40	Bluetooth glucometer
FORA	FORA 6 Connect	Bluetooth glucometer
GIMA	P15 - On Call Sure Synch	Bluetooth glucometer
A&D	UA-651BLE	Sphygmomanometer
Gima	LS808-BS	Sphygmomanometer
Roche	Coagucheck INRange	The CoaguChek® INRange system, consisting of the CoaguChek INRange measuring instrument and the CoaguChek XS® PT Test PST test strip, is intended for determining the time of prothrombin (PT) in fresh capillary blood
Shenzhen Creative Industry	POD-1W	Pulse oximeter
MIR	SmartOne	Spirometer
MIR	Spirobank Smart	Spirometer
A&D	UC-352BLE	Bathroom scale

- The APP is compatible with the Android and iOS operating system versions listed in the "Technical Features" chapter at the end of the document, please check the version of the operating system you are using 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 about any medical matter.
- Only data deriving from CE marked medical measuring devices are used by the medical modules for the medical purposes described in the intended use. Data deriving from other types of non-medical devices (e.g. FitBit) are not processed by medical modules and are not used for medical purposes and are therefore excluded from the device marking perimeter. Alarms generated from measurements not coming from medical devices must not be used to make diagnostic and/or therapeutic decisions.

Checks before use









- Check that the data or Wi-Fi connection is actually available. If not, place yourself in an area where there is a sufficient signal level to make a connection to the server.
- Verify that the battery level is above 50%, if not, fully recharge the device before using the application.

Controls during use








- Make sure that the name that appears on the CGM CARE MAP Mobile display always matches the patient's name. If it does not, contact the service department.
- The Bluetooth connection is effectively usable if the distance between the devices and the smartphone is on the order of several meters, also depending on the state of charge of the batteries and the presence of any noise. In case the connection breaks down or has malfunctions, make sure the battery is charged and bring the devices closer together until the connection is reliably restored.

Application information

At any time by clicking on the Settings > Information menu you can access the mask with version summary data and manufacturer references (CGM CARE MAP Mobile is part of the CGM CARE MAP medical device).

	CGM TELEMEDICINE S.r.l. Registered office: Foro Buonaparte, 70 – 20121 – Milano (MI) - Italy Operational headquarters: Via Emilia Parmense, 204 – 29122 – Piacenza (PC) - Italy	
	CGM CARE MAP	
CGM TELEMEDICINE		
Ver. 4.0.0.0		
Module Mobile		
	(01)00086000573683(8012)v.4.0.0.0	
	[www/mm/dd]	
		
	The instructions for use are available in electronic PDF format in the 'Manuals' section of the Operator menu. For viewing, any program that supports this format is sufficient (Acrobat Reader or similar). It is possible to request a paper copy by sending an email to the address <configured email>, which will be sent free of charge within 7 days.	

Explanation of the symbols:

	Manufacturer identification
	Device model
	Release date
	Read the user manual
	Symbol to indicate that IFUs are available in electronic format
	UDI vector
	Medical device



Compliant with Regulation (EU) 2017/745, MD Class IIa.

The 4-digit code indicates the notified body of the device.

FIRST START

Permissions

The first time you start the App after installation, the App may require certain permissions necessary for proper operation, such as to send notifications; accept the requests in order to use all functions of the App.

Bluetooth communication is required for the use of measurement devices, for which relevant permissions will be required, also depending on the operating system version, Android or iOS.

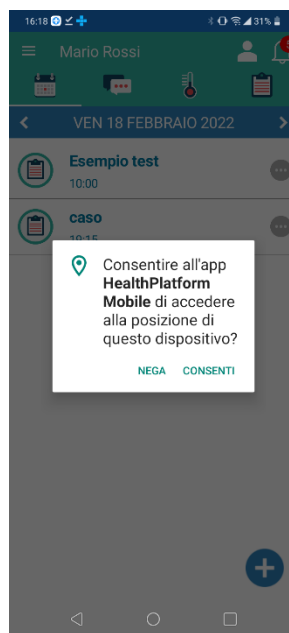
Android

For Android, the permission related to Bluetooth is included in the Geolocation ones and it is therefore necessary to provide both to allow dialogue with the devices, even if the App does not make any use of the device's location.

Depending on the version of Android there are some differences:

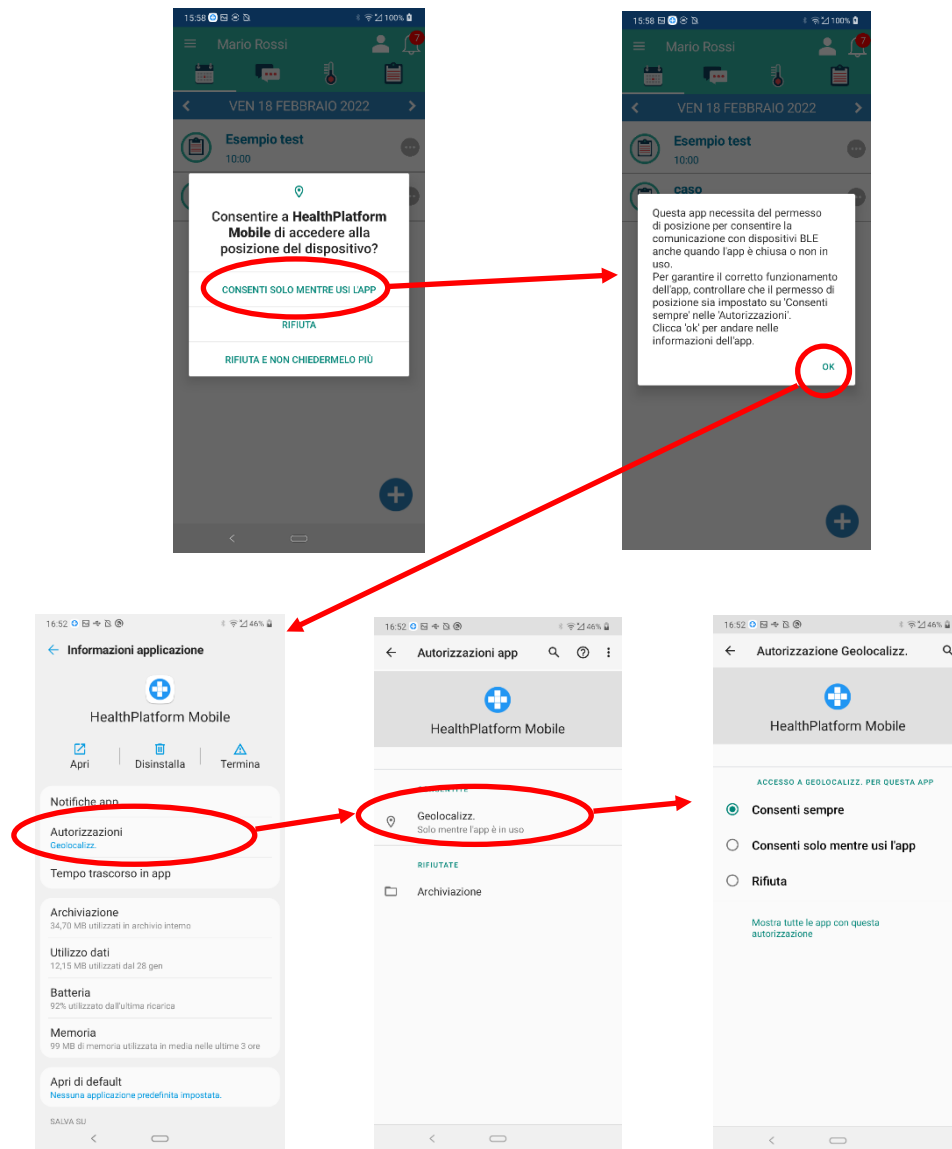
Android 9

Select the "ALLOW" option when the relevant screen is presented:



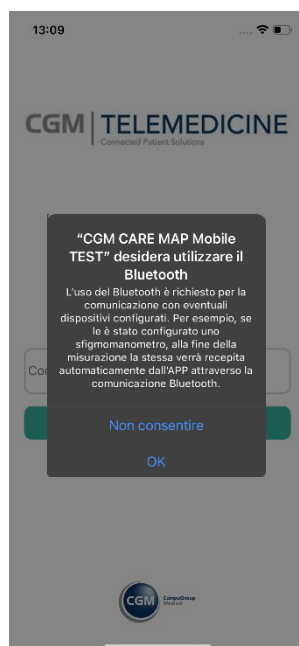
Android 10 or higher

For some measurement devices that require continuous communication with the App, such as the HI 3 LEADS ECG, it is necessary that permission be granted not only when the App is in use but also when it is not visible (App in background), in order not to interrupt measurement acquisition. To do this, it is necessary that on the Geolocation permission management page in the smartphone settings, "Allow always" and not "Allow only while using the app" is selected. If the permission for background use is not initially granted, the App will prompt the user to select it with an appropriate message, selecting OK will take you to the Settings page where you can sequentially select "Permissions" -> "Geolocation" and finally set the permission to "Allow always."



IOS

Authorization for Bluetooth is requested from the user via a special popup indicating the fact that Bluetooth communication is required, select OK:



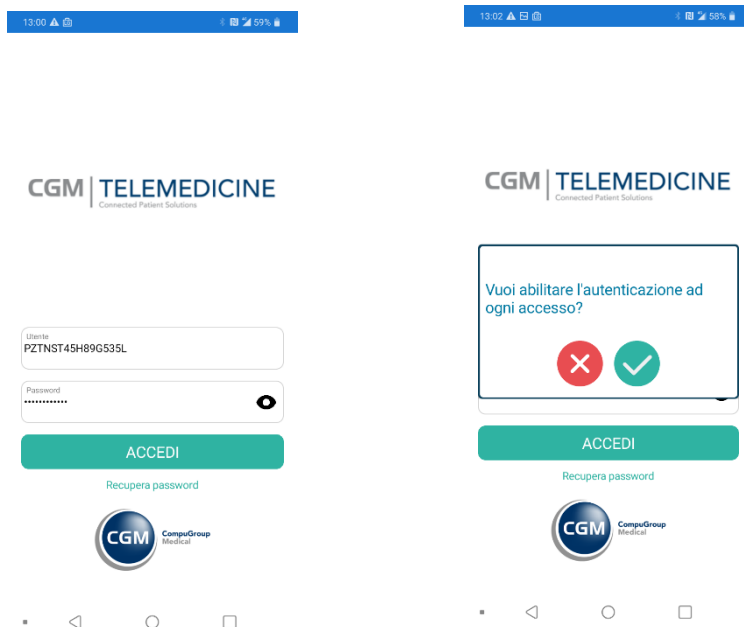
HOME SCREEN

When the App is first launched, you may be prompted for an instance code to identify the platform to connect to, enter the code that was provided to you during user assignment:



In subsequent starts, in case the device is not already surveyed and associated with an attendant, then the first screen displayed is the "Login" screen, in which User and Password are required to authenticate and download data.

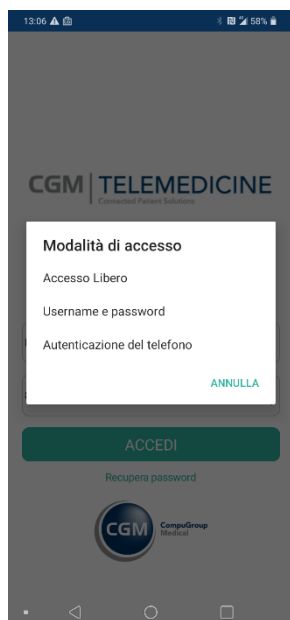
Characters entered in the Password box are replaced by '*' to protect its confidentiality, should it be necessary to verify the password entered simply click on the eye icon on the right and the text will be displayed normally. Clicking further returns to the protected view.



In case you decide to enable authentication every time you log in, you will be asked how you want to authenticate later, there are three possible options, but some may not be present depending on the configurations in place (later you can change the choice within the app from the Settings section):

- Free access: no authentication
- Username and password
- Phone authentication (method the user uses to unlock the phone)

(Android Operating System)



(iOS Operating System)

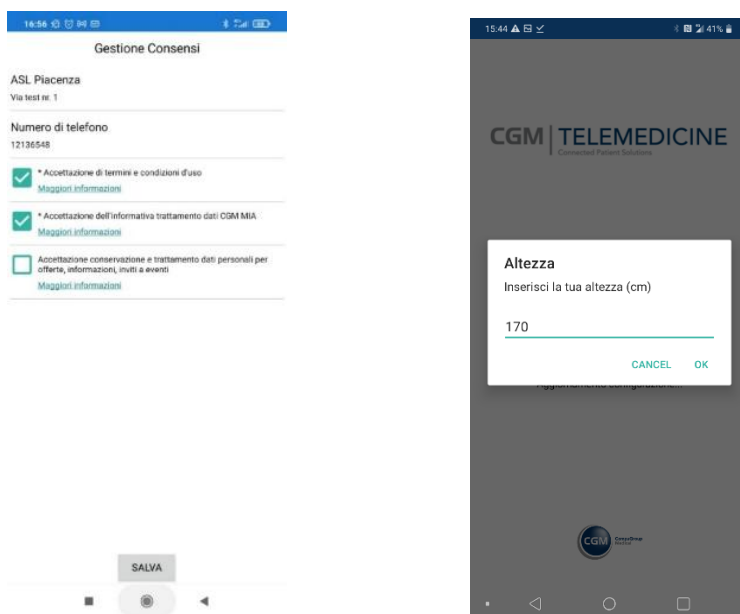


Once authenticated, you will be directed to the "Terms and Conditions" screen.

On first use, after requesting credentials, the "Consent Management" window is displayed:

The patient's home organization and phone number will be given.

The "Save" button will be enabled when at least the mandatory consents, marked with the symbol *, are selected.



