

COMPANY PROFILE

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

2024.1Q

VUNO

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

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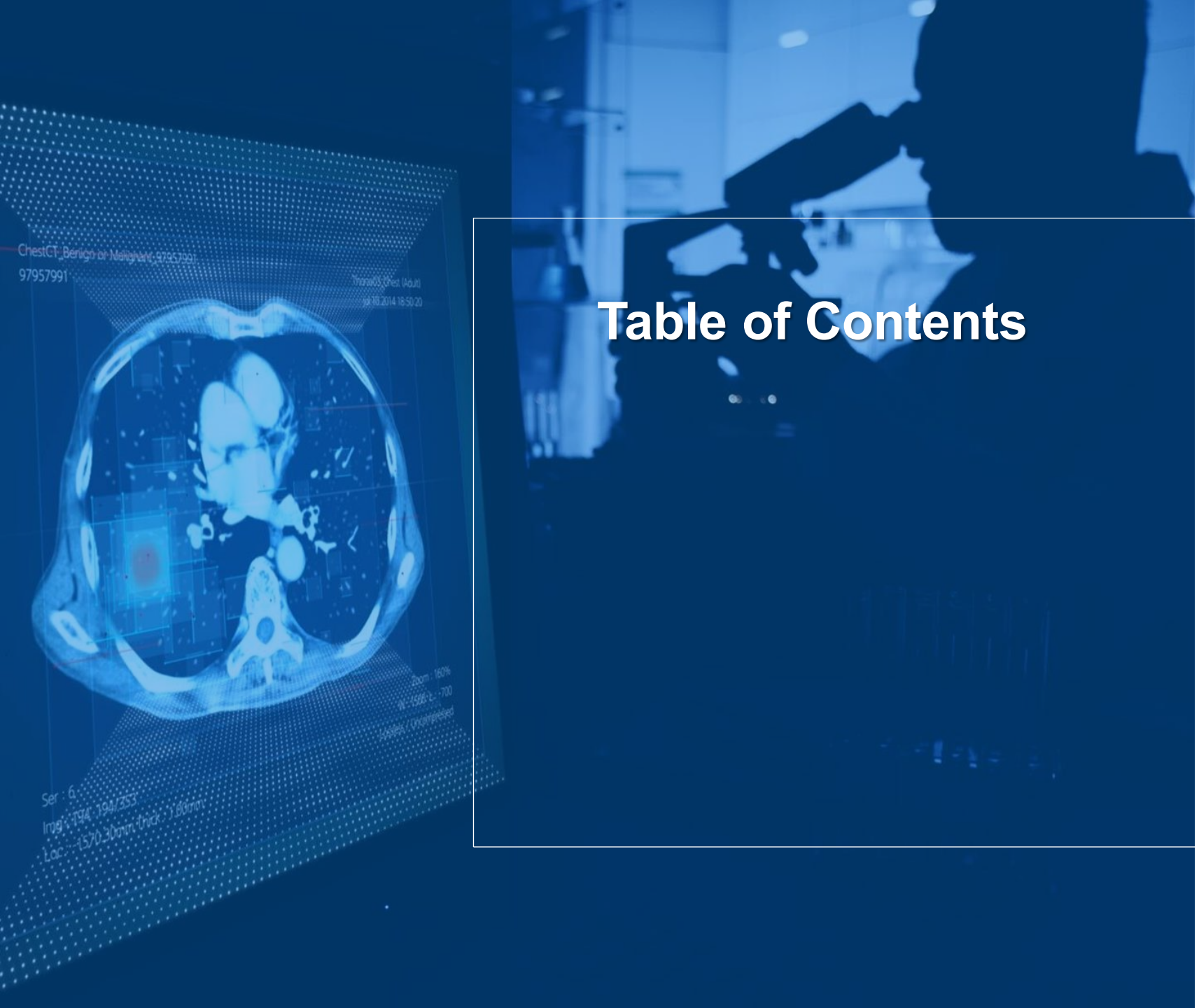


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CHAPTER 01

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

700+ 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

식품의약품안전처 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**

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

• Income Statement

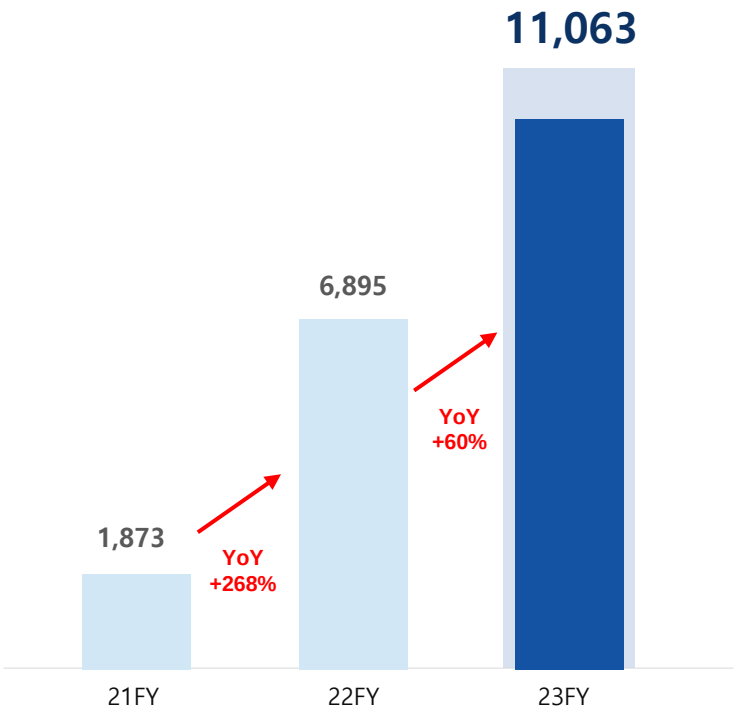
(Unit: USD 1,000)

