SURE™ Smart Duo

Sure and Simple

IDEAL FOR TYPE 1 PATIENTS

OWNER'S MANUAL

Blood Glucose & ß-Ketone Monitoring System

Bluetooth®

NIPRO

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1. Safety Information

Read the following Safety Information thoroughly before using the device.

- Use this device **ONLY** for the intended use described in this manual.
- Do **NOT** use accessories which are not specified by the manufacturer.
- Do **NOT** use the device if it is not working properly or damaged.
- This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only. Always consult your doctor to have the results interpreted.
- The blood glucose test strip can be used for the testing of newborns; The β-Ketone test strip must **NOT** be used for the testing of newborns.
- Before using this device to test blood glucose or β-Ketone, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
- Keep the device and testing supplies away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
- The use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
- Do **NOT** use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the correct operation.
- Proper maintenance as well as timely calibration of the device together with the control solution is essential in ensuring the longevity of your device. If you are concerned about the accuracy of the measurement, please contact the place of purchase or customer service representative for assistance.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

2. Important Information

- Severe dehydration and excessive water loss may cause readings which are lower than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- If your blood glucose or β-Ketone results are lower or higher than usual, and you do not have symptoms of illness, first repeat the test. If you have symptoms or continue to get results higher or lower than usual, follow the treatment advice of your healthcare professional.
- Use only fresh whole blood sample to test your blood glucose or β-Ketone. Using other substances will lead to incorrect results.
- If you are experiencing symptoms that are inconsistent with your blood glucose or β-Ketone test results and you have followed all instructions described in this owner's manual, call your healthcare professional.
- We do not recommend using this product on severely hypotensive individuals or patients in shock. Readings which are lower than actual values may occur for individuals experiencing a hyperglycaemic-hyperosmolar state, with or without ketosis. Please consult the healthcare professional before use.

3. Introduction

Intended Use

This system is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and by health care professionals in clinical settings as an aid to monitor the effectiveness of diabetes control. It is intended to be used for the quantitative measurement of glucose (sugar) and β-hydroxybutyrate (Ketone) in fresh whole blood samples with following indications.

Home use of blood glucose testing requires capillary blood samples from fingertip or alternate sites (AST) palm, forearm and upper arm. In addition, health care professionals may also use arterial and venous blood samples, as well as neonatal blood from the heel.

For professional use of blood glucose testing, only use heparin for anticoagulation of arterial, venous and capillary whole blood samples.

Home use of β-Ketone testing requires capillary blood samples from the fingertip only. (Alternate site testing is not supported). In addition, health care professionals can also use venous blood samples, however arterial, neonatal and alternate site testing is not supported.

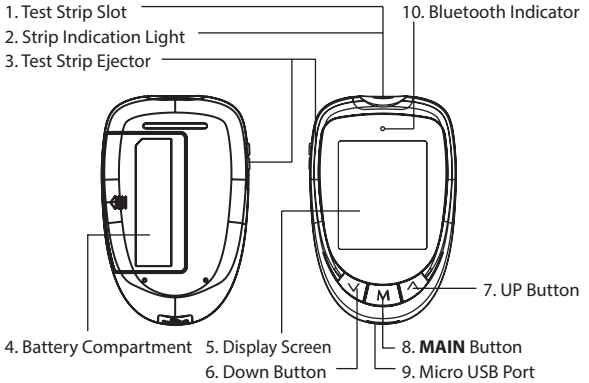
For professional use of β-Ketone testing, only use heparin for anticoagulation of venous and capillary whole blood samples.

This system is not intended for use in the diagnosis or screening of diabetes mellitus.

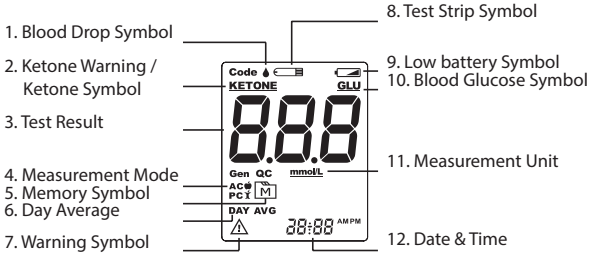
Test Principle

Your system measures the amount of glucose or β-Ketone in whole blood. The glucose or β-Ketone testing is based on the measurement of electrical current generated by the reaction of glucose or β-Ketone with the reagent of the strip. The meter measures the current, calculates the blood glucose or β-Ketone level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose or β-Ketone in the blood sample.

Product Overview



Screen Display



4. Getting Started

Initial Setup

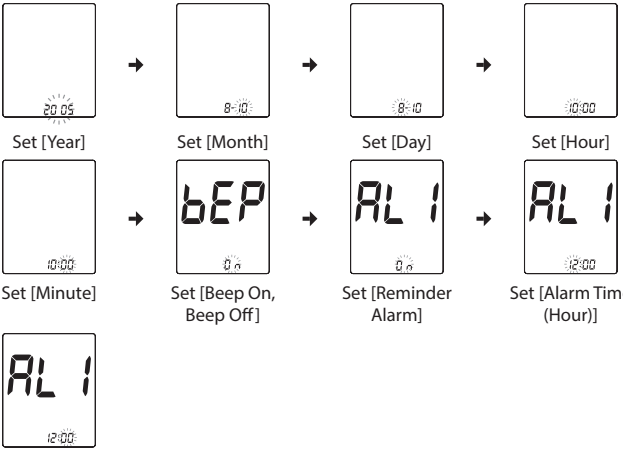
Please follow the initial setup procedure before using the device for the first time or after you have replaced the battery. When the battery power is extremely low and "E-b & 🔋" appears on the screen, the meter cannot be turned on.

Step 1: Enter the Setting Mode

1. The meter turns on automatically once a new battery is inserted.
2. Start with the meter off (no test strip inserted). Press and hold ∧ and ∨ at the same time for five seconds.

Step 2: Configuring the Settings (Date, Time, and Reminder Alarm)

Press ∧ or ∨ to adjust the value or enable/disable the setting. Then press **MAIN** button to confirm the setting and switch to another field.



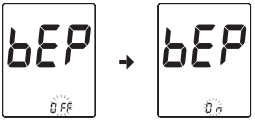
Set [Year] → Set [Month] → Set [Day] → Set [Hour]

Set [Minute] → Set [Beep On, Beep Off] → Set [Reminder Alarm] → Set [Alarm Time (Hour)]

Set [Alarm Time (Minute)]

Note:

• Press to select Beep On or Beep Off. Press **MAIN** button to confirm.



• When Beep is turned off, the alarm function will remain effective.

• You may set it up to four reminder alarms.

• To turn off the alarm, press ∧ or ∨ to change On to OFF. Press **MAIN** button to confirm.

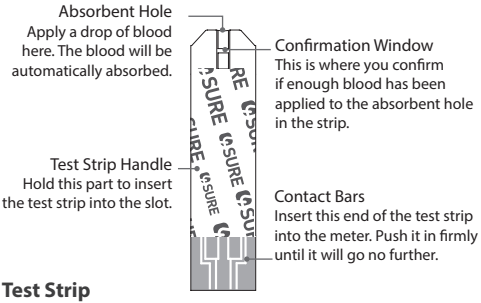
• When the alarm goes off, the device will automatically turn on. Press ∧ or ∨ to mute the alarm. If you do not press ∧ or ∨ , the device will beep for 2 minutes then switch off.

• If the device is idle for 2 minutes during the setting mode, it will turn off automatically.

5. Blood Glucose Testing

Before Testing Blood Glucose

Blood Glucose Test Strip Appearance



Inserting a Test Strip

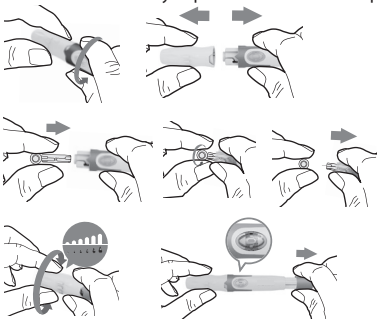
Insert the test strip into its slot.

Important!

The front side of test strip should face up when inserting the test strip. Test results might be wrong if the contact bar is not fully inserted into the test slot.

Preparing the Lancing Device

1. Remove the cap.
2. Insert a new lancet firmly into the white lancet holder cup.
3. Remove the protective disk on the lancet.
   Hold the lancet firmly in place and twist off the protective disk.



4. Replace the cap until it snaps or clicks into place.
5. Rotate the dial to set the desired lancing depth.
6. Pull the cocking control out until the orange bar appears on the release button window.

Important!

To reduce the chance of infection:

- Never share a lancet or a lancing device.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.

Obtaining the Blood Sample

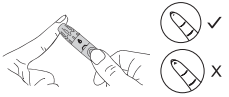
Please follow the suggestions below before obtaining a drop of blood:

- Wash and dry your hands before starting.
- Select the puncture site either on your fingertips or other body parts.
- Rub the puncture site for about 20 seconds before penetration.

❖**Blood from the fingertip**

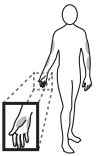
1. Press the lancing device tip firmly against the lower side of your fingertip.

2. Press the release button to prick your finger.
   A click indicates that the puncture is complete.



❖**Blood from sites other than the fingertip (For Blood Glucose Test Only)**

Alternative site testing (AST) is when individuals check their blood glucose levels using other areas of the body other than the fingertips. The 4SURE blood glucose test strips allow AST to be performed on sites other than the fingertips. Please consult your health care professional before you begin AST.

