

# COMPANY PROFILE

## VUNO Inc. / Global Leader in Healthcare AI (Artificial Intelligence)

2024.1Q

VUNO

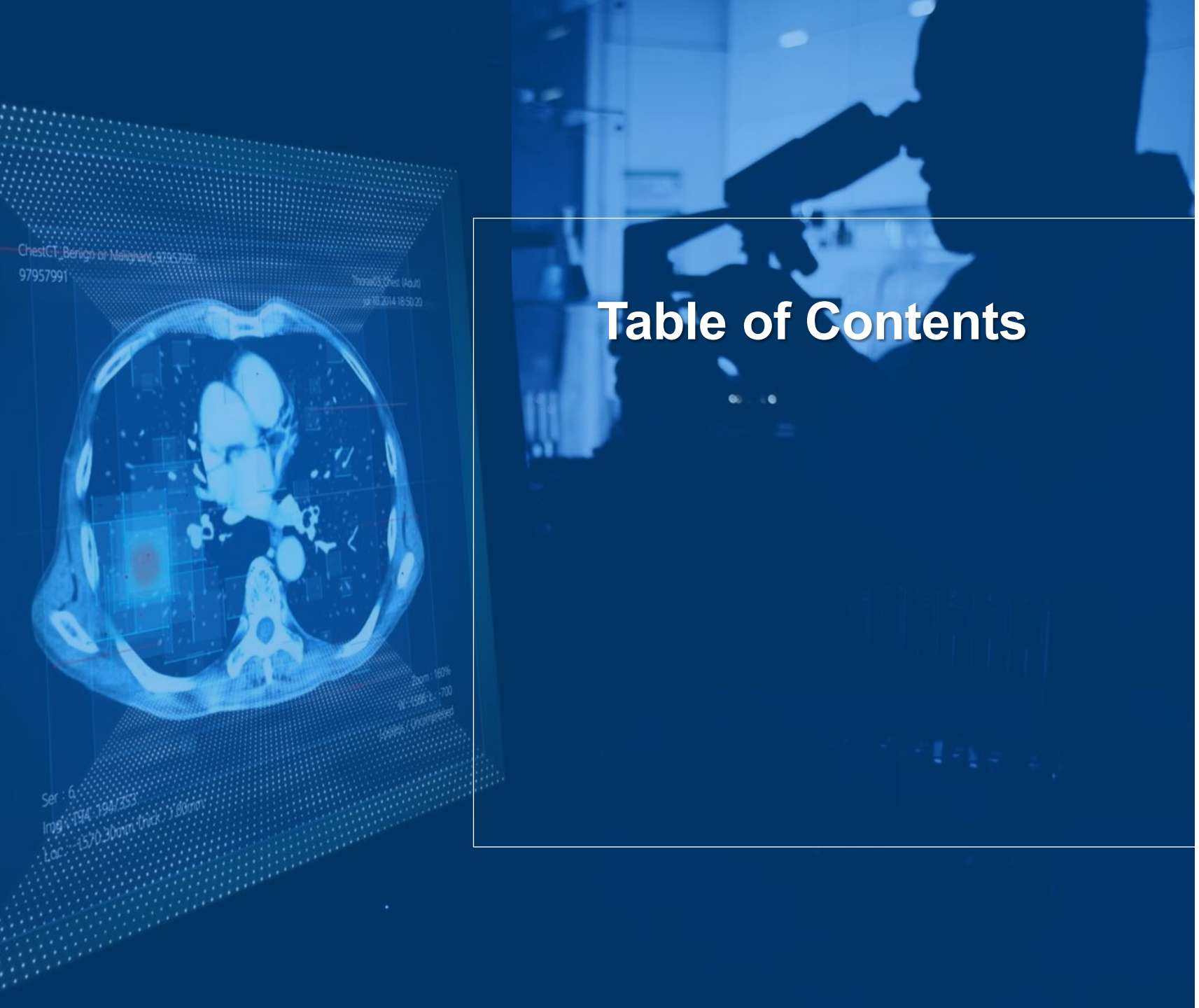
VUNO® VUNO Med®
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# Disclaimer

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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.



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CHAPTER 01

# Company Overview

## In full-fledged deployment

VUNO Med®

### Nationally recognized healthcare AI solutions

**1st**
- MFDS approved medical AI device
- Innovative medical device

**10** Ready to use solutions



### Proven clinical validity based on multiple clinical studies & real-world examples

**1,000+** Hospitals

**100+** Publications

**100+** Patents

RSNA Radiology · AJNR · American Academy of Ophthalmology · MICCAI · AACR · Clinical Cancer Research · ASCO · PLOS ONE · Critical Care Medicine · JAHA · ICASSP · INTERSPEECH

### Global network of collaborations

**Extensive Network of Global Partners**

M3, Inc. · LG Electronics · SAMSUNG · VIEWORKS · CHC HEALTHCARE GROUP · 서울아산병원 Asan Medical Center · HCK HEALTHCARE KONNECT · The University of Texas MD Anderson Cancer Center

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 Asan Medical Center (Seoul)

    Established **corporate R&D Center**

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

### 2016

12. Approval for K-GMP

    Participated in ***RSNA** 2016 & exhibited AI solutions

    * Participating every year since 2016

### 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. 1st AI medical device approved by MFDS (Kor), **VUNO Med-BoneAge**

    Commercialized medical speech record S/W VUNO Med-DeepASR (Automatic Speech Recognition)

09. Commercialized 1st AI medical device service (Kor)

### 2019

06. MFDS Approval for VUNO Med-**DeepBrain**
08. MFDS Approval for VUNO Med-**Chest X-Ray**
12. Korea's 1st PMDA certification for VUNO Med-**LungCT**

### 2020

04. MFDS Approval for VUNO Med-**Fundus AI / LungCT AI**
06. 5 VUNO Med Solutions – CE Certified
    Partnership w/ **M3, SONY Subsidiary**
07. VUNO Med-**Fundus AI** became Korea's **first-ever Innovative Medical Device**
09. VUNO Med-**DeepCARS** designated as 6th Innovative Medical Device