Type	'21 FY	'22 FY	'23 FY	YoY
Revenue	**1,873**	**6,895**	**11,063**	**60%**
Operating Expense	16,545	19,065	23,049	
Operating Loss	(14,672)	(12,170)	(11,986)	△2%
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)**	**(11,945)**	**△4%**

Note1) Based on unaudited separate income statement
Note2) Exchange Rate: 1 USD=1,200 KRW

• Revenue

(Unit: USD 1,000)



CHAPTER 01

Company Overview – '23 FY Review (YoY, QoQ)

• Income Statement

(Unit: USD 1,000)

Type	'23.3Q	'23.4Q	QoQ	'22.4Q Note3)	'23.4Q	YoY
Revenue (Included one-time revenues)	**2,973**	**4,105**	**38%**	**5,271**	**4,105**	**△22%**
Revenue Note3-2) (Excluded one-time revenues)				**3,188**		**29%**
Operating Expense	4,512	6,778		4,476	6,778	
Operating Loss	(1,539)	(2,673)	**74%**	796	(2,673)	**△436%**
Non-Operating Revenue	**(99)**	**(2,478)**		**(207)**	**(2,478)**	
Financial Income	88	63		58	63	
Other Income	24	646		(8)	646	
Non-Operating Expense	211	3,187		256	3,187	
Net Loss	**(1,638)**	**(5,151)**	**215%**	**589**	**(5,151)**	**△975%**

Note1) Based on unaudited separate income statement
Note2) Exchange Rate: 1 USD=1,200 KRW
Note3) One-time increase in revenues due to the conclusion of a business transfer agreement.
Note3-1) Company name: PuzzleAI(Unlisted Company) / Object of transfer: VUNO Med®-Deep ASR™ / puzzle-ai.io
Note3-2) Contract amount: USD 2,083 Thousand (KRW 2.5 Billion)



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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

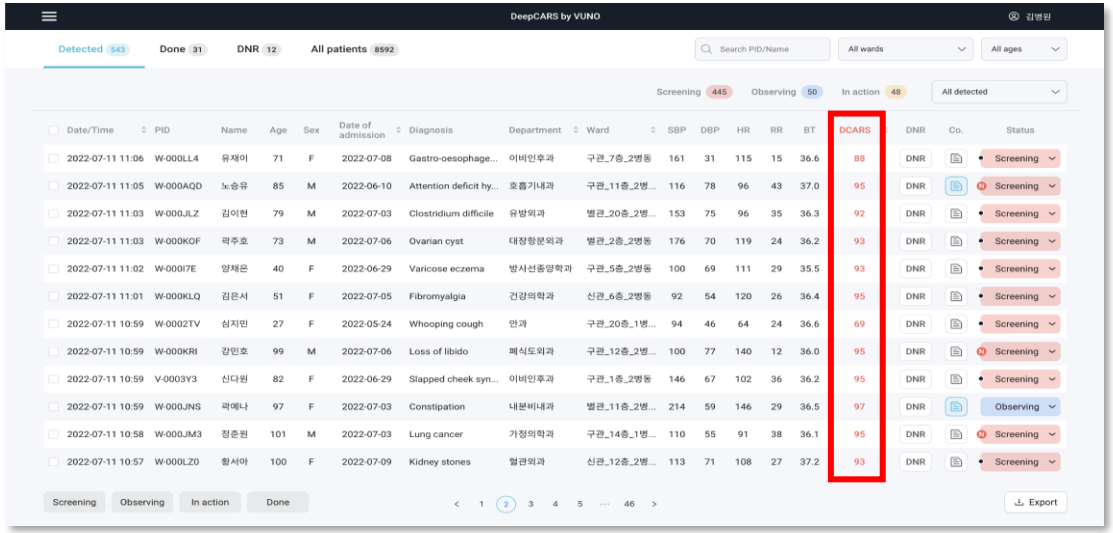
68%

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

Description	Predicts the risk of cardiac arrest **within 24 hours for general ward inpatients**
Indications	The VUNO Med®-DeepCARS™ is intended for use in helping identify **general ward patients** at a high risk of cardiac arrest
Mechanism	• Uses **4 vital signs (blood pressure, HR, respiratory rate, body temperature)** collected from collected from the electronic medical record (EMR) • Provides a risk score from zero 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