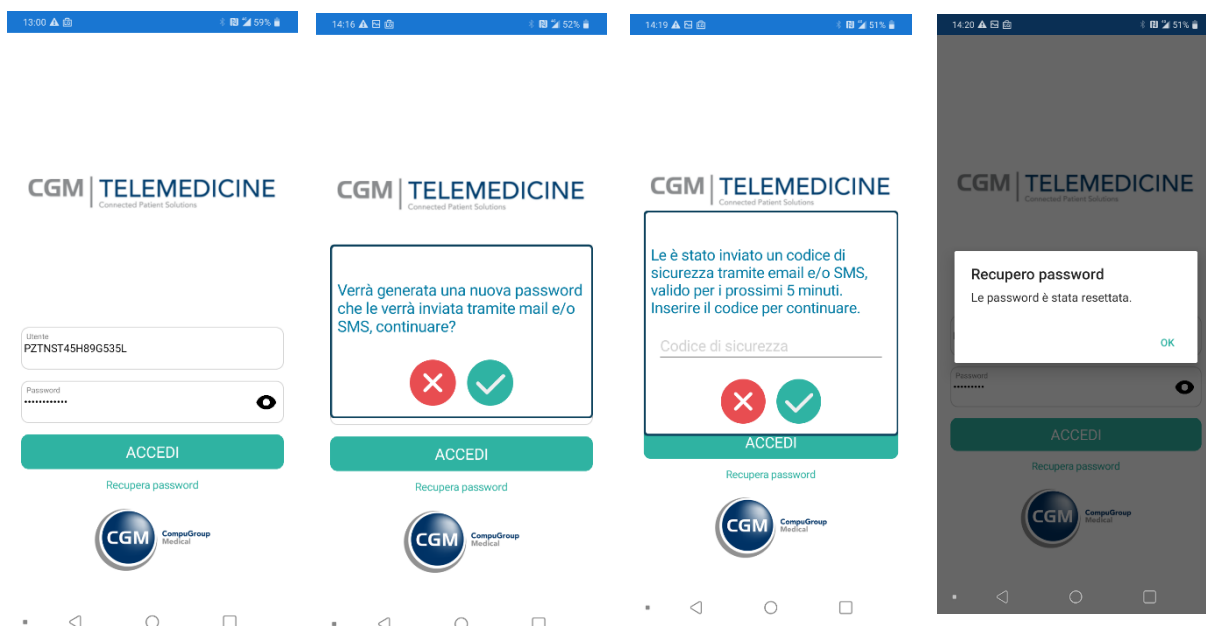
By accepting, you will continue to check the attendant's data, and once accepted, the agenda screen is displayed.

In case the height has not been entered, enter it before viewing the agenda. Pressing "OK" will open the main "AGENDA" screen.

Password recovery

It turns out that it is possible to retrieve the password from the main login screen by entering your user name. A code will be sent to the patient via SMS\Mail so that the password can be reset.

Then, once the code is entered, the patient will receive an email with the new password.



MAIN SCREEN

When the App is launched, the main screen is presented, with some information always present at the top:



- Name of the patient with whom the phone is associated
- User icon: only in case multi-patient option is enabled, allows selection of the current patient.
- Notifications icon: with possible indication of the number of unread messages.
- Navigation bar to navigate between sections (at the top for Android OS and at the bottom for iOS OS). If the chat function is enabled there is a message icon, with a red dot in case of unread notifications).

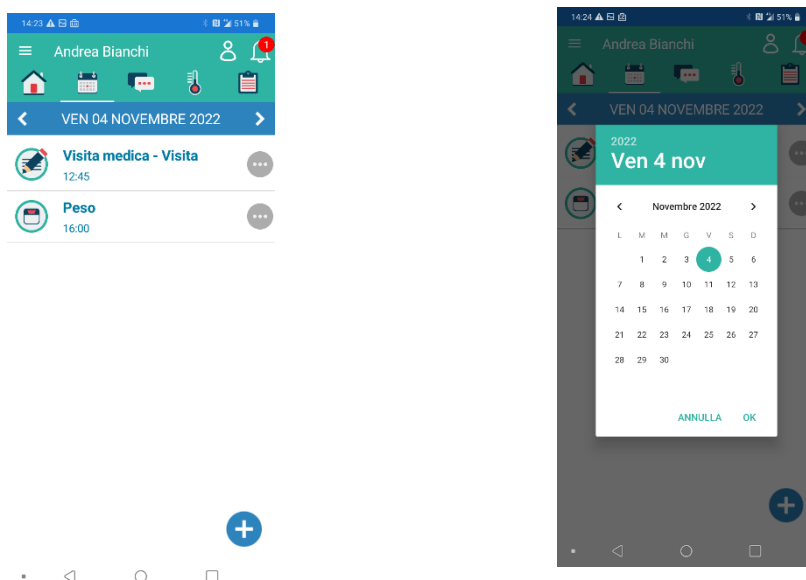
The central part contains a welcome message or information on the progress of the monitoring path, the icon of the referring organization with a short text, and a summary of upcoming activities planned in the calendar/agenda, which can be accessed by clicking the Calendar> label.

At the bottom are two buttons for direct access to the Documents and "About Us" section pages of the app(see later in the manual for details).

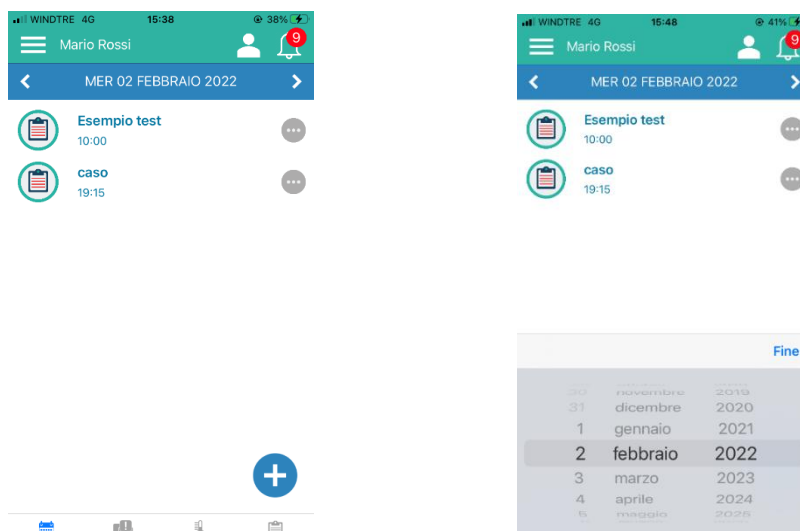
AGENDA SCREEN

The application's agenda screen shows the current calendar day, where the patient views the day's activities and can enter any notes and reminders. Clicking on the day opens the calendar so they can select a different day to move to more quickly.





(Android Operating System)



(iOS Operating System)

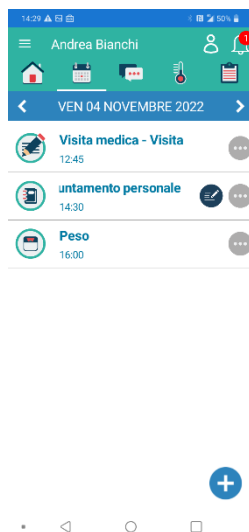
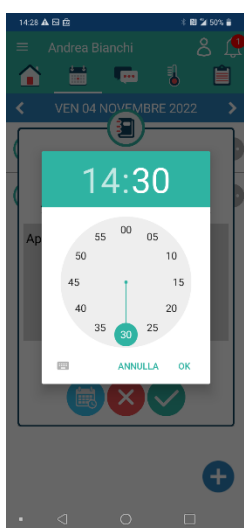
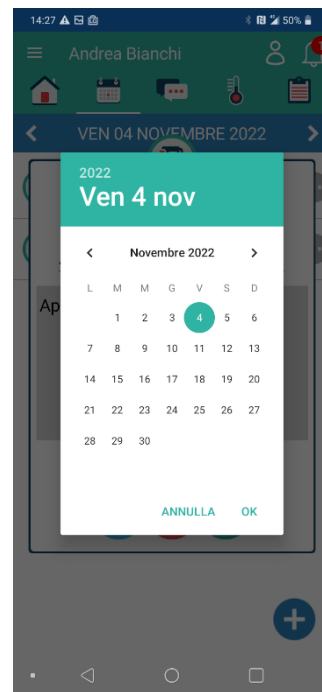
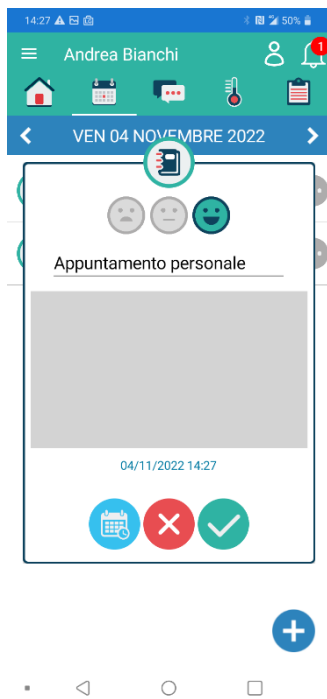
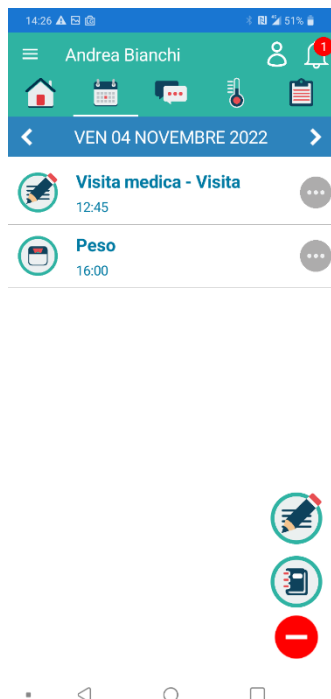


Activities may appear with the following icons:





-  : indicates that the task has yet to be performed.
-  : indicates that the activity has been performed
-  : indicates that the task was not performed on time (expired).
-  : indicates that the activity was created by patient and editable/deletable by patient.

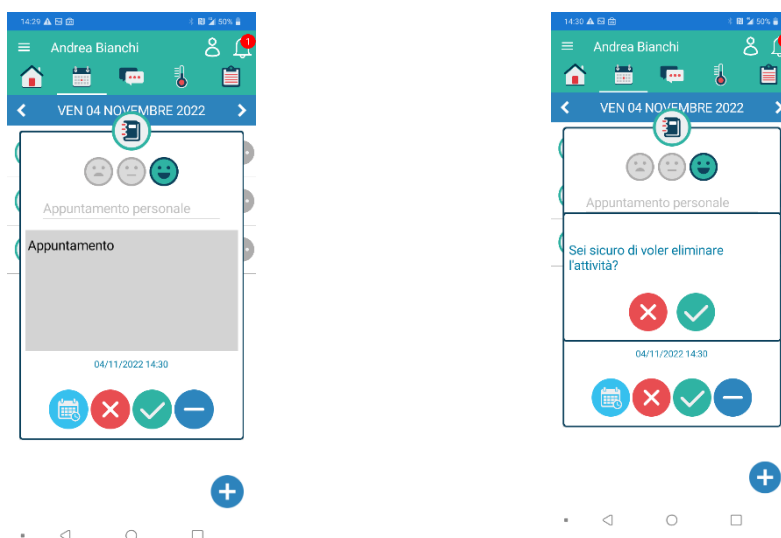
Memo and note entry:

Using the '+' icon, it is possible for patients to add tasks to their calendar (the type of tasks that can be added depends on the configuration of the application):



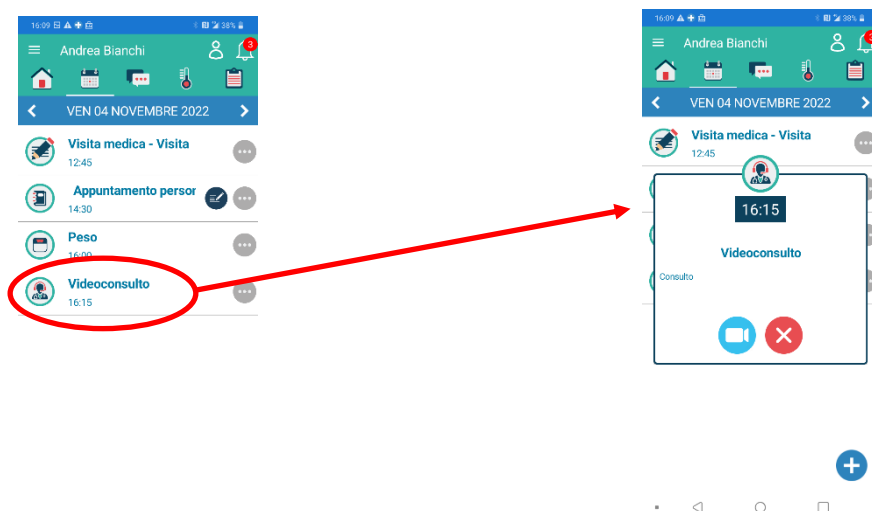
To be able to edit/delete the activity by clicking on the icon related to the creation of it will be possible:

-  : change date and time of the activity
-  : to exit without saving changes
-  : to save the changes made.
-  : to delete the activity. Where the patient will be asked for confirmation.



Video consultation activities:

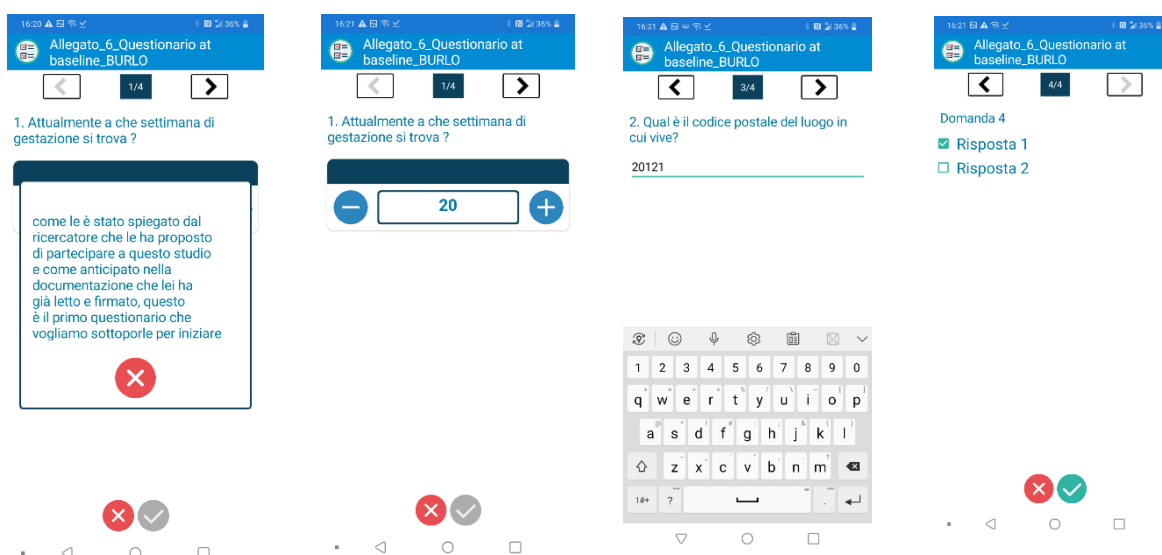
The video consultation activity allows you to make a video call by pressing on the activity to see the detail and then pressing on the camera icon



Questionnaires:

The activity involves filling out predefined questionnaires consisting of several questions with both closed and open-ended responses. When opening the questionnaire for completion, a screen with a descriptive text of the same may be displayed.

