telemon
Software platform

Keep This Manual Handy for Future Reference!

Welcome to the User Manual for telemon software platform. This guide is your go-to resource for ensuring the safe, effective, and efficient operation and maintenance of the software.

Manufacturer Information

Goldmann Systems, a. s.
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Important Notices:

- **Proper Use and Compliance:**
  - The SaMD (Software as a Medical Device) is designed for specific purposes and should only be operated by individuals who have thoroughly learned its characteristics, functions, and usage methods.
- **Usage and Maintenance:**
  - The SaMD does not include sterile components nor possesses measuring capabilities.
  - In case of any unexpected behavior or issues with the telemon application, please reach out to our Development Support Team. Direct interventions or attempts to alter the SaMD should not be undertaken by users. For assistance and to ensure the application's optimal functionality, contact Goldmann Systems a. s. support services.
  - For MDs intended to be used interoperably, adhere to the corresponding user manual. Should you suspect any malfunction of the MD, refrain from using telemon with the malfunctioning MD.
- **Modifications and Reporting:**
  - Warning: Altering the software without explicit permission from the manufacturer is strictly prohibited.
  - Any incident or undesirable event related to the SaMD's use should be promptly reported to both the manufacturer, Goldmann Systems a. s., and the appropriate regulatory authority within the user or patient's jurisdiction.

Table of Contents:

1. IDENTIFICATION OF THE SOFTWARE AS A MEDICAL DEVICE (SAMD)

Device Description: telemon is a Software as a Medical Device (SaMD) functioning as a remote patient monitoring (RPM) system. It is designed to collect, download, store, transfer, share, and display information about a patient's vital functions, recorded from multiple compatible FDA-cleared medical devices.

Core Functionality: telemon personal mobile application is engineered for compatibility across a broad spectrum of smartphones, offering both patients and healthcare professionals a dynamic tool for health management. It enables secure aggregation, storage, and access to health metrics collected from various FDA-cleared medical devices, facilitating enhanced monitoring and oversight of patient health. The application is pivotal in promoting patient engagement and supporting healthcare providers by offering insights into health trends based on provider-guided measurement plans, without directly intervening in diagnostic or therapeutic decisions.

Operational Excellence and Security: With a focus on patient safety and data security, telemon uses Bluetooth technology to securely transfer medical data to the user's smartphone, ensuring encrypted communication to the cloud. This safeguarding of data integrity is paramount in delivering remote care confidently and securely.

Advancing Global Healthcare: Remote measurements via the telemon platform deliver significant advantages, from cost reduction to lowering infection risks, marking a leap forward in Remote Patient Monitoring (RPM). As telemetry and telemedicine continue to evolve, Goldmann Systems a. s. is expanding the telemon solution worldwide, aiming to globalize its benefits.
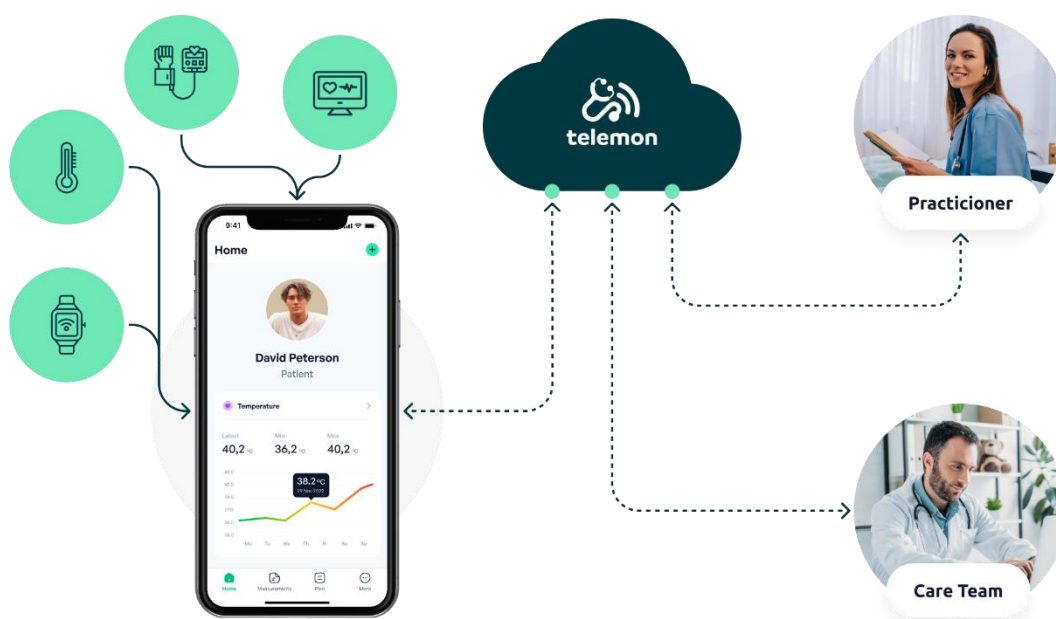
Software Information

- Product Name: telemon
- Product Version: v1.0
- Manufacturer: Goldmann Systems, a. s.
- Address: Dvořákovo nábrežie 4, 811 02 Bratislava, Slovak Republic

2. PURPOSE OF THE TELEMON SAMD

The telemon software, as a platform, facilitates the aggregation and review of health data from various FDA-cleared medical devices. It serves as a tool for healthcare professionals and patients to monitor health indicators, supporting enhanced health management. This function is performed without engaging in direct diagnostics or therapeutic decision-making, aligning with its status as an FDA-exempt medical device.

3. SIDE EFFECTS

As the telemon is a software platform and not a physical medical device, it does not have direct physical side effects.

4. SAFETY INSTRUCTIONS

To ensure your safety and the optimal performance of the Software as a Medical Device (SaMD), please adhere to the following guidelines:

- **Operation**: Do not use the SaMD if it cannot be operated as described in the User Manual. If you encounter any issues, please contact the manufacturer directly.

- **Intended Use**: Utilize the SaMD strictly for its designated purpose as outlined in the documentation.

- **Reporting Adverse Events**: Should you experience any significant adverse events related to the SaMD, it is imperative to report these to the manufacturer and the appropriate regulatory authority in your jurisdiction.

- **Age Restrictions**: The SaMD is designed for use by adults 18 years and older. Minors under the age of 18 should only use the SaMD under the supervision of a legal guardian or with their active assistance.

- **User Competency**: Operation of the SaMD should be limited to individuals who have familiarized themselves with the contents of the User Manual.

- **Compatibility**: Ensure that only MD confirmed to be interoperable are used in conjunction with this device.

- **Medical Guidance**: Avoid making any changes to your medication, dosage, or therapeutic interventions based on data from the SaMD without first consulting a healthcare professional.

- **Multiple Users:** If multiple users wish to use one interoperable measuring medical device with the telemon personal application, each user must have their own telemon personal mobile application installed on their mobile phone. This ensures clarity and prevents confusion during measurements.

5. INTENDED GROUP OF USERS

The telemon application is specifically designed for a diverse group of users, including:
- **Patients:** Individuals monitoring their own health data.
- **Relatives or Care Persons:** Family members or caregivers of patients who have been authorized to access the patient's health data.

- **Mid-Level Healthcare Staff:** Healthcare professionals involved in patient care who require access to health data for monitoring and decision-making purposes.
- **Doctors:** Medical doctors who utilize patient data for diagnostic, monitoring, and treatment purposes.

6. TECHNICAL DESCRIPTION

6.1. SaMD OVERVIEW

The telemon SaMD encompasses several key components designed to enhance patient health monitoring through advanced technology.

Mobile Application (telemon personal):

- **Compatibility:** Available for installation on mobile phones and tablets equipped with a data connection (Wi-Fi or mobile data) for internet access, Bluetooth for device communication, and GPS for location services.
- **Operating System Requirements:**
  - Android: Version 8.0 and above. Available on Google Play Store: https://play.google.com/store/apps/details?id=gs.telemon.mobile
  - iOS: Version 15 and above. Available on Apple App Store: https://apps.apple.com/sk/app/telemon-chronic-care/id1641864064

System Part:

- **Infrastructure:** Utilizes a server solution with cloud support for secure storage of patient data, adhering to the HL7 standard for healthcare information exchange.

