MEDICAL DEVICES AND DIAGNOSTICS
SETTING GLOBAL STANDARDS FOR INNOVATION AND QUALITY
Australia has a long and distinguished track record of health and medical research excellence. Today this continues with breakthrough discoveries, advancement of technologies into clinical trials and improvements in clinical practice. Australian medical technologies are making a global impact; solutions such as the cochlear implant (bionic ear) and continuous positive airway pressure (CPAP) devices for sleep apnoea are just two Australian inventions that have transformed the lives of people around the world.

The medical device and diagnostic industry in Australia has developed at a rapid rate, with strong growth in digital health technologies and devices using advanced materials, robotics, imaging, IT, design and adaptive diagnostic technology platforms. The industry is also evolving with the convergence of technology and skills from aligned innovation sectors, such as ICT, medical research and advanced materials.

The health and medical sector in Australia is supported by a robust regulatory and funding system that includes a competitive R&D tax incentive scheme and a world-class healthcare system that creates a highly favourable environment for innovation, investment and collaboration.

This Medical Devices and Diagnostics Industry Capability Report provides an overview of Australian capability in medical technologies and includes examples of some of the many companies with specialist expertise. These companies design, manufacture and test tools and instruments, apparatus and articles used for diagnosis, prevention, monitoring and treatment of health issues. Many of these devices are subject to approval by a therapeutic regulator, in Australia this is the Therapeutic Goods Administration (TGA).

Talk to your local Austrade representative for tailored advice and information on connecting and partnering with the Australian medical devices and diagnostics industry.
Australia’s medical devices industry comprises over 500 companies generating total revenue of A$11.8 billion, exporting over $2.1 billion each year and in 2013-14, employing over 19,000 people.

The Australian medical device, biotechnology and pharmaceutical industries are distinct but closely related, featuring strong inter-dependencies and a flow of ideas between medical research organisations, traditional and advanced manufacturing and the local healthcare system.

The Australian industry is characterised by a large group of small to medium sized enterprises (estimated at 54 per cent) and a smaller but sizable proportion of global multinational companies or their subsidiaries (about 35 per cent of the sector). These companies are delivering improved patient outcomes and efficiencies in healthcare systems around the world, as nearly all of the medical devices and diagnostics manufactured are exported.

In 2013, the global advanced medical technologies market (medical devices, medical imaging and patient monitoring) was worth US$342.8 billion, the Asia Pacific market (including Australia) was worth US$63.5 billion (18.5 per cent of the global market) and Australia’s share was US$6.81 billion (2 per cent).

Australia has 35 medical device and diagnostics companies listed on the Australian Securities Exchange (ASX). Total market capitalisation of listed medical devices companies had reached A$13 billion by August 2014, and the sector is delivering one of the strongest returns for investors on the ASX.

The majority of Australian companies (54 per cent) have grown from start-ups. Over one-third (35 per cent) of Australian companies were established as a subsidiary of a multinational company.

The Australian medical devices and diagnostics industry has pioneered niche products such as 3D customised titanium implants, non-invasive blood glucose monitoring systems, continuous positive airway pressure (CPAP) devices for sleep apnoea, long-wearing night and day contact lenses, melanoma detection devices, transdermal insulin delivery devices, and diagnostic technologies for sleep disorders, neurophysiology and cardiology.

This industry is supported by an entrepreneurial and globally-competitive Precision Engineering Industry (PEI), which covers the research, design, development, manufacture and verification of high accuracy components, as well as high precision machines and systems.

The top 10 destinations for Australian medical devices and diagnostics exports were the United States of America; New Zealand; the United Kingdom; Germany; the Netherlands; Japan; China; Singapore; Denmark; and the Republic of Korea.
INTRODUCTION

INDUSTRY OVERVIEW

1926
The world’s first electronic heart pacemaker

Late 1930s
In response to the polio epidemic, the humidicrib is developed

1961
Pioneering obstetrics with the first ultrasound scanner

1978
A bionic ear is first implanted, the Cochlear Ear

1981
Continuous Positive Airway Pressure (CPAP) machine was invented

1984
In response to child safety concerns in moving vehicles, the design of the baby capsule

1990
Development of low cost manufacturing of intraocular lenses

1993
WiFi technology supporting future growth of digital health technologies

1999
Extended wear soft contact lenses that can be worn continuously for 30 days

2005
Compact, lightweight, easy-to-use and battery-powered portable retinal camera for use in remote areas

2007
Shock absorbing liner for motorbike helmets

2010
Electrovestibulography or EVestG®, a diagnostic tool to detect mental and neurological illnesses

2013
Handheld bio-pen, a 3D printing device using living cells to repair damaged bones

2015
Personalised 3D printed titanium implants produced and implanted

2015
Development of the Nanopatch™, a needle-less vaccine

Figure 1. Snapshot of Australian ingenuity

MEDICAL DEVICES AND DIAGNOSTICS
Newly manufactured Cook Medical IVF Ovum Pick-Up Needles being prepared for sterilization. Image courtesy of Cook Medical.
Australia has a well established medical device industry, with an internationally recognised capability to innovate and develop world-class products. Key strengths include:

