code: 4188

AmCad BioMed

AmCad BioMed Corporation

2024 Institutional Investor Conference

Chairman and CEO
Yili Lee
2024/9/13

美吾華·懷特·安克生技集團
Maywufa Biopharma Group

Statement

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.

2.The future projections presented in this document reflect the company's views as of the current date. However, the company is not obligated to update this information in case of any events or changes in the environment.

3.Without the company's permission, the copying, modification, recompilation, reduction, or transmission of any content in this presentation, or the use of any such content for commercial purposes, is strictly prohibited.

4. The content of this presentation includes all entities belonging to the consolidated financial statements.

Company Profile

AmCad BioMed

安克生醫 Pioneering Ultrasound AI

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

*CAD = Computer-Aided Detection

Products

AmCAD-UT AmCAD-UO

Regulatory Certification

FDA FDA CE CFDA China Food and Drug Administration

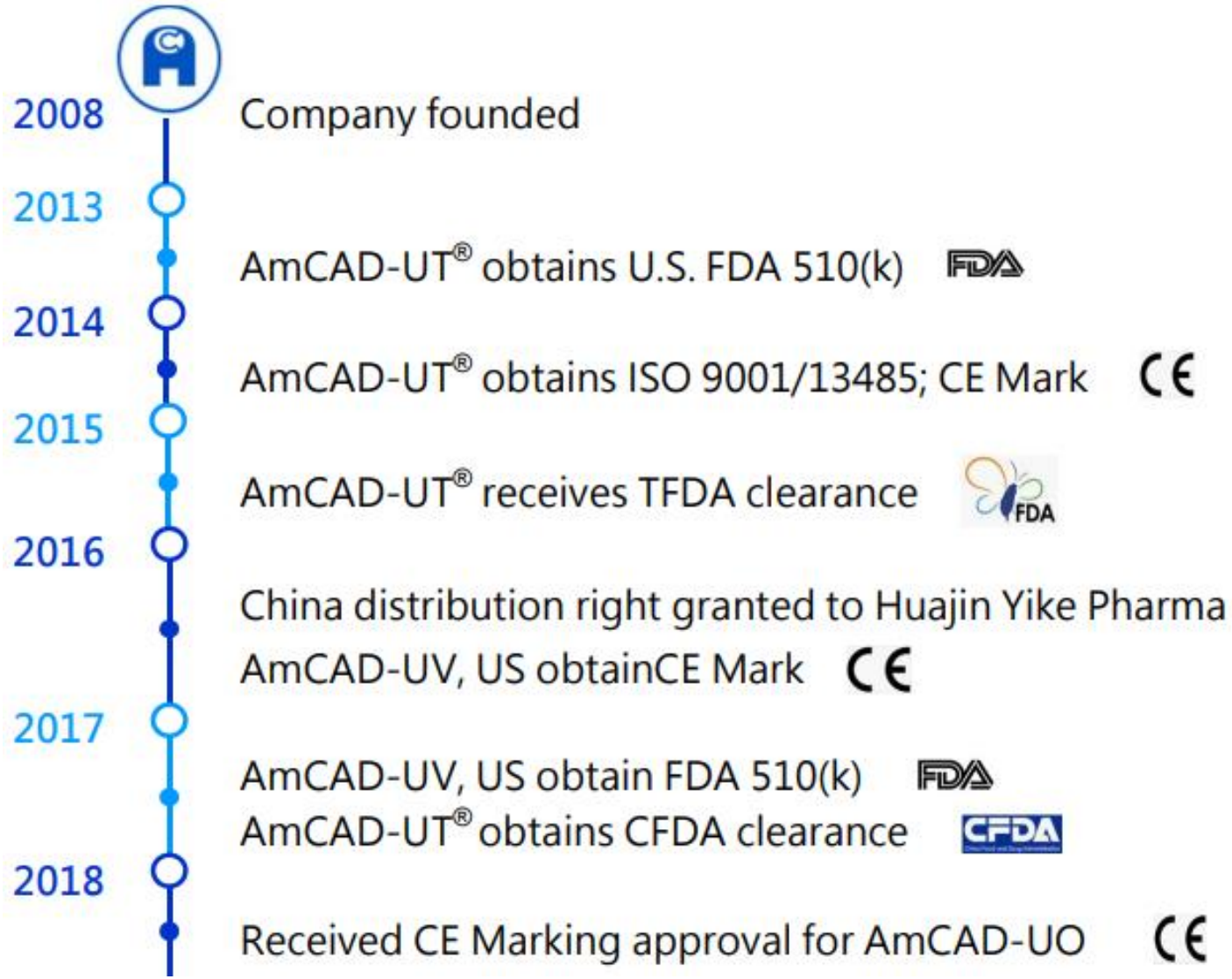
Obtained MDR CE certificate in November 2023.

AmCad BioMed Corporation

5F., No.167, Fuxing N. Rd., Songshan Dist., Taipei City 105403, Taiwan (R.O.C.)
SRN: TW-MF-000013445
has been assessed and certified as meeting the requirements of
MDR EU Quality Management System certificate (Annex IX QMS)
For the following products
Class IIa - MDA0315, MDS1009

Milestones

AmCad BioMed



Milestones

AmCad BioMed

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 Health Bureau UO self-funded official document approved$4,000
Signed MOU with Meridian Healthcare (MHC) in the United Arab Emirates to launch business cooperation in the Middle East

In 2024, we signed a cooperative research and licensing agreement with the University of the Pacific (UOP) School of Dentistry, sharing of research data, Thailand Walailuk University published a study to verify the application of Amcad UO in dentistry, and verification of clinical results in Switzerland. Screen the effectiveness of HNS treatment using Anker Respiratory Test.

Portfolio

4 CE marked and FDA 510(k) cleared products

AmCADUO

and Laser Alignment Tool (LAT)

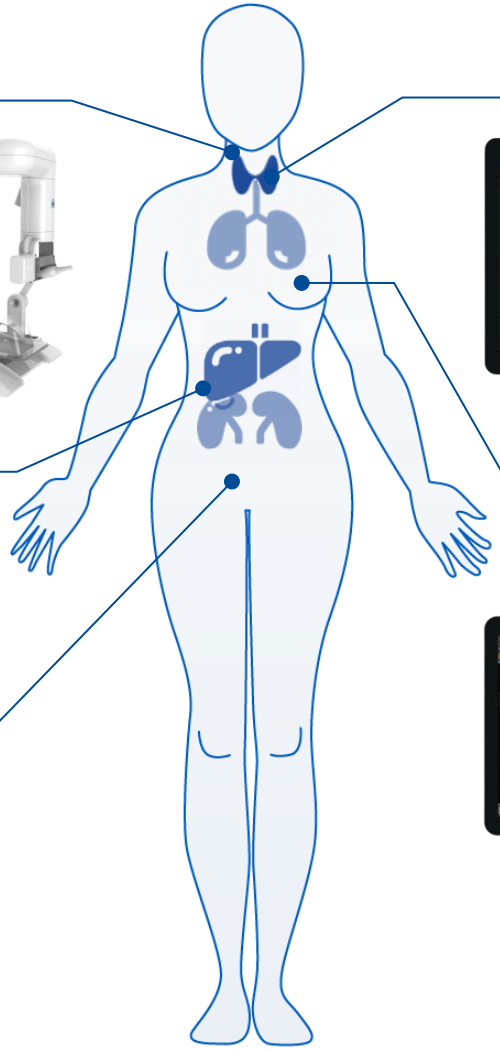
- FDA 510(k), CE, TFDA certified
- 10-minute AI-enabled solution for obstructive sleep apnea (OSA) assessment

AmCADUS

- FDA 510(k), CE certified
- Backscattered ultrasound imaging unlocks insights for tissue composition

AmCADUV

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



AmCADUT

- FDA 510(k), CE, TFDA, CFDA certified
- Real-time AI-assisted thyroid nodule assessment
- Automated reporting with eight (8) TI-RADS integration

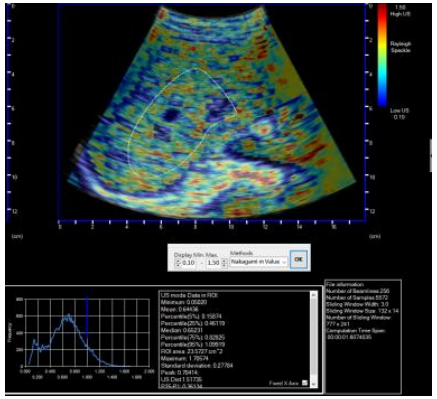
AmCADUB

- Real-time AI-assisted breast lesion assessment with descriptors based on BI-RADS

Patented Technology

33 Invention Patents

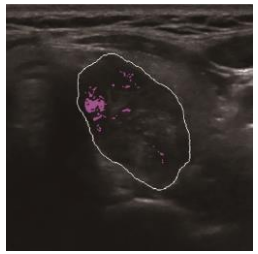
Patent: Ultrasound Scatterer Structure Visualization & Analysis



Patent: Tumor Contour Retrieval

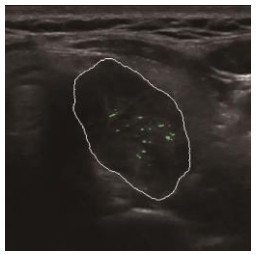
Patent: Multi-Layer Classifier & Echogenicity/ Tumor Feature/ Echo Texture Quantification

Anechoic Area

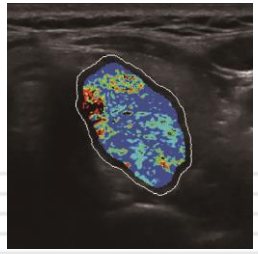


Echogenicity

Echogenic Foci

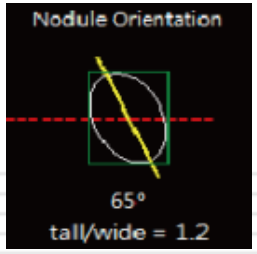


Texture

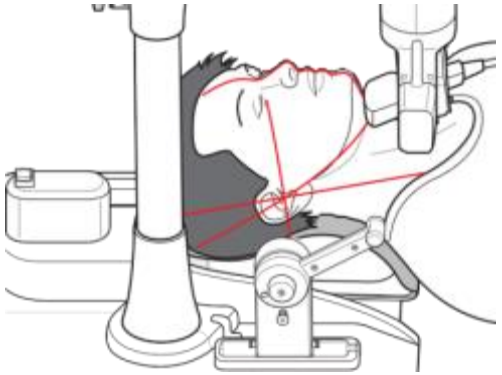


Margin

Nodule Orientation



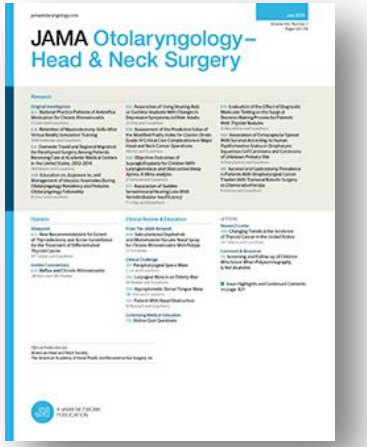
Patent: Method for Head & Neck Assessment or Intervention



Other Patent Titles	Countries
呼吸中止症評估方法及其系統/ METHOD ADAPTED TO DIAGNOSE AIRWAY OBSTRUCTION AND SYSTEM THEREOF	China
	EU (Germany)
	Japan
	Taiwan
	USA
COMPUTER-IMPLEMENTED METHOD FOR PREDICTING THE RISK OF OBSTRUCTIVE SLEEP APNEA	USA
	Taiwan
	EU
[USS] 利用散射子分布統計量分析超音波回音信號之方法 ANALYSIS METHODS OF ULTRASOUND ECHO SIGNALS BASED ON STATISTICS OF SCATTERER DISTRIBUTIONS	Taiwan
	China
	USA
	EU (Germany)
[USV] 聲波散射訊號之影像強化方法與成像加速系統 [TW] IMAGE ENHANCEMENT METHOD AND IMAGING ACCELERATION SYSTEM FOR ULTRASOUND SCATTERER SIGNAL [US]ACCELERATION AND ENHANCEMENT METHODS AND SYSTEM FOR ULTRASOUND SCATTERER STRUCTURE VISUALIZATION	USA
[UV] 超音波都卜勒影像之分群、雜訊抑制及視覺化方法 CLUSTERING, NOISE REDUCTION AND VISUALIZATION METHOD FOR ULTRASOUND DOPPLER IMAGES	Taiwan
	USA
細胞學影像特徵量化與視覺化方法及系統/ METHOD AND SYSTEM FOR QUANTIFICATION AND VISUALIZATION CHARACTERISTICS OF CYTOLOGY IMAGES	Taiwan
	USA

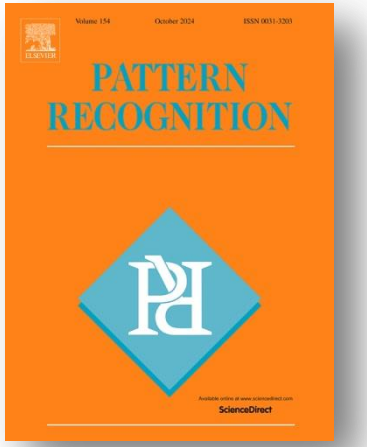
Academic Publications

60 publications in top-ranked journals by H-index



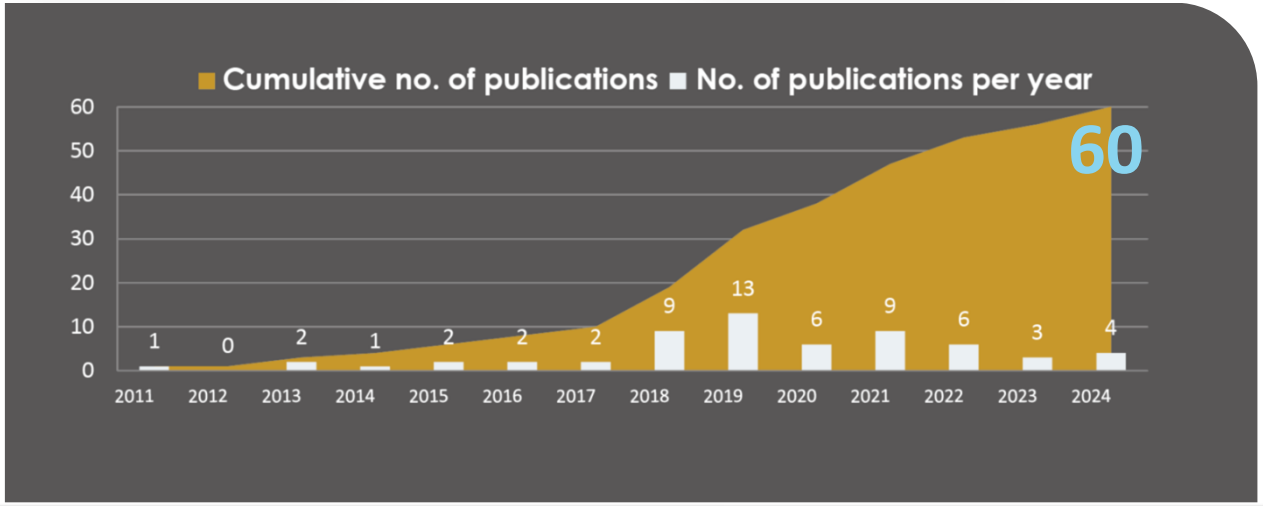
JAMA Otolaryngology - Head & Neck Surgery

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



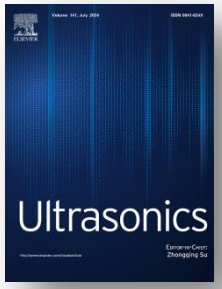
Pattern Recognition

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

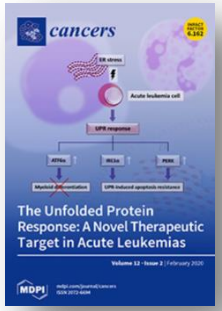
Clinical performance of ultrasonic backscatter parametric and nonparametric statistics in detecting early hepatic steatosis. vol. 142, 107391. Aug. 2024.

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.



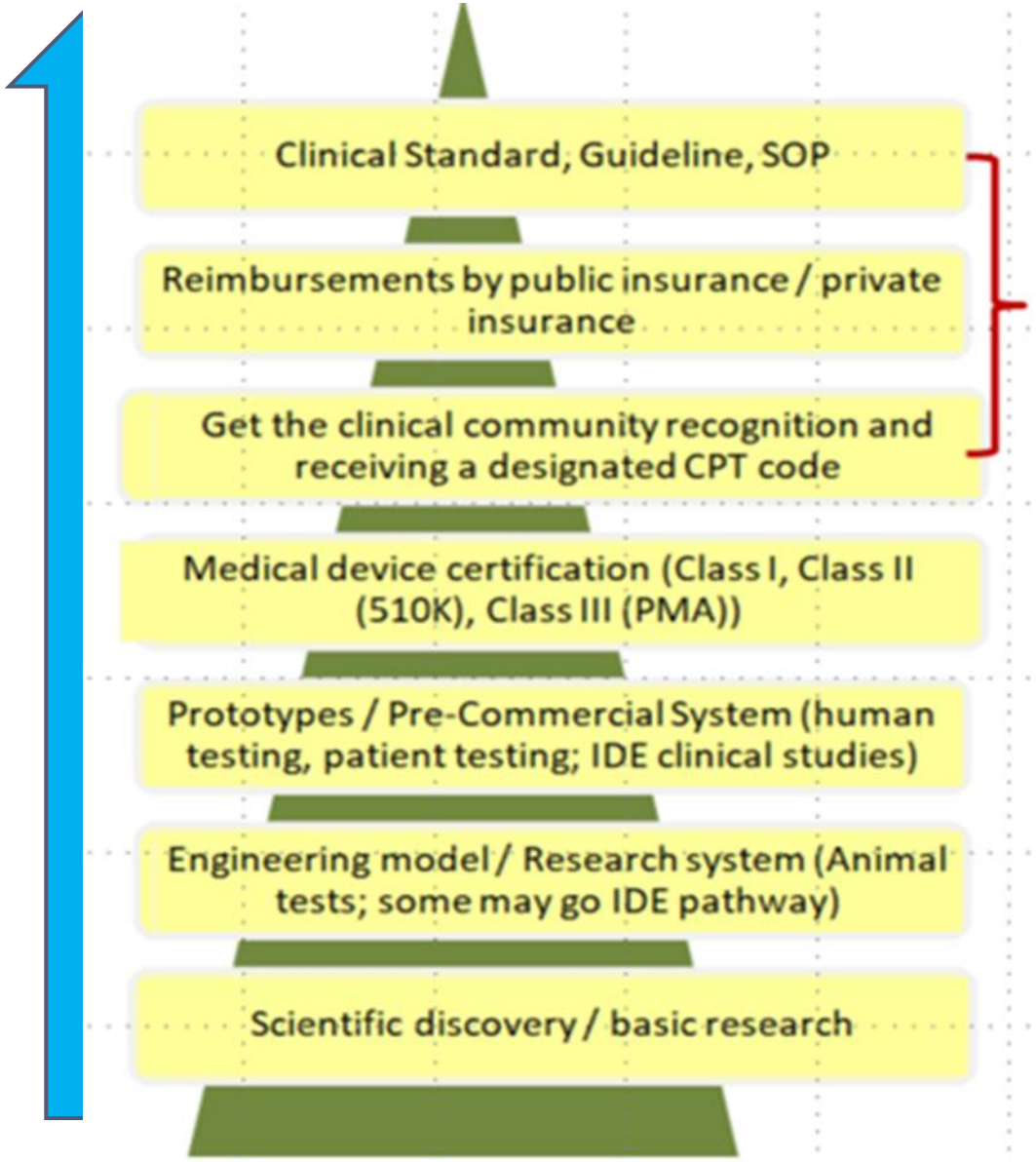
Cancers

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.

Roadmap of Medical Innovation Development



- AmCad obtained medical material regulatory certification and self-paid medical order code 安克甲狀偵
  - Apply for inclusion in health insurance benefits

  AmCad UO
  - certification
  - Prepare to apply for European Benefit Insurance Code

- 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

AmCad BioMed

CDMO / Licensing

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

Distribution

- Leasing
- Revenue Sharing
- Outright Sales
- Subscription

Exclusive or regional rights, single & multi-product deals.

Collaborative Marketing

Collaborate with enterprise imaging solutions providers to expand market access.

AmCad BioMed

Key progress

美吾華·懷特·安克生技集團
Maywufa Biopharma Group

Cash capital increase case officially takes effect on 6/7

- The 113-year cash capital increase plan officially came into effect on 6/7
- 7/23 Raised 230 million in funds
- Marketech international Corp., the supplier of AmCad's LAT, invested in AmCad and has now become a close strategic partner.

檔　　號：
保存年限：

金融監督管理委員會　函

地址：22041新北市板橋區縣民大道2段7號18樓
承辦人：黃小姐
電話：02-87735100分機7176

受文者：安克生醫股份有限公司（代表人李伊俐女士）

發文日期：中華民國113年6月7日
發文字號：金管證發字第1130343354號
速別：普通件
密等及解密條件或保密期限：
附件：

主旨：貴公司申報以現金增資發行普通股10,000,000股，每股面額10元，總額新臺幣100,000,000元一案，依「發行人募集與發行有價證券處理準則」第13條第1項規定，自113年6月7日申報生效，請查照。

說明：

一、依據貴公司113年5月10日發行新股申報書辦理。

二、請依照下列規定辦理：

(一)依照公司法第273條第2項之規定，至本會指定之資訊申報網站辦理公告。

(二)依照證券交易法第31條第1項之規定，向認股人交付公開說明書；並將修正後公開說明書定本以電子檔案方式上傳至本會指定之資訊申報網站。

(三)依照證券交易法第34條第1項之規定，於限期內交付股票，並於交付前至本會指定之資訊申報網站辦理公告。

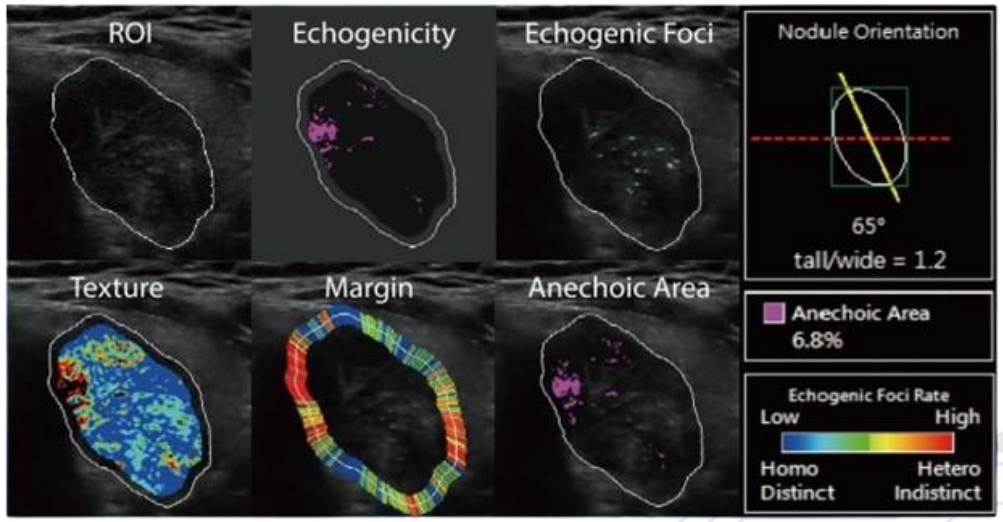
(四)請於實際發行價格確定後，至本會指定之資訊申報網站辦理輸入實際發行計畫，並修正公開說明書相關內容。

AmCAD UT LiveScan

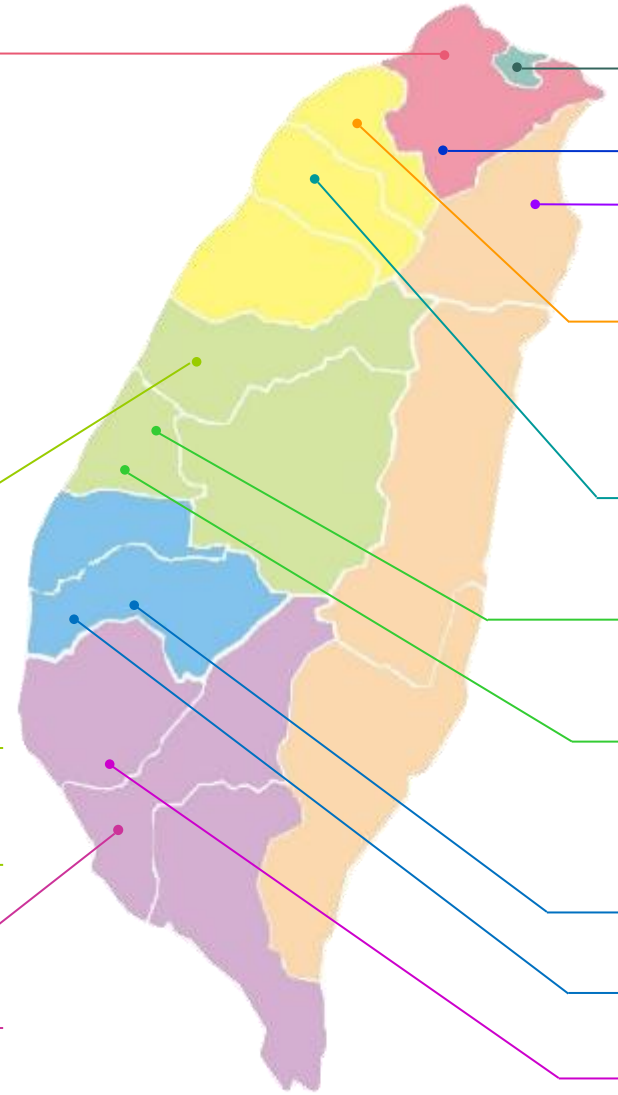
Real-time Thyroid Nodule Assessment

FDA | CE | TFDA | CFDA

1. **Real-time Guidance :** AI-powered real-time guidance for identifying thyroid structure and alerting suspicious findings
2. **Advanced Nodule Visualization:** Comprehensive analysis with detailed display of nodule characteristics
3. **TI-RADS Integration:** Automated risk stratification using the user selected TI-RADS from 8 TI-RADS selections



AmCad UT® More than 30 hospitals have adopted it



台北市
- 臺大醫院
  - 一般外科
  - 健康管理
- 三軍總醫院
  - 新陳代謝科
  - 健康管理中心
- 臺北市立萬芳醫院
  - 內分泌科(新陳代謝科)
- 臺北市立關渡醫院
- 聯安診所
- 玉山醫事檢驗所

台中市
- 臺中榮民總醫院
  - 內分泌新陳代謝科
  - 健康管理中心
- 中國醫藥大學附設醫院
  - 內分泌新陳代謝科
  - 健康管理中心
- 中山醫學大學附設醫院
  - 醫學影像部
  - 健康管理中心
- 童綜合醫院梧棲院區
  - 內分泌暨新陳代謝科

高雄市
- 高雄榮民總醫院
  - 內分泌新陳代謝科
- 高雄醫學大學附設中和紀念醫院
  - 內分泌新陳代謝科
  - 耳鼻喉頭頸外科
- 義大醫院
  - 健康管理中心

基隆市
- 基隆長庚紀念醫院
  - 內分泌暨新陳代謝科
  - 甲狀腺外科

新北市
- 陳敏玲內科診所

宜蘭市
- 陽明交通大學附設醫院
- 吳震世診所

桃園市
- 林口長庚紀念醫院
  - 內分泌暨新陳代謝科
- 敏盛綜合醫院
  - 內分泌暨新陳代謝科

新竹市
- 新竹馬偕紀念醫院
  - 內分泌暨新陳代謝科

彰化市
- 彰化基督教醫院
  - 內分泌新陳代謝科
  - 健康管理中心

彰化縣
- 彰濱秀傳紀念醫院
  - 健康管理中心
- 鹿港基督教醫院
  - 內分泌新陳代謝科

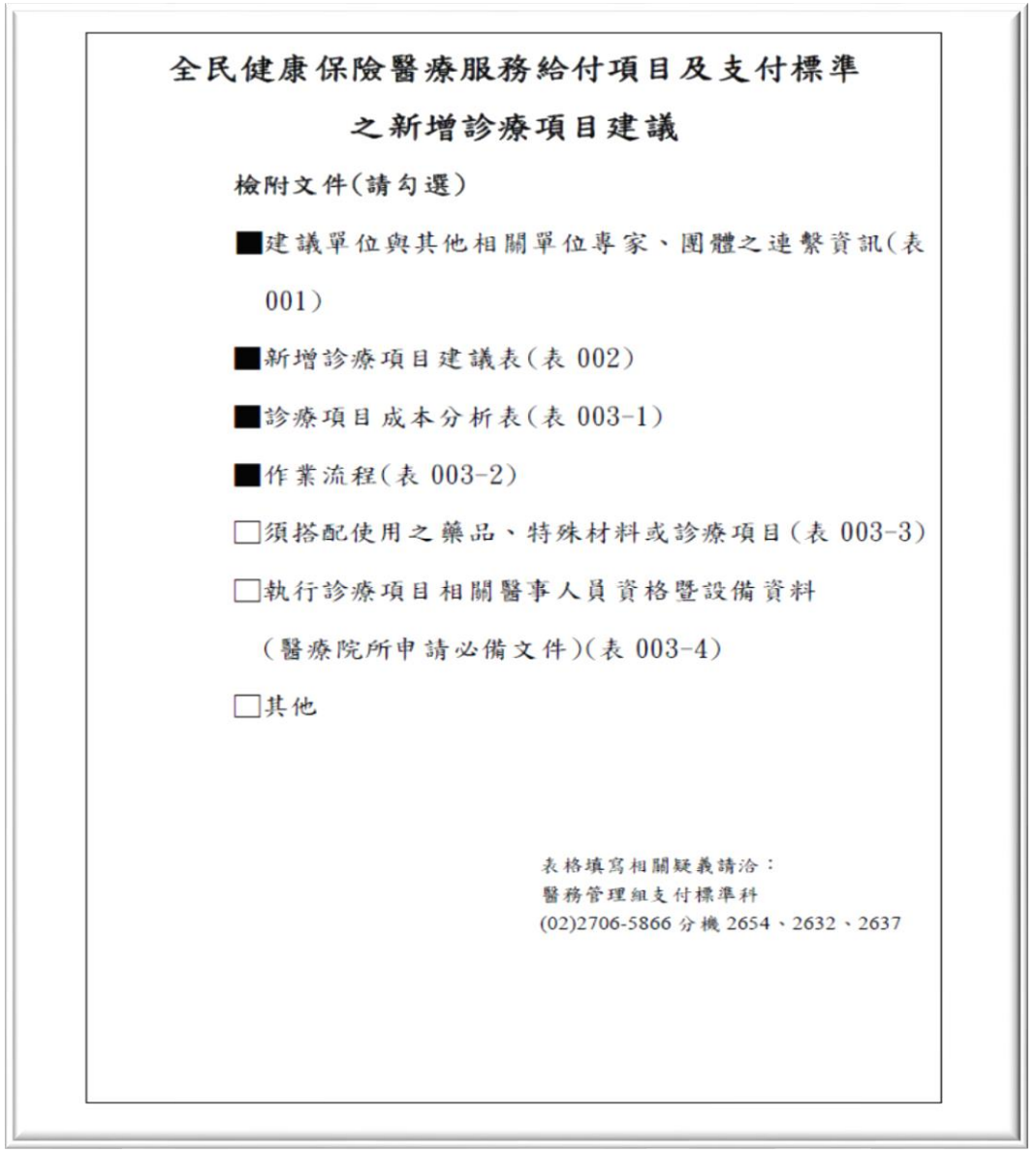
嘉義市
- 嘉義基督教醫院
  - 新陳代謝科

嘉義縣
- 大林慈濟醫院
  - 新陳代謝科

台南市
- 成大醫院
  - 內分泌及新陳代謝科

AmCAD-UT Application for health insurance benefits

- Reduce health insurance costs through AmCAD-UT intelligent analysis technology.
- CDE will issue an HTA report before the end of 2024, and a joint drafting meeting will be held in November.



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)

□其他

表格填寫相關疑義請洽：
醫務管理組支付標準科
(02)2706-5866 分機 2654、2632、2637

AI-assisted diagnostic tools to be included in health insurance

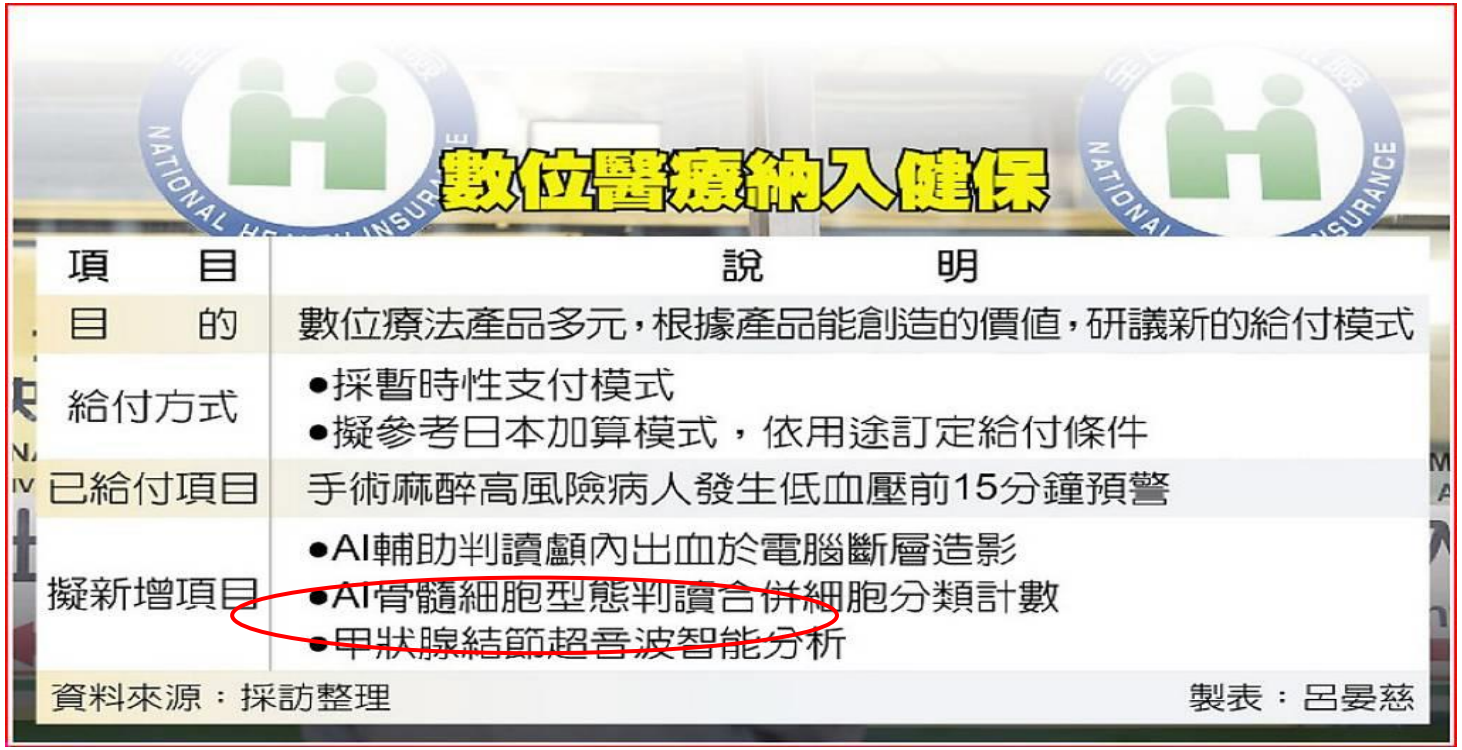
AmCad BioMed

日報 › 工商時報 ›

AI輔助診斷工具 擬納健保

石崇良：採暫時性支付模式，年底完成成本效益分析，作為未來數位醫療給付參考

2024.08.27 / 03:00 / 工商時報 呂晏慈



AmCAD-UT 2024

AmCad BioMed

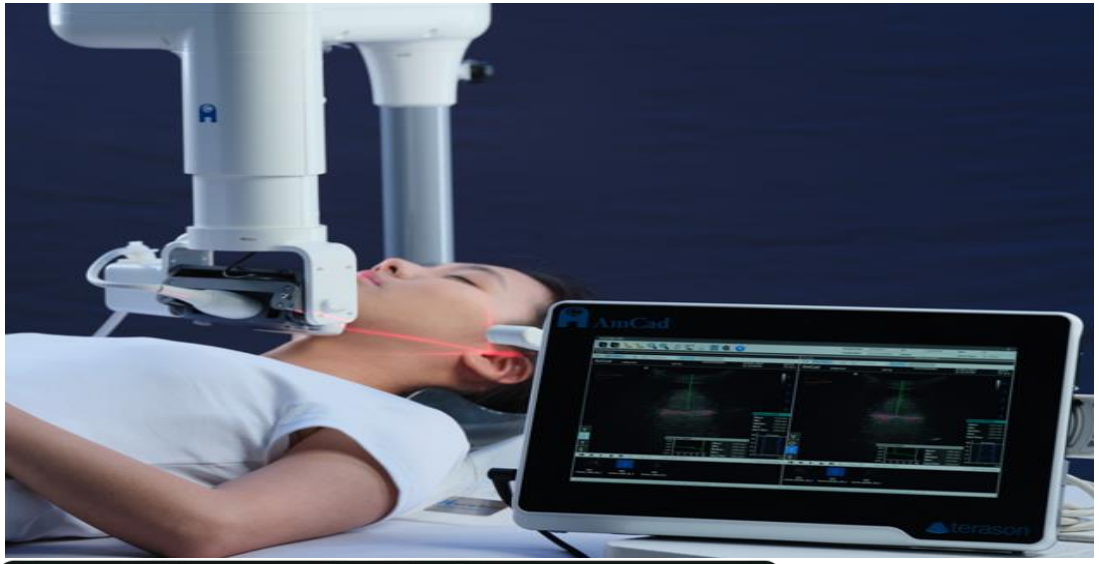
Domestic sales strategy

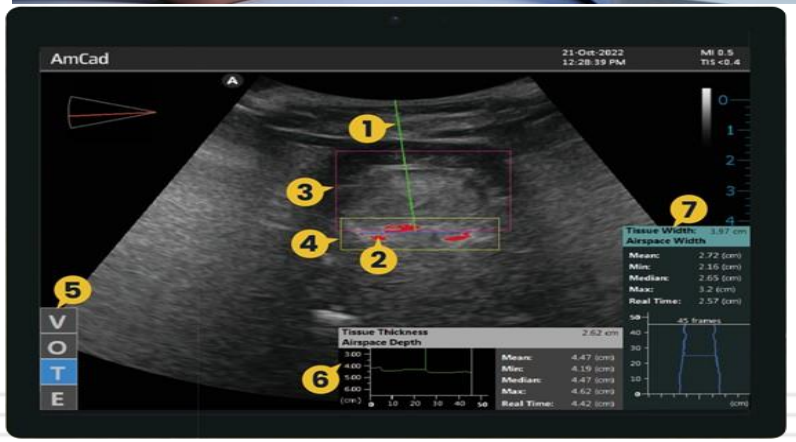
- Monthly carryover batch
- Health check subscription
- National Health Insurance Administration (HTA)

Domestic market strategy

- Health Check Center Subscription
- UT Simple Report Edition Subscription Plan (M[illegible]tation)
- Clinical expertise: Endocrinology
- Expanded departments: ENT/radiology/family[illegible]eral surgery
- Cooperation with ultrasound manufacturers
- Hospital tying strategy
- Clinic tie-in strategy, cooperation with Handheld ultrasound probe manufacturers
- New business opportunities
- Health Insurance Agency HTA
- ATA 2024 new Guidelines
- UT LiveScan

10-minute Obstructive Sleep Apnea (OSA) Assessment





1. airspace depth
2. airspace
3. tissue ROI
4. airspace ROI
5. sites of velum, oropharynx, tongue base, epiglottis (VOTE classification)
6. tissue thickness & airspace depth stats
7. tissue width & airspace stats

1. **Rapid Insights with 95% Accuracy:** Offer upper airway detailed & non-invasive insights into OSA risk factors
2. **Visualization & Quantification for Informed Decisions:** Help customize treatments like MADs or HNS using patient-specific data
3. **Tailored Treatment Plans**: Provides measurable feedback for personalized treatment adjustments

AmCAD-UO obtain Taipei City self-pay medical order code

- Taipei City Health Bureau UO self-funded official document approved$4,000

受文者：國立臺灣大學醫學院附設醫院

發文日期：中華民國113年4月16日
發文字號：北市衛醫字第1133110652號
速別：普通件
密等及解密條件或保密期限：
附件：核定表-國立臺灣大學醫學院附設醫院收費1份
(31232362_1133110652_1_ATTACH1.pdf)

主旨：核定貴院醫療費用收費項目：「上呼吸道超音波定位自動化掃描與智能分析」1項，請查照。

說明：

一、依據貴院113年4月10日校附醫主字第1131200128號函暨臺北市醫療費用收費標準核定原則辦理。

二、旨揭核定項目之核可內容如附件，請揭示於醫療機構及所屬網站，並於櫃檯備置經主管機關核定之紙本收費標準供病人查閱，以供民眾就醫參考及達資訊透明目的。對於是類對象，治療前應充分告知並取得病患同意，以確保其權益。

正本：國立臺灣大學醫學院附設醫院
副本：電子公文交換章 2024/04/16 14:08:29

Collaborated with Stanford to publish the second paper of AmCad UO

AmCad BioMed

ELSEVIER

Sleep Medicine

Volume 120, August 2024, Pages 15-21

Top three professional journals in the sleep field

Using standardized ultrasound imaging to correlate OSA severity with tongue morphology

Pien F.N. Bosschieter [a], Stanley Y.C. Liu [a], Pei-Yu Chao [b], Argon Chen [c], Clete A. Kushida [d]

[a] Department of Otolaryngology, head and Neck Surgery, Stanford University School of Medicine, Stanford, CA, USA

[b] AmCad BioMed Corporation, Taipei, Taiwan

[c] Institute of Industrial Engineering, National Taiwan University, Taipei, Taiwan

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Received 18 March 2024, Revised 21 May 2024, Accepted 28 May 2024, Available online 31 May 2024, Version of Record 5 June 2024.

South Korea's S1000 "AmCad UO" ultrasound equipment was successfully registered

AmCad BioMed

1. Product and classification: S1000 general ultrasonic, model UO-50.
2. Importer: MEK Healthcare Validity period: The certification is valid until March 28, 2029.

열 람 용

수인 24-168 호

의료기기 수입 인증서

(업 허가번호 : 제 3998 호)

구 분	[ ] 제조 / [✓] 수입	[✓] 품목 / [ ] 품목류	
명 칭 (제품명, 품목명, 모델명)	S1000,범용 초음파 영상 진단장치,UO-50	분류번호(등급)	A26380.01(2)
모 양 및 구 조	별첨		
원 재 료	별첨		
제 조 방 법	별첨		
성 능	별첨		
사 용 목 적	별첨		
사 용 방 법	별첨		
사 용 시 주 의 사 항	별첨		
포 장 단 위	별첨		
저장방법 및 사용기간	저장방법 : 별첨, 사용기간 : 별첨		
시 험 규 격	제 의기심 10-01-20231707-0087 호(2024.03.15.)한국산업기술시험원		
제조(수입)업자 정보	제조(수입)업자 : (주)멕헬스케어, 서울특별시 마포구 모래내로7길 12 , 4층(성산동, MEK빌딩(멕빌딩)) 제조원 : 별첨		
인 증 조 건	없음		
유 효 기 간	2024.03.29 ~ 2029.03.28		
소 재 지	서울특별시 마포구 모래내로7길 12 , 4층(성산동, MEK빌딩(멕빌딩))		
비 고			

「의료기기법」제6조·제15조 및 같은 법 시행 규칙 제6조제2항·제34조에 따라 위와 같이 인증합니다.

2024 년 03 월 29일

한국의료기기안전정보원장 (인)

변경 및 처분 사항 등

년 월 일	내 용
2024-03-29	최초허가

제품명

000

모 델 명

일련번호	모델명	비고	
		내수용	수출용
1	UO-50	[✓]	[✓]

포장단위

일련번호	포장단위
1	제조원 포장단위에 따름

제조원

일 련 번 호	제조업체명
1	AmCad BioMed Corporation(대만, F5., No.167, Fuxing N. Rd., Songshan Dist., Taipei City 105403, Taiwan (R.O.C.), 2F., No.12,Shih 2nd Rd., Yangmei Dist., Taoyuan City 326013, Taiwan, (R.O.C.))
일 련 번 호	제 조 자
1	Teratech Corporation(미국,77-79 Terrace Hall Avenue, Burlington, Massachusetts 01803 USA)

Signed a cooperation agreement with the UOP

AmCad BioMed

Collaborative Research and Supply Agreement

This Agreement is made and entered into as of Feb. 29th 2024 (the "Effective Data") by and between AmCad BioMed Corporation, a corporation with office at 5F., No.167, Fuxing N. Rd., Songshan Dist., Taipei City 105, Taiwan R.O.C (hereinafter referred to as "AmCad") and the University of the Pacific, Arthur A. Dugoni School of Dentistry located at 155 5th St, San Francisco, CA 94103, United States ("UOP"). AmCad and UOP are individually referred to as the "Party"; or collectively referred to as the "Parties".

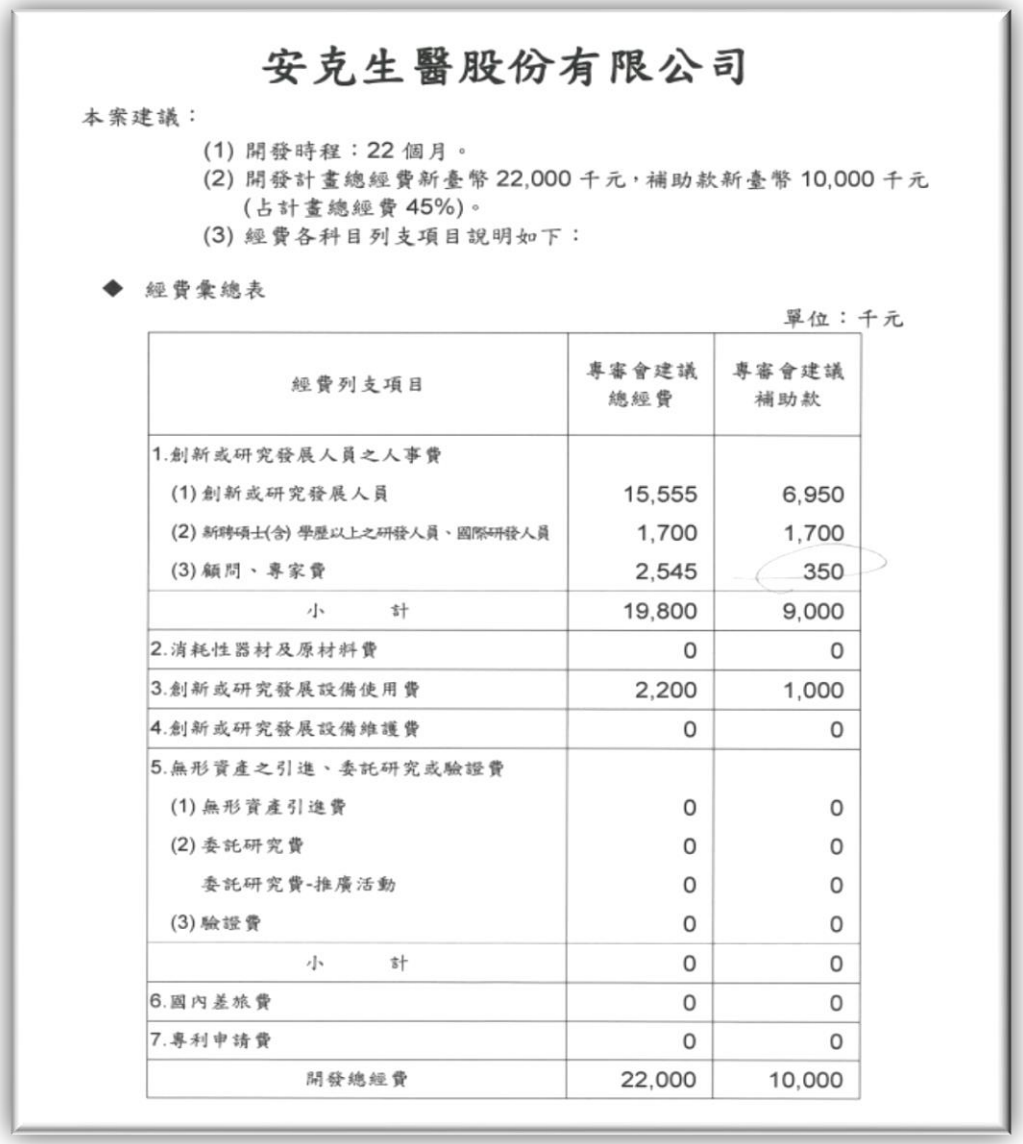
1. **Product Definition:** The "Product" referred to in this Agreement encompasses the AmCAD-UO solution, which integrates both AmCAD-UO software and the specified accompanying hardware as detailed in the table below:

Item Description	Qty
AmCad-UO computer aided detection (CAD) software	1
Head & Neck Laser Alignment Robotic Arm system	1
Terason uSmart 3200t ultrasound model	1
5C2A Curved probe (for AmCAD-UO application)	1

2. **Scope of Product Use:** UOP agrees to use the Product for clinical, teaching, and academic research purposes. This includes incorporating the Product into clinical trials, educational programs, and research studies conducted by UOP.

Ministry of Economic Affairs' Innovative Medical Products Market Access R&D Subsidy Program

- Using AmCAD-UO and international clinical cooperation, we will introduce sleep apnea into the dental market and develop product applications based on sleep braces treatment to accompany the diagnosis and treatment needs
- On June 17, the official document was approved by the review meeting, and the subsidy project was 10 million yuan, which will be implemented for 22 months.



安克生醫股份有限公司

本案建議：

(1) 開發時程：22 個月。
(2) 開發計畫總經費新臺幣 22,000 千元，補助款新臺幣 10,000 千元（占計畫總經費 45%）。
(3) 經費各科目列支項目說明如下：

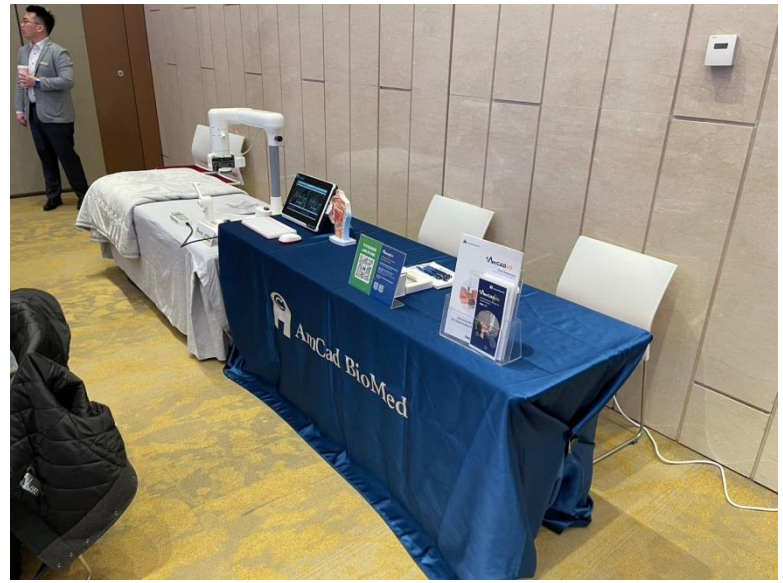
◆ 經費彙總表

單位：千元

經費列支項目	專審會建議總經費	專審會建議補助款
1.創新或研究發展人員之人事費		
(1) 創新或研究發展人員	15,555	6,950
(2) 新聘碩士(含) 學歷以上之研發人員、國際研發人員	1,700	1,700
(3) 顧問、專家費	2,545	350
小　　計	19,800	9,000
2.消耗性器材及原材料費	0	0
3.創新或研究發展設備使用費	2,200	1,000
4.創新或研究發展設備維護費	0	0
5.無形資產之引進、委託研究或驗證費		
(1) 無形資產引進費	0	0
(2) 委託研究費	0	0
委託研究費-推廣活動	0	0
(3) 驗證費	0	0
小　　計	0	0
6.國內差旅費	0	0
7.專利申請費	0	0
開發總經費	22,000	10,000

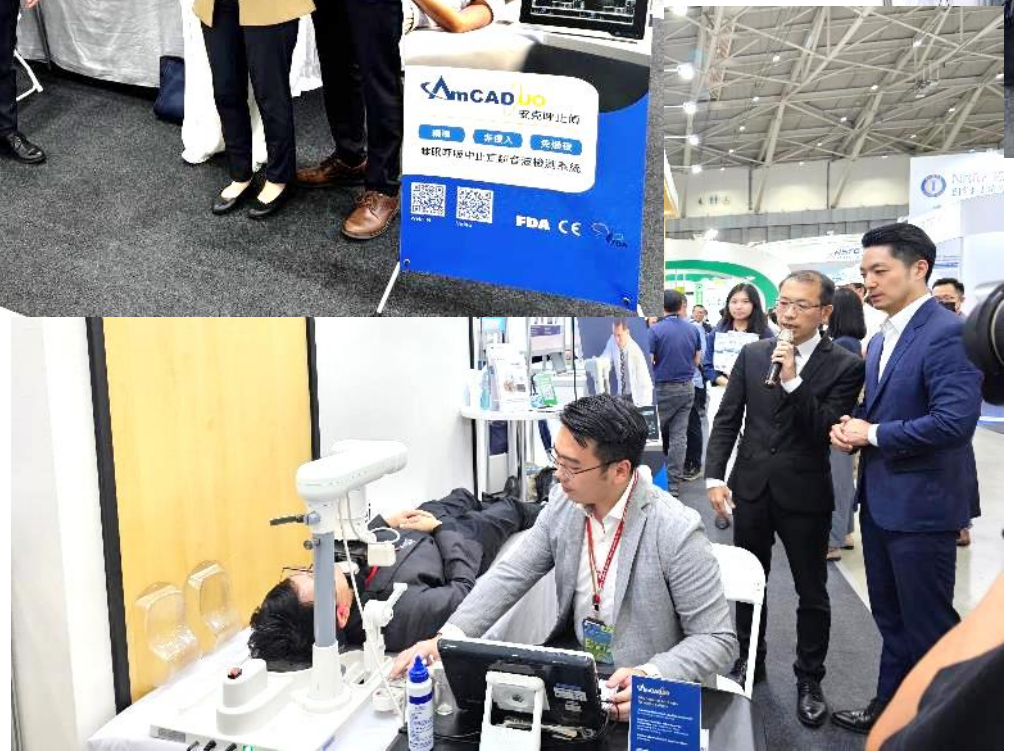
OSAWELL OSA interdisciplinary seminar

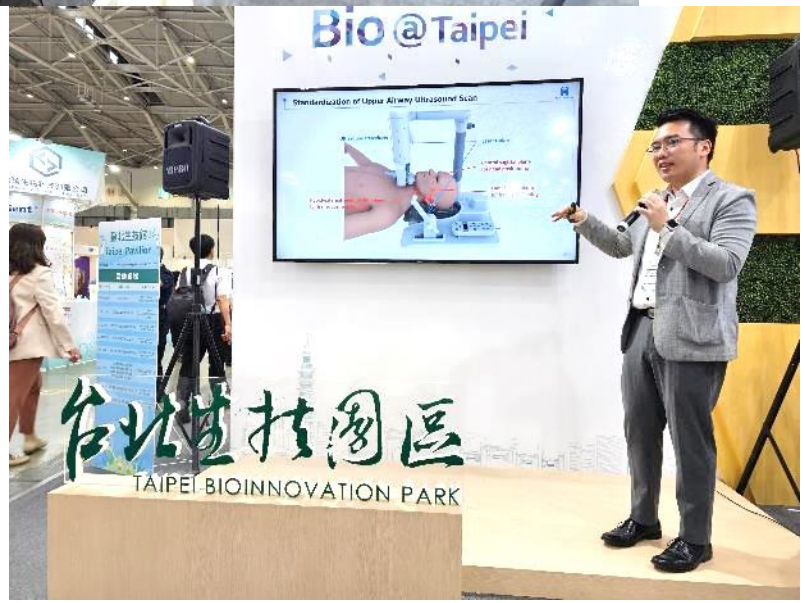
AmCad BioMed



BIO Asia Taiwan 2024

AmCad BioMed





Domestic business promotion

AmCad BioMed

Chang Gung Memorial Hospital Sleep Medicine Society

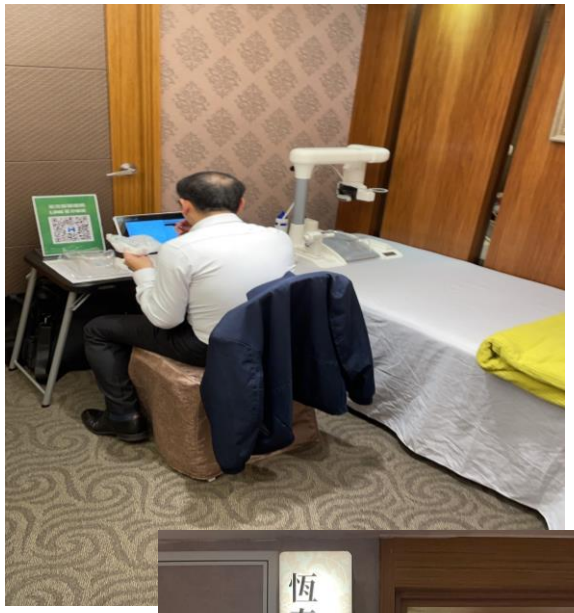
Tzu Chi Hospital Dental Department

Taipei Medical University Technical EMBA

Domestic business promotion

AmCad BioMed

WOB Female Directors Association



Zhenxing Hospital ENT

St. Paul's Health Screening Center

Chiayi Christian Hospital

Taipei Mackay ENT Morning Meeting

Launch the dental anti-snoring braces market

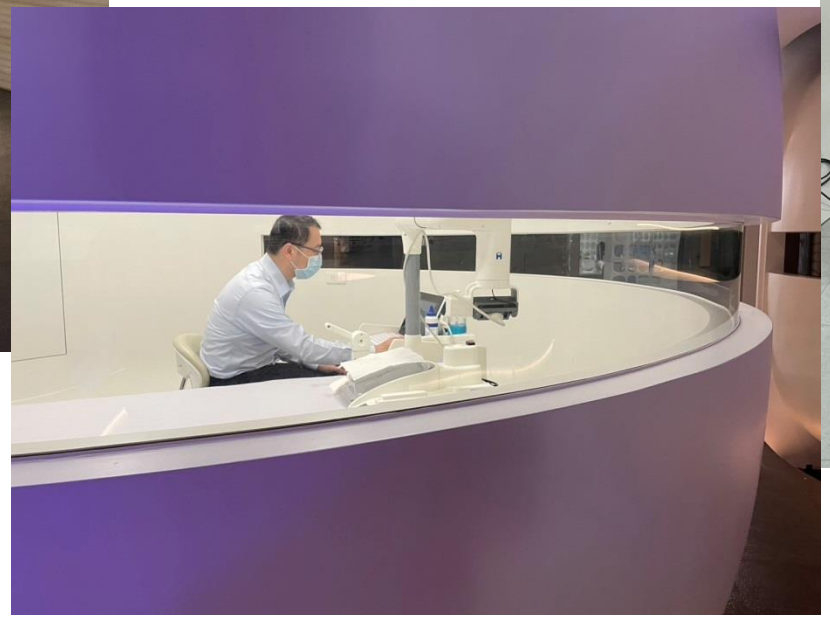
- **The largest chain of dental clinics in the country Dr. Wells**

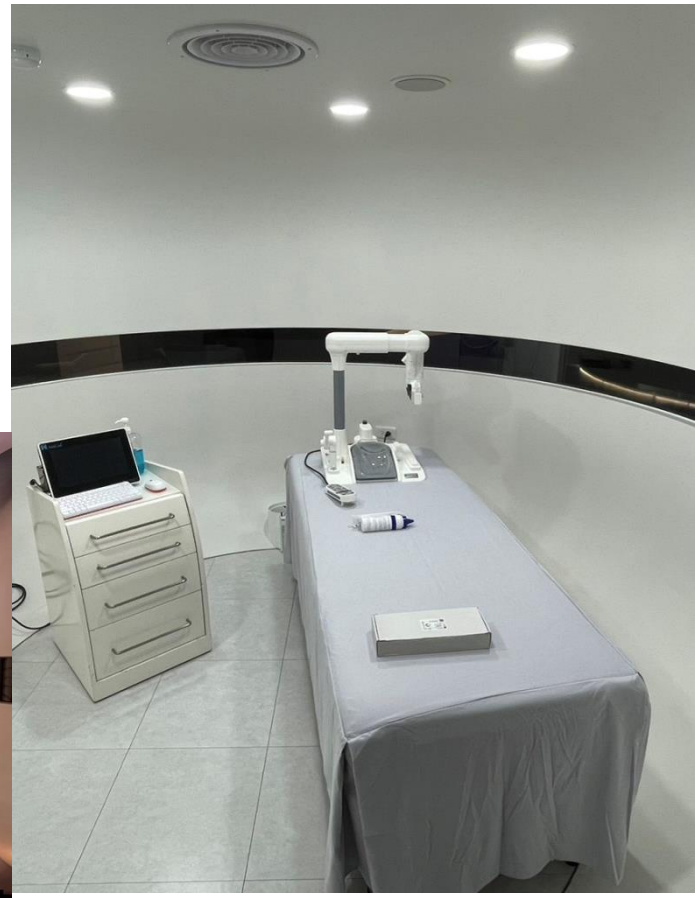
- **The largest brand agent of oral scanners in the market is owned by Xuda Group**

- **Daan Fengcai Sleep Medicine Aesthetics Dental Joint Clinic Dr.BreathE Strategic Cooperation Sleep Care Circle**

Shilin Weiyu Dental Clinic

AmCad BioMed

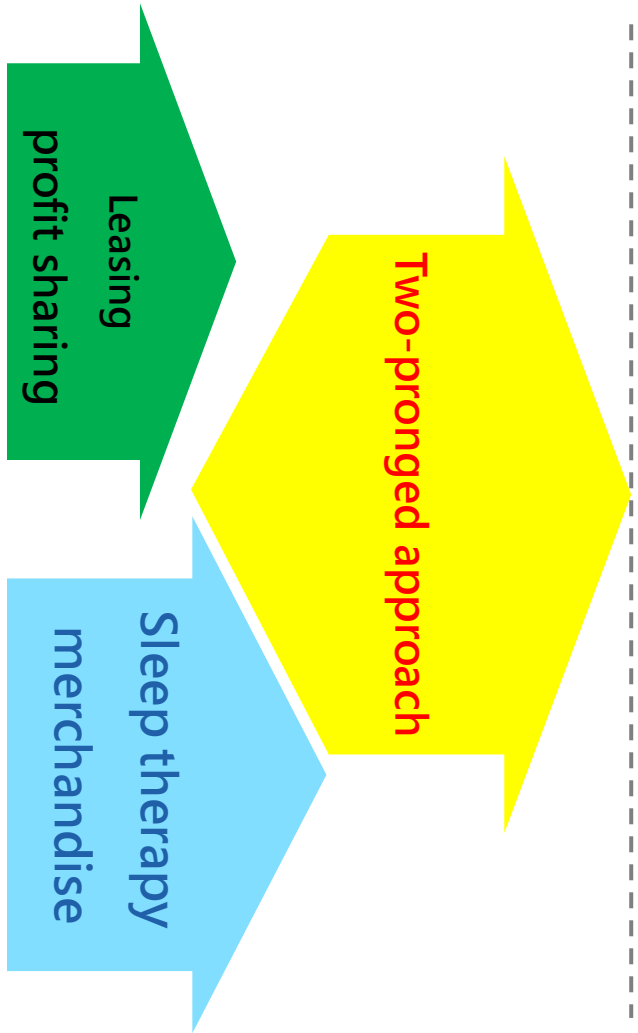




AmCAD-UO 2024

AmCad BioMed

Domestic market strategy



Domestic market strategy

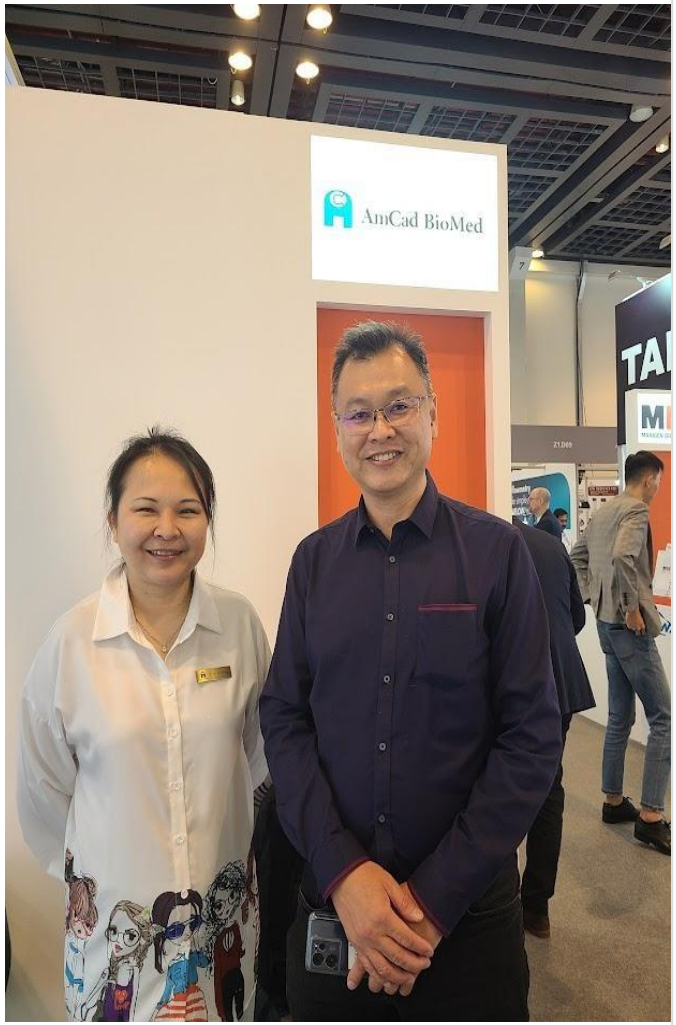
- Health examination centers: medical centers, high-volume regional hospitals and health clinics
- Clinical expertise:
- Sleep Center Product Introduction
- Otolaryngology, dentistry (sleep snoring), thoracic medicine
- sales integration
- UT domestic business team merges to promote UO
- High-end health examination center UT/UO joint sales
- Enterprise screening
- One Stop Solution/Service
- Cooperation with colleagues related to sleep therap
- Respirator manufacturers
- Braces manufacturers

AmCad BioMed

International exhibition industry

美吾華·懷特·安克生技集團
Maywufa Biopharma Group

AmCad’s products attract a lot of attention at Arab Health Exhibition 2024



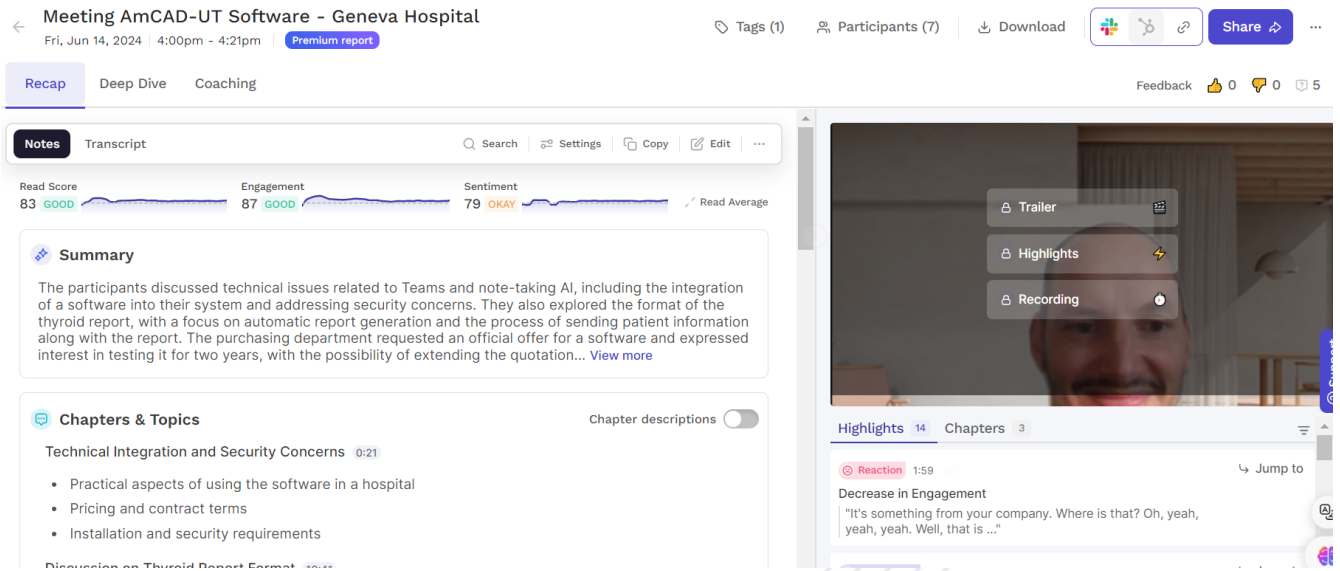
Signed MOU with Meridian Healthcare (MHC) in the United Arab Emirates to launch business cooperation in the Middle East

MERIDIAN HEALTHCARE
SCIENTIFIC OFFICE

Africa Excon: June 3-7

Negotiate cooperation with University Hospital of Geneva, Switzerland

The University Hospital of Geneva in Switzerland has expressed strong interest in introducing the AmCAD-UT system and is considering a two-year subscription model.



Swiss clinical research recognizes "Ankehuzhiding": the results were published at the ISSS conference

1. Backscatter technology can be used to screen OSA patients who may benefit from Inspire treatment before NHS treatment, thereby improving the success rate of treatment.
2. AmCad's backscatter technology can screen out patients who are expected to benefit before treatment, and can significantly improve the success rate of NNS treatment.

Swiss clinical results verify the effectiveness of using Anker to screen for HNS treatment

AmCad BioMed

Clinical results published: The University of Bern, Switzerland, and the Kantonsspital Baselland Swiss Spring Meeting of Head and Neck Surgery jointly published clinical results, confirming the effectiveness of Anker's respiratory detection technology in screening for HNS treatment.

Increase product visibility:

A joint publication by the University of Bern in Switzerland increases the visibility and credibility of Anker's products.

ORL Oto-Rhino-Laryngologie

Frühjahrsversammlung 2024
Assemblée de printemps 2024

Pädiatrische ORL: Bewährtes und Neues
ORL pédiatrique : bonnes pratiques et nouveautés

13.-14. Juni 2024 | 13-14 juin 2024
Palazzo dei Congressi, Lugano

Predictive Value of Standardized Submental Ultrasonography for Response to Hypoglossal Nerve Stimulation

Samuel Tschopp[1,2], Vlado Janjic[2], Yili Lee[3], Argon Chen[3], Pei-Yu Chao[3], Marco Caversaccio[1], Urs Borner[2], Kurt Tschopp[2]

1 Department of Otorhinolaryngology, Head and Neck Surgery, Inselspital, Bern
2 Department of Otorhinolaryngology, Head and Neck Surgery, Kantonsspital Baselland, Liestal
3 AmCAD Biomed, Taipei, Taiwan

Objective

The overall reported hypoglossal nerve stimulation (HNS) response rate for apnea-hypopnea index (AHI) reduction is approximately 60%. The present study aims to evaluate the predictive value of standardized submental ultrasonography.

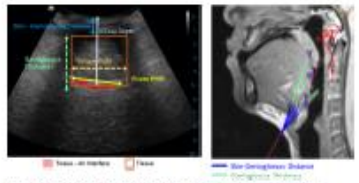
Methods

We performed ultrasonography in patients with HNS and healthy controls using the AmCAD-UO device. Anatomy of the soft tissue anterior to the upper airway and the tissue morphology using backscatter ultrasound images were measured. Backscatter imaging relies on scattering of ultrasound waves by tissue inhomogeneities to quantify tissue composition and structure. Responder status for AHI-reduction was defined according to the Sher criteria.

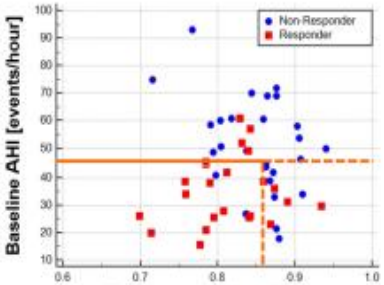
AmCAD ultrasonography with the robotic probe positioning for a standardized examination of the upper airway

Results

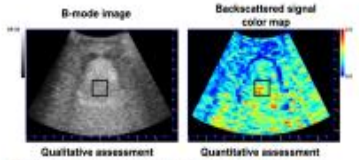
We enrolled 49 patients, of which 22 were responders and 27 were non-responders. In the HNS group, responders and non-responders were comparable in sex and age. However, the initial neck circumference (42.2 vs. 40.4cm), baseline AHI (50.8 vs. 34.7/h), and BMI (28.4 vs. 26.4kg/m2) were significantly higher in non-responders versus responders. The prediction of responders based on baseline AHI alone was 64%. A lower backscatter ultrasound image value, indicating less fat deposition in the tissue, was observed in the responder group. The backscatter ultrasound image from the oropharynx region, combined with baseline AHI, predicted responders with an accuracy of 81% and non-responders with 75% accuracy. When the baseline AHI and backscatter signal were combined, the area under the curve to predict treatment response to the HNS reached 0.80.



B-mode ultrasonography of the oropharynx with various anatomical structures marked (left). For reference, an MRI image of the assessed airway levels during standardized ultrasonography



Backscattered signal of the oropharynx region and baseline apnea-hypopnea index (AHI) predict responder to hypoglossal nerve stimulation



Axial scans of a patient with obstructive sleep apnea and hypoglossal nerve stimulation in B-mode for qualitative assessment and backscattered signal for quantitative analysis.

Conclusion

The combination of tissue morphology analyzed using standardized submental ultrasonography and patient characteristics is highly predictive for determining the treatment response in patients with HNS.

INSELSPITAL | Kantonsspital Baselland

Connect with Samuel Tschopp for more details or discussion: samuel.tschopp@insel.ch

Research conducted by Walailuk University in Thailand validates the application of Ankehuzhizhen in dental OSA

AmCad BioMed

1 Research Published: A study from Walailuk University Hospital School of Dentistry, published in Clinical Medicine, explores the relationship between adult cranial structures and airway characteristics, specifically in patients at high risk for OSA.
2. System application: Research points out that the AmCAD-UO system's ability to capture detailed airway images has an important impact on OSA screening and treatment planning. important impact.

Journal of *Clinical Medicine*

MDPI

Article

Relationship between Cephalometric and Ultrasonic Airway Parameters in Adults with High Risk of Obstructive Sleep Apnea

Anutta Terawatpothong [1], Chidchanok Sessirisombat [1], Wish Banhiran [2], Hitoshi Hotokezaka [3], Noriaki Yoshida [3] and Irin Sirisoontorn [1,*]

[1] Department of Clinical Dentistry, Walailak University International College of Dentistry (WUICD), 87 Ranong 2 Road, Dusit, Bangkok 10300, Thailand
[2] Department of Otorhinolaryngology, Faculty of Medicine Siriraj Hospital, Mahidol University, 2 Wanglang Road, Bangkoknoi, Bangkok 10700, Thailand
[3] Department of Orthodontics and Dentofacial Orthopedics, Nagasaki University Graduate School of Biomedical Sciences, 1-7-1 Sakamoto, Nagasaki 852-8588, Japan
* Correspondence: irin.sirisoontorn@gmail.com

Abstract: Background/Objectives: Polysomnography and cephalometry have been used for studying obstructive sleep apnea (OSA) etiology. The association between craniofacial skeleton and OSA severity remains controversial. To study OSA's etiology, cephalometry, fiberoptic pharyngoscopy, polysomnography, and sleep endoscopy have been used; however, airway obstructions cannot be located. Recent research suggested ultrasonography for OSA screening and upper airway obstruction localization. Thus, this study aims to investigate the relationship between specific craniofacial cephalometric and ultrasonic airway parameters in adults at high risk of OSA. **Methods:** To assess craniofacial structure, lateral cephalograms were taken from thirty-three adults over 18 with a STOP-Bang questionnaire score of three or higher and a waist-to-height ratio (WHtR) of 0.5 or higher. Airway parameters were assessed through submental ultrasound. **Results:** NSBA correlated with tongue base airspace width, while MP-H correlated with oropharynx, tongue base, and epiglottis airspace width. SNA, SNB, and NSBA correlated with tongue width at the oropharynx. At tongue base, ANB and MP-H correlated with tongue width. SNB and NSBA were associated with deep tissue thickness at the oropharynx, while MP-H correlated with superficial tissue thickness at velum and oropharynx. **Conclusions:** Cephalometric parameters (SNA, SNB, ANB, NSBA, and MP-H) were correlated with ultrasonic parameters in the velum, oropharynx, tongue base, and epiglottis.

Keywords: obstructive sleep apnea; lateral cephalometry; ultrasonography

check for updates

Citation: Terawatpothong, A.; Sessirisombat, C.; Banhiran, W.; Hotokezaka, H.; Yoshida, N.; Sirisoontorn, I. Relationship between Cephalometric and Ultrasonic Airway Parameters in Adults with High Risk of Obstructive Sleep Apnea. *J. Clin. Med.* **2024**, *13*, 3540. https://doi.org/10.3390/jcm13123540

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Received: 16 May 2024
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Accepted: 13 June 2024
Published: 17 June 2024

1. Introduction

Obstructive sleep apnea (OSA) is a breathing disorder caused by an upper airway constriction that prevents normal ventilation during sleep [1]. Respiratory effort increases to sustain airflow via a constricted airway, and this is followed by an increase in serum carbon dioxide (hypercarbia) and a drop in serum oxygen (hypoxemia). Cortical arousal is attributed to the increased work of breathing during sleep. Common symptoms of OSA include snoring, gasping, or choking respiration; frequent nighttime awakenings; excessive daytime sleepiness; and irritability. Many previous studies have reported that there are many factors that increase the risk of OSA, which include male sex, obesity (higher BMI), older age, greater neck and waist circumference, as well as craniofacial disposition and pharyngeal soft tissues [2–4]. Untreated obstructive sleep apnea (OSA) can lead to severe problems such as coronary artery disease, congestive heart failure, myocardial infarction, hypertension, stroke, cardiac arrhythmia, and mortality [5].

For diagnosing obstructive sleep apnea, polysomnography (PSG) is the most reliable technique [1,5]. The American Academy of Sleep Medicine (AASM) has proposed a classification system for the severity of OSA based on the apnea–hypopnea index (AHI).

OSA is classified as mild to moderate (AHI ≥ 5 events/h and AHI < 30 events/h) or severe (AHI ≥ 30 events/h). Without conducting home sleep apnea testing or PSG, the use of clinical devices, questionnaires, and prediction algorithms is not recommended to diagnose OSA in adults. Uncomplicated adult patients who present with signs and symptoms indicating an increased risk of moderate-to-severe OSA can be diagnosed using home sleep apnea testing with a suitable device or PSG, while adults with comorbid conditions are recommended to use PSG for OSA diagnosis rather than home sleep apnea testing [1]. Following diagnosis, a treatment plan should be developed, which may involve behavioral therapy, oral appliances, positive airway pressure devices, surgery, and/or additional treatments. OSA is regarded as a chronic condition that needs multidisciplinary therapy [1,6].

However, polysomnography (PSG) is costly, time-consuming, many sleep laboratories have long waiting lists of patients, and an unfamiliar environment may lead to discomfort and perhaps compromise sleep quality [7]. A previous study reported that PSG, fiberoptic pharyngoscopy, and sleep endoscopy have all been used to investigate the predisposing etiological variables of OSA. Nevertheless, even with the use of all available methods, there are limitations in accurately locating the site of the blocked airway because it is not possible to mimic the sleep state in awake individuals [8]. PSG gives a range of physiological data during sleep without determining the anatomic cause of OSA. Consequently, a significant number of people remain undiagnosed due to an inability to access treatment, being asymptomatic, or lacking awareness of their condition. It is essential to place importance on the screening procedures that help in the early identification of patients at risk or those with unrecognized OSA. The screening methods for OSA involve physical examination, upper airway examination, questionnaires, and imaging technologies.

The STOP-Bang questionnaire, Berlin Questionnaire (BQ), and Epworth Sleepiness Scale (ESS) are widely used screening tools facilitating the early identification of patients at risk [9]. The STOP-Bang questionnaire is a reliable tool for screening obstructive sleep apnea in adults. It consists of four subjective items (STOP: Snoring, Tiredness, Observed Apnea, and High Blood Pressure) and four demographic criteria (Bang: BMI > 35 kg/m², age > 50 years, neck circumference > 40 cm, and gender). With a high sensitivity, the STOP-Bang questionnaire can identify patients with moderate-to-severe OSA [10,11]. However, some adjustments are required for Thai patients. The Thai STOP-Bang questionnaire's optimal BMI cutoff point was >30 kg/m², which increased sensitivity at the AHI cutoff points of 5 and 15 by 88.7% and 93.2%, respectively. A patient is considered high-risk if at least three "yes" answers are provided [12]. Banhiran et al. reported that male gender and a waist-to-height ratio (WHtR) of 0.55 were significant predictors of moderate-to-severe OSA. The WHtR identifies central obesity, or visceral fat, and represents fat distribution [13]. However, some authors reported that if the WHtR is higher than 0.5 or 0.6, the risk of causing obstructive sleep apnea increases [14–17]. Therefore, the waist-to-height ratio (WHtR) should be incorporated into questionnaires for high-risk individuals to reduce the possibility of false-positive results.

Imaging technologies, such as cone-beam computed tomography (CBCT), lateral cephalometric radiographs, and ultrasonography, aid in the study of OSA. Cephalometric radiographs are routinely taken for orthodontic diagnosis and treatment planning by analyzing the relationship between the skull, maxilla, mandible, teeth, and soft tissues. The radiation dose from a lateral cephalogram is low, at approximately 5.6 μSv, whereas the CBCT is 15–26 times higher [18]. Previous research has found that most common variables, such as the angle between the anterior cranial base and the maxilla (SNA), the angle between the anterior cranial base and the mandible (SNB), the posterior airway space (PAS), the length of soft palate (PNS-P), and the distance from the hyoid bone to the mandibular plane (MP-H), may be correlated with the development and severity of OSA [19]. In addition, Banhiran et al. reported that the risk of moderate-to-severe OSA in Thai patients was also influenced by the cranial base angle (NSBA), which was 130 degrees or less. Abnormality of the skull's base may potentially contribute to the constriction of

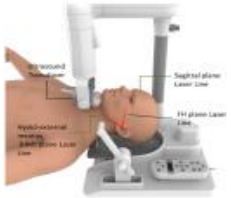

Figure 4. Submental ultrasonography equipment, laser alignment (AmCad BioMed Corporation).

The ultrasonic transducer is aligned with the HM plane's laser projection in the submental region to provide transverse, cross-sectional images (Figure 4). Three replicates were automatically scanned by an ultrasonic transducer during tidal breathing and Muller maneuvers at 30 degrees, covering the velum (V), the oropharynx (O), the base of the tongue (T), and the epiglottis (E) (Figure 5a).

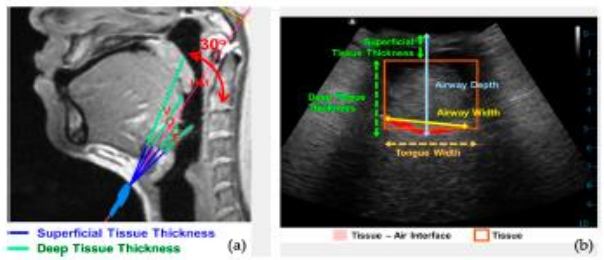

Figure 5. (a) The 30° segment of the upper airway; HM, hyoid-external meatus. (b) Transverse view of ultrasonographic images.

During scanning, patients were instructed to alternate between regular breathing and Muller maneuvers, completing a total of three repetitions. Muller maneuvers were conducted by inhaling vigorously with the mouth and nose close, simulating upper airway obstruction during awake.

The airway's width, airway's depth, tongue width, airspace–tissue width ratio, superficial tissue thickness, and deep tissue thickness were measured (Figure 5b). Dynamic changes in airway width during tidal breathing and Muller maneuvers, or percentages of airway contraction, were calculated as a percentage of pharyngeal diameters shortening from the diameters during tidal breathing to that during MM.

The risk of moderate-to-severe OSA (AHI ≥ 15/h) was evaluated as a percentage based on the assessment of ultrasonic parameters. The risk of 0–40% is classified as low, 40–80% is classified as medium, and 80–100% is classified as a high risk of moderate-to-severe OSA [24,27–29].

Cooperation negotiations with hospitals from various countries are in progress

We are currently actively negotiating cooperation with hospitals in three countries (Switzerland, Brazil, and the United Arab Emirates) to explore global market opportunities and expand our business scope.
Cooperation with hospitals in various countries will include product trials, market feedback, technology integration, etc., aiming to enhance the market competitiveness and application value of our products

UNIVERSITÉ DE GENÈVE

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Siriraj Hospital
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Walailak University
International College of Dentistry
Clinical Dentistry Program

AmCad BioMed

Financials

美吾華·懷特·安克生技集團
Maywufa Biopharma Group

Consolidated Balance Sheet

AmCad BioMed

ITEMS	2024.06.30	%	2023.12.31	%
Current Assets	298,456	62	325,893	64
Non-current Assets	182,872	38	186,753	36
Total Assets	**481,328**	**100**	**512,646**	**100**
Current Liabilities	21,272	4	24,419	4
Non-current Liabilities	8,504	2	10,279	2
Total Liabilities	**29,776**	**6**	**34,698**	**6**
Capital	533,184	111	533,306	104
Additional Paid-in Capital	8,899	2	8,016	2
Accumulated Deficit	(174,622)	(36)	(148,743)	(29)
Other Equity	(9,613)	(2)	(11,996)	(2)
Parent Equity	357,848	75	380,583	75
Minority Interest	93,704	19	97,365	19
Total Equity	**451,552**	**94**	**477,948**	**94**
Total Liabilities and Equity	**481,328**	**100**	**512,646**	**100**

- 7/24 After receiving the full share capital, the cash on account will be >480 million, providing sufficient funds for the company's future development.

Consolidated Income Statement

AmCad BioMed

Unit：K TWD

Items	2024Q2		2023Q2		YoY
	AMT	%	AMT	%	%
Sales Revenue	24,448	100	26,137	100	(6)
Gross Margin	14,466	59	14,928	57	(3)
Operating Expenses	(46,930)	(192)	(44,351)	(170)	6
Operating Loss	(32,464)	(133)	(29,423)	(113)	-
Non-operating Gain	2,924	12	5,135	20	(43)
Net Loss	(29,540)	(121)	(24,288)	(93)	-
Net Loss – Parent	(25,879)	(106)	(23,598)	(90)	-
Net Loss – Minority	(3,661)	(15)	(690)	(3)	-
EPS (TWD)	(0.48)		(0.44)		

- Operating income decreased slightly compared with the same period last year. In the second half of the year, through domestic and overseas business expansion and expansion of dental channels, revenue can be significantly increased.

AmCad BioMed

Future development

美吾華·懷特·安克生技集團
Maywufa Biopharma Group

New Trend in Medical Diagnosis: Ultrasound+ One-Device AI

Market background:

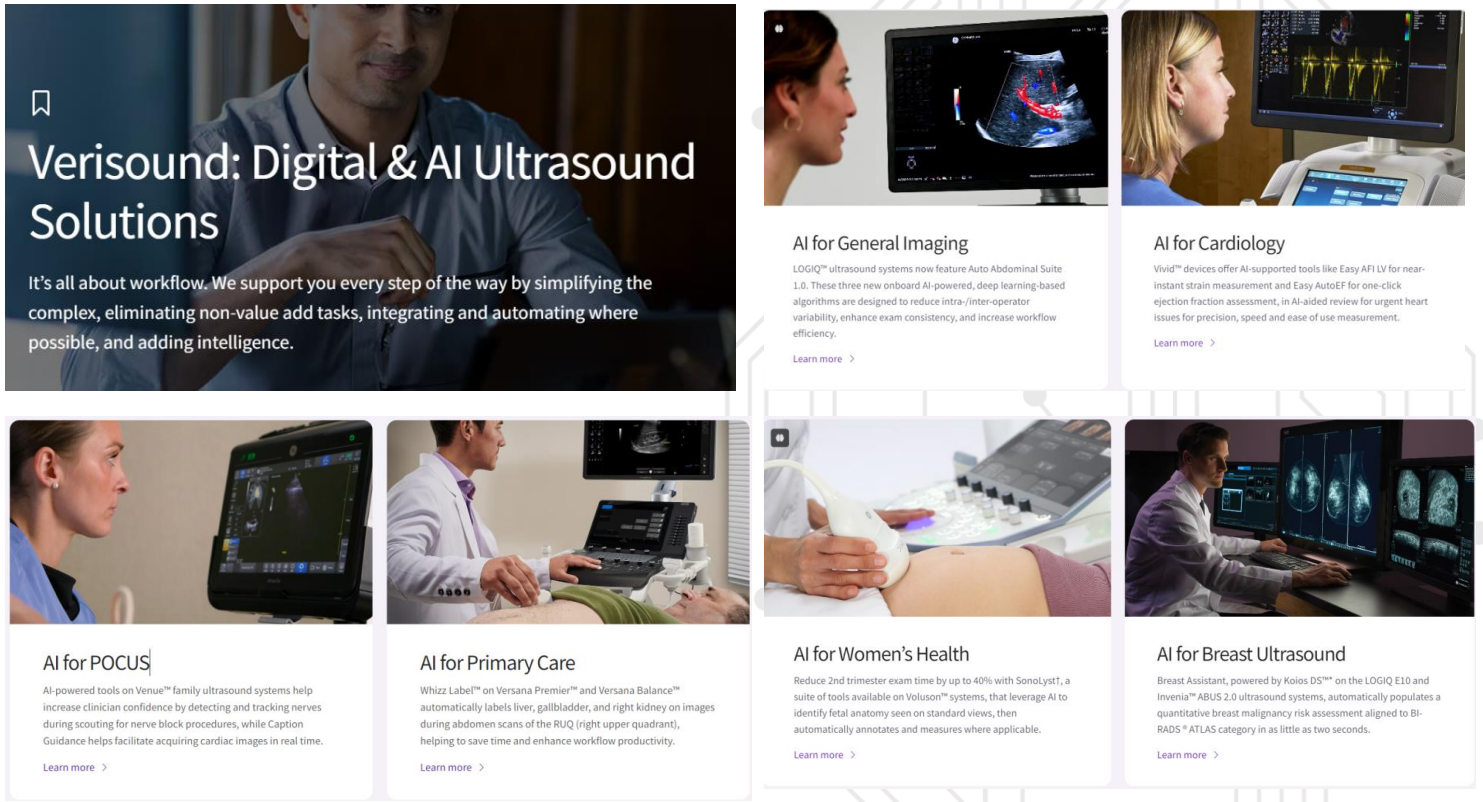
The application of AI in medical imaging is becoming increasingly popular.

AI combined with ultrasound is used to (a) improve diagnostic accuracy and efficiency; (b) reduce human errors; (c) provide instant diagnosis; (d) shorten diagnosis and treatment time

Importance of On-device AI:

- All AI processing is performed on the device without relying on the cloud, ensuring patient privacy, data security and fast processing.
- GE Development Story: GE has begun using On-device AI Ultrasound to improve the performance and reliability of its ultrasound technology

GE's Ultrasonic Developments



Handheld ultrasound and AI technology assist diagnosis

AmCad BioMed

Handheld ultrasound has not yet reached mainstream adoption, but the market is still forecast to reach over $500 million by 2026. Signify Research's newly-published Handheld Ultrasound Deep Dive Report 2022 shows the market revenues are estimated to have grown by approximately 30% in 2021, driven by strong growth in the U.S., the biggest market for handheld ultrasound. Despite the global challenges for handheld ultrasound vendors in 2022, such as rising inflation and supply chain disruptions, the handheld ultrasound market is expected to experience double-digit growth, and this is forecast to continue through to 2026. Most of the market growth will be fueled by increased adoption of handheld devices by new users of ultrasound, such as primary care physicians, nurses, emergency medical technicians (EMTs) and midwives. The key market trends are discussed below.

Trend 1: Artificial Intelligence

The steep learning curve and subsequent ultrasound skills shortage are two of the biggest barriers to the wider use of ultrasound. These challenges are exacerbated in handheld ultrasound, where there is a higher proportion of new and less experienced users compared to cart and compact ultrasound. As the expansion of the handheld ultrasound market in the coming years is expected to be strongly driven by new user groups, this barrier will be greater than ever before. These barriers can be partially addressed by artificial intelligence (AI) solutions that guide users with positioning and moving the ultrasound probe.

(from Imaging Technology News)

安AmCad AI real-time functions: UT, UB and Liver are integrated with handheld ultrasound, which can significantly enhance ultrasound technology, provide usability and effectiveness in various medical environments (POCUS), and serve as the beginning of entering the new blue ocean market

maximum POCUS integration capabilities as competitive advantage

Hardware Integration example with or without API/SDK

GE VScan® Air

Telemed MirUS Pro

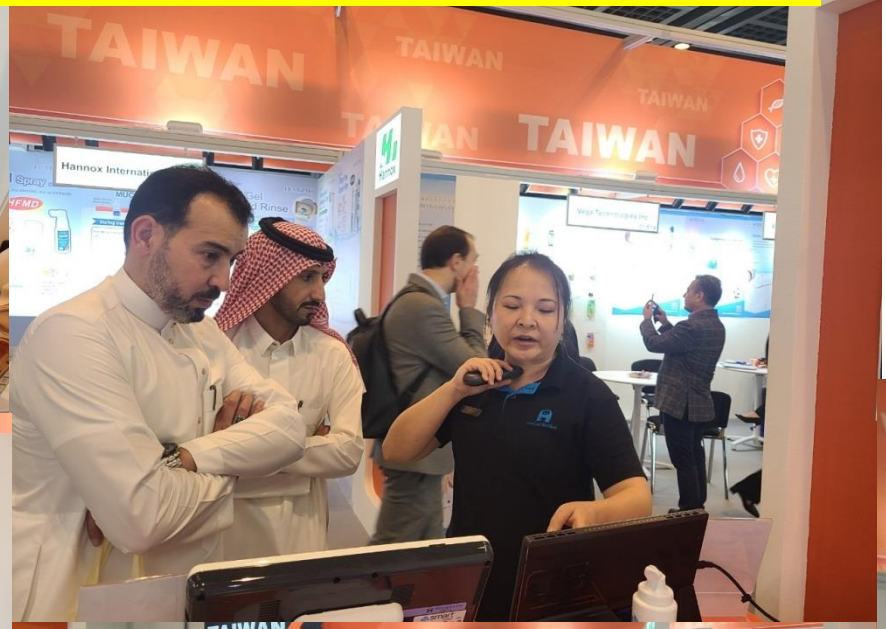
EchoNous Lexsa®

BenQ Handheld Ultrasound

Cooperate with ultrasound factory (POC+AI)

The AmCAD-UT LiveScan (instant scanning POCUS solution) exhibited at the Arab Health exhibition attracted an unprecedented number of visitors, with more than 160 companies participating.

Through the open SDK, any mobile phone can be integrated



安克未來發展策略

AmCad BioMed

◘ Technology collaboration, licensing, or cooperative development

Seize POCUS business opportunities and cooperate with internationally renowned hardware palm monitor manufacturers: combine our AI ultrasound technology with its palm monitors to develop "Amcad UT", "Amcad UO", and "Amcad UB" technical cooperation and licensing opportunities.

◘ 「AmCAD UO」Market expansion

Domestically, through health examination cenBoth parties authorize each other to use each other's technology with the imaging platform provider. Operate the market, share customers and sales profitsters and actively expanding dental access, abroad, through cooperation with famous Clinical cooperation with universities (Stanford, UOP, University of Bern, etc.), in Published articles in international journals have accumulated product reputation and recognition, combined with international strategic cooperation partners to expand global business opportunities.

◘ Market sharing

Both parties authorize each other to use each other's technology
with the imaging platform provider.
Operate the market, share customers and sales profits

◘ Actively signing agreements with distributors in multiple countries.