# **Instructions for Use**

### **CU-SPR**

The information in these Instructions for Use applies to the CU-SPR. This information is subject to change. Please contact CU Medical Systems, Inc. or its authorized representatives for information on revisions.

### **Revision History**

Edition 2

Publication Date: March, 2020 Document No.: SPR-OPM-E-02

Published by: CU Medical Systems, Inc.

Printed in the Republic of Korea

### Copyright

© 2019 CU Medical Systems, Inc.

No part of these Instructions for Use may be reproduced without the permission of CU Medical Systems, Inc.

#### **Medical Device Directive**

The CU-SPR complies with the requirements of the Medical Device Directive 2007/47/EC and its revisions.



### Important:

Quick defibrillation is needed if sudden cardiac arrest occurs. Since the chance of success is reduced by 7% to 10% for every minute that defibrillation is delayed, defibrillation must be performed promptly.

1

### **Contact Us**

### **Product and Order Inquiries**

#### **Overseas Sales Team**

CU Medical Systems, Inc. 5F, Cheonggye Plaza, 221, Anyangpangyo-ro, Uiwang-si, Gyeonggi-do, Republic of Korea Tel: +82 31 421 9700 / Fax: +82 31 421 9911

E-mail addresses : sales@cu911.com

German Branch Office CU Medical Germany GmbH, Cicero Str.26, 10709 Berlin, Germany Tel: +49 30 6781 7804

Fax: +49 30 6782 0901

### **Service and Technical Support**

#### **Customer Service Team**

CU Medical Systems, Inc. 5F, Cheonggye Plaza, 221, Anyangpangyo-ro, Uiwang-si, Gyeonggi-do, Republic of Korea Tel: +82 31 421 9700 / Fax: +82 31 421 9911 E-mail addresses: service@cu911.com



130-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Republic of KOREA

Tel: +82 33 747 7657 Fax: +82 33 747 7659

Homepage: http://www.cu911.com

Medical Device Safety Service
Schiffgraben 41, 30175 Hannover, Germany



**CU Medical Systems, Inc.** 

# **Table of contents**

INTRODUCTION			
OVEF	RVIEW	7	
1. 1	INTRODUCTION	8	
1.1	DEVICE DESCRIPTION	8	
1.2	Indicated Use	8	
1.3	Intended Users	9	
1.4	CONTRAINDICATIONS	9	
1.5	LOCAL PROTOCOL	9	
1.6	ADDITIONAL INFORMATION	9	
2. I	DEVICE FEATURES	10	
3. I	PREPARATION FOR USE	13	
3.1	STANDARD PACKAGE CONTENTS	13	
3.2	SETTING UP THE CU-SPR	14	
<b>4</b> . I	HOW TO USE THE CU-SPR	16	
4.1	CHAIN OF SURVIVAL	16	
4.2	PREPARATION FOR DEFIBRILLATION	17	
4.3	DEFIBRILLATION IN ADULT MODE	20	
4.4	DEFIBRILLATION PROCEDURES IN PEDIATRIC MODE	26	
5.	AFTER USING THE CU-SPR	27	
5.1	Maintenance After Each Use	27	
5.2	SAVING AND TRANSFERRING TREATMENT DATA	28	
5.	2.1 Device Usage	28	
5	2.2 Transferring Treatment Data	28	
5.3	DEVICE SETTING	30	
5.	3.1 CPR Guide Setting	31	
5.	3.2 Setting the CPR Guide	31	
6. I	MAINTENANCE	34	
6.1	DEVICE STORAGE	34	
6.2	MAINTENANCE	35	
6	2.1 Davida Ingraction	25	

6.2.2	Replacing Supplies	
Dispo	osable Battery Pack	35
Repla	cing the Pads	37
6.2.3	Cleaning the CU-SPR	38
7. DISP	OSAL	39
8. TRO	UBLESHOOTING	40
8.1 SEL	_F-TESTS	40
8.2 DEV	VICE STATUS	42
8.3 Tro	DUBLESHOOTING	43
8.3.1	Troubleshooting While the Device is Operating	43
8.3.2	Troubleshooting While the Device is not Operating	44
9. DEVI	ICE SERVICE	45
APPENDIX	x	47
A . RESCU	JE PROTOCOL	47
B . PARTS	50	
B.1 STAN	IDARD ACCESSORIES	50
В.2 Орті	ONAL ACCESSORIES	50
C . DESCR	IPTION OF SYMBOLS	51
C.1 CU-5	SPR DEFIBRILLATOR	51
C.2 CU-9	SPR Packaging	52
C.3 Acce	ESSORIES	53
C.3.1 L	Disposable Battery Pack (CUSA1103BS)	53
C.3.2 F	Pads (CUA1904S)	54
D . GLOSS	SARY	55
E . DEVICI	E SPECIFICATIONS	60
F . FLECTE	ROMAGNETIC COMPATIBILITY	68

### Introduction

These Instructions for Use contain information necessary for the correct use of this device. Please contact us regarding any questions or issues on the use of the device arising from information found in these Instructions for Use [Chapter 9: Device Service].

The company or its authorized distributor is not responsible for any injury incurred by the user or patient due to any apparent negligence or improper use by the user.

Hereinafter,

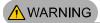
"device" refers to [CU-SPR]

"We" or "Us" refers to CU Medical Systems, Inc.

"Pads" refers to defibrillation electrode pads,

"Battery Pack" refers to a disposable battery pack.

These Instructions for Use emphasizes the safety procedures and precautions for the device use by using the terms below. Please acquaint yourself with the warnings, cautions and references stated in these Instructions for Use in order to safely use the device.



Conditions, hazards, or unsafe practices that can result in serious personal injury or loss of life.

### CAUTION

Conditions, hazards, or unsafe practices that can result in minor or moderate personal injury, damage to the device, or loss of treatment data stored in the device, particularly if precautionary steps are not taken.

### NOTICE

Used to denote items that are important during installation, operation, or maintenance of the device.

### **Overview**

Thank you for purchasing the CU-SPR. This device can be effectively and safely used for a long period if you familiarize yourself with the instructions, warnings, precautions, and notices contained in these Instructions for Use prior to its use.

### **⚠** WARNING

- A defibrillator discharges electric shock with high voltage and current. You must be wellacquainted with the instructions, warnings, and precautions contained in these Instructions for Use.
- You must follow the instructions, warnings, cautions, and notices in these Instructions for Use when using this device.
- The manufacturer will not be responsible for any problems involving the device that are caused by the user's negligence.
- This device shall be serviced only by the manufacturer or its authorized service centers.
- If the Device is intended to be connected to equipment other than those stated in these Instructions for Use, contact the manufacturer.
- If this Device does not operate properly, contact the manufacturer or its authorized service center.

### 1. Introduction

### 1.1 Device Description

**CU-SPR** is an easy-to-use Semi-Automated External Defibrillator (AED) that is small, light, and portable, and uses a battery.

The AED automatically reads the patient's electrocardiogram (ECG) and determines if a cardiac arrest that requires defibrillation has occurred, so that both medical professionals and the general public can easily operate it. Cardiac arrest can occur anytime to anyone at any place and may threaten the patient's life if the appropriate CPR and/or electric shock with a defibrillator are not applied within a few minutes.

The CU-SPR is a semi-automated external defibrillator (AED). If connected to a patient, the CU-SPR automatically acquires and analyzes the electrocardiogram (ECG) of the patient for the presence of Ventricular Fibrillation or Ventricular Tachycardia (also known as shockable rhythms). If a shockable rhythm is detected, the device automatically charges itself. Defibrillating shock is delivered when the you press the SHOCK button.

The CU-SPR is easy to use. It guides the you throughout a rescue operation using voice prompts and indicators (LED and graphical indicators).

The CU-SPR is small, light, highly portable, and battery powered. It is highly suitable for use in public, out-of-hospital settings.

### 1.2 Indicated Use

The **CU-SPR** is indicated for use on patients that are exhibiting the symptoms of sudden cardiac arrest (SCA) with all of the following signs:

- a) No movement and no response when shaken
- b) No normal breathing

Do not use the CU-SPR on patients who show either of the following signs:

- a) Movement or response when shaken
- b) Presence of normal breathing

When the victim is under 25kg or 8 years old, move the Adult/Pediatric Selection Switch to Pediatric Mode, and use the device.

CU-SPR is not intended for use on infant patients less than 1 years old.

### 1.3 Intended Users

The **CU-SPR** is intended for use in or out of the hospital by emergency care personnel or healthcare professionals or laypersons. The manufacturer recommends that users train on the use of the device.

### 1.4 Contraindications

None known.

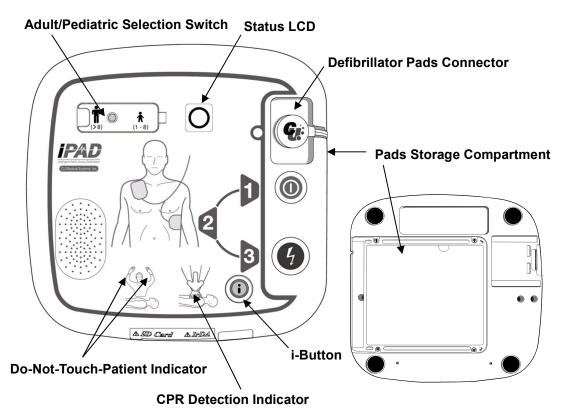
### 1.5 Local Protocol

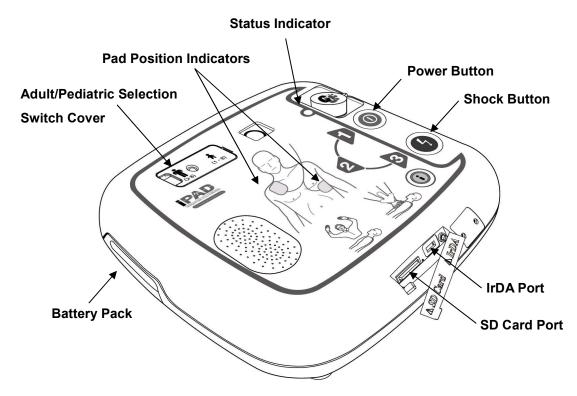
Please contact your local health authority for information on the requirements of ownership and usage of defibrillators.