6.2. INTEROPERABLE MEDICAL DEVICES (MDs)

The telemon SaMD only enables the automated transfer of measured data from interoperable medical devices that are FDA-approved.

Categories of interoperable medical devices:

- EKG,
- Glucometer,
- Oximeter,
- Spirometer,
- Thermometer,
- Blood Pressure Meter,
- Scale.

All interoperable medical devices are listed in Annex 1.

6.3. ACCESSORIES

The telemon SaMD does not come with any additional accessories.

6.4. LIFESPAN OF THE MEDICAL DEVICE

The telemon Software as a Medical Device (SaMD) has a designed lifespan of 5 years.

7. COMMISSIONING

7.1. MOBILE APPLICATION – TELEMON PERSONAL

The SaMD operates through a mobile application installed on a mobile phone. Adhering to the operating instructions provided by the mobile phone's manufacturer, as found in the phone's manual, is crucial for optimal functionality of the SaMD app. Similarly, operating instructions of any measuring devices intended to work with the SaMD, as outlined in their respective manuals, should be followed carefully.

7.1.1. APPLICATION INSTALLATION

Installing the telemon personal application is straightforward. Users should follow the standard installation process, which is easily manageable for anyone acquainted with this SaMD's User Manual.
For downloading the latest version of the application, please refer to Chapter 6.1.
Once installed, the telemon personal app icon will appear on your device's screen, ready to launch the application.
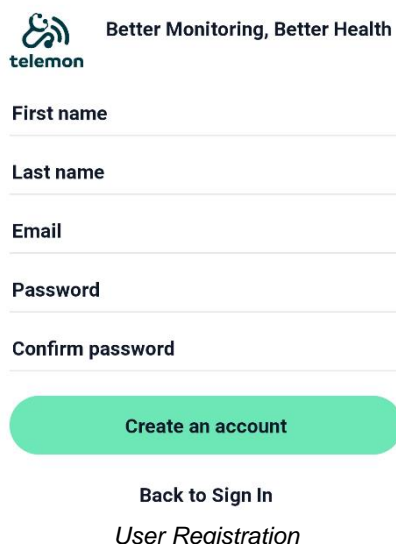Once installed, the telemon app transforms your mobile phone or tablet into a central point for managing health data, seamlessly connecting and coordinating with various FDA-cleared medical devices to support health monitoring and data sharing.

7.1.2. USER/PATIENT REGISTRATION

Upon launching the telemon personal application, the user is prompted to log in or register for application use. During registration, the user needs to provide their name, surname, and email, which will also serve as the login to the application. The user then chooses a password and repeats it for confirmation to prevent typing errors.
After submitting the registration details, a verification email will be sent to the provided email address. To complete the registration process and begin using the application, the user must click on the activation link contained within the verification email.

Important: Always keep your login password secure and do not share it with anyone.
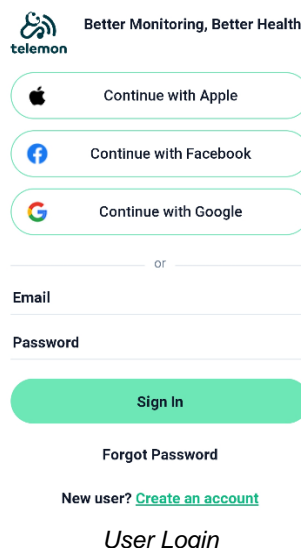
User Registration   *User Login*

7.1.3. LOGGING IN AS A USER/PATIENT

Once your email is verified, you can log into the application using your registered email and password.
For convenience, you also have the option to log in via your Apple, Google, or Facebook accounts.

