AgaMatrix

JAZZ * DoseCoach

OWNER'S GUIDE

DOSE HELPER AND BLOOD GLUCOSE METER



CAUTION: Please read all the instructions provided in this owner's guide and practice the testing procedures before using the JAZZ™ DoseCoach® Blood Glucose Meter. Self blood glucose monitoring should be done under the guidance of a healthcare professional.

Key features of JAZZ™ DoseCoach®:

- Dose Helper.
- Blood Glucose Meter.
- Tagging blood glucose readings.
- No coding required: The JAZZ[™] DoseCoach[®] Blood Glucose Meter does not require a calibration code. After inserting an AgaMatrix WaveSense JAZZ test strip, JAZZ[™] DoseCoach[®] is ready to measure your blood glucose.

Customer Service: UK Careline number 0800 093 1812 www.agamatrix.co.uk

In case of emergency, contact your healthcare professional or emergency medical response.



Manufacturer:

AgaMatrix, Inc. 7C Raymond Avenue Salem, NH 03079 USA



MDSS GmbH Schiffgraben 41 30175 Hannover Germany



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Notes on your treatment plan

Ask your healthcare professional to help you fill out this page – use it to record important information about your treatment plan. The information should also be recorded on your Quick Reference Guide (included in the box).

Name:

Your starting dose:

Your usual dose time:

What to do in case of sick days, changes to diet or activity, travel or vacation:

Healthcare professional contact details:

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Section 1:

KEY INFORMATION ABOUT JAZZ™ DOSECOACH®

This section gives you important safety information about your JAZZ™ DoseCoach[®].

Introduction

This section gives you important safety information about your JAZZ™ DoseCoach[®].

It also gives you a summary of the key information that is explained in more detail throughout this owner's guide.

You should refer back to this section to remind yourself of this key information, to find definitions of key terms, or for descriptions of icons you will see on the screen.

If you are not sure where to find information, remember to use the contents page at the beginning of the owner's guide to help you.

JAZZ[™] DoseCoach[®] – key information

Read all of the instructions in this owner's guide before using your JAZZ™ DoseCoach®.

About JAZZ™ DoseCoach®

JAZZ[™] DoseCoach[®] is for people with Type 2 diabetes who take insulin glargine once a day.

Your JAZZ™ DoseCoach® can help you manage your diabetes in two ways:

- **Dose Helper** gives dose suggestions to help you adjust how much insulin glargine to take.
- **Blood Glucose Meter** lets you measure your blood glucose and keep a record of your blood glucose readings.

JAZZ[™] DoseCoach® is for single patient use only. Do not share JAZZ[™] DoseCoach® with anyone else including other members of your family.

Before you start using JAZZ™ DoseCoach[®] you must:

- Select a user icon so you know which JAZZ[™] DoseCoach[®] is yours.
 Remember to check this icon each time you turn JAZZ[™] DoseCoach[®] on.
 Your healthcare professional should also write your name on the back of your device.
- Set the correct time and date during JAZZ[™] DoseCoach[®] set up. This is important for Dose Helper because it can affect your usual fasting and dose times.

>> See page 31 for selecting a user icon and for setting the correct time and date.

How to care for and dispose of JAZZ™ DoseCoach®

 All parts of the kit are considered 'biohazardous'. This means JAZZ™ DoseCoach[®] and the lancing device can potentially transmit infectious diseases, even after you have cleaned and disinfected them.

>> See page 161 for how to clean and disinfect JAZZ[™] DoseCoach[®] and the lancing device.

 Before you dispose of JAZZ[™] DoseCoach[®], make sure you remove the batteries, including the coin cell battery.

>> See page 168 for how to remove the batteries.

Who to contact for help and further information

- If you have any questions about your treatment, contact your healthcare professional.
- >> See page 1 for your healthcare professionals contact details.
- If you have any problems using JAZZ[™] DoseCoach[®] call customer service on 0800 093 1812

Note: All values shown on the JAZZ[™] DoseCoach[®] screen throughout this owner's guide are examples only. They may not reflect your treatment plan.

Key terms used in this owner's guide

These pages contain some useful definitions of terms that are used in the owner's guide.

- JAZZ[™] DoseCoach®: this is the name of the device.
- Blood Glucose Meter: the JAZZ[™] DoseCoach[®] function that you use to measure your blood glucose level.
- **Dose Helper:** the JAZZ[™] DoseCoach[®] function that provides insulin glargine dose suggestions.
- **(Usual) dose time:** the time you are meant to run Dose Helper to get dose suggestions. Your doctor or nurse sets this on your JAZZ[™] DoseCoach[®].

>> See page 148 for changing the usual dose time.

- Lancet (needle): the lancet unit used to lance (pierce) the skin.
- Strip port: the opening in the base of your JAZZ[™] DoseCoach[®] where you insert your test strip.
- **Strip vial:** the container that the AgaMatrix WaveSense JAZZ test strips are kept in.
- **Tag icon:** a label or icon (small picture) that you add to blood glucose readings. This shows when you measured your blood glucose.
- Blood glucose (BG): the level of glucose in your blood.

• Fasting blood glucose reading:

fasting blood glucose is measured after sleeping and before breakfast, when you have not eaten or had a drink containing sugar/glucose for at least 8 hours.

 (Usual) fasting time: the time you are supposed to measure your fasting blood glucose each day. You can adjust this time in the JAZZ[™] DoseCoach[®] settings. It is important that your usual fasting time is set correctly so it matches your daily routine. • **Hypoglycaemia (hypo):** you might get symptoms of hypoglycaemia if your blood glucose is too low (below 3.9 mmol/L).

The most common hypo symptoms are: palpitations, sweating, hunger, dizziness, tingling, blurred vision, difficulty in thinking, faintness, anxiety.

These symptoms may vary and you may have other symptoms. Contact your healthcare professional for more details.

• **Hyperglycaemia (hyper):** you might get symptoms of hyperglycaemia if your blood glucose is too high (above 13.3 mmol/L).

Icons and symbols used in this owner's guide

These pages contain descriptions of the blood glucose tag icons and other icons you will see on the JAZZ™ DoseCoach® screen.

Blood glucose icons



Fasting tag.



Before meal tag.



After meal tag.



Before bedtime tag.



No tag.



Warning triangle (high or low blood glucose reading).



Fasting blood glucose in target.

Insulin dose icons



Insulin dose recorded.



?

- No dose suggestion given.
- Unknown dose amount saved.
- Multiple doses saved in one day.

Dose suggestion icons



Fasting blood glucose target range.



Shooting star on the dose saved screen. The number of filled sections show the number of pairs (dose + fasting blood glucose) you have collected.



In fasting blood glucose target star on the dose saved screen. The star is filled when the most recent pair (dose + fasting blood glucose) has been collected.

History icons



Warning triangle (for low blood glucose readings or reported low blood glucose or hypo symptoms).



I

Dose Helper.



Time.

Date.

14

Screen type icons

- Question screen.
- Information screen.
- Warning screen.

Menu icons



History.



Settings.



Logbook.



Fasting blood glucose history.



Averages.



ooo Advanced history menu.



Other icons



Battery icon showing the level of power left in the batteries.

Dose Helper – key information

About Dose Helper

- Dose Helper is a tool built in to JAZZ[™] DoseCoach[®].
- It helps you self-adjust your insulin glargine doses by suggesting your next dose. Dose Helper does this using past information about your previous doses and your fasting blood glucose readings.
- Dose increases or decreases are suggested in line with the treatment plan set up by your doctor or nurse.
 Dose Helper should be used as one part of your self-titration treatment program lead by your doctor or nurse.

>> See Section 4 for more information on Dose Helper.

Only use Dose Helper to suggest doses for the type of insulin your doctor or nurse has activated it for.

You can check the type of insulin Dose Helper can be used with in the user agreement.

>> See page 151 for how to review the user agreement.

Dose Helper works best if:

- You measure your fasting blood glucose every day.
- You run Dose Helper and save the amount of insulin glargine that you take every day.

Your insulin doses have to be saved so they can be used by Dose Helper

- Save every insulin dose you take, whether suggested by Dose Helper or not.
- If you do not save your doses, Dose Helper might not be able to give you a dose suggestion or it could be incorrect.
- If you took any dose(s) in the last day that you did not save in Dose Helper, then you will be given the chance to enter it when you next run Dose Helper.

Always run Dose Helper before you take a dose.

• Use Dose Helper to save all doses you take.

Dose Helper needs at least three days of dose and fasting blood glucose data to give dose suggestions

- When you first use Dose Helper, you will have to save your doses and measure your fasting blood glucose for at least three days before it can start giving suggestions.
- Dose Helper will tell you if you need to get more data.
- >> See page 76 for how to get dose suggestions.

What to do if you cannot get a dose suggestion

- Dose Helper might not be able to give you a dose suggestion if it does not have enough information.
- Unless Dose Helper has turned off, you can get dose suggestions once you gather enough information. Dose Helper will tell you what to do to get enough information.
- You will have to save your doses (in Dose Helper) and measure your fasting blood glucose for at least three days before Dose Helper can start giving suggestions again.

>> See page 99 for getting dose suggestions again.

You make the decision on what dose you will take

- Dose Helper is a guide. It gives you a suggested dose. It is not a substitute for your judgement or for advice given by your doctor or nurse. You must make the final decision on what dose you will take.
- This is because you know more about your situation than Dose Helper does, for example if you feel ill, if you are planning travel or unusual activity, if your doctor or nurse has given you specific instructions, etc.
- Your doctor or nurse should explain in which cases you should take a different insulin dose, and other actions you might need to take in these cases.
- If you are not sure about what dose to take, talk to your doctor or nurse.

Tell Dose Helper about hypo symptoms or low blood glucose

- It is important to tell Dose Helper about any hypo symptoms, or low blood glucose measured on another blood glucose meter. Dose Helper already knows about any low blood glucose measured with JAZZ[™] DoseCoach[®].
- This is so Dose Helper can decide whether it is safe to increase your insulin glargine dose.
- If your insulin glargine dose is too high, your blood glucose could become very low and you may get symptoms of hypoglycaemia.

If you change your daily routine, you might need to take a different dose

- Dose Helper adjusts your dose based on past information. It cannot plan ahead for days when you are ill, or significantly change your daily routine, such as the amount you eat or activity you do.
- Changes to your daily routine can affect your blood glucose levels and you may need to take a different dose to the Dose Helper suggestion. Follow the instructions recorded on page 1, or contact your doctor or nurse if you are not sure what dose to take.
- Changing the time and date can affect Dose Helper. Contact your doctor or nurse if you plan to travel to a different time zone.

Do



Use Dose Helper once a day at vour usual dose time.

- Contact your doctor or nurse if you are not sure what dose to take
 - Only use Dose Helper if your doctor or nurse has told you how to self-adjust your insulin glargine dose and how to use Dose Helper safely.

Always run Dose Helper before you take a dose. When Dose Helper suggests an insulin glargine dose, take your dose straight away.

Do not



🖌 Do not use Dose Helper if you have gestational diabetes.

- 🖌 Do not use Dose Helper if you do not take your insulin glargine dose once daily, or if you do not take it at around the same time every day.
- - 🖌 Do not use Dose Helper if you take any insulin other than insulin glargine.

🖌 Do not use Dose Helper if you are under 18 years old.

>> See page 79 for the instructions you need to get from your doctor or nurse before using Dose Helper.

Blood Glucose Meter – key information

- The JAZZTM DoseCoach[®] Blood Glucose Meter can be used to help you self-monitor blood glucose levels at home and to store and display blood glucose data.
- It is used to measure the level of glucose in fresh, capillary whole blood this helps you to monitor the effectiveness of glycaemic control.
- Blood glucose measurements are done outside the body (in vitro use).

>> See Section 3 for more information on the Blood Glucose Meter.

Do



Use fresh capillary whole blood taken from the fingertip only.



Do not



Do not use the Blood Glucose Meter to diagnose diabetes.



- Do not use the Blood Glucose Meter for measuring blood glucose of neonates (children under 4 weeks old).
- Do not use the Blood Glucose Meter if you are testing blood from somewhere other than your fingertip.

Tagging your blood glucose readings

- A tag will be suggested based on the time of day you measure your blood glucose, your usual fasting time, and usual meal times.
- It is important that you 'tag' your fasting blood glucose readings as 'fasting' so they can be used by Dose Helper to suggest insulin glargine doses.
- To tag a blood glucose reading as fasting, select the fasting tag () when prompted on the screen.



 You can only tag a blood glucose reading as fasting if you have measured your blood glucose during the 4-hour fasting window.

>> See page 13 for descriptions of the tag icons.

>> See page 50 for information on how to measure your blood glucose and tag your reading.

>> See page 140 for how to change your usual fasting and meal times.

>> See page 184 for information on why the fasting tag is not available.

What to do if your blood glucose readings are high or low.

(1) If you get blood glucose readings below 3.9 mmol/L or above 13.3 mmol/L and you have hypo or hyper symptoms, follow your treatment plan or contact your healthcare professional right away.

(2) If you do not have hypo or hyper symptoms, measure your blood glucose again, carefully following the instructions in this owner's guide.

 If you get hypo or hyper symptoms, or continue to get blood glucose readings below 3.9 mmol/L or above 13.3 mmol/L, follow your treatment plan or contact your healthcare professional right away. (3) If you have hypo or hyper symptoms that are not consistent with your blood glucose readings, follow your treatment plan or contact your healthcare professional right away. This page has been left blank on purpose.

