

# AgaMatrix®

## JAZZ™ ★ DoseCoach®

### GUIDE FOR DOCTORS AND NURSES

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DOSE HELPER ACTIVATION KEYS  
AND PATIENTS' HISTORY DATA



**CAUTION: Please read all the instructions provided in this guide for doctors and nurses.**

Customer Service: **0800 093 1812**



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8100-10400 Rev A

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## Section 1:

# KEY INFORMATION ABOUT JAZZ™ DOSECOACH®

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

## Introduction

This guide for doctors and nurses shows you step-by-step how to activate the Dose Helper function on your patient's JAZZ™ DoseCoach®.

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

It also gives you a summary of the key information that is explained in more detail throughout this guide for doctors and nurses, and the 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 this guide for doctors and nurses, or the owner's guide, to help you.

## JAZZ™ DoseCoach® – key information

JAZZ™ DoseCoach® can help your patients manage their Type 2 diabetes in two ways:

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

>> See page 30, Section 3 “About the activation keys” for more information about the treatment plan activation keys.



Dose Helper can be activated for use with insulin glargine 100 Units/mL (U-100).

Use the correct treatment plan activation key for the type of insulin you would like your patient to use with JAZZ™ DoseCoach®.

## Key terms used in this guide

These pages contain some useful definitions of terms that are used in this guide for doctors and nurses.

- **JAZZ™ DoseCoach®:** this is the name of the device.
- **Blood Glucose Meter:** the JAZZ™ DoseCoach® function that measures your patient's blood glucose level.
- **Dose Helper:** the JAZZ™ DoseCoach® function that provides insulin glargine dose suggestions.
- **(Usual) dose time:** the time your patient is meant to run Dose Helper to get dose suggestions. A doctor or nurse sets this on JAZZ™ DoseCoach®.
- **Lancet (needle):** the lancet unit used to lance (pierce) the skin.
- **Strip port:** the opening in the base of JAZZ™ DoseCoach® where test strips are inserted.
- **Strip vial:** the container that the AgaMatrix WaveSense JAZZ Test Strips are kept in.
- **Tag icon:** a label or icon (small picture) that can be added to blood glucose readings. This shows when your patient measured their blood glucose.
- **Blood glucose (BG):** the level of glucose in the blood.

- **Fasting blood glucose reading:** fasting blood glucose is measured after sleeping and before breakfast, when your patient has not eaten or had a drink containing sugar/glucose for at least 8 hours.
- **(Usual) fasting time:** the time your patient is supposed to measure their fasting blood glucose each day. This is already set on JAZZ™ DoseCoach® at 07:00 (between 04:00 and 10:00). It is important that the usual fasting time is set correctly so it matches your patient's daily routine.
- **Hypoglycaemia (hypo):** your patient might get symptoms of hypoglycaemia if their 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.
- **Hyperglycaemia (hyper):** your patient might get symptoms of hyperglycaemia if their blood glucose is too high (above 13.4 mmol/L).

## Icons and symbols used in this 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 shows the number of pairs (dose + fasting blood glucose) your patient has collected.



Star on the dose saved screen when fasting blood glucose is in target. 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).



Dose Helper.



Time.



Date.

## Screen type icons



Question screen.



Information screen.



Warning screen.

## Menu icons



History.



Settings.



Logbook.



Fasting blood glucose history.



Averages.



Advanced history menu.



Standard day.

## 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 your patients self-adjust their insulin glargine doses by suggesting the next dose.

Dose Helper does this using past information about your patient's previous doses and their fasting blood glucose readings.

- Dose increases or decreases are suggested in line with the treatment plan you will set up for your patients.

Dose Helper should be used as one part of your patient's self-titration treatment program led by a doctor or nurse.

>> See Section 2 for more information about Dose Helper.

## Dose Helper works best if:

- Your patient measures their fasting blood glucose every day.
- Your patient runs Dose Helper and saves the amount of insulin glargine they take every day.

Dose Helper should not be used as a substitute for your patient's judgement, or for advice from a doctor or nurse.

## Your patient must tell Dose Helper about hypo symptoms or low blood glucose

- It is important that your patient tells 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 patient's insulin glargine dose.
- If your patient's insulin glargine dose is too high, your blood glucose could become very low and you may get symptoms of hypoglycaemia.

## If your patient changes their daily routine, they might need to take a different dose

- Dose Helper adjusts your patient's dose based on past information. It cannot plan ahead for days when they are ill, or significantly change their daily routine, such as the amount they eat or the exercise they take.
- Changes to your patient's daily routine can affect their blood glucose levels and they may need to take a different dose to the Dose Helper suggestion. Use the space on page 1 of the owner's guide to record what your patient should do.
- Changing the time and date can affect Dose Helper – your patient may need to re-establish their baseline if they are travelling to a different time zone.

## Do

- ✓ You need to set up Dose Helper before it can be used by your patient.
- ✓ Each JAZZ™ DoseCoach® and Dose Helper must only be used by the one patient Dose Helper has been set up for.
- ✓ Your patients can only use Dose Helper if they have been told by a doctor or nurse how to self-adjust their insulin glargine dose and how to use Dose Helper safely.

>> See page 53, Section 4 “Training your patient” for information on training your patient.

## Do not

- ✗ Do not activate Dose Helper for patients who have gestational diabetes.
- ✗ Do not activate Dose Helper for patients who do not take their insulin glargine dose once daily or who do not take it at around the same time each day.
- ✗ Do not activate Dose Helper for patients who take any insulin other than insulin glargine.
- ✗ Do not activate Dose Helper for patients who are under 18 years old.

## Blood Glucose Meter – key information

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

>> See Section 3 in the owner's guide for more information on the Blood Glucose Meter.

### Do

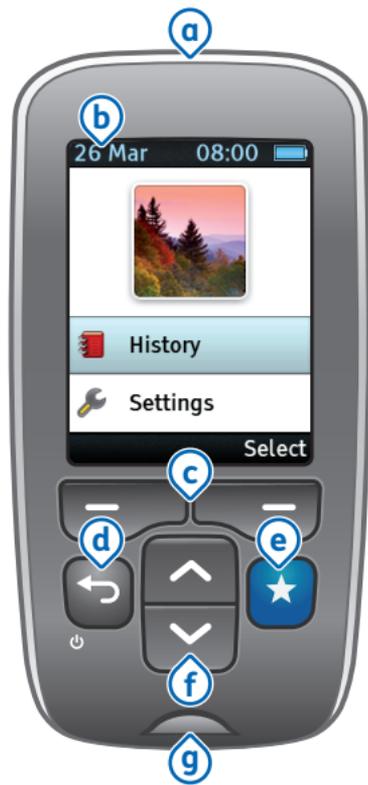
- ✓ Use fresh capillary whole blood taken from the fingertip only.
- ✓ Use with AgaMatrix WaveSense JAZZ Test Strips and AgaMatrix Control Solution only.

## Do not

- X** Do not use the Blood Glucose Meter to diagnose diabetes.
- X** Do not use the Blood Glucose Meter for measuring blood glucose of neonates (children under 4 weeks old).
- X** Do not use the Blood Glucose Meter to test blood from anywhere other than the fingertip.

>> See Section 3 in the owner's guide for more information on the Blood Glucose Meter.

## Get to know JAZZ™ DoseCoach®



**a Mini-USB port:** for inserting the activation key for the appropriate treatment plan.

**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.

**e Dose Helper button** : press this button to launch Dose Helper.

**f Up and down buttons** : press these buttons to choose an option or to show more information.

**g Strip port:** insert a AgaMatrix WaveSense JAZZ Test Strip here.

# GETTING TO KNOW DOSE HELPER

This section tells you how Dose Helper works and the information it needs to suggest insulin glargine doses.

## Dose Helper general principles

Dose Helper can help patients adjust their dose by suggesting next insulin glargine doses.

**a**

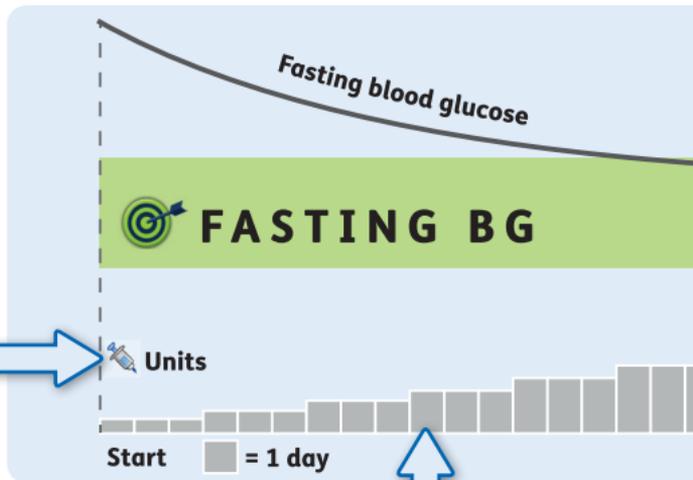
You will set up Dose Helper for your patient. During set up, you will provide Dose Helper with an individual treatment plan for each patient. This includes setting the starting dose, dose increase rules and the fasting blood glucose target range.

