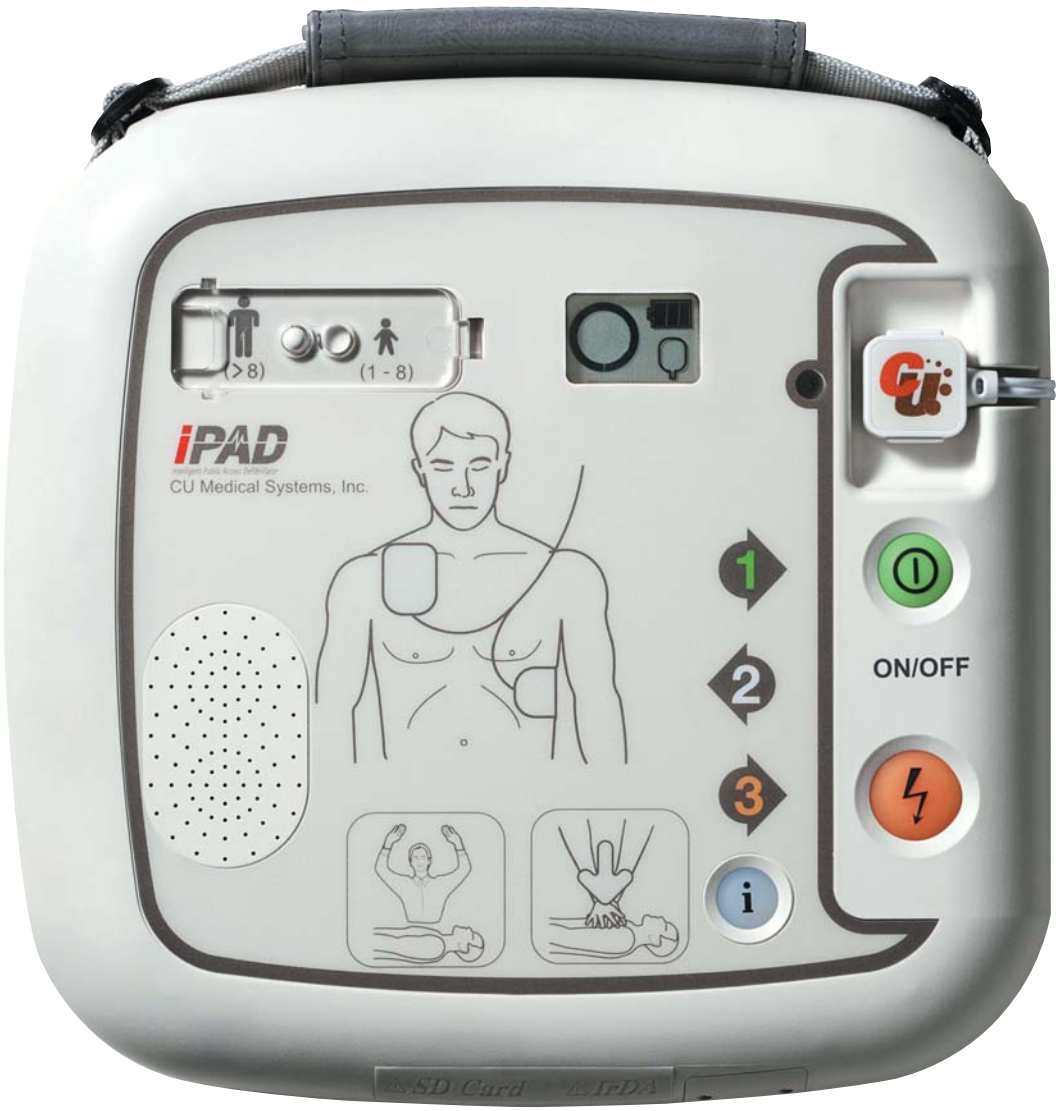
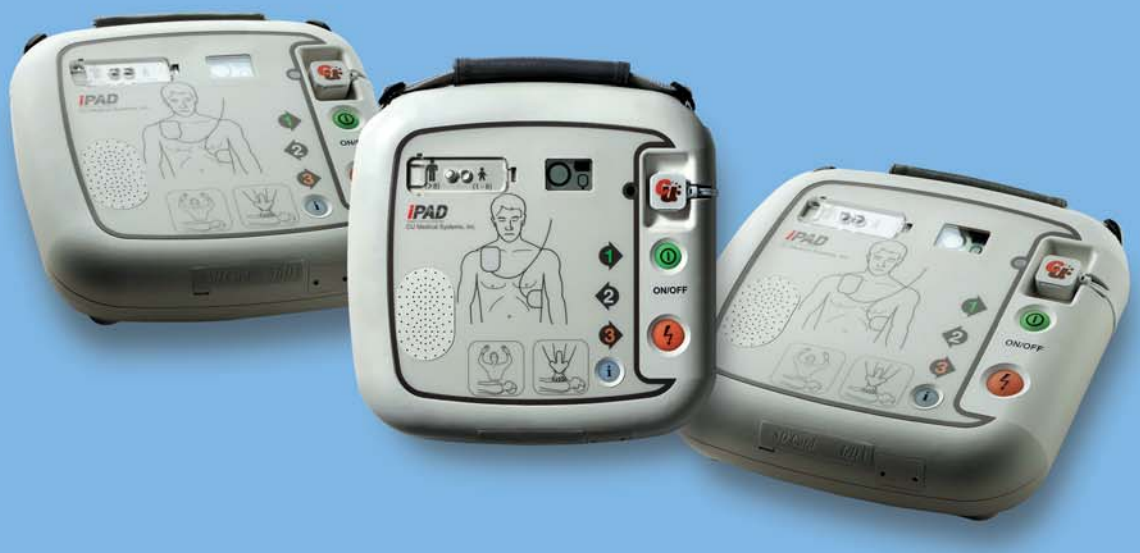
INTELLIGENT PUBLIC ACCESS DEFIBRILLATOR

