

Instructions for Use







Dear Element®NEO Blood Glucose Monitoring System Owner,

Thank you for choosing the Element®NEO Blood Glucose Monitoring System. This manual contains everything you need to know about your new glucometer and how it works. Please take a moment to read the instructions 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®NEO has been developed to provide you with a fast and accurate reading in a convenient and simple process. Our goal for the Element®NEO Blood Glucose Monitoring System is to provide you with 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®NEO Blood Glucose Monitoring System is for in-vitro diagnostic use only.

Customer Service is available 24 hours a day, 7 days a week, and 365 days a year. Please call customer support center in your local area.

Important Information

The Element®NEO 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 with fresh whole blood samples(Capillary and/or venous).

It should not be used for the diagnosis of diabetes.

Consult with 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®NEO Blood Glucose Monitoring System contains small parts, which could be a choking hazard for children if swallowed.

Test Principle

Element®NEO blood glucose test strip is the bio-sensor which has been made by the FAD-dependent glucose dehydrogenase(enzyme). FAD-GDH(enzyme) quantitatively reacts with the glucose in the whole blood and the mediator. Glucose in the whole blood sample reacts with the reagent of the test strip and generates an electrical. The amount of current, which is related with glucose concentration, is measured by the meter, for which the method is called amperometry. The measured current exists in proportion to the glucose concentration in the whole blood

WARNING

- All parts of the kit are considered bio-hazardous and can potentially transmit infectious diseases, even after you have taken cleaning and disinfection measures.
- 2. Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hands lotions, oil, dirt or debris in and/or on the lancets and reusable lancing device.
- Please refer to page 34 for cleaning and disinfecting Element[®]NEO Blood Glucose Monitoring System.
- Do not change your medication based on the Element®NEO meter test results without contacting your physician or healthcare professional first.
- 6. Do not assemble or disassemble the blood glucose test meter
- 7. Keep out of direct sunlight.

CAUTION

- 1. Please keep your monitoring system out of reach of children.
- 2. Make sure it does not come in contact with water and moisture.
- Avoid getting dirt and moisture.

NOTE:

- Blood Glucose Monitoring System may also be called as Blood Glucose Test Meter, the Meter, Test Meter in this manual, for which they have equal meaning to each other.
- Blood Glucose Test Strip may also be called as the Test Strip, Strip, for which they has equal meaning to each other.

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Learning the System

Intended use of Blood Glucose test meter

The Element®NEO test meter is used with Element®NEO test strip for the measurement of glucose in fresh whole blood samples(Capillary and/or venous).

It should not be used for the diagnosis or screening of diabetes or for the testing of new born babies.

Element®NEO Blood Glucose Monitoring System is intended for use outside the body only (in-vitro diagnostic use).

Element®NEO Blood Glucose Monitoring System is for self-testing by people with diabetes and by healthcare professionals.

Recorded results make it easier for your doctor to access your metabolic control.

However, the self-testing should not take the place of overall diabetes management assessment from your doctor.

CAUTION

- Do not use system for any other purpose than blood glucose test.
- Cholesterol concentrations > 500 mg/dL or triglyceride concentrations > 3,000 mg/dL may produce elevated reading.
- Icodextrin does not interfere with this version of Element®NEO test strips.
- Do not use during or soon after xylose absorption testing. Xylose in the blood will cause interference.
- Before using any product, please read all instructions.
- Consult with 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®NEO product, please contact your local representative.

WARNING

- Before using Element®NEO system, read all instructions in this manual, and practice for accurate and safe test. You should have commentary recommendation from your diabetes care professional for the proper use of the meter and daily management of your diabetes.
- If you think your blood glucose results are too low or too high, or if the results are doubtful, please contact your doctor.
- If your blood glucose result is unusually low or high, or you do not feel the result is correct, repeat the test again with a new test strip.
- If the results are still inconsistent, please consult with your physician before making any decision in controlling your diabetes.