7.1.3.1 FIRST-TIME LOGIN AND INITIALIZATION

Upon your first login, you will be directed through an initialization wizard designed to tailor the application to your personal and health-related specifics. The procedure encompasses several steps:

- **Initialization Wizard**: A structured guide facilitating the initial setup.
- **Submission of Personal Information**: You are required to complete forms with essential personal details, encompassing:
    - **Telephone Number**: For account security and customization.
    - **Birth Date**: To provide age-appropriate health insights.
    - **Height and Weight**: Vital statistics for accurate health monitoring.
    - **Gender Assigned at Birth**: To ensure health recommendations and diagnostic tools are appropriately tailored.
- **Health Status Configuration**: During this phase, you will indicate your medical history and current health status as follows:
    - **Primary Diagnosis**: Identify your principal health condition as diagnosed by your healthcare provider.
    - **Secondary Diagnoses**: Note any additional medical conditions you are addressing.
    - **Option for Self-Monitoring**: Should you be managing your health independently, please select this alternative.

7.1.3.2 HEALTH INFORMATION AND MEASUREMENT PLANS

The information you provide helps tailor the application to your needs. Based on your health details and diagnosis, the app places you in an appropriate patient group and suggests a customized measurement plan. While you can adjust this plan at any time, we recommend making changes in consultation with a healthcare professional to ensure the best outcomes for your health monitoring.

7.1.4. LOGGING IN THROUGH A PATIENT INVITATION

When a patient opts to share their health data within the telemon personal application with another individual—be it a doctor or a family member—they need to provide the contact's essential details: name, surname, email, and phone number. An invitation to join the telemon Personal application is then sent to this contact via email.
Upon receiving the invitation, the contact person can click on the provided link to access the telemon personal application. This action prompts them to create a password, completing their initial setup. With their email and newly set password, they can log into the application anytime to access the shared health data.

7.1.5. OPERATING MODES OF THE MOBILE APPLICATION

The telemon personal mobile application supports two primary operating modes to accommodate different connectivity scenarios:
- **Online Mode**: In this mode, your phone or tablet maintains an active internet connection. Activities such as application installation, patient registration, and the sending of invitations to patient contacts are exclusively performed while online.
- **Offline Mode**: Even without an internet connection, the application remains functional. During offline mode, the app can still communicate with measuring devices via Bluetooth technology. This allows for the transfer and display of measurement data on your device, although this data will not be uploaded to the server system and, consequently, will not be visible to patient contacts.

Data Synchronization and Accessibility:

- **Measurements**: Can be taken in both online and offline modes. When in offline mode, the application stores the data locally.
- **Data Transfer**: Once the application returns to online mode, it automatically syncs and uploads any measurements taken during offline periods to the server system. This ensures that patient contacts can access and view all measurements, including those taken when the device was offline.

For optimal performance and to ensure all data is accurately synchronized, it is recommended to switch the telemon personal application to online mode at least once a week.

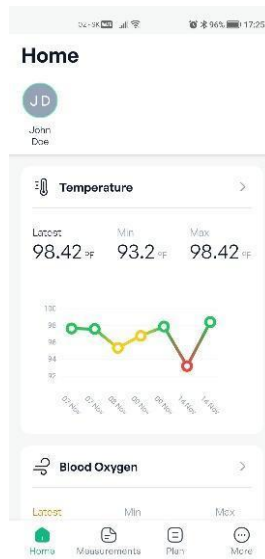### 7.1.6. MEASUREMENTS WITHIN THE MOBILE APPLICATION

Upon logging in, users are directed to the home screen, which serves as the central hub for accessing patient measurements. This screen organizes measurement data into categories, presented in both textual and graphical representations for easy interpretation. Categories with at least one recorded measurement will display this data; those without any will notify the user of the absence of measurements.

For Patients: A prominent button is available for patients, offering a straightforward pathway to record new measurements within any selected category. This feature ensures patients can actively engage in their health monitoring and data collection process.

For Contact Persons: For users logged in as contact persons (such as doctors or family members of one or more patients), the application adapts to highlight a list of their associated patients at the top of the screen. Selecting a patient/contact from this list updates the display to show relevant information for the chosen individual. This tailored viewing experience extends beyond the home screen to encompass all functionalities within the telemon personal application, ensuring contact persons have seamless access to the data they need.