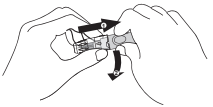


We strongly recommend that you perform AST **ONLY** at the following times:

- During a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

To obtain a blood sample from the alternative sites, please rub the puncture site for approximately 20 seconds.

1. Replace the lancing device cap with the clear cap.
2. Pull the cocking control out until the orange bar appears on the release button window.



Do **NOT** use AST if:

- You think your blood glucose is low.
- You may not notice if you are hypoglycemic.
- Your AST results are inconsistent with the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results often fluctuate.

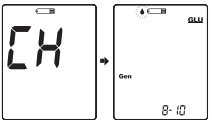
Important!

- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- Avoid lancing the areas with obvious veins to avoid excessive bleeding.

• It is recommended to discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

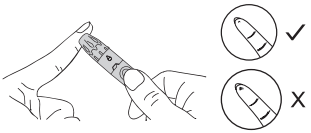
Performing A Blood Glucose Test

1. Insert the blood glucose test strip into its slot. Wait for the device to display the test strip " ▭ ", blood drop " 🩸", and **GLU**.

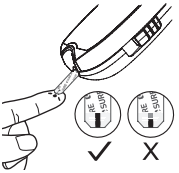


2. Press ∧ or ∨ to adjust the measuring mode, and press **MAIN** button to confirm it.
   - General Tests (**Gen**) - any time of day without regard to time since the last meal (this is also the default setting).
   - AC (**AC** 🍎) - before meal.
   - PC (**PC** 🍽) - 2 hours after a meal.

3. Obtain a blood sample.
   Use the pre-set lancing device to puncture your desired site. After penetration, discard the first drop of blood with a clean tissue or cotton. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample. The volume of blood sample must be at least 0.5 microliter (μL) for blood glucose test.



4. Apply the blood sample.
   Move your finger to meet the absorbent hole of the test strip and the blood drop will automatically be drawn into the test strip. Remove your finger until the confirmation window is filled. The meter begins to count down. Do not remove your finger until you hear a beep sound.



5. Read your result.
   The results of your blood glucose test will appear after the meter counts down to 0. The results will be stored automatically in the meter memory.

Ketone warning

- When your blood glucose result is higher than 13.3 mmol/L, the meter will display the blood glucose reading **GLU** as well as a Ketone warning (flashing **KETONE** and ⚠).
- The ketone warning is to notify you that you may be at risk of elevated Ketone levels and a Ketone test is recommended.
- For instructions on how to perform a Ketone test, please see section 6.

Disposing Used Test Strip and Lancet

To remove the used test strip, simply push the **Test Strip Ejector** button upward to eject the used test strip. The device will automatically turn off after the test strip is removed.

To remove the used lancet, remove the lancet from the lancing device after you have finished testing. Discard your used strip and lancet properly in a puncture-resistant container.

Important!

The used lancet and test strip may be biohazards. Please consult your health-care provider for proper disposal which complies with your local regulations.

6. β-Ketone Testing

Before Testing β-Ketone

Calibration

You must calibrate the device every time you begin to use a new box of β-Ketone test strips by setting the meter with the correct code. To ensure test accuracy, make sure the code number displayed on the display screen matches the number printed on the test strip vial or individual foil pack.

How to Code Your Meter

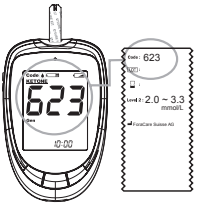
1. You will receive a code strip with every new pack of β-Ketone test strips. Insert the code strip into the test slot of the device. Wait for the device to display the code number.

2. Checking the Code Number

Make sure that the code number displayed on the device matches the number on the individual foil pack before you proceed.

If it matches, you can proceed with your test. Otherwise, please stop testing and repeat the calibration procedure.

If the problem persists, contact Customer Service for further assistance.

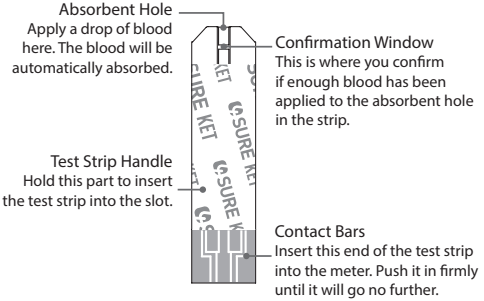


Important!

- It is important to make sure that the number on the code strip is the same as the number that is displayed on the meters LCD screen and on the test strip's individual foil pack. Failure to do so will cause in accurate results.

3. Remove the code strip, the display will show "OFF" indicating the device has finished coding and is ready for β-Ketone testing.

β-Ketone Test Strip Appearance



Inserting a Test Strip

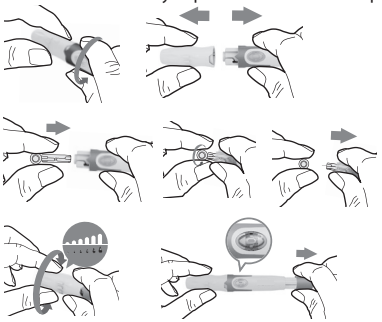
Insert the test strip into its slot.

