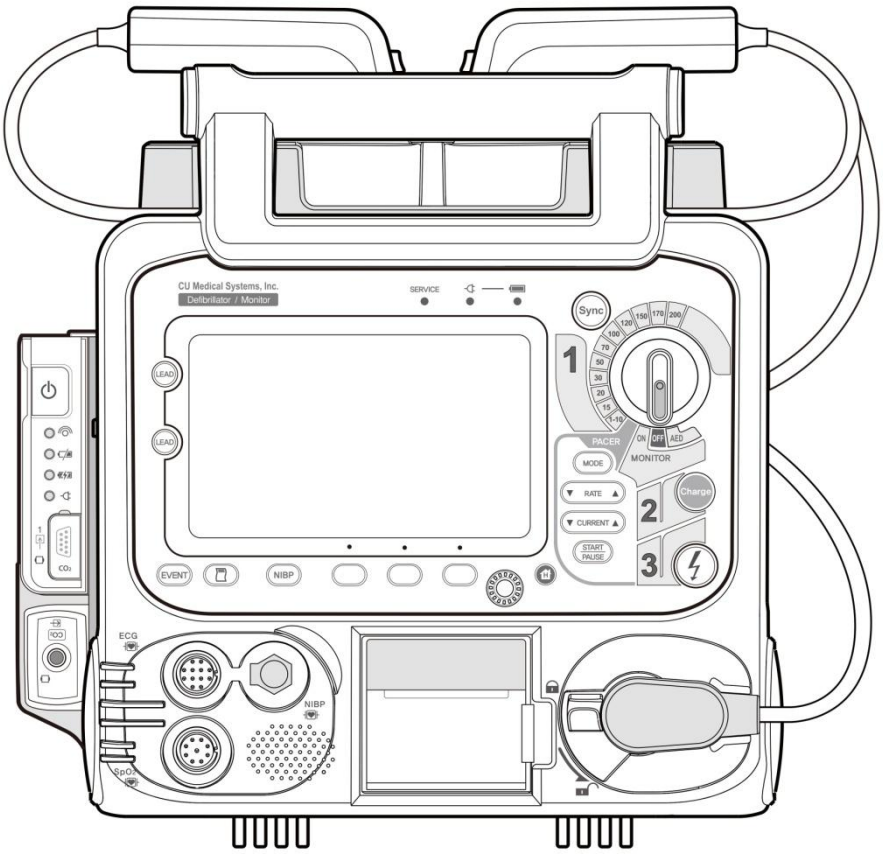

CU-HD1

This Operation manual is intended to provide information needed to use CU-HD1 that is developed and manufactured by CU Medical Systems, Inc.

Also this Operation manual is subject to change without prior notice.

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◎ Before You Begin

Thank you for purchasing **CU-HD1**. In order to use this product safely, it is necessary to familiarize yourself with this introduction manual and fully understand the operation methods and cautions before using the product.

CU-HD1 and CU Medical Systems, Inc. hereinafter referred to as "the Product" and "the Company" respectively.

This device provides the Automated External Defibrillator (AED) function, Manual Defibrillator function, Non-Invasive Pacing function and Patient Monitoring function.

Caution

High-voltage and high-current electric energy is applied to the defibrillator. Therefore, be sure to read through this Operation manual so that you can fully understand the safety cautions, operation methods, and general cautions before using this product.

◎ General Instructions

When using the product, be sure to follow instructions described in this Operation manual.

It is recommended to place the instruction manual near the product and refer to it when unsure about an item or a defect has possibly occurred.

In no event, shall the company be liable for any product problems arising out of careless operation or negligent misuse by the user.

All of the repair services for the product can provided only by CU MEDICAL SYSTEMS, INC. or its authorized agents.

Use only parts and accessories that are recommended by the company.

When you want to use the product in connection with other devices for which no usage instructions are provided in this Operation manual, be sure to contact us before starting operation.

If this product does not operate normally, stop using the product immediately, contact our company or a certified agency, notify of the failure details and request a repair.

◎ About This Operation Manual

◎ About This Operation manual

■ Contents of This Operation manual

This instruction manual includes necessary information for the user to operate this product correctly. If you have any questions or have any problems using the product, please contact us.

■ Safety Instructions and Cautions

※ In this Operation manual, following terms are used to highlight safety-related cautions that must be observed during the use of the product. You must fully understand the safety-related cautions described in this Operation manual to safely use the product.

※ If an injury has occurred to the user or a patient due to a clear instance of user negligence or misuse, the company or its authorized agent holds no liability.

Warning

A case that could result in dangerous situations, including death or severe injury if instructions are not observed

Caution

Instruction that directly or indirectly addresses the company policy in order to protect people or property

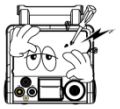
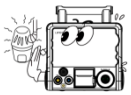
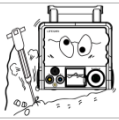
Note

Explanation of reference terms or additional operating methods for normal product usage

◎ Storage and Usage Environments

◎ Cautions for Installing and Storing the Product

For product installation and storage, be sure to refer to the following instructions and avoid damages to the product.

Symbol	Instruction
	Avoid installing or storing the product in a location with high humidity where is exposed to moisture or poor ventilation.
	Avoid installing or storing the product in a location with significant temperature variation. • Operation environment: Condition where both device and pads must be stored together, and are immediately usable in an emergency case. Temperature range: 0℃~40℃, Humidity range: 5%~95%, Non-condensing • Storage environment: Condition where device and pads are not stored together with device that has been stored or transported for a long time Temperature range: -20℃~60℃, Humidity range: 5%~95%, Non-condensing
	Avoid installing or storing the product in a location with a leak of chemicals or inflammable gas.
	Do not disassemble the product arbitrarily. In this case, the company is under no obligation.
	Avoid installing or storing the product in a location exposed to direct sunlight.
	Avoid installing or storing the product in a location near an electric heating appliance.
	Avoid installing or storing the product in a location where it may receive excessive impacts from vibrations.
	Proper caution must be taken to avoid exposure to impurities. Especially, great caution must be taken to avoid exposure to metal impurities.
	When disconnecting the power cord from the wall outlet, have it gently pulled out by grabbing the plug and not the cord.

◎ Storage and Usage Environments

◎ Storage and Usage Environments

※ Check for abnormalities on the exterior of the product, and if detected, contact and have the retailer inspect the product before using it.

※ If the product has been submerged under water, contact and have the retailer inspect the product before using it.

※ The status of the battery charge must be periodically monitored during the storage. Ensure that the remaining battery is sufficient (for operating the device).

※ If the battery is completely discharged while using the device, you can use the device while charging the battery by connecting the AC power module. At this time, turn off the device, connect the AC power module, and then turn on the device again.

※ Do not operate the device in electrically noisy environments near motors, generators, X-ray equipment, wireless transmitters or mobile phones as these will interfere with the signals being acquired. Such electrical noise interference may lead to a malfunction of the device.

※ After using the device, thoroughly clean the main body using a soft, dry cloth.

※ If the battery has been stored for a long period of time, charge the battery periodically. This will help preventing the occurrence of low battery level.

Warning

- Use the AC power adapter and car cigar jack in order to only recharge the battery.
- Do not use the device with the AC power adapter and car cigar jack connected to it.

Chapter 1. Product Introduction

The CU-HD1 is a medical device that is operated by battery and AC power.

This product is a medical device designed to be used by Level 1 and Level 2 emergency medical technicians and medical professionals.

This product provides the automated external defibrillation function and the manual defibrillation function. This product also provides the synchronized cardioversion function, transcutaneous pacing function, and patient monitoring function.

This product also has the Synchronized Cardioversion function, Transcutaneous Pacing function, and Patient Monitoring function. This product can be used by emergency medical technicians and medical professionals.

You can use the functions of the device with simple button operations, and check various information through the screen while using the product.

1.1 Intended Use

1.1.1 AED Mode

The Defibrillation function delivers an electric shock to a patient showing the symptoms of sudden cardiac arrest, such as ventricular fibrillation and ventricular tachycardia, in order to restore the normal ECG rhythm.

※ A patient with sudden cardiac arrest is a person with
① no response and
② no normal breathing.

In the Automated External Defibrillation (AED) mode, the patient's ECG obtained through the defibrillation pads is analyzed automatically and the guidance is provided through the voice and message, informing the user to press the electric shock button.

Warning

The product must not be used in AED Mode on patients who show any of the following symptoms: responsiveness, normal movement, normal breathing and a detectable pulse.

1.1.2 Manual Defibrillation Mode

In the manual mode an electric shock is delivered to a patient with arrhythmias according to the patient's status for treatment while checking the patient's signal directly.

Manual Mode is divided into two functions such as asynchronous defibrillation and synchronized cardioversion.

The Synchronized Cardioversion function analyzes the QRS of the patient's ECG to enable execution of the defibrillation according to the R wave.

In the manual mode, the synchronized cardioversion treatment can be used for a patient with unstable tachyarrhythmia, such as atrial flutter or atrial fibrillation, and a patient with cardiac ischemia who has insufficient blood volume.

Warning

- When the product is used for asynchronous defibrillation treatment in Manual mode, do not use it on patients who show any of the following symptoms:
  - responsiveness, normal movement, normal breathing and detectable pulse.
- There is a possibility of explosion or fire if the product is used in the presence of flammable agents or in an OXYGEN enriched atmosphere due to the arc discharged caused by electric shock.
- Do not deliver an electric shock when the patient's ECG signal is in the asystole state. It may lead to a failure to restore cardiac pacemaker functions in the heart, meaning the cardiac function will not be restored.
- This product must not be applied on patients implanted with the implantable pacemaker. If patients show all of the symptoms including no response, and abnormal breathing, use the product in the following ways:
  - Attach the pad at least 3cm away from the implantable pacemaker attached to the patient.
  - Do not attach the pad right on the area implanted with the implantable pacemaker.

1.1.3 Pacer Mode

Pacing is a method applied to patients who had lost natural cardiac movement functions, mostly used on patients with bradycardia.

The CU-HD1 functions to support non-invasive pacing, a way of helping maintain a patient's pulse by attaching its electrode to the patient's skin and delivering artificial electric stimulation to the heart.

Pacing mode is divided into the 'Fixed mode' and the 'Demand mode'.

Consult a physician and follow the manufacturer's instructions before treating a person with a permanent pacemaker or an implantable cardiac defibrillator. Pacing therapy should only be performed by trained medical personnel.

1.1.4 Patient Monitoring Mode

Patient monitoring mode features the ECG monitoring function, the function to measure the level of SpO_2, functional oxygen saturation in the blood, the function to measure the non-invasive blood pressure, and the function to measure the end-tidal carbon dioxide ($EtCO_2$).

For the ECG monitoring function, you can selectively use the 3-lead, 5-lead, or 10-lead ECG cables. If the patient's ECG is analyzed while monitoring the patient and if ventricular fibrillation or ventricular tachycardia occurs or it exceeds or falls below the range of set ECG, the alarm function will be activated.

SpO_2 is a noninvasive method of measuring functional oxygen saturation (SpO_2) in arterial blood. SpO_2 readings indicate the percentage of hemoglobin molecules in arterial blood which are saturated with oxygen.

A noninvasive blood pressure measuring device is divided based on patient status (adult, child and infant - classified as For adults, children, and infants and is used with an appropriate cuff to measure a patient's blood pressure.

End-tidal carbon dioxide ($EtCO_2$) provides end-tidal CO_2 level of the patient to monitor breathing or to determine whether CPR is being performed correctly.

※ For more detailed information about the patient monitoring mode, please refer to "Chapter 7_Patient Monitoring".

1.2 User-Specific Functions

1.2.1 Intended Users

The AED mode and Patient Monitoring mode can be used by Level 1 and Level 2 emergency medical technicians and medical professionals. The Manual Defibrillation mode and the Non-Invasive Pacing mode should be carried out by a medical professional.

1.2.2 Limited Usage by Users

The CU-HD1 is a product featuring the defibrillation, pacer and patient monitoring functions. Such product features are designed to apply to only one patient, and it is forbidden to use such features on more than two patients. For the purpose of maintaining patient records, the product must be used on only a single patient.

To apply the defibrillation or pacing functions on the emergency patient who is currently using the implantable cardiac defibrillator (ICD) or the cardiac resynchronization therapy defibrillator (CRT-D), you must contact a medical specialist.

⚠ Caution

- Do not use this Product on more than one patient at the same time.
- When using the storage function, initialize equipment usage time so that you can identify the specific patient information from others. If you set the Rotary switch to OFF for about 10 seconds, the device usage time will be initialized.

Chapter 2. Components of the Product

The CU-HD1 is comprised of a main body and various accessories.

This chapter is intended to provide information about the exterior view of the product, various buttons and indicators on the main body, Bluetooth communications with linkage to the outside, a real-time printing printer, screen symbols, texts and voice signals that intend to bring convenience to users.

Also, this chapter includes the guidelines on accessories mounted on the main body which are the power module, ECG cable, SpO_2 sensor, NIBP cuffs, and $EtCO_2$ module, etc.

Warning

- As for the pads designed and manufactured for the therapeutic purpose, ECG cables, and other related accessories except for disposable consumables, you must use what is provided by the CU Medical Systems, Inc.

Caution

- When there is any damage in disposable consumables or accessories, stop using the device and contact a customer service center for replacement. Also, if damage occurs to the equipment cable or reusable paddles, please contact a service center.

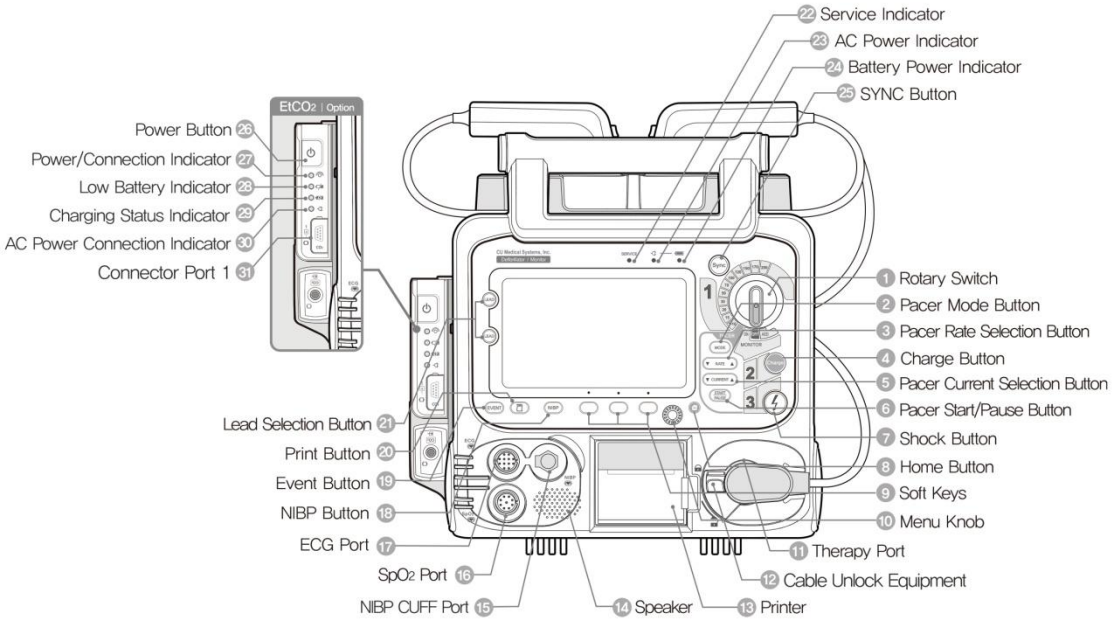
Note

- If your CU-HD1 does not have some of the optional functionality listed in this chapter, disregard these controls and the related information described throughout this manual.

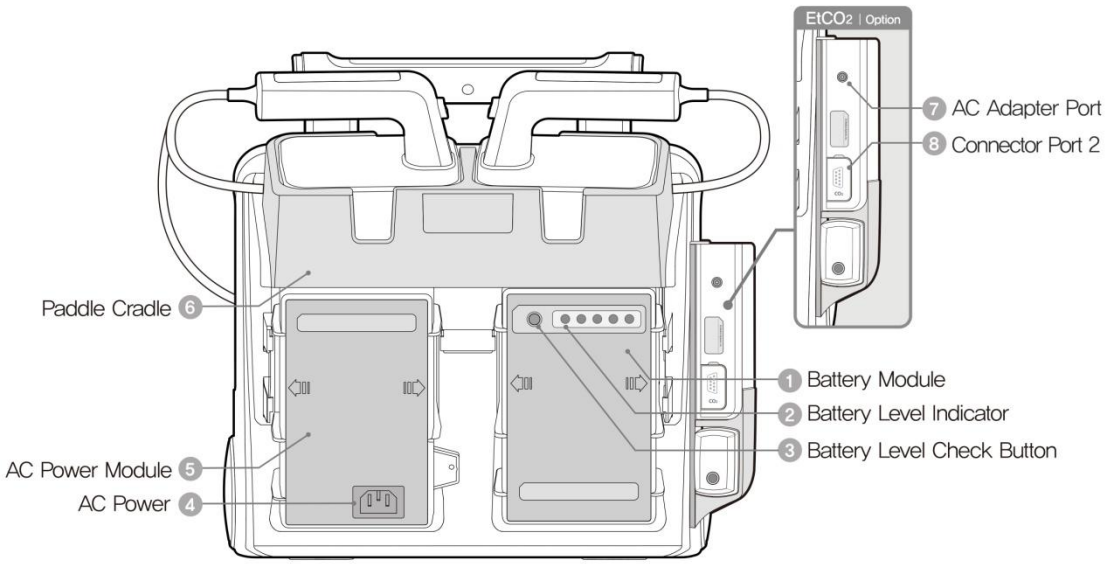
◎ Chapter 2_ Components of the Product

2.1 Exterior View of Product

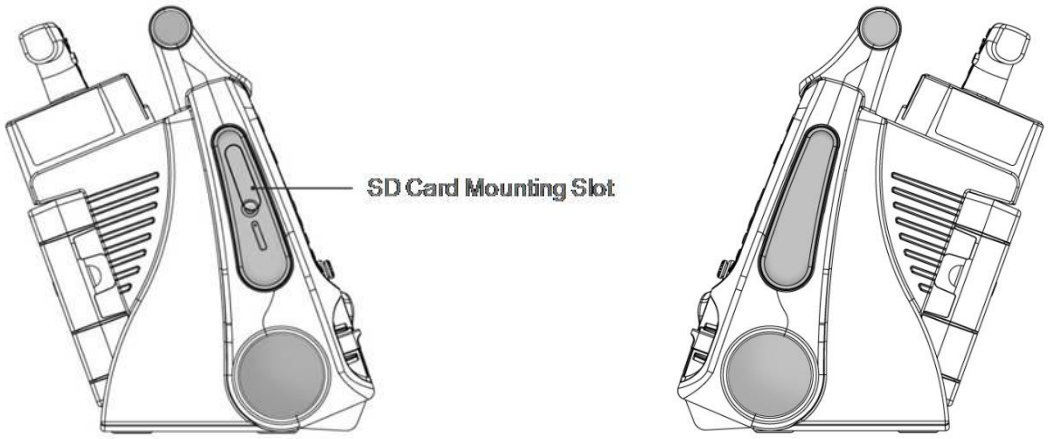
2.1.1 Front View



2.1.2 Rear View



2.1.3 Left/ Right Side View



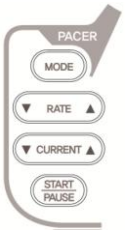
2.2 Switches and Buttons

There are ten buttons on the main body including switches to change the defibrillation mode and energy settings.

※ Each button's function is described below.

1) CU-HD1

Button	Function
	**Rotary Switch (Mode / Energy Selection Switch)** This button is used to select the desired mode (AED, Monitor, Manual) and turn the power on/off. When the mode is selected, the power is turned on simultaneously. When Manual mode is used, the user can select the volume of electric shock energy (1-10, 15, 20, 30, 50, 70, 100, 120, 150, 170, 200 Joule).
	**Charge Button** When an electricity shock needs to be done in the manual defibrillator mode, the defibrillation energy is charged according to the setting on the Rotary switch by pressing this button. When the battery has been completely recharged, the orange lamp of the Shock button will be on.
	**Shock Button** When a defibrillation electric shock is needed through an ECG signal analysis, the orange lamp of the Shock button will be on. By pressing the button at this time, the electric shock will be delivered to the patient.
	**Menu Knob** This key is used to navigate around the menu and select each mode. In addition, the entry of patient information and device setup can be done.
	**Soft Keys** These buttons facilitate selecting necessary functions in each mode.

Button	Function
	**SYNC Button** In the manual defibrillator mode and pacer mode, it is used for synchronized cardioversion. It analyzes the patient's ECG signal and synchronizes the transfer of defibrillation energy with the R wave among the QRS of the ECG signal within 60ms.
	• Pacer Mode Button Selects either the 'Fixed mode' or 'Demand mode' out of pacer modes for noninvasive cardiac pacing therapy. • Pacer Rate Selection Button: Controls the pacing rate. The pacer rate control buttons on right and left adjust the pacing rate. • Pacer Current Selection Button: Sets up the pacing current output using the pacing current control buttons on right and left. • Pacer Start/Stop Button Starts and stops the pacing therapy.
	**Lead Selection Button** The lead of the ECG that is indicated in the LCD can be chosen.
	**Print Button** Outputs the real-time ECG information or stops any printing during the printing process.
	**NIBP Button** Starts/Stops noninvasive blood pressure measuring.
	**Home Button** While changing the settings in the menu, pressing this button exits out from the menu screen.
	**Event Button** The medicine information given to patients is entered.

2) CU-CM1

Button	Function
	**Power Button** This button is used to select power on/off of CU-CM1

2.3 Indicators

1) CU-HD1

The indicators are located right over the main body's LCD display as shown below. They function to indicate the power state of the device or any problems that may happen in the device.

※ The symbols marked in the above indicators are summarized below.

Indicator	Description
	This indication shows whether the power is fed from the commercial power source through an AC power module, or from the car cigar jack.
	Once the battery is attached to the device, the LED lights up in green. When the green LED is blinking, it indicates that the battery is being charged through the AC power module and the car cigar jack. Once the charging is completed, it lights up in green.
SERVICE	When there is any problem in the system, the SERVICE LED lights up. If this happens, the device does not operate normally. Therefore, stop using it immediately and contact an authorized service center to repair the product.

2) CU-CM1

The four indicators are located on the left side of CU-CM1.

※ The symbols marked in the indicators are summarized below.

Indicator	Description
	**Power/Connection Indicator** The blue indicator will light up when the product turns on. If the CU-CM1 is in communication with the CU-HD1 via Bluetooth while measuring CO_2, the blue indicator will blink in 1 second intervals.
	**Low Battery Indicator** The yellow indicator will light up when the remaining battery of the CU-CM1 falls below 20%. Recharge the battery when the Low Battery Indicator turns on.
	**Charging Status Indicator** The green indicator will light up when the battery is charged with AC power. The indicator will turn off when battery charging is complete
	**AC Power Connection Indicator** The green indicator will light up when AC power is connected to the product.

3) IRMA Mainstream gas analyzer

※ The indications of the above indicator are summarized below.

Steady green light	System OK
Blinking green light	Zeroing in progress
Steady red light	Sensor error
Blinking red light	Check adapter

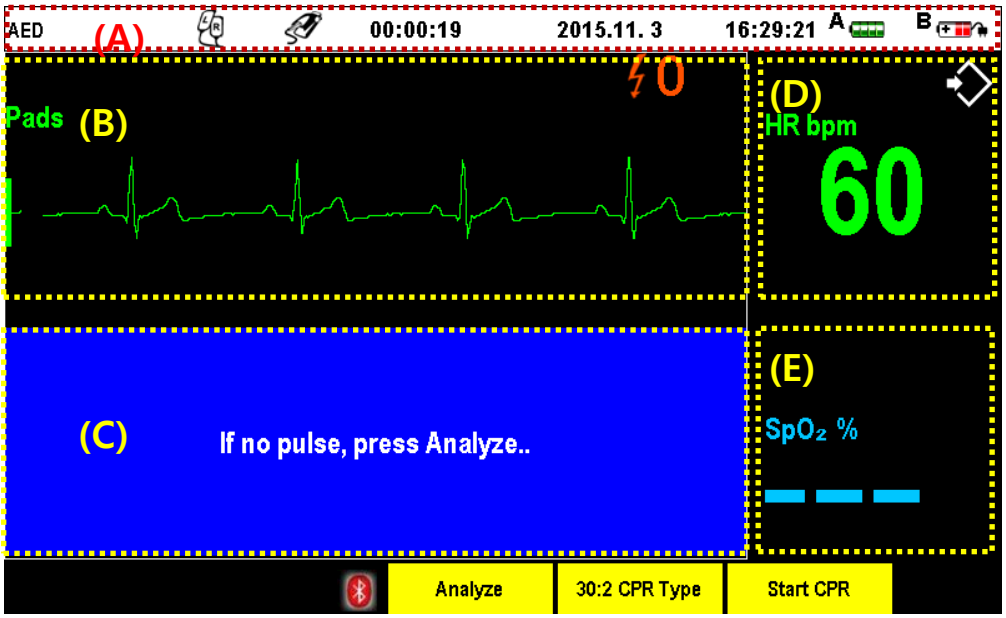
2.4 Screen Layout Elements

The CU-HD1 screen is differently composed depending on individual modes (AED, Manual Defibrillation, Pacer, and Patient Monitoring).

2.4.1 Screen Layout

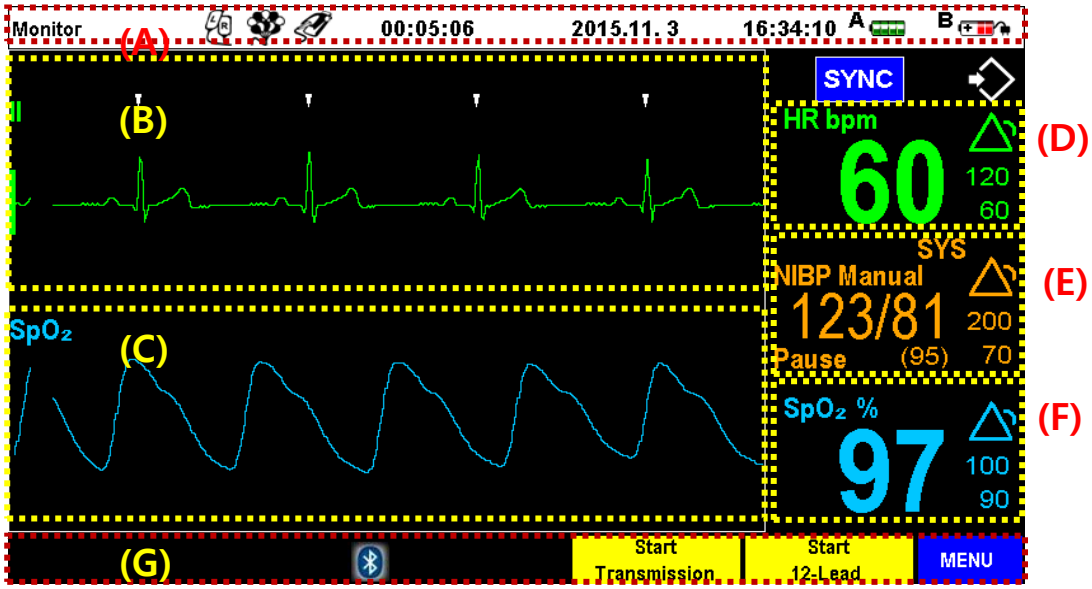
The screen shown on the LCD of the product is sectioned as shown in the figure below. According to the function of the CU-HD1, a different screen layout is displayed and the basic screen layout is shown below.

1) AED Mode



Screen Layout		
(A)	Device state indication area	Shows mode in use, connector state, Duration of device usage, current time, date, and power state
(B)	Sector 1	Display of ECG measured through the pads
(C)	Sector 2	Shows text prompt guides and progress of AED procedure
(D)	Heart rate indication area	Shows beat per minute(bpm)
(E)	SpO_2 indication area	Shows SpO_2(%)
(F)	Menu & Soft button area	Soft buttons to start analyze, change CPR type, start/stop CPR, and menu creation

2) Manual Defibrillation Mode, Patient Monitoring Mode, and Pacer Mode



Screen Layout		
(A)	Device state indication area	Shows mode in use, connector state, Duration of device usage, current time, date, and power state
(B)	Sector 1	Vital signs measured through the ECG electrodes, pads, paddles or sensors
(C)	Sector 2	
(D)	Heart rate indication area	Shows beat per minute(bpm), predefined alarm limit
(E)	NIBP indication area	Shows blood pressure(mmHg), Systole/diastole, mean blood pressure, predefined alarm limit
(F)	SpO_2 display area	Shows SpO_2(%),predefined alarm limit
(G)	Menu & Soft button area	Creates soft button menu by mode, shows alarming message, and Bluetooth connection

Caution

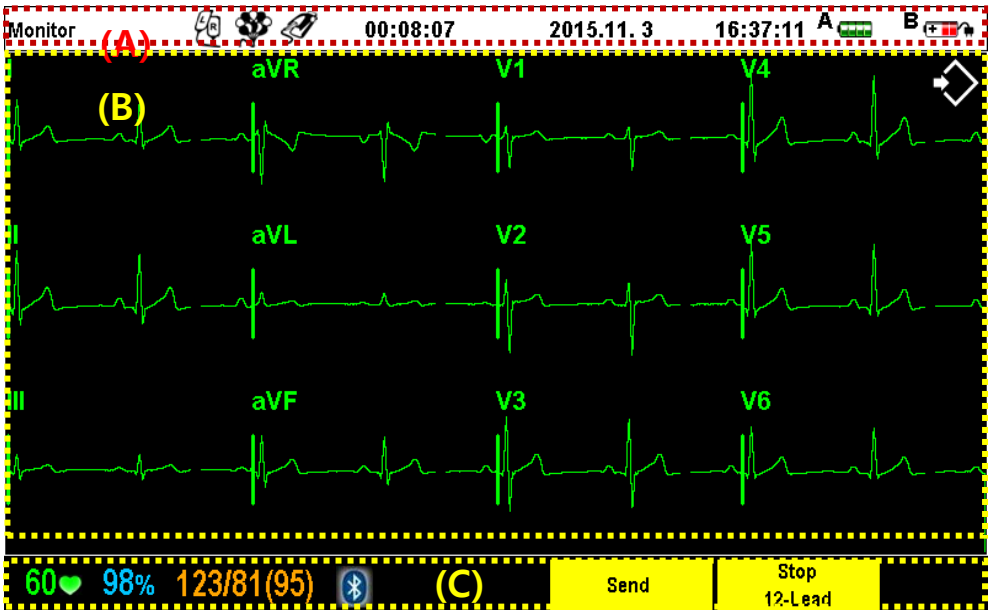
- Heart rate is expressed as the vital sign in Sector 1, while the vital sign set for Sector 2 does not affect the heart rate display.

Note

- When the ECG cables are not connected or when in Lead Fault condition, the ECG lead graph is displayed in dotted lines.
- When the pads or paddles are not connected or when the pads are not attached, the pad lead graph is displayed in dotted lines.

3) 12-Lead Screen Layout of Patient Monitoring Mode

By connecting a 10-lead cable, Patient Monitoring Mode can be switched to a mode that measures 12-lead ECG signals in the following screen layout.



Screen Layout		
(A)	Device state indication area	Shows mode in use, connector state, Duration of device usage, current time, date, and power state
(B)	12-lead ECG indication area	10-ECG signal measured form the lead ECG cable (I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6)
(C)	Patient vital signs & Bluetooth communication area	Displays heart rate, SpO_2, NIBP, Bluetooth communication connection status, soft button menu, and alarm message

2.4.2 Battery Indication Symbols

The product displays the battery status in the symbols depicted as follows:

Stage	Symbol	Description
Step1		Remaining battery is more than 90%
Step2		Remaining battery is 60~90%
Step3		Remaining battery is 40~60%
Step4		Remaining battery is 10~40%
Step5		Remaining battery is less than 10%

In addition, the icons related to the battery are summarized in the following table.

Symbol	Description
	AC power module input
	Battery is not connected

Caution

- It is recommended that battery charging must be done if it's Step 4, or two LEDs light at the battery gauge at least.

2.4.3 Soft Key

The usage of the soft keys is changed depending on individual modes the product offers. The function of each key by mode is summarized in the table below.

Soft Key	Description
Analyze	Starts an ECG analysis.
Stop analysis	Stops the ECG analysis.
30:2 CPR Type	Denotes that the CPR type is set to 30 : 2. Pressing the soft key switches the type to 15 : 2.
15:2 CPR Type	Denotes that the CPR type is set to 15 : 2. Pressing the soft key switches the type to 30 : 2.
Start CPR	Starts CPR.
Stop CPR	Stops CPR.
Disarm	The charged electric shock energy is internally discharged.
	Turns off an alarm that is occurring. Pressing the soft button will turn off an alarm and the button will change into the [Pause Alarm] button.
Pause Alarm	Stops the alarm temporarily.
Start 12-Lead	Starts the 12-lead mode.
Stop 12-Lead	Stops the 12-lead mode.
Send	Transfers the 12-lead data.
Start Transmission	Transfers the information of the patient being examined to the computer in real time. To see this, Bluetooth must be connected.
MENU	Once the pad is detached, the menu is activated. (Applied to all modes)

2.4.4 Display Symbols

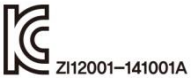
Symbol	Description
	Indicates the 3-lead ECG cable is connected.
	Indicates the 5-lead ECG cable is connected.
	Indicates the 10-lead ECG cable is connected.
	Indicates the pads are connected.
	Indicates the paddles are connected.
	The IRMA Mainstream Analyzer is connected to the CU-CM1.
	The ISA Sidestream Analyzer is connected to the CU-CM1.
	Indicates whether the Bluetooth communication is connected. (Blue: Bluetooth connected, Red: Bluetooth disconnected)
	Shows it is in the R-Sync mode.
	Indicates it is printing.
	Indicates the alarm function is on.
	Indicates the alarm function is off.
	Indicates the alarm function is temporarily stopped.
	Indicates heart rate at the 12-lead mode.
	Indicates the ECG storage function is being executed.
	Indicates the voice and ECG storage functions are being executed.

2.4.5 Symbols Used on the Operation manual and Equipment

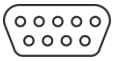
Any or all of the following symbols may be used in this manual or on this equipment.

1) CU-HD1 and Other accessories

Symbol	Description
	Consult instructions for use (Operation manual).
CE	Conformité Européenne Complies with the requirements of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC
	For EU only: Electrical and electric equipment shall be collected and recycled in accordance with Directive 2002/**96**/EC
	Defibrillation-proof type BF applied part
	Defibrillation-proof type CF applied part
EC REP	Authorized representative in the European Community
	Manufacturer
	Date of manufacture
	Use by date
SN	Serial Number
	General warning: Observe and follow all safety signs
	Warning: Electric Shock
	Do not immerse in water.

Symbol	Description
	Do not break, drill, or disassemble.
	Warning: Keep away from flammable materials.
	Direct current
	Alternating current
	Do not re-use
	LOT Number
	Catalogue number
	Temperature limit: Storage it in temperature environments ranging from 0℃ to 43℃.
	Do not fold.
	For Korea only: Confirmation of declaration (for battery module)
	Equipment or system which includes an RF transmitter or intentionally applies RF energy for the purpose of diagnosis or treatment.

2) CU-CM1

Symbol	Description
	Power Button (ON/OFF)
	Indicates connection of power and product
	Indicates low battery
	Indicates the charging status
	Indicates connection of AC power
	DC power input
	Serial port
	Gas Inlet
	Defibrillation-proof type BF applied part
	Consult instructions for use (Operation manual).
	Warning
	For Korea only: Certificate of Broadcasting and Communication Equipment
SN	Serial Number
	Date of manufacture

3) IRMA Mainstream gas analyzer

Symbol	Description
SN	Serial Number
REF	Catalog number
CE 0413	Complies with 93/42/EEC Medical Device Directive when connected to medical devices approved by PHASEIN AB.
Rx ONLY	Rx only Caution (U.S.): Federal law restricts this device to sale by or on the order of a physician.
⚠	Consult instrunctions for use.
IP44	IP classification indicating level of protection against ingress of water and solid foreign parts
	For EU only: Electrical and electric equipment shall be collected and recycled in accordance with Directive 2002/96/EC.

4) ISA Sidestream gas analyzer

Symbol	Description
SN	Serial Number
REF	Catalog number
CE 0413	Complies with 93/42/EEC Medical Device Directive when connected to medical devices approved by PHASEIN AB.
Rx ONLY	Rx only Caution (U.S.): Federal law restricts this device to sale by or on the order of a physician.
	Gas Inlet: Gas inlet for connecting the Nomoline Family sampling lines
	Gas Outlet (evac): Evacuation outlet
	Consult instrunctions for use.
IPX4	IP classification indicating level of water protection "Splash-proof"
	For EU only: Electrical and electric equipment shall be collected and recycled in accordance with Directive 2002/96/EC.
	Date of manufacture
	Defibrillation-proof type BF applied part
	Conforms to ANSI/AAMI ES60601-1:2005 Cert. to CAN/CSA-C22.2 No.60601.1:2008.

2.5 AED Mode Voice and Text Prompts

※ **Plug in pads connector**

It indicates that the pads connector or the paddles adapter must be connected to the main body.

※ **Attach pads**

Attach the disposable defibrillation pads to the patient's chest skin below the right clavicle and on the middle glands in the armpit below the left nipple, and connect the connector on the opposite side of the defibrillation electrode to the defibrillation pad connector correctly.

※ **Do not touch the patient**

It indicates that contact with the patient must be avoided for the accurate ECG analysis.

※ **Analyzing heart rhythm**

It indicates that it is under the analysis of the patient's ECG signal. Do not touch the patient. Also, when analyzing the ECG signal, if a patient makes any movements, the analysis may have errors.

※ **Shock advised**

It means that the patient needs to have electric shock treatment.

※ **Stand clear**

It means that a patient must avoid all contact with other people.

※ **Charging**

It indicates that sufficient energy is charged for electric shock treatment.

※ **Press the flashing orange button, now**

It indicates that the user must press the Shock button for electric shock treatment.

※ **Shock delivered**

It indicates that electric shock treatment was delivered to the patient.

※ **No shock advised**

It indicates that electric shock treatment is unnecessary.

※ **The shock button was not pressed**

It indicates that a prompt to press the Shock button has not been pressed within 15 seconds. (The device will discharge through an internal circuit after 15 seconds)

※ **Push the chest down fast two inches**

It indicates that you must administer cardiopulmonary resuscitation (chest compression).

※ **Begin CPR, now**

It means that you must begin CPR.

※ **Give two breaths**

It indicates that you must administer cardiopulmonary resuscitation (chest compression).

※ **If no pulse, press "Analyze"**

It indicates that there is no pulse in manual analysis mode. You must press the Analyze button.

※ **If no pulse, begin CPR**

If there is no pulse and not need electric shock, you must begin CPR.

2.6 Alarms and Errors

2.6.1 Alarm

Information and alarms for the patient or device state are transferred to the user through text messages in the LCD, beeper sounds or LED indicators of the CU-HD1. When an alarm is issued, the alarm will continue until the user confirms it. To cancel the alarm, you need to change alarm setting in the alarm item on the main menu or eliminate the factors causing the alarm.

※ The alarm settings can be changed under alarm list in the MENU. Default alarm settings are restored when the product is powered off and on. To change the default alarm setting, refer to the service manual.

Individual alarms and their description are summarized below.

• Indicator

It shows the information on the production operation and the state of the battery/AC power. For details, refer to the description in Section 2.3 - Indicators.

• Text

If the set limit of alarm occurrence is exceeded according to the patient's condition, an alarm of the patient's condition will be issued and the relevant alarm text will be displayed on the top left side of LCD. Also, if the cables, paddles or pads are not connected, a message indicating the relevant condition is displayed on the LCD.

When it is temporarily stopped, the alarm is done so for a predetermined period of time, and the temporal stop time is lapsed in 10-second interval until its preset time, enabling a checkup for a temporary alarm stop.

If the alarm condition continues to happen even after discontinuing the alarm, the same alarm continues to be issued.

• Sound alarm (Beep sound)

A beep sound is generated depending on the alarm conditions. You can mute the alarm sound (beep sound) by pressing the Mute Alarm button. When you press the Mute Alarm button, the alarm will be muted according to the set time, and the Mute Alarm button will change to the Pause Alarm button. If you press the Pause Alarm button, an alarm will not be issued according to the set time.

※ Alarm sound range: Max. 85 dB, Min 45 dB

Note

- If an arrhythmia (ventricular fibrillation/ventricular tachycardia) or cardiac arrest takes place, an alarm for the patient condition shall be issued at the patient monitor mode, pacer mode and manual defibrillation mode. If it is intended to monitor the patient, check the alarm settings on the menu.

1) The Type of Alarm

※ The following shows type or alarms corresponding alarm settings and patient conditions. They can be configured in the alarm section of the menu.

Alarm Item	Alarm Message (Color)
Ventricular Fibrillation / Ventricular Tachycarddia	VF / VT (Red)
Asystole	Asystole (Red)
Heart rate	Extreme Brady (Red)
	Extreme Tachy (Red)
	HR High (Yellow)
	HR Low (Yellow)
Pulse	Pulse Low (Yellow)
	Pulse High (Yellow)
SpO_2	SpO_2 Low (Yellow)
	SpO_2 High (Yellow)
NIBP	Systolic High (Yellow)
	Systolic Low (Yellow)
	Diastolic High (Yellow)
	Diastolic Low (Yellow)
	Mean High (Yellow)
	Mean Low (Yellow)
Capnography	$EtCO_2$ High (Yellow)
	$EtCO_2$ Low (Yellow)
	Respiration Rate High (Yellow)
	Respiration Rate Low (Yellow)
	Apnea (Red)

※ Red: High priority order Alarm, Yellow: Medium priority order Alarm

※ Latch / Non-Latch Alarm

Interval between alarm signals

- Latch alarms
  - Once the alarm is triggered, it will not be cleared until the [Pause Audio] or [Pause Alarm] button is pressed even after the patient recovers to normal.
  - This includes High priority order alarms.
- Non-Latch alarms
  - Once the alarm is triggered, it will clear automatically when the patient recovers to normal.
  - This includes Medium priority order alarms.

Note

- ECG alarms (VT/VF, asystole, heart rate) are generated only when Sector 1 is lead II or pads.
- To monitor ECG alarms, Sector 1 must be changed to 'Lead II' or 'Pads'.

2) List of Default Alarm Limits

※ The following list shows the defibrillator's default alarm settings. When the defibrillator is powered off and on, the following alarm settings are restored. To change the default alarm settings, see the Service Manual.