Section 2:

GETTING STARTED WITH JAZZ™ DOSECOACH®

This section shows you how to get started with JAZZ™ DoseCoach[®].

What comes in the box



JAZZ™ DoseCoach®





Lancing device with cap



1 vial of 10 AgaMatrix WaveSense JAZZ test strips



10 sterile lancets



2 AA lithium batteries

Other box contents (not shown):

- Carrying case.
- This owner's guide.
- Quick reference guide.
- Test strip insert
- Registration card.
- Prescription card.
- Log book.

Do



- Store AgaMatrix WaveSense JAZZ test strips in their original vial in a cool, dry place at 8°C to 30°C.
- Tightly close the vial of AgaMatrix WaveSense JAZZ test strips after you have removed a test strip.
 - Store your lancing device at room temperature protected from sunlight and moisture.

Do not



- Y Do not use JAZZ™ DoseCoach® or any other items included in the box if the box seal is broken or has been tampered with.
 - Do not bend, cut or alter AgaMatrix WaveSense JAZZ test strips.

Get to know JAZZ™ DoseCoach®



Mini-USB port: for inserting the activation key.

b Screen: blood glucose readings, symbols, messages, and graphs appear here.

C Left and right soft keys - - : select options shown in the black band at the bottom of the screen.

(d) Power/back button []: press this button to turn on JAZZ™ DoseCoach® or to go back a step. Press and hold this button to turn JAZZ™ DoseCoach® off. ● Dose Helper button ★: press this button to launch Dose Helper (see page 71).

f Up and down buttons

press these buttons to choose an option or to show more information.

(9) Strip port: insert an AgaMatrix WaveSense JAZZ test strip here (see page 50) Each time you turn on JAZZ™ DoseCoach®, it will perform a meter system check.

Do not use JA77™ DoseCoach[®] and call customer service at 0800 093 1812 if any areas of the start-up screen appear to be missing.

There are three possible start-up screens that might be shown (see below).

Note: Your user icon may be different to the icon shown in the examples below.





The main menu



The main menu appears on the screen when JAZZ™ DoseCoach® is turned on by pressing . You will see a start-up screen for a few seconds before it appears.

Date and time.

b Battery icon.

C User icon.

d History menu option.

e Settings menu option.

Getting started

Remember to read all of the instructions in this owner's guide before using your JAZZ™ DoseCoach[®].

Set the language.

1

- The first time you use JAZZ[™] DoseCoach[®] you will be asked to set the language.
- If the language has already been set by your healthcare professional, go to Step 2.







"Save".

Language	
Deutsch	
English (UK)	
Italiano	

2

Review navigation buttons.

- Do not use JAZZ™ DoseCoach® if any areas of the screen appear to be missing.
 The first time you use
 - JAZZ™ DoseCoach® you will be shown how to use the navigation buttons.

Press "Next" to go through all the screens.





Read the welcome message.

3

 Read the welcome message the first time you use JAZZ™ DoseCoach®. This shows the next steps you will go through.



Select your user icon.

4

The user icon helps you identify your own JAZZ™ DoseCoach® and helps to prevent getting it confused with someone else's.

Every time you turn on JAZZ™ DoseCoach® your user icon will appear.



The user icons you can choose from are shown below.



It is also shown on some other screens, such as when you receive a dose suggestion.



Choose an icon.



Do



Check your user icon is shown each time you use JAZZ™ DoseCoach®

Do not



✓ Do not use JAZZ™ DoseCoach[®] if you see a user icon that is not yours.

K Do not share your JAZZ™ DoseCoach[®] or use someone else's - it is meant for you only.
Press 🕤 to go back to previous screens.

Check the time and date.

5

- Setting the correct time and date is important for JAZZ™ DoseCoach[®].
- If the time and date are not set correctly Dose Helper will not work properly.
- If the time and date have not been set before, this screen will not be shown. You will be asked to set the clock.

If time and date are correct, press "Yes".





 If you pressed "No", JAZZ[™] DoseCoach[®] will ask you to correct the clock settings.



Set the correct year.

Go to the **"Next"** setting step.

• Repeat this to set month, day, hour and minutes.

"Gove" the clock changes at the last setting step.



Read the definition of Fasting BG.

6

• Read the fasting blood glucose definition carefully.

Then go to the **"Next"** screen.

Fasting BG

Fasting BG is measured after sleeping and before breakfast, when you have not eaten or had a drink containing sugar/glucose for at least 8 hours.

Next

Press 🕤 to go back to previous screens.

So Dose Helper can suggest next insulin glargine doses, it needs to know your fasting blood glucose reading each day. It is important to understand what time you should set as your usual fasting time.

Read the definition carefully before you set the fasting time:

Fasting blood glucose is measured after sleeping and before breakfast, when you have not eaten or had a drink containing sugar/glucose for at least 8 hours. 7

Set your usual fasting time.

- The usual fasting time sets the middle point of a 6 hour fasting window.
- You can only tag (label) blood glucose readings as fasting during this 6 hour window.

Choose a time for fasting that will fit your sleeping and eating habits.

"Save" the usual fasting time.

>> See page 140 for changing the usual fasting time.

>> See page 50 for how to tag your blood glucose readings.

> Fasting time Set your usual fasting time (before breakfast): 07:00 Fasting tag can be used between 04:00 and 10:00. Save

Congratulations, your JAZZ™ DoseCoach® is ready to use! Section 3:

USING YOUR BLOOD GLUCOSE METER

This section shows you how to measure your blood glucose using JAZZ™ DoseCoach®.

Important safety information

Do

- Only use JAZZ[™] DoseCoach[®] within a temperature range of 10°C to 40°C.
 - Only use JAZZ™ DoseCoach® below an altitude of 10,000 feet (around 3,000 meters) and only if humidity is within 25% to 90%.
 - Only apply blood or control solution to the AgaMatrix WaveSense JAZZ test strip, never apply blood or control solution directly to the strip port on JAZZ[™] DoseCoach®. This might cause a system failure.

Do not

- Do not use AgaMatrix WaveSense JAZZ test strips after the expiry date or 180 days after first opening the vial. They may give inaccurate blood glucose readings.
- Conot use AgaMatrix WaveSense JAZZ test strips that appear to be damaged or used. They may give inaccurate blood glucose readings.

Important health-related information

JAZZ™ DoseCoach® does not require a calibration code.

Insert an AgaMatrix WaveSense JAZZ test strip and you are ready to measure your blood glucose.

(1) Blood glucose readings below 3.9 mmol/L may mean low blood glucose levels (hypoglycaemia).

2 Blood glucose readings over 13.3 mmol/L may mean high blood glucose levels (hyperglycaemia). Checking ketones may be advisable.

(3) If you get blood glucose readings below 3.9 mmol/L or above 13.3 mmol/L and do not have symptoms of hypoglycaemia or hyperglycaemia, repeat the test.

If you have symptoms, or continue to

If you are critically ill do not use the Blood Glucose Meter. Inaccurate blood glucose readings may occur:

- If your haematocrit levels are below 20% or above 60%.
- If your blood pressure is very low (hypotension), or if you are in shock.
- If you are being given extra oxygen (oxygen therapy).
- If you have a hyperglycaemichyperosmolar state, with or without ketosis.
- If you are dehydrated, or have lost a lot of fluids. If you are severely dehydrated contact your healthcare professional right away.

get results that fall below 3.9 mmol/L or rise above 13.3 mmol/L follow your treatment plan or contact your healthcare professional right away.

(•) If you have symptoms that are not consistent with your blood glucose readings and you have followed all instructions described in this owner's guide, follow your healthcare professional's recommendations.

(5) If you get repeated error messages and have symptoms of hypo or hyperglycaemia, contact your healthcare professional right away as this may mean low or high blood glucose. If this error code persists on measuring again, contact your healthcare professional. >> See page 177 for information on Blood Glucose Meter error messages.

6 Always follow your healthcare professional's recommendations.

About the lancing device

The lancing device is a medical tool for collecting capillary blood samples for glucose monitoring or other tests which require one or two small drops of blood.

All parts of the kit are considered biohazardous. This means it can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

>> See page 161 for disinfecting JAZZ™ DoseCoach® and the lancing device.

Do not

Do not share the lancing device; it is meant for you only.

<	Do not leave the lancet in the
	device after use.

Do



Always use a new lancet, placed into the lancing device directly before measuring your blood glucose.



Discard the lancet after measuring your blood glucose.

- Clean the lancing device cap after using it.
- Always dispose of the used lancet in a safe way, for example, in a puncture resistant container, according to local regulations. Follow your healthcare provider's instructions for disposal. Keep out of reach of children. This device has many small parts and could be a choking hazard for children if swallowed.

About the lancing device



Cocking handle: cocks the device so it is ready to lance.

b Depth selector:

adjusts how deep the lancet will lance the skin.

© Depth: select from 5 levels of depth for skin penetration, indicated by a small dot (lowest setting) to the largest dot (highest setting).

d Release button: fires the lancet.

e Lancet ejector: safely ejects the used lancet.

(f) Lancet holder: holds the lancet into place inside the lancing device.

9 Lancing device cap:

covers the lancet when in lancing device.

(b) Lancet: lances the skin to produce a drop of blood.

(i) Lancet cover: covers the lancet for safety. Remove after inserting into the lancet holder.

Available lancets

The following lancets can be used with this device:

AgaMatrix lancets

About the AgaMatrix WaveSense JAZZ test strips

The AgaMatrix WaveSense • The front of the JAZZ test strips let you measure your blood glucose by using a small drop of blood, about the size of a pinhead (0.5 microliters).



Back

- AgaMatrix WaveSense JAZZ test strip is black. Always make sure the black side is up when you insert it into the strip port.
- The back of the AgaMatrix WaveSense JAZZ test strip is white.

(a) Contact bars: this end is inserted into the JAZZ™ DoseCoach[®] strip port.

(b) Fill window: this window will turn red when enough blood has been applied. This window will turn blue when enough control solution has been applied.

(c) Sample area: blood or control solution should be applied to the tip of this area.

When blood is applied to the AgaMatrix WaveSense JAZZ test strip it produces an electrochemical signal. The signal it produces depends on your blood alucose level. JAZZ™ DoseCoach[®] measures this signal and displays it as your blood glucose reading.

1

Getting the lancing device ready

Wash your hands with soap and warm water. Rinse and thoroughly dry your hands.

Remove the cap.

 Twist the cap off the lancing device by turning it counter-clockwise while holding the base firmly.

Insert a new lancet.

- Load a new sterile lancet directly into the bottom of the lancet holder.
- In case you accidently cocked the device at this point, press the release button before you move on.







Remove the lancet cover.

4

- While holding the lancet firmly, twist/ pull the lancet cover in a straight direction to remove.
- To avoid injury be careful not to touch the lancet tip.

Put the cap of the lancing device back on by turning it clockwise until it is fully into place.





Set the lancing depth.

- The lancing device offers 5 depth settings Select the skin penetration depth by sliding the depth selector to the desired depth.
- The 5 dots represent the 5 levels of depth settings, with the largest dot (highest setting) on the left progressing to the smallest dot (lowest setting) on the right.
- If you have never lanced before, it is recommended that you start at the third dot.



Cock the lancing device.

7

• Pull the cocking handle out until it clicks. This will cock the lancing device.



Do not

✓ Do not lance your finger before JAZZ™ DoseCoach[®] and the test strips are ready to use.

Measure your blood glucose

To get the most accurate blood glucose readings

Take blood samples from the side of the fingertip (excluding thumb and index finger).

Make sure there is no grease, oil or lotion on the fingertip you are going to use.

Keep your hand warm or gently massage the site you are lancing to help your blood flow.

Check the expiration date ("use by") on your AgaMatrix WaveSense JAZZ test strips before you use them.



Wash your hands carefully with soap and warm water to increase the circulation of the blood into the fingers.

 Make sure there is no grease, oil or lotion on the fingertip you are going to use.

1

 Keep your hand warm or gently massage the site you are lancing to help your blood flow.





Insert a new AgaMatrix WaveSense JAZZ test strip into the strip port.

• Insert the AgaMatrix WaveSense JAZZ test strip with the black side facing up.

2

- JAZZ[™] DoseCoach[®] will turn on when the test strip is fully inserted.
- Check the user icon on the start-up screen.
- Never use a JAZZ[™] DoseCoach[®] that is not yours.
- You will see this screen when JAZZ™ DoseCoach[®] is ready for a sample of blood.

 If you do not apply blood within 4 minutes of inserting the AgaMatrix WaveSense JAZZ test strip, JAZZ™ DoseCoach[®] will turn off. To restart, remove the test strip and reinsert it.



Use the lancing device.

3

- Hold the lancing device firmly against the side of the fingertip, with the cap resting on the fingertip.
- Note: the harder you press the lancing device against the finger the deeper the puncture.

• Press the release button to get a blood sample.



Get blood sample.

4

- Squeeze from the base of your finger up towards the tip, until a small drop of blood appears.
- If you do not see enough blood, set a deeper lancing level and try again. You might need to use a larger lancet to produce enough blood.



Do not

Do not squeeze directly around the lanced area.

Bring the AgaMatrix WaveSense JAZZ test strip to the drop of blood.



