IRISH MEDICINES BOARD

Notice Information: Medical Devices - Recall 15 November 2004

Part 1. Product Information

a)	Title:	AccessAED PAD, AccessAED and AccessALS Automated External Defibrillator Devices
b)	Product Name/Type:	AccessAED PAD, AccessAED and AccessALS Automated External Defibrillator Devices
c)	Reference:	SN2004(10)
d)	Manufacturer/Supplier:	Access CardioSystems Inc.

Part 2. Target Audience

a)	Target Audience:	Risk Managers; Medical Dental & Nursing Staff; Operating Theatres; Accident & Emergency; Intensive Care Units; Coronary Care Units; Medical Physics / EBME; Ambulance Staff & Paramedics; Resuscitation Officers; General Practitioners; Practice Nurses; Dental Practitioners

Part 3. Problem/Issue

a)	Problem/Issue:	Recall of specified serial numbers of AccessAED PAD (model numbers 9100-0010-0 and 9100-0015-0), AccessAED (model numbers 9100-0100-0, 9100-0100-1, 9100-0150-0, and 9100-0150-1), and AccessALS (model numbers 9100-0100-2 and 9100-0150-2) automated external defibrillator devices and discontinued support by the manufacturer of all other devices that are in use.

Part 4. Background Information

a) Background Information:

AccessAED PAD, AccessAED, and AccessALS automated external defibrillators may be in use in the hospital setting, GP practices, dental practices or the public domain. The company has become aware of two potential issues involving specified serial numbers of automated external defibrillators (AED): Potential failure of the shock delivery circuit. This affects serial numbers 075690 – 077140 Potential of the AED to turn on unexpectedly. This affects serial numbers 075180 – 084760 The company has initiated a recall of all the above affected devices. Access CardioSystems has ceased trading since 03 November 2004 and has discontinued manufacturing and marketing of all models of AEDs. They will no longer be in a position to support their AEDs that are currently in use on the market place. It should be noted that for all other Access CardioSystems AEDs not affected by the recall, orders for disposable parts used with the AEDs will no longer be accepted by Access CardioSystems. The company advises customers that when the supply of disposable parts is depleted AEDs should be removed from service.

Part 5. Action to be taken

a) Action to be taken:

Ensure that relevant all staff are advised of this Safety Notice. Ensure that all specified serial numbers listed below are immediately removed from use: AccessAED PAD, AccessAED, AccessALS, serial numbers 075180 – 084760 Replace all other AEDs, not specified in the scope of the recall, as soon as possible

Part 6. Enquiries

a) All enquiries should be made to:

All adverse incidents relating to a medical device should be reported to the: Medical Devices Department Irish Medicines Board Earlsfort Centre Earlsfort Terrace Dublin 2 If you have any enquiries, you may contact the Medical Devices Department at:
Telephone: +353-1-6764971 Fax: +353-1-6344033 Email: medicaldevices@imb.ie Website: www.imb.ie Manufacturers website for updated information: www.accesscardiosystems.com
Enquiries to the manufacturer should be addressed in the first instance to: Mr. John Webster Managing Director MDCI Limited (European Authorised Representative for Access CardioSystems)
Telephone: +44-1293-429608 Fax: +44-1293-519121
Email: JLWebster@mdci-eu.co.uk Enquiries to the distributors should be addressed to: Anaesthetic Services Limited 85b Moss Road Ballygowan Newtownards Co. Down BT23 6LF
Telephone: +44-2897-542995 Genesys Medical Solutions Limited 3 Wellington Park Malone Road Belfast
Telephone: +44-2890-923315 Fax: +44-2890-923334
Hibernia Medical Supplies St. Pauls North King St Dublin 7
Telephone: +353-1-6174862 Fax: +353-1-6771558
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Part 7. Keywords

a)	Keywords:	AccessAED PAD, AccessAED and AccessALS Automated External Defibrillator Devices