

## Insulin Pump Market Will Experience Solid Growth Over Next 18 to 24 Months

Companies: ABT, DXCM, MDT, PODD, SENS, TNDM

September 3, 2020

Report Type:  Previously Covered  Full Report  Update Ratings: ABT 4/5 DXCM 4/5 TNDM 4/5 PODD 3.5/5 MDT 2.5/5

### Research Question:

**As the continuous glucose monitoring market continues to innovate, integrate, and grow, are insulin pump makers Tandem, Insulet, and Medtronic poised to follow?**

## Summary of Findings

- The continuous glucose monitoring (CGM) and insulin pump markets are both expected to experience accelerated growth over the next two years, driven by the increasing incidence of diabetes, improved awareness of the disease and treatments by both providers and patients, technology advancements, collaborations, and DIY organization pressure ([Nightscout](#), [OpenAPS](#), [Loop](#), and [Tidepool](#)). Sources discussed growth rates from 10% to 75%. Tossing the extremes, the average expected growth rate was 23%.
- In the insulin pump market, [Tandem Diabetes Care Inc.](#)'s (TNDM) [t:slim X2 with Control-IQ Technology](#) combined with Dexcom's G6 is the clear tech leader and is expected to experience continued and sustained growth over the next 18 to 24 months. Most of Tandem's growth will be generated in the Type 1 market, as use of pumps by Type 2 diabetics is in its infancy, with growing interest but limited adoption, largely due to limited reimbursement.
- [Dexcom Inc.](#)'s (DXCM) [G6 CGM](#) and [Abbott Laboratories](#)' (ABT) [FreeStyle Libre](#) and recently FDA-approved [Libre 2](#) are the clear CGM leaders. The G6 is the gold standard, but the FreeStyle Libre, which already boasts over 2 million users, and the Libre 2 are poised to further penetrate both the Type 1 and 2 diabetes community and could generate pricing pressure in the space.
- [Insulet Corp.](#)'s (PODD) [Omnipod](#) tubeless insulin pump is considered a quality delivery solution that has become popular with active people and younger diabetics and their parents. Continued growth and adoption are expected; however, the system does not currently integrate with CGM systems, although collaborative agreements with both Dexcom and Abbott have been struck. Omnipod's upcoming next-gen system, [Horizon](#), will include CGM and could increase Insulet competitiveness.
- Medtronic PLC's (MDT) [diabetes division](#), once the leader in both CGM and insulin pumps, is losing share to both Tandem and Insulet. It has been surpassed technically and is now considered the 'old horse' and a 'second-tier' option for diabetics. Some sources expect Medtronic's new products will improve, but there is little excitement or enthusiasm about its next-gen offerings.
- [Beta Bionics](#) is generating excitement with its yet-to-be-approved fully automated bionic pancreas, [iLet](#). Sources think the combination insulin and glucagon delivery system will disrupt the pump market. A version with insulin only could be launched within one year, according to a research endocrinologist.

## Silo Summaries

### 1) Endocrinologists/Members of their Medical Team

All six sources expect adoption and use of both CGM and insulin pumps to continue to grow over the next two years. CGM will grow in the 30% to 50% range, according to two sources, and be used by both Type 1 and Type 2 diabetics. One source said eventually all diabetics will use CGM. Insulin pump growth will be in the 10% to 20% range and be dominated by Type 1 patients. However, one source said that, with improved technology, demand for pumps that loop could grow as high as 50% to 70% over the next two years. Another source said the use of insulin pumps in the Type 2 population is in its infancy and is hampered by high costs and limited insurance coverage..

### 2) Nurse Educators

All five nurse educators expect the use of CGM and insulin pumps to continue to grow over the next 18 to 24 months. CGM will grow in both the Type 1 and 2 market segments at a faster rate—30% to 60%, according to two sources that quantified their response. Insulin pump usage will also increase, but not as fast, and will be driven primarily by Type 1 diabetics. Improved provider knowledge regarding diabetes technology has helped spur adoption, according to one source; however, another said more education is needed, particularly with primary care providers, to further adoption of CGM and insulin pumps.

### 3) Diabetes Sales Channel

Diabetes sales professionals expect CGM and insulin pump growth to continue over the next 18 to 24 months at a rate of 15% to 40%. CGM adoption will precede and drive pump adoption. Type 1 diabetics will still make up most of the insulin pump market, but there is some growth anticipated with Type 2 insulin users. To gain traction in the Type 2 market insurance coverage must improve, patient cost must be reasonable, and the physical and psychological barriers associated with diabetes technology must be addressed.

### 4) Industry Specialists

All four industry specialists expect the CGM and insulin pump market to continue to grow in the 15% to 30% range over the next two years. Type 1 diabetics will be the dominant users of insulin pumps, but Type 2 diabetics taking multiple insulin doses are a growing market. Third-party reimbursement is improving and is a key driver of growth.

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	CGM Growth	Insulin Pump Growth	Potential Disruptors
Endocrinologists or Members of their Medical Team	↑	↑	Libre 2 Beta Bionics
Nurse Educators	↑	↑	Libre 2 Beta Bionics
Diabetes Sales Channel	↑	↑	Libre 2 Beta Bionics
Industry Specialists	↑	↑	Libre 2 Beta Bionics

## Background

Blueshift Research's [March 26 report](#) noted that Dexcom is seen as the leader in the CGM market and, as insurance coverage increases and pump manufacturers continue to integrate its CGMs with their devices, Dexcom sales will continue to increase. It also said that a Tandem pump combined with Dexcom's CGM is the insulin pump of choice, especially for younger diabetics. Tandem's t:slim X2 with Control-IQ Technology is expected to be the primary beneficiary of Medtronic's anticipated patient loss from the Class I recall of its MiniMed insulin pumps. Sources praised Tandem and its pumps as excellent, with the best trial results. Increased sales of the t:slim X2 are expected until the next technology breakthrough comes. Blueshift's [Oct. 23, 2019, report update](#) revealed Dexcom's and Tandem's growth trends would not be disrupted over the next six to 12 months. Sources cited ease of use, superior performance and reliability, solid insurance reimbursement, and strong research and development with exciting product pipelines as factors contributing to each company's success. These findings are in line with Blueshift's [June 19, 2019, Tandem report](#) and [April 25, 2019, Dexcom report](#).

Blueshift's ongoing research found the continues glucose monitoring market experiencing increasing demand from both Type 1 and Type 2 diabetics. The CGM space has also experienced the approval and introduction of next-gen products and new and expanded collaborative deals with all of the insulin pump makers. Tandem, Insulet, and Medtronic have all signed agreements with CGM producers to collaborate and integrate their products to encourage both Type 1 and Type 2 insulin users to consider CGM and automatic pumping. The insulin pump market has, for the most part, been limited to Type 1 diabetics requiring frequent insulin shots per day. The extent to which the proliferation of CGM use among both Type 1 and Type 2 diabetics can serve as a driver to increase pump adoption is unknown.

The CGM market has experienced a surge in [demand](#) during COVID-19 and GlobalData expects CGM market growth to reach mid-double digits in 2020. The three major CGM players—Dexcom, Abbott, and Medtronic—all reported high demand. Dexcom logged 44% year-over-year (YY) growth for Q1 and 34% in Q2, while Abbot grew 62.5% YY in Q1 and 60% in Q2. Medtronic reported high demand for its diabetic supplies and consumables, but its diabetic division is still experiencing declines.

The insulin pump market also experienced continued growth while navigating the coronavirus pandemic. Fortune Business Insights recently released a report that predicts a 9.4% increase in the insulin pump market by 2027. Tandem reported worldwide sales of its pumps up 17% YY and U.S. shipments up 15% YY in Q2. Insulet experienced a 25% YY revenue increase in the quarter and Medtronic, despite losing U.S. market share as it awaits FDA approval of its next-gen pump, saw revenue rise 2.2% on the strength of international sales of its [670G](#) hybrid closed-loop system.

On June 12, Abbott received FDA [approval](#) for its FreeStyle Libre 2 Flash Glucose Monitoring System. Abbott had been awaiting an FDA determination since April 2019. The Libre received iCGM designation with the exception that it cannot be used with automated insulin dosing (AID) systems due to inaccurate sensor readings when a patient is taking vitamin C supplements. Abbott still [plans](#) to pursue future integration with systems from Insulet, Tandem, Medtronic, and [Bigfoot Biomedical](#), but it is unclear if it will try for approval with the Libre 2 or wait until a future Libre is tested and approved.

Automated insulin delivery systems market leaders [Tandem](#) and [Insulet](#), along with startup [Bigfoot](#), have all partnered with Abbott and Dexcom to integrate their pumps with their CGM systems. These collaborations will provide more patient choice

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for which CGM system and pump they want to use, increasing the competitive environment. It is unclear, however, how the FDA's restrictions on the Libre 2 regarding integration with insulin pumps will affect these agreements and the diabetes community in general.

## Current Research

Blueshift Research assessed whether the continuous glucose monitoring market's continuous innovation, integration, and growth would lead insulin pump makers Tandem, Insulet, and Medtronic on the same path. We employed our pattern mining approach to establish five independent silos, comprising 20 primary sources (including five repeat sources) and three secondary sources focused on the CGM and insulin pump markets. Interviews were conducted August 17–28.

- 1) Endocrinologists or members of their medical team (6)
- 2) Nurse educators (5)
- 3) Diabetes sales channel (5)
- 4) Industry specialists (4)
- 5) Secondary sources (3)

## Next Steps

Blueshift Research will continue to research the CGM and insulin pump market to see if the Libre 2 is disruptive and if the pump market can accelerate its growth. We will monitor the top CGM and pump companies and the anticipated disruptors in the space to determine how their anticipated technically enhanced products will impact the market if and when they are approved.

## Silos

### 1) Endocrinologists or Members of their Medical Team

All six sources expect adoption and use of both CGM and insulin pumps to continue to grow over the next two years. CGM will grow in the 30% to 50% range, according to two sources, and be used by both Type 1 and Type 2 diabetics. One source said eventually all diabetics will use CGM. Insulin pump growth will be in the 10% to 20% range and be dominated by Type 1 patients. However, one source said that, with improved technology, demand for pumps that loop could grow as high as 50% to 70% over the next two years. Another source said the use of insulin pumps in the Type 2 population is in its infancy and is hampered by high costs and limited insurance coverage. Dexcom is considered the gold standard in CGM; however, Libre 2 has 'rocked the market' with its enhanced features and low cost and is contributing to the broad adoption of CGM, according to one source. [Senseonics Holdings Inc.'s](#) (SENS) [Eversense](#) implantable CGM is gaining traction outside the United States but has not caught on domestically. Tandem is the leading insulin pump, in combination with the Dexcom G6 CGM. Insulet pumps are favored by active and young diabetics and Medtronic is now considered 'second-tier' and is losing customers. One source referred to Medtronic as the 'old horse' but noted it was improving. A research endocrinologist said Beta Bionics is expected to be competitive within a year, launching an insulin-only pump and adding glucagon functionality in the future.

### Key Silo Findings

#### CGM/Insulin Pump Market Conditions and Growth Opportunities

- 6 said CGM and insulin pump growth will continue and is sustainable over the next 18 to 24 months.
- Both Type 1 and 2 diabetics will utilize CGM and Type 1s will dominate pump, use as insurance coverage for use of pumps by Type 2s is limited.

#### Tandem

- Tandem is the leading pump because of its integration with the Dexcom G6 CGM and its Control-IQ technology. Its competitiveness and growth are expected to continue.

#### Insulet

- Insulet's tubeless insulin delivery system is highly competitive with active and young diabetics and their parents. The lack of an integrated CGM is an issue.

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## Medtronic

- Medtronic is considered the 'old horse' that is now a second-tier insulin pump and losing share to Tandem and Insulet. One source did say Medtronic is stepping up its game.

## Miscellaneous

- Eversense CGM is gaining traction outside the United States but it is gaining limited traction domestically.
- Beta Bionics has the potential to disrupt the insulin pump market. The launch of an insulin-only pump is expected within a year and then glucagon capability will be added in the future.