Ministry of Food and Drug Safety

## Commercialization + Deployment (2021~)

### 2021

**02. Listed on KOSDAQ (Korean Stock Exchange)**
06. MFDS Approval for VUNO Med-PathQuant
08. MFDS Approval for VUNO Med-DeepCARS
**10. VUNO Med-DeepECG designated as 16th Innovative Medical Device**

### 2022

**05. VUNO Med-DeepCARS Desig. as Early Access Innovation Med Device**
06. VUNO Med-DeepBrain eligible for 3D MRI reading insurance reimbursement
**08. VUNO Med-DeepCARS eligible for out-of-pocket insurance (8.1. ~)**
**12. VUNO Med-LungCT designated as 22nd Innovative Medical Device**

### 2023

01. **Hativ (ECG Technology-based electrocardiograms) launched**
**06. VUNO Med-DeepCARS designated FDA Breakthrough device**
**10. VUNO Med-DeepBrain obtained FDA 510K clearance**

### 2024

01. VUNO Med-**LungCT won reimbursement in Japan**
03. VUNO Med-**Chest X ray expanded European market**

CHAPTER 01

# Company Overview

X-ray, MRI, CT, Funduscopy

EMR, ECG, Patient Monitor

**Medical Imaging**

**Bio Signal**

VUNO Med®

## Process Improvement

- VUNO Med-DeepASR

## 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
- VUNO Med-LungCT AI
  - Ministry of Food and Drug Safety
  - CE
  - Pmda
- VUNO Med-Fundus AI
  - Ministry of Food and Drug Safety
  - CE
- VUNO Med-DeepBrain AD
  - Ministry of Food and Drug Safety
- Hativ
  - Ministry of Food and Drug Safety
- VUNO Med-DeepECG
  - Clinical Trials in Progress

## Prediction & Prognosis

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

CHAPTER 01

# Company Overview – '23 FY Review

- **VUNO grows for the third year in a row and shows further gains in '23 FY**
  - **Sustained sales growth in every quarter (1Q~4Q) of ’23 & Stable SaaS sales structure established.**
  - **Solid sales growth in the Bio Signal is attributed to the continued expansion of hospitals using DeepCARS and the recent launch of the new product Hativ.**

• Income Statement

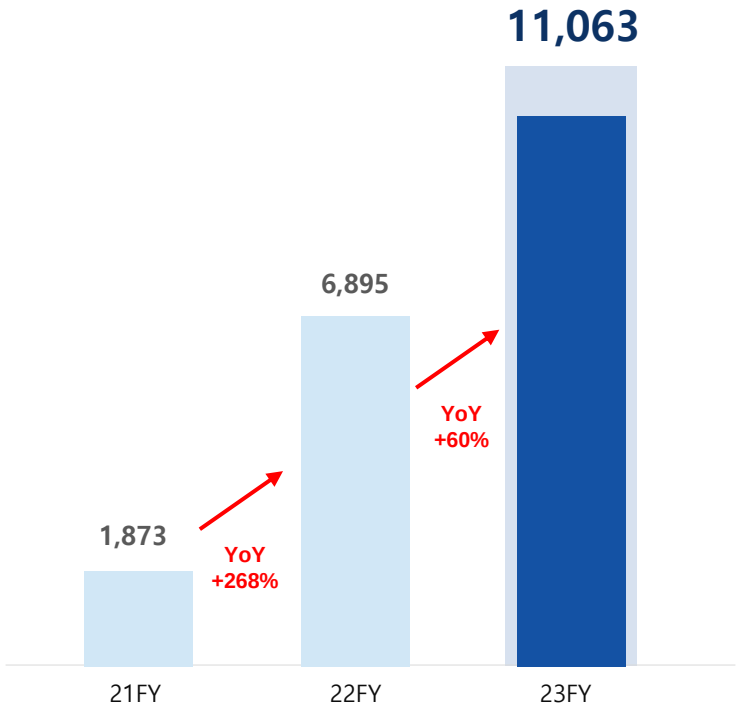
(Unit: USD 1,000)

