

The Business of Self-Monitoring of Blood Glucose: A Market Profile

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Abstract

The market for self-monitoring of blood glucose (SMBG) approached \$8.8 billion worldwide in 2008. Yet despite dramatic double-digit growth in sales of SMBG products since 1980, the business is now facing declining prices and slower dollar growth. Given that SMBG meters and test strips are viewed by consumers and insurers as essentially generic products, it will be extremely challenging for new market entrants to displace well-entrenched existing competitors without a truly innovative technology. Also, in the face of declining glucose test strip prices, market expansion can only occur through identification of more of the undiagnosed diabetes population and convincing existing diabetes patients to adopt glucose testing or to test more frequently. Ultimately, a combination of technology innovations, patient education, and economic incentives may be needed to significantly expand the SMBG market and build sustainable long-term dollar growth for SMBG vendors.

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Market Size and Growth

Self-monitoring of blood glucose (SMBG) is big business and is getting bigger every year. Since 1980, the market for blood glucose monitoring products has undergone phenomenal growth. While the United States is the single largest market for SMBG, with about 40% of the global market, there has been dramatic growth in demand for these products across the globe. To provide some perspective, Enterprise Analysis Corporation estimates that the world market for SMBG testing supplies was \$1.7 billion in 1994. By 2000, the market had reached approximately \$3.8 billion, and by 2008, worldwide sales of these products climbed to an astonishing \$8.8 billion (Figure 1). This represents an approximate 12.5% compound annual growth rate since 1994. In fact,

the SMBG testing market, which barely existed in 1980, now accounts for approximately 22% of the entire \$39 billion *in vitro* diagnostics industry.

Given the obesity epidemic and the virtual explosion in diabetes, there is likely to be continued growth in demand for SMBG products in the foreseeable future. However, the nature of the SMBG business is changing from a high-growth market to a maturing, commodity type of business, where consumers and insurance payers view all products essentially as the same. Thus, while unit volume sales may continue strong growth, *dollar* growth is slowing. It seems likely that the days of rapid double-digit dollar growth rates are in the past. As evidence,

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Abbreviations: (CBGM) continuous blood glucose monitoring, (SMBG) self-monitoring of blood glucose

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consider the worldwide market growth since 2006. From 2006 to 2007, the world market grew approximately 8%, and from 2007 to 2008, the world market grew only approximately 6% (in dollars). Moreover, growth in the U.S. market has been flat or nearly flat since 2006. In fact, the first quarter sales figures for 2009 show that some SMBG vendor sales actually declined.

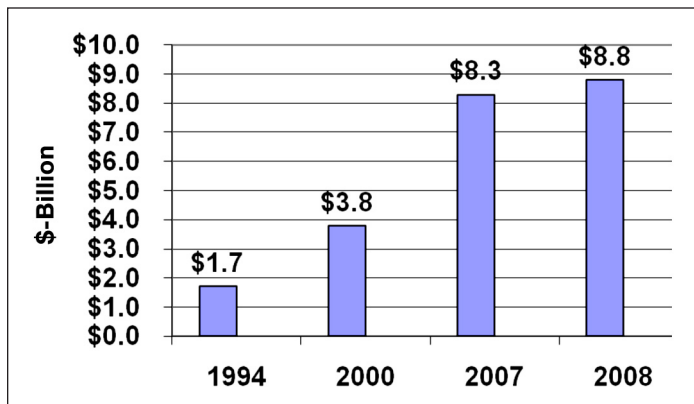


Figure 1. World market size for blood glucose monitoring products, including blood glucose products for hospital bedside and other decentralized test locations representing approximately 10% of the market. Data were supplied by Enterprise Analysis Corporation.

In the context of understanding the future growth potential of SMBG market, it is useful to examine some of the key market drivers and constraints. These opposing market forces are described as follows.

Market Drivers

- The ever-growing population of diabetes patients, both in the United States and worldwide. The Centers for Disease Control estimates 1.5 million newly diagnosed diabetes patients in 2007 in the United States and a total U.S. diabetes population of 23.6 million.¹ Meanwhile, the World Health Organization forecasts the worldwide diabetes population to grow from 171 million in 2000 to 366 million by 2030.² The growth of the diabetes population is driven, in turn, by the obesity epidemic in the United States, overall world population growth, and aging of the population in many developed countries (in which type 2 diabetes is more likely to occur).
- Expanding economies and growing affluence in China, India, and other countries of the Pacific Rim create additional opportunities to sell glucose monitoring products. Once considered marginal market opportunities, some vendors now view these markets as significant opportunities for market expansion.

- Attempts by health care professionals, insurance companies, and disease management companies to educate diabetes patients on the importance of SMBG. While there has been some progress on this front, the majority of diabetes patients still test far less frequently than recommended by the National Institutes of Health.
- Advances in SMBG testing technology that make it easier and more convenient to perform testing. These advances have facilitated more testing among some of the more motivated insulin-dependent diabetes patients and have also most likely persuaded some of the “nontesters” to adopt glucose monitoring.
- Wider availability of diabetes software programs that allow medical professionals to easily download patient data from glucose meters. This is likely to facilitate more open communication between healthcare providers and patients about blood glucose monitoring.

