

CPR Real-time Feedback Solution

New Solution to CPR

Products Introduction

 **CREDO**



What is CPR?

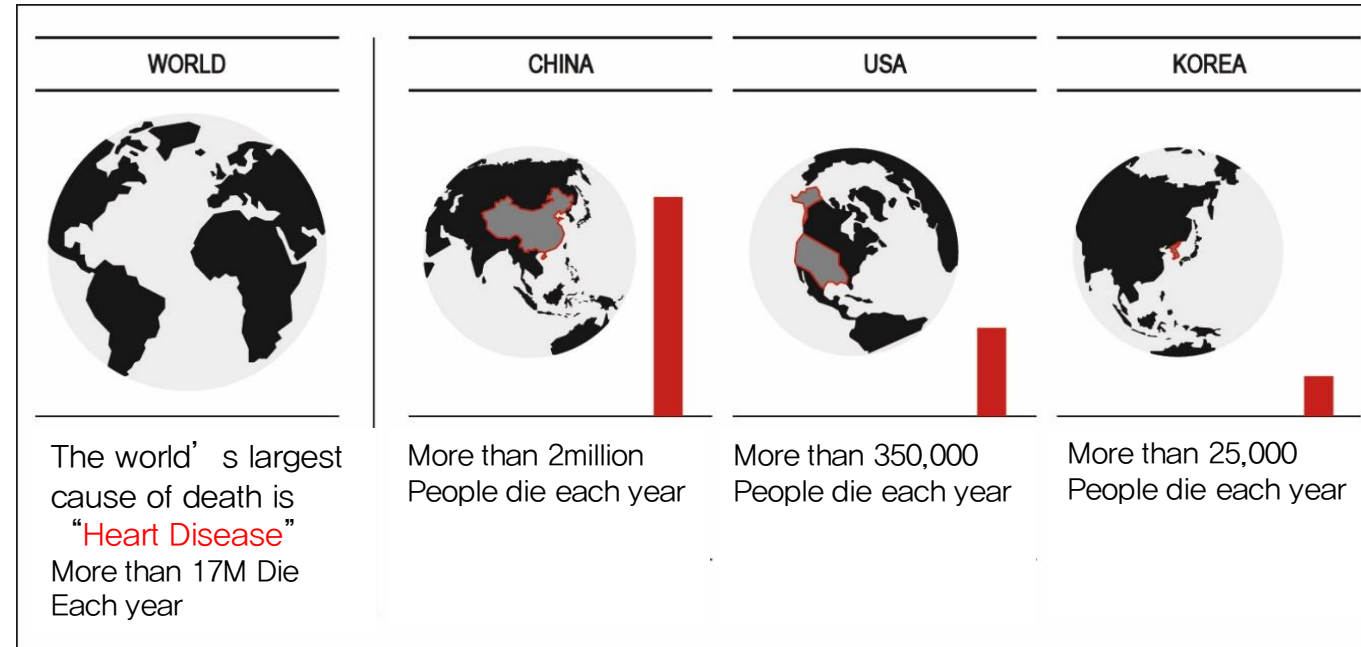
Cardio Pulmonary Resuscitation



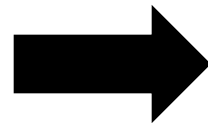
Compressing the chest of a heart attack patient 100 times per minute, 5~6cm

It is a principle to do until the patient is revived, but it is impossible to maintain accurate CPR due to the limitation of human physical stamina

Necessity of CPR



Meat-based diet
Lack of Exercise
Population aging

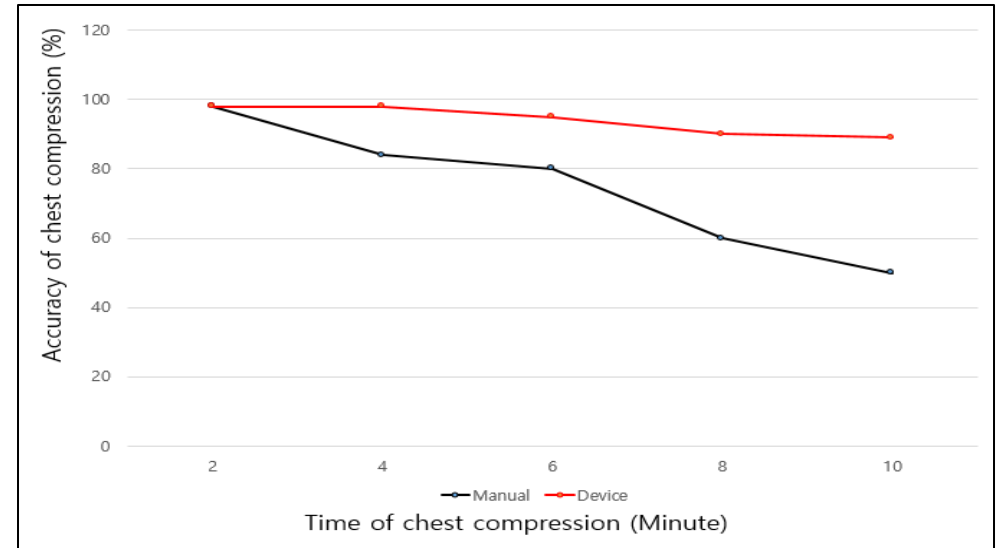
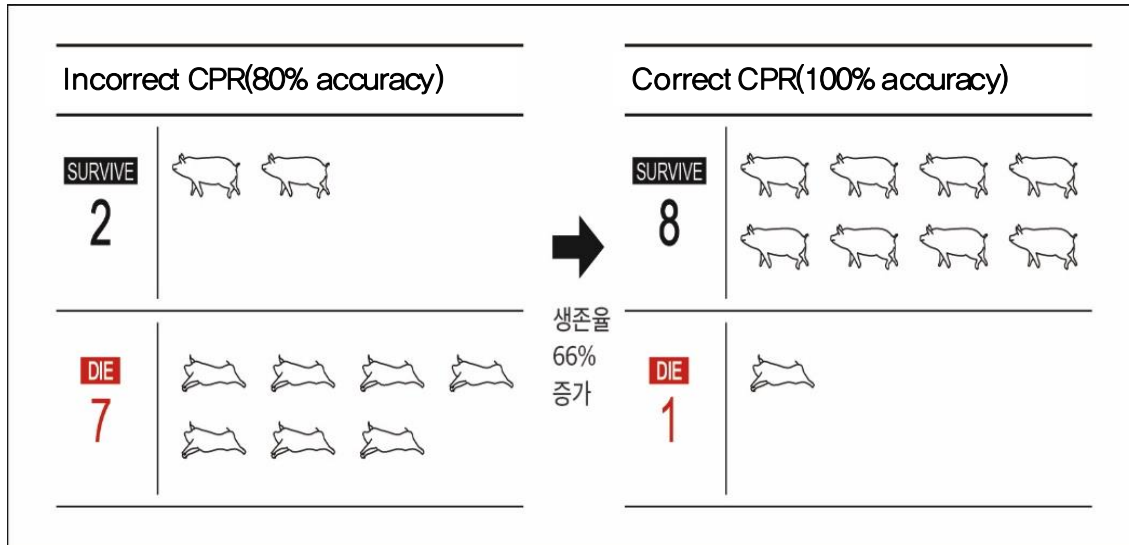


