CLOSER LOOK

MEMORANDUM

Automated Insulin Delivery (AID) Competitive Landscape - February 3, 2022

Executive Highlights

- **The tables below include an overview of the automated insulin delivery (AID) landscape in the US and internationally, to the best of our knowledge.** As of the end of 2021, we estimate the global AID userbase at >600,000. The list is organized first by products currently available (MiniMed 770G, MiniMed 780G, Tandem Control-IQ, Roche/Diabeloop/ Dexcom), then by expected time to market - meaning either pivotal trial or launch (whichever has been disclosed). We have separated primary players from those that are very early stage or that rarely give updates.
- **We acknowledge this list may be incomplete,** as there are likely other stealth startups or academic groups working to commercialize AID technology.
- **This list only includes organizations with a declared plan/timing to conduct a pivotal study and/or launch.** We have excluded longer-term R&D efforts (e.g., intraperitoneal, in-hospital), even though these could eventually be used in AID.
- **We will continuously update this list as timelines change,** but it is only up to date as noted above. The included timelines are based on publicly disclosed information as indicated in the "recent coverage" column. If you see an issue, please let us know.

February 3, 2022 update: With Omnipod 5 having received FDA clearance last week, we've updated our landscape to reflect the growing number of available systems and the changes seen in the pipeline over the past few months. The biggest update is, of course, Omnipod 5's FDA clearance - the first for a tubeless, patch pump-based AID system - and soon-to-begin limited launch. While Medtronic's MiniMed 780G, Tandem's Control-IQ smartphone control, and Tidepool's Tidepool Loop are all still under FDA review, Tandem and Medtronic have made progress internationally. Control-IQ has now launched in >20 geographies and is used by >200,000 people globally, and MiniMed 780G has launched broadly in >40 OUS markets on four continents. Both companies have also spoken on their long-term pipeline plans, with Medtronic again mentioning a patch pump project at JPM 2022 and Tandem discussing Tandem Mobi (f.k.a. t:sport), a docked-version of Mobi (Mobi: Tubeless), and a patch pump during its R&D Day in December. Insulet and Tandem both continue to progress in gaining expanded indications for their AID systems in preschoolers and type 2s, with Insulet in the lead in both efforts. Outside the "big three," the integrated Diabeloop x Roche x Dexcom AID system is now available in Germany, Spain, Italy, the Netherlands, and Switzerland, and real-world data from its European use was read out at EASD 2021. Cambridge-based CamDiab's CamAPS FX has seen several notable data readouts and publications, including a *NEJM publication* on CamAPS FX in preschoolers and a *Nature Medicine publication* on its type 2-specific algorithm. In December, Beta Bionics announced a data lock on its insulin-only iLet pivotal, which will be read out at ATTD 2022 in April in Barcelona, and the bi-hormonal iLet pivotal has begun recruitment, a major milestone for the company. Read on for more!

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Already Launched

- **Medtronic MiniMed 780G hybrid closed loop - Launched in over 40 OUS markets on four continents.** The OUS MiniMed 780G launch was announced in October during Medtronic's 2020 Investor and Analyst Day. MiniMed 780G received CE-marking in June 2020 and adds automatic correction boluses, Bluetooth, mobile app connection, and remote software updates with a next-gen pump and algorithm. In the US, Medtronic has submitted 780G to the FDA as a class III PMA submission that includes adult and pediatric data, as well as data to support the approval of and 780G integration with Medtronic's Guardian 4 Sensor. Medtronic expects clearance "in the first half of 2022." See more in Medtronic 3Q21.
- **Medtronic MiniMed 770G hybrid closed loop - In US markets since November 2020.** MiniMed 770G is the first AID system approved for use in 2-6-year-olds in the US, following FDA approval in September 2020. The system also received CE-Marking in June 2020. MiniMed 770G uses the series 700 pump hardware (i.e., the pump technology from MiniMed 780G), but has the same algorithm and Guardian Sensor 3 CGM as the MiniMed 670G system. MiniMed 770G includes Bluetooth connectivity and can interface with Medtronic's new MiniMed Mobile app (App Store; Google Play). While the pump updates in 770G are minimal, the big win will come when patients can upgrade their 770G systems to the 780G algorithm for free when MiniMed 780G launches in the US. In December 2021, CMS announced new rules that will allow for Medicare coverage of some adjunctive CGMs, including those used in the MiniMed 770G system, that will go into effect in late February 2022.
- **Tandem Control-IQ hybrid closed loop - More than 200,000 people are using Control-IQ (as of December 2021).** Currently, Control-IQ is approved for use in people with type 1 ages 6+. Control-IQ received FDA clearance as Class II iController in December 2019 and officially launched in January 2020. Control-IQ continues to roll out internationally: as of December 2021, the system is available in 20+ countries, slightly behind plans to expand to 25 geographies by the end of 2021. Smartphone bolus control is expected to launch in "early" 2022 via an app update, with additional algorithm enhancements and integrations with Dexcom G7 and Abbott CGMs to follow in 2022 and 2023. See more in Tandem 3Q21 and in Tandem R&D Day.
- **Roche, Diabeloop, and Dexcom's AID system - In select European markets**. The system integrates Roche's Accu-Chek Insight pump, Diabeloop's DBLG1 AID algorithm, and Dexcom G6. When it launched in March 2021, it became the first AID system that uses a pump with prefilled cartridges. The Roche/Diabeloop/Dexcom system is currently available in Germany, Spain, Italy, the Netherlands, and Switzerland, as of July 2021.
- **CamDiab's CamAPS FX - Launched in the UK.** University of Cambridge spinoff CamDiab's AID system, CamAPS FX, was CE-Marked and launched in the UK in March 2020. CamAPS FX uses an Android app (including smartphone pump control), Dexcom G6, and SOOIL Dana Diabecare RS pump. In addition to smartphone control, CamAPS FX is also the first AID system available for pregnant women and children down to one year old. In March 2020 when the system launched, CamAPS FX availability was limited to patients in 11 NHS clinics, where certified trainers are available. We have yet to receive an update on availability and coverage.
- **Medtronic MiniMed 670G hybrid closed loop - In US and select OUS markets with ~249,000 users globally** (as of 1Q20, likely far lower now that MiniMed 770G is widely available in the US and 780G is widely available internationally). The pace of userbase growth for MiniMed 670G has slowed in recent quarters, likely due to competition from Tandem and MiniMed 770G and 780G. The system was first approved by the FDA in 2016. In December 2021, CMS announced new rules that will allow for Medicare coverage of some adjunctive CGMs, including those used in the MiniMed 670 system, that will go into effect in late February 2022.
- **Tandem Basal-IQ predictive low glucose suspend - In US and select OUS markets, enabled on >50,000 pumps,** although this figure is several years old and likely lower now as

