Dose Check
Healthcare Professional User Guide
(Denmark)

Table of Contents

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]. Dose Check allows you to define a personalized titration plan for any of your type 2 diabetes patients using basal insulin or basal insulin combined with GLP-1 receptor agonists. The Dose Check device should not be used by patients with type 1 diabetes, gestational diabetes, or patients using an insulin pump.

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

Patients can access the titration plan that you create for them anywhere, anytime, through the Dose Check app. Patients receive real-time personalized in-app messaging that provides diabetes education and supports diabetes self-management.

Healthcare professionals can access the Dose Check web portal to select or customize a preset clinically validated titration plan for their patients. Dose Check allows them to control all elements of the titration plans that they assign to patients, including the starting dose, fasting blood sugar target, frequency with which the patient's dose is titrated, the scale used to change the patient's dose, hypo and hyperglycemia thresholds, and maximum dose. Certain medications have actual dose limitations recommended by the manufacturer. In Dose Check, the healthcare professional defines an upper threshold that will prevent the patient's dose from increasing any further. Patients will be asked to contact their healthcare professional to evaluate further treatment adjustments. Patient recorded blood sugar levels and dose data are accessible to healthcare professionals in the form of logbooks and graphs through the Dose Check web portal.

⚠	**Important** The titration plans included in Dose Check are derived from treat-to-target clinical study protocols conducted by the manufacturers, patient-directed titration studies, prescribing information from the manufacturers' labels, and/or recommendations by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) or other country-specific diabetes professional societies. They are not meant to replace the clinical judgment of the healthcare provider.

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 adult[1] patients understand and follow their healthcare professionals' titration plan for the following:

- Titration of basal insulins[2]
- Titration of combinations of basal insulin and GLP-1 receptor agonists[2]

Patients using Dose Check can record their blood sugar levels, view their healthcare professional's titration plan for supported medications[2], and record the medication dose taken.

Dose Check connects with the following devices[2]:

- 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.

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.

[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.

Indications for use

Dose Check is indicated for use by adult[1] patients with type 2 diabetes, and by their healthcare team to provide ongoing support for understanding and following a titration plan for supported medications[2], to reach an optimal medication dose and/or target fasting blood sugar control.

[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 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. Your patients should follow your instructions for managing emergency situations.

Chapter 2. Getting started

Chapter 2.1. Roles and profiles in Dose Check

There are different profiles in Dose Check:

- Healthcare professionals can be added to Dose Check by an administrator or may self-register in Dose Check[1].
- Office staff can be associated with one or many healthcare professionals in Dose Check. Contact your administrator if you would like to establish associations with one or more office staff.
    - **Office staff with patient enrollment rights** can add patients to Dose Check under the guidance and supervision of a healthcare professional.
    - **Office staff with read-only permission** can only view patient titration plan information and patient self-reported data.

[1]A healthcare professional's ability to self-register may not be available in all countries.

Chapter 2.2. Account created by an administrator

If you are added to Dose Check by an administrator, you will receive an email with a temporary password that will grant you access to Dose Check.

Steps to login as a new user

1. Click on the hyperlink in your welcome email to surface Dose Check in your web browser.
2. Enter your email address and the temporary password found in your welcome email into the login screen.
3. When prompted, set a new password.
4. Accept the terms and conditions and the legal disclaimers.

Chapter 2.3. Self-registration

If self-registration has been enabled in your country, you can register yourself as a healthcare professional in Dose Check. Office staff accounts can only be created by an administrator.

Steps to self-register for Dose Check:

1. Navigate to Dose Check in your web browser.
2. Select the option to self-register.
3. Complete all fields in the form.
4. Create a password.
5. Accept the terms and conditions and the legal disclaimer.

You will receive an email requesting that you confirm your email address by clicking on a hyperlink. While you can use Dose Check without completing this step, we request that you confirm your email address as soon as possible to help us ensure data accuracy.

Chapter 3. Add a patient to Dose Check

As a healthcare professional or an office staff with patient enrollment rights, you can add a patient to Dose Check. When doing so, you must create a titration plan for the patient. As an office staff you must select the name of the healthcare professional on behalf of whom you are adding the patient.