### 1.6 Additional Information

Please contact CU Medical Systems, Inc. or its local distributors for any additional information on the CU-SPR.

# 2. Device Features





**Power Button** Turns the device on or off. (When the device is on, a green LED is lit) i-Button • Reports device usage (the total hours of the last usage and number of shocks) • checks the S/W version · downloads events and ECG data via an IrDA and SD Card • sets the CPR mode (the number of compressions, breaths and cycles; compression rate per minute; pausing time; detailed guide on/off) · and checks for errors Status LCD, Status Displays the current status of the device, battery and pads. Indicator **Shock Button** Delivers defibrillating shock when pressed while flashing in orange. Adult/Pediatric Selects Adult/Pediatric modes. **Selection Switch** Adult/Pediatric Covers the Adult/Pediatric Selection Switch to prevent **Selection Switch** accidental switching. Cover **Defibrillator Pads** Connects with the connectors of the pads. Connector **Pads Position** Indicates the pads position on the patient. **Indicators Do-Not-Touch-Patient** Warns when not to touch the patient. Indicator

is not performed)

Indicates performance of CPR on the patient.

(The indicator is lit if CPR is performed, and flashes if CPR

**CPR Detection** 

Indicator

**Battery Pack** The disposable power source of the device.

IrDA Port Transmits and receives treatment data between the device

and a personal computer.

**SD Card (External** Port for copying device records to a SD card.

Memory) Port

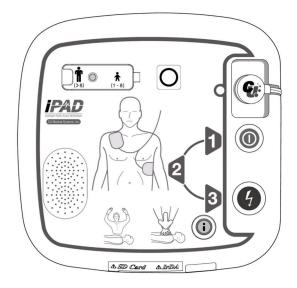
Pads Storage Stores pads.

Compartment

# 3. Preparation for Use

### 3.1 Standard Package Contents

The following are the standard package contents of this device



**CU-SPR Semi-automated External Defibrillator** 



Instructions for Use



1 Battery Pack (Disposable)



1 Pack of Adult Pads (Disposable)

Please contact the manufacturer for replacement supplies (refer to [Appendix B: Parts and Accessories] of these Instructions for Use).



✓ Only parts and accessories recommended and approved by CU Medical Systems, Inc. must be used with the CU-SPR. Using unapproved parts and accessories may compromise the safety and effectiveness of the CU-SPR.

### NOTICE

✓ Extra battery packs and pads are recommended.

### 3.2 Setting up the CU-SPR

Do the following to set up the CU-SPR

- Open the package and verify that it contains all the items listed in the packing list.
- Familiarize yourself with the device features by referring to [Chapter 2: Device Features] of
  these Instructions for Use.
- Insert the battery pack into the battery compartment on the device as shown in the figure below.





As the battery pack is inserted, the device starts a self-test. If the device status is normal, is shown on the Status LCD. If X is displayed on the Status LCD or flashes red or yellow on the Status indicator after the self test, please refer to [Chapter 8 : Troubleshooting] of these Instructions for Use.

If you have a carrying case, please safely store the Device in the carrying case. If you want to
 purchase the carrying case, please contact us by referring to [Appendix A: Accessories] of
 these Instructions for Use.

- Storage and maintenance considerations:
  - Refer to [Section 6.1: Device Storage] for proper device storage instructions.
  - When the device is in storage, check the Status LCD periodically to ensure that the device is in good condition.
  - Store the CU-SPR in accordance with your local emergency first aid protocol.
  - Store the device in an easy-to-access location where its Status LCD can be checked periodically and its technical alarms can be easily heard (e.g. alarm on low battery or other device problems).
  - It is also recommended to place an emergency use telephone near the device's storage area so that emergency medical services can be easily called during emergencies.
  - Store the accessories along with the device in the device's carrying case for easy and quick access.

### **⚠** WARNING

- Electromagnetic interference may affect the performance of the device. While the device is in use, it should be kept away from devices that cause electromagnetic interference. Devices that may cause such interference include motors, X-ray equipment, radio transmitters, and cell phones. Refer to [Appendix E: Electromagnetic Compatibility] of these Instructions for Use for more information.
- The use of accessories or cables other than those referred to in these Instructions for Use may increase electromagnetic radiation from the device or reduce the device's electromagnetic immunity. Only accessories and cables that are authorized by the manufacturer should be used with the CU-SPR.

## 4. How to Use the CU-SPR

### 4.1 Chain of Survival

If you think that you are witnessing someone go down in sudden cardiac arrest, perform the chain of actions recommended by the American Heart Association (AHA) in its Chain of Survival emergency response to sudden cardiac arrest.



- 1. Immediate recognition and activation of the emergency response system.
  - Check for a response by tapping the victim on the shoulder and shouting at the victim.
  - Activate the community emergency response system (e.g. call 911 or the equivalent service in your locality)
- 2. Early CPR
  - Perform CPR.

### 3. Early defibrillation

• Use this device (CU-SPR).

Using this device can be summarized in 3 steps:

After pressing the Power Button,

- Step 1: Place pads on the patient.
- Step 2: Press the Shock Button if instructed by the device.
- Step 3: Perform CPR.
- 4. Effective advanced life support Perform advanced care in order to restore spontaneous circulation.
- 5. Integrated post-cardiac arrest care Transfer the patient to a medical institution or a specialized facility

### NOTICE

• If finding and/or operating the defibrillator takes time, monitor the patient's status until the defibrillator is available, perform CPR if necessary.

### 4.2 Preparation for Defibrillation

① Set the Adult/Pediatric Selection Switch to match the victim.

### **Adult victim**

• Open the switch cover



• Set the switch to adult defibrillation mode as shown in the following picture



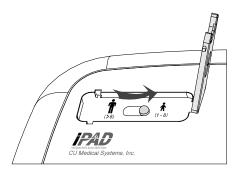
### Child victim (victim is under 25kg or 8 years old)

For pediatric patients, move the Adult /Pediatric Selection Switch to Pediatric Mode as shown in the figures below.

• Open the switch cover



• Set the switch to pediatric defibrillation mode as shown in the following picture



If a young victim is over 25kg or 8 years old, or if you are not sure of the exact weight or age:

- DO NOT DELAY TREATMENT
- Set the Adult/Pediatric Selection Switch to Adult mode.



 Never perform defibrillation in pediatric mode to a patient who is either heavier than 25 kg or older than 8 years old. Ensure the slide key for Adult/Pediatric Mode is as shown on the bottom.

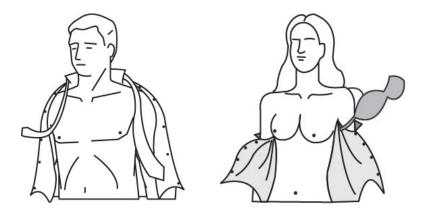
• You can switch the adult/pediatric selection switch before or after turning on the CU-SPR. However, the defibrillation mode should be changed before placing the pads on the patient. Once the pads are in place, you cannot change the defibrillation mode anymore. When the mode is correctly selected, the defibrillation energy is set to an adult value (150 J) or pediatric value (50 J).

### 2 Turn the device on by pressing the Power Button.



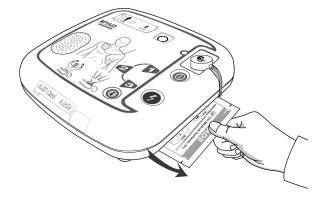
When the power turns ON the following occurs in sequence:

- the beeper will beep for 1 seconds
- Voice instruction: "Call emergency Medical services, now"
- 3 Remove clothes from patient's chest.



### **OCAUTION**

- Time is essential for the cardiac arrest patient. Tear or cut clothes if removing them will take time.
- Dry the patient's skin such that pads can adhere well on the chest. Shave hair on the chest if necessary.
- Remove the pads package from the Pads Storage Compartment at the bottom of the device.



**5** Open the pads package.



**6** Take pads out of the pads package.



### ${ \ensuremath{ {\mathfrak T}} }$ Refer to the pictures on both pads.

### **Adult Pads**







• The adhesive material on the pads starts to dry out as soon as the package is opened. Use immediately after opening. Refer to [Section 6.2: Maintenance] of these Instructions for Use for procedures on how to check the expiration date of the pads and pads maintenance.

### 4.3 Defibrillation in Adult Mode

### Step 1: Place pads on the patient.

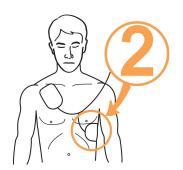
Remove pad 1 from the single liner and stick the pad to the patient's upper chest as shown below.





Remove pad 2 from the single liner, and stick the pad to the patient's side torso as shown below.