## 1) Physician assistant and primary pump manager at a major university's division of endocrinology; repeat source

This provider is a long-time Type 1 diabetes patient, which gives her added insight into the clinical and lifestyle considerations of various technologies and products. She is a primary provider within the division of endocrinology at a major private university-based research institution in the Southeast who manages all of their pump patients and is considered the division's pump expert. She indicates that Tandem's and Insulet's current growth rates are likely to continue. Tandem's reputation, technology, lifestyle, and broad insurance coverage are driving its growth. Insulet is popular with active diabetics and parents with diabetic children. Insurance coverage is the driver in a patient's decision process regarding which system they will use. While technology development is important, it is fairly irrelevant if the patient's insurance company does not cover that company's products. Dexcom CGM will maintain its lead domestically, while Eversense's CGM is gaining traction outside the United States.

March 26 interview summary: This source has both personal and professional experience with all of the major pump manufacturers. At her clinic Medtronic pumps are considered second tier. Confidence in Medtronic's pumps is declining, as is their market share. Tandem is the pump of choice for the younger population and is expected to gain share until the next technology breakthrough emerges. She does not actively steer her patients to any one manufacturer but relies on the recommendations of her nurse educators and patient preferences related to their lifestyles.

### CGM/Insulin Pump Market Conditions and Growth Opportunities

- "That Tandem and Insulet are clearly in the lead in terms of market presence is not surprising. I see this clinically as well. They're clearly the best."
- "The overall market is very competitive, especially for Type 1 patients."
- "Type 2 patients, as a pumper market, is very much still in its infancy. One of the primary factors here is Medicare, which has coverage issues with Type 2 patients using these systems."
- "With the exception of United Health, most other insurers will cover the other CGM/pump combinations. So, which set that a patient chooses is heavily driven by their insurance coverage. These are very expensive systems (\$10,000) that most people would never be able to afford without substantial insurance coverage."
- "New technology development in pump companies seems to be lagging behind that of the CGM companies. There are several pumps out there that aren't approved to be paired with CGMs. This doesn't bode well for their future, as the approval process is prolonged and expensive"
- "Abbott is developing a new system that I think is primarily targeted to the Type 2 patients. [Most of my Type 2 patients are on Medicare, so unless Medicare changes its coverage, the viability of this is questionable.] It will have audible alarms and will be easier to put in for patients with less dexterity."
- "The Dexcom/Tandem closed-loop system receives overwhelming positivity from my patients and the insurance coverage is quite good. They will continue to do well in the market."

### Tandem

- "Tandem's technology is what drives its popularity, especially with younger, more tech-savvy patients."
- "[Tandem's] growth rate is likely to continue, as it is clearly a leader in terms of reputation, technology, lifestyle, insurance coverage, etc."

### Insulet

- "As the only tubeless system, Omnipod is a favorite with active people and parents with young children from a lifestyle standpoint."

**[Tandem's] growth rate is likely to continue, as it is clearly a leader in terms of reputation, technology, lifestyle, insurance coverage, etc.**

*Physician assistant and primary pump manager at a major university's division of endocrinology*

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- “It is likely to continue as a major market leader, along with Tandem. There just aren’t others that can compete yet.”
- “Horizon is developing a closed-loop system designed to compete with Tandem. It was supposed to have its release at the end of this year, but COVID has interfered with all of this across the industry.”

## Medtronic

- “Medtronic is considered to be a second-tier pump among most clinicians.”
- “They have done this before where they say that they have improved their system’s accuracy and lifestyle aspects for patients but, many times, this really hasn’t come through.”

## Miscellaneous

- “Eversense is a new company that is making news overseas, but it isn’t taking hold at all in the U.S. Most patients will continue to use Dexcom.”
- “The development of an artificial pancreas is obviously the eventual goal of this whole industry. However, insulin, actually is the primary rate limiter here. It takes insulin about 15 minutes to take effect, so there is a substantial time lag that the CGM/pump system can’t anticipate yet. Patients still have to interact with their systems regarding the type of activity or meals that they are going to be planning for the systems to work properly. Anticipating and projecting all of this automatically is extremely complex.”
- “[Eli] Lilly [and Co./LLY] has recently received FDA approval for a [faster acting insulin](#) [called [Lyumcjey](#)], but it isn’t approved for use with pumps. Various insulins tend to clog pumps, so they have to be injected.”

## 2) Endocrinology doctorate of nursing practice (D.N.P.) at a university health system

This source sees a 5% to 10% increase in her facility’s inpatients with their own CGM and or CGM-pump systems and estimates the larger outpatient growth for these devices at 10% to 20% overall. She expects this growth to continue, with the fastest growing segment in Type 2 diabetes (more than 30%). Key contributors to increased adoption include the affordability of Libre CGM and the increased direct-to-patient education and communications from companies like Tandem and Insulet. One of the main barriers to adoption is the lack of familiarity with the options and reimbursement processes at the primary care level (Type 2 healthcare providers). The current pump manufacturers are becoming more competitive among themselves and are well positioned to grow with the marketplace. A true artificial pancreas will not dramatically increase the served market but will dramatically improve quality of life for Type 1 patients.

### CGM/Insulin Pump Market Conditions and Growth Opportunities

- “This is a very competitive environment, as there are strong competitors in the field, but there really are only a few that have risen to the top. More are coming, though.”
- “The CGM market is dominated by Dexcom—not Medtronic anymore. Libre has stepped in and rocked the market. It has ongoing alerts without putting the sensor up to the pump and is much less costly.”
- “In the inpatient setting, I am seeing approximately 5% to 10% increase in admitted CGM (and CGM-pump) patients, particularly the Libre, which has made CGM more affordable. Patients generally wish to stick to their system rather than use the hospital option. I expect this growth to continue, but it is not reflective of the overall growth, as people who have better glycemic control are less likely to end up in the hospital. The total CGM/pump system growth is 10% to 20% and growing. Type 2s are growing even faster, perhaps more than 30%, and I expect that to continue.”
- “A key contributor to more CGM adoption has been the affordability of the Libre.”
- “In endocrine practices, the staff are accustomed to qualifying requirements and complex reimbursement. This is generally not true of the general practice who are the primary care group for most Type 2 patients.”
- “The population of Type 1 patients that does not want the technology is very small—the CGM/pump market is primarily comprised of these patients. The market for insulin-dependent Type 2 patients, however, is wide open. The real obstacle for these patients lies at the primary care clinic where the providers and staff need to better understand the options and process for approval/reimbursement.”

**The total CGM/pump system growth is 10% to 20% and growing. Type 2s are growing even faster, perhaps more than 30%, and I expect that to continue.**

*Endocrinology doctorate of nursing practice (D.N.P.) at a university health system*

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- “Although there are detailed medical requirements, Medicare is better than it has ever been about reimbursement for monitoring and pumps.”
- “Type 2 patients can only qualify for reimbursement if they have multiple daily injections.”
- “Medicare has changed its stance of not reimbursing for any Type 2 patients to covering CGMs and pumps only if the pancreas has completely stopped working. That, in effect, makes these patients no different than Type 1 patients.”
- “Currently, about 25% to 35% of Type 1 patients are pumpers. This percentage will continue to increase due to the naturally increasing incidence of diabetes and also because the technology improvements are really attracting the attention of patients.”
- “I am seeing much better-informed patients with significantly greater awareness of innovations coming down the road through communications from companies like Tandem and Insulet. This keeps them informed, confident, and enthusiastic about both new innovations and their brand of choice.”
- “The existing players are becoming more competitive among themselves and are well poised to grow with the market.”
- “These same companies are the innovators. Medtronic is the ‘old horse’ but is starting to step up its game.”

## Tandem and Insulet

- “Patients have great results with the Dexcom technology and integration with Tandem [t:slim pump] and Insulet has been very successful.”
- “For the longest time Medtronic ruled the world, but they rested on their laurels. Competitive players [like Tandem and Insulet] are stepping up their branding and communication with both patients and diabetes providers [like nurse educators and endocrinologists]. More than ever, patients are aware of the options, particularly the Type 2 market. By the time they need multi-daily injections, they want to adopt the newest technology. Type 2 are definitely that fastest growing segment for these devices.”

## Medtronic

- “I have received negative feedback about Medtronic sensors. Patients still must manually calibrate. That said, patients who are very satisfied with the hybrid 670G pump will often stick to the Medtronic sensor regardless.”
- “The patients who are staying with Medtronic tend to be the older ones who are more technology- and change-averse. They didn’t feel that they had to compete until recently.”

## Miscellaneous

- “A true artificial pancreas will not dramatically expand the market size for CGM/pumps, but it will radically improve Type 1 patients’ quality of life. The Type 1 communities are abuzz with discussion of this technology, including companies like Beta Bionics. But I cannot see it really impacting the relatively well-controlled Type 2 market.”
- “The eventual development of an artificial pancreas will be a game changer. We aren’t all that far from this, but, frankly, they’ve been saying this for years. Beta Bionics, Medtronic, and Tandem are the companies that are the closest. This is very complex technology, as not only does the system have to stop introducing insulin when necessary but also giving glucagon.”
- “Those Type 1 patients with a do-it-yourself artificial pancreas absolutely love it. It has changed their life. When I hear a patient say that they never knew what it was like to sleep through the night before it, it makes a stark impression. It will be great for these folks once an FDA artificial pancreas system is available.”

### 3) Academic endocrinologist and research expert; repeat source

This diabetic research-focused endocrinologist sees continued growth of insulin pumps as more products come to market that are easier to use, better integrated, and more competitive in pricing. Tandem is the leader. Medtronic has work to do and Insulet growth opportunities are more limited. He does not perceive much growth over the next two years with Type 2 patient adoption. Next year Beta Bionics could make waves in the market—he thinks they will launch as an insulin pump and, probably one year later, will integrate glucagon.

March 26 interview summary: This source believes the recall will cause Medtronic sales to continue to decline until they have a new product on the market. Tandem is the leader and sales of its Control-IQ pump will continue to grow. Both Beta Bionics and Tidepool Loop will be important but will not be on the market for more than a year.

Oct. 23, 2019, Dexcom-Tandem interview summary: This source sees Dexcom and Tandem as both well positioned to remain dominant for the foreseeable future. The Control-IQ and t:sport pump are significant innovations for Tandem’s

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future, as is the recently announced partnership with Abbott. Interoperability is the way of the future. The new partnerships for Abbott with Tandem and Omada Health may be a future threat to Dexcom.

## CGM/Insulin Pump Market Conditions and Growth Opportunities

- “[There is] lots going on in the insulin pump market and [it is] too early to really know what’s going to happen.”
- “Libre 2 is a nice option for diabetics. I see the G6 and Libre 2 as continuing to grow—[there is] plenty of room in this market. I do believe that Dexcom’s G6 is still the gold standard.”
- “The pump market will grow as more of these products are integrated. Over the next 18 to 24 months we will see more products come to the market and, with better and easier to use devices, the pump market will continue to grow.”
- “I don’t see much growth in the next two years in the Type 2 market for pump adoption.”

## Tandem

- “Tandem t:slim is a great product. Beta Bionics’ introduction could be a significant challenger.”

## Insulet

- “Insulet will not be a major player over this time period. They definitely could grow, but only in the Type 1 space. [Their products are] not applicable to Type 2 patients, given the small insulin reservoir in their device.”

## Medtronic

- “Medtronic has work to do and will be on the outs for a while.”

## Miscellaneous

- “Beta Bionics could really shake things up in the next year. They will be insulin only at release and then the glucagon functionality will probably follow 12 months after.”

## 4) PharmD, endocrine pharmacy specialist at a teaching hospital in the Midwest

Within the next two years, demand for CGM/pumps will increase beyond 15% to 20%. This source is seeing more Type 2 patients prescribed CGM and believes that eventually all diabetes patients will use CGM. One of the biggest motivations for patients is the promise of minimizing or eliminating finger sticks. This source believes insulin delivery systems will see greater adoption with better system communication, ease of use, and discreet devices. She is particularly enthusiastic about smart pens and patches. The current pump manufacturers will remain in the market and more options should be introduced to meet the demand for better options. Dexcom-Tandem is this source’s preferred system, but non-downgradable software and English only is limiting. The Beta Bionics system promises to be very simple to use, which should appeal to primary care providers and patients alike.

## CGM/Insulin Pump Market Conditions and Growth Opportunities

- “I expect the demand for CGM/pump devices will increase beyond 15% to 20% in the next two years. We are seeing more Type 2 patients being prescribed CGM, especially Libre. Eventually every diabetes patient will use CGM.”
- “The primary driver behind increased CGM use is simply that patients hate to poke their fingers.”
- “Pump use varies. The demand for automated insulin delivery will increase as communication becomes more seamless, devices are more easily integrated into patients’ lifestyles, and more appealing technologies are introduced, like the smart pens and patches.”
- “Three pump manufacturers is not a big number. We should have more options. The market can definitely support it.”

