

Cardiex Limited (CDX)

Cardiex Unique FDA Cleared Blood Pressure Technology is Exactly What Apple and Samsung Want – But Can't Get (Yet!)

8th May 2025 Stuart Turner +61 402 128 454 stuart.turner@pelotoncapital.com.au Current \$0.06

\$0.27

SPEC BUY

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- 3 out of 4 people on the planet have a smartphone. An estimated 40%-50% of these users have downloaded at least one health app, as people are increasingly taking more interest in their health and longevity.
- The global health app market is experiencing significant growth. Simultaneously, the health apps are becoming increasingly medically significant, with Cardiex at the vanguard in the critical cardiovascular space.
- WITH FDA CLEARED PRODUCTS AND APPS, CARDIEX IS PIVOTING ITS GOLD STANDARD CENTRAL BLOOD PRESSURE MEASUREMENT TECHNOLOGY INTO THE CONSUMER SEGMENT AND INTO DIGITAL HEALTH SOLUTIONS THAT CREATE RECURRING REVENUE STREAMS.
- ▶ Cardiex's SphygmoCor technology accurately analyses central blood pressure, arterial stiffness, and other unique cardiovascular biomarkers – PROVIDING CLINICALLY MEANINGFUL MEDICAL-GRADE INFORMATION THAT STANDARD BLOOD PRESSURE TECHNOLOGY DOES NOT CAPTURE.
- Cardiex is seeking specific FDA approval of its SphygmoCor technology as "Software as a Medical Device" (SaMD) – the same technology embedded in the new FDA cleared PULSE blood pressure monitor.
- CRUCIALLY, this move will allow the adoption and licensing of Cardiex's proprietary SphygmoCor technology to external device manufacturers like Apple and Samsung, and lead to the creation of long-term, recurring technology licensing revenue streams.
- Cardiex is progressing its SaMD journey, announcing in March 2025 an "industry-first" Cardiologist Report which provides a comprehensive cardiovascular health assessment using its new FDA cleared PULSE device. In April 2025 Cardiex announced its CONNEQT customers will also be able to access key arterial health biomarkers directly through the Apple Health App.
- ➤ The CONNEQT PULSE blood pressure monitor is a world first. Initial sales commenced mid-Jan 2025. By the end of April, the annual revenue run rate was \$1.7m. Given current sales momentum, the June exit revenue run rate is expected to be \$4-5m p.a. (900 units pm) which will bring the group close to an EBIT breakeven run rate (1,000 units pm).
- We initiate coverage with a \$0.27 Target Price and SPEC BUY recommendation.

Company Data	
Number of shares (M)	405.2M
Options (M)	131.9M
Diluted number of shares (M)	537.1M
Market capitalisation – undiluted (A\$M)	\$21.1M
Market capitalisation – diluted (A\$M)	\$27.9M
Net Cash / (Debt) (A\$M)	\$0.2M
Enterprise Value - undiluted (A\$M)	\$20.8M
Enterprise Value - diluted (A\$M)	\$27.7M
12-month high/low	\$0.155 / \$0.048
12-month average daily volume	304,253

Substantial Shareholders & Associates	
C2 Ventures & Founders	36.0%
Regal Funds Management	5.9%
John Plummer	4.9%

Board of Directors

Niall Cairns, Chair, Exec Director Craig Cooper, CEO, ED
Randall Nelson, NED Charlie Taylor, NED



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VALUATION SCENARIO ANALYSIS – HIGHLY LEVERAGED TO EARLY ADOPTERS

			Scenario		
CLINICAL TRIAL	US\$m	Low	Med	High	Comments
Clinial Trial Market - New Trial Registrat	ions p.a.	3,000	3,500	4,000	refer to trial market data in this report
Innovator market share, say 2.5%		0.50%	0.70%	0.90%	per technology adoption curve
Innovators within Trial Sponsor Commu	inity	15	25	36	= # Trials x pct Innovators
Average trialists per trial		500	550	600	usually > 600
Number of participating trialists		7,500	13,475	21,600	= # Trials x # Trialists per trial
Average spend per trialist per month	US\$	50	50	50	Trial component payable to CDX for CBP data
Clinical Trial Segment Revenue	US\$m	4.5	8.1	13.0	= # Trialists x US\$ per month * 12
GM @ 85%	US\$m	3.8	6.9	11.0	
CONSUMER	US\$m	Low	Med	High	Comments
Target Market "Quantify Self" or "Selfers	" (million)	35	35	35	https://quantifiedself.com/
Proportion of "Selfers" buying device ea	ich year	0.04%	0.10%	0.17%	Early adopters represent c.2.5% of target Selfers
Implied monthly device sales		1,000	3,000	5,000	segment
Achievable by end of		CY25	CY26	CY27	PC Estimates
Initial Durchase					
Initial Purchase Individual device sale price US\$m		200	250	300	
•	щ				
Includes cardiologist reports	# US\$	2	3 50	4	
Price per cardiologist report		50		50	Driving alternatives reflect up discounted MCDD
Annual combined price	US\$	300	400	500	Pricing alternatives reflect un-discounted MSRP options at soft launch phase. PULSE is positioned as
Additional Report Bundles					a premium product.
Additional cardiologist reports	#	2	3	4	a premium product.
Monthly payment	US\$	5.99	7.99	10.99	
Annualised subscription revenue	US\$	72	96	132	i.e. 12 * monthly payments
Discount over standalone prices	ООФ	28%	36%	34%	i.e. discount to initial cardiologist report MSRP
Discount over standarone prices		2070	0070	0-770	no. discount to initiat cardiologist report north
Unit Economics					
PULSE unit cost	US\$	129	129	129	PC Estimate inc unit/chip/25% tarrif/marketing costs
GM	US\$	171	271	371	
GM%		57%	68%	74%	
Consumer Segment Revenue	US\$m	4.6	17.9	38.5	Based on initial purchase plus additional bundles
GM	US\$m	2.6	12.1	28.6	
	,				
AUDUSD CURRENCY CONVERSION RA	TE	0.65	0.65	0.65	
SUMMARY	A\$m	Low	Med	High	Comments
TOTAL REVENUE	A\$m	13.9	39.9	79.1	i.e. clinical trial + consumer segments
COGS	A\$m	-4.0	-10.7	-18.2	Cash costs lower due to levels of inventory held
Gross Margin	A\$m	9.9	29.2	60.9	seed to to to to to to the original production of the original prod
Overheads	A\$III	-11.0	-14.9	-20.8	\$11m baseline overheads reflects absence of one-off
R&D Rebate	A\$III				costs such as NASDAQ and resource optimisation
		1.5	1.5	1.5	initiatives.
TOTAL EBITDA	A\$m	0.4	15.8	41.6	madares.
EBITDA Margin		3%	40%	53%	DOF "
Assumed EV Multiple		15	9	7	PC Estimates
ENTERPRISE VALUE	A\$m	5.8	142.4	291.4	
ENTERPRISE VALUE per share	A\$	\$0.01	\$0.27	\$0.54	Fully Diluted (537m shares)