users transition to Control-IQ). Basal-IQ was approved by the FDA in June 2018 for ages 6+. Basal-IQ is currently available in "more than half" of Tandem's OUS geographies. Once users update to Control-IQ, they cannot "downgrade" to Basal-IQ.

US AID Next-Gen Pipeline and Timing - Primary Players

Company	Product	Latest Timing	Recent Coverage
Medtronic	**1. MiniMed 780G (a.k.a. Advanced Hybrid Closed Loop)** - Automatic correction boluses, Bluetooth connectivity, mobile app, and remote software updates - Glucose set points of 120 mg/dl and 100 mg/dl - Uses non-adjunctive Guardian Sensor 3 CGM (two cals/day) - Smartphone bolus feature in the pipeline per ATTD 2021 commentary - Smartphone app for secondary display and wireless data uploading **2. MiniMed 770G system** - pump hardware from MiniMed 700 series (Bluetooth connectivity) with MiniMed 670G algorithm; can update algorithm to 780G for free when available **3. MiniMed 720G system** - sensor-augmented pump; uses MiniMed 700 series pump hardware and provides readings from Medtronic CGM; no AID algorithm **4. Seven-day extended wear infusion set** **5. Tidepool Loop** - integration with Medtronic	**1. 780G algorithm submitted to FDA** as a class III PMA submission; approval slated for "first half of 2022" as of 3Q21 call but may be further delayed due to FDA warning letter received by Medtronic (delayed from previous expectations for 1H21) - FDA submission includes adult and pediatric data, as well as previously submitted Guardian 4 CGM (f.k.a. Zeus) - Pump hardware approved by the FDA in September 2020 (Series 700 pump hardware) - Received CE-Marking (ages 7-80) in June 2020; launched in >40 countries across four continents as of November 2021 - Adult pivotal data read out at ADA 2020 along with 780G TIR Impact with Adolescents, 780G vs. 670G, New Zealand Data - FLAIR study comparing 670G vs. 780G read out at ADA 2021; published in *The Lancet* in January 2021 **2. Received CE-Marking in June 2020 and FDA approval in September 2020** - Product first announced in 1Q20 update - Available in "countries around the world based on	JPM 2022 (January 2022) DTS symposium on Medtronic's Extended infusion set highlights cost-savings and low rates of set failure (December 2021) CMS to cover adjunctive CGMs used in Medtronic AID systems, a win for MiniMed 670G/ 770G users on Medicare (December 2021) Medtronic receives warning letter from FDA for inadequate quality systems at Diabetes Business facility in California (December 2021) Medtronic 3Q21 (November 2021) DTM 2021: MiniMed 780G FDA timing; EWIS cleared by FDA; EWIS data (November 2021) ISPAD 2021: pediatric 780G RWE (October 2021) EASD 2021: Three 780G real-world studies; pipeline updates; sub-analysis on best 780G settings;

	iCGM and ACE pump with iPhone app; ADA 2019 **6. Personalized Closed Loop** with advanced adaptation and meal handling, >85% TIR, mean BG <130 mg/dl, phone control, goal of "100% [time in] Auto Mode Capable" **7. Lower-cost AID system**	local market approvals and regulations" - First AID available for 2-6 year olds in US - US shipments began in November 2020 **3. Received CE-Marking in June 2020** after product first announced in 1Q20 - Worldwide availability depends of "local market approvals and regulations" **4. Approved by FDA in July 2021; no launch timeline offered** - US pivotal trial completed in November 2020 and read out at ADA 2021; feasibility data at ADA 2020 - Received CE-Marking in February 2020; available in some European counties since April 2021; being rolled out with MiniMed 780G system **5. Submitted to FDA in December 2020;** iCGM pivotal trial began at ADA 2020 and was published in December 2020 - "Really not a big focus" for Medtronic **6. FDA submission** was previously expected in November 2020-April 2021, with launch by ADA 2021, but clearly not on that timeline; received FDA Breakthrough Designation in February 2019; no recent updates **7. Launch after Personalized Closed Loop** (above); no recent updates	small RW 780G study; small comparison of 780G vs. 670G vs. older AID (September 2021) Medtronic 2Q21 (August 2021) ADA 2021: EWIS pivotal; first 770G RWE (June 2021) ATTD 2021: First 780G RWE; youth from MDI to 780G; MDT pipeline (June 2021) Medtronic 1Q21 (May 2021) Real-world AID data in DT&T: MiniMed 780G (April 2021) Medtronic launches its seven-day wear infusion set in Europe (April 2021)

