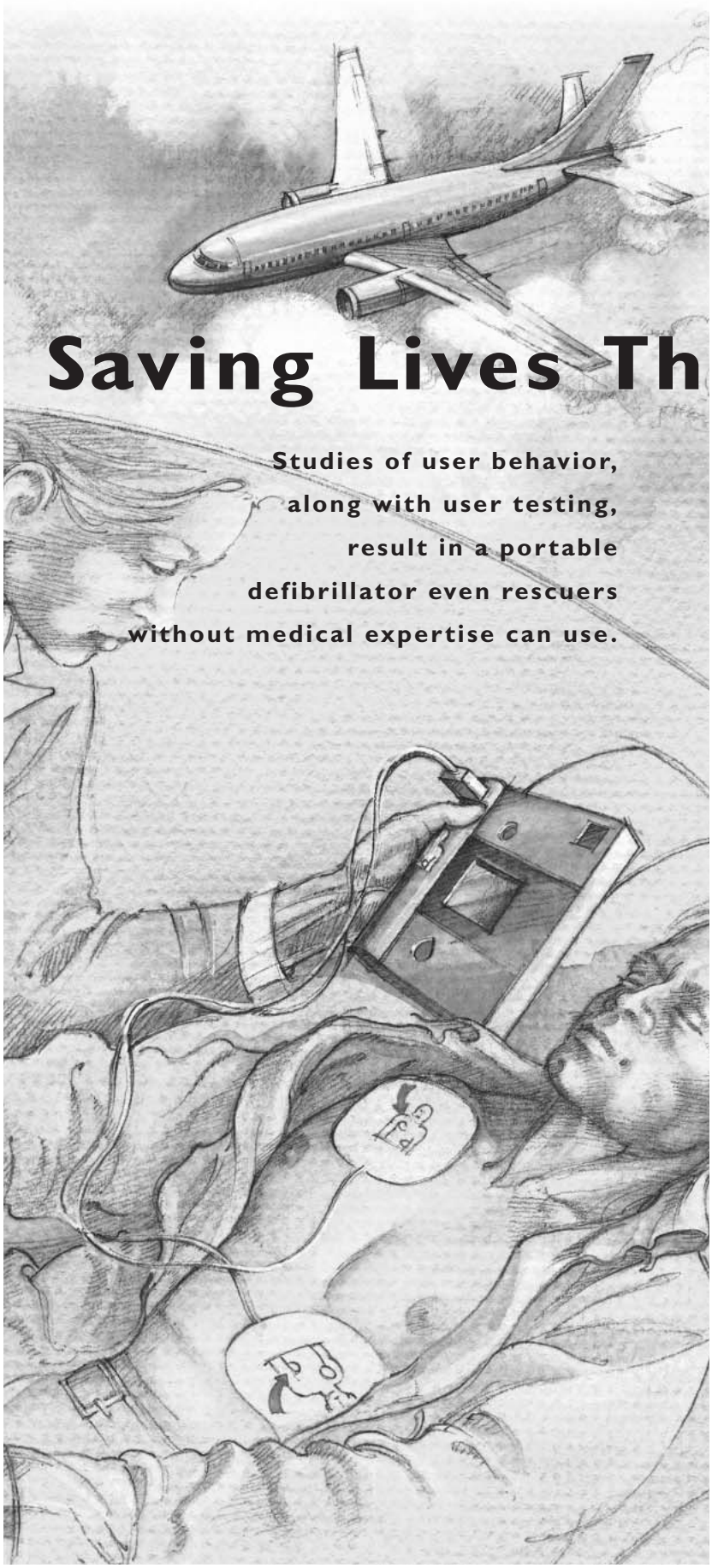


Saving Lives Through Design

Studies of user behavior, along with user testing, result in a portable defibrillator even rescuers without medical expertise can use.

BY JANE FULTON SURI

RITA AND RAY, IN THEIR MID-60S, are active retirees. They leave for a vacation, packing a portable defibrillator as instructed by the family doctor, who saw Ray narrowly survive his first heart attack at the age of 62. After a big meal, Ray lies down in their motel room complaining of indigestion. He gets up to go to the bathroom but collapses on the way. Rita grabs the device, kneeling down to administer treatment. But the device is new and unfamiliar to her, and she fumbles badly with it as she desperately tries to save her husband's life.