Increase of
Cardiac arrest
patients

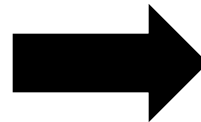


Related market growth
– CPR training
– Emergency Budget

Importance of CPR & Needs of CPR Assistance Device



Accurate CPR

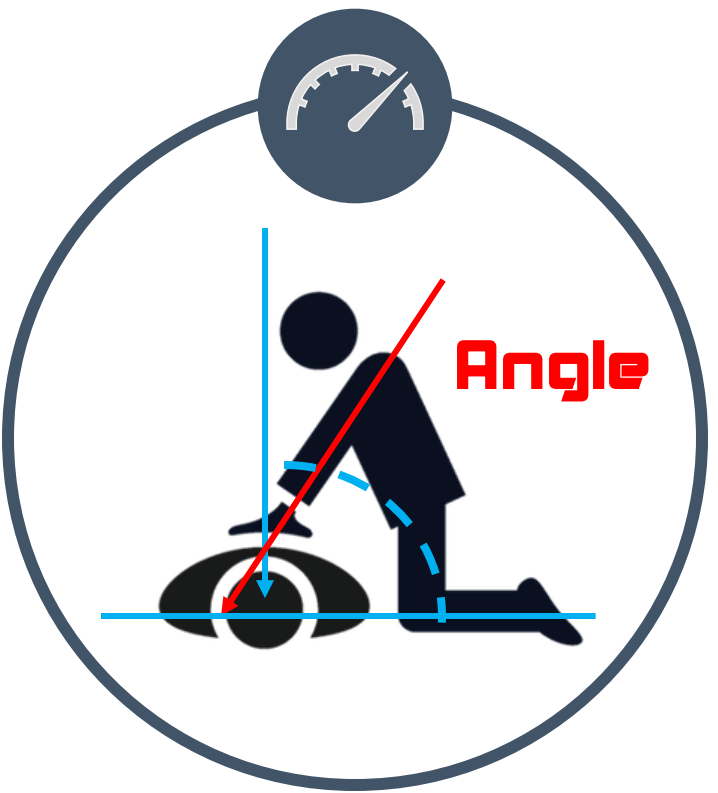


Increased survival rate of cardiac arrest patients

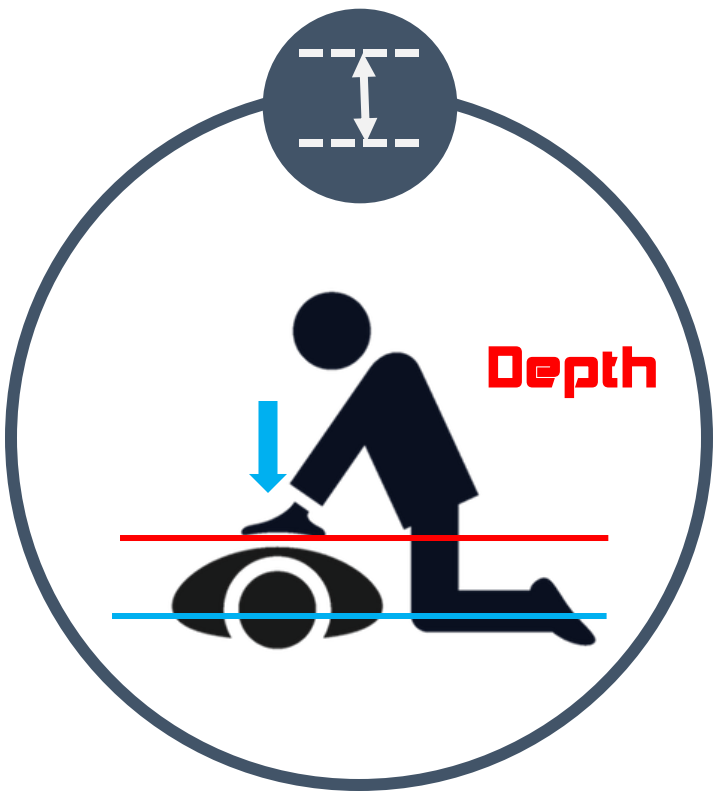
CPR Expert need CPR assistant device
It is impossible for a person to sustain accurate CPR

