GETTING STARTED WITH
THE MINIMED™ 640G SYSTEM

Medtronic

INTRODUCING THE MINIMED 640G SYSTEM

GETTING STARTED WITH THE MINIMED 640G INSULIN PUMP

GETTING STARTED WITH CONTINUOUS GLUCOSE MONITORING

APPENDIX

MiniMed® Care™

REGISTER TODAY

At Medtronic we aim to develop new and innovative products to help improve the lives of people with diabetes. We are also committed to providing our patients with ongoing personalised support and education to help them make the most of their diabetes management whilst being on pump therapy and continuous glucose monitoring.

Register now for My MiniMed Care for personalised support and education including:

- Quarterly newsletters with useful tips and tricks, testimonials and ongoing support

- Access to online personalised practical tools such as ordering pump clip replacements

- Online seminars and education

And come back soon to benefit from our constantly expanding servicescontent for pump users

Register for My MiniMed Care today at
www.medtronic-diabetes.co.uk/minimedcare_registration

MINIMED 640G SYSTEM

INSULIN DELIVERY

Medtronic offers a wide range of infusion sets so that you can choose the right infusion set for your comfort and safety.

CONTINUOUS GLUCOSE MONITORING

With our most responsive sensor system yet, you can continuously monitor your glucose levels with superior comfort* and accuracy**.

THERAPY MANAGEMENT TOOLS

Upload your pump to CareLink to conveniently track your glucose control and remotely share this information with your healthcare professional.

www.medtronicdiabetes.com/carelink

BLOOD GLUCOSE TESTING

With the accurate[1] CONTOUR NEXT LINK 2.4 meter you can wirelessly send blood glucose results to your MiniMed 640G insulin pump and deliver an insulin bolus discretely.

*The size of the new generation Enlite sensor has been reduced by 80%.
**When combined with the MiniMed 640G system and Guardian 2 Link transmitter. Enlite Sensor Performance addendum to user guide.
1. Section 8 clinical study. Data on file. Ascensia Diabetes Care.

GETTING STARTED WITH THE MINIMED 640G SYSTEM

Welcome! We are glad that you have chosen insulin pump therapy and are excited for you to begin using your MiniMed 640G system.

The MiniMed 640G system features innovative technology to more closely mimic the way a healthy pancreas delivers basal insulin to the body and help you achieve better glucose control. The MiniMed 640G system has been designed to provide you with:

- **Advanced protection** from dangerous high and lows
- **Personalised convenience** to help you manage daily diabetes tasks

The MiniMed 640G insulin pump also has a new, **improved design** for consistent ease of use.

Whether you are just starting pump therapy or upgrading from a previous pump model, this guide provides you step-by-step instructions on the basic operation and programming of your MiniMed 640G system, including Continuous Glucose Monitoring.

During your in-person training, your trainer will build on this information and help ensure you are confident to begin using your MiniMed 640G insulin pump.

We hope you enjoy learning about your new insulin pump.

DID YOU KNOW?
A complete explanation of the technical and operational aspects of your pump can be found in the *MiniMed 640G system User Guide.*

Information contained herein does not replace the recommendations of your healthcare professional.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

Please refer to the User Guide and your HCP for more information.

When using an insulin pump, check your blood glucose minimum 4 times a day.

IMPORTANT: Do NOT attach the insulin pump to your body or attempt to use insulin in your pump as you use this guide to practice and learn.
Attaching and using must only be done when you receive formal training with your healthcare professional or a certified product trainer.

THE DELIVERY OF INSULIN

INFUSION SET*

1 **Tubing:** carries insulin from the pump to you

2 **Reservoir Connector:** end of the tubing that attaches the reservoir which holds the insulin

3 **Insertion Site Section:** other end of the tubing that attaches to you

4 **Cannula:** tiny flexible tube placed into your body** by the insertion needle included in the insertion site section

5 **Adhesive:** holds the infusion set in place

6 **Reservoir Compartment:** part of the pump where the reservoir fits

You should replace both the infusion set and the reservoir every 2 to 3 days.

*Mio™ infusion set shown in illustration.

**Some infusion sets do not use a cannula but have a small needle that remains inserted in the body.

RESERVOIR

PUMP

LET'S GET STARTED!

This document does not replace the Instructions for Use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.
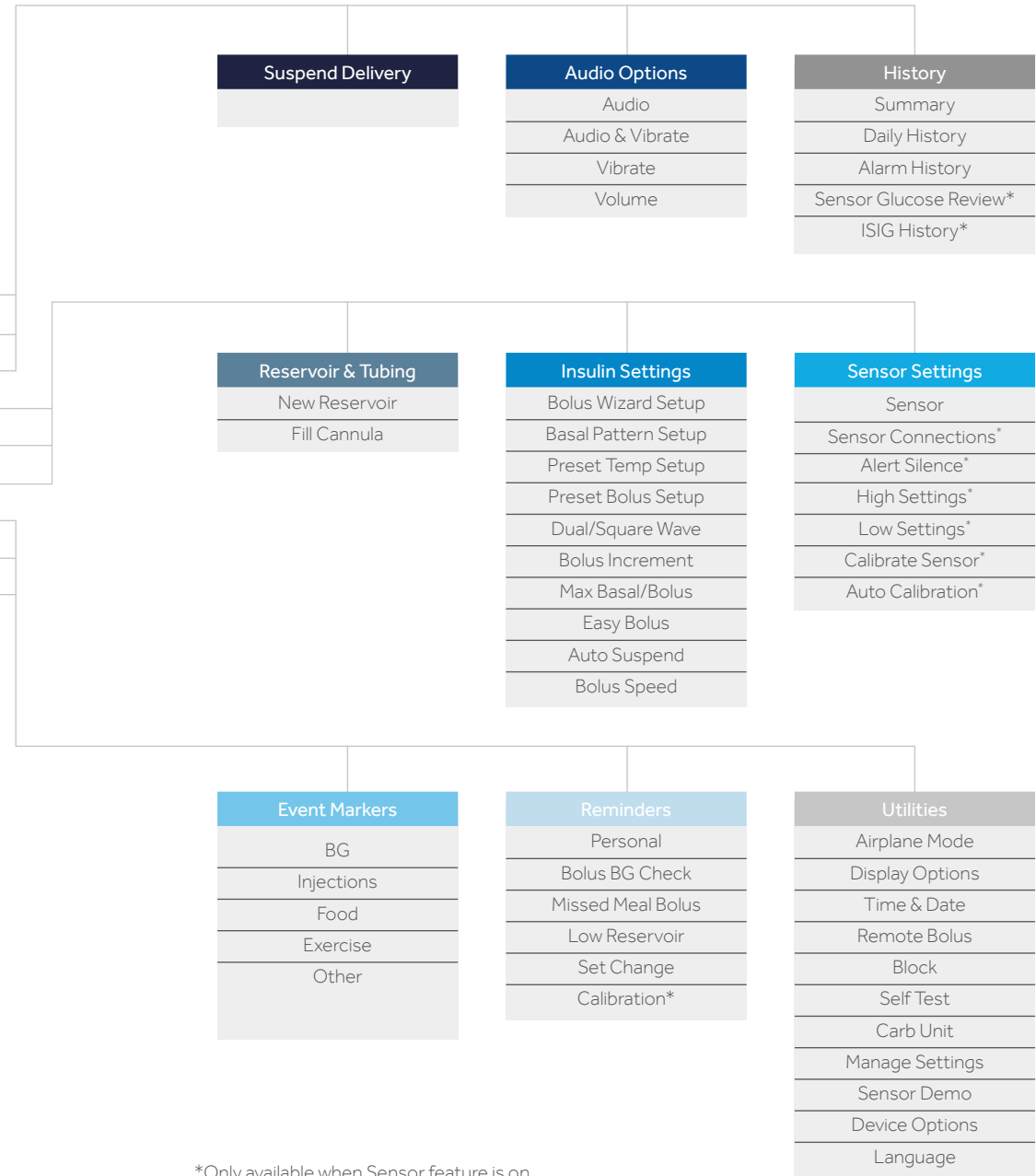
MENU MAP

Home Screen

Press 📖

Suspend Delivery
Audio Options
History
Reservoir & Tubing
Insulin Settings
Sensor Settings
Event Markers
Reminders
Utilities

Suspend Delivery

Audio Options
Audio
Audio & Vibrate
Vibrate
Volume

History
Summary
Daily History
Alarm History
Sensor Glucose Review*
ISIG History*

Reservoir & Tubing
New Reservoir
Fill Cannula

Insulin Settings
Bolus Wizard Setup
Basal Pattern Setup
Preset Temp Setup
Preset Bolus Setup
Dual/Square Wave
Bolus Increment
Max Basal/Bolus
Easy Bolus
Auto Suspend
Bolus Speed

Sensor Settings
Sensor
Sensor Connections*
Alert Silence*
High Settings*
Low Settings*
Calibrate Sensor*
Auto Calibration*

Event Markers
BG
Injections
Food
Exercise
Other

Reminders
Personal
Bolus BG Check
Missed Meal Bolus
Low Reservoir
Set Change
Calibration*

Utilities
Airplane Mode
Display Options
Time & Date
Remote Bolus
Block
Self Test
Carb Unit
Manage Settings
Sensor Demo
Device Options
Language

*Only available when Sensor feature is on.

NAVIGATION

Press 📖 from any screen to open the **Menu**.

Press ⌄ and ⌃ to scroll through the menu items.

Press ⊙ on the desired menu item to open.

The scroll bar appears on menus to indicate when additional text is available.

Press ⌄ to scroll down to view additional items.

Press ⌃ to scroll back up.

Press ↩ to go to previous screen. Hold ↩ to return to the **Home** screen.

SECTION 1: PUMP BASICS

Before inserting the battery or pressing any buttons, let's take a closer look at your pump.

THE FRONT OF YOUR PUMP

⌃ Up, ⌄ Down, ⟨ Left, and ⟩ Right

- Press to scroll up or down through a menu or list
- Press to move to desired area on the screen
- Press to change the value in an area

↩ Back

- Press to return to a previous screen
- Press and hold to return to the starting screen, called the Home screen

⊙ Select

- Press to select or confirm a value or menu option that is highlighted
- Press when directions say 'select '

▤ Menu

- Press to get to the Menu
- Press and hold to put pump into sleep mode

● Notification Light

- Flashes when an Alert or an Alarm is occurring

Up

Back

Notification Light

Left

Menu

Right

Select

Down

THE BOTTOM AND BACK OF YOUR PUMP

Medtronic MiniMed
Northridge, CA 91325 USA, (+1)818-576-5555
www.medtronicdiabetes.com
MiniMed® 640G [mmol/L]
IPX8
(C-34048-15?)

Medtronic Diabetes HelpLine Telephone Number

Pump Serial and Model Number

You may need to provide this information if you call for assistance.

INSERTING THE BATTERY

Your insulin pump is powered by a AA battery. A lithium, alkaline, or rechargeable AA battery can be used. The battery you place into your pump should always be new or fully charged.

To insert the battery and get started, you will need:
- The battery cap found with the pump
- The pump clip found with the accessories
- The AA battery found with the accessories

1
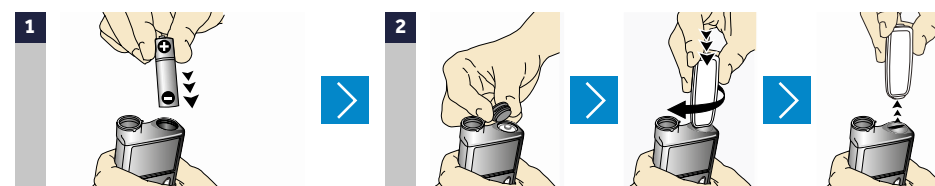
Place the battery into the battery compartment with the negative (flat) end going in first.