Tandem	**1. Control-IQ**: hybrid closed loop with Dexcom G6 CGM and TypeZero algorithm integrated into t:slim X2 ACE pump. Algorithm automates basal and delivers automatic correction boluses (details here)**.** **1a. t:slim X2 app**: allows wireless uploading of pump and CGM data - Smartphone bolus control still under FDA review, as of December 2021 **1b. Pediatric indication**: clearance down to 6+ years; trials underway to support indication down to age 2 **1c. Smartphone bolusing**: bolus control on both iOS and Android phones **1d. Tandem Source**: second-gen data management application (akin to Dexcom Clarity) - Connects providers, users, and caregivers app and web-based dashboard - Will house algorithms to drive insights and diabetes management changes - Aim to directly integrate data from CGMs and pumps **1e. FreeStyle Libre 2/3 and Dexcom G7 integrations** **1f. Type 2 indication** **2. Tandem Mobi (f.k.a. t:sport)**: miniaturized, no-screen tubed pump with integrated Control-IQ	**1. 200,000+ Control-IQ users globally in 20+ countries**, as of December 2021; two-thirds of pump users on Basal or Control-IQ (does not include new pumps shipped with Control-IQ), as of December 2021 - Smartphone bolus control slated for approval sometime in 2022, per November 2021 commentary - US launch in January 2020 - UnitedHealthcare now covers t:slim X2 with Control-IQ, as of July 2020 - Additional Control-IQ enhancements under review with FDA: expanded body weight and correction factor ranges + indication for use with admelog - More substantial Control-IQ algorithm changes ("Control-IQ 2.0") will require studies (including a pivotal) + FDA approval; clinical trials for "more meaningful" system improvements underway at UVA, as of November 2021 **1a.** Secondary display and wireless data upload, "t:connect mobile" app to launched in 2Q20 and downloaded by "more than 160,000" users, as of December 2021 **1b.** Expanded pediatric indication in June 2020; US pivotal trial (ages 6-13) read out at ATTD 2020; real-world data from adolescents (ages 6-13) read out at ISPAD 2020 - Preschool (ages 2-5) pivotal (PEDAP) enrollment continues	Tandem R&D Day (December 2021) DTM 2021: Control-IQ RWE from CLIO Study (November 2021) Tandem 3Q21 (November 2021) ISPAD 2021: Control-IQ RWE in children + adolescents; more peds Control-IQ (October 2021) EASD 2021: Control-IQ in high hypoglycemia risk PWD (September 2021) Tandem 2Q21 (August 2021) Keystone 2021: CLIO data on QOL and device satisfaction (July 2021) ADA 2021: Control-IQ in older type 1s; sub-analysis of CLIO by race (June 2021) ATTD 2021: Early vs. late adopters of Control-IQ; CLIO quantitative outcomes; Control-IQ sleep data (June 2021) Tandem 1Q21 (May 2021) Real-world Control-IQ data in DT&T (April 2021) Tandem 4Q20 (February 2021) Full results from Tandem's Control-IQ

	algorithm, smartphone or wireless handheld control, on-device bolus button, easier fill process - Uses new 4" infusion set - Algorithm runs on the pump even if phone is out of range - Will have new syringe-driven pumping mechanism - Rebranded in December 2021 at Tandem R&D Day - Current t:slim X2 users will be able to upgrade to Mobi ahead of warranty expiration **3. Mobi: Tubeless:** leverages Tandem Mobi pump platform but uses disposable on-body kit rather than infusion set - Pump is durable equipment, but on-body "dock" is disposable and will change **4. Patch pump:** no details disclosed **5. "Fully closed loop system":** aimed for "complete bolus and basal insulin automation"	to progress as of December 2021 (began in April 2021); primary completion still set for February 2024 - Preschool regulatory submission by end of 2022, per November 2022 commentary - Smaller feasibility study in young children (ages 2-5) shared at ADA 2020 in June **1c.** Smartphone bolusing submitted to the FDA as of November 2020; seen continued delays in FDA review; now slated for launch "early" in 2022, as of December 2021 **1d.** Launch in "select" international markets was slated for "later" in 2021 with a domestic launch to follow, as of 4Q20 call; have not received a timeline update in several months beyond plans for future personalization of Tandem Source during 2021 R&D Day **1e)** Integrate with G7 "within one month" of G7 clearance; Abbott integration "as soon as possible in 2022" - Abbott integration launch first in the US; unclear if will launch with Libre 2 or Libre 3 (or Libre 4); FreeStyle Libre 3 submitted to FDA in 2021, as of January 2022 **1f. Type 2 feasibility study began in November 2021**; pivotal trial slated for 2022, as of November 2021 - FDA submission in "late 2022 or 2023" with "probably a 2023 approval", as of November 2021	pediatric pivotal trial (n=101) published in NEJM (August 2020) Abbott and Tandem finalize partnership (June 2020) Pediatric Indication (ages 6-13) for t:slim X2 and Control-IQ (June 2020) ADA 2020: Real-World Control-IQ, Basal-IQ, pediatric Control-IQ (June 2020) UnitedHealthcare Coverage for t:slim X2 with Control-IQ (July 2020) Acquisition of Sugarmate app (June 2020)