Alarm Item	Default Alarm Limits		
VT / VF	Alarm setting		ON
Asystole	Alarm setting		ON
Heart rate	Alarm setting		ON
	Trigger condition		Under 60 BPM / Over 120 BPM
Pulse	Alarm setting		ON
	Trigger condition		Under 60 BPM / Over 120 BPM
SpO_2	Alarm setting		ON
	Trigger condition		Under 90% / Over 100%
NIBP	Alarm setting		ON
	Alarm standard		Systolic blood pressure
	Systolic alarm trigger condition		Under 70 mmHg / Over 200 mmHg
	Diastolic alarm trigger condition		Under 30 mmHg / Over 160 mmHg
	Mean alarm trigger condition		Under 40 mmHg / Over 180 mmHg
Capno-graphy	$EtCO_2$	Alarm setting	ON
		Trigger condition (if using %)	Under 2% / Over 6.7%
		Trigger condition (if using mmHg)	Under 15mmHg / Over 50mmHg
	Respiration rate	Alarm setting	ON
		Respiration rate trigger condition	Under 5 BPM / Over 30 BPM
		Apnea alarm trigger condition	Apnea for more than 20 seconds

2.6.2 Errors

The product may produce errors when there are problems during its operation in addition to alarms, and each error is represented in the LCD screen as a code.

※ To troubleshoot the errors, refer to "Chapter 12_Troubleshooting".

Warning

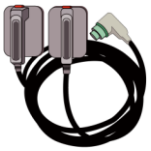
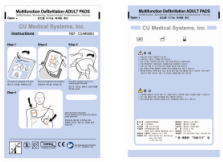
- Setting Alarm limits to extreme values can render the Alarm system useless.

Note

- If the rotary switch is not in the correct position, the 'Check the rotary switch.' message appears with a periodic alert sound. If this alarm message appears, check that the rotary switch is positioned correctly.

2.7 Accessories

The CU-HD1's accessories are composed of disposable accessories (disposable defibrillation pads, ECG electrodes, printing papers, etc.) as well as external defibrillation paddles used for electric shock, ECG cables, SpO_2 sensor and extension cable, NIBP cuff and NIBP connection tube, SD card, power supply devices (AC power module, car cigar jack, and battery module), and bed rack.

Image	Name	Description
	**External Defibrillation Paddle**	External defibrillation paddles are pressed against the patient's chest to deliver electric shock.
	**Conductive Gel**	Conductive gel is used to maximize electric contact between the patient and the metal surface of the paddles.
	**Disposable Defibrillation Pads (Adult)**	Disposable defibrillation pads are attached on the chest to measure the patient's ECG or, when necessary, to deliver electric shock. Always refer to the markings on the pads before attaching them.
	**Infant/Child Reduced Energy Defibrillation Pads**	Only for AED mode. Including a module that reduces the energy delivered to the patient, these disposable pads can be attached on the front or back of an infant/child patient in any direction.
	**Multifunction Defibrillation Pediatric Pads**	Only for manual defibrillation mode, pacer mode, and patient monitoring mode. These disposable pads can be attached on the front or back of an infant/child patient in any direction.
	**Pads Connection Adapter**	After removing disposable defibrillation pads (for adults or for infants/children) from package, use pad connection adapter to connect the pads to the defibrillator.
	**3-Lead ECG Cable**	This ECG cable is used for measuring 3-lead ECG waveforms · **Leads**: I, II, III
	**5- Lead ECG Cable**	This ECG cable is used for measuring 7-lead ECG waveforms · **Leads**: I, II, III, aVR, aVL, aVF, V
	**10- Lead ECG Cable**	This ECG cable is used for measuring 12-lead ECG waveforms · **Leads**: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6

◎ Chapter 2_ Components of the Product

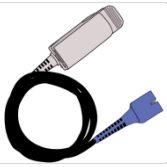
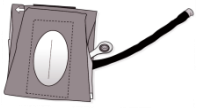
Image	Name	Description
	**Disposable ECG Monitoring Electrodes**	ECG monitoring electrodes are attached on the patient to measure ECG signals.
	**SpO_2 Sensor**	The sensor is attached to the patient's fingertip, etc. to measure SpO_2.
	**SpO_2 Sensor Extenstion Cable**	This extension cable is used to connect SpO_2 sensor to the CU-HD1.
	**Cuff for NIBP Measuring (Infant)**	This cuff is used for NIBP measurement of infants.
	**Cuff for NIBP Measuring (Child)**	This cuff is used for NIBP measurement of children.
	**Cuff for NIBP Measuring (Adult)**	This cuff is used for NIBP measurement of adults.
	**Connection Tube for NIBP Measuring**	This connection tube is used to connect the NIBP measuring cuff to the CU-HD1.
	**CO_2 Sensor Communication Module**	If the $EtCO_2$ option is selected for your CU-HD1, this communication module connects the CU-HD1 with the IRMA Mainstream or ISA Sidestream over Bluetooth.
	**IRMA Mainstream Analyzer**	This mainstream analyzer module measures $EtCO_2$.
	**ISA Sidestream Analyzer**	This Sidestream analyzer module measures $EtCO_2$.
	**IRMA Airway Adapter (Adult/ Pediatric)**	This adapter is connected to the IRMA Mainstream to measure $EtCO_2$ of an adult or child. Single patient use. Disposable.

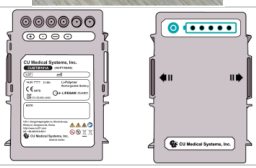
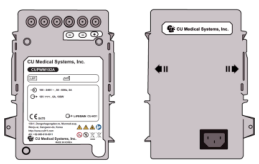
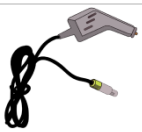
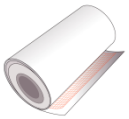
Image	Name	Description
	**IRMA Airway Adapter (Infant)**	This adapter is connected to the IRMA Mainstream to measure $EtCO_2$ of an infant. Single patient use. Disposable.
	**Nomoline (Adult/ Pediatric/ Infant)**	This is connected to the ISA Sidestream gas analyzer to measure $EtCO_2$. Single patient use. Disposable.
	**Nomoline Adapter (Adult/ Pediatric/ Infant)**	This is connected to the ISA Sidestream gas analyzer to measure $EtCO_2$. Multi patient use. Disposable.
	**Nomoline Airway Adapter Set (Adult/ Pediatric)**	This is connected to the ISA Sidestream gas analyzer to measure $EtCO_2$. Single patient use. Disposable.
	**Nomoline Extension**	This is connected to the ISA Sidestream gas analyzer to measure $EtCO_2$. Single patient use. Disposable.
	**T-Adapter (Adult/ Pediatric)**	This is connected to Nomoline and Monoline extension to measure $EtCO_2$. Single patient use. Disposable
	**Battery Module**	When charged, the battery module can supply power to the CU-HD1 without the need for an external power source. ※ For details on attaching, detaching and charging the battery, see **"3.2.1 Installing & Charging Battery".**
	**AC Power Module**	This module provides power to the CU-HD1 from a commercial 100-240V AC power source. It can also charge the battery module. ※ For details on attaching and detaching the AC power module, see **"3.2.2 AC Power Module Connection".**
	**AC Power Adapter**	The power adapter can be connected to the rear of the CU-HD1 to charge it.
	**Car Cigar Jack**	The car cigar jack can be connected to the rear of the CU-HD1 to charge it through the cigar jack in a car.

Image	Name	Description
	**Power Adapter for CU-CM1**	The power adapter can supply power to the CU-CM1.
	**CU-CM1 Cradle**	Cradle for holding the CU-CM1 and ISA Sidestream sensor in place.
	**Bed Rack**	The bed rack allows the CU-HD1 to be secured onto the patient's bed.
	**SD Card (Secure Digital Card)**	The SD card is used to save or export data generated by the CU-HD1.
	**Printing Paper**	Printing paper is required for the built-in printer. ※ For details on the printing paper, see **"Chapter 13. Product Specifications"**.
	**TEST LOAD**	Load resistance is used to check the defibrillation function in manual self-testing mode. ※ For details on manual self-testing, see **"8.5.1 Self Testing"**.
	**Carrying Bag**	Attached to the CU-HD1, the carry bag can house CU-HD1 accessories.

Warning

- Paddles or pads designed specifically for children are recommended when using the defibrillator on children aged 8 years or under or weighing 25 kg or below. In emergency situations, pads for adults may be used on children.
- Using the defibrillator on an adult with pads for children (without defibrillation energy reduction module) may cause necrosis of the cardiac muscles.

Note

- ECG cables with AHA in the product name are generally ECG cables following the US naming convention, while products with IEC in the product name are generally ECG cables following the EU naming convention

Location of electrode	AHA		IEC	
	Mark	Color	Mark	Color
Limbs electrode	RA	**White**	R	**Red**
	LA	**Black**	L	**Yellow**
	LL	**Red**	F	**Green**
	RL	**Green**	N	**Black**
Chest electrode	V	**Brown**	C	**White**
	V1	**Brown**	C1	**Red**
	V2	**Yellow**	C2	**Yellow**
	V3	**Green**	C3	**Green**
	V4	**Blue**	C4	**Brown**
	V5	**Orange**	C5	**Black**
	V6	**Violet**	C6	**Violet**

Chapter 3. Product Installation

This section is intended to provide basic information about how to install the CU-HD1 and its product parts.

For details regarding the operation of CU-HD1 besides the installation of accessories, refer to Chapters 4~7.

If the product is initially installed in an emergency situation, please check out if the product components are properly installed after the product has been used or during the periodic checkup session.

If the floor surface and your hands are wet, you may get shocked. Move to a dry location first and install the product.

Before using, turn on the device using the Rotary switch and check the charging status visually.

If an optional charger is used, charge it for at least 4 hours.

Double check any part connected to the patient directly.

3.1 Unpacking

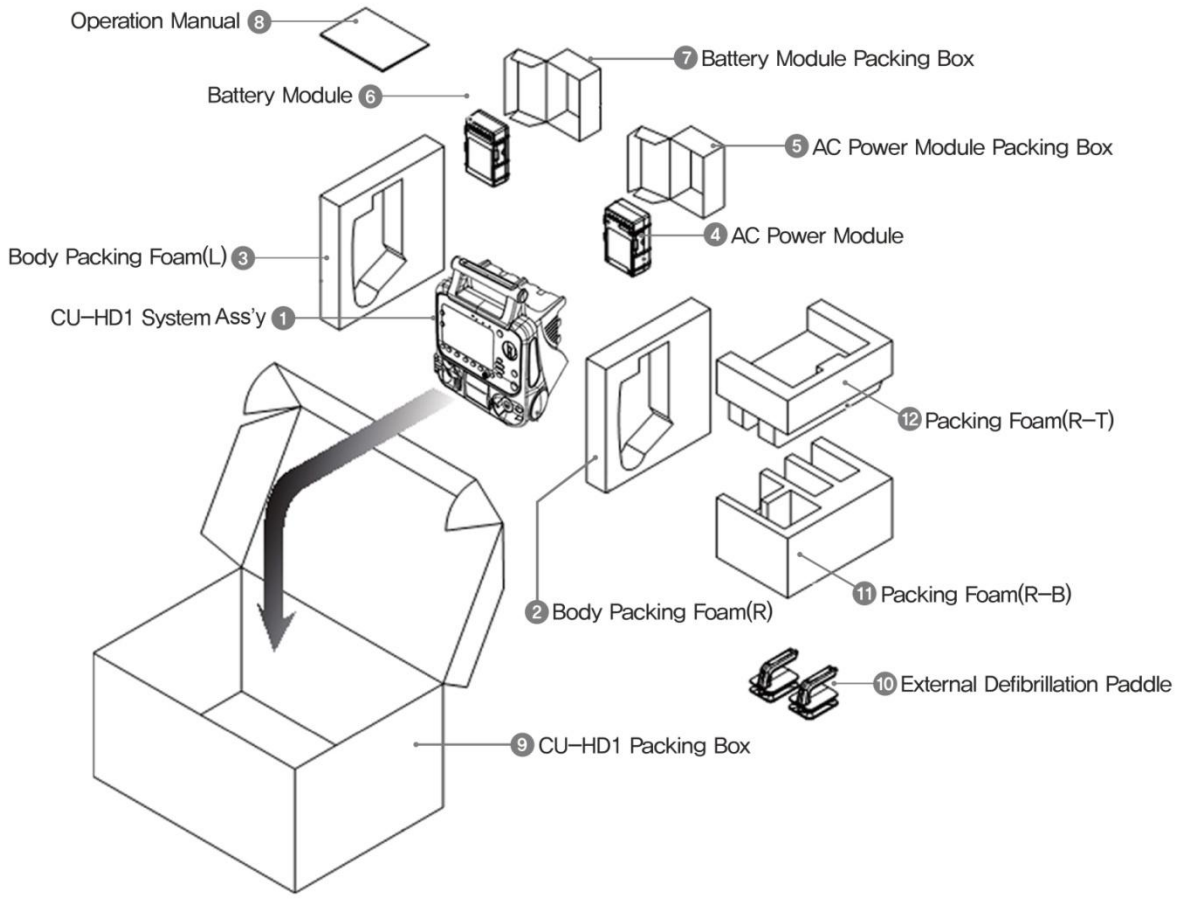
Take a careful look to see if there is any damage to the package container.

Check out whether there is any obvious damage to the device, which may have been caused during transportation.

Check if all of the components and accessories have been accurately provided according to the package item list.

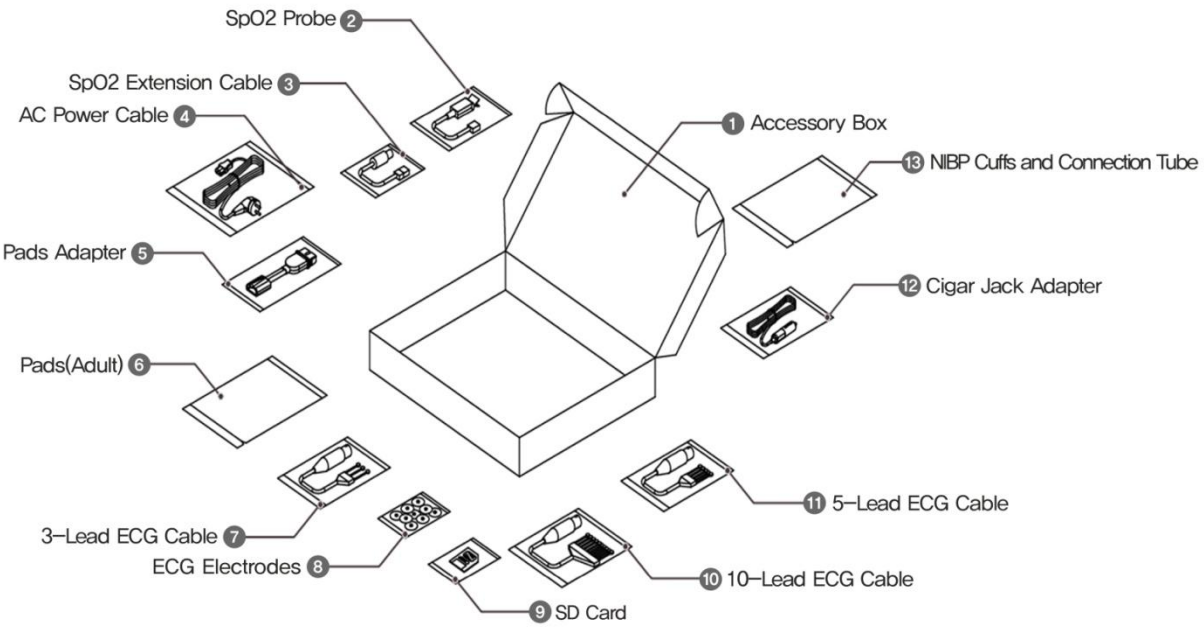
3.1.1 Package of the Main Body

As seen in the below figure, the main body package includes with the main body of CU-HD1 of the CU-HD1, an AC power module, and the battery module, etc.



3.1.2 Package of Accessories

The accessory package is composed of the below items, and each of the accessories are listed below.



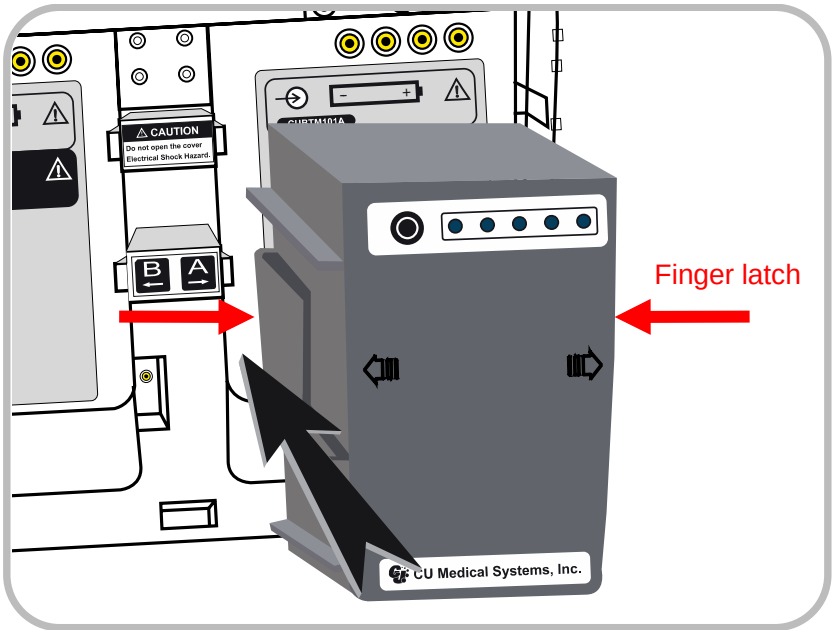
Caution

- Consist of accessories may be differed from an order. When unpacking, it is very important to check to make sure all accessories you have placed an order are included

3.2 Peripheral Device Connection

3.2.1 Installing Battery and Charging Battery

The battery module is mounted in the direction shown in the below figure. After the battery module has been mounted, be sure to hear a "click" sound when the battery module and the CU-HD1 are connected to each other.



The internal battery pack of the Product is fully charged before leaving the factory. Upon receiving the product, please charge the battery module.

To separate the battery from the main body, press the finger latches on both sides of the battery and pull the battery out.
Avoid exposing battery module to hot, humid or wet conditions.

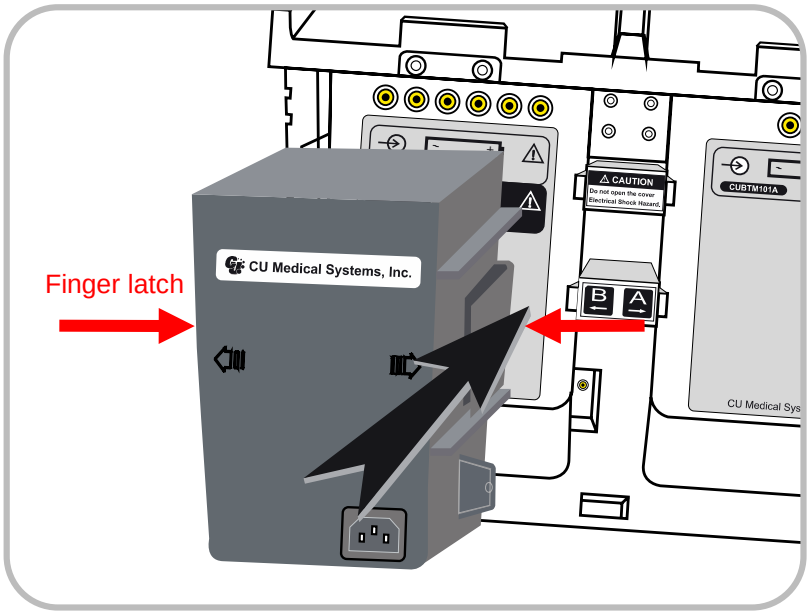
If the Low Battery status is indicated, please charge the battery module. When the battery is being recharged, the Battery Recharge indicator will blink. When the recharging process has been completed, the Battery Recharge indicator will shows green light.

Note

- To check the battery charging status, refer to the battery status displayed in the LCD screen.
- To check the battery status in terms of the charge level, refer to **"2.4.2 Battery Indication Symbols"** or use the Battery Level Indication button in the rear side of the battery.
- For more information about the safety tips for battery usage, please refer to **"11.6 Considerations for Handling Power and Battery"**.
- For more detail information about the charging battery, please refer to **"10.2 Power Management"**.

3.2.2 AC Power Module Connection

The AC power module is mounted in the direction shown in the below figure. After the AC power module has been mounted, be sure to hear a "click" sound when the AC power module and the CU-HD1 are connected to each other. After the AC power module has been mounted, use the AC power by plugging in the power cable.



To separate the AC power module from the main body, press the finger latches on both sides of the AC power module and pull the AC power module out.
Avoid exposing AC power module to hot, humid or wet conditions.

Caution

- Vendors and users should note that the AC power module has been rated for electromagnetic compatibility for work use (A Class). The defibrillator is appropriate for use in places other than homes.
- Caution should be taken on the mounting position of the battery module and the AC power module shown in the instruction manual.
- The battery module is mountable in both the A and B slots, but the AC power module is mountable only in the B slot.

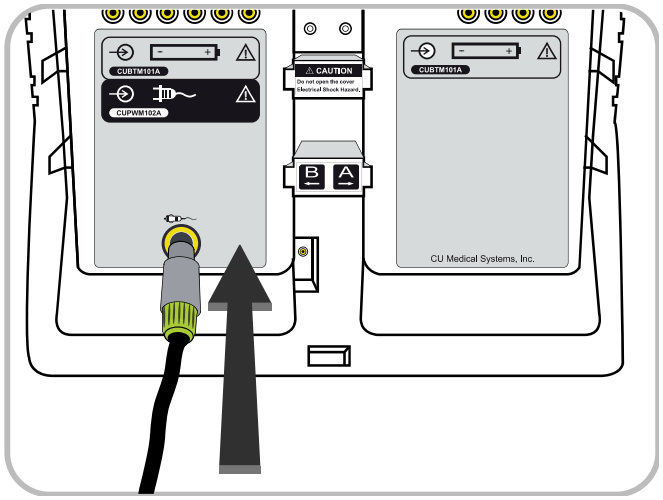
Note

- For more information about the safety tips for the AC power module, please refer to **"11.6 Considerations for Handling Power and Battery"**.

3.2.3 Connecting the Car Cigar Jack and AC Adapter

The car cigar jack is mounted in the direction shown in the figure below. The car cigar jack input terminals are located in the left lower part (the 'B' slot indicating terminal) of the rear side of the device.

The protruding part of the car cigar jack connector faces upward when mounting the car cigar jack.

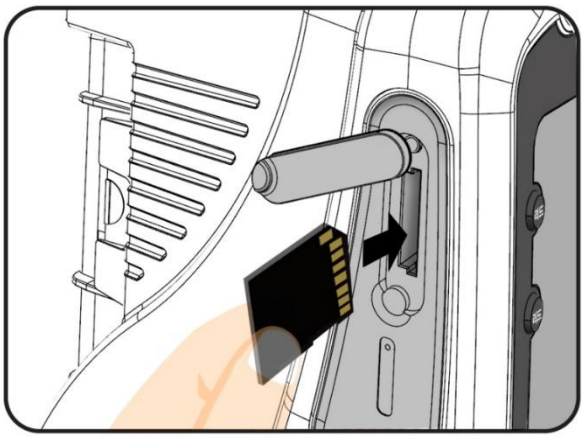


Caution

- The car cigar jack and AC power adapter are designed only to charge the battery. Therefore, do not use them for running the device.
- For more information, please refer to **"11.6 Considerations for Handling Power and Battery"**.

3.2.4 Mounting SD Card

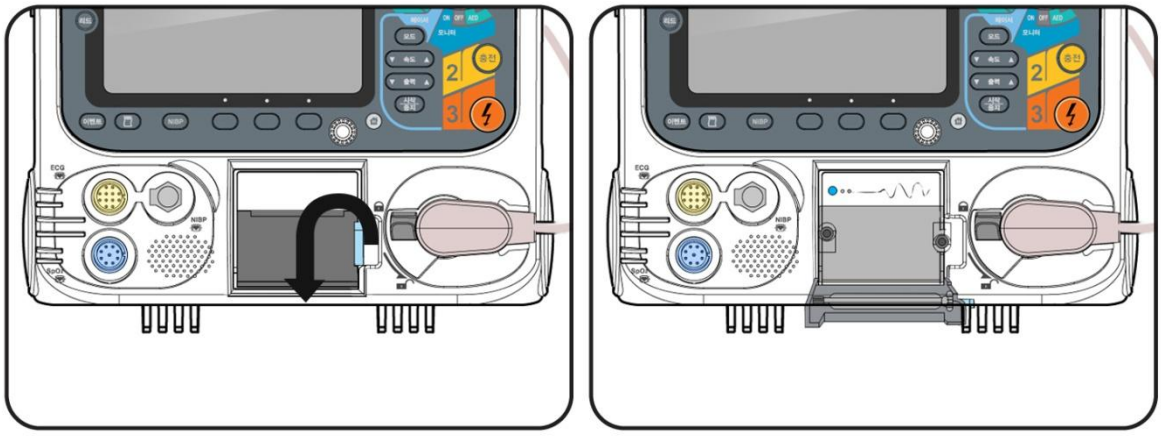
The SD card mounting slot is located in the left side of the main body. Open the protection cover from the slot and mount the SD card as shown below.



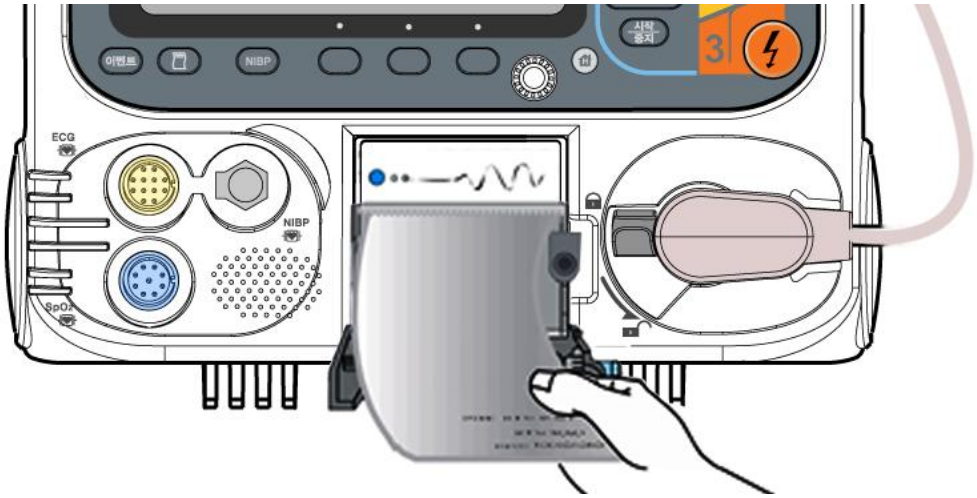
3.2.5 Feeding Printer Paper

For feeding the printer paper, load the paper according to the below sequence.

① In the left figure, pull the lever forward on the right side of the printer from the CU-HD1.
② The front cover of the printer will be open as shown in the figure on the right.



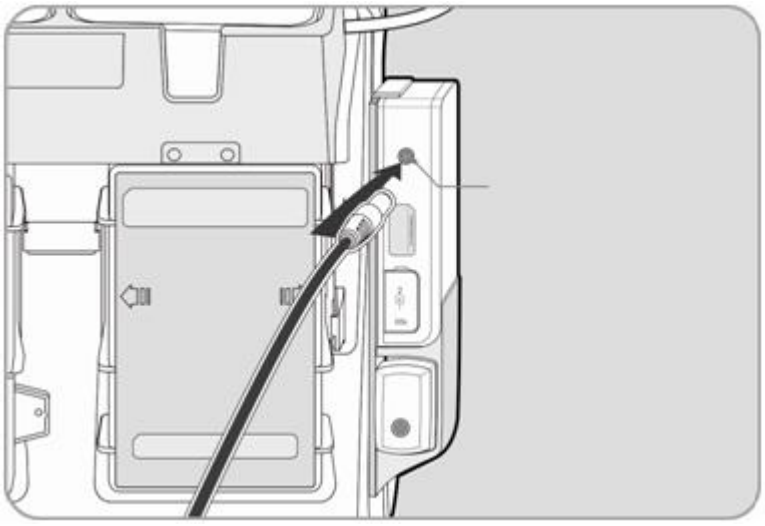
③ Place the printer paper into the printer, and pull out some paper.
④ Push the printer cover back to the default location until it makes a "click" sound.
⑤ If the Rotary switch is set to the monitor mode, the printer power amp will be light up green. You can use the [Feed] button to take as much printer paper as you want



⑥ When replacing the printer paper, repeat steps ① and ②, then detach the printer paper with your hand.

3.2.6 Connecting AC Adapter for charging CU-CM1

To charge the CU-CM1 battery, mount the charging adapter in the direction shown below. The input port is located in the top left of the CU-CM1.



3.3 Self-test

Whenever the product is turned on, it periodically initiates a self-test. This test is designed to ensure that the whole system is ready for use in emergencies. The Self-test performs the battery state checkup, the control system state checkup, and evaluates all functions provided by the product.

This product can also run a manual self-test. It is recommended to perform a manual self-test for first-time use. For detailed contents, refer to "10.1 Self-test".

3.4 Product Storage

Place the product in an accessible place so that it can be used readily during emergencies.

Do not disconnect the battery pack during storage. The battery must be charged fully enough to be turned ON during emergencies through the self-test.

Note

- If there are errors other than the battery error, contact CU Medical Systems, Inc. or an authorized agent. If a "Low Battery" error occurs, recharge the battery pack or plug in the AC power according to the instructions described in the Operation manual.

Caution

- For long-term storage, do not store the product in connection with the disposable defibrillation pads.

Chapter 4. Automated External Defibrillation (AED) Mode

■ **Overview**

The Automated External Defibrillation (AED) mode designed for patients with acute cardiac arrhythmia automatically analyzes whether the patient falls under cardiac arrhythmia like ventricular tachycardia or ventricular fibrillation, and produces corresponding results in the form of sound or text to help the user appropriately treat the patients.

This defibrillator supports two AED modes: Auto Analysis Mode (Auto Analysis Mode ON) which automatically analyzes the patient's ECG, and Manual Analysis Mode (Auto Analysis Mode OFF) which analyzes ECG when the 'Analyze' soft key is pressed. In addition, the defibrillator provides voice guidance to facilitate performance of CPR. In addition, the product provides a voice guide to facilitate the CPR procedure.

Warning

- Other medical devices that may be affected by defibrillation energy (strong electric shock) or become an obstruction to the protection of defibrillator should be removed from the vicinity of the patient.

Caution

- The CU-HD1 is not intended to be used for supplementing the abnormal functionality of the internal pacemaker. Therefore, if needed to recover the heart function of patients using the internal pacemaker, consult a medical specialist.
- The CU-HD1 does not have any functionality generating the alarm sound or warning message saying whether an internal pacemaker is used for the patient or not.

Note

- To safely shut the CU-HD1 down while in AED (Automated External Defibrillator) mode, rotate the rotary switch to the OFF position.

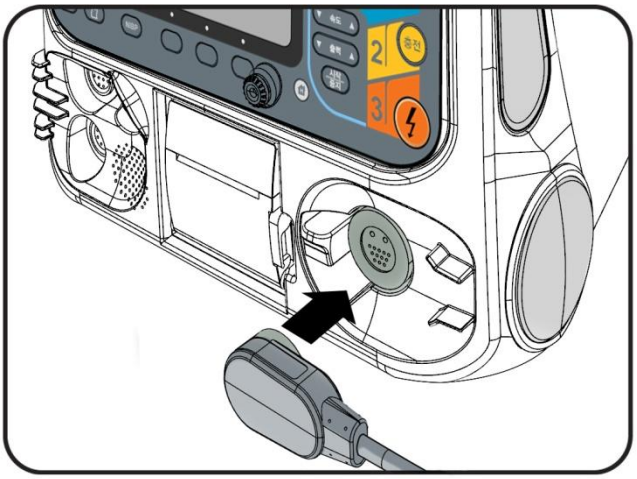
4.1 Preparing Defibrillation

4.1.1 Connecting to the device

1) Connecting the Pads connection adapter

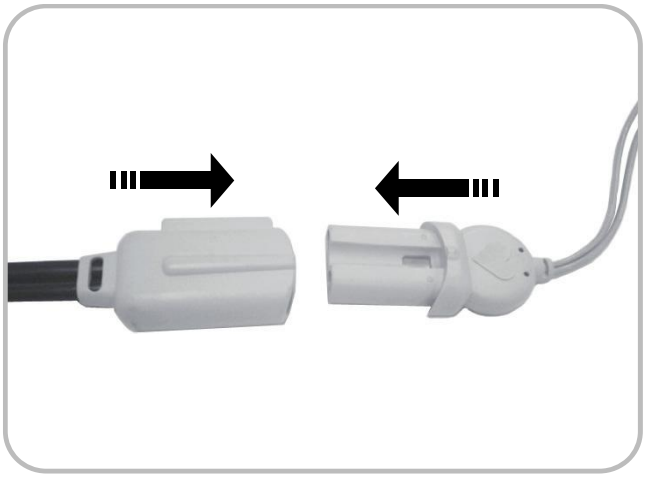
Connect the pad connector to the main body as shown in the figure below. Check the shape of the connector input terminal on the main body and the shape of the pad connector cradle.

When removing the defibrillation pads and paddles connector from the main body, for disconnection, turn a cable connector terminal in the unlocking direction, and pull it out from the main connector.



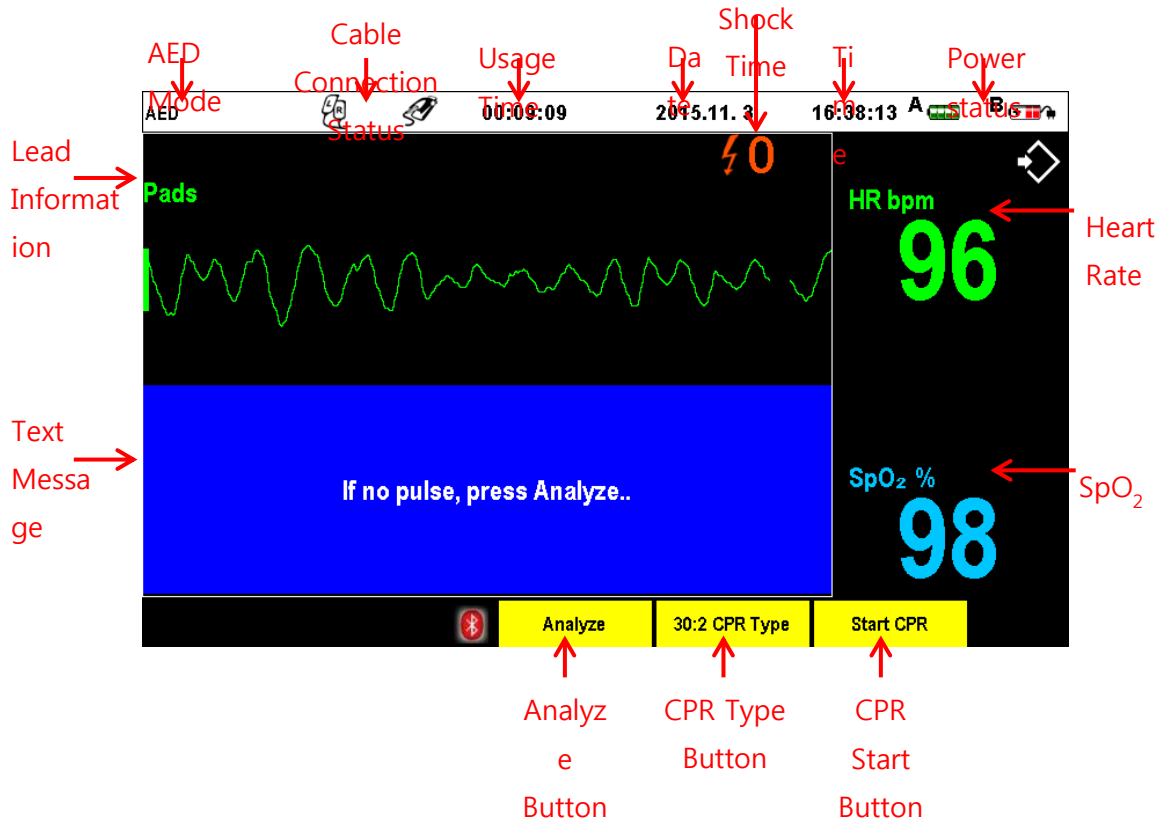
2) Connecting the Disposable defibrillation pads

Connect the disposable pad and the pad connector as shown in the figure below. There is a set direction of groove. Caution should be taken on this direction when connecting.



4.1.2 AED Mode Layout and Setting

1) AED Mode Layout

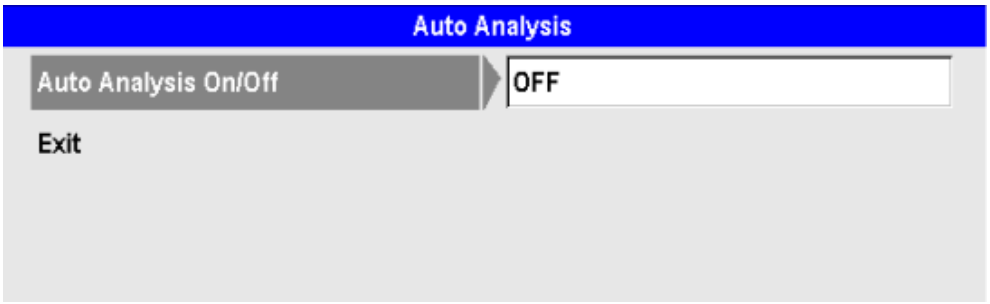


AED Mode	Informs which mode is running.
Usage Time	Displays the total time of use of the device after turning it on.
Date	Displays the date.
Shock Times	Shows the number of electric shocks delivered.
Current Time	Shows the current time.
Power Status	Shows the input power state when using the remaining battery indication or the AC power module.
Heart Rate/ SpO_2	Shows the heart rate and SpO_2.
Text Message	Shows the message telling the AED procedural information while using the AED mode and the battery charge state.
CPR Type Button	Controls the CPR rate. (30:2, 15:2)

2) Setting

2.1) Auto Analysis

Press the menu knob from "Auto Analysis" at the "Main Menu" and then the following screen will be prompted, where you can change the Auto Analyzing setting at the AED mode.



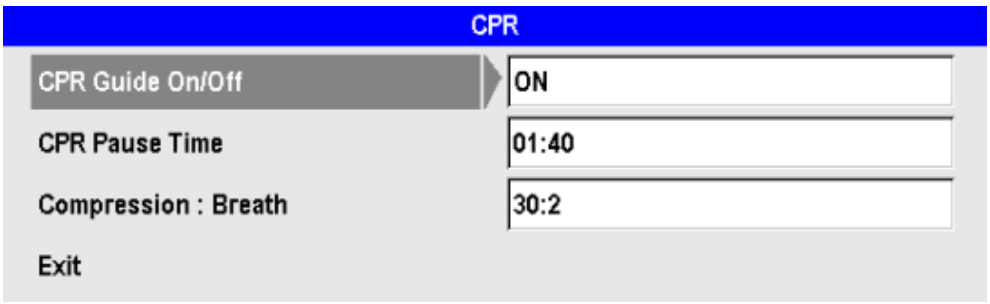
Note

- In Auto Analysis ON mode, patient ECG is automatically analyzed once the pads are correctly connected to the patient.
- In Auto Analysis OFF mode, patient ECG is not analyzed even when the pads are correctly connected to the patient.
  To analyze ECG, press the "Start Analysis" soft key.

2.2) CPR

Press the menu knob from "CPR" at the "Main Menu" and then the following screen will be prompted, where you can change the CPR setting at the AED mode. From the CPR menu, you can choose whether to turn on/off the CPR guide, or the method of CPR.

After changing the CPR settings, the changed values are applied by pressing the menu knob. Select Exit from "CPR" menu and press the menu knob to retrieve the "Main Menu".

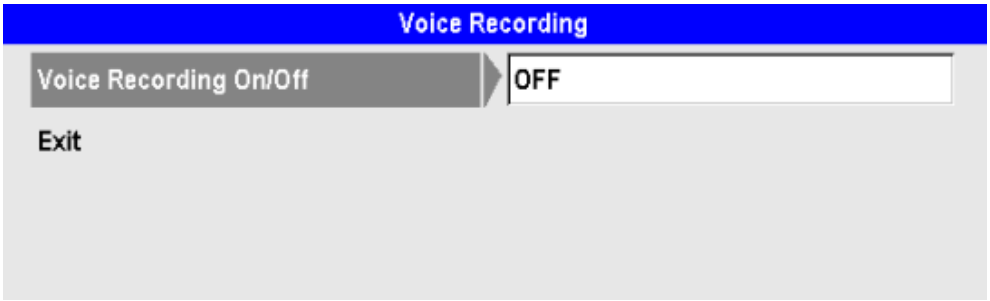


- **CPR Guide On/Off**
  You can set it to On/Off to use the CPR guide via the voice and text instruction functions.
- **CPR Pause Time**
  . When the CPR guide is set to off, the CU-HD1 can pause the device so that the user can perform CPR. .
- **Compression: Breath**
  You can choose 30 : 2 or 15 : 2 for CPR.

2.3) Voice Recording

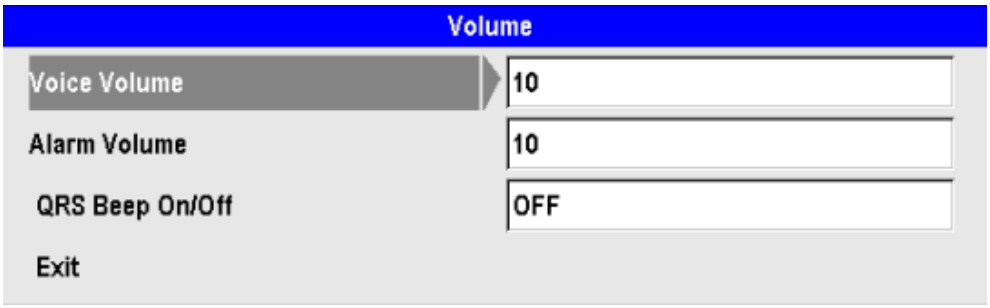
The CU-HD1 supports the voice recording function, and determines whether to use the voice recording function in this item.

The voice recording is available on AED mode only.



2.4) Volume

This is a sub-menu to control the speaker volume of the CU-HD1.

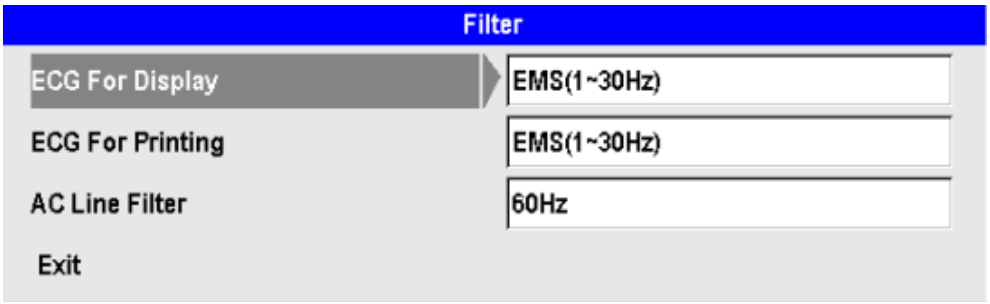


- **Voice Volume / Alarm Volume**
  The device has a volume scale of 10 levels, which can be changed by 1 unit with the menu selection button.
- **QRS Beep On/Off:**
  You can set it to On/Off to generate the beep sound when detecting the QRS of the ECG.