Important!

The front side of test strip should face up when inserting the test strip. Test results might be wrong if the contact bar is not fully inserted into the test slot.

Preparing the Lancing Device

1. Remove the cap.
2. Insert a new lancet firmly into the white lancet holder cup.
3. Remove the protective disk on the lancet.
   Hold the lancet firmly in place and twist off the protective disk.



4. Replace the cap until it snaps or clicks into place.
5. Rotate the dial to set the desired lancing depth.
6. Pull the cocking control out until the orange bar appears on the release button window.

Important!

To reduce the chance of infection:

- Never share a lancet or a lancing device.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.

Obtaining the Blood Sample

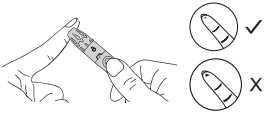
Please follow the suggestions below before obtaining a drop of blood:

- Wash and dry your hands before starting.
- Select the puncture site either on your fingertips or other body parts.
- Rub the puncture site for about 20 seconds before penetration.

❖Blood from the fingertip

1. Press the lancing device tip firmly against the lower side of your fingertip.

2. Press the release button to prick your finger. A click indicates that the puncture is complete.

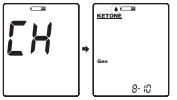


Important!

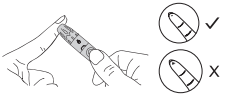
- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- Avoid lancing the areas with obvious veins to avoid excessive bleeding.
- It is recommended to discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

Performing a β-Ketone Test

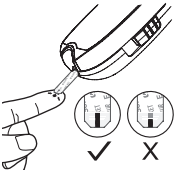
1. Insert the β-Ketone test strip into its slot. Wait for the device to display the test strip " ", blood drop " ", and **KETONE**.



2. Obtain a blood sample.
Use the pre-set lancing device to puncture your desired site. After penetration, discard the first drop of blood with a clean tissue or cotton. Gently squeeze the punctured area to obtain another drop of blood.
Be careful **NOT** to smear the blood sample. The volume of blood sample must be at least 0.8 microliter (μL) for blood glucose test.



3. Apply the blood sample.
Move your finger to meet the absorbent hole of the test strip and the blood drop will automatically be drawn into the test strip. Remove your finger when the confirmation window is filled. The meter begins to count down. Do not remove your finger until you hear a beep sound.



4. Read your result.
The results of your β-Ketone test will appear after the meter counts down to 0. The results will be stored automatically in the meter memory.

Disposing Used Test Strip and Lancet

To remove the used test strip, simply push the **Test Strip Ejector** button upward to eject the used test strip. The device will automatically turn off after the test strip is removed.

To remove the used lancet, remove the lancet from the lancing device after you have finished testing. Discard your used strip and lancet properly in a puncture-resistant container.

Important!

The used lancet and test strip may be biohazards. Please consult your health-care provider for proper disposal which complies with your local regulations.

7. Control Solution Testing

Important!

Please note there are two main types of 4SURE control solution available;

1. 4SURE blood glucose control solution (Level 1, 2, 3). This solution contains a known amount of glucose that reacts with the 4SURE blood glucose test strips and is used to ensure your meter and test strips are working correctly.
2. 4SURE β-Ketone control solution (level 1, 2). This solution contains a known amount of β-Ketone that reacts with the 4SURE β-Ketone test strips and is used to ensure your meter and test strips are working correctly.

Only use 4SURE blood glucose control solution to perform a blood glucose control tests. Only use 4SURE β-Ketone control solution to perform a β-Ketone control test.

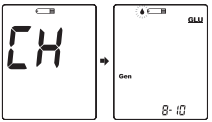
Control solution is not provided within your meter starter kit but is available from customer service. Tel: 0800 08 588 08.

Advice on when to perform a Control Solution Test:

- ✓ You suspect the device or test strips are not working properly.
- ✓ Your blood glucose or β-Ketone test results are not consistent with how you feel, or if you think the results are not accurate.
- ✓ You have dropped or think you may have damaged the device.

To perform a blood glucose control solution test, do the following:

1. Insert the blood glucose test strip into the test slot of the device. Wait for the device to display the test strip "▭" and blood drop "🩸".

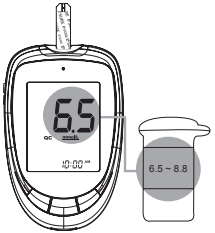


2. Apply the 4SURE blood glucose control solution. Shake the control solution vial thoroughly before use. Squeeze out a drop and wipe it off, then squeeze another drop and place it on the top of the vial cap. Hold the device to move the absorbent hole of the test strip to touch the drop. Once the confirmation window is filled completely, the device will begin counting down.

