code: 4188



## AmCad BioMed Corporation

## 2025 Institutional Investor Conference

Chairman and CEO Yili Lee 2025/9/2





- 1.Apart from historical data, the matters listed in this presentation that are forward-looking statements may be subject to significant risks and uncertainties, which could result in differences between these forward-looking statements and actual outcomes.
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- 4. The content of this presentation includes all entities belonging to the consolidated financial statements.

## **Agenda**



- 1. Company Overview
- 2. Key progress
- 3. International exhibition industry
- 4. Financials
- 5. Future development



# **Company Overview**

## **Company Profile**



## Pioneering Ultrasound Al

Helping physicians diagnose confidently and efficiently

The first medical device company to obtain FDA approval for ultrasound computer-aided diagnosis (CAD) in the United States. Leveraging world-leading technology combined with artificial intelligence (AI) and medical expertise, we are committed to addressing unmet clinical needs, providing optimal solutions, and serving as a pioneer in intelligent medical imaging.

**Founded** 

Dec. 2008

**Business** 

Product development, Manufacturing and Sales for Innovative Medical Device

Capital

TWD 630M

Subsidiary

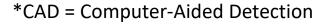
**Broadsound Corporation** 

**President** 

Yili Lee

Number of **Employees** 

76







**Regulatory Certification** 









**MDR** 

#### AmCad BioMed Corporation

9F., No. 167, Fuxing N. Rd., Songshan Dist., Taipei City 105403, Taiwan (R.O.C.)

as been assessed and certified as meeting the requirements of

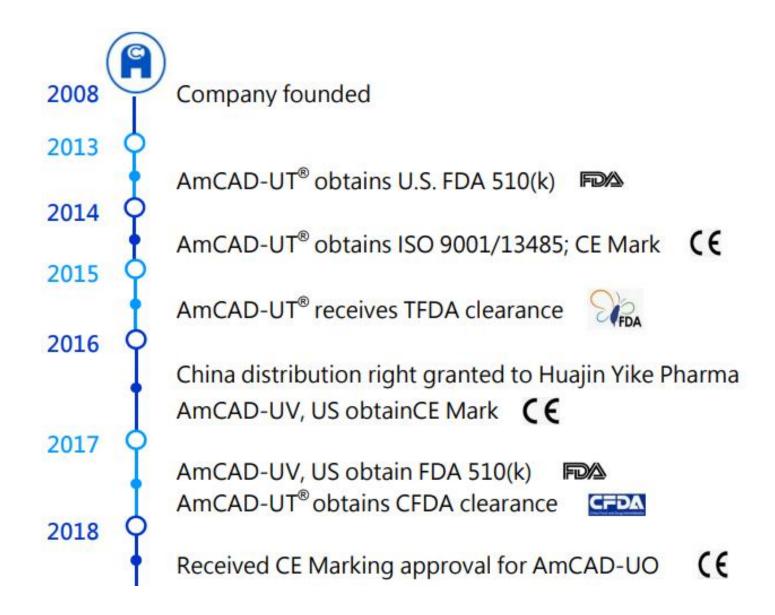
MDR EU Quality Management System certificate (Annex IX QMS)

For the following products lass Ita - MDA0315, MDS1009

The first smart medical software company in Taiwan to receive MDR certification.

### **Milestones**





#### **Milestones**



2019 AmCAD-UO obtains CE Mark & FDA 510(k) TFDA 2020 collaboration with Stanford School of Medicine 2021 Advanced AmCAD-UT with AI contouring function obtains FDA 510(k) approval 2023 AmCAD-UO, the research findings are featured in the top-ranked global medical journal in otolaryngology, 'JAMA Oto'. The AmCAD products (AmCAD UT UO US) have obtained the MDR CE certificate. 2024 South Korea's S1000 "AmCad UO" ultrasound equipment was successfully registered Taipei City Department of Health approved a self-pay code for UO at National Taiwan University Hospital. Signed MOU with Meridian Healthcare (MHC) in the United Arab Emirates to launch business cooperation in the Middle East New Taipei City Department of Health approved a self-pay code for UO at Far Eastern Memorial Hospital, Medical Foundation founded by Mr. Hsu Yuan-Tze. 2025 UO research published in the peer-reviewed journal OTO-HNS. Advanced AmCAD-UT Live implementation at Jordan Royal Medical Services (RMS). Chiayi City Department of Health approved a self-pay code for UO at Chiayi Christian Hospital, operated by the Ditmanson Medical Foundation. Hsinchu County Department of Health approved a self-pay code for UO at China Medical University Hsinchu Hospital.



