



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

August XX, 2007

URGENT: MEDICAL DEVICE RECALL

WELCH ALLYN AED20

(Part Numbers: 972200E, 972211E, 972212E, 972213E, 972214E, 972215E and 972216E)

Dear Valued AED20 Customer:

We are writing to inform you that your Welch Allyn AED20 defibrillator is being recalled to correct a condition that could result in a malfunction that prevents or unacceptably delays the delivery of a defibrillating shock, which may result in failure to resuscitate the patient. These devices were manufactured between October 2003 and January 2005 at the former MRL, Inc. facility in Buffalo Grove, IL. Welch Allyn acquired MRL, Inc. in April 2003 and has since moved manufacturing of these devices to the facility of Welch Allyn Protocol, Inc. in Beaverton, OR.

We have received 21 complaints about devices in this group of AED20s, corresponding to 1.2 percent of the 1,696 recalled devices, which we deem an unacceptable risk. We are taking corrective and preventative action to update this group of devices. No Welch Allyn devices other than those manufactured at the MRL facility between the above dates are subject to this recall.

This condition is caused by an intermittent connection between a pin and socket on a circuit board inside the device. The problem develops over time and is unpredictable. The AED20 has a self-monitoring feature that detects this problem and displays a "Defib Comm" error message. The problem is often identified while the AED20 is being tested before use but has also occurred while practitioners are attempting to use the device on a patient.

This recall is being conducted with the full knowledge of the U.S. Food and Drug Administration (FDA).

The affected AED20s are those with the serial numbers identified in Appendix 1 of this notice. You will find the serial number located on the lower right hand corner of the back panel of your AED20 unit, along with the model and part numbers, as illustrated in Appendix 2, Picture 2. Our records indicate that you purchased an AED20 affected by this potential problem, and you should verify this by matching the serial number of your unit with one identified in Appendix 4.

With the possibility of a failure, Welch Allyn is taking this precautionary measure to service your AED20 to address this issue, and we will provide you with a free loaner device during servicing to minimize any inconveniences this may cause.

It is important to note that your AED20 should be checked before each shift by using the self-test, which is automatically initiated by powering up the device. If a "Defib Comm" error message is displayed, or has been previously displayed, the device should be removed from service, if possible, and you should contact us to obtain priority servicing of your device and



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a loaner. If the "Defib Comm" error occurs during use, cycling the power off-on may clear the error. Even if power cycling clears the device, you should contact us to obtain priority servicing of your AED20.

Please respond to this notification within (5) working days by faxing or mailing the response form found in Appendix 3 to Welch Allyn at the identified address or fax number.

You will be contacted by a Welch Allyn representative shortly after we receive your response form, to schedule your AED20 for service and to arrange to send you a loaner AED20 for use while your device is being serviced. Included with the loaner will be instructions on how to return your AED 20 to Welch Allyn.

We greatly appreciate your cooperation and understanding in this matter.

Respectfully,


European Regulatory Manager
Welch Allyn



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APPENDIX 1

CORRECTION REQUIRED

(Part Numbers: 972200E, 972211E, 972212E, 972213E, 972214E, 972215E and 972216E)

SERIAL NUMBERS

206812	206026	206307	206344	206478	206684	206791	206850	206934	207058
206273	206115	206308	206345	206482	206686	206792	206851	206935	207059
205833	206134	206309	206346	206483	206687	206793	206852	206936	207060
205788	206159	206310	206347	206554	206688	206794	206853	206937	207061
205914	206178	206311	206348	206576	206689	206795	206854	206938	207067
206027	206252	206313	206375	206577	206731	206796	206867	206939	207101
206685	206264	206328	206379	206578	206732	206797	206868	206940	207139
205845	206271	206329	206395	206579	206733	206798	206869	206941	207140
205846	206272	206330	206396	206580	206751	206804	206870	206975	207159
205848	206274	206331	206398	206581	206762	206805	206887	207015	207160
205849	206275	206332	206399	206582	206763	206806	206888	207029	207161
205853	206276	206333	206400	206583	206764	206807	206889	207030	207213
206896	206277	206334	206413	206587	206765	206808	206892	207031	207214
207320	206278	206335	206429	206588	206782	206809	206901	207040	207215
207321	206279	206336	206430	206589	206783	206810	206926	207041	207216
207023	206280	206337	206432	206595	206784	206811	206927	207042	207217
207317	206281	206338	206433	206637	206785	206813	206928	207052	207218
205787	206302	206339	206443	206638	206786	206814	206929	207053	207219
205826	206303	206340	206447	206680	206787	206815	206930	207054	207220
205827	206304	206341	206448	206681	206788	206816	206931	207055	207221
205828	206305	206342	206449	206682	206789	206817	206932	207056	207222
205831	206306	206343	206477	206683	206790	206818	206933	207057	207223



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APPENDIX 1 Cont.