3 If the device detects the connection with the patient after placing the pads, follow the voice instruction of the device.

### NOTICE

- Defibrillation can be done even if the pads are reversed. If the locations of pads are switched, follow the next voice instruction without changing the directions of pads. It is more important to begin defibrillation as soon as possible.
- In the event the pad is not adhering well, check if the adhesive side of the pads is dry. Each pad has an adhesive gel. If the gel does not adhere well, replace it with a new pads.

### **⚠** WARNING

• Ensure the patient is not on a wet surface when performing defibrillation. If the patient's skin is wet, dry the skin first prior to using the device.

### Step 2: Press the Shock Button if instructed.

The device acquires and analyzes the patient's ECG immediately after being connected. The device will instruct you not to touch the patient by flashing the Do-Not-Touch-Patient Indicator and by issuing the voice prompt: "Do not touch the patient, analyzing heart rhythm". After analyzing

the ECG, the device will determine whether or not the patient needs defibrillation.



• Do not move or touch the patient during ECG analysis.

### If the patient needs defibrillation, the device will do the following:

The device announces that a defibrillation shock is needed, and instructs you to keep away from the patient.



 While the device is charging after a shockable rhythm is detected, the ECG of the patient is continuously acquired and analyzed. The device disarms itself if the ECG rhythm changes to a non-shockable rhythm before shock delivery.

### When it is charged, the device activates the following indicators in sequence:



- continuous beep while the Shock Button flashes in orange.
- the device instructs you to press the flashing orange Shock button;
   you should press the Shock Button at this time.

When the Shock Button is pressed, the device delivers a defibrillating shock to the patient. If defibrillation is properly done, the device reports that an electric shock has been delivered.

After shock delivery, the device indicates that you may touch the patient, and the CPR Mode Indicator is lit. Then, the voice instruction for CPR starts.

If the flashing Shock Button is not pressed within 15 seconds, the device will cancel the shock delivery and disarm. Then, the device issues CPR instructions.

#### If the patient does not need defibrillation, the device will do the following in sequence:

- the device announces that the patient does not need a defibrillating shock and that you may touch the patient.
- the CPR Mode Indicator is lit.

· voice instruction for CPR starts.

### **MARNING**

- Do not touch (you or anybody else) the patient during shock delivery.
- Before defibrillation, make sure that there is no contact between 1 and 2 below which may provide unwanted pathways for the defibrillating current.
  - the patient's body (such as exposed skin or head or limbs), conductive fluids (such as gel),
     blood, or saline
  - metal objects (such as bed frame or stretcher)

### **OCAUTION**

- While analyzing ECG, keep the patient still and minimize movements around the patient. Do
  not touch the patient and pads while the Do-Not-Touch-Patient Indicator is on. Electrical noise
  (interference) may delay the ECG analysis.
- As a safety measure, the device will not deliver a shock until the flashing orange SHOCK button is pressed. If the SHOCK button is not pressed within 15 seconds of the voice instruction to press the SHOCK button, the device will disarm itself (dumps the shock energy in its internal load) and will instruct you to make sure that emergency medical services have been called. The device will then instruct you to begin CPR.
- During defibrillation, disconnect other medical electrical equipment which has no defibrillation-proof applied parts from the patient.
- If the device malfunctions during a rescue operation, it will instruct you to get a replacement defibrillator and will start the voice instruction for CPR. Have CPR performed until the replacement defibrillator is ready to use.

### Step 3: Perform CPR.

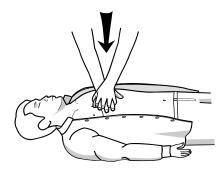
Perform CPR when the CU-SPR instructs you to do so.

By default, the CU-SPR gives voice instruction for CPR during pause for CPR after a shock delivery.

### [CPR Method]

### 1. Compression Point

Place the heel of your hand in the middle of the patient's chest between nipples (which is the lower half of the sternum), and put the heel of your other hand on top of the first so that your hands are overlapped and parallel.



### 2. Compression Speed and Depth

Compress the chest at least 5 cm deep, and at a rate of at least 100 compressions per minute.

### 3. Opening the Airway

While lifting the patient's chin up, tilt the head backward to open the airway.

### 4. Ventilation Method

Pinch the patient's nose as shown in the figure below, and give the patient enough breath to make the chest rise significantly.



### NOTICE

- If you have not been trained in CPR, you should perform only chest compression or follow the instructions of the emergency medical services' agent on the phone.
- If you are trained for CPR and able to perform ventilation, perform the chest compression along with ventilation.
- The CPR guide can be set on an administrator's mode. Refer to [Section 5.3: Device Setting] for more information.

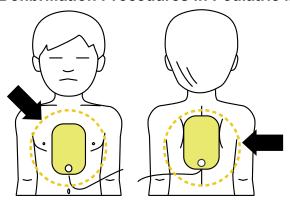
### **O**CAUTION

• While playing the CPR guide, the device does not analyze the patient's ECG. After the CPR guide, the device automatically starts the reanalysis of the patient's ECG.

### NOTICE

• In order to turn the device off after use, press the Power Button for at least 1 second.

### 4.4 Defibrillation Procedures in Pediatric Mode



When the patient is older than 1 year and younger than 8 years, set the Adult/Pediatric Selection Switch to Pediatric Mode and perform defibrillation according to the voice instructions. When the device is in pediatric mode, it automatically sets the defibrillation energy to 50 J and provides pediatric CPR guide.

Place pads on the middle of the chest and back as illustrated above. Pads are not specific to either chest or back.

### NOTICE

- Follow the instructions below when giving first aid during pediatric cardiac arrest.
  - When giving first aid during a pediatric cardiac arrest, ask others to call the emergency medical center and to bring the CU-SPR while you are performing pediatric CPR.
  - When there is no one else around, perform CPR for 1 to 2 minutes, call emergency medical services, and then get the CU-SPR.
  - If you witnessed the child's collapse, call emergency medical services immediately, and then get the CU-SPR.

# 5. After Using the CU-SPR

### 5.1 Maintenance After Each Use

- Check if the device for signs of damage and contamination.
- If there is dirt contamination, see Section 6.2.3 on how to clean the device.
- Run a battery insertion test. Refer to Section [8.1: Self-Tests] for the procedure.
  - If () is displayed on the Status LCD after running the test, the device status is normal.
- Dispose of the used pads properly. Place a new pouch of defibrillator pads into the pads storage compartment. See to it that the pads are not beyond their expiration date.
   The CU-SPR uses disposable pads. Do not reuse them. Refer to Section [6.2.2: Replacing Supplies] on how to replace the pads.

### **⚠** WARNING

- You should use only the defibrillator pads provided and recommended by the manufacturer.
- Do not open the pads package until immediately before use. Since the adhesive material on the pads starts to dry out as soon as the package is opened, the pads may not be usable regardless of the expiration date.

### 5.2 Saving and Transferring Treatment Data

#### 5.2.1 Device Usage

This device automatically saves the following treatment data:

- ECG data
- Usage information

The treatment data is automatically recorded in the internal memory. This data is not erased even if the device is turned off. The recorded treatment data may be transferred to a personal computer (PC).



- This CU-SPR keeps the data of the 5 most recent treatment operations and can save up to 3 hours of ECG data for each rescue operation. ECG data beyond 3 hours will not be recorded.
- When the device is used more than 5 times, it deletes the oldest treatment data to make room for data from a new treatment operation. It is recommended to transfer treatment data to a PC after each use of the device.
- If the battery pack is removed while the device is operating, treatment data cannot be properly recorded. If you wish to remove the battery pack, turn the power off by pressing the Power Button for at least 1 second before removing the battery pack.

### 5.2.2 Transferring Treatment Data

The treatment data may be transferred via a SD card or IrDA. The entire treatment data of all patients that is recorded on the device is transferred using only the SD card method, while the treatment data of one patient can be transferred using only the IrDA method.

#### 1. Copying Treatment Data by Using the SD Card

- Tormat the SD card on the PC to FAT (FAT16) format.
- Open the SD Card Cover on the device and insert the SD card into the port.



When the i-Button is pressed for more than 1 second in standby mode, the mode changes into

- administrator mode with voice guide.
- The device then gives you a summary (the total hours of the last device use and the number of defibrillation shocks delivered).
- The voice guide gives the S/W version of the device.
- When instructed by the voice guide to transfer the treatment history, press the i-Button to copy
   the data onto the SD card.

### If there is treatment data in the device's internal memory:

- The device informs you that copying of the treatment data onto the SD card has started, and starts to copy the data.
- When copying is completed, the device mode changes to CPR guide setting mode. Refer to [Section 5.3: Device Setting] for details regarding CPR guide setting.

#### If there is no treatment data in the device's internal memory:

 The device mode changes to CPR guide setting mode after informing you that no treatment data exists.

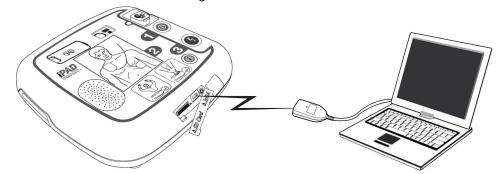
#### NOTICE

• If the file has already been transferred, the device will inform you that the same file exists in the PC. Press the Shock Button to overwrite the existing file in the PC or press the i-Button to cancel the copying of the file.

### 2. Transferring Treatment Data via IrDA

The data may be transferred to a PC using the data management software (CU Expert Ver.3.50 or higher) from the manufacturer. CU Expert includes ECG review and printing functions.

