Chapter 29

AUTOMATED EXTERNAL DEFIBRILLATORS FOR LAYPERSON USE

Technology to Change the Sudden Cardiac Arrest Treatment Paradigm

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Abstract: Sudden cardiac arrest (SCA) is a leading cause of death worldwide. Unlike other epidemics of this magnitude, there exists a definitive and proven therapy for SCA caused by ventricular fibrillation, which is defibrillation. It is estimated that fewer than 5% of people who experience sudden cardiac arrest survive, however, largely because a defibrillator does not arrive in time. Traditionally, defibrillators required extensive training, were large, bulky, maintenance-intensive, and expensive equipment, which limited their widespread deployment. Philips seized the opportunity and has since pioneered numerous technological solutions that have fundamentally changed how sudden cardiac arrest is treated around the world.

Keywords: AED, automated external defibrillator, defibrillator, sudden cardiac arrest, ventricular fibrillation, Heartstream

1. SUDDEN CARDIAC ARREST

Heart disease is a leading cause of death worldwide with no regard for geography, gender, or socio-economic status. It claims nearly 17 million lives each year[1]. In the United States and Europe alone, approximately one million of these deaths are from a specific heart condition called sudden cardiac arrest (SCA)[2,3]. In the U.S., sudden cardiac arrest claims more lives each year than breast cancer[4], prostate cancer[4], AIDS[4], traffic accidents[4], handguns[4], and house fires[5] *combined*.

Different from a heart attack, which is caused by a blockage in an artery, SCA is an electrical malfunction of the heart typically associated with an abnormal heart rhythm known as ventricular fibrillation (VF). Sudden

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cardiac arrest usually strikes without warning and the majority of people have no previously recognized symptoms of heart disease[2].

Unlike other epidemics of this magnitude, there exists a definitive and proven therapy for ventricular fibrillation. This therapy is defibrillation - the application of an electric shock to the heart - applied to the patient's chest with a defibrillator. Defibrillation eliminates the ventricular fibrillation and allows a coordinated electrical rhythm and pumping action to resume. For the best chance of survival from SCA caused by VF, a defibrillator should be used within 5 minutes. For every minute that goes by without defibrillation, the chance of survival decreases by 7-10%. After the first few minutes, survival is unlikely. The American Heart Association estimates that fewer than 5% of people who experience sudden cardiac arrest survive largely because a defibrillator does not arrive in time6.

In 1996, the U.S. Food and Drug Administration (FDA) cleared the Heartstream[i] ForeRunner automated external defibrillator (AED), which heralded a new era in the field of defibrillation. The ForeRunner was small, portable, easy-to-use, and less expensive than its emergency room counterparts. Defibrillation therapy was now packaged in a revolutionary way that made it practical to put defibrillators in the hands of non-medically trained responders in order to speed delivery of defibrillation to victims.

Starting with the ForeRunner, a number of pioneering technological solutions have fundamentally changed how sudden cardiac arrest is treated around the world.

2. HISTORICAL OVERVIEW: HEARTSTREAM AND THE FORERUNNER AED

Heartstream was founded by five individuals in 1992 with the mission of improving survival from sudden cardiac arrest. The vision was to improve access to AEDs by developing and deploying devices that could be used by virtually anyone to help save a life. The team understood from the beginning that survival depended upon early defibrillation and that in order to achieve it, widespread accessibility was mandatory. The goal was to develop a technological solution that would overcome the limitations of previous generations of defibrillators. Namely, the product had to be easy to operate,

[i] Heartstream, Inc. was founded in 1992. In 1998, the Hewlett-Packard Company (HP) acquired Heartstream. In 1999, HP created an independent test and measurement company, which included the Heartstream Operation. The new company was called Agilent Technologies. In 2001, Agilent Technologies' medical business was acquired by Philips Medical Systems.

virtually maintenance free, reliable, rugged, small, lightweight, and relatively inexpensive to own.