		- First mentioned in February 2021 when discussed aim for indication for Control-IQ + t:sport system as a "starting point," then to create dedicated solution **2. Submission timing** further delayed, as of December 2021, but timeline will not be disclosed until Control-IQ smartphone control receives approval; submission delayed from 4Q21 expectation set in February 2021, after being pushed back to "first half of 2021" and launch in the "second half of 2021," the timeline offered in April 2020; will be submitted with mobile app control - Will embed Control-IQ hybrid closed loop algorithm (see above) - Delay originally due to COVID and then due to human factors testing that revealed opportunities to improve system usability; now waiting on t:slim X2 smartphone control approval **3. No timeline offered yet;** will be released after t:slim X3 - First announced at Tandem R&D Day in December 2021 **4. No timeline offered;** first announced at Tandem R&D Day in December 2021 **5. First mentioned on Tandem's 4Q19 call**, pivotal study previously aimed for "2021," no major updates, as of December 2021	

Insulet	**1. Omnipod 5** (f.k.a. Omnipod Horizon) - Hybrid closed loop algorithm built into tubeless, wearable pod; pod talks direct to Dexcom G6 - Direct smartphone control, initially on Samsung Galaxy phones only (iOS users must use dedicated PDM) -Target setpoints can be set between 110 mg/dl and 150 mg/dl; can set different targets for different times of day - Activity feature (temporarily sets glucose target to 150 mg/dl and restricts insulin delivery) - Built-in smart bolus calculator in the app and controller that is informed by CGM values *and* trend arrow - Eventual integration with Dexcom G7 and Abbott FreeStyle Libre 2, as well as iOS smartphone control **2. Tidepool Loop integration** (see below)	**1. Received clearance in January 2021, after several delays due to FDA capacity;** limited launch to begin "in the coming days," as of FDA clearance announcement followed by full launch "sometime this year," as of January 2022 **-** Three-month pivotal trial read out at ENDO 2021 (adult + pediatric); published in *Diabetes Care* in August 2021; extension phase data read out at ADA 2021 (six-month extension) and EASD 2021 (nine-month extension) - Pre-school pivotal (ages 2-6, n=80) read out at ADA 2021; to be submitted to FDA soon now that Omnipod 5 is cleared for ages 6+, based on January 2022 commentary - Feasibility study in type 2s (n=30-40) in extension phase (as of November 2021) after primary completion in August; preliminary data (n=4) presented at ENDO 2021 - Discussions with FDA on type 2 pivotal to begin soon now that Omnipod 5 has been cleared - OUS work underway but no public timeline, as of January 2022 **2. Depends on Tidepool's FDA progress** (see below); Tidepool Loop submitted to the FDA in December 2020 but no timeline update since then	FDA clears Insulet's Omnipod 5 AID system (January 2022) FDA clearance of Omnipod 5 delayed to 1Q22 (December 2021) DiabetesMine Fall Innovation Days 2021 (November 2021) Insulet 3Q21 (November 2021) ISPAD 2021: OP5 across ages 2-25 (October 2021) EASD 2021: OP5 pivotal nine-month extension; symposium on provider bias; OP5 PROs (September 2021) Omnipod 5 pediatric and adult pivotal trials published in *Diabetes Care* (August 2021) Insulet 2Q21 (August 2021) ADA 2021: Preschool pivotal; OP5 pivotal six-month extension (June 2021) ATTD 2021: Post-hoc OP5 pivotal analysis on people with high rates of hypoglycemia (June 2021)

Tidepool	**Tidepool Loop iPhone app** (hybrid closed loop algorithm - basal-only) - Communicates via Bluetooth with interoperable ACE pumps and iCGMs - Insulet, Dexcom, and Medtronic are official iCGM and ACE pump partners - Talks ongoing with other device companies - two have reached "term sheet" stage	**Submitted to FDA** in December 2020 for 510(k) clearance - Will initially launch with Dexcom, Insulet, and iPhone compatibility - Six-month data from Tidepool/Jaeb observational study read out at ATTD 2020; results also published in *DT&T* in December 2020	DiabetesMine Summer D-Data Exchange 2021: Product Demo (June 2021) ENDO 2021: Tidepool's Brandon Arbiter: Device Interoperability is a Given at Tidepool, "We Don't Ask Why, But How" (March 2021) Tidepool Loop 510(k) submission (January 2021)
Beta Bionics	**Bionic Pancreas iLet** - Dual chambered Gen 4 iLet touchscreen device with built-in algorithm - Integrates with Dexcom and Senseonics' Eversense CGMs - Qualitative meal bolusing (e.g., large, medium, small), only bodyweight to startup - Secondary display mobile app **1. Insulin-only iLet** - 1.6 ml insulin cartridge, both manual fill and prefilled Novo Nordisk PumpCart **2. Bi-hormonal iLet (insulin + glucagon)** - 1.6 ml insulin cartridge, both manual fill and prefilled Novo Nordisk PumpCart - Zealand 1ml prefilled glucagon cartridge (4 mg; dasiglucagon)	**1. Insulin-only pivotal study** began in "summer" 2020; enrollment complete by FFL 2020; was set to achieve primary completion in August 2021; data lock for pivotal in December 2021; pivotal to be read out at ATTD 2022; extension study to complete in January 2022 per December 2021 update - 440 participants ages 6+ years, three-month RCT comparing iLet with usual care - Feasibility study of insulin-only iLet AID system in primary care setting will begin recruiting soon - Home-use bridging studies with Dexcom & Eversense CGMs, in both insulin-only and bi-hormonal configurations, read out at ADA 2019 **2. Bi-hormonal pivotal/ phase 3 study** with Zealand dasiglucagon began enrollment in December 2021, a delay from July 2020 expectations for a 1H21 start but in line with	Beta Bionics announces data lock for Insulin-Only Bionic Pancreas Pivotal Trial and begins enrollment for Bihormonal Bionic Pancreas Pivotal Trial (December 2021) Zealand 3Q21 (November 2021) FFL 2021 (July 2021) ADA 2021: Short cross-over RCT with bi-hormonal vs. insulin-only systems (June 2021) AACE 2021 (May 2021) Zealand R&D Day: Update on Partnership with Beta Bionics (March 2021) FFL 2020 (July 2020) ADA 2020: iLet Insulin-Only Pivotal