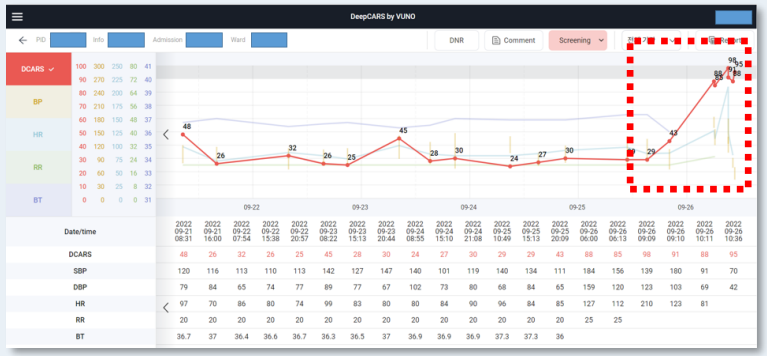


Exacerbation Intervention

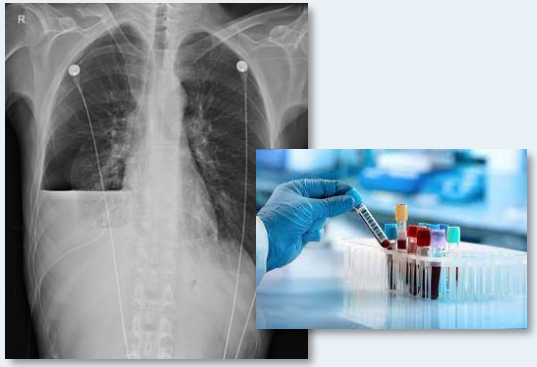
- Provide immediate and appropriate intervention depending on the exacerbation situation (airway management, medication and test formula, CPR etc.)

• 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~)

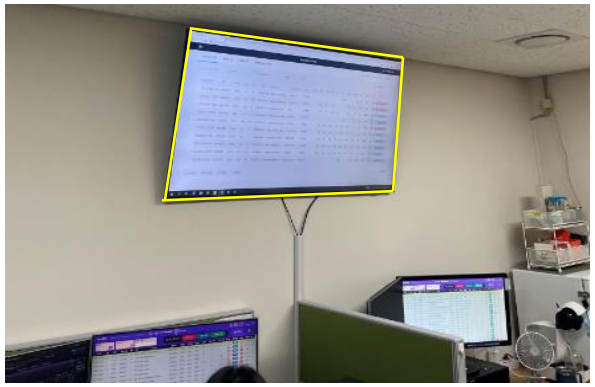
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VUNO Med-DeepCARS

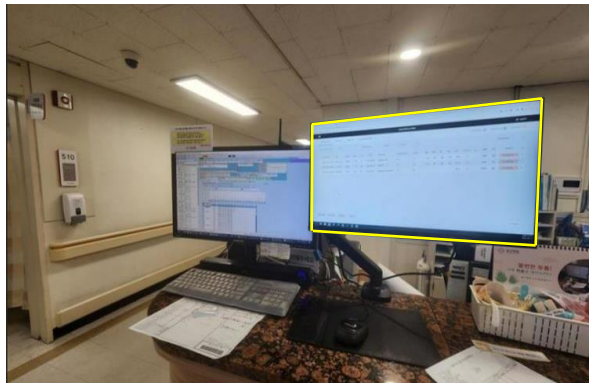
- **70+ hospitals totaling 28,000+ beds have adopted DeepCARS in Korea**
  - **Includes Tertiary Hospital 13, General Hospital 50 etc.)**

