

Accessible Blood Glucose Monitor Design 1

**University of Connecticut
Biomedical Engineering Senior Design
Team 2**

**Sponsored by the Rehabilitation Engineering Research Center on Accessible
Medical Instrumentation (RERC on AMI)**

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Table of Contents

Introduction.....	3
Design.....	4
Testing Procedure.....	6
Measurement Methods.....	6
Microprocessor.....	10
LCD Display.....	15
Hardware/Software.....	17
Circuit.....	18
Speech Module.....	20
Other Technical Specifications.....	21
Cost.....	22
Safety Issues/Constraints.....	22
Conclusion.....	22
Contacts.....	23

Figures and Tables

Figure 1-External views of Meter.....	4
Figure 2-General Block Diagram of Design.....	5
Figure 3-Test Strips Schematic.....	7
Figure 4-Graph of Applied Current and Measured Voltage vs. Time for Sample Detection Process.....	8
Figure 5-Graph of Applied Voltage and Resulting Current Response vs. Time for Measurement Method.....	9
Figure 6-Microprocessor Pin Diagram.....	11
Table 1-Microprocessor Pin Description.....	11
Table 2-LCD Screen Technical Specifications.....	15
Figure 7-Pin Assignments for LCD Screen.....	16
Figure 8-Software Flow Chart.....	17
Figure 9-Overall Circuit.....	18
Figure 10-Negative Feedback Circuit.....	19
Figure 11-Current to Voltage Converter Circuit.....	19
Figure 12-SP03 Text to Speech Synthesizer with Pin Description.....	20
Table 3-SP03 Pin Description.....	21
Table 4-Estimated Design Cost.....	22

Introduction:

Diabetes is a disease that currently affects 18.2 million Americans, comprising 6.3% of the American population, with new cases continually developing. It is the fifth leading cause of death in the United States. Diabetes is a disease where the body does not properly use or produce insulin. There are two major types of diabetes which are type I and type II. Type I diabetes is where an individual's body does not produce insulin. Type II diabetes is where a individual's body does not properly use insulin combined with a relative insulin shortage within the body. Type II diabetes is by far the more common type with about 90% of people with diabetes having this form. Insulin is a hormone produced in the human body which is needed for the conversion of sugar, starches, and other food into energy. With out insulin the body would not be able to receive the amount of energy needed to function, which is why diabetes is such a serious disease.

The major problem with diabetes is that the underlying causes of it are currently unknown. Various factors have been determined to play a role in diabetes such as genetics, obesity, and lack of exercise. At this time, there is no cure for diabetes so life-long treatment is the only alternative. These treatments can consist of blood glucose monitoring combined with insulin injections, keeping to a strict diet to control sugar intake, and exercise for weight control. A diabetic person who does not monitor their blood glucose levels runs the risk of falling into insulin shock and other very serious complications.

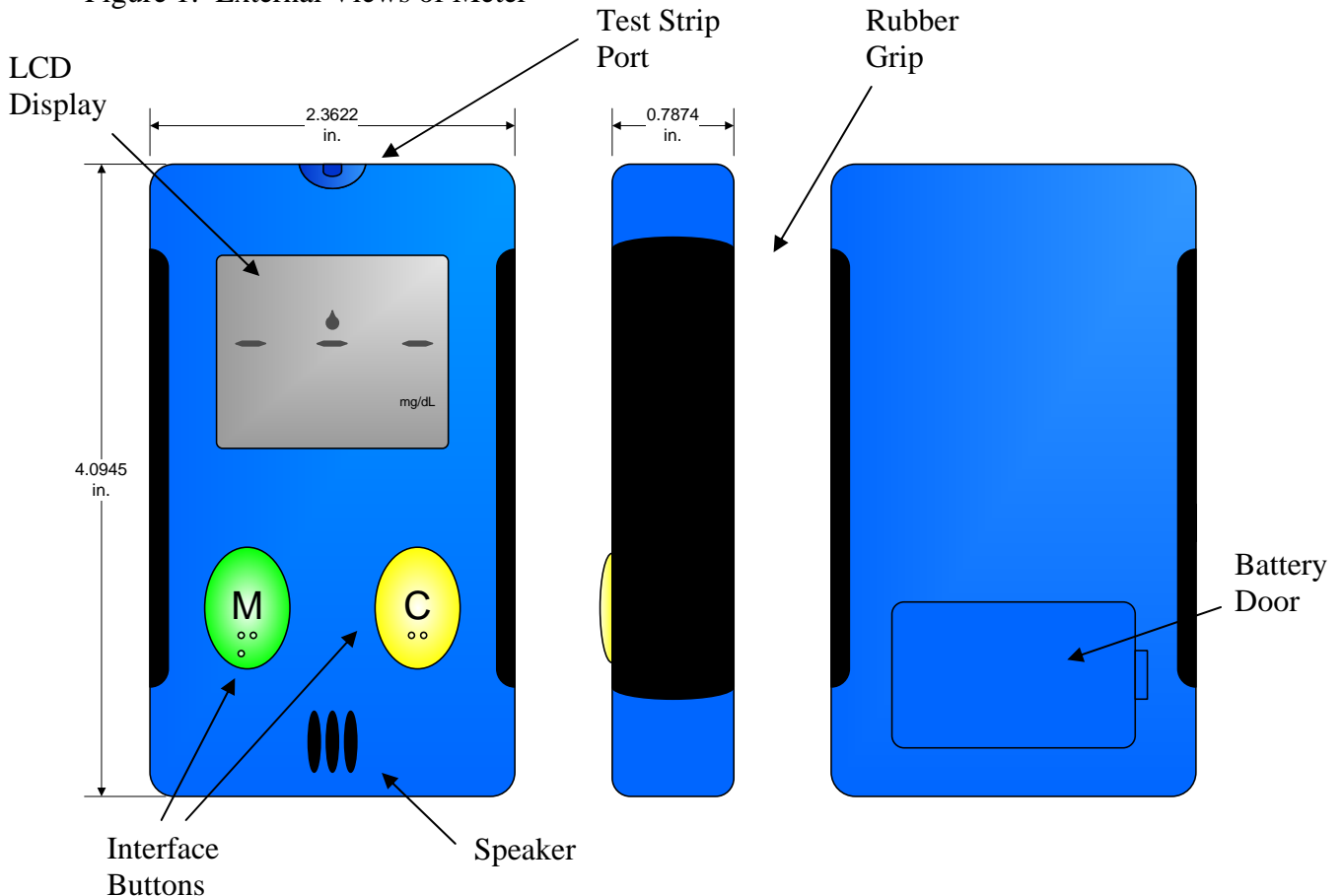
The most popular method for monitoring ones blood glucose levels is through the use of a portable glucose monitor. These devices are made relatively small to maximize their portability, but still perform their intended function. Portable meters are battery operated and can analyze a very small sample of blood to a high degree of accuracy. Over time, these devices have become more user-friendly and more reliable. However, the majority of the meters currently on the market are designed for an individual who has no physical limitations. That is, the meters do not facilitate the population of people who are diabetic and have disabilities. There are many disabilities commonly associated with diabetes such as vision loss, hearing impairment, and motor control impairment which hinder the use of a standard meter. Our assigned patients include: a young patient who has partial vision loss, an elderly patient who has total vision loss, a patient who has Parkinson's disease and has tremors, and a patient who has partial hearing loss. While a few meters do take the needs of these disabilities into consideration, they are very expensive and bulky as well.

