

Dose Check – GLP-1 Medication Patient User Guide (Saudi Arabia)

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Chapter 1. Introduction

Performance characteristics of Dose Check

Dose Check is an automated medication dosing solution developed to help adults who have type 2 diabetes and their healthcare professionals. You can access your medication plan anywhere, anytime on your mobile phone. You receive real-time personalized feedback and educational messages to help you manage your diabetes day-to-day. Your healthcare professionals can view your progress through a web-based portal that displays your latest blood sugar readings and medication doses.

Manufacturer



Amalgam Rx, Inc.
1007 N. Orange St.
Suite 400
Wilmington, DE 19801
United States

Usage guidelines

Dose Check should only be used under the guidance and supervision of a healthcare professional.

Intended use

Dose Check is intended to help adult¹ patients understand and follow their healthcare professionals' titration plan for the following:

- Titration of basal insulins²
- Titration of combinations of basal insulin and GLP-1 receptor agonists³

Patients using Dose Check can record their blood glucose levels, view their healthcare professional's titration plan for supported medications², and record the medication dose taken.

Dose Check connects with the following devices²:

- Glucose meters to transmit blood glucose data.

¹ Adult is defined by the country where Dose Check is used, and the age is configured according to governing regulations in that country.

² Supported medications listed and supported devices are configurable by country. Specific features, medications, and supported devices may or may not be applicable depending on country specific regulatory approvals.

- Smart insulin pens, caps, and attachments to transmit insulin dosage data to Dose Check and record the dose taken.

Dose Check is not intended to replace the care and management provided by a healthcare professional trained in the management of diabetes. Dose Check should not be used by patients with type 1 diabetes, gestational diabetes, or patients using an insulin pump.

Note: This user guide is focused on the configuration of Dose Check for use with GLP-1 medication.

Indications for use

Dose Check is indicated for use by adult³ patients with type 2 diabetes, and by their healthcare team to provide ongoing support for understanding and following a titration plan for supported medications⁴, to reach an optimal medication dose and/or target fasting blood sugar control.

Clinical benefit(s)

Dose Check may provide the following clinical benefit(s):

- Improves glycemic control.
- Reduces the number of hypoglycemic events.
- Decreases time to reach maintenance dose of insulin.

Contraindications

The following contraindications apply to the use of Dose Check:


- Use by a person who is not an adult.
- Use by patients in the event of an emergency.
- Use by patients with type 1 diabetes.
- Use by patients with gestational diabetes.
- Use by patients using an insulin pump.

Disclaimer

³ Adult is defined by the country where Dose Check is used, and the age is configured according to governing regulations in that country.

⁴ Supported medications are configurable by country. Specific features, medications, and supported devices may or may not be applicable depending on country specific regulatory approvals.

Understand that while Dose Check displays guidance to help patients who report hypoglycemic and hyperglycemic blood sugar measurements, it is not to be used for management of emergencies. Please contact emergency services as directed by your health care team.

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|---|---|
|  | <p>Important!</p> <p>Dose Check relies on a smartphone to deliver information about managing your diabetes. You are responsible for ensuring the settings on your smartphone are configured to support delivery of alerts. Be aware that certain hardware or software settings can interrupt the expected operation of your smartphone and/or applications. This can lead to harm if undetected.</p> |
|---|---|

Chapter 2. Getting started

To use all the features of Dose Check, you must first be enrolled in the system by your healthcare professional. Once you have been added by a healthcare professional, you will receive a text message that explains how to download Dose Check on your mobile phone.

Steps to complete patient registration

1. Download and open the Dose Check app.
2. Enter your phone number. This number must match the phone number that your healthcare professional entered when enrolling you in Dose Check. (If you have trouble accessing the app, verify what number was used for enrollment by your healthcare professional)
3. You will be texted a 4-digit verification code. Enter that code into the Dose Check registration form. The verification code is only valid for 10 minutes after it was texted to your mobile device. If the code expires before you login, tap the refresh icon to receive a new code.
4. You must select your date of birth from the date picker
5. You must agree to the Terms & Conditions and Privacy Policy to use Dose Check. Review them as desired before proceeding.
6. Tap the appropriate button to complete sign-up.

Patient Onboarding

1. You will be shown your profile. Confirm that your information is correct.
2. You will be prompted to create your own 4-digit PIN for future authentication.
3. If your phone has biometric authentication available, you may authorize Dose

Check to use your fingerprint or face ID for future authentication.

