

V.2 December 2024

User Manual

CGM POINT OF CARE

Synchronizing Healthcare



CompuGroup
Medical

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Introduction

This manual provides useful information for the proper use of the CGM POINT OF CARE (hereafter also POC) software present on the Tablet/PC with the supplied Windows operating system.

At the end of the document are the main evidences of compliance with Regulation (EU) 2017/745, such as the indication of the manufacturer, classification of the device (Class IIa), 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
- **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

This chapter provides the user with the necessary information in order to use the CGM POINT OF CARE application correctly and safely.

General

- Read the user manual carefully in all its parts before using CGM POINT OF CARE.

- The manufacturer warrants the safety, reliability, and performance of CGM POINT OF CARE 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 POINT OF CARE application needs to communicate with the central server (CGM CARE MAP) via an Internet connection to function properly.
- 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
- The installation and uninstallation of the product are carried out by the Manufacturer or by technicians specifically authorized by the same, contact the Manufacturer for further details.
- 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 authorized by the manufacturer.

Manufacturer	Model	Description
BI	BI-9900	Holter recorder intended for patients requiring ambulatory 12-channel ECG (Holter) monitoring from 1 to 48 hours, frequently used for Assessment of symptoms suggestive of myocardial arrhythmia or ischemia, Assessment of patients for ST segment changes, Assessment of patients with pacemakers, Evaluation of drug reaction in patients who have taken antiarrhythmic drugs.
Cardioline	Walk400h	Walk400h is an ECG holter recorder intended for continuous recording of the ECG signal. The signal recorded in the internal memory of the device is intended to be transferred to a PC for analysis using dedicated Holter ECG analysis software, via USB. The ECG signal is recorded with a patient cable that can have 5, 7 or 10 wires, depending on the number of ECG channels that need to be recorded: 3 channels with 5 or 7 wire cables and 12 leads with 10 wire cable.
A&D	TM 2430/2440	The recorder for ambulatory blood pressure monitoring arterial TM-2440 allows you to take measurements accurate automatic measurement of patients' blood pressure for pre-established durations (e.g. 24 continuous hours).

Cardioline	Walk200b	Walk200b is a non-invasive ambulatory blood pressure (ABP) recorder for 24-hour monitoring. The device measures systolic and diastolic blood pressure and heart rate. Pressure measurements are performed by applying the oscillometric method.
Abbott	iSTAT	i-STAT 1 Analyzer is intended for use in the in vitro quantification of various analytes in whole blood or plasma
Exdia	PT10s	Exdia PT10S is for the in vitro quantitative determination of clinical chemistry analytes in capillary blood with self-analysis
Voden	VChemys	The VChemys [®] system is an in vitro diagnostic medical device (IVD) intended for use in self-analysis and provides first-instance diagnostic data. The VChemys [®] system was designed for the quantitative determination of clinical chemistry values
Voden (DFI)	Uridoctor	UriDoctor TM is a self-analysis device, to be used together with the dedicated UriDoctor strips, for the semi-quantitative reading of urinary parameters
Beurer	BF 1000	Impedance scale for body analysis, with calculation of lean, fat and bone mass, water, metabolic rate
Heine	DeltaOne	Dermatoscope
HeartView	P12L	12-lead electrocardiograph
Cardioline	TouchECG/HD+	12-lead electrocardiograph
FORA	FORA 6 Connect	Bluetooth glucometer
GIMA	P15 - On Call Sure Synch	Bluetooth glucometer
A&D	UA-651BLE	Sphygmomanometer
GIMA	OXY-10	Pulse oximeter
Shenzhen Creative Industry	POD-1W	Pulse oximeter
Shenzhen Creative Industry	SP-20	Pulse oximeter
Hunan Accurate Bio-Medical Technology	WS20A	Pulse oximeter
MIR	MiniSpir New	Spirometer
MIR	Spirobank II	Spirometer
A&D	UC-352BLE	Bathroom scale

- The APP is compatible with the Windows operating system versions listed in the "Technical Specifications" 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.

Controls during use

- The Bluetooth connection is effectively usable if the distance between the devices and the Tablet/PC is of 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 batteries of the devices are charged and bring the devices closer together until the connection is reliably restored.

Software Version

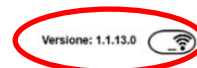
To view the version of the software installed on the pc, click on the icon at the top right of the CGM POINT OF CARE login interface.

Paziente: Nessuno

CGM POINT OF CARE

Nome Utente:

Password:






Then a screen is shown in which the version of the software currently in use and general information about the software manufacturer are shown.

	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 CGM POINT OF CARE	
UDI	(01)00086000573683(8012)v.4.0.0.0
	[www/mm/dd]
MD	
	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.

Login

If the POC does not start automatically when the PC starts, double click on the program icon on the desktop to start it.

When the POC is initiated, the behavior varies depending on the type of facility (and purpose) in which the POC is to operate. Depending on the settings, the POC can be configured to require authentication or to perform automatic authentication with a server-set user.

In case authentication is required, the following screen for entering "**Username**" and "**Password**" will be displayed. This information is provided to POC-enabled users and can also be used to access the Web Portal.

Paziente: Nessuno



Versione: 1.1.13.1 

Entering the required data and clicking on the "**Login**" button authenticates you and takes you to the screen for selecting the organization you want to work with. If the credentials are incorrect, however, an error message is shown.

Organization selection

The screen allows you to select the organization to operate on:

Paziente: Nessuno

Seleziona organizzazione

Versione: 1.1.10.0



Nome	Indirizzo	Telefono	Email
ASS 1 - Cure Ambulatoriali e domiciliari OSPEDALE MAGGIORE			
ASS 1 - Cure Ambulatoriali e domiciliari STOCK			
ASS 1 - SS Anziani e residenzialità VALMAURA			
ASS 5 - S.Giorgio di Nogaro			
Distretto Montale			
Farmacia Passione	Viale di Hes, 10	123456789	hes@test.it
MEDICOPERTUTTI S.R.L.	Via Emilio Praga 28 00137 Roma (RM)		

Avanti

15/03/2023

CGM POINT OF CARE

15:58

Select the organization from those proposed and press Next to display the patient selection screen.

Patient selection

The patient selection screen allows you to choose the patient for whom you want to perform the exam.

Initially, all patients visible to the operator are shown, depending on the user's own profile configuration.

Paziente: Nessuno

Seleziona Paziente

Versione: 1.1.13.0



Ricerca...

Nome:

Appuntamenti previsti

Cognome	Nome	Data di nascita
PAZIENTE DEMO SUPPORTO	Z-POC 001	01/01/2001
PAZIENTE DEMO SUPPORTO	Z-POC 002	02/01/2002
PAZIENTE DEMO SUPPORTO	Z-POC 003	03/01/2003
PAZIENTE EPR 0001	Z-TEST	29/04/2021
PAZIENTE EPR 0002	Z-TEST	28/04/2021
PAZIENTE	TEST	09/04/2012
Prova	Prova	04/10/2023
Rossi	Mario	12/05/1980
Verdi	Cristiano	08/08/1988

Aggiorna dati...

Esci

Nuovo Paziente



At the top is a search bar through which you can filter the list of patients by **first name, last name, social security number or date of birth**. The filter is applied as you type, with no need to press any confirmation key.

The screenshot shows the 'Seleziona Paziente' app interface. At the top, there is a search bar and a 'Paziente: Nessuno' indicator. The main title is 'Seleziona Paziente' and the version is '1.1.3.1'. Below the search bar, there is a section for 'Appuntamenti previsti' with a date of '10/03/2022'. There are buttons for '- 1 giorno' and '+ 1 giorno'. A table displays the appointment details:

Data	Esame	Stato	Paziente
10/03/2022 15:00	Checkup - Screening	Da fare	Paziente Demo 6

At the bottom, there is a 'Lista Pazienti' button and a status bar showing '10/03/2022', 'CGM POINT OF CARE', and '12:12'.

In the upper right corner is the "Scheduled Appointments" button that provides access to exams that were previously scheduled:

The list of booked examinations is displayed, showing the date, time, status (to be performed) and the patient for whom the booking was made.

Using the top bar you can filter appointments by day, moving forward or backward using the "-1 day" and "+1 day" buttons. In case you want to search in a time period, click on the selection box next to "Custom" and after selecting the start and end dates by clicking on them press "Search."

The screenshot shows the 'Appuntamenti previsti' app interface. At the top, there is a search bar and a 'Paziente: Nessuno' indicator. The main title is 'Appuntamenti previsti' and the version is '1.1.3.1'. Below the search bar, there is a section for 'Appuntamenti previsti' with a date of '10/03/2022'. There are buttons for '- 1 giorno' and '+ 1 giorno'. A table displays the appointment details:

Data	Esame	Stato	Paziente
10/03/2022 15:00	Checkup - Screening	Da fare	Paziente Demo 6

At the bottom, there is a 'Lista Pazienti' button and a status bar showing '10/03/2022', 'CGM POINT OF CARE', and '12:12'.

To change the selection dates click on them and change the day, month and year using the + and - buttons, clicking OK to confirm.

Paziente: Nessuno

Ricerca...

Personalizzato

20 - dicembre - 2023

Versione: 1.1.13.1

Cerca

OK

Annulla

New Patient Creation

If the patient you are looking for is not listed, you can add him or her: clicking on the **"New Patient"** button will present a screen where you can enter the **"Tax Code."** It is then necessary to enter a valid tax code and click on the **"Verify"** button in order to continue with the entry of the fields.

Paziente: Nessuno

Seleziona Paziente

Versione: 1.1.0.0

Nuovo paziente

Codice fiscale:

Verifica

Attendere...

If you want to enter an identifier for a person who does not have a valid tax code, for example because he or she is a non-Italian national, you can check the box "Foreign patient identifier code," in which case the formal check on the validity of the code entered will not be made.

If the tax code is already present in the system all other fields are also automatically filled in; if the tax code is not present, the system if possible automatically fills in *Date of birth and gender*; proceed with manual entry or correction of missing data and select "**Confirm.**" If the date of birth is entered incorrectly, the date 01/01/1980 will be entered.

If the "Online Report Pickup" box is checked, exam reports will be made available online and the patient can freely download them using the link received, within a period of time (maximum 45 days). Remember to ask the patient to agree to the specific consent provided in the privacy form.

Once a new patient entry is finished, it will automatically appear in the patient list on the POC and on the CGM CARE MAP WEB portal (showing all e-mail, phone, etc. data).

NB: In some service installations/configurations, the "New Patient" button may not be present or may be disabled, in which case only existing patients can be operated on.

Patient detail

Paziente: Nessuno **Seleziona Paziente** Versione: 1.1.1.0
Nuovo paziente

Paziente: Bianchi Andrea **Dettaglio paziente** Versione: 1.1.13.1

Dati generali

Nome:	Andrea	Cognome:	Bianchi
Data di nascita:	21/02/1967	Sesso:	Maschio
Telefono:	348123456	E-mail:	test_abianchi@test.it

[Visualizza informativa privacy](#)

Referti [Visualizza tutti i referti disponibili](#)

Esame	Data	Referto
Checkup	21/03/2023	

Esami [Nuovo esame](#)

Stato esame	Numero	Descrizione	Dettaglio
Prenotato	1	Holter ECG	
Inviato	1	Bilancia diagnostica	

[Aggiorna dati](#) [Indietro](#) [Modulistica](#) [Apri CGM CARE MAP](#)

Selecting a patient in the patient list opens a summary mask (Dashboard) in which the patient's main data, available reports, and examinations in progress, booked or sent to the referrer are summarized.

Using the appropriate buttons at the bottom, it is possible to access the forms section (diary, privacy form, referral withdrawal proxy) and the CGM CARE MAP web platform. Finally, at the top right, through the "View privacy policy" button, it is possible to access the documentation signed by the patient.

In case there is an exam booked for today, or an exam in progress, you can access the exam detail using the quick access button that appears in the upper right corner (e.g., Continue Holter ECG, in the screen below).

