

SMART CPR

Philips has augmented the HeartStart AED's well proven patient analysis logic with SMART CPR, a feature that provides a tool for Medical Directors and Administrators to implement existing or emerging protocols using the CPR First parameter. Currently, some emergency response protocols incorporate a CPR interval prior to applying the AED. Although this provides for initial CPR treatment, since the device is not attached to the patient it cannot collect data or provide the responder with prompts or an initial CPR interval.

Until recently, immediate defibrillation with an automated external defibrillator (AED) was the general rule. However studies now show the benefit of providing one to two minutes of quality CPR prior to a defibrillation shock if the response time to the patient is greater than five minutes.^{1,2,3} Unfortunately, it is often not possible for responders to determine on arrival how long the patient has been down.

When the CPR First setting is configured to SMART CPR AUTO1 or AUTO2 in the FR3, the defibrillator uses a separate, more refined treatment algorithm to evaluate key attributes of the patient's presenting heart rhythm and advises whether to initially treat shockable rhythms such as ventricular fibrillation (VF) with a shock, or with CPR immediately followed by a shock. (See discussion of settings on following pages.)

If a patient in VF is likely to experience a return of circulation with a shock (as is typical of short duration VF), the FR3 advises an immediate shock. Otherwise, the FR3 advises CPR prior to a shock. SMART CPR is designed to help responders make better-informed, more refined customized treatment decisions. It supports an emerging response protocol that current scientific literature suggests may improve survival for more patients.

Patients with some VF rhythms respond well to a shock and achieve a return of circulation. If the VF rhythm is of high frequency and amplitude — in other words, if the VF rhythm is coarse, spiky, and energetic — the heart is likely to return to circulation with an immediate shock (Figure 1a). For these rhythms, an immediate shock is beneficial.

Other VF rhythms are indicative of a heart that is not receptive to a shock. If the frequency and amplitude of the VF rhythm is low — if the rhythm is weak, fine, rather flat, and shapeless — it indicates that the heart's energy is depleted and a return to circulation is unlikely (Figure 1b). For these rhythms,

1. Wik L, Hansen TB, Fylling F, Steen T, Vaagenes P, Auestad B, Steen PA. Delaying Defibrillation to Give Basic Cardiopulmonary Resuscitation to Patients with Out-of-Hospital Ventricular Fibrillation: A Random Trial. *JAMA* March 19, 2003, 289:111389-1395.
2. Cobb LA, Fahrenbruch CE, Walsh TR, Copass MK, Olsufka M, Breskin M, Hallstrom AP. The Influence of Cardiopulmonary Resuscitation Prior to Defibrillation in Patients with Out-of-Hospital Ventricular Fibrillation. *JAMA*, April 7, 1999, 281:13:1182-1188.
3. Weisfeldt ML, Becker LB. Resuscitation After Cardiac Arrest: A 3-phase Time-sensitive Model. *JAMA*, December 18, 2002. 288:23:3035-3038.

an initial interval of CPR prior to a shock can be beneficial. Properly applied CPR oxygenates the heart, which can cause a weak VF to become more coarse and energetic and make the heart more receptive to a shock.

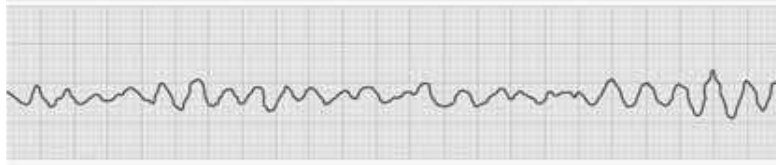


Figure 1a: Short-term VF rhythm with high frequency and amplitude, characteristic of a heart receptive to a defibrillation shock

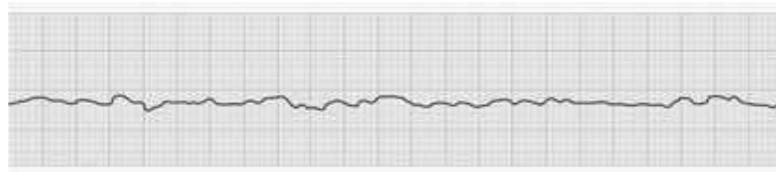


Figure 1b: Long-term VF rhythm with low frequency and amplitude, characteristic of a heart that is unlikely to return to circulation with a shock. CPR prior to a shock may improve the outcome.

