User Manual

ⓒ 2020 EOFLOW Co., Ltd. All rights reserved.
EOPatch is a registered trademark of EOFLOW Co., Ltd.
No part of these Instructions for Use may be reproduced without
the permission of EOFLOW. Co., Ltd.

1 INTRODUCTION 9

1.1 THIS USER GUIDE 9
1.2 INDICATIONS FOR USE & CONTRAINDICATIONS 9
1.2.1 INDICATIONS 9
1.2.1.1 Contraindications 9
1.2.2 BENEFITS & RISKS 10
1.2.2.1 Benefits 10
1.2.2.2 Risks 10
1.2.3 GENERAL WARNINGS & CAUTIONS 11
1.2.4 EMERGENCY KIT 12
1.2.5 WARRANTY PERIOD 12
1.2.6 OPERATING CONDITION 12
1.2.6.1 Patch Operation Condition 12
1.2.6.2 ADM Operation Condition 13
1.2.7 ORDERING SUPPLIES 13
1.2.8 INQUIRIES 13

2 THE EOPATCH INSULIN MANAGEMENT SYSTEM 14

2.1 THE ADM, PATCH AND ACCESSORIES 14
2.2 INITIAL SETUP 15
2.2.1 CHARGE THE ADM 15
2.2.2 TURN ON THE ADM 15
2.2.3 LANGUAGE 15
2.2.4 USER ID AND PHONE NUMBER 16
2.2.5 DATE OF BIRTH AND COUNTRY OF RESIDENCE 16
2.2.6 SCREEN LOCK 17
2.2.6.1 Pattern 17
2.2.6.2 Pin 18
2.2.6.3 Slide 19
2.2.7 TIME ZONE 19
2.2.8 DATE 20
2.2.9 TIME 20
2.2.10 MAX BOLUS 21
2.2.11 MAX BASAL RATE 22
2.2.12 BG TARGET RANGE 22
2.2.13 BASAL SETTING 23
2.2.13.1 Set the rate 23
2.2.13.2 To rename the basal setting: 23
2.2.13.3 To add Segments to your basal program: 24
2.2.14 TARGET BG AND CORRECTION THRESHOLD 25
2.2.14.1 To add additional Segments to the current Target BG and Correction threshold. 26

2.2.15 MIN BG FOR BOLUS CALC 27
2.2.16 IC RATIO 28
To add additional Segments for different times of day (U/hr) to IC Ratio 28
2.2.17 CORRECTION FACTOR 29
2.2.18 INSULIN ACTION 31
2.2.19 EXTENDED BOLUS OPTION 32
2.2.20 LOW RESERVOIR ALERTS 33
2.2.21 PATCH EXPIRATION ALERTS 33
2.2.22 INITIAL SETUP COMPLETE 34

3 ACTIVATING A PATCH 35

3.1 DEACTIVATION PROCESS 35
3.1.1 DEACTIVATE PATCH 35
3.2 ACTIVATION PROCESS 36
3.2.1 NECESSARY ITEMS 36
3.2.2 PATCH COMPONENTS 37
3.2.3 ACTIVATE PATCH 37
3.2.4 FILL THE NEW PATCH 38
3.2.5 PAIR AND PRIME THE NEW PATCH 40
3.2.6 SELECT AND PREPARE THE INSERTION SITE 40
3.2.7 APPLY THE NEW PATCH 41
3.2.8 INSERT CANNULA 43
3.2.9 BEGIN INSULIN DELIVERY 44
3.3 PATCH STATUS 46
3.3.1 CHECK CONNECTION STATUS THROUGH STATUS SCREEN ON ADM 46
3.3.2 CHECK CONNECTION STATUS THROUGH SETTINGS ICON ON THE ADM 46
3.4 PATCH MAINTENANCE 47
3.4.1 STORAGE 47
3.4.2 EXTREME TEMPERATURES 47
3.4.3 WATER RESISTANCE 48
3.4.4 EXPOSURE 48
3.4.5 CLEANING 48

4 USING THE ADM 49

4.1 THE PRIMARY SCREEN 49
4.2 THE STATUS SCREEN 49
4.3 THE HOME SCREEN 50
4.3.1 THE GLUCOSE SCREENS 50
4.3.1.1 Entering BG manually 50
4.3.1.2 Read BG via Bluetooth (from Blood Glucose Meter (BGM) 52
4.3.1.3 Editing BG tag 53

4.3.1.4 Receive BG readings 53
4.3.1.4.1 CGM 54
4.3.1.4.2 High glucose Alarms 55
4.3.1.4.3 Low glucose Alarms 56
4.3.1.4.4 CGM Alert settings 57
4.3.1.5 BG target range 59
4.3.2 THE BOLUS SCREENS 60
4.3.2.1 Correction Bolus 60
4.3.2.2 Bolus calc with carbohydrate 61
4.3.2.3 Bolus calc with carbohydrate and BG Reminder 62
4.3.2.4 Bolus calc with carbohydrate and Extended bolus 64
4.3.2.5 Bolus calc with Carb preset 65
4.3.2.6 Quick Mode with Insulin 67
4.3.2.7 Quick Mode with Bolus presets 68
4.3.2.7.1 Setting a Bolus preset 68
4.3.2.7.2 Using a Bolus preset 69
4.3.2.8 Cancel a Bolus 70
4.3.3 THE BASAL SCREENS 71
4.3.4 THE TEMPORARY BASAL SCREENS 71
4.3.4.1 Add a one-time Temp basal program 71
4.3.4.2 Add a New Temp basal program 72
4.3.4.3 Edit an existing Temp basal program 73
4.3.4.4 Change the name of a Temp basal program 74
4.3.4.5 Enable an inactive Temp basal program 75
4.3.4.6 Cancel an active Temp basal program 76
4.3.5 THE BASAL SCREENS 76
4.3.5.1 Edit an existing Basal program 76
4.3.5.2 Add additional segments to the current Basal program 78
4.3.5.3 Add a new Basal program 79
4.3.5.4 Change the name of a Basal program 81
4.3.5.5 Enable an inactive Basal program 82
4.4 THE GRAPH SCREEN 82
4.4.1 DAILY GRAPH 83
4.4.2 BG GRAPH 84
4.5 THE HISTORY SCREEN 84
4.5.1 INSULIN DELIVERY HISTORY 85
4.5.2 BG HISTORY 85
4.5.3 ALARM/ALERT HISTORY 86
4.5.4 CARB HISTORY 86
4.5.5 ALL HISTORY 87
4.6 THE CURTAIN SCREEN 88
4.6.1 SOUND 88
4.6.2 DISPLAY 88
4.7 ADM MAINTENANCE 89

4.7.1 STORAGE 89
4.7.2 BATTERY REPLACEMENT 89
4.7.3 EXTREME TEMPERATURES 89
4.7.4 WATER 89
4.7.5 EXPOSURE 90
4.7.6 CLEANING 90
4.7.7 DROPPAGE 90

5 SETTINGS 91

5.1 ADVANCED MENU SETTINGS 91
5.1.1 SUSPEND 91
5.1.2 RESUME 92
5.1.3 CHANGE PATCH 92
5.1.4 DELIVERY SETTINGS 93
5.1.5 ALERT/REMINDER SETTINGS 94
5.1.5.1 Auto-Off Alerts 94
5.1.5.2 Patch Expiration Alerts 95
5.1.5.3 Low reservoir Alerts 95
5.1.5.4 BG Reminders default 96
5.1.5.5 Meal bolus Reminder 96
5.1.5.5.1 Setting a Meal Bolus Reminder 97
5.1.5.5.2 Editing or Deleting an existing Meal Bolus Reminder 98
5.1.5.6 Delivery Reminders on Patch 99
5.1.5.7 Previous BG low Reminders 99
5.1.5.8 Custom Reminders 100
5.1.5.8.1 Setting a Custom Reminder 100
5.1.5.8.2 Editing or Deleting an existing Custom Reminder 101
5.1.6 FOOD LIBRARY 102
5.1.6.1 Saving food from Food Library to Carb Presets 102
5.1.7 MANAGE EOPATCH 103
5.1.7.1 Test Alarms 103
5.1.7.2 Initializing ADM 104
5.1.7.3 Update ADM 105
5.1.7.4 ADM Info 106
5.1.7.5 Patch info 106
5.1.7.6 View ADM on EOBridge external application 107
5.1.8 CGM 107
5.1.8.1 Activate CGM 107
5.1.8.2 Change CGM 108
5.2 ADM SETTINGS 109
5.2.1 BLUETOOTH 109
5.2.2 USER INFORMATION 110
5.2.2.1 User ID 110

5.2.2.2 Phone number 110
5.2.2.3 Date of Birth 111
5.2.2.4 Country of residence 111
5.2.2.5 Date and time 111
5.2.2.6 Set time zone 111
5.2.2.7 Use 24-hour format 112
5.2.2.8 Choose date format 113
5.2.3 DISPLAY 113
5.2.3.1 Brightness 113
5.2.3.2 Screen timeout 114
5.2.4 SOUND AND VIBRATE 114
5.2.4.1 Etiquette 114
5.2.4.2 Sound volume 115
5.2.4.3 Sound type 115
5.2.4.4 Others 116
5.2.5 LANGUAGE 116
5.2.6 HISTORY SCREEN DEFAULT 117
5.2.7 GRAPH SCREEN DEFAULT 117
5.2.8 SCREEN LOCK 118

6 ALARMS, ALERTS AND REMINDERS 120

6.1 VISUAL SIGNALS 120
6.2 AUDIBLE AND VIBRATION SIGNALS 120
6.2.1 THE RANGE OF SIGNAL LIMITS PROVIDED BY MANUFACTURERS 121
6.3 ALARM DESCRIPTIONS 122
6.3.1 HIGH RISK ALARMS 122
6.3.2 MEDIUM TO LOW RISK ALERTS 124
6.3.3 REMINDERS 126

7 DIABETES MANAGEMENT AND TROUBLESHOOTING 128

7.1 THE DIFFERENCE 128
7.2 COUNTING CARBOHYDRATE AND OTHER NUTRIENTS 128
7.2.1 FOOD CONTAINING CARBOHYDRATE 129
7.2.2 NUTRITION FACTS LABEL 129
7.2.3 ADM FOOD LIBRARY 129
7.2.4 OTHER NUTRIENTS THAT AFFECT BLOOD GLUCOSE 130
7.3 EXERCISE & SPORTS 130
7.4 HYPOGLYCEMIA 130
7.4.1 SYMPTOMS OF HYPOGLYCEMIA 131
7.4.2 HYPOGLYCEMIA PROTOCOL – THE RULE OF 15 131
7.5 HYPERGLYCEMIA AND DKA 132

7.5.1 SYMPTOMS OF HYPERGLYCEMIA 133
7.5.2 SYMPTOMS OF DKA (DIABETIC KETOACIDOSIS) 133
7.5.3 HYPERGLYCEMIA & DKA PROTOCOL 133
7.6 SICK-DAY MANAGEMENT 134
7.6.1 SICK-DAY PROTOCOL 134
7.6.1.1 Sick-day Supplies 134
7.7 TROUBLESHOOTING 134

8 APPENDIX 136

8.1 EOPATCH SYSTEM OPTIONS AND SETTINGS 136
8.2 PATCH SPECIFICATIONS 137
8.3 ADM SPECIFICATIONS 138
8.3.1 SYMBOLS, LABELS, ICONS & LED LIGHT COLORS 139
8.3.1.1 Symbols 139
8.3.1.2 Labels 139
8.3.1.3 Icons 140
8.3.2 LED LIGHT COLORS 141
8.4 EOPATCH INSULIN MANAGEMENT SYSTEM NOTICE REGARDING OCCLUSION 142
8.4.1 OCCLUSION DETECTION 142
8.5 EOPATCH INSULIN MANAGEMENT SYSTEM NOTICE REGARDING INTERFERENCE 142
8.6 ELECTROMAGNETIC COMPATIBILITY 143
8.6.1 GENERAL NOTES 143
8.6.2 EMC TEST REPORT 144
8.7 DELIVERY ACCURACY TEST RESULT 148
8.8 CONVERSION TABLE MMOL/L TO MG/DL 149
8.9 CUSTOMER RIGHTS 150
8.9.1 SCOPE OF SERVICES 150
8.9.2 COMPLIANCE 150
8.9.3 INQUIRIES 150
8.9.4 CHAP ACCREDITED 150
8.9.5 RIGHTS AND RESPONSIBILITIES 150
8.10 GDPR COMPLIANCE 151
8.11 INFORMATION ON DISPOSAL OF ELECTRICAL AND ELECTRONIC EQUIPMENT AND DISPOSAL OF BATTERIES AND ACCUMULATORS 151
8.12 LIMITED EXPRESS WARRANTY, DISCLAIMER OR IMPLIED WARRANTIES AND LIMITATION OF REMEDIES 152
8.12.1 LIMITED EXPRESS WARRANTY COVERAGE 152
8.12.2 LIMITED EXPRESS WARRANTY TERMS AND CONDITIONS 152
8.13 HIPAA PRIVACY NOTICE 154

9 GLOSSARY 160

10 INDEX **166**

11 REFERENCES **167**

1 INTRODUCTION

Congratulations on choosing the EOPatch Insulin Management System as your insulin delivery device. Whether you are new to insulin pump therapy or are embarking on it for the very first time, we are committed to helping you get the most from the system and supporting you along the way with training and technical support.

1.1 This User Guide

This user guide provides step-by-step instructions on how to use the Patch (a disposable drug infuser) and the Advanced Diabetes Manager (ADM: a smart, touchscreen remote controller). You must read this guide before using the Patch with insulin. Neither the manufacturer, nor its distributor(s), shall be liable for any consequential damage if the Patch and/or ADM are not used as defined in this guide.

Pay close attention to the following when using this guide:

WARNING: Alerts you to a potential safety hazard associated with the system, which, if not corrected, may cause injury or death.

Caution: Alerts you to a potential risk associated with the device.

WARNING: Alerts you to a potential safety hazard associated with the system, which, if not corrected, may cause injury or death.

WARNING: Alerts you to a potential safety hazard associated with the system, which, if not corrected, may cause injury or death.

1.2 Indications for Use & Contraindications

1.2.1 Indications

The EOPatch Insulin Management System is indicated for the delivery of subcutaneous delivery of insulin in persons requiring insulin. You must have a physician's prescription to use this product.

1.2.1.1 Contraindications

The EOPatch Insulin Management System is not recommended if you are unable or unwilling to:

- Unable to test your blood glucose at least (4) times per day
- Unable to maintain contact with your healthcare provider
- Unable to use the system according as instructed

1.2.2 Benefits & Risks

1.2.2.1 Benefits

- Research shows continuous delivery of insulin through an insulin pump lowers A1C more than multiple daily injections (MDI).[1] The EOPatch Insulin Management System provides an automated way to deliver basal and bolus insulin.
- Basal delivery can be customized with 8 different programs and can be set to temporarily deliver more or less when needed.
- Boluses can be delivered immediately or over an extended period of time.
- Research shows bolus calculators prevent stacking of insulin which can lead to hypoglycemia.[1] The EOPatch Insulin Management Systems' bolus calculator provides algorithms for insulin-to-carbohydrate ratio and insulin sensitivity factor that calculate insulin doses based on target blood glucose and insulin on board.
- The ADM screen in the EOPatch Insulin Management System assists in making important diabetes management decisions by providing access to data that gives you a quick look at your, previous blood glucose results, last bolus, current basal rate and other functional ADM information.
- The bolus calculator in the EOPatch Insulin Management System uses the user's individual parameters to estimate insulin needed for correction of blood glucose over the individual's target range and for the expected rise in blood glucose from carbohydrate in food you are going to eat. Research shows that bolus calculators in insulin pumps improve glycemic control and reduce the incident of hypoglycemia. [2,3]

1.2.2.2 Risks

The same risks with insulin injections are present with the delivery of insulin through an insulin pump: hypoglycemia, hyperglycemia, diabetic ketoacidosis, seizure, coma and death. In addition, risks specific to insulin pump therapy include:

- Pain or skin irritation such as bleeding, redness, itching and/or skin discoloration at the insertion site
- Infection at the insertion site
- Occlusions that may interrupt insulin delivery and can lead to hyperglycemia or diabetic ketoacidosis

1.2.3 General Warnings & Cautions

WARNINGS: Alarms, Alerts and Reminders

- The user is responsible for responding to Alarms, Alerts and Reminders. These occur in the ADM visually: LED and LCD, hearing: buzzer and speaker, and tactile: vibration.

WARNINGS: Environments

- Magnetic fields and strong radiation may affect the operation of the EOPatch and ADM. Do not use either near MRI, XRay, CT scan or any other equipment with a magnetic field or strong radiation.
- Low atmospheric pressure (below 700 hPA) may affect the operation of the EOPatch and ADM. This pressure is likely to occur and elevations above 10,000 feet (3,000 meters).
- High atmospheric pressure (more than 1062 hPA) and oxygen-rich environments (greater than 25% oxygen) may affect the operation of the EOPatch and ADM. These conditions are likely to occur in a hyperbaric chamber used in treatment of certain conditions.

Cautions: Environments

- Portable RF communication equipment, including antenna cables, and external antennas, should not be used within 12 inches (30.48 cm) of any portion of the EOPatch system. Degradation of the performance of this equipment could result.
- The Patch is an IP48 rated waterproof product; it guarantees 24-hour waterproof performance, at a water depth of 32 feet (1 meter), while it is attached to the skin.

WARNINGS: Insulin

- The Patch is designed to be used with rapid-acting, U100 insulin.
- If insulin deliver through the Patch is interrupted, be prepared to inject insulin from an alternative source.

WARNINGS: Healthy Use

- Do not attempt to use the EOPatch system before reading this User Guide. Failure to understand and follow all instructions may put your health at risk.
- Do not begin using your EOPatch system before your healthcare provider or insulin pump trainer educates you on its use. Failure to receive proper training may put your health at risk.
- Do not use the EOPAtch system if you are unable to test your blood glucose at least (4) times per day.
- Do not use the EOPAtch system if you are unable maintain contact with your healthcare provider.
- Do not use the EOPAtch system if you are unable to use the system according as instructed.

1.2.4 Emergency Kit

Emergencies can happen when you least expect them. It's important to have an emergency kit ready for those times. Suggested items for an emergency kit include:

- Extra Patches
- Blood glucose meter, strips, lancing device and lancets
- Ketone testing (urine or blood)
- Glucose tablets or candy (not chocolate)
- Glucagon
- Extra insulin vial or insulin pen in the refrigerator (If you also keep insulin unrefrigerated in the kit, change monthly)
- Sick-day supplies
- Over-the-counter medication
- Prescribed medication

1.2.5 Warranty period

The warranty/validity period of EOPatch Insulin Management System is as follows:

- Patch: 3.5 days (84 hours) from the moment of wake-up.
- ADM: 2 years (24 months) from date of purchase
- ADM rechargeable battery: 6 months from the date of purchase

NOTE: Please refer to Appendix for more information on the scope of services.

1.2.6 Operating Condition

Accuracy may not be maintained when operating outside the Patch and ADM operation condition below.

1.2.6.1 Patch Operation Condition

- Operation temperature range: 4.4~37℃ (39.92~98.6℉)

- Operating humidity range: 20~85 % RH, non-condensing
- Operating atmospheric pressure: 700~1,060 hPa

1.2.6.2 ADM Operation Condition

- Operation temperature range: 4.4~40℃ (39.92~104℉)
- Operating humidity range: 20~90 % RH, non-condensing
- Operating atmospheric pressure: 700~1,060 hPa

1.2.7 Ordering Supplies

To order supplies call the number on the back of the ADM.

1.2.8 Inquiries

If you have any questions or concerns, please contact your healthcare provider or EOFLOW.