- The test strip fills from the tip.
- The fill window of the test strip will turn red.



- When you hear the beep, remove the AgaMatrix WaveSense JAZZ test strip from the blood sample.
- Do not apply any more blood to the AgaMatrix WaveSense JAZZ test strip after the beep.

- An animation will appear on the screen while JAZZ™ DoseCoach[®] is calculating your blood alucose reading.
- Keep the AgaMatrix WaveSense JAZZ test strip inserted until you have completed the remaining steps.

If the calculation animation is not shown and you do not get a blood glucose reading, measure your blood glucose again using a new test strip.

Make sure you wait until the blood animation appears on the screen before you apply the blood sample and that you apply blood to the tip of the test strip.

If the problem continues call customer service at 0800 093 1812



If the fill window on the AgaMatrix WaveSense JAZZ test strip does not completely fill, you may get an inaccurate blood glucose reading. Measure your blood glucose again with a new AgaMatrix WaveSense JAZZ test strip and make sure the fill window is completely full.

Do not

- Do not put blood on the top surface of the AgaMatrix WaveSense JAZZ test strip.
- Do not scrape blood onto the test strip.

>

Do not press the test strip too hard against the test site.

Press 🕤 to go back to previous screens.

Review the blood glucose reading.

6

 Review your blood glucose reading carefully.

>> See page 63 for how to interpret the blood glucose reading screen.



A tag is a description label that you add to blood glucose readings.

What is fasting blood glucose and why is it important?

Fasting blood glucose readings:

Fasting blood glucose is measured after sleeping and before breakfast, when you have not eaten or had a drink containing sugar/glucose for at least 8 hours.

- Your fasting blood glucose readings are used to decide if your insulin dose should be increased or decreased.
- You have to tag, or mark, your readings when they are fasting.
 Telling JAZZ[™] DoseCoach[®] which blood glucose readings are 'fasting' is important for Dose Helper.

Tagging a fasting blood glucose reading.

When you measure your blood glucose inside the 4-hour fasting window, JAZZ™ DoseCoach® will ask you to confirm if the reading is a fasting blood glucose reading. You have 1 additional hour on either side to manually tag the reading as a fasting blood glucose measurement. reading, press **"Yes"**.

• If it is not a fasting reading, press "No".

• If you pressed **"No"**, you will be asked to choose the correct tag.



How to tag a blood glucose reading.

 When you have measured your blood glucose and the reading is displayed, there will be a menu of tag options.

8

- When the tagging screen appears, one of the options is highlighted.
- The suggested tag changes with the time of day based on the tag time settings.
- If you measure your blood glucose outside the 6-hour fasting window, the

fasting tag will not be available and will be greyed out.



"Save".

>> See page 13 for descriptions of the tag icons.

>> See page 140 for messages that may be triggered by tagging.



Check saved tag.

9

 Check that you saved the correct tag and review the blood glucose reading carefully.

>> See page 63 for how to interpret the blood glucose reading screen.



Remove the AgaMatrix WaveSense JAZZ test strip.

10

 The JAZZ™ DoseCoach[®] will turn off.



>> See page 175 for questions and answers on using the Blood Glucose Meter. If you choose the wrong tag and the blood glucose reading is still shown on the screen you can go back and change the tag.

If you turn JAZZ™ DoseCoach® off or move to the main menu you will not be able to go back and change the tag.

You will need to measure your blood glucose again if you need to tag a fasting blood glucose reading for Dose Helper.

Dispose of the lancet and the test strip

9

Remove the cap.

• Twist the cap off the lancing device by turning it counter-clockwise while holding the base firmly.



Used test strips, lancets and lancing devices may present a risk to the health of humans, animals or the environment (biohazardous medical waste) in your city or town.

Dispose of used materials properly. Follow your healthcare provider's instructions for disposal. 2

Dispose of the lancet and the test strip.



- Carefully re-cap the used lancet. Be careful
 not to touch the lancet tip.
- Push the lancet ejector downward with your thumb, ejecting the lancet safely into an appropriate sharps

container.

- Do not dispose of the lancing device.
- Wash your hands thoroughly after handling JAZZ™ DoseCoach®, the lancet, lancing device and test strips.

Put the cap of the lancing device back on by turning it clockwise until it is fully into place.



How to interpret the blood glucose reading screen

When you have measured your blood glucose, the blood glucose reading will be shown on the screen. The color of the screen will depend on your blood glucose reading.



(a) Blood glucose reading: the large numbers on the screen show the measured blood glucose. **(f) Message area:** not all blood glucose readings have messages.

>> See page 65 for possible messages

b Units of measurement: mmol/L

C Date of blood glucose reading.

d Time of blood glucose reading.

e Tag.



Messages on the blood glucose reading screen



High blood glucose Blood glucose readings over 13.3 mmol/L may mean high blood glucose levels (hyperglycaemia). Checking ketones may be advisable.

>> See page 67 for what to do if your blood glucose readings are high or low.



In fasting blood glucose target

When your doctor or nurse turns Dose Helper on for you, they will set your fasting blood glucose target range.

The fasting blood glucose in target icon will be shown if:

- you tag a blood glucose reading as fasting and
- the reading is within your fasting blood glucose target range and
- Dose Helper is active.



Low blood glucose

Blood glucose readings below 3.9 mmol/L may mean low blood glucose levels (hypoglycaemia).

>> See page 67 for what to do if your blood glucose readings are high or low. You might get symptoms of hypoglycaemia if your blood glucose is too low (below 3.9 mmol/L).

Common symptoms of hypoglycaemia are: palpitations, sweating, hunger, dizziness, tingling, blurred vision, difficulty in thinking, faintness, anxiety.

Your symptoms may vary and you may have other symptoms. Contact your healthcare professional for more details.

What to do if your blood glucose readings are high or low:

(1) If you get blood glucose readings below 3.9 mmol/L or above 13.3 mmol/L and you have hypo or hyper symptoms, follow your treatment plan or contact your healthcare professional right away.

(2) If you do not have hypo or hyper symptoms, measure your blood glucose again, carefully following the instructions in this owner's guide.

 If you get hypo or hyper symptoms, or continue to get blood glucose readings below 3.9 mmol/L or above 13.3 mmol/L, follow your treatment plan or contact your healthcare professional right away. (3) If you have hypo or hyper symptoms that are not consistent with your blood glucose readings, follow your treatment plan or contact your healthcare professional right away.

If your blood glucose readings appear to be higher or lower compared with another meter, perform a control solution test to check JAZZ[™] DoseCoach® is working correctly.

You cannot accurately compare blood glucose readings from different meters.

Tag times

This screen will appear the first time you tag a before meal or after meal reading.

- Check if the times are correct for your eating habits.
- These times will determine the meal for which your before meal and after meal tags are saved.

Check the tag times.
If the tag times are correct, press "Yes".
If not, press "No". You will be

forwarded to the usual tag time settings.

>> See page 140 for changing the tag times.

Are these usual times correct?		
Fasting	07:00	
Breakfast	07:30	
Lunch	12:30	
Dinner	19:00	

Fasting check

Press 🕤 to go back to previous screens.

This screen will appear:

- If you are tagging a fasting blood glucose reading for the first time.
- If you are tagging a fasting blood glucose reading away from your usual fasting time.
- If you are tagging a fasting blood glucose reading close to a reading that you tagged as a before meal or after meal reading.

Check if this is really a fasting blood glucose reading.

1

Press **"Yes"** to save the fasting blood glucose reading.

If you do not want to tag a fasting blood glucose reading, press **"No"**.



Fasting blood glucose is measured after sleeping and before breakfast, when you have not eaten or had a drink containing sugar/glucose for at least 8 hours.

Multiple fasting

This screen will appear if you have tagged more than one fasting blood glucose reading and need to choose one for Dose Helper to use.

1 Select the correct fasting reading.

Choose the fasting blood glucose reading to be used for Dose Helper.



Press "Select".

Or press "Details" to get more information.

Ø Multiple fa	sting		
Which fasting BG reading should Dose Helper use?			
5.7 mmol/L	08:00		
11.6 mmol/L	07:55		
Details	Select		
Section 4:

USING DOSE HELPER

This section shows you how to use your Dose Helper to help you adjust your insulin glargine dose. Dose Helper needs to be set up for you by your doctor or nurse.

Important safety information

Do

Read all of this section before using Dose Helper. If you do not follow these instructions, you may get too much or too little insulin glargine – this may affect your blood glucose levels.

- If you are not able to use these instructions or Dose Helper, ask your doctor or nurse for help.
- Run Dose Helper and take your dose at around the same time every day (your usual dose time). Ask your doctor or nurse what time of the day you should take your insulin glargine dose. Always run Dose Helper if you intend to take a dose.

- If your doctor or nurse told you to take your once-daily insulin glargine dose in the morning, measure your fasting blood glucose before running Dose Helper and taking your dose.
- Dose Helper requires you to have consistent diet, activity and daily routine.
 - Save all doses to Dose Helper (even if Dose Helper has not suggested the dose). If you don't, Dose Helper might not be able to give you a dose suggestion, or it could give an incorrect dose suggestion.

Dose Helper might not always be able to give you a dose suggestion. For example, because:

- You just began using Dose Helper.
- >> See page 79.
- You forgot to measure your fasting blood glucose, or did not measure with JAZZ™ DoseCoach[®].
- You did not run Dose Helper.
- You did not take your insulin glargine dose.
- >> See page 198 for other cases where Dose Helper may not

be able to give a dose suggestion.

Only use Dose Helper to suggest doses for the type of insulin your doctor or nurse has activated it for.

You can check the type of insulin Dose Helper can be used with in the user agreement.

>> See page 151 for how to review the user agreement. If you are not sure about what dose to take, talk to your doctor or nurse. a

b

Dose Helper general principles

Dose Helper is only available to help with the adjustment of your insulin glargine dose if your doctor or nurse has turned it on for you.

Dose Helper can help you adjust your insulin glargine dose to get your fasting blood glucose (fasting BG) to the fasting blood glucose target range set by your doctor or nurse.

Start with the insulin glargine dose set by your doctor or nurse.

The grey bars show the insulin glargine dose taken each day.





When you reach your fasting blood glucose target range, you can still use Dose Helper to help you adjust your dose to keep your fasting blood glucose in your fasting blood glucose target range.

glucose is above your fasting blood glucose target range.

>> See page 76 for adjustment details.

It can take between one to three months to find the dose that works for you. Do not worry if it takes some time to get there. 0

- The suggested dose is meant for you only. Do not share your JAZZ™ DoseCoach[®] with anyone else.
- Dose Helper can be run
 3 hours either side of the usual dose time.

How Dose Helper suggests insulin doses

a

b

Required information

Dose Helper works best if:

- You measure your fasting blood glucose every day.
- You run Dose Helper and save the amount of insulin glargine that you take every day.

>> See page 197 if you get a message "More information needed".

>> See page 198 if you get a message "Dose suggestion not possible".

Dose Helper needs your fasting blood glucose (fasting BG) readings. It can only use these if you also entered your previous insulin dose. Dose Helper pairs these together. For example, a pair might be yesterday's dose and today's fasting blood glucose reading.

The number of pairs (dose + fasting blood glucose) collected is shown on the shooting star graphic at the end of the Dose Helper sequence - after you have saved a dose.



Calculations

Dose Helper may suggest dose increases every three days if:

• Two of the last three fasting blood glucose readings are above your fasting blood glucose target range.

Dose Helper may suggest dose decreases if:

- Two of the last three fasting blood glucose readings are below your fasting blood glucose target range.
- You get any low blood glucose readings or report any hypo symptoms.

Dose Helper helps you adjust your insulin glargine dose based on past information. It cannot plan ahead for sudden changes, for example:

- Sick days
- Travel or vacation
- Changes in diet or activity.

If you are not sure what dose to take in these situations, check the information recorded on page 1 or contact your doctor or nurse.

Using Dose Helper for the first time

Start using Dose Helper when it is time for you to take your dose.

Dose Helper needs three fasting blood glucose readings from the next three days and the insulin dose that you take each day, before giving you a first dose suggestion on day 4. In these first three days of use:

- Measure your fasting blood glucose every day.
- Run Dose Helper and enter your insulin glargine dose every day.

Before you start using Dose Helper you need to know:

- How to measure your blood glucose and tag fasting blood glucose readings.
- How to recognise and treat hypo symptoms.
- How to use your insulin glargine safely.
- What to do in case of sick days, travel or vacation, or changes in diet or activity.
- What dose to take in the first days of using Dose Helper ("starting dose").

Ask your doctor or nurse if you are not sure about any of these topics.



Run Dose Helper.

1

When it is time for your dose, press 💉 to start Dose Helper.

- The first time you run Dose Helper you will be told about the Dose Helper button .
- Check the user icon on the start-up screen.
- Never use a JAZZ[™] DoseCoach[®] that is not yours.

>> If you get a message on the screen after pressing the Dose Helper button, see page 187 for questions and answers on using Dose Helper.



Press 🕤 to go back to previous screens.

Dose Helper menu.

The Dose Helper menu appears on the screen each time you run Dose Helper by pressing



2

Choose "Take a dose".

💻 Then go to the "Select" screen.

E			Or p	ores	s "E	xit"
to	go	bacł	(to	the	ma	in

menu.



>> See page 133, for

Helper settings.

how to change the Dose

Press 🔄 to go back to previous screens.

4

Read the user agreement.