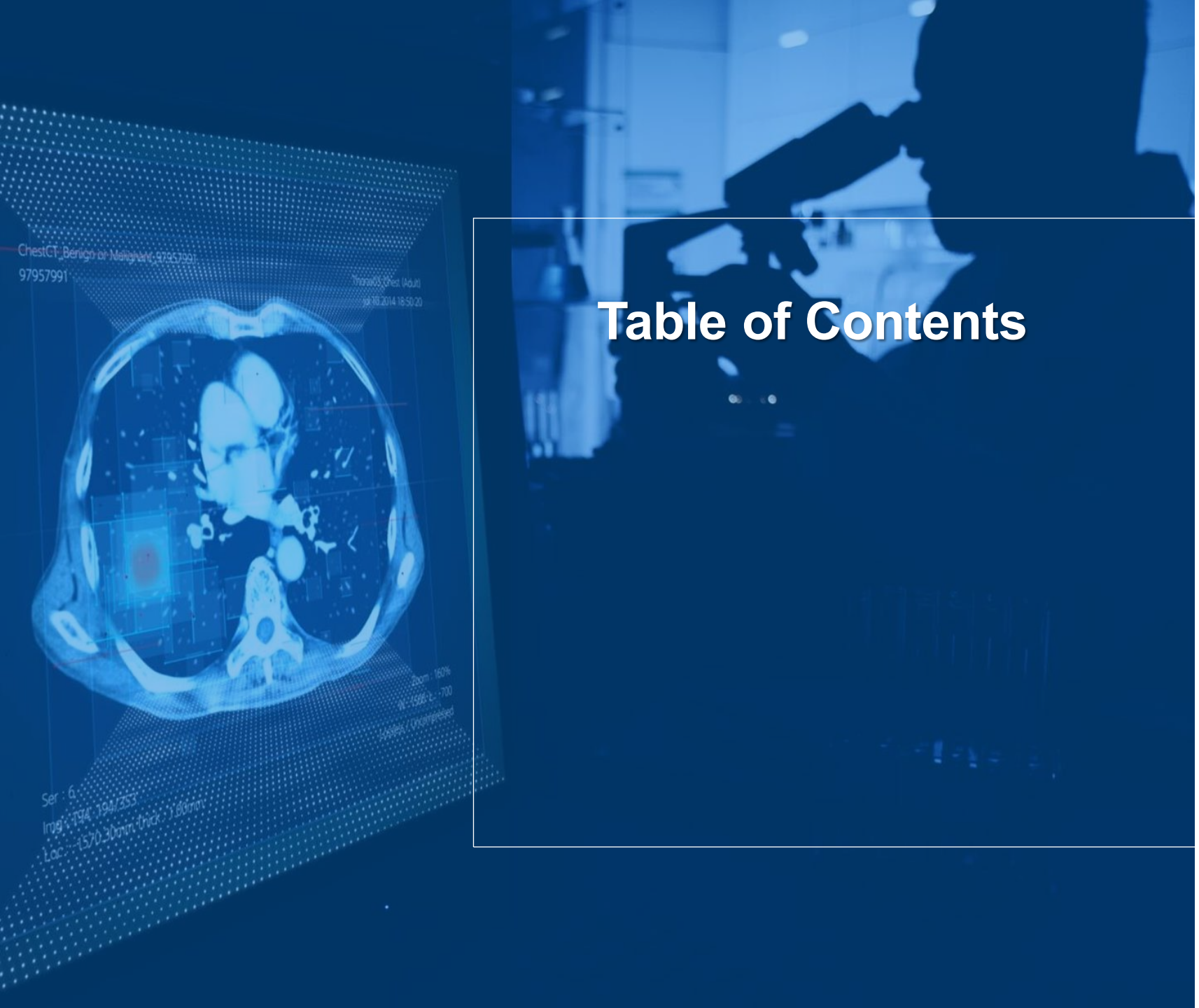
| Type | ’21 FY | ’22 FY | ’23 FY | YoY |
|---|---|---|---|---|
| **Revenue** | **1,873** | **6,895** | **11,063** | **60%** |
| Operating Expense | 16,545 | 19,065 | 23,503 | |
| Operating Loss | (14,672) | (12,170) | (11,440) | △**6**% |
| **Non-Operating Revenue** | **(1,453)** | **(246)** | **41** | |
| Financial Income | 315 | 201 | 433 | |
| Other Income | 15 | 71 | 3,419 | |
| Non-Operating Expense | 1,782 | 518 | 3,811 | |
| **Net Loss** | **(16,125)** | **(12,416)** | **(11,399)** | **△8%** |

Note) Exchange Rate: 1 USD=1,200 KRW

• Revenue

(Unit: USD 1,000)





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CHAPTER 02

# 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**

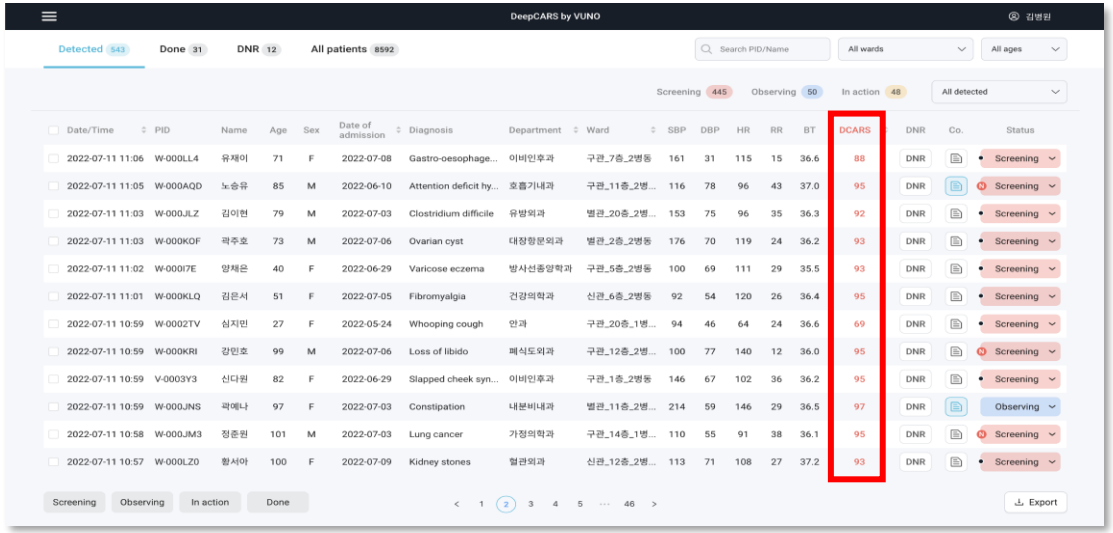
**A Lack of Effective Track-and-Trigger System**

**68%**
**Avoidable IHCA**[4]

## DeepCARS®

**Overcoming the limitations of traditional methods with AI**

**Efficient management with fewer false alarms, Higher sensitivity and specificity by using AI Model**




**Deep Learning(AI) based Cardiac Arrest Risk Management System**

| | |
|---|---|
| **Target** | Inpatient of **all ages** all ages in **general ward** |
| **Purpose** | Predicts the risk of cardiac arrest **within 24 hours** for patients |
| **Mechanism** | • Uses **5 vital signs (S/D Blood Pressure, Heart Rate, Respiratory Rate, Body Temperature) and age/vital sign recorded time** collected from the electronic medical record (EMR)<br>• Provides a risk score from **0 to 100** (the higher score the higher risk) |


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

# VUNO Med-DeepCARS

1



### Select risky-patient

- Check the rate of high-risk patients classified by DeepCARS
- After the 1st review, notify to ward medical team

2



### Planning

- Selected patient visits hospital, medical team reviews
- Share content with relevant departments
- Requirements reflection, make an intervention plan

