

3Q. 2024 Results

VUNO Inc. / Global Leader in Healthcare AI

VUNO®

VUNO® VUNO Med®
Registered in R.O.K. & U.S. Patent and Trademark Office

Disclaimer

This material has been prepared for the purpose of providing investors with information on VUNO's business prospects, management objectives, and business strategy, and is prohibited from being taken out, copied, or redistributed to others.

Please note that the forward-looking statements contained in this document relates to future events, not the past, and is inherently subject to uncertainty, and may not correspond to the company's actual operating results due to uncertainties such as changes in the market environment and risks beyond the company's control.

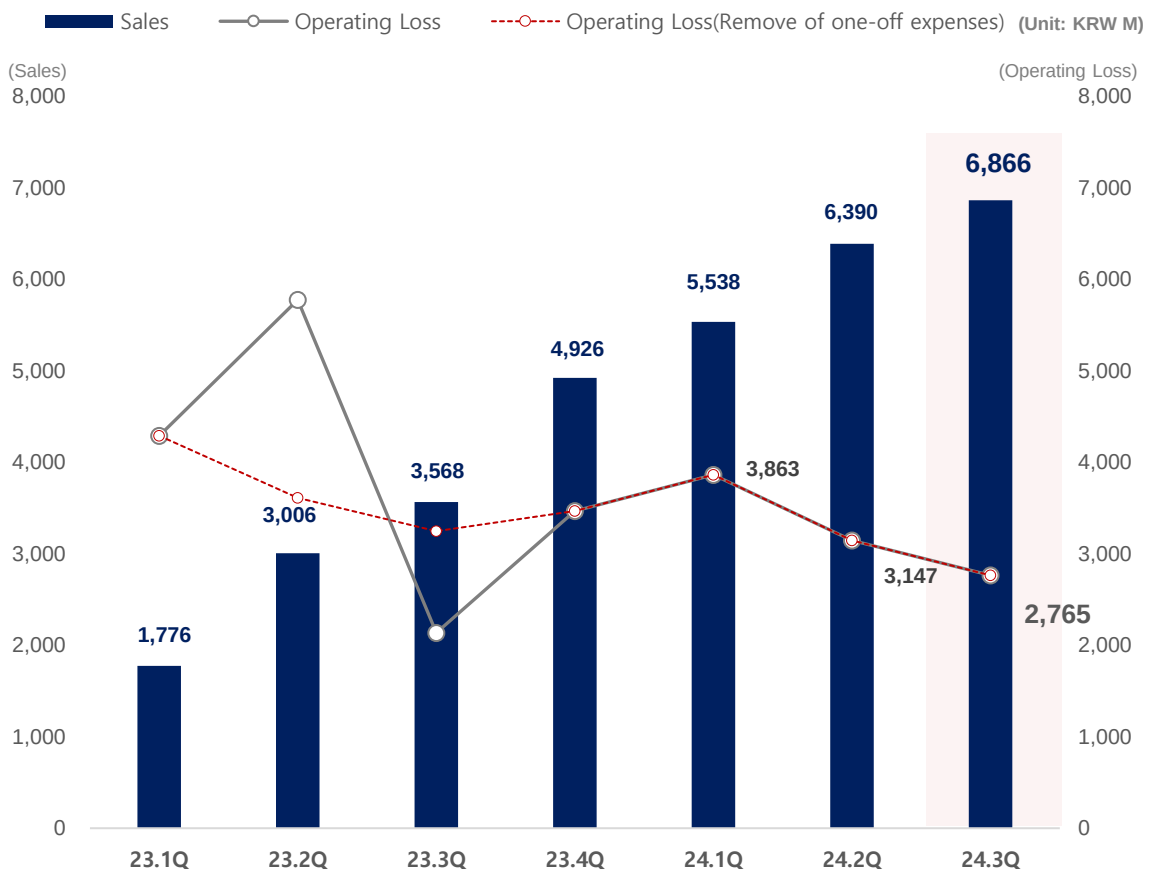
Finally, this material is intended as a reference for investors' investment judgment, and we do not provide any warranty or assume any liability to investors for the contents of this material.

Highlights

Executive Summary

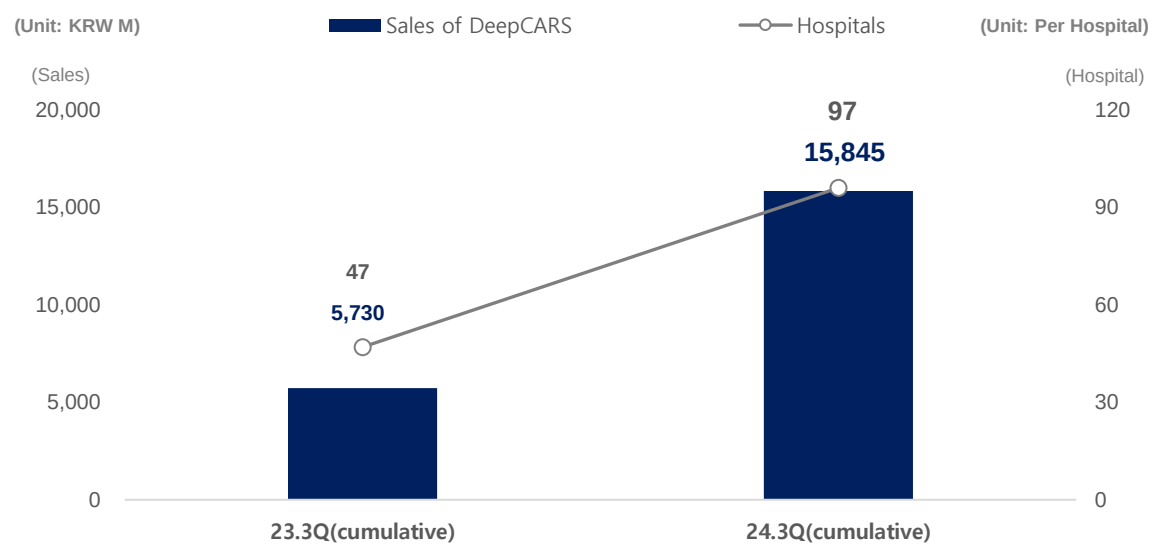
- **Q3 Revenue is KRW 6.9 billion (QoQ +7%, YoY +92%)**
  - **SaaS sales structure → Recorded all-time high revenue for 7 straight quarters and operating loss reduced about KRW 2 billion (QoQ -12%)**

Sales and Operating Loss



Note 1) Granted share-based payment to CEO etc. → Deducted from salary and temporary decreased in operating expenses in 2Q.'23.
Note 2) CEO abandoned share-based payment → Added from salary and temporary increased in operating expenses in 3Q.'23.

