Kaleido.

User manual

Table of contents

01. Welcome

Hello!	1
System description	2
Essential performance	2
Intended use	2
Target Population	3
Contraindications	4
General warnings	5
Benefits of Kaleido	7
Our icons	9
Alarms icons	11
Resource Level icons	11
Taking your first steps	12
Starter Kit	12
Top-up Kit	13
Introducing Kaleido	14
What's in your Starter Kit?	14
What's in your Top-up Kits?	16

02. Getting to know your Kaleido

Getting to know your Kaleido	20
First things first!	20
How do I charge my handset?	20
How do I charge my pumps?	22
Navigating your Kaleido handset	24
Hints for your handset	26
How do I turn my handset on?	26
How do I turn my handset off?	31
Inserting your Kaleido infusion set	
Where can I wear infusion sets?	33
How do I apply an infusion set?	34
Some important reminders	39
Powering up your pump	40
How do I fill my insulin cartridge with insulin?	41
How do I put my insulin cartridge into my pump?	49
How do I pair my Kaleido pump with my Kaleido handset?	51
How do I connect my Kaleido pump with my Kaleido handset?	53

How do I connect/pair my Kaleido pump to the Diabeloop® DBLG1 handset?	54
How do I apply my pump to my body?	55
Why do I need to prime my cannula?	60
Do I always need to prime my cannula?	60
How do I prime the infusion set and start pumping?	61
Can I remove an insulin cartridge and put it back in my pump?	64
What if I don't want to start pumping straight away?	70
What if I don't want to connect my handset to a pump straight away?	71
How do I take my pump off?	72
To remove your pump while it's paused or stopped	72
Removing your pump and infusion set at the end of use	74

03. Basal

How do I create a basal profile?	81
I need to check which basal profile is currently pumping.	85
How do I change to a different basal profile?	86
Editing your basal profiles	88
How do I modify a basal profile?	88
How do I rename a basal profile?	91
How do I duplicate a basal profile?	94
How do I delete a basal profile?	98
How do I set a temporary basal rate?	101
Can I stop a temporary basal rate once it's started?	104

04. Bolus

How do I use Kaleidoculator?	111
What do the numbers that make up Kaleidoculator's calculation mean?	116
What happens if Kaleidoculator's recommended bolus is a negative number?	118
What happens if the suggested bolus is bigger than my maximum bolus?	120
How do I deliver a Quick Bolus?	121
How do I deliver an Extended Bolus?	124
Can I stop a bolus?	129
What happens if I don't have enough insulin left to deliver a bolus?	131
How do I enter a BG reading?	133

05. Resource Levels

What is Insulin on Board?	139
How do I check my Insulin on Board?	141
How do I check how full my insulin cartridge and batteries are?	142
What do all the Resource Level icons mean?	143

06. Menu

History	147
How do I review my History?	148

Data	a Upload	151
Ho	ow do I upload my data using a data uploader?	151
Pers	sonal Info	155
Ho	ow do I add or view my Personal Info?	155
Ho	ow do I enter my name?	157
Ho	ow do I enter my age?	159
Ho	ow do I enter my Target BG?	161
W	hat are insulin to carb ratios?	163
Ho	ow do I enter my insulin to carb ratios?	164
W	hat are insulin to BG ratios?	167
Ho	ow do I enter my insulin to BG ratios?	168
Ho	ow do I enter my insulin activity time?	171
Ho	ow do I enter my maximum bolus?	173
Syst	em Settings	175
Ho	ow do I add or view my System Settings?	175
Ho	ow do I check if my handset is connected to a pump?	177
Ho	ow can I unpair my pump from my handset?	178
W	hat's Lock Screen and how do I turn it on?	181
ľv	e turned on Lock Screen – what happens now?	184
Ho	ow do I turn Lock Screen off?	185
W	hat's a Medic Message and how do I turn it on?	187
Ho	ow do I turn my Medic Message off?	191
W	hat are BG reminders and how do I turn them off?	193
Ho	ow do I change my handset's language?	195
Ho	ow do I change the time on my handset?	197
Ho	ow do I change the date on my handset?	199
	ow do I turn my handset button tones off?	201
Ho	ow do I set the volume of my handset?	203
Ho	ow do I set the brightness of my handset screen?	205
Ho	ow do I know which software version I'm using?	207

07. Status

Pausing your pump	211
How do I pause my pump?	211
How do I unpause my pump?	213
How do I stop my pump?	215
How do I restart my pump?	217

08. Alarms

What is a low priority alarm?	223
What is a high priority alarm?	223
How do I acknowledge alarms?	224
How to review alarms?	225

When will I get a low priority pump alarm?	226
When will I get a low priority handset alarm?	227
When will I get a high priority pump alarm?	229
When will I get a high priority handset alarm?	232
Kaleido technical alarm code handling	233
Pump alarms	234
Handset alarms	237
Precautions	239

09. Looking after your Kaleido

Looking after your Kaleido	242
How should I clean my Kaleido products?	242
How should I store my Kaleido products?	243
What do I do if I need to dispose of my Kaleido products?	244
Where can I get replacement Kaleido products?	245

10. FAQ's

How often should I take a BG reading?	249
Can I wear my pump during exercise?	249
What about water?	250
What about high altitudes?	250
Can I use lotion, sunscreen or insect repellent with Kaleido?	250
Can I use Kaleido in combination with another electronic medical device?	251
Where do I go for answers to my additional questions?	251
Can I wear my pump on aeroplanes?	251
What should be in my back-up kit?	252

11. Technical information

Technical specifications	256
Security	258
Symbols	258
Pump accuracy	260
Regulatory information	261
Guidance and Manufacturer's Declaration – Electromagnetic Emissions	261
Guidance and Manufacturer's Declaration – Electromagnetic Immunity	262
Recommended separation distances	265
Declarations & statements	266
Trademark information	267
Summary of Safety and Clinical Performance	267
Warranty	268
How to contact Kaleido Care	271
Any trouble ?	271

01. Welcome



Hello!

Welcome to Kaleido – it's nice to meet you

We're so excited that you've picked us, and we can't wait to get to know you better. Whether these are your first steps into insulin pump therapy or you're familiar with insulin pump therapy, we're here to help your transition to Kaleido.

Regardless of your level of experience with diabetes or insulin pump therapy, please read this User Manual carefully and thoroughly before using Kaleido. This User Manual can help you as a person with diabetes, as well as your carers and your healthcare providers to understand how to use Kaleido and answer common questions you might have. It contains important information and instructions to make sure you can use Kaleido safely.

If you have a prescription to use the Kaleido system in combination with Diabeloop® DBLG1 System, see page 54 for more information.

Your User Manual is here for you if you have any questions while using Kaleido. If you can't find the answer or solution, contact Kaleido Care. The number is on page 271. For all medical questions, please contact your healthcare provider. Before you can start using Kaleido, you should receive full training from one of our certified Kaleido trainers. They will provide you with most of the materials you need to start using Kaleido, and your healthcare provider will provide you with the rest.

Information contained in this User Manual:

To ensure the safe and convenient use of Kaleido and for you to get the most out of using it, some information in this User Manual requires your close attention. This information is shown as a "Warning" or "Quick Tip".

"Warning": informs you about possible risks to your health. Neglecting to follow the recommendations of these warnings may even lead to serious harm or life-threatening situations in some cases.

"Quick Tip": contains important information relating to the efficient and smooth operation of Kaleido.

System description

Kaleido consists of a portable handset, a pump which holds a cartridge of insulin (filled by the user) and a separate infusion set. You, as a user, are the intended operator of Kaleido. Kaleido is designed to be used in the home environment. The pump can be worn on the body. The handset and pump form a system that is capable of delivering pre-programmed basal rates and individually programmed boluses. The handset controls the pump via *Bluetooth®* wireless technology. All insulin delivered by the pump is carried out according to the commands programmed on the handset by the user. The insulin is pumped from the insulin cartridge to the infusion set by the pump.

Essential performance

The Kaleido system is capable of delivering U100 rapid acting insulin. The system delivers insulin with an accuracy of ±5% of the desired dose. Once started, the basal rate continues to operate unless otherwise programmed/stopped by the user and/or stopped by an alarm condition. The components of the Kaleido system which are in contact with insulin are for single use only, disposable and provided in a sterile state. The Kaleido system is capable of detecting infusion occlusions. The occlusion detection functionality meets the EN ISO 60601-2-24 standard. The Kaleido system provides audible, visual, and vibratory notifications specifically for alarms. The Kaleido system is also able to inform the user on the battery status of the pump, and when the remaining insulin volume is low.

Intended use

The Kaleido product is intended for continuous subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in adult persons requiring insulin as prescribed by a physician. The Kaleido product is intended for the use with NovoRapid® or Humalog® U-100 rapid-acting insulin. The Kaleido product requires a prescription.

Target Population

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.

Insulin therapy in patients with type 2 diabetes mellitus (T2DM) can be managed by different treatment strategies such as basal insulin only, twice-daily premixed insulin, basal-bolus therapy (by means of multiple daily injections [MDI] regimens). National guidelines, however, do not primarily recommend the use of CSII for this patient group. It is rather classified as a special option in case a given patient does not achieve his therapeutic goal by using MDI. As such, T2DM patients can also use the Kaleido insulin infusion system. However, the effectiveness of CSII in T2DM has not yet been robustly demonstrated, despite some positive evidence. T2DM is a heterogeneous disease with a substantial phenotypic variability. Therefore, it is difficult to provide general conclusions about the effectiveness of CSII in T2DM therapy. Most advanced functions like various bolus dosages offered by the Kaleido system are not needed for T2DM treatment and may complicate the device handling for this subject group.

Contraindications

Using the Kaleido product for pump therapy is NOT recommended for people who are:

- Unable to perform at least four (4) glucose tests per day;
- Unable to participate in the insulin pump training;
- Unable to use insulin doses correctly;
- Unable to maintain contact with their healthcare provider;
- Unable to understand and use the Kaleido product according to instructions;
- Unable to recognize alarms visually or audibly;
- Unable to read the Kaleido handset screen;
- Do not have the physical or mental capacity to operate the Kaleido product;

Elderly people living alone can use the Kaleido system if they are physically and mentally able, if they understand the pump functions and can manage the system as intended. Currently, the Kaleido system is not indicated for children or for use in infusion of other drugs (please refer to the statement of intended use, for a clear specification of indications of use and counterindications.

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, the Kaleido insulin infusion system is not a treatment for insulin allergy and, as such, is not recommended for people with insulin intolerance/allergy.

General warnings

WARNING

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.

WARNING

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

WARNING

Do not use your pumps and handset when there are flammable gases present.

WARNING

Only use accessories and materials described in the User Manual. Using other components that have not been supplied by ViCentra as part of your Kaleido system may result in increased electromagnetic emissions, and decreased electromagnetic immunity, or decreased safety of use. Using alternative parts and accessories from other suppliers could also damage your Kaleido products and will invalidate your warranty.

WARNING

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.

WARNING

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.

WARNING

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

WARNING

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

WARNING

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 the User Manual, safety of use cannot be guaranteed.

WARNING

Do not use Kaleido if the components are damaged. Immediately use an alternative form of therapy until the damage has been repaired or replaced.

WARNING

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

WARNING

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

WARNING

Turn off the handset in areas where it is prohibited to use *Bluetooth®* wireless technology.

WARNING

Only use Kaleido with Humalog® and NovoRapid® U100 rapid-acting insulin. Safety of use cannot be guaranteed if you use different insulin types, or a mix of insulin types.

WARNING

Dispose of your needles appropriately. We recommend always using a sharps bin. See page 244 for additional information on disposal of sharps.

WARNING

Do not reuse supplies out of the Topup Kit. Doing so may contaminate your insulin and lead to infection.

WARNING

Use Kaleido according to the User Manual. If you do not follow the instructions provided, safety of use and delivery accuracy of the Kaleido system may be affected.

WARNING

Always follow the advice given to you by your healthcare provider. For any BG/medical related concerns consult your healthcare provider.

WARNING

To avoid severe skin irritation, ViCentra recommends that users wash their hands before placing the system on their body. Likewise, users are instructed to clean the area of their skin with an alcohol wipe to prevent skin reactions. Likewise, to prevent severe skin irritation and damage, ViCentra recommends switching the site of insertion each time customers place the device on their body.

WARNING

Ensure you use the DBLG1 handset with your Kaleido pumps if you plan to make use of the closed loop capability. In this instance, you must not use the Kaleido handset. See page 54 for more information.

WARNING

Do not pair your pumps to your Kaleido Handset if you intend to use the system as part of the Diabeloop® DBLG1 System. See page 54 for more information.

Benefits of Kaleido

Pulse technology

Our system is one-of-a-kind and works with micro pulse delivery, which guarantees insulin pumping that is consistent and reliable every time. Knowing that you're getting exactly what you need, exactly when you need it means less time thinking about diabetes and more time living your life.

lt's discreet

Kaleido pumps and handsets are among the smallest around. Our pump is so compact and light you might forget you're connected, even with 200 units packed in. With it being only 5 by 3.5 by 1.25 cm big it's smaller than most matchboxes!

Interface

We've designed the Kaleido handset to be simple to use and quick to navigate. Our handset allows you to make adjustments on the go and stores up to 90 days of data that can be uploaded to and reviewed via compatible data management platforms, to be uploaded and accessible via data uploader software.

Programmable

The Kaleido handset is programmed to deliver basal insulin with the option based on up to 7 basal profiles. The insulin delivery is in increments of 0.05 units

Kaleidoculator™

The Kaleidoculator[™] helps you with calculating your boluses. There are two options to deliver a bolus, quick or extended, so all at once or over an extended period, the user decides.

Insulin on Board

The Kaleido handset is programmed to keep track of insulin on board (IOB) and will adjust the bolus offered depending on the Blood Glucose (BG) and IOB. This can help prevent insulin stacking, which can lead to hypoglycemia (low BG).

Live life on your own terms

You can choose to pause and remove the Kaleido pump at any time. Your handset will keep track of how much insulin you have missed while your pump is paused, so that you can make an informed decision about your insulin delivery when you are ready to start the pump again.

The handset home screen displays relevant data e.g. battery level of handset and pump, level of insulin in insulin cartridge, basal rate, last BG, last Bolus and pump status.

To patch or not to patch?

With the option to choose your favourite tubing length (5 or 30 cm) and different places to wear the pump, you can decide to show it off or tuck it out of sight.

Flexible

Kaleido combines the freedom of a patch pump with the versatility of a conventional pump. Keep it close with patches with short 5cm tubing or place it into your pocket with a longer 30cm option. Unlike other patch pumps, Kaleido doesn't get thrown away.

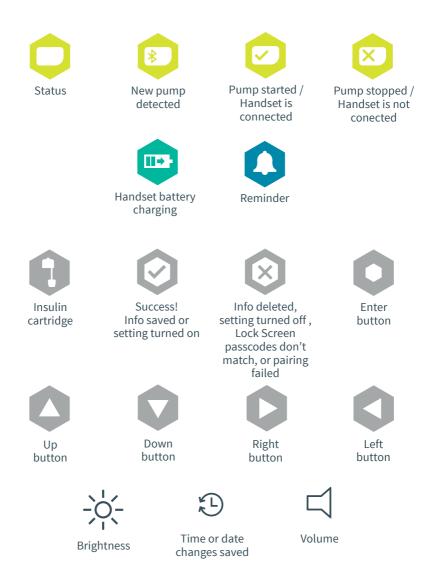
Kaleido comes with 6 or 9mm cannulas, so, with input from your healthcare provider you can choose what works for you. We've also designed an inserter to aid the cannula insertion.

Ouricons

A quick guide to all of the icons you'll find on your Kaleido handset and in this User Manual.



- * Carbohydrates
- ** Blood Glucose or interstitial glucose value



Alarms icons







High priority alarm inactivation



Low priority alarm inactivation



High priority alarm indicator



Low priority alarm indicator

Resource Level icons



Insulin cartridge



Insulin cartridge in low priority alarm mode



Insulin cartridge in high priority alarm mode



Pump battery



Pump battery in low priority alarm mode



Handset battery



Handset battery in low priority alarm mode

Taking your first steps

When you start using Kaleido, you will receive your Starter Kit and your very first Top-up Kit. Here's what you should find in each box:





01. Welcome

02

3

04

G

6

70

8

60

10

1

Top-up Kit

~	
~	
 ~	
 <u> </u>	
 -	
 ~	
\sim	
 <u> </u>	

User Manual x 1



2⇔0

Syringes x 10

Infusion sets x 10

Body patches

x10

© ₽ 1

Pump patches x 10

Alcohol wipes x 10

WARNING

Check the content of your kits for completeness prior to use. Contact Kaleido Care or your healthcare provider if the content is not complete.

WARNING

Do not use supplies out of the Top-up Kit when the packaging is damaged or the expiry date has passed. Sterility and safety of the products cannot be guaranteed once the packaging is damaged or the expiry date has passed.

Introducing Kaleido

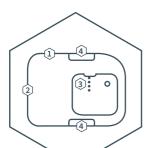
What's in your Starter Kit? The items you need to get started*

(or saline, if you start on saline the first time). User Manual Read the User Manual prior to use. Make sure you put it somewhere where you can find it again guickly, just in case any questions might pop up when you're using Kaleido. Kaleido pumps Kaleido pumps are reusable. We're sending you two of a different colour, so that you'll always have one to wear and one charged and ready to go. n (1) This is where you have to place your Insulin Cartridge (2) Groove for insulin cartridge tubing Kaleido handset The handset is what you'll use to communicate to your pump and program in what you'd like it to do. The handset and pump communicate using Bluetooth® wireless technology. Your 2 handset will only communicate to one pump at a time. Your handset can also help you keep track of the insulin deliveries you give via your pump, as well as any glucose readings and Kaleido carbs data you enter into your Kaleidoculator. It's also where you'll be able to quickly check the important details, like how much insulin is left in your insulin cartridge and how much power there is in your pump and handset batteries.

- (1) Power button
- 2 Screen
- (3) Navigation buttons (up, down, left, right)

* You'll need to provide your own insulin

- ④ Enter button
 ⑤ Micro USB port
- 6 Speaker



Charging dock

Alongside the connection cable and power adapter, your dock is what you'll use to charge your pumps. This way, they'll always be ready for action.

Charging status light

② Micro USB port

③ Contact pins

④ Release buttons



Connection cable

Only use this cable to connect your power adapter to either your Kaleido handset or your charging dock – whichever you need to charge next. You'll also need your connection cable if you want to upload your data.

WARNING

Your connection cable should only be used to charge your Kaleido products, or to upload data with a computer.



Power adapter

Once you've positioned your connection cable, you'll need your power adapter to plug into your electrical outlet and start charging.



Inserter

You will need this reusable inserter to insert your Kaleido infusion set. Ensure you keep it handy with your Kaleido disposables.

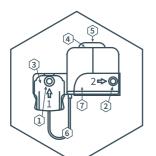
(1) Activation button

QUICK TIP

Do not store your inserter together with loose BG Strips. BG strips can enter the inserter and impair its functionality.

What's in your Top-up Kits?

The disposable items you need to keep you pumping



Kaleido insulin cartridge

The insulin cartridge holds the insulin you will need for up to three days of pumping. You will need to replace your insulin cartridge at least once every three days. You can choose from two lengths of tubing - go for 5cm or 30cm, just let us know which you'd prefer.

- (1) Hole 1
- 2 Hole 2
- (4) Plastic tab
- (5) Filling cradle catch (6) Insulin cartridge tubing
- (3) Insulin cartridge connector (7) Filling cradle



Syringes & needles

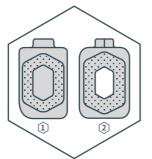
Our syringes and needles fit together and are the only ones that should be used to fill your insulin cartridges with insulin. You'll need one syringe and one needle for every new cartridge you prepare - that's one of each at least once every three days.



Infusion set

The infusion set is the part that connects your Kaleido pump to vour body. It uses an introducer needle (that's removed after you've inserted your infusion set) and tube (called a cannula). Just like your pump and insulin cartridge, you will need to replace your infusion set at least once every three days. Kaleido infusion set cannulas come in two sizes, 6 mm and 9 mm and insert at a 90° angle. Your healthcare provider will assist you in choosing the size that works best for you.

- (1) Paper backing (with sticky patch underneath)
- (2) Introducer needle, including cannula tube
- (3) Plastic cap
- (4) Plastic cap tabs

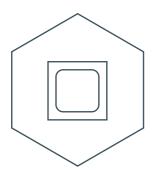


Body & pump patches

These patches will help you wear your Kaleido pump. The pump patch ① is the part that sticks to your pump and the body patch ② goes on your body.

You'll need to change these patches every time you change your pump, insulin cartridge and infusion set. You'll use one new body patch and one new pump patch at least once every three days.

Pump patch
 Body patch



Alcohol wipes

Ready for a new infusion set or placing the pump on the body? Use an alcohol wipe to make sure your skin is ultra clean first.

WARNING

It is highly recommended to keep a back-up kit with supplies on hand. Medical equipment can and does sometimes stop working due to technical issues/damage. It is essential that you are prepared for such times. See page 252 for more information on the contents for such back-up kit.



02. Getting to know your Kaleido

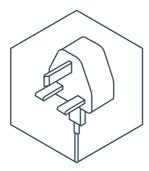
Getting to know your Kaleido

First things first!

So you've got everything you need to start pumping, but what's next? First, you need to:

- Remove your pumps and handset from their packaging
- Charge your handset and the pump you would like to use first

How do I charge my handset?





Vour handset battery is now charging Control of the second second

STEP 1

Start by connecting your power adapter and connection cable. Do this by inserting the larger end of the connection cable into the USB port at the bottom of the power adapter. STEP 2

Insert the smaller end of the connection cable into your handset's micro USB port. Ensure the Kaleido icon is facing upwards.

STEP 3

Plug your power adapter into an easily accessible electrical outlet and then switch the power on. You'll see a charging icon on your handset screen and the handset will give two beeps indicating the handset has started to charge.

WARNING

Ensure you use the DBLG1 handset with the Kaleido pump if you plan to make use of the closed loop capability. In this instance, do not use the Kaleido handset. See page "How do I connect/pair my Kaleido pump to the Diabeloop® DBLG1 handset?" on page 54 for more information.

2



STEP 4

If you are charging your handset for the very first time or recharging it after draining the battery right down to empty, we recommend that you charge it for at least two to four hours.

You can always check how charged your handset is by scrolling to the Resource Levels screen.

The handset battery is fully charged when the resource icon is fully filled (see also page 142).

QUICK TIP

You can send your handset to sleep mode at any time by briefly pressing the Power button. This will help you save your handset battery. You can wake it up again at any time just by pressing the Power button or the Enter button.

WARNING

Make sure you keep an eye on your handset battery and recharge it before the battery is empty. You should always keep your handset within reach in case you need to perform any action (adjusting your insulin delivery, or if there's an alarm) even when it's on charge. Your handset battery will last approximately 1.5 to 2 days at typical usage. But to prevent it from running low it is recommended to charge it every night.

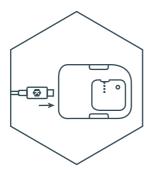
QUICK TIP

Charging your handset will automatically turn it on, even if it was previously turned off. You won't be able to turn your handset off while it's being charged.

WARNING

It is not recommended to let your handset battery go completely flat, or leave it uncharged for seven days or more. Should this occur, your handset's internal clock will automatically reset and you have to update the date and time the next time you turn your handset on.

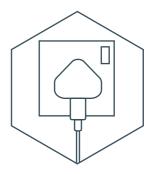
How do I charge my pumps?





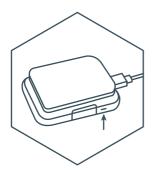
STEP 1

Detach your connection cable from your handset, then insert the connection cable into the micro USB port on your charging dock. Ensure the Kaleido-icon is facing upwards. STEP 2 Check that there isn't an insulin cartridge already in the pump you want to charge. If there is one there, stop your pump (see page 215) and remove it. Once the pump is free from an insulin cartridge, click your pump into place on the charging dock.



STEP 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.



STEP 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'll feel your pump release and you'll be able to remove it – no force needed.

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 four hours and the charging status light hasn't changed from orange to green, contact Kaleido Care.

QUICK TIP

Make sure your pump is fully charged before use.

QUICK TIP

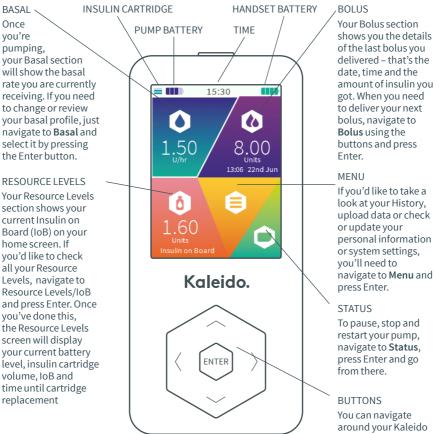
You'll wear each of your Kaleido pumps for up to three days at a time. Once you've removed a pump, it's a good idea to get into the habit of charging it as soon as you can, so that it's ready for the next time you need it.

WARNING

If the charging status light on the charging dock does not glow when your pump is connected, the pump is not being charged. Try an alternative electrical outlet first, and then contact Kaleido Care/your distributor if you continue to experience difficulties.

Navigating your Kaleido handset

We designed your handset to be as simple to use as possible. Your Home screen is divided into five sections, each of which leads you to a different menu. At the top, you'll also see handy details like the time and how full your insulin cartridge, pump and handset batteries are.



around your Kaleido handset simply by using the up, down, left, right and Enter buttons.