Each question is presented in its own screen, along with possible answers. In the case of closed answers, you need to choose one answer (or more, if multiple answers are possible) while in the case of open answers you can type your answer in the appropriate fields.



The top of the screen always displays the number of the current question with the number of total questions and arrows to move forward and backward in the compilation. When you reach the last question, it is necessary to confirm the compilation by pressing the green button in order to submit the answers to the web portal.

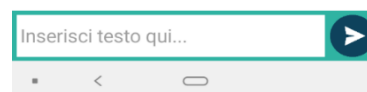
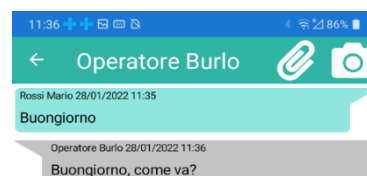
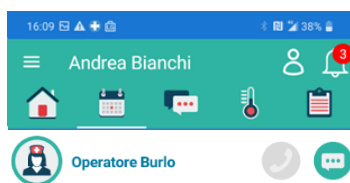
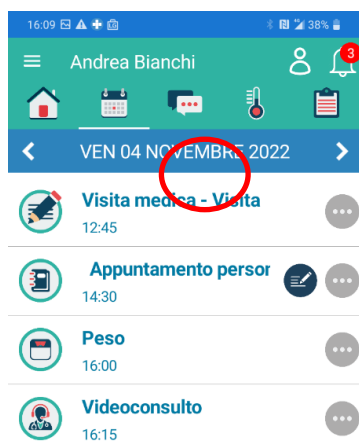
Once the questionnaire is submitted, it will still be visible among the activities, the answers given will be visible but cannot be changed.

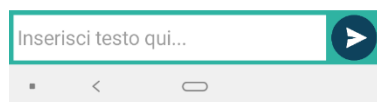
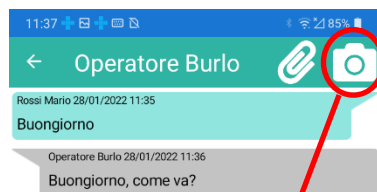
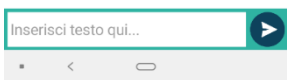
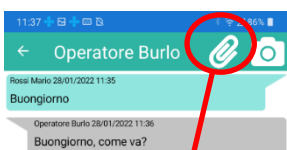
CHAT SCREEN.

If the chat section is enabled (the message icon is visible), the list of open conversations can be accessed via the appropriate icon in the bar.

The central part displays the chats available for the specific patient, including therapy groups. For each chat, it is visible whether there is a call or texting option or both.

The icons in the upper right corner allow you to send documents (pdf) and images.





SCREEN MEASURES

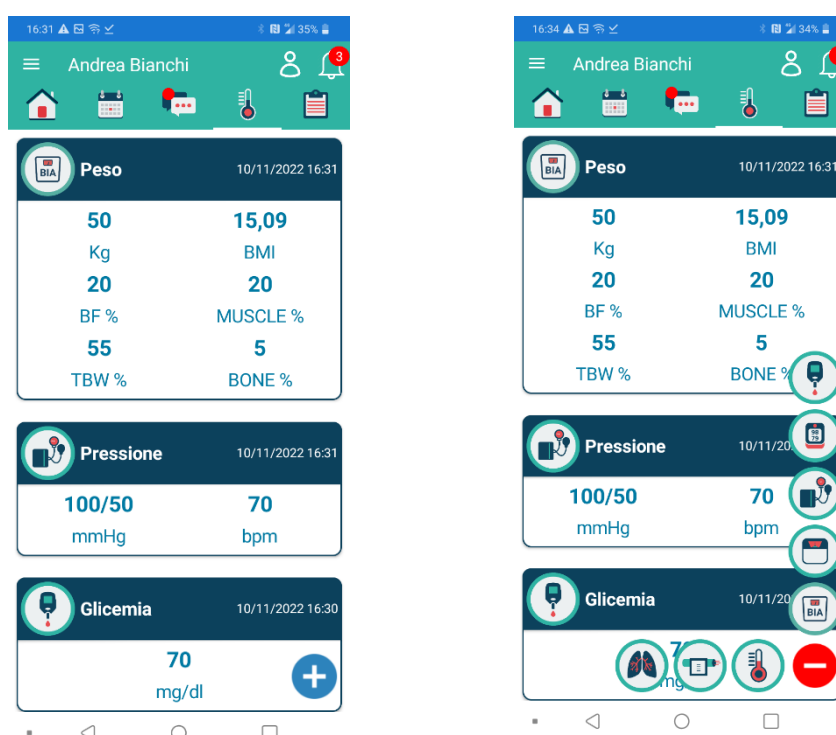
The measure screen has a box of the last measure acquired for each type.

If the patient has the device connected with medical devices, measurements can be captured automatically by the app, and the status of any planned measurement detection tasks will be updated automatically.

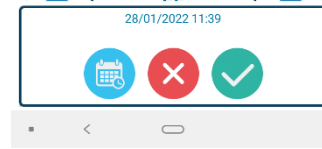
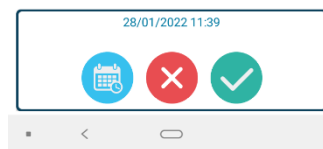
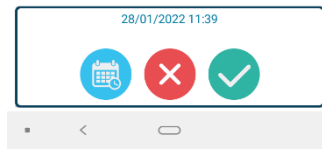
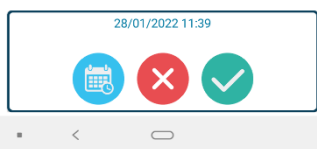
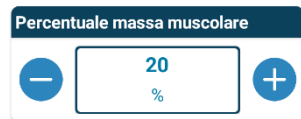
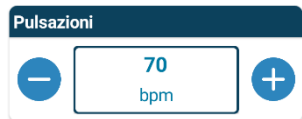
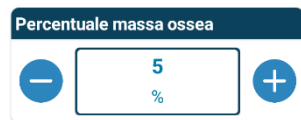
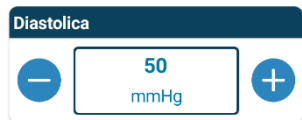
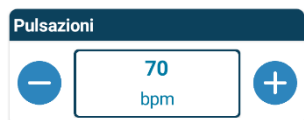
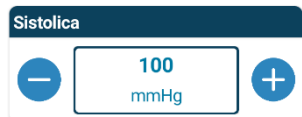
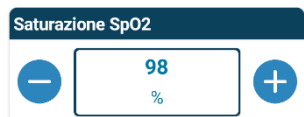
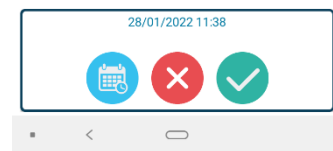
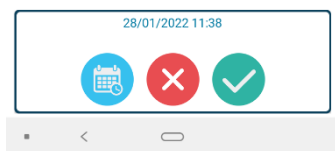
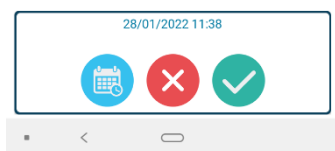
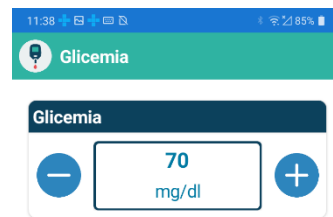
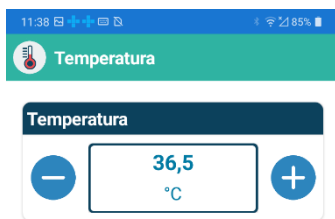
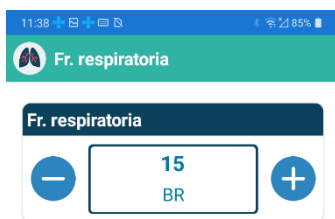
If the patient does not have the device connected with medical devices, from the activity the app allows the patient to manually acquire the value by opening the specific screen for the type of measurement.

Pressing the "+" in the lower right corner allows you to enter a measurement manually.

Possible manual measurements are: Respiratory rate, temperature, blood glucose, oximetry, blood pressure, weight, and spirometry.

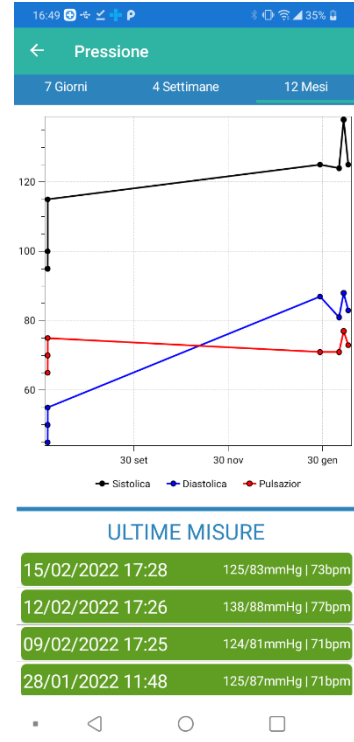
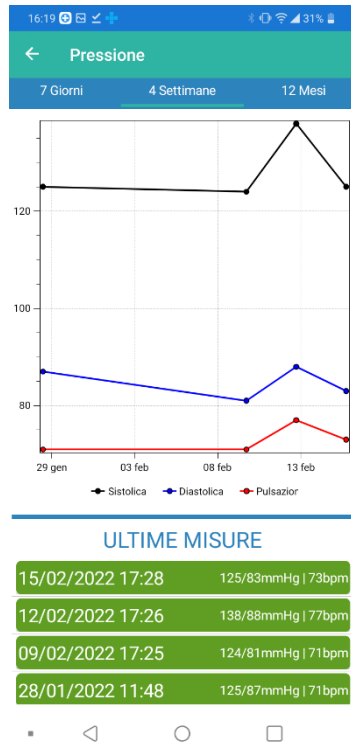
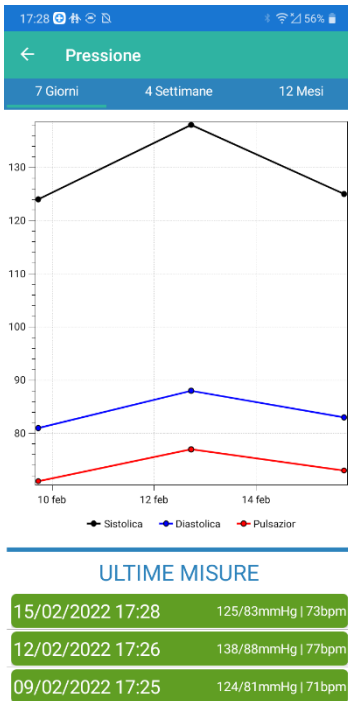


Addition of the various sizes:



SCREENSHOTS GRAPHICS

Each measurement box is selectable, and pressing it opens the screen with a graph of the values taken in the last 7 days related to the selected measurement; below the graph is the date and value of the measurements, ordered from most recent to oldest:



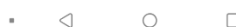
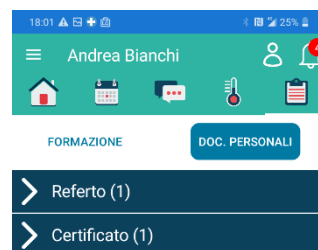
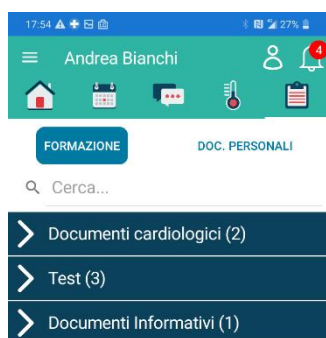
Pressing "4 Weeks" opens the graph of measurements taken in the last 4 weeks with always underneath the latest measurements.

Pressing "12 Months" opens the graph of averages (12, one per month) of measurements taken over the past 12 months with the most recent months below in order from most recent.

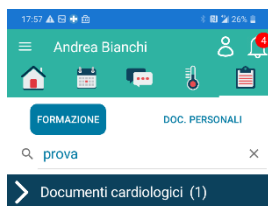
DOCUMENT SCREENS

Clicking on the documents icon takes you to the screen that includes the training documents with documents, sites, videos, and links available to the patient, in the 'TRAINING' tab and the patient's personal documents in the 'DOC. PERSONAL'.

By pressing on a document in Training, the app sends the patient to the reference site of the specific document or opens the attached pdf.