		more recent expectations for initiation by EOY 2021; 12 months of data collection - Three interventions: (i) bihormonal iLet with dasiglucagon; (ii) insulin-only iLet; (iii) "usual care" - Pediatric (n~350) and adult (n~350) type 1s - Primary endpoint: A1c reduction of bihormonal vs. insulin-only iLet at 26 weeks - Secondary endpoints: long-term safety and efficacy over 52 weeks; non-inferiority in time <70 mg/dl - Follows promising pre-pivotal results read out at ADA 2021 **FDA PMA reviews of the bi-hormonal system** - including a chronic indication for Zealand's dasiglucagon - are expected in 1H22 (adults) and 2H22 (teens). **Bi-hormonal iLet clearance** in "2022, maybe early 2023" based on July 2020 timeline (likely delayed ~6 months) - Small home-use study (n=10) comparing bi-hormonal vs. insulin-only presented at ADA 2020 - At ADA 2020, read out data showing 100 mg/dl glucose target reduces mean glucose and increases TIR w/out increasing hypoglycemia for bi-hormonal - Per Zealand 1Q20, dual hormone AP system on track for "late 2020" phase 3 start	Enrollment & Home-Use Bi-Hormonal vs. Insulin-Only, 100 mg/dL Set Point for Bi-Hormonal, Ultra-Rapid vs. Rapid Insulin (June 2020)

Lilly	**1. Partnership with Ypsomed** announced in November: gives Lilly exclusive US and non-exclusive global commercial rights for Ypsomed's YpsoPump and future mylife AID system **2. Hybrid Closed Loop System** with Lilly's proprietary pump, likely discontinued following Ypsomed partnership - Pump is "a white disk about the size of a shoe-polish tin" that carries 3-day supply of insulin; Dexcom G6 CGM; Class AP algorithm - Pump has an infusion set, no screen, and can be worn direct on the body or in the pocket. It will be controlled wirelessly from a handheld and possibly directly from an app. See more details here.	**1. Closed loop system expected to launch in 2023**; system = YpsoPump (durable pump), Dexcom CGM, and myLife Control smartphone app - YpsoPump CE-Marked in 2019 - ACE submission expected "in 2022" and FDA approval expected in 2023, as of November 2021; intends to have Dexcom connectivity - Previously expected FDA submission as traditional pump slated for June 2021 followed by ACE pump submission in December 2021 with approval expected by "mid-2022" **2. Halted internal pump development efforts,** based on remarks from November 2020; other Connected Care products are expected to launch in stages over 2019-2021, presumably starting with the smart pen that was under FDA review as of April 2019. No pivotal timing ever shared - First "phase 1" trial completed in February 2018 - AID still in "phase 2" per 1Q20 update, but likely discontinued as of November - First Lilly AID data presented at ADA 2020	Lilly obtains exclusive US rights for Ypsomed AID (November 2020) ADA 2020: First Lilly AID Data, Predictive Low Glucose Suspend Feature, Connected Pen (June 2020) Lilly 1Q20 (April 2020) Lilly and Dexcom Partner (December 2019) Lilly 2019 Investor Meeting (December 2018) Lilly Diabetes Blogger Summit at the Cambridge Innovation Center (May 2018)
Bigfoot Biomedical	**Bigfoot Autonomy** automated insulin delivery service (previously "Loop") - Disposable pump body married to durable controller with an embedded control	**Expected to launch in ~2023**, after the next-gen Bigfoot Unity system launches in ~2022; as of May 2021	Bigfoot adds three new hires to senior management team (December 2021) Bigfoot Unity launches in US (June 2021)

	algorithm - Pump talks directly to next-gen FreeStyle Libre CGM. Smartphone to serve as the window to the system and user interface - "Automatic dose titration" feature in future-gen versions of Unity smart pen and Autonomy AID		Bigfoot Unity receives FDA approval (May 2021) Bigfoot Unity submitted to FDA + interview with Bigfoot CEO Jeffrey Brewer (August 2020)