2 THE EOPATCH INSULIN MANAGEMENT SYSTEM

2.1 The ADM, Patch and Accessories

In addition to this User Guide, your shipment should contain the following:

- One or more boxes of 9 Patch blister packages, each containing 1 patch and a syringe and needle for injecting insulin into the Patch
- ADM, ADM battery, ADM power cable and adaptor, ADM jelly case, QuickStart Guide, User manual, product warranty card, and pouch for supplies

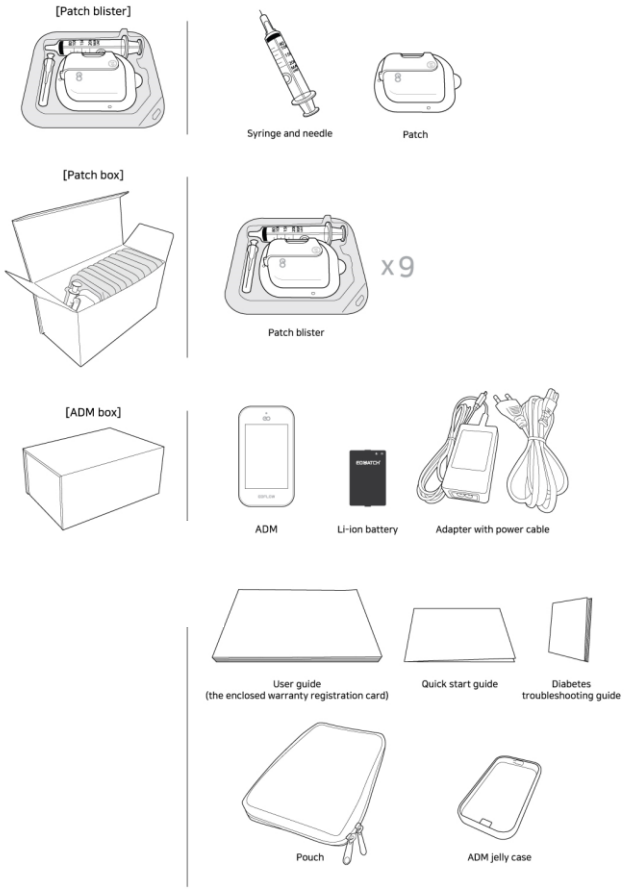


Figure 2-2-1 - Shipment Contents

NOTE: If any items are not in the box, please call EOFLOW Product Support at the number on the back of the ADM.

Caution: Use of accessories other than those specified or provided by the manufacturer of this equipment could result in improper operation due to increased electromagnetic emissions or decreased electromagnetic immunity.

2.2 Initial Setup

2.2.1 Charge the ADM

Like a mobile phone, the ADM contains a lithium battery that needs charging before use and whenever the battery is low. Before using the ADM for the first time, charge it fully using the charger and power cable included in the box.

2.2.2 Turn on the ADM

Turn on the ADM by pressing the power button on the upper right side. The ADM displays the EOFLOW logo, followed by a video screen that vibrates and plays 4 tones, followed by the welcome screen.

NOTE: When the ADM screen is black, simply touch the power button to wake it up.

NOTE: If the ADM is connected to a power source when you turn it on, the ADM displays the percent of battery charged. Press the on/off button again to access the screens.

2.2.3 Language

If your language is not displayed, change the language.

1. Touch the drop-down menu next to the displayed language.
2. A list of possible languages is displayed.
3. Touch your language and touch **Start.**

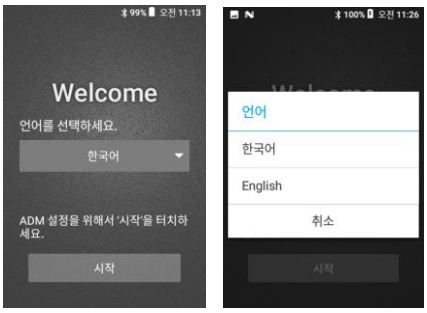


Figure 2-2-2 - Language

2.2.4 User ID and Phone number

Create a User ID, enter your Phone number.

1. Touch **User ID.**
2. Enter your desired User ID and touch **Next.**
3. Enter your phone number and touch **Done.**
4. Touch **Next.**

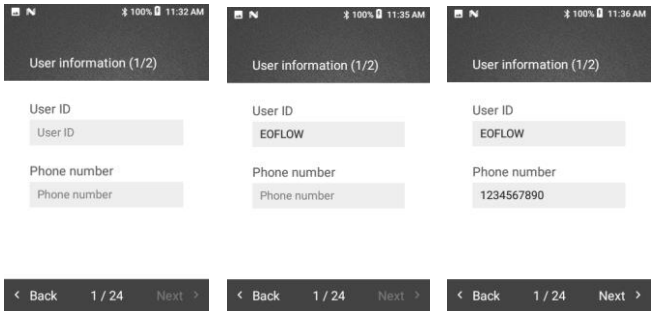


Figure 2-3 - User ID and Phone number

2.2.5 Date of birth and Country of residence

1. Touch **Date of birth.**
2. Scroll to your date of birth and touch **Confirm.**
3. Touch **Country of residence.**
4. Choose the option button next to your country of residence and touch **Confirm.**
5. Touch **Next.**

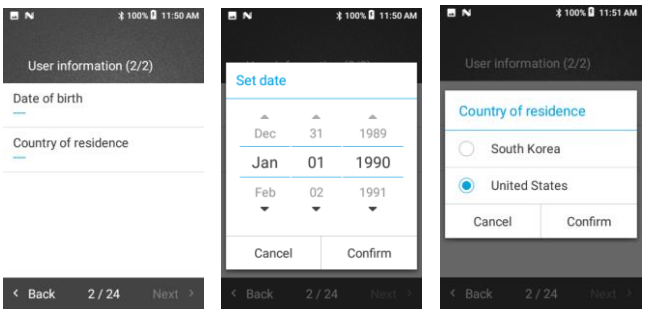


Figure 2-2-3 - Date of birth and County of residence

2.2.6 Screen lock

Select if you want to unlock your screen by a Pattern, PIN or a Slide (swipe).

2.2.6.1 Pattern

1. Touch **Pattern**.
2. Draw a pattern of at least 4 dots and touch **Next**.
3. Draw the same pattern again and touch **Next**.
4. Enter a backup pin and touch **Next**.
5. Enter then same backup pin again and touch **Next**.
6. The **Auxiliary setting question** screen is displayed. Touch the drop-down menu to choose a question to answer and answer the question and touch **Next.**

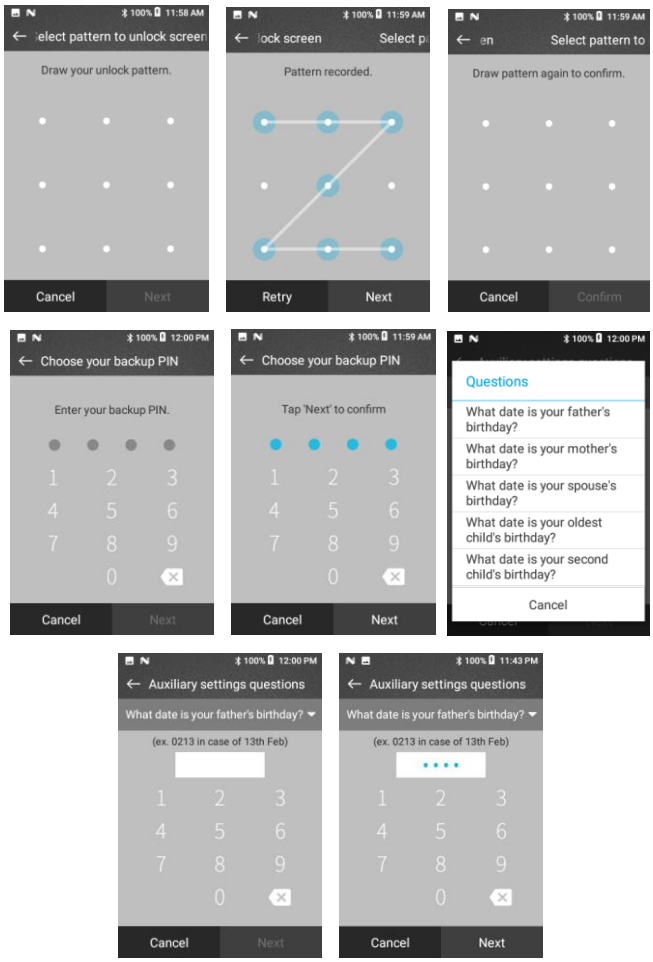


Figure 2-2-4 - Screen lock with Pattern

2.2.6.2 Pin

1. Touch **Pin.**
2. Enter a pin and touch **Next.**
3. Enter then same pin again and touch **Next.**
4. The **Auxiliary setting question** screen is displayed. Touch the drop-down menu to choose a question to answer and answer the question and touch **Next.**

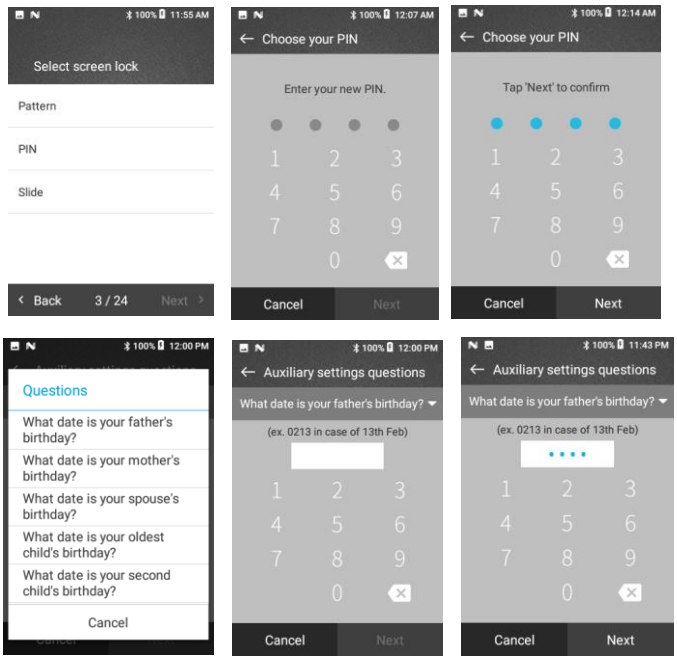


Figure 2-2-5 - Screen lock with Pin

2.2.6.3 Slide

1. Touch **Slide** (To unlock your ADM, swipe right from the Welcome screen.)

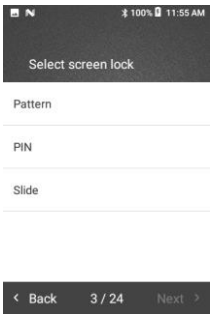


Figure 2-2-6 - Screen lock with Slide

Caution: To best protect your ADM from unwanted entry, choose either Pattern of PIN.

2.2.7 Time zone

Set the time zone in which you are most of the time.

1. Touch **Set time zone**.
2. Touch the **major city** in your time zone and touch **Next**.

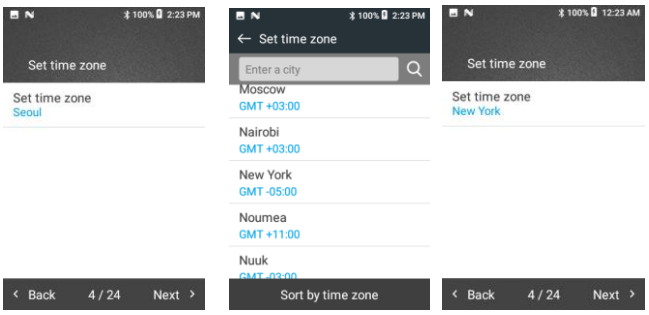


Figure 2-2-7 - Time zone

2.2.8 Date

1. Touch **Set date**.
2. Scroll to today's month, day and year and touch **Confirm**.
3. Touch **Confirm** to confirm that the date is set correctly.
4. Touch **Next**.

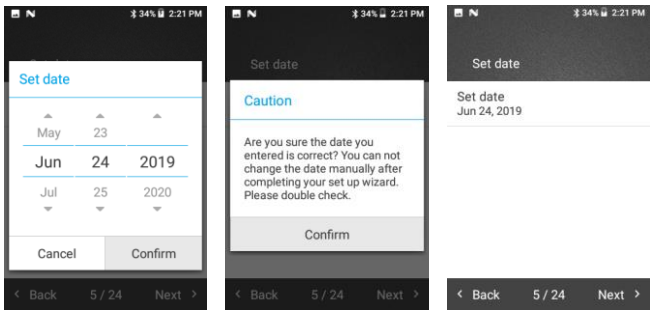


Figure 2-2-8 - Date

2.2.9 Time

1. Scroll to the time.
2. Set the time and touch **Confirm**.
3. Touch **Confirm** to confirm that the date is set correctly.
4. Touch **Next**.

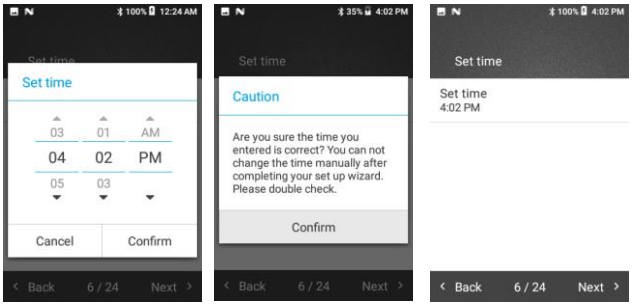


Figure 2-2-9 - Time

Did you know: As you continue with the initial set-up, you will notice that there may be settings with terms that are unknown to you. For more information about those terms, read the information in the **Did you know** boxes like this one and/or look in the **Appendix** section of this manual.

2.2.10 Max bolus

Set the most insulin you want you want to deliver in a single bolus. The default setting is 10.00 U.

1. Touch the number of units currently set.
2. Scroll to the number of units you want to set and touch **Next**.

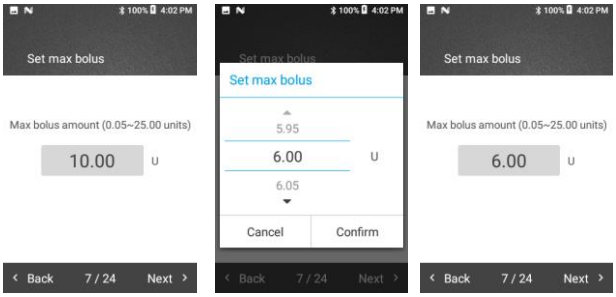


Figure 2-2-10 - Max bolus

Did you know: A bolus is the amount of insulin you will deliver for meals and to correct for high blood glucose readings. If you are new to insulin pump therapy and have been injecting short or rapid-acting insulin for food and correction, the boluses will take the place of those injections. The units of bolus insulin from the Patch will be similar to the units of short or rapid-acting insulin you were previously injecting. If you are unclear as to what this setting is for your individual blood glucose management, ask your healthcare provider or insulin pump trainer.

2.2.11 Max basal rate

Set the total amount of background insulin you want to deliver in an hour. The default setting is 3.00 U.

1. Touch the number of units currently set.
2. Scroll to the number of units per hour you want to set, and touch **Confirm**
3. Your Max basal is displayed, touch **Next**

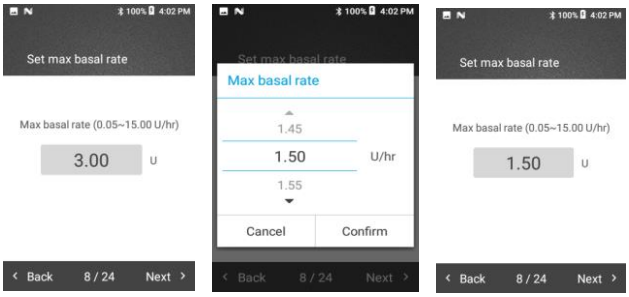


Figure 2-2-11 - Max basal rate

Caution: This is a safety feature to guard against programming too much basal insulin.

Did you know: The basal rate is the amount of background insulin the Patch will deliver in one hour. If you are new to insulin pump therapy and have been taking long-acting insulin once or twice a day, the basal insulin will take the place of your long-acting insulin. The total units of basal insulin from the pump may be up to 20% less than your total units of long-acting insulin due to the insulin being delivered continuously rather than in one or two injections a day.[6] If you are unclear as to the maximum basal rate for your individual blood glucose management, ask your healthcare provider or insulin pump trainer.

2.2.12 BG target range

Set the blood glucose range for your individual blood glucose goal. This range is displayed on the ADM screen, so you can view how well you are achieving your goal. The range for the setting is 70-200 mg/dL. The default setting is 70 – 140 mg/dL.

Touch the screen then scroll to enter your desired BG target range.

1. Touch the number of units currently set for the Upper limit.
2. Scroll to the number of units per hour you want to set for the Upper limit and touch **Confirm**.
3. Touch the number of units currently set for the Lower limit.
4. Scroll to the number of units per hour you want to set for the Lower limit and touch **Confirm**.

5. Your BG target range is displayed, touch **Next**.

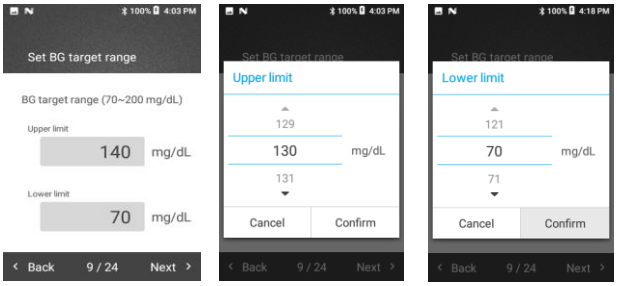


Figure 2-2-12 - BG target range

Did you know: The BG target range is your goal for your blood glucose range. If you are unclear as to what this setting is for your individual blood glucose management, ask your healthcare provider or insulin pump trainer.

2.2.13 Basal setting

2.2.13.1 Set the rate

To set the rate of background insulin delivery. The default setting is 0.05 U/hr.

1. Touch the number of units currently set for the basal rate.
2. Scroll to the number of units per hour you want to set for the basal rate and touch **Confirm**.
3. Your basal rate is displayed, touch **Next**.

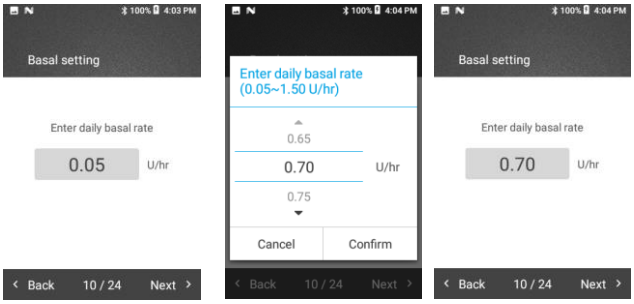


Figure 2-2-13 - Basal setting

2.2.13.2 To rename the basal setting:

1. Touch the **Name**, backspace and enter the new name and touch **Done**.

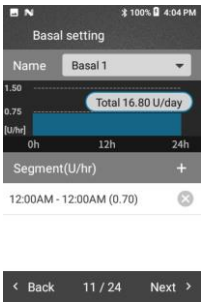
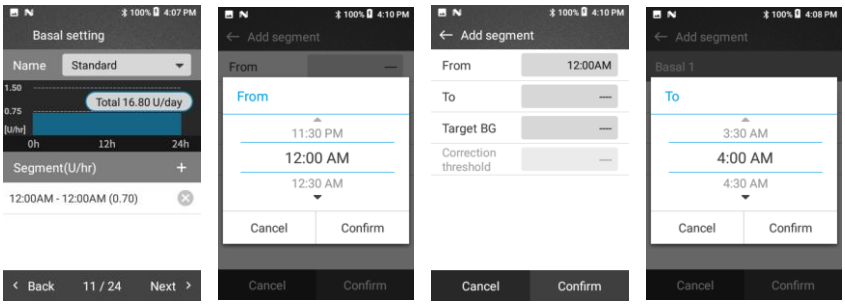


Figure 2-2-14 - Rename basal setting

2.2.13.3 To add Segments to your basal program:

You may add additional Segments for different times of day to the current basal program. The first segment begins at midnight and the last segment ends at midnight. You may enter a different basal rate as often as 30 minutes.

