
SFC Fluidics and Diabeloop announce development agreement to develop and bring AID system to market in the US - January 14, 2021

Partnership includes development of integrated AID system, collaboration in clinical trials, and FDA submission in pursuit of US launch; "Panda" patch pump received FDA breakthrough designation in Nov 2020

SFC Fluidics and Diabeloop recently [announced](#) a development agreement to integrate SFC Fluidics' "Panda" pod pump with Diabeloop's AID algorithm. In addition to developing the combined solution, the two companies will collaborate in applying for FDA approval and in conducting nonclinical and clinical trials, all in pursuit of bringing an integrated SFC-Diabeloop AID system to market in the US. Worth noting, the press release does not mention the CGM that will be used in the AID system; we'd guess that Dexcom could be a likely partner given that Diabeloop and Dexcom already have integrated Diabeloop's DBLG1 algorithm and Dexcom G6, although that is our speculation. There were no publicly shared timelines on any development milestones or launch.

SFC Fluidics aims to submit its Panda patch pump as an ACE pump, meaning the pump will be able to integrate with interoperable CGMs and third-party AID algorithms. The pump has a unique two-value safety system and utilizes "differentiating" Dispense Confirmation Sensor technology which detects the flow - or lack thereof - of insulin in real-time and signals lack of dispensation, offering high precision and accuracy at "extremely small" insulin doses. Presumably, this could help with avoiding DKA and hyperglycemia from under-delivery of insulin. According to the press announcement, SFC believes that its technology "effectively eliminates 95% of over and under dispenses of insulin." Notably, SFC received FDA breakthrough device designation for Panda [in November 2020](#).

This partnership comes as Diabeloop announces a slew of integrations. In the past few months, Diabeloop has also announced partnerships with Roche [in December](#) and with Terumo [in November](#) for integration and OUS AID system launches. In the US, Diabeloop's pivotal trial has not resumed yet, due to COVID-19. For Diabeloop, this partnership with SFC offers "an additional opportunity to enter the US market," according to co-CEO Marc Julien. As a reminder, to date, Diabeloop has developed two algorithms, DBLG1 and DBL-hu, both of which are CE-Marked and according to this most recent update, will launch in Europe "in 2021." Although CE-Marked in [November 2018](#), the Diabeloop DBLG1 System, which uses the DBLG1 algorithm, a Dexcom G6, and a Kaleido patch pump, is [still in](#) pre-launch reimbursement negotiations in France and Germany. More recently, DBL-hu, the first AID algorithm specifically designed for patients with highly unstable diabetes, was CE-Marked in [December 2020](#).

- **This expanded partnership with Diabeloop is the first major update we've received from SFC since [May 2019](#)**, when SFC announced partnerships with Diabeloop and PercuSense to use their respective algorithm and CGM in a single on-body CGM/patch pump AID system. The 2019 partnership was funded as part of the JDRF Industry Development and Discovery Partnership as part of JDRF's two-year commitment to fund SFC Fluidics' ACE pump development in [January 2018](#). Per this most recent announcement, JDRF is "excited to see the partnership between Diabeloop and SFC Fluidics continue to flourish," but no longer appears to be financing the partnership and SFC Fluidics' development of Panda.
- **We are thrilled to see Diabeloop and SFC Fluidics continue their partnership, but we are curious how (or if) Percusense fits into this expanded partnership** given that they were noticeably absent from the partnership announcement. When we checked in with Percusense CEO Brian Kannard in [in November](#), he declined to share any updates on the 2019 AID partnership between Percusense, Diabeloop, and SFC Fluidics. We would be curious to hear if this project and

three-way partnership is still active and whether the three have made progress on the innovative dual CGM/insulin pump design.

Close Concerns' Questions

- What are the financial aspects of the partnership? Once launched, how would Diabeloop and SFC Fluidics split profits from the AID system?
- What "adaptations" to Diabeloop's algorithms and data visualization platform might we see? Will a version of DBLG1 be used?
- What CGM will be used in the integrated AID system? A Dexcom or Percusense CGM, perhaps, based on previous partnerships?
- What is the rough timeline for clinical trials, FDA submission, FDA clearance, and eventual US launch?
- Might we see OUS launch of the combined AID system as well?
- Is SFC Fluidics still aiming to bring their pod pump to market for use outside the Diabeloop AID solution? If so, is SFC targeting US or OUS regulatory approval first?
- Is the partnership between SFC Fluidics, Diabeloop, and Percusense still active? If so, what progress has been made?
- Has JDRF's funding of SFC Fluidics' development of Panda and SFC Fluidics' partnership with Diabeloop and Percusense ended?



Next-generation Devices to Improve Diabetes Care

--by Katie Mahoney, Albert Cai, and Kelly Close