QUICK TIP

The navigation buttons are used to navigate on the handset screens. You'll use the up or down buttons to scroll through numbers and letters when entering details like your name and date of birth, and then right or left to move back and forth between the different letter and number boxes. The Enter button is used to confirm all your decisions and to move you on to any next steps.

QUICK TIP

When you receive confirmation messages from your handset, you have two options: either wait for them to time out automatically (this'll take a few seconds), or you can just press Enter to continue a little quicker.

QUICK TIP

Please be aware that when no button has been pressed for a few seconds, your handset screen will go to sleep. Just press the Power or Enter button to wake it back up.

QUICK TIP

You'll use your handset to communicate with your pump and control your insulin delivery. Unless you've paused, stopped or disconnected your pump, it will carry on delivering your current basal profile and any boluses that have already been programmed. This insulin delivery will even continue if you turn your handset off, if it runs out of battery or you leave it behind somewhere. Although you won't be able to make any changes, deliver new boluses or hear handset alarms until you recharge or are reunited with your handset.

WARNING

Recharge your handset on a frequent basis. If your handset runs out of battery you are no longer able to modify insulin deliveries until you recharge and turn your handset on again.

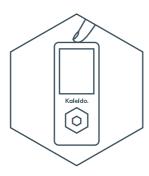
WARNING

Always keep your handset within reach in case you need to perform any actions.

Hints for your handset

Once your handset is charged, it's time to turn it on and start exploring.

How do I turn my handset on?





STEP 1

To turn your handset on, just press and hold the Power button for three seconds.

STEP 2

Turning on your new handset for the first time? You'll need to set your handset language first. Use the up or down buttons to scroll through the available languages. Choose your preferred language, then press the Enter button.

Press Enter again to select **Next**.



STEP 3

Enter the current date. Up or down will help you scroll from 0 to 9, right or left button will move you between the number boxes. Once you've set the current date, press Enter.

STEP 4

Press Enter again to select **Save**. If you've accidentally moved to **Save** too soon and you need to change the date you've entered, just press the up button to go back to the number boxes.



Ľ

2



TIME Please enter the time: 14:30 Cancel Save

STEP 5

A confirmation message will pop up. Your date is set. Press Enter to continue to the next screen a little quicker.

STEP 6

Enter the current time. Up or down will help you scroll from 0 to 9, right or left button will move you between the number boxes. Once you've set the current time, press Enter.



Press Enter again to select **Save**. If you've accidentally moved to **Save** too soon and you need to change the time you've entered, just press the up button to go back to the number boxes.

STEP 8

A confirmation message will pop up. Your time is set. Press Enter to continue to the next screen a little quicker.

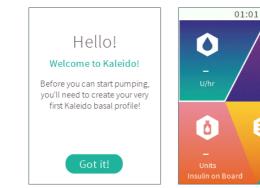
Time has been

saved as

14:30

QUICK TIP

It is really important that your handset is always set to the correct time. You can always change date and time settings later. For more information see page 197 for time settings and page 199 for date settings.



You'll be greeted by a welcome message telling you that you'll need to create your very first basal profile before you can start pumping. Press the Enter button to select **Got it!** and then start creating your first basal profile.

See "*How do I create a basal profile?*" *on page* 81 for more information.

STEP 10

If it's not the first time you've turned on your handset, pressing the Power button will take you straight to the Home screen.

How do I turn my handset off?



STEP 1

If you ever want to turn your handset off, press and hold the Power button for two seconds.

STEP 2

that you want to turn your handset off, select Yes if you do. If you decide not to turn off your handset, just scroll left to No and press the Enter button.

WARNING

If you turn off your handset, your pump will continue to deliver the currently programmed insulin deliveries. If your handset is turned off, you are not able to modify insulin deliveries until you turn your handset on again.



Would you like to

turn your handset off?

Inserting your Kaleido infusion set

Here's how to put on an infusion set.

You'll need:

- 1 x infusion set
- Your Kaleido inserter
- 1 x alcohol wipe

It's really important that you only ever place your infusion sets on the sites that are recommended by your healthcare provider. This ensures that you insert into the right tissue layer and your cannula doesn't go too deep or too shallow. If this does happen, contact your healthcare provider to discuss a different cannula length. The pictures on the page opposite are a guide to show exactly where these sites are, but your healthcare provider will be able to help you with this too.

QUICK TIP

It's important that you always keep your infusion sets clean while you're wearing them. If you ever choose to pause and remove your pump for a short period of time, always close the protective cover on your infusion set. You can find out exactly how to do this by checking out how to remove your pump while it's paused in *"How do I take my pump off?" on page 72*

2

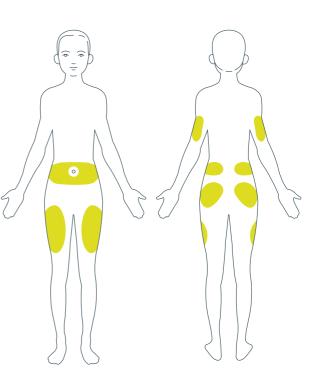
Where can I wear infusion sets?

Provided your healthcare provider has recommended you do so, you can wear an infusion set on any of the areas highlighted in green.

QUICK TIP

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
- Scartissue/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 maybe become kinked).



How do I apply an infusion set?





STEP 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.

STEP 2

Choose where you'd like to position your infusion set – it's good to choose an area where your clothing won't rub against it. Make sure the skin there is clean, dry and free from body moisturiser. Use an alcohol wipe to gently clean the area and then allow your skin to dry naturally.

WARNING

Do not reuse alcohol wipes. Doing so may affect the effectiveness of the disinfection and lead to infection.



STEP 3

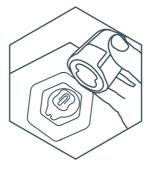
Check the expiry date and ensure the packaging and infusion set are not damaged before use. Remove the paper lid on your infusion set's packaging.

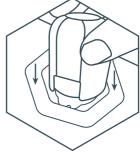
WARNING

The needle in the infusion set is sharp. Do not touch it before or after use and dispose of it according to instructions on page 244.

2







STEP 4

Remove the protective circle of plastic that's sitting on top of your infusion set.

WARNING

Do not touch the cannula before use. The cannula is sterile. Touching the cannula before using it may lead to infection.

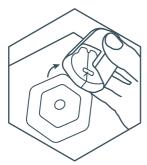
STEP 5

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's 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.

STEP 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.



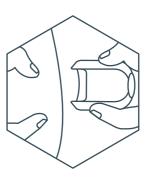
Lift your inserter out of the infusion set packaging. Check the needle is straight, but be careful not to touch it – it's important that it stays sterile.

If the needle doesn't look straight, take a new infusion set. Repeat from step 3 onwards. Once you have inserted your new infusion set and started up your pump.



STEP 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.



STEP 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. Don't forget to think about the direction and angle the tubing is coming from.

2





STEP 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.

STEP 11

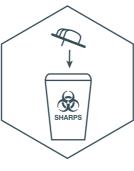
Now that's done, you can remove your inserter. Make sure you pull your inserter away from your body in a straight line, without twisting it, so that you don't damage the infusion set's cannula. Your infusion set will be securely stuck to your body and the plastic cap and needle will be inside your inserter. Put your inserter to one side for now, but be careful of the needle.

STEP 12

Gently rub the adhesive plaster around the edge of your infusion set to make sure it's sticking to your skin properly. If it's peeling at this stage, it's unlikely that it will last for three full days of wear, so you should remove it now and try again with another one. But, if it's feeling nice and secure, then your infusion set is ready to go.

0







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.

STEP 14

Make sure you dispose of the needle appropriately. See page 244 for more information on disposal of sharps.

STEP 15

Last but not least, don't forget to keep your inserter safe, ready for next time.

QUICK TIP

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 provider can advise you on a rotation pattern for the Infusion set that's right for you.

Ľ

2

Some important reminders...

WARNING

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.

WARNING

Make sure your infusion site stays clean. If you see contamination or dirt on your infusion set, you need to change it to prevent an infection occurring.

WARNING

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

WARNING

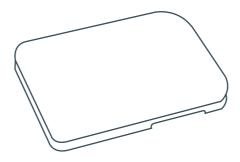
Do not let the Infusion set come in contact with water within the first hour of applying. Making the infusion set wet within the first hour of application may cause decreased adhesion properties.

QUICK TIP

When you apply your infusion set, bear in mind the length of your insulin cartridge's tubing. If 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.

Powering up your pump

So now you've got to know your handset, you've charged your first pump and put on your first infusion set, it's time to learn how to get your pump ready for action.



First, you'll need to prepare your new insulin cartridge. After that, it'll be time to put your insulin cartridge into your pump, put your pump on and then connect your pump to your handset. We'll walk you through all of this over the next few pages, but it might help to get everything that you'll need lined up and ready to go before you start.

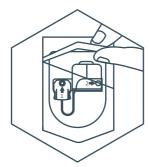
You'll need:

- 1 x fully charged Kaleido pump
- 1 x pouch-packaged insulin cartridge
- 1 x syringe
- 1 x needle
- Your vial of U100 rapid-acting insulin (at room temperature)

- 1 x body patch
- 1 x pump patch
- 1 x alcohol wipe
- Sharps bin

How do I fill my insulin cartridge with insulin?

Filling your insulin cartridge properly is really important, so find a clean, flat surface and make sure everything you need is within easy reach. When you're ready, follow these steps.



2=>(♠



STFP 1

Check the expiry date and ensure the packaging and insulin cartridge are not damaged before use.

Open up the packaging from vour insulin cartridge by pulling on the bottom.

If you are using an insulin cartridge with a 30cm tubing length, remove the paper tape from the tube.

WARNING

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

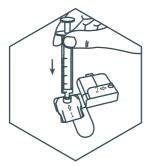
STFP 2

Remove the insulin cartridge and place the insulin cartridge on a flat surface so that the numbers 1 and 2 are facing towards vou.

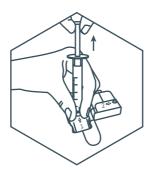
STEP 3 Remove your syringe from its packaging.

OUICK TIP

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 doesn't look right or the cradle is crooked, realign it by pulling the cartridge towards the tiny plastic tab at the top of the filling cradle.



Without moving the plunger, push the tip of the syringe firmly into Hole 1 so that it fits securely into the filling cradle.



STEP 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.



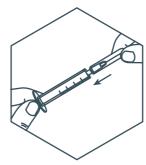
STEP 6

Now, remove your syringe from Hole 1 and push the plunger back towards the tip of the syringe.

QUICK TIP

When pulling the plunger to the top of the syringe, you should feel some resistance. If you don't 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 Kaleido Care about the issue afterwards.





Remove your needle from its packaging. No need to remove the needle cap just yet.

WARNING

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 according to instructions on page 244. Push the needle (with its cap still attached) onto the tip of the syringe until the two are securely connected.

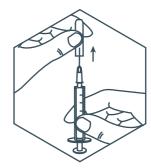
STEP 8

Check the expiry date and then clean the rubber stopper of the insulin vial prior to use according to the instructions provided by the insulin manufacturer.

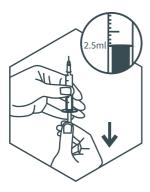
Ensure that you do not touch the rubber stopper of the insulin vial after cleaning it.

WARNING

Always follow the insulin manufacturer's instructions regarding storage and use of insulin, and always double check the expiration date of your insulin 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.



STEP 9 Remove the needle cap from the needle.



Draw the plunger down to

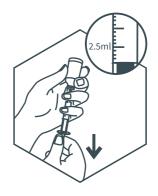
fill the syringe with 2.5ml

STEP 10

of air.

STEP 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.



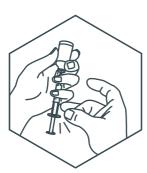
STEP 12

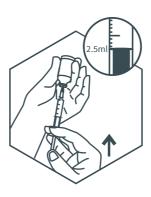
Turn the vial with the syringe upside down and slowly pull the plunger down until you have drawn just over 2.5ml of insulin in your syringe.

WARNING

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.

2





STEP 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.

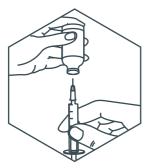
STEP 14

Push the plunger upwards to push the air bubbles back into the insulin vial. Ensure that there is 2.5ml of insulin in your syringe.



STEP 15

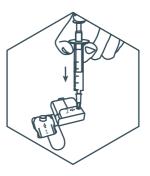
Check the syringe for air bubbles. If there are air bubbles, repeat steps 13 and 14 as often as needed to get rid of the air bubbles in the syringe. This will help make sure that there are no air bubbles in the syringe that can be pushed into your insulin cartridge during the filling process. Some small champagnesized air bubbles are acceptable.



Remove the syringe from the insulin vial. Be careful not to touch the needle.

STEP 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 don't get pushed into your insulin cartridge during filling.

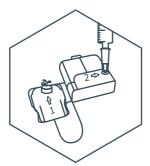


STEP 18

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.

WARNING

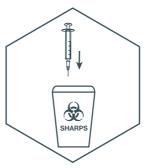
Only introduce the needle once into the insulin cartridge during the filling process. Introducing it more than once may result in leaks.



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.

WARNING

Your insulin cartridge should always be completely full before you start using it.

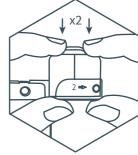


STEP 20

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. See page 244 for more information.

WARNING

Don't reuse your syringes or needles – doing so may contaminate your insulin and lead to infection. Once you've used a needle and syringe once, always dispose of them responsibly, straight away after use. We recommend always using a sharps bin. See page 244 for more information on disposal.



STEP 21

You'll 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's important that you squeeze the insulin cartridge twice (after unhooking the insulin cartridge) in order to succesfully prime your insulin cartridge.



Remove the insulin

cradle. Now, turn the

filling cradle over and

gently squeeze and lift

the tabs on either side

of your insulin cartridge

filling cradle can now be

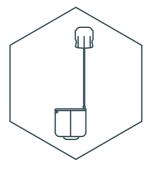
responsibly disposed of.

connector to unclip it. The

cartridge from the filling

STEP 23

After filling your insulin cartridge following the steps in this User Manual, there may be some small air bubbles in your insulin cartridge's reservoir. If they are champagne sized air bubbles, that's generally okay and you can use this insulin cartridge. You can use the above image 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 above.



STEP 24 Your insulin cartridge is now fully filled, primed and ready to use.

48 How do I fill my insulin cartridge with insulin?

Ľ

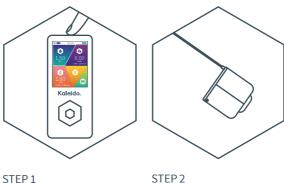
2

How do I put my insulin cartridge into my pump?

If you've put on your infusion set and filled your insulin cartridge, it's time for the next step. We've made sure it's as easy as possible to start using your pump, but it's always important that you take care and pay attention - especially if it's your first time.

QUICK TIP

Unless you are preparing a pump and insulin cartridge for the very first time, you'll need to make sure you've stopped the pump you were most recently using first. This is important because your pump can then update the handset with essential data, and if you don't stop your pump, you will get a pump alarm. Once you've done that, you can remove and dispose of the insulin cartridge appropriately. Then, put your old pump on charge and carry on with your new pump.



Check that your handset is turned on, that the screen is awake and that it's within range of the pump you're about to use (approximately 2 meters).



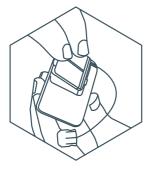
Make sure you have your fully filled insulin cartridge ready to go.

WARNING

Do not insert or remove an insulin cartridge while it is connected to your infusion set on your body. Your Kaleido pumps will dispense a small amount of insulin when you insert or remove an insulin cartridge.

WARNING

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



STEP 3

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.



STEP 4

With the tubing in the tubing groove, gently press the cartridge tab to feel it click into place. If everything's 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 handset.

QUICK TIP

50

Inserting an insulin cartridge into a pump turns the pump on. Removing the insulin cartridge turns the pump off. If you've successfully inserted an insulin cartridge, your pump will beep twice to let you know that everything has gone to plan and that it is ready to connect to your handset. Your handset will only be able to respond if it's turned on, within range of your pump, and if its screen is awake – if it is, after a few seconds it will also beep twice. As well as confirming that your pump and handset are ready to connect, the beeps let you know that your pump and handset alarm systems are working properly. If you don't hear the beeps, check that your insulin cartridge is inserted correctly, and that your handset is turned on and within communication range (approximately 2 meters). If those things don't help, contact Kaleido Care.

2

How do I pair my Kaleido pump with my Kaleido handset?

Pairing ensures that your pump and handset can communicate with each other. This only needs to be performed when you use that pump for the first time. Before you can pair a new pump (or try to connect your pump to your handset after you've paired them, as shown on page 53) you'll need to have set at least one basal profile.

If you have not yet set a basal profile, see page 81 for how to do this. After you have set your basal profile, make sure that your handset is turned on and that you have clicked the cartridge into place in the pump (see step 4 on page 50). Ensure you keep the pump and handset within reach during the whole pairing process.



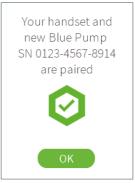
STEP 1

Once your handset recognizes you've inserted an insulin cartridge into your pump, your handset will show a message confirming that a pump has been detected. Make sure the pump colour on your screen matches the pump you're trying to pair. When you are ready to pair, press the Enter button to select **Pair**.



STEP 2

Your pump and handset are pairing. Wait for the pairing to succeed. This might take up to a minute.



STEP 3

Once the pairing process is successful, the handset will show a confirmation message and the pump will beep three times to indicate pairing was successful. Press the Enter button to continue.

WARNING

Do not pair your pumps to your Kaleido Handset if you intend to use the system as part of the Diabeloop® DBLG1 System. See page "How do I connect/pair my Kaleido pump to the Diabeloop® DBLG1 handset?" on page 54 for more information.

QUICK TIP

If you already have at least one basal profile saved, your handset will automatically connect to your pump after successful pairing (step 3) and ask you if you are using a new, fully filled insulin cartridge. You can now apply your pump to your body. See *"How do I apply my pump to my body?" on page 55.*

Do you want to

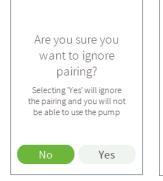
replace your previous

Blue Pump?

Selecting 'Yes' will unpair

your previous Blue Pump

Yes

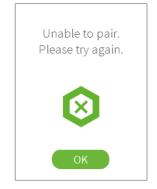


QUICK TIP

If you do not recognize the pump colour, or you didn't start the pairing process, you should ignore the pairing request. Just scroll right to **Yes** and press Enter to select it. Then, select **Yes** to ignore pairing.

QUICK TIP

In case you already paired another pump of that colour to the handset, a confirmation message will appear. Press the Enter button to select Yes. This will replace your previous pump of that name and unpair the previous pump from the handset. If you do not want to replace your previous pump, just scroll left to select **No** and press Enter to select it.



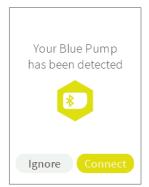
QUICK TIP

In some cases, pairing might not succeed the first time. Ensure your handset and pump are within reach. Press the Enter button to go back to the pairing message in step 1. If you are unable to pair your pump after a few attempts, check that your insulin cartridge is inserter properly. If this did not resolve the issue, contact Kaleido Care.

How do I connect my Kaleido pump with my Kaleido handset?

QUICK TIP

The Ignore option should only be used for training purposes. If you delayed connecting your handset to your pump for too long, your handset will go into sleep mode. It will remember that it's detected a pump and will beep once every minute as a reminder for you to wake the handset and complete the connection process. Complete the connection process and then follow the instructions on the screen. As your pump uses rapid-acting insulin only, do not delay in connecting your handset to your pump and connecting to your infusion set unless instructed by your healthcare provider.



STEP 1

Once it recognizes you've inserted a new insulin cartridge into your pump, your handset will show a message confirming that a pump has been detected. Make sure the pump name on your handset matches the pump you're trying to connect to. When you are ready, press the Enter button to select **Connect**.

QUICK TIP

Your pumps are named after their colour – if you have a purple pump, its name will be Purple Pump. A turquoise pump will be your Turquoise Pump.

QUICK TIP

Your handset won't be able to connect to a pump unless you have at least one basal profile saved. Your handset will let you know if there's a problem.

Sorry!

You need to have at least one Kaleido basal profile saved before your handset can connect to your pump!





How do I connect/pair my Kaleido pump to the Diabeloop® DBLG1 handset?

NOTE: This chapter only applies if you received a prescription to use Kaleido in combination with the Diabeloop® DBLG1 System.

Kaleido, in combination with the Diabeloop® DBLG1 (handset) and Dexcom G6 Continuous Glucose Monitoring (CGM) system provides an automated insulin delivery system for people with diabetes. The automated insulin delivery technology is developed by Diabeloop® and runs on the dedicated Diabeloop® handset. This technology analyses the real time user data, measured with the Dexcom G6, and determines the correct dose of the insulin to deliver. The DBLG1 in combination with the G6 and Kaleido pump offer the user a hybrid closed loop capability.

You received a full Kaleido Starter Kit that covers our whole Kaleido system, including the Kaleido Handset. If you have a prescription to use the Kaleido system in combination with the Diabeloop® DBLG1 System, **you must not use your Kaleido handset and you should check the User Guide provided with your Diabeloop® DBLG1 handset!**



To use the Diabeloop® DBLG1 system, you will need to have received the Diabeloop® DBLG1 handset and the Dexcom G6 device and their User Guides.

- Diabeloop[®] DBLG1 Handset
- 2 Dexcom G6
- (3) Kaleido Pump

WARNING

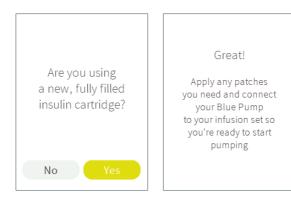
Ensure you use the DBLG1 handset with your Kaleido pumps if you plan to make use of the closed loop capability. In this instance, you must not use the Kaleido handset.

WARNING

Do not pair your pumps to your Kaleido Handset if you intend to use the system as part of the Diabeloop® DBLG1 System.

How do I apply my pump to my body?

First, you have to tell your handset whether you are using a new, fully filled insulin cartridge. After, you apply the pump to your body.



STEP 1

Your handset will ask if you have used a new, fully filled insulin cartridge. Select **Yes** if this is correct (if not, see "*Can I remove an insulin cartridge and put it back in my pump?*" *on page 64*).

STEP 2

A message will pop up to remind you to prepare and apply your pump. This message will time out after a few seconds, but you can press Enter to jump to the next screen a little quicker. Ľ

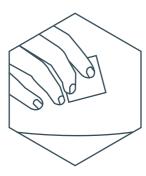
QUICK TIP

You'll find your body patches and pump patches in your Top-up Kit – you'll 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're wearing it.

QUICK TIP

STEP 3

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



Time to apply your pump.

location of your infusion

set and the length of your

decide where you'd like to

wear your pump. Choose somewhere your clothing won't rub against it and

make sure your skin is

alcohol wipe to gently clean the area and then

allow your skin to dry

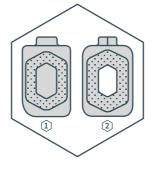
naturally.

clean, dry and free from

body moisturiser. Use an

insulin cartridge tubing,

Keeping in mind the



Pump patch
 Body patch

WARNING

Do not reuse alcohol wipes. Doing so may affect the effectiveness of the disinfection and lead to infection.



STEP 4

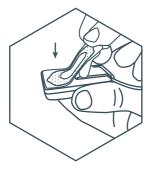
Take your pump patch ① and peel off the paper backing that covers the back of the patch. This will reveal the patch's adhesive.

Ľ

21

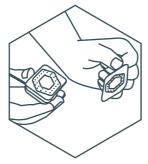
WARNING

Make sure that the back of your pump is clean and dry before you attach a pump patch. It'll ensure a better bond between the patch and pump, and prevent your pump from coming loose over time. See page 242 for more information on cleaning your Kaleido products.



STEP 5

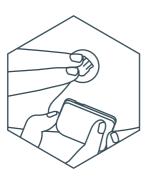
Stick the pump patch to the bottom of your pump, so that it covers the insulin cartridge and the fuzzy hexagon shape is facing outwards.

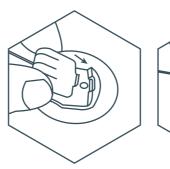


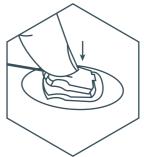
STEP 6

Take your body patch 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.



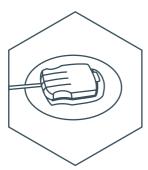






Being careful to support the weight of your pump, clip the connector at the end of your insulin cartridge tubing into your infusion set. You'll know it's secure when you hear the two distinct clicks as the right and left hand sides connect.

21



STEP 8

Check whether the connector is smoothly aligned with the infusion set. If connected properly it should feel like a smooth surface, with no bumps or gaps.



STEP 9

Holding onto your pump, peel off the paper backing from the top of your body patch.



STEP 10

Place your pump where you'd like to wear it. Be careful not to stretch or kink your insulin cartridge tubing. The sticky side of your body patch should now be touching your skin.

QUICK TIP

Once you've 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's stuck securely.

Why do I need to prime my cannula?

You have already primed your insulin cartridge tubing and connector during the cartridge filling process. If you're using a new infusion set you currently have inserted, you will still need to prime the cannula to ensure you receive the right amount of insulin straight away.

How much insulin do you need to deliver to prime your cannula? Kaleido is already programmed to give you the right amount of insulin to prime your cannula based on your cannula size. All you need to do is tell your handset which size cannula you're currently using – 6 mm or 9 mm. For a 6 mm cannula the prime volume is 0.20 units, and for a 9 mm cannula, the prime volume is 0.25 units.

Do I always need to prime my cannula?

