



Electronic Technology in Home Medical Equipment in Chinese Market

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Abstract <p>Home medical equipment has been an emerging industry in recent years, possessing small bulk, agile operation and relative inexpensive price. In the essay, the principle and classification of home medical equipment are introduced through the principle and structure of four types of essential home medical equipment: pulse oximeter, electronic sphygmomanometer, electronic thermometer and glucose meter. Then the application of photodiode, pressure sensor, biosensor, temperature sensor, amplifiers, filters and others are discussed and then the development tendency of electronic technology in the future is forecast.</p> <p>Also the Chinese home medical equipment market prospects based on economic and society environment via GDP, income and ageing population are analyzed, estimating China's enormous potential. China could become one of the largest market in the near future. Finally, SWOT analysis is used about entering Chinese home medical equipment market for domestic corporations.</p>			
Keywords oxygen saturation, photodiode, pressure sensor, biosensor, market prospect			

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1 Target of thesis

Last December, an article about the blossom of Chinese home medical equipment market which inspired me to research the home medical equipment. Electronic technology is widely applied in the medical device industry, therefore a deep study about it is necessary. And the article cited some conclusion from a report about Chinese HMEs market prospects, while it was difficult to read the report because it is not freely to achieve. So some materials were searched and extracted by myself so that to form an idea of my own about the prospects.

2 The introduction of home medical equipment

In this chapter, it is introduced what home medical equipment is, its development and the classification.

2.1 Definition of home medical equipment

Home medical equipment is mainly suitable for family use. It differs from the hospital medical equipment in simple operation, small volume, ease of carry. Many years ago, many families were equipped with a variety of simple medical apparatuses and instruments, such as thermometer, stethoscope and sphygmomanometer.

These simple medical apparatuses and instruments are very convenient and practical, especially for some patients with a chronic disease, for monitoring the patient's condition real-time and for timely medical treatment. In recent years, along with the rising of living standards, people have paid more and more attention to the health of themselves and their families. The antique medical apparatus and instruments cannot satisfy the need of some families and all kinds of simple and practical, fully functional new home medical equipment emerged and have become necessity in people's lives.

2.2 Classification of home medical equipment

Home medical equipment can be divided into three types in general.

Table 1. Classification of home medical equipment^[1]

Home health care equipment	Sphygmomanometer, Electronic thermometers, Blood glucose meter, Pulse oximeter
Home health massage product	Electric massage chair, Massage belt, Foot tub, Foot massage device, Slimming belt
Home medical rehabilitation equipment	Oxygen concentrator, Crutch, Wheelchair, Audiphones, Respiratory Assist devices, Artificial limb

3 Application of electronic technology in typical home medical equipment

Eight major trends in the development of electronic technology in HMEs (Home Medical Equipment):

- Low power consumption, compact structure, ease of operation
- Low cost, widespread
- Large batch, accuracy, conformance and reliability
- Safety, low side-effect
- Networked, intelligent
- Diversity, wide application
- Prevention first, sustainability
- Necessity in daily life

3.1 Pulse oximeter

This chapter will introduce the concept of oxygen saturation and pulse oximetry and the application and principle of electronic apparatus in pulse oximeter.

3.1.1 Oxygen saturation

Oxygen saturation (SpO₂)

Oxygen saturation is a significant physiological parameter to reflect breath and circulation. For people with COPD, asthma, anesthetic patients, premature babies and neonates, evaluating oxygen saturation and ascertaining low oxygen patients could be prevented from accidental deaths cause by hypoxia. [2]

What does SpO₂ mean?

SpO₂ stands for peripheral capillary oxygen saturation, an estimate of arterial oxygen saturation. More specifically, it is the percentage of HbO₂ (hemoglobin containing oxygen) compared to the total amount of hemoglobin in the blood (oxygenated and non-oxygenated hemoglobin). Formula:

$$S_pO_2 = \frac{HbO_2}{HbO_2 + Hb} \quad (1)$$

HbO₂ means the number of hemoglobin containing oxygen

Hb means the number of hemoglobin without oxygen

SpO₂ can be measured by pulse oximetry, an indirect, non-invasive method (meaning it does not involve the introduction of instruments into the body).

What is a normal SpO₂ level?

This value is represented by a percentage. If your device says 96%, this means that each red blood cell is made up of 99% oxygenated and 4% non-oxygenated hemoglobin. Normal SpO₂ values vary between 95 and 100%.

Good blood oxygenation is necessary to supply the energy your muscles need in order to function, which increases during a sports activity. If your SpO₂ value is below 94%, that could be a sign of poor blood oxygenation, also called hypoxia.^[3]

3.1.2 Pulse oximetry

What is pulse oximetry?

Pulse oximetry is a way to measure how much oxygen your blood is carrying. By using a small device called a pulse oximeter, your blood oxygen level can be checked without needing to be stuck with a needle. The blood oxygen level measured with an oximeter is called your oxygen saturation level, abbreviated SpO₂.

It works by emitting and then absorbing a light wave passing through blood vessels (or capillaries) in the fingertip. A variation of the light wave passing through the finger will give the value of the SpO₂ measurement because the degree of oxygen saturation causes variations in the blood's colour.

3.1.3 Structure and principle

The fundamental physical property that allows the pulse oximeter to measure the oxygen saturation of hemoglobin is that blood changes colour as hemoglobin absorbs varying amounts of light depending on its saturation with oxygen. Oxyhemoglobin does not absorb much red light, but as the hemoglobin oxygen saturation drops, more and more red light is absorbed and the blood becomes darker. At the near infrared range of light however, oxyhemoglobin absorbs more light than reduced hemoglobin.



Figure 1. Sample of pulse oximeter^[4]

Figure 1 illustrates a typical pulse oximeter, the upper number is the oxygen saturation and the number below means pulse.

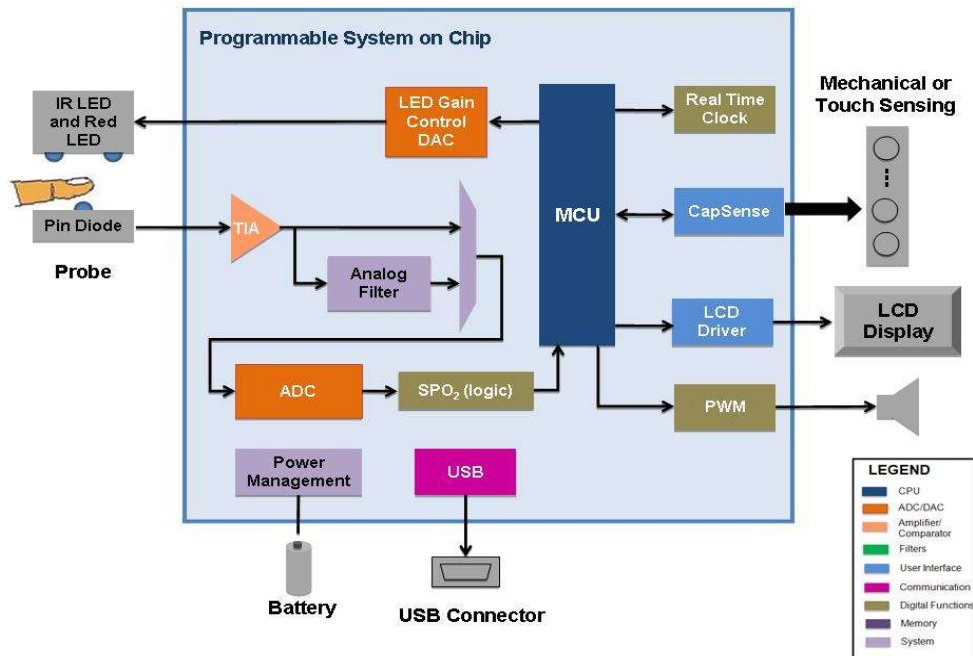


Figure 2. Pulse oximeter analogue^[5]

Basic measuring principle is shown in Figure 3, people put the finger on the probe with red light and infrared emission. The two LEDs have to be very nearby, ensuring that they are very close to the location of the finger, the accuracy of detection can be guaranteed.

