



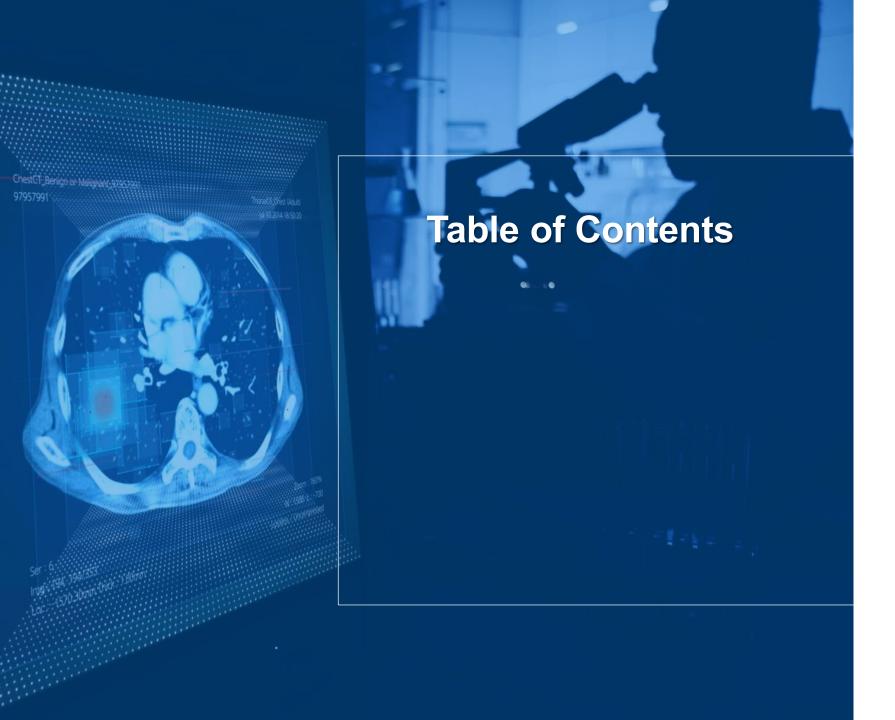


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Please note that the forward-looking statements contained in this document relates to future events, not the past, and is inherently subject to uncertainty, and may not correspond to the company's actual operating results due to uncertainties such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