Almost always, yes. If you've inserted a new infusion set, you should always prime your cannula. If you have only changed your insulin cartridge, or your pump, or you stopped your pump and then restarted it, you don't need to prime your cannula because it was already primed when you first started using it.

How do I prime the infusion set and start pumping?



STEP 1

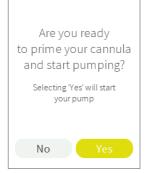
Back to your handset. It'll now ask you if your infusion set is new and if you would like to prime your cannula. You have three options to choose from:

• If you have a new infusion set with a 6 mm cannula, press Enter to select **Yes**, **6 mm**.

 If you have a new infusion set with a 9 mm cannula, scroll down to Yes, 9 mm, then press Enter to select it. • If you are not using a new infusion set, just press the left button to scroll to **No** and press Enter to select it. If you select No, you'll just be asked if you're ready to start pumping. If you select 'Yes' your pump will start.

You can find out more about priming your cannula by checking out *"Why do I need to prime my cannula?" on page 60.* E

2



QUICK TIP

If you've changed your mind, just press the left button to scroll to No. Press Enter to select it. Your handset will confirm that your cannula won't be primed and that your pump is stopped, and then you'll be taken back to the Home screen.

STEP 2

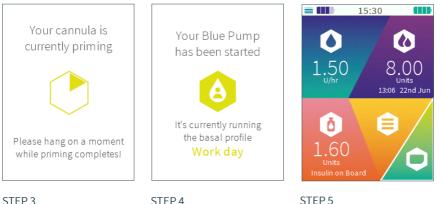
If you chose Yes, 6 mm or Yes, 9 mm you'll now be asked if you're ready to prime your cannula and start pumping. Are you wearing your prepared pump and infusion set and ready to start pumping? If so, select Yes again.

OUICK TIP

Once your pump and handset are connected and your pump is in use, make sure you always stop your pump first before removing the insulin cartridge from it - you'll get an alarm if you don't and imporant data won't be transferred from your pump to your handset.

OUICK TIP

The priming speed is 1 U per minute. Typically, priming will take only a few seconds



Your cannula is now being primed. The countdown displayed on vour handset indicates priming progress.

Once priming has completed, your handset will confirm that pumping has started. You can let the confirmation message time out after a few seconds, or press Enter to jump back to the Home screen a little guicker.



The Home screen will now display your new pump details.

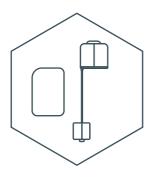
WARNING

Monitor your blood 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 Kaleido, stop using Kaleido and switch to an alternative therapy method as consulted with your healthcare provider.

Can I remove an insulin cartridge and put it back in my pump?

Sometimes, you might need to remove an insulin cartridge from your pump because of an alarm or for some other reason. If this happens, you can reinsert the cartridge to carry on using it, as long as:

- This was the last insulin cartridge in use
- The insulin and insulin cartridge are less than 3 days old
- The insulin and insulin cartridge have not been exposed to temperatures outside their recommended use
- The insulin cartridge is not empty



STEP 1

Before you remove (or reinsert) your insulin cartridge, first make sure that you've stopped your Kaleido pump and disconnected your pump from your infusion set (see *"How do I take my pump* off?" on page 72).

WARNING

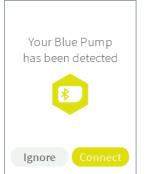
Your Kaleido pumps will dispense a small amount of insulin when you insert an insulin cartridge. For your safety, never insert or remove an insulin cartridge while wearing your Kaleido pump or if it's connected to your current infusion set.

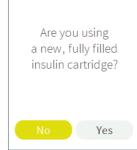
WARNING

Always stop your pump first before removing an insulin cartridge. Failure to do so will cause therapy data from your pump not being transferred to your handset.

QUICK TIP

If you're not ready to select either **Ignore** or **Connect**, your handset will remember that it's detected a pump and will beep once every minute as a reminder until you have connected your handset to your pump.





STEP 2

When you're ready, reinsert the insulin cartridge into your pump. Your handset will show a message confirming that it's detected your pump again.

Make sure the pump name on your handset matches the pump you want to use, then press the Enter button to select **Connect**.

STEP 3

Your handset will ask if you have used a new, fully filled insulin cartridge. This time, you'll need to scroll left to **No** and then press the Enter button to select.

WARNING

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



STEP 4

Your handset will ask if this is the insulin cartridge you were last using. If it is, select **Yes**.

If it's not the cartridge you were last using, select **No**. You won't be able to reuse the insulin cartridge and your handset will guide you through what to do next.

Great!

Apply any patches you need and connect your Blue Pump to your infusion set so you're ready to start pumping

STEP 5

A message will pop up to remind you to prepare and apply your pump as well as connecting your insulin cartridge to the infusion set – this message will time out after a few seconds, but you can press Enter to jump to the next screen a little quicker.

E

QUICK TIP

You need to replace your pump and body patches after you've reinserted an insulin cartridge. "How do I put my insulin cartridge into my pump?" on page 49, "How do I connect my Kaleido pump with my Kaleido handset?" on page 53 and "How do I apply my pump to my body?" on page 55 for a reminder of how to do this.



STEP 6

Your handset will now ask you if your infusion set is new and if you would like to prime your cannula. You have three options to choose from:

• If you have a new infusion set with a 6 mm cannula press Enter to select **Yes, 6 mm**.

 If you have a new infusion set with a 9 mm cannula, scroll down to Yes, 9 mm, then press Enter to select it. If you're not using a new infusion set, just press the left button to scroll to No, then press Enter to select it. If you select No, you'll be asked if you're ready to start pumping. If you select 'Yes' your pump will start.

You can find out more about priming your cannula by checking out *"Why do I need to prime my cannula?" on page 60.*



STEP 7

If you chose Yes, 6 mm or Yes 9 mm, you'll now be asked if you're ready to prime your cannula and start pumping. Are you wearing your prepared pump and infusion set and ready to go? Select **Yes** again.

Don't select **Yes** until you're wearing your pump and infusion set and ready to start receiving insulin. Your handset will stay on this screen for as long as you need it to.

QUICK TIP

If you've changed your mind, just press the left button to scroll to **No**. Press Enter to select it. Your handset will confirm that your cannula won't be primed and that your pump is stopped, and then you'll be taken back to the Home screen.

21



STEP 8

Your cannula is now being primed. The countdown displayed on your handset indicates priming progress. STEP 9 Once priming has completed, pumping will automatically start and your handset will confirm this for you. Press Enter to jump back to the Home screen a little quicker.

Your Blue Pump

has been started

It's currently running the basal profile

Work day

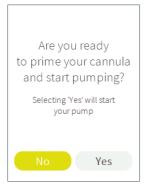


STEP 10

The Home screen will continue to display your pump's details.

What if I don't want to start pumping straight away?

There might come a time when you insert an insulin cartridge into your pump, but you're not ready to start pumping straight away. Here's what you'll need to do:







STATUS	
Start pumping	
Home	

STEP 1

When your handset asks you if you're ready to prime your cannula and start pumping (or just whether you're ready to start pumping if you've chosen not to prime your cannula), scroll left and press Enter to select **No**. Your pump will then enter Stop mode.

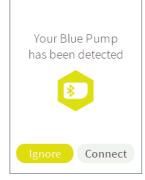
STEP 2

Later, when you're ready to start pumping, just go to the Status menu and select **Start pumping** to get going (see *"How do I restart my pump?" on page 217*). You'll be given another chance to prime your cannula at this point too.

QUICK TIP

When your pump is in Stop mode, your handset and pump will stay connected but your pump will not deliver any insulin. The Bolus menu will be inaccessible from your Home screen and you'll also be unable to set a temporary basal rate.

What if I don't want to connect my handset to a pump straight away?



STEP 1

You can choose to postpone connecting your handset and pump. All you have to do is select **Ignore** when your handset confirms that it has detected a new pump.

STEP 2

When you're ready to start a connection, ensure you are not connected up to your infusion set and then reinsert your insulin cartridge into your pump and follow the instructions on screen.

No problem!

If you want to connect later,

just insert a new insulin

cartridge into a charged pump and follow the steps

QUICK TIP

The **Ignore** option should only be used for training purposes. If you delayed connecting your handset to your pump and your handset went into sleep mode before connecting, it will remember that it's detected a pump and will beep once every minute as a reminder for you to turn it back on and complete the connection process. Complete the connection process and then follow the instructions on the screen. As your pump uses rapid-acting insulin only, do not delay in connecting your handset to your pump and connecting to your infusion set unless instructed by your healthcare provider.

How do I take my pump off?

There are two reasons why you might want to take off your pump:

- If you've paused or stopped it and want to remove it temporarily
- If you're ready to swap over to your other Kaleido pump

To remove your pump while it's paused or stopped





STEP 1 Wash your hands thoroughly.

STEP 2 Follow *"How do I pause my pump?" on page 211* to put your pump on pause.

STEP 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.

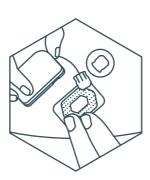
QUICK TIP

Always pause or stop your pump prior to removing the pump. Otherwise, insulin may be spilled. See *"How do I pause my pump?" on page 211* and *"How do I stop my pump?" on page 215* for more information.

2



STEP 4 Close the protective cover on your infusion set.



STEP 5

You can now take your pump off by lifting it away from your body patch.

If you're planning to put the pump back on soon, just leave your body patch in place.



STEP 6

When you're ready to put your pump back on, reconnect your insulin cartridge connector to your infusion set and reattach your pump.

For help to restart your pump once it is stopped, see "How do I unpause my pump?" on page 213.

Removing your pump and infusion set at the end of use





STEP 1 Wash your hands.

STEP 2 Follow *"How do I stop my pump?" on page 215* to stop your pump.

QUICK TIP

Stop your pump before you remove your insulin cartridge. You'll get an alarm if you don't. This way you make sure all the data from your pump has been communicated to your handset



STEP 3

Once your pump is stopped, 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.

2



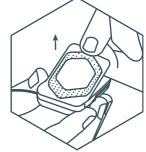
STEP 4

You can now take your pump off by lifting it away from your body patch.

WARNING

Do not reuse body and pump patches or use them longer than three days. Doing so may lose their adhesive properties, which could result in your pump becoming detached during use.





STEP 5

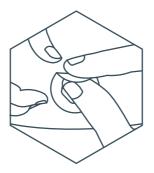
Once that's done, gently remove the body patch from your skin and the pump patch from the back of your pump.

QUICK TIP

When you need to swap over to your other pump, you must first stop your pump, then remove the old insulin cartridge from the pump you were just using. Then you can connect your handset to your new pump. This way you make sure your handset is not connected to your used pump, so that you can connect your new pump right away.



STEP 6 Take the insulin cartridge out of your pump.



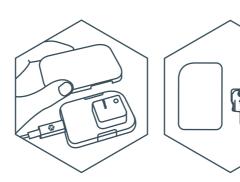
STEP 7

To remove your infusion set, peel the adhesive away from your skin- after a few days use, it will have lost a little of its stickiness, but take care not to pull it too hard.



STEP 8 Dispose of your infusion set, insulin cartridge, body and pump patches appropriately (see page 244 for more information on disposal) and then wash your hands again.

01



STEP 9

Make sure you recharge your pump straight away so it's ready to go the next time you need it. STEP 10 You're now ready to prepare your next insulin cartridge and pump.



03. Basal



Basal Rates

The Basal menu of your home screen contains all Kaleido's functions related to your basal insulin rates.

Instead of giving yourself one dose of long acting insulin every 24 hours, your pump delivers a pre-programmed, continuous dose of insulin throughout the day and night. This continuous dose is called a basal rate. A basal rate is programmed hour-by-hour in 24 hour chunks. This hourly rate is known as your basal rate and each pre-programmed 24 hour period is known as a basal profile. A basal rate is pre-programmed in advance, it doesn't take into account the food you eat or the activities you take part in. It works in the background, keeping things steady.

If you want to create a basal profile, follow the steps on the next page.

How do I create a basal profile?

Creating your own basal profiles using your Kaleido handset is pretty straightforward.

QUICK TIP

Your handset won't be able to pair or connect to a pump unless you have at least one basal profile saved on your handset.



STEP 1

On the Home screen, scroll to **Basal** and press Enter to select.

BASAL
Set temporary basal rate
View current profile
Change profile
Create new profile
oreate new prome
Edit profile
Edit profile

STEP 2

Scroll to and select **Create new profile**.

QUICK TIP

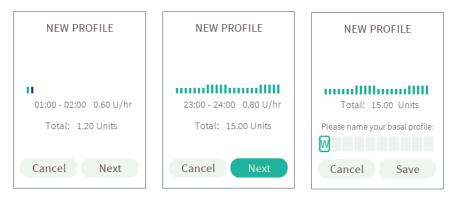
We all live very different lives, which means that the amount of insulin we need can be very different too. Your healthcare provider will advise you about the delivery of insulin that suits you best before you start creating basal profiles on your Kaleido handset.

QUICK TIP

You might not need the same amount of insulin on every single day of the week and that's why Kaleido can help you create lots of different basal profiles, up to seven. See *"How do I change to a different basal profile?" on page 86* for help with this. 11

QUICK TIP

To avoid confusion, it's a good idea to give all of your basal profiles a completely unique name (one that is applicable as to what they are programmed / designed for. e.g., sports day, holidays or weekend)



STEP 3

Press the left or right buttons to scroll between each hourly segment. You have to set a basal rate for all 24 hours of the day. Press the up or down buttons to select the basal rate recommended by your healthcare provider for each hour. Below the basal profile graph, you'll see details of the hour you're currently setting, along with the rate that you are entering.

You can set basal rates in increments as tiny as 0.05 units of insulin. The smallest basal rate you can set for an hour is 0.05 units, the largest is 5 units.

STEP 4

When you've entered a basal rate for each hour and your new basal profile is ready, press the Enter button. Press Enter again to select **Next**.

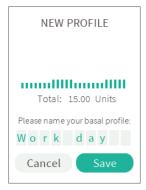
If you want to return to the basal profile graph before you select **Next**, just press the up button.

STEP 5

Next up, it's time to enter a name for your new basal profile.

Use the up or down buttons to scroll to the letter or number you want to use. Press the right button to move onto the next letter or enter a space.

To scroll through the alphabet quickly, just press and hold the up or down button. You can stop creating the basal profile at any point in the process by scrolling left and selecting **Cancel**. Just remember that you need one basal profile set before Kaleido can start pumping.



STEP 6

When you've named your basal profile, press Enter and select **Save**.

Your new basal profile Work day has been saved



QUICK TIP

If you're creating your very first basal profile, it will automatically be set as the default basal profile for pumping.

11

2

22

STEP 7

Your handset will confirm that your basal profile has been saved. Press Enter to return to the Home screen a little quicker.

In this chapter, example basal profiles are shown. To set up your own basal profiles, follow the settings you agreed on with your healthcare provider.

You have reached the maximum number of basal profiles

Please delete an existing profile and then try again



QUICK TIP

Your handset can store up to seven basal profiles at a time. In case there are already seven profiles, you'll need to delete a basal profile before you can create a new one. "How do I delete a basal profile?" on page 98 for more info.

I need to check which basal profile is currently pumping.



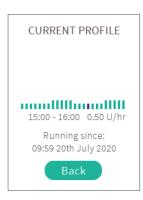
STEP 1

On the Home screen, scroll to **Basal** and press Enter to select.

BASAL
Set temporary basal rate
View current profile
Change profile
Create new profile
Edit profile
Delete profile
Home

STEP 2

Scroll to and select View current profile.



21

22

03. Basal

04

G

90

70

80

8

10

11

STEP 3

Your handset will show you the basal profile that you're currently pumping. Use the left or right buttons to scroll through the hourly basal rates. Press Enter and then Enter again to select **Back** and go back to the Basal menu.

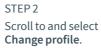
How do I change to a different basal profile?



STEP 1

On the Home screen, scroll to **Basal** and press Enter to select.

BASAL Set temporary basal rate View current profile Change profile Create new profile Edit profile Delete profile Home



SELECT PROFILE

Day off

Sports day

Work day

Back

STEP 3

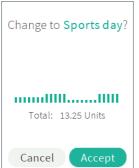
Your handset will show you a list of your saved basal profiles. Scroll to the one you'd like to change to and then press the Enter button.

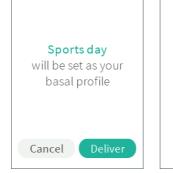
You won't be able to select the basal profile that you're currently running.

QUICK TIP

Running a temporary basal rate? You won't be able to change to a different basal profile while your temporary basal rate is still going, so you'll either have to stop your temporary basal rate first or just wait until it's finished to make your change.

2





STEP 4 Press Enter to select Accept.

STEP 5 Press Enter again to **Deliver** the new basal profile.



STEP 6

A confirmation message will pop up – press Enter to return to the Home screen a little quicker.

Editing your basal profiles

Over time, you may need to change your basal profiles. Let's take a look at all the changes you can make.

How do I modify a basal profile?

Need to adjust a basal profile? Just follow these steps:



STEP 1

On the Home screen, scroll to **Basal** and press Enter to select.

Set temporary basal rate View current profile

Change profile

Create new profile

Edit profile

Delete profile

Home

STEP 2

Scroll to and select **Edit** profile.

SELECT PROFILE
Day off
Sports day
Work day
Back
L

STEP 3 Scroll to and select the profile you'd like to modify.

You can't edit the basal profile that your pump is currently pumping, so you won't be able to select it from this list of saved basal profiles. If you want to edit the basal profile that your pump is currently pumping, first switch to another basal profile and then come back and edit the basal profile.

Modify profile

Rename profile

Duplicate profile

Back

SPORTS DAY

18:00 - 19:00 0.25 U/hr

Total: 13.25 Units

Cancel Save

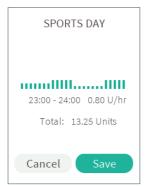
STEP 4 Select **Modify profile**.

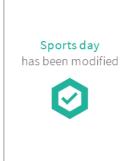
STEP 5

The profile you've selected will pop up on your handset. Press the left or right buttons to scroll between the hourly segments. Then, just like when you first created your basal profile, you can press the up or down buttons to increase or decrease any of the basal rate amounts.

QUICK TIP

You can select **Cancel** and return to the Edit profile menu whenever you like. If you do, any changes you've made won't be saved and your basal profile will remain unchanged. 21





STEP 6

When you have made the modifications, press Enter and then Enter again to select **Save**.

STEP 7

A confirmation message will pop up – your changes have been saved. Press Enter to return to the Home screen straight away.

02 03. Basal 04 05 06 07 08 09 10

11

21

How do I rename a basal profile?

If you want to change the name of a basal profile, follow these steps:



STEP 1

On the Home screen, scroll to **Basal** and press Enter to select.

BASAL

Set temporary basal rate View current profile

Change profile

Create new profile

Edit profile

Delete profile

Home

STEP 2

Scroll to and select **Edit profile**.

SELECT PROFILE

Day off Sports day

Work day

Back

STEP 3

Scroll to and select the profile you'd like to rename.

You can't rename the basal profile that your pump is currently pumping, and so you won't be able to select it from this list of saved basal profiles.

D	ΔY	0	F	F
ν	AT	U	Γ.	Ľ

Modify profile

Rename profile Duplicate profile

Back

DAY OFF Total: 13.25 Units Please name your basal profile: D a y t f f Cancel Save

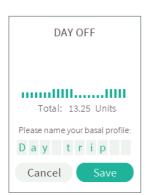
STEP 4 Scroll to and select **Rename profile** and press enter.

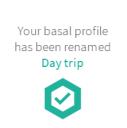
STEP 5

The profile you've selected will appear on your handset. Use the left, right, up or down buttons to scroll through the letters and change your profile's name. Each basal profile you set must have a different name.

QUICK TIP

You can select Cancel and return to the Edit profile menu whenever you like. If you do, any changes you've made won't be saved and the name of your basal profile will remain unchanged.





STEP 6

When you have named your basal profile, press Enter again to select **Save**.

STEP 7

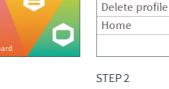
A confirmation message will pop up – your profile name has been changed. Press Enter to return to the Home screen.

How do I duplicate a basal profile?

Duplicating a basal profile is a great time-saver if you want to create a new basal profile that's similar to one you already have.

Here's how it's done:





On the Home screen, scroll to **Basal** and press Enter to select.

STEP 1

STEP 2 Scroll to and select **Edit profile**.

BASAL Set temporary basal rate View current profile

Change profile

Create new profile Edit profile

01

SELECT PROFILE

Day off

Sports day

Work day

Back

DAY OFF
Modify profile
Rename profile
Duplicate profile
Back

STEP 3

Scroll to and select the profile you'd like to duplicate.

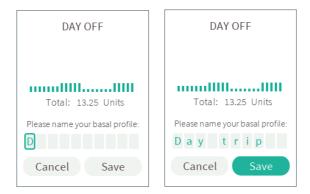
You can't duplicate the basal profile that your pump is currently pumping, so you won't be able to select it from this list of saved basal profiles.

STEP 4

Select Duplicate profile.

QUICK TIP

You can select **Cancel** and return to the Edit profile menu whenever you like. If you do, any changes you've made won't be saved and your basal profile won't be duplicated.



STEP 5

The profile you've selected will pop up on your handset. Use the left, right, up or down buttons to scroll through the letters and create a new name.

STEP 6

When you have set your new name, press Enter and then Enter again to select **Save**.

Your new basal profile **Day trip** has been saved

Ø

STEP 7

A confirmation message will pop up – your profile has been duplicated. Press Enter to return to the Home screen a little quicker.

QUICK TIP

Your handset can store up to seven basal profiles at a time. If you've filled your basal profile memory, you'll need to delete a basal profile you no longer wish to use, before you can create a new one. See *"How do I delete a basal profile?" on page 98* for more info. 90

20

80

00

10

11

How do I delete a basal profile?

If you've created a basal profile you no longer wish to use, you can delete that profile by following these steps:



STEP 1

On the Home screen, scroll to **Basal** and press Enter to select.

BASAL

Set temporary basal rate View current profile Change profile Create new profile Edit profile

Delete profile

Home

STEP 2

Scroll to and select **Delete profile**.

SELECT PROFILE Day off Sports day Work day Back

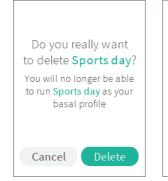
STEP 3

On your list of saved basal profiles, scroll to and select the one that you don't need anymore.

You can't delete the basal profile that your pump is currently pumping, so you won't be able to select it from this list of saved basal profiles.

QUICK TIP

Your handset can't pair or connect to your pump unless you have at least one basal profile saved. So, if you don't have a basal profile created, you'll need to set a new one before you can get pumping again.



STEP 4

Scroll to the right to select **Delete**. Press Enter to confirm.

STEP 5

A confirmation message will pop up – your profile has been deleted! Press Enter to return to the Home screen.

Sports day

has been deleted

Deleting a basal profile is final! Once a profile has been deleted, you won't be able to get it back.

QUICK TIP

You can select **Cancel** and return to the Delete profile menu whenever you like. If you do, any changes you've made won't be saved and your basal profile won't be deleted.



Temporary basal rates

Setting a temporary basal rate lets you increase or decrease your current basal profile by a specified percentage for a set period of time. This can be helpful if you decide to go for a run or skip your usual excercise on the spur of the moment.

Your healthcare provider can help with more advice on when to use a temporary basal rate.

How do I set a temporary basal rate?

If you want to temporarily change the amount of insulin you're receiving, you'll need to set a temporary basal rate. Your temporary basal rate can last for as little as half an hour and as long as 24 hours.



STEP 1

On the Home screen, scroll to **Basal** and press Enter to select.

BASAL
Set temporary basal rate
View current profile
Change profile
Create new profile
Edit profile
Delete profile
Home



Press Enter again to select **Set temporary basal rate**.



STEP 3

Set the percentage of your current basal profile that you'd like to receive. Press the left or right buttons to scroll through the number boxes and the up or down buttons to increase or decrease the percentage. You can choose a minimum of 0% to a maximum of 200%. Once you have set the correct percentage, press the Enter button.

QUICK TIP

Not all brands of insulin pumps work the same way when it comes to temporary basal rates and how to set them. Kaleido runs a normal basal rate at 100%, so if you select 110% as your temporary basal rate, you'll get a 10% increase of your basal rate. If you select 90%, you'll get a 10% decrease of your basal rate.

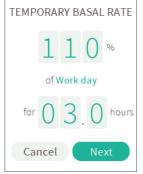
QUICK TIP

You can always select **Cancel** and return to the Basal menu. If you do, a temporary basal rate will not be set and your insulin delivery will stay the same.



STEP 4

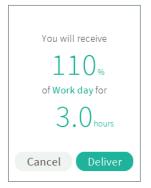
Set the amount of time you'd like your temporary basal rate to run for. Again, use the left or right buttons to scroll through the number boxes and the up or down buttons to increase or decrease the amount of time. You can choose a minimum of 0.5 hours right through to a maximum of 24 hours. Once you've chosen the amount of time, press the Enter button again.



STEP 5

Press the Enter button to select **Next**.

If you've accidentally moved to **Next** too soon and you'd still like to change the details of your temporary basal rate, just press the up button to return to the percentage settings.



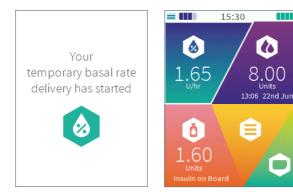
STEP 6

Your handset will now show you details of the temporary basal rate that you've set. If the details are correct and you'd like to start your temporary basal rate immediately, press Enter to select **Deliver**.