- one of the largest healthcare markets in the Asia-Pacific region, with a sophisticated clinical environment; high standards of care; first-class clinical trials infrastructure and skills; and widespread use of high-end medical devices and diagnostics
- a robust regulatory environment with one of the most effective intellectual property (IP) rights protection systems in the world
- a competitive R&D tax incentive scheme that rewards investment in Australian research and development
- fast development cycles, fostered by a strong culture of collaboration and partnerships between the academic, research and corporate sectors
- a burgeoning national culture of innovation and entrepreneurship with matching government policy and program settings, that is fostering a strong SME and startup sector
- internationally recognised expertise in the design, development and manufacturing of medical devices, with the help of a strong and diverse manufacturing skills base and world-class infrastructure
- a strong Australian IT sector including world-class expertise in UX technologies, game design, bioinformatics, hardware and software development
- a highly skilled workforce and a globally competitive business environment
- an ideal market for prototyping and testing new medical products
- strong ties with the fast-growing Asia-Pacific region, supported by Free Trade Agreements (FTAs).

Figure 2. The main categories of MedTech solutions supplied or manufactured in Australia 2014.
Figure 3. Australian Government Expenditure on Science and Research Priorities

- Health: $464.2m
- Food: $387.2m
- Environmental Change: $337.6m
- Energy: $192.8m
- Resources: $204.4m
- Advanced Manufacturing: $445.6m
- Cyber Security: $81.1m
- Transport: $111.9m
- Soil and Water: $440.0m

Approx. $2.65BPA
SOPHISTICATED PUBLIC AND PRIVATE HEALTHCARE SYSTEM

Australia has a world-class system of healthcare delivery and funding, which allows people to access publicly subsidised healthcare services, pharmaceuticals, medical technologies and devices through a range of service and funding arrangements. In the Asia-Pacific region, Australia has the highest per capita healthcare expenditure at A$6,430 and the second highest health to GDP ratio, behind Japan. Expenditure on health in Australia grew to A$147.4 billion in 2012–13.

Key features of the Australian healthcare funding system include:

• universal access to benefits for medical services under the Medicare system
• eligibility for public hospital services, which is free at the point of service
• private health insurance, which largely funds private hospital activity.

Around 11.2 million Australians (47.2 per cent) are covered by private health insurance, which is subsidised by the Australian Government through rebates.

AGILE, INNOVATION-DRIVEN ENTERPRISES

The Australian medical device industry consists mainly of SMEs, with a majority of companies (41 per cent) employing less than 20 people and just 10 per cent employing more than 100 people.

The Australian medical devices and diagnostics manufacturing sector is characterised by high investment in R&D, the protection of intellectual property and collaboration to innovate. The industry has an important role to play in meeting the challenges of an ageing population, a focus on wellness and preventative medicine, new and chronic diseases, escalating pressure on health systems and increasing lifestyle expectations. For SMEs in this industry the typical path of entry into Global Value Chains is via larger firms. SMEs tend to experience major challenges in funding the development of new devices, but despite this, they actively invest in new machinery, equipment and technology, new management and business practices, and innovative marketing activities.
Figure 4. Major Australian medical device export solutions (2013/14) by descending value
EXCELLENCE IN R&D

Australia benefits from sustained and substantial investment in research and development (R&D). The spend on R&D in 2012 for medical and surgical equipment manufacturing was A$237 million, an increase of approximately A$20 million from the previous year.

There is a wide range of funding and government assistance available for medical technology companies in Australia. New South Wales, Queensland, Victoria and South Australia have state government initiatives that provide assistance to the growing medical device sector in each state. Some local governments also offer support schemes to attract medical technology startups. A small number of venture capital (VC) firms in Australia invest in medical technology businesses and there is a robust angel investment community.

Australia is also a preferred location to conduct clinical research, including trials of medical devices. Clinical trials contribute around A$1 billion to the Australian economy every year. The number of clinical investigations conducted in Australia continues to grow steadily, particularly for the medical devices sector. In 2013 there were 570 medical technology device clinical trials registered in Australia - a growth of 19 per cent from 2012.

As global competition to attract clinical investigations increases, there is a clear need for Australia to remain competitive. Recognising this, the Australian Government established the Clinical Trials Action Group (CTAG) to identify and progress necessary reforms to secure Australia as a preferred destination for conducting clinical investigations.

Australia is well-known for cross-disciplinary problem solving, often bringing together computer scientists and mathematicians to assist clinicians and medical researchers develop solutions for clinical needs. This has successfully produced convergence of healthcare and IT applications in areas such as urinary incontinence, cardiac monitoring and bone scaffolding replacement. These strengths also attract multinationals like Cook Medical, GE Health, Medtronic, Fresenius Kabi and Baxter Healthcare to undertake R&D and/or manufacturing in Australia.
The Australian Medical Research Future Fund (MRFF) was established in 2015. The Fund, the largest of its kind in the world, will support research across the medical spectrum, including the discovery and development of new medical devices.

