## MINIMED<sup>™</sup> 670G SYSTEM & GUARDIAN CONNECT

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ASC Diabe Medtronic Further, Together

#### DAILY PERSISTENT HYPOGLYCEMIA OFTEN OBSERVED IN PATIENTS WITH AN A1C < 7%

Industry standards recommend A1C <7.0%\*

A1C	Mean blood glucose	
%	mg/dL	
12.0	298	
11.0	269	
10.0	240	
9.0	212	
8.0	183	
7.0	154	
6.0	115	
5.0	97	
4.0	50	

JDRF study subjects achieved A1C<7.0% but experienced 60 minutes per day in hypoglycemia<sup>1</sup>

(defined here as  $\leq$ 70 mg/dL)

### A1C ALONE DOES NOT TELL THE FULL STORY

#### WHAT IS TIME IN RANGE (TIR)? THE PERCENTAGE OF TIME GLUCOSE LEVELS ARE BETWEEN 70 -180 MG/DL PER UNIT OF TIME

Consensus Report Definitions<sup>1</sup>: In Range, Hypoglycemia, Hyperglycemia



## More Time in Range means less severe highs and lows – and is correlated with better quality of life<sup>2,3</sup>

1. Agiostratidou G, et al. *Diabetes Care*. 2017;40:1622–1630. 2. Vanstone M, et al. *Ont Health Technol Assess Ser*. 2015; 15(17): 1–29. 3. Ayano-Takahara S, et al. *Diabetes Care* 2015 Jan; 38(1): e1-e2.

### **RECENT CLINICAL DATA ANALYSES SHOWS...**

INCREASED Time in Range is strongly associated with REDUCED microvascular complications in patients with type 1 diabetes<sup>1</sup>



# Meta-analysis of 18 studies shows 70% TIR relates to 6.7% A1C (meeting ADA goal of 7%)<sup>2\*</sup>

1.Beck R et al. *Diabetes Care*. 2018 Oct; epub ahead of print dc181444. p<0.0001. 2. Vigersky RA. *Diab Tech Ther*. 2018 Dec 21. doi: 10.1089/dia.2018.0310. [Epub ahead of print] \*Due to inherent analyses limitations, caution is advised when attempting to extrapolate these results to new patients. There could be significant differences. TIR: Time in Range



### Why Smart CGM?

- 1. Strong protection against lows<sup>2</sup>
- Proactive support for managing diabetes<sup>3</sup>
- Text alerts for up to 5 of your family or friends
- Experience fewer high and low episodes<sup>4</sup>

### Meet the ONLY Smart CGM System:

- Predictive alerts up to 60 minutes before a high or low
- With no dedicated receiver required at purchase
- Automatically uploads to CareLink<sup>™</sup> software
- With access to the Medtronic family of products

## GUARDIAN™ CONNECT SMART¹ CGM SYSTEM

For people using insulin injections

The Guardian™ Connect system has the most customizable and advanced alerts of any CGM system.





#### **GUARDIAN<sup>TM</sup> CONNECT SYSTEM**





### GUARDIAN™ CONNECT CGM SYSTEM CLEARLY SMARTER



### SMART CGM<sup>1</sup> ALERTS WITH THE POWER OF PREDICTION



The <u>first</u> and <u>only</u> stand-alone CGM system that can alert your patients of potential highs and lows **up to 60 minutes in advance** 

In a recent CareLink<sup>™</sup> analysis<sup>2</sup> of real-world data, it was found that Guardian<sup>™</sup> Connect system users<sup>3</sup> **experienced 60% fewer low and 39% fewer high glucose episodes**<sup>4</sup>