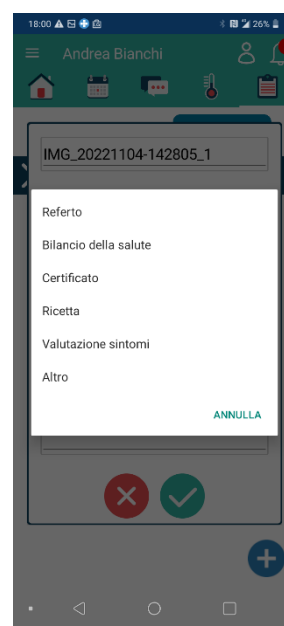
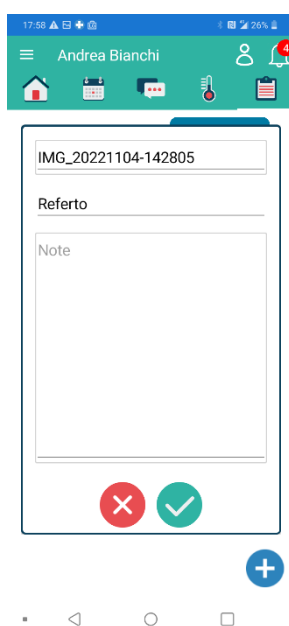
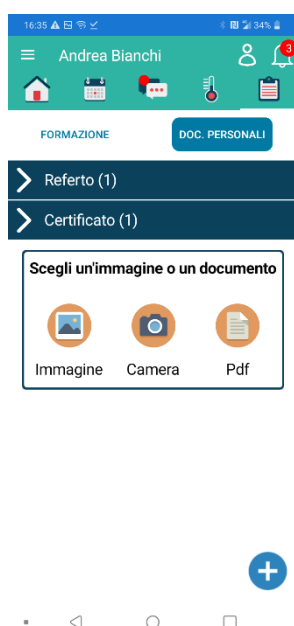
In the 'Training' section, documents are divided by section, which can be configured from the web, and it is possible to search by keywords, which can also be configured from the web:




Also in the section "DOC. PERSONAL" the documents are divided into sections, in this case they are not configurable from the web but are predefined and, currently, they are:

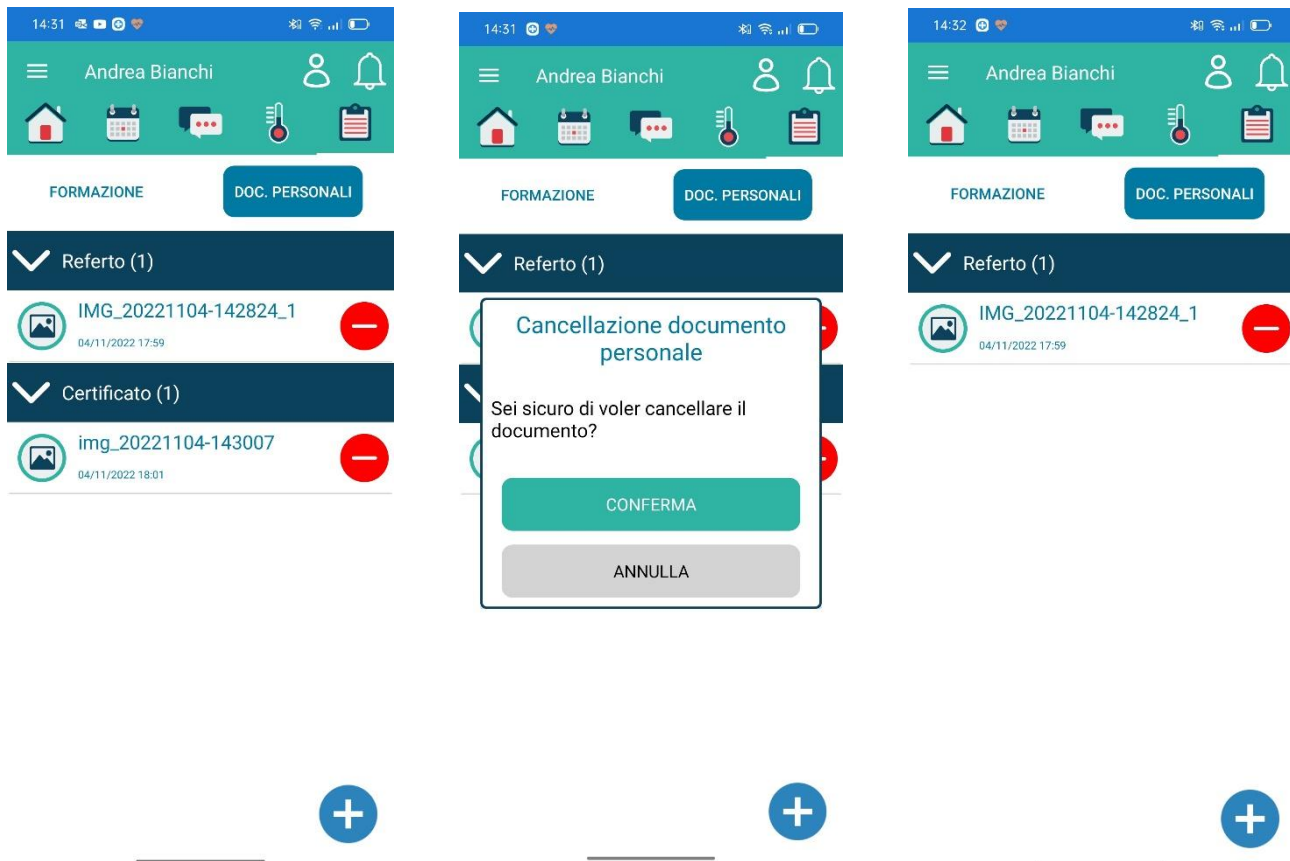
- Report
- Health budget
- Certificate
- Recipe
- Symptom assessment
- More

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



You can also delete a document that you do not want to appear in the list; the document remains stored on the server but is no longer visible to the user, although it remains visible to operators who need to access it.

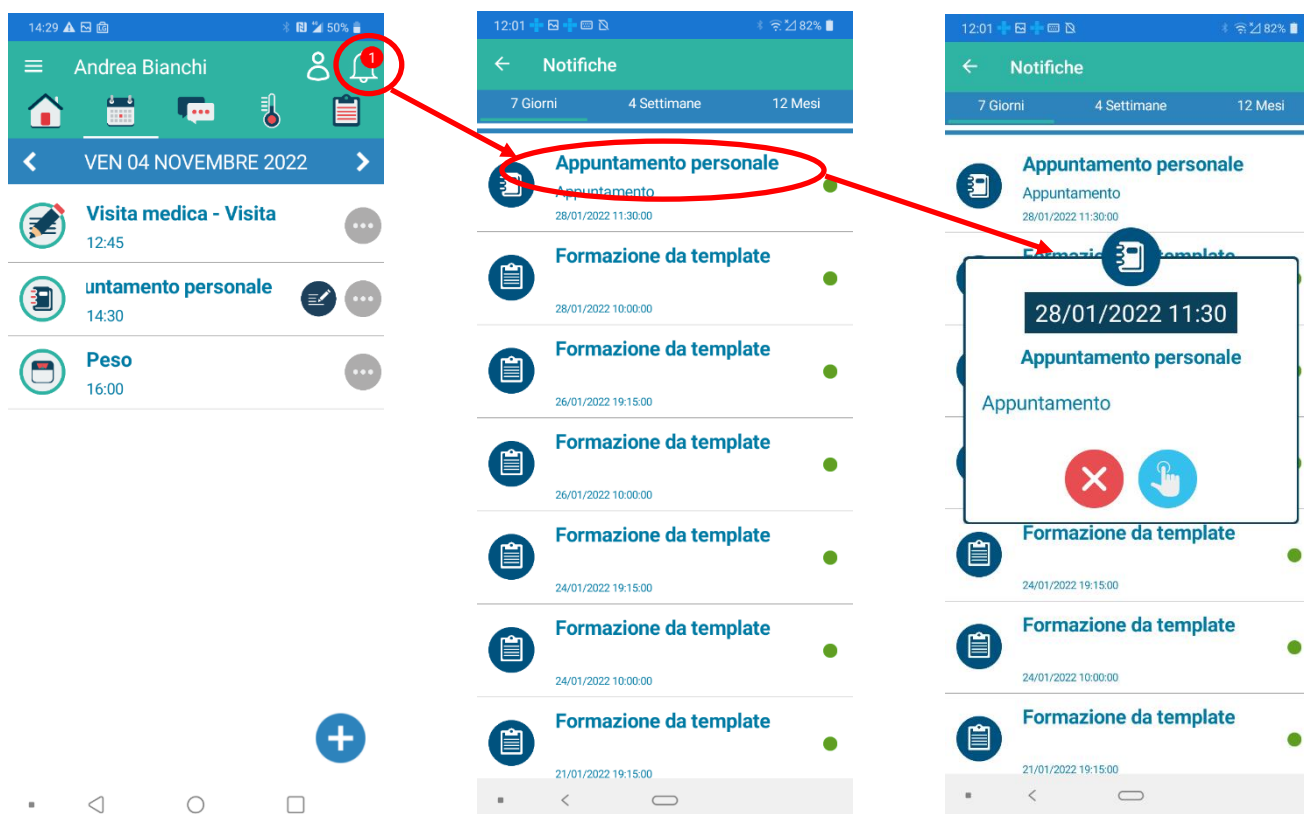
Next to each document is a special icon with a - on a red background  , pressing it will ask for confirmation of deletion, and pressing 'confirm' will remove the document and make it no longer visible.



NOTIFICATION SCREEN

In the upper right corner, pressing the bell icon (the small red number indicates the number of notifications not yet viewed) opens the notifications page with a time filter on notifications received in the last 7 days:

(Android Operating System)



By opening and confirming a notification is displayed and the dot (and associated number) disappears. In case the notification is linked to an activity in the agenda, the icon will also be displayed so that you can get to the task quickly and execute it.

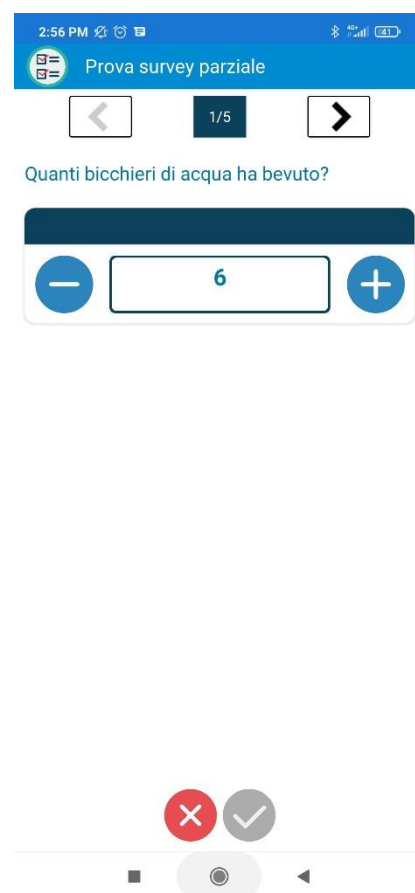
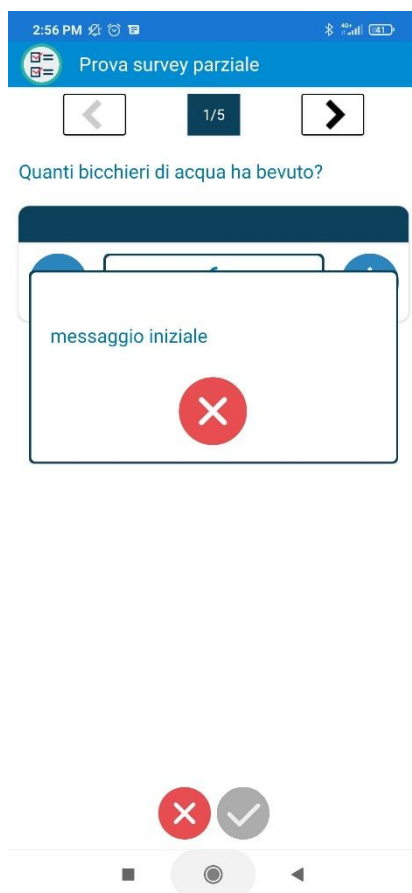


Pressing "4 Weeks" will load the notifications received in the last 4 weeks.

Pressing "12 Months" will load the notifications received in the past 12 months.

Push notifications:

Once you receive a push notification, which is the instant notification that comes when the phone is locked, reminding the patient of an activity in the calendar, you can directly access the activity by opening the notification you just received.



MENU SCREENS

"UPDATE" updates connected devices and status of measurements, notes, reminders, events.

Pressing on "DEVICES" opens the list of devices associated with the application with their respective tutorials.

Each device, if managed, will have its own tutorial page explaining how it works, viewable by pressing on the '?' icon next to the device name.

The sequence of screenshots illustrates the navigation process:

- Home Screen:** Shows the user's name "Andrea Bianchi" and a menu icon (hamburger menu) circled in red.
- Dispositivi Screen:** After tapping the menu icon, the "Dispositivi" screen is shown. The "Dispositivi" title and a stethoscope icon are circled in red.
- Dispositivi registrati Screen:** After tapping the stethoscope icon, the "Dispositivi registrati" screen is shown. A question mark icon next to the device name "EG B2BH4" is circled in red.
- Device Tutorial Screen:** After tapping the question mark icon, the tutorial page for the "LIFESCAN Glucometer OneTouch Verio IQ" is shown. The page includes an image of the device and instructions for pairing.

CGM HI 3 LEADS ECG è il dispositivo medico che utilizzerai per monitorare il tuo ritmo cardiaco.

Accoppiamento

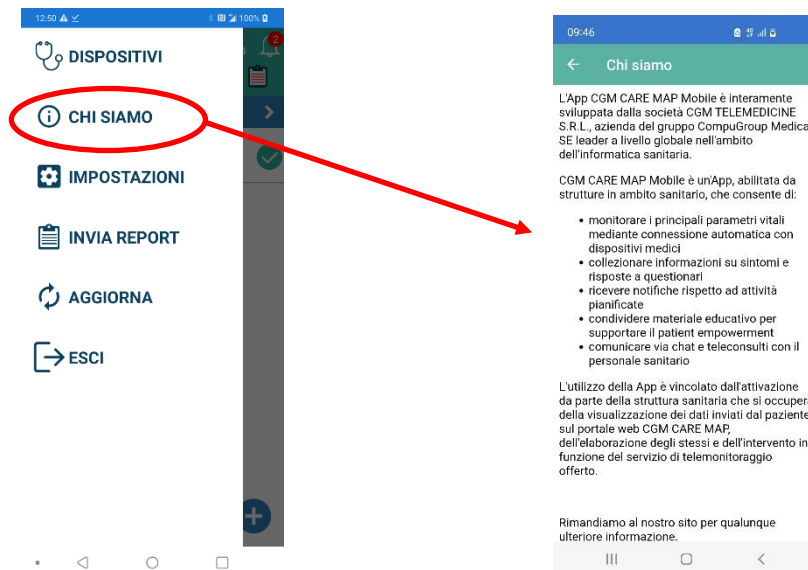
Per collegare CGM HI 3 LEADS ECG all'app HealthPlatform Mobile, è necessario:

- Aprire la sezione "Dispositivi" dal menù principale
- Cliccare il tasto "Aggiungi dispositivo"
- Selezionare CGM HI 3 LEADS ECG
- Avviare la scansione bluetooth cliccando sull'icona a lato

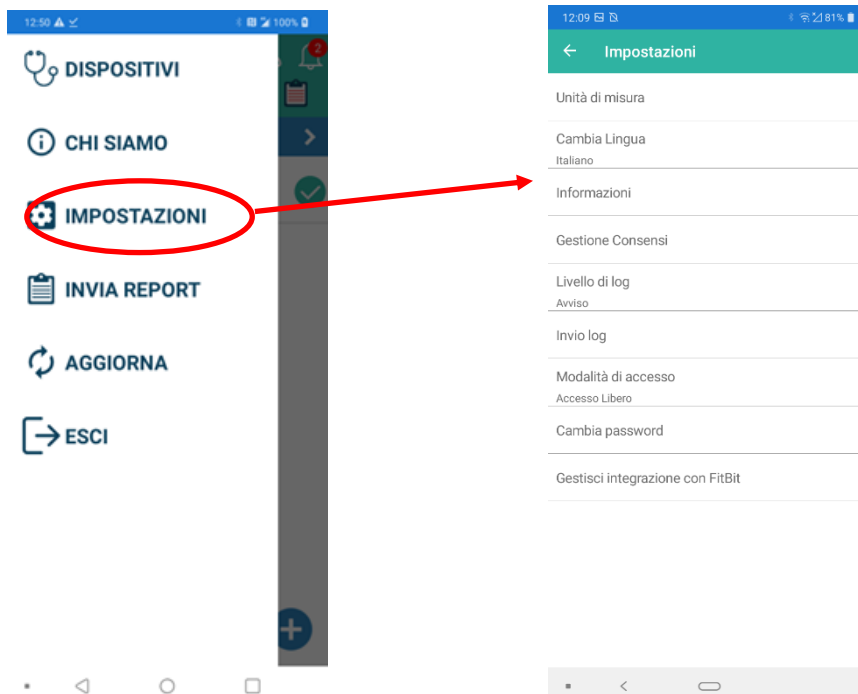
Se la scansione va a buon fine, CGM HI 3 LEADS ECG risulterà collegato all'app e pronto per essere utilizzato per il telemonitoraggio cardiologico.