Initially, the technology would be targeted towards emergency medical responders, such as paramedics and EMTs who were often trained to defibrillate, but who did not usually carry defibrillators as standard equipment. At the time, only 25% of ambulances and only 10-15% of fire companies with emergency "first-response" responsibilities were equipped with portable external defibrillators[7]. From the beginning, however, the Heartstream founders envisioned a day when their AEDs would be used by millions of first responders, which they believed would someday include lay responders in the home as well.

With this vision, a small development team set out to revolutionize the treatment of sudden cardiac arrest.

2.1 Biphasic waveform therapy

For the first 30 years of commercial external defibrillation, monophasic waveforms were used to deliver the "electric medicine" to treat SCA. With such waveforms, current throughout the pulse flows in one direction from one electrode pad through the body to the other electrode pad. To perform defibrillation with this technology, it was generally accepted at the time that between 200 and 360 joules of energy should be delivered. While a monophasic waveform was considered effective and relatively easy to create, it required a significant source of energy. The heavy rechargeable batteries typically used to power the pulse generator were expensive and maintenance intensive[8].

In the late 1980s, the biphasic waveform was introduced to implantable-cardioverter defibrillators (ICDs) in order to reduce the size, weight, and battery requirements of these devices. In a brief time, the biphasic waveform became the standard therapy in nearly all ICDs. With a biphasic waveform, the direction of the current flowing between the electrode pads placed on the patient's chest is reversed part way through the pulse. Importantly, less energy is required to achieve defibrillation efficacy comparable with monophasic waveforms. This means that the defibrillator itself and its energy source can be smaller and lighter[8]. Comparative studies of ICDs in humans demonstrated superior results of biphasic defibrillation over monophasic defibrillation[9,10]. Based on these results, scientists at Heartstream hypothesized that implementing a biphasic waveform in an AED could potentially result in smaller, lighter, and less costly AEDs appropriate for use by laypersons.

Heartstream chose to develop a 150 J biphasic waveform to facilitate the design of a portable AED. In addition, the team believed that the lower-energy 150 J biphasic waveform would help minimize dysfunction associated with higher energy shocks. The 150 J low-energy biphasic waveform was developed and validated first in an animal trial, which found that biphasic waveform techniques could be employed to achieve high defibrillation efficacy[11]. A pilot study in humans showed that the low-energy biphasic shocks were as effective as the higher-energy monophasic shocks[12].

Following the pilot study, Heartstream conducted the largest comparative study of defibrillation waveforms that has been performed to date[13]. The study results demonstrated that initial 130 J biphasic waveform shocks defibrillated as well as initial 200 J monophasic waveform shocks traditionally used in standard defibrillators. In a smaller subset of patients, the efficacies of 115 or 130 J initial biphasic shocks were not statistically different from 360 J initial monophasic shocks.

Once commercial shipments of the ForeRunner began in December 1996, researchers were eager to observe the field performance of the SMART Biphasic waveform. Two published studies resulted, which both concluded that the SMART Biphasic waveform was able to terminate long-duration VF at rates above those previously published for monophasic shocks[14,15].

Results of the only multi-center, randomized, controlled trial comparing the SMART Biphasic waveform to various monophasic waveforms in the out-of-hospital setting were published in 2000[16]. This study concluded that the SMART Biphasic waveform defibrillated at higher rates than the monophasic waveforms.

With its introduction in 1996, the ForeRunner became the first commercially available AED to use a low-energy biphasic waveform. Over the next several years, the AED industry embarked on the "energy wars," whereby multiple manufacturers made arguments for sticking with monophasic waveforms. Now virtually every AED on the market offers some variation of a biphasic waveform. Led by Philips, the biphasic waveform became the industry standard.

2.2 Impedance-controlled defibrillation

A defibrillator delivers "electric medicine." For a defibrillation pulse to be effective in terminating ventricular fibrillation, a sufficient "dose" of current must reach the heart. With external defibrillation, the electricity must first travel through skin, muscle, bone, organs, and other tissues. The defibrillator's design and construction must take into account that the electrical resistance, or *impedance*, of the chest varies significantly from

person to person. Impedance is influenced by several anatomical and physiological factors and cannot be estimated by looking at a person.