The design being proposed is an accurate, reliable glucose meter that will incorporate features aimed at catering to the needs of those patients with disabilities. Examples of such features include a large screen, step-by-step audio instructions, simple operation, and an anti-slip casing design. Diabetic patients have a wide range of age as well as various disabilities which makes the proposed blood glucose meter suitable for a major portion of the market.

Design:

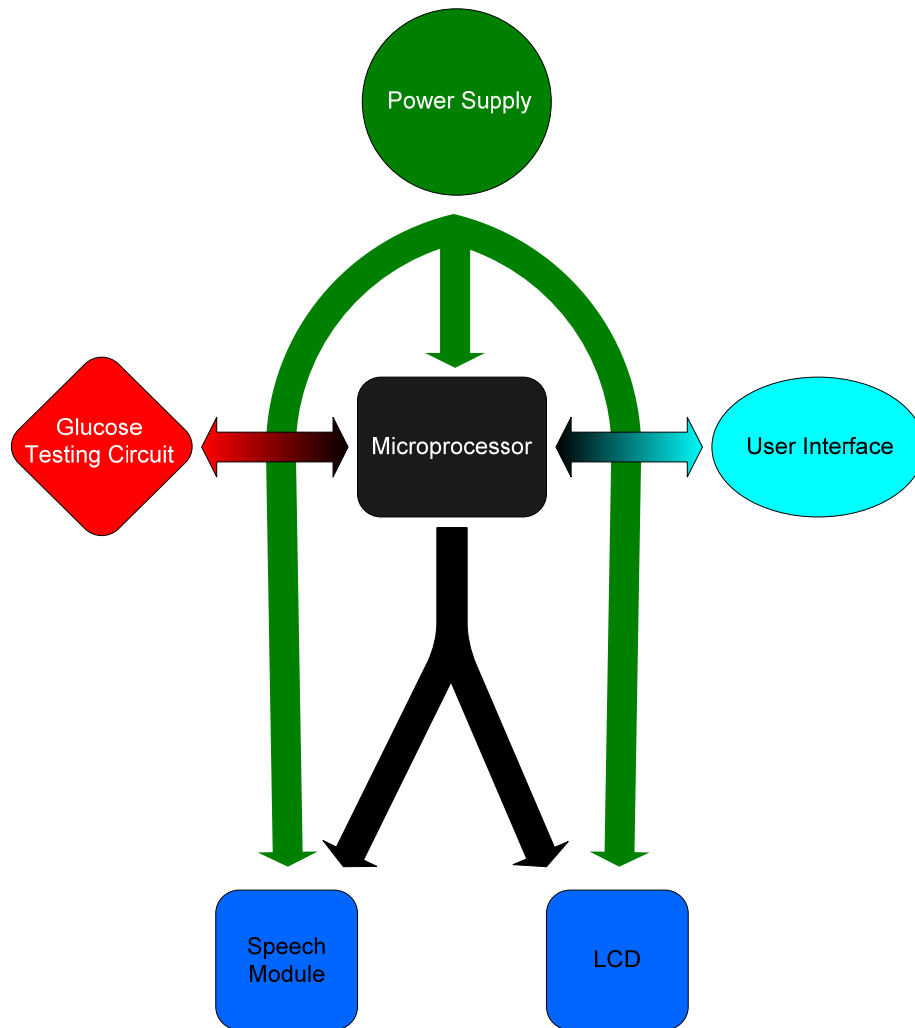
The proposed blood glucose meter will be able to cater to the needs of vision, hearing, and motor control impaired persons through the addition of several key features and modifications. A large, high contrast, liquid crystal display (LCD) will be used for easy viewing of the instructions and results for those patients with hearing loss or slight vision loss. It will have step-by-step audio output for those patients with severe to complete vision loss. This audio output will prompt the user through the complete testing procedure and as well as all other functions of the meter. The meter will also have distinctly colored, textured buttons and rubber side grips for those patients who have motor control difficulties. The size and texture of the buttons will allow the user, regardless of their disability, to easily distinguish between them. This will reduce the chance of user errors from their disabilities. The rubber side grips will allow for enhanced grip on the meter which results in easier handling for those patients with impaired motor control. In addition, the device will have an ON/OFF switch different from the operation buttons to reduce patient confusion. Also, to maintain portability, the meter will be battery powered. Figure 1 is an illustration of the casing design, and incorporated external features.

Figure 1: External Views of Meter



The glucose meter will be controlled through the use of a microprocessor. This microprocessor will essentially interface and communicate with each part of the proposed meter. Its main function is to communicate with the user interface and allow the patient to control what function the meter is performing. This will be done visually through the LCD screen, audibly through the speaker, or both. The microprocessor will receive incoming data from the glucose test circuit, the site of the chemical testing of the patients' blood. This will happen when the user inserts a test strip and adds a blood sample of the appropriate size. The LCD screen will display instructions and test results as from the microprocessor at the proper times. The audio output of the proposed meter will be generated from a speech module within the device. This speech module translates the data from the microprocessor and generates an audio output via the attached speaker for the user to hear. Figure 2 shows the block diagram of these described processes.

Figure 2: General Block Diagram of Design



Testing Procedure:

The proposed meter will use commercial test strips designed for the One Touch Ultra® glucose meter made by Lifescan. The testing procedure begins when a single glucose test strip is then inserted into the port at the top of the meter. An on-screen prompt asks the user for the condition of the test, ie. before a meal, after a meal, etc. This information is important because the time of day and food intake affects the measurement. The meter will then tell the user to apply the blood sample to the strip. The measurement will take approximately 10 seconds and the results will then be displayed on the screen and spoken verbally. Instructions to remove and dispose the test strip will follow.

If the meter is due for calibration with a stock glucose solution, the “C” button will initiate calibration routine. The calibration requires a test strip to be inserted into the meter and a stock glucose solution of a known concentration applied to the strip. The meter compares the results with the known concentration and adjusts accordingly. The “M” button serves as a recall button for the stored test results.

