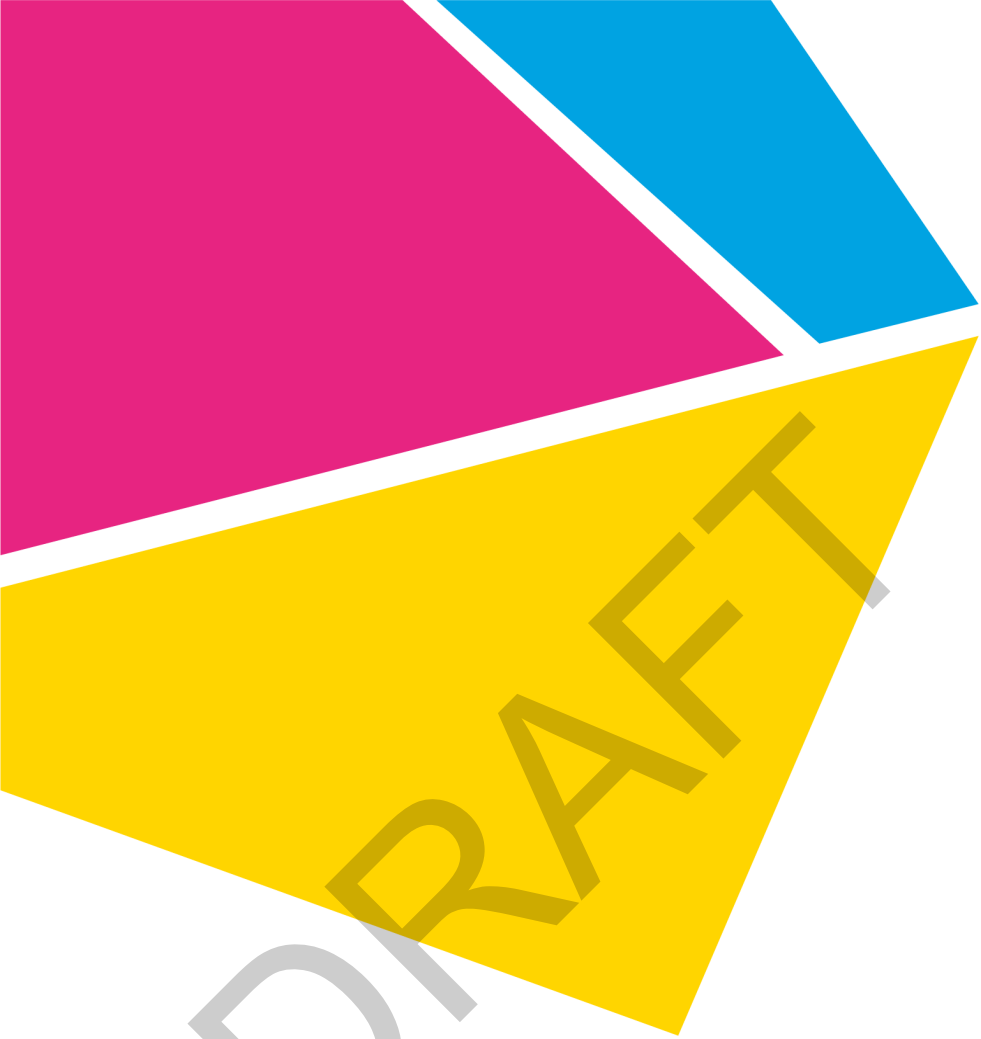
DBL G2 SYSTEM with Kaleido



# Android user guide


DRAFT

# Table of contents

## Part 3: Using your system in daily life

## Part 7: Product specifications



## Appendix: Symbols

# Part 1: Introduction

## About this user guide

This user guide provides indications, contraindications, warnings, precautions, operating instructions and other important information on using your DBLG2™ system. Carefully read through all the instructions prior to using the DBLG2 system.

**Reading this user guide is essential. It helps you use the DBLG2 system appropriately.**

- Warnings

⚠ A warning describes serious circumstances that could endanger your life, their consequences, how to avoid the danger and what you should do if faced with this danger.

- Precautions

⚠ A precaution describes special steps you must follow when you use the system, which help to prevent minor or moderate damages that could occur to you or your system.

- Operating instructions

An operating instruction contains additional information or advice on how to use the system correctly.

This logo means that a particular action must be carried out by someone who is part of a medical team so as to ensure correct operation of the DBLG2 system.

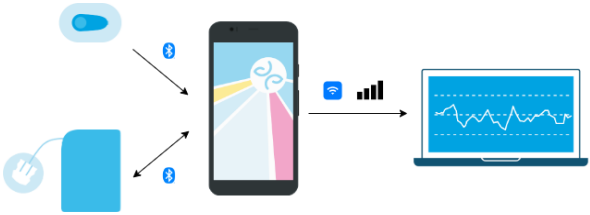
***The images shown in this user guide are for illustrative purposes only. Depending on your operating system, your application may look slightly different.***



## 1.1 – Purpose and intended users

DBLG2 is a mobile application for automated insulin delivery. The software includes an algorithm called loop mode and interacts with a continuous glucose monitoring device (CGM) and an insulin pump through restricted Bluetooth® Low Energy connections.

The DBLG2 software application gathers data from the CGM and the insulin pump, transmits alarms, alerts and information messages triggered by the CGM and the pump, and issues insulin delivery commands to the pump. It also transmits data to YourLoops®, a web-based data visualization platform. The following diagram illustrates the flow of communication between the various devices.



### 1.1.1 – Intended users

The intended users are:

- patients, who are expected to use the DBLG2 system after getting trained on its use by a competent healthcare professional and/or distributor.
- healthcare professionals and/or distributors, who have been trained to use the DBLG2 system and will assist the patient in its use.

### 1.1.2 – Intended purpose

The DBLG2 software is intended for adult patients with type 1 diabetes who are aged 18 or older, as well as healthcare professionals who have been trained on the system and will assist the patient in its use.

The main function of the DBLG2 software is to adjust the insulin delivery at the correct time in order to maintain the patient's blood glucose in the target range and thus minimize both hypoglycemic events and long-term complications associated with elevated average glycemia. To do this, the DBLG2 software takes into account the patient's profile, glycemia (current and predicted), announced meals and physical activities.

### 1.1.3 – Indications

The DBLG2 system, issued on a medical prescription, is intended for patients with type 1 diabetes who are more than 18 years of age.

The total daily dose of insulin required must be less than 90 units (U).[1]

The DBLG2 system is indicated for use with 100 U/mL rapid-acting insulin analog and is intended for single-patient use.

### 1.1.4 – Contraindications

This medical device is contraindicated for the following people.

- Patients receiving a total daily dose of insulin lower than 8 U.
- Patients suffering from a serious illness or undergoing treatment that might significantly impair diabetes physiology (i.e., glucose-insulin interactions) and which might interfere with the medical device (for example, irregular treatment by steroids).

[1]U: Unit (International Unit, also IU). Unit of measurement for insulin.

- Patients with severe uncorrected hearing impairment and/or severe uncorrected problems of visual acuity.
- Patients who are unable to understand and perform all of the instructions provided by Diabeloop SA.
- Patients who are unwilling or unable to maintain contact with the healthcare professional.
- Patients wanting to use any insulin that is not 100 U/mL rapid-acting insulin analog (for example, regular insulin; long-acting insulin analog; 200 U/mL rapid-acting insulin analog).
- Patients who are unable to use basic smartphone functionalities.

The DBLG2 system MUST NOT be worn during magnetic resonance imaging (MRI), computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The Dexcom G6 sensor (CGM) has not been tested in these situations. Magnetic fields and heat could damage the components of the Dexcom G6, which may cause it to display inaccurate glucose readings or may prevent alerts. Without Dexcom G6 sensor readings or alarm/alert notifications, you could be exposed to a severe low or high glucose event.

The safety and effectiveness of the DBLG2 system have not been tested or approved for the following categories of people.

- Patients with type 2 diabetes.
- Patients with highly unstable diabetes.
- Patients with gestational diabetes.
- Pregnant women with type 1 diabetes.
- Patients whose pancreas has been removed or is not functioning altogether.
- Patients with severely altered renal function (creatinine clearance <30 mL/min).
- Patients with a decreased feeling of hypoglycemia symptoms.
- Patients with islet/pancreas transplants.
- Patients on dialysis.
- Critically ill patients.

## 1.2 – Safety statements

Carefully read through the safety statements in this chapter before your first use of the DBLG2 system.

### 1.2.1 – General safety statements

You will use the DBLG2 system after getting trained on its use by a competent healthcare professional.

Contact your healthcare professional in certain situations described in this user guide.

Carefully read this user guide before you start using your DBLG2 system. It contains important information on the features and performance characteristics of your system, as well as troubleshooting information.

You should use the system as described in this user guide and according to the training provided by your healthcare professional. Incorrect use may lead to serious injury, life-threatening situations or even death.

This medical device is meant for personal use.

Make sure you always have a first-aid kit readily available. Even while using the DBLG2 system, severe hypoglycemia or hyperglycemia cannot be ruled out. To be prepared, always have your first-aid kit ready and tell someone you trust what to do in an emergency.

When changing pumps, put your second pump to charge right away so that you always have it available in case of an emergency.

Always check for ketones if your blood glucose reading is excessively high. If ketones are present, treat according to the advice given to you by your healthcare professional.

Keep the system out of reach of children and pets.


The DBLG2 system **cannot** be used:

- in the presence of electromagnetic fields (including any storage with magnetic clasps, MRI, X-ray and CT scanners) and ionizing waves.
- during radiation therapy.

In such cases, stop the delivery of insulin (System screen > pump section > Stop) and remove your equipment to keep it safe.

Ensure that you keep a maximum distance of 2 meters between the pump/sensor and your smartphone.

If, for whatever reason (unsuitable temperatures, prolonged loss of connection to the system, high electromagnetic environment, damage to the phone, etc.), the pump no longer receives any commands from the DBLG2 application, it automatically switches to safety mode and delivers the basal safety profile.

If one of the system components is disconnected for an extended period, loop mode is stopped. **Pay attention to any alarms.**

**Do not try to modify any of the components**
If you encounter a problem with one of your devices, contact your local support as soon as possible.
Do not try to modify, alter or disassemble any part of your DBLG2 system.

⚠ We recommend that you keep your smartphone close by when you have the volume set low.

### 1.2.2 – Safety statements about the Dexcom G6

The Dexcom G6 CGM (sensor and transmitter) is intended to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the Dexcom G6 results should be based on the glucose trends and several sequential readings over time. The Dexcom G6 also aids in the detection of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.

⚠ **Always follow the G6 instructions. If you do not, you could have a severe low or high glucose event.**

⚠ **Do not ignore low/high glycemic symptoms**
Do not ignore how you feel. If your glucose alerts and G6 readings do not match what you are feeling, use your blood glucose meter to make diabetes treatment decisions or, if needed, seek immediate medical attention.

If in doubt, use your meter.

⚠ **If no number or arrow is displayed**
If your G6 does not show a number or arrow, or your readings do not match your symptoms, use your meter to make diabetes treatment decisions. When in doubt, get your meter out.

⚠ Do not use the G6 if you are on dialysis or critically ill. It is not known how different conditions or medications common to these populations may affect the performance of the system. G6 readings may be inaccurate in these populations.

⚠ **Avoid sunscreen and insect repellent**
Some skin care products, such as sunscreens and insect repellents, can make the plastic used in your G6 crack. Before using your G6, make sure there are no cracks in your transmitter and transmitter holder. If you find a crack, contact your local support. Do not allow these skin care products to come into contact with your G6. After using skin care products, wash your hands before touching your G6. If any skin care products get on your G6, immediately wipe it with a clean cloth.

⚠ **Hydroxyurea precaution**
If you are taking hydroxyurea, your G6 readings may be falsely elevated and result in missed hypoglycemia alerts or errors in diabetes management decisions. The level of inaccuracy depends on the amount of hydroxyurea in your body. Use your blood glucose meter if you are undergoing treatment with hydroxyurea.

⚠ **Keep the transmitter close to your smartphone**
Always keep your transmitter and smartphone close to each other. Otherwise they might not be able to communicate.

⚠ Make sure your DBLG2 application is always running so that you can keep track of your G6 readings and receive alarms and alerts.

**G6 and water**

Once snapped into place, the transmitter is waterproof. Swim, shower, take a bath: there's no need to worry about water and your G6 – just leave your smartphone in a dry area.

Note that if the distance between the G6 and the smartphone is too great, connection between the two devices may be lost.

### Startup safety statements

**Use a meter during warmup**

When you start with a new sensor, you will not receive any G6 readings or alarm/alerts until the 2-hour warmup period has finished. During this time, use your meter to make treatment decisions.

**Use the correct sensor code**

When you start with a new sensor, you must enter a code into your DBLG2 application to use the G6 without fingerstick calibrations. Each sensor has its own code printed on the back of the adhesive patch. Do not use a code from a different sensor or make up a code. If you do not enter the correct code, your sensor will not work as well and could be inaccurate. If you lose the sensor code, you may calibrate the G6 using fingersticks.

### Calibration safety statements

Calibration is not required if you enter a sensor code. If you do not enter a sensor code, the following warnings and precautions apply.

**Do not wait – calibrate**

If you have not used the sensor code, you must manually calibrate your G6 daily, using values obtained from a blood glucose meter and fingersticks. You must calibrate immediately when the G6 notifies you. If you have not calibrated when notified, your G6 may not be accurate, so use your glucose meter to make treatment decisions until you calibrate your G6.

**Use your fingertips**

Use your fingertip to calibrate from your blood glucose meter. Blood from other areas may provide less accurate results and not be as timely.

**Be accurate, be quick**

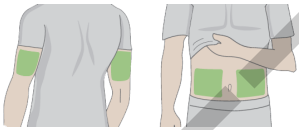
Enter the exact blood glucose value displayed on your meter within 5 minutes of using your meter. Do not enter the G6 reading as a calibration.

### System/Hardware/Software safety statements

**Sensor wire breaks off**
Do not ignore broken or detached sensor wires. A sensor wire could remain under your skin.

If a sensor wire breaks off under your skin and you cannot see it, do not try to remove it. Contact your healthcare professional. Also seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site.

**Where to insert: belly or back of arms?**
All patients can use their belly or back of upper arms. Look for a place on your belly or back of upper arms where you have some padding.



The sensor is not tested or approved for other sites. Talk to your healthcare professional about the best site for you.

**Where should you store the sensors?**
You can store your sensors at room temperature or in your refrigerator – as long as the temperature is between 2°C and 30°C. Do not store sensors in the freezer.

**Do not start past the use-by date**
Do not start a sensor past its use-by date as it may give incorrect results. The use-by date is in YYYY-MM-DD (year-month-day) format on the sensor package label beside the hourglass symbol.

**Check the packaging**
Do not use the sensor if its sterile package has been damaged or opened. Doing so could cause an infection.

### Transmitter safety statements

**Inspect**
Do not use a damaged or cracked transmitter. A damaged transmitter could cause injuries from electrical shocks and may cause the G6 to not work correctly.

**Use as directed**
The transmitter is small and may pose a choking hazard. Do not put it in your mouth or let children hold it without adult supervision.

**Reuse – do not throw away**
When ending a session, do not throw away the transmitter. The transmitter is reusable for three months.

### System safety statements related to Dexcom G6

**Treatment decisions**
Refer to your G6 reading and trend arrow if you need to make treatment adjustments when loop mode is OFF.

**Use the correct transmitter and sensor**
G6 components are not compatible with any previous Dexcom products. Do not mix transmitters and sensors from different generations.

**Going through security checkpoints**
When wearing your G6, request that the security personnel use a hand-held device or ask for a full-body pat-down and visual inspection instead of going through the advanced imaging technology (AIT) body scanner (also called a millimeter wave scanner) or putting any part of the G6 in the baggage X-ray machine. You can wear the G6 for the walk-through metal detector. If you do, use your meter for treatment decisions until you leave the security area.

The G6 has not been tested with every X-ray and scanner, so it is not known if they may cause damage. If you are unsure about what kind of technology is being used, keep your device safe. Ask for a hand-held device or a full-body pat-down.

## 1.2.3 – Safety statements about the Kaleido pump

While all patients with insulin-dependent diabetes can use insulin pumps, in patients with type 1 diabetes mellitus (T1DM), insulin therapy by means of continuous subcutaneous insulin infusion (CSII) with an insulin pump is a well-established therapeutic option. There is a large body of evidence showing beneficial effects of CSII in patients with T1DM, because it mimics the physiological situation by combining a (quasi) continuous insulin infusion rate to cover the basal insulin requirements with additional bolus deliveries to cover prandial insulin requirements and corrections of high glucose values.

**Do not make any modifications to your Kaleido products**
Safety of use cannot be guaranteed if modifications are made to the equipment. Any changes made will invalidate the warranty.

**Do not drop your pump**
If your pump has been dropped, make sure you examine it carefully for cracks or signs of damage. If it has been dropped or has been damaged, this might affect the waterproofness and functionality of the pump.

**Avoid extreme temperature conditions**
Avoid exposing the pump to temperature conditions above 37°C or below 5°C. Your pump is not suitable for use in hot tubs (sauna, jacuzzi, etc.) or hot showers. Extreme temperatures can adversely affect your insulin.

**Avoid extreme humidity conditions**
Avoid exposing the pump to relative humidity conditions (non-condensing) above 93% or below 15%.

**Avoid extreme pressure conditions**
In temperatures between 5°C and 37°C, your Kaleido pump can operate within an air pressure range of 0.7 bar – 1.06 bars. This air pressure is typically found from sea level up to an altitude of 2500 m. However, extreme altitude, temperatures or atmospheric conditions may affect your pump's performance. Therefore, it is advised to keep this in mind and always have other means of insulin therapy with you when doing any activities at extreme altitudes or temperatures.

Do not use your pump when there are flammable gases present.

**Conditions of waterproofness of the pump**
Your Kaleido pump is waterproof for a depth of 1.5 meters up to 1 hour. This means you can shower and take a swim as long as you do not go deeper than 1.5 meters or for longer than 1 hour in the water.

The charging dock, connection cable and power adapter are not waterproof. Make sure you keep these products safe and dry.

**Types of insulin to be used**
The DBLG2 system is not provided with the U100 insulin you need to use for your pump. For this, you should contact your healthcare professional.

Your Kaleido pump and insulin cartridges are only approved for use with Humalog® and NovoRapid® U100 insulins. You must only use U100 rapid-acting insulin and must **never** mix insulin types. Using a lesser or greater concentration or a mix of insulins can result in serious health consequences.

**Skin irritation**
To avoid severe skin irritation, we recommend that you wash your hands before placing the infusion set or the pump on your body. Likewise, you are instructed to clean the area of your skin with an alcohol wipe to prevent skin reactions. Furthermore, to prevent severe skin irritation and damage, we recommend switching the infusion site each time you place the device on your body.

**Strangulation risk**
Your connection cable and insulin cartridge tubing could pose a strangulation risk. Do not place this near or around a person's neck and keep out of reach of children or pets.

Do not open the packaging of the Kaleido disposables until immediately before use. Sterility of the package contents cannot be ensured when opening the packaging before immediate use. Using non-sterile components may result in infection.

Check for damage of the insulin cartridge, infusion set and pump if you notice that your glucose levels are high or when you need more insulin than expected. In case you see any damage on a Kaleido component, stop using it and contact your local support.

Do not keep Kaleido components near young children and pets. Swallowing small parts is a choking hazard.

⚠ Only use accessories and materials described in this user guide. Do not use components from other pump suppliers, as this may result in increased electromagnetic emissions, and decreased electromagnetic immunity, or decreased safety of use. Using alternative parts and accessories from other pump suppliers could also damage your pump and will invalidate your warranty.

⚠ Do not use or store your pumps near a magnetic field (e.g., magnets or an MRI). Doing so could result in damage to your pump.

⚠ Do not replace the lithium batteries of the pump. Replacement of lithium batteries could result in a hazard and will invalidate the warranty.

⚠ Only connect the power adapter to an appropriate power source to charge (100–240 V, 50–60 Hz). When using a power source not specified in this user guide, safety of use cannot be guaranteed.

⚠ Do not use or store the power adapter, connection cable and charging dock in a wet environment. Any water entering these components may lead to electric shock.

⚠ Do not position the pump in such a way that it is difficult to connect/disconnect the power adapter.

⚠ Use the Kaleido pump according to this user guide. If you do not follow the instructions provided, safety of use and delivery accuracy of the Kaleido pump may be affected.

⚠ Do not reuse supplies out of the top-up kit. Doing so may contaminate your insulin and lead to infection.

⚠ Always follow the advice given to you by your healthcare professional. For any blood glucose / medical related concerns consult your healthcare professional.

⚠ Elderly people living alone can use this medical device if they are physically and mentally able, if they understand the pump functions and can manage the system as intended.

⚠ Some skincare products, such as sunscreen lotions, moisturizer lotions or creams and insect repellents, can cause damage to the plastics used in Kaleido products and affect the adhesive of your body patches. After using such products, be sure to wash your hands prior to handling your pump. If you get any skincare products or insect repellents on your pump, wipe them off as soon as possible following the cleaning instructions (see Cleaning on page 105).

### 1.2.4 – Safety statements about the insulin

The DBLG2 system must be exclusively used with 100 U/mL rapid-acting insulin. Long-acting insulin cannot be used with this medical device. Diabeloop SA cannot be held responsible in case of a complication or side effect occurring after inappropriate use of the medical device due to an incorrect insulin type.

The Kaleido pump can be used with the following U100 insulin types: Humalog® and NovoRapid®. Your healthcare professional will prescribe the exact insulin type for treating your diabetes mellitus.

Insulin can be fatal at high doses while a lack of insulin can cause hyperglycemia. Therefore, it is important to ensure the accuracy of the calculation before manually injecting yourself with a dose of insulin.

Insulin freezes at 0°C and gets altered at high temperatures (above 30°C). When outdoors in cold weather, keep the pump close to your body or under warm clothing. In a hot environment, take necessary measures to keep the pump and the insulin at a moderate temperature.

Check the expiration date of your insulin vial before each use. Also make sure that you store it in accordance with the storage conditions specified by the insulin manufacturer. While using the system, if you feel that the bolus does not have any effect, it could be that the insulin is deteriorated. In this case, the insulin must be disposed of and replaced.

Insulin allergy prohibits the use of any insulin since subcutaneous insulin injections would result in large and painful red skin excoriations and destruction of the insulin by the immune system. Although very rare, insulin allergy is a clinical problem that can be tackled by specialized desensitization procedures. Desensitization is a procedure that alters the immune response to the drug and results in temporary tolerance, allowing the patient with a drug hypersensitivity reaction to receive an uninterrupted course of the medication safely. However, this system is not a treatment for insulin allergy and, as such, is not recommended for people with insulin intolerance/allergy.

## 1.3 – System components

### 1.3.1 – Composition of the DBLG2 system

Before you start, make sure you have all the components necessary to use the system. If you are missing a component, contact your local support.

If the packaging of any of your supplies is damaged in any way, do not use it. Sterility (if applicable), performance and security of the products may not be guaranteed. Contact your local support for a replacement.

⚠ Keep all of your packaging until you have finished using its contents. In the event of a problem with one of the components, you will be asked to provide the serial number, batch number and other identification number—all of which are written on the packaging—to your local support.

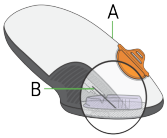
The DBLG2 system is composed of the following.

- DBLG2 software (with the loop mode algorithm) available from your official app store (medical prescription required for its use) and installed on a compatible smartphone.
- A Dexcom sensor and transmitter.
- A Kaleido insulin pump.

### 1.3.2 – Dexcom G6

The Dexcom G6® is a real-time continuous glucose monitoring (CGM) device intended to replace fingerstick blood glucose testing for diabetes treatment decisions. G6 readings can be viewed on the DBLG2 application and are refreshed every 5 minutes, without having to take samples from your fingertips. Your readings are carried out in the interstitial fluid by a disposable sensor inserted under the skin.

#### Overview

| Name (and lifetime) | Description | Illustration |
|---|---|---|
| Sensor (inside applicator)<br>(10 days of use) | The sensor gets glucose information. The sensor applicator (**A**) inserts the sensor (**B**: inside the applicator) under the skin (single use). |  |
| Transmitter<br>(3 months of use) | The transmitter sends glucose information from the sensor to the DBLG2 application. |  |

#### Features

**No fingerstick calibrations**: with the G6, there is no need to calibrate if you have entered the sensor code. Once you have entered the code, you will not receive any calibration requests.

**10-day sensor session**: your sensor session lasts 10 days. The number of days left is visible on the System screen of the DBLG2 application.

**Paracetamol/acetaminophen blocking**: with the G6, you can take paracetamol/acetaminophen and still use its readings.

⚠ Taking higher than the maximum dose of paracetamol/acetaminophen (> 1 gram every 6 hours in adults) may affect sensor readings and make them look higher than they really are.

**Sensor applicator**: the sensor applicator lets you insert a sensor quickly and easily.

### 1.3.3 – Kaleido insulin pump

The Kaleido® insulin pump is a medical device designed for the continuous and variable subcutaneous administration of insulin for the treatment of people with insulin-dependent diabetes mellitus.

