

BLOOD GLUCOSE MONITORING SYSTEM

DIAGNOSTIC[®]
GOLD CARE



INSTRUCTION FOR USE



ATTENTION!

**IT IS NECESSARY TO SET UP
THE DATE AND TIME**

REMEMBER!

**TO ALSO DO THIS EVERY TIME AFTER
REPLACING THE BATTERY**

TABLE OF CONTENTS

1. INTRODUCTION	3
2. INTENDED USE	5
3. IMPORTANT SAFETY INFORMATION	6
4. SYSTEM CONTENTS	7
5. DESCRIPTION OF THE GLUCOSE METER	8
5.1 EXTERNAL APPEARANCE OF THE GLUCOSE METER	8
5.2 DESCRIPTION OF DISPLAY COMPONENTS	9
5.3 CLASSIFICATION OF THE MEASUREMENT RESULT	11
5.4 DIAGNOSTIC GOLD TEST STRIP	13
5.5 DIAGNOSTIC GOLD CHECK CONTROL STRIP	13
5.6 VIAL WITH TEST STRIPS	15
5.7 INSERTING AND REPLACING THE BATTERIES	15
6. CONFIGURATION OF THE GLUCOSE METER	18
6.1 SETTING THE DATE AND TIME	18
6.2 SETTING THE BRIGHTNESS OF THE BACKLIGHT AND SCREEN TIMEOUT	20
6.3 SOUND SIGNAL	21
6.4 MEASUREMENT REMINDER AFTER TEST STRIP IS INSERTED INTO THE PORT	21
6.5 SWITCHING OFF THE BACKLIGHT OF THE TEST STRIP PORT ON/OFF	22
6.6 SETTING THE INDIVIDUAL AVERAGE MEASUREMENT VALUE FOR THE SELECTED TIME INTERVAL	23
6.7 SETTING ALARMS REMINDING OF THE MEASUREMENT	23
6.8 SETTING THE POST-MEAL ALARM	25
6.9 SETTING THE ALARM OF HIGH AND LOW BLOOD GLUCOSE LEVEL THRESHOLDS	25
6.9.1. SETTING THE ALARM OF HIGH AND LOW THRESHOLDS FOR UNMARKED MEASUREMENTS	25
6.9.2. SETTING THE ALARM OF HIGH AND LOW THRESHOLDS FOR PRE-MEAL SETTINGS	26
6.9.3. SETTING THE ALARM OF HIGH AND LOW THRESHOLDS FOR MEASUREMENTS AFTER A MEAL	27
6.9.4. SETTING THE ALARM OF HIGH AND LOW THRESHOLDS FOR MEASUREMENTS ON AN EMPTY STOMACH	28
6.10 SETTING THE MEASURING UNIT	29
7. PAIRING THE METER WITH THE ISEL HEALTH APP	30
7.1 INSTALLING THE ISEL HEALTH APP AND PAIRING WITH THE DIAGNOSTIC GOLD CARE METER	31
8. MEASURING BLOOD GLUCOSE LEVELS	46
8.1 PREPARATION FOR THE TEST	46

8.2 TAKING A BLOOD SAMPLE	47
8.3 APPLICATION OF BLOOD SAMPLES ON THE TEST STRIP	48
8.4 MARKING THE MEASUREMENT AS MEASUREMENT BEFORE OR AFTER A MEAL	50
8.5 REMINDER TO MARK THE MEASUREMENT AFTER THE TEST	51
8.6 DISPOSAL OF USED TEST STRIP AND LANCET	52
8.7 ALTERNATIVE SAMPLING POINTS	52
9. CHECKING THE OPERATION OF THE KIT – CONTROL SOLUTION TEST	54
9.1 CARRYING OUT A CONTROL SOLUTION TEST	54
9.2 COMPARING CONTROL SOLUTION RESULTS	56
10. MEMORY FUNCTIONS	57
10.1 VIEWING THE RESULTS STORED IN THE DEVICE'S MEMORY	57
10.2 EXITING THE MEMORY MODE	58
11. CLEANING AND DISINFECTION OF THE GLUCOSE METER	59
12. STORAGE OF THE GLUCOSE METER	60
13. MESSAGES DISPLAYED	61
14. TECHNICAL SPECIFICATION	67
15. ELECTRICAL STANDARDS	68
16. RESTRICTIONS OF USE	69
17. SERVICE AND WARRANTY	70
18. CUSTOMER SERVICE	70

1. INTRODUCTION

Thank you for choosing the Diagnostic Gold Care blood glucose monitoring device. Self-monitoring of blood glucose levels is a mandatory part of the treatment of people with diabetes. Diagnostic Gold Care System is characterised by simple operation and short time of measurement. The results are accurate and the measurement requires only a small amount of blood sample.

Diagnostic Gold Care has a white backlight in the test strip slot to facilitate measurement in low light or in the dark. The glucose meter also has a coloured backlight on both sides of the button  that corresponds to the target range you set (see definition on page 11). When the blood glucose level is below the target range, the backlight on the meter case next to the button  turns blue. If the result is within the set target range, the colour appears green, and if the result is above the target values, the backlight on the case lights up red. This feature makes it easier for the user to interpret the glucose measurement results.



Before using the Diagnostic Gold Care set, please read the enclosed instruction manual carefully. It is very important to follow the instructions in this booklet to avoid inaccurate results or improper handling. If you have any questions regarding the use of the device, please contact the manufacturer or your doctor.



Please keep the user manual for future reference.



Do not take any action of a medical nature without first consulting your doctor. Do not make any changes to your treatment without proper training in this area.



**Device for self-testing. In vitro diagnostic medical device.
External use only.**

If you have any further questions about this product, please contact the seller or call us:

HOTLINE (Polish language only):

OPEN:
Monday–Friday

HOURS:
8 a.m. – 4 p.m.

+48 800 70 30 11
for landlines (free call)

+48 85 874 69 28
for mobile phones (caller pays
the cost according to the
operator's tariff)

When calling Customer Service, have the Diagnostic Gold Care meter, Diagnostic Gold Strip test strips and other available accessories with you. This will allow us to respond to all your inquiries quickly and efficiently.

2. INTENDED USE

The Diagnostic Gold Care blood glucose meter is intended for home measurement of whole blood glucose levels in diabetic patients and for Medical Staff, as an aid in monitoring the effectiveness of diabetes. The Diagnostic Gold Care kit can only be used by one person.

The Diagnostic Gold Care glucose meter is used to measure glucose (sugar) levels in blood using fresh samples of whole capillary blood taken from the fingertip. The Diagnostic Gold Care kit also allows you to collect blood from alternative sites (AST) such as the palm or forearm. The Diagnostic Gold Care glucose meter can be connected to a variety of compatible mobile devices running applications that allow the user to view results, graph them, and generate useful reports. The readings from the Diagnostic Gold Care meter are transmitted to compatible devices via BLUETOOTH (wirelessly) or a USB cable.



Do not use the kit to diagnose diabetes or test newborns.



3. IMPORTANT SAFETY INFORMATION

Things to remember before making the measurement:

1. Store the test strips only in the original vials. Carefully close the vial immediately after taking out the test strip.
2. Use the test strips immediately after removing them from the vial. Each test strip may only be used once.
3. Do not use test strips and control solutions after the expiration date indicated on the package, as results may be inaccurate.
4. We do not recommend changing your medication based on the results of measurements taken with the Diagnostic Gold Care glucose meter without consulting your doctor.
5. Low or high blood glucose results may indicate a potentially serious condition. If your glucose level is unusually high or low, or if you do not feel as well as the result suggests, repeat the test with a new test strip. If your reading is not consistent with symptoms or if your blood glucose level is below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), you should contact your doctor and follow his/her instructions.
6. All kit components should be considered potentially capable of transmitting pathogens between the patient and medical personnel, even after cleaning and disinfection. To avoid endangering yourself and others, appropriate safety precautions indicated in the manual should be taken:
 - The meter and lancing device are intended for use by one person only. It is NOT allowed to share this equipment with other people, including family members! The product cannot be used by more than one person!
7. The glucose meter and its accessories should be kept out of the reach of young children, people who cannot communicate, animals and pests.
8. Small components of the kit, i.e. battery cover, batteries, test strips, lancets, lancet protection covers, control solution bottle cap, may pose a choking hazard. Do not swallow any components.
9. Do not consume test strips.
10. You should never attempt to repair the device yourself! All unauthorised attempts at opening the device will void the warranty!

4. SYSTEM CONTENTS

The Diagnostic Gold Care SYSTEM consists of several components. Detailed instructions and drawings in this manual will help you become familiar with the operation of the kit. Check the contents of the package for completeness.

The Diagnostic Gold Care kit consists of the following components:



Diagnostic Gold Care glucose meter



Lancing device together with IFU



Lancets 28G 10 pcs



Control strip Diagnostic Gold Check



Case



User manual and Quick start guide



Warranty Card



2 AAA batteries

In addition to the meter, the following items, which are not included in the kit, are required to carry out the test:

- **Diagnostic Gold Strip test strips - 50 pcs.** To measure your glucose with Diagnostic Gold Care use only Diagnostic Gold Strip test strips.
- **Diagnostic Gold control fluid (see chapter 9 for information on using the control fluid).**

REMEMBER!

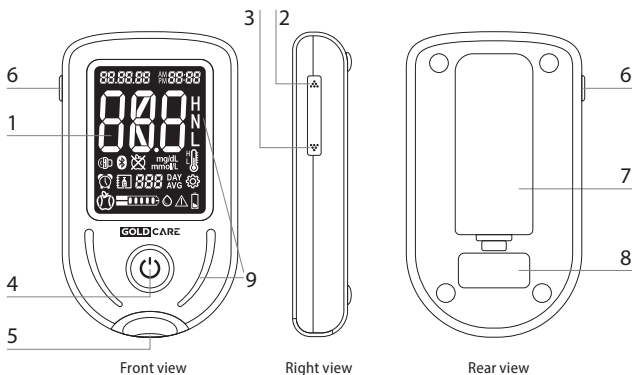
The test strips and control solution are sold separately. Contact Customer Service for information on availability of test strips and control solution.



WARNING! To obtain the amount of blood required for the test, we recommend using 28G lancets.

5. DESCRIPTION OF THE GLUCOSE METER

5.1 EXTERNAL APPEARANCE OF THE GLUCOSE METER



1. **Display.** The display shows measurement results and messages.
2. **Button .** Press and hold this button for 4 seconds to set the measurement reminder and high/low glucose alarms (HI/LO). The button is also used to increase the value / move to the next option in the device settings.
3. **Button .** The button is used to decrease the selected value during settings and to go back in the device settings. Press and hold this button for 4 seconds to access the brightness settings, display blanking time and beep settings.
4. **Button .** Press and hold this button to set year/day/time; display results and average value from memory; enter test mode with control solution; turn the device off.
5. **Test strip port with backlight.** Here you insert test strips.
6. **Data port.** Here you connect the data transfer cable to the computer.
7. **Battery cover.** It covers the battery compartment.
8. **Label.** On the label you can find, among others, the serial number.
9. **Classification of the measurement result.** It informs the user in which range the measurement of glucose level result falls.

5.2 DESCRIPTION OF DISPLAY COMPONENTS



1. **Date**
2. **Measurement result area.** The measurement result is displayed here.
3. **Meal indicator.** Displays the measurement on an empty stomach.
4. **Speaker/backlight symbol.** Setting the sound or backlight.
5. **Bluetooth® symbol.** It indicates a Bluetooth® connection.
6. **Clock symbol – Alarm function.** Displayed after setting the alarm.
7. **Control solution test.** The message is displayed during the control solution test. It designates the result as a control solution test.
8. **Average measurement symbol.**
9. **Meal indicator.** Indicates the measurement before or after a meal.
10. **Test strip symbol.** Its appearance indicates that the device is ready for measurement.
11. **Hour**
12. **Classification of the measurement result.** It informs the user of the measurement result's range.
13. **Temperature message.** It is displayed when the operating temperature of the device is out of the allowable range.

14. **Units of measurement.** The units “mmol/l” or “mg/dL” are displayed with the measured values.
15. **Average value / Number of days to calculate average.**
16. **Settings symbol.** It is displayed after entering the device settings.
17. **Blood drop symbol.** It flashes when the device is ready for placing a drop of blood on the test strip.
18. **Battery symbol.** It appears when the battery is low and should be replaced.
19. **Warning symbol.** Displayed when the measurement result is outside the acceptable range of the set glucose level.

5.3 CLASSIFICATION OF THE MEASUREMENT RESULT

The H, L or N classification displayed next to the glucose result helps the user interpret the result. This is an automatic notification of what range the glucose result falls within:

H – indicates a result above the target range

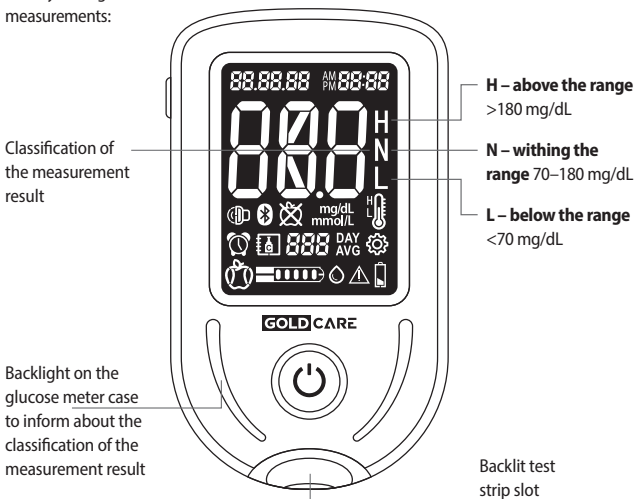
N – indicates a result within the target range

L – indicates a result below the target range

The marking corresponds to the set target ranges.

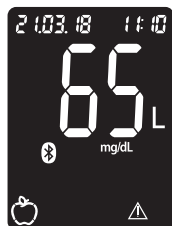
The range of the result is also indicated by backlight of the test strip slot on both sides of the  button. If the result is classified as high (H) according to the set ranges – the backlight lights up red. If the result is within the norm (N) – the backlight is green. If the result is below the set range (L) – the backlight is blue.

Factory settings for unmarked measurements:





WARNING: Measurement results should not be read and interpreted solely on the basis of the classification of the measurement result in the form of the letter H, L or N next to the measurement result and the colour classification of the measurement result on either side of the button . Always pay attention to the result shown on the display.



Measurement result
below **70mg/dL** *



The measurement result between
70 mg/dL and **180 mg/dL** *



Measurement result
exceeds **180mg/dL** *

* classification according to the factory settings of the target ranges



IMPORTANT: The target range is the appropriate lower and upper limits of glucose for each patient, which should be discussed with your doctor. Factors such as lifestyle and type of diabetes therapy used should be considered when setting or changing the limits. Please do not change the diabetes treatment plan without consulting your doctor.

5.4 DIAGNOSTIC GOLD TEST STRIP

A test strip consists of the following elements:

1. **Electrodes.** Insert the test strip into the test strip slot so that the gold stripes are facing upwards toward the meter.
2. **Yellow window (bottom edge).** Apply it to a drop of blood. Before applying blood, this window should be completely yellow. After applying blood, this window should be completely filled with blood.



IMPORTANT: Each test strip may only be used once.

5.5 DIAGNOSTIC GOLD CHECK CONTROL STRIP

Each Diagnostic Gold Care kit comes with a special control strip. This is a reusable electronic device for checking the correct operation of the meter electronics.

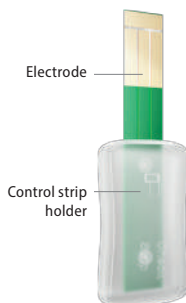
When should I check my meter with a control strip?

1. At any time to check that the meter electronics are working properly
2. Before using the meter for the first time
3. Whenever the result is not consistent with your physical condition
4. After a retest, if the result is still lower or higher than expected



IMPORTANT: Checking the meter with the Diagnostic Gold Check control strip does not replace the test with the control solution.

A control strip consists of the following elements:



How to use control strip?

1. Insert the electrode into the test slot with the gold side facing upwards, as shown in Fig. A. The meter turns on automatically.
2. When the control strip is properly inserted, the meter begins to check that the electronics are functioning correctly.



Fig. A

3. If the meter is working correctly, the display shows "OK" (Fig. B).



Fig. B

4. If the meter is not functioning correctly, the display shows the error message "EEE". (Fig. C)



Fig. C

- If the control strip has been inserted on the incorrect side, the test strip icon with a blinking blood drop will be displayed on the meter screen (Fig. D). Remove the control strip and reinsert it on the correct side.

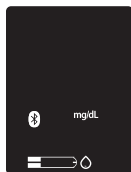


Fig. D

5.6 VIAL WITH TEST STRIPS

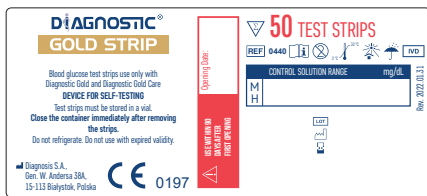
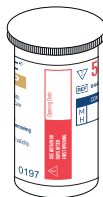


Fig. Example of vial label.



Example of a vial with test strips.

5.7 INSERTING AND REPLACING THE BATTERIES

When the batteries are almost exhausted, the device displays a warning signal. In this case, you must replace both batteries with new ones. After the low battery warning, as shown in Fig. 1, **the device can still perform about 50 measurements.** After the warning shown in Fig. 2 (flashing battery symbol and red back-light on the meter case), the device will not perform any more measurements. When the battery is fully discharged, the test strip slot and both sides of the $\odot$ button will not be backlit, and no indication will appear on the display. **Lithium batteries cannot be used.**

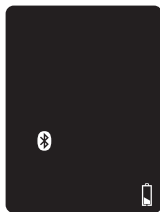


Fig. 1



Fig. 2

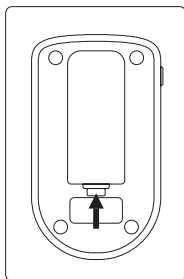


Fig. 3

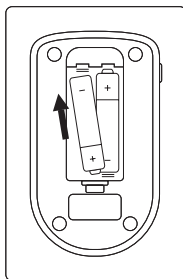


Fig. 4

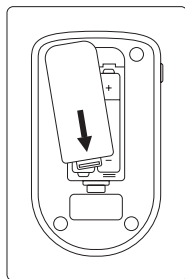


Fig. 5

To install or replace batteries:

1. Open the cover by sliding the plastic notch in the battery cover forward. (Fig. 3)
2. Insert the batteries into the battery compartment, making sure that the polarity (+ and -) is correct (Fig. 4).
3. Slide the battery cover back closed (Fig. 5).



IMPORTANT: After replacing the batteries, reset the date and time.

Do not replace the batteries when the glucose meter is connected to a PC. The contents of some batteries may leak, damaging the glucose meter or discharging the battery earlier than usual. You should replace the battery set with a new one immediately.

Use 2 new AAA batteries. Lithium batteries cannot be used.



Important safety information

1. Replace the batteries when the low battery indicator appears on the screen. Replace all the batteries with new ones at the same time.
2. Insert the batteries, being careful to observe the correct polarity indicated in the battery compartment.
3. Do not mix different battery types. It is recommended to use alkaline batteries with extended life. The use of 1.2 V batteries is not recommended.
4. Remove the batteries if the device will not be used for more than 3 months.
5. Dispose of batteries correctly by following local regulations.
6. Do not use new and old batteries at the same time.

7. Do not mix different battery types. Do not use lithium batteries. Alkaline batteries are recommended.
8. The battery has two poles: positive and negative. Do not force the battery into the device if it cannot be easily inserted.

6. CONFIGURATION OF THE GLUCOSE METER

Insert the batteries into the device. With the glucose meter turned off, perform the following activities.

