www.cu911.com

A **first step** of
saving life

![CU Medical Systems logo] **CU Medical Systems, Inc.**

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CE 2460

CU Medical Systems, Inc.

Company Overview

CU Medical Systems, Inc. is a high-technology medical device company that designs, develops, manufactures, and markets medical devices centered around one common characteristic: Intelligence

Mission

Our missions for our range of intelligent resuscitation and monitoring devices to become the standard tool for health and emergency organizations in their quest to save and preserve more lives.

Product Lines

IPAD

This is our line intelligent Public Access Defibrillators that are designed for the general public who may be the first on the scene of a cardiac arrest. These devices come with simple and straightforward user interfaces-perfect for the general public that seldom use defibrillators.

Paramedic

This is our line of intelligent patient care devices that consist of defibrillators designed for advance users such as emergency responder and health care organization personnel. These devices are light-weight and easy to use-perfect for rescuers in and out of the hospital.

LiFEGAIN

These defibrillators are designed for hospital use. These may run either in Manual or AED mode. Aside from defibrillation capability, these devices usually come integrated with physiological monitors such as 12-lead ECG and SpO$_2$. These features make this kind of defibrillators suitable for use by physicians inside a hospital.

Quality Credentials

Corporate Quality Policy

Since we design, develop, manufacture, sell and service our brand-new Paramedic series and AED and other products as well, we put a lot of importance on the quality of our products and services. It is our way of showing to our partners and customers not only concern for safety and reliability but also our belief that quality is the key for long term success in business.

- Do it right the first time to eliminate costly rework
- Listen to and learn from customers and employees
- Make Continuous improvement an everyday matter
- Build teamwork, trust, and mutual respect

Quality Assurance

CU Medical Systems, Inc. continuously encourage quality improvement through Total Quality Management to consistently improve the safety and reliability of our products as well as quality systems. With these perspectives, CU Medical Systems, Inc. strives to comply with the rigorous quality sysytem regulations of the following organizations:

- ISO 13485 : 2003 (Europe) (with yearly inspections) - EN46001 (Europe)
- Medical Device Directive (MDD 93/42/EEC) (Europe)
- Conformite Europeen (CE MARK) labeling
- KFDA Quality Approval (Korea)
- JFDA Approval (Japan) -Paramedic CU-ER1, i-PAD NF1200, CU-SP1
- FDA Approval (US) - i-PAD NF1200
- SFDA (China) : i-PAD NF1200, LiFEGAIN CU-HD1
- British Heart Foundation : i-PAD CU-SP1

Quality Achievements

It is gratifying when quality achievements come with official recognition from outside entities. In the past years, CU Medical Systems, Inc. has achieved and been honored with the following:

Excellent Korean Technology Mark (KT MARK) (June 11, 2003)
Development of automatic external defibrillator by utilizing entropy arrhythmia analysis algorithm
Ministry of Science Technology

Excellent Machinery, Mechanism Materials Mark (EM MARK) (Aug 30, 2003)
ATS (Agency for Technology and Standards)
Ministry of Commerce, industry Energy

Certificate of Excellent Quality Product (Oct 30, 2003)
Public Procurement Service, Republic of Korea

Won the 4th SMBA technological innovation prize for AED (Sep 24, 2003)
Small Medium Business Administration

Health Industry Technologies Exposition Korea 2003 Award (Dec 4, 2003)
Korea Health Industry Development Institute

Korean World-class Product Award 2005 (June 30, 2005)
Ministry of Commerce, Industry Energy

Leading company of regional Innovation Award 2005 (Oct. 5, 2005)
The Prime Minister, Presidential Committee on Balanced National Development.

