

How Networked Neighborhood AEDs Can Save Lives

This White Paper describes a **Residential AED Integrated Network** that will dramatically improve survivability from Sudden Cardiac Arrest (SCA). In addition to this currently available solution, we also describe our vision for a future in which this network is broadly connected to all affected parties via the Internet of Things.

Executive Summary

Sudden cardiac arrest is a leading cause of death among adults over the age of 40 throughout the world (<http://www.sca-aware.org/>). In the U.S. alone, over 400,000 men and women of all ages experience SCA. Tragically, nine out of 10 victims die. The number of people who die each year from SCA is roughly equivalent to the number who die from Alzheimer's disease, assault with firearms, breast cancer, cervical cancer, colorectal cancer, diabetes, HIV, house fires, motor vehicle accidents, prostate cancer and suicides combined.

The high fatality rate from SCA has not changed significantly in the forty years since doctors learned how to revive SCA victims through the use of Automatic External Defibrillators (AEDs) and such devices began to be widely available in public places as well as hospitals. The reason for this lack of improvement in the survival rate is quite apparent: most cases of SCA don't occur in public places within reach of an AED, they occur in the home where the most susceptible population spends the vast majority of its time. AEDs are rarely available in private residences and emergency medical services (EMS) personnel may not arrive in time.

Timely use of an AED greatly improves recovery from SCA, but "timely" means within 3-5 minutes. Once the heart stops working effectively, insufficient blood and oxygen reaches the brain. Every minute that passes from the time of the event itself increase the risk of death or disability. CPR will not restart the heart and only minimally extends the time in which an AED must be retrieved and used.

Defibrillators are typically located in emergency response vehicles, medical facilities and many public buildings. The devices are not complicated to use, but untrained bystanders typically cannot, *or will not*, utilize devices even when they are easily at hand (e.g., located in a wall-based storage unit within a public building). In the home, the typical scenario begins with panic, eventually leads to a call to 911, followed by an anxious wait for an ambulance to arrive. The response time in a well-served urban environment is typically eight minutes or more, and longer in purely suburban or rural settings or if the nearest first responder is already out on a call.

We believe that the keys to survival in the home setting are these:

- Placement of AEDs within a short distance of all homes in a given community
- Identification and training of resident volunteers who are willing to respond to an SCA emergency in their neighborhood

- Providing the volunteers with access to AEDs and relevant training in CPR and the use of AEDs
- Creation of the necessary ability to notify volunteers when an emergency occurs in the home of a resident at the same time as the call to 911 is placed
- Continual monitoring of the devices to determine battery condition and readiness
- A public education program to increase awareness of SCA and the steps the community has taken to minimize the time required for an AED to arrive at the site of a cardiac emergency

Ultimately, we expect every AED to be connected via a broadband/Bluetooth/cell phone infrastructure to emergency service providers, appropriately trained 911 and help center staff, and designated family and neighborhood contacts. Exhibit 1 depicts this vision.



Fully implemented, this solution will require a new working partnership between existing stakeholders such as AED manufacturers, broadband service providers, home security services, medical monitoring organizations, public services such as EMTs, wireless networks, and consumers and their families and friends. There is also a role for makers of wearable technology. CardioSpark intends to create and patent the design of such partnerships, and develop the tools, technology, and applications needed to connect the parties to the extent they are not now readily available or tailored to work well in this solution. We also believe that we have identified improvements to the sensing mechanisms that detect heart rhythms (or the lack of them) and methods of delivering shocks to the heart.

What is Sudden Cardiac Arrest?

SCA is the abrupt cessation of the body's circulation, usually due to ventricular fibrillation. This abnormal heart rhythm results in an immediate precipitous drop in blood pressure, a cessation of the oxygen supply essential to the tissues, and loss of consciousness. SCA usually occurs in someone who is unaware of the presence of heart disease and who may not be typically categorized as high risk by his or her history and habits. Without basic life support treatment, the brain will not survive after 10 minutes and may be seriously impaired at that point. Immediate CPR (basic life support) can sustain a helpful but greatly reduced blood circulation, and can provide a time-bridge until arrival of treatment with an external defibrillator. Today, this usually arrives in the hands of a paramedic.

Every second is precious particularly in the first five minutes of the collapse because this is the time window when defibrillation has shown its maximum effectiveness in a successful resuscitation with minimal brain damage, if any. It is important to understand that CPR does not terminate ventricular fibrillation; it is the sudden discharge of electrical energy from defibrillator pads on the torso of the victim that will "reset" the heart rhythm and restore the circulation. If defibrillation occurs within 5 minutes, the survival rate is greatly increased (from 5% to as much as 75%).

