

Dose Check
Patient User Guide
(EU – English)

Contents

Chapter 1 - Introduction	2
Chapter 2 - Getting started	3
Chapter 3 – Record blood sugar levels and insulin doses	4
Chapter 3.1 – Manual entry of blood sugar levels and insulin doses.....	6
Chapter 3.2 – Sync blood sugar readings from a glucose meter	6
Chapter 3.3 – Sync insulin doses with a smart insulin pen, or pen cap.....	6
Chapter 4 – Your insulin plan in Dose Check	7
Chapter 5 – Insulin adjustment day	7
Chapter 6 – Titration calendar	7
Chapter 7 – Maximum daily (weekly) dose	7
Chapter 8 – Low blood sugar	8
Chapter 9 – High blood sugar	9
Chapter 10 – Logbook	10
Chapter 10.1 – Blood sugar and insulin doses.....	10
Chapter 10.2 – Height and Weight	10
Chapter 11 – Pairing with wireless smart devices	10
Chapter 11.1 – Pairing with wireless Glucose meter.....	10
Chapter 11.2 – Pairing with a Smart Insulin Pen or Pen Cap.....	10
Chapter 12 – Other important information	11
Chapter 12.1 – Customer support.....	11
Chapter 12.2 – No internet connection	11
Chapter 12.3 – Delete account.....	11
Chapter 13 – Cybersecurity guidelines	12
About Dose Check	13
Appendix A – Symbols	17

Chapter 1 - Introduction

Performance characteristics of Dose Check

Dose Check is an automated insulin titration solution developed to help adults who have type 2 diabetes and their healthcare professionals titrate basal insulin and medications that combine basal insulin and GLP-1 receptor agonists (RA)¹. You can access your insulin plan anywhere, anytime ~~with support~~ 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 insulin medication doses.

¹ The number and variety of available basal insulin and basal insulin combination products varies by country..

Manufacturer



Amalgam Rx, Inc.
1007 N. Orange St.
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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 agonists²

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.
- 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.

¹Adult 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.

Indications for use

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.

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

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

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

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.

Chapter 2 - Getting started

Once you have been added to Dose Check 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. Open the Dose Check app and enter your phone number.

- a. This number must match the phone number that your healthcare professional entered when enrolling you in Dose Check.
2. You will be texted a 4-digit verification code. Enter that code and your birthdate into the Dose Check registration form.
 - a. 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.
 - b. Your birth date must match the one that your healthcare professional entered when enrolling you in Dose Check.
3. You must agree to the Terms & Conditions and Privacy Policy to use Dose Check. Review them as desired before proceeding.
4. Tap the appropriate button to complete sign-up.
5. You will be shown your profile. Confirm that your information is correct.
6. You will be prompted to create your own 4-digit PIN for future authentication.
7. If your phone has biometric authentication available, you may authorize Dose Check to use your fingerprint or face ID for future authentication.
8. You will be shown a welcome screen to confirm that your registration is complete.
9. You will be shown the insulin plan that your healthcare professional has recommended for you.
10. You will be shown instructions for how and when to take your insulin.
11. 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 insulin. It's recommended that you allow these notifications.
12. If you are taking weekly insulin, you can select the day of the week when you will take the insulin.



Important!

Dose Check can only provide insulin dose recommendation if you record your fasting blood sugars in Dose Check. If you fail to record your fasting blood sugar readings, your insulin adjustment day will be moved until you enter enough consecutive fasting blood sugars for Dose Check to determine your new dose of insulin. Contact your healthcare team if you have any questions about your insulin plan.

Chapter 3 – Record blood sugar levels and insulin doses

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 receive your daily reminder¹, Dose Check will default the reading to “fasting”. All other blood sugar readings will default to “non-fasting”. You can manually change a reading to fasting or non-fasting at any time.

It's important that fasting blood sugar readings are labeled appropriately.

¹ You can change the time of day that you receive these reminders from the settings.