1. Touch the plus sign icon +.
2. Touch **From** and scroll times you want the segment to start and touch **Confirm**.
3. Touch **To** and scroll times you want the segment to stop and touch **Confirm**.
4. Touch **Rate** and scroll to the units per hour for the rate and touch **Confirm**.
5. View the new segments. To change touch the times, to delete touch the X.
6. When correct, touch **Next**.



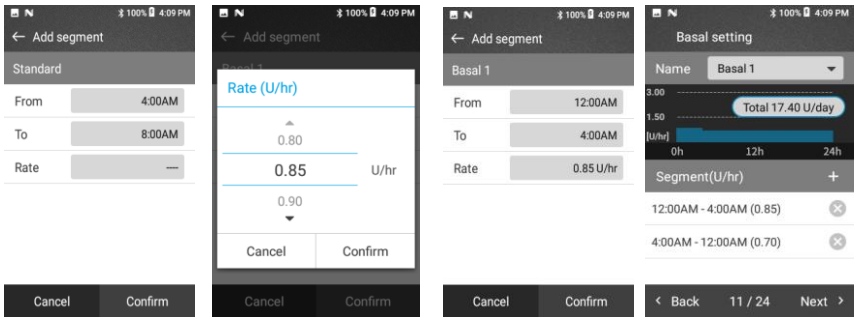


Figure 2-2-15 - Add segments to basal program

Did you know: There are several considerations when setting your basal settings. If you are new to insulin pump therapy, consider starting with a single basal rate and modifying it over time based on your blood glucose results. If you need more or less background insulin at different times of day, set a higher or lower basal rate for that time of day. For example, if you require more insulin in the early morning hours for the dawn phenomenon, you can increase your basal rate at that time. Also, it is possible to set different basal programs for different activities. For example, you may require less insulin for a day of hiking or bike riding.

2.2.14 Target BG and Correction threshold

Set the target BG you want the bolus calculator to use when making bolus suggestions. The range for the Target BG is 70-200 mg/dL. The default setting for the Target BG is 100 mg/dL. Set the Correction threshold over which you want the bolus calculator to begin making corrections. The range for the Correction threshold is 70-200 mg/dL.
The default setting for Correction threshold is 100 mg/dL.

1. Touch the number of mg/dL currently set for the Target BG.
2. Scroll to the mg/dL you want to set for the Target BG and touch **Confirm**.
3. Your Target BG is displayed.
4. Touch **Next** to display the next Correction threshold screen.
5. Touch the number of mg/dL currently set for the Correction threshold.
6. Scroll to the mg/dL you want to set for the Correction threshold and touch **Confirm**.
7. Your Target BG is displayed.
8. Touch **Next** to display the next Target BG and Correction threshold screen.

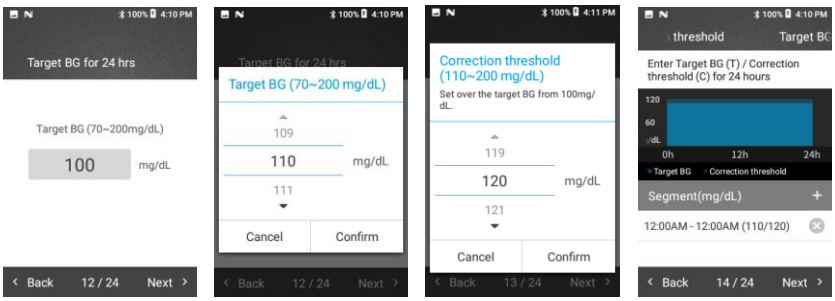


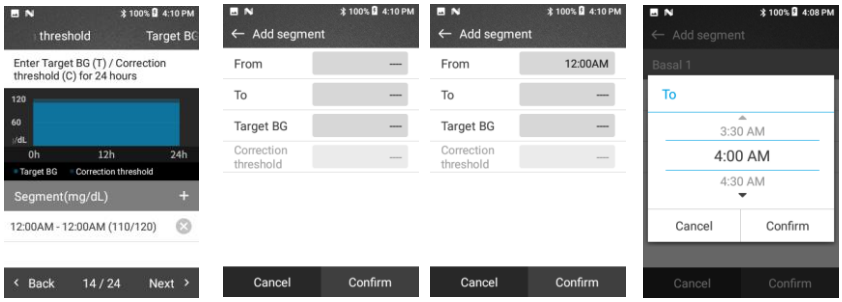
Figure 2-2-16 - Target BG and Correction threshold

Did you know: The Correction threshold is the mg/dL over which you want the bolus calculator to make corrections when your blood glucose reading is under your Correction threshold. For example, if your Target BG is 100 mg/dL, your Correction threshold is 120 mg/dL (and your actual is 110 mg/dL, the calculator will not correct because 110 mg/dL is lower than your correction threshold of 120 mg/dL.

2.2.14.1 To add additional Segments to the current Target BG and Correction threshold.

The first segment begins at midnight and the last segment ends at midnight. You may enter a different Target BG and Correction Threshold as often as 30 minutes.

1. Touch the plus sign icon +.
2. Touch **From** and scroll times you want the segment to start and touch **Confirm**.
3. Touch **To** and scroll times you want the segment to stop touch **Confirm**.
4. Touch **Target BG** and scroll to the mg/dL.
5. Touch **Correction threshold** and scroll to the mg/dL.
6. Touch **Confirm**.
7. View the new segments. To change touch the times, to delete touch the X.
8. When correct, touch **Next**.



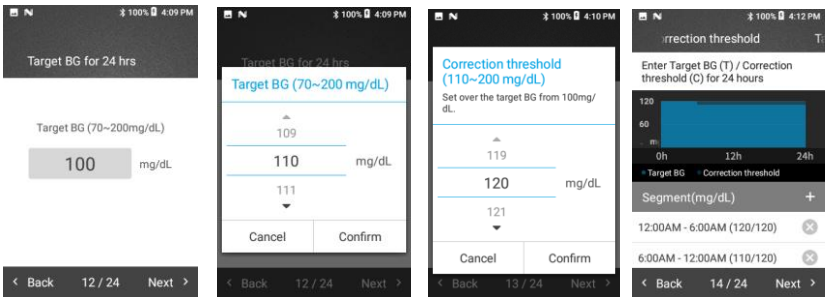


Figure 2-2-17 - Add segments to Target BG and Correction threshold

2.2.15 Min BG for bolus calc

Set the minimum blood BG you want the bolus calculator to use when making bolus suggestions. The bolus calculator will not make suggestions if your blood glucose is below this and will alert you to treat your low blood glucose. The range for the setting is 50-70 mg/dL. The default setting is 70 mg/dL.

1. Touch the mg/dL.
2. currently set for Min BG for bolus calc.
3. Scroll to the mg/dL.
4. you want to set for Min BG for bolus calc and touch **Confirm.**
5. Your Min BG for bolus calc is displayed.
6. Touch **Next**.

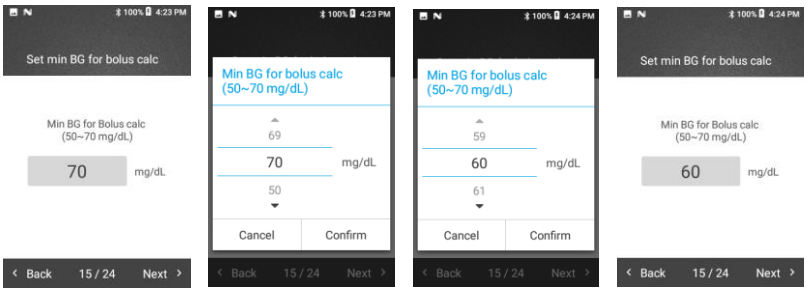


Figure 2-2-18 - Minimum BG for bolus calc

NOTE: If your blood glucose is lower than the min BG for bolus calc, a pop-up window saying, **"BG is too low to use calculator. Treat hypoglycemia."** will appear on the screen.

2.2.16 IC Ratio

Set the insulin to carbohydrate ratio you want the bolus calculator to use when making meal bolus suggestions. The default setting is 15g/U.

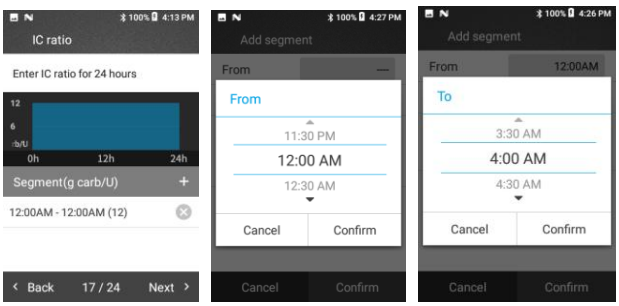
1. Touch the grams of carbohydrate per unit currently set for the IC ratio.
2. Scroll to grams of carbohydrate per unit you want to set for the IC ratio and touch **Confirm**.
3. Your IC ratio is displayed.
4. Touch **Next** to display the next IC ratio setting screen.

Figure 22-19 - IC ratio

To add additional Segments for different times of day (U/hr) to IC Ratio

The first segment begins at midnight and the last segment ends at midnight. You may enter a different basal rate as often as 30 minutes.

1. Touch the plus sign icon +.
2. Touch **From** and scroll times you want the segment to start and touch **Confirm**.
3. Touch **To** and scroll times you want the segment to stop and touch **Confirm**.
4. Touch **Rate** and scroll to the units per hour for the rate and touch **Confirm**.
5. View the new segments. To change touch the times, to delete touch the X.
6. When correct, touch **Next**.



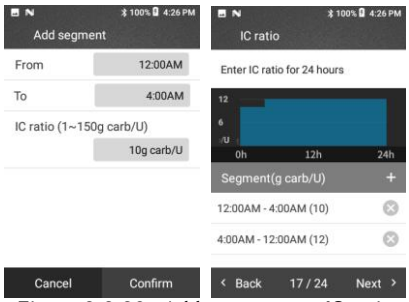


Figure 2-2-20 - Add segments to IC ratio

Caution: The higher the grams of carbohydrate in the insulin-to-carbohydrate ratio, the less insulin you will receive. For example, 1 unit for every 15 grams is more insulin per gram of carbohydrate than 1 unit for every 18 grams.

Did you know: The insulin-to-carbohydrate ratio expresses approximately how many grams of carbohydrate 1 unit of insulin will metabolize. For example, if your insulin-to-carbohydrate ratio is 1 unit for every 15 grams of carbohydrate and you are eating 45 grams of carbohydrate, you would need to deliver 3 units or insulin. If you are unclear as to what this setting is for your individual blood glucose management, ask your healthcare provider or insulin pump trainer.

2.2.17 Correction factor

Set the Correction factor you want the bolus calculator to use when making correction bolus suggestions. The range for the setting is 1- 400 mg/dL. The default setting is 50 mg/dL.

1. Touch the mg/dL.
2. currently set for Correction factor.
3. Scroll to the mg/dL.
4. you want to set for Correction factor and touch **Confirm**.
5. Your Correction factor is displayed.
6. Touch **Next** to display the next Correction factor setting screen.

Figure 2-2-21 - Correction factor

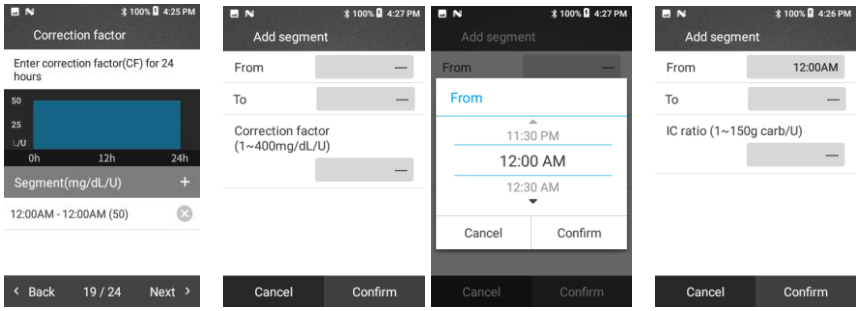
Caution: The higher the mg/dL in the correction factor, the less insulin you will receive. For example, 50 mg/dL for every 1 unit of insulin is more insulin than 60 mg/dL.

Did you know: The correction factor expresses approximately how many mg/dL your blood glucose will drop per 1 unit of insulin. For example, if your correction factor is 50 mg/dL for every unit of insulin you deliver, and your blood glucose is 150 mg/dL, 1 unit of insulin would lower your blood glucose to approximately 100 mg/dL.If you are unclear as to what this setting is for your individual blood glucose management, ask your healthcare provider or insulin pump trainer.

2.2.17.1 To add additional Segments for different times of day (U/hr) to the Correction factor.

The first segment begins at midnight and the last segment ends at midnight. You may enter a different basal rate as often as 30 minutes.

1. Touch the plus sign icon +.
2. Touch **From** and scroll times you want the segment to start and touch **Confirm**.
3. Touch **To** and scroll times you want the segment to stop and touch **Confirm**.
4. Touch **Rate** and scroll to the units per hour for the rate and touch **Confirm**.
5. View the new segments. To change, touch the times, to delete touch the X.
6. When correct, touch **Next**.



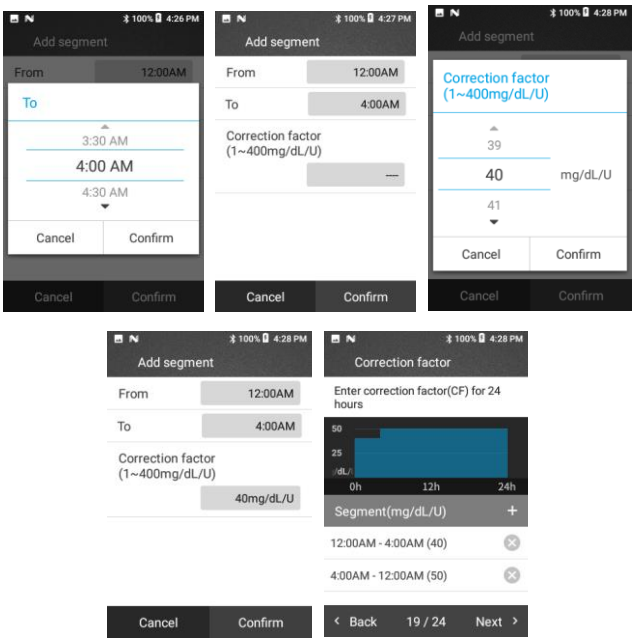


Figure 2-2-22 - Add segments to Correction factor

2.2.18 Insulin action

Set the Insulin duration you want the bolus calculator to use when making determining how much insulin you have on board (IOB) from previously delivered meal boluses. The range for the setting 2-8 hours, the default setting is 5 hours.

1. Touch the hours currently set for Insulin action.
2. Scroll to the hours you want to set for Insulin action and touch **Confirm**.
3. Touch **Next**.

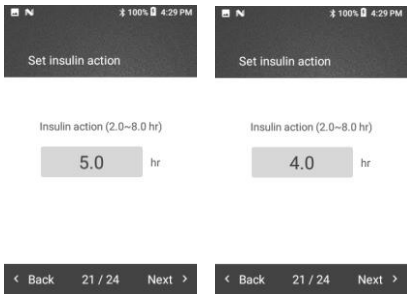


Figure 2-2-23 - Insulin action

Did you know: Insulin action is used to calculate the amount of insulin you have on board (IOB) from a previous bolus. For example, if your insulin duration is set at 4 hours and you programed a bolus of 4 units two hours ago, you will have approximately 2 units of IOB. If you are unclear as to what this setting is for your individual blood glucose management, ask your healthcare provider or insulin pump trainer.

2.2.19 Extended bolus option

Set Extended bolus option to ON if you want the ADM to give you the option of delivering some or all of the meal bolus over a longer period of time. The default setting is OFF.

1. Touch the option button on the screen to turn Extended bolus option ON.
2. Touch U or % to choose to set in Units or percent when extending a bolus.

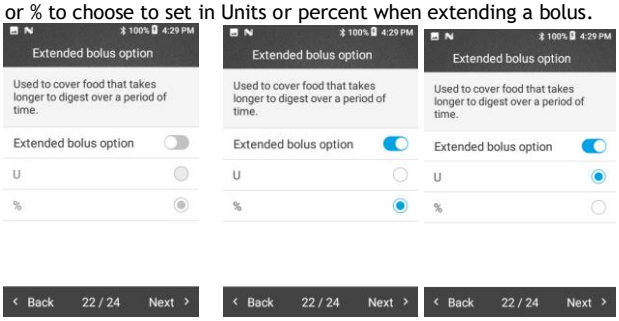


Figure 2-2-24 - Extended bolus

WARNING: When using the extended bolus feature, check your blood glucose more often to avoid unexpected hyperglycemia or hypoglycemia.

Did you know: Extended Bolus gives you the option on delivering a portion or all of a bolus over a longer period of time. You may choose to use an extended bolus for foods that you notice absorb slower than most because of the high content of fat, which slows down the absorption of carbohydrate in the food. A good example of this phenomenon is after eating pizza. For this reason, the extended bolus has often been labeled the "pizza bolus". If you are unclear as to what this setting is for your individual blood glucose management, ask your healthcare provider or insulin pump trainer.

2.2.20 Low reservoir Alerts

Set low reservoir Alerts to alert you when you have reached the number of units at which you choose to be alerted of a low reservoir. The range for the setting is 10-50 units. The default is 10 units.

1. Touch the units currently set for low reservoir Alerts.
2. Scroll to the units you want to set for low reservoir Alerts and touch **Confirm**.
3. Touch **Next**.

Figure 2-2-25 - Low reservoir alerts

2.2.21 Patch expiration Alerts

Set Patch expiration Alerts to alert you when you have reached the number of hours at which you choose to be alerted before the Patch expires. The range for the setting is 1-24 hours. The default is 4 hours.

1. Touch the units currently set for Patch expiration Alerts.
2. Scroll to the hours you want to set for the Patch expiration Alerts and touch **Confirm**.
3. Touch **Finish**.

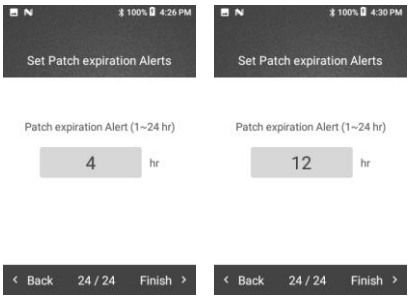


Figure 2-2-26 - Patch expiration Alerts

2.2.22 Initial Setup Complete

You have now completed the Initial Setup for the ADM. (The settings you just entered can be modified in the Advanced menu and ADM settings.) Next you will apply the Patch and begin using it to deliver insulin.

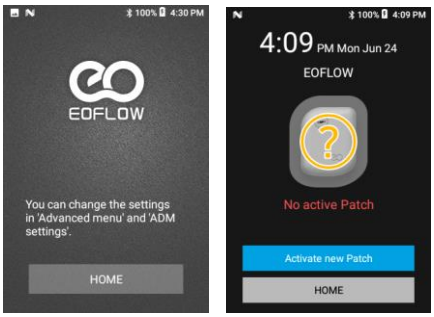


Figure 2-2-27 - Initial Setup complete

WARNING: If your ADM is not working correctly or is damaged, call EOFLOW Product Support for assistance, check your blood glucose frequently and contact your healthcare provider for

3 ACTIVATING A PATCH

In this section you will learn how to fill the Patch with insulin, apply the Patch and use it to deliver insulin.

