安克生醫股份有限公司

股票代號(4188)

2020年度法人說明會

公司設立: 2008年

股票上櫃: 2015年

資本額: NTD5.3億

負責人: 李成家

報告人

李伊俐 總經理

美吾華·懷特·安克生技集團
Maywufa Biopharma Group

免責聲明

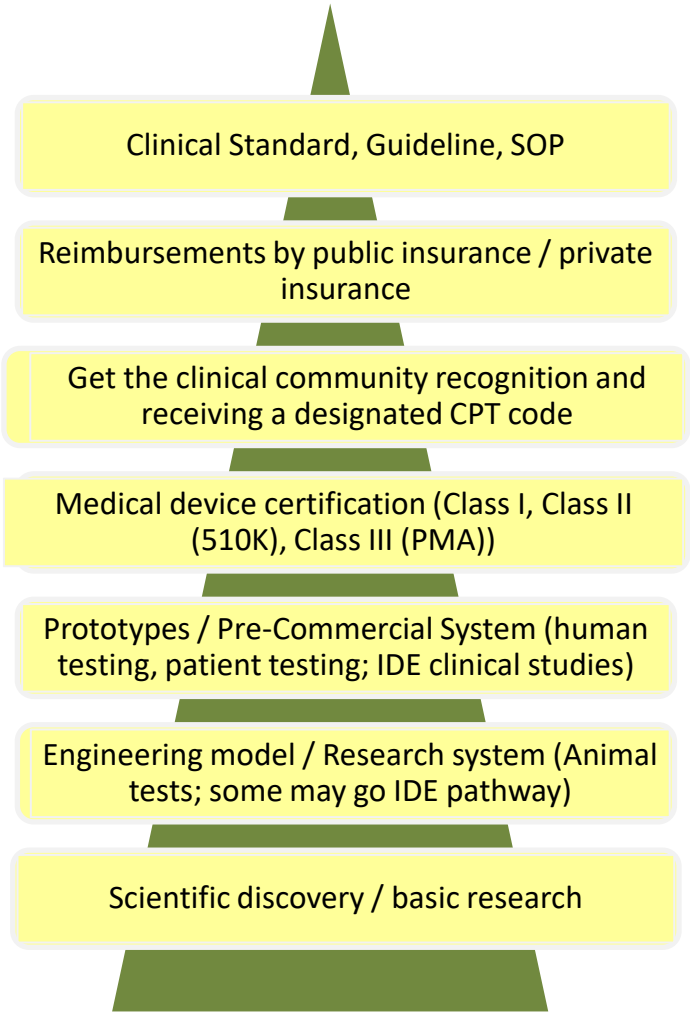
本資料除提供歷史信息外，部分內容若涉及未來展望的表述，因受到風險及不確定因素影響，實際結果與表述內容可能明顯不同，投資人應自行判斷與控制風險。

公司簡介及2020里程碑

基本資料

- 公司名稱:安克生醫股份有限公司
- 設立時間:2008.12.26
- 實收資本額:新台幣5.3億
- 主要業務:高階醫材研發、製造及銷售
- 負責人:李成家
- 營運總部:台北市
- 員工人數: 36 人
- 轉投資子公司:聲博科技股份有限公司(集團持股過半)

創新醫材產品發展Roadmap



2020年度重要里程碑

- 營運
- 研發
- 國內展業
- 國際研究
- 國際展業
- 財務報表
- 未來展望
- 結論

2020重要里程碑-營運

- ✓ Stanford國際睡眠中心臨床研究案7月中正式啟動收案
- ✓ 北市府補助案申請並通過獲得$250萬補助金
- ✓ 經濟部優勢與利基臨床研究補助申請並通過獲得$400萬補助金
- ✓ 通過SGS品質系統查核

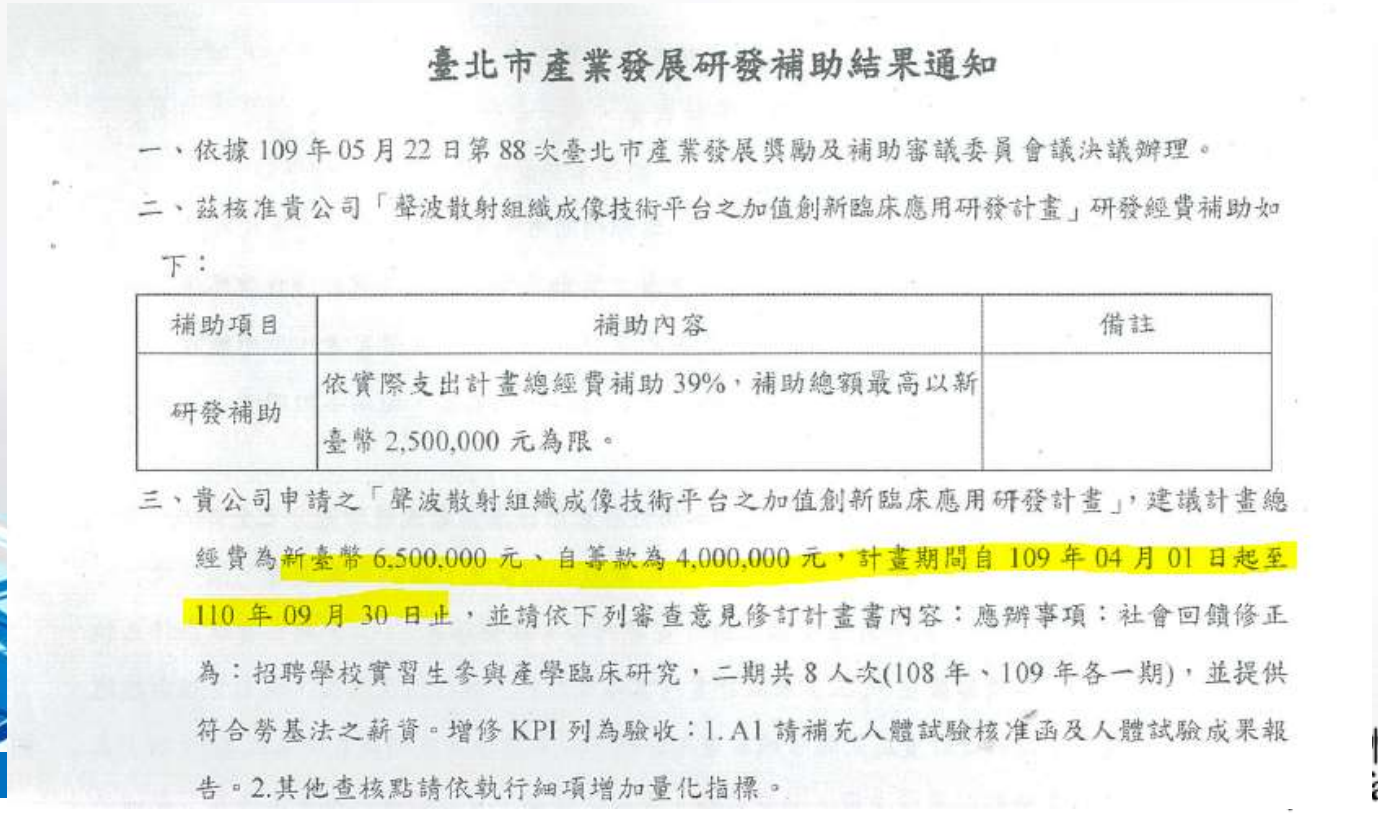
2020 Stanford UO 臨床訓練/ UT KOL 拜訪

- 2/6 教育訓練完成
- 7/15 啟動收案

與ATA Nodule Guidelines Co-chair 進行臨床合作洽談

北市府補助案：通過

- 計畫名稱：聲波散射組織成像技術平台之加值創新臨床應用研發計畫(AmCAD-US)
- 核定補助款250萬，自籌款400萬，總計畫經費650萬
  執行期間：109年4月1號 – 110年9月30日止。