Patient's Home Screen   *Contact Person's Home Screen*

7.1.6.1 INITIATING MEASUREMENTS

Patients can begin the measurement process in two ways:
- By tapping the green plus sign icon located in the upper right corner of the home screen.
- By selecting the same icon found on the measurement screen, which is accessible from the application's bottom menu.

7.1.6.2 VIEWING MEASUREMENTS

The measurement screen presents an organized list of the patient's most recent measurements across various categories. Selecting any category reveals a comprehensive overview of all measurements recorded in that category over a specified time frame—be it a day, week, month, or year—allowing patients to track their health trends over time easily.

Measurement Screen

List of Measurements – Glucose

7.1.6.3 STARTING THE MEASUREMENT PROCESS

The process of monitoring health metrics is initiated once a patient selects a health category within the app. The following steps outline the process:

- **Pairing a Measuring Device**: If the patient doesn't have a device paired in the chosen category, the app offers the option to connect a new one. Conversely, if a device is already paired, the patient can select it to start measuring immediately. In all scenarios, there's always the flexibility to input measured values manually.
- **Adding a New Device**: For patients looking to expand their device lineup within a specific category, additional devices can be paired through the application settings, a process detailed in the subsequent chapter.
- **Device Selection and Pairing**: Should the patient opt to add a new device, the telemon personal application presents a list of compatible measuring devices for the selected health category. Selecting a device initiates a guided pairing process, leveraging Bluetooth connectivity. Detailed instructions for this pairing are provided on-screen and, in the device's, accompanying user manual.
- **Completing the Pairing Process**: Once the device is successfully paired, patients are redirected to the start of the measurement process in their chosen category. They can then proceed with taking measurements using their newly paired device or continue to enter values manually as preferred.

7.1.6.4 TAKING MEASUREMENTS WITH A PAIRED DEVICE

The telemon personal application facilitates a seamless measurement process with paired devices. Detailed instructions on each screen guide patients through:

- Initiating the measurement
- Transferring data to the phone
- Patient confirmation of the data

It's important to note that only data confirmed by the patient is recorded in the app. When in online mode, this data is instantly uploaded to the server for secure storage and access.

7.1.6.5 MANUAL DATA ENTRY

Patients have the flexibility to manually input measurement data into the telemon personal app, allowing the use of any measuring device. Manual entries are easily identifiable by a pencil icon next to the data.

7.1.6.6 ALERTS FOR OUT-OF-RANGE VALUES

The application visually presents measurement values to aid user interpretation:
- An orange/red display serves as a visual alert to the user, indicating values that may warrant closer attention or consultation with a healthcare professional.
- These color-coded indicators are designed to facilitate user awareness and prompt further action if necessary, without the application making any clinical analyses or diagnoses.

In such cases:
- If online, the app sends alert emails to the patient's contacts (relatives, doctors) authorized to view their data.
- If offline, these notifications are queued and sent as soon as the app reconnects to online mode.

This system ensures patients and their designated contacts are promptly informed of any critical changes in health status, enhancing care and response times.

7.1.7. MEASUREMENT PLAN

To access your measurement plan, tap on the third icon from the left at the bottom of the screen, labeled "Plan." Here, you'll find a list of categories for which you've set alerts to remind you of regular measurements.

7.1.7.1 MODIFYING ALERTS

Within the plan section, you have the flexibility to:
- **Change** existing alerts to better suit your schedule or health monitoring needs.
- **Add** new alerts for additional categories to ensure comprehensive health tracking.
- **Cancel** any alerts you no longer need.

