

AmCad Biomed Corporation

Taiwan Stock Exchange (symbol:4188)

2020 Institutional Investor Conference

Established: 2008

Stock Exchange Listed: 2015

Capitalization: USD18.3M

Chairperson: C. C. Lee

General Manager

Yili Lee

2020 Milestone



2020 1H important milestone

- Operating
- R&D
- Local BD
- International research
- International BD



North City Government Subsidy Case-Pass

- 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。

Ministry of Economic Affairs Subsidy Case : Pass

- 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

台北市中山區復興北路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：基字第1090002189號

類別：普通件

密等及解密條件或保密期限：

附件：無

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，業經專案審查會議審查通過，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，並請鑄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

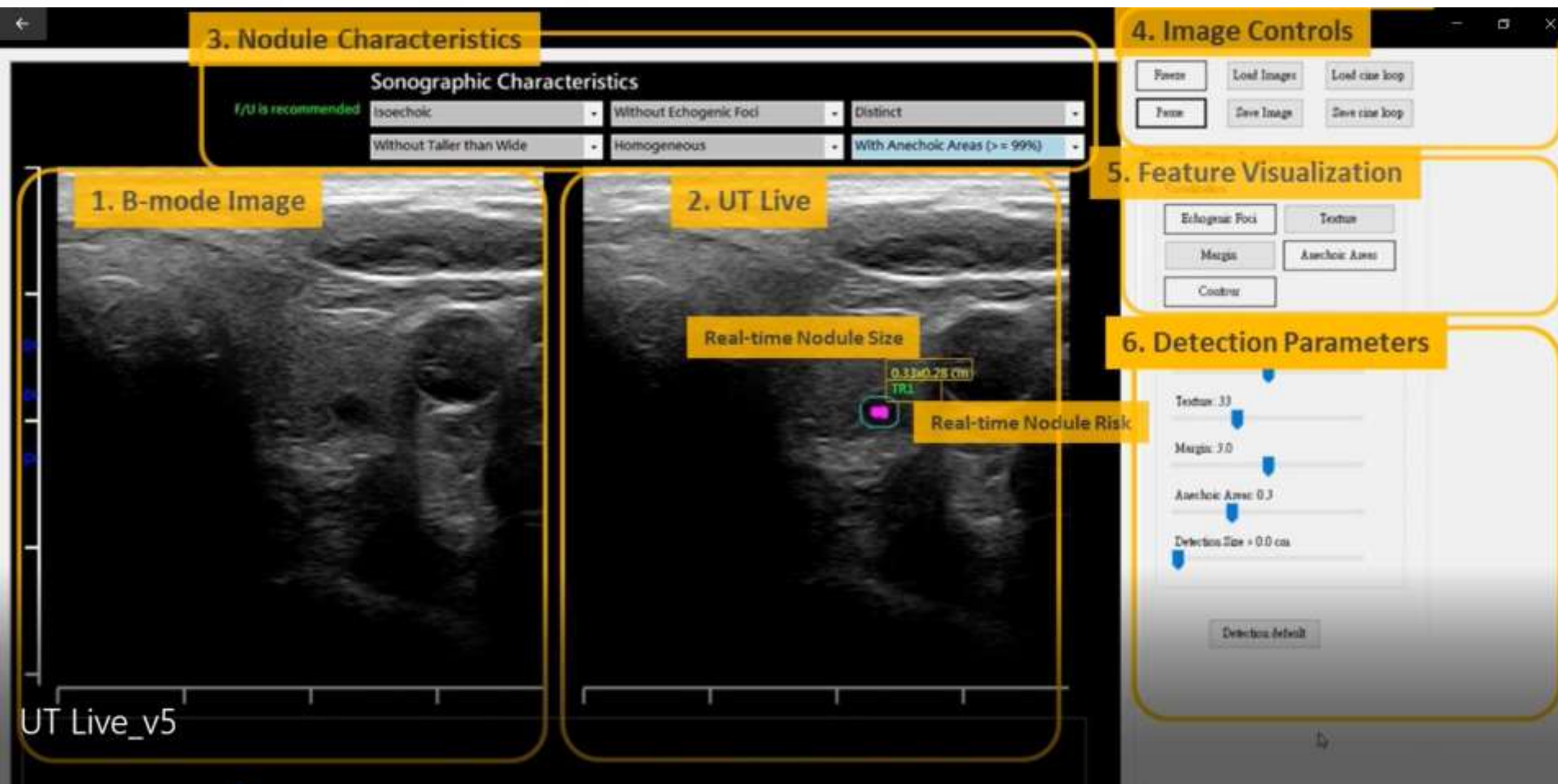
Maywufa Biopharma Group

Pass SGS auditing

✓ 通過SGS品質系統實地稽核，並已完成矯正與預防措施



AmCad UT AI Live Function



UT Published papers (I)

Clinical Benefits: Evaluation Accuracy comparable to experts: MRMC Study



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.