Paziente: Rossi Mario Versione: 1.1.13.0

Dettaglio paziente

Dati generali			
Nome:	Mario	Cognome:	Rossi
Data di nascita:	12/05/1980	Sesso:	Maschio
Telefono:	3314567652	E-mail:	mario.rossi@gmail.com

Visualizza informativa privacy


Continua Holter ECG

Referti

Referrals


Referti Visualizza tutti i referti disponibili

Esame	Data	Referto
Checkup	21/03/2023	

In the Reports section you can access the reports available to the patient. The list displays the most recent reports, clicking on the symbol  displays the pdf of the report and it is possible to print it and give it to the patient:

Paziente: Bianchi Andrea Versione: 1.1.13.1

Riferimento esame: 132.8.20221124154945



Esame Checkup	
Nome:	Andrea Bianchi
Sesso:	M
Data di nascita:	21/02/1967
Data:	24/11/2022 15:51
Codice Fiscale:	BLLNDR67XXXXXX

Misura	Valore	Unità di misura	Valore di riferimento
Glicemia	126 *	mg/dl	60 - 100

Annulla
Stampa

If you want to view any other reports not shown, clicking on "View all reports" opens a detail mask with a list of all the patient's reports; selecting the one you want opens the mask seen above with the possibility of printing.

Examinations

Esami

Nuovo esame

Stato esame	Numero	Descrizione	Dettaglio
Prenotato	1	Holter ECG	
Inviato	1	Bilancia diagnostica	

The most recent examinations performed by the patient are listed, indicating the status:

- Booked
- Ongoing, if there are examinations over several days as, for example, in the case of Holter examinations
- Executed, where the examination has been completed but has not been automatically sent to the server and, possibly, to the referrer
- Sent, i.e., examinations performed and automatically sent to the server and, possibly, to the reporter

For each examination you can view the detail by clicking on the symbol on the right side of the line  .

Paziente: Bianchi Andrea

Esami Prenotati

Versione: 1.1.13.1 

Esame	Data	Stato	Documenti
Holter ECG	21/12/2023 16:30	Prenotati	Nessun documento disponibile

Aggiorna dati

Indietro

Elimina

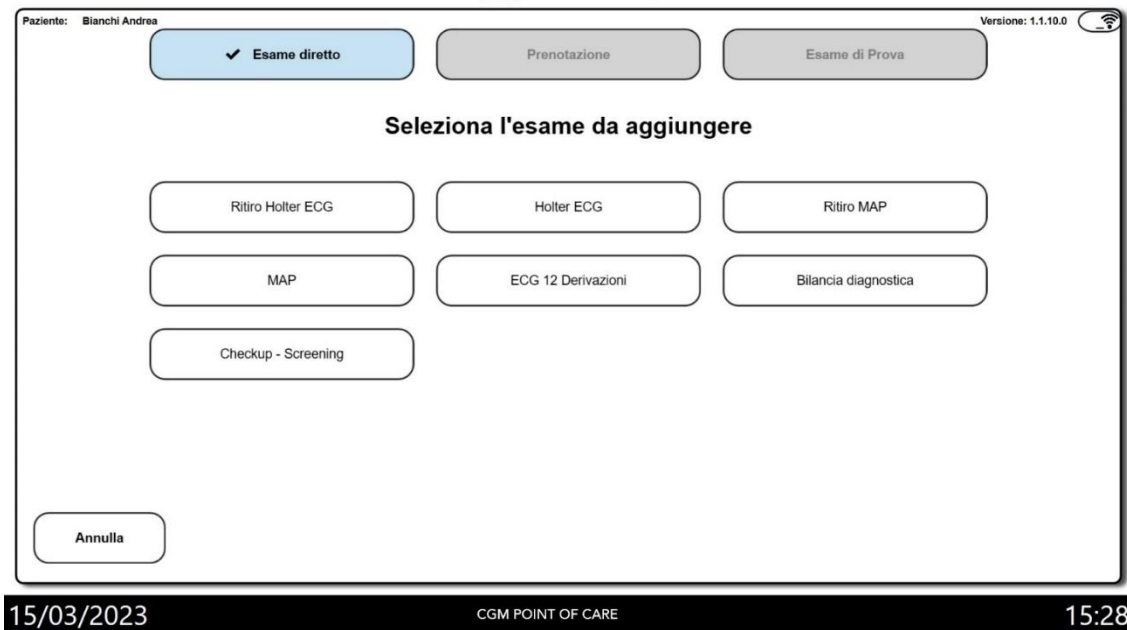
Nuovo esame

Avanti

If the exam has already been taken or submitted, you cannot edit it, while if it is in the Booked status you can delete it, take it (by pressing **Next**) or enter a new exam (by pressing New Exam).

If you want to run one of the exams/appointments already in the system, simply select the row corresponding to the desired exam and then click on the "Next" button. This will take you to the exam execution screen, specific to the type of exam you have chosen.

Pressing "New Exam," either in the initial screen or in this one, takes you to the following screen, where you can request an exam to be performed or booked by clicking on the corresponding button at the top of the screen. The list of examinations that can be selected depends on the devices configured on the POC.



If you select "Direct Examination" at the top of the screen, clicking on the examination will add it to the list of examinations (with current date/time) and you will be able to perform it immediately.

If "Reservation" is selected, it will be possible to indicate the date and time when the exam is to be performed; clicking on the exam will prompt for this information and the exam will be added to the reservation list. For convenience, selecting the date will show the appointments already entered for that day to avoid conflicts or overlaps:

Paziente: Bianchi Andrea Versione: 1.1.13.1

Dettaglio paziente

Visualizza

Appuntamenti in programma il 11/01/2024 :

Ora	Esame	Paziente

Data


Orario

10/01/2024
CGM POINT OF CARE
12:57

Selecting "Training/Testing Exams" will allow you to characterize the exam as a test and thus it will be accounted for separately from the actual exams. The button is only available if you are within the training period (usually the 15 days following training).

NB: If you do not perform an exam entered from POC (excluding booked exams), upon the operator's disconnection from POC it will be deleted and you will need to enter it again. Exams entered from the web, on the other hand, remain visible even after disconnection.

Edit patient master data

You can change the master data of an existing patient by selecting the patient and clicking on the  button to enter the patient's details.

Paziente: Rossi Mario Versione: 1.1.13.0

Dettaglio paziente

Visualizza

Modifica paziente

Codice fiscale:

Codice estero identificativo paziente

Nome:

Data di nascita:

Telefono:

Ritiro referto online:

Cognome:

Sesso:

E-mail:

Once you have made the necessary changes, click on Confirm to save them or Back to cancel them.

Forms

Pressing the "Forms" button provides access to the mask listing the available forms: Privacy, Proxy for Report Collection, and Diary.

Paziente: Bianchi Andrea Versione: 1.1.13.1

Dettaglio paziente

Seleziona il modulo da visualizzare

Selecting "Privacy Form" will open a mask to select the appropriate form based on the type of patient-Major, Minor or Disabled, clicking will open the pre-filled form with the pharmacy and patient data, which should be printed and had the patient (or parents/guardians) fill out.

Paziente: Bianchi Andrea Versione: 1.1.13.1

Dettaglio paziente

- Adult Patient: to be used for most patients, who are of legal age and able to independently express consent to data processing, requires only the patient's signature:

Paziente: Bianchi Andrea Versione: 1.1.9.0

DICHIARAZIONE DI CONSENSO DELL'INTERESSATO

Il sottoscritto Bianchi Andrea, presa visione dell'informativa sulla privacy sopra riportata e consapevole che il mio consenso è puramente facoltativo, oltre che revocabile in qualsiasi momento, esprimo il consenso al trattamento dei miei dati da parte di Prova :

- per la finalità di cui al punto 4.1: fornitura dei servizi Point Of Care (esami diagnostici di 1° e 2° livello), consapevole che il diniego rende impossibile l'erogazione dei servizi richiesti

ACCONSENTO NON ACCONSENTO

- per la finalità di cui al punto 4.2: invio dei referti all'utente tramite e-mail all'indirizzo:

.....

ACCONSENTO NON ACCONSENTO

- per la finalità di cui al punto 4.3: disponibilità dei referti on-line

.....

19/01/2023 CGM POINT OF CARE 19:05

- Minor patient: to be used if the patient is under 18 years of age, in which case consent is given by the minor's parents or a person having legal responsibility/representation:

Paziente: Bianchi Andrea Versione: 1.1.9.0

DICHIARAZIONE DI CONSENSO PER CONTO DELL'INTERESSATO MINORENNE

I sottoscritti:

1) nome cognome data di nascita

luogo di nascita documento riconoscimento n.ro

2) nome cognome data di nascita

luogo di nascita documento riconoscimento n.ro

esercitando la rappresentanza legale sull'assistito e/o la responsabilità genitoriale, in qualità di (specificare se

genitore, tutore, curatore),

oppure

Il Sig./ La Sig.ra. nato/a a

documento di riconoscimento tipo N° Valevole fino al

soggetto affidatario Familiare (indicare il rapporto di parentela)

del/della minore (Interessato/a): Bianchi Andrea

nato/a a il residente a

provincia di in via

Servizio di telemedicina richiesto:

presa visione dell'informativa sulla privacy sopra riportata e consapevole che il consenso è puramente facoltativo, oltre che revocabile in qualsiasi momento, esprimo/esprimiamo il consenso al trattamento dei

19/01/2023 CGM POINT OF CARE 19:05

- Psycho-physically impaired patient: allows consent to be given on behalf of a person incapacitated for psycho-physical reasons:

Paziente: Bianchi Andrea Versione: 1.1.9.0

DICHIARAZIONE DI CONSENSO PER IMPOSSIBILITÀ PSICO-FISICA DELL'INTERESSATO

Considerato che l'Interessato/a Sig./Sig.ra non può prestare il proprio consenso per impossibilità psico-fisica, per incapacità, anche temporanea, di agire o per incapacità di intendere o di volere (in stampatello):

Il Sig./ La Sig.ra.
nato/a a.....
documento di riconoscimento tipo.....**N°**..... **Valevole fino al**

Familiare (indicare il rapporto di parentela)

Convivente **Altro (es. badante, tc)**.....

presa visione dell'informativa sulla privacy sopra riportata e consapevole che il consenso è puramente facoltativo, oltre che revocabile in qualsiasi momento, esprimo/esprimiamo il consenso al trattamento dei dati dell'interessato da parte di Prova :

- per la finalità di cui al punto 4.1: fornitura dei servizi Point Of Care (esami diagnostici di 1° e 2° livello), consapevole che il diniego rende impossibile l'erogazione dei servizi richiesti

ACCONSENTO NON ACCONSENTO

19/01/2023

CGM POINT OF CARE


19:06

Privacy Policy

Pressing the "View Privacy Policy" button opens a mask listing the patient's privacy documents, such as completed and signed disclosures and consents.

Paziente: Bianchi Andrea Versione: 1.1.13.1

Documenti Informativa Privacy

Nome	Data	Documento
Modulo privacy paziente.pdf	12/20/2023 3:36:47 PM	

10/01/2024 11:41

To upload a new privacy document press "Upload document," the following mask will open:

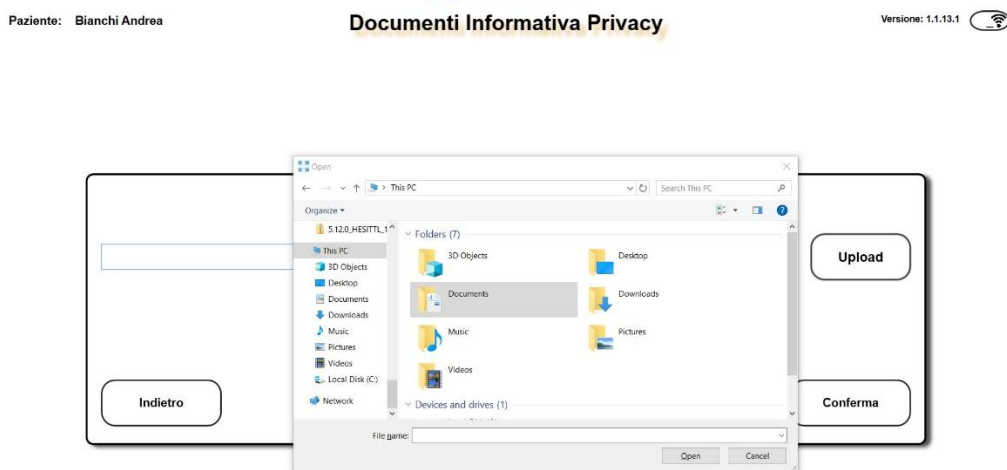


10/01/2024

CGM POINT OF CARE

11:45

In which you can select a local document and upload it to the server. Press "Upload" to open the file selection window, select the desired file and press ok, then press "Confirm" to upload the file.