Measurement Method:

The method for measuring the glucose concentration in a whole blood sample will be of the amperometric type. The glucose sensor is an electrochemical diagnostic strip which uses glucose oxidase enzymes in conjunction with three electrically conductive electrodes. Two of these electrodes are ‘working’ electrodes meaning they are the measured electrodes, and the third is a reference electrode (Fig 3). These electrodes have an impedance which makes them suitable for amperometric measurement. With a strip inserted into the meter, a predetermined current (1 μ A) is constantly applied between the working and reference electrodes. The potential difference of this current is constantly monitored by the meter while the strip is in place.

The enzymes of the strip are contained within a ‘reaction zone’. When the enzyme becomes catalytically active (blood sample is applied correctly), the enzyme and mediator compound transfer electrons to the electrode. This then bridges the gap between the electrodes and results in a rapid voltage drop. When this drop goes below a predetermined threshold, sample detection is initiated (Fig 4). A constant voltage (300 mV) is then applied to the strip, and the electrical response is measured for a predetermined amount of time (Fig 5). If there is a 10% difference in electrical response between the two working electrodes, then the meter deems an error. This requires either more blood or inserting a new strip and repeating the test. The determination of this requirement is related to the amount of time that has passed in error.

The current that is produced with correct fluid application is proportional to the glucose concentration of the sample. Determination of the glucose concentration comes from comparison to previously obtained control values. The current-to-glucose relationship becomes linear after about 3 seconds from the initiation time. The measurement is taken

at around 5 seconds after, to account for any delay. The measurement could be taken at a later time, but keeping the measurement process relatively fast is beneficial to the user. Of course, once a predetermined time is set (5s), accurate and precise results require that the same time be used each time. In any case, the accuracy of the current determination depends on the accuracy of the initiation determination.

Figure 3: Test Strip Schematic

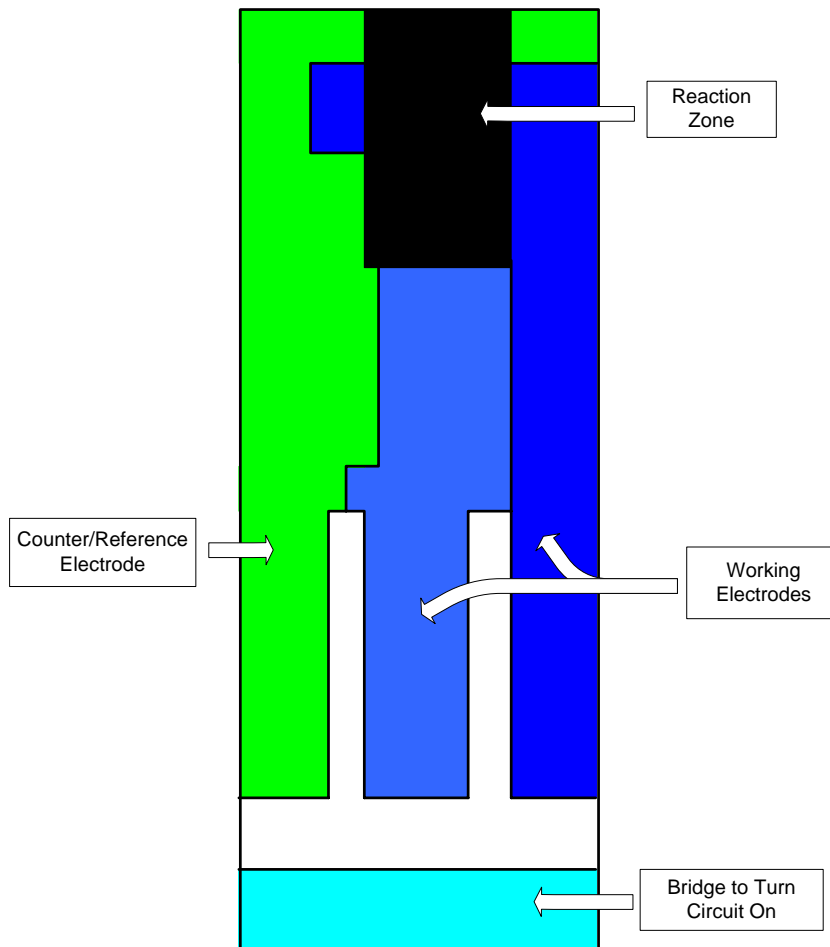
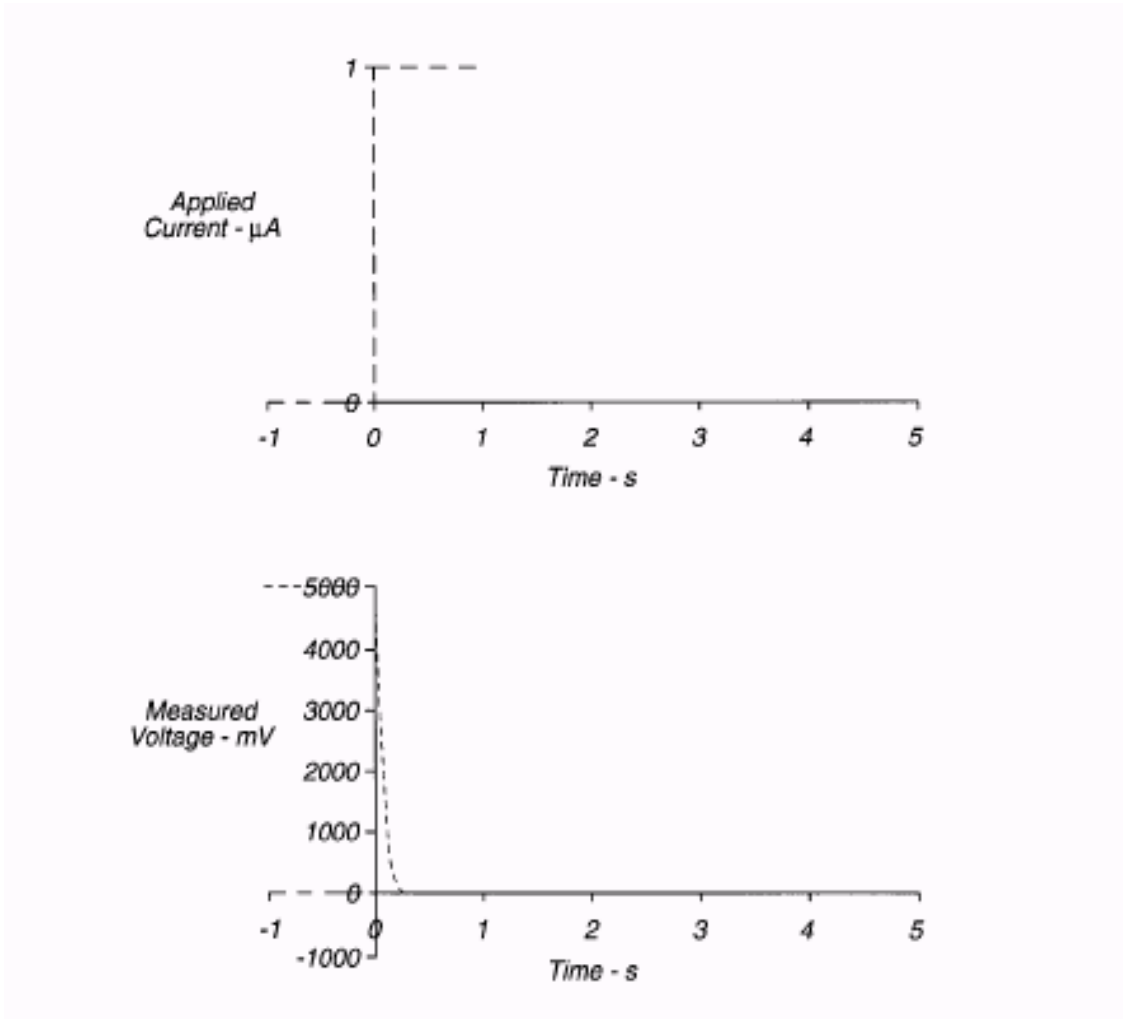