Element®NEO Kit Contents









- 1. Element®NEO Meter
- 2. Element®NEO Test strip
- Reusable Lancing Device
- 4 Lancets
- 5. Operation Manual

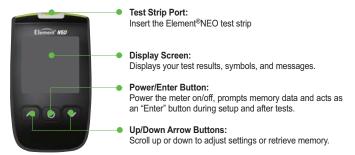
- 6. Warranty Registration Card
- 7. Carrying Case
- 8. Patient Logbook
- 9. 2EA 3V Coin Battery (CR2032)

Your Element®NEO Blood Glucose Monitoring System has been sealed to protect the contents.

If you find your seal has been broken, please return it to the place of purchase.



Element®NEO Meter





CAUTION

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

Element®NEO Meter Display





П

Low Battery Warning Symbol

Alarm Symbol

Troubleshooting Symbol

ALL Delete Results NFI

AVG Average Test Result System

Before Having a Meal

After Having a Meal

After Taking Medication

After Sport Activity

Control Solution Symbol

Blood Drop Symbol for Test

IN User ID Symbol

CODE Test Strip Code Symbol

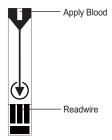
mmol/L mg/dL Test Result Unit Symbol

YR DATE 188.88 Temperature / Date

88:88 Time / Test Result Amount

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Element®NEO Test Strip



Caution

- Store the Element[®]NEO test strip vials in a cool, dry place. Keep out of direct sunlight. Do not freeze.
- Store test strips in their original vial only. Do not mix the test strips in new vials or in any other container.
- 3. Immediately replace the vial cap and close tightly after removing any test strips from the vial.
- 4. Make a note of the expiry date, which is six month from the date you first open a new vial of test strips. Throw Element®NEO test strips and vial away after the expiry date.
- Do not use the test strips after the expiration date printed on the package or vial, since it may cause inaccurate results.
- 6. Element®NEO test strips should be single use only. DO NOT RE-USE.
- 7. Do not test at temperatures below 10°C(50°F) or above 40°C(104°F).
- 8. Do not test in the condition that humidity is below 10% or above 90%.
- 9. Do not bend, cut, or alter the test strip.
- 10. Avoid getting dirt, food, and water on the test strip with wet hands.
- 11. Avoid getting dirt, food, and water on the color-coding label (backside of test strip)
- 12. Refer to additional information in the Element®NEO test strip package.
- 13. Use only Element®NEO test strip with your Element®NEO meter.

Before Testing

WARNING

To reduce the chance of infection:

- 1. Lancing device and lancets should NOT be shared with others.
- 2. Always use a new lancet and a new blood glucose test strip.
- 3. Practice using the lancing device and become accustomed with its use.
- 4. Lancets and blood glucose test strips should be single use only.
- 5. Wash your hands in warm and clean running water using soap before testing.
- 6. Avoid getting hand lotion, oils, dirt or debris on the lancets or on the lancing device.
- 7. Dry your hands completely before testing.

Setting Your Meter

The Element®NEO Meter has a wide variety of functions to choose. From the setup mode you can turn activity/meal flags, set the date/time, designate three unique averages, and set up to five daily alarms.



Power On Press (1) for 3 seconds at least.



User Activity Option After pressing and releasing either ▲ or ▼ buttons to turn the User Activity Option on/off, push 🖒 button.



User ID Option After pressing and releasing either ▲ or ▼ buttons to turn the User ID option on/off, push (1) button.



Year After pressing and releasing either ▲ or ▼ buttons to set the year. push (button.



Date / Time After pressing and releasing either ▲ or ▼ buttons to set the date and time, respectively push (1) button.



Test Unit After pressing and releasing either ▲ or ▼ buttons to set the test unit(ma/dL or mmol/L). push (1) button.



Temperature Unit After pressing and releasing either ▲ or ▼ buttons to set °C or °F and push (1) button.





Number of days for Alarm on/off average After pressing and After pressing and releasing releasing either ▲ or ▼ either ▲ or ▼ buttons to set buttons to turn the alarm the number of days for on/off, push (1) button. average calculation (3 different settings possible),



Alarm time After pressing and releasing either ▲ or ▼ buttons to set the alarm hour and minute. push (1) button.



push (1) button.

Alarm After programming the number of desired alarms (5 alarms possible), push (I) button



CAUTION

1. VERY IMPORTANT: Set the right test unit.

Your Element®NEO Meter is pre-set to mg/dL as test unit. A wrong test unit will lead to wrong test result display. Please consult your healthcare professional if you're not sure which test unit to use. 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 glucose test meter before use and also when new batteries are installed.