Note:

To avoid contaminating the control solution, do not directly apply the control solution onto a strip.

3. Read and compare the result. After counting down to 0, the test result of the control solution will appear on the display. Compare this result with the range printed on the test strip vial and it should fall within this range. If the test result is out of range, read the instructions again and repeat the control solution test.



4. The meter will detect the difference between control solution and blood samples automatically. It will automatically marks the result as a control solution test with "**QC**" display.

Note:

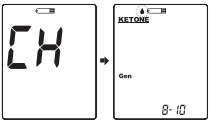
- Control solution test results are stored in the memory.
- The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose level.
- Refer to the Maintenance section for important information about your control solutions.

Out-of-range results:

If you continue to get results that fall outside the range printed on the test strip vial, it means that the meter and/or strips might not be working properly.

To perform a β-Ketone control solution test, do the following:

1. Insert the β-Ketone test strip into the test slot of the device. Wait for the device to display the test strip " " and blood drop " ".

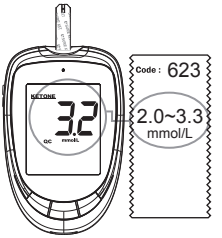


2. Apply the 4SURE β-Ketone control solution. Shake the control solution vial thoroughly before use. Squeeze out a drop and wipe it off, then squeeze another drop and place it on the top of the vial cap. Hold the device to move the absorbent hole of the test strip to touch the drop. Once the confirmation window is filled completely, the device will begin counting down.

Note:

To avoid contaminating the control solution, do not directly apply the control solution onto a strip.

3. Read and compare the result. After counting down to 0, the test result of the control solution will appear on the display. Compare this result with the range printed on the individual foil pack and it should fall within this range. If the test result is out of range, read the instructions again and repeat the control solution test.



4. The meter will detect the difference between control solution and blood samples automatically. It will automatically marks the result as a control solution test with " **QC** " display.

Note:

- Control solution test results are stored in the memory.
- The control solution range printed on the individual foil pack is for control solution use only. It is not a recommended range for your blood glucose level.
- Refer to the Maintenance section for important information about your control solutions.

Out-of-range results:

If you continue to get results that fall outside the range printed on the individual foil pack, it means that the meter and/or strips might not be working properly.

8. Reviewing Test Results

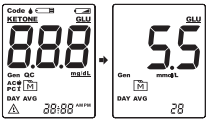
Your device stores the 1000 most recent test results along with respective dates and times in its memory. To enter the device memory, start with the device switched off.

To review all test results, do the following:

1. Press **MAIN** button or ∧. The "M" icon appears on the screen.
2. Press **MAIN** to review the test results stored in the device.
   Press ∧ or ∨ repeatedly to review other test results stored in the device. After the last test result, press **MAIN** again and the device will be turned off.

To review the day-average test results, do the following:

1. Press ∨ to enter memory mode for average results with "M" and **DAY AVG** displayed on the screen. Your 7-day average result measured in general mode will appear on the display.
2. Press ∧ or ∨ to review 7, 14, 30, 60 and 90-day average results stored in each measuring mode in the order of Gen, AC, then PC.



Note:

- Press and hold **MAIN** for 5 seconds to exit the memory mode or leave it without any action for 2 minutes. The device will turn off automatically.
- If using the device for the first time, the "---" icon will appear when you recall the test results or review the average result. This indicates that there is no test result in the memory.
- Control solution results are **NOT** included in the day average.

9. Transferring Data

Data Transmission to Smart Phone via Bluetooth

You can use your device with an iOS (5.0.1 or higher) Android system (4.3 API Level 18 or higher) to download data from your 4SURE Smart Duo via Bluetooth. Follow the steps below to transmit data from your 4SURE Smart Duo. Please contact Nipro Europe customer service for information regarding available Apps.

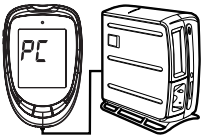
1. Turn on the Bluetooth function on your smart phone and open the App you wish to pair with.
2. After completion of measuring mode or memory mode on your 4SURE meter system, the Bluetooth will automatically be activated and the Bluetooth indicator will start to flash.
3. Follow the instructions on your App to pair the two devices.
4. Once the devices are paired, whenever your 4SURE meter turns off after a test, the Bluetooth will be initiated and data automatically transferred. If your mobile device is not within receiving range or switched off, the Bluetooth on your 4SURE meter will automatically deactivate after 2 minutes.

Note:

- While the meter is in transmission mode, it will be unable to perform a blood glucose or β-Ketone test.
- Make sure your device with iOS or Android system has turned on its Bluetooth before transmitting the data and the meter is within the receiving range.