4. You will be shown a welcome screen to confirm that your registration is complete.
5. You will be shown the GLP-1 medication plan that your healthcare professional has recommended for you.
6. If you are already on GLP-1 medication, you may select the period for which you have been taking the medication.
7. For weekly GLP-1 medication, you can schedule the dose day to take your medication dose.
8. You will be presented with information on how to take your medication.

Additional information (Optional and can be skipped during onboarding)

1. You can set goals in the app, which will help in personalizing Dose Check to help in reaching your targets.
2. You can record your current A1C level and weight (in lbs or kg). This will help in prediction to reach target set.
3. You can set the goal to achieve the ideal weight.
4. You can provide additional information such as gender at birth, race and/or ethnicity and any diabetic medication taken prior to GLP-1 medication.
5. If you are experiencing any side effects related to GLP-1 medication, you can select one or more from the displayed list.

Reminders and Notifications

1. You will be given the opportunity to allow mobile push notifications to remind you to test and record your fasting blood sugar and to take your medications according to your healthcare professional's recommendations. The app will be more useful to you if you allow these notifications.
2. You can set reminders for measuring and recording your fasting blood sugar.
3. You can also set reminders for intake of GLP-1 medication. For weekly medications, the reminder will be triggered once a week on the dose day specified by you.
4. For daily GLP-1 medication, you can also enable the timer to help you fast for 30 minutes before consuming your food after medication intake.

Chapter 2.1. Home Screen

On the Home screen, you will be able to view:

- An option to record your GLP-1 medication.
- If you are on the initial dose of the GLP-1 medication and your HCP has recommended escalation to a maintenance dose, the medication card on the

home screen will also show the number of days post which you must reach out to your HCP for the maintenance dose.

- A graphical representation of your data.
- Option to view the Logbook with all recorded data for selected time range.
- Option to record any side effects.
- A few articles (if available) on GLP-1 medication recommended for you.
- Bottom navigation bar with short cut menu options.

Chapter 2.1.1. Bottom Navigation Bar

1. The short cut menu options in the bottom navigation bar are: –
 - Home
 - Record
 - Connected devices (if included in your default country configuration)
 - Logbook
 - More
2. While navigating through various screens in the app, you can tap on the Home button to return to the Home screen of the patient app.
3. You can use the Record option to
 - Record your GLP-1 medication dose
 - Record your blood sugar (fasting or non-fasting)
 - Record your A1C level in the app.
 - Record your weight (in lbs or kg per country configuration)
 - Record your side effects
4. You can connect to a supported glucometer, pen cap or any other device or unpair the app from an already connected device through the Connected Devices option.
5. Tap on the Logbook option on the bottom navigation bar to view the data recorded by you in the app or view the graph for the same.
6. You can use the More option to view other menu options in the app such as:
 - Your profile information
 - Health Info
 - Resources
 - Settings (for updating PIN, Notifications preferences, Data Sharing consent)
 - Help (Product Labeling information)

Chapter 2.2. Record A1C and Weight

You can record your A1C level in the app by tapping on the “Record” option on the bottom navigation bar. You can select the A1C value from the picker and save the value in the app. You can also record your weight in the units of measurement (lbs or kg) as configured for your account. The current date is displayed by default, and you can edit the same to reflect the actual date on which the A1C value or weight was determined.

Chapter 2.3. Resources

You can view articles on GLP-1 medications and related topics from the More menu on the bottom navigation bar. You can tap on the bookmark icon against the article to save it for future references.

The Resources Library has 3 sections:

- For You – which displays a few unread articles tailored to suit your needs
- Topics – which contains the broader categories with the topics sorted under each category
- Saved – which contains the articles that you have bookmarked. You can tap the bookmark icon in a saved article to remove it from the saved section.

Chapter 2.4. Record Side effects

You can record side effect(s) experienced by you by tapping on the “Record” icon and selecting the option to do so. You can select a side effect from the displayed list and specify the severity of the symptom. Tap on a selected side effect to change its severity or to delete the side effect from the selected list. If you are experiencing frequent or severe symptoms, consult your HCP for further advice. The current date is displayed by default, and you can edit the same to reflect the actual date when you experienced the side effects.

