GLUCUBE

USER MANUAL

NON-INVASIVE blood glucose monitoring system

MODEL: ES0101
DOC VERSION: 4.0 – 01/2025

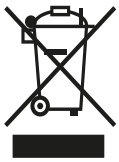
Revision history

Manual version	Date	Changes
Version 01	07-2024	New document
Version 02	09-2024	APP update
Version 03	11-2024	APP update: Offline mode Recommendations before the measure
Version 04	01-2025	Instructions for use of GLUCUBE PANEL

The non-invasive devices for monitoring blood glucose from IGLUCO TECH, S.L. comply with the following regulations:

European Directives: 2014/53/EU y 2015/863/EU

IGLUCO TECH, S.L. reserves the right to make any changes it deems appropriate without prior notice as part of the ongoing product development process.

	 IGLUCO TECH, S.L. Av. República Argentina, nº25, floor 8 Seville, 41011 (Spain)

This symbol indicates a possible risk of injury or harm to your own health or that of others.

Precaution. Refer to safety-related notes in the instructions for use that accompany the product.

This symbol draws attention to actions that could lead to improper operation or damage to the product.

This symbol draws attention to important information.

Content

1. Introduction

Intended use

GLUCUBE is a non-invasive system intended for monitoring blood glucose level evolution in adults (age 18 and older) with diabetes, in capillary blood of the fingertips. It is intended for autonomous use by users at home. The information obtained may be shown on a smartphone display and health care professionals can monitor users remotely. It does not require prescription.

GLUCUBE system allow readings to be made available directly to users in real time. This system aids in the detection of glucose level excursions outside from the desired range. It is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose meter, reducing the amount of daily finger pricks of the users.

Is currently intended for everyday use for detecting long-term trends and tracking patterns, to guide future management of the user and suggest when to take fingerstick blood glucose.

This system is not designed to replace the capillary glucometer. The GLUCUBE system should be used in conjunction with a capillary glucometer.

Treatment decisions and dose adjustments should not be based solely on the results of the GLUCUBE system. Before making therapeutic adjustments, you should confirm with a capillary glucometer.

You should not ignore symptoms related to high or low glucose levels. Use your capillary glucometer to check the results of the GLUCUBE system.

To obtain glucose measurements with the GLUCUBE system, an internet connection is required.

The user must contact a health professional for any clinical decision.

Benefits for use GLUCUBE

- Detection of deviations in blood glucose levels that can cause cardiovascular problems or develop diabetes in the general population.
- The non-invasive technique developed in the GLUCUBE system allows the user to improve their quality of life by not requiring punctures. The user can take additional measurements to know their glucose level more frequently. Moreover, by not requiring blood draws, it reduces the risk of infectious contagion and blood loss compared to any in vitro diagnostic method.
- Users can monitor glucose levels without needing to go to a healthcare facility.
- The portable system can be used both inside and outside the home.
- It allows for maintaining a historical record of the evolution of blood glucose levels, combined with data on the users' lifestyle habits.

Clinical performance

The non-invasive system GLUCUBE was evaluated with capillary blood samples from 105 individuals. A total of 1815 samples were collected within the validation range of [70-180 mg/dL]. Persons with Type I Diabetes, Type II Diabetes, pre-diabetics and persons without diabetes were included. Individuals collected measurements over a one-week period. Each pair of measurements includes one measurement with the standard glucometer (Contour®Next) and one measurement with GLUCUBE device.

N	1815
Range	70 – 180 mg/dL
Mean Absolute Relative Difference (MARD)*	19,28
Percentage within Zones A+B of Parkes**	98,18%

*For the reference measurements with a glucose value lower than 100 mg/dL the absolute error was calculated

**Zone A is defined in the Parkes error grid as the zone of "clinically accurate measurements with no effect on clinical action," and Zone B as the zone of "altered clinical action with little or no effect on clinical outcome".

	Within +-20%*	Within +-30%*	Within +-40%*
Accuracy for all results	1118 /1815 (61,60%)	1444 /1815 (79,56%)	1634 /1815 (90,03%)

*For the reference measurements with a glucose value lower than 100 mg/dL the absolute error was calculated.

In addition, a substudy was performed by taking a measurement with the standardized POC device for glucose determination (Accu-Check Inform II system) on the Visit 1 (Day 1) and the Visit 2 (Day 8). It was evaluated on 79 participants collecting 126 measurements in total within the validation range [70-180 mg/dL]. The following results were obtained by analyzing each day separately:

	DAY 1	DAY 8
Mean Absolute Relative Difference (MARD)*	20,91	14,65
Percentage within Zones A+B of Parkes**	100%	100%

*For the reference measurements with a glucose value lower than 100 mg/dL the absolute error was calculated

**Zone A is defined in the Parkes error grid as the zone of "clinically accurate measurements with no effect on clinical action," and Zone B as the zone of "altered clinical action with little or no effect on clinical outcome".

	Within +-20%*	Within +-30%*	Within +-40%*
Accuracy for all results Day 1	38 /72 (52,78%)	51 /72 (70,83%)	65 /72 (90,28%)
Accuracy for all results Day 8	39 /54 (72,22%)	46 /54 (85,19%)	52 /54 (96,30%)

*For the reference measurements with a glucose value lower than 100 mg/dL the absolute error was calculated.

Population

The non-invasive GLUCUBE blood glucose monitoring system is indicated:

- Adult users over 18 years for autonomous monitoring.

Intended user

The non-invasive GLUCUBE blood glucose monitoring system is indicated:

- Adult users over 18 years for autonomous monitoring.

The functions that the intended operator can perform are:

- Glucose measurement with the GLUCUBE device.
- Charging the GLUCUBE device.
- Cleaning and disinfection of the GLUCUBE device.

Do not perform any maintenance operations during operation of the GLUCUBE device

Modification of the GLUCUBE device is not permitted throughout its lifetime.

Only GLUCUBE technical personnel may carry out maintenance operations, not described above, and repair of the GLUCUBE device.

Warning and precautions

- This system is not designed to replace the blood glucose meter. GLUCUBE system should be used in conjunction with a blood glucose meter.
- Treatment decisions and dose adjustments should not be based solely on the results from GLUCUBE system. If GLUCUBE result is outside the ranges established by the health professional, you must use a blood glucose meter to contrast the measurement and to follow their instructions.
- You should not ignore symptoms related to high or low glucose levels. Use your blood glucose meter to verify the results from GLUCUBE system.
- System requires user calibration with blood glucose values. You should update the GLUCUBE calibration every two weeks at a minimum to ensure device performance. The performance of the GLUCUBE system when calibrated less frequently than the recommended minimum of every two weeks, has not been studied.
- To obtain glucose measurements with GLUCUBE system, an internet connection is required.
- GLUCUBE system has currently only been tested in adult persons with type 1 and type 2 diabetes and in adult persons without diabetes. The GLUCUBE system has not been evaluated for use in pregnant women or people less than 18 years of age.
- GLUCUBE system is not to be used for the screening of diabetes.
- GLUCUBE system should not be used in these environments:
    - In the presence of direct sun light exposure.
    - In the presence of direct light from very close fluorescent tubes.
- The GLUCUBE system measures the level of glucose in capillary blood. Correct blood flow must pass through the fingertip. Therefore, the fingertip should not have elements that impede blood flow such as very tight rings.
- The surface of the fingertip cannot be cold, it may make it difficult to correctly detect the signal. In this case you should perform a prior massage of the fingertip to warm it up.
- The appropriate finger for measurement is the ring finger, although the use of any other finger of the hand except the thumb and pinky finger is not prevented. If the capillarity is not adequate in the selected finger, the system will reject continuously the measurement and therefore you should try another finger.
- Talk to your healthcare professional:
    - Before setting any Target Range on your GLUCUBE system
    - Before changing your treatment or medication based on the results of the analysis.
    - Before making any other decision of medical importance.

Contraindications

GLUCUBE system is contraindicated and should not be used in the following cases:

- In users in shock or in a critical condition.
- In users who present calluses, malformations or wounds open to the air or protected with dressings or bandages on the hand's fingers.
- In users with an inability to keep the hand stable during measurement or with progressive nervous system disease that could cause hand movements that would affect the measurement.
- In users with visual impairment.
- In users with polished nails or any type of artificial nails.
- In users who have a condition that affects the blood circulation in the fingers, such as Raynaud's phenomenon.
- Pregnant women.

Limitations of use

The non-invasive GLUCUBE blood glucose monitoring system should not be used for self-analysis by:

- Users with some type of functional, physical or cognitive diversity, which hinders the execution of the measure or access to the results.
- Users with dementia or memory loss.

In such cases, the product is not contraindicated for the user, but the help of a person will be necessary to perform the measurement to the user.

Indications for the correct use of GLUCUBE

Consult these instructions for use, given the complexity of the product

Intended operator

The intended operator is the person who operates the GLUCUBE system in order to monitor blood glucose levels. The intended operator is:

- The user.

The functions that the intended operator can perform are:

- Perform a glucose measurement with te GLUCUBE device.
- Charging the GLUCUBE device.
- Cleaning and disinfecting the GLUCUBE device.

Do not perform any maintenance operations during operation of the GLUCUBE device

Modification of the GLUCUBE device is not permitted throughout its lifetime.

Only GLUCUBE technical personnel may carry out maintenance operations, not described above, and repair of the GLUCUBE device.

2. System description

The non-invasive GLUCUBE blood glucose monitoring system consists of:

- GLUCUBE measuring device (hereinafter also referred to as the "device").
- Power cable for charging the device's battery.
- APP for Smartphone (Android or iOS).
- Web platform for viewing records (GLUCUBE PANEL).
- Web service for calculating glucose levels.
- Instructions for Use.
- Carrying case.

The product requires the use of a smartphone (Android or iOS) compatible with the APP, not included as part of the product.

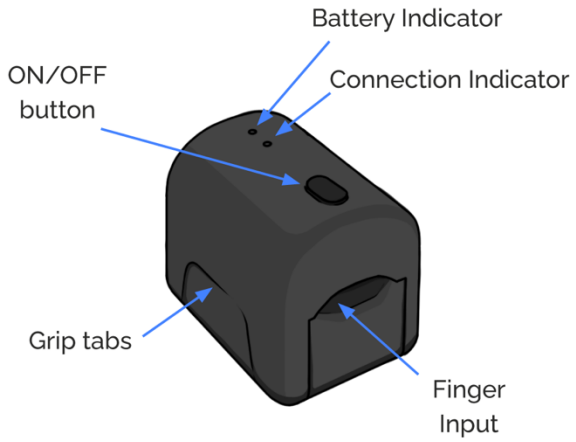
You can find the requirements of your smartphone for use with the GLUCUBE system in the Product Specifications section of this manual and in glucube.com

The use of the product requires the installation of the APP for Android or iOS smartphone.

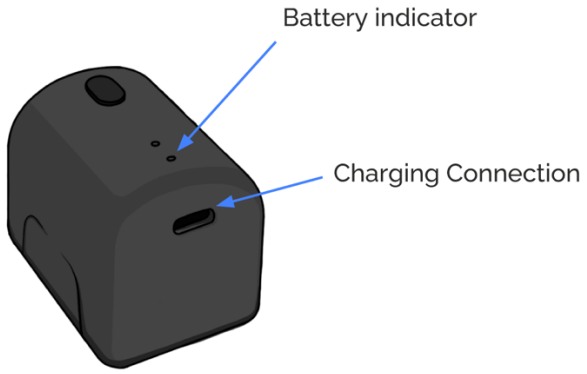
The use of the product requires that your smartphone has an internet connection in order to estimate the glucose value.

GLUCUBE device

Front view of the device



Rear view of the device



The GLUCUBE device is the sensing element of the non-invasive GLUCUBE blood glucose monitoring system. By means of a finger adjustment mechanism, it prevents the entry of external light into the measurement area as well as preventing the finger from moving during glucose measurements.

On the top of the device, we find the following elements:

- **On/off button:** it is used to turn on the device when we are going to take a glucose measurement or if we want to turn off the device.
- **Battery indicator:** indicates the status of the battery charging process.
- **Device connection indicator** with the APP.

On the back of the device is the **power connector** (USB Type-C) for battery charging.

On the sides of the device, the **grip tabs** are located on the bottom of the device, which allow you to hold the bottom of the device while lifting the top.

Inside the device is the **measurement area**, where the finger will be placed, and the blood glucose value will be measured. The infrared signals are emitted from the lower area, where the fingertip rests, and are collected in the upper area, above the nail, by means of a photosensitive component.

Principle of operation

The GLUCUBE device is based on the analysis of the transmissivity of radiation in the near-infrared spectrum through the tissues of the user's finger.

Before using your device

The device's battery may not be sufficiently charged when you use it for the first time.

Before using the device for the first time, connect the power supply to the device (the battery charge indicator will light up orange) until the battery charge indicator indicates full charge (battery charge indicator on blue).

Once the battery is charged, disconnect the power supply and turn on the device for normal use.

Do not use the GLUCUBE device while it is connected to the charging feeder.

As a protective measure, the device cannot be turned on while connected to the power supply.

Charge your device to its full capacity each time you charge. Misuse of the device can lead to deterioration in the device's battery.

Product Usage Environment

GLUCUBE is a portable device.

GLUCUBE is intended for use in a residential environment.

