Reduce Door-to-Balloon times with the advanced LiFEGAIN

LiFEGAIN CU-HD1

CU Medical Systems, Inc.

CONTACT INFORMATION

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

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

Branch Office in Europe
Kuester Strasse 6
30519 Hannover, Germany
Tel / Fax: +49 511 8486054

EU Authorized Representative
Medical Device Safety Service
Schiffgraben 41, 30175 Hannover, Germany
Tel: +49 511 6262 8630
Fax: +49 511 6262 8633

website: www.cu911.com

SHOULD BE ADVANCED. SHOULD BE EFFECTIVE AND…

CLINICAL, PROFESSIONAL REVOLUTION FOR THE ADVANCED TREATMENT

Coronary heart disease (CHD) is one of the leading causes of deaths worldwide. According to the World Health Organization, 7.2 million people died of coronary heart disease in 2004. It is the number one cause of death in high-income countries with 1.33 million deaths in 2004. In the United States, CHD caused about one of every five deaths in 2005. It is the largest single killer of American males and females.

In the treatment of CHD, patients are categorized into:

- STEMI - ST elevation myocardial infarction
- NSTEMI - Non ST elevation myocardial infarction
- UA - Unstable angina

Among the three, STEMI needs immediate attention the most as it usually involves a blockage of an epicardial coronary vessel. For percutaneous coronary intervention (PCI) the American Heart Association recommends a door-to-balloon inflation time of 90 minutes.

With the LiFEGAIN CU-HD1, door-to-balloon time can be reduced by having the patient's 12-lead electrocardiogram (ECG) monitored and transmitted to the hospital while the patient is in transit.

BEFORE THE PATIENT'S ARRIVAL AT THE HOSPITAL

Trustable defibrillator / monitor LiFEGAIN CU-HD1 being compatable with the latest IT should provide total solution for sophisticated patient care.

TELEMETRY SYSTEM WITH LiFEGAIN CU-HD1

Time is the matter when the patient suffering from CHD is in tight situation. From the street, office, school to Emergency Room, immediate and advanced patient treatment should be provided in advance.
Currently developed, actually installed and run by CU Medical Systems the LiFEGAIN CU-HD1 with Telemetry System is the right tool to tackle the time problem.
Where there is a mobile communications network, the vital signs of the patient can be transferred to an emergency room where doctors and nurses can read them in the room while the patient is still in transit.

REAL TIME VITAL SIGNS TRANSFERRED AND READ (INCLUDING 12 CHANNEL OF ECG)

Doctors do not have to wait until the patient's arrival since they can read all the patient's vital signs clearly in their room preparing the treatment while LiFEGAIN CU-HD1 keeps sending the signs.

DISTANCE NOTIFICATION

Medical staff might wonder where the ambulance is located at that moment arranging necessities for the patient. The Telemetry Systems thoughtfully provides how far the ambulance is from the hospital, how long it will take to get to the hospital.

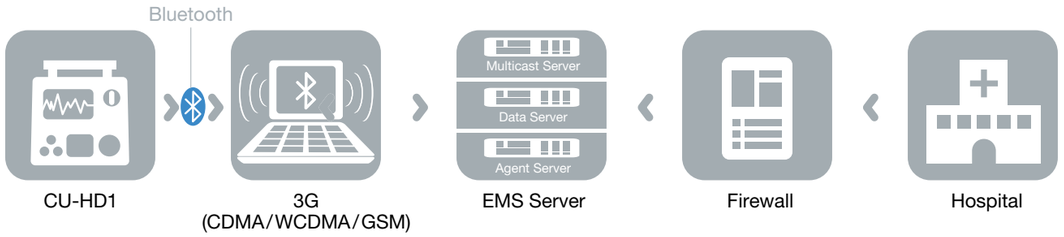
REAL TIME VIDEO AND AUDIO

To examine exact patient condition, doctors need to see the patient's looks, to listen to the patient's claim even though they are not with doctors. Remotely but in real time and as if the medical staff is consulting the patient face to face, these function should help to give right treatment to the patient.