Market Constraints

- Gradual shifting in SMBG products from retail pharmacies to discounted mail-order suppliers. Growth in the mail-order segment is outpacing retail outlets and now accounts for roughly 30–40% of the SMBG business in the United States.
- Increased penetration from private-label brands in retail outlets at discounted prices. Major drug store chains now have their own SMBG brands, and this has driven the overall average price per test strip downward.
- Price pressure from nationalized health insurance programs in foreign countries. In some countries where nationalized health insurance exists, glucose test strips are priced at less than half the U.S. prices.
- General unwillingness of diabetes patients (many of whom are low income or on fixed incomes) to pay more “out-of-pocket” expense. With copays generally rising, some patients are seeking lower-cost alternatives or testing less frequently.
- The challenge of educating the diabetes patient on the importance of frequent blood glucose testing in order to better manage their diabetes. A number of different surveys have indicated that most diabetes patients do not perform blood glucose testing anywhere near the recommended frequency.

Competition and Barriers to Entry

From a competition perspective, four companies dominate the SMBG business, controlling approximately 90% of the market: Roche Diagnostics (Hoffman-LaRoche, Basel, Switzerland), LifeScan (Milpitas, CA, a Johnson & Johnson company), Bayer Healthcare Division (Tarrytown, NY), and Abbott Laboratories (Abbott Park, IL). The “big four” offer a wide variety of SMBG products and have dominated the market since the late 1990s (Table 1). Numerous second-tier and third-tier competitors, including several in Asia, hold the remaining 10% of the market. Among the most notable are Arkray (Kyoto, Japan), Home Diagnostics, Inc. (Ft. Lauderdale, FL), and AgaMatrix (Salem, NH).

Table 1.
Major Competitors and Market Shares in the World Blood Glucose Monitoring Market^a

Company	Sales 2007 (million)	Sales 2008 (million)	Growth (2007–2008)	Market share 2008
Roche Diagnostics	\$2638	\$2709	3%	30.8%
LifeScan	\$2263	\$2385	5%	27.2%
Bayer Healthcare	\$1297	\$1438	11%	16.3%
Abbott	\$1249	\$1353	8%	15.4%
All others	\$800	\$895	8%	10.3%
Total	\$8247	\$8780	6%	100%

^a Data were supplied by Enterprise Analysis Corporation and company financial reports. Excludes sales of insulin pumps and other unrelated diabetes products.

Although company market shares have shifted somewhat, the same vendors still dominate the market as in 1998, illustrating the challenge of breaking into this market. With respect to the U.S. market, the principal barriers to entry can be summarized as follows:

- Competitive bidding for preferred status on managed care organization pharmacy formularies is intensifying. The key to maintaining market share is keeping “favored” status on these formulary programs where the patient must purchase the formulary product to get the lowest price or choose a nonformulary product at a higher price.
- Difficulty obtaining prime shelf space at the pharmacy. With so many products already on the market, a new entrant has to battle for visibility on the shelf.
- The challenge of influencing nurses and diabetes specialists to recommend or even show diabetes

patients yet another SMBG product. The already bewildering array of products can be confusing to the newly diagnosed patient.

- Achieving significant product differentiation in the eyes of the diabetes patient or insurance payer. Product differentiation is a key factor for market success in this highly competitive market. Yet the investment required to achieve product differentiation can be substantial, and the required technological innovations are not so easily achieved.

One example of the challenge of entering the SMBG market is that of BD (Franklin Lakes, NJ), which entered the SMBG market in 2003 but failed to gain any substantial market share despite having an already strong presence in the retail pharmacy with its insulin syringe business. After several unprofitable years, BD finally announced its withdrawal from the market in 2007.

Technology Trends

There has been a striking evolution in glucose monitoring technology since the first blood glucose tests for self-monitoring were introduced around 1980. Technology innovations have been an important aspect of the SMBG market in that they have allowed the SMBG vendors to remain competitive with each other and have contributed to the inevitable fluctuations in market share gains and losses among these vendors over the years. Consider where SMBG technology was in 1980 and where it is today:

- First-generation glucose meters in the early 1980s were somewhat bulky and plain, with very few features, and had many manual steps. Fast forward to today, where glucose meters come in an almost infinite variety of shapes, sizes, colors, and styles to appeal to every type of consumer. The “tech savvy” users can have a glucose meter built into Palm Pilots to manage and organize blood glucose data, store hundreds of results, transfer data, and even send alerts. Glucose monitors have even been built into cell phones. Meanwhile, the elderly grandfather with poor vision can buy a basic monitor devoid of all the fancy features except for a large LED screen so that he can read the results easily.
- Glucose meters now require tiny blood volumes and yield results in a matter of seconds. First-generation meters in the early 1980s required a large “hanging drop” of blood along with blotting of excess blood from test strips and then waiting a minute or more for results. Now we have pinhead size drops of blood

as small as 0.3 μ l, with test results available in as little as 5 s in many cases.