Red light (660nm) and infrared light (940nm) work separately. When the red light works, infrared light is turned off. When using one photo diode, it can be ensured that the red light and infrared light do not cause any interference. In itself, it is photoelectric sensor technology.^[6]

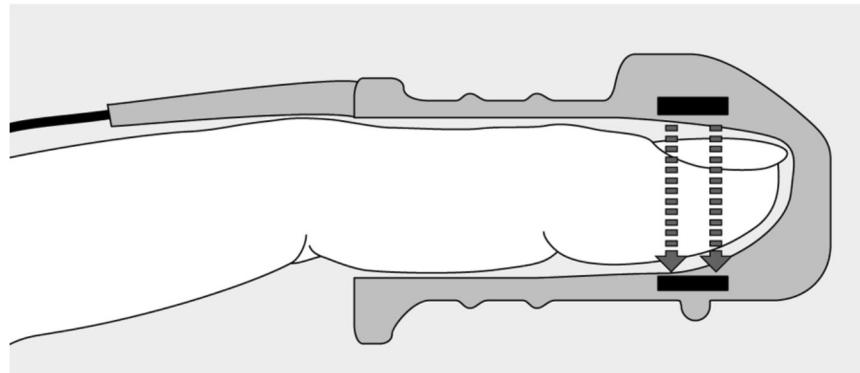


Figure 3. Finger detection^[7]

DAC (Digital to analogue converter) converts digital signal to analogue signal. In the pulse oximeter, it is used to control the current and filter of the two LEDs, guarantee low noise and relative pure output.



Figure 4. DAC^[8]

Photodiode

Photodiode is the most common photoelectric sensor, converting the optical signal to electric signal. The shape of photodiode is just like a general diode. The fundamental property of a diode is that current flows through only to one direction, called the forward direction. Current trying to flow in the reverse direction is blocked. The principle is the PN junction, which is constituted by a P-type semiconductor and an N-type semiconductor.^[9]

P-type semiconductor: P means positive, the majority charge carriers are holes with positive electric charge and fractions are electrons.

N-type semiconductor: N means negative, the majority charge carriers are electrons with negative electric charge and fractions are holes.

The holes in the P region tend to diffuse into N region, leaving negative charge ions in P region. Simultaneously, the electrons in the N region tend to diffuse into P region, and positive charge ions are left in N region.

As a consequence, the diffusion generates a space charge region, and an electric field generated in the space charge. Due to positive charge ions left in N region and negative charge ions left in P region, the direction of electric field is from N to P region, while the diffusion is reversed. The two simultaneous phenomena establish balance, charge carrier cannot flow through the electric field. With the exception that the minority holes in N region and electrons in P region generate an extremely small current, called dark current.

When LED light stimulates the photodiode, the photon with energy access is the PN junction, the energy will release the electrons on covalent bond and form more holes. Relatively larger amount of holes in N region and electrons in P region generate photocurrent just like dark current.

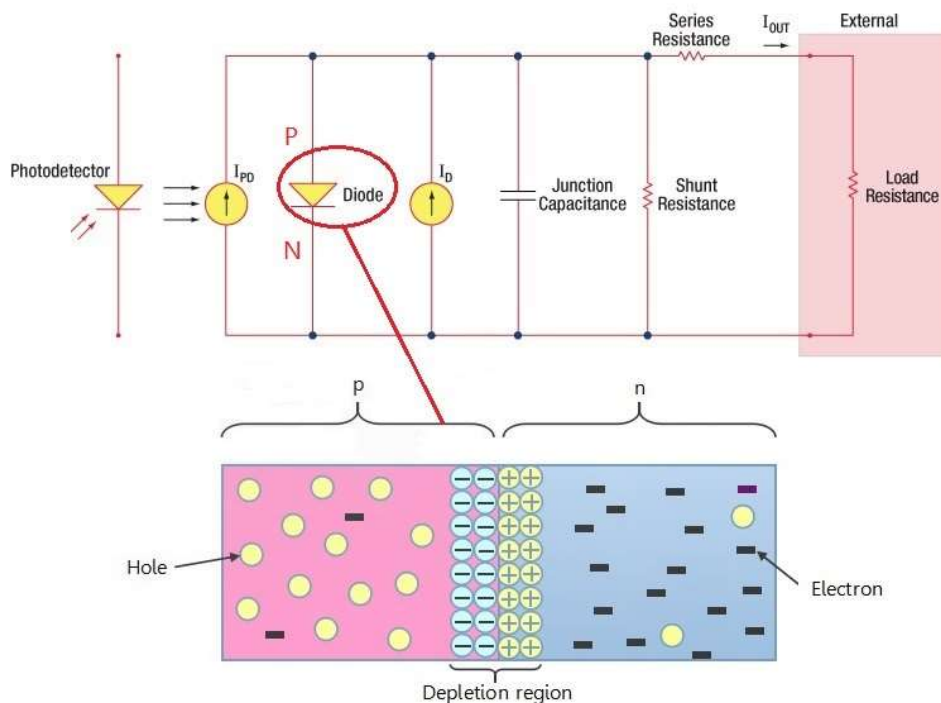
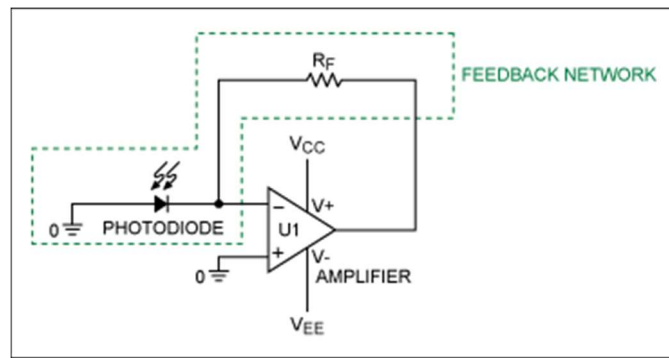


Figure 5. Photodiode circuit and PN junction^[10]

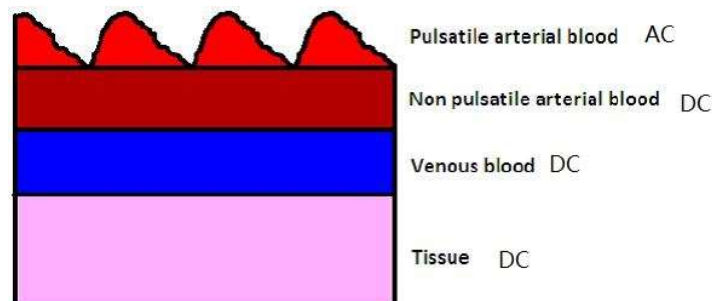
TIA (Transimpedance Amplifier)

Transimpedance amplifiers (TIAs) are widely used to translate the current output of sensors like photodiode to voltage signals, because many circuits and instruments can only accept voltage input.

An operating amplifier output through a feedback resistance to the inverting input is the simplest structure of TIA. Like in Figure 6.

Figure 6. Basic TIA circuit^[11]

When the photodiode captures the non-absorbed light from the LEDs, this current signal is inverted by an inverting operational amplifier (Op Amp), which is contained in the TIA. And through the amplifier, we can attain the hierarchy of light absorption. This output voltage signal represents the light that has been absorbed by the finger and is divided into DC component and AC component. The DC component represents the light absorption of the tissue, venous blood, and non-pulsatile arterial blood. The AC component represents the pulsatile arterial blood. The result of the signal is like the one in Figure 7.

Figure 7. Light absorption diagram^[12]

The light absorption coefficient of venous blood and tissue (include skin, muscle and fat) is constant, it only affects the DC component of light absorption. While the variation of amount of HbO_2 (oxyhemoglobin) and Hb (hemoglobin) in arterial blood is periodically following the pulsation. As a consequence, the light absorption in arterial blood is variable, pulsatile and non-pulsatile. Then the voltage signal flows via an analogue filter, the red and infrared light absorption will be separated.

Data Conversion

Next step is converting the voltage signal to digital number that represents the quantity's amplitude so that the SpO₂ could be calculated. ADC (analogue to digital converter) will be used. Formula^[13]:

$$R = \frac{(I_{AC}/I_{DC})R}{(I_{AC}/I_{DC})IR} \quad (2)$$

R: Light Absorption Ratio

(IAC)R: red light (660 nm) absorption in pulsatile arterial blood

(IDC)R: red light (660 nm) absorption in constant status (non-pulsatile arterial blood, venous blood and tissue)

(IAC)IR: infrared light (940 nm) absorption in pulsatile arterial blood

(IDC)IR: infrared light (940 nm) absorption in constant status (non-pulsatile arterial blood, venous blood and tissue)

So the formula could be simplified as:

$$R = \frac{(AC_{660}/DC_{660})}{(AC_{940}/DC_{940})} \quad (3)$$

MCU

Micro control Unit (Microcontroller Unit; MCU), also known as Single Chip Microcomputer, is the Central processing Unit (Central Process Unit, CPU) via appropriate abridgement on frequency and specification, and integrates the memory, counter, Timer, A/D conversion, USB, PLC and other peripheral interfaces.