- Position the IrDA adapter to face the IrDA port on the device as shown in the figure below.
- When the i-Button is pressed for at least 1 second in standby mode, the mode changes to administrator mode with a voice guide.



The device gives the you a summary (the total hours of the last device use and the number of

defibrillation shocks delivered).

- The voice guide gives the S/W version of the device.
- When instructed to transfer the treatment history, press the i-Button to transfer the data.

### If there is treatment data in the device's internal memory:

- The voice guide reports the total number of individual treatment data recorded in the device.
- ② By default, of a maximum of 5 individual treatment data, the first on the list is the most recent.
- In order to rearrange the order for copying to a PC, press the Shock Button to change the order to most recent last, and then press the i-Button to transfer the selected data.
- Run CU Expert on the PC. Refer to the CU Expert manual for detailed information regarding
   how to receive data.
- The device will be connected with the CU Expert within a few seconds, and data will be automatically transferred.
- When copying is completed, the mode changes to CPR guide setting mode. Refer to [Section 5.3: Device Setting] for details regarding changing CPR guide setting.

#### If there is no treatment data in the device's internal memory:

The device mode changes to CPR guide setting mode after informing you that no treatment data exists.



The distance between the IrDA port on the device and the IrDA adapter should be within 30 cm, while their angle should be within ±15°. Also, since external light source affects the IrDA, try to use it in indoors and away from fluorescent and/or incandescent lamps.

### 5.3 Device Setting

#### 5.3.1 CPR Guide Setting

The default CPR setting on CU-SPR is 5 cycles with 30 chest compressions and 2 breaths in accordance with the American Heart Association (AHA) 2010 CPR Guidelines. However, you may customize these.

You can set the following:

- · Number of chest compressions
- · Number of ventilation
- · Number of cycles
- · Number of chest compressions per minute
- · Pausing time
- · Detailed guide selection

### 5.3.2 Setting the CPR Guide

- When the i-Button is pressed for at least 1 second in standby mode, the mode changes into administrator mode with a voice guide.
- The device gives you a summary (the total hours of the last device use and the number of electric shocks).
- When instructed to transfer the treatment data, do not press the i-Button, but instead wait for 5 seconds.
- When instructed to set the CPR guide, press the i-Button to enter the CPR guide setting mode.
- When instructed to enter a password, enter the set password.

### NOTICE

• Password: press the following buttons in sequence:

i-Button → i-Button → Shock Button → i-Button → Shock Button → Shock Button



- The voice guide will give information regarding the current CPR guide setting.
- Press the Shock Button to change the setting, or press the i-Button to proceed to the next step.
- Settings can then be changed in the following order: Number of Chest Compressions, Number of Ventilation, Chest Compression rate, Pausing Time, and Detailed Guide Selection. Refer to [Table 1] CPR Guide Setting Options below.

- When the setting is completed, the voice guide will give information regarding the set CPR guide, which may be saved or canceled.
- Press the i-Button to save or the Shock-Button to cancel according to voice instructions.
- When the CPR guide setting is either saved or canceled, the device automatically shuts down.

### [Table 1] CPR Guide Setting Options

Number	Setting Option	Range	Unit	Default	Description	
	Number of				Perform 30 compressions.	
1	Chest	15, 30	15	30		
	Compression					
2	Number of	0 to 2	2 1	2	Give 2 breaths.	
	Ventilation	0 10 2				
3	Number of	2 to 10	2 to 10	1	5	Perform 5 cycles of chest
	Cycles		ı 	ວ	compression and ventilation.	
	Chest	100 to 120	to	100	Compress the chest at a rate of	
4	Compression		5		100 compressions per minute.	
	Rate		120			
5	CPR Pause	30 to	30 sec. 120 sec.	120 500	Pause for 120 seconds	
	time	180 sec.		(2 minutes).		
	Detailed  6 Guide On/Off  Selection				Turns ON or OFF detailed voice	
6			Off	instructions for the chest		
				compression and ventilation when		
	Selection				performing CPR.	

### NOTICE

- By default, Detailed Guide Selection is OFF during CPR so that you can concentrate on the compression rate and ventilation guidance. If you want the Detailed Guide Selection to be ON during CPR, set it ON as outlined in the previous pages.
- If the Detailed Guide Selection is OFF and the Number of ventilation is set to 0, the CU-SPR provides only chest compression guidance for 2 minutes. After 2 minutes, the CU-SPR automatically reanalyzes the patient's ECG.
- The CPR Chest Compression Rate can only be set in Pediatric mode. In Adult mode, the chest compression rate is fixed at 30 regardless of the set chest compression rate.

# 6. Maintenance

### 6.1 Device Storage

Please refer to the precautions below when storing the Device in order to avoid device damage.

• Do not operate or store the device in conditions that are beyond the following. specified limits.

### Standby Conditions

The device is stored together with the defibrillator pads and the battery pack is inserted - ready to be used in an emergency

Temperature:  $0 \,^{\circ} \sim 50 \,^{\circ} (32 \,^{\circ} \text{F} \sim 122 \,^{\circ} \text{F})$ Humidity:  $5\% \sim 95\%$  (non condensing)

### Storage/Transport Environment

device only, no defibrillator pads and battery pack included

Temperature:  $-20^{\circ}$ C  $\sim 60^{\circ}$ C  $(-4^{\circ}$ F  $\sim 140^{\circ}$ F)

Humidity: 5% ~ 95% (a location with no condensation)

- Do not store the device in areas that are directly exposed to sunlight
- Do not store the device in areas with highly fluctuating temperatures
- Do not store the device near heating equipment
- Do not store the device in areas where there is high vibration (in excess of Road Transportation and Helicopter Minimum Integrity of MIL-STD-810G Method 514.5C)
- Do not operate or store the device in environments with high concentration of flammable gas or anesthetics.
- Do not operate or store the device in areas with high concentration of dust
- Only personnel authorized by the manufacturer may open the device for servicing. There are
  no user serviceable components inside the device.

#### 6.2 Maintenance

### 6.2.1 Device Inspection

The CU-SPR has self-testing capability. The device performs a self-test as soon as the battery is inserted, turns itself off when the test is done, and periodically wakes up to perform the daily, weekly, and monthly self-tests. To initiate a battery insertion self test, remove the battery pack and reinsert. Refer to [Section 8.1: Self-Tests] for more information.



Inspect the CU-SPR daily to ensure that it is always ready for an emergency. Check the
current status of the device, battery, and pads as displayed on the Status LCD and Status
Indicator. Refer to [Section 8.2: Device Status] for information regarding the Status LCD and
Status Indicator.

#### 6.2.2 Replacing Supplies

Refer to [Section 8.2: Device Status] for information regarding the Status LCD and Status Indicator. Replace the battery pack or the defibrillator pads when it is depleted or when they go beyond their expiration date, respectively.

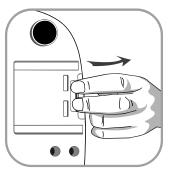
### **Disposable Battery Pack**

### Replacement of the Disposable Battery Pack

- Replace the battery pack when it becomes depleted. Refer to [Chapter 8: Troubleshooting] on how to check the battery status.
- Dispose of depleted battery packs in accordance with local environmental regulations.
- Use only the battery packs recommended and provided by the manufacturer.
- The battery pack is disposable. Do not recharge.

### Replacing the Disposable Battery Pack

 Remove the discharged battery pack by pulling it out while pressing the lock on the bottom of the device. Refer to the figure below.



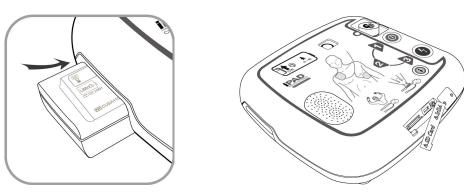




2. Insert a new battery pack in the direction of the arrow with the label facing upward as shown in the figure below.



3. Push the battery pack until you hear it click into place.





### Battery Pack Precautions

- Do not subject the battery pack to serious physical impact.
- Do not attempt to open or break apart the battery pack
- Do not let the battery pack come into contact with open flames or hot objects.
- Do not short-circuit the terminals of the battery pack.
- Keep out of the reach of children.
- If any leakage gets in the eye, immediately clean the eye with water and consult with a doctor.
- Do not store the battery pack under direct sunlight.
- Do not store the battery pack in a wet or very humid place.
- · Comply with local regulations when disposing of the battery pack.
- Do not destroy or incinerate the battery pack.
- Never attempt to recharge the disposable battery pack.

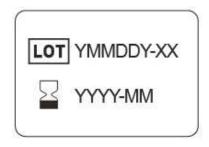
#### Replacing the Pads

- Check the pads status on the Status LCD and Status Indicator daily. Do not use pads that are beyond the expiration date.
- Check the pads package for damage.
- Check the cable outside the packaging pouch for possible defects.
- Only pads provided by the manufacturer should be used with the CU-SPR.

#### **Replacing Pads**

1. Check the expiration date of the pads. Refer to the figure below for checking the expiration date.





The expiration date is marked as

The expiration date is marked to the left of the "ADULT/PEDIATRIC Defibrillation

of the ADOLT/PEDIATRIC Delibrillation

PADS" label on the pads package.

follows:

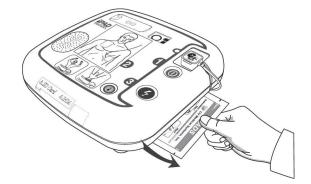
MM / YYYY

YYYY - Year

MM - Month

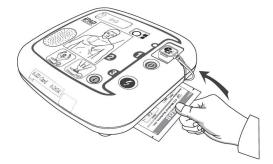
2. Used or expired pads should be replaced. Hold the top and bottom of the pads connector with your fingers, pull it out, and take the pads out from the Pads Storage Compartment as illustrated below.





