IRISH MEDICINES BOARD

MEDICAL DEVICE

SAFETY NOTICE

AccessAED PAD, AccessAED and AccessALS Automated External Defibrillator Devices

IMB Safety Notice: SN2004(10)

S A F E T Y

NOTICE

MANUFACTURER/SUPPLIER

Access CardioSystems Inc.

TARGET GROUPS

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

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.

BACKGROUND

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.

ACTION OR RECOMMENDATIONS

- 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

ENQUIRIES

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

SAFETY NOTICE

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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