

Auto-coding
Element™

Blood Glucose Monitoring System

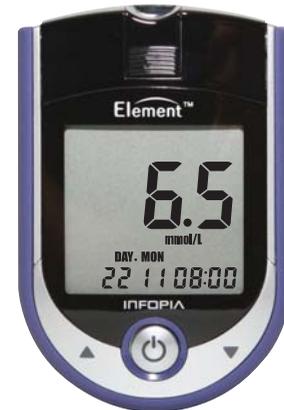


Diabetes Management Technology



infopia Co., Ltd.

Auto-coding
ElementTM
Blood Glucose Monitoring System



Diabetes Management Technology

Dear Element™ Blood Glucose Monitoring System Owner

Thank you for choosing the Element™ Auto-coding Blood Glucose Monitoring System. This booklet has important information you must know about the Element™ Auto-coding Blood Glucose Monitoring System. Please read it carefully.

We understand that self-testing of blood glucose level provides a way to control your diabetes and may give you peace of mind by testing regularly. As a result Element™ Auto-coding was developed to provide you with a fast and accurate reading with a convenient and simple process. Our goal at Element™ Auto-coding is to provide the best quality healthcare products coupled with superior customer service.

Always consult with your healthcare professional before making any changes to your diabetes management. The Element™ Auto-coding Blood Glucose Monitoring System is for in vitro diagnostic use only.

Important information

The Element™ Auto-coding Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use only). It should be used only for testing blood glucose and only with fresh capillary whole blood samples. It should not be used for the diagnosis of diabetes.

Consult your physician or diabetic healthcare professional about daily management of your diabetes and proper use of the glucometer.

Please pay close attention when handling blood. Improper procedures may cause serious hazards to your health.

The Element™ Auto-coding Blood Glucose Monitoring System contains small parts. Please keep your monitoring system out of reach of children.

Test Principle

The enzyme glucose oxidase on the blood glucose test strip reads specifically with the blood glucose. The current generated is converted and displayed as blood glucose value.

The Element™ Auto-coding Blood Glucose Monitoring System is plasma-calibrated to allow easy comparison of results with laboratory methods. Blood glucose test meter which is calibrated against a whole blood method may have different results in comparison to Element™ Auto-coding. The laboratory system used for calibration of the Element™ Auto-coding Blood Glucose Monitoring System is YSI 2300 STAT plus which is equipped with a glucose oxidase system.

Note

< Maintaining the Element™ Auto-coding blood glucose test meter >

1. Do not assemble or disassemble the blood glucose test meter.
2. It will have to keep in the place where the water does not reach.
3. Avoid getting dirt and moisture.
4. It does not have to keep in storage place of the chemical chemicals or the place where gas etc occurs.
5. Keep out of direct sunlight.

1. Learning the System	
Intended use of Element™ Auto-coding Blood Glucose Test Meter	7
Element™ Auto-coding Blood Glucose Monitoring System Kit Contents	8
Element™ Auto-coding Blood Glucose Test Meter	9
Element™ Auto-coding Blood Glucose Test Meter Display	10
Element™ Auto-coding Blood Glucose Test Strip Information	11-12
2. Before Testing	
Setting your blood glucose test meter	13-14
Auto-Coding Function	15
Performing a Glucose control solution test	16-17
3. Testing Your Blood Glucose	
Testing Your Blood-Preparation	18
Collecting a Drop of Blood	19-21
Testing Procedure	22-24
Testing Your Blood - Case of Setting user Option	25
Test Strip Ejector Function	26
4. Reviewing Your Results	27
5. Alternate Site Testing	28
6. Performing a Blood Test using and Alternate Site	29-30
7. Element™ Auto-coding Blood Glucose Test Meter Software	31
8. Taking Care of Your Blood Glucose Test Meter	
Cleaning Your Blood Glucose Test Meter and Maintenance	32
Replacing the Batteries	33
Dispose of meter and batteries	33
9. Troubleshooting	34-37
10. Specifications	38
11. Conversion table mmol/L ↔ mg/dL	39
12. Symbol reference	40
13. Warranty	41

The Element™ Auto-coding Blood Glucose Monitoring System is intended for in vitro diagnostic use only. Element™ Auto-coding Blood Glucose Monitoring System is for self-testing.

It should not be used for the diagnosis of diabetes or for the testing of newborns. The Element™ Auto-coding was designed to test a blood glucose (sugar) level and can be used with a capillary whole blood sample.

Do not use the Element™ Auto-coding Blood Glucose Monitoring System for any other than for blood glucose testing.