If you've changed your mind or want to make any last minute adjustments, just scroll left and press Enter to select **Cancel**.

OUICK TIP

Just so you know - you can't switch to a different basal profile while you're running a temporary basal rate. You also won't be able to access Change profile from the Basal menu and so you'll either need to stop your temporary basal rate first, or just wait until it's come to an end.



STEP 7

A confirmation will pop up – press Enter to return to the Home screen a little quicker.

STEP 8

To help you keep track, the Basal section of the Home screen will show you your temporary basal rate details for as long as the temporary basal rate is running.

Can I stop a temporary basal rate once it's started?



STEP 1

On the Home screen, scroll to **Basal** and press Enter to select.

BASAL

Stop temporary basal rate

View current profile

Change profile

Create new profile

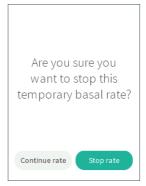
Edit profile

Delete profile

Home

STEP 2

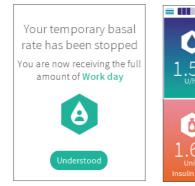
Press Enter again to select Stop temporary basal rate.



STEP 3

Scroll to the right to select **Stop Rate**. Press Enter to confirm.

If you don't wish to stop your temporary basal rate, scroll left to select **Continue rate** and press Enter to keep your temporary basal rate running as it was before.



Your temporary basal rate will stop as soon as you select Stop rate and your pump will start delivering your full basal rate again. Your handset will confirm this for you – press Enter to select **Understood** and return to the Home screen.

STEP 5

Your Home screen will update to show details of the basal rate that is now being delivered.

15:30

13:06 22nd Jun

WARNING

If you stop a temporary basal rate, bear in mind that part of the temporary basal rate may be already delivered. In this case, follow the instructions advised to you by your Healthcare Provider.



04. Bolus



What's a bolus?

A bolus is a single dose of insulin you deliver to cover any carbs you eat or to correct a high glucose (BG) level. You can choose the amount and type (Quick or Extended) of the bolus you give. Follow the recommendations made by your healthcare providers to determine the amount you bolus.

To access all things bolus related, just go to the Bolus menu of your home screen.

You can give two different types of bolus using Kaleido:



QUICK BOLUS If you choose a Quick Bolus, your bolus will be delivered all at once.

EXTENDED BOLUS An Extended Bolus allows you to deliver part of your bolus right away, and then the rest of it over a period of time – the duration of which you'll set yourself.

If you need a bit more help working out how much insulin to bolus, you can use Kaleidoculator. In the next chapter you'll find all the information you need on Kaleidoculator.

What is Kaleidoculator?

Kaleidoculator is a bolus calculator functionality in your handset. Kaleidoculator helps you to determine the correct bolus to be delivered, based on the personal information you have entered in the handset.

Kaleidoculator uses the personal settings you entered with help from your healthcare provider to advise you on the amount of insulin you'll need for the carbs you have entered or correcting your BG (if you have entered your BG). Not sure how much insulin to give for the carbs your about to eat? Or just trying to figure out what will get you back to your Target BG? Just fill in the numbers and Kaleidoculator will figure out how much insulin to bolus.

Once you've got your recommendation, you can choose whether you want to deliver it as either a Quick Bolus or an Extended Bolus based on the type of food you're eating. Not sure which one to use? Discuss this with your healthcare provider. If you want to tweak Kaleidoculator's recommendation, you can do that too.

How do I use Kaleidoculator?



BOLUS	
Kaleidoculator	
Quick Bolus	
Extended Bolus	
BG Reading	
Home	

STEP 1

On the Home screen, scroll to **Bolus** and press Enter to select.

STEP 2

Press Enter again to select **Kaleidoculator.**

QUICK TIP

You'll only be able to access Kaleidoculator from the Bolus menu if you've already worked with your healthcare provider to set a Target BG, insulin activity time, insulin to carb ratio and insulin to BG ratios (see "How do I enter my Target BG?" on page 161, *"How do I enter my insulin to carb ratios?" on page* 164, *"How do I enter my insulin to BG ratios?" on page* 168 and *"How do I enter my insulin activity time?" on page* 171).

WARNING

Only use Kaleidoculator when your healthcare provider indicated you should use it. The personal information needed for Kaleidoculator to work has to be determined together with your healthcare provider.





You'll need to enter the amount of grams of carbohydrate in the food that you're about to eat. Press the left or right buttons to scroll through the number boxes and press the up or down buttons to increase or decrease the number of carbs you have.

Once you've set the correct amount, press the Enter button.

Not eating, but still keen to use Kaleidoculator to help correct your BG? No problem, just leave the number boxes empty and press the Enter button to select **Next** and go to step 5.

STEP 4

Press the Enter button again to select **Next**.

If you've accidentally moved to **Next** too soon and you still want to change the carb details, just press the up button to get back to the number boxes.



STEP 5

You'll need to enter your current BG reading. Use your BG meter or approved continuous glucose monitor (CGM) to take a reading, then, just like before, press the left or right buttons on your handset to scroll through the number boxes and the up or down buttons to increase and decrease the numbers. When you've entered your BG correctly, press the Enter button.

It is possible to give a bolus without entering a BGreading, but it's important to follow instructions from your healthcare provider regarding glucose checks and bolusing to make sure you don't get too little or too much insulin.



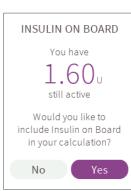
Press the Enter button again to select **Next**.

If you've accidentally moved to **Next** too soon and you need to change the BG reading you've entered, just press the up button to return to the BG reading.



QUICK TIP

In case your Insulin on Board has been recently reset, you will be notified of how long it will be before the Insulin on Board calculation will be accurate.



STEP 7

Kaleidoculator will show you your current Insulin on Board (that's how many units of insulin are still active in your body).

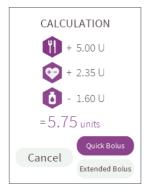
The Kaleidoculator allows you to accept or reject the Insulin on Board to be included in your calculation - just press the Enter button to select **Yes** or scroll to **No**. Not sure of what to do? Check with your healthcare provider to make sure you take the right steps.

QUICK TIP

Once you select **Next**, the BG reading and amount of carbs you've entered will be saved in History.

WARNING

Always check for ketones if your BG reading is excessively high (above 13.9 mmol/L). If ketones are present, treat according to the advice given to you by your healthcare provider.



Kaleidoculator will now show you details of its recommended bolus. You have three options to choose from:

• To deliver the recommendation as a **Quick Bolus**, just press Enter. Your handset will take you to the Quick Bolus entry screen, where your recommendation will be ready and waiting for you. Next, just follow along from step 4 of "How do I deliver a Quick Bolus?" on page 121.

You can also change the recommendation first, using the up, down, left or right buttons to adjust the amount of insulin to be delivered.

QUICK TIP

You can select **Cancel** and return to the Bolus menu whenever you like.

QUICK TIP

Kaleidoculator's calculation might not always result in a positive value for the number of units of insulin in its recommended bolus. See "What happens if Kaleidoculator's recommended bolus is a negative number?" on page 118 to find out what to do if it recommends a negative number.

QUICK TIP

If you've decided not to enter an amount for Food or BG, or chosen not to include your Insulin on Board, these things won't be included in your calculation. Instead, you'll see a dash where the suggested amounts of insulin would normally be.

• If you'd like to deliver the recommendation as an Extended Bolus instead. press the down button to select Extended Bolus and then press Enter to select it. This time, your handset will take you to the Extended Bolus entry screen and Kaleidoculator's recommendation will be set as the total bolus amount. Just follow along from Step 4 of "How do I deliver an Extended Bolus?" on page 124 to set up and deliver your bolus. If you'd like to change the recommendation first, use the up, down, left or right buttons to adjust the total amount of insulin to be delivered.

• Alternatively, if you decide you don't want to deliver a bolus after all, just scroll left and press Enter to select **Cancel** and go back to the Bolus menu instead.

QUICK TIP

To use Kaleidoculator, you'll need to make sure your handset knows your Target BG, and your personal insulin activity time, along with your insulin to carb and insulin to BG ratios and your maximum bolus. These are all part of your Personal Info. See "Personal Info" on page 155. Make sure your personal settings are up to date so you know for sure you're getting the right dose of insulin. Always work with your healthcare provider to determine and set these amounts.

WARNING

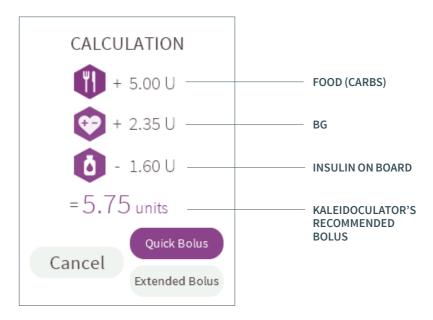
Do not change your personal insulin delivery parameters (e.g. Target BG, insulin activity time, maximum bolus, insulin to carb and insulin to BG ratios) without consulting your healthcare provider.

WARNING

If you have recently used an alternative method of insulin delivery, bear in mind that Kaleido can not calculate the Insulin on Board based on insulin which is delivered by another method (e.g. insulin pens).

What do the numbers that make up Kaleidoculator's calculation mean?

Kaleidoculator will do the hard work for you, so you don't have to think about the numbers running in the background, *but* knowing what they mean will help you make choices that make you happier.



FOOD (CARBS)

Food (Carbs) is the amount of insulin you need for the carbs you entered. Using the number of grams of carbohydrate that you've just entered, plus the insulin to carb ratios from your Personal Info, Kaleidoculator calculates the amount of insulin you'll need to cover the carbs you're about to eat and keep your BG level where it is.

So, if you're at 10 mmol/L, it'll calculate the insulin you'll need to keep you at 10 mmol/L. If you're at 4 mmol/L, it'll calculate how much you'll need to stay at 4 mmol/L. So, if you're entering your carb count, this number will always be positive. If you're not entering a carb count, you'll see a dash here, not a number, to show that carbohydrates aren't being taken into account.

BG

If your BG is too high or too low, you will need to deliver extra or less insulin to reach your Target BG. Kaleidoculator uses the BG reading you've just entered, plus the insulin to BG ratios and the Target BG from your Personal Info to calculate the amount of insulin you need to reach your target.

So, if your Target BG is 6.0 mmol/L and your current BG reading is 10.0 mmol/L, this number will be positive, because you'll need some extra insulin to lower it to your target. But, if your current BG reading is 4 mmol/L, this number will be negative, because you'll need less insulin (or no insulin if you're not entering any carbs at this time) to raise your BG back to your Target BG of 6.0 mmol/L. And, if you choose not to enter a BG reading at all, this number will be replaced with a dash.

INSULIN ON BOARD

Kaleidoculator uses the insulin activity time you've set in your Personal Info, and the information on previously delivered bolusses (throughout the duration of your insulin activity time), to work out what adjustment needs to be made to its recommendation to account for the insulin that might already be at work in your body.

So, if you already have 1.60 units of active insulin when you're using Kaleidoculator and you choose to include Insulin on Board, the calculated amount of Insulin on Board will be -1.60 units. In fact, if you ever have any insulin still active in your body, the value shown on the screen will be negative, if you choose to include it. If you don't have any active Insulin on Board, the number will be zero, and if you choose not to include your Insulin on Board in your calculation, you'll see a dash here instead. You can find out more about Insulin on Board by looking up *"How do I check my Insulin on Board?" on page 141*.

KALEIDOCULATOR'S RECOMMENDED BOLUS

For the final result, Kaleidoculator takes the calculated units of insulin for your carbs, BG and Insulin on Board and puts them all together to give you its recommended bolus amount.

In the example here, you can see that for the carbs it is +5.00 units, for the BG it is +2.35 units and for the Insulin on Board it is -1.60 units. All together, these total up to a recommended bolus of 5.75 units (5.00 + 2.35 - 1.60 = 5.75).

What happens if Kaleidoculator's recommended bolus is a negative number?

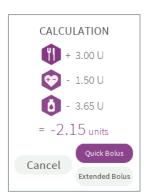
Sometimes, Kaleidoculator may indicate a negative amount of insulin as its recommended bolus for you – say, if you're not eating (or not eating very much carbohydrate) and if your BG is already below your Target BG. In that instance, you don't need *more* insulin, you actually need *less*.

But, just like you can't take out any insulin you've already delivered, you can't give a negative bolus. So, here's what will happen if you receive a negative number as your recommended bolus.

QUICK TIP

If you don't agree with Kaleidoculator's recommendation and would still like to deliver a bolus, you can do this by selecting either Quick Bolus or Extended Bolus from the Bolus menu instead. Your healthcare provider can help you out on what to do when a negative number appears.

2



STEP 1

Having followed steps 1 to 7 of *How do I use Kaleidoculator*?, you'll arrive at Kaleidoculator's recommended bolus calculation. This time though, you'll see that the bolus recommendation is a negative number.



STEP 2

The simplest thing to do if you spot a negative number as your recommended bolus, is just to scroll left to Cancel and press Enter to select **Cancel** and go back to the Bolus menu.

Hang on!

We've crunched the numbers and delivering a bolus right now is not recommended

Home

STEP 3

If you don't spot that the recommended bolus is a negative number though, your handset will help you out. If you select either Quick Bolus or Extended Bolus when your recommended bolus is a negative number, your handset will pop up with a quick reminder to tell you that giving a bolus isn't the safest thing to do at this time. Press Enter to select Home and return to the Home screen.

What happens if the suggested bolus is bigger than my maximum bolus?

Kaleidoculator has calculated a bolus

bigger than your maximum (30.00 units)

Would you like to continue with a bolus of 30.00 units?

Yes

To set or adjust your maximum bolus, head over to *"How do I enter my maximum bolus?" on page 173.*



STEP 1

You've followed Steps 1-7 of *How do I use Kaleidoculator*? and Kaleidoculator has made it's calculations and recommended a bolus. You've noticed that the recommended bolus is bigger than the maximum bolus you have in Personal Info.



No

If you'd like to deliver your maximum bolus, select your choice of **Quick Bolus** or **Extended Bolus**. Your handset will let you know that the calculation is more than your set maximum. Select **No** to return to the previous screen and review the calculation or scroll to

the right to select **Yes** and press Enter to deliver your maximum bolus. If your recommended bolus is higher than your maximum bolus, don't forget to deliver another bolus of the remaining units after your first bolus has finished to make sure you get all the insulin you need.

How do I deliver a Quick Bolus?







STEP 1 On the Home screen, scroll to **Bolus** and press Enter to select.

Scroll to and select **Quick Bolus**.

STEP 3

You'll need to set the amount of insulin that you'd like to deliver in your Quick Bolus. Press the left or right buttons to scroll through the number boxes and press the up or down buttons to increase or decrease the amount of insulin you want to deliver. Once you've set the correct amount, press the Enter button.

QUICK TIP

The bolus amount will automatically default to 01.00 unit.

QUICK TIP

You can set a bolus in increments as tiny as 0.05. The largest is 30 units.

QUICK TIP

You can select **Cancel** and return to the Bolus menu whenever you like. If you do, a Quick Bolus won't be set and no bolus will be delivered.





STEP 4

Press the Enter button to select **Next**.

If you've accidentally moved to **Next** too soon and you still want to change the details of your Quick Bolus, just press the up button to return to the insulin boxes.

STEP 5

Your handset will now show you details of the Quick Bolus you'd like to give. If the details are correct and you want to start your Quick Bolus, just press Enter to select **Deliver**.

If you've changed your mind or want to make a last minute adjustment, just scroll left and press Enter to select **Cancel**.

QUICK TIP

The bolus delivery rate is 1 U per minute.



Your Quick Bolus will start as soon as you select **Deliver**.

If your BG reminders are turned on, your handset will confirm that your Quick Bolus delivery has started. It'll also ask you if you'd like to set a reminder to check your BG in 2 hours time – just press Enter to select **Yes**. If you don't want to set a reminder this time, you can scroll left and then press Enter to select **No** instead.

If you have turned off BG reminders, you'll now see a message to confirm delivery has started. Press Enter to return to the Home screen a little quicker.



STEP 7

To help you keep track, the Bolus section on your Home screen will show your Quick Bolus delivery counting down (just make sure your handset is in range). Once you've received all of your Quick Bolus, the Bolus section will update to show you the details of the last bolus given – that's exactly how much insulin you received and when you received it.

REMINDER

It's been 2 hours since you delivered your last bolus Why don't you do a quick BG test? Reminder understood

QUICK TIP

If you choose to set a reminder to check your BG 2 hours after your bolus has been started, the reminder will pop up on your handset screen and your handset will sound a reminder tone. Once you've read and understood the reminder, just press the Enter button.

QUICK TIP

You can turn BG reminders on or off in System Settings. See "What are BG reminders and how do I turn them off?" on page 193 for more details. 2

How do I deliver an Extended Bolus?



BOLUS	
Kaleidoculator	
Quick Bolus	
Extended Bolus	
BG Reading	
Home	
	-

STEP 1

On the Home screen, scroll to **Bolus** and press Enter to select.

STEP 2

This time, scroll to and select **Extended Bolus**.

OUICK TIP

The total amount of insulin (the amount you want to give now plus the amount you want to spread out) you can give in an Extended Bolus cannot be higher than your maximum bolus. The minimum amount of bolus that you can deliver immediately is 0.05 units, and the maximum is your maximum bolus minus 0.05 units.



STEP 3

On the Extended Bolus screen, set the total amount of insulin you'd like to deliver using the left or right buttons to scroll through the number boxes. Press the up or down buttons to increase or decrease the amount of insulin. Once you have set the correct amount, press the Enter button.

OUICK TIP

The total bolus amount will automatically default to 01.00 unit.

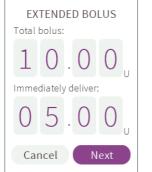
STEP 4

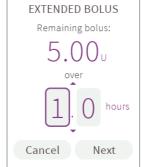
Set the amount of insulin that you'd like to deliver immediately. Just like before, press the left or right buttons to scroll through the number boxes and press the up or down buttons to increase or decrease the amount of insulin. Once you have set the correct amount, press the Enter button.

Next

QUICK TIP

Based on the total bolus and the amount of insulin you have chosen to deliver immediately, your Kaleido handset will calculate how much of your remaining bolus will be delivered over the time period you've chosen.





STEP 5

Press the Enter button to select **Next**.

If you've accidentally moved to **Next** too soon and you still want to change the details of your Extended Bolus, just press the up button to return to the Total bolus boxes.

STEP 6

Choose the amount of time you'd like to extend the second part of your bolus for. Use the left or right buttons to scroll between the number boxes and the up or down buttons to increase or decrease the time period – you can extend delivery over as little as 0.5 hours and as long as 9.5 hours. When you have set the correct time, press the Enter button.

QUICK TIP

You can select **Cancel** and return to the Bolus menu whenever you like. If you do, an Extended Bolus won't be set and your insulin delivery will remain unchanged.





STEP 7

Press the Enter button again to select **Next**.

Alternatively, if you've moved to **Next** too soon, just press the up button to return to the time selection box or, if you want to make any changes, you can scroll left and press Enter to select **Cancel** and go back to the previous screen.

STEP 8

Your handset will now show you the details of the Extended Bolus that will be delivered. If the details are correct and you want to start your Extended Bolus, press Enter to select **Deliver**. If you've changed your mind or want to make any last minute adjustments, just scroll left and press Enter to select **Cancel**.



Your Extended Bolus will start as soon as you select **Deliver**.

If your BG reminders are turned on, your handset will confirm that your Extended Bolus delivery has started. It'll also ask you if you'd like to set a reminder to check your BG in 2 hours time – just press Enter to select **Yes**. If you don't want to set a reminder this time, you can scroll left and then press Enter to select **No** instead.

If you have turned off BG reminders, you'll now see a message to confirm delivery has started. Press Enter to return to the Home screen a little quicker.



STEP 10

To help you keep track, the Bolus section of your Home screen will show you your Extended Bolus delivery counting down (you just need to make sure your handset is in range). Once you've received all of your Extended Bolus, the Bolus section will update to show you the details of the last bolus given - that's how much insulin you received and when you received it.

QUICK TIP

If you choose to set a reminder to check your BG 2 hours after your bolus has been started, the reminder will pop up on your handset screen and your handset will sound a reminder tone. Once you've read and understood the reminder, just press the Enter button.

QUICK TIP

You can turn BG reminders on or off in System Settings. See "What are BG reminders and how do I turn them off?" on page 193 for more details.

E

2

Can I stop a bolus?

Of course. We'd always recommend making sure your bolus details are correct before you choose to deliver, but we know that sometimes things can change quickly. If you need to stop a Quick or Extended Bolus, just follow these steps:



7.45_U of your bolus have yet to be delivered Would you like to stop your remaining bolus? No Yes

STEP 1

On the Home screen, scroll to **Bolus** and press Enter to select.

STEP 2

Your handset will show you a countdown of how much of your bolus still needs to be delivered. To stop the remaining bolus, scroll to the right and press Enter to select **Yes**.



Continue bolus

You will be asked to confirm that you'd like to stop your bolus. To do this, press Enter to select Stop bolus. You'll see on your Home screen that the countdown of your bolus has stopped. If your bolus was for carbs, make sure you eat enough carbs to cover the insulin that has already been delivered before you cancelled it. If the insulin was for an elevated BG, ensure you have delivered enough insulin to cover this.

Are you sure you

want to stop this bolus?

Alternatively, you can scroll left and press Enter to **Continue bolus**. Your bolus delivery will continue unaffected.

WARNING

If you stop a bolus, bear in mind that part of the bolus may be already delivered.



STEP 4

Your bolus delivery will stop as soon as you select **Stop bolus** and your handset will confirm this for you – press Enter to select **Understood** and return to the Home screen.

STEP 5

Your Home screen will update and show you details of the amount of bolus (if any) that was delivered before your bolus was stopped.

What happens if I don't have enough insulin left to deliver a bolus?

When you enter a bolus yourself into Quick or Extended Bolus, or if Kaleidoculator has suggested a number for you, we'll always give you a heads up if there isn't enough insulin left in your pump.

Sorry! You do not

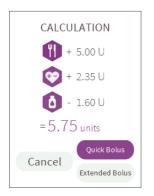
have enough insulin to deliver this bolus

Please change your

insulin cartridge!

Understood

× 🔺



STEP 1

Decide on the amount you'd like to bolus by following one of these three options:

• Follow Steps 1 - 7 of "How do I use Kaleidoculator?" on page 111.

• Follow Steps 1 - 4 of "How do I deliver a Quick Bolus?" on page 121.

• Follow Steps 1 - 8 of "How do I deliver an Extended Bolus?" on page 124.



Before you can select **Deliver** you'll receive a message letting you know it's not possible to deliver the bolus you wanted. This is because there's less insulin left in your insulin cartridge's reservoir than the amount you'd like to deliver.

Press Enter to select Understood. Your handset will take you back to the Home screen. From here go to the Status menu to stop your pump and take the (almost empty) insulin cartridge out. See "How do Istop my pump?" on page 215 for more information. Fill a new insulin cartridge and place it into your pump ("How do I fill my insulin cartridge with insulin?" on page 41 and "How do I put my insulin cartridge into my pump?" on page 49 for more information). Then, use the Kaleidoculator again.



Blood Glucose (BG)

You can enter BG readings in this section for a quick reference later on. But, if you require any bolus advise, we definitely recommend putting your BG into your Kaleidoculator. Any BGs you save in the BG section will not be transferred to the Kaleidoculator. Think of it as a BG-diary.

Also see "How often should I take a BG reading?" on page 249.

How do I enter a BG reading?



STEP 1 Use your glucose device to take a BG reading.



```
STEP 2
```

On the Home screen, scroll to **Bolus** and press Enter to select.

BOLUS
Kaleidoculator
Quick Bolus
Extended Bolus
PC Deading
BG Reading
Home

STEP 3 Scroll to and select **BG Reading**.





If you have saved a Target BG in Personal Info, the BG reading will automatically default to your Target BG when you start to enter it.

Enter your latest BG reading by using the left or right buttons to scroll through the number boxes and the up or down buttons to increase and decrease the numbers.

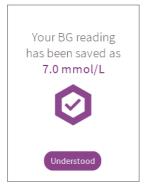
STEP 5

When you've entered your BG correctly, press the Enter button. Press the Enter button again to select **Save**.

If you've accidentally moved to **Save** too soon and you need to change the BG reading you've entered, just press the up button to return to the BG reading.

QUICK TIP

You can select **Cancel** and return to the Home screen whenever you like. If you do, your BG reading won't be saved on your handset.



A confirmation message will appear – your BG reading has been saved. Press Enter to select **Understood** and return to the Home screen.

15:30 15:30 15:30 15:30 8:00 Units 13:06 22nd Jun 1:50 1:60 Units Insulin on Board

STEP 7

Your BG reading is now saved and can be viewed by accessing your History.

See "How do I review my History?" on page 148.



05. Resource Levels



The Resource Levels section of your Home screen will show you your current Insulin on Board values and will direct you to your Resource Levels screen to check how full your insulin cartridge, pump and handset batteries, your current Insulin on Board values and when your insulin cartridge should be replaced.

80

8

10

11

2



What is Insulin on Board?

Insulin on Board is really pretty useful. When you deliver a bolus, the insulin that you deliver can take a little while to be absorbed and then start acting to lower your BG level. In fact, insulin can still be having an effect on your BG levels for quite a few hours after you've delivered it (for the duration of your insulin acting time). Just because it's been a while since you delivered your bolus, it doesn't mean that all that insulin will have been used up. In fact, some of your last bolus might not have even started working yet and your BG levels could still be on the way down. So, if you're bolusing without factoring in the insulin that's already active in your body, you may actually deliver more insulin than you really need, which could cause your BG to go below your target or even into a hypo. So, how does it work? Kaleido remembers all of the boluses that you've delivered via your pump and is able to calculate how much insulin is still active in your body at any given time, based on your insulin activity time.

QUICK TIP

As well as needing to be connected to a pump, your handset needs to be in range of the pump you're currently using in order to show you your Insulin on Board. If you try to check Insulin on Board when you're not connected to the pump you are currently using or if your handset is out of range of your pump, you won't be able to access Insulin on Board from the Menu section (if you're checking your Insulin on Board at the point your handset and pump go out of range of each other, the Insulin on Board number will disappear and it'll be replaced by a dash). To make Insulin on Board accessible again, make sure your handset is connected to a pump and – if your handset and pump are out of range – move them closer together. Now you'll be able to check Insulin on Board again – Just give your handset a moment to process the data.

How do I check my Insulin on Board?

QUICK TIP

Kaleido works out your Insulin on Board using the insulin activity time that you've set in Personal Info. So, if you haven't set an insulin activity time, you won't be able to access Insulin on Board from the Menu section. Always set your insulin activity time with the guidance of your healthcare provider- to find out more, see *"How do l enter my insulin activity time?" on page 171*.



STEP 1

On your Home Screen your Insulin on Board (IoB) will be shown. Go to Resource Levels and press Enter to select.

QUICK TIP

In case your Insulin on Board has been recently reset, the handset will notify you of how long it will be before your Insulin on Board calculation will become accurate.

Your Insulin on Board

has been reset

Its calculation will only be

accurate in 6.5 hours

 \boxtimes

10

11

How do I check how full my insulin cartridge and batteries are?

You can always check how full your insulin cartridge, pump and handset batteries are by looking at the icons at the top of your Home screen. If you need a little more in-depth info, just follow these steps to uncover more:



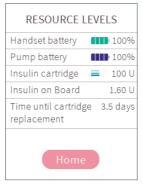
STEP 1

On the Home Screen go to **Resource Levels** and press Enter to select.

QUICK TIP

Make sure to check the resource levels frequently to be sure you have enough insulin and battery power left for use.

Check the resource levels of the insulin cartridge, pump battery and handset battery prior to use. See "How do I charge my handset?" on page 20, "How do I charge my pumps?" on page 22 and "How do I fill my insulin cartridge with insulin?" on page 41.



STEP 2

The Resource Levels screen will show you the following:

- How much power is left in your handset battery (as a percentage).
- How much power is left in your pump battery (as a percentage).
- How many units of insulin are left in your insulin cartridge (rounded down to the nearest full unit).
- The Insulin on Board
- Time until the final cartridge replacement alarm (in days/hours)

Once you have the information you need, press Enter to select **Home** and return to the Home screen.



If you have been using your insulin cartridge for three days, you will receive a reminder.

If you receive this reminder, press Enter to select **Understood** and return to the Home screen.

What do all the Resource Level icons mean?

If your insulin cartridge or either of your batteries are low enough to have triggered an alarm, you'll also see this in the icons on your Home and Resource Levels screens.

This is what the Resource Level icons mean:

		X
Insulin cartridge	Insulin cartridge in low priority alram mode	Insulin cartridge in high priority alarm mode
Pump battery	Pump battery in low priority alarm mode	
Handset battery	Handset battery in low priority alarm mode	

QUICK TIP

If you check your Resource Levels when your handset is not connected to a pump, you'll only be able to see the handset battery icon and information. Ľ

21

02

3



06. Menu



Menu

The Menu section of your Home screen will direct you to Data Upload and help show you your History, Personal Info and System Settings.

History

In the History functionality, you'll find a record of everything that's happened today, plus the last seven day of using your Kaleido, with the date and time shown for each event.

Do you want to look back further than last week? With access to an Uploader you can upload your data whenever you like. The handset is able to store up to 90 days of data in a typical use scenario. Once the History reaches capacity, the oldest entries are discarded.

For details of how to upload data, check out *"How do I upload my data using a data uploader?" on page 151.*

QUICK TIP

History will record when a pump is changed, started, paused, stopped or disconnected. It also takes note of any temporary basal rates that are set, the amount of carbs you've entered into Kaleidoculator, as well as any recommendations that Kaleidoculator makes and any Quick and Extended Boluses that are delivered (whether or not you've used Kaleidoculator to deliver them). It can also show you when you changed your insulin cartridge, primed a cannula, swapped your basal profile, saved a BG reading, uploaded data, changed the date or time, or updated your Personal Info or System Settings, plus any alarms that you have received. Last but not least, it'll keep a record of your total daily dose of insulin each day.

QUICK TIP

Charge your handset on a frequent basis to ensure you have sufficient battery power for use. If your handset's battery goes totally empty, even for a longer period, you won't lose any info. Your History will be updated and saved once you charge your handset and then you turn your handset on again.

QUICK TIP

The time that your handset is powered down is not captured in the history.

How do I review my History?



ST	FD	1
51		+

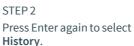
On the Home screen, scroll to **Menu** and press Enter to select.

М	ENU
History	
Data Uploa	d
Personal In	fo

System Settings

Home

HIS	HISTORY		
Τc	oday		
Mon 2	0th July		
Sun 1	Sun 19th July		
Sat 1	Sat 18th July		
Fri 17	Fri 17th July		
Thu 1	Thu 16th July		
Wed 15th July			
Tue 14th July			
Back	Home		



STEP 3

Scroll to the day you'd like to review and then press Enter to select it.

eview the ay, plus the seven days of ctivity.
uicklyjump

21

22

3

2

05

70

8

10

E

THU 1ST JANUARY Pump paused 0:00 0 hrs 23 mins (0.50 U missed) Pump stopped 0:00 Temp basal rate set 0:00 150% 2 hrs 30 mins Home Back

STEP 4

Use the up or down buttons to read through everything that happened on that day.

STEP 5

150%

When you're done, just scroll down to Home. Press Enter to select it and you'll be sent back to the Home screen.

THU 1ST JANUARY

0 hrs 23 mins (0.50 U missed)

Temp basal rate set

0:00

0:00

0:00

0:00

2 hrs 30 mins

Pump started

Pump paused

Pump stopped

Back

Work day

Alternatively, from Home, scroll left to Back and press Enter to return to the History menu.

QUICK TIP

You can re current da previous s Kaleido ad

OUICK TIP

You can g to the Home screen by pressing Enter twice from anywhere on the list of events.

QUICK TIP

Sometimes it can be useful to see exactly how much insulin you've received over the course of a day. History keeps a note of your total daily dose every single day. It'll always be one of the very last events to appear in your History at the end of each day – in fact, to make sure the total daily dose is totally accurate, your Kaleido's scheduled to calculate the information at 23:59 hrs. If an event is ever missing from History, make sure your handset and pump are in range, give them some time to process the data and then, check again – your handset needs up-todate information from the pump you're currently using to calculate your total daily dose, something it can't do if your pump is not in range.

Data Upload

Although you can always find lots of information about the last week in History, sometimes either you or your healthcare provider might want to look back a little further to get even more detail from your Kaleido. You can upload any BG, insulin and carb data as well as your basal settings and personal info you've entered into your Kaleido handset with a data uploader provided by compatible 3rd parties (e.g. Glooko®). Ask your healthcare provider to show you how to upload your data, or follow these steps.

How do I upload my data using a data uploader?



STEP 1

First things first – if this is your very first time using a data uploader, get started by logging on or creating a new account for yourself on the data sharing website.

Follow the instructions on the data sharing website to install the data uploader software program onto your computer.

STEP 2

Next (or if you've already completed step 1 in the past), start the program on your computer. STEP 3 Once the data uploader is ready, insert the larger end of your Kaleido connection cable into a USB port on your computer. 2

22

3

2

05

70

10

E

QUICK TIP

Although History will only show you your Kaleido activity from today plus the last seven days, depending on how much data it receives, your handset actually stores around 90 days of data in its memory. Uploading your data means you'll have access to all of this extra information – everything you can no longer see on your handset. It also means that you should aim to upload your data at least once every 90 days to make sure that you always have a complete record of everything that's happened.



STEP 4 Insert the smaller end of the connection cable into your handset's micro USB port.





Scroll to **Menu** on the Home screen and press Enter to select.

MENU		
History		
Data Upload		
Personal Info		
System Settings		
Home		

STEP 6 Scroll to and select **Data Upload**.



To start the upload, press Enter to select **Upload**.

Alternatively, if you've changed your mind, just scroll left to **Back** and press Enter to select it.



STEP 8

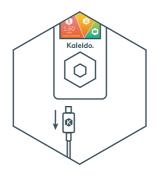
Your data will start to

be uploaded as soon as you select **Upload** on the handset. On your handset, you'll see an uploading countdown.



STEP 9

Your handset will give you a confirmation message as soon as the upload has completed. You can press Enter to jump back to the Home screen a little quicker.





Remove the connection cable from your handset and your computer.

If you see a "Sorry, something's gone wrong. Please try again" message, you need to remove your connection cable from your computer and handset and return to STEP 1 of "How do I upload my data using a data uploader?" on page 151. If this did not fix the issue, contact Kaleido Care.

QUICK TIP

You can follow your data uploader's instructions for details of how to view and use your data. Just remember to remove the connection cable from your handset and your computer, and keep it safe for the next time you need to use it.

Personal Info

The personal info section is exactly that: your personal information. Here you can put in your name and age, as well as all the settings you need to get your Kaleidoculator to work. This section will show you everything you need to know about Personal Info.

How do I add or view my Personal Info?



STEP 1

On the Home screen, scroll to **Menu** and press Enter to select.

MENU
History
Data Upload
Personal Info
System Settings
Home

STEP 2

Scroll to and select **Personal Info**.

PERSONAL INFO		
Age:		
Target BG:		
Insulin to carb:		
Insulin to BG:		
Insulin activity:		
Max. Bolus:	20.00 units	
Back	Home	

PERSONAL INFO	
Name:	
Age:	
Target BG:	
Insulin to carb:	
Insulin to BG:	
Insulin activity	:
Max. Bolus:	20.00 units
Back	Home

On the Personal Info menu, use the up or down buttons to read through all of your saved details.

STEP 4

When you've finished, scroll all the way down to **Home**. Press Enter to select it and you'll go right back to the Home screen. Alternatively, from Home, scroll left to **Back** and press Enter to go back to **Menu**.

How do I enter my name?





NAME Please enter your name: A b i Cancel Save

STEP 1

On the Personal Info menu, simply scroll to **Name** and press Enter to select.

STEP 2

Enter your name using the up or down buttons to scroll through the alphabet. The right button will help you move on to the next letter or add a space. When you're done, press Enter.

STEP 3

When you're ready to save your name, press Enter again to select **Save**.

If you've accidentally moved to **Save** too soon and you need to change the name you've entered, Just press the up button to return to the first letter box.

QUICK TIP

You can select **Cancel** and return to the Personal Info menu whenever you like. If you do, any changes you've made won't be saved. 10

Ľ



PERSONAL INFO		
Name:		
Age:		
Target BG:		
Insulin to carb:		
Insulin to BG:		
Insulin activity:		
Max. Bolus:	20.00 units	
Back	Home	

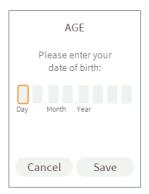
A confirmation message will pop up – your name has been saved. Press Enter to return to the Personal Info menu a little quicker.

STEP 5

Your name will now show up in the Personal Info menu.

How do I enter my age?

PERSONAL INFO		
Name:	Abi	
Age:		
Target BG:		
Insulin to carb:		
Insulin to BG:		
Insulin activity:		
Max. Bolus:	20.00 units	
Back	Home	





STEP 1

On the Personal Info menu, scroll to **Age** and press Enter to select.

STEP 2

Enter your date of birth using the up or down buttons to scroll through the numbers 0 to 9. Use the right button to move on to the next number. Once you've successfully entered your date of birth, press Enter.

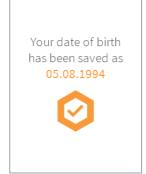
STEP 3

When you're ready to save your date of birth, press Enter again to select **Save**.

If you've accidentally moved to **Save** too soon and you need to change the date of birth you've entered. Just press the up button to return to the first number box.

QUICK TIP

You can select **Cancel** and return to the Personal Info menu whenever you like. If you do, any changes you've made won't be saved. 11



PERSONAL INFO		
Name:	Abi	
Age:		
Target BG:		
Insulin to carb:		
Insulin to BG:		
Insulin activity:		
Max. Bolus:	20.00 units	
Back	Home	

A confirmation message will appear – your date of birth has been saved. Press Enter to return to the Personal Info menu a little quicker.

STEP 5

Your handset will now use your date of birth to display your age in the Personal Info menu. If the age that shows is incorrect, check your handset's date settings *"How do I change the date* on my handset?" on page 199.

How do I enter my Target BG?

QUICK TIP

Target BG is one of the many important settings used in the Kaleidoculator. To find out more about Kaleidoculator, why not take a look at *"How do I use Kaleidoculator?" on page 111*. We suggest you have a chat to your healthcare provider to decide what your Target BG should be before you enter it into your Kaleido handset.

PERSONAL INFO	
Name:	Abi
Age:	26
Target BG:	
Insulin to carb	:
Insulin to BG:	
Insulin activity:	
Max. Bolus:	20.00 units
Back	Home

TARGET BG Please enter your Target BG: mmol/L Cancel Save



2

2

3

2

05

06. Menu

70

10

E

STEP 1

On the Personal Info menu, scroll to **Target BG** and press Enter to select.

STEP 2

Enter your Target BG using the up or down buttons to scroll through the numbers 0 to 9. Use the right button to move on to the next number.

Once you've successfully entered your Target BG, press Enter.

STEP 3

When you're ready, press Enter again to select **Save**.

If you've accidentally moved to **Save** too soon and you need to change the Target BG you've entered. Just press the up button to go back to the first number box.

QUICK TIP

You can select **Cancel** and return to the Personal Info menu whenever you like. If you do, any changes you've made won't be saved.



PERSONAL INFO	
Name:	Abi
Age:	26
Target BG:	
Insulin to carb:	
Insulin to BG:	
Insulin activity	c
Max. Bolus:	20.00 units
Back	Home

A confirmation message will pop up – your Target BG has been saved. Press Enter to return to the Personal Info menu.

STEP 5

Your Target BG will now be displayed in the Personal Info menu.

What are insulin to carb ratios?

An insulin to carb ratio tells you how much insulin you need to cover the carbohydrates that you eat. It tells you how many grams of carbohydrate 1 unit of insulin will cover. So, if you have an insulin to carb ratio of 10 grams/U (1:10), it means your body needs 1 unit of insulin to cover every 10g of carbs that you eat. That means you'd need 7 units of insulin to cover a meal containing 70g of carbs to prevent your BG level increasing from the carbs you're about to eat.

Not only are insulin to carb ratios different from person to person, you may also have a different insulin to carb ratio depending on what time of day it is. So, Kaleido allows you to save a different ratio for every hour of the day, which means that you and your healthcare provider can work together to set the ratios that work especially for you.

QUICK TIP

You might have already guessed, but if your BG level is already higher than your Target BG, you might not be satisfied by just covering out the carbs you're eating – depending on when your last correction bolus was and how long your insulin activity time is, you may need to bring your BG back down to target too. Kaleidoculator can help make sense of all the calculations and give a bolus recommendation based on your Personal Info. Take a look at *"How do I use Kaleidoculator?" on page 111* to find out more.

How do I enter my insulin to carb ratios?

PERSONAL INFO	
Name:	Abi
Age:	26
Target BG:	6.0 mmol/L
Insulin to BG:	
Insulin activity	<i>:</i> :
Max. Bolus:	20.00 units
Back	Home

STEP 1

On the Personal Info menu, scroll to **Insulin to carb** and press Enter to select.

INSULIN T	O CARB
01:00 - 02:00	10 grams/U
Cancel	Save

STEP 2

You can set a different

ratio for every hour of the day. Press the left or right buttons to scroll between each hourly segment and then press the up or down buttons to select the ratio you want for each hour. Below the insulin to carb ratio graph you'll see details of the hour you're currently setting, along with the ratio that you are entering.

If you're setting a ratio of 9.9 grams/U or less, you can set the ratio in increments of 0.1 grams/U. For any ratios of 10 grams/U or more, the increments change to 1 gram/U. The smallest insulin to carb ratio you can set for an hour is 0.1 grams/U and the largest is 99 grams/U.



Once you've entered an insulin to carb ratio for each hour, press the Enter button. Press Enter again to select **Save**.

If you want to return to the graph before you select **Save**, just press the up button. Or, if you've changed your mind completely, scroll left to **Cancel** and press Enter to select it.

Your insulin to carb
ratios have been
saved
\bigcirc

QUICK TIP

You can select **Cancel** and return to the Personal Info menu whenever you like. If you do, any changes you've made won't be saved.

04 05 06. Menu 07 08 09 10 11

21

2

3

STEP 4

A confirmation message will appear – your insulin to carb ratios have been saved. Press Enter to return to the Personal Info menu a little quicker.

PERSONAL INFO	
Name:	Abi
Age:	26
Target BG:	6.0 mmol/L
Insulin to carb	: 10 grams/U
Insulin to BG:	
Insulin activity	:
Max. Bolus:	20.00 units

Your insulin to carb ratios will now show up in the Personal Info menu. Your handset will always display your current insulin to carb ratio for the actual hour of the day you are viewing your Personal Info.

QUICK TIP

Kaleidoculator needs a complete set of insulin to carb ratios to be able to work – one for each hour of the day. So you won't be able to select **Save** if you haven't entered all 24 insulin to carb ratios. You won't be able to access Kaleidoculator from the Bolus menu if you haven't set your insulin to carb ratios either.

What are insulin to BG ratios?

Insulin to BG ratios also known as Insulin Sensitivity Factor (ISF) or Correction Factor (CF) is how much 1 unit of rapid-acting insulin will generally lower your glucose over 2 to 4 hours when you are in a fasting or pre-meal state. For example, an insulin to BG ratio of 2 mmol/L/U (1:2), means that every unit of insulin that you deliver lowers your BG by 2 mmol/L – so, if your BG is at 10 mmol/L and you want to get back to your Target BG of 6 mmol/L, you'd need to lower your BG by 4 mmol/L, which would take 2 units of insulin.

Insulin to BG ratios are different for everyone and can even change depending on the time of day. Kaleido lets you save a different ratio for each hour of the day, so that you and your healthcare provider can work together to set the ratios that work especially for you.

QUICK TIP

Remembering all the different factors you need to consider for calculating a bolus and making sense of all the maths can be challenging. Kaleidoculator can help make sense of all the calculations and give a bolus recommendation based on your Personal Info. Take a look at *"How do I use Kaleidoculator?" on page 111* to find out more.

How do I enter my insulin to BG ratios?

PERSONAL INFO	
Name:	Abi
Age:	26
Target BG:	6.0 mmol/L
Insulin to carb:	10 grams/U
Insulin to BG:	
Insulin activity:	
Max. Bolus:	20.00 units
Back	Home

STEP 1

On the Personal Info menu, scroll to **Insulin to BG** and press Enter to select.

STEP 2

Cancel

11

You now need to set a ratio for each hour of the day. Press the left or right buttons to scroll between hourly segments and the up or down buttons to select the ratio you'd like for each hour. Below the insulin to BG ratio graph you'll see details of the hour you're currently setting, along with the ratio that you are entering.

INSULIN TO BG

01:00 - 02:00 2.0 mmol/L/U

Save

The smallest insulin to BG ratio you can set for an hour is 0.1 mmol/L/U and the largest is 22.2 mmol/L/U, in increments of 0.1 mmol/L/U.

QUICK TIP

You can select **Cancel** and return to the Personal Info menu whenever you like. If you do, any changes you've made won't be saved.



STEP 3

Once you've entered an insulin to BG ratio for every hour, press the Enter button. Press Enter again to select **Save**.

If you want to return to the graph before you select **Save**, just press the up button. Or, if you've changed your mind completely, scroll left to **Cancel** and press Enter to select it.

QUICK TIP

Kaleidoculator needs a complete set of insulin to BG ratios to be able to work – one for each hour of the day. So you won't be able to select **Save** if you haven't entered all 24 insulin to BG ratios. You won't be able to access Kaleidoculator from the Bolus menu if you haven't set your insulin to BG ratios either.





A confirmation message will appear – your insulin to BG ratios have been saved. Press Enter to return to the Personal Info menu a little quicker.

STEP 5

Your insulin to BG ratios will now show up in the Personal Info menu. Your handset will always display your current insulin to BG ratio.

How do I enter my insulin activity time?

Your insulin activity time is the amount of time that any insulin you've received stays active in your body. Here's how to set your insulin activity time:

PERSONAL INFO	
Name:	Abi
Age:	26
Target BG:	6.0 mmol/L
Insulin to carb:	10 grams/U
Insulin to BG:	2.0 mmol/L/U
Max. Bolus:	20.00 units
Back	Home

STEP 1

On the Personal Info menu, scroll to **Insulin activity** and press Enter to select.

INSULIN ACTIVITY	
Please enter your insulin activity time:	
3.0 hours	
Cancel Save	

STEP 2

Now, enter your insulin activity time. Use the left or right buttons to scroll between the number boxes and the up or down buttons to scroll to the correct time – it can be as short as 2 hours and as long as 8. Once you've set the correct time, press the Enter button.



21

2

3

2

0 U

70

8

10

11

STEP 3

Press the Enter button again to select **Save**.

If you've accidentally moved to **Save** too soon and you need to change the insulin activity time you've entered. Just press the up button to go back to the selection box.

QUICK TIP

Insulin activity is one of the many important settings used in the Kaleidoculator. To find out more about Kaleidoculator, why not take a look at *"How do I use Kaleidoculator?" on page 111.*



PERSONAL INFO	
Name:	Abi
Age:	26
Target BG:	6.0 mmol/L
Insulin to carb:	10 grams/U
Insulin to BG:	2.0 mmol/L/U
	3.5 hours
Max. Bolus:	20.00 units
Back	Home

STEP 4

A confirmation message will pop up – your insulin activity time has been saved. Press Enter to return to the Personal Info menu a little quicker.

STEP 5

Your insulin activity time will now be displayed in the Personal Info menu.

QUICK TIP

Kaleido uses your personal insulin activity time to help calculate Insulin on Board. So, if you haven't set an insulin activity time, your Insulin on Board will not be shown on your Home Screen, in your Resource Levels screen or Kaleidoculator from the Bolus menu either.

How do I enter my maximum bolus?

Your maximum bolus is the total amount of insulin you can bolus in one go. Everyone's different, so here's how to set your maximum bolus to suit you:

PERSONAL INFO	
Name:	Abi
Age:	26
Target BG:	6.0 mmol/L
Insulin to carb:	10 grams/U
Insulin to BG:	2.0 mmol/L/U
Insulin activity: 3.5 hours	
Back	Home

STEP 1

On the Personal Info menu, scroll to **Max. Bolus** and press Enter to select.





STEP 2

Enter your maximum bolus. Up or down will help you scroll from 0 to 9, right or left will move you between number boxes. You can set it as low as 0.05 units, right up to 30. Once you've set your correct maximum bolus, press Enter.

STEP 3

Press Enter again to select **Save**. If you've accidentally moved to **Save** too soon and you need to change the maximum bolus you've entered, just press the up button to go back to the selection box.

OUICK TIP

Your maximum bolus will limit the amount of units you can select within Quick and Extended Bolus.

OUICK TIP

The handset will notify you if the Kaleidoculator calculated bolus is bigger than your set maxium bolus. Discuss with your healthcare provider if you should, and how to split a bolus to ensure you receive the correct amount of insulin.



STEP 4

A confirmation message will pop up. Your maximum bolus is set. Press Enter to return to the Personal Info menu a little quicker.

STEP 5

Your maximum bolus will now be displayed in the Personal Info menu.

Abi

26

6.0 mmol/L

Home

System Settings

Some of your Kaleido handset's System Settings will be preloaded before it's delivered to you. These are all the manufacturing settings like screen brightness and the sound of alarms. To ensure they meet your personal needs, we recommend reviewing them before you get started on Kaleido. This section covers everything you'll ever need to know to help you review and change your System Settings.

How do I add or view my System Settings?



MENU	
History	
Data Upload	
Personal Info	
System Settings	
Home	

STEP 1

On the Home screen, scroll to **Menu** and press Enter to select.

STEP 2

Scroll to and select **System Settings**.

QUICK TIP

With the exception of data and time all your System Settings are retained when the battery is totally empty.

SYSTEM SETTINGS

Connection:	Blue Pump
Lock Screen:	Off
Medic Message:	Off
BG reminders:	On
Language:	English
Time:	15:30
Date:	22.07.2020
Button tones:	On
Back	Home

STEP 3

On the System Settings menu, use the up or down buttons to read through your saved details.

QUICK TIP

There's additional settings below the Time in your System Settings. Make sure to scroll down all the way untill you see your Software version pop up.

STEP 4

Once you've finished, scroll all the way down to Home. Press Enter to select it and you'll be returned to the Home screen.

SYSTEM SETTINGS

Off

On

English

15:30

On

22.07.2020

Blue Pump

Connection:

Lock Screen:

Language:

Button tones:

Back

Time:

Date:

Medic Message: Off BG reminders:

Alternatively, from Home, scroll left to Back and press Enter to return to Menu.

How do I check if my handset is connected to a pump?

Your handset will connect to your Kaleido pumps using *Bluetooth®* wireless technology. If you ever want to double check if your handset is connected to a pump and, if it is, which one, you can do that in System Settings:

SYSTEM SETTINGS	
Connection:	Blue Pump
Lock Screen:	Off
Medic Message:	Off
BG reminders:	On
Language:	English
Time:	15:30
Date:	22.07.2020
Button tones:	On
Back	Home

STEP 1

On the System Settings menu, scroll to **Connection**. If your handset is connected to a pump, the pump's name will be displayed. If it is not currently connected, the Connection section will be empty.