Thanks to rapid advances in technology, companies can make smarter, smaller, cheaper, but highly sophisticated devices for distribution among people with minimal prior experience in using them. Designers find themselves making important decisions about the appearance and behavior of such products without access to directly applicable human factors guidance. This is almost always the case with new products, particularly ones involving new users in new contexts.

How do we find ways of providing human factors input to a design program in an efficient, timely fashion? This case study is an example of an eclectic, integrated design and research program leading to the successful design of a new medical product. The product is a portable defibrillator for emergency use by the general public in rescuing victims of sudden cardiac arrest.

Cardiac Arrest and the Need for Better Devices

Sudden cardiac arrest is a condition in which the heart's electrical impulses suddenly become chaotic, causing the heart to lose its normal rhythm. The heart muscle goes into spasm, a state known as *fibrillation*, and is no longer capable of pumping blood. Victims collapse and quickly lose consciousness. Unless their normal heart rhythm can be restored, they die within minutes.

At its simplest, a defibrillator is a device capable of generating an appropriately powerful electric shock to

stop the fibrillation and allow the heart to resume its coordinated rhythm and normal pumping action. It is important that a shock of that magnitude is given only when the heart is in fibrillation – given in error to a nonfibrillating heart, it would be enough to cause death or serious damage.

To protect against this potentially fatal error, *manual* defibrillators rely on operators to read and interpret an electrocardiogram (ECG) to assess whether the heart exhibits a fibrillating rhythm. *Automatic* defibrillators contain sophisticated electronics that can interpret an ECG and permit a shock only if fibrillation is detected. *External* defibrillators deliver the electric shock to the heart through electrodes applied to the chest, while *implanted* defibrillators have leads directly connected to the heart and are usually built into implanted pacemakers.

Every day, more than 1000 Americans suffer sudden cardiac arrest. Despite the existence and use of defibrillators, 95% of these victims die, usually because of delays in applying a defibrillating shock. The chance of survival is vastly better if victims receive an electric shock from a defibrillator within 5–7 minutes of collapsing. The American Heart Association (1996) estimated that at least 20,000 lives would be saved annually if defibrillators were available within this 5–7-minute time frame.

Recent advances in technology and cardiology make it possible to create *automatic external defibrillators* that are much simpler, smaller, lighter in weight, and less expensive than the traditional suitcase-sized versions. These portable devices have become economical and practical for wide distribution among emergency responders such as police and fire crews. Because the devices monitor the heart's rhythm and apply a shock only if appropriate, they may be used safely by people without medical expertise. They may ultimately become ubiquitous, like fire extinguishers. Indeed, this is the goal for public-access defibrillators.

Product Concept and Design Challenges

Heartstream's ForeRunner was one of the first public-access defibrillators available in the United States. Its design intent was to provide a complete and easily handled physical package that could be used safely by a minimally trained operator. Voice prompts guide the operator step-by-step through the rescue sequence. The operator must switch on the device, connect the electrode leads to the device, and stick the two adhesive pads to the victim's chest. These pads contain the electrodes that first function as ECG sensors to determine whether defibrillation is appropriate. If it is, the device indicates that a shock is necessary and begins to build up an electrical charge. The voice prompt then warns, "*do not touch the patient*" and instructs the operator to press the shock button to deliver the shock through the pads. After a shock, the device checks the cardiac rhythm and repeats the procedure until a normal heart rhythm is restored or medical professionals take over treatment.

Despite its ultimate simplicity, there were major challenges to be overcome in designing a defibrillator intended for public access. Very few people are familiar with defibrillators. Those who do are highly trained cardiologists or paramedics and operate within strict medical protocols. Some people have vague or partial understanding developed through vicarious experience, mainly television programs like *ER*, in which hospital rescue scenes show paddles being applied to a patient's chest, a shout of "Stand clear!" and the dramatic defibrillating shock jolting the patient. Other people have no knowledge at all. A product that accommodates this vast range of experience must be simplified to its essence.

We learned from trainers that the voice prompts of existing defibrillators would be more helpful if they were more explicit.

How should a powerful life-saving technology be packaged so that even inexperienced users can use it effectively? Cognitive, social, and emotional factors are all critical: The device must communicate immediately what it is, exactly what to do, and help users do it quickly, confidently, and accurately in socially and emotionally charged circumstances.