3

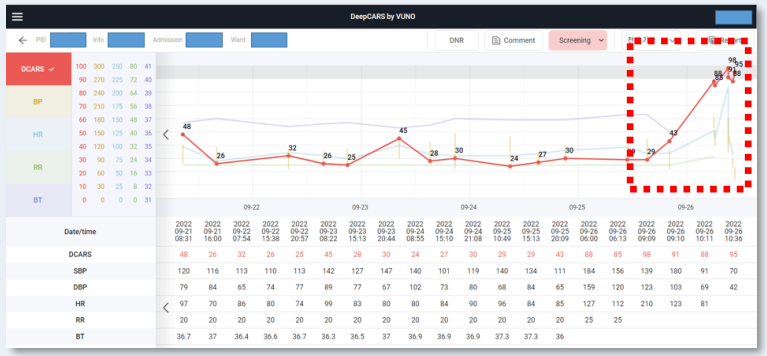


### Exacerbation Intervention

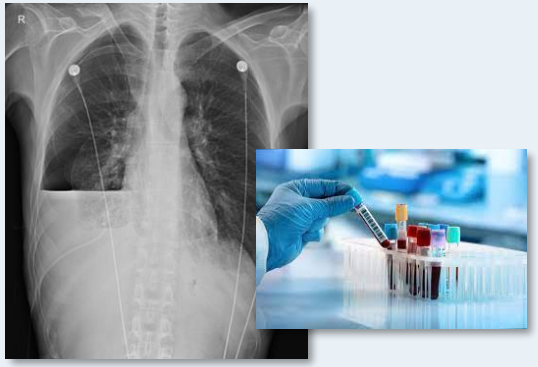
- Provide immediate and appropriate intervention depending on the exacerbation situation (airway management, medication and test formula, CPR etc.)

## • DeepCARS Use Case

① Can check the scores distribution and rate of high-risk patients classified based on the scores set by the DeepCARS




② Exacerbation patient visits a hospital, check symptom and proceed with additional inspections as necessary



③ Take measure to patient
e.g., After confirming signs of acute exacerbation, airway intubation was performed, and the patient was then transferred to the intensive care unit



CHAPTER 02

# VUNO Med-DeepCARS

## • DeepCARS® adoption expectations

### Patients

- Reduced cardiac arrest rates
- Improved outcomes through preventive measures

### Medical Staff

- Early identification of critically ill patients
- Rapid collaboration between healthcare providers

### Hospitals

- Efficient use of healthcare resources
- Help to promote the hospital

## • DeepCARS® pathway to go market




- Innovative Medical Device designated by MFDS (2020. 09)
- MFDS approval (Class II) (2021. 08)
- Designated as a candidate for New Health Technology Assessment (2021. 12)
- Designated as Early Access Innovation Medical Device (2022.05)
- Official Launching (2022.08~)

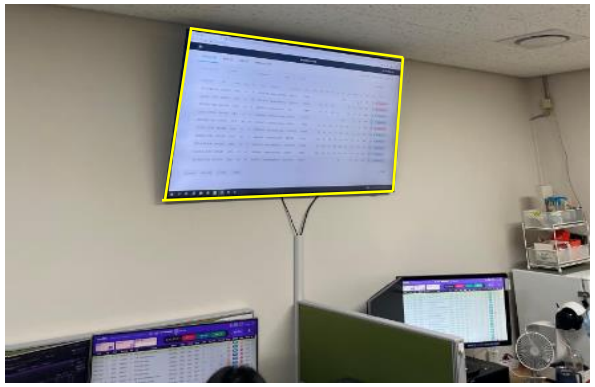
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02

# VUNO Med-DeepCARS

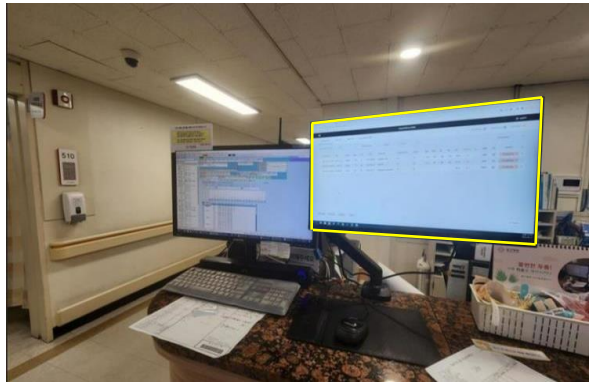
- **80+ hospitals totaling 33,000+ beds have adopted DeepCARS in Korea**
  - **Includes Tertiary Hospital 15, General Hospital 60+ etc.**

