HOW DESIGN TRENDS HAVE INFLUENCED MANUFACTURING ECONOMICS IN HANDHELD DIAGNOSTIC DEVICES

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ABSTRACT
One of the largest markets for electronic medical devices is blood glucose meters. Millions of these meters are manufactured and sold every year. The field of competitors is crowded and manufacturers continue to work to find new ways to differentiate themselves to consumers. Some have companies have decided to provide low-cost “bare-bones” meters while others have created innovative systems that offer a great deal of features in a small package.

Undeniably, two trends in glucose meter design and manufacture are merely echoes of the trends in consumer electronics in general; that is, reduction in form-factor and increased functionality. Moreover, there is a desire by manufactures to offer a more complete feature set at an acceptable price point.

IBIS Associates has studied the manufacture of these devices in detail from the manufacture of their plastic housings, to their PWB assemblies, through finally device assembly. This paper will compare the PWB assemblies that were used in these devices in the past with newer models and discuss key differences between the two with respect to design, component selection, and overall system cost. Key market trends will be highlighted and discussed and conclusions will be drawn as to how these will affect the medical device industry as a whole.

Key words: device manufacturing, economics, trends

BACKGROUND
Diabetes mellitus is a disorder in which the body has abnormally high levels of sugar (glucose) in the blood. There are two types.

Type 1 diabetes is when people do not produce insulin in their pancreas. These people are generally diagnosed in childhood; however there are cases that develop in adolescence or young adulthood. Type 1 diabetics need insulin and cannot use any of the other medications that exist for diabetes.

Type 2 diabetes occurs when the body doesn't use insulin appropriately. These people can use certain pills to effectively lower sugar levels, reduce sugar production in the body and reduce the resistance to their insulin. Newer medications can bolster a response within the pancreas to improve its insulin production. This form of diabetes runs in families. It also is related to being overweight.

As opposed to type 1 diabetes, type 2 diabetes can be well controlled with diet and exercise. A sugar-free diet and reduction in the carbohydrate content of meals make it easier to control. This doesn't mean that medications can always be avoided, but the need for them may be significantly reduced.

People with either kind of diabetes can benefit from understanding their disease. Blood glucose meters are essential for diabetics to monitor, manage, and control their diabetes.

A blood glucose meter is an electronic device for measuring the blood glucose level. A relatively small drop of blood is placed on a disposable test strip which interfaces with a digital meter. Within several seconds, the level of blood glucose will be shown on the digital display.

Blood glucose meters are a breakthrough in diabetes self care. As the drops of blood needed for the meter become smaller, the pain associated with testing is reduced and the compliance of diabetic persons to their testing regimens is improved. Although the cost of using blood glucose meters seems high, it is believed to be a cost benefit relative to the avoided medical costs of the complications of diabetes.

Blood Glucose Meter Performance Metrics
Makers of Blood Glucose Meters are able to differentiate there products in a number of ways, from the sample size required for an accurate reading, to sensing speed to the device’s memory and management system.

Sample Size Required
Discomfort associated with blood withdrawal is directly proportional to the size of the sample required. Some older meters require 10 microliters (mcL) of blood. They may include instructions that require the patient to massage the hand from the wrist to the finger-tip several times to maximize the amount of blood, mention that the patient apply more pressure with the bloodletting device to obtain a deeper puncture, and suggest that the patient massage the finger after puncture to obtain adequate blood volume. Newer monitors provide results with much smaller samples. For example, the FreeStyle only requires 0.3 mcL (the smallest sample required by any meter at present). Further,

some meters (e.g., Glucometer Dex 2) use capillary action to suck the sample of blood into the meter for testing. This prevents the patient from having to insert the strip into the meter.