### GUARDIAN<sup>™</sup> SENSOR 3: THE INTELLIGENT SENSOR, OPTIMIZED TO DETECT WHAT MATTERS

98.5% \* Detection Rate for lows\* with Predictive Alerts



**Intelligent diagnostics** monitor sensor health to ensure optimal accuracy and reliability.

<sup>1</sup> Smart CGM predicts future high and low sensor glucose events up to 60 minutes in advance and provides access to additional algorithms and insights that can inform users of clinically relevant glucose patterns <sup>2</sup> Cohen O, et al. Avoidance of Glucose Excursions by the Guardian<sup>™</sup> Connect CGM system - real world data. Poster presented at Advanced Technologies & Treatments for Diabetes Conference; 2018 February 14-18, Vienna, Austria. <sup>1</sup> Users from outside of the U.S., using an earlier version of the Guardian<sup>™</sup> Connect App. <sup>4</sup> Low episode is defined as ≤70mg/dL, high episode as ≥180mg/dL based on sensor glucose. <sup>4</sup> With threshold and predictive alerts within the 30 minute period before or after blood sugar goes below 70 mg/dL, Guardian<sup>™</sup> Safety and Efficacy data.

## THE MINIMED<sup>™</sup> 670G SYSTEM\* THE WORLD'S FIRST HYBRID CLOSED LOOP SYSTEM



WARNING: Medtronic performed an evaluation of the MiniMed<sup>™</sup> 670G close loop system and determined that it may not be safe for use in children under the age of 7 because of the way that the system is designed and the daily insulin requirements. Therefore, this device should not be used in anyone under the age of 7 years old. This device should also not be used in patient who require less than a total daily insulin does of 8 units per day because the device requires a minimum of 8 units per day to operate safely.

## THE MINIMED<sup>™</sup> 670G SYSTEM WITH SMARTGUARD<sup>™</sup> HCL TECHNOLOGY WHAT ARE THE COMPONENTS OF THE SYSTEM?



Indicated for people with type 1 diabetes age 7 and older.



#### TIME IN RANGE THERAPY PROGRESSION FROM MDI



1. Bergenstal R, et al. NEJM. 2010; 363(4): 311-320. 2. Beck R, et al. JAMA. 2017; 317(4):371-378. 3. Tandem t:slim X2TM insulin pump with Basal-IQTM summary of safety and effectiveness data PMA P180008 (SSED) 4. Bergenstal R, et al. JAMA. 2016;316(13):1407–1408.

#### MORE TIME IN RANGE IN PIVOTAL TRIAL WITH HCL SYSTEM ADDRESSING METRICS BEYOND A1C

SmartGuard<sup>™</sup> technology adjusts insulin in real time based on glucose levels. It can help keep levels between 70 to 180mg/dL 72% of the time, maximizing time in control day and night.

Sensor Glucose	Run-in % Time in Range	Study % Time in Range	Sensor Glucose	Run-in % Time in Range	Study % Time in Range
> 300 mg/dL	2.3	1.7	> 300 mg/dL*	2.1	1.4
> 180 mg/dL	27.4	24.5	> 180 mg/dL	26.8	21.6
71 – 180 mg/dL	66.7	72.2	71 – 180 mg/dL	66.8	75.3
≤ 70 mg/dL	5.9	3.3	≤ 70 mg/dL	6.4	3.1
≤ 50 mg/dL	1.0	0.6	≤ 50 mg/dL*	1.1	0.6

Night Time Only

Due to inherent study limitations, caution is advised when attempting to extrapolate these results to new patients. There could be significant differences. Bergenstal R, et al. Poster presented at the 76<sup>th</sup> Scientific Sessions of the American Diabetes Association, June 10-14, 2016, New Orleans. LA. P-99. Bergenstal R, et al, *JAMA*. 2016;316(13): 1407-1408.

**Overall** 

#### **PIVOTAL TRIAL SUMMARY OF RESULTS** STUDY PHASE PATIENTS MET A1C GOALS WITH ZERO SEVERE LOWS







OF PATIENTS REDUCED THEIR A1C



#### Data on File Data as measured by device sensor. Bergenstal RM, et al. *JAMA*. 2016;316(13):1407-1408. Garg SK, et al. *Diabetes Technol Ther*. 2017;19(3):155-163.

