Keywords: blood glucose meter, portable medical, home medical, test-strip, analog front end, blood sugar, electrochemical, optical-reflectometry, counter configuration, self biased configuration, blood sample, alternate site testing

TUTORIAL 4659

Blood Glucose Meters

By: John DiCristina
May 10, 2010

Abstract: This tutorial introduces the different types of glucose meters. It explains the different types of calibration used for test-strips, and discusses other variables that designers must consider when selecting products.

Overview

Blood glucose meters and other home medical devices today are small, portable, and easy to use. The mark of a good meter is one that the patient will use regularly and that returns accurate and precise results. Over the past few years the trend with blood glucose meters has been to maximize patient comfort and convenience by reducing the volume of the blood sample required. The blood sample size is now small enough that alternate-site testing is possible. This eliminates the need to obtain blood from the fingers and greatly reduces the pain associated with daily testing. Accurate and precise results have been increased by using better test strips, electronics, and advanced measurement algorithms. Other conveniences include speedy results, edge fill strips, and illuminated test strip ports, to name just a few.

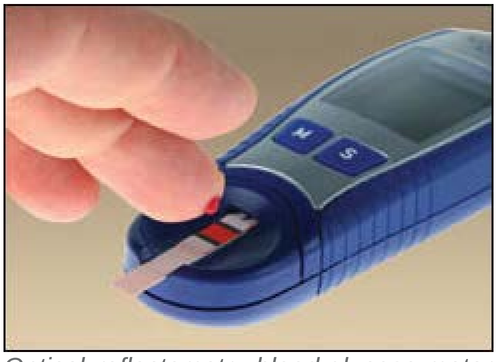
Meter Types

There are continuous and discrete (single-test) meters on the market today, and implantable and noninvasive meters are in development. Continuous meters are by prescription only and use a subcutaneous electrochemical sensor to measure at a programmed interval. Single-test meters use electrochemical or optical reflectometry to measure the glucose level in units of mg/dL or mmol/L.

The majority of blood glucose meters are electrochemical. Electrochemical test strips have electrodes where a precise bias voltage is applied with a digital-to-analog converter (DAC), and a current proportional to the glucose in the blood is measured as a result of the electrochemical reaction on the test strip. There can be one or more channels, and the current is usually converted to a voltage by a transimpedance amplifier (TIA) for measurement with an analog-to-digital converter (ADC). The full-scale current measurement of the test strip is in the range of 10µA to 50µA with a resolution of less than 10nA. Ambient temperature needs to be measured because the test strips are temperature dependent.

Electrochemical blood glucose meter.