Difficulty

When you do CPR



Angle



Depth



Rhythm

LED
Feedback the pressure
range of the normal range
by the indicator

Buzzer

Buzzer inside guides
chest compression rhythm

Angle

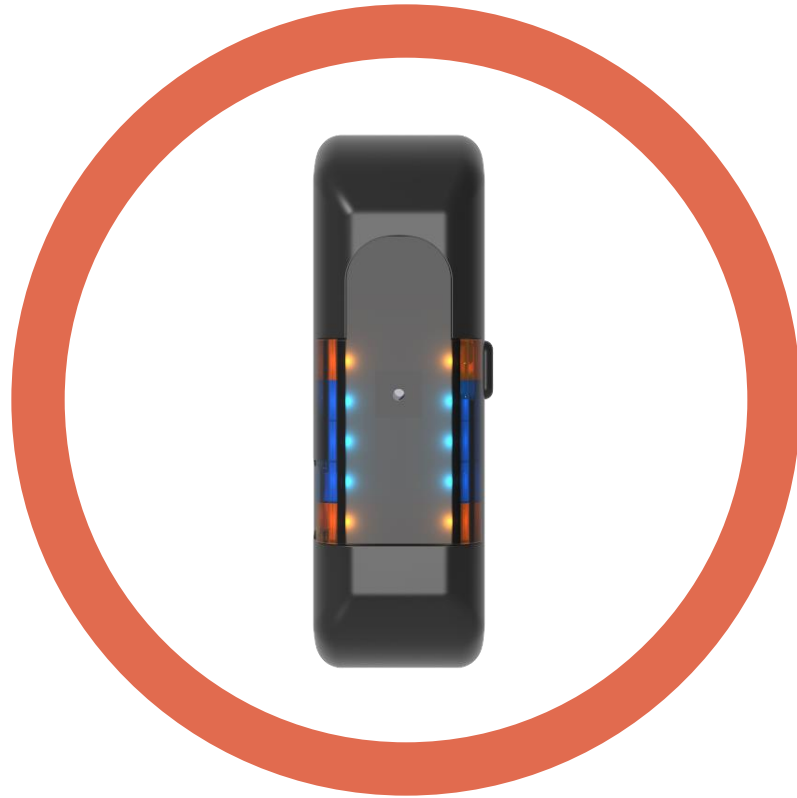
Feedback the right angle
chest compression by the
application.

What is CPRBAND?

New Solution to CPR

Products Introduction

 **CREDO**



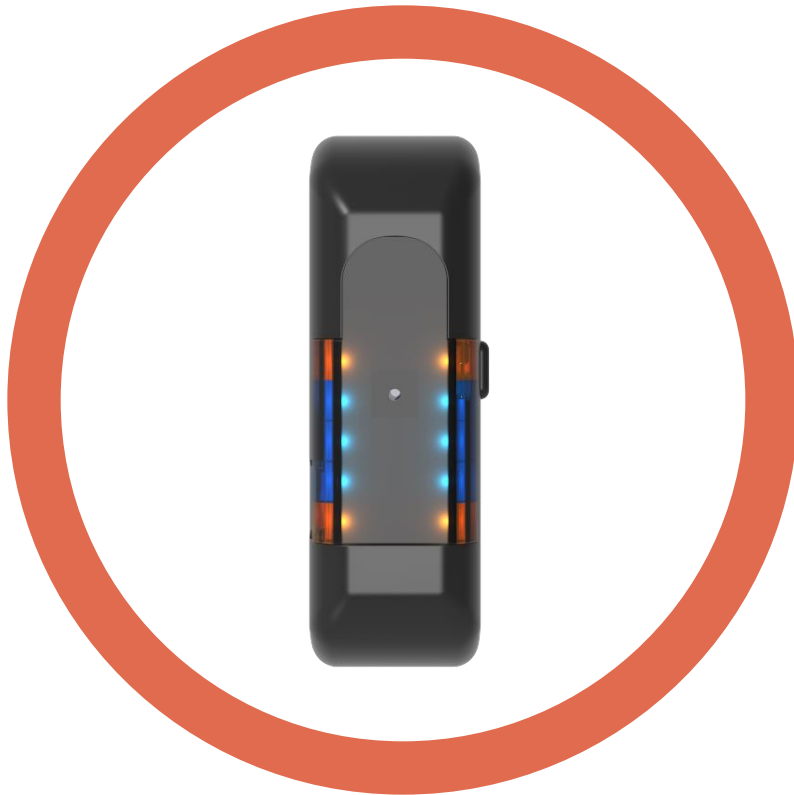
CPR Training Device
– For Manikin
– RF Certification(FCC)



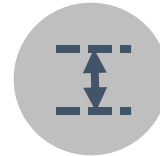
CPR Assistant Device
– For Real Human
– Medical Certification(CE_MDR)

Main Function

CPR Education Product
'CPRBAND for Training'



Compression **Angle** Measurement
Given information corrects CPR posture

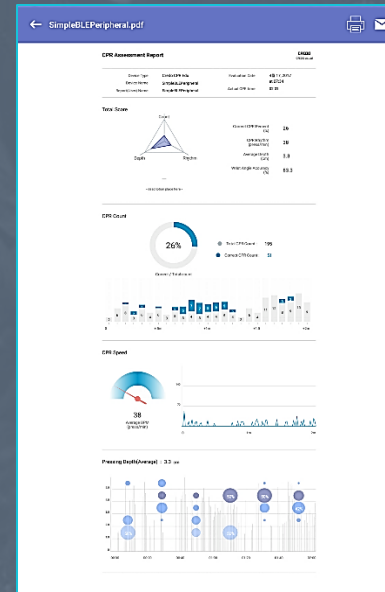
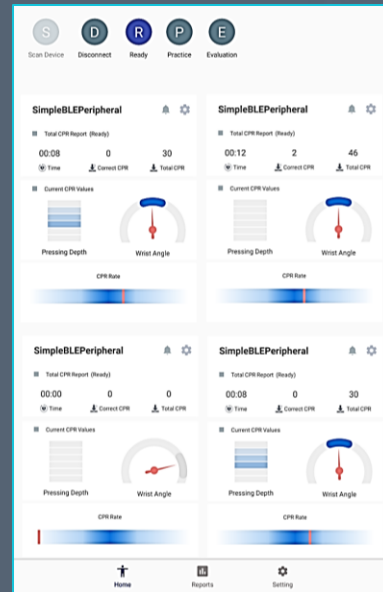
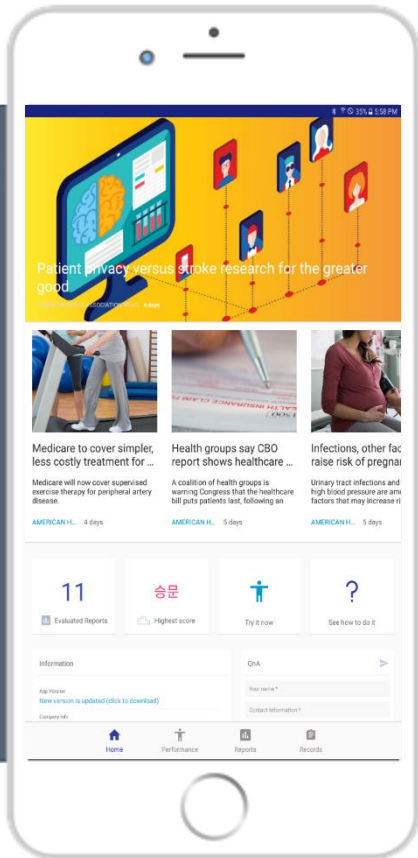