IR52 Jang Young Shil Award 2008 (May 20th, 2008) : i-PAD NF 1200
Korea Industrial Technology Association

iPAD CU-SP1 (Semi-Automated with 150J)
Intelligent Public Access Defibrillator

iPAD CU-SP1 Auto (Fully Automated with 150J)
Intelligent Public Access Defibrillator

(Intelligent Public Access Defibrillator)
Defibrillation capability for the general public

British Heart Foundation — NOMINATED DEVICE

Key Features
- Ambient noise detection (Auto volume adjusting)
- CPR detection
- Pads and battery status indicator
- Multi events recording
- Easy communication with CU-EX1 software
- Low cost of ownership

❖ Specifications

- **DEFIBRILLATOR**
  - Model : i-PAD CU-SP1
  - Standard Package : Defibrillator, Pads, Battery, Manual
  - Output Energy : Adult-150Joules / Pediatric-50Joules(Common usage)
  - Charging Time
    Charging time : Less than 10 seconds
    Charging time after CPR finished : At least 6 seconds

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

- **Enviroment**
  - Sealing :
    Waterjet proof IPX5 per IEC60529(IP55)
    Dust protected IP5X per IEC60529
  - Temperature : Operation/Standby (0 ~ 43℃)
  - Vibration : Meets MILSTD 810G

- **Data Recording and Transmission**
  - IrDA port : Wireless transmission of event data to PC, SD card
  - Internal Memory : ECG, Event
  - Storage Capacity : Multi Recording 5 events / Max 3 hours
  - Data Review PC Program : CU-EX1

- **Patient Analysis System**
  - Patient Analysis : Shockable rhythms (Ventricular Fibrillation, Ventricular Tachycardia)
  - Sensitivity/Specificity : Meets AAMI DF80 Guideline

- **Battery**
  - Capacity : - Type : DC 12 volt 4.2Ah, Lithium manganese dioxide
    - Minimum 200 shocks(150J)
  - Lifespan : 5 years (high capacity battery)
    (With the condition of the temperature of operation/standby, standby mode after the first initial check)

Semi Automated

iPAD

- Size : 260×256×69.5 (W×L×H, mm)
- Weight : 2.4kg

Fully Automated

iPAD — AED — Automatic Shock

iPAD — AED

- **Parts & Accessories**

  Standard Package
  - Device
  - Multifunction Defib. Pads
  - Disposable LiMnO₂ Battery Pack
  - User's Guide

  Opition
  - Carrying case
  - SD card
  - Software for data management
  - Wall bracket   - Wall cabinet

CU-SP1 Trainer
- 8 Standard rescue scenarios
- Powered by AAA disposable, rechargeable battery
- Simulates all the functions of CU-SP1

Auto volume adjusting, upto 90db
Ambient noise detector measures level of background noise and adjusts the volume of the voice prompts accordingly.

Smart pads storage, underneath the device
Integrated pad storage
- electrode pads are stored, pre-connected, in a clear compartment on the underside of the unit.

Smart CPR detection
- If CPR is not being performed, voice prompts encourage the responder to 'perform CPR'
- If CPR is being performed, voice prompts encourage the responder to 'continue CPR'

Easy communication
- Internal memory stores the last 5 events/3 hours of data
- Data can be transferred via the built in SD card and IrDA ports

Patient mode switch
- Easily switch from Adult to Child mode without changing pads
- Safety cover prevents accidental switching

IPAD CU-SP2

Intelligent Public Access Defibrillator
(Intelligent AED for professional use)

Key Features

- Manual Override, R-Sync function
- Graphic LCD status indicator
- Wireless ECG transmission device
- External Bluetooth Printer
- Ambient noise detection (Auto volume adjusting)
- Easy communication with CU-EX1 software

❖ Specifications

• DEFIBRILLATOR
- **Model :** i-PAD CU-SP2
- **Output Energy :**
  AED Mode : Adult-150/200J(fixed) or 150-200J, 150-150-200J(Energy Escalating)
  Manual Mode : 2~200J, R-Sync
- **Charging Time**
  Charging time : Less than 10 seconds
  Charging time after CPR finished : At least 6 seconds