MCU stored on the memory with calculated empirical formulas, which can calculate the SpO₂ value via R (light absorption ratio). A negative correlation between R and SpO₂^[14] was found. for instance,

A ratio of 1 represents a SpO₂ of 85%, a ratio of 0.4 represents SpO₂ of 100 %, and a ratio of 3.4 represents SpO₂ of 0 %.

LCD display

When the MCU calculates the result of SpO₂, the SpO₂ value can be viewed on the LCD display finally.

3.2 Electronic Sphygmomanometer

Electronic sphygmomanometer is medical apparatus which uses modern electronic technology and the principle of indirect measurement of blood pressure.

Electronic sphygmomanometer has become the main tool of home blood pressure self-test, and is being increasingly used in hospitals and other medical institutions.

3.2.1 Blood pressure

What is blood pressure?

When your heart beats, it pumps blood round your body to give it the energy and oxygen it needs. As the blood moves, it pushes against the sides of the blood vessels. The strength of this pushing is your blood pressure. If your blood pressure is too high, it puts extra strain on your arteries (and your heart) and this may lead to cardiovascular diseases.

- Systolic Pressure: blood pressure when the heart beats while pumping blood
- Diastolic Pressure: blood pressure when the heart is at rest between beats

Table 2. Stages of High Blood Pressure in Adults^[15]

Stages	Systolic (top number)		Diastolic (bottom number)
Prehypertension	120–139	OR	80–89
High blood pressure Stage 1	140–159	OR	90–99
High blood pressure Stage 2	160 or higher	OR	100 or higher

Normal blood pressure for adults is defined as a systolic pressure below 120 mmHg and a diastolic pressure below 80 mmHg.

3.2.2 Measurement methods

Auscultatory Method

Auscultatory method is based on Korotkoff sounds which are blood flow sounds that healthcare providers observe while taking blood pressure with a sphygmomanometer over the brachial artery in the antecubital fossa, named after Dr. Nikolai Korotkoff, a Russian physician who discovered them in 1905. These sounds appear and disappear as the blood pressure cuff is inflated and deflated. Auscultatory method is the most extensive approach to measure blood pressure, while outside sound vibration will affect the measurement accuracy and different pulse amplitude of people also has some impact on the result of the measurement.

Oscillometry Method

Oscillometry predates the method of Korotkoff but was not originally as popular. However, it is now the standard method for electronic sphygmomanometer. In 1885 the French physiologist Marey observed that. If he placed a patient's arm in a pressure chamber then the pressure of the chamber would fluctuate with the pulse and the magnitude of the fluctuation would vary with the pressure of the chamber. It is now known that these fluctuations correspond to the occluding effect on the artery of pressure applied uniformly to the arm and that the same effect can be observed in the pressure of an occluding cuff.

3.2.3 Structure and principle of oscillometric blood pressure measurement

Oscillometry is the main method applied on the electronic sphygmomanometer. This chapter will elaborate the principle and configuration of electronic sphygmomanometer.

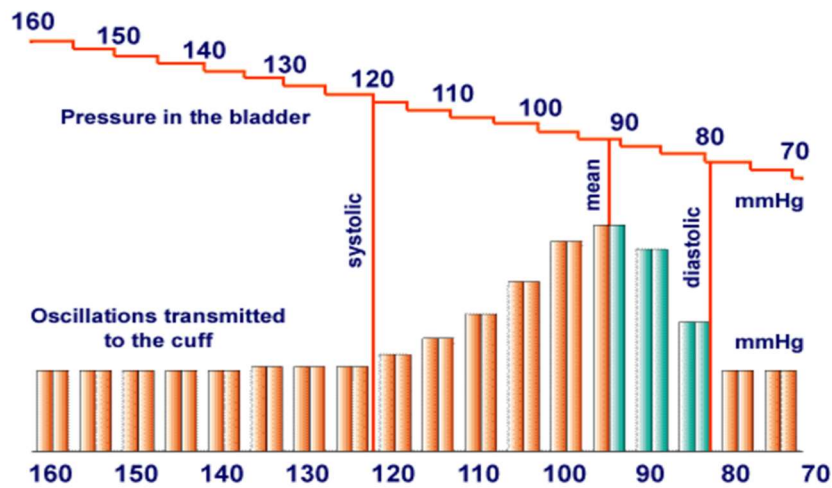


Figure 8. Oscillometric method^[16]

Principle

When the artery is compressed, pulsation cannot be detected by the device. With the decreasing of the pressure in the cuff, the oscillation will emerge and when the pressure descends to the systolic pressure, the amplitude has a conspicuous growth, until reaching the apogee in the mean pressure.

Then the oscillation can still be seen with the decreasing of pressure in the cuff, a dramatic drop occurs in the diastolic pressure.

Oscillometric method is widely used in electronic devices for the measurement of blood pressure attribute to its reliability and convenience albeit it is less accurate than the auscultatory method.^[17]

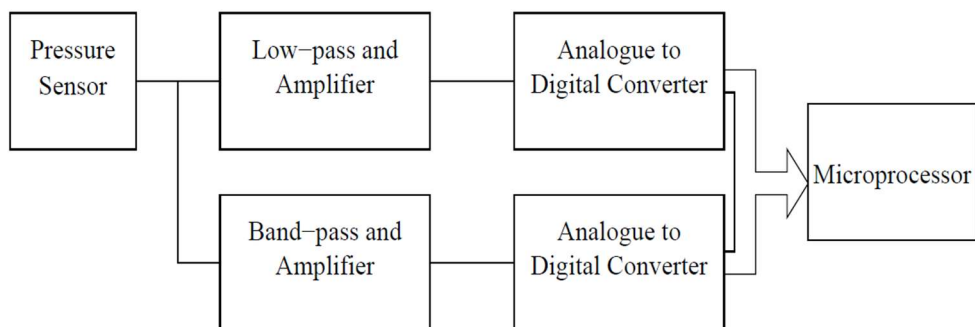


Figure 9. Oscillometric Blood Pressure system^[18]

Pressure sensor

Pressure sensors typically employ the piezo-resistive principle to convert pressure to an electrical signal. A silicon chip is micro-machined to give a diaphragm around which four resistors are diffused in a bridge configuration¹⁸, which is called Wheatstone bridge.

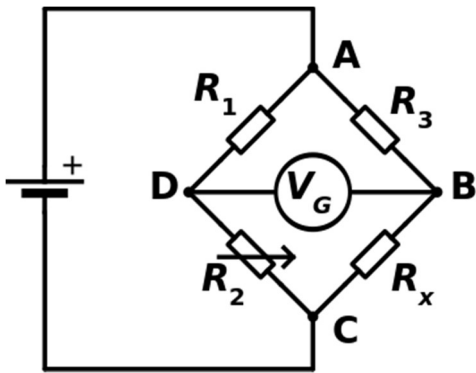


Figure 10. Wheatstone bridge^[19]

When pressure in the cuff is conveyed to the diaphragm, the value of these resistors will change, one side will increase, and another will descend. If the pressure leads to a value of resistor change ΔR , output voltage is $\Delta V = \Delta R \cdot I$ (4).

Filter and Amplifier

The electronic signal emitted from the pressure sensor includes not the systolic and diastolic pressure signal, but also some noise of high frequency such as friction between skin and cuff or the DC. Consequently, filter is the inevitable component in electronic sphygmomanometer.

Looking at figure 9, there are two filters, low-pass filter permitting relative low fluctuation (diastolic pressure) through, while band-pass filter allows systolic pressure signal.

Low-pass Filter

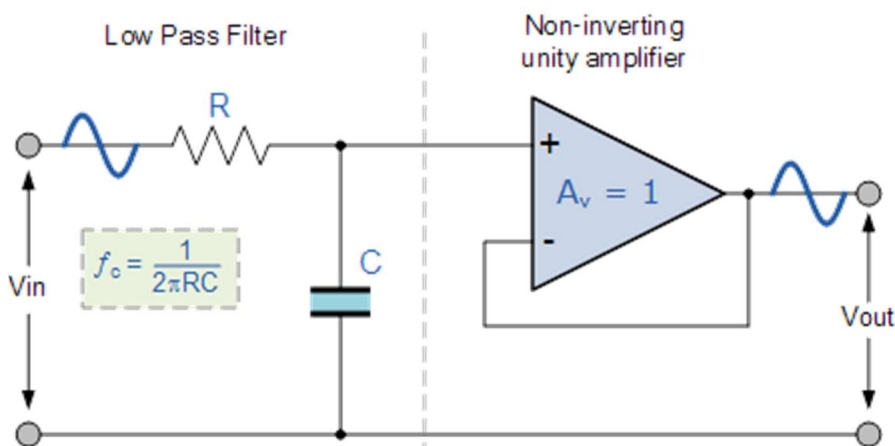


Figure 11. Active low-pass filter circuit^[20]

Low-pass filter includes a resistor and a capacitor and only allows low frequency signals from 0Hz to its cut-off frequency. The diastolic pressure with low frequency signal could pass the resistor and not be absorbed by capacitor, while the other higher frequency signals possess opposite effect, which will be assimilated by capacitor.

Band-pass Filter

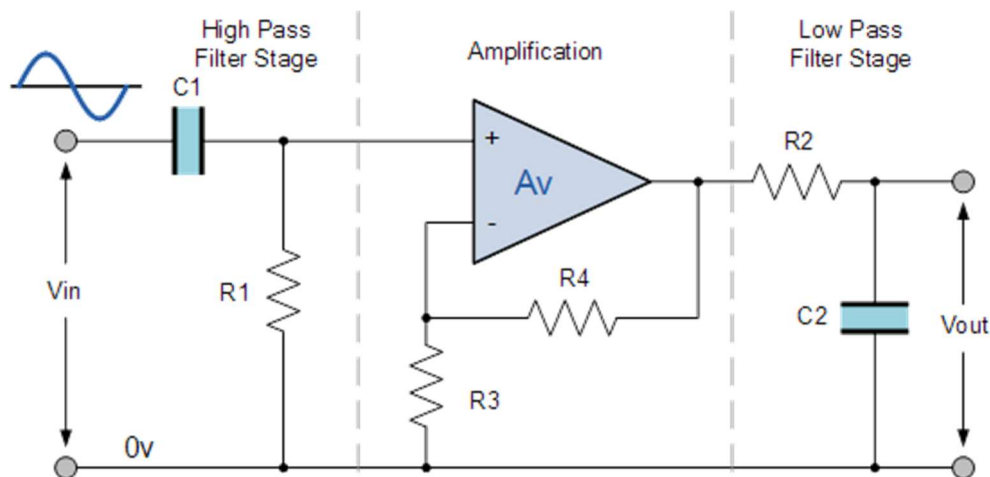


Figure 12. Active band-pass filter circuit^[21]

Band-pass filter includes a low-pass filter and a high-pass filter. The band pass filter allows signals falling within a certain frequency band setup between two points to pass through while blocking both the lower and higher frequencies either side of this frequency band.

Why is band-pass filter built-in? The systolic pressure signal has relatively higher fluctuation than diastolic pressure signal, but it is still less than other noise signal. So firstly through a high-pass filter the low frequency signal is eliminated, then via the low-pass filter ensure the high frequency noise signal is eliminated, so only the systolic pressure signal can come through the circuit.

Amplifier

Looking back at figure 11 and figure 12, both possess an amplifier circuit. Due to the diastolic and systolic pressure signal only approximately 0.04HZ and 1HZ.

Analogue to digital converter

The voltage signals output from pressure sensor will go all the way up to the A/D converter, then analogue to digital converter could convert it to digital signals. The resolution of the converter indicates the number of discrete values it can produce over

the range of analog values. The ideal blood systolic pressure is between 90-120 mm Hg, while considering the high blood pressure patients, an 8 bit A/D converter which give a dynamic range of 2^8 or 256 should be sufficient. ^[18]

Microprocessor

The final component is the microprocessor. It runs a program which controls the cuff (via the three phase cuff control circuitry, as considered above for the automation of the method of Korotkoff) and interprets the two pressure signals.

Firstly, the air pump will inflate the cuff, when the pressure reach 200 mm Hg, no pulse signal emerged, start to deflate the cuff. Capturing pulse signal every 5 ms and detect the peak and record the diastolic and systolic pressure. Commonly when the pressure in the cuff is less than 60 mm Hg, the pulse signal will disappear. If the program cannot detect the signal with continuous 4s, the system will spontaneously complete the measurement.

3.3 Electronic thermometer

Electronic thermometer uses electronic technology to measure body temperature, which is a significant healthy indicator for humankind.

3.3.1 History of the thermometer

The clinical application of thermometer started more than one hundred years ago, while the development history lasted almost three centuries.

In 1593, the brilliant Italian physicist Galileo Galilei invented a rudimentary water thermoscope, with which the temperature could be measured for the first time. It was contained an enclosed bulb and a glass tube put into water, with a temperature marking, the buoyancy of water changed with temperature, the altitude of water in the glass tube would change so the temperature could be measured.^[22]

Nevertheless the altitude variations also decided by the barometric pressure.

In 1612, the Italian inventor Santorio became the first inventor to put a numerical scale on his thermoscope. It was perhaps the first crude clinical thermometer, as it was designed to be placed in a patient's mouth for taking temperature. Both Galilei's and Santorio's instruments were lacked of accuracy.

In about 1654 Ferdinando II de' Medici, Grand Duke of Tuscany, made sealed tubes part-filled with alcohol, with a bulb and stem; the first modern-style thermometer,

dependent on the expansion of a liquid, and independent of air pressure. After that, mercury (which has a high coefficient of expansion) displaced the alcohol gradually. In 1866 Dr. Thomas Clifford Allbutt invented a clinical thermometer that measured body temperature specifically. Albeit mercury thermometer possessed adequate accuracy, confined by the contamination and safety issue. With the development of technology, electronic thermometers were devised at the end of the 20th century and then replaced mercury thermometer.

3.3.2 Structure and principle

The following flow chart shows the general principle of operation of a digital thermometer.

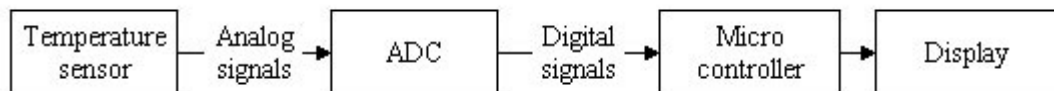


Figure 13. Structure of electronic thermometer^[23]

Electronic thermometers are temperature-sensing instruments that are easily portable, have permanent probes, and a convenient digital display. The way a digital thermometer works depends upon its temperature sensor type. They are generally resistance temperature detectors (RTD), thermocouple digital, thermistor digital thermometers and integrated circuit sensors (IC).^[24]

Resistance temperature detector

Resistance temperature detectors (RTDs) utilize the characteristic of conductor or semi-conductor that changes in resistance with changes in temperature.

RTDs measure temperature using the positive temperature coefficient of electrical resistance of metals. Resistance temperature detectors are widely used in measurement of $-200 \sim +750$ °C temperatures.

The raw material of manufacturing resistance temperature detectors should have as much as possible and stable temperature coefficient of resistance, albeit the resistance curve couldn't exhibit definitively linear output, usually designer will take digital disposition. The dotted line in Figure 14 is a straight line as contrast.

At present the most commonly used thermal resistance materials are copper and platinum.^[25]

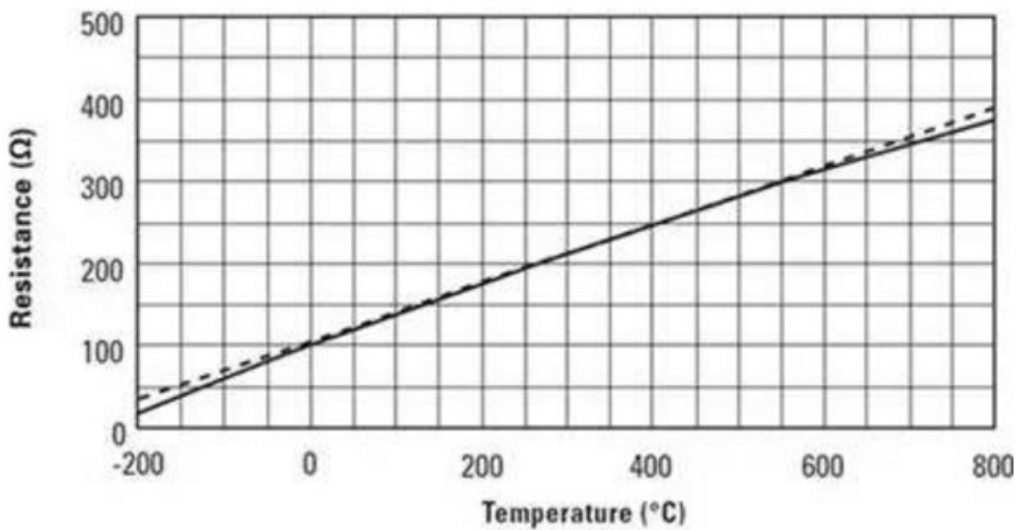


Figure 14. RTDs resistance-temperature^[26]

Resistance temperature detectors are composed of thermal resistance, connecting wires and display instrument. Thermal resistance can also be connected to the temperature transmitter, and temperature is converted into a standard current signal output.