# iPAD CU-SP1



# Advanced Performance iPAD CU-SP1




# AUTO VOLUME ADJUST

Public places can often be noisy. Crowded stations, airports with constant announcements and streets filled with cars and people often make it difficult to hear what's going on around you.

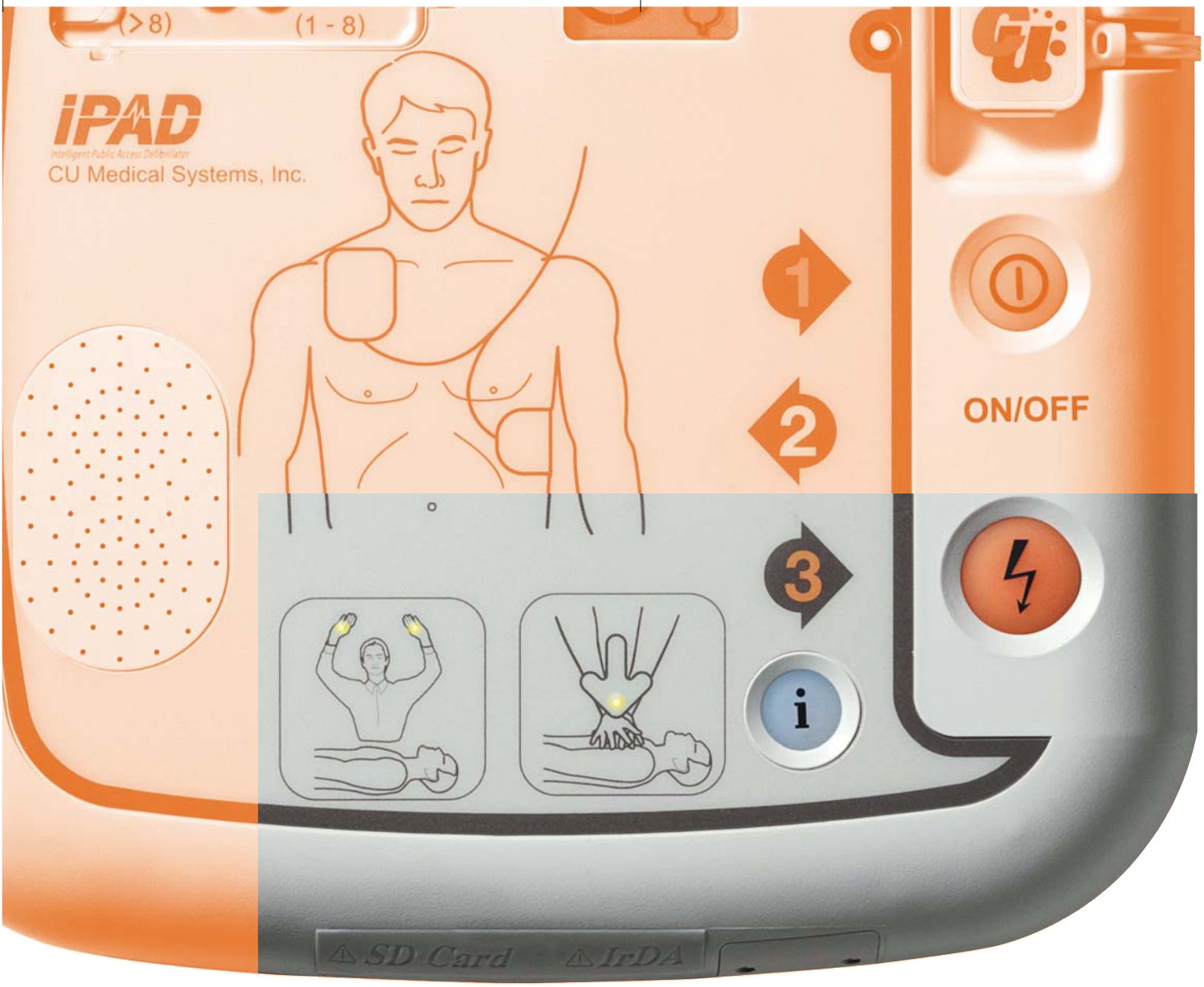
Trying to use an AED in noisy places can be difficult if the first responder can't clearly hear the voice prompts and instructions from the AED.