For such a product, designers must know how to create appropriately reassuring physical characteristics, how to arrange displays and controls, how to store and arrange the electrodes, and what audible feedback or labeling to use. These critical design details affect users' behavior, comprehension, feelings, and, consequently, the therapy's effectiveness. Designers need answers to questions like these:

- How should the design accommodate different contextual demands? Displays and audible prompts, for example, must be perceptible outdoors, day or night, amid traffic noise, but at the same time not be overly bright or deafening in an assisted living situation for the elderly.
- How should the design accommodate the influence of distress and anxiety on behavior?
- How can we prevent or minimize the consequences of user errors?
- How can we ensure personal safety? Should the device deliver a shock automatically, or should the shock be a function under the operator's control?

Figure 1:
Visits with current users showed how defibrillators are stored, carried, and used, yielding insights into design issues.

Learning from Existing Users

The team first made visits to emergency services facilities to watch and talk with people who use defibrillators in their daily work: firefighters, paramedics, emergency rescue trainers, and cardiologists (see Figure 1). We looked at the devices they use and how they transport, store, set up, and check them. We explored typical scenarios and existing protocols, and asked about their feelings and behavior in emergencies, as well as problems they encounter.

Although we were talking to a highly trained group, different in many ways from the ultimate end-users of this product, we learned about many pertinent, practical issues. For example, rescuers always had to remember to take along extra things such as shears to cut open the victim's clothing, razors to shave hairy chests, and spare electrodes, suggesting that we design a system that incorporates such accessories. We learned from trainers that the voice prompts of existing defibrillators would be more helpful, even to well-trained paramedics, if they were more explicit. All users would be better served by a message saying, "Check patient's airway, breathing, and pulse," rather than the existing, "Check patient" message, which left them to interpret and possibly muddle many details while under stress.

Even at this early stage, with our research incomplete, we began to sketch out initial design ideas to address usage issues, such as how to store items with the device, how to make it easy to check the device's status, and how to provide strong cues about its use. These early sketches (see Figure 2) helped us to identify gaps in areas we did not fully understand and to review assumptions with the people we interviewed.

Analysis of Tasks and Users

Without the opportunity to witness the application of a defibrillator in real rescues, we relied on training videos and event recorders (tapes from defibrillators are kept by some emergency services for review and training). We extrapolated from these sources to help us map out the detailed activities, issues, and needs of different future users in different situations. There were three distinct classes of users, with different needs and experience: (a) professionally trained rescuers, (b) people who make contact with the public as part of their job and have some first-aid training, and (c) family members with no rescue experience, who have the additional pressure of dealing with a relative.

We examined the behavior and needs of these three main user classes through sketched scenarios: firefighters attending a victim in the street; a staff member in a health club where a client collapses while using an exercise bike;

FIREFIGHTER

issues

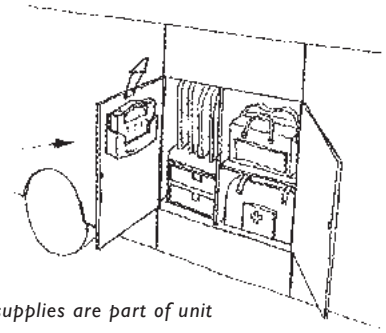
no major
storage issues

suggestions

on truck, in cabin,
hang on hook, slide into holder -
holder contains spares

on truck in storage compartment

integrated in first aid case/bag,
needs no handle, unit is a bag, extra supplies are part of unit



POLICE

issues

space in cabin limited

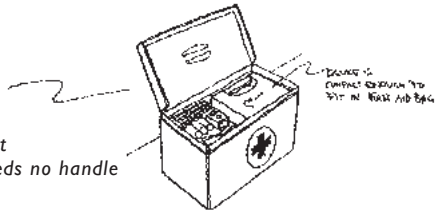
suggestions

under car seat

in trunk of car - needs restraint
integrated in first aid case, needs no handle

(soft) case is part of unit

unit is a bag, extra supplies are part of unit



WARD NURSE

issues

no major storage issues

suggestions

unit kept in stock room, on shelf, on wall

kept at nurse's station, under counter,
on desk, on wall

spares are kept in stock room

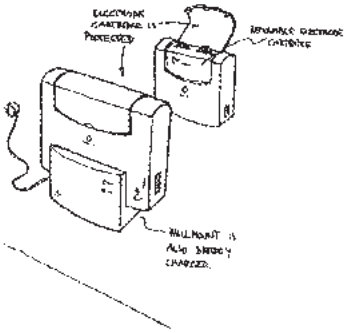


Figure 2:
Early sketches explored usage in different contexts, including first-response vehicles, clinical settings, and home environments.