QUICK TIP

Your pumps are named after their colour – if you have a purple pump, its name will be Purple Pump. 21

02

3

2

05

70

8

00

10

How can I unpair my pump from my handset?

The connection between your handset and your pump is really important - it allows you to change your basal and deliver boluses, and makes sure that your handset has all the information it needs to keep your Insulin on Board and Resource Levels up-to-date.

But, we understand that exceptional circumstances can occur every now and then. There may be a time when Kaleido Care asks you to unpair your pump from your handset, using the unpair feature. They will talk you through the steps you need to take. You can follow along with Kaleido Care using the instructions in this chapter.

WARNING

Only unpair your pump from your handset when instructed to do so by Kaleido Care or your distributor.

WARNING

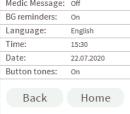
If you unpair your pump from your handset, the information since the last time of stopping the pump will not be transferred to your handset and will be permanently lost, even if you pair the pump to the handset again in the future. If possible, ensure you stop your pump before unpairing it from your handset.

QUICK TIP

You will be unable to control the pump after unpairing. After unpairing, the pump will turn off and any preprogrammed insulin deliveries will not be delivered.

Your handset is currently connected to your Blue Pump	
Back Unpair	

SYSTEM SETTINGS Lock Screen: Off Medic Message: Off



STEP 1

On the System Settings menu. scroll to **Connection** and press Enter to select.

STEP 2

Press the right button to scroll to Unpair and press Enter to select it.

If you decide you don't want to unpair after all, select Back. This will take you back to the System Settings menu and your handset will stay paired to your current pump.

You will only be able to unpair a pump from the handset if the two are already wirelessly connected.

Selecting 'Unpair' will make the handset forget your Blue Pump SN 0123-4567-8914 You will no longer be able to control your Blue Pump with this handset. Another handset will be able to pair to it.

Cancel

STEP 3

If you choose to continue with unpairing, you will be asked one last time to confirm that you definitely want to unpair. Press Enter to select Unpair.

Alternatively, if you decide you no longer want to unpair, just scroll left and press Enter to select Cancel.

In case the Serial Number (SN) is not shown, check the colour of your pump to ensure that you are unpairing the intended pump.

2

2

3

2

You have successfully unpaired your Blue Pump SN 0123-4567-8914



STEP 4

A confirmation message will pop-up - your pump has been unpaired from your handset. Press Enter to return to the System Settings menu a little quicker.

SYSTEM SETTINGS

Lock Screen:	Off
Medic Message:	Off
BG reminders:	On
Language:	English
Time:	15:30
Date:	22.07.2020
Button tones:	On
Back	Home

STEP 5

The Connection section of the System Settings menu will now be empty. You won't be able to access the Bolus section of your Home screen or set a temporary basal rate until you connect or pair a new pump.



STEP 6

If you press Enter again to select **Connection**, you will see an extra confirmation that you're not connected to a pump at the moment.

What's Lock Screen and how do I turn it on?

If you like, you can make your handset extra secure by switching on Lock Screen. This function allows you to set a passcode, which must then be entered correctly to unlock your handset whenever it's switched on or woken up. If you enter an incorrect passcode, your handset will not unlock. This is how to turn on Lock Screen and set your passcode:

SYSTEM SETTINGS	
Connection:	Blue Pump
Lock Screen:	Off
Medic Message:	Off
BG reminders:	On
Language:	English
Time:	15:30
Date:	22.07.2020
Button tones:	On
Back	Home

STEP 1

On the System Settings menu, scroll to Lock Screen and press Enter to select.

STEP 2

Cancel

Use the up or down buttons to select **On**, then press the Enter button. Press the Enter button again to select **Next**.

Next

LOCK SCREEN

Lock Screen is:

QUICK TIP

You can select **Cancel** and return to the System Settings menu whenever you like. If you do, any changes you've made won't be saved.

QUICK TIP

When you're saving a new passcode, as well as choosing something that's memorable, it's also a good idea not to choose something too simple either. Don't choose a code that uses the same button four times in a row.

QUICK TIP

If you ever want to change your passcode, just turn Lock Screen off, and then turn it back on again. Then start this section from the beginning, following the steps to save a new passcode.





STEP 3

Use the up, down, left or right buttons to set a four button passcode. Make sure it's something you'll remember! Press the Enter button, then enter your new passcode again to confirm the sequence. Press Enter again to move to **Next** and again to select it.

If you've accidentally moved to **Next** too soon and you need to change the passcode you've entered, just press the up button and re-enter your new passcode.

STEP 4

Your handset will confirm the passcode you're about to save. Press the Enter button to select **Save**.

Alternatively, scroll left and press Enter to select **Cancel** and return to the previous screen. Lock Screen has been turned on and your passcode has been saved



SYSTEM SETTINGS	
Connection:	Blue Pump
Medic Message:	Off
BG reminders:	On
Language:	English
Time:	15:30
Date:	22.07.2020
Button tones:	On
Back	Home

STEP 5

A confirmation message will pop up – Lock Screen has been turned on and your passcode has been saved. Press Enter to return to the System Settings menu a little quicker.

STEP 6

Your updated Lock Screen status will now be displayed in the System Settings menu.

I've turned on Lock Screen – what happens now?

When Lock Screen is turned on, you'll need to enter your passcode every time you want to unlock your handset. Your handset will ask you to enter your passcode and once you do, you'll either be taken to your Home screen or the screen you were last on. If you enter the wrong passcode, your handset will give you another try. You won't be able to gain access to your handset until you enter the correct passcode, so if you've forgotten it, just contact Kaleido Care and we'll help you reset it.



Your passcode screen will look like this.

This is how your screen will look if you also turn on your Medic Message. To set your Medic Message, follow the steps in the chapter "What's a Medic Message and how do I turn it on?" on page 187.

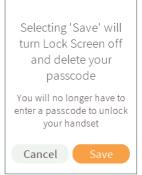
How do I turn Lock Screen off?

WARNING

If you turn the Lock Screen option off, your passcode will be deleted. If you want to turn Lock Screen back on, you will have to reset your passcode.

SYSTEM SETTINGS	
Connection:	Blue Pump
Lock Screen:	On
Medic Message:	Off
BG reminders:	On
Language:	English
Time:	15:30
Date:	22.07.2020
Button tones:	On
Back	Home

LOCK SCREEN	
Lock Screen is: Off	
Cancel Next	



STEP 1

On the System Settings menu, scroll to Lock Screen and press Enter to select.

STEP 2

Use the up or down buttons to select **Off**, then press the Enter button.

Press the Enter button again to select **Next**.

STEP 3

If you're sure you want to turn Lock Screen off, press the Enter button one last time to select **Save**.

Alternatively, scroll left and press Enter to select **Cancel**.

Lock Screen has been turned off and your passcode has been deleted



SYSTEM SETTINGS	
Connection:	Blue Pump
Lock Screen:	
Medic Message:	Off
BG reminders:	On
Language:	English
Time:	15:30
Date:	22.07.2020
Button tones:	On
Back	Home

STEP 4

A confirmation message will pop up – Lock Screen has been turned off and your passcode has been deleted. Press Enter to return to the System Settings menu a little quicker.

STEP 5

Your updated Lock Screen status will now be displayed in the System Settings menu.

WARNING

Do not leave your handset unattended or in a place where other items could accidentally press against the buttons if it is connected to your pump. It would allow someone else or other items to change insulin deliveries or system settings without you realizing.

What's a Medic Message and how do I turn it on?

Like a piece of Medic ID jewellery, setting a Medic Message on your Kaleido handset gives you the opportunity to share important details with people who might need to know who you are and what's going on in an emergency. For extra peace of mind, this is how you save and turn on your Medic Message so people can view it – it will show up whenever your handset is woken up.

SYSTEM SETTINGS	
Connection:	Blue Pump
Lock Screen:	On
	Off
BG reminders:	On
Language:	English
Time:	15:30
Date:	22.07.2020
Button tones:	On
Back	Home





STEP 1

On the System Settings menu, scroll to **Medic Message** and press Enter to select.

STEP 2

Use the up or down buttons to select **On**, then press the Enter button.

STEP 3 Press the Enter button again to select **Next**.

2

22

3

2

05

70

8

10

QUICK TIP

You can select **Cancel** and return to the System Settings menu whenever you like. If you do, any changes you've made won't be saved.



STEP 4

Enter the name of your emergency contact using the up or down buttons to scroll through the alphabet. You can use the right button to move on to the next letter, or to add a space. Once you've entered a name, press the Enter button.



STEP 5

Use the up, down, right or left buttons to enter your emergency contact's telephone number (up or down will help you scroll through the numbers 0 to 9, right and left will help you move between number boxes).

Once you've entered the phone number, press the Enter button to move to Next.

QUICK TIP

If you ever want to change your Medic Message, just turn the setting off, and then turn it back on again. Go back to the start of this section and follow the steps to save your new details.



STEP 6

Press Enter again to select **Next.**

If you've accidentally moved to **Next** too soon and you need to change your emergency contact's details, just press the up button to return to the first letter box.

STEP 7

Your handset will now show you a preview of your Medic Message. Press Enter to select **Save**.

Alternatively, scroll left and press Enter to select **Cancel**, then edit your message.





STEP 8

A confirmation message will pop up – your Medic Message has been saved and turned on. Press Enter to return to the System Settings menu a little quicker.

STEP 9

Your updated Medic Message status will now be displayed in the System Settings menu.

How do I turn my Medic Message off?

Should you want to, you can turn your Medic Message off at any time.

WARNING

If you turn the Medic Message option off, your message and emergency contact details will be deleted. If you want to turn the Medic Message back on, you will have to enter the message and emergency contact details again.





Selecting 'Save' will turn Medic Message off and delete your saved message 2

2

3

2

05

70

8

10

Ľ

Your handset will no longer display a Medic Message

STEP 1

On the System Settings menu, scroll to **Medic Message** and press Enter to select.

STEP 2

Use the up or down buttons to select **Off**, then press the Enter button.

Press Enter again to select **Next.**

STEP 3

Cancel

If you're sure you want to turn off your Medic Message, press the Enter button once more to select **Save.**

Alternatively, scroll left and press Enter to select **Cancel**.

Medic Message has been turned off and your saved message has been deleted



SYSTEM SETTINGS	
Connection:	Blue Pump
Lock Screen:	On
Medic Message:	
BG reminders:	On
Language:	English
Time:	15:30
Date:	22.07.2020
Button tones:	On
Back	Home

STEP 4

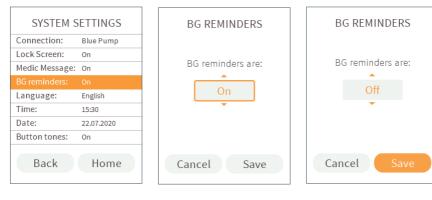
A confirmation message will pop up – your Medic Message has been turned off and deleted. Press Enter to return to the System Settings menu a little quicker.

STEP 5

Your updated Medic Message status will now be displayed in the System Settings menu.

What are BG reminders and how do I turn them off?

Sometimes remembering to check your BG after a meal or correction may slip your mind. That's where Kaleido's BG reminders come in. You can set yourself a reminder to do a BG test an hour and a half after you started delivering a bolus, just as an extra help. By default, BG reminders are turned on. Don't like or want the reminders? You can also turn them off - just follow these steps:



STEP 1

On the System Settings menu, scroll to **BG reminders** and press Enter to select.

STEP 2

Use the up or down buttons to select **Off**, then press the Enter button.

STEP 3

Press Enter again to select **Save**.

2

2

2

05

06. Menu

70

10

E

If you've accidentally moved to **Save** too soon, just press the up button to return to the selection box.

QUICK TIP

You can select **Cancel** and return to the System Settings menu whenever you like. If you do, any changes you've made won't be saved.

QUICK TIP

You can turn your BG reminders back on by selecting **BG reminders** in the System Settings menu, then using the up or down arrows to select **On**. Press the Enter button, then press it again to select **Save**.



SYSTEM SETTINGS	
Connection:	Blue Pump
Lock Screen:	On
Medic Message:	On
BG reminders:	
Language:	English
Time:	15:30
Date:	22.07.2020
Button tones:	On
Back	Home

STEP 4

A confirmation message will pop up – your BG reminders have been turned off. Press Enter to return to the System Settings menu a little quicker.

STEP 5

Your updated BG reminders setting will now be displayed in the System Settings menu.

How do I change my handset's language?

We'd recommend that you only ever use your Kaleido handset in your native language. In case of emergencies, it's really important that you're able to completely understand the language that is being used to communicate your pump information to you. If you do ever need to change your handset's language though, here's how you do it:

SYSTEM S	SETTINGS	LANGUAGE	LANGUAGE
Connection: Lock Screen: Medic Message: BG reminders:	Blue Pump On On Off	Please select the language you would like your handset to operate in:	Please select the languag you would like your hand: to operate in:
Language: Time:	English		· · · · · · · · · · · · · · · · · · ·
Date:	15:30 22.07.2020	Nederlands	Nederlands
Button tones:	On		
Back	Home	Cancel Next	Cancel Next

STEP 1

On the System Settings menu, scroll to **Language** and press Enter to select. STEP 2

Use the up or down buttons to scroll through the language options. Press Enter to select your preferred language.

STEP 3

Now, press Enter again to select **Next**.

2

2

3

2

05

70

8

10

Ľ

If you've accidentally moved to **Next** too soon and you need to change the language selected, just press the up button to return to the selection box.

QUICK TIP

You can select **Cancel** and return to the System Settings menu whenever you like. If you do, any changes you've made won't be saved.

WARNING

Only change your language settings if it's absolutely necessary for the safe continuation of your insulin therapy.



STEP 4

Your handset will confirm the language selection that you are about to make.

Press the Enter button again to select **Save**.

Alternatively, scroll left and press Enter to select **Cancel** and return to the previous screen.

STEP 5

A confirmation message will pop up – your handset language has been changed. Press Enter to return to the System Settings menu a little quicker.

INSTELLINGEN	
Verbinding:	Blauwe Pomp
Vergrendelscherm:	Aan
Medische Melding:	Aan
BG-herinneringen:	Uit
Tijd:	15:30
Datum:	22.07.2020
Toetstonen:	Aan

STEP 6

Your updated language setting will now be displayed in the System Settings menu. You'll also notice that your handset language has changed.

How do I change the time on my handset?

It's really important that your handset is always set to the correct time. Time plays a crucial role in the delivery of your basal profiles, the recording of your Insulin on Board and any other data entered into Kaleido, so make sure you've set the time correctly.

To change the time on your handset, just follow these steps.







STEP 1

On the System Settings menu, scroll to **Time** and press Enter to select.

STEP 2

Enter the current time using the up or down buttons to scroll through the numbers 0 to 9. Use the right button to move on to the next number.

QUICK TIP

You can select **Cancel** and return to the System Settings menu whenever you like. If you do, any changes you've made won't be saved.

QUICK TIP

Changed the time (or date) on your handset recently but forgotten when? Kaleido will give you a reminder of this in History – just look for the 🕒 symbol.

STEP 3

When you've successfully entered the time, press Enter and then Enter again to select **Save**.

If you've accidentally moved to **Save** too soon and you need to change the time that you have entered, just press the up button to return to the first number box.

WARNING

Ensure that you change the time and date on your handset to account for the difference in time zones if you travel. The handset will not automatically update it's time and date. If you travel through time zones, get in touch with your healthcare provider for advice on how to adjust the insulin deliveries gradually over time.



SYSTEM SETTINGS	
Connection:	Blue Pump
Resource Levels:	Good
Lock Screen:	On
Medic Message:	On
BG reminders:	Off
Language:	English
Date:	22.07.2020
Back	Home

STEP 4

A confirmation message will pop up – the time has been saved. Press Enter to return to the System Settings menu a little quicker.

STEP 5

The updated time will now be displayed in the System Settings menu and on your Home screen.

How do I change the date on my handset?

It's vital that your handset is always set to the correct date, so that you know your History data is always being recorded accurately. You won't be able to connect your handset to a pump until you've set the correct date first, so to set it for the first time (or if you ever need to update it), here's what to do:

SYSTEM SETTINGS BG reminders: Off Language: English Time: 14:30 Button tones: On Volume: 5 Brightness: 5 Software: 2.2.6.0 Back Home

STEP 1

On the System Settings menu, scroll to **Date** and press Enter to select.

STEP 2

Back

Day

Enter the current date using the up or down buttons to scroll through the numbers 0 to 9. Use the right button to move on to the next number.

Save

DATE

Please enter the date:

Month Year

QUICK TIP

You can select **Cancel** and return to the System Settings menu whenever you like. If you do, any changes you've made won't be saved.

QUICK TIP

Changed the date (or time) on your handset recently but forgotten when? Kaleido will give you a reminder of this in History – just look for the symbol.



STEP 3

When you've successfully entered the date, press Enter and then press Enter again to select **Save**.

If you've accidentally moved to **Save** too soon and you need to change the date that you have entered, just press the up button to return to the first number box. 05

06. Menu

70

10

WARNING

Ensure that you change the time and date on your handset to account for the difference in time zones if you travel. The handset will not automatically update it's time and date. If you travel through time zones, get in touch with your healthcare provider for advice on how to adjust the insulin deliveries gradually over time.



SYSTEM SETTINGS	
BG reminders:	Off
Language:	English
Time:	14:30
Date:	
Button tones:	On
Volume:	5
Brightness:	5
Software:	2.2.6.0
Back	Home

STEP 4

A confirmation message will pop up – the date has been saved. Press Enter to return to the System Settings menu a little quicker.

STEP 5

The updated date will now be displayed in the System Settings menu.

How do I turn my handset button tones off?

Turning your handset's button tones off enables you to use Kaleido more discreetly. See the steps below on how to do this.

SYSTEM S	SETTINGS
BG reminders:	Off
Language:	English
Time:	14:30
Date:	23.07.2020
Volume:	5
Volume: Brightness:	5
	-





STEP 1

On the System Settings menu, scroll to **Button tones** and press Enter to select.

STEP 2

Use the up or down buttons to select **Off**, then press the Enter button.

STEP 3

Press Enter again to select **Save**.

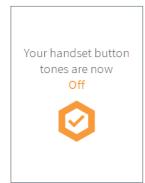
If you've accidentally moved to **Save** too soon, just press the up button to return to the selection box.

QUICK TIP

You can select **Cancel** and return to the System Settings menu whenever you like. If you do, any changes you've made won't be saved.

QUICK TIP

You can turn your button tones back on by selecting **Button tones** in the System Settings menu, then using the up or down arrows to select **On**. Press the Enter button, then press it again to select **Save**.



SYSTEM SETTINGS	
BG reminders:	Off
Language:	English
Time:	14:30
Date:	23.07.2020
Volume:	5
Brightness:	5
Software:	2.2.6.0
Back	Home

STEP 4

A confirmation message will pop up – your button tones have been turned off. Press Enter to return to the System Settings menu a little quicker.

STEP 5

Your updated button tone setting will now be displayed in the System Settings menu.

How do I set the volume of my handset?

Just like your button tones, the volume you want to set your Kaleido handset might change depending on where you are. Follow these steps to set the volume you'd like. This will only affect the volume of any notifications and reminders that you receive – not your alarms. Alarms will always play at maximum volume.

SYSTEM S	SETTINGS
BG reminders:	Off
Language:	English
Time:	14:30
Date:	23.07.2020
Button tones:	Off
Brightness:	5
Software:	2.2.6.0
Back	Home





STEP 1

On the System Settings menu, scroll to **Volume** and press Enter to select. STEP 2

Use the left button to make the volume quieter and the right button to make it louder, then press the Enter button.

STEP 3

Press Enter again to select **Save**.

If you've accidentally moved to **Save** too soon just press the up button to return to the volume selector.

QUICK TIP

You can select **Cancel** and return to the System Settings menu whenever you like. If you do, any changes you've made won't be saved.

WARNING

Do not block or cover the speaker at the bottom of your handset. If you do so, you may not be able to hear alarms when they go off.

QUICK TIP

Volume changes only apply to the volume of your handset speakers. For safety reasons, you cannot change the volume of the speakers on your pumps.

WARNING

Keep your handset close by when you have the volume set low. You may not be able to hear notifications when they go off in case the volume is low and you do not keep your handset close by.



SYSTEM SETTINGS BG reminders: Off Language: English Time: 14:30 Date: 23.07.2020 Button tones: Off Brightness: 5 Software: 2.2.6.0 Home Back

STEP 4

A confirmation message will pop up – your handset volume has been changed. Press Enter to return to the System Settings menu a little quicker.

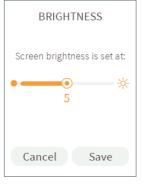
STEP 5

Your updated volume setting will now be displayed in the System Settings menu.

How do I set the brightness of my handset screen?

If you use your handset a lot at night, your eyes are sensitive to bright light or the battery is getting low before you can charge it, you may wish to lower the brightness of your handset screen. If you need to operate your handset in direct sunlight, you may need a higher brightness setting of your handset screen to be able to view the information on the screen. Here's how to adjust the brightness of your handset screen:

SYSTEM SETTINGS	
BG reminders:	Off
Language:	English
Time:	14:30
Date:	23.07.2020
Button tones:	Off
Volume:	3
Brightness:	
Software:	2.2.6.0
Back	Home





STEP 1

On the System Settings menu, scroll to **Brightness** and press Enter to select. STEP 2

Use the left button to make the screen less bright and the right button to make it brighter, then press the Enter button.

STEP 3

Press Enter again to select **Save**.

If you've accidentally moved to **Save** too soon just press the up button to return to the brightness selector.

QUICK TIP

You can select **Cancel** and return to the System Settings menu whenever you like. If you do, any changes you've made won't be saved.

QUICK TIP

Here's something to bear in mind – the brighter your handset screen, the more battery power your handset will use.



SYSTEM SETTINGS	
BG reminders:	Off
Language:	English
Time:	14:30
Date:	23.07.2020
Button tones:	Off
Volume:	3
Brightness:	
Software:	2.2.6.0
Back	Home

STEP 4

A confirmation message will pop up – the brightness of your handset screen has been changed. Press Enter to return to the System Settings menu a little quicker.

STEP 5

Your updated brightness setting will now be displayed in the System Settings menu.

How do I know which software version I'm using?

Sometimes it might come in handy to know which software version you're currently using. Here's how to find out which version your system is running:

SYSTEM SETTINGS	
BG reminders:	Off
Language:	English
Time:	14:30
Date:	23.07.2020
Button tones:	Off
Volume:	3
Brightness:	8
Back	Home

On the System Settings menu, scroll right down to the bottom to **Software**. The numbers displayed show which version you're using.



07. Status



Status

You'll need to access the Status section of your Kaleido handset when you want to pause, stop or restart the pump you're using. You can choose to pause and remove your pump at any time. For example, you might want to pause your pump (and take if off) temporarily while showering, swimming or trying on new clothes.

Your handset will keep track of how much insulin you've missed while your pump is paused, so that you can make an informed decision about your insulin delivery when you're ready to get going again.

How do I pause my pump?



STATUS
Pause pumping
Stop pumping
Home



STEP 1

On the Home screen, scroll to **Status** and press Enter to select.

You should speak to your healthcare provider for advice on when to pause your pump and the action you need to take when you later decide to unpause it.

STEP 2

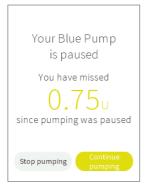
Scroll to and select **Pause pumping**.

STEP 3

Your handset will ask you if you want to pause pumping. Just press the Enter button to select **Yes**.

QUICK TIP

Changed your mind? Just press the left button to scroll to **No**. Press Enter to select it and return to the Status menu. 2



STEP 4

Your pump is now paused and insulin delivery has been stopped. On your handset, you'll be able to keep track of how much basal insulin you're missing out on.

WARNING

You won't be able to access any of your handset's other functions while your pump is paused.

QUICK TIP

You won't receive any insulin at all while your pump is paused.

QUICK TIP

Your handset keeps track of the insulin you've missed for information purposes only. It will not automatically deliver the insulin you have missed when you unpause your pump.

WARNING

Close the protective cover on your infusion set once you choose to take your pump off while it is paused. If you leave the protective cover open, dirt may enter into the opening which may cause infections or occlusions.

How do I unpause my pump?



STEP 1

When you're ready to restart your paused pump, take note of how much insulin you've missed and press the Enter button to select **Continue pumping**.

STEP 2

No

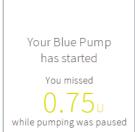
Your handset will ask you to confirm that you are ready to start pumping. Select **Yes** by pressing Enter.

Are you ready to

start pumping again?

QUICK TIP

Alternatively, you can press the left button to scroll to Stop pumping. If you select **Stop pumping**, your pump will enter Stop mode. "How do I stop my pump?" on page 215 for more details about Stop mode.



STEP 3

A confirmation message will pop up – your pump has unpaused and your insulin delivery has been restarted! Press Enter to return to the Home screen a little quicker.

STEP 4

Take a BG reading and, using the information your handset has given you about the insulin you missed, decide whether or not to deliver a bolus to top your insulin levels back up.

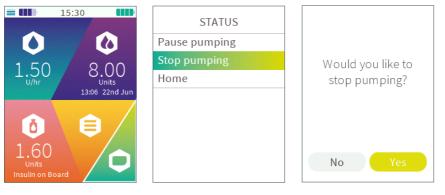
WARNING

Always take a BG reading when you start to pump after a break in your insulin delivery. This will help you make informed decisions about your immediate insulin requirements.