The GLUCUBE product may cause electromagnetic interference to other equipment. Do not use the GLUCUBE product in the vicinity of equipment that may be affected by this interference.

In the event of interference with other equipment, move the GLUCUBE device away from the equipment at a sufficient distance to avoid interference

In places where mobile phones are not allowed, you should disable your smartphone's Bluetooth function, Wi-Fi connection and connection to data networks, so you will not be able to take measurements.

Environmental conditions of use of the device

The conditions of use of the measuring device are:

- **Temperature:** between 10ºC and 35ºC
- **Relative humidity:** 10% to 95%, in the absence of condensation.
- **Atmospheric pressure:** 70 -106 kPa

Do not expose the GLUCUBE device to jets or splashes of liquids.

Do not use the GLUCUBE device in rainy conditions.

During measurements, do not expose the device to direct sunlight or strong ambient lighting that directly affects the device.

Precautions against electromagnetic disturbances

Do not use GLUCUBE in the vicinity of equipment that may cause electromagnetic disturbances, such as motorized appliances (washing machines, refrigerators, fans), microwave ovens, WiFi routers or repeaters, televisions, radio transmitter equipment.

While taking a measurement, maintain a minimum distance of 1 m between these equipment and GLUCUBE.

Outdoors, do not use GLUCUBE in the vicinity of transformer stations or high voltage lines.

It is possible that in the event of an electromagnetic disturbance, the GLUCUBE device may result in invalid measurements. This circumstance will be warned by the APP, urging it to repeat the measure.

In the event of an electromagnetic disturbance, the GLUCUBE device may stop responding to APP commands.

In this case, proceed to turn off the device as indicated in the section Turning off the GLUCUBE device. Once turned off, turn it back on as indicated in the Turn on the GLUCUBE device.

Battery charging

To charge the device, insert the power supply connector into the device's charging connector on the back of the device.

Charging battery

Fully charged battery

While the device is charging, the battery indicator will remain on in orange. When the device is charged, its color will turn blue. When you disconnect the charger, the battery indicator will turn off.

Orange: Charging battery (only turns on with the charger connected).

Blue: Battery charged (only turns on with the charger connected).

Use a power supply with the following characteristics:

- Output voltage: 5 V= (±5%)
- Output Current: 200 mA (minimum)
- Output connector: USB Type-C
- Insulated with 2 MOOP from supply mains

As a safety precaution, while the device is connected to the power supply, it will not be possible to perform measurements, as the device will not turn on.

Frequently used functionalities

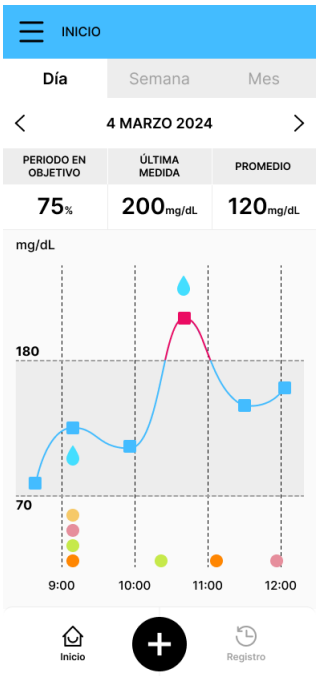
The GLUCUBE device is intended solely and exclusively for glucose measurements in the index, middle or ring fingers, both of the right and left hand. It does not have any other functionality.

APP (Android and iOS)

The GLUCUBE APP connects, via Bluetooth connection, with the GLUCUBE device.

Once connected to the device, it allows you to take measurements and, in addition, consult the data of the history of measurements taken.

Other functionalities of the APP are:



- Manage user profile data.
- Record new measurements manually.
- Record the hours and how many units you consume at meals.
- Record insulin usage data.
- Record the medications you take.
- Record the hours in which you perform physical exercise.
- Establish communication with the web service for the calculation of results.
- Visualize the evolution and average of user records for a day, a week and a month.
- Access to the Instructions for Use of the product.
- Check the availability of firmware updates for the measuring device in the web service and apply updates to it.
- Provide feedback to the user in case of problems in the processing of the data obtained.
- View the data of the linked GLUCUBE device (serial number, software version, hardware version, firmware version, MAC Address).
- Access to the knowledge base: https://kw.glucube.com/support

Power Cord

Connected to a power source and this in turn connected to a power grid and the measuring device, allows to charge the battery of the GLUCUBE device.

Replacing the charging cable

Use the cable provided with the product to charge the device. If you need a replacement cable, contact the manufacturer or their technical service.

Electromagnetic compatibility

Use the cable provided with the product to charge the device. The use of a different cable can affect the electromagnetic compatibility of the product, causing disturbances on other equipment.

If you need a replacement cable, contact the manufacturer or their technical service.

Risk of strangulation

Possible injuries from entanglement or strangulation with the power cord. Keep it away from children.

Web service for calculating the glucose level

The calculation of the glucose level from the measurements made with the GLUCUBE device is carried out using the GLUCUBE web service.

This means that, to obtain the results of the tests, the APP must have an internet connection (your smartphone must have an internet connection).

The connection to the service is made by the product's APP without any action being required on the part of the user.

3. Product specifications

Measurement Method	Near-infrared transmissivity
POWER SUPPLY	
Battery	Internal rechargeable battery, not user-replaceable
Load feeder	Not included with the device. Load Feeder Requirements: Output voltage: 5 V= (±5%) Output Current: 200 mA (minimum) Output connector: USB Type-C Insulated with 2 MOOP from supply mains
Charging cable	USB Type-A – USB Type-C Supplied with the product.
Autonomy	No measurements: 20 days Performing 5 measurements/day: 10 days Performing 10 measurements/day: 5 days *NOTE: Due to successive battery recharging cycles, the range may be progressively reduced over the life of the product.*
APP	
*The use of the product requires the installation of the APP for Android or iOS smartphone.	
APP operating systems	Android, iOS
COMMUNICATIONS	
Device-APP communication technology	Bluetooth Low Energy (BLE) Frequency range: 2.4-2.4835 GHz Maximum operating range: 2 m between device and smartphone (no obstructions)
Internet connection	The use of the product requires that the smartphone has an internet connection.

OPERATING ENVIRONMENT CONDITIONS	
Temperature	10°C to 35°C (50-95°F)
Relative humidity	10% to 95% non-condensing.
Atmospheric pressure	70 -106 kPa
Ambient lighting	Absence of direct sunlight on the device or the user's hand.
STORAGE CONDITIONS	
Temperature	0°C to 45°C (32-113°F)
Relative humidity	0% to 70% non-condensing.
CONDITIONS OF CARRIAGE	
Temperature	0°C to 45 °C (32-113 °F)
Relative humidity	0% to 70% non-condensing.
Atmospheric pressure	70 - 106 kPa
RESULTS	
Units of measurement	Mg/dL-mmol/L
Duration of the measurement	20 seconds
DIMENSIONS AND WEIGHTS	
Device dimensions	5.7 cm (length) 4.2 cm (width) 4.8 cm (height)
Device weight (Case not included)	64 grams
Device weight (Case included)	111 grams
SERVICE LIFETIME	
Lifetime	5 years
WATERTIGHTNESS	
Protection Index	IP21. Protection against solid bodies with a diameter greater than 12.5 mm and against the vertical fall of water droplets.

Smartphone requirements

Android smartphone requirements

Android Version	Android 8 or later
CPU Speed	Quad Core 1.2GHz or higher
RAM	2 GB (minimum)
Internal Storage	16 GB (minimum)
Connection	Wi-Fi or 4G (data service)
Screen	5'' (minimum)
Screen resolution	Minimum HD (1.280 x 720 pixels)

These smartphone requirements are current as of the date of publication of the manual.

You can view the most up-to-date version of the smartphone requirements for use with the GLUCUBE system on www.glucube.com

Do not install the product APP on an Android device that does not meet the above requirements.

Do not use the product with an APP other than the one provided by the manufacturer.

iOS smartphone requirements

iOS Version	iOS 13.4 or later
Minimum iPhone Version	iPhone 7

These smartphone requirements are current as of the date of publication of the manual.

You can view the most up-to-date version of the smartphone requirements for use with the GLUCUBE system on www.glucube.com

Do not install the product APP on an iOS device that does not meet the above requirements.

Do not use the product with an APP other than the one provided by the manufacturer.

Electromagnetic compatibility

Manufacturer's Guidance and Declaration - Electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment - Orientation**
RF emissions CISPR 11	Group 1	The device does not use radiofrequency energy.
RF emissions CISPR 11	Group B	The emission characteristics of this equipment make it suitable for use in industrial areas and in hospitals and nursing homes.

Manufacturer's Guidance and Declaration – Electromagnetic immunity			
Immunity test	**IEC 60601 Test Level**	**Level of compliance**	**Electromagnetic environment - Orientation**
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	Portable and mobile RF communications equipment should not be used closer to any part of the system than the recommended distance calculated from the equation applicable to the transmitter frequency. Recommended separation distance: $d = 1.2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80 MHz a 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz a 2,5 GHz Where P is the maximum power output of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m). The field strengths of fixed RF transmitters, as determined by an electromagnetic survey of the site (a), should be less than the level of conformity in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by the absorption and reflection of structures, objects, and people.			
a. The field strengths of fixed transmitters, such as radiotelephone base stations (mobile/cordless telephones) and terrestrial mobile radios, amateur radio installations, AM and FM broadcasting, and television broadcasting, cannot be accurately predicted theoretically. To assess the electromagnetic environment due to fixed radio frequency transmitters, an electromagnetic survey of the site should be considered. If the field strength measured at the location where the system is used exceeds the previously applicable RF compliance level, the system should be observed to verify its normal operation. If abnormal operation is observed, additional measures may need to be taken, such as reorienting or relocating the unit.			

Manufacturer's Guidance and Declaration - Electromagnetic immunity

Immunity test	IEC 60601 Test Level	Electromagnetic environment - Orientation
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
Magnetic field IEC 61000-4-8	30A/m	Magnetic fields at the mains frequency should be maintained at normal levels for a typical location in a commercial or hospital setting.

Manufacturer's Guidance and Declaration - Electromagnetic immunity

The system is intended to be used in an electromagnetic environment in which radiated RF disturbances are controlled. The system user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system, as recommended below, depending on the maximum output power of the communications equipment

Maximum rated transmitter output power W	**Separation distance according to emitter frequency m**		
	150 KHz to 80 MHz **$d = 1,2 \sqrt{P}$**	**80 MHz to 800 MHz** **$d = 1,2 \sqrt{P}$**	**800 Mhz to 6 GHz** **$d = 2,3 \sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the transmitter frequency, where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the highest frequency range applies.

NOTE 2: These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by the absorption and reflection of structures, objects, and people.

4. Symbols used

Different symbols are used on the measuring device, the software application and the labelling and packaging of the product. The meaning of these is described below:

Labeling symbols


Follow instructions for use


Operating/storage and transport temperature limits


Operation/storage and transport humidity limits


Operating/storage and transport pressure limits


Manufacturer identification

Manufacturing date

Catalog Reference

Lot Code

Serial Number


CE mark of conformity

IP Protection Index


Applied Part Type B

Device symbols

Device on/off button

Battery indicator

Connection indicator

Power connection

APP symbols

Symbols that accompany the APP messages

Informative messages: This symbol in the APP draws attention to important information to be taken into account during the handling of the product (APP or device).

Danger messages: This symbol in the APP indicates a possible risk due to malfunction of the product (APP or device).

Graphic symbols used in the APP

E-mail

Password

View password

Hide passwords

Start menu

Records Menu

 Connection menu

 Records drop-down menu

 Close records drop-down menu

 Close

 Advance

 Go back

 Open drop-down menu

 Calendar entries

 Birth date

 Country

 Calibration

 Device battery level above 75%

 Device battery level between 50% and 75%

 Device battery level between 25% and 50%

 Device battery below 25%

 Navigation drop-down menu

 Profile

 Access to about the device

 GLUCUBE device

 Manual record

 Food record

 Moment of the day of the food intake

 Insulin record

 Medication record

 Exercise or physical activity record

 Intensity of the exercise

 Delete

 Settings

 Language

 Maximum of the glucose range

 Minimum of the glucose range

 Checking signal

Measuring glucose levels

Calculating glucose levels

Selectable last meal

Selectable time elapsed since last meal

Height

Weight

Unpair device

Profile physiology

Advertence

Help

Info

Offline

Share

GLUCUBE PANEL symbols

Symbols that accompany GLUCUBE PANEL messages

Danger messages: This symbol in GLUCUBE PANEL indicates that something does not meet the expected requirements

Error message: This symbol in GLUCUBE PANEL indicates that the changes have not been made correctly.

Success message: This symbol in GLUCUBE PANEL indicates that the action has been carried out successfully

Graphic symbols used in GLUCUBE PANEL

Open drop-down menu

Principal Panel/Settings

Navigation drop-down menu

Graphics

Records menu

Log out

Security

Download of measures

Report

 GLUCUBE record

 Manual record

 Profile/Account

 Link measures

5. Product indicators and messages

Device indicators

The device cannot be used without being connected to the APP. For this reason, most of the device status alerts and indications will be displayed on the APP screen.

The indications incorporated in the device itself are indicated below.

Battery charge indicator

Orange: Charging battery (only turns on with charger connected).

Blue: Battery charged (only turns on with charger connected).