- 1. Successfully completed the first Sustainability Report (2024).
- 2. Completed disclosure in accordance with SASB standards.
- Completed greenhouse gas inventory.



#### AmCad six major product lines: Four have obtained U.S. FDA 510(k) clearance





- Standardized & Automated
   Upper Airway Ultrasound Scan
- Assessing OSA Severity
- FDA 510(k), CE, TFDA certified

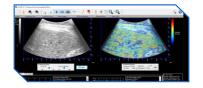




- FDA 510(k), CE, TFDA, NMPA certified
- Thyroid Nodule Ultrasound Risk Assessment



- FDA 510(k), CE certified
- Capable of differentiating tissues and performing visualized imaging and analysis





- FDA 510(k), CE certified
- Differentiation between pulsatile signal and noise





- Microscopic Cytology Image Analysis
- Visualizing and Quantifying Cytological Clinical Features



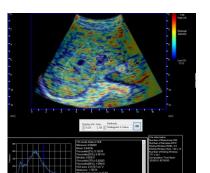


- Real-time AI Breast Ultrasound Imaging
- Breast Nodule Imaging Risk Assessment

#### **Comprehensive Patent Portfolio 30+ Invention Patents**

#### Obtained a new U.S. patent for AmCAD-UO in 2025.

**Patent: Ultrasound Scatterer Structure Visualization & Analysis** 



**Patent: Tumor Contour Retrieval** 



Patent: Multi-Layer Classifier & Echogenicity/ **Tumor Feature/ Echo Texture Quantification** 

**Anechoic Area** 

Echogenicity

**Echogenic Foci** 



**Texture** 



Margin

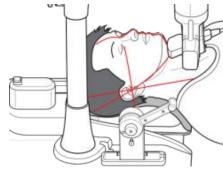




Nodule Orientation

**Nodule Orientation** 

Patent: Method for Head & Neck **Assessment or Intervention** 



INTERVENTION  Japan Taiwan USA  EU (Germany) Japan Thereof  METHOD ADAPTED TO DIAGNOSE AIRWAY OBSTRUCTION AND SYSTEM THEREOF  METHODS FOR PREDICTING THE RISK OF OBSTRUCTIVE SLEEP APNEA  [USA] ANALYSIS METHODS OF ULTRASOUND ECHO SIGNALS BASED ON STATISTICS OF SCATTERER DISTRIBUTIONS  Japan Taiwan  USA USA Taiwan  Taiwan  China USA EU		Other Patent Titles	Countries
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cytology images USA	cytology image	cytology images	

## Widely published in prestigious international clinical journals



#### 60+ in top-ranked journals by H-index



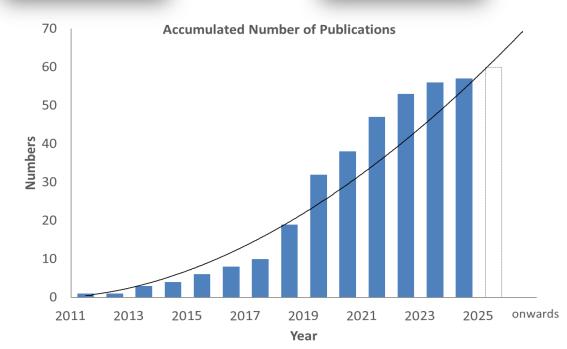
#### JAMA Otolaryngology -Head & Neck Surgery

Association of Backscattered Ultrasonographic Imaging of the Tongue With Severity of Obstructive Sleep Apnea in Adults. vol. 149,7 (2023): 580-586.



#### Pattern Recognition

Multivariate multi-layer classifier. vol. 131, 108896, July 2022.





#### **Sleep Medicine**

Using standardized ultrasound imaging to correlate OSA severity with tongue morphology. vol. 120 15-21. 31 May. 2024.



#### **Ultrasonics**

Clinical performance of ultrasonic backscatter parametric and nonparametric statistics in detecting early hepatic steatosis. vol. 142, 107391. Aug. 2024.