When the pump is paired with the DBLG2 application, loop mode automates the delivery of insulin. In certain situations, you can also make manual adjustments through the app.

#### Components of the Kaleido insulin pump

The Kaleido pump is a patch pump. It comes with 5- and 30-cm tubing and 6- or 9-mm cannulas. The pump also comes with an inserter to facilitate the insertion of the cannula. The Kaleido pump does not get thrown away; it comes with a charger.

⚠ Your connection cable should only be used with your Kaleido charging dock and power adapter to charge your pumps.

⚠ Check all your supplies and parts for damage before using them. In case of damage, immediately use an alternative form of therapy until the damage has been repaired or replaced, and contact your local support.

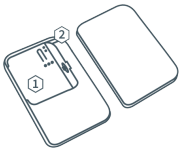
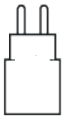
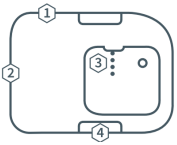
⚠ Check the content of your kits for completeness prior to use. Contact your local support if anything is missing.

⚠ Do not use supplies out of the top-up kit when the packaging is damaged or the expiration date has passed. Sterility and safety of the products cannot be guaranteed once the packaging is damaged or the expiration date has passed.

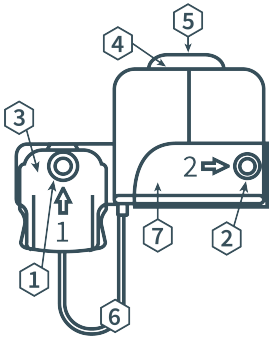
⚠ Do not store your inserter together with loose blood glucose testing strips. Blood glucose strips can enter the inserter and impair its functionality.

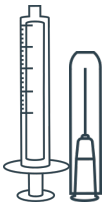
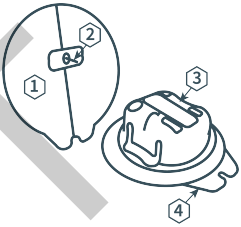
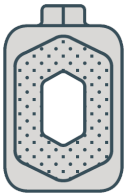
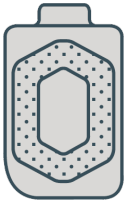
Starter kit

⚠ If your Kaleido kit also contains a Kaleido handset, do not pair your Kaleido pumps to the Kaleido handset when using the DBLG2 system. If your Kaleido pumps are currently or have previously been paired to a Kaleido handset or to the DBLG1, make sure you unpair both pumps from this handset before pairing them to the DBLG2 application. Refer to the Kaleido or DBLG1 System user guide for instructions.

| Name | Description | Illustration |
|---|---|---|
| Insulin pump<br>(x2) | Kaleido insulin pumps<br>**1**: Holder for the insulin cartridge<br>**2**: Groove for insulin cartridge tubing |  |
| Inserter<br>(x1) | Reusable inserter to insert your Kaleido infusion set. Ensure you keep it handy with your Kaleido disposables.<br>**1**: Activation button |  |
| Connection cable<br>(x1) | Connection cable USB–micro-USB<br>Length: 107 cm |  |
| Power adapter<br>(x1) | USB to mains power adapter |  |
| Charging dock<br>(x1) | Dock used to charge your pumps<br>**1**: Charging status light<br>**2**: Micro-USB port<br>**3**: Contact pins<br>**4**: Release buttons |  |

Top-up kit

| Name | Description | Illustration |
|---|---|---|
| Insulin cartridge<br>(x10) | Insulin cartridge (capacity = 200 units of U100 insulin)<br>Tubing: 5 cm or 30 cm<br>**1**: Hole 1<br>**2**: Hole 2<br>**3**: Insulin cartridge connector<br>**4**: Plastic tab<br>**5**: Filling cradle catch<br>**6**: Insulin cartridge tubing<br>**7**: Filling cradle |  |

| Name | Description | Illustration |
|---|---|---|
| Syringes and needle<br>(x10) | 2.5 mL syringes to fill insulin cartridges with insulin<br>Needle to connect at the end of the syringe |  |
| Infusion set<br>(x10) | Device for the subcutaneous injection of rapid-acting insulin<br>Cannula: 6 mm or 9 mm<br>**1**: Paper backing (with sticky patch underneath)<br>**2**: Needle, including cannula tube<br>**3**: Plastic cap<br>**4**: Plastic cap tabs |  |
| Alcohol wipe<br>(x10) | Wipe with an alcohol solution for disinfecting the insertion site |  |
| Body patch<br>(x10) | Patch to be stuck to the skin for attaching the pump |  |
| Pump patch<br>(x10) | Patch to be stuck on the back of the pump and put on the skin patch |  |



### 1.3.4 – DBLG2 software application

The DBLG2 application uses loop mode to recommend and schedule the delivery of appropriate insulin doses.

The DBLG2 application takes into account your personal settings (entered during the initialization phase), the G6 readings from the interstitial fluid, and your meal and physical activity declarations. It automatically calculates the correct dose of insulin (either the basal

rate, or a correction or meal bolus) and commands your pump to deliver it. Your insulin requirements are adjusted every 5 to 10 minutes with each new G6 reading.

Your DBLG2 application also recommends that you take rescue carbs if you are at risk of hypoglycemia.

Lastly, the application displays all system alarms, alerts and information messages.

If loop mode is switched off, you can still view the G6 readings and trend arrows via the DBLG2 application and use them to control the pump.

### 1.3.5 – Data sharing to YourLoops

YourLoops® is a web-based data visualization platform to which you can transmit your glycemia-related data so that it can be shared with your healthcare professional and your caregiver. You will have to create a YourLoops account when you initialize your DBLG2 application. Refer to Initializing the DBLG2 application on page 25.

## 1.4 – Composition of your first-aid kit

Always have a first-aid kit readily available.

Make sure you always carry with you the equipment required for changing the pump in case of an emergency. If you see any signs of damage to any of the components, or if the expiration date has passed for any one of them, do not use it.

⚠ Should insulin delivery from your pump be interrupted for any reason, and in order to prevent DKA (diabetic ketoacidosis) or very high blood-glucose levels, you must have a means to monitor your blood glucose and an alternative insulin therapy with you at all times.

Your first-aid kit must consist of:

- a spare insulin cartridge,
- your inserter for the infusion set,
- a Kaleido infusion set,
- your second charged Kaleido pump and its charging kit (charging dock, connection cable and power adapter),
- some rescue carbs,
- your blood glucose meter with test strips,
- a lancing device and lancets,
- acetonemia or acetonuria tests (i.e., ketone monitoring supplies),
- your alternative insulin therapy: rapid-acting insulin and an injection device with needles (your healthcare professional can help you with dosing instructions).

# Part 2: Setting up your system

## 2.1 – DBLG2 application

### 2.1.1 – Smartphone prerequisites and recommendations

The DBLG2 application runs on specific smartphones. A list of compatible phones is provided on Diabeloop's website. The DBLG2 application can be used **on only one smartphone**.

⚠ Make sure your smartphone has enough storage capacity to install the app and keep it running smoothly.

Your mobile phone plan should include at least 3G coverage and a subscription to mobile data.

The application is compatible with Android operating systems 10 to 15.

⚠ Do not upgrade your phone to an unsupported OS version. Refer to OS updates on page 90 for recommendations to follow after an OS update.

**Protect your smartphone**

Before downloading and installing the DBLG2 application, make sure your smartphone and personal data are adequately protected against theft, phishing attacks and viruses. **Secure your smartphone with a PIN code, biometric identification or other means.** You will not be able to start the DBLG2 application if your phone is not protected.

⚠ For security reasons if your phone is stolen, you should avoid using identical digits for a PIN code.

**Only install applications on your smartphone that you know to be from a reliable source.**

### 2.1.2 – Downloading the DBLG2 application

⚠ Before downloading the DBLG2 application, make sure your phone is charged.

You can download the DBLG2 application through the official app store. Its use requires an activation code, which will be provided by your healthcare professional once you have been trained to use the system.

### 2.1.3 – Initializing the DBLG2 application

⚠ **The DBLG2 application must be initialized by a healthcare professional trained to use the DBLG2 system. You will therefore be assisted by your healthcare professional to enter your personal and medical data.**

Before launching the DBLG2 application, you must configure your smartphone as follows.

- Switch Bluetooth® on.
- Make sure your smartphone is connected to the Internet (Wi-Fi or mobile network).

**For your application to operate optimally once it has been initialized, bear in mind the following.**

⚠ Do not disable notifications. Notifications enable you to use the system properly and be notified of important events. Disabling notifications can stop the application.

⚠ Never delete the application data. If you delete the application data you will have to reboot the application and re-initialize it. If the application was paired with a pump, the pump will become locked and unusable. Refer to Unlocking your pump on page 73 for the instructions to follow if this happens.

⚠ Never switch Bluetooth® off. Switching off Bluetooth® triggers an alarm (63000).

⚠ Never remove the security measures on your phone (code, biometric identification, facial recognition etc.).

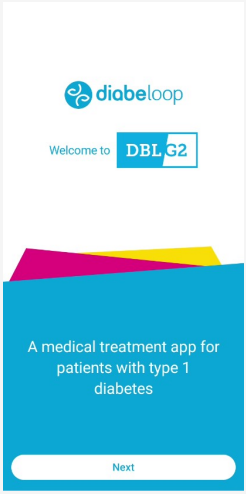
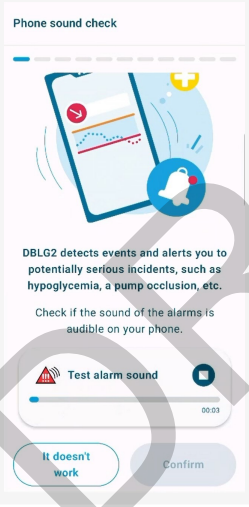
⚠ Do not change the automatic time setting on your phone. Switching from automatic time to manual time triggers an alarm (64000). Automatic time ensures consistent operation between the sensor, pump and application.

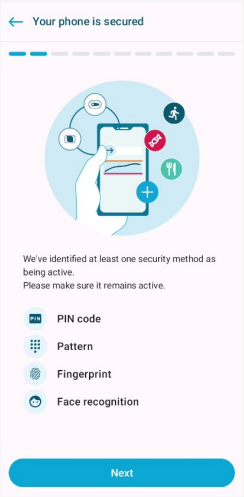
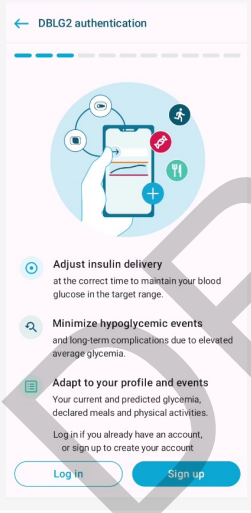
⚠ Make sure you always have an active Internet connection (Wi-Fi or mobile data). This is necessary for your medical data to be sent to YourLoops and for your application to work.

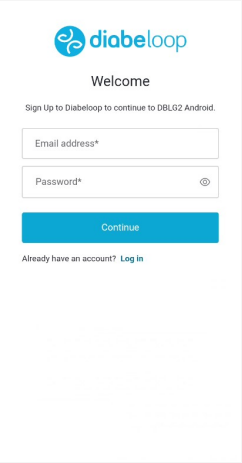
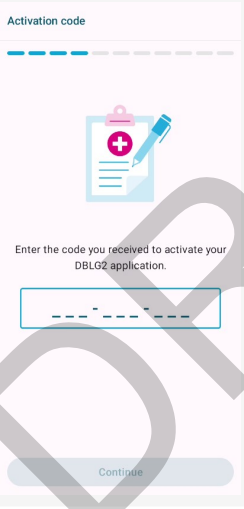
If you do not want to use your mobile data (consumption of approximately 0.05 Gb per month), choose Wi-Fi as the preferred method for transferring your medical data. Refer to Data sharing on page 102.

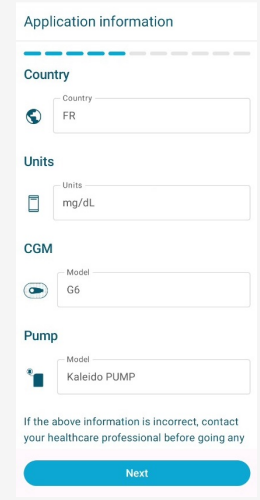
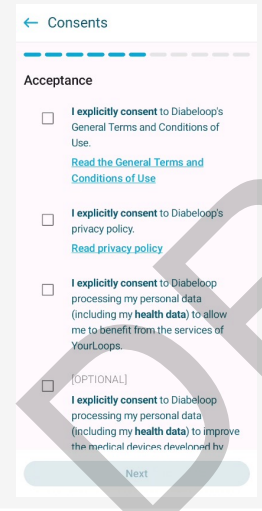
⚠ Make sure battery optimization for the DBLG2 application is not enabled on your phone. DBLG2 must be able to run in the background at all times.

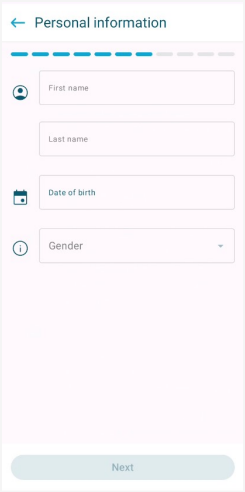
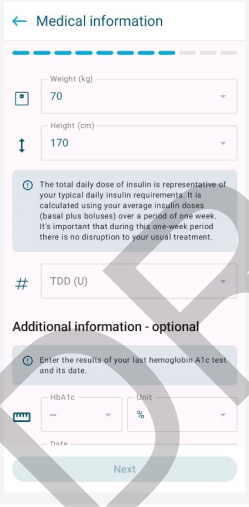
Upon launching the DBLG2 application, a welcome screen appears. The following steps are necessary to customize the system. For more information on the settings required for this initialization phase, refer to Profile menu on page 93.

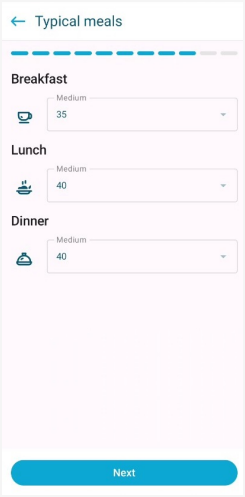
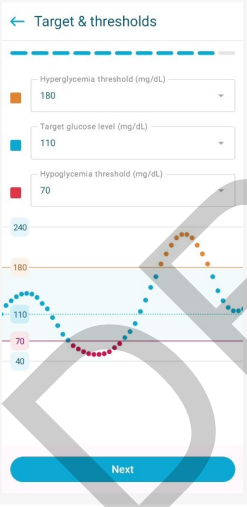
| | | |
|---|---|---|
| 1 |  | On the Welcome screen, tap Next. |
| 2 |  | Test the sound on your phone to ensure that alarms will be audible.<br>You must wait until the end of the test before you can tap Confirm. |

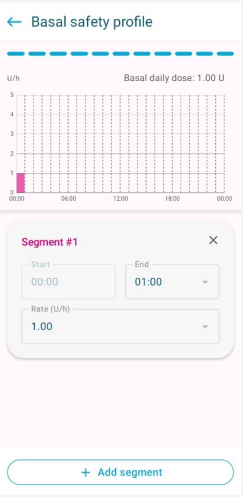
| | | |
|---|---|---|
| 3 |  | If you have not already done so, secure your phone by way of a PIN code, biometric identification or other means. Tap Next when done. |
| 4 |  | Tap on Sign up to create a YourLoops account (or on Log in if you already have an account). |

| | | |
|---|---|---|
| 5 |  | If you tapped Log in, enter your login (email) and password.<br><br>If you tapped Sign up, create your account with a unique email address and password, and tap Continue. If you already have a professional account, use another email address for the patient account.<br><br>Choose a password with at least 10 characters. For cybersecurity reasons, the password should contain upper- and lowercase letters, numbers and special characters, and should be unique to YourLoops.<br><br>> This account gives you access to YourLoops, a web-based data visualization platform.<br><br>You will receive a link by email inviting you to check your email address. Once you have confirmed your account, tap Continue again. |
| 6 |  | Enter the activation code provided by your healthcare professional (nine digits).<br><br>Tap Continue. |

| | | |
|---|---|---|
| 7 |  | Check that the information shown on the screen is correct: country, units for the G6 readings, sensor and pump models. If the information is incorrect, contact your healthcare professional.<br>Tap Next. |
| 8 |  | Use of the system requires acceptance of the terms and conditions of use.<br>Read and accept the general terms and conditions of use and the data privacy policy. Then tap Next. |

| | | |
|---|---|---|
| 9 |  | Enter your personal information.<br>Tap Next. |
| 10 |  | Enter your weight, height and total daily dose of insulin (TDD). The TDD is your usual total dose of insulin over a 24-hour period.<br>You can also enter some additional information.<br>• Last measured HbA1c and date of measure.<br>• Time spent in the target glucose range over the last two weeks.<br>• The type of treatment you were using before switching to DBLG2.<br>Tap Next. |

| | | |
|---|---|---|
| 11 |  | Enter the typical quantity of carbohydrates that you normally eat for a medium-sized meal for breakfast, lunch and dinner. With this information, DBLG2 calculates your insulin requirements for the meal bolus.<br>Tap Next. |
| 12 |  | Set your target glucose level and your hyperglycemia and hypoglycemia thresholds. By default these are set to 110, 180 and 70 mg/dL respectively. Adjust them as necessary.<br>Tap Next. |

| | | |
|---|---|---|
| 13 |  | Enter your basal safety profile: start time, end time and desired rate per hour for each time slot. One time slot can cover several hours. The maximum number of slots is 24. When loop mode is off, the DBLG2 system switches to this basal safety treatment.<br>Tap + Add segment between each entry.<br>When a 24-hour period has been recorded, tap Continue.<br>> Each basal rate slot can be set to between 0.05 U/h and 5 U/h.[1] If a slot is deleted, all subsequent slots are deleted as well and will have to be filled in again. |
| 14 | Grant all necessary permissions (override of Do Not Disturb mode, unrestricted battery usage, for example) and tap Next. | |

At the end of the initialization steps, the Home screen is displayed. To pair your sensor and set up your insulin pump, go to the System screen. Refer to Glucose sensor on page 37 and Insulin pump on page 45.



[1] U/h: insulin amount delivered in units per hour.

### 2.1.4 – Getting to know your app

#### *Home* screen

The Home screen displays the following information (from top to bottom).



- Active or inactive system devices. Refer to Checking the status of the sensor on page 44, Checking the status of your insulin pump on page 63 and Loop mode statuses on page 65 for a description of the pictograms shown on the Home screen.
- The latest G6 reading and trend arrow, as well as the amount of active insulin in your body. Refer to Glucose color variations on Home screen on page 42 and Trend arrows of the Dexcom G6 sensor on page 42 for further information.
- Temporary information, such as a bolus in progress, if you are in hyperglycemia (with the associated bolus) or hypoglycemia, if Zen mode is active, etc. When one or more events of this type are in progress, the badge on the Home screen icon displays the corresponding number (2).
- Your glucose curve.
- Events, such as meals, physical activities, rescue carb intakes and pen boluses.
  Refer to:
  - Declaring a meal on page 79
  - Declaring a physical activity on page 84
  - Declaring a rescue carb intake on page 87
  - Controlling the pump manually on page 66
  - Declaring a bolus injected with a pen (or other device) on page 88
  - Viewing events on page 89
- A bar chart (in the lower part of the screen) showing insulin delivery information such as:
  - your basal rate,
  - meal or correction boluses sent by loop mode,
  - meal boluses recommended by loop mode but not delivered,
  - boluses sent through the application or injected with a pen.
- The add event button (+) to declare meals, physical activities, rescue carb intakes and pen boluses.

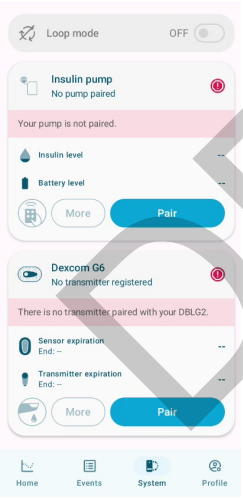
By default the Home screen shows activity over a 4-hour period. You can zoom in or out on a particular time frame or swipe horizontally to view past events over a 7-day period.

### *Events* screen


The Events screen displays all system events (declarations, alarms, alerts and information messages, boluses, etc), that have been monitored over a certain period of time.

Refer to Viewing events on page 89.

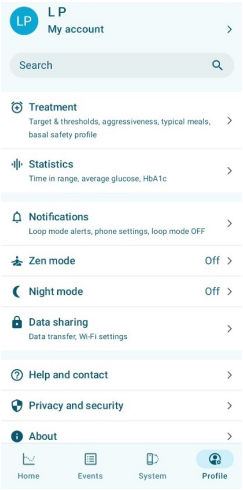
### *System* screen




The System screen is used to control your devices.

- Start or stop loop mode. Refer to Starting loop mode on page 64.
- Pair the pump, start or stop insulin delivery, send a manual bolus or change your basal rate temporarily. Refer to Insulin pump on page 45 and Controlling the pump manually on page 66.
- Pair or change the sensor and transmitter, calibrate the sensor. Refer to Glucose sensor on page 37.

### *Profile* screen




The Profile screen enables you to customize your DBLG2 application and view treatment- and application-related information.

Refer to Profile menu on page 93 for further information.

### App information on your phone

Your phone displays some DBLG2-related information in the status bar, in the notification drawer and on the lock screen. This information includes:

- your latest G6 reading and trend arrow.
- whether your Dexcom G6 is in its warmup phase.
- whether loop mode is running.
- alarms and alerts that have been triggered and require some form of action on your part, and information messages.
- your ongoing physical activity and its remaining duration.
- whether Zen mode is currently active and its remaining duration.
- whether you are currently in Night mode.

To see these notifications, swipe down from the status bar when your phone is unlocked, or tap on the icons visible on your lock screen, and then on the down arrow next to the DBLG2 logo.


Example of notifications on your phone

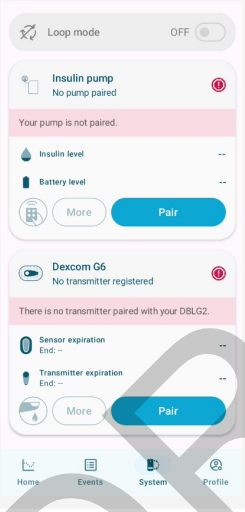
## 2.2 – Glucose sensor

### 2.2.1 – Pairing the sensor and the transmitter

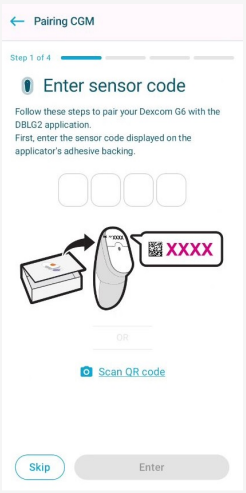
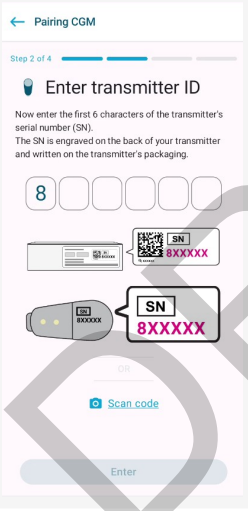
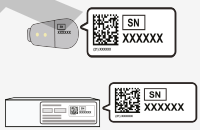
> Access to your phone's location is necessary to pair the external devices. It is not used for other purposes. A pop-up window is displayed during pairing requesting that you allow the DBLG2 application to access your phone's location.

> When the Dexcom G6 is used with the DBLG2 app, it can no longer be used with the Dexcom app. This is due to the restriction of the transmitter being connected to a single app/smart device.

1




Tap Pair (upon first use of the system) or Change sensor.

| | | |
|---|---|---|
| 2 |  | If you want to use the G6 without calibrating manually, enter the sensor code displayed on the applicator's adhesive backing and tap Enter.<br>  <br>Alternatively, tap Scan QR code to take a photo of the QR code, and follow the instructions on the screen to take the photo.<br>Tap on Skip if you want to use your G6 with manual calibration (calibration once a day). Refer to Calibrating your Dexcom G6 on page 42. |
| 3 |  | Enter the first six characters of the transmitter's serial number (SN). The SN is engraved on the back of your transmitter and written on the transmitter's packaging.<br>  <br>Tap Enter.<br>Alternatively, tap Scan QR code to take a photo of the corresponding QR code (also engraved on the back of your transmitter and written on the packaging). Then tap Next and follow the instructions on the screen to take the photo. When finished, tap Confirm. |
| 4 | Proceed with inserting your sensor and attaching your transmitter. | |

### 2.2.2 – Inserting the sensor and attaching the transmitter

**Where to insert: things to check**

Keep the safety guard on until you put the G6 applicator against your skin. If you remove the safety guard first, you may hurt yourself by accidentally pushing the button that inserts the sensor before you mean to.

Choose a site that is:

⚠

- at least 8 cm from the insulin infusion site,
- away from your waistband, scarring, tattoos, irritation and bones,
- unlikely to be bumped, pushed or laid on while sleeping.

Change your insertion site with each sensor. Using the same site too often might not allow enough time for the skin to heal, causing scarring or skin irritation.

Sensor placement is important. Follow these instructions. If you do not, you could have a severe low or high glucose event.

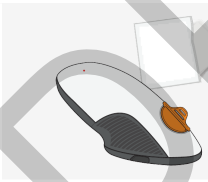
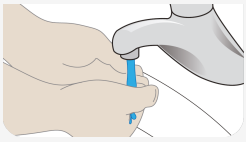
**Clean and dry the skin**

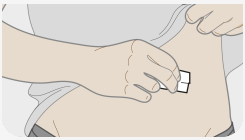
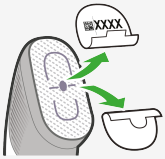
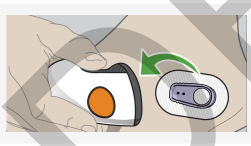
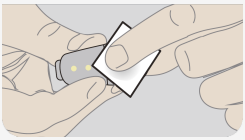
Clean and dry your hands and your insertion site before inserting your sensor. Wash your hands with soap and water, not gel cleaners, and then dry them before opening the sensor package. If your hands are dirty when you insert the sensor, you may get germs on the insertion site and get an infection.

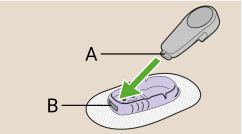
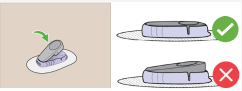
⚠

Clean your insertion site with alcohol wipes to prevent infections. Do not insert the sensor until your skin is dry. If your insertion site is not clean and completely dry, you run the risk of infection or of the transmitter holder not sticking well.

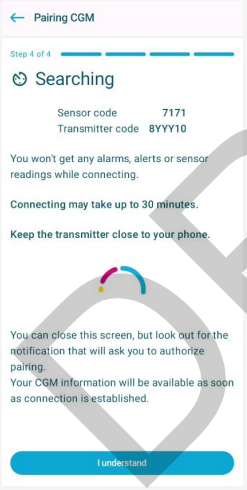
Make sure you do not have insect repellent, sunscreen, perfume or lotion on your skin.

| | | |
|---|---|---|
| 1 |  | Gather the materials: applicator (with the code you just entered), transmitter and wipes. |
| 2 |  | Pick a sensor site. Avoid bones, irritated skin, tattoos and areas that might get bumped. |
| 3 |  | Wash and dry your hands. |

| | | |
|---|---|---|
| 4 |  | Clean the sensor site with an alcohol wipe and let it dry. |
| 5 |  | Remove both adhesive backings from the applicator; do not touch the adhesive. |
| 6 |  | Place the applicator on the skin. |
| 7 |  | Fold and break off the safety guard. |
| 8 |  | Press the button to insert the sensor. |
| 9 |  | Remove the applicator from the skin leaving the patch and holder on. |
| 10 |  | Discard the applicator. Follow local guidelines for components that have come into contact with blood. |
| 11 |  | Clean the transmitter with an alcohol wipe. |

| | | |
|---|---|---|
| 12 |  | Insert the transmitter, tab (**A**) first, into the slot (**B**) on the holder. |
| 13 |  | Snap the transmitter onto the sensor. Snap the transmitter firmly into place (listen for the click). Make sure it is flat and snug in its holder. |
| 14 |  | Rub around the patch three times. |
| 15 | Tap Connect on your smartphone. | |

### 2.2.3 – Starting the sensor




Once your sensor and transmitter are installed on your body and you have tapped Connect, the DBLG2 application searches for the transmitter to set up the connection.

Check the codes are correct. Connection may take up to 30 minutes. Make sure you keep your phone close to the transmitter during this time (within 2 meters). During this time, you will **not** receive any readings or alarms or alerts from your G6.

You may tap I understand to close this screen while the connection is being set up. **Look out for the notification that asks you to authorize pairing.**

During this phase, the sensor's status on the System screen switches to *Searching*.

### Two-hour warmup period

Once your DBLG2 application is paired with the sensor, the sensor launches its warmup phase. This takes about 2 hours. The Home screen displays a warmup countdown.

During the warmup period, you will **not** receive G6 readings or alarms and alerts related to your glycemia.

You can use this time to set up the insulin pump. Follow the instructions described in Insulin pump on page 45. Once the warmup phase has finished, you will start receiving G6 readings and alarms and alerts.

### Glucose color variations on Home screen

| | |
|---|---|
|  | Hyperglycemia |
|  | Normoglycemia |
|  | Hypoglycemia |

### Trend arrows of the Dexcom G6 sensor

| Where your glucose is going | |
|---|---|
| → | **Steady**, changing up to 1 mg/dL each minute (30 mg/dL in 30 minutes). |
| ↗ or ↘ | **Slowly rising or falling**, changing between 1 and 2 mg/dL each minute (up to 30–60 mg/dL in 30 minutes). |
| ↑ or ↓ | **Rising or falling**, changing between 2 and 3 mg/dL each minute (up to 60–90 mg/dL in 30 minutes). |
| ⇈ or ⇊ | **Rapidly rising or falling**, changing more than 3 mg/dL each minute (90 mg/dL in 30 minutes). |
| -- | The trend cannot be determined. |

## 2.2.4 – Calibrating your Dexcom G6

If you chose manual calibration during the sensor's pairing phase (i.e., you did not enter the sensor code), you must calibrate your sensor with two capillary blood glucose values from your blood glucose meter at the end of the sensor's warmup phase. When the time comes to calibrate, a notification is displayed in your phone's status bar.

Five minutes after the first calibration, you must enter the second one. When you receive the second notification, calibrate again right away.

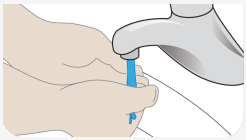
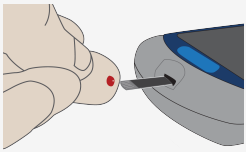
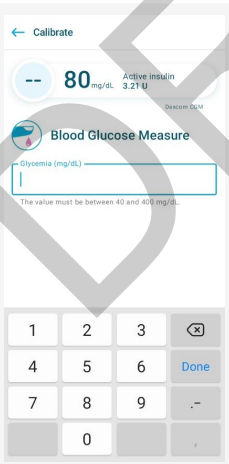
After these two calibrations, you can start viewing your Dexcom G6 readings. You will need to perform another calibration after 12 hours, followed by another 12 hours later. After that, one calibration will be required every 24 hours.

Reminder: your G6 readings are updated every 5 minutes on your smartphone.

**Be accurate, be quick**
Enter the exact blood glucose value displayed on your meter within 5 minutes of using your meter. Do not enter the Dexcom G6 reading as a calibration. Follow these instructions. If you do not, you could have a severe low or high glucose event.

Do not calibrate when your glucose is changing rapidly – more than 3 mg/dL in 1 minute (trend arrows: ⇈ ⇊).

Only calibrate with blood glucose meter values between 40–400 mg/dL.

| | | |
|---|---|---|
| 1 |  | Thoroughly wash your hands with soap and water, and dry them. |
| 2 |  | Use your blood glucose meter to get a meter value. |
| 3 |  | In the G6 section on the System screen, tap on the calibrate icon .<br>Enter the blood glucose value and tap Confirm, and then Confirm again on the pop-up screen. |

### When to use a meter instead of the G6

Rely on your blood glucose meter for treatment decisions in the following situations.

- When no number or arrow is displayed.
- When your G6 readings do not match your symptoms. For example, you do not feel right but your G6 readings show you are within the target. Wash your hands thoroughly and use your meter. If the meter value matches your symptoms, use the meter value as the treatment basis. Then, if you want to align your G6 with your meter, calibrate. You do not have to calibrate, but you can. When in doubt, use your meter.
- If your sensor cannot provide readings and you receive a sensor error alert (refer to List of alarms, alerts and information messages on page 110).

## 2.2.5 – Checking the status of the sensor

### Home screen statuses

| | |
|---|---|
|  | Sensor operating |
|  | No sensor/transmitter registered |
|  | No active sensor |
|  | Sensor is being connected |

### System screen statuses

| Status | Meaning |
|---|---|
| **No transmitter registered** | There is no transmitter paired with your DBLG2 application. |
| **Searching** | Your DBLG2 application is attempting to pair with your transmitter. |
| **Initializing** | Your sensor is in its 2-hour warmup phase. |
| **First calibration required** | You must enter an initial blood glucose value to calibrate the sensor (only for sensor in manual calibration). |
| **Second calibration required** | You must enter a second blood glucose value to calibrate the sensor (only for sensor in manual calibration). |
| **Pending calibration** | A calibration is required. |
| **Sending calibration** | The blood glucose value entered as a calibration is being sent to the transmitter. |
| **Starting sensor** | In the case of a sensor change, when your sensor is starting. |
| **Sensor operating** | Your sensor is operating normally and is sending readings. |
| **Stopping sensor** | You have just tapped Stop and the sensor is in the process of stopping. This may take several minutes. |
| **No active sensor** | Your sensor is no longer able to communicate with your DBLG2 application. You are no longer receiving G6 readings. |
| **Signal loss** | Connection to the sensor has been momentarily interrupted. The Home screen displays the symbol (**--**). |
| **No reading** | There are no G6 readings available. The Home screen displays the symbol **???** instead of a value. |

Tap More to view additional information on the current session (sensor code, transmitter's serial number, expiration date of each device).

## 2.3 – Insulin pump

### 2.3.1 – Setting up the Kaleido insulin pump

To set up your Kaleido insulin pump, make sure you have the following at hand.

- One fully charged Kaleido pump. Refer to Charging your pump on page 72.
- A pouch-packaged insulin cartridge.

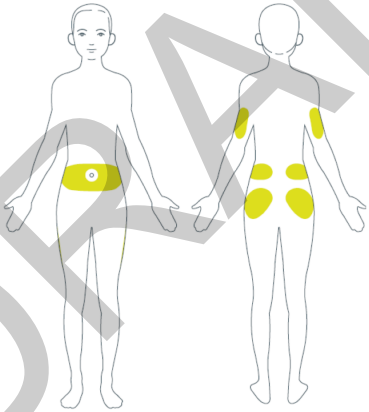
- A syringe.
- A needle.
- A body patch.
- A pump patch.
- An infusion set.
- The Kaleido inserter.
- An alcohol wipe.
- A vial of U100 rapid-acting insulin (at room temperature).

### 2.3.2 – Choosing your infusion site

⚠ Rotate your infusion sites whenever you change your infusion set. If you do not rotate your infusion sites, scar tissue may develop. Scar tissue can disturb the flow of insulin into your body and may limit your ability to absorb it properly in the future.

⚠ It is very important that you only ever place your infusion sets on the sites that are recommended by your healthcare professional. This ensures that you insert into the right tissue layer and your cannula does not go too deep or too shallow.

Strictly adhere to the infusion sites shown in green on the following diagram.



Avoid wearing your infusion set in the following areas or locations.

- Highly sensitive areas
- Under a waistband or tight clothing
- Areas exposed to rubbing or bumping
- Over a bone
- Bruised skin or areas with burns or cuts
- Blood vessels
- 5 cm around the belly button
- Scar tissue / surgical scars
- Areas with fatty tissue overgrowth
- Areas with body piercing
- Tattoos
- Moles
- Blood spots / birthmarks
- Any area that has tough/rough skin (as the cannula may not be inserted deep enough or may become kinked).

### 2.3.3 – Inserting the infusion set under your skin

You need to replace your infusion set at least once every 3 days.

Make sure your infusion set stays clean. If you see contamination or dirt on your infusion set, you need to change it to prevent an infection occurring. You may need to change it early, before its maximum of 3 days of use have come to an end.

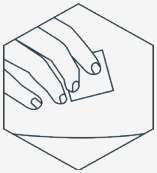
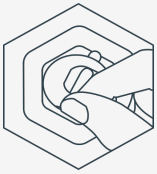
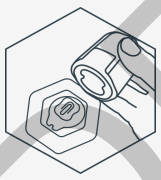
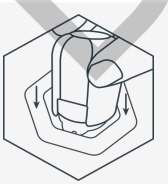
Do not reuse infusion sets. Doing so may contaminate your insulin and lead to infection and possible under or no delivery of insulin.

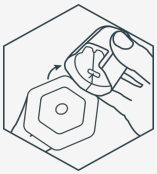
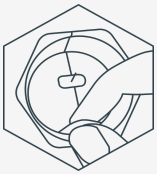
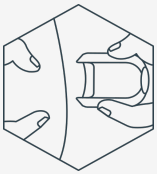
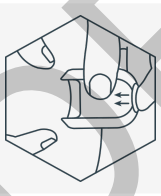
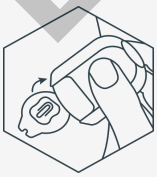
Do not let the infusion set come in contact with water within the first hour of applying. Making the infusion set wet within the first hour of application may cause decreased adhesion properties.

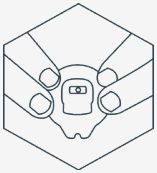
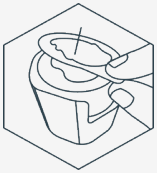
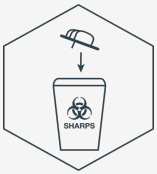
When you apply your infusion set, bear in mind the length of your insulin cartridge's tubing. If you are using the 5-cm tubing, make sure you position it close to where you want to wear your pump. The tubing should always be slack, never pulled tight.

The needle in the infusion set is sharp. Do not touch it before or after use and dispose of it properly; we recommend using a dedicated biohazard waste container.

| | | |
|---|---|---|
| 1 |  | Start by washing and drying your hands thoroughly. Grab everything you need to install your infusion set and lay it out on a clean, flat surface. |

| | | |
|---|---|---|
| 2 |  | Choose where you would like to position your infusion set – it is good to choose an area where your clothing will not rub against it. Make sure the skin there is clean, dry and free from body moisturizer.<br><br>Use an alcohol wipe to gently clean the area and then allow your skin to dry naturally.<br><br>⚠ Do not reuse alcohol wipes. Doing so may affect the effectiveness of the disinfection and lead to infection. |
| 3 |  | Check the expiration date and ensure the packaging and infusion set are not damaged before use.<br><br>Remove the paper lid on your infusion set's packaging. |
| 4 |  | Remove the protective circle of plastic that is sitting on top of your infusion set.<br><br>⚠ Do not touch the cannula before use. The cannula is sterile. Touching the cannula before using it may lead to infection. |
| 5 |  | With your infusion set still in its packaging, place it on a flat surface. Then, press the button on the top of your inserter to make sure it is ready to use, and line your inserter up with the top of your infusion set.<br><br>You can do this by matching up the shape of the infusion set with the imprint in the bottom of your inserter or making sure the gap in the base of the inserter sits above the tabs on the infusion set's plastic cap. |
| 6 |  | Holding your infusion set's packaging in place with one hand, use the other to firmly push your inserter onto the top of your infusion set. Push down until you hear the infusion set click into your inserter. |

| | | |
|---|---|---|
| 7 |  | Lift your inserter out of the infusion set packaging.<br><br>Check the needle is straight, but be careful not to touch it – it is important that it stays sterile.<br><br>If the needle does not look straight, take a new infusion set. Repeat from Step 3 onwards. |
| 8 |  | Peel the paper backing off the sticky part of the infusion set.<br><br>Try not to touch the sticky area underneath the paper as it could affect how well the infusion set sticks to your skin. |
| 9 |  | If possible, use one hand to hold your skin taut. Be careful not to touch the actual spot that you will insert the cannula into.<br><br>Then use your other hand to position your inserter on your skin.<br><br>Remember, you can use the gap in the base of your inserter as a guide for where your insulin cartridge will connect to your infusion set. This can help you get your infusion set in the right place for where you want to wear your pump.<br><br>Do not forget to think about the direction and angle the tubing is coming from. |
| 10 |  | When your inserter is in the right place, firmly press the button at the top of your inserter. Keep the inserter pressed firmly onto your skin to aid the insertion.<br><br>This will push the infusion set into your body. You may feel a small sting, but it will only last a moment. |
| 11 |  | You can now remove your inserter. Make sure you pull your inserter away from your body in a straight line, without twisting it, so that you do not damage the infusion set's cannula. Your infusion set will be securely stuck to your body and the plastic cap and needle will be inside your inserter.<br><br>Put your inserter to one side for now, but be careful of the needle. |

| | | |
|---|---|---|
| 12 |  | Gently rub the adhesive patch around the edge of your infusion set to make sure it is sticking to your skin properly.<br><br>If it is peeling at this stage, it is unlikely that it will last for 3 days of wear. So you should remove it now and try again with another one. But if it is feeling nice and secure, then your infusion set is ready to go. |
| 13 |  | Now you need to dispose of your needle. Carefully remove the plastic cap by holding onto the tabs to lift it out of the inserter. |
| 14 |  | Make sure you dispose of the needle appropriately. |
| 15 |  | Last but not least, keep your inserter safe, ready for next time.<br><br>Do not throw it away, it will be useful for future infusion set changes. |

You should establish a routine for rotation and visual examination of your infusion set insertion sites to ensure that the sites remain healthy and free of redness, irritation, swelling, pain or infection. If an infusion site becomes irritated or inflamed, the infusion set should be removed and another placed in a new location. Your healthcare professional can advise you on a rotation pattern for the infusion set that is right for you.

### 2.3.4 – Filling your insulin cartridge

⚠ Insulin cartridges can only be used for 3 days. After this time, you must change your cartridge.

⚠ Do not prefill your insulin cartridges. Only fill an insulin cartridge just before use.

⚠ Do not reuse insulin cartridges. Doing so may contaminate your insulin and lead to infection and possible under or no delivery of insulin.

If necessary, you may temporarily remove an insulin cartridge from your pump and then reinsert it immediately.

Do not fill an insulin cartridge with cold insulin. Only fill the insulin cartridge using room temperature insulin. Filling the insulin cartridge with cold insulin may cause air bubbles to form inside your insulin cartridge.

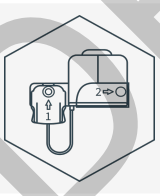
Always follow the insulin manufacturer's instructions regarding storage and use of insulin.

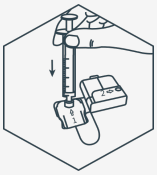
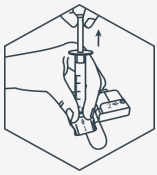
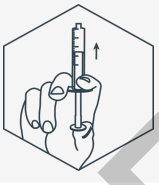
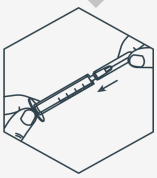
Always double check the expiration date of your insulin vial before you use it. If your insulin has passed its expiration date, discard and dispose of it according to the instructions provided by the insulin manufacturer.

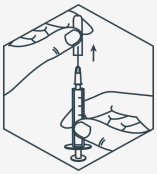
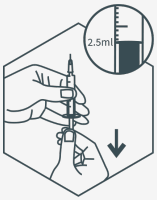
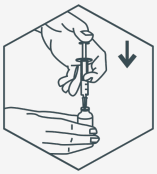
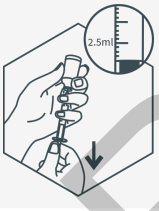
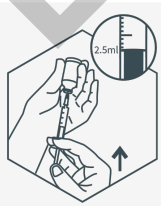
Do not reuse your syringes or needles – doing so may contaminate your insulin and lead to infection. Once you have used a needle and syringe once, always dispose of them responsibly, straight away after use.

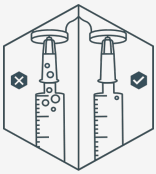
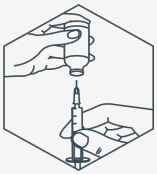
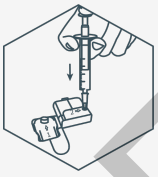
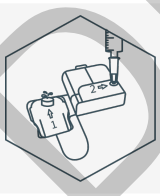
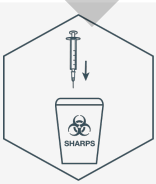
After each use, eliminate them according to the rules in force in your country. We recommend that you throw them in a sharps bins for potentially infectious sharps.

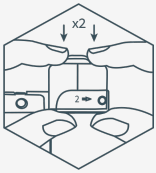
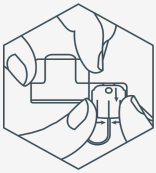
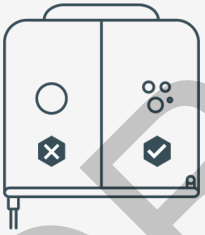
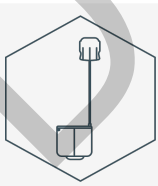
Sometimes the cartridge or filling cradle may have shifted during transit. Before you fill your cartridge, ensure the cartridge and filling cradle are aligned. If something does not look right or the cradle is crooked, realign it by pulling the cartridge towards the tiny plastic tap at the top of the filling cradle.

| | | |
|---|---|---|
| 1 |  | Check the expiration date and ensure that the packaging and insulin cartridge are not damaged before use. Open the packaging of your insulin cartridge by pulling on the bottom.<br>If you are using an insulin cartridge with a 30 cm tubing length, remove the paper tape from the tube. |
| 2 |  | Remove the insulin cartridge and place the insulin cartridge on a flat surface so that the numbers 1 and 2 are facing towards you. |
| 3 |  | Remove your syringe from its sterile packaging. |

| | | |
|---|---|---|
| 4 |  | Without moving the plunger, push the tip of the syringe firmly into Hole 1 so that it fits securely into the filling cradle. |
| 5 |  | Holding the syringe in place with one hand, use the other hand to carefully pull the plunger all the way up to the top of the syringe.<br><br>This removes any excess air from your insulin cartridge and reduces the risk of large air bubbles forming.<br><br>⚠ When pulling the plunger to the top of the syringe, you should feel some resistance. If you do not feel resistance and the plunger pulls up without any effort, the insulin cartridge may be damaged. Do not use this insulin cartridge, but use a new one instead. Contact your local support about the issue afterwards. |
| 6 |  | Now, remove your syringe from Hole 1 and push the plunger back towards the tip of the syringe. |
| 7 |  | Remove the needle from its packaging. Do not remove the needle cap just yet.<br><br>⚠ Always be careful when you are using the needle. The needle is sharp. Make sure not to touch the needle before and after use, and dispose of it appropriately. |
| 8 |  | Push the needle (with its cap still attached) onto the tip of the syringe. Make sure the two parts are securely connected.<br><br>Check the expiration date and then clean the rubber stopper of the insulin vial prior to use according to the instructions provided by the insulin manufacturer. Ensure that you do not touch the rubber stopper of the insulin vial after cleaning it. |

| | | |
|---|---|---|
| 9 |  | Remove the needle cap from the needle. |
| 10 |  | Draw the plunger down to fill the syringe with 2.5 mL of air. |
| 11 |  | Place the vial on a flat surface in front of you. Carefully push the needle through the rubber stopper of the insulin vial. Push the plunger all the way in to put all the air from the syringe into the vial. Hold the plunger down. |
| 12 |  | Turn the vial with the syringe upside down and slowly pull the plunger down until you have drawn just over 2.5 mL of insulin in your syringe. |
| 13 |  | Holding your syringe and insulin vial in one hand, firmly tap the syringe a few times on the bottom. This will help any air bubbles rise to the top of the syringe towards the needle. |
| 14 |  | Push the plunger upwards to push the air bubbles back into the insulin vial. Ensure that there is 2.5 mL of insulin in your syringe. |

| | | |
|---|---|---|
| 15 |  | Check the syringe for air bubbles. If there are air bubbles, repeat Steps 13 and 14 as often as needed to get rid of the air bubbles in the syringe. This will help make sure that there are no air bubbles in the syringe that can be pushed into your insulin cartridge during the filling process. Some small, champagne-sized air bubbles are acceptable. |
| 16 |  | Remove the syringe from the insulin vial. Be careful not to touch the needle. |
| 17 |  | Hold the syringe with the needle pointing down. With your other hand, give a few firm taps on the syringe. This step will help make sure that the air bubbles stay in the syringe near the plunger and do not get pushed into your insulin cartridge during filling. |
| 18 |  | Holding your insulin cartridge on a flat surface with the numbers 1 and 2 facing upwards, gently place the needle into Hole 2. Slowly push down the plunger, filling the insulin cartridge with insulin.<br>⚠ Only introduce the needle once into the insulin cartridge during the filling process. Introducing it more than once may result in leaks. |
| 19 |  | Stop pushing the plunger if the insulin cartridge is fully filled. Do not push the plunger completely down. You will know that the insulin cartridge is fully filled when you see a drop of insulin coming out of Hole 1. It is normal that some excess insulin may remain in the syringe after filling the insulin cartridge. |
| 20 |  | Remove the syringe from the insulin cartridge. Dispose of the needle and syringe into a sharps container / sharps bin. Be careful not to touch the needle. |

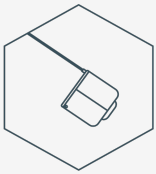
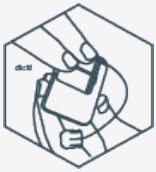
| | | |
|---|---|---|
| 21 |  | You need to prime and then remove your insulin cartridge from the filling cradle.<br><br>Hold the top of your insulin cartridge with your index fingers on both of the round edges and squeeze it further into the filling cradle. This will unhook the plastic tab on the insulin cartridge from the filling cradle so that the insulin cartridge pops back up. Then, squeeze the top of the round edges downwards fully into the filling cradle twice before releasing the insulin cartridge. It is important that you squeeze the insulin cartridge twice (after unhooking the insulin cartridge) in order to successfully prime your insulin cartridge. |
| 22 |  | Remove the insulin cartridge from the filling cradle. Now turn the filling cradle over and gently squeeze and lift the tabs on either side of your insulin cartridge connector to unclip it. The filling cradle can now be responsibly disposed of. |
| 23 |  | After filling your insulin cartridge following the steps described previously, there may be some small air bubbles in your insulin cartridge's reservoir. If they are champagne-sized air bubbles, that is generally acceptable and you can use this insulin cartridge. You can use the picture opposite to define if the air bubbles you see in your cartridge are "champagne sized" or if they might be too big. Do not use the insulin cartridge if the bubbles are bigger than what is shown in the picture opposite. |
| 24 |  | Your insulin cartridge is now fully filled, primed and ready to use.<br><br>⚠ Your insulin cartridge should always be completely full before you start using it. |



### 2.3.5 – Inserting the cartridge into the pump

⚠ Your pump will dispense a small amount of insulin when you insert an insulin cartridge. For your safety, never insert or remove an insulin cartridge while wearing your pump or if it is connected to your current infusion set.

⚠ Stop using your insulin cartridge immediately if you think it may have leaked. Replace it immediately with a new and fully filled insulin cartridge.

| | | |
|---|---|---|
| 1 |  | Make sure you have your fully-filled insulin cartridge ready to go. |
| 2 |  | Hold your pump with the pump's white parts facing up. Hold your cartridge above the space and line it up, tipping it to feed the tubing into the cartridge tubing groove. |
| 3 |  | With the tubing in the tubing groove, gently press the cartridge tab to feel it click into place. If everything is correct, the back of the insulin cartridge will sit flush with the back of the pump.<br><br>Listen out for two beeps – this means your insulin cartridge is correctly inserted into your pump and your pump is ready to connect to your DBLG2 application. |

Inserting an insulin cartridge into a pump turns the pump on. Removing the insulin cartridge turns the pump off.

Your application can only detect the pump if your phone is within range of the pump.

As well as confirming that your pump and application are ready to connect, the beeps let you know that your pump and the alarm system are working properly. If you do not hear the beeps, check that your insulin cartridge is inserted correctly.

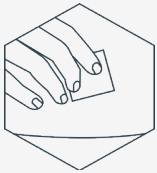
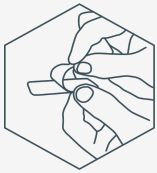
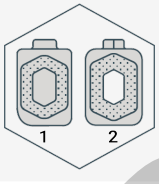
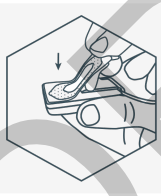
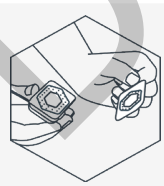
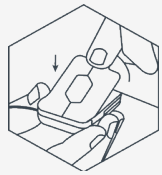
### 2.3.6 – Connecting your pump to the infusion set

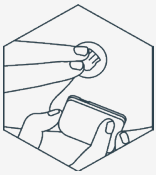
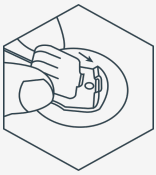
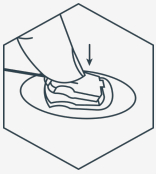
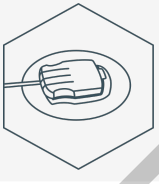
⚠ Make sure that the back of your pump is clean and dry before you attach a pump patch. This will ensure a better bond between the patch and pump, and prevent your pump from coming loose over time.

You will find your body patches and pump patches in your top-up kit – you will need one of each every time you change your pump or insulin cartridge. The two connect together and help keep your pump securely in place whenever you are wearing it.

Keep your fingers away from the sticky areas on your patches – touching them will make them less sticky.

Before sticking the patch to the pump, check that the identification number readable on the back of the pump is identical to the identification number on the label on your pump box. You will be asked to check this identification number while pairing the pump and the DBLG2 application.

| | | |
|---|---|---|
| 1 |  | Keeping in mind the location of your infusion set and the length of your insulin cartridge tubing, decide where you would like to wear your pump.<br><br>Choose an area where your clothing will not rub against it. Make sure your skin is clean, dry and free from body moisturizer. Use an alcohol wipe to gently clean the area and then allow your skin to dry naturally (about 5 minutes). |
| | ⚠ Do not reuse alcohol wipes. Doing so may affect the effectiveness of the disinfection and lead to infection. | |
| 2 |  | Take your pump patch (**1**) and peel off the paper backing that covers the back of the patch. This reveals the patch's adhesive. |
| |  | **1**: Pump patch<br><br>**2**: Body patch |
| 3 |  | Stick the pump patch to the bottom of your pump, matching the rounded corner. The patch now covers the insulin cartridge and the fuzzy hexagon shape is facing outwards. |
| 4 |  | Take your body patch (image **2** in Step 2) and, without removing its paper backing, stick it to your pump patch by pressing together the fuzzy hexagon shapes.<br><br>Try to make sure that your body patch lines up neatly with your pump. |
| |  | |

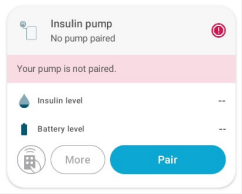
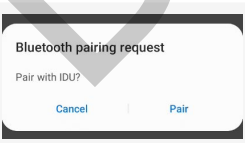
| | | |
|---|---|---|
| 5 |  <br>  <br>  | Being careful to support the weight of your pump, clip the connector at the end of your insulin cartridge tubing into your infusion set.<br><br>You will know it is secure when you hear the two distinct clicks as the right- and left-hand sides connect. |
| 6 |  | Check that the connector is correctly aligned with the infusion set. If connected properly it should feel like a smooth surface, with no bumps or gaps. |
| 7 |  | Holding onto your pump, peel off the paper backing from the top of your body patch. |
| 8 |  | Place your pump where you would like to wear it. Be careful not to stretch or kink your insulin cartridge's tubing. The sticky side of your body patch's adhesive should now be touching your skin. |

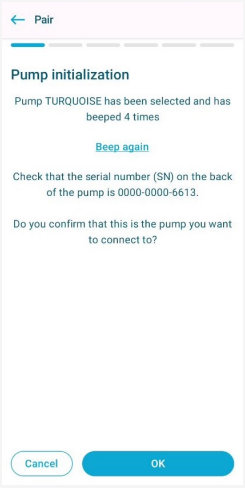
⚠ Once you have placed your pump where you want it, try not to play with it too much or bring it into contact with water during the first hour of wear. This will ensure that it remains stuck securely.

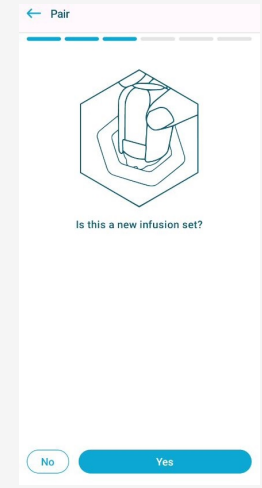
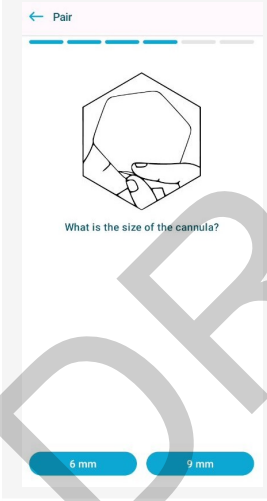
### 2.3.7 – Pairing the pump and DBLG2 for the first time

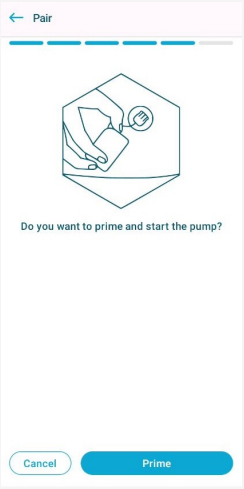
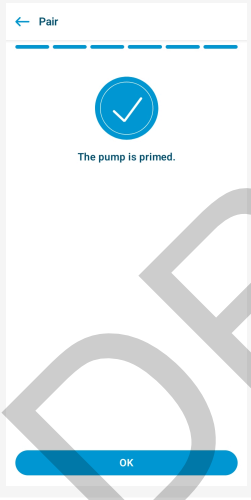
> For the insulin pump to be visible by the app, you must insert the full cartridge into the pump.

> The Kaleido pump can be identified from its color and its 12-digit serial number (SN). Once the DBLG2 application suggests pairing with a given pump, make sure that the color **AND** the serial number match.

| | | |
|---|---|---|
| 1 |  | Tap on Pair. |
| 2 |  | DBLG2 searches for available pumps and displays the list of pumps found.<br>Select a pump and tap Confirm.<br>DBLG2 initiates a connection with the selected pump. |
| 3 |  | Accept the Bluetooth® pairing request. The pump's name in your phone's Bluetooth® settings is "IDU" (insulin delivery unit). |

| | | |
|---|---|---|
| 4 |  | The selected pump beeps four times.<br>Check that the serial number displayed on the screen is the same as the one on the back of your pump. Then tap OK. |
| 5 |  | Ensure your cartridge is new and fully filled, then tap Yes. |

| | | |
|---|---|---|
| 6 |  | Ensure the infusion set is new and fixed to your body, then tap Yes. |
| 7 |  | Select your cannula size: 6 mm or 9 mm. |

| | | |
|---|---|---|
| 8 |  | Before starting the pump, the system must prime the cannula.<br>Tap Prime.<br>During the priming process, DBLG2 displays the message "In progress. Please wait". |
| 9 |  | The pump and DBLG2 are now paired.<br>Tap OK to start insulin delivery. |
| 10 |  | The System screen shows that the pump is now operating. |

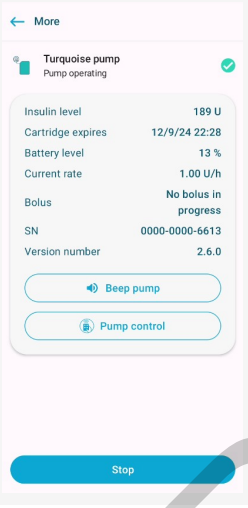


Monitor your glucose levels closely during the use of Kaleido. If you are unable to manage your glucose levels using Kaleido, or you feel that something is not right with using your pump, stop using Kaleido and switch to an alternative method of therapy as discussed with your healthcare professional.

### 2.3.8 – Checking the status of your insulin pump

⚠ At this stage, because loop mode has not been started, the DBLG2 application cannot send orders to the pump to adjust your insulin delivery automatically. Your pump is currently dispensing insulin according to your basal safety profile, which was set during the initialization phase. Refer to Starting loop mode on the following page.

You may be required to check the status of your pump based on the notifications (information messages/alerts/alarms) that you receive.




From the System screen, in the pump section, tap More. The screen displays the current status of the pump (refer to the tables hereafter) as well as:

- the number of insulin units remaining in the cartridge,
- the expiration date of the cartridge,
- the pump's battery level,
- your current insulin rate and bolus in progress if any,
- the pump's serial number (SN) and software version.

**Pump statuses on the Home screen**

| | |
|---|---|
|  | Pump operating |
|  | No pump paired or pump stopped |
|  | Searching for the pump |

### Pump statuses on the System screen

| Status | Meaning |
|---|---|
| **No pump paired** | No pump is paired with the DBLG2 application; the application cannot send orders to the pump. |
| **Connecting** | Transient state when pairing your pump or when the pump and the DBLG2 application are paired but have momentarily lost connection and are reconnecting. |
| **Priming** | Transient state just prior to the pump delivering state. |
| **Pump operating** | The pump is paired with the DBLG2 application. It is able to deliver insulin and may or may not be currently delivering. |
| **Pump stopped** | The pump is no longer delivering insulin but is still paired with the DBLG2 application. |
| **Shutting down** | Transient state when your pump is being disconnected from the DBLG2 application. |
| **Searching** | The pump is no longer connected to the DBLG2 application. It is delivering the last command sent by loop mode before connection was lost. The pump should reconnect automatically within a few minutes. |

## 2.4 – Loop mode

### 2.4.1 – Starting loop mode

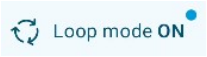
⚠ Do not start loop mode if you have injected a meal bolus or correction bolus without going through the system. Loop mode uses your active insulin for its decision-making process and a bolus has a high impact on your active insulin. Therefore, make sure you first declare this insulin dose in the application and *then* start loop mode.

Refer to Declaring a bolus injected with a pen (or other device) on page 88 for further information on external boluses.

Before switching loop mode ON, make sure that your sensor is working and that your insulin pump is delivering.

Go to the System screen and switch loop mode ON in the upper part of the screen.

### 2.4.2 – Loop mode statuses

| | |
|---|---|
|  | Loop mode is ON |
|  | Loop mode is OFF |
|   | Loop mode is waiting for the pump or for G6 readings |

# Part 3:
# Using your system in daily life

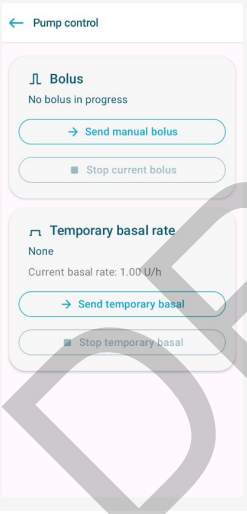
## 3.1 – Insulin pump

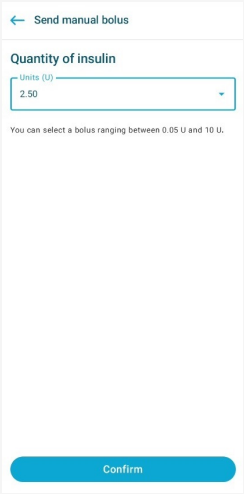
### 3.1.1 – Controlling the pump manually

The DBLG2 application has a manual control mode, which you can use to:

- send or stop a bolus when loop mode is ON or OFF.
- apply (and stop) a temporary basal rate when loop mode is OFF.

#### Sending a manual bolus

| | | |
|---|---|---|
| 1 |  | From the pump section on the System screen, tap More > Pump control or use the shortcut . Then tap Send manual bolus. |

| | | |
|---|---|---|
| 2 |  | Enter the number of units for the bolus and tap Confirm and then Confirm again on the popup screen.<br>> You can enter a bolus that ranges between 0.05 U and 10.00 U.<br>The Pump control screen displays the bolus in progress. |

The bolus in progress is also displayed on the Home screen (as text in the top part of the screen and as a bar graph in the bottom part of the screen) and in the Events menu.

### Stopping a bolus

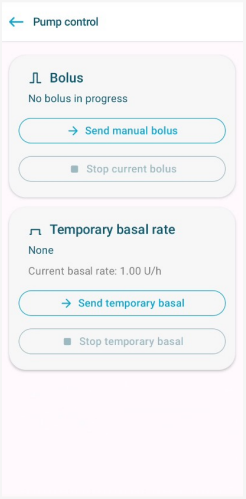
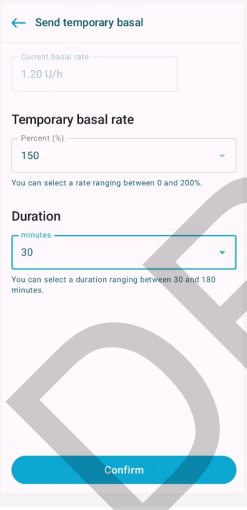
You can stop any type of bolus (manual bolus or correction/meal bolus sent by loop mode).

Tap on the bolus in progress message on the Home screen; this action takes you to the Pump control screen. Alternatively, go to the pump section on the System screen, tap More > Pump control or use the shortcut .

Tap Stop current bolus.

### Sending a temporary basal rate

**If loop mode is OFF** you can temporarily change your current basal rate.

| | | |
|---|---|---|
| 1 |  | From the pump section on the System screen, tap More > Pump control or use the shortcut . Then tap Send temporary basal. |
| 2 |  | Enter the temporary basal rate (% of the current basal rate).<br>Enter the duration in minutes for which the pump should apply this rate.<br>You can enter a temporary basal rate that ranges between 0 and 200% for a period that ranges from 30 minutes to 180 minutes.<br>Tap Confirm and then Confirm again on the popup screen.<br>The changed rate is immediately displayed on the Pump control screen. |

The temporary basal rate can be stopped at any time during administration, in which case the pump continues delivering insulin based on your basal safety profile (if loop mode has not been switched back on in the meantime). The rate and duration of both the temporary basal rate and the basal safety profile are visible on the pump details screen (System screen > pump section > More).

As soon as loop mode is switched back ON, the basal rate delivered is the one defined by the algorithm.

Refer to Basal safety profile on page 99 for further information on this setting.

### 3.1.2 – Stopping and restarting insulin delivery

To stop insulin delivery, simply tap Stop in the pump section on the System screen.

Tap Start to resume delivery.

If your insulin delivery is interrupted for any reason (for example, you stop the pump because of a technical problem such as a leaking cartridge or occlusion, or because the cannula has slipped out of the infusion site), you should check your blood glucose level and – if necessary – compensate for the missing insulin.

When the pump is stopped, the Pump control mode is disabled. Sending a bolus or changing the basal rate is no longer possible.

If the pump stops because of an alarm-triggering condition, an alarm sounds and a message is displayed on your phone and/or in your application. Refer to Display of alarms, alerts and information messages on page 109.

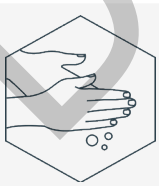
### 3.1.3 – Removing the pump to switch to another pump

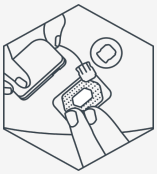
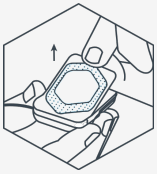
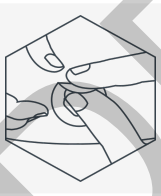
**This procedure applies if you are removing your pump and infusion set at the end of use so that you can switch to your other pump.**

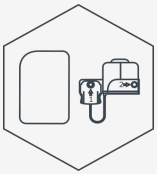
**Always stop your pump before removing an insulin cartridge.** Failure to do so triggers an alarm.

Always stop your pump prior to removing it. Otherwise, insulin may be spilled.

Remove the old insulin cartridge from the pump you were just using before connecting your DBLG2 application to your new pump. In this way, you ensure that your application is not connected to your used pump, and you can connect your new pump right away.

| | | |
|---|---|---|
| 1 | Stop the pump as described previously. | |
| 2 |  | Wash your hands. |
| 3 |  | Gently squeeze the tabs on the side of your insulin cartridge connector to unclip it from your infusion set – your pump and infusion set are now separated. |

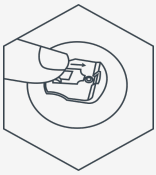
| | | |
|---|---|---|
| 4 |  | Take your pump off by lifting it away from your body patch. |
| 5 |  <br>  | Gently remove the body patch from your skin and the pump patch from the back of your pump.<br>⚠ Do not reuse body and pump patches or use them for longer than 3 days. Doing so may cause them to lose their adhesive properties, which could result in your pump becoming detached during use. |
| 6 |  | Take the insulin cartridge out of your pump. |
| 7 |  | To remove your infusion set, peel the adhesive away from your skin and then continue to peel away the whole infusion set – after a few days of use, it will have lost a little of its stickiness, but be careful not to pull it too hard. |
| 8 |  | Dispose of your infusion set, insulin cartridge, and body and pump patches appropriately and then wash your hands again. |

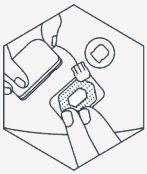
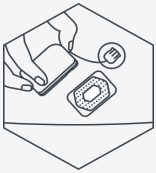
| | | |
|---|---|---|
| 9 |  | Make sure you recharge your pump straight away, so it is ready to use the next time you need it. |
| 10 |  | You are now ready to prepare your next insulin cartridge and pump.<br>Refer to Filling your insulin cartridge on page 50 and the procedures that follow. |

### 3.1.4 – Removing the pump temporarily

If you wish to temporarily remove the pump from your body for any reason, do not remove the cartridge. As long as the cartridge remains in place in your insulin pump, you can stop and restart the pump with the same insulin cartridge.

If you remove the cartridge, you will have to pair the pump again with the DBLG2 application.

| | | |
|---|---|---|
| 1 | Stop the pump. | |
| 2 |  | Wash your hands thoroughly. |
| 3 |  | Gently squeeze the tabs on the side of your insulin cartridge connector to unclip it from your infusion set – your pump and infusion set are now separated. |
| 4 |  | Close the protective cover on your infusion set.<br>⚠ If you leave the protective cover open, dirt may enter into the opening which may cause infections or occlusions. |

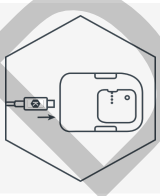
| | | |
|---|---|---|
| 5 |  | Lift the pump away from your body patch. If you are planning to put the pump back on soon, just leave your body patch in place. |
| 6 |  | When you are ready to put your pump back on, reconnect your insulin cartridge to your infusion set and reattach your pump. |

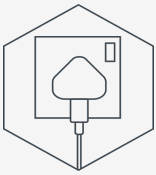
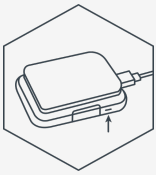
### 3.1.5 – Charging your pump

⚠ If the charging status light on the charging dock does not glow when your pump is connected and the power supply is switched on, the pump is not being charged. Try an alternative power supply first, and then contact your local support if you continue to experience difficulties.

When you charge your pump for the first time it can take up to 2 hours. If your pump has been on charge for more than 4 hours and the charging status light has not changed from orange to green, contact your local support for assistance.

You will wear each of your Kaleido pumps for up to 3 days at a time. Once you have removed a pump, it is a good idea to get into the habit of charging it as soon as you can, so that it is ready for the next time you need it. Make sure your pump is fully charged before use.

| | | |
|---|---|---|
| 1 |  | Insert the connection cable into the micro-USB port on your charging dock. Make sure the Kaleido icon is facing upwards. |
| 2 |  | Check that there is not an insulin cartridge already in the pump you want to charge. If there is one there, stop your pump and remove it.<br>Once the pump is free from an insulin cartridge, click your pump into place on the charging dock. |

| | | |
|---|---|---|
| 3 |  | Plug your power adapter into an easily accessible electrical outlet and then switch on the power. The charging status light on the charging dock will glow orange to let you know that charging has started. |
| 4 |  | Once your pump is fully charged, the charging status light on the dock will change from orange to green. Your pump is now ready to use.<br><br>To remove your pump from the charging dock, simultaneously press the release buttons on either side of the dock – there are two in total. You will feel your pump release and you will be able to remove it – no force needed.<br><br>If your pump has been charging for more than 4 hours and the charging status light has not changed from orange to green, contact your local support. |

### 3.1.6 – Unpairing the pump

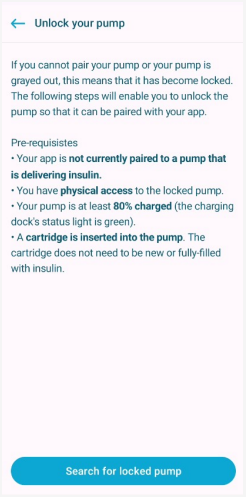
You only need to unpair your pump if you change phones.

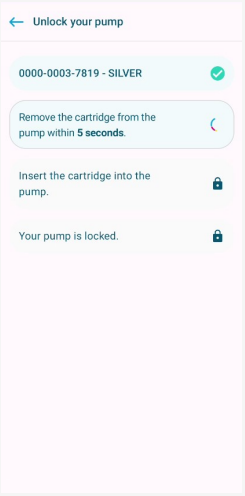
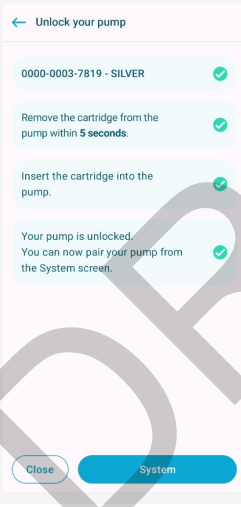
To unpair your pump, stop the pump, then tap More and Forget pump.

### 3.1.7 – Unlocking your pump

> Before unlocking a pump, stop insulin delivery and remove the cartridge temporarily to disconnect the pump currently in use. Check that the status on the System screen is **No pump paired**.

1. From the Profile screen, go to Help and contact and then Unlock your pump.

| | | |
|---|---|---|
| 2 |  | Tap on Search for locked pump. Make sure your pump is close by. It must be at least 80% charged and the cartridge must be inserted. |
| 3 |  | DBLG2 searches for any locked pumps. Select the pump you'd like to unlock and tap Unlock. |

| | | |
|---|---|---|
| 4 |  | Remove the cartridge from the pump (you only have 5 seconds to do this), and then insert the cartridge back into the pump when prompted.<br>If you did not remove the cartridge quickly enough, tap on Try again and continue from Step 2 above. |
| 5 |  | At the end of the process, the app displays the message "Your pump is unlocked." Tap on System to be redirected to the System screen so that you can pair your pump. |



## 3.2 – Glucose sensor

### 3.2.1 – Stopping the sensor

The sensor stops when the 10-day period comes to an end.

⚠ The alarm associated with the end of your sensor stops loop mode. Your pump continues delivering insulin based on your basal safety profile.

Reuse the transmitter – Do not throw it away

⚠ At the end of a session, do not throw away the transmitter. The transmitter is reusable for approximately 3 months.

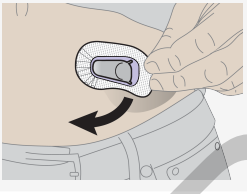
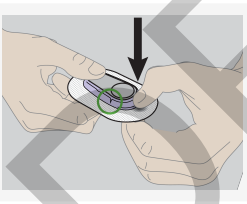
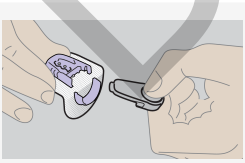
You may also have to stop the sensor prematurely at your own initiative or on infrequent occasions when DBLG2 detects issues related to the sensor and requests that you stop it.

In the G6 section on the System screen, tap Stop.

If your pump is administering when you stop the sensor, it continues delivering insulin based on your basal safety profile.

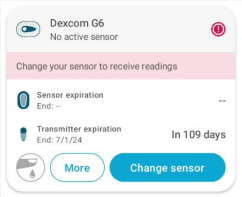
> When you change your sensor, you will not be able to view your readings or use loop mode during the 2-hour warmup period. However, you can turn loop mode ON right away from the System screen. Loop mode switches to the status **Waiting for glucose values** and will start automatically at the end of the warmup period.
>
> Note that loop mode cannot start if the sensor's status is **No active sensor** or **No transmitter registered**.

### 3.2.2 – Removing the sensor

| | | |
|---|---|---|
| 1 |  | Grab the edge of the adhesive patch and peel the patch up and away from your body. |
| 2 |  | Break the purple transmitter holder at the notches. |
| 3 |  | Slide the transmitter out of the holder and keep it for use with the next sensor.<br>Throw out the adhesive patch according to your local guidelines for disposal of components that have come into contact with blood. |

### 3.2.3 – Installing a new sensor and reusing the transmitter

Your transmitter is designed to last about 3 months. Reuse it for multiple sensor sessions. Follow the steps below to change the sensor and launch a new session.

| | | |
|---|---|---|
| 1 |  | On the System screen, tap Change sensor. |
| 2 | Enter the new sensor's code or scan its QR code as described in Step 2 of Pairing the sensor and the transmitter on page 37. | |
| 3 | Install the new sensor on your body and reattach the transmitter to the new sensor as described in Inserting the sensor and attaching the transmitter on page 39.<br>⚠ Make sure you wait 15 to 20 minutes before attaching the transmitter to the new sensor, otherwise the system may not recognize the sensor as a new one and will display an error message in this case.<br>The transmitter's serial number is recorded in the app. You do not need to enter this number when you change sensors. | |

You will receive an alert when the transmitter has less than one sensor session of battery life left (10111). **Wait until the next sensor session is due to start** and then **change the transmitter at the same time as the sensor**

### 3.2.4 – Changing both the transmitter and the sensor

Besides changing the transmitter because it has reached its end of use, you may be required to change it because of an alarm- or alert-triggering condition (such as a low battery). Refer to List of alarms, alerts and information messages on page 110 for the alarms and alerts that require a transmitter change.

**Whenever you change the transmitter, you must also change the sensor.**

To pair a new transmitter with your DBLG2 application, stop and remove your glucose sensor. Then tap More. Scroll down and tap Remove transmitter. DBLG2 is now ready to pair a new sensor and transmitter. Follow the steps described in Pairing the sensor and the transmitter on page 37.

### 3.2.5 – Troubleshooting your Dexcom G6

#### Accuracy issues

G6 readings do not match blood glucose meter values

Different body fluids give different numbers.

- A blood glucose meter measures glucose from the blood (i.e., glycemia).
- The G6 sensor measures glucose from interstitial fluid.

Calibrating may help align your G6 readings with your meter values.

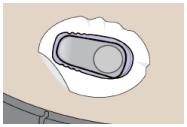
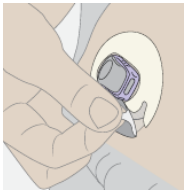
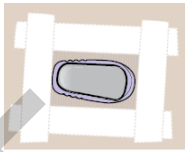
G6 readings do not match symptoms

If your G6 readings do not match your symptoms, wash your hands with soap and water and dry them, then take a fingerstick measurement with your meter. If the meter value matches your symptoms, use the meter value to treat.

Calibrating may help align your G6 readings with your meter values.

#### Issues with the adhesive patch

| Issue | Solution |
|---|---|
| **Applicator will not come off**<br>  | 1. Gently peel off the adhesive patch with applicator attached.<br>  <br>2. Check the insertion site to make sure the sensor is not left in the skin.<br>3. Do not reuse the applicator.<br>4. Contact your local support. |

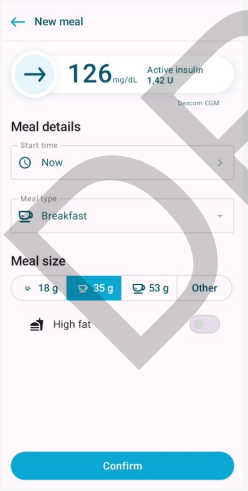
| Issue | Solution |
| --- | --- |
| **Adhesive patch peeling off body**<br>  | Once your sensor has been inserted, you can reduce peeling by putting medical tape (such as Blenderm) over the adhesive patch. Do not cover the transmitter. Avoid open wounds.<br>To order an Overpatch, contact your local support.<br>  <br>**Overpatch**<br>  <br>**Medical tape**<br>For your next sensor session, you can prevent peeling before inserting your sensor by:<br>• making sure your skin is clean and dry before inserting the sensor.<br>• using adhesive products (such as Mastisol®, SkinTac™) under the patch and avoiding the spot where the needle inserts.<br>• thoroughly rubbing the patch onto the skin. |
| **Skin irritation around sensor site** | Some people are sensitive to the sensor's adhesive. If you have significant skin irritation, such as itching, burning, and/or rashes at the site of the adhesive patch, contact your healthcare professional. |

## 3.3 – Meals

### 3.3.1 – Declaring a meal

For your DBLG2 system to be as effective as possible, we recommend that you declare meals.

⚠ If you declare your meal, we recommend that you do so 15 minutes in advance. This helps to adjust the meal bolus appropriately. However, a meal can also be declared on the spot, or later if you forgot to do so previously.

| | | |
|---|---|---|
| 1 |  | From the Home screen, tap on the blue + icon to add an event and select Meal. |
| 2 |  | Select a time for the meal from the drop-down list or tap Custom in the drop-down list to define a different time.<br><br>Then choose the type of meal (breakfast, lunch or dinner) and the size of the meal. The quantity of carbs displayed for a *medium* meal is the one that was set when the app was initialized. The quantities displayed for a small or large meal have been calculated automatically based on the medium meal size. Refer to Typical meals on page 99 for more information on meal sizes or if you wish to change the preset quantities.<br>Tap on Other if you wish to select another meal size from a drop-down list.<br><br>If you intend to have a high-fat meal, select the "High fat" option. Your system will adjust the insulin doses to compensate for delayed hyperglycemia, which is often observed with this type of meal.<br><br>> If you find it difficult to count your carbohydrates or determine what constitutes a high-fat meal in your case, contact your healthcare professional.<br><br>Tap Confirm and then Confirm again on the popup screen. The declared meal is displayed on the Home screen and is listed in the Events menu.<br><br>A bolus recommendation is then displayed, which you can confirm or not (see next section). |

### 3.3.2 – Meal bolus recommendations

After you have declared your meal, loop mode adjusts the post-meal glucose management strategy using your past, current and future (predicted) glycemic information. It calculates if a meal bolus is necessary, when it should be administered and the required amount of insulin. The bolus may be standard or biphasic (split into two parts).

> You must confirm the meal bolus suggested by loop mode before it can be delivered.

You may not receive a meal bolus recommendation right away in the following cases.

- You already have enough insulin in your body for the declared carbohydrates. Loop mode may recommend a meal bolus within the next 45 minutes.
- Loop mode has detected hypoglycemia conditions (current or short-term). Loop mode may recommend a meal bolus within the next 45 minutes.
- A sensor calibration is in progress. The bolus recommendation will be displayed once the calibration has finished.

If any one of the above conditions is detected, an alert is triggered (20105, 20106 or 20107). Refer to List of alarms, alerts and information messages on page 110.

If loop mode recommends a biphasic bolus, the method of administration depends on the type of meal.

- If you select the option High fat meal, the period between the two boluses is **approximately 60 minutes**.
- If you do not select the option High fat meal, the period between the two boluses is **approximately 30 minutes**.

> ⚠ Make sure you declare any planned physical activity BEFORE you confirm your meal bolus. If you have forgotten to report any upcoming physical activity, cancel the bolus, declare the physical activity and then wait for the new meal bolus calculation. The system will suggest a new meal bolus that takes into account the declared physical activity, which you can then confirm or not.


The bolus notification contains some essential information.

- The most recent G6 reading and the associated trend arrow.
- An estimate of the insulin still active in your body.
- The time at which you declared the meal and the quantity of carbohydrates that you declared.
- The type of recommended bolus: standard or two-part.
- The amount of insulin for the bolus.

> Use the drop-down menu to increase or decrease the size of the meal bolus if it does not seem appropriate.

Tap Confirm bolus and then Confirm again on the popup screen.

The bolus is displayed on the Home screen and is listed in the Events menu.

To reject the bolus recommendation, tap Cancel and select one of the three options displayed.

- Delete the meal
- Edit the meal
- Postpone the bolus (tap Not now)

If you postpone the bolus, another recommendation is sent within 5 minutes to remind you that a bolus is needed.

To stop a bolus, go to the Pump control screen and tap Stop current bolus (also see Stopping a bolus on page 67).

> ⚠ If a bolus has been interrupted and only partially delivered (due to an occlusion or because you have voluntarily stopped it, for example), and you wish to program another bolus or use a pen, make sure you take into account the dose that has already been administered.

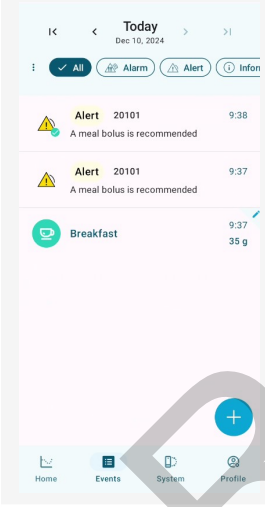
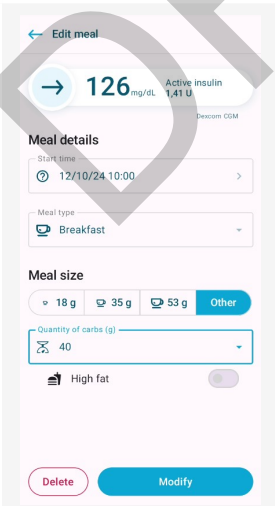
### 3.3.3 – Editing or deleting a meal declaration

#### If the bolus command has been sent to the pump

You cannot change or delete a meal declaration if the bolus command has been sent to the pump.

#### If the bolus command has not been sent to the pump

If you have ultimately chosen not to eat the quantity of carbohydrates that you declared or you have postponed your mealtime, we recommend that you change your meal declaration.

| | | |
|---|---|---|
| 1 |  | From the Events screen, select the meal to be edited. You can also access the meal from the Home screen. |
| 2 |  | Adjust the meal as needed and tap Modify. Then tap Confirm on the pop-up screen.<br>The meal is updated in the Events list to reflect the new information. |

The meal bolus is calculated using the new information you just provided to your DBLG2 application. Even after receiving the bolus notification, you can still change your declaration. Cancel the bolus notification and repeat the steps described above for modifying the meal.

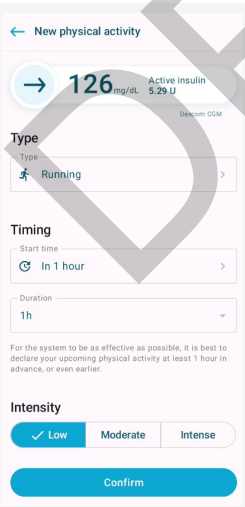
If you have decided not to eat the declared meal, tap Delete.

## 3.4 – Physical activities

### 3.4.1 – Declaring a physical activity

Loop mode automatically manages your glycemia before, during and after a physical activity by adjusting the basal rate and/or correction bolus and, if necessary, by recommending rescue carbs.

⚠ We recommend that you declare any upcoming physical activity **at least 1 hour before** the start of the activity. This allows loop mode to adjust insulin delivery to reduce the amount of active insulin in your body before the activity begins, so as to prevent hypoglycemia during or after exercise. The earlier you declare an activity, the better loop mode is able to regulate your glycemia.

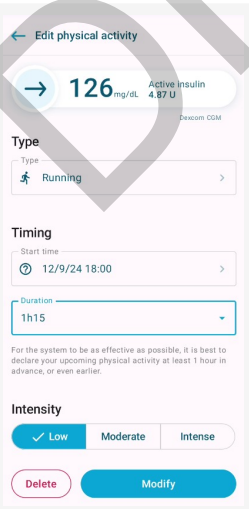
| | |
|---|---|
| 1 | From the Home screen, tap on the blue + icon to add an event and select Physical Activity. |
| 2 | Select the type of physical activity from the drop-down list. For activities such as housework or gardening, you can select Household chores. If your activity is not listed, you can select Sport, Sport – Anaerobic or Sport – Mixed. |
| 3 |  <br>By default, the system suggests starting the activity in one hour. Change the start time if necessary and tap Confirm. You can also declare a physical activity for a different day: in this case, tap Custom and choose a start date and time.<br>Select a duration from the drop-down list, and then select the intensity.<br>⚠ Sports intensity is specific to each person. You should understand how your body reacts to exercise in order to better adjust this declaration.<br>Tap Confirm and then Confirm again on the popup screen.<br>The declared physical activity is displayed on the Home screen and is listed in the Events menu. |

The type of physical activity affects your glycemia: aerobic activities tend to lower glycemia

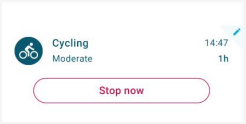
while anaerobic activities tend to raise it. If no specific activity is selected, the system considers that the activity is an aerobic one. However, selecting the type of activity enables loop mode to adapt more precisely to the variations in glucose levels linked to the type of activity, during and after the exercice.

### 3.4.2 – Editing or deleting a physical activity declaration

⚠ We recommend that you always notify the system of a change in the planned activity (a shorter or longer session, for example), even if the activity has already taken place. These measures ensure that your application continues to make appropriate adjustments.

| | | |
|---|---|---|
| 1 |  | From the Events screen, select the activity to be edited. You can also access the activity from the Home screen. |
| 2 |  | Adjust the activity as needed and tap Modify to save the new declaration or tap the back arrow to keep the initial declaration. Then tap Confirm on the pop-up screen.<br><br>The activity is updated in the Events list to reflect the new information.<br><br>If you do not intend to do your planned sport, delete the declaration. Your system will adjust to return to the standard configuration. |

### 3.4.3 – Stopping an ongoing physical activity

| | | |
|---|---|---|
| 1 | From the Home screen or the Events screen, tap on the ongoing physical activity. | |
| 2 |  | Tap Stop now.<br>The actual time spent doing the activity is adjusted in the list of events. |

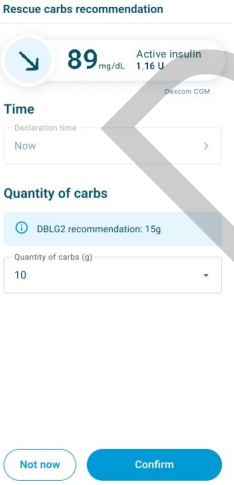
## 3.5 – Rescue carbs

### 3.5.1 – Rescue carb recommendations

Loop mode can recommend rescue carbs to prevent the occurrence of hypoglycemia. If your G6 reading is close to the hypoglycemia threshold that you defined, loop mode triggers an alert (20300) and a rescue carb recommendation is displayed. Confirm the recommendation or adjust the amount as needed. **Make sure you take the suggested or adjusted quantity.**

If the alert 20300 does not sound when your phone is in silent mode or Do Not Disturb mode, you can force it to always sound. Refer to Loop mode alerts on page 100.

⚠ Carefully read the quantity of carbohydrates to be taken, since each recommendation may be different. The system uses your rescue carb factor (which depends on your weight) as well as the difference between your predicted glycemia and your target glycemia to calculate this quantity.

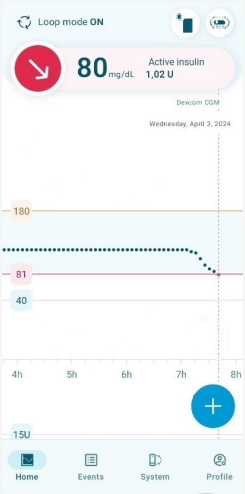
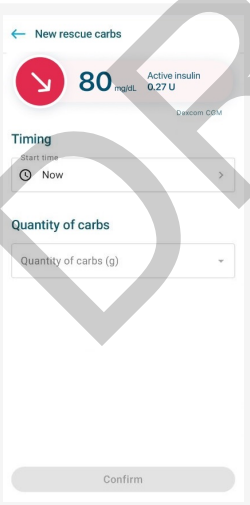



When you confirm the rescue carb recommendation, the rescue carb is displayed on the Home screen and listed in the Events menu. If you adjusted the quantity, both the recommended amount and the adjusted (taken) amount are displayed.

If you decide not to take the rescue carbs but the system still considers that you are at risk of hypoglycemia, you will receive another recommendation.

### 3.5.2 – Declaring a rescue carb intake

Loop mode calculates and recommends rescue carbs based on your predicted glycemia. Nevertheless, if you experience signs of hypoglycemia and feel the need to take some rescue carbs, make sure you declare these to the system. If necessary, check your capillary blood glucose.

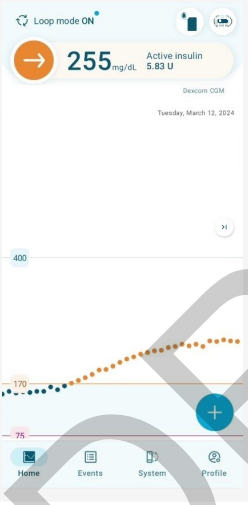
| | | |
|---|---|---|
| 1 |  | From the Home screen, tap on the blue + icon to add an event and select Rescue Carbs. |
| 2 |  | Enter the time for the rescue carb intake.<br>Next, select the quantity that you plan to eat or have eaten from the drop-down list.<br>> Make sure you enter the correct quantity before confirming, as the declaration cannot be changed once it has been confirmed. The system is more effective if the information you declare is accurate.<br>Tap Confirm. The declared rescue carbs are displayed on the Home screen and are listed in the Events menu. |

## 3.6 – Declaring a bolus injected with a pen (or other device)

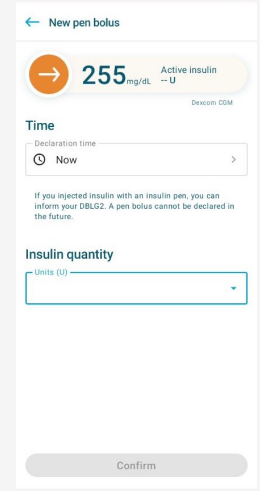
The system can only calculate active insulin (that is, the amount of insulin delivered by way of a bolus that is still circulating in your body) based on the insulin that it knows has been delivered. If you have recently used an alternative method of insulin delivery and you want to start loop mode, you must declare this quantity of insulin to the DBLG2 system.

If you are using an alternative method to inject a bolus but do not declare it to the system, you must stop loop mode for 3 hours. This is approximately the time required for your body to fully eliminate this insulin dose.

1



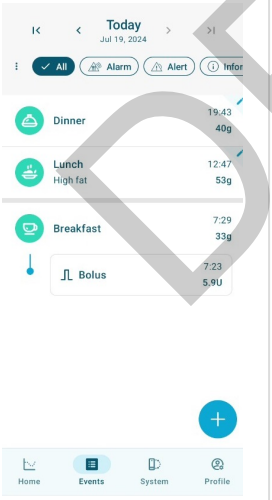

From the Home screen, tap on the blue + icon to add an event and select Pen bolus.

| | | |
|---|---|---|
| 2 |  | Choose or enter the time at which the bolus was injected as well as the quantity of insulin. Then tap Confirm, and Confirm again on the popup screen.<br>The declared bolus is displayed on the Home screen and is listed in the Events menu. |

## 3.7 – Viewing events

The Events screen displays all system events over the past 30 days and any events that have been declared in the future, such as a physical activity for the following day.

You can also refer to YourLoops for a complete history.




The events can be filtered by type.

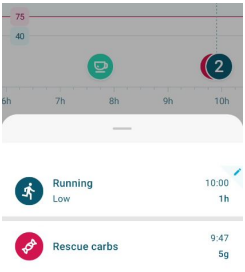
- Meals, physical activities or rescue carb intakes.
- Alarms, alerts or information messages. Refer to List of alarms, alerts and information messages on page 110.
- Meal boluses.
- Manual boluses delivered through the Pump control mode.
- Boluses delivered by another means (such as with a pen) and declared in the app.
- Calibrations.

To see the correction boluses sent by loop mode, tap on the ⋮ icon in the upper left part of the screen and select the relevant filter.

The pen icon ✎ next to an event means that the event can be edited.

Events are also displayed on the Home screen. Tap on an event pictogram to view event details; a contextual window opens from the bottom of the screen. A number displayed on a

group of events means that several events have occurred at around the same time. To view each event individually, pinch the screen to zoom in on the event.




## 3.8 – Your Diabeloop application

### 3.8.1 – Application data

Your data is regularly transferred to YourLoops. It is also stored in the phone's memory.

⚠ Never delete the application data. If you delete the application data you will have to reboot the application and re-initialize it. If the application was paired with a pump, the pump will become locked and unusable. Refer to Unlocking your pump on page 73 for the instructions to follow if this happens.

### 3.8.2 – Application updates

When an application update is available, a message is displayed in the app. Follow the instructions on the screen to download and install the latest updates.

### 3.8.3 – OS updates

After an OS update on your phone, you should:

- restart the app.
- grant any new necessary permissions that may be requested.
- check that the sensor and pump have reconnected automatically and are functioning correctly.
- activate Loop mode if it is switched off.

### 3.8.4 – Switching to another smartphone

If you want to use your DBLG2 application on a new phone, go to Profile > My account > Manage account and log out from your account. Follow the instructions on the screen to stop

and unpair your pump. Do not stop the sensor as you will not be able to reuse the same sensor with the new phone.

Then install the application on the new phone and initialize it using the same activation code, your YourLoops credentials and the settings visible on YourLoops, or with the help of your healthcare professional. Refer to Smartphone prerequisites and recommendations on page 25 and Initializing the DBLG2 application on page 25.

When you change phones, your history remains available on YourLoops but can not be transferred from one phone to the other.

**Make sure you perform the actions below before switching to the other phone.**

⚠ Pump: stop the pump, then tap More and Forget pump.

Sensor: logging out will stop the Bluetooth® communication. Do not stop the sensor as you will not be able to reuse the same sensor with the new phone.

### 3.8.5 – Account deactivation

If your activation code is deactivated by your healthcare professional or distributor (for example, if you wish to stop using DBLG2), the app stops automatically. You will be informed three days before the stop via email and a temporary information displayed in your application also mentions the exact ending date. When the date is reached, you will be prompted to unpair and unlock your pump(s).

## 3.9 – Traveling with your DBLG2 system

⚠ Before you travel, we recommend that you contact your healthcare professional for any instructions to be followed and that you find alternative insulin therapy methods if necessary. Also have your first-aid kit with you.

Note that the power adapter supplied with your pump may not be compatible with the country of visit; make sure you have a suitable power adapter with you. Otherwise, use your alternative insulin therapy.

### 3.9.1 – When flying

#### Checking in your luggage and going through airport security

⚠ Do not put any of your supplies in your checked-in luggage: the temperature in the hold can drop to freezing and there is always a risk of your luggage getting lost. Instead, keep everything with you in your hand luggage. Check with your airline beforehand for any specific guidelines.

⚠ Some components of the DBLG2 system cannot be used in the presence of electromagnetic waves (including X-rays) and have not been tested with full body scanners (known as AIT or millimeter wave scanners).

Do not pass through body scanners with parts of the system on your body. Instead, ask for a

full-body pat-down and visual inspection. Your healthcare professional may be able to provide you with a certificate attesting that you are required to carry medical equipment with you to manage your diabetes.

Alternatively, remove all system components from your body, pass through the body scanner and ask for a visual inspection of the system components.

#### During the flight

You can use your pump during a flight as long as the airplane's cabin is pressurized. It communicates with your DBLG2 application via Bluetooth®.

Airline restrictions can change over time, however, so we advise checking with your airline for any specific guidelines prior to traveling. If you are not allowed to use the pump, use your alternative insulin therapy.

Also note that airlines typically require you to switch your phone to Flight mode during takeoff and landing. Once Bluetooth® is reactivated, you can continue using your application as usual.

#### Time zones

If the option "Automatic date and time" is turned on in your smartphone settings, the default date and time is updated automatically when you travel across time zones.

⚠ Upon arrival, we advise you to check that the time on your smartphone is correct, particularly when you are traveling across multiple time zones.

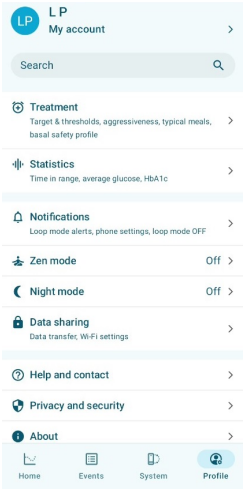
### 3.9.2 – Data transfer to YourLoops

When you travel to a country that is not covered by your mobile plan, your data stops being transmitted to YourLoops (unless you use a secure Wi-Fi hotspot). Data transmission resumes when you return to a covered country.

⚠ If your cellular or Wi-Fi connection is poor or nonexistent (for example, if you are at sea, in a mountainous area or in a region without any connection), the transmission of data to YourLoops may be impacted. Once you find a reliable access point, all your data will automatically be sent to YourLoops.

# Part 4:
# System settings and customization

## 4.1 – Profile menu




The Profile menu contains your application's key settings and modes, which can be customized to suit your needs.
This menu also provides some useful information on your system.

The following table summarizes the application's settings.

| Sub-menu | Purpose |
|---|---|
| My account | Update your personal information. |
| | Reconnect to YourLoops if you have been disconnected. Refer to YourLoops account on page 95. |
| | Change your YourLoops email and/or request a password reset. Refer to YourLoops email and password on page 95. |
| | View your activation code. Refer to Activation code on page 96. |
| | Delete or log out from your DBLG2 account. Refer to Manage account on page 96. |

| Sub-menu | Purpose |
|---|---|
| Treatment | Update your weight and height. Refer to Weight on page 96.<br><br>Adjust your daily insulin requirements. Refer to Total daily dose of insulin on page 97. |
| | Adjust your target glucose level and hyperglycemia and hypoglycemia thresholds. Refer to Target glucose level on page 97, Hyperglycemia threshold on page 97 and Hypoglycemia threshold on page 98. |
| | Adjust the aggressiveness settings to increase or reduce:<br><br>• the size of the correction bolus sent by loop mode when in hyperglycemia.<br>• the size of the meal bolus sent by loop mode after breakfast, lunch or dinner.<br>• the basal rate when in normoglycemia.<br><br>Refer to Aggressiveness factors on page 98. |
| | Change the typical amount of carbohydrates you normally eat for breakfast, lunch and dinner. Refer to Typical meals on page 99. |
| | Change your basal safety profile over a 24-hour period. Refer to Basal safety profile on page 99. |
| Statistics | View statistics on your time in range, average glucose levels, average daily dose of insulin, and estimated HbA1c over a period ranging from 1 to 90 days. Refer to Statistics on page 100. |
| Notifications | Configure the sound of some alerts that may be triggered when loop mode is ON. Refer to Loop mode alerts on page 100. |
| | Configure three glycemia-related alerts that may be triggered when loop mode is OFF. Refer to Loop mode OFF alerts on page 100. |
| | Manage sound and vibration settings on your phone. Refer to Phone settings for notifications on page 101. |
| | Check the sound of the alarms on your phone. |
| Zen mode | Turn Zen mode on or off, define by how much you want to increase your target glucose level when in Zen mode, and set a duration for the change. Refer to Zen mode settings on page 101. |
| Night mode | Customize a time range for night time and turn this mode on or off. During this period, the triggering conditions of three alarms and alerts are changed. Refer to Night mode on page 102. |

| Sub-menu | Purpose |
|---|---|
| Data sharing | Define Wi-Fi as your preferred method of transferring data to YourLoops.<br>Enable or disable the transfer of your medical data to YourLoops and define a time for automatic reactivation when disabled.<br>Refer to Data sharing on page 102. |
| Help and contact | Unlock your pump.<br>View the online Help menu.<br>View the user guide in PDF format.<br>Refer to Help on your system on page 102. |
| Privacy and security | View the general terms and conditions of use of the system.<br>View Diabeloop's privacy policy pertaining to your personal data.<br>Manage your consents.<br>Refer to Privacy and security on page 103. |
| About | View information on your product. Refer to About your DBLG2 application on page 103. |

## 4.2 – Account settings

### 4.2.1 – YourLoops account

Profile > My account > YourLoops account

A connection to YourLoops is required to use the DBLG2 application. If you have not used the app for an extended period, your YourLoops account might be disconnected. If this happens, a notification is displayed on the Home screen and the account status on the My account screen shows "Disconnected". You can tap the notification on the Home screen to access the YourLoops login screen or navigate to it directly from the My Account screen.

Enter the login (email) and password of your account. If you have forgotten your password, you have the option to create a new one.

### 4.2.2 – YourLoops email and password

Profile > My account > Change email or Change password

⚠ For cybersecurity reasons, the password should contain upper- and lowercase letters, numbers and special characters, and should be unique to YourLoops. Be alert to phishing attacks that mimic the YourLoops name and logo. Diabeloop will never request your password. Your password should never be communicated to a third party.

To change your email:

| | |
|---|---|
| 1 | Tap on Change email. |
| 2 | Enter the email address currently linked to your account, and then enter your new email address and tap Confirm new mail. A code will be sent to this new address. |
| 3 | Enter the code received and tap Change email. |

To change your password, tap on Change password. You will receive an email with instructions on how to reset your password.

### 4.2.3 – Activation code

Profile > My account > Activation code

An activation code is required to use the DBLG2 application. You can view this code here.

If you want to use your DBLG2 application on a new phone, make a note of this code as it will be needed to initialize the app on the new phone. This will automatically stop the app on the old phone.

### 4.2.4 – Manage account

Profile > My account > Manage account

This menu enables you to log out from your Diabeloop account (if you change phones for example) or delete your account.

If you log out from your account, your YourLoops session will be stopped and your data will be deleted from your phone. You will have to initialize the DBLG2 application again.

If you delete your account, you will stop using the system completely. All your data will be deleted from your phone and will no longer be accessible on YourLoops.

In both cases, you must stop loop mode and unpair the pump (refer to Unpairing the pump on page 73).

## 4.3 – Treatment settings

⚠ **To review the settings of your DBLG2 system, consult your healthcare professional who prescribed the device to you.**

**Inappropriate settings can lead to hyperglycemia or hypoglycemia.**

### 4.3.1 – Weight

Profile > Treatment > Medical information

Your weight is used to determine the amount of carbs needed as rescue carbs, and should be adjusted regularly as needed.

| Default value | Possible range |
|---|---|
| N/A | 35 to 150 kg |

### 4.3.2 – Total daily dose of insulin

Profile > Treatment > Medical information

The total daily dose of insulin is equivalent to your average daily insulin requirements for basal rates and meal and correction boluses. This information is entered with the help of your healthcare professional during the initialization phase of your DBLG2 application.

⚠ The total daily dose of insulin is not meant to be changed frequently. Careful consideration should be given to changing this setting as doing so may have an effect on how loop mode has adapted to your personal needs over time.

| Default value | Possible range |
|---|---|
| N/A | 8 to 90 U |

### 4.3.3 – Target glucose level

Profile > Treatment > Target and thresholds

The DBLG2 system uses your target glucose level to adjust insulin delivery by:

- reducing the basal rate if your glycemia is below your target.
- recommending rescue carbs and stopping the basal rate if your glycemia is too close to your hypoglycemia threshold.
- increasing the basal rate if your glycemia is higher than your target.
- delivering a correction bolus when you are at risk of hyperglycemia, depending on the active insulin.

| Default value | Possible range |
|---|---|
| 110 mg/dL | 100 to 130 mg/dL |

### 4.3.4 – Hyperglycemia threshold

Profile > Treatment > Target and thresholds

Hyperglycemia refers to abnormally high glycemia. When your hyperglycemia exceeds the limit that you have defined, the information on your smartphone is displayed in ORANGE.

> This threshold does not impact your treatment. Loop mode uses its own decision mechanisms to adjust your basal rate and/or order the administration of a correction bolus.

| Default value | Possible range |
|---|---|
| 180 mg/dL | 170 to 220 mg/dL |

### 4.3.5 – Hypoglycemia threshold

Profile > Treatment > Target and thresholds

Hypoglycemia refers to abnormally low glycemia. When your glycemia falls below the hypoglycemia limit that you have defined, the information on your smartphone is displayed in RED.

> If loop mode predicts that your glycemia will fall below your hypoglycemia limit, it can temporarily stop insulin delivery and may also recommend rescue carbs.

Changing this setting will affect your future rescue carb recommendations. The lower your hypoglycemia threshold, the less likely you are to receive a rescue carb recommendation, or you may receive them less frequently. Similarly, a higher hypoglycemia threshold will result in more frequent rescue carb recommendations.

| Default value | Possible range |
|---|---|
| 70 mg/dL | 60 to 85 mg/dL |

### 4.3.6 – Aggressiveness factors

Profile > Treatment > Aggressiveness

The aggressiveness factors determine how quickly the algorithm regulates the glucose level into the target range. They can be considered as the brakes or accelerators for your insulin doses.

> ⚠ This aggressiveness corresponds to your needs and should be discussed with your healthcare professional on a regular basis as your needs may change over time.

Aggressiveness factors have no direct effect on the amount of rescue carbs recommended by loop mode.

> If necessary, we recommend adjusting all aggressiveness settings in steps of 10%.

Aggressiveness during hyperglycemia: enables loop mode to adjust the quantity of insulin delivered by increasing or decreasing the size of the correction boluses.

Aggressiveness during normoglycemia: used by loop mode to adjust the quantity of insulin by increasing or decreasing the basal rate.

Meal aggressiveness: used by loop mode to adjust the quantity of insulin by increasing or decreasing the meal bolus for breakfast, lunch or dinner.

> Your meal bolus is assessed according to:
>
> - the quantity of carbohydrates consumed during the meal.
> - your glycemia at the start of the meal and the amount of active insulin in your body.
> - the type of meal: standard or high fat.

| Setting | Default value | Possible range |
|---|---|---|
| Aggressiveness in normoglycemia | 100% | 60% to 150% |
| Aggressiveness in hyperglycemia | 100% | 40% to 190% |
| Aggressiveness for breakfast/lunch/dinner | 100% | 50% to 200% |

### 4.3.7 – Typical meals

Profile > Treatment > Typical meals

The typical quantity of carbohydrates (that is, for a medium-sized meal) for breakfast, lunch and dinner is recorded during the initialization phase of the DBLG2 application. It is used to calculate the size of small and large meals so as to make your meal declarations easier. This menu allows you to change the quantities of carbs for a small, medium and large meal. Adjusting the Small and Large fields changes the declaration shortcut only.

> ⚠ Modifying the Medium field for a given meal affects the size of all future meal boluses recommended by loop mode. We strongly advise using the aggressiveness factors to make long-term adjustments to the size of the recommended meal boluses.

| Default value | Possible range |
|---|---|
| N/A | 1 to 300 g |

### 4.3.8 – Basal safety profile

Profile > Treatment > Basal safety profile

The basal safety profile corresponds to the basal rates over a 24-hour period—entered with the help of your healthcare professional during the initialization phase of the DBLG2 application—and is based on your prescription.

If loop mode switches to OFF, the DBLG2 system delivers this basal safety treatment. You can adjust your basal rates over time if you feel that they are no longer suitable.

> If a time slot is deleted, all the other slots are erased as well to prevent any risk of input error.

| Default value | Possible range |
|---|---|
| N/A | 0.05 to 5 U/h |

## 4.4 – Statistics

Profile > Statistics

The Statistics screen displays information related to your glycemia, such as your average glucose level, your average daily dose of insulin, your time in range, time in hyperglycemia and time in hypoglycemia, over a certain period of time. It also displays your estimated HbA1c (glycated hemoglobin). Also known as the glucose management indicator (GMI), this is a marker (obtained through a blood test) that shows your average glycated hemoglobin (as a percentage of your total hemoglobin) over the past 2 to 3 months.

## 4.5 – Notification settings

### 4.5.1 – Loop mode alerts

Profile > Notifications > Loop mode alerts

When loop mode is ON, you can configure alerts **20300 Rescue carbs are recommended** and **20102 Rapid rise in glycemia** to always sound, even if your phone is in silent mode or if Do Not Disturb mode is active.

### 4.5.2 – Loop mode OFF alerts

Profile > Notifications > Loop mode OFF alerts

If loop mode is OFF but your Dexcom G6 is connected, you may receive alarms and/or alerts relating to your glycemia. Three of the alerts are configurable.

- **Sensor signal loss alert** (10115): you can adjust the time before the alert is triggered.
- **Hyperglycemia alert** (10113): you can adjust the threshold above which the alert is triggered.
- **Hypoglycemia alert** (10117): you can adjust the threshold below which the alert is triggered.

| Alert | Default value | Possible range |
|---|---|---|
| Sensor signal loss alert (10115) | After 30 minutes | 20 to 240 minutes |
| Hyperglycemia alert (10113) | > 250 mg/dL | 120 to 400 mg/dL |
| Hypoglycemia alert (10117) | < 70 mg/dL | 60 to 85 mg/dL |

### 4.5.3 – Phone settings for notifications

Profile > Notifications > Phone notification settings

This menu is a shortcut to your phone's sound and vibration settings. Changes made here impact information messages and alerts only. **Alarms cannot be configured or muted.**

### 4.5.4 – Alarm sound check

Profile > Notifications > Check alarm sound

This menu enables you to check if the sound of the alarms is audible on your phone. Even if your phone is muted or in Do Not Disturb mode, alarms should remain audible.

## 4.6 – Zen mode settings

Profile > Zen mode

Zen mode is designed to reduce the risk of hypoglycemia in specific situations, such as a long car journey, an office meeting or any other situation where using your system could prove difficult. Activating Zen mode raises your target glycemia by 20 mg/dL. You can adjust this increase in target glycemia and the period during which Zen mode is active.

When Zen mode is active, this icon  is displayed on the Home screen and in the notification drawer of your phone, along with the time remaining in this mode. You can tap on the Zen mode notification on the Home screen to access the settings screen directly.

| Setting | Default value | Possible range |
|---|---|---|
| Increase of target glucose level | 20 mg/dL | 10 to 40 mg/dL* |
| Duration | 3 hours | 1 to 8 hours |

* Your target glycemia cannot be increased above 150 mg/dL (refer to Target glucose level on page 97 for the possible target glycemia ranges).

Note that when Zen mode is switched on, your hypoglycemia threshold is also raised by 20 mg/dL. This value, however, cannot be changed.

## 4.7 – Night mode

Profile > Night mode

This menu enables you to define a custom time range for night time. When Night mode is switched on, the following alarms/alerts become less intrusive.

| Alarm/alert | Behavior in Night mode |
|---|---|
| **21000** No glucose readings for over 30 minutes | Triggered when no readings have been received for over 120 minutes |
| **22000** Loop mode failed to start | Never triggered at night time |
| **20300** Rescue carbs are recommended | The hypoglycemia limit at which this alert is normally triggered is lowered by 10 mg/dL. |

When Night mode is active, this icon is displayed on the Home screen and in the notification drawer of your phone.

## 4.8 – Data sharing

### 4.8.1 – Using Wi-Fi for data transfer

Profile > Data sharing > Network preferences

You can choose to push your data to YourLoops using Wi-Fi only. For this, switch on Wi-Fi in this menu.

### 4.8.2 – Data transfer to YourLoops

Profile > Data sharing > YourLoops

The DBLG2 system allows you to stop transmitting your medical data to YourLoops for a specific period of time (3 hours, 12 hours, 1 day or 3 days). Set the data transfer to OFF and choose a duration. After the specified time, the transfer of data resumes automatically using your preferred method (Wi-Fi or mobile data). The data collected during the period of confidential mode is stored in your application only.

## 4.9 – Help on your system

### 4.9.1 – Unlock your pump

Profile > Help and contact > Unlock your pump

Your pump can become locked if it has not been properly unpaired from the application (refer to Unpairing the pump on page 73). Refer to Unlocking your pump on page 73 for instructions on how to unlock your pump.

### 4.9.2 – Help

Profile > Help and contact > Help

This section gives you access to an online help menu. A search box allows you to easily find information on how to use your system components.

### 4.9.3 – User guide

Profile > Help and contact > User guide

This section enables you to access and download a full PDF version of the user guide, available on Diabeloop's website.

## 4.10 – Privacy and security

### 4.10.1 – Terms of use

Profile > Privacy and security > Terms of use

This menu enables you to view the general terms and conditions of use of the DBLG2 system.

### 4.10.2 – Privacy policy

Profile > Privacy and security > Privacy policy

This menu enables you to view privacy and security information relating to the application's use.

### 4.10.3 – Manage consents

Profile > Privacy and security > Manage consents

During the initialization phase of the DBLG2 application, certain terms and conditions of use must be accepted in order to use the system. The consent whereby you authorize Diabeloop to use your personal data for research purposes is optional and can be revoked at any time.

## 4.11 – About your DBLG2 application

Profile > About

This section contains information relating to your DBLG2 application (software version, name and address of the manufacturer, product reference) as well as release notes and licenses.

# Part 5:
# Cleaning, storage and disposal

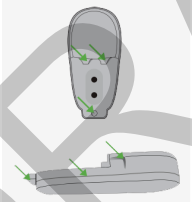
## 5.1 – Cleaning and storage

⚠ The system should be cleaned when you are not wearing the components on your body.

Do not clean the components if they are connected to a power supply (when the smartphone is charging, for example).

### 5.1.1 – Dexcom G6

#### Cleaning the transmitter

| | | |
|---|---|---|
| 1 | Preparation | Protect yourself by wearing clean gloves and goggles.<br>Prepare the soak by putting Clorox Healthcare® Bleach Germicidal Cleaner solution (Clorox) in a container deep enough to submerge the transmitter. |
| 2 | Cleaning |  <br>Rinse the transmitter in cold tap water scrubbing it with a soft bristle brush until all visible grime is gone.<br>Place the transmitter in the prepared soaking solution for 3 minutes. While immersed, scrub the uneven areas (see green arrows) with a soft bristle brush or a pre-saturated bleach wipe. |
| 3 | Rinsing and drying | Remove the transmitter from the soaking solution and rinse it under flowing cold tap water for 10 seconds.<br>Wipe the transmitter dry with a cloth. |
| 4 | Inspection | Check that there is no visible soil. If there is, clean it again. |

#### Storage

Storing your G6 correctly helps prevent system failures.

| | |
|---|---|
| Sensor | Keep it in its sterile packaging until you are ready to use it.<br><br>Store it in a place where the room temperature is between 2°C and 30°C. If the temperature is not within this range, this could result in inaccurate glucose level measurements. You can store your sensor at room temperature or in your refrigerator – as long as the temperature is between 2°C and 30°C. Do not store sensors in the freezer. |
| Transmitter | Keep it in a safe place when not in use.<br><br>Store it in a place where the room temperature is between 0°C and 45°C and the relative humidity is between 10% and 95%. |

### 5.1.2 – Kaleido insulin pump

#### Cleaning

⚠ Never wet or submerge your power adapter, connection cable, inserter or charging dock. Any water entering these components may lead to electric shock and damage the device.

⚠ Do not clean any of your Kaleido products while they are plugged into a power source. Doing so may result in an electric shock.

⚠ Do not let the USB port and the contact pins of the charging dock come into contact with liquids.

We recommend that you take 5 minutes to clean your Kaleido pump, your charging dock and your inserter at least once a week.

| | | |
|---|---|---|
| 1 |  | Dab a small amount of pH-neutral detergent onto a clean, dry cloth.<br><br>Most liquid soaps and baby shampoos are PH neutral. Never use harsh chemical cleaning detergents to clean your Kaleido products. |
| 2 |  | Using your cloth, gently wipe your pumps, charging dock and inserter. Remove any dirt or glue residues that might have built up from the body and pump patches. |
| 3 | Before you finish, make sure that you have wiped away any detergent residue and then, if necessary, pat your products dry with a non-fibrous cloth. | |

### Storage and transport

⚠ Do not store the unfilled insulin cartridge at a temperature above 37°C. The quality and performance of the insulin cartridges could be affected.

Keep your Kaleido products in a clean, dry place where you know you will be able to access them whenever you might need to. The pump must be stored in the same conditions as those of its use. The following table shows these limits.

| | Minimum | Maximum |
|---|---|---|
| Temperature | 5°C | 37°C |
| Relative humidity (non-condensing) | 15% | 93% |

⚠ If the packaging or the components have been exposed to environmental conditions outside of those specified above, safety of use and delivery accuracy of the Kaleido pump may be affected. If this occurred, only use non-damaged components. If this is not possible, change to an alternate method of insulin delivery, as recommended by your healthcare professional.

## 5.2 – Disposal and waste management

⚠ Your healthcare professional can advise you on how to dispose of medicines you no longer need, as well as items that have been contaminated with medicine and the waste generated through the use of the DBLG2 system.

Additionally, you should contact your local authority for guidance on the proper disposal of biohazardous material.

⚠ Dispose of your needles appropriately. Always safely cover needles and other sharp objects with the appropriate protective caps, and dispose of them in a sharps bin for biological hazards.

### 5.2.1 – Dexcom G6

⚠ Do not dispose of your G6 in a conventional waste container. Dispose of it using an appropriate recycling system.

The rules for disposal of electronic devices (transmitter) and components that have come into contact with blood or other bodily fluids (sensor) differ from place to place. Comply with applicable waste management requirements. We recommend that you use a biohazard waste container to dispose of injection equipment.

### 5.2.2 – Kaleido insulin pump

⚠ Always dispose of your waste from healthcare activities involving infection risks in a biohazard waste container, and make sure any protective cover is replaced before doing so.

When it is time to dispose of your pumps, charging dock or inserter, you can return them to your local support.

The items in your top-up kit should only be used once and then disposed of in an appropriate way straight after use. We recommend that you always use a sharps bin for needles.

# Part 6: Alarm system

## 6.1 – Introduction to the alarm system

The DBLG2 application is a relay for the alarm and alert conditions of your glucose sensor, pump and phone.

For your own safety, you cannot mute or change the volume of the alarms.

The Kaleido insulin pump emits an audible signal when an alarm is triggered.

If connection with the G6 is lost for more than 30 minutes (or 120 minutes in Night mode), your DBLG2 application triggers an alarm. Measure your glycemia using a glucose meter to make necessary treatment decisions.

If you do not understand an alarm or alert, contact your healthcare professional for advice and the best course of action to be followed, or your local support for any technical questions.

The system is designed to alert you to overly high or overly low glycemia levels, to low battery levels, etc. The tables further down in this section describe the various alarms and alerts.

### 6.1.1 – Classification of the alarm system

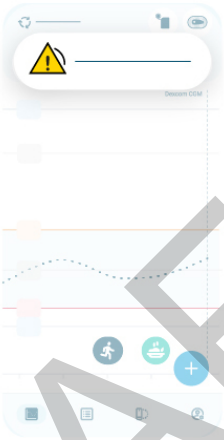
| Diabeloop symbol and designation | | Description |
|---|---|---|
|  | Alarm | High-priority alarm indicating a significant danger that requires immediate action. |
|  | Alert | Lower priority than an alarm. |
|  | Information message | Simply informs you about the status and use of your system. |

Follow the instructions in List of alarms, alerts and information messages on page 110 for the actions to take in response to an alarm or an alert.

### 6.1.2 – Display of alarms, alerts and information messages

When an alarm, alert or information message is triggered, it is displayed as follows.

- Alarm: by way of a popup if you are in the application itself.
- Alarm, alert or information message: by way of a scrollable notification at the top of the screen when you are in the app or in the notification center when your phone is locked.

| | | |
|---|---|---|
|  |  |  |
| Alarm on unlocked screen | Alert (or information message) on unlocked screen | Alarm, alert and information message on locked screen |

To acknowledge and resolve an alarm or alert, tap on the notification. If an action is required in the application, the system takes you to the dedicated screen to manage the event.

All alarms, alerts and information messages are saved and displayed in the Events list. Once an alarm or alert has been acknowledged and resolved, a green check mark is displayed next to it.

## 6.2 – List of alarms, alerts and information messages

Some alarms relating to the pump stop both your pump and the delivery of insulin. If an alarm causes your pump to stop, you should monitor your blood glucose levels closely until the issue is resolved and the pump resumes normal insulin delivery. Continue monitoring until your glycemia is stabilized.

When an alarm is triggered, the action that was being performed is interrupted. You must acknowledge the alarm before continuing with the previous action. For some alarms, if the triggering condition is not resolved, your app displays a reminder after a certain lapse of time.

An alarm has priority over an alert or information message.

If you are unsure about how to respond to an alarm or alert, stop using your system, switch to an alternative form of insulin therapy and contact your healthcare professional to discuss how to proceed.

Some alerts or information messages are only triggered when loop mode is OFF.

Check your glucose levels and act accordingly if you get an occlusion alarm (41004). You may not have received all of the insulin you expected.

If you receive an occlusion alarm (41004) and can detect the cause (for example, a kink in the insulin cartridge's tubing), note that rectifying the problem to restart the flow of insulin may result in the delivery of a small and unexpected amount of insulin. To avoid this, you should always disconnect your insulin cartridge and infusion set before releasing any occlusions.

| ALARM SYSTEM OF THE INSULIN PUMP | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| | Alarm / Alert / Information message | |
| **41001 Empty pump battery** | The pump has stopped because its battery is empty.<br>The pump can no longer deliver insulin. | 1. Detach your insulin pump from your skin.<br>2. Remove the insulin cartridge from the pump.<br>3. Prepare and pair your second pump and put the first one to charge. |

| ALARM SYSTEM OF THE INSULIN PUMP | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **41002 Empty insulin cartridge** | The pump has stopped because the insulin cartridge is empty.<br>The pump can no longer deliver insulin. | 1. Remove the empty cartridge from the pump.<br>2. Prepare a new insulin cartridge and insert it into the pump. |
| **41003 Insulin cartridge expired** | The pump has stopped because the insulin cartridge has expired.<br>The pump can no longer deliver insulin. | 1. Remove the expired cartridge from the pump.<br>2. Prepare a new insulin cartridge and insert it into the pump. |
| **41004 Occlusion** | The pump has stopped because there is an occlusion.<br>The pump can no longer deliver insulin. | 1. Check your glycemia and treat the glycemic situation as needed as a priority.<br>2. Check that your tubing has not become twisted or kinked. If it has, straighten it out. If not, try unclipping and reclipping your insulin cartridge connector. Then restart your pump.<br>3. If the issue is still not resolved, try replacing your infusion set. Then remove your cartridge to disconnect the pump and replace the cartridge. You will need to pair your pump with the app again.<br>4. If this does not resolve the issue, remove your cartridge again and clean the inside of the pump and the occlusion sensors. You will need to pair your pump with the app again.<br>5. If the above steps fail, remove your pump and infusion set completely. Switch to your other pump using a newly-filled insulin cartridge and new infusion set.<br>6. Lastly, if needed, switch to an alternative method of insulin therapy and contact your local support.<br>**Always check that your insulin delivery has resumed correctly.** |

| ALARM SYSTEM OF THE INSULIN PUMP | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **41005 Internal pump problem** | The pump has stopped because of a malfunction.<br><br>Reminder: every 5 minutes | 1. Restart the DBLG2 application.<br>2. Reconnect and/or restart your pump.<br>3. If the alarm continues, contact your local support to have the equipment replaced.<br>4. In the meantime, use your second pump or switch to your alternative insulin therapy.<br>5. Check your glycemia and adjust the insulin if necessary. |
| **41007 Cartridge removed while pump was running** | The insulin cartridge was removed from the pump while the pump was running.<br>The pump has stopped and can no longer deliver insulin. | 1. Insert the cartridge correctly into the pump until you hear two beeps.<br>2. Pair your pump with the DBLG2 application again. |
| **41008 Pump reset** | The pump has reset.<br>Insulin delivery has stopped. | 1. Pair the pump with the DBLG2 application again and restart insulin delivery.<br>2. If this is not possible, use the second pump and pair it, or use your alternative insulin therapy.<br>3. Contact your local support to return and replace the equipment. |
| **40101 Low pump battery** | The battery level of the pump is low.<br>There is less than 10% charge remaining. | Change your pump as soon as possible and put the first one to charge. |
| **40102 Low level of insulin in the cartridge** | There are less than 25 units of insulin remaining in the cartridge. | Schedule a cartridge change.<br>Note: this might be the right time to change your pump. |

| ALARM SYSTEM OF THE INSULIN PUMP | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **40104 Lost connection with the pump** | The pump and the application have been disconnected for more than 30 minutes. The pump is delivering your basal safety profile. | 1. Bring your phone and your pump closer together.<br>2. Cancel the search for the pump (tap on System > CANCEL in the pump section), then deactivate the Bluetooth. This will trigger alarm 63000, acknowledge the alarm and reactivate the Bluetooth.<br>3. If this fails, restart your phone.<br>4. If this does not resolve the issue, switch to the second pump, pair it and contact your local support regarding the first pump. |
| **40105 Failed to send meal bolus to the pump** | The last confirmed meal bolus was not sent.<br>Reminder: every 5 minutes | 1. Wait for the next bolus recommendation (about 5 minutes).<br>2. Confirm the bolus recommendation to administer the corresponding dose of insulin.<br>3. If the bolus delivery fails again, use your alternative insulin therapy to administer the meal bolus and declare it in the DBLG2 application.<br>Note: contact your local support if you receive the alert repeatedly. |
| **40106 Insulin cartridge will expire soon** | The insulin cartridge will expire in less than 6 hours. | Schedule a cartridge change.<br>Note: this might be the right time to change your pump. |
| **40108 Unsupported version of pump** | This pump version is not compatible with the DBLG2 system. | Contact your local support. |
| **40011 Low pump battery (less than 15%)** | The battery level of the pump is low. There is less than 15% battery remaining.<br>**IMPORTANT:** this information message is set to trigger when a system check is performed: at the time of a breakfast and dinner bolus when loop mode is ON, or at 9 am and 6 pm if loop mode is OFF. | |

| ALARM SYSTEM OF THE INSULIN PUMP | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **40012 Low level of insulin in the cartridge** | There is not enough insulin in the cartridge to cover your estimated needs of the next 12 hours. Change the cartridge soon.<br>**IMPORTANT:** this information message is set to trigger when a system check is performed: at the time of a breakfast and dinner bolus when loop mode is ON, or at 9 am and 6 pm if loop mode is OFF. | |
| **40013 Insulin cartridge will expire soon** | The insulin cartridge will expire in less than 8 hours. Change it soon.<br>**IMPORTANT:** this information message is set to trigger when a system check is performed: at the time of a breakfast and dinner bolus when loop mode is ON, or at 9 am and 6 pm if loop mode is OFF. | |

| ALARM SYSTEM OF THE SENSOR | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **11000 Sensor expired** | The sensor has expired.<br>**IMPORTANT:** if loop mode was ON, it has been turned OFF. | 1. Remove the sensor and the transmitter.<br>2. Dispose of the sensor according to the rules applicable in your country.<br>3. Use a new sensor and start a new session.<br>**IMPORTANT:** loop mode remains OFF during the warmup period of a new sensor. |
| **12000 Urgent low** | Your glycemia is below 55 mg/dL.<br>Reminder: every 30 minutes if the condition is still present. | 1. Do not ignore how you feel. If your glucose alerts and G6 readings do not match what you are feeling, use your blood glucose meter to make diabetes treatment decisions or, if needed, seek immediate medical attention.<br>2. Take some rescue carbs and declare them in the DBLG2 application.<br>3. Check your insulin rate.<br>4. Contact your healthcare professional if necessary. |

| ALARM SYSTEM OF THE SENSOR | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **13000 Permanent failure of the sensor** | There is a sensor error and no glucose readings are being received.<br>Loop mode has been turned OFF.<br>Reminder: every 5 minutes | 1. Remove the sensor and the transmitter.<br>2. Change the sensor and start a new session.<br>3. Restart loop mode. |
| **14000 Transmitter failure** | There is a transmitter error and no glucose readings are being received.<br>Loop mode has been turned OFF. | 1. Change the sensor and the transmitter and pair them both again.<br>2. Restart loop mode. |
| **15000 Hyperglycemia for a period** | Your glucose readings have been above 320 mg/dL for 90 minutes or more.<br>Reminder: every 90 minutes if the conditions are still present. | 1. Do not ignore how you feel. If your glucose alerts and G6 readings do not match what you are feeling, use your blood glucose meter to make diabetes treatment decisions or, if needed, seek immediate medical attention.<br>2. Check your ketones.<br>3. Treat the glycemic situation as needed as a priority.<br>4. Check the state of your system (pump, infusion set and loop mode). Visually inspect your tubing for obstructed or bent areas.<br>5. Change your infusion set and your cartridge if necessary.<br>6. Use your alternative insulin therapy if necessary.<br>7. If the alarm continues, contact your local support. |

| ALARM SYSTEM OF THE SENSOR | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **10100 Incorrect transmitter ID or transmitter expired** | The entered ID is incorrect or the transmitter has expired.<br>It is not possible to pair the DBLG2 application and the transmitter. | • Check the expiration date of the transmitter.<br>• Check that the serial number of the transmitter entered into the DBLG2 application corresponds to the one currently in use.<br>• Try pairing again.<br>• If all else fails, change the transmitter. |
| **10102 Failed to send the calibration** | The calibration could not be sent. | Try again. If the problem is recurring, contact your local support. |
| **10104 The sensor will expire soon** | The sensor will expire in the next 12 hours.<br>**IMPORTANT:** this alert is set to trigger when a system check is performed: at the time of a breakfast and dinner bolus when loop mode is ON, or at 9 am and 6 pm if loop mode is OFF. | Schedule a sensor replacement. |
| **10106 One sensor session left before transmitter expires** | You can use your transmitter for one more sensor session.<br>**IMPORTANT:** this alert is set to trigger when a system check is performed: at the time of a breakfast and dinner bolus when loop mode is ON, or at 9 am and 6 pm if loop mode is OFF. | Schedule a transmitter change. |

| ALARM SYSTEM OF THE SENSOR | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **10107 Sensor failed to start because transmitter has expired** | You cannot start a new sensor session with this transmitter because the transmitter has expired. | 1. Dispose of the expired transmitter according to the standards in force relating to the management of biohazardous electronic waste.<br>2. Use a new transmitter and pair both devices with the DBLG2 application. |
| **10109 Sensor error. Calibration required in 15 minutes.** | The sensor is experiencing an error and cannot provide readings.<br>The sensor needs to be calibrated in 15 minutes. | 1. Use your blood glucose meter in 15 minutes to get a meter value.<br>2. Enter this value in the DBLG2 application. |
| **10110 Sensor stopped because the sensor has already been used** | This sensor has already been used. It cannot be reused. | Change your sensor. |
| **10111 Low transmitter battery** | The transmitter has enough battery to finish the current sensor session but will not last for another complete session. | Change your transmitter as soon as possible. |
| **10112 Urgent low soon** | The transmitter predicts that your glucose will be at or below 55 mg/dL in 20 minutes.<br>**IMPORTANT:** this alert is triggered in loop mode OFF only.<br>Reminder: every 30 minutes | 1. Do not ignore how you feel. If your glucose alerts and G6 readings do not match what you are feeling, use your blood glucose meter to make diabetes treatment decisions or, if needed, seek immediate medical attention.<br>2. Take some rescue carbs and declare them in the DBLG2 application.<br>3. Check your insulin rate.<br>4. Contact your healthcare professional if necessary. |

| ALARM SYSTEM OF THE SENSOR | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **10113 Your glucose is high** | Glucose readings are above your configured hyperglycemia threshold.<br>The default value for this setting is 250 mg/dL.<br>**IMPORTANT:** this alert is triggered in loop mode OFF only.<br>Reminder: every 30 minutes | 1. Do not ignore how you feel. If your glucose alerts and G6 readings do not match what you are feeling, use your blood glucose meter to make diabetes treatment decisions or, if needed, seek immediate medical attention.<br>2. Check your ketones.<br>3. Treat the glycemic situation as needed as a priority.<br>4. Check the state of your system (pump, infusion set and loop mode). Visually inspect your tubing for obstructed or bent areas.<br>5. Change your infusion set and your cartridge if necessary.<br>6. Use your alternative insulin therapy if necessary.<br>7. If the problem continues, contact your healthcare professional. |
| **10114 No glucose readings for over 20 minutes** | The sensor is momentarily unable to provide readings. The symbol **???** is displayed instead of readings.<br>**IMPORTANT:** this alert is triggered in loop mode OFF only. | Do not calibrate.<br>1. Do not ignore how you feel. Use your blood glucose meter to make diabetes treatment decisions or, if needed, seek immediate medical attention.<br>2. Check the transmitter. Make sure it is flat and snug in its holder.<br>3. Wait up to 3 hours. If after 3 hours the problem continues, contact your local support.<br>You will not receive any alarms, alerts or G6 readings until the problem is resolved. |

| ALARM SYSTEM OF THE SENSOR | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **10115 Lost communication with the transmitter** | Communication with the transmitter failed. The DBLG2 application displays the symbol (--) instead of readings. The period of time after which this alert should ring is configurable.<br>**IMPORTANT:** this alert is triggered in loop mode OFF only. | Do not calibrate.<br>1. Check that your phone and the transmitter are within approximately 2 meters of each other and wait up to 30 minutes.<br>2. If this fails, deactivate the Bluetooth. This will trigger alarm 63000, acknowledge the alarm and reactivate the Bluetooth.<br>3. If this fails, restart your phone.<br>4. If the problem continues, contact your local support.<br>You will not receive any alarms, alerts or G6 readings until the problem is resolved. |
| **10116 Unsupported transmitter version** | This transmitter version is not compatible with the system. | Contact your local support. |
| **10117 Your glucose is low** | Glucose readings are below your configured hypoglycemia threshold.<br>The default value for this setting is 70 mg/dL.<br>**IMPORTANT:** this alert is triggered in loop mode OFF only.<br>Reminder: every 30 minutes | 1. Do not ignore how you feel. If your glucose alerts and G6 readings do not match what you are feeling, use your blood glucose meter to make diabetes treatment decisions or, if needed, seek immediate medical attention.<br>2. Take some rescue carbs and declare them in the DBLG2 application.<br>3. Check your insulin rate.<br>4. Contact your healthcare professional if necessary. |
| **10001 Calibration required** | Your sensor needs to be calibrated. | |

| ALARM SYSTEM OF THE SENSOR | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **10002 First calibration required** | A first calibration is required to finish setting up the sensor. | |
| **10003 Second calibration required** | A second calibration is required to finish setting up the sensor. | |
| **10004 24 hours left before sensor expires** | The sensor will expire in the next 24 hours.<br>**IMPORTANT:** this information message is set to trigger when a system check is performed: at the time of a breakfast and dinner bolus when loop mode is ON, or at 9 am and 6 pm if loop mode is OFF. | |
| **10006 Two sensor sessions left before transmitter expires** | You can use your transmitter for two more sensor sessions.<br>**IMPORTANT:** this information message is set to trigger when a system check is performed: at the time of a breakfast and dinner bolus when loop mode is ON, or at 9 am and 6 pm if loop mode is OFF. | |

| ALARM SYSTEM OF LOOP MODE | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **21000 No glucose readings** | The system has not received any glucose readings for over 30 minutes (or 120 minutes if Night mode is active).<br>**IMPORTANT**: this alarm stops loop mode. The system is delivering your basal safety profile. | 1. Check your glycemia using a blood glucose meter.<br>2. Bring your phone and G6 closer together.<br>3. Check the status of the sensor and loop mode.<br>4. Check for sensor-related alarms or alerts in the Events menu. Resolve the issue if needed. |

| ALARM SYSTEM OF LOOP MODE | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **22000 Loop mode failed to start** | As loop mode is switched off, the system is delivering your basal safety profile. | 1. Check the status of the sensor and the pump.<br>2. Restart loop mode from the System screen. You may have to wait up to 3 hours to be able to start loop mode.<br>3. If loop mode cannot be switched on after 3 hours, contact your local support. |
| **20100 No glucose readings for over 15 minutes. Risk of hypoglycemia.** | The system has not received any glucose readings for over 15 minutes. The last known reading was close to your hypoglycemia threshold. | 1. Do not ignore how you feel. If your glucose alerts and G6 readings do not match what you are feeling, use your blood glucose meter to make diabetes treatment decisions or, if needed, seek immediate medical attention.<br>2. Bring your phone and the G6 closer together.<br>3. Check the status of the sensor.<br>4. Contact your local support if necessary. |
| **20101 A meal bolus is recommended** | A meal bolus is recommended by the system.<br><br>Reminder: every 5 minutes if the bolus recommendation has been canceled. | Change the quantity of insulin as needed and confirm the meal bolus recommendation, or cancel it. |

| ALARM SYSTEM OF LOOP MODE | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **20102 Rapid rise in glycemia** | A sudden rise in glycemia has been detected.<br><br>Reminder: every 30 minutes if the conditions are still present. | 1. Do not ignore how you feel. If your glucose alerts and G6 readings do not match what you are feeling, use your blood glucose meter to make diabetes treatment decisions or, if needed, seek immediate medical attention.<br>2. Treat the glycemic situation as needed as a priority.<br>3. Declare your meal if you have forgotten to do so.<br>4. Check the state of your system (pump, infusion set and loop mode). Visually inspect your tubing for obstructed or bent areas.<br>5. Check the cartridge for any bubbles.<br>6. Change your infusion set and your cartridge if necessary.<br>7. Use your alternative insulin therapy if necessary. |
| **20104 Loop mode has been OFF for 2 hours** | Loop mode has been stopped for the last 2 hours.<br>**IMPORTANT**: this alert is not triggered if you have declared a physical activity and this activity is ongoing (since you may have put your pump and phone aside for your sports session). | 1. Check that the sensor and the pump are running.<br>2. Restart loop mode from the System screen. |
| **20105 Sensor calibration ongoing. Meal bolus cannot be computed.** | Loop mode has detected that a calibration is ongoing. The bolus recommendation will be displayed once the calibration has finished. | Wait for the bolus recommendation to be displayed. |

| ALARM SYSTEM OF LOOP MODE | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **20106 No meal bolus due to hypoglycemia** | Loop mode has detected hypoglycemia conditions and cannot recommend a meal bolus right away. If necessary, a recommendation will be sent in the next 45 minutes. | 1. Treat your hypoglycemia.<br>2. Eat your meal as planned and listen out for a meal bolus recommendation.<br>**DO NOT use a pen or other device to administer insulin.** |
| **20107 No meal bolus because you have enough insulin** | Loop mode has detected that you already have enough insulin in your body for the declared carbohydrates. Your meal has been recorded. If necessary, a recommendation will be sent in the next 45 minutes. | Eat your meal as planned and listen out for a meal bolus recommendation.<br>**DO NOT use a pen or other device to administer insulin.** |
| **20300 Rescue carbs are recommended** | A rescue carb intake is recommended by the system.<br>Reminder: approximately every 30 minutes. | 1. Stop all ongoing activities.<br>2. Accept the rescue carb recommendation or change the quantity as needed.<br>3. Take the suggested or adjusted quantity and acknowledge the alert to confirm the amount taken.<br>4. Wait for 30 minutes and check your glycemia regularly. |

| ALARMS, ALERTS AND INFORMATION MESSAGES RELATING TO THE PHONE OR TO THE APPLICATION | | |
|---|---|---|
| **Error code Name** | **Description and reminder** | **Action to be taken** |
| Alarm / Alert / Information message | | |
| **61000 The phone's battery is very low** | Your phone's battery is very low. | Charge your phone as soon as possible. |
| **63000 Bluetooth is disabled** | Bluetooth® is mandatory for DBLG2. | Make sure Bluetooth® is enabled on your phone. |
| **64000 Automatic time is disabled** | Your phone is not configured with automatic time. | Make sure automatic time is enabled on your phone. |
| **60100 Low phone battery** | Your phone's battery is low.<br><br>Reminder: every 15 minutes | Charge your phone as soon as possible. |

# Part 7:
# Product specifications

## 7.1 – System performance

### 7.1.1 – Essential performance

The DBLG2 system meets the following essential performance requirements.

- The application's user interface allows the user to:
  - declare meal intakes.
  - declare physical activities.
  - customize the system settings in order to achieve optimal glycemic performances.
  - display data of interest, such as glycemia, delivered insulin, meals, rescue carb intakes and physical activities declared to the system.
- The application embeds an algorithm (loop mode), which:
  - automatically adjusts the basal rate on a regular basis.
  - automatically sends correction boluses to the insulin pump when the patient's glycemic situation requires it.
  - suggests a rescue carb intake to the patient when the patient's glycemic situation requires it.
  - performs a particular treatment regarding meal management.
  - performs a particular treatment regarding physical activity management.
- The DBLG2 application is downloadable on a smartphone equipped with Bluetooth® Low Energy wireless technology. A Bluetooth® communication protocol is embedded in the application in order to communicate with the CGM and the pump to:
  - retrieve the estimated glycemia measurements from the CGM and transfer them to loop mode.
  - transfer the insulin recommendations computed by loop mode to the insulin pump so as to inject the required amount of insulin.
  - trigger low, medium and high-priority messages in relation to the sensor, pump and phone, with appropriate sound levels and tone.

### 7.1.2 – Expected service life of the components

| Component | Service life |
|---|---|
| Sensor | 10 days |
| Transmitter | 3 months |

| Component | Service life |
|---|---|
| Insulin pump | 4 years |
| Cartridge | 3 days |

### 7.1.3 – Expected effects of the system

The DBLG2 application has been adapted from the DBLG1 product (with minimal adjustments) and has been demonstrated to be equivalent to DBLG1. Therefore, the clinical data which supports the clinical evaluation of DBLG1 is applicable to DBLG2.

The DBLG1 System was compared to sensor-pump therapy in 63 adults with type 1 diabetes in a 12-week real-life study. This study was multi-center, open-label and randomized with a crossover design.

| ADULTS* | DBLG1 System (closed loop) | Sensor-pump therapy (open loop) |
|---|---|---|
| Percentage of time spent in range (70–180 mg/dL) | 68.5% ± 9.5% | 59.4% ± 10.3% |
| Average glycemia | 158.5 ± 16.7 mg/dL | 164.9 ± 16.7 mg/dL |
| Percentage of time spent < 70 mg/dL | 2.0% ± 2.4% | 4.3% ± 2.4% |

*Benhamou, Pierre-Yves, *et al.* "Closed-loop insulin delivery in adults with type 1 diabetes in real-life conditions: a 12-week multicentre, open-label randomised controlled crossover trial." The Lancet Digital Health 1.1 (2019): e17-e25.

These results have been confirmed in a multicenter interventional study comparing the DBLG1 System with usual treatment in 90 adults with type 1 diabetes.

Moreover, these results were corroborated by an observational study conducted in a large dataset of 3706 adults with type 1 diabetes using the DBLG1 System in real-world conditions.

| ADULTS* | DBLG1 System (closed loop) |
|---|---|
| Percentage of time spent in target (70–180 mg/dL) | 71.2% ± 11.0% |
| Average glycemia | 157.0 ± 17.1 mg/dL |
| Percentage of time spent < 70 mg/dL | 1.27% ± 1.23% |

*Benhamou P-Y, Adenis A, Lebbad H, *et al.* "One-year real-world performance of the DBLG1 closed-loop system: Data from 3706 adult users with type 1 diabetes in Germany." Diabetes Obes Metab. 2023; 25(6): 1607-1613. doi:10.1111/dom.15008.

For the patients where a baseline was known, the percentage of time in range (70–180 mg/dL) increased from 53.9 ± 18.3% to 72.4 ± 9.6%.

#### Expected clinical benefits of the system

The expected clinical benefits of the system are a better glycemic control, defined as less hypoglycemia, more time in range, and a lower risk of long-term complications.

Refer to the European database on medical devices (Eudamed) for a summary of safety and clinical performance. This summary is also available on request by sending a mail to qara@diabeloop.fr.

| | |
|---|---|
| Eudamed | https://ec.europa.eu/tools/eudamed (subject to Eudamed availability) |
| UDI | 376036478DBLG2-swST |

### 7.1.4 – Summary of potential risks related to the Diabeloop system for the lay user

The quantitative estimation of residual risks associated with the use of the Diabeloop system is based on the rules used in risk management activities and described in the Risk Management Plan.

| Probability rating | Description: per device lifetime |
|---|---|
| Frequent | Occurring at least 3 times a day per device |
| Probable | Occurs at least 3 times a week (but less than 3 times a day) per device |
| Occasional | Occurs at least once a month (but less than 3 times a week) per device |
| Remote | Occurs at least once in device lifetime (but less than once a month) per device |
| Improbable | Not likely to occur – never in device lifetime per device |

Using the Diabeloop system does not totally remove risks related to insulin therapy (hypoglycemia, hyperglycemia, severe hyperglycemia with or without ketosis, severe hypoglycemia, coma and death). The impact of using the Diabeloop system on insulin therapy can be seen in the outcomes of the listed clinical studies.

General risks related to the Diabeloop system may include:

- communication issues with the pump and sensor.
- software issues.
- usage errors (not hearing an alarm or alert, error in meal / rescue carb intake declaration, incorrect calibration, incorrect external insulin delivery declaration).

These situations might occur occasionally and could lead to hypoglycemia / severe hypoglycemia or hyperglycemia / severe hyperglycemia.

### Risks related to the Kaleido insulin pump

There is a remote possibility that inserting the infusion set of the insulin pump will cause localized infection or an allergic reaction, and wearing the adhesive patch might irritate your skin.