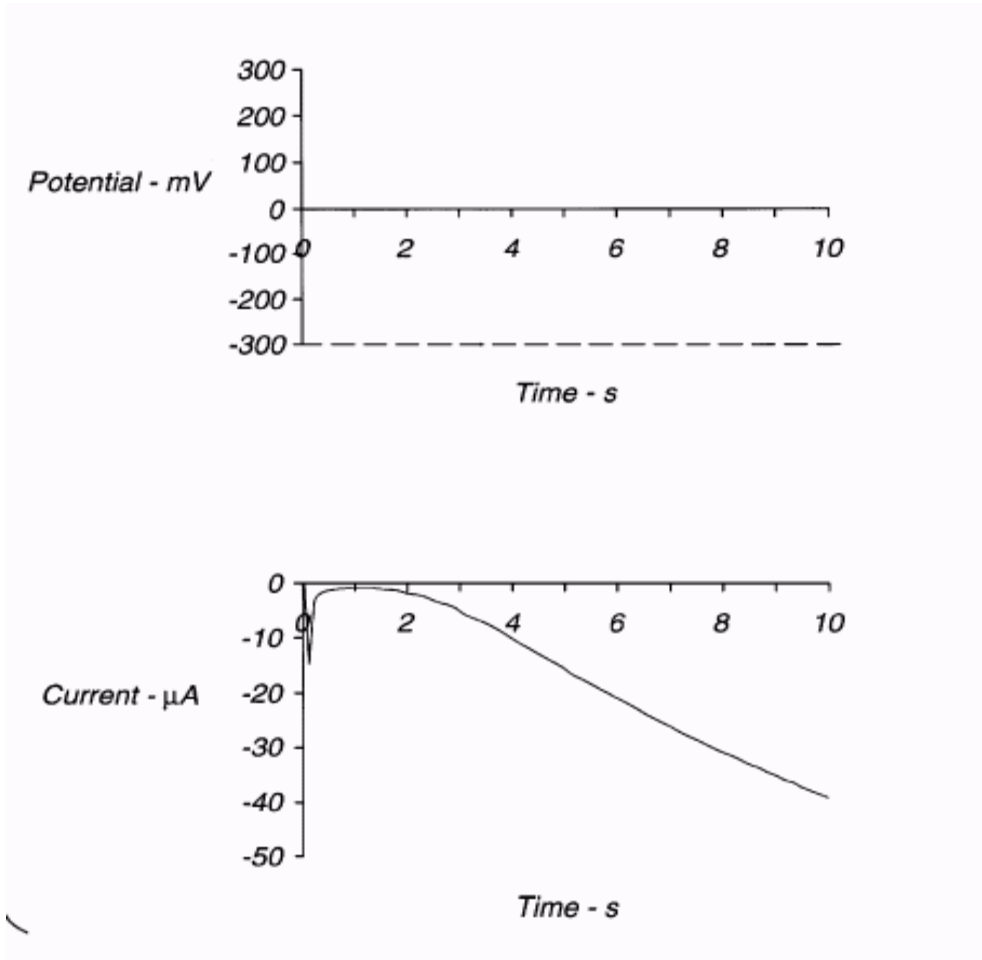
Figure 4: Graph of Applied Current and Measured Voltage vs. Time for Sample Detection Process



Source: U.S. Patent No. 4,545,382

Figure 4 is a plot of applied current and measured voltage that depicts the sample-detection process. Prior to the blood sample being introduced ($t < 0$), a constant 1 μA current is applied between the electrodes, but negligible current flows. The measured voltage is determined by the circuit power supply voltage which is 5 volts. When the sample is introduced into the cell ($t = 0$), the applied current can flow between the electrodes and the measured voltage falls rapidly. When the voltage falls below a threshold voltage, the device switches from constant applied current to constant applied voltage.

Figure 5: Graph of Applied Voltage and Resulting Current Response vs. Time for Measurement Method



Source: U.S. Patent No. 4,545,382

Figure 5 is a graph of the applied potential and measured current as a function of time after sample detection. Sample is detected at time $t=0$, and a voltage is applied between the working and reference electrodes immediately thereafter. As a result, current flows between the electrodes. The current after a predetermined time, generally at least about 3 seconds for glucose in blood, is a measure of the analyte concentration. That duration generally provides sufficient time to dissolve reagents and reduce an amount of mediator that is readily measurable.

Microprocessor:

The microprocessor we have chosen for this design is the PIC16F874A, manufactured by Microchip. This particular microprocessor incorporates all of the functions necessary to meet our specifications. The microprocessor will be used to control the glucose test circuit, analyze measurements, handle user input from buttons, drive an LCD display, and control a speech module. This chip will be easy to program due to the equipment and development software available in the lab. The microprocessor will be programmed in assembly using Microchip MPLabIDE.