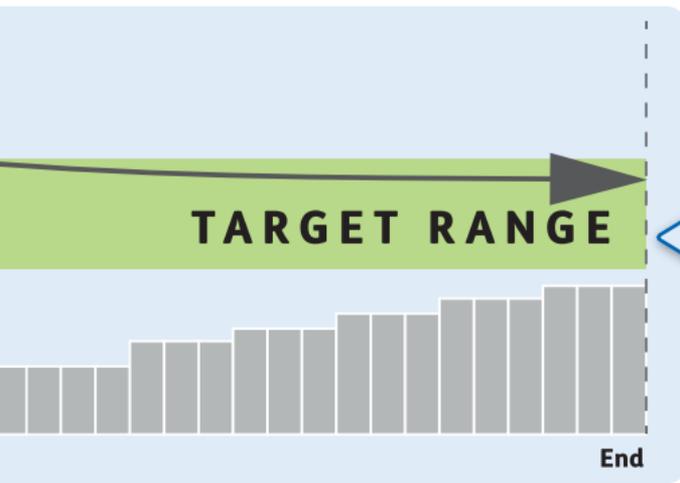
>> See page 30, Section 3, “About the activation keys” for information on how to set the individual treatment plan for your patient.

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

**b**

Dose Helper suggests dose adjustments to help get your patient’s fasting blood glucose into fasting blood glucose target range. If Dose Helper has all the information needed, it may suggest a dose increase every three days while your patient’s fasting blood glucose is above their fasting blood glucose target range.





>> See page 20 for adjustment details.

Dose Helper may ask your patient to contact their doctor or nurse. This happens if not enough information exists for a dose suggestion or if recorded information requires medical review.

>> See page 84 for a list of these “**Seek guidance**” warnings given to patients.

**C**

When the fasting blood glucose target is reached, Dose Helper suggests the dose adjustments needed to help keep your patient’s fasting blood glucose in the fasting blood glucose target range.

>> See page 20, Section 2 “How Dose Helper suggests insulin doses” for adjustment details.

**i**

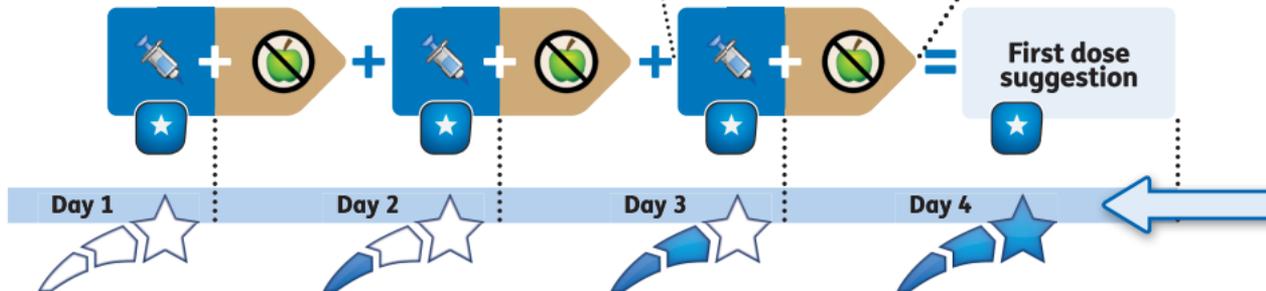
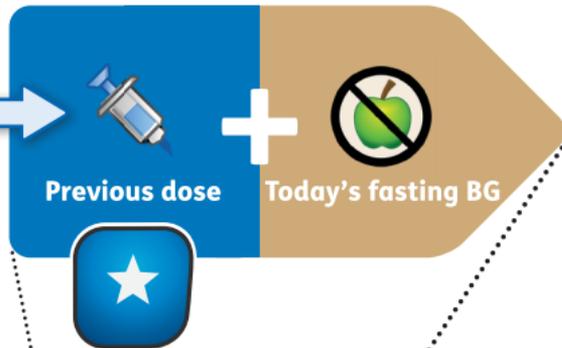
Dose Helper provides dose suggestions. It should not replace the care or advice of a doctor or nurse.

# How Dose Helper suggests insulin doses

## Pairs (dose + fasting blood glucose)

a

Dose Helper pairs fasting blood glucose (fasting BG) readings with your patient's previous insulin dose. For example, a pair might be yesterday's dose and today's fasting blood glucose.



**i**

Dose Helper supports adjustment of insulin glargine to a usual daily dose based on past information. It cannot plan ahead for sudden changes, for example:

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

**b**

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 your patients have saved a dose.

## Core Calculations

Dose Helper may suggest dose increases every three days if:

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

Dose Helper may suggest dose decreases if:

- Two of the last three fasting blood glucose readings are below the fasting blood glucose target range.
- The patient gets any low blood glucose readings or reports any hypo symptoms.

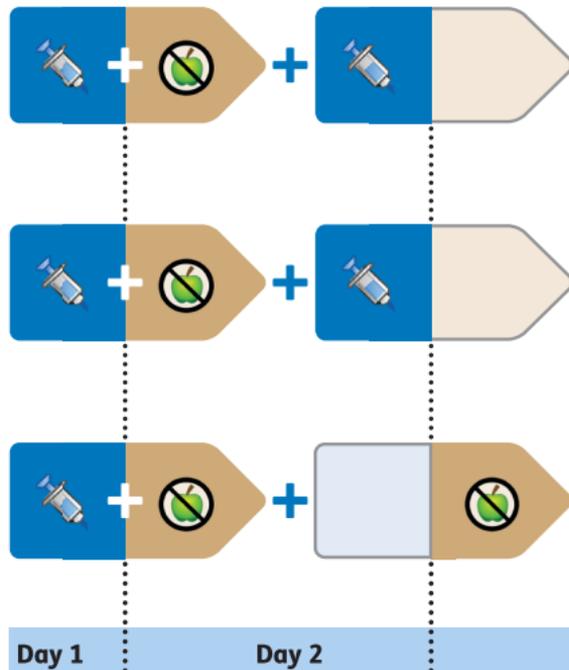
The core calculations vary depending on your patient's treatment plan.

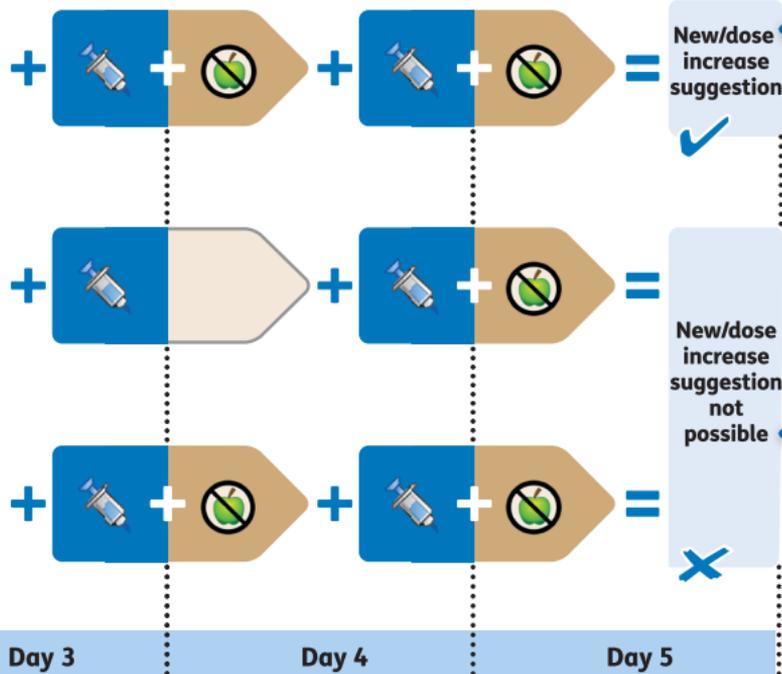
>> See page 30, Section 3 "About the activation keys" for the core calculation options of the treatment plans that are provided as activation keys.

## Required information for a new dose suggestion or to suggest a dose increase

To start dose suggestions (at first use, or to get suggestions again after Dose Helper has not been able to give a dose suggestion), Dose Helper requires at least three pairs of dose and fasting blood glucose information. Dose Helper requires the same amount of information to suggest dose increases.

- Missing fasting blood glucose information is allowed for a single day. This allows the three pairs (dose + fasting blood glucose) to be gathered over a four day period.
- Dose information needs to be entered for all days.





**a**

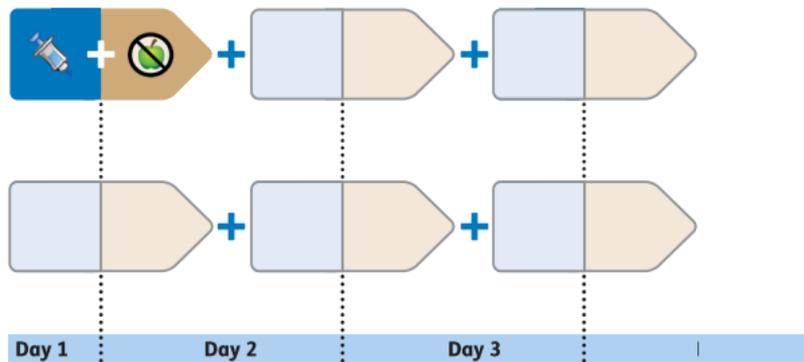
If a single fasting blood glucose reading is missing, the three pairs (dose + fasting blood glucose) can be gathered over a four day period.

**b**

Two or more missing fasting blood glucose readings (middle) or a missing dose (bottom) would prevent a new dose suggestion or a dose increase suggestion.

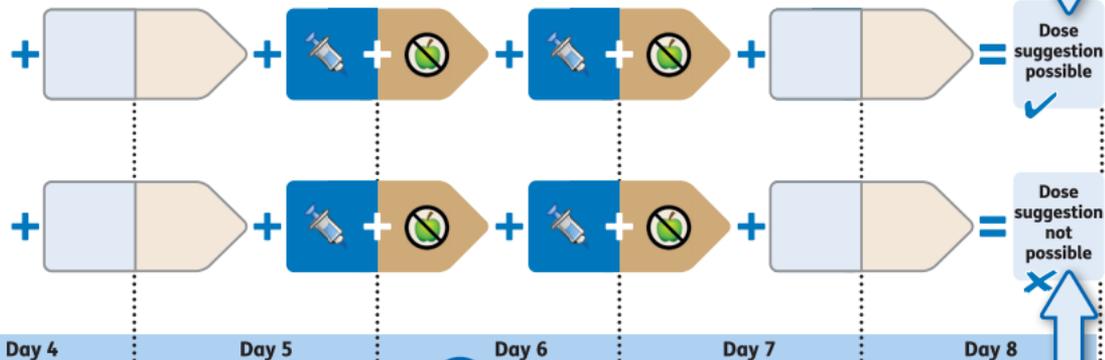
## Required information to keep the same dose or to suggest a dose decrease

To suggest to keep the same dose or to decrease the dose, Dose Helper requires at least three pairs (dose + fasting blood glucose) from the last seven consecutive days. In these situations, the Dose Helper requirements are more flexible than for dose increase suggestions.



**a**

As long as a minimum of three pairs (dose + fasting blood glucose) have been collected over the past seven days, Dose Helper can suggest to keep the same dose, or suggest a dose decrease.

**b**

If the minimum three pairs (dose + fasting blood glucose) are not collected, Dose Helper cannot suggest a dose. The patient needs to collect three new pairs (dose + fasting blood glucose) to get dose suggestions again.

## Other reasons why Dose Helper will not suggest a dose increase

Dose Helper will not suggest an insulin glargine dose increase if:

- Any fasting blood glucose readings are below the fasting blood glucose target range in the required three pairs (dose + fasting blood glucose).
- The patient's fasting blood glucose has regularly been in the fasting blood glucose target range. Once seven of the last seven to ten fasting blood glucose readings are below the upper limit of the fasting blood glucose target range and the dose has stayed the same across this time, then no further dose increases will be suggested unless the fasting blood glucose regularly goes above the fasting blood glucose target range (seven of the last seven to ten).
- The patient takes a dose that is different to the suggested dose or the patient enters that they took a dose of an unknown amount on any of the days they are collecting the required three pairs (dose + fasting blood glucose) for a dose increase suggestion.

## Time restrictions

Dose Helper suggests the dose patients should take “now” (the time when Dose Helper is run). Dose Helper can only suggest a dose within three hours on either side of the usual dose time and if the previous dose was recorded more than 18 hours ago.

Dose Helper will not be able to give dose suggestions if:

- The patient saved a dose to Dose Helper outside of the usual dose time (more than three hours either side).
- The patient saved two doses within 18 hours.
- The usual dose time was changed by more than three hours (within seven days).
- The clock time was changed by more than three hours (within seven days).

- The dose time and the clock were changed so that it adds up to more than three hours (within seven days).



The patient should record any dose they take to Dose Helper, whether the dose was suggested by Dose Helper or decided by the patient.

## Changed doses

It is important that the patient makes the final decision on what dose to take. Dose Helper will still work if the patient occasionally takes a dose that is different to the suggested dose.

- Dose Helper cannot suggest a dose if the patient takes more than one dose that is different to the suggested dose (changed dose) on the days they are collecting the required three pairs (dose + fasting blood glucose) for a dose suggestion.

# ACTIVATING DOSE HELPER

This section shows you how to activate Dose Helper, using activation keys for your patient's individual treatment plan.

## About the activation keys

- JAZZ™ DoseCoach® can be activated for use with insulin glargine 100 Units/mL (U-100).
  - There are three activation keys for individual treatment plans for insulin glargine 100 Units/mL (U-100).
  - To activate Dose Helper you only need to use one key.
  - First, choose whether Dose Helper should be activated for use with insulin glargine 100 Units/mL (U-100).
  - Then choose the key that matches your patient's required treatment plan.
  - The activation keys you can choose from are described on the following pages.
- When you are activating Dose Helper, you need to set the following for your patient:
    - Prescription expiry
    - Patient's weight
    - Starting dose
    - Dose time.

If Dose Helper has been activated in the past you can check the user agreement to see what type of insulin Dose Helper has been activated for.

>> See page 81, Section 5 in the owner's guide for how to review the user agreement.

## Do not

- ✗ Do not give the activation keys to your patients. The activation keys are for authorised doctors or nurses only.
- ✗ Do not dispose of the keys. Please return expired keys to AgaMatrix.

## i

- During activation you will set the prescription expiry date for Dose Helper. If you want your patient to continue using Dose Helper after that you need to activate it again.
- The activation keys for each treatment plan also have an expiration date (printed on the activation key), after which the key can no longer be used. In this case, contact customer service at: 0800 093 1812 to get a new key.



## Do

- ✓ Store the key in a dry and clean place. Keep away from direct sunlight.
- ✓ Always use the grip feature when inserting and removing the key to prevent damaging it.

- a** Activation key title.
- b** Insulin type for treatment plan.
- c** Fasting BG target range.
- d** Treatment plan.
- e** Grip feature.
- f** Connection tip.
- g** Doctor/nurse name field.
- h** Key expiration date.
- i** Serial number.

## About the activation key for treatment plan 1



- Fasting BG target range: 5.0-7.2 mmol/L.
- Dose Helper will suggest increasing the dose by 2 units every three days while 2 of 3 fasting blood glucose (fasting BG) values are above 7.2 mmol/L.
- If two of the last three fasting blood glucose readings are below the fasting blood glucose target range, Dose Helper will suggest decreasing the dose by 2 units (or by 5% of the dose, if 5% is greater than 2 units).
- If any low blood glucose readings (below 3.9 mmol/L) or any hypo symptoms are reported, Dose Helper will suggest decreasing the dose by 4 units (or by 10% of the dose, if 10% is greater than 4 units).

## About the activation key for treatment plan 2



- Fasting BG target range: 5.0-7.2 mmol/L.
- Dose Helper will suggest increasing the dose by 4 units every three days while 2 of 3 fasting blood glucose (fasting BG) values are above 10.0 mmol/L.
- Dose Helper will suggest increasing the dose by 2 units every three days while 2 of 3 fasting blood glucose values are at or below 10.0 mmol/L and above 7.2 mmol/L.
- Once seven of the last ten fasting blood glucose readings go below 10.0 mmol/L, the 4 unit dose increase will no longer be used until you activate Dose Helper again.
- If 2 of 3 fasting blood glucose values go back above 10.0 mmol/L, Dose Helper will suggest increasing the dose by 2 units every three days.
- If two of the last three fasting blood glucose readings are below the fasting blood glucose target range, Dose Helper will suggest decreasing the dose by

- 2 units (or by 5% of the dose, if 5% is greater than 2 units).
- If any low blood glucose readings (below 3.9 mmol/L) or any hypo symptoms are reported, Dose Helper will suggest decreasing the dose by 4 units (or by 10% of the dose, if 10% is greater than 4 units).

## About the activation key for treatment plan 3



- Fasting BG target range: 6.1-8.3 mmol/L.
- Dose Helper will suggest increasing the dose by 2 units every three days while 2 of 3 fasting blood glucose (fasting BG) values are above 8.3 mmol/L.
- If two of last three fasting blood glucose readings are below the fasting blood glucose target range, Dose Helper will suggest decreasing the dose by 2 units (or by 5 % of the dose, if 5 % is greater than 2 units).
- If any low blood glucose readings (below 3.9 mmol/L) or any hypo symptoms are reported, Dose Helper will suggest decreasing the dose by 4 units (or by 10 % of the dose, if 10 % is greater than 4 units).

## Dose Helper start-up

Each time you start the activation sequence the JAZZ™ DoseCoach® will perform a meter system check. This example shows the screen you will see first.