Sales of DeepCARS



Based on 25th November 2024

✓ No. of hospital using: total 103 (tier 1: 18, tier 2: 85)

✓ No. of beds using: total 42,000+

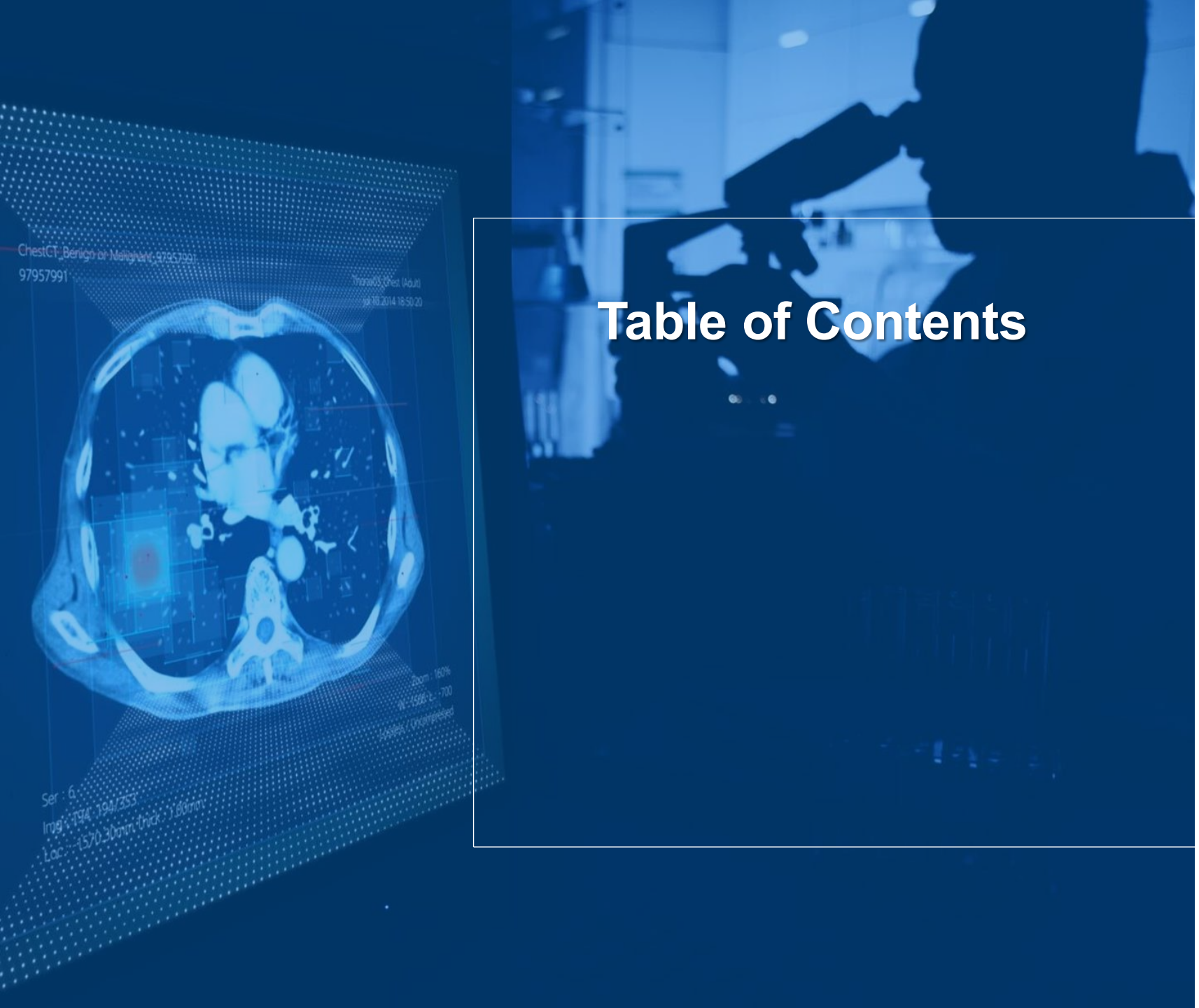


Table of Contents

CHAPTER 01
Company Overview

CHAPTER 02
VUNO-Bio Signal Solutions

CHAPTER 03
VUNO-Medical Imaging Solutions

CHAPTER 01

Company Overview

Established 2014.12

Building R&D Foundation (2015~)

2014

12. Selected as a Tech Incubator Program for Startup (TIPS) by Ministry of SMEs

2015

08. Deep-learning based case studies on lung images with Seoul Asan Medical Center

    Established corporate R&D Center

12. Top 5th in CLS of ImageNet IL SVRC 2015

2016

12. Approval for K-GMP

2017

01. IND Approval for VUNO Med-BoneAge

11. Participated in drafting MFDS regulatory approval guidelines for medical AI devices

Product Development (2018~)

2018

05. Designated as 1st AI Medical Device
    VUNO Med-BoneAge

    Commercialized medical speech record software
    VUNO Med-DeepASR

2019

06. MFDS Approval for VUNO Med-DeepBrain

08. MFDS Approval for VUNO Med-Chest X-ray

12. PMDA Approval for VUNO Med-LungCT AI

2020

04. MFDS Approval for
    VUNO Med-Fundus AI & LungCT AI

06. CE Certified for VUNO Med-5 Medical Imaging solutions

07. Designated as 1st Innovative Medical Device
    VUNO Med-Fundus AI

09. Designated as 6th Innovative Medical Device
    VUNO Med-DeepCARS

Commercialization (2021~)

2021

02. **Listed on KOSDAQ**

08. MFDS Approval for VUNO Med-DeepCARS

10. Designated as 16th Innovative Medical Device
    VUNO Med-DeepECG

2022

05. Designated as Early Access Innovation Medical Device
    VUNO Med-DeepCARS

06. Eligible for 3D MRI reading insurance reimbursement
    VUNO Med-DeepBrain

08. Eligible for **Out-of-Pocket insurance**
    VUNO Med-**DeepCARS**

12. Designated as 22nd Innovative Medical Device
    VUNO Med-LungCT AI

2023

01. Hativ launched (ECG based electrocardiograms)

06. Designated **FDA BDD** of VUNO Med-**DeepCARS**

10. Obtained **FDA 510k** of VUNO Med-**DeepBrain**

2024

01. Wins **reimbursement in Japan** of VUNO Med-**LungCT AI**

03. Expanded European market of VUNO Med-Chest X-ray

04. Received an **integrated review of innovative medical devices**
    VUNO Med-**Fundus AI**

10. Joined Saudi Arabia's national Healthcare SANDBOX initiative

11. Obtained **FDA 510k** of VUNO Med-**Chest X-ray**

CHAPTER 01

Company Overview

Automatic Detection, Quantification and Measurement

Medical Imaging

Diagnostic Support and Risk Prediction through ECG images analysis

Bio Signal



VUNO Med®

Quantification

- VUNO Med-DeepBrain — Ministry of Food and Drug Safety, FDA, CE

Diagnostic Support

- VUNO Med-BoneAge — Ministry of Food and Drug Safety, CE, PMDA
- VUNO Med-Chest X-ray — Ministry of Food and Drug Safety, CE, FDA, FDA
- VUNO Med-LungCT AI — Ministry of Food and Drug Safety, CE, PMDA
- VUNO Med-Fundus AI — Ministry of Food and Drug Safety, CE
- Hativ — Ministry of Food and Drug Safety

