POWER TO SAVE A LIFE

HEARTSTART
FR2+ DEFIBRILLATOR

PEDIATRIC DEFIBRILLATION: FREQUENTLY ASKED QUESTIONS

PHILIPS

FREQUENTLY ASKED QUESTIONS

Do children ever have treatable cardiac arrest?

A study of the Houston EMS system[3] states that in the United States, about 16,000 children under age 17 die annually due to unexpected pediatric cardiopulmonary arrest. The authors state that while the occurrence is significantly less frequent than that of adults, *years of life lost rivals that of adult cardiac arrest.*

It is not conclusively known how common it is for a child to exhibit ventricular fibrillation (VF) during cardiac arrest.[4] VF is a heart rhythm that can be shocked, often with good survival outcome.[4,5,6] So the presence of VF episodes is actually an opportunity to save a child, if it is detected.[4] Conventional wisdom holds that VF does not occur in children except in extremely rare instances. That conventional wisdom is now being challenged.[5]

The difficulty in determining the frequency of shockable VF in children stems from the fact that a child's ECG is often not seen until *well into* the emergency response, because emergency protocols typically call for the attachment of monitoring equipment late in the response. So there is little data on *the first few minutes* of pediatric cardiac arrest. If asystole (or "flatline") is found, it is often assumed that it was preceded by non-shockable bradycardia (progressively slowing heart rate), induced by respiratory arrest. However researchers suspect that VF may sometimes occur in children *early on*, and then degenerate into a non-shockable asystole by the time monitoring equipment is attached to the child. So the true occurrence of VF in small children may be under-reported.[5]

Having said that, current studies estimate VF in 6%[7] to 19%[5] of pediatric cardiac arrest cases. This rate is less than that estimated for adults, but it is still significant, as VF is considered a treatable condition. Mogayzel et al[5] concluded, "Ventricular fibrillation is not rare in child and adolescent pre-hospital cardiac arrest…Earlier recognition and treatment of ventricular fibrillation might improve pediatric arrest survival rates."

The American Heart Association's (AHA) Guidelines 2000[6] states, "In summary, although VF is not a common arrhythmia in children, it is observed in as many as 15% of pediatric and adolescent arrests. In these patients, rapid defibrillation may improve outcomes."

Young and Seidel[4] conclude that, "Current recommendations in pediatric patients do not emphasize early defibrillation because VF/VT is much less common in these patients. However, the smaller percentage of patients must be balanced with their improved survival. Perhaps a subgroup…can be identified that can benefit from EMS protocols emphasizing early defibrillation."

HeartStart FR2+ with infant/child pads

Dr. Frank Cecchin, pediatric cardiologist and researcher at Harvard University, sums it up this way: "We need to protect the most precious part of our society and that is our children. Pediatric capable automatic defibrillation needs to be available wherever children are present and should be part of the basic tools of all emergency response personnel. It is only then that we will save more children's lives."

Since VF may not be common in children, would an automated external defibrillator (AED) complicate the treatment of more typically seen respiratory arrest, thereby compromising pediatric care?

CPR for infants in respiratory arrest consists mainly of airway management and rescue breathing. However if cardiac arrest does occur, often as a result of respiratory arrest, focus must turn to getting the heart started again or the child will die. Airway management and rescue breathing alone are not enough.[6] It is noteworthy that the survival rate from pediatric cardiac arrest has not improved in the last decade,[4] despite an intense focus on airway management and rescue breathing.

An automated external defibrillator provides the first responder with the only hope of re-establishing a perfusing heart rhythm and resuscitating the child prior to the arrival of ACLS. It enables a first responder to take advantage of any shockable rhythm that may occur.

What are the causes of cardiac arrest in children?

Causes include SIDS, trauma or accident (auto accident, electrocution, drowning, overdose/poisoning), illness, and congenital heart disease.[8] A hard blow to the chest can bring on cardiac arrest. This has occasionally been seen in children struck by a baseball or playing lacrosse.

How does the pediatric-ready FR2+ work?

Using the defibrillator is simple. The responder presses the green button at the front of the FR2+ to power-up the unit, then places the special infant/child defibrillator pads on the victim. Next, the responder plugs the pads connector into the defibrillator. The device automatically analyzes the heart rhythm and determines whether a shock is needed. If a shockable rhythm is detected, the FR2+ instructs the responder to deliver defibrillation therapy.