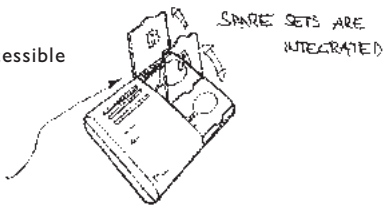
SEMI-PUBLIC SPACE

issues

has to be readily located and accessible
avoid abuse

suggestions

wall mounted
on shelf, under counter, desk
hanging on a hook
integrated in first aid case, needs no handle
unit is a bag, extra supplie are part of unit
instructions for use on display when unit stored



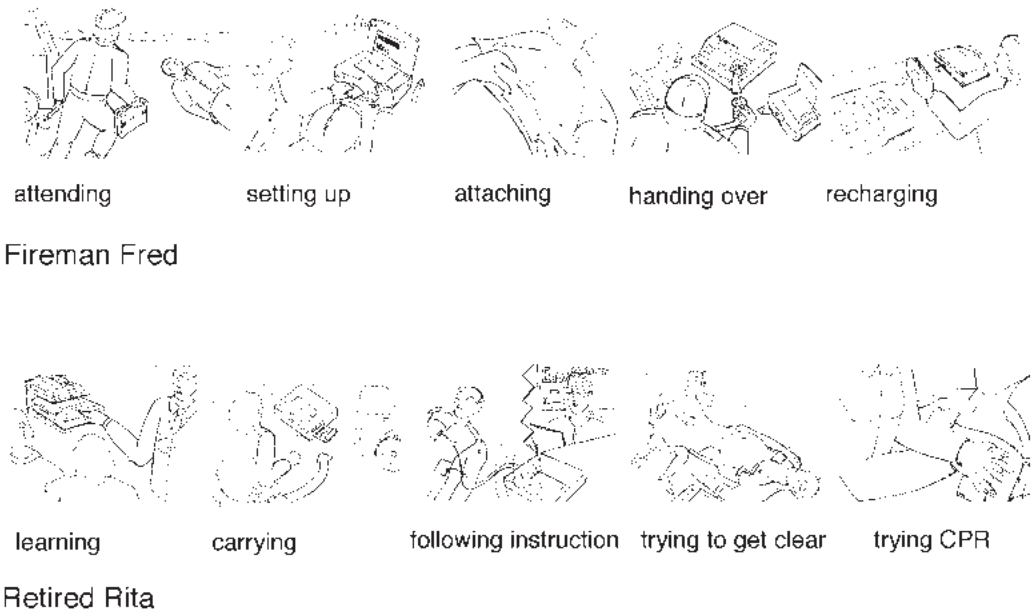


Figure 3: We developed these future scenarios as a graphic form of task analysis that was easy for the development team to understand. The scenarios represent two classes of users: a firefighter in a public street, and an active retired couple on vacation.

and an elderly couple on vacation when the husband collapses in the motel. These scenarios (see Figure 3) served as a graphic form of task analysis that was easy for the development team to understand. By incorporating some of the dramatic elements of people in an emergency situation, we were able to uncover and communicate problems that people might encounter in practice and to explore their potential solutions.

In the case of the fire service, frequently a fire crew is eventually relieved at the scene by paramedics, who use their own defibrillator. The electrodes should therefore be widely compatible with a range of other defibrillators rather than be exclusive to this device. But would nonproprietary electrodes fit the company's business model?

In the motel scenario, the elderly woman's version of the defibrillator has a cellular modem that automatically dials 911 and perhaps allows a remote operator to talk her through the rescue. What might be the cost implications of such a feature? This scenario also addresses the issue of automatic shock delivery; that is, she is unable to move away from her husband quickly and could be seriously injured by a shock if it were delivered while she is still touching him. In this case, an operator-initiated shock is clearly preferable.

Potential Errors and Safety Concerns

Against this background, we systematically catalogued errors that users might make. The key judgments facing users would be to (a) determine that a person may be in cardiac arrest, (b) correctly place electrodes on the patient's chest, (c) ensure that no bystanders are in contact with the patient, and (d) press a button to deliver the shock.