• User Interface
- **User Support :** Graphic guide, Detailed voice and text prompts
- **CPR guidance :** Voice prompts for CPR for adult and child patient
- **Controls :** On/Off button, I button, Shock button, 3 Menu buttons
- **Indicator :** Graphic LCD display (Device status, user's guide, ECG, heart rate, etc.)
- **Sensing :** Pads expiring date, Pads connection status, Pads usage detecting
- **ECG monitoring**
- **CPR monitoring**
- **Automatic Volume adjusting**

• Enviroment
- **Sealing :**
  Waterjet proof IPX5 per IEC60529(IP55)
  Dust protected IP5X per IEC60529
- **Temperature :** Operation/Standby(0 ~ 43℃)
- **Vibration :** Meets MILSTD 810G

• Data Recoding and Transmission
- **Internal Memory :** ECG, Event
- **IrDA :** Wireless transmission, SD card
- **Storage Capacity :** Multi Recording 3 events(up to 17 hours for each event)
- **Bluetooth :** Printer or CU-EM1
- **Data Review :** CU-EX1

• Patient Analysis System
- **Patient Analysis :** Shockable rhythms (Ventricular Fibrillation, Ventricular Tachycardia)
- **Sensitivity/Specificity :** Meets AAMI DF80 Guideline

• Battery
- **Rechargeable :** - Type : 11.1V DC, 1.9Ah Li-ion
  - Capacity : Minimum 60 shocks or 3 hours of operation
- **Disposable :** - Type : 12V DC, 4.2Ah LiMnO2
  - Capacity : Minimum 130 shocks or 5 hours of operation

- Size : 260×256×69.5(W×L×H,mm)
- Weight : 2.4kg

• Parts & Accessories

Standard Package
- Device
- Multifunction Defib. Pads
- Rechargeable Battery Pack
- Battery Charger
- User's Guide

Opition
- Carrying case
- SD card
- Printer
- CU-EM1 (ECG Transmission Device)

DEVICE SETUP	DATA REVIEW	EXIT
Device Mode		Manual Mode
Manual Override		CHARGE
Adult / Pediatric Mode		ADULT
Shock Energy		Escalating(150-150-200J)
ECG Gain		10 mm/mV
Device Volume		1
Graphic Indication		ON

1 / 2

Manual Mode
When in manual override, the user can set the energy value for defibrillation.
Using R-Sync will detect the R-wave of the patient's ECG, and display the R-Sync mark on the LCD Screen with a short beep.

Wireless ECG transmission device(CU-EM1)
In Monitor Mode, the i-PAD CU-SP2 uses Bluetooth to receive ECG data from the CU-EM1 and displays it on the LCD Screen.

Printer
The i-PAD CU-SP2 supports connection to an external Bluetooth printer

i·PAD NF1200 (Semi-Automated)
Intelligent Public Access Defibrillator

i·PAD NF1201 (Fully-Automated)
Intelligent Public Access Defibrillator

(Intelligent Public Access Defibrillator)
Defibrillation capability for the general public

♡ Key Features

- Patented *e~cube* Biphasic Truncated Exponential Shock Waveform
- Automatic Self-testing
- CPR coaching
- Multi event recording
- Pads status detection
- Simple operation
- LED status indicator

❖ Technical Specifications

• DEFIBRILLATOR
- **Model :** NF1200
- **Operation :** Semi-Automated (NF1200), Fully-Automated (NF1201)
- **Waveform :** Biphasic Truncated Exponential
- **Energy :** 200J (Fixed)
- **Shock-to-Shock Cycle Time :** Typically less than 20 seconds
- **Protocol :** Voice prompts and indicators guide user through protocol. Follow preconfigured settings. Can be modified with software
- **Voice Instructions :** Detailed voice messages guide responder through use of the defibrillator
- **Controls :** Shock Button (NF1200 only), i-Button, On/off Button
- **Indicators :** 4 LEDs (different colors), i-Button

