For additional information or to purchase the book, please go to: http://direct.aacc.org/ProductCatalog/Product.aspx?ID=6117.
The emergence of the consumer electronics industry has been a force that impacts every aspect of modern society. In this chapter, we analyze the relevance of the consumer electronics industry to the field of point-of-care testing (POCT). Some trends and key moments in the history of the consumer electronics industry will be highlighted in order to understand the impact of consumer electronics. Two cases will be discussed that illustrate how consumer electronics technology has already impacted POCT by enabling two of the largest POCT applications to become mainstream products. Next, some examples of an upcoming generation of POCT devices will be discussed, in which the benefits of consumer electronics have been utilized to a higher level. Finally, we consider how POCT could develop under the influence of consumer electronics.

HISTORY OF CONSUMER ELECTRONICS

The radio can be considered the first consumer electronics device. Guglielmo Marconi is generally considered to be the inventor of the radio—he transmitted radiotelegraphy signals without the use of wires in 1890 (1). In the early twentieth century, it became possible for the first time to transmit voice and music, but not until the 1920s did the radio become available to the general public when the first radio station came into operation. The invention of the radio paved the way for a whole breed of new electronic devices that would later include televisions, personal computers, and cell phones (2). The invention of the transistor in November 1947 by John Bardeen and Walter Brattain at AT&T Bell Labs played a pivotal role in shaping the consumer electronics industry, enabling electronic circuits to be mass produced at very high densities. The consumer electronics industry can be characterized based on five major trends:

1. Miniaturization: The portability of electronic devices such as MP3 players, cell phones, or laptops computers is taken for granted, but this has not always been the case. Early models of these devices cannot be considered portable; for example, the first computers easily filled an entire room. Advances in integrated circuit technology have enabled the placement of more power into a smaller and smaller sized form.

2. Falling prices: Besides the reduction in size, the invention of the transistor also led to a significant reduction in costs, which has become one of the overriding characteristics of the consumer electronics industry. For the past few decades, this development has obeyed Moore’s law, which states that, for a given price, semiconductor functionality doubles every two years.

3. Product convergence: Consumer electronics continues in its trend of convergence, combining elements of various consumer electronic items in a single device. A good example of a product displaying such convergence is the smart phone, which combines the functionality of a telephone with a music player, an electronic organizer, and Internet access.

4. Connectivity: A growing trend in consumer electronics is connectivity. Many devices that used to be operated in isolation now provide options to connect to the Internet or to a computer using a...
home network to get access to digital content (such as MP3 players) or share content with other
devices (e.g., uploading pictures to the Internet).

5. Environmental impact: Rapid technology change, low initial cost, and planned obsolescence have
resulted in a fast-growing surplus of electronic waste around the globe. The increased attention to
the environment has made the environmental impact of electronic devices an increasingly impor-
tant factor in the consumer electronics industry.

CONSUMER ELECTRONICS IN POCT: TWO KEY EXAMPLES

The driving force behind POCT is to bring a diagnostic test to the patient conveniently and immedi-
ately. This will allow treatment to start earlier, thus improving the quality of care. Two examples will
be discussed that illustrate how consumer electronics has been used to fulfill this requirement.

Glucose testing by diabetic patients is undisputedly the most successful example of POCT. The
first blood glucose measurements were carried out with small paper strips invented by Ames and
introduced in 1965 as Dextrostix® (3). A measurement is performed by adding a drop of blood to
a strip, which is then washed off after 1 min. Upon reaction with glucose in the blood, a blue color
develops, and the strip is read by comparing the color to a color chart that is provided with the strips.
This process cannot be considered quantitative; at best, it gives a semiquantitative indication of the
blood glucose level.

Upon realization that the Dextrostix strips were difficult to use, Ames developed an instrument
to read the strips more accurately. The Ames Reflectance Meter is generally accepted as the first glu-
cose meter. It measured the color change on the strip and displayed the result on a numerical scale
(Figure 8-1). With the electronic readout instrument, the accuracy of the glucose strips improved,
turning the outcome of a measurement from an indication into a quantitative result. This was a break-
through that can be largely attributed to the use of consumer electronics.