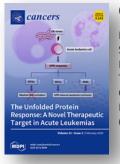
## **European Thyroid Journal**

Reliability of a computer-aided system in the evaluation of indeterminate ultrasound images of thyroid nodules. vol. 11,1. e210023. 1 Jan. 2022.



## Ultrasound in Medicine & Biology

Diagnostic performance of ultrasound computer-aided diagnosis software compared with that of radiologists with different levels of expertise for thyroid malignancy: A multicenter prospective study. vol. 47,1 (2021): 114-124.



#### **Cancers**

Multi-Reader Multi-Case Study for Performance Evaluation of High-Risk Thyroid Ultrasound with Computer-Aided Detection. vol. 12,2 373. 6 Feb. 2020.



#### Clinical Endocrinology

Differences in the ultrasonographic appearance of thyroid nodules after radiofrequency ablation. vol. 95,3 (2021): 489-497.

## May 2025 – Swiss study officially published in OTO-HNS



Original Research—General Otolaryngology

#### AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NIEK SURGERY

Otolaryngology-

Head and Neck Surgery 2025, Vol. 00(00) 1-7

© 2025 The Author(s). Otolaryngology-Head and Neck

American Academy of Otolaryngology-Head and Neck Surgery Foundation. DOI: 10.1002/ohn.1251 http://otolournal.org

WILEY

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## Backscattered Ultrasonographic Imaging of the Tongue and Outcome in Hypoglossal Nerve Stimulation

Samuel Tschopp, MD<sup>1,2</sup>\* <sup>©</sup>, Vlado Janjic, MD<sup>1</sup>\*, Yili Lee, MBA<sup>3</sup>, Argon Chen, PhD<sup>4</sup>, Pei-Yu Chao, PhD<sup>3</sup>, Marco Caversaccio, MD<sup>2</sup>, Urs Borner, MD<sup>2</sup>\*\*, and Kurt Tschopp, MD<sup>1</sup>\*\*

#### Abstract

Objective. Hypoglossal nerve stimulation (HNS) is an increasingly used therapy. However, not all patients undergoing HNS implantation benefit from the treatment, making an improved patient selection a priority. This study investigates whether backscattered ultrasonographic imaging (BUI) can predict the response to HNS therapy.

Study Design. Cross-sectional study.

Setting. Secondary and tertiary hospital.

Methods. In this multicenter cross-sectional study, we recruited patients who had undergone HNS implantation during their scheduled follow-up consultation. HNS therapy parameters were collected. Standardized submental ulrasonographic examination and home sleep apnea testing were performed. The primary outcome was assessing the response to HNS therapy using ultrasonographic features and preoperative patient characteristics.

Results. In total, 62 participants, 49 male, with a median (interquartile range [QR]) age of 62 (55-67) and a median (QR) body mass index of 27.6 (52-29.7). The follow-up was a median (IQR) of 19.5 (4.8-41.4) months after implantation. The apnea-hypopnea index (AHI) was preoperatively 40.5 (29.8-58.0) and reduced at follow-up to 21.0 (11.0-35.3). In total, 42% were responders to HNS. Preoperative AHI (34.8/hour vs 49.3/hour, r=0.44) was significantly higher in nonresponders than in responders. The average prediction accuracy of HNS therapy based on baseline AHI alone was 71%. A lower backscatter signal, indicating less fat deposition in the tissue, was observed in the responder group. When the baseline AHI and backscatter signal were combined, the prediction accuracy of response to the HNS reached 78%.

Conclusion. The combination of tissue composition analyzed using the backscattered signal and the preoperative AHI is highly predictive for determining the HNS treatment

Trial Registration. ClinicalTrials.gov identifier NCT06154577.

#### Keywords

hypoglossal nerve stimulation, obstructive sleep apnea, outcome, ultrasonography

Received November 18, 2024; accepted March 23, 2025.

ypoglossal nerve stimulation (HNS) is increasingly important in managing patients with obstructive sleep apnea (OSA) who do not tolerate continuous positive airway pressure therapy and are not eligible for other alternative treatment options, such as mandibular advancement devices or positional therapy. The number of HNS implantations is increasing, with several thousand new implantations per year, and they have found their place in treatment guidelines. Even with restrictive patient selection according to guidelines and optimal HNS titration, the responder rate remains around 50% to 60%. 13-6