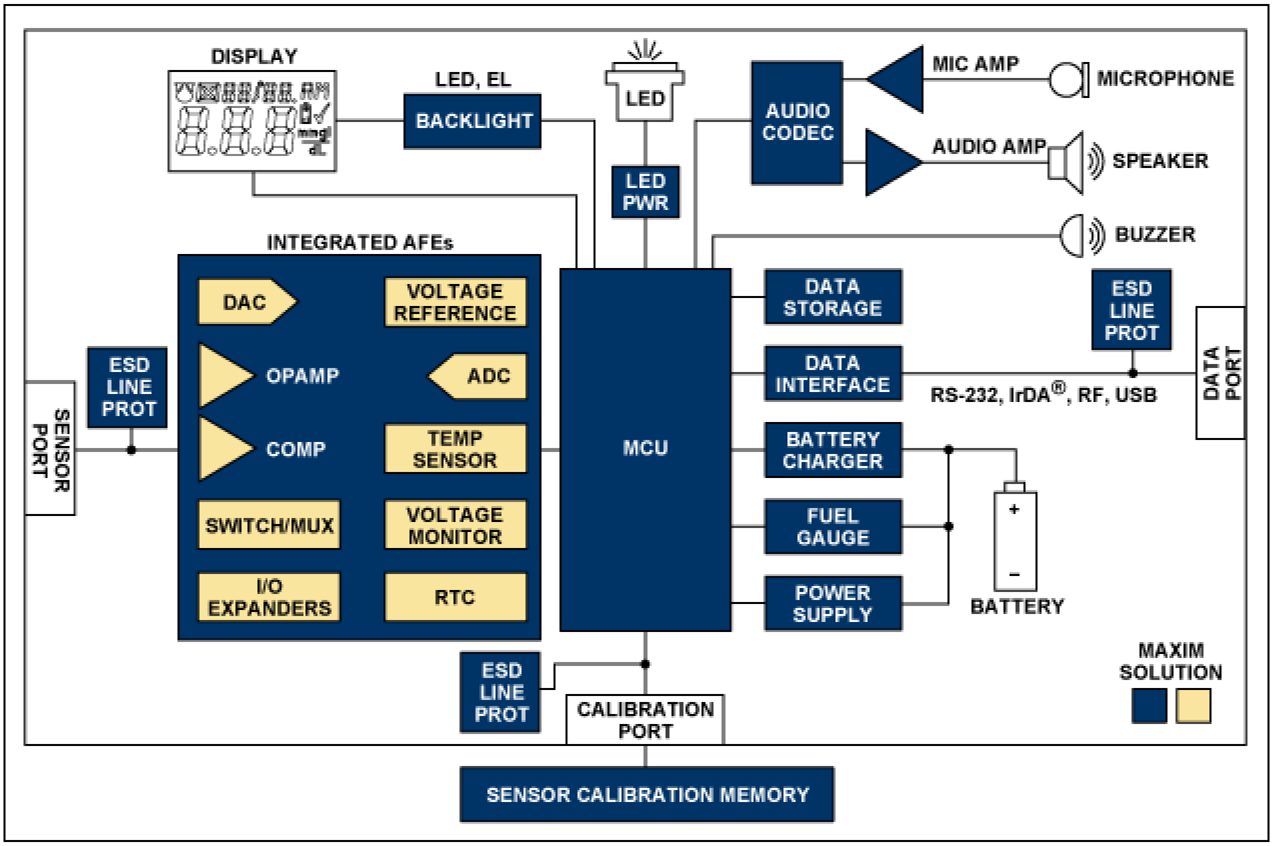
Optical-reflectometry test strips use color to determine the glucose concentration in the blood. Typically, a calibrated current passes through two light-emitting diodes (LEDs) that alternately flash onto the colored test strip. A photodiode senses the reflectedlight intensity, which is dependent on the color of the test strip, which, in turn, is dependent on the amount of glucose in the blood. The photodiode current is usually converted to a voltage by a TIA for measurement with an ADC. The full-scale current from the photodiode ranges from 1µA to 5µA with a resolution of less than 5nA. Ambient temperature is required for this method.


Optical-reflectometry blood glucose meter.

Test-Strip Calibration

The test strips usually need to be calibrated to the meter to account for manufacturing variations in the test strips. Calibration is done by entering a code manually or by inserting a memory device from the package of test strips. An EPROM or EEPROM memory device enables additional information to be transferred, which is a significant advantage over manually entering a code. A 1-Wire® memory device provides an additional benefit, because the unique serial identification number in each 1-Wire device ensures that the proper test strip is used.

Some meters use test strips that do not require any coding by the user. This "self-calibration" can be accomplished three ways: with tight manufacturing controls, built-in calibration on each test strip, or built-in calibration on a pack of test strips loaded into the meter. A pack of test strips inside the meter also facilitates testing because these often small strips do not need to be handled and inserted by the user.



Functional block diagram of a blood glucose meter. For a list of Maxim's recommended glucose-meter solutions, please go to: www.maximintegrated.com/glucose.

Glucose Meter Solutions

Accuracy and Precision

Both optical-reflectometry and electrochemical meters need to resolve currents in the single-digit nano-amp range. To meet the error budget for a meter, components must have extremely low leakage and drift over supply voltage, temperature, and time once the meter has been calibrated during manufacture. An operational amplifier's key specifications are ultra-low input bias current (< 1nA), high linearity, and stability when connected to a capacitive electrochemical test strip. The operational amplifier is typically configured as a TIA for both types of meters. A voltage reference's key specifications include a temperature coefficient less than 50ppm/°C, low drift over time, and good line and load regulation. A 10- or 12-bit DAC is used to set the bias voltage for an electrochemical test strip and to set the LED current for an optical-reflectometry test strip. Sometimes a comparator is employed with electrochemical test strips to detect when blood has been applied to the test strip. This saves power while waiting for blood to be applied to the test strip, and ensures that the reaction site is fully saturated with blood. The ADC requirements vary depending on the type of meter, but most require ≥ 14-bit resolution and low noise for repeatable results. Sometimes 12-bit resolution is used when there is a programmable gain stage before the ADC to extend the dynamic range.

Temperature Measurement

Ideally, the temperature of the blood on the test strip should be measured, but usually the ambient temperature near the test strip is measured. Temperature measurement accuracy varies by test-strip type and chemistry, but is typically in the ±1°C to ±2°C range. This measurement can be accomplished with stand-alone temperature-sensor ICs, or with a remote thermistor or PN junction together with an ADC.