CAUTION

Before using any product, please read all instructions. Consult your physician or diabetic healthcare professional about daily management of your diabetes and proper use of the glucometer. If you have any questions about the Element™ Auto-coding product, please contact Neon Diagnostics Ltd. Freephone patient helpline 0800 009 3378.

Element™ Blood Glucose Monitoring System KIT Contents



1. Element™ Auto-coding Blood Glucose Test Meter
2. Element™ Auto-coding Blood Glucose Test Strips
3. Lancing Device
4. Lancets
5. Operation Manual
6. Warranty Registration Card
7. Patient Logbook
8. Carrying Case
9. Two 3V Li-CR2032 Batteries
10. Control Solution (Normal)

Your Element™ Auto-coding Blood Glucose Monitoring System has been assembled and shown above. Please return the system to place of purchase or contact your nearest Element™ Auto-coding representative if the container seals are broken or parts are missing.

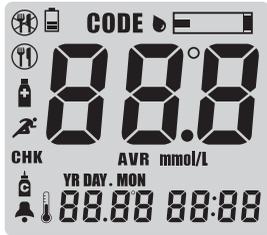
Element™ Blood Glucose Test Meter



CAUTION

1. Do not use Element™ Auto-coding blood glucose test meter in a dry environment, especially if synthetic materials are present. Synthetic clothes, carpets, etc., may cause damaging static discharges in a dry environment.
2. Do not use Element™ Auto-coding blood glucose test meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters, or other electronic or electrical equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the blood glucose test meter.

Element™ Blood Glucose Test Meter Display



Low Battery Warning Symbol

CODE

Strip Code Symbol



Blood drop symbol for test



Alarm Symbol



Before Having a Meal



After Having a Meal



After Sports Activity



After Taking Medication



Temperature / Date



Time / Test Result Amount

mmol/L

Test Result Unit Symbol



Control Solution Symbol

AVR

Average Test Result System

CHK

Troubleshooting Symbol

Element™ Blood Glucose Test Strip Information

Storage and Handling Caution

1. Keep out of direct sunlight.
2. Store the Element™ Auto-coding Blood Glucose Test Strip vials in a cool, dry place between 2-30° (36-86°). Do not freeze.
3. Make a notation of the discard date on the vial label when you first open it. Discard remaining Element™ Auto-coding blood glucose test strips 6 months after first opening the vial.
4. Close the vial cap tightly immediately after removing a Element™ Auto-coding blood glucose test strip.
5. Do not use test strips after the expiration date printed on the package or vial since it may cause inaccurate results.
6. Avoid getting dirt, food or water on the blood glucose test strip. Do not bend, cut, or alter the Element™ Auto-coding blood glucose test strip.
7. Element™ Auto-coding blood glucose test strips are for single use only.
8. Keep the blood glucose test strip vial away from children.
9. Please refer to the user's manual for Element™ Auto-coding blood glucose test strip for additional information.
10. Discard the used blood glucose test strip carefully to prevent any infection.

Use only Element™ Auto-coding brand blood glucose test strip with your Element™ Auto-coding blood glucose test meter.



Element™ Blood Glucose Test Strip Information

Limitations of System :

Element™ Auto-coding blood glucose test strips provide accurate results when the following constraints are observed:

- Use only the Element™ Auto-coding blood glucose test strips with the Element™ Auto-coding blood glucose test meter.
- Use fresh capillary whole blood only. Do not use plasma or serum.
- Do not use neonate samples.
- The blood glucose test strips are for single use only. Do not reuse.
- Dehydration may lower test results. If you are severely dehydrated, contact your physician immediately
- Inaccurate results may occur when in shock, hypotensive individuals, hyperglycemic, or hyperosmolar state, with or without ketosis.
- Element™ Auto-coding blood glucose test strips may be used at altitude up to 10,000 feet without an effect on test results.

Physicians - Please note the following interferences that may affect test results :

- Element™ test strip results can be used with hematocrit levels in the range of 20% to 60%. If the hematocrit range is out of the range(20~60%), then the test results may be lower or higher than actual value.
- Interferences: Acetaminophen, uric acid, ascorbic acid(vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
- Lipemic samples; Cholesterol up to 500 mg/dL or triglyceride up to 3000 mg/dL do not significantly affect the results. Glucose values, however, in specimens beyond these levels should be interpreted with caution.
- Blood samples that contain a high concentration of dissolved oxygen may lower the test result.

Performance Characteristics :

The performance of Element™ Auto-coding blood glucose test strips has been evaluated in laboratory and in clinical tests (Please refer to strip manual for more details).

Measurement Range: The measurement range of the Blood Glucose Monitoring System is 0.6 to 33.3 mmol/L.