Source: Peloton Capital

CARDIEX LIMITED

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BLOOD PRESSURE MEASUREMENT TECHNOLOGY IS UNCHANGED AFTER 130 YEARS - THERE IS A VASTLY BETTER WAY:

UP UNTIL TODAY:

THE TECHNOLOGY YOU BUY IN THE CHEMIST TODAY IS NO **DIFFERENT TO THE TECHNOLOGY AVAILABLE IN 1896**:

CARDIOVASCULAR BIOMARKERS

Brachial BP Systolic

Diacilial Dr Systolic	
Brachial BP Diastolic	©
Central Blood Pressure (cBP)	×

Central Pulse Pressure (PP)	×
	_

Pulse Pressure Amplification	×
Pulse Pressure Ampunication	

	•
Augmentation Pressure (AP)	
Auginemation Flessure (AF)	

Augmentation Index	(Alx)	×

Subendocardial Viability Ratio	

SphygmoCor Reference Age	×

	_
Beat to beat heart rate	K)

REIMBURSEMENT CODE (USA)

THE FUTURE - CARDIEX SPHYGMOCOR TECHNOLOGY:

UTILISES PROPRIETARY PRESSURE WAVE FORM ANALYSIS MEASURES CLINICALLY SIGNIFICANT CENTRAL BLOOD PRESSURE CARDIEX SPHYGMOCOR IS NON-INVASIVE, ELIMINATING RISK PROVIDES A SUITE OF NEW MEDICAL GRADE CARDIOVASCULAR BIOMARKERS

WHY THIS IS SO IMPORTANT

_	
	The state of the s
	High brachial blood pressure is a major risk factor in heart disease.
•	,

cBP is the blood pressure at the base of the aorta.	

It is a more accurate predictor of subclinical cardiovascular disease.

PP is the pressure experience by key organs like the heart, brain and kidneys experience.

It is used to identify the risk of end-organ damage.

This is the change in amplitude of pressure waves as they transit from the heart to peripheral arteries. The increase in amplitude speaks to arterial stiffness, wave reflection as well as blood flow efficiency.

AP is the additional "push" your heart needs to pump blood because of stiff arteries, like how a pump has to work harder to move water through narrow pipes. Elevated AP is associated with cardiovascular risk.

Alx is related to Augmentation Pressure. It describes how much of your heart's total effort is due to the additional "push" required to pump blood through stiff arteries.

This assesses the supply of blood flow to the inner heart muscle in relation to demand. It offers insight into how well a persons heart can handle the stress of exercise.

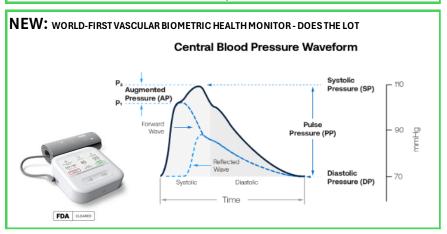
This is the estimated age based on central pressure and arterial stiffness parameters of healthy individuals without cardiovascular and metabolic diseases.

Medical grade - ie beat to beat - on par with ECG-based methods.

The only blood pressure devices that allow physician reimbursement for full arterial health measurements. Eligible for CPT Code 93050 for enhanced revenue in clinical practice.

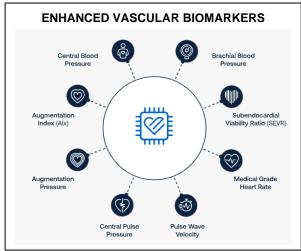
OLD: MEASURES SYSTOLIC/DIASTOLIC ONLY





CARDIEX FDA CLEARED SPHYGMOCOR TECHNOLOGY REPLACES TRADITIONAL BLOOD PRESSURE TECHNOLOGY AS THE FIRST LINE SCREENING AND MONITORING OF ARTERIAL **HEALTH STATUS**

- Evaluates those at greater risk of cardiovascular, metabolic, renal and neurological diseases
- Provides early detection of disease onset stiffening of arteries is an early indicator
- Regular assessments track changes over time to signal improvement or worsening of condition
- Progressive treatment evaluation assesses the efficacy of pharmacological and lifestyle interventions