In the further evolution of the glucose meter, the main trends in consumer electronics can be
clearly recognized. Miniaturization helped to bring the size down from a tabletop instrument to a
device that can easily fit in a shirt pocket and be taken anywhere. The Ames Reflectance Meter was
very expensive in the beginning (costing the equivalent of a month’s wage) (4), but the price of glucose
meters has come down to such low levels that now the meters are given away for free to stimulate the
sales of the disposable glucose strips. Connectivity has also become one of the basic features of today’s

Figure 8-1  The Ames Reflectance Meter. Reprinted with permission from Bayer HealthCare AG.
glucose meters; most meters can be connected to a personal computer and to the Internet to allow tracking glucose levels over long periods of time.

Another major example of POCT devices are membrane strips, through which a small volume of sample liquid is transported by capillary forces. These so-called lateral flow tests are based on the binding of labels in the presence of analyte through an immunochemistry reaction. Typically, small gold particles are used as labels; the binding of the particles results in the visual appearance of a colored dot or line (Figure 8-2).

For a pregnancy test, typically there will be a clear color change visible because the hormone concentrations increase markedly after conception. Judging by eye whether a result is positive or negative can be considered acceptable for the home setting to determine pregnancy. However, in other settings, such a subjective judgment could pose a problem. For example, lateral flow strips are used by the police to determine whether a suspect has used an illicit drug of abuse. Clearly any ambiguity and resulting subjectivity in judgment in such a situation is highly undesirable. The problem becomes even more significant for quantitative tests, in a similar way as in the previous example of blood glucose testing. To obtain a quantitative result, the user would have to compare the intensity of the line to a set of reference lines to determine the outcome, resulting in poor accuracy.

For lateral flow–based diagnostic tests, consumer electronics are now also used to objectify the readout of the test. A good example is the introduction of the Clearblue DIGITAL Pregnancy Test® (SPD Development Company, Bedford, United Kingdom) (Figure 8-3). Not only does it provide an unambiguous readout of the result (pregnant or not pregnant), but it also provides an indication of the number of weeks since conception. Without changing the underlying basis of the test, the value of the diagnostic has been increased significantly by applying consumer electronics. As this example demonstrates, the ever lower prices of consumer electronics even allow for usage in a disposable device, only increasing the cost of the overall test slightly.

**USER INTERFACE**

The two examples discussed in the previous section clearly illustrate how consumer electronics technology can improve the value of POCT. In both cases, the user interface of the test was addressed. Not only does the addition of electronics improve the accuracy of the test in the hands of a medical professional, but it also enables nonexpert operators to read out the test with the same accuracy. Operator independence and improved ease of use improve the interchangeability of the results and pave the way toward self-testing by patients. Enabling patients to take care of themselves at home is considered an important way to control the increasing costs of healthcare.

In addition to aiding the readout of an instrument, consumer electronics technology can also be used to support the user during the entire testing procedure. For example, by adding a large display,
the user can be given graphical instructions on what operations are to be carried out, and the display can provide feedback on the progress of the test. The use of consumer electronics is still increasing, and almost everybody, from small children to the elderly, now use consumer electronics devices such as cell phones and MP3 players. These advances in consumer electronics also offer opportunities to further improve the acceptance of POCT.

**CONVERGENCE AND CONNECTIVITY**

To improve the reliability of a diagnosis, a combination of multiple modalities is often needed, such as the combination of vital signs, in vitro diagnostic testing, and questionnaires. Consumer electronics can bundle these results into a single overview by transmitting the results to a central hub via wireless communication using standards like Bluetooth or WiFi. In the home setting, such a central hub could be a set-top box that presents the result on a television, a device that every patient would know how to use. The central hub can also be used to submit the results to the physician in charge of the patient, which will enable monitoring the patient from a distance. In this way, the physician can remain in full control of the treatment while the patient can stay in the comfort of his or her home.

Besides bundling and sending the results to the physician, the central hub could also perform a first level of interpretation of the results. Clinical decision support software could compare the actual results to normal levels and give user feedback in the form of advice. This advice could vary from “everything is okay” to “please see your physician.” This lowers the burden on both the patient and the physician by reducing the number of patient visits only to the situations where a visit is really needed.

