

Philips Healthcare

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The FDA will, from time to time, issue statements of inquiry in order to gather more information on a specific subject. Philips welcomes this process, as isolated, anecdotal case reports are difficult to draw general conclusions from. On November 5, 2009, the FDA posted a communication concerning energy levels in external biphasic defibrillators and cited 14 adverse incidents. In the FDA communication, anyone who reported an adverse event was asked for at least **eight different variables** beyond defibrillator energy that might affect cardioversion and defibrillation outcomes. The FDA states “these variables include patient attributes, such as the size and shape of a person’s body, presenting rhythm, defibrillator attributes, such as energy level and waveform, and treatment conditions such as drug therapy and oxygenation.”

The FDA’s communication states that current AHA guidelines should be followed, as should the manufacturer’s instructions. Current scientific evidence as reflected in the American Heart Association Guidelines 2000 and 2005 specifically supports Philips SMART Biphasic technology. Aside from asking healthcare professionals to inform the FDA if they have experienced a similar situation, the FDA is not recommending taking any action or making any judgment.

To put this issue in perspective, the FDA statement identified 14 reported events occurring over a 3-year period, in which a 360J biphasic defibrillator was used successfully subsequent to a 200J biphasic defibrillator. Of note, these 14 reports represent a small fraction of the total number of instances of cardioversion / defibrillation attempts. This sample size is important to consider given the FDA’s statement that they are gathering information in order to determine if additional future action may be necessary.

Since a majority of the reports identified in the FDA communication are associated with cardioversion of atrial fibrillation, we believe a pertinent study would be Santomauro et al.¹ This paper found that the Philips SMART Biphasic waveform had an efficacy of 100% using a five shock protocol of 70J, 100J, 150J 200J, 200J. Neither the Zoll rectilinear nor the Zoll monophasic waveform achieved 100%. The conversion rates for this 5 shock series using a Laerdal device incorporating the Philips SMART Biphasic waveform were 15%, 55%, 80%, 95% and 100% respectively—the highest of any waveform included in the study.

¹ Santomauro M, Borrelli A, Ottaviano L, et al. [Ital Heart J Suppl.](#) 2004 Jan; 5(1 Suppl):36-43

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The FDA statement mentions a study by Stiell et al. which presented results on ventricular fibrillation treated with a Physio-Control defibrillator delivering a 150J, 150J, 150J protocol for which the Physio-Control waveform is not optimized, and another Physio-Control unit at their recommended escalating protocol of 200J, 300J, 360J, for which their device is optimized. **The design of this study was not consistent with AHA guidelines, which recommend comparing waveforms when used according to manufacturer instructions.** This study clearly does not take into consideration differences in waveforms and peak current delivered since the study compared Physio-Control to Physio-Control.² Essentially, we believe the statement references a study which does not provide an appropriate “apples to apples” comparison because it failed to include a device designed and optimized for low-energy defibrillation.

In 2004, a study by Tang, et al observed: *“With respect to patient outcome, these results suggest that peak current is a more appropriate measure of defibrillation dose than either energy or average current and that toxicity may be minimized by simultaneously reducing both of the latter... survival was maximized and myocardial dysfunction minimized using a waveform that simultaneously delivered higher peak current while minimizing energy and average current.”*³

The Philips waveform maximizes peak current for shock efficacy while minimizing energy to limit toxicity and dysfunction for an already compromised heart. The study by Tang, et al demonstrates that this is a beneficial combination. It means Philips can deliver its most potent therapy from the very first shock.

In 2005, a study by Niemann, et al concluded that among different defibrillators, shock energy is an inaccurate measure of true shock intensity. Both the Philips SMART Biphasic and Physio-Control biphasic waveforms were studied. At 150J, Philips SMART Biphasic delivered 30% greater peak current than the Physio-Control biphasic waveform. The Niemann investigators concluded that peak current provides a better measure of true shock intensity.⁴ Philips combines high peak current for potency, with low energy to avoid unnecessary myocardial dysfunction.

AHA Guidelines 2005 state: *“Because it is accepted that defibrillation is accomplished by the passage of sufficient current through the heart, the concept of current-based defibrillation is*

² Letter by Tang et al Regarding Article, “BIPHASIC Trial: A Randomized Comparison of Fixed Lower Versus Escalating Higher Energy Levels for Defibrillation in Out-of-Hospital Cardiac Arrest,” Circulation, 2007; 116e522.

³ Tang et al. The effects of biphasic waveform design on post-resuscitation myocardial function, Journal of the American College of Cardiology, Vol. 43, No. 7, 2004.

⁴ Niemann, et al. “Intracardiac voltage gradients during transthoracic defibrillation: Implications for post-shock myocardial injury,” Academic Emergency Medicine, Volume 12, Issue 2, February 2005.



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*appealing. Energy is a non-physiologic descriptor of defibrillation despite its entrenchment in traditional jargon. Transition to current-based description is timely and should be encouraged.*⁵

We are very proud of the efficacy of, and scientific peer-reviewed and published evidence supporting, Philips SMART Biphasic defibrillation technology. No other external defibrillation therapy is supported by more peer-reviewed clinical data. We believe very strongly in our technology and the mass of peer-reviewed evidence supporting it. Again, the FDA informed Philips that our defibrillators were not used in the incidents referenced in their 5 Nov 2009 note.

Philips has advanced the fields of resuscitation and emergency care with innovations including SMART Biphasic technology, CPR focused technologies, STEMI support, ease of use throughout our product portfolio, temperature modulation therapy from our newest acquisition, InnerCool Therapies, and much more.

⁵ Part 5: Electrical Therapies, Automated External Defibrillators, Defibrillation, Cardioversion, and Pacing, Circulation Guidelines, 2005, 2005; 112:IV-41.