

# Element™ *Auto-coding* Blood Glucose Test Strips

**IMPORTANT:** Please read this information and your Element™ Auto-coding Blood Glucose Monitoring System Operation manual before using Element™ Auto-coding blood glucose test strips.

## Intended Use :

Element™ Auto-coding blood glucose test strips are used with Element™ Auto-coding blood glucose test meter for the quantitative measurement of blood glucose level in whole blood. Blood Glucose Monitoring Systems are plasma-calibrated to allow easy comparison of results with laboratory methods. Element™ Auto-coding blood glucose test strips are for testing outside the body (in vitro diagnostic use only).

Element™ Auto-coding Blood Glucose monitoring system is for Self-testing.

## General :

Element™ Auto-coding blood glucose test strips adopts a new bio-sensor technology composed of electro-chemical components and requires a small 0.3uL volume of blood giving you less pain. (• 0.3uL)  
Element™ Auto-coding blood glucose test meter can store 365 readings in memory with date & time and with the bio-sensor technology, you can easily store your readings on your PC (optional). This will provide an easier and better way to control your glucose levels.



## Storage and Handling :

- Store the Element™ Auto-coding blood glucose test strip vials in a cool, dry place between 2-30°C (36-86°F). Keep out of direct sunlight. Do not freeze.
- Store blood glucose test strips in its original vial only. Do not mix the blood glucose test strips in new vials or in any other container.
- Immediately replace the vial cap and close tightly after removing an Element™ Auto-coding blood glucose test strip.
- This keeps the strips fully functional right up to the expiry date.
- Use blood glucose test strip immediately after removing it from the vial.
- Do not use blood glucose test strips after the expiry date printed on the package or vial since it may cause inaccurate results.
- 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 3 months after first opening the vial.
- Avoid getting dirt, food, and water on the blood glucose test strip. Do not handle blood glucose test strips with wet hands.
- Do not bend, cut, or alter any Element™ Auto-coding blood glucose test strip.
- Element™ Auto-coding blood glucose test strips are for single use only. Do not re-use.
- Do not perform blood glucose determinations at temperature below +10°C(50°F) or above +40°C(104°F), at humidity below 10% or above 90%.
- Discard the used blood glucose test strip carefully, to prevent any infection.

**Warning!** Keep the blood glucose test strip vial away from children.

## Care Procedures :

- Code the Element™ Auto-coding blood glucose test meters to match the code number printed on the Element™ Auto-coding blood glucose test strip vial.
- Use only Element™ Auto-coding blood glucose test strips with the Element™ Auto-coding blood glucose test meter to obtain accurate and consistent results.
- Do not reuse blood glucose test strips. Single use only.
- If you experience any symptoms that are not consistent with your blood glucose test results and you have followed the instructions described in your Blood Glucose Monitoring System Operation Manual, call your physician.
- Do not make significant changes to your diabetes control program.
- Do not ignore physical symptoms without consulting your physician.

## Test Principle :

Glucose in the blood sample will react to the electrodes in the blood glucose test strip, generating an electrical current that will stimulate a chemical reaction. This reaction is measured by the Element™ Auto-coding blood glucose test meter and displayed as your blood glucose result.

*Note:* Different levels of reactions will occur depending on the amount of glucose in the blood sample

## Reagent Composition :

Each Element™ Auto-coding blood glucose test strip contains:

Glucose Oxidase:	1 Unit
Mediator (Hexaammineruthenium chloride):	60 µg
Binder:	1.9 µg
Stabilizer:	28.6 µg

## The procedure for Blood Glucose Measurement :

Materials provided : Element™ Auto-coding blood glucose test strips

## Obtaining Blood Sample :

Element™ Auto-coding blood glucose test strips are designed to be used with fresh whole blood. Element™ Auto-coding blood glucose test meter gives you the ability to obtain a blood sample for testing your glucose level from different areas of your body. You may obtain a blood drop from either a finger or an alternative site.

## To obtain a drop of blood, follow these steps :

**Step 1 : Cleanliness:** Wash your hands or body part to be probed with warm soapy water. Dry hands or body part to be probed thoroughly. You may also use an alcohol wipe to clean your finger or body part to be probed. Make sure it is completely dry before you obtain the blood sample. (Dirt or perspiration may affect the test result).



**Step 2 : Insert the blood glucose test strip:** Remove blood glucose test strip from the vial. Recap the vial immediately to prevent moisture from affecting the other strips. Insert the blood glucose test strip into the port of the blood glucose test meter with "infopia" logo facing up. The blood glucose test meter will automatically turn on and display the code number. Make sure the code number on display matches the code number on the blood glucose test strip vial. If the code number does not match, refer to the Element™ Auto-coding Blood Glucose Monitoring System Operation Manual. Once completed, blood symbol will appear.



