

Media Release

AUSTRALIAN MANUFACTURER EXPORTS LOCALLY DEVELOPED CONCUSSION DIAGNOSIS DEVICE TO THE U.S

- *Australian MedTech manufacturer Headsafe has commercialised a portable brain injury assessment device to provide faster diagnosis of potential concussions called Nurochek*
- *Backed by co-investment from the Advanced Manufacturing Growth Centre (AMGC) the home-grown technology is FDA cleared and available in the United States with further markets to follow*
- *As a result of the project, Headsafe has established local manufacturing capabilities, doubled its R&D expenditure, and will generate substantial export sales*
- *The Headsafe project will employ 17 new staff and is expected to generate \$84 million in revenues over the next five-years*

Every four minutes, someone in Australia is hospitalised with a head injury, with 24 per cent of all concussive episodes caused by sport.*

The time taken for a patient to be diagnosed with concussion has largely been based on rudimentary field assessments, and diagnosis is often delayed as patients are transported to scanning equipment in hospitals. As a result, the potential for misdiagnosis or delay in treatment is high.

With support from AMGC, Headsafe will change this, with the introduction of a 'brain scanner in a briefcase' dubbed Nurochek. Nurochek is a world-first device able to be deployed in mobile and clinical settings for rapid assessment and response to head injuries at the point of injury and at treating doctors or clinics.

Verified extensively in the United States (US) and Australia, this US FDA-cleared portable headset uses patented technology to measure the brain's electrical activity and sends the results to an online AI algorithm for analysis and later to the 'cloud' for secure storage.

In a two-minute assessment, Nurochek will aid doctors and patients understand if a concussion has occurred. If so, then the patient can be appropriately managed and ensured a safer return to activities.

Nurochek has multiple applications beyond sport, offering assessments for Traumatic Brain Injury from:

- Falls
- Motor vehicle accidents
- Military incidents
- and potentially early-stage diagnosis of other acute and chronic brain conditions.

The two-year project, involving 11 collaborative partners, saw Headsafe adapt the technology to suit in-the-field deployment including the development of the technology while improving the data, processing, and usability capabilities of the product. Headsafe and its collaborators designed a new user interface, analysis algorithms, device design, power usage and cloud analysis capabilities.

CEO and Founder of Headsafe, Dr. Adrian Cohen said, “Speed and accuracy of concussion diagnosis is key to better patient outcomes. Far too often head injuries are left undiagnosed, or untreated, because of delays in attaining a diagnosis or guesswork in the field – be it a sporting, motor vehicle or other injury. Nurochek aims to take the uncertainty out of head injury diagnosis, all in the service of better patient outcomes.”

“Support from the Advanced Manufacturing Growth Centre and our collaborative partners have been instrumental in translating a clinical technology into an in-field solution with export potential. This project means that this world-leading product, its home-grown IP and our ability to manufacture it remains onshore in Australia” said Dr. Cohen.

Following FDA clearance, Headsafe will commence export of Nurochek to the United States and is currently working towards Australian, New Zealand, South African and European Union certification in order to make it available in these markets.

Dr. Jens Goennemann, Managing Director of AMGC said, “Headsafe’s product epitomises the potential of Australian Medtech manufacturing.

“Rather than taking Australian ideas offshore, Headsafe has turned the table by creating a local ecosystem that generates jobs and prosperity, while attracting investment and customers from abroad. Being globally competitive is the sweet spot for Australian manufacturing.” Said Goennemann

The Headsafe project will employ 17 new staff and is expected to generate \$84 million in revenues over the next five years. The project was supported by GPC Electronics, Blue Quality Studios, Blackwattle IP, Western Sydney University, RQM+, Wearable Sensing, CLC consulting, Access Pointe, and international collaborators at the Icahn School of Medicine at Mount Sinai.

To learn more about Headsafe’s project with AMGC, visit <https://www.amgc.org.au/project/development-of-the-nurochek-pro/>

*<https://www.aihw.gov.au/reports/injury/head-injuries-in-australia-2020-21/contents/about>

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About Headsafe.

Headsafe was established in Sydney, Australia in 2017 by Dr. Adrian Cohen to develop and commercialise the patented NUROCHEK™ system[^]. Headsafe’s current focus lies in scientific and clinical research into the NUROCHEK system and its application in the assessment of brain function with research partnerships in the United States, Australia and New Zealand.

[^]FDA K231914 Clearance Statement The Nurochek-II System is intended for prescription use in healthcare facilities for subjects aged between 16 and 46 years old, for the aid in diagnosis of mild traumatic brain injury (mTBI) in conjunction with a standard neurological assessment.

<https://headsafe.com/>

About Advanced Manufacturing Growth Centre (AMGC)

The Advanced Manufacturing Growth Centre (AMGC) is an industry-led, not-for-profit organisation established through the Australian Government’s Industry Growth Centres Initiative. AMGC’s vision is to transform Australian manufacturing to become an internationally competitive, dynamic and thriving industry with advanced capabilities and skills at its core.

Through the delivery of its world-leading research, Manufacturing Academy, workshops, and ground-breaking projects, AMGC aims to develop a highly skilled and resilient local manufacturing industry that

delivers high-value products – via the integration of innovative technology – to domestic and international markets.

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