7.1.7.2 IMPORTANT RECOMMENDATION

While the app empowers you to tailor your measurement plan, any changes to alerts are best made in consultation with a healthcare professional. This ensures that your measurement schedule aligns with medical advice and effectively supports your health management.
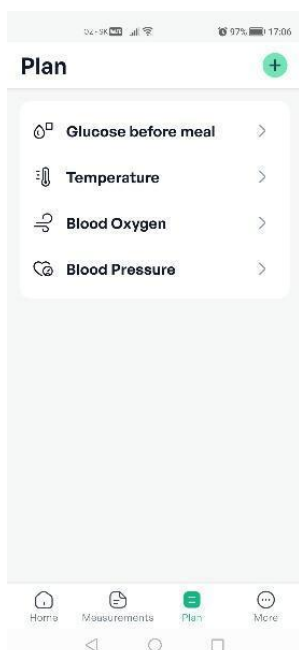
Measurement Plan
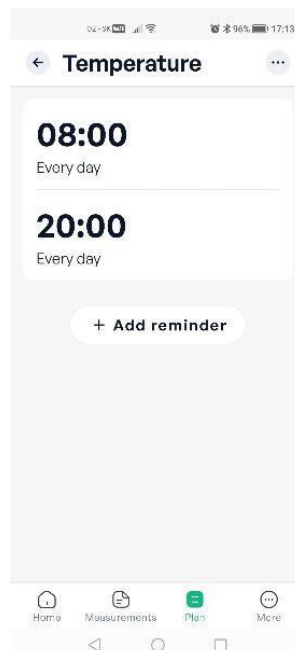
*Alerts for Measurements*

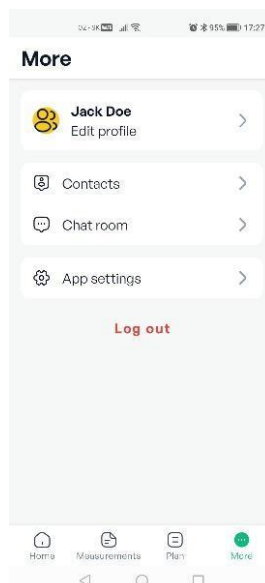### 7.1.8. MOBILE APPLICATION SETTINGS

Accessing the settings in the telemon personal application is straightforward. Simply tap on the "More" icon, located as the last option in the bottom menu. This action opens up a user-friendly menu offering several options for customization and management:

- **Edit Profile**: Update your personal information to keep your account current.
- **Prepaid Package**: Manage your subscription options for enhanced app features (*Available to patients only*).
- **Devices**: Add new measuring devices for more comprehensive health tracking or remove ones no longer in use.
- **Emergency Contacts**: Designate or update your emergency contacts for added safety (*Emergency contact addition/removal also accessible to contact persons*).
- **Alerts**: Customize notification settings to receive important alerts related to your health.
- **Diagnosis Overview**: Review and manage your listed diagnoses for accurate health monitoring (*Available to patients only*).
- **Chat**: Engage in discussions for support or to connect with others.
- **App Settings**: Additional customization options including:
  - **Units**: Choose between imperial or metric units for displaying measured values.
  - **Values**: Adjust the thresholds for various health metrics.
  - **Privacy & Legal Terms**: Review the app's usage conditions and privacy policies.

Note: Features marked with an asterisk (*) are exclusive to logged-in patients. The feature marked with two asterisks (**) allows contact persons to access specific patient information, including health data and notification preferences.
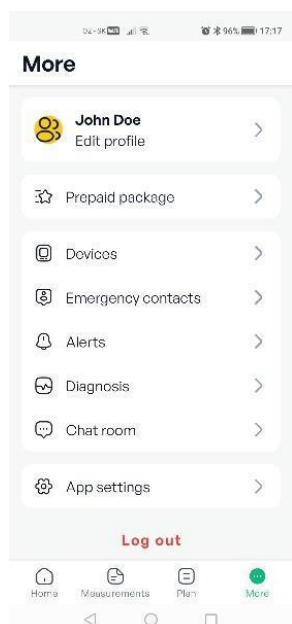
Application Settings for the Patient	*Application Settings for the Contact Person*

7.2. WEB APPLICATION TELEMON

7.2.1. LOGGING INTO THE WEB APPLICATION

The user opens the web application through the web browser. The login screen is displayed, where user enters the same login data as in the mobile application, i.e. e-mail and password or user can use sign in with its Apple, Google or Facebook account. After successful login will be displayed
- the patient screen, if logged user is a patient,
- the list of patients, if logged user is not a patient (is a doctor or care person). List of patients contains only those patients, who have made their data available to the user and user can choose the patient whose data he wants to work with.