Current anatomical and physiological selection criteria for respiration-triggered HNS include moderate to severe OSA, intolerance to continuous positive airway pressure therapy, body mass index (BMI), drug-induced sleep endoscopy (DISE), and exclusion of central sleep apnea,

<sup>1</sup>Department of Otorhinolaryngology, Head and Neck Surgery, Kantonsspital Baselland Liestal, Liestal, Switzerland

<sup>2</sup>Department of Otorhinolaryngology, Head and Neck Surgery, Inselspital, University Hospital and University of Bern, Bern, Switzerland

<sup>3</sup>AmCad Biomed Corporation, Taipei, Taiwan <sup>4</sup>Graduate Institute of Industrial Engineering, National Taiwan University

\*These authors contributed equally to this article and are equally contributing first authors.

\*\*These authors contributed equally to this article and are equally contributing last authors.

#### Corresponding Author:

Samuel Tschopp, MD, Department of Otorhinolaryngology, Head and Neck Surgery, Inselspital, University Hospital and University of Bern, Freiburgstrasse 20, 3010 Bern, Switzerland.

Email: samuel.tschopp@insel.ch

- The paper was officially published in the authoritative journal OTO-HNS, demonstrating professional recognition of our research findings.
- Strengthens product credibility and supports expansion into European and American markets.



## Partnering with Leading Global Medical Institutions



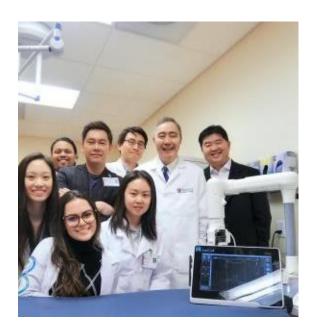








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## Roadmap of Medical Innovation Development





AmCad has obtained medical device regulatory approval

#### **AmCAD-UT**

► Submitted to National Health Insurance in March 2024; CDE issued the Health Technology Assessment (HTA) report in April 2025.

#### AmCad UO

- ►In the past year, newly obtained self-pay medical codes from New Taipei City, Chiayi City, and Hsinchu County.
- Continue to enter major domestic hospitals, health clinics/dentist channels
- Work with well-known teaching hospitals at home and abroad to implement post-market clinical research cases and publish papers to expand product application
- And through international exhibitions, academic exhibitions and online marketing to promote the popularity of accumulated products

## **Business Model**





Use our expertise in developing product according to our strategic partners' needs/specifications.





Marketing

Collaborate with enterprise imaging solutions providers to expand market access.



# Key progress

## Introduction to Core Products: Mmcaput LiveScan (FDA · CE · CFDA)

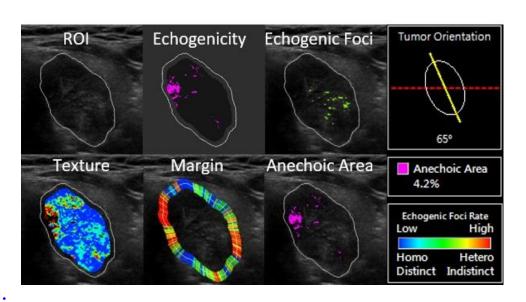




#### AmCAD-UT Product Features

- Accuracy exceeding 90%, enabling consistent automated nodule analysis.
- Built-in risk scoring based on eight international TI-RADS guidelines.
- Patented nodule quantification and visual feature analysis
- Multi-platform compatibility reduces human error with real-time AI guidance.
- Al-assisted real-time automatic annotation.
- Invested in the development of a brand-new UI/UX system.







