

Defibrillator technology: HELP IN A HEARTBEAT

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Advances in medicine normally come from the laboratories of white-coated scientists and physicians. This time, designers can take the credit for an evolutionary step in automatic-defibrillator technology that could save as many as 100,000 lives a year.



On February 18, Robert Giggey, a 52-year-old North Carolina executive rushed to catch his American Airlines flight from Dallas-Fort Worth International. As he boarded the plane, his heart went into full cardiac arrest, and he lost consciousness. Within minutes, flight attendants and an off-duty paramedic were at his side following the audio instructions given by a small onboard medical device. A new generation of automatic defibrillators saved Giggey's life and promises to put lifesaving medical therapy within minutes of the onset of cardiac arrest.

Cardiac arrest is the nation's leading single cause of sudden death, striking more than 350,000 victims annually—almost 1000 per day. The victim's heart electrically malfunctions and stops pumping

blood. Almost immediately, breathing stops, and the victim falls unconscious. Most victims die within 10 minutes. Yet, there is a medical treatment: A controlled electric shock applied to the heart by a defibrillator during the first 8 to 10 minutes can restore electrical activity and give the victim a good chance of survival. The problem is that most defibrillators sold over the past decade are large, expensive devices available only in hospitals and selected emergency-response vehicles. Currently, there's little probability of getting the required shock therapy, and most cardiac arrest victims die. The American Heart Association (www.americanheart.org) estimates that readily available automatic defibrillators could save 100,000 lives annually.

Cardiac arrest results from an electrical abnor-

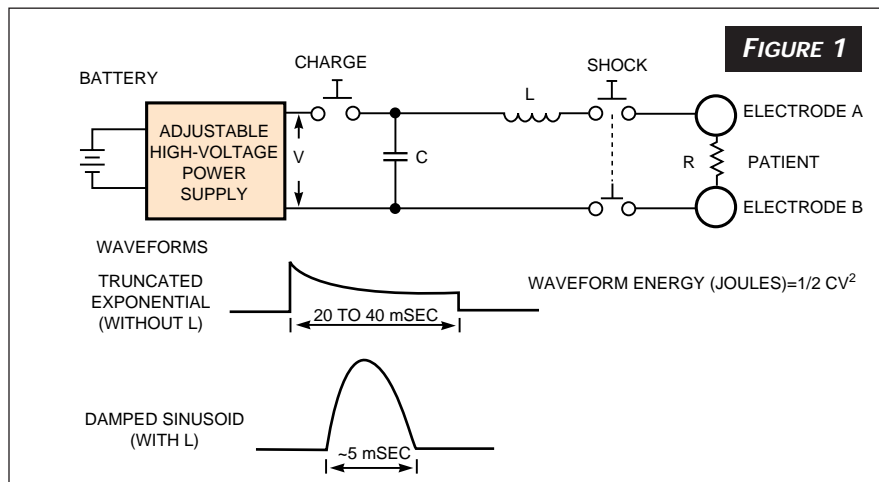
Defibrillation within the first 8 to 10 minutes is the only treatment for sudden cardiac arrest (left, courtesy Heartstream). Automatic external defibrillators are small and lightweight and offer zero-maintenance standby times (middle, courtesy Physio-Control). Weighing 4 lbs, Heartstream's ForeRunner AED (right) is designed to be deployed among emergency first responders.

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@ a glance

- Lower voltage waveforms increase defibrillator efficiency and reduce size and weight.
- Widely deployed portable defibrillators, by enabling prompt treatment of cardiac-arrest victims, could save as many as 100,000 lives a year in the United States.
- By automatically analyzing heart rhythms, smart defibrillators help untrained users aid cardiac-arrest victims without assistance from a physician or medical technician.
- Engineering challenges abound in designing a portable defibrillator: fail-safe operation, extreme ease of use, long battery life, low cost, and safe application of a 50-kW pulse to the human body.

mality called “ventricular fibrillation.” Chaotic electrical impulses stop the coordinated contractions of the heart, leaving a ventricular quiver and loss of blood pressure. Physicians are unsure of what causes cardiac arrest, and there are plenty of cases in which the victim has no history of heart problems. The average age of victims is 65, but cardiac arrest strikes many in their 30s and 40s. Even well-conditioned athletes, such as basketball star Hank Gathers of Loyola Marymount University (Los Angeles) have succumbed to sudden cardiac arrest (SCA). Although people often use the terms “SCA” and “heart attack” interchangeably, the two conditions differ (see sidebar “Heart attack or cardiac arrest?”).



