

# IMPORTANT PRODUCT INFORMATION

Medtronic

## Discontinuation of Sof-sensor<sup>®</sup> Glucose Sensor

September 30, 2015

Dear Valued Customer,

We are contacting you today to inform you that on December 1<sup>st</sup>, 2015, the Sof-sensor glucose sensor will be discontinued. Please note that this discontinuation does not concern the safety or performance of Sof-sensor.

As of December 1<sup>st</sup>, 2015, we will no longer sell a CGM (continuous glucose monitoring) sensor approved for use with the following products:

- 1) Paradigm<sup>®</sup> REAL-Time insulin pump
- 2) Paradigm<sup>®</sup> REAL-Time Revel<sup>™</sup> insulin pump
- 3) Guardian<sup>®</sup> REAL-Time Continuous Glucose Monitoring System

Our records indicate you may currently be using Sof-sensors with one of the above products. Please note that although Medtronic will no longer be able to provide Sof-sensors after December 1<sup>st</sup>, 2015, a Paradigm pump can continue to be used as a standalone insulin pump. Our 24-Hour HelpLine team will also continue to provide technical support for Sof-sensors for as long as you need us.

We recognize you as one of our most loyal and appreciated customers, and we know that CGM is an important part of your diabetes management. In an effort to make your transition as easy as possible, we would like to offer you our latest insulin pump and CGM technology, the MiniMed<sup>®</sup> 530G with Enlite<sup>®</sup> sensor<sup>1</sup>, at **no cost to you**. Additionally, to help get you started on Enlite, we will provide your first three (3) month supply of Enlite sensors at **no cost to you**.

We understand the impact this has on you, and we wish to offer our support and guidance during this transition:

- 1) Please reach out to your healthcare provider to discuss your options. We have already notified endocrinologists and diabetologists about this discontinuation.
- 2) You may continue to use Sof-sensors while your supplies last. A customer care representative will be reaching out to you in the coming days to check up on your remaining sensor supply, and to provide you with details on the upgrade to MiniMed 530G with Enlite at no cost to you. For more information on the benefits of the MiniMed 530G with Enlite system, visit: [www.medtronicdiabetes.com/MM530G](http://www.medtronicdiabetes.com/MM530G).
- 3) For more information on the discontinuation of Sof-sensor, review our frequently asked questions at [www.medtronicdiabetes.com/notice3A](http://www.medtronicdiabetes.com/notice3A). Should you have any other questions or concerns, please contact our support line at 1.888.472.0623 Monday through Friday 8:00AM – 6:00PM Central Time.

Please know we did not reach the decision to discontinue Sof-sensor easily. As we prepare to pave the way for new products with improved therapeutic benefit, we must ensure only our most advanced CGM sensor technology remains on the market. As a result, we have found it necessary to discontinue Sof-sensor, our oldest CGM sensor.

We value your loyalty and commitment to Medtronic, and are dedicated to partnering with you during this transition.

At your service,

Medtronic Diabetes

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## Questions and Answers

### 1. Why am I getting this letter?

Our records show that you have ordered Sof-sensor in the past, and we are notifying you that we are discontinuing sale of this glucose sensor.

### 2. Why is Sof-sensor not being sold anymore?

We know it is disappointing when a product is no longer available and we do not make the decision to discontinue a product lightly. Please note that this discontinuation does not concern the safety or performance of Sof-sensor. We are committed to introducing new technologies with advanced therapeutic benefits. In order to make our future technology available to you, we must ensure only our most advanced sensor technology remains on the market. As a result we have found it necessary to discontinue Sof-sensor, our oldest CGM sensor, which was first released in 1999.

### 3. Do I need to stop using Sof-sensors right now?

No, we encourage you to continue using Sof-sensors until you are fully transitioned to an alternative glucose sensor. You can continue to purchase Sof-sensors until December 1<sup>st</sup>, 2015. Upon that date, Medtronic will no longer be selling Sof-sensors. As always, you may place an order for glucose sensors by contacting our Supply Management team at 1.800.646.4633 Option 2; Monday through Friday 8:00AM – 6:00PM Central Time.

### 4. What is the difference between Sof-sensor and Enlite?

There are many improvements in comfort and accuracy with the Enlite sensor. When compared to Sof-sensor, Enlite has 69% less sensor volume and is 38% shorter under the skin<sup>2</sup>. There is a 31% improvement in overall accuracy, and when it's used with MiniMed 530G there is a 93% hypoglycemia detection rate<sup>3</sup>. For more information on the benefits of the Enlite sensor, visit:

<http://www.medtronicdiabetes.com/products/enlite-sensor>

### 5. Is Guardian REAL-Time approved for use with the Enlite sensor?

Unfortunately the Enlite sensor is currently not approved for use with the Guardian REAL-Time system. We encourage you to reach out to your healthcare provider to discuss your options.

### 6. Do I need a prescription from my doctor to get on the MiniMed 530G with Enlite?

New insulin pump and CGM upgrades generally require a prescription, and most prescriptions are valid for one (1) year. We will work with your healthcare professional to get a new prescription if one is needed.

## **7. Will my insurance cover MiniMed 530G with Enlite?**

We will cover any out of pocket costs associated with your upgrade to MiniMed 530G and your first three (3) month order of Enlite sensors. If your Sof-sensors are currently covered by your insurance provider, then any future purchases of Enlite sensors should be as well. For a courtesy insurance verification, contact our Supply Management team at 1.800.646.4633, Option 2 (Mon-Fri 8AM – 6PM Central Time).

## **8. Will Enlite sensors cost more?**

If you have insurance, this will depend on your insurance coverage. The list price for a box of Enlite sensors is more than a box of Sof-sensors, but the Enlite is approved for 6 days of use, so the cost for a 30-day supply is similar. If you are interested in learning more, contact our Supply Management team at 1.800.646.4633, Option 2 (Mon-Fri 8AM – 6PM Central Time).

If you do not have insurance, please contact our Supply Management team at the number above, and they will provide you with the retail prices for the Enlite sensor.

## **9. Will I receive training on the new MiniMed 530G with Enlite system?**

Yes. Once you have upgraded to MiniMed 530G with Enlite, a Medtronic training specialist or certified product trainer will reach out to you to schedule an in-person training. In the meantime, we encourage you to refer to the MiniMed 530G with Enlite user guide included in your shipment box, or online at:

[www.medtronicdiabetes.com/MM530G-User-Guide](http://www.medtronicdiabetes.com/MM530G-User-Guide)

You can also access the many online training resources we have available through our website at

<http://www.medtronicdiabetes.com/customer-support>

If you require additional assistance after training, or any time you have a question or concern about your system, our 24-Hour HelpLine is available for you 24 hours a day at 1.800.646.4633 Option 1.

1. MiniMed 530G with Enlite approved for ages 16 and older; not indicated for use with people who are pregnant or on dialysis  
2. Data on file: MiniMed 530G User Guide, Paradigm REAL-Time Revel User Guide  
3. Enlite Sensor Performance Clinical Appendix; Sensor calibrated 3-4 times a day and predictive and low alerts both turned ON  
Please visit for Product and Safety Information: <http://www.medtronicdiabetes.com/important-safety-information>.