

# iSage Rx Patient User Guide

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# Chapter 1. Introduction

## Performance characteristics of iSage Rx

iSage Rx 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)<sup>1</sup>. You can access your insulin 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 insulin medication doses.

## Manufacturer



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

## Usage guidelines

iSage Rx should only be used under the guidance and supervision of a healthcare professional.

## Intended use

iSage Rx is intended to help adult<sup>2</sup> patients understand and follow their healthcare professionals' titration plan for the following:

- Titration of basal insulins<sup>3</sup>
- Titration of combinations of basal insulin and GLP-1 receptor agonists

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

iSage Rx connects with the following devices<sup>3</sup>:

- Glucose meters to transmit blood glucose data.

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<sup>1</sup> The number and variety of available basal insulin and basal insulin combination products varies by country.

<sup>2</sup> Adult is defined by the country where iSage Rx is used, and the age is configured according to governing regulations in that country.

<sup>3</sup> 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 iSage Rx and record the dose taken.

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

### Indications for use

iSage Rx is indicated for use by adult<sup>4</sup> patients with type 2 diabetes, and by their healthcare team to provide ongoing support for understanding and following a titration plan for supported medications<sup>25</sup>, to reach an optimal medication dose and/or target fasting blood sugar control.

### Clinical benefit(s)

iSage Rx 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 iSage Rx:

- 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 iSage Rx 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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<sup>4</sup> Adult is defined by the country where iSage Rx is used, and the age is configured according to governing regulations in that country.

<sup>5</sup> 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><b>Important!</b></p> <p>iSage Rx 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>
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## Chapter 2. Getting started

To use all the features of iSage Rx, 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 iSage Rx on your mobile phone.

### Steps to complete patient registration

1. Download and open the iSage Rx app.
2. Enter your phone number. This number must match the phone number that your healthcare professional entered when enrolling you in iSage Rx. *(If you have trouble accessing the app, verify what number was used for enrollment by your healthcare professional)*  
You will be texted a 4-digit verification code. Enter that code into the iSage Rx 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.
3. You must select your date of birth from the date picker
4. You must agree to the Terms & Conditions and Privacy Policy to use iSage Rx. Review them as desired before proceeding.
5. Tap the appropriate button to complete sign-up.

### Patient Onboarding

1. Confirm that the information shown in your profile 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 iSage Rx 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 insulin plan that your healthcare professional has recommended for you.
6. Based on that plan, you will be shown instructions for how and when to take your insulin.
7. You must set the scheduled time to take your insulin dose.
8. You must set the scheduled time when you will test and record your fasting blood sugar.
9. 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 according to your healthcare professional's recommendations. The app will be more useful to you if you allow these notifications.
10. If you are taking weekly insulin, you can select the day of the week when you will take the insulin.

**Important!**

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

## Chapter 2.1. Home Screen

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

- An option to record your insulin
- A graphical representation of your data
- Option to view the Logbook with all recorded data for a selected time range
- A few articles (if available) on the disease or medication
- Bottom navigation bar with short cut menu options

### Chapter 2.1.1. Bottom Navigation Bar

The short cut menu options in the bottom navigation bar are:

- Home
- Record
- Connected devices (if included in your default country configuration)
- Logbook
- More

1. 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.

2. You can use the Record option to
  - Record your Insulin dose
  - Record your blood sugar (fasting or non-fasting)
  - Record your A1C level in the app.
  - Record your weight (in lbs or kg per your country configuration)
3. 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.
4. 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.
5. You can use the More option to view other menu options in the app such as:
  - Your profile information
  - Medication Plan
  - 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. The current date is displayed by default, and you can edit the same to reflect the actual date on which the A1C value was determined. You can also record your weight in the units of measurement (lbs or kg) as configured for your account.

## Chapter 2.3. Resources

You can view articles on Diabetes Mellitus 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 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 have set your daily schedule time<sup>6</sup>, iSage Rx 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. You can also change the time or date. Verify everything is correct and then click the “Submit” button.

It's important to record every insulin dose that you take in iSage Rx. At least one dose must be recorded per titration cycle in order for the next dose to be determined. You can record a dose any time from the home screen- iSage Rx uses the recorded insulin doses in calculating the next dose adjustment.

- 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, iSage Rx will prompt you to take and record your insulin later.
- If you are taking a weekly insulin, you will be prompted to take and record your insulin on the day of the week identified as your Dose Day.

iSage Rx will inform you of your recommended insulin dose and you should always take your recommended dose while using iSage Rx 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.

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

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<sup>6</sup> You can change the schedule time from the settings options under the more tab.

**Important!**

Since iSage Rx 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).

iSage Rx takes the number of fasting blood sugars your healthcare professional specifies to calculate the average FBS which is used to titrate the new insulin dose (based on country configuration)

**Important!**

Some users who switch from a once daily to a once weekly insulin 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 iSage Rx instructions as iSage Rx 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.

