

MiniMed Announces FDA Clearance of MiniMed Flex™, the Company's Smallest Insulin Pump Featuring Its First Smartphone-Controlled Design

MiniMed Flex™ is about half the size of the previous generation MiniMed™ 780G system, and features the SmartGuard™ adaptive algorithm to automatically adjust and autocorrect insulin delivery in real-time

NORTHRIDGE, Calif., March 18, 2026 /PRNewswire/ -- MiniMed (Nasdaq: MMED), a global leader in diabetes technology, today announced U.S. Food and Drug Administration (FDA) clearance of MiniMed Flex™, a next-generation discreet, smartphone-controlled insulin pump designed to fit seamlessly into everyday life.

About half the size* of the MiniMed™ 780G pump and roughly the size of two stacked insulin vials, MiniMed Flex™ is the company's first screenless design created in partnership with people living with diabetes to deliver an intuitive, lifestyle-friendly way to manage the condition. MiniMed Flex™ is powered by the company's most advanced SmartGuard™ algorithm with Meal Detection™ technology, which has proven clinical performance that exceeds worldwide Time in Range recommendations.^{1,2} At commercial launch, MiniMed Flex™ will support the company's newest sensor portfolio, including Simplerla Sync™ sensor and the Instinct sensor, made by Abbott.

"At MiniMed, our Mission is to make every day a better day for people with diabetes," said Que Dallara, chief executive officer of MiniMed. "MiniMed Flex™ embodies that promise. It's designed to work quietly and reliably in the background – advanced automation wrapped in a compact, smartphone-controlled pump. The result is technology that lets people spend less time managing diabetes and more time living their lives. Securing FDA clearance for our first product as a standalone, public company – just one week after our IPO – marks a major milestone and underscores our commitment to delivering the breakthrough innovation our customers deserve."

MiniMed Flex™ represents a major redesign of MiniMed's insulin pumps. Key features include:

- **Small, sleek design with high insulin capacity:** Designed to be worn wherever users prefer – in a pocket or out of sight – while delivering a 300-unit insulin reservoir to support a range of insulin needs.
- **Smartphone-controlled:** Managed through a compatible mobile app, eliminating the traditional pump screen, with seamless software updates delivered through iOS and Android devices at launch.
- **Sensor compatibility:** At commercial launch, MiniMed Flex™ will support the company's newest sensor portfolio, including Simplerla Sync™ sensor and the Instinct sensor, made by Abbott.
- **Extended infusion set options:** Works with MiniMed's infusion set portfolio, including the Extended™ infusion set with up to 7 days of wear, delivering up to 96% fewer injections compared with traditional insulin therapy.⁰
- **Proven AID performance:** Real-world results have demonstrated 80% Time in Range with recommended settings.^{3**}

"MiniMed Flex™ represents an important leap forward for MiniMed," said Anders Carlson, MD, Medical Director of the International Diabetes Center at Park Nicollet, Director of the HealthPartners Diabetes Program, and an assistant professor in the University of Minnesota Medical School. "For many people living with diabetes, the burden of daily management can be overwhelming. By combining a discreet, screenless form factor with a powerful adaptive algorithm that responds quickly to changes in glucose, MiniMed Flex™ brings meaningful innovation exactly where it's needed—into the flow of everyday life. This level of automation, paired with the freedom of smartphone control, has the potential to improve consistency, confidence, and ultimately clinical outcomes for a broad range of patients with diabetes."

Launch of MiniMed™ Forward Program: Enabling a Seamless Upgrade from the MiniMed™ 780G system to MiniMed Flex™ system
MiniMed also announced the MiniMed™ Forward Program, which allows customers who start on the MiniMed™ 780G system to upgrade to the MiniMed Flex™ system for \$0.*** New MiniMed™ 780G system users who enroll in the program will be notified when the MiniMed Flex™ system becomes commercially available in the U.S. and will receive instructions for completing the upgrade.

The launch of the MiniMed Flex™ system will begin with a customer experience phase this spring involving select current MiniMed customers, followed by a broader commercial launch planned for the summer.

MiniMed Flex™ is cleared for individuals ages 7 and older with type 1 diabetes, and for individuals 18 years and older with insulin-requiring type 2 diabetes.

Frequently Asked Questions

Q: What is the MiniMed Flex™ system?

A: The MiniMed Flex™ system is MiniMed's next-generation automated insulin delivery system featuring a small, smartphone-controlled

insulin pump powered by the proven SmartGuard™ algorithm with Meal Detection™ technology. The system includes a 7-day infusion set, a 300-unit reservoir, and is designed with a compact form factor for users to wear as they like – in a pocket or out of sight.

Q: Can current MiniMed™ 780G users upgrade to MiniMed Flex™ system?

A: Yes. Eligible users of the MiniMed™ 780G system may upgrade to MiniMed Flex™ through the MiniMed™ Forward Program. Because MiniMed Flex™ maintains compatibility with MiniMed's existing reservoir and infusion set portfolio, the transition is designed to be straightforward for current users.

Q: What sensors are compatible with MiniMed Flex™ system?

A: At commercial launch, MiniMed Flex™ will support the company's newest sensor portfolio, including Simplera Sync™ sensor and the Instinct sensor, made by Abbott.

About MiniMed

MiniMed is a global leader in insulin delivery, constantly advancing therapies that support people with diabetes in 80 countries. Our full-stack, integrated ecosystem, including our insulin delivery systems, CGMs, algorithms, and easy-to-use app experience, is designed to work seamlessly together, supported by white-glove, wrap-around service. For over 40 years, we've pioneered therapies people can rely on by anticipating needs, reducing burden, and helping make life with diabetes easier. Our mission is to make every day a better day for people with diabetes.

Any forward-looking statements are subject to risks and uncertainties such as those described in MiniMed's filings with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

*Pump dimensions on File - IFU Labeling. Overall size related to volume.

**Due to inherent real-world study limitations, caution is advised when attempting to extrapolate these results to new patients. There could be significant differences.

***Applies to customers who have purchased a MiniMed™ 780G system between February 18, 2026, and launch.


◇ Assumes 4 injections per day for 30 days and one infusion set change every seven days

- Arrieta A, et al. *Diabetes Obes Metab.* 2022;10.1111/dom.14714.
- American Diabetes Association Professional Practice Committee; 13. Older Adults: Standards of Care in Diabetes–2025. *Diabetes Care* 1 January 2025; 48 (Supplement_1): S266-S282.
- Nally LM, et al.; SUCCEED Study Group. Safety and Glycemic Outcomes of the MiniMed 780G System with a Disposable All-inOne Sensor. *Diabetes Technol Ther.* 2026 Feb;28(2):109-120. doi: 10.1177/15209156251368928.

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Additional assets available online: 

https://stage.mediaroom.com/minimed_mr/2026-03-18-MiniMed-Announces-FDA-Clearance-of-MiniMed-Flex-TM-,the-Companys-Smallest-Insulin-Pump-Featuring-Its-First-Smartphone-Controlled-Design