**CHAPTER 01** 

**Company Overview** 

**CHAPTER 02** 

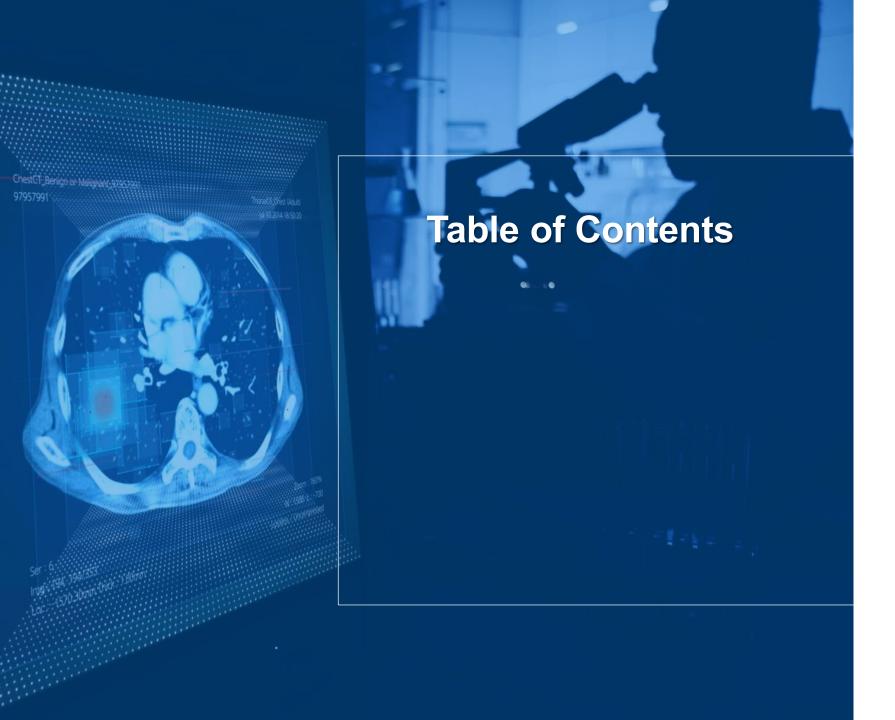
**VUNO-Bio Signal Solutions** 

**CHAPTER 03** 

**VUNO-Medical Imaging Solutions** 

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Conclusion



#### **CHAPTER 01**

### **Company Overview**

CHAPTER 02 VUNO-Bio Signal Solutions

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# **Company Overview**

# In full-fledged deployment

**VUNO Med®** 

Nationally recognized healthcare Al solutions

MFDS approved medical Al device

Innovative medical device

10 Ready to use solutions



**1,000+** Hospitals

100+ Publications

100+ Patents

Global network of collaborations

**Extensive Network** of Global Partners













































# **Company Overview**



VUNO

**Established** 2014.12

**Building R&D Foundation**  $(2015<math>\sim$ )

#### 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** $(2018 \sim)$

#### 2018

05. Designated as 1st Al 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 Al
- 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 22<sup>nd</sup> Innovative Medical Device VUNO Med-LungCT Al

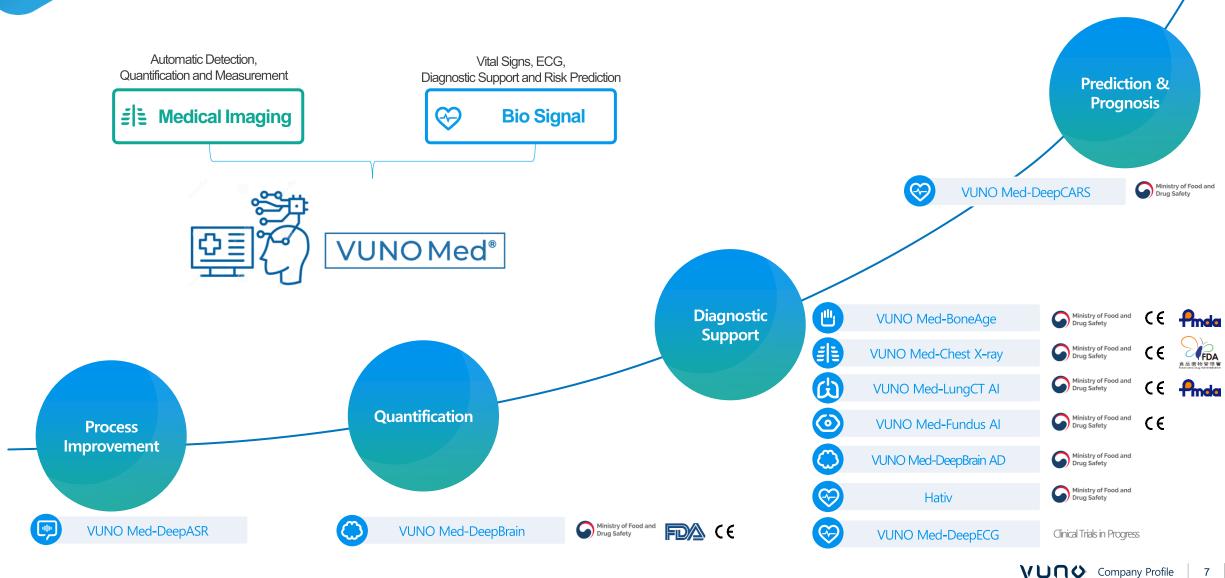
#### 2023

- 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 Al
- 03. Expanded European market of VUNO Med-Chest X-ray
- 04. Received an integrated review of innovative medical devices VUNO Med-Fundus Al