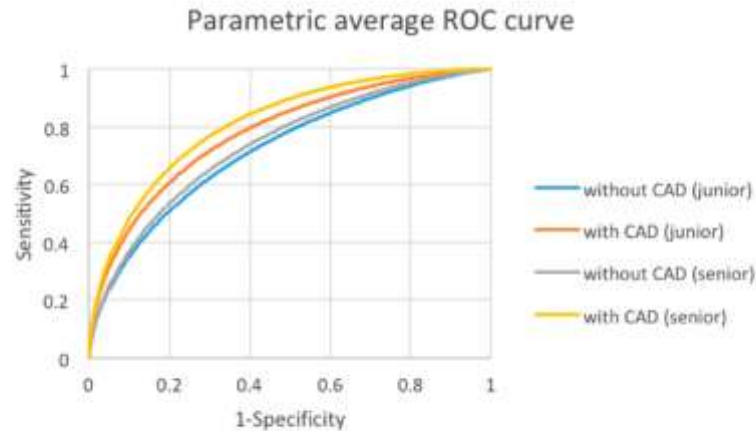


Figure 3. Average AUC Without and With CAD of junior group and senior group. Blue = junior group without CAD; Orange = junior group with CAD; Gray = senior group without CAD; Yellow = senior group with CAD.

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

AmCad UT Published papers (II)

Clinical Benefits: Accuracy comparable to experts: Diagnostic Performance



and malignant lesions and thus can help to reduce application time by lowering the different characteristics of the nodules automatically, preventing those that are more difficult to visualize (such as isohypic foci) or the detection of nodules that are being overlooked and undetected. Finally, each system can be also useful for the working process. In this regard, the objectivity of the system, the systematic of the exploration process (reducing it to avoid all the characteristics of the nodules in all cases and standardized), its ability to report results according to different scoring systems, and the fact that the results can be recorded and reviewed as many times as required are characteristics that can be very useful in the learning process for clinicians who are interested in the use of US in clinical practice.

The availability of the commercial and certified CADx system has allowed us to apply for the first time its usefulness in clinical practice in Europe. In the present study, we have evaluated that US classification of nodules: low risk compared to a highly discriminative and accurate method, although an experienced operator is needed to obtain these good results [35]. We found that a CADx program was able to assess the risk of malignancy in thyroid nodules by analyzing US images at a level of diagnostic performance that was comparable to that of a trained and experienced endocrinologist, showing a similar sensitivity and NPV. Nevertheless, the commercialized system showed a lower specificity and PPV than did the clinical expert. The fact that an expert would achieve superior results is unsurprising, given that the CADx system learns from the accumulated experience of imaging experts, which is needed in its function.

In our series, up to one-third of nodules undetected according to the ATA reporting system [6] were classified as non-specific because in ATA classification the risk between 20-70% is not well defined, so in the case of suspicious nodules, risk classification. As a result, when this classification system was applied, it improved the sensitivity of the system.

With respect to the type of image used, the AmCAD-UT system is able to analyze both B-Mode and Doppler images. In the present study, we compared the results obtained using both types of images, and the system obtained the same results (data not shown), showing that either of the two formats can be used. This clearly supports the usefulness of the program at the clinical level.

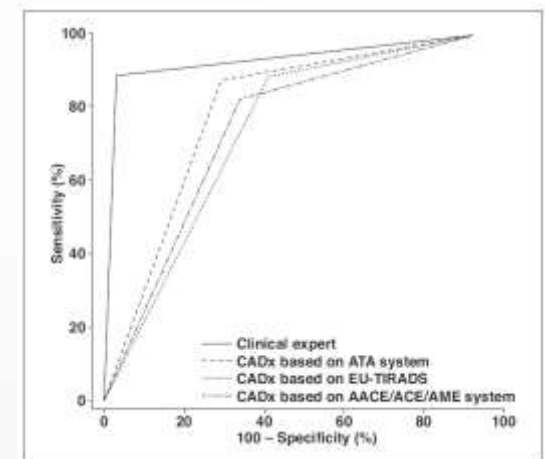
The strengths of the present study are the relatively large series of nodules evaluated in the clinical setting and the availability of pathologic diagnoses for these nodules. However, the study has certain limitations. First, the retrospective nature of the protocol may have introduced some bias. Second, analysis was based on recorded images and not on scanning data evaluated in real time. However, because the CADx system analyzes static images, the most important thing is that these images must have the highest quality possible. In our study, the high definition of the US device used when the US data were originally obtained resulted in the images that we evaluated having excellent image quality. Of interest, a CADx system that is integrated into the US machine and is able to access some of the characteristics associated with malignancy during exploration was recently reported in a study involving a limited number of patients [34]. A final shortcoming of the present study is that only one clinician evaluated the images. A second endocrinologist serving as computer would have added validity to the results. However, given the goal of the study, which was to evaluate the effectiveness of the AmCAD-UT system, the second set of expert images was not needed.