Defibrillators deliver a 1500 to 4000V burst of energy through a victim's heart.

As early as the 1950s, physicians recognized that an electrical current applied through the heart could stop ventricular fibrillation and restore a normal heartbeat. A basic defibrillator contains a high-voltage power supply, a storage capacitor, an optional inductor, and patient electrodes (Figure 1). A highly damped sinusoid results when you discharge the capacitor through the inductor and the chest-cavity resistance of the patient. Most of the energy dissipates within a few milliseconds. Without the inductor, the circuit delivers a truncated exponential waveform. Both waveforms are common in today's defibrillators.

In early defibrillators, a physician read the patient's electrocardiogram (ECG) to assess the heart's rhythm before administering any shock treatment. The ECG patterns representing ventricular fibrillation are well-defined, and physicians have identified shock-

able rhythms requiring immediate defibrillation. Applying a shock to a patient with a normal ECG may disrupt the heartbeat, so it is important to verify that the heart is in ventricular fibrillation. To eliminate the need for an attending physician, manufacturers in the 1980s developed automatic defibrillators with circuitry to capture ECG signals from the therapy electrodes. All current automatic defibrillators contain processors to run an ECG-analysis algorithm that identifies shockable rhythms. ECG analysis takes about 5 seconds, and the CPU then advises the operator about whether defibrillation is necessary.

Low survival rate

These automatic defibrillators speed up ECG diagnosis and improve patients' safety; however, less than 5% of SCA victims survive. Patients sometimes die before the defibrillator arrives

TABLE 1—REPRESENTATIVE PORTABLE EXTERNAL DEFIBRILLATORS

Manufacturer	Device	Waveform	Battery	Weight (lbs)	Energy (joules)
Heartstream Circle No. 500	ForeRunner	Truncated exponential biphasic	Lithium	4.4	150 nominal (function of patient impedance)
Laerdal Circle No. 501	Heartstart 911	Truncated exponential	Lead-acid rechargeable	9	200, 300, 360
Physio-Control Circle No. 502	LifePak 500	Damped sinusoidal	Lithium or lead-acid rechargeable	7.3	200, 300, 360
SurVivaLink Circle No. 503	FirstSave	Truncated exponential	Lithium	6.75	200, 300, 360

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because emergency workers or physicians have only 8 to 10 minutes from the start of SCA to deliver the shock. In congested New York, where the average emergency-response time is 12 min-

utes, only 1% of SCA victims survive. Seattle's average response time is 4 to 6 minutes, and the survival rate is 30%. Today, only 50% of ambulances, less than 15% of fire-department first-