# **Company Overview**

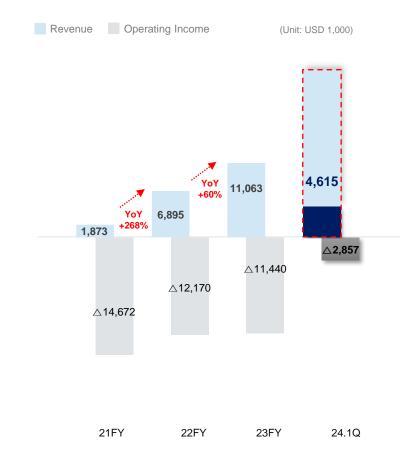


# **Company Overview – Financial review**

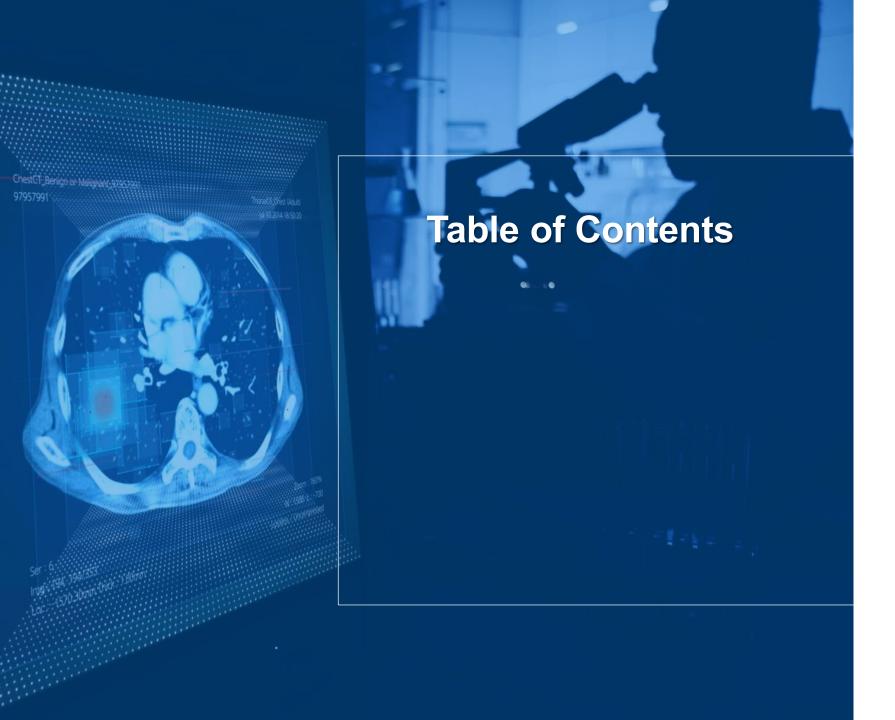
- Achieved USD 4.6 million in revenue, with earnings growing by QoQ +12%, YoY +212%
- Stable SaaS structure and continued expansion of hospitals using DeepCARS etc.

<u>Separate</u>	2023				2024
Income Statement (Unit: USD 1,000)	1Q	2Q	3Q	4Q	1Q
Revenue	1,480	2,505	2,973	4,105	4,615
DeepCARS	1,000 (67.6%)	1,574 (62.8%)	2,199 (74.0%)	3,115 (75.8%)	3,724 (80.7%)
Medical Imaging	308 (20.8%)	302 (12.1%)	469 (15.8%)	625 (15.2%)	443 (9.6%)
Hativ and Server etc.	172 (11.6%)	310 (12.3%)	305 (10.2%)	342 (8.4%)	434 (9.4%)
Others	-	319 (12.8%)	1 (0.0%)	23 (0.6%)	14 (0.3%)
Operating Expense	4,815	6,944	4,512	6,232	7,472
Operating Income	△3,334	△4,440	△1,539	△2,127	△2,857
Net Income	△3,324	△1,832	△1,638	△4,605	△2,884
EBITDA	△3,047	△4,154	△1,225	△1,832	△2,557

Q1		
QoQ	YoY	
+12.4%	+211.8%	
+19.6%	+272.3%	
-29.1%	+43.9%	
+26.8%	+152.7%	
-39.5%	-	
+19.9%	+55.2%	
+34.3%	-14.3%	
-37.4%	-13.2%	
+39.6%	-16.1%	