Use in a Medical Emergency Team



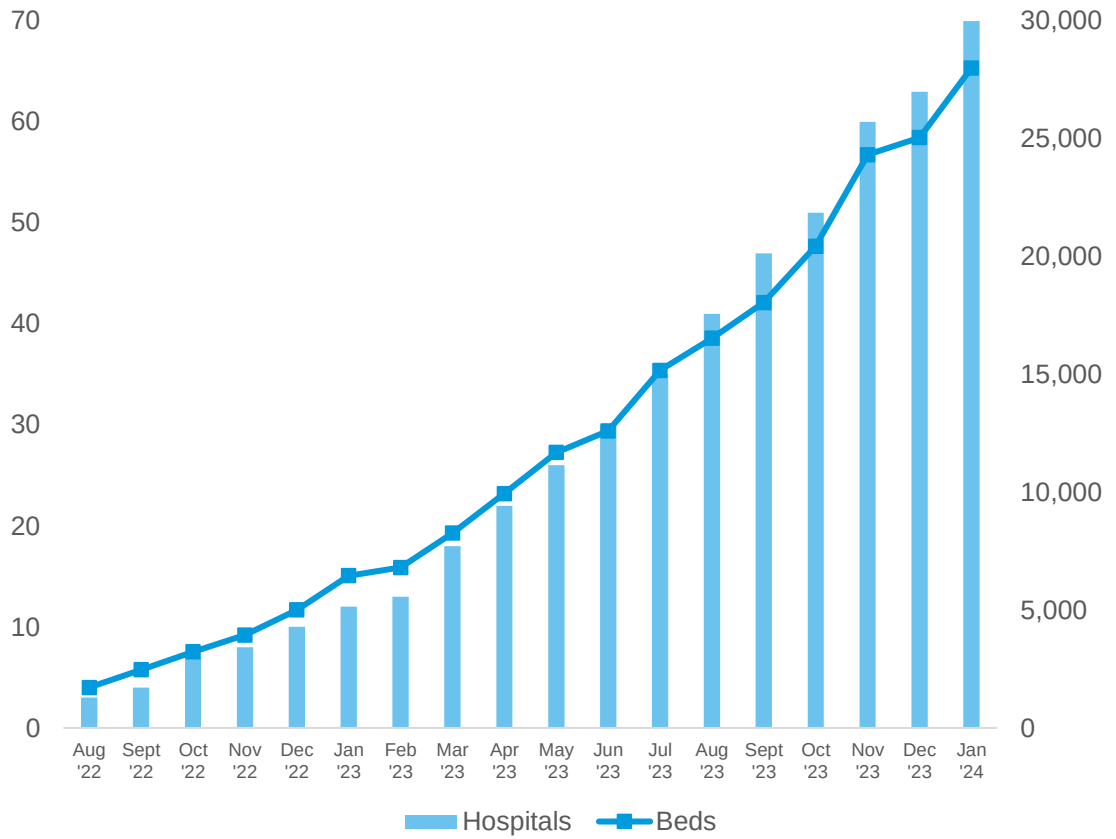


Use in a Nurses' Station





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](#) (JAHA, 2018)

Critical Care Medicine

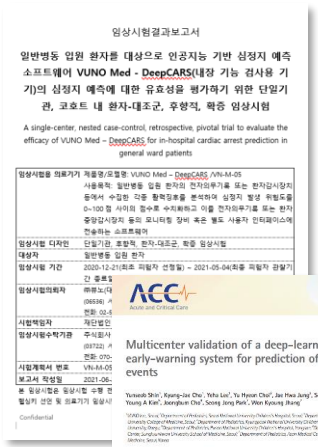
[Detecting patient deterioration using artificial intelligence in a rapid response system](#)
(CCM, 2020)

RESUSCITATION
OFFICIAL JOURNAL OF THE EUROPEAN RESUSCITATION COUNCIL

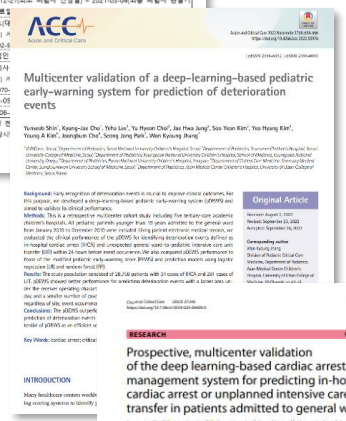
[A multicenter validation study of the deep l earning-based early warning score for pred icting in-hospital cardiac arrest in patients admitted to general wards](#)
(RESUSCITATION, 2021)

Biomedical Journal

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

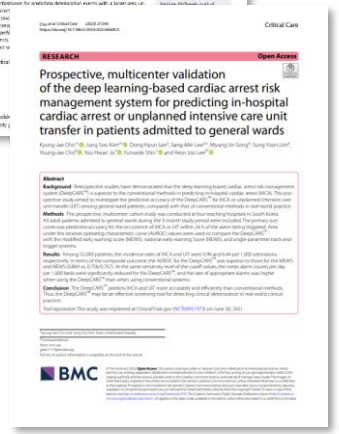


VUNO Med – DeepCARS의 심정지 예측에 대한 유효성을 평가하기 위한 단일기관 임상시험
(Clinical trial result by MFDS, 2021)



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)