- 2. You cannot test your blood glucose in the setting mode.
- 3. To turn the meter off during the setup, press (b) for at least 3 seconds.



Auto-coding Function



 Element®NEO has automatic code recognition function (e.g. 17)



It recognizes the code number automatically. This is a very convenient function preventing the inconvenience of setting the code number on the glucose test meter every time. Check the code on the vial to see if the codes match each other

CAUTION

- 1. Do not bend the glucose test strip to prevent the automatic code recognition failure.
- If the code recognition label is damaged, code recognition may fail. Please check the code number on the LCD window together with the code number on the glucose test strip vial to see if code numbers match each other.

LED Function



When inserting Element®NEO glucose test strip (starting measuring process), LED light will turn on for 10 seconds.

After the test result displays, LED light will last for 10 seconds.

By pressing the power button (moving into memory mode),
 LED light will turn on for 10 seconds.

When pressing the power button for 3 seconds (entering the setting mode), LED light will turn on for 10 seconds.

 When inserting the PC cable into the USB port, LED will turn on for 10 seconds.

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Performing a Glucose Control Solution Test

Element®NEO control solution contains a known amount of glucose that reacts with Element®NEO test strip. By comparing your control solution test results with the expected range printed on the test strip vial, you are able to check that the meter and test strips are working properly, and that you are performing the test correctly. It is very important that you perform routine checking to ensure accurate results.

The Glucose control solution should be used

- Before using a new box of test strips.
- 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 results 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.
- When using the meter for blood glucose tests after any disinfection procedure.



Firmly insert the test strip into the meter test port. Insert deeply in direction of arrow on test strip (arrow up). Please do not insert the glucose test strip upside down.



When you insert the glucose test strip into the glucose test meter, the power automatically adjusts the meter accordingly.



Press and release either the \blacktriangle or \blacktriangledown button, then, Control Solution bottle icon will appear. Then, press ((1)).



1.Check the expiration date before performing a control solution test. Do not use if expired. Please note the expiration date marked on the control solution bottle.



2.Gently shake the control solution before use.



Discard the 1st drop of control solution. This will eliminate any residue.

Place a drop of control solution liquid on a clean, dry surface (e.g. the lid of the test strip vial)



4.Dip the test strip into the control solution liquid. Results will appear in 5 seconds.

Compare the result to the range printed on the test strip vial. Result should fall within that range.

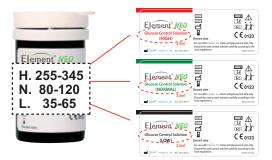
CAUTION

- Control solutions is for in-vitro diagnostic use only. This means that it is only used for testing outside the body.
- Control solution is exclusively made for the Element®NEO Blood Glucose Monitoring System. Do not use other brand control solutions made by other manufacturers.
- 3. Check the expiration date on the vial. Do not use, if expired.
- Once opened, use it for the next three months only. Record the discard date on the control solution bottle. Discard after three months.
- 5. Do not swallow. This is NOT for human or animal consumption.
- 6. The control solution bottle icon contains letter 'C,' so as not to be confused with the medication bottle. This will allow you to understand differences between a control solution test and an actual blood test.



For example only

If you are using the normal control solution, according to this particular vial of strips, your meter should show a number between 80 and 120.



Please note that the control values shown in the picture are not control ranges.

NOTE

- It is recommended that glucose control solution is stored at room temperature 20~25
 °C (68~77°F) before testing.
- Check the expiration date before performing a glucose control solution test.
- Do not use if it expired. Once opened, the control solution expires after 3 months.
- In order to perform the more accurate glucose control solution test, you can use the control solution 3 different levels – low. normal and high.

You can buy each Element®NEO control solution (low, normal and high levels) separately, please consult your local distributor about control solutions

If your control solution test falls out of range, please follow the next steps before contacting customer support:

- Check the expiration dates on all the products you are using. Be sure you are using Element®NEO Control Solution.
- Try another control solution test.

If this test falls out of range, try another control solution test with a new unopened bottle of test strips.

After following the appropriate steps and the control test still falls out of range, do not perform a glucose test. Please call customer support in your local area.