**Step 3 : Lancing:** Prepare the lancing device and lancet. Insert a clean needle (lancet) in the lancing device. The lancing device is a pen-sized holder for the lancet. It holds, positions, and controls how deeply the lancet goes into the skin. (Refer to the Element™ Auto-coding Blood Glucose Monitoring System Operation Manual for more information).



**Step 4 : Applying blood sample:** Prick the area where you have decided to obtain the blood. The blood sample must be at least 0.3uL in volume. While the blood glucose test meter displays the blood symbol, place the edge of the blood glucose test strip to the drop of blood. The blood will automatically be drawn into the test strip channel. When there is enough blood, the blood glucose test meter will automatically count down. Do not push your finger against the blood glucose test strip or try to apply a smeared sample. If you do not fill the test strip channel before the blood glucose test meter begins to count down, do not add blood to the blood glucose test strip; discard the blood glucose test strip and retest.



*Note:* Do not prick the tip of your fingertip it will be more painful, instead prick the SIDE of your fingertip. Do not squeeze the fingertip or puncture site of the body. You may get an inaccurate result if the blood sample is not completely filled in a single action.



**Step 5 : Accurate Results in Seconds.** Your blood glucose result will be displayed in 3 seconds in the LCD window. The blood glucose test meter will begin testing and your blood glucose results are automatically stored in the blood glucose test meter memory. Turn the blood glucose test meter off by removing the blood glucose test strip.

## Important Information About Using Alternate Site 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 site 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.

## Test Results :

Blood glucose test results are displayed on the Element™ Auto-coding blood glucose test meter as either milligrams of glucose per deciliter of blood (mg/dL) or millimoles of glucose per liter of blood (mmol/L), contingent upon the type of measurement you have selected.  
The Element™ Auto-coding blood glucose test meter display results between 10~600mg/dL (0.6~33.3mmol/L).

If the test result is below 10mg/dL (0.6mmol/L), "Lo" will appear on the blood glucose test meter display. "Lo" results indicate severe hypoglycemia (low blood glucose). Consult with your physician immediately in how to treat hypoglycemia (low blood sugar).

If the test result is above 600mg/dL (33.3mmol/L), "HI" will appear on the blood glucose test meter display. "HI" results indicate severe hyperglycemia (High blood glucose). Seek medical assistance immediately.

**IMPORTANT NOTE:** Blood glucose levels can appear to be lower or higher after a meal, physical exercise or any other event that may affect blood glucose levels. Before taking the Element™ Auto-coding blood glucose test, wait two hours prior or after a meal, physical exercise to retrieve more accurate results.

## Range of Expected Values :

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Self-testing of blood glucose levels provides a way to control your diabetes. Consult with your physician to determine the best range of expected blood glucose values for you.

Expected blood glucose levels for people without diabetes\*:

Fasting and before meal:	< 100 mg/dL (5.6 mmol/L)
2 hours after meal:	< 140 mg/dL (7.8 mmol/L)

\*American Diabetes Association: Diagnosis and Classification of Diabetes Mellitus (Position Statement), Diabetes Care 34 (Supplement 1), 2011

**IMPORTANT:**  
If you have a test result below 60mg/dL (3.3mmol/L) or over 240mg/dL (13.3mmol/L) contact your physician immediately.  
If your blood glucose result is unusually low or high, or you do not feel the way the result indicates, repeat the test again with a new blood glucose test strip.  
If the results are still inconsistent, please consult your physician before making any decision to control your diabetes.

## Quality Control (System Maintenance) :

Element™ Auto-coding Glucose Control Solution is used to check that the blood glucose test meter and the blood glucose test strips are properly working together to provide you with the most accurate reading.

*Note:* The Element™ Auto-coding Glucose Control Solution is sold separately. The low, normal and high level glucose control solution can be obtained through local representative.

Glucose Control Solution Test can only be used with the Element™ Auto-coding Monitoring System and should be used during the following:

- When a new vial of blood glucose test strips are opened.
- Any suspicion that the blood glucose test meter or blood glucose test strips are not working properly.
- When your blood glucose test results are not consistent with your symptoms, or if you think they are not accurate.
- If you drop the blood glucose test meter.
- Use routinely to obtain accurate results.

