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**Medical Device  
 Recalls  
 Class 1 Recall  
 Welch Allyn AED10**



<b>Date Recall Initiated</b>	October 26, 2007
<b>Date Posted</b>	November 06, 2007
<b>Recall Number</b>	Z-0129-2008
<b>Product</b>	Welch Allyn AED 10, Automated External Defibrillator, a portable 12V internal battery powered defibrillator; Model AED10; Part Numbers: 970302E,970308E,970309E, 970310E and 970311E;
<b>Code Information</b>	Serial numbers of units affected: NA036960, NA036970, NA037000, NA037004, NA037005, NA037009, NA037010, NA037012, NA037014, NA037015, NA037020, NA037022, NA037025, NA037027, NA037029, NA037030, NA037030, NA037031, NA037032, NA037034, NA037035, NA037036, NA037044, NA037045, NA037046, NA037048, NA037050, NA037051, NA037052, NA037053, NA037056, NA037057, NA037058, NA037088, NA037090, NA037091, NA037092, NA037093, NA037094, NA037095, NA037097, NA037098,

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**Recalling Firm/  
Manufacturer**

Welch Allyn Protocol, Inc  
8500 Sw Creekside Pl  
Beaverton , Oregon 97008

**For Addition  
Information Contact**

Robert W. Berry  
503-526-8500

**Reason For  
Recall**

Failure to Deliver Shock; a defective capacitor may cause the delay or non-delivery of the defibrillating shock which may result in failure to resuscitate the patient

**Action**

The firm issued a press release on 10/30/07, and has set up a call center for customers, and plans to send three (3) certified mailings to notify affected customers, alert them of the issue, and provide instructions on how to return their device. The first letter dated 10/26/07 was sent via certified mail to customers on 10/26/07. The letter informs customers of the firm recalling the product to correct faulty capacitors on the circuit board, and which could result in a malfunction that prevents or delays delivery of a defibrillating shock. The letter indicates the faulty AED10 devices were manufactured between 3/29/07 and 8/9/07. The letter also indicates the serial numbers affected, and where the serial number is located - upper left hand corner of the back panel of the device. In addition the letter includes a response form, the firm's contact information, and indicates that the firm will exchange the recalled defibrillator with a replacement and new

five (5) year warranty.

**Quantity in Commerce** 1,795 distributed - 1176 in US and 619 internationally

**Distribution** Worldwide.

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