



Quality Assurance & Regulatory Affairs
8500 SW Creekside Place
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Blown Fuse

4,568 units manufactured between May 18, 2004 and December 30, 2004 have experienced 23 blown F1 fuses. The blown fuse would render the AED 10 inoperable and cause a visual status indicator warning of the inoperable condition. This issue may be identified during the unit's weekly self-test by a "do not use" red circle with a red line through it in the system status indicator of the AED 10; an example is shown on the back of the device. The blown fuse also could occur unexpectedly during use, which would prevent delivery of therapy. There are no known injuries or deaths associated with this issue. Recalled units will receive an improved fuse.