REMOTELY PLACING MEDICAL ORDERS

With the vital signs, distance from the hospital, patient's look and claim, doctors can place medical orders with text message (computer) or real time audio for the immediate patient therapies.

CONNECTING PATIENT DATA ACROSS YOUR SYSTEM



LiFEGAIN CU-HD1 DEFIBRILLATOR / MONITOR

THE ENDLESS PROGRESS IN EMERGENCY THERAPY

Not limited to the usage in the ambulance, LiFEGAIN CU-HD1 should be a suitable defibrillator / monitor for the hospital. Compact and good sized LCD screen is enough to display physiological signals for monitoring the patient's condition.
Its own software, the CU-EX2(expert2), is compatible with the telemetry system software to build and to furnish network to be able to review the patient data.

MONITORING FEATURES

ECG
- 3-lead, 5-lead, and 12-lead monitoring through ECG electrodes.
- 12-lead ECG transmittable via mobile phone network and internet.
- Single lead (lead II) monitoring through defibrillation pads.
- Arrhythmia detection (Ventricular Fibrillation and Ventricular Tachycardia).
- ECG output through liquid crystal display and printer.
- ECG recording in removable SD Card.
- Lead fault detection.
- With alarm settings.
- Adjustable ECG size including auto gain.
- Adjustable frequency response (Emergency, Monitoring, Diagnostic).
- With power line frequency notch filter (50Hz, 60Hz).

SpO_2
- Nellcor SpO_2 module featuring the OxiMax® Pulse Oximetry System - provides superior levels of monitor and sensor performance.
- Sensor calibration coefficients are programmed in the sensor giving the module flexibility in the accommodation of various sensors. Creates latitude for accommodating future sensor designs.
- Delivers accurate SpO_2 and pulse rate readings even when confronted with challenging conditions, such as patient motion combined with low perfusion. Nellcor provides the Max-Fast® Forehead Sensor especially for patients with low perfusion.
- With plethysmographic waveform display.
- Compatible with all Nellcor reusable and single-patient-use OxiMax sensors.

NIBP
- Automatic and manual oscillometric blood pressure measurement using NIBP module from SunTech Medical with Standard Motion Tolerance (SMT) technology.
- Accurate and reliable blood pressure monitoring, when and where you need it.
- Provided with alarms that let you know when systolic or diastolic or mean arterial pressure goes beyond the limits that you set.
- Indicated for adult, pediatric, and neonate patients.

SUITABLE FOR THERAPIES

HOSPITAL

MANUAL MODE
- Features the same impedance compensated e-cube biphasic shock waveform (biphasic truncated exponential type) as in AED mode.
- Has SYNC option for synchronized cardioversion.
- Defibrillation shocks may be delivered using defibrillation pads or paddles.
- Indicated for both adult (using adult pads or paddles) and pediatric (using pediatric pads or pediatric paddles) defibrillation.
- Paddles contain contacts for both adult and pediatric patients. When the adult contacts are removed, the paddles may be used for pediatric patients.
- Paddles have charging and shock delivery switches. Eliminates the need to press buttons on the device panel during manual defibrillation using paddles.
- Device has contact quality indicator on the LCD display that indicates whether the paddles have good contact with the patient or not.

NONINVASIVE PACER
- Rectangular monophasic waveform with 20 ms pulse width.
- With demand and fixed modes.
- Adjustable pacing amplitude from 5 to 200 mA.

EMS

DEFIBRILLATION / AED MODE
- Features impedance compensated e-cube biphasic shock waveform (biphasic truncated exponential type).
- Preset 200 Joules shock energy into 50Ω, nonescalating.
- Text and voice prompts guide you through defibrillation and CPR
- Rescue protocol is in accordance with the American Heart Association 2005 Guidelines for CPR and ECC.
- Indicated for both adult (using adult pads) and pediatric (using pediatric pads) defibrillation.