3. Insert the pads connector of the new pads into the Defibrillator Pads Connector, and then put the pads package in the Pads Storage Compartment as illustrated below.





#### 6.2.3 Cleaning the CU-SPR

Clean the device with a soft cloth. The following detergents may be used to clean the exterior of the device:

- · Dilute soap and water
- Dilute chlorine bleach (dilute 30 ml of chlorine bleach in one liter of water)
- Dilute ammonia-based cleaners
- · Dilute hydrogen peroxide



- Do not immerse the device or its accessories in liquids.
- Be careful not to allow any liquids to get into the device.
- If the device is immersed in liquids, immediately contact the manufacturer or its authorized service center.
- Giving excessive force or shock while cleaning the device may cause damage.
- Do not use an acetone-based strong detergent or abrasive when cleaning the device. In particular, the filter on the IrDA port may be damaged.
- Do not use a detergent containing abrasive ingredients.
- Do not sterilize the CU-SPR.

## 7. Disposal

The life expectancy of the device depends on the frequency of use and the duration of use and maintenance. With proper care, the life expectancy of the device is 5 years.

Dispose of CU-SPR and its accessories in accordance with local regulations.

If you want to use the device after the device's life span, please check the safety and performance part by the manufacturer or designated company.

We are not responsible for any accidents that occur after the device's lifetime.

# 8. Troubleshooting

### 8.1 Self-Tests

The following table lists the self-tests done by the device.

Self-Test Type	Description	
Battery	Runs when the battery pack is inserted into the device.	
Insertion Test	Perform this test:	
	Before the device is deployed	
	After each use	
	When replacing the battery	
	When the device is suspected to be damaged	
	CAUTION	
	Do not run this test when you are about to use the device to treat a	
	sudden cardiac arrest victim because this test takes time (around 20 seconds).	
	If a new battery pack is inserted just before a treatment, do the	
	following to cancel this test:	
	Press the Power Button	
	Wait for the device to turn OFF.	
	Press the Power Button again to turn the device ON.	
	Aside from testing its internal systems, the device also tests the	
	following during this self-test:	
	<ul> <li>Shock Button and i-Button – press the buttons one by one when instructed</li> </ul>	
	Defibrillator pads status – the device tests the connection status	
	(whether connected or not) and the expiration date of the	
	defibrillator pads.	
	If no error is detected, O will be displayed on the Status LCD.	
	If an error is detected, 🗶 will be displayed on the Status LCD and	
	the i-Button will flash in red. When the i-Button is pressed as directed	
	by the voice instructions, the device will report the error and turn itself	
	off. Refer to [Section 8.3: Troubleshooting] for more information.	

Self-Test Type	Description
Power ON Test	The device performs a self-diagnostic test when the Power Button is
	pressed
Run-time Test	The device monitors itself in real-time during its operation.
Periodic	This device performs self-diagnostic tests daily, weekly and monthly.
Self-Diagnostic	The periodic self-test checks important features of the device such as
Test	the battery status, pads status and internal circuits.

If the device fails to perform any self-test during use and is unable to defibrillate, it will instruct the you to replace the device and start the voice instruction for CPR. In order to check the error, turn the device off by pressing the Power Button. If you press and hold the i-button, the voice will direct the you to press the blinking red i-Button. You can verify the cause of the error via the voice instruction by pressing the i-Button. Refer to [Section 8.3: Troubleshooting] for more information.



• It is recommended to run the battery insertion test only during the times enumerated in the table above. The battery insertion test consumes battery power and will shorten battery life if done more frequently than necessary.

## 8.2 Device Status

The status of the device is indicated by the following symbols:

Indicator	Description	Note
Status LCD	The device is functioning normally	
Device Operation	The device is functioning normally.	
Status LCD	The device has an array	
Device Operation	The device has an error.	
Do-Not-Touch-Patient	V	
Indicator: Off	You may touch the patient.	
Do-Not-Touch-Patient	Variable of the Late of the La	
Indicator: Light	You may not touch the patient.	
CPR Detection Indicator: Light	Indicates that CPR is being performed.	
CPR Detection Indicator:	Indicates that CPR is not performed or not	
Flashing	properly performed.	
i Button Floobing in Bod	The device detected an error.	
i-Button: Flashing in Red	Press the i-Button for more information.	
Oh a ala Bartta ara	The device is ready to deliver a defibrillating	
Shock Button:	shock.	
Flashing in Orange	Press the Shock Button to deliver a shock.	

#### 8.3 Troubleshooting

The device informs you of its current status or of problems via status indicators, beeps, and/or voice instruction. Refer to the following for details:

#### 8.3.1 Troubleshooting While the Device is Operating

Symptom/Voice Instruction Cause Resolution				
Status LCD Device Operation	An error has occurred in the device.	Immediately replace the defibrillator and perform CPR if appropriate.		
Voice Prompt : "Low battery", "Replace the battery with a new one."	The battery is low.	Replace the battery with a new one.		
Voice Prompt : "Plug the pads connector into the device."	The Pads Connector is disconnected	Ensure the Pads Connector is properly connected.		
Voice Prompt : " Used pads", "Replace the pads with a new one"	The pads has been previously used.	Replace the pads with a new one.		
Voice Prompt:  "The pads are beyond their expiration date",  "Replace the pads with a new one"	The pads has expired.	Replace the pads with a new one.		
Voice Prompt : " Press the pads firmly to the bare skin of the patient"	The pads is not properly attached to the patient's skin.	Check if the pads is securely attached to the patient's skin.		
Voice Prompt : " No shock delivered"	The pads is not properly adhering to the patient's skin.	Press the pads firmly to the patient's skin. Shave chest hair or wipe off moisture if necessary before attaching the pads.		
Voice Prompt : " Shock button was not pressed"	Although an electric shock is needed, the Shock Button was not pressed within 15 seconds.	Deliver an electric shock by pressing the Shock Button with the next voice instruction.		

- If the problem cannot be solved during an emergency, you should follow the following steps:
  - Quickly replace the defibrillator if possible.
  - If no replacement device is available, check the patient's condition and perform CPR as
     necessary. Continuously check the patient's condition and perform CPR until the emergency
     medical services arrives.

## 8.3.2 Troubleshooting While the Device is not Operating

Symptom	Cause	Resolution
		Press the i-Button and hold for at
		least 1 second. The device then
		goes into Administration Mode.
		After going into Administration
		Mode, the device will issue the
Status LCD •		voice instruction "Press the
<b>Y</b>	System error	flashing red i-Button"
Device Operation		
		Press the flashing red i-Button and
		the device will then announce
		system error and the associated
		error code.
		Contact us by referring to [Chapter
		9: Device Service].

• If the problem is not resolved or if no replacement battery is available, contact the manufacturer (refer to [Chapter 9: Device Service])

## 9. Device Service

#### **Device Warranty**

Device Name	Model Name	
Purchase Name	Serial No.	
Distributor	Person in Charge	

- This device is warranted by CU Medical Systems, Inc. against defects in materials and workmanship for five full years from the date of original purchase. During the warranty period, we will repair or, at our option, replace at no charge a device that proves to be defective, provided you return the device, shipping prepaid, to us or to our authorized representative.
- This warranty does not apply if the device has been damaged by accident or misuse or as the
  result of service or modification by entities other than CU Medical Systems, Inc. or its authorized
  representatives. IN NO EVENT SHALL CU MEDICAL SYSTEMS BE LIABLE FOR
  CONSEQUENTIAL DAMAGES.
- Only devices with serial numbers and their accessories are covered under this warranty.
   PHYSICAL DAMAGE CAUSED BY MISUSE OR PHYSICAL ABUSE IS NOT COVERED UNDER THE WARRANTY. Items such as cables and modules without serial numbers are not covered under this warranty.

#### **Warranty Disclaimer**

The following renders this warranty null and void:

- · Servicing by unauthorized personnel.
- If the factory seal is broken without proper authorization from CU Medical Systems, Inc.
- Failure or damage caused by a fall or external shock after purchase
- Damage by natural disasters such as fire, earthquake, flood and/or lightning
- · Failure or damage by environmental pollution or abnormal voltage
- Damage caused by storage in conditions beyond the specified limits.
- · Failure due to depletion of consumables
- · Failure caused by sand and/or soil getting inside the device
- The purchase date, customer name, distributor name, batch number and other listed information being arbitrarily changed
- · No proof of purchase provided along with the device warranty
- Usage of accessories and parts not recommended by the manufacturer.
- Other failure or damage caused by inappropriate operation.