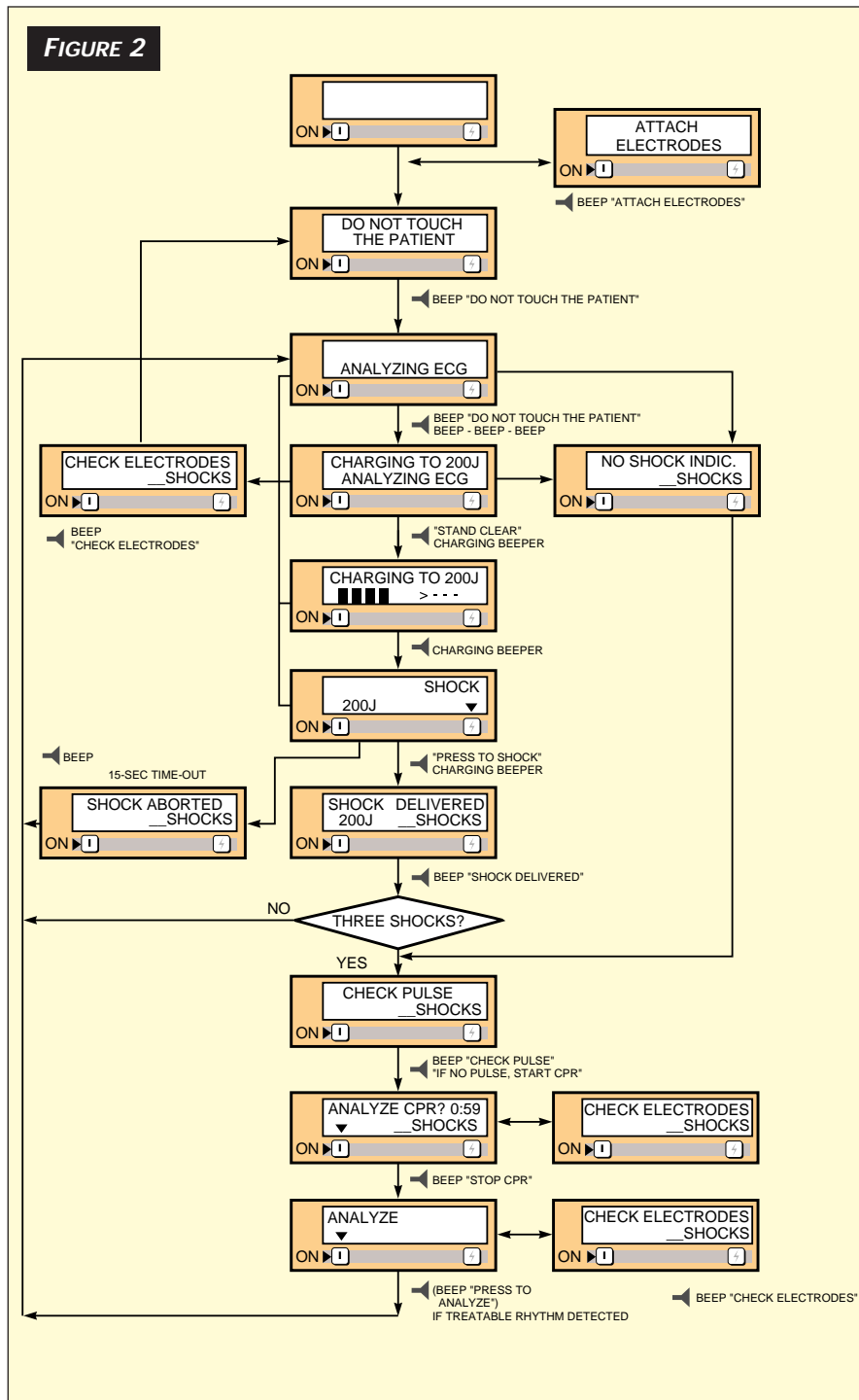
response vehicles, and less than 1% of police vehicles carry defibrillators.

The low survival rate prompted the American Heart Association to develop its "chain-of-survival" program for cardiac arrest. This program includes a 911 call for help, cardiopulmonary resuscitation (CPR), early defibrillation, and advanced cardiac care. The program recommends that the first people to respond to emergencies—police, firefighters, security, and flight attendants—have access to automatic external defibrillators (AEDs).

Vendors recognized that there were problems with the widespread deployment of defibrillators. A defibrillator may be suited to a hospital emergency room or an ambulance, yet maintenance and training problems arise in low-usage situations, such as airlines, stadiums, and office buildings. Rechargeable batteries require constant attention to ensure that defibrillators are always ready to produce a 50-kW pulse on command. In a study sponsored by the Food and Drug Administration (www.fda.org), the major cause of defibrillator failure was improper care of rechargeable batteries (see sidebar "Defibrillators and regulatory standards"). This study prompted most vendors to recommend rechargeable-battery tests during each shift—a major headache at any low-usage site. A new trend in defibrillators is to employ single-use batteries. Heartstream, Physio-Control, and SurVivaLink now offer disposable lithium-manganese-dioxide (LiMnO₂) batteries in their AEDs. Lithium batteries provide a shelf life of five years and a standby life of more than one year. All AEDs contain battery-test circuitry to indicate a low-battery condition.