Setting Your Blood Glucose Test Meter

The Element™ Auto-coding Blood Glucose Test Meter has a variety of excellent functional modes; beep sound to alert when function is set, date, time, five daily alarms, ability to designate activities related to the test result, and the ability to designate three unique data averages.



Power On

Press  for 3 seconds at least.



User Activity Option

After pressing and releasing either  or  buttons to turn the user Activity option on/off, confirm with .



Year

After pressing and releasing either  or  buttons to set the year (from 2007 to 2099), confirm with .



Date / Time

After pressing and releasing either  or  buttons to set the date and time, confirm each with .

Temperature unit

Press and release either  or  buttons to set °F or °C. Enter .

Setting Your Blood Glucose Test Meter



Number of days for average

After pressing and releasing either ▲ or ▼ buttons to set the number of days for average calculation (3 different possible), confirm with ⏻.

Alarm on/off

After pressing and releasing either ▲ or ▼ buttons to turn the alarm on/off, confirm with ⏻.



Alarm time

After pressing and releasing either ▲ or ▼ buttons to set the alarm hour and minute, confirm with ⏻.

Alarm

After programming the number of desired alarms (5 alarms possible), confirm with ⏻.

CAUTION

1. ****VERY IMPORTANT:** Correct test unit.
Your Element™ Auto-coding blood glucose test meter is pre-set to mmol/L as test unit.
See also conversion table on page 39.
2. Without setting the date properly, the average glucose level and the results in memory will not show proper values. It is recommended to set the meter before use and when new batteries are installed.
3. You can't test your blood glucose while in the setting mode.
4. To turn the meter off during setup, press ⏻ for at least 3 seconds

Auto-Coding Function



1. Element™ Auto-coding has automatic code recognition function.



2. It recognizes automatically the code number. This is a very convenient function preventing the inconvenience of setting the code number on the blood glucose test meter every time.

CAUTION

1. Do not bend the blood glucose test strip to prevent the Automatic code recognition failure.
2. If the code recognition label is damaged, the code recognition may fail. Please check the code number on the LCD display window with the code number on the blood glucose test strip vial.

Performing a Glucose Control Solution Test

The glucose control solution should be used when there is suspicion that the blood glucose test meter or the blood glucose test strips are not working properly. For example: if strips have been exposed to extreme conditions or if you drop the blood glucose test meter.

Check the expiration date before performing a glucose control solution test. Do not use if expired. Once opened, solution expires after 3 months.

The Glucose control solution should be used

- Whenever you suspect the blood glucose test meter or blood glucose test strip is not functioning properly.
- If your blood glucose test results are not consistent with your symptoms or if you think they are not accurate.
- If you have dropped the blood glucose test meter.
- For quality control in the point of care usage.
- For teaching or learning the system.

1. Shake the glucose control solution before use.
2. Discard the 1st drop of glucose control solution, this will eliminate any residue.
3. Place a drop of glucose control solution on a clean dry surface (ex. The lid of the blood glucose test strip vial).

4. Insert a blood glucose test strip into the port and press the up arrow. A glucose control solution vial will appear on the bottom left hand side of the screen, above the date and time.



This will allow you to differentiate between a glucose control solution test and an actual blood test for future reference.

5. Dip the blood glucose test strip into the glucose control solution.
6. Results appear in 3 seconds.
7. Compare the result to the range printed on the blood glucose test strip vial, the results should fall within that range.
8. If your glucose control solution falls out of range, do not perform a glucose test, please contact your local representative.

Performing a Glucose Control Solution Test

Note: - Element™ glucose control solution is sold separately.
- It is recommended that glucose control solution is stored at room temperature 20~25℃ (68~77°F) before testing.

For example
If you use a normal glucose control solution, you must use the normal range printed on the side of the blood glucose test strip vial.



- Results that fall outside the expected range may indicate:
- Test not performed at room temperature.
- An error in the way you are doing the test.
- Expired or contaminated glucose control solution.
- A problem with the blood glucose test meter.
- Glucose control solution that is too warm or cold.
- Failure to discard the first drop of glucose control solution and to wipe the bottle tip clean.
- Failure to shake the glucose control solution adequately.

CAUTION

- If your glucose control solution falls out of range, do not perform a glucose test, please contact your local representative.
- The Glucose Control Solution range is not the recommended range for your blood glucose level.

Testing Your Blood - Preparation

Before testing, be sure to read this section and blood glucose test strip package insert found in the blood glucose test strip box carefully. Make sure you have all the necessary items to begin testing:



- Element™ Auto-coding blood glucose test meter
- Element™ Auto-coding blood glucose test strip
- Lancing Device
- Sterile Lancets

CAUTION

To reduce the chance of infection.