臺北市產業發展研發補助結果通知

一、依據 109 年 05 月 22 日第 88 次臺北市產業發展獎勵及補助審議委員會議決議辦理。

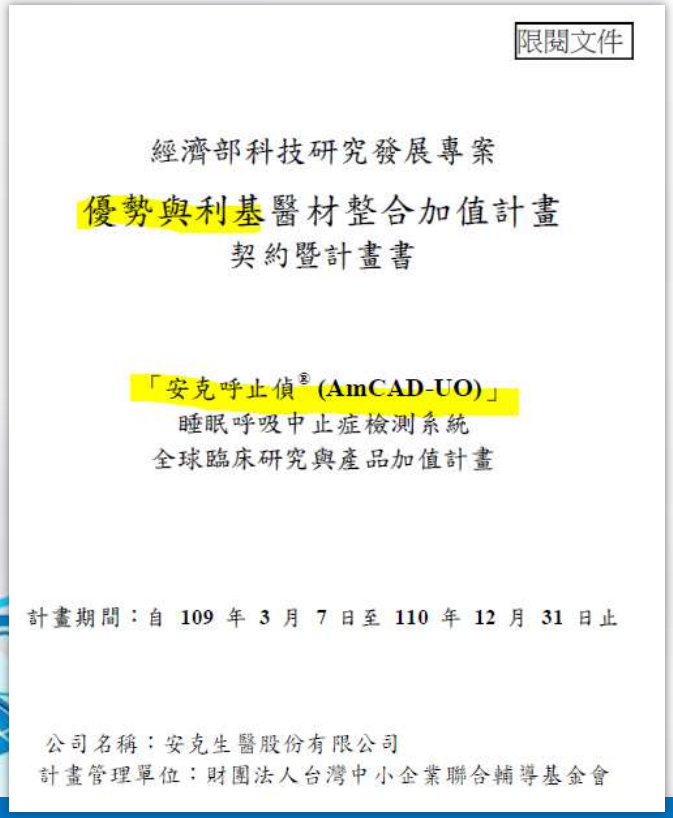
二、茲核准貴公司「聲波散射組織成像技術平台之加值創新臨床應用研發計畫」研發經費補助如下：

補助項目	補助內容	備註
研發補助	依實際支出計畫總經費補助 39%，補助總額最高以新臺幣 2,500,000 元為限。	

三、貴公司申請之「聲波散射組織成像技術平台之加值創新臨床應用研發計畫」，建議計畫總經費為新臺幣 6,500,000 元、自籌款為 4,000,000 元，計畫期間自 109 年 04 月 01 日起至 110 年 09 月 30 日止，並請依下列審查意見修訂計畫書內容：應辦事項：社會回饋修正為：招聘學校實習生參與產學臨床研究，二期共 8 人次(108 年、109 年各一期)，並提供符合勞基法之薪資。增修 KPI 列為驗收：1. A1 請補充人體試驗核准函及人體試驗成果報告。2.其他查核點請依執行細項增加量化指標。

經濟部優勢與利基臨床研究補助案：通過

- 計畫名稱：「安克呼止偵® (AmCAD-UO)」睡眠呼吸中止症檢測系統全球臨床研究與產品加值計畫
- 核定補助款400萬，自籌款600萬，計畫總經費1,000萬
  執行期間：109年3月7號 – 110年12月31日止



限閱文件

經濟部科技研究發展專案

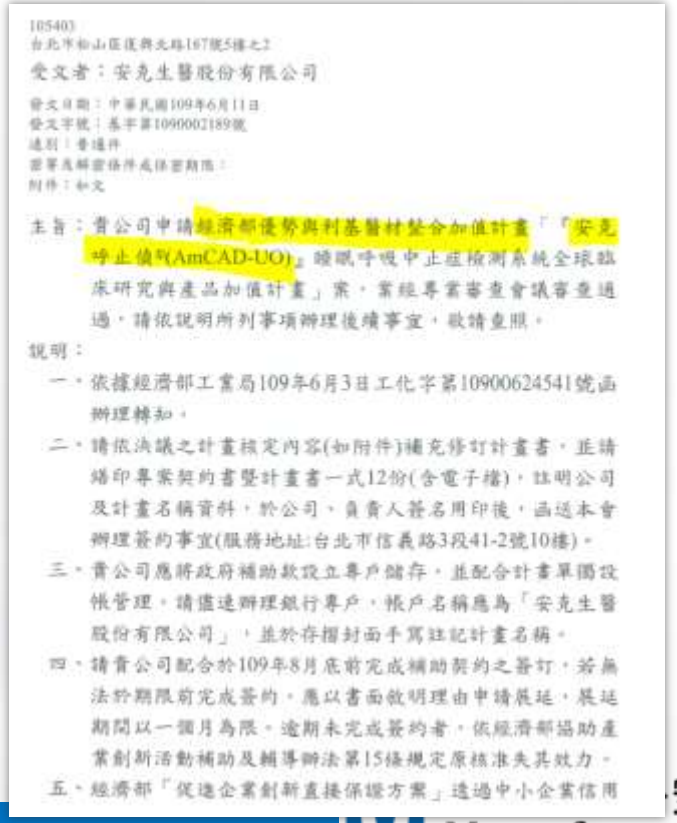
優勢與利基醫材整合加值計畫

契約暨計畫書

「安克呼止偵® (AmCAD-UO)」
睡眠呼吸中止症檢測系統
全球臨床研究與產品加值計畫

計畫期間：自 109 年 3 月 7 日至 110 年 12 月 31 日止

公司名稱：安克生醫股份有限公司
計畫管理單位：財團法人台灣中小企業聯合輔導基金會



10543
台北市松山區復興北路167號5樓之2
受文者：安克生醫股份有限公司

發文日期：中華民國109年6月11日
發文字號：基半算1090002189號
速別：普通件
密等及解密條件或保密期限：
附件：如文

主旨：貴公司申請經濟部優勢與利基醫材整合加值計畫「「安克呼止偵®(AmCAD-UO)」睡眠呼吸中止症檢測系統全球臨床研究與產品加值計畫」案，業經專業審查會議審查通過，請依說明所列事項辦理後續事宜，敬請查照。

說明：

一、依據經濟部工業局109年6月3日工化字第10900624541號函辦理轉知。

二、請依決議之計畫核定內容(如附件)補充修訂計畫書，並請繕印專案契約書暨計畫書一式12份(含電子檔)，註明公司及計畫名稱資料，於公司、負責人簽名用印後，函送本會辦理簽約事宜(服務地址:台北市信義路3段41-2號10樓)。

三、貴公司應將政府補助款設立專戶儲存，並配合計畫單獨設帳管理，請儘速辦理銀行專戶，帳戶名稱應為「安克生醫股份有限公司」，並於存摺封面手寫註記計畫名稱。

四、請貴公司配合於109年8月底前完成補助契約之簽訂，若無法於期限前完成簽約，應以書面敘明理由申請展延，展延期間以一個月為限。逾期未完成簽約者，依經濟部協助產業創新活動補助及輔導辦法第15條規定原核准失其效力。