2.5) Filter

At the "Filter" menu, you can set a bandwidth with which you can check out the ECG signal detected by the CU-HD1.

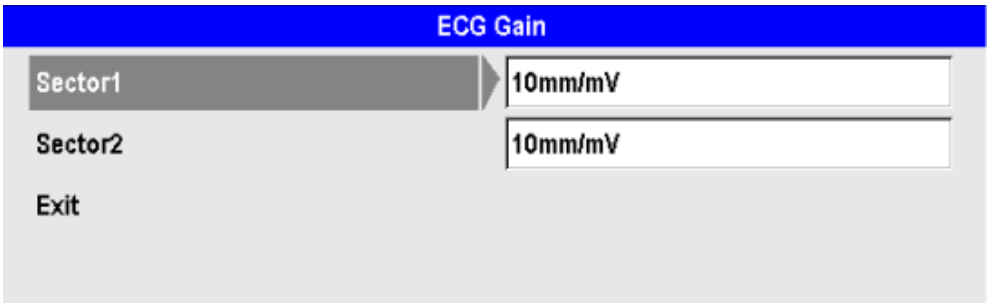
Support for the function of filtering the LCD monitor and printer ECG signal, and individual optional item is listed as follows.



- **ECG For Display**
  You can select the filter bandwidth of EMS (1~30Hz) and Monitor (0.5~40Hz). Default setting is EMS.
- **ECG For Printing**
  You can select the filter bandwidth of EMS (1~30Hz), Monitor (0.5~40Hz), and Diagnostic (0.05~150Hz). Default setting is EMS.
- **AC Line Filter**
  This is an item to remove the power noise. Select 60Hz or 50Hz according to the power source. Default setting is 60Hz.

2.6) ECG Gain

This is the menu item that takes control of the ECG sensitivity degree. If the ECG signal is too high or too low, you can change the signal level to an extent that you can easily verify it. Default setting is 10mm/mV.



- **Sector 1**
  As for the ECG signals displayed in the Sector 1, click the menu knob to choose the ECG signal size from Auto Gain, 5mm/mV, 10mm/mV, and 20mm/mV.
- **Sector 2**
  As for the ECG signals displayed in the Sector 2, click the menu knob to choose the ECG signal size from Auto Gain, 5mm/mV, 10mm/mV, and 20mm/mV.

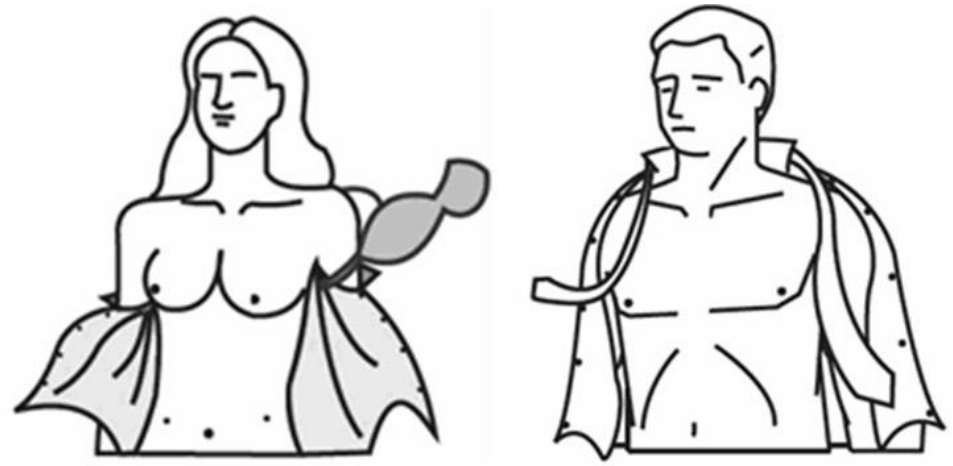
4.1.3 Attaching the Defibrillation Pads

The pads are attached in the order of taking off upper-body clothes, opening the pads and connecting the pads connectors to the main body of the CU-HD1.

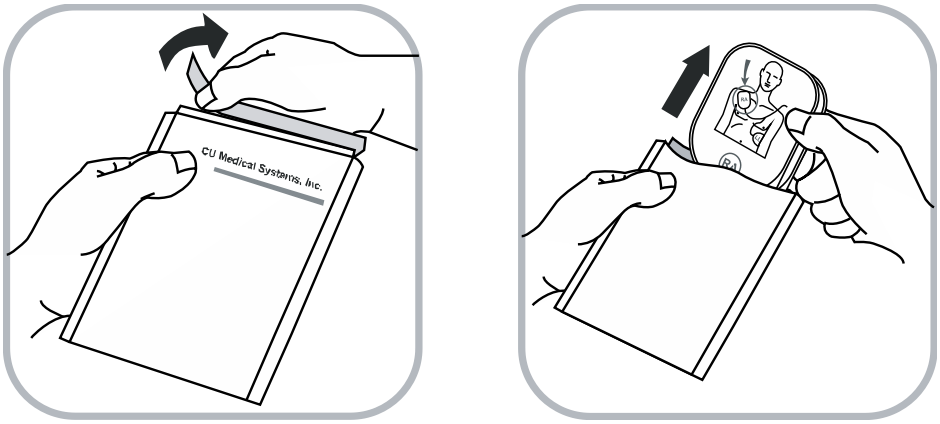
※ Attach and connect the defibrillation pads in the order described below.

① Take off all the upper-body clothes including any under-garments.

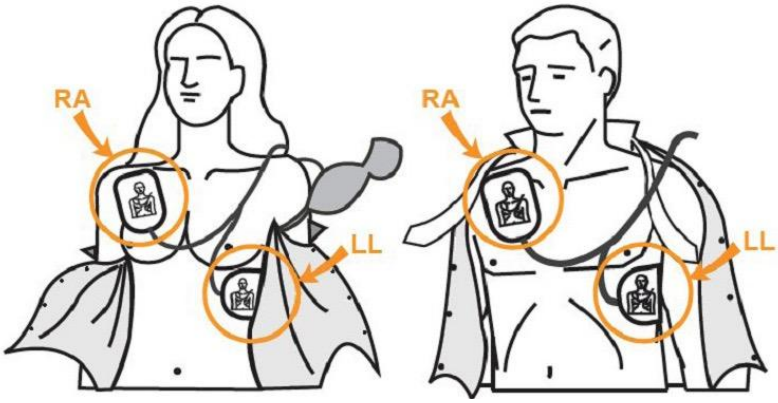
② If the chest to which the pads are attached is too hairy, shave it using a razor or with scissors.



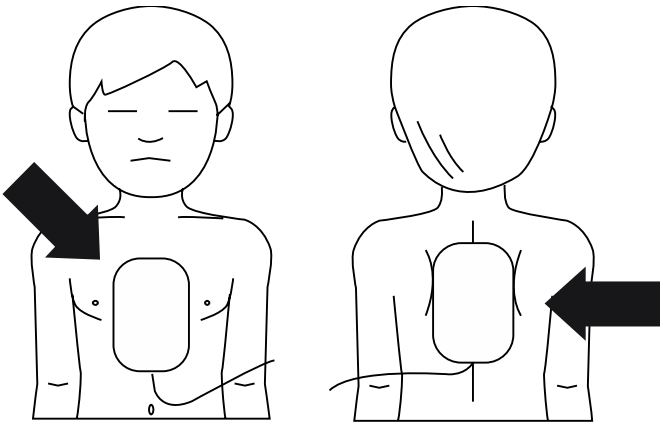
③ Tear off the defibrillation pads package along the cutting line. Select the adult or pediatric pads according to the patient.



④ Attaching pads – Following the directions indicated in the figure below. Attach the pads to the upper body of the patient. Individual pads have a drawing showing the attaching location. It is best to follow the exact locations.



[Attaching locations for adult pads]



[Attaching locations for pediatric pads]

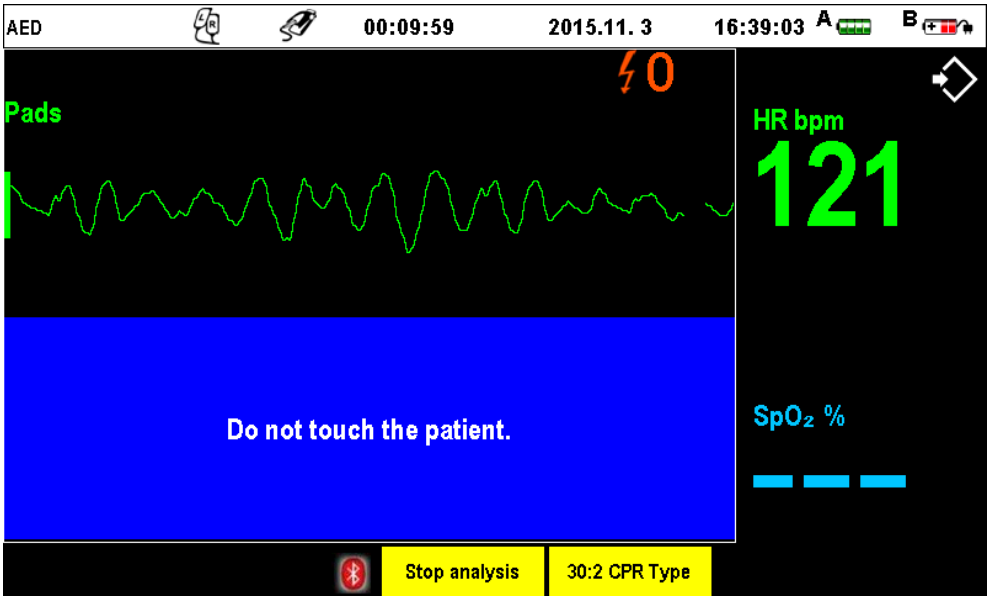
Caution

- If the pediatric pads are used in the AED mode, make sure they have the defibrillation energy attenuation module.
- Maintain the position where the pads are attached dry. If the patient's skin surface is moist or wet, a problem may occur when the device recognizes the patient and defibrillation energy may leak during defibrillation.
- If using the disposable pads, do not use the defibrillation-specific gel. The defibrillation-specific gel must be used for the external defibrillation paddles.
- Check for any damage to the pads and the packages of the pads as well as the expiration date. If damaged or expired, discard the package without using it.
- When the patient is less than 8 years old or weighs less than 25 kg (55 lb), use Pediatric defibrillation pads. Do not delay therapy to determine the patient's exact age or weight.

4.2 Analyzing Patient

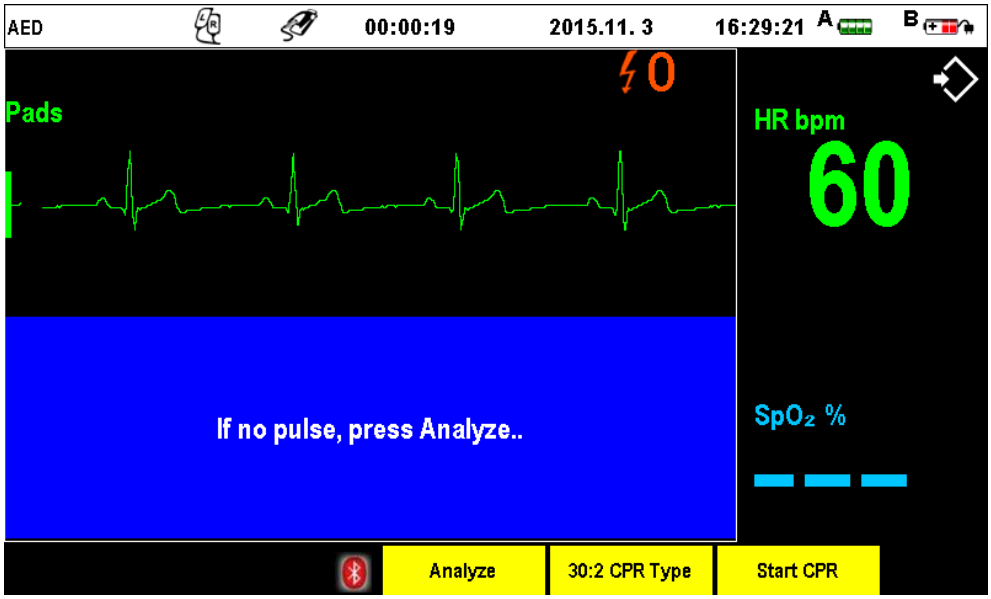
Once the pads are attached, the AED mode operates according to the Auto Analyzing settings. Operating sequence is as follows.

4.2.1 Auto Analysis Mode (Auto Analysis Mode ON)



① Once attaching the pads to the patient correctly, his or her ECG is automatically analyzed.
② If the patient's ECG analysis results require defibrillation, it delivers the defibrillation electricity shock and reanalyzes the ECG automatically.
③ During CPR after the defibrillation electricity shock has been delivered, there is no ECG analysis.

4.2.2 Manual Analysis Mode (Auto Analysis Mode OFF)



① Push the soft key called "Analyze" to analyze the patient's ECG.
② As this time, the voice and text messages that are "If no pulse, press 'Analyze'." shall be displayed.
③ Using the manual analysis mode, therefore, the user must use the device according to the patient's ECG on the LCD screen.
④ In addition, if the ECG analysis results in requiring defibrillation, it does not automatically reanalyze the patient's ECG after delivering the defibrillation electricity shock. Rather, press the "Analyze" button again to reanalyze his or her ECG.

Warning

- Do not analyze the patient ECG during patient movement. A patient must be motionless during ECG analysis. Do not touch the patient during analysis. Cease all movement via stretcher or vehicle before analyzing the ECG.

4.3 Performing AED

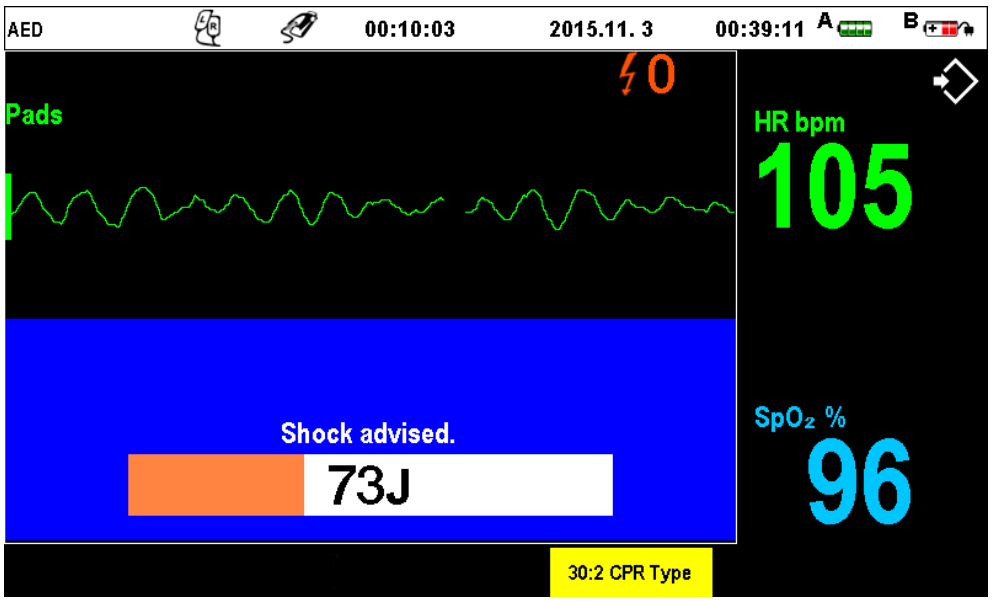
4.3.1 Checking Analysis Results and Voice Instructions

If defibrillation is necessary as a result of analyzing the patient's ECG through the pads, the instructions to deliver an electric shock will be provided. If the defibrillation is not necessary, the instructions to carry out CPR and continuous ECG analysis will be provided according to the patient's condition.

4.3.2 AED Treatment

1) Charging Defibrillation Energy

The device automatically starts charging. The charging process can be checked through the display shown below, and once charging has been completed, the beeper sound will starts and the Shock button will blink.



※ Effective shock level of the CU-HD1 is set at 200J for adults and 50J for children.

Warning

- Do not allow defibrillation pads of paddles to touch each other or to touch other ECG monitoring electrodes, lead wires, dressings, etc. Contact with metal objects may cause electrical arcing and patient skin burns during defibrillation and may divert current away from the heart.
- While charging or carrying out the defibrillation, do not allow the operator or other individuals to come into contact with the patient or any device connected to the patient.

Caution

- Do not allow exposed portions of the patient's body to come in contact with metal objects, such as a bed frame, as unwanted pathways for defibrillation current may result.

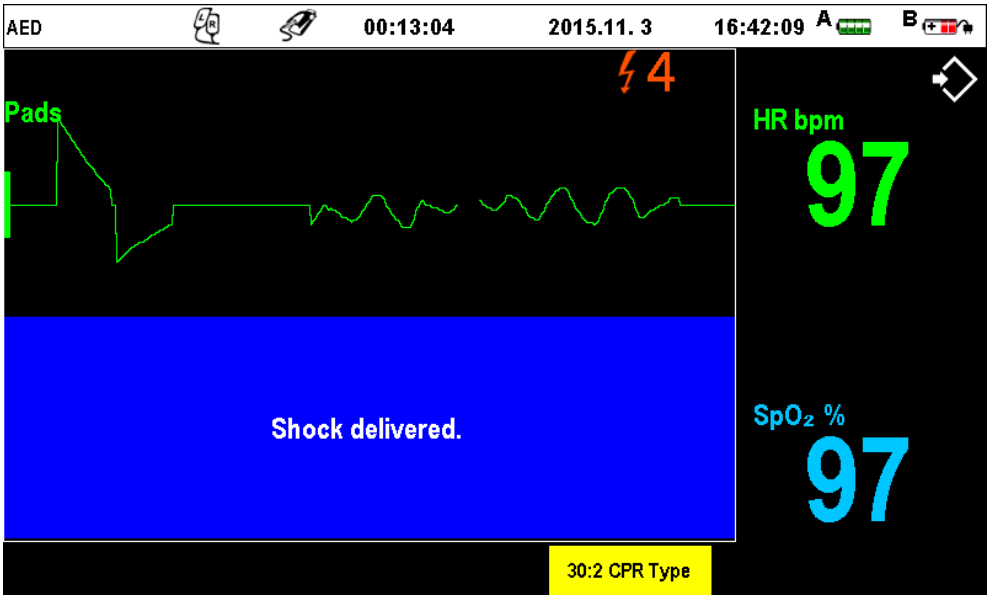
Note

- If the Shock button is not pressed within 15 seconds after the charge energy has been charged, the charged energy is discharged internally.

2) Delivering Defibrillation Energy

Pushing the Shock button delivers the defibrillation energy to the patient. Since there may be an injury due to a leak of the energy, do not have contact with the patient. Before pressing the button, warn people with a loud and clear warning to stand back from the patient.

The below figure displays when the defibrillation energy is delivered.



3) Performing CPR

As the function to help CPR, CU-HD1 provides the guidance on the CPR procedure with voice and text messages.

At the AED mode, press the "Start CPR" soft button to perform CPR without defibrillation.

The CPR rate (Compression : Respiration) can be selected through the "CPR Type 30:2" / "CPR Type 15:2" soft button.

4.3.3 Things to Do following Defibrillation

Carry out CPR 5 times (this will take approximately 2 minutes) and analyze the patient's ECG. Depending on the analysis results of the patient's ECG, carry out additional defibrillation and CPR.

Note

- While delivering the defibrillation energy, the patient's ECG through the pads does not show up in the screen. When it's delivered, the Biphasic wave is shown.

4.4 AED alarm

The alarm occurring in the AED mode is a technical alarm. If the device operation failure and SpO2 malfunction are detected, an alarm will be issued.

4.4.1 Type of Alarm

1) Technical Alarm

Alarm Message	Priority	Indication	Condition
Equipment malfunction	High	Alert tone with red alarm message with alert sound	An error is preventing the equipment from functioning.
SpO_2 Error	Low	Alert tone with turquoise alarm message with alert sound	There is a problem with the SpO_2 module.

Chapter 5. Manual Defibrillation & Synchronized Cardioversion

■ Overview

The manual defibrillation mode that should be carried out by a medical personnel to deliver electric shocks depending on the conditions of the arrhythmia patient while directly checking the patient's ECG signals displayed on the screen.

In the manual defibrillation mode, both paddles and pads can be used.

When the synchronized cardioversion function is used, the synchronization with the R wave will be established and an electric shock will be delivered.

Note

- To safely shut the CU-HD1 down while in Manual Defibrillation mode, rotate the rotary switch to the OFF position.

Warning

- Defibrillating asystole can inhibit the recovery of natural pacemakers in the heart and completely eliminate any chance of recovery. Asystole should not be routinely shocked. Begin CPR.
- To avoid stress to the defibrillator or the tester, never attempt to repeatedly charge and discharge the defibrillator in rapid succession. If a need for repetitive testing arises, allow a waiting period of at least 2 minutes after every third discharge.

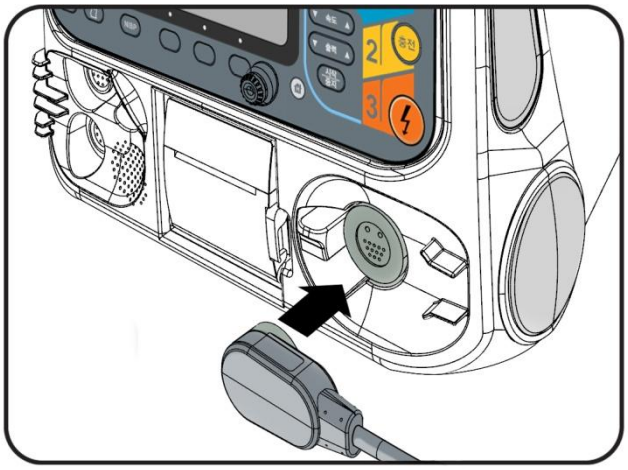
5.1 Preparing Defibrillation

5.1.1 Connecting to the Device

1) Connection of the paddles and the pad connector

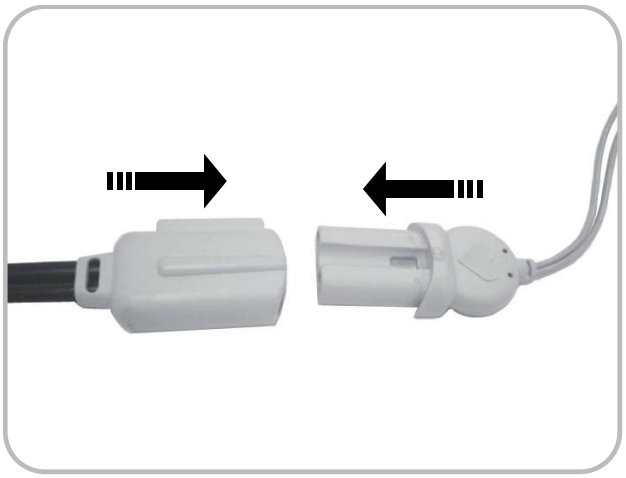
Connect the pad connector or the paddle cradles to the main body as shown in the figure below. Check the shape of the connector input terminal on the main body and the shape of the pad connector or the paddle cradles.

To remove the paddles and the pad connector from the main body, remove these items by rotating them in the unlock direction on the lock figure shown in the connector input terminal of the main body.



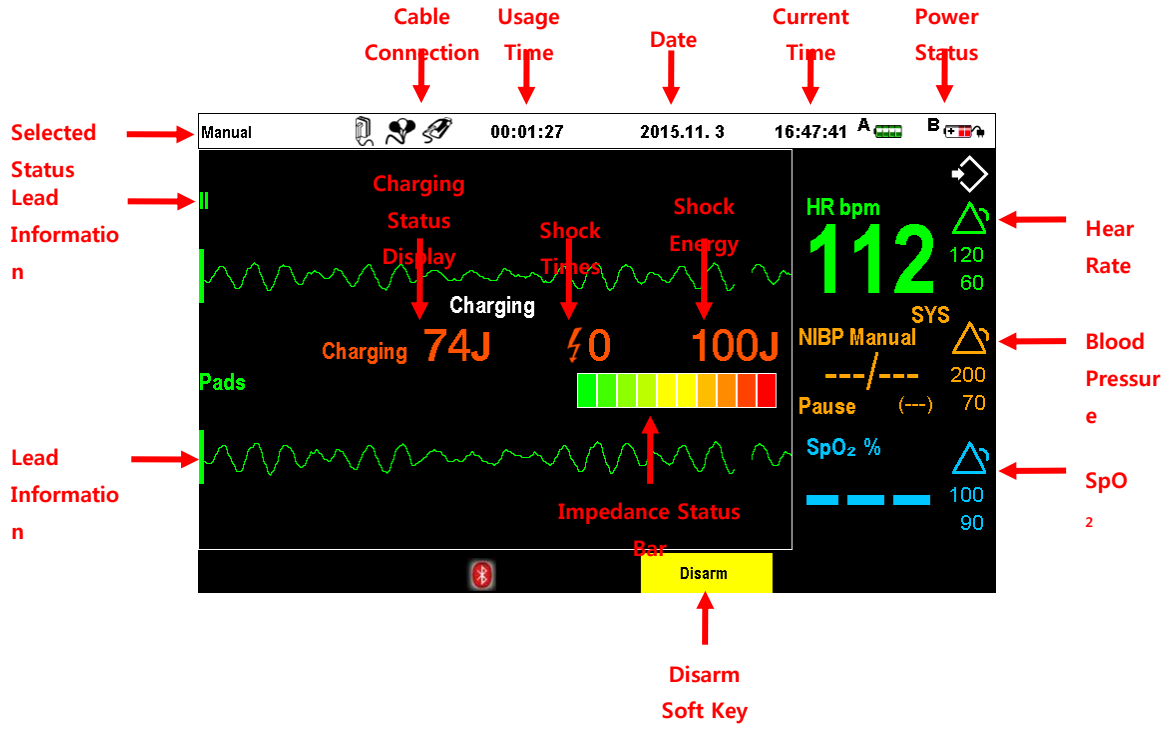
2) Connecting the Disposable Defibrillation Pads

Connect the disposable pad and the pad connector as shown in the figure below. There is a set direction of groove. Caution should be taken on this direction when connecting.



5.1.2 Manual Defibrillation Mode Layout and Setting

1) Layout



Selected Status	Informs which mode is running.
Cable Connection	Informs connection status of cable which is using.
Usage Time	Displays the total time of use of the device after turning it on.
Date	Displays the date.
Current Time	Shows the current time.
Power Status	Shows the input power state when using the remaining battery indication or the AC power module.
Heart Rate	Informs measured heart rate and predefined alarm limit
Blood Pressure	Informs measured blood pressure and predefined alarm limit
SpO_2	Informs measured SpO_2 and predefined alarm limit
Disarm Soft Key	Discharges the charged energy into the inside of the device.
Lead Information	Informs ECG cable and lead information.
Charing Satus Display	Shows the energy level being charged for pressing the Shock button, and disappears when the charge completes.
Shock Times	Shows the number of electric shocks delivered.
Shock Energy	Shows the symbol of the energy value being delivered to the patient.

2) Setting

※ Manual Defibrillation Mode

The strength of the electric shock energy can be chosen among 1-10, 15, 20, 30, 50, 70, 100, 120, 150, 170 and 200J by switching the rotary switch while checking any change in the patient's ECG signals according to the electric shock treatment.

※ Synchronized Cardioversion

The synchronized cardioversion transfers energy in sync with the 'R' wave of the ECG signals measured. Paddles and pads may be used for the synchronized cardioversion. Synchronized Cardioversion is enabled in the manual defibrillation mode.

Note

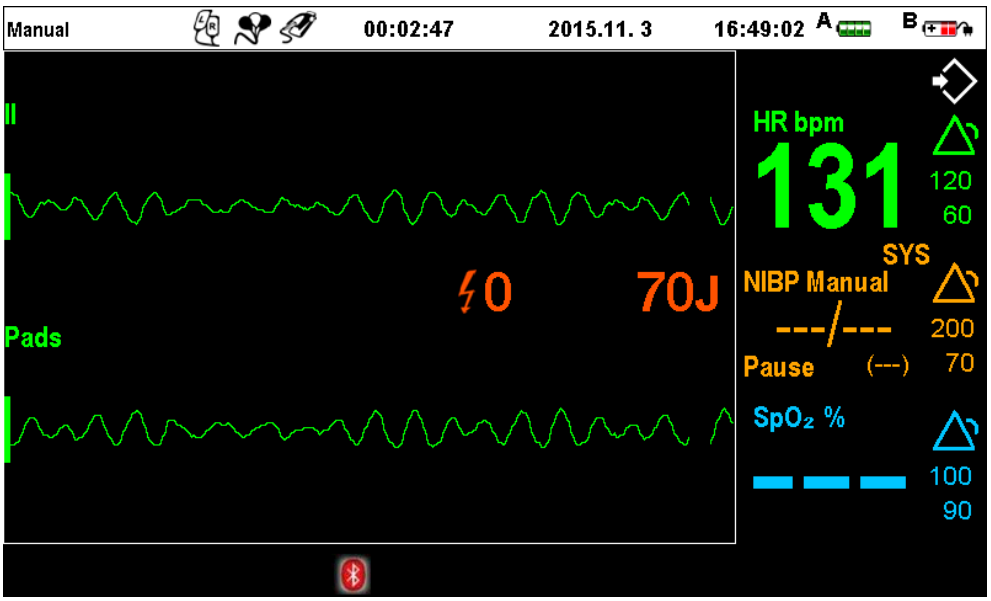
- When using the supplied pediatric pads which are specified for the CU-HD1, the energy level must not exceed 50J.

5.1.3 Attaching Defibrillation Pads and Paddle

Hair or foreign substances on the patient's chest should be removed in order not to affect the defibrillation.

1) Defibrillation Pads

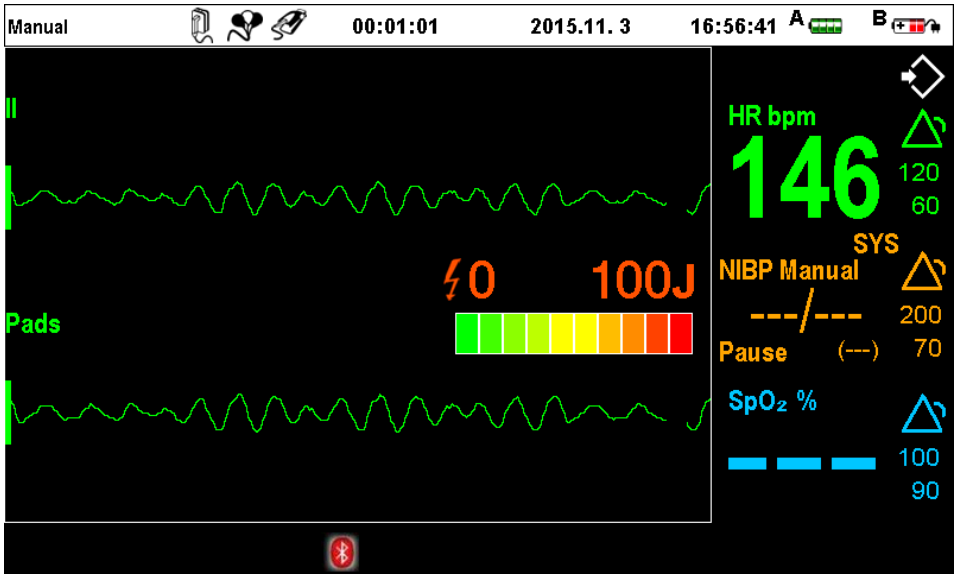
For how to use the pads, follow the same steps as explained in **Section 4.1.3**, which describes pads attachment and connecting pads for AED.



[Basic layout after attaching pads]

2) External Defibrillation Paddle

Undress the patient's top, including inner wear. If necessary, dry the patient's chest and remove hair or foreign substances on the patient's chest using a razor or scissors in order not to affect the defibrillation. When using the external defibrillation paddles, their locations are shown in the figure below of section 2.1), and it's recommended to use the defibrillation-specific gel.



[Basic layout after attaching paddles]

Note

- The impedance connection status bar must be green or above. This may not be possible according to a patient's physical conditions. In such cases, maintain the status bar in yellow (5 bars) or above.

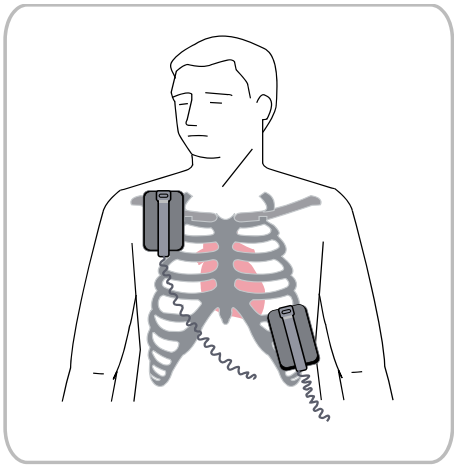
Caution

- Rubbing the paddles together without applying enough conductive gel on the paddle electrode surface may scratch or damage the surface.
- After using the conductive gel, clean off the gel that may be left on the paddles with wet clothes or gauze. If any leftover gel dries on the pads or paddles, it may cause problems in future use.

Warning

- Apply an ample amount of conductive gel on the paddle electrodes. Do not allow the gel to dry or accumulate in between the chest wall and paddle electrodes. Failure to remove gel residue from previous use may result in burns to the patient or a reduction of delivered energy.
- When the impedance connection status bar is not in the green area or above, incorrect defibrillation or vital sign measurement may occur. The status bar must be in the green area or above for correct defibrillation.

2.1) Using the External Defibrillation Paddle



① Remove the paddles from the paddle cradle by pulling the paddles straight out.

② If foreign substances exist on the surface of the paddles, remove such foreign substances completely.

③ Apply the conductive get supplied by CU Medical Systems, Inc. on the paddles.

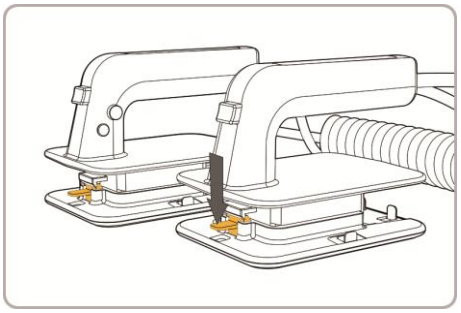
④ While holding the paddle handles, adjust the paddle pressure and positions. Watch the impedance connection status bar and keep the level above green.

2.2) Using the Pediatric External Defibrillation Paddle

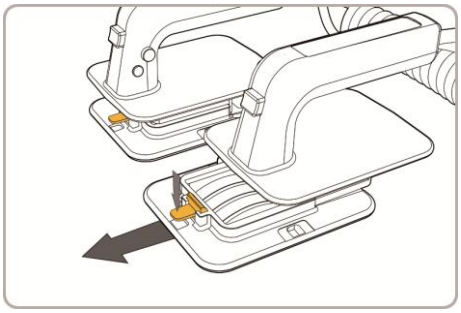
The American Heart Association recommends that small paddles be used on children weighing less than 10 kg. Large paddles may be used if they can be kept from interfering or contacting with one another.

The external defibrillation paddle for children is inside the external defibrillation paddle. Use it in the following manner.

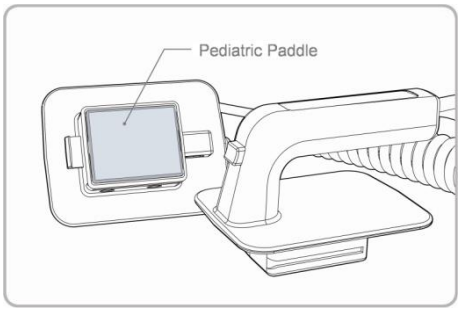
① Push the yellow switches on the paddles in the direction of the arrow as indicated.



② While pressing the yellow switches, pull them in the direction of the arrow.



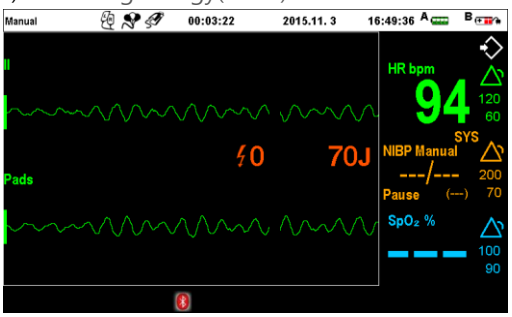
③ After separating both paddles as shown in the figure below, use them in the same way as those of the adult paddles.



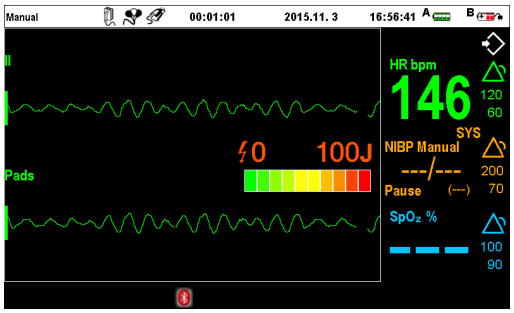
5.2 Manual Defibrillation (Asynchronous)

Manual defibrillation is done in three stages with the CU-HD1 by rotating the rotary switch.

1) Selecting Energy( )



[Default Screen after Pad Connection]

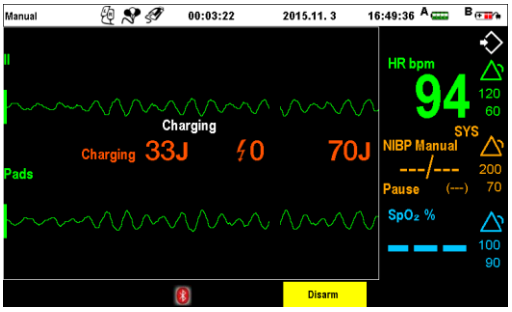


[Default Screen after Paddle Connection]

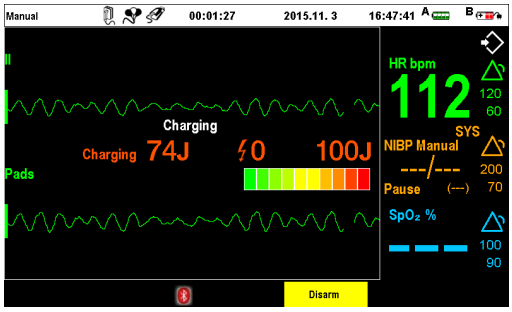
2) Charging Energy

Using Pads: Press the Charge button ( ) on the front of the defibrillator to start charging energy.

Using Paddles: Press the yellow button next to the paddle handle to start charging.



[Charging Screen when using pads]

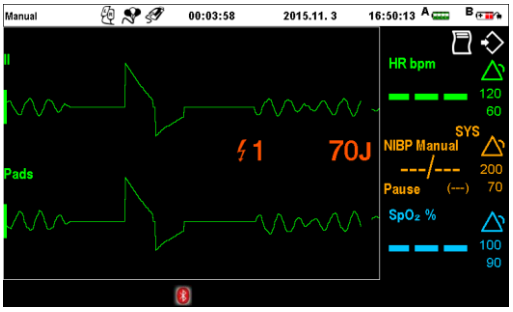


[Charging Screen when using paddles]

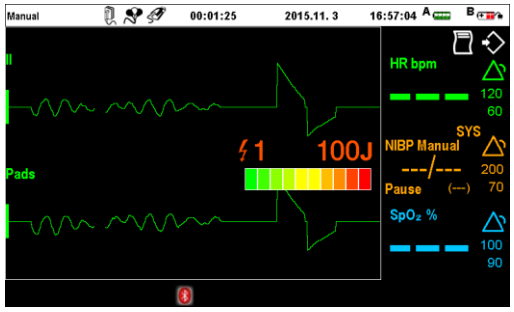
3) Performing Defibrillation

Using disposable pads: Press the Shock button ( ) on the front of the defibrillator to deliver defibrillation energy to the patient.

Using Paddles: Press the two orange buttons on the front of the paddle handles at the same time to deliver defibrillation energy to the patient.



[Defibrillation Screen when using pads]



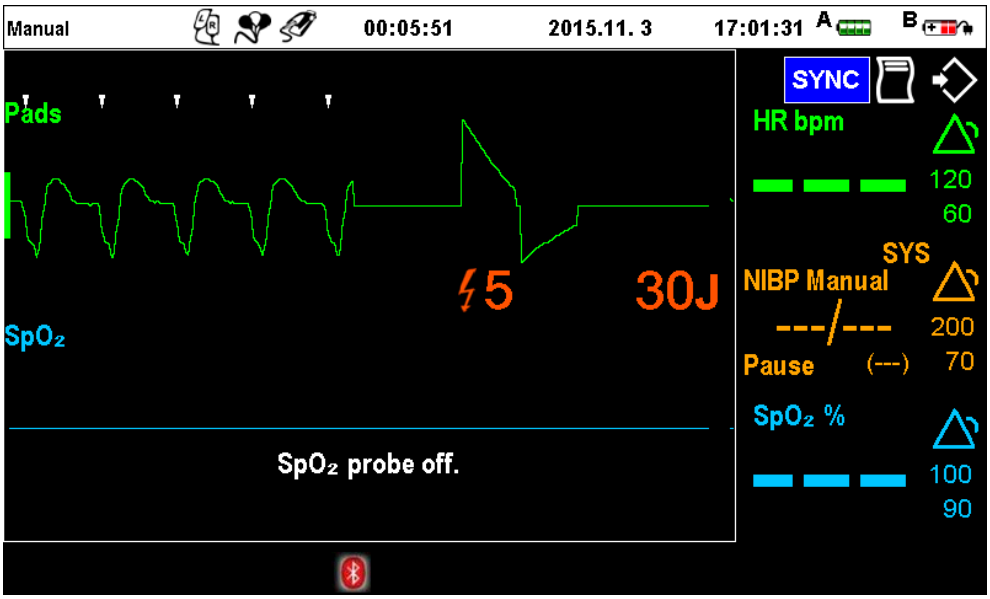
[Defibrillation Screen when using paddles]

Caution

- If the energy level is changed while charging the defibrillation energy, charging will be canceled. To charge the device again at the newly selected energy level, press the Charge button again.
- When the paddle is used and you press the Shock button while the impedance is not recognized after charging is finished, the charged energy will be discharged internally. Charge the device again by pressing the Charge button on the paddle handle, then carry out the defibrillation.