- The Lancing Device and sterile lancets should NOT be shared with others.
- Always use a new, sterile lancet and new blood glucose test strip.
- Lancets are for single use only. DO not reuse.
- Avoid getting hand lotion, oils, dirt, or debris in or on the Lancets and the Lancing Device.
- Dry your hands completely before testing.

Practice using the lancing device and become accustomed with its use. Wash your hands with warm, clean water and soap. Dry your hands completely before testing.

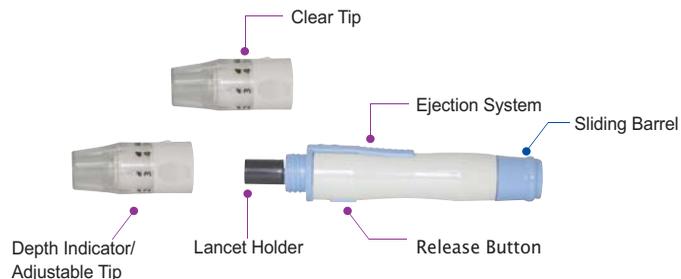
Collecting a Drop of Blood

The lancing device is a convenient medical tool for collecting capillary blood samples for glucose monitoring or other tests which require one or two drops of blood. As a more advanced lancing device, it provides ultimate safety and comfort for obtaining blood samples. An adjustable tip offers 5 levels of skin penetration for individual user's comfort and a lancet ejector enables the safe disposal of the used lancet.

PRECAUTIONS

- Never use a lancet that has been used by someone else. This could lead to contamination.
- If the lancing device is to be used by another person, the unit must be properly disinfected and a new tip and lancet must be used.
- Do not leave the lancet in the device after use.
- A new lancet must only be placed into the lancing device directly before testing.
- This device has many small parts and could be a choking hazard for children if swallowed.
- In the case of hospital use, hospitals need to consult their own infection control protocols in order to avoid any contamination.
- Always dispose of the used lancet in a biohazard garbage container.

COMPONENTS



Collecting a Drop of Blood



1. Unscrew the tip of the lancet device by turning it counter-clockwise while holding the base firmly.



2. With two fingers, pull out the lancet carrier and hold it in place.



3. While holding the lancet carrier, insert a new sterile lancet into the bottom of lancet carrier.



4. Twist the cap of the lancet off.



5. Put the tip of the lancet device back on and turn it clockwise.



6. Hold the tip firmly in one hand then pull out the sliding barrel with the other hand. This will cock the lancet device.



7. Place the lancet device in place. Hold it firmly against the side of the finger, with the cap resting on the finger. (The harder it is pressed the deeper the puncture.) Press the release button to take a sample.



8. Unscrew the tip of the lancet device by turning it counter-clockwise.



9. Push the lancet ejector forward with the thumb and simultaneously pull out the sliding barrel to dispose of the used lancet in a proper biohazard container.

Collecting a Drop of Blood

Disposing of your lancet



1. Push the needle into the protective cover.



2. Pull the lancet out and discard accordingly.

RECOMMENDED AVAILABLE LANCETS

Some general sterilized lancets are BD-Ultra Fine, Cleanlet Fine, E-Z Ject, G-P Lite, Microlet, Monolet, One Touch, Soft Touch, Therasense, Ultra TLC and Unilet GP.

Note: Some less known lancets may not work properly with the due to their dimensions. Please, contact your supplier to make sure you are using proper lancets.

USING THE CLEAR TIP (AST)

1. Place the lancet device on the skin in the chosen area, press and hold it continuously for a few seconds. Then, push the release button to take a sample.
2. Watch through the clear tip until a sufficient blood sample is taken. If there is not enough blood, gently massage the area until a sufficient sample has been collected.

STORAGE

Products must be stored at room temperature protected from sunlight or moisture.

CLEANING AND DISINFECTION

Clean and wipe the outside of the lancet device a minimum of once a week with a soft cloth, dampened with mild soap and water. Wash the adjustable tip and the clear tip once a week with mild soap. DO NOT immerse the lancet device in liquid.