New Diagnostic Method

- VUNO Med-DeepECG — Ministry of Food and Drug Safety
- VUNO Med-DeepBrain AD — Ministry of Food and Drug Safety

Prediction & Prognosis

- VUNO Med-DeepCARS — Ministry of Food and Drug Safety

CHAPTER 01

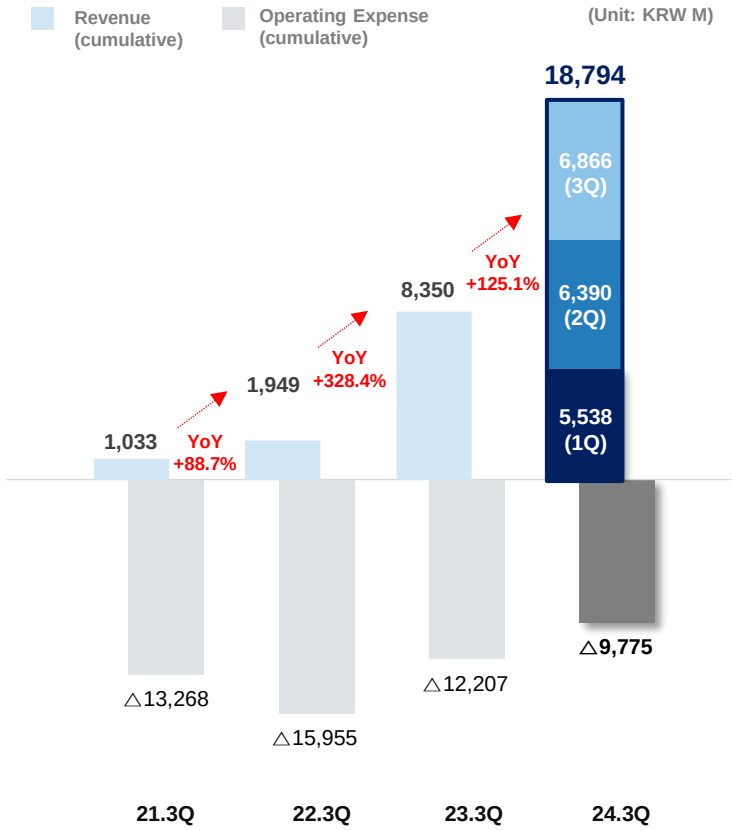
Company Overview – Financial review (Consolidated Basis)

- **Q3 Cumulative revenue: KRW 18.8 billion | Q3 Revenue: KRW 6.9 billion**

  - Recorded all-time high revenue for 7 straight quarters

  - Operating loss reduced about KRW 2 billion, despite one-off expenses for overseas expansion

Consolidated IS (Unit: KRW M)	2023				2024			3Q	
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	QoQ	YoY
Revenue	1,776	3,006	3,568	4,926	5,538	6,390	**6,866**	+7.4%	+92.4%
DeepCARS	1,201 (67.6%)	1,888 (62.8%)	2,641 (74.0%)	3,735 (75.8%)	4,469 (80.7%)	5,476 (85.7%)	**5,900 (85.9%)**	+7.7%	+123.4%
Medical Imaging	370 (20.8%)	363 (12.1%)	564 (15.8%)	745 (15.2%)	535 (9.6%)	357 (5.6%)	**458 (6.7%)**	+28.3%	-18.8%
Hativ & Server	205 (11.6%)	371 (12.3%)	363 (10.2%)	415 (8.4%)	519 (9.4%)	400 (6.3%)	**507 (7.4%)**	+26.8%	+39.7%
Others	-	384 (12.8%)	-	31 (0.6%)	15 (0.3%)	157 (2.4%)	**-**	-99.4%	-
Operating Expense	6,068	8,784	5,705	8,395	9,401	9,538	**9,630**	+1.0%	+68.8%
Operating Income	△4,292	△5,778	△2,137	△3,469	△3,863	△3,147	**△2,765**	-12.1%	+29.4%
Net Income	△4,279	△2,649	△2,256	△6,443	△3,895	△3,221	**△2,837**	-11.9%	+25.8%
EBITDA	△3,949	△5,434	△1,761	△3,114	△3,504	△2,790	**△2,356**	-15.6%	+33.8%