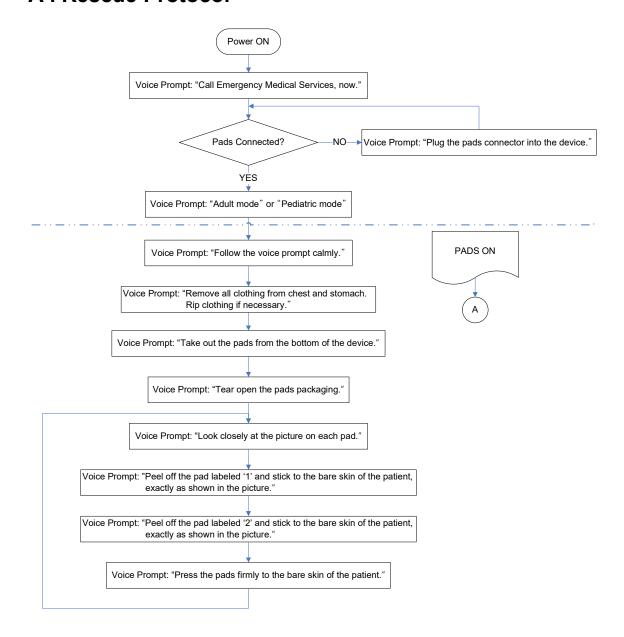
#### Service

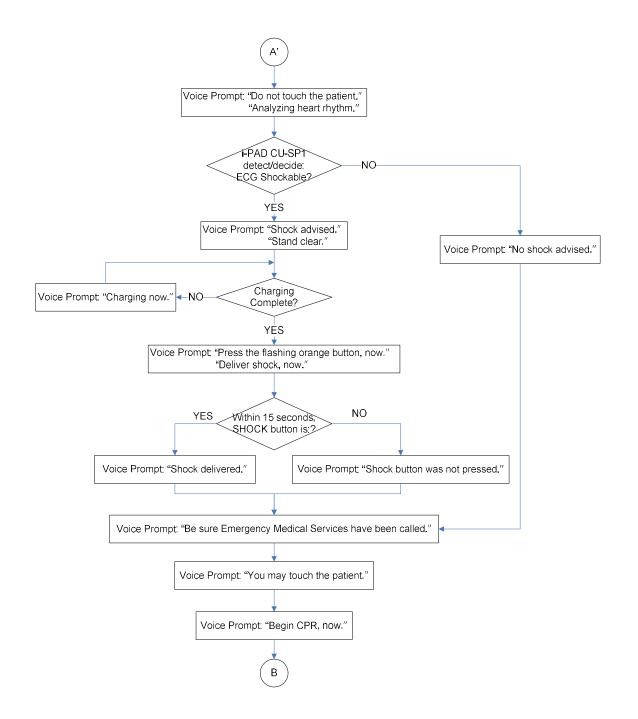
- The CU-SPR must be serviced only by authorized personnel.
- The CU-SPR will be serviced free of charge during the warranty period. After the warranty period, the cost of material and service shall be shouldered by the user.
- When the CU-SPR is not operating properly, immediately bring it for servicing to an authorized service center.
- Please fill out the following table with the necessary information when requesting for service.

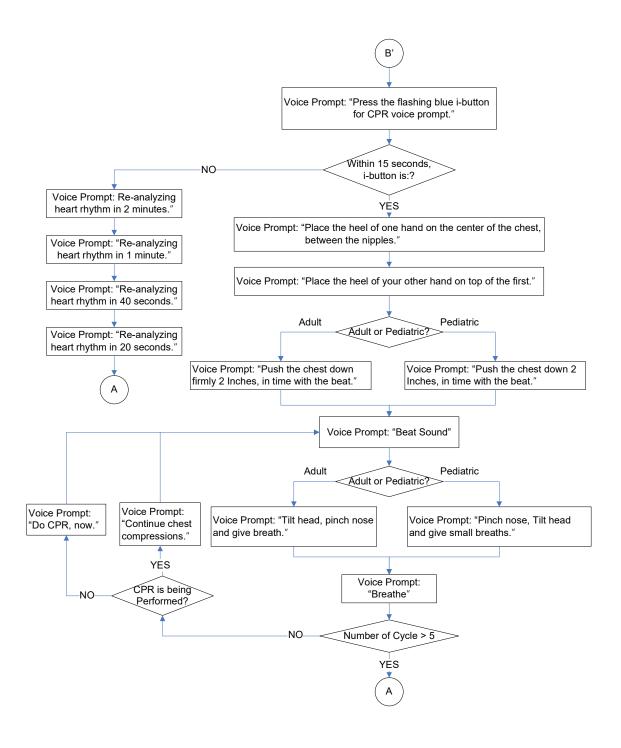
Device classification		Semi-Automated External Defibrillator		
Device Name		i-PAD	Model Number	CU-SPR
Serial N	Serial Number		Date of Purchase	
Sales Rep	resentative			
User	Name			
Information	Address			
IIIIOIIIIalioii	Contact no.			
Brief description of the problem				

## **Appendix**

## A. Rescue Protocol







## **B** . Parts and Accessories

To order replacement parts and accessories, cite the part and ordering numbers given in the following table.

B.1 Standard Accessories			
Name	Part Number	Ordering Number	
Adult/Pediatric Pads (disposable)	CUA1904S	SPR-OA02	
Disposable Battery Pack	CUSA1103BS	SP1-OA03	
Instructions for Use	SPR-OPM-E-01	-	
B.2 Optional Accessories	B.2 Optional Accessories		
Carrying Case	SPR-A-BAG-3010	SPR-OA01	
IrDA Adapter	IR-220LPLUS	SP1-OA06	
PC S/W	CU Expert ver. 3.50 or higher	SP1-OA07	
SD Card	HD1-CARD-SD	SP1-OA10	
SD Card Reader	HD1-CARD-READER	-	

# **C** . Description of Symbols

## C.1 CU-SPR Defibrillator

Symbol	Description
	Power ON/OFF button
i	i-Button
4	SHOCK button
(1 - 8)	Adult / Pediatric Selection Switch
	Do-Not-Touch-Patient Indicator
Contract of the contract of th	CPR Detection Indicator
<b>┤</b>	BF type, defibrillation-proof equipment
<u> </u>	Attention: Refer to accompanying documents.
<b>C</b> € 2460	CE Mark; meets the requirements of the European Medical Device Directive 2007/47/EC and its revisions.
SN	Serial Number
~~	Date of manufacture
EC REP	Authorized EU Representative
A	Do not discard the battery indiscriminately.
	Discard in accordance with local regulations.
	Manufacturer
<b>③</b>	Refer to instruction manual/booklet
<u> </u>	General warning sign
$\bigcirc$	General prohibition sign

## C.2 CU-SPR Packaging

Symbol	Description
6	Stack up to 6 cartons high only
<u>††</u>	This side up
Ť	Keep dry
	Fragile; breakable
<b>C</b> *	Use no hooks
100°F / 43°C	Storage Temperature limits: 0°C to 43°C(32°F to 109°F)
	Recyclable
<b>C</b> € 2460	CE Mark; meets the requirements of the European Medical Device Directive 2007/47/EC and its revisions.
EC REP	Authorized EU Representative
SN	Serial Number
~~	Manufactured Date

### C.3 Accessories

## C.3.1 Disposable Battery Pack (CUSA1103BS)

Symbol	Description
LiMnO <sub>2</sub>	Lithium Manganese Dioxide Battery
LOT	LOT Number
~~	Manufactured Date
	Manufacturer
	Do not break or apply pressure on the battery.
	Do not discard the battery indiscriminately.  Discard in accordance with local regulations.
(3)	Refer to instruction manual/booklet
<u>^</u>	General warning sign
	Warning: Flammable material
(€	CE Mark

#### C.3.2 Pads (CUA1904S)

Symbol	Description
0C 710F	Temperature limits: 0℃ to 43℃(32°F to 109°F)
LOT	Lot number
	Expiration date
REF	Order reference number
2	Single use only; do not reuse
	Do not fold or bend.
Contains no Latex	Contains no latex
EXP. MM / YYYY	Expiration Date and Lot number sticker
<u></u>	Attention: Refer to accompanying documents
<b>C €</b> 2460	CE Mark; meets the requirements of the applicable European directive

### D. Glossary

1 CPR

1 CPR consists of 5 cycles. (When the device is set to 5 cycles as default)

1 Cycle

Refers to 30 chest compressions followed by 2 breaths during CPR. (When the device is set to the default setting [30:2]) If you specify the number of compression and number of breath, the cycle is performed in accordance with the specified protocol. Refer to [Section 5.3: Device Setting] for detailed setting method.

**Abrasive** 

A material used to sharpen and clean the surface of metal, glass, stone and wood, which includes emery, quartz powder and glass dust. Do not use these abrasives to clean the device.

Adhesive Material on the Pads (Gel)

The adhesive material on the pads is very important for maintaining the optimum adhesion between the skin and pads. Therefore, never open the pads package when the pads is not needed, and periodically check the expiration date of the pads.

**Adult** 

The adult in these Instructions for Use is defined as a person who is older than 8 years or heavier than 25 kg.

American Heart
Association (AHA)
2010 CPR
Guidelines

The default settings of this device direct the you to perform CPR immediately after one electric shock in accordance with the 2010 CPR Guidelines. Also, the CPR guide is composed of 5 cycles with the chest compression to ventilation ratio of 30:2 (if the device is set to a default setting of 5 cycles, 30:2). If you are not trained in ventilation, perform only the chest compression. Refer to [Section 5.3: Device Setting] for the CPR setting. Please contact the manufacturer for additional information.

**Arrhythmia** An abnormal heart rhythm.

**Battery Pack** A disposable battery that supplies power to the CU-SPR.

Cardiac Arrest A patient with cardiac arrest symptoms. This device should be

Patient used for the patient with the following symptoms: No

response, no movement and no normal breathing.

**Communication** A port that sends and receives data between the device and

Port PC.