Open CGM CARE MAP

Allows you to access the CGM CARE MAP portal directly in the detail of the patient you are operating on.

A new window in the PC browser is opened and an automatic login is performed, so that you do not have to enter credentials again, showing the patient detail mask with master data; you can then view and edit data as needed.

Jimmy Connors

Prodotto 1: Prodotto per test 1472; Codice: 00000005; Tel: 0523111111; 0214533658; Mail: marco.rai@cgm.com; Patologie: Note: mah

Stato: Attivo; Data nascita: 15/03/1999

Dati assistito

Nome: Jimmy
 Cognome: Connors
 Codice Fiscale: UTNASS50A01A001B Paziente straniero:
 Tessera Sanitaria: 803800008000846170C Codice esterno:
 Data di nascita: 15/03/1999
 Luogo di nascita: East St. Louis
 Sesso: Maschio Altezza: 170 cm
 Lingua: Italiano
 Nazionalità: USA
 Note: mah
 Indirizzo: test - 29020

Informazioni di contatto

Telefono: 0523111111
 Mail: marco.rai@cgm.com
 Cellulare: 0214533658
 Altri contatti: Azienda fittizia /Altro Coniuge Smith/Coniuge
 Operatore test b Operatore test p/Medico Specialista
 test test 1381/Farmacia Samuele Losi 8Care Giver

Ulteriori informazioni

Condizione assistito: In famiglia, autonomo
 Organizzazione: Ospedale Burlo Garofalo
 Stato monitoraggio: Attivo DISATTIVA
 Fuso orario: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna

SALVA

Performing examinations

Checkup Screening

When you choose to perform the checkup-type examination, you can take one or more of the following measures, depending on the devices actually available:


- Weight
- Pressure
- Pulse oximetry
- Body temperature
- Capillary blood analysis
- TAO Monitoring - INR
- Urinalysis

All selected measurements are listed in the waiting screen, with their respective status ("to be executed" if the measurement has not yet been acquired, or highlighted in green and with the value if already acquired).

Consult the user manual of each device to understand its proper use.

Paziente: Demo 2 Patient

Screening
Misurazioni da fare

Versione: 1.1.13.1 


Tipologia	Misurazioni
Autoanalisi	DA FARE
Indice glicemico	DA FARE

NOTE: It is possible to take the same measurement several times, each new run will replace the previous value with the new one.

With each measurement taken the acquired value is entered into the screen and the examination type is considered completed, once all measurements have been acquired you can end the examination by pressing "End Measurement" to return to the patient summary screen.

Paziente: Demo 6 Paziente

Screening
Misurazioni da fare

Versione: 1.1.3.1 

Tipologia	Misurazioni
Pulsossimetria	Pulsazioni: 74 bpm - Saturazione: 96 %

When the measurements are completed, pressing the "End Measurement" button confirms data acquisition, which is then sent to the server.


It is possible to enter a measurement manually, for example, if it has been taken but its value has not been acquired by the system. Pressing the "Add Measurement" button takes you to the mask that lists the possible measurements that can be entered, divided into single and multiple:

Paziente: Demo 2 Patient Versione: 1.1.13.1 

Screening
Misurazioni da fare

Tipologia	Misurazioni
Autoanalisi Indice glicemico	<p style="text-align: center;">DA FARE</p> <p style="text-align: center;"><input checked="" type="radio"/> Misura singola <input type="radio"/> Misura multipla</p> <p style="text-align: center;">Seleziona il tipo misura</p> <div style="border: 1px solid gray; padding: 5px; margin-bottom: 5px;"> <input type="text"/> </div> <p>Valore*: <input type="text"/></p> <p>Unità: <input type="text"/></p> <p style="text-align: center;"> <input type="button" value="Chiudi"/> <input type="button" value="Inserisci"/> </p>

Select the type of measurement to be entered from the drop-down list:

Paziente: Demo 2 Patient Versione: 1.1.13.1 

Screening
Misurazioni da fare

Tipologia	Misurazioni
Autoanalisi Indice glicemico	<p style="text-align: center;">DA FARE</p> <p style="text-align: center;"><input checked="" type="radio"/> Misura singola <input type="radio"/> Misura multipla</p> <p style="text-align: center;">Seleziona il tipo misura</p> <div style="border: 1px solid gray; padding: 5px; margin-bottom: 5px;"> <input type="text"/> </div> <ul style="list-style-type: none"> Colesterolo Non-HDL Colesterolo totale Creatinichinasi Creatinina cTnI Ematocrito Emoglobina

And then enter a value for the measurement:

Paziente: Demo 2 Patient

Screening

Misurazioni da fare

Versione: 1.1.13.1 

Tipologia	Misurazioni
Autoanalisi Indice glicemico	DA FARE <input checked="" type="radio"/> Misura singola <input type="radio"/> Misura multipla Seleziona il tipo misura Creatinina Valore*: 10 Unità: mg/dl <input type="button" value="Chiudi"/> <input type="button" value="Inserisci"/>

Pressing "Insert" adds the measure to the list.

Paziente: Demo 2 Patient

Screening


Misurazioni da fare

Versione: 1.1.13.1 

Tipologia	Misurazioni
Indice glicemico	DA FARE
Autoanalisi	DA FARE
Creatinina	10 mg/dl

Similarly, multiple measurements can be entered by selecting "Multiple Measurement" at the top of the form. Unlike before, a list of values is shown, each with a field in which to enter the value and relative unit of measure.

Paziente: Demo 2 Patient

Screening
 Misurazioni da fare
Versione: 1.1.13.1 

Tipologia	Misurazioni
Indice glicemico	DA FARE
Autoanalisi	
Creatinina	

Seleziona il tipo misura

Misura singola Misura multipla

Ossimetria

Misurazione	Valore	Unità
% di ossigeno		%
Frequenza Cardiaca		bpm

Annulla
misurazione

Aggiungi
misurazione

Fine misurazione

It is necessary to fill in all the required vlors for the selected measure type and press "Insert," the measure will be saved and sent to the portal. The measurement mask will list all the values entered in the row for the measurement type.

Paziente: Demo 2 Patient

Screening
 Misurazioni da fare
Versione: 1.1.13.1 

Tipologia	Misurazioni
Indice glicemico	DA FARE
Autoanalisi	DA FARE
Creatinina	10 mg/dl
Ossimetria	% di ossigeno: 99 % - Frequenza Cardiaca: 60 bpm

Annulla
misurazione

Aggiungi
misurazione

Fine misurazione

12-lead ECG

Start examination

When the performance of a 12-lead ECG is initiated, a screen is displayed where some additional information about the patient can be entered, such as height, weight, risk factors, reason for the examination, and pathology, as well as any notes:

Paziente: Bianchi Andrea Versione: 1.1.8.2

<p>Altezza (cm)(*): <input style="width: 100%;" type="text" value="182"/></p> <p>Fattori di rischio(*):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Fumatore <input type="checkbox"/> Ex fumatore <input type="checkbox"/> Obesità <input checked="" type="checkbox"/> Diabete mellito di tipo I <input type="checkbox"/> Diabete mellito di tipo II <input type="checkbox"/> Ipertensione arteriosa <input type="checkbox"/> Dislipidemia <input type="checkbox"/> Nessuno 	<p>Peso (kg)(*): <input style="width: 100%;" type="text" value="85"/></p> <p>Motivo dell'esame (*): <input style="width: 100%;" type="text" value="Controllo"/></p> <p>Patologie(*): <input style="width: 100%;" type="text" value="Lieve scompenso"/></p> <p>Note: <input style="width: 100%;" type="text"/></p>
---	---

Inserire i dati obbligatori del paziente prima di procedere con l'esame.

Fields indicated with (*) are mandatory and must be filled in before we can proceed.

The following are instructions for correctly acquiring an ECG for the various ECG devices that are usable with CGM POINT OF CARE.

Aerotel HeartView 12L



When the execution of a 12-lead ECG is launched, we are presented with a screen showing how to prepare the patient and how to properly connect the electrodes.



After connecting the electrodes to the patient, you can proceed with the actual execution of the examination. To do this, simply press and hold the "REC" button on the device for a few seconds until a sound is emitted.



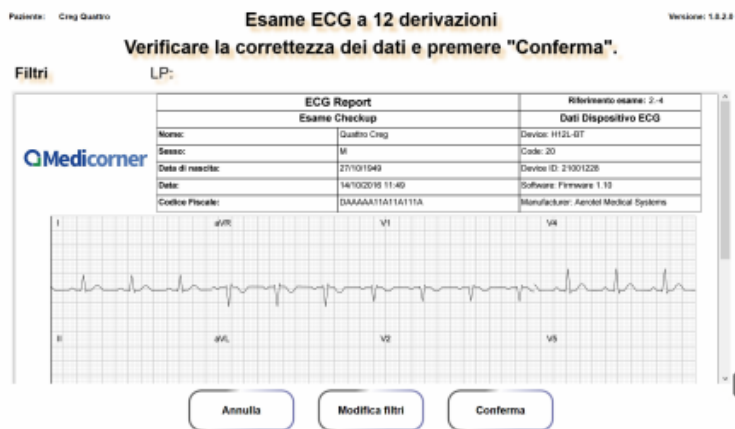
If the electrodes are not all correctly connected, the device will emit a series of intermittent "beeps" (and the "LEAD OFF" LED will flash). It is then necessary to place the electrodes correctly in order to continue.

When all electrodes are properly connected, the device will start acquisition and emit a continuous whistle.

Once the data acquisition is finished, the device sends it to the tablet. We will then see the following screens:



Finally, once the data interpretation is finished, we will see the result of the acquired plot.



If the plot has noise attributable to the environment (e.g., neon lamps), the "Edit Filters" button can be used to apply the desired filter type. This tool is to be used only for environmental interference.



If, on the other hand, the tracing has inaccuracies or some leads were not taken correctly, you can press "Cancel" to be able to redo the examination (after correcting the position of the electrodes).

Instead, pressing "Confirm" accepts the exam, which will then be saved and sent to the web portal for reporting.

Paziente: Ciro Quattri

Esame ECG a 12 derivazioni Versione: 1.0.2.3

Verificare la correttezza dei dati e premere "Conferma".

Filtri LP:

ECG Report		Riferimento esame: 2-4
Esame Checkup		Dati Dispositivo ECG
Nome:	Quattri Ciro	Device: H12_BT
Sexo:	M	Code: 23
Data di nascita:	27/10/1949	Device ID: 21801220
Data:	14/10/2016 11:43	Software: Firmware 1.10
Codice Fiscale:	DAAAAA15A15A111A	Manufacturer: Ansel Medical Systems

We then return to the appointment selection screen, where we will see the status of our exam change to "Done" status.

Paziente: Ciro Quattri

Selezione Appuntamento Versione: 1.0.2.3

Data	Esame	Stato
14/10/2016 11:41	ECG 12 Derivazioni	Eseguito
14/10/2016 11:42	Spirometria	Da fare

If you stay in this screen, after a few seconds we will see the status change to "Sent" (if there is network coverage to be able to send).

Paziente: Cing Quattro

Selezione Appuntamento

Versione: 1.0.2.0

Data	Esame	Stato
14/10/2016 11:41	ECG 12 Derivazioni	Inviato
14/10/2016 11:42	Spirometria	Da fare

Aggiorna dati...