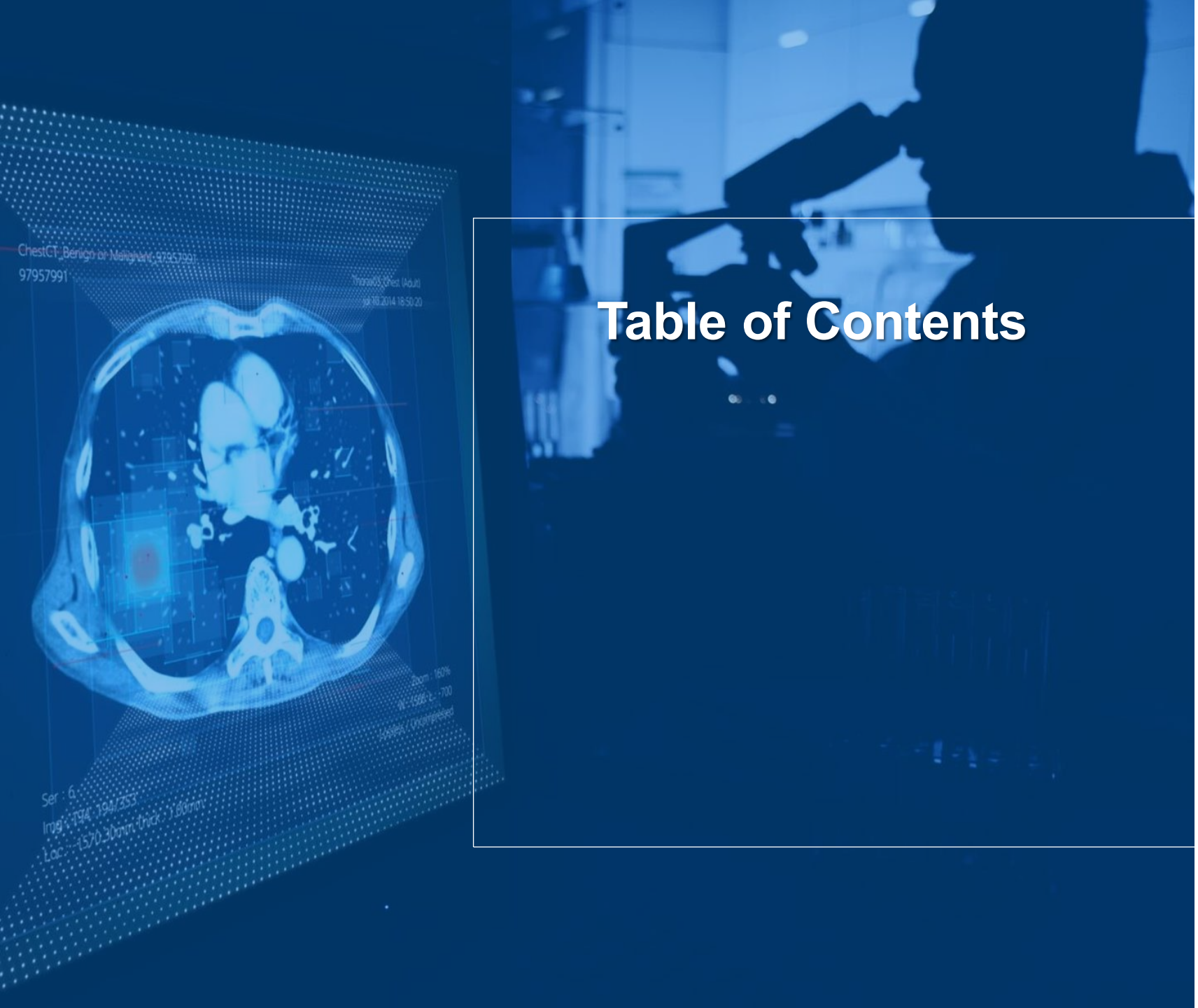


Table of Contents

CHAPTER 01
Company Overview

CHAPTER 02
VUNO-Bio Signal Solutions

CHAPTER 03
VUNO-Medical Imaging Solutions

CHAPTER
02

Bio Signal Solutions – VUNO Med-DeepCARS

In-hospital Cardiac Arrest (IHCA)

3,600 cases[1]

Warning Signs/ Early symptoms

80%[2] (2,880)

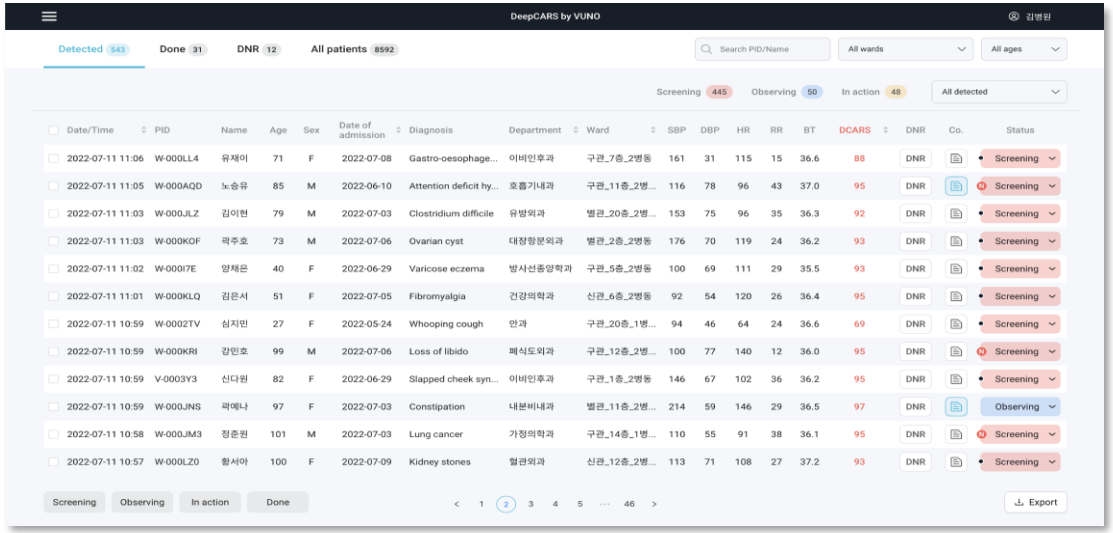
IHCA Death

75%[3] (2,700)

Severe Shortage of Medical Staff

A Lack of Effective Track-and-Trigger System

68%
Avoidable IHCA[4]



AI-Based Cardiac Arrest Risk Management System

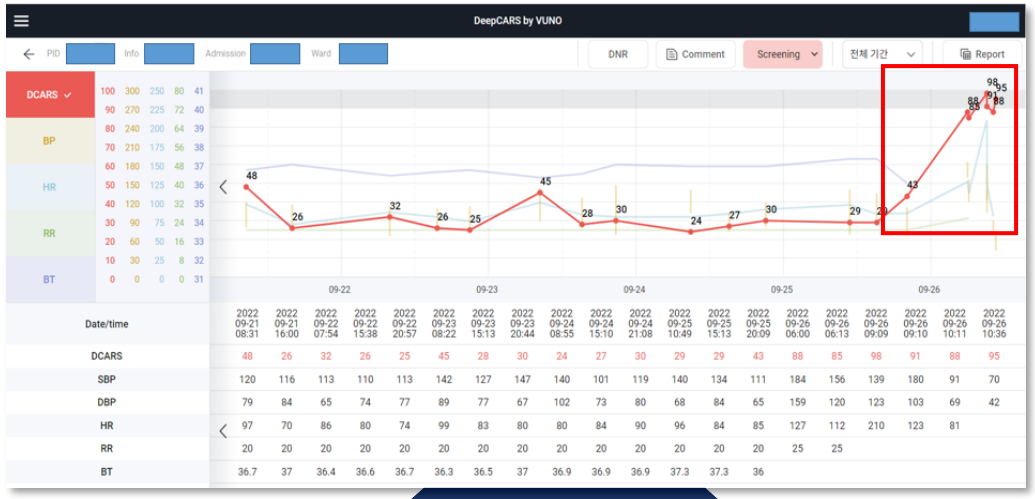
Target	Inpatients of **all ages** in **general ward**
Purpose	Predicts the risk of cardiac arrest **within 24 hours** for inpatients
Mechanism	• Uses **5 vital signs*** and age/vital sign recorded time collected from the electronic medical record. (EMR) * S/D Blood Pressure, Heart Rate, Respiratory Rate, Body Temperature • Provides a risk score from **0 to 100**.
Data	• **96,000+** patients in three hospitals in Korea

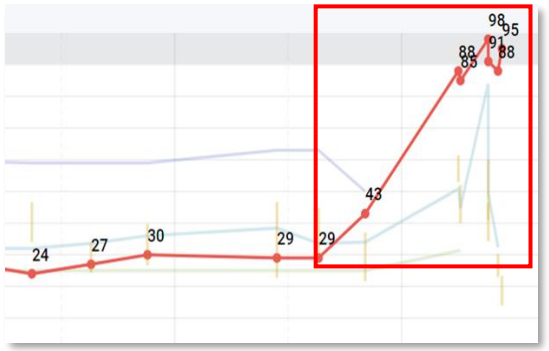
1) Crit Care Med. 2012;39:2401-2406
2) Resuscitation. 2004;62(3):275-282. doi:10.1016/j.resuscitation.2004.05.016
3) JAMA 2019;321(12):1200-1210
4) Resuscitation. 2002 Aug;54(2):115-23

CHAPTER
02

Bio Signal Solutions – VUNO Med-DeepCARS

• Patient Details Page





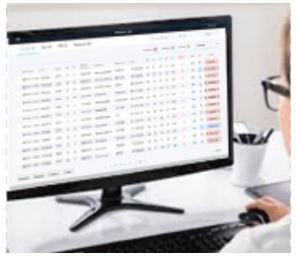
If the score increases,

monitor the patient more closely.