Compression **Depth** Feedback
LED indicate depth in real time



Compression **Rhythm** Guide
The buzzer sounds the appropriate chest compression

APPLICATION



CPR report

- CPR time
- Chest Compression depth
- Chest Compression rate
- Chest Compression axis
- Chest Compression graph
- Report transmission function



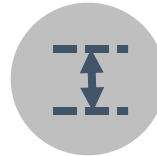
Main Function

Professional CPR Training Device
'CPRBAND for Training All in One'



Compression **Angle** Measurement

Given information corrects CPR posture



Compression **Depth** Feedback

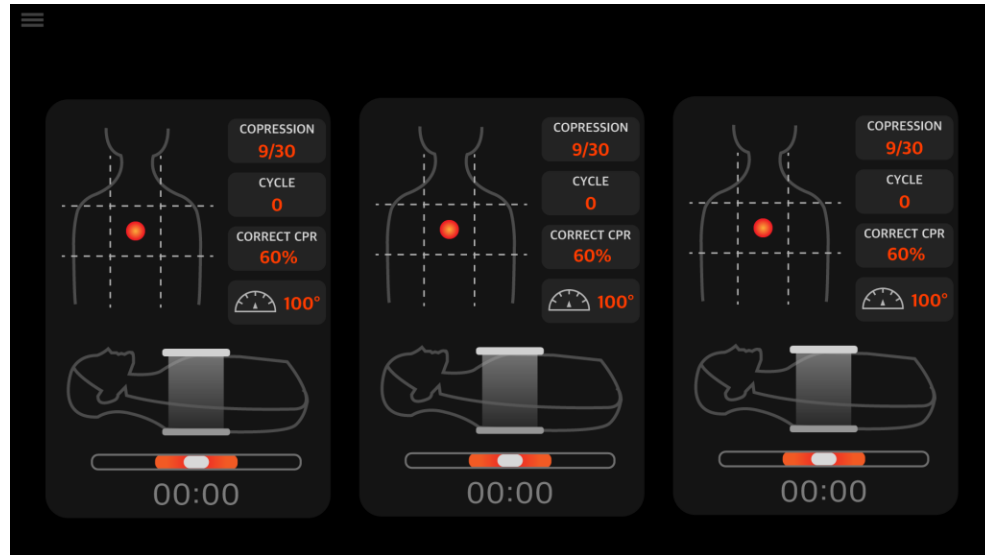
LED indicate depth in real time



Compression **Rhythm** Guide

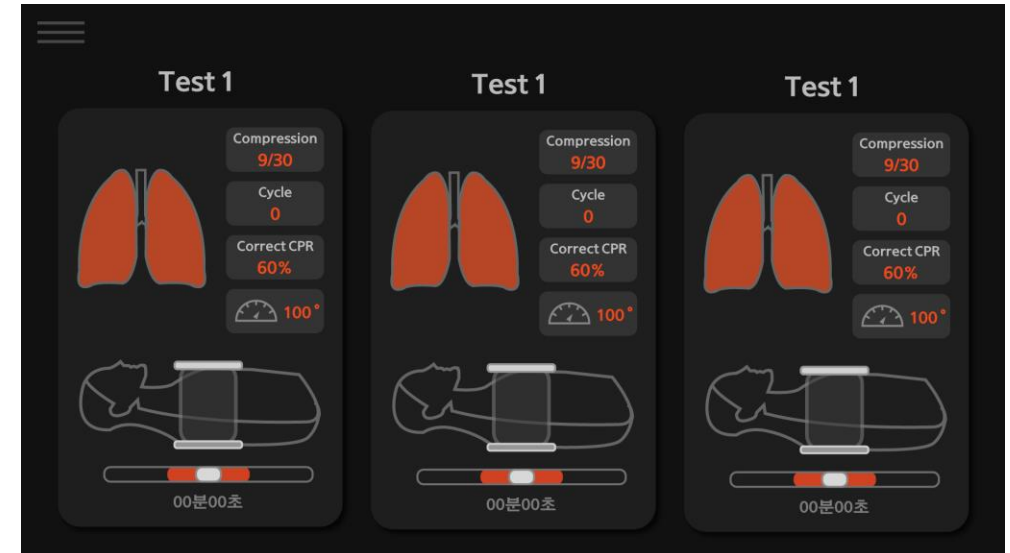
The buzzer sounds the appropriate chest compression