Despite the tremendous strides in medical and surgical treatment for patients discovered to have heart disease (new drugs, new devices, new stent technology, improvements in heart surgery) the vast majority of SCA victims do not get a chance at these solutions since defibrillation comes too late if at all.

Current Approach to Combatting Sudden Cardiac Arrest

There are now more than 2 million public AEDs in high traffic locations such as airports, schools, athletic facilities, and similar places. The American Heart Association recommends these three elements in response to SCA: call 911, begin CPR, and perform early defibrillation ASAP. All emergency rooms are in communication with 911 services and stand by around-the-clock in a state of readiness to respond to cardiac events. In addition, every major city offers a rapid response paramedic/911 service. A large public health effort is ongoing to train as many citizens as possible to correctly perform CPR, but such training may not typically cover the purpose or use of an AED.

Despite these efforts, the likelihood of surviving a SCA, remains largely unchanged over the last 15 years: less than 10%. What is the reason for the poor impact on this problem with so great a public health effort at hand? There are two primary reasons.

- First, the benefit of early defibrillation is unrealized for most victims, because defibrillators are not immediately available. Most (80%) of sudden death episodes occur at home where defibrillators rarely exist, not in public places. An AED may be down the street or in an ambulance on the way. However,

unless the AED arrives and is used to defibrillate within five minutes, the likelihood of survival is greatly reduced.

- Second, most of the time (probably greater than 95% of the time as estimated by the Emory University School of Medicine) AEDs are not even used by bystanders when they are available in public places. Most bystanders are seeing a defibrillator for the first time and may be reluctant to step forward and use it.

An AED has many important features but is relatively easy to use. Correctly attached to the victim's torso and initiated, an AED is capable of autonomous performance to analyze the patient's heart beat, deliver an announcement of an impending electrical defibrillation shock if warranted, and to deliver that shock. However, AEDs as currently manufactured may be bulky, appear to be complex on first encounter, and can be intimidating to a spontaneous, untrained user.

Calling 911, starting modern (compression only) CPR, and waiting for the paramedics is the usual scenario. While paramedics respond quickly, their arrival is often not within the 5-minute window of time to defibrillate. Simply put: there are not enough AEDs available, people don't use the ones that are available, particularly among individual consumers.

CardioSpark's Safe Neighborhood Architecture

Our goal is to find a way to make AEDs available within 3-5 minutes to as many homes in America as possible, which is where they are needed most, and enable consumers to use them with confidence. We plan to do this not by making a better AED, although we think improvements are possible, but by creating a "safe neighborhood architecture" that requires collaboration by a partnership of existing manufacturers; services that provide broadband entertainment, security, and medical monitoring services to millions of residences in America; cell phone networks; smartphone application developers; emergency service providers; and consumers and their families and friends. This partnership is depicted in Exhibit 1 repeated below.



Exhibit 1: The CardioSpark “Safe Home” Solution Architecture



Here is more detail regarding the roles of the partners we envision being a part of this architecture.

In the AED space, manufacturers need to step up to make their devices more affordable, more portable, and less intimidating to use. Their devices need to connect via Bluetooth, wireless, or other means to enable them to be located, their battery status monitored, and alerts to be sent when they are activated. This can be accomplished by the manufacturers or by attaching RFID or other add-ons to them.

Home broadband, security, and medical monitoring services need to put in place the ability to connect to AEDs and communicate with the devices and their users. An emergency call center staffed with trained medical personal should be connected automatically and lead users through the steps to ensure that AEDs are used promptly and correctly when warranted. When an AED is activated, alerts should automatically be transmitted to emergency service providers such as ambulance services or fire departments. Alerts should also be enabled for family, friends, and neighbors.

Wireless networks should be prepared to play a similar role, particularly in the unlikely case that broadband service is not available. AEDs should connect via Bluetooth or wireless to smartphones. The smartphones should have applications that can also recognize the activation of an AED, contact emergency call centers and emergency services and guide users through the steps involved in ensuring successful use of the device.

Application developers should produce software for smartphones with the functionality described above. They should be able to interact with AEDs, connect

users to emergency services, and provide guidance to AED users in emergency situations. These applications are critical to the safe home architecture CardioSpark is designing.

Regarding AED devices themselves, the past several years have been marked by substantial improvements in battery size, reliability and performance. Similar technological progress has made possible the ability to miniaturize complex electronics and to manufacture AED components inexpensively. Our research strongly suggests that a smaller, simple to use, single use device can be manufactured and profitably sold at a price below the cost of current AEDs on the market. We believe that a lower price point will put personal AEDs within consumer reach as a commodity item for home safety not unlike a smoke alarm or fire extinguisher.