## Use in a Medical Emergency Team



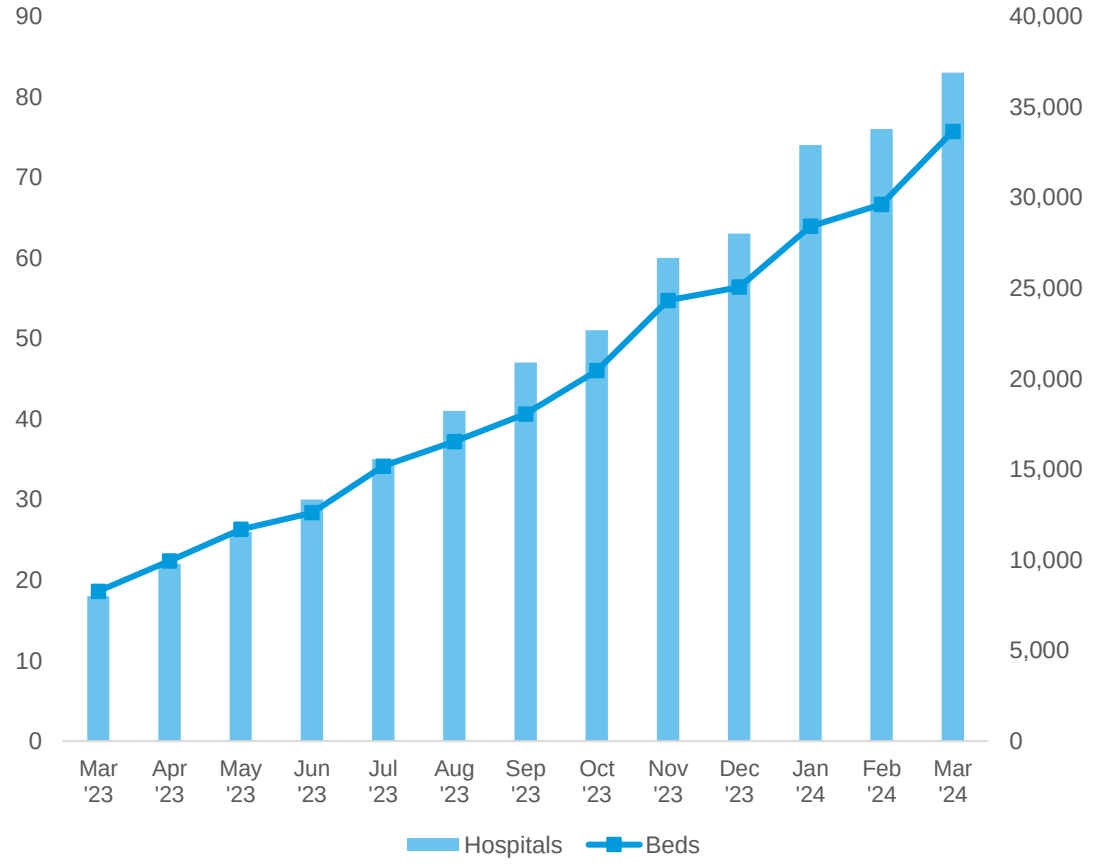


## Use in a Nurses' Station





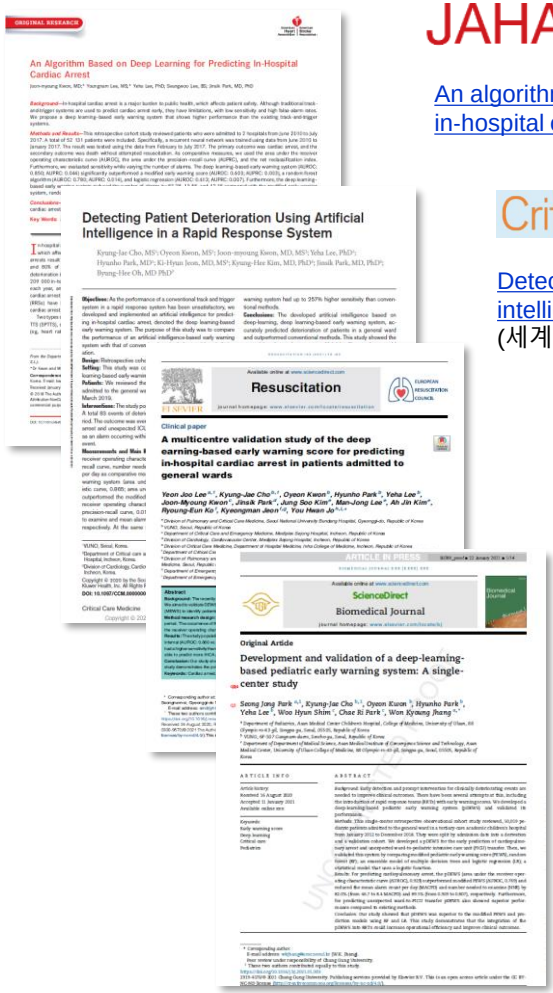
## Number of Hospitals / Beds Monitored



CHAPTER
02

# VUNO Med-DeepCARS

- **Demonstrated superior cardiac arrest prediction performance through clinical publications in Resuscitation, ACC, CCM, etc.**




JAHA

[An algorithm based on deep learning for predicting in-hospital cardiac arrest](#) (미국심장협회, 2018)

Critical Care Medicine

[Detecting patient deterioration using artificial intelligence in a rapid response system](#)
(세계중환자의학회, 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® 서울아산병원 Asan Medical Center

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

ACC 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)

# VUNO Med-DeepCARS

- **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 cardiac arrest on **average 15.78 hours** in advance

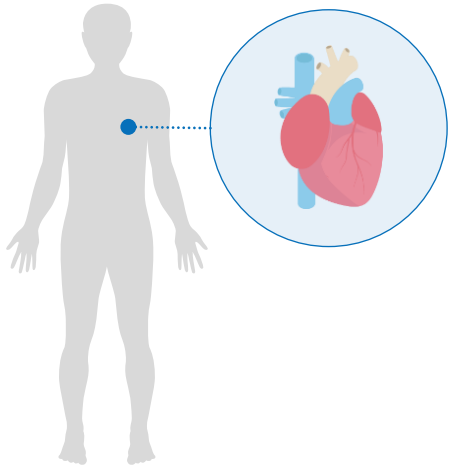


**Applies to all inpatients on general wards**

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

# VUNO Med-Solutions - DeepECG

## Cardiovascular Disease



**1st leading cause of death worldwide[1)]**

- Approximately 17.9 million people die each year from **cardiovascular disease**, 31% of all deaths worldwide
- 2nd leading cause of death in Korea after cancer and 1st in medical expenses
- Increase in cardiovascular complications due to an increase in younger chronic disease patients

Note) World Health Organization, 'The top 10 causes of death'

## ECG test types by number of inductions



**12-Lead**

- Electrocardiography in the Clinical Setting
- High accuracy based on 12-lead ECG
- Difficult to use in daily life due to low portability/convenience



**6-Lead**

- Tests with 12-lead accuracy and the portability, convenience of 1-Lead
- Higher accuracy compared to 1-Lead, suitable for medical diagnostic aids