CPR Training Device – CBT AIO



Chest Compression

- Location
- Depth
- Angle
- Rhythm
- Release
- Hand-off Time
- Time



Respiration

- Insufficient Volume
- Correct Volume
- Over Volume



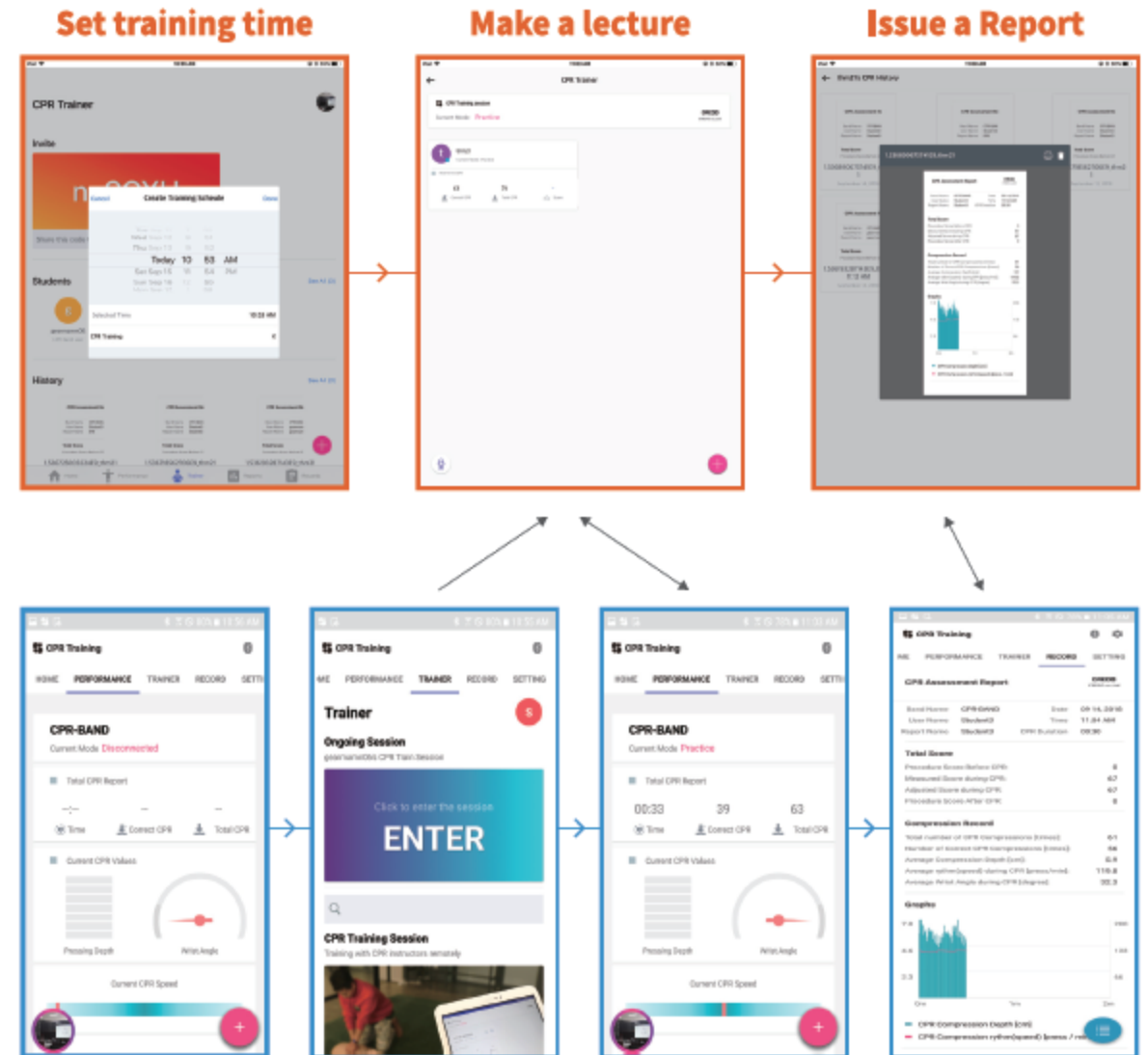
Distance Education

Trainer Application

- Instructor-specific code issuance
- Set lecture time
- Open a remote lecture
- Concurrent access to **more than 20 students**
- Practice and evaluation
- Online Feedback(Voice, Text)
- Collect and publish student report
- **Simultaneous training anywhere in the World**

Trainee Application

- Increased stability with 1 by 1 connection
- Educational Alarms with Instructor follow
- CPR Feedback through reports



CPR Band Connect and lecture Enter

Specification

Module

- Dimension: 45x19x8 mm
- Weight: 11.0g
- Battery: 100mAh
- Operating condition
- Temperature: 0~40°C
- Humidity: 0~95%
- Atmospheric pressure: 1,014~617 mbar