All other features open their respective pages:

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



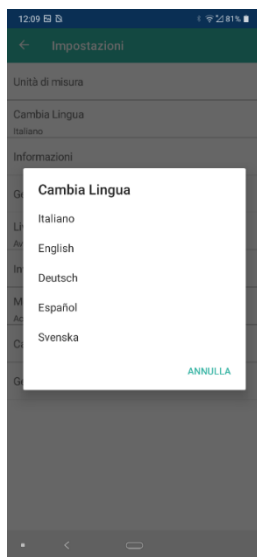
"SETTINGS" contains all user-modifiable settings:



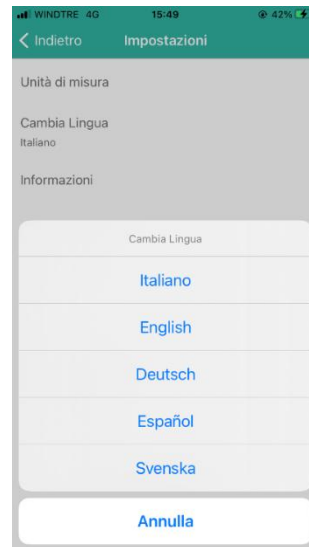
"Units of Measurement" allows you to change some units of measurement with which parameters are displayed, opens a popup with measurement types that have multiple units available so you can select the one with which to display measurements in the app:










"Change Language" opens a popup with selectable languages (Android Operating System)



(iOS Operating System)

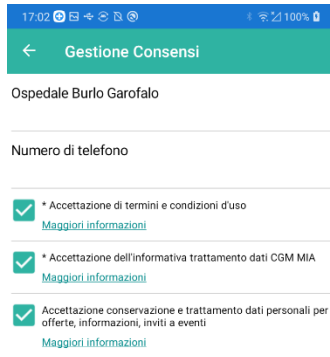


The "About" menu opens the screen with information about the manufacturing company.

	CGM TELEMEDICINE S.r.l. Registered office: Foro Buonaparte, 70 – 20121 – Milano (MI) - Italy Operational headquarters: Via Emilia Parmense, 204 – 29122 – Piacenza (PC) - Italy	
	CGM CARE MAP	
Ver. 4.0.0.0		
Module Mobile		
	(01)00086000573683(8012)v.4.0.0.0	
	[yyyy/mm/dd]	
		 0051
	The instructions for use are available in electronic PDF format in the 'Manuals' section of the Operator menu. For viewing, any program that supports this format is sufficient (Acrobat Reader or similar). It is possible to request a paper copy by sending an email to the address <configured email>, which will be sent free of charge within 7 days.	

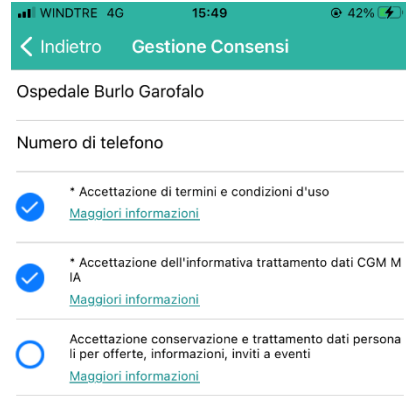
The "Consent Management" menu opens the screen with the accepted terms and conditions.

(Android Operating System)



SALVA

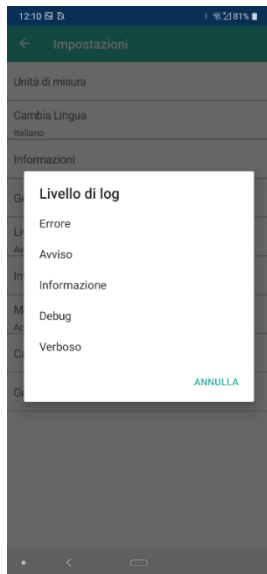
(iOS Operating System)



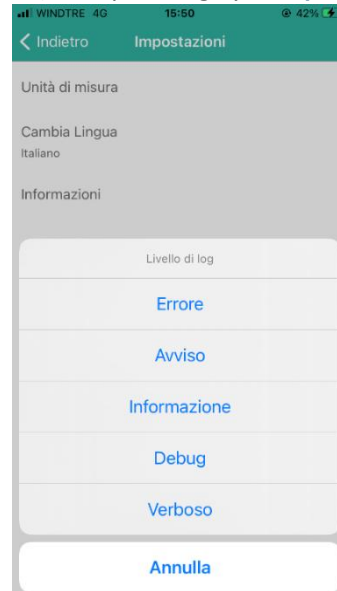
Salva

"Log level" opens a popup with selectable logs, used only upon service request:

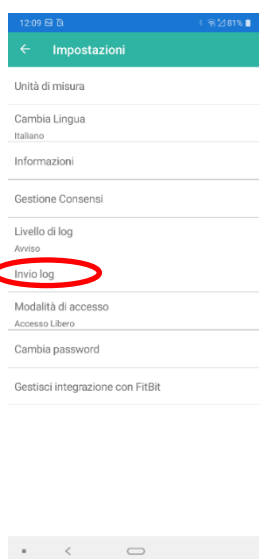
(Android Operating System)



(iOS Operating System)

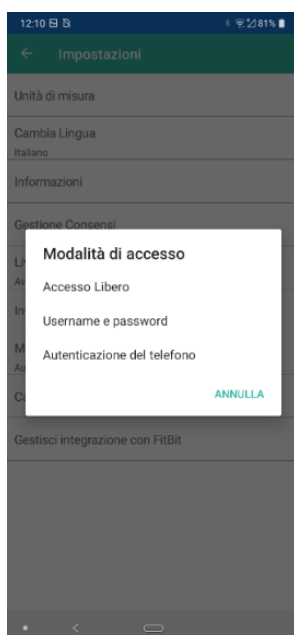


The "Send Logs" menu sends the server the logs recorded so far and not yet sent, which are used only upon service request:

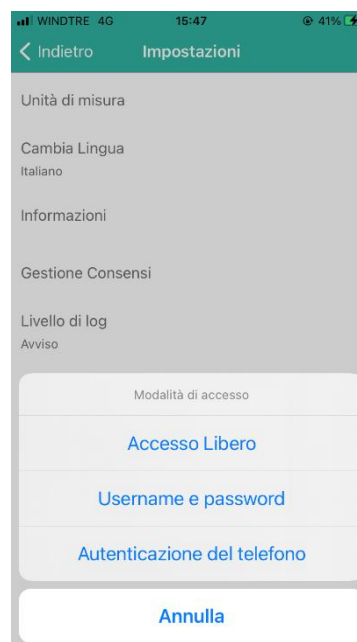


The "Access Mode" menu allows you to change the authentication method previously chosen to access the app:

(Android Operating System)



(iOS Operating System)



The "Change Password" menu allows you to change the patient's password.

You need to make sure you have network coverage as the App needs to communicate with the server to complete the change. In order to protect the security of the password all related fields have the content hidden by replacing the real characters with an asterisk, if you want to verify the content simply press the eye-like symbol present in the far right of the field.

You are first prompted to enter your current password to verify your identity, and then after pressing "Verify Password" if the password is correct you are prompted to enter your new password.

At the top of the screen are criteria that must be met for the new password chosen to be considered sufficiently secure, such as the presence of uppercase characters, numbers, and special characters, as well as a minimum length:

13:07

← Cambia password

Password corrente

VERIFICA PASSWORD

13:09

← Cambia password

- Inserire almeno 1 lettera maiuscola
- Inserire almeno 1 lettera minuscola
- Inserire almeno 1 numero
- Inserire almeno 1 carattere tra @#\$%^&*!=",.-;~\`_
- Inserire almeno 10 caratteri

Nuova password

CONFERMA

As the characters of the new password are entered, whenever a criterion is met the corresponding marker is checked and colored green; when all criteria are met a new text box is displayed in which to re-enter the password for confirmation. Then if the two passwords match the "Confirm" button is enabled, pressing it sends the password change request to the server to complete the change.

13:10

← Cambia password

- Inserire almeno 1 lettera maiuscola
- Inserire almeno 1 lettera minuscola
- Inserire almeno 1 numero
- Inserire almeno 1 carattere tra @#\$%^&*!=",.-;~\`_
- Inserire almeno 10 caratteri

Nuova password

1

CONFERMA

13:10

← Cambia password

- Inserire almeno 1 lettera maiuscola
- Inserire almeno 1 lettera minuscola
- Inserire almeno 1 numero
- Inserire almeno 1 carattere tra @#\$%^&*!=",.-;~\`_
- Inserire almeno 10 caratteri

Nuova password

1234567890

Conferma password

CONFERMA

13:11

← Cambia password

- Inserire almeno 1 lettera maiuscola
- Inserire almeno 1 lettera minuscola
- Inserire almeno 1 numero
- Inserire almeno 1 carattere tra @#\$%^&*!=",.-;~\`_
- Inserire almeno 10 caratteri

Nuova password

1234567890

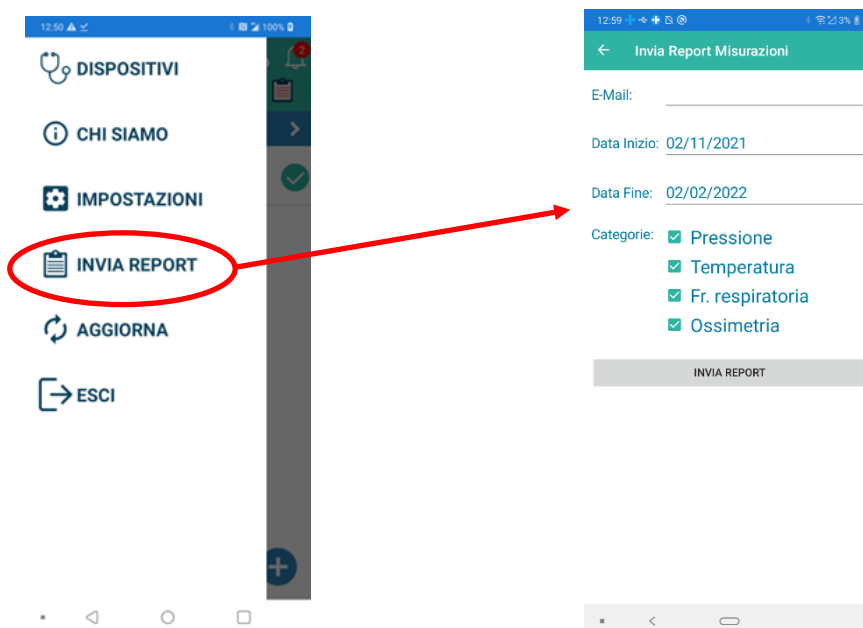
Conferma password

1234567890

CONFERMA



"SEND REPORT" allows generating a report that will be received by email, containing the measurements (user-selectable type) collected in a specific period (indicated by the patient), specifying the recipient's email:



DEVICES

UC352BLE - Scales AND

Coupling

Before taking measurements, it is necessary to pair the scale with the phone. To perform pairing, press and hold the "Set" button on the back of the scale until "Pr" appears on the display, then release the button. After a few seconds, "End" will appear on the scale display to indicate that the procedure was successful. In case of an error, however, an error code (e.g. "E-10") will appear: in such a case, the procedure must be repeated.

Recommendations

Weekly weight measurement is shown; the weight measurement allows BMI to be calculated.

The calculation of BMI (Body Mass Index) indicates the weight status of an adult person and is also given by the ratio of mass to height.

Warning: this is only an indicative result! There are, in fact, several factors: constitution, age, gender, muscle mass or body conformation can affect body weight.

UA651BLE - Blood Pressure Monitor AND

Coupling

Before taking measurements, it is necessary to pair the sphygmomanometer with the phone. To perform the pairing, press and hold the "START" button on the sphygmomanometer until "Pr" appears on the display, then release the button. After a few seconds, "End" will appear on the sphygmomanometer display to indicate that the procedure was successful. On the other hand, in case of an error, an error code (e.g. "E-10") will appear: in this case, the procedure must be repeated.

Recommendations

Throughout the blood pressure measurement and until the cuff is completely deflated, keep in mind the following simple recommendations:

- The patient should be relaxed, sitting comfortably, in a quiet environment with comfortable temperature for at least five minutes.
- No caffeinated beverages should be consumed in the previous hour, nor should one have smoked for at least a quarter of an hour (in fact, one should never smoke!).
- The arm should be supported and the cuff should be at heart height. It does not matter which arm is used for measurement, but it should be remembered that there are sometimes appreciable differences in the values measured in the two arms. In such cases, the arm with the higher pressure should be used for measurement.

The size of the rubber cuff should be adapted to the patient's arm size. In the case of children or very thin adults, smaller than standard cuff sizes should be used, while in the case of very strong people or obese patients, the cuff length should be longer.

GD40 DELTA - Bruno Glucometer

By following these simple directions, you will be able to use the Glucometer and take the Blood Glucose measurement accurately.

Recommendations

- Wash your hands and dry them thoroughly
- Do not use any disinfectant
- Massage your finger for about 20 seconds on the spot where the puncture will be made
- Always use a new smear and lancing device for each measurement

Instructions on the use of the glucose meter

- Insert a new test strip inside the compartment at the bottom of the glucose meter-the meter will turn on automatically
- Place the lancing device on the outer side of the chosen finger: blood supply is better in this area
- Remove the first drop of blood with a cotton ball or sterile gauze pad
- Place the smear on the blood drop and wait for the acoustic sensor to make a slight sound
- Wait for the countdown to the glycemic value measurement
- Eject the smear by pressing the dedicated button at the top of the glucose meter or by pulling the smear with your fingers
- The measurement arrives on the mobile device automatically. If it does not, press down the dedicated button on the left side of the glucose meter
- The blood glucose value just taken will be visible on the mobile device within the "Measurements" area (it may take a few seconds)

To view all previous blood glucose values use the mobile device and refer to the "Measurements" area.