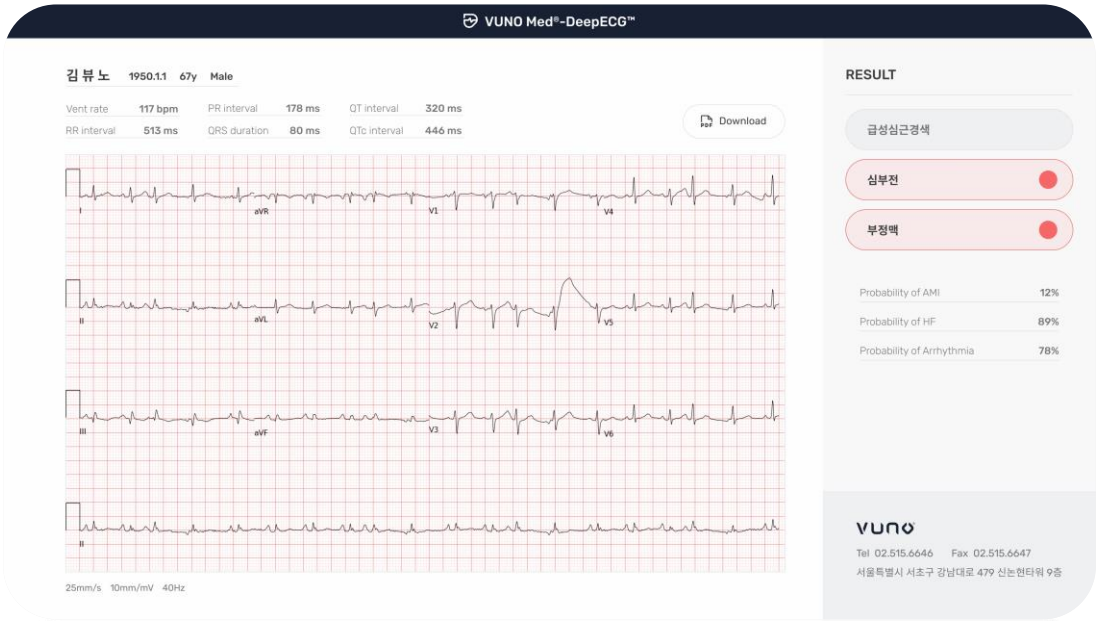

**1-Lead**

- Highly portable and convenient
- Because it uses a 1-Lead electrocardiogram limited information for medical purposes

CHAPTER
03

# VUNO Med-Solutions - DeepECG

## VUNO Med-DeepECG + Hativ ('23.01 Launched)




### AI-BASED ECG ANALYSIS SOLUTION

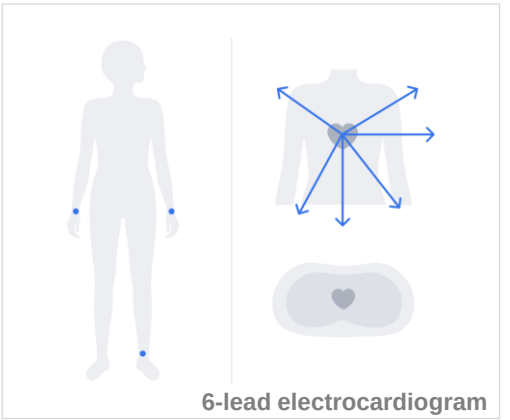
| | |
|---|---|
| **Description** | • Detects abnormalities in patient's ECG data that could indicate cardiovascular and other critical diseases (e.g., chronic kidney disease)<br>• Allows at risk patients susceptible to kidney and heart disease to self-measure and receive early treatment |
| **Method** | • Analyzes ECG data from portable mobile ECGs and other devices |

## Hativ

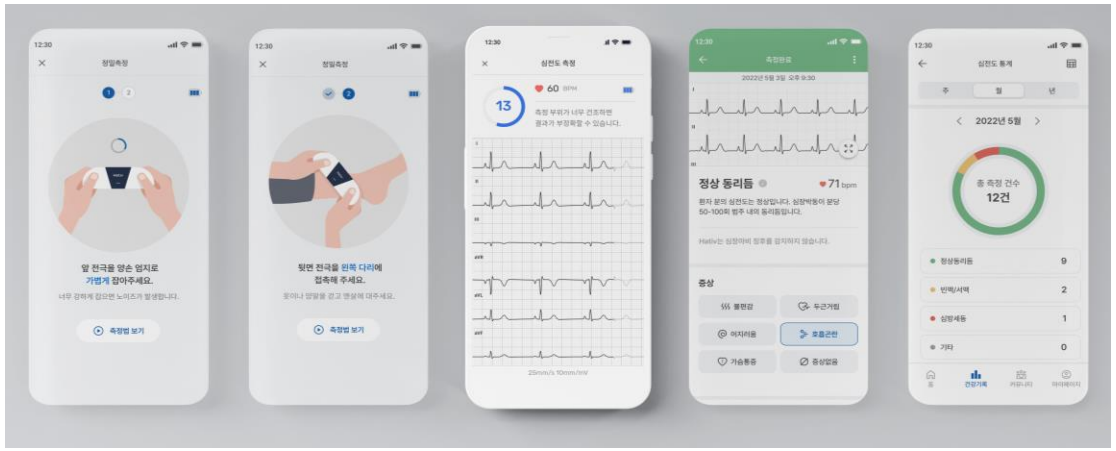
**Portable ECG device to monitor cardiovascular and other critical diseases using AI software to analyze ECG data**

