
PainChek® granted US patent for pain assessment invention

July 24th 2019: Listed Australian company PainChek® (ASX:PCK) announced today the United States Patent Office has issued a Notice of Allowance for its pain assessment invention. This indicates that patent prosecution has been successfully completed. The patent, when granted, will allow PainChek® to protect the intellectual property of its invention in the United States and provides a platform for growing the brand in international markets.

The US patent, when granted, gives PainChek® exclusive rights to exclude others from making, using, selling or importing the invention for 20 years from the filing date in the US (17 February 2017).

PainChek® is the world's first smartphone pain assessment and monitoring device. The app automatically assesses pain via artificial intelligence and facial recognition technology. Research¹ shows it is already driving higher quality aged care and improved pain management in residential settings around Australia.

According to Philip Daffas, PainChek® CEO, the patent is the latest in a series of growth milestones for the company in 2019.

“After working on this application since early 2017, our team is delighted with the United States Patent and Trademark Office (USPTO) grant. The PainChek® technology effectively gives a voice to people who can't verbalise their pain and this patent will further expand our commercial efforts,” said Mr Daffas.

The announcement comes as PainChek is also on track to obtain United States FDA De Novo regulatory clearance in 2020. The De Novo process provides a regulatory pathway for PainChek® to market the adult version App in the US.

“Our ongoing De Novo application confirms we are a first in kind from a regulatory standpoint and the granting of the US patent confirms that we are first in kind from an intellectual property standpoint.

“From a business perspective, the US is the largest medical device market in the world and more than six Million people are living with dementia². Establishing our intellectual property in the US is a crucial step forward as part of protecting and growing the PainChek® brand internationally,” added Mr Daffas.

PainChek® is currently completing national filings for the same patent in Australia, China, Europe, Japan and the United Kingdom.

¹ Clinical Studies' PainChek 2019, <https://www.painchek.com/clinical-studies/>

² www.alz.co.uk/sites/default/files/conf2018/3_DY_Suharya_Asia_Pacific_response_to_global_action_plan_on_dementia.pdf

Recent Developments

The PainChek® Adult App is clinically validated³ and regulatory-cleared⁴ technology that uses automated facial recognition and analysis to identify, quantify and monitor pain in adults that are unable to verbalise their pain.

The PainChek® Adult App is now in clinical use in more than 80 residential aged care homes across Australia helping to better assess pain severity levels for residents living with dementia and cognitive impairment.

Earlier this year, the Australian Federal Government announced it will invest A\$5M to facilitate the implementation of the company's pain recognition app in Australian Aged Care Facilities⁵. The Company has also entered the United Kingdom market through a distribution agreement with leading Aged Care software provider Person Centred Software⁶.

PainChek® has also announced it will be collaborating with Murdoch Children's Research Institute (MCRI), to clinically test a version of the PainChek® App for infants⁷.

The PainChek® Infant *PainFaces* study will be led by Professor Franz Babl (MCRI) and Associate Professor Di Crellin (MCRI) in the Emergency Department (ED) of the Royal Children's Hospital, Melbourne. Lead researcher on the project Associate Professor Crellin has recently evaluated the validity and reliability of two observational children's pain assessment tools, the Face, Legs, Activity, Cries and Consolability (FLACC) scale and the Modified Behavioural Pain Scale (MBPS), in assessing procedural pain in the ED.

In this new study, which is expected to commence later this month, the pain scores derived using the PainChek® Infant App will be compared to those obtained using the FLACC by two independent assessors in approx. 100 infants undergoing painful procedures within the ED.

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3. Atee M, Hoti K, Hughes JD. A Technical Note on the PainChek™ System: A Web Portal and Mobile Medical Device for Assessing Pain in People With Dementia. *Front Aging Neurosci.* 2018 Jun 12;10:117. doi: 10.3389/fnagi.2018.00117. eCollection 2018.

4 PainChek® Adult App has TGA and CE Mark regulatory clearances as a Class 1 Medical Device

5 ASX release dated 29 April 2019

6 ASX release dated 27 May 2019

7 ASX announcement dated 2 July 2019

About PainChek®

PainChek® Ltd is an Australian based company that develops pain assessment technologies.

PainChek® is a smart-phone based medical device using artificial intelligence to assess and score pain levels in real time and update medical records in the cloud. PainChek® records a short video of the person’s face and analyses the images that indicate pain and records them.

Next, the caregiver uses PainChek® to record their observations of other pain related behaviours that complete the assessment. Finally, PainChek® calculates an overall pain score and stores the result allowing the caregiver to monitor the effect of medication and treatment over time.

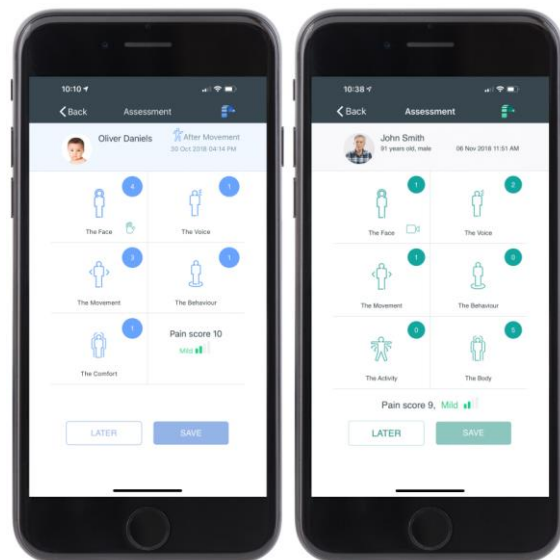
PainChek® is being rolled out globally in two phases: first, PainChek® for adults who are unable to effectively verbalise their pain such as people with dementia, and second, PainChek® for Children who have not yet learnt to speak.

The PainChek® Shared Care Program is a PainChek® licensing model which enables a professional carer to share their resident or patient data securely with other healthcare professionals or designated homebased family carers for ongoing pain assessments or clinical data review.

To find out more, visit www.painchek.com



PainChek® artificial intelligence assesses facial micro-expressions that are indicative of the presence of pain.



PainChek® domains of pain assessment that calculates pain severity score.