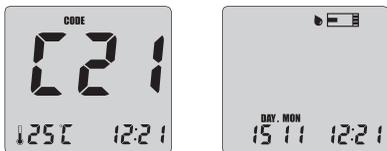
WARRANTY

Lancet device has a 2-year warranty from the date of purchase. A malfunctioning device should be returned to the following address:

GMMC
Room No. 1112, Ace Tower 9th Bldg., 345-30, Kasan-Dong, Kumchon-Ku, Seoul, South Korea
Tel : +82 2 2104 0470
Fax : +82 2 2104 0472

ECIREP GMMC, S.L.
C/Jordi de S. Jordi 13, 6-23 46022 Valencia SPAIN
Tel : +34 963 691 484
Fax : +34 961 125 949

Testing Procedure



Step 1

- Firmly insert the blood glucose test strip into the blood glucose test meter port with the “infopia” facing towards you.
- The blood glucose test meter automatically turns on displaying the code, ambient temperature and the date and time.
- The Element™ Auto-coding will automatically recognize the blood glucose test strip code number.
- A blinking blood glucose test strip will appear at the top of the screen indicating the blood glucose test meter is ready for testing.

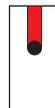
Note : Inserting the test strip in the wrong direction will turn the meter on, but you will be unable to test.

CAUTION

1. If the code is not displayed after for a while, pull the blood glucose test strip out of the port, and re-start the procedure from the beginning.
2. If the code on the LCD display window and on the test vial does not match, try another new blood glucose test strip. If the mismatch persists, please contact your local representative for help.
3. If the meter does not power on, pull the blood glucose test strip out of the port, and re-insert the blood glucose test strip.
4. Avoid testing under direct sunlight, for a more accurate test result.
5. If you apply your blood sample too early, ERROR5 message will appear on LCD (refer to p34).

Testing Procedure

● Correct

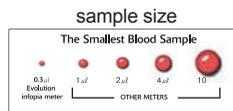


Completely Filled

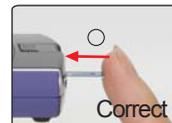
● Incorrect



Poorly filled



● Applying Blood



• **Element™ Auto-coding** blood glucose test meter only requires 0.3µl sample volume.

• Apply your blood to the glucose test strip and do not take off your finger until you get the beep sound.

The test will automatically start.

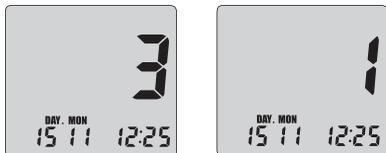
Step 2

- Place the top edge of the blood glucose test strip to the area you prepared for testing.
- The blood will automatically be “drawn” into the blood glucose test strip channel.
- When the chamber has enough blood, your blood glucose test meter will automatically count down.

CAUTION

1. If the countdown does not start, do not add more blood to the blood glucose test strip! Discard the blood glucose test strip and restart testing.
2. If you do not conduct the test within 3 minutes, the blood glucose test meter will automatically power off to save battery life. In this case you need to start the test procedure again from the beginning.
3. You may get an inaccurate result if the blood sample is not completely filled in a single action.

Testing Procedure



Step 3

- After beeping sound, the test will begin automatically and your results will appear in 3 seconds. It should begin counting down from 3 to 1 second on the LCD window. The LCD window will display the result of your blood glucose level, including temperature and time.
- Record the result value in your Element™ Auto-coding logbook. When you pull out the blood glucose test strip, the meter turns off automatically.

CAUTION

1. If the test result is out of the test range, the Hi/Lo message will be shown on the LCD window. (refer to p35)
2. Safely discard used blood glucose test strips and lancets.

Testing Your Blood - Case of Setting User Option



Step 4

- If you selected to use the User Activity option during set up, press ▲ and ▼ button to select the activity that correlates with your result (refer to p10), then press ⏻.
- If you did not select to use user activity option during set up, press ⏻ to continue to step 4-2.

CAUTION

1. If you did not activate the User Activity option, Step4 procedure is not conducted.
2. Please refer to page 13, if you want to set the User Activity option.

Test Strip Ejector Function



Press and Push forward



Eject your blood glucose test strip

1. Once the test is completed, slide the ejector button forward to remove the blood glucose test strip from the blood glucose test meter.
2. Discard the used blood glucose test strip and lancet accordingly.

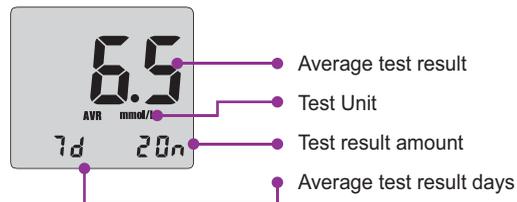
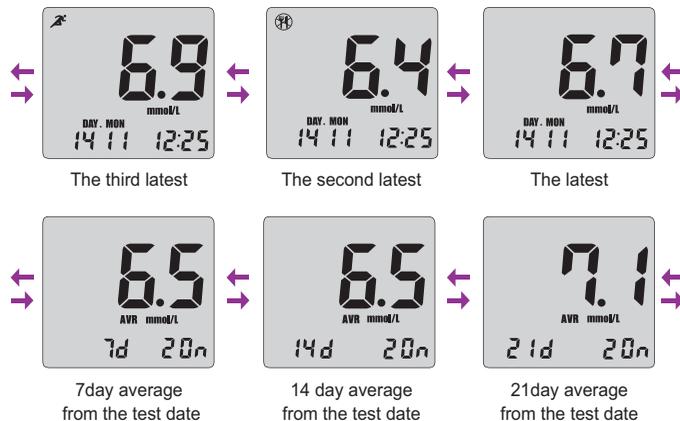
CAUTION

1. If you push the ejector button forward too much, it may cause the failure of the part.
2. Do not give strong impact to blood glucose test meter.