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



## Activating Dose Helper

1

### Select an activation key.

- Select the activation key that best suits your patient's treatment plan.
- The main treatment parameters are printed on the activation key.

### Do not

-  Do not activate more than one treatment plan on multiple devices for each patient.

## 2

## Insert the activation key.

- Insert the activation key connection tip into the mini-USB port on JAZZ™ DoseCoach®.
- JAZZ™ DoseCoach® will turn on and indicate that the key has been detected.
- The language selection may appear.
- Leave the key inserted until you have finished all activation steps.
- An example activation key is shown here.

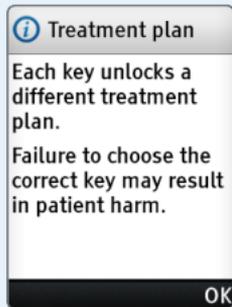
>> If the key is not detected, see page 98, Section 7 “Nothing happens when you insert an Activation key” for possible reasons why.



## 3

**Read the warning message.**

- Check you have inserted the correct treatment plan activation key for your patient. >> See page 30, Section 3 “About the activation keys” for more information about the treatment plan activation keys.



Press  to go back to previous screens.

4

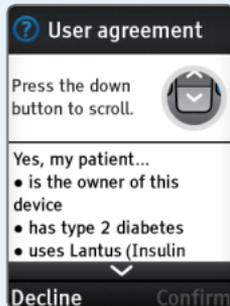
### Read the user agreement.

 Read to the end.

  Then  
“**Confirm**” the user agreement.

  Or press  
“**Decline**”.

- You can only activate Dose Helper if you confirm the user agreement.
- Until you scroll down and read all of the user agreement “**Confirm**” will be grey and you cannot go on.



i

The insulin type shown in the user agreement will depend on the treatment plan activation key you select for your patient. In this example, the user agreement shows Dose Helper is being set up for use with insulin glargine 100 Units/mL (U-100).

If a treatment plan for the incorrect insulin type has been selected, complete the activation again with the correct treatment plan activation key.

## 5

**Check the clock.**

- Setting the correct clock time and date is important for Dose Helper.
- Dose Helper can only suggest doses during the dose time range (three hours either side of the usual dose time).
- The clock time affects the dose time range.

  If the time and date are correct, press **“Yes”**.

  If not, press **“No”**.

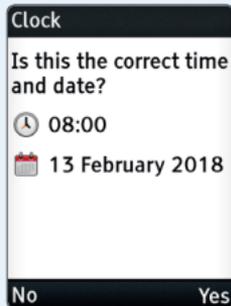
- If you pressed **“No”**, JAZZ™ DoseCoach® will ask you to correct the clock settings.

  Set the correct year.

  Go to the **“Next”** setting step.

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

  **“Save”** the clock changes at the last setting step.



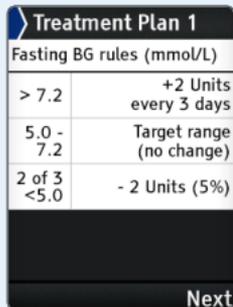
Press  to go back to previous screens.

6

### Check the fasting blood glucose rules.

- Review the fasting blood glucose (fasting BG) rules. They depend on the selected treatment plan.

 Then press **“Next”**.



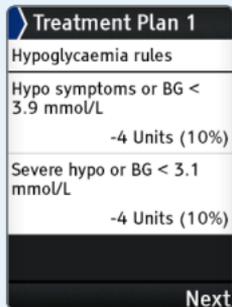
Treatment Plan 1	
Fasting BG rules (mmol/L)	
> 7.2	+2 Units every 3 days
5.0 - 7.2	Target range (no change)
2 of 3 <5.0	-2 Units (5%)

7

### Check the hypoglycaemia rules.

- Review the hypoglycaemia (hypo) rules. They depend on the selected treatment plan.

 Then press **“Next”**.



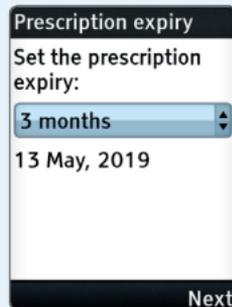
Treatment Plan 1	
Hypoglycaemia rules	
Hypo symptoms or BG < 3.9 mmol/L	-4 Units (10%)
Severe hypo or BG < 3.1 mmol/L	-4 Units (10%)

8

### Set the prescription expiry.

 Choose how long you want this treatment plan to remain active.

- After this date Dose Helper will expire and you will need to activate it again.

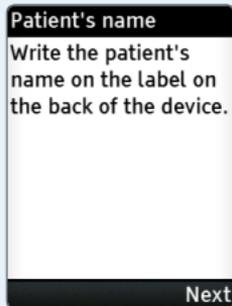


Prescription expiry	
Set the prescription expiry:	
3 months	
13 May, 2019	

## 9

**Label the JAZZ™ DoseCoach®.**

- Write your patient's name on the back of JAZZ™ DoseCoach®. This is especially important if your patient will be participating in a group training session.
  - It is important your patient only uses their own JAZZ™ DoseCoach®.
  - They may be at risk if they use Dose Helper on another patient's JAZZ™ DoseCoach®.
-  Then press **“Next”**.



Press  to go back to previous screens.

10

### Enter the patient's weight.

- Dose Helper uses the patient's weight to calculate the maximum dose it can suggest.
- This is calculated at 1 unit per kg.
- The resulting maximum dose is shown in the activation summary.
- The maximum dose cannot be higher than 200 units.
- This means for patients who weigh 200 kg or over, Dose Helper will suggest

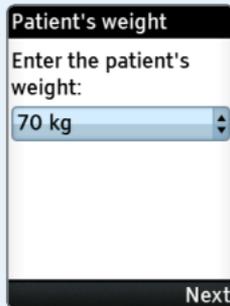
a maximum dose of 200 units.



Enter your patient's weight.



Then press "Next".



Patient's weight

Enter the patient's weight:

70 kg

Next

i

Setting a starting dose which is too high for your patient may cause severe hypoglycaemia. Please refer to the labeling of insulin glargine to determine the correct starting dose.

## 11

## Set the starting dose.

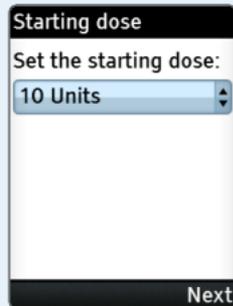
- The starting dose default is 0.2 units/kg  $\times$  patient weight – this can be changed during activation.
- Decide the starting dose your patient should take. Make sure you tell your patient what starting dose they need to take.
- To start giving dose suggestions, Dose Helper needs three pairs (dose + fasting blood glucose).
- Dose Helper will start giving dose suggestions

as long as the patient measures their fasting blood glucose every day and runs Dose Helper to enter their insulin glargine dose every day for the first three days.

- During this time, the patient should take the same dose each day. This dose should not be more than 4 units higher than the starting dose (10% higher for larger starting doses).
-  Enter the starting dose for your patient.

 Then press “Next”.

>> See page 22, Section 2 “Required information for a new dose suggestion or to suggest a dose increase” for more information about required information for a new dose suggestion.



Press  to go back to previous screens.

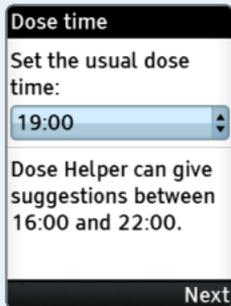
12

### Set the usual dose time.

- The usual dose time defines a 6-hour window (three hours either side of the usual dose time) when Dose Helper can suggest doses.
- Outside this time range, Dose Helper cannot suggest doses. This is because a consistent dose time is required.
- The usual dose time can be changed in the **“Settings”**.

  Enter the usual dose time for your patient.

  Then press **“Next”**.



i

- Insulin glargine should be taken at the same time each day.
- Patients who take their dose of insulin glargine in the morning should run Dose Helper **after** measuring their fasting blood glucose.

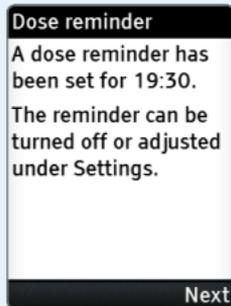
13

### Explain the dose reminder to your patient.

- A dose reminder is automatically set for 30 minutes after the usual dose time.
- The dose reminder plays a sound if your patient has not used Dose Helper to save a dose by then.
- The reminder can be changed or turned off in the “**Settings**”.



Press “**Next**”.



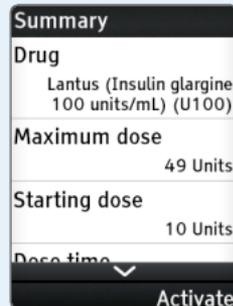
14

### Complete the treatment plan activation.

-  Review the entire summary of the activated treatment plan.



If all details are correct, press “**Activate**”.



Press  to go back to previous screens.

**i**

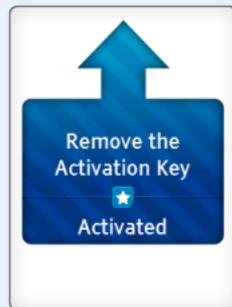
- The insulin type shown in the summary will depend on the treatment plan activation key you selected for your patient.
- If a treatment plan for the incorrect insulin type has been selected, complete the

activation again with the correct treatment plan activation key. In this example, the summary shows Dose Helper has been activated for use with insulin glargine 100 Units/mL (U-100).

**15**

### Remove the activation key.

- Pull out the key when instructed.
- Dose Helper is now activated – your patient can start using Dose Helper when it is time for their next dose.



## Activating Dose Helper again after expiry

- Dose Helper can be used until the treatment plan prescription expires (as decided during setup).
- If you want your patient to continue using Dose Helper you need to activate Dose Helper again.

>> See page 30, Section 3 “About the activation keys” for how to activate Dose Helper using the right activation key for your patient’s treatment plan.



JAZZ™ DoseCoach® has an internal coin cell battery. If this battery runs empty, the Dose Helper function will stop working and can no longer be activated. The battery should last about 4 years.

The patient will need a new JAZZ™ DoseCoach® to continue using Dose Helper.

## Changing the treatment plan for patients already using Dose Helper

If you want to select a different treatment plan to the one that is already activated, perform a new activation with the desired activation key. This will replace the previous treatment plan with the new treatment plan.

>> See page 30, Section 3 “About the activation keys” for how to activate Dose Helper using the right activation key for your patient’s treatment plan.



After each activation, Dose Helper needs to gather new fasting blood glucose readings and insulin doses in order to give suggestions again.



If you are advising your patient remotely (for example, over the phone) and need the patient to come to the office to change the treatment plan in the device, clearly tell your patient what insulin glargine dose(s) to take until their visit.

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# TRAINING YOUR PATIENT

This section gives you a checklist for the training topics you should cover with your patients before they can use Dose Helper.

## Training checklist

Dose Helper suggests insulin glargine doses, but your patients should make the final decision on what dose they take.

It is important that your patients learn the rules for safe management of insulin dosing and to call you when they are not sure what dose to take.

Use this checklist to cover the following topics when training your patient.

### ① How to use Key Features of JAZZ™ DoseCoach®

- Overview of device:
  - the identification of buttons (for example, the best way to turn JAZZ™ DoseCoach® on and off),
  - when and how to use the Dose Helper button,
  - how to use the soft keys,
  - how to navigate through the screens, including how to scroll up and down.
- JAZZ™ DoseCoach® setup, including the purpose of the user icon and name labeling.
- How to navigate menus and find key menus in the history and settings (for example, how to change the time and date settings, and Dose Helper settings).

## ② How to measure blood glucose

- Measuring blood glucose using JAZZ™ DoseCoach®, including the process of washing hands, insert test strip, apply sample, how to read and store results.
- Understanding blood glucose measurements.
- Tagging and the associated terms, including the key terms and symbols.
- How to tag a blood glucose reading, including what to do if the wrong tag is chosen.
- How to correctly read the “**Logbook**” and other history screens.

## ③ How to use insulin glargine safely

- Injection sites and technique.
- Recognising and treating hypoglycaemia (hypo) and hyperglycaemia (hyper) symptoms.

## ④ How to self-adjust insulin glargine dose

- Fasting blood glucose readings and how these are used to self-adjust insulin glargine doses.
- Fasting blood glucose target range.
- Core calculations.

## ⑤ How to manage and adjust the insulin glargine dose for:

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



Use the blank fields in the owner's guide and quick reference guide to note down your patient's treatment information (starting dose, sick day rules, etc.). These come in the JAZZ™ DoseCoach® box.

## ⑥ How to use Dose Helper

- General use of Dose Helper, including how to use the soft keys to navigate the menu screens, saving a dose and understanding the dose question screens.
- How to exit Dose Helper without recording a dose (for example, if Dose Helper is opened accidentally and it is not time for an insulin dose).
- How to change the Dose Helper settings, such as the usual dose time.
- Understand the warnings associated with Dose Helper and how to resolve them, including the multiple dose, previous dose and hypo questions, and how to confirm suggested doses.
- What Dose Helper is for (i.e. support for patients' decision making).

- Getting the first dose suggestion and what starting dose to take during first days of use.
- Normal use of Dose Helper and usual dose time.
- What Dose Helper is not for (i.e. replace advice of doctor or nurse).
- Situations that Dose Helper cannot account for.
- What to do if Dose Helper cannot give dose suggestions.

### ⑦ **When to contact you for support**

- General advice: Patients should contact you if they are not sure what dose to take. They should not wait for JAZZ™ DoseCoach® to instruct them to do so.
- Other situations in which you want your patients to contact you.

**This page has been left blank on purpose.**

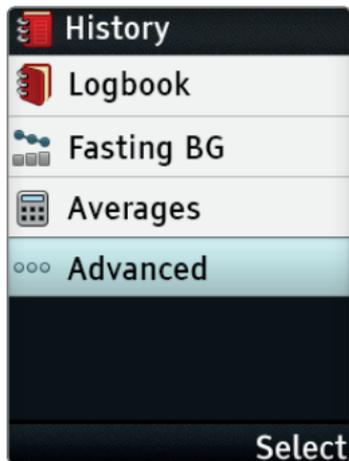
# REVIEWING YOUR PATIENT'S HISTORY DATA

JAZZ™ DoseCoach® keeps your patient's blood glucose readings and other information they enter. You can view this data on graphs and tables in the history. This section shows you how to use the history data.

## About the history data

There are four options in the “History” menu:

- **Logbook:** lists your patient's blood glucose readings and insulin glargine doses with time and date.
- **Fasting BG:** three graphs that show your patient's 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.

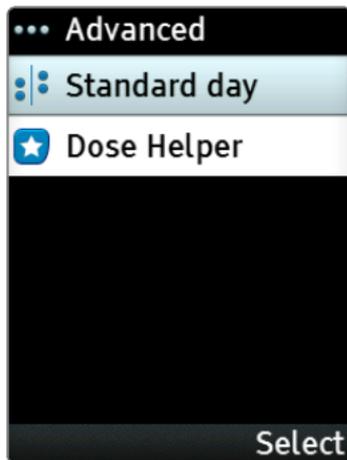


Press  to go back to previous screens.

There are two options in the “**Advanced**” history menu:

- **Standard day:** this graph shows your patient’s 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 your patients saved to Dose Helper.

>> See page 77, Section 5 “Standard Day” for more information on the “Advanced” history menu.



## Do not

- ✗ Do not make treatment decisions based on stored blood glucose readings, doses, averages, and graphs.

## Accessing the “History” menu:

Press  to go back to previous screens.

1

Press  to turn on **JAZZ™ DoseCoach®**.

- Check the user icon on the start-up screen is correct for your patient.



2

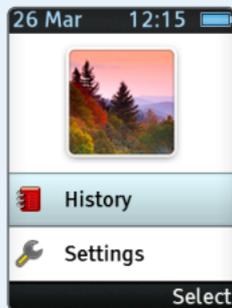
Select “History”.



Choose “**History**”.



Then press  
“**Select**”.



3

Select an option.

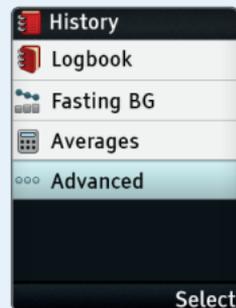


Choose an option.



Then press  
“**Select**”.

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



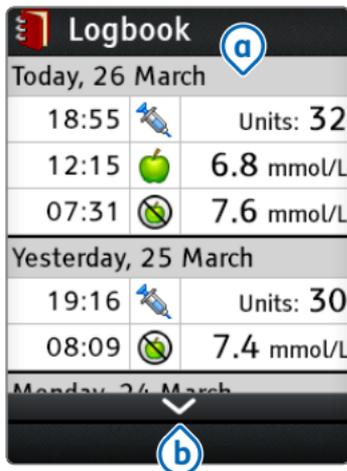
# Logbook

## About the “Logbook”

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

**b** **More information:** use  to show more information.

>> See page 8, Section 1 “Icons and symbols used in this guide/blood glucose icons” for a list of all blood glucose icons.



Logbook		
Today, 26 March		
18:55		Units: 32
12:15		6.8 mmol/L
07:31		7.6 mmol/L
Yesterday, 25 March		
19:16		Units: 30
08:09		7.4 mmol/L
Monday, 24 March		

Logbook	
Today, 26 March	
18:55	Units: 32
12:15	6.8 mmol/L
07:31	7.6 mmol/L
Yesterday, 25 March	
19:16	Units: 30
08:09	7.4 mmol/L
Monday, 24 March	

## Blood glucose readings

07:31	7.6 mmol/L
-------	------------

**a** **b** **c**

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.

Press to go back to previous screens.

Logbook	
Today, 26 March	
18:55	Units: 32
12:15	6.8 mmol/L
07:31	7.6 mmol/L
Yesterday, 25 March	
19:16	Units: 30
08:09	7.4 mmol/L
Monday, 24 March	

## Insulin doses

18:55	Units: 32
-------	-----------

**a** **b** **c**

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.

The screenshot shows a logbook for 'Today, 26 March'. The entries are:

Time	Icon	Units	Value
18:55	Blue arrow icon	Units: 32	
12:15	Green apple icon		6.8 mmol/L
Clock change			
07:31	Green apple icon		7.6 mmol/L

Below this, it shows 'Yesterday, 25 March' with an entry at 19:16 (Units: 30) and a partially visible entry at 08:00 (7.6 mmol/L).

## Clock changes



This example shows a clock change entry.

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

The screenshot shows a logbook for 'Today, 26 March'. The entries are:

Time	Icon	Units	Value
18:55	Blue arrow icon	Units: 32	
15:24	Green apple icon		14.4 mmol/L
12:15	Green apple icon		6.8 mmol/L
07:31	Green apple icon		7.6 mmol/L

Below this, it shows 'Yesterday, 25 March' with an entry at 19:16 (Units: 30) and a partially visible entry at 08:00 (7.6 mmol/L).

## High blood glucose readings



This example shows a high blood glucose reading entry.

- Blood glucose readings above your patient's high blood glucose limits are shown with an orange background.

The screenshot shows a 'Logbook' for 'Today, 26 March'. It lists three entries: 18:55 with 'Units: 32', 12:15 with '6.8 mmol/L', and 07:31 with '3.6 mmol/L'. The 07:31 entry is highlighted with a red background and a green 'X' icon. Below the entries is a red triangle icon with the text 'Hypo symptoms or BG < 3.9 mmol/L'. The previous day's entry for 'Yesterday, 25 March' at 19:16 with 'Units: 30' is partially visible at the bottom.

Logbook	
Today, 26 March	
18:55	Units: 32
12:15	6.8 mmol/L
07:31	3.6 mmol/L
▲ Hypo symptoms or BG < 3.9 mmol/L	
Yesterday, 25 March	
19:16	Units: 30

## Low blood glucose readings

07:31 3.6 mmol/L

This example shows a low blood glucose reading entry.

- Blood glucose readings below your patient's low blood glucose limits are shown with a red background.

The screenshot shows a 'Logbook' for 'Today, 26 March'. It lists three entries: 18:55 with 'Units: 32', 12:15 with '6.8 mmol/L', and 07:31 with '7.6 mmol/L'. The 07:31 entry is highlighted with a yellow background and a green 'X' icon. Below the entries is a red triangle icon with the text 'Hypo symptoms or BG < 3.9 mmol/L'. The previous day's entry for 'Yesterday, 25 March' at 19:16 with 'Units: 30' is partially visible at the bottom.

Logbook	
Today, 26 March	
18:55	Units: 32
12:15	6.8 mmol/L
07:31	7.6 mmol/L
▲ Hypo symptoms or BG < 3.9 mmol/L	
Yesterday, 25 March	
19:16	Units: 30

## Hypo symptoms

▲ Hypo symptoms or BG < 3.9 mmol/L

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

- On days where your patient had a low blood glucose reading or 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.

Logbook		
Today, 26 March		
18:55		Units: 32
12:15		6.8 mmol/L
07:31		7.6 mmol/L
▲ Severe hypo or BG < 3.1 mmol/L		
Yesterday, 25 March		
19:16		Units: 30

## Severe hypo symptoms

▲ Severe hypo or BG < 3.1 mmol/L

This example shows an entry of reported low blood glucose less than 3.1 mmol/L or severe hypo symptoms.

- On days where your patient had a very low blood glucose reading or 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.

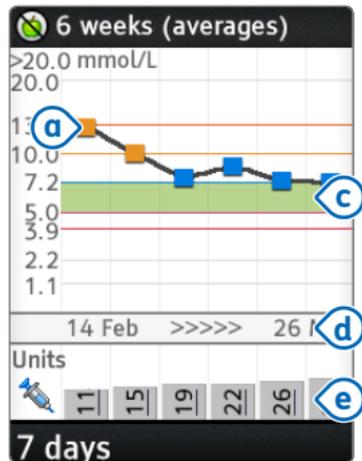
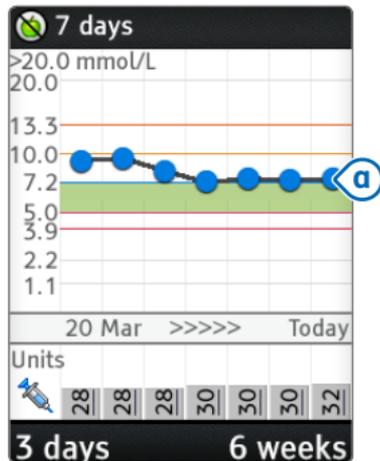
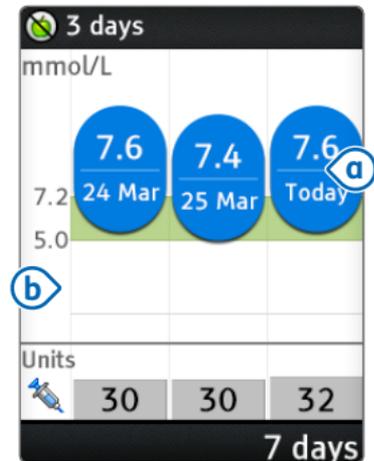
## Fasting blood glucose (Fasting BG)

### About “Fasting BG” history

“3 days” shows your patient’s fasting blood glucose readings and insulin glargine doses for the last 3 days.

“7 days” shows your patient’s fasting blood glucose readings and insulin glargine doses for the last 7 days.

“6 weeks (averages)” shows weekly averages of your patient’s fasting blood glucose readings and insulin glargine doses for the last 6 weeks.



Press  and  to move between the three graphs.

**a** **Colored bubbles or squares:** show your patient's 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 Section 3, “How to interpret the blood glucose reading screen” in the owner's guide 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 patient's exact blood glucose readings, please consult the “**Logbook**”.

**c** **Green area:** shows your patient's 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.

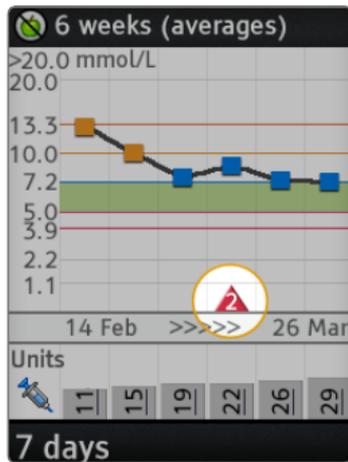
Press  to go back to previous screens.

## Hypo triangle

- On the 3 and 7 days graphs on days where your patient had a low blood glucose reading or reported low blood glucose (below 3.9 mmol/L) or hypo symptoms in Dose Helper, a red triangle is shown once for that day.
- On the 6 weeks (averages) graph in weeks where your patient had a low blood glucose reading or 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 or hypo symptoms.



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

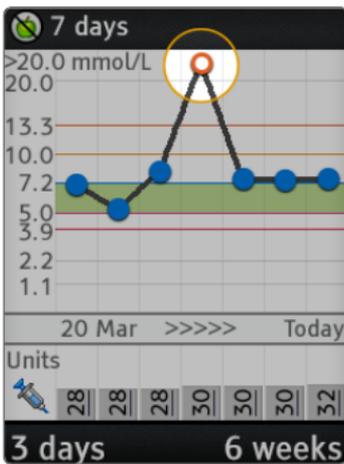


Please note that patients may report hypo symptoms (through Dose Helper) even though their average fasting blood glucose is not below the fasting blood glucose target.

## 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 Section 3, “How to interpret the blood glucose reading screen” in the owner’s guide for the different color ranges.

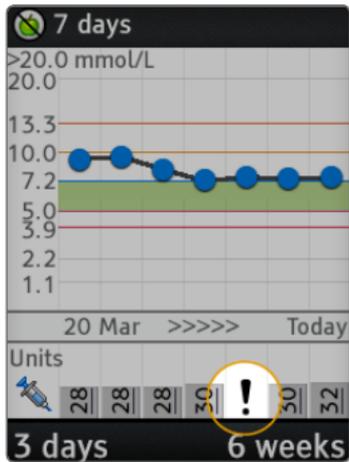


## Multiple doses in one day

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

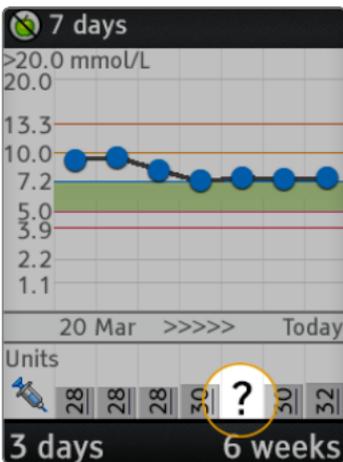


Dose Helper should only be used if your patient takes insulin glargine once daily.