Nuovo

Elimina

Indietro

Avanti

Cardioline Touch ECG HD+



Turn on the ECG by pressing the center button on the front, the blue LED will start flashing quickly, and then the device will beep briefly and the LED will start flashing slowly. Press "Continue Examination."

The screen that opens shows how to prepare the patient and how to connect the electrodes correctly. Connect the electrodes to the patient at the location indicated. In addition, after pressing Next, the Cardioline software is automatically started to establish the connection with the device and acquire the ECG signal.

Paziente: Bianchi Andrea

Esame ECG a 12 derivazioniVersione: 1.1.8.2 **Una corretta registrazione è alla base dell'esame elettrocardiografico****PREPARAZIONE DEL PAZIENTE**

- Far assumere al Pz una posizione rilassata, disteso con torace, polsi e caviglie scoperte

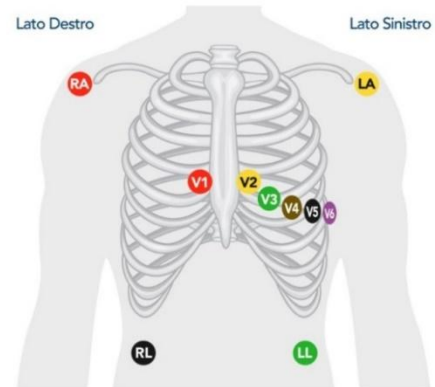
Gli Elettrodi, si applicano al paziente, nell'esecuzione di un tracciato di base, sono 10:

- 4 si applicano agli arti

- 6 al torace, in regione precordiale.

Questi elettrodi registrano 12 derivazioni, ossia 12 punti di vista del cuore.

Il cavo paziente comprende 10 cavetti, ognuno contrassegnato da colori diversi

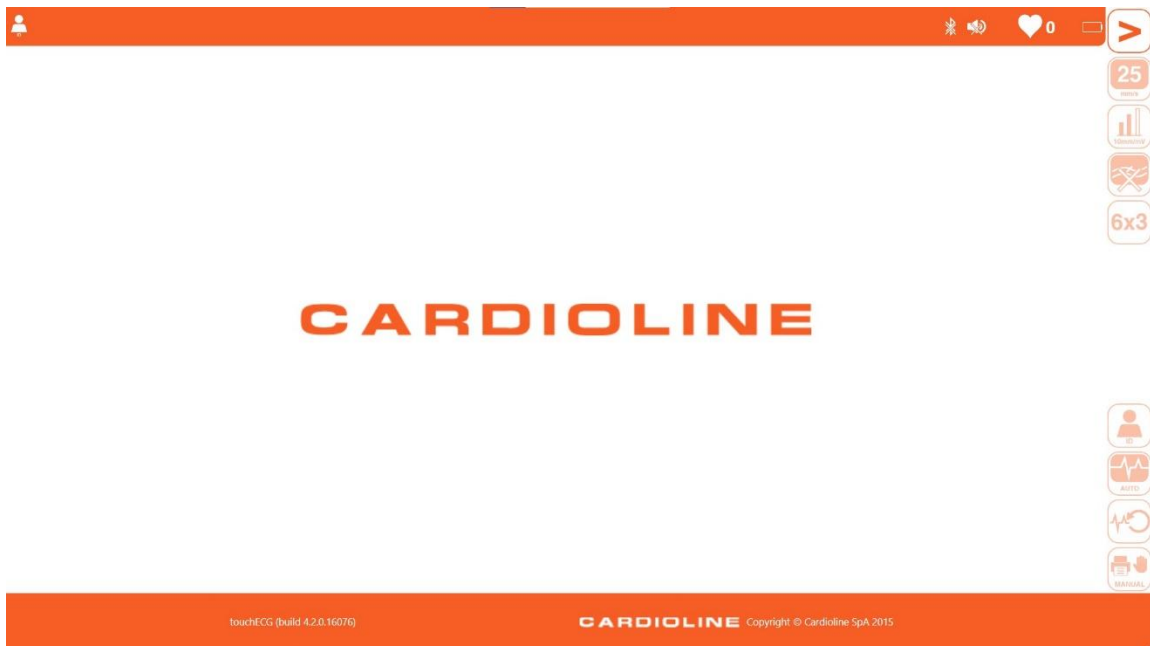
**Effettuare l'esame e attendere la trasmissione del risultato.**

Annulla

17/11/2022

CGM POINT OF CARE

15:19



The program searches for the device via Bluetooth, and once the connection is established, the blue LED light on the front of the device turns solid and the screen changes, showing the serial number of the connected device in the top bar and the patient's name in the upper left. In the middle part, real-time ECG traces are displayed so that the correct connection of all electrodes and signal quality can be checked:

Paziente: Bianchi Andrea

Esame ECG a 12 derivazioni

Versione: 1.1.8.2 

Una corretta registrazione è alla base dell'esame elettrocardiografico

PREPARAZIONE DEL PAZIENTE

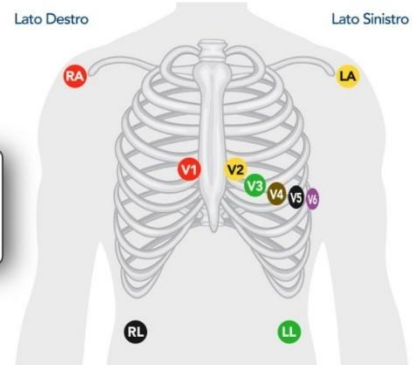
- Far assumere al Pz una posizione rilassata, disteso con torace, polsi e caviglie scoperte

Gli Elettrodi, si applicano al paziente, nell'esecuzione di un tracciato di base, sono 10:

- 4 si applicano agli arti
- 6 al torace, in regione precordiale.

Questi elettrodi registrano 12 derivazioni, ossia 12 punti di vista del cuore.

Il cavo paziente comprende 10 cavetti, ognuno contrassegnato da colori e sigle diversi



Verifica completata. Generazione report in corso...

Annulla

17/11/2022

CGM POINT OF CARE

15:23

Finally, once the interpretation of the data is finished, we will see the result of the acquired plot.

Paziente: Bianchi Andrea

Esame ECG a 12 derivazioni

Versione: 1.1.8.2 

Verificare la correttezza dei dati e premere "Conferma".

Filtri

LP: 20

ECG Report		Riferimento esame 132.2.2022112412293 7
Esame ECG		Dati Dispositivo ECG
Nome	Bianchi Andrea	Device:
Sesso	M	Code: 0
Data di nascita	21/02/1967	Device ID: 08171608
Data	24/11/2022	Software: Firmware 13
Codice Fiscale	BLLNDR67XXXXXX	Manufacturer: Cardioline SpA

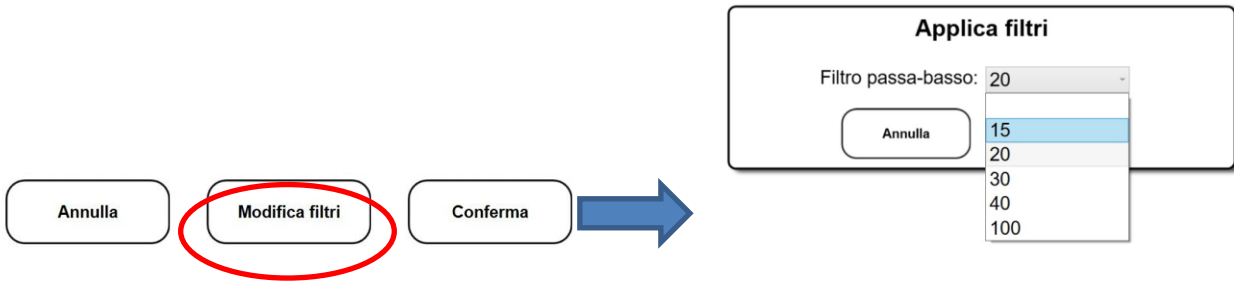
Annulla
Modifica filtri
Conferma

24/11/2022

CGM POINT OF CARE

12:57

If the plot has noise attributable to the environment (e.g., neon lamps), the "Edit Filters" button can be used to apply the desired filter type. This tool is to be used only for environmental interference.



If, on the other hand, the tracing has inaccuracies or some leads were not taken correctly, you can press "Cancel" to be able to redo the examination (after correcting the position of the electrodes).

Instead, pressing "Confirm" accepts the exam, which will then be saved and sent to the web portal for reporting.

Paziente: Bianchi Andrea Versione: 1.1.8.2

Esame ECG a 12 derivazioni

Verificare la correttezza dei dati e premere "Conferma".

Filtri LP: 20

Esame ECG		Dati Dispositivo ECG	
Nome	Bianchi Andrea	Device:	
Sesso	M	Code:	0
Data di nascita	21/02/1967	Device ID:	08171608
Data	24/11/2022	Software:	Firmware 13
Codice Fiscale	BLLNDR67XXXXXX	Manufacturer:	Cardiline SpA

24/11/2022
CGM POINT OF CARE
12:57

We then return to the appointment selection screen, where we will see the status of our exam change to "Done" status.

Paziente: Bianchi Andrea Versione: 1.1.8.2

Seleziona Appuntamento

Data	Esame	Stato
24/11/2022 12:29	ECG 12 Derivazioni	Eseguito

24/11/2022
CGM POINT OF CARE
12:58

If you stay in this screen, after a few seconds we will see the status change to "Sent" (if there is network coverage to be able to send).

Turn off the ECG device by holding down the middle button for at least 5 seconds.

Spirometry

MIR MiniSpir New



When a spirometry exam is started, if the device is not already connected to the tablet, a screen will be presented asking you to connect it.



To connect the spirometer you must use the supplied MicroUSB cable, which should already be connected to the tablet (if it is not already connected, you can still plug it into any of the tablet's USB ports).



Connect the MicroUSB cable to the spirometer (the connector is located at the bottom of the device).



The tablet immediately recognizes the spirometer when it is connected to the MicroUSB cable and asks for confirmation of the data to calculate theorists.

Once these data have been entered, we press "Continue Examination" to continue with the examination. NOTE: Data for "Ethnic Group," "Height," and "Weight" need to be entered only the first time. Subsequent times they will be automatically populated (but you will still be able to edit them).



The tablet switches to the examination execution mode.



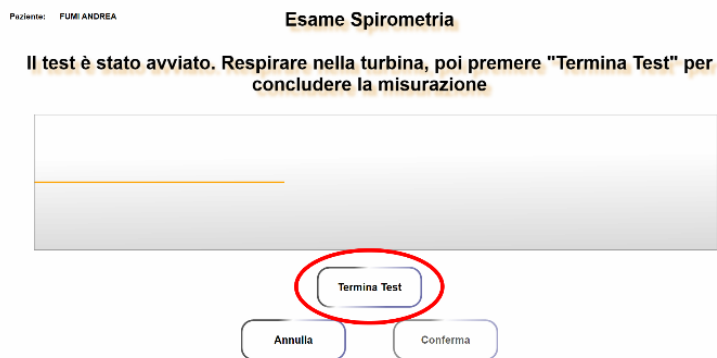
Press the "Start New Test" button on the tablet to start reading data.



Inhale and exhale at the top of the lungs 3 or 4 times.

If the graph shows a flat line, it means the device is not reading the airflow.

Then press "End Test" on the tablet to stop reading the data.

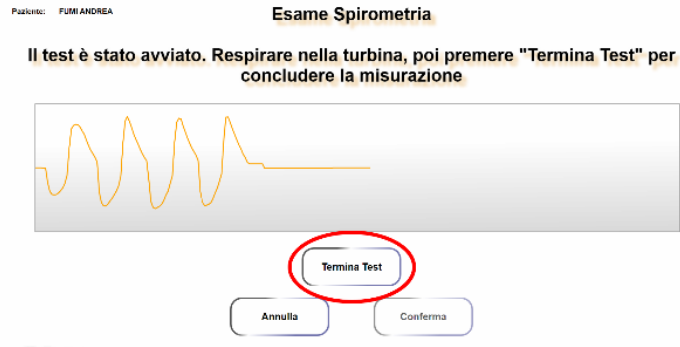


Then check that the disposable turbine is inserted correctly all the way in, and that it is positioned in the right direction.