WARNINGS:

- Using the Patch with insulin without the direction of your health care provider or insulin pump trainer could cause serious injury or death.
- Do not use the Patch if you have allergies or sensitivity to acrylic, adhesives or fragile skin.
- Because the EOPatch Insulin Management System uses only rapid-acting insulin, hyperglycemia can occur quickly if insulin delivery is interrupted. Discuss the treatment for interrupted insulin delivery with your healthcare provider. In the case of the interruption of insulin delivery from the Patch, your healthcare provider may instruct you to take an injection of rapid-actin insulin through a syringe or pen.
- The contents of the blister package are sterile unless opened or damaged. Do not use the Patch if the sterile blister package is open or damaged or if the Patch is dropped after removal from the package.
- Do not use a Patch if past the expiration date on the package.
- Keep the Patch blister package and its contents away from small children as they pose a swallowing risk.

3.1 Deactivation Process

3.1.1 Deactivate Patch

If you are not currently wearing a Patch, disregard this step.

1. Touch the menu icon on Home screen.
2. Touch **Change Patch**.
3. On the Change Patch screen, touch **Confirm** to deactivate the current Patch.
4. A Caution making sure you want to change the Patch is displayed. Touch **Yes**.
5. The Patch will beep 3 times. A screen stating Patch deactivated is displayed with instructions to Remove Patch. Remove and discard the Patch and touch **Next**.
6. A screen asking if you would like to activate a Patch is displayed.

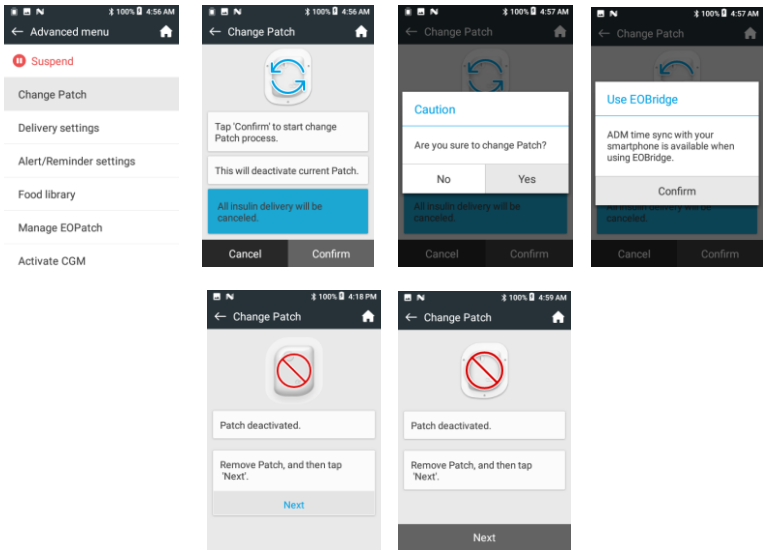


Figure 3-3-1 - Patch deactivation

WARNINGS:

- Remove the Patch from your body after deactivation as there is a risk that it may still deliver insulin and put you at risk for hypoglycemia.
- Disable all alarms sounding on the discarded Patch.

Caution: The Patch must be replaced if the reservoir contains less than 10 units or if the current Patch is defective.

NOTE: The battery life of the Patch should allow the Patch to be used for up to 84 hours. After wearing the Patch for 84 hours, you will receive an alert notifying you that the Patch has expired. After you receive the alert, you will have 12 hours to change the Patch before you receive an alarm letting you know that insulin delivery has stopped.

3.2 Activation Process

3.2.1 Necessary Items

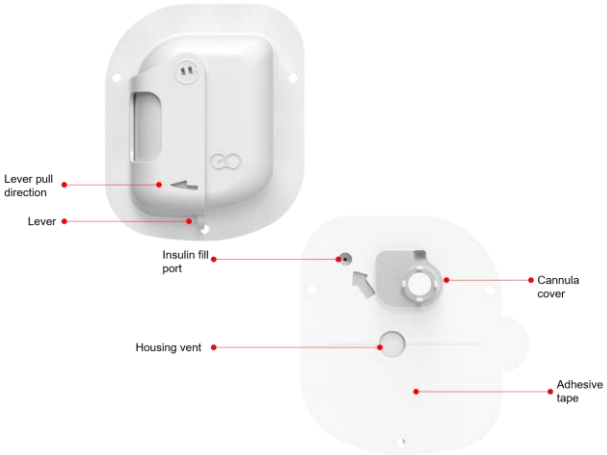
Before replacing or applying Patch, gather these necessary items:

- New, unopened Patch blister package: this package includes a Patch, a syringe for insulin injection, and a needle.
- ADM
- Alcohol swab for disinfection of insulin vial and skin
- Vial of rapid-acting, U-100 insulin

WARNING: Do not use the Patch if the sterile blister package is open or damaged.

3.2.2 Patch Components

Familiarize yourself with the parts of the Patch before you continue with the activation process.



3.2.3 Activate Patch

You may activate a Patch from the Status screen, the menu icon on the Home screen or the Advanced menu. (See page 84 for Advanced menu.)

1. Unlock the ADM through the method you previously chose: Pattern, Pin or Slide, to display the Status screen. (Alternatively, touch the menu icon on Home screen.)
2. Touch **Activate new Patch**.
3. A screen asking if you would like to activate a Patch is displayed, touch **Yes**.
4. A screen is displayed instructing you to fill a new Patch with insulin.

NOTE: Do NOT press Next until you have filled the Patch as instructed in the next step.

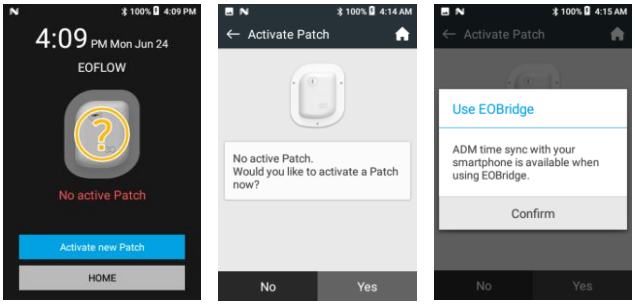


Figure 3-3-2 - Activate Patch from Home screen

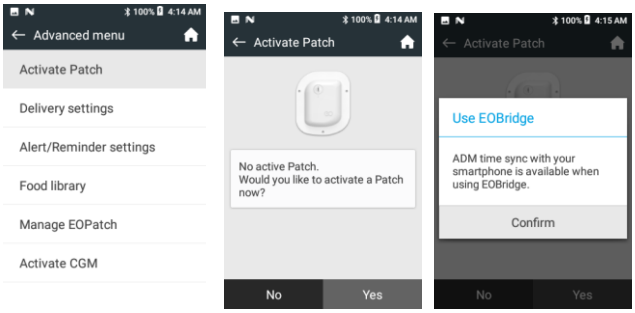


Figure 3-3 - Activate Patch from Advanced menu

3.2.4 Fill the new Patch

1. Wash your hands.
2. Open a new blister package containing the Patch, syringe and needle. Then assemble the syringe and needle.
3. Disinfect the top of the vial, rapid-acting insulin with an alcohol swab.
4. Assemble syringe.
5. Inject air into the insulin vial in approximately the same amount as you will use in the Patch.
6. Draw insulin from the vial in the amount you use in up to 96 hours. You must inject at least 80 units and no more than 200 units into the Patch for optimal performance. You must also add at least 10 extra units because the Patch will not operate without at least 10 units remaining.
7. Remove air bubbles from the syringe.
8. Insert the syringe needle into the insulin fill port on the back of the Patch and slowly inject the insulin.
9. Move the Patch next to the ADM.

10. You will hear the wake-up sound of 1 beep.

WARNING: Do not use the Patch if the sterile blister package is open or damaged.

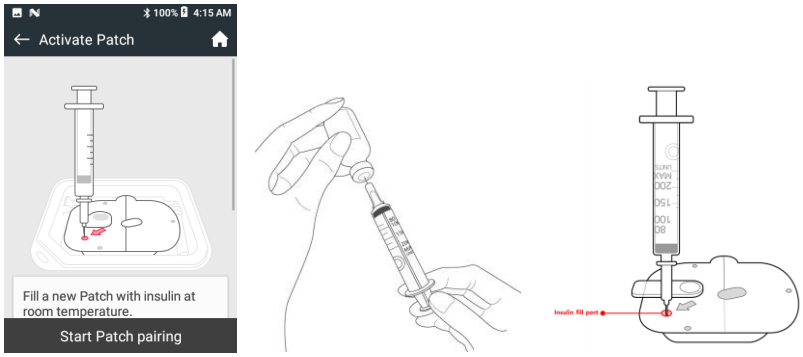


Figure 3-3-4 - Fill Patch

NOTE: The temperature of the insulin injected into the Patch should be at room temperature or at least 50° F (10°C).

Did you know: To fill a syringe with insulin, set the vial of insulin on the counter. Pick up the syringe and draw air into the syringe at approximately the desired amount of insulin. Insert the needle down into the vial and insert the air. While the needle is still in the vial, hold the syringe and turn the vial over so the needle is now pointing up and withdraw the desired amount of insulin. While the needle is still pointing up, remove the syringe, tap the sides of the syringe to move the bubbles toward the needle and slowly push out the bubbles. Finally, while the needle is still pointing up, reinsert the needle into the vial of insulin and slowly fill the syringe to the desired amount.

WARNINGS:

- If you feel resistance while filling a Patch, discard the Patch and use a new one.
- Do not inject air into the Patch to avoid an interruption in insulin delivery.
- Only use the rapid-acting insulin prescribed by your healthcare provider. Never fill the Patch with any other medication or liquid.

Cautions:

- To prevent infection, do not use the Patch if the blister package is damaged or if the Patch is dropped after opening.
- Use caution to not touch the needle when attaching it to the syringe.
- To ensure communication, the Patch must be within 12 inches (30.48 cm) of the ADM while activating.
- To ensure accurate insulin delivery, remove air bubbles when filling the Patch.

3.2.5 Pair and Prime the new Patch

After filling the Patch and placing it next to the ADM, the Patch will begin pairing with the ADM and display instructions for inserting the Patch.

NOTE: If pairing is not successful, a Communication error message is displayed with instructions on next steps.

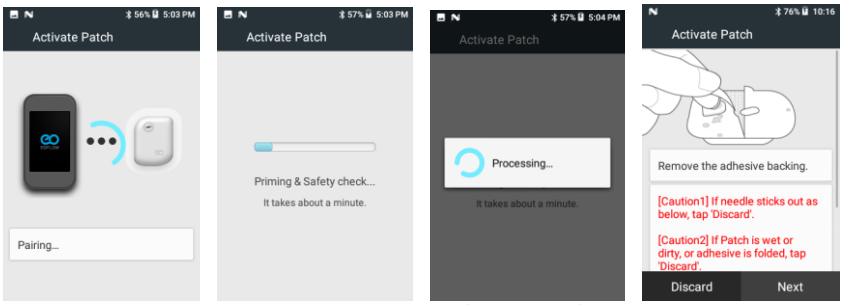


Figure 3-3-5 - Pair and Prime Patch

WARNING: Once you begin the process of Patch activation, it must be completed within 60 minutes of the wake-up beep. The ADM will display a reminder every 5 minutes. If not completed within 60 minutes, an alarm screen is displayed, and the Patch must be discarded.

3.2.6 Select and prepare the insertion site

1. Use the chart below to select an insertion site.
2. Wash your hands.
3. Disinfect the area around the insertion site with an alcohol swab and wait for it to completely dry.
4. Remove the cannula cover on the bottom of the Patch.

5. Touch **Next**.

WARNING: After removing the cannula cover, ensure that the cannula does not protrude, and the Patch is clean (If not, touch Discard and start the activation process over.)

Caution: When you first begin using the EOPatch system, choose an insertion site that is easily accessible so you can become familiar with the procedure of inserting the cannula and removing the lever. (See page 37 for insertion sites.)

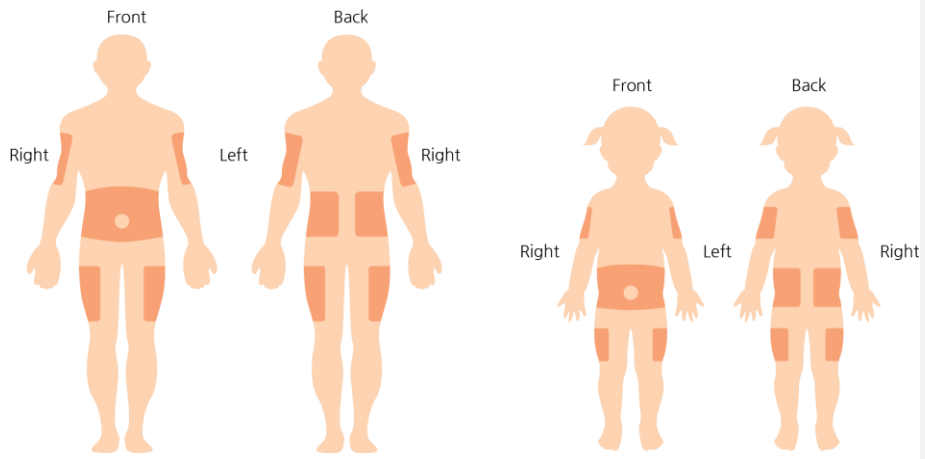


Figure 3-3-6 - Insertion sites

Did you know: To preserve the integrity of your skin, it is important to rotate your sites and insert the Patch on skin that is free from scratches, tattoos or other blemishes. Since insulin absorbs best in subcutaneous tissue, the abdomen provides the best absorption of for most people but be sure to stay at least 2 inches (5 cm) away from your belly button and sensor sites. You may use your arms and legs; just be aware than they are prone to changes in absorption from varying activity. Finally, to prevent dislodging the Patch, avoid insertion areas that are prone to friction from belts or undergarments.

3.2.7 Apply the new Patch

1. Remove the adhesive tape.
2. Place the Patch on the cleaned insertion site and make sure the tape adheres to the skin.
3. Touch **Next.**

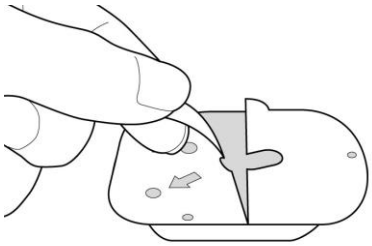


Figure 3-3-7 - Adhesive tape

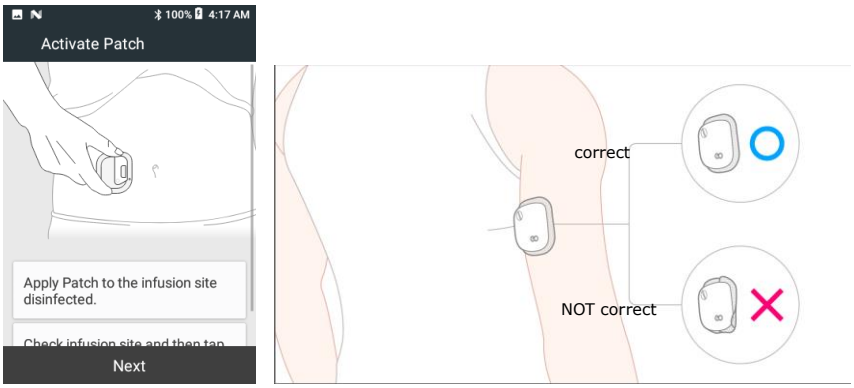


Figure 3-3-8 - Patch placement

WARNING: If you are applying a Patch to a lean area without fatty tissues, squeeze the skin around the Patch throughout the process.

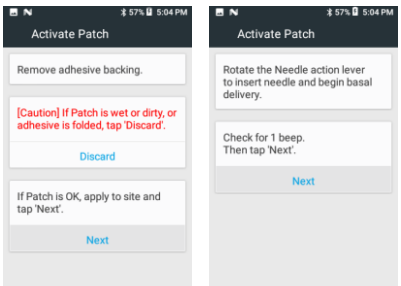
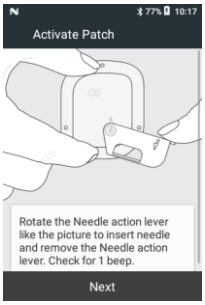


Figure 3-3-9 - Patch placement instructions

3.2.8 Insert cannula

1. Press and hold the Lever while turning it clockwise in the direction of the arrow far as you can turn it. (The lever will turn 110°. While you are turning the lever, the needle will be inserted into and retracted from your subcutaneous tissue. Only the cannula will remain.
2. The Patch buzzer sounds when the cannula is properly inserted.
3. After the Patch buzzer sounds, remove the Lever from the Patch.
4. Discard the Lever.
5. Touch **Next.**



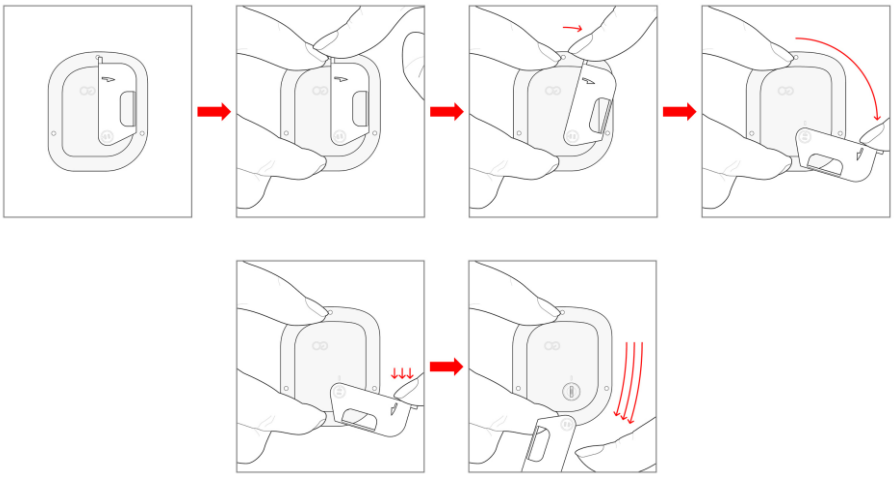


Figure 3-3-7 - Cannula insertion

NOTE: Do not be concerned if a small amount of blood appears at the insertion site but do check blood glucose more frequently to ensure proper insulin delivery.

3.2.9 Begin insulin delivery

1. The Patch status displays as Active and basal delivery begins.
2. Check the injection site and cannula for proper insertion.
3. Touch **Next**.
4. The Patch buzzer sounds once, a yellow light blinks on the ADM, the ADM sounds, and a screen displays letting you know that the activation is successful.
5. After 1.5 hours, a Check Patch Reminder screen displays to remind you to check your blood glucose after Patch insertion.

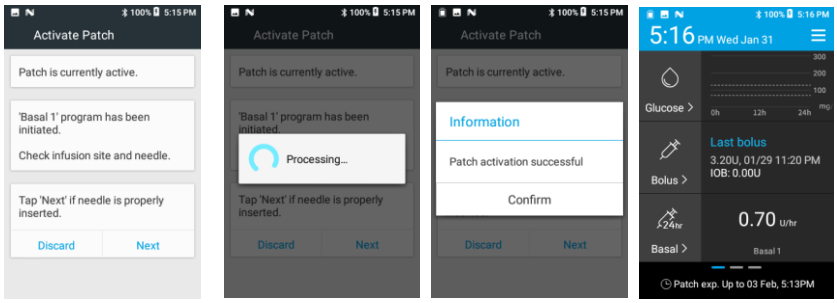


Figure 3-3-8 - Begin insulin delivery

WARNINGS:

- Check the infusion site after insertion. Improper insertion may prevent insulin delivery and cause hyperglycemia.
- Check blood glucose after Patch insertion to ensure insulin delivery. If blood glucose is high and doesn't resolve with one correction bolus, discard Patch and activate a new Patch.
- Check Patch frequently. If any sign of infection, change the Patch using and different infusion site and contact your healthcare provider for next steps.
- Check the infusion site frequently. If the tape is wet or you can smell insulin and your blood glucose is high, the Patch may not be delivering insulin into your subcutaneous tissue. Discard Patch and activate a new Patch.