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



CHAPTER 01
Company Overview

#### **CHAPTER 02**

**VUNO-Bio Signal Solutions** 

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In-hospital Cardiac Arrest (IHCA)

**3,600** cases<sup>1</sup>



Severe Shortage of Medical Staff

BP HR RT BT

Warning Signs/ Early symptoms

**80%**<sup>2</sup> (2,880)



**IHCA Death** 

**75%**<sup>3 (2,700)</sup>

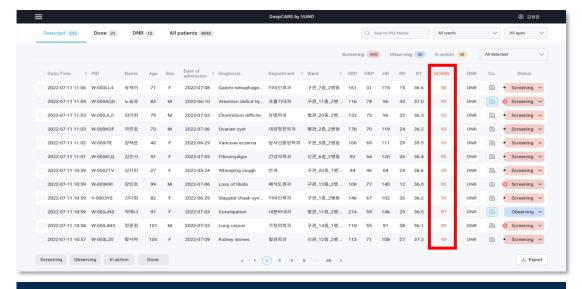


A Lack of Effective Track-and-Trigger System

68% Avoidable IHCA

Overcoming the limitations of traditional methods with Al

Efficient management with fewer false alarms, higher sensitivity and specificity by using Al model



## Al-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	<ul> <li>Uses 5 vital signs* and age/vital sign recorded time collected from the electronic medical record. (EMR)</li> <li>* S/D Blood Pressure, Heart Rate, Respiratory Rate, Body Temperature</li> <li>Provides a risk score from 0 to 100.</li> </ul>	
	(The higher score the higher risk)	

<sup>1)</sup> Crit Care Med. 2012;39:2401-2406

<sup>2)</sup> Resuscitation. 2004;62(3):275-282. doi:10.1016/j.resuscitation.2004.05.016

<sup>3)</sup> JAMA 2019;321(12):1200-1210

<sup>4)</sup> Resuscitation. 2002 Aug;54(2):115-23



#### Select risky-patient

- Check the rate of high-risk patients classified by DeepCARS.
- Notify to medical team.



#### **Planning**

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

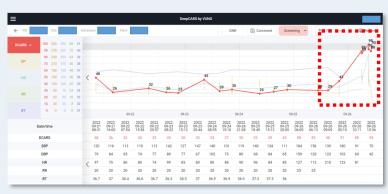


#### Do an Intervention

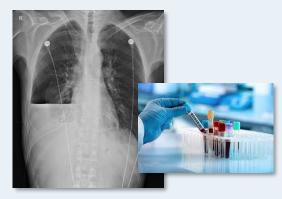
 Provide an intervention depending on the situation. (Airway management, CPR etc.)

### DeepCARS Use Case

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



Patient visit a hospital, check symptom and proceed with additional inspections as necessary.



- 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.



DeepCARS® adoption expectations



- Reduced cardiac arrest rates
- Improved outcomes through preventive measures



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



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

# • DeepCARS® pathway to go market



- **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)

- (Apr. '24) 85 hospitals totaling 34,000+ beds have adopted DeepCARS in Korea
- Includes Tier 1 Hospitals 15, Tier 2 Hospitals 70 etc.

# Use in a Medical Emergency Team

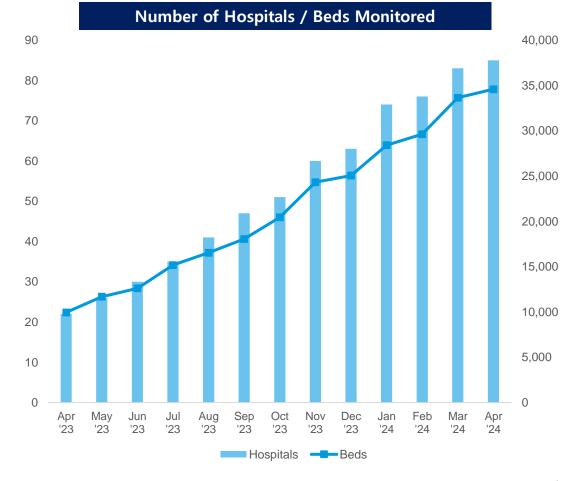




#### Use in a Nurses' Station







- Demonstrated superior cardiac arrest prediction performance through global clinical publications
- Resuscitation, JAHA, 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 (Critical Care Medicine, 2020)