The iPAD CU-SP1 listens to the ambient noise, and automatically adjusts the volume of its prompts to make them clear andeasily heard over the background noise. When the correct volume has been reached the iPAD CU-SP1 keeps the prompts at this level.

# SMART PADS - SMART STORAGE!

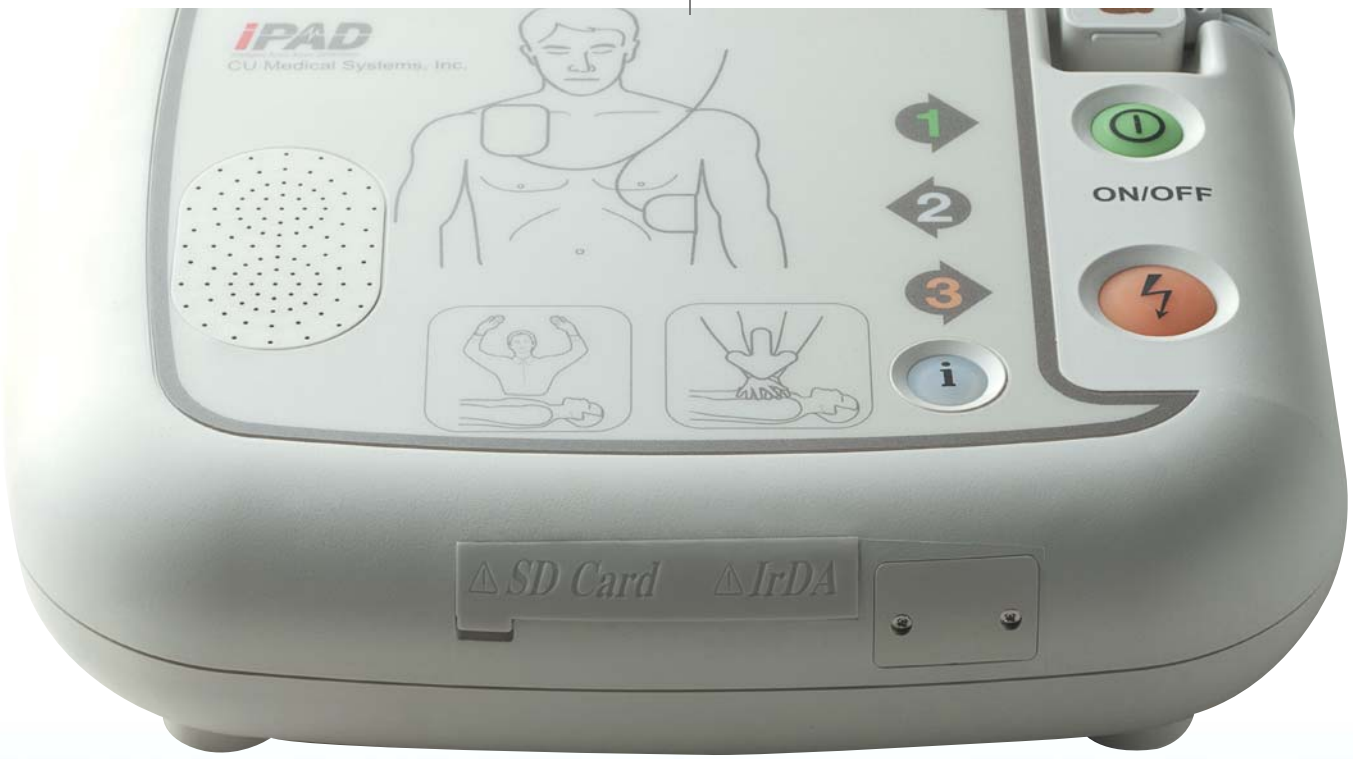
The pre-connected ‘Smart’electrode pads are stored in a clear storage compartment on the underside of the unit. This ensures that the iPAD SP1 is always ready to be used in the shortest amount of time possible.