6.1 SETTING THE DATE AND TIME

1. Press and hold the button  for 4 seconds when the power is off to enter the time format selection mode. Press  or , to select the 24-hour or 12-hour format. If you set the 12-hour format, an AM symbol (for the time before noon) and a PM symbol (for the time after noon) appear next to the time, for example, 7:01 PM means 19.01. Press the button , to confirm the settings (Fig. 6).
2. An hour flashes on the screen. Use the  and , buttons to select the hour. Press the button , to confirm the settings (Fig. 7).
3. A minute flashes on the screen. Use the  and , buttons to select the minute. Press the button , to confirm the settings (Fig. 8).



Fig. 6



Fig. 7



Fig. 8

4. A year (YEAr) flashes on the screen. Use the  and , buttons to select the year. Press the button , to confirm the settings (Fig. 9).



Fig. 9

5. A month (Month) flashes on the screen. Use the  and , buttons to select the month (Fig. 10). Press the button , to confirm the settings. Next, a day (dAy) symbol flashes on the screen. Use the  i  buttons to select the day. Press the button , to confirm the settings (Fig. 11).



Fig. 10



Fig. 11

6. The device displays the set date and time. Press the button , to turn the device off.



Fig. 12



IMPORTANT: If you have not set the date and time in the glucose meter, the display shows 0:00. The measurements taken are stored in the meter's memory but are not taken into account when calculating the average (see chapter 6.1 Setting the date and time), nor are they sent to the Istel Health application or the Istel Care System.

6.2 SETTING THE BRIGHTNESS OF THE BACKLIGHT AND SCREEN TIMEOUT

1. Press and hold the button  for 4 second when the meter is off to enter the configuration mode.
2. A flashing light icon appears on the display  (Fig. 13). Press . You can now adjust (using the arrows  / ) brightness of the display backlight from 10-100. Confirm your selection by pressing . The factory setting of the brightness level of the display backlight is 50.
3. Press , to enter screen timeout settings.
4. A flashing lamp and clock icons appear on the display (Fig 13A).
5. Press the button  and set the screen timeout from 5 to 90 seconds with the arrows  / . After setting the desired value, confirm your selection with .
6. You can then proceed to the settings (see chapter 6.3) or exit your settings at this point by pressing the button  until END SEt appears in the display and then confirming with the button .



Fig. 13

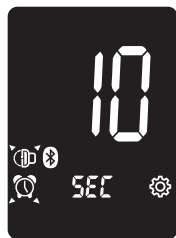


Fig. 13A

REMEMBER!

The factory preset screen timeout is 10 seconds.

6.3 SOUND SIGNAL

1. To enter the beep configuration mode, press and hold the button  for approximately 4 seconds when the meter is off.
2. Keep pressing the button  until the icon appears on the display  (Fig. 14).
3. Press  to turn the beep on/off. By pressing  and , you can enable (ON) or disable (OFF) the beep.
4. Confirm your choice with .
5. Now you can move on to the “Measurement reminder after test strip is inserted into the port” setting (chapter 6.4) or exit your settings at this point by pressing the button  until END SET appears in the display and then confirming with the button .



Fig. 14

REMEMBER!

The beep is preset as ON.

The beep switches the button sound on or off.

6.4 MEASUREMENT REMINDER AFTER TEST STRIP IS INSERTED INTO THE PORT

1. To enter the “Measurement reminder after test strip is inserted into the port” mode, press and hold the button  for approximately 4 seconds when the meter is off.
2. Keep pressing the button  until the icons  and  appear on the display (Fig. 15)
3. Press the button  to turn on/off the alarm that reminds of the need to make measurement with the inserted test strip. By pressing  and , you can enable (ON) or disable (OFF) the alarm.
4. You can then proceed to the settings for switching off/on the backlight of the test strip slot (see chapter 6.5) or exit your settings at this point by pressing the button  until END SET appears in the display and then confirming with the button .



Fig. 15



WARNING! After inserting the test strip into the port, the time for making a measurement is 3 minutes. After this time the meter turns off. In the last minute of the meter's readiness for measurement, a counter (clock) appears on the display, measuring the time until the meter turns off. At the same time, you can hear beeps at 60 seconds, 50 seconds, 40 seconds, and 30 seconds to indicate the need for a measurement. If you want to use this function of the meter, make sure that the beep is activated (see chapter 6.3) and that the reminder to measure after inserting the test strip into the slot has been set, as described in chapter 6.4.

6.5 SWITCHING OFF THE BACKLIGHT OF THE TEST STRIP PORT ON/OFF

1. To enter the backlight of the test strip slot mode, press and hold the button  for about 4 seconds when the meter is off.
2. Keep pressing the button  until the flashing icon  and  appear on the display (Fig. 16)
3. Press the button  to turn on/off the test strip port backlight. By pressing  and  you can enable (ON) or disable (OFF) backlight.
4. Confirm your choice with .
5. The factory setting of the backlight of the test strip port is (ON).
6. You can then proceed to the individual average measurement value for the selected time interval (see 6.6) or exit your settings at this point by pressing the button  until END SET appears in the display and then confirming with the button .



Fig. 16

6.6 SETTING THE INDIVIDUAL AVERAGE MEASUREMENT VALUE FOR THE SELECTED TIME INTERVAL.

1. To set the individual average value of measurements for a given time interval, press and hold the button  for approximately 4 seconds when the meter is off.
2. Keep pressing the button  until the "USER" inscription shows up in the upper left corner of the display (Fig. 17).
3. Press the button  to change the number of days for which the average value of measurements will be calculated.
4. You can set the average measurement value for the selected time interval from 8 to 180 days using the  and  buttons. Press  to confirm your selection.
5. The preset number of days for which the average value of measurements is calculated is 21 days.
6. To exit the settings, press . The display shows End SEt. Confirm that you exit the settings using .



Fig. 17

6.7 SETTING ALARMS REMINDING OF THE MEASUREMENT

The meter allows you to set 4 alarms **to remind you to take measurements** (the alarms are disabled by default).

1. Press and hold the button  for 4 seconds when the meter is off to enter the configuration mode.
2. The first reminder alarm flashes on the screen (Fig. 18). Press the button  and use the  and  buttons to activate the first alarm "ON" or "OFF" (Fig. 19)



Fig. 18



Fig. 19

3. After selecting "OFF" and pressing , the device returns to the reminder alarm setting mode.
4. When "ON" is selected, the time value flashes on the screen (Fig. 20). Use the  and  buttons to select the hour. Press the button  to confirm the settings.



Fig. 20

5. Now a minute value flashes on the screen (Fig.21). Use the  and  buttons to select the minute. Press the button  to confirm and move to the next reminder alarm settings.



Fig. 21

6. Use  and  to select the reminder alarm from no 2 to 4. Repeat the steps 3 to 5 to set the other 3 reminder alarms (if needed).
7. By pressing  you can now move on to the setting of the post-meal alarm (see chapter 6.8) or exit your settings at this point by pressing the button  until END Set appears in the display and then confirming with the button .

REMEMBER!

When an alarm sounds, press any button to turn it off (the alarm will turn off automatically after 30 seconds)

6.8 SETTING THE POST-MEAL ALARM

The post-meal alarm setting allows the user to set the alarm for 60, 90 or 120 minutes after the end of the meal.

1. With the device off, press and hold the button  for 4 seconds to enter the configuration mode. Keep pressing the button  until you can set a post-meal alarm (Fig. 22). Confirm your choice by pressing  (the apple symbol stops flashing).
2. Use the  and  buttons to select the "OFF" or "ON" alarm. Confirm your choice by pressing . If you have selected "ON" (alarm on), use the arrow buttons  and  to select the alarm time after the meal: 60, 90 or 120 minutes. Confirm your choice by pressing .
3. After the post-meal alarms have been set, press the button  to continue configuring the blood glucose alarms for the upper threshold (HI) and lower threshold (LO), or exit the settings at this stage by clicking  until End SEt appears on the display. Confirm that you exit the settings using .



Fig. 22

6.9 SETTING THE ALARM OF HIGH AND LOW BLOOD GLUCOSE LEVEL THRESHOLDS

6.9.1. SETTING THE ALARM OF HIGH AND LOW THRESHOLDS FOR UNMARKED MEASUREMENTS

1. Press and hold the button  for 4 seconds to access the settings for the upper and lower threshold of the for the blood glucose level for unmarked measurements.
2. Keep pressing the button  until you reach the settings for the blood glucose alarm for unmarked measurements (Fig. 23).
3. Press the button , to change the alarm value. The alarm value flashes (Fig. 24).
4. Use the  and  buttons until you reach the desired value, then confirm your selection by pressing the button .

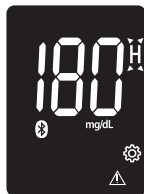


Fig. 23

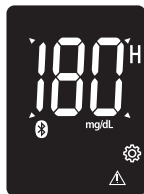


Fig. 24

(The alarm range for hyperglycaemia is 100–240 mg/dL / 5.6–13.3 mmol/L, the factory set value is 180 mg/dL / 10 mmol/L).

5. Press the button , to access the settings for the lower alarm threshold for unmarked measurements (Fig. 25).

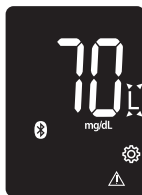


Fig. 25

6. Press the button , to access the settings for the lower alarm threshold for unmarked measurements (Fig. 25).

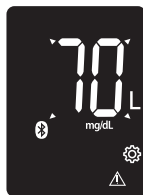


Fig. 26

7. Use the  and  buttons until you reach the desired value, then confirm your selection by pressing the button . (The alarm range for hypoglycaemia is 45–90 mg/dL / 2.5–5.0 mmol/L, the factory set value is 70 mg/dL / 3.9 mmol/L).



IMPORTANT! The value of hypoglycaemia (LO) and hyperglycaemia (HI) alarms must be set after consulting your doctor.

6.9.2. SETTING THE ALARM OF HIGH AND LOW THRESHOLDS FOR PRE-MEAL SETTINGS

1. After completing the settings in point 6.9.1, press the button , to access the settings for the high blood glucose threshold alarm for measurements before a meal (Fig. 27).