The disposable FR2 infant/child pads can be used with any model of FR2 or FR2+ defibrillators. They employ an *attenuator* in their connector that automatically absorbs energy from the shock coming out of the defibrillator. This results in a lower energy shock (50 J instead of 150 J) being delivered to the patient; an appropriate dose for an infant or child under 8 years or 55 pounds.[8]

Is 50 Joules appropriate for *all* children under 8 years old, including infants?

Yes. The use of a single level of energy is an appropriate model for an AED. It is analogous to our successful non-escalating adult therapy of 150 J for older children and adults of all sizes. The use of a single energy dose eliminates the necessity to guess the child's age and/or weight and adjust the dose accordingly – a protocol complication that is not suitable for less experienced responders. 50 J provides sufficient energy to ensure that children up to 8 years or 55 pounds receive *at least* 2 J/kg, per AHA guidelines.[6] An attenuated 50 Joules from the FR2+ was tested on pigs with long downtime VF. These pigs had weights that varied from 3.5 kg (comparable to a human infant) to 25 kg (comparable to a typical 8 year old child). Resuscitation was always successful and all survived. For all, post-resuscitation hemodynamic and myocardial function quickly returned to baseline values.[2] In fact, the *smallest* animals showed the *fastest* return to baseline cardiac performance! One can conclude that 50 J works well for the entire size range seen in infants and children under 8 years, without detrimental side effects.

What about human studies?

A study tested the Patient Analysis System algorithm of the FR2+ for sensitivity and specificity on a database of 696 *human* pediatric rhythms.[1] The Patient Analysis System performed exceptionally well for sensitivity (correctly deciding to shock) and specificity (correctly deciding not to shock). VF sensitivity was 96% and specificity was 100%, both well above the AHA goals for AEDs. The specificity results are particularly significant because one never wants to risk shocking a child unnecessarily. This is a concern for those defibrillators with algorithms that base shock/no shock decisions on heart rate alone because children tend to experience very fast heart rates under high stress conditions, yet a shock may be inappropriate. The analysis algorithm of the FR2+ demonstrated specificity results that preclude inappropriate shocks because it considers more than just heart rate. It considers the combination of rate, conduction, amplitude, and stability.

For ethical reasons, it is virtually impossible to perform prospective and statistically significant defibrillation clinical trials on children to test for shock efficacy *using actual shocks*. On the other hand, pig physiology is highly comparable to humans, making them good surrogate subjects. Using pigs to test new therapies is a generally accepted practice. The research approach and results are described in the Summary of Safety and Effectiveness that was considered by the FDA[9] prior to clearing the FR2-series defibrillators for pediatric use (a copy of this summary is available from Philips upon request).

Does the FR2+ still do impedance compensation with these pads?

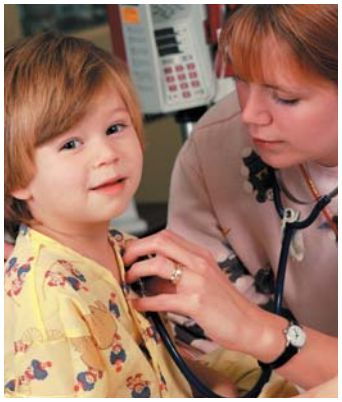
Yes. The defibrillator's algorithm performs impedance compensation exactly as it does with adult pads.

Why do these infant/child pads have a pink teddy-bear connector?

One of Philips' guiding requirements is that AEDs must be completely intuitive for the least experienced, and most stressed responder. It is vital that the correct pads are chosen for adults and for children, especially since the infant/child pads would deliver a therapy that may be ineffective on adults. Choosing the right pads must be automatic, with little thinking required. So Philips employed a tiered strategy which begins with simple, identifiable packaging and then follows with a substantially different connector that clearly communicates at an instinctive level "Child!" A pink teddy-bear poking out of an AED will give the responder pause and an opportunity to verify that the correct pads are being used.

I see Anterior/Posterior (A/P) pad placement is used. Why?

In extensive user testing, responders found it much easier to perform good pad placement using A/P placement (i.e., one pad on the chest and one on the back) on infants' and small children's tiny torsos.



Does this mean Anterior/Anterior (A/A) placement won't work?

Philips has data demonstrating good pad performance when placed correctly in the A/A position, however A/P positioning is recommended due to the reasons cited above. A/A placement is shown in the infant/child pads user guide as an alternative position, however it is not shown on the packaging in order to keep instructions simple for inexperienced responders.

What is the impact on training?