Device status indicator

Green – Flash every 2 sec.: Device turned on, looking for connection to the APP.

Green – Fixed: Device turned on and connected to the APP.

Green – Intermittent: Low battery level.

Acoustic signals of the device

1 short beep after pressing the power button on the device.	The device is turned on.
1 double beep.	The device has been connected to the APP.
1 long beep (1 second) after device shutdown operation.	The device has been turned off.
3 short beeps.	The device has been reset.

APP Messages

MESSAGE	MEANING	USER REQUIRED ACTION
Before making a decision, contrast the value with another method of self-diagnosis	The glucose value has exceeded the established target range	Contrast the value with another self-diagnosis method
The GLUCUBE APP collects location data to enable connection to the GLUCUBE measuring device even if the app is closed or not in use. For more information, please read our Privacy Policy	Location permission must be enabled to enable connection to the GLUCUBE device	Tap OK to accept the permission
We have detected Android 12 or higher on your device. In order to continue, you must activate the "Nearby Devices" permission	Access to the permission of nearby devices is requested on those smartphones with Android 12 or later	Tap go to permissions and turn on the Nearby Devices permission
New update of the GLUCUBE device. We recommend that you update your GLUCUBE device to the latest version. This new version includes improvements and fixes for possible bugs. Thank you!	There is a new update of the GLUCUBE device	Update your GLUCUBE device if possible, or contact GLUCUBE Technical Service
New update of the GLUCUBE APP. We recommend that you update the GLUCUBE APP to the latest version. This new version includes improvements and fixes for possible bugs. Thank you!	There is a new update to the GLUCUBE APP	Update the GLUCUBE APP if possible, or contact GLUCUBE Technical Service

6. Configuration of the GLUCUBE system

No specific skills are required for the configuration and use of the GLUCUBE system

Installing the APP

Android

Using your smartphone, go to the Play Store and, in Search apps, enter GLUCUBE APP. Tap Install. Once the APP has been installed on your smartphone, you can run it using the on-screen icon.

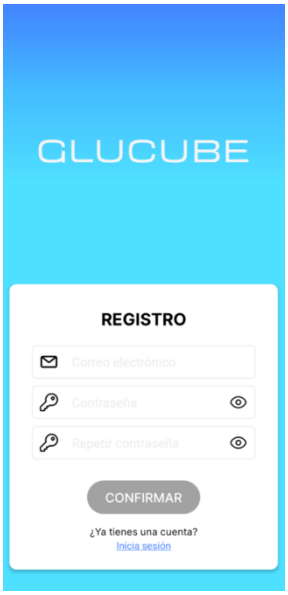
DISPONIBLE EN Google Play

iOS

Using your smartphone, go to the App Store and, under Search Apps, enter GLUCUBE APP. Tap Install. Once the APP has been installed on your smartphone, you can run it using the on-screen icon.

Consíguela en la App Store

Getting started in the APP



Step 1: Email and Password Introduction

New account: In the registration screen, enter your email address and your new password in the appropriate boxes. If this email is recognized by our database, an existing account advice will be displayed for you to log in from the login screen. The password must contain at least 8 characters, at least one uppercase letter, at least one lowercase case and at least one symbol or digit. If the password is correct you will access to the next step.

Remember not to share this password with anyone.

Write down the password in a safe place in case you need to remember it. If you have forgotten your password or think someone may have access to your account, click Forgot your password? to restore it.

It is necessary to accept the terms of conditions and the privacy policy in order to create an account.

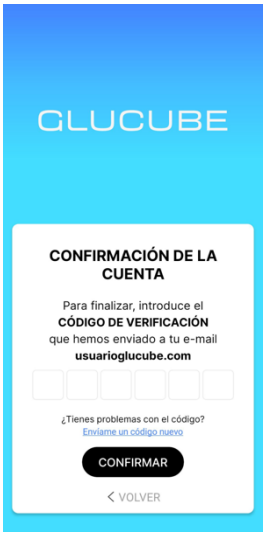
Existing account: In the login screen, enter your email address and your password in the appropriate boxes. If the email is registered and the password is correct you will directly access to the home screen of the APP.

If you have forgotten your password, you can click on *Forgot your password?* and the system will automatically send a link to the email entered to set a new password.

Step 2: Account confirmation (new accounts)

When you enter a new email address (you have not previously registered with GLUCUBE), an account verification code will be sent to that email address so that you can proceed with the creation of a new user on GLUCUBE. Enter that code in the APP.

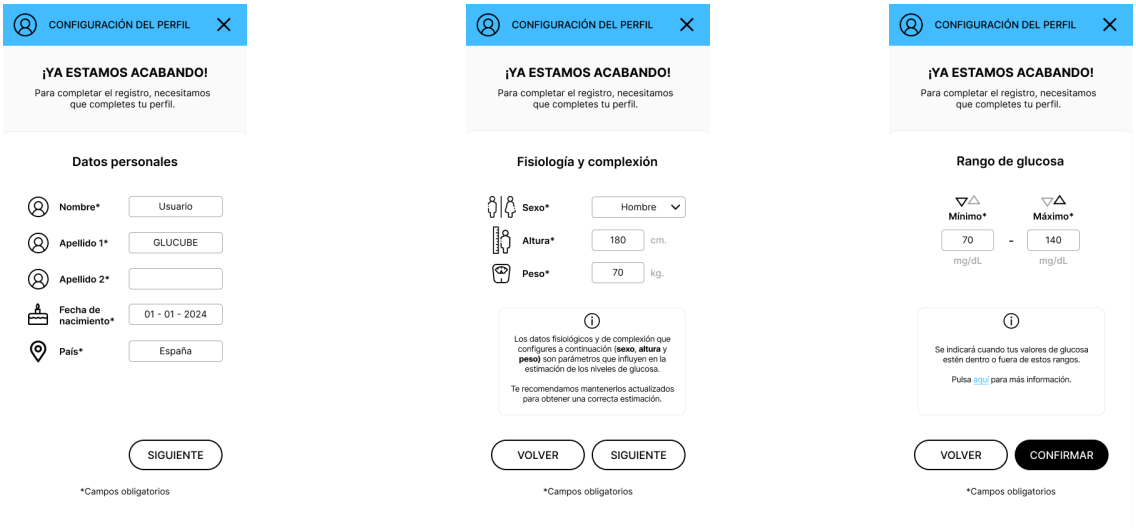
If you do not receive the email, click on "SEND ME A NEW CODE" and it will be sent to you again.



Step 3: Profile Settings (new accounts)

To set up your profile, you will need to enter your personal details. In addition, you will have to enter biological sex, height, weight and establish a target glucose range. These ranges allow the APP to indicate whether your glucose measurements are within or outside this range.

Follow all the steps indicated by the APP to complete the account creation.

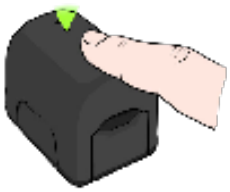


The physiological and build data you set up below (physiology, height, and weight) are parameters that influence the estimation of glucose levels.

We recommend that you keep them updated to get a correct estimate.

Turn on the GLUCUBE device

To turn on the device, press and hold the power button for 2 seconds. You will then hear 1 short beep.



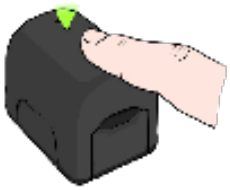
Green – Flash every 2 sec.: Device turned on, looking for connection to the APP.

If the status LED does not flash during power-up, or you do not hear the acoustic signal, the device may be out of battery, try charging it. If the problem persists, the device may have a problem. In this case, please contact Customer Service.

Turn off the GLUCUBE device

To turn off the device, press and hold the power button for at least 4 seconds.

A beep will occur, and the device will turn off (connection indicator off).



Green – Flash every 2 sec.: Device turned on, looking for connection to the APP.

If during the shutdown of the GLUCUBE device, the LED does not turn off, or does not hear the acoustic signal, it is possible that the device has a problem. In this case, do not use the product and contact Customer Service.

Reset the GLUCUBE device

If you have problems pairing your device or connecting your device, follow these steps:

1. First, delete the link with the GLUCUBE device on your smartphone. In your smartphone's bluetooth settings, find and unpair the paired GLUCUBE device.
2. Turn on the device
3. Press the power button and hold it.
4. After 3 seconds, you will hear a beep and the connection LED will turn off.
5. While still pressing, wait 15 more seconds.
6. The connection LED will light up and after a second it will turn off and you will hear 3 beeps. The device will be reset.

Remember, you need to unpair the paired GLUCUBE device in your smartphone's bluetooth settings.

To re-pair the GLUCUBE device, follow the following section of this manual: *Pairing the GLUCUBE device with the APP*

Pairing the GLUCUBE device with the APP

The pairing must be done from the APP. It can NOT be done from the smartphone's bluetooth panel.

To pair the GLUCUBE device with the APP, you must have Bluetooth connection and location enabled on your smartphone.

1. On the Home screen of the GLUCUBE APP, access the side menu and click on **"Connect your device"**
2. Turn on the GLUCUBE device. The device's connection indicator will be:


Green – Flash every 2 sec.: Device turned on, looking for connection to the APP.

3. With the device turned on, tap on **"Find device"**

In order to connect the GLUCUBE device, you must grant the following permissions to the APP:

- Exact location. Read more about why this information is collected in our Privacy Policy https://www.glucube.com/politica-de-privacidad
- Nearby devices. This permission will only be required on smartphones running Android 12 or later.

For more information about APP permissions:
https://kw.glucube.com/support/permisos-app

4. Select the GLUCUBE device to pair. The GLUCUBE device will beep twice and the connection LED will remain solid.
5. On your smartphone, a pop-up window will appear asking you to pair the device. Tap link and you'll then be prompted for a pairing code. Enter the PIN **002244**.

If a link request message does not appear:

- Check in the notifications of your smartphone.
- Check pop-up notification permissions.
- Restart the APP and retry the process.
- Restart the Smartphone and retry the process.

If the device pairing with the device has been successful, the device connection indicator will be:

Green – Fixed: Device turned on and connected to the APP.

In the APP, the GLUCUBE measurement will start. For more information, see section 7. Performing a glucose measurement.

Once the GLUCUBE device is paired with your smartphone, it will automatically connect when you turn it on with the APP open.

If the status LED does not flash during power-up, or you do not hear the acoustic signal, the device may be out of battery, try charging it. If the problem persists, the device may have a problem. In this case, please contact Customer Service.

If you have any problems pairing your GLUCUBE device to your smartphone, follow the steps in the Reset your GLUCUBE device section and try again. If the problem persists, please contact Technical Service.

Date and time adjustment

It is not necessary to adjust the date and time, the system will use the date and time of the smartphone.

Edit profile data

You can modify the data entered during user setup if you wish in the side menu, at the top left of the Home screen, by clicking on the username.

How to calibrate the GLUCUBE system

The GLUCUBE system adjusts or adapts to the glucose values manually entered into the application. The GLUCUBE system requires an initial calibration period so that it can be adapted to the user's measurements. Once this period is complete, the system will ask you to introduce spot calibration measurements to update the calibration of the system.

How to perform a calibration measurement

A calibration measurement consists of a measurement with the GLUCUBE device linked to a measurement obtained with the capillary glucometer. Here's how to link:

1. Take a GLUCUBE measurement (see section *Perform a glucose measurement*.) After the GLUCUBE measurement is complete, the glucose value will appear.

BEFORE SAVING, you will need to enter the value obtained by the capillary glucometer.

2. Perform a measurement with the capillary glucometer.

Enter the value obtained in the GLUCUBE APP, in the "Manual Record" section, and click on "SAVE".

Initial calibration

When you start using the GLUCUBE system, you will need to enter 10 calibration measurements with a capillary glucometer during the first week of use. To ensure optimal calibration adapted to the user, it is advisable to carry out these measurements in a distributed manner over time, with more than 2-3 hours between each one.

The GLUCUBE system adapts to manually entered glucose values. It is recommended to perform calibration measurements in a timely manner to update the initial calibration of the system.

To ensure correct calibration, the capillary glucometer measurement must be introduced within less than 5 minutes of the GLUCUBE measurement.

7. Perform a glucose measurement

We recommend taking the measurement on the ring finger, although the measurement can also be taken on the index and middle fingers.

The GLUCUBE device allows measurements to be made on fingers of the right or left hand.

Do not use your thumb or pinky finger.

Handling the GLUCUBE device and placing the finger

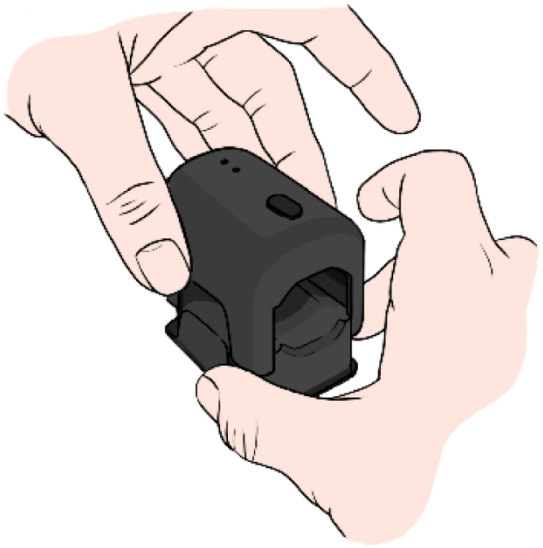
The opening and closing mechanism of the GLUCUBE device is designed to ensure light tightness and stability during measurement and automatically adjusts to the user's finger.