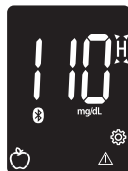


Fig. 27

2. Press the button , to change the alarm value. The alarm value flashes (Fig. 28).
3. Use the  and  buttons until you reach the desired value, then confirm your selection by pressing the button . (The alarm range for hyperglycaemia is 100–240 mg/dL / 5.6–13.3 mmol/L, the factory set value is 110 mg/dL / 6.1 mmol/L).

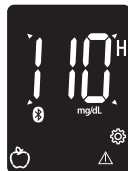


Fig. 28

- Press the button  to access the settings for the lower threshold alarm for measurements before a meal (Fig. 29).
- Press the button , to change the alarm value. The alarm value flashes (Fig. 30).



Fig. 29



Fig. 30

- Use the  and  buttons until you reach the desired value, then confirm your selection by pressing the button . (The alarm range for hypoglycaemia is 45–90 mg/dL / 2.5–5.0 mmol/ L, the factory set value is 70 mg/dL / 3.9 mmol/L).



IMPORTANT! The value of hypoglycaemia (LO) and hyperglycaemia alarms must be set after consulting your doctor.

6.9.3. SETTING THE ALARM OF HIGH AND LOW THRESHOLDS FOR MEASUREMENTS AFTER A MEAL

- After completing the settings in point 6.9.2, press the button  to access the settings for the high blood glucose threshold alarm for measurements after a meal (Fig. 31).

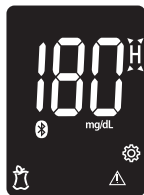


Fig. 31

- Press the button , to change the alarm value. The alarm value flashes (Fig. 32)
- Keep pressing the  and  buttons until you reach the desired value, then confirm your selection by pressing the button . (The alarm range for hyperglycaemia is 100–240 mg/dL / 5.6–13.3 mmol/ L, the factory set value is 180 mg/dL / 10.0 mmol/L).

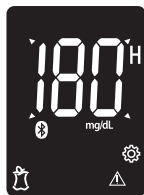


Fig. 32

- Press the button , to access the settings for the lower alarm threshold for measurements after a meal (Fig. 33).

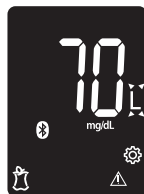


Fig. 33

- Press the button , to change the alarm value. The alarm value flashes (Fig. 34).

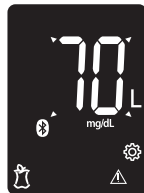


Fig. 34

- Keep pressing the  and  buttons until you reach the desired value, then confirm your selection by pressing the button . (The alarm range for hypoglycaemia is 45–90 mg/dL / 2.5–5.0 mmol/L, the factory set value is 70 mg/dL / 3.9 mmol/L).



IMPORTANT! The value of hypoglycaemia (LO) and hyperglycaemia (HI) alarms must be set after consulting your doctor.

6.9.4. SETTING THE ALARM OF HIGH AND LOW THRESHOLDS FOR MEASUREMENTS ON AN EMPTY STOMACH

- After completing the settings in point 6.9.3, press the button , to access the settings for the high blood glucose threshold alarm for measurements on an empty stomach (Fig. 35).
- Press the button , to change the alarm value. The alarm value flashes (Fig. 36).

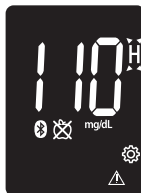


Fig. 35

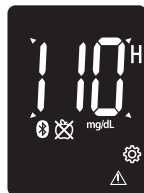


Fig. 36

3. Keep pressing the  and  buttons until you reach the desired value, then confirm your selection by pressing the button . (The alarm range for hyperglycaemia is 100–240 mg/dL / 5.6–13.3 mmol/L, the factory set value is 110 mg/dL / 6.1 mmol/L).
4. Press the button  to access the settings for the lower alarm threshold for measurements on an empty stomach (Fig. 37).
5. Press the button , to change the alarm value. The alarm value flashes (Fig. 38).
6. Keep pressing the  and  buttons until you reach the desired value, then confirm your selection by pressing the button . (The alarm range for hypoglycaemia is 45–90 mg/dL / 2.5–5.0 mmol/L, the factory set value is 70 mg/dL / 3.9 mmol/L). The display shows End SEt. Confirm that you exit the settings using .



Fig. 37



Fig. 38



IMPORTANT! The value of hypoglycaemia (LO) and hyperglycaemia (HI) alarms must be set after consulting your doctor.

6.10 SETTING THE MEASURING UNIT

The Diagnostic Gold Care blood glucose meter measures in the unit of measurement: mg/dL. This is the most commonly used unit of measurement in Poland and is preset in the Diagnostic Gold Care.

The device can also measure in mmol/L. To change the unit of measurement from mg/dL to mmol/L, return the device to Diagnosis Service or change the unit settings using the settings options in the Istel Health app when connected to the Diagnostic Gold Care glucose meter.

7. PAIRING THE METER WITH THE ISEL HEALTH APP

The Diagnostic Gold Care blood glucose meter with Bluetooth® Low Energy module transmits glucose measurement data to compatible wireless devices (smartphone, tablet). The minimum requirements for such devices are:

- A device with Android 7 or higher, with Bluetooth Low Energy, or
- An iPhone with iOS 10.1 or higher, or
- An iPad with iPadOS 10.1 or higher.

The recommended app for the Diagnostic Gold Care meter is the **ISEL Health**, app, which allows you to monitor the progress of your diabetes treatment. It allows you to transfer the measurement results from the meter thanks to the Bluetooth function. It is compatible with Android 7 and higher. The Isel Health app requires the use of a major, stable version of the system software provided by the manufacturer of your mobile device (smartphone, tablet, etc.). Test, developer, or beta versions are not supported.

The Isel Health app allows:

- Quick access to glucose measurement results
- Settings of the meter functions at the application level
- Creation of clear reports that you can share with your doctor before or during your doctor's visit
- Easily interpret results and better understand blood glucose levels thanks to colour-coded readings

The Isel Health application works with the Isel Care system available in a web browser at www.iselcare.pl – an innovative telemedicine solution that allows remote monitoring of patients' health. It allows you to easily and securely share results with the doctor or exchange data with your health carer. Using the Isel Health application, you can create an account in the Isel Care system. Data can be transferred from the Diagnostic Gold Care meter to the Isel Care system using a dedicated USB cable after connecting to a computer.

For more information about the Isel Care system, please visit www.iselcare.pl or call +48 885 961 858 (Mon–Fri, 8 a.m. – 4 p.m.)

7.1 INSTALLING THE ISTEL HEALTH APP AND PAIRING WITH THE DIAGNOSTIC GOLD CARE METER

1. The ISTEL app should be downloaded from:



Google Play

or



App Store

2. After installing and launching the ISTEL Health application, create a new profile by entering your username and setting your PIN (Fig. 35). Confirm using the OK button.

NOTE!

Remember your PIN number.

If you forget it, you will lose your measurement results.

3. You will be asked if you want to link your profile to your Istel Care account (Fig. 36). Select YES or NO. Once you have selected YES:
 - Select your **location** and accept your choice (Fig. 36A).
 - **If you already have an Istel Care account**, enter your details and click Login and then Synchronise to upload your existing measurements to the System (Fig. 37).
 - or **Create Account** by clicking Create New Istel Care Account (Fig. 37). If you have chosen to create a new account, complete the form (Fig. 38) and confirm by pressing OK.

Fig. 35

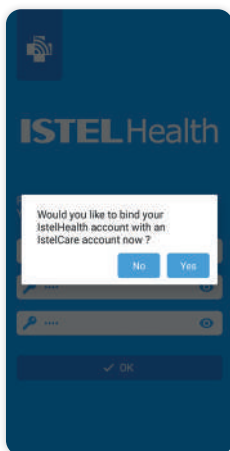


Fig. 36

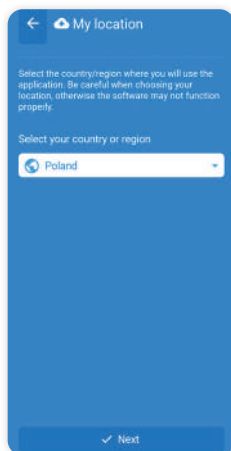


Fig. 36A

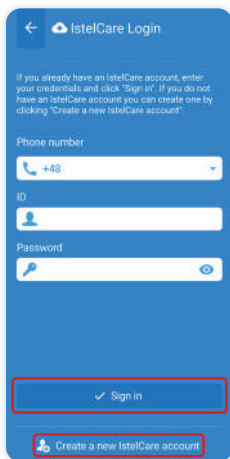


Fig. 37

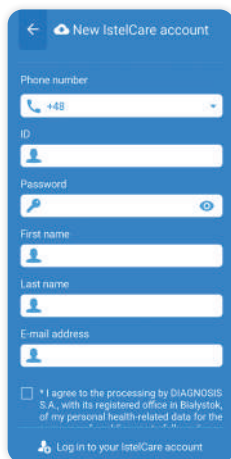


Fig. 38

4. In the main application window, select Glucose Level
- To connect the IStel Health application to the Diagnostic Gold Care meter, select the Connect button (Fig. 39). Switch on the meter by pressing . The device will be searched (Fig. 40).

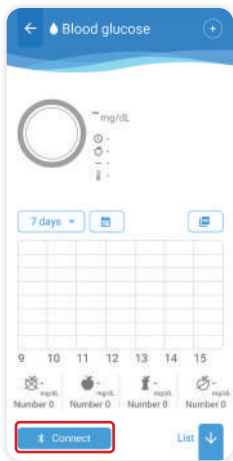


Fig. 39

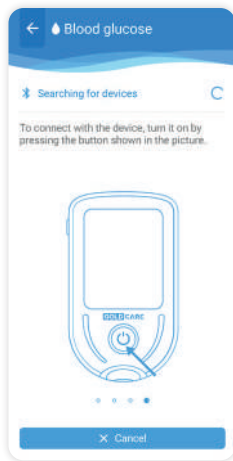


Fig. 40

NOTE!