Cardiex's SphygmoCor technology accurately analyses central blood pressures and arterial stiffness - PROVIDING NEW CLINICALLY MEANINGFUL INFORMATION that standard blood pressure technology SIMPLY CANNOT CAPTURE

- "Central haemodynamic variables are independent predictors of cardiovascular disease and all-cause mortality" (Journal of Human Hypertension, 2019)
- "Central aortic pressure is a better independent predictor of cardiovascular and kidney outcomes" (CAFE study, 2006)
- "Arterial stiffness parameters proved to be predictors of increased vascular age besides the classic risk factors" (Cardiology Journal, 2013)
- "Arterial stiffness can be increased even in pre-diabetic populations with impaired glucose tolerance, and in those with the metabolic syndrome, well before the onset of overt diabetes mellitus" (Atherosclerosis, 2015)
- "Arterial stiffness is sensitive predictor of cognitive impairment, and arterial stiffness severity has the potential to serve as an indicator used to facilitate treatments designed to prevent or delay the onset and progression of dementia in elderly individuals" (Journal of the Neurological Sciences, 2017)
- "Arterial stiffness measurements may also be useful in predicting preeclampsia and may play a role in the increased risk of future cardiovascular complications seen in women with a history of preeclampsia" (Journal of Hypertension, 2012)

UNIQUE NEXT GENERATION TECHNOLOGY

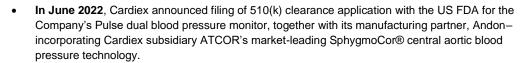
- Gold standard FDA-cleared devices for the measurement of central blood pressure and cardiovascular risk parameters
- Clinical trials market and consumer market applications, Device agnostic (based on current development schedule).
- Proprietary IP & technology in cardiac load, athletic capacity, arterial stiffness, arterial age and other consumer health diagnostic parameters published in over 2,400+ peer reviewed studies
- 26 issued and non-expired US and international patents
- 31 US and international trademark registrations
- 22 pending US and international trademark applications

WITH FDA CLEARED PRODUCTS AND APPS, CARDIEX IS PIVOTING ITS GOLD STANDARD PREDICATE CENTRAL BLOOD PRESSURE MEASUREMENT TECHNOLOGY INTO THE CONSUMER SEGMENT AND INTO DIGITAL HEALTH SOLUTIONS THAT CREATE RECURRING REVENUE **STREAMS**

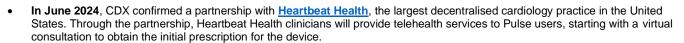
In 2018, Cardiex began building up its consumer platform via acquisition and partnership. Simultaneously, Cardiex began development of a new consumer-oriented product suite, including a cuff based (PULSE) device and wearables. This sensibly leveraged the SpygmoCor technology behind Cardiex's ATCOR central blood pressure device which is FDA cleared and is the gold standard in clinical and research markets. Key achievements along the way include:

- In September 2020, Cardiex announced a commercial partnership agreement with Mobvoi, a Google backed company known for its wearable technology, to develop and commercialise a heart health monitoring smartwatch.
- In May 2021, Cardiex announced the CONNEQT consumer brand featuring the next generation of home health devices complemented with a suite of digital products. This included the CONNEQT Pulse cuff-based home and point of care central blood pressure monitor and the CONNEQT Band health technology.
- In March 2022, Mobvoi, a leading global consumer electronics and enterprise Al developer, launched a new consumer smartwatch, the Mobvoi TicWatch GTH Pro, with advanced heart health features powered by Cardiex's FDA cleared SphygmoCor technology. The TicWatch (pictured) represented the first commercial implementation of Cardiex SphygmoCor technology in a wearable device.

This watch featured dual photoplethysmogram (PPG) sensors to enable assessment of Cardiex's cardiovascular biomarkers. The PPG sensor technology optically detects blood volume changes in the microvascular bed of tissue. The Mobvoi paired with an innovative app on your phone which recorded blood pressure history and other proprietary cardiovascular biomarkers.



- In April 2023, the United States Food and Drug Administration (FDA) granted 510(k) clearance for the CONNEQT Pulse, a dual blood pressure monitor that provides both brachial and central blood pressure measurements along with other clinically meaningful arterial health biomarkers.
- In April 2024, Cardiex successfully completed its primary study validating the use of its predicate SphygmoCor® technology in wearables by way of a PPG sensor. Importantly, this laid the groundwork for the submission of the CONNEQT Band technology for FDA clearance.
- In June 2024, Cardiex re-launched the ConnegtHealth.com website, which included a waitlist for those looking to get first access to the Pulse. Cardiex also re-launched the Cardiex.com website in order to showcase the company's expertise in kye market segments and cardiovascular technology.
- In June 2024, the first physician partnership with PhysioAge is a subscription based medical diagnostic portal use by concierge and cash-pay physicians for managing their patients' health biomarkers. Its CardioAge feature is powered by Cardiex's SphygmoCor arterial and cardiovascular health algorithms.



In March 2025, CDX launched its Cardiology Report, a comprehensive, individualised cardiovascular health assessment giving unique cardiovascular health insights over time. The report is available through the CONNEQT app and lays the foundations of future digital revenue streams and the evolution of Cardiex technology into the Software as a Medical Device (SaMD) space.

MOBVOI TICWATCH



CONNEQT PULSE



CONNEQT BAND



OWNING THE ARTERIAL HEALTH CATEGORY. START BY WORKING THROUGH THE WAITLIST + REFINING ONGOING MARKETING EFFORTS

Prior to first sales, Cardiex ramped up production of the Pulse device while simultaneously taking and nurturing pre-orders.

The original digital sales funnel included Doctor groups, influencers, consumers, and healthcare groups. Sensibly, this dovetailed into the 2025 **CES Technology Conference** in Las Vegas, held between Jan 7-10, 2025. The conference boasted 141k+ visitors, with over 4,500 exhibitors and 6,000+ global media content and industry analysts.



Sales commenced mid-January 2025 with approximately 3,000 units sold in the first 2.5 months/March quarter. This comprised of initial waitlist backlog sales PLUS new sales generated from marketing activities. Waitlist conversions were in line with expectations and continue to yield as CDX adds new features to the product such as the Cardiology Reports (ASX 25 March) and Apple Health integration (ASX 1 April).

The original waitlist with its discounted offer is now closed and Cardiex has moved to a direct to consumer (DTC) order/fulfill model.

The strategy is to amplify digital presence and sales through a combination of online ads, programmatic advertising, influencer, and search engine marketing. CDX is investing heavily in growth campaigns across Facebook, Instagram, YouTube and TikTok as well as though the CONNEQT subscriber email ecosystem.

To stimulate awareness and interest, Cardiex is actively targeting industry conferences such as NextMed Health, and through industry associations such as American College of Sports Medicine, North American Artery, Drug Information Association and the American Heart Association. Other channels targeted include Trade Shows; Practitioner Groups, Influencer & Affiliate marketing; Media and PR outreach and Key Opinion Leaders.

April 2025 Sales closed with an exit annual revenue run rate of \$1.7m. Efforts are concentrated on identifying and scaling the most cost-effective platforms to minimise customer acquisition costs (CAC). The current blended CAC is \$60 per unit and as the business scales up, the CAC can be expected to come down rapidly and materially.

Given current sales momentum, the June exit sales rate is expected to by \$4-5m pa. This equates to approximately 900 units per month or 30 units per day.

CDX indicates that the group would achieve EBIT breakeven run rate with PULSE sales at 1,000 units per month. This includes successful cost initiatives which have resulted in a reduction in the company's cost base by 30%.

OWNING THE ARTERIAL HEALTH CATEGORY – DEPLOYING A UNIQUE DISRUPTIVE FDA CLEARED TECHNOLOGY INTO A DATA CENTRIC MARKETPLACE

Through the Cardiology Reports, customers can for the first time access vital, clinically validated biomarkers and actionable insights into their cardiovascular health - in home and without the expense and time out to visit a cardiologist. Traditional blood pressure measures do not tell the whole story. Cardiex has successfully pivoted it's unique world leading FDA cleared predicate technology - into the consumer segment at a time when consumers are shifting to preventative medicine and the demand for longevity-focused solutions is increasing significantly.

For years, Apple has been empowering people with their health information, with over one third of smartphone users now tracking their health. The free Apple Health app allows users to access and store their health information in one spot, with many third party apps including Cardiex CONNEQT app compatible with it.

Data lakes are an essential part of the evolution of the digital health marketplace. Cardiex's unique data suite addresses one of the world's major health areas - cardiovascular health. For these reasons, Cardiex is positioned to own the space in the same way other category technologies have successfully shown:

Arterial Health - The World's Largest **Category Ownership Opportunity**

Metabolic Health	I, LEVELS	(US \$450m)*
Blood Biomarkers	Function	(US \$1.2B)*
Performance Fitness	//I-IOOP	(US \$3.8B)*
Sleep	ŌURA	(US \$5.2B)*
Pulse Oximetry	€ Masimo	(US \$9B)*
Arterial Health	♦ CARDIEX	(US \$???)

These brands show the power of leadership and the extent to which the consumer marketplace is embracing preventative medicine and longevity focused health solutions.

How We Compare to Patient-Centric Cardiovascular Screenings

Test	Price	Heart Risk Assessed	# of Reports	In-Home Test
Full-Body MRI Scan	Up to \$2,500	None	One-Time	No
Cleerly Heart Scan	Up to \$1,500	Detailed coronary artery plaque analysis	One-Time	No
Coronary Calcium Scan	Up to \$500	Measures calcium buildup in arteries	One-Time	No
DEXA Scan	Up to \$500	None	One-Time	No
CONNEQT. Arterial Health Assessment	\$350	Quantifies risk of heart attack & stroke	Two (2)	Yes
Carotid Artery Screening	Up to \$300	Detects blockages in carotid arteries	One-Time	No
Lipid Panel	Up to \$40	Measures cholesterol and triglycerides levels	One-Time	No

Importantly, Cardiex **CONNECT PULSE offers** arterial health assessment in-home and indefinitely depending on the frequency of reports required by the user. After initial purchase, additional reports can be acquired as required at a very competitive price.

CARDIEX LIMITED

PRODUCT PIPELINE AND CATALYSTS: PENDING FDA SUBMISSIONS AND CLEARANCES

Cardiex's future FDA pipeline highlights the ongoing development path and future catalysts:

Integration of the full suite of cardiovascular biomarkers into the Apple Health app.

Initially systolic and diastolic blood pressure information have been integrated into the Apple Health app to prove up the connection.

SphygmoCor Software as a Medical Device – the intention is to separate the patented IP associated with the SphygmoCor algorithms and learning from the physical device. This paves the way for the adoption and commercialisation of the technology into other (non-Cardiex) devices.

The technology is already approved when included with existing device suite, i.e. EXCEL, Oscar2 and PULSE.

TGA approval of the PULSE for sale in Australia. - Formal application lodged per ASX 6 May 2025

The TGA registration process is expected to take 3-6 months

CONNEQT Band technology - currently in pre submission phase. Submission to the US FDA for 510(k) clearance is anticipated later this year - clearance +6 to +9 months.

The acceleration of PULSE sales is the current priority

Pulse OTC – meaning the best personal blood pressure monitor in the market can be purchased directly by an individual "Over The Counter" at a store, without a prescription, although the company does not consider this a priority in terms of driving sales growth given its existing sales efforts and strategy.

This will open up a new and important retail sales channel

Separate clearance sought to use the Pulse device for maternal health applications such as preeclampsia. Other specific use cases tbc will be targeted to expand the potential medical industry uptake.

This will provide access to pregnant women who require separate approval

SOFTWARE AS A MEDICAL DEVICE (SaMD) – BETTER HEALTH OUTCOMES FROM BETTER DATA

Software as a Medical device (SaMD) is "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." (International Medical Device Regulators Forum)

The US FDA notes that use of Software as a Medical Device is continuing to increase. It can be used across a broad range of technology platforms, including medical device platforms, commercial "off-the-shelf" platforms, and virtual networks, to name a few. Such software was previously referred to by industry, international regulators, and health care providers as "standalone software," "medical device software," and/or "health software," and can sometimes be confused with other types of software.

Clinical Decision Support (CDS) software falls under the aegis of SaMD. CDS are important tools in modern health care. While some CDS software has been excluded from the definition of a medical device by the 21st Century Cures Act (Cures Act), many software functions continue to meet the definition of a medical device and are the focus of the Food and Drug Administration's (FDA) regulatory oversight.

CDS will increasingly draw on the potential of Artificial Intelligence and Machine Learning. The FDA describe **Artificial Intelligence** as a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. Artificial intelligence systems use machine- and human-based inputs to perceive real and virtual environments; abstract such perceptions into models through analysis in an automated manner; and use model inference to formulate options for information or action.

The FDA also describes **Machine Learning** as a set of techniques that can be used to train Al algorithms to improve performance at a task based on data. Some real-world examples of artificial intelligence and machine learning technologies include:

- An imaging system that uses algorithms to give diagnostic information for skin cancer in patients.
- A smart sensor device that estimates the probability of a heart attack.

US FEDERAL DRUG ADMINISTRATION:

"AI/ML technologies have the potential to transform health care by deriving new and important insights from the vast amount of data generated during the delivery of health care every day. Medical device manufacturers are using these technologies to innovate their products to better assist health care providers and improve patient care. One of the greatest benefits of AI/ML in software resides in its ability to learn from real-world use and experience, and its capability to improve its performance."

Cardiex's digital strategy is to extend its unique proprietary vascular biometrics, with deeper insights and better health outcomes, into patient data pools – what it calls **Arterial Intelligence**.

In March 2025, Cardiex launched its new Cardiology Report feature in the CONNEQT app. The report advocates and enables proactive heart health management by tracking key cardiovascular indicators, *identifying potential risks early* and making informed lifestyle or medical decisions.

In April 2025, Cardiex announced that customers of its CONNEQT Health subsidiary will be able to access key arterial health biomarkers directly through the Apple Health app on the iPhone. Following early client feedback, the integration of all Cardiex proprietary cardiovascular biomarkers into the Apple Health App is a key priority as users seek to aggregate all their health data into one data lake.

The Apple Health informatics mobile app was first announced in 2014. It has evolved from a basic health and fitness tracker to a comprehensive platform for managing and understanding your health data, including features like trend analysis, alerts, and integrations with other apps and devices. By definition, a health app is more focused on managing overall health and medical information, while a fitness app is focused on tracking physical activity and improving fitness.

Apple Health's strategy is to create a ubiquitous data rich platform that services all user profiles, whether they lean to the fitness side of the spectrum or the health side of the spectrum. With healthcare providers becoming increasingly tech enabled, this creates a significant opportunity in the years to come. Apple are betting that if the data is on their platform, then they are in the box seat to monetise it. It works nicely because simultaneously, users become more bonded to their iPhone.

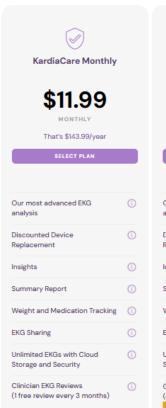
Samd Monetisation Strategies – Its all about the Data

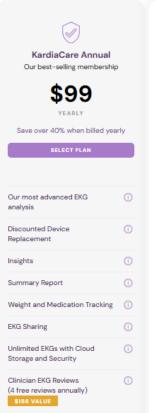
The explosion of interest in personal health management, awareness, devices, apps and data has spawned a range of monetisation strategies including single payments for an upfront device to regular programmed service payments, depending on their health circumstances. We observe that for Cardiex, initial consumer revenues using a device-only model maximise near term cashflow and potentially work well in the early high growth stages.

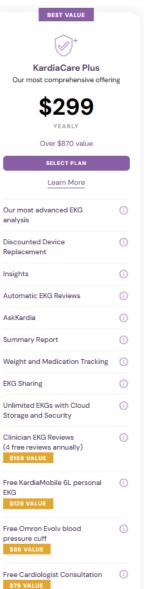
As market adoption increases, pricing models evolve to include recurring revenue and membership fees options combined with service revenues such as users purchasing a bundle of reports, discounted replacement devices or bundled offerings. Being hosted in the cloud allows providers to push through software updates as algorithms are improved and refined, and additional services added.

A **Device + Usage** model is envisaged for the Cardiex Pulse in the consumer segment. This addresses the need for ongoing health reports and disease risk information charged on a usage basis (e.g. per cardiologist report). This results in better quality long-term revenue streams and a far better health outcome for users. "Packages" of pay per use health reports will be offered depending on user health needs and demand. Payment strategies could also include membership plans such as in the example of AliveCor's KardiaCare (100,000+ subscribers, below).