Make sure that the finger on which you are taking the measurement is clean. If necessary, wash your hands with soap and water and dry them before taking the measurement

The use of the GLUCUBE device held in the air or on an unstable surface may cause errors in the measurement results.

Always take measurements with the device resting on a horizontal, flat and stable surface. With the arm and hand relaxed and without movement.

1



Hold the device by the grip tabs and lift the top case to allow the finger to be inserted.

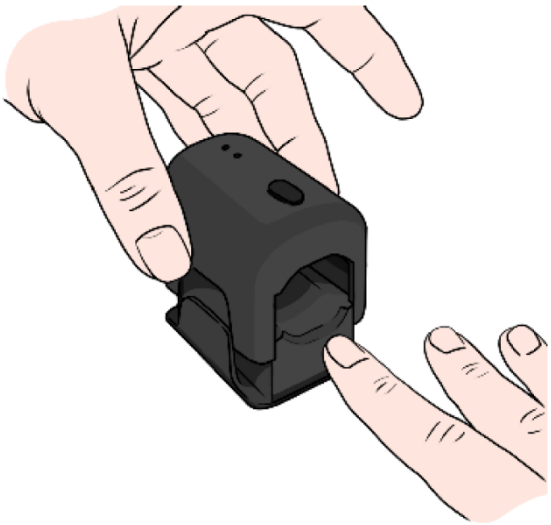
2

Insert your finger into the device and place it on the measurement window. Once the finger is in position, lower the upper case.

3

Keep your finger inside the device until the measurement is performed.

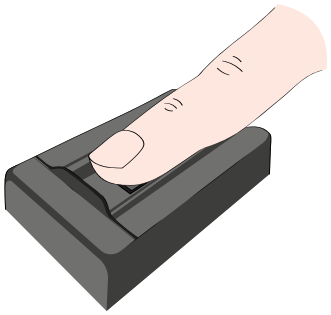
4

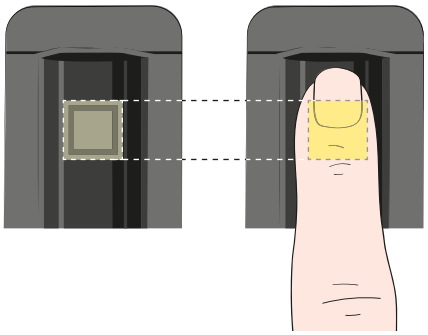


When prompted by the APP, lift the upper casing and pull out your finger.

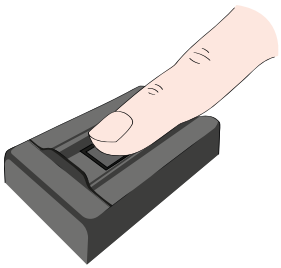
Correct placement of the finger on the measuring area

Correct placement

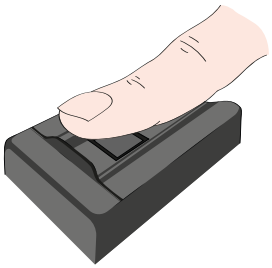




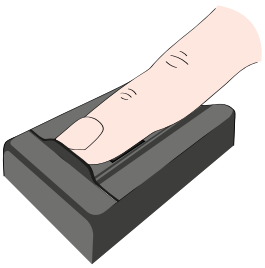
Incorrect placement



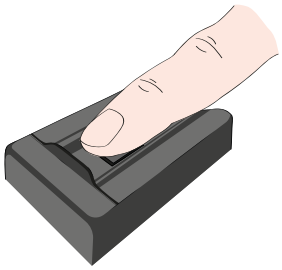
Without covering the window



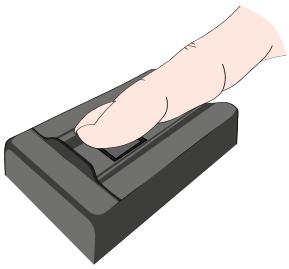
Raised slightly



Too introduced



Too much pressure



Sideways

Before performing a measurement

Sit so that your back and arm can be well supported. Make sure that you can rest the arm and the device on a horizontal, flat and stable surface during the measurement.

Avoid forced hand and finger positions that may impede the proper flow of blood.

Keep your smartphone at a distance of 10-20 cm from the device to ensure a good connection.

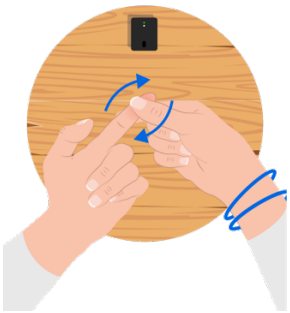
Cold hands and fingers can make it difficult to detect the signal. Rub your hands together and massage the fingertip to warm it and increase the blood flow.

To perform a measurement, the GLUCUBE device needs to be paired with the smartphone. See section *Pairing the GLUCUBE device with the APP.*

Make sure that the finger on which you are performing the measurement is clean. If necessary, wash your hands with soap and water and dry them before performing the measurement.

Perform the GLUCUBE measurement

Before taking the measurement, rub your hands together and massage the fingertip to warm it up and increase blood flow. Cold hands and fingers make it difficult to detect the signal.



Start the GLUCUBE measurement

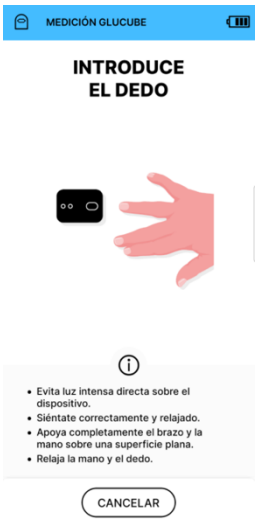
Open the APP and turn on the GLUCUBE device.

The device will start searching for connection, and if the pairing is successful, it will connect automatically. The connection indicator on the device will be:

Green – Fixed: Device turned on and connected to the APP.

The device connection indicator should be fixed. After the beep. Otherwise, follow the procedure in the section *Pairing the GLUCUBE device with the APP.*

In the APP, the following screen will appear. The device will be waiting for you to insert your finger to start the measurement. Insert your finger to start the measurement.



To save device battery, after. 10 seconds without inserting your finger, the device will turn off and a warning will appear in the APP of expired timeout.

GLUCUBE measurement process

The font size of your smartphone may cause visual errors in the APP. You can change the size in the smartphone settings.

Once you have inserted your finger, the measurement process will start. It consists of 3 steps.

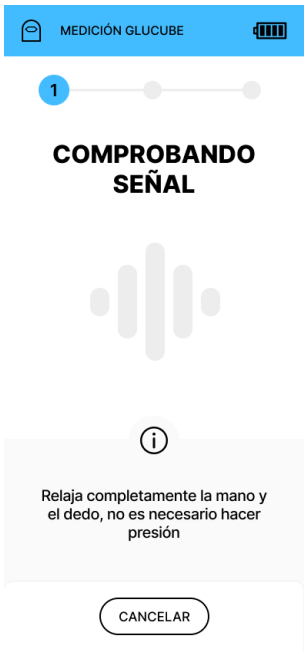
Step 1: Checking signal

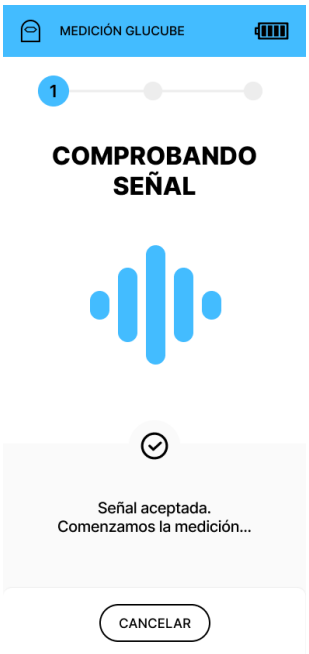
Ensure that the device and hand are supported in a stable and relaxed manner, without too much incident light.

In this step, it will be checked that the signal is correct to perform the measurement, for this the placement of the finger, the ambient light and if there are interferences that impair the optimal operation of the device will be analyzed.

To do this, an indicator will appear on the screen that will reflect the quality of the signal. If there is an incident in any of the checks, the indicator will not change of color and a short help message will appear.

When the signal quality is optimal, the indicators will appear filled in blue and you will go directly to the next step.

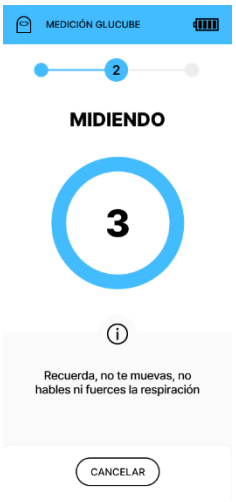




In case an error is displayed during this step, you will need to exit the measurement and turn the device back on to start another measurement. For more information about errors, see the *Errors and Warnings in the GLUCUBE measurement* section. If these errors persist, please contact Customer Service.

Step 2: Measuring…

In this step glucose levels are being measured, you must keep your finger in a stable position and without moving it for 20 seconds to ensure a correct measurement.



Do not move your device or hand during this step.

Do not talk, yawn or force your breath, it may affect the results.

Step 3: Calculating…

Finally, the measurement is processed to calculate the blood glucose level. You can now remove your finger from the device. After a few seconds, the value will be displayed in the APP.

Make sure you have an internet connection.

Save the GLUCUBE measurement

If the measurement has been performed correctly, the value will be displayed in the APP.

To save the measurement, select on the screen what your last meal was:

- Breakfast
- Mid-morning
- Lunch
- Snack
- Dinner

Select how long ago was the last meal:

- Less than 1 hour
- Between 1 and 2 hours
- Between 2 and 3 hours
- Between 3 and 6 hours
- More than 6 hours

Click on "SAVE" to record the measurement.

In case of entering a contrast value, it will be mandatory to enter what your last meal was and how long ago it was. If a contrast value is not entered, the measurement can be saved without entering these values.

Perform the GLUCUBE measurement offline

Start the GLUCUBE measurement

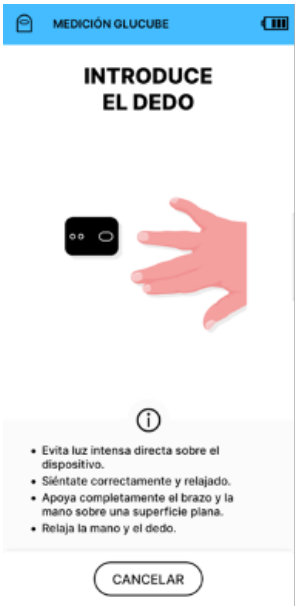
Open the APP at the top right, this symbol will appear indicating that there is no connection. Make sure that you have activated the Bluetooth of the smartphone and turn on the GLUCUBE device.

The device will start searching for connection, and if the pairing is successful, it will connect automatically. The connection indicator on the device will be:

Green – Fixed: Device turned on and connected to the APP.

The device connection indicator should be fixed. After the beep. Otherwise, follow the procedure in the section *Pairing the GLUCUBE device with the APP.*

In the APP, the following screen will appear. The device will be waiting for you to insert your finger to start the measurement. Insert your finger to start the measurement.



To save device battery, after. 10 seconds without inserting your finger, the device will turn off and a warning will appear in the APP of expired timeout.

GLUCUBE measurement process

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Once you have inserted your finger, the measurement process will start. It consists of 3 steps.

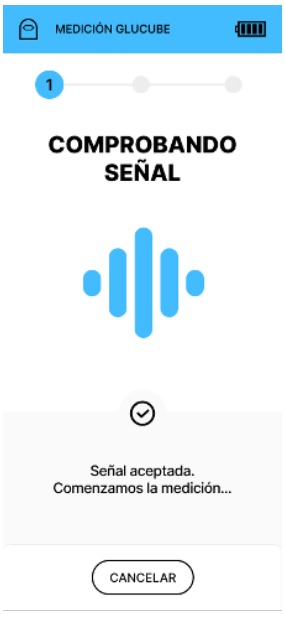
Step 1: Checking signal

Ensure that the device and hand are supported in a stable and relaxed manner, without too much incident light.

In this step, it will be checked that the signal is correct to perform the measurement, for this the placement of the finger, the ambient light and if there are interferences that impair the optimal operation of the device will be analyzed.

To do this, an indicator will appear on the screen that will reflect the quality of the signal. If there is an incident in any of the checks, the indicator will not change of color and a short help message will appear.

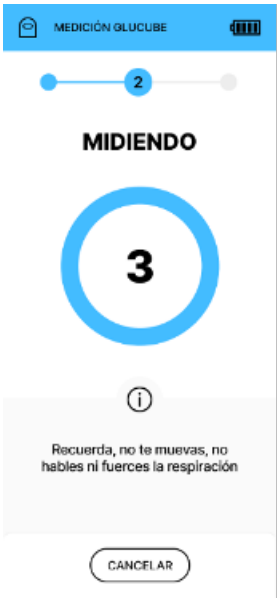
When the signal quality is optimal, the indicators will appear filled in blue and you will go directly to the next step.