Identifying a potential victim of cardiac arrest involves checking the person's airway, breathing, and pulse. If a person is breathing or has a pulse, he or she is not in cardiac arrest and will not be helped by a defibrillator. Although it is a waste of rescue time and effort to connect defibrillator electrodes to such a patient, the consequences are not in themselves dangerous. But because the ForeRunner permits a shock to be administered only if it detects the chaotic electrical signature of a fibrillating heart, patients and others are protected from inappropriate use of the device.

The most complex difficulty for inexperienced users is connecting electrodes to the device and attaching them correctly to the patient. Visual and audible prompting from the device would help users through this process. We also wanted the system to tolerate incorrect placement of the electrodes on a victim's chest as far as possible, but at the same time to avoid ambiguity by clearly indicating correct placement.

Brainstorming and Conceptual Design

We tackled some of the following design challenges in group brainstorms with human factors designers, design engineers, and rescuers:

1. How can we clearly indicate the sequence of operational steps?
2. How can we make it easier to attach electrodes to the victim?
3. How should we configure the device?

These brainstorms yielded a wealth of ideas; we selected the most promising and developed them into more detailed concept sketches. We then made three-

dimensional, weighted foam models to look at different appearances and basic configurations, and models with electrodes to examine different deployment strategies (see Figure 4).

Ultimately, we developed five basic configurations for the device, each of which presented a different form factor and method for storage and deployment of electrodes:

a. A simple flat unit with screen and controls on the front face (similar to the model illustrated in Figure 4b), with separate electrodes.
b. A simple unit similar to *a*, but with electrodes stowed in a side compartment, like a videotape in its sleeve.
c. A wedge-shaped form, like a desktop phone, with electrodes stowed behind the screen.
d. A clamshell unit, like a laptop computer, with a hinged screen, and controls and electrodes on the horizontal surface.
e. A hinged clamshell unit that opened like a book to reveal the screen on the right and electrodes on the left (illustrated in Figure 4a).

We designed simulated rescue trials to help us discover the advantages and disadvantages of each design, especially for inexperienced users.

We designed simulated rescue trials (see Figure 5, next page) to help us discover the advantages and disadvantages of each, especially for inexperienced users. Trial participants had some prior training in CPR. Each was invited into a room where a CPR practice doll lay on the floor. They were handed one of the defibrillator models, without explanation of its operation, and were told to assist the "victim" using the defibrillator. We videotaped them, measuring the time it took each person to work out what to do and to correctly connect the electrodes to the patient. In each event, the time measurements were far less useful than our direct observations of participants' handling of the models and electrodes, and of the evidently distracting, ambiguous, or confusing elements in the models' graphics and forms.

It was clear that the aforementioned hinged configurations, items *d* and *e*, were good in that they forced a sequence of steps and progressive discovery of information as the units were opened up. But these two models also created difficulty for users by failing to provide an overview of the whole sequence. Users were also unsure of how to orient the devices and how to open them. These hinged versions enabled us to investigate the concept of the device turning on automatically when it was