3.3 Patch Status

The ADM periodically notifies you of the connection status of the Patch. Additionally, you may check the connection status yourself in two ways.

3.3.1 Check connection status through Status screen on ADM

1. Press the button on the top right side of the ADM to display the Primary screen.
2. Depending on your previous choice to lock the ADM, enter your personal pin, draw your personal pattern or swipe to the right to display the Status screen.
3. Your current basal rate is displayed on the Status screen letting you know that the Patch is dispensing insulin.
4. On occasion, the Status screen may display a **Patch out of range message**. This message refers to the proximity of the Patch to the ADM. **The Patch is still dispensing insulin when this message is displayed.** Simply move the ADM closer to the Patch and touch **Communication check** to allow the Patch and ADM to communicated.

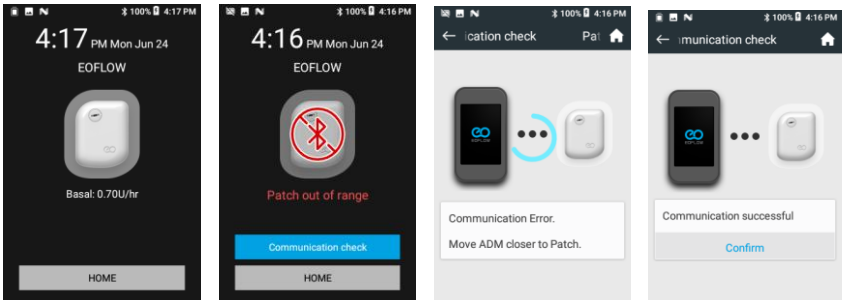


Figure 3-3-9 - Connection status on Status screen

3.3.2 Check connection status through Settings icon on the ADM

1. Press the button on the top right side of the ADM to display the Primary screen.
2. Depending on your previous choice to lock the ADM, enter your personal pin, draw your personal pattern or swipe to the right to display the Status screen.
3. Touch **Home** to display the Home screen.
4. Touch the menu icon ☰ on the top right corner of Home screen.
5. Touch **EOPATCH diag and reset.**
6. Touch **Patch info** to display the information of the current Patch.
7. Touch Pa

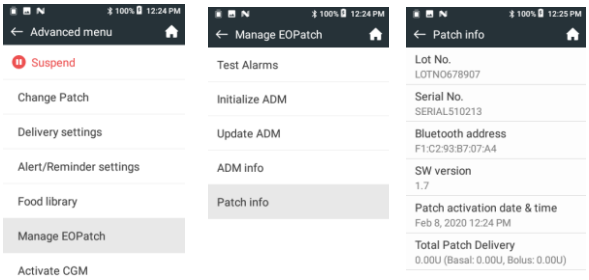


Figure 3-3-10 - Connection status through Advanced menu

WARNINGS:

- The Patch can deliver insulin without being attached to your body. The only way to know if the Patch is delivering insulin into your subcutaneous tissue is by testing your blood glucose.
- If the areq under and around the tape holding the Patch onto your skin is wet or if you can smell insulin, the Patch may not be pumping insulin into your subcutaneous tissue.
- A full or partial occlusion can occur in the Patch causing it to deliver less or no insulin. The ADM has an occlusion alarm, but this alarm only works when there is a full occlusion. The only way to know if the Patch is delivering insulin at the correct rate is by testing your blood glucose.

NOTE: Once a Patch is activated, it does not need to be in proximity to the ADM to continuously deliver the basal rate.

3.4 Patch Maintenance

3.4.1 Storage

Store all unopened Patches in a cool, dry area. If unopened Patches are exposed to extreme temperatures, inspect each Patch before use and discard any Patches that seem affected.

3.4.2 Extreme temperatures

- The Patch should not be exposed to direct sunlight or heat for long periods of time nor should it be allowed to freeze.
- Insulin should be used within the temperature range of 39.92°- 98.6°F (4.4°C~37 °C).

WARNING: Insulin which has frozen or has been kept at a temperature over 98.6°F (37°C) should not be used because extreme temperatures break down the insulin and cause it to become less potent.

3.4.3 Water resistance

- The Patch is an IP48 rated waterproof product; it guarantees 24-hour waterproof performance at a water depth of 32 feet (1 meter), while it is attached to the skin.
- After swimming with the Patch, dry the Patch, check that the tape is secure and that there is no wetness or smell of insulin under the tape.

WARNING: Do not wear the Patch in water deeper than 32 feet (1 meter) or in water for over 24 hours.

3.4.4 Exposure

- Portable RF communication equipment, including antenna cables, and external antennas, should not be used within 12 inches (30.48 cm) of any portion of the EOPatch system. Degradation of the performance of this equipment could result.

Caution: The EOPatch Insulin Management System uses Bluetooth Low Energy (BLE) to link the ADM and the Patch. Other electronic equipment in your home and environment also use BLE to communicate (e.g. cell phones and computers). Please ensure that your ADM is only coupled with your patch to ensure proper function.

3.4.5 Cleaning

- Since the Patch is waterproof, you may clean it with mild soap and water.

Caution: When cleaning the Patch, hold it against your body so you do not dislodge the cannula

4 USING THE ADM

In this section you will become more familiar with the ADM screens.

4.1 The Primary screen

The Primary screen is the screen you see when you wake up the ADM. If the ADM has been shut down, the primary screen is the screen you see after the ADM goes through the process of waking up.

1. Press the button on the top right side of the ADM to display the Primary screen.
2. Depending on your previous choice to unlock the ADM, draw your personal pattern, enter your personal pin or swipe to the right to display the Status screen.

Figure 4-4-1 - Primary

4.2 The Status screen

The Status screen is the screen you see after you unlock the Primary screen. The Status screen displays the status of the Patch. If there is an active Patch, the current basal rate is displayed. If there is no active Patch, you have the option to activate a Patch from this screen.

1. To activate a new Patch from this screen, touch Activate new Patch. (See page 33 for instructions on activating a new Patch.)
2. To continue to the Home screen, touch Home.

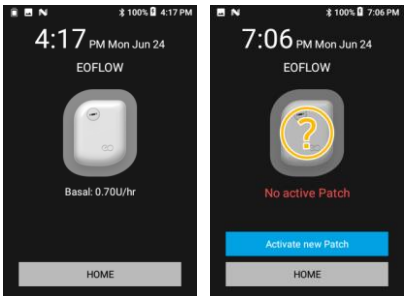


Figure 4-4-2 - Status Screen

4.3 The Home screen

The Home screen is the hub of the ADM. You use the Home screen to perform the daily functions of the EOPATCH Insulin Management system.

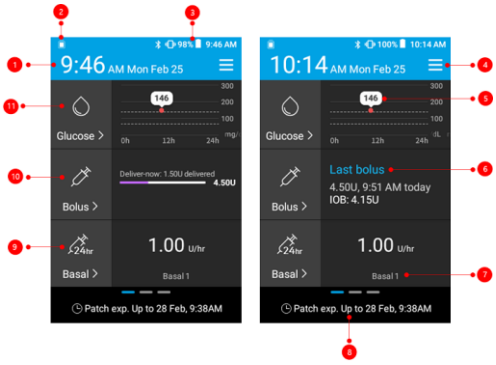


Figure 4-4-3 - Home Screen

1. Date & Time
2. Insulin Remaining
3. Remaining battery Charge
4. Advanced menu
5. Last Bolus
6. Last Blood Glucose
7. Current Basal Rate
8. Patch Expiration date
9. Basal Menu
10. Bolus Menu
11. Glucose Menu

4.3.1 The Glucose screens

Having access to blood glucose data allows you to see your blood glucose patterns and make changes in your management to improve your glucose control.

4.3.1.1 Entering BG manually

1. Touch the Glucose icon on the Home screen.
2. Touch **Enter BG manually**.

3. Touch **BG** value and scroll to your BG reading.
4. To add a **BG tag category**, touch the drop-down menu, touch the option button next to your chosen category and touch Confirm. (This is optional.)
5. To add a **BG tag**, touch the drop-down menu, touch the option button next to your chosen category and touch Confirm. (This is optional.)
6. The BG value now contains the BG tag category and tag for future reference.
7. Touch Confirm

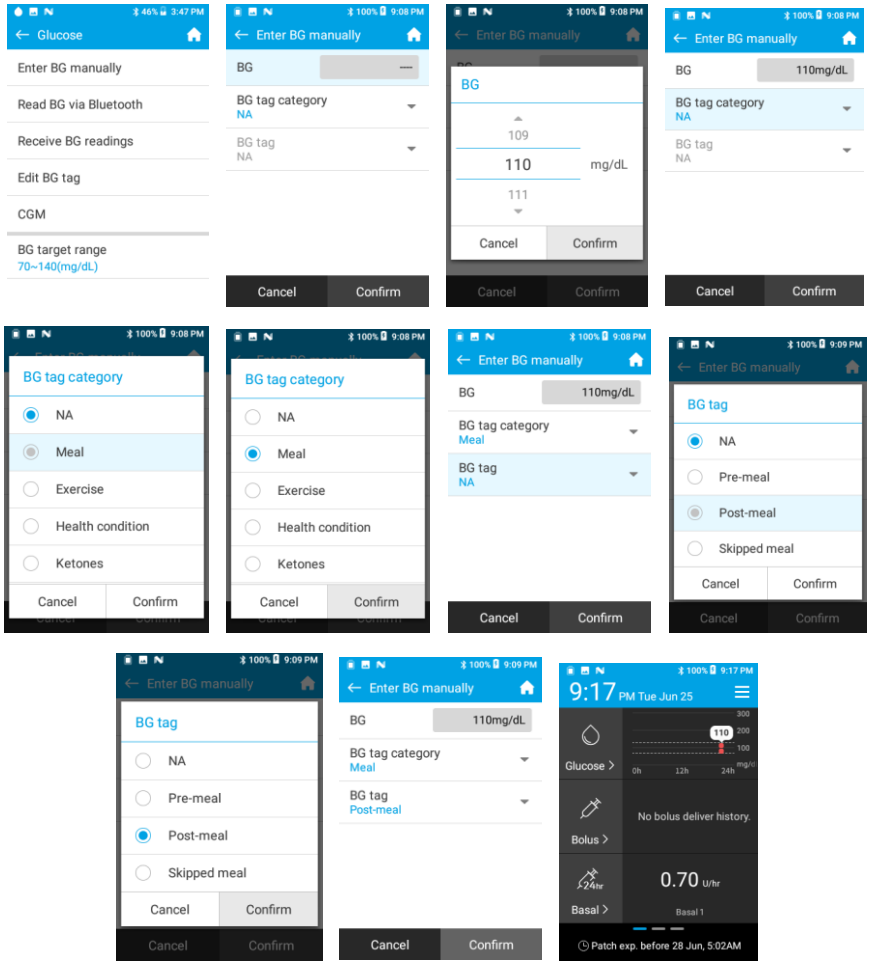


Figure 4-4-4 - Entering BG manually

4.3.1.2 Read BG via Bluetooth (from Blood Glucose Meter (BGM)

The ADM is capable of reading the most recent blood glucose reading from a Bluetooth enabled meter.

1. Touch the icon on the Home screen.
2. Touch the Read BG via Bluetooth menu. Wait up to 10 minutes for the reading to appear in the ADM.

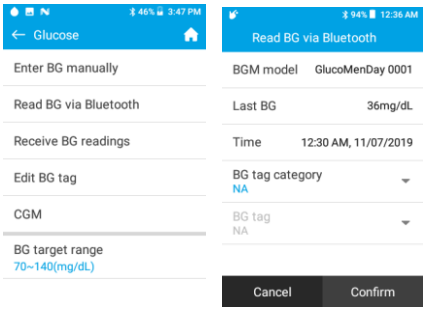


Figure 4-5 - Read BG via Bluetooth

NOTE:

- All features in the ADM available for blood glucose data entered manually (e.g. Bolus calculator, BG tags, etc.) are available for blood glucose data read via Bluetooth.
- If the ADM does not read the blood glucose result within 10 minutes, a pop-up will notify you to repeat the procedure.
- If two readings occur within 10 minutes, the ADM will save the most recent reading.
- If no meter is connected to the ADM by Bluetooth, a pop-up message will display “Paired BGM not found”. If two devices are found, select the correct meter from the list displayed.
- If the blood glucose reading is below the correction threshold or below the lower limit for the bolus calculator, a pop-up will display with information regarding the blood gluco se reading.
- When there is an active Patch, the ADM can read only the last 5 blood glucose readings. When there is no active Patch, all blood glucose data is available to be read by the ADM.

4.3.1.3 Editing BG tag

1. Touch the Glucose icon on the Home screen.
2. Touch **Edit BG tag**.
3. Touch the BG entry you want to edit. (The calendar displays today. If you prefer a different date, touch the calendar, then touch the date and touch Confirm)
4. Touch the BG value of with the tag you want to edit.
5. To add a **BG tag category**, touch the drop-down menu, touch the option button next to your chosen category and touch Confirm.
6. To add a **BG tag**, touch the drop-down menu, touch the option button next to your chosen category and touch Confirm.
7. The BG value now contains the BG tag category and tag for future reference.

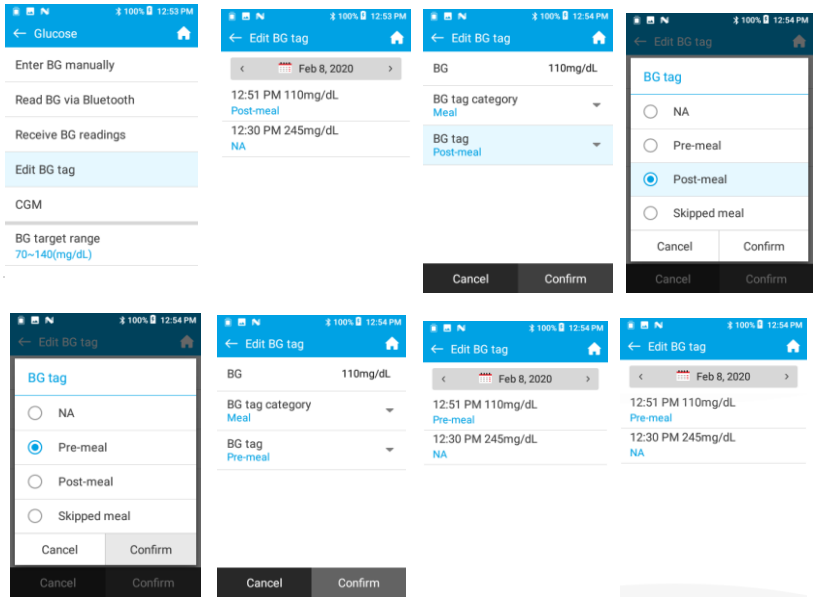


Figure 4-6 - Editing BG tag

4.3.1.4 Receive BG readings

The ADM is capable of receiving blood glucose readings from a Bluetooth enabled meter. If a Patch is active, the ADM is capable of receiving the last 5 readings. If there is no active Patch, the ADM is capable of receiving up to 500 readings.

1. Touch the icon on the Home screen.
2. Touch the Receive BG readings.

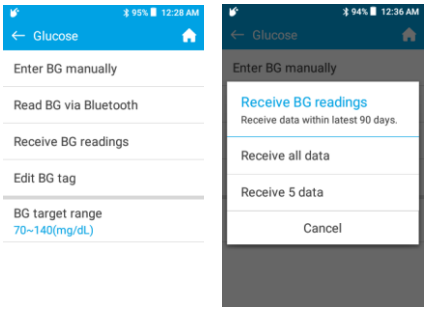
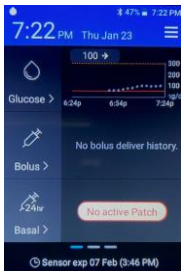


Figure 4-7 - Receive BG Readings

4.3.1.4.1 CGM

4.3.1.4.1.1 CGM Readings

1. Your CGM readings and directional arrows appear in the top of the Home screen



4.3.1.4.1.2 CGM Status

2. Touch the Glucose icon on the Home screen.
3. Touch **CGM**.
4. Touch **CGM Status**.
5. The current CGM status is displayed. Touch **Confirm**.

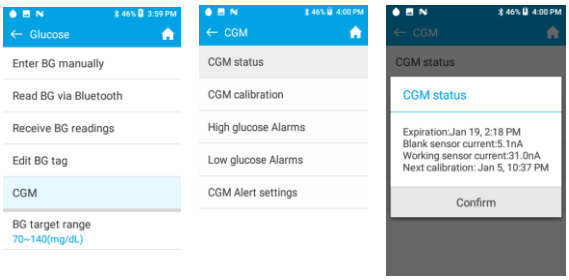


Figure 4-6 - CGM Status

4.3.1.4.1.3 CGM Calibration

1. Touch the Glucose icon on the Home screen.
2. Touch **CGM**.
3. Touch **CGM Calibration**.
4. Test your blood glucose with a meter, scroll to the result and touch **Confirm**.

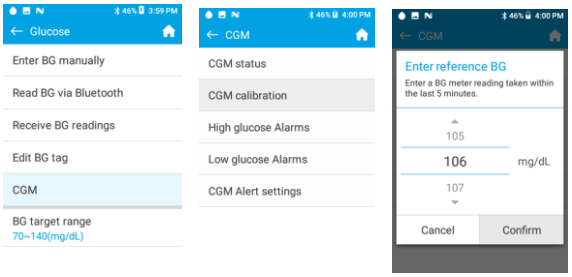


Figure 4-7 - CGM Calibration

4.3.1.4.2 High glucose Alarms

1. Touch the Glucose icon on the Home screen.
2. Touch **CGM**.
3. Touch **High glucose Alarms**.
4. Touch **High glucose threshold**.
5. Scroll to the mg/dL you want the ADM to alert you of a high blood glucose reading and touch **Confirm**.
6. Touch **Snooze time**.
7. Scroll to the time you want the ADM to wait to again alert you of a high blood glucose reading and touch **Confirm**.