五、經濟部「促進企業創新直接保證方案」透過中小企業信用

安克生技集團
Maywufa Biopharma Group

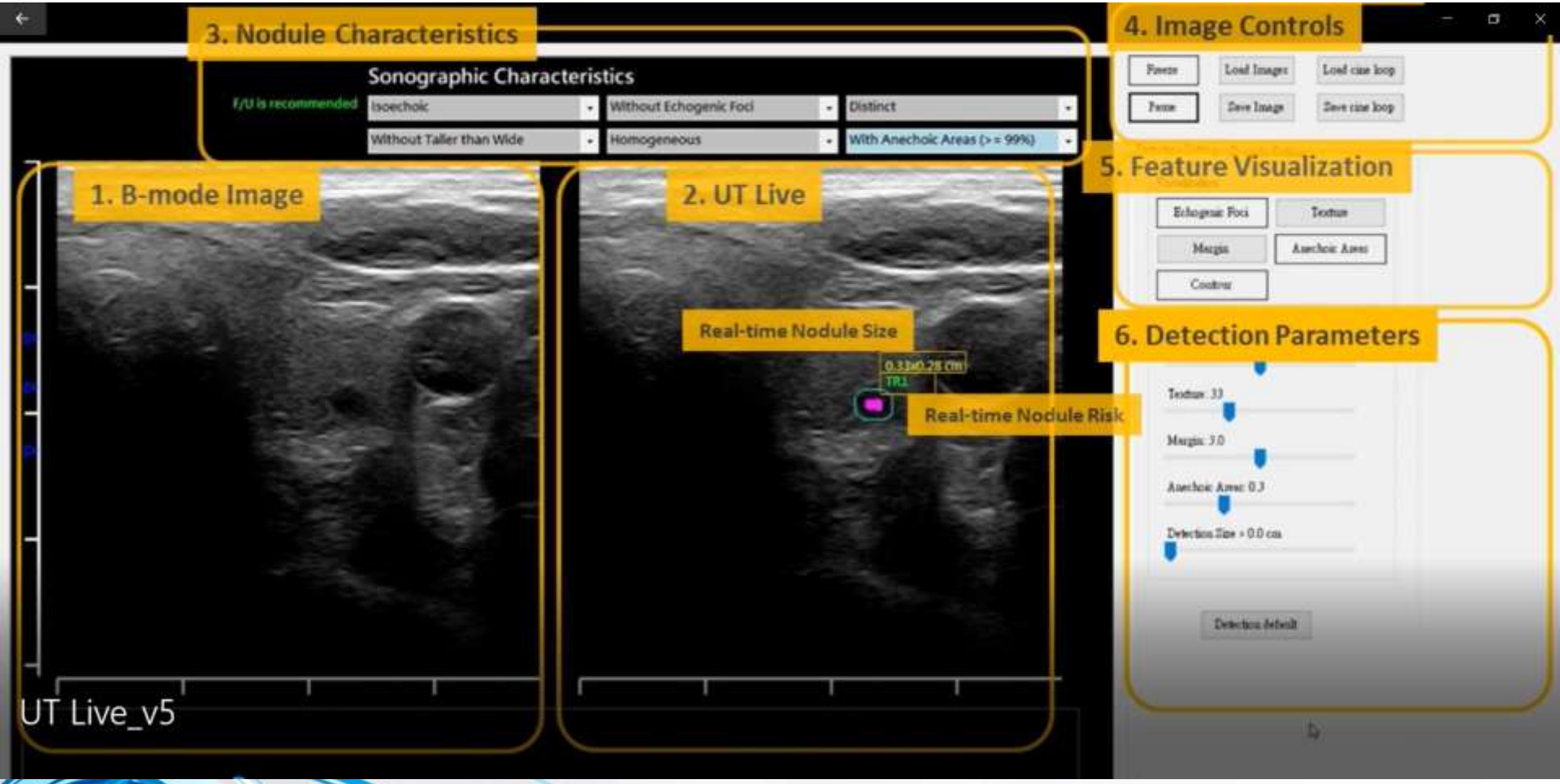
通過SGS品質系統查核

✓ 通過SGS品質系統實地稽核，並已完成矯正與預防措施

2020上半年重要里程碑-研發

- ✓ 安克甲狀偵整合超音波硬體，開發AI Live(即時掃描及時分析)功能
- ✓ 安克甲狀偵與國際各國醫師合作發表高影響力期刊論文
- ✓ 安克組織分析軟體 (AmCAD-US) 開啟與台大復健部臨床收案研究
- ✓ 安克呼止偵史丹佛大學睡眠中心多種族臨床收案研究
- ✓ 安克細偵進階版完成，將支援更多國際應用的染色法以執行細 胞及組織的影像分析，可推廣至全球研究單位

安克甲狀偵 AI Live(及時掃描及時分析)功能



安克甲狀偵發表高影響力期刊論文 (I)

Clinical Benefits: EvaluationAccuracy comparable to experts: MRMC Study

cancers

MDPI

Multi-Reader Multi-Case Study for Performance Evaluation of High-Risk Thyroid Ultrasound with Computer-Aided Detection

Ming-Huan Wu [1], Kuen-Yuan Chen [2], Shyang-Rong Shih [3], Ming-Chih Ho [1], Hao-Chih Tai [1], King-Jen Chang [1], Argon Chen [4,*] and Chiang-Nien Chen [1,*]

[1] Department of Surgery, National Taiwan University Hospital, Taipei 10002, Taiwan; ...
[2] Department of Internal Medicine, National Taiwan University, Taipei 10002, Taiwan; ...
[3] Graduate Institute of Industrial Engineering, National Taiwan University, Taipei 10617, Taiwan; ...
[4] Correspondence: achen@ntu.edu.tw (A.C.); mchen@ntu.edu.tw (C.-N.C.); Tel.: +886-2-3366-3366 (A.C.)

Received: 3 January 2020; Accepted: 4 February 2020; Published: 6 February 2020

Abstract: Physicians use sonographic characteristics as a reference for the possible diagnosis of thyroid cancers. The purpose of this study was to investigate whether physicians will be more effective in their tentative diagnosis based on the information provided by a computer-aided detection (CAD) system. A computer computed software-defined and physician-adjusted tumor loci. A multicenter, multireader, and multicase (MRMC) study was designed to compare clinician performance without and with the use of CAD. Interobserver variability was also analyzed. Excellent, satisfactory, and poor segmentations were observed in 25.3%, 58.9%, and 15.8% of nodules, respectively. There were 200 patients with 265 nodules in the study set. Nine [illegible] physicians scored the malignancy potential of the nodules. The average [illegible] under the curve (AUC) of all readers was 0.728 without CAD and significantly increased to 0.792 with CAD. The average standard deviation of the malignant potential score significantly decreased from 10.97 to 6.29. The more malignant potential score significantly decreased from 29.01 to 31.24 for benign cases. With the CAD system, an additional 7.9% of malignant nodules would be suggested for further evaluation, and biopsy would not be recommended for an additional 10.8% of benign nodules. The results demonstrated that applying a CAD system would improve clinicians' interpretations and lessen the variability in diagnosis. However, more studies are needed to explore the use of the CAD system in an actual ultrasound diagnostic situation where much more benign thyroid nodules would be seen.

Keywords: ultrasonography; thyroid nodule; thyroid cancer; computer-aided detection

1. Introduction

Thyroid nodules are very common findings. The clinical importance of thyroid nodules lies primarily with the possibility of thyroid cancer, which occurs in approximately 5–15% of all thyroid nodules [1]. Accurate initial thyroid nodule work-up is key to identifying clinically significant thyroid cancer, and new diagnostic tools, such as Fourier transform infrared (FTIR) and Raman spectroscopy, are sought to complement the present medical procedures [2–4].

