

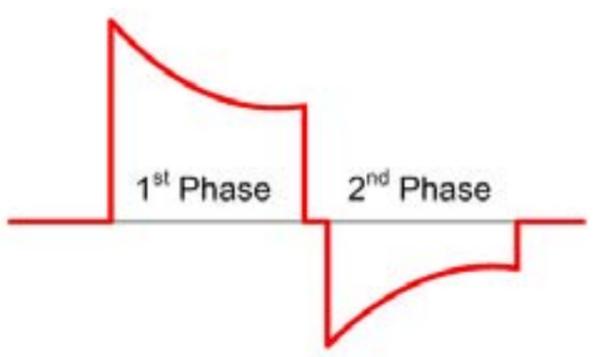
### 13. Product Specifications

This chapter shows you the specifications of LIFEGAIN CU-HD1. This chapter describes specifications in relation to the exterior view, defibrillation, ECG, SpO<sub>2</sub>, battery/charging function, communication, and data storage.

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

Exterior View	
Dimensions (Paddle included)	326mm (W) x 253mm (L) x 358mm (H) (Width xLength xHeight)
Weight	Body: 4.7kg or below / 8.2kg or below if paddles, cables (ECG cable, SpO <sub>2</sub> sensor), print paper, and storage device included. Paddle (with cables): 1.2kg or below. Battery, AC power module: 0.5kg, 0.7kg respectively.

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	76%
NON SHOCKABLE	Normal Sinus Rhythm	100 minimum (arbitrary)	> 99% specificity	100	0	100	100% (100/100) specificity	97%
	AF,SB,SVT, heart block, idioventricular 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%

Defibrillation Feature	
Operation Mode	<ul style="list-style-type: none"> <li>Semi-automatic</li> <li>Manual : Sync, Asynchronous Defibrillation</li> </ul>
Output Waveform (Manual / Automatic)	 <p><i>e-cube</i> biphasic (Truncated exponential type)</p> <p>※ Parameters of waveforms are adjusted according to the patient's impedance.</p>
Shock Delivery	Delivers shock using paddles or internal paddles, disposable defibrillation pads.
Defibrillation Shock Impedance Range	25 ~ 175 Ohms

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 %

Manual Mode	
Charging Time (200 Joules)	<ul style="list-style-type: none"> <li>• Less than 7 sec. : If a rechargeable battery is fully-charged.</li> <li>• Less than 6 sec. : If an AC power module is used (only when power is more than 90%).</li> <li>• Less than 7 sec. : If the battery has been discharged more than 15 times after it had been fully charged.</li> <li>• Less than 7 sec.: If the battery has been discharged more than 15 times after the battery module had been replaced.</li> </ul>
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, Rotary switch, Charge button, Shock button, SYNC button, MENU key, HOME button
Indicator	LCD for ECG display, Power/Error display indicators
Charging Indicator	<ul style="list-style-type: none"> <li>• Text prompts of Charge Energy</li> <li>• Beep when charging</li> <li>• Shock button flashes in orange</li> </ul>
Energy Selection	Rotary Switch
Defibrillation Shock Impedance Range	<ul style="list-style-type: none"> <li>• 25~175 Ohms</li> </ul>
Charge Manipulation	Charge button
Shock Delivery	Shock button
SYNC	<ul style="list-style-type: none"> <li>• Use SYNC button for synchronous cardioversion.</li> <li>• Analyze the patient's ECG signals and synchronize R-wave of QRS in ECG with shock delivery within 60ms.</li> </ul>

AED Mode	
Charging Time (200 Joules)	<ul style="list-style-type: none"> <li>• Less than 7 sec. : If the battery is full-charged.</li> <li>• Less than 7 sec. : If a new battery module is used.</li> <li>• Less than 6 sec. : If an AC power module is used (only when power is more than 90%).</li> <li>• Less than 7 sec. : If the battery has been discharged more than 15 times after it had been fully charged.</li> <li>• Less than 7 sec. : If the battery has been discharged more than 15 times after the battery module had been replaced.</li> </ul>
AED Energy	200 Joules fixed
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	<ul style="list-style-type: none"> <li>• Progress bar of the amount of energy charged and text prompts</li> <li>• Beep when charging has been finished</li> <li>• Shock button flashes in orange</li> </ul>
Patient Analysis	<ul style="list-style-type: none"> <li>• Analyzes the patient's ECG to determine whether defibrillation is needed or not. (When the automatic patient analysis feature is enabled)</li> </ul>
Defibrillation-needed rhythm	Ventricular Fibrillation or Fast Ventricular Tachycardia, 150bpm or above
Algorithm Sensitivity and Specification That Require Defibrillation	AHA 2005 guideline is met.