Connect 6 - FORA Glucometer



By following these simple directions, you will be able to use the Glucometer and take the Blood Glucose measurement accurately.

Recommendations

- Wash your hands and dry them thoroughly
- Do not use any disinfectant
- Massage your finger for about 20 seconds on the spot where the puncture will be made
- Always use a new smear and lancing device for each measurement

Instructions on the use of the glucose meter

- Insert a new test strip inside the compartment at the top of the glucose meter-the meter will turn on automatically
- Place the lancing device on the outer side of the chosen finger: blood supply is better in this area
- Remove the first drop of blood with a cotton ball or sterile gauze pad
- Place the smear on the blood drop and wait for the acoustic sensor to make a slight sound
- Wait for the countdown to the glycemic value measurement
- Eject the smear by pressing the dedicated button on the left side of the glucose meter or by pulling the smear with your fingers
- The measurement comes to the mobile device automatically. If this does not happen let the glucose meter turn off, then press the M
- The blood glucose value just taken will be visible on the mobile device within the "Measurements" area (it may take a few seconds)

To view all previous blood glucose values use the mobile device and refer to the "Measurements" area.

OnCallSure - Glucometer



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

Operating Instructions

- If a PIN is requested during the first pairing of the device, use the last 6 characters of the glucose meter serial number.
- During setup when the device is turned on, make sure that the 'AUTO' mode is on for sending measurements at the end of the survey.
- Press the 'OK' button on the glucose meter.
- Insert the blood glucose detection strip into the space provided on the top of the device.
- Make the top of the strip come in contact with blood.
- Wait until the glucose meter has detected the measurement and slide the side button to eject the used strip.
- Simultaneously press the 2 arrow buttons on the glucose meter to download the measurements taken on the app if saving the measurement on the app was not done at the time of the measurement.

You can view all previous blood glucose values on your mobile device on the 'Measurements' screen.

Spirobank/SmartOne - MIR Spirometers



By following these simple directions, you will be able to use the spirometer and take the measurement accurately.

Operating Instructions

Enter your weight and ethnicity

Once you find the spirometer, take a deep breath and exhale as fast as you can inside the turbine

Wait for the value of the measurement taken

To view all previous spirometry values use the mobile device and refer to the "Measurements" area.

IR21b - FORA Thermometer



By following these simple directions, you will be able to use the thermometer and take your body temperature measurement accurately.

Recommendations

- It is possible to take temperature from both the forehead and the ear.
- At least one minute must elapse between the detection of one measurement and the next, otherwise the second measurement will not be accepted

Operating Instructions

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

To view all previous temperature values use the mobile device and refer to the "Measurements" area.

IR42b - FORA Thermometer



By following these simple directions, you will be able to use the thermometer and take your body temperature measurement accurately.

Recommendations

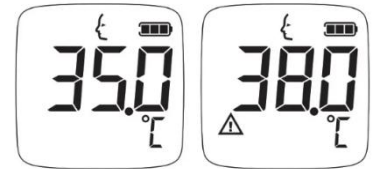
- You can take the temperature in the center of the forehead by keeping the thermometer at a distance of 3 to 7 cm from the surface of the skin.
- At least one minute must elapse between the detection of one measurement and the next, otherwise the second measurement will not be accepted.

Operating Instructions

- Remove the protective cap. The forehead should be free of hair and sweat.
- Aim at the center of the forehead at a distance of 3 to 7 cm from the skin surface. Make sure the thermometer is perpendicular to the surface of the skin.



- Press the power button once to take a measurement. A double beep indicates that the measurement has been taken and can be seen on the device 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 value to be transmitted to the app.



To view all previous temperature values use the mobile device and refer to the "Measurements" area.

POD-1W - Pulse Oximeter



Recommendations

By following these simple directions, you will be able to use the Pulse Oximeter and perform the Oximetry measurement accurately.

- Do not use the pulse oximeter with nail polish on your nails
- Rest your arm on a stand and hold your finger still
- Do not use clothing that may restrict blood circulation

Instructions on use

- Insert the index finger inside the instrument with the nail pointing upward
- Make sure your finger reaches the end of the guide without putting too much pressure on it
- Wait for the oximetry and pulse measurement values to appear on the display
- Wait about 15 seconds without moving the finger for the pulse oximeter to detect the correct measurement
- The oximetry value just taken will be visible on the mobile device within the "Measurements" area
- Remove your finger from the pulse oximeter

To view all previous oximetry values use the mobile device and refer to the "Measurements" area.

B2BH4 - CGM HI 3 LEADS ECG

It is a wearable device that placed on the chest allows electrocardiogram (ECG) and other physiological parameters to be acquired.



Coupling

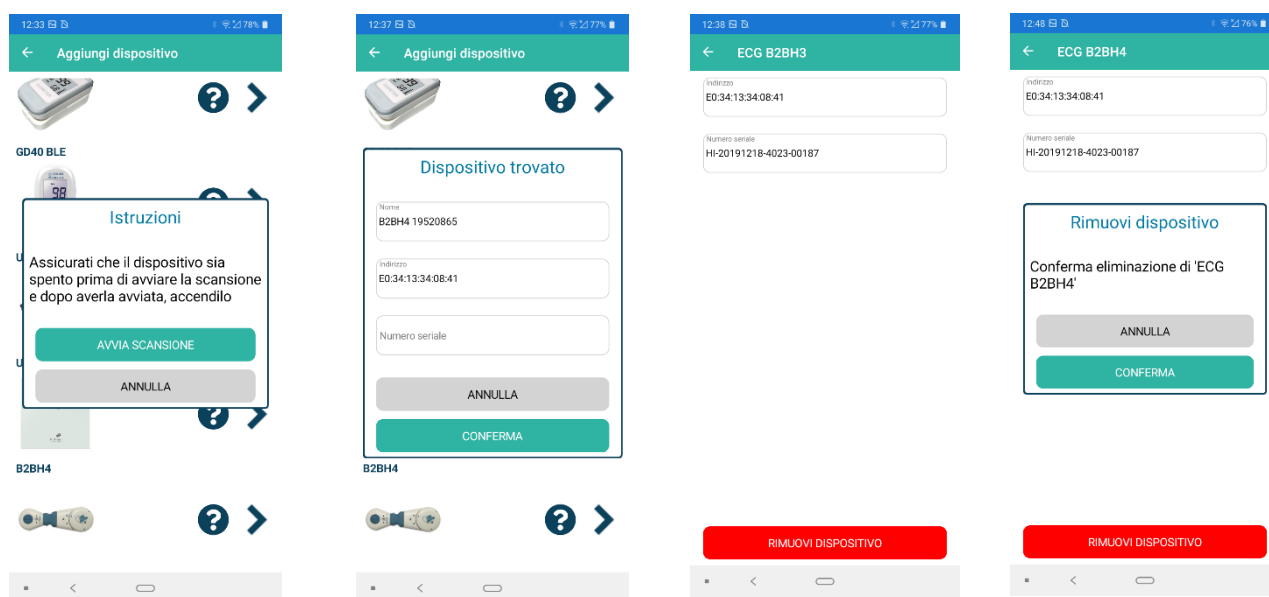
Before taking measurements, it is necessary to pair the Hi device with the phone. To perform pairing, select the main menu and then the "Devices" item, the list of currently registered devices will appear.

Press the "ADD DEVICE" button at the bottom of the screen and in the window that is presented scroll through the list of devices, select the ">" symbol located to the right of the image at the name "B2BH4". A screen will appear that allows you to start the device discovery scan, in the following order:

- Turn off the device, if it is turned on
- Start the scan by pressing the "START SCAN" button.
- Turn on the Hi device.

If a request for permission to use Geolocation appears, which is actually necessary for the use of Bluetooth communication, accept the use (refer to the Permissions section at the beginning of the document)

Once the App has found the device, a screen with the device's identification data is shown, press the "CONFIRM" button to finish the pairing procedure.



You can verify the association with the device by going to the Devices menu and verifying that there is an entry "ECG B2BH4" in the list of registered devices.

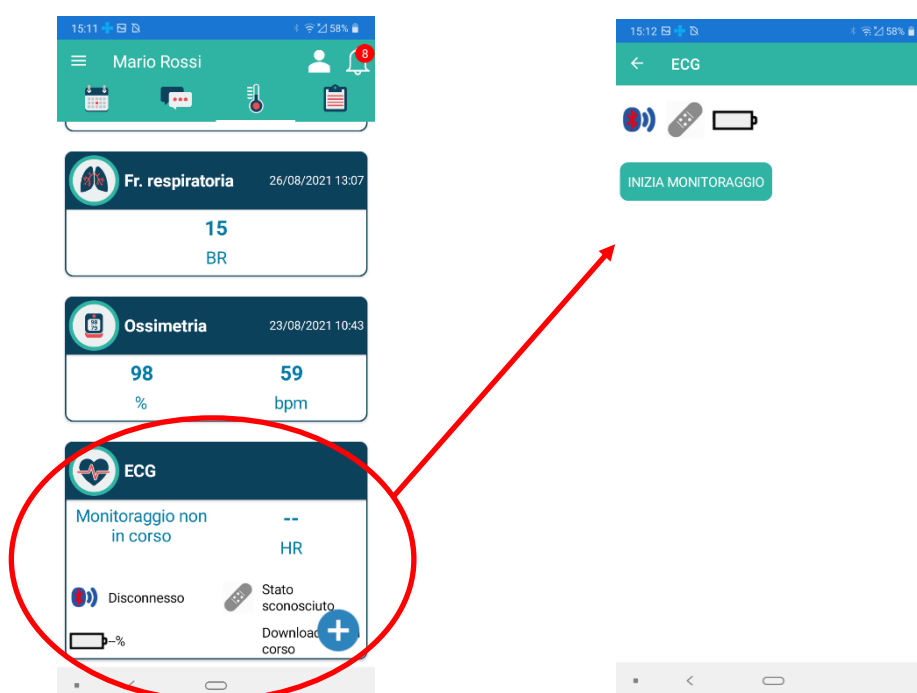
By clicking on the device name, some information about the device is displayed, and at the bottom of the screen there is a "REMOVE DEVICE" button to carry out the removal of pairing; pressing it asks for confirmation that

you really want to disassociate; pressing the "CONFIRM" button removes the pairing. If you want to use the device again, it is necessary to make a new pairing.

Instructions on the use of the ECG

To collect the ECG trace, a monitoring session must be initiated, during which the App reads data from the device via Bluetooth and sends it to the web portal.

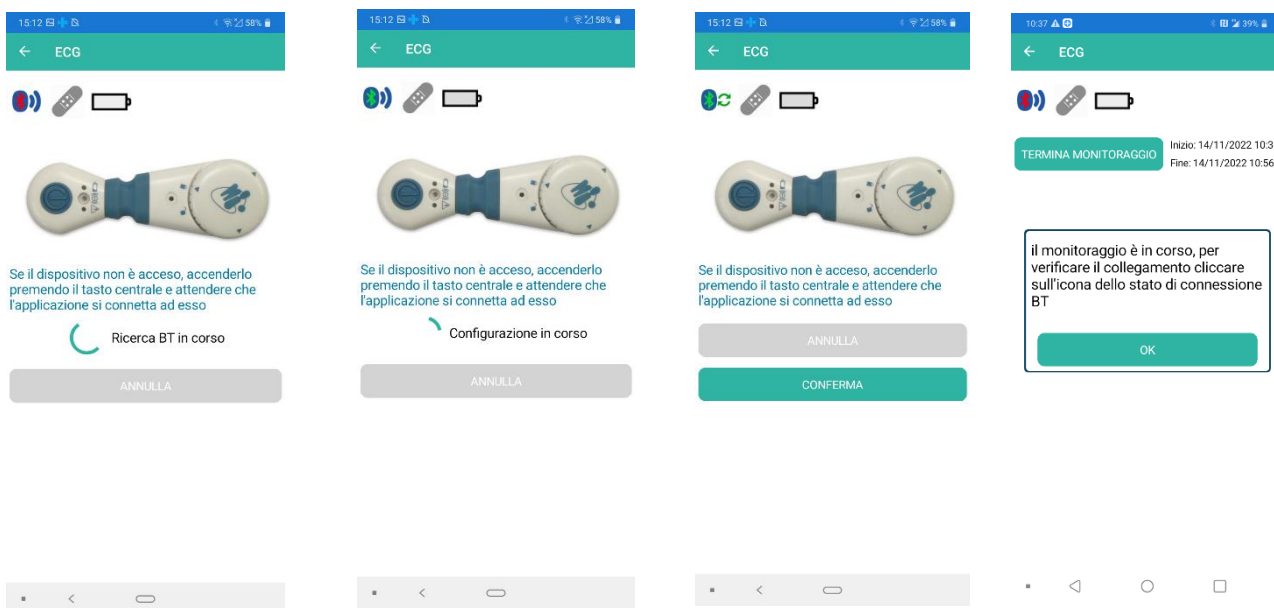
After properly wearing the Hi device and turning it on, following the directions in the relevant manual, you need to go to the measurements section and check that there is an ECG box where information about the current status of the device is displayed (Monitoring session status, Heart rate, Bluetooth connection status, electrode status, battery level, data download in progress).



Tapping within the ECG pane shows the Monitoring screen, where you can start and stop monitoring and check during the session the status of data acquisition and any reports of abnormalities, such as disconnection of one or more electrodes.