- **Early detection** and timely intervention on deteriorating patients.
- **Efficient monitoring** leading to time savings for more patient visit.

• Use Case

1



Select risky-patient

- Check the rate of high-risk patients classified by DeepCARS.
- Check the scores distribution and rate.

2



Planning

- Patient visits hospital and medical team reviews.
- Requirements reflection and make an intervention plan.

3



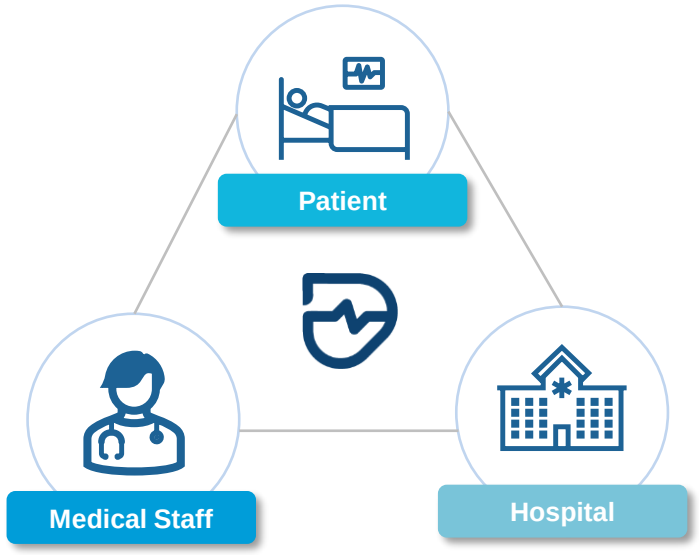
Do an Intervention

- Take measure to patient.
- CPR, transfer to ICU etc.

CHAPTER 02

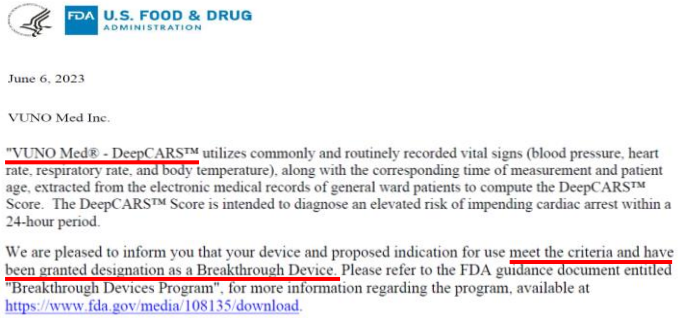
Bio Signal Solutions – VUNO Med-DeepCARS

• Business Model



✓ Fixed price of VUNO Med DeepCARS
: 7,000 KRW (Based on per patient / per bed / per day)

• Pathway to go U.S. market



FDA U.S. FOOD & DRUG ADMINISTRATION

June 6, 2023

VUNO Med Inc.

"VUNO Med® - DeepCARS™ utilizes commonly and routinely recorded vital signs (blood pressure, heart rate, respiratory rate, and body temperature), along with the corresponding time of measurement and patient age, extracted from the electronic medical records of general ward patients to compute the DeepCARS™ Score. The DeepCARS™ Score is intended to diagnose an elevated risk of impending cardiac arrest within a 24-hour period.

We are pleased to inform you that your device and proposed indication for use meet the criteria and have been granted designation as a Breakthrough Device. Please refer to the FDA guidance document entitled "Breakthrough Devices Program", for more information regarding the program, available at https://www.fda.gov/media/108135/download.

Designated as a BDD by FDA (Jun 2023)
(Breakthrough Device Designation)

- First in the Korean medical AI industry

✓ Provide to innovative medical technologies.
✓ Help to reach the market more quickly.

• Pathway to go domestic market



혁신의료기기 지정서

의료기기 제조 허가증

한국보건의료연구원

식품의약품안전처장

Innovative Medical Device designated by MFDS (Sep 2020)

MFDS approval (Aug 2021)

Designated as a candidate for New Health Technology Assessment (Dec 2021)

Designated as Early Access Innovation Medical Device (May 2022)

Official Launching (Aug 2022)

Bio Signal Solutions – VUNO Med-DeepCARS

• Comparison with Early Warning Systems

[Early Warning Systems]

- Large number of input variables
- Low accuracy
- High false alarm rate

[DeepCARS]

- Utilizes 4 classic vital signs
- High accuracy
- Low false alarm rate

	Product A	Product B	DeepCARS
Systolic BP	○	○	○
Diastolic BP			○
Heart Rate	○	○	○
Respiratory Rate	○	○	○
Body Temperature	○	○	○
SpO2		○	
Oxygen Therapy	○		
Consciousness	○		
Urine Output	○	○	

• Clinical trial result by MFDS (KFDA)

Predicting cardiac arrest with superior performance

- **High Sensitivity** Products
  - Prediction accuracy based on AUROC: 0.8934

Enough time to take preventive action

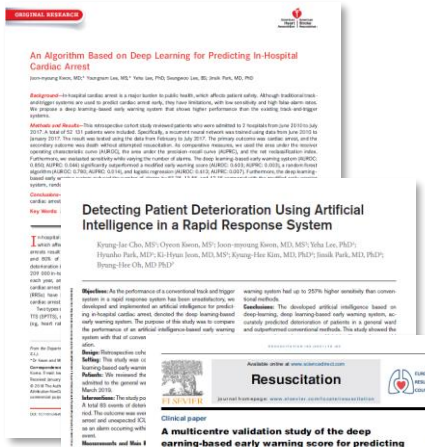
- Predicts on **average 15.78 hours** in advance

Applies to all inpatients in general wards

- No difference in sensitivity by **age, gender, or specialty**

CHAPTER
02 Bio Signal Solutions – VUNO Med-DeepCARS

- **Demonstrated superior cardiac arrest prediction performance through global clinical publications**



JAHA

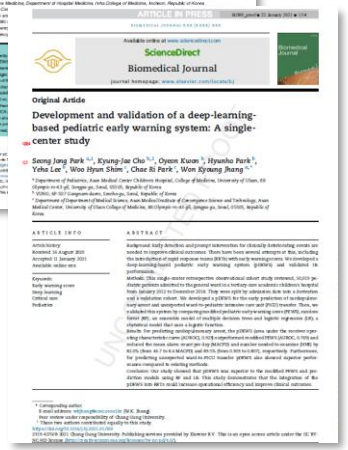
An algorithm based on deep learning for predicting in-hospital cardiac arrest (JAHA, 2018)

Critical Care Medicine

Detecting patient deterioration using artificial intelligence in a rapid response system
(Critical Care Medicine, 2020)