2

Place the battery cap onto the pump.
Use the edge of the pump clip to turn the cap to the right (clockwise) and tighten until the slot is horizontal to the pump. See image below.

> 💡 **NOTE:** Do not undertighten or try to overtighten the battery cap. It should be aligned horizontally with the pump case as shown here.
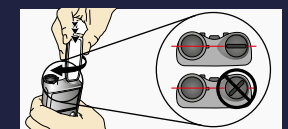
Once the battery is inserted, the pump will power on and the **Startup Wizard** will begin. You will need to follow it step-by-step to set up your language, time format, time and date.

Language
Select Language
English ✓
العربية
中文
Čeština

SECTION 2: HOME SCREEN

The Home Screen will be your starting place to access all features in the pump.

Status bar: provides a quick look at the pump's status

Bolus: gives you access to the bolus delivery screen and other bolus insulin options

Current time

BG reading: displays a BG taken in the last 12 minutes

Active insulin: displays any insulin still active from a previous bolus

Basal: gives you access to basal insulin options

BACKLIGHT

When you are not pressing buttons on your pump, you will notice that the Backlight will soon turn off. The pump is still on; it is just saving battery life. You can simply press any button to make the screen reappear.

UNLOCKING THE PUMP

After the Backlight has been off for a few minutes, the pump goes into Sleep mode and the pump is locked. When you begin using your pump again, you will see a screen like the one shown here when you leave the Home screen. You will need to press the arrow key that is highlighted to unlock the pump. This confirms you are reading the screen and the button presses are not accidental.

If the wrong arrow key is pressed, you will be asked to try again.

You can press and hold 🗐 if you wish to put the pump into Sleep mode and keep it locked when you are not using it. Doing this can also help save battery life.

STATUS BAR

The Status Bar displays the following icons so you can quickly view important information.

Battery icon: Shows the level of charge your battery has. As the battery charge decreases, the icon will become less full and change to yellow and then red.

Reservoir icon: Shows the approximate amount of insulin left in your reservoir. As insulin is used, the icon will become less full and change to yellow and then red.

Audio icon: Shows the audio mode you are using: audio ◁ , vibrate or audio and vibrate.

> **NOTE:** If you are using a 1.8mL insulin reservoir, the range of reservoir icons will start with the **second green icon**.
>
> **If starting with a full 1.8mL** reservoir and using **the minimum amount of insulin** recommended to fill the shortest tubing (45 cm) and a **steel** cannula, **the pump will display the second green (not full) reservoir icon after the reservoir and infusion set change is complete.**
>
> Not displayed with a 1.8mL reservoir
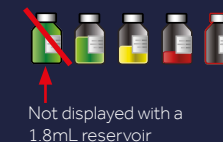
STATUS SCREENS

There will be times when you need additional status information such as the number of insulin units left in your reservoir, the last BG entered or your current basal rate.

To access the Status Screens, press ⌄ to highlight the **Status Bar** and press ◉.

> **REMEMBER:** You can go back to the previous screen by pressing ↩.

SECTION 3: BASAL PATTERNS

Basal insulin is delivered throughout the day and night to cover insulin needs between meals and during the night.

The pump supplies basal insulin by delivering small amounts of short-acting insulin throughout each hour, every hour of the day and night. This allows for insulin to be increased and decreased to adjust for your body's needs.

Basal insulin amounts must be programmed into your pump. This is done by setting a basal pattern. A basal pattern consists of one or more basal rates being delivered over the course of 24 hours.

BASAL PATTERNS SET UP - MULTIPLE BASAL RATES

It is likely when you start on pump therapy, that you will need more than one basal rate throughout the day and night to meet your body's insulin needs.

For example, a Basal Pattern may look like this:
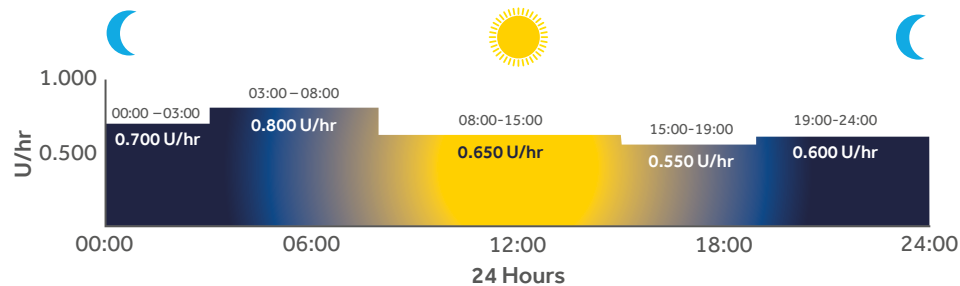
In this example, the basal pattern includes 5 different basal rates over 24 hours.

NOTE: The basal rates shown are for illustration purposes only – your basal settings will be different.
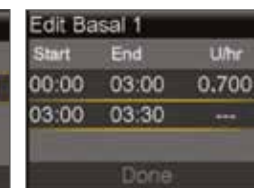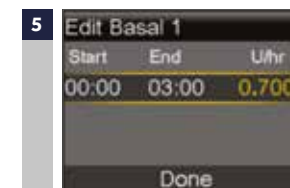
SETTING MULTIPLE BASAL RATES

1

From the Home screen, select **Basal > Insulin Settings > Basal Pattern Setup.**

2

Select **Basal 1 > Options > Edit.**

3
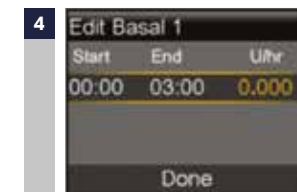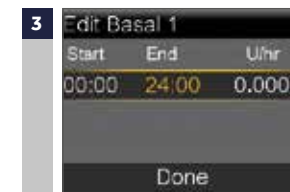
Press ⊚ on the time segment. The **End** time will be flashing.
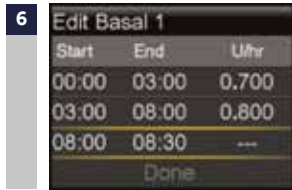
4

Press ⌃ to change End time to 03:00 and press ⊚.

5

Press ⌃ to 0.700 U/hr and press ⊚.

You can see you are automatically asked to enter the end time of the second basal rate. This basal rate will need to end at 8:00 and will need to be changed to 0.800 U/hr.

6

Change End time to 08:00 and basal rate to 0.800 U/hr using ⌃ and press ◎ .You can now enter the next end time.

7

Repeat steps 3 to 6 to enter the 3 next time segments and basal rates. For the last time segment, you will need to enter 24:00 as the end time to complete the full 24 hours.

8 Select **Done**.

9 Verify that **Basal 1** is entered correctly. Press ❯ to view all basal rates.

10

This basal pattern delivers 15.85 U over 24 hours.

If NO changes need to be made: Select **Save**.

11 *If changes need to be made:* Press ↩. Press ⌃ and press ◎. Repeat steps 7 to 9.

12 Select **Save**.

TEMPORARY (TEMP) BASAL RATE

This feature lets you immediately increase or decrease your basal insulin for the period of time (duration) that you set. It is the easiest way to immediately adapt your basal rate according to your daily life and is often used for exercise and sick days.

A Temp Basal can be set in either Percent (delivers a percent of the current basal rate) or by Rate (delivers the amount that you enter).

SET TEMP BASAL RATE

1

From the Home screen, select **Basal** > **Temp Basal**.

2 Press ⌃ to set duration and press ◎.

3

Select **Next**.

4

Select **Percent**.

Note: If you choose to use Rate, select Type, and you can then enter the U/hr desired.

5 Press ⌃ or ⌄ to enter the percent of current basal rate desired ◎.

6

Select **Begin**.

NOTE: The Home screen reads Basal (T) since you have a Temp Basal active. Select **Basal (T)** to review the details of the active Temp Basal. When the Temp Basal is complete, the basal will automatically return to the regularly programmed basal rate.

CANCEL TEMP BASAL RATE

If you ever set a Temp Basal and decide you do not need it, it can be canceled.

1

From the Home screen, select **Basal (T)**.

2
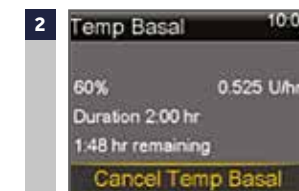
Select **Cancel Temp Basal**.

Note: Basal rate has now returned to the currently programmed rate.

SECTION 4: GIVING BOLUSES

A bolus is given to cover food that contains carbohydrate and/or to correct glucose levels that are above your target range.

BOLUS WIZARD CALCULATOR

Calculating how much bolus insulin to give can be challenging. When using the Bolus Wizard feature, all you will need to do is enter your current BG reading along with the amount of carbs you are about to eat.

Once you do this, the Bolus Wizard calculator uses the individual settings provided by your health care professional to estimate your bolus amount. Because these settings are specific to you, you can use it to calculate the precise amount of bolus insulin you need for your food and BG. This can help you better control your glucose levels.

> **NOTE:** Before using the Bolus Wizard calculator, you need to program your individual settings with the help of your health care professional.

TURNING THE BOLUS WIZARD FEATURE ON AND SETUP

1
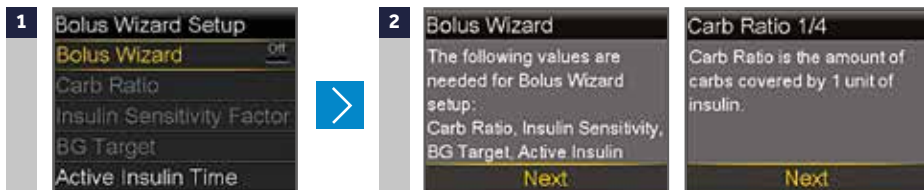
From the Menu, select Insulin **Settings > Bolus Wizard Setup > Bolus Wizard.**

2

Press ⌄ to continue reading text and select **Next**.

3 Follow the instructions to program the following settings: Carb Ratio, Insulin Sensitivity Factor (Sensitivity), BG Target and Active Insulin Time. Each setting will include a short description: you need to select **Next** and enter the requested data.

Carb Ratio | Insulin Sensitivity Factor | BG Target | Active Insulin Time

4 Select **Save.**
THE BOLUS WIZARD CALCULATOR SETUP IS NOW COMPLETE.

USING THE BOLUS WIZARD FEATURE

Here you can see the Bolus Wizard calculation screen and a short description of the steps below:

If you have tested your glucose using your compatible Ascensia meter, the BG and correction dose will already be showing.

You will first test and enter your current BG.

You will then enter grams of carbohydrates to be eaten.

The pump displays estimated amount of insulin to be delivered.

> **NOTE:** The boluses shown are for illustration purposes only – your settings and bolus results will be different.

GIVING A MANUAL BOLUS

When giving a manual bolus, you simply enter the amount of bolus insulin that you think you need for the carbohydrates you are eating, or to lower your BG if it is high.

1 From the Home screen, select **Bolus**.

2

Press ⌃ to 1.0 u and press ⊙.

3

Select **Deliver Bolus**.

4

Confirmation that Bolus has started will appear.

The Home screen will show the amount as it is being delivered.

Once the bolus has finished delivering, the pump will return to the normal Home screen.

Notice that **Stop Bolus** also now appears.

Notice there is **Active Insulin** now displayed. Active insulin is insulin from boluses that are still working to lower your blood glucose level and/or to cover your carbohydrate intake that is still not absorbed. Each time you give a bolus, it is added to the active insulin amount. As time passes, the amount will decrease. You will learn more about active insulin during your training.

STOPPING A BOLUS

To stop a bolus while it is delivering:

1

From the Home screen, select **Stop Bolus**.

2

Press ⟩ and select **Yes**.

3

The **Bolus Stopped** screen will show you how much of the bolus insulin was delivered before it was actually stopped.

Select **Done**.

CHECKING LAST BOLUS

There may be times when you need to see the time or amount of the last bolus that was given. You can see the last bolus delivered in the **Quick Status** screen. From the Home screen, select the **Status Bar** > **Quick Status** (see page 13).
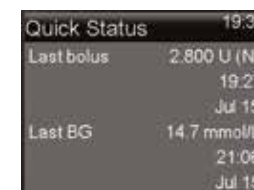
The (N) behind the Last bolus amount means the bolus was delivered as a normal bolus. There are additional ways to give a bolus which you will learn about later.

CHECKING BOLUS HISTORY

You may also want to review the last several boluses that were delivered. You can see the last several boluses delivered in **Daily History**. Press **Menu** button > **History** > **Daily History**.
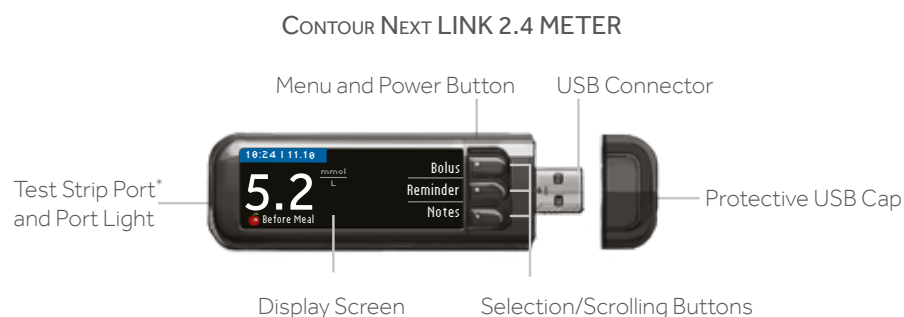
SECTION 5: CONTOUR NEXT LINK 2.4 METER

The CONTOUR NEXT LINK 2.4 meter from Ascensia is the only blood glucose meter able to communicate wirelessly with your MiniMed 640G insulin pump.
With the CONTOUR NEXT LINK 2.4 meter, you can:

- ■ Wirelessly send glucose readings to your pump
- ■ Deliver a bolus remotely
- ■ Upload your pump data to CareLink Personal software

Review the parts of your meter here:

CONTOUR NEXT LINK 2.4 METER

Menu and Power Button   USB Connector

Test Strip Port* and Port Light

Protective USB Cap

Display Screen   Selection/Scrolling Buttons

CHARGING YOUR METER

Your meter has a permanent rechargeable battery. **It is important that the meter be charged prior to your in-person training.** To charge your meter:

1. Plug the USB connector into a computer.** **The computer must be ON and not in sleep, hibernate or power save mode.**
2. The meter will briefly display **Do Not Test-charging** and the test strip port light will flash. You cannot do a blood glucose test while the battery is charging.
3. When charging is complete, the test strip port light will turn off. You can then unplug your meter.

* The CONTOUR NEXT Link 2.4 meter only works with CONTOUR™ NEXT glucose testing strips.
** If you would prefer not to charge your meter using your computer, you can purchase a compatible outlet charger by calling Ascensia Customer Service.

CONNECTING YOUR PUMP AND METER

You will connect your pump and meter at your in-person training. For more information on using your meter, see the User Guide found in the meter box.
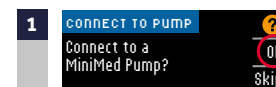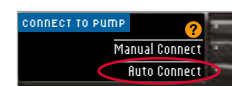
1   Press **OK** when asked **Connect to a MiniMed Pump?**

2   Press **OK**.

3   Press **Auto Connect**.
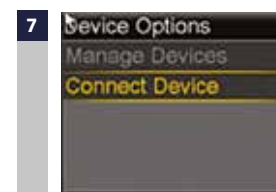
4   Press ▣ on your pump.

Put the meter down and pick up your pump.

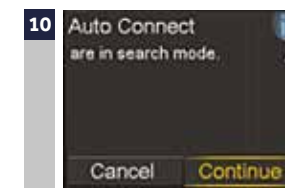**5**   Select **Utilities**.

6   Select **Device Options**.

7   Select **Connect Device**.

8   Select **Auto Connect**.
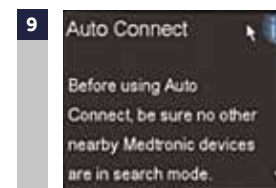
9   Press ⌄.

10   Select **Continue**.

Place the meter and pump next to each other.

11

New Device

See User Guide to connect new device. Select Search below when ready.

Search

Select **Search** on your pump.

12

CONNECT TO PUMP

Select "Search" on Your Pump and meter.
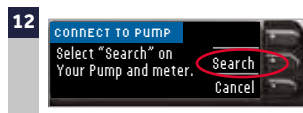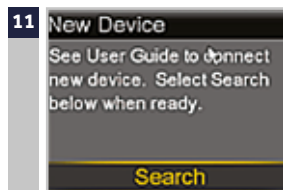
Search
Cancel

Select **Search** on your meter.
The search may take up to 2 minutes.

13 Check to see that the Device SN (serial number) on the pump screen matches the Device SN on the meter.

14

Confirm Device SN

New Device
SN: BGJ133333F

CONNECT TO PUMP
Use Pump to confirm Device SN:
BGJ133333F

Cancel   Confirm
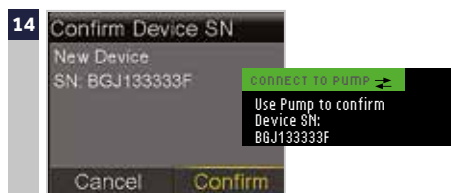
If they match, select **Confirm** on the pump.

15 Check to see that the SN on the back of the pump matches the SN now on the meter screen.

16

PUMP CONNECTED
MiniMed Pump connected:
AA1234567B

Next
Delete

Select **Next** on the meter.

UPLOADING YOUR PUMP TO CARELINK PERSONAL SOFTWARE

CareLink Personal software is a web-based program that is provided free of charge. This software allows you to upload the data from your pump and glucose meter and review it on easy-to-read reports. This enables you to **conveniently track your glucose control** and **remotely share** this information with your healthcare professional.

To upload information from your pump to CareLink Personal software, you will use the CONTOUR NEXT LINK 2.4 meter as the communication device from the pump to your computer, through the USB connector of the meter.
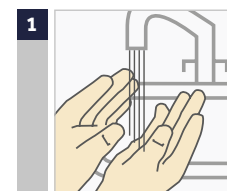
To set up your CareLink Personal software account, go to

www.medtronicdiabetes.com/carelink

SECTION 6: INFUSION SET AND RESERVOIR

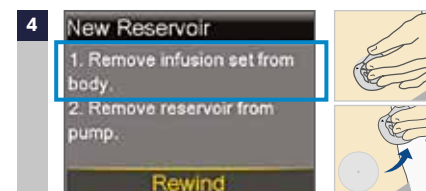The following is a step-by-step guide to changing the Mio™ Infusion set.
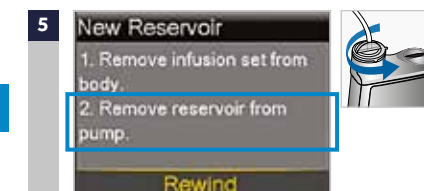
START HERE:

1

Wash your hands.
Press 🔳.

2

Menu
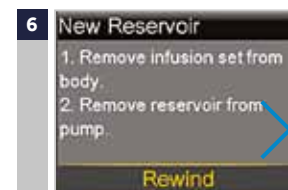Suspend Delivery
Audio Options
History
Reservoir & Tubing
Insulin Settings

Select **Reservoir & Tubing.**

3

Reservoir & Tubing
New Reservoir
Fill Cannula

Select **New Reservoir.**

4

New Reservoir
1. Remove infusion set from body.
2. Remove reservoir from pump.

Rewind

Remove the infusion set you have been using by loosening the adhesive and pulling away from body.

5

New Reservoir
1. Remove infusion set from body.
2. Remove reservoir from pump.

Rewind

Remove the used reservoir from the pump.

6

New Reservoir
1. Remove infusion set from body.
2. Remove reservoir from pump.

Rewind

New Reservoir
1. Fill reservoir.
2. Connect tubing to reservoir.
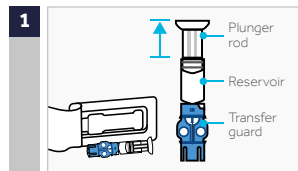DO NOT CONNECT TO BODY.
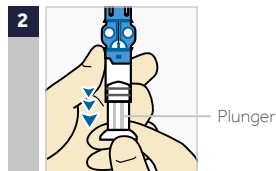
Next

Select **Rewind.**

Continued on next page

FILL RESERVOIR & CONNECT TO THE INFUSION SET TUBING

Follow the next steps to fill reservoir with insulin and connect to the infusion set tubing.

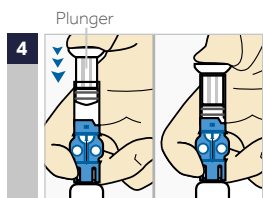**1**

Plunger rod

Reservoir

Transfer guard

Remove from package. Make sure insulin vial is at room temperature to reduce the risk of air bubbles.

2

Plunger

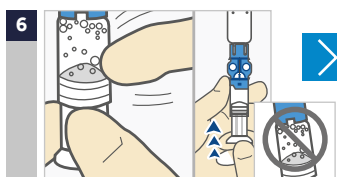Pull plunger down to the amount that you plan to fill with insulin.

3

Transfer guard
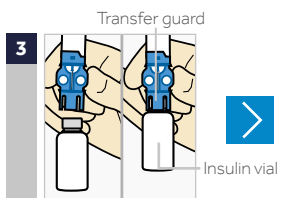
Insulin vial

Wipe vial with alcohol. Place vial on table. Firmly press the blue transfer guard onto vial.

4

Plunger

Push and hold plunger down.

5

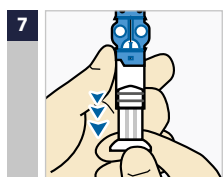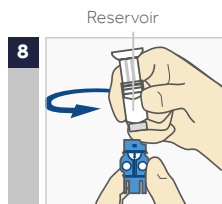Insulin vial   Plunger
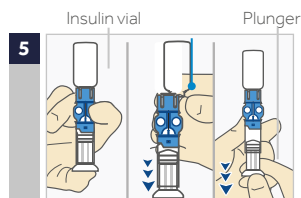
With your thumb still on the plunger, flip over so vial is on top. Release thumb and pull plunger down to fill with insulin.

6

Tap the reservoir to move air bubbles to top of reservoir. Push plunger up to move air into vial.

7

If needed, pull plunger back down to amount of insulin needed for 2-3 days.

8

Reservoir

To avoid getting insulin on top of the reservoir, turn vial over so it is upright. Hold transfer guard and turn reservoir counter-clockwise and remove from transfer guard.

IMPORTANT: Do not use the reservoir or infusion set if any liquid gets on the top of the reservoir or inside the tubing connector. Liquid can temporarily block the vents and may result in the delivery of too little or too much insulin, which can cause hypoglycaemia or hyperglycaemia.
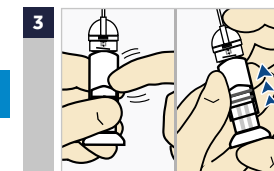
CONNECT RESERVOIR TO INFUSION SET

You will place the reservoir connector onto the end of the infusion set to the filled reservoir.

1

Remove the infusion set from packaging by pulling down the red plastic tab. With one hand press the three raised markings on the sides of the lid. Free tubing from slot. Gently unwind tubing in counter clockwise direction.