**Important!**

The user is responsible for the accuracy of user entered data. Please make sure your entries are correct.

## 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. Adjust the date and time for accuracy.
4. Save your entry.
5. If it is time to take your insulin, iSage Rx will display your recommended dose.
6. After taking your insulin, make any adjustments necessary to ensure that your insulin entry in iSage Rx matches exactly how much insulin you took.

## 7. Save your entry.

Sometimes, after recording your insulin, iSage Rx 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 meter<sup>1</sup> (*Please refer Section 11.1*) with iSage Rx, you can sync your blood sugar readings from the glucose meter to iSage Rx. You can view these readings at any time from the iSage Rx logbook. These readings are used to track your progress and determine your insulin dose so do not share your glucose meter with anyone else.

<sup>1</sup>The 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 cap<sup>7</sup> with iSage Rx (*Please refer Section 11.2*), you can sync your insulin doses from that device. Depending on the type of connected device, this process may be automatic, or you may need to actively sync the device with the iSage Rx app. You can verify synced entries in the iSage Rx logbook.

In the logbook, synced values will have an indicator next to the entry to show it was from a connected device

**Note:** You can edit or delete incorrect manual entries from logbook. If the entry was synced from a glucose meter or connected Pen or Pen Cap, you cannot edit the entry. If

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<sup>7</sup> The presence and variety of wireless smart insulin pens and pen caps vary by country.

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 4. Your insulin plan in iSage Rx**

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

When iSage Rx 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 the insulin plan they have recommended or about 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 the 4<sup>th</sup> day from the scheduled insulin adjustment day, you can record your weekly dose in the app, but the next insulin adjustment day will be rescheduled to a week from the day you record your weekly dose.

## **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 iSage Rx, your healthcare professional specifies an upper threshold dose limit for how high iSage Rx can titrate your insulin dose. Certain medications have actual dose limitations recommended by the manufacturer. In iSage Rx, 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 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.

### 8.1. 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.

## **8.2. Reduction of Insulin dose on reporting low blood sugar symptom or value**

- For Daily Insulins - If you experience low blood sugar symptom or report a hypo value below threshold within 48 hours from the current time (from 12 am of previous day to current time) and report the same in the app, iSage Rx will decrement your daily insulin dose, irrespective of the average blood sugar values.
- For weekly Insulins - If you experience low blood sugar symptom or report a hypo value below threshold on any day within 7 days prior to the current dose day and report the same in the app, iSage Rx will decrement your weekly insulin dose, irrespective of the average blood sugar values.

## **8.3. Reduction of Insulin dose on reporting below target blood sugar value for weekly insulins.**

If you record a blood sugar value that is below the target range set by your HCP, on any day within 3 days leading to the dose day, iSage Rx will decrement your weekly insulin dose, irrespective of the average blood sugar values.

*Please note that insulin dose is decremented only once if both low blood sugar symptom and hypo event (below threshold or below target BG value) occurs*

## **8.4. Correcting a low blood sugar**

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

iSage Rx will adapt your titration schedule and your insulin dose accordingly. If you have not recorded your insulin dose for the day, or weekly insulin dose for the week, iSage Rx will recommend a reduced insulin dose compared to your previous dose. If you have already recorded your insulin dose for the day or week, iSage Rx will recommend that you take a reduced insulin dose on the next day for daily insulins, or on the next dose day for weekly insulins and reset the next titration schedule to start from that day.

**Important!**

Contact your healthcare professional if you continue to have low blood sugars while using iSage Rx. 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 iSage Rx, 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 iSage Rx. 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 iSage Rx 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 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. A1C and Weight**

You can view and edit the Weight and A1C values recorded in the Patient logbook. You can view the A1C levels and weight trends in a graph, filtered by date intervals.

# **Chapter 11. Pairing with wireless smart devices**

## **Chapter 11.1. Pairing with a wireless glucose meter**

You can pair a wireless glucose meter<sup>8</sup> 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 iSage Rx 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 11.2. Pairing with a Smart Insulin Pen or Pen Cap**

You can pair a wireless smart insulin pen or pen cap<sup>9</sup> during onboarding or at any time from the Connected Devices option on the bottom navigation bar. To pair a smart pen or pen cap, select the make and model from the list and follow the instructions.

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<sup>8</sup> The presence and variety of wireless glucose meters varies by market and country

<sup>9</sup> The presence and variety of wireless smart insulin pens and pen caps varies by country.



If you are pairing the wireless smart pen cap with insulin of various strengths, you must specify the type of insulin pen on which the pen cap is mounted and synced with the app. When you use a new cartridge, you squirt out a few drops to make sure the air is out, and the needle is good. This is called priming. The connected device records the amount used for this as a dose. To make sure that iSage Rx does not include this amount in your daily insulin total dose, it **must** be labeled as a **Primer dose**. When you sync your pen, be sure to verify in the logbook that these small amounts are labeled as **Primer** doses. iSage Rx will not consider the values marked as Primer doses for calculating the new insulin dose on the dose adjustment day.