Advances in high-resolution ultrasonography (US) have led to an increased availability of information on thyroid nodules and to efficient and effective diagnosis of patients with malignant thyroid nodules [1]. US is useful for not only detection of but also discrimination between benign and

evaluation, and biopsy would not be recommended for an additional 10.8% of benign nodules. The results demonstrated that applying a CAD system would improve clinicians' interpretations and lessen the variability in diagnosis.

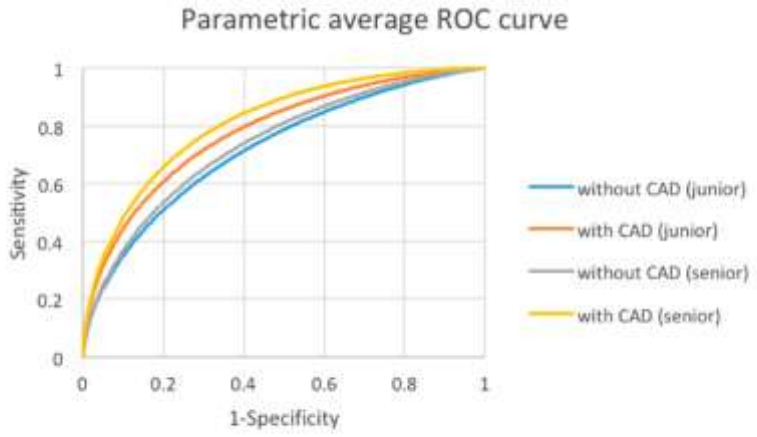


Figure 3. Average AUC Without and With CAD of junior group and senior group. Blue = junior group without CAD; Orange = junior group with CAD; Gray = senior group without CAD; Yellow = senior group with CAD.

Reference: **Multi-Reader Multi-Case Study for Performance Evaluation of High-Risk Thyroid Ultrasound with Computer-Aided Detection** *Cancers* **2020**, *12*, 373; doi:10.3390/cancers12020373

美吾華·懷特·安克生技集團
Maywufa Biopharma Group

安克甲狀偵發表高影響力期刊論文 (II)

Clinical Benefits: Accuracy comparable to experts: Diagnostic Performance

AJR American Journal of Roentgenology
Diagnostic Imaging and Related Sciences

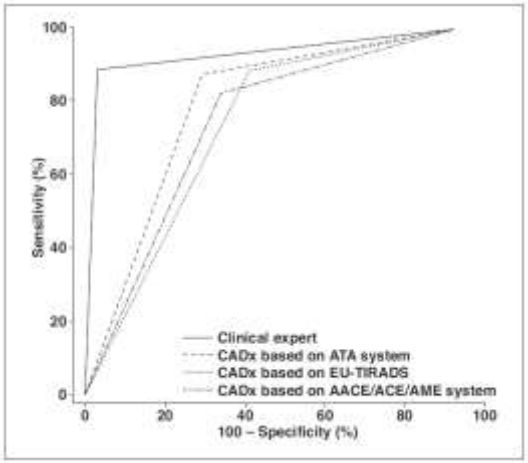
Jordi L. Reverter[1,2]
Federico Vázquez[1]
Manuel Puig-Domingo[1,2]

Diagnostic Performance Evaluation of a Computer-Assisted Imaging Analysis System for Ultrasound Risk Stratification of Thyroid Nodules

TABLE 1: Diagnostic Effectiveness of Evaluation of Ultrasound Images by Clinical Expert and Computer-Aided Diagnosis (CADx) Program Based on Different Classification Systems

Evaluator or Evaluating System	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	AUC Value
Clinical expert using ATA system	87.0	91.2	90.5	90.9	0.88
CADx based on ATA system[a]	87.0	68.8[a]	64.5[b]	86.3	0.72[b]
CADx based on EU-TIRADS[c]	85.2	50.2[b,d]	50.1[b,d]	82.6[b]	0.71[b]
CADx based on AACE/ACE/AME system[e]	81.5	53.2[b,d]	51.8[b,d]	80.8[b]	0.70[b]

In conclusion, according to our results, CADx systems in general—and the AmCAD-UT in particular—are reliable and easy to use and thus are useful in clinical practice. Given the high sensitivity and NPV that we reported (at least for preliminary screening



Reference: Reverter JL, Vázquez F, Puig-Domingo M. (2019). Diagnostic Performance Evaluation of a Computer-Assisted Imaging Analysis System for Ultrasound Risk Stratification of Thyroid Nodules. American Journal of Roentgenology, 213: 169-174.

安克組織分析軟體 (AmCAD-US) 進展

- 安克AmCAD-US領先全球的技術成為全球大廠仿效對象
- 進行脂肪肝檢測之最後臨床驗證收案
- 台大醫院進行肩膀(五十肩)、腕隧道收案
  - 五十肩案例分析，初步分析健康組與病患有顯著差異，後續將根據不同的病因分析
  - 腕隧道案例分析，初步雖與問卷量測有相關性

510(K) Summary: K192903

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. Date Prepared – October 11, 2019

2. Manufacturer
   SAMSUNG MEDISON CO., LTD.
   3366, Hanseo-ro, Nam-myeon,
   Hongcheon-gun, Gangwon-do 25108,
   REPUBLIC OF KOREA

3. Primary Contact Person
   Ji Yea Lee
   Regulatory Affairs Specialist
   Phone: +82.2.2194.1594
   Fax: +82.31.8017.9576
   Email: jiyea722.lee@samsungmedison.com

   Secondary Contact Person
   Ninad Gujar
   Director of Regulatory & Quality
   Phone: +1.978.564.8632
   Fax: +1.978.564.8677
   Email: ngujar@neurologica.com

4. Proposed Device

Common Name:	Diagnostic Ultrasound System and Accessories
Trade/Device Name:	RS85 Diagnostic Ultrasound System
Additional Marketing Name:	RS85 Prestige Diagnostic Ultrasound System
Regulation Name:	Ultrasound pulsed Doppler imaging system
Panel/ Regulatory Class:	Radiology / II
Product Code:	IYN, IYO, ITX
Regulation No./Product Code	892.1550, 892.1560, 892.1570

5. Predicate Device
   - Predicates
     - RS85 Diagnostic Ultrasound System (K191115) : Primary
     - HERA W10 Diagnostic Ultrasound System (K182595)
     - HS50/HS60 Diagnostic Ultrasound System (K181336)
   - Reference
     - AIXPLORER & AIXPLORER Ultimate Ultrasound Diagnostic Systems (K173021)
     - Fibroscan (K150949)
     - AmCAD-US (K162574)