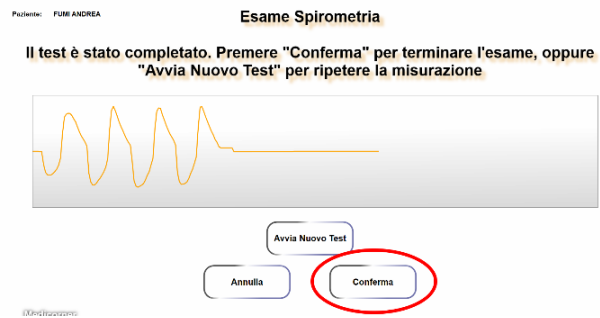
If necessary, try pulling it out and inserting it in the other direction.

Press "Start new test" again.

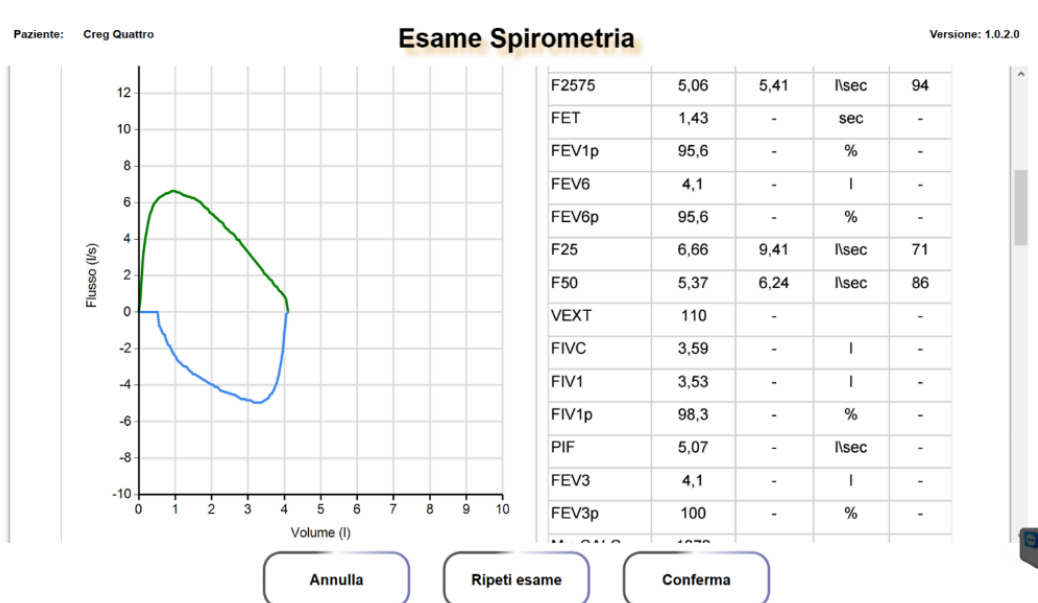
If the graph shows a correct wave of inhalation and exhalation flow, wait for 3 or 4 complete breath acts and then press "End Test."



If the result is satisfactory, press "Confirm," otherwise follow the procedure again and press "Start New Test."



After pressing "Confirm" the summary screen is shown where you can preview the trace that is sent to the referring physician.



If the curve is acceptable (similar to the image above) and the values seem correct, you can confirm the examination by pressing "Confirm", otherwise by pressing "Repeat Examination" you can perform spirometry again.

Press "Exit" to return to the reservation screen.



MIR Spirobank II

Select the Spirometry examination:

Paziente: PAZIENTE DEMO SUPPORTO 2-TEST 001

Versione: 1.1.11.0

Esame diretto Prenotazione

Seleziona l'esame da aggiungere

The POC performs Bluetooth scanning to search for the device. During this step, the spirometer automatically turns on



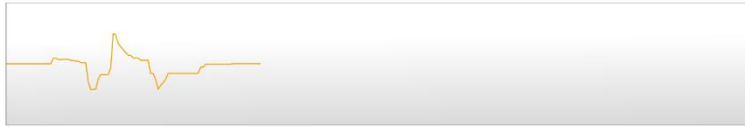
Once the device is connected, the screen for collecting anamnestic information is displayed:

Fill in the fields and press "Confirm Examination" to continue, the information to successfully run the examination is displayed. Press on "Start New Examination."



To perform the spirometry test, place your lips on the white cardboard mouthpiece of the turbine and first perform a forced inhalation, then a forced exhalation. A trace showing the detected airflow is displayed at the bottom of the screen:

Il test è stato avviato. Respirare nella turbina, poi premere "Termina Test" per concludere la misurazione



Termina Test

Once the exam is finished, press "End Test."

On the screen that appears, click on "Add Measurement" to record a new spirometry curve; alternatively, select the spirometry curve to be included within the report and click on "Finish Examination."

Editor's note: It is recommended that the spirometry test be performed at least three times to obtain a repeatable and acceptable result.

Paziente: PAZIENTE DEMO SUPPORTO 2-TEST 001 **Esame Spirometria** Versione: 1.1.11.0

Riferimento esame: 171.4.20230406102825

Esame Spirometria	
Nome:	Z-TEST 001 PAZIENTE DEMO SUPPORTO
Sesso:	M
Data di nascita:	26/05/2019
Data:	06/04/2023
Codice Fiscale:	ZTSPZT01A01A001A

CGM CARE MAP
Connected Patient System

Altezza: 170cm
Peso: 88kg

Annulla Ripeti esame Conferma

After selecting the curves and clicking on "Conclude Exam," on the screen that appears give click on "Confirm" to proceed to final closing of the exam.

Dermatoscopic Analysis

HEINE DELTAOne



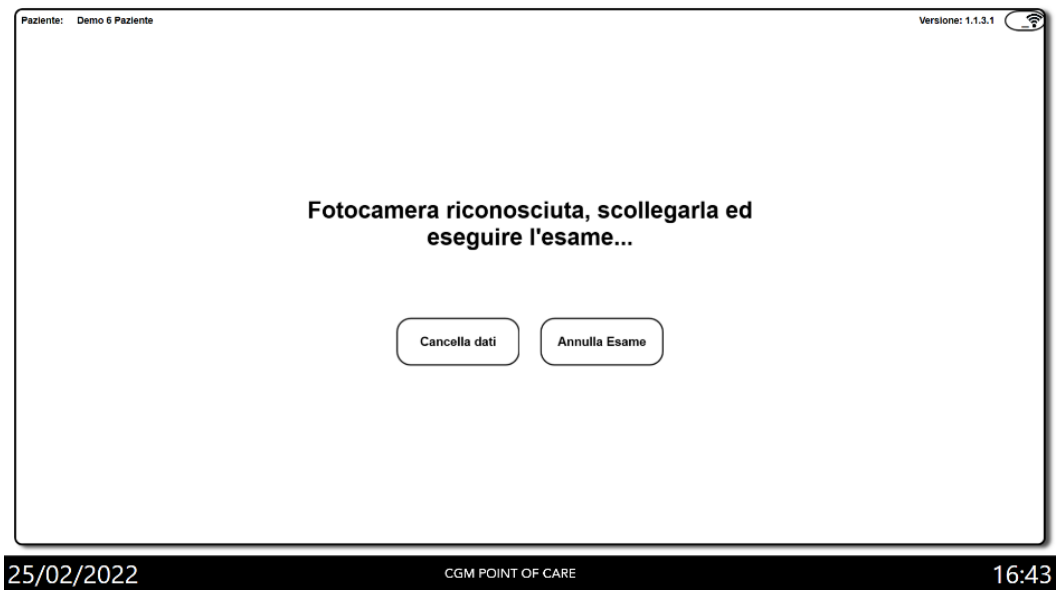
The examination is performed using the smartphone camera and the special adapter provided with the instrument, which allows the dermatoscope to be mechanically connected to the cell phone. When starting a dermatoscopy examination, the PC/tablet prompts to connect the camera.



To do this, simply make sure the smartphone is turned on, plug the appropriate USB cable into any free USB port (if it is not already plugged in), and then connect the cable to the smartphone via the regular charging usb connector.



Press under "Select Device" to select the smartphone from the listed devices and press "Confirm," a mask will appear confirming the connection:



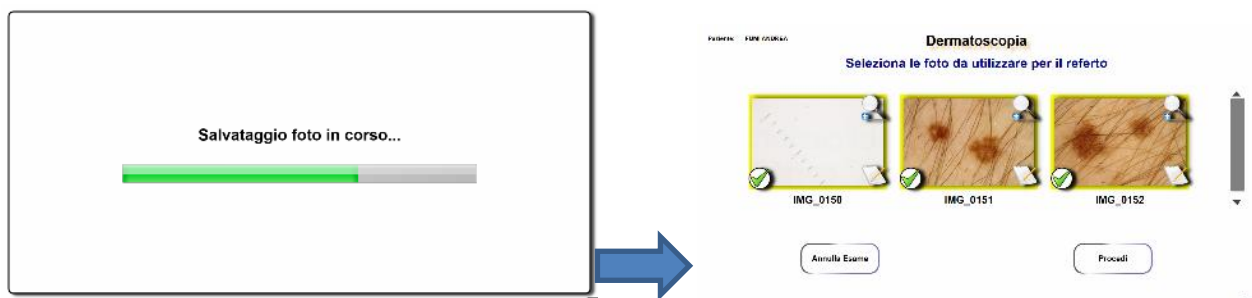
Then disconnect the smartphone and proceed with image acquisition.

When you have finished "taking" photos (or capturing images), you can proceed to turn off the internal illumination of the dermatoscopic lens using the center button.

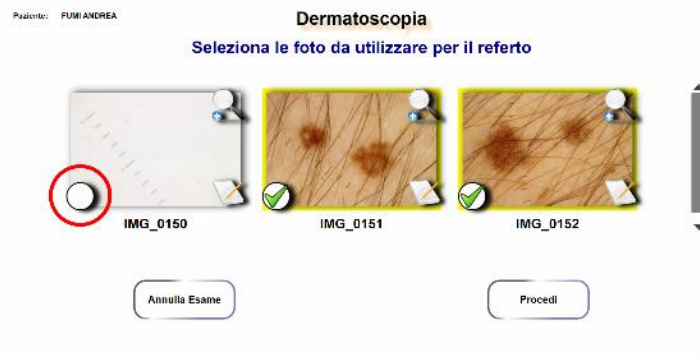
Connect the smartphone to the PC/tablet.



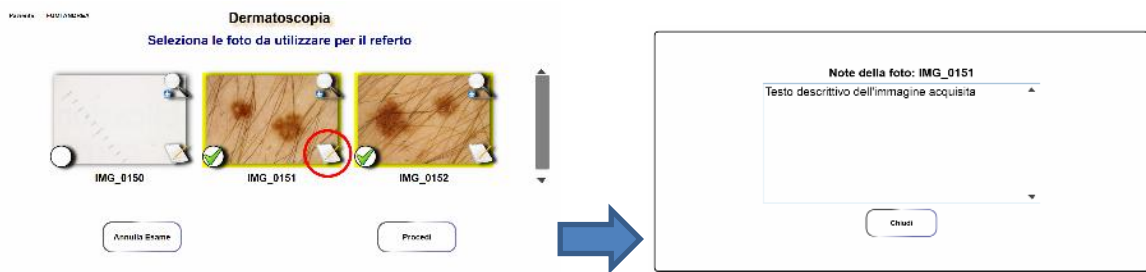
Images are downloaded automatically.



Select only "valid" images, that is, that we want to send the referring physician. To do this, simply remove the green check mark in the lower left corner of each photograph to prevent it from being sent.



Descriptive text (if needed) can also be added for each photograph by pressing the notebook icon in the lower right corner of each photograph.