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

Reverter et al.

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	88.8 ^b	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 ^d	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

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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.

(AmCAD-US) Processes

- 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

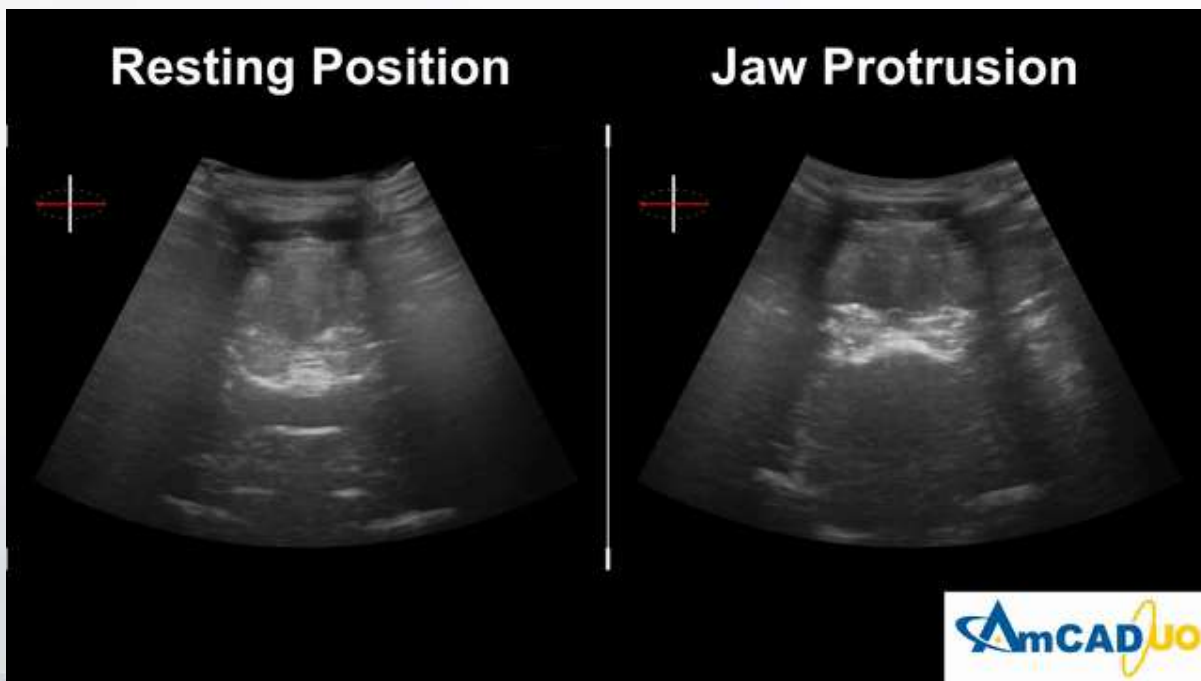
In accordance with 21 CFR 807.92 the following summary of information is provided:

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)

(AmCAD-UO) develop status

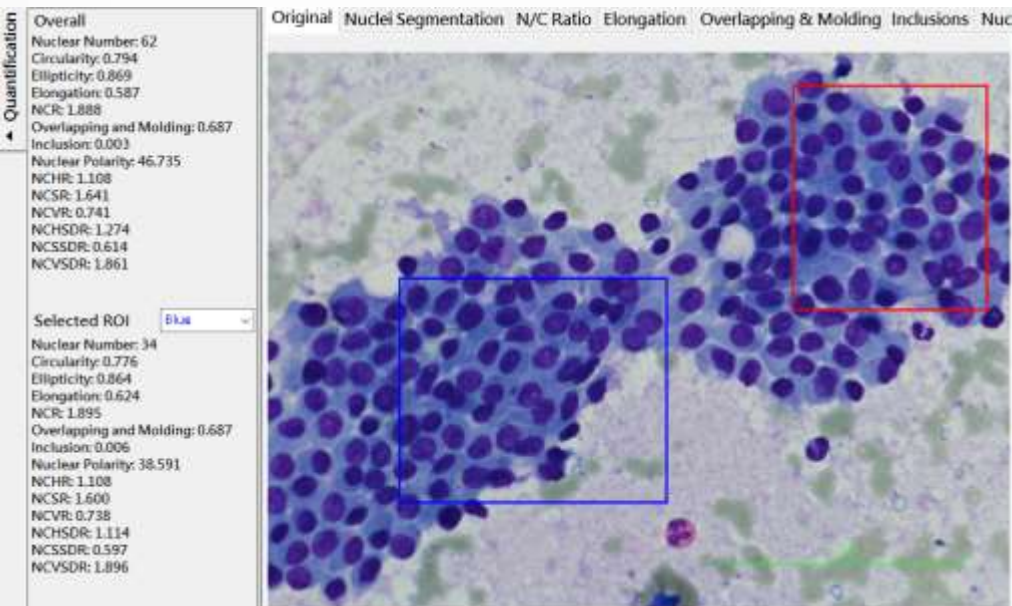
- 完成報告上傳客戶端PACS系統功能
- 根據分析結果產生相對應檢查描述與建議
- 史丹佛大學睡眠中心多種族臨床收案研究