Traditionally, to ensure that defibrillation would be effective on most patients, defibrillators were designed to deliver a high dose of energy such that victims with high chest impedances would receive sufficient current to defibrillate their hearts. This meant that on a relatively frequent basis, victims with low chest impedances potentially received substantially higher amounts of current than was necessary.

The challenge was to design a defibrillator that could effectively measure and compensate for patient impedance in order to deliver the correct dose of current (and energy) on the *first* shock. Rather than delivering a high dose of energy to all victims regardless of need, the ForeRunner was designed to use a special method of instantaneously measuring chest impedance and automatically optimizing the waveform for each victim. This innovative process, called impedance-controlled defibrillation, compensates for patient impedance variations across a wide range of the anticipated patient population. The ForeRunner was designed to measure impedance and dynamically vary the waveform's attributes accordingly on every shock, making it unnecessary to increase the energy on successive shocks. The optimal therapy (or dose) would be delivered starting with the first shock.

As the most well studied external defibrillator waveform, substantial evidence now supports that the low-energy 150 J biphasic waveform performs as well as or, in most studies, far better than the "gold standard" monophasic defibrillation waveform on the first shock without the need to escalate[17,18,19].

2.3 Advanced patient diagnosis and safety

All AEDs analyze ECG information to make therapy recommendations based upon proprietary computational processes that are commonly referred to as algorithms. Algorithm performance is evaluated on two criteria: sensitivity - the ability of an algorithm to correctly detect life-threatening ventricular arrhythmias; and specificity - the ability of the algorithm to correctly discriminate normal rhythms or arrhythmias that should not be shocked. The key is to retain a likelihood of shocking rhythms that need it while reducing the possibility of an accidental or inappropriate delivery of a shock.

Heartstream developed revolutionary detection system known as "SMART Analysis" to allow sophisticated and accurate rhythm interpretation beyond simple rate-based analysis. The system used four key parameters, including rapidity of signal conduction, ECG amplitude, heart rate, and stability of

ECG complexes. No single parameter could lead to a "shock advised." The SMART Analysis system was tested against a database of more than 3,000 ECG rhythms, comprised of a wide variety of rhythms and patient settings. All rhythms were reviewed and classified as shockable and non-shockable by three independent, board-certified cardiologists. With the SMART Analysis system, the ForeRunner could automatically determine if a shock was appropriate, eliminating the need for the user to be trained in electrocardiogram interpretation. Furthermore, ForeRunner was designed to activate the shock button only when a shockable rhythm was identified. Following clearance, a study of the first 100 consecutive uses of the ForeRunner reported that SMART Analysis correctly identified all patients who required a shock (100% sensitivity) and all patients who did not require a shock (100% specificity)[14].

In order for SMART Analysis to work effectively, it requires relatively "clean" ECG signals from the patient. Touching the patient or trying to perform CPR during analysis can induce "artifact," which is an unwanted electrical signal present in the ECG data but unrelated to the electrical characteristics of the heart. Artifact can cause an incorrect analysis and potentially lead to an inappropriate shock/no shock decision. Some types of artifact are controllable, such as touching the pads, moving the patient, radio transmissions, or ground transport. Other types are non-controllable and may be caused by electrical interference, patient seizures, or an implantable pacemaker. SMART Analysis was engineered to "see through" many kinds of non-controllable artifact signals and correctly assess the signal from the heart. It was also designed to detect many other controllable, artifact signals and interrupt the analysis if the ECG was significantly corrupted and direct the user to troubleshoot the problem.

2.4 Ease of maintenance

By incorporating a low-energy, biphasic waveform, the energy storage and delivery challenges were significantly reduced. To power the ForeRunner, the Heartstream team selected a lithium-based battery system. It offered long-life batteries that required essentially no maintenance, were highly reliable, and were a fraction of the size and weight of rechargeable batteries. At the time, lithium batteries were increasingly being used in a range of medical and non-medical applications. A well-known and proven example was cardiac pacemakers. Lithium-based batteries were also widely used in the camera industry as they provided a dense source of energy for flash and motorized film advance photography. Mass production of lithium batteries to support the camera industry alone made them readily available and cost-effective[8].