KardiaCare offer a range of bundled plans based on their medical grade 6-lead ECG technology. Periodic clinical reviews and consultations







are included in the packages, simulating the vastly more expensive and time-consuming alternative of physically going to a specialist.

Like the CONNEQT Pulse, Kardia is integrated with Apple Health. The ECG data can be uploaded into the Apple Health platform, noting the simple Apple single lead ECG data cannot be downloaded into the KardiaCare app.

Generally, we believe the lower cost to deliver via SaMD will result in improved access to specialist medical services and will drive positive public health outcomes.

Long term, Cardiex technology will be device agnostic and can be licensed out to external device makers. At its heart, Cardiex SphygmoCor technology is essentially algorithms which are supplied with data from multiple sensor formats.

Recognising this, and the potential for other device manufacturers to use the technology, Cardiex intends seeking FDA clearance for the technology standalone as Software as a Medical Device (i.e. SaMD).

This could see companies like Apple (for the Apple Watch), Fitbit, Oura etc – whose customers will be able to access medical grade blood pressure data for the first time through their respective devices and apps, using Cardiex's FDA cleared SphygmoCor technology.

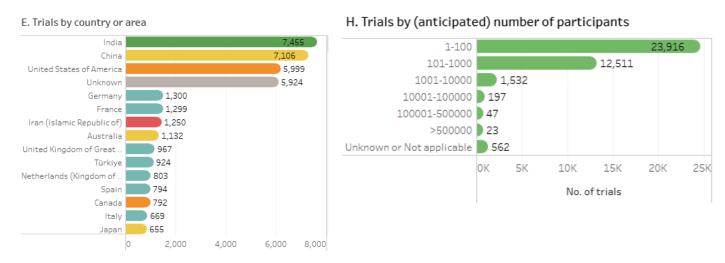
This could potentially include revenue share of subscription and usage, or per-report based fees – but importantly leverages whole new customer ecosystems.

THE CLINICAL TRIAL MARKET HAS EASED BUT STILL OFFERS OPPORTUNITY

According to the WHO, there have been over 900,000 clinical trial registrations since 1999. These trials can last for months or years and target a vast range of conditions. Depending on the phase and nature of the trial, trials can involve over 500,000 participants, however trial size is more often a lot less than this. Of the 900k+ cumulative total trials, over 76k related to cardiovascular diseases including hypertension, over 130k trials related to all forms of cancer, and over 108k trials related all forms of neuropsychiatric conditions.

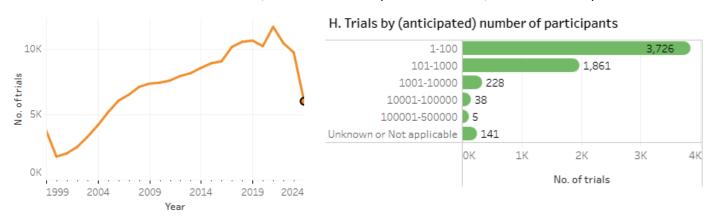
In 2024 there were over 38k new trial registrations globally, compared with 73k recorded in 2023. These trials are profiled by country and size as follows:

GLOBAL 2024 CLINICAL TRIAL LISTINGS BY COUNTRY AND SIZE



The 5,999 new clinical trial registrations in the USA in 2024 compared with 9,720 in 2023. We estimate that this would equate to anywhere between 5-7m individual trialists for these newly registered trials, not allowing for trialists still participating in ongoing trials registered in previous years.

USA CLINICAL TRIAL LISTINGS HISTORICALLY, AND BY TRIAL SIZE (2024 YEAR WITH 5,999 TOTAL TRIALS)



Cardiex's current addressable new trial market consists of approximately 4,000 – 6,000 new trial sponsors, with each trial averaging 750-1,000 individual trialists. This means the annual market opportunity for Cardiex is at least US\$1.8bn assuming the average target revenue of a trialist is US\$50 per month payable for Cardiex's unique proprietary blood pressure parameters, or US\$600 pa.

CARDIEX'S CLINICAL TRIAL GROWTH STRATEGY LEVERAGES THE CAPABILITIES OF NEW PRODUCTS AND CARDIOVASCULAR BIOMARKERS

The clinical trial market is intermediated by Clinical Research Organisations (CROs) who are contracted by pharma, biotech, medtech and research organisations to manage and conduct clinical trials. Cardiex's focus is on pharma and CROs with a dedicated resource now addressing this opportunity. The recent introduction of the PULSE device complements Cardiex's industry gold standard XCEL device and the Oscar2 Ambulatory Blood Pressure Monitor. This invigorated market offering provides Cardiex with a clear competitive advantage delivering critical blood pressure parameters to CROs.

Cardiex's enhanced vascular biomarkers help clinicians more precisely define clinical phenotypes based on arterial stiffness and improve the results of clinical trials. This has been observed in the study of resistant hypertension, for example. Resistant hypertension is common in the chronic kidney disease population and conveys increased risk for adverse cardiovascular outcomes and the development of kidney failure (American Journal of Kidney Diseases).



CLINICAL TRIAL BUSINESS LEVERS OF GROWTH:

- 1. Cardiex's vascular biomarkers can be used to identify specific profiles that correlate with vascular treatment outcomes. This enhances trial stratification and ensures that only likely beneficiaries are included. Improved trial outcomes help reduce costs associated with ineffective treatments. This provides Cardiex unique comparative advantage.
- 2. Expanding from the academic/university and research sector, with its relatively less ability to pay, into the bigger pharma sector and other related service providers such as clinical research organisations.
- 3. The CONNEQT PULSE enables decentralised data collection without the need for individual trialists to visit clinical sites. This approach enhances participant engagement, reduces logistical burdens, and expands trial participant reach across broader areas.