3

Read to the end.

Then "Confirm" the user agreement.

Or press "Decline"

Dose Helper will only • work if you confirm the user agreement.



Read the welcome message.

 This shows the next steps you will go through.

Then go to the "Next" screen



Read the hypo definition.

5



💶 Then go to the "Next" screen.

Hypo definition

Most common symptoms are:

Anxiety, palpitations, sweating, hunger, dizziness, tinalina, blurred vision. difficulty in thinking, faintness

The most common hypo symptoms are: Palpitations, sweating, hunger, dizziness, tingling, blurred vision, difficulty in thinking, faintness, anxiety.

These symptoms may vary and you may have other symptoms. Contact your healthcare professional for more details.

Correctly reporting any hypo symptoms or low blood glucose readings is important to get correct dose suggestions.

Dose Helper knows about any low blood glucose measured with JAZZ™ DoseCoach®. These auestions tell Dose Helper about any hypo symptoms you had or if you measured low blood alucose with a different blood glucose meter.

Answer the hypo questions.

If you have not had any low blood glucose readings or hypo symptoms in the last day(s), press **"No"**.

If you have, press **"Yes"**.

 If you pressed "Yes", you will be asked another hypo question to find out how bad your hypo was.

When you are asked to confirm your hypo, press **"Save"**.

1 Hypo questions

In the last day, have you had either:

- Hypo symptoms?
- Low BG (less than 3.9 mmol/L)?

Yes

Hypo questions Did you have hypo symptoms that required help from another person?

No

Yes



No

Read the previous dose message.

7

The first time you run Dose Helper you do not need to enter any previous doses.



OK

So that Dose Helper can provide dose suggestions, all previous doses must be recorded.

Previous dose

Since this is the first time running Dose Helper, you will not be asked to enter any previous doses.

Press 🕤 to go back to previous screens.

Read about how to get a dose suggestion.

 Dose Helper needs three fasting blood glucose readings from the last three days and the insulin dose that you took each day to give a dose suggestion on day 4.

>> See page 76 for more information.

3 Today's dose
Once there is enough information, Dose Helper will provide a dose suggestion.

 Therefore, follow the instructions on the screen every day for the next three days.

Go to the "Next" screen.

Details" to get more information.



Decide whether to take a dose.

If you will take a dose now, press "Yes".

The set of the set of



Decide what dose to take.

Enter the insulin glargine dose that you will take now (as advised by your doctor or nurse).

- The starting dose chosen by your doctor or nurse is shown on the screen. It is 10 units in this example.
- After you have entered an insulin glargine dose, press "Next" to take you to the next step.

 Until you enter an insulin glargine dose,
 "Next" will be grey and you cannot go on.

Go to the "Next" screen.

Cancel".



Remember that you have to **use Dose Helper every day, for at least three days** before Dose Helper can suggest a first dose.

Press 🕤 to go back to previous screens.

Check the dose.

M

• Check that you will save the correct dose.





Take your insulin glargine dose.

12

- Take your insulin glargine dose immediately after you have saved your dose on JAZZ™ DoseCoach[®].
- For details about taking insulin glargine, please read the instructions that came with your injection device.



Exit Dose Helper.

13

- Doses not suggested by Dose Helper have a grey background.
- The number of filled sections on the shooting star shows the number of pairs (dose + fasting blood glucose) you have collected.



	Or	pres
'Menu"		





>> See page 76 for



Normal use of Dose Helper

This section explains the steps for when you use Dose Helper every day and Dose Helper has enough information to make dose suggestions.



Run Dose Helper

When it is time for your dose, press 🗙 to start Dose Helper.

- Check the user icon on the start-up screen.
- Never use a JAZZ[™] DoseCoach[®] that is not yours.

>> If you get a message on the screen after pressing the Dose Helper button, see page 187 for questions and answers on using Dose Helper.

Dose Helper menu.

The Dose Helper menu appears on the screen each time you run Dose Helper by pressing 📩.

^

2

Choose **"Take a** dose".

"Select" screen.

Or press **"Exit"** to go back to the main menu.



>> See page 147 for

Helper settings.

how to change the Dose

No

Answer the hypo questions.

If you have not had any low blood glucose readings (on another blood glucose meter) or hypo symptoms in the last day(s), press "**No**".

The set of the set of

 If you pressed "Yes", you will be asked another hypo question to find out how bad your hypo was.

When you are asked to confirm your hypo, press **"Save"**.



The most common hypo symptoms are: Palpitations, sweating, hunger, dizziness, tingling, blurred vision, difficulty in thinking, faintness, anxiety.

These symptoms may vary and you may have other symptoms. Contact your healthcare professional for more details.

Answer the previous dose question.

taken any dose of insulin you will be asked to glargine since the last saved dose, press "No".

If you have,

press "Yes".

If you have not • If you pressed **"Yes**", enter the dose



Go to the "Next" screen.

2 Previous dose	
-----------------	--

Did vou take anv dose since this one? Yesterday, 25 March

Units: 30

No

19:16 🐔

Yes

2 Previous dose	
On what day did you take the dose?	
March 26, 2019	-
Yesterday	
Ne	vt



• Repeat this to enter the dose time and dose amount.

■ If you are not sure what dose you took, press **"Not sure"**. >> If you get a message on the screen after answering this question, see page 187 for questions and answers on using Dose Helper.



Decide what dose to take.

• Read the suggestion for your insulin glargine dose carefully.

Find out more details about your suggested dose.

If you will take the suggested dose, press "**Next**".

• If you will take a different dose, press "Change".

• If you pressed "Change", you will be asked to enter the different dose. Enter the insulin glargine dose that you will take now.



"Next" screen.



Suggestee	d dose
Previous	30
Adjustment	+ 2
Now	32
	Units
Long-ad	ting insulin
Details	
× •	
Change	Next

Previous:	30
Suggested:	32
Select the dose you will take now:	
32 Units	\$

Check the dose.

- Check that you will save the correct dose.
 - **"Save"** the

dose.

6



Take your insulin glargine dose.

7

- Take your insulin glargine dose immediately after you have saved your dose on JAZZ™ DoseCoach[®].
- For details about taking insulin glargine, please read the instructions that came with your injection device.



Exit Dose Helper.

8

- Dose suggestions from Dose Helper have a blue background.
- Doses not suggested by Dose Helper (i.e., doses entered manually) have a grey background.
- The number of filled sections on the shooting star shows the number of pairs (dose + fasting blood glucose) you have collected.



• Or press • Menu". >> See page 76 for more information about the shooting star.





Getting dose suggestions again (if a dose suggestion is not possible)

Dose Helper might not be able to give you a dose suggestion if it does not have enough information.

- You should still take your dose of insulin glargine at your usual time.
- You should still complete the Dose Helper steps in order to enter your dose information.

Dose Helper needs three fasting blood glucose readings from the last three days and the insulin dose that you took each day before giving you dose suggestions again on day 4. In these three days:

- Measure your fasting blood glucose every day.
- Run Dose Helper and enter your insulin glargine dose every day.



Run Dose Helper

1

When it is time for your dose, press 🖈 to start Dose Helper.

- Check the user icon on the start-up screen.
- Never use a JAZZ[™] DoseCoach[®] that is not yours.

>> If you get a message on the screen after pressing the Dose Helper button, see page 187 for questions and answers on using Dose Helper.

Press 🕤 to go back to previous screens.

Dose Helper menu.

2

- The Dose Helper menu appears on the screen each time you run Dose Helper by pressing *.
 - Choose "Take a dose".

"Select" screen.

Cor press "Exit" to go back to the main menu.



>> See page 147 for

Helper settings.

how to change the Dose

Read the warning message.

• The warning message will explain why a dose suggestion cannot be made.

Go to the "Next" screen.

>> To find out about Dose Helper warning messages, see page 187 for questions and answers on using Dose Helper.

Dose suggestion

Next

A not possible
 Dose Helper needs

more fasting BG

and/or dose

information.

• Therefore, follow the instructions on the screen every day for the next three days.

Go to the "Next" screen.

Details" to get more information.



If you are not sure about what dose to take, contact a doctor or nurse.

Decide whether to take a dose.

• Check if it is time for your dose and you know what dose to take.

4

- If you will take a dose now, press **"Yes"**.
- **If** you will not take a dose now, press **"No"**. This will take you back to the main menu.

• Always record your insulin glargine dose in Dose Helper.



Do you want to record a dose now?

If you are not sure about your dose, contact your doctor or nurse.

No

Yes

Press 🕤 to go back to previous screens.

Decide what dose to take.



5

Enter the insulin glargine dose that you will take now.



Or press "Cancel".



Check the dose.

 Check that you will save the correct dose



Save" the

dose

6



Take your insulin glargine dose.

- Take your insulin glargine dose immediately after you have saved vour dose on JAZZ™ DoseCoach®.
- For details about taking insulin glargine, please read the instructions that came with your injection device.



Exit Dose Helper.

8

- Doses not suggested by Dose Helper have a grey background.
- The number of filled sections on the shooting star shows the number of pairs (dose + fasting blood glucose) you have collected.





>> See page 76 for more information about the shooting star.



This page has been left blank on purpose.
Section 5:

REVIEWING YOUR HISTORY DATA

JAZZ[™] DoseCoach[®] keeps your blood glucose readings and other information you enter. You can view this data on graphs and tables in the history. This section shows you how to read your history data.

About your history data

There are four options in the **"History"** menu:

- **Logbook:** lists your blood glucose readings and insulin glargine doses with time and date.
- Fasting BG: three graphs that show your fasting blood glucose (fasting BG) readings and insulin glargine doses over the last 3 days, 7 days and 6 weeks.
- Averages: shows the average and standard deviation (a measure of variability) for different categories of readings taken in the last 7, 14, 30 and 90 days.
- Advanced: this option takes you to the "Advanced" history menu.



There are two options in the **"Advanced"** history menu:

- **Standard day:** this graph shows your before meal and after meal blood glucose readings (breakfast, lunch, dinner) for the last 7, 14 and 30 days, grouped by their tag.
- Dose Helper: lists the doses suggested by Dose Helper and the doses that you saved to Dose Helper.

>> See page 107 for more information on the **"Advanced"** history menu.

>> See page 13 for a list of icons used in the history.

Press 🕤 to go back to previous screens.



Do not

Do not make treatment decisions based on stored blood glucose readings, doses, averages, and graphs. All health-related decisions should be made with guidance from your healthcare professional.



Press 🕤 to go back to previous screens.



Press 🔁 to turn on JAZZ™ DoseCoach®.

- Check the user icon on the start-up screen.
- Never use a JAZZ™ DoseCoach[®] that is not yours.

Select "History".



Choose "History".





Select an option.



3

Choose an option.



Then press

"Select".

More information about the **"History"** menu options is included on the following pages.



Logbook

About the "Logbook"

O Date: any blood glucose readings and insulin glargine doses are shown below the date they were saved on.

b More information: use more information.



>> See page 13 for a list of all blood glucose icons.



Press 🔄 to go back to previous screens.

📒 Logbook				
Today, 26 March				
18:55	*	Units: 32		
12:15	Ó	6.8 mmol/L		
07:31	8	7.6 mmol/L		
Yesterday, 25 March				
19:16	1	Units: 30		
08:09	8	7.4 mmol/L		
Monday 26 March				

Blood glucose readings



This example shows a blood glucose reading entry.

a Time: time of the blood glucose reading. (b) Tag icon: shows the tag selected for the blood glucose reading, in this example the fasting blood glucose tag. **(c)** Blood glucose reading: shows the measured blood glucose.





This example shows an insulin glargine dose entry.

a Time: time of the insulin glargine dose. b Insulin dose icon: shows that an insulin glargine dose was saved.

(c) Units: the number of units of the insulin glargine dose.



Clock changes

🕓 Clock change

This example shows a clock change entry.

- You will see this when the time or date on JAZZ™ DoseCoach® has been changed.
- Entries above the clock change are saved in the new time or date.

>> See page 136 for more information about changing the clock.



High blood glucose readings



This example shows a high blood glucose reading entry.

 Blood glucose readings above your high blood glucose limit are shown with an orange background.



Low blood glucose readings

07:31 🚫 3.6 mmol/L

This example shows a low blood glucose reading entry.

 Blood glucose readings below your low blood glucose limit are shown with a red background.



Hypo symptoms



This example shows an entry of reported low blood glucose or hypo symptoms.

 On days where you had a low blood glucose reading or you reported low blood glucose (below 3.9 mmol/L) or hypo symptoms in Dose Helper, a logbook entry marked with a red triangle is made once for that day.



Severe hypo symptoms



This example shows an entry of reported low blood glucose less than 3.1 mmol/L or severe hypo symptoms. On days where you had a very low blood glucose reading or you reported very low blood glucose (below 3.1 mmol/L) or severe hypo symptoms in Dose Helper, a logbook entry marked with a red triangle is made once for that day. This page has been left blank on purpose.

Fasting blood glucose (Fasting BG)

About "Fasting BG" history

"3 days" shows your fasting blood glucose readings and insulin glargine doses for the last 3 days.

"7 days" shows your fasting blood glucose readings and insulin glargine doses for the last 7 days.

"6 weeks (averages)"

shows weekly averages of your fasting blood glucose readings and of your insulin glargine doses for the last 6 weeks.







Press 🕤 to go back to previous screens.