At the onset of cardiac arrest, VF typically starts out quite coarse and energetic. As minutes pass without treatment, however, the heart depletes its fuel reserves, and the VF rhythm progressively weakens, getting flatter and finer. Note that time is not the only contributor to a weak VF. Other factors include the degree of underlying heart disease and the cause of the arrest.

It is not surprising, therefore, that recent studies are showing that patients with rhythms typical of short-duration VF respond better when they receive an initial treatment of defibrillation, while patients with rhythms typical of long-duration VF (> 5 minutes) have higher survival rates when they receive an initial interval of CPR prior to defibrillation shocks.

One such study, by Wik et al.,¹ looked at cardiac arrest patients in an EMS system. Patients were divided into two groups. One group received shocks as the initial treatment. In this group, the patients with short-duration VF had markedly higher survival if they received immediate shocks. However, survival rates with this protocol dropped precipitously the longer the patients were in VF. The other group received an interval of CPR followed by shocks. Figure 2 shows the survival curve over time for that group of patients. Of particular interest is that the figure also shows that, among

1. Wik L, Hansen TB, Fylling F, Steen T, Vaagenes P, Auestad BH, Steen PA. Delaying defibrillation to give basic cardiopulmonary resuscitation to patients with out-of-hospital ventricular fibrillation a randomized trial. *JAMA*. 2003 Mar 19; 289(11):1389

patients with longer-duration VF, those in the group receiving an interval of CPR prior to a shock had significantly better survival.

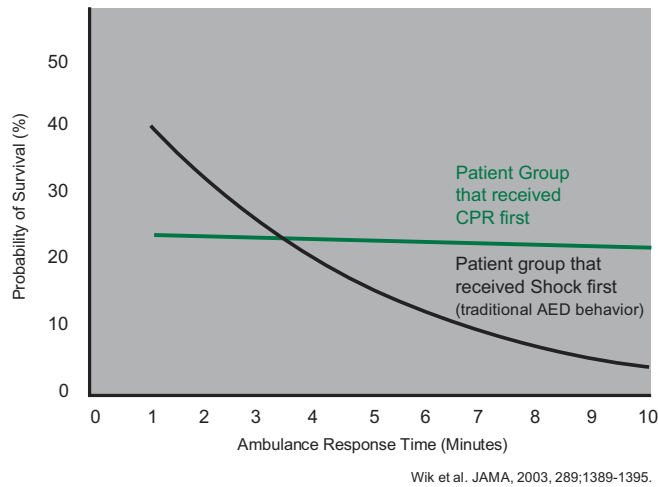


Figure 2: Patients with short-duration VF had good survival rates when they received immediate shocks. Those with long-duration VF had higher survival rates when receiving CPR prior to a shock.

This data suggests an opportunity to improve survival of cardiac arrest with a simple change in response protocol: provide immediate shocks to patients in short-duration VF, but provide initial CPR to patients in long-duration VF (Figure 3). Indeed, the current literature proposes such a protocol – and using AEDs that support it – as a way to improve survival.

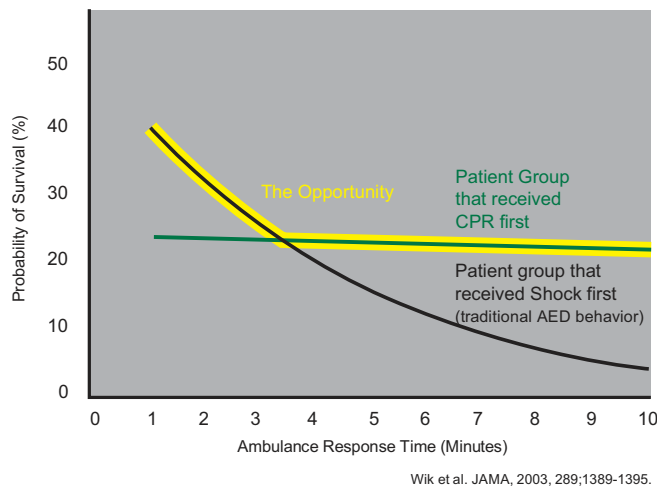


Figure 3: The opportunity to improve survival of SCA with a change in response protocol.

The EMS responder faces a dilemma when, as is often the case, there is insufficient information upon arrival to determine the best course of treatment: Did EMS witness the arrest? How long has the patient been in

arrest? How long after the victim's collapse was it before emergency response was called? Was bystander CPR performed prior to arrival of EMS? If so, was it effective CPR? What is the underlying condition of this individual patient's heart? What should the arriving responder do—shock first or perform CPR first? The choice may not be obvious.