Follow-up Action

- 1. Check your meter and test strips with the glucose control solution.
- 2. Perform your test again.

CAUTION

- If your glucose control solution falls out of range, do not perform a glucose test and please contact your local representative.
- 2. The glucose control solution's measurement range has nothing to do with individual's blood glucose level, as its own purpose is to check the status of test strip and meter. Discard the used control solution and test strips carefully, according to the local regulation.

Performing Your Test

Testing Blood - Preparation

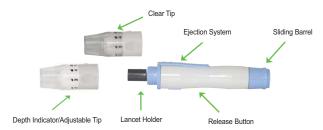
Lancing device is a convenient medical tool for collecting capillary blood samples for glucose monitoring or other tests which require one or two drops of blood.

Being a more advanced lancing device, it provides ultimate safety and comfort for obtaining blood samples. An adjustable tip offers 5 different strength levels of skin penetration for individual user's comfort, while a lancet ejector enables the safe disposal of the used lancet. As an added bonus, this also comes with a transparent tip for AST (Alternative Site Testing).

CAUTION

- 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 use a new tip or properly disinfected
- 3. Do not leave the lancet in the device after use.
- 4. 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 observe their own infection control protocols in order to avoid any contamination.
- 7. Always dispose of the used lancet in a biohazard garbage container.

COMPONENTS



RECOMMENDED AVAILABLE LANCETS

Some general sterilized lancets are infolet, ELEMENT, Lanzo, Gleenlan 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)

- Place the lancing device and lancet on the skin in the chosen area, press and hold it continuously for a few seconds, then push the release button to take a blood sample.
- 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 is collected.

<u>STORAGE</u> Products must be stored at room temperature protected from sunlight or moisture.

CLEANING AND DISINFECTION

- -Clean and wipe the outer part of lancing device once a week at the minimum with a soft cloth dampened with mild soap and water. Wash the adjustable tip and clear tip, once a week with mild soap.
- -DO NOT immerse the lancing device in water or liquid.

WARRANTY

Lancing device has a 2-year warranty from the date of purchase.

A malfunctioning device should be returned to the following address: address:



Performing a blood test with your fingertip

Step 1



Firmly insert the test strip into the meter test port in the direction of arrow on test strip (arrow up). Please do not insert the glucose test strip upside down.



When you insert the glucose test strip into the glucose test meter, the power automatically turns on with the code and temperature. Make sure the code number matches on the test strip bottle (e.g. 17). Element®NEO automatically recognizes the test strip code number and adjusts the meter accordingly.



A blinking test strip will appear at the top of the screen, which indicates that the meter is ready for testing.

CAUTION

- If the code is not displayed after for a while, pull the glucose test strip out of the port, and re-start the procedure from the beginning.
- If the code on the LCD display window as well as on the glucose test strip vial does not match, try another new glucose test strip. If the mismatch persists, please contact your local representative for assistance.
- 3. Avoid testing under direct sunlight, for a more accurate test result.
- If you apply your blood sample too early, Er5 message will appear on LCD. Please refer to Page 40.

Step 2

To obtain a suitable blood samples

 Before obtaining a blood sample, wash your hands with warm, clean water and soap. Dry hands completely before testing.

WARNING

- 1. All parts of the kit are considered bio hazardous and can potentially transmit infectious disease, even after you have conducted cleaning and disinfection measures.
- 2. Avoid getting hands lotion, oil, dirt or debris in or on the lancets (single use only) and the lancing device.
- Wash your hands thoroughly with soap and clean water after handling the meter, lancing device and/or test strip.



1. Unscrew the lancing device tip.



2. Insert a sterile lancet into the lancing device.



3. Twist the protective cover off. Do not discard.

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4. Put the lancing tip back and twist it tightly.



5. To adjust the depth setting: Use strength level 1-2 for soft skin, 3 for average skin, 4-5 for thick or calloused skin.



6 Pull the end of the lancet device back



7. To prick your finger, push the center button.

CAUTION

- 1. If the blood smears or runs, do not use such blood sample. Dry the area and gently squeeze another drop or puncture a new area of the finger.
- 2. Do not share reusable lancing device with anyone including other family members.