## Tandem

- “I think the Dexcom G6-Tandem t:slim is the best option available now. But there are a few limitations with Tandem in that there is no way to downgrade the software, meaning once upgraded a patient cannot downgrade from Control-IQ to Basal IQ [and pregnant women cannot use Control-IQ because it has too high a target]. It is also only available in English, which is problematic for many patients.”

I expect the demand for CGM/pump devices will increase beyond 15% to 20% in the next two years. We are seeing more Type 2 patients being prescribed CGM, especially Libre. Eventually every diabetes patient will use CGM.

*PharmD, endocrine pharmacy specialist at a teaching hospital in the Midwest*

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## Insulet

- Did not discuss.

## Medtronic

- Did not discuss.

## Miscellaneous

- “The Beta Bionics hybrid closed-loop system promises to be really simple to use, which should make it appealing to the primary care provider.”
- “The 14-day Libre has a vitamin C contraindication also [false elevation with 500 mg]. Most of these patients are CGM only. These types of problems are certainly surmountable; however, acetaminophen issues have been resolved.”

## 5) Family nurse practitioner and director of diabetes education at a university-associated healthcare system

This source expects the demand for CGM/pumps to increase but declined to estimate the rate, other than to describe that the improvements in technology will influence adoption. This source estimated that the majority of new pumps will be for Type 1 patients, half of new CGM systems will be for Type 1 patients, and 60% of new pumps will be upgrades. Technology advances and increased automation are what will drive the growth. Introduction of an artificial pancreas will significantly increase demand, as many patients are waiting for total automation. A primary obstacle to adoption is insurance coverage/cost to the patient. The three pump manufacturers are here for the long term. Tandem’s clear advantage is their closed-loop software. Introduction of Insulet’s next generation will increase their market share and demand overall.

### CGM/Insulin Pump Market Conditions and Growth Opportunities

- “I expect the demand for CGM/pumps to increase significantly in the next few years. For insulin pumps, 80% will be for Type 1 patients [with 20% for Type 2] and for CGM, 50% will be for Type 1 patients [with 50% for Type 2]. Sixty percent of the new pumps placed will be upgrades from older technology.”
- “One of the major obstacles to adoption is limited insurance coverage, copays, and deductibles.”
- “The primary drivers for growth are technology advances and increased automation.”
- “The current pump manufacturers will remain competitive over the long term.”

## Tandem

- “Tandem’s primary advantage currently is the Control-IQ software.”

## Insulet

- “The tubeless insulin delivery is a clear advantage. However, the current Omnipod is not integrated with a CGM so there is a lack of system automation. Their next generation closed-loop system will both increase their market share as well as the total population interested in the use of diabetes technology.”

## Medtronic

- “One of the advantages of Medtronic is their auto-mode feature. But the user requirements, including calibrations and glucose checks, are a distinctive disadvantage.”

## Miscellaneous

- “Introduction of artificial pancreas technology will definitely increase market demand for technology. Many patients are holding out for full automation.”

I expect the demand for CGM/pumps to increase significantly in the next few years. For insulin pumps, 80% will be for Type 1 patients [with 20% for Type 2] and for CGM, 50% will be for Type 1 patients [with 50% for Type 2]. Sixty percent of the new pumps placed will be upgrades from older technology.

*Family nurse practitioner and director of diabetes education at a university-associated healthcare system*

## 6) Family nurse practitioner and certified diabetes educator for an endocrinology practice in the South

This source estimates the market growth could increase by as much as 50% to 75% in the next two years—75% will be Type 1 patients because the coverage is much more reliable. The biggest obstacle to more growth is insurance coverage



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and out-of-pocket costs. The three pump manufacturers will remain competitive into the foreseeable future. Tandem's Dexcom relationship and release of Control-IQ has made them leaders in the market. Insulet's big advantage is the tubeless technology. Despite a strong presence and reputation, Medtronic's sensor needs to be calibrated multiple times daily and is not covered by Medicare. Newer technology will both expand the market and improve lives.

## CGM/Insulin Pump Market Conditions and Growth Opportunities

- "The demand for the pumps with the ability to loop will continue to rise. As technology improves and guesswork is reduced, the demand will be there. I would estimate it would be possible to grow much as 50 to 75% in the next few years."
- "Approximately 75% of technology patients will remain Type 1 because insurance coverage is reliable. But Type 2 patients also benefit if they qualify."
- "The biggest obstacle to growth is cost and coverage. I see this daily. CGMs are still quite expensive and with the other costs [especially insulin] it can be prohibitive. This is unfortunate as, a majority of the time, the technology can improve control greatly. Medicare in particular has several hoops to jump through and these can be difficult barriers for the elderly."
- "Practical limitations to the current devices include tape issues [like reactions and adhesion]."
- "The current big three pump manufacturers will be around for a while as they each have a niche."

The demand for the pumps with the ability to loop will continue to rise. As technology improves and guesswork is reduced, the demand will be there. I would estimate it would be possible to grow much as 50 to 75% in the next few years.

*Family nurse practitioner and certified diabetes educator for an endocrinology practice in the South*

## Tandem

- "I would have predicted that Tandem might not make it, but with their Dexcom partnership and the recent release of Control-IQ, they are becoming leaders in the market."
- "Tandem advantages include: pairing with Dexcom, which is covered by Medicare and does not need to be calibrated daily; lower target glucose; calculations based on basal versus algorithm [which makes it easier to adjust for things like a steroid burst]; and a slim design."

## Insulet

- "Insulet has the appeal of tubeless technology, which is a distinct advantage for many people who do not want to be tethered."
- "Insulet advantages include tubeless/untethered technology, a separate personal diabetes manager (PDM) which is not on the body, and ease of use for people frequently in the water."

## Medtronic

- "Medtronic has always been a strong force in our area, but they are losing customers to the newer Tandem pump."
- "Medtronic's advantages include strong presence and reputation, leaders in closed-loop technology, non-touch screen [that appeals to older patients], and large buttons. Disadvantages [are that] their sensor is not covered by Medicare, needs to be calibrated multiple times daily, and only lasts 7 to 10 days."

## Miscellaneous

- "New technology will both expand the market and improve lives. This includes 'artificial pancreas' technology, improved length of sensors, improved accuracy, and, I hope, improved availability, decreased size, and increased length of wear."
- "Disease management cost is a major concern for everyone with diabetes and the technology devices are no different."

## 2) Nurse Educators

All five nurse educators expect the use of CGM and insulin pumps to continue to grow over the next 18 to 24 months. CGM will grow in both the Type 1 and 2 market segments at a faster rate—30% to 60%, according to two sources that quantified their response. Insulin pump usage will also increase, but not as fast, and will be driven primarily by Type 1 diabetics. Improved provider knowledge regarding diabetes technology has helped spur adoption, according to one source; however, another said more education is needed, particularly with primary care providers, to further adoption of CGM and insulin pumps. Abbott's Libre 2 is viewed positively by four of the five sources. Ease of use and affordability were cited as its primary

# Insulin Pump Market

strengths. One source added that it could disrupt the CGM space and create significant pricing pressure. Libre 2's restriction from integrating with insulin pumps is not expected to negatively impact its adoption. Tandem is the leading insulin pump, surpassing Medtronic which is not user friendly and has fallen behind in technology. One source did say they were confident Medtronic would improve. Insulet is viewed as a good insulin delivery system that is easy to use and affordable. Beta Bionics' iLet could be a 'huge game changer,' according to one source. Another said the iLet will have a Type 1 diabetic focus and is a complicated system.

## Key Silo Findings

### CGM/Insulin Pump Market Conditions and Growth Opportunities

- 5 said CGM and insulin pump growth will continue over the next two years. 2 sources quantified growth for CGM at 30% to 60%, with pump growth at a slower rate.
- Improved provider knowledge regarding diabetes technology and third-party reimbursement is helping drive growth, but more is needed practically at the primary care level.
- 4 were positive regarding Abbott's Libre 2, citing its ease of use and low cost. 1 said it could create pricing pressure in the CGM space. The Libre 2 insulin pump integration restriction is not expected to hurt adoption.

### Tandem

- Tandem is the leading insulin pump. Its advanced technology, accuracy, and ease of use were all cited as competitive advantages.

### Insulet

- Insulet is considered a good insulin delivery system that is easy to use, affordable, and popular with younger diabetics and their parents. Insulet's next-gen system is expected to integrate with the Dexcom G6 CGM and could generate some share shifts.

### Medtronic

- Medtronic, the former CGM and insulin pump leader, is no longer competitive. It is behind in technology, is not user friendly, and users and professionals are skeptical about future products. 1 source did say they expect Medtronic to improve.

### Miscellaneous

- Beta Bionics is generating excitement and has the potential to be a game changer in the insulin pump market because of the insulin/glucagon functionality. 1 source cautioned that the proposed device seems complicated.

## 1) Diabetes educator and registered dietitian at a VA hospital in the Midwest; repeat source

This outpatient nurse educator sees continued growth in the CGM market, with the Libre 2 as a marketplace disruptor for CGM. Non-integration with insulin pumps is not a major concern and will be worked out. The insulin pump market will see significant growth and should move to 30% of all Type 1 diabetics, with Tandem as leader. This source believes Medtronic has lost support but should rise to the occasion and resolve their MiniMed problems. Insulet patients remain pleased with the product and the company should continue with its current growth. Tandem should continue to grow at 15%. Type 2 patient growth will be significant for CGM but this source does not foresee growth in the pump market in the next 2 years for this segment.

March 26 interview summary: Medtronic has been very active in following up after the recall and is inspecting all MiniMed pumps. This source has not seen any patients switching from the MiniMed due to the recall but believes that, if there have been switches, they would be to the Tandem t:slim X2. The MiniMed 600 series has historically had many patient complaints due to the frequency of calibration and problems with accuracy. The t:slim X2 Control-IQ system is exciting, and they believe it will gain healthcare professional support over its competitors.

June 19, 2019, Tandem interview summary: Most of the people with diabetes at this facility are older and have Type 2 diabetes, so they would not qualify for a pump. Patients who use a pump are losing interest in Medtronic's 670G because they have experienced or heard complaints about the system's frequent and lengthy alerts. This VA decided to add Tandem's t:slim to its formulary because they heard it was easy; however, they are having difficulty getting Tandem's sales reps and educators to come to their facility. Patients are also anxious to try the Dexcom, which they have heard positive things about. Their patients are not particularly interested in wireless, although some ask for an Omnipod, and some express interest in a closed-loop system.

# Insulin Pump Market

## CGM/Insulin Pump Market Conditions and Growth Opportunities

- “I think Abbott will continue to grow and improve technology to integrate the CGM with pumps as soon as possible. Pump integration is essential and they should be able to fix this issue. They won’t wait till the next-generation CGM.”
- “The Libre 2 will disrupt the marketplace. The price point is the key. Libre 2 priced near the Freestyle Libre is something many of our patients can afford.”
- “There is room for both products to grow. More and more patients will need CGM capabilities and with Libre 2 at lower cost, consumers/patients will benefit. I believe more patients—Type 1 and 2—will want to use them. Research supports this.”
- “Regarding which CGM is the best, from a quality standpoint, Dexcom G6 is the gold standard. If cost is a concern, Libre 2 is the preferred device. Medical status, patient needs, medical history will determine which monitor is the best. There is room for both products to grow in this market.”
- “The impact of Libre 2 not integrating with pumps [is minimal]. Libre 2 will be used widely despite this. [It is] not a concern that they are not integrating with pumps at this time.”
- “Re: pumps, I think they will continue to grow but not nearly at the rate of CGMs, [which are] growing at 40% to 60%. Most diabetics could benefit from using a CGM. This is not the case with pumps.”
- “I’m not certain of the exact percentage of Type 1 patients on a pump but I think that 30% of patients would be on a pump after the next 18 to 24 months.”
- “I don’t perceive that the Type 2 diabetic use of pumps will change much in the next 18 to 24 months but I do believe that CGM use in this population will grow considerably, as it has in the past year. Greater numbers of patients will be able to afford the Libre 2 and maybe pricing pressure will impact the competitors.”