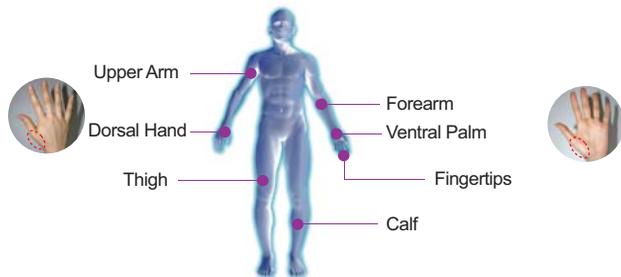
Reviewing Your Result

The Element™ Auto-coding blood glucose test meter stores up to 500 test results in its built-in memory, along with the average sugar level for the number of days which you had preset the blood glucose test meter to calculate. These values can be retrieved on the LCD display at any time.

- Press and release button.
- Check your previous result by pressing the arrow button.
- Check your average data by pressing the arrow button.



Alternate Site Testing



Important Information About Using Alternative Sites Testing :

- Alternate sites where you can test are dorsal hand, ventral palm, upper arm, forearm, calf, and thigh.
- Under certain conditions, blood glucose test results obtained using samples taken from your alternate sites may differ significantly from fingertip samples
- The conditions in which these differences are more likely to occur are when your blood glucose is changing rapidly such as following a meal, as insulin dose, or associated with physical exercise.
- When blood glucose is changing rapidly, fingertip samples show these changes more quickly than alternate sites samples.
- When your blood glucose is falling, testing with a fingertip sample may identify a hypoglycemic (low blood glucose) level sooner than a test with an alternate sites sample.
- Use alternate sites samples only for testing prior to or more than two hours after meal, insulin doses, or physical exercise.
- Testing performed within two hours after meals, insulin doses, or physical exercise or whenever you feel that your glucose levels may be changing rapidly should be done from the fingertip.
- You should also use fingertip testing whenever you have a concern about hypoglycemia (insulin reactions) such as when driving a car, particularly if you suffer from hypoglycemic unawareness (lack of symptom to indicate as insulin reaction), as forearm testing may fail to detect hypoglycemia.

Important :

We recommend that you test on your fingertips if you are testing for hypoglycemia (low blood glucose) or if you are suffering from hypoglycemia unawareness.

Performing a Blood Test Using and Alternate Site



To ensure accurate results when lancing your forearm, upper arm, hand, thigh, or calf, wash the test site with soap and water.

Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

CAUTION

- To ensure accurate results when lancing your arm (Upper arm or forearm), leg (calf or thigh) or palm (ventral palm or dorsal hand), wash your hand and test site with soap and water.
- To receive accurate test results, at least 0.3 μ l minimum sample volume is required.

Performing a Blood Test Using and Alternate Site

To bring fresh blood to the surface of the test site, rub the test site vigorously for a few seconds until you feel it getting warm.



Lance the test site with the lancing device:

1. Hold the clear cap down against the top of your test site. Press the release button. Do not lift up.

2. Continue to hold the lancing device and gradually increase pressure for several seconds.

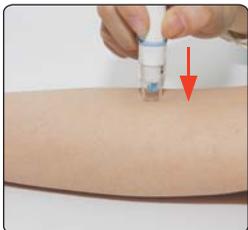
3. While holding the lancing device on your test site, look through the clear cap; until a drop of blood appears approximate ● size

4. Lift the lancing device straight up; be careful not to smear the blood on your testing site.

5. Place the edge of the blood glucose test strip to the drop of blood.

6. The blood will automatically draw into the channel of the blood glucose test strip.

You may get an inaccurate result if the blood sample is not completely filled in a single action.