Step 3

Correct



Applying Blood





Incorrect

Completely Filled







Element®NEO Test Meter only requires 0.5 ul sample volume.

- Stick the edge of the test strip to the drop of blood.
- The blood will automatically be 'drawn' into the test strip channel.
- When your sample blood is enough, your meter will automatically count down.
- 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.
- · Please respect recommended quantity of blood sample. Too much blood may cause malfunction of your meter by contaminating it.

CAUTION

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



Step 4













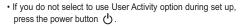
and time.

· After the beeping sound, test

will begin automatically, and

your results will appear in 5

seconds. It should begin counting down from 5 to 1 second on the LCD display window. LCD window will display the result of your blood glucose level, temperature





- If you selected to use the User ID option during set up, press ▲ and ▼ button to select the correct User ID, then press the power button (1).
- Record the result value in your logbook. When glucose test strip is removed, glucose test meter turns off automatically.

CAUTION

- 1. If the test result is out of the test range, "HI/Lo" message will be shown on the LCD window
- 2. Safely discard used glucose test strips and lancets in the proper place, according to the local regulation.

Test Strip Ejector Function

Disposing of your test strip



1. Once the test is complete, push the test strip forward to remove the test strip from the meter



2. Used test strips may be considered bio hazardous waste in your area.

Be sure to contact your local representative for proper disposal.

Disposing of your lancet



1. Push the needle into the protective cover.



2. Pull the lancet out and discard accordingly.

CAUTION

- 1. If you push the ejector button forward too much, it may be part of the failure.
- 2. Do not give strong impact to blood glucose test meter.
- 3. Please follow the waste disposal regulations on the used lancets and strips imposed by your local authorities.



Reviewing Your Results

The Element®NEO meter stores up to 365 test results in its built-in memory, along with the average glucose level for the number of days, which you had preset the glucose test meter to calculate.

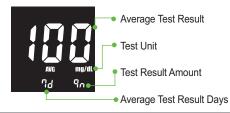
Reviewing Your blood glucose



Reviewing Your averages



Press and release the $\, \blacktriangle \,$ button, and your average result will be displayed.



Reviewing your results with activated user ID



Pressing the $\begin{tabular}{l} \begin{tabular}{l} \begin{tabular}{l}$

After entering the user ID mode, use ▲ or ▼ buttons to scroll and choose the correct user ID, then press the ♂ button.



If you choose the User ID to check the stored results, only the results of the selected user ID are displayed.

Deleting Test Results



Deleting individual test result

To delete any individual test result in the memory, press

▲ or ▼ button for 3 seconds. Then displayed DEL icon
will start blinking. After the third beep sound, you may
hear that the test result has been deleted

dEL

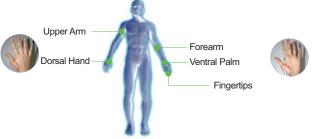
Deleting all the test results

To delete all test results in the memory press ▲ and ▼ button for 3 seconds. Then displayed 爲LL, DEL will start blinking. After the third beep sound you may hear that the test results have been deleted.

CAUTION

Deleted test results cannot be recovered. Please be careful in deleting the testresults.





Element®NEO blood glucose monitoring system gives you the ability to obtain a blood sample for testing your sugar from different areas of your body.

The figure shown above displays the areas where you can test using your Element®NEO meter.

You may test your blood sugar from your forearm, upper arm, palm (ventral palm or dorsal hand), or fingertips.

IMPORTANT

It is recommended that alternative site testing be used when glucoses are stable: before meals and before bedtime. However, when glucoses are changing, blood from the fingertip may show these changes sooner than blood from other body areas.

LIMITATION

- Alternative site testing results should never be used to calibrate continuous glucose monitoring systems.
- 2. Alternative sampling results should never be used in insulin dosing calculations.

Lancing and sampling from an alternative site area

Sampling from your upper arm, forearm, ventral palm, or dorsal hand allows you to use your fingertips less often.

You may find that obtaining a blood sample from an alternative site is less painful than using a fingertip. Getting a blood sample from your forearm or palm is different than getting a sample from your fingertip.

Ventral palm/Dorsal hand



Choose a fleshy area on the palm, below your thumb or pinky finger. Select a spot without any visible veins and away from any deep lines. This may cause your blood sample to smear.