#### PAmCAD-UT Revamped UX/UI – Integration and Optimization with Clinical Insights





#### **User Interviews & Usability Testing**











## AmCAD-UT 2025



#### Domestic sales strategy





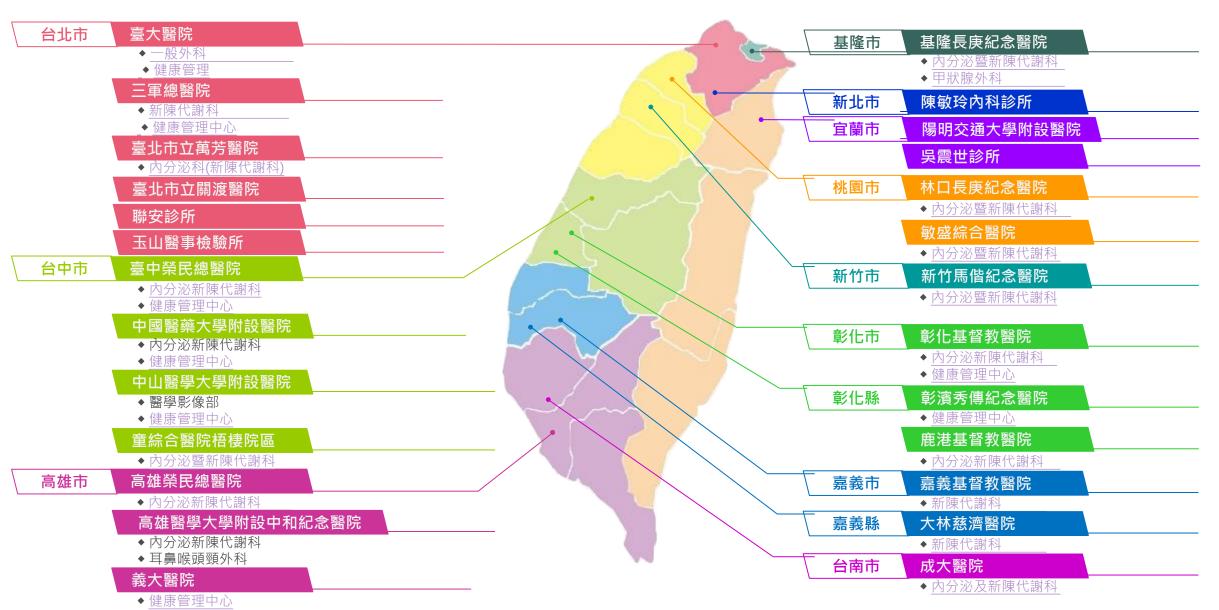
#### Domestic market strategy

- Health Checkup Center Annual Subscription
- Clinical Focus: Endocrinology / ENT / Radiology
- Expanded departments: family medicine/general surgery
- Cooperation with ultrasound manufacturers
  - Hospital tying strategy
  - Clinic tie-in strategy, cooperation with Handheld ultrasound probe manufacturers
- New business opportunities AmCAD-UT Live Scan



## A list of AmCad UT® medical institutions





## AmCAD-UT Application for health insurance benefits



- Assist physicians in diagnosis, aiming to achieve precision medicine and enhance patient well-being through AmCAD-UT intelligent analysis technology.
- ▶ In 2025, CDE issued the Health Technology Assessment (HTA) report.
- ▶ In the second half of 2025, expert meetings and consensus meetings will be held, and National Health Insurance coverage expected by year-end.

## 全民健康保險醫療服務給付項目及支付標準 之新增診療項目建議 檢附文件(請勾選) ■建議單位與其他相關單位專家、團體之連繫資訊(表 001) ■新增診療項目建議表(表 002) ■診療項目成本分析表(表 003-1) 作業流程(表 003-2) □須搭配使用之藥品、特殊材料或診療項目(表 003-3) □執行診療項目相關醫事人員資格暨設備資料 (醫療院所申請必備文件)(表 003-4) 一其他 5-5866 分機 2654、2632、2637

•Reports and software updates from 30+ medical centers/regional hospital UT departments.









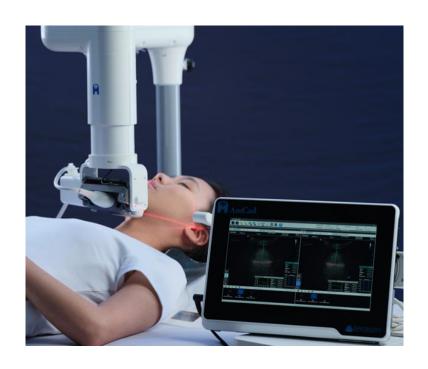


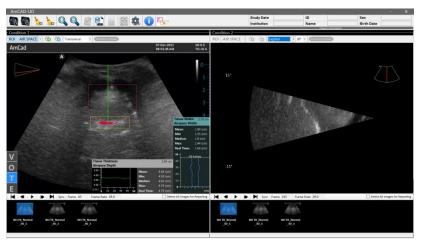












#### **AmCAD-UO Product Features**

- Fast, non-overnight, non-invasive screening for obstructive sleep apnea.
- Accuracy up to 95%.
- Visualize and quantify upper airway data to develop the optimal personalized treatment plan for each patient's unique airway anatomy.
- Helps identify patients for whom orthodontic and sublingual nerve stimulation treatments are ineffective, as well as the reasons for poor suitability.