When the glucose control solution is applied to the top edge of the Element™ Auto-coding blood glucose test strip, you should get results within the expected range printed on the label of the blood glucose test strip vial. If the glucose control solution test results fall outside the range, repeat the test. Results that fall out-side the range may be caused by:

- Error in performing the test.
- Failure to shake the glucose control solution vial well enough (must shake vigorously).
- Failure to discard the first drop of glucose control solution.
- Expired or contaminated glucose control solution.
- Blood glucose test strip deterioration.
- Blood glucose test meter malfunction.
- Glucose Control solution that is too warm or cold.

**IMPORTANT NOTE:** If the Element™ Auto-coding Glucose Control Solution test results continuously falls outside the range printed on the vial, the Element™ Auto-coding, Blood Glucose monitoring system may not be functioning properly. DO NOT use the system to test your blood until you get a glucose control solution test result that falls within the range. If you continue to have problems, contact your local representative immediately.

## 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 :

- Extremes in hematocrit may affect test results. Hematocrit levels less than 20% may cause falsely high reading and hematocrit levels greater than 60% may cause falsely low readings. If you do not know your hematocrit level, consult your healthcare professionals.
- 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 values should be interpreted with caution.
- Blood samples that contain a high concentration of dissolved oxygen may lower the test result.
- EDTA containing tube is recommended as an anticoagulant tube.

## Performance Characteristics :

The performance of the test strips has been evaluated in laboratory and in clinical tests.

Measurement Range: The measurement range of the Element™ Auto-coding System is 10 to 600 mg/dL.

## Accuracy:

The accuracy results obtained with the Element™ Auto-coding System were compared to glucose results obtained with the Hitachi Glucose Auto analyzer 747, a laboratory instrument. Glucose levels were measured on 160 fresh capillary samples at three different clinical centers.

System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)

Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
43/56(77 %)	56/56 (100 %)	56/56 (100 %)

System accuracy results for glucose concentration > 75 mg/dL (4.2 mmol/L)

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
149/264(56%)	224/264 (85%)	251/264 (95%)	262/264(99%)

*The study shows that the Element™ Auto-coding System compares well with the laboratory method.*

## Precision:

Precision Results for venous blood samples.

Mean (mg/dL)	40.5	79.2	131.6	204.0	319.2
CV (%)	3.5	2.2	1.6	1.3	0.9

Precision Results for control solutions.

Mean (mg/dL)	41	119	347
CV (%)	2.5	1.9	1.2

## IMPORTANT:

- Before using the Element™ Auto-coding blood glucose test meter and blood glucose test strips, read all of the operating instructions (Element™ Auto-coding Blood Glucose Monitoring System Booklet) to practice for safe and accurate testing.
- Consult with your physician with use of the Element™ Auto-coding blood glucose test meter and daily management of your diabetes.
- Please pay extreme attention when handling blood. Improper procedures may cause serious injury to your health.
- If you have any questions about use of the Element™ Auto-coding product, please contact your local representative.

## References :

- 1) National Committee for Clinical Laboratory Standards. Point-Care Blood Glucose Testing in Acute and Chronic care Facilities ; Approved Guideline, 2nd Edition. NCCLS Document C30-A2 (ISBN1-56238-471-6)
- 2) National Committee for Clinical Laboratory Standards. Statistical Quality Control for Quantitative Measurements ; Principle and Definitions; Approved Guideline, 2nd Edition. NCCLS Document C24-A2 (ISBN1-56238-371-X). 1999
- 3) National Committee for Clinical Laboratory Standards. User Demonstration of performance for Precision and Accuracy ; Approved Guideline. NCCLS Document EP15-A (ISBN1-56238-451-1)
- 4) National Committee for Clinical Laboratory Standards. Interference Testing in Clinical Chemistry ; Proposed Guideline. NCCLS Document EP7-P (ISSN 0273-3099)
- 5) Krall, L.P., and Beaser, R.S.: Joslin Diabetes Manual. I. Philadelphia: Lea and Febiger(1989), 138
- 6) Beaser, R.S. and Hill, Joan: The Joslin Guide to Diabetes. New York: Simon and Schuster (1995), P158

## OUR COMMITMENT TO YOU :

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 , accurate reading through a convenient and simple process. Our goal is to provide you the best quality healthcare products coupled with superior customer service. If you have any questions or comments, please contact your local representative.

## NOTE :

Please refer to the table below to identify symbol

	Consult operating instructions
	Used By
	This product fulfills the requirements of Directive 98/79/EC on invitro diagnostic medical devices.
	Caution, consult accompanying documents
	For In Vitro Diagnostic Use
	Batch code
	Catalogue Number
	Temperature limitation
	Date of Manufacture
	Do not re-use
	For Self-testing
	Manufacturer
	Authorized representative

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IMS07-100 Rev.2011-06-04