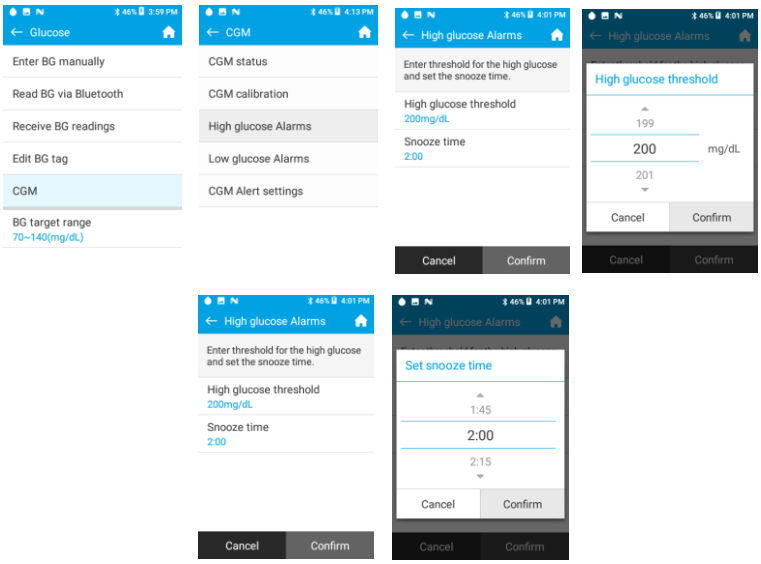
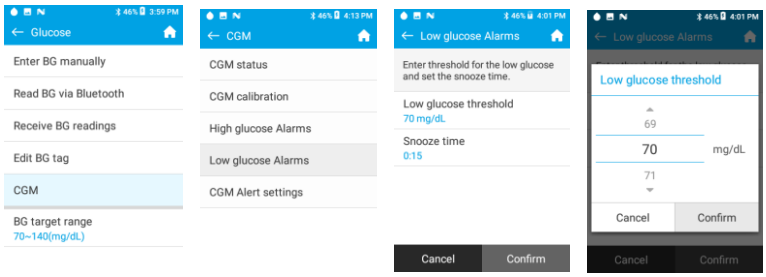


Figure 4-8 - High Glucose Alarms

4.3.1.4.3 Low glucose Alarms

1. Touch the Glucose icon on the Home screen.
2. Touch **CGM**.
3. Touch **Low glucose Alarms**.
4. Touch **High glucose threshold**.
5. Scroll to the mg/dL you want the ADM to alert you of a high blood glucose reading and touch **Confirm**.
6. Touch **Snooze time**.
7. Scroll to the time you want the ADM to wait to again alert you of a high blood glucose reading and touch **Confirm**.



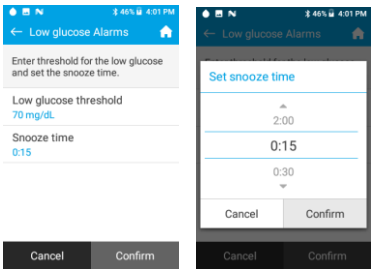


Figure 4-9 - Low Glucose Alarms

4.3.1.4.4 CGM Alert settings

4.3.1.4.4.1 SG rise rate Alert

1. Touch the Glucose icon on the Home screen.
2. Touch **CGM**.
3. Touch **CGM Alert settings**.
4. Touch **SG rise rate Alert**.
5. Touch the **SG rise rate** you prefer.

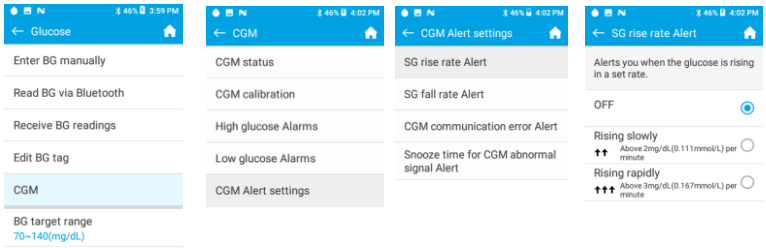


Figure 4-10 - SG Rise Rate

4.3.1.4.4.2 SG fall rate Alert

1. Touch the Glucose icon on the Home screen.
2. Touch **CGM**.
3. Touch **CGM Alert settings**.
4. Touch **SG fall rate Alert**.
5. Touch the **SG fall rate** you prefer.

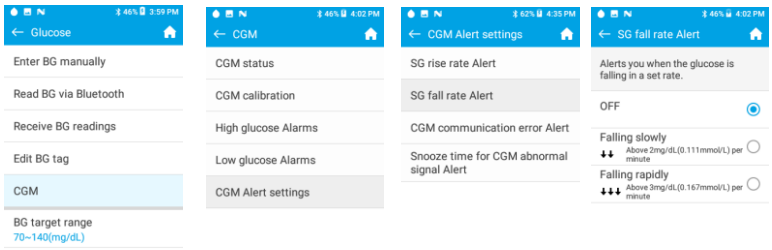


Figure 4-11 - SG Fall Rate

4.3.1.4.4.3 CGM communication error Alert

1. Touch the Glucose icon on the Home screen.
2. Touch **CGM**.
3. Touch **CGM Alert settings**.
4. Touch **CGM communication error Alert**.
5. Touch the repeated time you prefer to be alerted for **communication errors.**

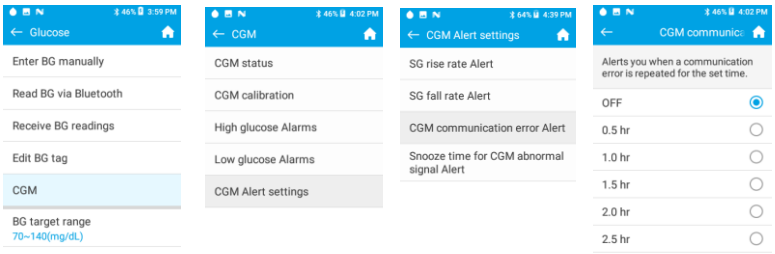


Figure 4-12 - CGM Communication Error Alert

4.3.1.4.4.4 Snooze time for CGM abnormal signal Alert

1. Touch the Glucose icon on the Home screen.
2. Touch **CGM**.
3. Touch **CGM Alert settings**.
4. Touch **Snooze time for CGM abnormal signal Alert**
5. Touch the repeated time you prefer to be alerted for **abnormal signal alerts.**

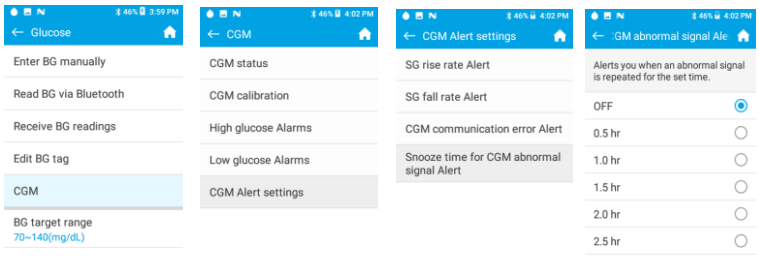


Figure 4-13 - CGM Abnormal Signal Alert

4.3.1.5 BG target range

1. Touch the Glucose icon on the Home screen.
2. Touch **BG target range.**
3. Touch **Lower limit**, scroll to the new value and touch **Confirm**.
4. Touch **Upper limit**, scroll to the new value and touch **Confirm**.
5. The BG target range now contains the updated range.

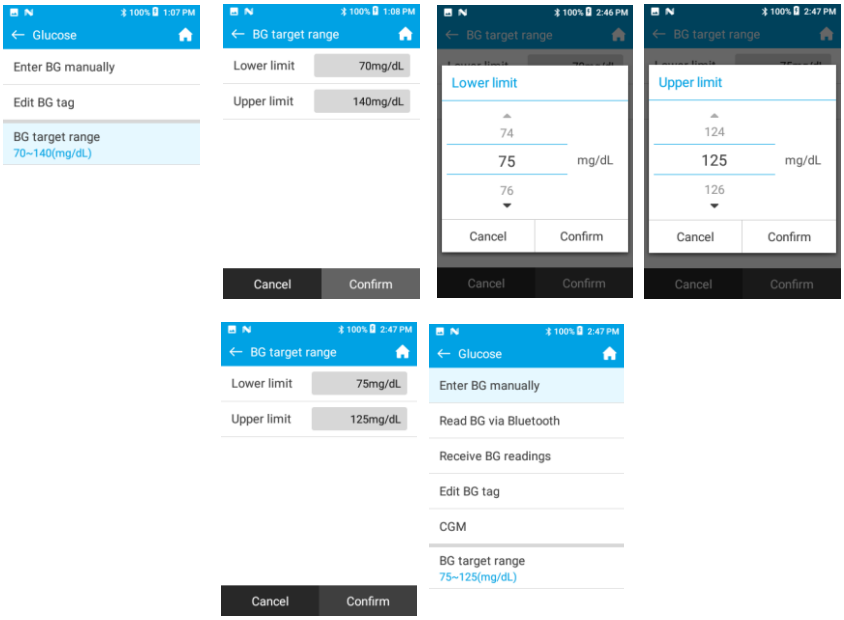


Figure 4-4-14 - BG target range

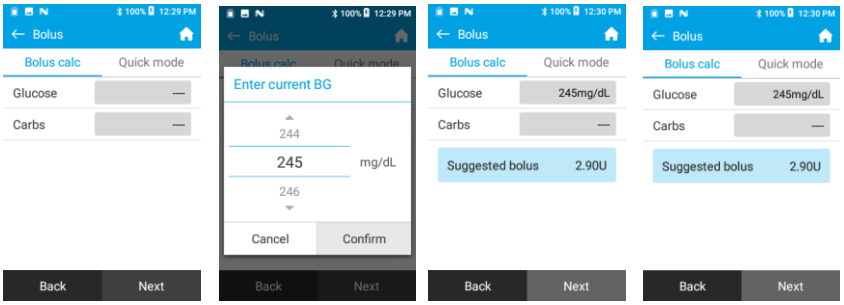
4.3.2 The Bolus Screens

The bolus delivery is set by you for the expected rise in blood glucose from eating carbohydrate or to lower blood glucose that is above your target range. Programming a bolus is equal to giving an injection in injection therapy.

The ADM has two means of delivering a bolus: **Bolus calculator** and **Quick mode.** A bolus in Bolus calculator can be programed by entering blood glucose alone to deliver a correction bolus or carbohydrate alone to deliver a carbohydrate bolus or blood glucose and carbohydrate to deliver a correction and carbohydrate bolus. A bolus in Quick mode can be programed by entering the amount of insulin you want to deliver or by using a Bolus preset, which is an amount you have previously set.

4.3.2.1 Correction Bolus

1. Touch the Bolus icon on the Home screen.
2. Touch **Bolus calc** to calculate a bolus.
3. Touch **Glucose** and scroll to enter your current glucose value.
4. Touch **Confirm.**
5. Suggested **bolus** is displayed, touch **Next.**
6. A screen showing **Glucose**, **Carbs** and **Bolus dose** is displayed, touch **Next**. (You may change the bolus amount on this screen.)
7. A screen allowing you to enter a **BG Reminder** is displayed.
8. A screen allowing you to **Extend** the bolus is displayed. (See page 28 for information on extended bolus.)
9. Touch Next.
10. Touch **Confirm.**
11. The **Start bolus** screen is displayed.
12. Touch **Yes.**
13. The Home screen displays the bolus as it delivers.



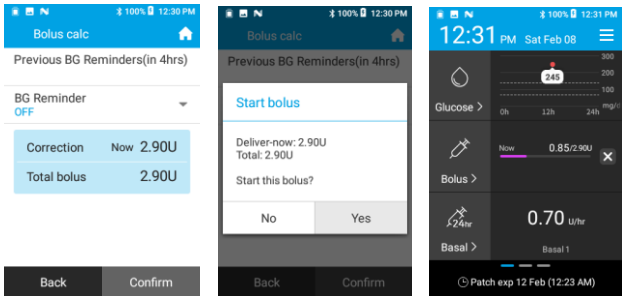


Figure 4-15 - Correction Bolus

4.3.2.2 Bolus calc with carbohydrate

14. Touch the Bolus icon on the Home screen.
15. Touch **Bolus calc** to calculate a bolus.
16. Touch **Glucose** and scroll to enter your current glucose value.
17. Touch **Confirm**.
18. Touch **Carbs** and scroll to enter the grams of carbohydrate you are going to eat.
19. Touch **Confirm**.
20. An information screen is displayed, touch **Yes**.
21. Suggested **bolus** is displayed, touch **Next.**
22. A screen showing **Glucose**, **Carbs** and **Bolus dose** is displayed, touch **Next**. (You may change the bolus amount on this screen.)
23. A screen allowing you to enter a **BG Reminder** is displayed.
24. A screen allowing you to **Extend** the bolus is displayed. A screen allowing you to **Extend** the bolus is displayed. (See page 28 for information on extended bolus.)
25. Touch Next.
26. Touch **Confirm.**
27. The **Start bolus** screen is displayed.
28. Touch **Yes.**
29. The Home screen displays the bolus as it delivers.

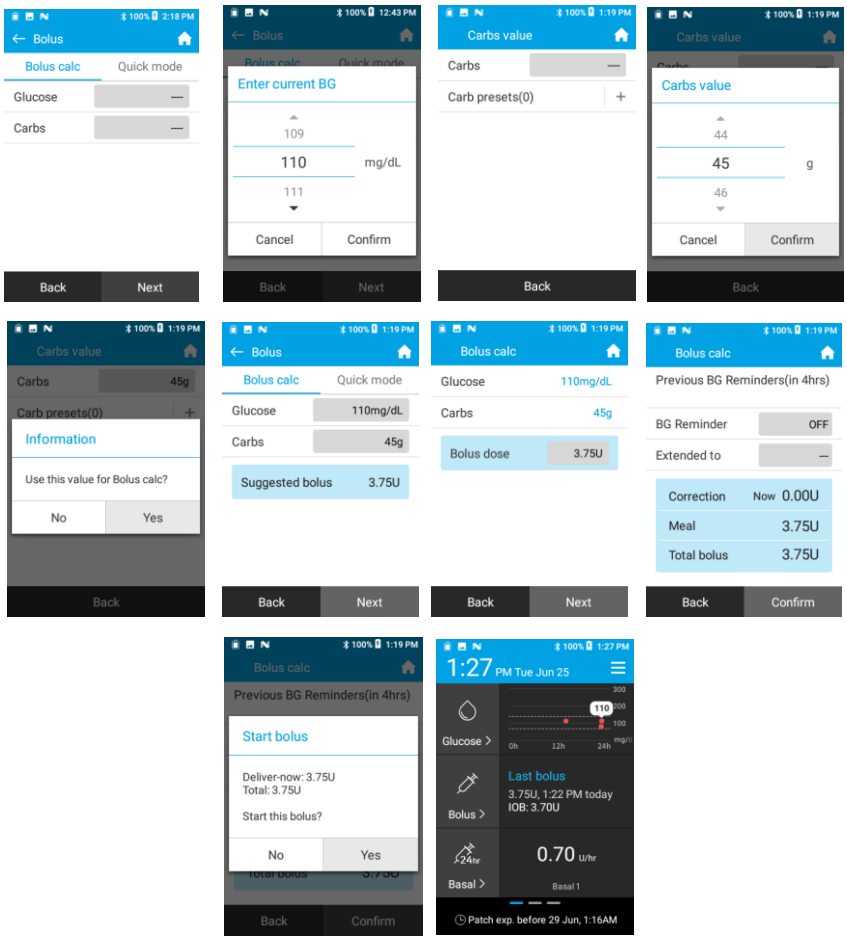
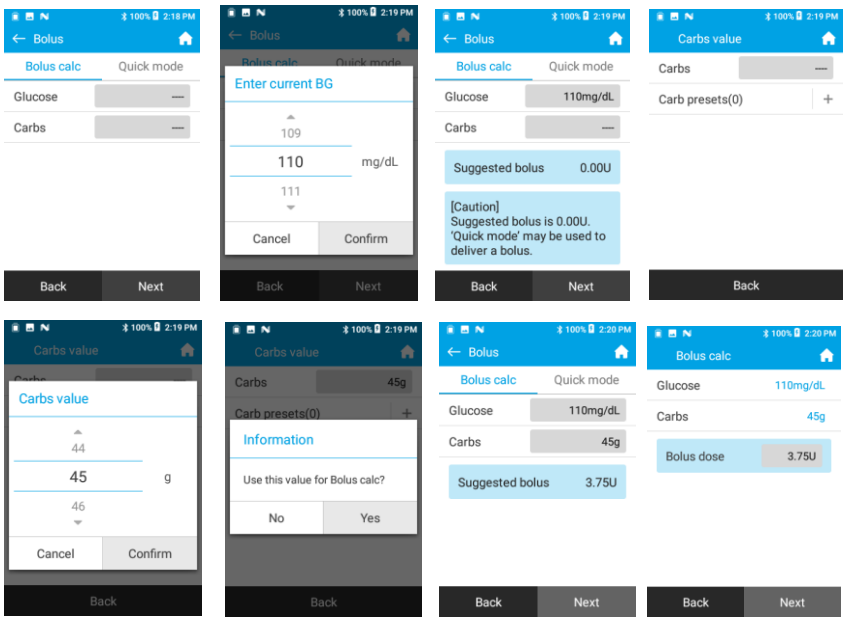


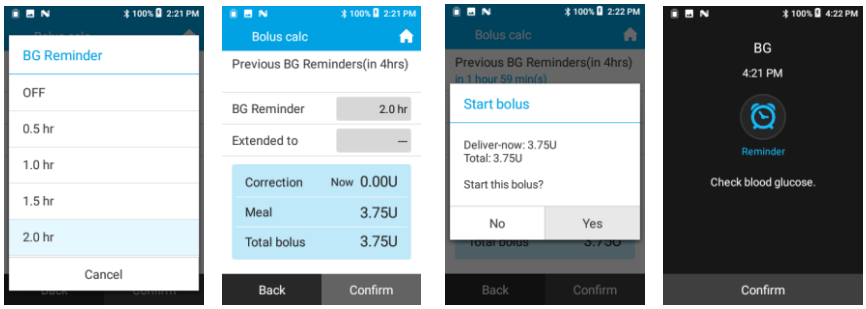
Figure 4-4-16 - Bolus calc with carbohydrate

4.3.2.3 Bolus calc with carbohydrate and BG Reminder

1. Touch the Bolus icon on the Home screen.
2. Touch **Bolus calc** to calculate a bolus.
3. Touch **Glucose** and scroll to enter your current glucose value.
4. Touch **Confirm**.
5. Touch **Carbs** to display the **Carbs value** screen.
6. Touch **Carbs** and scroll to enter the grams of carbohydrate you are going to eat.
7. Touch **Confirm**.

8. An information screen is displayed, touch **Yes**.
9. Suggested **bolus** is displayed, touch **Next.**
10. A screen showing **Glucose**, **Carbs** and **Bolus dose** is displayed. (You may change the bolus amount on this screen.)
11. Touch **Next.**
12. A screen allowing you to enter a **BG Reminder** is displayed. The default is **OFF**.
13. Touch **OFF** to scroll to the number of hours in which you want to be reminded. The reminder is set in 0.5-hour increments.
14. A screen allowing you to **Extend** the bolus is displayed. (See page 28 for information on extended bolus.)
15. Touch **Confirm.**
16. After the time set in the Reminder, the Reminder icon will appear on the screen and the ADM will emit the Reminder sound.





4.3.2.4 Bolus calc with carbohydrate and Extended bolus

17. Touch the Bolus icon on the Home screen.
18. Touch **Bolus calc** to calculate a bolus.
19. Touch **Glucose** and scroll to enter your current glucose value.
20. Touch **Confirm**.
21. Touch **Carbs** to display the **Carbs value** screen.
22. Touch **Carbs** and scroll to enter the grams of carbohydrate you are going to eat.
23. Touch **Confirm**.
24. An information screen is displayed, touch **Yes**.
25. Suggested **bolus** is displayed, touch **Next.**
26. A screen showing **Glucose**, **Carbs** and **Bolus dose** is displayed. (You may change the bolus amount on this screen.)
27. Touch **Next.**
28. A screen allowing you to enter a **BG Reminder** is displayed.
29. A screen allowing you to extend the bolus is displayed. To set an extended bolus, touch **Extend to** and scroll to the number of hours you wish to extend some or all of the bolus. (See page 28 for information on extended bolus.)
30. A screen showing you how much insulin will be delivered now and how much will be delivered later is displayed. This screen is 50% now and 50% later.
31. You may touch **Confirm** to deliver this amount or touch either **Deliver-now** or **Deliver-later** to change the ratio of now and later.
32. Touch **Confirm.**
33. The **Start bolus** screen is displayed.
34. Touch **Yes.**
35. The Home screen displays the both the **Deliver-now** and **Deliver-later** boluses as they deliver.

