Kerrin Rennie Award 2019 Application

Section 1: Application Summary

Name of Product	**Medtronic MiniMed 670G System**
Australian launch date	**11 February 2019**
Products used in (please select)	✔ diagnosis ✔ prevention ✔ treatment ✔ management
Contact details	**Medtronic Australasia Pty Ltd**

Your details

Name	**Donna McCann**	Position	**Director | Communications**
Email	**donna.mccann@medtronic.com**	Phone	**0420 987 936**
Name of Company	**Medtronic Australasia Pty Ltd**	ABN	**47 001 162 661**

Executive Summary: [200 words max.] NB Executive Summary must be suitable for use in Award promotion

The MiniMed 670G is an insulin pump system which automatically self-adjusts to deliver people living with type 1 diabetes (T1D) precise amounts of insulin when they need it – regardless of whether they are asleep or on the go. The only technology of its type approved in Australia, the insulin pump system intuitively administers insulin as needed and also withholds insulin release when a drop in sugar levels is detected – a long-awaited breakthrough in the Australian diabetes community in their quest to better manage the chronic disease. The system is designed to learn an individual's insulin needs by measuring the glucose level of people living with T1D every five minutes and to take action to minimise both high and low glucose levels. As a result, the technology requires minimal input providing peace of mind for the users.

Section 2: Product Details

Describe the technology [300 words max.]

Internationally, Medtronic has worked towards the Medtronic MiniMed 670G System (MM670G) for 26 years - each new insulin pump provides another level in the quest for fully-automated insulin delivery. We have worked with users, researchers, product developers, advocacy groups and Government regulators across the globe – including Australia - to ensure the system meets the needs of people with Type 1 Diabetes (T1D) and the evolution in technology continues. Simultaneously, advocacy to determine appropriate pathways to market and access for Australian patients involved advocacy groups government and industry to ensure that once available, the innovation was given the best chance to succeed.

The MM670G System continuously monitors glucose and provides updates to the pump every five minutes, which then adjusts the amount of insulin required based on the previous 2-6 days' worth of data. This automation works to maximise Time in Range (TIR), or the time blood sugar levels stay within a predefined target range. It does this using an advanced learning algorithm, thus allowing the person to live their lives without multiple daily injections and without having to calculate the insulin dose they require. The person must only enter the carbohydrate counts of their food and the pump takes over all remaining decision making from there.

Developing the technology and bringing it to market is only one part of the puzzle. Despite the advanced nature of the technological innovation, the ability of people to access the MM670G is hindered by incomplete funding in Australia. Medtronic worked extensively with community groups, government and industry, to champion CGM reimbursement for three segments of the community, thereby giving the technology and our community the best chance for adoption to help improve and save lives. Insulin pumps are available to those with the correct level of private health insurance.

What health problem is the technology addressing and how does it address the problem? [300 words max.]

People with T1D need insulin to survive. They also have high variability in glucose levels, which can lead to long-term complications (such as amputations – 4400/year in Australia [1] and short-term issues. 1-2% (750-1000) of people living with T1D for longer than 25 years have problematic hypoglycaemic awareness and they are unable to work or live a normal life [2].
Glucose variability and its consequences are a well-known aspect of T1D. The goal of diabetes management is to keep blood glucose levels as close to the normal range as possible which can be difficult to achieve. If the person doesn't have optimised time in target glucose range, these reactions can lead to serious short-term complications including seizure or coma as well as long-term complications including eye disease, kidney disease, nerve damage and amputation.

The development of insulin and technology like insulin pumps has been on-going for over a decade. However, continuous consultations with patients and physicians, clarified that a pump that proactively reduces glucose variability was needed. As such, the MM670G insulin pump combines CGM to create a system that's able to take action according to the individuals needs and help people stay within a target glucose range 24 hours/day – thereby reducing dangerous glucose variability.

1. https://www.diabetesaustralia.com.au/news/15266?type=articles
2. Diabetes Care. 2015 Jun;38(6):1016-29. doi: 10.2337/dc15-0090. 2.Diabetes Care 36:1384–1395, 2013

What other products are currently available to address this issue and how does this technology differ from and/or improve on existing technology? [300 words max.]