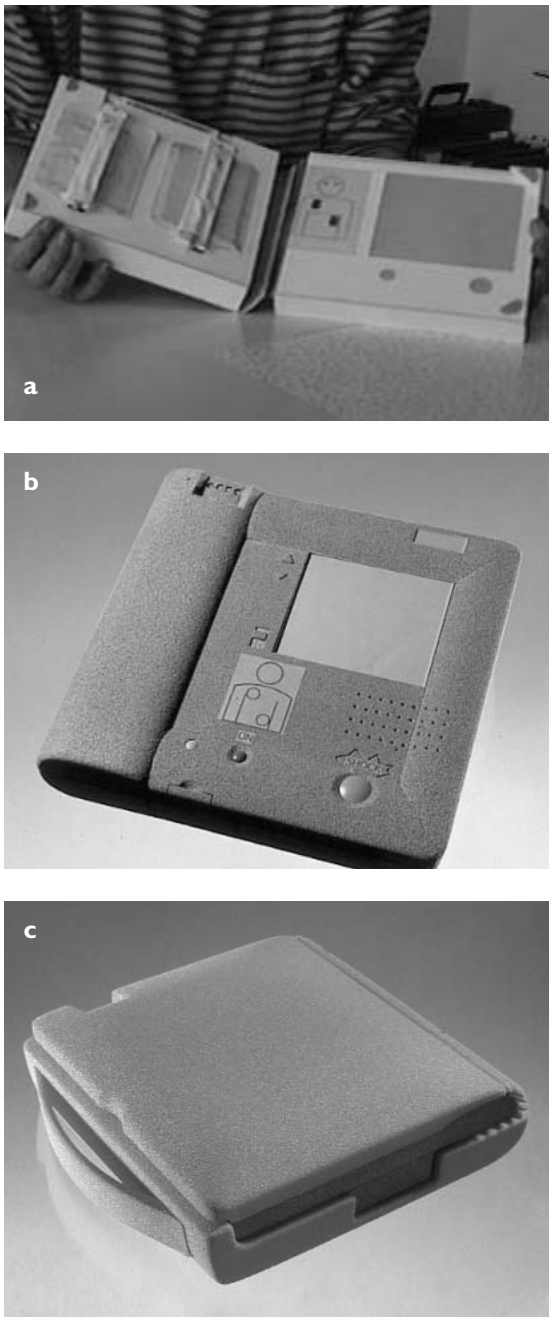


Figure 4:
Three-dimensional models exploring different configurations, each with a different form factor, storage method, and electrode deployment. (a) A hinged clamshell unit that opens like a book. This is an example of a weighted model. Examples of foam models are shown in (b) and (c). (b) Simple flat unit with screen and controls on the front face.

Figure 5:
We observed first-time users in simulated rescues that helped us understand and measure the advantages and disadvantages of each prototype.

opened up, saving operators a critical initial step. But all participants looked for an ON switch during the trials (even with the crude nonworking devices), and participants expressed concerns about the reliability of automatic switches and accidental initiation.

The configurations that held electrodes within the body of the unit, items *b* and *c*, were tidily self-contained but caused a good deal of fumbling in trying to access them.

Clear numbers associated with regions on the unit's face helped participants perform the sequence of operations, particularly when the entire sequence was visible at a single glance. The book form, shown in Figure 4b (see page 9) encouraged people to grab the spine, orient it to the left, and interact with it from top to bottom.

We communicated these recommendations in visual form as sketches (see Figure 6). The sketches summarize the device's key features in typical usage contexts, including storage, carrying, connecting, operating, packing away, and maintaining.

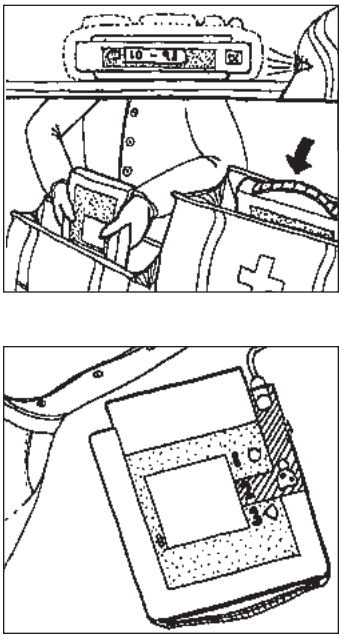


Figure 6:
Examples of sketches used to summarize our research findings.
(a) The unit should be easy to grab, and the battery indicator and status display must be visible while the device is in storage.
(b) The device's primary area, which indicates a simple conventional sequence with minimal distraction.

The Final Design

With these recommendations as a foundation, Heartstream continued to test increasingly high fidelity prototypes in a series of simulated rescue trials, until the product could be used effectively and efficiently by people previously unfamiliar with it. Figure 7 shows the final product.

Final implementation of the defibrillator has a red (signifying first aid) carrying case of heavy-duty fabric. The case has a cut-away to allow a view of the status indicator visible on the unit's front face. The carrying case provides room for labeling, such as an identification number or emergency service unit's name. It also accommodates accessories such as shears, razors, and spare electrodes, which would otherwise need to be carried separately.

The conspicuous color of the case and its simple, compact form make it easy to find and recognize among clutter at an emergency scene. But once opened and in action, the device offers a much more subdued background color of a soft blue-gray. The user then attends to audible prompts and the critical task-related regions of the front face: the ON button, the flashing connector prompt, the screen, and the flashing shock button prompting the rescuer to press it. Less critical controls, such as the volume adjuster, are located on the side of the device to avoid distraction from the main sequence of rescue steps.