Press — and — to move between the three graphs.

(a) Colored bubbles or squares: show your fasting blood glucose readings for a day or average fasting blood glucose for a week.

• The color of each bubble or square shows what range the blood glucose reading is in.

>> See page 63 for the different color ranges.

b Blood glucose scale (mmol/L):

the scale is stretched so that blood glucose readings for lower values get more space. To see your exact blood glucose readings, please consult your "Logbook". **C** Green area: shows your fasting blood glucose target range if Dose Helper is turned on.

d Timescale: runs from the starting date (shown on the left) to today (shown on the right).

e Grey bars: show the insulin glargine dose for a day or average dose for a week.

Insulin doses will only be shown if your doctor or nurse has turned Dose Helper on for you and you are entering your insulin glargine dose each day.

Press 🕤 to go back to previous screens.

Hypo triangle

- On days where you had a low blood glucose reading or you reported low blood glucose (below 3.9 mmol/L) or hypo symptoms in Dose Helper, a red triangle is shown once for that day.
- In weeks where you had a low blood glucose reading or you reported low blood glucose (below 3.9 mmol/L). or hypo symptoms in Dose Helper, a red triangle is shown once for that week.
- The number in the triangle is the number of days within that week with a low blood glucose reading, or with reported low blood glucose (measured with another meter), or hypo symptoms.



Note: The hypo triangle can also appear in the 3 and 7 days graphs.

High blood glucose readings above 20.1 mmol/L

 Blood glucose readings above 20.1 mmol/L are marked with an orange circle on the graph and are shown at the same vertical position.

>> See page 63 for the different color ranges.



Multiple doses in one day

• If you see ! on a graph, it means that more than one insulin glargine dose was saved that day.

Only use Dose Helper if you take insulin glargine once daily.



Dose unknown

• If you see ? on a graph, it means you confirmed that you took an insulin glargine dose but that you were unsure about the amount of insulin glargine you took.



Clock change

(a) If you see a zig-zag line on a graph, it means that the time or date was changed.

b The start of the date range is not shown if there has been a time or date change.

Changing the time or date can affect Dose Helper.

>> See page 198 for more details.



Averages

Press 🕤 to go back to previous screens.

About "Averages"

Output State A to a state a constraint of the state a constraint of

number of recent days included in the calculations for averages and standard deviation.

To change the number of days:

Ē

Press "Options".

Then choose the number of days.

"Select".

b Average of all blood glucose readings, or readings with the same tag.

© Standard deviation (±SD) of all blood glucose readings or readings with the same tag.

(d) Shows the tag icon, tag description and the number of blood glucose readings included in the calculation of the average and standard deviation (7 fasting blood glucose readings in this example).

e More information:

Scroll to show more information.



The averages, standard deviations and trend graphs are calculated using the average of all blood glucose readings and all doses within the given time period (7, 14, 30 or 90 days). They do not include the current day in their calculations.

- Blood glucose readings of 33.3 mmol/L or above, and 1.1 mmol/L or below, will be included as values of 33.3 mmol/L and 1.1 mmol/L, respectively.
- Blood glucose readings without a valid time or date, as well as control solution test results,

are not included in averages, standard deviations and trend graphs.

 Missing dose values are not included in averages, standard deviations and trend graphs.

Standard day

Press 🕤 to go back to previous screens.

About the "Standard day" graph

The Standard day graph is accessed from the **"Advanced"** history menu.

(a) Number of days: the number of recent days for which data is shown on the graph.

To change the number of days shown:

Press **"Options"**. Then choose the number of days. Then press **"Select"**.

b The tags are ordered in sequence across the day, from breakfast to lunch

to dinner then before bed For each meal, the before meal and after meal readings are shown in separate columns. The first column shows the fasting and/or before breakfast blood glucose readings. If there are only fasting blood glucose readings, the fasting icon is shown. If there are any before breakfast readings, then the before breakfast icon is shown.

>> See page 13 for a list of all blood glucose icons.



C Orange line: shows your high blood glucose limit.

d Grey dots: show your blood glucose readings.

• When readings overlap, the dots appear darker.

e Red line: shows your low blood glucose limit.

f Before meal tag.

(9) After meal tag.

h Meal name.





Dose Helper history

Press 🕤 to go back to previous screens.

The Dose Helper history is accessed from the "Advanced" history menu.

🚼 Dose Helper					
<u> </u>	Suggest Dose	ed	Taken Dose		
26 Mar	32	U	32	U	
25 Mar	30	U	30	U	
24 Mar	30	U	30	U	
23 Mar	30	U	30	U	
22 Mar	28	U	28	U	
21 Mar	28	U	28	U	
	\sim				

About "Dose Helper"

History



The Dose Helper history shows the suggested dose and the taken (saved) dose for each day you have run Dose Helper or saved a dose. Each row shows:

O Date: the date of the dose entry or entries.

b Suggested dose

(from Dose Helper).

C Taken (saved) dose.

If the taken dose was the same as the suggested dose, it will be shown in blue, as in this example.

Press to show more information.

	Sugges Dose	ted	Taker Dose	
26 Mar	32	U	32	U
25 Mar	30	U	30	U
24 Mar	30	U	30	U
23 Mar	30	U	30	U
22 Mar	28	U	26	U
21 Mar	28	U	28	U

Changed doses

22 Mar 28 U 26 U

If the taken dose was different to the suggested dose, it will be shown in black, as in this example.

Suggest Dose	ted	Taken	
		Dose	
32	U	32	U
30	U	30	U
30	U	30	U
30	U	30	U
28	U	?	U
28	U	28	U
\sim			
	32 30 30 30 28 28 28	32 U 30 U 30 U 30 U 28 U 28 U	32 0 32 30 u 30 30 u 30 30 u 30 28 u ? 28 u 28

Unknown taken doses



Press 🔄 to go back to previous screens.

The ? means you confirmed that you took an insulin glargine dose but that you were unsure about the amount of insulin glargine you took.

🚼 Dose Helper					
<u> </u>	Suggest Dose	ed	Taken Dose		
26 Mar	32	U	32	U	
25 Mar	30	U	30	U	
24 Mar	30	U	30	U	
23 Mar	30	U	30	U	
22 Mar			28	U	
21 Mar	28	U	28	U	
	~				
				.,	

Missing dose suggestions

22 Mar	28	U
--------	----	---

The empty box shows you did not get a dose suggestion from Dose Helper that day.

🚼 Dose Helper					
Suggested Taken Dose Dose					
26 Mar	32 U	32 U			
25 Mar	30 U	30 U			
24 Mar	30 U	30 U			
23 Mar	30 U	30 U			
22 Mar	*	28 U			
21 Mar	×	28 U			
	\sim				

Dose suggestion not possible

22 Mar	*	28	U
--------	---	----	---

The 🗱 icon means that a dose suggestion was not possible that day. For example, Dose Helper did not have enough data to suggest a dose.

>> See page 71 for the information Dose Helper needs to suggest a dose.

📩 Dose Helper					
	Suggest Dose	ted	Taker Dose	1	
26 Mar	32	U	32	U	
👃 Clock change					
25 Mar	30	U	30	U	
24 Mar	30	U	30	U	
23 Mar	30	U	30	U	
22 Mar	28	U	28	U	
	\sim				

Clock changes

ㅅ Clock change

This example shows a clock change entry in the **"Dose Helper"** history.

Changing the time or date can affect Dose Helper.

>> See page 198 for more details.

Section 6:

CHANGING THE JAZZ™ DOSECOACH® SETTINGS

If you need further help after reading these instructions, please contact your healthcare professional, or call customer service at 0800 093 1812.

Accessing the settings menu



Press 🔁 to turn on JAZZ™ DoseCoach®.

- Check the user icon on the start-up screen.
- Never use a JAZZ™ DoseCoach[®] that is not yours.



Press 🕤 to go back to previous screens.

Select an option.

There are eight options in the **"Settings"** menu:

Clock.

3

- Tagging.
- User icon.
- BG limits.
- Volume.
- Language.
- Dose reminder.
- Dose Helper.





These settings are described in more detail on the following pages.



1

The clock setting menu

There are four options in the "Clock" menu:

• **Time:** the current time will be shown.



- Date: the current date will be shown.
- Time format: you can choose between the 24 hour (13:00) or 12 hour (1:00pm) format.
- Date format: you can choose between the day-month-year (26 March, 2019) or month-day-year (March 26, 2019) format.



Press "Select"

to change the settings.

Changes to the time or date may affect Dose Helper.

Check the information recorded on page 1, or ask your doctor or nurse what to do if you travel or change your daily routine.

Changing the Time or Date



Read the message.

- If this message does not appear, go to **Step 2**.
 - Press "OK".

🛕 Clock change

Changing the time or date may affect Dose Helper.

OK

Set the time and date	4.

Set the correct year.

Go to the **"Next"** setting step.

• Repeat this to set month, day, hour and minutes.

"Control of Save" the clock changes at the last setting step.

If you get a **"Clock reset"** message, it means you will need to change the clock again.

Clock		Clock		Clock	
Set the year:		Set the month:		Set the day:	
2019	\$	March 2019	\$	26 Mar, 2019	¢
				Wednesday	
	Next		Next		lovt

Changing the time format

Set the time format.



1

Choose an option.

- 24 hour (e.g. 13:00) or
- 12 hour (e.g. 1:00pm).



"Contractions of the second s

changes.

• Or press • Cancel".



Changing the date format



Changing the usual tag times (fasting and meal times)

What is fasting blood glucose and why is it important?

Fasting blood glucose readings: Fasting blood glucose is measured after sleeping and before breakfast, when you have not eaten or had a drink containing sugar/ glucose for at least 8 hours.

- Your fasting blood glucose readings are used to decide if your insulin dose should be increased or decreased.
- You have to tag, or mark, your readings when they

are fasting. Telling JAZZ™ DoseCoach® which blood glucose readings are fasting is important for Dose Helper.

- The fasting time sets the middle point of a 6-hour fasting window.
- You can tag blood glucose readings as fasting during this 6-hour window.
 However, the fasting tag will only be suggested by JAZZ™ DoseCoach[®] for two hours before and two

hours after your usual fasting time.

- If you adjust the fasting time, all meal times may move based on your fasting time.
- Meal times must be at least two hours apart.
- The dinner time and fasting time must be at least six hours apart.

Changing the usual tag times (fasting and meal times)

C A tag is a description label that you add to The different shaded blocks show the tags that blood alucose readings. JAZZ[™] DoseCoach[®] will suggest across the day. These are based on the usual fasting time and usual meal times that you can change in the settings. 24:00 03:00 06:00 09:00 12:00 No Fasting taa After breakfast Usual fasting time Usual breakfast time (here 07:00) (here 07:30) h Fasting tags will be suggested two hours either side of the usual fasting time. In this example, from 5:00 to 9:00.

Before meal tags will be suggested between two hours before a meal time to one hour after a meal time. In this example, before lunch tags will be suggested from 10:30 to 13:30. Note: These are example values and may not reflect your treatment plan.



Press 🕤 to go back to previous screens.

Select the usual tag time you would like to change.



1

Choose an option.



 Tagging

 Fasting
 07:00

 Breakfast
 07:30

 Lunch
 12:30

 Dinner
 19:00

 Meal times must be at least 2 hours apart.

 Dinner and Fasting must be at least 6 hours apart.

 Select

2 Set the usual time. Change the selected tag time. Save" your 🐨 changes. Or press "Cancel". Breakfast Set your breakfast time: 07:30 Fasting 07.00 Breakfast 07.30 Lunch 12:30 19:00 Dinner Save Cancel
Changing your user icon



Set your user icon.

- You must check the user icon on the start-up screen each time you turn JAZZ™ DoseCoach[®] on.
- Never use a JAZZ[™] DoseCoach[®] that is not yours.





• Or press • Cancel".

The user icons you can choose from are shown below.





Changing the blood glucose (BG) limits

If Dose Helper is turned off, you can set your **"High BG"**, **"General BG target"** and **"Low BG"** limits.

If Dose Helper is turned on, you can only set your **"High BG limit"**.

• The **"Low BG"** and **"General BG target"** limits will be automatically set to default values. Select the BG limit you would like to change.



Press
"Select".



Set the BG limit.



2

Change the blood glucose (BG) limits.



Cancel".

Set your high B	G limit
13.3 mmol/L	

Changing the volume





Changing the dose reminder

If the dose reminder option is turned on by your doctor or nurse, JAZZ™ DoseCoach® will remind you when your dose of insulin glargine is due. It does this by playing a sound.



The dose reminder goes off if you have not used Dose Helper to save a dose by the reminder time.

>> You can also change the dose reminder in the Dose Helper settings menu. See page 133.

1
Set the dose reminder.
Choose when you would like to be reminded to take your dose.
Save" your changes.
• Or press "Cancel".
Dose reminder
Off At dose time (19:00)
30 minutes after (19:30)
1 hour after (20:00)
Cancel Save
Currect Sure

Changing Dose Helper settings



Dose Helper settings.

You can access the Dose Helper settings through the JAZZ™ DoseCoach® settings menu, or from the Dose Helper welcome screen.

There are six options in the **"Dose Helper"** menu:

• **Dose time:** this is the time you usually take your insulin glargine dose.

- Fasting BG rules: you can view these but only your doctor or nurse can change them.
- **Hypo rules:** you can view these but only your doctor or nurse can change them.
- User agreement: here you can re-read the user agreement that you confirmed before using Dose Helper.
- Turn off: this will turn Dose Helper off.