2
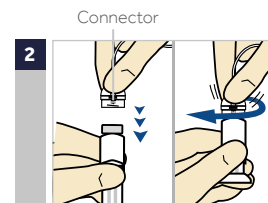
Connector

Gently push connector onto reservoir. Turn clock-wise until locked. You will hear a click.

IMPORTANT: Do not touch the top of the reservoir before connecting it to the infusion set. Please make sure that the connector and the top of the reservoir are dry.

3

If you see air bubbles, tap reservoir to move them to top. Push plunger just a bit to move them into tubing.

4

Twist plunger counter-clockwise to loosen and remove.

THE BACKLIGHT MAY HAVE TURNED OFF

Press any button to turn the screen back on

Select Load Reservoir and unlock the pump if necessary.

New Reservoir
1. Fill reservoir.
2. Connect tubing to reservoir.
DO NOT CONNECT TO BODY.
Next
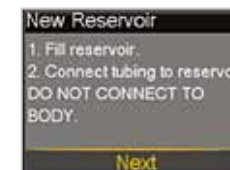
Select Next.

PLACE RESERVOIR INTO PUMP

Now place the filled reservoir into the reservoir compartment of the pump.

1
New Reservoir
3. Place reservoir into pump and lock.
DO NOT CONNECT TO BODY.
Next

2
Place reservoir into pump.
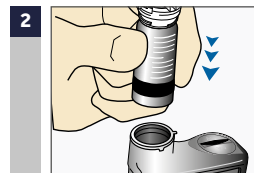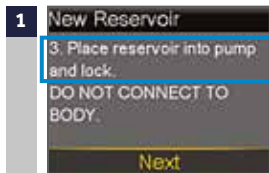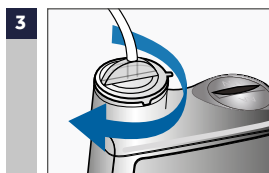
3
Turn clockwise, until you feel reservoir lock into place.

4
New Reservoir
3. Place reservoir into pump and lock.
DO NOT CONNECT TO BODY.
Next

Select **Next**.

LOAD RESERVOIR AND FILL TUBING

Follow these steps to load the reservoir and fill the tubing.

1
Load Reservoir
Select Load and hold until complete
DO NOT CONNECT TO BODY.
Load   Next

Select **Load** and keep holding ⊙.

2
Load Reservoir
Complete
DO NOT CONNECT TO BODY.
Load   Next

When you see this screen, select **Next**.

3
Fill Tubing
DO NOT CONNECT TO BODY
Hold Fill until drops appear. Then select Next.
0.0 u
Fill   Next
Drops at end of tubing

Select **Fill** and keep holding ⊙ until you see drops at the end of tubing, then let go.

4
Fill Tubing
DO NOT CONNECT TO BODY.
Hold Fill until drops appear. Then select Next.
11.3 u
Fill   Next
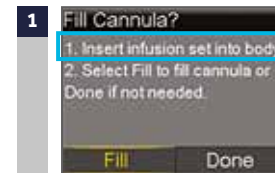
After you see drops, press ⟩ and select **Next**.

INSERTING THE INFUSION SET

Next, follow the steps to insert the infusion set into your body.

1
Fill Cannula?
1. Insert infusion set into body.
2. Select Fill to fill cannula or Done if not needed.
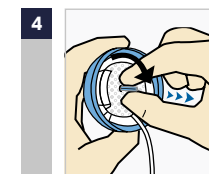Fill   Done

Gently peel paper to expose adhesive.
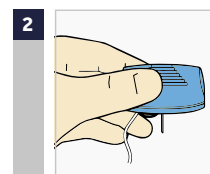
2
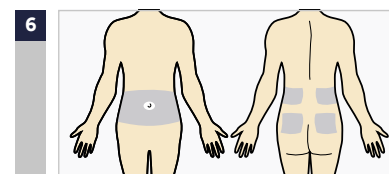Turn over and hold by the lined ridges on the sides.
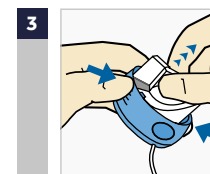
3
With other hand pull up on centre of serter until it clicks and locks into place.

4
Carefully hold needle guard by tip. To remove it, gently turn needle guard & pull away to expose needle.
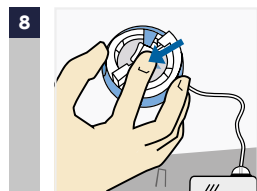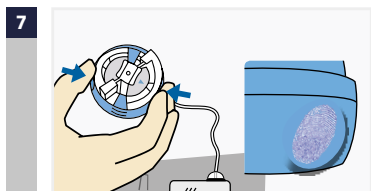
5
Place tubing in slot on side of serter.

6
Choose an insertion site from the shaded areas shown here.

7

Place against prepared site on body. Press the round indentations on each side of serter to insert needle.

8

Push down on centre of serter to press adhesive against skin.

9

To remove serter, hold the centre handle and gently pull it straight out away from body. Press adhesive securely against skin.
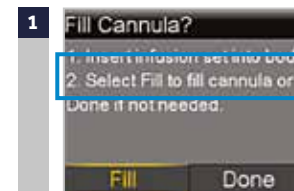
10

Place lid back onto serter to safely discard needle.

NOTE: Alternative infusion sets offered are Quick-set™, Silhouette™ and Sure-T™. Most of the steps described in this section will be different for each infusion set. Please refer to the instructions for insertion included in the infusion set box.

FILL CANNULA

You will now fill the cannula, the little tube under your skin, with insulin.

1

Fill Cannula?
1. Insert infusion set into body.
2. Select Fill to fill cannula or Done if not needed.
Fill   Done

Select **Fill**.

2

Fill Cannula
1. Verify Fill amount.
2. Select Fill Now when ready. Select Back to cancel.
Fill amount   ---- u
Fill Now

Select **Fill amount** and enter:
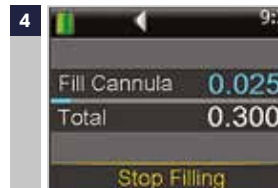- 0.300 if using 6mm cannula
- 0.500 if using 9mm cannula
Then press ◎ .

NOTE: Your pump will remember the **Fill amount** that you used last. Always verify that the Fill amount is correct.
▪ If it is correct, press ⌄ to **Fill Now** and press ◎ .
▪ If it is incorrect, press ◎ . Change to correct amount and. Press ◎ . ◎ **Fill Now**.

3

Fill Cannula
1. Verify Fill amount.
2. Select Fill Now when ready. Select Back to cancel.
Fill amount   0.300 u
Fill Now

Select **Fill Now**.

4

9:2
Fill Cannula   0.025
Total   0.300 u
Stop Filling

The Home screen displays the insulin as it fills the cannula.

NOTE: Select ◎ **Stop Filling** if you need to stop, for example, if you notice the **Total** amount is incorrect. This should rarely happen if you have verified the **Fill amount** on the previous screen.

YOUR INFUSION SET CHANGE IS NOW COMPLETE!

SECTION 7: ALERTS AND ALARMS

ALERTS

An alert makes you aware of a situation that may need your attention. When an alert occurs, you should check to see what your pump is telling you. Examples of alerts include **Low reservoir** or **Low battery**.

ALARM

When an alarm occurs, something has been detected that is preventing insulin from being delivered. You are not getting insulin. **It is important that you address an alarm right away**. Examples of alarms are **Insulin flow blocked** and **Replace battery now**.

WHEN AN ALERT OR ALARM OCCURS:

	ALERT	ALARM
Notification Light	The red light on the pump will blink once followed by a pause. This sequence continues until the alert is cleared. The flashing pattern is shown here: ● ● ● ● ●	The red light on the pump will blink twice followed by a pause. This sequence continues until the alarm is cleared. The flashing pattern is shown here: ●● ●● ●● ●● ●●
Audio	Depending on your Audio Option settings, the pump emits a repeated alert tone, a continuous three-pulse vibration, or both.	
Display	The pump will display a notification with a yellow icon and instructions on what to do.	The pump will display a notification with a red icon and instructions on what to do.

Notification light ———
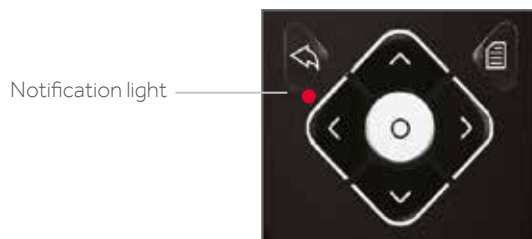
TO ADDRESS AND CLEAR THE ALERT OR ALARM:

1. Read the text on the screen to understand the alert or alarm and the steps that should be taken
2. Press ⌄.
3. Press ◯ on the desired option.

Example of alarm:

Press ⌄

- Alert: the audio/vibration pattern repeats every 5 minutes or every 15 minutes (depending on the alert) until the alert is cleared.
- Alarm: the audio/vibration pattern repeats every minute for 10 minutes if the alarm is not cleared. **After 10 minutes, the alarm begins to siren**.

IMPORTANT: It is important that you are able to address an **Insulin flow blocked** alarm. This alarm means that insulin is not able to get through the tubing or cannula. If this alarm occurs, check your blood glucose and check to see if your infusion set has become dislodged or if your tubing is kinked.
- If you don't detect an issue and are unable to change your reservoir and infusion set right away, you might choose to select **Resume Basal**. If an Insulin flow blocked alarm occurs again, follow the steps on the screen. Select **Rewind** and change your reservoir and infusion set.
- If you detect an issue or if your reservoir has run out of insulin, follow the steps on the screen. Select **Rewind** to change your reservoir and infusion set.

You can call the Product helpline if you have questions about your pump, alerts or alarms.

SECTION 8: SUSPEND DELIVERY

Remember your pump is delivering basal insulin throughout every hour of the day. Although you should never stop this insulin delivery for more than an hour or so, there will be times when you will want to manually suspend, or stop delivery, and disconnect from your pump.

This is done using the **Suspend Delivery** feature. Using Suspend Delivery stops all insulin delivery.

The most common reasons to manually suspend delivery might include bathing and water activities. Infusion sets are designed so you can easily disconnect from your pump and leave it in a safe place.

When the pump is manually suspended, all insulin delivery stops. All insulin delivery will remain stopped until you resume delivery.

When the delivery is resumed, basal insulin will begin to deliver again. **The pump will not deliver any of the basal insulin you missed while the pump was suspended.**

If you manually suspend delivery while a bolus is delivering, the bolus delivery will stop. **When you resume delivery, the remainder of the bolus will not be delivered.**

To place the pump in Manual Suspend: from the Menu, select **Suspend Delivery** > Press ⟩ and select **Yes.**

Notice that the Home screen has changed.

To resume Basal Insulin Delivery, select **Resume** from the Home screen.

SECTION 9: INTRODUCTION TO CONTINUOUS GLUCOSE MONITORING

Continuous glucose monitoring (CGM) gives you a more complete picture of your glucose control:

- Using a sensor allows you to receive up to 288 sensor glucose readings every 24 hours, filling the gaps between your BG tests.
- **Graphs** and **trend arrows** show the speed and direction your glucose levels are moving.
- CGM alerts notify you of high and low glucose values.

MiniMed 640G insulin pump also includes **SmartGuard** technology, Medtronic's exclusive closed loop technology.

SmartGuard technology mimics some functions of a healthy pancreas, to provide you with advanced protection from hypoglyceamia[1]. SmartGuard technology can:

- **PREDICT** when you are approaching low glucose levels 30 minutes in advance
- Automatically **STOP** insulin delivery before you go hypoglycemic
- And automatically **RESUME** it when your glucose levels recover*.

| YOUR CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM INCLUDES 3 KEY ITEMS:	
1 GLUCOSE SENSOR	The Enlite™ sensor measures glucose levels in the body.
2 TRANSMITTER**	The Guardian™ 2 Link transmitter connects to the glucose sensor and sends glucose readings to your insulin pump.
3 INSULIN PUMP	The MiniMed 640G insulin pump displays glucose readings.