Once you have paired a smart pen or pen cap, you may also need to sync each of your insulin doses wirelessly to iSage Rx rather than manually entering them. Some devices will sync automatically but others need to be synced each time.

You can unpair a smart pen or pen cap at any time from the More menu. If you are switching to a different type of smart pen or pen cap, the current one must first be unpaired before pairing with the new one.

## Chapter 12. Other important information

In iSage Rx, 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 which will prompt iSage Rx 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 iSage Rx. Login using your 4-digit PIN. Your data will be retained, and you can resume using iSage Rx 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 iSage Rx logbook version (if enabled in your country configuration) to log your blood sugar values and insulin doses till the new HCP accepts your request.

## Chapter 12.1. Customer support

If you have any feedback for iSage Rx 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 iSage Rx and report the same information to your local health authority according to local laws.

## Chapter 12.2. No internet connection

iSage Rx 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. iSage Rx 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 iSage Rx account at any time, thereby removing all personally identifiable information (PII) from iSage Rx.



### **Important!**

If you choose to delete your account, all your account details (including your personal identifiable information) will be permanently erased from your iSage Rx account. Once deleted, you will not have the ability to access the data you recorded in iSage Rx 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 iSage Rx promptly. These updates often contain important security enhancements.


### **Staying updated:**



Our team regularly releases updates to enhance the functionality and security of iSage Rx. 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](mailto:security@amalgamrx.com). Your security is our top priority, and we are here to assist with any concerns you may have.

## **About iSage Rx**






	Intertek Medical Notified Body AB. Sweden n. 2862
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	<p><b>Manufacturer</b>  Amalgam Rx, Inc.  1007 N. Orange St  Suite 400  Wilmington, DE 19801  United States</p>
	<p>ISR-XX-001  (where XX refers to the Country code and will be filled based on the Country configuration)</p>
	<p><b>Intended use</b>  iSage Rx is intended to help adult<sup>1</sup> patients understand and follow their healthcare professionals' titration plan for the following:</p> <ul style="list-style-type: none"> <li>• Titration of basal insulins<sup>2</sup></li> <li>• Titration of combinations of basal insulin and GLP-1 receptor agonists<sup>2</sup></li> </ul> <p>Patients using iSage Rx can record their blood sugar levels, view their healthcare professional's titration plan for supported medications<sup>2</sup>, and record the medication dose taken.  iSage Rx connects with the following devices<sup>2</sup>:</p> <ul style="list-style-type: none"> <li>• Glucose meters to transmit blood sugar data.</li> <li>• Smart insulin pens, caps, and attachments to transmit insulin dosage data to iSage Rx and record the dose taken.</li> </ul> <p>iSage Rx is not intended to replace the care and management provided by a healthcare professional trained in the management of diabetes. iSage Rx should not be used by patients with type 1 diabetes, gestational diabetes, or patients using an insulin pump.</p> <p><sup>1</sup>Adult is defined by the country where iSage Rx is used, and the age is configured according to governing regulations in that country.  <sup>2</sup> 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><b>Indications for use</b></p> <p>iSage Rx is indicated for use by adult<sup>1</sup> patients with type 2 diabetes, and by their healthcare team to provide ongoing support for understanding and following a titration plan for supported medications<sup>2</sup>, to reach an optimal medication dose and/or target fasting blood sugar control.</p> <p><sup>1</sup>Adult is defined by the country where iSage Rx is used, and the age is configured according to governing regulations in that country.</p> <p><sup>2</sup> 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>
	<p><b>Caution</b></p> <p>The following contraindications apply to the use of iSage Rx:</p> <ul style="list-style-type: none"> <li>• Use by a person who is not an adult.</li> <li>• Use by patients in the event of an emergency.</li> <li>• Use by patients with type 1 diabetes.</li> <li>• Use by patients with gestational diabetes.</li> <li>• Use by patients using an insulin pump.</li> </ul> <p>Understand that while iSage Rx 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.</p>
	<p><b>Operating systems</b></p> <p>iSage Rx supports the following operating systems. When a new operating system update becomes available, compatibility tests will be conducted prior to the next release.</p> <ul style="list-style-type: none"> <li>• Android: 10.x or later</li> <li>• iOS: 16.x or later</li> <li>• Google Chrome: 115.x or later</li> <li>• Firefox: 115.x or later</li> <li>• Microsoft Edge: 115.x or later</li> <li>• Safari: 16.x or later</li> <li>• IE browser is not supported.</li> </ul> <p><b>Device hardware</b></p> <p>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.</p>

	<p><b>Availability of instructions for use</b></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

	Manufacturer
	Caution, Attention
	Conformité Européenne (CE) Mark
	Model Number
	Consult instructions for use