International AID Pipeline and Timing - Primary Players

Company / Academic Group	Product	Latest Timing	Recent Coverage
Cambridge (CamDiab)	**1. CamAPS FX**: Cambridge MPC algorithm on Android phones, Dexcom G6, and Dana R/RS pumps equipped smartphone control and with data streaming to Diasend/Glooko **2. CamAPS HX**: Cambridge CamAPS HX algorithm (specified for people with type 2 diabetes and end-stage renal disease on dialysis) on Android phones, Dexcom G6, Dana RS pump with smartphone control and data streaming to Glooko/Diasend	**Launched in UK** in select NHS clinics in March 2020 for people with type 1 diabetes ages 1+ and for pregnant women for £70-£80/ month (~$86-$98/ month) - RCT in youth ages 6-18 read out at ADA 2021 - Ongoing studies as of June 2021: (i) four-year use in newly diagnosed adolescents; (ii) four-month use in adults ages 60+; (iii) use in pregnant women through pregnancy; (iv) two-month use of a fully closed-loop system (no boluses) in type 2s **2. Feasibility study** in type 2s with end-stage renal disease on dialysis published in August 2021	NEJM publishes KidsAP02 RCT of preschoolers on CamAPS FX (January 2022) EASD 2021: KidsAP02 result readout (September 2021) AP-Renal study published in *Nature Medicine* (August 2021) ADA 2021: RCT in youth ages 6-18 (June 2021) ATTD 2021: App usage by age group; clinical trial pipeline (June 2021) CamAPS FX CE-Mark and UK Launch (March 2020)

Medtronic	**1. MiniMed 780G** (see above for details) **2. Seven-day wear infusion set**	**1. Available in >40 countries on four continents**, as of November 2021 - Real-world users achieving strong TIR ("90s") and staying in Auto Mode longer - European launch of 780G announced at Medtronic 2020 Investor Day in October 2020 - CE-Mark received (ages 7-80) in June 2020 - New Zealand study for CE-Marking presented at ADA 2020 - Real-world data published in *DT&T* in April 2021; read out at ATTD 2021; EASD 2021 **2. Launch "progressing" in "select" EU countries,** as of November 2021, after launch began in November 2020 in Finland - CE-Marking announcement in February 2020 - "Positive customer feedback" thus far	JPM 2022 (January 2022) DTS symposium on Medtronic's Extended infusion set highlights cost-savings and low rates of set failure (December 2021) CMS to cover adjunctive CGMs used in Medtronic AID systems, a win for MiniMed 670G/ 770G users on Medicare (December 2021) Medtronic receives warning letter from FDA for inadequate quality systems at Diabetes Business facility in California (December 2021) Medtronic 3Q21 (November 2021) DTM 2021: MiniMed 780G FDA timing; EWIS cleared by FDA; EWIS data (November 2021) ISPAD 2021: pediatric 780G RWE (October 2021) EASD 2021: Three 780G real-world studies; pipeline updates; sub-analysis on best 780G settings; small RW 780G study; small comparison of 780G vs. 670G vs. older AID

			(September 2021) Medtronic 2Q21 (August 2021) ADA 2021: EWIS pivotal; first 770G RWE (June 2021) ATTD 2021: First 780G RWE; youth from MDI to 780G; MDT pipeline (June 2021)
Diabeloop	**1. Diabeloop / Roche / Dexcom System** - Diabeloop DBLG1 algorithm on wireless locked-down Android controller, Roche Accu-Chek Insight pump, Dexcom G6 CGM - DBLG1 algorithm offers predictive low-glucose suspend, basal rate adjustment automation, and automatic correction boluses **2. Diabeloop / Kaleido / Dexcom System** - Diabeloop algorithm running on a wireless locked-down Android controller, Kaleido (formerly ViCentra) patch pump, Dexcom G6 CGM, qualitative meal bolusing. **3. Diabeloop DBL-hu system** for patients with "highly unstable" (a.k.a. brittle diabetes) diabetes - Updated version of DBLG1 system allowing increased personalization adapted to the glycemic profiles of patients with highly unstable diabetes **4. Diabeloop/Terumo AID system** with Terumo insulin patch pump and Diabeloop DBLG1 algorithm; likely with Dexcom G6 CGM	**1. Now available in Germany, Spain, Italy, the Netherlands, and Switzerland** as of July 2021; real-world data read out at EASD 2021 - Combined system first launched in March 2021 - Partnership with Roche to "advance the management of insulin pump therapy" announced in December 2020 - First AID system available with pump that has a pre-filled cartridge **2. Launched in Europe as of December 2021;** Kaleido's $74 million Series C (December 2021) and ~$34 million in Series B fundraising (December 2019) will enable a broader European launch. Although the launch geographies have not been disclosed, it is likely France and/or Germany based on previous commentary. **3. CE-Marked** in December; no public launch timelines	Diabeloop and Terumo expand partnership to bring AID system to Europe (November 2021) ViCentra, developer of Kaleido pump, closes $74 million Series C and launches Kaleido as part of AID system with Diabeloop's DBLG1 in Europe (December 2021) EASD 2021: Real-world data from Diabeloop / Roche / Dexcom system users (September 2021) Roche 2Q21 (July 2021) ATTD 2021: Tech fair (June 2021) Roche 1Q21 (April 2021) Roche, Diabeloop, and Dexcom AID system launches in Europe (March 2021)