• ENVIRONMENTAL / PHYSICAL REQUIREMENTS
- **Temperature :** Operating : 32º ~110º F (0º ~ 43℃)
  Standby : 32º ~ 110º F (0º ~ 43℃)
- **Humidity :** Operating - 0% to 60% relative, non-condensing
  Standby - 0% to 95% relative, non-condensing
- **Vibration :** Meets EN1789 random and swept sine, road ambulance specification in operating and standby states
- **EMI** (Radiated/Immunity) : Meets EN55011 Group 1 Level B Class B and EN61000-4-3

• Sealing
- Meets IEC60529 class IP54 with battery installed

• BATTERY
- **Type :** 12 Volt DC, 4.2 Ah, lithium manganese dioxide, disposable long-life primary cell
- **Capacity :** Minimum 200 shocks or 4 hours of operating time (25℃)

• AUTOMATED AND USER-ACTIVATED SELF-TESTS
- **Daily Self-Tests :** Tests internal circuitry, waveform delivery system, battery capacity and software
- **Battery Insertion Test :** Upon battery insertion, extensive automatic self-tests and user-interactive test check device readiness

• Data stored
- Maximum 7 events can be saved.
- 1 event can be recorded for 75 minutes
- If 7 events are recorded, maximum recording duration for each event is 5 minutes

- Size : 220×281×82 (W×L×H, mm)
- Weight : 2.2kg

• Parts & Accessories

Standard Package
- Device
- Multifunction Defib. Pads
- Disposable LiMnO₂ Battery Pack
- User's Guide
- Quick Reference Card

Opition
- Carrying case
- IrDA connector for data communication
- Software for data management with key file
- Wall bracket
- Wall cabinet

Semi Automated

Pads Connector Guide & LEDs
- Indicates the position of the pads connector
- Guide the user during rescue operation

Shock Button (NF1200 only)
- Delivers the shock

Fully Automated

Information Button
- When pressed, guides the user
- during CPR and system trouble shooting

State LED
- Indicates operational state of the device

Battery Pack
- Disposable LiMnO₂ Battery Pack

IrDA Port
- Used for data communication
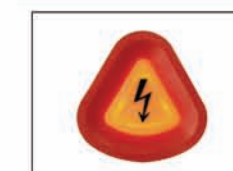
TRAINER

i-PAD NF1200 T1
- 8 standard Rescue Scenarios
- Infrared remote control operation
- Powered by an external disposable battery pack or rechargeable battery pack
- Simulates all the functions of the NF-1200

i-PAD NF1200 T2
- 8 standard Rescue Scenarios
- Powered by AA Battery
- Function Switch
- Simulates all the functions of the NF-1200

Paramedic CU-ER5

(Multifunction Defibrillator / Monitor)

The Paramedic CU-ER5 defibrillator / monitor is
designed to accommodate both basic and advanced life support personnel.

External Paddle
(Adult, Pediatric)

❖ Specifications

• Defibrillation
- ECG Lead Select — I, II, III, aVR, aVL, aVF, V, Paddle/Pads, Ext ECG
- Waveform — *e~cube* Biphasic (Biphasic Truncated Exponential type)
- Output Energy — Manual : 1~10J, 15J, 20J, 30J, 70J, 100J, 120J, 150J, 170J, 200J
  AED : 150J (Fixed)
  Internal Paddle : 1~10J, 15J, 20J, 30J, 50J
- Charge Time — Less than 10 seconds to 150J
- Shock Delivery — Via multifunction defib. electrode pads or paddle
- Patient Impedance — Shock range : 25 Ohm ~ 175 Ohm
- AED Mode — Shock advisory sensitivity and specificity meet AAMI DF-80 guidelines
- Synchronous Cardioversion — Energy transfer begins within 60ms of QRS peak
- Voice & Text Prompts — Multi language support

