

# Medical Safety Information

Pharmaceuticals and Medical Devices Agency

 No.10 May, 2009

## Good Management & Maintenance of Automated External Defibrillators (AEDs)

### **POINT** Key points for safe use

#### Points for Management & Maintenance on AED Installation

- ① Assign AED Inspection Coordinators.
- ② Regularly Check the AEDs.
- ③ Check and Replace Consumables appropriately.

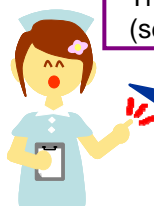
### 1 Daily Inspection

- Check the lamp color or display indicator on the AED main unit **every day to confirm the AEDs are ready for use.**
- If the indicator display or lamp shows **any abnormalities, contact the manufacturer or take appropriate measures immediately.**

#### Indicator Check



The color of the indicator lamp or display differs depending on product model (see page 3).



Assign AED inspection coordinators and check and record the AED indicator display daily.

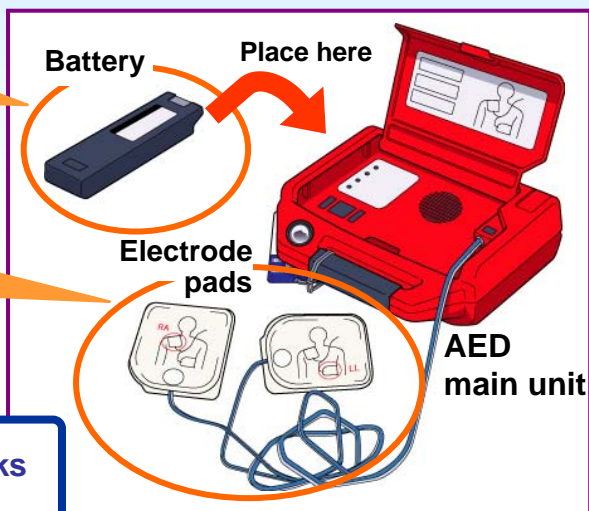
## 2 Check and Replacement of Consumables

- Replace consumable items (batteries and electrode pads) appropriately.

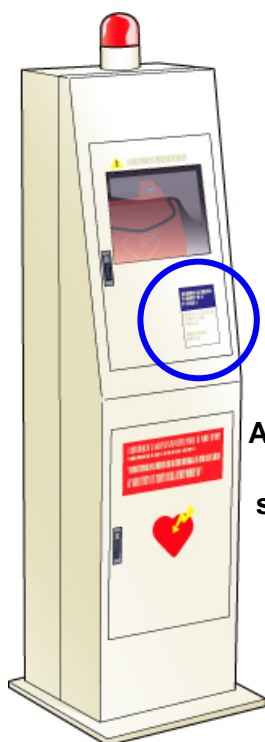
The battery needs replacing even when the AED remains unused.

Old electrode pads may be unable to deliver adequate electrical shocks.

Attach labels and make regular checks of the consumables.



### Where to attach labels



Attach a label to the AED storage box.

### <Example label>

AEDは救命処置のための医療機器です。AEDを設置したら、いつでも使用できるように、AEDのインジケータや消耗品の有効期限などを日頃から点検することが重要です。

成人用 電極パッド使用期限	2010年	5月
小児用 電極パッド使用期限	2010年	12月
バッテリー装着日	2008年	4月23日

バッテリーの待機寿命は3年です。  
 ※ただし、設置環境や使用状況によっては短くなります。

(provided by Nihon Kohden Corp.)



Attach a label to the AED main unit.

\*AEDs are emergency medical care devices. Once AEDs are installed, AED indicator displays and expiration dates of consumables should be checked regularly.

\*Replacement date of electrode pads for adult use  
 May, 2010

\*Replacement date of electrode pads for child use  
 December, 2010

\*Battery replacement date  
 April 23, 2008

\*The life expectancy of a battery is three years for a standby state.

\* Battery life span may be shorter depending on environment and AED usage.

\*This part is indicated in Japanese.



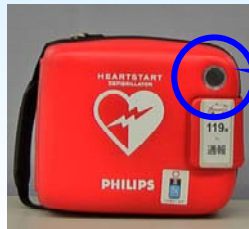
Attach labels in a prominent place for easy viewing of the consumable exchange date (Labels are provided by the AED manufacturer).  
 When consumables are replaced, make sure to renew the label.