## Dose unknown

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



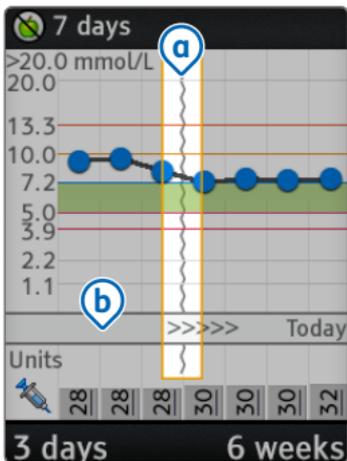
## Clock change

- 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 27, Section 2 “Time restrictions” for more details.



# Averages

Press  to go back to previous screens.

## About “Averages”

**a** **Number of days:** the number of recent days included in the calculations for average and standard deviation. To change the number of days:

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

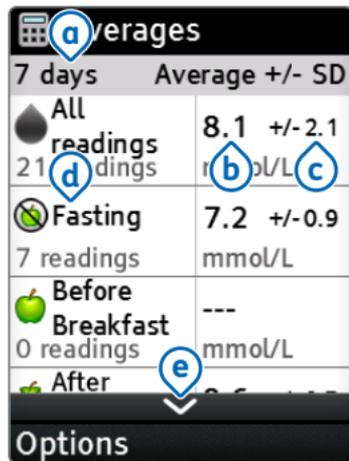
**b** Average of all blood glucose readings, or readings with the same tag.

**c** Standard deviation ( $\pm$ 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.



	7 days	Average	+/- SD
All readings	21 readings	8.1	+/- 2.1
Fasting	7 readings	7.2	+/- 0.9
Before Breakfast	0 readings	---	---
After	0 readings	---	---

- 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 33.4 mmol/L or above, and 1.1 mmol/L or below, will be included in averages as values of 33.4 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**”.

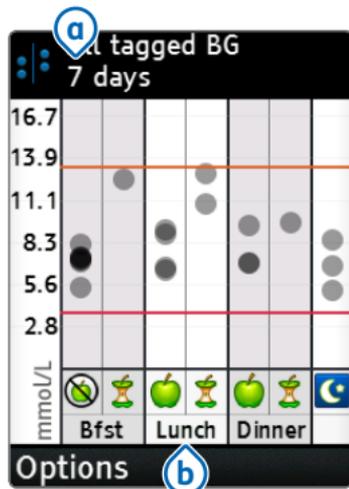
 Then choose the number of days.

 Then press “**Select**”.

**b** The tags are ordered in sequence across the day, from breakfast to lunch >> See page 8, Section 1 “Icons and symbols used in this guide/

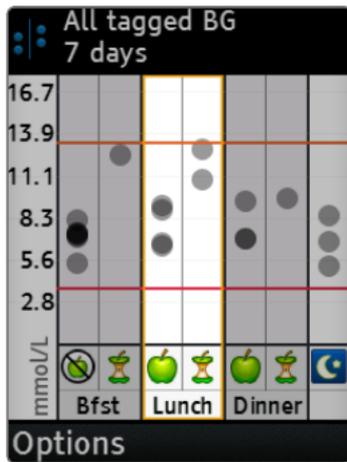
to dinner then before bed. For each meal, the before meal and after meal readings are shown in separate columns.

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.



blood glucose icons” for a list of all blood glucose icons.

- c Orange line:** shows your patient's high blood glucose limit.
- d Grey dots:** show your patient's blood glucose readings.
  - When readings overlap, the dots appear darker.
- e Red line:** shows your patient's low blood glucose limit.
- f Before meal tag.**
- g 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.



	Suggested Dose	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

### About “Dose Helper”



25 Mar	30 U	30 U
--------	------	------

The Dose Helper history shows the suggested dose and the taken (saved) dose for each day your patient has run Dose Helper or saved a dose.

Each row shows:

**a** **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.

Dose Helper		
	Suggested Dose	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	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.

Dose Helper		
	Suggested Dose	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	? U
21 Mar	28 U	28 U

### Unknown taken doses

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

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

★ Dose Helper			
	Suggested Dose	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 your patient did not run Dose Helper that day.

★ Dose Helper			
	Suggested Dose	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

## 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 22, Section 2 “Required information for a new dose suggestion or to suggest a dose increase” for the information Dose Helper needs to suggest a dose.

Dose Helper			
	Suggested Dose		Taken Dose
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

## Clock changes



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



Changing the time or date can affect Dose Helper.

>> See page 27, Section 2 “Time restrictions” for more details.

# WARNINGS AND MESSAGES GIVEN TO PATIENTS

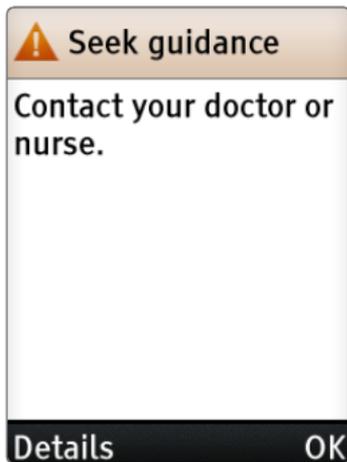
This section helps you to be prepared for your patients' questions resulting from warnings and messages shown on JAZZ™ DoseCoach®.

## “Seek guidance” warnings

JAZZ™ DoseCoach® may tell patients to contact their doctor or nurse if information is recorded that requires medical review.

You may need to adjust your patient’s treatment plan.

The following pages list the situations when **“Seek guidance”** warnings are shown to your patient.



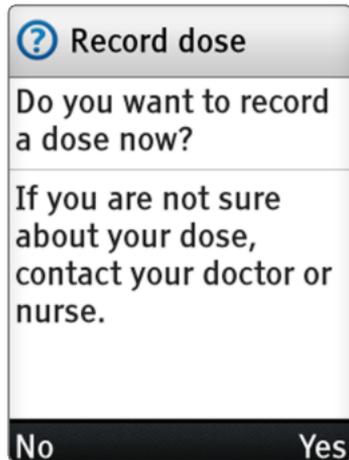
Warning shown to your patient	What this means
You had very low BG.	Your patient had a blood glucose (BG) reading less than 3.1 mmol/L.
You had very low BG or hypo symptoms needing help.	Your patient had a blood glucose (BG) reading less than 3.1 mmol/L or reported very low blood glucose (measured on another meter), or hypo symptoms needing help from another person.
You had frequent low BG.	Your patient had three or more hypos or blood glucose (BG) readings less than 3.9 mmol/L in the last three weeks.
Your dose is low.	<p>Your patient's suggested dose has gone below 10 units or below their starting dose (if this was lower than 10 units). This may occur due to:</p> <ul style="list-style-type: none"> <li>• Reported hypos.</li> <li>• Low blood glucose readings.</li> <li>• Patient's manual entry of a lower dose.</li> </ul>

Warning shown to your patient	What this means
<p>Your fasting BG is not decreasing as expected.</p>	<p>Your patient's fasting blood glucose (BG) readings are above the fasting blood glucose target range and have not come down by at least 10% over the past month. In addition to possible medical causes, this may occur if your patients are not using JAZZ™ DoseCoach® enough (for example, not measuring fasting blood glucose every day, not running Dose Helper every day, not taking their dose every day) and so not adjusting their dose.</p>
<p>You are near your maximum dose of 70* units. Dose Helper will turn off if you reach your maximum dose of 70* units.</p> <p>*This is an example value and may not reflect your patient's treatment plan.</p>	<p>Your patient has almost reached the maximum dose that Dose Helper can suggest. Dose Helper will stop suggesting doses when the maximum dose limit is reached. The maximum dose was set up during the activation of Dose Helper.</p>
<p>You may need a dose reduction, but Dose Helper does not have enough information.</p>	<p>Your patient had a blood glucose reading less than 3.9 mmol/L or reported low blood glucose or hypo symptoms.</p>

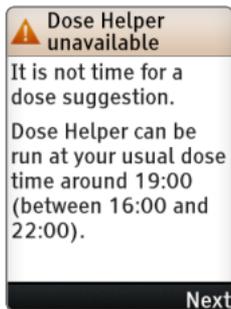
## “Dose Helper unavailable” warnings

JAZZ™ DoseCoach® may tell patients to contact their doctor or nurse if Dose Helper cannot give a dose suggestion. You may need to tell your patients what dose to take.

The **“Record dose”** question is always preceded by a warning. The following pages list the warnings that are shown to your patient.



## Warning shown to your patient



## What this means

Your patient has tried to run Dose Helper outside of the usual dose time window. Dose Helper can only be run within three hours either side of the usual dose time.

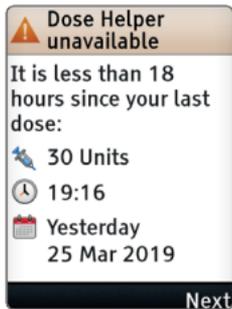
Dose Helper can only give suggestions if your patients run Dose Helper and take the dose at their usual dose time. The usual dose time is shown in the message.