Automatic instructions

Operator training is also a problem in low-usage situations. The security guard that receives a defibrillator training session may feel uneasy in a high-stress cardiac-arrest emergency six months later. Manufacturers have responded with audio instructions and visual prompts to guide the operator through the defibrillation procedure. In a typical defibrillation sequence (Figure 2), the AED instructs the user to attach the



Audio and visual instructions guide the operator through defibrillation therapy (courtesy Laerdal).

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HEART ATTACK OR CARDIAC ARREST?

Heart attack	Cardiac arrest
Cause A clot or blockage of a coronary artery that stops the blood flow to the heart muscle	Chaotic electrical signals that stop the heartbeat
Symptoms Pain in the chest or left arm; victims may remain conscious	No pulse or breathing, loss of consciousness
Time to treatment Within the first few hours	Within 8 to 10 minutes
Treatment Remove the blockage with clot-dissolving drugs, angioplasty, or bypass surgery	Defibrillation
A massive heart attack results when a heart attack initiates cardiac arrest.	

patient electrodes and starts acquiring ECG data. If the AED analyzes the patient's ECG and detects a shockable rhythm, the capacitor is charged. Then, following the instructions, the operator presses the shock button to deliver the high-voltage pulse. Many jurisdictions and medical directors also require that the AED record the audio from the scene of a cardiac arrest for postevent analysis. Manufacturers take different approaches to scene audio. SurViva-Link's FirstSave contains a slot for a 4-Mbyte compact flash card, and the Heartstart 911 from Laerdal has an optional microcassette recorder.

All AEDs include a means to store and retrieve patient ECG patterns; however, Physio-Control's LifePak 500 extends this capability. After a defibrillation event, an operator can download LifePak's audio and ECG data through its RS-232C port to PC-based data-management software for analysis. The LifePak 500 stores events such as when the operator connected the electrodes, pushed the analyze button, and pushed the shock button, so that LifePak can display these occurrences in relation to the patient's ECG. Physio-Control's Code-Stat software accepts data from the LifePak 500 to create an integrated patient-information database for statistical reports or to review cases.

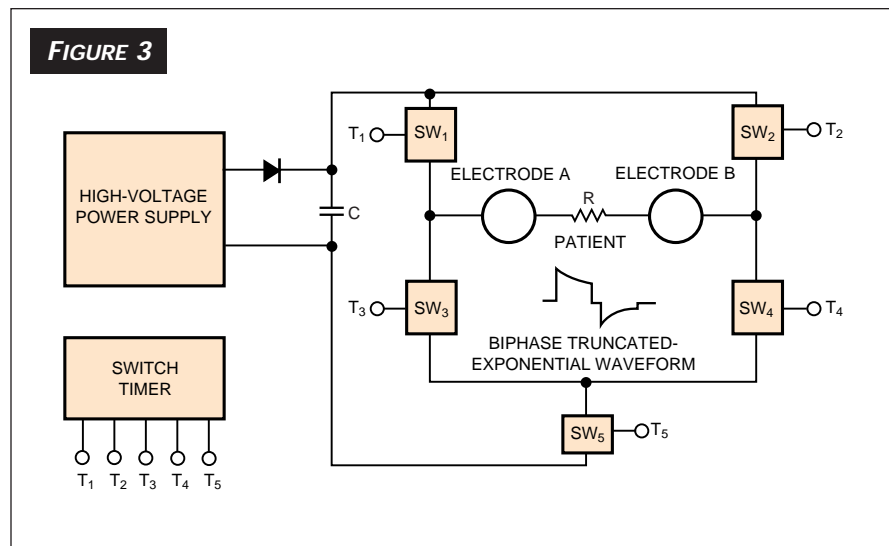
The ideal defibrillator for widespread

deployment may sit on the shelf for a year between uses. Users want zero maintenance and a visual indicator of operational status. These requirements call for an extensive self-test schedule designed around failure probabilities and battery conservation. According to Heartstream Project Manager Dan Powers, daily low-power CPU self-checks, ROM CRC, power-supply/capacitor measurements, and partial waveform-delivery-circuit tests conserve power. Weekly tests add magnitude and phase