A multicenter validation study of the deep learni ng-based early warning score for predicting in-h ospital cardiac arrest in patients admitted to ge neral 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)



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



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 inhospital cardiac arrest in patients admitted to general ward on operating and non-operating time of rapid response system

(Critical Care Medicine, 2024)



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 in general wards

No difference in sensitivity by age, gender, or specialty

#### **Korea Market Size**

- Number of total average general ward beds in Tier 1 & Tier 2: 1,251
- ① Number of average general ward beds in Tier 1: 941
- 2 Number of average general ward beds in Tier 2: 310
- Number of total general ward beds in Tier 1 & Tier 2: 139,964
- ① Tier 1 (45 Hospitals): 41,161
- ② Tier 2 (319 Hospitals): 98,803
- Formula of annual market size

Number of general ward × Circulation rate of general ward (Approx. 90%) × 365 days × Price

- Annual market size with price assumptions of KRW 7,000 \*
- \* Based on per day / per person / per bed

Туре	Annual Market Size (KRW)	Annual Market Size (USD) Note)
Tier 1	KRW 94.5 billion	USD 78.8 million
Tier 2	KRW 202.0 billion	USD 168.3 million
Total	KRW 296.5 billion	USD 247.1 million

#### **Global Market Size**

Annual market size with price assumptions

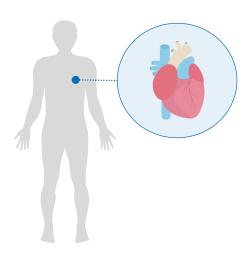
Global market size was estimated based on annual Korea market size.

It was estimated using market coefficients applied by global medical device companies.

Country	Annual Market Size (USD) Note)	
North America	USD 2,320 million	
EMEA	USD 2,195 million	
APAC (Excluding China)	USD 387 million	
LATAM	USD 574 million	
Total	USD 5,476 million	

# **VUNO Med-Solutions – DeepECG + Hativ**

#### **Cardiovascular Disease**



#### 1<sup>st</sup> leading cause of death worldwide Note)

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

### **ECG Test Types by Number of Inductions**



- Electrocardiography in the clinical setting.
- High accuracy based on 12-lead ECG.
- Difficult to use in daily life due to low portability and convenience.



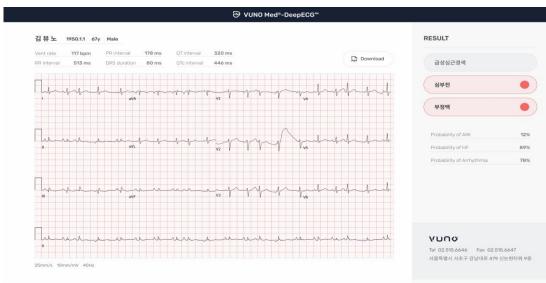
- Tests with 12-lead accuracy and the portability, convenience of 1-lead.
- Higher accuracy compared to 1-lead, suitable for medical diagnostic aids.



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

# **VUNO Med-Solutions – DeepECG + Hativ**

### **DeepECG**



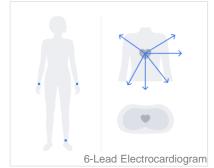
#### **AI-Based ECG Analysis Solution**

#### · Provide diagnostic support on the detection of cardiovascular diseases and kidney disease. **Description** Allows at risk patients susceptible to kidney and heart disease to self-measure and receive early treatment. Analyzes ECG data from portable mobile ECGs and Method other devices. Can detect to arrhythmia. · Preparing to expand to Disease 1 Myocardial Infarction, Heart Failure in '24. 2) Hyperkalemia, Chronic Kidney Disease in '25.