Chapter 2.5. Record blood sugar levels

To obtain your fasting blood sugar levels, you should test your blood sugar before eating or drinking anything. If you record a blood sugar reading within 2 hours of the time at which you have set your reminder, Dose Check will default the reading to “fasting”. All other blood sugar readings will default to “non-fasting”.

Steps to record blood sugar levels

1. Tap the option to record blood sugar.
2. Enter your blood sugar level and ensure that it is labeled appropriately as either “fasting” or “non-fasting”.
3. Adjust the date and time for accuracy.
4. Save your entry.

After recording your blood sugar, Dose Check will share a brief in-app message with you intended to provide encouragement or education. These messages are displayed based

on your tracking history.

Chapter 2.6. Record medication doses

It's important to record every GLP-1 medication dose that you take in Dose Check. You can record a dose any time from the home screen or from the record option in the bottom navigation bar.

Dose Check will inform you of your dose day (every day of the week for daily medications and specific day of the week for weekly medications). You must select the day(s) on which you have taken your medication and save the details in the app. You can record the dose for previous weeks by navigating back in the weekly calendar.

Chapter 2.7. Sync blood sugar readings from a glucose meter

With Dose Check, you have options to enter your blood sugars manually, or by syncing with connected devices. You can also record using a combination of manual and synced entries.

If you have paired your wireless glucose meter¹ (*Please refer Section 7.1*) with Dose Check, you can sync your blood sugar readings from the glucose meter to Dose Check. You can view these readings at any time from the Dose Check logbook.

¹The presence and variety of wireless glucose meters varies by country.



Important!

Do not share your connected glucose meter with anyone.

Note: You can edit or delete incorrect manual entries from logbook. If the entry was synced from a glucose meter, you cannot edit the entry. If it was entered in error, you can delete any entry. Checking the logbook for duplicate entries and accuracy of your entries helps you and your healthcare professional track your diabetes management.

Chapter 3. Your medication plan in Dose Check

You can view the medication plan that your healthcare professional has recommended for you. Dose Check will notify you if your healthcare professional makes any changes to your medication plan. Please contact your healthcare professional if you have questions about the medication plan under the Health Info menu that they have recommended or other questions about your GLP-1 medication dose.

Chapter 4. Low blood sugar

Hypoglycemia can be serious and, if left untreated, can lead to loss of consciousness or death. It is important to recognize when you have symptoms of low blood sugar and to treat it immediately.

Some signs of hypoglycemia include:

- Feeling shaky
- Sweating
- Weakness
- Confusion

However, checking your blood sugar is the only way to be sure that your symptoms are related to hypoglycemia. Ask your healthcare professional about low blood sugar and what you should do to treat it.

Chapter 4.1. Reporting of low blood sugar symptoms

If you experience symptoms related to hypoglycemia, you can report them in the app. If the symptoms were experienced prior to current date and time, you can edit the date and time while reporting them. You must also specify if the symptoms have been handled by self or with help.

Chapter 4.2. Correcting low blood sugar

If you record a blood sugar level that is below the threshold, Dose Check will prompt you to consume fast-acting carbohydrates and recheck your blood sugar in 15 minutes. Dose Check will remind you after 15 minutes to re-test your blood sugar. When entering your blood sugar levels after re-testing, Dose Check will recognize this as a non-fasting value.

**Important!**

Contact your healthcare professional if you continue to have low blood sugars while using Dose Check. In case of emergency, please contact emergency services as directed by your healthcare professional.

Chapter 5. High blood sugar

High blood sugar (“hyperglycemia”) means your body does not have enough insulin or your body cannot use the insulin you have effectively. High blood sugar can be serious. If left untreated, hyperglycemia can be life-threatening.

Some common causes of high blood sugar include:

- Eating more than usual
- Lack of Physical activity
- Illness
- Stress
- Missing or incorrect insulin doses

Some common symptoms include having to urinate more frequently and feeling thirsty. However, checking your blood sugar is the only way to be sure that your symptoms are related to hyperglycemia. Ask your healthcare professional about high blood sugar and how you should treat it.

Alerts on recording a High Blood Sugar level

When you are enrolled in Dose Check, your healthcare team will set a threshold for your blood sugar level, above which is considered hyperglycemia.



Important!

Contact your healthcare professional if you continue to have high blood sugars while using Dose Check. In case of emergency, please contact emergency services as directed by your healthcare professional.

Chapter 6. Logbook

Your healthcare professional has access to view the data you record in Dose Check on their web portal. You can generate a PDF report of your logbook data and share it securely with your Healthcare Professional via shared apps in your device.

Chapter 6.1. Blood sugar and GLP-1 medication doses

You can view a chronological list of all blood sugar levels and medication doses that you have recorded on the logbook screen. You can edit these readings at any time. You will have the option to view your fasting blood sugar levels and medication doses in a graph, filtered by date intervals.

Chapter 6.2. A1C, Weight and Side effects

You can view and edit the Weight, A1C values and count and severity of the side effects recorded in the Patient logbook. You can view the A1C levels and weight trends in a graph, filtered by date intervals. You can also view the graph of the count or severity of the side effects recorded in the selected date interval.

Chapter 7. Pairing with wireless smart devices

Chapter 7.1. Pairing with a wireless glucose meter

You can pair a wireless glucose meter⁵ during onboarding or at any time from the home screen. To pair a wireless glucose meter, select the make and model of your glucose meter from the list and follow the instructions. Once you have paired a glucose meter, you can sync your blood sugar readings wirelessly to Dose Check rather than manually entering them.

You can unpair a glucose meter at any time in the app. If you are switching to a different glucose meter, you must first unpair the current one before pairing the new one.

Chapter 8. Other important information

In Dose Check, you can:

- Change your name and date of birth, view your healthcare professional's name, and view your prescribed medication type.
- Create a new 4-digit PIN.
- Enable / disable the biometric authentication.
- Enable / disable the notifications prompting you to record fasting blood sugar level

⁵ The presence and variety of wireless glucose meters varies by market and country

and medication dose.

- Enable / disable your consent for data sharing.

If you forget your PIN or enter the incorrect PIN 5 consecutive times, please contact customer support to have your account reset. You will be able to login again using your phone number which will prompt Dose Check to text you a new 4-digit verification code. All your data will be retained.

If you get a new phone, navigate to the App Store/Google Play Store and download Dose Check. Login using your 4-digit PIN. Your data will be retained, and you can resume using Dose Check as you had previously.

If you wish to change your phone number, you must delete your account and create a new account with your new phone number.

If you are switching from your current HCP to a new one, you can use the Dose Check logbook version (if enabled in your country configuration) to log your blood sugar values and medication doses till the new HCP accepts your request.

Chapter 8.1. Customer support

If you have any feedback for Dose Check or need to report any issues, please contact our customer support team using the contact information provided in the help section. Please use the same contact information to report any serious incident(s) observed while using Dose Check and report the same information to your local health authority according to local laws.

Chapter 8.2. No internet connection

Dose Check works both with and without an internet connection. If you do not have an internet connection, you can still record your blood sugar values and medication doses. Once you reconnect to the internet, your healthcare professional will have access to the data you entered while offline.

Chapter 8.3. Delete account

You may delete your Dose Check account at any time, thereby removing all personally identifiable information (PII) from Dose Check.



Important!

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| If you choose to delete your account, all your account details (including your personal identifiable information) will be permanently erased from your Dose Check account. Once deleted, you will not have the ability to access the data you recorded in Dose Check including your blood sugar levels and medication doses. |
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Chapter 9. Cybersecurity guidelines

Protecting your data:

At Amalgam Rx, we take your privacy and security seriously. Our app uses state-of-the-art encryption and secure servers to ensure that your health information is protected at all times. Regular security updates and continuous monitoring help us to safeguard your data against unauthorized access and cyber threats.

Understanding cybersecurity risks:

While we strive to provide the highest level of security, no system is completely immune to risks. Potential cybersecurity threats could include unauthorized access to your personal health information, data breaches, or loss of data due to malware and other cyberattacks. We are committed to quickly addressing any security vulnerabilities and encourage our users to participate in keeping their data secure.

Your role in cybersecurity:

- **Strong Passwords:** Always choose a strong, unique password for your account and change it regularly.
- **Secure Network:** Ensure that you are using a secure and private Wi-Fi connection when accessing the app.
- **App Updates:** Install updates for Dose Check promptly. These updates often contain important security enhancements.






Staying updated:

Our team regularly releases updates to enhance the functionality and security of Dose Check. You will receive notifications within the app whenever a new update is available. For your safety, we recommend always keeping your app up to date.