When the procedure of selecting images and entering descriptive texts has been completed, pressing the "Proceed" button displays the summary of the 'examination.



You can press "Back" to change your selection, or "Proceed" to finally confirm the examination and send the data to the referring physician.

Disconnect the smartphone from the PC/tablet.

Holter Pressur

This feature allows a Holter pressure test to be performed by handing over a special device to the patient for a period of time of 24 or 48 hours and downloading the recording data once it is returned.

Delivery to the patient

The steps necessary to properly initiate the examination for both types are described below, leaving the operational description of the specific steps for each device to subsequent chapters.

From the assisted list, select the patient to open the dashboard and press the "New Examination" button:

Paziente: PAZIENTE DEMO SUPPORTO Z-TEST 021 **Dettaglio paziente** Versione: 1.1.13.0

Dati generali:
 Nome: Z-TEST 021
 Data di nascita: 09/03/2003
 Telefono: 3474193986
 Cognome: PAZIENTE DEMO SUPPORTO
 Sesso: Maschio
 E-mail: ocramilazza@gmail.com

[Visualizza informativa privacy](#)

Referti
 Nessun referto disponibile

Esami [Nuovo esame](#)

Stato esame	Numero	Descrizione	Dettaglio
Prenotato	0		📄

[Aggiorna dati](#) [Indietro](#) [Modulistica](#) [Apri CGM CARE MAP](#)

Select the Holter pressor exam on the next screen:

Paziente: PAZIENTE DEMO SUPPORTO Z-TEST 021 **Dettaglio paziente** Versione: 1.1.13.0

[Visualizza](#)

Esame diretto Prenotazione

Seleziona l'esame da aggiungere

[Dermatoscopia](#) [Checkup - Screening](#) [ECG 12 Derivazioni](#)

[Spirometria](#) [Holter pressorio](#) [Holter ECG](#)

[Annulla](#)

On the next screen, the patient's medical history information must be entered, then click "Next."

Paziente: PAZIENTE DEMO SUPPORTO Z-TEST 021 **Holter pressorio** Versione: 1.1.13.0

1 **Anamnesi** **2** **Modulistica** **3** **Configurazione device**

Fattori di rischio(*):

- Fumatore
- Ex fumatore
- Obesità
- Diabete mellito di tipo I
- Diabete mellito di tipo II
- Ipertensione arteriosa
- Dislipidemia
- Nessuno

Motivo dell'esame (*): controllo

Patologie(*): nessuna

Annulla Avanti

Download the diary and give it to the patient for recording symptoms felt during the recording.

Download the device intake form and have the patient sign it (1). You can upload the signed form using the "Taking Charge Form" upload button on the right side of the following screen (2).

Finally, in order to proceed give confirmation that you have had the intake form signed and handed the diary to the patient (3). Then click on "Next."

Paziente: PAZIENTE DEMO SUPPORTO Z-TEST 021 **Holter pressorio** Versione: 1.1.13.0

1 **Anamnesi** **2** **Modulistica** **3** **Configurazione device**

1 Download

Diario Modulo presa in carico

Delega ritiro referto

3 Confermi di aver consegnato al paziente il diario e fatto firmare il modulo presa in carico del dispositivo?

Upload

Modulo di presa in carico **2**

N.B. Upload non obbligatorio

Annulla Indietro Avanti

You must then specify the recording duration in the daytime and nighttime time slots. Select the recording duration in the night time slot. Click on "Next."

Paziente: PAZIENTE DEMO SUPPORTO Z-TEST 021 **Holter pressorio** Versione: 1.1.13.0

1 Anamnesi 2 Modulistica 3 Configurazione device

Seleziona la fascia notturna prevista

Ora Inizio: 21:00 Ora Fine: 07:00

Annulla Avanti

Select in the same way the measurement interval for the daytime range.

Pressure measurements will be taken every 15 minutes during the day, every 30 minutes at night. Click on "Next."

Paziente: PAZIENTE DEMO SUPPORTO Z-TEST 021 **Holter pressorio** Versione: 1.1.13.0

1 Anamnesi 2 Modulistica 3 Configurazione device

Seleziona l'intervallo di misurazione

Giorno Notte

15 minuti 30 minuti

Annulla Avanti

Specify the recording duration, select 24 or 48 hours, and click "Next."

Paziente: PAZIENTE DEMO SUPPORTO Z-TEST 021 **Holter pressorio** Versione: 1.1.13.0

1 Anamnesi 2 Modulistica 3 Configurazione device

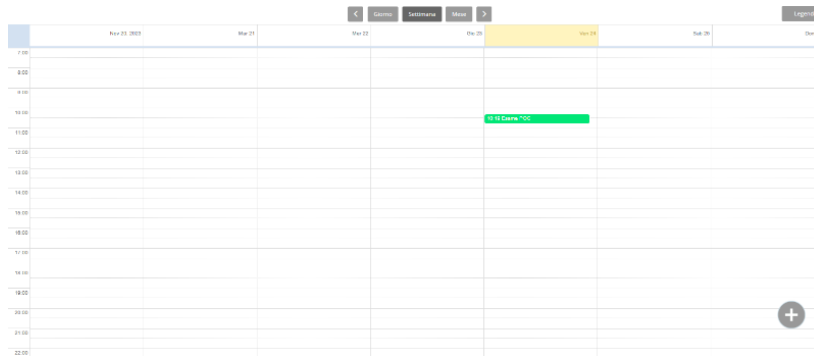
Impostare la durata prevista della registrazione.

24 ore

48 ore

Annulla Indietro Avanti

This configuration automatically creates a "POC EXAMINATION" type activity on the patient calendar, also visible on the operator's calendar, on the day the patient finishes registration and returns to the facility for device return and data download.



At this point it is necessary to connect the device to the POC to clear the data and prepare it for the new session. **CAUTION:** If this step is not performed there is a risk that if a new "MAP" exam is performed directly, previously recorded data may be reused and associated with the selected patient.

Paziente: PAZIENTE DEMO SUPPORTO Z-TEST 021 **Holter pressorio** Versione: 1.1.13.0

1 Anamnesi 2 Modulistica 3 Configurazione device

Collegare il dispositivo

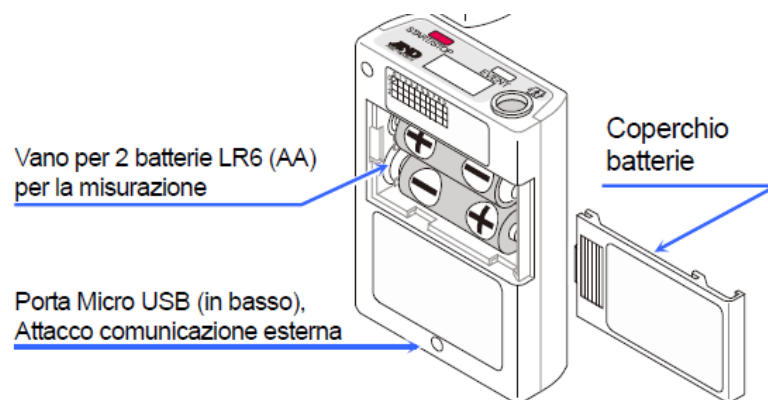
Annulla Indietro

The following shows the operations to be performed depending on the device used.

A&D TM-2440

It is always recommended to replace the batteries before handing the device to the patient, as if the batteries have insufficient charge it may fail to complete the 24/48 hours of recording.

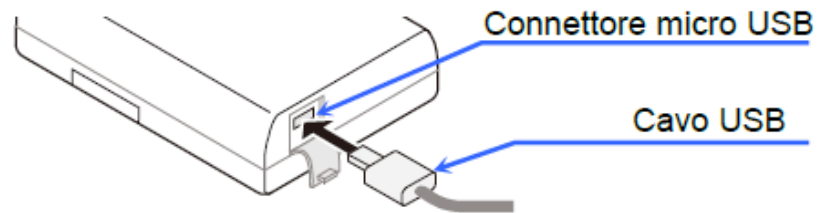
Once the batteries are inserted, the device automatically turns on showing the current time on the display.



Connect the supplied USB cable (USB cable with Micro-USB connector, maximum length 1.5 m) to the PC/Tablet.



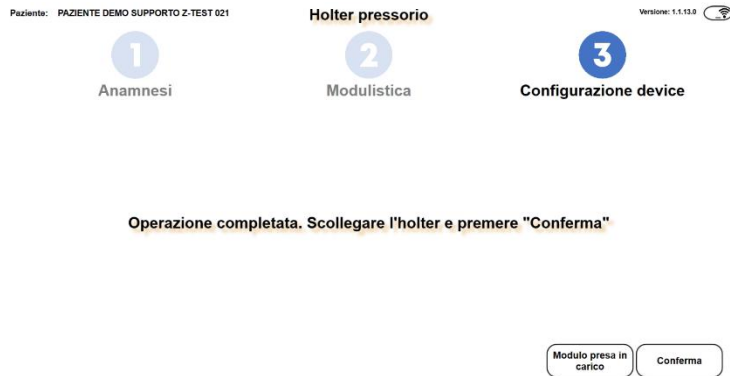
Plug the cable plug into the connector on the underside of the device, covered by the rubber stopper.



The device display shows a key and the word OFF



The PC/tablet configures the device in seconds and signals when the device can be disconnected.



Click on "Confirm" to conclude the device configuration.



Once the holster is disconnected from the POC, press the EVENT key to make the screen light up: check that the time is correct and that the clock symbol (indicated by the arrow in the illustration) appears on the left side, indicating that the automatic measurement program set up is active. In case the symbol does not appear, press and hold the EVENT button until it appears.



Have the patient wear the cuff.

Place the cuff with the tube facing upward and the white stamp on the vein. The cuff should be positioned so that it is one to two centimeters from the elbow crease.

The tube should pass behind the patient's neck.




Insert the end of the cuff tube into the round socket on the front of the device and screw the terminal clockwise.


Insert the device inside the case that was provided with the device. Attach the case to the patient's waist, taking advantage of either the belt provided with the device or the patient's belt, if he or she is wearing one.

At this point the patient can be discharged and will return at the end of the examination to return the device.

Cardioline Walk200b



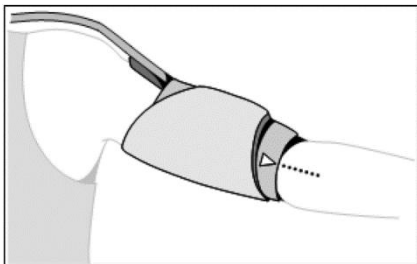
Insert the batteries into the device and turn it on with the ON/OFF button .


Press the  button for five seconds to turn on the Bluetooth connection and wait until BT appears on the screen. Once the Bluetooth connection is turned on, the CGM POINT OF CARE software automatically connects to the device and loads the previously set registration configuration.



Click on "Confirm" to conclude the device configuration.

- Place the cuff on the upper arm, running the air tube around the patient's neck to the recording device.
- Connect the air hose to the device: push the hose firmly onto the connection until you hear a click.



- Before starting the holter recording, it is necessary to make a manual recording by pressing the 
- This measurement will be used to verify the correct operation of the device. Holter recording will start automatically with the measurement frequency set during device configuration.

At this point, the patient can be discharged and will return at the end of the examination to return the device and download the data.

Return of the device

At the end of registration, the patient returns the device and data downloading takes place.

CAUTION: There is no congruence check on the selected patient, which must be the one used for the "MAP Withdrawal" exam.

Once the patient is selected from the Assisted list, click on "Continue Holter pressorio" on the button in green in the upper right corner of the patient dashboard. Alternatively, open the detail from the exam list below.

Paziente: PAZIENTE DEMO SUPPORTO Z-TEST 021 **Dettaglio paziente** Versione: 1.1.13.0

Dati generali
 Nome: Z-TEST 021 Cognome: PAZIENTE DEMO SUPPORTO
 Data di nascita: 09/03/2003 Sesso: Maschio
 Telefono: 3474193986 E-mail: ocramilazza@gmail.com

Visualizza informazioni privacy
 Continua Holter pressorio

Referti
 Nessun referto disponibile

Esami Nuovo esame

Stato esame	Numero	Descrizione	Dettaglio
In corso	1	Holter pressorio	

Aggiorna dati Indietro Modulistica Apri CGM CARE MAP

- Loading the patient diary.