It's important to record every insulin dose that you take in Dose Check, which you can do at any time from the home screen.

- If you are taking a daily insulin in the morning, you will be immediately prompted to take and record your insulin dose after recording your fasting blood sugar.
- If you are taking a daily insulin in the evening, Dose Check will prompt you to take and record your insulin later.
- If you are taking a weekly insulin¹, you will be prompted to take and record your insulin on the day of the week that you have specified.

Dose Check will inform you of your recommended insulin dose and you should always take your recommended dose while using Dose Check for insulin titration. However, if for any reason you take a dose of insulin that differs from your recommended dose, you should record how much insulin you actually took.



Important!

Since Dose Check uses only fasting blood sugar readings to calculate your insulin dose, it is important that you label your blood sugar readings correctly (fasting or non-fasting).



Important!

Users taking once weekly insulins¹ will be prompted to specify a day of the week on which they plan to take their insulin.

Some users who switch from a once daily to a once weekly insulin¹ may find that their healthcare professional recommends a one-time additional dose that is larger than their weekly dose. If your healthcare professional recommends this one-time additional dose, take the increased amount of insulin only once and then start taking your weekly prescribed dose. Follow the Dose Check instructions as Dose Check will show you the recommended amount of insulin to take each week.



Important!

Please contact your healthcare professional if you have questions about your insulin plan or your insulin dose.

¹Weekly insulin availability varies by country.

Chapter 3.1 – Manual entry of blood sugar levels and insulin doses

Steps to record blood sugar levels and insulin doses

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. Save your entry.
4. If it is time to take your insulin, Dose Check will display your recommended dose.
5. After taking your insulin, make any adjustments necessary to ensure that your insulin entry in Dose Check matches exactly how much insulin you took.
6. Save your entry.

Sometimes, after recording your insulin, 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.



Important!

If for any reason you take a dose of insulin that differs from your recommended dose, you should record how much insulin you actually took

Chapter 3.2 – Sync blood sugar readings from a glucose meter

If you have paired your wireless glucose meter¹ (*Please refer Section 11.1*) 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. These readings are used to track your progress and determine your insulin dose so do not share your glucose meter with anyone else.

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



Important!

Do not share your connected glucose meter with anyone.

Chapter 3.3 – Sync insulin doses with a smart insulin pen, or pen cap

If you have paired your wireless smart insulin pen or pen cap¹ with Dose Check (*Please refer Section 11.2*), you can sync your insulin doses from that device. You can view these doses at any time from the Dose Check logbook.

¹The presence and variety of wireless smart insulin pens and pen caps varies by country.

Chapter 4 – Your insulin plan in Dose Check

You can view the insulin plan that your healthcare professional has recommended for you. Dose Check will notify you if your healthcare professional makes any changes to your insulin plan.

When Dose Check recommends a new insulin dose for you that differs from your prior dose, you will be shown the new recommended dose and how it was determined.

Please contact your healthcare professional if you have questions about your insulin plan or your insulin dose.

Chapter 5 – Insulin adjustment day

Your healthcare professional will set the frequency of dose adjustments. This titration frequency ranges between 1 and 7 days. If the insulin adjustment day is every 1, 2 or 3 days, it is important that you record your fasting blood sugar every day to receive a new recommended dose. If the insulin adjustment day is every 4,5,6 or 7 days, it is important that you record your fasting blood sugar on your insulin adjustment day and on the two consecutive days prior.

If you are on a weekly insulin, record your insulin dose on the day of the week you have selected to take your insulin. In case of a delay in taking your weekly dose, you must record your insulin dose within 10 days from the previous insulin adjustment day to remain on schedule.

If you record your insulin after 10 days from the previous insulin adjustment day, you will be instructed to skip the next insulin dose. The next insulin adjustment day will be rescheduled accordingly.