安克呼止偵
AmCAD-UO

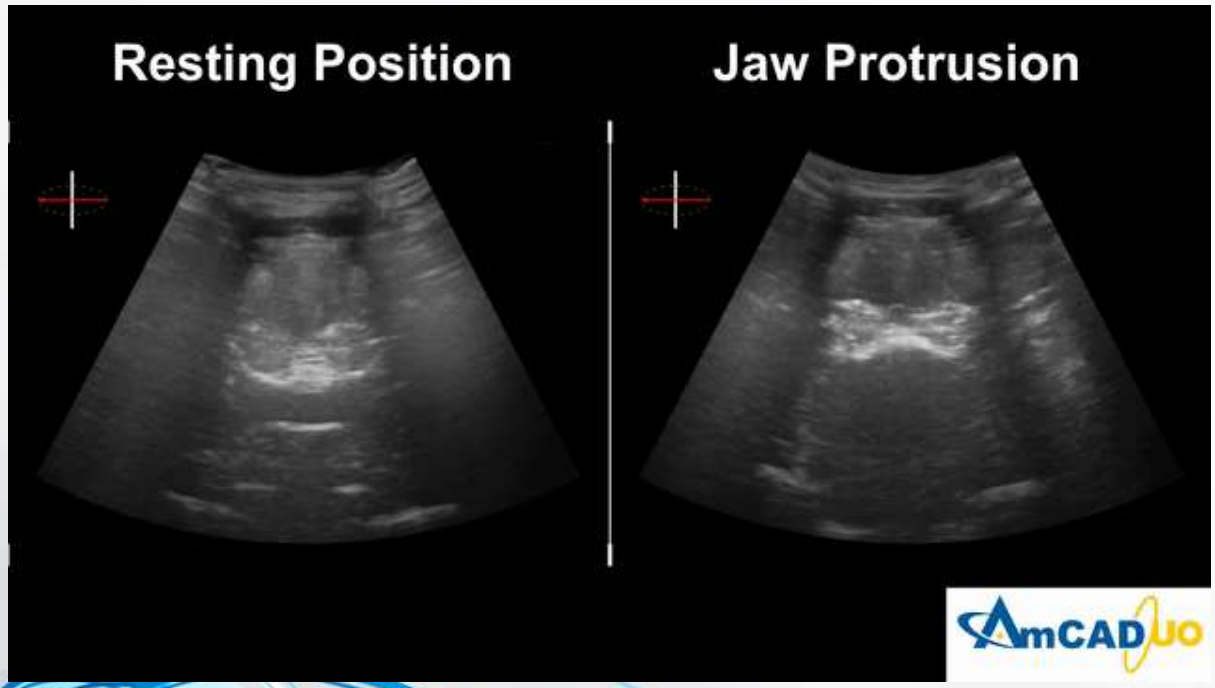
10分鐘呼吸中止症檢測系統

- 美國FDA、歐盟CE、台灣TFDA核准
- 專利雷射定位系統
- 自動掃描一致性結果
- 精密上呼吸道分析
- 快速檢測

美吾華·懷特·安克生技集團
Maywufa Biopharma Group

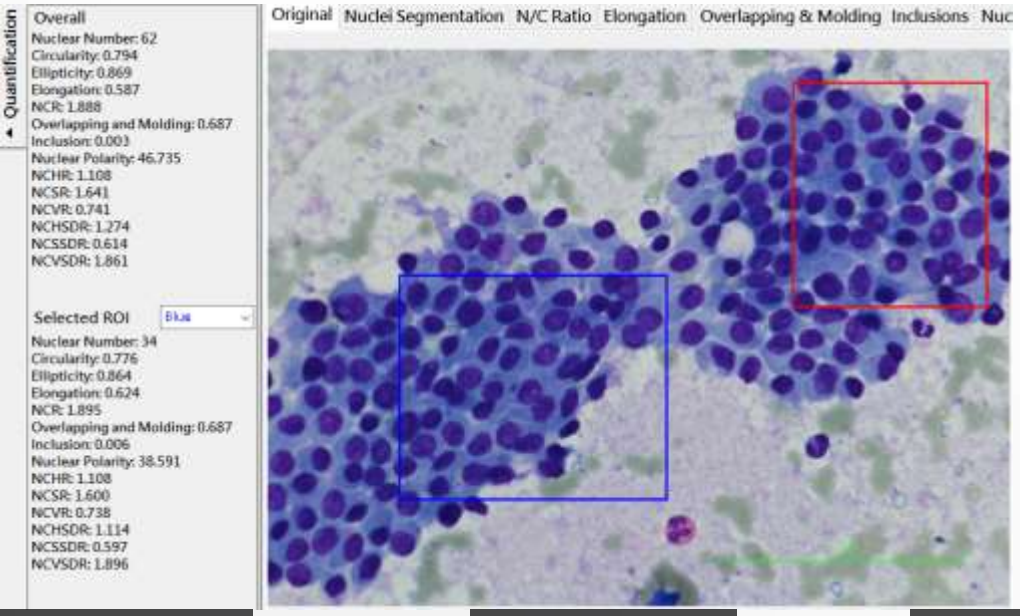
安克呼止偵 (AmCAD-UO) 研發進展

- 完成報告上傳客戶端PACS系統功能
- 根據分析結果產生相對應檢查描述與建議
- 史丹佛大學睡眠中心多種族臨床收案研究

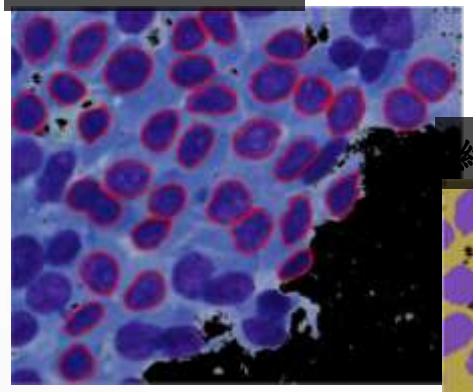


Jaw Protrusion
NB

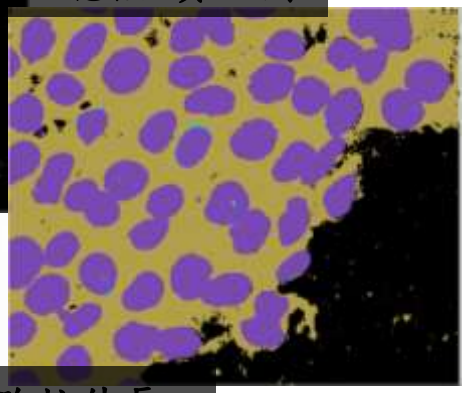
安克細偵支援更多國際常用的染色法



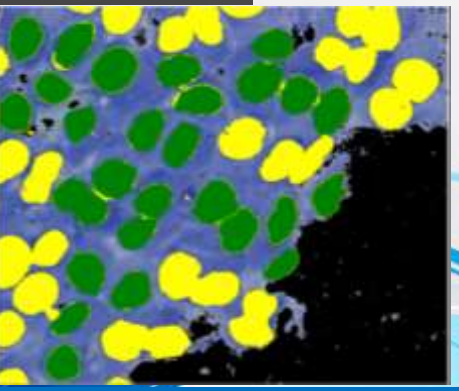
細胞核分割



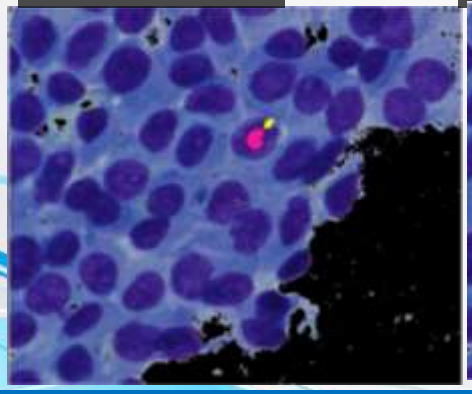