Turn on Bluetooth on your mobile device.

- The display will ask you to enter your PIN code.

NOTE!

The PIN needed to pair the meter with the IStel Health app is on the label on the back of the meter. It is the 6 digits from the serial number after the letter G (Fig. 41). It must be entered and accepted by pressing OK (Fig. 42).

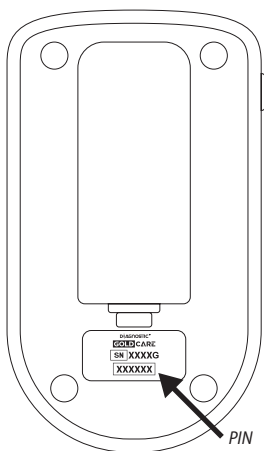


Fig. 41

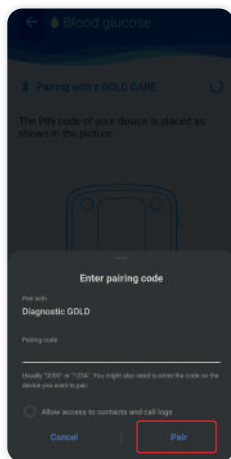


Fig. 42

5. The device will start connecting to the application (Fig. 43).
6. Once the Diagnostic Gold Care meter is connected to the ISTEEL Health app, select the "Synchronise" button to transfer the data from the meter (Fig. 44).
7. Once all measurements have been uploaded, a window with the measurement results will appear in the application. By pressing the "List of Measurements" arrow, all results from the selected time interval will appear (Fig. 45).



Fig. 43

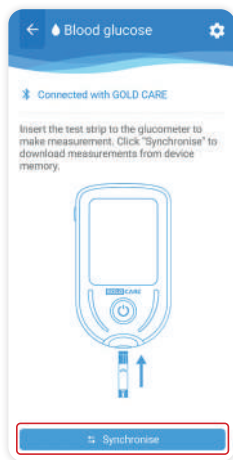


Fig. 44



Fig. 45

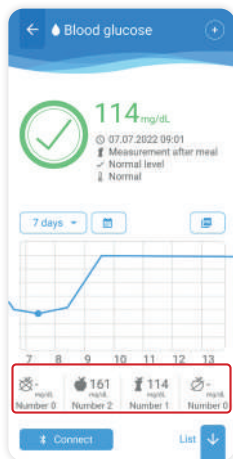


Fig. 46

The 'Glucose Level' window shows:

- The value of the most recent and/or chosen measurement labelled as: measurement on an empty stomach, measurement after a meal, measurement before a meal or unmarked measurement, as well as a coloured classification marker (green: result within normal range, red: too high result, blue: low result).
- The number of days and calendar you want to see on the chart (see Figures 47 and 48).
- Average measurements and number of all measurements for: measurements on an empty stomach, unmarked / before a meal / after a meal measurements from a given time frame (highlighted in the box in Fig. 46).
- View of time interval setting for presenting data on the chart (can be set to 1 day, 7 days, 14 days, 30 days) (Fig. 47).

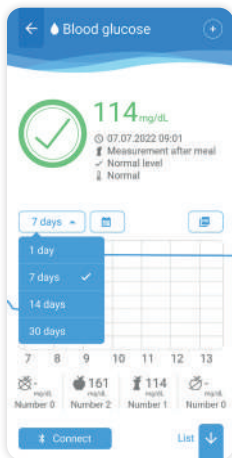


Fig. 47

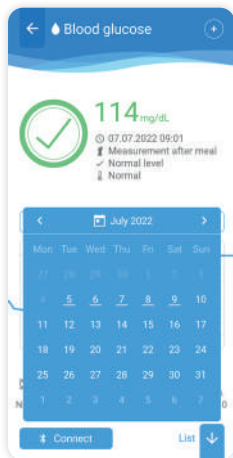


Fig. 48

Description of symbols and colours:



Apple crossed out with a single line – unmarked measurement



Apple crossed out with two lines – measurement on an empty stomach



Apple core – measurement after a meal



Apple – measurement before a meal

• 80 mg/dL

A dot next to a measurement result – manually entered measurement



Plus sign – allows the glucose result to be manually added (when the + sign is selected (Fig. 49), the view of the form for manually adding the measurement result appears (Fig. 50 and Fig. 51))

Description of colours:

Measurement indicated using:

- **Green colour**, a result within the defined desired glucose range
- **Red colour**, a result above the defined desired glucose level range
- **Blue colour**, results below the defined desired glucose range

NOTE!

You can set the desired glucose ranges in the app after consulting your doctor (Fig. 55, page 40)



NOTE!
If several measurements are taken within one minute, the last measurement will be displayed in the app.

Fig. 49
 View of the drop-down list of measurements

The screenshot shows the 'Add measurement' form in the 'Blood glucose' app. The form includes the following fields:

- Date:** 2022-07-09
- Hour:** 13:12
- Glucose level:** Input field with 'mg/dL' unit.
- Meal:** Dropdown menu with 'After' selected.
- Ambient temperature:** Dropdown menu with 'Normal' selected.
- Physical activity:** Dropdown menu with 'Unlabelled' selected.
- Stress:** Dropdown menu with 'Unlabelled' selected.

At the bottom, there are 'Cancel' and 'Save' buttons.

Fig. 50

The screenshot shows the 'Add measurement' form in the 'Blood glucose' app, with the 'Notes' section expanded. The form includes the following fields:

- Date:** 2022-07-09
- Hour:** 13:12
- Glucose level:** Input field with 'mg/dL' unit.
- Meal:** Dropdown menu with 'After' selected.
- Ambient temperature:** Dropdown menu with 'Normal' selected.
- Physical activity:** Dropdown menu with 'Unlabelled' selected.
- Stress:** Dropdown menu with 'Unlabelled' selected.
- Notes:**
 - ☐ Meal
 - ☐ Medications
 - ☐ Illness
 - ☐ Alcohol

At the bottom, there are 'Cancel' and 'Save' buttons.

Fig. 51

View of the form for manual addition of a measurement result

8. ISTEEL Health app settings.

Press the symbol of three lines in the top right corner (Fig. 52) and then “Settings” (Fig. 53) to access the application settings.

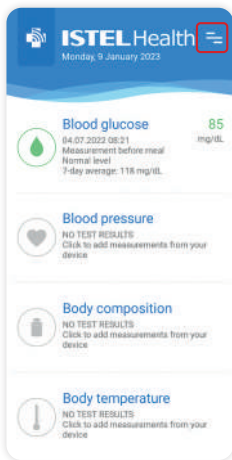


Fig. 52

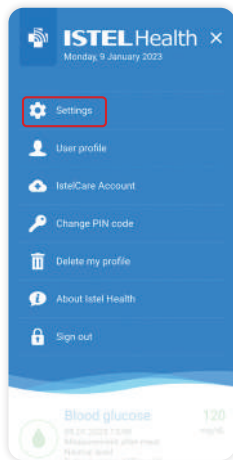


Fig. 53

Functions that can be set by navigating to the settings in the application (Fig. 54, 55)

- Pressure unit: choose between mmHg and kPa.
- Temperature unit: choose between °C and °F.
- Metric units: kg, m, or lb can be selected.
- Unit of glucose: can be set in mg/dL or mmol/L.
- Desired glucose range for measurements before a meal, after a meal and for unmarked measurements. Confirm your settings with the “Save” button.

NOTE!

You can set your own desired glucose ranges, which you have previously discussed with your doctor.

The factory settings for glucose ranges are as follows:

- On an empty stomach: 70–110 mg/dL
- Before a meal: 70–110 mg/dL
- After a meal: 70–180 mg/dL
- Unmarked measurement: 70–180 mg/dL

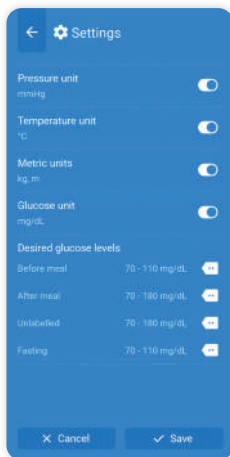


Fig. 54

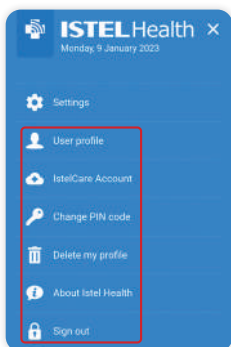
Use the switch on the right (dot/slider) to set the selected unit.



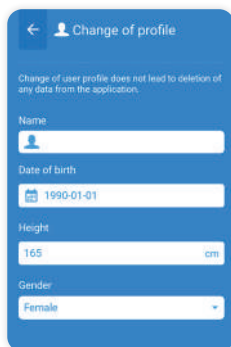
Fig. 55

View of setting the desired glucose ranges

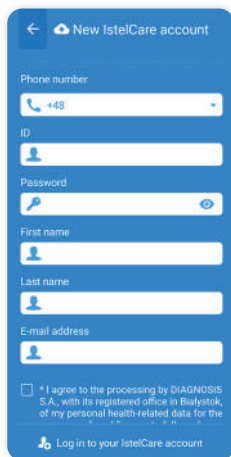
Press the arrow in the upper left corner of the application in the settings window to return to the window with the other options.



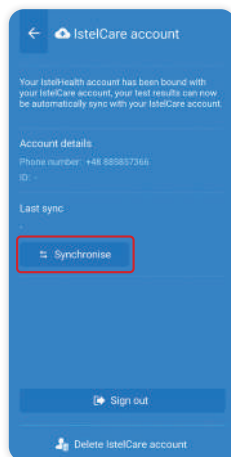
*Fig. 56
Other options*



*Fig. 57
User profile*



*Fig. 58 Istel Care account
View of the login form for linking the
application to an existing Istel Care
System account and the button for
creating an Istel Care System account.*



*Fig. 59 Istel Care account
A view of the Synchronise button after
linking an application profile to an account
in the Istel Care System. When "Synchronise"
is pressed, the data from the application is
transferred to the Istel Care System.*

← Change of PIN code

A new PIN code must consist of four digits.
Please remember the PIN code. If you forget it, you will lose access to your profile and measurements!