	5. SFC Fluidics partnership - Plans to develop an integrated AID system using SFC Fluidics' "Panda" patch pump	**4. No timeline announced for launch in Europe or Japan** - AID partnership is expansion of existing partnership and was announced in November 2021 **5. Expanded partnership with SFC Fluidics in January 2021; launch timing unclear** - Panda received FDA breakthrough designation from the FDA in November 2020 - Announced partnerships with Diabeloop for algorithm and PercuSense for CGM in May 2019 - Received two-year JDRF funding in August 2018 to develop an open-protocol, interoperable patch pump	Roche's Accu-Chek Insight pump now integrated with Diabeloop's DBLG1 AID algorithm (March 2021) SFC Fluidics and Diabeloop announce development agreement to develop and bring AID system to market in the US (January 2021) Roche partners with Diabeloop marking entrance into AID field (December 2020) Diabeloop receives CE-mark for DBL-hu AID algorithm for patients with highly unstable diabetes (December 2020) Diabeloop announces integration plans with Terumo's patch pump for new AID system (November 2020) DTM 2020 Startup Showcase (November 2020)
Tandem	**1. Control-IQ hybrid closed loop** (see product details above) **2. t:sport** - miniaturized, no-screen tubed pump with Control-IQ	**1. Launched in "more than half" of Tandem's existing markets,** as of February - Launched in 20 geographies by end of 2021; had previously planned to launch in 25 geographies by the end of	Tandem R&D Day (December 2021) DTM 2021: Control-IQ RWE from CLIO Study (November 2021) Tandem 3Q21 (November 2021) ISPAD 2021:

		2021 **2. No recent updates for OUS;** CE-Mark submission previously expected in 2020; major updates/delays for US (see above)	Control-IQ RWE in children + adolescents; more peds Control-IQ (October 2021) EASD 2021: Control-IQ in high hypoglycemia risk PWD (September 2021) Tandem 2Q21 (August 2021) Keystone 2021: CLIO data on QOL and device satisfaction (July 2021) ADA 2021: Control-IQ in older type 1s; sub-analysis of CLIO by race (June 2021) ATTD 2021: Early vs. late adopters of Control-IQ; CLIO quantitative outcomes; Control-IQ sleep data (June 2021) Tandem 1Q21 (May 2021) Real-world Control-IQ data in DT&T (April 2021)
Ypsomed	**1. YpsoPump** - Partnership with Lilly announced in November 2020: gives Lilly exclusive US and non-exclusive global commercial rights for Ypsomed's YpsoPump and future mylife AID system **2. mylife AID system:** Closed loop system with YpsoPump (durable pump), Dexcom CGM, and myLife Control smartphone	**1. ~17,500 YpsoPump users in Europe and Australia**, as of May 2021 - ACE submission expected "in 2022" and FDA approval expected in 2023, as of November 2021; intends to have Dexcom connectivity - In talks with one CGM	Ypsomed F1H22 (November 2021) Ypsomed FY21 (May 2021) Lilly obtains exclusive US commercialization rights for Ypsomed's YpsoPump and future mylife AID system

	app expected to launch in 2023. - Partnership with Dexcom announced in May - Signed deal for access to "TypeZero's algorithm" (presumably inControl) **3. Joined JDRF's open protocol AID initiative** in August 2018	company per May 2019 commentary - Slated to launch with AID capabilities in "June 2022," as of November 2021; AID partner not yet named but suspect it may be Diabeloop - Need ~50,000 users for product to be profitable - In Canada, received reimbursement in Ontario and in negotiations in British Columbia; Health Canada approval came in May 2019 **2. Will be ready for a regulatory pathway in ~2 years**; currently updating YpsoPump to be open-protocol (i.e., ACE pump) - Data integration with Dexcom was expected by end of 2020; unclear if achieved - Smartphone bolusing was expected by "end of Q1 2021"; timeline not achieved - Closed loop by "mid-2023" **3. Had planned to ship** "open-protocol" YpsoPumps to Baker Institute (Australia) for closed loop algorithm clinical trials; no update in FY20 report or since	(November 2020) Diabetes Mine Innovation Days 2020 Product Demo (November 2020) Ypsomed F1H1 (November 2020) EASD 2020 Exhibit Hall (September 2020) Ypsomed FY20 (May 2020) Ypsomed and Dexcom Partnership (May 2020) ATTD 2020: Exhibit Hall (February 2020) Ypsomed F1H20 (November 2019)

Earlier-Stage Players and/or Those with Rare Updates

Company / Academic Group	Product	Latest Timing	Recent Coverage

University of Virginia (UVA)	**RocketAP -** Zone-based model predictive controller (similar to Control-IQ which was also developed by UVA) with additional meal prediction features - New bolus priming system module designed to detect unannounced meals and deliver bolus ahead of lengthy hyperglycemia episode - Multistage MPC that allows for disturbance (e.g., exercise, eating) prediction for the following two hours and optimal dose to address	**Data on efficacy of bolus priming algorithm presented at ATTD 2021;** data on efficacy of disturbance prediction algorithm and predicting unannounced meals presented at DTM 2021	DTM 2021 (November 2021) ATTD 2021 (June 2021)
WaveForm (AgaMatrix)	**AID system:** Plans to develop a "vertically integrated" AID system with its own CGM, a pump it owns or has built, and a licensed algorithm from OHSU	**No AID system updates in a long time** - Waveform's Glucomen CGM (previously known as Cascade) CE Marked in November 2019; European launch in June 2020 driven by A. Menarini; FDA iCGM filing in "2020" and US launch in "2021" as of November 2020, but timeline clearly missed - Commercial agreement with Bayer to bring Waveform's CGM to China announced in June 2020 - Based on November 2021 timeline, reduced calibration version of Cascade CGM expected to receive CE-Mark in December 2021; no update on whether this timeline was achieved, seems unlikely	DTM 2021 (November 2021) Waveform Commercial Agreement with Bayer (June 2020) WaveForm Receives CE Mark for Cascade CGM (November 2019)

