Subject: Change in Warranty Fulfillment

Dear Patient,

As you know, we made the difficult decision to discontinue the sale of Animas® Vibe® and OneTouch Ping® insulin pumps in the United States and are working diligently to transition all Animas patients to another insulin delivery system and exit the market by September 2019.

Warranty Fulfillment

As part of this transition, Animas is making changes to the way we fulfill insulin pump warranties. While we will continue to honor your pump warranty, **beginning November 12, 2018, we will give you the choice of either the MiniMed™ 670G system or the MiniMed™ 630G system* instead of an Animas insulin pump** in the event of a pump failure. We will work to ensure continuity of therapy while you receive the appropriate training to onboard you onto a Medtronic pump. We are committed to continuing to fulfill our warranty obligations as referenced in the Owner's booklet by providing a comparable replacement insulin pump to ensure the continuity of your therapy.

If you have additional questions regarding this change in warranty fulfillment, please call 877.937.7867, option 1.

As always, **patient safety and continuity of care are of the utmost priority to Animas**. Ultimately, the choice of therapy options is yours, but the goal of our partnership with Medtronic is to ensure this transition goes as smoothly as possible for you and your healthcare provider.

Again, ensuring you avoid disruption of pump therapy is a top priority. Start exploring your new options today.

Sincerely,

Animas® LLC

* Optional Continuous Glucose Monitoring (CGM).

Children under the age of 7 will be exempt, and there may be exceptions for medically urgent circumstances or in other situations that do not allow for a pump transition to a Medtronic MiniMed™ 670G System or MiniMed™ 630G System.

IMPORTANT SAFETY INFORMATION: MINIMED™ 670G SYSTEM

The Medtronic MiniMed 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, seven 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 670G system includes SmartGuard 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 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 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. Also, 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.

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 670G system has not been studied in pregnant women. For complete details of the system, including product and important safety information such as indications, contraindications, warnings and precautions associated with 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.

IMPORTANT SAFETY INFORMATION: MINIMED™ 530G SYSTEM AND MINIMED™ 630G SYSTEM
Indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus. MiniMed™ 630G system is approved for ages 14 years or older with Guardian™ Sensor 3 and MiniMed™ 530G system is approved for ages 16 years or older with Enlite™ sensor. Both systems require a prescription. Insulin infusion pumps and associated components of insulin infusion systems are limited to sale by or on the order of a physician and should only be used under the direction of a healthcare professional familiar with the risks of insulin pump therapy. Pump therapy is not recommended for people who are unwilling or unable to perform a minimum of four blood glucose tests per day. Pump therapy is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional. Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms. Insulin pumps use rapid-acting insulin. If your insulin delivery is interrupted for any reason, you must be prepared to replace the missed insulin immediately. Replace the infusion set every 48–72 hours, or more frequently per your healthcare professional's instructions. Insertion of a glucose sensor may cause bleeding or irritation at the insertion site. Consult a physician immediately if you experience significant pain or if you suspect that the site is infected. The information provided by CGM systems is intended to supplement, not replace, blood glucose information obtained using a blood glucose meter. A confirmatory fingerstick using a CONTOUR®NEXT LINK 2.4 meter is required prior to making adjustments to diabetes therapy. Always check the pump display when using a CONTOUR®NEXT LINK 2.4 meter, to ensure the glucose result shown agrees with the glucose results shown on the meter. Do not calibrate your CGM device or calculate a bolus using a result taken from an Alternative Site (palm) or a result from a control solution test. 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. 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**.** The MiniMed™ 630G or MiniMed™ 530G system are not intended to be used directly for preventing or treating hypoglycemia but to suspend insulin delivery when the user is unable to respond to the Suspend on low alarm and take measures to prevent or treat hypoglycemia themselves. Therapy to prevent or treat hypoglycemia should be administered according to the recommendations of the user's healthcare provider.
WARNING: The SmartGuard™ feature will cause the pump to temporarily suspend insulin delivery for two hours when the sensor glucose reaches a set threshold. Under some conditions of use the pump can suspend again, resulting in very limited insulin delivery. Prolonged suspension can increase the risk of serious hyperglycemia, ketosis, and ketoacidosis. Before using the SmartGuard feature, it is important to read the SmartGuard™ feature information in the User Guide and discuss proper use of the feature with your healthcare provider.

See www.medtronicdiabetes.com/importantsafetyinformation and the appropriate user guides for additional important details.

You are receiving this material because you are currently on an Animas® pump. Visit Animas.com/privacy-policy to view the Notice of Privacy Practices for Animas® Corporation. To opt out of communications from Animas®, contact us at 877-937-7867.

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