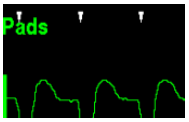
5.3 Delivering Synchronized Cardiac Pacing Energy

In order to treat a patient's unstable tachyarrhythmia, such as atrial flutter or atrial fibrillation, defibrillation should be carried out through the synchronization with the ECG R wave. The synchronized cardioversion is a method recommended for treating the patient's unstable tachyarrhythmia, such as atrial flutter or atrial fibrillation. CU-HD1's synchronized cardioversion function detects the ECG R wave and delivers an electric shock energy according to the R wave.



Caution

- When using the synchronized cardiac pacing function, check that the marker indication, position and heart rate are consistent.
- The white inverted triangle mark indicates the position of the R wave signal which is measured through synchronization.



5.3.1 Steps to Deliver Pacing Energy

① Place the rotary switch to Manual Defibrillation and press the "Sync" button on the top left side of the rotary switch to see if the blue button light is lit.

② Check whether the R-Sync marks which is in sync with the R-wave of the measured ECG shows up.

③ Select the desired defibrillation energy by rotating the rotary switch.

④ Pushing either the Charge button or the yellow charge button of the paddles, charging energy is displayed on the screen. To cancel the defibrillation energy, use the "Disarm" soft button. If defibrillation is not done within 15 seconds, the defibrillation energy is automatically cancelled. If changing the defibrillation energy that is charged, since changing the rotary switch to the energy level desired cancels the charged energy inside the device, recharge energy by pressing the Charge button again.

⑤ When the defibrillation energy is fully charged, loudly and firmly instruct the patient and surrounding individuals not to contact with an object connected to the patient.

⑥ When using the pad, press the Shock button on CU-HD1. When using the paddle, press the orange button. When the R wave is detected, defibrillation will be delivered automatically.

Note

- Pressing the "Sync" button above the rotary switch lights the lamp in blue and activates the synchronized cardiac pacing mode. Pressing the "Sync" button again dims the blue light and deactivates the synchronized cardiac pacing mode.
- If markers do not appear above the R waveform, select another ECG lead. If synchronization markers do not appear, it means that the R wave could not be detected and therefore synchronized cardiac pacing energy cannot be delivered.

Warning

- If there is interference generated by patient movement while attached with the paddles or pads, or external contact, it may sense the R-wave and deliver the defibrillation energy to the patient. Therefore, avoid any contact with the patient during pacing.
- Since defibrillation may bring harm to the performer or surrounding people. Make sure to keep a safe distance from the patient and any electronic devices and conductive metals connected to the patient during defibrillation.
- Poor adherence and/or air under the defibrillation pads can lead to the possibility of arcing and skin burns.
- After pressing the Shock button, keep hands away from the electrode plates.
- Medical electrical equipment which does not incorporate defibrillator protection should be disconnected during defibrillation.
- Do not allow defibrillation pads of paddles to touch each other or to touch other ECG monitoring electrodes, lead wires, dressings, etc. Contact with metal objects may cause electrical arcing and patient skin burns during defibrillation and may divert current away from the heart.

5.4 Alarm for Manual Defibrillation Mode

For details on alarms generated in manual defibrillation mode, see alarm information for each vital sign measurement function (ECG, SpO_2, NIBP, $EtCO_2$) in **"Chapter 7_Patient Monitoring"**.
Details on alarm configuration and settings are available.

5.4.1 Type of Alarm

1) Physiological Alarms

Classification	Alarm Message	Priority	Indication	Condition
Algorithm	VT / VF	High	Red alarm message with alert sound	Patient's ECG measurement indicates ventricular fibrillation / ventricular tachycardia.
	Asystole	High	Red alarm message with alert sound	Patient's ECG measurement indicates cardiac arrest.
	Extreme Brady	High	Red alarm message with alert sound	Heart rate measurement exceeds the maximum set value by more than 20.
	Extreme Tachy	High	Red alarm message with alert sound	Heart rate measurement falls below the minimum set value by more than 10.
	HR High	Medium	Yellow alarm message with alert sound	Heart rate measurement exceeds the maximum set value.
	HR Low	Medium	Yellow alarm message with alert sound	Heart rate measurement falls below the minimum set value.
SpO_2	Pulse High	Medium	Yellow alarm message with alert sound	Pulse measurement exceeds the maximum set value.
	Pulse Low	Medium	Yellow alarm message with alert sound	Pulse measurement falls below the minimum set value.
	SpO_2 High	Medium	Yellow alarm message with alert sound	SpO_2 measurement exceeds the maximum set value.
	SpO_2 Low	Medium	Yellow alarm message with alert sound	SpO_2 measurement falls below the minimum set value.

Classification	Alarm Message	Priority	Indication	Condition
NIBP	Systolic High	Medium	Yellow alarm message with alert sound	Systolic blood pressure measurement exceeds the maximum set value.
	Systolic Low	Medium	Yellow alarm message with alert sound	Systolic blood pressure measurement falls below the minimum set value.
	Diastolic High	Medium	Yellow alarm message with alert sound	Diastolic blood pressure measurement exceeds the maximum set value.
	Diastolic Low	Medium	Yellow alarm message with alert sound	Diastolic blood pressure measurement falls below the minimum set value.
	Systolic High	Medium	Yellow alarm message with alert sound	Mean blood pressure measurement exceeds the maximum set value.
	Systolic Low	Medium	Yellow alarm message with alert sound	Mean blood pressure measurement falls below the minimum set value.
$EtCO_2$	Apnea	High	Red alarm message with alert sound	Respiration is not measured during the set duration (seconds).
	$EtCO_2$ High	Medium	Yellow alarm message with alert sound	$EtCO_2$ measurement exceeds the maximum set value.
	$EtCO_2$ Low	Medium	Yellow alarm message with alert sound	$EtCO_2$ measurement falls below the minimum set value.
	Respiration Rate High	Medium	Yellow alarm message with alert sound	Respiration rate measurement exceeds the maximum set value.
	Respiration Rate Low	Medium	Yellow alarm message with alert sound	Respiration rate measurement falls below the minimum set value.

2) Technical Alarms

Alarm Message	Priority	Indication	Condition
Transmission failed	Low	Turquoise alarm message with alert sound	Real-time Bluetooth transmission failed or 12-ch Bluetooth transmission failed.
Low battery level.	Low	Turquoise alarm message with alert sound	Low battery level.
NIBP Measurement Failure	Low	Turquoise alarm message with alert sound	NIBP measurement failure.
NIBP signal has noise artifacts	Low	Turquoise alarm message with alert sound	Oscillometric signal has noise.
NIBP Pneumatic Blockage	Low	Turquoise alarm message with alert sound	NIBP operation is interrupted by bent tubes, etc.
NIBP air leak or loose cuff	Low	Turquoise alarm message with alert sound	Air is leaking from tubes, etc.
NIBP Cuff Overpressure	Low	Turquoise alarm message with alert sound	NIBP is over-pressurized.
NIBP Error	Low	Turquoise alarm message with alert sound	There is a problem with NIBP module operation.
NIBP Calibration overdue	Low	Turquoise alarm message with alert sound	NIBP module calibration has expired.
NIBP Equipment Malfunction	Low	Turquoise alarm message with alert sound	NIBP device is faulty.
SpO_2 Error	Low	Turquoise alarm message with alert sound	There is a problem with the SpO_2 module.
Unidentified accessories	Low	Turquoise alarm message with alert sound	Invalid accessory ID.

Alarm Message	Priority	Indication	Condition
CO_2 : Out of range accuracy	Low	Turquoise alarm message with alert sound	Measurement value of the CO_2 sensor is outside the reference accuracy range.
CO_2 : Out of range/internal temperature	Low	Turquoise alarm message with alert sound	Internal temperature of the CO_2 sensor is outside the reference range.
CO_2 : Out of range/ambient pressure	Low	Turquoise alarm message with alert sound	The CO_2 sensor is outside the ambient pressure range.
CO_2 : Need zero calibration	Low	Turquoise alarm message with alert sound	The CO_2 sensor requires zero calibration.
Software Error	Low	Turquoise alarm message with alert sound	The CO_2 sensor has a software error.
Hardware Error	Low	Turquoise alarm message with alert sound	The CO_2 sensor has a hardware error.
Motor Speed out of bounds	Low	Turquoise alarm message with alert sound	The CO_2 sensor motor exceeds the speed range.
Factory calibration data loss	Low	Turquoise alarm message with alert sound	There is an error with the CO_2 sensor calibration value.
Equipment malfunction	High	Red alarm message with alert sound	An error is preventing the equipment from functioning.

Chapter 6. Noninvasive Pacer Mode

■ Overview

This mode helps maintain a heart rate by periodically contracting the heart with electric stimuli to the patient whose normal heart contraction is not observed.

An electric stimulus is delivered through the pads attached to the patient in a noninvasive manner.

The pacing method consists of two modes: 'Demand mode' that the pacing signals are transferred to when the patient's heart rate is slower than the preset pacing rate, and the 'Fixed mode' where the electric stimulus is delivered to the patient at a fixed heart rate.

Warning

- Do not deliver any defibrillation energy to any patients using the pacing function.
- If defibrillation is necessary, remove the cables connected with the pacing electrodes before carrying out the defibrillation.

Caution

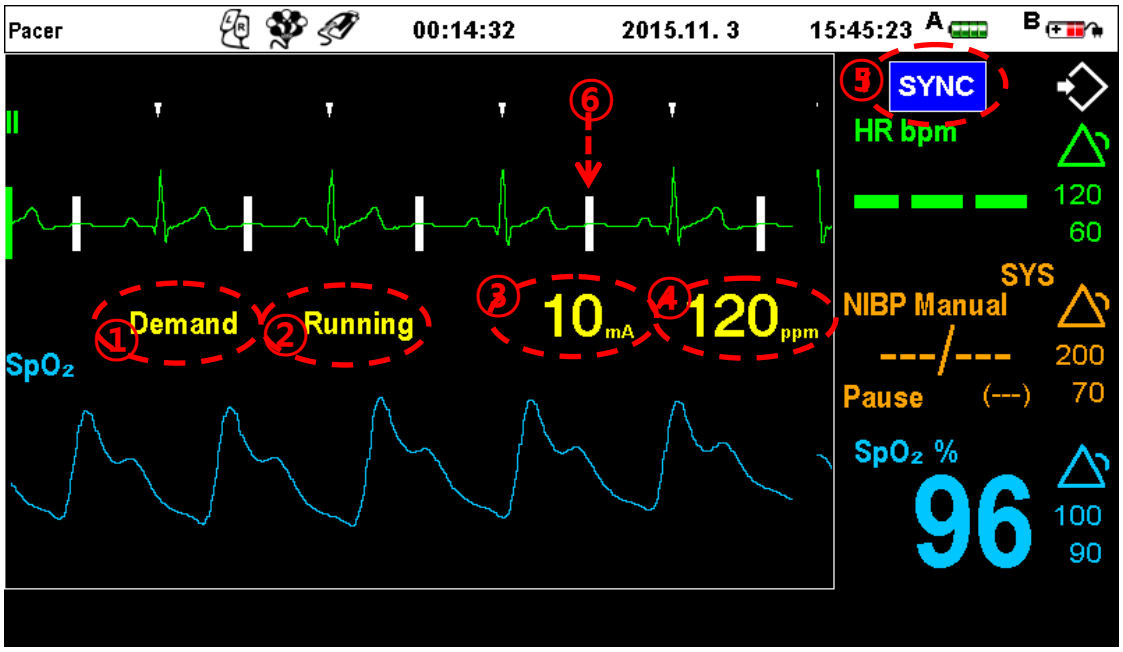
- Do not use the noninvasive pacer to any patients using the internal pacemaker.

Note

- The pacing controller is used in the same manner as pacer.

6.1 Preparing Pacing

6.1.1 Pacing Mode Layout



Pacer Mode	Shows whether the device is running in the Pacer mode.
①Pacer Mode	Shows the Pacer's mode (Fixed/Demand)
②Pacer Status	Shows whether the pacer is running or stopped.
③Current	Shows the current to be delivered.
④Pacing Rate	Shows the pacing rate (pacing times per minute).
⑤R-Sync Mark	Shows the R-Sync mark in sensing the R-wave while analyzing the ECG.
⑥Pacing Display	Shows a white indication when delivering the pacing pulse to the patient.

Caution

- During pacing, heart rate is shown on the screen as '---' due to inaccurate ECG.
- Since the diagnosis function on patient conditions is not offered by pacing, continue to watch the patient during pacing.

6.1.2 Preparing and Connecting Patient Monitoring Device

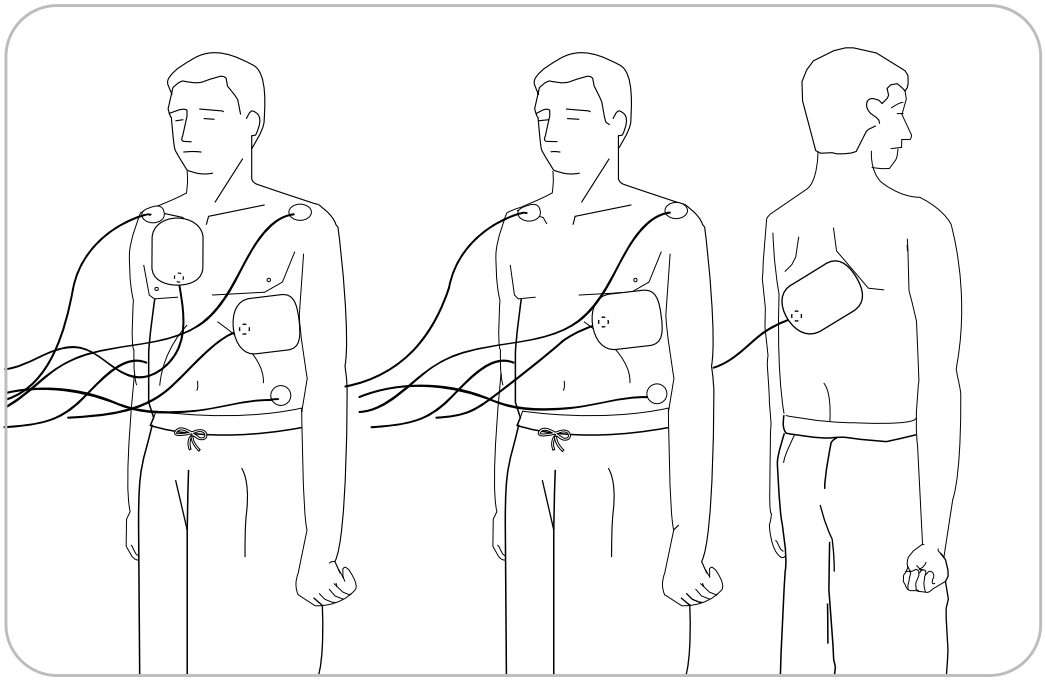
In order to check the patient's condition according to pacing, CU-HD1 displays vital signs detected from the 12-lead ECG and SpO2, NIBP, EtCO2 sensor on the screen. Each item can be selected using the lead select button and setting the Patient Monitoring mode function. It is necessary to check the patient's heart rate due to pacing and evaluate the patient's vital sign occasionally or continuously while carrying out the pacing treatment.

1) Connecting and Attaching the Pacing Pad

A disposable defibrillation pad is used for pacing.
(Refer to CUA0508O, CUA0809PM - 2.7 Accessories)

For how to connect and attach the pad, refer to "4.1.1 Connecting to the Device" and "4.1.3 Attaching and Connecting the Defibrillation Pads".

Attach the pads on the positions as shown in the figure below according to the patient's condition and circumstance.



[Attachment positions of pacing pads and ECG electrodes]

2) Connecting and Attaching the ECG electrodes

To check the pacing result through the ECG electrodes during pacing, use new disposable ECG electrodes.

For connecting the ECG cable, refer to **"7.1.1.1 Connecting ECG Cable"**.

Remove hair or foreign substances on the patient's body where the electrodes are attached using a razor or scissors.

Attach the ECG electrodes within an appropriate distance from the pads. If the ECG electrodes are placed close to the pads, the ECG signals may be distorted due to the pacing current. For the attachment position, refer to the figure above.

3) Measuring SpO_2, NIBP, and $EtCO_2$

To measure SpO2, NIBP and EtCO2 during pacing, refer to **"Chapter 7_Patient Monitoring"**.

⚠ Caution

- Maintain a proper distance between the pacing pads and the conductive part of the ECG electrodes, so as not to attach them together.
- If the pads are detached from the patient, a confirmation alarm will be issued.

6.1.3 Attaching Pacing Pads and ECG Electrodes

For accurate measurement of the ECG signals to check the pacing results in the Demand mode for pacing, it is recommended to use disposable ECG electrodes ever as not used as possible. If the skin with which the ECG electrodes contact is dirty, it may impact accurate measurement of the ECG signals.

Disposable defibrillation pads may be used for non-invasive demand mode pacing. And for details of how to attach disposable defibrillation pads to the patient, refer to Section **"4.1.3 Attaching the Defibrillation Pads".**

Caution

- Maintain a proper distance between the pacing pads and the conductive part of the ECG electrodes, so as not to attach them together.
- The patient's skin where the pads and the electrodes are attached should be kept dry. The patient's skin should be dry in order not to affect the measurement of the ECG signal. In such a case, no current will leak and/or the adhesive strength of the pads will not be maintained during pacing.
- Before using the pads and the electrodes, check the expiration date and any damage to the packaging. If damaged or expired, discard the package without using it.
- If pacing is carried out for a long period of time, replace the pads periodically.

Note

- If the pads are detached from the patient, a confirmation alarm will be issued.

6.2 Demand Pacing Mode

The Demand mode pacing was adopted to maintain the patient's heart rate when it is slower than a predefined heart rate.

6.2.1 Selecting Demand Pacing Mode

The Demand mode pacing can be selected by the "Mode" button. The Demand mode pacing and Fixed mode pacing can be switched back and forth by this button.

6.2.2 Steps of Demand Pacing

① To evaluate the pacing process, select the ECG by pressing the LEAD Selection button.

② If needed, measure SpO_2, NIBP, or $EtCO_2$.

③ Using the Rate and Current buttons on the pacer menu, the pacing rate and pacing current can be adjusted.

④ To start pacing, use the Start/Stop button. To stop it during pacing, stop it using the Start/Stop button.

⑤ Check whether pacing is in progress or displayed on the screen.

⑥ Check the patient's heart rate with respect to pacing through the ECG, SpO_2, pulse, NIBP, and $EtCO_2$. If the heart rate is not enough after checking his or her symptoms, increase the strength of the pacing current as needed.

⑦ Patient conditions may require a change in the current level as time goes on. During pacing, the performer must continue to monitor the patient.

Caution

- Do not touch the patient nor have the patient touch any devices while the pacing electric stimulus is active. Otherwise, the ECG will be distorted, impacting the pacing.
- If touching the patient to check the heart rate of the patient while delivering the pacing energy to him or her, it may be possible to be exposed to the pacing current.

6.3 Fixed Pacing Mode

The Fixed mode pacing delivers the pacing current to the patient at a predefined, constant heart rate regardless of the patient's heart rate.

6.3.1 Selecting Fixed Pacing Mode

The Fixed mode pacing can be selected the same way as the Demand mode pacing. Push the Mode button to select.

6.3.2 Steps of Fixed Pacing

① To evaluate the pacing process, select the ECG by pressing the LEAD Selection button.

② If needed, measure SpO_2, NIBP, or $EtCO_2$.

③ Using the Rate and Current buttons on the pacer menu, the pacing rate and pacing current can be adjusted.

④ To start pacing, use the Start/Stop button.

⑤ Check the patient's heart rate. If no pulse is recognized, increase the current level till the heart rate is sensed, and gradually adjust the current to the minimum level where the pulse is detected.

6.4 Ending Pacing

Stop pacing if defibrillation is needed while it's in progress. Perform defibrillation and CPR according to the AED and manual defibrillation methods described in Chapter 4 and 5.

Note

- It's recommended to use the Demand Pacing mode. The Fixed mode is normally used when there is ECG interference or noise that makes it difficult to sense the reliable R-wave in the Demand mode.

6.5 Alarm for Pacing Mode

For details on alarms generated in pacing mode, see alarm information for each vital sign measurement function (ECG, SpO_2, NIBP, $EtCO_2$) in **"Chapter 7_Patient Monitoring"**.
Details on alarm configuration and settings are available.

6.5.1 Type of Alarm

1) Physiological Alarms

Classification	Alarm Message	Priority	Indication	Condition
Algorithm	VT / VF	High	Red alarm message with alert sound	Patient's ECG measurement indicates ventricular fibrillation / ventricular tachycardia.
	Asystole	High	Red alarm message with alert sound	Patient's ECG measurement indicates cardiac arrest.
	Extreme Brady	High	Red alarm message with alert sound	Heart rate measurement exceeds the maximum set value by more than 20.
	Extreme Tachy	High	Red alarm message with alert sound	Heart rate measurement falls below the minimum set value by more than 10.
	HR High	Medium	Yellow alarm message with alert sound	Heart rate measurement exceeds the maximum set value.
	HR Low	Medium	Yellow alarm message with alert sound	Heart rate measurement falls below the minimum set value.
SpO_2	Pulse High	Medium	Yellow alarm message with alert sound	Pulse measurement exceeds the maximum set value.
	Pulse Low	Medium	Yellow alarm message with alert sound	Pulse measurement falls below the minimum set value.
	SpO_2 High	Medium	Yellow alarm message with alert sound	SpO_2 measurement exceeds the maximum set value.
	SpO_2 Low	Medium	Yellow alarm message with alert sound	SpO_2 measurement falls below the minimum set value.
NIBP	Systolic High	Medium	Yellow alarm message with alert sound	Systolic blood pressure measurement exceeds the maximum set value.
	Systolic Low	Medium	Yellow alarm message with alert sound	Systolic blood pressure measurement falls below the minimum set value.

Classification	Alarm Message	Priority	Indication	Condition
	Diastolic High	Medium	Yellow alarm message with alert sound	Diastolic blood pressure measurement exceeds the maximum set value.
	Diastolic Low	Medium	Yellow alarm message with alert sound	Diastolic blood pressure measurement falls below the minimum set value.
	Systolic High	Medium	Yellow alarm message with alert sound	Mean blood pressure measurement exceeds the maximum set value.
	Systolic Low	Medium	Yellow alarm message with alert sound	Mean blood pressure measurement falls below the minimum set value.
$EtCO_2$	Apnea	High	Red alarm message with alert sound	Respiration is not measured during the set duration (seconds).
	$EtCO_2$ High	Medium	Yellow alarm message with alert sound	$EtCO_2$ measurement exceeds the maximum set value.
	$EtCO_2$ Low	Medium	Yellow alarm message with alert sound	$EtCO_2$ measurement falls below the minimum set value.
	Respiration Rate High	Medium	Yellow alarm message with alert sound	Respiration rate measurement exceeds the maximum set value.
	Respiration Rate Low	Medium	Yellow alarm message with alert sound	Respiration rate measurement falls below the minimum set value.

Caution

- While pacing is being carried out, an ECG-related alarm will not be issued.

2) Technical Alarms

Alarm Message	Priority	Indication	Condition
Transmission failed	Low	Turquoise alarm message with alert sound	Real-time Bluetooth transmission failed or 12-ch Bluetooth transmission failed.
Low battery level.	Low	Turquoise alarm message with alert sound	Low battery level.
NIBP Measurement Failure	Low	Turquoise alarm message with alert sound	NIBP measurement failure.
NIBP signal has noise artifacts	Low	Turquoise alarm message with alert sound	Oscillometric signal has noise.
NIBP Pneumatic Blockage	Low	Turquoise alarm message with alert sound	NIBP operation is interrupted by bent tubes, etc.
NIBP air leak or loose cuff	Low	Turquoise alarm message with alert sound	Air is leaking from tubes, etc.
NIBP Cuff Overpressure	Low	Turquoise alarm message with alert sound	NIBP is over-pressurized.
NIBP Error	Low	Turquoise alarm message with alert sound	There is a problem with NIBP module operation.
NIBP Calibration overdue	Low	Turquoise alarm message with alert sound	NIBP module calibration has expired.
NIBP Equipment Malfunction	Low	Turquoise alarm message with alert sound	NIBP device is faulty.
SpO_2 Error	Low	Turquoise alarm message with alert sound	There is a problem with the SpO_2 module.
Unidentified accessories	Low	Turquoise alarm message with alert sound	Invalid accessory ID.
CO_2 : Out of range accuracy	Low	Turquoise alarm message with alert sound	Measurement value of the CO_2 sensor is outside the reference accuracy range.
CO_2 : Out of range/internal temperature	Low	Turquoise alarm message with alert sound	Internal temperature of the CO_2 sensor is outside the reference range.
CO_2 : Out of range/ambient pressure	Low	Turquoise alarm message with alert sound	The CO_2 sensor is outside the ambient pressure range.
CO_2 : Need zero calibration	Low	Turquoise alarm message with alert sound	The CO_2 sensor requires zero calibration.

Alarm Message	Priority	Indication	Condition
Software Error	Low	Turquoise alarm message with alert sound	The CO_2 sensor has a software error.
Hardware Error	Low	Turquoise alarm message with alert sound	The CO_2 sensor has a hardware error.
Motor Speed out of bounds	Low	Turquoise alarm message with alert sound	The CO_2 sensor motor exceeds the speed range.
Factory calibration data loss	Low	Turquoise alarm message with alert sound	There is an error with the CO_2 sensor calibration value.
Equipment malfunction	High	Red alarm message with alert sound	An error is preventing the equipment from functioning.

Chapter 7. Patient Monitoring

■ Overview

The patient monitoring mode enables observing patient conditions by measuring the patient's ECG, SpO_2, NIBP, and $EtCO_2$ using the ECG cables (3-, 5- and 10-lead), SpO2 sensor, NIBP cuff, and $EtCO_2$ measuring module.

In addition, with the alarm setting on the menu, an alarm is issued whenever an abnormality of the patient's ECG is detected, leading to appropriate treatment.

The 12-lead ECG measures and patient monitoring information can be checked by connecting into a computer through the Bluetooth communication. For details of information transfer, refer to **"Chapter 9_Communication and Data Management"**.

Caution

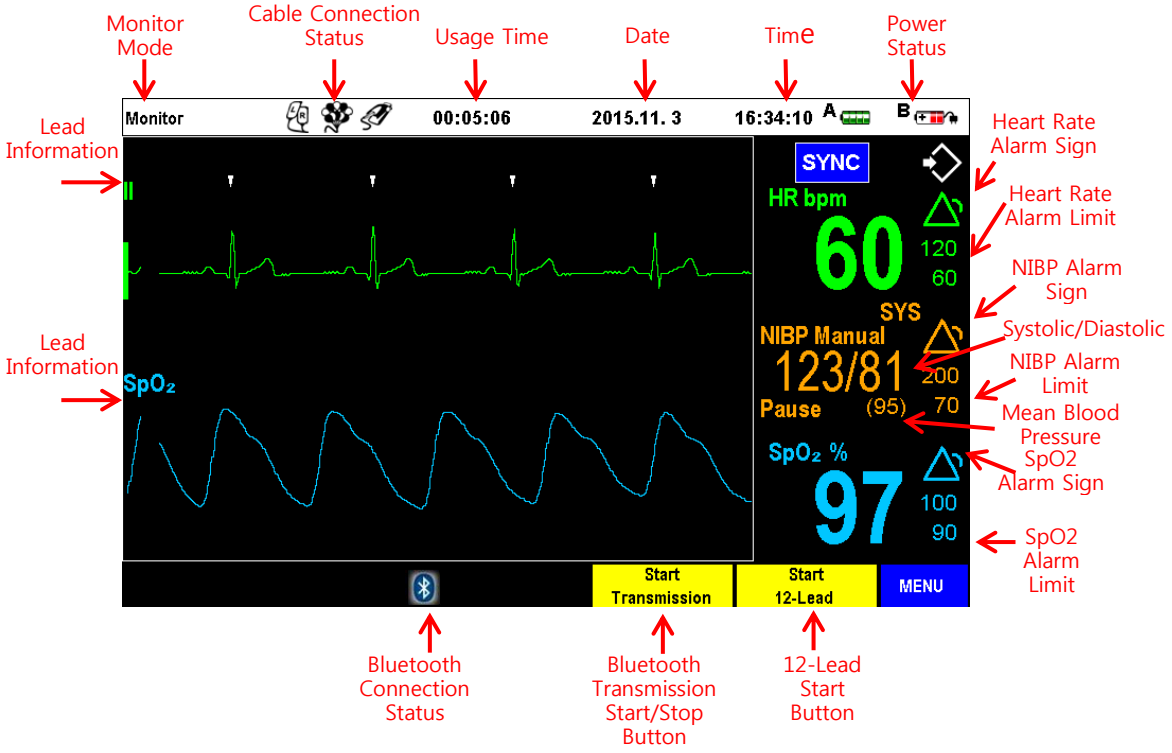
- If attaching the pads to the patient to use the defibrillation function while measuring the ECG in the patient monitoring mode, make sure that the electrodes used in measuring the ECG and defibrillation paddles or pads do not make any contact.
- If it is necessary to monitor for a long period of time, replace the ECG electrodes or the pads periodically.

Note

- To safely shut the CU-HD1 down while in Monitor mode, rotate the rotary switch to the OFF position.

◎ Patient Monitoring Mode Layout

Turning the Rotary switch to "Monitor" brings up the following screen. Push the LEAD Change button on the left to change the ECG lead shown on the upside of the monitor.



Monitor Mode	Informs which mode is running.
Usage Time	Displays the total time of use of the device after turning it on.
Date	Displays the date.
Current Time	Shows the current time.
Power Status	Shows the input power state when using the remaining battery indication or the AC power module.
Heart Rate	Shows beat per minute(bpm), predefined alarm limit
SpO_2	Shows SpO_2(%),predefined alarm limit
NIBP	Shows blood pressure(mmHg), Systole/diastole, mean blood pressure, predefined alarm limit
"Start 12-Lead" Button	Starts 12-Lead Mode.

Caution

- While printing, pressing the lead change button in Sector 1 stops the printing.
- If only Sector 1 is printing, the lead for Sector 2 can be changed while printing.
- If both Sector 1 and Sector 2 are printing, the lead for Sector 2 cannot be changed while printing.

7.1 Monitoring ECG

■ Overview

The CU-HD1 can be used with 3-lead, 5-lead or 12-lead ECG patient cables, ECG electrodes, and defibrillation pads to perform ECG monitoring.

The equipment analyzes ECG and provides alarms based on heart rate, ventricular fibrillation or ventricular tachycardia.

For ECG monitoring over long periods or for more precise ECG measurement, make sure to select an appropriate channel (I, II, III, aVR, aVF, aVL, V1 - V6) based on the patient's condition as monitored with ECG electrodes.

The patient's ECG obtained through the amplification and operation of differential voltages between minute electromotive forces occurred due to the cardiac activities measured through the electrodes is displayed on the monitor as waveforms and values. When this value exceeds the range of set values for alarm, an alarm will be issued, indicating the abnormal condition of the patient.

Warning

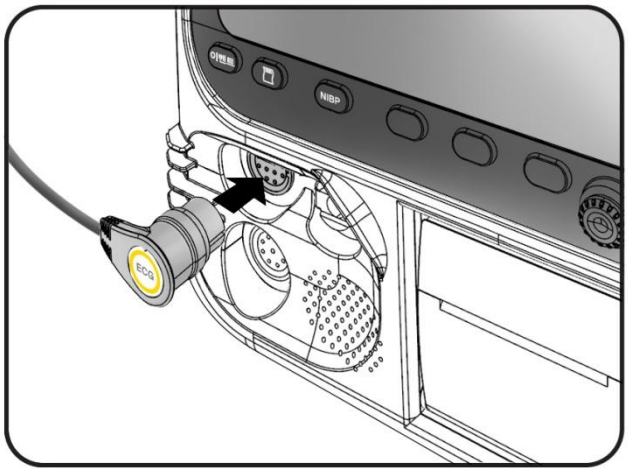
- The monitoring alarm of CU-HD1 is set to adult by default. If it is necessary to monitor an infant, change the alarm settings according to the circumstances of the infant. Using the product without changing the alarm settings may result in inaccurate alarms.
- When monitoring is done on patients with pacemakers, monitoring accuracy deteriorates significantly. In this case, asystole, etc. may not be detected. Check the operation and integrity of the CU-HD1 and ECG cable regularly by performing the Self-test.

7.1.1 ECG Monitoring Setup

7.1.1.1 Connecting ECG Cable

Connect the ECG cable and CU-HD1 by checking the grooves on the ECG cable connector and the ECG terminal on the main body.

If you would like to measure ECG by using 3-lead, 5-lead, 10-lead, all of the cables must be inserted into the ECG terminal.



7.1.1.2 Setting

1) Inputting the information for patient monitoring

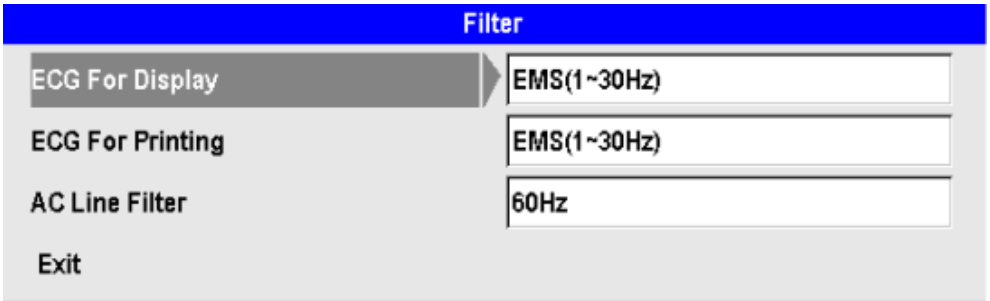
In Monitor Mode, use the Menu knob to enter patient information.

For more details on entering information, see **"8.1 Patient Information".**

2) Filter

At the "Filter" menu, you can set a bandwidth with which you can check out the ECG signal detected by the CU-HD1.

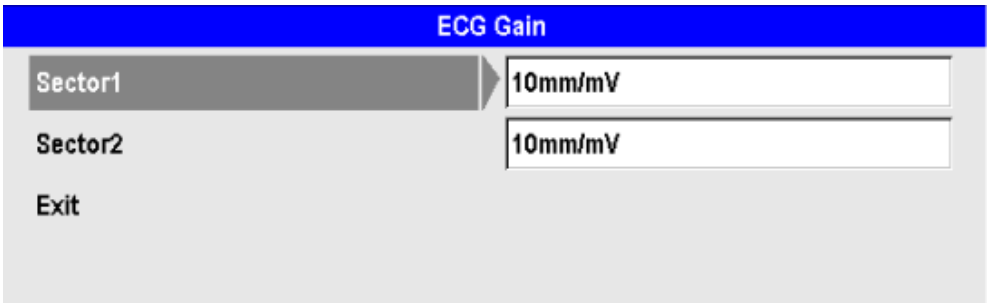
Support for the function of filtering the LCD monitor and printer ECG signal, and individual optional item is listed as follows.



- **ECG For Display**
  You can select the filter bandwidth of EMS (1~30Hz) and Monitor (0.5~40Hz). Default setting is EMS.
- **ECG For Printing**
  You can select the filter bandwidth of EMS (1~30Hz), Monitor (0.5~40Hz), and Diagnostic (0.05~150Hz). Default setting is EMS.
- **AC Line Filter**
  This is an item to remove the power noise. Select 60Hz or 50Hz according to the power source. Default setting is 60Hz.

3) ECG Gain

This is the menu item that takes control of the ECG sensitivity degree. If the ECG signal is too high or too low, you can change the signal level to an extent that you can easily verify it. Default setting is 10mm/mV.



- **Sector 1**
  As for the ECG signals displayed in the Sector 1, click the menu knob to choose the ECG signal size from Auto Gain, 5mm/mV, 10mm/mV, and 20mm/mV.
- **Sector 2**
  As for the ECG signals displayed in the Sector 2, click the menu knob to choose the ECG signal size from Auto Gain, 5mm/mV, 10mm/mV, and 20mm/mV.

Note

- Changes made to the settings in the menu are not saved. To change the default settings, see the Service Manual.

7.1.1.3 Preparing ECG Monitoring

1) Attaching ECG Electrodes to patient

① Remove hair or foreign substances on the location where the electrodes are attached using a razor or scissors as necessary.

② Use rubbing alcohol to wipe any grease off the skin.

③ Remove all moisture from the skin and allow it to dry completely before attaching electrodes.

④ Connect electrodes to the ECG cable (3-lead, 5-lead, or 12-lead) firmly before connecting electrodes to the patient.

⑤ Check expiry dates and condition of the electrodes, then remove electrode packaging. Attach the electrodes to the patient one at a time.

⑥ When connecting the electrodes, check that the entire electrode is firmly attached to the patient and that the wire is not detached outside the electrode.

⑦ For details on attachment positions of the electrodes, see **"7.1.1.4 Location of ECG Electrodes"**.

Note

- If monitoring for an extended period of time, monitoring electrodes and multifunction electrode pads may need to be changed periodically. Refer to the manufacturer's documentation for replacement frequency.

Caution

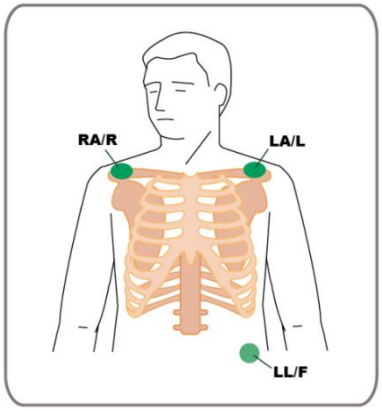
- Do not allow the conductive unit of the electrodes, including the neutral electrode and relevant connections, to come into contact with any other conductors, including the ground.

Warning

- When using ECG electrodes, always check the expiry date. Also, remove the ECG electrodes from sealed packaging immediately before use.
- When using the expired disposable ECG electrode and the disposable ECG electrode whose envelope is lost, the accurate ECG measurement is not guaranteed.

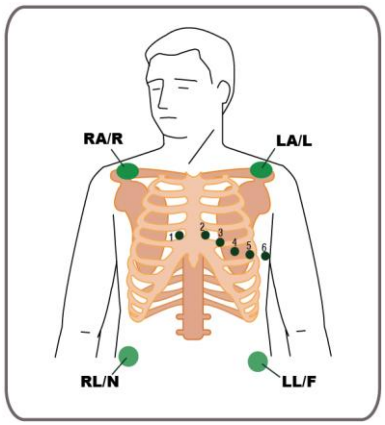
7.1.1.4 Location of ECG Electrodes

1) 3-Lead



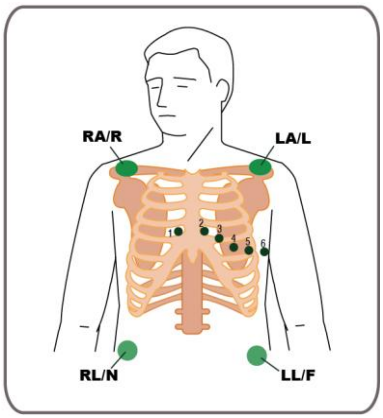
- **RA/R** Underneath the right shoulder collarbone, or the right arm
- **LA / L** Underneath the left shoulder collarbone, or the left arm
- **LL / F** Left lower abdomen or left leg

2) 5-Lead



- **RA/R** Underneath the right shoulder collarbone, or the right arm
- **LA / L** Underneath the left shoulder collarbone, or the left arm
- **LL / F** Left lower abdomen or left leg
- **RL/N** Right lower abdomen
- **V/C** Among 12-lead locations, select the desired one from V1 ~ V6

3) 12-Lead

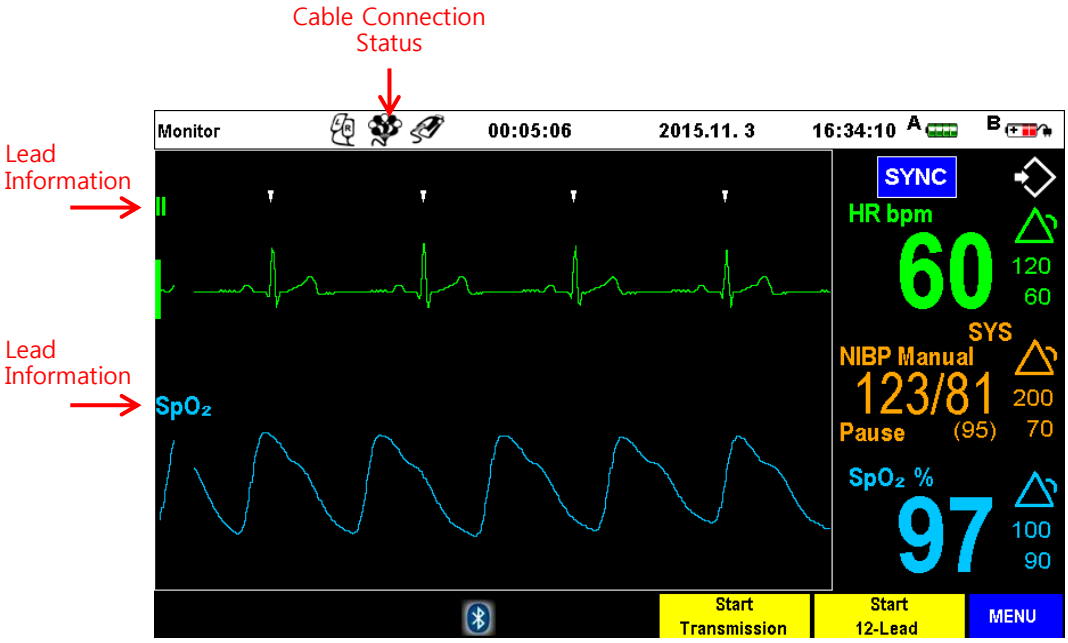


- **RA/R** Underneath the right shoulder collarbone, or the right arm
- **LA / L** Underneath the left shoulder collarbone, or the left arm
- **LL / F** Left lower abdomen or left leg
- **RL/N** Right lower abdomen
- **V1/C1** Right 4th sterna intercostal
- **V2/C2** Left 4th sterna intercostal
- **V3/C3** Middle between V2 and V4
- **V4/C4** 5th sternal intercostal in the medial line of left collarbone
- **V5/C5** Anterior axillary line in the horizontal line to V4
- **V6/C6** Medial axillary line in the horizontal line to V4

7.1.1.5 Measuring ECG

During ECG measurement, it is very important to select an appropriate lead for accurate detection of the QRS complex through monitoring.

If necessary, select an appropriate ECG waveform size.



1) Selecting Lead

Type of ECG	Type of applicable lead
3-Led	I, II, III
5-Lead	I, II, III, aVR, aVL, aVF, V
12-Lead	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6

Note

- Setting "Device Management / ECG Size" to "Auto Gain" automatically shows the adequately sized ECG waveform on the screen.
- Should a "Lead Fault" message appear, check the ECG cable or electrode connections. If the problem persists, replace the cables and electrodes.
- Dotted lines on the ECG denote invalid ECG signals in the waveform sector.
- In this case, check that an appropriate lead has been selected, and that the pads, ECG electrode cable and electrodes are attached correctly.
- When replacing the lead cables, dotted lines appear momentarily.
- Dotted lines appear when the "Lead Fault" error occurs.

