



New Device Clearance

Heartstream FR2 AED with Attenuated Defibrillation Pads K003819



Product Name: Heartstream FR2 AEDs (model numbers M3860A and M3861A) and Laerdal Heartstart FR2 AEDs (model numbers M3840A and M3841A) with Attenuated Defibrillation Pads (model number M3870A).

Manufacturer: Agilent Technologies, Inc. Heartstream Operation

Address: 2401 4th Avenue, Suite 500, Seattle, WA 98121

Clearance Date: May 2, 2001

510(k) Statement: <http://www.fda.gov/cdrh/pdf/K003819.pdf>

What is it? This device is an automated external defibrillator (AED) system, a life-saving device that sends an external electric shock through the patient's chest to restore normal heart rhythm. This system has been designed especially for infants and young children who experience a sudden condition called ventricular fibrillation, when the heart no longer beats efficiently enough to pump blood through the body. This is fatal unless the infant or child receives defibrillation shocks within a few minutes.

How does it work? The FR2 pediatric pads use an attenuator, a component that reduces the electrical energy (shock) delivered to the chest of the patient. The shock given with this device for infants and children is about one-third the shock delivered to adults.

When is it used? The FR2 AED with attenuated defibrillation pads is indicated for use on infants and children with sudden ventricular fibrillation who are

- 8 years old or younger,
- weigh 55 lbs. (25 kg) or less,
- not responsive, and
- not breathing.

If the child appears larger or older, medical personnel will use the Heartstream Adult Defibrillation Pads, because it is important not to delay treatment in order to determine the child's exact age and/or weight.

What will it accomplish? This new device system provides defibrillation for infants and small children younger than 8 years of age, at a level of care equal to that of adults. This could improve the chance of survival for children who experience ventricular fibrillation.

When should it not be used? The FR2 AED should not be used if the child is responsive or breathing. The pediatric pads should not be used on children who are older than 8 years or weigh more than 55 lbs. (25 kg).

Additional information: Substantial Equivalence letter is available at:
<http://www.fda.gov/cdrh/pdf/k003819.pdf>

Other:

- FDA Talk Paper: <http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01082.html>
- AEDs in general http://www.fda.gov/cdrh/consumer/AED_PAD.html
- FDA article "When Heartbeats Go Haywire: New Treatments Can Save Lives"
http://www.fda.gov/fdac/features/1997/397_hart.html
- American Heart Association: <http://www.americanheart.org/>

[[Accessibility](#)]

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