From the device perspective, defibrillator use remains simple if instructors direct students to simply "look at the pictures on the pads and place them as shown." Because the prompts of the FR2+ are the same for adult and pediatric patients, only proper infant/child pad positioning needs to be added to FR2+ training. However, as with adult defibrillator training, it is important that FR2+ users who are likely to use the defibrillator on pediatric patients receive training in pediatric basic life support (BLS) techniques prior to or at the same time they learn pediatric defibrillation.

Philips has developed a pediatric supplement for the FR2 Instructor Toolkit and reusable infant/child training pads are available. Philips is also working with major emergency care training providers to update their materials to include appropriate information on pediatric defibrillation with the FR2+ defibrillator.

I see that these pads can only be used with the FR2 or FR2+, and not with manual defibrillators. Why?

This is a necessary safety precaution. It ensures that ALS responders arriving at the scene with manual defibrillators do not unplug the FR2 infant/child pads from the AED, plug it into their manual unit at handoff, and inadvertently select an energy level that does not take into account the pads' attenuator. This would result in a potentially ineffective shock at 1/3 the energy level the responder intended. So the pads' connector has a shape that only fits the FR2 or FR2+. Since Philips offers adapters that enable handoff to manual defibrillators, the connector's shape also keeps the pads from working with these adapters.

What is the AHA's position on these pads?

The AHA will be evaluating data on the use of Philips defibrillators on small children. For now, AED use on small children retains its "indeterminate" level of evidence within the AHA guidelines.[6] This was the status initially given to automated external defibrillators delivering *adult* doses of electric therapy to small children, long before the introduction of this ground-breaking pediatric capability in Philips automated external defibrillators. It is important to understand what this status means.

The classification "indeterminate" means "Available evidence insufficient to support a final class decision."[6] The AHA summarizes the interpretation of this status as follows, "Interventions classed indeterminate can still be recommended for use, but reviewers must acknowledge that research quantity/quality fall short of supporting a final class decision... Indeterminate is limited to promising interventions."[6]

In a recent position statement,[10] the AHA reviewed its previous concerns about the lack of data regarding an AED's ability to accurately make shock/no shock decisions and then deliver appropriate doses to small children in the event of a shock decision. In response to the introduction of Phillips' pediatric capability, the AHA said, "The development of this new pad and cable system for this AED is a very encouraging development that helps address the AHA's safety concerns about electrical 'overdosing' of infants and children." With regard to the recently released clinical trial of the Philips SMART Analysis system,[1] the AHA said, "The results of this recent study are highly encouraging and suggest that the rhythm detection of the AED tested may perform well when used to actually assess the cardiac rhythm of children."

More recently, the Resuscitation Council for the United Kingdom took this position on Philips' pediatric capability: "One manufacturer has [clearance] for use of its defibrillator with special pediatric pads which deliver a fixed energy level of 50 Joules. This machine would be preferable to a defibrillator delivering only "adult" fixed doses in situations where children may require defibrillation and a fully adjustable defibrillator is unavailable or unsuitable."[11]

EXTENDING THE EARLY DEFIBRILLATION STANDARD OF CARE TO OUR CHILDREN

Philips offers the only automated external defibrillators cleared for use on children under 8 years or 55 pounds (25 kilograms). Because you may have questions about defibrillating infants and small children, we provide the following answers to frequently asked questions. Feel free to contact your Philips sales representative for more information.

Why is this capability important?

Children who might have been saved die from cardiac arrest. Broadly deployed new automated external defibrillator technology affords the opportunity for early defibrillation within minutes of cardiac arrest onset, which is now the standard of care for victims of cardiac arrest over 8 years of age. Unfortunately, children under 8 have not received that same standard of care.

When a small child suffers cardiac arrest, many response protocols have traditionally called for basic CPR without automated external defibrillator use until a paramedic with a manual defibrillator arrives. Treatment may be tragically delayed while awaiting paramedic care. By the time a paramedic arrives, hope of successful resuscitation is severely diminished. This can be devastating.

Philips wants to change things and enable the saving of more kids' lives. With the demonstrated ability of our FR2-series* defibrillators to accurately analyze pediatric ECG rhythms[1] and the availability of special infant/child defibrillator pads which reduce shock energy to a level appropriate for children,[2] the tools are available to help save precious young lives.

*FR-series includes all models of FR2 and FR2+ defibrillators. Throughout this document, references to the FR2+ also apply to the FR2.

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