The lithium battery system, coupled with automated self-testing, made the ForeRunner virtually maintenance free. The need for recharging was eliminated. Once a lithium battery pack was inserted in the ForeRunner, it automatically performed a comprehensive self-test of the battery and the internal circuitry and continued to perform these tests on a daily basis. Periodically, the ForeRunner would perform an internal discharge and verify its calibration. Each battery cartridge was typically capable of maintaining the device in a state of readiness for more than one year (or about 100 shocks). Similar to a fire extinguisher, the ForeRunner had a visual status indicator that could be checked at a glance to ensure it was ready for use[8].

2.5 Intuitive operation

Previously, emergency responders who defibrillated had to remember the protocol, including the number of shocks before pausing for CPR and the energy level for each shock. The goal was to help automate the protocol so that a broad group of users with minimal training could effectively use the product. Furthermore, the user interface had to be intuitive so that the user could move quickly through the steps in order to deliver the first shock if needed. Simplicity seemed like an obvious concept, but the team soon discovered that simplicity is difficult. From the beginning, real-world testing became a key component of the Heartstream industrial design process.

The industrial design team developed several symbols, or icons, to communicate with the user, which were considered a key innovation from a human factors standpoint. These icons were developed and refined through several rounds of design and real-world testing. Once such example was the icon developed to assist with proper pad placement, which is commonly recognized as the most difficult part of using an AED. In an innovative move, the team decided to put pictures of the pad placement on the electrode pads themselves. After testing several versions of the "trodeman" icon, they arrived at the design that is still used today. It took the insight of adding a circle around the pad to be placed that finally helped people understand pad placement.

The team's focus on the importance of industrial design was widely recognized and handsomely rewarded. In 1997, Heartstream received two prestigious Industrial Design Excellence Awards (IDEA) for its break-through in AED technology design. The ForeRunner captured a Gold award, the IDEA's highest honor, in the category of Medical & Scientific Products and a Silver award in the category of Design Exploration. *Popular Science* cited the ForeRunner in its end-of-year "Best of What's New" issue and called it "one of the year's 100 greatest achievements in science and

technology." The ForeRunner was a finalist in the Computerworld Smithsonian Awards and received the German Red Dot Award for High Design Excellence. Finally, in Peter S. Cohen's book, *The Technology Leaders: How America's Most Profitable High-Tech Companies Innovate Their Way to Success*, Heartstream was cited as one of America's most innovative technology leaders.

The awards in combination with studies of successful use by non-traditional emergency responders, such as security guards and flight attendants, helped demonstrate ForeRunner's ease of use[20,21]. However, one published study clearly highlighted the ease of use of the ForeRunner and caught the interest of the popular press when it reported that paramedics trained to use the device were only moderately faster at deploying the AED than sixth graders in a simulated response scenario using the ForeRunner without training[22].

2.6 Small, lightweight, and rugged

Early AEDs weighed up to 20 pounds and were as bulky as a portable typewriter. The use of innovative technology and materials resulted in a durable product the size of a hardcover book that weighed just 4 pounds, making it the lightest AED then available. For emergency responders already weighed down by equipment, an AED that fit compactly into an already crowded emergency vehicle and did not add substantially to the load of equipment carried to the emergency site made it a much more attractive tool.

The ForeRunner was designed to withstand a wide variety of adverse conditions commonly encountered in the "real" out-of-hospital emergency world, including water, mud, dust, and severe impact. The solid-state components were housed in a high-impact polycarbonate casing and were extensively tested. The team even went so far as to drive over a ForeRunner with a fire truck. It still worked.

2.7 Launching the ForeRunner AED

On September 12, 1996, Heartstream launched the ForeRunner AED (Figure 29-1). Over the next 48 hours, nearly every major news media outlet in the United States picked up the story reaching over 100 million Americans with the news. Shortly thereafter, American Airlines announced their decision to equip their fleet with ForeRunner AEDs. This unprecedented decision garnered widespread media coverage as well, even finding its way into David Letterman's monologue one night on *The Late Show with David Letterman*. The launch media coverage as well as that surrounding many of the subsequent sales and saves around the country played an important role

in raising awareness about sudden cardiac arrest and the need for early defibrillation. Previously, this was a topic not covered by the popular press. This awareness helped fuel the momentum behind the growing AED movement.