Pacer Mode	
Pacing Type	Non-invasive Pacing
Energy Waveform	Monophasic Rectangular
Pacing Mode	Demand mode, Fixed mode
Energy Magnitude	5 ~200 mA ( $\pm 5$ mA)
Pulse Width	20ms ( $\pm 10\%$ )
Pacing Rate	30 ~ 180 ppm ( $\pm 1.5\%$ )
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
Demand Mode Analysis	Analyzes the patient ECG to determine whether to deliver pacing energy or not in the Demand mode.

ECG Monitoring Mode	
ECG Input	<ul style="list-style-type: none"> <li>ECG type: 3-Lead, 5-Lead, 12-Lead</li> <li>Able to see ECG results using LCD or an external printer.</li> </ul>
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 : $\pm 3$ bpm)
Heart rate Alarm Setting	<ul style="list-style-type: none"> <li>Heart rate alarm setting range</li> <li>Minimum: 30~300 bpm (though, it should be set to a value lower than the maximum)</li> <li>Maximum: 30~300 bpm (though, it should be set to a value higher than the minimum)</li> </ul>
ECG Size	<ul style="list-style-type: none"> <li>5 mm/mV, 10 mm/mV, 20 mm/mV</li> <li>AUTO : 0.3 ~ 5.5 mV, Display inputted ECG signals as 10mm on the screen.</li> </ul>
Frequency Range	<ul style="list-style-type: none"> <li>Emergency : 1 ~ 30 Hz (-3 dB)</li> <li>Monitoring: 0.5 ~ 40 Hz (-3 dB)</li> <li>Diagnosis : 0.05 ~ 150 Hz (-3 dB)</li> <li>50Hz, 60Hz Notch Filter</li> </ul>
Patient Isolation (Defibrillation Check)	CF Type

SpO <sub>2</sub> Pulse Oximetry	
Pulse rate	20 ~ 250 bpm (±3 bpm)
SpO <sub>2</sub> Measurement Range:	1 ~ 100%
SpO <sub>2</sub> Accuracy	80 ~ 100% (±3 digit)
Perfusion	0.2%
SpO <sub>2</sub> Alarm Setting	<ul style="list-style-type: none"> <li>• Minimum: 1% ~ 100% (though, it should be set to a value lower than the maximum)</li> <li>• Maximum: 1% ~ 100% (though, it should be set to a value higher than the minimum)</li> </ul>
Display Update Interval	6 sec.
Resolution	1%
SpO <sub>2</sub> Sensor: Nellcor Sensor (DS100A Sensor)	
Sensor Light	660 nm(Red), 890 nm(Infrared)
Power Consumption	15mW or below

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	3 mmHg
Measuring Range	Systolic - Adult: 40 ~ 260 mmHg - Pediatric: 40 ~ 160 mmHg - Neonate: 20 ~ 130 mmHg Diastolic - Adult: 20 ~ 200 mmHg - Pediatric: 20 ~ 120 mmHg - Neonate: 20 ~ 100 mmHg
Overpressure Limit	Adult: 300 mmHg Pediatric: 300 mmHg Neonate: 150 mmHg
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. 3 m

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	20,000 hours (time when brightness is reduced to 50%)
ECG Viewing Time	6 sec.

Event Storage	
External Storage SD Card(if 1GB)	Store more than 192 hours of events and ECG data. Or, store more than 8 hours of events, ECG data, and voice data
ECG Data Print	Output ECG directly from LIFEGAIN CU-HD1 or output ECG data by transferring it through Bluetooth communication.

**Internal Printer**

Print Method	Thermal line printing
Resolution	203dpi X 406dpi (dpi: dot per inch <sup>2</sup> )
Print Width	48mm
Print Rate	25mm/sec
Feed Rate	About 62.5mm/second
Input Power	7.2V 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 papers)

**Printer paper**

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

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

Battery Module	
Battery Type	Lithium Polymer
Size	170mm X 116mm X 51mm (Width X Length X Height)
Weight	0.5kg or below
Output	14.8 VDC 3100 mAh
Capacity	100 shocks(based on 150Joules) or at least 4 hours of patient monitoring (25° C)
Charging Time	About 5 hours
Battery Capacity Check	Level 5
Operation Temperature	Charge: 0° C ~ 40° C Discharge: -20° C ~ 60° C Humidity: 90%, Non-condensing
Storage Temperature	-20° C ~ 45° C Humidity: 90% or below, Non-condensing

AC Power Module	
Input	100 ~ 240 VAC, 50 ~ 60 Hz
Output	18 VDC, 5 A 12 VDC, 0.5 A
Size	170mm X 116mm X 60mm (Width X Length X Height)
Weight	0.7kg or below
Operation Temperature	-20° C ~ 40° C Humidity: 90% or below, Non-condensing
Storage Temperature	-20° C ~ 60° C Humidity: 90% or below, Non-condensing

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

AC Power Adapter	
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% or below, Non-condensing
Storage Temperature	-20° C ~ 60° C Humidity: 90% or below, Non-condensing