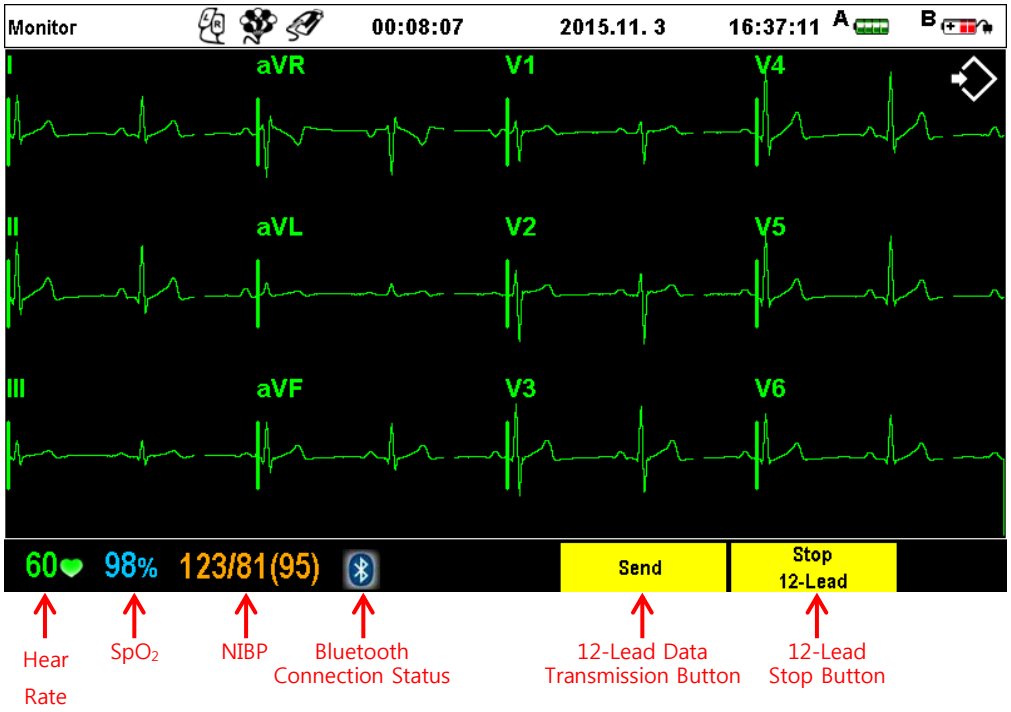
7.1.2 12-Lead ECG measurement

Use the lead selection button to select a lead to display from the 12-lead ECG (I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6) shown in Section 1 and Section 2.

◎ Layout

Push the "Start 12-lead" soft key. And check the ECG signal while the patient keeps his/her body in the same position.

If needed, press the MENU key to enter patient information.



Heart Rate	Shows the heart rate.
SpO_2	Shows the SpO_2 value measured for the patient.
NIBP	Shows the NIBP value measured for the patient.
Blutooth Connection Status	Displays whether the device is connected to Bluetooth communication. (Blue: Connected, Red: Disconnected)
12-Lead Data Transfer	Transfers the 12-lead data by the use of Bluetooth communication.
Stop 12-Lead	Stops 12-lead measurement.

Warning

- Do not connect many devices to the patient at once. The leakage limit of the current may be exceeded.
- Adjusting the ECG waveform size on the screen does not affect the ECG data used in arrhythmia analysis.

Caution

- In case of a patient implanted with a pacemaker, the heart rate meter may count the pacemaker rate even if cardiac arrest or other arrhythmias occurs. To avoid a shock hazard and interference from nearby electrical equipment, keep electrodes and patient cables away from grounded metal and other electrical equipment.
- ECG monitoring of the patient can be measured accurately when the patient is motionless.
- Physiological alarms may be triggered by environmental factors.

7.1.3 Alarm for ECG Measuring

7.1.3.1 Type of Alarm

1) Physiological Alarms

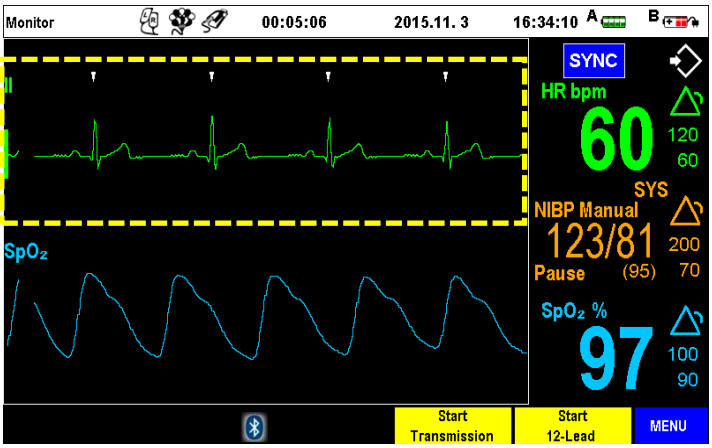
Alarm Message	Priority	Indication	Condition
VF / VT	High	Red alarm message with alert sound	Patient's ECG measurement indicates ventricular fibrillation / ventricular tachycardia.
Asystole	High	Red alarm message with alert sound	Patient's ECG measurement indicates cardiac arrest.
Extreme Brady	High	Red alarm message with alert sound	Heart rate measurement exceeds the maximum set value by more than 20.
Extreme Tachy	High	Red alarm message with alert sound	Heart rate measurement falls below the minimum set value by more than 10.
HR High	Medium	Yellow alarm message with alert sound	Heart rate measurement exceeds the maximum set value.
HR Low	Medium	Yellow alarm message with alert sound	Heart rate measurement falls below the minimum set value.

2) Technical Alarms

Alarm Message	Priority	Indication	Condition
Transmission failed	Low	Turquoise alarm message with alert sound	Real-time Bluetooth transmission failed or 12-ch Bluetooth transmission failed.

Warning

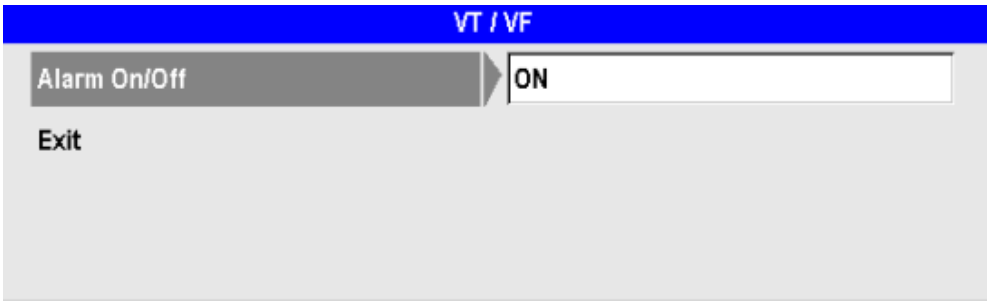
- Arrhythmias-related alarms only occur when lead II of the pads or the ECG electrodes is selected for Sector 1 in Monitor mode. To monitor the patient's ECG, set the pads or ECG lead II for the lead section from Sector 1 (yellow box in the figure below).



7.1.3.2 Alarm Setting

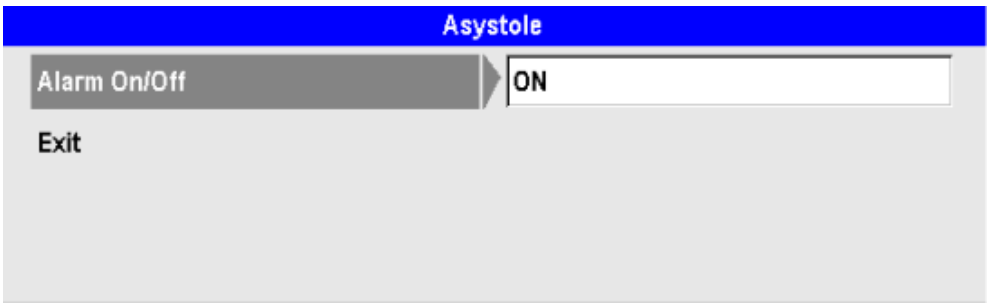
1) VT/VF

This is a screen to set it to On/Off to generate the alarm sound when detecting Ventricular Tachycardia (VT), or Ventricular Fibrillation (VF).



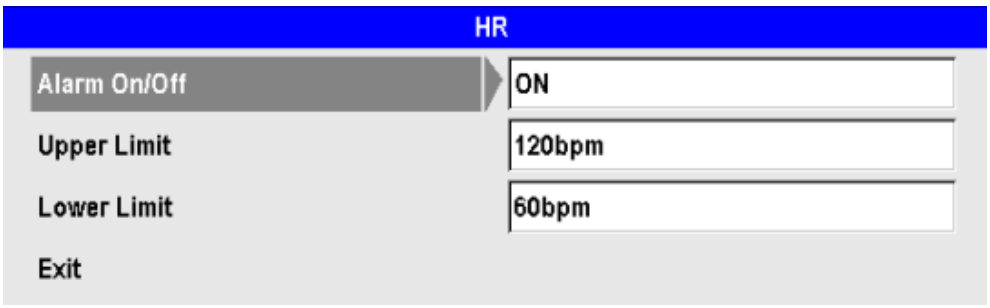
2) Asystole

This is a screen to set it to On/Off to generate the alarm sound when detecting Asystole.



3) Heart Rate

This is an item to set the alarm according to Heart Rate (HR) measured through the ECG cable or pad.



- **Alarm On/Off**
  You can set it to On/Off to generate an alarm sound when the patient HR goes beyond the assigned numeric setting.
- **Upper Limit**
  This is the maximum value of patient HR that generates an alarm sound, which can be changed by 5bpm with the Menu selection button. Numeric values you can set range from 35 to 300bpm.
- **Lower Limit**
  This is the minimum value of patient HR that generates an alarm sound, which can be changed by 5bpm with the Menu selection button. The numeric values that you can set ranges from 30 to 295bpm.

7.2 Measuring Pulse CO-Oximetry(SpO_2)

■ **Overview**

The SpO2 Module measures functional oxygen saturation in the blood. The measurement determines the oxygenated hemoglobin as a percentage of the hemoglobin that can transport oxygen. The SpO_2 Pulse Oximetry is used as one of supplementary measures, enabling to measure SpO_2 and pulse rate.

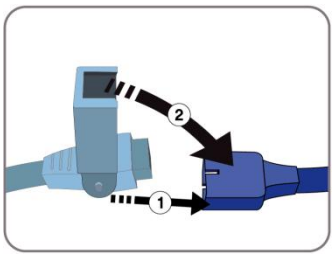
The product uses the principle of spectrophotometry. SpO2 is measured percutaneously using a difference in the optical density occurring when two lights at a natural wavelength pass through material with a different concentration, while pulse waveform, value of SpO2 concentration, and heart rate are displayed on the monitor through the operation. When this value exceeds the range of set values for alarm, an alarm will be issued, indicating the abnormal condition of the patient.

7.2.1 Preparing to Measure SpO_2

7.2.1.1 Connecting to the Device

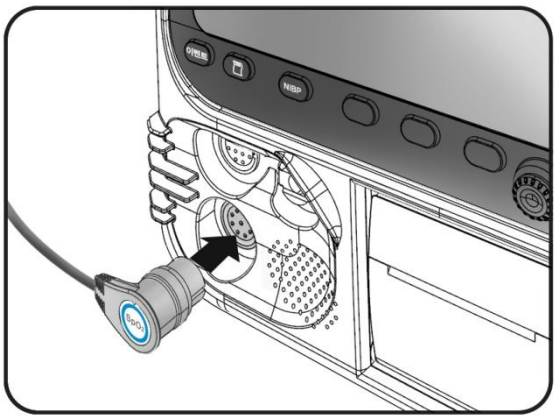
A SpO2 alarm is issued when the measurement exceeds or falls below the range of the set values. The SpO2 alarm is a non-latch alarm, so it will be canceled when the measurement falls under the range of the set values.

1) Connection to the SpO_2 Sensor and SpO_2 Sensor Extension Cable



2) Connecting SpO_2 Sensor Extension Cable to the Main body

How to connect the SpO_2 connection cable and the CU-HD1 is shown below, and the groove of the connector and input terminal prevents inaccurate connection.

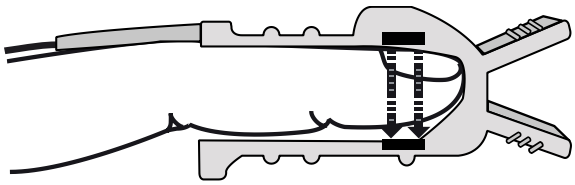


7.2.1.2 Inputting the information for patient monitoring

In Monitor Mode, use the Menu knob to enter patient information.

For more details on entering information, see **"8.1 Patient Information".**

7.2.1.3 Applying the SpO_2 Sensor



① Position the sensor so the cable is above the finger.

② Ensure the sensor is correctly connected to the finger as illustrated.

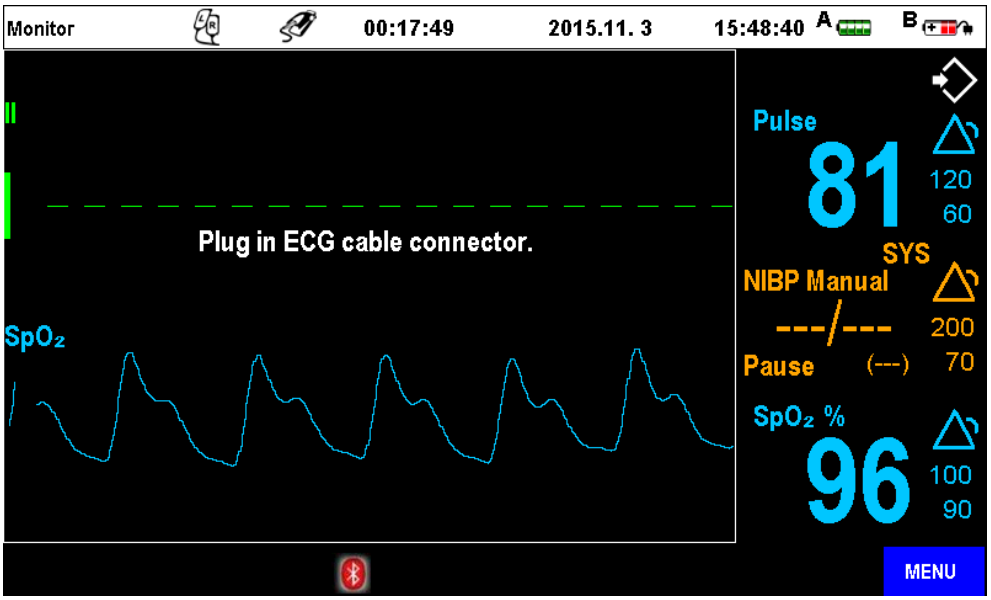
③ After use, remove the sensor from the patient, wipe the entire sensor pad clean with 70% isopropyl alcohol and allow it to air dry.

⚠ Caution

- On the finger to be measured, there must be the presence of normal perfusion.
- LED light must be located in the location where light can be passed through the body.
- Take caution that bright sun rays and bright light in the surgery room will be not detected by the sensor.
- If necessary, cover the sensor site with opaque fabric or tape so that light cannot pass through the sensor part.
- Always keep the sensor dry.
- If excessive movement occurs to the object to be measured, SpO2 cannot be measured.
- Inspect the sensor application site at least every two hours for changes in skin quality, correct optical alignment and proper sensor application. If skin quality is compromised, change the sensor site. Change the application site at least every four hours. More frequent checking may be required due to an individual patient's condition

7.2.1.4 Measuring SpO_2

When the SpO_2 sensor is attached to the finger, the CU-HD1 automatically starts measurement and displays SpO_2 and pulse on the screen as illustrated.



[SpO_2 Measurement Screen]

Note

When measuring SpO_2 only, the screen shows **[SpO_2 Measurement Screen]** above, along with a pulse. When pads, paddles, or ECG cables are connected (not in Lead Fault condition) and ECG is measured, pulse is shown in HR bpm.

Caution

SpO_2 is one of the supplementary measures to check the patient's status; the measurement value is subject to change according to the patient's status and ambient condition. Measurement values may change in the following cases.

- Hypothermic patient or Acidotic patient
- Patients that are receiving a photosensitive drug
- Patients that are receiving vasoconstrictor medications
- Patients that have poor circulation
- Hemoglobin malfunction patient
- Severe anemia patient
- Elevated levels of bilirubin
- Interference by carboxyhemoglobin and methemoglobin
- Injected dyes such as methylene blue
- Exposure to excessive illumination such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps or direct sunlight
- Equipment with an inaccurate sensor

Warning

- Always use DS100A sensors and extension cables approved by CU Medical Systems, Inc. Check compatibility before use of sensors or extension cables from other manufacturers, as they may affect defibrillator performance.
- The CU-HD1 is calibrated to display functional oxygen saturation.
- Incorrect usage of the sensors under excessive pressure for long periods may result in pressure damage.

Note

- Some models of commercially available bench top functional testers and patient simulators can be used to verify the proper functionality of pulse oximeter sensors, cables and monitors. See the individual testing device's operation manual for the procedures specific to the model of tester that you are using.
- SpO_2 measurement accuracy can only be evaluated in vivo by comparing pulse oximeter readings with values traceable to SpO_2 measurements obtained from simultaneously sampled arterial blood using a laboratory CO-oximeter.
- Functional test equipment designed for SpO_2 testing cannot be used to assess the accuracy of the SpO_2 readings.
- See the sensor's operation manual for the maximum temperature possible at the sensor-skin interface and other information such as intended patient population, sensor application sites and use criteria.
- Information about wavelength range can be useful to clinicians, especially those performing photodynamic therapy

7.2.2 Alarm for Measuring SpO_2

SpO_2 alarms with measurement settings are activated when the measurement exceeds or falls below the set value. SpO_2 alarms are non-latch alarms; they are automatically deactivated when the trigger condition no longer exists.

7.2.2.1 Type of Alarm

SpO_2 measurement mode has physiological alarms and technical alarms.

1) Physiological Alarms

Alarm Message	Priority	Indication	Condition
Pulse High	Medium	Yellow alarm message with alert sound	Pulse measurement exceeds the maximum set value.
Pulse Low	Medium	Yellow alarm message with alert sound	Pulse measurement falls below the minimum set value.
SpO_2 High	Medium	Yellow alarm message with alert sound	SpO_2 measurement exceeds the maximum set value.
SpO_2 Low	Medium	Yellow alarm message with alert sound	SpO_2 measurement falls below the minimum set value.

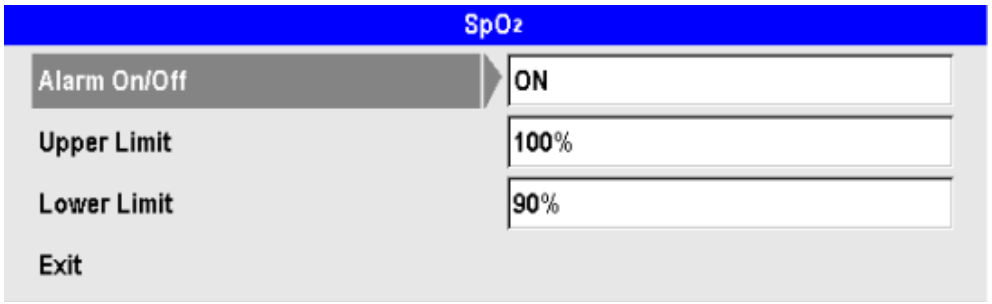
2) Technical Alarms

Alarm Message	Priority	Indication	Condition
SpO_2 Error	Low	Turquoise alarm message with alert sound	There is a problem with the SpO_2 module.

7.2.2.2 Alarm Setting – SpO_2

You can set the SpO_2 measurement alarm trigger range. Available fields include "Alarm On/Off", "Upper Limit" and "Lower Limit".

Press the Menu Knob and select Alarms → SpO_2 to open the SpO_2 Alarm Settings screen.

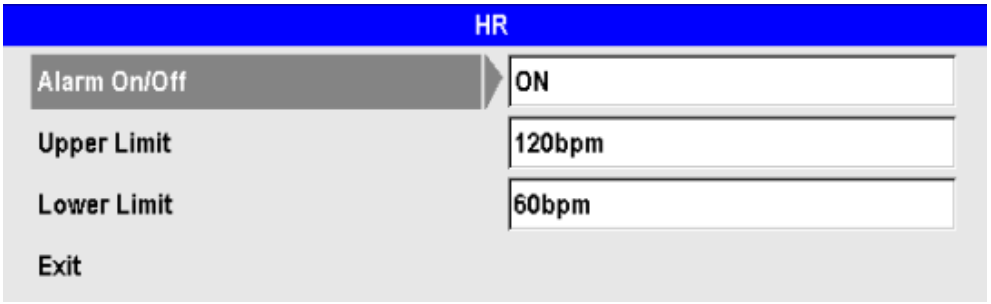


- **Alarm On/Off**
  You can set it to On/Off to generate the alarm sound when the measured SpO_2 value goes beyond the assigned numeric range.
- **Upper Limit**
  This is the maximum value of SpO_2 that generates the alarm sound, which can be changed by 1% with the Menu selection button. The numeric values that you can set range from 2 to 100%.

- **Lower Limit**
  This is the minimum value of SpO2 that generates the alarm sound, which can be changed by 1% with the Menu selection button. The numeric values that you can set ranges from 1 to 99%.

7.2.2.3 Setting Alarm – Heart Rate

This is an item to set the alarm according to Heart Rate (HR) measured through the SpO_2 sensor.



- **Alarm On/Off**
  You can set it to On/Off to generate an alarm sound when the patient HR goes beyond the assigned numeric setting.
- **Upper Limit**
  This is the maximum value of patient HR that generates an alarm sound, which can be changed by 5bpm with the Menu selection button. Numeric values you can set range from 35 to 300bpm.
- **Lower Limit**
  This is the minimum value of patient HR that generates an alarm sound, which can be changed by 5bpm with the Menu selection button. The numeric values that you can set ranges from 30 to 295bpm.

7.3 Measuring Noninvasive Blood Pressure (NIBP)

■ **Overview**

The systolic and diastolic blood pressures are measured using a vibration occurring when the blood flow resumes at the time of inflation and deflation of the cuffs. The average from the resumption of blood flow when expanding and the mean arterial pressure is calculated and displayed on the monitor. If the systolic and diastolic blood pressures go outside the range of set value for alarm, an alarm will be issued, indicating the abnormal condition of the patient.

The systolic and diastolic blood pressures are measured using a vibration occurring when the blood flow resumes at the time of inflation and deflation of the cuffs. The average from the resumption of blood flow when expanding and the mean arterial pressure is calculated and displayed on the monitor. If the systolic and diastolic blood pressures go outside the range of set value for alarm, an alarm will be issued, indicating the abnormal condition of the patient.

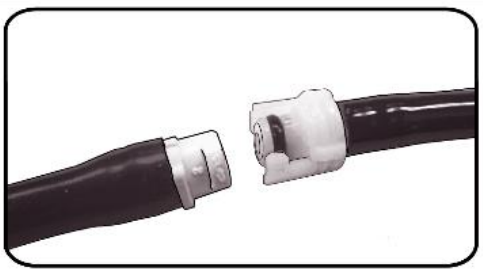
Non-invasive blood pressure (NIBP) is displayed on the monitor in modes other than Automatic Defibrillation mode, and in case of 12-lead ECG mode, measurements are displayed only at the bottom of the screen. Automatic occasional NIBP measurement and manual NIBP measurement functions are provided. Occasional time and alarm-related measurement settings can be modified in the menu.

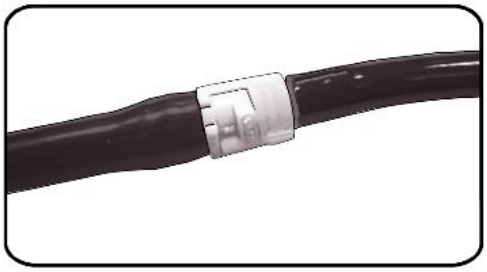
7.3.1 Preparing to Measure NIBP

7.3.1.1 Connecting to the Device

To mount the cuff for noninvasive blood pressure (NIBP) measuring to the CU-HD1, a separate connection tube is needed.

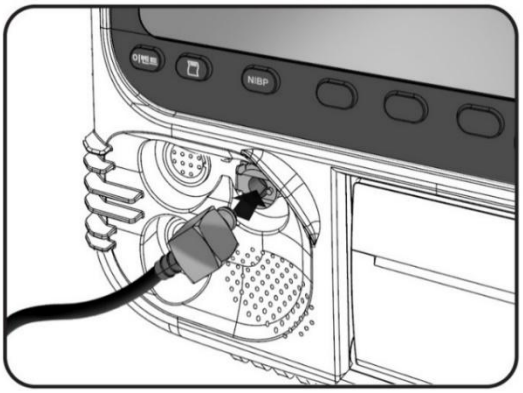
1) Connecting the Cuff and the Connection Tube for NIBP Measuring





2) Connecting the Connection Tube to the Main body

To use the NIBP function, you need to mount the tube connected with the cuff to the NIBP input port of the main body as shown below. Hold the metal connector of the tube and pull it in the opposite direction of the product to disconnect the tube from the main body.



7.3.1.2 Inputting the information for patient monitoring

In Monitor Mode, use the Menu knob to enter patient information.

For more details on entering information, see **"8.1 Patient Information"**.

Warning

Before measurement, choose the correct Patient Category from the menu. It is important for the safety of the patient that you choose the correct "Patient Category" (Adult, Pediatric, Neonate) since the maximum expansion pressure is determined based on your selection.

For details on changing Patient Category, see Menu. The default setting is "Adult".

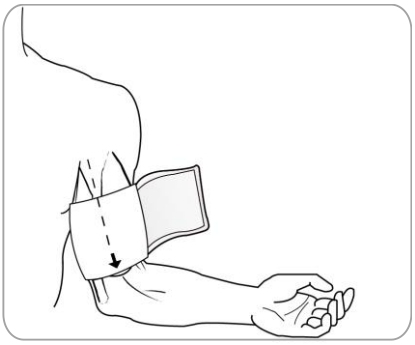
7.3.1.3 Applying the Cuff to the Patient

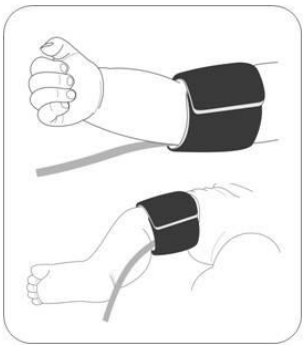
① Select an appropriate cuff for the patient.

② If there is no cuff that fits the patient well, select a larger cuff rather than a smaller one.

Adult	Pediatric	infant
circumference 23~33cm	circumference 12~19cm	circumference 8~13cm

※ Proper location of cuff





③ Ensure the patient is lying down or comfortably seated with legs uncrossed, both feet on the floor, and back supported. The limb to be used for NIBP measurement should be relaxed, extended, and placed on a smooth surface for support. The operator position is not restricted during NIBP measurement.

④ Sqeeze as much air from the cuff as possible before placing it on the patient.

⑤ Place the suff 2 to 5cm above the elbow crease.

⑥ Adjust the cuff so that the artery marker on the cuff is over the artery, pointing to the hand or foot.

⑦ Check that the cuff ends between the range lines marked on the cuff.

⑧ If they do not line up, use a different size cuff.

⑨ Wrap the deflated cuff snugly around the limb without impeding blood flow.

⑩ Ensure that the hose is routed th avoid kinking or compression.

⑪ Keep the cuff placement at the same level as the heart.

Warning

- Avoid using the cuff on parts of the body where damage to the tissue from external air pressure can be expected.
- Never use anything other than the cuff supplied with the defibrillator. CU Medical Systems, Inc. will not be liable for any problems caused by the use of products other than the cuff supplied.

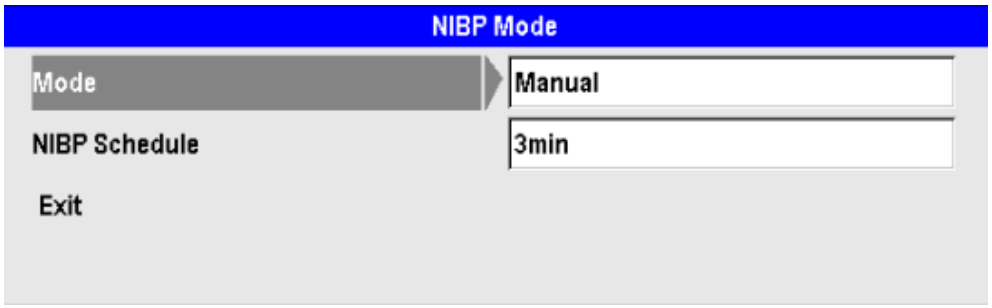
Caution

- Select and use a proper cuff according to the patient for accurate measurement of noninvasive blood pressure (NIBP) by referring to "2.7 Accessories". If a cuff which is too small is used, the measured blood pressure will be higher than the actual blood pressure of the patient, and if a cuff which is too large is used, the measured blood pressure will be lower than the actual blood pressure of the patient.
- When the blood pressure is measured while the cuff is loose or air remains in the cuff, the measured blood pressure may be higher than the actual blood pressure. Use the cuff by adhering it to the patient as closely as possible while it is being deflated.

7.3.1.4 Measuring NIBP

① Selecting Mode

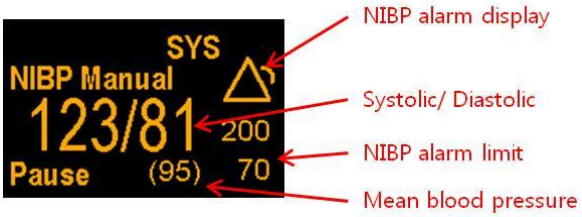
This product takes NIBP measurements in manual and automatic modes. Mode selection (automatic or manual) can be made using the menu.



Mode	Description
Manual Mode	Pressing the NIBP button starts the measurement.
Auto Mode	When NIBP Mode is set to "Automatic", measurements can be taken by adjusting the measurement interval to 1, 3, 5, 10, 15, 30, 60 or 120 minutes.

② Measuring NIBP

Pressing the "NIBP" button starts the measurement according to the selected mode. During measurement, the cuff attached to the patient expands and pressure applied is shown on the screen. When measurement is complete, the systolic and diastolic blood pressures (mean blood pressure) are displayed on the screen. Pressing the NIBP button once during measurement stops the measurement.



During measurement, press the NIBP button to stop the measurement.

Warning

- Use clinical judgment to decide whether or not to perform automatic blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb wearing the cuff.
- Do not apply the cuff to a limb that has an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.
- Prolonged series of NIBP measurements in automatic mode may be associated with purpura, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements immediately
- Care should be taken when using an NIBP measurement mode on patients with decreased consciousness, neuropathy, irregular cardiac rhythm, labile high blood pressure, increased arm activity, or arterial insufficiency especially if the unit is utilized for a prolonged period. Pay particular attention to unconscious patients since they cannot alert you if the pain is present.
- Accurate measurements are not guaranteed in circumstances such as dramatically fluctuating barometric pressure (inside airplane or elevator) or hyperbaric chamber.
- Do not allow the NIBP tube to become kinked or crushed. This could prevent normal cuff deflation resulting in patient injury due to prolonged restriction of blood flow.
- Do not place cuff over a wound, as this can cause further injury.
- Repeated use of SpO_2 measurements on the same patient over a short time interval can affect blood pressure readings, limit circulation to the limb, and cause injury to the patient.
- Observe the patient's limb periodically to ensure that circulation is not impaired for a prolonged period of time.
- Do not place the NIBP cuff on the same arm or leg as an SpO_2 sensor. Inflation of the cuff causes the SpO_2 monitor to read incorrectly.
- Do not attach the NIBP cuff to the arm on the side of the body where a mastectomy has been performed. Attach the cuff on the other arm for blood pressure measurement.

Caution

- The pulse measured during NIBP measurement is not displayed on the screen. For patient heart rate information, use the SpO_2 sensor or ECG electrodes.
- A major air leak can be preventing cuff inflation. Check hose and cuff connections, replace a defective hose or cuff, as necessary, and reattempt NIBP measurement. Check hose for kinks. Kinked hose can be preventing the correct measurement.
- Do not compress or restrict pressure tubes during an NIBP measurement.
- If a spill occurs and liquid appears inside the tubing, contact your service personnel.
- If the circumference of the upper arm is less than 8-13 cm, noninvasive blood pressure cannot be measured for the patient.

Note

- NIBP measurement accuracy can be improved by minimizing patient movement.
- Do not talk during the measurement. Keep quiet and stay calm for the entire process.
- Patient movement, very low pulse volume, or vibration from outside sources can influence the accuracy of blood pressure measurements.
- Blood pressure readings may be affected by the position of the patient, their physiologic condition, the presence of arrhythmia and other factors.
- NIBP Measuring function cannot be used on AED Mode.
- Activating the pacer function or charging the defibrillation energy automatically stops NIBP measurement in Pacer Mode or Manual Defibrillation Mode.

7.3.2 Alarm for NIBP Measuring

A NIBP alarm is issued when the measurement exceeds or falls below the range of the set values. The NIBP alarm is the non-latch alarm, so it will be canceled when the measurement falls under the range of the set values.

Note

- An NIBP alarm is issued due to an occasional measurement. Once the alarm is issued, the EXIT button will be activated immediately.

7.3.2.1 Type of Alarm

NIBP measurement mode has physiological alarms and technical alarms.

1) Physiological Alarms

Alarm Message	Priority	Indication	Condition
Systolic High	Medium	Yellow alarm message with alert sound	Systolic blood pressure measurement exceeds the maximum set value.
Systolic Low	Medium	Yellow alarm message with alert sound	Systolic blood pressure measurement falls below the minimum set value.
Diastolic High	Medium	Yellow alarm message with alert sound	Diastolic blood pressure measurement exceeds the maximum set value.
Diastolic Low	Medium	Yellow alarm message with alert sound	Diastolic blood pressure measurement falls below the minimum set value.
Mean High	Medium	Yellow alarm message with alert sound	Mean blood pressure measurement exceeds the maximum set value.
Mean Low	Medium	Yellow alarm message with alert sound	Mean blood pressure measurement falls below the minimum set value.

2) Technical Alarms

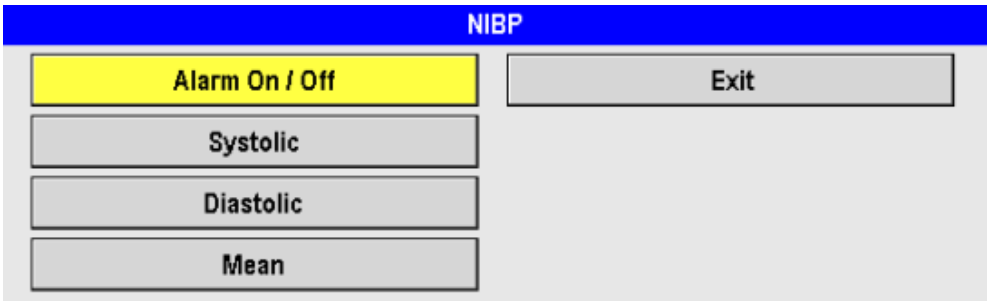
Alarm Message	Priority	Indication	Condition
NIBP Measurement Failure	Low	Turquoise alarm message with alert sound	NIBP measurement failure.
NIBP signal has noise artifacts	Low	Turquoise alarm message with alert sound	Oscillometric signal has noise.
NIBP Pneumatic Blockage	Low	Turquoise alarm message with alert sound	NIBP operation is interrupted by bent tubes, etc.
NIBP air leak or loose cuff	Low	Turquoise alarm message with alert sound	Air is leaking from tubes, etc.
NIBP Cuff Overpressure	Low	Turquoise alarm message with alert sound	NIBP is over-pressurized.
NIBP Error	Low	Turquoise alarm message with alert sound	There is a problem with NIBP module operation.
NIBP Calibration overdue	Low	Turquoise alarm message with alert sound	NIBP module calibration has expired.
NIBP Equipment Malfunction	Low	Turquoise alarm message with alert sound	NIBP device is faulty.

7.3.2.2 Alarm Setting

You can set the NIBP-related alarm ON/OFF. You can set an item to issue an alarm among the measured NIBP results.

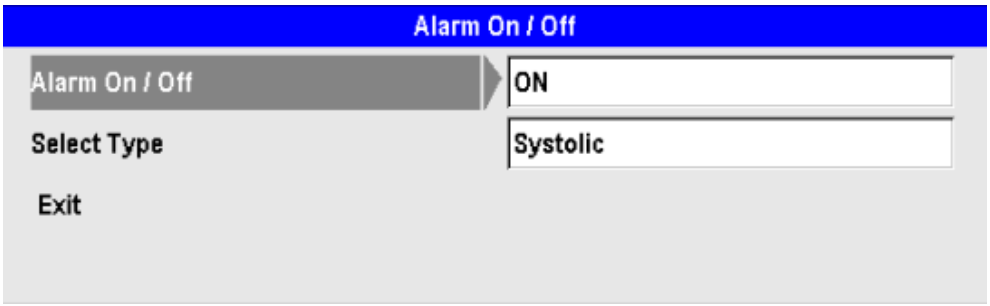
1) Alarm Setting Screen

Press the Menu knob and select Alarms → NIBP to open the NIBP Alarm Setting screen.



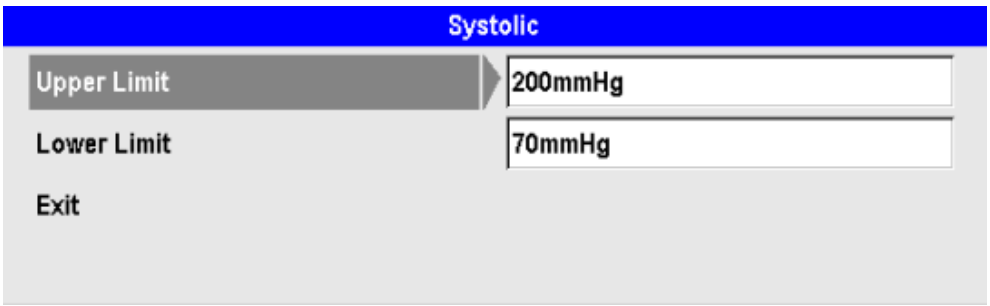
2) Alarm On/Off

Turns the alarm on or off for noninvasive blood pressure. You can set the alarm only for the selected items out of the results of noninvasive blood pressure measuring.



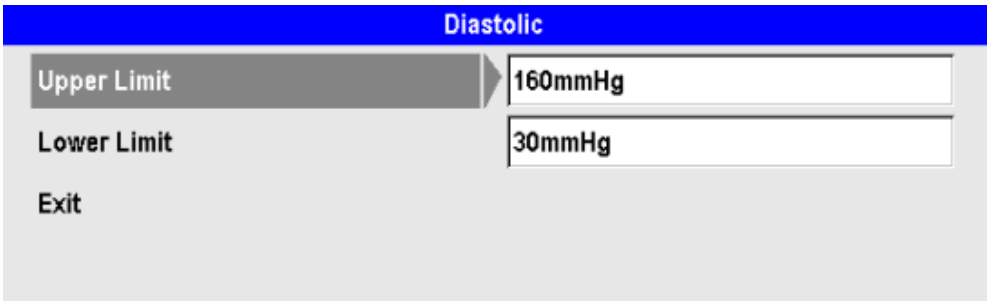
3) Systolic Blood Pressure

Ye can set the alarm range for systolic blood pressure out of the measured values.



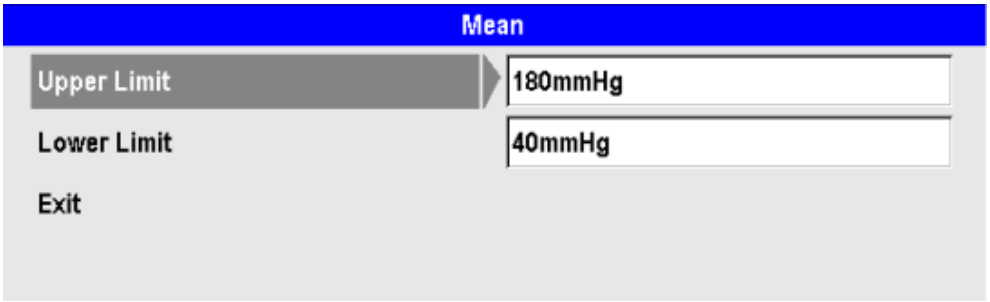
4) Diastolic Blood Pressure

You can set the alarm range for diastolic blood pressure out of the measured values.



5) Mean Blood Pressure

You can set the alarm range for mean blood pressure out of the measured values.



Caution

- Changes made to the alarm settings in the menu are not automatically saved. When the equipment reboots, the default alarm settings are restored. To change the default alarm settings, they must be changed and saved in Administrator Mode. For details on entering Administrator Mode or changing default alarm settings, see the Service Manual.

Note

- Calibrate the NIBP measurement device every year by contacting CU Medical Systems, Inc. for service.
- If the device does not work properly, see Troubleshooting for Problems Related to NIBP Measuring. For other problems, please contact the CU Medical Systems Service Center.

7.4 Measuring End-tidal CO_2 ($EtCO_2$)

■ Overview

The CU-CM1 allows you to measure CO_2, $EtCO_2$, and RR (Respiration Rate). CO_2 can be measured in Patient Monitoring Mode, Pacer Mode and Manual Mode on the CU-HD1.

The CU-CM1 offers two methods for measuring CO_2, namely Mainstream and Sidestream and it is measured through infrared absorption of CO_2.

CO_2 continues to be measured through a sampling line or the adapter. $EtCO_2$ is measured through the concentration of CO_2 at every end of the patient's exhalation. It can be a critical means of monitoring the respiration of the patient. For example, it allows you to see if chest compressions were administered properly to a patient during CPR, and is used to confirm successful intubation. It also allows you to check respiratory ailments in the lungs or bronchi.

Note

- CU-CM1 is not compatible with any other products other than CU-HD1.
- Either Mainstream or Sidestream measurement method can be selected and used.
- When cleaning the IRMA Mainstream gas analyzer, always wipe it with a soft cloth. Remove the airway adapter before cleaning the analyzer.
- Wipe the outside surface using a formula of 70% or less ethanol and a 70% or less isopropyl alcohol.
- This device does not provide an automatic air pressure compensation function.