#### **Hativ**

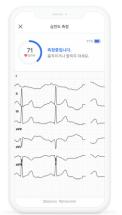
- Medical-grade portable ECG device.
- · Monitor to cardiovascular diseases and kidney disease using AI software to analyze ECG data.
- Approved medical device for myocardial infarction detection Al software.
  - → Plan to connect the Hativ with Myocardial Infarction Al software.





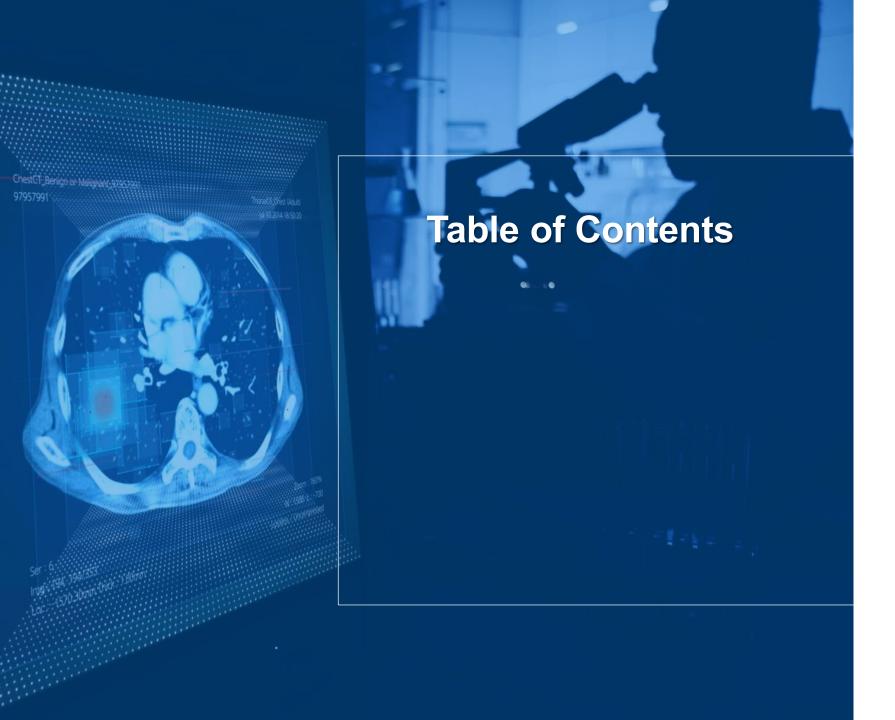












#### **CHAPTER 03**

**VUNO-Medical Imaging Solutions** 

### **VUNO Med-Solutions**

### **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
- Allows **PACS** integration.

# VUNO Med-DeepBrain AD



### Al 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)
- Provide **score report** to patient for further consultation needs.

### **Deep Learning-based Brain Parcellation and Atrophy Quantification**

 Improves patient satisfaction and understanding by providing the brain atrophy report with the statistical analysis results and visualized graphs within 1 minute.











To-be







#### MRI-Based Alzheimer's Risk Detection Medical Device

- Preparations are underway for commercialization by 2024.
- Utilized MR images collected from more than 3,000 patients.
- Expected to be widely used in the diagnosis of Alzheimer's disease in the future.





### **VUNO Med-Solutions**

### **VUNO Med-Chest X-ray**





#### Al Diagnostic Support for Abnormalities in Chest X-Ray

- Detects presence of 5 lung abnormalities Note1), abnormality score and location.
- Allows **PACS** integration.
- 98% accuracy in image-wise classification of normal or abnormal.
- Reduced reading time by more than 50%. Note2)

Can be embedded into X-Ray devices. (Portable X-ray machines and detector)

B2B expansion to X-ray equipment companies

Sustained sales channel expansion in Korea and overseas markets.