#### Sensor Glucose Distribution - MINIMED™ 670G System



#### IMPORTANT SAFETY INFORMATION: MINIMED<sup>™</sup> 670G SYSTEM

The Medtronic MiniMed<sup>™</sup> 670G system is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of type 1 diabetes mellitus in persons, fourteen years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed<sup>™</sup> 670G system includes SmartGuard<sup>™</sup> technology, which can be programmed to automatically adjust delivery of basal insulin based on continuous glucose monitor sensor glucose values, and can suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values. The system requires a prescription. The Guardian<sup>™</sup> Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. A confirmatory finger stick test via the CONTOUR®NEXT LINK 2.4 blood glucose meter is required prior to making adjustments to diabetes therapy. All therapy adjustments should be based on measurements obtained using the CONTOUR®NEXT LINK 2.4 blood glucose meter and not on values provided by the Guardian<sup>™</sup> Sensor (3). Always check the pump display to ensure the glucose result shown agrees with the glucose results shown on the CONTOUR®NEXT LINK 2.4 blood glucose meter. Do not calibrate your CGM device or calculate a bolus using a blood glucose meter result taken from an alternative site (palm) or from a control solution test. It is not recommended to calibrate your CGM device when sensor or blood glucose values are changing rapidly, e.g., following a meal or physical exercise. If a control solution test is out of range, please note that the result may be transmitted to your pump when in the "Always" send mode. WARNING: Medtronic performed an evaluation of the MiniMed™ 670G system and determined that it may not be safe for use in children under the age of 7 because of the way that the system is designed and the daily insulin requirements. Therefore this device should not be used in anyone under the age of 7 years old. This device should also not be used in patients who require less than a total daily insulin dose of 8 units per day because the device requires a minimum of 8 units per day to operate safely. Only use rapid acting U100 insulin with this system. Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms. Pump therapy is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional. The safety of the MiniMed<sup>™</sup> 670G system has not been studied in pregnant women. For complete details, including product and important safety information concerning the system and its components, please consult http://www.medtronicdiabetes.com/important-safety-information#minimed-670g and the appropriate user guide at http://www.medtronicdiabetes.com/download-library

#### ADDITIONAL WARNINGS: MINIMED™ 670G SYSTEM

WARNING: Do not use Auto Mode for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in Auto Mode. Therefore, Auto Mode could deliver too much insulin. Too much insulin may cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you resume Auto Mode.

WARNING: Suspend before low and Suspend on low are not intended to be a treatment for low blood glucose. Having insulin suspended when glucose is low may not bring your blood glucose back to your target range for several hours. In that case, you run the risk of hypoglycemia. Always confirm your blood glucose readings with your BG meter and treat according to the recommendations of your healthcare professional.

WARNING: Do not use the Suspend on ow feature until you have read the information in this user guide and received instructions from your healthcare professional. The Suspend on low feature causes the pump to temporarily suspend insulin delivery for a maximum of two hours. Under some conditions of use, the pump can suspend again, resulting in limited insulin delivery. Prolonged suspension can increase the risk of serious hyperglycemia, ketosis, and ketoacidosis.

WARNING: Do not make therapy treatment decisions based on sensor glucose values. Sensor glucose (SG) and blood glucose (BG) values may differ. If your sensor glucose reading is low or high, or if you feel symptoms of low or high glucose, confirm your sensor glucose reading with your BG meter prior to making therapy decisions to avoid hypoglycemia or hyperglycemia.

### **MEDTRONIC DIABETES CLOSED LOOP PIPELINE**

#### **IN MARKET**



#### MiniMed<sup>™</sup> 670G System

Advanced protection from lows & highs Real-world outcomes Peds indication (7 and up)



**CONNECTED PUMP** | Enabled with remote wireless updates & auto-uploads

MiniMed<sup>™</sup> 770G<sup>+</sup>

- Peds (2+ yr)
- Automatic wireless uploads to CareLink
- Smartphone display of pump data
- Remote software upgrades

#### MiniMed<sup>™</sup> 780G <sup>+</sup>



**PIPELINE GOALS | Reducing burden, improving outcomes** 

ADVANCED HYBRID CLOSED LOOP | Auto correction bolus + ease of use

- Improved handing of hyperglycemia
- Simplified meal management
- >80% TIR
- Remote software upgrades

#### **Personalized Closed Loop<sup>+</sup>**



Breakthrough Device Designation

**CONNECTED PUMP WITH ANALYTICS |** Personalized algorithm to optimize therapy for each individual patient

- Personalized control adaptations
- Optional meal announcements
- Goal of >85% TIR
- Remote software upgrades