

FDA Probes External Biphasic Defibrillator Energy Levels

General Q&A Document for Physio-Control Distribution Partners

Summary:

- FDA is investigating biphasic external defibrillators with energy limited to 200J.
- FDA has received reports of 14 events in which a 200J device was ineffective, but a subsequent 360J shock from a different defibrillator was effective.
- FDA recommends that users of devices that do not go beyond 200J continue to use their devices following AHA Guidelines and the manufacturer's instructions
- The link for more information on this investigation is:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm189839.htm>

Notes to Assist with Questions from Customers:

Q: What are joules?

A: A joule is a unit of measurement of energy. Energy has 3 components:

Energy (joules) = voltage (volts) X current (amps) X time (msec)

Current defibrillates the heart. Defibrillation shocks must maintain effective current levels for a long enough period of time to successfully defibrillate. Energy is not the same as current. Current is the flow of an electrical charge. Increasing energy when necessary is the most effective way to increase current flow.

Q: Do different AEDs deliver different levels of energy?

A: Yes. The following chart shows the default energy settings that manufacturers' provide in their AEDs:

AED Manufacturer Default Energy Settings	120J	150J	200J	300J	360J
Philips® HeartStart On-Site AED					
Philips HeartStart FRx AED					
Defibtech Lifeline® AED					
Defibtech ReviveR™ AED					
ZOLL® AED Plus					
Cardiac Science™ Powerheart® AED G3 Plus					
Physio-Control® LIFEPAK CR® Plus AED					
Physio-Control LIFEPAK® 500 AED					

Q: Why do different manufacturers sell AEDs with different levels of energy?

A: We cannot answer that question for all manufacturers. It has and will continue to be the company philosophy of Physio-Control to manufacture and sell defibrillators with the capability to escalate energy up to 360J because some sudden cardiac arrest victims are more difficult to defibrillate than others and may need more than a 200J shock.

The Physio-Control decision to only offer AEDs with a full range of energy with default escalating settings of 200J-300J-360J is supported by clinical study results. In a study conducted by Stiell, there was a statistically significant benefit for higher escalating shocks compared to fixed lower energy shocks in patients with ventricular fibrillation who required more than one defibrillation shock. _ Also, the American Heart Association has provided guidance on the importance of minimizing interruptions in CPR. _ Ineffective defibrillation shocks contribute to interruptions in CPR. For these reasons, Physio-Control offers the full range of energy in all of our defibrillation products.

Q: Does higher energy damage the heart?

A: Some companies that do not offer AEDs with higher dosing capabilities may say that energy higher than 200J may damage the heart. In fact, there are no human clinical studies that have shown myocardial injury from shocks at any biphasic energy level.

Q: Isn't peak current more important than joules, or energy, when it comes to terminating fibrillation in the heart?

A: To terminate ventricular fibrillation, it is necessary to expose enough of the heart to enough current for a long enough period of time. Average current and energy are both better predictors than peak current. If the current starts out high, but decreases quickly, it will not be as likely to succeed, compared to starting out high and decreasing more slowly. In these examples, the peak current can be the same but the average current will be different.

To learn more about 360J, go to www.360-joules.com. Or if your customer would like to discuss higher energy in greater detail, please consult your Physio-Control Account Manager.

_ Stiell IG, Walker RG, Nesbitt LP, et al. The BIPHASIC Trial: A randomized comparison of fixed lower versus escalating higher energy levels for defibrillation in out-of-hospital cardiac arrest. *Circulation*. 2007;115:1511-1517.

_ 2005 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2005;IV-43