



MedTech to Watch 2024 Diabetes

Diabetes care devices



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Diabetes care technology is poised for significant growth, driven by ongoing advancements in medical technology and an expanding population of individuals affected by diabetes. Key factors affecting growth in this highly competitive market remain innovation, increasing availability of non-invasive alternatives, diversification of the market with the entry of new competitors, and increasing patient awareness.

Beyond these developments, significant activity is also underway in developing alternative treatment options for diabetes management, including new drug therapies and medical procedures that could potentially impact the growth trend of the diabetes care technology market in the coming years.

Why is continuous glucose monitoring and closed loop insulin delivery a medical technology to watch?

A new wave
of non-invasive
CGMs is
emerging.

Continuous Glucose Monitoring (CGM) has grown rapidly in recent years and is poised to expand exponentially. Currently, Dexcom and Abbott Laboratories dominate this market, having made considerable strides in their existing products, with a focus on compact, all-in-one sensor transmitter designs and device optimization. These market leaders continue to drive market expansion for CGM devices. For example, DexCom recently received FDA approval for the first over the counter CGM device in the USA, Stelo, which is targeted at Type 2 diabetes patients who do not use insulin. Furthermore, DexCom and other manufacturers are encouraging the FDA to support use of CGM as a diagnostic tool to detect prediabetes and undiagnosed Type 2 diabetes.

In the USA, the recent expansion of Medicare coverage for CGM devices to encompass individuals with type 2 diabetes using any form of insulin, along with certain non-insulin users who may qualify for CGM device coverage due to a history of problematic hypoglycemia, has made CGM devices more accessible to a broader patient base, further bolstering market growth within this space in coming years.

While existing CGM companies focus on minimizing the sensor size to make it aesthetically appealing, Senseonics and Gilyson take a different approach featuring a sensor that is implanted under the skin and lasts more than six months, compared to current patch-based devices which lasts for weeks at most. This innovation caters to patients seeking a discreet and **long-lasting solution**, requiring relatively few sensor changes.

A new wave of **non-invasive CGMs** is emerging, potentially disrupting the traditional CGM market. Examples include Know Labs' KnowU system and Nemaura Medical's sugarBEAT CGM, which would eliminate the need for sensor implantation or insertion into the body. While these advancements represent significant potential, accessibility remains a key concern. Establishing both clinical efficacy and affordability will be crucial for widespread adoption of these novel CGM technologies.


Minimizing device size and reducing device complexity remains a key focus for manufacturers. This is evident by the recent growth in the **patch pump market**; a type of insulin pump segment designed to be worn directly on the skin like an adhesive patch, exemplified by the strong performance of Insulet's Omnipod 5 and more recently approved Roche's Accu-Chek Solo patch pump. Recognizing the growing patch pump market within hybrid closed-loop systems, competitors like Medtronic and Tandem Diabetes Care are developing their own patch pumps.

Additionally, new entrants like Pharmasens are seeking FDA approval for their niia patch pump, promising extended wear time and potentially improving user convenience. The widespread physician adoption of established brands might initially limit the market share of new entrants. Despite this, these upcoming launches are expected to contribute to the overall market growth by offering patients more choices and potentially driving innovation in the insulin pump space.

Next the introduction of **hybrid closed-loop systems**, is fueling the overall growth of diabetes care technology. Medtronic, was the first to enter this market, receiving FDA approval for their advanced Minimed 780G in April 2023. Currently, the use of hybrid closed-loop systems is more common among individuals with type 1 diabetes. But several companies are conducting clinical trials to test the effectiveness of these hybrid closed loop systems for type 2 diabetic population. For instance, Medtronic's (Minimed 780G), Insulet's (Omnipod 5) are conducting clinical trials to study

the effectiveness of its insulin pump devices. Positive outcomes from these trials could pave the way for expanded indications, making these systems accessible to a much wider range of type 2 diabetes patients.

Another significant area worth monitoring is the **fully closed-loop insulin delivery system**. On May 22, 2023, the US Food and Drug Administration (FDA) granted 510(k) clearance to Beta Bionics' iLet Bionic Pancreas, marking a pivotal milestone in diabetes management technology. The iLet stands as the first and sole fully automated insulin delivery system approved for individuals with type 1 diabetes aged six and above. Unlike conventional pumps that necessitate users to calculate and administer insulin doses, the iLet autonomously determines and dispenses both basal and bolus insulin based on CGM data and an algorithm. Alongside Beta Bionic's iLet Bionic Pancreas, the EOfFlow' EOpatch pump is another device within the closed-loop insulin delivery market that has submitted its device for FDA approval.



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How will Diabetes care devices impact the Metabolic market?

The CGM market is expected to boost the overall diabetes care device market and is projected to reach \$7.5 bn USD by 2032 in USA.

The extended CMS coverage makes the device affordable to a larger type 2 diabetic patient pool, thereby increasing the demand and patient base for these products. Nonetheless, the entry of new competitors under **non-invasive glucose monitoring** segment is going to expand the existing glucose monitoring device market. At present, non-invasive alternatives are not likely to pose a major immediate threat to the established CGM market primarily due to limited accuracy,