The HeartStart FR3 with SMART CPR enabled assesses the initial heart rhythm to determine if it is shockable. If it is, SMART CPR determines if the rhythm has the specific attributes of a heart likely to benefit from an initial defibrillation shock. If this is the case, the FR3 will advise a shock. Otherwise, it will advise a period of CPR first, followed quickly by a shock, anticipating that CPR may render the heart more receptive to that shock (Figure 4). Either way, the FR3 adjusts its voice instructions accordingly.

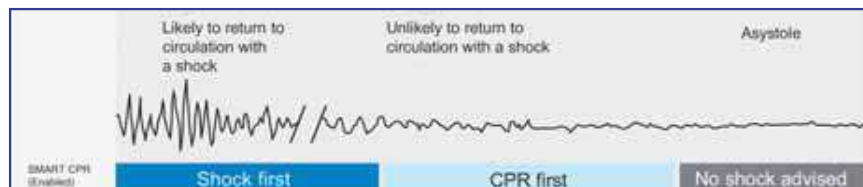


Figure 4: A conceptual representation of the progression of VF over time, showing SMART CPR's response.

In deciding whether to enable SMART CPR in the FR3, the Medical Director should consider the overall impact the selected setting would have on the SCA emergency response system, and train responders accordingly. Other factors to be considered include:

- Emergency system response times
- Responder skill level
- Prevailing protocols and time and cost for training
- Expected changes in response protocols

Based on a consideration of these factors, the Medical Director can configure the FR3 to any of four CPR First settings: OFF, SMART CPR AUTO1, SMART CPR AUTO2, and USER. These are defined in greater detail below.

OFF SETTING

The OFF setting means the FR3 will not provide an initial CPR interval prior to defibrillation of a shockable rhythm. Thus, once the FR3 is attached, it will advise an immediate shock for all SCA patients presenting with a shockable rhythm — even those who may benefit from CPR first — before it provides a CPR interval. This setting represents the historical behavior of AEDs, including the ForeRunner and FR2+. It is therefore the default setting for CPR First.

SMART CPR AUTO1 AND AUTO2 SETTINGS

It is often not possible for the responder to know whether an individual patient in SCA might benefit from CPR first or defibrillation first. When set to AUTO1 or AUTO2, the FR3 analyzes the patient's initial rhythm and automates the decision as to whether an individual shockable patient will receive an initial shock or CPR first. Based on a comprehensive database of ECG recordings of actual resuscitation attempts,¹ the SMART CPR algorithm evaluates the initial ECG's amplitude and frequency characteristics — both known predictors of shock success — and calculates the likelihood of the return of spontaneous circulation (ROSC) following a defibrillation shock. If the likelihood is low, the FR3 will provide a CPR interval prior to defibrillation in an effort to increase the likelihood of successful defibrillation. If high, the device will advise immediate defibrillation. In either case, the device adjusts its voice and text prompts appropriately.

WARNING: Although SMART CPR can be used for adults and children, the performance of the SMART CPR AUTO1 and AUTO2 settings has not been established in patients under 8 years or 55 lb. (25 kg).

SMART CPR AUTO1. Provides immediate defibrillation for more than 90%ⁱ² of shockable patients who are likely to achieve ROSC (less than 10% receive CPR first). Of those shockable patients who are unlikely to achieve ROSC, more than 50% will receive CPR first.

SMART CPR AUTO2. Provides immediate defibrillation for more than 80%[†] of shockable patients who are likely to achieve ROSC (less than 20% receive CPR first). Of those shockable patients who are unlikely to achieve ROSC, more than 60% will receive CPR first.

USER SETTING

The USER setting provides the responder with a means to manually initiate a CPR interval, based on either a patient assessment or standing orders from the Medical Director. The FR3 can thus be applied immediately to the patient, enabling the device to collect data and provide reminder text prompts that the CPR Pause key is available. The responder presses the CPR Pause key to start a CPR interval. The FR3 will continue with rhythm analysis unless the CPR Pause key is pressed.

With the FR3 CPR First setting set to USER, the FR3 provides an opportunity for the responder to initiate a CPR interval for all patients — even those who may benefit from immediate defibrillation.

1. Data collected from multi-center, multi-national out-of-hospital and in-hospital adult sudden cardiac arrest rhythms. The SMART CPR algorithm was developed based on VF, polymorphic VT, and ventricular flutter rhythms.
2. Based on observed performance. ROSC was determined by several parameters, including patient assessment, ECG analysis, and/or patient impedance cardiography.