If you are testing the Dose Check product to explore its functionality and simulate patient experience, you can do so by adding a patient and marking them as “Test Patient”. The data pertaining to these test patients will be excluded in analysis of the real-time data of actual patients that you manage.

Chapter 3.1. Steps to add a new patient with insulins

1. Click the button to add a new patient.
2. Complete all fields in the patient information section.
3. Select the units of measurement[1] in which the patient will record their blood sugar levels in the app.
4. Select the insulin or insulin combination medication that your patient is taking.
5. Select a titration plan from the dropdown. View the insulin section that's populated based on the titration plan you selected. You may edit any aspects of this titration plan to customize it for your patient.
6. View the blood sugar alerts section and make any edits to the threshold values as necessary.
7. Scroll to the bottom of the page to "Save" and view the "Success" screen to verify your titration plan.

Considerations when adding a patient with a weekly insulin:

- The titration schedule for weekly insulin is fixed at 7 days.
- You can use the Dose Calculator to determine the weekly dose and the one-time additional dose for the patient (if applicable). The one-time additional dose is optional and is applicable only if your patient is switching from a once daily insulin to a weekly insulin.
- If your patient is currently on a daily insulin, the weekly dose is calculated as 7 times the current daily dose that your patient is taking.
- If a one-time additional dose is also recommended, then the first dose (the sum of weekly dose and one-time additional dose) is calculated as 10.5 times the current daily dose that your patient is taking.
- The units of weekly insulin dose that your patient can take are rounded off to the nearest 10 units, as the pre-filled insulin pens are only supplied in increments of 10 units.

You can select the date on which the Patient should take their first weekly insulin dose from the calendar. Please confirm with the patient before selecting the first dose date, as this will set the day of the week when the patient should take their weekly insulin and the day of the week for the first dose cannot be changed after the patient completes onboarding in the app

⚠ **Important**

You are solely responsible for selecting the appropriate titration parameters for your patient. As there may be slight differences between the referenced study evidence and the Dose Check titration plans, you should review and adjust the auto-populated values based on the individual patient's needs and their medical assessment.

After successfully adding a patient to Dose Check, you will be presented with a summary of the titration plan that you recommended in a printer-friendly format. You may print this page and hand it to your patient if you desire. Your patient will receive a text message with a link that will navigate them to the App Store / Google Play Store where they can download Dose Check to their mobile phone.

[1]A healthcare professional's ability to select units of measurement in the titration plan may not be available in all countries.

Chapter 3.2. Steps to add a new patient with GLP-1 medication

1. After adding all fields in the patient information section, select the GLP-1 medication from the dropdown list
2. Select the appropriate dosage from the dropdown list. The dosage list will be displayed based on the medication brand selected.
3. Depending on the dosage selected, you can select the dose escalation option to receive reminders for patients to transition to a maintenance dose after a specific time period.
4. You can set the target fasting blood sugar range values and threshold values for the blood sugar alerts, as necessary.
5. Save the patient record and view the prescription page with GLP-1 medication plan. There are options to create a printout or to send the prescription via email.

Chapter 3.3. Connect with a patient already using Dose Check

1. When you add a new patient in Dose Check, the system will recognize via the phone number if the patient is already registered in Dose Check.
    a. If the patient is not connected to any healthcare professional[1], you can proceed and define a titration plan or medication plan with the same steps as adding any new patient.
    b. If the patient is already connected with another healthcare professional, the patient must initiate a request to connect with you as their healthcare professional[2].
2. The patient record is added to your dashboard with the status as "Request Sent" under the "Patient requests" tab.
3. If the patient accepts your request, the patient record is added to the active patients list under the "All patients" tab.
4. If the patient declines your request, the patient status in the "Patient requests" tab will change to "Request Declined" and the patient will continue to only be able to use Dose Check without your titration plan or medication plan.

Alternatively, a patient already registered in Dose Check can initiate a request to connect with you[2]. You will be informed of their request. You can view their record under "Patient requests" tab with the status marked as "Connection". You can accept or decline their request.