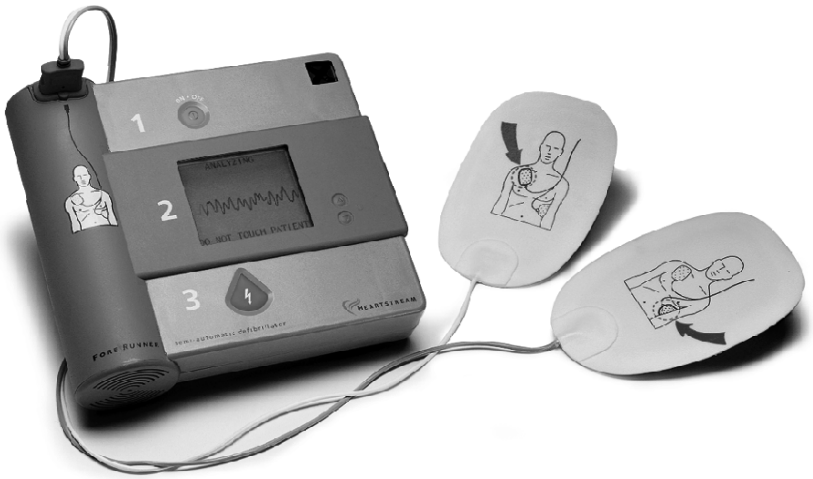

Figure 29-1. The Heartstream ForeRunner AED.

2.8 The true measure of success

With more than 500,000 people passing through Grand Central Terminal each day, the Metro North Railroad/Grand Central Terminal emergency response team felt that since they traveled to emergency situations in the terminal by way of an electric cart, the lightweight, durable ForeRunner AED would be a welcome addition to their first aid procedures. When their ForeRunners arrived on July 2, 1997, that had no idea they would need to use one so soon.

Bob Adams, a 41-year-old lawyer, was healthy, athletic, and had no history of heart disease. On July 3, 1997 he was about to catch the commuter train home from Grand Central when he collapsed. Within four minutes of starting CPR and using their new ForeRunner, the emergency responders had Bob's heart beating normally and he regained consciousness. Bob was taken to a local hospital where he made a full recovery.

Bob, his wife, and his three young children traveled to Heartstream that December for the annual holiday party. "I'm alive today because of two things," Bob told the team, "Technology and the people who came to my

aid." Bob's visit started a long tradition that continues today of survivors coming to Heartstream to share their incredible stories. Each story serves to inspire the team and reaffirms their commitment to developing and designing defibrillators as if the life of someone they love depends upon it.

3. TECHNOLOGY SOLUTIONS FOR THE YOUNGEST PATIENTS

In 2001, a study was published that underscored the need for treatment of infants and children with AEDs[23]. Previously, AEDs, including the ForeRunner, had only been cleared for use on people over the age of 8 or weighing more than 55 pounds. Yet, an estimated 5,000-7,000 children were dying from SCA each year without exhibiting prior symptoms[24].

The team faced several challenges as they set out to develop a solution to treat infants and children. They had to confirm that the FR2's (the next generation of the ForeRunner introduced in 2000) analysis algorithm could effectively analyze pediatric arrhythmias. They had to determine how to reduce the energy delivered to these small patients. Finally, they had to ensure that the infant/child solution was easy to use and did not complicate adult defibrillation.