Reporting security concerns:

If you have any concerns about cybersecurity or notice any suspicious activity within the app, please contact us immediately at security@amalgamrx.com. Your security is our top priority, and we are here to assist with any concerns you may have.

About Dose Check

| | |
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|  | Intertek Medical Notified Body AB. Sweden n. 2862 |
|  | Manufacturer Amalgam Rx, Inc. 1007 N. Orange St Suite 400 Wilmington, DE 19801 United States |
|  | Importer Amalgam Rx EU 70 Sir John Rogerson's Quay Dublin 2 D02 R296 Ireland |
|  | Authorized Representative Medical Device Safety Service GmbH Schiffgraben 41 30175 Hannover, Germany |
|  | DSC-SA-001 |
|  | Basic UDI-DI 0850006610ISPXX |

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| | <p>Intended use</p> <p>Dose Check is intended to help adult¹ patients understand and follow their healthcare professionals' titration plan for the following:</p> <ul style="list-style-type: none"> • Titration of basal insulins² • Titration of combinations of basal insulin and GLP-1 receptor agonists² <p>Patients using Dose Check can record their blood sugar levels, view their healthcare professional's titration plan for supported medications², and record the medication dose taken.</p> <p>Dose Check connects with the following devices²:</p> <ul style="list-style-type: none"> • Glucose meters to transmit blood sugar data. • Smart insulin pens, caps, and attachments to transmit insulin dosage data to Dose Check and record the dose taken. <p>Dose Check is not intended to replace the care and management provided by a healthcare professional trained in the management of diabetes. Dose Check should not be used by patients with type 1 diabetes, gestational diabetes, or patients using an insulin pump.</p> <p>¹Adult is defined by the country where Dose Check is used, and the age is configured according to governing regulations in that country.</p> <p>² Supported medications listed and supported devices are configurable by country. Specific features, medications, and supported devices may or may not be applicable depending on country specific regulatory approvals.</p> |
| | <p>Indications for use</p> <p>Dose Check is indicated for use by adult¹ patients with type 2 diabetes, and by their healthcare team to provide ongoing support for understanding and following a titration plan for supported medications², to reach an optimal medication dose and/or target fasting blood sugar control.</p> <p>¹Adult is defined by the country where Dose Check is used, and the age is configured according to governing regulations in that country.</p> <p>² Supported medications are configurable by country. Specific features, medications, and supported devices may or may not be applicable depending on country specific regulatory approvals.</p> |

**Caution**

The following contraindications apply to the use of Dose Check:

- Use by a person who is not an adult.
- Use by patients in the event of an emergency.
- Use by patients with type 1 diabetes.
- Use by patients with gestational diabetes.
- Use by patients using an insulin pump.

Understand that while Dose Check displays guidance to help patients who report hypoglycemic and hyperglycemic blood sugar measurements, it is not to be used for management of emergencies. Please contact emergency services as directed by your healthcare professional.

Operating systems

Dose Check supports the following operating systems. When a new operating system update becomes available, compatibility tests will be conducted prior to the next release.












- Android: 10.x or later
- iOS: 16.x or later
- Google Chrome: 115.x or later
- Firefox: 115.x or later
- Microsoft Edge: 115.x or later
- Safari: 16.x or later
- IE browser is not supported.

Device hardware

Optimized for iOS and Android devices running the latest two versions of their respective operating systems. Performance on older devices or operating systems may vary. Always ensure your device has the latest software updates for the best results.

| | |
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| | <p>Availability of instructions for use</p> <p>The Instructions for Use (IFU) for this device are provided in electronic form and can be accessed on our official website. This allows us to provide you with the most up-to-date information in a convenient and environmentally friendly format.</p> <p>If you prefer to have the IFU in paper form, you can request a free copy by contacting us via email at the Customer Support contact details provided in the Help screen in the application, or by mail at our mailing address above. We will aim to fulfill your request within 7 calendar days.</p> <p>Please note that the electronic version of the IFU is the most current and should be referred to for the latest information about the use of our device.</p> |
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Appendix A – Symbols

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|  | Manufacturer |
|  | Caution, Attention |
|  | Conformité Européenne (CE) Mark |
|  | Distributor |
|  | Importer |
|  | Authorized Representative |
|  | Model Number |
|  | Serial number |
|  | Date of manufacture |
|  | Consult instructions for use |
|  | Unique Device Identifier |