The Fund has received an initial contribution of $1 billion. As proposed, the MRFF will build to a $20 billion perpetual fund, providing annual disbursements of $1 billion by 2022–23.
COLLABORATING TO FIND SOLUTIONS

While many companies specialise in one sub-field of medical devices, research by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and Australian universities is wide-ranging. The benefits of collaboration are well documented, particularly in the medical research and technologies space. Collaboration intensity is a strong indicator of commercial and clinical impacts and Australia has identified industry/academic collaboration as an innovation driver, with new policies, programs and dialogue improving engagement rates and accelerating growth.

Australian R&D in medical devices and diagnostics features many thriving public-private partnerships. Some examples of collaborative efforts include:

Cooperative Research Centres (CRCs) is an Australian Government program designed to support industry-led collaborations between researchers, industry and the community. There are four CRCs currently working in advanced manufacturing and medical devices:

- HEARing Cooperative Research Centre (CRC) is a consortium of research, clinical and industry organisations, focused on improving prevention and management of hearing loss. HEARing CRC has developed HEARLab, a world-first technology that detects sound registering in an infant’s brain. It has also developed international standards for fitting hearing aids, and collaborated with Cochlear on important advances in implant technology.
- Cooperative Research Centre for Polymers (CRC-BT) seeks to improve health outcomes by developing products that require polymer technologies for therapies, and advancing their delivery in human and animal health applications.
- Wound Management Innovation Cooperative Research Centre (WMI CRC) is a leading organisation for integrated and collaborative research into innovative wound care tools, systems and technologies.
- Aikenhead Centre for Medical Discovery (ACMD) will establish the first biomedical engineering research and education centre in Australia. The purpose-built collaborative research centre leverages a multi-stakeholder collaboration between five universities, St Vincent’s Hospital in Melbourne and research institutes on and around the St Vincent’s campus.

Bionic Vision Australia (BVA) is a national consortium of industry and academic researchers working together to develop a bionic eye that can restore the sense of vision to people with vision impairment due to retinitis pigmentosa and age-related macular degeneration.

ARC Training Centre in Biodevices is Swinbunre University is transforming the approach to training doctoral students and introducing a new framework for industry collaboration with the university sector. A key component of the PhD program is compulsory training in entrepreneurship and innovation, with all students and post doctororal researchers spending at least one third of their time within industry partners.

Medical Devices Research Institute (MDRI) is a uniquely multi-disciplinary research network that aims to be the national research leader in the medical devices industry. The MDRI is a network of researchers, highly skilled in the development and application of a diverse range of medical technologies. This collaborative approach makes the MDRI ideal as a single site for product development and testing - taking projects from fundamental concepts right through to preliminary clinical trials.

The New South Wales Medical Devices Partnering Program (MDPP) facilitates collaborations between researchers, industry, end-users and government to develop prototypes, proof of concept and/or commercialisation planning for potential Australian medical device products. MDPP has a particular focus on finding solutions for clinicians, the ageing and the disabled.

The Medical Technologies and Pharmaceuticals Growth Centre is part of a $225 million Industry Growth Centers initiative. Established in 2015, the plan is to capitalise on the sectors competitive advantage and establish Australia as an Asia Pacific hub for medical technology and pharmaceutical companies.
The nanopatch by Vaxxas is a dissolvable silicon patch that delivers vaccine to immune cells in the skin, without the need for needles.
AN ACTIVE PATENT ENVIRONMENT

2706 medical device inventions originated in Australia between 2001 and 2012, placing Australia 13th in medical device patents globally.18

In Australia, medical technology patent applications made up 7.8 per cent of the total number of applications between 1999-2013 (comparable to pharmaceuticals 6.5 per cent and civil engineering 7.7 per cent).19 The number of Australian medical technology patent grants has shown a steady increase since 2009.

ResMed, Cochlear and Cook Medical are the top three patent applicants, and between 2001 and 2012 they contributed almost 20 per cent of the total inventions filed in the medical devices and diagnostics field. These applicants are corporations with a focus on research, production and the sale of products in very specialised areas of technology; respiratory (ResMed), hearing (Cochlear) and stents (Cook).

Surgical and electromedical/diagnostics, and implants and vision are also growing patent sub-fields.