The unique technology built in to the iPAD CU-SP1 and the ‘Smart’electrode pads allows the unit to detect, when connected, if a set of pads has already been used. If they have, the user is advised of this. In addition, the visual indicator on the front of the iPAD CU-SP1 indicates if the connected pads are within their life expectancy. The indicator will change when the pads have only 3 months life left before their expiry date-giving you plenty of time to arrange for replacements. The indicator will change again when the expiry date is reached. Checking the life of your pads is as quick and simple as looking at the LCD display.




# CPR DETECTION

CPR is vital to ensure that the casualty has the best chances of survival. The iPAD CU-SP1 detects if CPR is being performed when appropriate prompts and encourages the first responder. If CPR is not being performed, the iPAD CU-SP1 prompts the first responder to ‘perform CPR’. If CPR is already being performed, the iPAD CU-SP1 encourages the first responder by prompting them to ‘continue CPR’.guide the users.




# EASY COMMUNICATION WITH CU-EX1 SOFTWARE

Getting information from the iPAD CU-SP1 after an event is now easier than ever! Installing CU-EX1 software onto a computer allows you to see and analyse the usage history of the unit. Information such as time of 'power on', the casualty's heart rhythm and shocks delivered are all presented in an easy to understand fashion.

The iPAD CU-SP1 can store up to 5 events with up to 3 hours of ECG analysis on an SD memory card. The data can be transferred by either simply removing the SD card, or by using the inbuilt infra-red (IrDA) port. Having the data on an SD Memory card allows the card to be removed for analysis whilst another card is inserted, making the unit ready to use again whilst retaining the original information.

**The iPAD CU-SP1 - Advanced Features - Advanced Performance**

# CU-SP1 SPECIFICATION

## 1. Defibrillator

**Model** CU-SP1
**Standard Packgage** Defibrillator, Pads, Battery, Manual
**Output Energy** Adult-150Joules /
Pediatric-50Joules (Common usage)
**Charging time**
1) Charging time : Less than 8 seconds
2) Charging time after CPR finished : At least 8 seconds

## 2. User Interface

**User support** Detailed voice prompts and flashing indicators
**CPR guidance** Voice prompts for how to perform CPR for adult and child patient
**Controls** On/Off button, I button, Shock button
**Indicator** LCD display
(Device status, Battery status, Pads status)
**Sensing** Pads expiring date, Pads connection status
**CPR Monitoring**
**Automatic Volume adjusting**

## 3. Enviornment

**Sealing** Waterjet proof IPX5 per IEC60529 (IP55)
Dust protected IP5X per IEC60529
**Temperature** Operation/standby (0℃ - 40℃)
**Vibration** Meets MILSTD 810F

## 4. Data Recording and Transmission

**IrDA port** wireless transmission of event data to PC, SD Card
**Internal Memory (Nand-flash)** ECG, Event
**Storage capacity** Multi recording 5 events / Max 3 hours
**Data review PC Program** CU-EX1

## 5. Patient Analysis System

**Patient Analysis** Shockable Rhythms - Ventricular Fibrillation, Ventricular Tachycardia
**Sensitivity/Specificity** Meets AAMI DF80 Guideline

## 6. Battery

**Standard**
+ Type : DC 12 Volt 2.8 Ah, Lithium manganese dioxide
+ Capacity : Minimum 100shocks (150J )

**High Capacity**
+ Type : DC 12Volt 4.2Ah, Lithium manganese dioxide
+ Capacity : Minimum 200shocks (150J )

**Lifespan** 5 years (High capacity battery)
(With the condition of the temperature of operation/ standby, standby mode after the first initial check)

## 7. Pads

Common usage for adult and child
**Expiring date** 30 months (from the date of manufacturing)

CU Medical Systems, Inc.