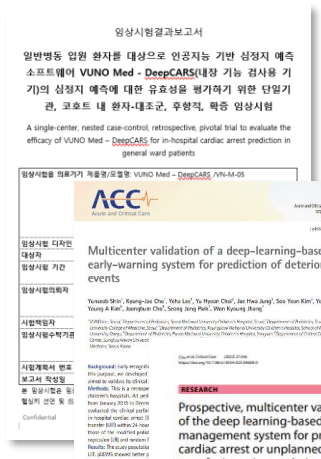
RESUSCITATION
OFFICIAL JOURNAL OF THE EUROPEAN RESUSCITATION COUNCIL

A multicenter validation study of the deep learning-based early warning score for predicting in-hospital cardiac arrest in patients admitted to general wards
(RESUSCITATION, 2021)

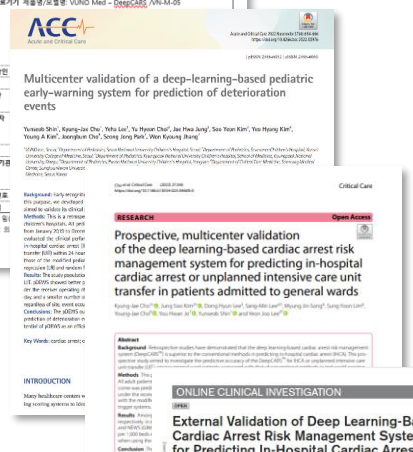


Biomedical Journal

Development and validation of a deep-learning-based pediatric early warning system
(Biomedical Journal 2021)



VUNO Med – DeepCARS의 심정지 예측에 대한 유효성을 평가하기 위한 단일기관 임상시험
(식약처 확증 임상시험, 2021)



Acute and Critical Care

Multicenter validation of a deep-learning-based pediatric early-warning system for prediction of deterioration events
(Acute and Critical Care 2022)

Critical Care

Prospective, multicenter validation of the deep learning-based cardiac arrest risk management system for predicting in-hospital cardiac arrest or unplanned intensive care unit transfer in patients admitted to general wards
(Critical Care 2023)

Critical Care Medicine

External validation of deep-learning based cardiac arrest risk management system for predicting in-hospital cardiac arrest in patients admitted to general ward on operating and non-operating time of rapid response system
(Critical Care Medicine, 2024)

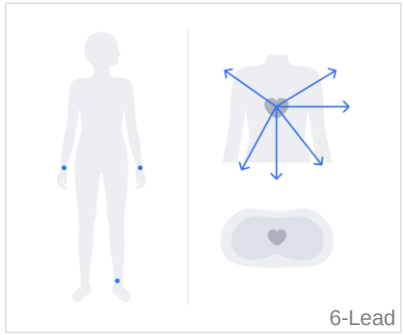
CHAPTER
02

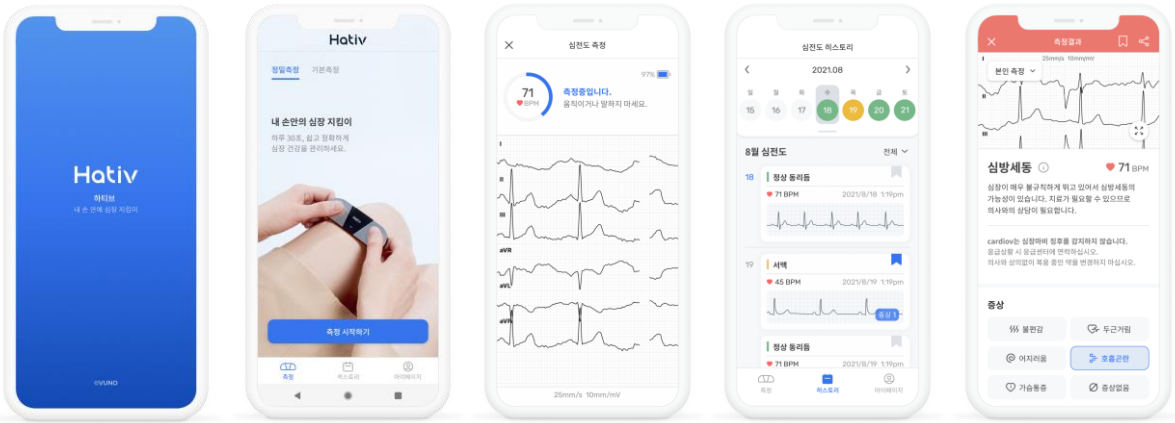
Bio Signal Solutions – Hativ & VUNO Med DeepECG

Hativ

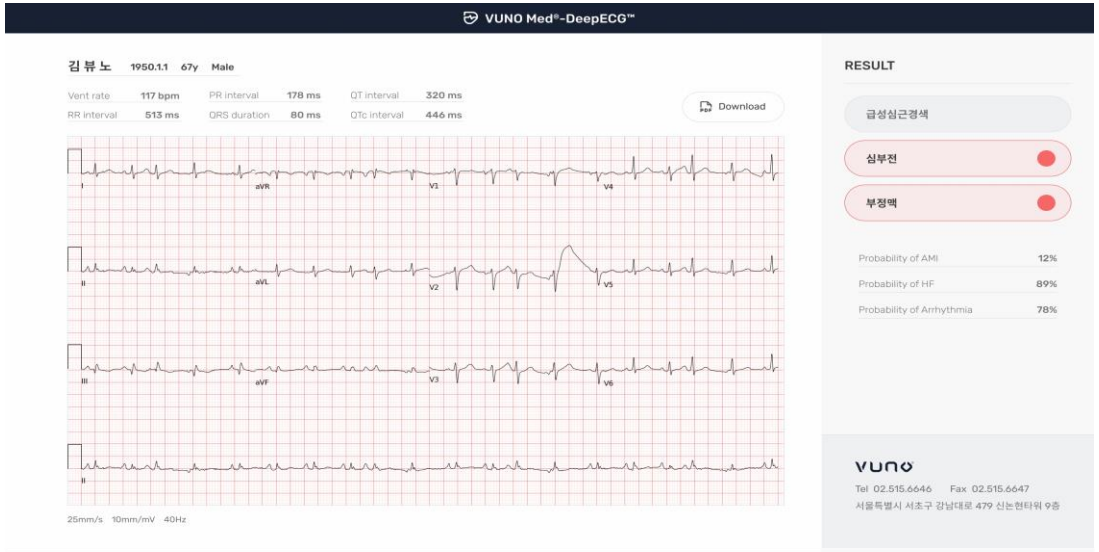
- **Medical-grade portable ECG device.**
- Connect to **app** and measurement of 1-lead and 6-lead ECG in **30 seconds**.
- Disease : **Arrhythmia**, **Myocardial Infarction, Heart Failure, Hyperkalemia**
  Chronic Kidney Disease (’25)