7.2.2. PATIENT DETAILS

The "Patient Details" section consolidates comprehensive information about the patient, as entered in the "Patient Card" section of the telemon personal mobile application or through web application inputs. This information is pivotal for personalizing patient care and ensuring accurate health monitoring. Below is a detailed breakdown of the patient details captured:
- **Name and Surname**: The full legal name of the patient.
- **Identification Number**: The specific number associated with the patient's chosen form of identification.
- **Date of Birth**: The patient's birthdate, crucial for age-specific health management.
- **Gender**: The patient's gender, as provided.
- **Start of Records**: The date when the patient's health records began accumulating in the system.
- **Health Insurance**: Information regarding the patient's health insurance coverage.
- **Type of Health Insurance**: Specifies the nature of the health insurance (e.g., private, public).
- **Health Care Organization**: The name of the organization or provider offering health care services to the patient.
- **Patient's Address**: The current residential address of the patient.
- **Patient Contacts**: Contact details such as phone numbers and email addresses.
- **Contact Persons of the Patient**: Names and contact information of individuals designated by the patient for emergency situations or for sharing health data.

Patient Details

7.2.3. MENU

After clicking in the left menu, the user has the option to display:

- **PATIENT CARD:** patient detail described in the previous chapter
- **MEASUREMENT PLAN:** a list of all planned measurements for the patient,
- **ALERTS:** list of sent notifications,
- **REPORTS:** the possibility of creating reports about the patient,
- **MEASUREMENTS:** a list of types of measurements implemented in the telemon personal application, after selection type of measurement, the patient's measurements are displayed in graphic and descriptive form (graph, date of measurement, time of measurement, measured value, unit of measurement) – if these measurements were carried out. if were not, the screen for measured values is blank.

Goldmann Systems

⌂ **telemon** 📊 Dashboard 👥 Patients 🔔 Alerts 🗺 Map of alerts 💻 Devices 🏢 Administration 📊 Reports ⚙ 📞 ⛶ ⊚

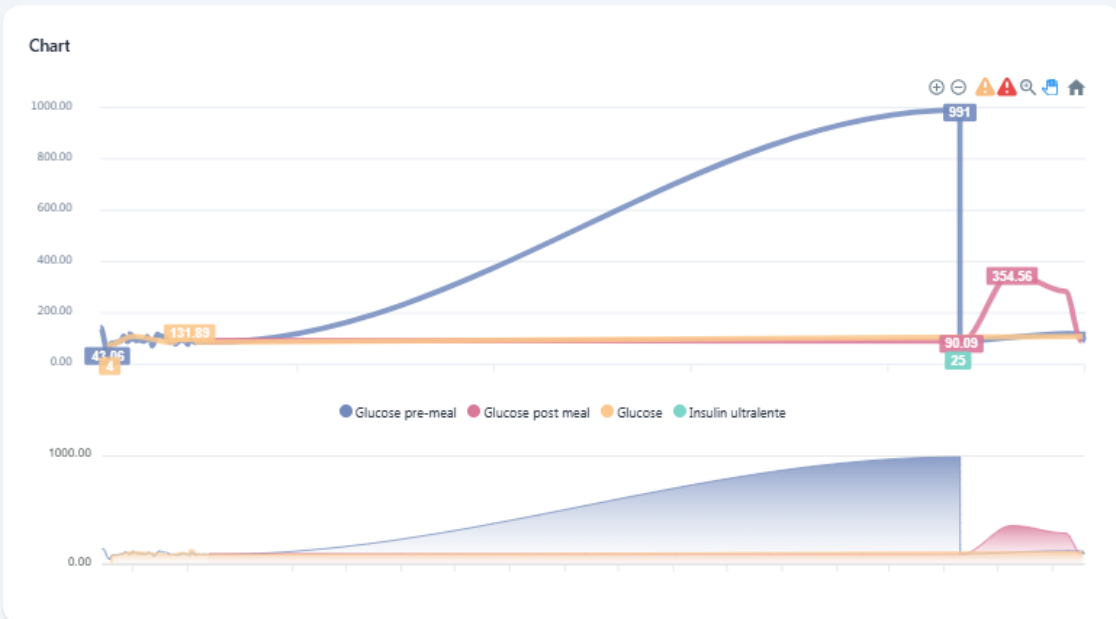Patients > Patient card

Baker Mary

☰ 25.03.1951   Female   EMAIL: marien.b.baker@gmail.com   Last measurement: 📱 04.07.2024 13:57