The usual dose time depends on the clock time on JAZZ™ DoseCoach®. Therefore, the clock time must be correct.

If the usual dose time does not fit your patient's daily routine, they can change it in the settings menu.

If your patient decides to take a dose now, Dose Helper should be used to save the dose.

## Warning shown to your patient



## What this means

Your patient has tried to run Dose Helper when the previous dose was taken less than 18 hours ago.

Dose Helper can only be run at least 18 hours after your patient's previous dose, and within three hours either side of the usual dose time. This is because taking two doses too close together may cause low blood glucose. If your patient decides to take a dose now, Dose Helper should be used to save the dose.

## “Dose suggestion not possible” warnings

Warning shown to your patient	What this means
<p>Dose Helper needs more fasting BG and/or dose information.</p>	<p>Your patient has not collected enough fasting blood glucose (BG) readings or insulin doses. Dose Helper needs a minimum amount of information to give dose suggestions (see page 22, Section 2 “Required information for a new dose suggestion or to suggest a dose increase”).</p> <p>Dose Helper needs to gather <b>new</b> fasting blood glucose readings and insulin doses in order to give suggestions again.</p>
<p>You recently took a dose outside your usual dose time of 19:00* (16:00* to 22:00*).</p> <p>*These are example times and may not reflect your patient’s treatment.</p>	<p>Dose Helper cannot suggest a dose because your patient took a dose outside the usual dose time.</p> <p>Dose Helper needs to gather <b>new</b> fasting blood glucose readings and insulin doses in order to give suggestions again.</p> <p>If the usual dose time does not fit your patient’s daily routine they can change it in the settings menu.</p>

Warning shown to your patient	What this means
2 doses taken less than 18 hours apart.	<p>Dose Helper cannot suggest a dose because your patient took two doses within 18 hours. Taking two doses too close together may cause low blood glucose and affects Dose Helper.</p> <p>Dose Helper needs to gather <b>new</b> fasting blood glucose readings and insulin doses in order to give suggestions again.</p>
You changed the clock time and/or your usual dose time significantly.	<p>Dose Helper cannot suggest a dose because: Your patient changed the clock time by more than three hours.</p> <p><b>OR:</b> Your patient changed the usual dose time by more than three hours.</p> <p><b>OR:</b> Your patient changed the clock time and the usual dose time. The combined change is more than three hours (see page 27, Section 2 “Time restrictions”).</p> <p>Dose Helper needs to gather <b>new</b> fasting blood glucose readings and insulin doses in order to give suggestions again.</p>

Warning shown to your patient	What this means
You changed your dose.	<p>Dose Helper cannot suggest a dose because your patient took different doses from the suggested dose. Dose Helper needs a minimum amount of fasting blood glucose readings and previous insulin doses. These insulin doses need to be at a consistent dose. See page 22, Section 2 “Required information for a new dose suggestion or to suggest a dose increase” for the dose changes that Dose Helper can accept. Dose Helper needs to gather <b>new</b> fasting blood glucose readings and insulin doses in order to give suggestions again.</p>

Warning shown to your patient	What this means
<p>Dose information was missing when the clock was changed. This information cannot be interpreted.</p>	<p>Your patient recently changed the 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 <b>new</b> fasting blood glucose readings and insulin doses in order to give suggestions again.</p>
<p>Dose Helper cannot restart if you recently had low BG or hypo symptoms.</p>	<p>Dose Helper cannot restart because your patient recently had a low blood glucose (BG) reading less than 3.9 mmol/L or has reported low blood glucose (measured with another meter), or hypo symptoms. Dose Helper needs to gather <b>new</b> fasting blood glucose readings and insulin doses in order to give suggestions again.</p>

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

**Warning shown to your patient**

Dose Helper cannot restart unless you consistently take the same dose.

**What this means**

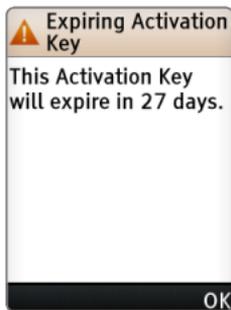
Dose Helper cannot restart because your patient recently entered differing doses. Dose Helper needs a minimum amount of fasting blood glucose readings and insulin doses at the same daily dose in order to give suggestions (see page 22, Section 2 “Required information for a new dose suggestion or to suggest a dose increase”). Dose Helper needs to gather **new** fasting blood glucose readings and insulin doses in order to give suggestions again.

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# QUESTIONS AND ANSWERS ON ACTIVATING DOSE HELPER

## Questions and answers on activating Dose Helper

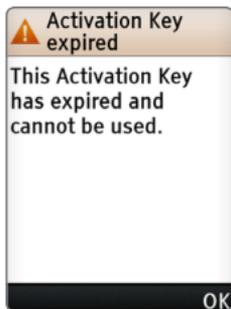
What happened	What this means and what to do
<p>You lost one, or more, of the activation keys or all keys.</p>	<p>To get new keys, call customer service at 0800 093 1812</p>
<p>Nothing happens when you insert an activation key.</p>	<p>JAZZ™ DoseCoach® batteries may be empty or installed incorrectly. Check the batteries.</p> <p><b>OR:</b> The key may be damaged. Try a different key. If that key works check the mini-USB connector of the initial key for any dirt and try this key again. If the problem continues, your key may be damaged. Call customer service at 0800 093 1812</p> <p><b>OR:</b> JAZZ™ DoseCoach® may be damaged. If none of your keys work, call customer service at 0800 093 1812</p> <p><b>OR:</b> You inserted an activation key when JAZZ™ DoseCoach® was already in use. Remove the key from the mini USB port, turn JAZZ™ DoseCoach® off by pressing  and try again.</p>

**What happened****What this means and what to do**

Each activation key has an expiration date. The key will expire in the number of days shown on the screen. After this date, the activation key can no longer be used to activate Dose Helper.

Complete the activation sequence as usual. The expiration date of your key has no impact on the lifetime of a Dose Helper activation.

To get a new key, call customer service at 0800 093 1812

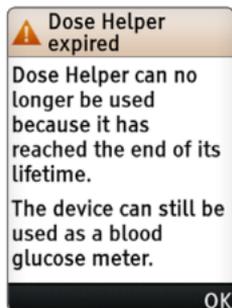


Each activation key has an expiration date. The key has expired and can no longer be used to activate Dose Helper.

To get a new key, call customer service at 0800 093 1812

Do not dispose of the keys. Please return expired keys to AgaMatrix.

## What happened



JAZZ™ DoseCoach® does not allow you to set the starting dose as high as you are trying to.

## What this means and what to do

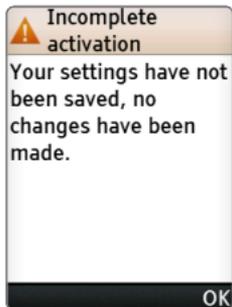
JAZZ™ DoseCoach® has an internal coin cell battery. If this battery runs empty, the Dose Helper function will expire and can no longer be used or activated. The battery should last about 4 years.

JAZZ™ DoseCoach® can continue to be used for measuring blood glucose. If you want your patients to continue using Dose Helper, you should give them a new JAZZ™ DoseCoach®.

The starting dose is limited by the maximum dose that is set based on the patient's weight. You cannot set a starting dose higher than the maximum dose.

- 1 Check if you are setting the correct starting dose.
- 2 Press  to check the patient's weight. The maximum dose is calculated at 1 unit per kg. The maximum dose cannot be higher than 200 units.

## What happened

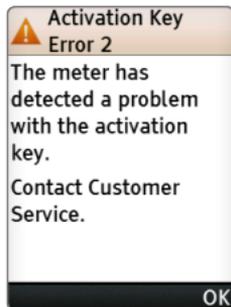
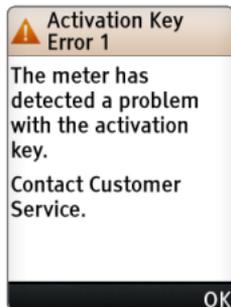


## What this means and what to do

You have removed the activation key before completing Dose Helper activation.

- ① Insert the key again to restart the activation sequence.
- ② Keep the key inserted until JAZZ™ DoseCoach® tells you to remove it.

## What happened



## What this means and what to do

A problem has occurred related to the activation key. The key may be damaged. Try a different key. If that key works check the mini-USB connector of the initial key for any dirt and try this key again.

If the problem continues, your key may be damaged. Call customer service at 0800 093 1812

Section 8:

# SYMBOLS USED ON PACKAGING

## Symbols used on packaging

**SN** Serial Number: a unique number that belongs to your patient's JAZZ™ DoseCoach®.



Manufacturer.

**IVD**

*In Vitro* Diagnostic Medical Device.

**LOT**

Batch code.



Consult instructions for use.



Do not reuse.

 Temperature limitation: must only be used in a room temperature above 10°C and below 40°C



Use by.

**REF**

Catalogue number.

**EC REP**

European Authorised Representative.

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8100-10400 Rev A