Processor Features

- Operating Speed: 20 MHz clock input
- FLASH Program Memory: 4096 words
- Data Memory: 192 bytes
- EEPROM Data Memory: 128 bytes

Peripheral Features

- Synchronous Serial Port (SSP) with SPI (Master mode) and I2C (Master/Slave mode)
- Universal Synchronous Asynchronous Receiver Transmitter (USART/SCI)
- Parallel Slave Port (PSP) 8-bits wide with external Read, Write, and Chip Select controls

Analog Features:

- 10-bit, 8 Channel Analog-to-Digital Converter (A/D)
- 2 Analog Comparators
- Programmable on-chip voltage (Vref) module
- Programmable input multiplexing from device inputs and internal voltage reference

Special Features:

- 100,000 erase/write cycle Enhanced FLASH program memory
- 1,000,000 erase/write cycle Data EEPROM memory
- In-Circuit Serial Programming
- Programmable code protection
- Power saving SLEEP mode
- In-Circuit Debug

Figure 6: Microprocessor Pin Diagram

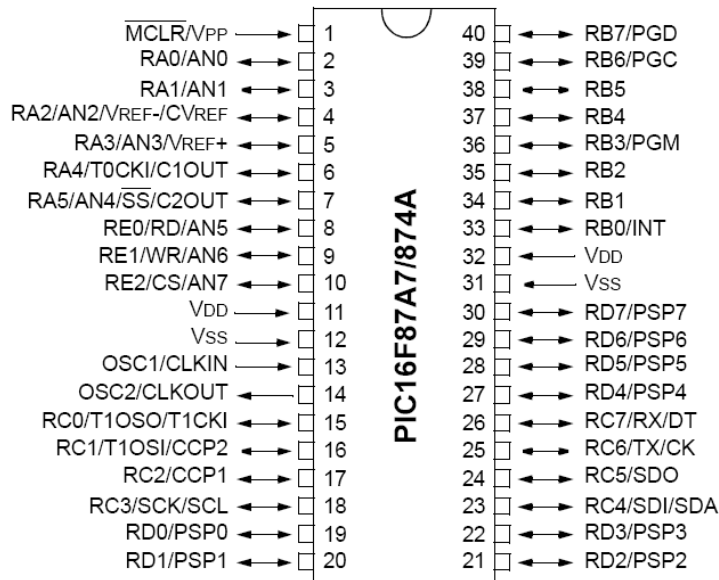


Table 1: Microprocessor Pin Descriptions

Pin	Description	Use	Component	Component Detail
1	Vpp	Programming Voltage		
2	CinA	Comparator Input A	Glucose input	working electrode 1
5	CinB	Comparator Input B	Glucose input	working electrode 2
8	RD'	Parallel Read Control	LCD	LCD Read
9	WR'	Parallel Write Control	LCD	LCD Write
10	CS'+	Parallel Chip Select Control	LCD	LCD Chip Select
11	Vdd	Positive Supply Voltage		
12	Vss	Ground reference		
19	PSP0	Parallel Slave Data Port	LCD	LCD data in
20	PSP1	Parallel Slave Data Port	LCD	LCD data in
21	PSP2	Parallel Slave Data Port	LCD	LCD data in
22	PSP3	Parallel Slave Data Port	LCD	LCD data in
25	TX	Transmit serial (USART)	Speech Module	
26	RX	Receive serial (USART)	Speech Module	Measurements output
27	PSP4	Parallel Slave Data Port	LCD	LCD data in
28	PSP5	Parallel Slave Data Port	LCD	LCD data in
29	PSP6	Parallel Slave Data Port	LCD	LCD data in
30	PSP7	Parallel Slave Data Port	LCD	LCD data in
31	Vss	Positive Supply Voltage		
32	Vdd	Ground reference		
37	RB4	Digital Out	Speech Module	Phrase select
38	RB5	Digital Out	Speech Module	Phrase select
39	RB6	Digital Out	Speech Module	Phrase select
40	RB7	Digital Out	Speech Module	Phrase select

Chip Programming:

As previously stated, the microprocessor will be programmed using MPLabIDE and Hi-Tech C. Programming modules will be needed for serial communication to the speech module and LCD display drivers. The code will be written in C or C++ and translated into assembly language and transferred to the microprocessor. Additional programming support may come from National Instruments LabView and the Application Builder toolkit. The Application Builder is capable of converting a virtual instrument (VI) into a Windows Shared Dynamic Link Library (DLL). The DLL may then be called in C routine and then converted to assembly.

The speech module will be connected to two different ports on the microprocessor. One port contains the transmit and receive USART pins used to pass measurement values to the text-to-speech portion of the speech module. The other port contains the digital pins used to select any of the 30 prerecorded phrases stored on the module.

The following code was taken from <http://www.microchip.com/sourcecode> configures the microprocessor for serial communication to the speech module.

```
/*
Interface PIC
Designed by Shane Tolmie Feb 2001.
Microprocessor: Microchip PIC16F87x
Compiled with:      Hitech-C v7.87, developed using MPLAB v5.3
Note: all references are to PIC16C7X PDF version of Microchip manual,
DS30390E

Overall goal:      serial comms using USART to comm port of an ibm pc
compatible computer
*/
#include    <pic.h>
#include    <conio.h>
#include    <stdio.h>
#include    "always.h"
#include    "delay.h"
void serial_setup(void)
{
    /* relates crystal freq to baud rate - see above and PIC16F87x
data sheet under 'USART async. modes'
    BRGH=1, Fosc=3.6864MHz          BRGH=1, Fosc=4MHz          BRGH=1,
Fosc=8MHz          BRGH=1, Fosc=16MHz
    -----
    -
    Baud  SPBRG          Baud  SPBRG          Baud  SPBRG          Baud  SPBRG
1200  191              1200  207.3          1200  415.7          9600   103
2400   95              2400  103.2          2400  207.3          19200   51
4800   47              4800  51.1           4800  103.2          38400   25
9600   23              9600  25.0           9600  51.1           57600   16
19200  11              19200 12.0           19200 25.0           115200   8
```

```

* Comms setup:
*/

#define BAUD 19200
#define DIVIDER ((PIC_CLK/(16UL * BAUD) -1))
#define HIGH_SPEED 1

SPBRG=DIVIDER;
BRGH=HIGH_SPEED; //data rate for sending
SYNC=0; //asynchronous
SPEN=1; //enable serial port
pins
CREN=1; //enable reception
SREN=0; //no effect
TXIE=0; //disable tx interrupts
RCIE=0; //disable rx interrupts
TX9=0; //8-bit transmission
RX9=0; //8-bit reception
TXEN=0; //reset transmitter
TXEN=1; //enable the
transmitter
}
unsigned char dummy;
#define clear_usart_errors_inline
if (OERR)
{
    TXEN=0;
    TXEN=1;
    CREN=0;
    CREN=1;
}
if (FERR)
{
    dummy=RCREG;
    TXEN=0;
    TXEN=1;
}
//writes a character to the serial port
void putch(unsigned char c)
{
    while(!TXIF) //set when register is empty
    {
        clear_usart_errors_inline;
        CLRWDI();
    }
    TXREG=c;
    DelayUs(60);
}

/*
writes a character to the serial port in hex
if serial lines are disconnected, there are no errors
*/