CHAPTER 02

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**

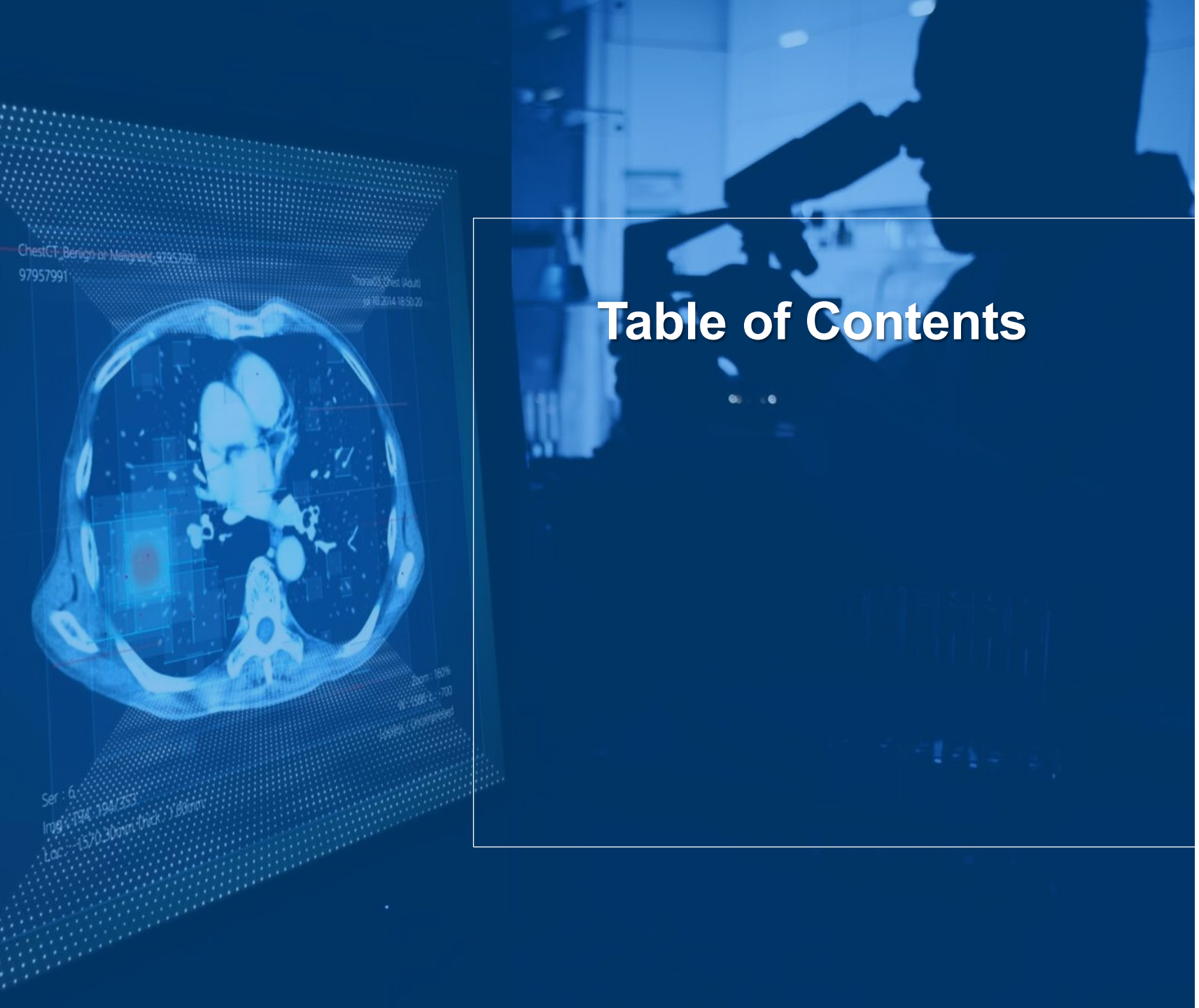


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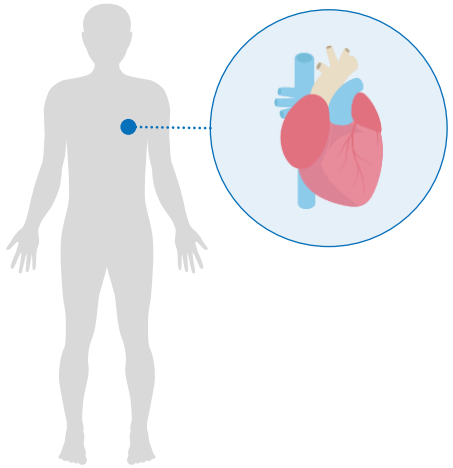
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CHAPTER 03

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 1) 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