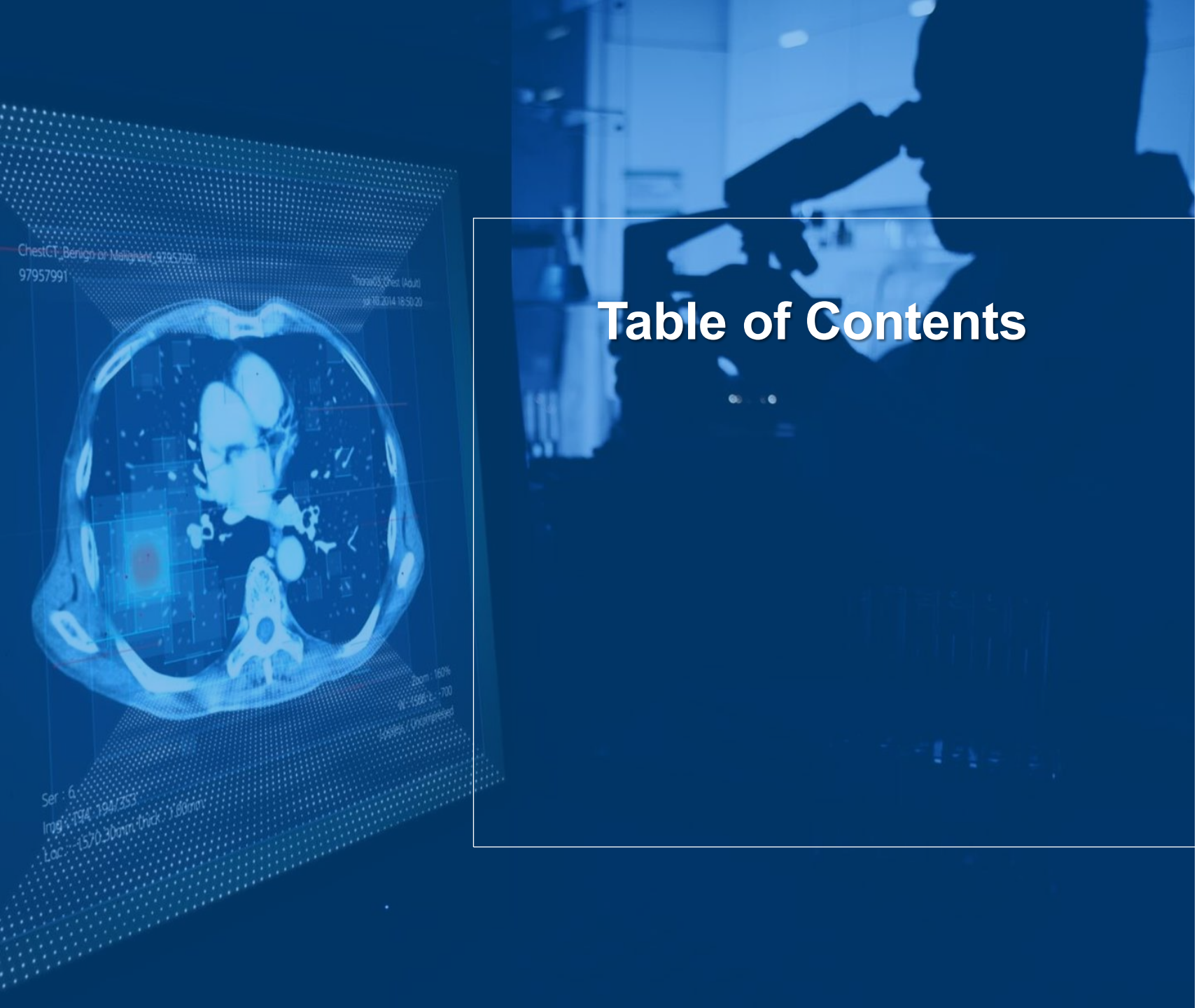
(Arrhythmia, Heart Failure, Myocardial Infarction, Kidney Failure, Hyperkalemia)



6-lead electrocardiogram





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# VUNO Med-Solutions

## VUNO Med-DeepBrain

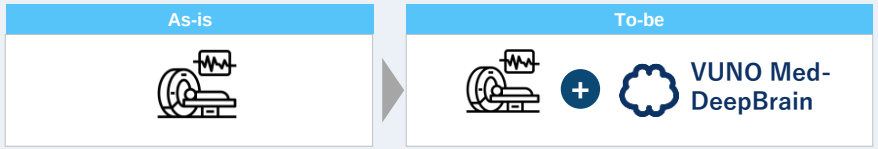


**Brain MRI-based quantification solution**

- Analyzes 3D brain MRI images to provide volumetric data of **104 brain regions** through brain parcellation (brain volumes, cortical thickness, White Matter Hyperintensity(WMH)) **within 1 minute**
- Helps to diagnose **Major neurodegenerative diseases** (e.g mild cognitive Impairment,(MCI) Alzheimer's disease, dementia, etc)

### Neurodegenerative Disease Diagnosis with 3D Brain Images

- **Improves patient satisfaction** and understanding by providing the Brain Atrophy Report with the **statistical analysis results and visualized graphs within 1 minute**



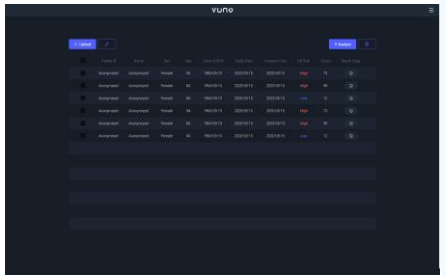

**Regulatory Approval**

Ministry of Food and Drug Safety, CE 2195, FDA ('23.10)

**R&D Partners**

서울아산병원 Asan Medical Center, 분당서울대학교병원 SEOUL NATIONAL UNIVERSITY BUNDANG HOSPITAL

## VUNO Med-DeepBrain AD



**AI Diagnostic Support for Alzheimer's Disease in MRIs**

- **Assist Alzheimer's disease (AD) diagnosis by providing AD risk score calculated from T1 MR image.**
- Allows medical professionals to identify patients with high risk of AD with high accuracy (AUC 0.937) and provide AD Score Report to patient for further consultation needs

* Alzheimer's disease: a degenerative neurological disease in which abnormal proteins accumulate in the brain and brain neurons slowly die, leading to mild cognitive impairment and dementia (7th cause of death in Korea, 7,500 deaths per year)

### World's First Brain MRI-Based Alzheimer's Risk Detection Medical Device

- Approved by MFDS and preparations are underway for commercialization by '24
- Trained on MR T1 images of 3,000 Amyloid PET positive patient scans collected from leading institutions in S. Korea and on Alzheimer's Disease Neuroimaging Initiative (ADNI)'s data
- Expected to be widely used in the diagnosis of Alzheimer's disease in the future (domestically & overseas)