Paziente: PAZIENTE DEMO SUPPORTO Z-TEST 021 **Holter pressorio** Versione: 1.1.13.0

3 Configurazione device 4 Caricamento diario paziente 5 Scaricamento dei dati

Carica il diario paziente

Annulla Indietro Avanti

The diary will be saved and made available to the referrer in the exam detail. Alternatively, the "Diary" section of the CGM CARE MAP web platform can be accessed to download the patient diary.

Configure the actual nighttime bands of registration for proper dipping profiling of the patient.



Turn on the device and connect it via USB or Bluetooth with CGM POINT OF CARE to download data, similar to what was done during delivery. (A&D TM-2440: If the clock symbol is still on the device display, you must turn off the automatic acquisition mode by holding down the "EVENT" button for about 3 seconds until the clock symbol disappears).



The summary of the examination is shown on the screen, if the data is correct, press the "Confirm" button.



Then the examination is concluded and automatically sent to the referee.

Paziente: PAZIENTE DEMO SUPPORTO Z-TEST 021 **Holter pressorio** Versione: 1.1.13.0

3 Configurazione device 4 Caricamento diario paziente 5 Scaricamento dei dati

Verificare la correttezza dei dati e premere "Conferma".

Riferimento esame: 214.5.20231026113700

Esame Holter pressorio	
Nome:	Z-TEST 021 PAZIENTE DEMO SUPPORTO
Sesso:	M
Data di nascita:	09/03/2003
Data:	25/10/2023 12:03

MEDICOPERTUTTI

Annulla Conferma

Holter ECG

Delivery to the patient

From the assisted list, select the patient for whom to perform the examination and press the "New Examination" button found on the patient dashboard.

Paziente: Nessuno **Seleziona Paziente** Versione: 1.1.13.1

Ricerca... Nome: Appuntamenti previsti

Cognome	Nome	Data di nascita
PAZIENTE DEMO SUPPORTO	Z-POC 002	02/01/2002
PAZIENTE DEMO SUPPORTO	Z-POC 003	03/01/2003
PAZIENTE EPR 0001	Z-TEST	29/04/2021
PAZIENTE EPR 0002	Z-TEST	28/04/2021
PAZIENTE	TEST	09/04/2012
Prova	Prova	04/10/2023
Rossi	Mario	12/05/1980
Verdi	Cristiano	08/08/1988

Aggiorna dati... Esci Nuovo Paziente

Paziente: DEMO 014 PAZIENTE **Dettaglio paziente** Versione: 1.1.13.1

Dati generali
 Nome: PAZIENTE Cognome: DEMO 014
 Data di nascita: 01/01/1919 Sesso: Maschio
 Telefono: E-mail: A@A.AA

Visualizza informativa privacy

Referti (Visualizza tutti i referti disponibili)

Esame	Data	Referto
ECG 12 derivazioni	15/11/2023	

Esami **Nuovo esame**

Stato esame	Numero	Descrizione	Dettaglio
Prenotato	0		
Eseguito	2	Holter ECG, Holter pressorio	
Inviato	3	Spirometria, Ritiro holter cardiaco	

Aggiorna dati Indietro Modulistica Apri CGM CARE MAP

Then select the "Holter ECG" exam from the list of available exams.

Paziente: DEMO 014 PAZIENTE **Dettaglio paziente** Versione: 1.1.13.1

Visualizza

Esame diretto Prenotazione

Seleziona l'esame da aggiungere

Spirometria Holter ECG Checkup - Screening

ECG 12 Derivazioni Associa kit telemedicina Dissocia kit telemedicina

Holter pressorio

Annulla



Enter the patient's medical history information, then click "Next."

Paziente: DEMO 014 PAZIENTE Holter ECG Versione: 1.1.13.1

1
2
3

Anamnesi
Modulistica
Configurazione device

Fattori di rischio*:

- Fumatore
- Ex fumatore
- Obesità
- Diabete mellito di tipo I
- Diabete mellito di tipo II
- Ipertensione arteriosa
- Dislipidemia
- Nessuno

Motivo dell'esame*:

Patologie*:

test

Annulla
Avanti

Download the diary and give it to the patient for recording symptoms felt during the recording.

Download the device intake form and have the patient sign it (1). You can upload the signed form using the upload button "Intake form" found on the right side of the following screen (2). Finally, give confirmation that you have had the intake form signed and handed the diary to the patient (3). Then Click on "Next."

Paziente: DEMO 014 PAZIENTE Holter ECG Versione: 1.1.13.1

1
2
3

Anamnesi
Modulistica
Configurazione device

↓
Download

1
Diario

Modulo presa in carico

Delega ritiro referto

3 Confermi di aver consegnato al paziente il diario e fatto firmare il modulo presa in carico del dispositivo?

↑
Upload

2

Modulo di presa in carico

N.B. Upload non obbligatorio

Annulla
Indietro
Avanti

Set the duration of registration. This configuration, in addition to setting the recording duration, automatically creates an activity type "POC EXAMINATION" on the patient calendar, which is also visible on the operator's calendar, on the day the patient finishes recording and returns to the facility for device return and data download.

Paziente: DEMO 014 PAZIENTE Holter ECG Versione: 1.1.13.1

1
2
3

Anamnesi
Modulistica
Configurazione device

Impostare la durata prevista della registrazione.

- 24 ore
- 48 ore

Annulla
Indietro
Avanti



Then prepare the device for use and prepare the patient to perform the examination.
 This operation differs depending on the device used, below are the details for each.

Cardioline Walk400h

Insert the battery into the compartment located in the back.



Turn on the device and plug the USB cable into the device socket. The other end of the USB cable should be connected to the POC.



Connect the device to proceed with the configuration. Then, click on "Confirm."

Paziente: DEMO 014 PAZIENTE 1 Anamnesi	Holter ECG 2 Modulistica	Versione: 1.1.13.1 Paziente: DEMO 014 PAZIENTE 3 Configurazione device	Paziente: DEMO 014 PAZIENTE 1 Anamnesi	Holter ECG 2 Modulistica	Versione: 1.1.13.1 Paziente: DEMO 014 PAZIENTE 3 Configurazione device
Collegare l'holter.			Operazione completata. Scollegare l'holter e premere "Conferma"		
Annulla		Indietro		Modulo presa in carico Conferma	

Then disconnect the USB cable from the holer and connect the cable with the electrodes.



Patient preparation

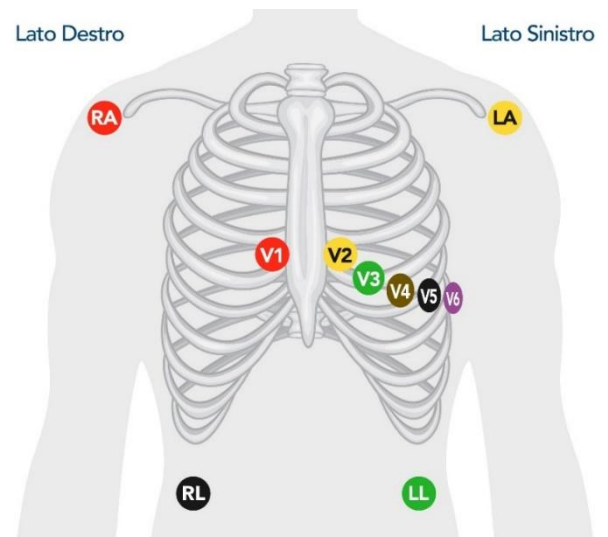
- ✓ Have the patient assume a relaxed, lying or semi-reclining position
- ✓ Cleansing the chest
- ✓ Place the 10 electrodes according to the following scheme

Peripheral electrodes

- Yellow electrode (LA): left humerus
- Red electrode (RA): right humerus
- Black electrode (RL): right hip
- Green electrode (LL): left hip

Precordial electrodes:

- Red electrode (V1): right hemithorax, at the fourth rib
- Yellow electrode (V2): left hemithorax, at the fourth rib
- Green electrode (V3): along the submammary line, slightly to the left of V2
- Brown electrode (V4): along the submammary line, at a distance of 3 cm from V3
- Black electrode (V5): along the submammary line, at a distance of 3 cm from V4
- Lilac electrode (V6): along the sub-axillary line, at a distance of 3 cm from V5




Turn on the device by pressing the center knob.

From the main screen you can access:

- Settings menu to access system settings.
- Start Recording menu to start holter recording.
- Information menu to access device information.
- Power off to put the device on standby or turn it off.



- Click on the "Start Recording" button to proceed with holter recording. 
- Click "Next" on the holter recording settings screen (a). Then click "Next" again to skip the voice recording step(b).

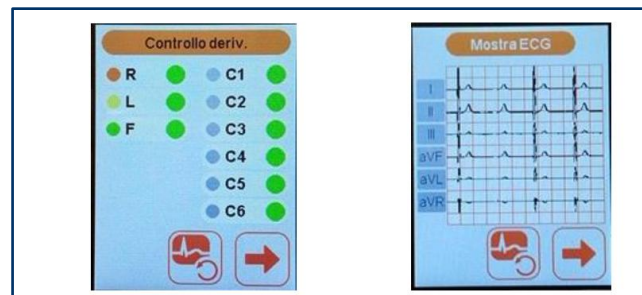



(a)



(b)

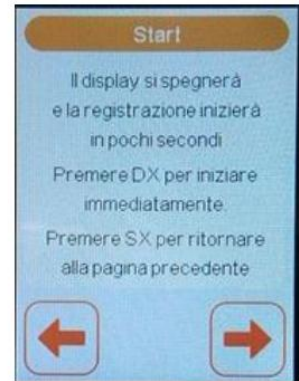
View the ECG tracing taken in real time on the 12 leads and check for proper electrode adhesion. On the first page you can see the ECG trace for the first six leads; click "Next" to view the remaining six leads on the second page.



- Then press "Next" to confirm . Click Next again to confirm and start recording. Recording starts after 30 seconds.

The start and stage of registration are reported as follows:

- the device display goes out;
- the blue status LED starts flashing (test in progress);
- the green battery led goes out.

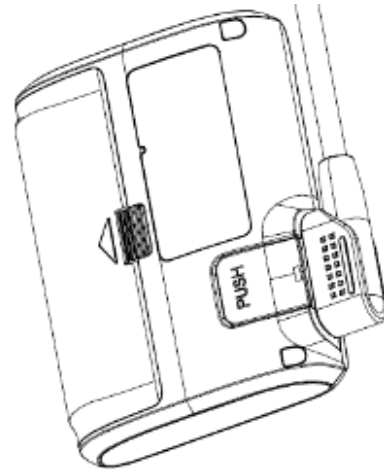


- Insert the device inside the case that was provided with the device. Attach the case to the patient's waist, taking advantage of either the belt provided with the device or the patient's own belt, if he or she is wearing one. You may dismiss the patient who will return at the end of the examination to return the device.

BI 9900



Press the center button on the device, the Holter will turn on and then display the message "Connect patient cable!" Now connect the appropriate USB cable to the device and then to the PC.



"PC Connection" appears on the display and the POC performs device configuration, when finished the POC prompts to disconnect the Holter and press the "Confirm" button.



CAUTION: This step will also erase any previous exams still in the device's memory; make sure you have properly downloaded the data as they will no longer be recoverable after erasure.

Disconnect the USB cable from the POC and device, connect the patient cable to the device, and perform electrode placement on the patient (see detail described for Walk 400h), the ECG trace graph appears on the device display and you can verify that the connections are correct.



If everything is okay, quickly press the center button twice (double click) to start the recording session. The display will show the words "WAIT" and a 2-minute countdown, after which the device beeps audibly and the display turns off, while the LED in the upper right corner flashes slowly to indicate that the session is in progress.