CORRECTION REQUIRED

(Part Numbers: 972200E, 972211E, 972212E, 972213E, 972214E, 972215E and 972216E)

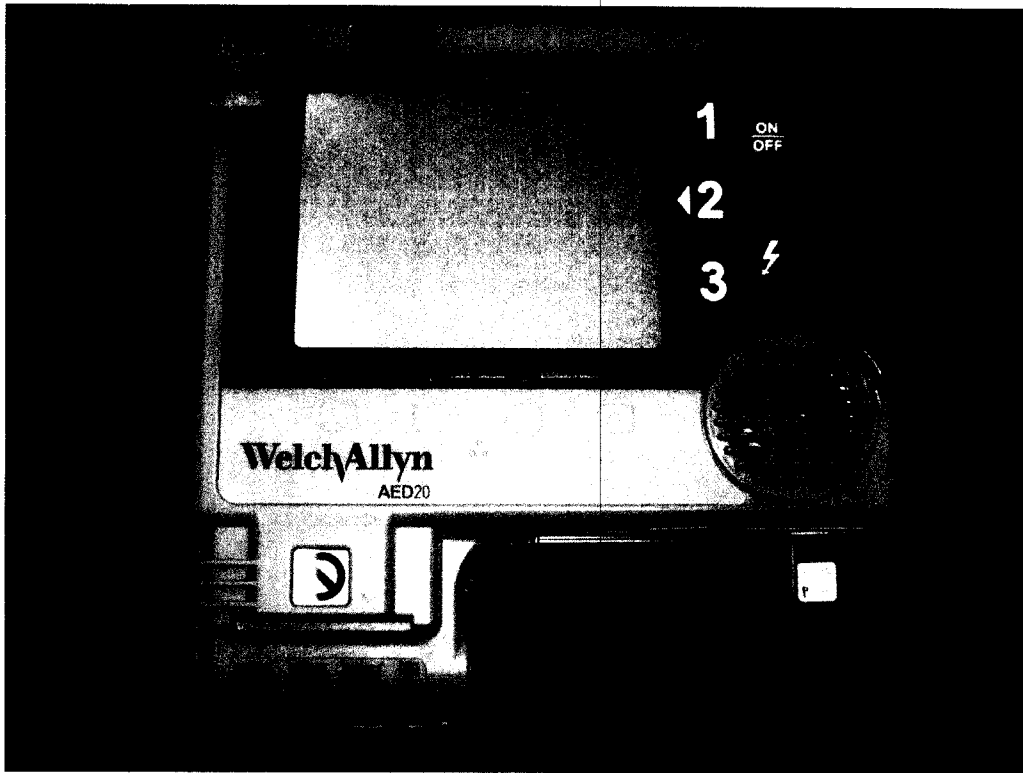
SERIAL NUMBERS

207224	207331	207411	205877	207044	206441	206009	206102	206186	206219
207225	207332	207414	205994	207045	206442	206011	206103	206187	206220
207226	207340	207415	206022	207046	205789	206082	206104	206188	206221
207228	207341	207416	206023	207047	206925	206083	206105	206189	206222
207229	207342	207422	206114	207048	207373	206084	206106	206190	206223
207230	207343	207423	206327	207049	205879	206085	206107	206191	206224
207231	207349	207426	207249	207050	205880	206086	206108	206192	206225
207246	207360	207427	206202	207051	205881	206087	206109	206193	206226
207247	207361	207428	206895	207314	205882	206088	206110	206194	206227
207248	207362	207429	206799	206571	205883	206089	206111	206195	206228
207274	207364	207430	206800	206567	205884	206090	206112	206196	206229
207277	207365	207431	206855	207016	205885	206091	206113	206197	206230
207283	207374	207432	206013	207252	205886	206092	206125	206198	206231
207285	207393	207433	206014	207253	205887	206093	206126	206199	206232
207286	207396	207434	206016	207261	205888	206094	206127	206200	206233
207287	207397	207435	206562	207262	206002	206095	206128	206201	206234
207288	207398	207450	206563	206382	206003	206096	206129	206213	206235
207289	207399	207470	206564	205957	206004	206097	206130	206214	206236
207290	207400	205823	206833	205958	206005	206098	206182	206215	206237
207291	207401	205825	205923	206312	206006	206099	206183	206216	206238
207306	207403	205874	206834	206349	206007	206100	206184	206217	206239
207323	207404	205875	207043	206431	206008	206101	206185	206218	206240
206241	206242	206243	206244	206245	206010				