## Indicator Displays

### Philips Electronics Japan, Ltd.



HEARTSTART HS1



HEARTSTART FRx



HEARTSTART FR2+



In order	Out of order
[ The green light is flashing ]	[ The green light is off ]

In order	Out of order
[ The black hourglass mark is flashing ]	[ The red cross mark is on or flashing ]

Where to call: TEL 0120-802-337, AED Call Center, Philips Electronics Japan  
<http://www.philips.co.jp/>

Needs service  
 \*This part is indicated in Japanese.

### Medtronic Japan Co., Ltd.



LIFEPAK 500/500B

In order	Out of order
[ An OK mark is displayed ]	[ Other marks and messages are displayed ]

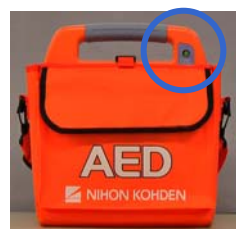


LIFEPAK CR plus

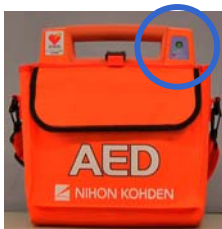
In order	Out of order
[ An OK mark is displayed ]	[ Other marks are displayed ]

Where to call: TEL 0120-715-545, LIFEPAK Consumer Center, Medtronic Japan Co., Ltd.  
<http://www.medtronic-lifepak.com/>

### Nihon Kohden Corporation



cardiolife  
AED-9100/9110/9200



cardiolife  
AED-9231



cardiolife  
AED-1200

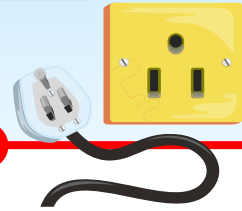
In order	Out of order
[ Green is displayed ]	[ Red is displayed ]

Where to call: TEL 0120-233-821, AED Maintenance call center, Nihon Kohden Corporation  
<http://www.nihonkohden.co.jp/aed/>

MBS Co., Ltd. (Distributor: Daewoo International Japan Corp.)



Paramedic CU-ER1

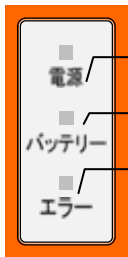


Attention!

This product is usable **only when charged regularly.**



In order



[ All lamps are off ]

Out of order



[ The red error lamp is on ]

\*This part is indicated in Japanese.

Where to call: TEL 0120-915-256 or 03-3224-7143, Daewoo International Japan Corp.  
<http://japan.daewoo.com/index.jsp>



**AEDs are emergency medical care devices. Once AEDs are installed, AED indicators and expiration dates of consumables should be checked regularly for keeping them available.**

Ministry of Health, Labour and Welfare (MHLW) issued notifications related to PMDA Medical Safety Information No. 10:

- "Implementation of appropriate management/maintenance of automated external defibrillators (AEDs) (Alert and request to bring this information to the attention of relevant organizations)" (Reference) "Q&A about implementation of appropriate management/maintenance of AEDs" (HPB Notification NO. 0416001 and PFSB Notification No. 0416001 by joint issue on April 16, 2009)
- "Implementation of appropriate management/maintenance of automated external defibrillators (AEDs)" (PFSB/SD Notification No. 0416001 issued on April 16, 2009)

Information on this notification is available

at the Pharmaceuticals and Medical Devices Information website (in Japanese)

<http://www.info.pmda.go.jp/mdevices/file/md2009-0416001.pdf>

<http://www.info.pmda.go.jp/mdevices/file/md2009-0416002.pdf>

#### About this information

- \* PMDA Medical Safety Information is issued by the Pharmaceuticals and Medical Devices Agency for the purpose of providing healthcare providers with clearer information from the perspective of promoting the safe use of pharmaceuticals and medical devices. The information presented here has been compiled, with the assistance of expert advice, from cases collected as Medical Accident Information Reports by the Japan Council for Quality Health Care, and collected as Adverse Drug Reaction and Malfunction Reports in accordance with the Pharmaceutical Affairs Law.
- \* We have endeavored to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy into the future.
- \* This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals.