DBL G1 SYSTEM

with Kaleido

User guide

Table of contents

Part 4: Warranty, maintenance and disposal

Part 5: Alarm system and troubleshooting

Part 6: Technical specifications

Part 1: Getting started

About this user guide

This user guide provides indications, contraindications, warnings, precautions, operating instructions and other important information on using your DBLG1® System. Carefully read through all the instructions prior to using the DBLG1 System.

Reading this user guide is essential. It helps you use the DBLG1 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

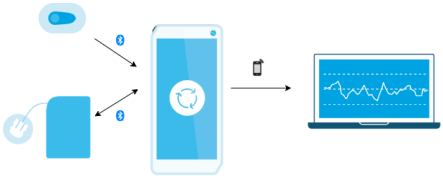
An operating instruction contains additional information or advice on how to use the system correctly.

1.1 – Introduction to the DBLG1 System

The DBLG1 System with Kaleido (hereafter referred to as "DBLG1 System") is an automated insulin delivery system composed of different medical devices that interact with one another through restricted Bluetooth® Low Energy connections.

- DBLG1 software (which includes the loop mode algorithm).
- A handset.
- A continuous glucose monitoring system (CGM).
- An insulin pump.

The DBLG1 software gathers data from the CGM and the insulin pump, transmits alarms and alerts 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.



When you first receive the DBLG1 System, you will receive assistance from your healthcare professional, who has been trained to use it.

1.1.1 – Intended purpose

The DBLG1 software is intended for adult patients with type 1 diabetes who are aged 18 or older.

The main function of the DBLG1 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 DBLG1 software takes into account the patient's profile, glycemia (current and predicted), announced meals and physical activities.

1.1.2 – Indications

The DBLG1 System, issued on a medical prescription, is intended for adult patients with type 1 diabetes who are more than 18 years of age.

The total daily dose required must be less than 90 U[1].

The DBLG1 System is indicated for use with 100 U/mL rapid-acting insulin analog and is intended for single-patient use.

1.1.3 – Contraindications

This medical device is contraindicated for the following people.

- Patients receiving a total daily dose of insulin below 8 U.
- Patients who are less than 7 years old.
- 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).
- 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).

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

The DBLG1 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 DBLG1 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 DBLG1 System.

1.2.1 – Symbols

The following table describes the symbols relating to your DBLG1 System components and their labels.

Warning	Caution	Refer to the instructions for use	Consult instructions for use or consult electronic instructions for use
SN Serial number	LOT Batch code	REF Catalog number	PN Part number

UDI Unique device identifier (UDI)	Use-by date	Do not re-use	Date of manufacture
Manufacturer	CC Country of manufacture	MR MR (magnetic resonance) unsafe	Bluetooth® wireless technology
Class II equipment	Type BF applied part	Direct current (DC)	Keep away from sunlight
Temperature limit	Humidity limitation	Universal serial bus (USB) port/plug	Keep dry
IP22 Degrees of ingress protection provided by enclosures: objects ≥ 12.5 mm diameter; water drops (15° tilted)	IP28 Degrees of ingress protection provided by enclosures: objects ≥ 12.5 mm diameter; continuous immersion in water	IP68 Degrees of ingress protection provided by enclosures: dust-tight; continuous immersion in water	Fragile, handle with care
Do not use if package is damaged and consult instructions for use	STERILE R Sterilized using irradiation	STERILE EO Sterilized using ethylene oxide	EC REP Authorized representative in the European Union

Family ID number	Non-ionizing electromagnetic radiation	Single patient multiple use	Do not re-sterilize
Single sterile barrier system	Alternating current (AC)	WEEE waste disposal Follow local requirements for proper disposal	
Distributor	Medical device	European conformity mark	

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 DBLG1 System.

⚠ The images shown in this user guide are for illustrative purposes only. Your product may look different.

1.2.2 – General safety statements

As a patient, you are viewed as an operator and are expected to use the DBLG1 System independently at home after getting trained on its use by a competent healthcare professional and/or local support.

Contact your healthcare professional in certain situations described in this user guide. As the DBLG1 System is worn on the body and delivers a drug continuously, it may be operated outside of the home environment.

⚠ Carefully read this user guide before you start using your DBLG1 System. It contains important information on the features and performance characteristics of your system, as well as troubleshooting information.

To use the DBLG1 System, you must be:

- willing to learn about and maintain good self-management of your diabetes.
- able to understand and use insulin doses correctly.

Correct use of the system as described in this user guide and according to the training provided by your healthcare professional will guarantee enhanced accuracy of the system as a whole and ensure you use it safely.

Using the DBLG1 System incorrectly (for example failure to follow the instructions taught in training and outlined in this user guide) may lead to serious injury, life-threatening situations or even death.

The DBLG1 System can only work with specific components: the Kaleido® insulin pump and the Dexcom G6 sensor. Modification of this device is strictly forbidden.

This medical device is meant for personal use.

Make sure you always have a first-aid kit readily available. Despite the use of the DBLG1 System, severe hypoglycemia 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 the pump, make sure that you charge your second pump to 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 DBLG1 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 insulin delivery (on the DBLG1 go to System status > [pump section] > MORE > STOP) and remove the system to keep it safe.

Ensure that you keep a minimum distance of 15 cm between your DBLG1 System and any portable communicating equipment (such as mobile phones) that uses radio frequencies.

Ensure that you keep a maximum distance of 2 meters between the pump/sensor and the DBLG1.

If, for whatever reason (unsuitable temperatures, prolonged loss of connection to the system, high electromagnetic environment, damage to the DBLG1), the pump no longer receives any commands from the DBLG1, it automatically switches to safety mode and delivers the basal safety profile.

If connection between components is lost, an alarm will sound.

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

Do not try to modify 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 DBLG1 System.

We recommend that you keep your DBLG1 close by when you have the volume set low.

1.2.3 – 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.

No number, no arrow, no CGM treatment decision
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. Then, if you want to align your G6 with your meter, calibrate. You do not have to calibrate, but you can.

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 DBLG1
Keep your transmitter and DBLG1 within 2 meters of each other, with no obstacles (such as walls or metal) between them. Otherwise, they might not be able to communicate.

Make sure your DBLG1 is always switched on 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 water resistant, but the DBLG1 is not. Swim, shower, take a bath: there's no need to worry about water and your G6 – just leave your DBLG1 in a dry area.

Note that if the distance between the G6 and the DBLG1 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 DBLG1 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.

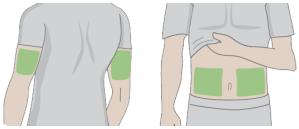
Be accurate, be quick
Enter the exact blood glucose value displayed on your meter within 5 minutes of using your meter. Do not enter the G6 reading as a calibration.

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.

1.2.4 – 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 once modifications to the equipment are made, and it will invalidate your 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 2500 m altitude. However, extreme altitude, temperatures or atmospheric conditions may affect your pump's performance, so keep this in mind, take care 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 DBLG1 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 system on your body. Likewise, you are instructed to clean the area of your skin with an alcohol wipe to prevent skin reactions. Likewise, 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 the 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 102).

1.2.5 – Safety statements about the DBLG1

Lithium-ion battery
The DBLG1 is delivered with a lithium-ion battery. If the battery is not working, contact your local support. Do not expose the battery to extreme temperatures.

Recharge your battery at temperatures between –10°C and +50°C.

Keep the battery out of reach of children.

The maximum autonomy of the DBLG1 is 35 hours. If the battery of the DBLG1 does not last a full day, contact your local support for a battery replacement.

⚠ Your DBLG1 must be charged every day (nighttime is the recommended period).

Electrical power outlet

The electrical outlet must:

- be installed near the equipment and be easily accessible.
- meet standards and regulations in the country where used.

You should always connect the DBLG1 connection cable to the power adapter and to the DBLG1 BEFORE connecting the power adapter to a power socket.

⚠ Keep the battery out of reach of animals. Also keep it away from any sharp objects. Not complying with these instructions could cause a fire.

⚠ Do not handle the device if you see that the lithium-ion battery is leaking.

⚠ The charging cable of the DBLG1 could pose a strangulation risk. Do not place it near or around a person's neck.

⚠ Do not charge your DBLG1 close to flammable materials. It may heat up and cause a fire.

Do not charge your DBLG1 when it is placed on fabric. Charge your DBLG1 in a properly ventilated area.

⚠ **Opening up the DBLG1**
Do not attempt to open the outer casing of the DBLG1. You can only open the battery cover for actions described in this user guide.

⚠ Your DBLG1 is an electronic device that generates heat in its normal operating mode. During extended use in a poorly ventilated area, direct contact with the skin may cause irritations or mild burns. Therefore, handle your DBLG1 with care when it is operational.

Do not expose your DBLG1 to mechanical vibrations or impacts.

Do not place your DBLG1 close to a source of heat such as a radiator or a stove.

Do not expose the DBLG1 to excessive amounts of smoke, dust or high relative humidity conditions. Do not allow your DBLG1 to come into contact with liquids or wet objects.

Do not drop your DBLG1.

Do not touch the DBLG1 screen with a pointed object; you may damage it.

Cleaning the DBLG1
Unplug all cables from the DBLG1. Do not clean the electrical connections.

Shipping and storage
Use the original packaging whenever shipping or storing the DBLG1. Disconnect the cables from the DBLG1 during shipping. It is recommended that you remove the battery from the DBLG1 for shipping.

The DBLG1 must be stored in a place where:

- the temperature is between –25°C and +70°C.
- the atmospheric pressure is between 700 hPa and 1060 hPa.
- the relative humidity is between 15% and 90%.

Disposal
The abandonment or uncontrolled disposal of waste can cause harm to the environment and to human health. If your DBLG1 no longer works, contact your local support.

Never attempt to disassemble your DBLG1. You alone are responsible for how you use your DBLG1 and any consequences of its misuse.

Do not use your DBLG1 in damp areas (bathroom, swimming pool, etc). Protect it from liquids and moisture.

Do not expose your DBLG1 to extreme temperatures: lower than –25°C and higher than 70°C. The recommended operating temperature range is between –10°C and +50°C.

Electrical safety
Only use the battery and charger (DBLG1 connection cable to the power adapter) provided with your DBLG1. Using any other battery and charger may be dangerous; it will also invalidate your warranty. The line voltage must be exactly the one indicated on the charger's serial plate.

Explosive materials
You must comply with radio equipment usage restrictions in places such as those where chemicals are used.

Electronic medical equipment
Your DBLG1 is a radio transmitter that may interfere with electronic medical equipment or implants, such as hearing aids, pacemakers, etc. It is recommended that a minimum separation of 15 cm be maintained between the DBLG1 and an implant. Your healthcare professional or the manufacturers of such equipment can provide any advice you may need in this area.

Hospitals
Always make sure that your DBLG1 is switched off in hospitals when so instructed by warning signs or medical staff.

Systematically disconnect the charger from the plug socket when the battery is completely charged to ensure that it does not consume energy needlessly. The actual service life of the battery depends on the network configuration, settings of the product, usage, the battery itself and external conditions.

While charging, you can continue to use your DBLG1 in the operating conditions defined for the device.

1.2.6 – Safety statements about the insulin

The DBLG1 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 DBLG1 System has been tested with the U100 rapid-acting insulin. The Kaleido pump can be used with the following U100 insulin types: Humalog® and NovoRapid®. The exact insulin type for treating your diabetes mellitus will be prescribed by your healthcare professional.

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 DBLG1 System

⚠ Make sure your DBLG1 System kit contains everything listed here before starting. If any component is missing, call your local support directly.

⚠ If the packaging of any of your supplies is damaged in any way, do not use it as we will not be able to guarantee the sterility (if applicable), performance and security of the products. Contact your local support for a replacement.

⚠ Your DBLG1 System comes in several boxes. Once you have opened them, keep them until you have finished using their contents. If there is any problem with a component, you will have to provide the serial numbers, batch number and other identification numbers to your local support for investigation. You can find all these numbers on their respective boxes.

Your DBLG1 System kit contains all the equipment listed below. Contact your local support to find out how to obtain more supplies.

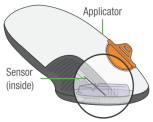
1	Handset with pre-installed DBLG1 software	Supplied by Diabeloop SA
1	Charger for the DBLG1 (USB-C connection cable and power adapter)	
1	Battery for the DBLG1	
1	DBLG1 System user guide	
1	Dexcom transmitter box	Supplied separately
2	Kaleido insulin pumps	
1	Inserter to be used with the infusion set of the Kaleido pump	
1	Kaleido charging kit containing 1 charging dock, 1 connection cable, 1 power adapter	

⚠ The Kaleido kit also contains a Kaleido handset. Do not pair your Kaleido pumps with the Kaleido handset when using the DBLG1 System. Ensure you pair your pumps with the DBLG1 handset.

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 DBLG1 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) (10 days of use)	The sensor gets glucose information. The sensor applicator inserts the sensor under the skin (single use).	
Transmitter (3 months of use)	The transmitter sends glucose information from the sensor to the DBLG1.	

Features

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

10-day sensor session: your sensor session lasts 10 days. The expiration date is visible from the System status menu (glucose sensor section).

Paracetamol/acetaminophen blocking: previously, paracetamol/acetaminophen could affect your readings, making them look higher than they really were. 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.

Transmitter holder and transmitter: the transmitter and its holder are thin. Once your sensor session is over, you can easily break open the transmitter holder to remove the transmitter.

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.

Through your DBLG1 you can:

- define a basal safety profile over a 24-hour period.
- administer your meal-time bolus and/or correction bolus when necessary.
- modify your basal insulin rate based on an upcoming physical activity or events of hypoglycemia/hyperglycemia.
- view system alarms and alerts.

When the pump is paired with the DBLG1 with loop mode ON, the decision-making process about the insulin doses to be injected is automated. However, the system also allows you to manually adjust the recommended insulin dose in certain situations, for instance following a meal declaration.

Components of the Kaleido insulin pump

Kaleido combines the freedom of a patch pump with the versatility of a conventional pump. Keep it close with patches with short 5 cm tubing or place it into your pocket with a longer 30 cm option. Unlike other patch pumps, Kaleido does not get thrown away. Kaleido comes with 6 or 9 mm cannulas, so, with input from your healthcare professional you can choose what works for you. Your Kaleido pump also comes with an inserter to aid the cannula insertion.

⚠ 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.

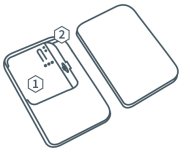
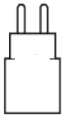
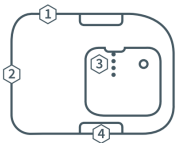
⚠ Check the content of your kits for completeness prior to use. Contact your local support if anything is missing.

⚠ 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.

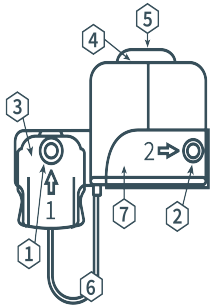
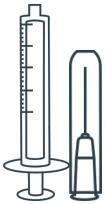
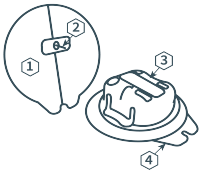
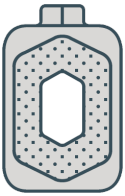
⚠ Do not store your inserter together with loose blood glucose testing strips. Blood glucose strips can enter the inserter and impair its functionality.

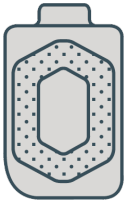
Starter kit

⚠ The Kaleido kit also contains a Kaleido handset. Do not pair your Kaleido pumps with the Kaleido handset when using the DBLG1 System. Ensure you pair your pumps with the DBLG1 handset.

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

Top-up kit

Name	Description	Illustration
Insulin cartridge (x10)	Insulin cartridge, which can be filled with 200 U of U100 insulin Tubing: 5 cm or 30 cm **1**: Hole 1 **2**: Hole 2 **3**: Insulin cartridge connector **4**: Plastic tab **5**: Filling cradle catch **6**: Insulin cartridge tubing **7**: Filling cradle	
Syringes and needle (x10)	2.5 mL syringes to fill insulin cartridges with insulin Needle to connect at the end of the syringe	
Infusion set (x10)	Device for the subcutaneous injection of rapid-acting insulin Cannula: 6 mm or 9 mm **1**: Paper backing (with sticky patch underneath) **2**: Needle, including cannula tube **3**: Plastic cap **4**: Plastic cap tabs	
Alcohol wipe (x10)	Wipe with an alcohol solution for disinfecting the insertion site	
Body patch (x10)	Patch to be stuck to the skin for attaching the pump	

Name	Description	Illustration
Pump patch (x10)	Patch to be stuck on the back of the pump and put on the skin patch	

1.3.4 – DBLG1

The DBLG1 uses an algorithm (loop mode) for recommending and scheduling the delivery of appropriate insulin doses.

The DBLG1 takes into account your personal settings you enter 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 [both subject to validation]) and commands your pump to deliver it. Your insulin requirements are adjusted every 5 to 10 minutes with each new G6 reading.

Your DBLG1 also recommends that you take rescue carbs if you are at risk of hypoglycemia.

If loop mode is OFF, you can still view the G6 readings and trend arrows on the DBLG1 screen and use them to control the pump.

DBLG1 (supplied with a charging cable, power adapter and battery).

Loop mode is pre-installed on the DBLG1.

1.3.5 – Data sharing to YourLoops

YourLoops is a web-based data-visualization platform to which your glycemia-related data can be transmitted automatically so that it can be shared with your healthcare professional. You

will be prompted to create a YourLoops account when you first initialize your DBLG1. Refer to Initialization procedure on page 33. The use of YourLoops is not mandatory for the proper functioning of the system.

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).
- your favorite rescue carb intake.
- 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).

1.5 – Traveling with your DBLG1 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. Keep your first-aid kit with you.

Note that the power adapter supplied with your system may not be compatible with the country of visit. If this is the case, use your alternative insulin therapy.

1.5.1 – 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.

⚠ The DBLG1 System cannot be used in the presence of electromagnetic waves (including X-rays) and has not been tested with full body scanners (known as AIT or millimeter wave scanners).

DO NOT pass through a body scanner 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

During the flight, use your alternative insulin therapy.

Time zones

When traveling across time zones, your DBLG1 sets the default date and time automatically if the option "Automatic time zone" is activated (refer to Time on page 98).

⚠ We advise you to regularly check that the time on your DBLG1 is correct, particularly when you are traveling across multiple time zones.

Discuss any necessary adjustments to your medical settings with your healthcare professional if you plan to travel across multiple time zones.

1.5.2 – Data transfer to YourLoops

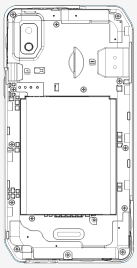
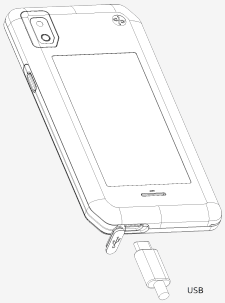
When you travel to some countries, the SIM card in your DBLG1 will not be able to transmit data to YourLoops. The data will be transmitted to YourLoops on the first day of the month following the return to a covered country.

⚠ If your cellular 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.

Part 2:
Using your system

2.1 – DBLG1: first-time use

2.1.1 – Installing the battery and charging the DBLG1

1		Remove the back cover of the DBLG1. Insert the battery in the dedicated space and replace the back cover.
2		Connect the DBLG1 connection cable to the power adapter (USB-A end) and the DBLG1 (USB-C end). Connect the power adapter to the electrical outlet.

2.1.2 – Turning the DBLG1 on

Press the ON/OFF button on the right edge (long press). Press again to switch off the DBLG1.

The DBLG1 can take up to 5 minutes to start when it has been switched off.

> If no action has been taken on the DBLG1 for more than a few seconds, the screen switches to sleep mode. Briefly press the ON/OFF button to turn the screen back on.

2.1.3 – PIN code

Access to the Diabeloop application requires a four-digit PIN code. The PIN code is known only to you. You can change it but for security reasons you cannot deactivate it.

The code required for the first launch of the DBLG1 is 0000. You will be required to enter a new PIN during the initialization phase of the device. For security reasons if the device is stolen, you should avoid using four identical digits.

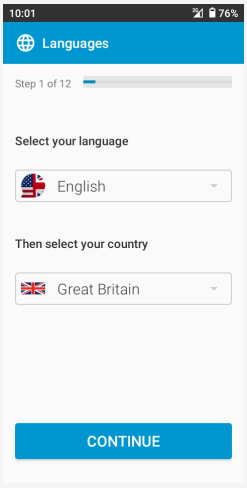
When your DBLG1 is locked, swipe upwards from the bottom of the screen. Enter your PIN code using the numerical keypad displayed on the screen. Confirm your code using the green arrow to the right of the digit 0.

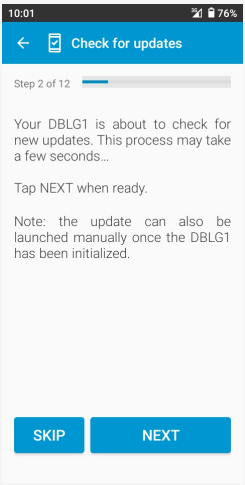
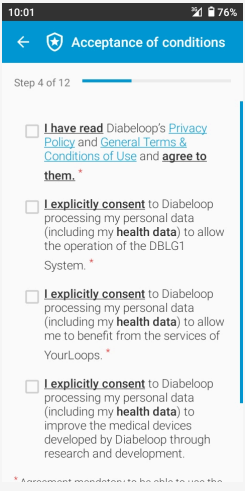
2.1.4 – Initialization procedure

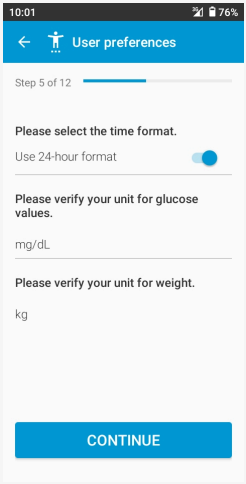
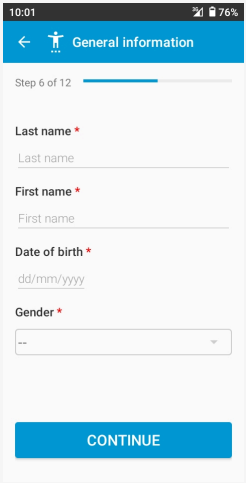
Your DBLG1 must be initialized by a healthcare professional trained to use the DBLG1 System. You will therefore be assisted by your healthcare professional to enter your personal and medical data.

After turning on the DBLG1, wait until the initialization screen appears. The following steps are necessary to customize the system for the patient.

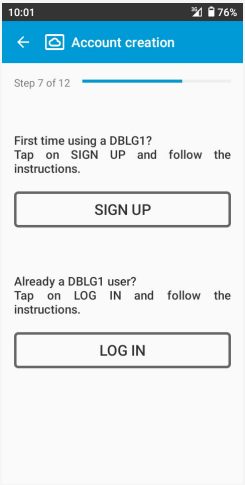
For more information on the settings required for the initialization of the DBLG1, refer to Medical settings on page 89.

1		Choose your language and tap CONTINUE.

2		Your DBLG1 suggests checking for software updates. Tap NEXT and then follow the instructions on the screen to check for updates and install them right away. Otherwise tap SKIP. > If you choose to skip the update at this stage, refer to Updates on page 98 for instructions on how to manually check for an update at a later time and the installation options that are available.
3	Tap CONTINUE again on the Welcome screen.	
4		Use of the system requires acceptance of the terms and conditions of use. Read and accept the general terms and conditions of use and the data privacy policy. Then tap CONTINUE.

5		Select the time format. Check the units for the G6 readings and for the weight. These units are set by default. Tap CONTINUE.
6		Fill in your personal information. This step is used to create your profile on YourLoops. Tap CONTINUE.

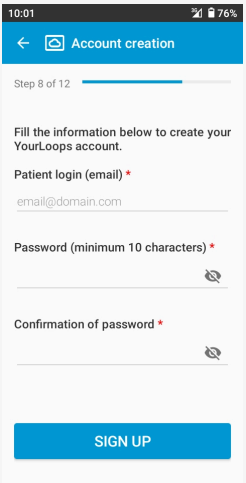
7



If you do not already have a YourLoops account, tap on SIGN UP.

If you already have an account, tap on LOG IN and enter your login (email) and password.

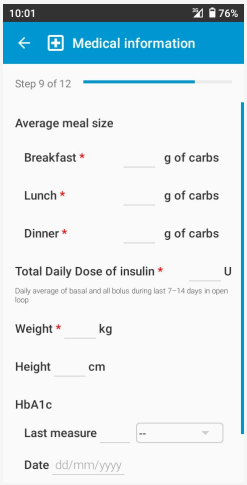
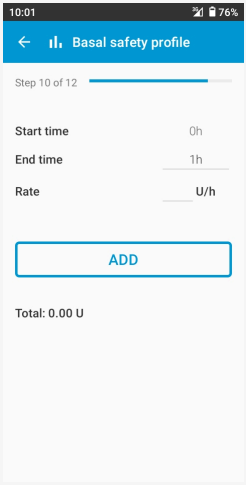
8



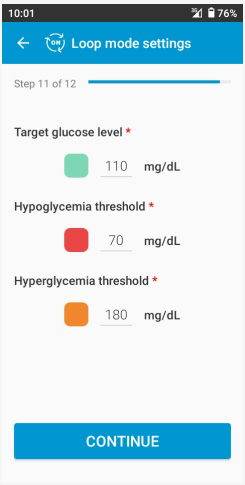
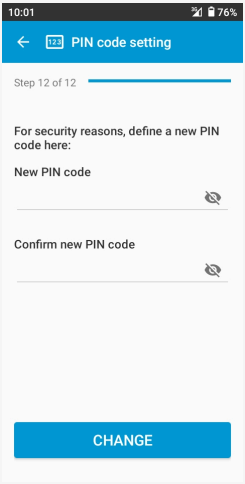
Create your account with a unique email address. If a professional account already exists, use another email address for the patient account.

> Choose a password with at least 10 characters. For cybersecurity reasons, the password should contain upper- and lower-case letters, numbers and special characters, and should be unique to YourLoops.

Tap SIGN UP. You will receive a link by email inviting you to connect to YourLoops.

9		Fill in your medical information. • Average quantity of carbohydrates for each meal (the patient must provide the healthcare professional with this information). • Total dose of insulin in 24 hours. • Weight and height. • Last measured HbA1c and date of measure. With this information, the DBLG1 System calculates the insulin requirements for: • a basal rate. • a correction bolus. • a meal bolus. Tap CONTINUE.
10		Enter your basal safety profile (based on the prescription): start time, end time and desired rate for each time slot. If loop mode switches off, the DBLG1 System will deliver this basal safety treatment. Tap ADD between each entry. When a 24-hour period has been recorded, tap CONTINUE. > For midnight, use 00:00 (the time displayed for the slot will be "24h" or 12:00 AM depending on the time format). > Deleting a slot with an associated basal rate is definitive and results in all subsequent slots being erased as well. You will have to fill in all the slots again. The maximum number of slots is 24 (one slot can cover several hours). Each basal rate slot can be set to between 0.05 U/h and 5 U/h.[1]

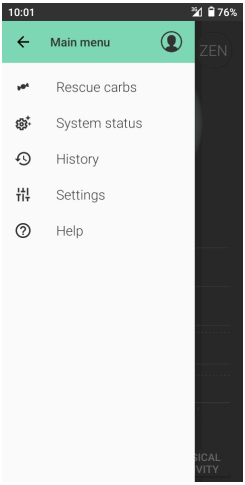
[1] U/h: insulin amount delivered in units per hour.

11		Set your target glucose level and your hypoglycemia and hyperglycemia thresholds. By default these are set to 110, 70 and 180 mg/dL respectively. Adjust them as necessary. Tap CONTINUE.
12		Enter a new PIN code and tap CHANGE. For security reasons if the device is stolen, you should avoid using four identical digits.

At the end of the initialization steps, you will be directed to either the System status screen from which you can proceed with pairing your sensor and pump (tap YES), or to the Home screen (tap NO).

2.1.5 – Main menu

From the Home screen, tap on the ☰ icon to display the main menu.



(Profile): view your personal profile as defined during the initialization phase of your DBLG1.

Rescue carbs: announce a rescue carb intake.

System status

- Pair your sensor and pump, start/stop the sensor, pump or loop mode, calibrate the sensor.
- Check the status and version of the sensor and pump, check the status of loop mode.
- Send a manual bolus or change your basal rate temporarily.

History

- View your daily graph.
- View events (alarms, alerts and notifications).
- Manage your meals and physical activities.
- View glycemia-related statistics.
- View your calibrations.
- Declare an external bolus (injected with a pen, syringe or other pump).
- View the administered boluses.

Settings (refer to Medical settings on page 89 and DBLG1 settings on page 93)

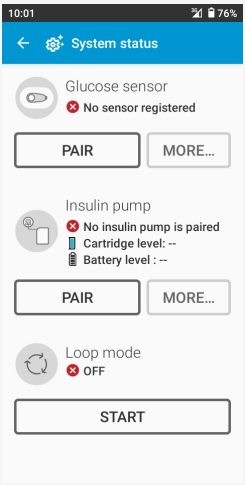
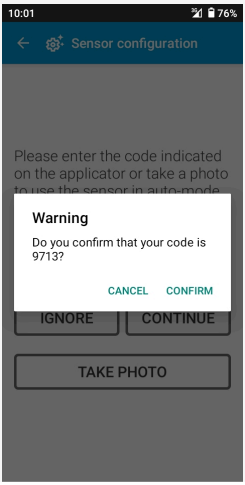
- Configure your DBLG1 System.
  - Set your thresholds, define settings for loop mode, and change your patient and Zen mode settings.
  - Define user preferences relating to the sound levels for system events, language and display, time format, data sharing options, etc.
  - Manage your credentials (YourLoops, PIN code).
- Access your personal profile.
- Check for system updates.

Help

- Obtain help on the various components of your DBLG1 System.
- Test the sounds for alarms, alerts and notifications.
- View release notes, information on the product and manufacturer, software version installed, and terms of use and privacy policies.

2.2 – Setting up the glucose sensor

2.2.1 – Entering the sensor code

1		Tap on ☰ > System status > [glucose sensor section] > PAIR.
2		If you want to use the G6 without calibrating manually, enter the sensor code displayed on the applicator's adhesive backing and tap CONTINUE. Then tap CONFIRM.  Alternatively, tap TAKE PHOTO to take a photo of the QR code. Then tap NEXT and follow the instructions on the screen to take the photo. OR Tap IGNORE if you want to use your G6 with manual calibration (calibration once a day).
3	Put your DBLG1 down and set up your G6 as described below before pairing the transmitter and launching the sensor.	

2.2.2 – Using the applicator to insert the built-in sensor

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:

⚠
- at least 8 cm from the insulin pump's infusion set or from the injection site.
- away from 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.

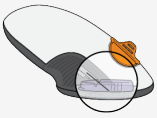
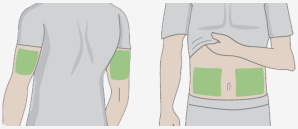
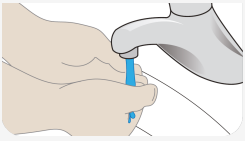
Clean and dry the skin

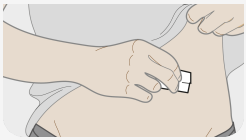
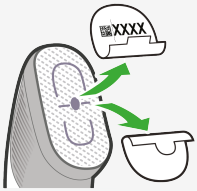
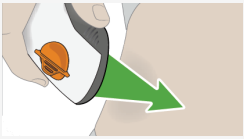
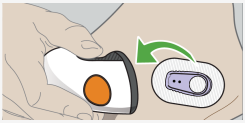
Clean and dry your hands and your insertion site before inserting your sensor. Wash your hands with soap and water, not gel cleaners, and then dry them before opening the sensor package. If your hands are dirty when you insert the sensor, you may get germs on the insertion site and get an infection.

⚠

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.

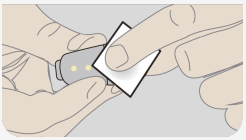
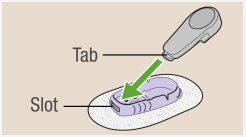
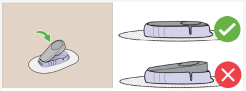
Make sure you do not have insect repellent, sunscreen, perfume or lotion on your skin.

1		Take the applicator with built-in sensor out of the sensor box. 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; 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.

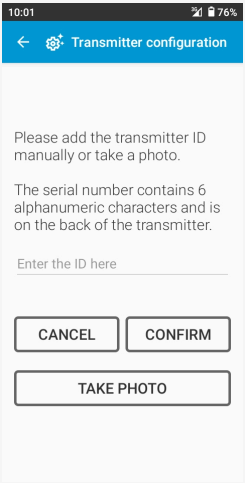
2.2.3 – Attaching the transmitter

1		Take the transmitter out of the box.

2		Clean the transmitter with an alcohol wipe.
3		Insert the transmitter, tab first, into the holder.
4		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.
5		Rub around the patch three times.

2.2.4 – Pairing the transmitter and starting the sensor session

Pairing the transmitter



Enter the transmitter's ID (SN: serial number) manually. The ID is engraved on the back of your transmitter and written on the transmitter's packaging. Tap CONFIRM.

Alternatively, tap TAKE PHOTO 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.

Once you have entered your serial number, your G6 searches for the transmitter. The screen reverts back to the System status screen and the sensor status indicates **Searching**. Wait up to 30 minutes during this search phase. During this time, you will **not** receive any readings or alarms/alerts from your G6. If this phase fails, you are notified through the DBLG1. Refer to the List of alarms and alerts on page 108 for actions to be taken.

> During the pairing phase, always keep the DBLG1 within 2 meters of the transmitter.

Two-hour warmup period

Once your DBLG1 is paired with the sensor, the sensor launches its warmup phase. This takes about 2 hours. The Home screen displays a warmup countdown.

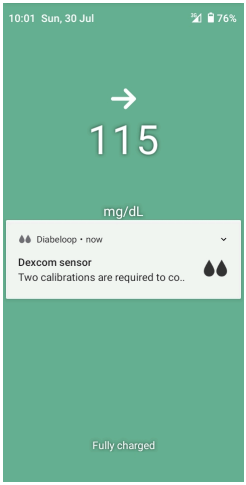
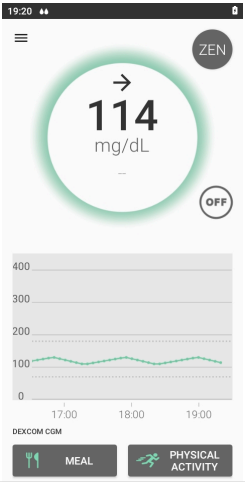
During the warmup period, you will **not** receive G6 readings or alarms and alerts related to your glycemia.

You can use this time to set up the insulin pump on your body. Once the warmup phase has finished, you will start receiving G6 readings and alarms and alerts.

	Home screen: G6 readings are displayed in the central circle.
	Lock screen: G6 readings are displayed in the center of the screen.

2.2.5 – Calibrating your Dexcom G6 (optional)

If you chose manual calibration during the sensor 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 period. When the time comes to calibrate, the symbol 🩸🩸 is displayed on your DBLG1.

Calibration notification on the lock screen	Calibration notification in the status bar on the Home screen
	

Five minutes after the first calibration, you must enter the second one. When you see the symbol 💧💧, calibrate again right away.

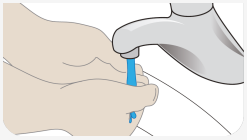
Once you have performed these first two calibrations, you can start following your Dexcom G6 readings. Another calibration will be required after 12 hours, and again 12 hours after that. Then one calibration every 24 hours will be necessary.

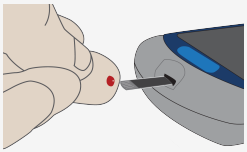
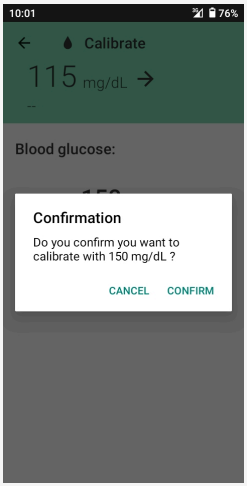
Reminder: your G6 readings are updated every 5 minutes on your DBLG1.

⚠ **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.

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		Tap on ☰ > System status > [glucose sensor section] > MORE > CALIBRATE. Enter the blood glucose value and then tap CONFIRM twice.

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.

2.2.6 – Checking the status of the sensor

Tap on ☰ > System status.

Status	Meaning
No sensor registered	There is no sensor paired with your DBLG1.
Searching	Your DBLG1 is attempting to pair with your transmitter.
Initializing	Your sensor is in its 2-hour warmup period.

Status	Meaning
Please input your first calibration	You must enter an initial blood glucose value for calibrating the sensor (only for sensor in manual calibration).
Please input your second calibration	You must enter a second blood glucose value for calibrating the sensor (only for sensor in manual calibration).
Sending the calibration value	The blood glucose value entered as a calibration is being sent to the transmitter.
Stopping	You have just tapped STOP, and the sensor is in the process of stopping its session. This could take several minutes.
No active session	Your sensor is no longer able to communicate with your DBLG1. You will no longer receive any G6 readings.
Active session	Your sensor is sending its G6 readings.
Signal loss	Connection to the sensor has been momentarily interrupted. The symbol (**--**) is displayed on the Home screen.
No value available	There are no G6 readings available. The symbol (**???**) is displayed on the Home screen.

Tap MORE to view additional information on the current session (transmitter ID, sensor code, expiration date of each device).

2.2.7 – Stopping the sensor session

⚠ The alarm associated with the end of your sensor session stops loop mode. Your pump continues to deliver your basal safety profile.

⚠ Reuse the transmitter – Do not throw it away

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

The sensor session is stopped when the 10-day period comes to an end. You may also have to end the session prematurely at your own initiative or on infrequent occasions when the DBLG1 detects issues related to the sensor and requests that you end the session.

Refer to the List of alarms and alerts on page 108 for the alarms and alerts that require the sensor session to be stopped.

Tap on ☰ > System status > [glucose sensor section] > STOP to end the current session. If your pump is administering when you end the sensor session, it will continue with your basal safety profile.

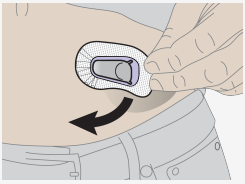
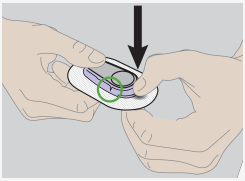
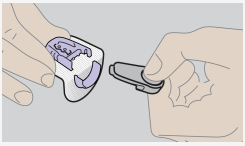
When you change your sensor, you will not be able to view your readings or use loop mode during the 2-hour warmup period. Tap START right away in the loop mode section on the System status screen. The status of loop mode will be **Waiting for glucose values** and loop mode will start automatically at the end of the warmup period.

Note that you will not be able to launch loop mode if the sensor status is **No active session** or **No sensor registered**.

2.2.8 – Removing the sensor

After the sensor session has ended, follow these steps to:

1. take the sensor off your body.
2. remove your transmitter from the holder.

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. Throw out the adhesive patch according to your local guidelines for disposal of components that have come into contact with blood.

2.2.9 – Reusing your transmitter and restarting a sensor session

Your transmitter is designed to last 3 months. Reuse it for multiple sensor sessions. Follow the procedures described in Entering the sensor code on page 40 and Using the applicator to insert the built-in sensor on page 41 to install a new sensor.

⚠ The transmitter's serial number is recorded in the memory of the DBLG1. You do not need to enter this number when you change sensors.

Make sure you wait 15 to 20 minutes before attaching the transmitter to the new sensor, otherwise the system will not recognize the sensor as a new one and will display an error message.

Once you have reached the 3 months of use (90 days), wait until your next sensor session is due to start and then change your transmitter.

2.2.10 – Changing the transmitter

Refer to the List of alarms and alerts on page 108 for alarms and alerts requiring a transmitter change (such as a low battery).

To pair a new transmitter with your DBLG1, stop your glucose sensor. Then tap MORE to display the sensor's information; scroll down and tap REMOVE THE TRANSMITTER. The DBLG1 is now ready to register a new transmitter. Follow the procedure described in Pairing the transmitter and starting the sensor session on page 43 to pair it.

2.3 – Setting up the insulin pump

2.3.1 – Setting up the Kaleido insulin pump

⚠ Before removing a used cartridge and/or changing the pump, always stop your pump using the DBLG1. Remove and discard the insulin cartridge appropriately. Put your pump to charge. These steps are important because your DBLG1 cannot pair with a new pump if it is still paired with the previous one.

⚠ You must not reuse old insulin cartridges in your Kaleido pump. It is important that you only use newly prepared insulin cartridges or an insulin cartridge that has been removed from your pump temporarily and then immediately reinserted.

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

- One fully charged Kaleido pump. Refer to Charging your pump on page 75.
- 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 – 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 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.

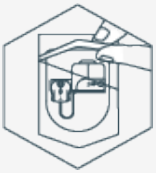
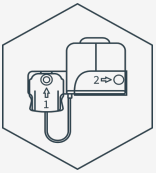
Always double check the expiration date of your insulin vial before you use it. If your insulin has passed its expiration date, discard and dispose of it according to the instructions provided by the insulin manufacturer.

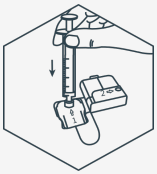
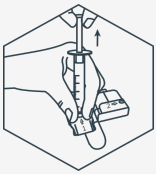
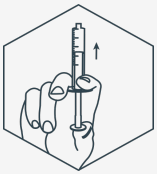
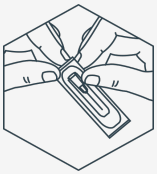
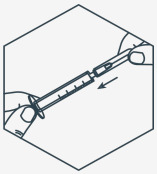
⚠ Do not reuse insulin cartridges. Doing so may contaminate your insulin and lead to infection and possible under or no delivery of insulin.

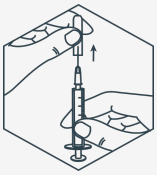
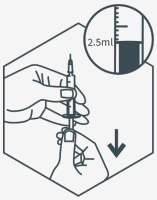
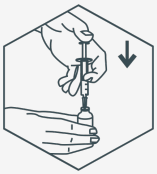
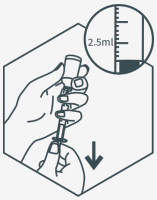
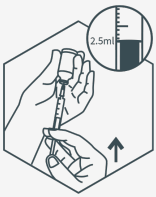
⚠ Do not reuse your syringes or needles – doing so may contaminate your insulin and lead to infection. Once you have used a needle and syringe once, always dispose of them responsibly, straight away after use.

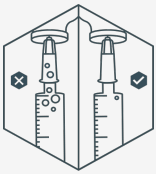
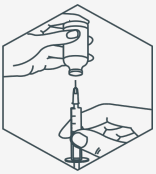
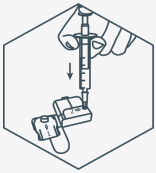
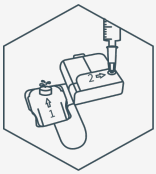
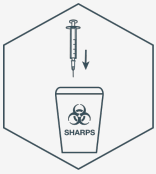
After each use, eliminate them according to the rules in force in your country. We recommend that you throw them in a sharps bins for potentially infectious sharps.

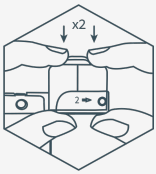
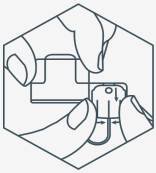
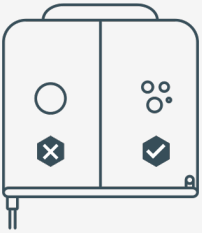
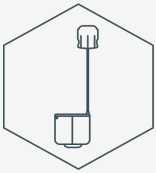
⚠ Sometimes the cartridge or filling cradle may have shifted during transit. Before you fill your cartridge, ensure the cartridge and filling cradle are aligned. If something does not look right or the cradle is crooked, realign it by pulling the cartridge towards the tiny plastic tap at the top of the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

1		Check the expiration date and ensure that the packaging and insulin cartridge are not damaged before use. Open up the packaging from your insulin cartridge by pulling on the bottom. 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. This will remove any excess air from your insulin cartridge. This action reduces the risk of formation of large air bubbles. ⚠ 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. ⚠ 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. 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 assist 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.

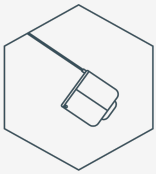
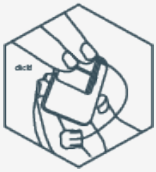
15		Check the syringe for air bubbles. If there are air bubbles, repeat Steps 13 and 14 as often as needed to get rid of the air bubbles in the syringe. This will help make sure that there are no air bubbles in the syringe that can be pushed into your insulin cartridge during the filling process. Some 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 will ensure that any air bubbles that remained in the syringe go upwards near the plunger. 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. ⚠ 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 will need to prime and then remove your insulin cartridge from the filling cradle. Hold the top of your insulin cartridge with your 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 and then release 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 okay 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. ⚠ Your insulin cartridge should always be completely full before you start using it.

2.3.3 – 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 good, the back of the insulin cartridge will sit flush with the back of the pump. 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 DBLG1.

Inserting an insulin cartridge into a pump turns the pump on. Removing the insulin cartridge turns the pump off. If you have successfully inserted an insulin cartridge, your pump will beep twice to let you know that everything has gone according to plan and that it is ready to connect to your DBLG1.

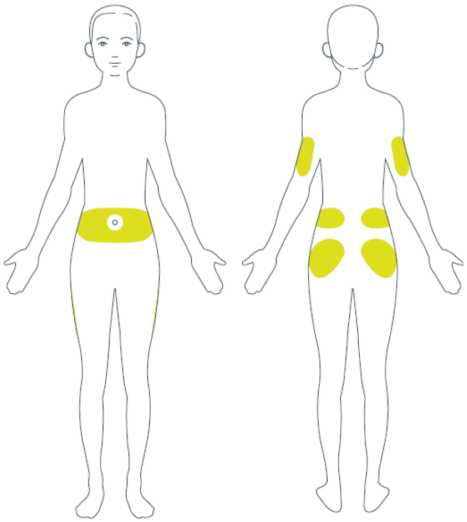
Your DBLG1 will only be able to respond if it is turned on and within range of your pump.

As well as confirming that your pump and DBLG1 are ready to connect, the beeps let you know that your pump and DBLG1 alarm systems are working properly. If you do not hear the beeps, check that your insulin cartridge is inserted correctly, and that your DBLG1 is turned on and within communication range (approximately 2 meters). If those things do not help, contact your local support.

2.3.4 – Choosing your infusion site

⚠ 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).

2.3.5 – 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.

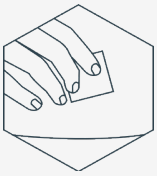
Do not reuse infusion sets. Doing so may contaminate your insulin and lead to infection and possible under or no delivery of insulin.

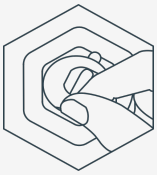
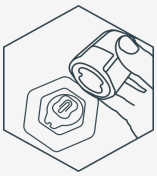
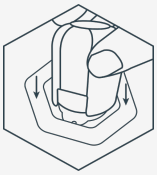
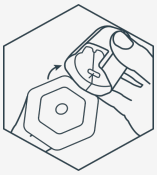
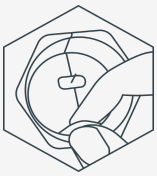
Do not let the infusion set come in contact with water within the first hour of applying. Making the infusion set wet within the first hour of application may cause decreased adhesion properties.

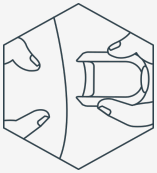
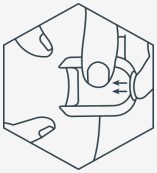
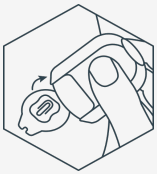
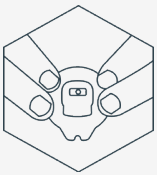
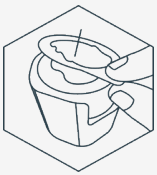
Rotate your infusion sites whenever you change your infusion set. If you do not rotate your infusion sites, scar tissue may develop. Scar tissue can disturb the flow of insulin into your body and may limit your ability to absorb it properly in the future.

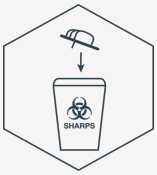
When you apply your infusion set, bear in mind the length of your insulin cartridge's tubing. If you are using the 5 cm tubing, make sure you position it close to where you want to wear your pump. The tubing should always be slack, never pulled tight.

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 change 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. Use an alcohol wipe to gently clean the area and then allow your skin to dry naturally. 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. 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. ⚠ 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. 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. Check the needle is straight, but be careful not to touch it – it is important that it stays sterile. 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. 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. Then use your other hand to position your inserter on your skin. 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. 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. 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. 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. 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. Do not throw it away, it will be useful for future infusion set changes.

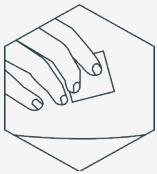
You should establish a routine for rotation and visual examination of your infusion set insertion sites to ensure that the sites remain healthy and free of redness, irritation, swelling, pain or infection. If an infusion site becomes irritated or inflamed, the infusion set should be removed and another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

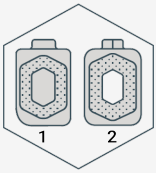
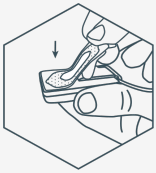
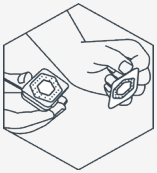
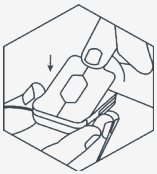
2.3.6 – Connecting your pump to the infusion set

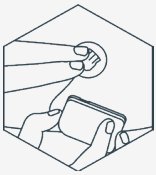
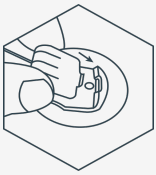
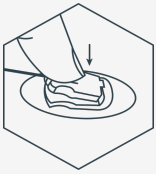
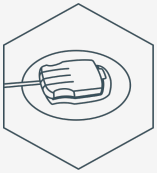
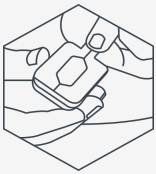
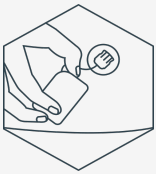
⚠ Make sure that the back of your pump is clean and dry before you attach a pump patch. This will ensure a better bond between the patch and pump, and prevent your pump from coming loose over time.

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.

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. 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 **2**: Body patch
3		Stick the pump patch to the bottom of your pump so that it 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. Try and make sure your body patch lines up neatly with your pump.

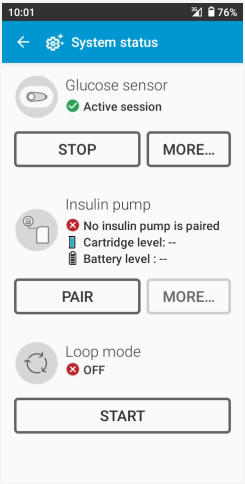
5	  	Being careful to support the weight of your pump, clip the connector at the end of your insulin cartridge tubing into your infusion set. You will know it is secure when you hear the two distinct clicks as the right- and left-hand sides connect.
6		Check that the connector is correctly aligned with 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.

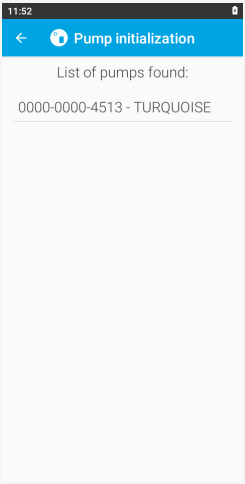
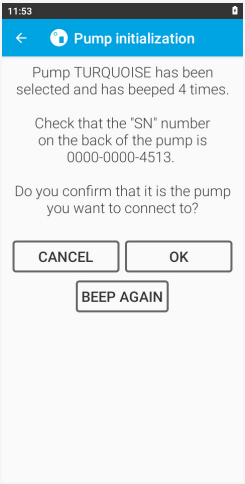
⚠ Once you have placed your pump where you want it, try not to play with it too much or bring it into contact with water during the first hour of wear. This will make sure it is stuck securely.

2.3.7 – Pairing the Kaleido pump and the DBLG1

> For the insulin pump to be visible by the DBLG1, you must fix the full cartridge into the location provided for this purpose in the pump body.

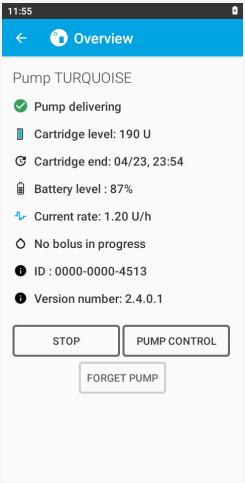
> The Kaleido pump can be identified from its color and its 12-digit identification number (ID). Once the DBLG1 suggests pairing with a given pump, make sure that the color **AND** the identification number match.
>
> Before starting the pairing procedure, check that the identification number readable 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 DBLG1.

1		Tap on ☰ > System status > [pump section] > PAIR.

2		The DBLG1 searches for the pump and displays the list of pumps found. Select the pump's serial number on the DBLG1. The DBLG1 then starts the initialization with the detected pump. Wait during this process.
3		The paired pump beeps four times. Confirm on the DBLG1 that you have heard the pump beep. Then tap OK. If you did not hear the pump beep, tap BEEP AGAIN.

4		Ensure your cartridge is new and fully filled, and tap YES.
5		Ensure the infusion set is new and fixed to your body, and tap YES.

6		Select your cannula size: 6 MM or 9 MM.
7		Before starting the pump, the system must prime the cannula. Tap PRIME. During the priming process, the DBLG1 displays the message "In progress. Please wait".

8		Your pump has been successfully primed and the DBLG1 and the pump are now paired. Tap OK to start insulin delivery.
9		The DBLG1 displays the pump overview screen.

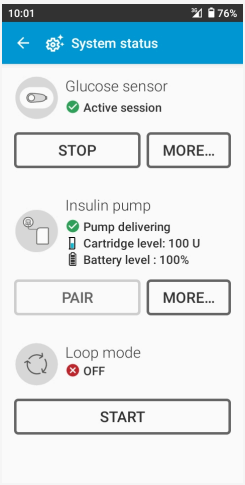
Monitor your glucose levels closely during the use of Kaleido. If you are unable to manage your glucose levels using Kaleido, or you feel that something is not right with using your pump, stop using Kaleido and switch to an alternative method of therapy as discussed with your healthcare professional.

2.3.8 – Checking the status of your insulin pump

Once your pump starts, it dispenses insulin according to your basal safety profile, which was set during the initialization phase of the DBLG1.

⚠ Important: at this stage, automatic adjustment of your insulin delivery is not yet operational since loop mode has not been started. Your DBLG1 System cannot yet send orders to the pump to adjust your insulin intake. Refer to Starting loop mode on the facing page to start loop mode on your DBLG1.

During this period, you may be required to check the status of your pump based on the messages (notifications/alerts/alarms) that you receive on your DBLG1.



Tap on ☰ > System status.

In the insulin pump section, you can see whether the pump is currently delivering or not, the remaining amount of insulin in the cartridge and the remaining battery level.

By tapping MORE you can see your current basal rate, any boluses in progress, the expiration date of the cartridge, the pump's ID number and the software version installed on your pump.

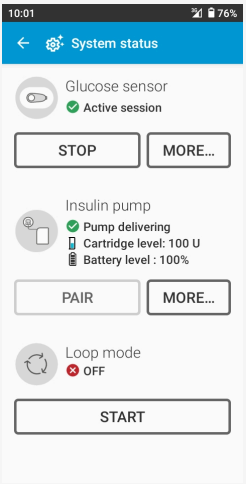
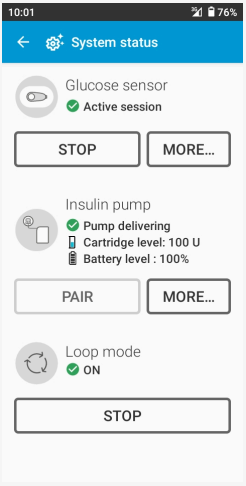
The following table describes the various pump statuses.

Status	Meaning
No insulin pump is paired	Your DBLG1 does not have any pump in its memory and therefore is not able to send it any orders.
Connecting	Transient state when configuring your pump.
Pump delivering	Your device is paired with a pump and can communicate with it via Bluetooth® to send insulin delivery commands.
Stopping	Transient state when stopping your pump.
Pump stopped	Your pump is no longer delivering insulin but is still paired with your DBLG1 and can communicate with it via Bluetooth®.
Searching	Your pump is no longer connected to the DBLG1 but is still delivering your basal safety profile. Wait for about 2 minutes; your pump should reconnect automatically.

2.4 – Managing loop mode

2.4.1 – Starting loop mode

⚠ Do not start loop mode if you have injected a meal bolus or correction bolus without the DBLG1 and the Kaleido insulin pump. Make sure you add this insulin dose to the bolus history on your DBLG1 (☰ > History > Bolus > +) before starting loop mode.

1		Tap on ☰ > System status. Make sure that your sensor is working and your insulin pump is delivering.
2		Tap START in the loop mode section. All indicators are green. You are now in closed loop mode.

2.4.2 – Checking the status of loop mode

When loop mode is ON, you can see this icon ON on the Home screen and the green indicator on the System status screen. Sometimes, the pump or the sensor may be temporarily disconnected from the DBLG1. If this happens, the loop mode icon on the Home screen switches to OFF. The pump then delivers the basal safety profile. The pump's status changes to Searching and the sensor's status changes to Signal loss.

When connection between the pump or the sensor and the DBLG1 is re-established, the pump applies orders received from the DBLG1. The loop mode status switches back to ON.

2.4.3 – Stopping loop mode

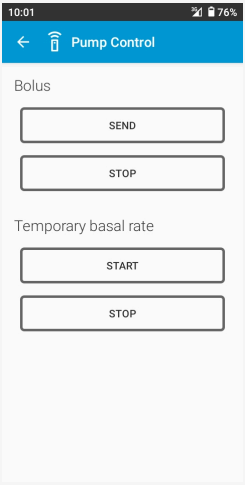
Tap on ☰ > System status > [loop mode section] > STOP.

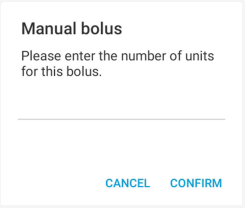
2.5 – Using your pump in daily life

2.5.1 – Controlling the pump manually

When loop mode is OFF, you can still administer a correction bolus or a meal bolus, or modify your basal rate in order to compensate for an undesirable glycemic situation. You can control your pump from the DBLG1 via the PUMP CONTROL mode.

Sending a bolus

1		Tap on ☰ > System status > [pump section] > MORE > PUMP CONTROL > [bolus section] > SEND.

2		Enter the number of units for the bolus and tap CONFIRM then OK. The DBLG1 informs you that the bolus request has been sent successfully. Tap OK again.

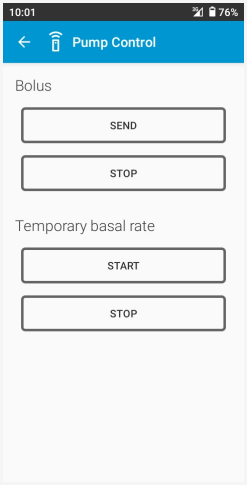
> You can enter a bolus dose of between 0.05 U and 10.00 U. If you enter a value less or greater than these two values, you will not be able to confirm the delivery of your bolus.

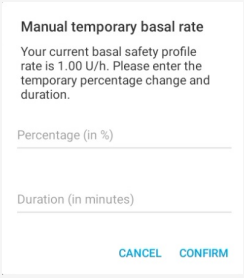
The bolus in progress is displayed on the pump's overview screen and on the Home screen. It can be stopped at any time (regardless of the status of loop mode). Tap on ☰ > System status > [pump section] > MORE > PUMP CONTROL > [bolus section] > STOP.

Once it has been fully delivered, the bolus can be viewed in the bolus history.

Sending a temporary basal rate

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

1		Tap on ☰ > System status > [pump section] > MORE > PUMP CONTROL > [temporary basal rate section] > START.

2		Enter the temporary basal rate (% of the current basal rate). The value must be a multiple of 10%. Enter the duration in minutes for which the pump should apply this rate. Tap CONFIRM.

> You can enter a temporary basal rate ranging between 0 and 200% for a period ranging from 30 minutes to 180 minutes. If you enter a rate outside this range, you will not be able to confirm the sending of this basal rate.

The temporary basal rate can be stopped at any time during administration. Tap on ☰ > System status > [insulin pump section] > MORE > PUMP CONTROL > [temporary basal rate section] > STOP. The pump then returns to your basal safety profile. The rate and duration of both the basal safety profile and temporary basal rate are visible on the pump overview screen.

2.5.2 – Stopping and restarting insulin delivery

To stop insulin delivery, tap on ☰ > System status > [pump section] > MORE > STOP. This action is immediate and does not require any confirmation.

To resume insulin delivery, tap on ☰ > System status > [pump section] > MORE > START. You can check the status of your pump to ensure that the insulin delivery has been stopped or restarted.

> ⚠ If your insulin delivery is interrupted for any reason (you stop the pump, there is a technical problem, the cartridge is leaking, there is an occlusion or the cannula has slipped out of the infusion site), check your blood glucose level and replace the missing insulin immediately.
>
> When the pump's status is **pump stopped**, it no longer dispenses insulin and the PUMP CONTROL mode is no longer accessible. You therefore will not be able to send a bolus or change your basal rate.

> If the pump stops because of an alarm-triggering condition, an alarm sounds and a message is displayed on your DBLG1.

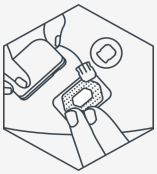
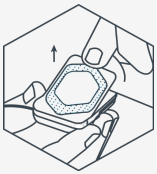
2.5.3 – Removing the pump to switch to another pump

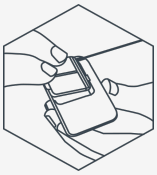
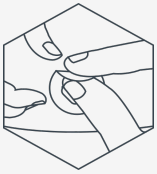
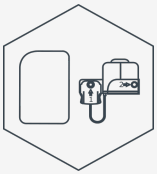
> ⚠ Always pause or stop your pump prior to removing the pump. Otherwise, insulin may be spilled.

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

Always stop your pump before removing an insulin cartridge. Failure to do so will prevent therapy data from your pump from being transferred to your DBLG1.

Remove the old insulin cartridge from the pump you were just using before connecting your DBLG1 to your new pump. In this way, you ensure that your DBLG1 is not connected to your used pump, and you can connect your new pump right away.

1	Stop the pump as described above.	
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	 	Gently remove the body patch from your skin and the pump patch from the back of your pump. 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.

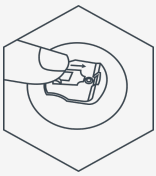
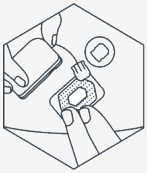
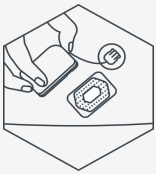
6		Take the insulin cartridge out of your pump.
7		To remove your infusion set, peel the adhesive away from your skin and then continue to peel away the whole infusion set – after a few days of use, it will have lost a little of its stickiness, but be careful not to pull it too hard.
8		Dispose of your infusion set, insulin cartridge, 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.

2.5.4 – Removing the pump temporarily

⚠ Close the protective cover on your infusion set if you choose to pause and remove your pump for a short period of time. If you leave the protective cover open, dirt may enter into the opening which may cause infections or occlusions.

If you wish to remove the pump from your body (while taking a shower or going for a swim, for instance), do not remove the cartridge. This could force you to use a new cartridge and pair a pump again with the DBLG1.

As long as the cartridge remains in place in your insulin pump, you can stop and restart the pump with the same insulin cartridge.

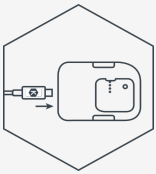
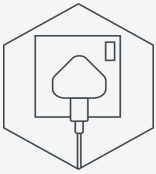
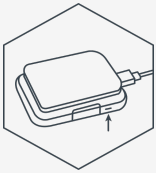
1	Stop the pump.	
2		Wash your hands thoroughly.
3		Gently squeeze the tabs on the side of your insulin cartridge connector to unclip it from your infusion set – your pump and infusion set are now separated.
4		Close the protective cover on your infusion set.
5		Lift the pump away from your body patch. 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.

2.5.5 – 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.

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.

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.

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. 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. 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. 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.

2.5.6 – Declaring an external bolus on the DBLG1

⚠ 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 in the bolus history.

You can declare different types of external bolus.

- Bolus injected with a pen or a syringe.
- Bolus injected with another pump.

⚠ If you are using one of the above types of alternative insulin therapy 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 the insulin dose.

To declare an external bolus, tap on ☰ > History > Bolus > +. Enter the time and the quantity injected and tap CONFIRM.

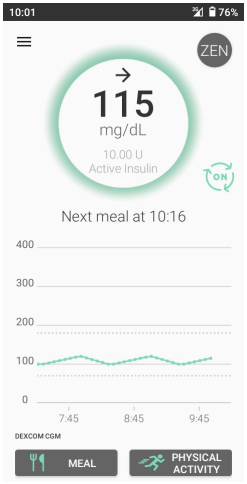
2.5.7 – Unpairing the pump

On the DBLG1, tap on ☰ > System status. In the insulin pump section, tap MORE and then FORGET PUMP.

⚠ Loop mode must be turned off to unpair the pump. Do not forget to turn loop mode on again once a new pump is paired.

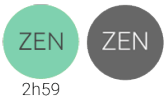
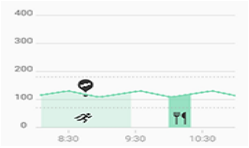
2.6 – Information displayed on the DBLG1

2.6.1 – DBLG1 Home screen



The Home screen of the DBLG1 is composed of the following elements.

- Status bar (black bar at the top of the screen) showing:
  - the time, battery level, cellular signal strength and if Bluetooth® and/or flight mode are activated.
  - when swiping down, the remaining life of the sensor, the pump's battery level and the remaining amount of insulin in the cartridge.
- Central part of the screen with:
  - the G6 reading and trend arrow.
  - contextual information relating to ongoing boluses, meals or physical activities to come, or any other useful information.
  - the daily graph with the glucose curve.
- Buttons to declare meals and physical activities.

Understanding your Home screen	
	Main menu
	Trend arrow indicating how your interstitial glucose concentration varies. Displays the G6 readings measured within the last 5 minutes. Displays the amount of active insulin.
	Green: normoglycemia Your G6 reading is between your hypoglycemia and hyperglycemia thresholds.
	Orange: hyperglycemia. Your G6 reading is above the hyperglycemia threshold that you configured. Above 400 mg/dL, the reading is replaced by HIGH.
	Red: hypoglycemia. Your G6 reading is below the hypoglycemia threshold that you configured. Under 40 mg/dL, the reading is replaced by LOW.
	Status of loop mode **ON**: loop mode is working. The color of this logo changes according to your glycemia. **OFF**: loop mode is stopped.
	Status of ZEN mode (refer to Zen mode settings on page 93). Green: ZEN mode activated. The color of this logo changes according to your glycemia. Gray: ZEN mode deactivated.
	Graph summarizing the past 3 hours, with events such as meals, rescue carbs and physical activities.
	Button for declaring a meal
	Button for declaring a physical activity

2.6.2 – Lock screen of DBLG1

The lock screen of your DBLG1 contains some of the same information as the Home screen, in particular the latest G6 reading along with the associated trend arrow.

2.6.3 – Trend arrows of the Dexcom G6 sensor

Trend arrows	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.
--	**No arrow**: cannot determine trend.

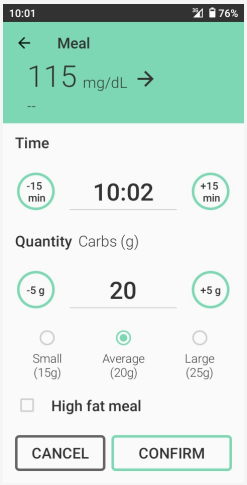
2.7 – Meals

2.7.1 – Declaring a meal

⚠ For your DBLG1 System to be as effective as possible, we recommend that you announce meals at least 15 minutes in advance. This helps in adjusting the meal bolus appropriately.

However, a meal can also be announced on the spot, or later if you forgot to do so previously. You should always declare all meals on the DBLG1.

1	On the Home screen, tap on  .
2	Enter the time at which the meal will begin or use the shortcuts.

3		Enter the quantity of carbohydrates or select a predefined quantity: Small/Average/Large. If you intend to have a high-fat meal, select this option. Your system will adjust the insulin doses to compensate for delayed hyperglycemia, which is often observed with this type of meal. Tap CONFIRM. > If you have difficulty counting your carbohydrates or determining what constitutes a high-fat meal in your case, you should contact your healthcare professional.

2.7.2 – Meal bolus recommendations

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

> You must confirm the meal bolus suggested by loop mode before it can be delivered. If you cancel the recommended bolus, you will be asked if you want to edit or delete the declared meal. If you simply cancel the bolus, you will receive a new message within 5 minutes reminding you that a bolus is necessary.

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. If necessary, loop mode will recommend a meal bolus within the next 45 minutes.
- Loop mode has detected hypoglycemia conditions (current or short term). If necessary, loop mode will recommend a meal bolus within the next 45 minutes.
- A sensor calibration is ongoing. The bolus recommendation will be displayed once the calibration has finished.

If one of the above conditions is detected, you will receive an alert (20105, 20106 or 20107 – refer to the List of alarms and alerts on page 108).

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

- If you select the option High fat meal, the period between the two boluses will be **approximately 60 minutes**.
- If you do not select the option High fat meal, the period between the two boluses will be **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, announce 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 readings and the associated trend arrow.
- An estimate of the insulin still active in your body.
- The start time of the meal and the quantity of carbohydrates that you have announced.
- The insulin dose recommended by the system.
- The type of bolus used for administering the insulin: standard or biphasic.

> The meal bolus recommendation can be adjusted if it does not appear to be appropriate. Use the buttons ⊖ and ⊕ to reduce or increase the size of the bolus.

Tap CONFIRM to start the bolus administration.

You can also decide to cancel the bolus recommendation. In this case, tap CANCEL. You will then be able to choose amongst three options: delete the meal, modify the meal or postpone the bolus.

⚠ If a bolus has not been delivered in its entirety (for example, there has been an occlusion or you have voluntarily stopped the bolus to change the insulin dose that you confirmed on the DBLG1) and you then have to supplement the bolus manually, you must take into account the insulin dose already administered when you calculate the dose for the supplement.

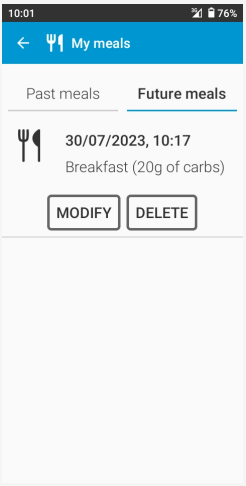
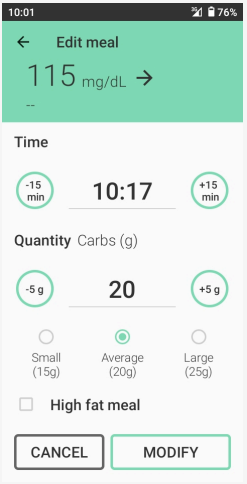
2.7.3 – Modifying or deleting a meal

If the bolus has been sent to the pump

You cannot modify or cancel a meal if your bolus has been sent to the pump.

If the bolus 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, you should change your meal declaration.

1		Tap ☰ > History > My meals and then Future meals or Past meals. Select the meal and tap MODIFY.
2		Adjust the time and/or the quantity of carbohydrates. Tap MODIFY again to save the new declaration.

The meal bolus is calculated using the new information that you just provided to your DBLG1. You can eat while listening carefully for any bolus alerts. You can still change this declaration even after you receive a bolus notification. Cancel the bolus notification and repeat the steps described above for modifying the meal.

If you have decided not to eat the meal announced to the DBLG1, delete it.

2.8 – Physical activities

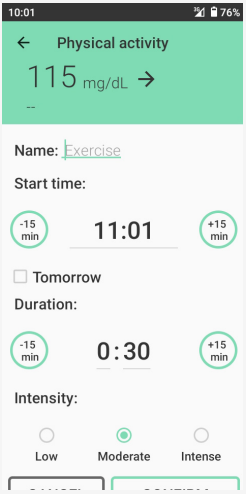
⚠ If you wish to take up a sport, you should seek advice from your healthcare professional.

⚠ When doing contact sports there's a risk of accidentally pulling out your cannula, damaging your infusion set site or damaging your pump. Therefore we recommend taking your pump off during these types of exercise.

2.8.1 – Declaring a physical activity

⚠ Loop mode automatically manages your glycemic balance during physical activities by recommending rescue carbs and by adjusting the basal flow rate and/or correction bolus if necessary.

We recommend that you declare any upcoming physical activity **at least 1 hour** before the start of the activity so that loop mode can adjust your glucose levels to avoid hypoglycemia during or after the physical activity.

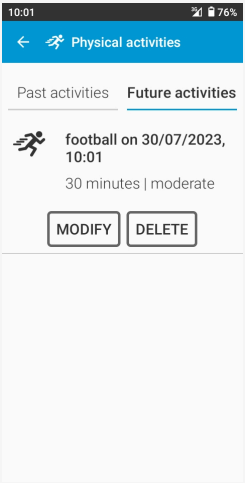
1	On the Home screen, tap on PHYSICAL ACTIVITY.
2	Enter the name of the physical activity.
3	 By default, the system suggests starting the activity in one hour. Change the time if necessary by using the shortcuts or by entering the time manually. You can declare a physical activity for the current day or for the following day. Select a duration and intensity. ⚠ Sports intensity is specific to each person. It is therefore important that you know how your body reacts to exercise in order to better adjust this declaration. Tap CONFIRM.

If necessary, do not forget to take rescue carbs while you exercise.

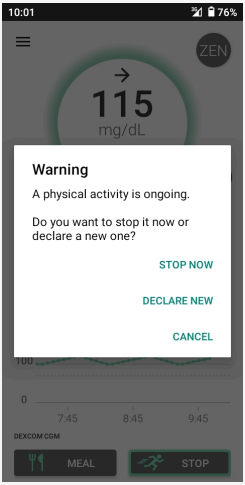
2.8.2 – Modifying or deleting a physical activity

⚠ We recommend that you always notify the system of a change in the planned activity (shorter or longer session, for example), even if the activity has already taken place. If you do not intend to do your planned sport, delete the activity.

These measures will ensure that your DBLG1 continues to make the correct adjustments.

1	Tap on ☰ > History > Physical activities.	
2		Tap on Future activities or Past activities. Tap MODIFY and change the relevant information. Tap MODIFY again to save the new information.

2.8.3 – Stopping an ongoing physical activity

1	On the Home screen, tap STOP.	
2		Confirm that you want to stop the ongoing physical activity or tap DECLARE NEW if you wish to declare another session. The actual time spent doing the physical activity will be adjusted in the history.

2.9 – Rescue carb intake

2.9.1 – Rescue carb recommendations

The rescue carb recommendation is automatically implemented by loop mode to prevent the occurrence of hypoglycemia. If your G6 reading is close to the hypoglycemia threshold that you defined, an alarm is triggered and the system recommends that you take some rescue carbs. Simply confirm the rescue carb recommendation or adjust the amount as necessary. **Make sure that you take the suggested or adjusted quantity.**

⚠ Make sure that you 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.

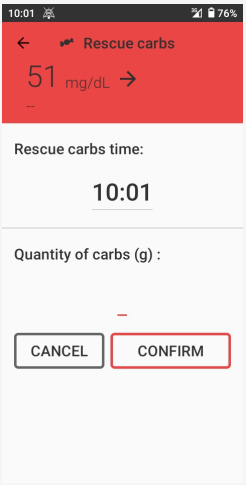
When you confirm the rescue carbs, you are redirected to the Home screen. It now indicates, under your G6 readings, the time at which you took your most recent rescue carbs. The summary graph of the last 3 hours indicates, by way of this icon , that you have confirmed a rescue carb intake.

If you decide not to take the rescue carbs but the system still considers that you are in danger of hypoglycemia, you will receive another recommendation within 5 minutes.

2.9.2 – Entering a rescue carb intake manually

⚠ Loop mode calculates and controls the rescue carb recommendations based on your predicted glycemia. Nevertheless, if you experience signs of hypoglycemia, you must check your capillary blood glucose and, if necessary, take rescue carbs and declare them manually to the system.

You cannot change a rescue carb declaration. You must therefore consume what you declared to the system. The system is more effective if you announce accurate information.

1	Tap on ☰ > Rescue carbs.	
2	Enter the time for the rescue carb intake. By default, the time shown is the current time on the DBLG1.	
3		Tap in the Quantity of carbs (g) field and enter the quantity that you plan to take or have taken. Tap CONFIRM.

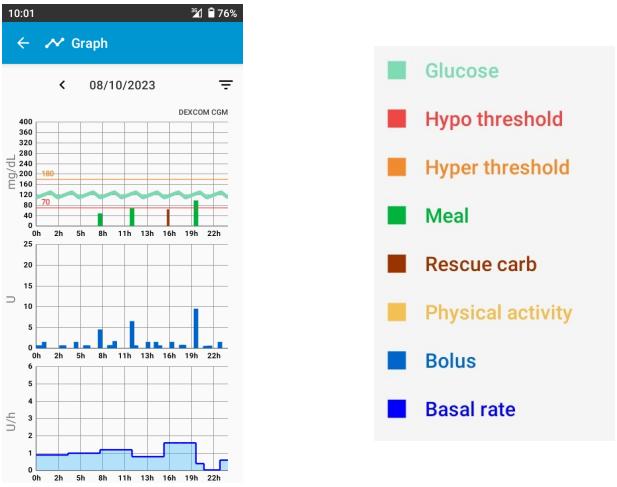
2.10 – History

Your DBLG1 stores 3 months of data (glycemia, injections, meals, activities, device events, etc.). Consult YourLoops to see all your data.

2.10.1 – History graph

Tap on ☰ > History > Graph or directly on the summary graph on the Home screen to access detailed history information. Three distinct graphs show:

- your glycemia, along with:
  - your hypoglycemia and hyperglycemia thresholds.
  - your rescue carb intakes.
  - your physical activities.
  - your meals.
- any administered correction or meal boluses.
- your basal rate.



If the DBLG1's power supply is interrupted, the data in memory is not lost. However, the date and time of the power interruption are not recorded in the events log.

After a power interruption:

- the glycemia information of the past 3 hours is recovered.
- if the pump is still paired with the DBLG1, the insulin delivery history of the past 24 hours is recovered.

Data related to any actions performed during this interruption will not be visible in the history graph for this period (for example, meals, rescue carb intakes, pen or other external boluses...). This type of information must be declared manually when the DBLG1 is restarted.

2.10.2 – Detailed history of the bolus doses

Tap on ☰ > History > Bolus to access the bolus history. The screen displays:

- the date, time and status of the bolus.
- the amount of insulin delivered.
- the **type** of bolus and its duration:
  - *Part 1* or *Part 2*: biphasic (two-stage) meal bolus,
  - *Standard*: standard meal bolus,
  - *Correction*: bolus sent by loop mode or through the PUMP CONTROL mode,
  - *Manual*: external bolus injected with another device.
- the **origin** of the bolus:
  - *Algo*: initiated by loop mode,
  - *User*: initiated by the user through the PUMP CONTROL mode.

External boluses (e.g., pen bolus or bolus with a syringe, or bolus delivered with another pump) are taken into account by the system and available in the history as soon as they have been manually declared to the system. Refer to Declaring an external bolus on the DBLG1 on page 76.

2.10.3 – Detailed history of the calibrations

Tap on ☰ > History > Calibrations to view a list of your calibrations (date and blood glucose value for each one).

2.10.4 – Statistics

Tap on ☰ > History > Statistics.

The Statistics menu displays information related to your glycemia, such as your average glucose level, 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.

2.11 – About your Diabeloop application

This section contains information about your Diabeloop application version.

The software version associated with your DBLG1 is 1.15.x.

When an update is scheduled, a notification is displayed on your DBLG1 informing you of the time for the new installation. At the end of the update, your device may restart. A popup message is displayed which informs you that the update has been completed successfully. Tap OK to confirm that you have read this information.

To view details on the application update, tap on ☰ > Help > About > Release notes.

Part 3:
System settings and customization

The DBLG1 System includes a number of key settings that may be modified to suit your needs.

- Medical settings, which include:
  - your thresholds.
  - loop mode settings.
  - patient settings such as weight, favorite meals, basal safety profile and total daily dose of insulin.
  - Zen mode settings.
- DBLG1 settings, which include:
  - sound and vibration settings.
  - your credentials (YourLoops, PIN code).
  - data sharing options.
  - language, display and time preferences.

When you change a setting:

this logo on your DBLG1 indicates that the setting can be changed at any time.

this logo on your DBLG1 indicates that the setting can be changed only if loop mode is OFF. Once the change is saved, you must restart loop mode.

3.1 – Medical settings

Since each patient has different insulin requirements, we recommend that you consult your healthcare professional for the appropriate dosage for your particular needs. Also, numerous physiological factors, such as stress or illness, can have an effect on your glycemia and therefore on your daily insulin requirements. If you experience these types of events, you should closely monitor your glycemia *and* consult your healthcare professional.

> **To change a setting go to Settings. The default, minimum and maximum values are given in a table for each setting.**

3.1.1 – Thresholds

The Thresholds settings contain your personal hyperglycemia and hypoglycemia limits, which determine how your glycemia is displayed on the DBLG1.

The hyperglycemia threshold

Hyperglycemia refers to abnormally high glycemia. When your hyperglycemia exceeds the limit that you have defined, the information on your DBLG1 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.

The hypoglycemia threshold

Hypoglycemia refers to abnormally low glycemia. When your glycemia falls below the hypoglycemia limit that you have defined, the information on your DBLG1 is displayed in RED.

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

Changing this setting will affect your future rescue carb recommendations. The lower your hypoglycemia threshold, the less likely you are to actually 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.

Settings > Medical > Thresholds	Default value	Possible range
• Hyperglycemia threshold	180 mg/dL	170 to 220 mg/dL
• Hypoglycemia threshold	70 mg/dL	60 to 85 mg/dL

3.1.2 – Loop mode settings

Loop mode includes six settings: the target glycemia, aggressiveness during normoglycemia and hyperglycemia, and aggressiveness for breakfast, lunch and dinner.

To review the settings of your DBLG1 System, consult your healthcare professional who prescribed the device to you.

Inappropriate settings can lead to hyperglycemia or hypoglycemia.

The target glycemia

The DBLG1 System uses your target glycemia 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, depending on the active insulin.

Aggressiveness of loop mode

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 carbs proposed by loop mode as rescue carbs.

> 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.

Settings > Medical > Loop mode	Default value	Possible range
• Target glucose level	110 mg/dL	100 to 130 mg/dL
• Aggressiveness in normoglycemia	100%	59% to 147%
• Aggressiveness in hyperglycemia	100%	43% to 186%
• Aggressiveness for breakfast/lunch/dinner	100%	50% to 200%

3.1.3 – Loop mode OFF settings

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

An alert (10115) is triggered when the G6 signal is lost and loop mode is OFF. You can adjust the time before the alert is triggered.

Hyperglycemia alert

An alert (10113) is triggered if hyperglycemia occurs when loop mode is OFF. You can adjust the hyperglycemia threshold above which the alert is triggered.

Hypoglycemia alert

An alert (10117) is triggered if hypoglycemia occurs when loop mode is OFF. You can adjust the hypoglycemia threshold below which the alert is triggered.

Settings > Medical > Loop mode OFF	Default value	Possible range
• Sensor signal loss alert	after 30 minutes	20 to 240 minutes
• Hyperglycemia alert	> 250 mg/dL	120 to 400 mg/dL
• Hypoglycemia alert	< 70 mg/dL	60 to 85 mg/dL

3.1.4 – Patient settings

To review the settings of your DBLG1 System, consult your healthcare professional who prescribed the device to you.

Inappropriate settings can lead to hyperglycemia or hypoglycemia.

Weight and height

Your weight is used to determine your rescue carbs factor and intake each time rescue carbs are necessary, and should be adjusted regularly as needed.

Favorite meals

Your average quantities of carbohydrates are recorded for each meal during the initialization phase of the DBLG1. Their purpose is to make your meal declarations easier.

Modifying the average quantity of carbohydrates for a given meal affects the size of the meal bolus recommended by loop mode.

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 DBLG1—and is based on your prescription. If loop mode switches off, the DBLG1 System will deliver this basal safety treatment. You can adjust your basal rates over time if you feel that they are no longer suitable for your needs.

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

Total daily dose of insulin

Your total daily dose of insulin is the average sum of the basal rates and all meal and correction boluses delivered per day. This information is entered with the help of your healthcare professional during the initialization phase of your DBLG1.

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.

Settings > Medical > Patient	Default value	Possible range
• Weight	N/A	35 to 150 kg
• Favorite meals	N/A	1 to 300 g
• Basal safety profile	N/A	0.05 to 5 U/h
• Total Daily Dose of insulin	N/A	8 to 90 U

3.1.5 – Zen mode settings

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.

To activate Zen mode from the Home screen, tap on the ZEN icon: 

Settings > Medical > Zen mode	Default value	Possible range
• Offset on target glucose level	20 mg/dL	10 to 40 mg/dL*
• Duration	3 hours	1 to 8 hours

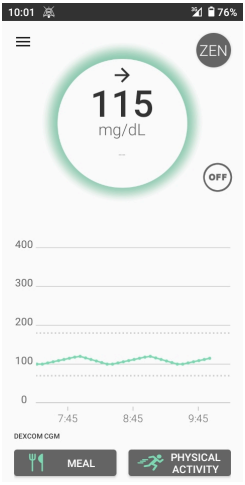
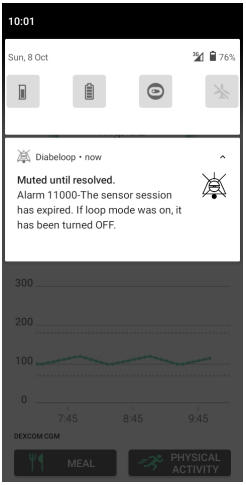
* Your target glycemia cannot be increased above 150 mg/dL.

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

3.2 – DBLG1 settings

3.2.1 – Sound and vibration settings (alerting you to a risk)

Your DBLG1 System sends messages to inform you on the status of one of the system components.

Lock screen	Home screen	
		
On the lock screen, messages are displayed under the G6 reading.	An icon displayed in the status bar indicates that there is a message.	Swipe down from the top of the Home screen to access details about the message.

The system alerts you to upcoming dangers and risks via:

- alarms, which indicate a significant danger if no action is taken.
- alerts, which indicate a non-immediate risk.
- notifications for clarification on the status of your system, with no upcoming risk.

Alarms cannot be configured. When an alarm is triggered, your DBLG1 vibrates and beeps. The volume of the beeps increases gradually.

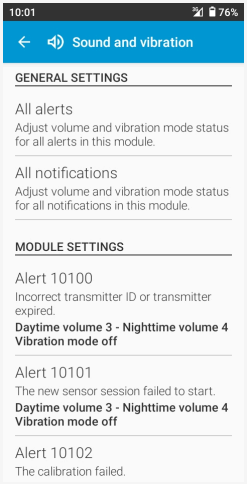
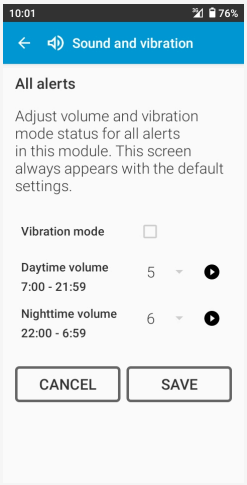
Configuring the sound of alerts and notifications

⚠ If you deactivate or reduce the sound of alerts and/or notifications, you may miss a message concerning a non-critical problem, but which could be important for the proper functioning of your system.

You can configure the sound of alerts and notifications related to your system components: insulin pump, sensor, loop mode and DBLG1.

By default, the DBLG1 System beeps twice when it sends an alert and once when it sends a notification.

Unlike alarms and alerts, notifications are not listed in this user guide. They only appear on your DBLG1.

1	Tap on ☰ > Settings > DBLG1 > Sound and vibration > *Glucose sensor* or *Insulin pump* (for example).	
2		To configure all the alerts or notifications related to the component: within the section GENERAL SETTINGS, tap All alerts or All notifications. To configure a specific alert or notification: within the section MODULE SETTINGS, scroll to the corresponding error code.
3		Select Vibration mode if you wish to use this mode. Change the Daytime volume by pressing the corresponding number. Change the Nighttime volume by pressing the corresponding number. To test the volume, tap on ▶. Tap SAVE.

3.2.2 – Credentials

From this menu, you can change your PIN code and your YourLoops login and/or password or request a password reset. You can also check that your data has been correctly uploaded to YourLoops.

PIN code

Tap on ☰ > Settings > DBLG1 > Credentials > PIN code.

Enter your current PIN code. Then enter the new PIN code and confirm it. For security reasons if the device is stolen, you should avoid using four identical digits.

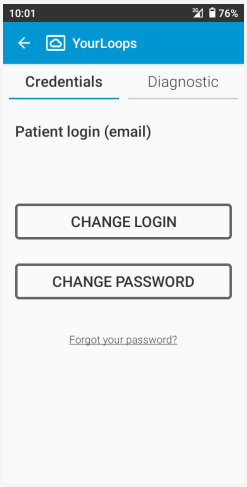
If you have forgotten your PIN code, you can request a PIN reset. On the lock screen, tap FORGOT PIN and follow the instructions on the screen.

YourLoops

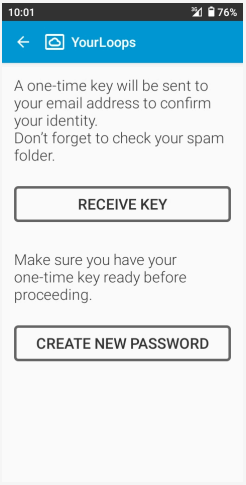
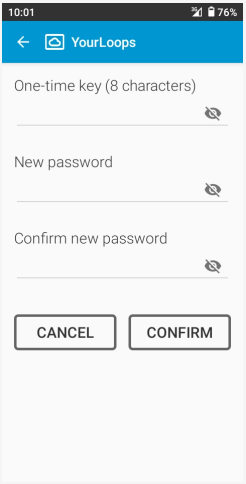
Tap on ☰ > Settings > DBLG1 > Credentials > YourLoops.

⚠ For cybersecurity reasons, the password should contain upper- and lower-case 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.

Changing your credentials

1		Tap CHANGE LOGIN or CHANGE PASSWORD.
2	Enter a new email address and confirm it. Enter your current password and then your new password and confirm it.	

Requesting a password reset

1		Tap forgot your password? on the previous screen and then RECEIVE KEY. A one-time key will be sent to your email address. Once you have received the key, tap CREATE NEW PASSWORD.
2		Enter the alphanumeric key (no spaces, with capital letters) and new password (10 characters, no spaces). Tap CONFIRM.

YourLoops diagnostic

To perform a diagnostic of your YourLoops account and check that your data has been uploaded correctly, tap on the Diagnostic tab on the YourLoops screen. If the Confidential mode has been activated, data cannot be uploaded.

3.2.3 – Data sharing

Confidential mode

You can activate Confidential mode to stop transmitting your medical data to YourLoops for a specific duration (3 hours, 1 day or 3 days). Tap on ☰ > Settings > DBLG1 > Data Sharing > Confidential mode. Alternatively, swipe down from the status bar on the Home screen and tap on the icon to activate or deactivate.

Flight mode

You can activate Flight mode so as to switch off your cellular connection for a period ranging from 3 to 24 hours. No data is transmitted to YourLoops while Flight mode is active. The transmission of data is resumed once Flight mode is deactivated. However, any data also corresponding to an active Confidential mode period during the time that Flight mode was active is not transmitted. Activating Flight mode does not deactivate your Bluetooth® connectivity.

Tap on ☰ > Settings > DBLG1 > Data Sharing > Flight mode. Alternatively, swipe down from the status bar on the Home screen and tap on the icon to activate or deactivate.

3.2.4 – Language

Change the language of the interface. Tap on ☰ > Settings > DBLG1 > Language.

3.2.5 – Preferences

Manually adjust the brightness of the screen or optimize the brightness according to the ambient lighting, and set the automatic screenlock timeout. Tap on ☰ > Settings > DBLG1 > Preferences > Display.

3.2.6 – Time

Change the time format, activate/deactivate the automatic change of time zone or manually choose the time zone. Tap on ☰ > Settings > DBLG1 > Time.

⚠ Your DBLG1 uses time zones to set the default date and time automatically when the option is enabled and when a cellular data network is available. Nevertheless, we advise you to regularly check that the time on your DBLG1 is correct, particularly when you are traveling across multiple time zones. Discuss any necessary adjustments to your settings with your healthcare professional if you plan to travel across multiple time zones.

3.2.7 – Updates

Check for system updates (operating system and/or software version) and manage the time of the update.

⚠ During an update, DO NOT switch off your DBLG1. Your device may restart automatically after the installation has finished.

Checking for updates

⚠ Make sure your DBLG1 is charged to at least 25% before proceeding with an update.

Updates cannot be installed while you are declaring a meal or a physical activity. Complete any meal declarations or physical activity declarations before proceeding with an update.

To check if an update is available, tap on ☰ > Settings > DBLG1 > Updates > Check for updates. Then tap CHECK. If an update is available, tap DOWNLOAD. If your DBLG1 has enough battery, you can choose to install the update right away (tap INSTALL NOW) or leave the update time to the default time set by the system (simply tap OK).

You can also postpone the default update time by 1 hour. In this case, tap POSTPONE 1H when you see this option (displayed up to 5 minutes before the default time). The new update time is shown on the Home screen.

Defining a specific time for an update

To define a specific time for an update, tap on ☰ > Settings > DBLG1 > Updates > Update time. Select a time and tap SAVE.

⚠ The update must be carefully monitored; for safety reasons, it cannot be programmed for night time.

Note that if an update is already automatically scheduled by the system for that day, the change of time will be applied to all future updates.

Part 4:
Warranty, maintenance and disposal

4.1 – Warranty

4.1.1 – What is covered and for how long

Diabeloop SA provides a limited warranty to the original purchaser, under which the DBLG1 System is free from defects in material and workmanship under normal use for the period starting from the date of reception to the end of the warranty period.

Warranty of the DBLG1 System: see contractual warranty.

4.1.2 – What is not covered

This limited warranty is conditional upon the proper usage of the product by the purchaser. This limited warranty does not cover: (a) defects or damages resulting from accident, misuse, abuse, neglect, unusual physical, electrical or electromechanical stress, modification of any part of the product or domestic damages; (b) equipment that has the serial number or IMEI removed or made illegible; (c) all surfaces and other externally exposed parts that are scratched or damaged under normal use; (d) malfunctions resulting from the use of the product in conjunction with accessories, products or ancillary or peripheral equipment not supplied or approved by Diabeloop SA; (e) defects or damage from improper testing, operation, maintenance, setup or adjustment; (f) setup and servicing of products; or (g) equipment that has been disassembled.

4.1.3 – Obligations of Diabeloop SA under this limited warranty

During the warranty period, Diabeloop SA will replace, at its sole expense and without any additional charge to the purchaser, any defective DBLG1 System under normal use.

The purchaser must return the product to a customer support department authorized by Diabeloop SA in its original packaging for shipping, accompanied by the purchaser's sales receipt or a comparable proof of sale showing the date of purchase, the serial number and/or IMEI of the product, as well as the distributor's name and address. For any assistance on the replacement of a DBLG1 System, contact your local support. Diabeloop SA will promptly replace the defective product. If Diabeloop SA identifies that any products are not covered by this limited warranty, the purchaser will have to pay all shipping charges for the return of the said product. If the returned product is out of warranty, the purchaser may be billed for the replacement product.

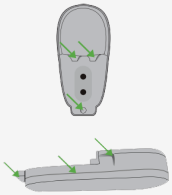
4.2 – Cleaning and storage

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

Never try to clean any of the components of the DBLG1 System while it is connected to a power source.

4.2.1 – Dexcom G6

Cleaning the transmitter

1	Preparation	Protect yourself by wearing clean gloves and goggles. Prepare the soak by putting Clorox Healthcare® Bleach Germicidal Cleaner solution (Clorox) in a container deep enough to submerge the transmitter.	
2	Cleaning		Rinse the transmitter in cold tap water scrubbing it with a soft bristle brush until all visible grime is gone. 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. Wipe the transmitter dry with a cloth.	
4	Inspection	Check that there is no visible soil. If there is, clean it again.	

Disinfecting the transmitter

1	Preparation	Protect yourself by wearing clean gloves and goggles. Prepare the soaking solution and the syringe: put CaviCide® solution in a container deep enough to submerge the transmitter and fill the syringe with about 30 mL of Cavicide.

2	Disinfection	Rinse: focus on the uneven areas. Swirl in Cavicide for 10 seconds and refill the syringe. Scrub: saturate a clean cloth or wipe with Cavicide and wipe the entire transmitter for at least 3 minutes or until all grime has been removed. Focus on the uneven areas. Rinse: as before, focus on the uneven areas and swirl in Cavicide for 10 seconds. Soak: put the transmitter in the prepared soak. Swirl it for 30 seconds and let it soak for another 3 minutes.
3	Rinsing and drying	Remove the transmitter from the soaking solution and rinse it under flowing cold tap water for 10 seconds. Wipe the transmitter dry with a cloth.

Storage

Storing your G6 correctly will help prevent system failures.

Sensor	Keep it in its sterile packaging until you are ready to use it. 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. 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%.

4.2.2 – Kaleido insulin pump

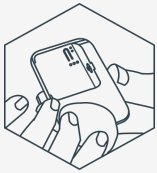
Cleaning

⚠ 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.
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.	

Most liquid soaps and baby shampoos are PH neutral. Never use harsh chemical cleaning detergents to clean your Kaleido products.

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.

4.2.3 – DBLG1

⚠ Never try to clean the DBLG1 while it is connected to a power source.

⚠ The DBLG1 is not waterproof. Do not use too much water during the cleaning process.

Cleaning

Unplug all cables from the DBLG1.

Use a soft cloth that is only **slightly dampened** with soapy water to clean the outside of the DBLG1. Do not clean the electrical connections.

Storage and transport

Use the original packaging whenever shipping or storing the DBLG1. Disconnect the cables from the DBLG1 during shipping. We recommend removing the battery from the DBLG1 for shipping.

	Minimum	Maximum
Temperature	–25°C	+70°C
Relative humidity (non-condensing)	15%	90%
Atmospheric pressure	700 hPa	1060 hPa

4.3 – Disposal and waste management

⚠ Your healthcare professional will be able to advise you on how to dispose of medicines that you no longer need, as well as items that have been contaminated with medicine and the waste generated through use of the DBLG1 System.

You should also contact your local authority for advice on the proper method of disposal of biohazardous material.

⚠ It is important to 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 (biological hazards).

4.3.1 – 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 for disposing of injection equipment.

Contact your local support for the waste management methods in your region.

4.3.2 – 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.

4.3.3 – DBLG1

The abandonment or uncontrolled disposal of waste can cause harm to the environment and to human health.

Contact your local support for the disposal of your DBLG1. The DBLG1 will then be returned by your local support to Diabeloop SA for destruction. Any health data stored on the DBLG1 will be erased by Diabeloop SA before the DBLG1 is destroyed. The SIM card is the property of Diabeloop SA and must be returned with the DBLG1.

Part 5:
Alarm system and troubleshooting

5.1 – Alarm system

The DBLG1 is a relay for the alarm conditions of your glucose sensor and your pump. It will also trigger its own alarms, alerts and notifications when specific conditions are met.

⚠ 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.

⚠ The G6 sensor does not have its own alarm transmission system. If connection is lost for more than 30 minutes, your DBLG1 will trigger an alarm. Use the glycemia value obtained from fingerstick glycemia testing, measured using your 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.

If your DBLG1 is fully powered off (deliberately shut down or malfunctioning) but your pump is still operational, if any events occur on the pump, you will be alerted via audio signals from the pump.

When the DBLG1 is switched on, it displays the corresponding event on the screen if it is still in the pump's memory. The error code is visible in the Events menu. A total power outage will not affect the events that are already recorded in the DBLG1 memory.

5.1.1 – Classification of the alarm system

Diabeloop designation and symbol	Description	Conformity with standard EN 60601-1-8
Alarms	Indicate a significant danger that requires immediate action	High-priority alarms
Alerts	Lower priority than an alarm	Low-priority alarms
Notifications	Inform you about the status of your system	N/A

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

5.1.2 – Testing the alarm system

To test the sound of the alarm system, go to ☰ > Help > Support > Sound.

> The tested sound is played at its maximum volume. The purpose of this feature is to check that the sound of the DBLG1 is operational.

5.1.3 – Symbols associated with the alarm system

The symbols associated with the alarm system appear on the DBLG1 as popups on the lock screen and as icons in the status bar of the Home screen.

Symbol	Definition as per standard EN 60601-1-8
	Indicates that you have acknowledged an alarm and/or alert for an undetermined duration (there will be no reminder). The symbol only disappears once the condition that triggered the alarm has been resolved.
	Indicates that you have acknowledged an alarm and/or alert for a given time interval (temporarily muted). This interval is indicated in the column entitled "Reminder interval after acknowledgment".
	Indicates that the sound of an alert and/or notification has been silenced.

5.1.4 – List of alarms and alerts

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, you will receive a reminder after a certain lapse of time.

An alarm has priority over an alert or notification.

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 alarms are only triggered when loop mode is OFF.

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

If you receive an insulin blockage alarm 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 insulin blockages.

When an alarm or alert is triggered, it is displayed on your DBLG1 within 1 second.

All alarms, alerts and notifications are saved and displayed in the Events menu of the DBLG1.

ALARM SYSTEM OF THE INSULIN PUMP		
Error code + Name	**Description and reminder**	**Action to be taken**
⚠ Alarm / 🔔 Alert / Reminder if problem not resolved		
⚠ **41001 Empty pump battery**	The pump will stop because its battery is empty. The pump can no longer deliver insulin.	1. Detach your insulin pump from your skin. 2. Remove the insulin cartridge from the pump. 3. Prepare and pair your second pump and then charge the discharged pump.

ALARM SYSTEM OF THE INSULIN PUMP		
Error code + Name	**Description and reminder**	**Action to be taken**
⚠ Alarm / 🔔 Alert / 🔔 Reminder if problem not resolved		
⚠ **41002 Empty insulin cartridge**	Your pump stopped because the insulin cartridge is empty. The pump can no longer deliver insulin.	1. Remove the empty cartridge from the pump. 2. Prepare a new insulin cartridge and insert it into the pump. Note: this might be the right time to change your pump.
⚠ **41003 Insulin cartridge expired**	Your pump stopped because the insulin cartridge has expired. The pump can no longer deliver insulin.	1. Remove the expired cartridge from the pump. 2. Prepare a new insulin cartridge and insert it into the pump. Note: this might be the right time to change your pump.
⚠ **41004 Occlusion**	The pump has stopped because it has detected an occlusion. The pump can no longer deliver insulin.	1. Check your glycemia and treat the glycemic situation as needed as a priority. 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. 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 again with the DBLG1. 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 again with the DBLG1. 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 infusion set. 6. Lastly, if needed, switch to an alternative method of insulin therapy and contact your local support. **In all cases, 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 / 🔔 Reminder if problem not resolved		
⚠ **41005 Internal pump problem**	The pump stopped due to a malfunction. 🔔: Every 5 minutes	1. Restart the DBLG1. 2. Reconnect and/or restart your pump. 3. If the alarm persists, contact your local support to have the equipment replaced. 4. Use the second pump or switch to the alternative insulin therapy. 5. Check your glycemia and adjust the insulin if necessary.
⚠ **41007 The insulin cartridge was removed from the pump while it was running**	The insulin cartridge was removed from the pump while it was running. The pump stopped and can no longer deliver insulin.	1. Insert the cartridge correctly into the pump until you hear 2 beeps. 2. Pair your pump with the DBLG1 again. If you do not see the alarm on the DBLG1, remove the cartridge completely from the pump and then reinsert it before pairing the pump again.
⚠ **41008 Pump reset**	Your pump has reset. The pump stopped and can no longer deliver insulin.	1. Pair the pump with the DBLG1 one more time and restart it. 2. If this is not possible, use the second pump and pair it, or use your alternative insulin therapy. 3. Contact your local support to return and replace the equipment.
🔔 **40101 Low pump battery**	The battery level of the pump is low. There is less than 10% charge remaining.	1. Schedule a pump change. 2. Connect the discharged pump for charging as soon as you have changed it.
🔔 **40102 Low insulin reservoir level**	There are less than 25 U remaining.	Schedule a cartridge change. Note: this might be the right time to change your pump.
🔔 **40103*** **Insulin cartridge will expire soon**	The insulin cartridge will expire in less than 2 hours.	Schedule a cartridge change. 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 / 🔔 Reminder if problem not resolved		
🔔 **40104 Connection with the pump has been lost**	The system detected a loss of connection between the pump and the DBLG1 for more than 30 minutes. The pump is delivering the basal safety profile.	1. Bring the DBLG1 and the insulin pump closer together if they are further away from each other than the recommended distance. 2. Cancel the search for the insulin pump (tap on ☰ > System status > CANCEL in the pump section), then restart the DBLG1. 3. If this fails, switch to the second pump, pair it and contact your local support.
🔔 **40105 Failure in sending a meal bolus to the pump**	The sending of the last validated meal bolus failed. 🔔: Every 5 minutes	1. Wait for the next bolus recommendation (about 5 minutes). 2. Confirm the bolus recommendation to administer the corresponding dose of insulin. 3. If it still fails, use your alternative insulin therapy to administer the meal bolus and declare it on the DBLG1. Note: contact your local support if the alert repeats.
🔔 **40106 Insulin cartridge will expire soon**	The insulin cartridge will expire in less than 6 hours.	Schedule a cartridge change. Note: this might be the right time to change your pump.
🔔 **40108 Unsupported version of pump**	This pump version is not compatible with the DBLG1 System.	Contact your local support.

*** This alert is only applicable to pump versions 2.5.0 and previous. Refer to the pump's overview screen to see which pump version you currently have.**

ALARM SYSTEM OF THE SENSOR		
Error code + Name	**Description and reminder**	**Action to be taken**
⚠ Alarm / 🔔 Alert / Reminder if problem not resolved		
⚠ **11000 Sensor session expired**	The sensor session has expired. **IMPORTANT:** if loop mode was ON, it has been turned OFF.	1. Remove the sensor and transmitter. 2. Dispose of the sensor according to the applicable rules of the country. 3. Insert a new sensor to start a new 10-day session. **IMPORTANT:** loop mode is OFF during the warmup period of a new sensor.
⚠ **12000 Hypoglycemia**	Your glycemia is below 55 mg/dL. **IMPORTANT:** this alarm is triggered only if loop mode is OFF. : 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. 2. Check the current insulin delivery. 3. Take rescue carbs and declare the rescue carb quantity on the DBLG1. 4. Contact your healthcare professional if necessary.
⚠ **13000 Permanent failure of the sensor**	There is a sensor error and no glucose readings are being received. Loop mode has been turned OFF. : Every 5 minutes	1. Remove the sensor and transmitter. 2. Change the sensor to start a new 10-day session. 3. Restart loop mode. 4. Keep the old sensor and contact your local support to arrange for an investigation.
⚠ **14000 Transmitter failure**	There is a transmitter error and no glucose readings are being received. Loop mode has been turned OFF.	1. Change the sensor and the transmitter and start a new session. 2. Restart loop mode.

ALARM SYSTEM OF THE SENSOR		
Error code + Name	**Description and reminder**	**Action to be taken**
⚠ Alarm / 🔔 Alert / 🔔 Reminder if problem not resolved		
⚠ **15000 Glucose readings have been above 320 mg/dL for 20 minutes or more**	Your glucose has been above 320 mg/dL for 20 minutes or more. 🔔: 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. 2. Check your ketones. 3. Treat the glycemic situation as needed as a priority. 4. Check the status of your system pump, infusion set) and loop mode. Visually inspect your tubing for obstructed or bent areas. 5. Change your infusion set and your cartridge if necessary. 6. Use your alternative insulin therapy if necessary. 7. If the alert persists, contact your healthcare professional.
🔔 **10100 Incorrect transmitter ID or transmitter expired**	The entered ID is incorrect or the transmitter has expired. It is not possible to pair the DBLG1 and the transmitter.	• Make sure the transmitter is flat and snug in its holder. • Check the expiration date of the transmitter. • Check that the ID of the transmitter in the DBLG1 corresponds to the one currently in use. • Repeat the transmitter search step on the DBLG1. • If all else fails, change your transmitter. Check your blood glucose during the warmup period because your sensor is not yet operational.

ALARM SYSTEM OF THE SENSOR		
Error code + Name	**Description and reminder**	**Action to be taken**
⚠ Alarm / 🔔 Alert / 🔔 Reminder if problem not resolved		
🔔 **10101** **The new sensor session failed to start**	The launch of the sensor session failed.	1. Check the expiration date of the sensor and transmitter. Change your equipment if necessary. 2. Restart the session. 3. If the alert persists, contact your local support. Never use equipment that has expired.
🔔 **10102** **The calibration failed**	The calibration of the sensor failed.	1. Redo a calibration with your blood glucose meter. 2. Enter this value in the DBLG1.
🔔 **10103** **Failed to stop the sensor session**	The request to stop the sensor session failed.	1. Wait for 5 minutes after the first stop attempt. 2. Try again. 3. If the problem persists, restart the DBLG1 and then try again.
🔔 **10104** **The sensor will expire soon**	The sensor will expire within the next 12 hours. **IMPORTANT**: a sensor check is performed twice a day. When loop mode is ON, this alert can only be triggered at the time of a breakfast or dinner bolus. When loop mode is OFF, it can only be triggered at 9 am and 6 pm.	Schedule a sensor replacement.

ALARM SYSTEM OF THE SENSOR		
Error code + Name	**Description and reminder**	**Action to be taken**
⚠ Alarm / 🔔 Alert / 🔔 Reminder if problem not resolved		
🔔 **10105** **The transmitter will expire soon**	Your transmitter will expire within the next 24 hours. **IMPORTANT**: a transmitter check is performed twice a day. When loop mode is ON, this alert can only be triggered at the time of a breakfast or dinner bolus. When loop mode is OFF, it can only be triggered at 9 am and 6 pm.	Schedule a transmitter change.
🔔 **10107** **The transmitter is about to expire. Sensor session failed to start.**	The transmitter is about to expire. It is not possible to start a new sensor session with this transmitter.	1. Dispose of the expired transmitter according to the standards in force concerning the management of biohazardous electronic waste. 2. Use a new transmitter and pair the sensor to the DBLG1. 3. Check your blood glucose during the warmup period because your sensor is not yet operational.
🔔 **10109** **Sensor error, calibration needed in 15 minutes**	The sensor is experiencing an error and cannot provide readings. The system will need to be calibrated in 15 minutes.	1. Use your blood glucose meter within 15 minutes to get a meter value. 2. Enter this value in the DBLG1. 3. Wait for 5 minutes to ensure that the calibration has been saved. View the calibration history of your DBLG1 if needed.

ALARM SYSTEM OF THE SENSOR		
Error code + Name	**Description and reminder**	**Action to be taken**
⚠ Alarm / 🔔 Alert / 🔕 Reminder if problem not resolved		
🔔 **10110** **Sensor session stopped because the sensor has already been used**	The current sensor has already been used.	Change your sensor and restart the session.
🔔 **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. **IMPORTANT:** this alarm is triggered only if loop mode is OFF. 🔕: 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. 2. Check the current insulin delivery. 3. Take rescue carbs and declare the rescue carb quantity on the DBLG1. 4. Contact your healthcare professional if necessary.

ALARM SYSTEM OF THE SENSOR		
Error code + Name	**Description and reminder**	**Action to be taken**
⚠ Alarm / 🔔 Alert / 🔔 Reminder if problem not resolved		
🔔 **10113** **Your glucose is high**	Glucose readings are above your configured threshold (250 mg/dL by default). **IMPORTANT:** this alert is triggered only if loop mode is OFF. 🔔: 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. 2. Check your ketones. 3. Treat the glycemic situation as needed as a priority. 4. Check the status of your system pump, infusion set) and loop mode. Visually inspect your tubing for obstructed or bent areas. 5. Change your infusion set and your cartridge if necessary. 6. Use your alternative insulin therapy if necessary. 7. If the alert persists, 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. **IMPORTANT:** this alert is triggered only if loop mode is OFF.	Do not calibrate. 1. Do not ignore how you feel. Use your blood glucose meter to make diabetes treatment decisions or, if needed, seek immediate medical attention. 2. Take a rescue carb if necessary and declare it on your DBLG1. 3. Check the transmitter. Make sure it is flat and snug in its holder. 4. Wait up to 3 hours. If the problem continues, contact your local support. No alarms/alerts or G6 readings until the problem is fixed.

ALARM SYSTEM OF THE SENSOR		
Error code + Name	**Description and reminder**	**Action to be taken**
⚠ Alarm / 🔔 Alert / 🔕 Reminder if problem not resolved		
🔔 **10115 Lost communication with transmitter**	Communication with the transmitter failed. The DBLG1 displays the symbol (--) instead of readings. The time interval for this alert can be configured. **IMPORTANT:** this alert is triggered only if loop mode is OFF.	Do not calibrate. 1. Check that the DBLG1 and the transmitter are within 2 meters of each other and that there are no obstacles in between. 2. Wait up to 30 minutes. 3. If the problem persists, contact your local support. No alarms/alerts or G6 readings until the problem is fixed. Use your meter for any treatment decisions.
🔔 **10116 Unsupported version of transmitter**	This transmitter version is not compatible with the DBLG1 System.	Contact your local support.
🔔 **10117 Your glucose is low**	Glucose readings are below your configured threshold (70 mg/dL by default). **IMPORTANT:** this alert is triggered only if loop mode is OFF. 🔕: 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. 2. Check the current insulin delivery. 3. Take rescue carbs and declare the rescue carb quantity on the DBLG1. 4. Contact your healthcare professional if necessary.

ALARM SYSTEM OF LOOP MODE		
Error code + Name	**Description and reminder**	**Action to be taken**
⚠ Alarm / 🔔 Alert / 🔔 Reminder if problem not resolved		
⚠ **21000 No glucose readings for over 30 minutes**	The system has not received any glucose readings for over 30 minutes. Loop mode is OFF. Loop mode will restart automatically once sufficient readings have been received. **IMPORTANT**: this alarm stops loop mode. The system is delivering your basal safety profile.	1. Check your glycemia using a blood glucose meter. 2. Bring the DBLG1 and the G6 closer together if they are further away from each other than the recommended distance. 3. Check the status of the sensor and loop mode. 4. Check for sensor-related error messages in the Events menu of the DBLG1. Resolve the problem in case of an error message.
⚠ **22000 Loop mode failed to start**	Loop mode failed to start. The system is delivering your basal safety profile. **IMPORTANT:** this alert is triggered only if loop mode is OFF.	1. Check that the sensor and the pump are running. 2. Restart loop mode from the System status screen.
⚠ **23000 Rescue carbs are recommended**	A rescue carb intake is recommended by the system. **IMPORTANT**: this alarm is triggered only if loop mode is ON. 🔔: Every 35 minutes	1. Stop all ongoing activities. 2. Follow the rescue carb recommendation or change the quantity as needed. 3. Confirm the alarm to validate the amount of rescue carbs taken. 4. Wait for 30 minutes and check your glycemia regularly.

ALARM SYSTEM OF LOOP MODE		
Error code + Name	**Description and reminder**	**Action to be taken**
⚠ Alarm / 🔔 Alert / 🔔 Reminder if problem not resolved		
⚠ **24000 Hypoglycemia**	You have been in hypoglycemia for at least 25 minutes. **IMPORTANT**: this alarm is triggered only if loop mode is ON. 🔔: Every 30 minutes if the conditions are still present	1. Take some rescue carbs if necessary. 2. Declare the rescue carb intake (Rescue carbs menu) on your DBLG1.
🔔 **20100 No glucose readings for over 15 minutes. Risk of hypoglycemia.**	The system has not received any glucose readings for over 15 minutes. However, the last known reading was less than 100 mg/dL. **IMPORTANT**: this alert is triggered only if loop mode is ON.	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. 2. Bring the DBLG1 and the G6 closer together if they are further away from each other than the recommended distance. 3. Check the status of the sensor. 4. Contact your local support if necessary.
🔔 **20101 A meal bolus is recommended**	A meal bolus is recommended by the system. **IMPORTANT**: this alert is triggered only if loop mode is ON. 🔔: Every 5 minutes if the bolus is not sent.	1. Unlock the DBLG1. 2. Change the quantity as needed and confirm or reject the meal bolus suggestion.

ALARM SYSTEM OF LOOP MODE		
Error code + Name	**Description and reminder**	**Action to be taken**
⚠ Alarm / 🔔 Alert / 🔔 Reminder if problem not resolved		
🔔 **20102 Rapid rise in glucose level**	A sudden rise in glycemia has been detected. **IMPORTANT**: this alert is triggered only if loop mode is ON. 🔔: 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. 2. Treat the glycemic situation as needed as a priority. 3. Declare your meal if you have forgotten to do so. 4. Check the status of your system (pump and infusion set) and loop mode. Visually inspect your tubing for obstructed or bent areas. 5. Check the cartridge for any bubbles. 6. Change your infusion set and your cartridge if necessary. 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. **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 DBLG1 aside for your sports session).	1. Check that the sensor and the pump are running. 2. Restart loop mode from the System status screen. 3. Check the Events menu in the DBLG1, and then resolve the problem if an error message caused the shutdown.

ALARM SYSTEM OF LOOP MODE		
Error code + Name	**Description and reminder**	**Action to be taken**
⚠ Alarm / 🔔 Alert / 🔔 Reminder if problem not resolved		
🔔 **20105** **A sensor calibration is ongoing. The bolus recommend-ation cannot be computed for the time being.**	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.
🔔 **20106** **No meal bolus can be delivered at this time because hypoglycemia conditions have been detected**	Loop mode has detected hypoglycemia conditions and cannot recommend a meal bolus right away. If necessary, a recommendation will be sent within the next 45 minutes.	First, treat the hypoglycemia situation. Eat your meal as planned and listen out for a meal bolus recommendation. You will receive one within the next 5 to 45 minutes if it is required. **DO NOT inject yourself a bolus manually.**
🔔 **20107** **No meal bolus will be delivered for the time being because you have enough active 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 within the next 45 minutes.	Eat your meal as planned and listen out for a meal bolus recommendation. You will receive one within the next 5 to 45 minutes if it is required. **DO NOT inject yourself a bolus manually.**

ALARM SYSTEM OF DBLG1		
Error code + Name	**Description and reminder**	**Action to be taken**
⚠ Alarm / 🔔 Alert / 🔔 Reminder if problem not resolved		
⚠ **61000 The handset battery is very low**	The DBLG1's battery is very low (5%). Your DBLG1 may shut down. 🔔: Every 15 minutes	Charge your DBLG1 as soon as possible. To be on the safe side, charge your DBLG1 every night.
⚠ **62000 Internal error detected**	Your DBLG1 may not be operating normally. 🔔: Every 5 minutes	The DBLG1 regularly tests all functionalities. If one of these tests fails, this alarm is triggered. You must restart the DBLG1 to resume normal operation. If this alarm occurs again after restarting, return the DBLG1 to your local support.
⚠ **63000 Problem detected by the supervisor**	The supervisor has detected a problem. Your DBLG1 does not seem to be operating normally. 🔔: Every 5 minutes	Restart your DBLG1. If the problem persists, return the DBLG1 to your local support.
🔔 **60100 Low handset battery**	The DBLG1's battery is low (15%). 🔔: Every 15 minutes	Charge your DBLG1 as soon as possible. To be on the safe side, charge your DBLG1 every night.

5.2 – Troubleshooting

5.2.1 – 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.

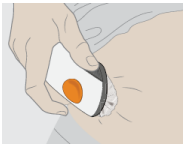
Calibrating may help align your G6 readings with your meter values.

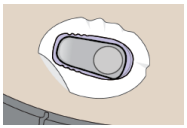
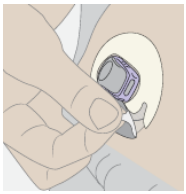
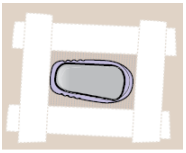
G6 readings do not match symptoms

If your G6 readings do not match your symptoms:

- Wash your hands with soap and water. 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 	1. Gently peel off the adhesive patch with applicator attached.  2. Check the insertion site to make sure the sensor is not left in the skin. 3. Do not reuse the applicator. 4. Contact your local support.

Issue	Solution
Adhesive patch peeling off body 	Once your sensor has been inserted, you can reduce peeling by putting an Overpatch or medical tape (such as Blenderm) over the adhesive patch. Do not cover the transmitter. Avoid open wounds. To order an Overpatch, contact your local support.  **Overpatch**  **Medical tape** For your next sensor session, you can prevent peeling before inserting your sensor by: • making sure your skin is clean and dry before inserting the sensor. • using adhesive products (such as Mastisol®, SkinTac™) under the patch and avoiding the spot where the needle inserts. • 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.

Part 6:
Technical specifications

6.1 – Medical device and general information

6.1.1 – Essential performance

The following requirements have been identified as essential performance, as per the EN 60601-1 medical standard.

- The device must embed a graphical user interface allowing the user to:
  - declare meal intakes.
  - declare physical activities.
  - customize the system settings in order to achieve optimal glycemic performances.
  - display the data of interest to the patient, including glycemia, delivered insulin, meals, rescue carb intakes and physical activities declared in the system.
- The device must embed 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 DBLG1 must embed a Bluetooth® Low Energy communication protocol with the sensor and with the pump, in order to:
  - transfer the insulin recommendations computed by loop mode to the insulin pump so as to inject the required amount of insulin.
  - transfer the estimated glycemia measurements to loop mode.
- The device must trigger low, medium and high priority messages coming from the DBLG1, the sensor and the insulin pump, with appropriate sound levels and tone.

6.1.2 – Service life of the components

Component	Service life
Sensor	10 days
Transmitter	3 months
Insulin pump	4 years
Cartridge	3 days
DBLG1	4 years

6.1.3 – Potential risks

Risks related to sensor use

General risks related to sensor use may include:

- skin rash.
- infection.
- allergic reaction.
- sensor breakage or damage.

Risks related to insulin administration and Kaleido pump use

Due to the use of insulin, there is a risk related to the infusion of insulin and the potential interruption of insulin delivery. These general risks may include:

- hypoglycemia.
- hyperglycemia.
- severe hyperglycemia with or without ketosis.
- severe hypoglycemia.
- coma.
- death.
- pump breakage or damage.

Risks related to the infusion set of the insulin pump

General risks related to the infusion set of the insulin pump may include:

- localized infection.
- skin rash.
- allergic reaction.
- occlusions that can interrupt insulin delivery and lead to hyperglycemia or severe hyperglycemia with or without ketosis.
- pump breakage or damage.

Risks related to the Diabeloop system

General risks related to the Diabeloop system may include:

- communication issues with the pump and sensor that can lead to hyperglycemia or hypoglycemia.
- software issues that can lead to hyperglycemia / severe hyperglycemia or hypoglycemia / severe hypoglycemia.
- usage error (no alarm/alert hearing, error in meal / rescue carb intake declaration, wrong calibration, wrong external insulin delivery declaration), that can lead to severe hypoglycemia or severe hyperglycemia with or without ketosis.

Risks related to cybersecurity

The Diabeloop system has been developed and manufactured in compliance with state-of-the

art cybersecure principles. Security of use is dependent on the user's compliance with the terms and conditions of use and data privacy policies.

General risks related to cybersecurity may include:

- disclosure of data if the device 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.
- phishing attacks (Diabeloop will never request your login or password).
- disclosure of data from lack of awareness of best practices relating to cybersecurity (for example, password strength or reuse, PIN codes, etc.).

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 ensure 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

6.2 – Dexcom G6

6.2.1 – Performance characteristics summary

When LOWER is better

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

When HIGHER is better

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

*Reference is Yellow Springs Laboratory Instrument (YSI).

6.2.2 – Technical specifications of the product

Technical specifications of the sensor

Glucose range	40–400 mg/dL
Calibration range	20–600 mg/dL Recommended 40–400 mg/dL
Useful life of the sensor	Up to 10 days
Storage and transport conditions	Temperatures: 2°C – 30°C 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 Relative humidity (RH): 10% – 95%
Storage and transport conditions	Temperatures: 0°C – 45°C 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
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

6.2.3 – 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) IEC 61000-4-2	±8 kV contact ±15 kV air
Magnetic field (50Hz) IEC 61000-4-8	30 A/m
Electric fast transient / burst IEC 61000-4-4	N/A
Surge IEC 61000-4-5	N/A
Voltage dips and interruptions IEC 61000-4-11 IEC 60601-1-11	N/A
Conducted Field Disturbance IEC 61000-4-6	N/A
Radiated Field Disturbance IEC 61000-4-3	10 V/m at 80 MHz to 2700 MHz (AM modulation)
Radiated and conducted fields Aircraft use	FAA RTCA / DO-160 edition G section 20 category T 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 CISPR 11	Group 1, Class B
RF emission Aircraft use	Meets FAA RTCA / DO-160 edition G Section 21, Category M for in-cabin use

6.2.4 – Radio regulations compliance

For radio regulations compliance statements, refer to Dexcom.com.

6.3 – Kaleido insulin pump

6.3.1 – Technical specifications

Technical specifications of the insulin pump

Environmental operating and storage conditions	Temperature range: 5°C – 37°C Humidity range: 15% – 93% relative humidity, non-condensing Pressure range: 0.7 bar – 1.06 bars
Dimensions	Pump: 12.5 mm x 50 mm x 35 mm Charging dock: 60 mm x 45 mm x 15 mm
Weight	Pump: 19 g Charging dock: 13 g
Insulin cartridge capacity	200 U
Ingress protection	Pump: IP68 (dustproof and waterproof up to 1.5 meters for 1 hour) 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 Insulin cartridge, infusion set, body and pump patches: single use, up to 3 days in use Alcohol wipes, syringes and needles: single use

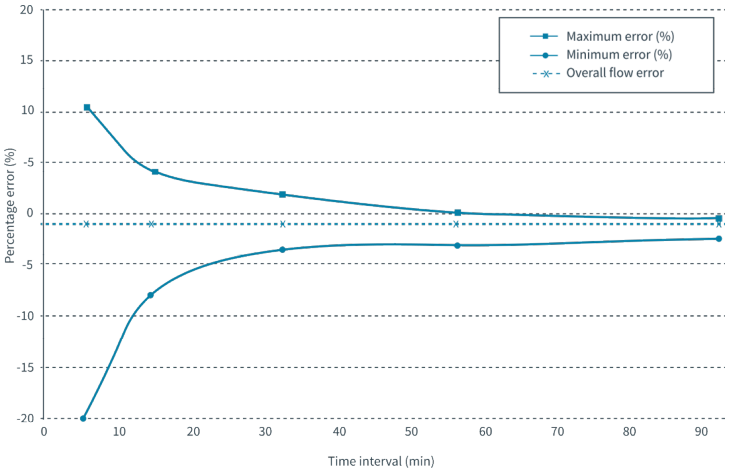
Alarm volume	>50 dB
Wireless radio	Bluetooth® Low Energy Class 3 transmitter with peak power of 1 mW
Wireless frequency	2.4 GHz
Delivery accuracy	±5% in all operating conditions
Maximum infusion pressure at occlusion	1 bar
Occlusion alarm threshold	1 U
Maximum time to occlusion alarm	1 hour at a basal rate of 1 U/h 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	Pump versions 2.5.0 and previous: the system memory is retained for 30 days following switch off. Pump version 2.6.0: the system memory is retained for 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 Infusion set: by ethylene oxide gas Alcohol wipe: by irradiation Syringe: by ethylene oxide gas Needle: by ethylene oxide gas
Product classification (IEC 60601-1)	Class II
Bolus functionality	Minimum bolus dosage: 0.05 U Maximum bolus dosage: 30 U Bolus dosage increments: 0.05 U

Basal rate functionality	Minimum basal rate: 0.05 U/h Maximum basal rate: 5 U/h Basal rate increments: 0.05 U
Maximum delivery speed	1 U/min 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 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%.



6.3.2 – 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 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 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 IEC 61000-3-3	Compliant	
Harmonic emissions 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) IEC 61000-4-2	8 kV contact 15 kV air	8 kV contact 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%.

Immunity test	Test level IEC 60601	Compliance level	Directives related to the electromagnetic environment
Electric fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±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 IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±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.
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 70% U_T for 25/30 cycles 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 6 V in ISM and amateur radio bands 150 kHz to 80 MHz	3 V 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 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 (m)	Immunity test level
385	380–390	TETRA 400	Pulse modulation[2] 18 Hz	1.8	0.3	27
450	430–470	GMRS 640, FRS 460	FM[3] ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704–787	LTE Band 13, 17	Pulse modulation[2] 217 Hz	0.2	0.3	9
745						
780						
810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[2] 18 Hz	2	0.3	28
870						
930						

Test freq. (MHz)	Band[1] (MHz)	Service[1]	Modulation[2]	Max. power (W)	Distance (m)	Immunity test level
1720	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
1845						
1970						
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	5100–5800	WLAN 802.11 a/n	Pulse modulation[2] 217 Hz	0.2	0.3	9
5500						
5785						

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 m		
	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 (m) 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.

6.3.3 – 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.

6.4 – DBLG1

6.4.1 – Expected effects of the DBLG1 System

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	Sensor augmented pump
Percentage of time spent in target (70–180 mg/dL)	68.5% ± 9.4%	59.4% ± 10.2%
Average glycemia (mg/dL)	156.8 ± 14.4	164.0 ± 14.4
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.

Expected clinical benefits of the DBLG1 System

The expected clinical benefits of the DBLG1 System are a better glycemic control, defined as less hypoglycemia, more time in range, and a lower risk of long-term complications.

A summary of safety and clinical performance will be available on the European database on medical devices. This summary is also available on request: qara@diabeloop.fr

Eudamed	https://ec.europa.eu/tools/eudamed (subject to Eudamed availability)
UDI	376036478DBLG1-swSL

6.4.2 – Technical specifications of the handset

Operating conditions	Temperatures: –10°C to +50°C Relative humidity (RH): 15% to 90% Atmospheric pressure: 700 hPa to 1060 hPa
Dimensions	142.1 mm x 69.5 mm x 11.75 mm
Weight	167 g (battery included)
Display size and definition	4.95 inches / FWVGA+

Degree of protection from dust and water	IP22
Battery type	Li-Ion 3.8 V / 2500 mAH
Battery autonomy	Approximately 35 hours
Service life	4 years
Alarm volume	66.8 dB
Possible sound levels for alerts	0–64 dB
Average active efficiency	78.7%
No load power consumption	0.10 W
Charger input power	100–240 V, 50/60 Hz, 0.3 A
Charger output power	5 V, 2 A
Output power	10.0 W
Charging cable type and length	USB-C, 1 m
Power supply classification	Class II
Operation during movement	Yes
Mobile component	Yes
Portable component	Yes
Storage and transport conditions	Temperatures: –25°C to +70°C Relative humidity (RH): 15% to 90% Atmospheric pressure: 700 hPa to 1060 hPa

6.4.3 – Frequency bands and maximum radio frequency power

Frequency bands	Maximum radio frequency power
GSM 850/900	33.5 dBm
DCS 1800 / PCS 1900	31 dBm
WCDMA 1/2/5/8	24.5 dBm
LTE 1/3/18/19	23.5 dBm
LTE 7	21.5 dBm
LTE 8	24.5 dBm
LTE 20/28	24 dBm
LTE 41	23 dBm

Frequency bands	Maximum radio frequency power
Bluetooth® 2.4 GHz	5 dBm
Wi-Fi 2.4GHz	18.5 dBm
Wi-Fi 5GHz	18 dBm

6.4.4 – Electromagnetic immunity and emissions: declaration and guidance

Electromagnetic emissions specifications

Immunity test	Compliance
RF Emission CISPR 11	Group 1, Class B
Conducted emissions CISPR 11	Group 1, Class B
Voltage fluctuations / flicker emissions IEC 61000-3-3:2014	Compliant

Electromagnetic immunity

Immunity test	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air
Radiated RF EM Fields electromagnetic field IEC 61000-4-3	80 MHz to 2.7 GHz: 10 V/m
Proximity fields from RF Wireless communications equipment IEC 61000-4-3	IEC 61000-4-3 table 9. Compliant.
Electric fast transient / burst IEC 61000-4-4	±2 kV for power supply lines
Surge IEC 61000-4-5	±2 kV line(s) to earth ±1 kV line(s) to line(s)
Conducted Fields Disturbance IEC 61000-4-6	150 kHz to 80 MHz: 3 V/m
Magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m (50 Hz)
Voltage dips and interruptions IEC 61000-4-11	Compliant

6.4.5 – Manufacturer's declarations and statements

Specific Absorption Rate (SAR)

Your DBLG1 is designed not to exceed the limits for exposure to radio waves recommended by international guidelines and those in force in France. These guidelines, developed by an independent scientific body (ICNIRP), include a significant safety margin to ensure people's safety, regardless of age or level of health.

The unit of measurement used for these guidelines is the SAR. For mobile devices, the maximum SAR allowed is 2.0 W/kg. The maximum SAR values for this model, permitted in accordance with the ICNIRP Guidelines, are valid only for devices intended to be used within the European Union.

	DBLG1	Max value
Head	N/A – the device does not support voice function	2.0 W/kg
Body 5 mm	1.209 W/kg	2.0 W/kg
Limbs 0 mm	2.583 W/kg	4.0 W/kg

SAR testing was carried out on this product, worn at a distance of 0.5 cm from the body.[1]

To meet RF exposure guidelines, the device must be worn at least this distance away from the body.

During use, actual SAR values for this device are generally substantially lower than the values indicated above. This is because, for the purpose of system efficiency and to reduce network interference, the operating power of your DBLG1 is automatically reduced if full power is not required for the transmission. The lower the power output of the device, the lower the SAR value.

Furthermore, it is not recommended that the DBLG1 be left in close proximity to the abdomen of pregnant women, as well as to the lower abdomen of children and adolescents.

Declaration of REACH directives

The REACH Directives of the European Parliament (EC) No 1907/2006 require manufacturers to ensure that the substances they manufacture, place on the market and use do not harm human health or the environment. MobiWire SAS confirms that its DH22 products respect these directives.

Declaration of RoHS compliance

In order to minimize the environmental impact and to act with more responsibility towards our

[1]These tests are performed in accordance with standards EN 50360, EN 50566, EN 62209-1 and EN 62209-2.

planet, this document constitutes a formal declaration that the handset produced by MobiWire SAS is compliant with the directive 2011/65/EC of the European Parliament (Directive RoHS concerning the restriction of the usage of hazardous substances).

Declaration of Conformity to Directive 2014/53/EU

MobiWire SAS hereby declares that the type of DH22 radio equipment complies with Directive 2014/53/EU.

Index

C

D

L

M

P

R

S

T

Report any serious incident that has occurred in relation to the DBLG1 System to your local support.

Report any serious incident that has occurred in relation to the DBLG1 System to the competent authority in the country in which you are established.

An electronic version of this user guide is available on Diabeloop's website at the following URL: https://www.dbl-diabetes.com/features-dblg1system-dh22

You may also scan the QR code:

CE 0123

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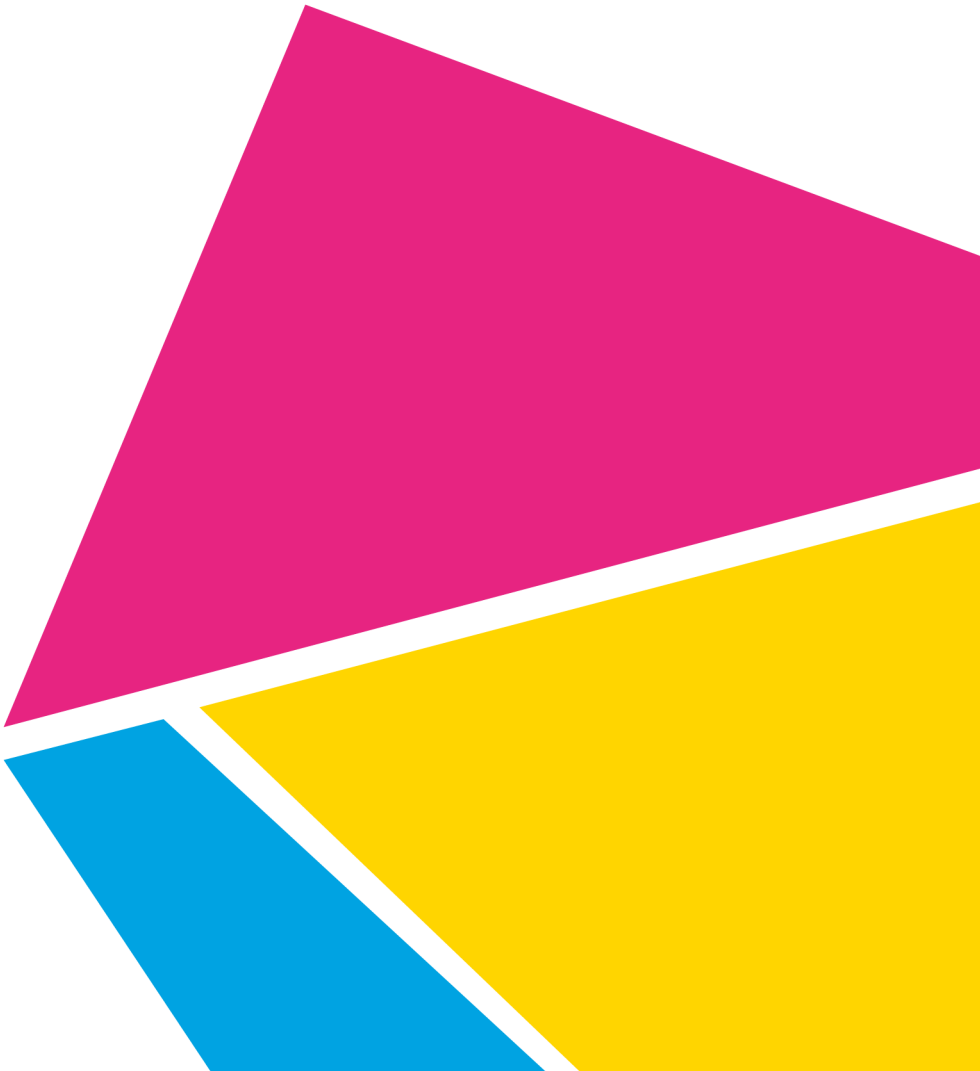

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