Current PIN code

New PIN code

Retype PIN code

× Cancel ✓ Save

Fig. 60
Changing the PIN code

← Deleting profile

When a profile is deleted, all assigned measurements and data will also be deleted. It will be impossible to reverse the operation. Confirm the operation by entering the PIN code.

PIN code

× Cancel ✓ Delete

Fig. 61
Deleting a profile

ISTELHealth
Version 2.31

Diagnosis S.A.
ul. Gen. W. Andersa 38A
15-113 Białystok, Poland
e-mail: diagnosta@diagnosis.pl
Helpline: 800 70 30 11

CE

Fig. 62
Information about the application

ISTELHealth

To run the application, you must sign in to your profile or create a new profile.

Monika

PIN code

✓ Sign in

Create a new profile

Fig. 63
View after logging out

9. Settings available from the app only after connecting the meter to the app and clicking on the settings icon (highlighted by a box in Figure 64)

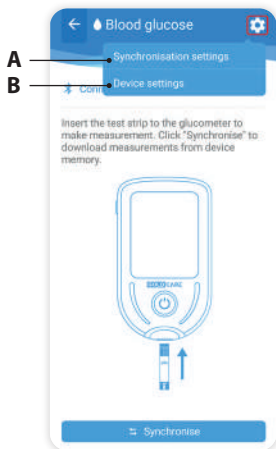


Fig. 64

A. Automatic Settings, we can select:

- Time synchronisation: after connecting the Diagnostic Gold Care meter to the ISTEEL Health app, the meter's date and time will be set to match those on the mobile device (Fig. 65).
- Range synchronisation: when the Diagnostic Gold Care meter is connected to the ISTEEL Health app, the glucose unit and desired glucose ranges in the meter are set to the app's settings (Fig. 65).

NOTE!

To automatically set the date and time on the meter, after you have switched the meter on with the ON/OFF button for the first time, click this button 7 times until the device switches off. Then switch the meter on again and connect it to the Istel Health app by following the steps described in this chapter. A synchronisation of the date and time on the meter will appear when the meter is switched on again.

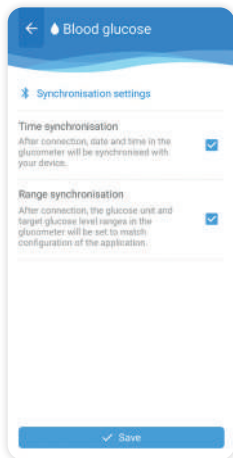


Fig. 65

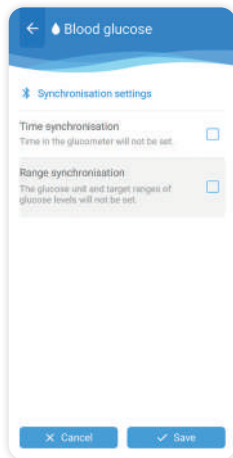


Fig. 66

If the **Time Synchronisation** and **Range Synchronisation** options are unchecked, the settings on the Diagnostic Gold Care meter will not change when connected to the application (Fig. 66).

- B.** In the Settings of the device, it is possible to change the time format (24h or 12h) and to set 4 alarms to remind you of the measurement, as well as a post-meal alarm (Fig. 67). The post-meal alarm can be set for 60, 90 or 120 minutes after a meal (Fig. 68). Confirm the settings with the “Save” button. The changes made in the ISTEEL Health application will be saved in the Diagnostic Gold Care meter.

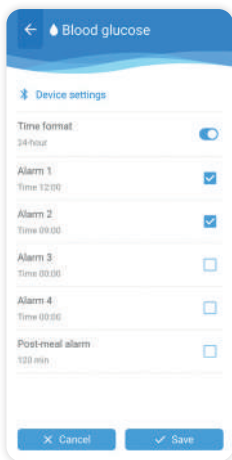


Fig. 67

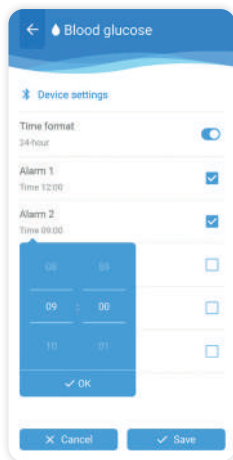


Fig. 68

8. MEASURING BLOOD GLUCOSE LEVELS

To measure blood glucose levels, you need:

1. Diagnostic Gold Care glucose meter
2. Diagnostic Gold Strip test strips
3. Adjustable automatic lancing device to obtain a blood sample
4. Sterile lancet for the lancing device

8.1 PREPARATION FOR THE TEST

1. Wash your hands with soap and warm water. Rinse your hands thoroughly and dry them. This reduces contamination of the puncture site and improves blood circulation. You can also massage your finger (Fig. A).
2. Prepare the lancing device to puncture the fingertip.
3. Pull the test strip out of the vial and close the vial immediately.
4. Insert the test strip into the test strip port according to the direction of the arrow on the test strip (Fig. B).
5. The device beeps and the test strip symbol and flashing sign  appear (Fig. C).
6. Use the  and  buttons to select the meal indicator and mark the test as a measurement before a meal , after a meal , on an empty stomach  or without indicator that is unmarked measurement (factory setting: without indicator).
7. You can now take a blood sample.

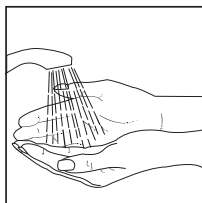


Fig. A

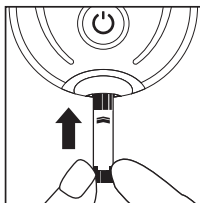


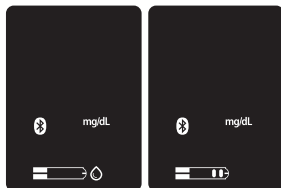
Fig. B



Fig. C

REMEMBER!

When the device is ready for a blood sample, the blood drop symbol  flashes after the test strip is inserted. The blood drop symbol  turns off when the test strip is filled with a sample and the device starts the countdown.



WARNING! If the display does not show any messages, please check the display brightness settings (for instructions on setting the display brightness, see chapter 6.2) or contact Diagnosis Customer Service at +48 85 874 69 28 (Mon–Fri, 8 a.m. – 4 p.m.)

8.2 TAKING A BLOOD SAMPLE

Blood samples can be taken from the fingertip, hand or forearm. Please refer to the instructions provided with the lancing device for details on blood collection.

To take a blood sample:

1. Turn the cap of the lancing device and remove it.
2. Insert the lancet into the lancet holder.
3. Rotate and remove the lancet cap to expose the tip of a sterile needle.
4. Replace the cap on the lancing device and tighten it.
5. Pull the tightening mechanism as far as it will go.
6. Press the lancing device firmly on the fingertip and press the release button.
7. After collecting the sample, carefully remove the cap with the used lancet.
8. Pull the lancet out of the lancing device. Dispose of the lancet in accordance with the applicable legislation.



WARNING! To reduce the risk of infection:

- **Never let anyone else use your lancet or lancet device.**
- **Always use a new, sterile lancet. Lancets are for single use only.**
- **Wash your hands thoroughly with soap and water after using the meter, lancing device and test strips.**
- **For information on cleaning and disinfecting the meter and the lancing device, see “Cleaning and disinfection” on page 59.**

8.3 APPLICATION OF BLOOD SAMPLES ON THE TEST STRIP

1. After blood is drawn, the strip with a meter is placed against a drop of blood on the fingertip.
2. The blood is automatically sucked into the test strip (Fig. D).
3. Hold the tip of the test strip in contact with the blood drop until the device beeps briefly (if the beep is on).
4. Once enough blood has filled the confirmation window (see Fig. G on the next page) in the test strip, the meter will begin counting down from 5 to 1 (Fig. E).
5. Your blood glucose result appears on the screen and is automatically stored in the meter's memory. (Fig. F).

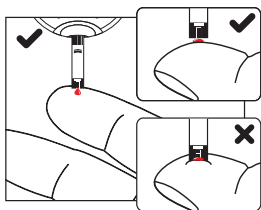


Fig. D

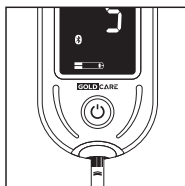


Fig. E



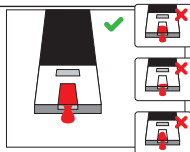
Fig. F

6. After the result is displayed, the meter will automatically turn off after 3 minutes if no more measurements are taken. When you have finished measuring, you can remove the test strip and dispose of it in a suitable waste container.
7. The results displayed by the Diagnostic Gold Care glucose meter have the range from 10 to 600 mg/dL (0.56 to 33.3 mmol/L). If the message “HI”

appears on the display, it means that the Diagnostic Gold Care meter has detected a blood glucose level greater than 600 mg/dL (33.3 mmol/L). We recommend repeating the measurement with a new Diagnostic Gold Strip test strip to confirm the result.

REMEMBER!

If an insufficient blood sample was used for the measurement, the message ER2 will be displayed on the meter screen (see table on page 63).



*Fig. G
The correct appearance of the test strip after the blood sample has been taken*

If the message “LO” appears on the display, it means that the Diagnostic Gold Care meter has detected a blood glucose level of less than 10 mg/dL (0.56 mmol/L). We recommend that you repeat the measurement using a new Diagnostic Gold Strip test strip to confirm the result. If the result is repeated, you should consult your doctor immediately.

8.4 MARKING THE MEASUREMENT AS MEASUREMENT BEFORE OR AFTER A MEAL

Marking of the measurement is possible before a drop of blood is placed on the test strip or after the measurement (before the strip is removed).

REMEMBER!

