Press Release
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DBLG1 self-learning algorithm: easy to use for optimized and personalized T1D management

From its inception, Diabeloop has been developing innovative solutions to automate and personalize Type 1 diabetes management, with a patient-perspective always in sight. The French company aims to empower people living with T1D while optimizing their user experience to make diabetes management easier and less omnipresent. DBLG1 algorithm requires only a minimal patients' input to deliver a satisfying, automated and personalized experience.

DBLG1: easy to set up, simple to use, designed for every profile of T1D

Relieving people with Type 1 diabetes from their heavy mental burden begins at the early stages of the experience with DBLG1. To safely automate and personalize insulin delivery, DBLG1's state-of-the-art algorithm only requires **4 settings** to be entered. At set-up, people equipped with DBLG1 enter their body weight, their total daily insulin dose (TDD), their typical meals (in grams of carbs) and their safety basal rate (for open-loop only). With Diabeloop's algorithm, there is no need to provide complex computations. Users do not have to figure out their meal ratio, their insulin sensitivity correction factor, nor their insulin action curve.

The 4 initial settings entered in the system by the patient are enough for DBLG1 self-learning algorithm to run, calculate and adjust the insulin dose as often as every five minutes, as needed.

> *"We designed DBLG1 algorithm to be as simple as possible for people with Type 1 diabetes, while giving them the opportunity to fine-tune some parameters according to their specific needs and/or lifestyle. When people make changes, the algorithm takes them into account automatically. DBLG1 algorithm does automatic optimizations as needed, without requiring any action from the patient. It makes changes smooth and almost "invisible" for people using the system." - declared **Yousra Tourki**, Diabeloop's Head of Algorithms Design.*

In addition to the initial input, DBLG1 System offers people living with Type 1 diabetes the possibility to fine-tune their diabetes management and treatment with adjustable settings, such as algorithm aggressiveness, hypo/hyper thresholds or target glycemia.

__Nicole Wetzels__, Trainer at Roche Diabetes Care in the Netherlands, equipped with DBLG1 System with Accu-Chek Insight insulin pump said: "I have been living with Type 1 diabetes for more than 42 years and I have started using DBLG1 System with Accu-Chek Insight insulin pump a few months ago. Starting up has been very easy: inserting the battery, charging the handset and entering only 4 parameters. Declaring a meal is one of the only things I have to do myself and it is quite easy! In parallel, I still have the opportunity to make the system more personalized by adjusting some settings like the target glycemia or the hypo limit values. With very small actions I have such good results. With this AID System, I no longer have to spend all day controlling and managing my diabetes. This is just like holidays from my T1D!".

DBLG1 AID solution: minimal patients' input required

To assess DBLG1 System usability, Diabeloop conducted a scientific study based on the real-world evidence data from the pre-launch clinical trial[1]. The objective was to analyze the number of settings changes performed by the people using the system in real-life. During the first week of use of DBLG1 System, on average, patients made only 1.6 setting changes (± 2.3), and only 0.2 setting changes (± 0.5) during the last week of the trial after 11 weeks of use.

The main conclusion is that in real-life, when they are not in a controlled environment without specific medical follow-up and/or recommendations of settings changes by their care teams, people equipped with DBLG1 System made minimal adjustments to benefit from a satisfactory, automated and personalized diabetes management.

Another scientific analysis[2] demonstrates the ease of use of Diabeloop's Automated Insulin Delivery System. It showed that during the first week, 50% of people using DBLG1 System made no setting changes. More importantly, during the 8th week of use, over 85% of people equipped with the system made no settings changes.

It confirms that, since the very first steps, Diabeloop's self-learning algorithm optimizes Type 1 diabetes management and requires minimal patients' input to provide them with the required support.

__Bernhard Gehr__, MD, Diabetologist, Center for Diabetes and Metabolic Diseases, specialist clinic m&i Fachklinik Bad Heilbrunn, commented: "I am equipped with DBLG1 System with Accu-Chek Insight insulin pump. Start-up and initial operation is very simple. The simplicity of the user interface supports quick and easy entry of necessary information. I have been impressed by the performances of DBLG1 System. I had very good metabolic control from day one. The therapy effort is significantly lower, I have more peace of mind! With this system, I have less, almost no micromanagement of my therapy. I was pleasantly surprised at how well the algorithm got me through the first night - with so few inputs for initialization."