• ECG Monitoring
- Input — Lead I, II, III (3-lead ECG cable)
  Lead I, II, III, aVR, aVL, aVF or V (5-lead ECG cable)
- Heart Rate Display — 30 to 300 bpm
- ECG Size — 5, 10, 20mm/mV and Auto-gain
- Heart Rate Alarm — Less than minimum setting rate / Over than maximum setting rate
- Waveform Sweep Speed — 25mm/sec

• SpO₂ Pulse Oximetry (Nellcor)
- Saturation — 70~100% (±3digits)
- Pulse Rate — 20~250bpm (±3bpm)
- Perfusion — 0.2%

• Power
Internal Battery
- Type — Rechargeable / 12V 4.5Ah Ni-MH battery pack
- Capacity — When new, minimum of 200 shock deliveries (200J)
- Recharging Time — Minimum of 4 hours for full charging

External Battery Pack
- Type — Disposable / 15V 4.2Ah LiMnO₂ battery pack
- Capacity — When new, minimum of 200 shock deliveries (200J)

AC/DC Adapter
- Input — 100~240V AC 50/60Hz
- Output — DC 12V, 3.6A
- Car Cigar Lighter — DC 12V

• Physical
- Dimensions — Without eternal paddle : 254*365*105 (mm)
  With external paddle : 455*365*105 (mm)
- Weight — 4.7Kg (with external paddle)

• Environmental Requirement
- Temperature — Operation : 0℃ ~ 40℃
  Storage : -20℃ ~ 60℃
- Humidity — 5% ~ 95%

• Size : 455×365×105 with paddle (W×L×H, mm)
• Weight : 4.7kg (with external paddle)

• Display
- LCD Dimensions — 4 ″ diagonal (80mm*60mm)
- Type — High resolution mono graphic LCD
- Resolution — 320*240 pixels
- Wave Viewing Time — 3.2 seconds (ECG)
- Back Light — EL back light

• Data Storage & Management
- Internal Flash Memory — 12 hours of event and ECG recording
- Data Card (SMC 32M) — 42 hours of event and ECG recording or 1 hours if voice recording is enabled
- Data Transfer to PC — UART / IrDA

• Self-Test
- Power on Self-Test
- Run Time Self-Test
- Manual Self-Test
- Periodic Automatic Self-Test (Daily / Weekly / Monthly)

• Parts & Accessories

Standard Package
- Device
- External Paddle (Adult, Pediatric)
- 3-Lead ECG Cable
- Power Cord
- AC Adapter
- Internal Battery (Ni-MH)
- User's Guide

Options
- Thermal Printer
- Printer Paper (10 rolls)
- Cigar Lighter Jack for Car
- Multifunction Defib. Pads
- Adapter for Defib. Pads
- 5-Lead ECG Cable
- ECG Electrodes (50EA)
- SpO₂ module set (probe, extension cable)
- Disposable Battery Pack (LiMnO₂)
- IrDA Adapter for Data Communication
- Software for Data Management with Key File (UART Cable included)

LiFEGAIN CU-HD1

(Multifunction Defibrillator / Monitor)

Someone goes down in cardiac arrest, resuscitation is just a hand away...

❤Key Features

- Efficient *e~cube* Biphasic technology (BTE Type)
- Manual and AED operation
- Defibrillation using paddles, pads or internal paddles
- ECG Monitoring (3-Lead ECG / 5-Lead ECG / 10-Lead ECG)
- SpO₂ pulse oximetry with alarms (Nellcor)
- Noninvasive pacing mode
- NIBP (Non-Invasive Blood Pressure)
- EtCO₂ (End-Tidal CO₂)

❖ Specifications

• Display

- LCD Dimensions : 7 inch Diagonal (152mm * 91mm)
- Type : TFT Color
- Resolution : 800 * 480 pixels

• Defibrillation

Defib Common
- Waveform : Truncated Exponential Biphasic (e~cube)
- Charge Time : Adapter : Less than 5 seconds to 200 Joules
             Battery : Less than 5 seconds to 200 Joules