Insert the device inside the case that was provided with the device. Attach the case to the patient's waist, taking advantage of either the belt provided with the device or the patient's belt, if he or she is wearing one.

At any time it is possible to check the status of the session by pressing the down arrow button on the right, "RECORD" is displayed on the screen, the elapsed time since the start of the session, the date and time, and the expected duration of the session.

Pressing the down arrow key and then the middle key records a user event, the display lights up and "Event" appears in red at the bottom right.

It is possible to dismiss the patient who will return at the end of the examination to return the device.

Return of the device

At the end of registration, the patient returns the device and data downloading takes place.

BI 9990: If the recording session has not yet ended, press the center key and the two arrow keys simultaneously, a confirmation prompt appears with "No" highlighted. Press an arrow key to highlight "Yes" and then press the center key. "END" and the total duration of the session is shown.

Once the patient is selected from the Assisted list, click "Continue Holter ECG" on the button in green in the upper right corner of the patient dashboard. Alternatively, open the detail of current examinations from the examination list below.

Paziente: DEMO 014 PAZIENTE **Dettaglio paziente** Versione: 1.1.13.1

Dati generali
 Nome: PAZIENTE
 Data di nascita: 01/01/1919
 Telefono:
 Cognome: DEMO 014
 Sesso: Maschio
 E-mail: A@AAA

Visualizza informativa privacy
 Continua Holter ECG

Referti
 Nessun referto disponibile

Esami

Stato esame	Numero	Descrizione	Dettaglio
Prenotato	0		
In corso	1	Holter ECG	

Aggiorna dati Indietro Modulistica Apri CGM CARE MAP

Load the patient diary, then click "Next."

Paziente: DEMO 014 PAZIENTE **Holter ECG** Versione: 1.1.13.1

3 Configurazione device 4 **Caricamento diario paziente** 5 Scaricamento dei dati

Diario.pdf

Annulla Indietro Avanti

The diary will be saved and made available to the referrer in the exam detail. Alternatively, the "Diary" section of the CGM CARE MAP web platform can be accessed to download the patient diary.

Turn on the device and connect it via USB to CGM POINT OF CARE. Wait for the data to download, then click "Confirm" to confirm the data and close the exam.

Paziente: DEMO 017 PAZIENTE **Holter ECG** Versione: 1.1.13.1

3 Configurazione device

4 Caricamento diario paziente

5 **Scaricamento dei dati**

Scaricamento dati in corso. Attendere prego...

Annulla

Paziente: DEMO 014 PAZIENTE **Holter ECG** Versione: 1.1.13.1

3 Configurazione device

4 Caricamento diario paziente

5 **Scaricamento dei dati**

Verificare la correttezza dei dati e premere "Conferma".

Data inizio	Data fine	Fine esame
01/01/0001 00:00	01/01/0001 00:00	

Annulla

Conferma

The amount of data recorded by the device is large and is high even for short sessions, so the transfer time is significant and normally about 10 minutes. Wait for the download to finish before disconnecting the cable.

If the exam was successfully registered, the summary screen is displayed; press "Confirm" to end the procedure. The exam is concluded and automatically sent to the reporter.

Withdrawal Report

At Pharmacy

The patient can go to the pharmacy to pick up the exam or can delegate to pick up the report.

The proxy form can be printed from the POC.

Selecting the patient, "**Next**," and selecting "**Print Forms**," select "**Referral Pickup Delegation**," with pre-filled pharmacy and patient data.



Paziente: Bianchi Andrea Versione: 1.1.9.0

Seleziona il modulo da visualizzare

19/01/2023 CGM POINT OF CARE 19:02

Paziente: Bianchi Andrea Versione: 1.1.9.0

CGM CARE MAP
Connected Patient Platform

DELEGA RITIRO REFERTO

Nome farmacia: Prova

Indirizzo farmacia:

Il/La sottoscritto/a Bianchi Andrea
nato il 21/02/1967, codice fiscale BLLNDR67XXXXXX,
Documento di identità n. _____,
Rilasciato da _____ il _____

DELEGA

il/la sig./sig.ra _____
Nato/a _____ il _____
Residente in via _____ CAP _____
Città _____ Prov _____

19/01/2023 CGM POINT OF CARE 19:10

Via Web: Patient

The patient can request viewing of the report via the web, via access to the CGM CARE MAP portal. Select the patient from the "Select Patient" screen and select "**Edit Patient**"

Paziente: Nessuno Versione: 1.1.1.0

Seleziona Paziente

Ricerca...
Nome:

Cognome	Nome	Data di nascita
brava	carlo	01/01/1980
Demo 1	Paziente	21/06/1953
Fumi	Andrea	19/01/2021
Marina	Matteo	14/03/1998
Test0001	Paziente	11/05/1992
VergataTest	Sara	27/01/2021

Check the box to "**Pick up report online**"; the patient will receive credentials to access the web portal at the indicated e-mail address, which will be delivered once the exam performed has been reported. Remember to collect the relevant explicit consent from the patient via the appropriate form that can be printed from the program.

Paziente: Nessuno Versione: 1.1.1.0

Seleziona Paziente

Nuovo paziente

Codice fiscale:

Nome: Cognome:




Data di nascita: Sesso:

Telefono: E-mail:

Ritiro referto online:

Referto disponibile online

 HPW-POC@hes.it

 Rispondi  Rispondi a tutti  Inoltra 

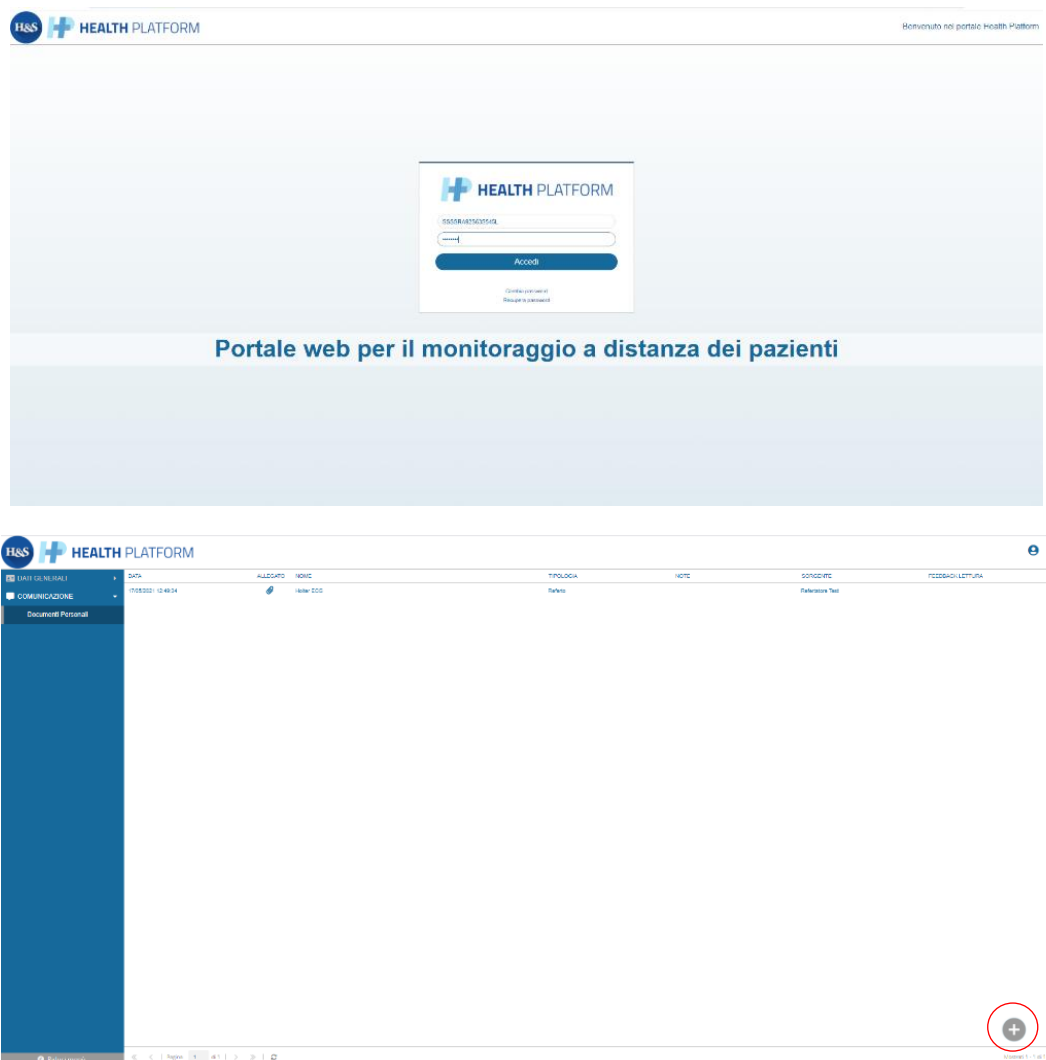
lunedì 17/05/2021 12:50

This email originated from outside of CGM. Please do not click links or open attachments unless you know the sender and know the content is safe

Gentile Test0001 Paziente,
 Le comuniciamo che il referto dell'esame da lei effettuato è disponibile al seguente indirizzo: <https://hpw3-poc.hes.it/site>
 Può accedere usando le seguenti credenziali:
 Username: SSSRA925635545L
 Password: VCSN46GH
 Mail generata automaticamente si prega di non rispondere.
 Lo staff di HealthPlatform.

By accessing the link provided in the email, the patient will be taken to the CGM CARE MAP web portal and entering the credentials received via email, a 5-minute code will be sent to confirm access.

The patient will be able to view the reported examinations performed via POC and interact with the doctor, attaching documents via the "+" function.



The screenshot displays the Health Platform web portal. The top navigation bar includes the H&S logo and the text 'HEALTH PLATFORM'. Below this, there is a login form with fields for 'ID COGNOME/COGNOME' and a password field, followed by an 'Accedi' button. The main heading reads 'Portale web per il monitoraggio a distanza dei pazienti'. The lower portion of the image shows a dashboard with a sidebar menu on the left containing 'LAVORI DA REALIZZARE', 'COMUNICAZIONE', and 'Documenti Personali'. The main content area features a table with columns for 'DATA', 'ALLEGATO', 'INVIATO', 'TIPOLOGIA', 'NOTE', 'SPEDITE', and 'PESOGRAFO/LETTORE'. A red circle highlights a '+' icon in the bottom right corner of the dashboard area.

Program exit

If you wish to exit the program, return to the initial patient selection page and press the 'Exit' button.

Attention: if there are exams that have not yet been sent to the server, a warning message is displayed. If you continue with exiting the program, the exams will be sent to the server only at the next startup.

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 indexis, 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.

Technical specifications.

Minimum hardware requirements:

- CPU: Intel i3 gen.7
- RAM memory: min 8 GB
- Disk space: min 256GB
- Bluetooth: 5.0
- USB: at least one port
- Network or WiFi connection

Operational platform:

- Microsoft Windows 11 Pro

Interface features:

The software is equipped with an intuitive and quick-use graphic interface, in order to facilitate the immediate understanding of the information and the execution of the exams.

Characteristics of computer networks:

In order to use the software, a connection with the CGM CARE MAP server is required, in order to authenticate the operator, download the configurations and send the acquired data. For the connection, either the Ethernet or WiFi connection can be used, if available.

Cyber security measures, including protection against unauthorized access:

The following security measures are in place:

- Login required with passwords renewed periodically and subject to expiry (the credentials are the same used to access the web portal).
- Data storage only for the time strictly necessary for management and sending to the server.
- All communications take place via secure protocols (HTTPS, TLS 1.2).

Manufacturer

CGM POINT OF CARE is produced by:

CGM TELEMEDICINE S.R.L.

Registered office: Foro Buonaparte, 70 - 20121 - Milan

Headquarters: Via Emilia Parmense, 204 - 29122 Piacenza

Tel. +39 0523 603311

Fax +39 0523 603364

In the operational headquarters in Piacenza.