VUNO Med-DeepECG



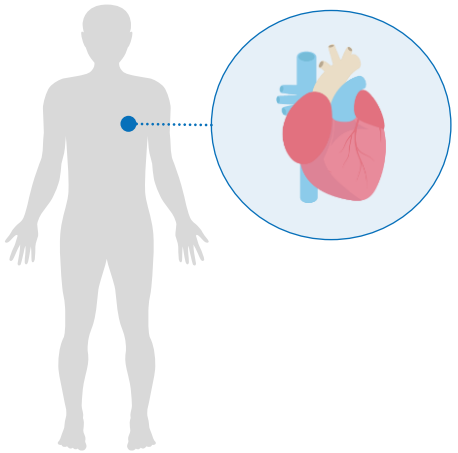
AI-Based ECG Analysis Solution

Description	• Provide diagnostic support on the detection of **cardiovascular diseases** and **kidney disease.** • Allows at risk patients susceptible to kidney and heart disease to self-measure and receive early treatment.
Method	• Analyzes **ECG data** from portable mobile ECGs and other devices.
MFDS (K-FDA)	• Designated as an innovate medical device ① **Myocardial Infarction(AMI)** (May ’24) ② **Heart Failure(LVSD)** (Aug ’24) ③ **Hyperkalemia** (Oct ’24)

CHAPTER 02

Bio Signal Solutions – Hativ & VUNO Med DeepECG

Cardiovascular Disease



1st leading cause of death worldwide Note 1)

- 17.9 million people die each year from **cardiovascular disease.**
  → 31% of all deaths worldwide.
- 2nd leading cause of death and 1st in medical expenses in Korea.
- Increase in cardiovascular complications with young chronic disease patients.
- **Arrhythmias** account for 90% of sudden death.

ECG Test Types



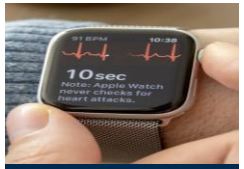
12-Lead

- Electrocardiography in the hospital.
- High accuracy based on 12-lead ECG.
- Difficult to use in daily.



6-Lead

- Has a **high accuracy** of 12-lead ECG.
- Has a **portability** and **convenience** of 1-lead ECG.
- Approved as medical device by MFDS(K-FDA). (Oct ’22)



1-Lead

- Portable and convenient.
- Low accuracy based on 1-lead ECG.
- Has a **limited information** for **medical purpose.**

Note 1) World Health Organization, ‘The top 10 causes of death’

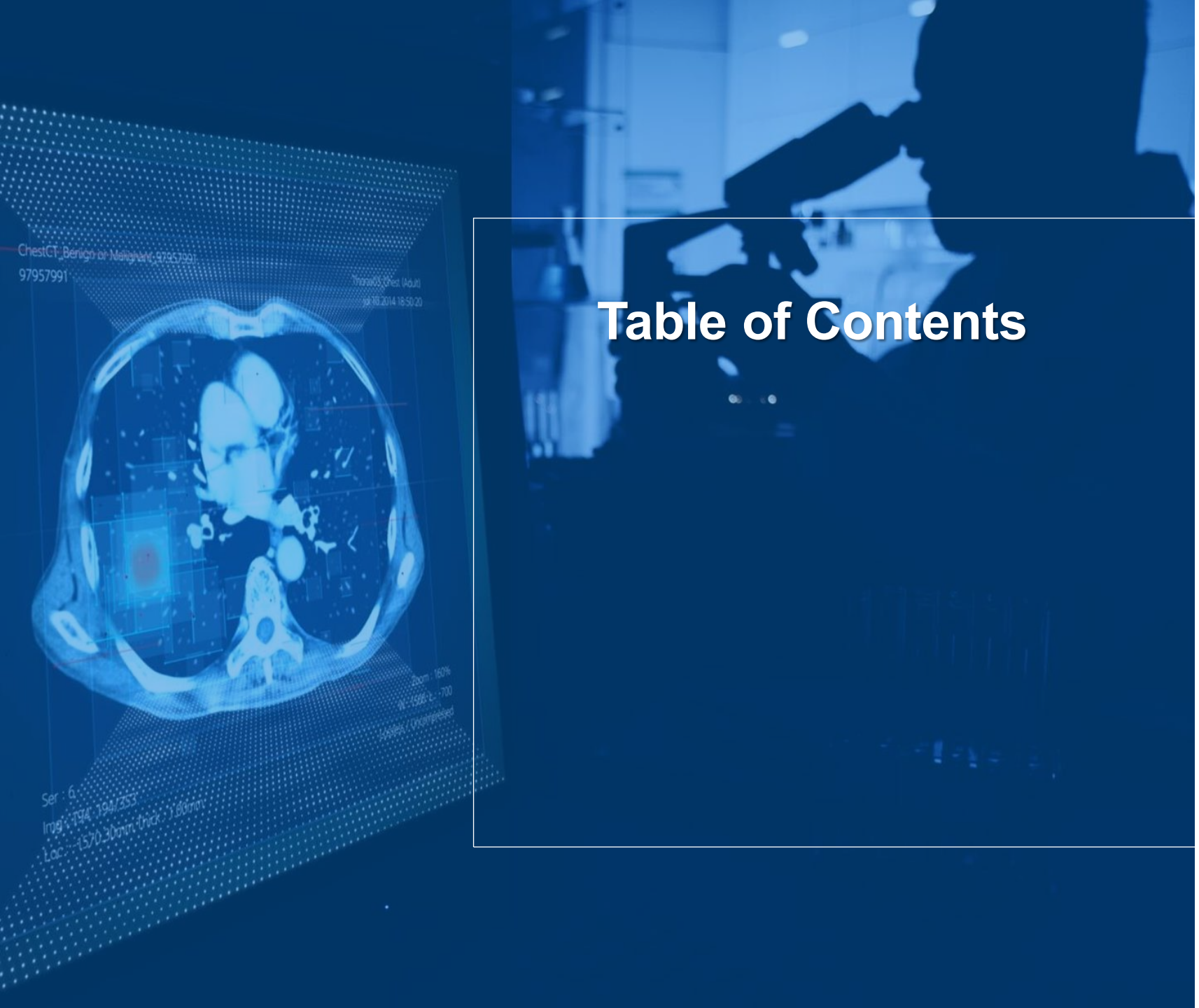


Table of Contents

CHAPTER 01
Company Overview

CHAPTER 02
VUNO-Bio Signal Solutions

CHAPTER 03
VUNO-Medical Imaging Solutions

CHAPTER 03

Medical Imaging Solutions – VUNO Med DeepBrain

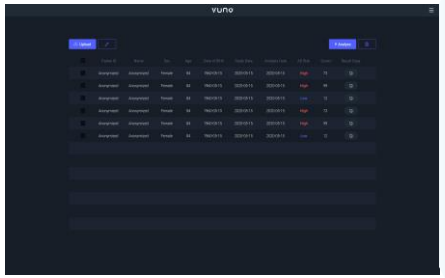
VUNO Med-DeepBrain



Brain MRI-based Quantification Solution

- Provides **volumetric data of 104 brain regions** through brain parcellation in **1 minute**.
  ① Brain volume ② Cortical thickness ③ WMH
- Support to diagnose **neurodegenerative diseases.**
  ① MCI ② Alzheimer's Disease ③ Dementia

VUNO Med-DeepBrain AD



AI Diagnostic Support for Alzheimer's Disease in MRI

- Assist **Alzheimer's disease** diagnosis by providing **risk score** calculated from MRI image.
- Allows medical professionals to identify patients with high risk with high accuracy. (AUC 0.937)

FDA 510(k) Clearance Medical Device (Oct '23)

- Officially launched in the U.S. market at the AAIC & Registered U.S. patents for 2 core technologies. (Jul '24)
- Enable observing side effects ARIA [Note 1)] and predicting prognosis.
- LEQEMBI, approved by MFDS(K-FDA) (May '24) → Expect to use for early diagnosis.