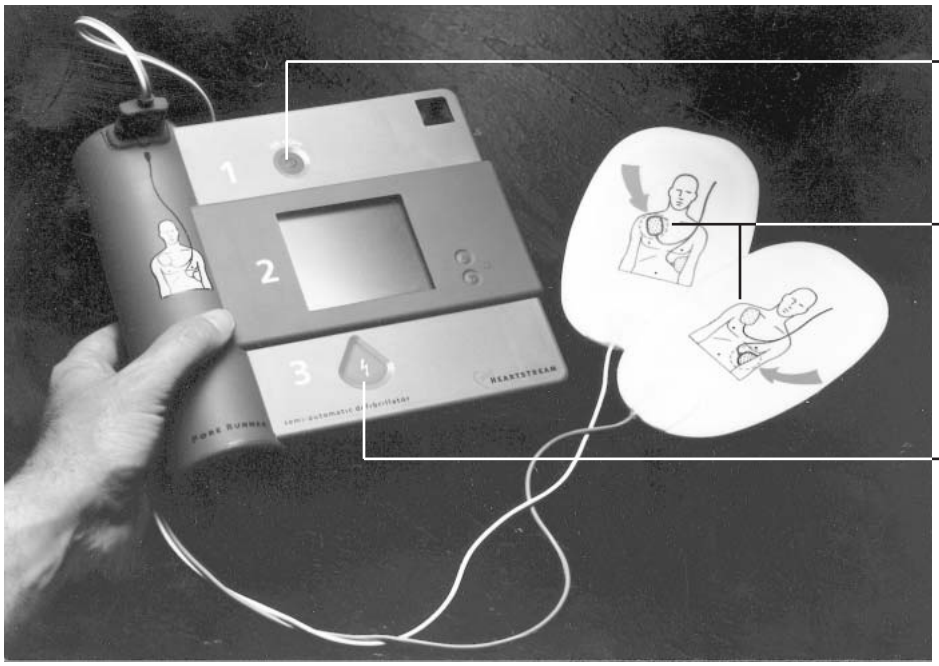
For people acting under the stress of a life-threatening emergency, the product indicates the correct sequence of actions and how to perform them:

- We selected the simple book form because it immediately suggests an appropriate orientation for carrying and use. Its spine is a significant cue for operators, suggesting the appropriate area to grip the device and highlighting the front-facing connector point. The

book form is actually a significant functional element of the device, housing the capacitor responsible for building up the charge that provides the therapeutic shock.

- The ON button is prominently positioned at the top of the device and colored green to invite interaction.
- The step-by-step sequence is indicated by the vertical progression of high-contrast number labels and by creating clearly distinct areas for the control or display feature associated with that step: (1) the connector for plugging in the electrodes, (2) the screen that displays an electrocardiogram, and (3) the shock button to press if and when instructed to do so.
- Audible voice prompts also follow this sequence. Through progressive testing, Heartstream learned that operators responded best to instructions delivered in an authoritative male voice. They used the calm and trusted voice of Peter Thomas, the narrator of the television science program, *Nova*. British users, though, preferred a British accent. Five additional language versions are now available.
- Redundant visual and audible feedback is provided to indicate that the device is reacting to the user's actions. For example, as the voice prompt instructs the operator to connect electrode leads to the device, a light at the connection point flashes, and instructions are repeated until the connection is completed. The shock button is illuminated by a flashing backlight when the voice prompt instructs the operator to press it.
- The electrodes will work, in sensing and shock delivery, as long as they are stuck to the patient's chest, regardless of which one is placed on the right or left side. But we learned that many people expected that it would matter which went where, so to avoid confusion, each indicates independently where it should be located. A separate graphic is repeated on the device itself.
- The shock button is the key function of the device. It is colored red-orange to draw attention to its significance and seriousness, but its shape is nonthreatening and distinguishes it from the standard function buttons. It was important that it not look like a stop button. The shock button has a backlight that flashes to draw attention to itself when it should be pressed.

Redundant visual and audible feedback is provided to indicate that the device is reacting to the user's actions.



the "on" button is prominent and colored green to invite interaction

each electrode indicates independently where it should be located

the "shock" button is colored and shaped to draw attention to its significance but is clearly not a standard stop button

• the face of the unit is organized and leveled to show clearly 3 sequential steps

• the "book" form suggests the appropriate orientation for carrying and use

• to minimize distraction, other controls are downplayed and located elsewhere

Figure 7:
The final design, as implemented by Heartstream.