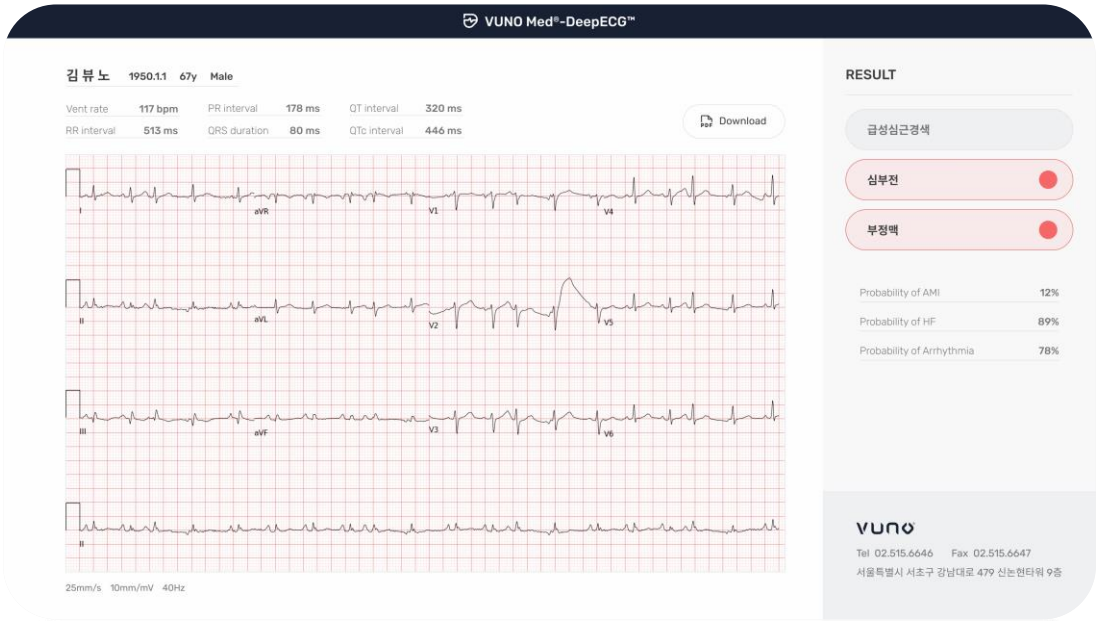
1-Lead

- 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

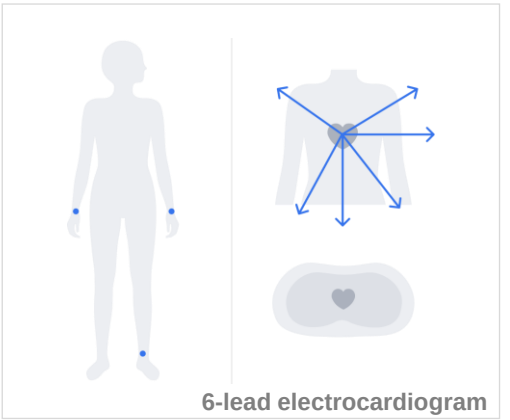
Description	• Detects abnormalities in patient's ECG data that could indicate cardiovascular and other critical diseases (e.g., chronic kidney disease) • Allows at risk patients susceptible to kidney and heart disease to self-measure and receive early treatment
Method	• Analyzes ECG data from portable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

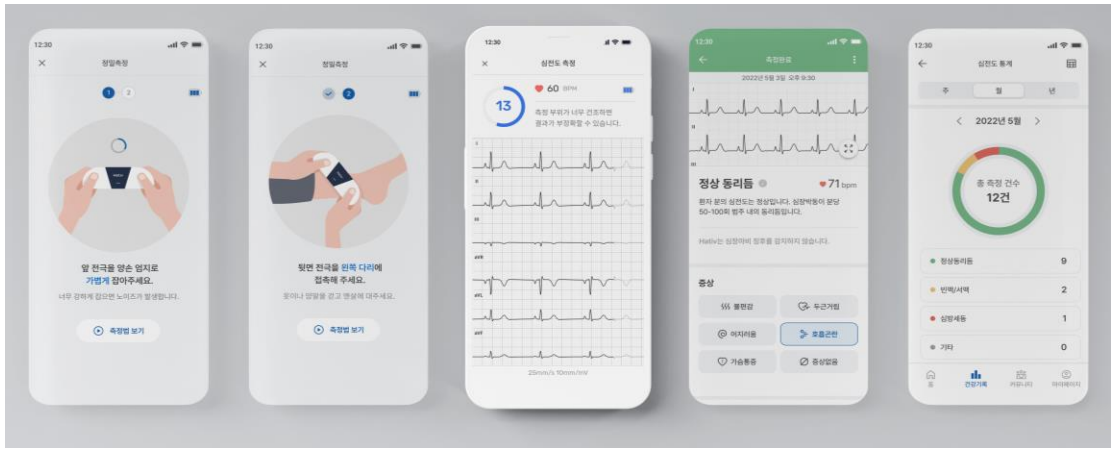
Hativ

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)





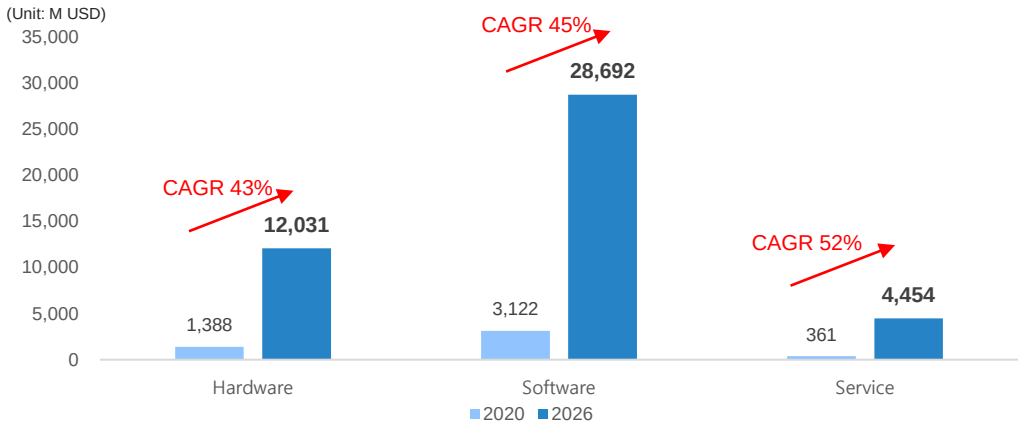


CHAPTER 03

VUNO Med-Solutions - Medical Imaging Market

• **Global AI in Healthcare Market Size : ('20) 4.86 Bil USD → ('26) 45.17 Bil USD (Total Market CAGR 47%)**