Forearm



Upper arm



Choose a fleshy area of the forearm or upper arm away from bone, visible veins and thick hairs of the arm. Sometimes there is less blood flow to these areas than to the fingertip. To help you get enough drops of blood, you may gently massage or apply a heating pad to the site to increase blood flow

IMPORTANT

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





To ensure accurate results when lancing your arm (forearm or upper arm), or palm (ventral palm or dorsal hand), clean 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.

WARNING

To reduce the chances of getting infection: never share a lancet or lancing device with anyone.

The lancing device clear tip is used for alternate site testing Lance the test site with the lancing device



1. Remove the lancing tip by twisting off.



2. Insert lancet and replace with the clear tip.



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. Applying heat may be helpful.



 Adjust clear tip to the highest setting. Hold the clear tip down against a fleshy area on the alternative site. Press the release button. Do not lift up.









- Continue to hold the lancing device and gradually increase pressure for several seconds.
- While holding the lancing device on your test site, look through the clear tip until a round drop of blood appears.
- Lift the lancing device straight up; be careful not to smear the blood on your testing site.
- 8. Stick the edge of the test strip to the drop of blood. Blood will automatically be drawn up.

REMEMBER

- 1. Consult with your healthcare professional before using alternate site testing.
- Choose a different puncture site each time you test. Repeated punctures in the same spot may cause soreness and calluses.
- If bruising occurs at an alternate site or you have difficulty getting a sample, consider sampling from a fingertip instead. You may want to review the choice of sites with your healthcare professional.
- 4. Do not share reusable lancing device with anyone including other family members.

CAUTION

Do not test on your Alternative Site Test when

- You think you blood glucose is rapidly falling. For example within two hours of exercise, rapid-action insulin injection, or an insulin pump bolus.
- Testing with a fingertip sample may identify hypoglycemia or an insulin reaction sooner than testing with a forearm or palm sample.

Caring for Your Element®NEO System

Cleaning your meter and maintenance

Blood alucose test meter:

Your blood glucose test 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's operation temperature is 10~40°C(50~104°F). It is recommended that you store the blood glucose test meter in the portable pouch after each use.

A cloth dampened with water and mild detergent can be used to wipe down the outer part of the blood glucose test meter. Your Element®NEO blood glucose test meter is a precision instrument. Please handle it with care.

Lancing device:

Clean the lancing device and tips with soap and tepid water. To disinfect the lancing device, prepare a disinfectant solution household bleach and water in 1(bleach): 9(water) ratio. Dampen a cloth with this solution and wipe the lancing device thoroughly. Soak only the tip for at least 30 minutes in the disinfectant solution. Do not soak the lancing device in liquid. Rinse the lancing device and tip with water, and dry thoroughly.

- For detailed instructions concerning Element®NEO blood glucose test strips, refer to the blood glucose test strip package inserted and found in the blood glucose test strip box.
- Please store the Element®NEO blood glucose monitoring system in a cool and dry area, out of reach of children. Do not freeze. For a more accurate test result, avoid testing under direct sunlight.
- 3. Do not soak the blood glucose test meter or blood glucose test strips in water or liquid.
- 4. Do not subject the meter or blood glucose test strips to excessive heat.
- 5. Use your 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.
- 7. Discard the used lancets carefully, to prevent any infection.

Storage of your Element®NEO System

To prevent the meter and test strips from getting dirt, dust or other contaminants, please wash and dry your hands thoroughly before use

Meter Storage

- Storage condition: 2~30°C or 36~86°F (Temperature)
- · Always store and transport the meter in its original storage case.
- · Avoid dropping and strong impact.
- · Avoid direct sunlight and humidity.

Test Strip Storage

- Storage condition: 2~30 °C or 36~86 °F (Temperature)
- Store your test strips in their original vial only. Do not store the test strips in other containers.
- · Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.
- · Do not freeze.
- After removing a test strip from the vial, immediately close it tightly.
- Record the discarded date (date vial opened, plus 6 months) on the test strip label.
- Do not use if it is expired(2 years) after manufacturing.
- Touch the test strip with clean and dry hands.
- Do not use if 6 months have been passed, since the opening of the vial cap for test strips.