Occlusions and air bubbles in the tubing or a dislodged cannula might occasionally affect insulin delivery and could lead to hyperglycemia or severe hyperglycemia with or without ketosis.

There is a remote chance a pump could break or be damaged, which could lead to hyperglycemia or severe hyperglycemia with or without ketosis.

### Risks related to sensor use

There is a remote possibility that inserting the sensor will cause infection, bleeding or pain, and wearing the adhesive patch might irritate your skin.

There is a remote chance a sensor wire could break or detach and remain under your skin. Sterile broken sensor wires usually do not pose a significant medical risk.

### Risks related to cybersecurity

The Diabeloop system has been developed and manufactured in compliance with state-of-the art cybersecure principles. By design, communication between the DBLG2 application and the insulin pump or the glucose sensor is encrypted. Security of use is dependent on the user's compliance with the terms and conditions of use and data privacy policies.

There are no residual cybersecurity risks related to DBLG2. There are, however, improbable general risks related to cybersecurity that may include the following.

- Disclosure of data if the phone is stolen.
- Interception of the Bluetooth® signal while pairing two devices ("man-in-the-middle" attack). By nature, Bluetooth® devices such as continuous glucose monitoring systems and pumps may be visible to third parties. However, these devices claim to have secure procedures.
- Phishing attacks (Diabeloop will never request your login or password).
- Use of a public Wi-Fi network.
- Disclosure of data from lack of awareness of best practices relating to cybersecurity (for example, password strength or reuse, PIN codes, installation of applications from unknown app stores or editors, etc.).

The DBLG2 application must not be installed and operated on a rooted device. Rooted devices have modified security features, which make them less secure.

By design and in production, the Kaleido device software programming and any update is performed under a controlled process. Users cannot update the software at home once it is sent to them in the specified starter kit. The Kaleido software is cryptographically signed using a digital certificate that proves that the software is from ViCentra and has not been altered. Before software can be loaded onto the Kaleido system, the system performs a check on the digital signature and prevents any unauthorized or unsigned software from being run on the Kaleido system. Additionally, the pump allows no access to the programming interface of the

system once produced. Via these mechanisms, ViCentra ensures the Kaleido system includes protection against unauthorized access.

**To prevent a cybersecurity risk, carefully read the instructions and recommendations provided in this user guide.**

In the event of a cybersecurity breach, you can send an email to dpo@diabeloop.fr.

## 7.2 – Dexcom G6

### 7.2.1 – Performance characteristics summary

#### When LOWER is better

| Adults | Performance metrics* |
|---|---|
| 9.8% | Overall accuracy<br>Mean ARD% (MARD): 40–400 mg/dL<br>(% average absolute error versus reference across all glucose levels) |
| Day 1: 8.6%<br>Day 2: 8.7%<br>Days 4–5: 10.7%<br>Day 7: 10.6%<br>Day 10: 10.6% | Accuracy over time<br>Mean ARD% (MARD): 40–400 mg/dL |

#### When HIGHER is better

| Adults | Performance metrics* |
|---|---|
| 92% [100%] | Clinical accuracy<br>% of readings that were in the Clarke Error Grid (CEG) [% CEG A+B Zone] |

*Reference is Yellow Springs Laboratory Instrument (YSI).

### 7.2.2 – Technical specifications

#### Technical specifications of the sensor

| | |
|---|---|
| Glucose range | 40–400 mg/dL |
| Calibration range | 20–600 mg/dL<br>Recommended 40–400 mg/dL |

| | |
|---|---|
| Useful life of the sensor | Up to 10 days |
| Storage and transport conditions | Temperatures: 2°C – 30°C<br>Store sensors in a cool, dry place. |
| Sterilization | Sterile by radiation |

#### Technical specifications of the transmitter

| | |
|---|---|
| Electrical safety class | Internally powered |
| Battery longevity (typical) | 3 months |
| Battery charging time | Non-rechargeable |
| Operational conditions | Temperatures: 10°C – 42°C<br>Relative humidity (RH): 10% – 95% |
| Storage and transport conditions | Temperatures: 0°C – 45°C<br>Relative humidity (RH): 10% – 95% |
| Operating altitude | –396 meters to 4,206 meters |
| Ingress protection | IP28: protection against insertion of large objects and immersion in water for up to 2.4 meters for 24 hours |
| Protection against electrical shock | Type BF applied part[1] |
| Alarm audible output | N/A |
| TX/RX frequencies | 2.402–2.480 GHz |
| Bandwidth | 1.07 MHz |
| Maximum output power | 1.0 mW EIRP |
| Modulation | Gaussian Frequency – Shift Keying |
| Data rate | 1 Mbps |
| Data communication range | 6 meters |

[1] The maximum surface temperature of the applied part is 43°C.

### 7.2.3 – Electromagnetic immunity and emissions: declaration and guidance

#### Electromagnetic immunity and emissions

The transmitter is intended for use in the electromagnetic environment specified in the following table. The end user of the transmitter should ensure that it is used in such an environment.

| Immunity test | Compliance level |
|---|---|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ±8 kV contact<br>±15 kV air |
| Magnetic field (50Hz)<br>IEC 61000-4-8 | 30 A/m |
| Electric fast transient / burst<br>IEC 61000-4-4 | N/A |
| Surge<br>IEC 61000-4-5 | N/A |
| Voltage dips and interruptions<br>IEC 61000-4-11<br>IEC 60601-1-11 | N/A |
| Conducted Field Disturbance<br>IEC 61000-4-6 | N/A |
| Radiated Field Disturbance<br>IEC 61000-4-3 | 10 V/m at 80 MHz to 2700 MHz (AM modulation) |
| Radiated and conducted fields<br>Aircraft use | FAA RTCA / DO-160 edition G section 20 category T<br>Can be used on aircraft according to the directions provided by the operator of the aircraft |

Since EMC environmental monitoring cannot be guaranteed, electromagnetic interference is always possible in the home healthcare environment. Interference can result in discrepancies between G6 readings or gross inaccuracies. The user is encouraged to try to mitigate these effects by taking one of the following measures.

If your symptoms do not match your G6 readings, use your meter when making treatment decisions. If your G6 readings do not always match your symptoms or the meter readings, ask your healthcare professional how you should use the Dexcom G6 to help you manage your diabetes. Your healthcare professional can help you decide on how best to use this device.

#### Electromagnetic emissions specifications

| Immunity test | Compliance |
|---|---|
| Radio frequency emissions<br>CISPR 11 | Group 1, Class B |
| RF emission<br>Aircraft use | Meets FAA RTCA / DO-160 edition G Section 21, Category M for in-cabin use |

### 7.2.4 – Radio regulations compliance

Dexcom, Inc. declares that the radio equipment type Dexcom G6 System is in compliance with

Directive 2014/53/EU. For the full text of the EU declaration of conformity, refer to dexcom.com/doc.

## 7.3 – Kaleido insulin pump

### 7.3.1 – Technical specifications

#### Technical specifications of the insulin pump

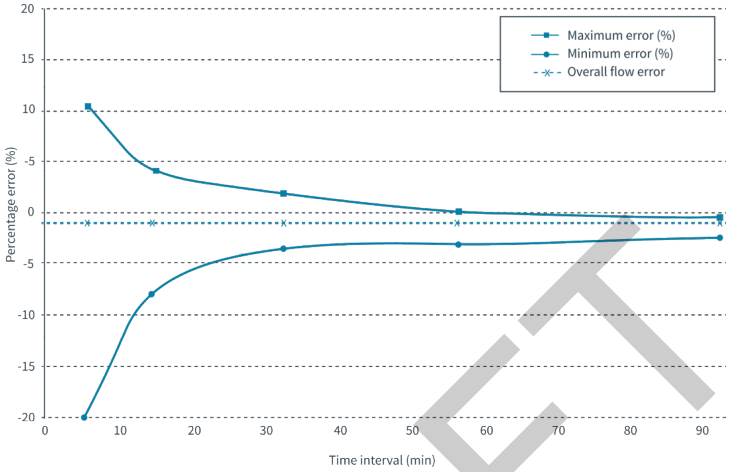
| | |
|---|---|
| Environmental operating and storage conditions | Temperature range: 5°C – 37°C<br>Humidity range: 15% – 93% relative humidity, non-condensing<br>Pressure range: 0.7 bar – 1.06 bars |
| Dimensions | Pump: 12.5 mm x 50 mm x 35 mm<br>Charging dock: 60 mm x 45 mm x 15 mm |
| Weight | Pump: 19 g<br>Charging dock: 13 g |
| Insulin cartridge capacity | 200 U |
| Ingress protection | Pump: IP68 (dustproof and waterproof up to 1.5 meters for 1 hour)<br>Charging dock, power adapter and connection cable: keep dry |
| Batteries | Pump: 260 mAh rechargeable lithium polymer |
| Battery life | Pump: one cartridge cycle up to 3 days on a full charge with a maximum insulin use of 200 units over 3 days |
| Service life | Pump, charging dock, connection cable, inserter and power adapter: 4 years<br>Insulin cartridge, infusion set, body and pump patches: single use, up to 3 days in use<br>Alcohol wipes, syringes and needles: single use |
| Alarm volume | >50 dB |
| Wireless radio | Bluetooth® Low Energy<br>Class 3 transmitter with peak power of 1 mW |
| Wireless frequency | 2.4 GHz |
| Delivery accuracy | ±5% in all operating conditions |
| Maximum infusion pressure at occlusion | 1 bar |

| | |
|---|---|
| Occlusion alarm threshold | 1 U |
| Maximum time to occlusion alarm | 1 hour at a basal rate of 1 U/h<br>20 hours at a basal rate of 0.05 U/h |
| Unintended bolus volume generated at occlusion | 1 U |
| Maximum delivery under single fault condition | 0.05 U |
| Charger power input | 100–240 V, 50–60 Hz |
| Charger power output / pump power input | 5 V DC, 1.0 A |
| System memory | 90 days following switch off |
| Administration sets used for all tests performed under EN 60601-2-24 | Kaleido insulin cartridge 5 cm and 30 cm tubing |
| Sterilization components and their sterilization method | Insulin cartridge: by irradiation<br>Infusion set: by ethylene oxide gas<br>Alcohol wipe: by irradiation<br>Syringe: by ethylene oxide gas<br>Needle: by ethylene oxide gas |
| Product classification (IEC 60601-1) | Class II |
| Bolus functionality | Minimum bolus dosage: 0.05 U<br>Maximum bolus dosage: 30 U<br>Bolus dosage increments: 0.05 U |
| Basal rate functionality | Minimum basal rate: 0.05 U/h<br>Maximum basal rate: 5 U/h<br>Basal rate increments: 0.05 U |
| Maximum delivery speed | 1 U/min<br>This means the maximum bolus of 30 U will be delivered at the maximum delivery speed in 30 minutes. Note that the delivery speed of a bolus can be decreased as the speed is dependent on your basal safety profile delivery running in the background. |
| Priming volume | Infusion set 6 mm cannula variant: 0.20 U<br>Infusion set 9 mm cannula variant: 0.25 U |

### Pump accuracy

The accuracy of your system is dependent upon it being used correctly and in accordance with your training and the instructions for use provided in this user guide.

Typical insulin delivery accuracy for the Kaleido pump was tested according to IEC 60601-2-24 at a basal rate of 1 U/h under environmental conditions of 20°C and 65% relative humidity, showing an average flow error of <5%.




### 7.3.2 – Electromagnetic immunity and emissions: declaration and guidance

⚠ Use of Kaleido products adjacent to or stacked with other equipment should be avoided as this could result in improper operation. If such use is necessary, Kaleido products should be observed to verify that they are operating normally.

⚠ Use of accessories and cables other than those specified or provided by ViCentra could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ Portable RF communications equipment (including peripherals such as antenna cables, external antennas and mobile phone) should be used no closer than 30 cm to any part of the pump, including cables specified by ViCentra. Otherwise, degradation of the performance of this equipment could result (e.g., disruptions in the Bluetooth® communication).

#### Electromagnetic emissions

The Kaleido pump is intended for use in the electromagnetic environment specified below and should be used in these conditions only.

| Emission control test | Compliance | Directives related to the electromagnetic environment |
|---|---|---|
| RF emission<br>CISPR 11 | Group 1 | The Kaleido pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emission<br>CISPR 11 | Class B | The Kaleido pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Voltage fluctuations / flicker emissions<br>IEC 61000-3-3 | Compliant | |
| Harmonic emissions<br>IEC 61000-3-2 | Class A | Not applicable, as rated power is less than 75 W |

### Electromagnetic immunity

The Kaleido pump is intended for use in the electromagnetic environment specified below and should be used in these conditions only.

| Immunity test | Test level IEC 60601 | Compliance level | Directives related to the electromagnetic environment |
|---|---|---|---|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | 8 kV contact<br>15 kV air | 8 kV contact<br>15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electric fast transient / burst<br>IEC 61000-4-4 | ±2 kV for power supply lines<br>±1 kV for input/output lines | ±2 kV for power supply lines<br>±1 kV for input/output lines | The Kaleido pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Surge<br>IEC 61000-4-5 | ±1 kV line(s) to line(s)<br>±2 kV line(s) to earth | ±1 kV line(s) to line(s)<br>±2 kV line(s) to earth | The Kaleido pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |

| Immunity test | Test level IEC 60601 | Compliance level | Directives related to the electromagnetic environment |
|---|---|---|---|
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0% $U_T$ for 0.5 and 1 cycle<br>70% $U_T$ for 25/30 cycles<br>0% $U_T$ for 250/300 cycles | | The Kaleido pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical use environment. |

**Note:** $U_T$ is the AC mains voltage prior to application of the test level.

| Immunity test | Test level IEC 60601-1-2 | Compliance level | Directives related to the electromagnetic environment |
|---|---|---|---|
| RF Common mode/ Conducted Susceptibility IEC 61000-4-6 | 3 V<br>6 V in ISM and amateur radio bands<br>150 kHz to 80 MHz | 3 V<br>6 V in ISM and amateur radio bands | Portable RF communications equipment (including peripherals such as antenna cables, external antennas and mobile phone) should be used no closer than 30 cm to any part of the pump, including cables specified by the manufacturer. Otherwise, it may result in degradation of the performance of this equipment (e.g. disruptions in the Bluetooth® communication). The Kaleido pump is tested for radiated RF immunity only at selected frequencies, and use of the Kaleido pump near transmitters at other frequencies can cause improper operation. |
| Radiated RF Electromagnetic Field IEC 61000-4-3 | 10 V/m<br>80 MHz to 2.7 GHz | 10 V/m | |
| Proximity fields from RF wireless communication systems IEC 61000-4-3 | Refer to the following table. | | |

| Test freq. (MHz) | Band[1] (MHz) | Service [1] | Modulation [2] | Max. power (W) | Distance in meters | Immunity test level |
|---|---|---|---|---|---|---|
| 385 | 380–390 | TETRA 400 | Pulse modulation[2] 18 Hz | 1.8 | 0.3 | 27 |

| Test freq. (MHz) | Band[1] (MHz) | Service [1] | Modulation [2] | Max. power (W) | Distance in meters | Immunity test level |
|---|---|---|---|---|---|---|
| 450 | 430–470 | GMRS 640, FRS 460 | FM[3] ±5 kHz deviation<br>1 kHz sine | 2 | 0.3 | 28 |
| 710<br>745<br>780 | 704–787 | LTE Band 13, 17 | Pulse modulation[2] 217 Hz | 0.2 | 0.3 | 9 |
| 810<br>870<br>930 | 800–960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation[2] 18 Hz | 2 | 0.3 | 28 |
| 1720<br>1845<br>1970 | 1700–1990 | GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25 UMTS | Pulse modulation[2] 217 Hz | 2 | 0.3 | 28 |
| 2450 | 2450–2570 | Bluetooth®, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation[2] 217 Hz | 2 | 0.3 | 28 |
| 5240<br>5500<br>5785 | 5100–5800 | WLAN 802.11 a/n | Pulse modulation[2] 217 Hz | 0.2 | 0.3 | 9 |

**General note:** if necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and Kaleido may be reduced to 1 m . The 1 m test distance is permitted by IEC 61000-4-3.

[1] For some services, only the uplink frequencies are included.

[2] The carrier shall be modulated using a 50% duty cycle square wave signal.

[3] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

#### Recommended separation distances between portable and mobile RF communications equipment and Kaleido

The Kaleido pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Kaleido pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Kaleido pump, as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter in W | Separation distance according to frequency of transmitter in meters | | |
|---|---|---|---|
| | 150 kHz to 80 MHz d = 1.17 √P | 80 MHz to 800 MHz d = 0.35 √P | 800 MHz to 2.5 GHz d = 0.7 √P |
| 0.01 | 0.12 | 0.04 | 0.07 |
| 0.1 | 0.37 | 0.11 | 0.22 |
| 1 | 1.17 | 0.35 | 0.70 |
| 10 | 3.70 | 1.11 | 2.21 |
| 100 | 11.70 | 3.50 | 7.00 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**General notes**

At 80 and 800 MHz, the higher frequency range separation distance applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

### 7.3.3 – Manufacturer's declarations and statements

The Kaleido pump is in compliance with the essential requirements and other relevant provisions of directive 2014/53/EU.

Medical electrical equipment requires special precautions regarding EMC and needs to be commissioned in accordance with the EMC information provided in this document.

Kaleido contains a radio transmitter and receiver intended to be worn on your body. It is designed not to exceed the limits for exposure to radio waves (radio frequency

electromagnetic fields) recommended by the International Commission on Non-Ionizing Radiation Protection (ICNIRP). These limits include a substantial safety margin designed to ensure the safety of all persons, regardless of age and health.

The radio wave exposure guidelines use a unit of measure known as the Specific Absorption Rate, or SAR. The SAR limit for a body-worn mobile device is 2 W/kg . Kaleido uses a low-powered standard technology for radio communication operating in the frequency band from 2.402 to 2.48 GHz. Due to the very low output power (typically 0.35 mW), the radio wave exposure from Kaleido is far below the established limits.

Other radio equipment may interfere with your Kaleido pump, even if that other equipment complies with CISPR emission requirements. Radio devices should be kept at least at a distance of **d** (as calculated with the tables) away from Kaleido.

Each of your Kaleido products has a unique serial number which helps us identify important information, such as when it was made. For your Kaleido pumps, this information also includes details of the version of Kaleido software your products run on. This information is securely held for you by ViCentra and Diabeloop SA.

# Appendix: Symbols

The following table describes the symbols relating to your DBLG2 system components and their labels. Some of these symbols may not have meaning in your region and are listed for informational purposes only.

| | |
|---|---|
|  | Atmospheric pressure limitation |
| EC REP | Authorized representative in the European Union |
| CH REP | Authorized representative of Switzerland |
| LOT | Batch code |
|  | Bluetooth® wireless technology |
| REF | Catalog number |
|  | Caution |
|  | Class II equipment |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Country of manufacture |
|  | Danger: piercing object |
|  | Date of manufacture |
| IP22 | Degree of ingress protection provided by enclosures: objects ≥ 12.5 mm diameter, water drops (15° tilted) |
| IP68 | Degrees of ingress protection provided by enclosures: dust-tight; continuous immersion in water |

| | |
|---|---|
| IP28 | Degrees of ingress protection provided by enclosures: objects ≥ 12.5 mm diameter, continuous immersion in water |
|  | Direct current |
|  | Distributor |
|  | Do not re-sterilize |
|  | Do not re-use |
|  | Do not use if package is damaged |
|  | Electronic piercing waste |
|  | Electronic piercing waste disposal box |
|  | European conformity mark |
|  | For indoor use only |
|  | Fragile, handle with care |
|  | French Triman logo: recycle and dispose of separately |
|  | Humidity limitation |
|  | Importer |
|  | Keep away from rain |

| | |
|---|---|
|  | Keep away from sunlight |
|  | Manufacturer |
|  | Medical device |
|  | MR (magnetic resonance) unsafe |
|  | Non-ionizing electromagnetic radiation |
|  | Part number |
|  | Pharmacy |
|  | Piercing object disposal box |
|  | Prescription only |
|  | Refer to instruction manual/booklet |
|  | Serial number |
|  | Single patient multiple use |
|  | Single sterile barrier system |
|  | Single sterile barrier system with protective packaging outside |
|  | Sterilized using ethylene oxide |
|  | Sterilized using irradiation |
|  | Temperature limit |

| | |
|---|---|
|  | Type BF applied part |
|  | UK marking of conformity |
|  | UK responsible person |
|  | Unique device identifier (UDI) |
|  | Universal serial (USB) port/plug |
|  | Use-by date |
|  | Warning |
|  | Waste Electrical and Electronic Equipment (WEEE) - follow local requirements for proper disposal |
|  | WEEE waste disposal - Follow local requirements for proper disposal *(accumulators and batteries)* |

# Index

## L

## R



## S

Report any serious incident that has occurred in relation to the DBLG2 system to the competent authority in the country in which you are established and to your local support.

An electronic version of this user guide is available on Diabeloop's website at the following URL:
https://www.dbl-diabetes.com (Resources)

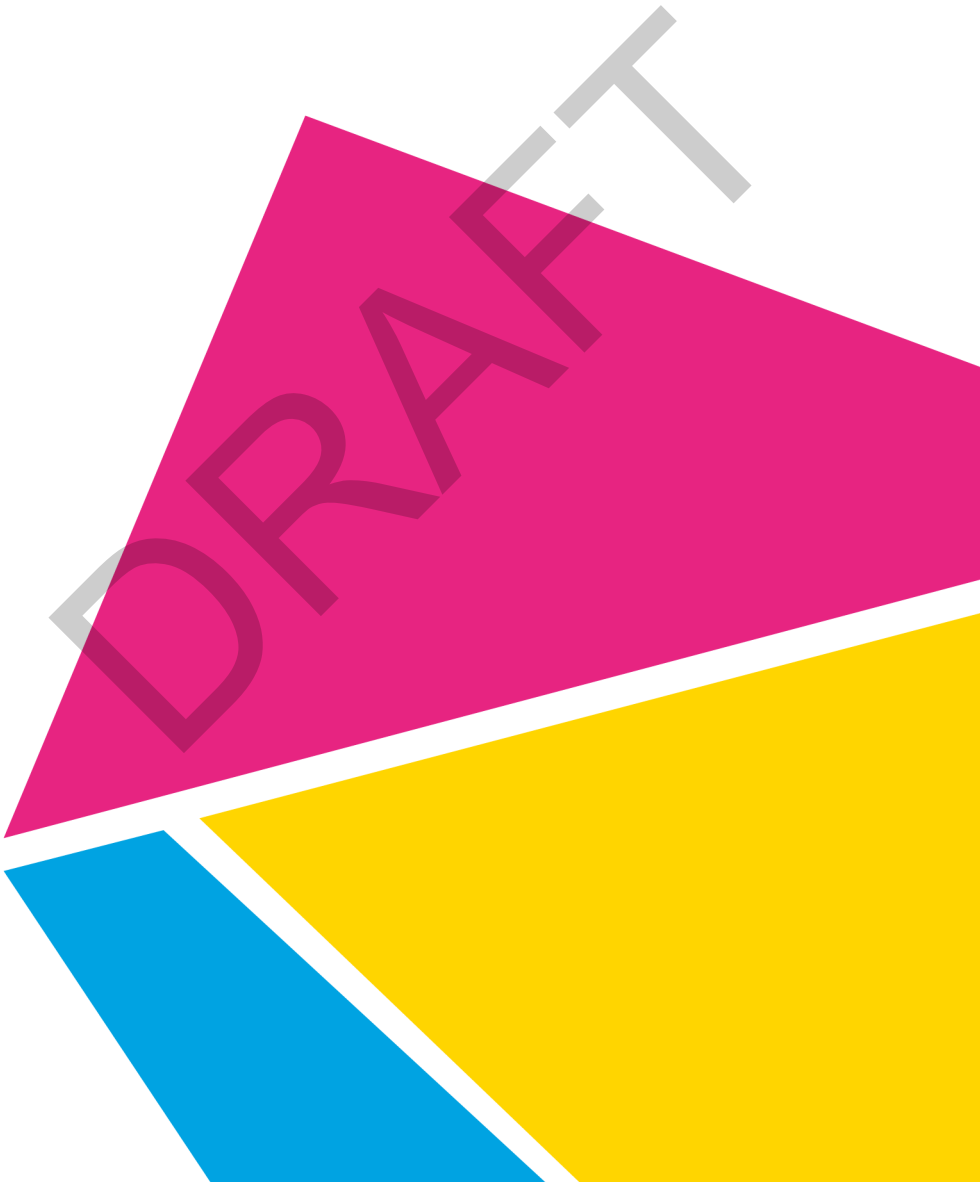
You may also scan the QR code:

A paper version can be provided upon request, within 7 days.

CE 0123

UDI 376036478DBLG29M

Diabeloop SA
17 rue Félix Esclangon - 38000 GRENOBLE (FRANCE)
www.diabeloop.fr
contact@diabeloop.fr



DBLG2-RA-IFU-001-mgdl-en-Rev7-DRAFT
Effective date: 2025-05-XX



diabeloop