DID YOU KNOW THAT TODAY'S LIMITED HUMAN BLOOD PRESSURE MEASUREMENT TECHNOLOGY DATES BACK TO 1896?

The first recorded human blood pressure measurement occurred in the mid 1800's using arterial cannulation, where a catheter was inserted into an artery and connected to a U-shaped tube attached to a floating measurement arm. This was unsatisfactory and highly risky - the race was on to find a better way without going into the artery. The first non-invasive human blood pressure measurement technology emerged in the 1880's (right). These original "sphygmomanometers" consisted of a water or mercury filled rubber ball connected to a pressure gauge or manometer. The ball is pressed against the radial artery and inflated until the pulse was suppressed and the blood pressure read from the manometer. This *only* measured systolic blood pressure at a time when the medical fraternity questioned the medical usefulness of blood pressure.





In 1896, the device was improved by Scipione Riva-Rocci who placed an inflatable cuff over the upper arm to constrict the brachial artery. The cuff was connected to a glass manometer filled with mercury similar to the picture (left). In operation, as the cuff is inflated, it obliterates the pulse at which point the manometer records the corresponding blood pressure.

It is important to note that this early sphygmomanometer was also only able to determine systolic blood pressure: Systolic pressure is the maximum arterial pressure during contraction of the left ventricle of the heart – the time at which ventricular contraction occurs is called systole.

In 1905, Russian surgeon Nikolai Korotkoff made a breakthrough discovery, observing that during the inflation and deflation of the cuff, blood made certain sounds as it went through the artery. Crucially,

Korotkoff used a stethoscope while inflating and deflating the cuff and he figured that the diastolic pressure corresponded to the pressure associated with the fourth of the so-called Korotkoff sounds. **Diastolic pressure is important because it measures the brachial blood pressure when the heart muscle rests between beats.**

The equipment has not significantly changed since Korotkoff. One early modification was the addition of a stethoscope as shown in the picture on the right. The stethoscope allowed the health-care worker to assess the sounds in the artery which correspond to the time to measure the subject's systolic and diastolic pressure. This method is still used in many clinical practices today.

Later, the mercury sphygmomanometer when used in conjunction with a stethoscope, went on to become the gold standard in blood pressure monitoring.

In 1974, Panasonic released a digital blood pressure monitor which instead of the Korotkoff sounds, uses associated oscillations and algorithms as a proxy for determining when to measure systolic and diastolic pressure. While many still regard the mercury sphygmomanometer as the gold standard in blood pressure measurement, environmental concerns about the use of mercury in the mercury sphygmomanometers has seen them replaced in hospitals and banned by many governments.





The now ubiquitous modern digital blood pressure monitor, such as the one pictured left, still only informs as to systolic and diastolic blood pressure parameters. Algorithms overlay the technology which was first conceived in 1896 by Riva-Rocci for systolic blood pressure and improved in 1905 by Korotkoff to inform diastolic blood pressure.

The advantages of today's digital monitors are they are quick, easy to use, portable, consistent and reliable, *HOWEVER* they still only inform on two parameters, systolic and diastolic blood pressure something first achieved in 1905.

As in 1896, today's cuff blood pressure monitors only inform blood pressure in the brachial artery, when in fact blood pressure varies materially throughout the circulatory system and around critical organs such as the heart, brain, kidneys etc.

DR MICHAEL O'ROURKE, CARDIEX'S FOUNDER, WAS ALSO A WORLD PIONEER IN NON-INVASIVE CENTRAL BLOOD PRESSURE MONITORING.

Cardiex's unique FDA-cleared and patented SphygmoCor technology has been consistently acknowledged as the gold standard, and an FDA benchmark, in measuring arterial stiffness and central blood pressure parameters. It has also been featured in over 2400 peer-reviewed studies with over 4,400 SphygmoCor systems used in clinical-grade trials worldwide by medical and research institutions and global pharmaceutical companies.

Founded in 1994 by the late <u>Dr Michael O'Rourke</u> AM, Emeritus Professor at the Faculty of Medicine, University of New South Wales, Cardiex was formerly known as AtCor Medical Holdings before changing its name to Cardiex in June 2018 and splitting into two divisions, ATCOR and CONNEQT.

Dr Michael O'Rourke AM was a true pioneer in cardiovascular medicine. After graduating from Sydney University with a MB BS in 1960, he worked as a registrar at St Vincent's Hospital, Sydney, before undertaking postgraduate research and achieving a Doctor of Medicine degree in 1968, also at Sydney University.

At this point in his career, he was inspired by work into the bio-physical relationship of blood pressure and flow in arteries and how this presented novel ways of interpreting the information in the arterial pulse in terms of waves travelling throughout the arterial tree and being reflected from the periphery.

Dr O'Rourke's ideas on the arterial pulse were solidly based on his early years in research and did not waver throughout his career. He went on to create a legacy that spans the globe. His fundamental work on pulsatile hemodynamics has been the basis of many academic and scientific careers in North and South America, Canada, UK, the European Continent, Greece, South Africa, China, Japan, Korea and other parts of Asia.

Professor Michael O'Rourke AM MD DSC FRACP

28 July 1937 – 5 February 2024

Dr O'Rourke's work led to the inclusion of the pulse wave to the conventional measurement of blood pressure. He was subsequently granted a patent for the technology and founded AtCor Medical Holdings in 1994 to produce devices based on pulse wave analysis. The company's SphygmoCor system for measuring arterial stiffness and central aortic blood pressure non-invasively has become the global industry standard.