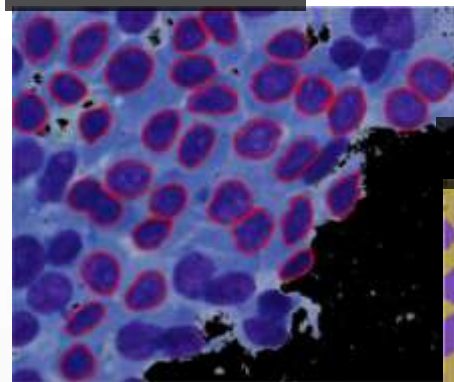
Jaw Protrusion
NB

AmCad CA Support more internationally used dyeing methods

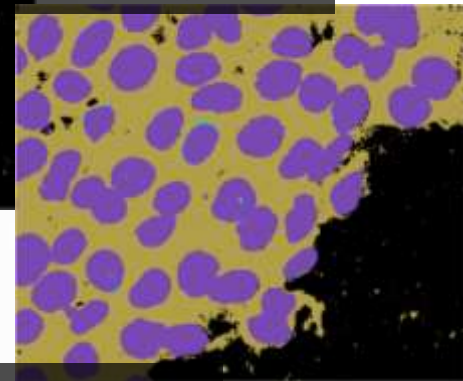
已可銷售實驗室通路



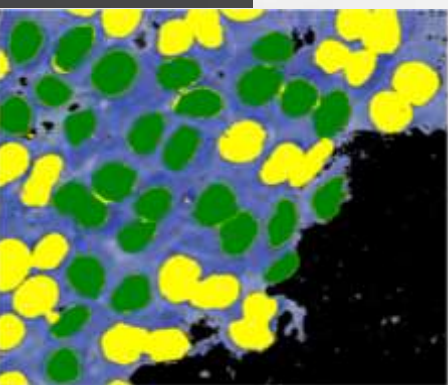
細胞核分割



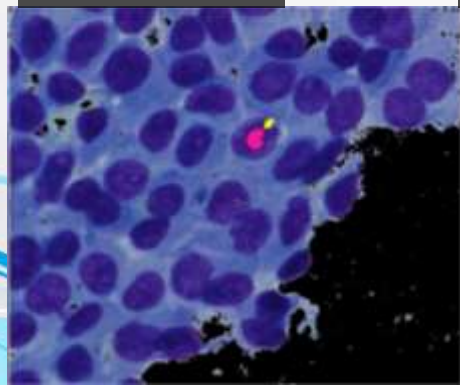
細胞核/質比例



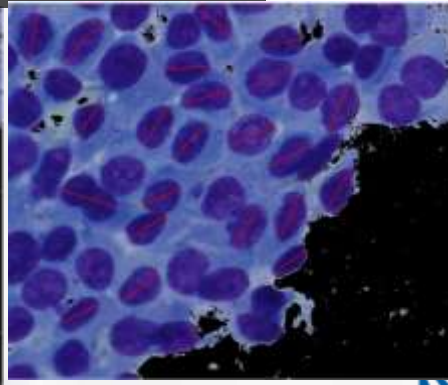
