References

1. American Diabetes Association. 1993. Consensus Statement: Self-monitoring of blood glucose. *Diabetes Care* 16: 60–65.
2. American Diabetes Association. 1987. Consensus Statement: Self-monitoring of blood glucose. *Diabetes Care* 10: 95–99.
3. Gough DA, Armour JC, and Baker DA. 1997. Advances and prospects in glucose assay technology. *Diabetologia* 40: S102–S107.
4. Kilpatrick ES. 1997. Problems in the assessment of glycaemic control in diabetes mellitus. *Diabetic Medicine* 14: 819–831.
5. Peterson CM (ed.). 1982. *Diabetes Management in the '80s: The Role of Home Blood Glucose Monitoring and New Insulin Delivery Systems.* New York: Praeger Publishers.
6. Skyler JS. 1982. Self-monitoring of blood glucose. *Medical Clinics of North America* 66(6): 1227–1250.
7. Burrin JM and Price CP. 1985. Measurement of blood glucose. *Annals of Clinical Biochemistry* 22: 327–342.
8. Burtis CA and Ashwood ER (eds.). 1994. *Tietz Textbook of Clinical Chemistry.* 2nd ed. Philadelphia: WB Saunders Company.
9. Kaplan LA and Pesce AJ (eds.). 1996. *Clinical Chemistry: Theory, Analysis, Correlation.* 3rd ed. St. Louis: Mosby-Year Book, Inc.
10. Vreeke MS. 1997. Electrochemical bisensors for affinity assays. *IVD Technology.* July/August: 39–45.

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BLOOD GLUCOSE MONITORING SYSTEMS—CURRENT TECHNOLOGIES

A BRIEF HISTORY OF BLOOD GLUCOSE MONITORING[1-6]

Self-monitoring of blood glucose (SMBG) has become an integral part of many diabetes treatment plans. The technologies of SMBG have evolved over the past 20 years, and two particular technologies—reflectance photometry and electrochemistry (amperometry)—have emerged as important approaches to developing reliable and easy-to-use blood glucose monitoring systems (BGMSs).

The earliest devices available for self-monitoring of glucose were urine dipsticks or test tapes. A chemical reaction created a measurable (colored) product on the dipstick or tape; the glucose concentration in urine was estimated by visually comparing the intensity of color with a reference color chart. While simple to use, these devices were inconvenient and lacked the precision necessary for insulin dosage adjustments. Accurate and precise measurement of blood glucose levels could be achieved only with laboratory instruments.

In the late 1970s, similar test strips for measuring glucose in whole blood samples were introduced. Like the earlier urine dipsticks, the whole blood test strips used a reagent-impregnated pad on a plastic strip to enzymatically convert glucose to a colored product. Proper use of the whole blood test strips required removal of excess sample (by wiping or blotting), careful timing, and visual estimation of glucose concentration; the quality of results was highly operator-dependent.

Shortly after the introduction of visually read test strips, the first generation of hand-held blood glucose meters reached the market. By incorporating a small optical system (a reflectance photometer), these meters allowed the user to read the test strips electronically to measure the color intensity on the test strips. Optical readings were converted to a digital display of blood glucose concentration. Although such systems still required wiping and timing, their enhanced performance allowed people with diabetes to accurately and precisely self-monitor their blood glucose levels.

Second-generation meters for SMBG reached the market in the mid to late 1980s. These meters eliminated the need for wiping and timing. A second technology—electrochemistry—joined reflectance photometry for blood glucose monitoring. Both technologies use an enzyme to convert glucose to a measurable product, but instead of measuring a colored product, electrochemical meters quantify the number of electrons generated by the enzymatic reaction and convert that number to blood glucose concentration.