Data Transmission to PC via Micro USB Cable

1. Install the software on your computer (Your PC will need window 8 or higher) Download 4SURE Diabetes Manager and follow the instructions to install the software on your computer.
2. Connect the device with your computer using a Micro USB Cable
   Connect the Micro USB cable to the USB port on your computer. With 4SURE Smart Duo switched off, connect the other end of the Micro USB cable to the 4SURE Smart Duo data port. "PC" will appear on the meter display, indicating that the meter is in communication mode.



3. Transfer data to your computer
   Follow the software on-screen instructions to transmit data. Remove the cable and the device will automatically turn off.

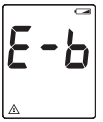
Note:

- While the meter is in transmission mode, it will be unable to perform a blood glucose test.

10. Maintenance

Changing Battery

You must change the battery immediately and reset the date and time when the battery power is extremely low and "E-b & ▭" appears on the screen. The meter cannot be turned on.



To change the battery, do the following:

1. Press the edge of the battery cover and lift it up to remove the cover.
2. Remove the old battery and replace with one 1.5 V AAA size alkaline battery.
3. Close the battery cover. If the battery is inserted correctly, you will hear a "beep" afterwards.

CAUTION RISK OF EXPLOSION IF BATTERY IS REPLACED BY AN INCORRECT TYPE.

DISPOSE OF USED BATTERIES ACCORDING TO THE INSTRUCTIONS.

Note:

- Replacing the battery does not affect the test results stored in memory.
- Keep the battery away from small children. If swallowed, promptly seek medical assistance.
- Battery may leak chemicals if unused for a long time. Remove the battery if you are not going to use the device for an extended period.
- Properly dispose of the used battery according to your local environmental regulations.

Caring for Your Device

- To clean the exterior of the device, wipe it with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft dry cloth. Do NOT rinse with water.
- Do NOT use organic solvents to clean the device.

Device Storage

- Storage condition: -20°C to 60°C (-4°F to 140°F), below 95% relative humidity.
- Always store or transport the device in its original storage case.
- Avoid dropping and heavy impact.
- Avoid direct sunlight and high humidity.

Meter Disposal

The used meter should be treated as contaminated and may carry a risk of infection during measurement. The batteries in this used meter should be removed and the meter should be disposed in accordance with local regulations.

The meter falls outside the scope of the European Directive 2002/96/ EC-Directive on waste electrical and electronic equipment (WEEE).

Caring for Your Test Strips

- Storage condition: 2°C to 30°C (35.6°F to 86°F), below 85% relative humidity. Do **NOT** freeze.
- Store your test strips in their original vial only. Do not transfer to another container.
- Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately close the vial cap tightly.
- Touch the test strip with clean and dry hands.
- Use each test strip immediately after removing it from the vial.
- Do not use test strips beyond the expiry date. This may cause inaccurate results.
- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for assistance.

For further information, please refer to the test strip package insert.

Important Control Solution Information

- Use only 4SURE control solutions with your device.
- Do not use the control solution beyond the expiry date or 3 months after first opening. Write the opening date on the control solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test be done at room temperature 20°C to 25°C (68°F to 77°F). Make sure your control solution, device, and test strips are at this specified temperature range before testing.
- Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser tip to ensure a pure sample and an accurate result.
- Store the control solution tightly closed at temperatures between 2°C to 30°C (35.6°F to 86°F). Do **NOT** freeze.

11. Important Safety Instructions for Healthcare Professionals

- Always wear gloves when performing tests and follow your facility's infection control policy and procedures.
- Use a new pair of gloves when performing a patient test. Change gloves between patients.
- Wear protective glasses and/or other protective clothing if necessary.
- The meter should be disinfected after use on each patient. Please refer to section Taking Care of the Meter & Strips for cleaning and disinfection procedures.
- Only auto-disabling, single use lancing devices may be used with this device.
- To reduce the chance of infection, never share a lancet or the lancing device.

Please refer to the following practice guidelines for more information about the correct procedure:

Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at http://www.cdc.gov/biosafety/publications/ bmbl5/

"Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition" Clinical and Laboratory Standards Institute (CLSI) M29-A3.

Control Solution Test

- Control solution tests shall be performed regularly, between specific time intervals, or after a certain number of patients have been tested.
- The quality control procedure of the meter can be customized to meet the requirements of each facility.
- Tests of Level 1, Level 2, and Level 3 control solutions may vary depend on the facility's policy.
- Perform quality control testing each time you begin to use a new lot or a new vial of test strips, and perform the quality control testing once per day. A minimum of 2 levels of control solution tests are required.

Taking Care Of The Meter & Strip

WARNING: Potential Biohazard!

Healthcare professionals using this system on multiple patients should follow the infection control procedure approved by their facility. All products or objects which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral diseases.

To avoid the meter and test strips attracting dirt, dust or other contaminants, please wash hands thoroughly with soap and water before and after use.

When to clean and disinfect the meter:

All surface of meter if visibly soiled must be physically cleaned to remove gross soil. Disinfect the meter between each patient to prevent infection.

How to clean and disinfect the meter:

The meter must be cleaned prior to the disinfection. Use one disinfecting wipe to clean exposed surfaces of the meter thoroughly and remove any visible dirt, blood, or any other body fluid with the wipe. Use a second wipe to disinfect the meter by following the disinfecting procedure below. Do **NOT** use organic solvents to clean the meter.

Disinfecting Procedures:

1. Put on non-sterile gloves.
2. Take out one disinfecting wipe from the package and squeeze out any excess liquid in order to prevent damage to the meter.
3. Wipe all meter's exterior surface display and buttons.
   Hold the meter with the test strip slot pointing down and wipe the area around the test slot but be careful not to allow excess liquid to get inside. Use two or more wipes if necessary.
4. Remove the wipe. Allow the meter surface to dry completely.
5. Discard the used wipes and never reuse them.
6. Remove and discard gloves in appropriate receptacles and wash hands.
   Improper system cleaning and disinfection may result in meter malfunction. If you have a question, please contact the customer service for assistance.

Note:

- Do **NOT** clean and disinfect the meter while performing tests.
- Do **NOT** allow cleaning and disinfecting solution to get in the test slot, battery compartment, or strip-ejection button.
- If you do get moisture in the test strip slot, wipe it away with a corner of tissue.
- Always dry the meter thoroughly before using it.
- Do **NOT** spray the meter directly with cleaning solutions especially those containing water (i.e. soapy water), as this could cause the solution to enter the case inside and damage the electronic components or circuitry.

12. Reference Values

Please consult your doctor to determine a target range that works best for you.

Reference Value (for blood glucose test)

The device provides you with plasma equivalent blood glucose results.

Time of day	Normal plasma glucose range for people without diabetes
Fasting and before meals	< 5.6 mmol/L
2 hours after meals	< 7.8 mmol/L

Source: American Diabetes Association (2012). Clinical Practice Recommendations. Diabetes Care, 35 (Supplement 1): S1-100.

Reference Value (for β-Ketone test)

If you do a blood β-Ketone test:

- lower than 0.6 mmol/L is a normal reading
- 0.6 to 1.5 mmol/L means you're at a slightly increased risk of DKA and should test again in a couple of hours
- 1.6 to 2.9 mmol/L means you're at an increased risk of DKA and should contact your diabetes team or GP as soon as possible
- 3 mmol/L or over means you have a very high risk of DKA and should get medical help immediately

Source: Diabetic ketoacidosis. (2017, April 24). Retrieved from https://www.nhs.uk/conditions/diabetic-ketoacidosis/

13. Symbol Information

Symbol	Referent
IVD	For *in vitro* diagnostic use
	Consult instructions for use
	Use by
LOT	Batch code
SN	Serial number
	Keep away from sunlight
	Keep Dry
	Disposal of waste equipment
1.5V ⎓	1.5 Volts DC
	Battery

Symbol	Referent
	Do not reuse
	Storage/ Transportation temperature limitation
CE 0123	CE Mark
	Manufacturer
	Dispose of the packaging properly after use
	Caution, consult accompanying documents
STERILE R	Sterilized using irradiation
	Do not use if package is damaged
	Storage/ Transportation humidity limitation

Icon Explanations

5 Second reaction time for blood glucose testing.

1000 Test Memory

Meter calculates and displays past 7,14,30,60,90 day average results

Bluetooth connectivity for data sharing/transfer

Device meets and exceeds current ISO standard EN ISO 15197:2015

Meal tagging; Pre meal = AC (Ante Cibum) Post meal = PC (Post Cibum)

Suitable for people with Gestational diabetes

Small sample size of just 0.5 µL for blood glucose testing

Test strip port light for easier test strip insertion

Test strips can be used from first opening the vial until expiration date on the vial

Automatically detects Control Solution

Backlit display making results easier to read

Wide Haematocrit range of 0-70% for blood glucose testing

Beta Ketone testing

USB connectivity for data sharing/transfer

Suitable for drivers - Meets DVLA guidelines

Test strip eject button

14. Troubleshooting

If you follow the recommended steps but the problem persists, or error messages other than the ones below appear, please call your local customer service.

Do not attempt to repair the device yourself and never try to disassemble the device under any circumstances.

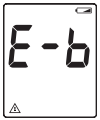
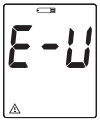
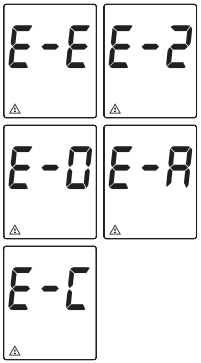
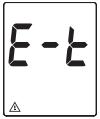
Result Readings (for blood glucose test)

Message	What it Means
	< 0.5 mmol/L
	> 33.3 mmol/L

Result Reading (for β-Ketone test)

Message	What it Means
	< 0.1 mmol/L
	> 8.0 mmol/L

Error Message

Error Message	Cause	What To Do
	The batteries cannot provide enough power for a test.	Replace the battery immediately and reset date and time on the meter setting.
	Strip has been used.	Repeat the test with a new strip.
	Problem in operation.	Review the instructions and repeat the test with a new strip. If problem persists, contact the local customer service for assistance.
	You may have removed the strip after applying blood, or insufficient blood volume.	Review the instructions and repeat test with a new test strip.
	Ambient temperature is below the system's operation range. Ambient temperature is above the system's operation range.	System operational range is 8°C to 45°C (46.4°F to 113°F). Repeat the test after the device and test strip have reached the above temperature.

Blood Glucose Measurement

Problem	Cause	What To Do
The device does not display a message after inserting a test strip.	Batteries exhausted.	Replace the battery immediately and reset date and time on the meter setting.
	Test strip inserted upside down or incompletely.	Insert the test strip with contact bars end first and facing up.
	Defective device or test strips.	Please contact customer service.
The test does not start after applying the sample.	Insufficient blood sample.	Repeat the test using a new test strip with larger volume of blood sample.
	Sample applied after the device is automatically turned off.	Repeat the test with a new test strip. Apply sample only when flashing "💧" appears on the display.
	Defective device.	Please contact customer service.
The control solution testing result is out of range.	Error in performing the test.	Read instructions thoroughly and repeat the test again.
	Control solution vial was poorly shaken.	Shake the control solution vigorously and repeat the test again.
	Expired or contaminated control solution.	Check the expiration date of the control solution.
	Control solution that is too warm or too cold.	Control solution, device, and test strips should be at room temperature (20°C to 25°C / 68°F to 77°F) before testing.
	Defective test strip.	Repeat the test with a new test strip.
	Device malfunction.	Please contact customer service.

15. Specifications

Memory	1000 measurement results with respective date and time
Dimensions	89.8 (L) x 54.9 (W) x 18 (H) mm
Power Source	One 1.5 V AAA alkaline battery
Weight	46.1 g (without battery)
External output	Bluetooth V4.0 or Micro USB
Features	Auto electrode insertion detection Auto sample loading detection Auto reaction time count-down Auto switch-off after 2 minutes without action Temperature warning
Operating Condition	8°C to 45°C (46.4°F to 113°F), below 85% R.H. (non-condensing)
Storage/ Transportation Condition	***Meter:*** -20°C to 60°C (-4°F to 140°F), below 95% R.H
	Test Strip: 2°C to 30°C (35.6°F to 86°F), below 85% R.H
Measurement Units	Fixed mmol/L
Measurement Range	0.5-33.3 mmol/L for glucose test and 0.1~8.0 mmol/L for β-Ketone test
Hematocrit range	0~70% for glucose testing and 10~70% for β-Ketone test
Test Sample	For blood glucose testing - whole blood samples from capillary, arterial, venous and neonatal heel. For β-Ketone testing - whole blood sample from capillary and venous.
Test Result	Glucose measurements are reported as plasma equivalents

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, EN 61326-, IEC/EN 61326-2-6, EN 301 489-17, EN 300 328.

16. Limited Lifetime Warranty Terms and Conditions

With respect to disposable products, Nipro Diagnostics (UK) Ltd warrants to the original purchaser that, at time of delivery, each standard product supplied by Nipro Diagnostics (UK) Ltd shall be free from defects in material and workmanship and, when used for the purposes and indications described on the labeling, is fit for the purposes and indications described on the labeling. All warranties for a product shall expire as of the product expiration date, or if none, be for a lifetime, as long as it has not been modified, altered, or misused. Nipro Diagnostics (UK) Ltd warranty hereunder shall not apply if:

(i) a product is not used in accordance with its instructions or if it is used for a purpose not indicated on the labeling; (ii) any repairs, alterations or other work has been performed by the buyer or others on such item, other than work performed with Nipro Diagnostics (UK) Ltd authorisation and according to its approved procedures; or (iii) the alleged defect is a result of abuse, misuse, improper maintenance, accident or the negligence of any party other than Nipro Diagnostics (UK) Ltd. The warranty set forth herein is conditioned upon proper storage, installation, use and maintenance in accordance with applicable written recommendations from Nipro Diagnostics (UK) Ltd.

The warranty furnished hereunder does not extend to damaged items purchased hereunder resulting in whole or in part from the use of components, accessories, parts or supplies not supplied by Nipro Diagnostics (UK) Ltd.

Your Nipro Diagnostics (UK) Ltd Customer Service representative will be able to help to provide detailed information regarding procedures for returning products if necessary.

NIPRO

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CH-9000 St. Gallen, Switzerland

For self-testing and point-of-care-testing
of whole blood glucose and ß-Ketone
Model No.: GD87

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