```

```

void putchhex(unsigned char c)
{
    unsigned char temp;
    // transmits in hex
    temp=c;
    c=(c >> 4);
    if (c<10) c+=48; else c+=55;
    putchar(c);
    c=temp;
    c=(c & 0x0F);
    if (c<10) c+=48; else c+=55;
    putchar(c);
}

void putinthex(unsigned int c)
{
    #define ramuint(x)
    (*((unsigned int *) (x)))
    #define ramuint_hibyte(x)
    (*((unsigned char *)&x)+1)
    #define ramuint_lobyte(x)
    (*((unsigned char *)&x)+0)
    #define ramuchar(x)
    (*((unsigned char *) (x)))
    putchhex(ramuint_hibyte(c));
    putchhex(ramuint_lobyte(c));
    #undef ramuint(x)
    #undef ramuint_hibyte(x)
    #undef ramuint_lobyte(x)
    #undef ramuchar(x)
}

```

LCD:

The LCD screen that has been chosen for is an Optrex F-51553GNBL-LW-AB. This screen is ideal for this system because it will easily integrate with the chosen microprocessor. It is also of sufficient size that is needed to display the intended information. The LCD display will be controlled by the microprocessor using the Parallel Slave Data Port. The screen will show the instructions for proper operation of the meter and display results after test completion. Example code for a PIC16C74 is available at the PICList website (<http://www.piclist.com/techref/microchip/dotlcd.src>). Similar code will be used to setup the microprocessor to display graphical information on the LCD screen. The LCD screens technical specifications are displayed below:

Table 2: LCD Screen Technical Specifications

Technical Specifications	
Module Type:	Monochrome-Graphic
Size:	2.8"
Type:	Transmissive
LCD Mode:	Blue/White
Backlight:	White LED
Dot Format:	128*64
Operating Temperature:	-20 to 70
Storage Temperature:	-30 to 90
Luminance:	100 at backlight surface
Contrast Ratio:	8:1
Mass:	33.8
Vertical Viewing Angle:	-35/35
Horizontal Viewing Angle:	-40/40
Viewing Direction:	6:00
Outer Dimension:	89.7mm (W) x 49.8mm (H) x 11.8mm (D)

Figure 7: Pin Assignments for LCD Screen:

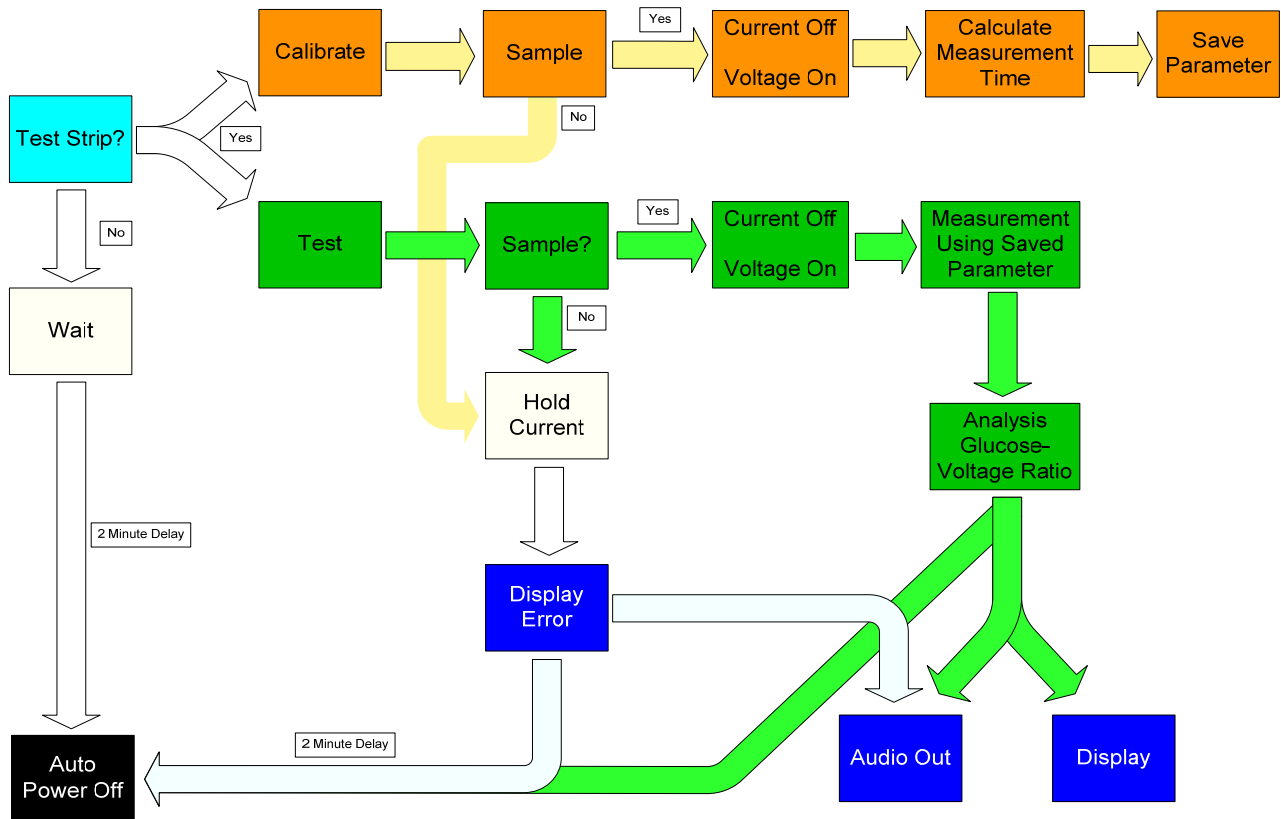
4. I/O Terminal		
4.1. Pin Assignment		
CN1		
No.	Symbol	Function
1	$\overline{CS1}$	Chip Select Signal L : Active
2	\overline{RES}	Reset Signal L : Reset
3	A0	H : D0~D7 are Display Data L : D0~D7 are Instructions
4	\overline{WR}	Write Signal L : Active
5	\overline{RD}	Read Signal L : Active
6	D0	Data Bus Line
7	D1	Data Bus Line
8	D2	Data Bus Line
9	D3	Data Bus Line
10	D4	Data Bus Line
11	D5	Data Bus Line
12	D6	Data Bus Line
13	D7	Data Bus Line
14	V _{DD}	Power Supply for Logic
15	GND	Power Supply (0V, GND)
16	V _{OUT}	DC/DC Voltage Converter Output
17	CAP3-	DC/DC Voltage Converter Negative Connection
18	CAP1+	DC/DC Voltage Converter Positive Connection
19	CAP1-	DC/DC Voltage Converter Negative Connection
20	CAP2-	DC/DC Voltage Converter Negative Connection
21	CAP2+	DC/DC Voltage Converter Positive Connection
22	V ₁	Power Supply for LCD Drive V ₁ = 1/7, V _s
23	V ₂	Power Supply for LCD Drive V ₂ = 2/7, V _s
24	V ₃	Power Supply for LCD Drive V ₃ = 5/7, V _s
25	V ₄	Power Supply for LCD Drive V ₄ = 6/7, V _s
26	V ₅	Power Supply for LCD Drive V ₅ , V _{OUT}
27	VR	Voltage Adjustment Pin
28	C86	Interface Mode Select Signal H : 68 series L : 80 series
29	P/S	Parallel / Serial Data Select Signal H: Parallel L: Serial
30	IRS	This terminal selects the resistors for the V ₅ voltage level adjustment. IRS="H" :Use the internal resistors IRS="H" :Do not use the internal resistors. The V ₅ voltage level is regulated by an external resistive voltage divider attached to the VR terminal.