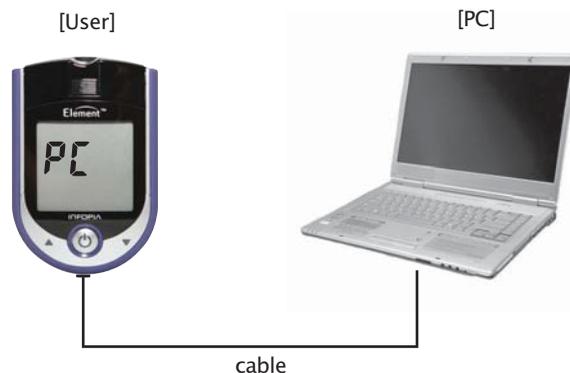
Element™ Blood Glucose Test Meter Software

You can transfer test results from the Element™ Auto-coding blood glucose test meter to a computer.

You can download the software from our web site.

(<http://www.infopia21.com>)

You can purchase the computer communication cable separately from a local representative.



Cleaning Your Meter and Maintenance

Meter

Your meter does not require special maintenance or cleaning. Avoid getting dirt, dust, blood, glucose control solution, or liquids on the blood glucose test meter, the test port, or data port. Your blood glucose test meter operation temperature is 10°C~40°C (50°F~104°F).

It is recommended that you store the meter in its carrying case after each use. A cloth dampened with water and mild detergent can be used to wipe down the outside of the blood glucose test meter. Your Element™ Auto-coding blood glucose test meter is a precision instrument. Please handle it with care.

Lancet Device:

Clean the lancing device and caps with soap and tepid water. To disinfect the lancing device, prepare a disinfectant solution of one part household bleach to 10 parts water. Dampen a cloth with this solution and wipe the lancing device thoroughly. Soak only the cap for at least 30 minutes in the disinfectant solution. Do not soak the lancing device in liquid. Rinse the lancing device and cap with water and dry thoroughly.

- For detailed instructions concerning Element™ Auto-coding blood glucose test strips, refer to the test strip package insert found in the blood glucose test strip box.
- Please store the Element™ Auto-coding blood glucose monitoring system in a cool, dry area, out of reach of children. Do not freeze. For a more accurate test result avoid testing under direct sunlight.
- Do not soak the blood glucose test meter or blood glucose test strips in water or liquid.
- Do not subject the blood glucose test meter or blood glucose test strips to excessive heat.
- Use your blood glucose test meter according to the instructions in the manual.
- If you need to purchase the lancing device, lancets or blood glucose test strips, contact your local representative.
- Discard the used Lancets carefully, to prevent any infection.

Replacing the Batteries

The low battery icon will appear in the upper left corner of the LCD screen to alert you when the battery power is running low, indicating a new battery is needed.



Your Element™ Auto-coding blood glucose test meter uses only two 3V Lithium batteries (CR2032), which are included. When replacing the batteries, only CR2032 or equivalent lithium battery should be used.

After changing the batteries, please be sure to recheck your meter settings.

<Follow-up Action>

1. Check your meter with the glucose control solution (p16-17)
2. Perform your test again (p22 - 24)
3. If you are experiencing symptoms that are not consistent with your blood glucose test results, call your healthcare professional.

Dispose of meter and batteries

Dispose of meter:

The meter must be disposed of according to the local regulations concerning the disposal of electrical and electronic equipment.

The Waste Electrical and Electronic Equipment(WEEE) regulation implement provisions of the European Parliament and Council Directive 2012/19/EU aimed to reducing the amount of EEE waste going for final disposal.

The manufacturer, has specific instructions for the recovery of the meter.

Please contact your distributor.

Dispose of batteries :

Please recycle or dispose of used batteries using your local battery collection systems and in compliance with your local environmental laws and regulations.

Batteries contain chemicals that, if released, may affect the environment and human health. The crossed-out wheeled-bin symbol indicates the need for the separate collection for batteries.

CAUTION

Remove both batteries from the battery compartment and dispose of them according your institution's guidelines.

Troubleshooting

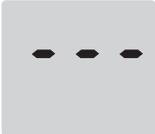
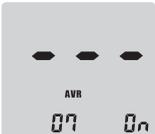
The following chart may help you identify certain problems, but may not solve all problems that can occur. Please contact your local representative if the problem persists.