Every person with T1D needs to inject insulin to survive. Standard of care is daily short and long acting insulin delivered by pens. Amount is determined by a blood glucose sample that it taken via a fingerstick. This means there is a lot of variability in delivery of insulin and it is very hard to match the amount of insulin needed to the body's real time requirements.

There are other pumps that also minimise injections by in 90% available (Tandem, Ypsomed) and other CGM (Dexcom) that can also send glucose data to either the pump or mobile phone. However, data does not enable the pump to act and automatically vary the insulin needed to match the persons need. Flash Glucose Monitoring (Freestyle Libre) also provides data for the person to act upon but there is no automation.

The path to achieving this goal has involved iterations of insulin pump technology – the one preceding the MM670G being the MM640G System. This is available and acts to suspend insulin based on a predictive algorithm.

What the MM670G system does differently, is to adjust (basal) the person's insulin delivery to meet the body's requirement in real time. Thereby avoiding a large number of highs and lows. It has been designed to keep glucose levels close to 6.7mmol/l. We know this is helping people because we now have 8 million days recorded in Carelink1 and they show people are now spending over 17 hours per day between 3.9 and 10 mmol/l.2,3
Globally, Medtronic continues to innovate towards a full closed loop, and the Australian diabetes community continues to be part of this journey through participation in clinical trials and testing.

1. Aggregated Data on File. US MiniMed 670G system users from CareLink(TM) Personal data is from March 17 2017 to May 9, 2019 and CareLink(TM) System data is from March 17 2017 to March 1, 2019. Users= 119,274; Patient days: 7,984,915.
2. Bergenstal, R. M. et al. Jama. 2016; 316 (13): 1407 – 1408 .
3. Garg SK et al. Diabetes Technol Ther. 2017 Mar;19(3):155-163.)

Having regard to the consumer's quality of life, does the product provide a balance between invasiveness and efficacy? [300 words max.]

Since our launch, we have over a 2000 people using the system in Australia. However, T1D is a condition that drastically impacts an individuals' family. Parents can trust the system to keep their children safe so that they can go to school and even sleep in peace at night, without experiencing dangerous highs and lows. This includes the parents of the 7809 children age 15 or younger (NDSS March 2019).

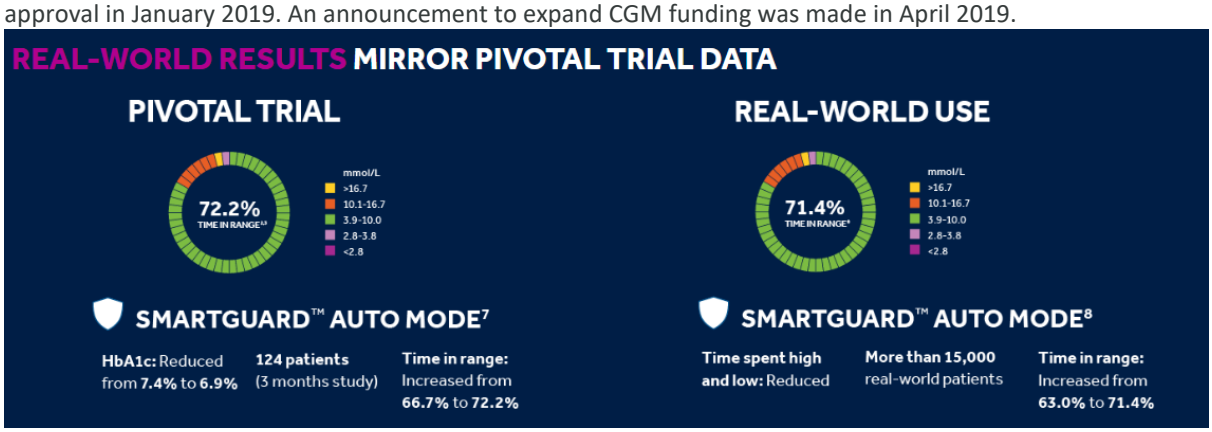
By 2020, we anticipate over 3000 T1D will be using the MM670G system. The adoption rate of this technology has been phenomenal with over 1000 people upgrading therapy to this one within the first 3 months of launch.

This is the first system that allows someone with T1D to hand over control for their treatment of hyperglycaemia as well as hypoglycaemia. This allows them more freedom to concentrate on their lives outside of diabetes as they don't have to spend so much time on the management of diabetes. The improved quality of life that people experience can be seen in the four case studies on our website homepage:

www.medtronic-diabetes.com.au and in the next section of this submission.