DBLG1, people keep control on their diabetes management

DBLG1 System ease of use and personalization capacity empower people living with diabetes to keep control on various settings.

On a daily-basis, DBLG1 System offers people the possibility to adapt the target glycemia in order to adjust insulin delivery and avoid hypo- and hyperglycemia. One of Diabeloop's studies[3], presented at ATTD 2021, revealed that on average a decrease of the glycemic target triggers a decrease of the average glycemia in almost the same magnitude. For example, -10% of the glycemic target will lead to -10% of the average glycemia.

In keeping with Diabeloop's mission to reduce the heavy mental burden of people with T1D and enable them to live without interruption, an optional Zen Mode, inspired by patients' experiences temporarily increases target range of blood glucose levels: to enjoy a movie or attend a meeting without being interrupted by hypoglycemia and associated alarms, people may turn on the Zen Mode, temporarily increasing their target blood glucose for a set time of their choice.

A person equipped with DBLG1 System with Accu-Chek Insight insulin pump shared: "ZEN mode is for all those moments when we need to feel “safer”: driving, classes, exams”.

A scientific study[4] led by Diabeloop and presented at ATTD 2021, demonstrated that after 90 minutes of Zen Mode activation, the impact on average blood glucose level is stabilized, with no increase of time spent in hyperglycemia.

It concludes that, for a set time defined by the patient, the ZEN Mode keeps them out of hypoglycemia, while avoiding hyperglycemia as well. The ZEN Mode results in a slight increase in average glycemia, with a very limited impact on time-in-range.

The simplicity of use of DBLG1 self-learning algorithm contributes to make diabetes management easier and to unload the mental burden of people living with this chronic condition so they can live without interruption!

Some people with T1D using DBLG1 System shared their personal experiences on social media channels:

> → *“Great response with such simple information entered. It starts working from the very first moment, great improvement”.*
>
> → *“Very intuitive, few information to give at set-up”.*
>
> → *“It's great not to have to change ratios”.*

DBLG1 System with Accu-Chek Insight is now available with a medical prescription.

To take it a step further, Diabeloop is developing a new feature: Unannounced Meals, which is, for the moment, embedded on DBLG1 algorithm clinical version (simulators) only.

About Diabeloop

Diabeloop’s mission: to relieve people living with Type 1 diabetes from dozens of therapeutic decisions and reduce their heavy mental burden. Initially conceived from a medical research project, Diabeloop was created in 2015 by Dr. Guillaume Charpentier, now Chief Medical Officer, and Erik Huneker who has co-managed the company with Marc Julien since 2016. This complementary management team works with experienced partners, CEA-Leti (a research laboratory) and CERITD (a French research team of diabetologists).

In 2018, DBLG1® System, Diabeloop’s first medical device for automated diabetes management, obtained CE marking, followed by DBL-hu, its solution for highly unstable Type 1 diabetes management in 2020.

A second round of financing of 31 million euros concluded in November 2019 to speed up the international commercial rollout of the DBLG1® iController and support an ambitious R&D program.

Today, Diabeloop gathers the personality, the passion and the skills of over 100 talented individuals who work hard to improve the quality of life for every person living with Type 1 diabetes.

References:

[1]Diabeloop DBLG1 closed-loop system enables patients with type 1 diabetes to significantly improve their glycemic control in real-life situations without serious adverse events: 6-month follow-up. Amadou C, Franc S, Benhamou PY, Lablanche S, Huneker E, Charpentier G, Penfornis A; Diabeloop Consortium. Diabetes Care. 2021 Mar;44(3):844-846. doi: 10.2337/dc20-1809. Epub 2021 Jan 1.
[2]Evolution of % of patients that do not change their parameters per week - data presented at DiaTec 2020.
[3]Effect Of Glycemic Target Change In Diabeloop's Artificial Pancreas On Average Glycemia For Patients With Type 1 Diabetes - data presented at ATTD 2021.
[4]Zen Mode of Diabeloop's DBLG1 System: Stabilization of impact after 90 minutes - data presented at ATTD 2021.

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