The resistance temperature detector circuit includes amplifier and analogue digital converter (ADC). Sometimes a power supply is alternative, however, the power could increase the detector is internal temperature so that damaging the accuracy.

Advantages of RTDs include their stable output for long periods of time. They are also easy to calibrate and provide very accurate readings.

Disadvantages include a relative smaller overall temperature range and higher initial cost.

Thermocouple

Thermocouples consist of a pair of dissimilar metal wires joined in the junction. One metal junction at a reference temperature (like 0 °C on ice or else known temperature) and the other junction at the temperature to be measured. The metal junction will generate a temperature-dependent voltage according to the temperature difference between the metal wires, which is called Seebeck effect. Thermocouples are accurate, highly sensitive to small temperature changes, and quickly respond to changes in the

environment. The voltage displayed is read using the calibration formula and the temperature of the object can be calculated.^[27]

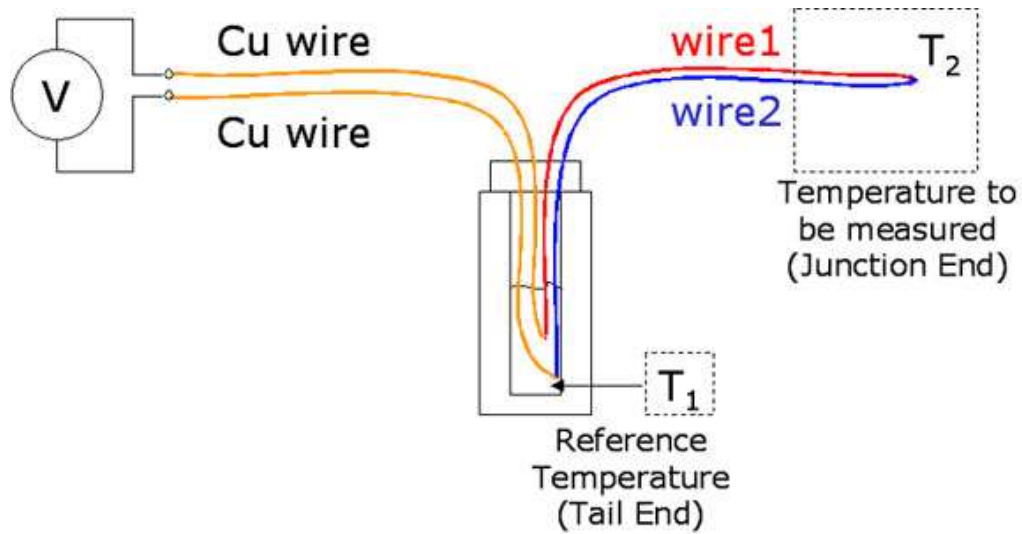


Figure 15. Thermocouple circuit^[28]

Thermocouples are available in different combinations of metals or calibrations. The most common ones are the "Base Metal" thermocouples known as Types J, K, E and T. K Type Thermocouples are known as general purpose thermocouples due to their low cost and extensive temperature range. Each type of thermocouple has corresponding calibration formula. The voltage displayed is read using the calibration formula and the temperature of the object can be calculated.

Table3 is an example of K type thermocouple calibration formula, but it is only a part, actually the whole temperature range of K type is from -200 to 1250 centigrade.

Table 3. Part of K type thermocouple calibration^[29]

Temperature°C	K type thermocouple voltage (mV) reference temperature is 0°C									
	0	1	2	3	4	5	6	7	8	9
-50	-1.889	-1.925	-1.961	-1.996	-2.032	-2.067	-2.102	-2.137	-2.173	-2.208
-40	-1.527	-1.563	-1.6	-1.636	-1.673	-1.709	-1.745	-1.781	-1.817	-1.853
-30	-1.156	-1.193	-1.231	-1.268	-1.305	-1.342	-1.379	-1.416	-1.453	-1.49
-20	-0.777	-0.816	-0.854	-0.892	-0.93	-0.968	-1.005	-1.043	-1.081	-1.118
-10	-0.392	-0.431	-0.469	-0.508	-0.547	-0.585	-0.624	-0.662	-0.701	-0.739
0	0	-0.039	-0.079	0.118	-0.157	-0.197	0.236	-0.275	-0.314	-0.353
0	0	0.039	0.079	0.119	0.158	0.198	0.238	0.277	0.317	0.357
10	0.397	0.437	0.477	0.517	0.557	0.597	0.637	0.677	0.718	0.758
20	0.798	0.838	0.879	0.919	0.96	1	1.041	1.081	1.122	1.162
30	1.203	1.244	1.285	1.325	1.366	1.407	1.448	1.489	1.529	1.57
40	1.611	1.652	1.693	1.734	1.776	1.817	1.858	1.899	1.94	1.981
50	2.022	2.064	2.105	2.146	2.188	2.229	2.27	2.312	2.353	2.394
60	2.436	2.477	2.519	2.56	2.601	2.643	2.684	2.726	2.767	2.809
70	2.85	2.892	2.933	2.875	3.016	3.058	3.1	3.141	3.183	3.224
80	3.266	3.307	3.349	3.39	3.432	3.473	3.515	3.556	3.598	3.639
90	3.681	3.722	3.764	3.805	3.847	3.888	3.93	3.971	4.012	4.054

Advantages of thermocouples include their high accuracy and reliable operation over an extremely wide range of temperatures. They are also well-suited for making automated measurements both inexpensive and durable.

Disadvantages include errors caused by the thermocouple materials which are subject to corrosion, which can affect the thermoelectric voltage, and two temperatures are required to make measurements, the calibration formula is only suitable if the reference temperature is 0°C , otherwise cold junction compensation needs to be implemented.

Thermistor

Thermistor elements are the most sensitive temperature sensors available. Thermistors exhibit a large, predictable and precise change in electrical resistance when subjected to a corresponding change in body temperature. ^[30] There are two types of thermistors.

Negative temperature coefficient (NTC) thermistors are the most common type of thermistor. NTCs possess inverse property between temperatures and their resistance, and exhibit decrease in electrical resistance when subjected to an increase in temperature. NTCs are constructed from oxides of materials such as nickel, copper, and iron. These metal oxides possess semiconductor characteristics, the amount of charge carrier decreases so that the electrical resistance increases in low temperature, with the temperature rising charge carrier increase causes the electrical resistance to descend.

Positive temperature coefficient (PTC) thermistors are used in electric current control. They function is opposite to NTC that the resistance increases as temperature increases. PTCs are constructed from thermally sensitive silicon or polycrystalline ceramic materials. ^[31]

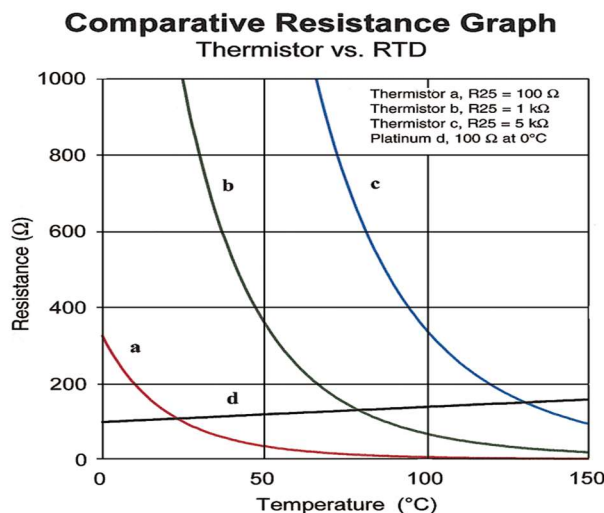


Figure 16. Thermistor temperature graph^[32]

The main discrepancy compared with resistance temperature detector (RTD) is the correlation of electrical resistance and temperature is not a linear output. In addition, the measured temperature range is confined.

Advantages include small size and high degree of stability. The variation of electrical resistance is conspicuous, which means high sensitivity, accuracy, easy to volume production and inexpensiveness.

Disadvantages include their non-linearity, limited measurement range and unsuitability for use in extreme temperatures.

Correlation of thermistor electrical resistance and temperature:

$$R_T = R_0 e^{-B(1/T_0 - 1/T)} \quad (5)$$

T is the temperatures to be measured in kelvin

T₀ is 25°C = 298.15 K

R_T is the resistance at temperature T

R₀ is the resistance at temperature T₀

B is the constant, represent the sensitivity for temperature, but for different thermistor material, the B is different.