Band

- Dimension: 247x15x9 mm
- Weight: 20.4g



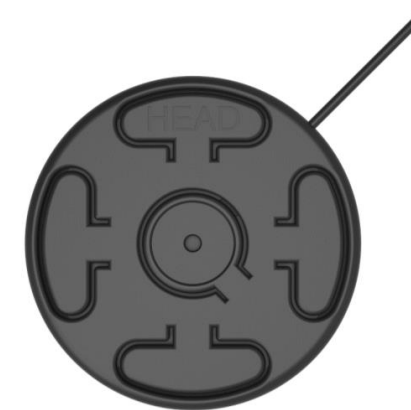
Specification

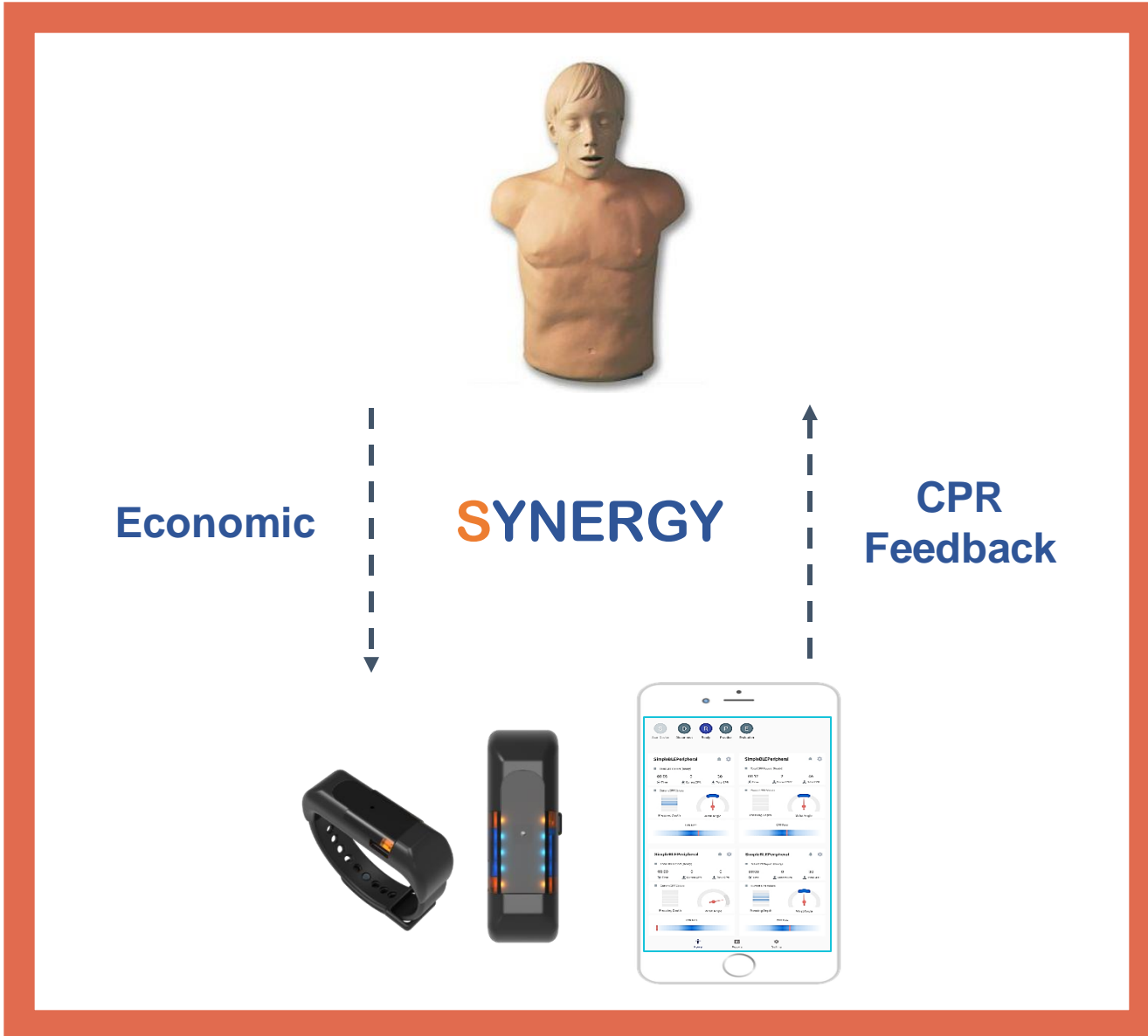
○ AIO Module

- Dimension : 68x66x52 mm
- Weight: 67.7g
- Battery: AAA x 4EA
- Operating Condition
- Temperature: -18~55°C
- Humidity: 0~95%
- Atmosphere Pressure: 1,014~617 mbar

○ AIO Pad

- Dimension: 110x110x9.2 mm
- Weight: 42g





Compatibility

CPRBAND can improve the quality of education in any mannequin.

This means that you do not have to replace your existing CPR mannequin.

Any compressible object other than mannequin can be used.

The advantage of wearing on the wrist.



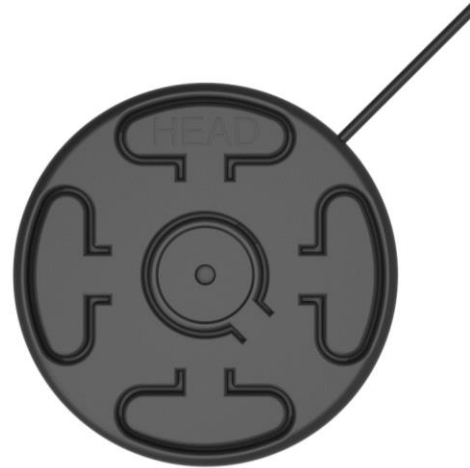
Chest Compression Axis

It is the only product that accurately measures the chest pressure angle.

It can now make more accurate CPR training.

It can check the flexion of the elbow as well as the compression axis.

It can see the overall accuracy of CPR postures.



Remote Education

Free support for distance education and training systems with video conferencing

There is no longer any need to train trainees in one place

You can receive real-time training and feedback from experts wherever CREDO's equipment is installed

Basic set






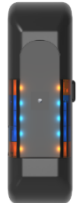
- 1 CPRBAND for Training
- 1 Charging Cable
- 1 Manual

Premium set

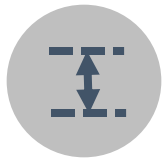


- 6 CPRBAND for Training
- 1 Charging Bag
- 1 Manual

Comparison Table

Product Picture					
Product Name	QCPR Resusci Anne	Brayden Pro	HeartiSense	CPRBAND for Training	
Manufacture	Laerdal	Innosonian	I.M.LAB	CREDO	
Using Existed Manikin	X	X	O	O	
Function Difference	Display Compression Level	X	O	X	O
	Rhythm Alarm	O	O	O	O
	Axis Checking	X	X	X	O
	CPR Report	O	O	O	O
	Connecting Quantity	1~6	1~6	1~6	1~50
	Ventilation Check	O	O	O	X
	S/W Accessibility	Separate Purchase	Free	Partial paid	Free
사용 센서	Infrared, Compression	Infrared, Compression	Compression	Acceleration, Gyro	
가격	5,500 USD	900 USD	300 USD	200 USD	

CPR Assistant Device – CPRBAND



Compression Depth Feedback
LED provide depth accuracy in real time



Compression Rhythm Guide
Buzzer provide correct tempo guide



Compression Axis Check
Provide quantitative posture
Information by Blue-tooth

LED

Feedback the pressure
range by the LED indicator



Buzzer

Buzzer inside guides
chest compression rhythm

Angle

Feedback the right angle
chest compression by the
application.

**ALL IN ONE!
CPRBAND**

CPR Assistant Device – CPRBAND

APPLICATION



CPR report

- CPR time
- Chest Compression depth
- Chest Compression rate
- Chest Compression axis
- Chest Compression graph
- Report transmission function

Other Function

- Time
- Pedometer
- Calorie burned check
- Movement distance measurement
- Check the drug injection time

Specification

Module





- Dimension: 45x19x8 mm
- Weight: 11.0g
- Battery: 100mAh
- Operating condition
- Temperature: 0~40°C
- Humidity: 0~95%
- Atmospheric pressure: 1,014~617 mbar

Band

- Dimension: 247x15x9 mm
- Weight: 20.4g



Comparison with similar medical device

Product Picture					
Model Name		CPRmeter2	CPR-1100	CPRBAND	
Manufacturer		Laerdal(Norway)	Nihon Kohden(Japan)	CREDO(Republic of Korea)	
Medical Device(For Human)		○	○	○	
Functional Difference	Compression Depth	○	X	○	
	Rhythm Guide	○	X	○	
	Compression Axis	X	X	○	
	CPR Data Save	○ (SD card)	○ (Use with Defibrillator)	○	
	Reusable Battery	X	X	○	
	Independent Indicator	○	○	○	
	Wireless Communication	○	X	○	
Sensor		Acceleration, Compression	Acceleration, Compression	Acceleration, Gyro	
How to Use		Put it on the patient's chest and press it		Worn on the wrist and use it	
Consumer Price		695 USD	660 USD	650 USD	

IP

Patent

- KOR: Registration(2건) Application(4건)
- USA: Application
- EUR: Application
- CHN: Application
- JPN: To be applied

Trademark(CPRBAND)

