November 2009
AED Product Field Update
Supplementary FAQs

Why did the FDA send out their own alert and state "the company's communication does not sufficiently describe the existing defect in the affected devices" and "the FDA is also concerned that the company's proposed actions do not adequately address the problem, and believes that additional precautions are warranted."

The FDA has their own processes they need to follow when they perceive there is a public health issue. We have been in constant dialogue with them on this issue, and we believe what we have advised customers to do **– leave their AEDs in service, follow the scheduled maintenance guidelines and call us immediately if they see their unit is not rescue ready** – is completely appropriate given any risk a customer would face when using their Cardiac Science AED.

In the FDA alert, they stated that the "FDA is gathering more data about this situation to better understand its potential public health impact." **We are in the process of providing them additional data that we believe supports exactly the recommendations we're making.**

(Tell customers the facts):

- The risk of the issue occurring during a rescue is less than 0.0013% - **less than 1 in 75,000 units will ever experience the issue**. We have very strong data to support this.
- With more than 300,000 units in the field, **the issue occurred in TWO rescue situations in a period spanning more than six years.**
- In all other cases where the product issue came up, it was identified in the AED's daily self-testing.

The FDA suggested we contact the company for repairs or replacements – what do I do to get my unit repaired or replaced?

There is no reason to have your unit replaced. The probability of the issue occurring is extremely rare (go back to the facts). In their release, the FDA stated **"the consequences of not attempting to defibrillate a patient outweigh the risk that these devices may fail"** – our extensive data shows the devices are highly reliable and that the risk is remote.

We will be providing all of our customers that have one of the affected AEDs with a software update that will further enhance the self-testing of the AED. This will be available by May, 2010. You will be notified as soon as this update is available for your unit.

In your press release and customer letter, you tell me to check my AED daily to make sure the status indicator is "green," and that will tell me if my AED is "rescue ready."

The FDA said "visual inspection of a green light may not reveal defective or non-working components inside the AED." If it doesn't do any good, why are you telling me to do it?

There were 64 complaints associated with the issue the FDA is describing. Of those 64 complaints, 62 of them were identified through the AED's self-testing, and resulted in the AED clearly indicating that there was an issue with the device. **This is why we suggest conducting the visual inspection as outlined in the Scheduled Maintenance section of the Operator and Service manual – in the vast majority of cases, the issue is identified by self-testing.**

Since the component issue was solved in August, why will it take so long to address the devices in use by customers (9 months)?

We are in the process of developing the software update now. Since we have shipped approximately 300,000 affected devices in hundreds of configurations and variants we must create versions of the software to address each of these. In addition, we must perform extensive testing to ensure that the software will work as intended on every device. As you can imagine, this is an extensive and time consuming process.

What did you do in August, 2009 to render units produced since then "not affected"?

In August, 2009 we began screening and testing components more strenuously during production to identify components that might exhibit the issue. **To put it into perspective, the screening process instituted in August reduces the likelihood that the issue would occur in a device during its lifetime to less than one in 345,000 devices.**

Once the FDA has reviewed all of the data, will they issue a softer public statement regarding the issue?

We do not know if the FDA will update their alert. The FDA is not under any obligation to retract or modify any statements they have made. However, once they have an opportunity to review all of the applicable data we hope that they will agree that the action we are taking is appropriate and communicate this to the public in some fashion.