Published research has shown the MM670G can be used by adolescents and adults with T1D in an outpatient setting with no episodes of severe hypoglycaemia and Diabetic ketoacidosis.
Three key clinical studies and over 100,000 users globally show how the system can help improve diabetes management. Real-world evidence matches that experienced in the pivotal study[1]

The excellent patient outcome results (Glucose Outcomes with the In-Home Use of a Hybrid Closed-Loop Insulin Delivery System in Adolescents and Adults with Type 1 Diabetes) meant that the system received TGA approval in January 2019. An announcement to expand CGM funding was made in April 2019.



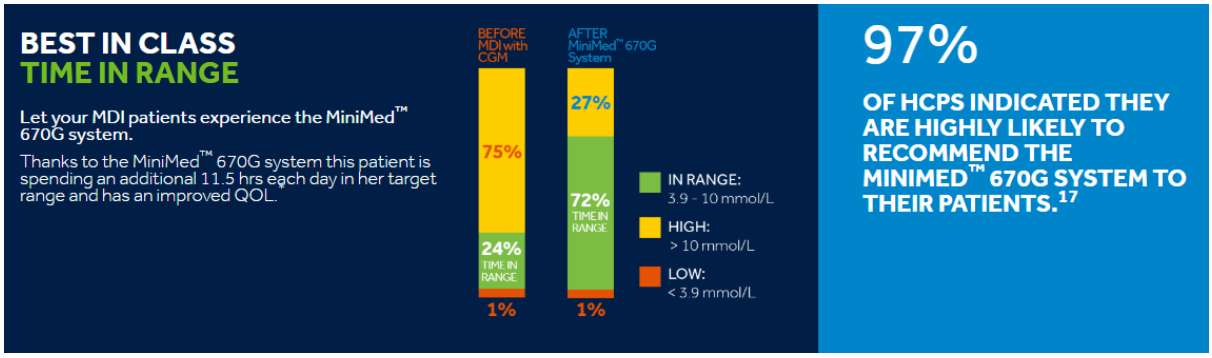
Data On File. Medtronic Diabetes. Northridge, CA.
Data On File. Medtronic Diabetes. Northridge, CA. Continued access phase HCP interview notes.
1. Bergenstal R, Garg S, Weinzimer S, et al. Safety of a hybrid closed-loop insulin delivery system in patients with type 1 diabetes. JAMA. 2016;316(13):1407-1408

Include scientific evidence to support the claims. This may include published data, unpublished scientific data, results of clinical trials and/or patient feedback. Photographs may be submitted. Product samples will not be accepted.

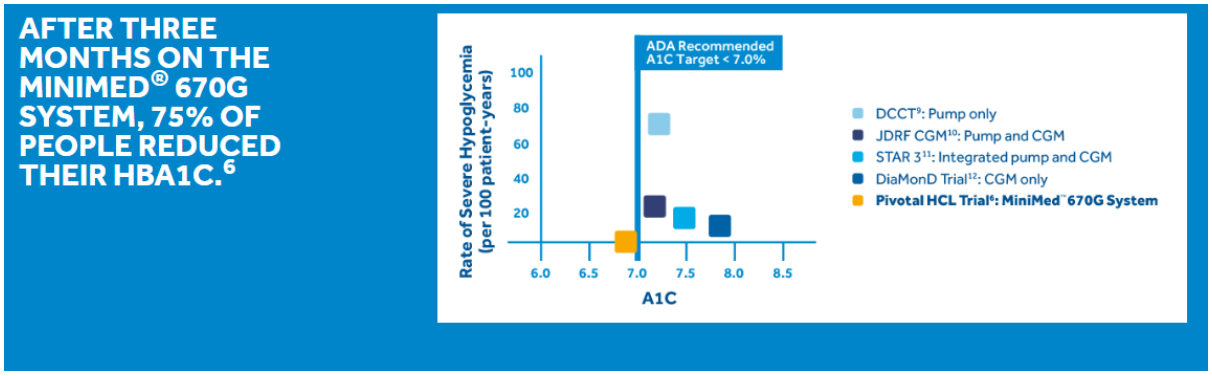
SCIENTIFIC EVIDENCE

There were five clinical investigative sites in Australia that carried out research on the system prior to launch. These were funded by grants to researchers from the Australian Type 1 Diabetes Clinical Research Network (T1DCRN, which is funded by the federal government.

https://www.jdrf.org.au/research/research-progress/clinical-research-resource-map.