Today, Cardiex's ATCOR division is a world-leading developer of medical devices used to measure arterial stiffness and central blood pressure waveforms. ATCOR's focus is servicing specialist healthcare providers, clinical research organisations, on-site clinical trials, research programs and hospital networks with a variety of vascular biomarker solutions.

Pivoting its world leading blood pressure measurement technology to the consumer segment, the CONNEQT division now targets consumer health with its connected, FDA cleared PULSE device and is expanding its product suite into the rapidly growing consumer wearables space.



APPENDIX 4C – QUARTERLY CASHFLOW REPORT

(A\$'000)	3 Mths Mar-23	3 Mths Jun-23	3 Mths Sep-23	3 Mths Dec-23	3 Mths Mar-24	3 Mths Jun-24	3 Mths Sep-24	3 Mths Dec-24	3 Mths Mar-25
Cashflows from operating activities			•				·		
Receipts from customers	799	1,625	1,085	7,439	690	886	496	683	1,172
Payments for:									
research & development	(778)	(762)	(385)	(354)	(576)	(386)	(530)	(706)	(426)
product mfg & optg costs	(749)	(128)	(381)	(493)	(1,544)	(459)	(150)	(346)	(410)
advertising & marketing	(307)	(392)	(68)	(144)	(223)	(162)	(121)	(300)	(254)
leased assets	(63)	(77)	(56)	(59)	(58)	(58)	(58)	(58)	(53)
staff costs	(2,634)	(2,534)	(1,887)	(2,282)	(3,543)	(2,627)	(1,950)	(2,261)	(2,681)
admin & corporate costs	(1,136)	(460)	(320)	(1,214)	(857)	(695)	(832)	(748)	(862)
Dividends received	-	-	-	-	-	-	-	-	-
Interest received	_	_	_	13	1	1	_	_	1
Interest & other finance costs	_	_	_	-	-	-	_	_	-
Income taxes paid	_	_	_	_	_	_	_	_	_
Govt grants & incentives	_	724	_	_	_	692	_	_	1,455
Other (industry prize)	_	-	_	532	_	-	_	793	-,
Net Cash From Operating Activities	(4,868)	(2,004)	(2,012)	3,438	(6,110)	(2,808)	(3,145)	(2,943)	(2,058)
Cashflow from investing activities	(, ,	(, ,	(, ,	,	(, ,	(, ,	, ,	, ,	, ,
Payments to acquire for									
property plant & equipment	(16)	(1)	_	(8)	(111)	_	_	_	(22)
intellectual property	-	-	_	-	-	_	_	_	-
Proceeds from disposal of	_	_	_	_	_	_	_	_	_
Cashflow from loans	_	_	_	_	_	_	_	_	_
Dividends received	_	_	_	_	_	_	_	_	_
Other	_	_	_	_	_	_	_	_	_
Net cash from investing activities	(16)	(1)		(8)	(111)				(22)
Cashflow from financing activities	,	()		()	,				, ,
Proceeds from issue of equity	3,990	_	_	_	7,133	_	_	2,785	140
Proceeds from issue of convertible notes	-	2,175	1,470	_	_	_	_	-	-
Proceeds from exercise of options	_	-,	_,	_	_	_	_	_	_
Transaction costs related to equity & CNs	(268)	_	(14)	(8)	(635)	(16)	_	(217)	(18)
Transaction costs related to US capital activities	-	_	-	-	(271)	(30)	_	-	-
Proceeds from borrowings	_	_	_	_	-	-	1,120	_	_
Repayment of borrowings	_	(725)	_	_	(209)	(740)	(145)	_	(1,456)
Transaction costs related to lending	_	-	_	_	(37)	-	(15)	_	(2, .00)
Dividends paid	_	_	_	_	-	_	-	_	_
Other - inc proceeds from C2 Ventures	_	_	_	717	_	_	2,250	3,229	250
Net cash from financing activities	3,722	1,450	1,456	709	5,981	(786)	3,210	5,797	(1,084)
Net increase/(decrease) in cash for the period	0,7	2, .00	2, .00	, 00	0,001	(700)	0,220	5,7.57	(2,00.)
Cash at beginning of period	2,482	1,282	716	160	4,296	4,073	481	546	3,400
Net cash from operating activites	(4,868)	(2,004)	(2,012)	3,438	(6,110)	(2,808)	(3,145)	(2,943)	(2,058)
Net cash from investing activities	(16)	(1)	(_, _,)	(8)	(111)	-,500	-	-	(22)
Net cash from financing activities	3,722	1,450	1,456	709	5,981	(786)	3,210	5,797	(1,084)
Effective movement in exchange rates	(38)	(11)	-,	(3)	17	(700)	(2)	-	(1,004)
Cash at end of period	1,282	716	160	4,296	4,073	481	544	3,400	236
Source: Peloton Capital	1,202	, 10	100	- ,200	- ,070	-101	J-1-1	0,400	200

[•] Post 31 March 2025, the company has entered into a variation agreement with Mitchell Asset Management increasing the facility limit and drawing down an additional \$446,000.

[•] Operational restructuring has resulted in a reduction in the annualised expense base from \$17m to \$10m. Full impact expected Q1FY26.

[•] Sales of PULSE gaining momentum with annualised June exit sales rate of \$4-5m pa expected.

^{3,000} PULSE units sold to date. Cardiex note they expect to reach EBIT breakeven with sales @12,000 units pa.

CARDIEX LIMITED

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