response of the ECG-acquisition circuitry. Each month, the CPU twice charges the defibrillator to full energy—once to calibrate the capacitor value and once to stress-test the waveform-delivery system. The CPU actively drives a front-panel LCD to indicate that the defibrillator is operating. A fail-safe circuit displays a red X on the LCD and chirps a piezo beeper if the CPU stops updating the LCD. This approach indicates the status of the defibrillator, even with extremely low battery power.

Lower voltage waveforms

One clever technique to reduce the size and weight of defibrillators is to reduce the amount of energy they deliver to patients. Defibrillators from Heartstream use a biphasic, truncated-exponential waveform. Clinical studies show that reversing the current direction during the application of the waveform reduces the amount of energy necessary to stop ventricular fibrillation. An H-bridge circuit switches the current direction and provides waveform timing (**Figure 3**). Heartstream also compensates for patient chest resistance by evaluating the slope of the discharging capacitor voltage and adjusting the length of each waveform phase. The lower energy waveform creates many opportunities to reduce the size of the product. Lower voltage levels reduce the size of and clearance dis-



An H-bridge circuit reduces automatic-external-defibrillator voltages with a biphasic truncated-exponential waveform.

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DEFIBRILLATORS AND REGULATORY STANDARDS

As you might guess, there are plenty of device and safety standards that manufacturers must follow to produce a medical instrument that can apply a 50-kW pulse through the human body without an attending physician present. The Association for the Advancement of Medical Instrumentation (AAMI, www.aami.org) develops standards for defibrillator operation. AAMI DF-2 and DF-39 specify the waveforms, recharge times, pulse amplitudes, and electrocardiogram-analysis rules.

The US Food and Drug Administration regulates all medical devices for sale in the United States. Device manufacturers must prepare a documentation and quality-assurance package for FDA approval and periodic inspection. If a device requires clinical trials or studies, the FDA performs the statisti-

cal analysis and develops the testing rules. Some states also have device-manufacturing agencies and additional approvals. In addition, medical products for sale in Europe must carry the CE European certification marking. The German TÜV performs product-safety and operational analysis testing for CE certification.

"Of all the regulating bodies that I've had to deal with, TÜV has been the most interesting," says Carl Morgan, Heartstream's vice president of research. "We had them in on design reviews looking at our circuits. Their approach to product regulation is to hire people who are experts in their field. The person who reviewed our product had a PhD in safety-critical software systems."

tances between high-voltage components. The largest benefit of size and weight reduction is a smaller battery system. In addition, each vendor developed its own operating software to minimize the processing system drain on the battery.

"We had to keep this thing very inexpensive and low-power," says Heartstream's Powers. The defibrillator runs on a battery that must last for a long time to give customers value, he says. The company's programmers hand-coded the time-critical portions of the algorithm and wrote everything else in C. For code safety, the company placed an independent watchdog on the processor and program-flow monitor-

ing into the software. To spot software errors, the company designed user-interface- and algorithm-state-machine transitions around Hamming distances—the number of bit differences between two equally long code words.

Even with all the technology problems solved, cost will be a major factor in putting defibrillators in the hands of those likely to be first on the scene of a cardiac arrest. Companies must deploy defibrillators in thousands of police, security, and fire vehicles. Even at their current prices of \$3000 to \$4000, widespread defibrillator deployment will be expensive. At higher production rates, you can expect the prices to decrease somewhat, but an FDA-regulated med-

ical instrument will remain costly.

Defibrillator vendors have produced instruments suitable for widespread deployment. The units are small, lightweight, easy-to-use and have zero-maintenance standby times. Thanks to the electronic designer, the technology is now in place to meet the goal of public-access defibrillation.

Reference

1. Poole, Jeanne E, Roger D White, et al, "Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest," *Journal of Cardiovascular Electrophysiology*, December 1997.

Acknowledgments

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