細胞核重疊



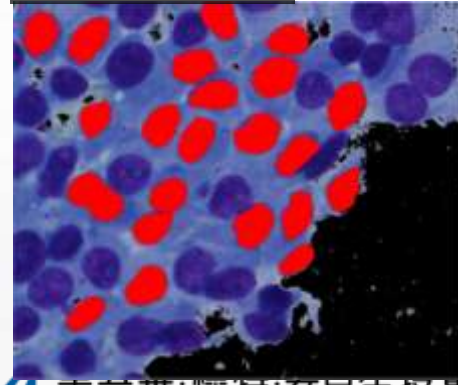
包涵體



細胞極性



細胞核伸長



AmCad CA Support histological image analysis

Overall

Group 1 = 0.07504115

Group 2 = 0.1922385

Estimated Number of Nuclei: 102

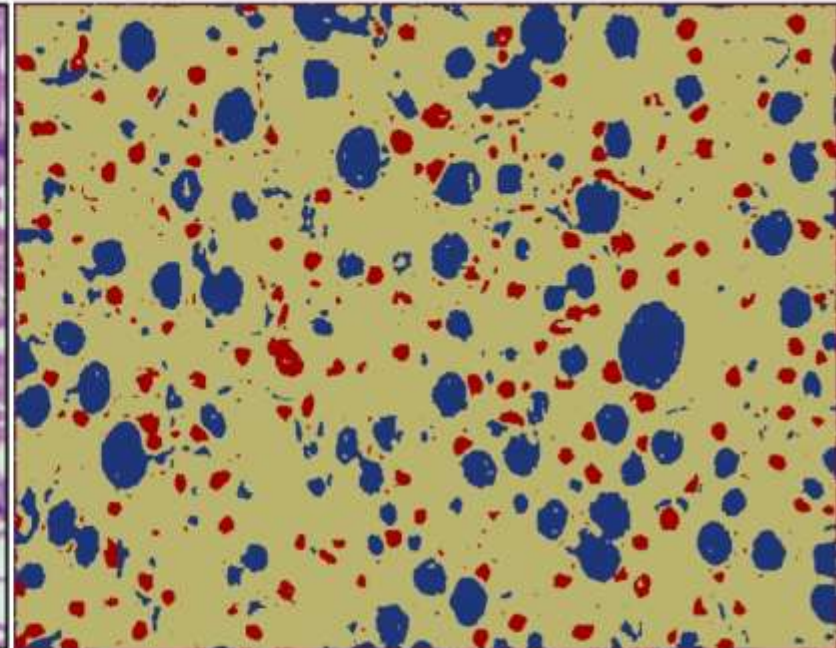
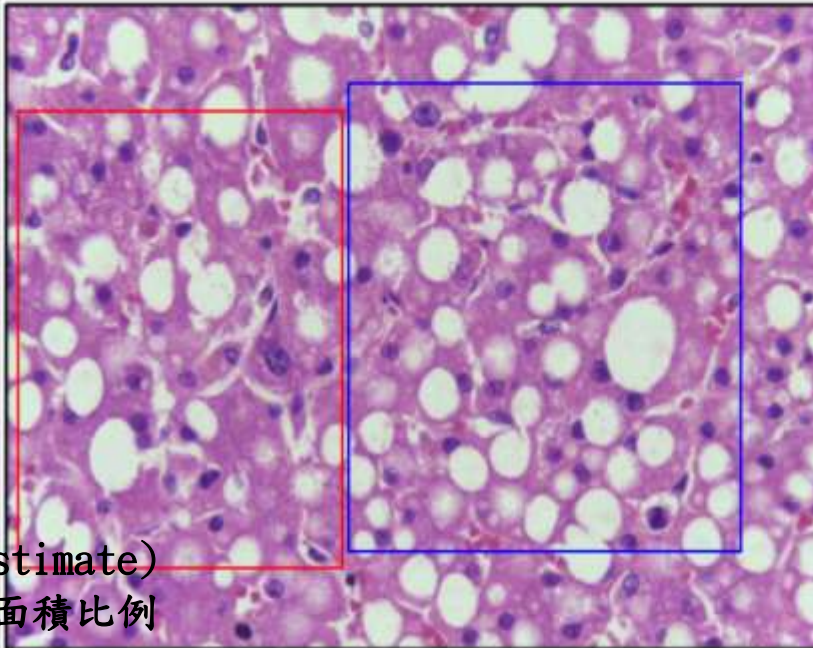
Select a ROI Red