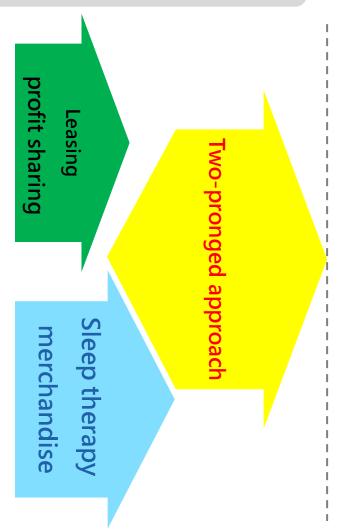
Software UI/UX Optimization Project.



## **AmCAD-UO** 2025



#### Domestic market strategy



### Domestic market strategy

- Health examination centers: medical centers, highvolume regional hospitals and health clinics
- Clinical expertise:
  - Sleep Center Product Introduction
  - Pulmonology, Otolaryngology, Dentistry (Sleep Apnea
     & Snoring Treatment)
- Sales integration
  - Premium Health Screening Center Joint Sales of UT/UO
  - Enterprise screening
  - One Stop Solution/Service
- Cooperation with colleagues related to sleep therapy
  - CPAP Device Suppliers
  - Snoring Mouthguard Suppliers / Clinics

## \* AmCAD-UO Progress on Health Bureau Self-Pay Code



Region	Approval Number	Name	Approval Date	Self-Pay Price	Market Price
Taichung City Health Bureau	Taichung City Health Bureau Document No. 1120033618	Upper Airway Al Ultrasound	2023.4.14	4,000	Taichung City Health Bureau Medical Institutions Approved Self-pay Item Number: 2230
Taipei City Department of Health	Taipei City Health Bureau Document No. 1133110652	Automated Ultrasound Localization and Intelligent Analysis of the Upper Airway	2024.4.10	4,000	NTU Hospital Self-funded Item Fee Standards (Local Patients) Item: 1528 Medical Order Code: 000H0601
New Taipei City Department of Health	New Taipei City Health Bureau Document No. 1131402796	Upper Airway Al Ultrasound	2024.10.25	4,500	New Taipei City Approved Self-pay Medical Services at Far Eastern Memorial Hospital, a Medical Foundation of the Yu-Chi Hsu Foundation. Item: 320
Chiayi City Department of Health	Chiayi City Health Bureau Document No. 1142701073	Automated Ultrasound Localization and Intelligent Analysis of the Upper Airway	2025.2.3	4,000	Dadeson Medical Foundation, Chiayi Christian Hospital's Self-pay Medical Service Fee Items.
Hsinchu County Public Health Bureau	Hsinchu County Health Bureau Document No. 1148550913	Upper Airway Al Ultrasound	2025.7.10	4,000	China Medical University Hstructure Hospital Fee Schedule

 AmCAD-UO Domestic Business Development (Dentistry, Professional Associations, Corporate Health Checks)











## AmCAD-UO Academic Conference



#### 2024 Sleep Medicine Society Annual Meeting









## Super Dental Sleep 101 (OSA Well)







## AmCAD-UO Healthcare+ Expo Taiwan 2024











## Medical Taiwan 2025















# International exhibition industry

#### Record Attendance for Amcad at the MEDICA Exhibition



• Engaged with multiple companies in Europe, South Asia, and Latin America on UO/UT collaboration.

The TAITRA Chairman personally attended and endorsed the product launch event organized by

TAITRA.











## RSNA 2024 – Partnership Progress & Future Opportunities



## Engaging with major companies for potential collaboration:

GE Healthcare: Exploring the business opportunities of integrating AI with handheld ultrasound solutions.

DeepC and other platform leaders: Beginning strategic collaboration discussions.