Last measurement - 19.06.2024 12:33:31

Glucose pre-meal: 91.17 mg/dL

Chart

⊕ ⊖ ⚠ ⚠ 🔍 🗖 🏠

● Glucose pre-meal   ● Glucose post meal   ● Glucose   ● Insulin ultralente

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Measurements

🔻 📄

Date and time ↓	Glucose pre-meal ⊙	Glucose post meal ⊙	Glucose ⊙	
19.06.2024 12:33:31	91.17 mg/dL			Normal
18.06.2024 13:32:00	95.5 mg/dL			Normal
18.06.2024 13:32:00	91.89 mg/dL			Normal
18.06.2024 13:32:00	99.1 mg/dL			Normal
18.06.2024 13:32:00	⚠ 108.11 mg/dL			Abnormal
18.06.2024 13:32:00	99.1 mg/dL			Normal
18.06.2024 13:32:00			⚠ 109.11 mg/dL	Abnormal

Patient Measurements - Glucose

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8. MAINTENANCE, PERIODIC INSPECTION AND DISPOSAL

The telemon personal application, along with its underlying system infrastructure, is supported by an integrated maintenance plan. This plan encompasses regular activities and continuous monitoring to ensure the optimal performance and security of all software components and system infrastructure. The system is regularly monitored and updated to ensure its functionality and reliability are maintained. Given that the telemon personal is a software platform, concerns regarding cleaning, disinfection, and physical disposal do not apply. As a digital product, it is exempt from the processes typically associated with tangible medical devices. Users should, however, follow best practices for digital data management and device security to protect their information.

9. SPECIFICATION OF SAMD USAGE

The telemon personal application is designed to facilitate comprehensive health monitoring through seamless integration with a range of medical devices. Below is a summary of the usage specifications that outline how this software MD can be utilized effectively.

9.1. INDICATION

The telemon Software as a Medical Device (SaMD) software is designed to enhance patient care through advanced data management capabilities. Its primary functions include:
- **Data Reception:** Gathering information from interoperable medical devices that measure vital patient functions.
- **Data Storage:** Securely keeping the collected health data for future reference and analysis.
- **Data Transmission:** Sending health information to healthcare providers or other authorized entities as needed.
- **Data Sharing:** Allowing patients to share their health information with doctors, caregivers, or family members involved in their care.
- **Data Display:** Presenting the health data in an understandable format, aiding in health monitoring and management.

9.2. CONTRAINDICATIONS

The telemon Software as a Medical Device (SaMD) software is not designed for use by patients who are in a serious or critical condition.

9.3. AGE REQUIREMENTS

- **Adults:** The telemon Software as a Medical Device (SaMD) is intended for use by individuals aged 18 and older.
- **Minors:** Individuals younger than 18 may use the SaMD under the active supervision and assistance of a legal guardian or representative.

9.4. HEALTH REQUIREMENTS

- **General Use**: The telemon Software as a Medical Device (SaMD) is designed for individuals who are mentally and sensorily capable of operating the device and understanding its outputs.
- **Assisted Use**: Individuals who may not meet these mental or sensory capabilities are still able to use the SaMD under the supervision and guidance of a responsible or authorized caregiver or representative.

9.5. WEIGHT CONSIDERATIONS

When utilizing a weight scale interoperable with the telemon Software as a Medical Device (SaMD), patients are required to adhere to the conditions and guidelines outlined in the scale's user manual. Apart from these specific instructions for scale use, there are no general weight restrictions for using the SaMD.

9.6. ETHNICITY CONSIDERATIONS

Ethnicity has no bearing on the use or effectiveness of the telemon Software as a Medical Device (SaMD).