- Collecting the blood sample is now less painful. In addition to the smaller sample sizes, other advances in lancing technology have made blood sampling less painful for diabetes patients; pain being a major impediment to more frequent testing. Many blood glucose meters are now approved for sampling from sites other than the fingertips (e.g., palms, forearms, and thighs), where there are fewer nerve endings.
- The testing process itself has been greatly simplified. Most of the glucose meters today do not require any controls or “coding,” and some have a built-in cartridge or “drum” that contains the test strips, which are ready at the push of a button, thereby eliminating manual handling of the test strips.

Perhaps one of the more significant recent technology trends is the emergence of continuous blood glucose monitoring (CBGM), where a sensor implanted under the skin provides continuous glucose measurements. Three companies, Abbott, Medtronic, and DexCom, have recently introduced CBGM products. While the reimbursement situation for CBGM remains uncertain and the current CBGM products are “pricey,” clinical evidence suggests that such products offer diabetes patients a means to achieve much better glucose control through minute by minute glucose measurements.

Arguably, these technology innovations have facilitated more frequent blood glucose monitoring among some diabetes patients, primarily the insulin-dependent diabetes patients. Yet it is somewhat ironic that, despite the remarkable advances in glucose testing technology, the vast majority of diabetes patients, particularly type 2 diabetes patients, still do not test nearly as frequently as they should and some still do not test at all.

Market Outlook and Future Prospects

Given the increasingly competitive nature of the SMBG business and the declining prices, it will very likely be difficult for a *new* entrant to succeed in the SMBG market in the absence of a truly major technological innovation. With prices likely to decrease, yet another “me too” glucose meter/strip manufacturer has little chance to succeed.

For the existing players in the market, the key question becomes how to sustain strong growth while still maintaining adequate profit margins in the future. Given that raising test strip prices will be difficult, if not

impossible, and that newly diagnosed diabetes patients entering the pool are essentially offsetting the price decline, two sources of growth are left for vendors:

1. Expanding the total SMBG market size “pie.” This involves convincing existing diabetes patients to test their glucose levels more frequently, convincing the “nontesting” population to adopt glucose monitoring, and identifying more of the currently undiagnosed diabetes population.
2. Take market share away from the competition using technological innovations and marketing and pricing tactics, or a combination of all.

On point 1, it seems abundantly clear that technology alone is not the answer to expanding the SMBG market pie and that educational efforts have had only a limited impact to date. So if technology and education are not effective, what are the other options? One obvious first step is for SMBG vendors to simply sponsor or support programs (e.g., local health fairs) to identify the millions of undiagnosed diabetes patients and try to push as many as possible to adopt glucose monitoring (not unlike cholesterol-screening programs). A second way to expand the U.S. market, albeit more controversial, may lie in some kind of a health economic “reward/punishment” approach employed by the insurance payer or the patient’s employer. As a possible example, if the patient does not reduce their hemoglobin A1c level below 7%, then he or she is hit with an insurance premium increase (essentially, a fine). Such economic incentives may be a way to change the behavior of diabetes patients just as raising prices on tobacco reduced the number of smokers. On the other hand, the notion of levying a fine on a 75-year-old diabetes patient on a fixed income who already has difficulty in paying for drug prescriptions may be a “nonstarter.” In any case, such a health economic model would need to be driven by insurers, disease management firms, and possibly even the employers paying the insurance premiums. However, the SMBG vendors would clearly benefit, and there may yet be ways for the various stakeholders to work together creatively to make such a model a reality.

On point 2, taking market share from competitors often relies on product differentiation as a result of technological innovations. If the technological innovation is significant enough, it can yield both market share gains and an expansion of the market. Noninvasive blood glucose testing is an example of such a revolutionary technology, but no product is likely to be available in the

market for many years. In the near term, the emergence of CBGM technology may represent the best opportunity to reinvigorate market growth with a premium priced technology that could yield substantial market share gains and possibly expand the overall market size. Ultimately, the health outcomes and cost-savings data will dictate how successful CBGM technology will be and how much insurance companies are willing to pay for such technology.

In conclusion, SMBG remains a sizeable and growing market. However, it faces some challenges ahead in sustaining the kind of growth and profits it has enjoyed in the past. Technology innovation alone is probably not the *sole* solution for strong, sustainable market growth. But from an SMBG vendor perspective, the best *near-term* opportunity to reviving dollar growth may lie in CBGM technology.

Disclosure:

Over the 22-year history of Enterprise Analysis Corporation, the company has served as a consultant to various companies active in the diabetes field.

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