**Regulatory Approval**

Ministry of Food and Drug Safety

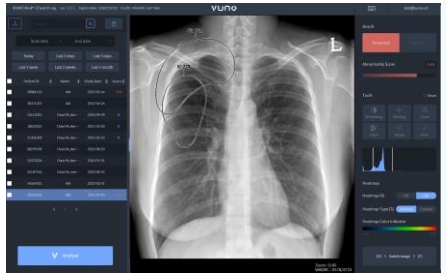
**R&D Partner**

분당서울대학교병원 SEOUL NATIONAL UNIVERSITY BUNDANG HOSPITAL

CHAPTER 03

# VUNO Med-Solutions

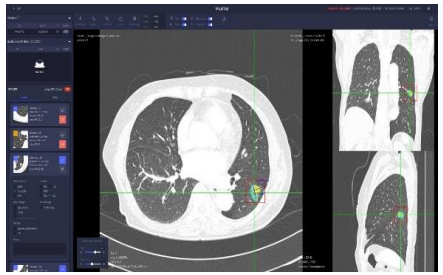
## VUNO Med-Chest X-ray



### AI Diagnostic Support for Abnormalities in Chest X-Rays

- Instantly detects and flags **five chest abnormalities (Nodule/Mass, Consolidation, Interstitial Opacity, Pleural Effusion, Pneumothorax),** which are indicative of **major pulmonary diseases (inc. TB & Pneumonia)** from chest X-ray images.
- Provides information on findings of chest related abnormalities, abnormality scores as well as their locations, maximizing the reading accuracy and efficiency of radiological reporting [1]

## VUNO Med-LungCT AI



### Detection of Pulmonary Nodules in Chest CTs

- Detects the presence, types and locations of pulmonary nodules, and predicts lung-RADS (malignancy) score.
- The **super-resolution algorithm** optimizes nodule detection performance and enhances CT images.
- Provides physicians with proofreading tool for false negatives; detected 269 nodules in 9,952 cases reported as normal [2]

### B2B expansion to X-ray equipment companies

- **Embedded into X-Ray equipment** e.g., Samsung Electronics (Portable X-Ray Machines) and Vieworks (X-Ray Detector)
- Sustained sales channel expansion in domestic and overseas markets

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

**Regulatory Approval**

Ministry of Food and Drug Safety · CE 2195 · FDA

**R&D Partners**

서울아산병원 Asan Medical Center · 분당서울대학교병원 SEOUL NATIONAL UNIVERSITY BUNDANG HOSPITAL

### Focus on Japan and U.S. markets

- **Japan : Won reimbursement in Japan (Since Jan '24)**
  1st **PMDA approval in S. Korea +** Japan's health authority (MHLW) decides to give insurance reimbursement (Since Jun '23)
  Collaborates with Japan's **largest medical data company, M3**
- **U.S. : Clinical trial* with MGH (Massachusetts General Hospital) underway,** currently pre-marketing in the U.S. Office located in Boston

* Clinical trial - Expected to be completed in **late '24**

**Regulatory Approval**

Ministry of Food and Drug Safety · CE 2195 · Pmda

**R&D Partners**

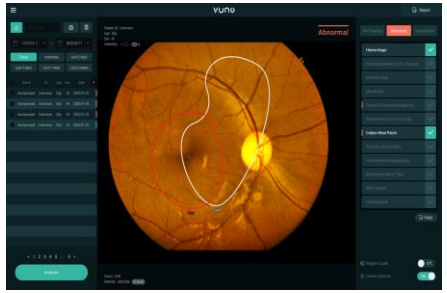
서울아산병원 Asan Medical Center · SAMSUNG 강북삼성병원 · MASSACHUSETTS GENERAL HOSPITAL

1) Added Value of Deep Learning–based Detection System for Multiple Major Findings on Chest Radiographs: A Randomized Crossover Study, Radiology. 2021. Mar.
2) A Deep Learning-Based CAD that Can Reduce False Negative Reports: A Preliminary Study in Health Screening Center, RSNA 2019

CHAPTER
03

# VUNO Med-Solutions

## VUNO Med-Fundus AI



**AI Screening Solution for Fundus Images / Abnormalities**

- Diagnostic support on common ocular diseases based on detection of **12 retinal findings** associated with diagnosis of vision-threatening ocular diseases(e.g DR, Glaucoma, etc)
- Automatically detects the location of macula and optic disc and labels the **8 regions of the fundus**
- Korea's **1st innovative medical device** (Class Ⅲ)

### Accurate & Time-Saving Interpretation Assistance for Fundus Images

- Accurately detects and locates (AUROC = 95% and above) fundus abnormalities.
- Trained on **100,000+ fundus images by 57 Ophthalmologists**
- Increase market penetration through collaboration with **pharmaceutical and biotechnology companies** such as eye care products to target internal medicine / checkup centers

**Regulatory Approval**

Ministry of Food and Drug Safety · CE 2195

**R&D Partners**

분당서울대학교병원 SEOUL NATIONAL UNIVERSITY BUNDANG HOSPITAL

## VUNO Med-BoneAge



**Automatic BoneAge Assessment in Hand X-Rays**

- Korea's 1st AI Medical Device
- Provides bone age assessment based on the 3 most likely candidates for bone age results, probability (%) and provides the AI based bone age → **Improved accuracy and efficiency compared to traditional bone age method**
- Improved quality of patient care with comprehensive "Key Growth & Development' report

### Deep-Learning Based Instant Bone Age Assessment

- Bone age estimates skeletal maturity, typically based on X-ray of the left hand of a child to assess if their development is within the normal range.
- Evaluates how fast or slowly a child's skeleton is maturing, which it can be used to predict: when a child will enter puberty, the child's ultimate height etc.
- Can be used to monitor treatment of kids with conditions that affect growth such as growth hormone levels, 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



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# Conclusion







**Solutions that are Medically Necessary for your customers**

**Solutions that are economically beneficial to customers**

**Solutions that are effectively communicated to customers**

**VUNO's Business Approach**

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