Marking a measurement as before a meal, after a meal or on an empty stomach is only possible if the measurement was unmarked before the blood drop was applied. If the measurement before the application of the blood drop was marked as "before a meal", "after a meal", "on an empty stomach" or "with control solution", it is not possible to change the marking after the measurement. Remember to confirm your choice with the button  after the measurement has been marked. If you remove the strip or the meter turns off automatically after 3 minutes, the measurement is saved as unmarked.

8.5 REMINDER TO MARK THE MEASUREMENT AFTER THE TEST

If the measurement was not marked before the drop of blood was applied to the test strip, a flashing apple icon (Fig. H) appears on the meter screen when the result is displayed.

This reminds you to mark the reading as before a meal 🍏, after a meal 🍽️, or on an empty stomach 🍽️. Select the mark using the arrows ⬅️➡️ and confirm your choice by pressing ⏻.

Remember that changing the measurement marker from unmarked to before a meal, after a meal or on an empty stomach may affect the classification of your measurement according to the set target values (see chapter 6.9). It is possible that the backlight on both sides of the button ⏻ will change, indicating the classification of the test result, and the classification of the test result will change in the form of the letters H, L or N displayed next to the test result indicating in which range your result falls (Fig. I). Remember to keep this in mind when marking a measurement after you have taken it.



Fig. H



Fig. I



8.6 DISPOSAL OF USED TEST STRIP AND LANCET

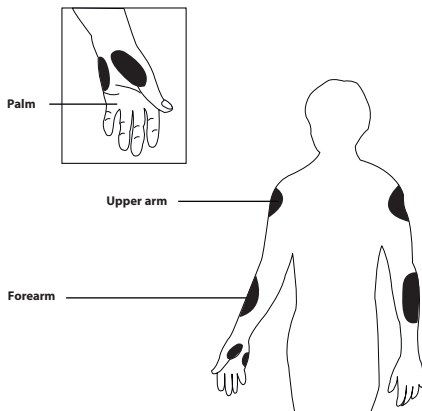
WARNING!

- *Always dispose of used test strips and lancets in the appropriate waste container.*
- *Used lancets and test strips can be a potential source of infection. They should be disposed of according to local regulations for proper waste disposal.*
- *Lancets are intended for single use only. After each use, the lancet must be discarded. Use due care to avoid accidental injury.*

8.7 ALTERNATIVE SAMPLING POINTS

Palm, forearm and upper arm

The Diagnostic Gold Care blood glucose kit allows you to test at alternative sites (AST). The kit allows you to test using a blood sample from your palm, forearm or arm. The results are comparable in accuracy to a blood sample from the fingertip. There are limitations to using alternative puncture sites, so you should consult your doctor.





WARNING! Physiological differences in blood circulation between the fingertip and other sites, such as the forearm or palm, may cause the results of glucose measurements to vary when blood is drawn from these sites. Changes in glucose levels can be detected more quickly when blood is drawn from the fingertip than when blood is drawn from other sites. Rub the alternative site for about 20 seconds before making a puncture. If you are testing for hypoglycaemia (low blood glucose) or if you are unaware of hypoglycaemia, we recommend taking a blood sample from the fingertip.



Consult your doctor about using alternative sites. With a little knowledge, you can give your fingertips some rest and test more often than before. For diabetics, more frequent testing of blood glucose levels is desirable. Remember, if you want to get a more accurate and current blood glucose reading, always take a sample from your fingertip.



It is strongly recommended to use alternative puncture sites at the following intervals ONLY:

- Before a meal or on an empty stomach (more than 2 hours after the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.



DO NOT use alternative sites if:

- You feel your blood sugar is low.
- You are unaware of hypoglycaemia.
- Your result at an alternative site does not match how you feel.
- You are testing for hypoglycaemia.
- Your glucose level normally fluctuates.
- You are pregnant.

9. CHECKING THE OPERATION OF THE KIT – CONTROL SOLUTION TEST

It is possible to check whether the measurement results provided by the meter are correct. The control solution is used to check that the meter and the test strips are working properly and that the measurement is correct.

When should a control solution test be performed?

- When you use the device for the first time.
- When you use a new set of test strips.
- Each time you have doubts about the correct operation of the kit, or periodically from time to time to confirm correct operation.
- When changes in the treatment of diabetes.
- When the glucose test result is lower or higher than your normal values.
- If the meter falls down

REMEMBER!

Two control solutions are available in different glucose ranges (M – medium and H – high). The control solutions are not included in the kit. They can be purchased separately in a pharmacy.

9.1 CARRYING OUT A CONTROL SOLUTION TEST

Observe the following precautions when performing the control solution test:

1. The test with the control solution should be carried out at (18°C to 30°C or 64.4°F to 86°F).
2. Shake the vial for 5 seconds. Unscrew the cap from the vial. Do not use the first drop of control solution.
3. Squeeze on another drop of control solution. You must apply the solution to a clean, non-absorbent surface (such as clean wax paper) that must be prepared before performing the test. Do not apply the control solution directly from the bottle to the test strip.
4. Insert the test strip into the port (Fig. 69). The meter turns on automatically.

5. A flashing light and test strip symbols  (Fig. 70) appear on the display.

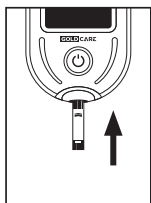


Fig. 69



Fig. 70



Fig. 71



Fig. 74



Fig. 73

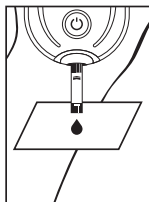


Fig. 72

6. Press and hold the button  for 4 seconds to enter the control solution mode. A symbol  appears indicating that the meter will mark the next test as a control solution test (Fig. 71). You are now ready to use the control solution.
7. Gently touch a drop of control solution to the end of the test strip (Fig. 72). The control solution is automatically drawn into the test strip. The meter starts counting down from 5 to 1 (Fig. 73); the result for the control solution is displayed (Fig. 74).

9.2 COMPARING CONTROL SOLUTION RESULTS

The meter is working properly if the test result is within the range of the control solution printed on the test strip vial. Repeat the test if the result is out of range.

A result that is out of range may be due to the following:

1. Mistake when performing the test
2. The test with the control solution should be carried out at 18°C to 30°C or 64.4°F to 86°F
3. Exceeding the expiration date or contamination of the control solution
4. Exceeding the expiration date or damage to the test strips
5. Failure of the glucose meter

REMEMBER!

The result is not used to calculate the average when the meter is in control solution mode.

REMEMBER!

Do not use the Diagnostic Gold Care kit if the abnormal test result is repeated with control solution. In such a case, please contact Diagnosis Customer Service at 85 874 69 28 from 8 a.m. to 4 p.m. Monday to Friday.

10. MEMORY FUNCTIONS

10.1 VIEWING THE RESULTS STORED IN THE DEVICE'S MEMORY

1. Turn on the blood glucose meter using .
2. Use the  and  buttons to scroll through the results. Press the button  to exit memory and turn the meter off.



NOTE: NOTE! If you have not set a date and time in the glucose meter, the display shows 0:00. The measurements taken are stored in the meter's memory but are not taken into account when calculating the average (see chapter 6.1 Setting the date and time), nor are they sent to the Istel Health application or the Istel Care System.

3. Press the button  to turn the meter on. First you see the date and time (Fig. 75). Press again  to see average results.
4. First you see the result for the control solution. Press the button  to switch between average results from 7 days (Fig. 76).
5. Press the button  to display average results for 7, 14, 30, 60, 90 and 21 days (factory set value – change settings as described in chapter 6.6 on page 23) for each mode: averages from unmarked measurements, averages from measurements before a meal, averages from measurements after a meal and averages from measurements on an empty stomach. Along with the average results, the information about the number of measurements taken to calculate the average appears. Press the button  to scroll back. Press the button  to turn the device off.



Fig. 75



Fig. 76

REMEMBER!

The device stores 1000 results in its memory. When the memory is full, the oldest result is deleted and the most recent result is stored. The Diagnostic Gold Care glucose meter allows you to view the average result for consecutive 7/14/30/60/90 and 21 days (factory set value). For results in the range below the low threshold (LO, below 10 mg/dL) and above the high threshold (HI, above 600 mg/dL), only the LO or HI information is displayed in the device memory (these values are not included in the calculation of the average).

10.2 EXITING THE MEMORY MODE

1. Press the button  to turn the device off at any time.
2. The device automatically will turn off after 3 minutes of inactivity.

11. CLEANING AND DISINFECTION OF THE GLUCOSE METER

When cleaning the meter, gently wipe the outer surface with a damp, soft cloth. **Do not use organic solvents (such as acetone) for cleaning. Clean the meter and lancing device if they become dirty.**



WARNING!

Healthcare professionals using the kit on multiple patients should remember that all parts that come into contact with human blood should be treated as a potential biological hazard. Users should follow the guidelines for the prevention of blood-borne diseases in healthcare facilities for potentially infectious human blood samples, in accordance with applicable regulations.

How to clean / disinfect the glucose meter and lancing device?

1. Cleaning agent: 70% isopropyl alcohol
2. Wipe the outside of the meter and lancing device with a cotton pad or cloth soaked in cleaning/disinfecting agent.
3. Allow the cleaning/disinfecting agent to act on the meter for at least 2 minutes.
4. Wipe any remaining moisture and liquids from the meter case.
5. Allow it to dry before taking new measurements.



WARNING! Make sure that the cotton pad or cloth is only damp, but not wet. If any liquid enters the meter, it may cause a malfunction. Wash your hands thoroughly with soap and water after using the meter, lancing device and test strip. Be careful not to get any liquid, dirt, dust, blood, or control solution into the test strip or data port. Do not spray the cleaning solution on the meter or immerse it in any liquids. If you have any questions, please contact our Customer Service department at +48 85 874 69 28.

12. STORAGE OF THE GLUCOSE METER

1. Use the meter with caution. Dropping the product may cause damage.
2. Do not expose the meter, test strips or control solution to extreme conditions such as high humidity, heat, frost or dust.
3. The meter should be stored at room temperature in a dry and clean place. Do not store the meter in direct sunlight or in locations with high humidity/dust. It is recommended that the meter and its accessories be stored in the carrying case provided.