A recent example of convergence and connectivity is the GlucoPhone™ that was introduced by the company HealthPia in 2008 (Genesis Health Technologies, Paducah, KY, USA). The GlucoPhone consists of a glucose meter that is built into a cell phone. The patient checks their blood glucose, and the result is displayed on the phone screen. The results are sent by phone to a database where the results are stored. Optionally, a text message can be sent to the caregiver via the database in case unusual values are detected. The GlucoPhone results in the database can also be accessed online. The GlucoPhone has now been superseded by the GlucoPhone gDrive™ meter (Genesis Health Technologies) that has a mini USB port connector that will plug directly into a number of different cell phones, thus enabling many different phones to have a glucose testing capability (http://www.genesishealthtechnologies.com) (Figure 8-4). Similar types of connectivity have been developed for glucose meters intended specifically for children (ages 5–14 years) with diabetes (e.g., the Bayer DIDGET™ meter;
The Role of Consumer Electronics in Point-of-Care Testing

http://www.bayerdiabetes.com; Bayer HealthCare, Tarrytown, NY, USA). These devices plug into common game systems (e.g., Nintendo DS™; Nintendo, Kyoto, Japan). Yet another meter with USB connectivity is the Bayer CONTOUR® USB glucose meter that plugs into a computer (http://www.bayercontourusb.us).

ENVIRONMENTAL IMPACT

In the previous sections, some potential advantages of the increasing role of consumer electronics have been discussed, namely more accurate readout, improved user interaction, and connectivity. However, the ubiquitous presence of electronics also has a disadvantage. The environmental impact of consumer electronics devices is on the rise, leading to increased attention to electronic waste in the entire consumer electronics industry. With an ever higher amount of electronics being used in POCT, the topic of electronic waste will also become more important for POCT.

Most POCT tests have a disposable element, since the biochemical components of the test can only be used once. The environmental impact of such a disposable will become quite important as POCT increases in popularity. For a POCT device such as a pregnancy test, it may be acceptable to integrate a simple piece of electronics in each disposable, but for high-volume tests such as glucose monitoring (with multiple tests per day for life), the environmental impact will be significant. If POCT with incorporation of disposable electronic components is to become a mainstream alternative for central laboratory testing, then the problem of disposal needs to be addressed.

A straightforward solution to address this problem would be to design POCT devices in such a way that the active electronic components are located in a reusable instrument and to keep the disposable free from active electronics as much as possible. For the most mature application in the field, namely blood glucose monitoring, this has actually already happened. The disposable test strips are very small, and except for a couple of simple electrodes, all active components are located in the blood glucose meter. Other applications will likely have to copy this model for POCT to become an acceptable alternative to central laboratory testing, both from an environmental perspective and from an economic perspective. Therefore, it is not to be expected that advanced consumer electronics will be used in high volume in ever more complex diagnostic disposables. In the next section, some potential POCT technologies will be discussed in order to assess how consumer electronics can be used in the point-of-care tests of tomorrow.

CONSUMER ELECTRONICS IN POCT: NEXT GENERATION

The use of consumer electronics has had far-reaching advantages for blood glucose monitoring, which has benefited from all major trends in consumer electronics. For more complex diagnostics applications, such as immunodiagnostics applications, the use of consumer electronics has been less pervasive. In the example of pregnancy testing, an electronic module has been added to an existing POCT device to improve readout and the subsequent data handling. This approach has the advantage that the underlying diagnostic test itself hardly needs any modification, which reduces the development effort, but at the same time, this is also a missed opportunity. By not changing the test, there is also no fundamental improvement in analytical performance.

In particular, the precision of quantitative immunodiagnostics POCT leaves room for improvement. One of the key reasons for the inferior precision of POCT devices is that steps of the assay that are well defined in central laboratory instruments are typically passively triggered in POCT. For example, in a lateral flow test, many of the steps of the central laboratory instrument are present including incubation, binding, and washing. These steps are actively controlled in the central laboratory, whereas they are passively triggered by the flow speed in a lateral flow test. Minor variations (e.g., timing) in each of the steps add up to large variations of the final test result.

Consumer electronics technology can be used to increase the level of assay control. The first two examples discussed in the following paragraphs take central laboratory equipment as a reference and miniaturize it in a POCT format.
One of the earliest examples of this new class of POCT devices is the i-STAT® system (Abbott Laboratories, Abbott Park, IL, USA). This system consists of a handheld analyzer instrument (Figure 8-5) for performing electrolyte, coagulation, glucose, cardiac marker, and other chemistry and hematology tests. Wet assay reagents are stored in the cartridge and are actively pumped by the analyzer by mechanical displacement to perform the various steps of the assay. This active pumping enables accurate assay timing and well-controlled liquid displacement.
Another example is the Atolyzer® system (Figure 8-6) that was developed by Atonomics (Atonomics A/S, Copenhagen, Denmark). The central idea behind this instrument is to mimic the steps that take place in central laboratory equipment with equivalent steps in a disposable cartridge. The Atolyzer system uses magnetic particles similar to those used in the central laboratory equipment, and the immunoassay protocol (reagents, mixing/incubations steps, and washing of solid phase) has much in common with the central laboratory protocols. The implementation in the system is achieved by pumping of on-cartridge liquids and movement of the magnetic particles. The first test on this POCT platform will be an assay to measure the cardiac marker brain natriuretic peptide (BNP). Also in this system, a significantly higher degree of assay control is achieved by carrying out every step of the assay by actively triggered actions.