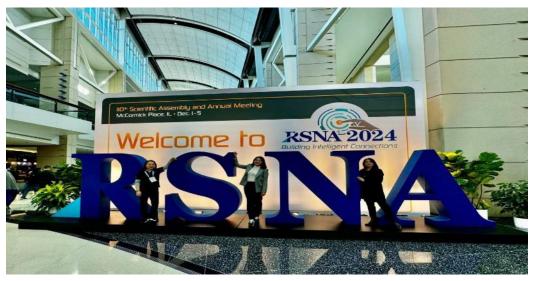
#### **Showcasing Our AI Technology's Strength:**

Successfully demonstrated compatibility with leading POCUS ultrasound brands.

Validated the clinical value of AI-assisted diagnosis.

#### **Strategic Value:**

Establishing AI as a key differentiator in the POCUS market.



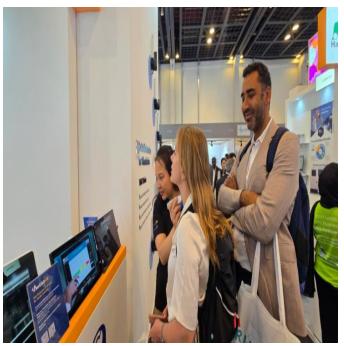


## Exhibited at the Arab Health Exhibition in Dubai.





 Discussing collaboration with multiple distributors in the Middle East, including AHC, Meridian, and Noum.





# AmCAD-UO & UT Successfully Implemented at GluCare AI Diabetes Clinic – Strategic Middle East Demonstration Hub



- In Q4 2024, AmCAD-UO & UT product orders were shipped to GluCare AI Diabetes Clinics, already in use with initial positive clinical feedback.
- Strategic Value: Establish the first AI ultrasound application demonstration center in the Middle East. Create a model of collaboration for high-end AIpowered diabetes care clinics. Lay the groundwork for post-2026 Arab Health market development.





# AmCAD-UT LIVE+ AI solution, has been successfully installed in Jordan and is now in the trial stage.



 In Q2 2025, we completed the installation and activation of AmCAD-UT LIVE (POCUS, Point-ofcare Ultrasound) solution, at a client site. This system integrates real-time Al-powered analysis with a thyroid ultrasound assistance software, laying the groundwork for future clinical applications in rural areas.

# Strategic Value: Deploying for clinical trials in rural healthcare settings to hasten medical application validation and regional expansion.



## AmCAD-UT Clinical Validation Study Approved at a Leading Tertiary Medical Center in Brazil



In collaboration with Brazil's Einstein Hospital, we will conduct a prospective study on 100 cases. The hospital will build its own virtual server to deploy AmCAD-UT.

- Strategic Value:
   This project is representative of the South American region and will help us expand into neighboring markets in Central and South America.
- According to the recent "World's Best Hospitals 2024" ranking published by the North American magazine Newsweek, Brazil's Einstein Hospital was ranked 28th globally.





## Initiating AI Platform Integration – NDA Signed with DeepC (Germany)



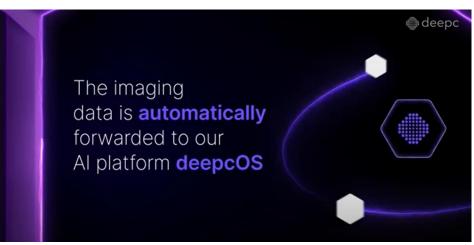
 In Q3 2025, both parties officially signed a new NDA and initiated API integration.

#### Strategic Value :

If successfully implemented, this project will signify that our product meets European platform-level integration standards. This will enable us to connect with more AI platforms in Europe and the U.S., thereby increasing the barrier to entry and accelerating market expansion.









# **Financials**

## Consolidated Balance Sheet



Items	2025.06.30	%	2024.12.31	%
Current Assets	434,184	68	418,085	60
Non-current Assets	207,158	32	276,788	40
Total Assets	641,342	100	694,873	100
Current Liabilities	17,707	3	25,143	3
Non-current Liabilities	4,224	1	6,012	1
Total Liabilities	21,931	(4)	31,155	4
Capital	633,329	99	633,329	91
Capital surplus	141,817	22	141,523	20
Accumulated deficits	( 229,053)	(36)	( 199,320)	(28)
Other components of equity	( 13,989)	(2)	(6,880)	(1)
Parent Equity	532,104	83	568,652	82
Non-controlling interests	87,307	13	95,066	14
Total Equity	619,411	96	663,718	96
Total Liabilities and Equity	641,342	100	694,873	100

<sup>►</sup> Healthy Cash & Low Debt, Solid Financial Structure.