Figure 5. Total number of Australian medical technology patent grants from 2000–201220
SUPPORTIVE COMMERCIAL AND REGULATORY ENVIRONMENT

Australia provides an ideal environment for the development and commercialisation of medical devices. The health and medical industry is also supported by an effective national regulator, the Therapeutic Goods Administration (TGA), which regulates medical devices and diagnostics according to a risk-based framework. The TGA’s operations closely align with the principles of the international best practice framework developed by the Global Harmonization Task Force (GHTF), a group including both regulators and industry representatives from Australia, Canada, the European Union, Japan and the USA. The GHTF has now been replaced by the International Medical Device Regulators Forum (IMDRF) which includes the five original members of the GHTF plus Brazil, with membership of China and Russia expected soon. The IMDRF builds on the foundations of the GHTF and continues to facilitate international trade.

An independent review of medicines and medical devices regulation in Australia was undertaken in 2014. The review highlighted areas that could be improved to enhance opportunities and operational efficiencies for local and international companies seeking approval and market entry in Australia. The key findings from the review included:

• areas of unnecessary regulation that could be removed or streamlined without compromising the safety or quality of therapeutic goods available in Australia
• opportunities to enhance the regulatory framework to enable Australia to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods.

Access to capital is a critical component of supporting an innovation ecosystem. The Research and Development (R&D) Tax Incentive is a cornerstone initiative that is driving considerable activity for local and international medical technology developers. The Incentive is a targeted, generous and easy to access entitlement program that helps businesses offset some of the costs of doing R&D in Australia. Introduced in 2011, the program aims to help more businesses innovate and invest in R&D activities. For SMEs the Incentive is fundamental to their ability to continue to invest and plan development, offering a 45 per cent cash refund for companies with turnover of less than $20 million and operating at a loss, or an offset for those in profit. For larger companies with a turnover over $20 million, the offset is 10 per cent. The program is open to eligible local and international business and there is no requirement for intellectual property from eligible R&D projects to be held in Australia.

The $1.1 billion Innovation Statement, released by the Federal Government in December 2015, highlights a major shift in accelerating Australia’s innovation investment and advancing a knowledge economy. Tax incentives for investors in startup technology companies, and a number of major funding opportunities in science and technology, will foster discovery, collaboration, commercialisation and skills.

The Federal Government also recognises crowdfunding as an attractive and important driver for startups in the innovation technology sector Australia. In support of a platform of initiatives to foster innovation and SMEs, a recent review of equity crowdfunding regulations has been undertaken aiming to improve access to capital.

More broadly, Australia is also committed to supporting business and investment through FTAs. These eliminate tariffs, address behind-the-border barriers that impede the flow of goods and services between parties, and enhance cooperation.
Admedus bio-scaffolds are proving integral to cardiac repair

Admedus is a specialist healthcare company that uses its proprietary ADAPT® tissue engineering process to produce implantable bio-scaffolds for various soft tissue repair applications. During the ADAPT tissue engineering process, scientists take a piece of animal pericardium (the heart covering membrane), treat it to remove all RNA, DNA and remnants of animal cells, and are left with a collagen scaffold that functions like human native tissue (the patient’s own tissue), without the issues related to previous tissue implants.

Admedus’ first commercial product using the ADAPT® engineering technology is CardioCel®. This product is a bio-scaffold used for cardiovascular repairs, and several thousand patients have been implanted with the tissue.

Admedus’ bio-manufacturing facility in Perth supplies CardioCel® to the US, Canada, Singapore, Hong Kong and Europe and is currently used in over 110 heart centres worldwide. CardioCel is also available under special access in several other countries including Australia.

“Admedus is aiming to build a profitable and global company. Our first product to market, CardioCel, is used in some of the world’s biggest heart centres and is preferred by surgeons as it avoids calcification, while supporting native cell infiltration, growth and differentiation. We are currently focused on the research and development of other tissue products and we are always looking for opportunities to partner and collaborate. Recently, we partnered with a researcher in Western Australia to investigate the delivery of stem cells using our ADAPT engineered tissue,” said Admedus Managing Director, Mr Lee Rodne.

Admedus is using the ADAPT tissue technology to generate additional regenerative tissue products targeting vascular tissue repairs, dura mater repair of the membrane surrounding the brain and spinal cord, whole vessel replacement for CABG and AV fistulas, stem cell or stem cell factor delivery, abdominal and hernia repair, and gynaecological repair.

admedus.com
Anatomics - manufacturing innovative biomaterials

Anatomics was one of the first companies in the world to use medical imaging and 3D printers to manufacture medical devices. Their product range now includes cranial, facial and orthopaedic implants, a product for tissue engineering used in post-mastectomies, surgical, electrosurgical and neuromonitoring tools, as well as the software and hardware surgeons require to design implants.

Anatomics remains a nimble innovator - a standout example is its development of PoreStar. Conventional surgical implants comprise non-porous, inflexible materials. Anatomics, in collaboration with the Commonwealth Scientific and Industrial Research Organisation (CSIRO), developed an implant made of polyethylene, a type of plastic. It is capable of being moulded by surgeons and integrating with the patient's own tissue, making it particularly useful for craniofacial surgery.