AED Mode
- Output Energy : 200J
- Shock Delivery : Via multifunction defib electrode pads
- AED Develop Guideline : Shock advisory sensitivity and
                       Specificity meet AAMI DF-80 guidelines
- Voice & Text Prompts : Guide the user through the protocol
                       via multifunction defib electrode pads

Manual Mode
- Output Energy : 1~10J, 15J, 20J, 30J, 50J, 70J, 100J, 120J,
  (Selected)   150J, 170J, 200J
- Shock Delivery : External paddle (with Pediatric) / Internal paddle
- Synchronous Cardioversion

• Printer

- Continuous ECG Strip : Real-Time (8 seconds delay)
- Auto Printing : Recorder can be configured to print marked
                event, charge, shock and alarms
- Printing Speed : 25mm/s
- Paper : 50mm Width / 40mm Diameters

• Automatic Self-Test

- Power On Self-Test
- Run Time Self-Test
- Manual Self-Test
- Periodic Self-Test (Daily / Weekly / Monthly)

• Data Storage

- External memory card
  : SD Card (ECG data, Event, Voice)

• ECG Monitoring

- Input : 3-Lead Cable : I, II, III
        5-Lead Cable : I, II, III, aVR, aVL, aVF or V
        10-Lead Cable : I, II, III, aVR, aVL, aVF or V1, V2, V3, V4, V5, V6
        (Display View : All 12-Lead ECG waves display simultaneously)
- Lead Fault : "Lead Fault" message and dashed line display, if an electrode or lead wire becomes disconnected
- Heart Rate Display : 30 to 300 bpm (±3bpm)
- ECG Size : 5, 10, 20mm/mV and Auto-gain
- Heart Rate/Arrhythmia Alarm : HR, Asystole, VF, VT

• Power Source

External Battery Pack : Lithium Polymer
- Type : 14.8V 3.1Ah (Rechargeable)
- Capacity : When new, minimum of
           100 shock deliveries (200J)

AC Power Pack
- Output : 18V, 6A

• Noninvasive Pacing

- Waveform : Monophasic Truncated Exponential
- Mode : Demand and Fixed Mode
- Amplitude Accuracy : 0 ~ 200mA (±5mA)
- Pulse Width : 20ms (±1.5%)
- Pulse Rate : 30 ~ 180ppm (±1.5%)
- Refractory Period : 340 msec (30 to 80 ppm)
                    240 msec (90 to 180 ppm)

• SpO₂ Pulse Oximetry

- Saturation : 70 ~ 100% (±3digits)
- Pulse Rate : 20 ~ 250 bpm (±3bpm)
- Perfusion : 0.2%
- Module Manufacturer : Nellcor
- SpO₂ Alarm : Less than Minimum setting rate
             Over than Maximum setting rate

• NIBP

- Patient Population : Adult, Pediatric, Neonate
- Method : Oscillometric
- Control : Autometic and manual measurements
- Auto Intervals : 1, 3, 5, 10, 15, 30, 60, 120 min
- Displayed Pressures : Systolic, Diastolic, MeanmmHg
- Displayer Units : Adult : 40 to 260 mmHg
                  Pediatric : 40 to 160 mmHg
                  Neonate : 40 to 130 mmHg
- Systolic Range : Adult : 20 to 200 mmHg
                 Pediatric : 20 to 120 mmHg
                 Neonate : 20 to 100 mmHg
- Diastolic Range : ±3mmHg
- Pressure Transducer : Adult : 300 mmHg
  Accuracy   Pediatric : 300 mmHg
                    Neonate : 150 mmHg
- Redundant Circuit Overpressure Limit

• EtCO₂

- Range : 0 ~ 99 mmHg
- Accuracy : ± (1.5 mmHg + 2 % of gas level)
- Respiration Range : 0 - 150 bpm
- Respiration Rate Accuracy : ± 1 bpm
- Sampling Flow Rate : 50 ± 10 ml/min
- Typical Response Time : ⟨1 sec(IRMATM), ⟨3sec(ISATM)