Chapter 6 – Titration calendar

The titration calendar provides you with a view of your titration history and level of tracking completeness towards your next insulin adjustment day. This view includes:

- Days on which you have recorded a fasting blood sugar level.
- Days on which you have recorded an insulin dose.
- The day planned for your next insulin adjustment.

You can fill any gaps in your tracking history by tapping on a past date in the titration calendar, which will take you to the fasting blood sugar and/or insulin dose entry screen.

Chapter 7 – Maximum daily (weekly) dose

When setting up your insulin plan in Dose Check, your healthcare professional specifies an upper threshold dose limit for how high Dose Check can titrate your insulin dose. Certain medications have actual dose limitations recommended by the manufacturer. In Dose Check, the healthcare professional defines an upper threshold that will prevent your dose from increasing any further. You will be asked to contact your healthcare professional to evaluate further treatment adjustments.



Important!

After you reach your maximum daily (or weekly) dose of insulin, your insulin dose will not be adjusted higher until your healthcare professional has updated your insulin plan. If you reach your maximum daily (or weekly) dose of insulin, please contact your healthcare professional.

Chapter 8 – Low blood sugar

Hypoglycemia can be serious and, if left untreated, can lead to unconsciousness 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.

Correcting a 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.

Dose Check will adapt your titration schedule and your insulin dose accordingly. If you have not recorded your insulin dose for the day, Dose Check will recommend a reduced insulin dose compared to your previous dose.



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 9 – 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. If you record a blood sugar reading above the threshold, you will see an alert on the screen and will be prompted to record your blood sugar again in 3 hours.



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 10 – Logbook

Your healthcare professional has access to view the data you record in Dose Check on their web portal.

Chapter 10.1 – Blood sugar and insulin doses

You can view a chronological list of all blood sugar levels and insulin 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 insulin doses in a graph, filtered by date intervals. If you have switched from one insulin to another, you can view the list of blood sugar levels and insulin doses for both the previous and the current insulin.

Chapter 10.2 – Height and Weight

The Dose Check app determines your body mass index using the height and weight you enter. Dose Check will retain your height but prompt you to enter a new weight each time you visit this section.

Chapter 11 – Pairing with wireless smart devices

Chapter 11.1 – Pairing with wireless Glucose meter

You can pair a wireless glucose meter¹ during onboarding or at any time from the settings menu. 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 from the settings menu.

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

Chapter 11.2 – Pairing with a Smart Insulin Pen or Pen Cap

You can pair a wireless smart insulin pen or pen cap during onboarding or at any time from the settings menu. To pair a smart pen or pen cap, select the make and model from the list and follow the instructions.

Once you have paired a smart pen or pen cap, you can sync your insulin doses wirelessly to Dose Check rather than manually entering them.

You can unpair a smart pen or pen cap at any time from the settings menu.

¹The presence and variety of wireless smart insulin pens and pen caps varies by country.

Chapter 12 – 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 insulin type.
- Create a new 4-digit PIN.
- Enable / disable the biometric authentication.
- Enable / disable the notifications prompting you to record fasting blood sugar level and insulin 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 and birth date, 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.

Chapter 12.1 – 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 12.2 – 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 insulin doses. Dose Check also continues to titrate your insulin dose based on your healthcare professional's recommended insulin plan. Once you reconnect to the internet, your healthcare professional will have access to the data you entered while offline.

Chapter 12.3 – Delete account

You may delete your Dose Check account at any time, thereby removing all personally identifiable

information (PII) from Dose Check.



Important!

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 insulin doses.

Chapter 13 – 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

	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-XX-001 (XX refers to country code and will be filled based on country configuration)
	Basic UDI-DI 0850006610ISPXX

	<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: 9.x or later
- iOS: 14.x or later
- Google Chrome: 100.x or later
- Firefox: 99.x or later
- Microsoft Edge: 100.x or later
- Safari: 15.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.












Availability of instructions for use

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.

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.

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.

Appendix A – Symbols

	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