APPENDIX 2

SAMPLE WELCH ALLYN AED 20

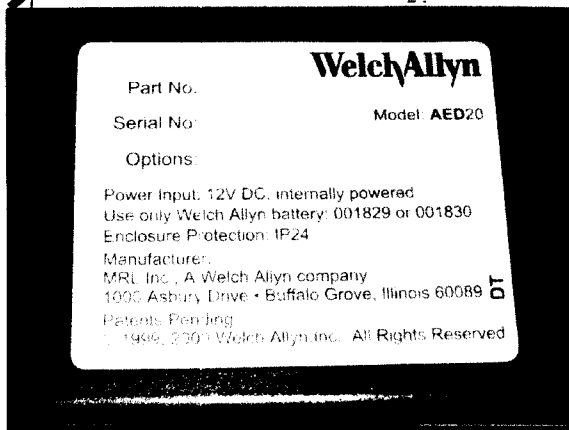
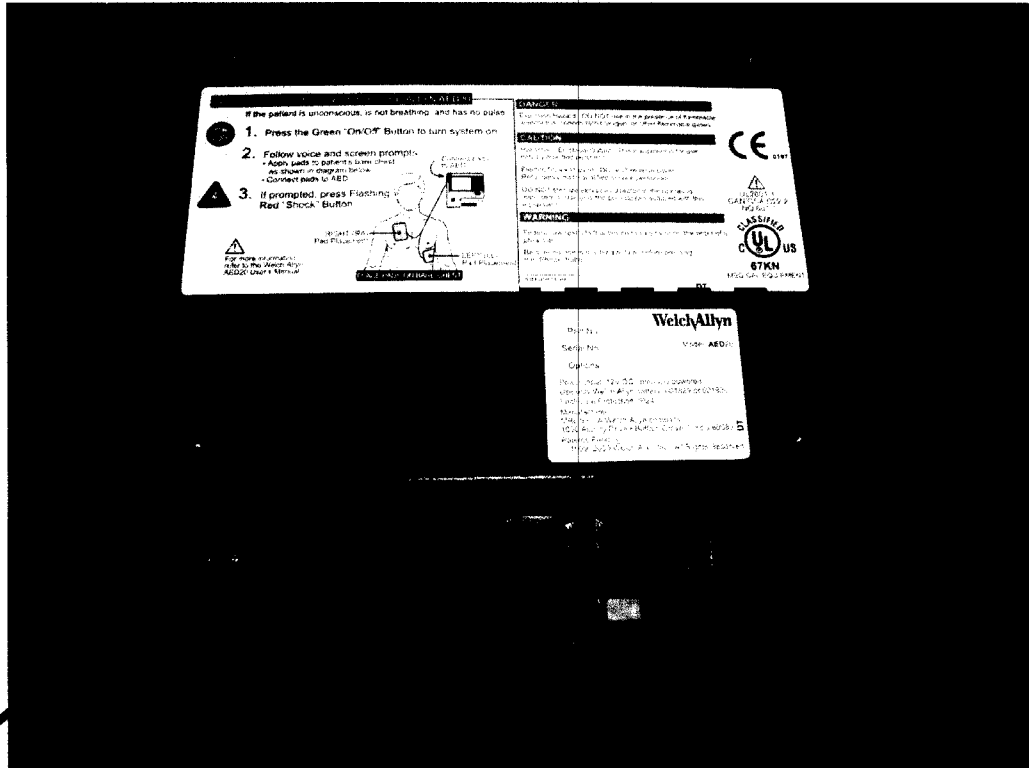
(Part Numbers: 972200E, 972211E, 972212E, 972213E, 972214E, 972215E and 972216E)



Picture 1. AED 20 Front Panel

APPENDIX 2 Cont.

SERIAL NUMBER LABEL



Picture 2 AED 20 Back Panel

The Welch Allyn serial number, along with the model and part number, is located on the lower right hand corner of the back panel of the AED 20.



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**APPENDIX 3
 RESPONSE FORM
 WELCH ALLYN AED 20**
 (Part Numbers: 972200E, 972211E, 972212E, 972213E, 972214E, 972215E and
 972216E)

Please check ALL appropriate boxes.

- We have read and understand the instructions provided in the recall letter.
- We have and will return the following AED 20 defibrillator(s) with serial number(s) listed in Appendix 1: (please list serial numbers you have below)

- We no longer have AED 20 defibrillators with serial numbers subject to the recall (Please describe what happened to the unit(s), i.e. retired/thrown out, provided to another party)

To be completed by Customer:

Name (please print):	
Signature/Date	
Title:	
Telephone No.	
Email Address:	
Firm Name:	
Address:	
City/State:	

PLEASE FAX OR MAIL COMPLETED RESPONSE FORM WITHIN (5) WORKING DAYS TO:

**Welch Allyn Ltd
 IDA Business Park
 Dublin Road
 Navan
 County Meath
 Republic of Ireland
 Fax. 00 353 46 90 67755.**



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APPENDIX 4.

Our records indicate the following Serial Numbers have been supplied to you.

[list of serial numbers, country/customer specific]