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*Diabetes educator and registered dietitian at a VA hospital in the Midwest*

## Tandem

- “I think we will see another 15% growth. I work a little with t:slim at our clinic; these patients are generally seen at a different site.”

## Insulet

- “We are not using [Insulet] at the VA regularly. I assume from patients I see at other sites that they will continue to grow. Other providers seem very happy with the products.”

## Medtronic

- “Medtronic has lost support since their recalls but I am hopeful that they will rise to the occasion and line improvements will be made.”

## 2) Nurse educator at a diabetes management center in the South

This source, as are many diabetes professionals, is a long-time Type 1 diabetes patient. He works as an inpatient nurse at a major community hospital in the Southeast. Technology development is moving quickly but insurance coverage is still the primary determinant of which technology a patient decides to use.

## CGM/Insulin Pump Market Conditions and Growth Opportunities

- “The dominant [CGM] player in the market is clearly Dexcom. It has the best accuracy and is the most sought after. CGM is all that they do and they are the best at it.”
- “The first generation of Medtronic was OK, but the second generation will be better—but we haven’t seen it yet, so I am a bit skeptical.”
- “Libre is really in a lower category. It is comparatively inconvenient to use. You have to physically scan the device to get results.”
- “I now have quite a few Type 2 patients who use CGMs and pumps. Many also just use CGMs. They get a lot better data and compliance, as many patients just do finger sticks once or twice a week. This way it’s constantly being monitored and it’s easier. Convenience is a big part of diabetes management. The firms and technology that make it the easiest will be the winners.”
- “Now that Dexcom has partnered with Tandem and Omnipod, they are going to be really hard to beat.”

# Insulin Pump Market

- “Approximately 35% to 45% of my Type 1 patients use CGMs and pumps, while about 20% to 25% of my Type 2 patient use them.”
- “Market growth is going to continue at current rates for some time well into the future. My patients are really getting turned on by the improvements in the technology—how it makes their lives easier and noticeably healthier. I have many patients who have had significantly fewer admissions and visits to the doctor when they migrated to one of these sets of technology. The insurers are really beginning to notice and are covering this technology much better. This is a huge help, obviously.”
- “Tandem is clearly the best pump, with its updates via downloads, its rechargeable battery, and touch screen.”
- “Omnipod is less expensive, but still a great pump and Medicaid covers it in our state.”
- “The primary decision drivers that patients consider in deciding which set of technology to use [are]: insurance coverage; tubing—yes or no (no tubing is preferred); technology—touch screen, color screen, CGM communicates with pump, etc.”
- “Libre is still considered a second-tier device. Until it talks with the pump, it will go nowhere.”

## Tandem

- “Tandem is the best! Its accuracy is the best and it’s very easy to use.”
- “It has had no significant issues like other devices.”

## Insulet

- “Insulet is the closest competition to Tandem.”
- “It is a lower-cost device than most of the others on the market.”
- “It has updated to the Omnipod Dash which is flashier and easier to use than the first-generation machine.”

## Medtronic

- “[Medtronic is] just not competitive anymore.”
- “[It] is well known for mechanical failures with [the] current model.”
- “Next-generation is supposed to knock our socks off, but I’ve heard that before. I’ll believe it when I see it.”

Market growth is going to continue at current rates for some time well into the future. My patients are really getting turned on by the improvements in the technology—how it makes their lives easier and noticeably healthier. I have many patients who have had significantly fewer admissions and visits to the doctor when they migrated to one of these sets of technology. The insurers are really beginning to notice and are covering this technology much better. This is a huge help, obviously.

*Nurse educator at a diabetes management center in the South*

### 3) Nurse practitioner, diabetes educator, and diabetes center owner

The demand for diabetes technology will increase approximately 30% over the next two years. One of the significant drivers of that growth is increased provider knowledge. Whereas in previous years manufacturers educated patients on devices directly, prescribers are now more comfortable and knowledgeable about the technology and, therefore, more likely to recommend. Type 1 and Type 2 growth rates will be relatively equal in the short term but, in the long run, as qualified Type 2 patients increase (those that need multiple daily injections) and technology gets simpler and less expensive, more of that patient segment will be penetrated. There is plenty of room in the marketplace for the existing pump manufacturers, as well as new entrants. Although Medtronic was once the clear leader, the company was not focused on diabetes and their CGM technology was cumbersome and inaccurate. Tandem is becoming the new leader. The t:slim pump with the Dexcom CGM is the best option currently—and the ability to upgrade via software is a huge benefit. This source used the Insulet Omnipod and felt it was somewhat bulky, although the tubeless feature is appealing. She felt that the Insulet sales representative denigrating the competition is largely what soured her on the brand. CGM leads, pumps follow. This source believes the days of pump-only use will fall by the wayside. She is interested but skeptical about new developments, such as the so-called artificial pancreas. It will need to operate simply and be covered by insurance to make a real impact. The vitamin C contraindication will not significantly impact Libre 2 sales, as the majority of these patients are not pumpers.

#### CGM/Insulin Pump Market Conditions and Growth Opportunities

- “I think the demand will continue to increase, probably by 30% in the next 2 years. Technologies have gotten easier to teach. From a prescriber perspective, the early interventions were difficult to teach so they were dependent on the

# Insulin Pump Market

manufacturer to have a great training system. There was a lot of disconnect; prescribers did not understand the products. For the past 10+ years the patients became more knowledgeable about the products than the providers. But more recently the products have gotten much simpler and prescribers became more comfortable, so the interaction between the provider and the patient is getting more aligned to the technology. The providers' comfort and recommendation will be the driver behind the increase."

- "With the influx of simpler to use technology and more patient awareness through direct-to-consumer advertising, patients are becoming more knowledgeable about their options. In the past, the primary prescribers came from the endocrinology clinic. I am now seeing more primary care-initiated technology recommendations."
- "I think both Type 1 and Type 2 growth rates will be fairly equal in the short term. Type 2s that qualify will increase at a faster pace as these modalities become less expensive, more simple, and less reimbursement restricted. The Type 1s who do not have access to CGM/pumps is the fault of their providers."
- "It infuriates me when people come to me and say they could not adopt diabetes management technology because of the lack of insurance coverage. If someone wants a CGM and is testing their blood four times and injecting three times each day, pretty much everyone will qualify. CGM can be used to qualify a patient. If they agree to wearing a CGM for two weeks, I can use that data to gain carrier approval and bill for the testing and interpretation—everybody wins. Part of the confusion is that the primary care providers are not as familiar with the products, the qualifiers, and the reimbursement processes."
- "One factor in the lack of prescriber knowledge is the fact that a lot of clinics do not let sales reps visit anymore. This has nothing to do with COVID. As more independent practices are purchased by IDNs [integrated delivery networks], sales visits have been severely limited or eliminated altogether based on the concern that prescribers were being influenced by company-furnished 'gifts,' often in the form of the food accompanying an educational event. This is short-sighted and limits access to education and new technology awareness."
- "There is plenty of room for the current pump manufacturers, as well as new entrants."
- "We will not continue to see many pumps without CGMs. With the early system, patients may have simply been exasperated by the CGM interface. Medtronic's CGM was terrible even though the pumps were good. But if a pump does not 'know' what the blood glucose level is, it is just a delivery system without the proper information to accurately time and dose insulin."

## Tandem

- "Tandem is becoming the new market leader. Their t:slim pump paired with the Dexcom CGM is the best option available currently. A big part of the popularity is the software-driven upgrades. That really pushed them forward."

## Insulet

- "I personally did not like the way Omnipod felt; it was cumbersome. I have certainly been influenced by my familiarity and comfort with the system I use [t:slim/Dexcom] and I like to be comfortable with what I am prescribing. My experience with the Insulet sales representative bashing the competition also left a bad taste in my mouth and a bias against the brand."

## Medtronic

- "Medtronic used to be the king. The company got greedy and they were not focused on diabetes alone. I knew their technology inside-out because I used it, but it was complicated. I now use Tandem t:slim because the Dexcom CGM is the best product on the market."
- "Companies more focused on diabetes seem to provide the best technology and customer support. Medtronic support is poor in comparison to the others."
- "Medtronic is getting ready to release a new generation, but I am not confident it will be a game changer. They have made a lot of promises that never came to fruition. I used to be part of their early release program and often wondered how their new products received approval in the first place, as they did not live up to the promises."
- "Medtronic sales representatives would always fish for Type 2 patients that would qualify for a pump. One of their biggest problems is they never got approval for their CGMs to be covered by Medicare. Their new system will need Medicare coverage."

I think the demand will continue to increase, probably by 30% in the next 2 years. Technologies have gotten easier to teach. ... The providers' comfort and recommendation will be the driver behind the increase.

*Nurse practitioner, diabetes educator,  
and diabetes center owner*

# Insulin Pump Market

## Miscellaneous

- “Type 2 patients do not need glucagon, so Beta Bionics will be solely focused on Type 1. It will be more complex so fewer primary care providers will take interest in learning and recommending the system.”
- “Type 1 diabetes affects approximately 10% of the population. The Type 2 diagnoses are continually increasing based on lifestyle choices. These are two different diseases that need totally different treatment and management.”
- “The simpler the products get and the less patients need to prick themselves, the quicker technology will be adopted.”
- “I don’t think the vitamin C issue will affect the popularity of Libre. The market has seen this type of problem before (e.g., Dexcom CGM and Tylenol) and it gets resolved. The Libre is really not used with pump patients anyhow. I would not prescribe a Libre CGM for a pumper.”

## 4) Certified diabetes educator for a Midwestern endocrinology and diabetes center

The market demand for CGM/pumps will definitely increase with more user-friendly systems available and advancing technology, especially if insurance coverage is favorable. This source estimates that more than 90% of Type 1 patients are currently using technology but notes the Type 2 market is wide open. Type 2 demand for CGM/pumps could increase 30% or more in the next two years. A few years ago, most of this source’s patients were using the Medtronic 670G. It is not user friendly and the number of alarms drive patients crazy. Once patients qualify for a new system, most move to Dexcom CGM and Tandem Control-IQ pump. Insulet will be introducing the Omnipod 5 system in 2021 (powered by Horizon) with its own algorithm for managing basal rates without the need for tubing. It will be interesting to see how many shift to that system. Insulet’s position as an “insulin delivery device” rather than a pump is very attractive to younger patients. Medtronic is behind in its technology and, although this source is hopeful its next generation will be an improvement, she remains skeptical. The Medtronic sales representative has not shared much information about the new system. There is room for all the pump manufacturers, as they target different market segments/patient preferences. This source expects the demand and growth will remain strong. The Abbott Libre is very simple and inexpensive. Patients like it for its ease of use and this source expects current users will want to upgrade to the Libre 2 for the alarms and alerts. The Abbott sales representative advised they will not be promoting the Libre 2 with any specific pump and described the vitamin C issue. The representative also advised that patients could use Libre 2 with pump technology as long as the provider did a medication review. Beta Bionics’ iLet is very exciting. It will be a huge game changer for upgrading Type 1 patients who will be the majority of that technology’s users.

## CGM/Insulin Pump Market Conditions and Growth Opportunities

- “Technology advancements and increased simplicity will definitely support ongoing market growth. More than 90% of our Type 1 patients are already using CGM with or without pumps. Some of these will upgrade to newer systems when they are eligible. User-friendly systems will be particularly appealing to the Type 2 market, which I expect will grow 30% or more in the next two years.”
- “Adoption will largely depend on insurance coverage. A lot of insurers require patients be on two different insulin types, long- and short-acting, to qualify. We are starting to get details for the Libre CGM.”
- “Younger, technology savvy patients adopt these systems more readily than older patients.”
- “The three pump manufacturers are here for the long run.”

## Tandem

- “Tandem has gained a lot of market share from Medtronic.”

## Insulet

- “Initially patients can be leery about on-body technology, but once they become accustomed to it, my patients like the Omnipod. We are excited about the next-generation, closed-loop system, Omnipod 5, which we expect to be available in 2021. It will provide the algorithm benefits to manage basal rates via Dexcom CGM without the need for tubing.”

Technology advancements and increased simplicity will definitely support ongoing market growth. More than 90% of our Type 1 patients are already using CGM with or without pumps. Some of these will upgrade to newer systems when they are eligible. User-friendly systems will be particularly appealing to the Type 2 market, which I expect will grow 30% or more in the next two years.