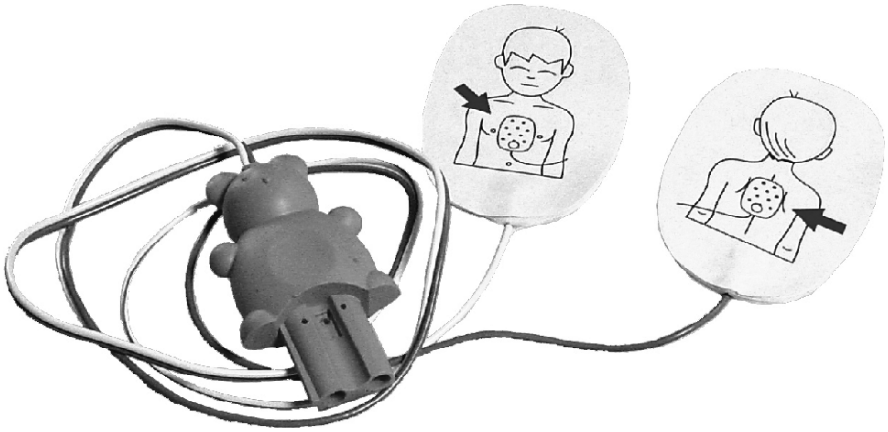

Figure 29-2. Philips infant/child pads.

In May 2001, Philips became the first manufacturer to obtain FDA clearance permitting use of an AED on infants and children under the age of eight (Figure 29-2). The related patent - granted for the process of attenuating defibrillation energy to an appropriate level for pediatric

defibrillation - has been placed to the public domain to permit other manufacturers to develop pediatric solutions for their AEDs. To date, four other AED manufacturers have used this technology to develop infant/child pads for their AEDs.

4. BRINGING DEFIBRILLATORS HOME

From the time Heartstream was founded, the team envisioned a day when defibrillators would be as commonplace as fire extinguishers. It had long been recognized that the majority of sudden cardiac arrests happen in the home. Many estimates place the figure near 80%[25]. Given the growing acceptance of AEDs on airplanes, and in airports, workplaces, and communities, the home was the next logical frontier.

The use of defibrillators in the home was much more than a new marketing opportunity. A home defibrillator would represent the first time in the history of medical products that this type of lifesaving therapy would be packaged for broad consumer use. The development of such a product had to be taken seriously and responsibly in order to deliver a device that would truly support broad consumer use.

The technology platform developed for the ForeRunner and FR2, and proven in billions of hours of field service provided the underlying architecture for the home defibrillator, including the low-energy SMART Biphasic waveform, the SMART Analysis system, the artifact detection system, the battery technology, and the automated self-test. These technologies would address the safety and reliability requirements. The ForeRunner had proven easy to operate in the field, but it was primarily used by trained first responders typically with a duty to respond. The team recognized that the key to the home defibrillator would be the human factors as it had to be so easy that virtually anyone could use it in an emergency.

Thousands of hours were spent studying the way people use AEDs to fully understand the next product evolution that had to take place in order to develop the ideal defibrillator for broad consumer use from a human factors standpoint. Once again, the industrial design team employed an iterative design process to develop what would become the Philips HeartStart Home Defibrillator. Iterations of the device were field tested with targeted users in libraries, malls, and senior centers and the results significantly influenced the design process.

4.1 Launching the first home defibrillator

In November 2002, FDA clearance of the Philips HeartStart Home Defibrillator (Figure 29-3) was announced. It was the first new-generation defibrillator specifically designed for the home. Its introduction met with media broad interest, receiving an astounding 500,000,000 media impressions in the first few weeks following launch, including major TV events like *The Tonight Show* by Jay Leno or *Saturday Night Live's Weekend Update*. These mainstream mentions were an important indication that the defibrillator was permeating American culture - a key step towards gaining acceptance of this new technology into people's everyday lives.

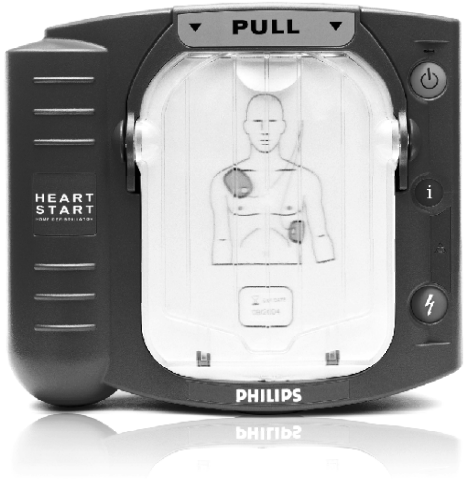

Figure 29-3. The Philips HeartStart Home Defibrillator.