Using a thermistor in a half-bridge configuration driven by the same reference as the ADC provides more accurate results because this design eliminates any voltage-reference errors. Remote or internal PN junctions can be measured with highly precise integrated analog front-ends (AFEs).

Electrochemical Test-Strip Configurations

Most test strips are proprietary and vary by meter manufacturer. The variations include the reagent formulation, the number of electrodes, the number of channels, and biasing method of the reagent. The simplest configuration is a self-biased test strip (**Figure 1**) which has two electrodes with current measured at the working electrode and the common electrode grounded. There can be multiple channels on a single test strip; the additional channels are used for a reference measurement, initial blood detection, or to ensure that the blood has saturated the reaction site.

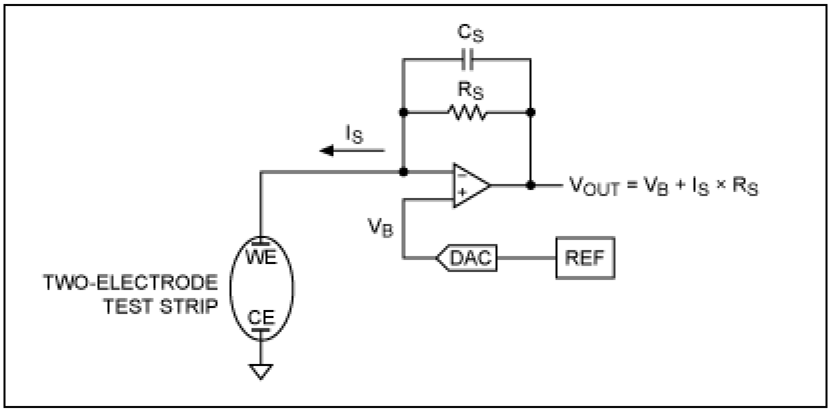


Figure 1. Electrochemical test strip in a self-biased configuration.

An alternate configuration actively drives both electrodes and measures at the common electrode.

Another more advanced design is a counter configuration (**Figure 2**). Here there are three electrodes with current measured at the working electrode and a force-sense circuit drives the common and reference electrodes. There is an important advantage to this configuration: the bias voltage at the reaction site on the test strip is set and maintained more accurately throughout the measurement. The disadvantage of this design is its additional complexity and the larger headroom required to allow the force-sense amplifier to swing negative to maintain the bias voltage during current flow.

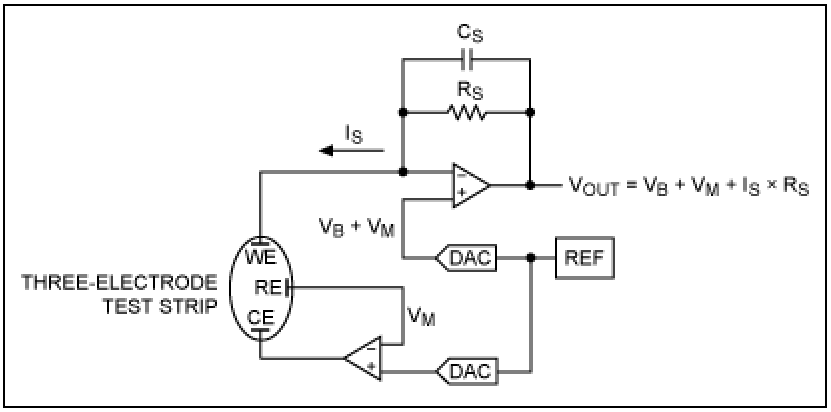


Figure 2. Electrochemical test strip in a counter configuration.

Integrated AFE

Maxim's precision AFEs integrate all the functionality discussed in the previous sections, and are designed for the specifications and performance required in blood glucose meters. The AFEs are also suitable for similar applications such as coagulation and cholesterol meters.

Display and Backlighting

Most blood glucose meters use a simple liquid-crystal display (LCD) with about 100 segments that can be driven with an LCD driver integrated in the microcontroller. Some meters feature a more complicated dotmatrix LCD which usually requires using a module with the glass, bias voltages, and drivers assembled together. The dot-matrix display also requires additional memory to store the messages to be displayed. There are also color displays that require additional and higher voltages than both the segment or dot-matrix LCDs. Backlighting can be added by using one or two white LEDs (WLEDs) or an electroluminescent source.