“Innovative products, manufacturing techniques and communication with global customers allow us to pioneer manufacturing here in Australia. Collaboration with local research organisations and universities like CSIRO and RMIT University will result in greater commercialisation opportunities for the sector” said Andrew Batty, CEO of Anatomics.

In collaboration with technology from CSIRO and RMIT, Anatomics has also developed titanium implants. In 2014 the company made world headlines after custom printing a titanium heel implant that allowed a cancer patient to keep his leg.

This was followed by the world’s first 3D printed titanium sternum and partial rib cage in September 2015. The implant was designed and manufactured in Melbourne, in collaboration with the CSIRO, and then successfully implanted into a cancer patient in Spain. The 54-year old man was suffering from a chest wall sarcoma.

“When envisaging the future of medicine people imagine amazing advances,” said Paul D’Urso, Founder of Anatomics. “Those will happen, but the fundamental issue is much more prosaic. It’s stopping healthcare costs spiraling out of control and creating affordable solutions for patients.”

Today Anatomics exports around the world via an independent reseller network.

anatomics.com

Read more at http://www.australiaunlimited.com/technology/the-neurosurgeon-s-bone-factory
AtCor Medical - at the heart of blood pressure

Doctors and medical researchers around the world are using Australian made instruments to detect and treat hypertension (high blood pressure) more accurately and effectively than ever before. From its headquarters in Sydney, AtCor Medical manufactures the SphygmoCor range of products, measuring patients' central blood pressure (the pressure at the heart, not the arm) and arterial stiffness.

Both of these measures have been shown to be better than normal cuff blood pressure in determining the future risk of heart attack and stroke. Using a cuff similar to standard blood pressure cuffs, SphygmoCor XCEL painlessly provides instant readings of the pressure that the heart, brain and kidneys actually experience.

SphygmoCor central blood pressure has become the global gold standard for pharmaceutical clinical trials and research, and is being rapidly embraced in clinical treatment of hypertension. AtCor’s products are now distributed throughout North America, Europe and the Asia Pacific region by a network of over 60 distributors.

Recent trials using SphygmoCor have shown that arterial stiffness is a major cause of hypertension, and can be detected with the SphygmoCor seven to ten years before the patient becomes hypertensive. Treating arterial stiffness early may actually prevent a patient from developing high blood pressure in the future. SphygmoCor is currently being used in more than 3000 hospitals worldwide and has been the subject of more than 1000 published clinical articles, highlighting the value of central blood pressure monitoring in identifying patients at risk of cardiovascular damage.

atcormedical.com
Atomo Diagnostics to deliver world’s first integrated rapid test for Ebola

Australian medical device company Atomo Diagnostics has developed the world's first integrated rapid blood test platform. The AtomoRapid™ platform enables any number of diseases to be individually tested, and Atomo Diagnostics has already commercialised an HIV and malaria test. The once-off, disposable AtomoRapid™ platform has an auto-retracting safety lancet removing the risk of needle stick injury and a calibrated, automated blood collection unit that removes risk of blood splatter.

AtomoRapid™ HIV commercially launched in January 2014 in South Africa, and has already captured a significant share of South Africa’s private sector market for rapid blood testing. The impressive customer base includes private health screening companies, large multi-nationals, South Africa's two largest private health insurers and its second largest pharmacy chain.

Atomo Diagnostics is currently working with BBI Solutions in the United Kingdom (UK) to launch the world’s first integrated rapid test for Ebola. Bringing together the AtomoRapid™ test platform with a high quality rapid test developed by the UK’s Department of Defence, this test is ideally suited for deployment in high risk regions, especially with a disease as contagious and deadly as Ebola.

Clinical performance of the product is very strong, and the test is currently being reviewed by the United States Food and Drug Administration for Emergency Use Authorisation so that it can quickly and effectively be deployed into the field.

Atomo Diagnostics is headquartered in Sydney, with corporate offices in South Africa and the UK.

atomodiagnostics.com
Cochlear’s success story is heard around the world

From the vision of an Australian researcher in the 1970s to the sophisticated technology now used to help hundreds of thousands of people worldwide, the ‘bionic ear’ is one of the best-known success stories in Australian medical devices.

Hearing solutions provider Cochlear was formed in the 1980s out of a collaboration between Professor Graeme Clark and a medical device group, with support from the Australian Government, to develop and market a commercially available cochlear implant.

In 1982 the first patient received a commercial multichannel cochlear implant. Three decades on, over three hundred and fifty thousand people around the world have received hearing solutions from Cochlear and the company now employs over 2700 people.

Since the first cochlear implant, Cochlear’s range of products has expanded to cater for different types of hearing loss and now includes bone conduction and acoustic implant systems. Cochlear also focuses on adapting its products to better meet the needs of patients in various markets, such as modifying the software used in its devices to be more appropriate for tonal languages. It is also involved in clinical education, and a wide range of ongoing support services for its recipients.