Message	Problem	Action Required
	Problem with the blood glucose test meter	Place the battery again, and set the blood glucose test meter. If the problem persists, Please contact your local representative if the problem persists.
	Caused by either used or wet blood glucose test strip	Please insert a new blood glucose test strip and perform your test again
	Caused by less blood	Please insert a new glucose test strip and apply the blood sample.
	Blood glucose test strip is damaged	Please insert a new blood glucose test strip and perform your test again
	User applied the blood sample before the LCD display  was blinking	Please wait for the LCD to display icon blinking before applying your blood sample

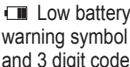
Troubleshooting

Message	Problem	Action Required
	Problem with the Auto-coding label	Please insert a new blood glucose test strip and perform your test again. If the problem persists, Please contact your local representative if the problem persists.
	The ambient temperature is too low	Place the blood glucose test meter within the operating temperature range for 10 minutes or more and retest.
	The ambient temperature is too high	Place the blood glucose test meter within the operating temperature range for 10 minutes or more and retest.
	The test result is lower than 0.5 mmol/L	Check the accuracy of your blood glucose test strip by performing a glucose control solution test. If the test results in a normal reading, re-test your blood sample two or three times. If "Lo" persists, consult your doctor immediately.
	The test result is higher than 33.3 mmol/L	Check the accuracy of your blood glucose test strip by performing a glucose control solution test. If the test results in a normal reading, re-test your blood sample two or three times. If "Hi" persists, consult your doctor immediately.

Troubleshooting

Message	Problem	Action Required
The blood glucose test meter does not power on	Battery is dead or there is a problem with the blood glucose test meter	Change the battery and if the problem persists, please contact your local representative.
Test does not start after applying blood sample	Poor blood sample	Please insert a new blood glucose test strip and perform your test again (refer to the P.23)
The result is inconsistent	There may be a problem with the blood glucose test strip	Please insert a new blood glucose test strip and perform your test again
	No readings in memory to display	
	Not enough readings in memory to display designated averages	

Troubleshooting

Message	Problem	Action Required
 Low battery symbol appears in the upper left corner of the LCD screen	Low battery	Battery needs replacing. For your free replacement batteries, please contact Neon Diagnostics Ltd. Freephone Patient Helpline: 0800 009 3378
 Low battery warning symbol and 3 digit code	Low battery	Battery needs replacing. For your free replacement batteries, please contact Neon Diagnostics Ltd. Freephone Patient Helpline: 0800 009 3378

Specifications

Sample type	Capillary whole blood
Sample volume	0.3 μ l
Test Range	0.55 ~ 33.3 mmol/L
Reading time	3 seconds
Calibration	Plasma - Equivalent
Altitude	\leq 3048m (10,000 feet)
Operating Temperature	10-40? (50-104?)
Operating Humidity	10-90%
Strip storage temperature	2-30? (36-86?)
Display Type	LCD
Dimension	76 X 56 X 18 (mm)
Weight	45g (Including Battery)
Power rating	3 V Li Battery (CR2032) X 2
Battery Life	One year after purchasing
PC communications port	Communication available

Conversion table mmol/L \longleftrightarrow mg/dL

mmol/L	0,6	1,0	1,5	2,0	2,2	2,5	2,8	3,0	
mg/dL	10	18	27	36	40	45	50	54	
mmol/L	3,3	3,9	4,0	4,4	4,7	5,0	5,5	6,0	6,1
mg/dL	60	70	72	80	85	90	100	108	110
mmol/L	6,7	7,0	7,2	7,5	7,8	8,0	8,3	8,9	
mg/dL	120	126	130	135	140	145	150	160	
mmol/L	9,0	9,4	10,0	10,5	11,0	11,1	12,0	12,5	13,9
mg/dL	162	170	180	190	196	200	216	225	250
mmol/L	14,4	15,0	16,0	16,6	17,0	18,0	19,0	20,0	
mg/dL	260	270	288	300	306	325	342	360	
mmol/L	20,8	22,2	23,0	24,0	25,0	26,4	27,7	30,0	33,3
mg/dL	375	400	414	432	450	475	500	540	600

Symbol Reference

Symbol	Description
	Consult Instructions for use
	Used By
	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices
	Caution, consult accompanying documents
	For In Vitro Diagnostic Use
	Batch code
	Catalogue Number
	Temperature limitation
	Serial number
	Date of Manufacture
	Manufacturer
	Keep away from sunlight
	For Self-testing
	Separate collection for waste electrical and electronic equipment
	Authorised representative in the European community
	Biohazard
	Waste batteries and accumulators

Warranty

Three - Year Warranty

If, at any time during the first three years after purchase, the blood glucose test meter does not work for any reason with the exception of obvious abuse, misuse, or disastrous damage, infopia Co.,Ltd. will replace your Element Auto-coding blood glucose test meter or equivalence free of charge.

The Warranty Policy of infopia Co.,Ltd. only applies to the original purchaser of the Meter and will not include the batteries supplied with the blood glucose test meter set.

Please fill in the warranty card attached to the set.
Mail or fax it back to us.

The Element™ Auto-coding blood glucose test meter has a full three-year warranty from the original date of your purchase. For your convenience, please include your date and place of purchase.