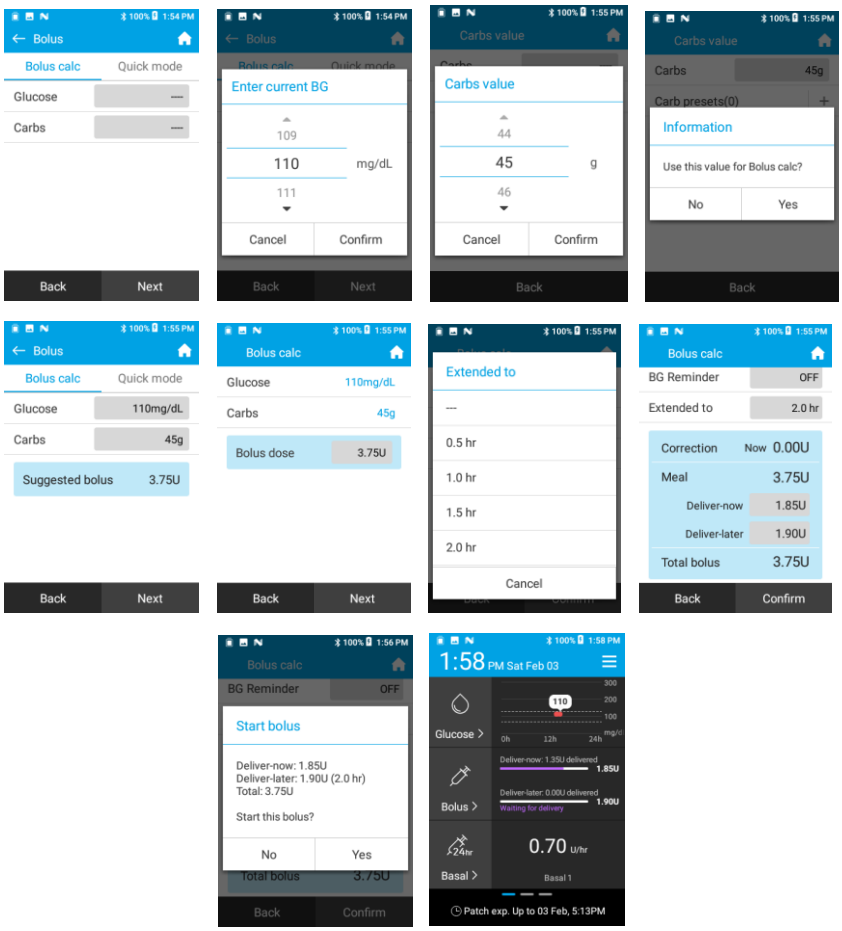


Figure 4-4-17 - Bolus calc with carbohydrate and Extended bolus

4.3.2.5 Bolus calc with Carb preset

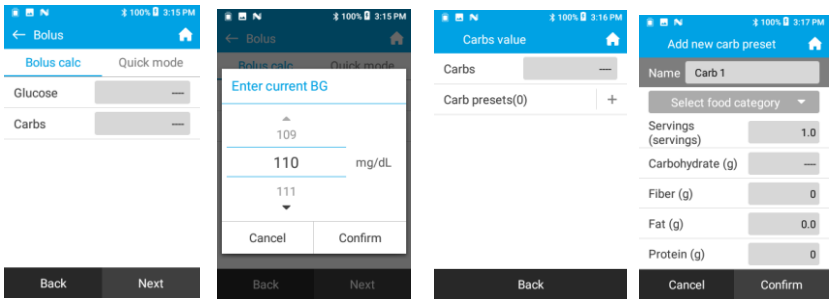
1. Touch the Bolus icon on the Home screen.
2. Touch **Bolus calc** to calculate a bolus.
3. Touch **Glucose** and scroll to enter your current glucose value.
4. Touch **Confirm**.
5. Touch **Carbs** to display the **Carbs value** screen.
6. Touch **Carb preset.**
7. Touch the plus sign + to enter a new Carb preset. (If you have previously entered a Carb

preset and want to use that, touch **Carb presets** to display your list.)

8. Add new carb preset is displayed.
9. Touch the **Name,** backspace and enter a name you will recognize for the food you are adding.
10. Touch **Done**.
11. Enter the **Carbohydrate (g)** of the food you are adding. (If you typically eat more than one serving of the food you are adding, change the **Servings** and **Carbohydrate** accordingly. You may also enter **Fiber**, **Fat** and **Protein** but these are not used by the bolus calculator.)
12. Touch **Confirm**.
13. **Carb presets** is displayed. Touch the option button to choose the food and touch **Confirm**.
14. An information screen is displayed, touch **Yes**.
15. An information screen is displayed, touch **Yes**.
16. A screen showing **Glucose**, **Carbs** and **Bolus dose** is displayed (You may change the bolus amount on this screen.)
17. Touch **Next**.
18. A screen allowing you to enter a **BG Reminder** is displayed.

36. A screen allowing you to **Extend** the bolus is displayed. (See page 28 for information on extended bolus.)

19. Touch Next.
20. Touch **Confirm.**
21. The **Start bolus** screen is displayed.
22. Touch **Yes.**
23. The Home screen displays the bolus as it delivers.



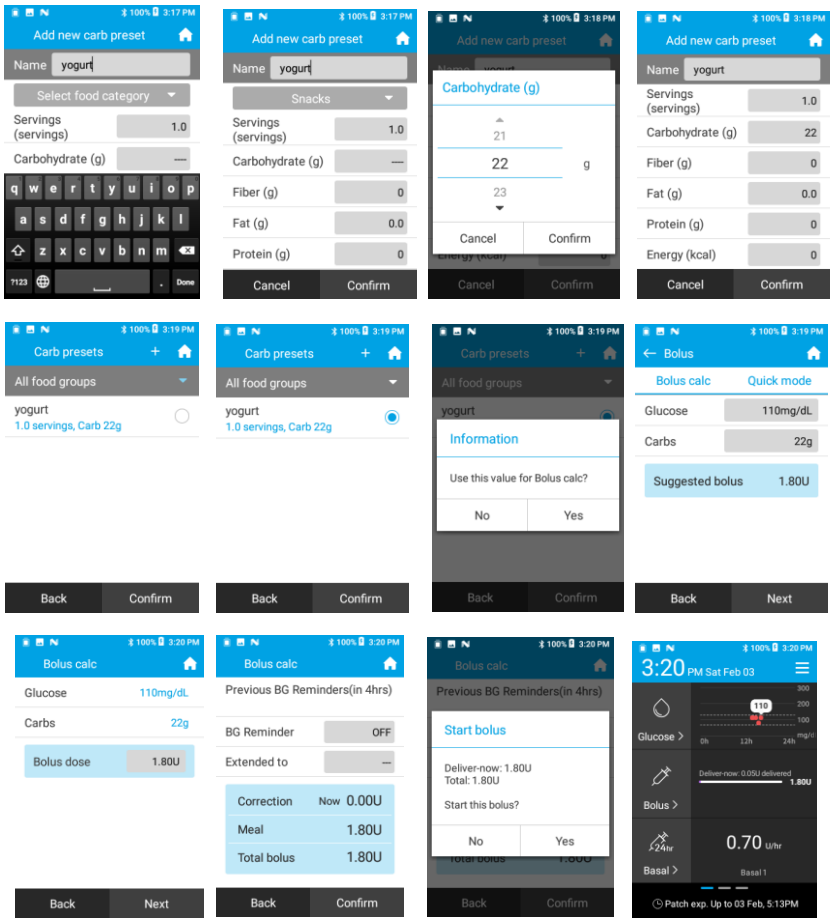


Figure 4-4-18 - Bolus calc with Carb preset

4.3.2.6 Quick Mode with Insulin

1. Touch the Bolus icon on the Home screen.
2. Touch **Quick mode** to enter the units of insulin you want to deliver.
3. Touch the value in **Insulin** and scroll to enter the units of insulin you want to deliver.
4. Touch Confirm.
5. The **Quick mode** screen is displayed with the number of units of insulin you want to deliver.
6. Touch **Next.**

7. A screen allowing you to enter a **BG Reminder** is displayed.

37. A screen allowing you to **Extend** the bolus is displayed. (See page 28 for information on extended bolus.)

8. Touch **Confirm**.

9. The **Start bolus** screen is displayed.

10. Touch **Yes**.

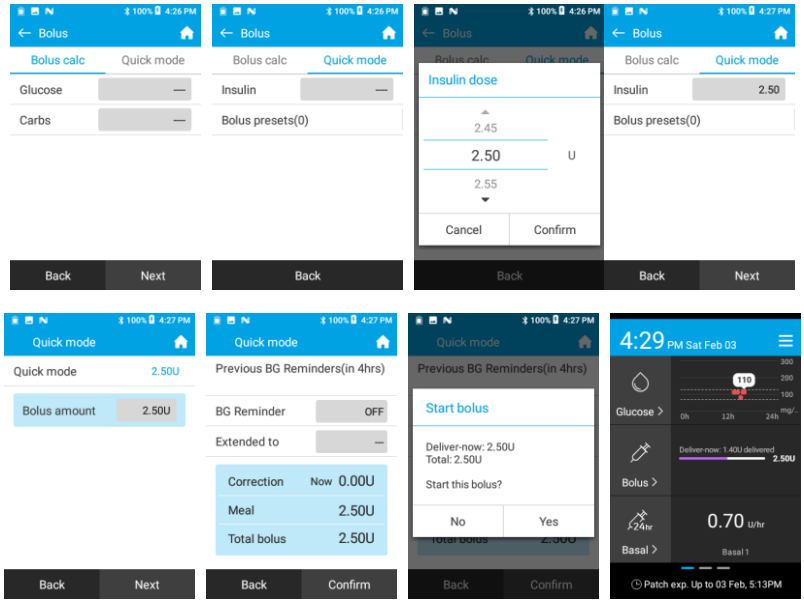


Figure 4-4-19 - Quick mode with insulin

4.3.2.7 Quick Mode with Bolus presets

4.3.2.7.1 Setting a Bolus preset

1. Touch the Bolus icon on the Home screen.

2. Touch **Quick Mode.**

3. Touch **Bolus presets.**

4. Touch **Add/Edit bolus presets.**

5. Touch **Add new**

6. Touch Insulin and scroll to the enter the number of units you want to deliver.

7. Touch **Confirm.**

8. To change the name of the Bolus preset, touch the caret next to name and choose the name from the dropdown.

9. Touch **Confirm**.

10. The Add new bolus preset screen is displayed, touch **Confirm**.

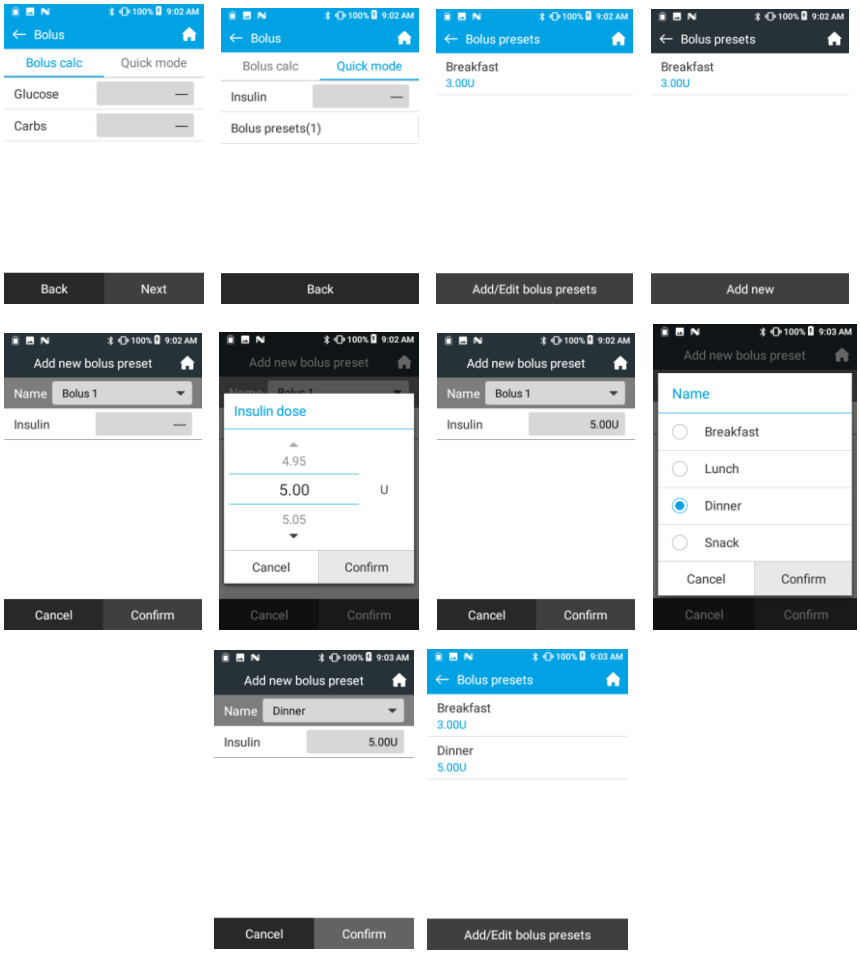


Figure 4-4-20 - Settings a bolus preset

4.3.2.7.2 Using a Bolus preset

1. Touch the Bolus icon on the Home screen.

2. Touch **Quick Mode.**

3. Touch **Bolus presets** to display the list of previously entered bolus presets.

4. Touch **Bolus presets** to display the list of previously entered bolus presets. If you have not set a Bolus preset, you may set it here.
5. Touch the **Bolus preset** you want to deliver, and touch Start.
6. Touch **Next**. The Bolus amount is displayed.
7. Touch **Next**.
8. A screen allowing you to enter a **BG Reminder** is displayed.
9. A screen allowing you to **Extend** the bolus is displayed. A screen allowing you to **Extend** the bolus is displayed. (See page 28 for information on extended bolus.)
10. Touch **Confirm**.
11. The **Start bolus** screen is displayed.
12. Touch **Yes**.

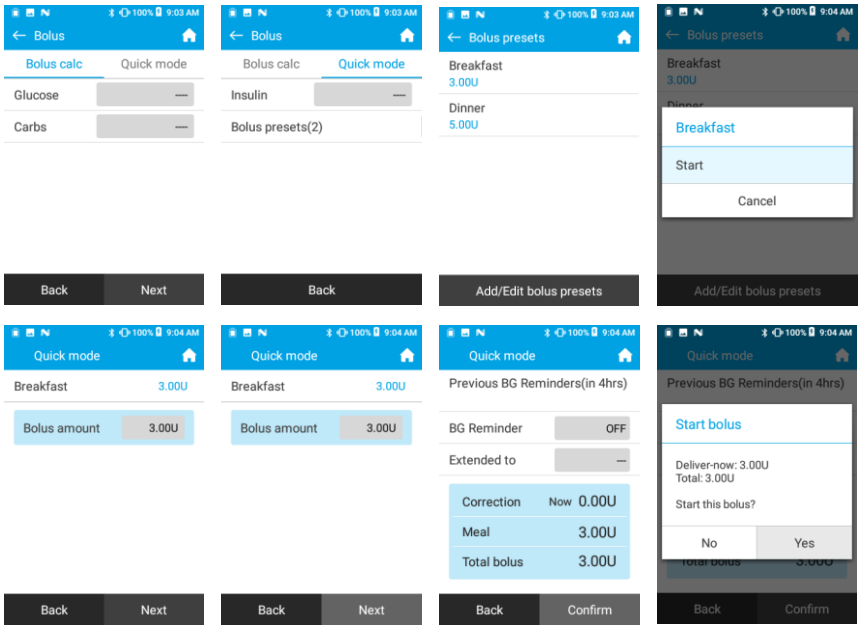


Figure 4-4-21 - Using a bolus preset

4.3.2.8 Cancel a Bolus

While a bolus is delivering, it can be canceled from the Home screen.

1. Touch the X icon ✕ on the Home screen.
2. Touch **Yes**.

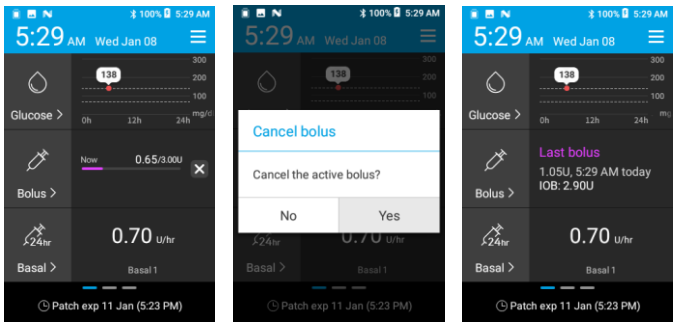


Figure 4-22 - Cancel a bolus

4.3.3 The Basal Screens

The Basal program is the function that sets insulin pump therapy apart from injection therapy because the ability to adjust the background infusion of insulin at different times of day and night allows you to closely simulate your metabolic need for insulin from the pancreas. Up to 8 basal programs can be added.

You already set a basal program in the Initial Settings section. From the Home screen Basal directory, you can edit an existing basal program, add additional segments to the current basal program, add a new basal program, change the name of a basal program, enable an inactive basal program, and cancel an existing basal program.

In order to edit or add segments to an existing basal program, you must first suspend insulin delivery. (See page 84 for instructions on suspending insulin delivery.)

4.3.4 The Temporary Basal Screens

The Temp basal allows you to further adjust your basal program for situations that require more or less background insulin for a period of time. Examples of these situations include exercise that may lower blood glucose, and medication or sick days that may raise blood glucose.

From the Home screen Basal directory, you can enter a one-time Temp basal program, add a new Temp basal program, edit an existing Temp basal program, change the name of a Temp basal program, enable an inactive Temp basal program, and cancel an existing Temp basal program

4.3.4.1 Add a one-time Temp basal program

1. Touch the Basal icon on the Home screen.
2. Touch **Enter Manually** under **Temp basal**.
3. **Temp basal programs** is displayed.
4. Touch **Enter manually**
5. Touch the U/hr (unit per hour) or % (percent) to select your preferred method of calculating a Temp basal.

6. Touch the Adjusted rate and scroll to the rate you want to enter.
7. Touch **Confirm.**
8. Touch the **Duration** and enter the number of hours for the Temp rate to be active.
9. Your Temp basal is displayed with the U/hr, duration and the ability to start the Temp rate
10. To start the Temp rate, touch **Yes.**
11. The basal screen is displayed with a bullet • next to the active rate.

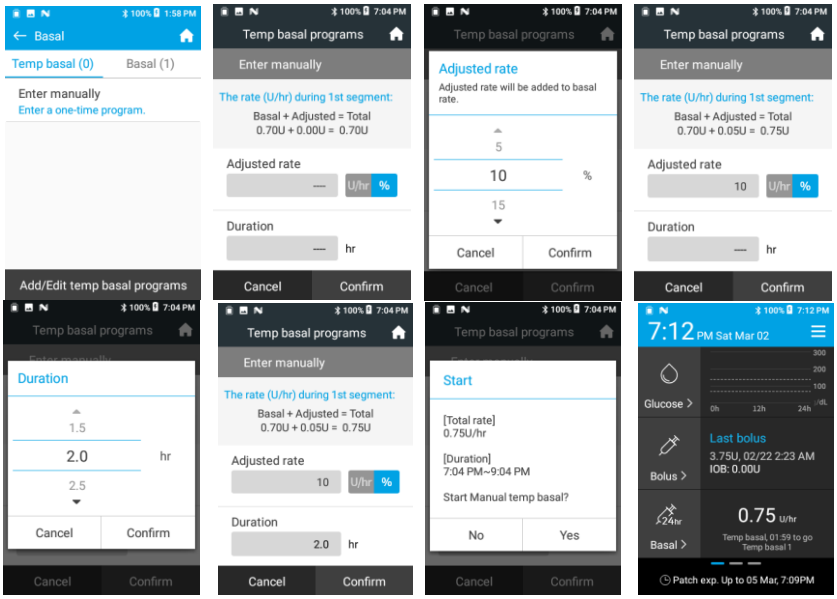


Figure 4-4-23 - Add one-time Temporary Basal program

4.3.4.2 Add a New Temp basal program

1. Touch the Basal icon on the Home screen.
2. **Temp basal programs** is displayed.
3. Touch **Add new** at the bottom.
4. Touch the U/hr (unit per hour) or % (percent) to select your preferred method of calculating a Temp basal.
5. Touch **Adjusted rate** and scroll to the rate you want to enter.
6. Touch **Confirm.**
7. Touch **Duration** and enter the number of hours you want the Temp rate to be active.
8. Touch **Confirm.**

9. Your Temp basal is displayed with rate and duration.
10. Touch **Confirm.**
11. To start the Temp rate, touch **Yes.**
12. The basal screen is displayed with a bullet • next to the active rate.