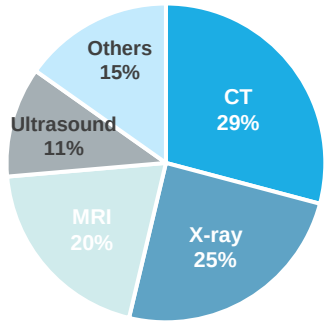
Global Market Size AI in AI Medical Diagnosis



Ratio of AI Medical Diagnosis by Product

(Unit: M USD)

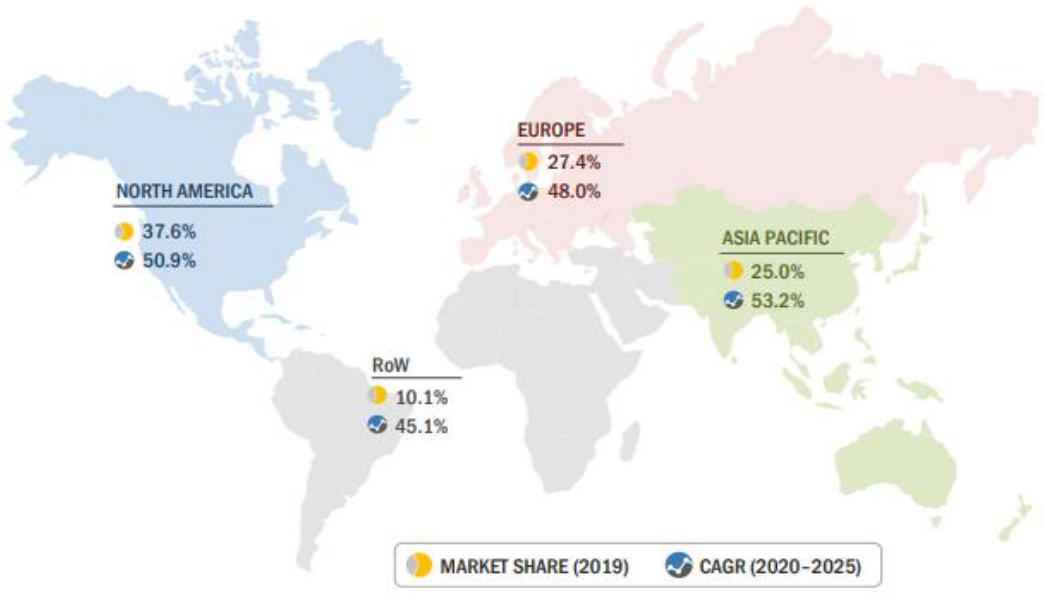
Modality	2019	2020	2025
CT	96.4	132.2	1,087.2
X-ray	86.3	117.2	918
MRI	73.9	99.6	743.1
Ultrasound	43.2	57.8	416.6
Others	62.4	82.5	567.7
Total	362.2	489.4	3,732.6



Note) VUNO has CT, X-ray and MRI

Source) Markets&Markets, Artificial Intelligence in Healthcare Market, 2020

Global Market Ratio in AI Medical Diagnosis



- **The global market size is increasing at an accelerated pace due to development of medical AI**
- **North America market is growing at a share of 37.6% and a CAGR of 50.9%**

Source) Markets&Markets, Artificial Intelligence in Healthcare Market, 2020

CHAPTER 03

VUNO Med-Solutions

VUNO Med-DeepBrain

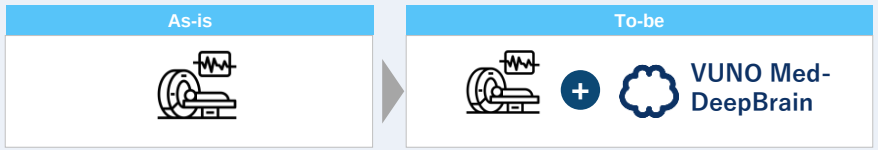


Brain MRI-based quantification solution

- 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**



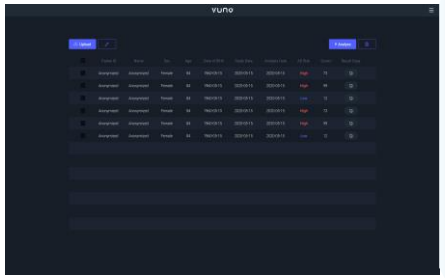
Regulatory Approval

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

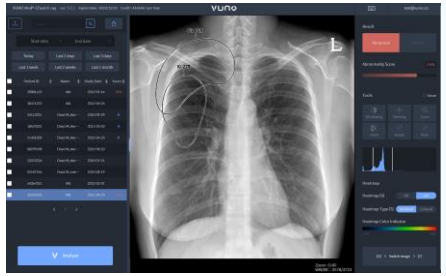
R&D Partner

분당서울대학교병원 SEOUL NATIONAL UNIVERSITY BUNDANG HOSPITAL

CHAPTER 03

VUNO Med-Solutions

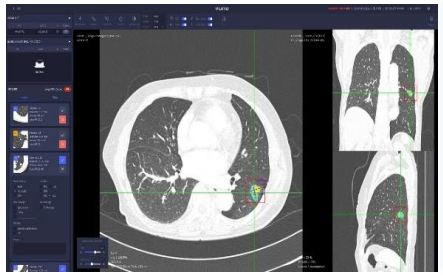
VUNO Med-Chest X-ray



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)