*Certified diabetes educator for a Midwestern endocrinology and diabetes center*

# Insulin Pump Market

- “I think we will see more shift toward the Insulet option once they release their next generation.”
- “Insulet is marketing the Omnipod as an ‘insulin delivery device’ rather than a traditional pump. It is the easiest to train patients to use. The simplicity makes it a good option for Type 2 patients.”

## Medtronic

- “A few years ago most patients were using Medtronic, but it is cumbersome to operate and all the bells and whistles drive patients crazy. There has been a significant shift toward Tandem.”
- “More than half of our Medtronic patients are upgrading from the 670G, which requires a lot of attention, to the Tandem Control-IQ, which is a lot easier to use and integrates with the well liked Dexcom CGM.”
- “The Medtronic CGM is way behind Tandem and Insulet. Although I am excited about the potential for their next generation, which is supposed to be more like an artificial pancreas, I am skeptical. Their sales representative has not shared much information with us.”

## Miscellaneous

- “The Libre is very user friendly. Patients like the design and the simplicity of insertion, but the first generation did not have the alarms and alerts, which made many choose Dexcom. With the introduction of Libre 2, I will be interested to see if Dexcom will lose market share to Abbott.”
- “The vitamin C contraindication for Libre 2 is definitely a concern as more and more patients take supplements. However, our Abbott representative advised that our providers would be OK to use Libre 2 with a pump as long as patients received a medication review.”
- “Beta Bionics’ iLet, with the addition of a stable glucagon, promises to be a huge game changer for Type 1 patients. I expect it will gain market share from the other technologies.”

## 5) Certified diabetes educator in a large integrated delivery network in the western United States

Although this source had limited experience with insulin pumps, she believes if communication between the healthcare provider and patient regularly included the pump option, and insurance coverage was easily approved and processed, 90% of her patients would use them. She expects CGM to grow overall as the devices become simpler to use. Although the Medtronic pump is the most commonly used in her practice, the Tandem option is less complex and more user friendly.

### CGM/Insulin Pump Market Conditions and Growth Opportunities

- “I don’t see a lot of pump patients. Most are CGM only. I think that is due to the lack of communication between the primary care provider/endocrinologist and the patient about the pump option.”
- “People are interested in insulin pumps when they are aware of the option. If the insurance coverage was adequate so that it was financially viable, 90% of my patients would opt for pump integration.”
- “There is also the problem that the office staff may not be familiar with how to secure insurance coverage and/or non-coverage for insulin pumps with Type 2 diabetes. Insurance coverage for pumps in Type 1 is an easier process.”
- “CGM will definitely continue to grow, especially as the devices become simpler to use.”

### Tandem

- “Tandem’s pump is less complicated and more user friendly.”

### Insulet

- Did not discuss.

### Medtronic

- “Most of my pump patients use Medtronic. It is easy to work with but it looks a little intimidating at first. It is an older model and more complicated to operate compared with the Tandem pump.”

### Miscellaneous

- “Once a patient becomes accustomed to a particular pump, they generally stick with that brand.”

**CGM will definitely continue to grow, especially as the devices become simpler to use.**

*Certified diabetes educator in a large integrated delivery network in the western United States*

# Insulin Pump Market

## 3) Diabetes Sales Channel

Diabetes sales professionals expect CGM and insulin pump growth to continue over the next 18 to 24 months at a rate of 15% to 40%. CGM adoption will precede and drive pump adoption. Type 1 diabetics will still make up most of the insulin pump market, but there is some growth anticipated with Type 2 insulin users. To gain traction in the Type 2 market insurance coverage must improve, patient cost must be reasonable, and the physical and psychological barriers associated with diabetes technology must be addressed. Abbott's Libre and Libre 2 are highly regarded, as they are easy to use, reasonably priced, and are available through the pharmacy distribution channel. One source described the Libre as the "training wheels" for CGM. The Libre 2 insulin pump integration restriction is expected to be resolved quickly. Tandem is highly regarded and considered the insulin pump leader. It offers strong studies, "cool" technology, was praised for its Control-IQ, and has gained share from Medtronic. Insulet, popular with younger and active diabetics, was referred to as a "niche player." Its next-generation Horizon system is expected to be a strong offering. Medtronic is struggling with lost patient confidence and has lost share to both Tandem and Insulet. Its recent purchase of [Companion Medical](#) and their [InPen](#) are expected to help it recover. In the CGM space, Senseonics, with its implantable device, was discussed as unique and attractive to new patients seeking a discreet monitoring solution. Beta Bionics is viewed as a company of the future and should be competitive within two years. Bigfoot Biomedical is expected to become competitive with its insulin pen and dosing app following FDA approval. The diabetic DIY movement that created technology is considered a positive, as it reduces dependency on the existing manufacturers and has pushed development with its creations.

### Key Silo Findings

#### CGM/Insulin Pump Market Conditions and Growth Opportunities

- 5 said growth in the use of CGM and/or insulin pumps will continue in the 15% to 40% range over the next 18 to 24 months.
- Improved third-party reimbursement, ease of use, and product innovation are all driving increased adoption of CGM and insulin pumps.
- Abbott's Libre 2 is expected to cause some market disruption, offering improved technology, attractive pricing, and distribution through the pharmacy channel. It will have traction in both Type 1 and 2 markets. The lack of approval for integration with pumps is expected to be resolved.

#### Tandem

- 5 view Tandem positively, citing its strong studies, ease of use, innovative technology—including Control-IQ, and remote software updates. Tandem is gaining share from Medtronic and is considered the leader in the insulin pump market.

#### Insulet

- Insulet is popular with younger and active diabetics. Its next-generation product is expected to be of high interest when approved. Market share gains came at the expense of Medtronic. 1 said the Insulet delivery system is a niche product.

#### Medtronic

- Once the leader in CGM and insulin pumps, Medtronic is now struggling, having not kept current with technology upgrades. Its recent purchase of Companion Medical and its InPen and dosing app is considered a positive. Medtronic's next-gen product is of interest, but many diabetics have lost faith with the company.

#### Miscellaneous

- Senseonics offers a unique implantable CGM solution and, when approved for 180 days, it could be more competitive.
- Beta Bionics is viewed as a product of the future which should become competitive within the next two years.
- Bigfoot Biomedical is also expected to gain some traction with its insulin pen offering.
- The diabetes DIY group is viewed positively as a catalyst for innovation.

## 1) Former Medtronic diabetes device sales representative now working for international pharma company in diabetes space; repeat source

This source experienced a drop-off in Medtronic insulin device sales, while watching Dexcom and Abbott flourish in CGM and Tandem lead in insulin pumps. He believes Tandem's t:slim will grow more than 15% over next 18 to 24 months if it



# Insulin Pump Market

does not have production problems. Medtronic just announced its intention to acquire Companion Medical and its InPen—a smart insulin pen that integrates with a companion app. This will help get Medtronic back in the game. Beta Bionics should have a major impact in this time period. Rumors are that [Roche Holding AG](#) (RHHBY) will re-enter the pump market with a slightly modified older product. Insulet's Omnipod will not be a big factor and will continue as a niche player.

Oct. 23, 2019, Dexcom-Tandem interview summary: There are no substantial market changes expected for the next six to 12 months for the growth of Tandem's or Dexcom's products. There are two potential future disruptors: First, Abbott's deals with Tandem and Omada Health have the potential to impact Dexcom's growth but are subject to FDA approval, which pushes this out at least 12 months. Second, the additional CGM to pump interfaces may confuse patients and diabetes educators having to deal with additional combinations and cross-company issues. This may benefit Medtronic, which has both devices under one roof.

June 19, 2019, Tandem interview summary: Tandem's success is related directly to Dexcom's G6 CGM compatibility and Tandem's juvenile diabetic use. Tandem has not been in the market long and, as many other big companies have exited the market, one cannot be sure about its future success. The greatest opportunity is with Type 2 diabetes patients but there is much resistance with payers to cover costs with these patients.

## CGM/Insulin Pump Market Conditions and Growth Opportunities

- “Reimbursement remains the biggest issue impacting the growth of pumps and CGM. Medicare is the biggest payer and they are powerful in determining what gets used. The Type 2 diabetes market is huge and the gains with Type 2 users is growing but pumps use in this group is limited and won't change much in the next 18 to 24 months.”
- “Libre 2 should have a big impact on the market. They are distributed and reimbursed as a pharma product and not DME [durable medical equipment], making it easier for the prescriber and patient.”
- “I've heard that Roche is going to be reintroducing an insulin pump—much like or the same as their old pump but with updates.”
- Dexcom and their G6 are growing the strongest. CMS/Medicare approved the Dexcom CGM and not the Medtronic CGM.”

### Tandem

- “Tandem's t:slim should exceed 15% growth—as long as they have no production capacity issues.”

### Insulet

- “The Omnipod is a good product but a real niche player. They do not have integration with CGM—like Tandem—but appeal to new users, especially in pediatrics.”

### Medtronic

- “Medtronic has bad problems and is losing share. One would think that with their financing and R&D, they will recover in the future, but it may take more than 24 months. In August they announced the planned acquisition of Companion Medical which will give them the connected InPen—a smart pen for insulin delivery that integrates with a companion app.”

### Miscellaneous

- “The company that is developing the insulin pump combined with glucagon delivery is the product of the future. I think that is Beta Bionics.”

**Tandem's t:slim should exceed 15% growth—as long as they have no production capacity issues.**

*Former Medtronic diabetes device sales representative now working for international pharma company in diabetes space*

## 2) Regional sales manager with major insulin device company; repeat source

This experienced diabetes device sales leader sees positives with the introduction of Abbott's Libre 2 and continued growth with both CGM devices and insulin pumps. Libre 2 should be able to work out the integration issues and will disrupt the CGM market. Insulin pump growth will continue. A guarded estimate of 25% growth of Tandem pumps is reasonable, due to CGM growth, integration, and partnerships across the market. Medtronic is struggling to regain user confidence and the MiniMed 680 is not enough to turn them around. Insulet is far behind the leaders but will be boosted when the Horizon platform is approved. Beta Bionics will be a future player and will impact this market within the next two years. Studies are showing that Type 2 patients benefit from pumps and future growth is predicted in this market.

# Insulin Pump Market

**March 26 interview summary:** This source said promoting Tandem's new t:slim X2 is "a salesperson's dream." Tandem sales focus on the new Control-IQ product and the reception has been incredibly positive. Patients on the older Basal-IQ product can upgrade to the new Control-IQ pump for free. Endocrinologists and their staff are initiating discussions on switching from MiniMed on every call and Medtronic is losing patients.

**Oct. 23, 2019, Dexcom-Tandem interview summary:** There are few disruptors to change either Dexcom's or Tandem's growth rates. Tandem should have few negative factors for at least the next year. Dexcom should continue to grow, as new competitive products are not ready to release and are subject to FDA processes. Both companies have positive developments that continue to improve their products.

**June 19, 2019, Tandem interview summary:** Tandem's continued growth and future are very positive, due to its easier to use t:slim X2 with Basal-IQ technology and the strong product pipeline. Market leader Medtronic is losing its grip, as the 670G pump is complicated to teach and learn, leading to higher discontinuation rates. Tandem is putting the burden on the machine—not the patient. The Animus exit is favoring Tandem, as its CGM and infusion sets are the most compatible. Tandem is expanding its field presence and has added a team focused on renewals to improve its 50% renewal rate.

## CGM/Insulin Pump Market Conditions and Growth Opportunities

- "Libre 2 is a major introduction. I believe they will work out their problems that limit their indication and gain approval for pump use with this product. All CGMs have some complications or limits. [I] don't see this as a major problem."
- "Libre 2 will disrupt the CGM market. A lot of healthcare providers prefer the ease of use and cost of the Abbott CGMs."
- "There is definitely room for both the Libre 2 and the Dexcom G6 in the marketplace. Many patients still need CGMs that are not using them."
- "Dexcom G6 is still the gold standard for CGM."
- "Regarding insulin pumps, I see their adaptation continuing to accelerate. The biggest obstacle is wearing a CGM and wearing a second device. There are many partnerships in place to optimize the integration. As more products are introduced, there will be more flexibility for patient variability and diverse needs."
- "Increased pump adoption by Type 2 diabetics will occur within 24 months. Medtronic has been focused on the Type 2 patient for some time and Dexcom is definitely targeting this market for increased CGM adoption."