The set contains small parts that pose a choking hazard. Keep it away from small children and persons lacking the ability to communicate, pets and pests.



This marking on the product or associated materials indicates that it should not be disposed of with household waste at the end of its working life. Return used product  and batteries to a waste collection point. It contains environmentally hazardous components. Proper disposal of the equipment and batteries allows the recovery of valuable resources and the prevention of negative effects on health and the environment, which can be endangered by improper waste disposal. If you have any doubts where to dispose of your used product, contact Diagnosis. (Contact details on page 56).

13. MESSAGES DISPLAYED

Message displayed	Meaning	Action
	The meter is ready to measure from a drop of blood.	Now you can apply the strip to the blood sample.
	The meter is ready to measure from the control solution.	Now you can the test strip to a drop of control solution.
	The symbol Δ is displayed when the result is HIGHER than the set high threshold (HI).	Remember that you can change the default setting of 180 mg/dL according to the instructions on page 25.
	The symbol Δ is displayed when the result is LOWER than the set low threshold (LO).	Remember that you can change the default setting of 70 mg/dL according to the instructions on page 25.
	The measurement result is out of the sensor range (too high)	Repeat the test with a new test strip. If the result is still too high (HI), see your doctor immediately.

Message displayed	Meaning	Action
	The measurement result is out of the sensor range (too low).	Repeat the test with a new test strip. If the result is still too low, see your doctor immediately.
	High ambient temperature when performing the test. The glucose meter will take a measurement, but it may be unreliable.	Change ambient temperature (10–45°C or 50–113°F) and wait 15 minutes before repeating the test.
	Low ambient temperature when performing the test. The glucose meter will take a measurement, but it may be unreliable.	
	Ambient temperature is too high to perform the test. The glucose meter will not take the measurement.	Repeat the test in a warmer environment (10–45°C or 50–113°F). Wait 15 minutes before measuring again.
	Ambient temperature is too low to perform the test. The glucose meter will not take the measurement.	Repeat the test in a warmer environment (10–45°C or 50–113°F). Wait 15 minutes before measuring again.

Message displayed	Meaning	Action
	The battery level is too low to turn on the device and perform the measurement.	Insert 2 new AAA batteries immediately
	Error message indicating a problem with the test strip – moisture on the test strip or used test strip.	Read the instructions for use and repeat the test with a new test strip.
	Error message indicating a blood sample error.	Not enough blood was used for the measurement. Dispose of this test strip and measure again with a new test strip and a larger blood sample.
	Error message indicating a problem with the glucose meter memory.	Remove and reinsert the batteries. If the problem persists, contact customer service.
	The self-diagnosis device procedure has detected irregularities in the measuring system	Remove and reinsert the batteries. If the problem persists, contact customer service.

Message displayed	Meaning	Action
	The test strip was removed during the measurement.	Remove it and insert a new test strip.
	The glucose meter has not gone through the full manufacturing/calibration process.	Remove and reinsert the batteries. If the problem persists, contact customer service.
	Memory error.	Pay special attention to the correct date and time.
	Low battery. The device will perform about 50 more tests.	Insert 2 new AAA batteries.
	The batteries are too low for the device to continue operating.	Insert 2 new AAA batteries immediately.

Message displayed	Meaning	Action
	The glucose meter is connected to a PC.	Follow the instructions displayed by the application to download the measurement results.
	The set alarm has been triggered to remind you to measure your blood glucose level.	Press any key to switch off the alarm. The alarm turns off automatically after 30 seconds.
	The blood glucose meter checked with the Diagnostic Gold Check control strip is working correctly.	You can now perform a glucose test.
	A test with Diagnostic Gold Check control strip showed malfunction of the meter's measuring elements.	Turn the meter off and then on again. If the problem persists, contact Customer Service.

Other problems	Action
The test strip is not inserted properly into the meter.	Read the instructions for use and insert the test strip correctly into the test strip port (arrow facing upwards).
Defective test strip.	Repeat the test with a new test strip.
The test strip remains in the test strip port for more than 3 minutes before testing.	The meter will be automatically turned off. Insert a new test strip into the port.
No message is displayed on the LCD screen during the test attempt (no visible segments).	Replace the batteries. If this does not help, please contact Customer Service.

If your device does not work properly after applying the above solutions, please contact your dealer or the product manufacturer. Hotline +48 800 70 30 11 or +48 85 874 60 45, +48 85 874 69 28 (8 a.m. to 4 p.m.).

SERIOUS INCIDENT REPORTING:

Any serious incident involving the device should be reported to the manufacturer as well as the competent authority of the Member State in which the user is located.

14. TECHNICAL SPECIFICATION

Measurement range	10–600 mg/dL (0.56–33.3 mmol/L)
Calibration	Test result as plasma glucose concentration
Unit of measurement	mg/dL or mmol/L
Test sample	Fresh whole capillary blood
Sample volume	≥0.9 µl
Haematocrit	20–60%
Test duration	5 s
Alternative testing sites	Hand, forearm and upper arm
Memory capacity	The last 1,000 results
Output	USB interface
Power supply	3 V (2 × AAA battery)
Wireless communication	Bluetooth Low Energy
Frequency band	2 402–2 480 MHz
Max. power in the frequency range	+2 dBm
Battery lifetime	About 2000 measurements at 23°C (73.4°F)
Dimensions	94×54×17 mm
Weight	47 g (without batteries)
Permissible height above sea level	3776 m a.s.l.
Temperature during the measurement	10–45°C (50–113°F)
Product lifetime	(refers to glucose meter) 5 years
Transport and storage of the glucose meter	
Temperature	–20–50°C (–4–122°F)
Humidity	<93% ±3% relative humidity

For technical specification of blood glucose test strips, see their instruction for use.

15. ELECTRICAL STANDARDS

This device has been tested in compliance with the electrical and safety requirements specified by: IEC/EN 61010-1, IEC/EN61010-2-101, EN 61326-1, IEC/EN 61326-2-6.

The device complies with electromagnetic compatibility (EMC) requirements. The electromagnetic emissions from the product are low and should not cause interference with the operation of adjacent electronic equipment.

The device has been tested for immunity to electrostatic discharge and radio wave interference. The kit complies with the requirements of Directive 98/79/EC and EN ISO 15197:2015. We hereby declare under our sole responsibility that the product complies with the requirements of RED Directive 2014/53/EU.

The product may only be used in the EU Member States or in the country where it was purchased. If used in other countries, you may be in breach of the laws and regulations on radio communication there.



Use of this meter in close proximity to electrical and electronic equipment that is a source of electromagnetic radiation may cause interference with the proper functioning of this blood glucose meter. We recommend avoiding measurements in close proximity to sources of electromagnetic radiation.

16. RESTRICTIONS OF USE

Limitations for Diagnostic Gold Strip test strips and Diagnostic Gold Care meter.

Diagnostic Gold Strip test strips do not cause interference with haematocrit range 20–60%. Haematocrit index is the volume percentage of red cells in the blood. Limit values of the haematocrit can influence the measurement result. A haematocrit value below 20% can lead to falsely high results. A haematocrit level above 60% may lead to falsely low results. If you do not know the value of your haematocrit, you should consult your doctor.



WARNING! The Diagnostic Gold Care kit is intended for in vitro testing only and not for testing newborn babies. Diagnostic Gold Strip test strips are for use with fresh whole capillary blood samples taken from the fingertip, hand or forearm. Testing under severe dehydration, severe hypotension, shock or hyperosmolar hyperglycaemia may result in abnormal results. If you think you are suffering from any of the above symptoms, contact your doctor immediately.

17. SERVICE AND WARRANTY



WARNING! The Diagnostic Gold Care blood glucose monitoring kit is intended for in vitro diagnostic use only. Diagnosis does not guarantee the functioning of the Diagnostic Gold Care kit when used with any strips other than the Diagnostic Gold Strip strips specifically designed for the Diagnostic Gold Care meter. The manufacturer's warranty for the Diagnostic Gold Care Kit is valid only if the instructions for use described in the User Manual are followed and becomes invalid if the Diagnostic Gold Care Kit and Diagnostic Gold Strip test strips are not used according to the instructions.

18. CUSTOMER SERVICE

If you have any questions or concerns about this product or its operation, or if you need to solve a problem, please contact our Customer Service.

HOTLINE (Polish language only):

OPEN:
Monday–Friday

HOURS:
8 a.m. – 4 p.m.

+48 800 70 30 11
for landlines (free call)

+48 85 874 69 28
for mobile phones (caller pays
the cost according to the
operator's tariff)

e-mail: info@diagnosis.pl

When calling Customer Service, have the Diagnostic Gold Care meter, Diagnostic Gold Strip test strips and other available accessories with you. This will allow us to respond to all your inquiries quickly and efficiently.

Guidance and manufacturer's declaration – electromagnetic immunity

The DEVICE is intended to work in the electromagnetic environment specified below.
The recipient or the user of the DEVICE should assure that it is used in such environment.

Immunity tests	Test level	Level met	Electromagnetic environment – information
Electrostatic discharge (ESD) according to IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency magnetic field in accordance with IEC 61000-4-8	–	–	Power frequency magnetic field should be at the level which is typical for a normal positioning in a commercial or hospital environment.

EXPLANATION OF THE SYMBOLS USED			
	Temperature limit		Batch code
Rev.	Revision		Catalogue number
	Battery type used in the meter		In vitro diagnostic medical device
	Direct current		Consult instructions for use
	Do not re-use		Caution
	Protect from sunlight		Use-by-date
	Do not use if the packaging is damaged		Manufacturer
	Keep dry		Serial number
	Unique Device Identifier		Manufacturing date



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Visit the educational website:

www.StrefaDiabetyka.pl

Find out:

What diabetes is and its possible complications.

What proper self-monitoring of blood glucose is.

The importance of diet, physical activity and foot care.

Watch instructional videos and download free educational materials.

www.diagnosis.pl



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