Cochlear continues to explore new technologies, with R&D teams based in Australia, Sweden, Belgium and the United States and collaborations with over 100 external research partners based in 20 countries.

cochlear.com
The sky’s the limit for Compumedics

Sleep study equipment produced by Australian firm Compumedics is used in hospitals, research laboratories and homes around the world – and even by astronauts training to go into space.

Since its establishment in 1987, the company has been designing and installing sleep clinic solutions, laboratory sleep systems, home monitoring products and portable systems.

Compumedics achieved technology endorsement when in 1995, NASA chose its P-Series for two separate contracts, the first involving Space Shuttle mission preparation, and the second the international space station mission preparation.

The P-Series was further endorsed when Compumedics won the contract, against considerable international competition, to supply diagnostic equipment to the largest sleep study in the world, the US funded Sleep Heart Health Study (SHHS).

More recently, the Compumedics Home Sleep Testing System was selected for use in the U.S. National Institute of Health (NIH)-sponsored Multi-Ethnic Study of Atherosclerosis (MESA) Sleep Study.

Compumedics specialises in computer-based patient monitoring and diagnostic systems and is currently leveraging its existing technology to continue its expansion into a number of related market sectors including epilepsy, cardiac diagnostics, fatigue monitoring, in-depth anaesthesia monitoring and sleep disorders therapy. More recently, Compumedics is entering into the exciting e-Health space.

All products are developed, designed, manufactured and marketed from the company’s Australian corporate headquarters in Melbourne and supplied worldwide through field offices in the USA, Singapore, Hong Kong and Germany and via an international network of distributors.

compumedics.com.au
Cook Medical - integrating medical devices, drugs and biologic grafts

Cook Medical is one of the world's largest privately owned medical technology manufacturers and is the pioneer of medical devices used to perform minimally invasive procedures – predominantly for aortic intervention and reproductive health.

The company manufactures advanced endovascular grafts for the treatment of aortic aneurysms and also manufactures endovascular grafts that are custom-made for individual patients.

The company assists reproductive health with EchoTip® needles, which incorporate technology that makes the needle tip clearly visible under ultrasound during the IVF process.

Cook Medical Australia’s products use technology pioneered and patented locally. Recognition of the company’s success in 2015 included winner of the Premier of Queensland’s Export Award for Health and Biotechnology and overall winner of the Lord Mayor’s Business Awards.

Cook provides its products to 135 countries around the world and approximately 92.5 per cent of Cook’s Australian-manufactured goods are exported overseas, to Hong Kong, Korea, Thailand, Malaysia, India, Singapore, Taiwan, New Zealand and New Caledonia. In 2014, the company manufactured a record 10,000 stent grafts for aortic aneurysms, more than 3,000 custom-made stent grafts, and just over 750,000 EchoTip® needles.

Barry Thomas, Managing Director of Cook Medical Australia, Director Cook Medical Asia and Vice President Cook Medical commented, “at Cook Medical Australia our mission is simple: we are dedicated to bold leadership in pioneering medical solutions to enhance patient care worldwide.”

Cook Medical’s locations throughout the Asia-Pacific operate in keeping with local culture and provide regional support and interaction. To enhance this, the Asia-Pacific New Technologies Team was established internally to identify opportunities for medical device innovation across the region.

cookmedical.com
**Dynek delivers – around the world**

Dynek was established in 1974, and since then has developed a range of over 9000 absorbable and non-absorbable surgical sutures, manufactured in Australia to CE Mark and ISO13485 standards, to cover suturing requirements for all surgical procedures.

Since it was awarded its first overseas government contract in 1975, Dynek has developed export links to over 50 countries, and successfully and continuously supplies this vital surgical device to regions that may experience procurement obstacles due to sanctions or restrictions applied by other countries. The United Nations has declared surgical sutures to be a humanitarian product, to be available to all.

Dynek’s dedicated export department is based at its manufacturing headquarters in Adelaide, South Australia. Dynek has worked closely with Ministries of Health, Austrade, consular contacts in Australia, and networks developed at exhibitions such as Arab Health, to create a smooth passage for the reliable supply of sutures to its customers, wherever they are.

Where there is a need to develop an ‘own brand’ label, Dynek has available its original equipment manufacturing laboratory, ensuring that the product is of the highest standard of manufacturing and sterility. In addition, research and development, along with training options, supports both distributors and medical facilities.

Successful distributors of Dynek sutures enjoy the benefits of a long term contract to promote these products in their country, while Dynek assists with product certification with local Ministries of Health, transport/delivery and customs regulations.

[dynek.com](http://dynek.com)
Nanosonics cleans up infection control

Every day around the world, millions of intracavity and surface ultrasound examinations are performed. This means that ultrasound probes need high level disinfection between every patient, to prevent healthcare acquired infections (HAIs). Because heat sterilisation can damage probes, manual cleaning and soaking in toxic disinfectant solution was previously the only practical option.

Australian company Nanosonics developed the proprietary trophon® EPR for fast, automated high level disinfection (HLD) of ultrasound probes. The device generates a sonically activated, ultrafine hydrogen peroxide mist at a low temperature and is clinically proven to be effective against a wide range of bacteria, viruses and fungi. A clinical paper published in November 2015 shows that trophon is the only high level disinfection system for ultrasound probes that kills high-risk, cancer-causing human papillomavirus (HPV). This sets trophon apart from all other available systems. The system is environmentally friendly, the by-products are oxygen and water, and helps protect both patients and healthcare staff from the effects of harmful bulk liquid disinfectants.

The trophon EPR is approved for sale in most major markets including the United States (US), Canada, Australia, New Zealand, Europe, Singapore, Hong Kong, South Korea and Japan. Nanosonics has direct operations in North America and Europe alongside distribution partners; GE Healthcare in North America, and Toshiba, GE Healthcare and Miele Professional in Europe.

Trophon EPR is now used in 43 of the top 50 hospitals in the US. Factors driving global adoption include changing disinfection guidelines, growing awareness of HAIs relating to ultrasound processes, and mounting clinical evidence showing that old HLD methods are ineffective.

The technologies that have delivered trophon provide the foundation for future product development. Nanosonics has an active research and development program to progress innovation and deliver new applications of the core platform technology and chemistries for the infection control market.

nanosonics.com.au
Image courtesy of Nanosonics
Sharp thinking pays off for QlickSmart

Handling and disposal of sharps is a big issue for medical staff and patients. In the United States alone, between 600,000 and one million sharps injuries are reported by healthcare workers each year.

When Queensland-based company Qlicksmart started developing its range of devices, it knew there was plenty of scope to improve staff and patient safety. The QlickSmart range is designed to be simple to use, in order to make safety compliance a practical reality for busy healthcare facilities. Products include:

- QlickSmart BladeFLASK - a world-first single-handed scalpel blade remover which helps reduce the risk of injuries caused by removing blades with fingers, forceps or re-sheathing
- QlickSmart BladeCASSETTE – a puncture-proof sharps removal system and container that automatically prevents overfilling
- QlickSmart SnapIT – a compact device to open glass ampoules while protecting the user’s fingers from sharp edges
- QlickSmart CliplT – a way to label syringes with the name of the medication that has been drawn up directly by attaching the drug ampoule to the syringe, thus reducing the risk of medical errors.

The company has won numerous Australian and international awards for its innovations, including a gold medal at the 2000 International Exhibition of Inventions, New Techniques and Products in Geneva, Top Nominee at the INDEX Awards in Denmark, 2007, and winner of the International Federation of Inventors Association (IFIA) Prize in 2000.

qlicksmart.com
Patients around the world breathe easier with ResMed

From modest beginnings, Australian company ResMed has grown into a leading developer, manufacturer and distributor of medical equipment for treating, diagnosing, and managing sleep-disordered breathing and other respiratory disorders.

Developed in 1981 by Professor Colin Sullivan and colleagues at the University of Sydney, nasal continuous positive airway pressure (CPAP) provided the first successful noninvasive treatment of obstructive sleep apnea (OSA).

ResMed was formed in 1989 to commercialise a CPAP device. Since then, the company’s operations have grown dramatically through the introduction of a number of highly innovative product lines, including sleep therapy systems, non-invasive ventilation systems, laboratory systems, bilevel technologies, masks and humidifiers.

By December 2010, ResMed had over 3,000 patents granted or pending worldwide. It now operates in over 70 countries via direct offices and a network of distributors. The company is actively involved in research initiatives into sleep-disordered breathing and associated areas of clinical focus such as cardiovascular disease, chronic obstructive pulmonary disease, type 2 diabetes, occupational health and safety and perioperative care.

ResMed also provides education and support for healthcare professionals across multiple clinical disciplines, including critical care, anesthesia and post-anesthesia, cardiovascular recovery, medical-surgical, sleep therapy and home care, emergency, and other specialties.

resmed.com
Signostics takes ultrasound into new fields

Medical and veterinary practitioners can now perform ultrasound examinations nearly anywhere, thanks to a simple-to-use, palm-sized device from Australian company Signostics.

The size of a smart phone, the Signos RT is the world’s smallest ultrasound system, weighing less than 400 grams. It is also significantly more affordable than conventional ultrasound systems. It is small enough to be carried in a pocket, or worn around the neck like a stethoscope, making it easy to incorporate ultrasound scanning into routine physical examinations.

The Signos RT system is designed for point-of-care use in a variety of clinical settings, such as primary care medicine, rural and remote medicine, maternity and midwifery, bladder scanning, emergency and intensive care medicine. It is also suitable for a wide range of veterinary applications, primarily aimed at companion animals.

Established in 2005, and with sales operations in Seattle, Washington, Signostics launched its first-generation Signos device into the veterinary market in 2009 before gaining regulatory approvals to enter the human medical device market in Australia, the United States (US) and Europe.

In February 2013, Signostics signed an agreement with Konica Minolta Medical & Graphic Inc to sell its devices exclusively through Japan, the US, China and India.

The President and CEO of Konica Minolta Medical & Graphic Inc, Atsushi Kodama, said ‘we are very excited about selling this truly portable and flexible point-of-care imaging tool and incorporating it into our product portfolio. Signostics has developed a revolutionary product which we believe will have a significant impact across our global markets.’

Recently, Signostics has also forged a distribution partnership with Thermo Fisher Scientifics’ Healthcare Division to exclusively promote and distribute Signos RT in Australia and New Zealand.

signostics.com.au
Image courtesy of Signistics
**Voyager Imaging streamlines medical imaging**

Image and report distribution to clinicians and specialists is a crucial part of the medical diagnostic process, and Voyager Imaging provides mechanisms to ensure this process is efficient and user friendly.

As Australia’s pioneering medical imaging company, Voyager Imaging has specialised in radiology software for more than 20 years. Products include teleradiology, picture archiving and communication systems (PACS), radiology information systems (RIS), and automated CD/DVD burning and integration services.

Voyager PACS provide efficient loading of images for radiologist reporting, as well as smart imaging streaming technology for fast delivery of images to key users connected to the network.

One of Voyager Imaging’s international clients is the Papua New Guinean (PNG) Ministry of Health, with products provided through a local distribution partner, Premier Healthcare in Port Moresby. Products include Voyager PACS for image storage, distribution and reporting of medical imaging examinations, and teleradiology solutions to connect remote hospitals and clinics with specialists based in Port Moresby and internationally.

Voyager Imaging products were selected as they are robust, cost effective and are able to operate in PNG’s medium and low bandwidth environments. They have the ability to connect various medical imaging equipment such as general x-rays, ultrasounds and CTs, with treating physicians. In addition, remote hospitals in PNG can connect with external specialists based in Port Moresby and internationally, providing a significantly higher level of healthcare for the population.

Other benefits include a faster response time for diagnosis, the ability to gain expert external medical reports on patients, and the ability to maintain a fast and efficient method of image storage, archive and retrieval.

These products are available in the Asia Pacific, Middle East, Europe and the United States through an extensive distribution and partner network.

voyagerpacs.com
INTRODUCTION

INDUSTRY OVERVIEW

INDUSTRY STRENGTHS

COMPANIES AND CAPABILITIES

FURTHER INFORMATION

The following are some of the government and industry bodies involved in the Australian medical devices and diagnostics industry. Contact your local Australian Trade Commission representative about connecting and partnering with this industry.

austrade.gov.au

GOVERNMENT ORGANISATIONS

The Department of Industry, Innovation and Science is the Australian Government department that helps the industry to become more efficient, competitive and innovative through engagement with business, research bodies, tertiary education sectors, government and the broader community industry.gov.au

Therapeutic Goods Administration (TGA) is Australia’s regulatory authority for therapeutic goods, which carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard, with the aim of ensuring that the Australian community has access within a reasonable time to therapeutic advances tga.gov.au

INDUSTRY ASSOCIATIONS

AusBiotech is a network of over 3,000 members in the life sciences, including therapeutics, medical technology (devices and diagnostics), food technology and agricultural, environmental and industrial sectors that works to provide representation and services to promote the global growth of Australian biotechnology ausbiotech.org

Australian Dental Industry Association (ADIA) is the peak representative body for suppliers of quality dental products with members that manufacture, import and supply the products used by dentists and allied oral healthcare professionals adia.org.au

Australian Self Medication Industry (ASMI) is the peak body representing companies involved in the manufacture and distribution of consumer healthcare products in Australia asmi.com.au

IVD Australia is the peak body representing Australian sponsors and manufacturers of in vitro diagnostics ivd.org.au

Medical Technology Association of Australia (MTAA) is the national association representing manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability mtaa.org.au

Science Industry Australia (SIA) is the peak national industry association for organisations which are a producer, provider or user of science industry goods and/or services. Members include scientific and life science product and equipment suppliers, scientific, analytical and diagnostic equipment and consumable manufacturers, exporters and importers, chemical and gas companies, software companies, analytical-reference-testing-pathology laboratories and specialised recruiters scienceindustry.com.au
REFERENCES

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13. Private Health Insurance Administration Council, Quarterly Statistics March 2015, Canberra
The Australian Trade Commission – Austrade – contributes to Australia’s economic prosperity by helping Australian businesses, education institutions, tourism operators, governments and citizens as they:

• develop international markets
• win productive foreign direct investment
• promote international education
• strengthen Australia’s tourism industry
• seek consular and passport services.
Austrade helps companies around the world to identify and take up investment opportunities in Australia as well as to source Australian goods and services.

Our assistance includes:

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• identifying potential investment projects and strategic alliance partners
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W www.austrade.gov.au
E info@austrade.gov.au