# FDA Clears MiniMed Fit™ -- World's First and Only Tubeless Insulin Pump with Up to Seven-Day Wear and Zero Interruptions

*The only tubeless pump with no charging or cartridge changes for up to seven days, combined with a 300-unit insulin capacity and advanced insulin automation*

NORTHRIDGE, Calif., Nov. 16, 2026 /PRNewswire/ -- MiniMed (Nasdaq: MMED) today announced U.S. Food and Drug Administration (FDA) clearance of MiniMed Fit™, the company's first tubeless insulin pump, offering people with diabetes a new differentiated option that combines up to seven days of wear, a 300-unit insulin capacity, app control and proven SmartGuard™ technology.

MiniMed Fit™ marks a significant expansion of the company's insulin delivery portfolio, bringing its advanced automated insulin delivery technology to a tubeless design for the first time. With up to twice the wear time of other tubeless options* and 50% more insulin capacity,† the system reduces the number of pump changes and daily decisions, so there is less to do and less to think about with diabetes management.

"People with diabetes shouldn't have to choose between the freedom of tubeless wear and the health outcomes they deserve," said Que Dallara, chief executive officer of MiniMed. "MiniMed Fit™ brings the technology people trust from MiniMed into a tubeless design that fits their lives. Clearing FDA ahead of schedule is more proof we're executing our strategy. It puts MiniMed Fit in U.S. customers' hands sooner, and the pharmacy channel makes it easier to get."

**Everything a tubeless pump should be**

MiniMed Fit™ is designed to automate more of the work of diabetes management and reduce interruptions in daily routines. It combines a discreet, waterproof tubeless pump with app control on compatible iOS and Android devices and at commercial launch will offer the choice of two all-in-one sensors: Simplera Sync™ with up to seven days of wear and Instinct™, made by Abbott, with up to 15 days of wear.

- **Fewer changes. More freedom.** With up to seven days of wear and 300-unit insulin capacity, MiniMed Fit™ offers up to twice the wear time and more insulin than other tubeless insulin pump options, meaning fewer pump changes and more time to focus on what matters. *†‡
- **Automation every five minutes.** Powered by SmartGuard™ technology, the system automatically adjusts insulin delivery and can deliver correction doses every five minutes.§
- **Easier mealtimes.** With Meal Detection™ technology, the system can deliver additional insulin when a meal dose is sometimes missed or underestimated. §‖
- **More time in range, day and night.** Real-world users of SmartGuard™ technology have achieved up to 80% Time in Range and 91% overnight Time in Range with recommended settings, helping people spend more time in their target glucose range. ¶ #**1,2
- **Flexible wear locations and insulin compatibility.** Wear locations are back of arm, lower back, upper buttocks, abdomen, and thigh. Compatible insulins are Humalog, NovoLog, and Admelog.
- **Easier access through the pharmacy.** MiniMed Fit™ will be available through the pharmacy channel, offering a convenient way for people to access.
- **Built for what's next.** MiniMed Fit™ is designed for future innovation, including the planned integration with MiniMed's next-generation fully closed-loop technology (investigational).

The MiniMed Fit™ launch is expected to begin with a phased rollout in the U.S. in spring 2027, following an early customer experience phase expected to begin in MiniMed's fourth quarter of fiscal year 2027.

In preparation for launch, MiniMed has been building manufacturing capacity and commercial infrastructure alongside the regulatory process. The company plans to significantly expand manufacturing capacity as commercialization progresses to support growing demand and capitalize on a new growth opportunity in tubeless insulin pumps.

MiniMed Fit™ is cleared for people with Type 1 and Type 2 diabetes ages 7 and older. People interested in learning more about MiniMed Fit™ availability can request to receive updates at minimed.com/fit.

**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 periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.**

**Footnotes & References**

*Tandem Mobi can be worn up to 7 days with a required cartridge change at 3 days. Omnipod can be worn up to 3 days. Mint has 3-day wear, plus a 12-hour grace period for insulin delivery. See user guides for more details.

† Omnipod, Mint, and Mobi tubeless devices hold 200 units. See product IFUs for details.

‡ 7-day wear achievable with less than 42 units of total daily dose. Total daily dose may impact frequency of changes.

§ Refers to SmartGuard™ feature. Individual results may vary.

‖ Taking a bolus 15–20 minutes before a meal helps to keep blood sugar levels under control after eating.

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

# Real-world evidence. N=101,629. 86.3% users achieved >70% Time in Range

** Overnight period: 12:00 AM- 6:00 AM. Number of users with ≥10 days of sensor glucose data; Optimal settings are glucose target at 100 mg/dL (5.5 mmol/L) and Active Insulin Time (AIT) at 2 hours and used >95% of the time.

∞ Pump is waterproof up to 8 feet (2.4 meters) for 1 hour and 45 minutes. If you choose to stay connected while in water, CGM readings may not be transmitted to the pump.

1. Choudhary P, et al. Celebrating the Data from 100,000 Real-World Users of the MiniMed™ 780G System in Europe, Middle East, and Africa Collected Over 3 Years: From Data to Clinical Evidence. *Diabetes Technol Ther.* 2024;26 (Suppl. 3):S32-S37.15

2. McVean JJF, Niu F, Liu M, et al. Automated insulin delivery with the MiniMed™ 780G system reduces burden by improving sleep and glycaemic control overnight. *Diabetes Obes Metab.* 2026;28(3):2456-2460. doi:10.1111/dom.70380

SOURCE MiniMed

For further information: CONTACTS: Ashley Patterson, Communications, +1 (818) 576-3025, OR Ryan Weispfenning, Investor Relations, +1 (763) 505-4626

---

Additional assets available online: Photos

https://news.minimed.com/2026-11-16-FDA-Clears-MiniMed-Fit-TM-Worlds-First-and-Only-Tubeless-Insulin-Pump-with-Up-to-Seven-Day-Wear-and-Zero-Interruptions