17.Customer Training Phase-Data on File. 2. Priority Access Phase-Data on File (n>13,000)



6. Bergenstal R, Garg S, Weinzimer S, et al. Safety of a hybrid closed-loop insulin delivery system in patients with type 1 diabetes. JAMA. 2016;316(13):1407-1408.

PATIENT PERSPECTIVES

LEANNE*, DIAGNOSED AT AGE 11: https://www.medtronic-diabetes.com.au/minimed670g-ambassador-leanne After years of dealing with fluctuating highs and lows using Multiple Daily Injections, a friend recommended she consider Insulin Pump Therapy. Leanne was hooked and has spent years throwing herself into research trials not only to find the best therapy for herself, but to help others find better ways to manage their diabetes. As the first person in Australia to try the MM 670G System, Leanne cannot think of life without it. She has been able to maintain an A1c of 6.2, increased her time in range to over 80%, reduced the impacts of the Dawn Phenomenon and now finds that she wakes up every morning refreshed and ready to take on the world – no matter where she finds herself. *"I have a philosophy that diabetes needs to fit in with my life, not the other way around. The MM670G system with Auto Mode technology does exactly that!"*

NICKY, DIAGNOSED AT AGE 10: https://www.medtronic-diabetes.com.au/minimed670g-ambassador-nicky
Nicky and her family wanted to know that her glucose levels were in control and in range when she was doing her favorite things. They wanted to be confident that she was stable and in range all through the day and night. When Nicky and her family discovered the MM670G automatically kept her glucose levels in range day and night, they knew she would feel more confident managing her diabetes. Now Nicky wakes up refreshed and ready to conquer the world. *"Freedom! That's what the MiniMed® 670G's Auto Mode Technology means to me".*

RYAN, DIAGNOSED AT AGE 12: https://www.medtronic-diabetes.com.au/minimed670g-ambassador-ryan
Diagnosed with type 1 diabetes as a child, his mum looked after him day and night to make sure his glucose levels stayed in range and that he stayed safe. Wildly energetic on the ice one minute, and then exhausted the next. Ryan's mother wanted to find a better solution for her son. Together they discovered that with the MM670G. Ryan's glucose levels were kept in range automatically-even after hockey practice when he liked to catch a bite with friends. With his glucose in range no matter where he is, Ryan's getting his first true taste of independence. His mum feels comfortable letting him travel with his hockey team and Ryan can enjoy life as a teenager even more. *"The MiniMed 670G system gives us all more peace of mind."*

JOHN, DIAGNOSED AT AGE 16: https://www.medtronic-diabetes.com.au/minimed670g-ambassador-john
As he grew older, John started to think more about the long term complications and his family's concern about his glucose levels dropping too low at night - especially when away. John refused to put his life on hold. He put all his energy into exploring ways to stay in range. Then he discovered the MM670G.
With new information to optimise his glucose levels when he travels for work, John has become the confident traveller he always wanted to be - and his family sleep better knowing that his glucose levels are automatically stabilised due to the SmartGuard Auto Mode technology. *"The doctors told me to take it easy. I don't know what that means!"*

MEDIA REPORTING
The availability of the MM670G System brought attention to medtech advances in T1D through Australian media channels. A sample of this reporting is below:
Channel 9: https://www.youtube.com/watch?v=0k6crny8WrI
The Queensland Times: https://www.pressreader.com/australia/the-queensland-times/20190220/282269551671454
Health Dispatch: https://healthdispatch.com.au/news/medtronic-launches-new-insulin-pump-system
PulseLine: http://www.pulseline.com.au/future-of-medtech/artificial-pancreas-game-changer

Section 3: Declaration

I certify that the information provided in this application is accurate and that the company accepts the Rules of the Award. Representative/s of the company will participate in promotional activities relating to the Award.

Name: Donna McCann *Position:* Director | Communications

Signature of the CEO/Authorised Representative: _____

Date: 26 / 7 / 2019

Please send your application to MTAA Secretariat – Kerrin Rennie Award

CLOSING DATE: **26 JULY 2019**