If you accept their request, you must update their record with a titration plan or medication plan.

Your patient will receive confirmation that their request has been accepted, and they will be able to start following their titration or medication plan. If you reject their request, the patient may still be able to continue using Dose Check without your titration or medication plan if this feature is available in your country[1].

Please note that your patient will be able to use Dose Check logbook version without a titration or medication plan till you accept their request. Once you accept their request and add them into your dashboard, you can view their historic data along with the data that they recorded in the Dose Check app without a titration or medication plan.

[1] The ability for a patient to use Dose Check without a connection to a healthcare professional may not be available in all countries.

[2] The ability for a patient to initiate a connection request with a healthcare professional may not be available in all countries.

Chapter 4. Titration calculation

If a patient is using a titration schedule with intervals of three days or longer, Dose Check will use three fasting blood sugar readings accumulated during the two days preceding and the day of titration. A patient's insulin dose will only be increased if more than 50% of the blood sugar readings are above target and the patient has recorded zero blood sugar readings below target.

All three readings used to titrate must be accumulated on consecutive days. If a patient fails to record a fasting blood sugar reading on one of the three consecutive days, Dose Check will delay titrating the patient's dose until the patient records fasting blood sugar readings on three consecutive days.

⚠ **Important**

Since Dose Check uses only fasting blood sugar readings to calculate the insulin dose, it is important that the patient labels their blood sugar readings correctly (fasting or non-fasting).

⚠ **Important**

If a patient records more than one fasting blood sugar reading on the same day, only the most recent reading is used for titration calculations.

Chapter 5. Custom titration plans

As a healthcare professional, you can customize and save a titration plan to use with future patients. Office staff cannot save custom titration plans but will be able to use or view the custom titration plans that you create if they are associated with your profile.

Steps to create a new custom titration plan

1. Select the custom titration plan option from the settings tab.
2. Tap to create a new custom titration plan.
3. Create a unique name for your titration plan and specify the name of the insulin.
4. Select an existing titration plan from which the custom titration plan will be derived.
5. Modify any aspects of the titration plan that you wish and save the custom titration plan.

Alternatively, after making any modifications to a titration plan for a specific patient, you will be given the option to save the changes as a new custom titration plan.

You can modify or delete any custom titration plan that you have created at any time.

Chapter 6. Low blood sugar

As a healthcare professional or an office staff with enrollment rights, you will have the opportunity to specify hypoglycemic thresholds for your patients using Dose Check. These thresholds can also be adjusted for each patient.

If a patient enters a blood sugar reading in Dose Check below your specified hypoglycemic threshold, the patient will be prompted to consume carbohydrates and re-test their blood sugar in 15 minutes. They will also be directed to seek medical guidance if they feel their hypoglycemia constitutes an emergency. You may specify a second[1], lower tier of hypoglycemic threshold that, if a patient enters a blood sugar reading that breaches that lower threshold, will cause Dose Check to prompt the patient to consume a larger volume of carbohydrates before retesting their blood sugar level.

Patients can also report symptoms of low blood sugar in the app for current or past dates along with the time and how these symptoms were treated. Following the entry of a below threshold blood sugar value, or any self-reported low blood sugar symptoms, the next dose will be decremented, and the titration cycle will restart.

[1]Availability of a second, lower tier of hypoglycemic threshold is country dependent. This might not be available in your country.

⚠ **Important**
Dose Check is not intended to replace patient diabetes self-management education.

Chapter 7. High blood sugar alerts

As a healthcare professional or an office staff with enrollment rights, you will have the opportunity to specify hyperglycemic thresholds for your patients using Dose Check. These thresholds can also be adjusted for each patient.

If a patient enters a blood sugar reading in Dose Check above your specified hyperglycemic threshold, the app will display a message that they have hyperglycemia and to seek emergency services if the hyperglycemia persists.

Chapter 8. Patient management

The Dose Check landing page displays a list of patients alongside live information extracted from their tracking history. As a healthcare professional, you will see the patients that you added directly or that an office staff added on your behalf. As an office staff, you can view the patients added by all the healthcare professionals you are associated with, or you can filter by healthcare professional.