Group 3 = 0.1922385

Group 2 = 0.1922385

Estimated Number of Nuclei: 102

Original Nuclei Segmentation



7. 量化:
- 細胞數(Estimate)
 - Groups間面積比例

Segmentation Setting

Background Removal



Saturation



359

Hue



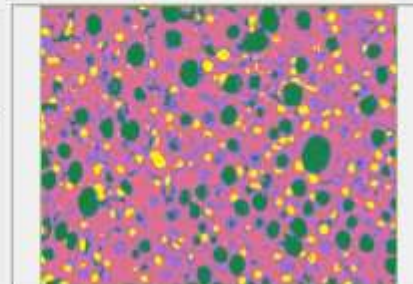
255

Setting

Number of Clusters ☒ 4 ☐ 5

Weighting 0.5

☐ Default



Define Clusters



Group 1

Default Setting

Local BD



安克甲狀偵



中國附醫Health Check Center

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Health Check Center



高醫UT/UO product introduction

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



Local BD



安克呼止偵

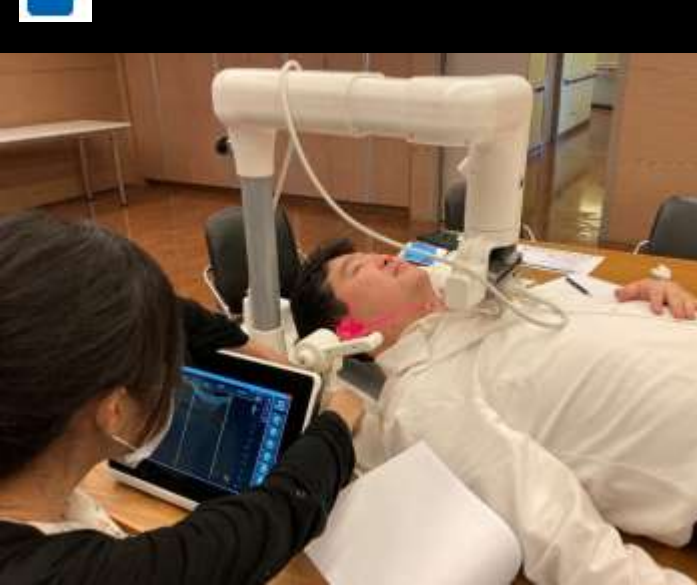
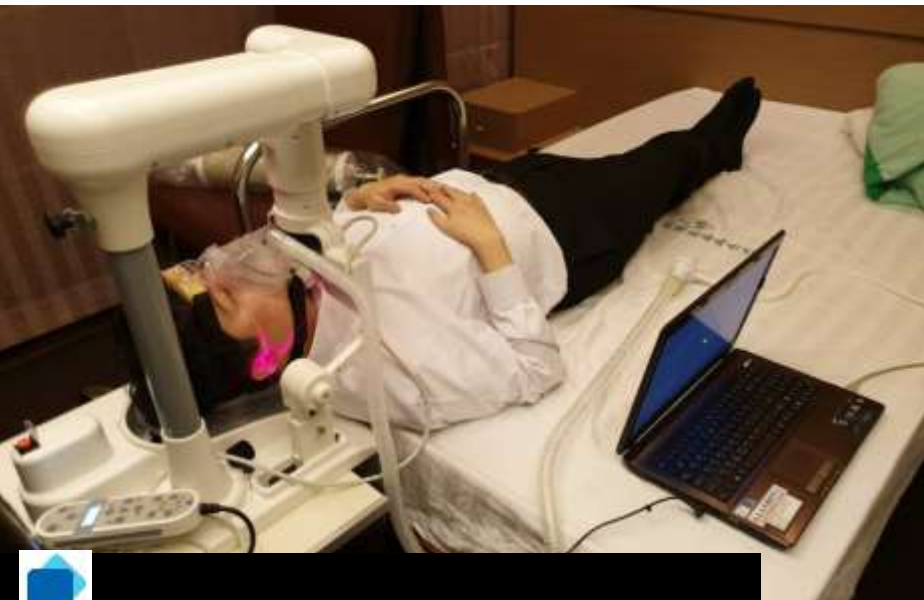
聯新醫院UO product introduction

■ 已完成與睡眠中心簽約共同進入尊爵健診



聯新醫院吳清平院長

桃園長庚Sleeping center



UO VIP Satisfying experience



華·懷特·安克生技集團
WuFa Biopharma Group

2020 Stanford UO Clinical training

- ◆ 2/6 教育訓練完成
- ◆ 7/15 啟動收案



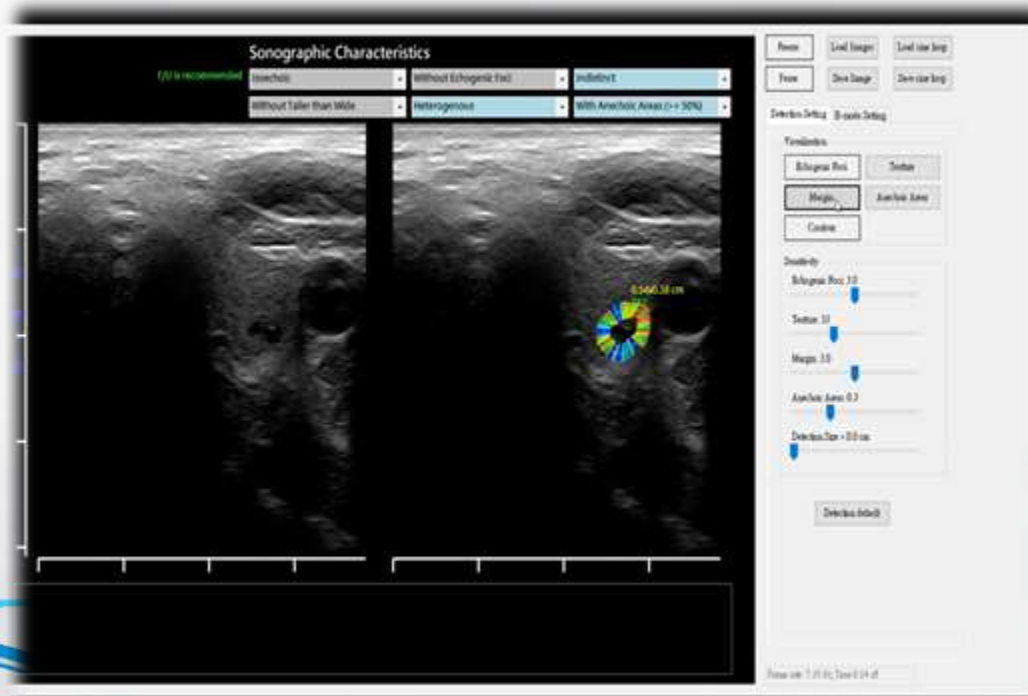
與ATA Nodule Guidelines Co-chair 進行臨床合作洽談



美吾華·懷特·安克生技集團
Maywufa Biopharma Group

2020 UT licensing

- 簽訂合作MOU進行CAD 與超音波結合之評估
- 持續與緊密溝通與線上會議



2020 international BD

Letter of Intent

土耳其 Medeltip, Jan



越南 Advantech Vietnam, Jul



厄瓜多 Bimerecu, Apr



泰國 Winergy, May



埃及 Jeppenson, Mar



中美洲 Mederi N V, Jan

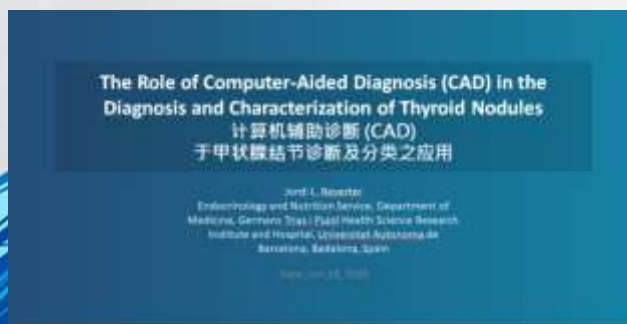


Zoom Meeting with Global Partners

45 meetings with 16 countries



Online Thyroid Ultrasound Forum-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

1Y+1.5m Service Fee:

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



MedicalExpo Transitions from an Online Exhibition to a B2B Marketplace

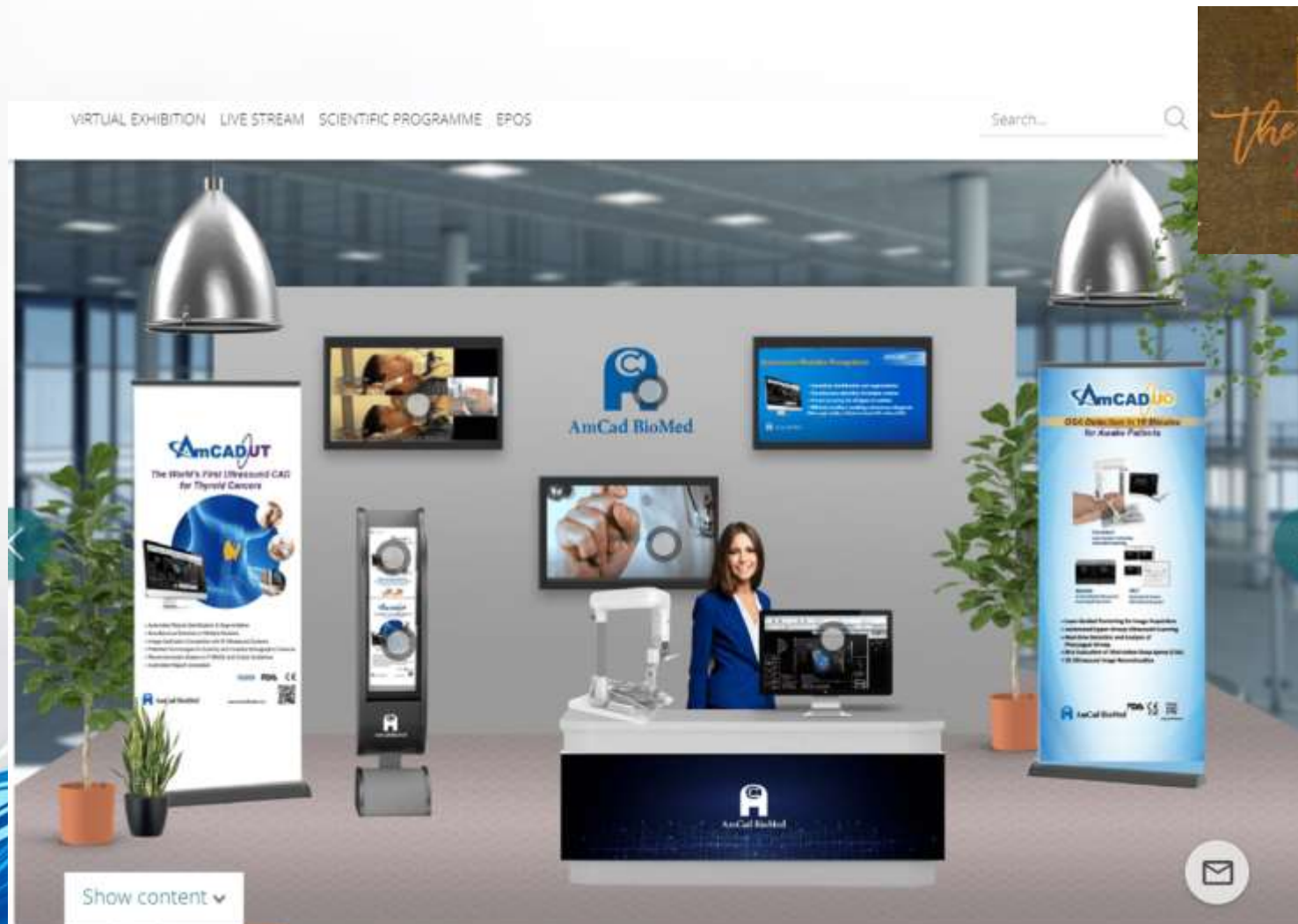
By Celia Sampil, Camille Rustici and Erin Tallman