SAMSUNG · VIEWORKS · DIGIRAY · LG Household & Health Care · rayence · MeVis

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 :** Wins reimbursement in Japan (Since Jan 15th '24)
  1st **PMDA approval in S. Korea +** Japan's health authority (MHLW) decides to give insurance reimbursement (Since Jun 22nd '23)
  VUNO 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

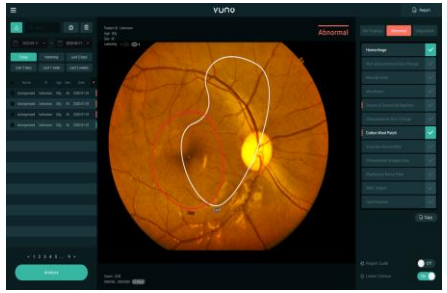
서울아산병원 Asan Medical Center · SAMSUNG 강북삼성병원 · MASSACHUSETTS GENERAL HOSPITAL

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

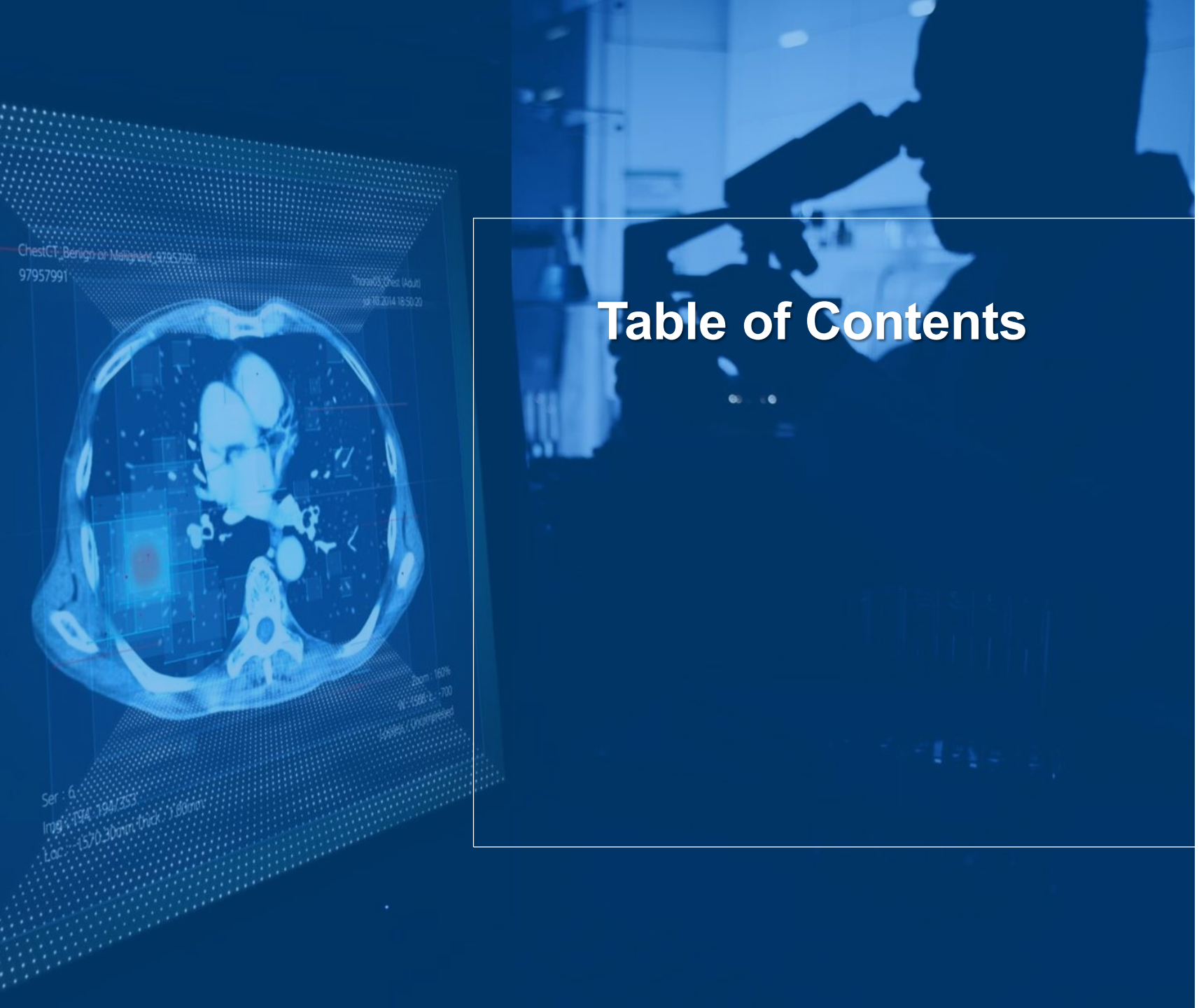


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Conclusion







Solutions that are Medically Necessary for your customers

Solutions that are economically beneficial to the customer

Solutions that are effectively communicated to customers

VUNO's Business Approach

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