**CONTACT INFORMATION**

Head Office
CU Medical Systems, Inc.
4th, 5th Floor, Cheonggye Plaza,
991-4 Cheonggye, Uiwang City, Gyeonggi Province,
Republic of Korea
Tel: +82 31 421 9700
Fax: +82 31 421 9911
email: admin@cu911.com

Plant
CU Medical Systems, Inc.
Dongwha Medical Instrument Complex
1647-1 Dongwha, Munmak, Wonju City, Gangwon Province,
Republic of Korea
Tel: +82 33 747 7657
Fax: +82 33 747 7657

European Representative Office
Kuester Strasse 6
30519 Hannover, Germany
Tel / Fax: +49 511 8486054

website: www.cu911.com

# CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU1106403
Order No.: 176071

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15th December 2005 relating to medical devices pursuant to act no. 6 of 12th January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below:

| | |
|---|---|
| Name and address of the manufacturer: | CU Medical Systems, Inc.<br>Donghwa Medical Instrument Complex<br>1647-1 Dongwha-ri, Munmak-eup,<br>Wonju-si,Gangwon-do<br>220-801 Republic of Korea |
| Device category: | Defibrillator |
| GMDN code: | 47910 |
| Models: | See Appendix 1 to this certificate |
| Risk class as defined by the manufacturer: | IIb |
| Standards/provisions: | The audit of the quality system was based upon and assessed according to the provisions in Annex II of the EC-Directive 93/42/EEC, with the exemption of section 4. |
| Date of last audit: | 2010-09-20/21 |
| Date of the end of the validity: | 2016-07-01 |
| Nemko EC notification No.: | 0470 |

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

Date of issue: 2011-06-22

Signature: Frank Skarpsno
*Lead auditor /Principal Engineer*

Date of verification: 2011-06-22

Signature: Arild R. Hansgård
*Lead auditor /Principal Engineer*


Nemko AS
P.O. Box 73, Blindern
N-0314 Oslo, Norway

Office address
Gaustadalléen 30
Oslo

Internet
www.nemko.com

Telephone
+47 22 96 03 30
Enterprise number:

Fax
+47 22 960 550
NO 9443522430

# CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Certificate No.: EU1106403
Order No.: 176071

Manufacturer: CU Medical Systems, Inc.
Donghwa Medical Instrument Complex
1647-1 Dongwha-ri, Munmak-eup,
Wonju-si,Gangwon-do
220-801 Republic of Korea

Device category: Defibrillator

## Appendix 1: Page 1 of 1.

The certificate referred to above includes the following device/model:

**CU-SP1**

Date of issue: 2011-06-22

*Signature:* Frank Skarpsno
*Lead auditor /Principal Engineer*

Date of verification: 2011-06-22

*Signature:* Árild R. Hansgård
*Lead auditor /Principal Engineer*

KFDA
Korea Food & Drug Administration
식품의약품안전청

Osong Health Technology Administration Complex,
187 Osongsaengmyeong2(i)-ro,Gangoe-myeon,
Cheongwon-gun,
Chungcheongbuk-do, Korea 363-951
Tel: +82-43-719-1010, Fax: +82-43-719-1000

No. of Certificate : 20110063463 Date : 2011/06/03

# Certificate of Free Sales

Exporting(certifying) country : Republic of Korea
Importing(requesting) country : Not Determined

**The Korea Food and Drug Administration, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is(are) permitted to be freely sold in domestic and overseas markets.**

Manufacturer (Registered No. : 1464)

CU Medical Systems, Inc.
1647-1, Donghwa-ri, Munmak-eup, Wonju-si, Gangwon-do, Korea

| Product-License No. | Classification |
|---|---|
| 06-231 | Defibrillator |
| 07-699 | Defibrillator, lowpowered |
| 11-494 | Defibrillator, lowpowered |

※ Attached : List of Product Classification and Model

Director of Diagnostic Medical Device Div.
Medical Device Safety Bureau
Korea Food & Drug Administration

KFDA
Korea Food & Drug Administration
식품의약품안전청

Osong Health Technology Administration Complex,
187 Osongsaengmyeong2(i)-ro,Gangoe-myeon,
Cheongwon-gun,
Chungcheongbuk-do, Korea 363-951
Tel: +82-43-719-1010, Fax: +82-43-719-1000

No. of Certificate : 20110063463 Date : 2011/06/03

**Product License No. : 06-231** **(2006/03/29 )**

**Classification :** Defibrillator

**Model (Export Name)**

i-PAD NF1200

**Product License No. : 07-699** **(2011/05/09 )**

**Classification :** Defibrillator, lowpowered

**Model (Export Name)**

LiFEGAIN CU-HD1

**Product License No. : 11-494** **(2011/05/03 )**

**Classification :** Defibrillator, lowpowered

**Model (Export Name)**

i-PAD CU-SP1