Dose Helper	
Dose time	19:00
Fasting BG rules	
Hypo rules	
User agreement	
Turn off	
Expires: 15 Aug 201	9

Select

Changing the usual dose time

Read the message.

• If this message does not appear, go to **Step 2**.



1

Press "OK".

🛕 Dose time change

Changing your usual dose time may affect Dose Helper. Contact your doctor or nurse before changing your usual dose time.

OK

Set the usual dose time.

Dose Helper can be run three hours either side of your usual dose time.

- Change the dose time.
- changes.

"Save " yo

```
Or press
```

```
"Cancel".
```

Cancel



Save

Changes to dose time may affect Dose Helper. Ask your doctor or nurse what to do if you travel or change your daily routine.

Do



Section 6 — Changing the JAZZTM DoseCoach® settings

Reviewing the "Fasting BG rules"

- These rules describe how Dose Helper calculates a dose increase or decrease suggestion based on your fasting blood glucose (fasting BG or FBG).
- You can view these rules but only your doctor or nurse can change them.

Fasting BG rules	
Fasting BG rules (mmol/L)	
>7.2	+2 Units every 3 days
5.0 - 7.2	FBG target range (no change)
7 of 10 <5.0	-4 Units (10%)

Reviewing the "Hypo rules"

- These rules describe how Dose Helper calculates a dose decrease suggestion if you report low blood glucose (below 3.9 or 3.1 mmol/L), or hypo symptoms.
- You can view these rules but only your doctor or nurse can change them.

Hypo rules

Hypoglycaemia rules

Hypo symptoms or BG < 3.9

-2 Units (5%)

Severe hypo or BG < 3.1

-4 Units (10%)

Reviewing the user agreement



Read the message.



Read the rest of the user agreement.

In the user agreement you can check the type of insulin Dose Helper can be used with.

User agreement

Yes. I have read all the instructions in the manual.

Yes, my doctor... has activated Dose Helper.

 has adjusted Dose Helper to my needs.

Turning Dose Helper off



1

If you want to turn Dose Helper off now, press **"Yes"**.

If you do not want to turn Dose Helper off, press **"No"**.

A Dose Helper off?

Are you sure you want to turn off Dose Helper?

Only your doctor or nurse can turn Dose Helper back on.

Yes

No

Only your doctor or nurse can turn Dose Helper back on. Section 7:

MAINTAINING YOUR JAZZTM DOSECOACH®

If you need further help after reading these instructions, please contact your healthcare professional, or call customer service at 0800 093 1812.

153

Performing a control solution test

Do

- Control solution should only be used for 90 days after first opening the bottle or until the date of expiry printed on the label, whichever comes first.
- You should only use AgaMatrix control solution with JAZZ™ DoseCoach[®].
- Always put the cap on the control solution bottle right after you have used it.
- Do not add water or any other liquid to the control solution.
 - Control solution tests should be performed within the temperature range of 10°C to 40°C.

The control solution is used to:

- Make sure that the AgaMatrix WaveSense JAZZ test strips work with JAZZ[™] DoseCoach[®].
- Practice measuring without having to use your own blood.

Control solution tests should be done when you:

- First get your JAZZ™ DoseCoach®.
- Think your JAZZ[™] DoseCoach[®] or test strips are not working properly.
- Think your readings are inaccurate.
- Have dropped or damaged your JAZZ[™] DoseCoach[®] or got liquids such as water on it.
- Are told by your healthcare professional to do so.



Insert a new AgaMatrix WaveSense JAZZ test strip into the strip port.

• Wash your hands with soap and warm water. Rinse and dry thoroughly before every test.

1

- Insert the test strip with the black side facing up.
- JAZZ[™] DoseCoach[®] will turn on when the test strip is fully inserted.
- You will see this screen when JAZZ™ DoseCoach[®] is ready for the AgaMatrix control solution.

 If you do not apply control solution within 4 minutes of inserting the test strip, JAZZ™ DoseCoach® will turn off. To restart, remove the test strip and reinsert it.

Prepare the AgaMatrix control solution.

- JAZZ[™] DoseCoach[®] has two different levels of control solution:
 - normal or
 - high.

2

- Choose the level of AgaMatrix control solution you want to use.
- Gently swirl the control solution bottle to make sure the control solution is mixed well.

 Put a drop of control solution on a tissue then throw the tissue away. Wipe the tip of the bottle using a clean tissue.

Apply the AgaMatrix control solution.

 Put a second drop of AgaMatrix control solution on a clean surface such as a plastic bag.

3

- Bring the tip of the test strip to the drop of AgaMatrix control solution.
- The test strip fills from the tip.
- The fill window of the test strip will turn blue.

 JAZZ[™] DoseCoach[®] will beep once to tell you when you should remove the tip of the test strip from the drop.



If the fill window on the AgaMatrix WaveSense JAZZ test strip does not completely fill, you may get an inaccurate test result.

Test again with a new test strip and make sure the fill window is completely full. This image will appear on the screen while JAZZ™ DoseCoach® is calculating your test result.

•



View control solution test results.

 The results of the control solution test will be shown on the grey-colored background screen.

4

• Compare the result of your control solution test to the range printed on the test strip vial label.



- Make sure you look at the control solution level (normal or high) that you used when you compare the results. Your control solution test result should fall within this range.
- If your control solution test results are out of this range, repeat the test.

Results from control solution tests do not give you information about your blood glucose level.

- The control solution range is a target range for control solution only.
- It is not a target range for your blood glucose level and will not be shown with your blood glucose readings in the history.

Control solution checks

Out of range test results may be due to:

- Out of date or faulty control solution.
- Out of date or faulty test strip.
- Mistake in performing a test.
- Watered-down control solution.
- The JAZZ[™] DoseCoach[®] is not working properly.
- The control solution test was done outside the temperature range of 10°C to 40°C.
- Not mixing the control solution enough before using.
- Not throwing away the first drop of control solution and wiping the bottle tip clean.

If the results from the control solution tests continue to be out of range, do not use JAZZ™ DoseCoach[®] to test your blood glucose. Call customer service at 0800 093 1812.

Important disinfection procedures

- When using JAZZ[™] DoseCoach[®], avoid getting dirt, dust, blood, control solution, water, or any other liquid inside the test strip port, battery compartment and mini-USB port.
- You should clean and disinfect JAZZ[™] DoseCoach[®] once a week. Disinfecting will kill bacteria and viruses that you cannot see.
- If JAZZ[™] DoseCoach[®] is being used by a second person who is caring for the patient, JAZZ[™] DoseCoach[®] and the lancing device should be cleaned and disinfected before they are used by the second person.
- To clean the lancing device cap, take the cap off, wash it in warm water, rinse well and dry.

Do

- ✓ Be careful when cleaning and disinfecting JAZZ[™] DoseCoach[®].
- Avoid getting liquid inside the test strip port and mini-USB port.

Do not



✓ Do not immerse JAZZ™ DoseCoach[®] or the body of the lancing device in water or any other liquid solution.

Cleaning and disinfecting JAZZ™ DoseCoach[®] and the lancing device

See the table below for the validated disinfecting wipe. Other brands of wipes have not been tested and may cause cosmetic damage to JAZZTM DoseCoach[®] and the lancing device.

EPA	Brand Name	Manufacturer	Available at	Contact time
9480-4*	Super Sani Cloth Germicidal Disposable Wipes	Professional Disposables International, Inc. (PDI)	Online: Amazon.com Officedepot.com	2 minutes

*Active ingredient: Quaternary ammonium chlorides and isopropanol.

Note: Availability of disinfecting wipe may vary. For updated information, call customer service at **0800 093 1812**



1

- Make sure JAZZ[™] DoseCoach[®] is turned off.
- Before you clean and disinfect JAZZ™ DoseCoach[®] and the lancing device, pre clean the outside of JAZZ™ DoseCoach[®]



and the lancing device with a disinfecting wipe.

2

Clean and disinfect with a new wipe.



- Use a new disinfecting wipe listed in the table on page 162.
- Follow the instructions on the disinfecting wipe container label for safe handling of the wipes.



 Wipe each side of JAZZ[™] DoseCoach[®] and the lancing device with moderate pressure using the following method:

 Wipe up and down three times.
 Wipe left and right three times.

 Avoid getting disinfectant inside the test strip port and the mini-USB port.

Let the disinfectant take effect.

3



 Wash your hands thoroughly with soap and water after handling JAZZ™ DoseCoach®, the lancet, lancing device and test strips. If you have any questions about cleaning and disinfecting JAZZ™ DoseCoach® or the lancing device, call customer service at 0800 093 1812

 After 2 minutes of contact time, let JAZZ[™] DoseCoach[®] and the lancing device air dry. If you suspect JAZZ™ DoseCoach® is not working properly after cleaning and disinfecting, check that your system is working properly by performing a control solution test.

>> See page 154 for performing a control solution test.

Note: The disinfection instructions in this section were validated for 260 cleaning and disinfecting cycles, for a total of 520 wipes (260 cleaning wipes plus 260 disinfecting wipes) on JAZZ™ DoseCoach® and the lancing device. The life of the JAZZ™ DoseCoach® Blood Glucose Meter, defined as 5,000 test strip insertions, is between 3 to 5 years, depending on use. The number of cleaning and disinfecting wipes used simulates cleaning and disinfecting JAZZ™ DoseCoach® once a week for 5 years. Stop using JAZZ™ DoseCoach® or the lancing device after cleaning and disinfecting in the following cases:

- If you notice any signs of deterioration (such as clouding on the JAZZ[™] DoseCoach[®] display, corrosion or erosion of JAZZ[™] DoseCoach[®] and the lancing device plastic housing, or cracking of plastic housing, display or buttons).
- If JAZZ[™] DoseCoach[®] does not turn on.
- If the lancing device does not work after cleaning and disinfecting.

In these cases, call customer service at 0800 093 1812

Looking after JAZZ[™] DoseCoach[®]

- To help stop JAZZ[™] DoseCoach[®] from getting damaged, always keep it in the carrying case when you are not using it.
- Do not drop JAZZ™ DoseCoach[®].

If you think JAZZ™ DoseCoach® may be damaged, do not use it. Call customer service at 0800 093 1812 1

Changing your JAZZ™ DoseCoach[®] batteries

Remove the battery door.

- JAZZ[™] DoseCoach[®] comes with two primary (nonrechargable) AA lithium batteries. Changing the batteries will not cause JAZZ[™] DoseCoach[®] to lose any data.
- JAZZ[™] DoseCoach[®] also has an internal coin cell battery. As long as this coin cell battery has not reached the end of its lifetime, changing the batteries will not cause JAZZ[™]

DoseCoach® to lose the clock time.

 Slide open the battery door on the back of JAZZ[™] DoseCoach[®].



Change the batteries.

 To remove the used primary (nonrechargable) AA lithium batteries, use a non-metallic tool at the positive (+) end to pop out the batteries. Only use AA lithium batteries in your JAZZ™ DoseCoach®.

Discard batteries according to your local environmental regulations.

>> See page 170 for discarding batteries.

Discarding your JAZZ[™] DoseCoach[®] and batteries

- JAZZ[™] DoseCoach[®] is an electronic device. When you discard JAZZ[™] DoseCoach[®] you should follow all local environmental regulations.
- JAZZ[™] DoseCoach[®] also has an internal coin cell battery. When this battery runs out Dose Helper will come to the end of its lifetime.
- This battery should only be removed when JAZZ[™] DoseCoach[®] is ready to be discarded.

Remove the coin cell battery before discarding.

- Slide open the battery door on the back of JAZZ™ DoseCoach[®].
- Open the coin cell battery cover using a screwdriver and remove the coin cell battery.
- Discard the battery according to your local environmental regulations.



Section 8:

QUESTIONS AND ANSWERS ON JAZZ™ DOSECOACH®

If you need further help after reading these instructions, please contact your healthcare professional, or call customer service at 0800 093 1812.

General questions and answers on JAZZ[™] DoseCoach[®]

What happened	What this could mean and what to do
JAZZ™ DoseCoach® does not turn on when you press ᡨ.	The JAZZ [™] DoseCoach [®] batteries have insufficient power. Change the batteries (see page 168). OR: The JAZZ [™] DoseCoach [®] batteries are not installed or are installed incorrectly. Check that both batteries are installed correctly. OR: JAZZ [™] DoseCoach [®] may be damaged. Call customer service at 0800 093 1812
When turning on JAZZ™ DoseCoach®, areas of the start-up screen appear to be missing.	Compare your start-up screen with the ones shown on page 29 Do not use JAZZ™ DoseCoach® and call customer service at 0800 093 1812 if any areas of the start-up screen appear to be missing.
Low battery warnings are shown soon after you change the batteries.	You may be using Alkaline or other non-lithium batteries. Replace the batteries with two new AA lithium batteries (see page 168).

What happened	What this could mean and what to do
The history shows no information.	You may have just started using JAZZ [™] DoseCoach [®] and have not collected enough information. Measure your blood glucose and use Dose Helper (if turned on). The history will fill automatically. OR : You may not have tagged your blood glucose readings. Some of the history only show tagged blood glucose readings. Use the tag function when measuring your blood glucose and the history will fill automatically. OR : The meter has been activated for a different type of insulin. This would happen if you were given a different prescription by your healthcare professional from the one you used before.