How do I stop my pump?

You can also stop your pump from the Status menu. Stopping your pump should always be your very first step when you're preparing to take your pump off. This is especially important if you're getting ready to swap pumps so that important data is transferred to your handset – in fact, you'll get an alarm if you remove an insulin cartridge from a pump without stopping your pump first.

Once you've followed the steps here, you can find out more about removing pumps (and infusion sets) by checking out "How do I take my pump off?" on page 72.



STEP 1

On the Home screen, scroll to **Status** and press Enter to select. STEP 2 Scroll to and select **Stop pumping**.

STEP 3

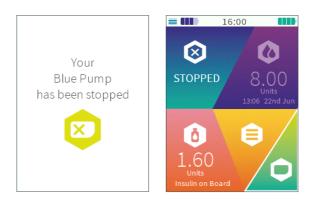
Your handset will ask you if you'd like to stop pumping. Press the Enter button to select **Yes**.

QUICK TIP

Decided you don't want to stop your pump after all? Just press the left button to scroll to **No**. Press Enter to select it and return to the Status menu.

WARNING

When your pump is in Stop mode, the handset will not keep track of any insulin deliveries that you have missed. Also the insulin delivery functionalities (e.g. temporary basal rate, bolus) are not available during Stop mode.



STEP 4

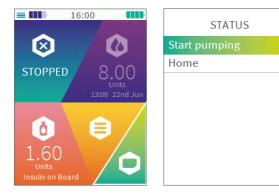
A confirmation message will pop up – your pump has been stopped and you are no longer receiving any insulin. Press Enter to return to the Home screen a little quicker. STEP 5

Your Home screen will update to show that your pump is in Stop mode.

How do I restart my pump?

When your pump is in Stop mode, your handset and pump will stay connected to each other. This means you can choose to start pumping again whenever you like – your pump will just restart the same basal profile you were using when you stopped it.

You can also follow these steps if you need to start your pump if you chose not to immediately start pumping when you first connected your pump to your handset.



STEP 1

On the Home screen, scroll to **Status** and press Enter to select.

STEP 2

When you're in Stop mode, there are two options to select - Home or Start pumping. To **Start pumping** – press Enter to select it.



STEP 3

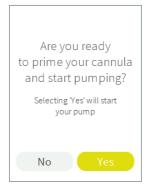
Just in case you're using a new infusion set, your handset will now give you another chance to prime your cannula. There are three options for you to choose from:

 If you'd like to prime a new infusion set with a 6 mm cannula, press Enter to select Yes, 6 mm. If you do, you'll be asked if you're ready to prime your cannula and start pumping, and your handset will walk you through what to do next.

• If you'd like to prime a new infusion set with a 9 mm cannula, scroll down to **Yes**, **9 mm**, then press Enter to select it. If you do, you'll be asked if you're ready to prime your cannula and start pumping, and your handset will walk you through what to do next.

• If you're not using a new infusion set, just press the left button to scroll to **No** and press Enter to select it.

You can find out more about priming your cannula by checking out *"Why do I need to prime my cannula?" on page 60.*



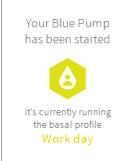
STEP 4

If you chose **No**, your handset will now ask you if you'd like to start pumping. Press the Enter button to select **Yes**.

Make sure you don't select Yes until you wear and connect your pump and Infusion set, and you are ready to start receiving insulin. Your handset will stay on this screen for as long as you need it to.

QUICK TIP

If you've changed your mind, just press the left button to scroll to **No**. Press Enter to select it and then return to the Status menu.



STEP 5

A confirmation message will pop up – your pump has been started. Your handset will show you the basal profile it's currently running. You can press the Enter button to jump to the Home screen a little quicker.



STEP 6

Your Home screen will update to show you all your pumping details.



STEP 7 Take a BG reading to make sure your current insulin delivery matches your requirements.

WARNING

Always take a BG reading when you start to pump after a break in your insulin delivery. This will help you make informed decisions about your immediate insulin requirements. 21



08. Alarms

Alarms in Kaleido

The intelligent alarm system in your Kaleido uses algorithms and sensors to monitor the state of the system. If something isn't quite going to plan, Kaleido will generate alarms to let you know of an issue with your pump, handset, or insulin cartridge. These alarms will interrupt any other actions that you are running on your Kaleido. There are low priority and high priority alarms. Kaleido uses no medium priority alarms.

If multiple alarms occur at the same time, the intelligent alarm system will notify you of high priority alarms first before notifying you of low priority alarms. If the alarms have equal priority, then the one with the lowest alarm number (see page 233) is shown first. Each alarm must be individually acknowledged before the next alarm can be presented.

What is a low priority alarm?

You'll receive a low priority alarm if your pump or handset needs to warn you about something that's important but not urgent yet.

For low priority alarms related to your pump, the pump will sound a pattern of 3 short beeps. When in range of your pump, your handset will also sound this beeping pattern, vibrate, and show an alarm message containing a yellow low priority alarm icon \triangle , explaining what the alarm is for. These sounds and vibrations will repeat until you acknowledge the alarm message on your handset.

For low priority alarms that are related to your handset but not your pump, only the handset will notify you with a pattern of 2 or 3 short beeps, vibrations, and an alarm message. Depending on the specific alarm condition, these sound and vibration patterns will either occur once or repeat until you acknowledge the alarm message on your handset (see page 222-224 for instructions on how to resolve the specific alarm issue).

WARNING

You should always keep your handset within reach in case there's an alarm and keep the handset battery sufficiently charged.

What is a high priority alarm?

High priority alarms only occur if something serious is going on that requires your full attention immediately.

High priority alarms related to your pump will immediately stop your pump. Your pump will notify you by sounding a pattern of 10 short beeps. When in range of your pump, your handset will also sound this beeping pattern, vibrate, and show an alarm message with the red high priority alarm icon \triangle , giving you more details about what's going on. The alarm sounds and vibrations will repeat until you acknowledge the alarm message on your handset.

For high priority alarms that are related to your handset but not your pump, only the handset will notify you with a pattern of 10 short beeps, vibrations, and an alarm message. Once you acknowledge the alarm, your handset will shut down, but your pump will continue to operate (see pages 225-228 for instructions on how to resolve the specific alarm issue). The alarm sounds and vibrations will repeat until you accept the alarm message on your handset.

WARNING

High priority pump alarms will immediately stop your pump. Bear in mind that your pump will not deliver insulin during Stop mode. Once you've sorted the issue that caused the alarm, you will need to manually restart pumping using your handset.

WARNING

High priority handset alarms will turn off your handset once you have acknowledged the alarm, but will not stop your pump. Your pump will continue to deliver insulin as programmed. You have to resolve the issue with your handset before you can continue using it to modify your insulin deliveries.

How do I acknowledge alarms?

Once you have read and understood the alarm message, press the Enter button to acknowledge the alarm. Acknowledging an alarm will silence the alarm sounds or vibrations on the handset and pump for that particular alarm and close the alarm message on the handset. If the alarm is related to a high priority alarm on the handset, the handset will shut down. Otherwise, the handset will return to where you left off on the handset before the alarm occurred.



For low priority alarms, the handset will show an alarm inactivation symbol on the main screen 💥 to signify that the alarm has been silenced. Additionally, the handset will also show an alarm indicator
 for low priority alarms to let you know there is an existing alarm condition your Kaleido.



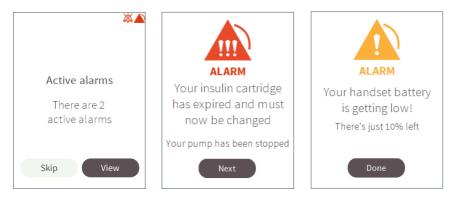
For high priority alarms, the handset will show an alarm inactivation symbol on the main screen X to signify that the alarm has been silenced. Additionally, the handset will also show an alarm indicator flashing for high priority alarms to let you know there is an existing alarm condition your Kaleido.

If there are multiple alarms, the symbols associated with the highest priority alarms will be shown. The alarm inactivation symbol and alarm indicator will stay on the top right corner of your handset until you have resolved the issue that caused the alarm (see page 226, page 227, page 229 and page 232 for more information).

2

How to review alarms?

Once you acknowledge an alarm and close the alarm message on the handset, there are 2 ways to review the alarm again. The first way is to check the History Menu (see page 147). The History Menu will show the time the alarm occurred along with a short description of the alarm. The second way is to wake your handset from sleep mode by shortly pressing the power button or the Enter button. If there are active alarms in Kaleido when your handset wakes up, the handset will request you to review the alarm messages of these active alarms.



STEP 1

Wake up your handset by shortly pressing the power button or the Enter button. The handset will notify you if there are active alarms. Scroll right to press **View** to review the alarm messages for these active alarms or Scroll left and press **Skip** to skip viewing the alarm messages.

STEP 2

Review each alarm message and then press the Enter button to select **Next** to go on to the next active alarm message.

STEP 3

Once you have reviewed the alarm messages of all active alarms, press Enter to select **Done** to return to where you last left off on the handset.

When will I get a low priority pump alarm?

You'll get a low priority alarm related to the pump if:

• Your pump battery is getting low



You'll receive this alarm when your pump battery has 10% of its power remaining.

If you receive this alarm, it's important to start keeping an eye on your pump battery. You should charge your pump as soon as possible, so make sure everything you need to replace your pump is nearby so that you can switch over to your other pump quickly before your current pump's battery is empty. Again, you can keep a check on how low your pump battery is by checking your Resource Levels.

The alarm pattern of 3 beeps will repeat until you acknowledge the alarm. • You've been using the same insulin cartridge for three days



Insulin cartridges can be used for up to three days straight before they must be replaced. Once you've received this alarm, you'll have six hours until your insulin cartridge expires – and your infusion set too if you started using them at the same time.

Sometimes it might not be possible to replace your insulin cartridge straight away, however, you should always try to replace your insulin cartridge, pump and (if it's also three days old) your infusion set as soon as possible after getting the alarm. So make sure you keep everything you'll need to do this nearby • Your insulin cartridge volume is getting low



To keep you in the loop about how much insulin is left in the cartridge, you'll receive this alarm when you have 25 units of insulin left in your insulin cartridge.

If you have less than 25 units left in your insulin cartridge. the basal profile you're running and any boluses vou deliver could empty your insulin cartridge pretty quickly. When you get this alarm, vou'll need to keep a close eye on your insulin cartridge levels and make sure everything you need to replace your insulin cartridge is nearby, just in case. Just like with your handset and pump batteries, you can see how full your insulin cartridge is by checking your Resource Levels.

When will I get a low priority handset alarm?

You'll get a low priority alarm related to the handset if:

- Your handset battery is getting low
- ALARM Your handset battery is getting low! There's just 10% left Understood
- You'll receive this alarm when you have just 10% of your handset battery remaining.
- You should charge your handset as soon as possible. You can keep an eye on how low your handset battery is by checking your Resource Levels.
- The alarm pattern of 3 beeps will repeat until you acknowledge the alarm.

• There is a communication error between your handset and your pump

ALARM

No action with

the pump

Your handset was unable to

communicate with your

pump. Please try again!

• Your Insulin on Board has been reset



If this alarm pops up, retry the action you were trying to perform on the handset (you could also try moving your handset closer to your pump too). If that doesn't work, contact Kaleido Care and we can help you work out what's going on.

The alarm pattern of 3 beeps will repeat until you acknowledge the alarm. This alarm might pop up in case your handset battery has drained or the pump unpaired from your handset. When this alarm pops up, your Insulin on Board has been reset. Your pump will continue to deliver your insulin according to how you programmed it.

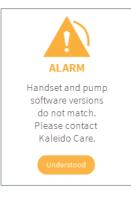
This alarm is meant to notify you that, as the Insulin on Board has been reset, the Insulin on Board and Total Daily Dose might not be accurate for the amount of time indicated by the alarm. Keep this in mind when delivering insulin with Kaleido during the time indicated by the alarm.

The alarm pattern of 2 beeps will not repeat.

• Your handset battery is empty



The alarm pattern of 3 beeps will repeat until you acknowledge the alarm. • Your handset and pump software versions do not match



If you get this alarm, you cannot use your system. Switch to an alternative method of insulin delivery and contact Kaleido Care for help.

The alarm pattern of 3 beeps will repeat until you acknowledge the alarm.

When will I get a high priority pump alarm?

You'll get a high priority alarm related to the pump if:

• Your pump battery is empty and infusion stopped



Your pump battery is empty and your pump has been stopped. Unclip your infusion set to disconnect from your current pump and remove its old cartridge.

Then swap to your other, fully charged Kaleido pump by either reinserting your current insulin cartridge (if you still have enough insulin and are using it for less than three days) or by inserting a newly filled insulin cartridge.

It's important to charge the pump you've removed as soon as possible, so that it's ready to use when you next need it.





You've used up all of your insulin, so you'll need to remove your existing insulin cartridge and replace it with a new, filled cartridge before you can restart your pump. While you're at it, you should change your Kaleido pump, and also your infusion set if you've been using the same one for three days too. • The insulin cartridge you're using has expired



You've been using your insulin cartridge for too long and you'll need to replace it with a new, filled cartridge before you can restart pumping. If you started using your current pump and infusion set at the same time as your old insulin cartridge, you should replace them now too.

• Your pump has an insulin blockage



Insulin blockages (sometimes known as occlusions) can be caused by problems with your infusion set or insulin cartridge. To solve this, there are a few different things you can try.

Have a look at your tubing to see if it's become twisted or kinked. If it has, straighten it out. If not, try unclipping and reclipping your insulin cartridge connector.

If the issue still isn't resolved, try replacing your infusion set before restarting your pump. If this didn't resolve the issue, replace your insulin cartridge with a new fully-filled one. If infusion blockage is still not resolved:

Remove your Kaleido pump and infusion set completely. Switch to your other pump using a newly filled insulin cartridge and infusion set and restart pumping. If the issue is still not resolved, switch to an alternative method of insulin delivery and contact Kaleido Care for help.

WARNING

Disconnect your insulin cartridge and infusion set before removing any insulin blockages. Rectifying the problem to restart the flow of insulin may result in the delivery of a small and unexpected amount of insulin.

WARNING

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. • Your insulin cartridge has come out of your pump while it was pumping



Your insulin cartridge has come out of your pump while it was pumping

Your pump has been stopped

Unfortunately, your insulin cartridge has come out of your pump while your pump was in use. This might have happened because you forgot to stop your pump before intentionally removing your insulin cartridge, but it's also possible that it happened accidentally. without you realising. To make sure you're always aware if you're no longer receiving insulin, you'll get an alarm if your insulin cartridge is removed from your pump while your pump is running.

If you get this alarm, ensure you are not connected to your infusion set, then reinsert your current insulin cartridge (or a new one if you're changing your cartridge), reconnect your pump and handset, clip your insulin cartridge connector to your infusion set and start pumping again. In case your insulin cartridge is still in the pump when you receive this alarm, refer to page 233 for more help.

• There's a problem with your Kaleido pump



In the bottom right corner of your screen you'll see a 4 digit number. If you receive this alarm, see page 234 for a list of possible alarms and steps you can take to solve the issue yourself. In case you are not able to resolve the issue, contact Kaleido Care. Kaleido Care will ask you for the 4 digit number to work out how best to help you.

We'll do all we can to get you back up and running quickly, but if we can't, you'll need to swap to your other Kaleido pump while we work out. Can't contact Kaleido Care straight away? Just switch to your other Kaleido pump or if needed, an alternate method of insulin

delivery and then contact us when you can.

When will I get a high priority handset alarm?

You'll get a high priority alarm related to the handset if:

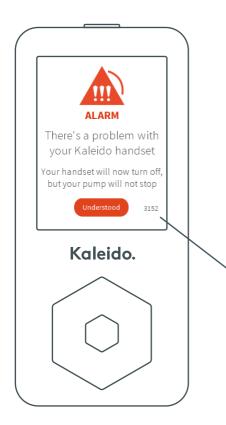
• There's a problem with your Kaleido handset



In the bottom right corner you'll see a 4 digit number. If you receive this alarm, see page 237 for a list of possible alarms and steps you can take to solve the issue yourself. In case you are not able to resolve the issue, contact Kaleido Care. Kaleido Care will ask you for the 4 digit number to work out how best to help you. Can't contact Kaleido Care straight away? Your pump will only continue delivering your basal and any boluses that are running, so you should contact us as soon as you can. In the meantime, if you don't want to use your Kaleido pump without your handset, just unclip your insulin cartridge connector from your infusion set and remove your pump (see *"How do I take my pump off?" on page 72*) and switch to an alternative form of insulin delivery.

21

Kaleido technical alarm code handling



For some pump and handset alarms, the handset will show a 4 digit number in the bottom right corner. The alarm number can also be found in your History on the handset. This section contains a list of most common alarms and steps you can take to solve the issue. In case you are not able to resolve the issue, contact Kaleido Care. Kaleido Care will ask you for the 4 digit number to work out how best to help you.

4 DIGIT ALARM NUMBER

QUICK TIP

If you are unable to solve the alarm yourself after consulting the instructions on the following pages, contact Kaleido Care.

Pump alarms

Alarm number	What's on the alarm screen?	Steps to take to solve the issue
1004, 1020, 1021, 1055	There's a problem with your Kaleido pump Your pump has been stopped	 Your pump has a hardware issue and needs to be replaced. Your pump has been stopped. 1. Acknowledge the alarm. 2. Disconnect your insulin cartridge connector from your infusion set, then take the insulin cartridge out of the pump andchange to the other pump. 3. Contact Kaleido Care to inform them about your alarm. We will replace your pump as soon as possible!
1005	There's a problem with your Kaleido pump Your pump has been stopped	 Your pump has a software issue and needs to be replaced. Your pump has been stopped. 1. Acknowledge the alarm. 2. Disconnect your insulin cartridge connector from your infusion set, then take the insulin cartridge out of the pump andchange to the other pump. 3. Contact Kaleido Care to inform them about your alarm. We will replace your pump as soon as possible!
1030	There's a problem with your Kaleido pump Your pump has been stopped	 Something went wrong with your insulin delivery. Your pump has been stopped. 1. Acknowledge the alarm. 2. Your pump will reboot by itself. 3. The connection screen should appear automatically. Press Enter to connect, selecting the option to reuse your last insulin cartridge. Restart pumping. 4. If cartridge reuse isn't possible, disconnect your insulin cartridge connector from your infusion set, then take your your insulin cartridge out of your pump (you'll hear 2 beeps when this happens) and try connecting using a new and fully filled insulin cartridge instead. Restart pumping. 5. If the same alarm sounds again, switch over to your other pump. Contact Kaleido Care and we'll take care of it for you.

Alarm number	What's on the alarm screen?	Steps to take to solve the issue
1071, 1091	There's a problem with your Kaleido pump Your pump has been stopped WARNING Your IOB (Insulin On Board) and TDD (Total Daily Dose) may not be accurate.	 Your pump has unexpectedly reset and is now stopped. Acknowledge the alarm. The pump will reboot (you will hear 2 beeps). The connection screen should appear automatically. Press Enter to connect, selecting the option to reuse your last insulin cartridge. Restart pumping. Cartridge reuse not possible? Disconnect your insulin cartridge connector from your infusion set, then take the insulin cartridge out (hear 2 beeps) and try connecting using a new and fully filled insulin cartridge. Restart pumping. Do not rely on Insulin on Board (IOB) records for the time set for your insulin activity (i.e. if set for 3 hours, then Insulin on Board should be deemed inaccurate for 3 hours from the point of restarting the pump). The Total Daily Dose (TDD) is also invalid for that day. If the same alarm sounds again, switch over to your other pump. Contact Kaleido Care and we will try to help you as soon as possible.
1078	There's a problem with your Kaleido pump Your pump has been stopped	 Your pump can't process this request and has stopped. Acknowledge the alarm. The pump will reboot (you will hear 2 beeps). The connection screen should start automatically. Try to connect, stating that the last insulin cartridge is being reused. Restart pumping. Cartridge reuse not possible? Disconnect your insulin cartridge connector from your infusion set, then take the insulin cartridge out (hear 2 beeps) and try connecting using a new and fully filled insulin cartridge. Restart pumping. If you hear the same alarm again after you've inserted a new insulin cartridge, switch over to your spare pump. Contact Kaleido Care and we will try to help you as soon as possible.

Alarm number	What's on the alarm screen?	Steps to take to solve the issue
1090	Your insulin cartridge has come out of your pump while it was still pumping	 QUICK TIP When the pump is running and detects that the cartridge is removed, pumping stops. The beeping of this pump alarm can only be stopped by acknowledging the alarm via the handset. 1. Check if the insulin cartridge is out of the pump If the insulin cartridge is out of the pump: 2. Acknowledge the alarm. 3. Disconnect your insulin cartridge connector from your infusion set, then try to reinsert the insulin cartridge, stating that the last insulin cartridge is being reused, or insert a new and fully filled insulin cartridge (either because this was the initial plan, or because reusing the last cartridge isn't possible). 4. Follow the steps on the connection screen to connect the pump to the handset. If the insulin cartridge is still in the pump: 2. Acknowledge the alarm. 3. Disconnect your insulin cartridge connector from your infusion set, then take the insulin cartridge connect of the pump and change to the other pump. 4. Contact Kaleido Care to inform them about your alarm. We will replace your pump a s soon as possible.
1092	There's a problem with your Kaleido pump Your pump has been stopped	 There's a problem with your Kaleido pump. Acknowledge the alarm. Disconnect your insulin cartridge connector from your infusion set, then try to reinsert the insulin cartridge, stating that the last insulin cartridge is being reused, or insert a new and fully filled insulin cartridge. Disconnect your insulin cartridge connector from your infusion set, then take the insulin cartridge out of your pump. The connection screen should start automatically. Try to connect, stating that the last insulin cartridge is being reused. Restart pumping. Cartridge reuse not possible? Disconnect your insulin cartridge connecting using a new and fully filled insulin cartridge. Alarm keeps reoccurring? Charge your pump fully (minimum 2 hours) and try reconnecting then. You can switch to your other pump in the meantime. If the alarm keeps repeating, change to your other pump. Contact Kaleido Care and we will try to help you as soon as possible.

Handset alarms

Alarm number	What's on the alarm screen?	Steps to take to solve the issue
2005, 3083	There's a problem with your Kaleido handset Your handset will now turn off, but your pump will not stop	 Your handset has a software issue and needs to be replaced. Acknowledge the alarm. Your handset will turn off, but your pump will continue to deliver your basal profile if there was one active. You will not be able to deliver a bolus or change your settings. Contact Kaleido Care to inform us about your alarm. We will replace your handset as soon as possible.
2012, 3086	There's a problem with your Kaleido handset Your handset will now turn off, but your pump will not stop	 There's a problem with your handset battery. If the pump was running at the time of the alarm, it will continue to deliver insulin. Acknowledge the alarm. The handset will turn off. Charge the handset for a minimum of 10 minutes, ignoring the alarm. Accept the alarm after 10 minutes. The handset will reboot. If the issue is resolved, check Time and Date settings are correct. If the alarm keeps repeating, please contact Kaleido Care. We will try to help you as soon as possible.
2041	There's a problem with your Kaleido handset Your handset will now turn off, but your pump will not stop	 Your handset has unexpectedly reset. 1. If the pump was running at the time of the alarm, it will continue to deliver insulin. 2. Acknowledge the alarm. The handset will reboot. 3. Turn the handset back on by pressing the on/off button for 3 seconds. 4. If the issue is resolved, check Time and Date settings are correct. 5. If the alarm keeps repeating, please contact Kaleido Care. We will try to help you as soon as possible.

Alarm number	What's on the alarm screen?	Steps to take to solve the issue
3084	There's a problem with your Kaleido handset Your handset will now turn off, but your pump will not stop WARNING Your IOB (Insulin On Board) and TDD (Total Daily Dose) may not be accurate.	 Your handset has unexpectedly reset. If the pump was running at the time of the alarm, it will continue to deliver insulin. Acknowledge the alarm. The handset will reboot. Turn the handset back on by pressing the on/off button for 3 seconds. If the issue is resolved, check Time and Date settings are correct. Check if the pump is running and restart if necessary, stating that the last insulin cartridge is being reused. Do not rely on Insulin on Board (IOB) records for the time set for your insulin activity (i.e. if set for 3 hours, then Insulin on Board should be deemed incorrect for 3 hours from the point of restarting the pump). The Total Daily Dose (TDD) is also invalid for that day. If the alarm keeps repeating, please contact Kaleido Care. We will try to help you as soon as possible.
3149	There's a problem with your Kaleido handset Your handset will now turn off, but your pump will not stop	 This alarm indicates that an unknown error has occurred. 1. Acknowledge the alarm. The handset will reboot. 2. Turn the handset back on by pressing the on/off button for 3 seconds. 3. Wait to see if the pump restarts automatically. If it doesn't, disconnect your insulin cartridge connector from your infusion set, then remove the insulin cartridge from the pump, then reinsert. 4. The connection screen should start automatically. Try to connect, stating that the last insulin cartridge is being reused. 5. If there is no effect, acknowledge the alarm. Disconnect your insulin cartridge connector from your infusion set, then take the insulin cartridge out (hear 2 beeps) and try connecting using a new insulin cartridge. 6. If the alarm keeps repeating, please contact Kaleido Care. We will try to help you as soon as possible.

2

Precautions

Kaleido will let you know straight away if there's a pump, handset or infusion set blockage issue that needs your attention. But in very exceptional circumstances, there may be times when your pump and handset can't detect that there's a problem. For example if you have accidentally pulled out your infusion set or the insulin cartridge connector is no longer connected to your infusion set.

