



U.S. Department of Health and Human Services

Food and Drug Administration

## RECALLS AND FIELD CORRECTIONS: DEVICES -- CLASS II

### AccessAED, AccessALS, ACCESS CARDIOSYSTEMS

Source: FDA Enforcement Report November 13, 2002

<http://www.fda.gov/bbs/topics/enforce/2002/ENF00769.html>

#### PRODUCT

Portable Automated External Defibrillators [AED]

Model No. 9100-0100:

a) AccessAED

b) AccessALS

Recall # Z-0248-3.

#### CODE

Model Number: 9100-0100

S/N's: 5212, 5886, 5887, 5888, 5889, 5943, 5944, 5945, 5946, 5421, 5422, 5426, 5428, 5431, 5441, 5469, 5470, 5617, 5619, 5633, 5636, 5638, 5639, 5401, 5411, 5414, 5424, 5502, 5508, 5658, 5671, 5673, 5674, 5675, 5677, 5691, 5693, 5710, 5713, 5715, 5719, 5721, 5755, 5773, 5774, 5780, 5782, 5786, 5802, 5811, 5814, 5819, 5820, 5823, 5847, 5853, 5854, 5855, 5856, 5857, 5858, 5860, 5861, 5863, 5864, 5867, 5868, 5869, 5870, 5871, 5875, 5879, 5911, 5915, 5917, 5918, 5919, 5922, 5923, 5924, 5927, 5522, 5526, 5530, 5531, 5471, 5471, 5635, 5635, 5641, 5641, 5644, 5644, 5645, 5645, 5646, 5646, 5609, 5620, 5631, 5632, 5634, 5643, 5650, 5656, 5665, 5676, 5678, 5680, 5682, 5684, 5685, 5686, 5687, 5688, 5689, 5692, 5694, 5695, 5696, 5697, 5699, 5701, 5702, 5703, 5704, 5206, 5397, 5436, 5605, 5914, 5928, 5939, 5954, 5955, 5957, 5959, 5960, 5648, 5651, 5653, 5466, 5468, 5458, 5459, 5463, 5281, 5323, 5797, 5798, 5799, 5800, 5803, 5805, 5809, 5812, 5827, 5828, 5829, 5831, 5832, 5833, 5834, 5835, 5837, 5838, 5839, 5840, 5842, 5845, 5850, 5851, 5852, 5474, 5479, 5245, 5284, 5662, 5698, 5722, 5723, 5726, 5728, 5729, 5730, 5731, 5732, 5733, 5735, 5736, 5738, 5739, 5740, 5741, 5742, 5743, 5744, 5745, 5746, 5747, 5748, 5756, 5757, 5758, 5759, 5762, 5763, 5764, 5765, 5769, 5804, 5822, 5830, 5883, 5885, 5894, 5909, 5920, 5930, 5938, 5961, 5982, 5983, 5984, 5985, 5265, 5277.

#### RECALLING FIRM/MANUFACTURER

Recalling Firm: Access Cardiosystems, Concord , MA, by e-mail on October 14, 2002.

Manufacturer: Access Cardiosystems Inc., concord, MA

Firm initiated recall is ongoing.

#### REASON

Portable External Defibrillator May Fail Self Test and Fail to Function.

#### VOLUME OF PRODUCT IN COMMERCE

227.

#### DISTRIBUTION

AZ, NY, MD, NV, OR, TX, WA, WI and Internationally.