## Tandem

- "Studies released in June with Tandem's t:slim X2 show efficacy with the Type 1 and Type 2 patients. This will help to open the Type 2 market up."
- "I will guess that the insulin pump market over the next 18 to 24 months will grow by 25% but I can't say I'm real good at these long-term predictions."
- "Tandem has the best insulin pump at this time."

## Insulet

- "Omnipod adoption will be slower than others, due largely to lack of CGM integration. They have announced positive results with their Horizon platform. The study was paused due to the COVID pandemic but has been resumed this summer. They are far behind the leaders in the market. Due to their tubeless feature, they are attractive to 'new to therapy' patients but hurt by their lack of integration with devices."
- "Competitors target Omnipod by differentiating their integration with CGM and other software vs. Omnipod's lack of integration."

## Medtronic

- "Medtronic is struggling since their recall. They must rebuild their credibility in the marketplace. It will take time. I don't see the introduction of the MiniMed 680 as the catalyst to spur significant growth for Medtronic."

## Miscellaneous

- "Beta Bionics is a force for the future and could impact the market. They are recruiting to assemble a sales team and start their promotion. I have heard they will introduce their product as an insulin delivery system and follow up with a glucagon integration system."

Regarding insulin pumps, I see their adaptation continuing to accelerate. The biggest obstacle is wearing a CGM and wearing a second device. There are many partnerships in place to optimize the integration. As more products are introduced, there will be more flexibility for patient variability and diverse needs.

*Regional sales manager with major insulin device company*

# Insulin Pump Market

- “Bigfoot has not gone away—they are still out there. They announced filing for their smart pens integrated with apps to direct patients to the optimal insulin dose for each meal.”

## 3) CGM/insulin pump sales specialist for a durable medical equipment company

This source has seen 15% to 25% CGM/pump market growth and expects it to continue in the next 18 to 24 months. Most carriers will cover these devices for qualified Type 1 and Type 2 patients after the six- to 12-month post-diagnosis honeymoon period, but copays and deductibles vary. This source does not see many new Type 2 patients for CGM/pumps and believes the reluctance may be a result of the fear that the perceived burden does not outweigh the quality of life improvement. Three to four pump manufacturers have gone out of business in the last five years. The existing pump manufacturers are well poised to compete and flourish.

### CGM/Insulin Pump Market Conditions and Growth Opportunities

- “We have seen 15% to 25% year-over-year growth in CGM/insulin pumps and expect this rate is sustainable.”
- “New sales are attributed to three groups—existing system patients seeking an upgrade, existing diabetes patients ready for CGM/pump, and new diabetes diagnoses—[but I’m unable to estimate the percentage of each].”
- “Most carriers will not reimburse for these devices until six to 12 months after a new diagnosis. This is due to the fact that the pancreas is typically still making some insulin during that period. Once the so-called ‘honeymoon period’ is over and the pancreas no longer makes insulin, CGM/pumps are covered.”
- “Most insurance carriers now cover pumps for Type 1 and Type 2, but deductibles and copays differ and can be expensive. The pumps themselves run \$4,000 to \$6,000. Medicaid typically covers pumps if a patient qualifies [based on c-peptide levels] and Medicare has different qualifiers.”
- “I do not see a lot of new Type 2 patients for CGM and pumps, although Medtronic is pushing the systems for insulin-dependent Type 2 patients. But Type 2s need to be injecting insulin at least three times per day to qualify for a pump. Much of the reluctance to use a pump still revolves around the impression that wearing a device all the time is simply too much of a burden without enough improvement in quality of life.”
- “In the last five years, three or four pump manufacturers went out of business. There was not enough demand and available market share to sustain them. But the three who have survived are likely to be around for the long term. Each has their own advantages/market segments.”

**We have seen 15% to 25% year-over-year growth in CGM/insulin pumps and expect this rate is sustainable.**

*CGM/insulin pump sales specialist for a durable medical equipment company*

### Tandem

- “Tandem is the newcomer but they have all the cool tools. And when a patient uses a Tandem pump, the company currently covers the cost of upgrading to the latest technology. So, all a patient needs to do is get a prescription from their doctor for the upgrade (e.g. Control-ID).”

### Insulet

- “Insulet pods are really liked by younger, active patients because there is no tubing—the device sticks directly to the body and is controlled by a handheld device. The latest Omnipod Dash is exclusive to the pharmacy channel so DME companies cannot offer it. But I am not certain what percentage of PBMs [pharmacy benefit managers] will cover them.”

### Medtronic

- “Medtronic has been around the longest and enjoys a lot of brand recognition and trust.”
- “As far as innovations go, Medtronic’s device is not really an artificial pancreas, but it is a step in that direction.”

### Miscellaneous

- “Although I am not aware of the vitamin C contraindication for Libre 2, these Abbott CGMs have a distinctive price advantage. They are also less complex and so are attractive to cost-consciousness, technology-limited patients (e.g., older folks).”
- “When artificial pancreas technology is finally developed, it will be the work of one or more of the existing companies. Currently the software and algorithms are just not there yet. And, although that technology, once perfected, will be a breakthrough for patients, it may not be the disruptive market change companies expect.”

# Insulin Pump Market

## 4) Former clinical manager, physician assistant, and certified diabetes educator for a CGM manufacturer

This source estimates the CGM/pump market growth at 20% to 40% and expects it to continue. Type 1 patients comprise the majority of users, but Type 2 patients are a very large, relatively untapped market. A number of barriers exist to adoption, including coverage and physical and psychological challenges. Pump use, however, can be made very simple and patients can benefit without the use of CGM or counting carbohydrates. Endocrine practices are very knowledgeable about the various technologies, qualifications, and reimbursement procedures but the complexity may deter more general practice providers from encouraging their Type 2 patients to evaluate CGM/pump options. Tandem and Insulet benefited from Medtronic's limitations with the launch of their closed-loop system, as well as the ability to integrate with the Dexcom CGM. The current pump manufacturers serve different market segments, invest in innovation, and will continue to grow with the market demand. Existing patients (those looking for upgrades) are the most common new users for a next-generation pump, but CGM-naïve patients comprised the majority of Senseonics' Eversense implantable device. The DIY CGM/pump software is a life changing improvement for insulin-dependent diabetes patients. Beta Bionics promises to be the first truly artificial pancreas and, although it may not increase the total available market, it will dramatically increase the quality of life for Type 1 diabetes patients. The Libre is considered a training wheels CGM. It is very simple and inexpensive. Despite not having the best sensor and only flash monitoring, it does benefit patients, especially for surveillance/prediabetes and improved Type 2 management.

### CGM/Insulin Pump Market Conditions and Growth Opportunities

- "With all the new diabetes technology, there is definitely increasing demand for CGM/pumps. People want better, simpler ways to manage their diabetes. The market is probably growing at 20% to 40% and will remain strong. Type 1 patients are the majority, but Type 2 is a huge market and less than 50% are achieving their A1C goals. There are a number of barriers to entry, however, including: insurance reimbursement issues, physical challenges (e.g., tape allergy, kinked cannula), discomfort with technology, and psychological barriers to using these devices. But pumps can be used as simply as a patient needs them to be. New pump patients experience better control even without CGM and/or carbohydrate counting."
- "Type 2 patients with a family practitioner as their primary care may be less likely to learn about new diabetes technologies and the office staff may not be familiar with the reimbursement qualifications and processes. In the endocrinology clinic there is a much greater degree of comfort with the systems and requirements. Once a new practice does become more immersed in the technology and reimbursement procedures, the providers and staff become strong advocates."

### Tandem

- "Insulet and Tandem's integration with Dexcom has been a huge advantage. Tandem's Control-IQ has done well."

### Insulet

- "Insulet will be coming out with their hybrid closed-loop version soon."
- "The Insulet pharmacy channel strategy may be a distinct advantage for some, as it is an easier process. The wireless technology is also a distinct advantage for some patients."

### Medtronic

- "Medtronic had most of the pump user market and actively pursued the Type 2 market. In 2017 when they released their first hybrid closed-loop system, however, it fell flat for a variety of reasons, sensor and transmitter issues among them. This allowed Tandem and Insulet to shine."

### Miscellaneous

- "It is wonderful to have multiple pump options. Patients can select the best fit that works for them. There is definitely space for all as the manufacturers continue to innovate, grow, and serve unique segments of the patient population."
- "Typically, when an existing manufacturer launches a new [next-generation] pump, the majority of the patients are upgrades. But the new patients for Senseonics' implantable CGM were mostly CGM naïve, despite the added complication of the implant procedure."
- "The DIY CGM/pump software has been a godsend for diabetes patients. A1C and time-in-range improves significantly. This is the closest thing to an artificial pancreas we currently have, even though it is not FDA approved."

With all the new diabetes technology, there is definitely increasing demand for CGM/pumps. People want better, simpler ways to manage their diabetes. The market is probably growing at 20% to 40% and will remain strong.

*Former clinical manager, physician assistant, and certified diabetes educator for a CGM manufacturer*

# Insulin Pump Market

It offers dramatic improvement in quality of life and decreased long-term complications. I use it myself and can finally sleep through the night.”

- “Beta Bionics will be the first official artificial [bionic] pancreas. It promises to effectively replace the endogenous activity. It is a very promising technology. Ultimately, the closer the technology gets to an endogenous pancreas the better. Although it may not impact the size of the available market, it will dramatically impact the quality of life, particularly for Type 1 diabetes patients.”
- “Libre is inexpensive and simple to operate. Many providers considered it ‘training wheels’ for new patients. It is not a continuous monitor and is relatively inaccurate, but it provides quite a lot of benefit for prediabetes, surveillance, and Type 2 management nonetheless.”
- “I am not specifically aware of the Libre 2 vitamin C contraindication, but this has happened to other manufacturers in the past [with both vitamin C and acetaminophen warnings/contraindications]. In those cases, the CGMs were still allowed to integrate with pumps.”

## 5) Certified diabetes care and education specialist, clinical dietitian, and former sales trainer for major diabetes technology companies

This source believes market growth will remain in the 15% to 20% range for the next two years but expects that had COVID-19 not impacted the economy so significantly the growth would be greater than 25%. Insurance coverage and patient costs are an obstacle, but the greater issue for Type 2 patients is that they are less involved in effectively managing their own disease and feel a stigma that their behavior caused it. Less than 10% of Type 2 patients are targets for diabetes technology. CGM is the brain and leads pump technology. Although pumps have been around a lot longer, CGM is more important in disease management. Insulin delivery is the easy part. The main driver for patients is the ability to avoid finger sticks. Universal CGM/pump integration would be a great advancement, allowing patients to customize to their needs and preferences. There is room in the market for the current pump manufacturers and newer technologies. Medtronic stopped thinking about the patient, so Tandem and Insulet have been able to gain market share with more user-friendly features. The vitamin C issue with Libre 2 is likely to be short lived, but most Libre patients are not pumpers.

### CGM/Insulin Pump Market Conditions and Growth Opportunities

- “I do not see the CGM/insulin pump growth slowing down. It is likely to stay in the 15% to 20% range even in the face of people losing their employment and insurance coverage. If COVID had not happened, I would say the market would grow more than 25%.”
- “There will be growth with Type 2 patients, but there is still the issue of insurance coverage. There is also the challenge that Type 2 patients often do not understand and even deny their disease. They are not as involved in disease management and the long-term complications are too far in the future to worry about. The stigma that Type 2 patients did this to themselves also makes them reticent to use visible technology. Type 2 just comes with a different mindset than Type 1. Probably less than 10% of Type 2 patients are good candidates for diabetes management technology.”
- “Type 1 and Type 2 diabetes are really completely different diseases.”
- “Plenty of Type 1 patients take intermittent breaks from the technology. We call it ‘diabetes vacation’ when these patients remove the technology with all its associated bells and whistles and go back to manual injections for a while. All that data all the time can simply get overwhelming.”
- “I have had plenty of patients that thought the CGM and/or pump would magically do everything for them so they wouldn’t have to think about their disease. But they do have to think and still need back-up strips and insulin. That can be a disappointment for many.”
- “Having a variety of technology options that meet different patient needs is great. The three pump manufacturers will continue to do well and there is even more room for others. What I hope happens is eventually patients will be able to use any CGM with any pump.”
- “Pumps have been around a lot longer than CGM, which has really only caught on in the last five years or so. The CGM is the more important part: it provides the information to know when and how much insulin to take. It is the

**I do not see the CGM/insulin pump growth slowing down. It is likely to stay in the 15% to 20% range even in the face of people losing their employment and insurance coverage. If COVID had not happened, I would say the market would grow more than 25%.**

*Certified diabetes care and education specialist, clinical dietitian, and former sales trainer for major diabetes technology companies*

# Insulin Pump Market

brain. Administering the insulin is not the hard part. All Type 1 patients should be on CGM, which helps improve time in range, lower and stabilize A1C, and ultimately reduce disease complications. The patients who are on pump only are likely to be older, but I do not expect many new patients are given a pump without CGM. CGM leads pumps.”