You need your current BG information to help you make diabetes management related decisions should a problem occur, so you should make sure you always test vour glucose levels at least four times a day (or as recommended by your healthcare provider) while you're using an insulin pump. If you ever have an unexpected glucose level, check your Kaleido pump and handset, your insulin cartridge, the insulin itself and the infusion set. to make sure everything is as it should be. Also check that you haven't missed a bolus. You can also check if the device you're using to check your BG is functioning correctly.

Additionally, there is a small chance that you may have missed an alarm, so it's a good idea to double-check your History too. If in doubt, keep an alternative insulin delivery system on standby, just in case, and contact Kaleido Care for help. If you feel unwell or you're measuring extremely high or low glucose levels, always call your healthcare provider for advice.

Note that when the handset is powered off, no alarm messages can appear on the handset screen. When the handset is powered on, any alarms will automatically be displayed and updated in the History.

WARNING

Do not use Kaleido if you are unsure how to react to an alarm. Switch to an alternative form of insulin therapy, and contact Kaleido Care, your distributor or your healthcare provider for assistance.



09. Looking after your Kaleido

Looking after your Kaleido

In order to keep your Kaleido in good condition, charge your pumps, handset and clean Kaleido on a regular basis. Other than cleaning and charging, there are no serviceable parts for Kaleido.

How should I clean my Kaleido products?

We recommend that you take five minutes to clean your Kaleido pumps, handset, charging dock and inserter at least once a week. Here's how you do it:



STEP 1

Dab a little bit of pH neutral detergent onto a clean, non-fibrous dry cloth.

QUICK TIP

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

WARNING

Do not let the USB port of the Handset and the contact pins of the Charging dock come in contact with liquids. STEP 2 Using v

Using your cloth, gently wipe your pumps, handset, charging dock and inserter. Remove any dirt or glue residues that might have built up from to your body and pump patches.

STEP 3

Before you finish, make sure you've wiped away any detergent residue and

then, if necessary, pat your products dry with a nonfibrous cloth.

WARNING

Do not clean any of your Kaleido products while they are plugged into a power source, computer, or a data uploading device. Doing so may result in an electric shock.

WARNING

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

10

2

How should I store my Kaleido products?

Keep your Kaleido products in a clean, dry place where you know you'll be able to access them whenever you might need to. Your Kaleido products should be stored and used at temperatures between 5°C and 37°C and a relative humidity (non-condensing) between 15% and 93%,



It's important to remember that once you've filled an insulin cartridge, you should start using it immediately.

WARNING

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

WARNING

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 system 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 provider.

What do I do if I need to dispose of my Kaleido products?

Pumps, handset, charging dock, power adapter, connection cable and inserter

When it's time to dispose of your Kaleido pumps, handset, charging dock or inserter, you can return them to us at the following address and we'll take care of them for you:

ViCentra B.V. Rijnzathe 6 3454 PV Utrecht The Netherlands



Top-up Kit contents

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.

QUICK TIP

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

Waste packaging materials

Packaging materials from the Starter kit, or Top-up Kit can be disposed of through your regular waste system.

Where can I get replacement Kaleido products?

Kaleido Care, your authorized distributor or your healthcare provider will automatically send you a brand new Top-up Kit before you use everything from your current kit.

Of course, if you need an extra Top-up Kit want to change what you receive, or you need to update your delivery address, just contact Kaleido Care, your authorized distributor or your healthcare provider.

The Kaleido Care team will also be ready and waiting to help you if you ever need a replacement pump, handset, charging dock, connection cable or inserter^{*}.

*For more information on replacement of Kaleido, please refer to the Warranty conditions on page 268.

2

22

2



10. FAQ's



In this chapter you will find our most frequently asked questions - and the answers to those questions, so you have them all in one spot. How often should I take a BG reading?

Checking your glucose levels often is the safest and most effective way to make sure the insulin you have delivered does what it should. It'll help to keep you aware of any potential highs or lows before they start causing problems. It's important that you take a BG reading to check your glucose levels at least four times a day:

- once when you wake up
- once before eating your meals
- before you go to sleep

You might also want to take a BG reading:

- about 2 hours after delivering a bolus
- · before any snacks
- when your pump is paused or stopped (and when you restart it)
- after changing your insulin cartridge and infusion set.

Consult your healthcare provider for more information on when and how to check your BG.

Can I wear my pump during exercise?

WARNING

Check for damage of the insulin cartridge, infusion set and pump in case you notice that your glucose levels are high or when you need more insulin than expected. Also check the BG measuring device you are using is functioning correctly. In case you see any damage on a Kaleido component, stop using it, contact Kaleido Care/your distributor and replace the component.

We designed your Kaleido to be worn during all sorts of physical activities, but whether to leave it on or take it off depends on the type of exercise that you are doing and what happens to your BG before, during and after exercise. Different types of exercise might have a different impact on your BG. Make sure to consult with your healthcare provider for advice on whether to leave your pump on, pause and remove it or set a temporary basal rate. For more information, see "How do I pause my pump?" on page 211 and "How do I stop my pump?" on page 215. See also "How do I set a temporary basal rate?" on page 101

QUICK TIP

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.

QUICK TIP

If you remove your pump for any length of time, the most important thing to remember is to check your glucose levels more frequently. This can help you to avoid any unexpected changes and can come in handy with catching any highs or lows early too. Also remember to close the protective cover on your infusion set.

QUICK TIP

Some sports and exercises can be pretty energetic – we designed your Kaleido with real life in mind, but we recommend never putting them – or yourself – at unnecessary risk.

What about water?

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 don't go deeper than 1.5 meters or for longer than 1 hour in the water. Remember to clean your pump in case it becomes dirty (see page 242).

WARNING

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 your pump.

WARNING

Do not use your Kaleido system in high temperatures (e.g. a hot tub or hot shower), the insulin may be affected with temperatures higher than 37°C.

What about high altitudes?

In temperatures between 5°C and 37°C, your Kaleido pump can operate within an air pressure range of 0.7-1.06 bar. This air pressure is typically found from sea level up to 2500m 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.

Can I use lotion, sunscreen or insect repellent with Kaleido?

Some skin care products, such as sunscreen lotions, moisturizer lotions or creams and insect repellents, can cause damage to the plastics used in Kaleido and affect the adhesive of your body patches. After using such products, be sure to wash your hands prior to handling Kaleido. If you get any skin care products or insect repellents on Kaleido, wipe them off as soon as possible following the cleaning instructions on page 242.

Can I use Kaleido in combination with another electronic medical device?

Consult your healthcare provider (and the technical information in your User Manual) prior to using Kaleido in combination with any other electronic medical device (e.g. pacemaker). Also consult the User Manual or manufacturer of the other medical device for warnings and precautions.

Where do I go for answers to my additional questions?

We'd love to help you out with any questions you might have regarding Kaleido and how to use it. If you have any medical questions or general diabetes questions, reach out to your healthcare provider.

Can I wear my pump on aeroplanes?

Yes, you can so long as the aeroplane's cabin is pressurised. If this is the case, your pump will continue to deliver your insulin while you're up in the air. Most airlines will ask you to turn your electronic appliances off during take-off and landing. Kaleido uses *Bluetooth*[®]Low Energy to connect your pumps to your handset. Airline restrictions can change over time though, so you might want to contact your airline at least 48 hours in advance to check their specific guidelines. If the use of Kaleido is not allowed during taxi, take off, flight and landing, discuss an alternate back up option with your healthcare provider.

It's a good idea to ask your healthcare provider for a letter to confirm that you're wearing your Kaleido and carrying insulin and Top-up kit components for medical purposes.

When you travel make sure you take plenty of supplies with you, as well as another method of insulin therapy, just in case.

What should be in my back-up kit?

Medical equipment can and does sometimes stop working due to technical issues/ damage. It is essential that you are prepared for such times. It is highly recommended to keep the following supplies on hand in a back-up kit such as spare insulin, hypo treatment and sterile Kaleido disposables with you in case of an emergency. This enables you to change these items if necessary.

Such a back-up kit should contain:

- 1 x each of the items in your Kaleido Top-up Kit
- 1 x insulin pen* containing your rapid acting insulin
- 1 x pen needle designed for use with your insulin pen OR alternatively, 1 x syringe and 1 x needle (approved for subcutaneous injection)
- 1 x insulin vial* containing your rapid acting insulin
- 2 x alcohol wipes
- Hypo treatment
- Glucose monitoring equipment
- The contact details for Kaleido Care
- The contact details of your healthcare team
- The contact details of your family, friend or support person
- Flashlight (you can also use the light on your smart phone if you use one)
- 1 x pen/pencil + paper
- 1 x your instructions/Multiple Daily Injection dosage regime from your healthcare provider

*Ensure your insulin is always within the expiry date and is kept within the required temperatures as specified by the insulin manufacturer.



11. Technical information

Technical specifications

Specification	Description
Environmental operating and storage conditions	Temperature range: 5 - 37°C Humidity range: 15 - 93% relative humidity non- condensing Pressure range: 0.7 bar- 1.06 bar
Dimensions	Pump: 50 mm x 35 mm x 12.5 mm Handset: 107 mm x 50 mm x 9 mm Charging dock: 60 mm x 45 mm x 15 mm
Weight	Pump: 19 g Handset: 60 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) Handset: Keep dry Charging dock, power adaptor and connection cable: Keep dry
Batteries	Pump: 260 mAh rechargeable lithium polymer Handset: 550 mAh rechargeable lithium polymer
Battery life	Pump: One cartridge cycle up to three days on a full charge with a maximum insulin use of 200 units over three days Handset: Approximately 1.5 to 2 days at typical usage on a full charge
Service life	Pump, handset, charging dock, connection cable, inserter and power adapter: 4 years' use.
	Insulin cartridge, infusion set, and body & pump patches: single use, up to 3 days in use.
	Alcohol wipes, syringes and needles: single use.
Alarm volume	> 50 dB
Wireless radio	<i>Bluetooth</i> [®] Low Energy Class 3 transmitter with a 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	1U
Maximum time to occlusion alarm	1 hour at a basal rate of 1 U/hr 20 hours at a basal rate of 0.05 U/hr

Unintended bolus volume generated at occlusion	10
Keep open rate	The Kaleido product has no keep open rate
Maximum delivery under single fault condition	0.05 U
Maximum BG input	33.3 mmol/L
Charger power input	100 - 240 V AC, 50/60 Hz
Charger power output/Pump power input	5 V DC, 1.0 A
System memory	The system memory is retained for up to 90 days
Administration sets used for all tests performed under EN60601-2-24	Kaleido insulin cartridge 5 cm and 30 cm tubing
Sterilisation components and their sterilisation	Insulin cartridge: by irradiation
method	Infusions set: by ethylene oxide gas
	Alcohol wipe: by irradiation
	Syringe: by ehtylene oxide gas
	Needle: by ethylene oxide gas
Product classification (IEC 60601-1)	Class II medical equipment
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/hr
	Maximum basal rate: 5 U/hr
	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 profile delivery running in the
	background.
Priming volume	Infusion set 6 mm cannula variant: 0.20 U
Marked and free data materia transfer	Infusion set 9 mm cannula variant: 0.25 U
Method used for determining insulin on board	Static calculation that takes the insulin activity time as input for linear insulin decay

The power adapter is the means of isolation from the supply mains. The combination of the pump, handset, charging dock, connection cable and power Adapter is considered the Medical Electrical System.

The pump is the applied part (type BF) of the medical electrical equipment.

Security

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 and Handset allow no access to the programming interface of the system once produced.

Via these mechanisms, ViCentra ensure the Kaleido system includes protection against unauthorized access.

Regarding pairing by design, the Just Work Pairing method also provides additional security during pairing to mitigate any malicious attacks. The pump and handset communicate using the BLE 4.2 standard which encrypts data transferred between paired devices.

Symbols

Any symbols we've used on your Kaleido products and their labelling are internationally recognised. Here's what they mean.

C E 2460		\sim	
CE Marking	Manufacturer	Date of manufacture	Use by date
LOT	REF	SN	MD
Batch code	Catalogue number	Serial number	Medical Device



UD

Unique Device Identifier



Keep dry



Direct current (DC)





Alternating current (AC)



Do not use if the packaging is damaged and consult the User Manual



Temperature limit



Sterilised using ethylene oxide



Refer to the User Manual The blue colour is a mandatory action



Translation



Type BF applied part



Humidity limitation



Sterilised using irradiation



Consult User Manual

Repackaging



Class II

equipment

Universal Serial

Bus (USB), port/

plug

Do not

resterilize

STER



Distributor



Non-ionizing electromagnetic radiation



Waste Electrical and Electronic Equipment (WEEE)



Single Sterile Barrier System



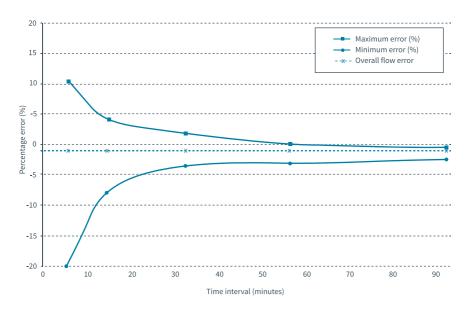
Single patient Multiple use



Importer

Pump accuracy

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



WARNING

The accuracy of your system is dependent upon it being used correctly and in accordance with your training and the provided User Manual.

WARNING

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

WARNING

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.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables, external antennas and mobile phones) should be used no closer than 30 cm (12 inches) to any part of the pump or handset, including cables specified by ViCentra. Otherwise, degradation of the performance of this equipment could result (e.g. disruptions in the *Bluetooth*[®] communication).

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Kaleido is intended for use in the electromagnetic environment specified below. The customer or the user of the Kaleido system should assure that it is only used in the following environment:

Emissions test	Compliance level	Electromagnetic environment — guidance
RF emissions CISPR 11	Group 1	The Kaleido system 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 emissions CISPR 11	Class B	The Kaleido system is suitable for use in all establishments, including domestic establishments and those directly connected
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	Not applicable, as rated power is less than 75W.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Kaleido system is intended for use in the electromagnetic environment specified below. The customer or the user of the Kaleido system should assure that it is only used in the following environment:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
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%.
Electrical 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	Kaleido 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	Kaleido 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 _τ for 0.5 and 1 cycle 70 % U _τ for 25/30 cycles 0 % U _τ for 250/300 cycles		Kaleido 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: $U_{_{\rm T}}$ is the AC mains voltage prior to application of the test level.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment — guidance
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 equip- ment (including peripherals such as antenna cables, external antennas and mobile phones) should be used no closer than 30 cm (12 inches) to any part of the pump or handset, including
Radiated RF Electro- magnetic Field IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	cables specified by the manufacturer. Otherwise, it may result in degradation of the performance of this equipment (e.g. disruptions in the <i>Bluetooth</i> [®] communication). The Kaleido system
Proximity fields from RF wireless communication systems IEC 61000-4-3	Refer to table on next page	Refer to table on next page	is tested for radiated RF immunity only at selected frequencies, and use of Kaleido system near transmitters at other frequencies can cause improper operation.

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27
450	430-470	GMRS 640, FRS 460	FM ^{c)} ± 5 kHz devi- ation 1 kHz sine	2	0.3	28
710			Pulse			
745	704-787	LTE Band 13, 17	modulation ^{b)}	0.2	0.3	9
780			217 Hz			
810		GSM 800/900,	Pulse			
870	800-960	TETRA 800, iDEN 820,	modulation ^{b)} 18 Hz	2	0.3	28
930		CDMA 850, LTE Band 5	10112			
1720		GSM 1800; CDMA 1900;				
1845	1700-1990	GSM 1900; DECT; LTE Band	Pulse modulation ^{b)} 217 Hz	2	0.3	28
1970		1, 3, 4, 25; UMTS	211112			
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240			Pulse			
5500	5100-5800	WLAN 802.11 a/n	modulation ^{b)}	0.2	0.3	9
5785		,	217 Hz			

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.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) 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

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

Rated maximum	Separation distance according to frequency of transmitter in \boldsymbol{m}			
output power of transmitter in W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
	<i>d</i> = 1.17 √ <i>P</i>	d=0.35√P	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 metres (*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.

- NOTE 1: At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.
- NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Declarations & statements

Hereby, ViCentra B.V. declares that this Insulin infusion pump is in compliance with the essential requirements and other relevant provisions of directive 2014/53/EU. Please contact the manufacturer, ViCentra B.V., if you would like a copy of the declaration of conformity.

Medical electrical equipment needs special precautions regarding EMC and needs to be put into service according to 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 electromagentic fields) recommended by the International Commission on Non-Ionizing Radiation Protection (ICNIRP). These limits include a substantial safety margin designed to assure the safety of all persons, regardless of age and health.

The radio wave exposure guidelines use a unit of measurement 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 system, even if that other equipment complies with CISPR emission requirements. Radio devices should be kept away from Kaleido at least at a distance *d* (as calculated with the tables in page 265).

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

Trademark information

Kaleido[®], Kaleido Care[®] and ViCentra[®] are registered trademarks of ViCentra B.V.

The *Bluetooth*[®] word mark and logos are registered trademarks owned by the Bluetooth SIG, Inc. and any use of such marks by ViCentra B.V. is under license. Other trademarks and trade names are those of their respective owners.

Glooko[®] is a registered trademarks of Glooko, Inc.

Humalog[®] is a registered trademark of Eli Lilly and Company.

NovoRapid[®] is a registered trademark of Novo Nordisk A/S.

Diabeloop[®] and DBLG1 are either registered trademarks or trademarks of Diabeloop SA in Europe and/or in other countries.

Dexcom [®] and Dexcom G6 [®] are registered trademarks of Dexcom, Inc. in the United States and/or other countries.

Summary of Safety and Clinical Performance

The Summary of Safety and Clinical Performance is available upon request or by accessing it on the European Database on Medical Devices (EUDAMED) website.

Warranty

These warranties apply in the U.K., The Netherlands, Germany and France.

QUICK TIP

Kaleido is a valuable medical device. We strongly encourage you to add Kaleido to your home and contents insurance policy (or other special insurance policy available for insulin pumps) to protect you in case of accidental loss or damage. Check with your insurance agent or healthcare provider for further details.

Hardware warranty

In addition to the user's rights under applicable mandatory law ViCentra® B.V. ("ViCentra®") warrants the Kaleido® Hardware against defects in materials and workmanship for the period of 4 (four) years from the original date of shipment of the Hardware to the original end user (the "Warranty Period"). During the Warranty Period, ViCentra® will replace any defective Kaleido® Hardware, subject to the conditions and exclusions stated herein.

Throughout this warranty the words "Kaleido[®] Hardware" shall comprise a Kaleido[®] insulin pump, a Kaleido[®] handset, a Kaleido[®] infusion set inserter, a Kaleido[®] insulin pump charging dock, a Kaleido[®] connection cable and a Kaleido[®] power adapter as supplied in the Kaleido[®] Starter Kit. The term "Hardware" shall mean one or more items of Kaleido[®] Hardware and Kaleido[®] User Manual.

If, during the warranty period, the Hardware should fail because of a defect in material or workmanship, the faulty item may be returned to ViCentra® and ViCentra® will, at its discretion, either repair or replace the same Hardware with a new or recertified Hardware, at ViCentra®'s option, without charge to the end user. In certain circumstances and at its sole discretion, ViCentra® may instead elect to refund all or a portion of the purchase price of the Hardware to the end user.

Freight and transportation charges, where applicable, incurred in shipping Hardware to be repaired or replaced under this limited warranty will be paid by ViCentra[®]. In the event Hardware is replaced or repaired under this warranty, the Warranty Period shall not be extended. In the event that ViCentra[®] elects to provide replacement Hardware prior to receipt of the original Hardware back to ViCentra, return your original Hardware to ViCentra[®] upon receiving the replacement Hardware. In the event it is not returned, this warranty shall be void and the user will not be entitled to future Hardware replacement or repairs.

The warranty is valid only if Kaleido® Hardware is used in accordance with ViCentra® instructions and will not apply to the following:

- damage resulting from changes or modifications made to the Kaleido[®] Hardware by the user or third persons after the date of manufacture;
- use with other than approved software and modifications to the Kaleido® software;
- damage results from service or repairs performed to any part of the Kaleido[®] Hardware by any person or entity other than ViCentra[®] and its authorised representatives;

- if a non-Kaleido[®] insulin cartridge, infusion set, needle or syringe is used with the Kaleido[®] Hardware;
- damage results from a force majeure or other event beyond the reasonable control of ViCentra[®];
- damage results from negligence or improper use, including but not limited to improper storage, physical abuse or use outside the ranges specified in the technical data such as excess altitude or humidity; or
- cosmetic damage or 'wear and tear' including but not limited to scratches not effecting functionality.

This limited warranty extends only to the original end user and is not transferable. Any sale, rental or other transfer or use of the Kaleido[®] Hardware covered by this warranty to or by a user other than the original end user shall cause this warranty to immediately terminate. This warranty only applies to the Kaleido[®] Hardware as defined above and not to other products or accessories.

The remedies provided for in this warranty are the exclusive remedies available in the event of any breach hereof. Except for such remedies, ViCentra®, its suppliers, and its distributors shall not, to the extent permitted by law, be liable for any losses, liabilities, claims, or damages of any kind or nature whatsoever, including, without limitation, any indirect, consequential, incidental, or special damages caused by or arising from a defect of the Hardware.

Save as expressly set forth in this limited warranty, all other warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

Infusion set and insulin cartridge warranty

In addition to the user's rights under applicable mandatory law ViCentra® B.V. ("ViCentra®") warrants the Kaleido® insulin cartridge and infusion set against defects in materials and workmanship for the period 3 (three) days after the individual insulin cartridge/infusion set sterile packaging has been opened, not to exceed 6 (six) months from the original date of shipment of the insulin cartridge or infusion set to the original end user (the "Warranty Period"). During the Warranty Period, ViCentra® will replace any defective Kaleido® insulin cartridge or infusion set, subject to the conditions and exclusions stated herein.

The warranty is valid only if the insulin cartridges and infusion sets are used in accordance with the ViCentra® instructions and will not apply:

- if the insulin cartridge or infusion set has been used for more than a single-time use by a single end-user;
- if damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the associated User Manual;
- if the sterile package is compromised while in the control of the user by any means other than purposeful opening by the user at the time of intended product use;
- if damage results from changes or modifications made to the insulin cartridge or infusion set by the user or third persons after the date of manufacture;
- if a non-Kaleido[®] infusion set inserter is used with the Kaleido[®] infusion set and insulin cartridge

- if damage results from service or repairs performed to any part of the insulin cartridge or infusion set by any person or entity other than ViCentra®;
- if damage is caused by use of the insulin cartridge or infusion set with any non-Kaleido[®] insulin pump;
- if damage results from a force majeure or other event beyond the control of ViCentra®; or
- if damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.
- if damage results from using Kaleido with other components than what is supplied by ViCentra® or stated in the User Manual.

This limited warranty extends only to the original end user and is not transferable. Any sale, rental or other transfer or use of the Kaleido® insulin cartridges and infusion sets covered by this warranty to or by a user other than the original end user shall cause this warranty to immediately terminate. This warranty only applies to the Kaleido® insulin cartridges and infusion sets as defined above and not to other products or accessories.

The remedies provided for in this warranty are the exclusive remedies available in the event of any breach hereof. Except for such remedies, ViCentra®, its suppliers, and its distributors shall not, to the extent permitted by law, be liable for any losses, liabilities, claims, or damages of any kind or nature whatsoever, including, without limitation, any indirect, consequential, incidental, or special damages caused by or arising from a defect of the insulin cartridges or infusion sets.

Save as expressly set forth in this limited warranty, all other warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

Consumables warranty

In addition to the user's rights under applicable mandatory law ViCentra[®] B.V. ("ViCentra[®]") warrants the Kaleido[®] Consumables against defects in materials and workmanship for the period of 6 (six) months from the original date of shipment of the Consumables to the original end user (the "Warranty Period"). During the Warranty Period, ViCentra[®] will replace any defective Kaleido[®] Consumables, subject to the conditions and exclusions stated herein.

Throughout this warranty the words "Kaleido® Consumables" shall include syringes, needles, body patches, pump patches and alcohol wipes supplied by ViCentra®.

If a defect exists, ViCentra[®], at its option and to the extent permitted by law will either:

- 1. repair the product at no charge using new or refurbished parts;
- 2. exchange the product with a functionally equivalent product that is new or refurbished; or
- 3. refund the original purchase price.

This warranty is available only to the original end user and excludes damage resulting from abuse, accident, modifications or other causes that are not defects in materials and workmanship.

This warranty is not applicable to any devices labelled as demonstration use, or 'Not for Human Use'.

The remedies provided for in this warranty are the exclusive remedies available in the event of any breach hereof. Except for such remedies, ViCentra®, its suppliers, and its distributors shall not, to the extent permitted by law, be liable for any losses, liabilities, claims, or damages of any kind or nature whatsoever, including, without limitation, any indirect, consequential, incidental, or special damages caused by or arising from a defect of the consumables.

Save as expressly set forth in this limited warranty, all other warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

How to contact Kaleido Care

Telephone:+44 808 189 2146Email:kaleidocare.uk@hellokaleido.comWebsite:www.hellokaleido.com

Any trouble ?

Report any serious incident that has occurred in relation to the Kaleido product to ViCentra and to the competent authority in the country in which you are established.



Manufacturer: Address:

Telephone: Email: ViCentra B.V.

Rijnzathe 6 3454 PV Utrecht The Netherlands +31 (0) 88 3232 871 hello@hellokaleido.com



Kaleido User Manual (mmol/L version) Document number: 100110-19

Issue date: 22 June 2023

Kaleido.