



Quality Assurance & Regulatory Affairs
8500 SW Creekside Place
Beaverton, OR 97008

Electromagnetic Noise Interference

All Welch Allyn AED 10 devices comply with applicable standards as to sensitivity and specificity for detecting shockable arrhythmias in the presence of a 10 amp per meter electromagnetic field. There has been one known incident in which a shock was delivered to a patient with a non-shockable rhythm possibly in the presence an electromagnetic field exceeding 10 amps per meter. In addition, there have been 7 known incidents where the device has failed to recognize a shockable rhythm during routine bench tests using an ungrounded simulator.

10,735 units manufactured between October 3, 2002 and December 30, 2004 will receive a revised version of software with improved electromagnetic noise filtering.