## Tandem

- “Tandem with Dexcom CGM is much more user friendly than the Medtronic system. I like that it is a lot more intuitive. Reports are easier to interpret. Software updates are great.”

## Insulet

- “Insulet with Dexcom CGM is a good option for younger patients because it is more discreet and tubeless.”

## Medtronic

- “Medtronic has their own CGM which works with their pump and does not integrate with other brands. I think they would get more pump sales if they integrated with other CGM brands. They need to start thinking outside the box. They owned the industry so long that I think they stopped thinking about the patient. They get stifled in their own processes and are not really seeing what people want.”

## Miscellaneous

- “Libre is very reasonably priced and simple to operate. I do not think the vitamin C contraindication will really impact sales. CGMs have had these types of issues in the past with acetaminophen but the manufacturers work it out. I don't think the pump integration problem will be too long lived. Notably, also, most people who wear Libre are not pumpers. They are just tired of finger sticks but generally OK with insulin injections.”
- “The Senseonics implantable CGM is just the size of a Tic Tac, but it does require a surgical procedure and recovery, which necessitates provider training and patient scheduling. Currently it is only approved for 90 days so requires replacement every three months. They are waiting on their 180-day use approval [in the United States, which they already have in the EU] which will be significantly more convenient for patients. The clear advantage is the discretion. Alerts are associated with vibration in the arm, but the transmitter is required to get the data. The transmitter placement can be tricky. It needs to be placed just right to get reliable and consistent readings.”
- “If CGMs and pumps ever become truly interchangeable it would be a big advancement allowing for more personalized systems.”
- “Another needed advancement is more ease in data downloading, so all that data can be analyzed in whatever form the patient prefers.”
- “There is a lot of anger in diabetes, a lot of bitterness. Diabetes patients have a love-hate relationship with the technology and the pharmaceutical industry [because of the price of insulin]. There is not much in the diabetes industry that is not price insulting. When patients are sold something super expensive and it does not do what's expected, there is no turning back. The DIYers are demonstrating that they do not have to be completely at the mercy of the manufacturers.”
- “Manufacturers really need to invest in robust patient websites with clear, concise, and purposeful information and help, on demand.”

## 4) Industry Specialists

All four industry specialists expect the CGM and insulin pump market to continue to grow in the 15% to 30% range over the next two years. Type 1 diabetics will be the dominant users of insulin pumps, but Type 2 diabetics taking multiple insulin doses are a growing market. One source said the coronavirus pandemic is motivating diabetics to take better care of themselves and could drive additional adoption of both CGM and insulin pumps. Third-party reimbursement is improving and is a key driver of growth. Tandem and Insulet are considered strong insulin pump competitors with significant technology and ease of use advantages over Medtronic. Despite Medtronic lagging behind the competition in both technology and ease of use, the company's size and next-gen products are expected to keep it competitive. Beta Bionics was discussed as an emerging competitive company, but it still faces challenges with its insulin and glucagon delivery system. Bigfoot Biomedical was discussed as still being a few years out with its insulin delivery system.

### Key Silo Findings

#### CGM/Insulin Pump Market Conditions and Growth Opportunities

- 4 said the CGM and insulin pump market will continue to grow over the next 18 to 24 months in the 15% to 30% range.

# Insulin Pump Market

- Type 1 diabetics will make up the bulk of the pump market, but Type 2 patients that require multiple insulin doses per day is a growing segment
- 1 said the coronavirus pandemic is motivating diabetics to adopt CGM and insulin pumps.
- Third-party reimbursement for CGM and insulin pumps is improving and is a key growth driver.

## Tandem

- 4 were positive regarding Tandem's insulin pumps.
  - o 1 praised its Control-IQ technology, user friendliness, and said the Dexcom G6 and t:slim pump is the strongest in the market.
  - o 1 said Tandem is close to the artificial pancreas.
  - o 1 said Tandem is taking share from Medtronic.

## Insulet

- 4 were positive regarding Insulet's insulin delivery system.
  - o 1 said Insulet has strong marketing with PBMs.
  - o 2 said the Insulet pump is simple and smart.
  - o 1 said some patients are drawn to Insulet because there is no tubing.

## Medtronic

- 4 were negative regarding Medtronic, although they did acknowledge the company has the resources to turn it around.
  - o 1 said Medtronic's CGM and insulin pumps are not user friendly and are outdated.
  - o 1 said Medtronic's product are complex and its development is slow and often disappointing.
  - o 1 said Medtronic is lagging behind the competition.
  - o 1 said Medtronic has not improved its technology, which has allowed Tandem to gain share.

## Miscellaneous

- The CGM and insulin delivery market is highly competitive. Sources discussed several companies and their product development and offerings in the space, however, no significant of disruptive technology is expected in the near term.
  - o Abbott's Libre and Libre 2 are strong CGM systems with expectation of wide integration, but the Libre 2 integration restriction is a setback.
  - o [Bioling's](#) technology is said to be a potential disruptor.
  - o [Becton Dickinson and Co.](#) (BDX) has been developing a product since 2009; however, commercialization is considered unlikely.
  - o Bigfoot Biomedical offers some promise but its technology still has challenges to overcome.
  - o Beta Bionics also has innovative technology and faces similar challenges to Bigfoot.

## 1) Diabetes technology consultant

The CGM/pump market will continue to grow at 20% to 25%, with 60% consisting of existing user upgrades and 40% from new diagnoses. Type 1 represents the majority of the users, but the insulin-dependent Type 2 users will grow faster. A key adoption driver is reimbursement. Commercial insurance coverage varies but is improving. Pump manufacturers will be able to keep up with demand. Insulet has a strong PBM strategy that Tandem and Medtronic cannot compete with. Medtronic technology is not user friendly, but they have a great pump. Medtronic's purchase of Companion Medical is expected to help them transition device-naïve patients to their CGM/pump systems. From an insulin delivery standpoint, this respondent sees nothing disruptive on the horizon.

### CGM/Insulin Pump Market Conditions and Growth Opportunities

- "The CGM/insulin pump growth rate is around 20% to 25%. Certainly, there will be patient brand switches [estimated at 60%] but there is still room for new patient growth, mainly from new diagnoses [estimated at 40%]."
- "There will be a lot of new growth for Type 2, particularly with CGM as more Type 2 patients become insulin dependent. Although Type 1 will make up the majority of the market, as a percentage, there will be faster growth in Type 2."
- "A key driver to adoption is the reimbursement mechanism. Pharmacy benefits typically cover CGM. Commercial [medical] payer coverage varies, although it is improving as more insurers are realizing that insulin dependence should be the primary consideration, not whether the patient is Type 1 or Type 2."

# Insulin Pump Market

- “With Type 2 patients on oral medications, the novelty of a CGM might wear off in a few months, particularly if they feel well. But for those patients requiring multiple injections every day [which is ~1.3 million patients in the United States], patients are more likely to be compliant long term.”
- “Although there are influencing factors including patient age, comfort with technology, and confidence in the accuracy of the system, most will stick to a CGM/pump system with which they are familiar as long as they feel well and can make sound dosing decisions. If confidence is low, patients are more open to exploring other brands and systems.”
- “Most insurers cover CGMs regardless of brand, but copay varies. This could influence selection with cost-conscious patients.”
- “Pump warranties are typically four years and a replacement will not be covered unless there is a failure.”
- “The pump manufacturers can definitely keep up with the demand and growth. They have the ability to scale from manufacturing to patient on-boarding.”

The CGM/insulin pump growth rate is around 20% to 25%. Certainly, there will be patient brand switches [estimated at 60%] but there is still room for new patient growth, mainly from new diagnoses [estimated at 40%].

*Diabetes technology consultant*

## Tandem

- “Tandem has received a lot of praise for its Control-IQ [automated insulin delivery algorithm]. It is perceived by both healthcare practitioners and patients as very user friendly. The strongest pairing on the market is the Tandem pump paired with the Dexcom G6 CGM and its market-leading sensor accuracy.”

## Insulet

- “Insulet is able to handle the growth. They have a great team and a strong pharmacy strategy.”
- “Tandem is pushing the newest disposable Omnipod for exclusive pharmacy coverage, bypassing DME, so that a patient does not have to go through the medical benefit approval process. Tandem and Medtronic cannot put a [\$4,000 to \$5,000] pump through the pharmacy benefit system.”

## Medtronic

- “Medtronic has not done much with their sensor technology since 1999/2000. They are like the dial-up fax machines of CGMs. And their 670 CGM is very complex. Patients have to calibrate sensors manually. It is not user friendly. But they do have a great pump.”
- “Medtronic also purchased Companion Medical which will allow them to capture naïve patients with the smart pen and introduce them to data capture and technology-assisted diabetes management, which will allow for easier transition to CGM/pump when the patient is ready.”
- “Medtronic is a big company with a lot of egos, but they have had a change of heart from more arrogant days. They are more practitioner friendly now. But they will need to have great patient segmentation and improved ease of use to remain leaders in the space. Presently, Tandem is eating their lunch.”
- “Medtronic device supplies through the pharmacy channel is variable. This is primarily the result of short-term [two-year] business unit leadership postings and a reluctance to make significant changes in their business model/processes.”

## Miscellaneous

- “Pumps acquired through durable medical equipment companies typically have better patient engagement and, therefore, improved compliance. Supporting seamless processes, logistics, customer support, and one-stop shopping is part of the DME business model. They typically lose money on-boarding a new diabetes patient, so there is financial incentive to keep that patient engaged and compliant over the long term.”
- “Although I would typically expect Abbott to phase out Libre 1 in favor of Libre 2, they are unlikely to do so in the face of the pump integration limitation. The adoption of Libre 2 as a standalone CGM will rely on Abbott’s high powered/budgeted marketing efforts and effective patient segmentation.”
- “Biolinq utilizes a unique array technology to measure a variety of analytes. It is a very interesting technology that could be a potential disrupter.”
- “Becton Dickinson has been trying to develop a patch pump since 2009. Although an interesting concept, I am not confident they will ever have a commercial product.”
- “Bigfoot Biomedical has a smart pen product in FDA. They envision a comprehensive ecosystem vision to integrate with Abbott [Libre 2] and potentially develop an integrated pump. But this would be years off.”
- “From an insulin delivery [pump] perspective, I do not see anything disruptive on the horizon.”



# Insulin Pump Market

## 2) Business development manager with CGM/insulin pump expertise

CGM/insulin pump demand will grow 25% to 30% in the next 18 to 24 months. Sales will come primarily from Type 1 diabetes patients, with the majority upgrading to the next generation devices. Patients who are comfortable with their technology and feeling physically well are likely to stick to the same brand. Type 2 insurance coverage is not as robust and up to 40% of Type 2 patients will become non-compliant within a year. Medtronic devices are unnecessarily complicated and each model has had a distinctive consumer disadvantage. Tandem and Insulet are strong companies able to fulfill demand. Simplicity, convenience, and affordability are the key factors to strong market growth.

### CGM/Insulin Pump Market Conditions and Growth Opportunities

- “CGM/insulin pump demand will probably increase 25% to 30% in the next 18 to 24 months. But almost all of the sales growth will come from Type 1 diabetics who really need this technology. Moreover, much of it will be existing CGM/pump users upgrading technology.”
- “Type 1 insurance coverage is well funded. This is not the case with Type 2. Many Type 2 diabetics cannot afford these systems.”
- “Of those who use CGM/pumps, approximately 90% of patients with Type 2 diabetes are enthusiastically compliant for about six months; by the one-year point that drops to 60%. Compliance is just not great over time.”
- “Type 2 patients get fatigued and frequently stop using the devices and/or may lose the insurance/means to pay for them. Meters and strips are inexpensive and can be used as needed.”