Other items include: Enlite serter, Enlite overtape, Guardian 2 Link charger and watertight tester.

Always use the components that were sent with your MiniMed 640G system.

SECTION10: SENSOR GLUCOSE (SG) AND BLOOD GLUCOSE (BG)

Your **BG meter** measures glucose levels in your **blood**. The **glucose sensor** measures glucose in the fluid surrounding the cells of your tissue called **interstitial fluid**.

Transmitter
Skin
Glucose Sensor
Interstitial Fluid
Cell
Glucose
Blood Vessel
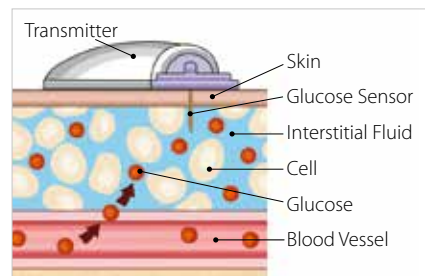
Glucose travels between these two areas (blood and interstitial fluid). Most of the time, it travels to your blood first, and then to your interstitial fluid. Because of how glucose moves, **your BG meter readings (BG) and sensor glucose readings (SG) will be close, but will rarely match exactly**. This difference is normal and should be expected.

When glucose levels are rising or falling quickly, you should expect to see an even larger difference between your BG meter readings and the sensor glucose readings.

Examples of times when this larger difference may occur include:

- After meals or taking a bolus of insulin
- During exercise
- When arrows appear on your pump screen as explained in the next section

> **IMPORTANT:** Sensor glucose is not the same as blood glucose. Your SG and BG readings will be close to one another, but will rarely match exactly.
> Sensor glucose values should not be used to make diabetes treatment decisions.
> **Always confirm your glucose value with a BG meter first.**

SECTION 11: TRENDS

Sensor glucose trends give insight into the direction and the speed that your glucose is changing. The sensor graph and trend arrows are used to show your trend information.

> **IMPORTANT:** When using CGM, focus less on each individual glucose number and more on the direction and speed that your glucose is changing.

Example of Sensor information on the Home Screen

Trend Arrows
Sensor Glucose Reading
Sensor Glucose Graph

By looking at the sensor information above, you can see that your current glucose reading is 5.6 mmol/L. When you look at the graph, you can see that you are trending downward.

Furthermore, you see arrows above the number. These arrows indicate the rate that your glucose values are moving up or down:

↑ or ↓ - SG has been rising or falling by about 1-2 mmol/L over the last 20 minutes

↑↑ or ↓↓ - SG has been rising or falling by about 2-3 mmol/L over the last 20 minutes

↑↑↑ or ↓↓↓ - SG has been rising or falling by about 3 mmol/L over the last 20 minutes

> **NOTE:** You may be likely to notice your glucose trending up or down after eating, giving a bolus, or when exercising.

SECTION 12: PERSONALISED ALERTS

Your CGM alert and suspend settings are most beneficial if they are personalised for your needs. Your healthcare professional will work with you to determine your initial settings and help with adjustments that need to be made, as you learn more from the information that CGM provides.

The graph below shows an example of the different settings that can be personalised for both High and Low sensor glucose readings.

Personalised Alerts
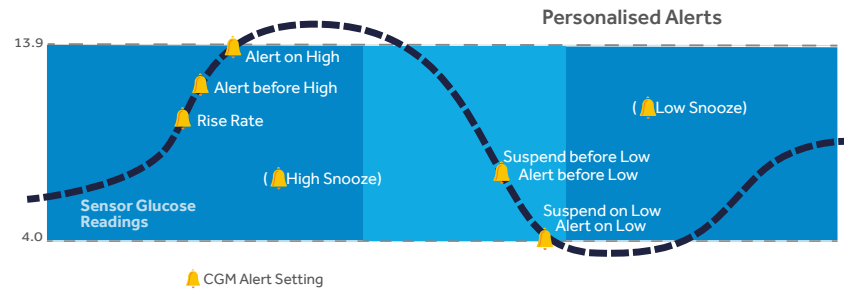
TURNING SENSOR FEATURE ON

Before setting any of these **sensor** alerts, you must first turn the **sensor** feature on. To turn the sensor feature on, go to the Menu > **Sensor Settings** and select **Sensor**.
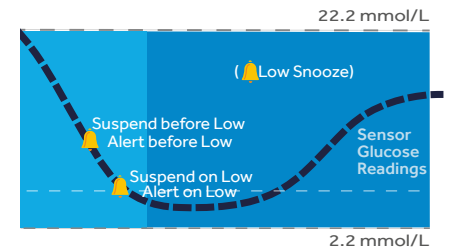

LOW SETTINGS

The Low Settings include alerts, as well as the **SmartGuard™** technology features. You can choose to be alerted if your sensor glucose:
- is approaching your low limit **(Alert before low)**
- has reached your low limit **(Alert on low)**

The SmartGuard technology features can automatically suspend insulin if your sensor glucose:
- is approaching your low limit **(Suspend before low)**
- has reached your low limit **(Suspend on low)**

This will keep you from getting additional insulin that would continue to lower your sensor glucose level.

Your low (**Lo**) limit can be set from 2.8 to 5.0 mmol/L. This is the value on which the other low settings described below are based. You can set up to eight low limits for different periods of the day or night.

Alert	Reason	Steps to take
Alert before low Alert before low	If S**uspend before low is on**, you will be alerted when insulin is suspended. If **Suspend before low is off**, you will be alerted when the sensor predicts you will reach your low limit in 30 minutes.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat if necessary based on instructions from your healthcare professional and continue to monitor.
Alert on low	Sensor glucose value is equal to or lower than your low limit.	

> **NOTE:** If either Suspend on low or Suspend before low is turned on, Alert on low will automatically be set to on so you know that your glucose is at or below your low limit.

SmartGuard Suspend features	Impact on insulin delivery if suspend feature is turned on	Information displayed by the pump	
Suspend before low	Insulin delivery is temporarily stopped if sensor glucose value **is approaching your low limit.**	You will receive this alert message and need to check your BG. Insulin delivery will remain suspended after the alert is cleared. If the alert is not cleared in 10 minutes, the pump will begin to siren.	After the alert or alarm message is cleared and insulin delivery has stopped, the Home screen will display: ■ **Suspended before low** or **Suspended on low** at the bottom of the screen ■ a shaded area to represent the time when insulin has been suspended ■ a flashing SmartGuard technology icon.
Suspend on low	Insulin delivery is temporarily stopped if sensor glucose value **has reached or fallen below your low limit.**	You will receive this alarm message and need to check your BG. Insulin will remain suspended after the alarm is cleared. If the alarm is not cleared after 10 minutes, the pump will begin to siren and an emergency message will appear on the pump screen.	

> **NOTES:**
> ■ Only one suspend feature can be used during each time segment; you cannot turn both Suspend before low and Suspend on low on.
> ■ Insulin delivery will not be suspended if you are more than 3.9 mmol/L above your low limit.

RESUMING BASAL INSULIN

Automatic Basal Resume

In addition to suspending insulin delivery, the pump can also automatically resume delivery of basal insulin. If insulin has been suspended by either Suspend before low or Suspend on low, insulin delivery will automatically be resumed:

■ if SG values are above the low limit and are trending upward. If you have the **Resume basal alert** on, you will be alerted when this occurs.

■ after a maximum suspend time of 2 hours. You will always be alerted (even if the Resume basal alert is off) when this occurs. It is important that you check your BG and ensure your glucose is at a safe level.

Manual Basal Resume
You can choose to resume basal insulin delivery yourself at any time. You simply need to select Suspended before/on low on the Home screen and follow the instructions on the screen.
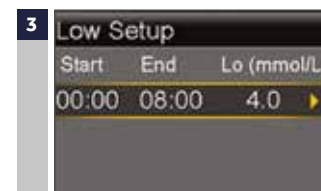
SETTING UP YOUR LOW SETTINGS:

In this example, we will set up multiple time segments with different alert and suspend settings.

1
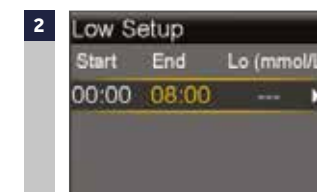
From the Menu, go to **Sensor Settings** > **Low Settings** and select **Low Settings** to turn On.

2

Press ⊙ on the time segment.

3

Press ⌃ or ⌄ to set **Lo** limit and press ⊙.

4

Press ⊙ to continue onto the next screen.

5

Select each feature you wish to turn on. *In this example, Suspend before low has been turned on. Notice that Alert on low is automatically turned on.*

6 Once settings are selected, select **Next**.

7

Press ⊙ on the time segment. Repeat steps 3 to 7 to enter the next time segment and select the features you want to turn on for this segment. *In this example, Alert before low, Suspend on low, and Resume basal alert have been turned on.*

8

Select **Done**.

9
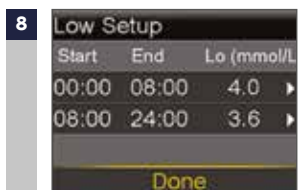
Verify that settings are correct and select **Save**.

10

If snooze time needs to be changed, press ⌄ to Snooze and press ⊙ . *The low snooze time can be set from 5 minutes to 1 hour.*

11 Press ⌃ or ⌄ to the correct time and press ⊙ .
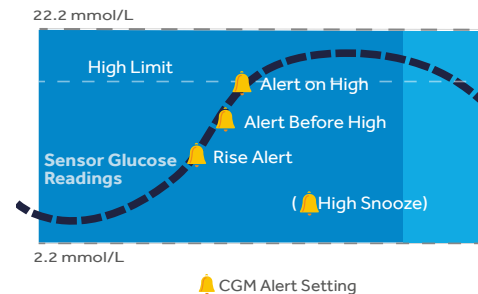
YOUR LOW SETTINGS SETUP IS NOW COMPLETE.

REMEMBER: Sensor glucose values must be confirmed with a BG meter reading before diabetes treatment decisions can be made.

HIGH SETTINGS

The High Settings allow you to be alerted if your sensor glucose:

- is rising rapidly **(Rise Alert)**
- is approaching your high limit **(Alert before high)**
- has reached your high limit **(Alert on high)**

22.2 mmol/L

High Limit

Alert on High

Alert Before High

Sensor Glucose Readings

Rise Alert

(🔔 High Snooze)

2.2 mmol/L

🔔 CGM Alert Setting

Your high (**Hi**) limit can be set from 5.6 to 22.2 mmol/L. This is the value on which other high settings described below are based.

> **REMEMBER:** Your high limit is not the same as your glucose target. Your healthcare professional will help you determine the best setting so that you are alerted when needed while preventing unnecessary or inconvenient alerts.

Alert	Reason	Steps to take
Alert before high	Sensor glucose reading is expected to reach the high glucose limit in the length of time that you set for the Time before high*.	
Alert on high	Sensor glucose value is equal to or higher to the high limit you set.	
Rise Alert	Sensor glucose reading is increasing at a rate that is equal to or faster than the Rate Limit that you set. The Rise Alert can be set to alert if glucose is rising as follows: ↑ - SG is rising at a rate of 0.056 mmol/L per minute or more ↑↑ - SG is rising at a rate of 0.111 mmol/L per minute or more ↑↑↑ - SG is rising at a rate of 0.167 mmol/L per minute or more **Custom** - SG is rising at the rate that you set. This can be set from 0.050 to 0.275 mmol/L per minute	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat if necessary based on instructions from your healthcare professional and continue to monitor.