Memory

Most blood glucose meters have the capacity to store previous readings (along with the time and date); the volume of storage varies with the specific meter.[6] Some only store 20 to 100 results (e.g., Glucometer Elite, Accu-Chek Advantage, Glucometer Dex 2), while others store as many as 1,000 (e.g., Accu-Chek Complete). Most meters have download capabilities that allow the patient to transfer readings directly to a home computer, keeping them in a logbook. The patient may be required to purchase a cable to allow the meter/home computer interface to be made, and may also need to download software from the meter manufacturer's website (e.g., Win Glucofacts Diabetes Management Software for the Glucometer Dex, Glucometer Dex 2, Glucometer Elite XL) to accomplish data transfer and facilitate data manipulation. Patients can then calculate 14- and 30-day averages and averages of all readings at a specific reading time (e.g., 6:00 am, 12:00 noon, 6:00 pm or 9:00 pm). A few meters (e.g., Glucometer Elite) lack data port features and diabetes management software integration.

Test Strip Calibration

Some meters require the user to insert a strip or chip into the meter when a new package is purchased so that the meter might be calibrated. Others require the user to manipulate a button until the code displayed matches the code of the package of strips. For both products with enclosed test strips (e.g., Glucometer Dex 2, Accu-Chek Compact), calibration occurs automatically when the patient places the cartridge/drum inside the meter.

Power

The ideal meter should have batteries that are readily available and easy to replace. Most meters now require two common alkaline batteries of AA or AAA size (e.g., One Touch SureStep; Accu-Chek Advantage, Complete and Compact). Nevertheless, the Glucometer Dex 2 uses two lithium watch batteries (CR 2016) that may be more difficult to locate when the patient is in a hurry, as might the two AAAA batteries required by the Free Style.

In addition to the preceding attributes, manufacturers also compete on how quick a result can be had, how accurate their readings are, features, form factor, and of course cost. Blood Glucose Meters are priced anywhere from $30 to $100 each, but these prices are heavily subsidized by their manufactures through rebates. Furthermore, most insurance carriers reimburse the expense of the meters.

STUDY SCOPE

Over the course of five years IBIS Associates study two successive generations of Blood Glucose Meters from a select group of manufacturers. The meters spanned the spectrum from inexpensive, very simple designs to extremely complex and expensive meters. The goal of this work was to understand how manufacturing and assembly costs varied among participants and to highlight key differences between meters that contributed to overall meter manufacturing economics. The first set of meters was studied in 1998 and the second group was analyzed in 2003. By comparing these two generations of products we shall endeavor to relate how overall trends in the medical device as well as the broader electronics market have affected the Blood Glucose Meter industry and what might we expect from this segment in the future.

METHODOLOGY

Upon acquisition, each meter was subsequently deconstructed and all of their components were inventoried. A Bill of Materials for the individual electronic components was created and pricing was obtained for each from several large distributors. Furthermore, IBIS employed its Technical Cost Modeling methodology to estimate the direct manufacturing cost of fabricating each meter's PWB. Technical Cost Modeling estimates a product's manufacturing economics by relating known physical parameters like part size, lines and spacing, number of vias and their respective size to processing parameters such as material usage, equipment through put and yield.

Technical Cost Modeling was also used to estimate the cost of PWB assembly for each of the meters.

ANALYSIS

Electronic Components

A given Blood Glucose Meter design can consist of anywhere from twenty-five to one-hundred separate components including passives. These components work in concert to read the test sample, calibrate the test strip, control meter operation, display and store test results. The micro controller unit (MCU) is the "brains" of the meter and also one of the most expensive components.

In 1998 most of the meters under consideration used proprietary MCUs, and some meters required more than one. It was observed in 2003 that not only did the cost of MCUs decline by nearly 20%, but all manufacturers were able to design meters that required just one MCU. While the difference in cost between the successive generations is primarily due to the elimination of one of the MCUs, some manufacturers were able to get away from proprietary designs and incorporate standard MCUs into their meters, thus reducing their expense even further.

Average Cost Per Unit of Electronic Components
Segmented by Meter Element

Meter Set	ASIC/ MCU	LCD	Other Comps	Passives	Total
1998	$8.21	$2.67	$9.42	$0.19	$20.47
2003	$4.72	$3.17	$5.06	$1.01	$19.02
Cost Reduction					**7%**

The LCD unit is another common element to all Blood Glucose Meters and the designs can vary considerably. All displays are of the passive matrix, super twisted nematic

(STN), segmented character variety. Prices for these components vary depending upon their size and the number of characters required. In general, LCD size was reduced from 1998 to 2005. This fact is mostly related to the smaller form factors of the more recent generation. Be that as it may, the cost for the LCD's increased due to the increased need to display more information. For the most part, meters in 2003 offered more features than their earlier counterparts, and therefore the displays were specified to meet the information density requirements.