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Section 9:

BLOOD GLUCOSE METER MESSAGES

If you need further help after reading these instructions, please contact your healthcare professional, or call customer service at 0800 093 1812.

Questions and answers on measuring your blood glucose

What happened	What this could mean and what to do
JAZZ™ DoseCoach® does not enter test mode after inserting an AgaMatrix WaveSense JAZZ test strip.	The JAZZ [™] DoseCoach [®] batteries have insufficient power or are installed incorrectly. Check both batteries are installed correctly or replace the batteries (see page 168). OR: The test strip has not been inserted fully, or has been inserted upside down or the other way around. Remove the test strip from the strip port. Reinsert the test strip with the black side up so the contact bars are inserted into the strip port (see page 52). Ensure that the test strip is fully inserted. OR: Your test strip may be damaged. Measure your blood glucose with a new test strip. Check the expiration date of your test strips. OR: JAZZ [™] DoseCoach [®] may be damaged, or blood or foreign objects have been put into the strip port. Call customer service at 0800 093 1812. Have the JAZZ [™] DoseCoach [®] serial number (located on the back of JAZZ [™]

Blood Glucose Meter error messages

JAZZ[™] DoseCoach[®] might show error messages after you have measured your blood glucose, or warning messages about your insulin treatment. This section gives information about the Blood Glucose Meter error messages. If you see a message, read it carefully and follow the instructions.

In certain cases, JAZZ[™] DoseCoach[®] may return an error code or provide an inaccurate blood glucose reading if it is being used near electrical equipment, like a power generator or a computer monitor. If this is the case, move JAZZ[™] DoseCoach[®] away from the source of electrical interference.

Error messages and what to do



If this message appears the moment the test strip is inserted, the test strip may be wet or damaged. Measure your blood glucose with a new test strip (see page 50). **OR:** If this message appears during a test, the test strip may have been removed too early. Measure your blood glucose again with a new test strip (see page 50). **OR:** If this message appears after the calculation animation instead of a blood glucose reading, it may mean that you applied more blood after testing began. Measure your blood glucose again with a new test strip (see page 50).


The test strip may be partially filled. You should check the window of the test strip to make sure that it is full. Measure your blood glucose again with a new test strip. Ensure that enough whole blood is applied to the test strip when measuring again (see page 50). **OR:** The sample may not be blood or control solution. Measure your blood glucose again with a new test strip. Make sure the test site is clean before measuring your blood glucose and that the control solution bottle tip is wiped clean before performing a control solution test.



The test strip may have been improperly stored (for example, in hot or humid conditions) or may have expired. Check the test strip vial for the expiry date. Do not use test strips after the expiry date or 180 days after first opening the vial. You may need to measure your blood glucose again with a new test strip from a new vial of test strips.

OR: The test strip may have been mishandled by vigorous bending or shaking. Measure your blood glucose again with a new test strip (see page 50). **OR:** Parts of the test strip may have become covered in grease, oil or lotion. Measure your blood glucose again with a new test strip (see page 50).

OR: The test strip port connector may be dirty. Call customer service at 0800 093 1812. Have the JAZZ[™] DoseCoach[®] serial number (located on the back of JAZZ[™] DoseCoach[®]) available.

Error 4	The meter was unable to produce a result or unusual test strip problems have occurred that may be related to extreme conditions. This error may be caused by extremely high blood glucose. If you have symptoms of hyperglycaemia, contact your healthcare professional right away. Measure your blood glucose again where it is closer to a room temperature of 21°C to 24°C. If this error code persists on retesting, contact your healthcare professional.
Error 5	This may be caused by a non-blood sample or a combination of high glucose and other medical conditions (see page 39). Measure your blood glucose again. OR: If this error code persists on measuring again, contact your healthcare professional.

Error 6	This may be caused by a combination of cold operating temperature and high haematocrit levels. Measure your blood glucose again in a warmer location. OR: If this error code persists on measuring again, call customer service at 0800 093 1812. Have the JAZZ [™] DoseCoach [®] serial number (located on the back of JAZZ [™] DoseCoach [®]) available.
Error 7	A problem has occurred related to the meter hardware. Call customer service at 0800 093 1812. Have the JAZZ™ DoseCoach® serial number (located on the back of JAZZ™ DoseCoach®) available.



A problem has occurred related to the meter hardware. This may be caused by connecting a mini-USB cable to the meter while testing. Disconnect the cable and measure your blood glucose again.

OR: If this error code persists on measuring again, call customer service at 0800 093 1812. Have the JAZZ[™] DoseCoach[®] serial number (located on the back of JAZZ[™] DoseCoach[®]) available.





Move to an area with an ambient temperature of 10°C to 40°C. Wait for JAZZ[™] DoseCoach[®] and test strips to reach the new temperature (usually 10 to 20 minutes) and measure again.

Questions and answers on tagging a blood glucose reading

What is fasting blood glucose and why is it important?

Fasting blood glucose readings:

Fasting blood glucose is measured after sleeping and before breakfast, when you have not eaten or had a drink containing sugar/glucose for at least 8 hours.

- Your fasting blood glucose readings are used to decide if your insulin dose should be increased or decreased.
- You have to tag, or mark, your readings when they are fasting.
 Telling JAZZ[™] DoseCoach[®] which blood glucose readings are fasting is important for Dose Helper.

The fasting blood glucose tag is not available (greyed out).



What this means and what to do

You can only use the fasting tag within three hours either side of your usual fasting time.

(1) Check if this is really a fasting blood glucose reading. If not, choose a different tag.

(2) Check if the fasting time fits your daily routine. Change the fasting time settings if needed.

>> See page 140 for changing the usual tag times (fasting and meal times).

"Seek guidance" messages and what to do

What happened	What this means and what to do
A Seek guidance	You had a blood glucose (BG) reading less than 3.1 mmol/L. Contact your healthcare professional before your next dose - they may want to adjust your treatment plan.
A Seek guidance	You had three or more hypos or low blood glucose readings in the last three weeks. Contact your healthcare professional – they may want to adjust your treatment plan.
Fasting BG above target range	Your recent fasting blood glucose readings were above the fasting blood glucose (BG) target range. Use Dose Helper to get suggestions for adjusting your insulin glargine dose. >> See page 99 for getting dose suggestions again.

Section 10:

QUESTIONS AND ANSWERS ON DOSE HELPER

If you need further help after reading these instructions, please contact your doctor or nurse, or call customer service at 0800 093 1812.

General questions and answers on Dose Helper

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You forgot to take your dose (and did not run Dose Helper).

What this means and what to do

(1) If you are not sure about what to do or what dose to take, contact your doctor or nurse.

2 If you will take a dose now, run Dose Helper:

- If Dose Helper is available (within usual dose time range), run through the Dose Helper steps as usual.
- If Dose Helper is unavailable (outside usual dose time range), record this dose information.



Dress **"Yes"** to the **"Record dose**" question to record a dose.

You ran Dose Helper and saved the dose, but you forgot to take the suggested dose.

What this means and what to do

1 If you are not sure about what to do or what dose to take, contact your doctor or nurse.

(2) If you will take a dose now, run Dose Helper to record this dose information.

Do you want to record a dose now?
lf you are not sure about your dose, contact your doctor or nurse.
No Ye

Press **"Yes"** to the **"Record**

lose" question to record a dose.

What happened	What this means and what to do	
You took a dose without running Dose Helper.	(1) Run Dose Helper when it's time for your next insulin glargine dose. You will be able to enter any recent doses at this time by answering the previous dose question (see page 94).	
You are running Dose Helper, but you are planning to take a dose that is different to the suggested dose (for example because your doctor or nurse told you to).	① Follow the steps on page 96 to enter the changed dose.	
You have or have had hypo symptoms, but Dose Helper is not available to report them.	 If you are experiencing hypo symptoms now, follow your treatment plan or contact your doctor or nurse right away. Run Dose Helper when it is time for your next insulin glargine dose (usual dose time). You will be able to enter any recent hypo symptoms at this time (see page 92). 	

Dose reminder went off but you already took your dose.

What this means and what to do

1 The dose reminder goes off if you have not used Dose Helper to save a dose by then.

• If you already took your dose but did not use Dose Helper, do not run Dose Helper now. Instead, remember to run Dose Helper just before you take your next dose. You will be able to enter any recent doses at this time.

Dose reminder goes off at an unexpected time.

What this means and what to do

Dose reminder is normally set by your doctor or nurse to go off 30 minutes after your usual dose time. The reminder only goes off if you have not already used Dose Helper to save a dose.

(1) Check if the usual dose time fits your daily routine. Change the usual dose time settings if needed (see page 148).

Do

Take your dose at the usual time as instructed by your doctor or nurse. Contact your doctor or nurse before changing your usual dose time.

Check if the dose reminder time fits your daily routine. Change the dose reminder settings if needed (see page 146).

(3) Check the clock time. Change the clock settings if needed (see page 137).

Sick days, travel or vacation, changes in diet or activity

What happened	What this means and what to do
You have a sick day.	Follow your doctor's advice on how to manage your diabetes on sick days. If you are not sure what to do or what dose to take, contact your doctor or nurse. Sick days can cause changes in your blood glucose. Dose Helper cannot plan ahead for sudden changes, such as sick days.
You are planning to travel or to go on vacation to a different time zone.	Contact your doctor or nurse before you travel or go on vacation to get advice on how to manage your diabetes during this time. Dose Helper cannot plan ahead for sudden changes, such as travel and vacation. When you arrive at your travel destination, change the time and date on your JAZZ™ DoseCoach® to the new local time before measuring your blood glucose or running Dose Helper.

You had a sudden change in your diet or activity.

What this means and what to do

If you are making significant changes to your diet or level of activity, contact your doctor to get advice on how to manage your diabetes during this time. Sudden changes in diet or your activity can cause changes in your blood glucose. Dose Helper cannot plan ahead for sudden changes, such as changes to your diet or activity.

"Dose Helper unavailable" warnings

What happened What this means and what to do You tried to run Dose Helper outside of your usual dose Dose Helper unavailable time range. You can only run Dose Helper within three It is not time for a hours either side of your usual dose time. dose suggestion. Dose Helper can be (1) Check if the clock time on JAZZ™ DoseCoach® is set run at vour usual dose correctly. Set the clock to the correct local time if needed time around 19:00 (between 16:00 and (see page 137). 22:00). (2) Check if the usual dose time fits your daily routine. Change the usual dose time settings if needed (see Next page 148). Do Take your dose at the usual time as instructed by your doctor or nurse. Contact your doctor or nurse before changing your usual dose time. (3) If you decide to take a dose now, use Dose Helper to save the dose you decide to take (see page 90). If you are not sure what to do or what dose to take, contact your doctor or nurse.



It is less than 18 hours since your last dose:



9 Yesterday 25 Mar 2019

Next

What this means and what to do

You tried to run Dose Helper when your last dose was less than 18 hours ago. You can only run Dose Helper at least 18 hours after your last dose, and within three hours either side of your usual dose time. Taking two doses too close together may cause low blood glucose.

(1) If you decide to take a dose now use Dose Helper to save the dose you decide to take (see page 90). If you are not sure what to do or what dose to take, contact your doctor or nurse.

"More information needed" messages

What happened	What this means and what to do
 More information needed Dose Helper works best if you: measure your fasting BG every day use Dose Helper every day 	You have not collected fasting blood glucose (BG) readings or insulin doses every day. Dose Helper cannot increase your suggested dose if you have not collected three of the last four fasting blood glucose readings and the insulin dose that you took each day. Dose Helper can still suggest increases if you missed measuring your fasting blood glucose on one day out of four, as long as you entered your insulin dose for all days. This may delay your treatment. (1) To have enough information for a possible increase: • Measure your fasting blood glucose every day. • Use Dose Helper every day. >> See page 76 for details about how Dose Helper suggests a dose.

"Dose suggestion not possible" warnings

When you receive a **"Dose suggestion not possible"** warning, do the following:

(1) If you are not sure about what to do or what dose to take, contact your doctor or nurse.

Obse Helper needs three fasting blood glucose readings from the last three days and the insulin dose that you took each day before giving you dose suggestions again on day 4. In these three days:

- Measure your fasting blood glucose every day.
- Run Dose Helper and enter your insulin glargine dose every day.

>> See page 99 for getting dose suggestions again.



Dose Helper needs more fasting BG and/or dose information.

What this means

Dose Helper cannot suggest a dose because you have not collected enough fasting blood glucose (BG) readings or insulin doses. Dose Helper needs a minimum amount of fasting blood glucose readings and the insulin dose that you took before each fasting blood glucose reading to give suggestions (see page 76).

Dose Helper needs to gather **new** fasting blood glucose readings and insulin doses in order to give suggestions again.

You recently took a dose outside your usual dose time of 19:00* (16:00* to 22:00*).

*These are example times and may not reflect your treatment plan.

What this means

Dose Helper cannot suggest a dose because you took a dose outside the usual dose time. If the usual dose time does not fit your daily routine you can change it in the settings menu.

Do



Take your dose at the usual time as instructed by your doctor or nurse. Contact your doctor or nurse before changing your usual dose time.

Dose Helper needs to gather **new** fasting blood glucose readings and insulin doses in order to give suggestions again.

>> See page 148 for changing the usual dose time.