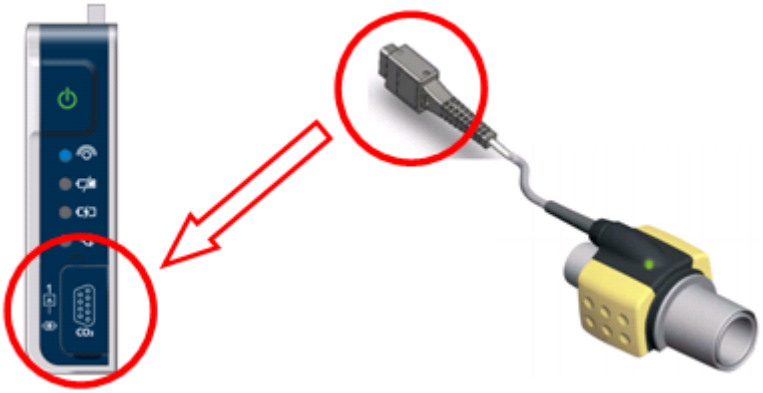
Warning

- If the zero calibration of the CO2 sensor is necessary, if correct air pressure is not set of if the pre-heating time is not enough, the EtCO2 and RR measurements may not be accurate. A sensor application error or environmental conditions may also affect the measurements.
- Accessories of IRMA Mainstream gas analyzer and ISA Sidestream gas analyzer can only be used once. Do not clean, sterilize, or reuse them.
- Check if CO2 waveform (capnogram) is appropriate on the monitor screen. Always check if the patient's ventilator is connected correctly.
- If it is loosely connected or damaged, the patient's breathing may become abnormal or the measurement of respiratory gases may become inaccurate. Connect it securely and check the connected part for leaks.
- If spray medicine or anesthetic gas is used, the CO2 measurement may be inaccurate.
- Carry out zero calibration while the airway adapter is not connected to the patient.

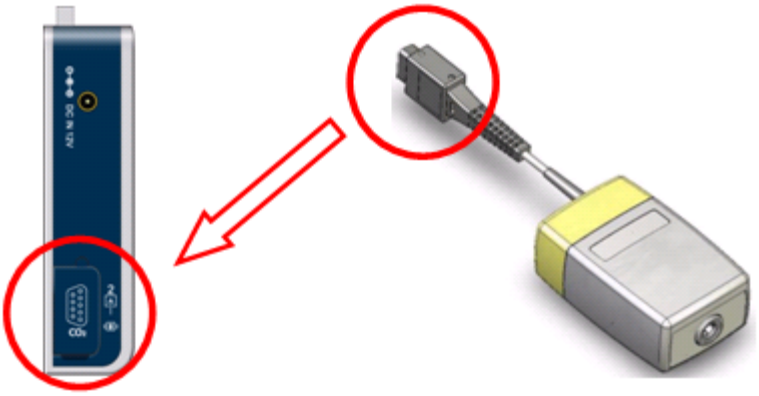
- Preparing the Measurement of EtCO2

7.4.1.1 Connecting to the Device

1) Connecting the IRMA Mainstream to CU-CM1 (Front View)



2) Connecting the ISA Sidestream to CU-CM1 (Rear View)



Caution

- When selecting an accessory, always check the patient category (adult, pediatric, neonate), patient airway (ventilation), and ventilation status (humidified ventilation).
- Use only accessories provided by CU Medical Systems, Inc. for correct and accurate measurement of CO_2.

7.4.1.2 Setting

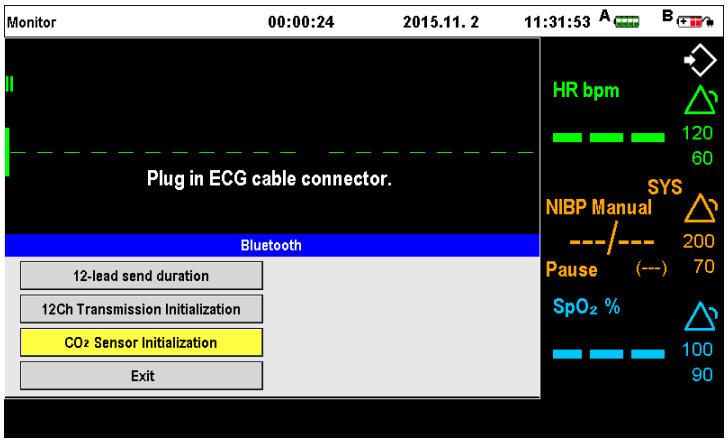
The CU-CM1 measures the amount of CO_2 and transmits the measured value to the CU-HD1 via Bluetooth. The CU-HD1 displays it on the LCD screen. CO_2 can be measured in Patient Monitoring Mode, Pacer Mode and Manual Mode on the CU-HD1.

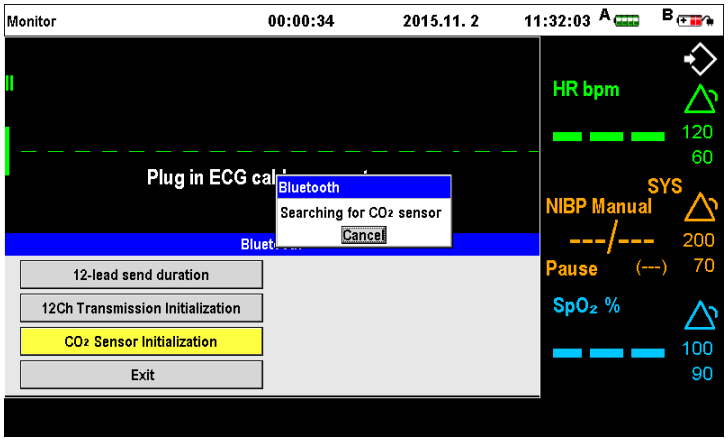
First, pairing the CU-CM1 with the CU-HD1 is needed for using CU-CM1. For details on pairing the CU-CM1 is shown below.

1) Pairing

If a new CU-CM1 is purchased or replaced, it can be used only after pairing with CU-HD1.

① Select "CO_2 Sensor Initialization" in Bluetooth as below for pairing via Bluetooth. ("MENU" → "Device Management" → "Bluetooth" → "CO_2 Sensor Initialization")

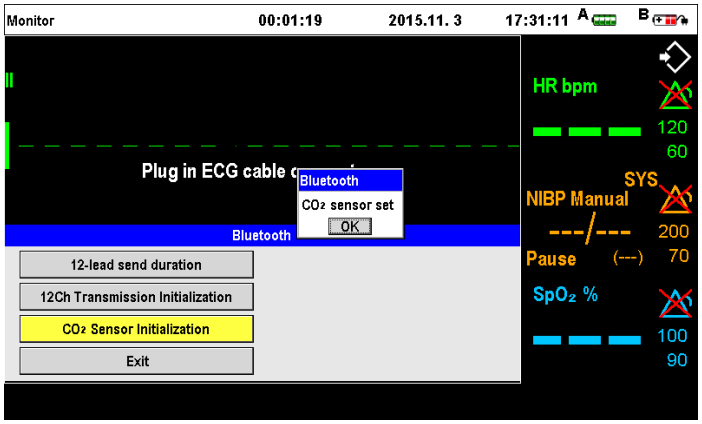




Note

- CU-HD1 may be obstructed by other devices, even if those other devices meet the KN emission requirements.

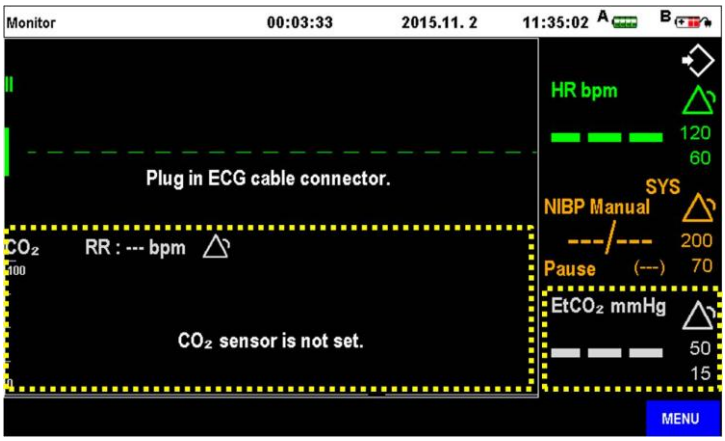
② When the CU-CM1 is turned on and is paired with the CU-HD1 via Bluetooth, a long beep will sound three times. The following window will pop up on the CU-HD1 screen to show that pairing is complete.



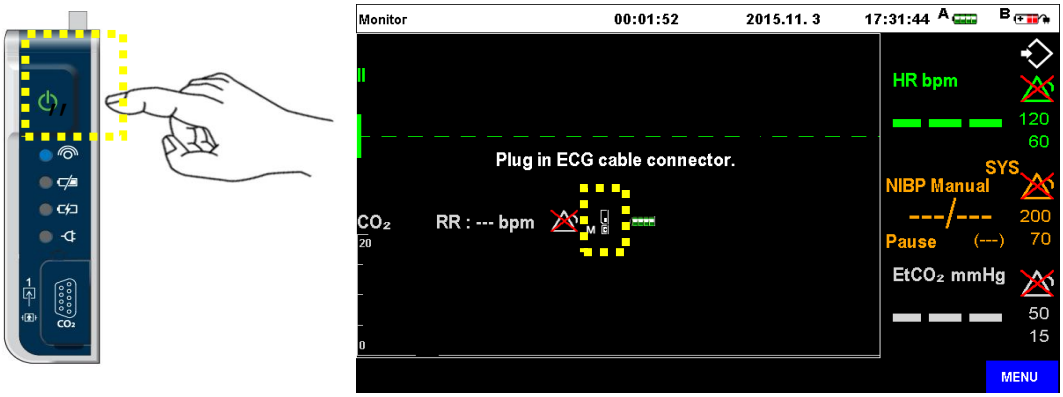
Note

- Communication is not possible with devices that are not designated by CU Medical Systems, Inc.
- Before pairing the CU-HD1, turn on the power of the device to be connected.

③ Select CO_2 by pressing the lead selection (Sector 2) button on the CU-HD1. When Sector 2 is selected as CO_2, the CO_2 measurement screen appears and the CU-HD1 attempts to connect to the CU-CM1.

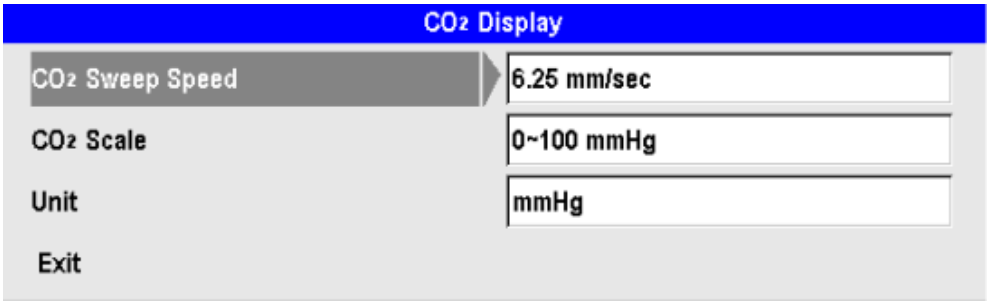


④ When you turn the CU-CM1 on by pressing the power button, the CU-HD1 is connected to the CU-CM1. When the CU-HD1 is connected to the CU-CM1, the screen shows information on the Mainstream and Sidestream connections, as well as the battery status of the CU-CM1.



2) CO_2 Display

You can change the sweep speed, scale, and unit by selecting "MENU → Device Management → Etc. → CO_2 → CO_2 Display".



2.1) CO_2 Seep Speed

In Menu on the CU-HD1, you can change the sweep speed in the CO_2 measurement graph. You can change it within the following range.

- 6.25 mm/sec (default setting)
- 12.5 mm/sec
- 25 mm/sec

2.2) CO_2 Scale

In Menu on the CU-HD1, you can change the scale in the CO_2 measurement graph. You can change it within the following range.

- 0~100 mmHg or 0~14 % (default setting)
- 0~50 mmHg or 0~7 %
- 0~20 mmHg or 0~4 %

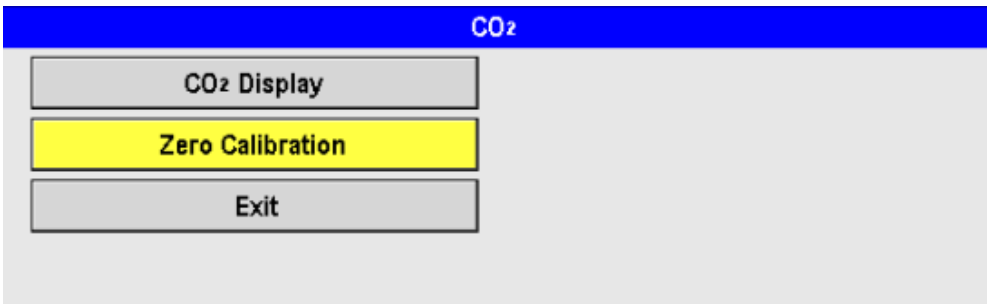
2.3) Unit

In Menu on the CU-HD1, you can change the display unit in the $EtCO_2$. You can change it within the following range.

- mmHg (default setting)
- %

3) CO_2 Zero Calibration

When CO zero calibration is required, select "Menu → Device Management → Etc. → CO_2 → Zero Calibration" to perform zero calibration.

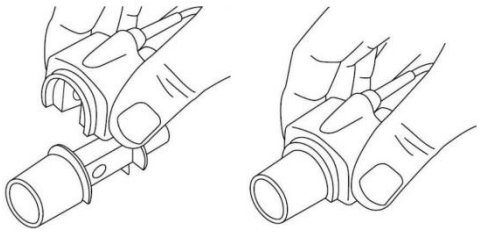


7.4.2 Using the Analyzer

7.4.2.1 Using the IRMA Mainstream Analyzer

① Plug the IRMA connector into the IRMA input of CU-CM1 and switch the power on.

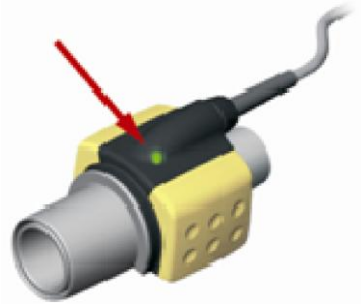
② Snap the IRMA probe on top of a new IRMA airway adapter. It will click into place when properly seated.



③ If necessary, perform zero calibration for the analyzer on the CU-HD1. (MENU → Device Management → Etc. → CO_2 → Zero Calibration)

④ During the calibration a message "Zero calibration in progress" will appear on CU-HD1 and the green LED on the IRMA Mainstream Analyzer will blink.

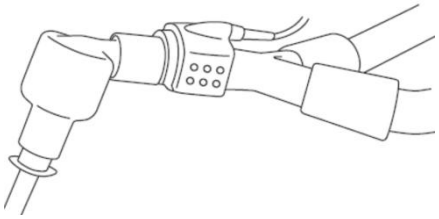
⑤ When zero calibration is completed, the message will disappear and the green LED will be steady.



⑥ Connet IRMA airway adapter 15mm male connector to the breathing circuit Y-piece.

⑦ Connet the IRMA airway adapter 15mm female connector to the patient's endotracheal tube.

⑧ Connect the patient's endotracheal tube to the patient, and measure the CO_2.



Caution

- Perform zero calibration for the analyzer while the Airway adapter is not connected to the patient.

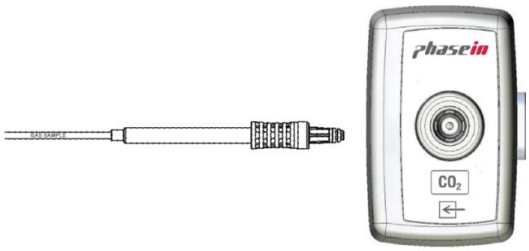
Note

- For more accurate measuring CO2, perform the zero calibration whenever you replace the Airway adapter.
- When zero calibrating the IRMA Mainstream Analyzer, additional calibration gas is not required.
- Before measuring the amount of CO_2 using the IRMA Mainstream Analyzer, it is required for the analyzer to warm-up for 10 seconds after you turn it on. For accurate measurement, use the equipment approximately 30 seconds after the IRMA Mainstream gas analyzer has been powered on.

7.4.2.2 Using the ISA Sidestream Analyzer

① Connect the ISA Sidestream analyzer connector into the CU-CM1 rear connector port.

② Connet the Nomoline connetor to the ISA Sidestream analyzer.



③ After ensuring the nasal cavity is clear, insert the tip of the nasal cvity Nomoline into the patient's nostril for measurement.

Note

- Before measuring the amount of CO2 using the ISA Sidestream Analyzer, it is required for the analyzer to warm-up for 1 minutes after you turn it on. For accurate measurement, use the equipment approximately 2 minutes after the ISA Sidestream gas analyzer has been powered on.

Caution

- If the "Sampling line is interrupted" message appears or the measurement value begins to show error, replace the nomoline connector.
- Disposable accessories, such as disposable nomoline adapter set and T adapter set, should be used for only one patient.

Warning

- If the patient's nostrils are blocked partially or completely or the patient is breathing using his/her mouth when the ISA Sidestream gas analyzer is used, the EtCO2 measurement may become lower.
- Reflux of gastric contents, mucus, pulmonary edema fluid or endotracheal epinephrine introduced into the detector may increase airway resistance and affect breathing. If such a case occurs, dispose of the accessories.
- EtCO2 should be measured after ensuring the nomoline airway is not bent and a physical blockade is not occurring as a result of the patient lying on top of nomoline airway.
- Using a flammable anesthetic mixed with air, oxygen or nitric oxide poses a danger of explosion. If it is exposed directly to laser, the ESU device, or high heat while oxygen exists, the nomoline airway may ignite. If a procedure using laser, an electrosurgery device, or high heat is carried out on the patient's head and neck, special caution should be taken to prevent the occurrence of fire in the nomoline or the surrounding environment.
- The sidestream CO2 sensor port should be ventilated to the outside. If the discharge port of the sidestream sensor is blocked, the measurement may be significantly delayed while such a problem is not displayed.
  Place the nomoline airway carefully, so as not to choke the patient's neck or body.

7.4.3 Alarm for $EtCO_2$

7.4.3.1 Type of Alarm

$EtCO_2$ measurement mode has physiological alarms and technical alarms.

1) Physiological Alarms

Alarm Message	Priority	Indication	Condition
Apnea	High	Red alarm message with alert sound	Respiration is not measured during the set duration (seconds).
$EtCO_2$ High	Medium	Yellow alarm message with alert sound	$EtCO_2$ measurement exceeds the maximum set value.
$EtCO_2$ Low	Medium	Yellow alarm message with alert sound	$EtCO_2$ measurement falls below the minimum set value.
Respiration Rate High	Medium	Yellow alarm message with alert sound	Respiration rate measurement exceeds the maximum set value.
Respiration Rate Low	Medium	Yellow alarm message with alert sound	Respiration rate measurement falls below the minimum set value.

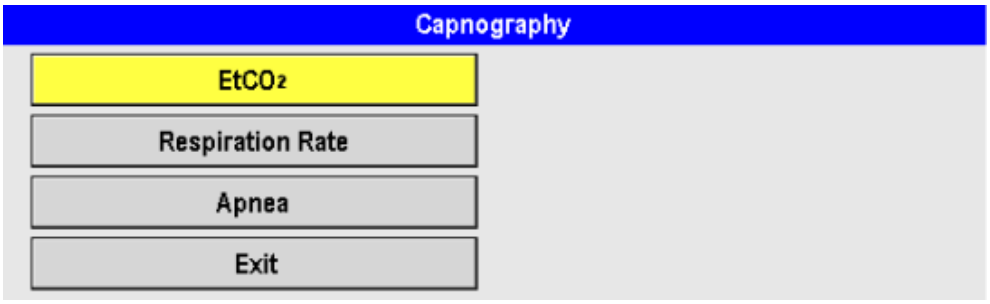
2) Technical Alarms

Alarm Message	Priority	Indication	Condition
CO_2 : Out of range accuracy	Low	Turquoise alarm message with alert sound	Measurement value of the CO_2 sensor is outside the reference accuracy range.
CO_2 : Out of range/internal temperature	Low	Turquoise alarm message with alert sound	Internal temperature of the CO_2 sensor is outside the reference range.
CO_2 : Out of range/ambient pressure	Low	Turquoise alarm message with alert sound	The CO_2 sensor is outside the ambient pressure range.
CO_2 : Need zero calibration	Low	Turquoise alarm message with alert sound	The CO_2 sensor requires zero calibration.
Software Error	Low	Turquoise alarm message with alert sound	The CO_2 sensor has a software error.
Hardware Error	Low	Turquoise alarm message with alert sound	The CO_2 sensor has a hardware error.
Motor Speed out of bounds	Low	Turquoise alarm message with alert sound	The CO_2 sensor motor exceeds the speed range.
Factory calibration data loss	Low	Turquoise alarm message with alert sound	There is an error with the CO_2 sensor calibration value.

7.4.3.2 Setting Alarm

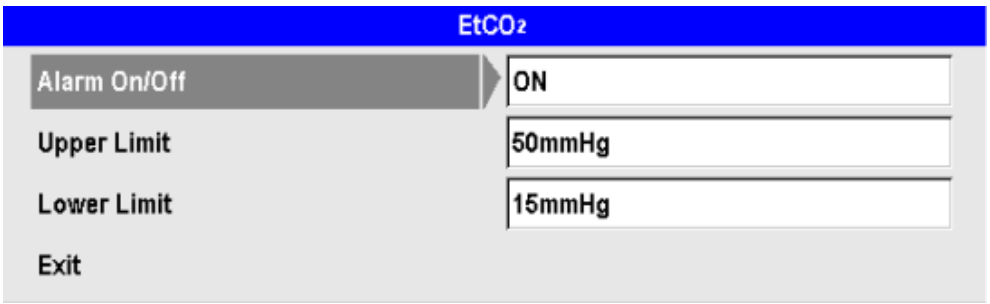
1) Capnography

Set the range for generating capnography-related alarms. Available alarm range options include "$EtCO_2$", "Respiration Rate" and "Apnea".



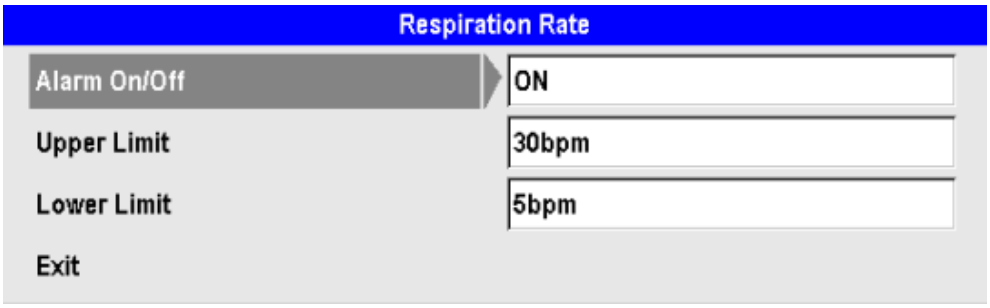
2) $EtCO_2$

You can set the alarm range of $EtCO_2$ out of the measured values.



3) Respiration Rate

You can set the alarm range of respiration rate out of the measured values.



4) Apnea

You can set the alarm range of apnea out of the measured values.

Caution

- Changes made to the alarm settings in the menu are not automatically saved. When the equipment reboots, the default alarm settings are restored. To change the default alarm settings, they must be changed and saved in Administrator Mode. For details on entering Administrator Mode or changing default alarm settings, see the Service Manual.

7.5 Transferring Patient Monitoring Information

The CU-HD1 supports the SD card and Bluetooth Communication as the medium to transfer or deliver the measured patient information to other devices.

For information on the real-time printer, SD card and Bluetooth communications please refer to **"Chapter 9_ Communication & Data Management".**

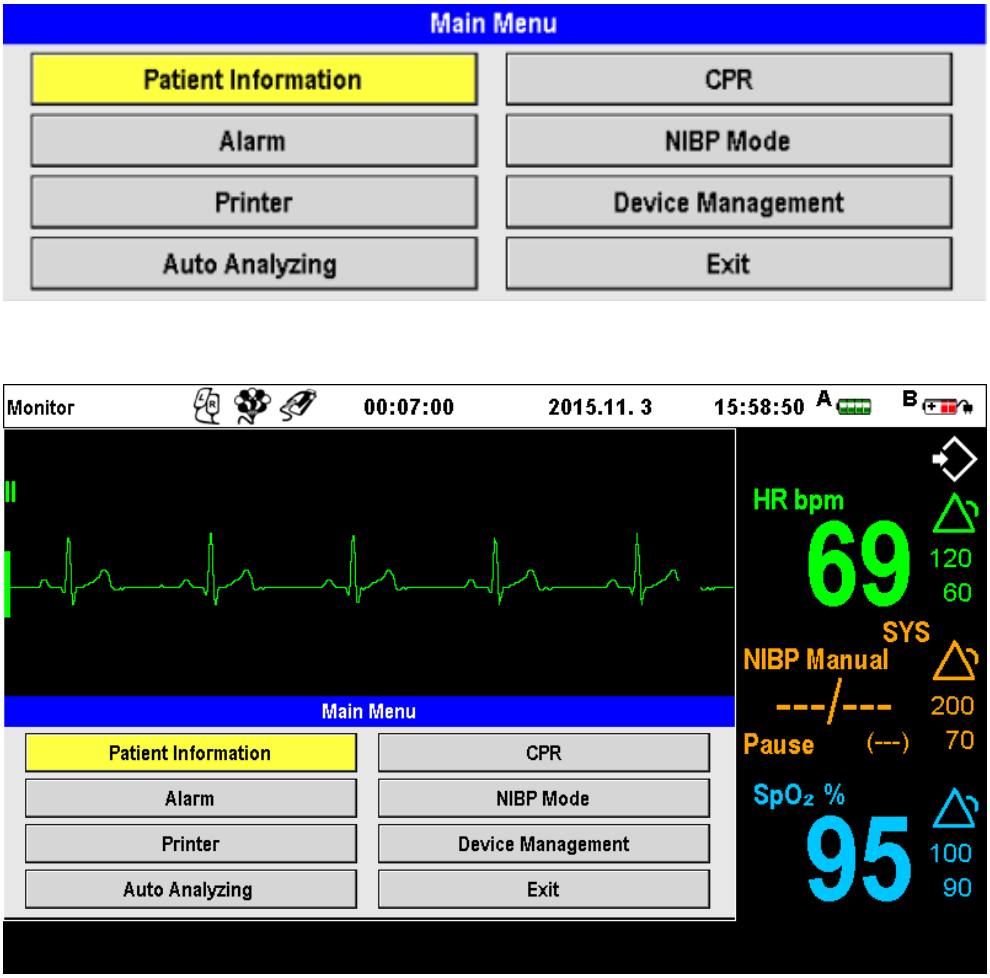
Chapter 8. MENU Composition

■ **Overview**

The CU-HD1 MENU key may be used to change the settings of patient information, alarm, printer, CPR, device configuration, and automatic analysis.

To change the menu composition, use the menu knob or the soft button at the bottom of the LCD screen.

The MENU key is activated in the condition where there is no connection to a patient with pads or paddles in other modes than the Patient monitoring mode (Monitor mode).



[Main Menu Display]

8.1 Patient Information

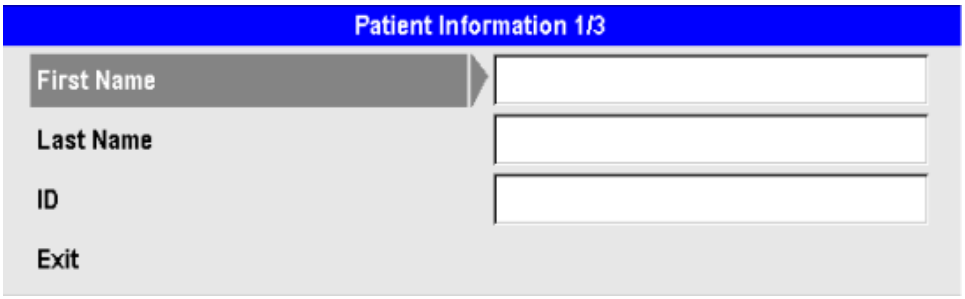
Press the Menu knob from "Patient Information" at the "Main Menu" to view the following menu display where you can change patient information. Patient Information comprises of three sub-menus. Use the soft keys of "Previous Page" and "Next Page" to change the sub-menu.

To change patient information, turn your Menu knob left or right to select the patient information item. If you press the Menu knob, a text input window will be prompted at the bottom of the menu. Also, you can change the information about the number or gender information by switching between Increase and Decrease, On and Off using the Menu knob.

After changing the sub items of Patient Information, press the Menu knob to apply the changed data. Select "Exit" from each of the Patient Information input menu to return to the "Main Menu".

8.1.1 Patient Information 1/3

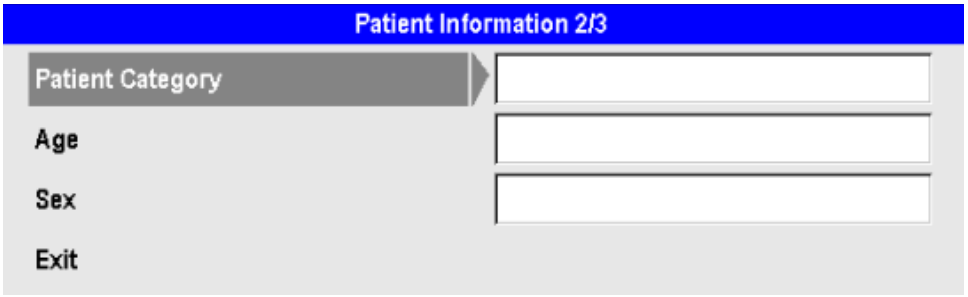
The following screen is a Patient Name and ID setting menu where you can change the information fitting for each of items. (Default setting: N/A)



8.1.2 Patient Information 2/3

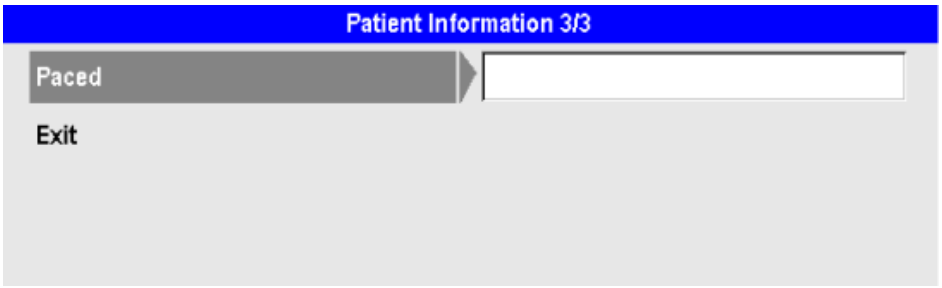
The following screen is the second screen of the Patient Information sub-menu where you can change the patient category, age and gender.
Each of the detailed settings is listed as follows.

- Patient category includes Neonate, Pediatric and Adult.
- The age of a patient can be increased/decreased (0-150) by 1 using the Menu selection button.
- Patient gender can be changed to female or male



8.1.3 Patient Information 3/3

The following figure displays a screen where you can change information about whether a patient is using an Implantable Cardiac Defibrillator (ICD). It can be set to "Put on" or "Put off" according to the patient status.



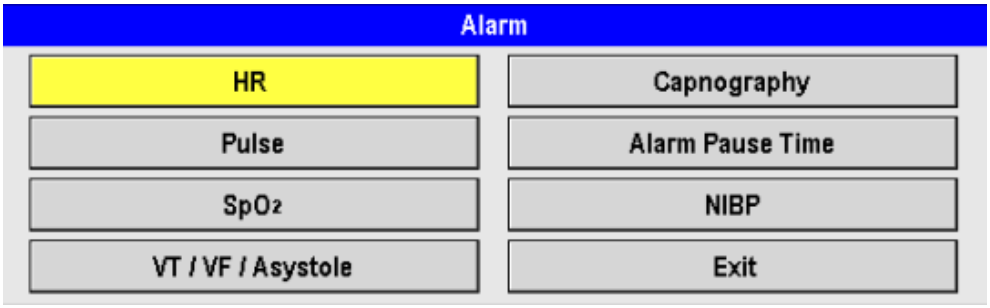
Warning

- Make sure to enter a patient category before measuring noninvasive blood pressure.

8.2 Alarm

Press the Menu knob from the "Alarm" item at the "Main Menu", and then the following MENUs will be prompted so that you can change the alarm setting. For the setting of the alarm menu, you can change the on/off status of alarm, and the maximum/minimum value of the alarming frequency.

After the detailed items have been changed, the changed values are applied by pressing the Menu knob.
Select "Exit" from each of the alarm menus, and press the Menu knob, the "Main Menu" will be prompted.

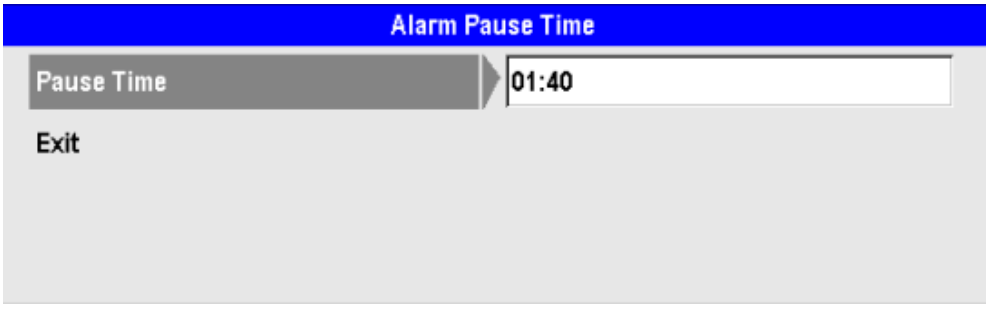


Note

- Changes made to the alarm settings in the menu are not automatically saved. When the equipment reboots, the default alarm settings are restored. To change the default alarm settings, they must be changed and saved in Administrator Mode. For details on entering Administrator Mode or changing default alarm settings, see the Service Manual.
- Changes made to the filter settings in the menu are not automatically saved. To change the default settings, see the Service Manual.

8.2.1 Alarm Pause Time

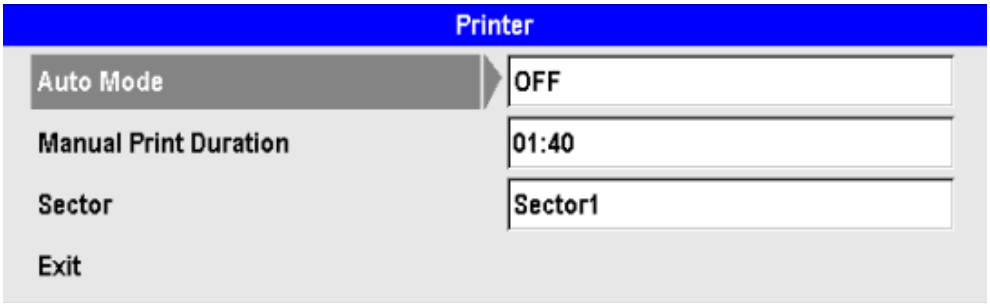
This is a screen to set the amount of "alarm pause time from the time when the **"Alarm Pause"** button is pressed to when to generate the next alarm sound.
Alarm Pause Time can be changed by 10 second with the Menu knob.
The amount of alarm pause time that you can set ranges from 30 seconds to 2 minutes.



8.3 Printer

Press the Menu knob from "Print" at the "Main Menu" to view the following menu display where you can change the printer settings.

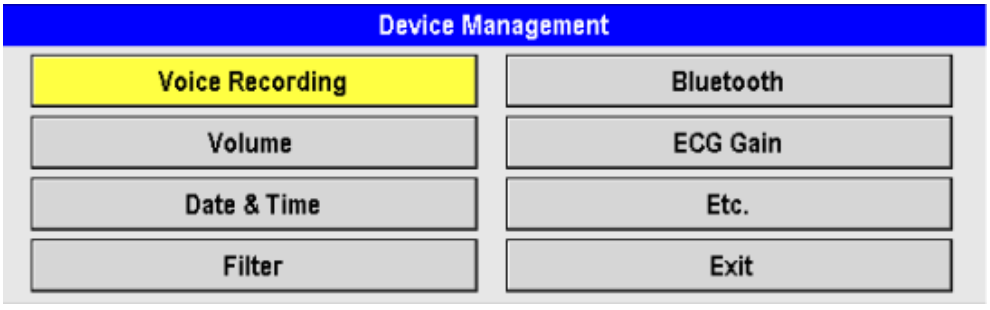
After the detailed items have been changed, the changed values are applied by pressing the Menu knob. Select "Exit" from the "Printer" menu, and press the Menu knob, the "Main Menu" will be prompted.



- **Auto Mode**
  This is a function to set it to the automatic printing mode, printing the defibrillation process after permitting defibrillation shock. The Menu knob may be used to set the automatic mode setting to On or Off.
- **Manual Print Duration**
  A function to set the Manual Print Duration time, for printing after the Printer button has been pressed. By clicking the Menu knob, the duration time can be changed by 10 seconds. The amount of time that you can set ranges from 30 seconds to 2 minutes.
- **Sector**
  Set the number of vital sign sectors which are printed by pressing the Print button. 'Sector 1' prints Sector 1 only and 'Sector 2' prints both Sector 1 and Sector 2.

8.4 Device Management

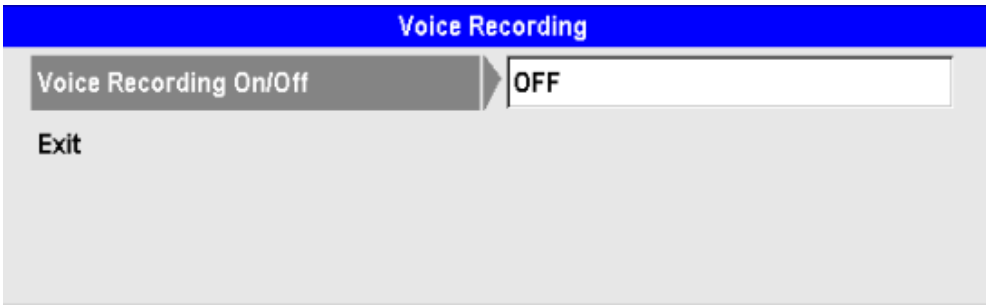
Click the Menu knob from "Device Management" at the "Main Menu" and then the following screen will be prompted, where you can change and manage the various settings of the CU-HD1.
The following screen displays the "Device Management" sub-menu which is comprised of voice recording, volume control, time adjustment, filter function selection, self-device test, Bluetooth communication function, and ECG gain control.



8.4.1 Voice Recording

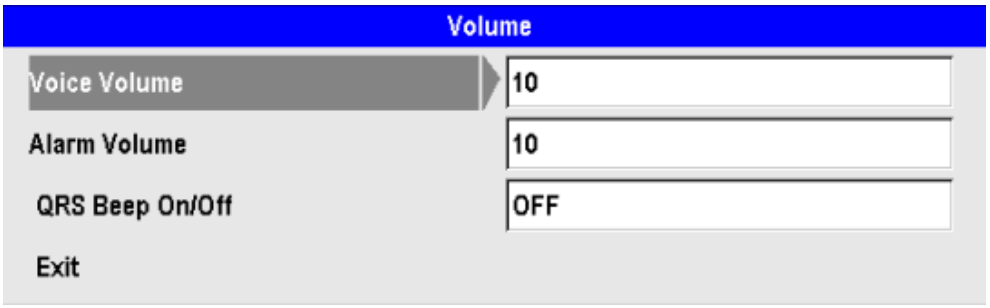
The **CU-HD1** supports the voice recording function, and determines whether to use the voice recording function in this item.

The voice recording is available on AED mode only.



8.4.2 Volume

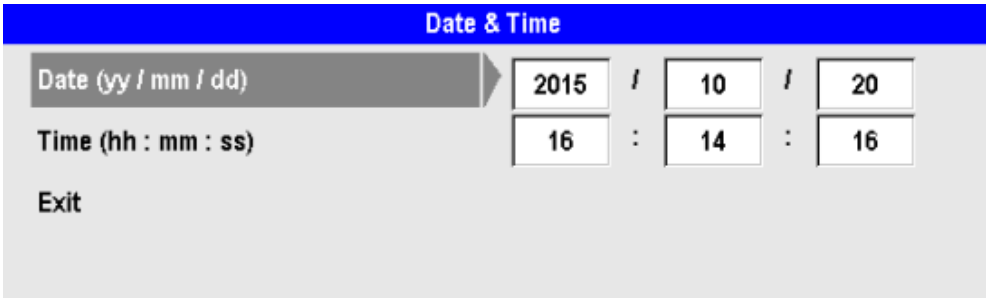
This is a sub-menu to control the speaker volume of the **CU-HD1**.



- **Voice Volume / Alarm Volume**
  The device has a volume scale of 10 levels, which can be changed by 1 unit with the menu selection button.
- **QRS Beef On/Off**
  You can set it to On/Off to generate the beep sound when detecting the QRS of the ECG.

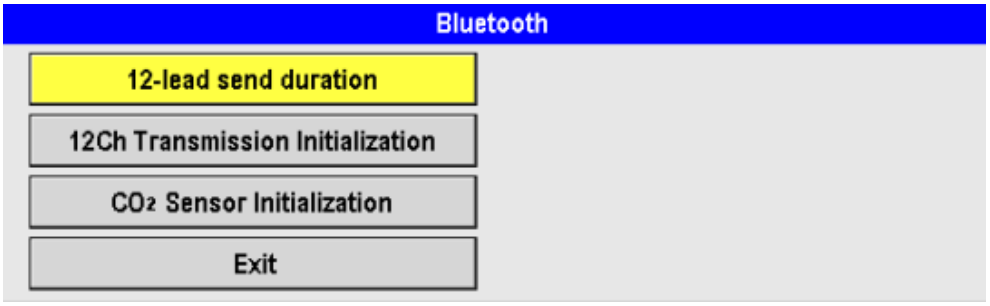
8.4.3 Date & Time

You can set the date and time. Date is entered in the order of year, month and date, and time is entered in the order of hour, minute and second. After selecting an item to be changed, press the Menu knob to enter the date and time. After finishing, press the Menu knob to change the setting in order by pressing the Menu knob.

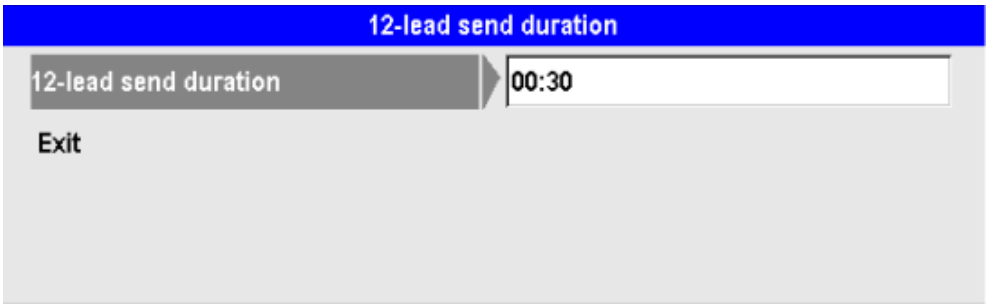


8.4.4 Bluetooth

The Product supports wireless communication using Bluetooth. The "Bluetooth" menu is composed of the following menus that connect Bluetooth to external devices.



