



**A
D
V
I
S
O
R
Y
NOTICE**

Automatic External Defibrillator (AED) / Public Access Defibrillator (PAD)

IMB Advisory Notice: SN2009(11)
Circulation Date: 28th October 2009

MANUFACTURER/SUPPLIER

Various

TARGET GROUPS

General Practitioners
General Public
Community First Responder schemes
Risk Managers
Hospitals
Nursing Homes
Schools
Sports clubs

ISSUE

The purpose of this notice is to highlight the importance of correct storage of Automatic External Defibrillator (AED) medical devices. In particular, the Irish Medicines Board (IMB) would like to remind users to follow the manufacturer's recommendations in the instructions for use (IFU) regarding appropriate storage locations.

BACKGROUND

The IMB has received several reports advising of incidents where the storage and/or use of an AED at low temperatures is suspected to have adversely affected the performance of the device. The effects of exposure to extreme temperatures can include unexpected battery depletion, adverse effects on the gel of the defibrillator pads and consequently a failure to function as intended.

ACTIONS OR RECOMMENDATIONS

The IMB recommend:

1. When considering the purchase, maintenance, storage and use of such devices, individuals should study in detail the documentation provided with the device to confirm that the device is stored and used in recommended conditions. The 'instructions for use' should also provide information on what action is required if the device is to be used following exposure to very low or high temperatures.

S A F E T Y

NOTICE

2. Devices already in service should be checked to confirm that the storage is appropriate in accordance with the manufacturer's recommendations.
3. If you discover that devices have not been stored at the optimum conditions, contact the manufacturer of the device and arrange for it to be checked to ensure it continues to operate as intended.

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Human Products Safety Monitoring Department
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie