

Center for Devices and Radiological Health
CDRH

Questions for the Panel

Question 1

Usability Testing and Product Labeling

In terms of how a lay user would interact with the device, Philips' usability testing focused on the ability of untrained users to set up the device, to place pads promptly, to deliver shocks safely, and to know when to choose adult or pediatric pads. Philips' usability testing did not cover other tasks, such as self-training, storage, and maintenance.

Question 1 cont 'd

Usability Testing and Product Labeling

- a) Please comment on the adequacy of the testing that was performed and the product labeling and training materials that are provided to support the notion that lay users would know *when* to use the product.
- b) If you do not believe that the testing and/or labeling are adequate in part (a) above, please comment on the type of testing or type of labeling changes that would be necessary to support the removal of the prescription label.

Question 2

Usability Testing and Product Labeling

Safe and effective use of the device may depend on the ability of the untrained lay person to determine in what situations the AED should be used.

- a) Please comment on the adequacy of the testing that was performed and the product labeling and training materials that are provided to support the notion that lay users would know *when* to use the product.

Question 2 cont 'd

Usability Testing and Product Labeling

- b) If you do not believe that the testing and/or labeling are adequate in part (a) above, please comment on the type of testing or type of labeling changes that would be necessary to support the removal of the prescription label.

Question 3

Usability Testing and Product Labeling

The timing of CPR relative to defibrillation is one concern for this type of device, as it impacts survival in certain cases (e.g., asystole or pulseless electrical activity). According to the current American Heart Association recommendations, CPR should precede defibrillation in the chain of survival. The Philips device addresses the need for CPR in two ways:

Question 3 cont 'd

Usability Testing and Product Labeling

by identifying the need for AED/CPR training in the labeling and by including device prompts during the defibrillation process that are based on the patient's underlying rhythm (e.g.: normal sinus rhythm, ventricular fibrillation, PEA, asystole)

Question 3 cont 'd

Usability Testing and Product Labeling

- a) Please comment on whether these recommendations regarding CPR are enough, or whether other measures are needed.
- b) Please comment on whether this concern is unique to an over-the-counter AED, or whether the same concern exists for the prescription version of the device.

Question 4

Usability Testing and Product Labeling

Over-the-counter (non-prescription) products such as cold medicines typically assist the lay person in determining whether they need to buy the product by presenting in the outer packaging information describing the intended use of the product. Please comment on the adequacy of the external carton labeling in conveying important information to the lay user that would allow them to know whether this product is right for them.

Question 5

Usability Testing and Product Labeling

Philips is seeking over-the-counter status for this AED to be used with both adult and pediatric pads. Both the adult and pediatric pads are already FDA cleared with prescription status. In support of the usability of the device with pediatric pads, the sponsor has provided the results of simulated use testing of pediatric electrode patches with the AED performed on 10 subjects.

Question 5 cont 'd

Usability Testing and Product Labeling

The purpose of the test was to determine whether users could recognize the need to change from adult pads to pediatric pads. Please comment on whether this testing is sufficient to remove the prescription-only label on the pediatric pads.

Question 6

Usability Testing and Product Labeling

According to the AHA, the first link in the chain of survival is to activate the EMS system (e.g., calling 9-1-1). The sponsor has addressed this concern by placing a prominent sticker (“Call 9-1-1 / Call EMS”) on the AED case. Please comment on the adequacy of this approach

Question 7

Tracking Users in the Event of a Recall

Automatic external defibrillators are currently “tracked” devices, by FDA regulations. “Tracking” requires the sponsor to have processes in place to promptly identify users in the event of a recall. At this time, removing the prescription labeling will not alter the tracking requirement for these devices.

Question 7 cont 'd

Tracking Users in the Event of a Recall

[In Philips response to this question (Section 4: FDA Review Memos of the panel pack, Question 6), they state that they have submitted a petition requesting a waiver of the tracking requirements for its AEDs.

Please note that the panel is not being asked to comment on the merits of such a petition.]

Please comment on the adequacy of Philips' description of the methods they have in place to identify users in the event of a recall.

Question 8

Post-Market Device Reporting to FDA

FDA develops an understanding of how devices are performing in the post-market period by the reports that come into FDA through the Medical Device Reporting (MDR) system. The sponsor has described the measures they have taken to encourage use of FDA's MDR system in Section 4, FDA Review Memos of the panel pack, Question 12. Please comment on the adequacy of their response.

Question 9

Post-Market Study

The sponsor has proposed to conduct a post-market evaluation of this device [Section 5-7]. The primary objective is to assess the safety and effectiveness after use of the device. Please comment on the adequacy of this proposal to collect information about the device used in the post-market period.