F-51553GNBJ-LW-AB (AB) No. 2002-0243	OPTREX CORPORATION	Page 14/24
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Hardware / Software:

The basic glucose meter is modeled as a power source, a variable resistor for the test strip, and an analog to digital (A/D) converter. Glucose levels are determined by inserting a test strip into the meter and applying a drop of blood. A voltage is then applied to the test strip and the current that is returned is a direct linear relationship to the amount of glucose in the blood. Higher concentrations of glucose return a larger current. The test strips can be modeled as variable resistors based on the amount of glucose in the blood sample. Once the voltage has been applied, a 10 second delay allows the strip to reach equilibrium. After this delay the voltage drop across the strip is measured and converted in the A/D converter. The A/D converter is connected to an input of the mini-computer and the results are interpreted and displayed by the software.

Figure 8: Software Flowchart



Circuit:

The electrical circuit for the measurement of glucose concentration has specific functions that must be performed. These functions include:

- Apply a predetermined current between the working and reference electrodes
- Monitor a potential difference across the electrodes
- Determine when the potential difference falls below a predetermined threshold voltage to indicate sample detection
- Response to sample detection for applying a predetermined constant voltage to the sample
- Measure the resulting electrical response
- Calculate the glucose concentration by using the measured electrical response.

Figure 9: Overall Circuit

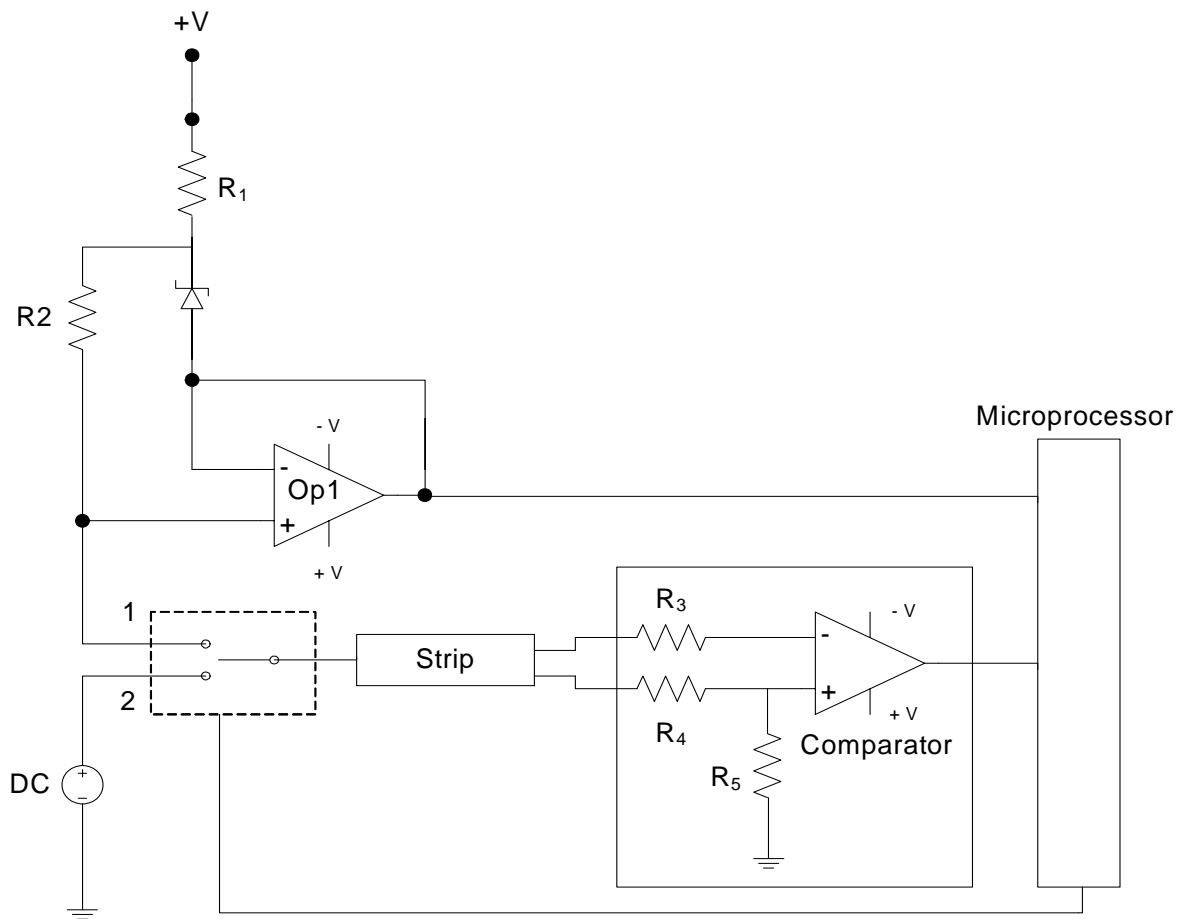
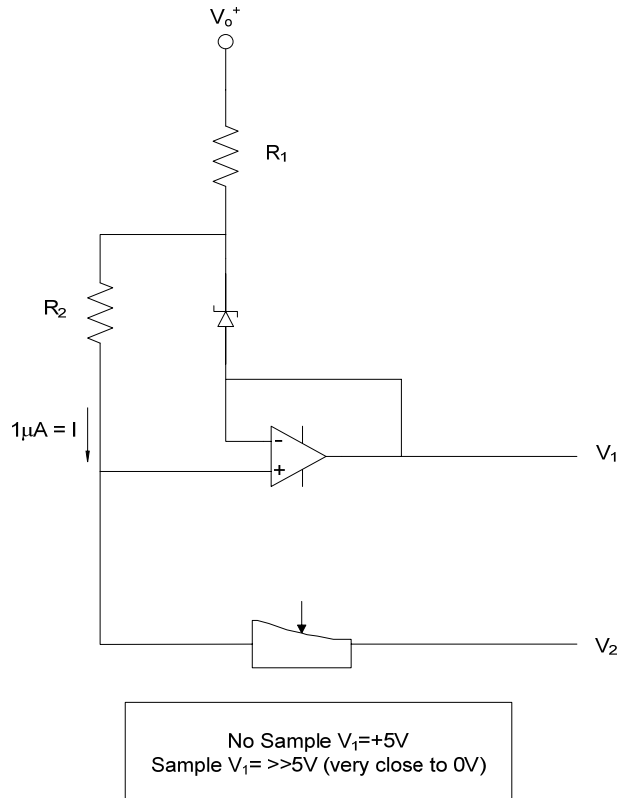