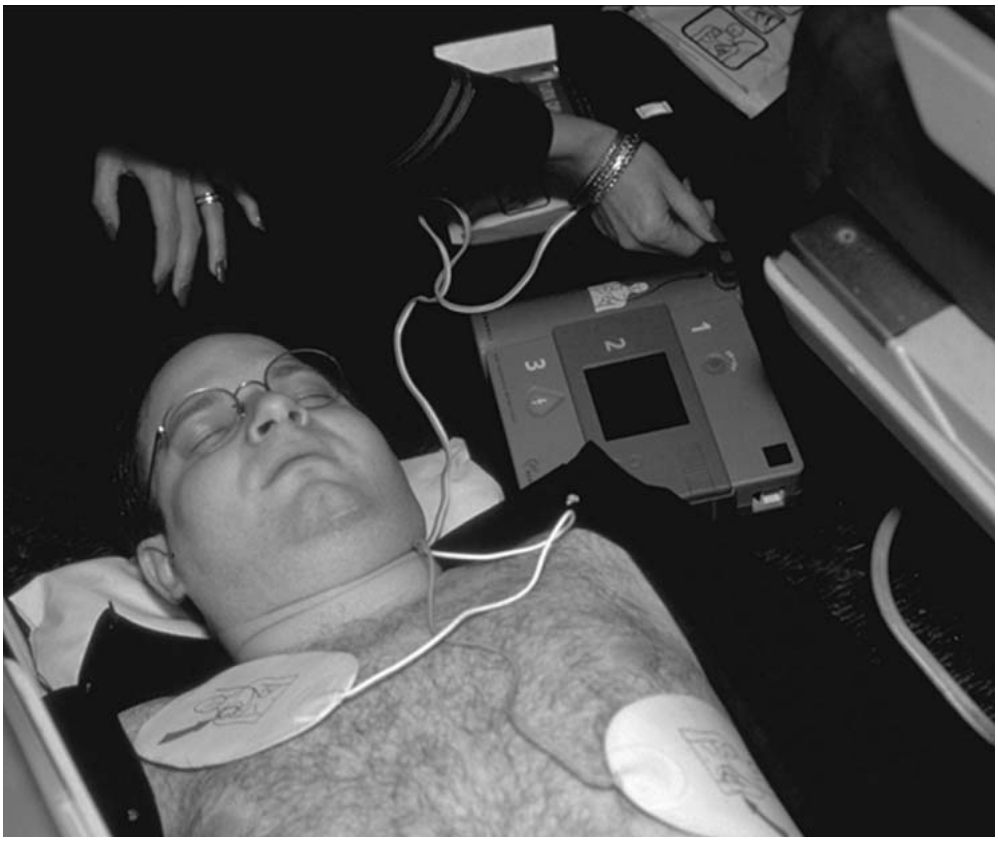


Figure 8:
The final product is now carried as standard first-aid equipment on several major passenger airlines, where it has saved several passengers' lives. This image is from a dramatization of such a rescue. Photo courtesy of Rick English.

Subsequent Developments

The final product received U.S. Food and Drug Administration approval for general use in 1996. It is now used by paramedics and other first responders such as the National Ski Patrol and by an increasing number of fire and police service personnel. For the first time, defibrillators are now carried as standard equipment on several passenger airlines for use by the cabin crew (Figure 8).

This program's success highlights the value of using multiple techniques concurrently and the value of integrating research and design throughout the development process. An initial research phase was not enough to provide a design specification or even a definitive set of user requirements. But it did provide a starting point for initial design concepts and subsequent rounds of inquiry.

The most valuable methods in this process were those involving scenario-based explorations and prototype testing; they enabled the team to keep focused on the device's use in context and to move gradually toward an integrated, workable solution to which all design team members were able to contribute.

Reference

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Jane Fulton Suri is head of Human Factors Design and Research at IDEO. She is based in San Francisco, Pier 28 Annex, The Embarcadero, San Francisco, CA 94105. *She thanks Heartstream for the opportunity to work on this project and Sigi Moeslinger, Naoto Fukasawa, and Ben Shaw, who were key contributors to the early conceptual work undertaken by IDEO with the Heartstream team. Later development work and final product implementation was by Heartstream, with industrial design credit for the final product to Jon Bishay. For further information, go to http://www.healthcare.agilent.com/mpgcpd/heartstream/*