- Size : 318×208×355 (W×L×H, mm)
- Weight : 6kg (with external paddle)

• Parts & Accessories

Standard Package
- Device
- External Paddle
  (Adult, Pediatric)
- 3 Lead ECG cable
- ECG electrodes
- Defi pads & Adaptor
- Built in printer
- Power cord & SMPS
- Internal Battery
- Gel
- User's Guide

Option
- Carrying case
- SD card
- SD card reader
- Pediatric pads
- 5 Lead ECG cable
- Car cigar lighter jack
- SpO₂ Module Set
- Pacer
- 10 Lead ECG cable
- NIBP (Non- Invasive
  Blood Pressure)
- EtCO₂ (Mainstream /
  Sidestream)
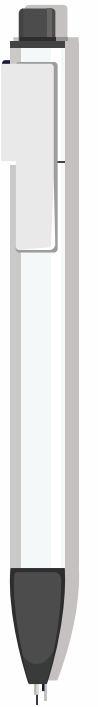- Software for data
  management (CU-EX2)

Software CU-EX1
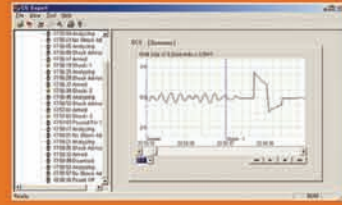
- Patient and Data Management Software
- Easy Data Communication between PC and Product (SD card, IrDA)
- Records ECG Data and Voice
- Easy Printing by all kinds of Printers
- Data Communication with i-PAD, Paramedic, Lifegain

CU-EX1 displays ECG data on the computer after receiving the data from i-PAD, Paramedic, Lifegain
If you use CU-EX1, you are able to analyze, record and manage ECG data of the patients more efficiently.
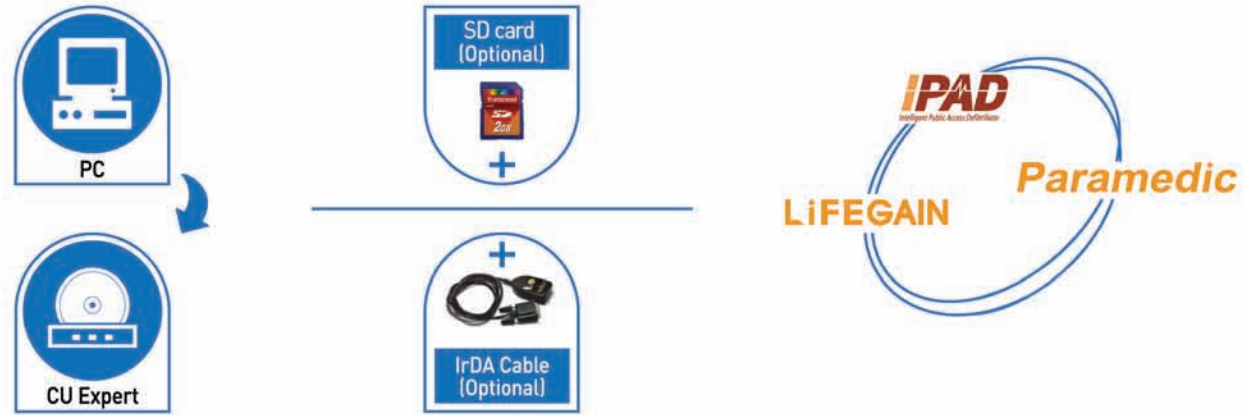
Memo

Date

Subject

Memo

Requested Matters

Method

PC

CU Expert

SD card (Optional)

+

IrDA Cable (Optional)

iPAD

LiFEGAIN

Paramedic

Method to connect SD card for wireless communication

1.Connect — SD card — 2.Connect

Method to connect IrDA cable for wireless communication

PC COM Port — IrDA Port

1.Connect — IrDA Cable — 2.Locate closely