### Tandem

- “Tandem is a strong company and will maintain steady growth with the ability to fulfill demand.”

### Insulet

- “Insulet has grown steadily over the years. Patients like their technology. It is very simple and provides the need-to-know information, which wins out over complexity and detail. The company has good people, is responsible with money, and has a strong position in the market.”

### Medtronic

- “Medtronic has a breadth of product line but has unnecessary layers of complexity. They are a large, slow moving company that haven't made the most of their technology and have definite disappointments.”
- “The 670 has the desirable auto shut-off for low glucose and a data download feature, but it is too complicated for many patients. The 630 has carbohydrate and insulin level indicators, but the screen is too small for many people to read, even with glasses. And the 530G is not watertight so patients cannot wear it in the shower, the LCD light level is too low to read in daylight, and the bolus function is too slow for effective management.”

### Miscellaneous

- “The available [commercialized] CGM systems are not highly differentiated. The disruptive technologies are brewing in the background, developing transformational technologies at lower costs. Successful introduction of simple, convenient (e.g., implantable), and affordable CGM/pump systems could potentially drive significant new patient adoption.”
- “For most patients, they are ready for a new device with renewal cycle eligibility. If they are comfortable with their brand and physically feeling well, they are more apt to stay with that brand. Familiarity is comfortable, and good enough is good enough. Others will investigate new technologies.”

## 3) Jay Warner, biotechnology executive, diabetes expert

The market growth will remain steady in the range of 15% to 20% in the next two years but there is much more room to grow. Type 2 patients have a slower technology adoption than Type 1 based on their disease progression. Once they need to inject insulin multiple times a day, they are typically referred to an endocrinologist/diabetes educator who is well versed in the available technologies and insurance requirements/processes. Using CGM as a two-week diagnostic is a newer, billable tool for the primary care practitioner. The three existing pump manufacturers will be in the market for the long run; the greater risk is the viability of new companies. The Tandem pump is getting closer to an artificial pancreas and upgrades are done through software only. Insulet is soon to come out with a competing smart pump. When it gets there, they will be more competitive. Medtronic's software is lagging and its pump is the least elegant. It has to step up its game but is big enough to ride it out. Beta Bionics is very simple: weigh yourself and it takes over. It uses the Dexcom CGM. Its next generation will use both insulin and glucagon. The question is how much greater the time in range will

# Insulin Pump Market

actually be, as it is already more than 70% with most CGMs. Bigfoot is doing something similar but interfacing with the Abbott Libre.

## CGM/Insulin Pump Market Conditions and Growth Opportunities

- “The CGM/pump market will maintain 15% to 20% growth in the next two years but there is still a lot of room to grow.”
- “The Type 2 market will grow, but differently. Technology will have to be very simple. Type 2s have to progress in their disease to be interested in these tools.”
- “People on multiple daily injections are the proper targets. There is not an urgent need for many Type 2s to adopt technology, as they do not have immediate and severe concerns like going ketonic. They get more interested as their disease progresses.”
- “CGM has already gone down the path of clinical trials for Type 2. But these individuals are more likely to use it intermittently—[once a month/quarter, etc.]. CGM has also found a niche as a billable two-week initial diagnostic tool in the primary care clinic.”
- “The three pump manufacturers will survive and thrive but will have to remain competitive with newer technologies.”

**The CGM/pump market will maintain 15% to 20% growth in the next two years but there is still a lot of room to grow.**

*Jay Warner, biotechnology executive,  
diabetes expert*

## Tandem

- “Tandem is probably my favorite pump. It is getting closer to the artificial pancreas. Upgrades are done by software.”
- “Tandem is big enough to fight off some of the newcomers.”

## Insulet

- “Omnipod is soon to come out with their own smart pump. When they get there, they will be even more competitive.”

## Medtronic

- “Medtronic software is lagging. Their CGM is not factory calibrated so requires two sticks per day. It’s a burden and not as smart as the Tandem. Medtronic’s pump is the least elegant. They are behind but are big enough to ride it out.”

## Miscellaneous

- “Beta Bionics is very simple and uses Dexcom technology. A patient weighs themselves and the system takes over. The use of glucagon suggests more time in range. Their next generation will include both insulin and glucagon.”
- “Time in range for existing CGM systems is more than 70%. It is unclear whether the Beta Bionics will be significantly better.”
- “Bigfoot is trying to emulate the weigh-and-go approach. They will be integrating with the Libre CGM.”
- “The vitamin C issue is probably not a big concern for Libre 2, as the users are primarily Type 2. The Dexcom CGM is preferred by Type 1 for its greater accuracy.”

## 4) Board of directors of a diabetes technology startup company

The market for CGM/insulin pumps will continue on its current 15% to 20% growth trajectory for the next two years but the introduction of simpler, discreet devices—including FDA-approved artificial pancreas technology—will increase the penetration by another 50%, targeting new diagnoses and people who are currently unhappy with the technology they are using. The COVID-19 epidemic has more diabetic patients concerned about taking better care of themselves to avoid long-term complications. Although most patients who regularly visit their endocrinologist are using technology, 60% to 70% of the total Type 1 patient population is not using CGM/pump devices. Two significant factors impede market penetration and growth: 1) Economics—technology can be costly without adequate coverage and 2) Discretion—people with diabetes want simple and discreet technology; pump tubing/device tethering can be seen as too much of a burden and/or embarrassing. In the past, pump technology (insulin delivery devices) had the power, but CGMs now lead in adoption as devices become smarter, more accurate, and easier to operate. As a result, CGM will grow faster and the pump market will be pulled along. The current pump manufacturers are in the market for the long run. Insulet’s Omnipod’s No. 1 driver of adoption is that it is not tethered. Because Medtronic has not made great advances in its technology, Tandem has gained a significant amount of its market share. Although potentially promising, this source advises that there may be technical issues with glucagon delivery with the Beta Bionics iLet system. The diabetes

# Insulin Pump Market

technology market is very competitive, with a great deal of ongoing research, but one of the fundamental disease management issues is the cost of insulin—no one is addressing that problem.

## CGM/Insulin Pump Market Conditions and Growth Opportunities

- “The CGM/pump market will continue at existing growth rates [of 15% to 20%] over the next two years. Key drivers include the COVID pandemic, which is making Type 2 diabetes patients more acutely aware that they need to better care for themselves to avoid long-term complications.”
- “60% to 70% of Type 1 patients do not use CGMs. A busy endocrinology clinic definitely pushes technology but a lot of patients do not have regular access to specialists.”
- “CGM barriers are coming down. Patch technologies are more readily acceptable. Flash CGM is easy breezy.”
- “One of the factors pulling market growth back is economic uncertainty. Patients have to be more cautious with discretionary income and out-of-pocket costs for many of these devices are high.”
- “CGM is a bridge into pumping. As such, CGM will grow ahead of the pump market.
- “Current pump manufacturers are here for the long haul. For a long time the pump companies had the power; everything was focused on the delivery mechanism. But the power of the CGM is overshadowing the pumps now. Even the least accurate is better than a finger stick.”
- “People with diabetes are in denial—the more technology can help them hide the fact that they have this disease, the better.”

The CGM/pump market will continue at existing growth rates [of 15% to 20%] over the next two years. Key drivers include the COVID pandemic, which is making Type 2 diabetes patients more acutely aware that they need to better care for themselves to avoid long-term complications.

*Board of directors of a diabetes technology startup company*

## Tandem

- “The Tandem-Dexcom system is a strong option and preferred to Medtronic.”

## Insulet

- “Disposable insulin pumps [like the Omnipod] are not tethered [which is their] number one driver to adoption.”
- “[Insulet] Continues to take business from competitors.”

## Medtronic

- “Medtronic hasn’t advanced their technology which has allowed Tandem to take market share.”

## Miscellaneous

- “I think the energy behind the concept of artificial pancreas technology will drive adoption. Beta Bionics will focus on newly diagnosed, technology naïve patients. They will learn on their system. Another target segment will be those unhappy with their current technology, but they will not specifically target the technology savvy.”
- “Beta Bionics may have an issue with the glucagon delivery aspect [of bolus versus basal].”
- “This market is extremely competitive [and there is] a lot of research, but one of the fundamentals is that insulin is very expensive, and no one is addressing that issue.”

## Secondary Sources

These three secondary sources focus on the FreeStyle Libre 2’s availability through Medicare, the size of the global insulin pump market, and the announcement by an Israeli company that it plans to test a “bionic pancreas.”

### Sept. 1 Drug Delivery Business News [article](#)

Abbott announced that the FreeStyle Libre 2 is eligible for Medicare reimbursement.

- “Abbott (NYSE:ABT) announced today that its next-generation FreeStyle Libre 2 iCGM is now available to Medicare patients.”
- “The integrated continuous glucose monitoring (iCGM) system met the codes for therapeutic CGM systems used for coverage by the U.S. Centers for Medicare & Medicaid Services (CMS), making it accessible to all Medicare patients with diabetes who meet the eligibility criteria, according to a news release.”

# Insulin Pump Market

- “Abbott Park, Ill.-based Abbott’s FreeStyle Libre 2 includes a sensor worn on the back of the upper arm for up to 14 days, using a handheld reader over the sensor to provide real-time glucose readings, trend arrows and eight-hour history to help healthcare providers and users make informed treatment decisions.”
- “The system also includes real-time alarms and minute-by-minute glucose measurements, while Abbott touts it as the longest-lasting self-applied iCGM sensor currently available, eliminating the need for finger sticks and costing a third of the price of other CGM systems.”
- “‘Abbott designed the FreeStyle Libre portfolio for performance, access and affordability to make it broadly available to people with diabetes who need it,’ Abbott senior VP of diabetes care Jared Watkin said in the release. ‘By securing reimbursement, Abbott is making sure our latest life-changing technology can get to everyone who needs it, whether they’re children, adults or seniors eligible for Medicare.’”

## Aug. 21 Market Watch [article](#)

The global insulin pump market is expected to have a compound annual growth rate (CAGR) of 9.4% over the period of 2019 (when the pump market was \$4.15 billion) to 2027 (when it is projected to reach \$8.50 billion).

- “The global ‘[Insulin Pump Market Share](#)’ is likely to gain impetus from the ever-increasing prevalence of diabetes reported worldwide. Coupled with this, the rising geriatric population and surging number of people affected by type 1 diabetes would drive the market growth. Fortune Business Insights™ provided this [information](#) in a recent report, titled, ‘Insulin Pump Market Size, Share and Industry Analysis, By Product Type (Pumps (Tethered Pumps, Patch Pumps, and Others), and Consumables), By Disease Indication (Type 1 Diabetes and Type 2 Diabetes), By Distribution Channel (Hospital Pharmacy Retail Pharmacy, and Online Stores), and Regional Forecast, 2020-2027.’ The report further states that the insulin pump market size was USD 4.15 billion in 2019 and is projected to reach USD 8.50 billion by 2027, exhibiting a CAGR of 9.4% during the forecast period.”

## July 23 *The Guardian* [article](#)

An Israeli company plans to begin trial in the UK of its “bio-artificial” pancreas which would free diabetics from the need for insulin injections.

- “An Israeli company claiming to have created a tiny micro-pancreas that can ‘cure’ diabetes for millions of people has said it will submit a request next month for human clinical trials in the UK.”
- “Betalin Therapeutics said its ‘bio-artificial’ pancreas aims to free patients of the need for insulin injections and blood sugar monitoring. It is designed for people with type 1 diabetes, and those with type 2 diabetes who require insulin.”
- “The Jerusalem-based firm told the Guardian it would provide a plan for clinical trials to Britain’s regulatory agency in August. Betalin aims to begin human testing early next year, with the hope of delivering to the market by 2024.”
- “Central to the innovation is a biological scaffold, adapted from pig lung tissue, that holds beta cells. Those cells release insulin based on the patient’s blood sugar levels. The miniature artificial pancreas, just visible to the naked eye, is implanted under the skin on the thigh using local anesthesia.”
- “‘Our unique technology allows the body to heal itself,’ said Nikolai Kunicher, the chief executive of Betalin. ‘For now, the focus is on diabetes, but there are many more diseases that we intend to cure with the aid of this technology.’”

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Additional research by Pam Conboy, James Boland, and Bruce Wicks.

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