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 ECR Virtual Booth



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)



Speakers



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



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

Financial report



Consolidated Balance Sheet

Item	108.6.30	%	107.12.31	%
CURRENT ASSETS	475,766	65%	522,147	87%
NON-CURRENT ASSETS	259,888	35%	256,331	13%
TOTAL ASSETS	735,654	100%	778,478	100%
CURRENT LIABILITIES	31,390	4%	59,115	5%
NON-CURRENT LIABILITIES	32,782	4%	31,014	6%
Total LIABILITIES	64,172	9%	90,129	11%
Share capital - ordinary	529,904	72%	529,904	76%
Capital surplus	93,962	13%	93,661	54%
Retained Earnings	-52,257	-7%	-44,679	-41%
Other equity	-10,387	-1%	-5,275	-
Parent equity	561,222	76%	573,611	89%
Minority	110,260	15%	114,738	-
Total equity	671,482	91%	688,349	89%
TOTAL LIABILITIES AND EQUITY	735,654	100%	778,478	100%

Consolidated income statement

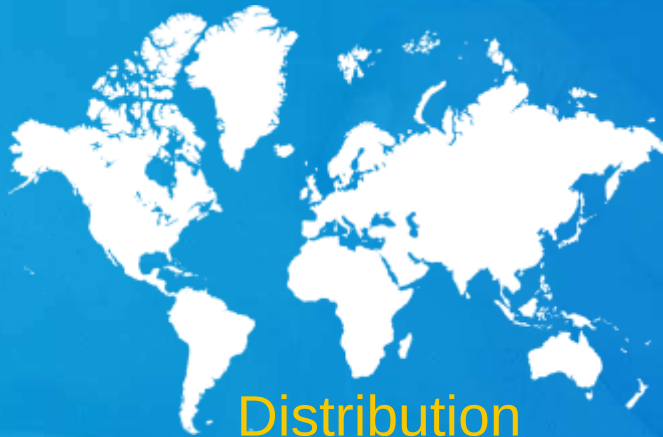
Item	1081H		107IH		growth%
	(A)	%	(B)	%	(A-B)/B
NET SALES	53,706	100	41,275	100	30
MARGINE	42,680	80	30,168	73	41
OPERATING EXP.	(57,462)	(107)	(65,193)	(158)	(12)
OPERATING LOSS	(14,782)	(27)	(35,025)	(85)	(58)
NON OPERATING GAIN(LOSS)	2,722	5	35,141	85	(92)
NET LOSS	(12,060)	(22)	116	0	(10,497)
LOSS-PARENT	(7,578)	(14)	(9,290)	(23)	(18)
LOSS-MINORITY	(4,482)	(8)	9,406	23	(148)
EPS	(0.14)		(0.18)		

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.

Future outlook

- ✓ Domestic UT and UO actively promote health diagnosis programs, establish successful business models, and effectively penetrate the market.
- ✓ The international exhibition industry uses AmCad's innovative medical materials and software to connect international medical channels, ultrasonic wave manufacturers and CPAP manufacturers to create a win-win situation through licensing, dealer contracts and collaborative marketing models.

Q & A

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Maywufa Biopharma Group