Data Interface

The ability to upload test results to a computer has existed for many years, but utilization of this data interface has been low. Initially to keep the cost of the meter down, the incremental cost for this functionality was designed into a proprietary cable. Today meters are moving from proprietary data interfaces to industry-standard interfaces such as USB and Bluetooth®. The added cost of these open interfaces is now moving into the meters, a movement driven, in part, by the Continua Health Alliance® and the push to conveniently upload patient data to your health-care provider.

Audio

Audible indicators range from simple buzzers to more advanced talking meters for the vision impaired. A simple buzzer can be driven by one or two microcontroller port pins with pulse-width modulation (PWM) capability. More advanced voice indicators and even voice recording for test result notes can be achieved by adding an audio codec along with speaker and microphone amplifiers.

Power and Battery Management

Meters with simple displays can run directly off of a single lithium coin cell or two alkaline AAA primary batteries. To maximize battery life, this meter requires electronics capable of running from 3.6V down to 2.2V for the lithium coin cell or 1.8V for the alkaline AAAs. If the electronics require a higher or regulated supply voltage, then a step-up switching regulator can be used. Powering down the switching regulator during sleep mode and running directly off the batteries extends battery life, as long as the sleep circuitry can run from the lower battery voltages. Adding a backlit or a more advanced display will require higher and sometimes additional voltages. A more advanced power-management scheme may be required at this point. Rechargeable batteries such as single-cell lithium ion (Li+) can be used by adding a battery charger and fuel-gauge circuitry. Charging with USB is certainly a convenient option for the user, if USB is available in the meter. If the battery is removable, then authentication may be required for safety and aftermarket control.

Electrostatic Discharge

All meters must pass 61000-4-2 electrostatic discharge (ESD) requirements. Using electronics with built-in ESD protection or adding ESD line protectors to exposed traces can help meet this requirement.

Functional Scalability

Once the core meter design is complete using a precision, integrated AFE, the goal is not to redesign that portion of the meter when another feature is needed later. Instead, standard parts with a singular function targeted for portable medical devices can be used to add a feature with minimal disruption. That minimal disruption translates into lower risk, easier FDA approvals, and faster time to market. It also means that more meters will be available with the features that patients want and need. Blood glucose testing will be more frequent with the predictable result of increased compliance to acceptable glucose levels and better individual health.

1-Wire is a registered trademark of Maxim Integrated Products, Inc.
Continua Health Alliance is a registered service mark of Continua Health Alliance.
IrDA is a registered service mark of Infrared Data Association Corporation.
The Bluetooth word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Maxim is under license.

Related Parts		
DS28E01-100	1Kb Protected 1-Wire EEPROM with SHA-1 Engine	Free Samples
MAX11359A	16-Bit, Data-Acquisition System with ADC, DAC, UPIOs, RTC, Voltage Monitors, and Temp Sensor	Free Samples
MAX1329	12-/16-Bit DAS with ADC, DACs, DPIOs, APIOs, Reference, Voltage Monitors, and Temp Sensor	Free Samples
MAX17043	Compact, Low-Cost 1S/2S Fuel Gauges with Low-Battery Alert	Free Samples
MAX1811	USB-Powered Li+ Charger	Free Samples
MAX1832	High-Efficiency Step-Up Converters with Reverse Battery Protection	
MAX1833	High-Efficiency Step-Up Converters with Reverse Battery Protection	Free Samples
MAX1834	High-Efficiency Step-Up Converters with Reverse Battery Protection	
MAX1835	High-Efficiency Step-Up Converters with Reverse Battery Protection	
MAX6018A	Precision, Micropower, 1.8V Supply, Low-Dropout, SOT23 Voltage Reference	Free Samples
MAX6018B	Precision, Micropower, 1.8V Supply, Low-Dropout, SOT23 Voltage Reference	Free Samples
MAX9910	200kHz, 4µA, Rail-to-Rail I/O Op Amps with Shutdown	Free Samples
MAX9911	200kHz, 4µA, Rail-to-Rail I/O Op Amps with Shutdown	Free Samples
MAX9912	200kHz, 4µA, Rail-to-Rail I/O Op Amps with Shutdown	
MAX9913	200kHz, 4µA, Rail-to-Rail I/O Op Amps with Shutdown	Free Samples
MAXQ2010	16-Bit Mixed-Signal Microcontroller with LCD Interface	Free Samples

More Information
For Technical Support: http://www.maximintegrated.com/support
For Samples: http://www.maximintegrated.com/samples
Other Questions and Comments: http://www.maximintegrated.com/contact

Application Note 4659: http://www.maximintegrated.com/an4659
TUTORIAL 4659, AN4659, AN 4659, APP4659, Appnote4659, Appnote 4659