細胞核/質比例



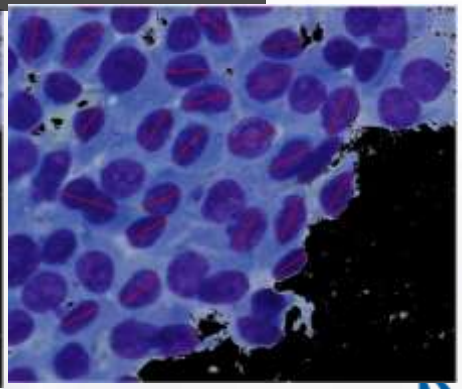
細胞核重疊



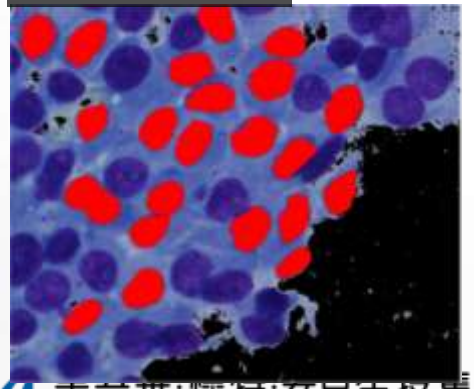
包涵體



細胞極性

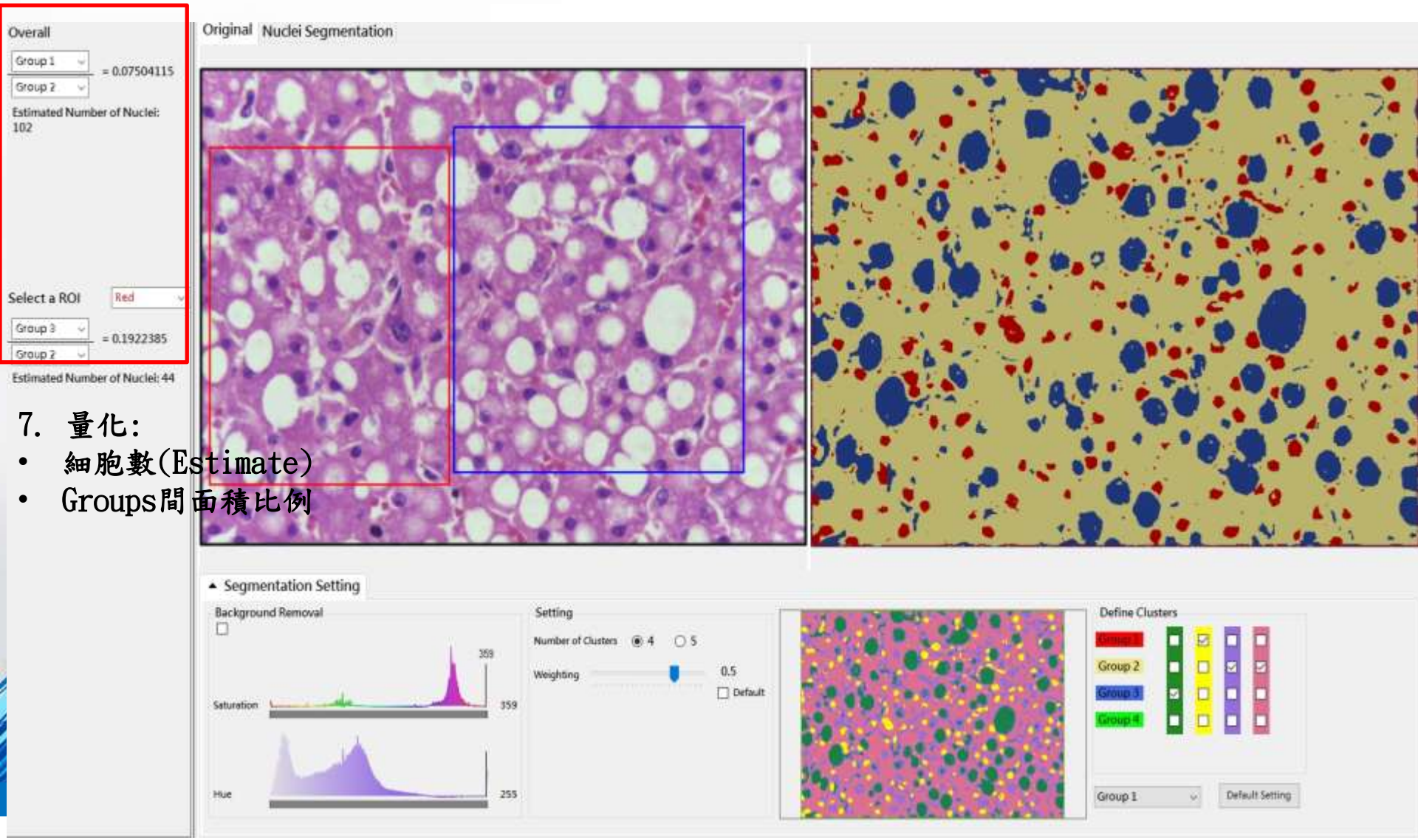


細胞核伸長



安克細偵支援組織學影像分析

https://commons.wikimedia.org/wiki/File:Fatty_change_liver_-_Lipid_steatosis_40X.jpg



7. 量化:
- 細胞數(Estimate)
- Groups間面積比例

2020國內展業重要里程碑

- ✓ 甲狀偵和呼止偵與數家健診中心簽約，搶攻COVID-19疫情後健診商機
- ✓ 甲狀偵下半年推出健診訂閱專案，鎖定10家健檢中心拓市場提高營收
- ✓ 呼止偵已與專業經銷商永定簽約，推廣至振興及聯新健檢使用，結合後續CPAP銷售分潤，開創新的營運模式
- ✓ 呼止偵與睡眠中心簽訂租賃合約，7月起開始認列租金收入