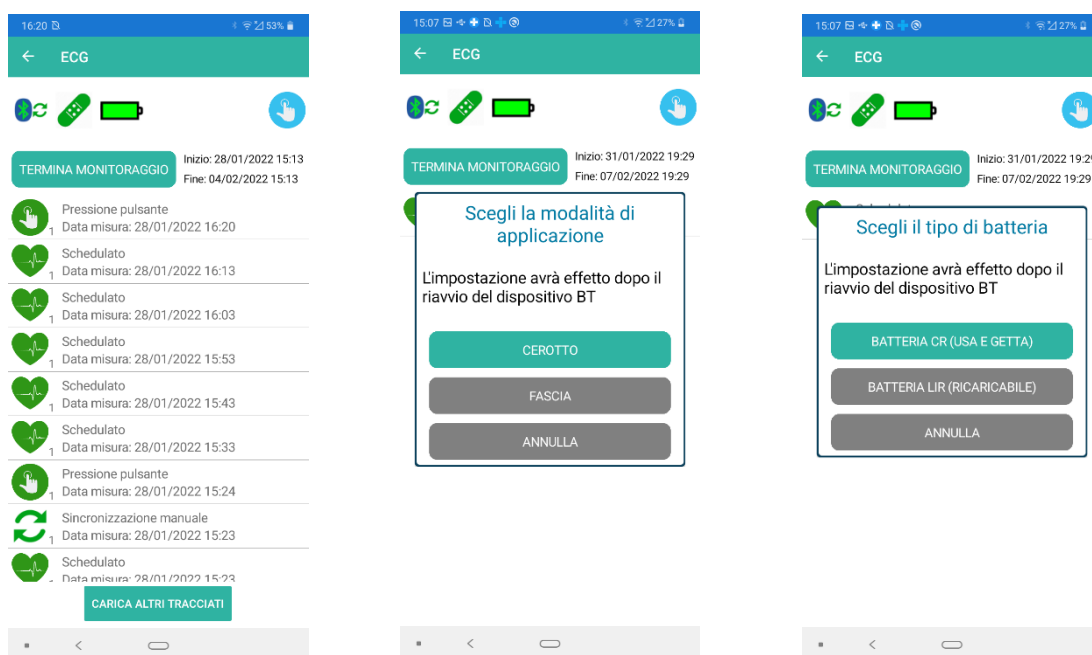
If a session was previously started, the date and time when it ended is also displayed.

Pressing the "START MONITORING" button opens the monitoring screen, with the monitoring status information icons (Bluetooth connection, electrode status and battery level) at the top, and the App searches for the previously associated Hi device and once found is asked to confirm the start of the session. By pressing the "CONFIRM" button, the session is started and the App starts receiving data and any notifications according to the session configuration; the device's central LED switches from steady on to off with a blink every 10 seconds, while pressing "CANCEL" does not start the session and returns to the previous page.




During the session, the scheduled start and end dates of the session are displayed, as well as a "TERMINATE MONITORING" button with which the session can be terminated early.




The central part of the screen shows the list of recent events received during the session, such as receipt of ecg data and electrode disconnection events. As events are collected older events are hidden to prevent the list from becoming too long, if there are available events that are not displayed the "LOAD MORE TRACKS" button is shown with which you can include them in the list.



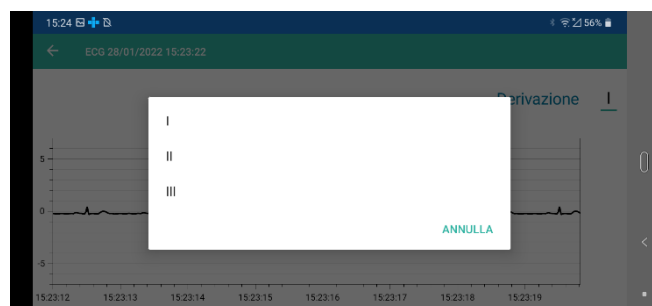
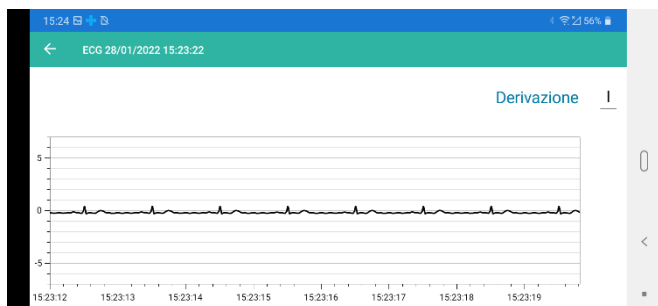
Status icons are displayed at the top of the screen:

-  Bluetooth: indicates the status of the Bluetooth connection between the smartphone and Hi, green if the connection is active and red if it is disabled. The App automatically restores the connection in case of interruptions, such as due to excessive distance between smartphone and device or Hi being turned off. Tapping the icon can initiate the acquisition of a short ecg trace from the device, which is added to the event list and can be viewed by tapping the relevant line and opening a special screen

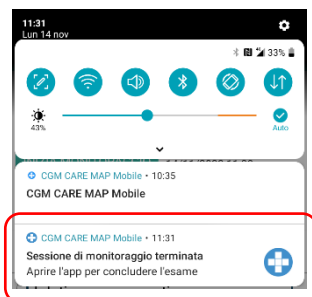
with the trace; It is possible to view individual leads by selecting them using the indicator in the upper right corner (I, II, III).

-  Electrodes: the patch-shaped icon changes color depending on the status of actual contact of Hi's three electrodes with the skin: green if all electrodes are properly connected, gray if at the moment it is not possible to know the status (typically the first time you start a session), red if at least one of the electrodes is not connected or the contact with the skin is not enough to have a good signal. In this case, it is necessary to check that the electrodes are properly connected; the App will notify the user with periodic notifications. By tapping the icon you can select the mode of electrode application: CERCH (normally used configuration) or BAND.
-  Battery: Indicates battery level: green = charged battery, yellow = medium charge, orange = low battery, red = low battery, arrange for replacement immediately. Tap the icon to select the type of battery used, disposable or rechargeable.
-  Manual event: by pressing the button, a manual event, such as an illness or cardiac event deemed abnormal, can be entered so that it can be taken into account by medical personnel who will analyze the trace. The effect is the same as pressing the physical button on the device.

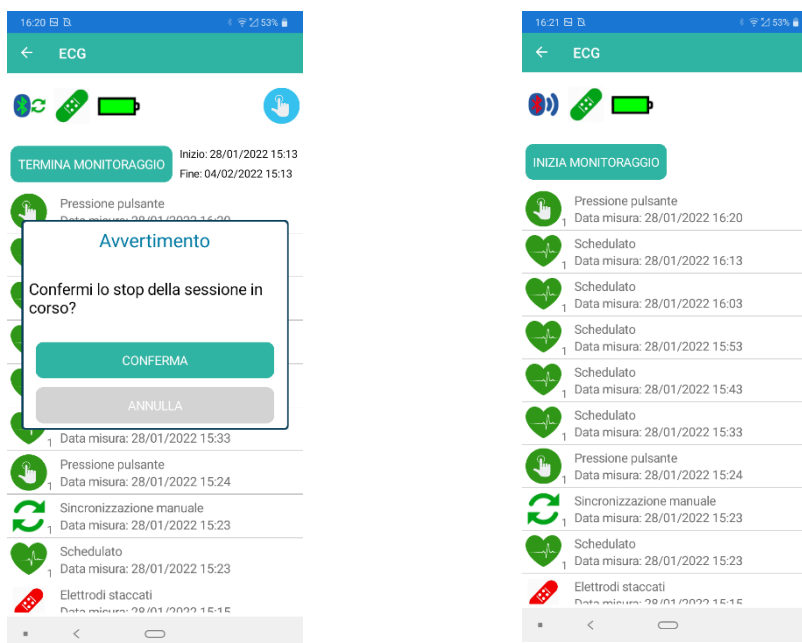
During monitoring you can view the ECG traces collected by tapping the corresponding row in the list, a screen will open where you can view the signal graph for the three leads. You can scroll back and forth through the graph by tapping and the graph and holding by scrolling left and right, to choose the lead to view select its number in the upper right corner.



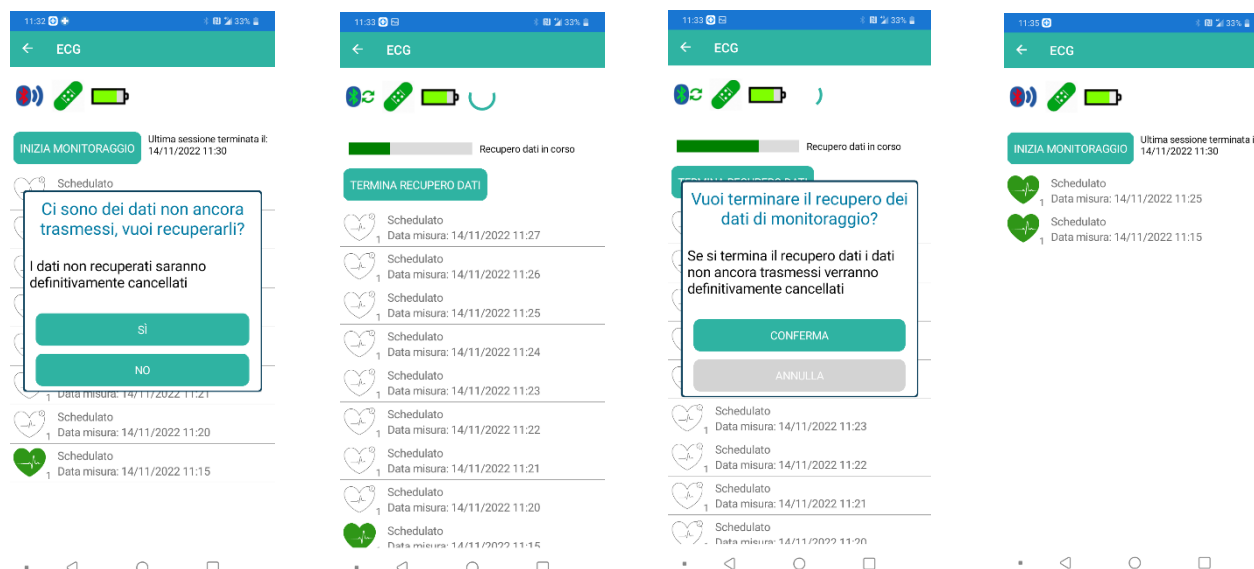
The monitoring session is terminated once the end time set during startup is reached and the connection with the Hi device is closed after retrieving the last available data. You will receive an appropriate notification to indicate the end of the session and possibly request to complete it by initiating the retrieval of data not yet acquired if necessary.



If you want to terminate the session early, you can do so by pressing the "TERMINATE MONITORING" button, a confirmation message is displayed, and pressing the "CONFIRM" button terminates the session.



If the session is terminated prematurely, it is possible that some data have not yet been recovered by the App, a screen is presented asking whether you want to initiate the recovery of the missing data or terminate the session without data recovery.



Pressing Yes starts the missing data recovery, the progress of which is shown with a gray horizontal bar that turns green upon completion, and upon completion the session is closed. If you want to prematurely terminate data recovery press "TERMINATE DATA RECOVERY," the App asks for confirmation and if you press "CONFIRM" the session is terminated without recovering any further data.

WARNING: If you stop the recovery operation, any uncollected data will be deleted from the device and can no longer 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 then available to health care personnel for reference.

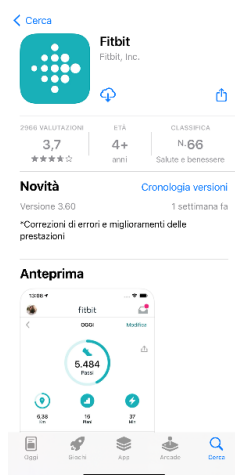
The data will be collected and sent to the server via the FitBit App normally used by the user, which then must be installed on the smartphone and properly configured through the creation of a FitBit profile; CGM CARE MAP Mobile does not make any Bluetooth connection with the FitBit device.

Arrangement

In order for integration with FitBit to be enabled, the user must have:

- installed the FitBit App on a smartphone (not necessarily the one on which the CGM CARE MAP Mobile App is installed, since the latter does not interface with the FitBit device)
- created a FitBit profile
- associated the FitBit device with your smartphone and your FitBit profile.

The installation of the App must be done through the store corresponding to the system on the smartphone (Google Play for Android and App Store for iOS), verifying that the features of the smartphone fall within those compatible with the FitBit App:



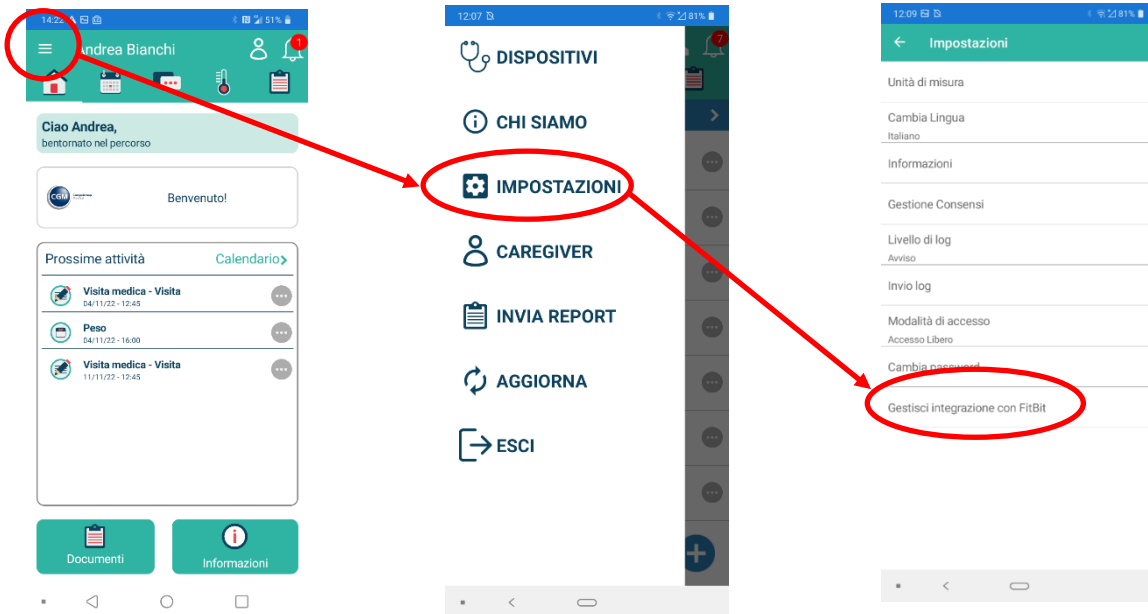
Once the App is installed and launched, if you do not have a FitBit account you must proceed to create one by clicking on "Join Fitbit " and following the instructions displayed by the app. To create a Fitbit account you are asked to enter your date of birth, height, weight and gender to calculate your stride length and estimate your distance, basal metabolic rate and calories burned.