In case an error is displayed during this step, you will need to exit the measurement and turn the device back on to start another measurement. For more information about errors, see the *Errors and Warnings in the GLUCUBE measurement* section. If these errors persist, please contact Customer Service.

Step 2: Measuring…

In this step glucose levels are being measured, you must keep your finger in a stable position and without moving it for 20 seconds to ensure a correct measurement.

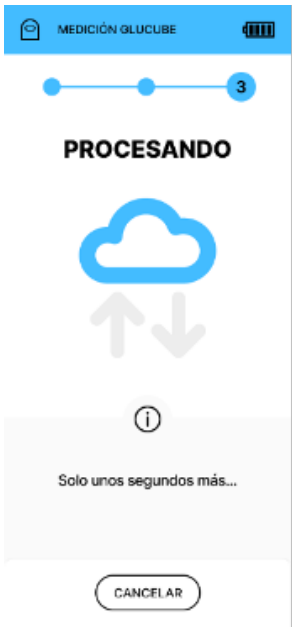


Do not move your device or hand during this step.

Do not talk, yawn or force your breath, it may affect the results.

Step 3: Calculating…

Finally, the measurement is processed to calculate the blood glucose level. You can now remove your finger from the device.



Step 4: Get the measurement

This screen will then appear, indicating that this is a measurement without an internet connection. If the measurement has been carried out correctly, when you are connected again, the glucose value obtained will be automatically saved.

You can carry out as many measurements as you need

Warnings and error in the GLUCUBE measurement

Make sure that the GLUCUBE device is charged. Low battery may cause undesired behavior of the device.

In the event of an incident occurring during the measurement, it will be indicated in the APP. In the upper left corner, there is a code that identifies the error caused. A list of each of them is shown below.

Error capture with the marked code:

CODE	CAUSE	WHAT TO DO
E1 - 1 ... E1 - 4	Connection error with the GLUCUBE device.	Click on "EXIT", turn on the device and repeat the measurement process. In case it is not solved, try restarting the smartphone. If the error persists, please contact Customer Service.
E2 - 1	The maximum waiting time has passed between turning on the device and inserting the finger.	When connecting the device with the APP, if 10 seconds pass without inserting the finger, it turns off. Click on "EXIT", turn on the device and repeat the measurement process. If the error persists, please contact Customer Service.
E2 - 2	The finger was not in a correct position when preparing the measurement and therefore the measurement has not started.	The finger may not be placed correctly on the measuring area inside the device. Follow the instructions in the section *Correct placement of the finger on the measuring area* Click on "EXIT", turn on the device and repeat the measurement process. If the error persists, please contact Customer Service.
E2 - 3	Timeout error in overall measurement quality - error during STEP 2.	Click on "EXIT", turn on the device and repeat the measurement process. In case it is not solved, try restarting the smartphone. If the error persists, please contact Customer Service.

E2 - 4	Estimate Service Timeout Error - Error During STEP 3.	Click on "EXIT", turn on the device and repeat the measurement process. In case it is not solved, try restarting the smartphone. If the error persists, please contact Customer Service.
E2 - 5	GLUCUBE device data submission timeout error - error during STEP 3.	Click on "EXIT", turn on the device and repeat the measurement process. In case it is not solved, try restarting the smartphone. If the error persists, please contact Customer Service.
E3 - 1 ... E3 - 9	Slight movements that have caused instability in the signal. Forced breathing that may have caused signal instability. Very cold hands that do not allow a correct signal to be detected. Performing the measurement on an unstable surface. Use of nail polish or acrylic nails that may make it impossible to detect the signal.	Keep your hand as stable as possible by avoiding movements. Avoid forced positions that impede the proper flow of blood flow in the hand. Perform the measurement on a stable surface. Do not speak and breathe calmly, avoiding forcing your breath. Make sure that your finger covers the window correctly and that it is in a correct position by following the instructions for use of the device. If the error persists, please contact Customer Service.
E3 - 10	The signal conditions have changed from the previous measurement.	Click on "EXIT", turn on the device and repeat the measurement process. In case it is not solved, try restarting the smartphone. If the error persists, please contact Customer Service.
E3 - 100	Communication failure with the cloud service.	Click on "EXIT", turn on the device and repeat the measurement process. In case it is not solved, try restarting the smartphone. If the error persists, please contact Customer Service.

E3 - 101	Communication failure with the device.	Access to the side menu > "About the device" > Hardware configuration. Change to "Adapted". Repeat the measurement. In case it is not solved, try restarting the smartphone. If the error persists, please contact Customer Service.
E3 - 102	Incorrect profile data.	Check that the profile data is complete and correctly filled in. If the error persists, please contact Customer Service.
E4 - 1 ... E4 - 3	Other errors.	Click on "EXIT", turn on the device and repeat the measurement process. In case it is not solved, try restarting the smartphone. If the error persists, please contact Customer Service.
E4 - 4	Loss of internet connection that makes it impossible to synchronize correctly with the cloud.	Check if you are in a place with adequate coverage. Check if you have a good connection to be able to perform the measurement.
E4 - 5	Disconnection of Bluetooth from the device during the measurement. Disconnection of the device during the measurement.	Check that the smartphone's Bluetooth is activated and that it does not turn off during the measurement. Check that your device is properly charged.
E4- 6 ... E4 - 7	Other errors.	Click on "EXIT", turn on the device and repeat the measurement process. In case it is not solved, try restarting the smartphone. If the error persists, please contact Customer Service.
E5 - 1 ... E5 - 4 **E5 - 10 ... E5 - 16**	Hardware failure.	Click on "EXIT", turn on the device and repeat the measurement process. If the error persists, please contact Customer Service.

8. Add other records in the APP

The font size of your smartphone may cause visual errors in the APP. You can change the size in the smartphone settings.

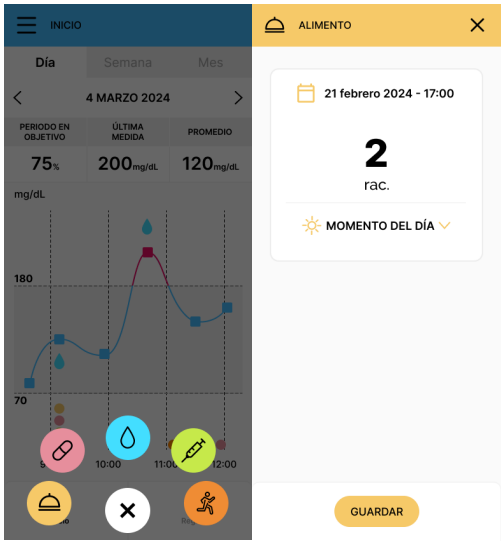
Food

To record a food intake, expand the records menu (+) and access the *Food* section.

Then, enter:

- **Date:** Date of food intake.
- **Hour:** Time of food intake.
- **Moment of the day:** Moment of the day in which the food was taken: breakfast, lunch, snack or dinner.
- **Servings:** Number of servings eaten.

Click on "SAVE", to save the record.



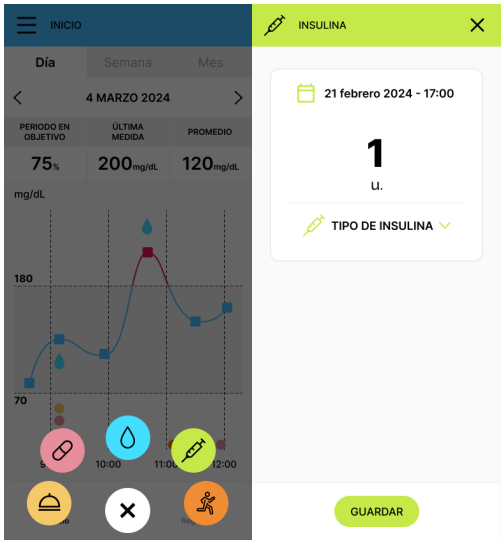
Insulin

To register an insulin application, expand the registration menu (+) and access the *Insulin* section.

Then, enter:

- **Date:** Date of the insulin application.
- **Hour:** Time of the insulin application.
- **Insulin type:** Type of applied insulin: fast or slow.
- **Quantity:** Amount of insulin applied, in insulin units (u).

Click on "SAVE", to save the record.



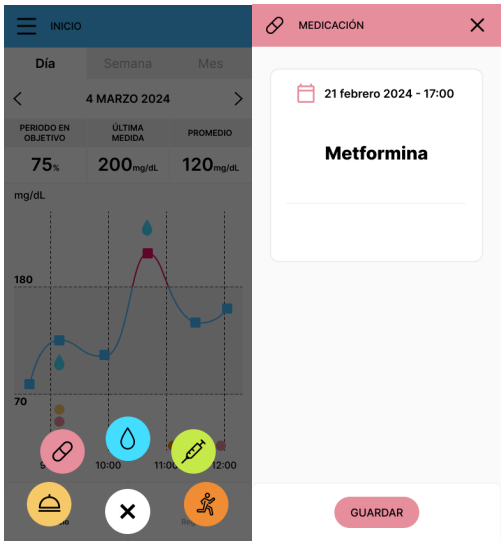
Medication

To record an intake of a medication, expand the records menu (+) and access the *Medication* section.

Then, enter:

- **Date:** Date of medication intake.
- **Hour:** Time of medication intake.
- **Medication:** Name of the medication.

Click on "SAVE", to save the record.



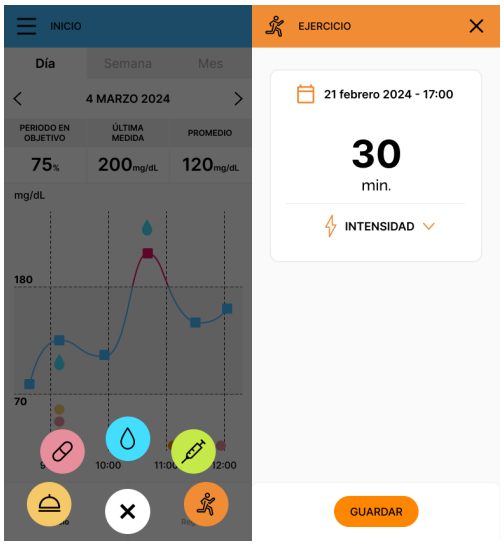
Sport

To record the performance of physical activity, display the records menu (+) and access the Sports section.

Then, enter:

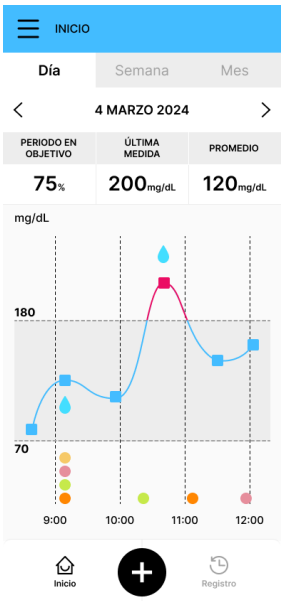
- **Date:** Date of the perform of the physical activity .
- **Hour:** Time of the perform of the physical activity.
- **Intensity:** Intensity of the. performed physical activity: light, moderate or intense.
- **Time:** Duration of the physical activity.

Click on "SAVE", to save the record.



9. Measurements history

Graph of the evolution of measurements



On the Home screen of the GLUCUBE application you can find the measurement evolution graph. The target glucose range that was set in the profile settings is represented in shade.

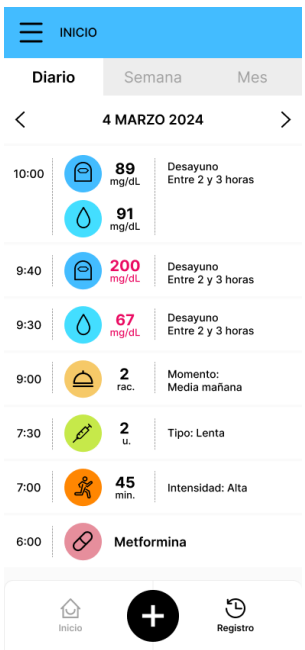
You will be able to visually differentiate the measurements made on a curve from the measurements made with the GLUCUBE device. In addition, glucose values that you add manually are represented.

If you click on an indicator on the graph, you can see the value of the record and the date it was saved.

You can filter the display of the measurements by selecting a specific date and clicking on the icon (full screen icon) you can see the graph in full screen.

In addition, you will be able to view the average of the records prior to the selected day, of a week and a month. In these graphs, selecting a point you will be able to see the average, and in shade, the maximum and minimum glucose value of each day.

Records book



On the Registration screen, you can view all the registrations made. You can set up daily, weekly and monthly display. This will display the records saved during that range of days until the selected date.

It indicates what type of each record is, its value, the date on which it was registered, and the information entered in each of them.

Edit and delete records

To edit a record, tap on the record you want to edit, and the record screen will open where you can change the date, time, and other data entered. Once the changes have been made, you must click on "SAVE".

To delete a record, swipe left on the record you want to delete and click on  .

GLUCUBE measurement records cannot be edited or deleted

10. Other functionalities of the APP

Accessing to the side menu ☰ you will find several additional functionalities.

Profile

From the profile section you can view and edit all the data associated with the account. In addition, you can log out or request permanent deletion of the account.

Calibration

From the calibration section you can consult the calibration measurements recorded and the measurements pending to be made.

About the device

You will be able to display various information about the device: APP version, firmware version (GLUCUBE device) and its update, serial number of the paired GLUCUBE device, operating system version (Android or iOS), hardware configuration, MAC of the paired GLUCUBE device and OS version of the mobile device.