Integrated circuit temperature sensor

Integrated circuit temperature sensors, also known as semiconductor temperature sensors are the devices which come in the form of integrated circuits on the silicon, could be used to measure temperature and output of the analogue signal.

Advantages include small size, inexpensiveness and absolutely linear output. IC sensors enable simple interfacing with other electronic devices like amplifiers, digital signal processors, and microcontrollers.

Disadvantage includes deficiency in measurement range, only from -55°C to 200°C.

Comparison and choosing the temperature sensors

Each kind of temperature sensor possesses merits and demerits, the designer will choose optimal solution for the particular circumstances.

Nevertheless, the electronic thermometer as a kind of home medical equipment, the IC sensor is adequate albeit its temperature range is confined. And its small volume corresponds to the electronic thermometer as well.

Table 4. Merits and demerits of the four type sensors [26]

Criteria	RTD	Thermistor	Thermocouple	IC sensor
Temperature range	-250°C to +750°C	-100°C to +500°C	-267°C to +2316°C	-55°C to +200°C
Accuracy	Best	Depends on calibration	Good	Good
Linearity	Good	Worst	Good	Best
Sensitivity	Less	Best	Worst	Good
Circuitry	Complex	Depends on accuracy/power requirements	Complex	Simplest
Power consumption	High when taking measurement		Low-high	Lowest
Relative system cost	\$\$-\$\$\$	\$-\$\$\$	\$\$-\$\$\$	\$

3.4 Glucose Meter

Glucose meter is a medical device for determining the approximate concentration of glucose in the blood. The concept of blood glucose, diabetes and principle of glucose meter will be introduced in this chapter.

3.4.1 Blood glucose

Glucose ($C_6H_{12}O_6$) is a carbohydrate whose most important function is to act as a source of energy for the human body, by being the essential precursor in the synthesis of ATP (adenosine triphosphate). The energy stored in ATP can then be used to drive processes requiring energy, including biosynthesis, and locomotion or transportation of molecules across cell membranes. According to cellular requirements, glucose can also be used in the creation of proteins, glycogen, and lipids.

The blood glucose concentration is very tightly regulated. Human body has two hormones released by pancreas that have opposite effects: insulin and glucagon. Insulin is produced by β cells of the pancreas while glucagon is produced by α cells. The release of insulin is triggered when high levels of glucose are found in the bloodstream, and glucagon is released with low levels of glucose in the blood.

This blood glucose regulation process can be explained in the following steps^[33]:

After the glucose has been absorbed from the food eaten, it gets released in the bloodstream. High blood glucose levels triggers the pancreas to produce insulin. Insulin enables the muscle cells to take glucose as their source of energy and to form a type of molecule called glycogen that works as secondary energy storage in the case of low levels of glucose. In the liver cells, insulin instigates the conversion of glucose into glycogen and fat. In the fat cells of the adipose tissue, insulin also promotes the conversion of glucose into more fat and the uptake of glucose.

The pancreas will continue to release insulin and liver and fat cells continue to use glucose till the drop of concentration of glucose is below a threshold; in that case, glucagon will be released instead of insulin.

When glucagon reaches the liver cells, it initiates the conversion of glycogen into glucose, and fat into fatty acids, which many body cells can use as energy after the glucagon enables them to. The cells will continue to burn fat from the adipose tissue as an energy source, and follow with the protein of the muscles, until the levels of glucose increase again by the digestion of food, and that terminates the cycle.

3.4.2 Diabetes

Diabetes is a chronic disease which means your blood glucose, also called blood sugar, is too high. Blood glucose is the main type of sugar found in your blood and your main source of energy. Glucose comes from the food you eat and is also made in your liver and muscles. Your blood carries glucose to all of your body's cells to use for energy. In 2013 it was estimated that over 382 million people throughout the world had diabetes.

There are three types of diabetes:

Type 1 Diabetes - the body does not produce insulin. Approximately 10% of all diabetes cases are type 1.

Type 2 Diabetes - the body does not produce enough insulin for proper function. Approximately 90% of all cases of diabetes worldwide are of this type.

Gestational Diabetes -this type affects females during pregnancy.^[34]

3.4.3 Principle of glucose measurement

Most glucose meters are based on electrochemical technology. They use electrochemical test strips to perform the measurement. A small drop of the solution to be tested is placed on a disposable test strip that the glucose meter uses for the glucose measurement. The most common method used in electrochemical measurement of glucose are the amperometric method.

Amperometric method

Amperometric method utilizes electrochemical glucose biosensor which is based on the glucose oxidase enzyme, which catalyzes the oxidation of glucose to gluconolactone which is hydrolyzed to gluconic acid and hydrogen peroxide (H_2O_2). These reactions causes an increase in pH. Decrease in the partial pressure of oxygen and hydrogen

peroxide will decompose to hydrogen ion and oxygen. The concentration of glucose can be achieved via electrochemical detection of the electrons released by hydrogen peroxide.

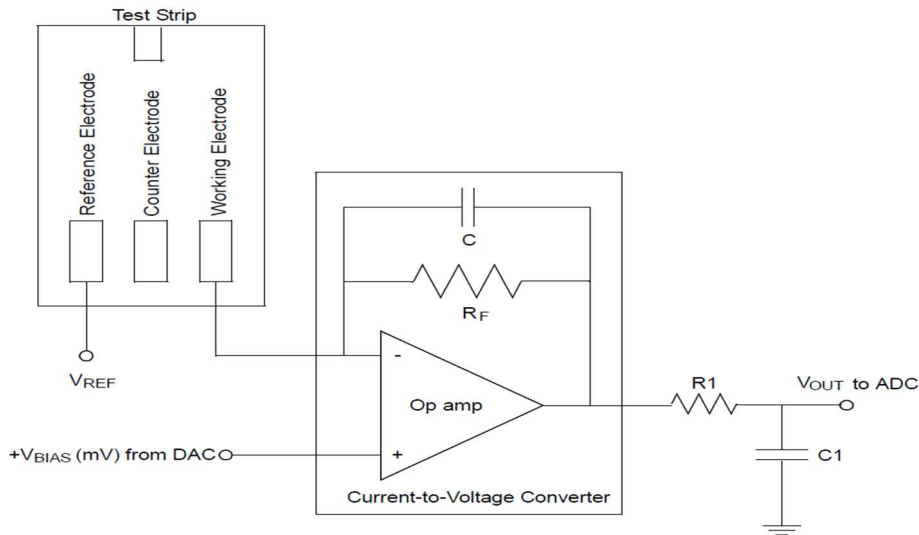
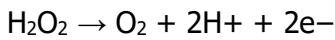
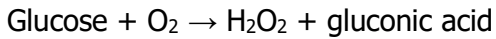


Figure 17. Glucose meter test working strip principle^[35]

Test strip

The test strip is an electrochemical glucose biosensor as core component of the glucose meter. Figure18 illustrates the test strip which has the following electrodes:

Working electrode: Electrons are produced here during the chemical reaction. This electrode is connected to the current-to-voltage amplifier.

Reference electrode: Held at a confirmed constant voltage to the working electrode to push the desired chemical reactions.

Counter electrode: Supplies current to the working electrode.

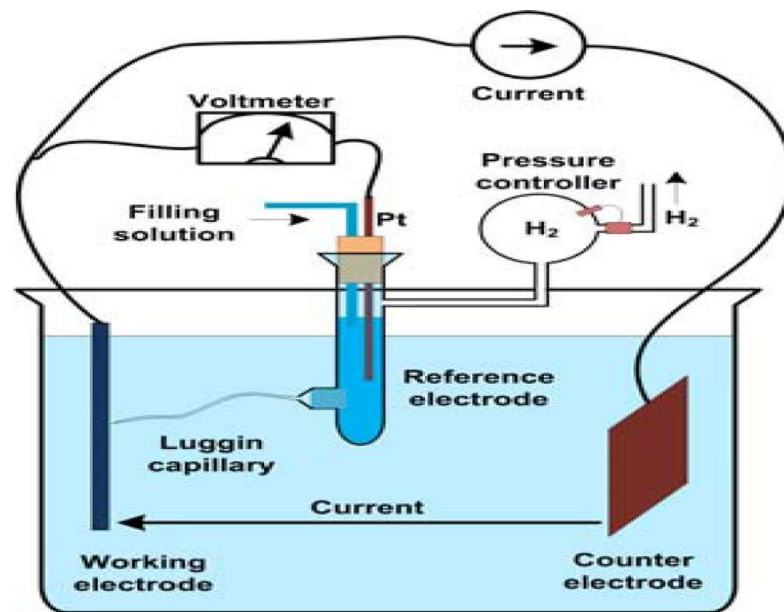


Figure 18. Three electrodes system^[36]

An electrochemical reaction requires at least two electrodes in theory. When the user places solution sample (blood) on the test strip, the reaction of the glucose with the enzyme takes place. The working electrode and counter electrode compose a circuit which transfers the charge generated by the electrochemical reaction. The counter electrode must have a known potential to measure the potential of working electrode, because the working electrode potential will be applied to calculate the amount and electrons. Nevertheless, for the counter electrode it is difficult to maintain a constant potential when going through the current, due to the polarization.