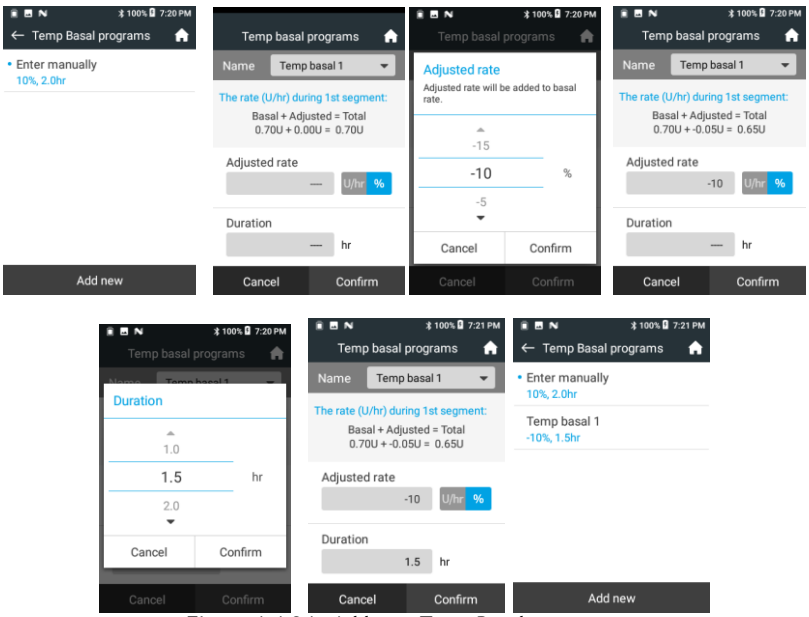


Figure 4-4-24 - Add new Temp Basal program

4.3.4.3 Edit an existing Temp basal program

1. Touch the Basal icon on the Home screen.
2. Touch **Add/Edit** temp basal programs at the bottom of the screen.
3. Touch **Add New** to display the Temp basal setting screen.
4. Touch the U/hr (unit per hour) or % (percent) to select your preferred method of calculating a Temp basal.
5. Touch **Adjusted rate** and scroll to the rate you want to enter.
6. Touch **Confirm.**
7. Touch **Duration** and enter the number of hours for the Temp rate to be active.
8. Touch **Confirm.**
9. Your Temp basal is displayed with the rate and the duration and the ability to start the Temp rate.
10. To start the Temp rate, touch **Yes.**

11. The basal screen is displayed with a bullet • next to the active rate.

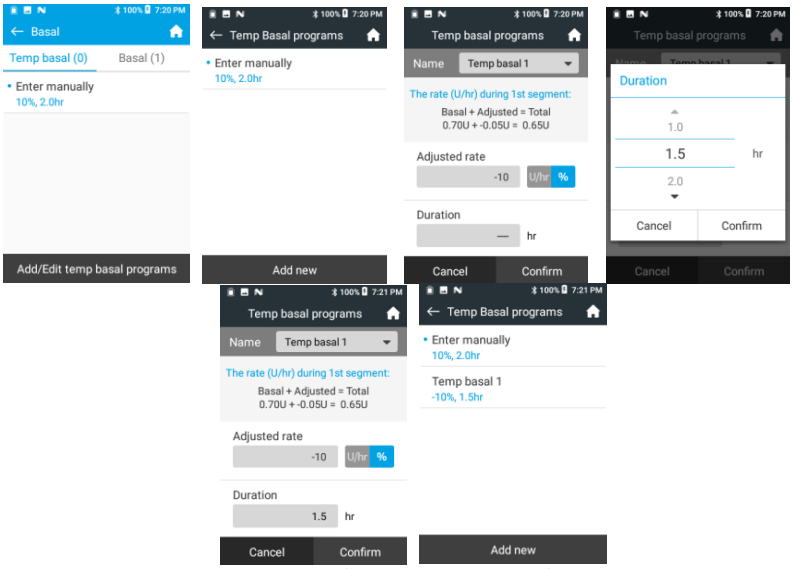
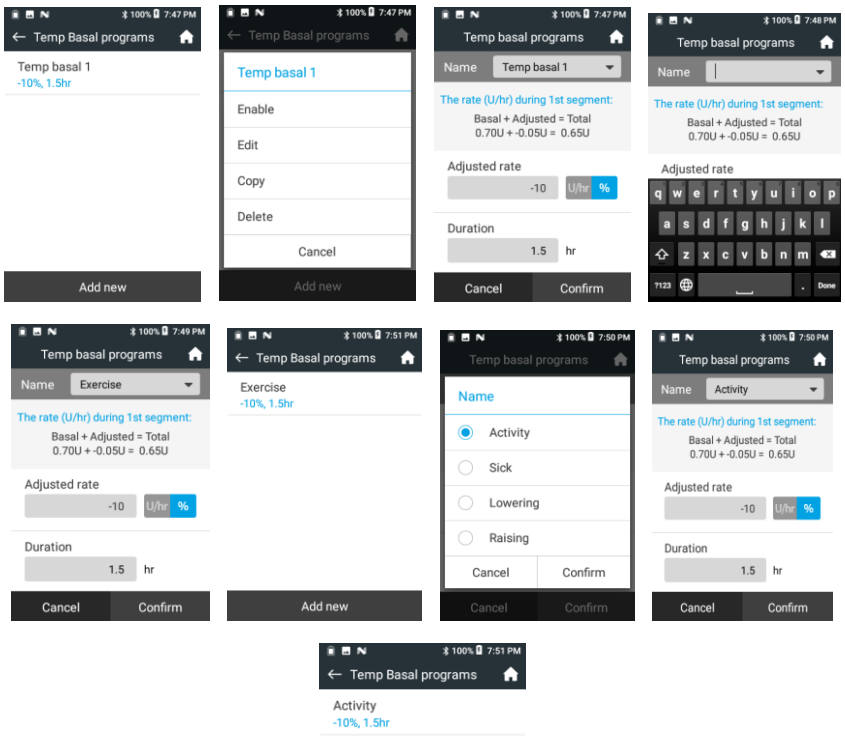


Figure 4-4-25 – Edit existing Temp Basal program

4.3.4.4 Change the name of a Temp basal program

1. Touch the Basal icon on the Home screen.
2. Touch the Temp basal program you want to rename.
3. Touch **Edit** at the bottom of the screen to display the Temp basal program.
4. Touch the **Name** of the program, backspace to erase the current name and type in the new name. (Alternatively, use the dropdown menu to give the program a new name.)
5. Touch **Done.**
6. Your basal program with the name changes you made is displayed.
7. Touch **Confirm** to save the changes.



Add new

Figure 4-4-26 - Change name of Temp Basal program

> **NOTE:** Alternatively, you can change the name of the Temp basal program while making other changes to that program.

4.3.4.5 Enable an inactive Temp basal program

1. Touch the Basal icon on the Home screen.
2. Touch the inactive Temp Basal program you want to enable.
3. Touch **Enable** to enable that Basal program.
4. A screen asking you if you ware sure you want to make this change is displayed.

5. Touch **Yes** to begin using this Basal program.

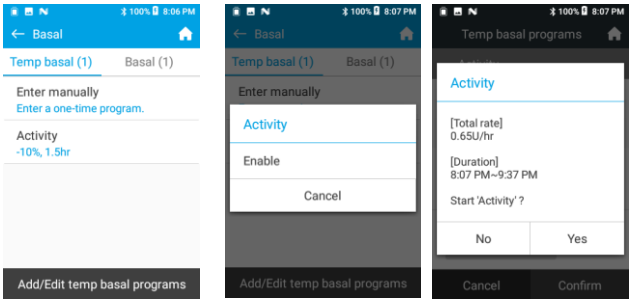


Figure 4-4-27 - Enable inactive Temp Basal program

4.3.4.6 Cancel an active Temp basal program

1. Touch the Basal icon on the Home screen.
2. Touch the Temp Basal program you want to cancel.
3. Touch **Cancel temp basal**.
4. A screen with the Temp basal information is displayed questioning if you want to cancel.
5. Touch **Yes**.

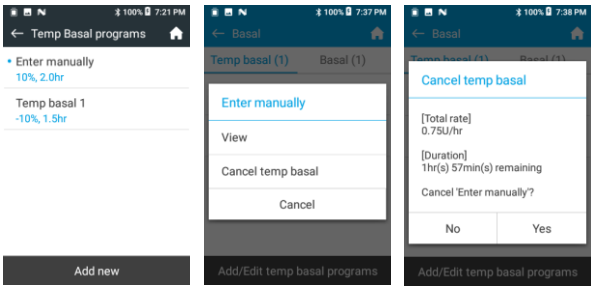


Figure 4-4-28 - Cancel active Temp Basal program

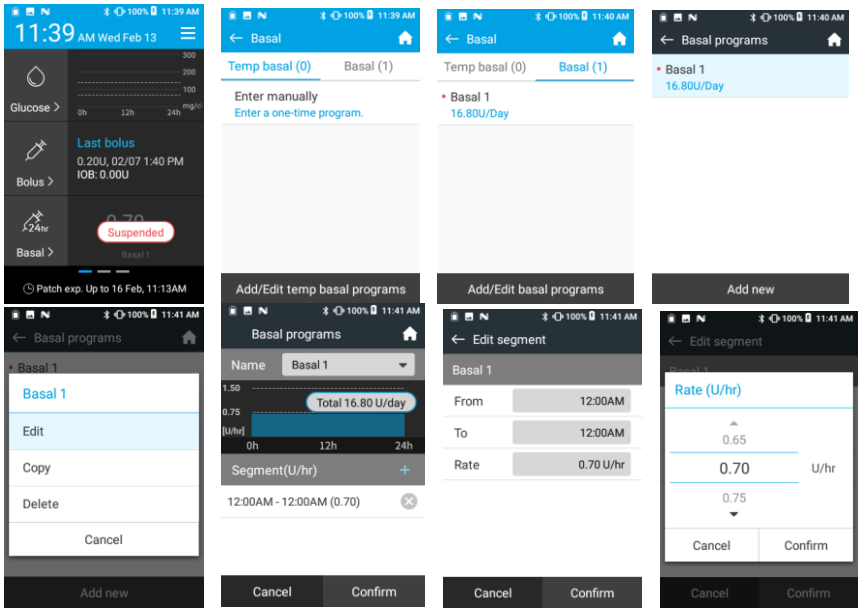
> **Did you know:** The advantage of choosing a percent (%) for a Temp basal is so if you basal rate changes while the Temp basal is active, the Temp basal delivery amount changes too. Choosing units per hour (U/hr) delivers the chosen amount for the duration of the Temp basal.

4.3.5 The Basal Screens

4.3.5.1 Edit an existing Basal program

To edit an existing basal program, you must first suspend insulin delivery. (See page 84 for instructions on suspending insulin delivery.)

1. Touch the Basal icon on the Home screen.
2. Touch the **Basal** option.
3. Touch **Add/Edit temp basal programs** to display the Basal programs screen.
4. Touch the active program with a bullet • next to it to display your options.
5. To edit one of the segments, touch that segment to display the times the segment starts and stops and the units per hour.
6. Touch the portion of the segment information you want to edit and scroll to the desired changes.
7. Touch **Confirm** to return to the Basal setting screen.
8. Your basal profile with the changes you made is displayed.
9. Touch **Confirm** to save the changes.



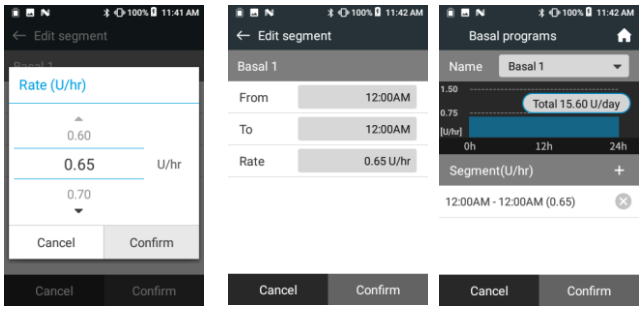


Figure 4-4-29 - Edit existing Basal program

WARNING: Remember to resume insulin delivery after editing an existing basal program. The ADM will alert you when the time you set to suspend is up; however, the ADM will NOT restart without you resuming delivery.

4.3.5.2 Add additional segments to the current Basal program

To add segments to an existing basal program, you must first suspend insulin delivery. (See page 84 for instructions on suspending insulin delivery.)

1. Touch the Basal icon on the Home screen.
2. Touch the **Basal** option.
3. Touch **Add/Edit temp basal programs** to display the Basal programs screen.
4. Touch the active program with a bullet • next to it to display your options.
5. To edit one of the segments, touch that segment to display the times the segment starts and stops and the units per hour.
6. Touch the plus sign icon + next to the word Segment (U/hr).
7. Scroll and touch the times you want the segment to start, to stop and the U/hr.
8. Touch **Confirm.**
9. Your basal profile with the changes you made is displayed.
10. Touch **Confirm** to save the changes.

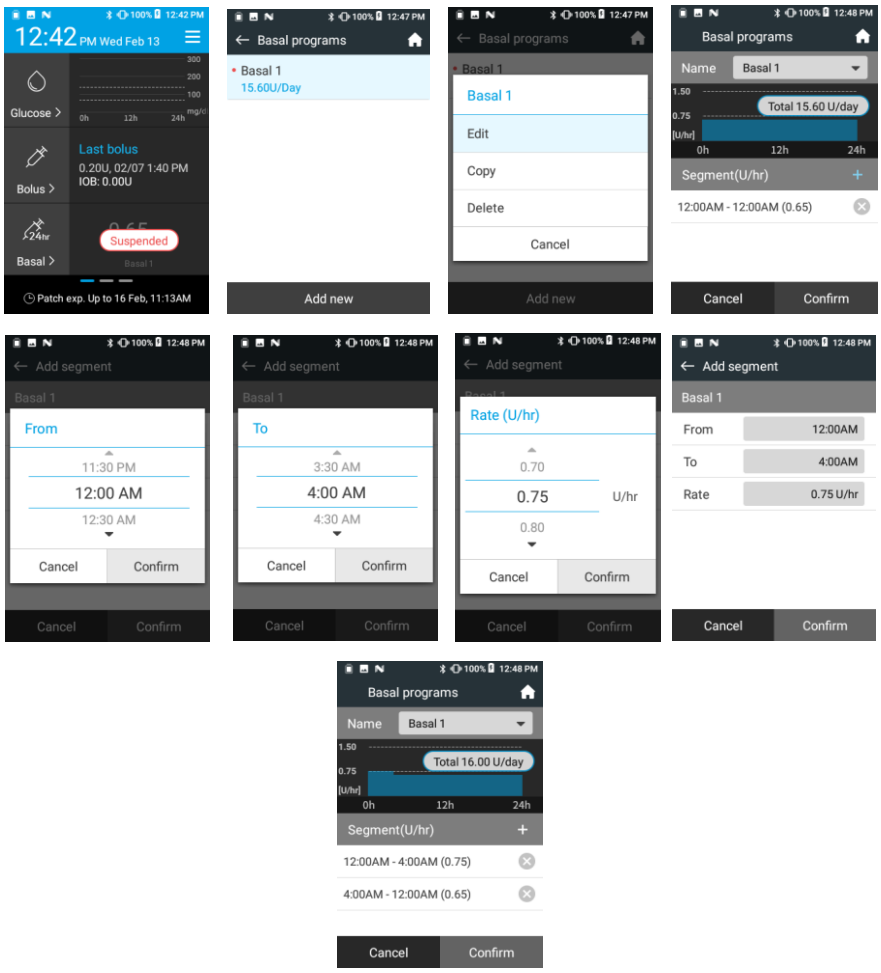


Figure 4-4-30 - Add segments to existing Basal program

Caution: Remember to resume insulin delivery after editing an existing basal program

4.3.5.3 Add a new Basal program

To add a new basal program, you must first suspend insulin delivery. (See page 84 for instructions on suspending insulin delivery.)

Touch the Basal icon on the Home screen.

1. Touch the **Basal** option.

2. Touch **Add/Edit temp basal programs** to display the Basal programs screen.
3. Touch **Add new**.
4. Scroll and touch U/hr for the new basal program.
5. Touch **Confirm.**
6. Your basal profile with the changes you made is displayed.
7. Touch **Confirm** to save the changes.
8. Rate U/hr is displayed. Touch the rate and scroll to the rate you want to enter.
9. Touch **Confirm.**
10. Your new basal profile is displayed.
11. Touch **Confirm**.

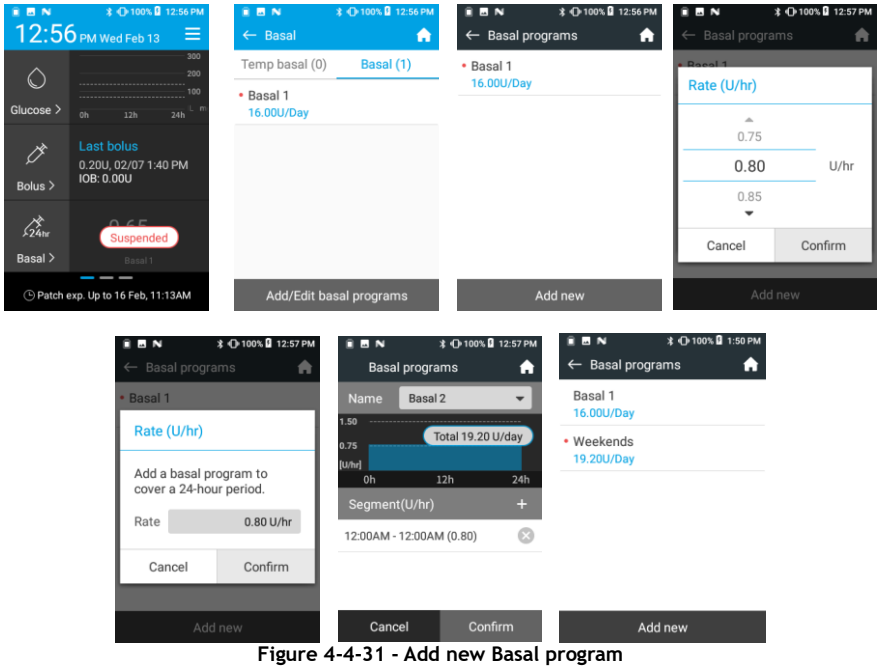


Figure 4-4-31 - Add new Basal program

NOTE: Alternatively, you can add a new program by copying a current program and make changes to that program.

4.3.5.4 Change the name of a Basal program

To change the name of an existing basal program, you must first suspend insulin delivery. (See page