The i-STAT system and the Atolyzer use consumer electronics technology to miniaturize central laboratory technology to bring the size and cost down sufficiently to be used for POCT. The reduction in size to the microscale also enables exploitation of different physical principles compared to the macroscale of the laboratory instruments. This offers some interesting possibilities for a higher degree of integration.

The Fluidics-on-Flex® technology from Epocal (Epocal, Ottawa, Ontario, Canada) is a good example to illustrate this point. Epocal’s one-step immunoassay cartridge contains a microporous antibody/incubation pad, a microporous capture pad, and a pump manifold with multiple electro-osmotic pumps (Figure 8-7). The electro-osmotic pumping offers significant integration advantages because it can be achieved using electrodes instead of moving parts. This simplifies the interface between the disposable test device and the readout instrument. Furthermore, the disposables can be manufactured in a
Figure 8-8  The Magnotech from Philips uses the controlled movement of magnetic nanoparticles. *Reprinted with permission from Philips.*
reel-to-reel process that demonstrates similarity with the way smart cards are made. This technological change enables the scaling advantages of manufacturing methods from the electronics industry to be realized.

The Magnotech® system, developed by Philips (Philips Healthcare, Eindhoven, the Netherlands), is another example of a system that utilizes different physical principles to implement the essential steps in an assay. In this system, the traditional liquid manipulation steps have been replaced by magnetically controlled movement. Magnetic nanoparticles in a stationary liquid are used to perform the assay (Figure 8-8). Because no additional buffer liquids are needed in this system, the fluidics have become as simple as a glucose strip. A droplet of sample liquid is drawn in by capillary forces to fill a measurement chamber in which all the subsequent steps of the assay are performed. The magnetic forces offer a high degree of control over every step of the assay. The signal is read out by optics that share a high degree of similarity with the optics found in CD/DVD players.

The last two examples illustrate how advances in electronics, magnetics, and optics from the consumer electronics industry can be used to replace some of the traditional assay steps found in central laboratory instrumentation with steps that perform the same function but are implemented by different physical methods. The main driver behind this trend of integration is to further simplify POCT devices, in particular the disposable part of the tests. By leveraging the advances in consumer electronics, the cost of POCT can be further reduced. This trend can be described as “integration,” in contrast to the trend of “miniaturization.”

CONCLUSIONS

In this chapter, we analyzed how consumer electronics influence POCT. The technology from the consumer electronics industry offers a great opportunity for the design of POCT devices that provide advantages in user interaction and connectivity and reduce the prices of tests. In fact, consumer electronics technology has been one of the key driving forces behind the most successful POCT application of blood glucose monitoring, enabling it to grow to a massive 8 billion dollar market today that is still expanding.

In the more advanced immunodiagnostic POCT, the use of consumer electronics technology is on the rise. A new generation of devices can be identified that uses consumer electronics technology to offer a higher degree of control over the test in order to improve the precision of the result. There is an increasing focus on simplification of the disposable by using different physical principles to fulfill the same functions as the steps used in the central laboratory equipment but that can be integrated more easily.

We have not discussed the field of molecular diagnostics because it cannot (yet) be considered POCT at the time of writing. However, it is to be expected that molecular diagnostics will be the next area that benefits from the use of consumer electronics technology. Currently, these tests typically
involve a number of manual steps that can only be carried out by a trained operator. Integration and automation of these steps powered by consumer electronics technology may enable molecular diagnostics to make the transition to POCT in the near future.

Schematically, the degree of influence of consumer electronics on the various POCT fields is depicted schematically in Figure 8-9. Consumer electronics technology has allowed blood glucose testing to evolve into a mass market application, and these measurements are now being integrated into other consumer electronics applications. Immunodiagnostics follows closely, where miniaturization and integration will increase the analytical performance of POCT to a level where it becomes a significant alternative to central laboratory testing. Molecular diagnostics still has some way to go; in particular, a higher degree of integration will be required for the rather complicated sample pretreatment currently required for such tests.

REFERENCES