Control Solution Storage

- Storage condition: Store in a cool, dry place at between 8~30 °C or 46~86 °F (Temperature)
- · After use, close cap tightly.
- Make sure the control solution bottle is tightly closed
- Record the discarded date (date vial opened, plus 3 months) on the control solution on the bottle.
- · Do not use if expiry date has passed.
- · It expires 24 months after manufacturing date.
- It expires 3 months after opening the vial cap.



CAUTION

- Store the Element®NEO test strip vials in a cool, dry place. Keep out of direct sunlight. Do not freeze.
- Store test strips in their original vial only. Do not mix the test strips in new vials or in any other container.
- Immediately replace the vial cap and close tightly after removing any test strips from the vial.
- 4. Make a note of the discard date, which is six months from the date you first open a new vial of test strips. Throw Element®NEO test strips and vial away after the discard date
- Do not use the test strips after the expiration date printed on the package or vial, since it may cause inaccurate results.
- 6. Do not test at temperatures below 10°C(50°F) or above 40°C(104°F).
- 7. Do not test with humidity below 10% or above 90%.
- 8. Do not bend, cut, or alter the test strip.
- 9. Avoid getting dirt, food, and water on the test strip with wet hands.
- 10. Avoid getting dirt, food, and water on the color-coding label (backside of test strip)

Transferring Your Result Data

You can transfer test results from the Element®NEO meter to a computer.

You will need to download the software from the following web site

(http://www.infopia21.com) and purchase the computer cable from your local representative.

This is sold separately.

* Please use the exclusive USB cable provided by infopia.



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Battery Installation

The low battery icon will appear in the upper left corner of the LCD display to alert you when the battery power is running low, which is an indication that a new battery are needed.







Your Element®NEO 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.

Follow-up Action

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

NOTE

- 1. Make sure your date and time are correct after changing your battery.
- Remove both batteries from the battery compartment and dispose of them, according to your institution's guidelines.

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.

Disposing of your Blood glucose test strips and lancets

Discard your Blood glucose test strip



Once the test is complete, pull the Blood glucose test strip forward to remove the Blood glucose test strip from the Element®NEO Blood glucose test meter.



Dispose of used Blood glucose test strip in a sealed container with your household waste in accordance with local regulations

Discard your Blood glucose test Lancet



Push the needle into its protective cover.



Pull the lancet out and discard appropriately.



Trouble-shooting

The following chart may help you identify certain problems, but may not solve all the problems that could occur. Contact your authorized representative or customer support center of Infopia Co.,Ltd., if the problem continues.

Massaga	Mhat it maar-	A otion required
Message	What it means	Action required
Er :	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 authorized representative or customer support at Infopia Co., Ltd.
Erz DATE (3 1100	Caused by either used or wet blood glucose test strip	Please insert a new glucose test strip and perform your test again.
Er 3	Caused by less blood or irregular blood fill	Please insert a new glucose test strip and apply the blood sample completely and regularly.
Erk DATE (, 3 (F.DD	Caused by the failure in test strip recognition	Please insert a new glucose test strip and perform your test again.

Trouble-shooting

Message	What it means	Action required
Er 5	User applied the blood sample before the LCD display •= # was blinking	Wait for the meter to display the blinking icon before applying your blood sample.
Er 5 DATE 1. 3 1 1:00	Caused by color bar contamination	Please insert a new glucose test strip and perform your test again. If blinking with "Sun", avoid the direct sunlight and re-test. Contact your local representa- tive or customer support at Infopia Co, Ltd., if the problem persists.
LoI SE	The ambient temperature is less than 10°C (50°F)	Place the meter at a temperature between 10 \sim 40°C (50 \sim 104°F) for more than 30 minutes or more and test again.
H 11.	The ambient temperature is over 40 °C (104°F)	Place the meter at a temperature between 10 ~ 40°C (50 ~ 104°F) for more than 30 minutes or longer, and then test again.
L @ 1.000	Test result is lower than 10 mg/dL(0.6mmol/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 with your doctor immediately.