Share

You can generate a code with which the data can be shared with a professional, who will have access to the user's glucose values.

Help

How to perform a GLUCUBE measurement. Explanation of the measurement process with the GLUCUBE device

User Manuals. You will be able to access and download this user manual in digital format.

Last errors Recording of the last 4 errors detected in the GLUCUBE measurements made

Support. Access to the technical assistance portal with chat for resolution of doubts and incidents.

Legal. You can access the content of our privacy policy and terms of conditions

Warnings. Indications for use of the GLUCUBE device

Settings

Language. Select APP language.

Synchronize data with the cloud. Sync your latest saved data in the APP.

Units. Change the units for glucose measurements between mg/dL and mmol/L.

11. Updates

Updates to both the APP and the GLUCUBE device are mandatory for optimal operation of the product.

APP update

When an app update is required, you will be prompted when you launch the APP. You will need to access the Play Store (Android) or Apple Store (iOS), search for the GLUCUBE APP and update. When you launch the APP again, it will be up to date.

GLUCUBE device update

When an update of the GLUCUBE device is required, you will be prompted when you launch the APP. You will need to access the menu, under About the device, the device version will be indicated and next to it will appear "Update".

12. GLUCUBE PANEL instructions

No specific skills are required for the configuration and use of the GLUCUBE system

Introduction

Intended use

GLUCUBE PANEL is a tool that allows users to consult and review the data recorded through GLUCUBE APP, as well as share it with healthcare professionals.

Other GLUCUBE PANEL features include:

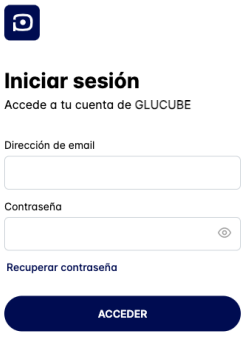
- Managing user profile data.
- Viewing the evolution and average of user records by day, week and month.
- Viewing and filtering the data collected in the GLUCUBE APP.
- Exporting and downloading the data recorded in the GLUCUBE APP.
- Sharing your glucose measurements and other records with healthcare professionals you authorize. They will be able to monitor them remotely and in real time, speeding up their responses.
- Generating detailed reports and graphics to help you and healthcare professionals control your glucose.

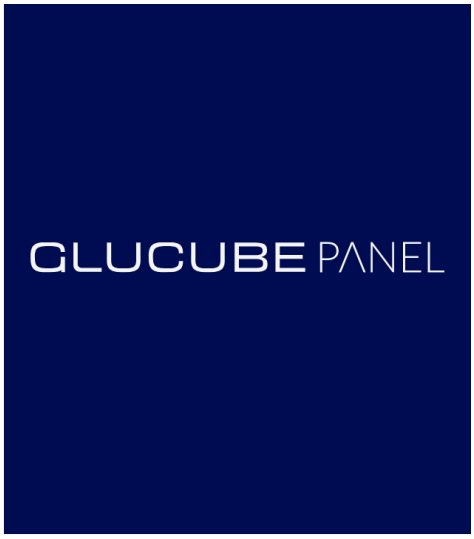
Privacy Policy

The use of GLUCUBE PANEL is subject to the terms and conditions of GLUCUBE's privacy policy. The latest version of this document can be found on the website www.glucube.com.

Getting started with GLUCUBE PANEL

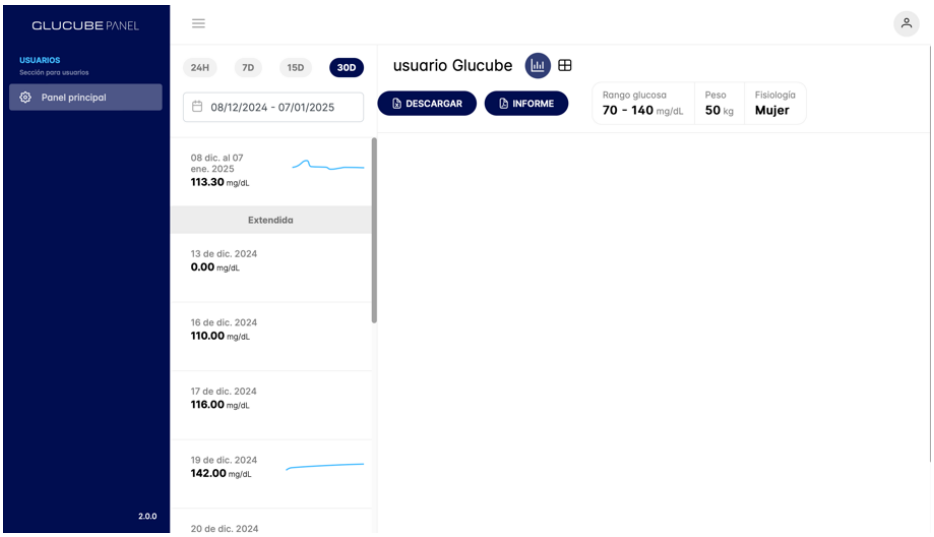
Step 1: Access to GLUCUBE PANEL





Use an electronic device to access to GLUCUBE PANEL

Step 2: Log in



To log in GLUCUBE PANEL, enter the email and password you used to create your account from GLUCUBE App. And click on "**Login in**" button.

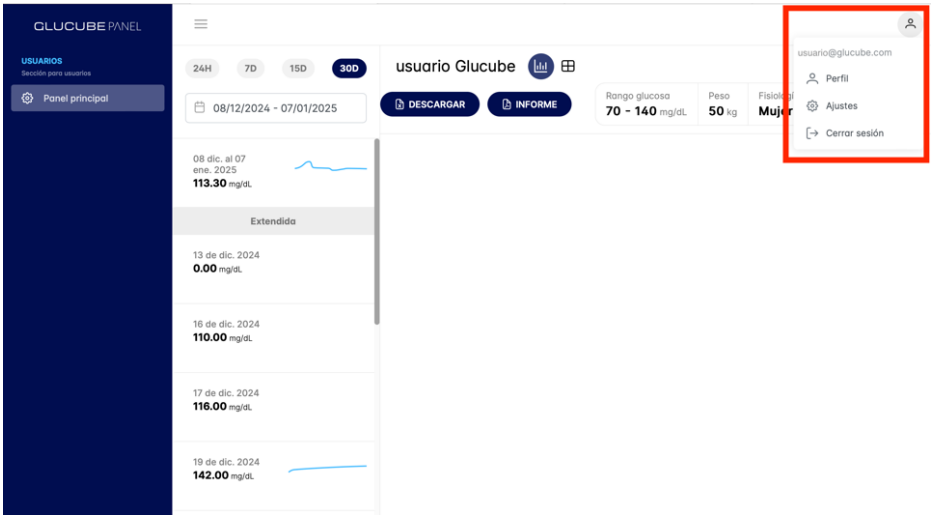
If you have forgotten your password or think someone may have access to your account, click "**Recover password** "to restore it.

Step 3: Edit profile

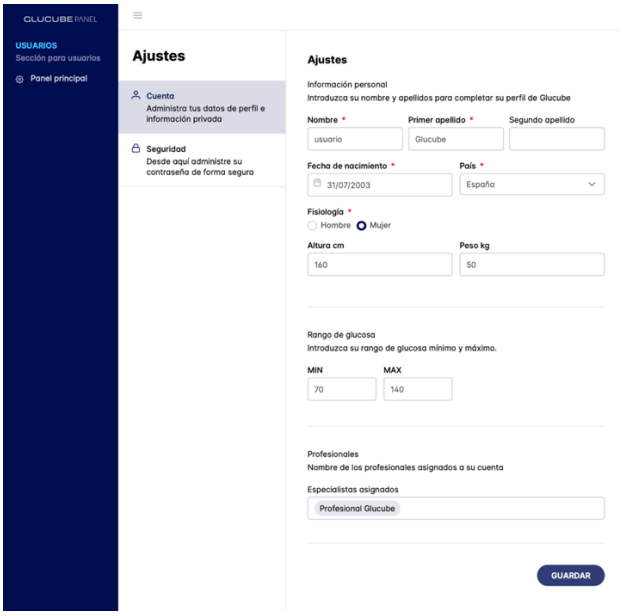
You can edit your profile at any time, so you will be able to edit your personal information and password.

To access the profile editing screen, you must click on the icon located at the top right of the screen to open the drop-down menu.

Select the "Profile" button to access the screen for editing your data, or the "Settings" button to access the password editing screen.

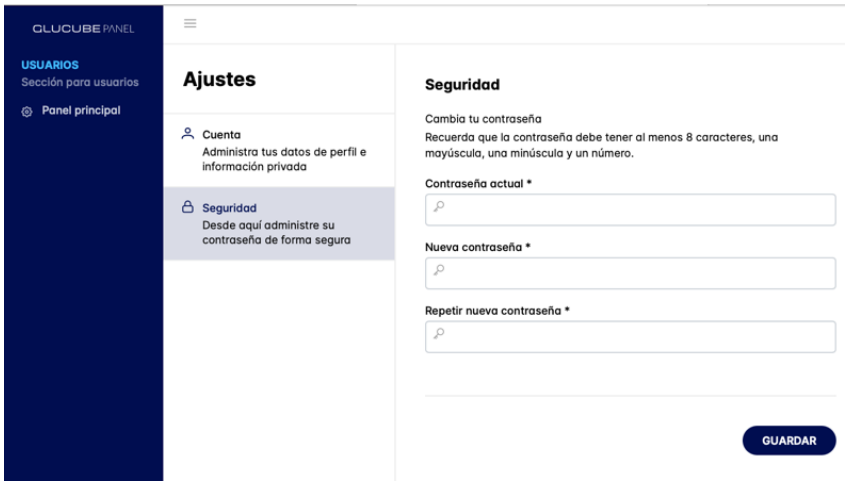


In the left side menu, the "Account" and "Security" sections will appear.



The "Account" section allows the user to view and edit their personal information. It also allows to change the established glucose range. At the bottom of the page, the professionals assigned to their account will appear, who will be able to easily access and view their measurements and graphs.

"Security" section is designed to protect the user's account. It serves to change the password, which is essential to ensure the security of the data stored on the platform.

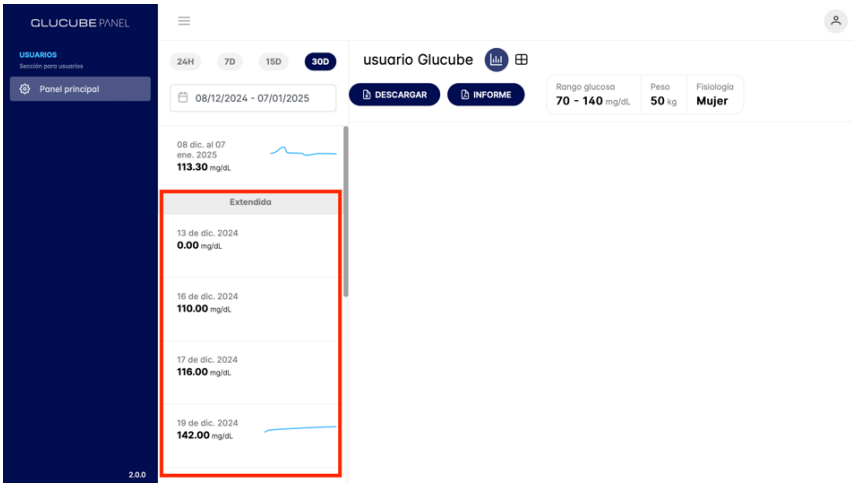


GLUCUBE PANEL zones

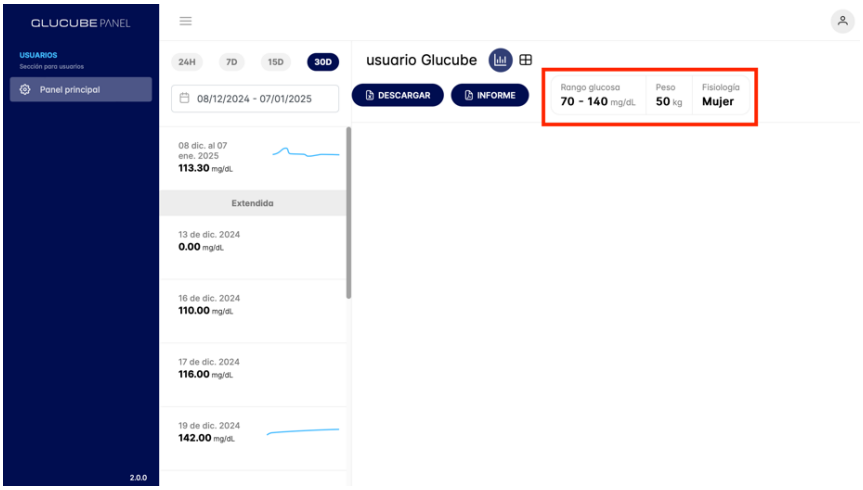
After logging in, the following will appear on home screen:

A summary graph based on the dates selected for the search. You can filter the display for a specific date. To enlarge the graph, click on it.