The category in the table above titled "Other Comps" refers to all of the remaining active components and connectors required for each meter. The cost associated with these components dropped dramatically; approximately 46%. More startling, is that this cost reduction came with an enhanced set of meter features. The group of meters considered in 2003 had more memory, the ability to self calibrate, and in some cases infra red data transmission. Over the intervening years, as these elements became more affordable, meter manufacturers adopted them in order to give their customers more functionality.

Taken in total, as the preceding table indicates, the 2003 group was able to reduce their overall cost by 7% over five years, while still managing to offer the user more meter features.

PWB Fabrication

As mentioned previously, overall form factor for the meters in the 2003 was reduced. This can be seen from the data displayed in the following table.

Comparison of PWB Fabrications and Resulting Cost

Meter Group	Average Board Dimensions: Length (inches)	Width (inches)	Via Size (mil)	Area (in^2)	Density (vias/in^2)	PWB Cost $/unit
1998	3.0	2.0	30	10.4	17.2	$1.53
2003	2.5	1.7	15	4.1	48.3	$2.67
Delta	**-18%**	**-18%**	**-51%**	**-60%**	**180%**	**75%**

The printed wiring boards used in the more recent meters were almost half the size, on an areial basis, of the boards used in the 1998 meters; however, the median number of metal layers in 2003 increased to four (4) from two (2). Furthermore, the via density increased for the more recent group, even as via size was reduced. All of the factors combine to increase the average cost of the boards used in 2003 group by 75%. Apparently, a conscious decision was made by the meter manufacturers to reduce the size of their meters; even at the expense of higher manufacturing costs. Smaller form factor is desirable to users, as it allows the meter to be more convenient to travel with as well as enabling the user to be more discrete when they test.

PWB Assembly

The final element considered in this analysis is the assembly of components on to the PWB. As indicated by the following table, on average, the number of components per board has been reduced between generations. It is worth noting that within a five year timeframe nearly all of the thru-hole placements in preceding generation of products have been supplanted by surface mount technology. In fact, in 1998 all of the meter designs included some type of thru-hole placement; whereas, in the later generation products the majority of PWB Assemblies have no thru-hole components whatsoever.

Comparison of PWB Assemblies and Resulting Cost

Meter Group	Average # of Thru-hole Components	Average # of SMT Components	Average Asssembly Cost ($/meter)
1998	4	57	$2.06
2003	1	42	$2.14
Delta	**-75%**	**-26%**	**4%**

There is also a notable trend in the reduction of overall components, when comparing the two groups of meters. Once again, we see the effect of IC suppliers being able to offer more sophisticated products than combine functions and enable device manufacturers to reduce overall component count. Surprisingly, the cost of assembly is not similarly reduced. It is important to note that the assembly cost was modeled assuming the devices were made in their country of origin. The majority of the meters in the 1998 group were assembled in low cost geographic locations. In contrast, the later group of meter manufacturing sites was equally divided amongst low cost and high cost geographic areas. If we were to compare the assembly costs at a geographically neutral spot it would be evident that the overall cost did in fact decrease based on the reduction of placements. Given this fact, it is expected that the majority of medical device PWB Assembly, especially for high volume products like blood glucose meters, will be produced in low cost geographic areas such as China.

DISCUSSION

Through this cursory analysis of two successive generations of Blood Glucose Meters it is possible to see some of the broad overarching industry trends of the past decade. Device manufacturers are constantly redesigning their products in order to take advantage of new technologies.

Consumers have shown that they prefer meters that are more compact, but still have a great deal of functionality. As this industry continues to progress, designers will have to leverage new packaging and interconnection paradigms in order deliver the performance users want. This past March this type of innovation was demonstrated by company who has developed a technology to provide real-time continuous glucose monitoring. The possibilities are endless so long as the enabling technologies are affordable.