Hence, the reference electrode works as an auxiliary tool to ensure the potential of working electrode. Reference electrode possesses a constant potential and there is no current through the reference electrode.

In brief, the working electrode and counter electrode compose a current circuit, while the working electrode and reference electrode compose a voltage circuit.

TIA and ADC

The current is measured using a transimpedance amplifier (current-to-voltage converter) for the measurement with an Analog-to-Digital Converter (ADC).

The current generated by the test strip represents the glucose concentration. This current must be converted to voltage by the transimpedance amplifier so that it can be properly filtered and treated.

The output of the transimpedance amplifier will be seen as a variation in the voltage with varying glucose concentrations in the solution. Finally the output voltage signal will be fed to the analogue to digital converter.

4 Market prospects of Chinese HMEs

Market for Chinese home medical equipment (HME) is an emerging market and possesses merits including low barrier, high return of investment and relative low venture, appealing to more and more capital both domestic and abroad. The HME Corporations are concentrated in Yangtze River Delta area and Pearl River Delta area, particularly in Shenzhen where the most cardinal district of home medical equipment has developed, possessing around 300 manufacturing and 400 commercial companies, accounting for 30% of total production in China.

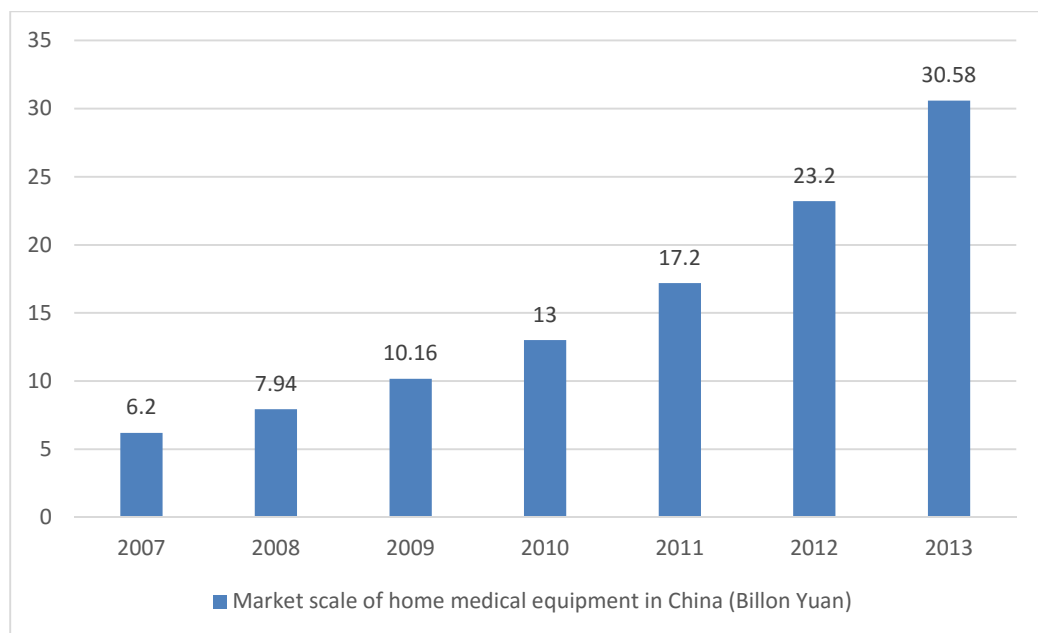


Figure 19. Market scale of HMEs^[37]

In 2013, market sales scale of home medical equipment were about 30.58 Billion Yuan (4.2 Billion Euros), on average increasing 28.5% from 2006-2013, it is forecast the sales will maintain approximate 25% growth rate in next several years.

Nevertheless, home medical equipment only accounts for 14% of turnover of whole medical instruments market, while in developed areas is usually 25%. Per capita expenditure on home medical equipment in America is 20-30 times bigger than in China, so the market still possesses wide developing prospects, far from the saturation.

4.1 Economic and Society environment for Chinese market

GDP

According to the data from World Bank, the Gross Domestic Product (GDP) in China was worth 10354.80 billion US dollars in 2014. The GDP value of China represents 16.70 percent of the world economy. GDP in China averaged 1437.04 USD Billion from

1960 until 2014, reaching an all-time high of 10354.80 USD Billion in 2014 and a record low of 46.68 USD Billion in 1962.



Figure 20. China GDP annual growth rate^[38]

From 2013 to 2016 first quarter, the Chinese GDP which was creeping increasing, Chinese economy expanded by 6.9 percent in 2015, lower than 7.3 percent in 2014 and the weakest since 1990. The GDP per capita was 3865.88 US dollars in 2014. The GDP per Capita in China is equivalent to 31 percent of the world's average.

Inflation Rate

National Bureau of Statistics of China indicate the consumer prices in China rose by 2.3 percent year-on-year in February of 2016, that following a 1.8 percent rise in January and above market consensus of a 1.9 percent increase. It is the highest inflation rate since July 2014, as politically sensitive food prices surged by 7.3 percent over the Lunar New Year holiday and cold weather while non-food cost rose at a slower 1.0 percent, hence the prices keep stable in home medical equipment market. Inflation Rate in China averaged 5.51 percent from 1986 until 2016, reaching an all-time high of 28.40 percent in February of 1989 and a record low of -2.20 percent in April of 1999.^[39]

Engel's Coefficient

Engel's Coefficient is the proportion of total food spending compared with the proportion of the total amount of personal consumption expenditure. In the 19th century German statistician Engel according to statistical data, creating a pattern to reflect the

change of consumption configuration: a family more poor, the proportion of food expenditure accounting for total household income was greater, with the increase of family income, the ratio of household income used to buy food spending will decline. By extension, if a country is poor, the Engel's Coefficient is higher, with rich countries, the proportion is declining. The United Nations (UN) uses the Engel coefficient to show living standards:

- A coefficient above 59 percent represents poverty
- 50-59 percent, indicates barely meeting daily needs
- 40-50 percent, a moderately well-off standard of living
- 30-40 percent, a well-to-do standard of living
- Below 30 percent, represents a wealthy life.

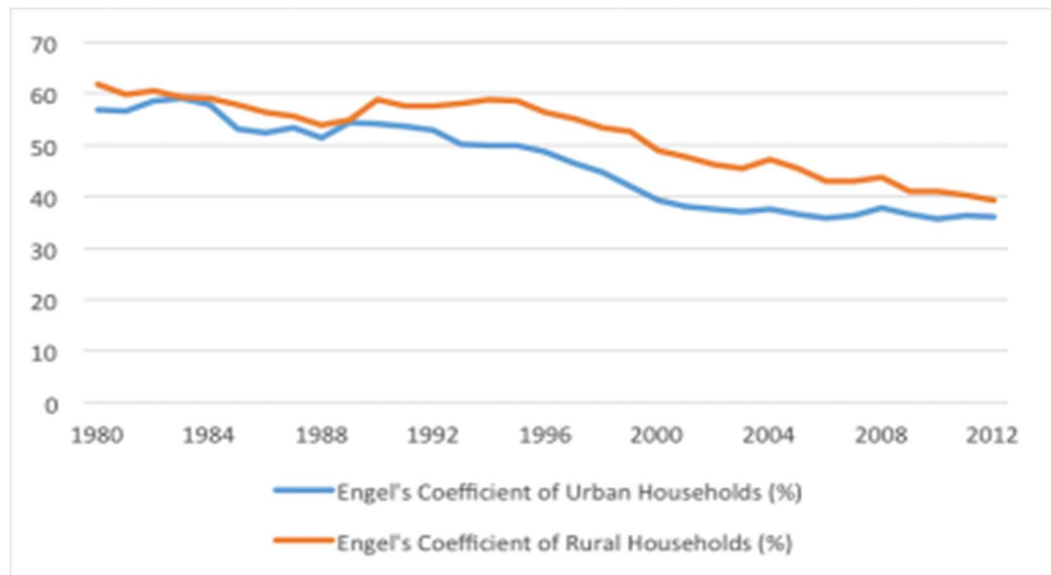


Figure 21. China's Engel's Coefficient of Urban and Rural Households (%)^[40]

China's Engel's Coefficient indicates downside, less than 40% means China has developed a well-to-do country.