FIRE FIGHTERS

DEFIBRILLATION / AED MODE
The LiFEGAIN HD1 has been designed to meet the exacting requirements of emergency first responders.

- Transit Drop Test: tested according to MIL-STD-810F Method 516.5 with a drop height of 1.2 meters.

- IEC60529 IP Rating: IP 43
  First numeral: IP 4X: the LiFEGAIN HD1 is protected against objects 1 mm in diameter or larger.
  Second numeral: IP X3: the LiFEGAIN HD1 is protected against spraying water.

These tests assure you that the LiFEGAIN HD1 will perform in the tough environment of pre-hospital resuscitation.

FEATURE-RICH

LiFEGAIN CU-HD1 continues to give you the rugged performance and advanced technology you need to give your patients the best care possible. Now you can track a patient's status from emergency response.

❸ Wide, robust handle that is easy to grip even with a gloved hand.

❷ Operating mode and energy selection is via a rotary switch that allows quick switching between operating modes (AED, Monitor, Pacer) and energy levels in manual mode. Device turns ON automatically when an operating mode is selected.

❶ Front

General : Big button switches that could accommodate gloved hands. Related switches are logically grouped together with distinct demarcations for ease of use.

Rugged Construction

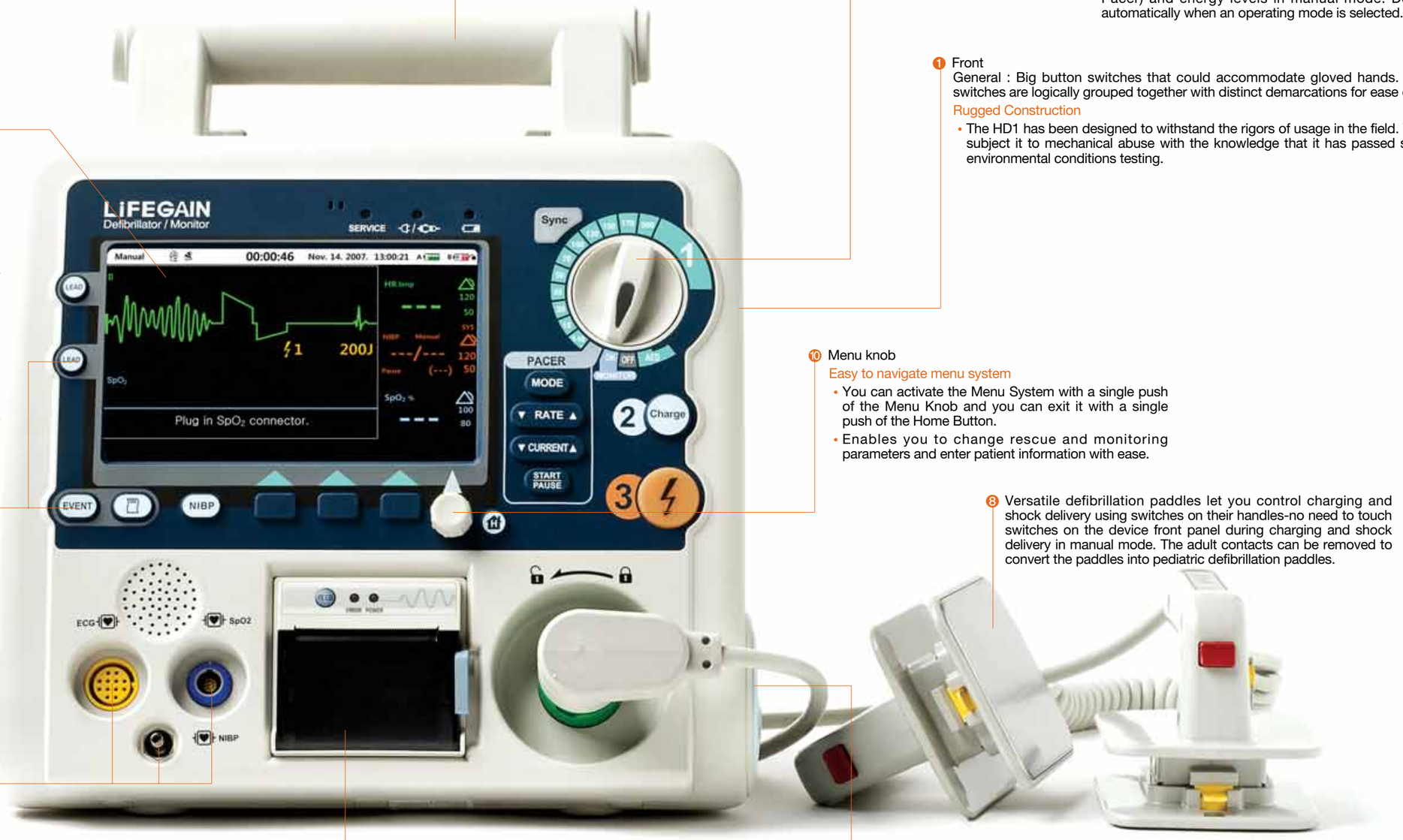
- The HD1 has been designed to withstand the rigors of usage in the field. You can subject it to mechanical abuse with the knowledge that it has passed stringent environmental conditions testing.