From the "12-lead send duration" on the "Bluetooth" menu, you can set the 12-lead ECG time that is transferred when the 12-lead ECG information is transferred to other devices. The time bracket you can set ranges from 10 seconds to 2 minutes by the 10 second unit. The following shows the menu for "12-lead send duration".



If you select Initialize Bluetooth from the "Bluetooth" menu, the following window will be prompted, waiting for the connection to Bluetooth communication.

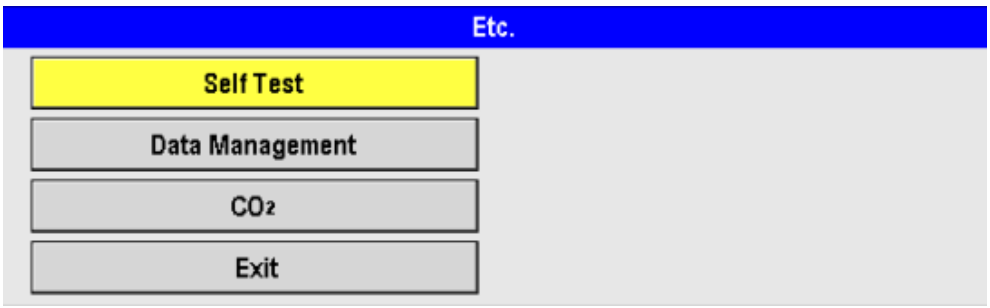
If the Bluetooth communication device is not detected, press the "Cancel" button. The window will be prompted, saying that Bluetooth is not connected yet.
Through the following window, you can verify that there is Bluetooth communication established between the CU-HD1 and the computer. For information on computer and communication, please refer to **"Chapter 9_Communication and Data Management"**.

Note

- CO2 connection can be reset using a product with the EtCO2 function. For details on connecting to a product with the EtCO2 function, see **"7.4.1.1 Connecting to the Device"**.

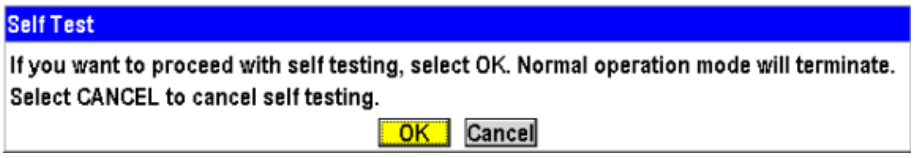
8.5 Etc.

The following screen displays the "Etc." sub-menu which is comprised of self-test, data management, and CO_2.



8.5.1 Self Test

The CU-HD1 performs a self-test on a periodic basis when the device is turned on. If a user selects the menu to use the self-test function of the device, the following confirmation window will be prompted.



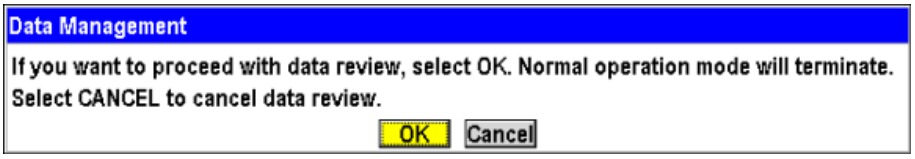
After the device has been inspected, it is impossible to use the function of device treatment and diagnosis. So, please turn off the device and turn it on again. The list of items tested in the manual test is as follows.

Test Item	Inspection Details
Normal System Test	Inspects functions necessary for the system operation.
Mode Rotary Key Test	Checks out the Rotary switch functions.
Charging Button Test	Checks the button status to prevent unintended recharging.
Shock Button Test	Checks the Shock button status.
Audio Test	Inspects whether the audio function works normally.
Defibrillation Test	Inspects the charging/discharging functions.
Pacer Test	Inspects the pacer function.
ECG Lead Test	Inspects the ECG function.
Battery (Part A/B) Test	Inspects the function of battery terminals (A/B)
SpO_2 Test	Inspects the function of SpO_2 module.
Printer Test	Inspects the printer working status.

※ For more detailed information on the manual diagnosis process, please refer to Section 10.1.3 – Manual Self-test.

8.5.2 Data Management

If a user selects the menu to use the data management function of the device, the following confirmation window will be prompted.



Chapter 9. Communication and Data Management

■ Overview

Bluetooth communication is available in the CU-HD1 when transferring measured data externally, and when verifying stored patient information using programs installed in an adjacent computer.

Other than communicating with an external device, you can transfer digitalized voice and patient measurement information externally by the use of an SD Card. Also, you can use the real-time printer to print out ECG information and device usage history.

The CU-HD1 uses a data management function to record/manage patient vital sign data in the internal memory. Up to 100 records of context information can be stored. When storing a single data type, data can be stored for up to 192 hours continuously.
Context information is recorded in the following modes.

- AED Mode
- Manual Defibrillation Mode
- Patient Monitoring Mode
- Pacer Mode

※ Context information in data management is displayed as date of the context, start time, duration, and usage mode.

Data Management 00:10:36 2015.11. 3 19:06:00 A B

Data Management

Date	Start Time	Elapsed Time	Used Mode
2015.11. 3	19:05:09	00:00:11	Monitor Mode
2015.11. 3	19:03:54	00:01:12	Manual Mode
2015.11. 3	19:03:12	00:00:40	Pacer Mode
2015.11. 3	19:02:49	00:00:22	Monitor Mode
2015.11. 3	19:02:32	00:00:15	AED Mode
2015.11. 3	19:01:59	00:00:31	Monitor Mode
2015.11. 3	19:01:46	00:00:11	AED Mode
2015.11. 3	19:01:29	00:00:15	Monitor Mode
2015.11. 3	19:01:06	00:00:21	Pacer Mode
2015.11. 3	19:00:34	00:00:30	Manual Mode

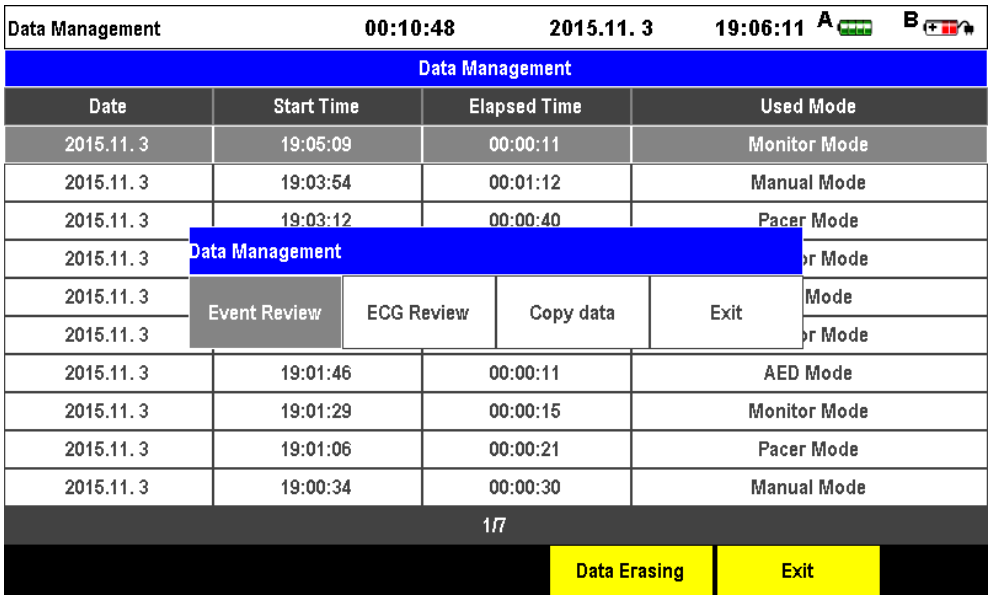
1/7

Data Erasing Exit

Note

- General functions are unavailable while using the data management function. Entering Data Management mode disables Normal mode. Exiting Data Management mode turns the equipment on again.
- When 100 context information records have been stored in the internal memory, the defibrillator will store new context information by overwriting the oldest context information.

※ In data management, Event Review, ECG Review, Copy Data, or Data Erasing can be used for context information.



Event Review shows the start date and time of the event and details of the event. ECG Review shows ECG information of up to 16 seconds per page on the screen. Partial and Total Print are also available in Event Review and ECG Review.

Copy Data allows you to select and copy context information stored in the internal memory it to external memory (SD card).

Data Erasing erases all context information stored in the internal memory.

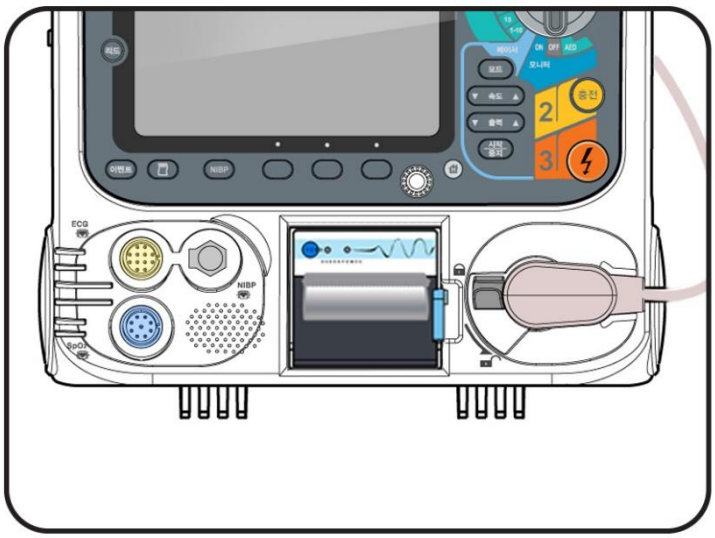
.

Caution

- Do not insert or remove the external memory (SD card) while the defibrillator is in use. Doing so may cause the defibrillator to malfunction.

9.1 Built-in Printer

The CU-HD1 printer can print out the following information.



9.1.1 ECG Signal Output

① Press the Lead Select button to select ECG for print out.

② Press the Print button to start printing.

③ Out of information displayed on the LCD, the ECG information displayed in the upper part will be print out. Press the Lead Select button to choose the ECG to be printed from 3/7/12-lead and pads ECG information at the upper part of the Monitor mode and Manual Defibrillation mode LCD screen.

④ Press the Print button to print out the measured ECG.

⑤ When you want to stop the real-time ECG printing process, press the Print button.

⑥ Items to be printed include patient information, product information, printed wave information, heart rate, print filter characteristics, data, and time.

9.1.2 Defibrillation Result Report

When it comes to automatic defibrillation or manual defibrillation results, a report will be made on the defibrillation results after defibrillation has been implemented and it will be printed. If the Automatic mode is turned on from the Print item on the menu, the printing job will be done automatically.

Items to be automatically printed include the patient information, product information, patient's ECG measured with pads or paddles, heart rate, print filter characteristics, date and time, defibrillation process (analysis, recharging, and defibrillation energy delivery) and SpO2 information.

If you don't want to print out the defibrillation report, you can change a setting on the Printer menu, or force the printer into pause by pressing the Print button when it starts into motion.

Note

- If there is not enough printer paper before the printing job is finished, the remaining information will be printed out by feeding paper into the printer without turning off the device.
- For the information on how to feed printing paper into the printer, please refer to **"Chapter 3_Product Installation"**.
- When the noninvasive blood pressure measuring process is complete, the measured values are printed.
- While printing, $EtCO_2$ pauses and the "Will reconnect after printing" message appears.

9.2 Data Storage: SD Card

The CU-HD1 provides two saving functions. One functions to save the patient's ECG, and the other works to record and save voice uttering during the use of the product.

9.2.1 Voice Recording

If the voice recording function is turned on in the menu with a SD card inserted, a voice will be automatically recorded on the SD card when the device is turned on.

9.2.2 Saving ECG

When an SD card is inserted on the CU-HD1, the patient's ECG is automatically saved, and the saved ECG information can be viewed on your personal computer.

Caution

- When using the saving function, install an SD card before turning on the product. When using a new SD card, connect the SD card to a PC and format it in FAT32 before inserting it in the defibrillator.

Warning

- If there are 10 MB or less of free space on the SD card, replace it or delete unnecessary data before use. Otherwise, further data storage may not be possible or the existing data may be damaged.
- Do not remove the SD card from the product during the usage. It may cause a malfunction.
- When verifying the saved information, close the current process and remove the SD card.

9.3 External Communications: Bluetooth Communication

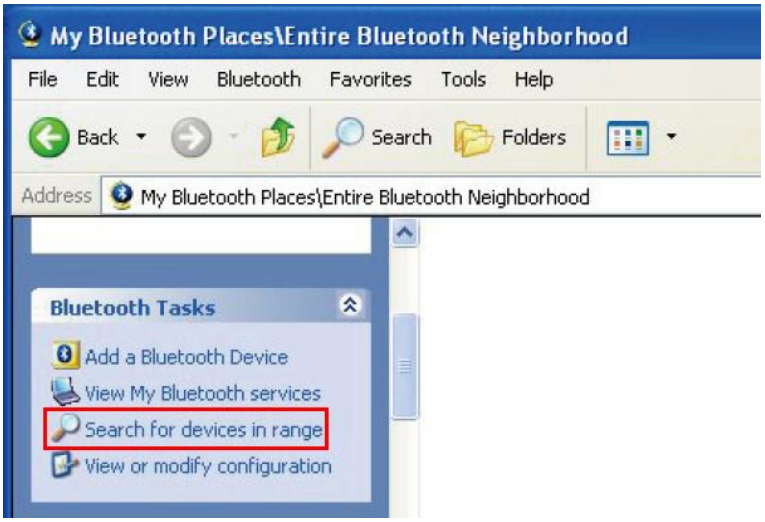
9.3.1 Initializing Bluetooth Connection

1) Searching the Device

① Select "Initialize Bluetooth Connection" from the 'Bluetooth" menu to prepare the Bluetooth connection as shown below. ("MENU" > "Device Management' > "Bluetooth" > "Initialize Bluetooth Connection")

② Double click "My Bluetooth Places" from the desktop.

③ When executing "My Bluetooth Places", the following screen will be prompted. Double click "Search for devices in range" on the following screen.



Caution

- If you purchase your PC and the CU-HD1 together, Bluetooth has should already have been completed. If you need to initialize the Bluetooth connection due to a PC problem, you must disconnect Bluetooth first, and then initialize the Bluetooth connection.

④ If the Bluetooth device is detected, the following screen will be prompted, and the CU-HD1 can be identified with its serial number.

⑤ After clicking the detected Bluetooth device, right-click the device connection. And then the following window will be prompted. At this time, type the security code.

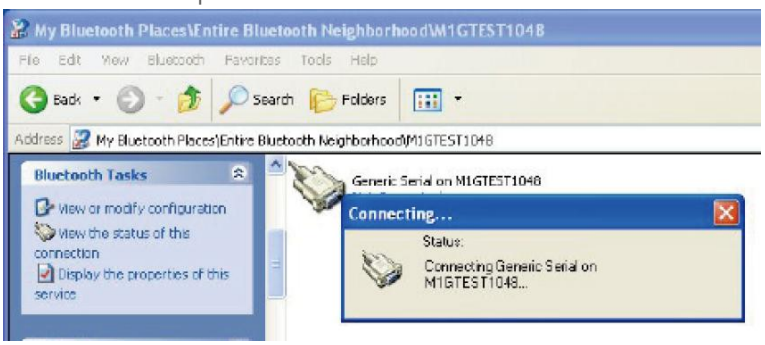
※ For more information on how to type security code, please contact us.

⑥ Click the "OK" button after you have accurately entered the secure code. If the security code has been typed correctly, a check mark will be displayed to the Bluetooth device icon as shown below.

⑦ Double click the detected Bluetooth device and check the port connected to the device.

2) Connecting the Device

If you double click the above device and make a connection, the communication connection will be completed between the computer and the CU-HD1.

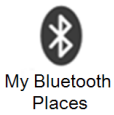


3) Verifying the Device Connection

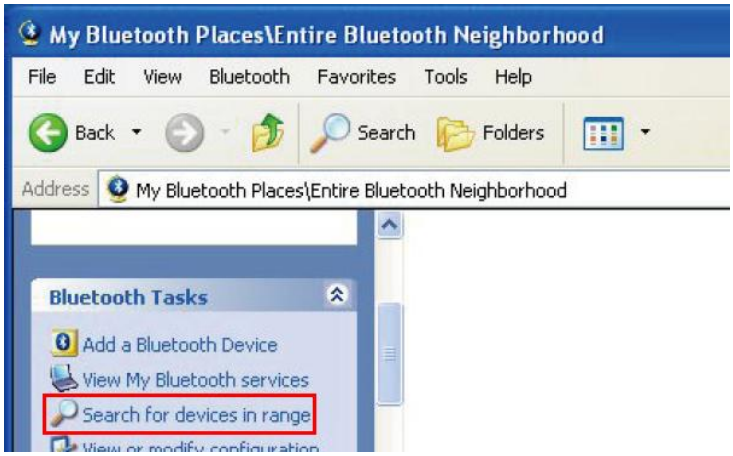
If the Bluetooth is successfully connected, the following window will be prompted in the CUHD1 screen, notifying that the connection had been successfully made.

9.3.2 Unpair Device

① Turn off the CU-HD1. Double click "My Bluetooth Palces" form the desktop of pc.



② Double click "Search Bluetooth Device" form "My Bluetooth Places".



③ The Bluetooth device is searched. At this time, the name of the searched Bluetooth device should be matched to the product serial number..

④ Click the searched device and right click.

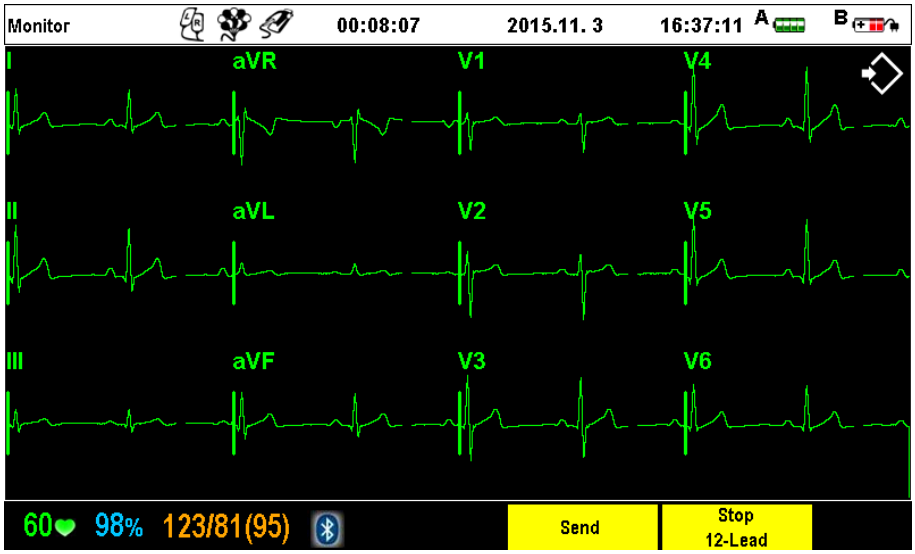
⑤ Click "Unpair Device". Close the "My Bluetooth Palces" window.

9.3.3 12-Lead ECG Transfer

The sequence to send 12-lead ECG information via Bluetooth communication is shown as follows.

① Connection between a patient and the CU-HD1 10-lead ECG. (Refer to **"Chapter 7_Patient Monitoring"**.)

② Press the "Send" soft button.
(The "Send" soft button is activated after 10 seconds from 12-lead starting.)



If the connection for transferring patient information is made between the computer and the Bluetooth device, it should be possible to verify the above 12-lead measurement screen. If Bluetooth is connected, the Bluetooth icon at the bottom of the screen appears blue, and the "Send" soft button should be activated. If Bluetooth is disconnected, the icon should appear red, and the "Send" soft button should disappear.

③ Press the "Send" soft button and transfer patient information via transfer program.

9.3.4 Real-time Transfer

You can verify the ECG and SpO_2 information displayed on the screen in the real-time remote mode by connecting the Bluetooth communication to the computer's agent program.
(Real-time transfer is available only when Bluetooth is connected. If the real-time transfer is not available, verify the Bluetooth connection status.)

① Launch the EKG Monitor Agent program on tour computer.

② Click the Bluetooth icon from the EKG Monitoring Agent program to connect Bluetooth communication. And then verify that Bluetooth (the blue icon) is connected to the product.

③ If you press the "Real-time Transfer" soft key form the product, the patient's information will be transferred to the computer via the Bluetooth connection. (10 seconds later after Bluetooth is connected, the "Real-time transfer" soft key will be created.)

9.3.5 Connecting Bluetooth with Smartphone (for Android)

① To pair the equipment with a smart phone, download and install the **'EMS12 Agent'** from the Android Google Market.

② In monitor mode, select MENU > Device Management > Bluetooth > **12Ch Transmission Initialization** and wait until a connection is made over Bluetooth with the chosen smart phone.

③ On your smart phone, go to Setting > Bluetooth and **scan for available devices**.

④ **Add the scanned device to your smart phone**. (The PIN is the same as the device serial number.)

⑤ Launch the 'EMS12 Agent ' app, select Settings > Scan Devices, then **add the registered device to the app**.

⑥ Tap the **'Connect CU'** button to connect to the equipment over Bluetooth.

⑦ When the Bluetooth connection is established, the **'Bluetooth connected'** message appears on the equipment message window.

9.4 Data Management

9.4.1 Event Review

To review the events of context information stored in the internal memory, follow the steps below.

① Rotate the rotary switch to Monitor, Pacer, Manual or AED mode. No pads should be attached to the equipment.

② Press the Menu knob to select 'MENU'.

③ Use the Menu knob to select 'Device Management' and press the Menu knob.

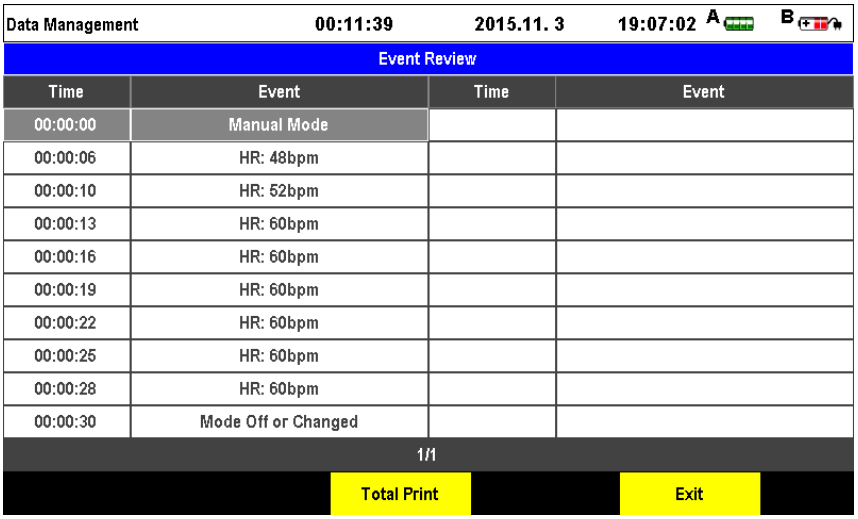
④ Select 'Etc.' and press the Menu knob.

⑤ Select 'Data Management' and press the Menu knob.

⑥ Press the 'OK' button with the Menu knob to exit normal mode.

⑦ Rotate the Menu knob left/right to select a context information record and press the Menu knob.

⑧ Select 'Event Review' and press the Menu knob.



1) Partial printing in Event Review

① For partial printing, **press the Menu knob once, then rotate the Menu knob left/right** to select events.

② After making the selection, **press the Menu knob**.

③ At the message window confirming partial printing, press the **'OK'** button to execute partial printing.

2) Total printing in Event Review

① Press the **'Total Print'** (softkey) button.

② At the message window confirming total printing, press the **'OK'** button to exectue total printing.

9.4.2 ECG Review

To review the ECG data stored in the internal memory, follow the steps below.

① Rotate the rotary switch to Monitor, Pacer, Manual or AED mode. No pads should be attached to the equipment

② Press the Menu knob to select **'MENU'**.

③ Use the Menu knob to select **'Device Management'** and press the Menu knob.

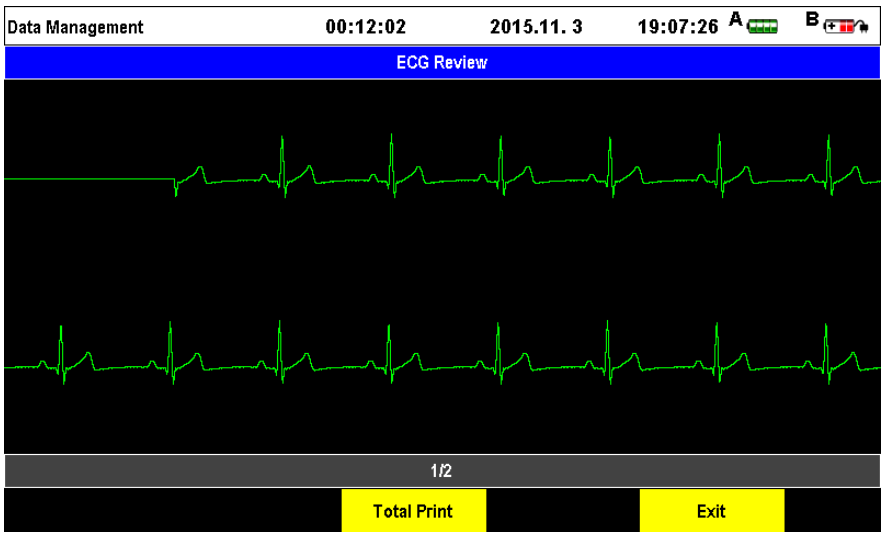
④ Select **'Etc.'** and press the Menu knob.

⑤ Select **'Data Management'** and press the Menu knob.

⑥ Press the **'OK'** button with the Menu knob to **exit normal mode**.

⑦ Rotate the Menu knob left/right to select a context information record and press the Menu knob.

⑧ Select **'ECG Review'** and press the Menu knob.



1) Partial printing in ECG Review

① For partial printing, press the Menu knob once, then rotate **the Menu knob left/right** to select events.

② After making the selection, **press the Menu knob**.

③ At the message window confirming partial printing, press the **'OK'** button to execute partial printing.

2) Total printing in ECG Review

① Press the **'Total Print'** (softkey) button.

② At the message window confirming total printing, press the **'OK'** button to exectue total printing.

9.4.3 Data Copy

To copy the context information stored in the internal memory, follow the steps below.

① Mount the external memory device (SD card).

② Rotate the rotary switch to Monitor, Pacer, Manual or Automatic Defibrillation Mode. The pads must be OFF.

③ Press the Menu knob to select **'MENU'**.

④ Use the Menu knob to select **'Device Management'** and press the Menu knob.

⑤ Select **'Etc.'** and press the Menu knob.

⑥ Select **'Data Management'** and press the Menu knob.

⑦ Press the **'OK'** button with the Menu knob to exit the normal mode.

⑧ Rotate the Menu knob left/right to select a context information record and press the Menu knob.

⑨ Select **'Copy Data'** and press the Menu knob.

⑩ At the message confirming data copying, select the **'OK'** button.

⑪ The selected context information is automatically copied to the external memory.

9.4.4 Data Delete

To delete the context information stored in the internal memory, follow the steps below.

① Rotate the rotary switch to Monitor, Pacer, Manual or Automatic Defibrillation Mode. The pads must be OFF.

② Press the Menu knob to select **'MENU'**.

③ Use the Menu knob to select **'Device Management'** and press the Menu knob.

④ Select **'Etc.'** and press the Menu knob.

⑤ Select **'Data Management'** and press the Menu knob.

⑥ Press the **'OK'** button with the Menu knob to exit the normal mode.

⑦ Select **'Data Erasing'** (soft key) button.

⑧ At the message confirming data erasing, press the **'OK'** button to erase data.

Note

- We advise regular back up of the context information in the internal memory and erasure of the data for more systematic management.

Caution

- Before erasing data, copy all context information in the internal memory to the external memory (SD card).
- Data erasing deletes all context information from the internal memory.

Chapter 10. Maintenance

■ Overview

This chapter is intended to provide detailed information on management methods and instructions and the product self-test functions for the maintenance and management of the CU-HD1.

Familiarize yourself with the product functions and management method introduced in this chapter in order to maintain the product at the condition for optimal and immediate use.

You can check all of the main systems that are needed to properly run the product through the automatic or manual self-test.

10.1 Self-test

The product is a medical device. Therefore, it performs a self-test in order to make sure that all of its functions work normally. If an error lamp is ON, immediately stop using the device and contact CU Medical Systems, Inc. or an authorized sales agent.

10.1.1 Power On Self-test

To ensure that the device is always ready for any emergencies, a self-test is performed by the device. The list of items tested in this test is as follows.

- **Battery Capacity Test**
  Verifies that the battery capacity is sufficient for proper operation.
  If the battery level becomes too low, the device prompts you on the low battery condition
- **Button Functionality Test**
  Checks whether the Charge button is pressed or not, preventing unintended recharging.
- **Charging and Discharging Test**
  Verifies the proper functioning of the charging and discharging subsystems.

Caution

- If the "Low Battery" status is indicated, please recharge the battery.
- If there are errors other that "Low Battery", please refers to **"Chapter 13_Troubleshooting"**, and contact an authorized sales agent.

10.1.2 Periodic Self-test

When the device is stored with a charged battery pack connected to it, it performs a periodic self-test to ensure that it is ready for use in emergencies. There are three types of periodic self-tests.

1) Daily Self-test

This test is done on a daily basis and the following items are checked.

- This test is the same as the battery capacity test done during the "power on" self-test.
- Checks the Charge button status to prevent unintended recharging.
- Checks the Shock button status of the device.

2) Weekly Self-test

This test is done on the weekly basis and the following items are checked.

- Checks the daily self-test items.
- Verifies the functionality of the SpO2 Pulse Oximeter.
- Verifies the functionality of the internal ECG circuit.

3) Monthly Self-test

This test is done on a monthly basis and the following items are checked.

- Weekly self-test items are tested.
- Charging and Discharging test: Tests whether the product can replenish itself with 2J energy, and checks the functionality of charging and discharging through internal discharging.

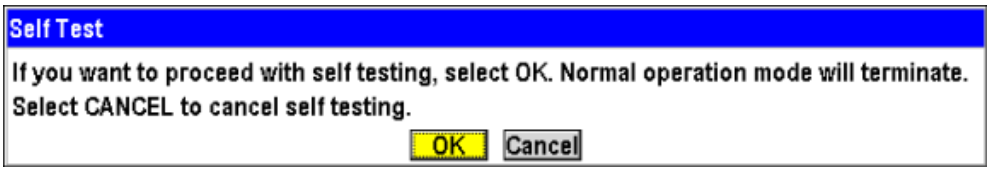
10.1.3 Manual Self-test

The product can also run a manual self-test that requires your intervention.

The manual mode test evaluates all functions tested in all the self-test modes. To initiate a manual self-test, use the "Self Test" in the "Device Management" menu. During the self-test process, there is a process for the user to make sure whether the device functions properly.

① Go to "MENU" > "Device Management" > "Self Test" items.
(To check out the defibrillation energy status, please connect the test resistance to the product.)

② A window will be prompted for verification. Please check it again.



The Product cannot be used during the manual self-test session. The following section will give you the step-by-step testing guidelines.

① If the mode is switched to the "Self Test" mode, product information (model name, serial number), software version information, and the date when the self-test had been done at the last time will be displayed on screen.
② Normal System Test : The test is run on the general system.
③ Mode Rotary Key Test : Checks the Rotary switch. If the instruction window is prompted, move the Rotary switch to 150J of the manual defibrillator mode.
④ Charging Button Test : Process to verify the functionality of the Charge button. Press the Charge button accoridng to the instructions.
⑤ Shock Button Test : Process to verify the functionality of the Shock button. Press the Shock button according to the instructions.
⑥ Audio Test : Checks the speaker functions. After the voice test, there is a process to check whether to operate the voice function by clicking the Menu knob.
⑦ Defibrillation Test : Items to check the defibrillation functionality, including the test of automatically charging 200J and delivering the defibrillation energy. To test 200J defibrillation operation, you must press the Shock button, and use the checkup resistance to implement the test. If there is no resistance or simulator connection to deliver the defibrillation energy, the device discharges the internally charged energy, leading to failure.
⑧ Pacer Test : Test about the pacer function.
⑨ ECG Lead Test : Tests 12-lead ECG measurement.
⑩ Battery Part A Test : Inspects the functionality of power terminal 'A'.
⑪ Battery Part B Test : Inspects the functionality of power terminal 'B'.
⑫ SpO_2 Test : Inspects the functionality of SpO_2 measurement module.
⑬ Printer Test : Inspects the functionality of the printer.

If the above manual test function has been finished, a message window will be prompted, saying that the device must be closed.

In the course of the self-test process, if there is any problem with the test results, or the self-test is put into pause during the test, or the test result indicates failure because the verification request had not been properly performed, an additional self-test can be provided according to the result of the power on the self-test.

10.2 Power Management

Power supplies of the **CU-HD1** include the battery module to charge, the AC power module, and a car cigar jack adapter. For the information on how to supply power for those, refer to **"Chapter 3_Product Installation"**.

The **CU-HD1** is an emergency medical product that must be usable even in a situation without AC power. So it is important to check the battery status when preparing for an emergency. For the charged battery capacity, check the remaining battery gauge or remaining battery status displayed on the LCD screen.

10.2.1 Charging Battery

The battery can be charged with an AC power module, or car cigar jack.

The AC power module and battery must be mounted at the same time. In case where AC power is supplied to the AC power module, the Product can be operated by the use of power supplied by an AC power module, and the mounted battery will proceed into its charging process. It is recommended to use the car cigar jack only for the purpose of battery charging.

If the battery is completely discharged, it takes less than 7 hours to completely charge the battery.

Battery life depends on the frequency and duration of use. When properly cared for and used in its intended environment, the battery module has a useful life of approximately 2 years. Use outside those conditions could significantly reduce battery life.

For details of information on battery module and power, please refer to **"Chapter 13_Product Specifications"**.

Warning

- During storage, regularly ensure the battery is adequately charged. The battery is a consumable part which requires regular inspection and replacement.

10.3 Cleaning

For any device problems resulting from the negligence of the below cleaning instructions, the free repair service may not be applied even during the warranty period.

Keep the main body and cables away from dust and pollution, and in the normal time, clean it using a soft cloth.
There is a risk of device damage from forcible pressing or shock.

10.3.1 How to clean and Take Precautions

- Always keep the product clean, and check the damage status. If damaged, make a service request.
- Check the product operation periodically to see if the product operation and functions are carried out normally. Maintain the product performance to enable correct operation in an emergency situation.
- Check the major terminals such as the defibrillation cable ports and DC power ports whether they maintain normal condition without damage.
- In particular, check the expiration period of the defibrillation pads and disposable parts among the product accessories and replace them with new parts if expired.
- Dispose used consumable parts according to the relevant regulations. Be careful not to cause environmental pollution when disposing.
- Disposing the device while the battery is being mounted poses a risk of electric shock.
- Then dispose of the device and accessories in accordance with your country's regulations for equipment containing electronic parts.
- Wipe the product and accessories with a soft cloth for cleaning. Excessive force or impact may cause a product failure.
- Do not immerse any part of the product or accessories in fluid or soap. Do not let any fluid enter the case of the device.
- Do not use strong, acetone-based cleaners or abrasive materials in cleaning the device.
- Especially, the filter of the LCD could be damaged.
- The IRMA Mainstream Analyzer can be cleaned using a cloth moistened with maximum 70% ethanol or maximum 70% isopropyl alcohol.
- Remove the disposable IRMA Airway Adapter prior to cleaning the IRMA Mainstream Analyzer.
- Airway Adapter is disposable. Do not sterilize, immerse, or reuse.

※ Do not sterilize the product.

10.4 Maintenance Activities

The user shall not repair this product at their own discretion. Basic maintenance can increase the lifespan of the product, and maintain the normal condition of the device.

10.4.1 User Maintenance Activities

Frequency	Activity	Actions to be taken
Daily, Monthly, or after using the product	Check the Product for any error messages that might have been generated during the self-test.	For any error messages, that you cannot handle, please call an authorized sales agent.
	Ensure that there is no dirt, water droplets, or dew at the connector gates of defibrillator pads/paddles, SpO_2, ECG cables, NIBP Cuff.	If dirt, water droplets, or dew, remove them before use. If you cannot remove them, please call us or an authorized representative.
	Check supplies, accessories, and spare parts for damage and expiration.	If any supplies have expired, replace them immediately.
	Perform the manual self-test.	For any errors issued by manual testing, please call the manufacturer or its authorized sales agent.
	Check the case of the device and the accessories for any sign of apparent damage.	If there is any apparent damage to the case of the device, consult the manufacturer.
	Check for dirt contamination.	If there is dirt contamination, clean the case as suggested in Section 10.3.

Caution

- It is recommended to carry out periodic inspections of the product in preparation for an emergency situation.

Note

- Detailed technical information required for service support and servicing by certified personnel is provided in the Service Manual.

10.4.2 Maintenance Checklist

CU-HD1

Serial Number: _____ Location/ Vehicle ID: _____

Date						
Schedule						
Exterior Condition						
Accessory Maintenance Status						
Error Correction or Measures						
Inspected by Signature of Operator						

The used supplies must be discarded according to the related law applicable to the local region. When discarding the used defibrillation pads, special caution must be paid not to cause environmental pollution. As for the battery replacement, please consult the manufacturer or the authorized sales agent. If there is a need for discarding the battery, it must be discarded according to the related law.

Chapter 11. Safety Considerations

■ **Overview**

When using the product, you must understand the follow safety considerations.

Safety considerations are described repeatedly in many parts of this manual. The safety instructions are repetitively described in this guide.

Each of the safety considerations displays risk factor, such risk factors are categorized as follows according to the seriousness of potential accidents.

Warning

- A case that could result in a dangerous situation, including death or severe injury if instructions are not observed

Caution

- Instruction that directly or indirectly addresses the company policy in order to protect people or property

Note

- Explanations for referential terms or additional operation tips helping you properly use the product

11.1 Considerations during Product Management

Safety Level	Possible Risks or Risk Factors
Warning	Do not use the Product if it has been immersed in water. If the product has been submerged in water, immediately contact us or the authorized sales agent.
Warning	If you connect a damaged device or an accessory to the device, the product may not work properly, causing injuries to the user and the patient.
Caution	Do not immerse the product or the accessories in fluids. Do not let any fluid enter the case of the device. Do not spill liquids on the case of the device. If a spill occurs on the case, there is a risk of fire or electric shock. Do not sterilize the product. Do not use abrasive materials in cleaning the product, especially on the LCD filter.
Caution	If any damage occurs to a defibrillation pad during its use or handling, replace it with a new one.
Caution	This product is designed to resist any physical shock that may occur in the work site. However, excessive shock may lead to damage to the product. If damage is suspected, implement a manual self-test.
Caution	When changing the "Default Value" setting, follow the instructions of medical professionals.
Caution	The user shall not repair this product at one's own discretion. If the user tries to disassemble the device arbitrarily, an electric short may be caused. This product is in relation to high-voltage and high-current, the repair service for this product shall go to the company or the authorized sales agent.
Caution	I t is important to carry any "must-have" accessories at all times. When unpacking, check to make sure all of the accessories are included without omission.
Caution	To increase the product's safety and reliability, only the accessories the company provides must be used.
Caution	When storing the product, disconnect the defibrillation pads from the device. To prevent the gel on the pads from drying up, do not open them before use.
Caution	If the device is continuously used, the battery must be kept connected. If the battery and power are not connected, a self-test cannot be performed.
Caution	If there is gel left on the paddles, it may cause other problems in defibrillation functionality in future. Check the surface of the paddles during maintenance and clean off any leftover gel.
Caution	The product is graded as follows. - The product's Electric Shock Prevention is graded in Class 1. Do not use this product with a flammable anesthetic or near a solvent. - Noise Class by IEC/EN 60601-1 (safety of electro medical equipment) is "B". - Noise Alleviation Class by IEC/EN 60601-1-2 (electromagnetic compatibility) is "B".
Caution	Carry out the maintenance according to the maintenance instructions of this Operation manual.

11.2 Considerations for Product Usage

Safety Level	Possible Risks or Risk Factors
Warning	Do not operate the device in environments with flammable materials or gas chemicals. There is a possibility of explosion or fire if the Product is used in the presence of a concentration of oxygen or inflammable anesthetics.
Warning	High-voltage and high-current electric energy is applied when using the Product. Before using this product, gain the full knowledge on how to operate the device from the Operation manual.
Warning	Do not modify this equipment without authorization of the manufacturer
Warning	Operation of the device below specified amplitude or value of vital sign may cause inaccurate results.
Warning	Use with designated accessories only.
Warning	While performing maintenance, calibration, etc., without tools, once the cover, connectors, etc. are removed, do not touch the patient at the same time as touching any of the non-electric parts of the medical device which can be touched in the patient environment.
Warning	For the patient's safety, do not place the device in a location where a risk factor may occur, such as a location where the device may fall down on top of the patient.
Warning	If the floor surface and your hands are wet, you may get shocked. Move to a dry location first and install the product.
Warning	If you discover any abnormality while using the product, turn off the power and refer to the user manual.
Warning	This device should be connected to a power source with protective grounding in order to avoid the risk of electric shock.
Caution	Only a user who is appropriately trained and certified must use the product. The Manual mode or Pacing function must be used by medical personnel who have knowledge on the ECG analysis.
Caution	Any electric devices that produce electric waves such as wireless devices or mobile phones may deteriorate the performance of the product. The electric waves from these devices may cause noises on the ECG signals measured from the patient, and the device to malfunction.
Caution	Check the SD card direction. Do not force it to prevent any damage to the SD card slot.
Caution	Do not use the ECG cables or connectors accompanied with the product with other vender's ECG monitoring devices.

Safety Level	Possible Risks or Risk Factors
Caution	Do not remove the SD card mounted while using the product.
Caution	Do not expose this product to X-ray or a strong magnetic field (MRI).
Note	With the ECG Monitoring mode, the patient's heart rate is measured and displayed on the LCD screen. It neither analyzes the ECG nor delivers defibrillating shocks.
Note	This product can be used in a place with high-frequency surgical equipment without an additional protective device. The accuracy of this product may be degraded temporarily during electric surgery or defibrillation but this does not affect the safety of the product or a patient. This product must not be exposed to X-ray or strong magnetic fields (MRI).