**Condensation** Moisture has an adverse effect on the device when

condensation is formed on the device surface. The device should be stored in a dry environment without excessive

humidity.

CPR Mode The device provides guidance for CPR while pausing analysis

of the patient's ECG such that you can easily perform CPR.

The CPR mode on this device complies with AHA's 2010 CPR

Guidelines. Refer to [Section 4.3., Step 3: Perform CPR] for

more information.

**Defibrillation** Is a process in which an electronic device gives an electric

shock to the heart. This helps reestablish normal contraction rhythms in a heart having dangerous arrhythmia or in cardiac

arrest.

**Defibrillator Pads** A connector on the device that is used to connect the device

**Connector** with defibrillator pads.

**Disposable Battery** A disposable battery pack that provides power to the device.

Pack Never charge this battery pack.

ECG An abbreviation for electrocardiogram. A record of the heart's

electrical rhythm as detected by the defibrillation pads.

Electric Shock This device charges large energy in a short time and performs

defibrillation via an electric shock.

**Error** A status in which the device does not properly operate. Refer

to [Section 8.3: Troubleshooting] for more information.

**Fibrillation** Refers to an irregularity of the heart causing ineffective

circulation. Ventricular fibrillation is accompanied with an

acute cardiac arrest.

**Flashing** A status in which the indicator is flashing.

**i-Button** A button to check the most recent device usage, to report

error messages, to transfer the ECG and event data, and to

change the CPR guide settings.

IrDA Port A communication port that sends and receives data between

the device and computer. Since this IrDA port utilizes light (infrared), care needs to be taken to reduce interference.

Refer to the [CU Expert] manual for more information.

**Light** A status in which the indicator is lit.

Operation Mode An O on the Status LCD while the device is on indicating

that the device is properly operating.

Pads The pads stated in these Instructions for Use refers to a pads

(disposable) for defibrillation.

Pad 1 Refers to a pad that is placed under the right clavicle. Please

refer to the picture on the pad. (The position may be switched

with pad 2.)

Pad 2 Refers to a pad that is placed on the ribs on the patient's

lower left chest directly under the armpit. Please refer to the

picture on the pads (the position may be switched with pad 1).

Pads Connector The connector on the pads that is used to connect the pads

with the CU-SPR.

PC S/W CU Expert

(CU-EX1)

PC software used to modify the settings of the CU-SPR and

to manage treatment data. Refer to the appendix on

accessories if you want to purchase this software.

**Pediatric** The child in these Instructions for Use is defined as a person

who is older than 1 year and younger than 8 years as well as

lighter than 25 kg.

**Power Button** A green button on the front of the device. The device turns on

when the Power Button is pressed during Standby Mode, and it turns off when the Power Button is pressed for one second while the device is on. If the Power Button is pressed during

the battery insertion test, the battery insertion test is canceled.

**Device** The Device referred to in these Instructions for Use is the CU-

SPR Semi-Automated External Defibrillator (AED).

Pads liner The liner that protects the conductive gel of the pads during

storage inside the pads pouch.

SD Card An external memory card that could be used to store

treatment data (ECG and event) from the internal memory of

the device.

**Self- Test** Self diagnostic tests that verify the proper operation of the

subsystems of the device.

Internal discharge

(disarm)

The CU-SPR dumps the charge in its defibrillating capacitor into an internal load If you do not press the Shock Button or if

the device determines that the patient does not need an

electric shock due to the change in the patient's ECG.

**Semi-Automated** A device that delivers a defibrillating shock after analyzing **External** and recognizing a shockable rhythm. You must concur with **Defibrillator** the shock delivery by pressing the SHOCK button. (AED) The button that you must press to deliver an electric shock to **Shock Button** a cardiac arrest patient. **Standby Mode** The mode of the CU-SPR when the Power Button is OFF but the battery pack is inserted. If is ston on the Status LCD while the device is in standby mode, the device is ready to be used as needed in an emergency).

Refers to CU Medical Systems Inc.

We

## **E**. Device Specifications

Model Name: CU-SPR

Physical |

Category Nominal Specifications

**Dimensions** 260mm x 256mm x 69.5mm (Width x Length x Height)

Weight 2.4kg (Including the battery pack and pads)

Environmental =

Category Nominal Specifications

Operational Status (The device is in emergency use)

**Temperature**: 0 °C ~ **50** °C (32°F ~ **122**°F)

**Humidity**: 5% ~ 95% (non condensing)

**Standby Status** (The device is stored together with the defibrillator pads and the battery pack is inserted - ready to be used in an emergency)

Temperature:  $0^{\circ}$ C ~  $43^{\circ}$ C ( $32^{\circ}$ F ~  $109^{\circ}$ F)

**Humidity**: 5% ~ 95% (non condensing)

Storage /Transport Status (device only, no defibrillator pads and battery pack included)

**Temperature**:  $-20^{\circ}\text{C} \sim 60^{\circ}\text{C} (-4^{\circ}\text{F} \sim 140^{\circ}\text{F})$ 

**Humidity**: 5% ~ 95% (non condensing)

Altitude 0 to 15,000 feet (operational and storage)

**Drop** Withstands 1.2-meter drop to any edge, corner, or surface

**Vibration** Operating: Meets MIL-STD-810G Fig.514.6E-1, random

Standby: Meets MIL-STD-810G Fig.514.6E-2, swept sine(helicopter)

Sealing IEC 60529: IP55

**ESD** Meets IEC 61000-4-2:2008

**EMI (Radiated)** Meets IEC 60601-1-2 limits, method EN 55011:2016 +A1:2017

Group 1, Class B

EMI (Immunity) Meets IEC 60601-1-2 limits, method EN 61000-4-3:2006 +A2:2010 Level 3

(10V/m 80MHz to 2500MHz)

**Defibrillator** 

Nominal Specifications Category

**Operating Mode** Semi-automated

Waveform e-cube biphasic (Truncated exponential type)

**Output Energy** 150 J at 50  $\Omega$  load for adults

50 J at 50  $\Omega$  load for children

**Charge Control** Controlled by an automated patient analysis system

**Charging Time** Within 10 seconds from when the voice instruction, "An electric shock is

needed." is issued.

Time from initiation of rhythm analysis (voice instruction: New battery pack "DO NOT TOUCH PATIENT, ANALYZING HEART RHYTHM") 10 Seconds, typical

to readiness for discharge (voice instruction: "PRESS THE

New battery pack: 16th shock FLASHING ORANGE BUTTON, NOW. DELIVER SHOCK, NOW") discharge 11 Seconds, typical

Time from Power ON to readiness for discharge New battery pack: 16th shock (voice instruction: "PRESS THE FLASHING ORANGE discharge 25 Seconds, typical

**BUTTON, NOW. DELIVER SHOCK, NOW")** 

· Voice Instruction "Press the Flashing Orange Button, Now. Deliver Shock, Now" Charging

Indicator · Flashing Shock Button

Beeper

Time from CPR to At least 6 seconds from the completion of CPR to shock delivery Shock

Discharge

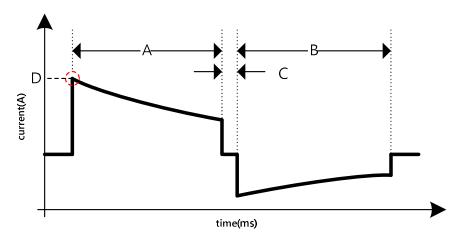
The device performs a self-discharge in the following events:

- When the patient's ECG changes to a rhythm that does not require defibrillation.
- · When the Shock Button is not pressed within 15 seconds from the completion of the charge.
- When the device is turned off by pressing the Power Button for at least second.
- When the pads is detached from the patient's body or the pads connector is detached from the device.
- · When the impedance of the patient is out of the range of defibrillation  $(25 \Omega \sim 175 \Omega)$

**Shock Delivery** Shock is delivered if the SHOCK button is pressed while the CU-SPR is armed.

**Shock Delivery** · Adult pads in the anterior-anterior position Vector · Pediatric pads in the anterior-posterior position

**Patient Isolation** Type BF, defibrillation protected



## **Biphasic Truncated Exponential Type.**

The shock waveform profile is automatically compensated for the patient's transthoracic impedance.

A = first phase duration

B = second phase duration0

C = interphase duration

D = peak current

### **Output Waveform for Adult (150 Joules)**

Patient Impedance (Ohms, Ω)	First Phase duration (milliseconds, ms)	Second Phase duration (milliseconds, ms)	Peak Current (A)	Energy (Joules, J)	Energy Accuracy (Joules, J)
25	2.4	2.4	64.5	147.8	150(±15%)
50	4.4	4.4	32.7	149.7	150(±15%)
75	6.3	6.3	22.5	151.5	150(±15%)
100	8.8	8.8	15.9	148.1	150(±15%)
125	10.7	10.7	13.0	149	150(±15%)
150	12.7	12.7	11.0	148.2	150(±15%)
175	15.0	15.0	9.5	148.8	150(±15%)

#### **Output Waveform for Child (50 Joules)**

Patient Impedance (Ohms, Ω)	First Phase duration (milliseconds, ms)	Second Phase duration (milliseconds, ms)	Peak Current (A)	Energy (Joules, J)	Energy Accuracy (Joules, J)
25	2.3	2.3	35.4	50.2	50(±15%)
50	4.3	4.3	18.4	50.7	50(±15%)
75	6.3	6.3	12.3	49.7	50(±15%)
100	8.5	8.5	9.1	49.5	50(±15%)
125	10.6	10.6	7.3	50.3	50(±15%)
150	12.7	12.7	5.8	49	50(±15%)
175	15.0	15.0	4.9	49.6	50(±15%)

**ECG Acquisition** 

Category Nominal Specifications

Acquired ECG Lead Lead II

Frequency Response 1 Hz to 30 Hz

#### **ECG Analysis System**

Category Nominal Specifications

**Function** Determines the impedance of the patient and evaluates the ECG of the

patient to

determine whether it is shockable or non shockable

Impedance Range  $25\Omega$  to  $175\Omega$  (shock will not be delivered if the patient's impedance is

beyond this range).