Medtrum	**1. A6 system** - predictive low glucose suspend, semi-disposable patch pump, 7-day CGM, handheld controller or smartphone control **2. A7 system**: adds secondary display app, 14-day CGM **3. P7 system** - direct smartphone control and no-calibration CGM	**1. Available in six European countries**, with ~200 users as of February 2019; no recent updates **2. Previously expected** to launch in 2019 in Europe; no recent updates **3. In R&D phase**; no recent updates	ATTD 2020 (February 2020) ATTD 2019 (February 2019)
EOFlow	**1. EOPatch insulin patch pump**: tubeless, ~3.5-day wear time, locked-down smartphone control, Bluetooth connectivity, app can connect to Dexcom G6 and control insulin delivery **2. EOPatchX:** AID system that integrates EOPatch pump with Dexcom G6 and TypeZero's algorithm **3. EOPancreas System**: single-patch, on-body CGM/algorithm/pump patch - Partnering with China-based POCTech for the CGM technology in the all-in-one patch	**1. Received CE-Mark with smartphone control in May 2021;** European launch was anticipated in 2H21 at time of CE-Mark through distribution agreement with Menarini of Italy for the Western European market, which was announced in 2019 Launched in Korea in March 2021 and will be available to customers in "early April" 2021; distributed through pharmaceutical and consumer health giant Huons **2. Targeted for an "early 2023" US launch,** as of May 2021 - Feasibility trial (n=15) in Australia to start "soon," as of May 2021 - Pivotal trial (n=105) in Korea to start in 2021, no update on whether this happened **3. Targeted for an ambitious "2023" launch** - Initial commercialization expected throughout Asia - JDRF partnership to fund this work, as well as EOPatchX, was announced in February 2018 - Received FDA Breakthrough	EOFlow receives CE-Mark for EOPatch insulin patch pump with smartphone control (May 2021) Korean startup EOFlow launches EOPatch insulin patch pump in Korea (March 2021) EASD 2019 (September 2019) EOFlow receives FDA Breakthrough Device Designation for single on-body AID patch, EOPancreas (March 2019)

		Device Designation in March 2019	
SFC Fluidics	**AID system:** Open protocol, fully interoperable patch pump that seamlessly integrates with interoperable CGMs and third-party AID algorithms, which "may include DIY solutions"	**Expanded partnership with Diabeloop** in January 2021 to develop an integrated AID system using SFC Fluidics' "Panda" patch pump; launch timing unclear - Panda received FDA breakthrough designation from the FDA in Nov 2020 - Announced partnerships with Diabeloop for algorithm and PercuSense for CGM in May 2019 - Received two-year JDRF funding in August 2018 to develop an open-protocol, interoperable patch pump	SFC Fluidics re-ups partnership with Diabeloop (January 2021) SFC Fluidics partners with Diabeloop and PercuSense (May 2019)
AMF Medical	**Sigi patch pump:** smartphone-controlled rechargeable insulin pump compatible with prefilled insulin cartridges - Smaller and thinner than both Insulet's Omnipod and Roche's AccuChek Solo "micropump" - Semi-disposable	**Human clinical trials** to start **in 2022,** as of November 2021; FDA submission slated for 2H24, with CE submissions to follow ramped up commercial rollouts in 2024 and 2025 - Received breakthrough designation in November 2021 - Has built a proof-of-principle and user experience prototype - Has participated in a pre-sub meeting with the FDA - Expect Sigi to be "loop ready" upon launch	Sigi receives FDA Breakthrough designation (November 2021) ATTD 2021: Tech fair (June 2021) Swiss-based AMF Medical brings its Sigi patch pump out of stealth mode, launches website (February 2021)
Inreda	**Bihormonal AID system:** Bihormonal pump, two CGM sensors for redundancy, fully automated (no meal announcement) - Currently designing an AID system for children with feedback from children with diabetes, as	**CE-Marked in March 2020 but additional studies planned;** small study completed in summer 2019, ahead of larger studies in 2020; reimbursement expected for 2023 - "Several groups" have been able to start with an "AP" treatment, as of December	Winter Newsletter (December 2021) Winter Newsletter (in Dutch) (December 2020) Spring Newsletter (in Dutch) (April 2020) CE-Marked (March 2020)

	of April update - Second AID system that would be "smaller and lighter" for increased comfort and wearability is in the works	2021	Inreda company website update (March 2020)
Cellnovo	**Cellnovo patch pump** with integrated TypeZero inControl AP algorithm; and a Dexcom CGM Separately used in Diabeloop system (above) and PEPPER project	**Stopped commercial operations** and manufacturing in April 2019; assets could be acquired by another company. No recent updates	Cellnovo stops commercial operations and manufacturing (April 2019)
Roche, Senseonics, & TypeZero	Roche Accu-Chek Insight pump with Senseonics Eversense XL CGM (180 day implantable) and TypeZero inControl AP algorithm	**Appears to be discontinued** following dissolution of partnership between Roche and Senseonics and new partnership with Diabeloop**;** trial on hold as of November 2019 - presumably related to Dexcom's acquisition of TypeZero; no recent updates - Senseonics' financial troubles (as of 1Q20) might further complicate this collaboration - Joined JDRF Open Protocol Initiative as of ATTD 2018	Senseonics 3Q19 (November 2019)

--by Armaan Nallicheri, Hanna Gutow, Katie Mahoney, and Kelly Close