Regulatory Approval

Ministry of Food and Drug Safety · CE 2195 · FDA

R&D Partners

서울아산병원 Asan Medical Center · 분당서울대학교병원 SEOUL NATIONAL UNIVERSITY BUNDANG HOSPITAL

Alzheimer's Disease Risk Score Solutions

- PET CT (High cost, Low accessibility) → DeepBrain AD (Low cost, High accessibility)
- Approved by MFDS(K-FDA) and preparations are underway for commercialization.

Regulatory Approval

Ministry of Food and Drug Safety

R&D Partner

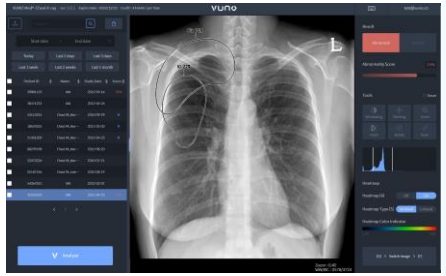
분당서울대학교병원 SEOUL NATIONAL UNIVERSITY BUNDANG HOSPITAL

Note 1) ARIA(Amyloid-Related Imaging Abnormalities): Side effect of Alzheimer's treatment.

CHAPTER 03

Medical Imaging Solutions – VUNO Med Chest X-ray & LungCT AI

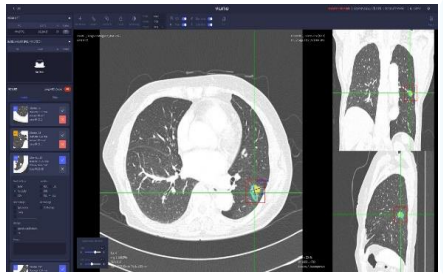
VUNO Med-Chest X-ray



AI Diagnostic Support for Abnormalities in Chest X-ray

- Detects presence of **5 lung abnormalities** Note 1), abnormality score and location.
- 98% accuracy in image-wise classification of normal or abnormal.
- Reduced reading time by more than 50%. Note 2)

VUNO Med-LungCT AI



Detection of Pulmonary Nodules in Chest CT

- Accurate detection and volumetric quantification of **pulmonary nodules** in 1 minute.
- **Super-resolution** algorithm allows reconstruction of CT scan slices into 1mm section thickness.
- Detected 269 nodules in 9,952 cases reported as normal.

FDA 510(k) Clearance Medical Device (Nov ’24)

- Proven high accuracy with a comparative study of pneumonia screening solutions. Note 3)
- B2B Expansion to X-ray equipment companies → Focus on overseas market.
- Expansion of target medical institutions.
  Radiology → Internal medicine and family medicine etc.

rayence VIEWORKS DRGEM Your Best Healthcare
SAMSUNG LG Household & Health Care DIGIRAY

Regulatory Approval

Ministry of Food and Drug Safety · CE 2195 · FDA · FDA

R&D Partners

서울아산병원 Asan Medical Center · 분당서울대학교병원 SEOUL NATIONAL UNIVERSITY BUNDANG HOSPITAL

Japan Local Insurance Reimbursement

- **Japan : Expected to gain momentum in sales growth**
  ① Wins reimbursement in Japan. (Jan ’24)
  ② M3 AI signed MOU with Canon Medical Systems for sales.
  → M3 AI have over 30% of PACS market share.
  ③ MHLW updated to the health insurance fee system.
  → Can be reach out and contact more medical institutions.

Regulatory Approval

Ministry of Food and Drug Safety · CE 2195 · Pmda

R&D Partners

서울아산병원 Asan Medical Center · SAMSUNG 강북삼성병원 · MGH MASSACHUSETTS GENERAL HOSPITAL

Note 1) Nodule/Mass, Consolidation, Interstitial Opacity, Pleural Effusion, Pneumothorax.
Note 2) Added Value of Deep Learning–based Detection System for Multiple Major Findings on Chest Radiographs: A Randomized Crossover Study, Radiology. 2021. Mar.
Note 3) A Comparative Study of Deep Learning Models for Pneumonia Detection: Journal of RADIATION INDUSTRY 2024.

CHAPTER 03

Medical Imaging Solutions – VUNO Med Fundus AI & BoneAge

VUNO Med-Fundus AI



AI Screening Solution for Abnormalities in the Fundus

- Detection of **12 retinal findings** Note 1) associated with diagnosis of vision-threatening ocular diseases in 2 seconds.
- Automatically detects the location of **8 regions** of the fundus.

VUNO Med-BoneAge



Automatic Bone Age Assessment in hand X-ray

- Provides a 3 nearest bone age results in 5 seconds.
  ① Height Percentile.
  ② Bone Age assessment results.
  ③ Growth curve and adult height prediction.
- Reduce reading time by 40% and increased diagnostic accuracy by 16%.

Out-of-Pocket Insurance

- Proven clinical utility through improved detection sensitivity and reduced image reading time. Note 2)
- Approved an integrated review of innovative medical devices by MFDS. (Apr ′24)
  → Eligible for **out-of-pocket insurance**. (Oct ′24~)
- Expansion of target medical institutions.
  Ophthalmology → Internal medicine, chronic disease clinic and checkup center etc.

Regulatory Approval

Ministry of Food and Drug Safety

CE 2195

R&D Partners

분당서울대학교병원 SEOUL NATIONAL UNIVERSITY BUNDANG HOSPITAL

Expanding Medical Center Penetration

- Used in 11 medical institutions in ′18 → 1,000+ medical institution in ′24.
- Expanding medical center penetration → Pediatrics, orthopedics and dental clinic.
  (Growth hormone, genetic growth disorders, orthopedic or orthodontic problems.)

Regulatory Approval

Ministry of Food and Drug Safety

CE 2195

R&D Partner

서울아산병원 Asan Medical Center

고려대학교의료원 KOREA UNIVERSITY MEDICINE

Note 1) Hemorrhage, Hard Exudate, Cotton Wool Patch, Drusen, Membrane, Macular Hole, Myelinated Nerve Fiber, Vascular Abnormality, Chorioretinal Atrophy, Retinal Nerve Fiber Layer Defect, Glaucomatous Disc Change, Non-glaucomatous Disc Change
Note 2) Korean Society of Radiation Industry. Vol. 18, No. 3, pp. 177-182, 2024

VUNO®



VUNO®

VUNO® VUNO Med®
Registered in R.O.K. & U.S. Patent and Trademark Office