❹ Wide full-color liquid crystal display

- Lets you view the following simultaneously
  - all 12 ECG lead or
  - 2 ECG lead or
  - 1 ECG lead and SpO_2 Plethysmograph
- 6 in X 3.6 in
- 800 X 480 pixels, RGB

Screen Layout

- The following display features enable the user to quickly locate information.
  - Heart rate, SpO_2, and NIBP values are shown in large numeric font size.
  - Waveforms (ECG and plethysmograph waveform) are logically grouped and clearly labeled.
  - Alarm status and limits are clearly displayed.
  - Battery pack charge level and AC mains connection icons clearly show power supply status.



❺ Shortcut buttons for often used features such as lead selection, event marking, and printing

- Related buttons and knobs are grouped together that enables the user to locate them quickly during emergency rescues.
- Buttons are big and differentiated that can be easily manipulated even with a gloved hand.
- All monitoring and therapy ports are on the front panel of the device for ease of connection verification by the user.

❻ Therapy and monitoring connectors are located on the front panel for easy connection and verification of connection integrity during rescue operations.

- ECG Cable, SpO_2, NIBP

❼ Integrated printer lets you print the patient's ECG automatically or manually

- Enables you to print ECG strips automatically or manually.
- In automatic printing mode, the printer prints the patient's ECG after a shock is advised.
- In manual printing mode, you may print the patient's ECG anytime during defibrillation or monitoring mode with a push of the Print Button. Strip length may be set from 30 seconds to 2 minutes.

❽ Versatile defibrillation paddles let you control charging and shock delivery using switches on their handles-no need to touch switches on the device front panel during charging and shock delivery in manual mode. The adult contacts can be removed to convert the paddles into pediatric defibrillation paddles.

❾ Versatile power supply system lets you power the HD1 using rechargeable lithium polymer battery pack, mains power, or a vehicle's cigar lighter jack.

Flexible Power Supply System

- The internal power supply system of the HD1 may be supplied from various sources:
  - Rechargeable Lithium Polymer battery pack.
  - AC/DC SMPS module powered by the AC mains.
  - DC power from a vehicle's electrical system through a cigar lighter jack.
- A battery level indicator indicates the charge level of the Lithium Polymer battery pack.
- With the supply flexibility and battery level indicator, you are ensured that the HD1 will be ready for emergencies.

❿ Menu knob

Easy to navigate menu system

- You can activate the Menu System with a single push of the Menu Knob and you can exit it with a single push of the Home Button.
- Enables you to change rescue and monitoring parameters and enter patient information with ease.

THE LiFEGAIN CU-HD1 IS LOADED WITH FEATURES THAT AID YOU IN EFFICIENTLY ADMINISTERING YOUR RESCUES.