*Time before high determines how many minutes before reaching the high limit that you will receive an Alert before high. This can be set from 5 to 30 minutes.

> **REMEMBER:** You can set up to 8 different time segments throughout the day and night. Each time segment can have different high limits and high alerts that work best for you during that time of day or night.

SETTING UP YOUR HIGH SETTINGS:

1
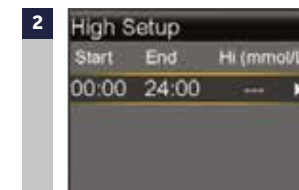
From the Menu, go to **Sensor Settings > High Settings** and select **High Settings** to turn **On**.

If you are changing settings that are already entered, press ⌄ to **Setup** and press ◎.

2

Press ◎ on the time segment. If you are setting multiple time segments with different high limits and alerts, press ⌃ to set the first **End** time and press ◎. *In this example, only one time segment is set.*

3

Press ⌃ or ⌄ to set **Hi** limit and press ◎. *In this example, the limit is set to 13.8 mmol/L.*

4

Press ◎ to continue onto the next screen and select each alert you wish to turn on.

5

Once settings are selected, select **Next**. *In this example, the Alert on high has been turned on.*

6

Select **Done**.

7

Verify that settings are correct and select **Save**.

8

If snooze time needs to be changed, press ⌄ to **Snooze** and press ⃝. *The high snooze time can be set from 5 min to 3 hours.*

9 Press ⌃ or ⌄ to the correct time and press ⃝.

YOUR HIGH SETTINGS SETUP IS NOW COMPLETE.

CHANGING HIGH AND LOW SETTINGS

To make changes to your existing High or Low settings, go to **Sensor Settings > High Settings** or **Low Settings > Setup** and select **Edit**.

ALERT SILENCE

If a sensor alert occurs when Alert Silence is on, a Sensor alert occurred message is displayed and the notification light flashes, but there is no beep or vibration during the set period of time.

To set Alert Silence: from the Menu, go to **Sensor Settings > Alert Silence**.

You can select which alerts you would like to silence and set the time you want these alerts to be silent for.

Alerts will automatically return to audio and/or vibrate at the end of the duration that you set.

NOTE: If an alert is received during Alert Silence, go to the Menu > **History** and select **Alarm History** to see the alerts that occurred.

SECTION 13: READING THE SENSOR DISPLAY

Once the sensor has started giving you sensor glucose readings, the Home screen will display them similar to what you see here.

High Alert Limit

3-hour Sensor Glucose Graph

Low Alert Limit

Additional Sensor Icons

Trend Arrows

Most recent Sensor Glucose (SG) Reading

SmartGuard technology Icon

Bolus Marker

The Sensor Glucose reading is updated every 5 minutes.

STATUS BAR

In addition to the pump icons, you will see additional sensor icons on the Status Bar when using CGM.

Connection icon: shows radio frequency (RF) communication between the pump and sensor.

Calibration icon: represents the time left until next calibration is due. The icon empties as time decreases. Down arrow means calibration is needed.

Sensor Life icon: represents the number of days before sensor needs to be changed.

Additional icons: appear when the sensor is in warm up, pump and transmitter are out of range, system cannot be calibrated, or calibration or sensor age are unknown.

SMARTGUARD TECHNOLOGY ICON

During any time segment when either Suspend before low or Suspend on low is set to on, you will see the Suspend by sensor icon on the Home screen :

Suspend before low or Suspend on low is on and ready. If either suspend becomes active, the icon will flash while insulin delivery is stopped.

Suspend before low or Suspend on low is on but is unavailable. This can be due to a recent suspend or when no SG values are available.

SENSOR STATUS

You can go to the Sensor status menu to see, for example, when your next calibration is due, time left on your sensor, and battery life remaining on your transmitter.

From the Home screen, select the Status Bar and select **Sensor**. You will also see additional sensor status information in **Notifications, Quick Status**, and **Settings Review screens**.

SENSOR GRAPH

A graph that shows the last 3 hours of sensor glucose readings will always display on the Home screen. Your high and low glucose limits entered in your sensor settings will be shown in red.

You can also view 6-hour, 12-hour and 24-hour glucose trend graphs by selecting the sensor graph. Blue squares at the bottom of the graph represent a bolus.

A gold shaded area represents time when insulin was suspended by sensor.
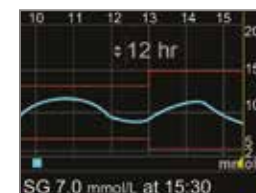
SECTION 14: CONNECTING YOUR PUMP AND TRANSMITTER

Before using the sensor for the first time, you will need to wirelessly connect the pump and transmitter so that they can communicate with each other. This allows the sensor information to be displayed on the pump screen.

TO WIRELESSLY CONNECT YOUR PUMP AND TRANSMITTER:

1

charger
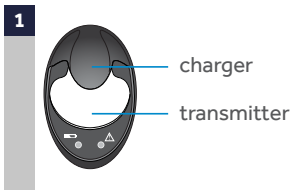
transmitter

Attach your transmitter to the charger and make sure it is fully charged.

2

Press 📖 and select **Utilities** > **Device Options** > **Connect Device**. *Only one transmitter can be connected to the pump at one time. When you need to connect a new transmitter, you must first select Manage Devices, select the transmitter number and select Delete.*

3

Select **Auto Connect** > Press ⌄ > Select **Continue**. *Steps for Manual Connect can be found in the MiniMed 640G system User Guide.*

4

Make sure the transmitter is on the charger before proceeding. Now start the search processes on both devices.

4a
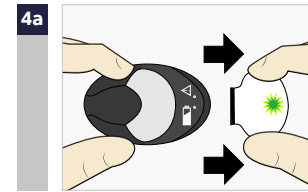
Remove transmitter from charger. *If green light on transmitter does not flash, reconnect to charger until fully charged.*

4b

Immediately select **Search** on the pump. *The search can take up to 2 minutes.*

5

Once device is found, confirm that the serial number (SN) shown on the pump is the serial number on the back of your transmitter and select **Confirm**. *If you receive the **No devices found** message, place the transmitter back onto the charger. Then remove the transmitter from the charger and immediately select **Retry** on the pump.*

6

Connection is now complete. The transmitter serial number will be displayed on the pump screen.
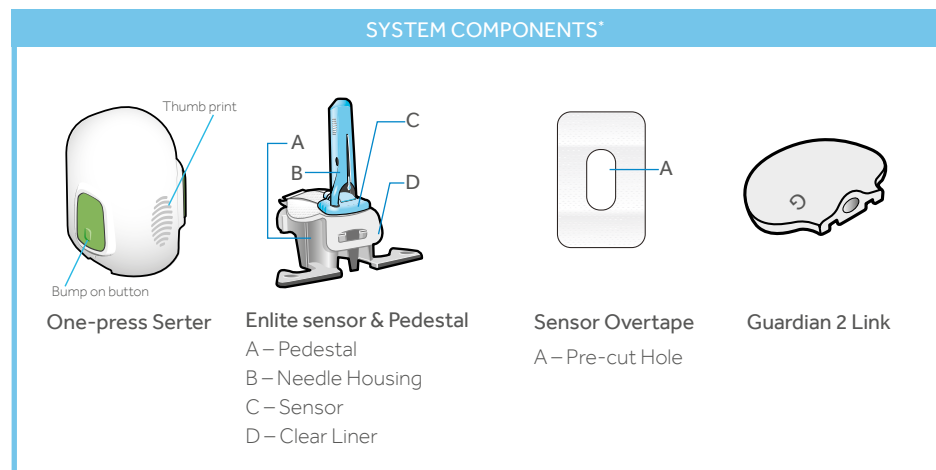
NOTE: These steps only need to be done as a first time set-up. You will not have to repeat with each new sensor you start.

NOTE: If you stop using CGM for a period of time and need to store your transmitter, please make sure to leave it connected to the charger during the storage period. This will help ensure you get the most life out of your transmitter battery.

SECTION 15: INSERTING AND STARTING THE SENSOR***

Before you insert your sensor, gather all of your supplies:

SYSTEM COMPONENTS*

Thumb print

A
B
C
D

Bump on button

One-press Serter

Enlite sensor & Pedestal
A – Pedestal
B – Needle Housing
C – Sensor
D – Clear Liner

Sensor Overtape
A – Pre-cut Hole

Guardian 2 Link

*For more details on the system component, consult the User Guides

One-press serter is required in order to insert the sensor properly

Enlite sensor is individually packaged and comes attached to a plastic pedestal which is necessary for proper loading into the serter

Sensor overtape is required to keep the sensor securely in place

Guardian 2 Link transmitter is connected after the sensor is inserted and covered with the overtape

***Please refer to the One-press serter user Guide and your HCP for more information.

SELECTING YOUR SITE

Your sensor can be inserted in any of the shaded areas shown here**. The sensor insertion site should be at least:

- 5 centimetres from your navel
- 2.5 centimetres from your insulin pump infusion site
- 2.5 centimetres from any manual insulin injection site
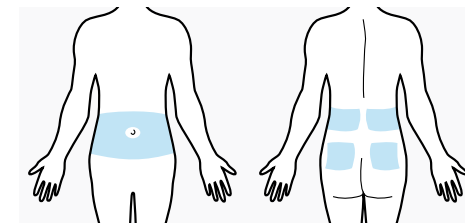
**Clinical trials for glucose sensors were performed on sensors inserted in these areas.

FOR GOOD SENSOR GLUCOSE PERFORMANCE, AVOID SITES:

- Where clothing may rub or constrict (for example, your beltline)
- Where your body naturally bends a great deal which may cause the sensor to pull out
- That are scarred or have hardened tissue or stretch marks
- Where there is a great deal of motion or friction

PREPARING YOUR SITE

- Wash your hands with soap and water.
- Do not use IV prep or the sensor may not work properly.

INSERTING YOUR SENSOR

The instructions below only refer to the One-press Serter. If you have a different serter model, please refer to your serter User Guide for instructions on how to insert the sensor.

1a Hold sensor by plastic pedestal. Remove sensor with attached pedestal by holding pedestal only. Place sensor/ pedestal on a clean, flat surface (such as a table).

1b Tuck adhesive tab. Make sure that sensor's adhesive tab is tucked under sensor connector and snaps.

Correct   Incorrect

2 Load sensor into serter. Grip serter exactly as shown with thumb on thumbprint marking on serter. Do not hold side buttons. Push serter down onto pedestal until base of serter sits flat on table.

Correct   Incorrect

3 Detach serter from pedestal. To detach serter from pedestal, grip serter as shown, with thumb on thumb print on serter. With other hand, place two fingers on pedestal arms, and slowly pull serter straight up. Note: Make sure that pedestal is firmly on table before pulling serter away. Warning: Do not detach pedestal from serter in mid-air as this may damage sensor.

NOTE: The sensor remains inside the serter after removing the pedestal. The arrow on both sides of serter indicate location of the sensor needle.

4a Place serter on body. Hold serter steadily against your cleaned insertion site, without pushing serter too deeply into skin. Note: Failing to hold serter securely flat against body may allow serter to spring back after pressing buttons and result in improper insertion of sensor.

4b Insert sensor. Press and release bump on both buttons at same time.

4c Hold serter against body. Continue holding serter against body to allow adhesive time to stick to skin.

4d Remove serter from body. Slowly pull serter away from skin, making sure buttons are not pressed.

5 Remove needle housing. Gently hold base of sensor against skin with one hand. With other hand, hold needle housing at top and slowly pull it straight, away from sensor. Dispose of needle housing in a sharps container. Warning: Watch for bleeding at the insertion site. If bleeding occurs under, around, or on top of the sensor, apply steady pressure using sterile gauze or a clean cloth placed on top of the sensor for up to three minutes. The use of non-sterile gauze can cause an infection. If bleeding does not stop, remove the sensor and apply steady pressure until the bleeding stops.

6a Remove adhesive pad liner. Hold sensor in place and gently remove liner from under adhesive pad. Do not remove the adhesive liner from the rectangular adhesive tab.

6b Press entire adhesive pad to skin. Firmly press adhesive against skin and smooth entire adhesive pad so it sticks to skin. NOTE: Enlite sensor adhesive is pressure-sensitive. Continue applying pressure to ensure sensor remains inserted in skin for whole 6 days of wear.

7a Untuck adhesive tab. Untuck adhesive tab from under sensor connector.

7b Straighten adhesive tab. Straighten adhesive tab so it lies flat against your skin, but do not remove adhesive liner yet.

TAPING YOUR SENSOR

Before you connect the Guardian 2 Link transmitter to your Enlite sensor it is very important that you properly secure the sensor against your skin using the sensor overtape.
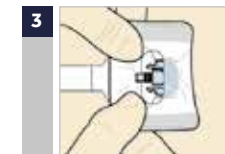
1 Remove large paper backing from overtape. Do not remove two smaller paper tabs on sides of overtape.

2 Attach the overtape to both the rounded part of the sensor and the skin in front of the sensor.
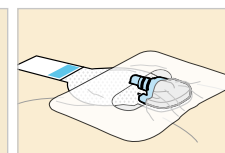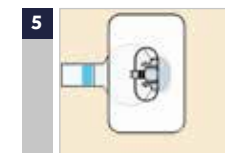
Important: Make sure there is overtape on both the rounded part of the sensor and the skin.

3 Apply rest of overtape, but do not block sensor connector with overtape. Press overtape to your skin for several seconds.

4 Remove two paper tabs from sides of overtape. Press overtape against skin.

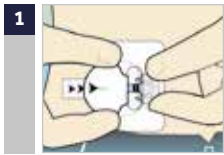**5** These images show overtape applied correctly.

IMPORTANT: All Enlite tapes and adhesives stick best when you apply pressure for several seconds after putting them on your skin. Doing so helps the Enlite sensor stay securely placed and fully inserted.
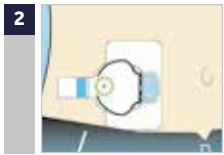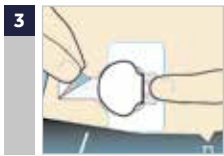
Properly applying the overtape is key to ensuring your success with the Enlite sensor. Due to the sensor's small size and flexible nature, the overtape helps to secure it from body motion or physical activity that can cause it to be pulled out.
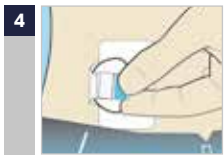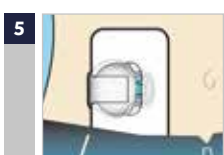
CONNECTING YOUR TRANSMITTER TO YOUR SENSOR

Before connecting the transmitter, make sure the **Sensor** feature is **On**. See page 38 if you need help with these steps.

1 With one hand, hold sensor in place. With other hand, connect transmitter to sensor.

2 You may hear a faint "click" when the two components are connected. Check for green light to flash on transmitter.

3 Remove the paper on adhesive tab.

4 Fold adhesive tab over transmitter. **Be careful not to pull the adhesive tab too tightly or it may cause the transmitter to pull from the sensor connection.**

5 Press adhesive onto transmitter. *Apply additional tape over transmitter as needed.*

> **IMPORTANT:** If you do not see a green light flashing on the transmitter after it is connected to the sensor, then disconnect the transmitter and place it back on the charger to ensure that it is fully charged. Then reconnect the transmitter to the sensor. If for any reason you disconnect the transmitter from the sensor, wait 5 seconds before reconnecting it to the sensor.

> **IMPORTANT:** Applying an additional piece of tape over the transmitter once it is connected to the sensor as shown here helps to ensure the transmitter and sensor stay secure and connected during wear. The Enlite overtape or any other medical tape can be used.
>
> Enlite overtape   Medical tape*
>
> *A piece of Tegaderm™ cut in half is shown in this image.

> **NOTE:** When your transmitter is connected to your sensor they form a water-tight seal to a depth of 2.4 meters for up to 30 minutes. You can shower and swim without removing them.

It is very helpful to remember the order of these three steps when changing your sensor:

1 **Insert** the sensor.
2 **Tape** the sensor in place.
3 **Connect** the transmitter.

STARTING THE SENSOR

Once you have inserted the sensor and connected the transmitter, the pump and transmitter will begin to communicate. Make sure your pump is on the Home screen so that the message below (in step 1) will be displayed when the sensor is ready to be started. *This typically takes less than a minute, but may take up to 10 minutes.*
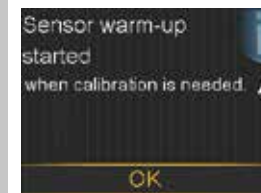
1 Select **Start New Sensor**.
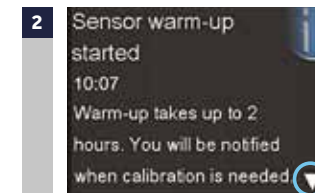
2 The **Sensor warm-up started** message will appear.

3 Press ⌄ and then ⊙ to clear. **Warm up**... will appear on the Home screen until sensor is ready for the first calibration. *If 15 minutes have passed and the Warm up bar does not appear or it looks like it is not progressing, look in the **Quick Status** screen, if you see the time of **Next cal** listed, the sensor is in Warm up.*

> **NOTE:** The next time you connect a transmitter, you will see these screens. Select **Start New Sensor** if you have just inserted a new sensor. Select **Reconnect Sensor** if you have only disconnected and reconnected the transmitter.
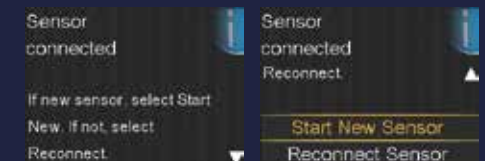
SECTION 16: CALIBRATING

Your continuous glucose monitoring system requires blood glucose meter readings in order to provide you with sensor glucose readings. These BG meter readings are entered into the pump and are for sensor **calibrations.** Calibration is essential for optimal CGM performance. CGM does not eliminate the need for BG meter tests.

To calibrate, you must test your blood glucose on your meter and then enter that value into your pump. The pump will accept BG meter readings between 2.2 mmol/L and 22.2 mmol/L.
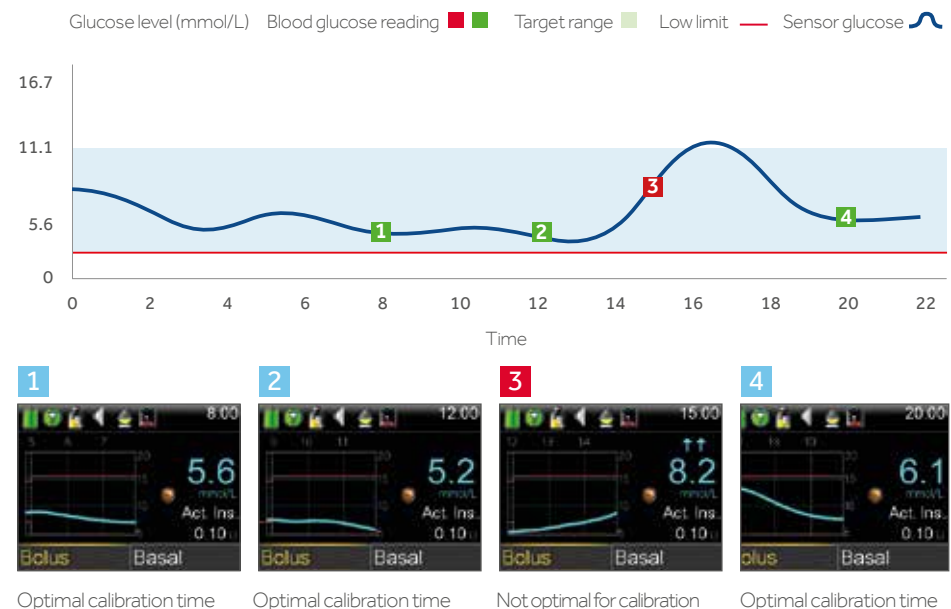
After inserting a new sensor, a calibration is needed:

- Within **2 hours** after you connect the transmitter to your sensor and start the **Warm up** period. Your pump will notify you with a **Calibrate now** alert when it is ready for its first calibration.

- Again within **6 hours** (first day of inserting sensor only)

- Again every **12 hours** (when a calibration is necessary you will receive a **Calibrate now alert**).

> ⚠ **IMPORTANT:** After the first day, the minimum number of calibrations required is one every 12 hours. However, **calibrating 3-4 times a day is optimal** and these can be done when it is convenient for you. To help you remember to calibrate, think "before is best" - typically the best times to calibrate are before meals, before taking insulin, and before bedtime. Also check for arrows - **calibrating when there are 2 or 3 arrows may decrease sensor accuracy** until the next calibration.

EXAMPLE OF OPTIMAL CALIBRATION TIMES

Glucose level (mmol/L) Blood glucose reading ■ ■ Target range ■ Low limit — Sensor glucose

1	2	3	4
Optimal calibration time	Optimal calibration time	Not optimal for calibration	Optimal calibration time

When receiving a **Calibrate now** alert, if you cannot calibrate right away, you can set the **Snooze** to remind you to calibrate in the time that you set.

If you plan to test BG and calibrate right away, simply select **Snooze**.

Once you select Snooze, **Calibration required** will appear on the Home screen until you enter a BG to calibrate.
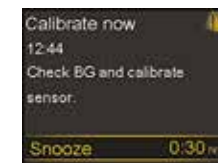
> ☑ **REMEMBER:** Calibrations are necessary in order to continue to receive sensor glucose readings, alerts and alarms.

CALIBRATING THE SENSOR

There are 5 different ways that you can enter a BG reading to calibrate the sensor.

CALIBRATING BY USING THE CONTOUR™ NEXT LINK 2.4 METER

When you use the compatible Ascensia meter, you will see the meter value automatically displayed on the home screen, as shown here.

Select **Calibrate Sensor** or if you plan to give a bolus using Bolus Wizard, select **Bolus**.
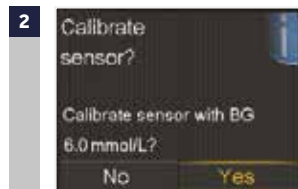
If you have selected **Bolus**, select **Yes** to Calibrate Sensor? after bolus is delivered.

CALIBRATING THROUGH THE BOLUS WIZARD

In the Bolus Wizard:
Select **Deliver Bolus**.

Select **Yes** to calibrate sensor.

CALIBRATING THROUGH HOME SCREEN GRAPH

Select ⌃ to the **sensor graph**, press ◉ and hold.

Press ⌃ or ⌄ to enter BG value, press ◉ and select **Calibrate**.

OTHER WAYS TO CALIBRATE

The 2 other ways to calibrate your sensor are through:

- **Sensor Settings:** from the Menu, go to **Sensor Settings** > **Calibrate Sensor**, select **BG** and press ⌃ or ⌄ to enter BG value > press ◉ and select **Calibrate**.
- **Event Markers:** from the Menu, go to **Event Markers** > **BG** > **Enter BG** > press ◉ > select **Save** > select **Yes** to calibrate sensor.

Once you have entered a calibration BG, the Home screen will show you that the system is calibrating.

You will start seeing sensor glucose readings again in 5-15 minutes.

> **IMPORTANT:** If you notice a large difference between your BG meter reading and sensor glucose readings, wash your hands and do another BG fingerstick test to help ensure a more accurate reading. Check the sensor site to ensure the sensor overtape is still holding the sensor in place. If there is still a large difference in glucose readings, another calibration may be needed to bring the readings closer together again.

You can use the **Calibration Reminder** to give you notice before the next calibration is necessary.

The Calibration Reminder defaults On with a reminder time of 1:00 hour and you can change it by going to the **Reminders** menu option.

SECTION 17: OTHER SENSOR ALERTS

We discussed personalised alerts earlier in Section 12. There are other sensor alerts that you will receive as well. The most common alerts that you can expect to receive when using CGM can be found in the table below.

Alert	Reason	Steps to take
Calibrate now	A calibration is needed in order to receive sensor glucose readings.	Enter BG value into your pump to calibrate.
Lost sensor signal	Communication between pump and transmitter has been lost for 30 minutes during or after warm-up.	Check that the sensor is still inserted in the skin and the transmitter and sensor are still connected. Move your pump closer to your transmitter.
Calibration not accepted	Your system was unable to use the BG meter readings you entered to calibrate your sensor.	After 15 minutes, enter a new BG meter reading for calibration. If you receive a Calibration not accepted alert on your second calibration after 15 minutes, a Change sensor alert occurs.
BG not received	The transmitter was unable to receive the calibration BG reading from the pump.	Move your pump closer to your transmitter and select OK. The pump will try sending the BG again.
Sensor expired	Sensor has reached the end of its useful life.	Remove the sensor and follow the instructions for inserting and starting a new sensor.
Change sensor	You have received two Calibration not accepted alerts in a row.	Remove the sensor and follow the instructions for inserting and starting a new sensor.
Cannot find sensor signal	The pump has not received a signal from the transmitter.	Disconnect and reconnect your transmitter and sensor and select OK.

For a complete list of Alerts and Alarms, refer to the MiniMed 640G system User Guide.

CHARGING AND STORING THE GUARDIAN 2 LINK TRANSMITTER
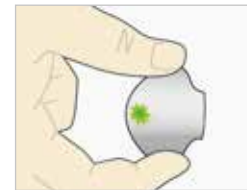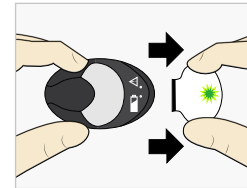
Charge the transmitter before each use. When the transmitter is charging, a green light will flash on the charger. This green light will turn off when the transmitter is completely charged. You will need to charge the transmitter after each sensor use. A fully charged transmitter can be used for a maximum of six days without recharging. It can take up to an hour to fully recharge.

When you remove the transmitter from the charger, a green light should flash on the transmitter. This indicates that it has enough battery power to be connected to the sensor. If you do not see the green flashing light on the transmitter place it back on the charger until it is fully charged.

Store the transmitter, charger, and test plug in a clean, dry location at room temperature. Although not required, you may store the transmitter on the charger. If the transmitter is not in use, you must charge it at least once every 60 days.

If you connect transmitter to charger and you see no lights on the charger: replace the battery in the charger.

While charging your transmitter you see a flashing red light on the charger: replace the battery in the charger.

While charging your transmitter you see a mix of short and long flashing red lights on the charger: replace the battery in the charger and fully charge the transmitter.

Refer to your Guardian 2 Link transmitter and charger User Guides for more information.

CARELINK PERSONAL SOFTWARE

WHAT IS CARELINK SOFTWARE?

CareLink Personal software is a web-based software that allows you to upload information from your MiniMed™ 640G system to a secure online (internet) site for viewing.

CareLink software organises all of your insulin pump, sensor glucose and blood glucose meter information into reports (charts, tables and graphs) that can help you track glucose levels, insulin usage and carbohydrate intake over time.

With CareLink software, you can grant your healthcare provider online access, so that your information can be discussed at your next appointment.

BENEFITS OF CARELINK SOFTWARE

CareLink Personal software makes it easier to track your glucose levels and see how they are affected by your insulin delivery, meals and exercise routines. CareLink Personal software provides a secure place to store your information and uncover patterns in your glucose control that meter and logbooks alone cannot reveal.

Information from CareLink software can help you and your healthcare provider make more informed therapy decisions aimed at improving your glucose control.

> CareLink reports can help you and your healthcare provider make decisions that improve your control and fit your lifestyle.
> The combination of insulin pump therapy, continuous glucose monitoring and CareLink software provides you with the tools and information you may need to optimise your therapy.

For more information on how to upload information to CareLink Personal software using the Contour™ Next LINK 2.4 glucose meter from Ascensia, see page 24.

X-RAYS, MRI, OR CT SCAN

If you are going to have an X-ray, MRI, CT scan, or other type of diagnostic imaging involving radiation exposure, remove your insulin pump, transmitter, and glucose sensor and place them outside of the testing area.

TRAVELING BY AIR

If you wear a CGM device, you may need to stop the wireless communication between the transmitter and the pump during the flight.

To temporarily stop wireless communication, turn Airplane Mode on. From the Menu, go to **Utilities > Airplane Mode**, select Airplane Mode to turn **On** and **Save**.

The transmitter continues to measure glucose levels when in Airplane Mode.

To resume wireless communication, turn Airplane Mode off:

When Airplane Mode is turned off and communication resumes, the transmitter will send up to 10 hours of sensor data to your pump.

If Airplane Mode was on for <6 hours:
1) Wait 15 minutes for sensor data to appear on pump screen

If Airplane Mode was on for >6 hours:

1) Disconnect transmitter from sensor and then reconnect it.

2) Select **Reconnect Sensor** when it appears on the pump screen to begin sensor warm-up.

3) The sensor data (up to 10 hours) will appear on the pump.

4) You will be asked to calibrate in 2 hours to resume sensor readings.

Always remember that it is important when traveling to be extra attentive to monitoring your glucose and prepared to respond if needed.

The images below show additional detail about using the SmartGuard technology features of your MiniMed 640G system.

Sensor glucose trend
Estimated sensor glucose trend
Sensor glucose trend during suspend
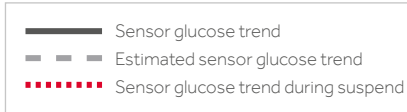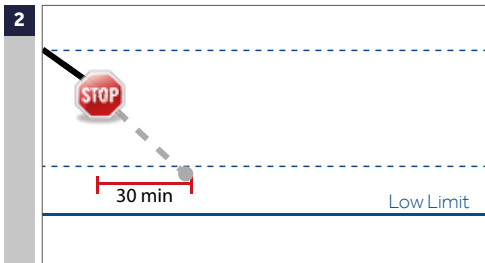
Suspend on low event:
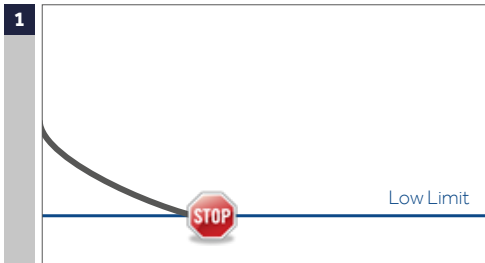
If sensor glucose (SG) reaches your low limit, insulin delivery will be stopped.

You will always receive a message and alarm when this occurs.

You will have 10 minutes to respond before the pump begins to siren and emergency message appears.
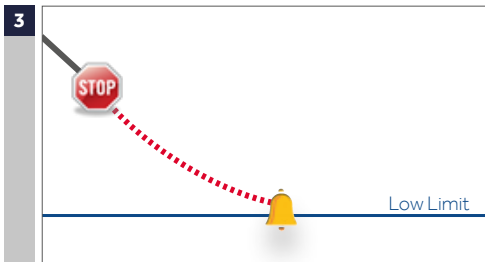
Suspend before low event:

To help keep sensor glucose (SG) from reaching your low limit, insulin delivery will be stopped if SG is:

- at or within 3.9 mmol/L above the low limit

- predicted to be approaching the low limit in 30 minutes

If **Alert before** low is on, you will receive an alert when insulin is suspended.
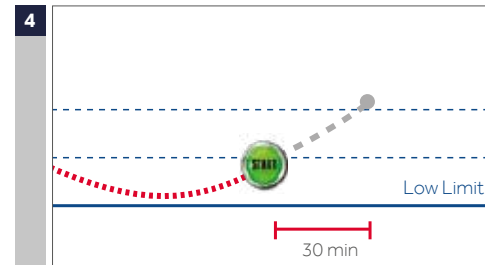
Alert on low during Suspend before low:

If insulin delivery has stopped due to **Suspend before low**, SG may still reach your low limit.

You will always be alerted when this occurs.

You will have 10 minutes to respond before the pump begins to siren.

Automatic basal resume based on sensor glucose (SG) value:
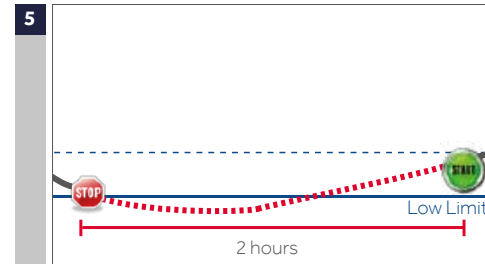

During **Suspend before low** or **Suspend on low**, basal insulin will automatically resume if:

- SG is above the low limit and trending upward

- insulin has been suspended by sensor for at least 30 minutes

If **Resume basal alert** is on, you will receive an alert when this occurs. Remember you can manually resume basal insulin at any time.

Automatic basal resume due to 2 hour maximum suspend:

During either **Suspend before low** or **Suspend on low**, if basal insulin is not resumed due to SG values, it will automatically resume after 2 hours.

You will always receive an alert when you reach the 2 hour maximum suspend time, even if the **Resume basal alert** is set to off. Remember you can manually resume basal insulin at any time.

Suspend by sensor unavailable:
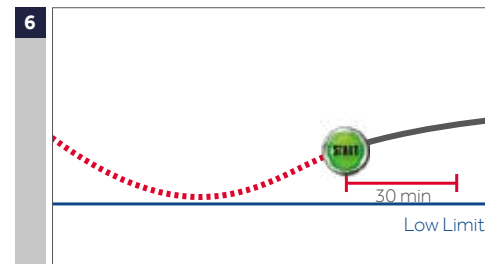
Once basal insulin resumes following either a **Suspend before** low or a **Suspend on low**, there will be a period of time when suspend by sensor is unavailable.

This will most often be 30 minutes if you respond to the suspend alarm, but can be up to 4 hours. See the User Guide for more specific information about this unavailable period.

WHO TO CONTACT AND WHEN?

CONTACT MEDTRONIC

Please contact Medtronic for further guidance and technical advice on using your MiniMed pump.

- If you have any concerns that your pump isn't functioning correctly.

- If your pump displays a warning sign or alarm which you cannot switch off.

- For more information about a certain pump function.

- For guidance when adjusting your basal insulin dose, as instructed by your doctor.

Visit our website at:
www.medtronic-diabetes.co.uk

Alternatively call our customer support helpline **01923 205167**

CONTACT YOUR HEALTHCARE PROFESSIONAL

For all other inquiries regarding your health and continuing care please contact your healthcare professional.

Medtronic

Europe
Medtronic International Trading Sàrl.
Route du Molliau 31
Case postale
CH-1131 Tolochenaz
www.medtronic.eu
Tel: +41 (0)21 802 70 00
Fax: +41 (0)21 802 79 00

United Kingdom
Medtronic UK Ltd.
Building 9
Croxley Park
Watford, Hertfordshire
WD18 8WW. UK
www.medtronic.co.uk
www.medtronic-diabetes.co.uk
Tel: +44 (0)1923 205 167
Fax: +44 (0)1923 241 004

Medtronic Ireland
Cherrywood Business Park
Block G
Cherrywood Science and
Technology Park
Loughinstown
Co. Dublin
Ireland
www.medtronic.ie
www.medtronic-diabetes.ie