We envision that AEDs could be bundled into home broadband or security and medical monitoring services, for example, and leased much in the same way that broadband providers now lease modems to their subscribers. This option may be more attractive to consumers than outright purchase of a device.

We believe that the same safe home architecture can be made mobile and extended to medical service providers like MDs, RNs, and medical students; public servants like policemen, security guards, park rangers; public transportation vehicles like taxis and postal trucks and many more. We also envision 3rd party groups and organizations such as home security networks, homeowner associations, condo complexes, and hotels will likely be a market for the connected solution we have designed.

The Current Device Marketplace

FDA approved AEDs for public placement are designed and configured so that a bystander with or without knowledge of how to use a defibrillator can be guided in its set up and then instructed to let the device function automatically. Good Samaritan Laws shield the bystander from liability. However, when an AED is publicly sited and advertised as available, a responsibility arises to maintain and assure the functional quality of the device. The onus of this responsibility and implied liability risk complicates the decision to place devices in privately owned places. Furthermore, more than 50,000 complaints of possible AED malfunctioning have been reported to the FDA surveillance committee.

Manufacturers selling AEDs into the US market offer devices with list prices ranging from \$1500 to \$5000. These FDA regulated devices have been placed at approximately two million sites. Business-wise, the growth target of for public siting is over 80 million. This is the saturation level that is believed to be necessary to maximize bystander/Samaritan use. We believe that this number drives the business objectives of the existing manufacturers. There is one manufacturer offering a device for home use, which can be purchased without a prescription for \$1,100. A low cost but

fully functional personal safety device potentially would disrupt existing business models of the manufacturers and is one possible explanation why AED retail prices have never dropped below \$1100.

RAIN

While we conduct further research and develop the applications, devices, and partnerships needed to fully realize our vision, we have created a Residential AED Integrated Network (RAIN) service. RAIN integrates available technology such as 911 call centers reachable by smart phones and/or landlines, AEDs placed in private residential areas accessible to trained volunteers, agreements with public safety agencies to notify the volunteers when an emergency occurs in a covered neighborhood, and public education initiatives that increase awareness of SCA and the urgency of a timely response. In a neighborhood with the RAIN service, a witness to a cardiac emergency will call 911, knowing that the Fire Department, for example, will notify both the nearby neighborhood volunteers and the nearest emergency service teams at the same time. A one-page summary of the RAIN service is attached as Addendum A to this paper.

The RAIN model improves upon elements of existing community-based neighborhood watch systems, such as one called Neighbors Saving Neighbors serving The Villages in Florida. That system alerts trained resident volunteers of medical emergencies involving unconscious persons who do not appear to be breathing. The public safety department helps with CPR training, selection of AEDs and outdoor cabinets, and sharing of the alerts. Among other improvements, RAIN offers a complete end to end system and enables communities to supplement available volunteer resources with professional support.

CardioSpark also provided support to a 2018 study of community volunteer responder (CVR) response times in a community of 442 homes in Green Valley, Arizona, that validates our model. The study was sponsored by the Arizona Center for Advanced Biomedical Innovation (ACABI) at the University of Arizona. The Principal Investigators are cardiologists associated with the Sarver Heart Center in Tucson. An abstract of the paper describing the results of this study is available on our website (www.cardiospark.com). The paper includes the credentials of the research team and notes the conclusion of the investigators that programs like RAIN and Neighbors Saving Neighbors in residential areas have the potential to increase successful resuscitation rates by as much as 240%.

Conclusion

We believe that the partners that are key to implementing our Safe Neighborhood Architecture solution exist, but they currently operate in their own disconnected “silos”. Our goal is to connect them and thereby remove barriers to placing AEDs in more homes and neighborhoods, making them available and easy to use where they are needed most. We believe this message will resonate with consumers. We expect to

enlist the cooperation of public safety officials, foundations that actively seek to place AEDs where they will do the most good, and business partners who will see the home as a significant market opportunity.

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Addendum A Key Elements of the RAIN System

- Community awareness and enthusiasm
- Fire Department/EMS support
- Sufficient volunteer responders
- Designated resident coordinator/point person
- CPR, AED, and responder safety training
- Accessible AEDs in secure cabinets
- Resident opt-in/opt-out
- Integrated alerting system
- Up to date resident and volunteer contact information
- Emergency location matching
- AED monitoring and maintenance
- Refresher training
- Regular program evaluation
- HeartSafe Community designation and signage



Community
Engagement



Resident
Training



AED
Deployment



AED
Readiness



Coordinated
Response

About CardioSpark

CardioSpark LLC is a company whose mission is to develop and implement integrated residential AED systems for foster safer communities. Our goals for each covered neighborhood is to expedite the arrival of an AED with a trained user within minutes of a 911 call coded as a suspected cardiac arrest.