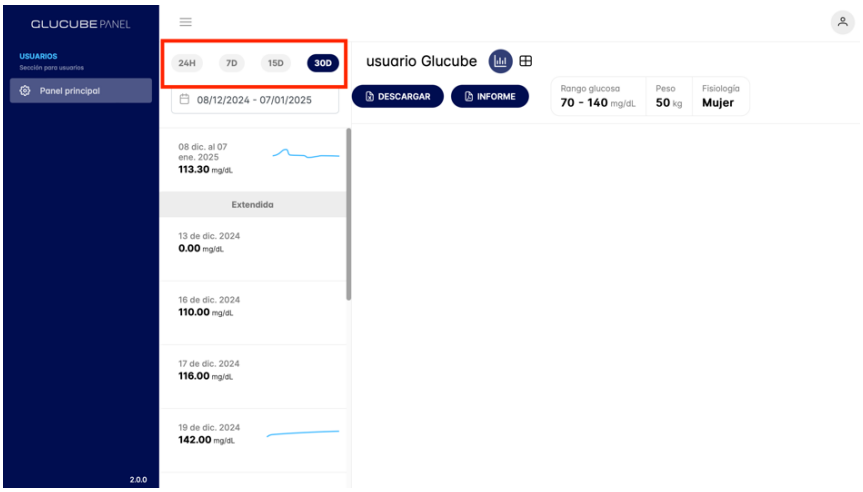
The minimum and maximum glucose values will be shaded, while each point will represent the average of the recorded GLUCUBE measurements per day.



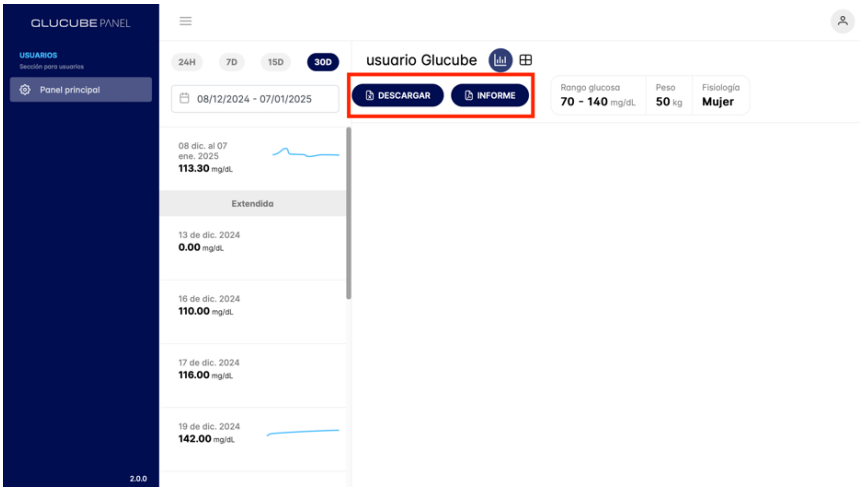
A set of detailed graphs that will allow you to accurately view the measurements collected on each of the days corresponding to the search criteria, including manual records and any other type of record included by the user.



The data associated with the user and the glucose range, which will be located at the top right of the screen.

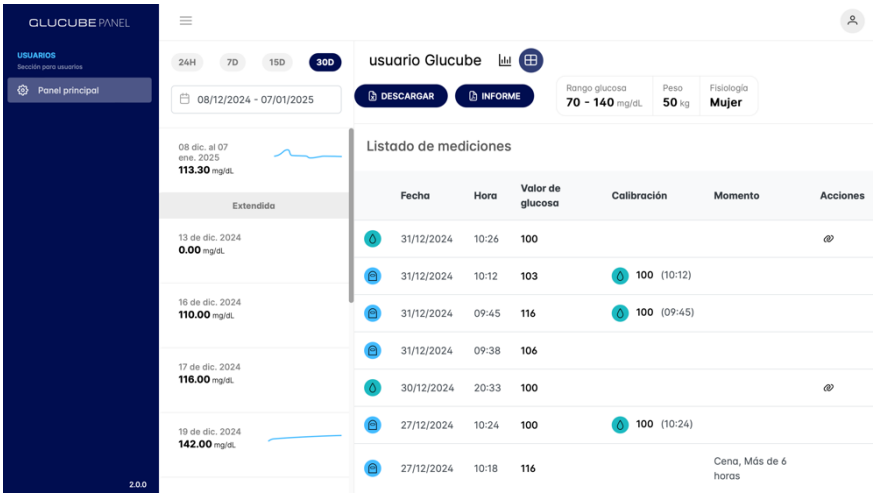


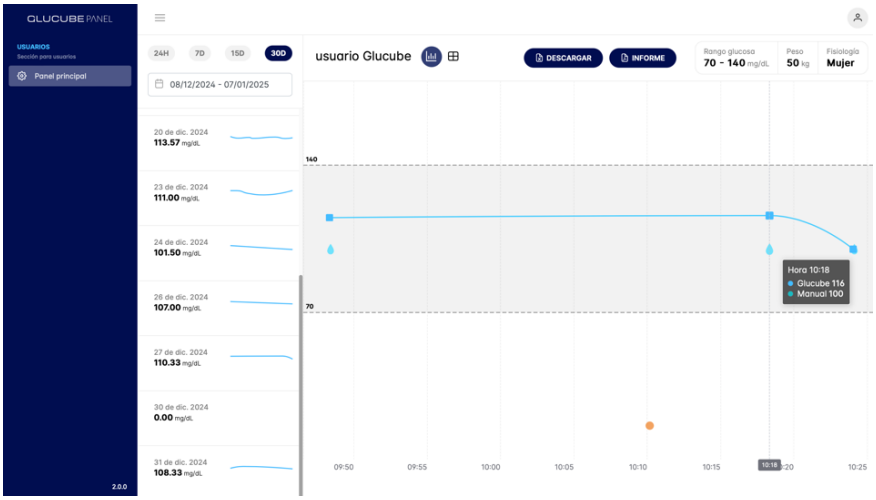
An area that allows you to download the recorded data in list format and a report with all the data



An area that allows you to download the recorded data in list format and a report with all the data

In turn, the glucose records associated with the user can be viewed in list form by selecting the table display mode ⊞ located in the upper right, to the right of the graph icon 📊.





The list shows all glucose measurements associated with the user within the established date range, both GLUCUBE measurements and manual measurements.

Indicating the following fields for each of them:

- Date
- Time
- Glucose value
- Result of the calibration measurement, if applicable
- Time of the measurement
- Actions

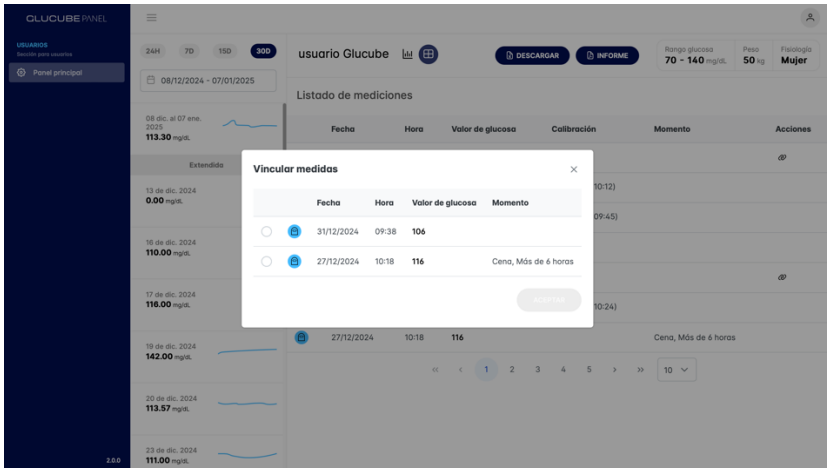
You can visually distinguish measurements made with Glucube through squares connected by a line. In addition, glucose values that you add manually are represented by a drop. And other types of records added through the GLUCUBE APP will appear represented with colored dots, depending on the type of record. Just like in the App.

If you click on an indicator in the graph, you can see the value of the record and the time at which it was saved.

Link a manual measure

You can link a manual measurement to a Glucube measurement as long as the latter does not already have a manual measurement associated with it.

In table view mode ⊞ you can link measurements. In "Actions" column, click on the symbol of the manual measurement you want to link. A list of Glucube measurements that do not have a manual glucose value associated will appear. Select the Glucube measurement you want to link it to and click on "Save" to complete the process.



Download data recorded in GLUCUBE APP

In this process we will download the records of the measurements collected in GLUCUBE APP.

Generating records process

Fecha	Hora	Valor de glucosa	Automática
31/12/2024	10:26:26	100	Manual
31/12/2024	10:12:31	103	Glucube
31/12/2024	09:45:38	116	Glucube
31/12/2024	09:41:16	100	Manual
31/12/2024	09:38:46	106	Glucube
30/12/2024	20:33:42	100	Manual
27/12/2024	10:24:08	100	Manual
27/12/2024	10:24:03	100	Glucube
27/12/2024	10:18:21	116	Glucube
27/12/2024	10:18:21	100	Manual
31/12/2024	10:26:26	100	Manual
31/12/2024	10:12:31	103	Glucube
31/12/2024	09:45:38	116	Glucube
31/12/2024	09:41:16	100	Manual
31/12/2024	09:38:46	106	Glucube
30/12/2024	20:33:42	100	Manual
27/12/2024	10:24:08	100	Manual

To download measurement records, tap the download symbol at the top of the screen and select the period for which you want the report. The download of the records will then begin.

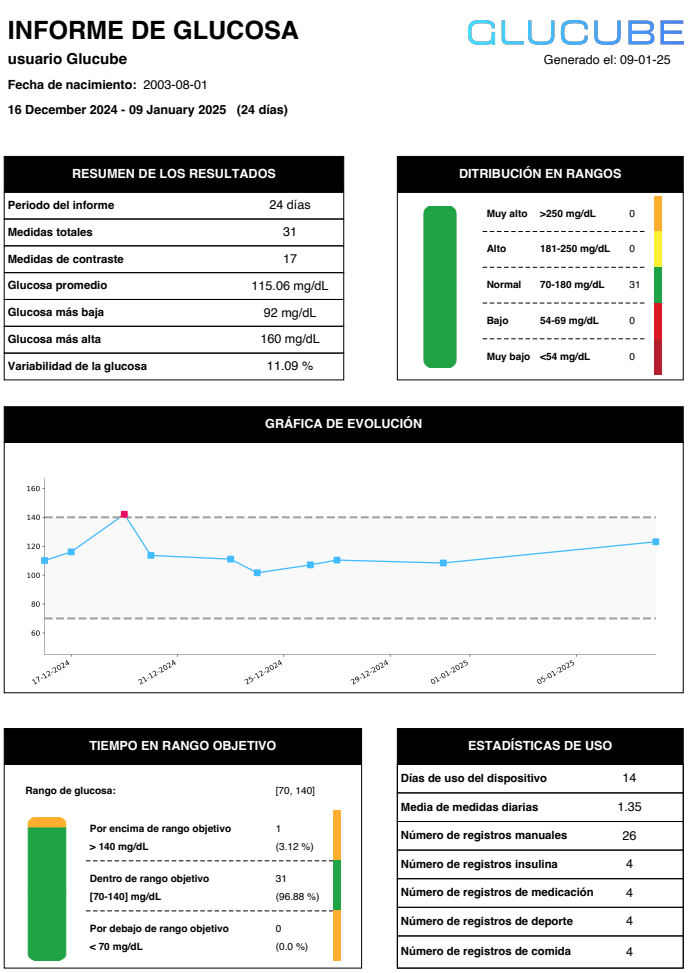
The list shows all glucose measurements associated with the user within the established date range, both GLUCUBE measurements and manual measurements. For each of them, the following fields are indicated:

- Date of the measurement
- Time of the measurement
- Glucose value
- Type of measurement

Generate report

This process is used to generate a detailed report with the data collected in GLUCUBE APP. You will be able to see the data summarized in a report.

Report generation process



INFORME DE GLUCOSA

usuario Glucube

Fecha de nacimiento: 2003-08-01

16 December 2024 - 09 January 2025 (24 días)

GLUCUBE

Generado el: 09-01-25

RESUMEN DE LOS RESULTADOS	
Periodo del informe	24 días
Medidas totales	31
Medidas de contraste	17
Glucosa promedio	115.06 mg/dL
Glucosa más baja	92 mg/dL
Glucosa más alta	160 mg/dL
Variabilidad de la glucosa	11.09 %

DITRIBUCIÓN EN RANGOS

Muy alto	>250 mg/dL	0
Alto	181-250 mg/dL	0
Normal	70-180 mg/dL	31
Bajo	54-69 mg/dL	0
Muy bajo	<54 mg/dL	0

GRÁFICA DE EVOLUCIÓN

160 140 120 100 80 60

17-12-2024 21-12-2024 25-12-2024 29-12-2024 01-01-2025 05-01-2025

TIEMPO EN RANGO OBJETIVO

Rango de glucosa: [70, 140]

Por encima de rango objetivo > 140 mg/dL	1	(3.12 %)
Dentro de rango objetivo [70-140] mg/dL	31	(96.88 %)
Por debajo de rango objetivo < 70 mg/dL	0	(0.0 %)

ESTADÍSTICAS DE USO

Días de uso del dispositivo	14
Media de medidas diarias	1.35
Número de registros manuales	26
Número de registros insulina	4
Número de registros de medicación	4
Número de registros de deporte	4
Número de registros de comida	4

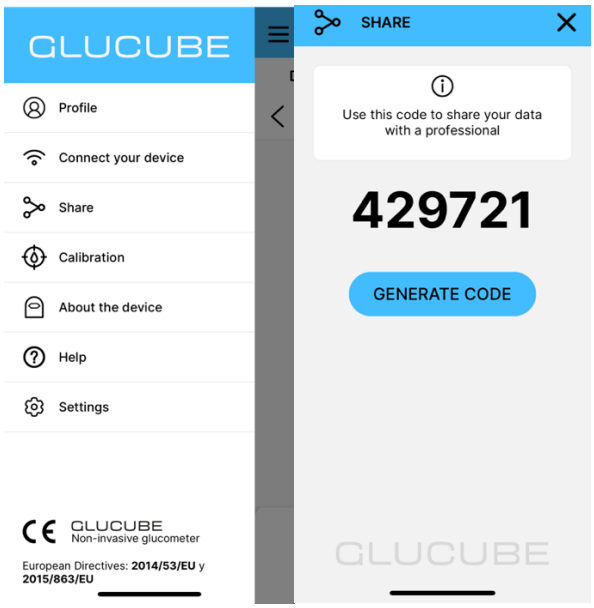
To generate the report, click on the report symbol at the top of the screen and select the period you want the report. A pop-up window will open with the report where you can view and download it.