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Trouble-shooting

Message	What it means	Action required
DATE 1:00	Test result is higher than 600 mg/dL(33.3mmol/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 with your doctor immediately.
	There are no reading stored in the meter	
ave Id On	Not enough reading in the memory to display designated average	
The glucose test meter is not powered ON	Battery is dead, or there is a problem with the meter	Change the battery and if the problem persists, contact your local representative or customer support at Infopia Co., Ltd.
Glucose test meter does not start after being applied blood sample.	Insufficient amount of blood.	Please insert a new test strip and perform your test again.
Results are inconsistent	There may be a problem with the glucose test strip	Please insert a new test strip and perform your test again.

Inconsistent or Unexpected Test Results

If you continue to get unexpected results, check your system with control solution. If you experience symptoms that are not consistent with your glucose results, review and follow all the instructions in this manual. Do not ignore symptoms or make significant changes to your diabetes control program by informing healthcare professional of your symptoms and/or concerns.

CAUTION

- 1. Low Glucose Results: If your result is lower than 70mg/dL, it may mean hypoglycemia (low blood sugar). This may require immediate treatment, according to your healthcare professional's recommendations. Although this result could be due to a test error, it is safer to treat first and you may test another.
- 2. High Glucose Results: if your test result is higher than 180 mg/dL, it may mean hyperglycemia (high blood sugar). If you are uncertain about your test results, consider re-testing. Your health care professional will help you to decide how you need to act. If the meter displays "HI" all the time, please re-check your blood sugar. If the "HI" continues, please consult with your healthcare professional immediately.

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Warranty

Manufacturer's Warranty

Infopia Co.,Ltd. warrants to the original purchaser that this instrument will be free from defects in workmanship for 3 years from the date of original purchase.

Limitations of Warranty

This warranty is subject to the following exceptions and limitations.

- Infopia Co.,Ltd. shall not be required to replace any units which are damaged or malfunctioning due to abuse, accidents, alteration, neglect, misuse, maintenance by someone other than Infopia Co.,Ltd. or failure to operate, in accordance with the instructions.
- Infopia Co.,Ltd. reserves the right to make changes in design without obligation to incorporate such changes into previously manufactured instruments.
- Infopia Co.,Ltd. has no knowledge of the performance of the instrument when the test strip is altered or modified in any manner.

For Warranty Service

Purchaser must contact the customer service department of Infopia Co.,Ltd. by calling +82-31-460-0300, for assistance and/or instructions for obtaining service of this instrument. Alternatively, you are requested to contact your place of purchase in your country for initial warranty request.

Service Information

Infopia Co.,Ltd. has trained specialists to help you 24 hours a day, 7 days a week, and 365 days a year.

IMPORTANT NOTICE

Please confirm with the Infopia Co.,Ltd. representative before returning your meter for any reason. You will be given the information needed to get your problem handled correctly and efficiently. Keep your meter, test strip and control solution with you, when you call.

Specifications

Sample Type	Capillary and/or venous whole blood
Sample Volume	0.5 μℓ
Test Range	10 ~ 600 mg/dL(0.6~33.3mmol/L)
Reading Time	5 seconds
Calibration	Plasma – equivalent
Hematocrit	20 ~ 65%
Altitude	3048 meter Up to (10,000 feet)
Operating Temperature	10 ~ 40°C (50 ~ 104°F)
Operating Humidity	10 ~ 90%
Test Strip Storage Temperature	Store 2~30°C(36~86°F)and no direct sunlight. Do not Freeze
Display Type	LCD
Dimension(HxDxT)	96 X 56 X 24 (mm)
Weight	58±1g (Including batteries)
Power Source	3V (Coin Battery, CR2032 X 2EA)
Battery life	1,000 running tests

Symbol Reference

Symbol	Description
(li	Consult Instructions for use
Σ	Use By date
C € ₀₁₂₃	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices
\triangle	Attention, See Instructions for use
IVD	For In Vitro Diagnostic Use
LOT	Batch code
8	Do not reuse
SN	Serial number
<u>~</u>	Date of Manufacture
•••	Manufacturer
*	Keep away from sunlight
	Waste electrical and electronic equipment Symbol
1	Temperature limitation
REF	Catalogue Number
SELF-TESTING	Self-testing Used
EC[REP]	Authorized representative in the European community
X	Waste batteries and accumulators
\triangle	Biohazard



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