Among the information displayed is a "status" column.

Hypo status – If a patient's status reads "hypo," this indicates that the patient's most recent blood sugar reading breached your specified hypoglycemic threshold. The patient's status will remain "hypo" until they enter a subsequent blood sugar reading that is above your specified hypoglycemic threshold. Any patient with a status of "hypo" will be moved to the top of your patient list.

Max Dose status – If the patient status reads "Max dose," this indicates that the patient has titrated their insulin dose up to the dose that you specified as their maximum dose. Dose Check will not increase the patient's dose any further unless you increase the max dose by editing the patient's titration plan. The status will remain "Max dose" until you increase the patient's maximum dose, or they record a low blood sugar, which will cause Dose Check to decrease the patient's dose. While only certain medications have maximum doses specified in product labeling, this field can also be used to set a dose level at which the patient is alerted to contact their healthcare professional to evaluate further dose adjustments.

Chapter 8.1. Patient logbook

Dose Check allows you to view a patient's logbook. Within a patient's logbook, you can view the blood sugar readings, insulin doses, weight, and A1C values that a patient has recorded, in either a list or graphical format. In the logbook, the blood sugar readings will be clearly indicated if they have been synced or manually recorded in the patient app. If the patient has been switched from one insulin to another, you can view the insulin doses for both the previous insulin and the new insulin, without any loss in data. If patients have reported symptoms of low blood sugar, these are included in the logbook data for your review.

Chapter 8.1.1. Logbook view for patients on GLP-1 medication

For patients on GLP-1 medication, you can view the blood sugar readings, GLP-1 medication intake, weight, and A1C values as recorded by the patient. If the patient has recorded more than one value for weight or A1C, Dose Check will allow you to view the predictive graphs for weight and / or A1C displaying the trends across the time periods when they have been reported. If the patient has reported side effects related to the GLP-1 medication, the logbook will contain the count of side effects reported along with their severity. The dashboard in the logbook will display these values as a graphical representation.

Chapter 8.2. Updating a patient's titration plan

You can update a patient's titration or medication plan at any time by selecting the action button next to the patient record for whose titration or medication plan you want to update. You may edit any field except the phone number. If you have the ability to specify the units of measurement for your patient[1], you can edit this field only if the patient has not started recording their blood sugar levels in the app.

You can switch the patient from one daily insulin to another daily or a weekly insulin while updating their titration plan. The current dose of the previous insulin will remain as the current dose for the new insulin. You will be restricted from switching the patient from a weekly insulin to a daily insulin.

Once you have saved your changes, your patient will receive a notification with an option to view the updated titration or medication plan.

[1]A healthcare professional's ability to select units of measurement in the titration plan may not be available in all countries.

Chapter 8.3. Deactivate patients

As a healthcare professional or an office staff with patient enrollment rights, Dose Check allows you to deactivate a patient. Once deactivated, a patient will no longer be able to access Dose Check. Their patient record will be removed from your list of active patients. You can always retrieve the patient record and reactivate the patient from your list of deactivated patients.

Chapter 9. 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 on the "About Dose Check" screen. 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.

If you have been locked out due to too many failed authentication attempts, you can tap on forgot password on the web portal login page and set a new password via the link received by email.

Chapter 10. 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

CE 2862	Intertek Semko AB Sweden. Notified Body 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
EC REP	**Authorized Representative** Medical Device Safety Service GmbH Schiffgraben 41 30175 Hannover, Germany
REF	DSC-DN-001
UDI	**Basic UDI-DI** 0850006610ISPXX

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Use by a person who is not an adult.
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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 instruct your patients to contact emergency services as needed.</td>
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<td></td>
<td>Operating systems

Dose Check supports the following operating systems. When a new operating system update becomes available, compatibility testing 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

Dose Check is 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.</td>
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	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 page 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
	Importer
CE 2862	Conformité Européenne (CE) Mark
EC REP	Authorized Representative
REF	Model Number
UDI	Unique Device Identifier