11.3 Considerations for Defibrillation

Safety Level	Possible Risks or Risk Factors
Warning	When the electric shock is delivered, high voltage and currents are used so that it may affect not only the user but also people standing nearby. Do not make contact with the patient receiving the electric shock.
Warning	Do not have the defibrillation pads make contact with other materials including the ECG electrode, wire, or dressing.
Warning	Do not use the gel-dried pads. Do not allow air to enter between the pads and skin. The air entered between the pad and skin will cause skin burn.
Warning	Do not place the patient on a wet surface.
Warning	When carrying the patient in a paramedic vehicle, it is impossible to perform an accurate ECG signal analysis so when detecting the heart rhythm needed for electric shock, be sure to stop the vehicle and perform a reanalysis before using it.
Warning	The pediatric pads with the defibrillation energy attenuation module must be used only for AED mode. If you use it in the Manual Defibrillator mode, contact the manufacturer.
Caution	Do not forcibly perform the serial internal disarm.
Caution	If you do CPR during the analysis of a patient's ECG signal analysis, you may perform an incorrect analysis due to the interference of the patient's ECG signal analysis.
Caution	When attaching the defibrillation pads to the patient's skin, following the instructions described in the rear side of the pad. Do not use the damaged pad. The defibrillation pad is disposable, do not reuse.
Caution	After using the conductive gel, remove the remaining gel on the paddles completely using a wet towel or gauze.
Note	In the course of CPR, the device provides the beep sound based on the 5 time cycle according to the 2005 CPR Guideline Instructions (30:2, 15:2).

11.4 Considerations for Pacer Mode

Safety Level	Possible Risks or Risk Factors
Warning	Do not make contact with the patient who is receiving the Demand pacing mode treatment. If an unintended ECG signal is created, it may affect the pacing treatment.
Warning	Do not deliver any defibrillation energy to any patients using the pacing function. If defibrillation is necessary, remove the cables connected with the pacing electrodes before carrying out the defibrillation.
Warning	If touching the patient to check the patient status, it may be possible to be exposed to pain or other inconvenience due to the leakage of pacing current.
Warning	Do not use the gel-dried pads. Do not allow air to enter between the pads and skin. If long-term pacing is needed, replace pads during the periodic checkup schedule.
Warning	Do not move a patient on a wet surface.
Warning	If you perform long-term pacing treatment using the battery, perform periodic checks for the battery capacity.
Caution	Always check the patient's condition while carrying out pacing. Do not leave the patient while the product is functioning.
Caution	Check the location indicating mark displayed in the rear side of the pads when attaching pads to the patient.

11.5 Considerations for Patient Monitoring Mode

Safety Level	Possible Risks or Risk Factors
Warning	Do not contact the patient whose ECG is being measured.
Warning	Place the ECG electrode on the accurate ECG location to be measured.
Warning	When a body part such as tissue is expected to be damaged while measuring noninvasive blood pressure, you need to see a physician first.
Warning	Before measuring noninvasive blood pressure, make sure to classify and enter user information.
Caution	When a patient's skin surface is wet, have the skin area dried off for the ECG electrode, and attach the electrode.
Caution	When attaching the ECG electrode to a patient's skin, do not use the electrode whose shelf life has expired or whose package has been compromised.
Caution	Make sure that the connection tube of the cuff is not twisted or folded.
Note	This product is used to measure patient's ECG by the use of defibrillation pads and ECG electrodes (3-lead, 5-lead and 10-lead).
Note	In cases when the patient is carried by a vehicle, or makes movements, it is not possible to gain a completely accurate ECG results.

11.6 Considerations for Handling Power and Battery

Safety Level	Possible Risks or Risk Factors
Warning	Caution must be taken to prevent battery module breakage. In addition, do not charge the battery for excessively long amounts of time.
Warning	When using this device with the AC power module, make sure to connect the module to a power source with protective grounding to avoid the risk of electric shock.
Warning	When using with the AC power module, always use the rated input power specified in the user manual. For details on rated input power, see **"13.15 AC Power Module"**.
Warning	If integrity of the protective grounding cable or the installed protective grounding system cannot be ascertained, use the battery.
Caution	The AC power module is attachable only to the B slot. When using AC power, take precautions to mount the battery.
Caution	When there is an alarm indicating low battery capacity, stop using it, and use the AC power module to charge or replace the battery.
Caution	Use a car cigar jack and AC adapter only to charge the battery. In addition, to prevent the vehicle battery from discharging due to the usage of a car cigar jack, star t the vehicle engine, and use the car cigar jack.
Caution	During the use of the product, do not connect or disconnect the AC power module. The replacing of the product power during the operation may cause a malfunction of the device.
Caution	Check the daily self-test results on a periodic basis.
Caution	When installing this defibrillator by connecting it to the AC power module, keep the defibrillator at least 30 cm from the wall to allow easy disconnection of the AC power cable.
Caution	Always use the designated original charger.
Caution	Never leave the defibrillator unattended in a car during summer.
Caution	Always use the designated battery.
Caution	Do not expose the defibrillator to high temperatures of 60°C or above.
Note	If the "Low Battery" message is indicated, please charge the battery.

Chapter 12. Troubleshooting

■ Overview

This Chapter describes malfunctions caused by errors that may take place during running the CU-HD1, and problems and their remedial actions.

When the device malfunctions, the corresponding text message(s) shall be issued to inform the device state. If the device still malfunctions after the associated troubleshooting described in this chapter has been carried out, contact an authorized representative.

Warning

- Any repairs on the product must be carried out by trained service personnel. When a problem that may not be resolved takes place, do not disassemble the product arbitrarily. Otherwise, it could result in an injury.

12.1 General Troubleshooting

The table shown below summarizes problems that may be considered malfunctioning, their cause and remedial action to resolve them is shown.

Error Symptom	Cause	Actions to be Taken
When pads or paddles cannot be connected	No connector connected	- Check the connection to the connectors for the pads and paddles.
When pads cannot be connected	No pads cable connection Incorrect pads connection	- Check the cable state to see if the connection between the pads and the product is correct and there is any damage to the cable. - Check the pads attached to the patient. - Check the expiration date and state of the pads. - Replace the pads if they are damaged.
When the message "The shock button was not pressed." "No shock advised." has been prompted	Auto internal discharging	- The charged energy is discharged by itself if the Shock button has not been pressed within 15 seconds. - Recharge the energy by pressing the Charge button if the charged energy discharged.
	No connection to the patient, or permissible range of the measured patient impedance diverged	- Check the connection state between the pads or paddles and the product. - Check the connection between the patient and the pads. - Check whether the impedance is able to deliver the energy at the contact point between the patient and paddles.
When canceling the charged energy at the manual defibrillator mode	Defibrillation energy changed	- Charge the defibrillation energy again after pressing the Charge button and selecting it using the Rotary switch.
	Auto internal discharging	- The charged energy is discharged by itself if the Shock button has not been pressed within 15 seconds. - Recharge the energy by pressing the Charge button if the charged energy discharged.
	Bad paddle contact	- Use the conductive gel if the contact between the paddles and the patient skin is not good. - Check if there is any impurity on the conductive plates of the paddles that has contact with the patient.
"Check the rotary switch" message with alert sound	Rotary switch is not in the correct position.	- Adjust the rotary switch to the correct position.

12.2 Troubleshooting for Problems Related to Defibrillation & Pacing Treatment

The table below describes the problems that may be encountered during defibrillation and pacing therapy, their causes and remedial action to resolve them.

Error Symptom	Cause	Actions to be Taken
When pads or paddles cannot be connected	No connector connected	- Check the connection to the connectors for the pads and paddles.
When pads cannot be connected	No pads cable connection Incorrect pads connection	- Check the cable state to see if the connection between the pads and the product is correct and there is any damage to the cable. - Check the pads attached to the patient. - Check the expiration date and state of the pads. - Replace the pads if they are damaged.
When the message "The shock button was not pressed." "No shock advised." has been prompted	Auto internal discharging	- The charged energy is discharged by itself if the Shock button has not been pressed within 15 seconds. - Recharge the energy by pressing the Charge button if the charged energy discharged.
	No connection to the patient, or permissible range of the measured patient impedance diverged	- Check the connection state between the pads or paddles and the product. - Check the connection between the patient and the pads. - Check whether the impedance is able to deliver the energy at the contact point between the patient and paddles.
When canceling the charged energy at the manual defibrillator mode	Defibrillation energy changed	- Charge the defibrillation energy again after pressing the Charge button and selecting it using the Rotary switch.
	Auto internal discharging	- The charged energy is discharged by itself if the Shock button has not been pressed within 15 seconds. - Recharge the energy by pressing the Charge button if the charged energy discharged.
	Bad paddle contact	- Use the conductive gel if the contact between the paddles and the patient skin is not good. - Check if there is any impurity on the conductive plates of the paddles that has contact with the patient.

12.3 Troubleshooting for Problems Related to ECG Measuring

The table below describes the problems that may be encountered while measuring the ECG, their causes and remedial action to resolve them.

Error Symptom	Cause	Actions to be Taken
When the 12-lead button is not activated	Bad cable contact	- Check the contact state of the 10-lead ECG cable and the device.
When excessive ECG noise happens	Bad ECG electrode contact	- Check the contact state between the ECG electrodes and the patient. - Replace the ECG electrodes if they are defective or bad. - Select other leads if the patient's skin is wet, and dry off the location where the ECG electrodes are to be attached.
	Contact between the patient and another	- Make sure there is no contact with the patient.
	Excessive patient movement	- Settle down the patient or stop the ECG measuring temporarily.
	ECG cable damaged	- Replace the ECG cable.
When the ECG is not measured	Bad cable connection	- Check the connection between the product and the ECG cable.
	Inappropriate cable use	- Replace with the ECG cable of the CU-HD1.
	ECG cable damaged	- Replace the ECG cable.
	Bad ECG connection No ECG connection	- Check that the ECG cable makes correct contact with the ECG electrodes. - Check the connection state of the ECG cable. - Check the state of the ECG electrodes (damage or contamination).
When it drifts away from the 12-lead mode while 12-lead ECG measuring	10-lead cable dropped	- Check the state of the 10-lead cable. - Check the connection state between the 10-lead cable and the Input terminal.

12.4 Troubleshooting for Problems Related to SpO_2 Measuring

The table below describes the problems that may be encountered during measuring the SpO_2, their causes and remedial action to resolve them.

Error Symptom	Cause	Actions to be Taken
Measuring failure	Excessive patient movement	- Settle down the patient or move the sensors to locations where no movement is possible.
	Sensor failure	- Replace the sensor.
	Bad sensor connector	- Replace the sensor connector.
	Product failure	- Contact an authorized sales agent.
	Inappropriate cuff location	- Replace the NIBP cuff if it is located close to heart in a body par where SpO_2 is measured.
When the measuring signals are weak.	Inappropriate sensor location	- Check that the sensors are appropriately located.

12.5 Troubleshooting for Problems Related to NIBP Measuring

The table below describes the problems that may be encountered while measuring noninvasive blood pressure, their causes and remedial actions to resolve them.

Error Symptom	Cause	Actions to be Taken
Measuring failure	Excessive patient movement	- Check if a patient moves excessively. - Settle down the patient or move the sensors to locations where no movement is possible.
	Inappropriate use	- Use an appropriate cuff for a patient category. - Check if the cuff is tightened up. - Check if the cuff is located correctly. - Check if the cuff size is correct. - Remove any part of clothes between the cuff and the patient's arm. - Check if the connection tube is twisted or folded. - Check if the patient is pressing the cuff or the tube.
	Sensor failure	- Contact an authorized sales agent.
	Product failure	- Contact an authorized sales agent.
	Accessory failure	- Replace the cuff and connection tube.
Exceeded measuring time	Incorrect use or damage of the cuff and tube	- Check if the cuff, tube and equipment are connected properly. - Check if the cuff is tightened up. - Check if the cuff is located correctly. - Check if the cuff size is correct. - Check if air is leaked from the cuff. - Check if the tube is damaged.
		- Attach the cuff to the upper arm of the patient closely and remove air from the cuff completely before use.
Excessive pressure	Incorrect use	- Check if the cuff size is correct. - Check if the connection tube is twisted or folded. - Check if the cuff is located correctly. - Check if the patient is pressing the cuff or the tube.

12.6 Troubleshooting for Problems Related to $EtCO_2$ Measuring

The table below describes the problems that may be encountered while measuring $EtCO_2$, their causes and remedial actions to resolve them.

Error Symptom	Cause	Actions to be Taken
Measuring failure	Paring or Bluetooth connection failure	- Turn the CU-CM1 on. - Connect the CU-CM1 with the CU-HD1 where there are no obstructions between them, within a maximum radius of 10 m. - Connect the CU-CM1 to the CU-HD1 via Bluetooth, and conduct zero calibration.
	Sampling line is twisted or connection error	- Reconnect the sampling line. - Check if the sampling line is twisted. - If the problem persists, replace the sampling line.
	Poor condition of adapter	- Replace the adapter with a new airway adapter. - Connect the airway adapter.
	An error of the IRMA Mainstream or ISA Sidestream Analyzer.	- Reconnect the analyzer to the CU-CM1. - If the problem persists, replace the analyzer. - Connect the desired analyzer to the connector on the CU-CM1.
	CO_2 options are not installed	- If you want to add CO_2 options, please contact us.
	CO_2: Out of range accuracy	- Conduct zero calibration. - If the problem persists, replace the analyzer
	CO_2: Out of range internal temperature	- Check the operating environment. - Use the device in the correct operating environment by referring to **"Chapter 13_Product specification"**
	CO_2: Out of range ambient pressure	- Check the operating environment. - Use the device in the correct operating environment by referring to **"Chapter 13_Product specification"**
	Motor Speed out of bounds	- Reconnect the analyzer to the CU-CM1. - If the problem persists, please contact us.
Software or hardware error	An error of the IRMA Mainstream or ISA Sidestream Analyzer.	- Reconnect the analyzer to the CU-CM1. - If the problem persists, please contact us.
Factory calibration data loss	An error of the IRMA Mainstream or ISA Sidestream Analyzer.	- Reconnect the analyzer to the CU-CM1. - If the problem persists, please contact us.

12.7 Troubleshooting for Problems Related to Printing

The table below describes the problems that may be encountered when using the printer, their causes and remedial action to resolve them.

Error Symptom	Cause	Actions to be Taken
When the paper does not move	Paper jam	- Open the printer cover and remove the jammed paper. - Refer to **"Chapter 3_Product Installation"** for feeding the paper into the printer.
When not running at all (red LED blinking)	Paper feeding issue	- Use the recommended paper. Refer to **"Chapter 13_Product specification"** for feeding the paper into the printer.
	Printer failure	- Contact an authorized sales agent.
When the printout is blurry or unreadable	Inappropriate paper used	- Use the recommended paper. Refer to **"Chapter 13_Product specification"** for feeding the paper into the printer.
	Bad paper fitting	- No printing is done when the paper has been fed in the wrong way. Refer to **"Chapter 3_Product Installation"** for paper fitting.
When no printing occurs	Printer failure	- Contact an authorized sales agent.

12.8 Troubleshooting for Problems Related to Using SD Card

The table below describes the problems that may be encountered during using SD cards, their causes and remedial action to resolve them.

Error Symptom	Cause	Actions to be Taken
When installation is not possible	Storage device other than SD card	- SD card can be installed to the CU-HD1. Other types of storage device cannot be applies.
	Installation direction error	- For information on how to install the SD card, please refer to **"Chapter 3_Product Installation"**.
Storage failure	SD card damage	- SD card may have internal damages. Use another device. - If a normally working SD card is not working properly, contact the service center.
	No free space	- Free space of the storage device is less than 1MB, the create data is not saved. Back up the saved information or install another empty storage device. - If the saved files outnumber 100, storage is not possible Back up the saved information or install another new storage device.
Storage error	Erros	- For the following error, take the following remedial actions. - "Insufficient capacity for external storage device" - "Too many files stored in the external storage device" - "External storage device errors" - Troubleshooting: Use an empty SD card. If you turn on the device again storage process will be continued.

12.9 Troubleshooting for Problems Related to Bluetooth Communication

The table below describes the problems that may be encountered when using Bluetooth communication, their causes and remedial actions to resolve them.

Error Symptom	Cause	Actions to be Taken
Bluetooth connection failure	No connection with Bluetooth or not powered on	- Please install (setup) the Bluetooth feature on your computer. - Please place your computer within an area allowing for Bluetooth communication connectivity.
Bluetooth disconnected	Bluetooth disconnected	- Make sure that your computer is placed within an area allowing for Bluetooth communication connectivity. - Please reconnect Bluetooth to your computer.
Transfer failure	Bluetooth disconnected	- Please check the connection to Bluetooth communication. - Check if the patient information transfer program works properly on your computer. - Try reconnection.
	Product feature error	- Contact an authorized sales agent.

Chapter 13. Product Specification

■ Overview

This chapter shows you the specifications of the CU-HD1. This chapter describes specifications in relation to the exterior view, defibrillation, ECG, SpO_2, NIBP, $EtCO_2$, battery/charging function, communication, and data storage.

13.1 Exterior of Product

The followings are the standard exterior view specifications of this product.

CU-HD1	
Dimentions (Paddle included)	326mm (W) x 253mm (L) x 358mm (H) (Width×Length×Height)
Weight	Body: 4.7kg or below / 8.2kg or below if paddles, cables (ECG cable, SpO2 sensor), print paper, and storage device included. Paddle (with cables): 1.2kg or below. Battery, AC power module: 0.5kg, 0.7kg respectively.

CU-CM1	
Dimentions	128.6mm (W) x 78.7mm (L) x 32mm (H) (Width×Length×Height)
Weight	210g or below if battery included. IRMA Mainstream, ISA Sidestream analyzer: 25g, 130g or below, respectively.

13.2 Environmental Condition

CU-HD1	
Operation Environment	Condition where both the equipment and pads must be stored together, which are immediately usable in an emergency case Temperature: 0 ~ 40 ℃ Humidity : 5% ~ 95%, Non-condensing
Storage Environment	Condition where the equipment and pads are not stored together, with only the equipment stored or transported for a long time Temperature: -20 ~ 60 ℃ Humidity : 5%~95%, Non-condensing
Shock/ Fall/ Abuse tolerance	Satisfying the condition of IEC 60601-1 Section 21
Vibration	MIL-STD-810E Method 514.4 Category 10
Package	Satisfying the condition of IEC 60601-1 Section 44
ESD	Satisfying the condition of IEC 61000-4-2:2001
EMI (emission)	Satisfying the condition of IEC 60601-1-2 EN55011:1998+ A1:1999 +A2:2002, Group 1, Class B
EMI (tolerance)	IEC 60601-1-2 limits, method EN 61000-4-3: 2001 Level 3 (10V/m 80MHz to 2500MHz)
Dustproof/ Waterproof Classification	IP43 according to the condition of IEC 60529
Pads Usage Environment	Standby Temperature: 0 ~ 43 ℃ Usage Temperature: 0 ~ 40 ℃ Humidity : 5%~95%, Non-condensing
Battery Usage and Storage Environment	Condition to store or transport only the battery for a long time Temperature: -20 ~ 45 ℃ Humidity : 5%~95%, Non-condensing

CU-CM1	
Operation Environment	Temperature: 0℃ ~ 40℃ Humidity : 10% ~ 95%, Non-condensing
Storage Environment	Temperature: -20℃ ~ 60℃ Humidity : 5% ~ 95%, Non-condensing
Altitude	0~4,572m
ESD	Satisfying the condition of IEC 61000-4-2:1995+A1:: 1998+A2: 2001
EMI (emission)	Satisfying the condition of IEC 60601-1-2 EN 55011:2007+A2:2007, Group 1, Class B
EMI (tolerance)	Satisfying the condition of IEC 60601-1-2 EN 61000-4-3: 2006+A1:2008 Level 3 (10V/m 80MHz to 2500MHz)

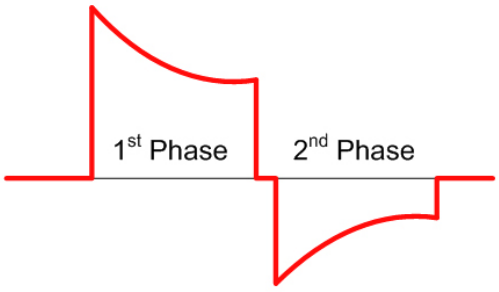
Defibrillation-proof type BF	
Operation Environment	Temperature: 0℃ ~ 40℃ Humidity : 10% ~ 95%, Non-condensing
Storage Environment	Temperature: -40℃ ~ 75℃ Humidity : 5% ~ 100%, Non-condensing
Altitude	0~4,572m
Dustproof/ Waterproof Classification	IP44

Defibrillation-proof type BF	
Operation Environment	Temperature: 0℃ ~ 50℃ Humidity : 10% ~ 95%, Non-condensing
Storage Environment	Temperature: -40℃ ~ 70℃ Humidity : 5% ~ 100%, Non-condensing
Altitude	0~4,572m
Dustproof/ Waterproof Classification	IPX4

13.3 ECG Analysis system – ECG Database Test

ECG Analysis system – ECG Database Test								
ECG Rhythm Class	Rhythms	Minimum test sample size	Performance 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	97%
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%

13.4 Defibrillation Feature

Defibrillation Feature	
Operation Mode	· **Semi-automatic** · **Manual**: Sync, Asynchronous defibrillation
Output Waveform (Manual / Automatic)	 *e-cube* biphasic (Truncated exponential type) **※ Parameters of waveforms are adjusted according to the patient's impedance.**
Shock Delivery	Delivers shock using paddles or disposable defibrillation pads.
Impedance Rage of Defibrillation Shock	25 ~ 175 Ohms

13.5 Delivered Defibrillating Energy according to the Load Impedance

(Delivered Defibrillating Energy according to the Load Impedance								
Selected Energy (Joules)	Load Impedance (Ohms)							Accuracy
	25	50	75	100	125	150	175	
1	1	1	1	1	1	1	1	±1 J
2	2	2	2	2	2	2	2	±1 J
3	3	3	3	3	3	3	3	±1 J
4	4	4	4	4	4	4	4	±1 J
5	5	5	5	5	5	5	5	±2 J
6	6	6	6	6	6	6	6	±2 J
7	7	7	7	7	7	7	7	±2 J
8	8	8	8	8	8	8	8	±2 J
9	9	9	9	9	9	9	9	±2 J
10	10	10	10	10	10	10	10	±2 J
15	15	15	15	15	15	15	15	±3 J
20	20	20	20	20	20	20	20	±3 J
30	30	30	30	30	30	30	30	±15 %
50	50	50	50	50	50	50	50	±15 %
70	70	70	70	70	70	70	70	±15 %
100	100	100	100	100	100	100	100	±15 %
120	120	120	120	120	120	120	120	±15 %
150	150	150	150	150	150	150	150	±15 %
170	170	170	170	170	170	170	170	±15 %
200	200	200	200	200	200	200	200	±15 %

13.6 Manual Mode

Manual Mode	
Charging Time (200 Joules)	· **Less than 7 sec.** : If a rechargeable battery is fully-charged. · **Less than 6 sec**. : If an AC power module is used (only when power is more than 90%). · **Less than 7 sec.** : If the battery has been discharged more than 15 times after it had been fully charged**.** · **Less than 7 sec**. : If the battery has been discharged more than 15 times after the battery module had been replaced.
Shock Energy Selection	Manual: 1J~4J±1J, 5J~10J±2J, 15J±3J, 20J±3J, 30J±15%, 50J±15%, 70J±15%, 100J±15%, 120J±15%, 150J±15%, 170J±15%, 200J±15% (50Ω load)
Operation Keys and Buttons	Soft button, LEAD Selection button, Print button, Rotary switch, Charge button, Shock button, SYNC button, MENU key, HOME button
Indicators	LCD for ECG display, Power/Error display indicators
Charing Indicator	· Text prompts of Charge Energy · Beep when charging · Shock button blinks in orange
Eenergy Selection	Rotary switch
Impedance Range of Defibrillation Shock	25~175 Ohms
Charging Manipulation	Charge button
Shock Delivery	Shock button
SYNC	· Use SYNC button for synchronized cardioversion. · Analyze the patient's ECG signals and synchronize R-wave of QRS in ECG with shock delivery within 60ms.

13.7 AED Mode

AED Mode	
Charging Time (200 Joules)	· **Less than 7 sec. :** If the battery is full-charged. · **Less than 7 sec. :** If a new battery module is used. · **Less than 6 sec. :** If an AC power module is used (only when power is more than 90%). · **Less than 7 sec. :** If the battery has been discharged more than 15 times after it had been fully charged. · **Less than 7 sec. :** If the battery has been discharged more than 15 times after the battery module had been replaced.
AED Energy	Semiautomatic: 200J±6J fixed (50Ω load)
Text and Voice Prompts	Gives step-by-step guidelines to the user on how to take proper measures for the emergency situation.
AED Operation Key and Button	Analyze button, Stop Analysis button, Shock button, CPR Type 30:2 / 15:2, Start/Stop CPR
Indicator	LCD for ECG display etc., Text instruction, Alarm indication, Soft button, MENU key
Charging Indicator	· Progress bar of the amount of energy charged and text prompts · Beep when charging · Shock button blinks in orange
Patient Analysis	Analyzes the patient's ECG to determine whether defibrillation is needed or not. (When the automatic patient analysis feature is enabled)
Defibrillation-needed Rhythm	Ventricular Fibrillation or Fast Ventricular Tachycardia, 150bpm or above
Sensitivity and Specificity of Algorithm that requires Defibrillation	AHA 2010 guidelines is met.
Disposable Pads for Adult	Surface area: 100Cm / Length of cable: approximately 55cm or above
Disposable Pediatric Pads for AED Mode	Surface area: 40Cm / Length of cable: approximately 120cm or above

13.8 Pacer Mode

Pacer Mode	
Pacing Type	Noninvasive Pacing
Energy Waveform	Monophasic Rectangular
Pacing Mode	Demand mode, Fixed mode
Energy Magnitude	5 ~200 mA (±5mA)
Pulse Width	20ms (±10%)
Pacing Rate	30 ~ 180 ppm (±1.5%)
Impedance Range in which Pacing is possible	25 ~ 175 Ohms
Operation Key and Button	Mode button, Rate button, Print button, MENU key, HOME button, and LEAD Selection button
Indicator	LCD for ECG display etc., text prompt, QRS detection display, patient monitoring information display, pacing signal delivery display
Analysis in Demand Mode	Analyzes the patient ECG to determine whether to deliver pacing energy or not in the Demand mode.

13.9 Patient Monitoring Mode

ECG Monitoring	
ECG Input	· ECG type: 3-Lead, 5-Lead, 10-Lead · Able to see ECG results using LCD or an external printer.
Lead Fault	· Detects when the ECG cable(s) is detached (if the ECG cable is disconnected from the patient or the device) · Apply 31.227nA (excluding internal resistance of cable)
Heart Rate Display	30 ~ 300 bpm (accuracy: ±3 bpm)
Setting of Heart Rate Alarm	· Heart rate alarm setting range (minimum < alarm < maximum) · Minimum: 30~300 bpm (though, it should be set to a value lower than the maximum) · Maximum: 30~300 bpm (though, it should be set to a value higher than the minimum)
ECG Size	· 2.5mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV · AUTO: 0.3 ~ 5.5 mV, Display inputted ECG signals as 10mm on the screen.
Frequency Range	· Emergency: 1 ~ 30 Hz (-3 dB) · Monitoring: 0.5 ~ 40 Hz (-3 dB) · Diagnosis: 0.05 ~ 150 Hz (-3 dB) · Notch Filter: OFF, 50Hz, 60Hz
Patient Isolation (Defibrillation Check)	Defibrillation-proof type CF
Sweep Speed	25mm/sec

ECG Monitoring	
Recovery time of defibrillation-proof type applied unit	5 seconds (Recovery time after delivering the defibrillation voltage)
Heart Rate Averaging	Determined by calculation algorithm of heart rate every 2 seconds
Response Time	· A step increase from 80bpm to 120bpm: approximately 6.52 seconds · A step decrease from 80bpm to 40bpm: approximately 18.46 seconds
Time to alarm for Tachycardia	Approximately 10.5 seconds, regardless of amplitude and heart rate

SpO2 Monitoring	
Pulse rate	20 ~ 250 bpm (± 3 bpm)
SpO2 Measuring Rage	1 ~ 100%
SpO2 Accuracy	80 ~ 100%(± 3 digit)
Perfusion	0.2%
SpO2 Alarm Setting	Minimum: 1% ~ 100% (though, it should be set to a value lower than the maximum) Maximum: 1% ~ 100% (though, it should be set to a value higher than the minimum)
Display Update Interval	6 seconds
Resolution	1%
SpO_2 Sensor	Nellcor sensor(DS100A Sensor)
Sensor Light	660 nm(Red), 890 nm(Infrared)
Power Consumption	15mW or below

NIBP Monitoring	
Patient Category	Adult, Pediatric, Neonate
Measuring Method	Oscillometric
Operation Mode	Manual/ Auto mode
Time Interval for Auto Mode	1, 3, 5, 10, 15, 30, 60, 120 munutes
Display	Systolic / Diastolic / Mean blood pressure, Alarm setting
Error Range for Pressure	± 3 mmHg

NIBP Monitoring	
Measuring Range	Systolic - Adult: 40 ~ 260 mmHg - Pediatric: 40 ~ 160 mmHg - Neonate 20 ~ 130 mmHg Diastolic - Adult: 20 ~ 200mmHg - Pediatric: 20 ~ 120 mmHg - Neonate: 20 ~ 100 mmHg
Overpressure Limit	Adult: 300mmHg Pediatric: 300mmHg Neonate: 150 mmHg
Cuff Type	Adult: 23~33cm Pediatric: 12~19cm Neonate: 8~13cm
Connection Tube	Material: Polyurethane Length: approximately 3m

$EtCO_2$ Monitoring	
Capnography Input	The result of measuring CO_2 acquired from the IRMA Mainstream analyzer or ISA Sidestream analyzer is displayed on the CH-HD1 LCD.
Display Range	0 ~ 99 mmHg (0~14 %)
$EtCO_2$Accuracy	0~99 mmHg: ± (1.5 mmHg + 2% of reading) 0~14 vol%: ± (0.2 vol% + 2% of reading)
Sweep Speed	• 6.25 mm/sec (Default setting) • 12.5 mm/sec • 25 mm/sec
Scale	• 0~100 mmHg or 0~14 % (Default setting) • 0~50 mmHg or 0~7 % • 0~20 mmHg or 0~4 %
Display Unit	mmHg or %
$EtCO_2$ Alarm Setting	• Minimum: 10 ~ 94 mmHg • Maximum: 11 ~ 95 mmHg
Respiration Rate Accuracy	± 1 bpm
Respiration Rate Alarm Setting	• Minimum: 1 ~ 149 bpm • Maximum: 2 ~ 150 bpm
Apnea Alarm Setting	20 ~ 60 seconds

IRMA Mainstream Analyzer		
Cable Length		2.5m ± 0.1m
Range		0 ~ 99 mmHg
Accuracy	Nomal Condition (22 ±℃, 1013 ± 40hPa)	0~99 mmHg : ± (1.5 mmHg + 2% of reading) 0~14 vol%: ± (0.2 vol% + 2% of reading)
	All Condition	± (2.25mmHg + 4% of reading)
Resolution		1 mmHg
Warm-up Time		10 seconds or below
Rise Time		≤90 ms
Total Response Time		<1 seconds
Isolation of Patient (Check Defibrillation)		Defibrillation-proof type BF
Recovery time of defibrillation-proof type applied unit:		5 seconds (Recovery time after delivering the defibrillation voltage)
Note 1. The accuracy specification is valid for the operating temperature and humidity conditions specified, except for interference specified in the table **"$EtCO_2$ Measuring – Interfering gas and vapor effects"**.		

ISA Sidestream Analyzer		
Cable Length		0.5m ± 0.025m
Range		0 ~ 99 mmHg
Accuracy	Normal Condition (22 ±℃, 1013 ± 40hPa)	0~99 mmHg: ± (1.5 mmHg + 2% of reading) 0~14 vol%: ± (0.2 vol% + 2% of reading)
	All Condition	± (2.25mmHg + 4% of reading)
Resolution		1 mmHg
Warm-up Time		10 seconds or below
Rise Time		≤200 ms
Total Response Time		<3 seconds
Sampling Flow		50 ± 10 sml/min
Isolation of Patient (Check Defibrillation)		Defibrillation-proof type BF
Recovery time of defibrillation-proof type applied unit:		5 seconds (Recovery time after delivering the defibrillation voltage)
Note 1. The accuracy specification is valid for the operating temperature and humidity conditions specified, except for interference specified in the table **"EtCO2 Measuring – Interfering gas and vapor effects"**.		

13.10 Display

Display	
Type	TFT LCD (including backlights)
Screen Size	152.4(W) X 91.44(H) mm
Resolution	800 X 480 X 3(RGB) pixels
Dot Pitch	0.0635(W) X 0.1905(H) mm
Backlight LED Life Time	20,000hours (time when brightness is reduced to 50%)
ECG Viewing Time	6 seconds

13.11 Event Storage

Event Storage	
External Storage SD Card (if 1GB)	Store up to 100 events and ECG data. Store more than 192 hours of single event or ECG data. Or, store more than 8 hours of events, ECG data, and voice data
ECG Data Print	Output ECG directly from the CU-HD1.

13.12 Built-in Printer

Built-in Printer	
Print Method	Thermal line printing
Resolution	203dpi X 406 dpi (dpi: dot per inch)
Print Width	48mm
Print Rate	25mm/sec
Feed Rate	About 62.5mm/sec
Input Power	7.2 V DC Power consumption in a standby state: 70mA Maximum power consumption: 2.4A
Operation Temperature	5 °C ~ 40 °C Humidity: 30%~85%, Non-condensing
Storage Temperature	-10 °C ~ 50 °C Humidity: 30%~90%, Non-condensing (without printer paper)

Printer Paper	
Type	Roll type
Size	Width: 58mm Roll size: Maximum diameter 40mm

13.13 Bluetooth

Bluetooth	
Applied Module	Parani-ESD210 (Bluetooth – Serial Module)
Version	Bluetooth v 1.2
Frequency Range	2.402 GHz ~ 2.480GHz
Send Output	Max. +4 dBm
Receive Sensitivity	-80 dBm(0.1%BER)
Antenna	Standard antenna and dipole antenna
Communication Distance	Within 30m (based on open space)
Operation Temperature	-10°C ~ 55°C (Humidity: 90%, Non-condensing)
Storage Temperature	-20°C ~ 70°C (Humidity: 90%, Non-condensing)
Miscellaneous	Transmission Method : FHSS(Frequency Hopping Spread Spectrum) Modulation Method : GFSK(Gaussian-filtered Frequency Shift Keying)

13.14 Battery Module

Battery Module (for CU-HD1)	
Battery Type	Lithium Ion
Size	170mm X 116mm X 51mm (Width X Length X Height)
Weight	0.5kg or below
Output	14.4 VDC, 5000 mAh (standard) 14.4 VDC, 10000 mAh (bulk: standard battery 2EA))
Capacity	Based on 150 Joules, 100 shocks or at least 4 hours of patient monitoring and continuous detecting of ECG (25 ° C, standard battery)
Charging Time	About 7 hours (standard battery)
Battery Capacity Check	Level 5
Operation Temperature	Charge: 0°C ~ 40°C Discharge: -20°C ~ 60°C Humidity: 90% of below, Non-condensing
Storage Temperature	-20°C ~ 45°C Humidity: 90% or below, Non-condensing

13.15 AC Power Module

AC Power Module (for CU-HD1)	
Input	100 ~ 240 VAC, 50/60 Hz 2.5A MAX(110 AC) 1.5A MAX(220V AC)
Output	18 V DC, 2 A
Size	170mm X 116mm X 60mm (Width X Length X Height)
Weight	0.7kg or less
Operation Temperature	-20°C ~ 40°C Humidity: 90% of below, Non-condensing
Storage Temperature	-20°C ~ 60°C Humidity: 90% of below, Non-condensing

13.16 Car Cigar Jack

Car Cigar Jack (for CU-HD1)	
Output	12VDC, 6.3A (Max.)
Length	1800 ± 50mm
Weight	0.08kg or less
Operation Temperature	-20°C ~ 40°C Humidity: 90% of below, Non-condensing
Storage Temperature	-20°C ~ 60°C Humidity: 90% of below, Non-condensing

13.17 AC Power Adapter

AC Power Adapter (for CU-HD1)	
Input	100~240V, 50~60Hz
Output	12V/3.6A
Length	1900 ± 50mm
Weight	0.4kg or less
Operation Temperature	-20°C ~ 40°C Humidity: 90% of below, Non-condensing
Storage Temperature	-20°C ~ 60°C Humidity: 90% of below, Non-condensing

13.18 Internal Battery

Internal Battery (for CU-CM1)	
Battery Type배터리 타입	Lithium Polymer
Output	7.4 VDC, 950 mAh
Capacity	Minimum 3 hours or more
Charing Time	About 3 hours

13.19 Power Adapter

Power Adapter (for CU-CM1)	
Input	100~240V, 50~60Hz, 0.3A
Output	12 VDC, 1A
Test Standard	Complies with IEC 60601-1:1998+A1: 1991+A2: 1995

Chapter 14. Service Guidelines

■ Product Warranty

Device Name		Model Name	
Purchase Date	(MM/DD/YY)	Serial No.	
Distributor		Person in Charge	

■ About Service

The products of CU MEDICAL SYSTEMS, INC. are designed and manufactured in compliance with the Medical Devices Act and the relevant notifications of the Ministry of Food and Drug Safety, including the Standards and Specifications of Medical Devices, General Requirements for Basic Electric and Mechanical Safety of Medical Devices, and Medical Devices Manufacturing and Quality Control Standards.

※ You are entitled to free servicing of the product for any problem that occurs during the warranty period (2 years for the product and 1 year for the battery) under normal usage conditions.
(Warranty period shall be reduced by half if the device is used for commercial purposes.)

Problem Type		Compensation	Note
Requesting repairs for performance or functional defects occurring under normal usage conditions within 1 month of purchase		Product replacement or servicing free of charge	
Performance or functional problems occurring under normal usage conditions within warranty period	Repairable defects	Free repair	
	Non-repairable defects	Product replacement or refund	Refund after straight-line depreciation
	Replacement unavailable	Refund	
Problems occurring because service parts are not held during the part holding period	Within warranty period	Product replacement	
		Product replacement after paying the amount required for paid servicing	
	After warranty period	Refund of amount plus 10% after straight-line depreciation	
Product lost by service provider after consumer has requested service	Within warranty period	Product replacement or refund	Refund after straight-line depreciation
	After warranty period	Refund of amount plus 10% after straight-line depreciation	

※ Even within the warranty period, the following defects are not covered by warranty.

- Failures caused by operations performed against instructions in the Operation manual or other incorrect operation.
- Failures caused by repair or modification in service centers other than those designated by 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.
- Damage caused by use or storage of the device in environments subjected to high temperature, high humidity, chemical compounds, microorganisms, etc. which are detrimental to use of the device.
- 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 (such as adapter, battery, etc. and parts not recommended by the manufacturer.
- Other failure or damage caused by inappropriate operation.

■ Product Registration

After purchasing, please register the product on our website (www.cu911.com) to receive continued customer support and product information.

■ Technical Support and Service

Website

http://www.cu911.com

Online Support

Go to our website (www.cu911.com) -> Customer Service -> Contact Us

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Chapter 15. Electromagnetic Compatibility

■ **Guidance and Manufacturer's Declaration – Electromagnetic Emissions**

The CU-HD1 is intended for use in the electromagnetic environment specified below. The customer or the user of the CU-HD1 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - Guidance
RF emissions CISPR 11	Group 1	The CU-HD1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CU-HD1 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Warning

- Do not use the product near other electronic devices. If you use the product in such an environment, check if it is working properly.
- If cables or accessories that are not designated by CU Medical Systems, Inc. are used, the product may be affected by EMC

■ **Guidance and Manufacturer's Declaration – Electromagnetic Immunity**

The CU-HD1 is intended for use in the electromagnetic environment specified below. The customer or the user of the CU-HD1 should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Comliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV Contact ± 8 kV air	± 6 kV Contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2kV common mode	± 1 kV differential mode ± 2kV common mode	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 IEC 61000-4-11	<5 % UT (> 95% dip in UT): for 0.5 cycle 40% UT (60% dip in UT): for 5 cycle 70% UT (30% dip in UT): for 25 cycle <5 % UT (>95% dip in UT): for 5s	<5 % UT (> 95% dip in UT): for 0.5 cycle 40% UT (60% dip in UT): for 5 cycle 70% UT (30% dip in UT): for 25 cycle <5 % UT (>95% dip in UT): for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CU-HD1 image intensifier requires continued operation during power mains interruptions, it is recommended that the CU-HD1 image intensifier be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE. U_T is the a.c. mains voltage prior to application of the test level.			

■ Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Life-Supporting Functions)

The CU-HD1 is intended for use in the electromagnetic environment specified below. The customer or the user of the CU-HD1 should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Comliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz ~ 80 MHz outside ISM bans[a]	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the CU-HD1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 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 meters (m).[b] Field strengths[c] from fixed RF transmitters, as deter-mined by an electromagnetic site survey, should be less than the compliance level in each frequency ranged.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 
	10 Vrms 150 kHz ~ 80 MHz in ISM bands[a]	10 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80MHz ~ 2.5GHz	10 V/m	
	20 V/m 80MHz ~ 2.5GHz	20 V/m	

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.	
a	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.
b	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.
c	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-HD1 is used exceeds the applicable RF compliance level above, the CU-HD1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CU-HD1.
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-HD1 – for Life-supporting equipment and System

The CU-HD1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CU-HD1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CU-HD1 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]					
	150kHz to 80MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	150kHz to 80MHz in ISM bands $d = [\frac{12}{V_2}]\sqrt{P}$	80MHz to 800MHz $d = [\frac{12}{E_1}]\sqrt{P}$		800MHz to 2,5GHz $d = [\frac{23}{E_2}]\sqrt{P}$	
	V_1 = 3Vrms	V_2 = 10Vrms	E_1 = 10V/m	E_1 = 20V/m	E_1 = 10V/m	E_1 = 20V/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	0.6	2.30	1.15
10	1.11	3.79	3.79	1.90	7.27	3.64
100	3.50	12.00	12.00	6.0	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

◎ EtCO2 Measuring – Interfering gas and Vapour Effects

◎ $EtCO_2$ Measuring – Interfering gas and Vapor Effects

Gas or vapor	Gas level (vol%)	CO_2	
		IRMA Mainstream	ISA Sidestream
N_2O (Nitrous oxide)	60	— [1, & 2]	— [1, & 3]
Halothane	4	— [1]	
Enflurane Isoflurane Sevoflurane	5	+8% of reading [4]	
Desflurane	15	+12% of reading [4]	
Xenon	80	-10% of reading [4]	
Helium	50	-6% of reading [4]	
Metered dose inhaler propellants	Not for use with metered dose inhaler propellants		
C_2H_5OH (Ethanol)	0.3	— [1]	
C_3H_7OH (Isopropanol)	0.5		
CH_3COCH_3 (Acetone)	1		
CH_4 (Methane)	3		

Note 1. Negligible interference, effect included in the specification "$EtCO_2$ Accuracy" above.

Note 2. IRMA Mainstream measures N_2O.

Note 3. Negligible interference with N_2O / O_2 concentrations correctly set, effect included in the specification "$EtCO_2$ Accuracy" above.

Note 4. Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO_2 and 50 vol% Helium, the measured CO_2 concentration will typically be (1-0.06)*5.0 vol% = 4.7 vol% CO_2.

Operation Manual

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CE

The CU-HD1 complies with the requirements of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC.