股票代號
4188

AmCad BioMed

安克生醫股份有限公司

AmCad BioMed Corporation

2024年度法人說明會

李伊俐 董事長暨總經理

2024/9/13

美吾華·懷特·安克生技集團
Maywufa Biopharma Group

免責聲明

- 除了過去資料外，本次說明會所列事項若為前瞻性看法，此前瞻性看法可能受重大風險和不確定性因素影響而與實際結果有所差異。
- 本簡報中對於未來之展望，係反應本公司截至目前為止對於未來的看法。對於這些看法，倘若未來有因任何事件或環境變遷，本公司並不負有更新資料之責任。
- 未經本公司許可的情況下，不可複製、修改、重新編譯、刪減或傳送本簡報任何內容或將任何該等內容用於商業用途。
- 本簡報內容包含所有歸屬於合併報表之個體。

公司基本資料

AmCad BioMed

安克生醫 Pioneering Ultrasound AI

Helping physicians diagnose confidently and efficiently

第一個獲美國FDA核准超音波電腦輔助診斷(CAD)醫材公司。以世界領先技術結合人工智慧(AI)及醫師專業，將持續針對未被滿足的臨床需求，提供最佳解決方案扮演智慧醫療影像的領航者

設立時間	2008年12月
主要業務	高階醫材研發、製造及銷售
實收資本額	新台幣 6.3億元
轉投資子公司	聲博科技股份有限公司
負責人	李伊俐
員工人數	76人

已上市產品

安克甲狀偵 AmCAD-UT　安克呼止偵 AmCAD-UO

法規認證

FDA　FDA　CE　CFDA China Food and Drug Administration

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

*CAD = Computer-Aided Detection

重要里程碑

AmCad BioMed

2008 公司設立

2013 安克甲狀偵(AmCAD-UTe)獲得美國上市許可 FDA

2014 安克甲狀偵(AmCAD-UTe)獲得歐盟CE認證 CE

2015 安克甲狀偵(AmCAD-UTe)獲得衛生福利部(TFDA)銷售許可 FDA

2016 安克甲狀偵(AmCAD-UTe)大陸授權

聲波散射組織成像平台(AmCAD-US)
安克彩優(AmCAD-UV) 獲得歐盟上市許可 CE

2017 安克彩優(AmCAD-UV)
聲波散射組織成像平台(AmCAD-US) 獲得美國510(k)產品上市許可 FDA
安克甲狀偵(AmCAD-UTe)獲得中國CFDA上市許可 CFDA

2018 「安克呼止偵」分析軟體取得歐盟上市許可 CE

重要里程碑

2019
「安克呼止偵」分析軟體取得美國FDA上市許可
「安克呼止偵(AmCAD-UO)」獲得衛生福利部(TFDA)上市許可

2020
安克與Stanford Medical Center簽約進行安克呼止偵post-market臨床研究

2021
「安克甲狀偵」深度學習進階版產品取得美國FDA上市許可

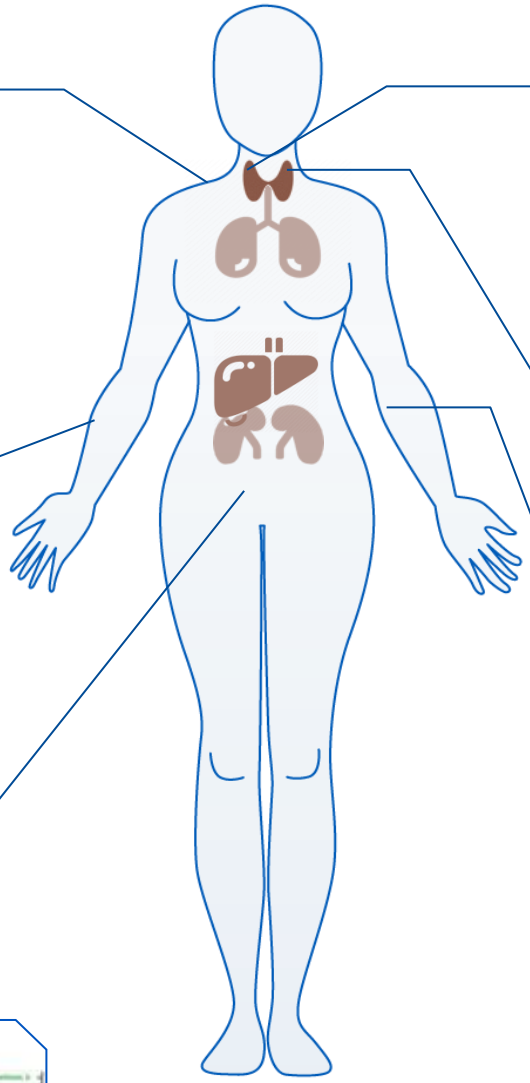
2023
「安克呼止偵」研究成果登全球耳鼻喉科排名第一醫學期刊《JAMA Oto》
安克產品(AmCAD UT UO US)取得MDR CE證書

2024
韓國S1000「安克呼止偵」超音波設備成功註冊
台北市衛生局核定台大醫院UO自費金額4,000
與阿聯酋Meridian Healthcare簽訂MOU啟動中東業務合作

2024年與美國太平洋大學(UOP)牙醫學院簽署的合作研究及安克呼止偵®授權協定，研究數據共享、泰國Walailuk 大學發表研究驗證安克呼止偵在牙科OSA的應用、瑞士臨床結果驗證使用安克呼止偵篩查HNS治療之有效性。

安克6大產品線：4項已取得美國FDA 510(K)

AmCad BioMed



安克呼止偵

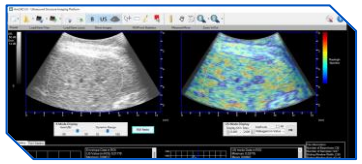
AmCAD UO

- 標準化及自動化上呼吸道超音波掃描
- 評估睡眠呼吸中止症(OSA)程度
- 美國510(K)，歐盟CE Mark上市許可
- 2024/4取得台北自費醫令碼

聲波散射組織成像平台

AmCAD US

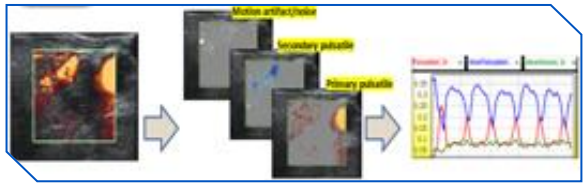
- 美國510(K)，歐盟CE Mark上市許可
- 能辨識不同組織並進行視覺化成像與分析



安克彩優

AmCAD UV

- 美國510(K)，歐盟CE Mark上市許可
- 能區別血管脈動訊號與雜訊



安克甲狀偵

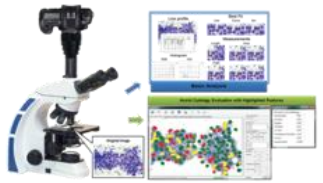
AmCAD UT

- 美國510(K)、歐盟CE Mark、中國CFDA、台灣TFDA上市許可
- 甲狀腺結節超音波影像風險度評估
- 2024/3/28 健保沙盒送件

安克細偵

AmCAD CA

- 顯微鏡細胞學影像分析
- 視覺化及量化細胞學臨床特徵



安克乳安偵

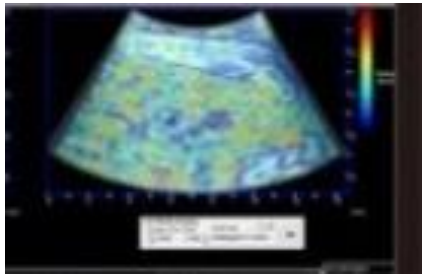
AmCAD UB

- 即時乳房超音波AI成像
- 乳腺結節影像風險度評估

專利佈局完整

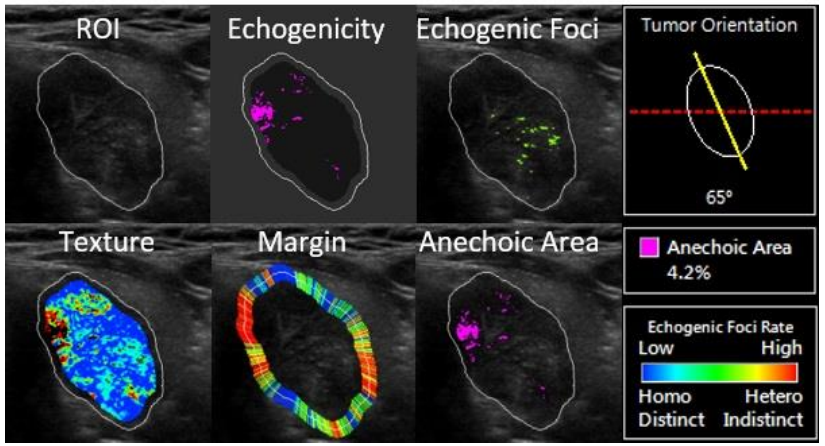
33項創新發明專利

Scatterer Structure Visualization & Ultrasound Echo Analysis



Tumor Contour Retrieval

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



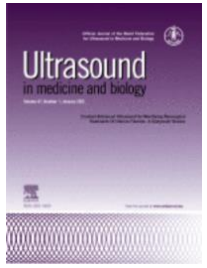
Other Patent Titles	Countries
用於頭頸部評估或介入治療的定位裝置/ POSITIONING APPARATUS FOR HEAD AND NECK ASSESSMENT OR INTERVENTION	China
	EU (Germany)
	Japan
	Taiwan
	USA
呼吸中止症評估方法及其系統/ METHOD ADAPTED TO DIAGNOSE AIRWAY OBSTRUCTION AND SYSTEM THEREOF	China
	EU (Germany)
	Japan
	Taiwan
	USA
COMPUTER-IMPLEMENTED METHOD 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

期刊文獻發表

產品相關之60篇學術論文，發表於國際知名期刊

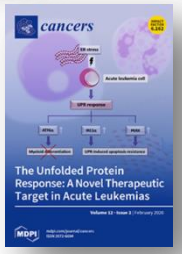
Association of Backscattered Ultrasonographic Imaging of the Tongue With Severity of Obstructive Sleep Apnea in Adults. "*JAMA Otolaryngology Head & Neck Surgery " 2023, 149(7), 580-586.*

Using Standardized Ultrasound Imaging to Correlate OSA Severity with Tongue Morphology. "*Sleep Medicine" 2024, Volume 120, 15-21.*

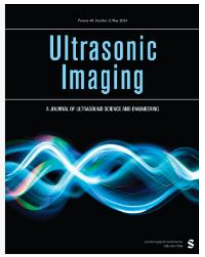


Diagnostic performance of ultrasound computer-aided diagnosis software … "*Ultrasound in Medicine and Biology" 47(1), 114-124.*

Re-liability of a computer-aided system in the evaluation of indeterminate ultrasound images of thyroid nodules. "*ETJ" 21-0023.*



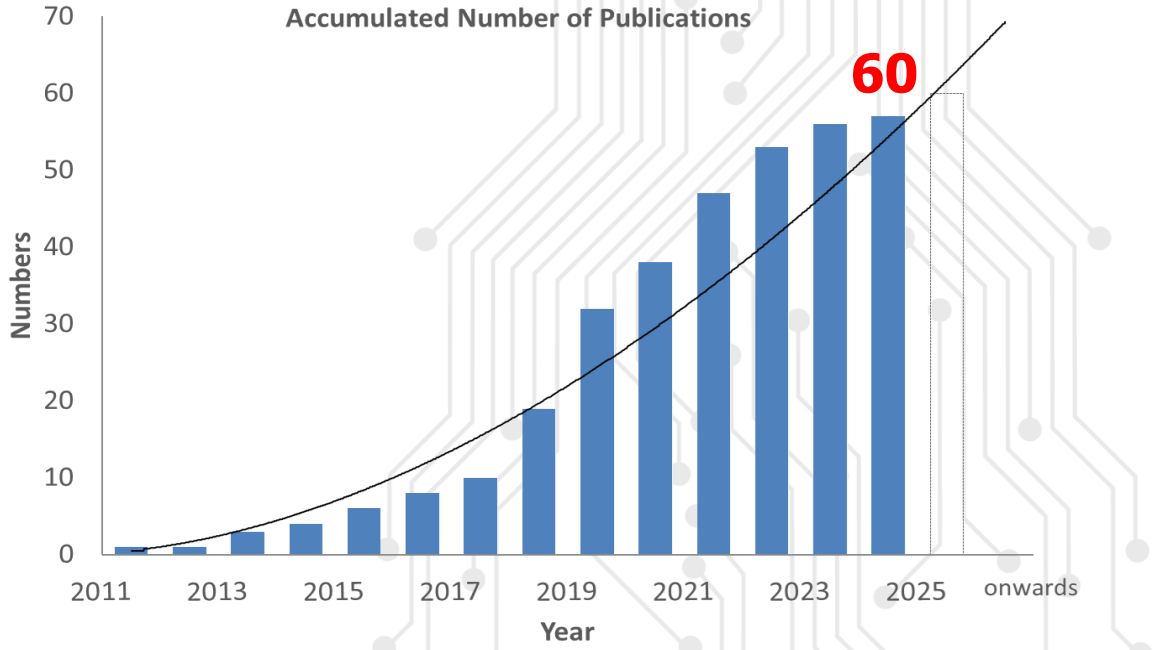
Multi-Reader Multi-Case Study for Performance Evaluation of High-Risk Thyroid Ultrasound….in "Cancers" *2022, 12(2), 373.*



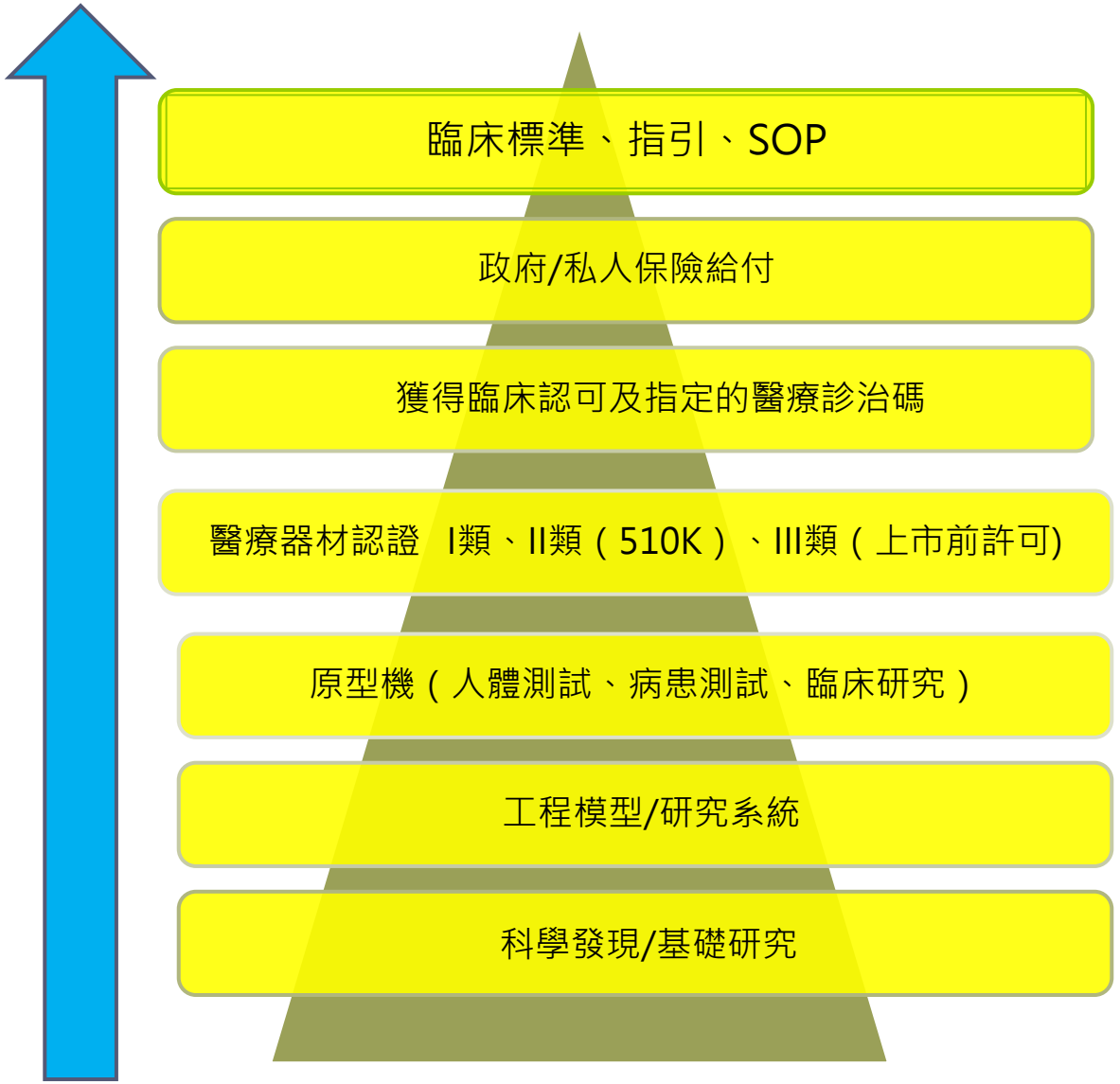
Ultrasound Backscatter Envelope Statistics Parametric Imaging for Liver Fibrosis in "Ultrasonic Imaging" Volum 42, Issue 2

Computer-aided diagnosis system of thyroid nodules ultrasonography ….in "*Medicine" 99(23), e20634.*

Differences in the ultrasonographic appearance of thyroid nodules after radiofrequency ablation in "*Clinical Endocrinology" Volume 95, Issue 3*



創新醫材產品發展藍圖



- 安克己取得醫材法規認證、自費醫令碼，

安克甲狀偵
- ▸健保送件

安克呼止偵
- ▸通過KFDA認證
- ▸準備申請歐洲給付保險碼

- 持續進駐國內各大醫院、健診/牙醫通路
- 與國內外知名教學醫院執行上市後臨床研究收案及論文發表，擴大產品運用
- 並透過國際展會、學術展及網路行銷推廣累積產品的知名度

商業模式

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

重要進展

現金增資案6/7 正式生效

- 安克113年現金增資案6/7正式生效
- 7/23募足資金2.3億
- 安克呼止偵雷射定位儀的供應商帆宣系統科技(股)公司投資安克現增成為緊密的策略合作夥伴。

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。

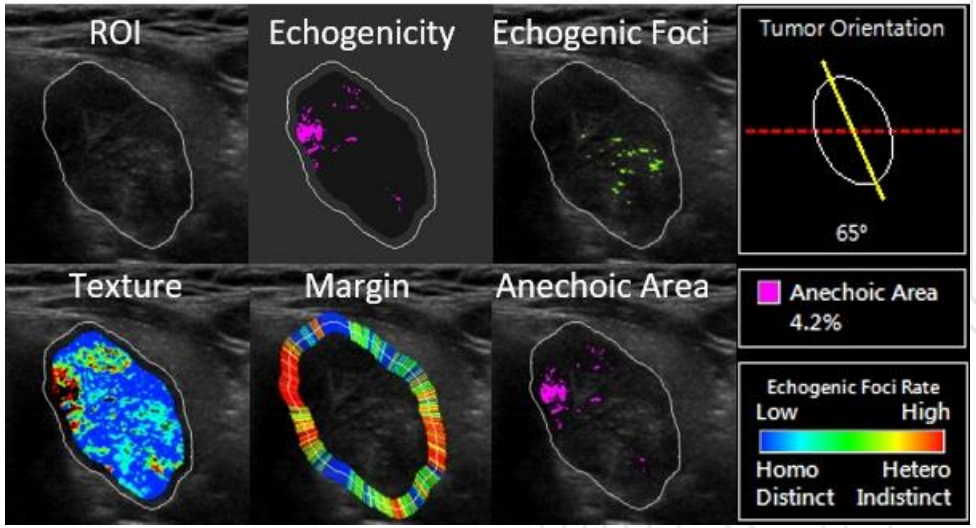
(三)依照證券交易法第34條第1項之規定，於限期內交付股票，並於交付前至本會指定之資訊申報網站辦理公告。

(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。

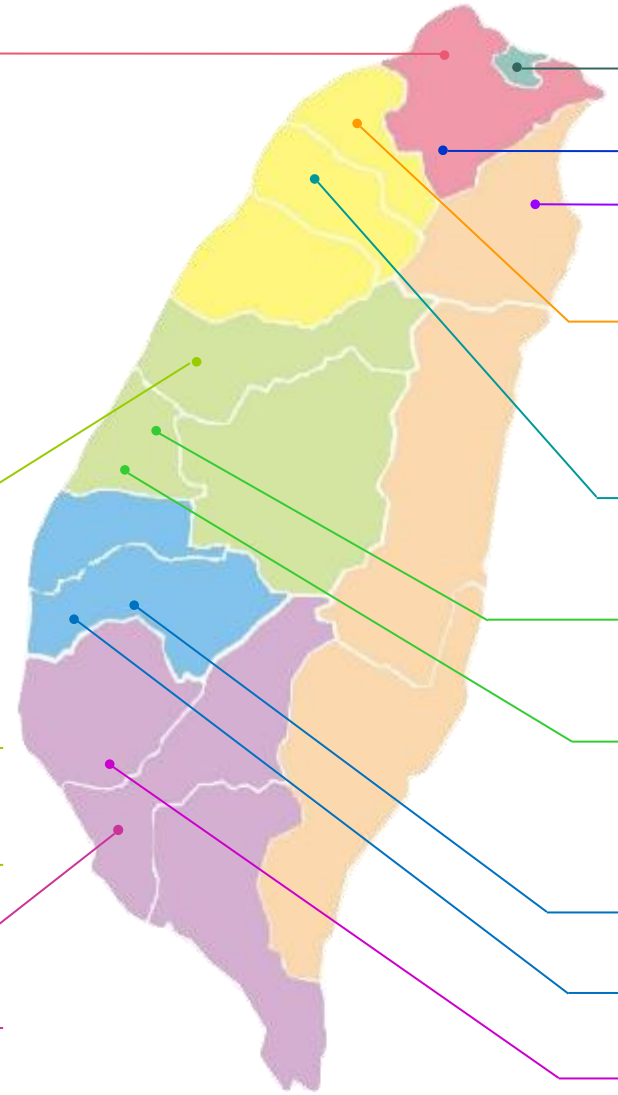
核心主力產品介紹: AmCAD UT 安克甲狀偵® (FDA、CE、CFDA)

安克甲狀偵®產品特色

- 準確性高達9成以上，實現一致性自動結節分析
- 內建8個國際TI-RADS指南的風險評分
- 專利結節量化 &視覺化特徵分析
- 多平台相容性,減少人為疏失，即現AI導引



安克甲狀偵®醫療院所一覽表 (全省已超過30家醫療院所採用)



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

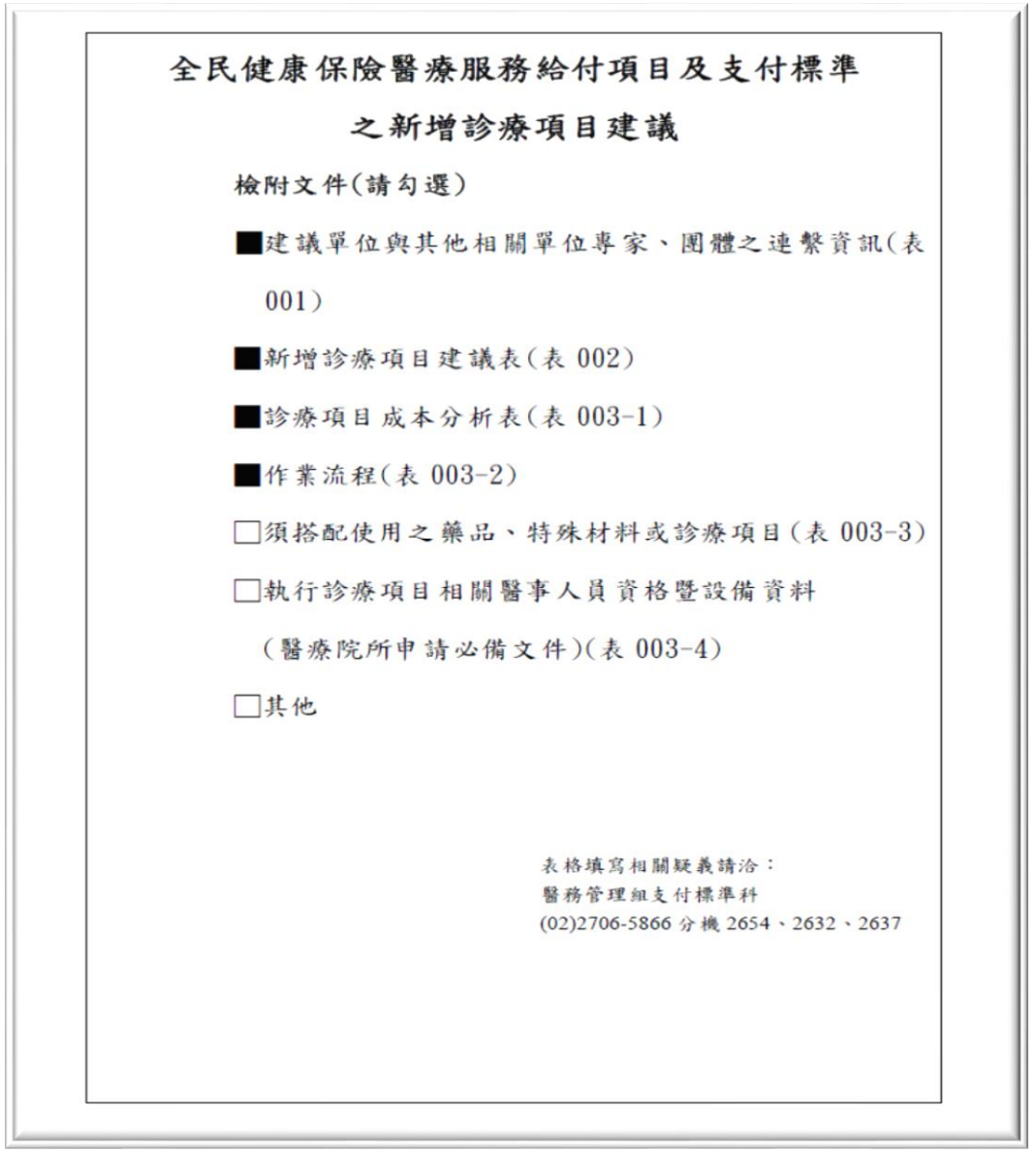
嘉義市
- 嘉義基督教醫院
  - 新陳代謝科

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 申請健保給付

- 藉由AmCAD-UT甲狀腺結節超音波智能分析技術，減少健保支出成本。
- 2024年底前CDE會出HTA報告，並於11月召開共擬會議。



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)

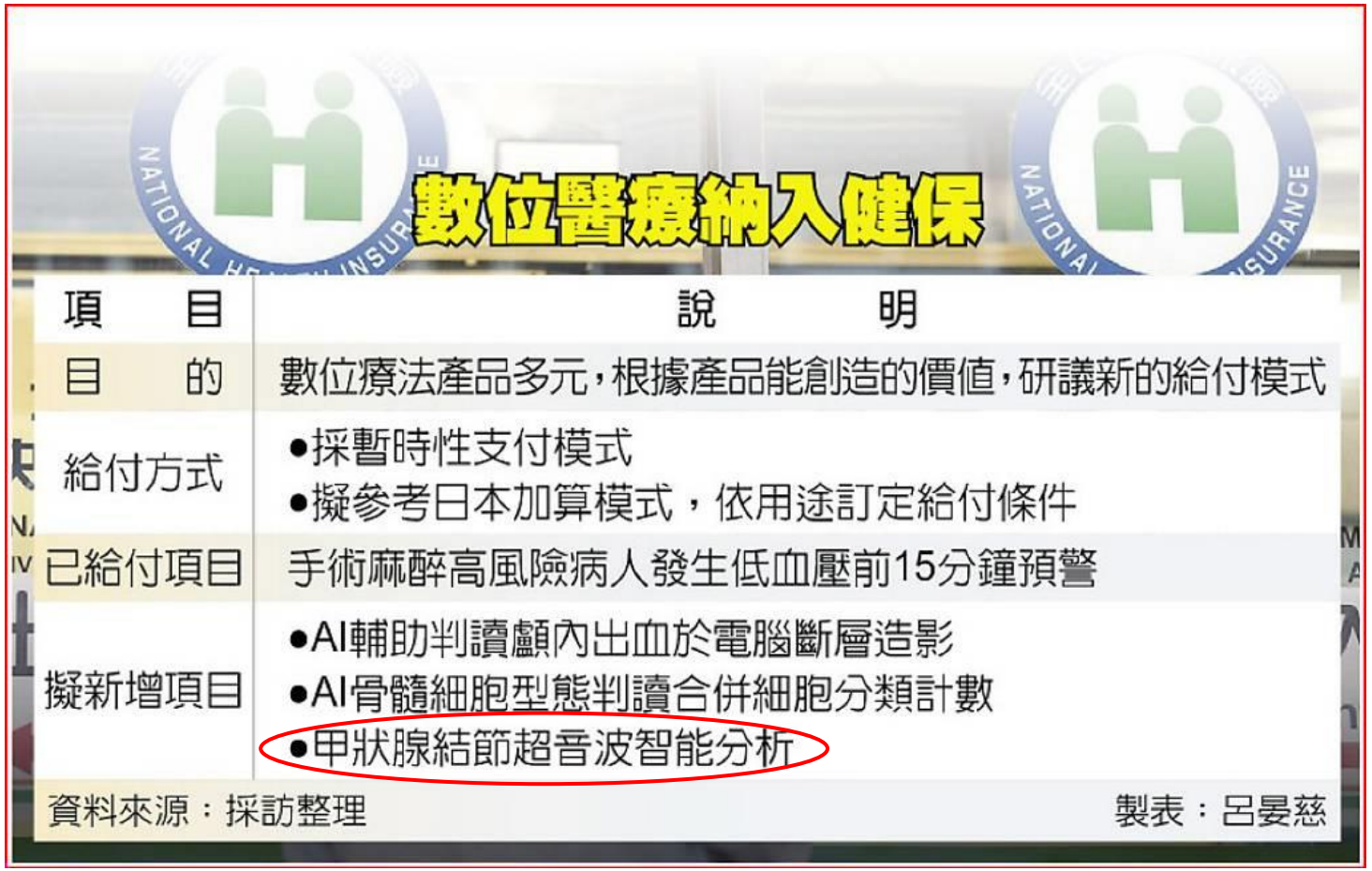
□其他

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 安克甲狀偵 2024

AmCad BioMed

國內銷售策略

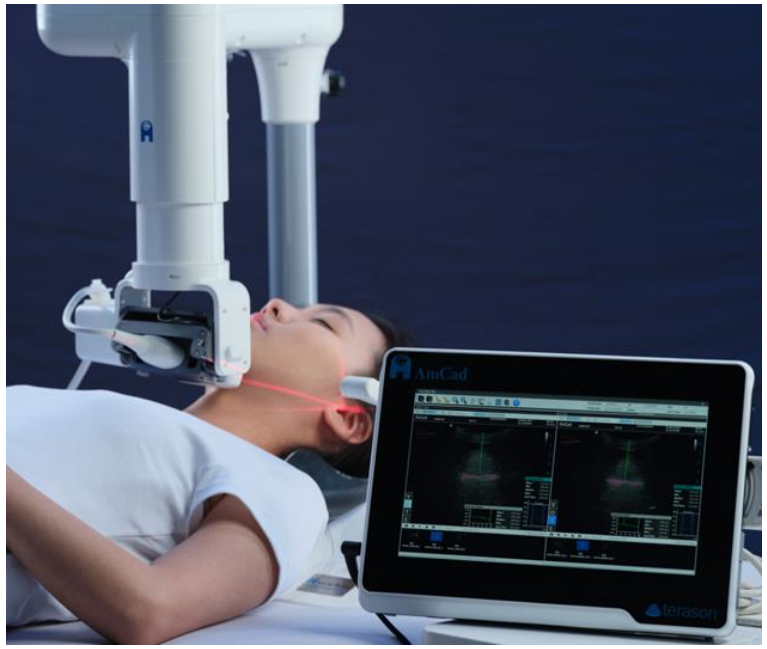
- 月結轉批次
- 健檢訂閱
- 健保署HTA

國內市場策略

- 健檢中心訂閱
- UT簡易報告版訂閱方案(市場區隔)
- 臨床深耕：內分泌科
- 擴科： ENT/放射科/家醫科/一般外科
- 超音波廠商合作
  - 醫院搭售策略
  - 診所搭售策略，與Handheld超音波探頭廠商合作
- 新商機
  - 健保署HTA
  - ATA 2024 new Guidelines
  - UT LiveScan

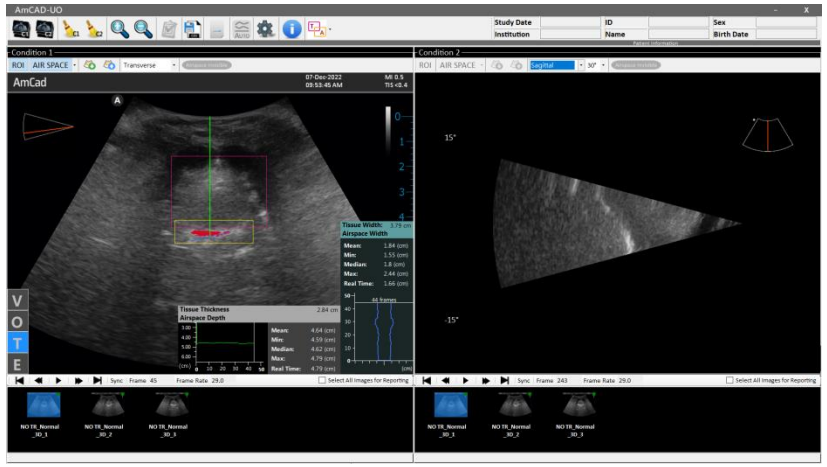
健保署劉林義組長- 數位醫療發展政策與大家醫計劃

核心主力產品介紹: AmCAD-UO 安克呼止偵® (FDA &CE)



安克呼止偵®產品特色

- 快速、免過夜，非侵入式阻塞型呼吸中止症篩檢。
- 準確性高達95%
- 視覺化和量化上呼吸道數據，針對每個病患的獨特呼吸道形態,制定最佳的個人化治療計劃
- 與帆宣系統合作開發之 雷射定位儀(LAT) -用於定位頭部和探頭，提供標準化的超音波成像。
- 有助於篩查出牙套& 舌下神經刺激治療中之無效患者及不適配原因



AmCAD-UO 取得台北市自費醫令碼

AmCad BioMed

- 台北市衛生局 UO 自費公文 核定$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

與Stanford合作發表安克呼止偵第二篇論文

AmCad BioMed

ELSEVIER

Sleep Medicine

Volume 120, August 2024, Pages 15-21

前三名睡眠領域專業期刊

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

[d] Department of Psychiatry & Behavioral Sciences, Stanford University School of Medicine, Stanford, CA, USA

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

韓國S1000「安克呼止偵」超音波設備成功註冊

AmCad BioMed

S1000超聲波設備在韓國的註冊已經順利完成：

1. 產品與分類：S1000的通用超聲波，型號為UO-50。
2. 進口商：MEK Healthcare
有效期限：認證的有效期至2029年3月28日。

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

)00

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)

與美國太平洋大學牙醫學院簽訂合作

AmCad BioMed

與美國UOP牙醫學院簽署的合作研究協定，將促進安克呼止偵在牙科領域的合作研究，並增加在美國市場牙科領域據點

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.

經濟部創新醫療產品市場准入研發補助計畫

- 以AmCAD-UO搭配國際臨床合作，進行睡眠呼吸中止症的牙科市場導入，藉由睡眠牙套治療伴隨診療需求，進行產品的應用開發。
- 6/17取得審議會通過公文，補助案1,000萬，執行22個月。

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：

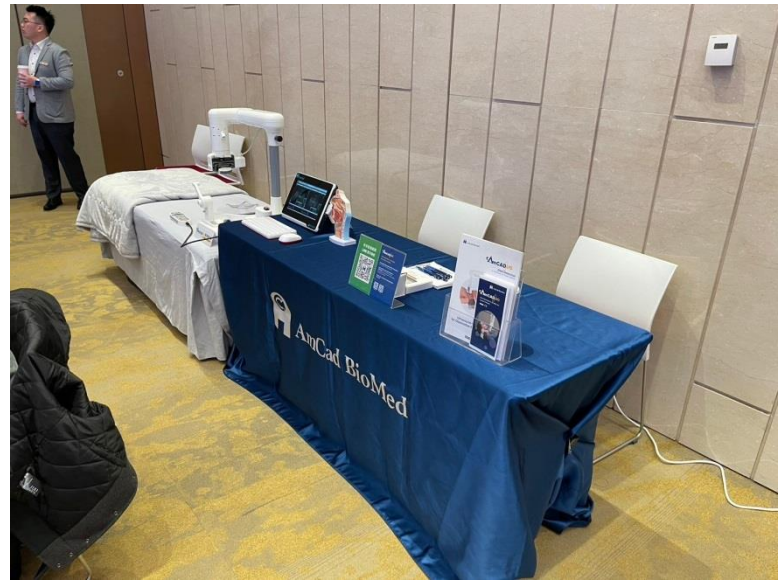
◆ 經費彙總表

單位：千元

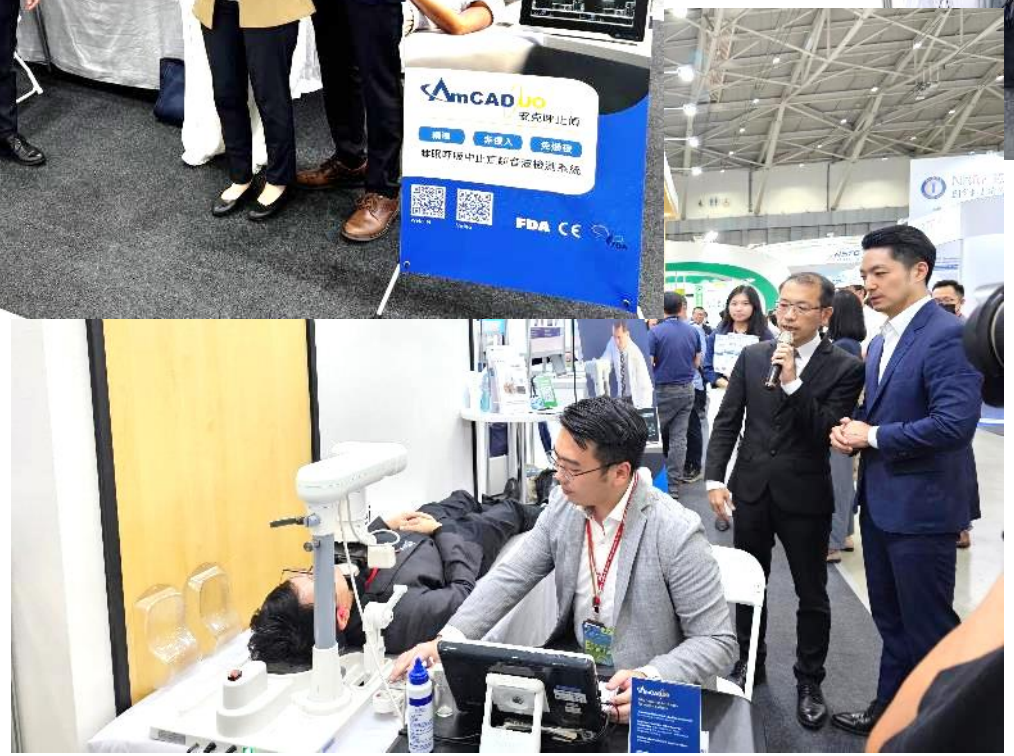
經費列支項目	專審會建議總經費	專審會建議補助款
1.創新或研究發展人員之人事費		
(1) 創新或研究發展人員	15,555	6,950
(2) 新聘碩士(含) 學歷以上之研發人員、國際研發人員	1,700	1,700
(3) 顧問、專家費	2,545	350
小　　計	19,800	9,000
2.消耗性器材及原材料費	0	0
3.創新或研究發展設備使用費	2,200	1,000
4.創新或研究發展設備維護費	0	0
5.無形資產之引進、委託研究或驗證費		
(1) 無形資產引進費	0	0
(2) 委託研究費	0	0
委託研究費-推廣活動	0	0
(3) 驗證費	0	0
小　　計	0	0
6.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

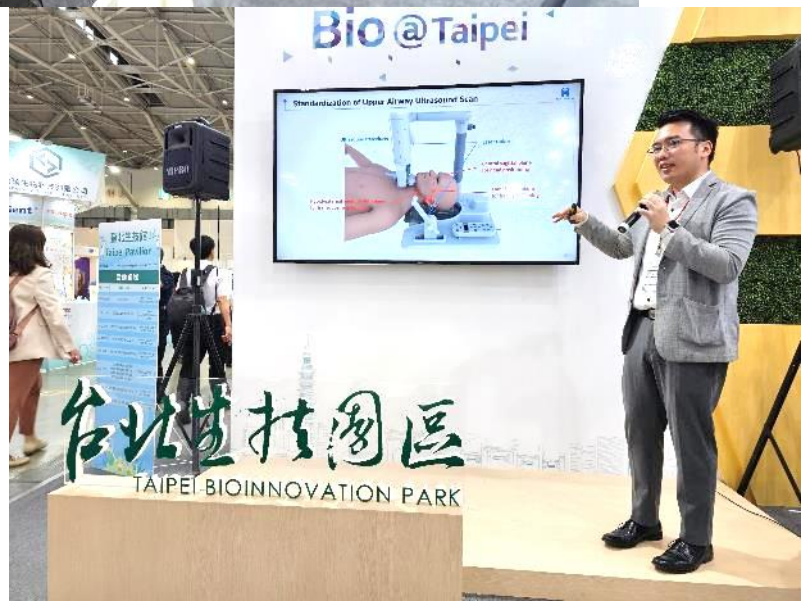
OSAWELL OSA跨科研討會

AmCad BioMed



BIO Asia Taiwan 2024亞洲生技大展





國內業務推廣

AmCad BioMed

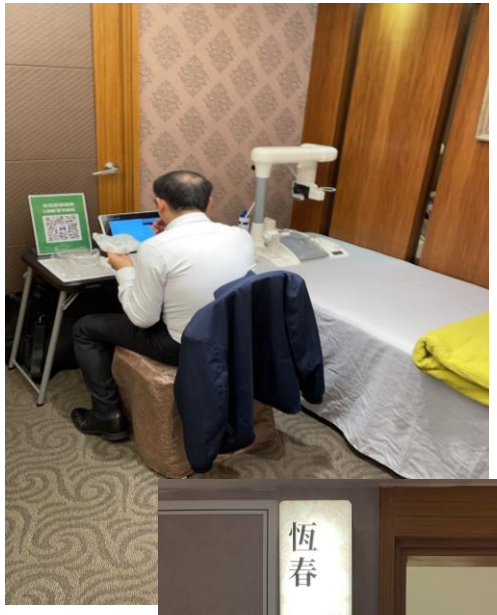
慈濟醫院牙科部

長庚醫院睡眠醫學會夏季會

臺北醫學大學生技EMBA

國內業務推廣

WOB女董協會



振興醫院ENT

聖保祿健檢中心

嘉義基督教醫院

台北馬偕ENT晨會

開展牙科止鼾牙套市場

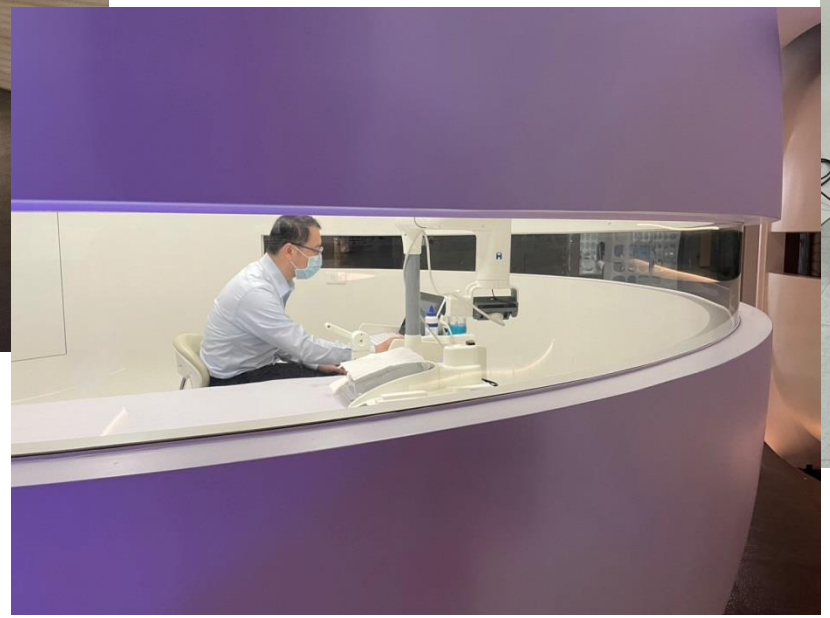
- **國內最大連鎖牙科診所Dr. Wells**合作
  - 第1個UO跨科合作示範點：士林**維育牙醫**診所

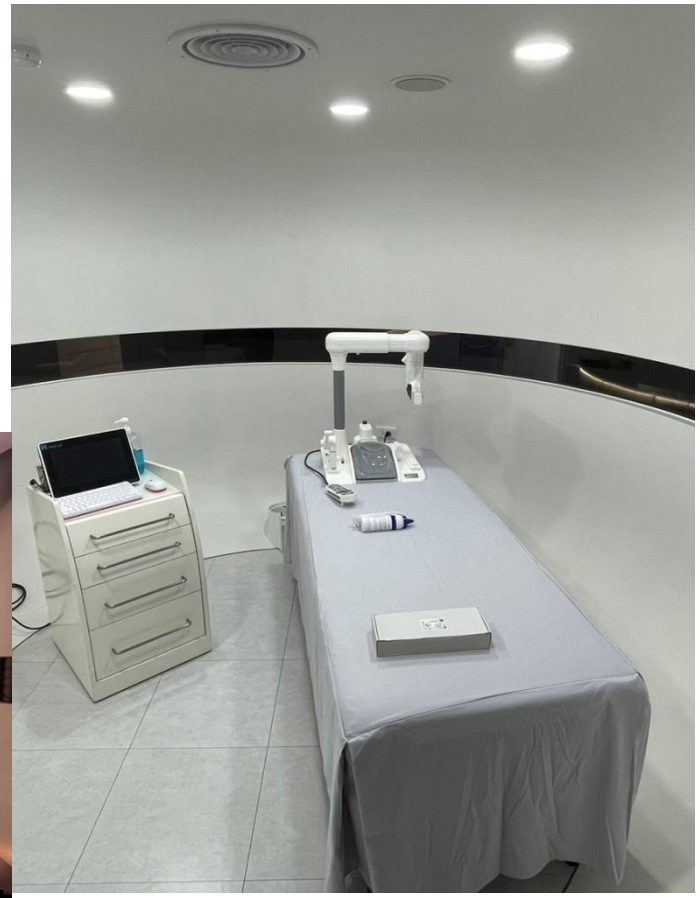
- **口掃機最大市佔品牌**代理商旭達集團旗下**OSAWELL公司**合作洽談
  - 3/10 OSA跨科研討會中推廣與現場展示UO，增加產品曝光度
  - 台北**嶺先牙醫**診所
  - 台中**雅緹斯牙醫**診所

- 大安丰采睡眠醫學美學牙醫聯合診所**Dr.BreathE**策略合作**睡眠照護圈**
  - 院長：北醫教授(原雙和醫院睡眠中心主任)
  - CPAP/舒眠枕銷售合作

士林維育牙醫診所

AmCad BioMed





AmCAD-UO 安克呼止偵 2024

AmCad BioMed

國內銷售策略

租賃+分潤

雙管齊下

結合睡眠治療週邊商品

國內市場策略

- **健檢中心：**醫學中心、高檢查量之區域醫院及健診
- **臨床深耕：**
  - 睡眠中心產品介紹
  - **耳鼻喉科、牙醫(睡眠止鼾)**、胸腔內科
- **銷售整合**
  - UT國內業務團隊合併推廣UO
  - 高階健檢中心UT/UO共同銷售
  - **企業篩檢**
  - One Stop Solution/Service
- **睡眠治療相關同業合作**
  - 呼吸器廠商
  - 牙套廠商

AmCad BioMed

國際展業

美吾華·懷特·安克生技集團
Maywufa Biopharma Group

2024年Arab Health展覽會安克產品吸引眾多關注

Arab Health展覽會上展出的AmCAD-UT LiveScan（即時掃描POCUS解決方案）吸引了前所未有的參觀人潮，與會的公司數量超過160家。

與阿聯酋Meridian Healthcare (MHC)簽訂MOU啟動中東業務合作

技術平台利用：針對安克甲狀偵 & 安克乳安偵產品透過與MHC的合作，利用其在影像代理及多年AI技術平台的豐富經驗，進一步提升對市場需求的理解。
市場反饋：MOU合作將提供AmCAD-UT產品試用，並接受市場的實際反饋，以便優化和改進我們的產品。
技術整合：未來若成功合作，除產品銷售外，還能增進在國際醫院與PACS的串接整合經驗。

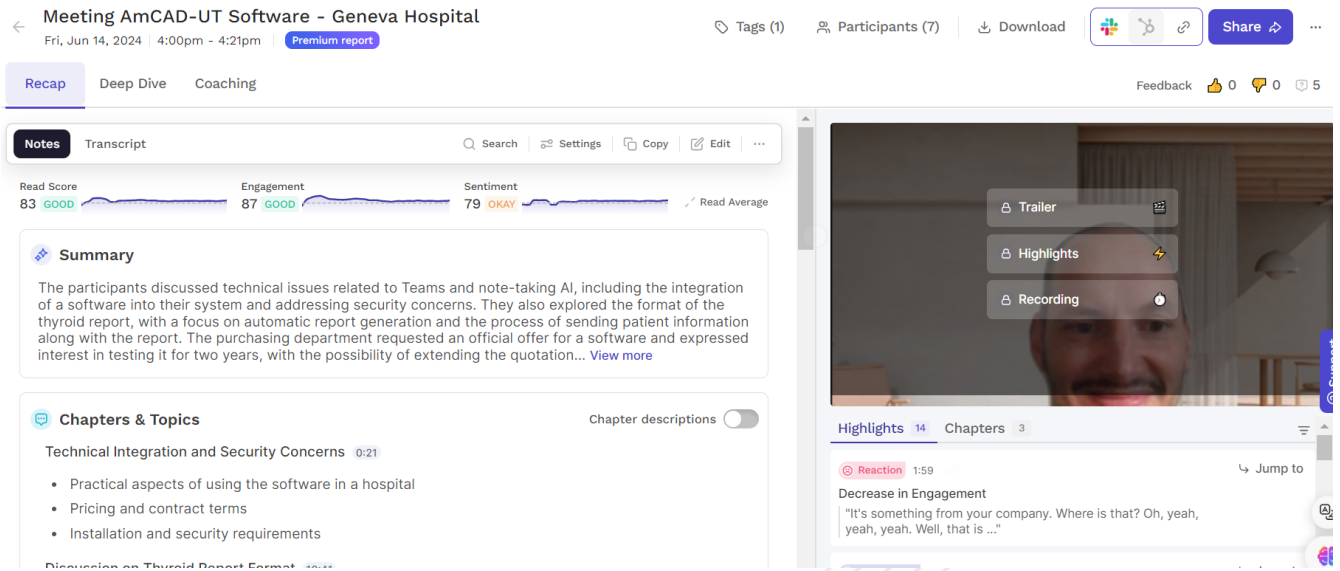
MERIDIAN HEALTHCARE
SCIENTIFIC OFFICE

Africa Excon: June 3-7 (客戶攤位)

與瑞士日內瓦大學醫院的合作洽談

瑞士日內瓦大學醫院表達了引入 AmCAD-UT 系統的強烈意願，並考慮採用兩年訂閱模式。

預計下半年引入 AmCAD-UT 系統，這是對安克甲狀偵技術的認可，也是進一步拓展歐洲市場的重要步驟。



瑞士臨床研究認可「安克呼止偵」：ISSS大會上成果發表

1. 利用Backscatter技術能在NHS治療前篩選出可能受益於Inspire治療的OSA患者，從而提高治療成功率。
2. 「安克呼止偵」Backscatter 技術能在治療前篩選出有望受益的患者，能顯著提高NNS治療成功率。

瑞士臨床結果驗證使用安克呼止偵篩查HNS治療之有效性

- **臨床結果發表：**瑞士伯恩大學（University of Bern）和Kantonsspital Baselland瑞士頭頸外科春季會聯合發表了臨床結果，證實了安克呼止偵能篩查HNS治療有效性。
- **提升產品知名度:** 瑞士伯恩大學的聯名發表，增加安克產品知名度和信譽。

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[1], 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.

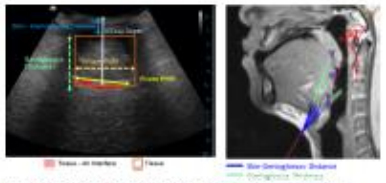
Methods

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.

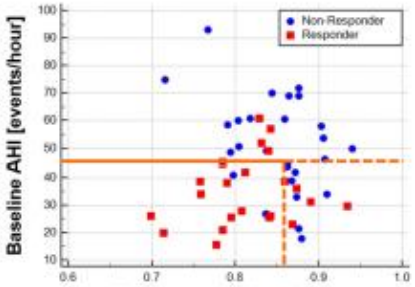
AmCAD ultrasonography with the robotic probe positioning for a standardized examination of the upper airway

Results

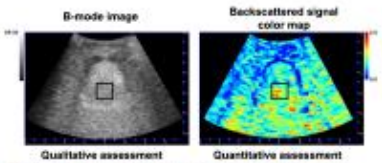
We enrolled 49 patients, of which 22 were responders and 27 were non-responders. In the HNS group, responders and non-responders were comparable in sex and age. However, the initial neck circumference (42.2 vs. 40.4cm), baseline AHI (50.8 vs. 34.7/h), and BMI (28.4 vs. 26.4kg/m2) were significantly higher 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

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泰國Walailuk 大學研究驗證 安克呼止偵在牙科OSA的應用

AmCad BioMed

1 研究發表：《Clinical Medicine 臨床醫學雜誌》上刊登了 Walailuk 大學醫院牙科學院的研究，探討成人頭顱結構與氣道特徵之間的關係，特別針對高風險OSA患者。

2. 系統應用：研究指出 AmCAD-UO 系統在捕捉詳細氣道圖像方面的能力，對OSA的篩查和治療規劃具有重要影響。重要影響。

Journal of *Clinical Medicine*

MDPI

Article

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

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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

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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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/m^2, 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/m^2, 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).

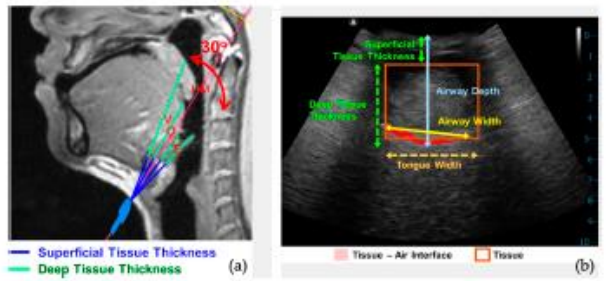


Figure 5. (a) The 30° segment of the upper airway; HM, hyoid-external meatus. (b) Transverse view of ultrasonographic images.

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.

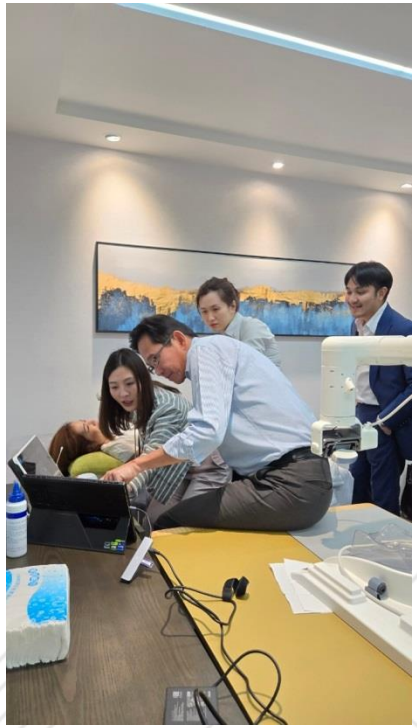
The airway's width, airway's depth, tongue width, airspace–tissue width ratio, superficial tissue thickness, and deep tissue thickness were measured (Figure 5b). Dynamic changes in airway width during tidal breathing and Muller maneuvers, or percentages of airway contraction, were calculated as a percentage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

泰國客戶及Srinakharinwirot University醫師參訪

- 建立與泰國Srinakharinwirot University (詩大) 醫院ENT部門高層聯繫，奠定AmCAD-LiveScan POCUS未來客戶基礎 ，達成初步意向，開闢在泰國新業務機會。

- 參訪Dr. Well牙科診所，獲取安克呼止偵在睡眠牙科醫療推廣的第一手資訊，及技術發展戰略。



與各國醫院的合作洽談進行中

多國合作洽談：目前正積極與三國 (瑞士、巴西、阿聯酋) 醫院進行合作洽談，探索全球市場機會，擴大我們的業務範圍。
戰略合作：各國醫院合作將包括產品試用、市場反饋、技術整合等，旨在提升我們產品的市場競爭力和應用價值。

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美吾華·懷特·安克生技集團
Maywufa Biopharma Group

簡明合併資產負債表

AmCad BioMed

科　目	2024.06.30	%	2023.12.31	%
流動資產	298,456	62	325,893	64
非流動資產	182,872	38	186,753	36
資產總計	**481,328**	**100**	**512,646**	**100**
流動負債	21,272	4	24,419	4
非流動負債	8,504	2	10,279	2
負債總計	**29,776**	**6**	**34,698**	**6**
股本	533,184	111	533,306	104
資本公積	8,899	2	8,016	2
保留盈餘	(174,622)	(36)	(148,743)	(29)
其他權益	(9,613)	(2)	(11,996)	(2)
母公司權益	357,848	75	380,583	75
非控制權益	93,704	19	97,365	19
權益總計	**451,552**	**94**	**477,948**	**94**
負債及權益總計	**481,328**	**100**	**512,646**	**100**

1.現金充足，負債比率低

2.7月現增收足股款後，帳上合併現金>4.8億，為公司未來發展提供充足的資金。

簡明合併綜合損益表

AmCad BioMed

單位：新台幣仟元

科　目	2024年上半年度		2023年上半年度		YoY
	金額	%	金額	%	%
營收淨額	24,448	100	26,137	100	(6)
營業毛利	14,466	59	14,928	57	(3)
營業費用	(46,930)	(192)	(44,351)	(170)	6
營業損失	(32,464)	(133)	(29,423)	(113)	-
營業外收支淨額	2,924	12	5,135	20	(43)
稅後淨損	(29,540)	(121)	(24,288)	(93)	-
稅後淨損-母公司業主	(25,879)	(106)	(23,598)	(90)	-
稅後淨損-非控制權益	(3,661)	(15)	(690)	(3)	-
每股虧損(元)	(0.48)		(0.44)		

▶ 營業收入較去年同期略減，下半年透過國內外展業及拓展牙醫通路，可大幅提升營收

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未來展望

美吾華·懷特·安克生技集團
Maywufa Biopharma Group

醫療診斷的新趨勢: 超音波+ One-Device AI

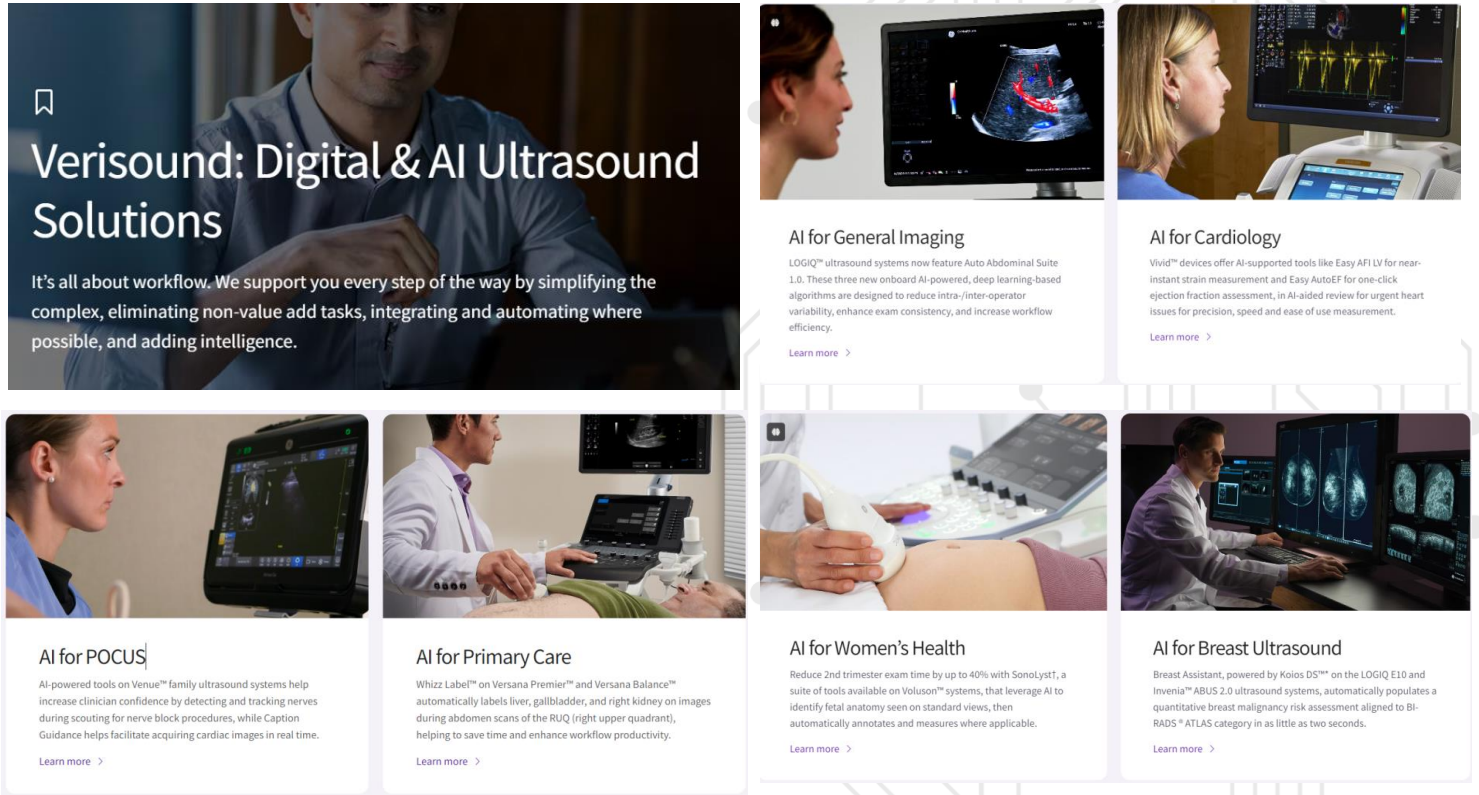
市場背景:

- AI在醫療影像中的應用日益普及。
- AI搭配超音波用以 (a) 提高診斷精準度和效率; (b) 減少人為錯誤; (c) 提供即時診斷; (d) 縮短診療時間。

On-device AI 的重要性:

- 所有AI處理均在設備上進行，無需依賴雲端，確保病患隱私，資料安全和快速處理。
- GE 的發展案例：GE 已經開始用 On-device AI Ultrasound 提升其超音波技術的效能和可靠性。

GE 的超音波發展



手持式超音波搭配AI技術協助診斷

AmCad BioMed

摘自Key Market Trends in Handheld Ultrasound

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)

安克AI即時功能：UT、UB及Liver與手持式超音波整合，可顯著增強超音波技術，提供在各種醫療環境的可用性和有效性(POCUS)，作為進入新藍海市場之開端

以極大化POCUS整合能力作為競爭優勢

即使不依賴 API 或 SDK，安克的AI軟體
也可以跟任何廠牌的掌超整合

GE VScan® Air

EchoNous Lexsa®

BenQ Handheld Ultrasound

Telemed MirUS Pro

POCUS+AI 商機潛力大

展覽會上展出的AmCAD-UT LiveScan（即時掃描POCUS解決方案）吸引了前所未有的參觀人潮，與會的公司數量超過160家。POCUS吸睛商機大

安克未來發展策略

- **技術合作或授權，與硬體廠商聯合銷售**
  掌握POCUS商機，與國際著名硬體掌超大廠合作：將我們的AI超聲技術與其掌超結合，開發出「安克甲狀偵 」、「安克呼止偵 」、「安克乳安偵 」 技術合作及授權機會。
- **「安克呼止偵」持續增加臨床價值以擴張市場**
  國內透過健檢中心並積極拓展牙醫通路，國外則透過與著名大學(Stanford、UOP、University of Bern等) 臨床合作，在國際期刊發表論文累積產品聲量與獲得認同，結合國際策略合作夥伴，拓展全球商機。
- **共同行銷與分潤**
  與影像平台商雙方互相授權使用對方的技術，在影像平台商營運市場，共享客戶及銷售分潤。
- **積極推展多國經銷商**