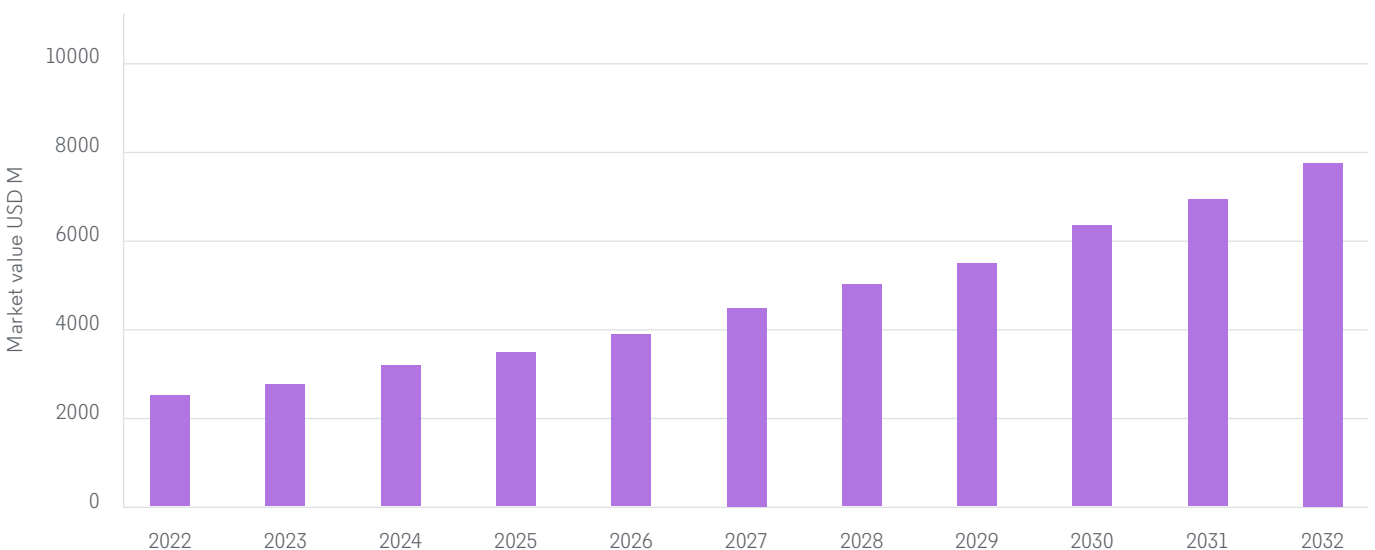
cost concerns, and current lack of clinical backing. This doesn't necessarily mean non-invasive options won't be disruptive in the future. However, current limitations create a significant barrier to immediate widespread adoption.

The future of **hybrid closed-loop systems** in the diabetes care market looks promising, especially with more manufacturers entering this space, competition is likely to intensify. Within the hybrid closed-loop system, the patch pump segment is going to experience significant growth when compared to tethered pumps and is estimated to grow at a CAGR of 13%

by 2032 globally. Further, if clinical trials show positive results for type 2 diabetes, it could expand treatment options for this population, providing an alternative to traditional insulin therapy and oral medications. This would unlock a significant market opportunity, potentially generating substantial revenue through the increased patient base.

Nonetheless, the fully closed loop systems offer numerous advantages over existing hybrid closed systems, and significant growth is anticipated in this product segment as more companies endeavor to enter this space. This segment is poised to be the most lucrative area for growth in the future.

Figure 1: Continuous Glucose Monitors Device Market (CGM)



What gaps in treatment do these devices fill?

The major challenge within treating Type 1 and Type 2 diabetes lies in the continuous management of blood sugar levels, mediated often by various methods of insulin injection. Advances in CGM technology seek to make blood sugar readings more accessible to patients, for example by increasing the lifespan of the CGM, reducing its invasiveness, or making the implant more aesthetically appealing. With greater usability for patients, CGMs aim to help patients adhere to treatment plans, leading to better long-term outcomes.

Closed-loop systems aim to aid patients in maintaining appropriate blood sugar levels through the direct pairing of an insulin pump to a CGM, which is intended to reduce patient burden and automatically adjust insulin levels in response to patient blood sugar. The development of closed-loop insulin systems benefits patients by offloading the work that patients would otherwise perform with multiple daily insulin injections.

What hurdles will Diabetes devices face in terms of adoption?

A potential hurdle for long-term adoption of diabetes care technology is the recent rise of GLP-1 receptor agonists (GLP-1 RAs), due to its demonstrated efficacy in blood sugar control in individuals with type 2 diabetes. However, due to the high relative penetration for insulin pumps in the type 1 diabetic population, GLP-1 are not expected to have a strong effect on the insulin pump market in the short term. Instead, GLP-1 use on those in the early stages of Type 2 diabetes is more likely to limit market uptake by reducing the addressable population of those requiring insulin. Given the low penetration of insulin pump use in Type 2 diabetes, the effect of GLP-1 adoption on the insulin pump market will be restricted, pending approvals for insulin pump systems in type 2 patients.

In contrast, GLP-1 RAs may have a paradoxically positive impact the CGM market in the long run. Industry leaders like Abbott and Dexcom reported increased stronger correlated use of CGMs with GLP-1 RAs, suggesting stronger adherence to treatment plans with their combined use and reflecting

healthcare professionals' advocacy for complementary use of both CGMs and GLP-1 drugs.

Additionally, disease-modifying procedures, like those being developed by Endogenex, Fractyl Health, and Morpnic Medical, could potentially limit the diabetes care technology market. These procedures aim to address the root cause of the disease, potentially offering a more long-term solution compared to traditional medications. Endogenex's RECET procedure, for example, uses electroporation therapy to stimulate the regeneration of insulin-producing cells. Similarly, Morpnic Medical's (formerly GI Dynamics) RESET device is undergoing clinical trials to assess its ability to significantly reduce A1c and weight. These procedures do not pose an immediate threat as the current market penetration is low, but they could potentially limit the sales of insulin and insulin pumps. However, the associated cost of these procedures and reimbursement availability will be a key factor in determining the growth of these procedures in the long run.

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