In brief, albeit the Gross Domestic Product (GDP) growth rate has shown decelerating trend in recent years, the per capita income has still shown stable increase and the disposable income per capita has reached 31195 CNY in 2015 according to the data from National Bureau of Statistics of China. The consumption potential of Chinese people is colossal, the home medical equipment market possesses a brilliant and stabilized economic circumstance.

Aging of population

Over the past two decades, China's population has been aging rapidly. As a result of China's "one-child" policy and low mortality, the proportion of elderly citizens will continue to grow very quickly, increasing the stress on the already troubled health care system. By 2050 approximately a quarter of the population will be over 65 years old.

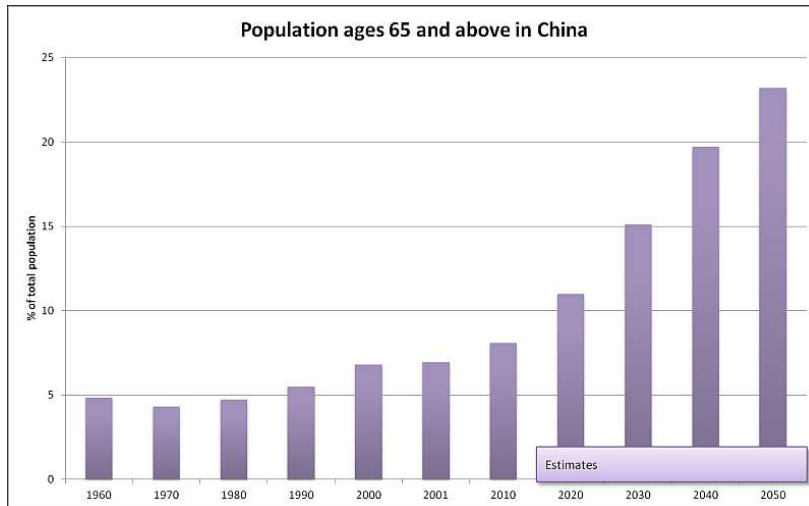


Figure 22. Actual and projected percentage of people above 65 in China^[41]

Many home medical equipment correlate with elder and chronic diseases, such as hypertension, diabetes and cardiovascular diseases. With the aging of Chinese population, increasing of income and health care consciousness, home medical equipment will attract more and more Chinese people.

4.2 SWOT Analysis for home medical equipment market in China

Strengths

Consumption ability and ideology of Chinese people has had conspicuous variation with economic reform and development in recent years. The improvement of living standard and quality drive people's health care consciousness. With population density and pace of life increasing, only 15 per cent of Chinese people could gratify the definition for Health by World Health Organization (WHO), and 15 per cent are sick and the rest 70 per cent are sub healthy. Meanwhile, aging of Chinese population facilitates the pattern that the daily prevention and treatment for elder's chronic diseases is transferred to community and family. Chinese medical structure has rapidly developed towards comprehensive and specialized hospitals for the mainstream, community hospitals for branch, family health care, rehabilitation and prevention for complement, lots of patients need continuous treatment by medical equipment outside the hospital. These

market demands bring colossal chance for home medical equipment which emphasizes health care and prevention.

On the home medical equipment market in developed countries, due to the stable market demand, home medical equipment could maintain the market albeit the circumstance in economic depression. On the Chinese market at present, in fact, almost every kind of home medical equipment holding rate is low. For example, it has been reported that China has reached 100 million in diabetic patients, only 1.5% have purchased glucose meter, in European and American countries the proportion is as high as 90%. China have nearly 100 million patients with sleep apnea, only a limited number of patients will see doctors, breathing machine buyers are much rarer.[42]Hence, the home medical equipment possesses colossal potential market in China.

Weaknesses

With the improvement of consumption, Chinese people emphasize more self-health care. Many foreign companies take part in Chinese market gradually, such as Omron, Philips, GE and Siemens. These foreign brand's products possess delicate outlook and advanced function, while the domestic home medical equipment have more moderate price.

However, the competition complexion is adverse for Chinese companies, due to the fact that many consumers prefer to believe these international brands although with higher expenditure. And many domestic products have demerits indeed, small size of corporation, low technology and deferring product development lead to the disadvantage when competing with foreign home medical equipment.

Opportunities

In china, there are about 2.6 million patients suffering from side effects of drugs every year, people worry about the medical safety and reliability. Meanwhile, home medical equipment possesses complete functions, no side effect can attract more consumers. And recent years, people's income maybe has increased 10 times, but medical expenses could have increased 100 times. In-hospital healthcare can be prohibitively expensive, and many patients prefer to be convalescing at home. Additionally, in China the aging of population was started, while also arousing significant increase in patients with chronic diseases that require long-term care. The prices of home medical equipment are commonly no more than 1000 CNY and can be utilized for more than ten years so that decreasing medical expenditure drastically.

Furthermore, most home medical equipment are minimized and innovated by hospital medical devices. They possess more integrated and intelligent control, the elder people can easily operate it. The fast expansion of technology is also one key driver of the Chinese home healthcare market's quick growth, particularly the application of biology and electronic technology, even face neoplasm, diabetes and cardiovascular diseases could provide accurate diagnosis.[43]

Another aspect about Chinese culture, sending gifts about fitness has become a kind of culture trend with relatives and friends. Several years ago, people used to send some health care drugs instead of home medical equipment.

Threats

High profits will attract a lot of investment, so no matter choosing to do home medical device manufacturers or agents, retailers, realize that while the market demand is so great, and also can have a greater risk of competition.

Manufacturer enterprise's risk is difficulty to form its own flagship brand, when facing the competitive market environment including many distinguished international medical enterprises. To avoid such risks, investors can seek cooperation, set joint ventures, and then integrate to form scale and industrialization, improving overall competitiveness.

Retailers or agents in the face of the future competition risk, can find some more effective marketing methods, such as start consciously with the hospital or the doctor to establish long-term relations of cooperation and choose online sales which has become very popular in China recent years.

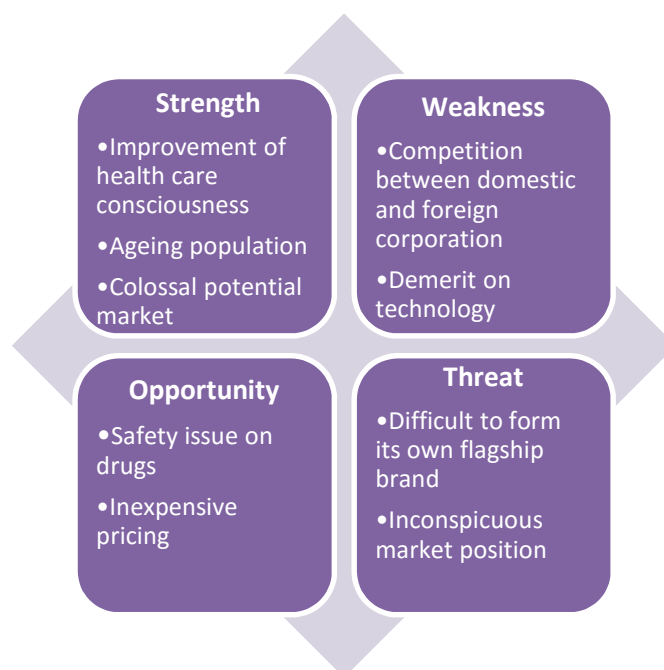


Figure 23. SWOT Analysis for home medical equipment market in China^[44]

5 Conclusion

Majority home medical equipment without colossal bulk, possess advanced electronic technology. In the thesis, four types of home medical equipment: pulse oximeter, electronic sphygmomanometer, electronic thermometer and glucose meter were introduced, which are the most essential and crucial medical devices for monitoring pulse, oxygen saturation, hypertension, body temperature and glucose. This home medical equipment is portable and inexpensive, keeping the durability, accuracy at the same time, and have benefited from the development of electronic technology. The sensor technology is the most widely application in these home medical equipment, including photodiode, pressure sensor, temperature sensor and biosensor. What's more, there are also lots of amplifiers and filter circuits in the home medical equipment. Sensors contact the object measured and transform the signal to electrical signal which can be detected. Some electronic technology in these devices has developed into 2nd even 3rd generation, it is conceivable that the electronic technology will have enormous progress with the increasing of people's demands in the future.

And comparing with America and European countries, the market of HMEs in China is still an emerging market, but with the stable increase in economic and aging of population, more and more Chinese people will realize the importance of home medical equipment, it could be one of the largest HME markets in the near future.

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