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What happened	What this means	
2 doses taken less than 18 hours apart.	Dose Helper cannot suggest a d two doses within 18 hours. Takin together may cause low blood of Helper. Dose Helper needs to gather ne readings and insulin doses in or again.	ose because you took ng two doses too close glucose and affects Dose w fasting blood glucose der to give suggestions
You changed the clock time and/or your usual dose time significantly.	Dose Helper cannot suggest a d You changed your clock time by OR: You changed your usual dos three hours. OR: You changed your clock time and the usual dose time. The combined change is more than three hours. Dose Helper needs to gather new fasting blood glucose readings and insulin doses in order to give suggestions	ose because: more than three hours. se time by more than Changes to dose time may affect Dose Helper. Ask your doctor or nurse what to do if you travel or change your daily routine.

_	
lper	What happe
s and answers on Dose Hel	You changed dose.
Section 10 — Questio	Dose Helper restart if you recently hac or hypo sym

at happened	What this means
ı changed your se.	Dose Helper cannot suggest a dose because you took different doses from the suggested dose. Dose Helper needs a minimum amount of fasting blood glucose readings and insulin doses. These insulin doses need to be at a consistent dose. Dose Helper needs to gather new fasting blood glucose readings and insulin doses in order to give suggestions again.
se Helper cannot tart if you ently had low BG nypo symptoms.	Dose Helper cannot restart because you recently had a low blood glucose (BG) reading less than 3.9 mmol/L or you reported low blood glucose (measured with another meter), or hypo symptoms. Dose Helper needs to gather new fasting blood glucose readings and insulin doses in order to give suggestions again.

What happened	What this means
Dose Helper cannot restart if you recently had BG below your fasting BG target range.	Dose Helper cannot restart because you recently had two or more fasting blood glucose (BG) readings below your fasting blood glucose target range. Dose Helper needs to gather new fasting blood glucose readings and insulin doses in order to give suggestions again.
Your recent taken doses have been consistently higher than suggested doses. Talk to your doctor or nurse about continued use of Dose Helper.	The recent doses you entered into Dose Helper were too far above the dose that Dose Helper suggested. Dose Helper needs to gather new fasting blood glucose readings and insulin doses in order to give suggestions again.

What happened	What this means
Dose Helper cannot restart unless you consistently take the same dose.	Dose Helper cannot restart because you recently entered differing doses. Dose Helper needs a minimum amount of fasting blood glucose readings and insulin doses at the same daily dose in order to give suggestions (see page 76). Dose Helper needs to gather new fasting blood glucose readings and insulin doses in order to give suggestions again.
Dose information was missing when the clock was changed. This information cannot be interpreted.	You recently changed your clock time while some previous dose information was missing. Missing doses, or doses entered in the previous dose questions, cannot be reliably interpreted after a clock change. Dose Helper needs to gather new fasting blood glucose readings and insulin doses in order to give suggestions again.

"Seek guidance" warnings

When you see a **"Seek guidance"** warning, contact your doctor or nurse.

Press **"OK"** to confirm the warning.

Press **"Details"** to get more information.



nurse.

Details OK

lper	What happened	What this means
Jose He	You had very low BG.	You had a blood g 3.1 mmol/L.
nd answers on	You had very low BG or hypo symptoms needing help.	You had a blood g 3.1 mmol/L or you (measured with a needing help from may want to adju
lestions a	You had frequent low BG.	You had three or r readings less than Your doctor or nur
n 10 — Qu	Your dose is low.	Your suggested da number of units. Y adjust your treatn
Section	Your fasting BG is not decreasing as expected.	Your fasting blood above your fasting not come down e doctor or nurse m

vnat nappenea	what this means
ou had very low BG.	You had a blood glucose (BG) reading less than 3.1 mmol/L.
ou had very low BG r hypo symptoms eeding help.	You had a blood glucose (BG) reading less than 3.1 mmol/L or you reported very low blood glucose (measured with another meter), or hypo symptoms needing help from another person. Your doctor or nurse may want to adjust your treatment.
ou had frequent ow BG.	You had three or more hypos or blood glucose (BG) readings less than 3.9 mmol/L in the last three weeks. Your doctor or nurse may want to adjust your treatment
our dose is low.	Your suggested dose has gone below a minimum number of units. Your doctor or nurse may want to adjust your treatment.
our fasting BG is ot decreasing as xpected.	Your fasting blood glucose (BG) readings have been above your fasting blood glucose target range and have not come down enough over the past month. Your doctor or nurse may want to adjust your treatment.

What happened	What this means
Dose Helper will turn off if your dose reaches 200 Units.	You have almost reached the maximum dose that Dose Helper can suggest for you. Dose Helper will stop suggesting doses when you reach the maximum dose limit. Your doctor or nurse may want to adjust your treatment.
You may need a dose reduction, but Dose Helper does not have enough information.	You had a blood glucose reading less than 3.9 mmol/L or you reported low blood glucose (measured with another meter), or hypo symptoms. Your doctor may want to adjust your treatment.

"Dose Helper off" warnings

When you see a **"Dose Helper off"** warning, do the following:

(1) If you are not sure about what to do or what dose to take, contact your doctor or nurse.

(2) To use Dose Helper it must be turned on by your doctor or nurse.

Go to the "Next"



🛕 Dose Helper off

If you are not sure about your dose, contact your doctor or nurse.

Talk to your doctor or nurse about turning on Dose Helper for dose suggestions.

OK

screen.



What happened	What this means
Dose Helper has not been turned on.	Your doctor or nurse has not turned Dose Helper on for you.
You did not provide Dose Helper with enough information.	You have not used Dose Helper to get a dose suggestion in the last 30 days.
Dose Helper activation has expired.	During Dose Helper setup your doctor or nurse will set an expiry date for your treatment plan. After this period, Dose Helper activation expires. It can be renewed by your doctor or nurse.
You reached the maximum dose amount.	You reached the maximum dose that was set by your doctor or nurse. Contact your doctor or nurse.
Your dose went too low.	You reached the minimum dose. Contact your doctor or nurse.

What happened	What this means
You turned off Dose Helper.	You or your doctor or nurse turned off Dose Helper.
Dose Helper is	You indicated to Dose Helper that you switched to
only for use with	multiple dosing. Dose Helper can only be used with
once-daily insulin	insulin glargine taken once-daily.
glargine.	Contact your doctor or nurse.
There was a problem	Dose Helper was disabled. JAZZ™ DoseCoach® may have
while using Dose	lost power or it may have been dropped.
Helper.	Contact your doctor or nurse.

"Dose Helper interrupted" warning



"Back button unavailable" warning

What happened	What this means
Sorry, you can't go back To leave Dose Helper, press "Exit". Restart Dose Helper if you wish.	You pressed the back button when Dose Helper was unable to go back in dose calculations. If you need to enter missing hypo or dose information you should restart Dose Helper.
	Press "OK" to continue in Dose Helper.
Exit OK	▶ Press "Exit" to leave Dose Helper. Use ★ to restart Dose Helper.
	Dose Helper will start from the beginning and allow you to add information (for example, hypos or previous doses). You cannot change or delete information that you saved before.
	If you are not sure about what dose to take, contact your doctor or nurse.

Expiration warnings

What happened	What this means
Expiring activation Dose Helper activation expires in 27 days. Talk to your doctor or nurse about renewing your Dose Helper activation.	During Dose Helper setup your doctor or nurse will set an expiry date for your treatment plan. After this period, Dose Helper activation expires. It can be renewed by your doctor or nurse.
Expiring Dose Helper Dose Helper is reaching the end of its life. Talk to your doctor or nurse about getting a new device. Details Next	JAZZ [™] DoseCoach® has an internal coin cell battery. This battery will run empty shortly. Dose Helper will expire then and can no longer be used or activated. JAZZ [™] DoseCoach® can continue to be used for measuring blood glucose. Talk to your doctor or nurse about getting a new JAZZ [™] DoseCoach®.

What this means

Dose Helper expired

Dose Helper can no longer be used because it has reached the end of its lifetime.

The device can still be used as a blood glucose meter.

OK

JAZZ[™] DoseCoach[®] has an internal coin cell battery. This battery has run empty. Therefore, Dose Helper has expired and can no longer be used or activated. JAZZ[™] DoseCoach[®] can continue to be used for measuring blood glucose.

Talk to your doctor or nurse about getting a new JAZZ™ DoseCoach®.
At and out of fasting blood glucose target messages

What happened Hoorav! Most of your recent fasting BG readings were below your upper fasting BG target limit of 7.2 mmol/L. Next Dose Helper will not suggest any further increases unless most of your fasting BG readings go above your upper fasting BG target limit of 7.2 Nex

What this means

Your fasting blood glucose (BG) readings have been consistently within your fasting blood glucose target range.

Dose Helper should still be used but no further dose increases will be suggested unless your fasting blood glucose regularly goes out of fasting blood glucose target.

When using Dose Helper and saving doses, the in fasting blood glucose target star will be shown instead of the shooting star. The star is filled when the most recent pair (dose + fasting blood glucose) has been collected.

What happened

What this means

Fasting BG above target range

Your fasting BG has gone above your fasting target range.

Use Dose Helper to help you get back in range.



Your recent fasting blood glucose (BG) readings were above the fasting blood glucose target range.

(1) Use Dose Helper to get suggestions for adjusting your insulin glargine dose.

>> See page 99 for getting dose suggestions again.

Section 11:

JAZZ[™] DOSECOACH[®] SPECIFICATIONS

If you need further help after reading these instructions, please contact your healthcare professional, or call customer service at 0800 093 1812.

JAZZ[™] DoseCoach[®] specifications

Assay method: dynamic electrochemistry.

Maximum altitude: 10,000 feet (3,048 meters).

Calibration: plasma equivalent.

Coding: no code.

Sample: whole blood, capillary.

Sample size: 0.5 microliters.

Average glucose test time: 5 seconds.

Measurement units: mmol/L.

Result range: 1.1 to 33.3 mmol/L.

Haematocrit: 20% to 60%.

Operating relative humidity: 25% to 90%.

Operating temperature: 10°C to 40°C.

Control solution storage temperature: 2° C to 30° C.

Test strip storage temperature: 8°C to 30°C.

Dose reminder: programmable alarm.

Power source: two replaceable primary AA lithium batteries and one nonreplaceable coin cell battery. If the coin cell battery runs out, Dose Helper expires and cannot be used anymore.

Size: 11 cm × 6 cm × 2.5 cm. (4.3" × 2.4" × 1") **Weight:** 100g (3.5oz) including batteries. Equipment not suitable for use in the presence of flammable mixtures.

This JAZZ[™] DoseCoach® complies with the applicable standards for Electromagnetic Compatibility; however it is not recommended that it be used in the presence of strong electromagnetic fields.

When using JAZZ[™] DoseCoach®, keep away from sources of electromagnetic disturbances such as electric motors, mobile phones, computer monitors or radio transmitting equipment.

JAZZ[™] DoseCoach[®] should not affect the normal operation of other devices. If this does occur, provide more distance

between JAZZ™ DoseCoach® and the affected device.

SEGGER is a licensor of the JAZZ™ DoseCoach[®] software.

The meter is verified as giving "plasma equivalent" glucose readings, which are traceable to a primary calibrator.

JAZZ™ DoseCoach® Performance Results

N= 600

Range of reference values: <1.68 to 29.1 mmol/L

Finger stick summary of system accuracy results for glucose concentrations <5.5 mmol/L:

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
113/180 (62.8%)	162/180 (90.0%)	180/180 (100.0%)

Finger stick summary of system accuracy results for glucose concentrations ≥5.5 mmol/L:

Within ± 5%	Within ± 10%	Within ± 15%
200/420 (47.6%)	351/420 (83.6%)	401/420 (95.5%)

Summary of total number of acceptable results per EN ISO 15197:2015

Total (percent)	Acceptance criterion of 95% within ± 0.83 mmol/L and within ± 15%
581/600 (96.8%)	Meets Criterion

All results were within the clinically acceptable A and B zones of the Parkes Error Grid with 100% falling within zone A.

Precision:

The repeatability of the test strips and meter was evaluated with blood samples and control solution in the laboratory.

Repeatability (Within Run)

Blood	Level 1	Level 2	Level 3	Level 4	Level 5
Average, mmol/L	2.0	4.9	7.0	12.4	21.4
SD, mmol/L	0.13	0.18	0.20	0.32	0.62
CV, %	N/A	3.7	2.8	2.6	2.9

Intermediate precision (Day to Day)

Control	Low (Level 1)	Normal (Level 2)	High (Level 4)
Average, mmol/L	3.1	7.2	17.7
SD, mmol/L	0.11	0.24	0.72
CV, %	N/A	3.3	4.1

Accuracy for Lay Users:

A study evaluating glucose values from fingertip capillary blood samples obtained by 101 lay persons showed the following results:

94.1% within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.5 mmol/L, and 98.8% within 15% of the medical laboratory values at glucose concentration at or above 5.5 mmol/L.

Symbols used on packaging



Serial Number: a unique number that belongs to your JAZZ™ DoseCoach®.



Manufacturer.



] In Vitro Diagnostic Medical Device.



Batch code.



Consult instructions for use.



Do not reuse.

10°C 4°C Temperature limitation: store at a temperature above 8°C and below 30°C.





Catalogue number.

EC REP

European Authorised Representative. This page has been left blank on purpose.