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A COMPARISON OF REFLECTANCE AND ELECTROCHEMICAL TECHNOLOGIES

MEASUREMENT OF BLOOD GLUCOSE[7–9]

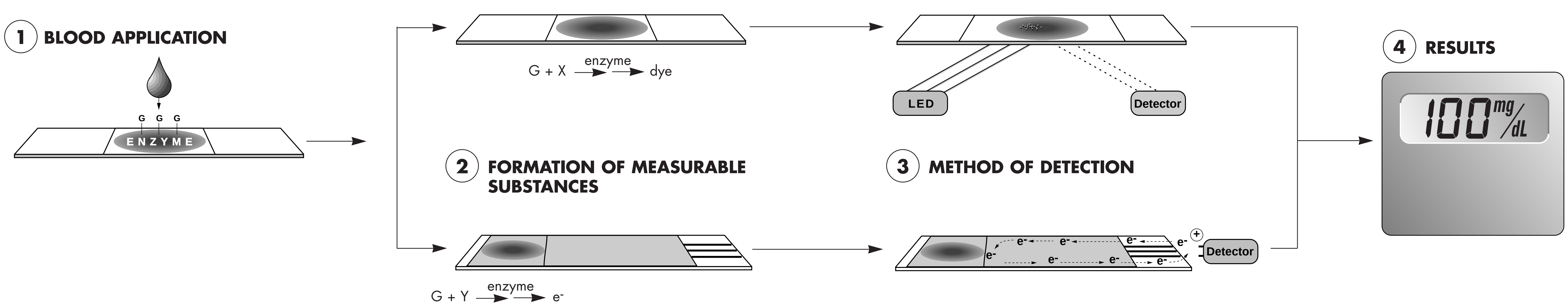
Because direct measurement of glucose (**G**) is difficult and inconvenient, it is routinely done by indirect methods. The concept of indirect measurement is simple—convert the analyte (i.e. glucose) to a substance that is easily measured. Current blood glucose monitoring systems use one of two technologies: reflectance photometry (which measures a colored product) or electrochemistry (which measures electrical current). Both technologies have been used for measurements in the laboratory.

COLORED PRODUCT[8,9]

Using an enzyme as a catalyst, glucose (**G**) is reacted with another compound (**X**) to generate a colored product, or dye. The amount of colored product is directly proportional to the amount of glucose present in the sample: the more glucose, the more color; the less glucose, the less color.

REFLECTANCE PHOTOMETRY[8,9]

Reflectance photometry quantifies the intensity of the colored product generated by the enzymatic reaction. A light source such as a light-emitting diode (LED) emits light of a specific wavelength onto the test strip; since the colored product absorbs that wavelength of light, the more glucose in a sample (and thus the more colored product on a test strip), the less *reflected* light. A detector captures the reflected light, converts it to an electronic signal, and translates that signal to its corresponding glucose concentration.



ENZYMES USED IN BGMSs[8,9]

Enzymes are used to catalyze the reactions that convert glucose to a measurable substance. Enzymes used in blood glucose monitoring systems are specific for glucose and produce substances that are readily measured by either reflectance photometry or electrochemistry. As a result, routine blood glucose measurements have become rapid, accurate, and sensitive. Enzymes commonly used in the measurement of glucose include glucose oxidase, glucose dehydrogenase, and hexokinase.

ELECTRONS[8,10]

Using an enzyme as a catalyst, glucose (**G**) is reacted with a mediator (**Y**) to generate electrons (**e-**). The number of electrons captured by the mediator is directly proportional to the amount of glucose present in the sample: the more glucose, the more electrons; the less glucose, the fewer electrons.

ELECTROCHEMISTRY (AMPEROMETRY)[8–10]

Electrochemistry quantifies the number of electrons generated by the oxidation of glucose. A mediator captures the electrons; when a voltage is applied, the electrons are transferred to and counted at the electrodes. A detector converts the resulting current to an electronic signal and translates that signal to its corresponding glucose concentration.

TECHNOLOGY INFLUENCES ON RESULTS

Reflectance and electrochemical technologies have inherent limitations and benefits. As a result, attributes and trade-offs are often associated with the selection of a meter technology. Meter technologies can influence accuracy, precision, interference effects, cleaning requirements, calibration, test time, sample volume, and meter size. Understanding the importance of these attributes and trade-offs based on individual needs will aid in selecting the appropriate meter.