國內展業

安克甲狀偵

中國附醫健檢中心–引進安克甲狀偵

5月中完成系統整合並開始銷售，成功加入婦女標準健檢專案

東元醫院放射科及高級健檢產品說明

高醫耳鼻喉科UT/UO產品介紹

6/24進行介紹, 耳鼻喉科醫師反應熱烈，要求安裝在診間電腦

國內展業

安克呼止偵

聯新醫院UO產品介紹 - 院長親自試用

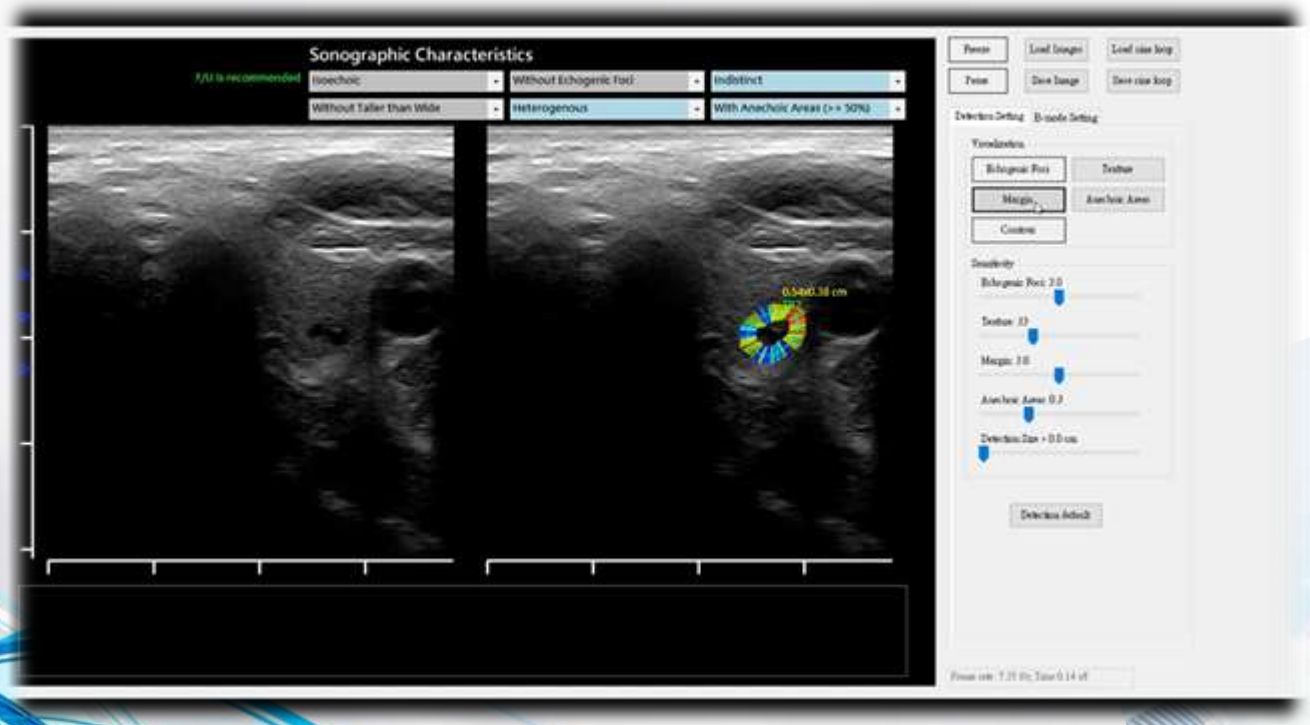
- 已完成與睡眠中心簽約共同進入尊爵健診

桃園長庚睡眠中心

安克呼止偵滿意體驗

2020 授權合作案

- 與超音波大廠簽訂合作MOU進行CAD 與其超音波結合之評估
- 持續與期進行緊密溝通與線上會議



2020國際展業重要活動

1. 與土耳其、埃及、泰國、越南經銷商簽定LOI
2. 與超音波大廠洽談甲狀偵授權
3. 與大陸經銷商聯合舉辦線上超聲論壇
4. Medica Expo(線上行銷推廣)
5. ECR On line symposium with AmCad booth

2020安克生醫國際展業拓展

Letter of Intent

土耳其 Medeltip , Jan

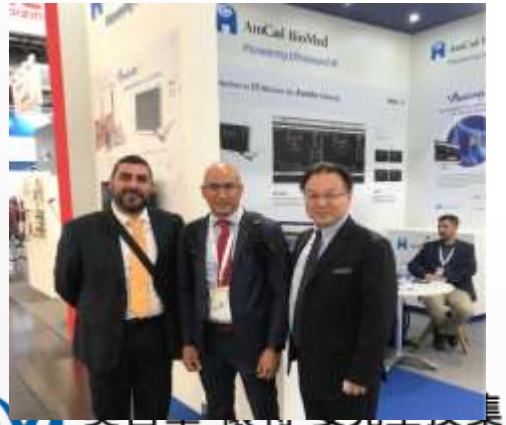
越南 Advantech Vietnam, Jul

厄瓜多 Bimerecu, Apr

泰國 Winnergy, May

埃及 Jeppenson, Mar

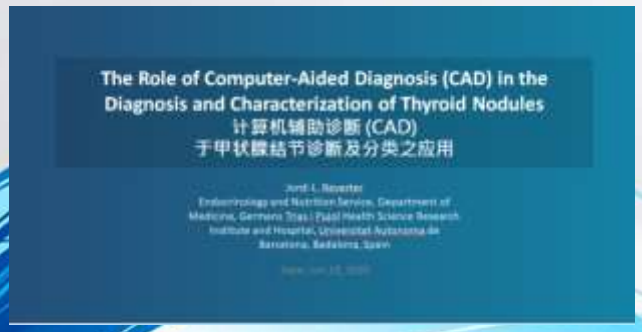
中美洲 Mederi N V, Jan

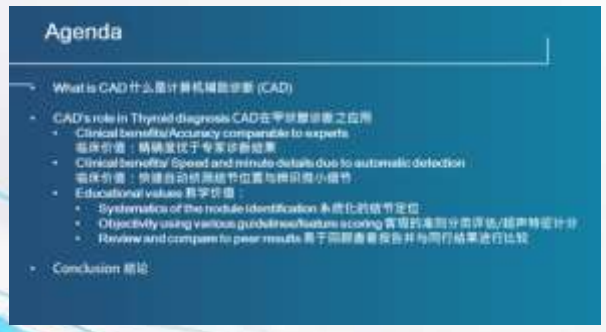


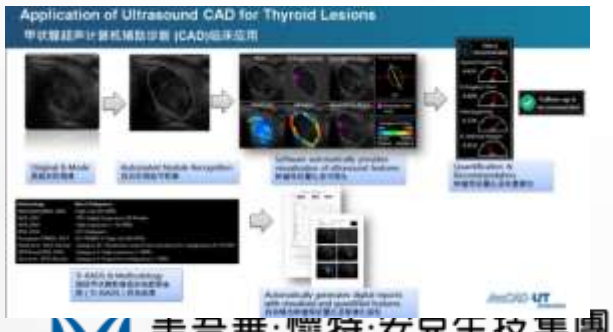
Maywufa Biopharma Group

Zoom Meeting with Global Partners

線上甲狀腺超聲論壇-June







Medical Expo: 4/15-7/15

Click here to see your proposal
(you will be able to review it before confirming)

MedicalExpo -- Membership Offer Starting Package Fewer details

Billing upon acceptance

Account Manager: Antoine VERHAEGHE Telephone: +33.4.86.57.42.38

Start date: **Sep 1, 2020** Termination date: **Sep 1, 2021** Validity termination date: **Jul 15, 2020**

ME - AmCad BioMed

Item	Geographic Area:	Quantity	Price
ONLINE STAND - 12 MONTHS	Worldwide	1	3,996.00 EUR
HIGHLIGHT - Newsletter complimentary			

Payment due date: 30 days of receipt of invoice

Total number of items:	3,996.00 EUR
10% Discount	-399.60 EUR
Price before tax:	3,596.40 EUR

1Y+1.5m Service Fee:

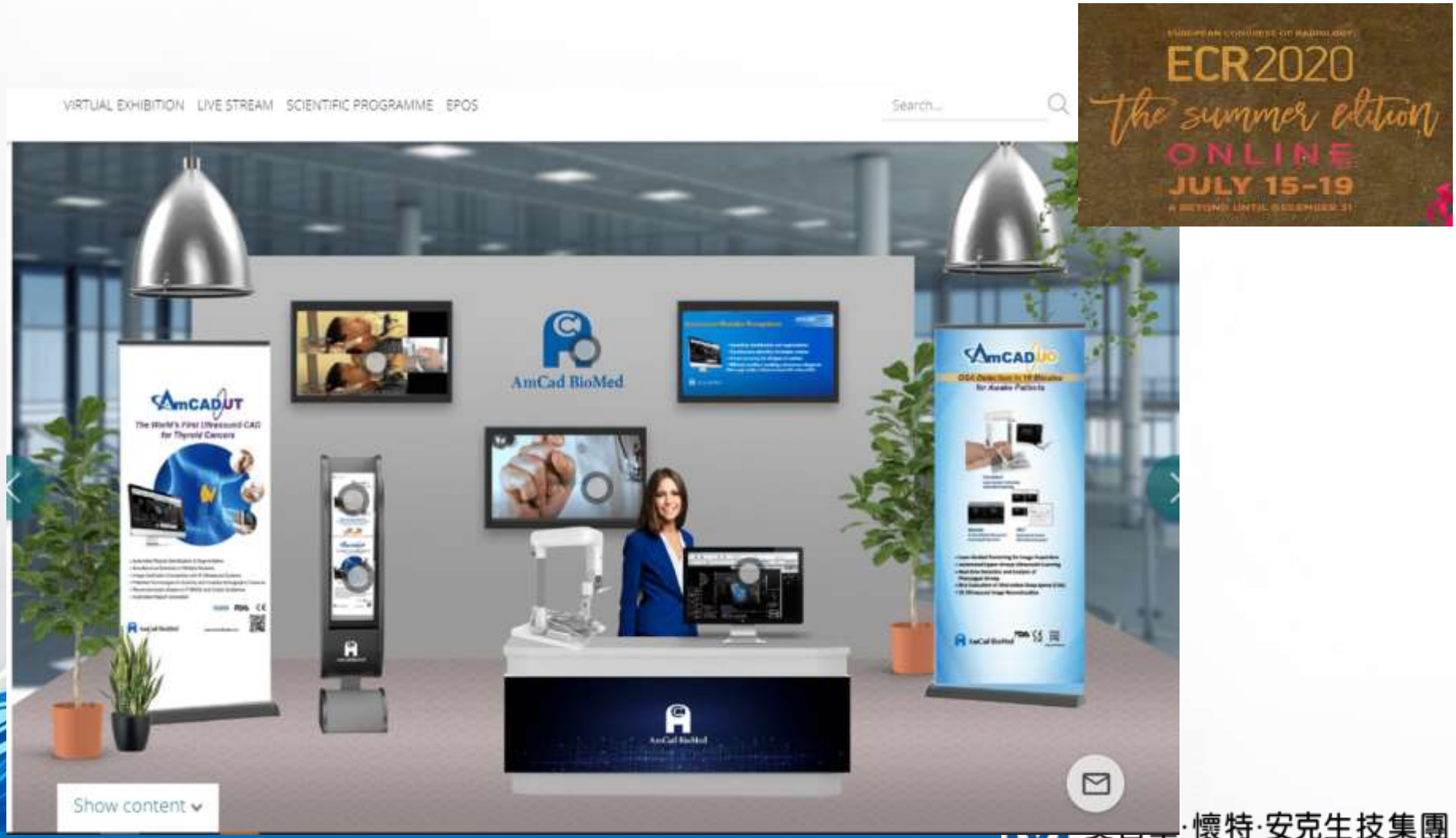
MedicalExpo Transitions from an Online Exhibition to a B2B Marketplace

By Celia Sampol, Camille Rustici and Erin Tallman

As companies continue expanding the online market by creating their own marketplaces, the year 2020 might be the cut-off for those interested in entering the competition. That's what Vincent Gerard, CEO of the French company VirtualExpo Group which powers MedicalExpo, thinks. Today, the company is officially launching its new online marketplaces.

美吾華·懷特·安克生技集團
Maywufa Biopharma Group

2020 安克國際線上展位~ ECR Virtual Booth



財務報表

一、簡明合併資產負債表

單位：新台幣仟元

科　　目	109.6.30	%	108.12.31	%
流動資產	444,207	65	481,716	66
非流動資產	241,558	35	252,586	34
資產總計	**685,765**	**100**	**734,302**	**100**
流動負債	59,775	8	72,049	10
非流動負債	16,634	2	24,172	3
負債總計	**76,409**	**10**	**96,221**	**13**
股本	532,214	78	532,214	72
資本公積	94,920	14	94,553	13
保留盈餘	(103,705)	(15)	(82,420)	(11)
其他權益	(14,115)	(2)	(11,248)	(1)
母公司權益	509,314	75	533,099	73
非控制權益	100,042	15	104,982	14
權益總計	**609,356**	**90**	**638,081**	**87**
負債及權益總計	**685,765**	**100**	**734,302**	**100**

註：109.6.30 及 108.12.31 合併資產負債表分別經會計師核閱及查核。

財務結構健全
1.銀存4.1億
2.流動比例7.4倍
3.負債比例10%

二、簡明合併綜合損益表

單位：新台幣仟元

科目	109 年上半年度		108 年上半年度		成長率%
	(A)	%	(B)	%	(A-B)/B
營收淨額	29,468	100	53,706	100	(45)
營業毛利	19,481	66	42,680	80	(54)
營業費用	(50,085)	(170)	(57,462)	(107)	(13)
營業損失	(30,604)	(104)	(14,782)	(27)	107
營業外收支淨額	4,379	15	2,722	5	61
稅後淨損	(26,225)	(89)	(12,060)	(22)	117
稅後淨損-母公司業主	(21,285)	(72)	(7,578)	(14)	181
稅後淨損-非控制權益	(4,940)	(17)	(4,482)	(8)	10
每股虧損	(0.40)		(0.14)		

註：109 年上半年度及 108 年上半年度合併綜合損益表均經會計師核閱。

上半年受疫情影響出貨耽延，4Q起逐漸回溫

未來展望

BD&L : Business Model

Licensing

License technology to equipment makers and receive licensing fees or royalty.

Distribution

- Leasing
- Revenue Sharing
- Outright Sales
- Subscription

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

Collaborative Marketing

Collaborate with PACS/AI platforms to market and expand access.

2020 INTERNATIONAL FORUM ON NEW TECHNOLOGIES AND CLINICAL DIAGNOSIS OF THYROID ULTRASOUND

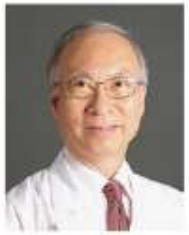
13TH NOV, 2020 (1.5 HOURS) LIVE WEBINAR
10:00 - 11:30 A.M. Spain
16:00 - 17:30 P.M. Indonesia | Vietnam
17:00 - 18:30 P.M. Taiwan | Singapore| Malaysia

Taiwan Society of Ultrasound in Medicine

AmCad BioMed

Register to join webinar

Date: Friday, November 13, 2020
Time: 17:00 -18:30 p.m. (CST/ Taipei time)



Prof. Yi-Hong Chou

- Vice President of the World Federation for Ultrasound in Medicine and Biology (WFUMB)
- Chair and Professor of Radiology at Yuanpei University of Medical Technology and National Yang Ming University School of Medicine

Agenda

- **Opening Remarks**
- **Special Messages from Prof. Yi-Hong Chou**
- **The Trend and New technologies for Thyroid Cancer Diagnosis**
  By Prof. Tsung-Lin Yang MD, PhD
- **Artificial Intelligence (AI) and Its Applications to Sonographic Diagnostics of Thyroid Nodules**
  By Prof. Argon Chen
- **The Role of Computer-Aided Diagnosis (CAD) in the Diagnosis and Characterization of Thyroid Nodules**
  By Prof. Jordi L. Reverter
- **Q&A Panel Discussion**
- **Closing Remarks**

Speakers

Prof. Tsung-Lin Yang MD, PhD

- Professor and Chief, Head and Neck Surgery, Department of Otolaryngology & Head Neck Surgery, National Taiwan University Hospital
- Chief Executive Officer, Research Center for Development Biology and Regenerative Medicine, National Taiwan University

Prof. Argon Chen

- Professor, Industrial Engineering and Mechanical Engineering, National Taiwan University
- Chief R&D Officer, AmCad BioMed

Prof. Jordi L. Reverter

- Senior specialist Endocrinology, Germans Trias i Pujol University Hospital
- Professor of Medicine, Autonomous University of Barcelona, Spain

結論

- ✓ 國內甲狀偵和呼止偵積極推動健診方案，建立成功的營運模式，有效滲透市場。
- ✓ 國際展業透過授權、經銷商合約及協同行銷等模式，以安克創新的醫材和軟體連結國際醫療通路、超音波大廠及呼吸器大廠合作，共創雙贏。

Q & A