SPECIFICATIONS

EXTERIOR VIEW

Dimensions(Paddle included)
326mm(W)×253mm(L)×358mm(H)
(Width×Length×Height)

Weight
Body : 4.7kg / 8.2kg if paddles, cables (ECG Cable, SpO_2 sensor), printer paper and storage device included
Paddle (with cables) : 1.2kg
Battery, AC power module : 0.5kg, 0.7kg respectively

Temperature
Operating & Standby: 0℃ ~ 40℃
Shipping and Storage: -20℃ ~ 60℃
(without pads)

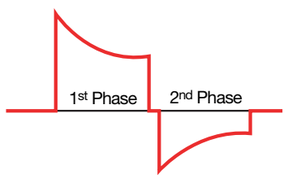
Humidity
Operating: 5% ~ 95% (non condensing)
Standby: 5% ~ 95% (non condensing)
Shipping and Storage 5%~95%
(non condensing)

Solids / Water Resistance
IP43

DEFIBRILLATOR

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 external paddles or disposable defibrillation pads

Patient Impedance Range
25~175 Ohms

MANUAL MODE

Charging Time(200 Joules)
Less than 7sec. : if the rechargeable battery is fully-charged
Less than 6sec. : if an AC power module is used (only when power is more than 90%) Less than 7sec. : If the battery has been discharged 15 times after it had been fully charged.
Less than 7 sec : If a new battery module is fully charged then discharged 15 times

Shock Energy Selection
1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100, 120, 150, 170, 200 Joules

Operation Key and Button
Soft button, LEAD selection button, Print button, NIBP button Rotary switch, Charge button, Shock button, SYNC button, MENU key, HOME button

Indicator & Disply
LCD for ECG display, Power/Error display indicators

Charging Indicator
Text prompts of charge energy
Beep when charging
Shock button flashed in orange

Energy Selection Rotary switch

Patient Impedance Recognition Range
25~175 Ohms

Charge Switch Charge button

Shock Delivery Shock button

SYNC
Use SYNC button for synchronous cardioversion
Shock delivery is within 60 milliseconds of a QRS peak

AED MODE

Charging Time(200 Joules)
Less than 7sec. : if a rechargeable battery is fully-charged
Less than 7sec. : if a new battery module is used
Less than 6sec. : if an AC power module if used (only when power is more that 90%)
Less than 7sec. : If the battery has been discharged 15 times after it had been fully charged
Less than 7 sec : If a new battery module is fully charged then discharged 15 times

AED Energy 200 Joules fixed

Text and Voice Prompt
Guides the user throughout defibrillation and CPR

AED Operation Key and Button
Analyze button, Stop analyze 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 has been finished
Shock button flashes 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

Arrhythmia Detector Algorithm Performance Meets ANSI/AAMI DF80 sensitivity and specificity requirements

PACER MODE

Pacing Type Non-invasive Pacing

Waveform
Monophasic Rectangular

Pacing Mode
Demand mode, Fixed mode

Refractory Period
340 msec (30 to 80 ppm)
240 msec (90 to 180 ppm)

Current Pulse Amplitude
0~200mA (±5mA)

Pulse Width 20ms (±10%)

Pacing Rate 30~180 ppm (±1.5%)

Pacing Transthoracic Impedance Range

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

Demand Mode Analysis
Analyzes the patient ECG to determine whether to deliver pacing energy or not in the Demand mode

ECG MODE

ECG Input
ECG type : 3-Lead, 5-Lead, 12-Lead
Able to see ECG results using LCD or an integrated printer

Lead Fault
Detects when the ECG cable(s) is detached (if the ECG cable is disconnected from the patient or the device)

Heart Rate Display
30~300 bpm (Accuracy : ±3 bpm)

Heart Rate Alarm Setting
Heart rate alarm setting range
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
5mm/mV, 10mm/mV, 20mm/mV
AUTO : 0.3~5.5mV, Display inputted ECG signals as 10mm on the screen