Once the account is created, you need to pair your Fitbit device with your smartphone so that the Fitbit device and smartphone can communicate with each other and synchronize their data. If the pairing is not automatically

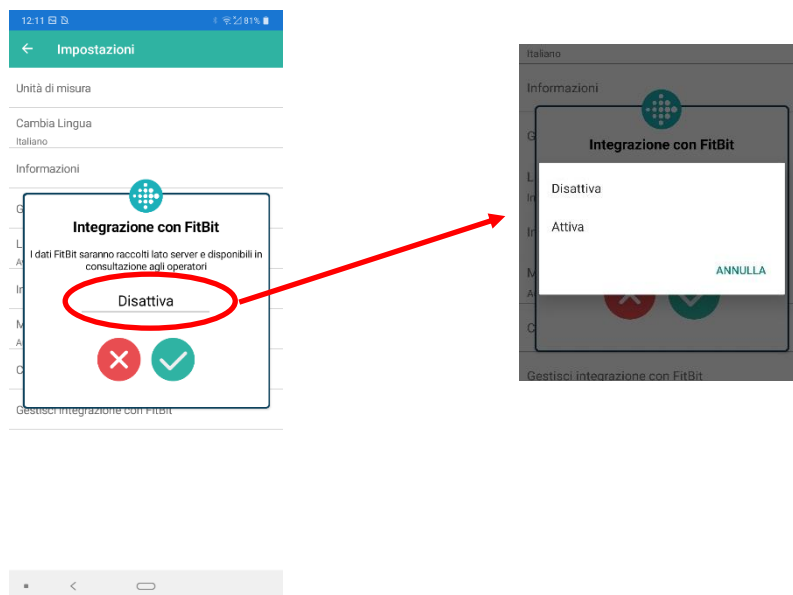
proposed by the FitBit App, click on the "Today" tab , click on the profile picture and then click on "Configure a device," and then choose your device from those displayed in the list.

Enabling and configuring the FitBit service.

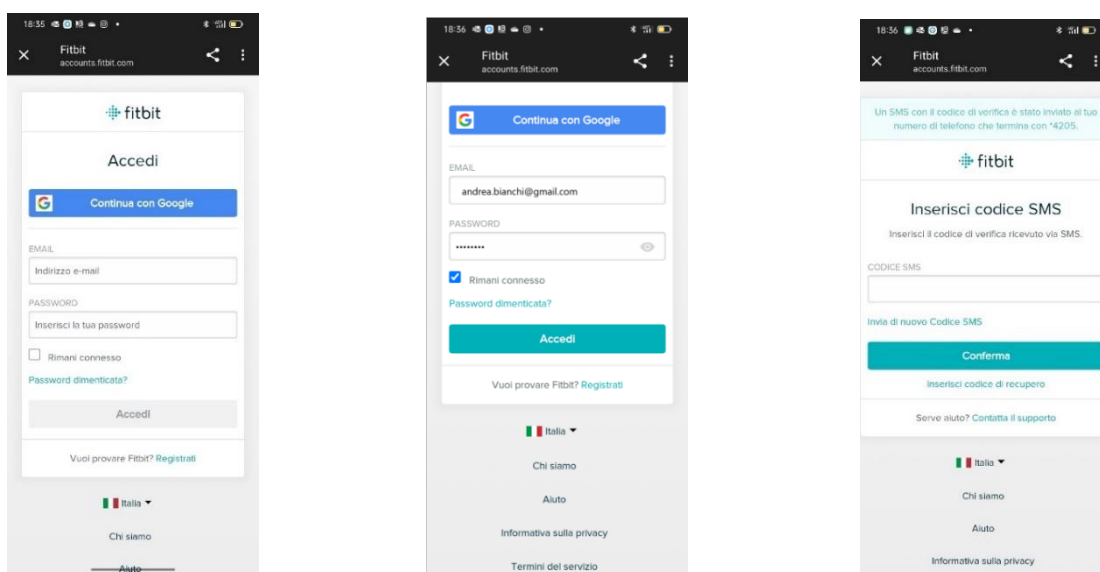
To enable the receipt of data collected by the FitBit device, it is necessary to go to the SETTINGS menu and click on "Manage FitBit Integration."



A mask is presented in which the current status of the integration service is displayed, initially 'Inactive'. Click on 'Disabled' and in the list that appears select 'Enable' and then click on the green check mark to proceed. Verify that you have an active Internet connection because dialogue with the server is required.

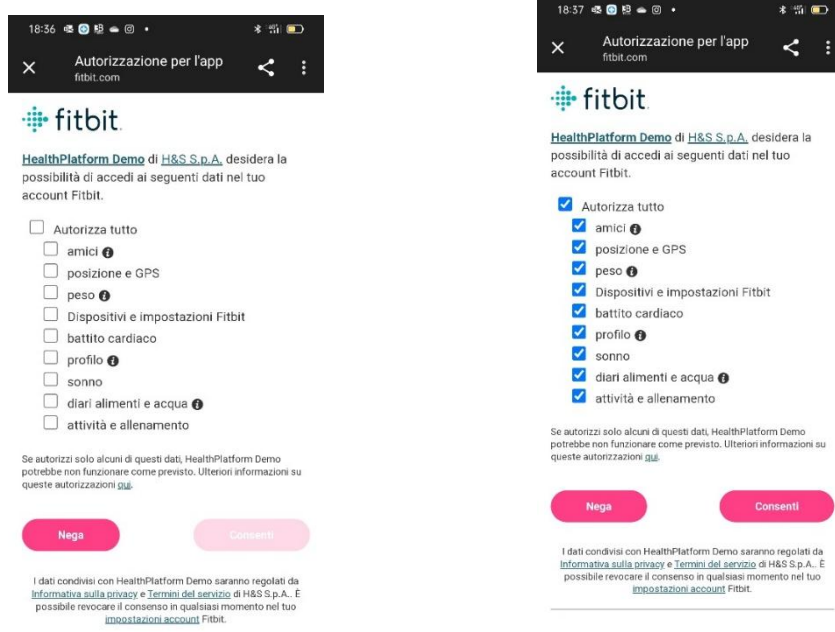


A window opens in which you need to enter the credentials (email and password) of your FitBit account so that FitBit can record your permission to share data with the CGM CARE MAP portal.



Once you have entered your credentials press 'Sign In' to continue. If two-factor authentication is enabled on the FitBit account an additional window will appear in which to enter the code received via SMS and press 'Confirm'.

In the next window you are asked to select the types of data that can be read by the CGM CARE MAP portal. It is possible to select 'Authorize All' or select only some items, but in the latter case some data will not be captured by CGM CARE MAP and the service may not work as expected.



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

Click 'Allow' to authorize access to the data and continue, a registration conclusion window is shown confirming the association of the FitBit profile with your account on the CGM CARE MAP portal, which will proceed daily to capture the recorded data from your Fitbit device.



Using the FitBit service

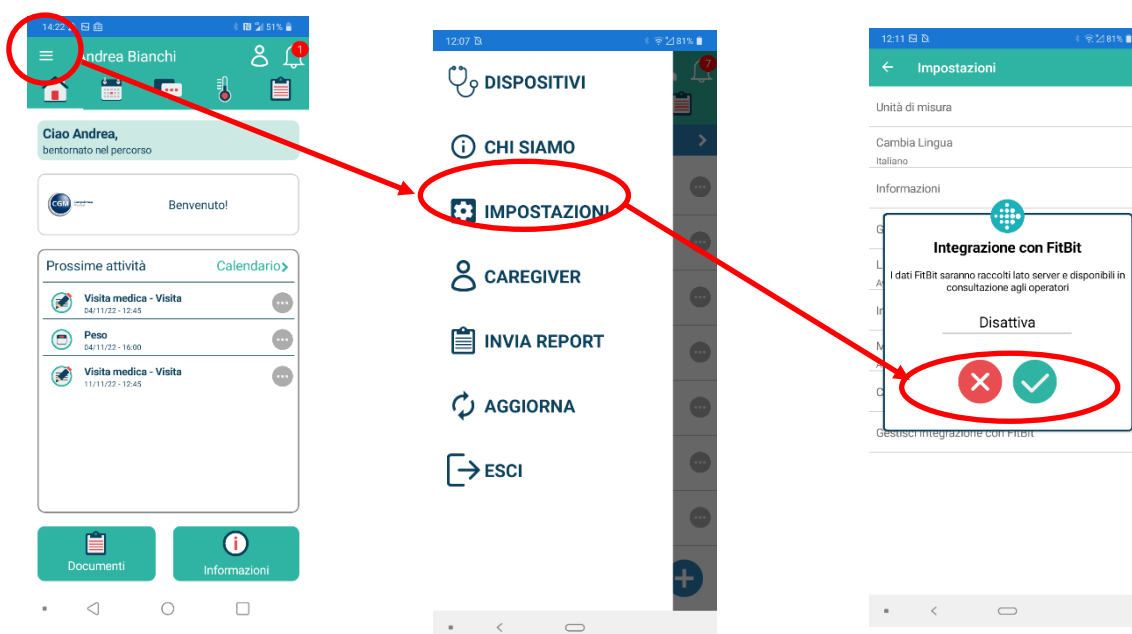
Use the FitBit device normally as needed, wearing it regularly so that it can acquire data continuously.

In order for the acquisition flow to continue normally, it is necessary for the FitBit App to regularly dialogue with the device and send data to the FitBit server so that the CGM CARE MAP portal can read it.

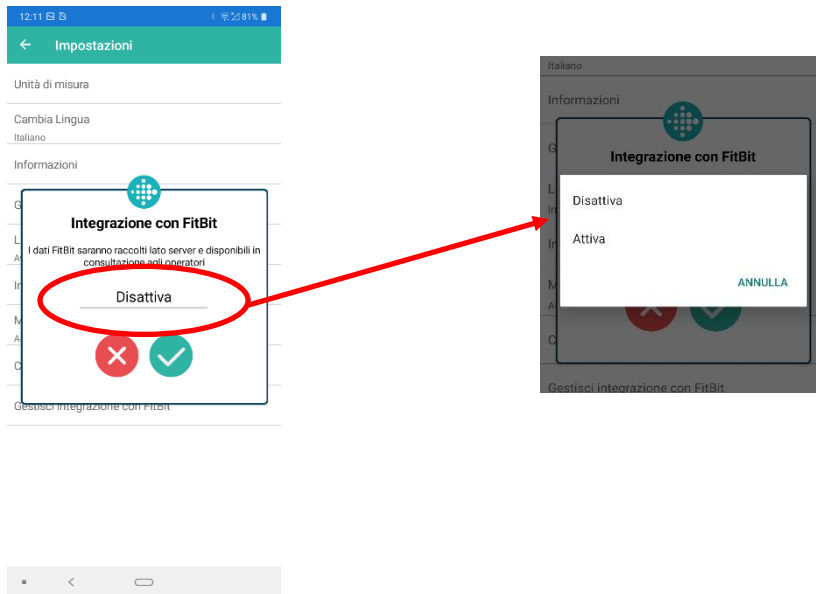
It is possible that on particular occasions the permission granted will expire. In this case, the portal will send the CGM CARE MAP Mobile App a notification advising the user of the inability to access the data and requesting that he or she repeat the enabling procedure explained in the previous section, so as not to interrupt data acquisition.

Disabling the FitBit service

If you want to stop the FitBit service, as with activation you need to go to the SETTINGS menu and click on "Manage FitBit integration."



In the service management mask, where the current integration status is displayed, click on 'Active' and in the list that appears select 'Disable,' then click on the green check mark to confirm.



General information and references

Intended Use

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

- create graphs that show the trend of the monitored vital parameters, set numerous types of personalized thresholds by the doctor and the consequent prioritization and management of the alarms generated;
- view ECG traces, use rulers to measure the trace and apply filters (LowPass, HighPass);
- in case of pressure holter, calculate average values and standard deviation of pressure and heart rate, systolic/diastolic interval, compare with the thresholds set to indicate discarded measurements and calculate the percentage above the threshold;
- in case of spirometry, view the curves received, calculate the theoretical value for various parameters (FVC, FEV1, etc.) and the ratio between real value and theoretical value (% Theoretical).
- in case of continuous oximetry, view the trace and calculate the minimum, maximum and average of the saturation and pulse values, as well as indicating the time intervals in which the value was lower than a series of predefined reference values (e.g. 90 %, 88%, 80%, 70%, 60%).

This allows telemonitoring 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 environments or on patients where the nature of the variations in vital parameters is such that it could create an immediate danger for the patient. (e.g. intensive care units or patients connected to life support systems).

Classification

Classification according to Regulation (EU) 2017/745 Article 51 - Annex VIII rule 11 class IIa.

For product qualification as a medical device, the decision-making scheme found in MDGC 2019-11 is followed, which allows a SW to be qualified as a software DM (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 the patients themselves or with the help of caregivers
- CGM POINT OF CARE: used by healthcare professionals (doctors, nursing staff, pharmacists)

Patients, indications and contraindications

The device is used for patients who require continuous remote monitoring; usually these are patients suffering from chronic pathologies, for which it is important to monitor various clinical parameters and keep the state of health under control. Use in settings and on patients is excluded where the nature of the variations in vital parameters is such that it could create an immediate danger for the patient (for example, intensive care units or patients connected to life support systems). No further limitations of use/specific contraindications for the use of the SW have been identified, in terms of age or characteristics of the patients; It is also possible to use it in the case of patients with reduced cognitive and motor capacity, as they are usually assisted by family members or caregivers, 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

Headquarters: Vie Emilia Parmense, 204 - 29122 Piacenza

Tel. +39 0523 603311

Fax +39 0523 603364

In the operational headquarters in Piacenza.

Specifications

Use of the APP is expected on Android and iOS devices, provided they meet the following limitations on minimum versions of operating systems and hardware:

Minimum hardware requirements:

- RAM memory: min 2GB
- Internal memory: min 32GB
- Connectivity: WiFi and/or 4G-5G, Bluetooth
- Screen of at least 4.7"
- Camera

Operational platform:

- 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 safe source available. Avoid installing applications from unofficial stores or by direct upload of the setup file to your device. We are not responsible for any damage or malfunction due to installations not made through official stores.

Interface features:

The App is equipped with a graphic interface designed specifically for use on mobile devices and is intuitive, in order to facilitate the immediate understanding of the information and data collected.

Characteristics of computer networks:

In order to use the App, a connection with the CGM CARE MAP server is required, in order to authenticate the user, download the configurations and send the acquired data. For the connection, the 4/5G mobile connection or WiFi can be used indifferently, if available.

Some functions are also available offline, such as the acquisition of measurements, the data exchange will then be carried out as soon as the network is available.

Cyber security measures, including protection against unauthorized access:

For the first access it is necessary to use the credentials (and a connection to the server for validation), it is then possible to use the phone authentication method.

The data is stored in encrypted format in a dedicated portion of the smartphone's memory and deleted after a configured period of time.

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

Specific characteristics of the mobile computing platform or other devices or equipment needed to run the software as intended:

To download the App from the Android/iOS stores you must have a valid account to log in.

MANUFACTURED

CGM TELEMEDICINE S.R.L.

a CompuGroup Medical company



WEBSITE.