## Consolidated Income Statement



Items	2025H1		2024F	YoY	
	AMT	%	AMT	%	%
Operating revenue	14,939	100	24,448	100	(39)
Gross profit	5,276	35	14,466	59	(64)
Operating Expenses	(47,349)	(317)	(46,930)	(192)	1
Operating Loss	(42,073)	(282)	(32,464)	(133)	-
Non-operating Gain	2,609	18	2,924	12	(11)
Net Loss	(39,449)	(264)	(29,540)	(121)	-
Net Loss – Parent	(31,690)	(212)	(25,879)	(106)	-
Net Loss – Non-controlling interests	(7,759)	(52)	(3,661)	(15)	-
EPS (TWD)	(0.50)		(0.48)		

<sup>►</sup> Revenue decreased compared to the same period last year; expected to be boosted in H2 through domestic and international business development and successful health insurance reimbursement approvals.



# Future development

## Global Market & Licensing Strategy



#### **Market Opportunity:**

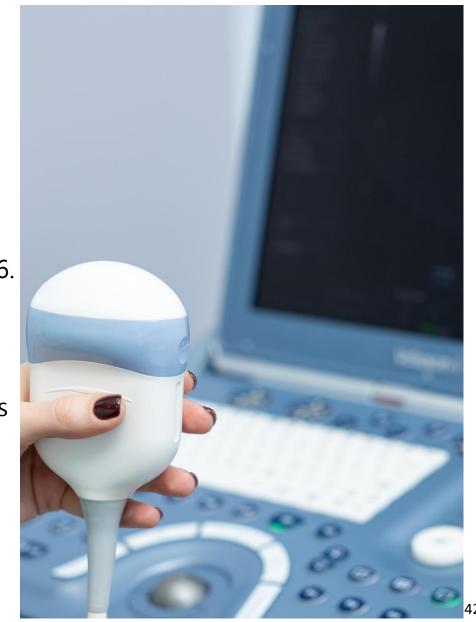
The global AI medical imaging market is projected to grow at a CAGR of 29% from 2025–2030, with the ultrasound AI segment growing at approximately 24% annually.

#### **Regional Targets:**

Middle East: Building on our successful case study in Dubai, we plan to establish two additional demonstration sites by 2026. Europe: Following API integration with a German platform provider, our goal is to finalize licensing and collaboration with additional platforms by 2026.

Asia: Focusing on sales through distributors, targeting markets in Southeast Asia and rural areas.

**Licensing Model:** : Adopting a Hybrid model that includes one-time licensing and usage-based revenue sharing. This strategy targets large platforms and international medical device manufacturers to mitigate single-market risk.



## • Technology & Product Strategy



#### **POCUS Integration:**

Targeting completion of integration testing with 5 major handheld ultrasound devices by the end of 2025 (compatibility with several handheld devices already verified). Launch interface improvements to enhance user experience.

#### **On-device Al:**

Continue developing edge computing to achieve <1-second image analysis, increasing penetration in rural and mobile healthcare settings.

#### **Product Line Development:**

AmCAD-UT: After completing the health insurance sandbox program, rapid adoption by medical institutions is expected in 2026.

AmCAD-UO: Introduce to dental and sleep therapy channels to boost sales growth and channel reach.

AmCAD-UB: Develop high-sensitivity entry-level screening AI module, targeting primary care market entry.



## MCADUT maximum POCUS integration capabilities as competitive advantage



AMCAD AI software is compatible with any brand of handheld ultrasound.

**Ultrasound** 



## Future Strategy



#### **Domestic Market**

#### Health Insurance & Hospital Adoption:

UT: Target health insurance approval by the end of 2025; deploy to medical centers and regional hospitals across Taiwan in 2026.

UO: Continue expanding into dental and sleep centers; aim to penetrate all six major cities in Taiwan by 2026.

**Health Screening Center Collaboration:**Launch "two-in-one" (UT + UO) service packages targeting premium health screening centers to increase per-customer revenue.

#### **Brand & International Visibility:**

- Actively participate in major international medical exhibitions (RSNA, MEDICA, Arab Health), attending at least three top-tier events annually.
- Collaborate with international KOLs and leading medical centers to publish clinical papers in renowned international journals.



# Thank you