- KOR: Registration
- USA: Registration
- EUR: Application
- CHN: Registration
- JPN: Registration

Certification

CPRBAND for Training

- KOR: KC complete
- USA: FCC complete
- EUR: CE complete
- CAN: IC complete
- JPN: JPMIC complete



CPRBAND

- KOR: MFDS(Class 2)
- USA: FDA 510k(Class II)
- EUR: CE MDR(Class I)
- Quality: GMP, ISO 13485
- Environment: RoHS
- Safety: IEC 60601





March 6, 2021

Credo
% Dongha Lee
Regulatory Affairs Consultant
KMC, Inc.
Room no. 904, 27, Digital-ro 27ga-gil, Guro-gu
Seoul, 08375
Republic of Korea

Re: K201581
Trade/Device Name: CPR Band
Regulation Number: 21 CFR 870.5210
Regulation Name: Cardiopulmonary Resuscitation (CPR) Aid
Regulatory Class: Class II
Product Code: LIX
Dated: June 8, 2020
Received: June 11, 2020

Dear Dongha Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

EU DECLARATION OF CONFORMITY

Manufacturer:

CREDO
#302, 86, Baeul-ro, Wonju-si, Gangwon-do, Republic of Korea

EU Representative:

KTR EUROPE GMBH
Mergenthalerallee 77, 65760
Frankfurt/ Eschborn, Germany

- **Product Name:** Cardiopulmonary Resuscitation Assistance Product
- **Brand Name:** CPR BAND
- **Model:** CREDO-CB, CREDO-CB-MO
- **GMDN Code:** 60368
- **SRN:** (After the number is issued through EUDAMED, it will be prepared)
- **Basic UDI-DI:** 88000672CREDOCBFK
- **Classification:** Class I (According to Rule 4 of (EU)2017/745, Annex VIII)
- **Reference to Technical Documentation:** CREDO-CB-000 (Rev.0)
- **Reference Standard (Including CS):** See the next pages (Appendix I)

We hereby declare that the device is in conformity with the (EU) 2017/745 and with any other relevant union legislation that provides for the issuing of an EU declaration of conformity. The device has been designed and manufactured under a quality management system according to Annex IX (excluding chapter 2 and 3) of (EU) 2017/745.



The above mentioned declaration of conformity is issued under the sole responsibility of CREDO.

Gangwon-do, Korea 2020-04-28
Place, date

Name Jongkuk, Choi
Legally binding signature, Function



CPR Market

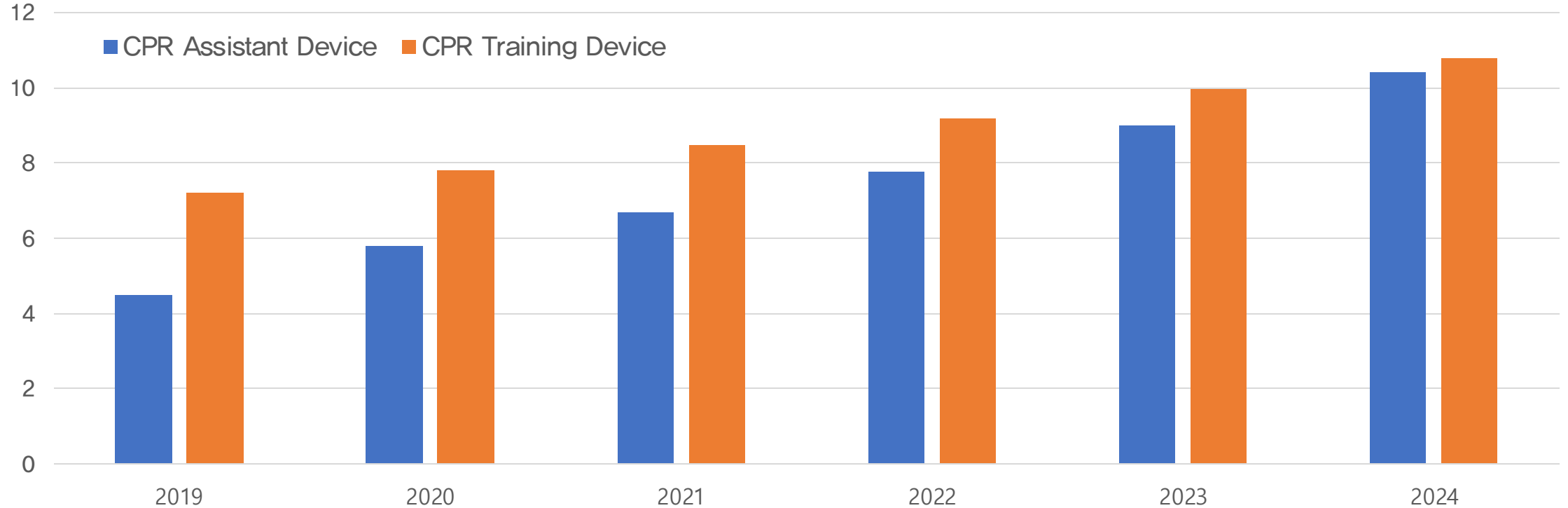
New Solution to CPR

Product Introduction

 **CREDO**

World wide CPR Market Size

Unit: Billion USD



Automatic Electronic Defibrillator Market(CPR Assistant Device)
4.47 Billion USD
Now, KOR 35k, USA 2.4m Supply
15.8% annual growth until 2025
Reference: Transparency Research Market

CPR Training Market Size
7.2 Billion USD
8.43% annual growth until 2022
Reference: TechNavio