The technological achievements of the Heartstream design team were recognized with numerous design awards including, *BusinessWeek/USA Today* "Best Product of the Year," a *BusinessWeek*/Industrial Design Excellence Award (Gold) 2003, and a Medical Design Excellence Award 2003. In addition, *Popular Science* named HeartStart "Best of What's New".

4.2 Making widespread availability a reality

While the HeartStart Home Defibrillator faced little overt opposition from the medical community, it was not readily embraced. In order to purchase a defibrillator, a consumer had to obtain a prescription from his or her physician. The prescription itself put physicians in an awkward position.

It is virtually impossible for a physician to predict who will suffer a sudden cardiac arrest, when it will occur, and who will be present to use the defibrillator. For whom was the physician writing a prescription?

Philips had begun discussions with the FDA regarding removal of the prescription requirement in 1999. At first, the idea was met with skepticism. Yet, Philips firmly believed that without removal of the prescription requirement, widespread access to defibrillators would be constrained. Such constraints would continue to limit the choice of Americans to be prepared for life-threatening SCA emergencies.

As a result, pursued over-the-counter (OTC) clearance for the HeartStart Home Defibrillator has been pursued. The FDA and Philips worked together for years to understand the requirements of an OTC defibrillator. In order to receive OTC clearance, it had to demonstrated that the device had an established history of safe use and that it could be used safely and for its intended purpose based upon its labeling alone.

In terms of establishing its history of safe use, Philips drew upon the vast field performance data amassed since the introduction of the ForeRunner in 1996. During that time, AEDs had accumulated an impressive and substantial track record. Philips also undertook two studies to demonstrate that the HeartStart Home Defibrillator could be used safely and for its intended purpose based upon its labeling alone.

In September 2004, the FDA cleared the Philips HeartStart Home Defibrillator as the first and only defibrillator available without a prescription. It was an historic moment in the AED movement. This move eliminated one of the most significant barriers to widespread access and was an important step in helping to make the HeartStart Home Defibrillator more easily available to consumers for home use, where the majority of cardiac arrests occur. Again, the news generated broad media coverage, including being named a "Best Product of the Year" by *Fortune* magazine.

With the prescription requirement removed, Philips was able to pursue traditional distribution for the HeartStart Home Defibrillator. The product became available at several leading consumer retailers such as Amazon.com, Drugstore.com, Staples.com, Walgreens.com, CVS.com, and Sam's Club. These new avenues of distribution were an important step forward in making the product more widely accessible and giving both the problem of sudden cardiac arrest and the solution of HeartStart greater visibility.

5. LOOKING TOWARDS THE FUTURE

The research work done by Philips has played a critical role in helping to make defibrillation an effective therapy. It has led to important changes in defibrillation protocols, the adoption throughout the industry of a more effective waveform, and solutions for the youngest victims. We plan to stay at the forefront of resuscitation research and to continue making contributions that drive the industry.

Philips also plans to maintain its leadership role in developing innovative technology solutions to treat SCA because until every person is within a few minutes of a defibrillator, there will continue to be a need for technology that helps increase accessibility. This will also include developing solutions for patients for whom their event is unwitnessed, defibrillation is delayed, or CPR is required.

We are also looking beyond the treatment of sudden cardiac arrest. As a result of the aging of the post-WWII generation there is an ever-increasing need for technologies that address a range of cardiac-related conditions. One such technology in development leverages our world-renowned expertise in wearable electronics, as described in Chapter 28. Scientists are developing a wearable, wireless monitoring system that can warn patients with underlying health problems, assist clinicians in the diagnosis and monitoring of patients at risk, and automatically alert emergency services in the case of an acute medical event. This technology is designed to disappear into its surroundings from where it can work seamlessly to improve quality of life or personal healthcare.

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