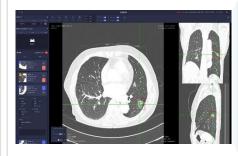








### **VUNO Med-LungCT AI**





#### Detection of Pulmonary Nodules in Chest CT

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

#### Focus on Japanese and U.S. Market

- Japan: To increase local sales and strengthen marketing
  - ① Wins reimbursement in Japan. (Jan. '24)
  - 2 M3 Al partners with Canon Medical Systems to cooperate for sales.
  - → Allows M3 Al to reach over 30% of hospitals that use PACS.
  - (3) MHLW announced updates to the health insurance fee system.
  - → Expanding coverage to include more hospitals.
- U.S.: Clinical trial with MGH (Massachusetts General Hospital) underway.





### **VUNO Med-Solutions**

### **VUNO Med-Fundus Al**





#### Al Screening Solution for Abnormalities in the Fundus

- Detection of 12 retinal findings Note) associated with diagnosis of vision-threatening ocular diseases in 2 seconds.
- Automatically detects the location of 8 regions of the fundus.
- Korea's 1st innovative medical device.

# **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%.
- Korea's 1st Al medical device.

#### Increase market penetration / Out-of-Pocket insurance

- Developed with 100,000+ fundus images and 57 ophthalmologists.
- Collaboration with pharmaceutical & bio companies to target internal medicine and checkup centers. → Increase market penetration
- Received approval for an integrated review of innovative medical devices. (Apr. '24)

Note) 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

→ Enables the use of as an Out-of-Pocket insurance

### **Deep Learning-based Automatic Bone Age Assessment**

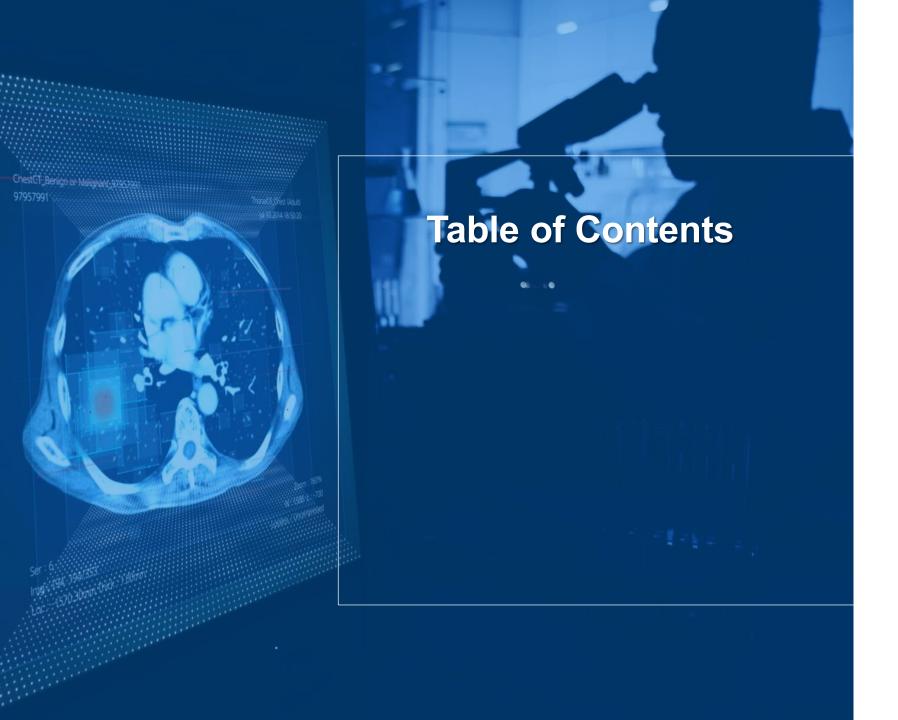
- Can be used to monitor treatment of kids with conditions that affect growth such as growth hormone levels, genetic growth disorders, orthopedic or orthodontic problems.
  - → Expanding medical center penetration to pediatrics, orthopedics and dental clinic.











**CHAPTER 04** Conclusion

# **Conclusion**







**Solutions that are** economically beneficial to customers



**Solutions that are** effectively communicated to customers

**VUNO's Business Approach** 