You will be able to view a graph with the average of the recorded GLUCUBE measurements. In addition, you will have other information such as a summary of the results, the distribution in ranges, usage statistics or the time in target range.

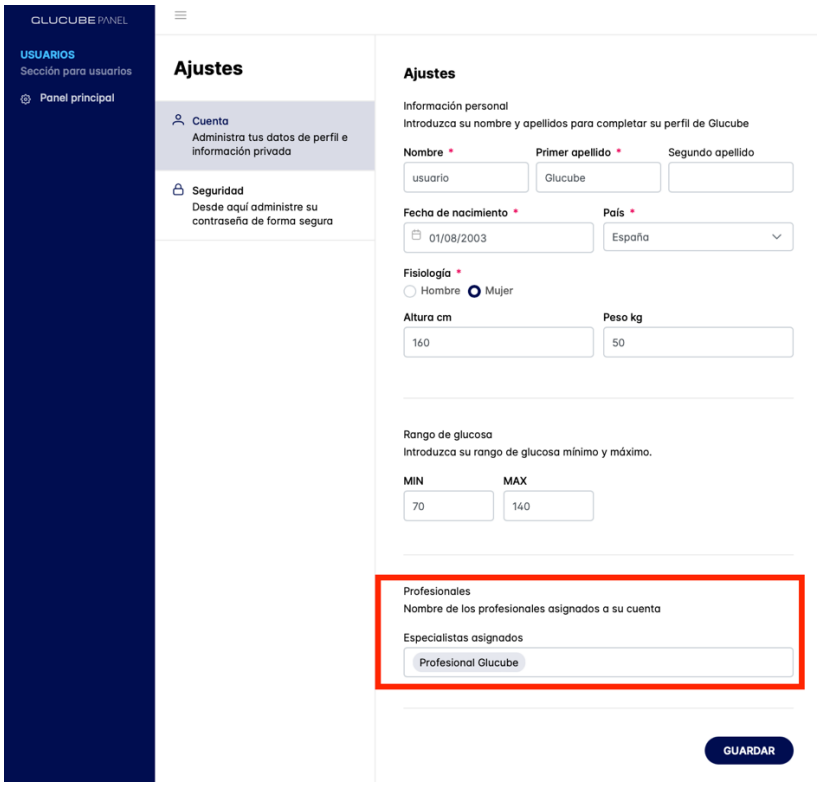
Link your account with a professional

To link your account with a professional, open the side menu of Glucube App and click on "Share."

You will then be given a number that you will need to share with your specialist.



In GLUCUBE PANEL, at the bottom of the page, in the "Account" section, all the professionals assigned to your account will appear and they will be able to easily access and view their measurements and graphs.



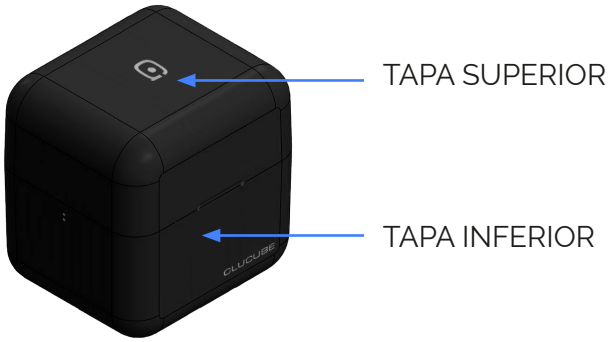
13. Product Maintenance

To use the product with maximum safety and effectiveness, follow the maintenance instructions below.

Storing the product

To ensure the protection of the GLUCUBE device, always store and transport the device in its carrying case.

GLUCUBE Device Carrying Case



Keep the product away from heat sources and direct sunlight.

Avoid exposing the product to sudden changes in temperature, which could cause condensation in the measurement area.

If you detect humidity in the measurement area, dry it using a soft chamois.

Device storage environmental conditions

The storage conditions of the measuring device are:

- Temperature: between 0°C and 45°C.
- Relative humidity: less than or equal to 70%, in the absence of condensation.

Batteries

The device is powered by a rechargeable battery. If the battery life after the battery is fully charged is significantly less than stated in the technical specifications, please contact the Customer Service.

The device's battery can NOT be replaced by the user.

Do not attempt to disassemble the device.

Only authorized personnel may make modifications to the battery.

Do not store the device for extended periods with a dead battery. May lead to a reduction in product life.

Cleaning and disinfection of the device

Normal use of the product may cause dirt to settle on the device.

Although the device incorporates mechanisms to verify the quality of the measurement, dirt in the measurement area can affect the proper functioning of the measurement system.

Avoid dirt deposition by always washing your hands before using the device.

Cleaning and disinfection are different operations for device maintenance, both being necessary.

Cleaning is part of normal care and maintenance and should be done prior to disinfection.

Cleaning does not kill germs. Disinfection is the only way to protect yourself from disease.

Cleaning

Do not allow water or other liquids to enter the charging connector of the device.

Do not use undissolved alcohol for cleaning the device.

Do not use solvent products (acetone, MEK, universal solvents, etc.) for cleaning the device.

Do not use abrasive products for cleaning the device.

Do not dry clean the device, especially the inside (measuring area). It could scratch the transparent windows of the sensors.

Prevent liquids from entering the device.

Do not spray liquids directly onto the device.

Do not immerse the device in water or other liquids.

Clean the device at least once a week.

You can clean the device using a water solution with liquid dish soap of a normal strength and a soft cloth.

1. Dampen a soft cloth in soapy water
2. Clean the device, both the outside and the area where you insert your finger. Pay special attention to the measuring area.
3. Dry the device using a soft cloth.

Disinfection

Before disinfecting, pre-clean the device following the instructions above.

For disinfection, you can use household bleach (with a minimum content of 5.5% sodium hypochlorite as the active ingredient) *. Prepare a solution with 1 part bleach and 9 parts water.

**Follow the manufacturer's instructions for handling and storing bleach.*

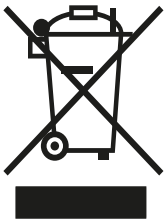
1. Use a soft cloth dampened with the bleach solution to clean the outside of the device and the measuring chamber
2. Cover the device with a cloth dampened in bleach for 1 minute.
3. Rinse the device with a clean, soft, water-dampened cloth.

Wash your hands thoroughly with soap and water after disinfecting the device.

Product disposal

The product falls within the scope of the European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE).

The presence of the symbol (see symbol at the end of this text) on the product or on the packaging indicates that this product should not be disposed of in the municipal unsorted waste stream. It is the user's responsibility to dispose of this product by taking it to a designated collection point for the recycling of waste electrical and electronic equipment. Separate collection of this waste helps to optimise the recovery and recycling of any recyclable material and also reduces the impact on health and the environment. For more information about the proper disposal of this product, please contact the local authority or distributor where you purchased this product.



14. Problem solving

Device issues

PROBLEM	POSSIBLE REASONS	WHAT TO DO
The device does not turn on	It has no battery	Charge the device correctly until the battery has been fully charged.
"Error during measurement" Warning pops up during measurement.	The measuring chamber is dirty.	Carefully clean the area where the finger is inserted as indicated in the section *Cleaning and disinfection of the device* in this document.
	The fingertip has not been inserted properly into the measuring chamber.	Insert the finger correctly as indicated in the section *Handling the GLUCUBE device and placing the finger*.
	The tip of the finger is dirty.	Clean and dry your finger before putting it back into the device.
	Finger doesn't fit the size of the device.	Insert another finger that better fits the size of the device.
	The finger suffers from calluses, malformations or open wounds.	Insert another healthy finger and repeat the measurement.
	The device is not correctly positioned.	Repeat the measurement with the device on a horizontal, stable, vibration-free surface.
"Critical Failure" Notification Emerges.	One or more components have failed.	Contact Customer Service.

APP issues

PROBLEM	POSSIBLE REASONS	WHAT TO DO
Error saving a measurement.	There is no internet connection. GLUCUBE Cloud Connection Error.	Check the internet connection (WI-FI, mobile data...) If the error persists, contact Customer Service.
The APP does not work properly or the screen freezes.	Problem in the operation of the APP.	Restart the APP and check if the error continues. Delete and reinstall the APP and check if the error continues. Restart the smartphone and check if the error continues. If the problem persists, please contact Customer Service.
Connection to the GLUCUBE device failed	The GLUCUBE device does not appear in the list of Bluetooth devices in the APP.	Check the notification bar on your smartphone. Enable floating notifications from the GLUCUBE APP in your smartphone settings. Restart the APP. Reset the GLUCUBE device. Restart your smartphone. If the problem persists, please contact Customer Service.
	Notification to pair the GLUCUBE device and enter the pairing PIN does not appear.	Check the notification bar on your smartphone. Enable floating notifications from the GLUCUBE APP in your smartphone settings. Restart the APP. Reset the GLUCUBE device. Restart your smartphone. If the problem persists, please contact Customer Service.

	GLUCUBE measurement does not start.	Make sure that you have the smartphone's bluetooth activated. Make sure you have your smartphone's location turned on. Restart the APP. Reset the GLUCUBE device. Restart your smartphone. If the problem persists, please contact Customer Service.

15. Warranty Statement

IGLUCO TECH, S.L. ("iGluco") warrants that the GLUCUBE device ("Measuring Device") will be free from defects in materials and workmanship for a period of 3 years from the original date of purchase or the date of delivery, whichever is later, provided that it is not modified, altered or misused. Under this Limited Warranty, if the device is defective in materials or workmanship, iGluco's sole obligation is to repair/replace the device, free of charge, as determined by iGluco in its sole discretion. iGluco guarantees the performance of the device in accordance with its specifications if it is used in accordance with the instructions described in the instructions for use and provided that the performance failure or defective performance of the device has not been caused, in whole or in part, by the use of accessories not supplied by iGluco.

Warranty Limitations and Exceptions:

This warranty is limited to repair/replacement due to defects in material or workmanship. iGluco will not repair/replace any unit whose malfunctions or performance are due to misuse, accidents, alterations, modifications, misuse, carelessness, repairs made by unauthorized persons, or failure to follow instructions when using the device.

It also does not cover transport costs and risks, the failure or wear of optional parts or other accessories other than the main device, damage of any kind, including personal damage caused accidentally or as a result of incorrect use.

iGluco reserves the right to make changes to the design of this device without the obligation to incorporate such changes into previously manufactured devices.

TO THE EXTENT PERMITTED BY LAW, THESE ARE IGLUCO'S COMPLETE EXPRESS WARRANTIES WITH RESPECT TO THE DEVICE AND STATE ITS EXCLUSIVE REMEDIES; IGLUCO MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, AND IGLUCO EXCLUDES AND DISCLAIMS ALL OTHER WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT, AND ANY REMEDIES INCLUDING, BUT NOT LIMITED TO, REMEDIES UNDER CONTRACT OR TORT LAWS. IGLUCO DOES NOT WARRANT THAT THE OPERATION OF THE DEVICE WILL BE UNINTERRUPTED OR ERROR-FREE.

Limitation of Liability.

TO THE EXTENT POSSIBLE UNDER THE LAW, IGLUCO SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING DIRECTLY OR INDIRECTLY FROM THE USE OF THE DEVICE OR THE FAILURE OF THE DEVICE TO PERFORM IN ACCORDANCE WITH THE SPECIFICATIONS.

Some jurisdictions do not allow the exclusion or limitation of other express or implied warranties or incidental or consequential damages, so the above limitations may not apply to you.

This Limited Warranty extends only to the original purchaser and is not subject to assignment or transfer. To receive warranty service, please contact Customer Service for assistance and/or instructions for repair/replacement. For contact information you can consult the packaging, the User Manual or the product website: https://www.glucube.com/.

This warranty will apply only if the device is returned in full along with the original ticket/invoice.

16. Customer Service

IGLUCO TECH establishes the following communication channel with the customer, to solve problems related to the use of the product:

https://www.glucube.com/contact

IGLUCO TECH's customer service is available during office hours from 09:00 a.m. to 5:00 p.m. from Monday to Friday (working days).