# Dose Check
# Account Administrator User Guide (Denmark)

# 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.

An account administrator can create and manage users of the Dose Check web portal and can create custom titration plans. However, administrators cannot add patients, nor can they assign titration plans to patients.

| ⚠ | **Important!**<br><br>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. |
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## Manufacturer

Amalgam Rx, Inc.

1007 N. Orange St.

Suite 400

Wilmington, DE 19801

United States

## Usage guidelines

This device 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 professional's titration plan for the following:

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

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.[2]

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 region.

[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.

[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:

a. Use by a person who is not an adult.

b. Use by patients in the event of an emergency.

c. Use by patients with type 1 diabetes.

d. Use by patients with gestational diabetes.

e. 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. Patients should follow their healthcare professional's instructions for managing emergency situations.

# Chapter 2 - Getting started

Once you have been established as an administrator, you will receive an email containing a link to Dose Check and a temporary password.

**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 3- Managing an account

If you are an administrator of multiple accounts, you must select the account which you wish to manage.

# Chapter 3.1 - Creating users for an account

As an administrator, you can create Dose Check users and assign to them one of the following roles:

- Healthcare professionals
- Office staff with patient enrolment rights
- Office staff with read-only permission

**Steps to create a new user:**

1. Click the button to create a new user.
2. Complete the information required in the form.
3. Assign the user one of the available roles.

The field "license number" will be made available only if you assign a user the role of healthcare professional.

If you assign a user the role of an office staff, you must associate that user with one or more healthcare professionals.

## Chapter 3.2 – Managing users for an account

. You can edit the information for any users who you have created at any time.

**Steps to edit a user's record:**

1. If you are an administrator of multiple accounts, you must select the account which you wish to manage.
2. On the Users tab, you can view the list of users managed by you within that account.
3. Select the action button next to the user whose details you wish to edit.
4. Edit the desired information.

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

## Chapter 3.3 - Create custom titration plans

You can create custom titration plans and make them available to any healthcare professional and office staff with patient enrollment rights who you have added to the account.

**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.

Any custom titration plans must be associated with a particular insulin brand as there are differences in the pharmacokinetics and pharmacodynamics of the insulins.

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

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

# Chapter 4 – Profile

The Profile in the top right corner provides you access to:

1. Terms and Conditions
2. About Dose Check (Product Labelling Information)

## How to unblock your account

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 5 – 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 "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.

# Chapter 6 – 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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| CE | Intertek Semko AB Sweden. Notified Body n. 2862 |
| ▲ | **Manufacturer**<br>Amalgam Rx, Inc.<br>1007 N. Orange St<br>Suite 400<br>Wilmington, DE 19801<br>United States |
| 🌐 | **Importer**<br><br>Amalgam Rx EU<br>70 Sir John Rogerson's Quay<br>Dublin 2 D02 R296<br>Ireland |
| EC REP | **Authorized Representative**<br><br>Medical Device Safety Service GmbH<br>Schiffgraben 41<br>30175 Hannover, Germany |
| REF | DSC-DN-001 |
| UDI | **Basic UDI-DI**<br><br>0850006610ISPXX |

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| ⚠ | **Caution**<br><br>The following contraindications apply to the use of Dose Check:<br><br>• Use by a person who is not an adult.<br><br>• Use by patients in the event of an emergency.<br><br>• Use by patients with type 1 diabetes.<br><br>• Use by patients with gestational diabetes.<br><br>• Use by patients using an insulin pump.<br><br>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. |
| | **Operating systems**<br><br>Dose Check supports the following operating systems. When a new operating system update becomes available, compatibility test will be conducted prior to release.<br><br>• Android: 10.x or later<br>• iOS: 16.x or later<br>• Google Chrome: 115.x or later<br>• Firefox: 115.x or later<br>• Microsoft Edge: 115.x or later<br>• Safari: 16.x or later<br>• IE browser is not supported.<br><br>**Device hardware**<br><br>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 |
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| | 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

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|  | Manufacturer |
|  | Caution, Attention |
|  | Importer |
| CE 2862 | Conformité Européenne (CE) Mark |
| EC REP | Authorized Representative |
| REF | Model Number |
| UDI | Unique Device Identifier |