Figure 10: Negative Feedback Circuit

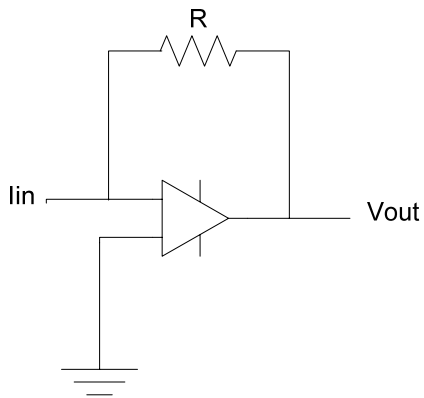


$$R=R_1+R_2$$

$$V=IR$$

$$R=V/I$$

Figure 11: Current to Voltage Converter Circuit



$$V_{out} = I_{in} R$$

Speech Module:

Of the estimated 18.2 million Americans who have diabetes, more than half are at risk for vision loss. After 20 years of diabetes without strict control of blood glucose levels, there is a 90 percent chance of developing eye disease. Ocular complications of diabetes include retinopathy, vitreous hemorrhage, cataract, and glaucoma. About 40 percent of people with diabetes will have at least mild retinopathy, which is characterized by leakage of fluid or blood from vessels in the retina. Retinopathy causes blurred or hazy vision and can even lead to complete blindness if damage to the eye has progressed to hemorrhaging and scarring.

With this direct correlation of diabetes to vision loss, it is evident that personal glucose meters are used by individuals with impaired eyesight. Thus, a glucose meter with an incorporated voice output would prove to be very useful. An SP03 speech synthesizer is a voice module that allows for output of audible numbers, words, and phrases. Shown in Figure 11, the module can be programmed to output up to 30 predefined phrases. These phrases can be instructions to operate the meter, as well as the glucose reading at the end of a test.

There are 32 serial commands that can be sent to the SP03. Thirty of these (commands 1 to 30) are used to speak one of the thirty predefined phrases. To speak any phrase, it is a matter of sending a single command byte to the SP03. When the SP03 is finished speaking, it will return the command as an acknowledgement. When the command is acknowledged, the module will be ready to receive another command. Once programmed, the SP03 will be controlled by the microprocessor to implement the necessary phrases with the corresponding screens.

Figure 12: SP03 Text to Speech Synthesizer with Pin Description

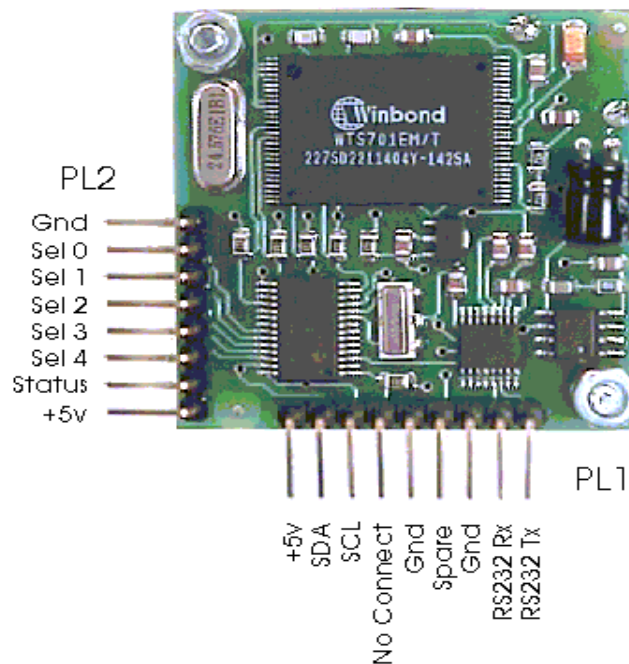


Table 3: SP03 Pin Descriptions

PL1	
Pins	Description
+5V	5V Power Supply - up to 100mA
SDA	IC2 bus SDA connection
SCL	I2C bus SCL connection
Gnd	The 0 volt Ground line
Spare	
Gnd	The 0 volt Ground line
RS232 Rx (receive)	Connect to Tx on the PC
RS232 Tx (transmit)	Connect to Rx on the PC
PL2	
Gnd	The 0 volt Ground line
Sel 0	These are the binary select inputs. They select one of the 30 predefined phrases.
Sel 1	
Sel 2	
Sel 3	
Sel 4	
Status	High when speaking, Low when done
+5V	5V Power Supply - up to 100mA

Source: <http://www.robot-electronics.co.uk/htm/Sp03doc.shtml>

Other Technical Specifications:

Test Parameters:

Result Range: 20-600 mg/dL

Calibration: Plasma – Equivalent

Sample: Flesh Capillary Whole Blood

Sample Size: 1.0 µL minimum

Test Time: 5 Seconds

Assay Method: Glucose Oxidase Biosensor

Glucose Units: mg/dL

Hematocrit Range: 30-55% (% of red blood cells in whole blood)

Cost:

The total cost of the meter has been estimated to be about \$260.00 as shown in Table 4. This \$260 cost is broken down into the essential components that are listed. As the project moves forward, there may be significant variance in this overall cost due to unplanned events and design changes.

Table 4: Estimated Design Costs

Part	Cost
Microprocessor	\$7.00
SP03 Speech Module	\$102.00
LCD Screen	\$30.00
Circuit Boards	\$17.00 each \$51.00 for 3
Case	\$20.00
Other components	\$50.00
Total	\$226.00

Safety Issues/Constraints:

The device should take into consideration user safety. The user should be protected from the risk of electrical shock through proper or improper handling. The meter should not have any sharp edges or dangerous pieces. The meter should not be used in extreme temperatures or extreme moisture.

Conclusion:

Current blood glucose meters do not adequately accommodate all of the needs of diabetic clients. The proposed Accessible Blood Glucose Meter will incorporate features to assist blood sugar monitoring in patients with vision impairment, hearing loss, tremors, and motor control difficulties. The user interface will be easy to learn for clients of all ages and abilities. The proposed meter will be easy to calibrate, operate, and handle. The on-screen and audio instructions will make blood glucose monitoring more accessible for patients. The device will also be an attractive lower cost alternative to commercially available blood glucose meters.

Accessible Blood Glucose Monitor

**University of Connecticut
Biomedical Engineering Senior Design
Team 2**

**Sponsored by the Rehabilitation Engineering Research Center on Accessible
Medical Instrumentation (RERC on AMI)**

Team 2 is: Matthew Bularzik, David Price, Michael Rivera

Email: gPodProject@gmail.com

Website: <http://www.bme.uconn.edu/bme/sendes/Spring06/Team2/index.html>

