

The next generation of diabetes technology



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New devices are coming, but the real advances will involve combinations.

On an earnings call last month Abbott's chief executive, Robert Ford, called the group's continuous glucose monitor Freestyle Libre 3 a "very, very compelling product". It is only compelling in Europe, however: though it was CE marked in 2020, it has yet to gain US approval.

Abbott's rival Dexcom, whose latest glucose sensor was CE marked last month, is in the same situation. Developers in diabetes tech must innovate constantly just to keep up, and a new generation of devices is poised to enter the market. After that, the next step is even more crucial, as makers of sensors and insulin pumps seek to collaborate on creating closed-loop artificial pancreas systems.

Libre 3 is a key product launch for Abbott, and the company says its rollout in Europe is going well. But it exemplifies the time lag frequently seen between Europe and US approvals: the previous iteration [took two and a half years to reach the US](#) after it had already gained European CE mark. For Libre 3 the gap is 18 months and counting.

Selected current and forthcoming diabetes devices - in-house

Company	Technology	Type	Status
Abbott	Freestyle Libre 2	iCGM	CE marked Oct 2018; FDA approved Jun 2020
Abbott	Freestyle Libre 3	iCGM	CE marked Sep 2020; awaiting FDA approval
Dexcom	G6	iCGM	FDA approved Mar 2018; CE marked Jun 2018
Dexcom	G7	iCGM	CE marked Mar 2022; awaiting FDA approval
Insulet	Omnipod Dash	Insulin pump	FDA approved Jun 2018; CE marked Sep 2019
Insulet	Omnipod 5*	Insulin pump	FDA approved Jan 2022; awaiting CE mark
Tandem	t:slim X2	Insulin pump	FDA approved Aug 2017; CE marked Apr 2018
Tandem	t:slim X3	Insulin pump	In development
Tandem	Mobi	Insulin pump	Expected 2022
Ypsomed	Mylife YpsoPump	Insulin pump	CE marked Jun 2016
Medtronic	Minimed 770G	Closed-loop	FDA approved Aug 2020; CE marked
Medtronic	Minimed 780G	Closed-loop	CE marked Jun 2020; awaiting FDA approval

*iCGM = continuous glucose monitor. *Formerly called Omnipod Horizon. Source: company communications & analyst notes.*

It is a similar story for Dexcom, which makes a blood sugar monitor called the G7. In the US these advanced glucose sensors are used by 80-90% of patients with type 1 diabetes, according to Stifel analysts – the other patients use more basic gadgets that use regular fingerstick blood tests to measure sugar levels.

These machines are filed with the FDA as interoperable, or integrated, continuous glucose monitors (iCGM), meaning that they can transmit data to connected devices, including automated insulin pumps. Dexcom dominates the market for current-generation iCGMs, with 80-90% of users. But approval for Libre 3 with pump integration could move the needle towards Abbott, the analysts write. The race is on between these two groups to get their blood sugar monitors approved in the US.

Combos

The aim of integrating sensors and pumps is to produce a closed-loop system that can adjust the insulin dose without input from the user – a so-called artificial pancreas.

With this aim in mind developers of iCGMs have for many years partnered with insulin pump makers, using their systems together. Theoretically, a new generation of closed-loop systems should be on the cards very soon after the individual devices get the nod from the regulators.

But one of the key insulin pump makers, Insulet, finds itself in an unusual position. Its new-generation product, a tubeless device called Omnipod 5, is approved in the US but not yet in Europe. Combination with either Abbott's or Dexcom's iCGMs will require regulatory action on one, and ideally both, sides of the Atlantic.

The other main developer of advanced insulin dosing systems is Tandem Diabetes Care. Tandem has two new products approaching the market: the next step-change of its flagship t:slim device, the X3, and a leadless pump called Mobi. Mobi is expected to gain approval this year, but no timeline has yet emerged for the t:slim X3.

Tandem is the current leader in terms of share. Between 60% and 80% of type 1 diabetics currently use insulin pumps, with 70-75% of this group using Tandem pumps, versus around 20% using Insulet's products. However, Stifel expects this mix to shift dramatically to closer to fifty/fifty following the full rollout of Omnipod 5 in Europe and its launch in the US.

One of the underdogs here recently scored a coup. Last week Abbott agreed to combine its Libre 3 iCGM with a pump from the Swiss company Ypsomed; the combination is still in development but could give both groups a fillip if it launches next year.

Selected current and forthcoming diabetes devices - collaborations

Companies	Technology	Type	Status
Insulet/Dexcom	Omnipod 5* with G6	Closed-loop	Approved US Jan 2022
Insulet/Dexcom	Omnipod 5 with G7	Closed-loop	Expected 2022
Insulet/Abbott	Omnipod 5 with Freestyle Libre 2	Closed-loop	Expected 2023
Insulet/Abbott	Omnipod 5 with Freestyle Libre 3	Closed-loop	Expected 2023
Ypsomed/Abbott	Mylife YpsoPump with FreeStyle Libre 3	Closed-loop	Expected 2023
Tandem/Dexcom	t:slim X2 with G6	Closed-loop	FDA approved and CE marked Dec 2019
Tandem/Dexcom	t:slim X2 with G7	Closed-loop	Expected 2022 or 2023
Tandem/Abbott	t:slim X2 with Freestyle Libre 2	Closed-loop	Expected 2022
Tandem/Abbott	t:slim X2 with Freestyle Libre 3	Closed-loop	Expected 2022 or 2023

**Formerly called Omnipod Horizon. Source: company communications & analyst notes.*

The outlier here is Medtronic. The world's biggest device seller is the only group to have developed a closed-loop system - indeed, a sequence of them - in-house. The latest version is the Minimed 780G, available in Europe but not yet in the US.

In prior years this series has done well, but in December Medtronic [received an FDA warning letter](#) regarding quality control at the headquarters of its diabetes tech business that will delay the 780G's launch.

The interesting aspect of the market for advanced diabetes devices is that it is a mixture of competition and collaboration. The rivalry between makers of similar devices is furious, yet at the same time these groups are collaborating with developers of complementary systems. 2022 sees the stage set for a showdown between many of these companies; the stakes are high, and investors as well as patients are ardent for success.

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