Frequency Range
Emergency : 1~30Hz (-3 dB)
Monitoring : 0.5~40Hz (-3 dB) Diagnosis : 0.05~150Hz (-3 dB) 50Hz, 60Hz Notch filter

Patient Isolation
CF Type

SpO_2 PULSE OXIMERTY

Pulse Rate 20~250 bpm (±3 bpm)

SpO_2 Value 0~100% (±3 digit)

Perfusion 0.2%

SpO_2 Alarm Setting
Minimum: 0~100% (though, it should be set to a value lower than the maximum)
Maximum: 0~100% (though, it should be set to a value higher than the minimum)

Display Update Interval
6sec.

Resolution 1%

NONINVASIVE BLOOD PRESSURE (NIBP) MEASURING DEVICE

Patient Category
Adult, Pediatric, Neonate

Measuring Method Oscillometric

Mode Manual / Auto mode

Time Interval for Auto Mode
1, 3, 5, 10, 15, 30, 60, 120 minutes

Display
Systolic blood pressure / Diastolic blood pressure / Mean blood pressure, Alarm setting

Error Range for Pressure
3mmHg

Measuring Range
Systolic
- Adult : 40~260mmHg
- Pediatric : 40~160mmHg
- Neonate : 20~130mmHg

Diastolic
- Adult : 20~200mmHg
- Pediatric : 20~120mmHg
- Neonate : 20~100mmHg

Overpressure Limit
Adult : 300mmHg
Pediatric : 300mmHg
Neonate : 150mmHg

CUFF & CONNECTION TUBE

Cuff Type
Adult : 23~33 cm (corresponding to the adult patient category)
Child : 12~19 cm (corresponding to the pediatric patient category)
Infant : 8~13 cm (corresponding to the neonate patient category)

Connection Tube
Material : Polyurethane
Length : Approx. 3m

DISPLAY

Type TFT Color LCD

Screen Size 152.4(W)×91.44(H)mm

Resolution 800×480×3(RGB)pixels

Dot Pitch 0.0635(W)×0.1905(H)mm

Backlight LED Life Time
20,000 hours (time when brightness Is reduced to 50%)

ECG Viewing Time 6sec.

EVENT STORAGE

External Storage SD Card (if 1GB)
Store more than 192 hours of events and ECG date
Or, store more than 8 hours of events, ECG data and Voce date

ECG Data Print
Output ECG directly from LiFEGAIN CU-HD1 or output ECG data by transferring it through Bluetooth communication

INTEGRATED PRINTER

Printer Method Thermal line printing

Resolution
203 dpix406 dpi (dpi : dot per inch2)

Printer Width 50mm

Printer Rate 25mm/sec

Feed Rate About 62.5mm/second

PRINTER PAPER

Type Roll type

Size
Width : 58mm
Roll size : Minimum diameter 40mm

BLUETOOTH

Frequency Range
2.402GHz~2.480GHz

Send Output Max. +4 dBm

Receive Sensitivity
-80 dBm (0.1% BER)

Communication Distance
Within 30m (Based on open space)

Miscellaneous
Transmission Method : Frequency Hopping Spread Spectrum (FHSS)
Modulation Method : Gaussian-filtered Frequency Shift Keying (GFSK)

BATTERY MODE

Battery Type Lithium Polymer

Size
170mm×116mm×51mm
(Width×Length×Height)

Weight 0.5kg or below

Output
14.8 VDC
3100 mAh

Capacity
100 shocks (based on 200 Joules) or at least 4 hours of patient monitoring (25℃)

Battery Capacity Check Level 5

AC POWER MODULE

Input 100~240 VAC, 50~60Hz

Output
18 VDC, 5 A
12 VDC, 0.5 A

Size
170mm×116mm×60mm
(Width×Length×Height)

Weight 0.7kg or below

CAR CIGAR LIGHTER JACK

Output 12 VDC, 6.3 A (Max.)

Length 1800 ±50mm

Weight 0.08kg or less