Business Model

CPR Training Device



Fire Department



School, University

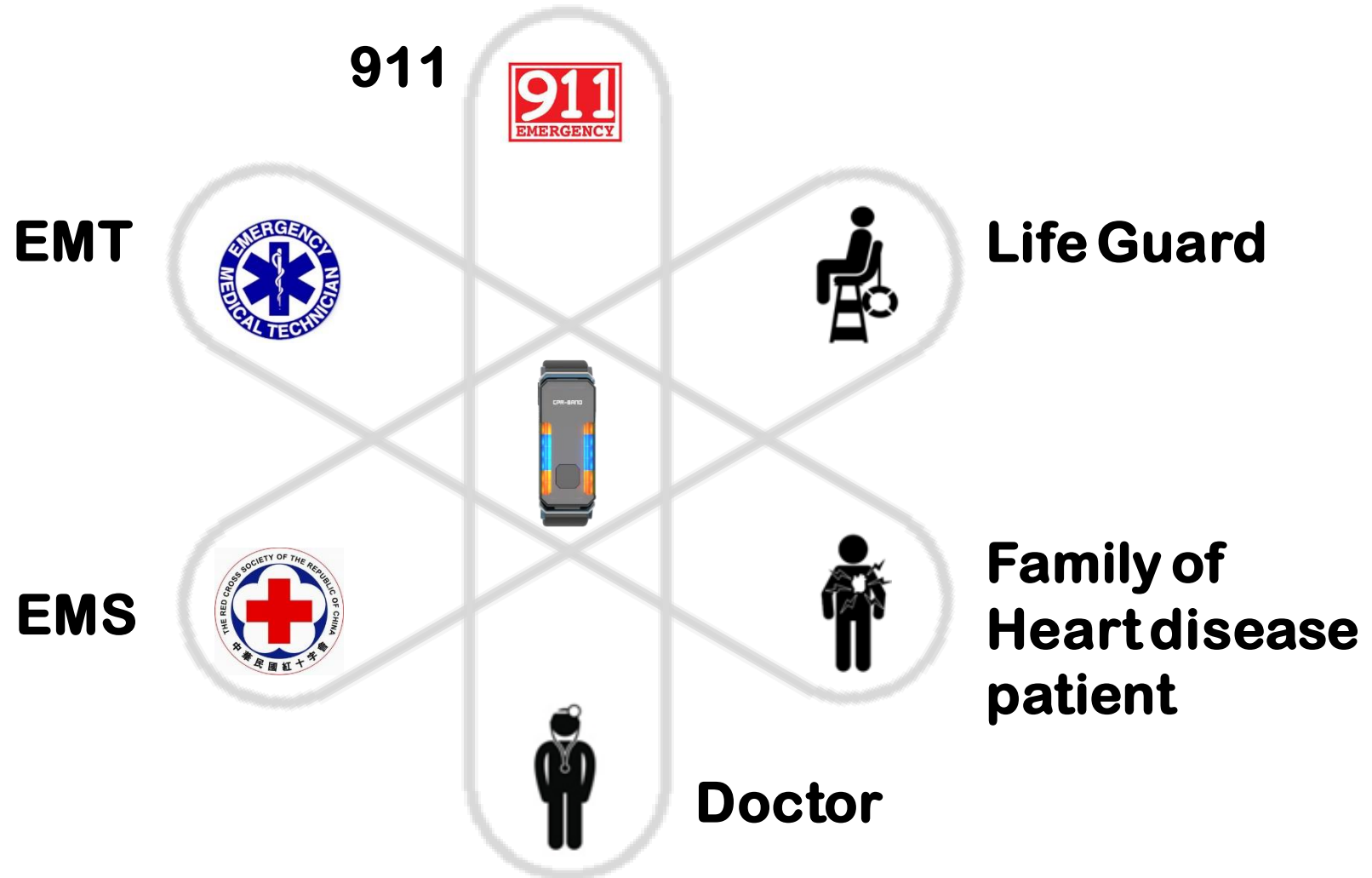


Training Center

Overseas Distributor

- US, Australia, Italy, Ireland, Indonesia, Singapore, Germany, Thailand

Sales Market



CPR Trend of Emergency Academy(ICEM 2019)



Philips



Zoll



Nihon Kohden

- : CPR Feedback Device
- : AED or Defibrillator



- Chest Compression is more important than Ventilation
- Non-expert do not ventilation Only Chest Compression
- CPR feedback device is mandatory at adult CPR education at 2019(AHA).

CPRBAND is the most focused product
On Chest Compression



Next Item

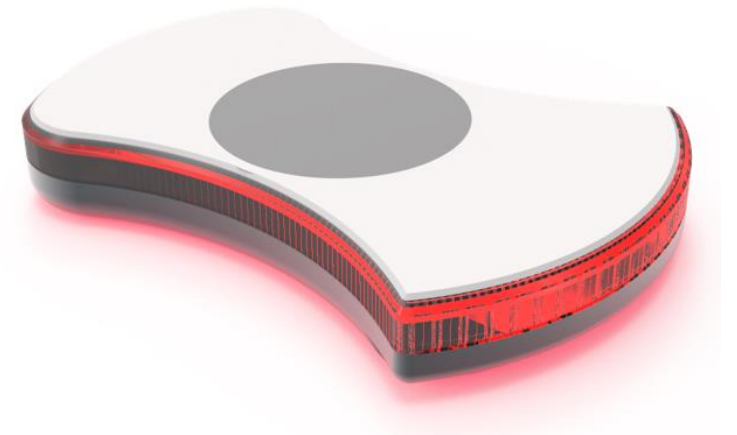
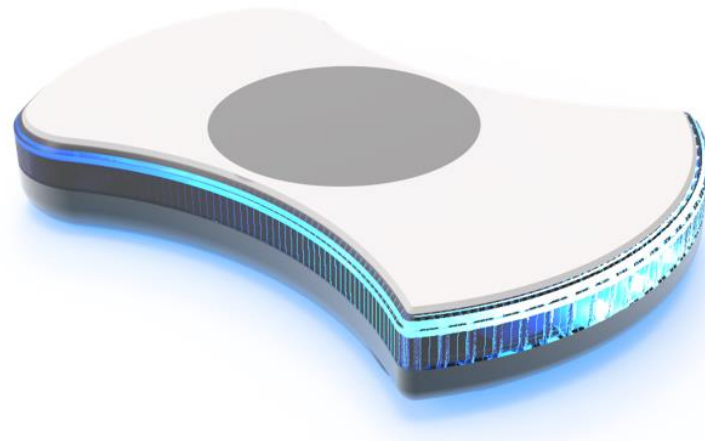
New Solution to **CPR**

Product Introduction

 **CREDO**

CPR Feedback Device – CPRPAD

- CREDO have technology of Small and accurate CPR Feedback device
- Can provide various methods(Ex. OEM)
- Can make various product(Reusable, Disposable)
- Can make various function(for Training, for Assistance)
- Can provide various communication(Wire, Wireless)



Sometimes, We have to be 'HERO' for our loved ones.
CPRBAND will help you.



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