Shockable Rhythms Ventricular Fibrillation or Fast Ventricular Tachycardia

Non Shockable ECG rhythms excluding ventricular fibrillation and ventricular tachycardia

**Rhythms** When a rhythm that does not require defibrillation is detected, the device

directs you to perform CPR.

Analysis Protocol Prepare for shock delivery of pause for CPR, depending on the results of

analysis.

Sensitivity and

Meets ANSI/AAMI DF80 guidelines

**Specificity** 

## **ECG Analysis System - ECG Database Test**

ECG Rhythm Class	Rhythms	Minimum test sample size	Performan ce goal	Test sample size	Shock Decision	No Shock Decision	Observed Performance	90% One Sided Lower Confidence Limit
SHOCKABLE	Coarse VF	200	>90% sensitivity	219	213	6	97.26% (213/219) sensitivity	95%
	Fast VT	50	>75% sensitivity	137	111	26	81.02% (111/137) sensitivity	76%
NON SHOCKABLE	Normal Sinus Rhythm	100 minimum (arbitrary)	> 99% specificity	100	0	100	100% (100/100) specificity	97%
	AF,SB, SVT, heart block, idioven- tricular PVC's	30 (arbitrary)	> 95% specificity	219	1	218	99.54% (218/219) specificity	98%
	Asystole	100	> 95% specificity	132	5	127	96.21% (127/132) specificity	93%

#### Control Devices, Indicators, Voice Instructions

Category Nominal Specifications

Control Devices Power Button, i-Button, Shock Button, Adult/Pediatric Selection Switch

Status LCD Displays device status.

Indicator Do-Not-Touch-Patient Indicator: Lights when the defibrillator is analyzing or

delivering an electric shock.

Pads Position Indicators: Flashes when the defibrillator is turned on; turns off

when the pads is attached on the patient.

Pads Connector Status Indicator: Flashes red or yellow depending on the

status of the battery and pads

CPR Detection Indicator: Lights if CPR is detected; flashes if CPR is not

detected.

Shock Button: Flashes orange when the defibrillator is charged and ready to

deliver a shock.

Blue i-Button: Flashes when guiding CPR, transferring the treatment history

and setting the CPR mode.

Red i-Button: Flashes when an error occurs.

**Speaker** Plays back voice instructions.

Beeper Various beeping output

Battery Level The battery level is automatically performed during periodic self tests, power

ON self-test, and run-time self-test.

Shown on the Status LCD, announced via voice instruction, and indicated via

**Low Battery** the flashing red i-Button

Indicator When the device detects Low Battery, it warrants 10 shocks and 30 minutes of

operation.

**Voice Instruction** Guides the user via voice instructions.

#### Self-Diagnostic Test ■

Auto 
• Power On Self-Test, Run-time Self-Test

· Daily, Weekly, and Monthly Self-Test

Manual Battery Pack Insertion Test (done when the user inserts the battery pack into the

battery pack compartment of the device)

#### **Disposable Battery Pack**

Category Nominal Specifications

Battery Type 12V DC, 2.8Ah LiMnO<sub>2</sub>, Disposable: Standard

Capacity At least 50 shocks for a new battery

or 4 hours of operating time at room temperature

Standby Life (After At least 2 years from the date of manufacture if stored and

**Inserting the Battery)** maintained in accordance with the instructions in this document.

Ŧ

Temperature Ranges 

• Operating

Temperature: 0 °C ~ 50 °C (32°F ~ 122°F)

Storage

Temperature:  $-20^{\circ}\text{C} \sim 60^{\circ}\text{C} (-4^{\circ}\text{F} \sim 140^{\circ}\text{F})$ 

#### Adult Defibrillation Pads (CUA1904S)

Category Nominal Specifications

Type Adult/Pediatric

Electrode Area 120 cm<sup>2</sup>

Cable Length Total 120 cm (Inside the pouch: 95 cm, Outside the pouch: 25 cm)

**Shelf life** At least 24 months from the date of manufacture

### Data Storage and Transfer

Category Nominal Specifications

**IrDA** For PC communications

Internal Memory Data 5 individual treatments, up to 3 hours per treatment

Capacity

**SD Card** External memory. Data may be copied from the internal memory to the SD

Card.

## F . Electromagnetic Compatibility

#### Guidance and manufacturer's declaration - electromagnetic emissions

The CU-SPR is intended for use in the electromagnetic environment specified below. The customer or the user of the CU-SPR should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	The CU-SPR uses RF energy only for its internal function. Therefore, its emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The CU-SPR is suitable for use in all
Harmonic emissions IEC 61000-3-2	Not applicable	establishments, including domestic establishments and those directly connected to the public low-
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	voltage power supply network that supplies buildings used for domestic purposes.



The CU-SPR should not be used adjacent to or stacked with other equipment.
 If adjacent or stacked use is necessary, the CU-SPR should be observed to verify normal operation in the configuration in which it will be used.

## Guidance and manufacturer's declaration - electromagnetic immunity

The CU-SPR is intended for use in the electromagnetic environment specified below. The customer or the user of the CU-SPR should assure that it is used in such an environment.

Immunity Test	IEC 60601-1 test	Complianc e level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV Contact	±6 kV Contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative
Electrical fast transient/burst IEC 61000-4-4	±15 kV air  ±2 kV for power supply lines ±1 kV for input/output	±15 kV air  Not  Applicable	humidity should be at least 30%  Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines	<5 % U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycles  40 % U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles  70 % U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles  <5 % U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 s	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CU-SPR image intensifier requires continued operation during power mains interruptions, it is recommended that the CU-SPR image intensifier be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m mains voltage prior to ap	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

## Guidance and manufacturer's declaration - electromagnetic immunity

The CU-SPR is intended for use in the electromagnetic environment specified below. The customer or the user of the CU-SPR should assure that it is used in such an environment.

Immunity	IEC 60601 Test	Complia	Electromagnetic environment - guidance
Test	level	nce level	
			Portable and mobile RF communications
			equipment should be used no closer to any part
			of the CU-SPR, including cables, than the
			recommended separation distance calculated
			from the equation applicable to the frequency of
			the transmitter.
			Recommended separation distance
Conducted	3 Vrms	3 Vrms	3 5
RF IEC	150 kHz to 80 MHz		$d = \left[\frac{3.5}{V1}\right]\sqrt{P}$
61000-4-6	outside ISM bandsª		V 1
	10 Vrms	10 Vrms	12
	150 kHz to 80 MHz		$d = \left[\frac{12}{V2}\right]\sqrt{P}$
	in ISM bands <sup>a</sup>		V Z
Radiated	10 V/m	10 V/m	42
RF IEC	80 MHz to 2,5 GHz		$d=[rac{12}{F1}]\sqrt{P}$ 80 MHz ~ 800 MHz
61000-4-3			
	20 V/m	20 V/m	, r <sup>23</sup> 1 / P
	80 MHz to 2,5 GHz		$d=[rac{23}{E1}]\sqrt{P}$ 800 MHz ~ 2,5 GHz
			where P is the maximum output power rating of
			the transmitter in watts (W) according to the
			transmitter manufacturer and d is the
			recommended separation distance in metres
			(m) <sup>b</sup>
			Field strengths from fixed RF transmitters, as
			deter-mined by an electromagnetic site survey <sup>c</sup> ,
			should be less than the compliance level in each
			frequency range <sup>d</sup> .
			Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1. At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2.** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and refection from structures, objects and people.

The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765

MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz

The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CU-SPR is used exceeds the applicable RF compliance level above, the CU-SPR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CU-SPR

d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V / m.

Recommended separation distances between portable and mobile RF

#### communications equipment and the CU-SPR

The CU-SPR is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CU-SPR can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CU-SPR as recommended below, according to the maximum output power of the communications equipment.

Detect	Separation distance according to frequency of transmitter [m]							
Rated maximum output	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands	80 MHz to 8	300 MHz	800 MHz to 2,5 GHz			
power of transmitter	$d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	$d = \left[\frac{12}{V2}\right]\sqrt{P}$	$d = \left[\frac{12}{E1}\right]\sqrt{P}$		$d = \left[\frac{23}{E1}\right]\sqrt{P}$			
[W]	V1 = 3 Vrms	V2 = 10 Vrms	E1 = 10 V/m	E1 = 20 V/m	E1 = 10 V/m	E1 = 20 V/m		
0.01	0.06	0.12	0.12	0.06	0.23	0.16		
0.1	0.11	0.38	0.38	0.19	0.73	0.36		
1	0.35	1.20	1.20	0.60	2.3.0	1.15		
10	1.11	3.79	3.79	1.90	7.27	3.64		
100	3.50	12.00	12.00	6.00	23.00	11.50		

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE 1)** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 2)** The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

**NOTE 3)**An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

**NOTE 4)** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and refection from structures, objects and people