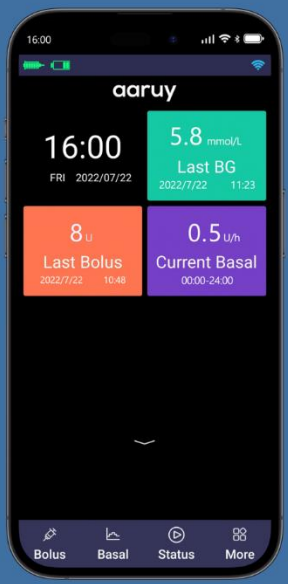
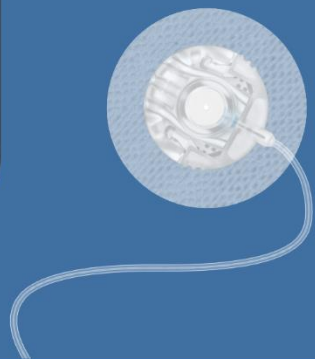
aaruy®

Insulin Pump System

Instruction Manual

Product Name: Insulin Pump
Product Model: AR-B200A AR-B200B
AR-B200C AR-B200D
Matching Insulin Pump Controller Model: AR-AN100
AR-iOS100





Consumables of AR-B200 Series

Infusion Set

AR-I06B, AR-I09B

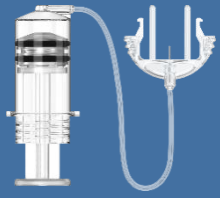
AR-I0608B, AR-I0908B

AR-I06C, AR-I09C

AR-I06015A, AR-I06060A
AR-I09015A, AR-I09060A

Reservoir

AR-C3006B

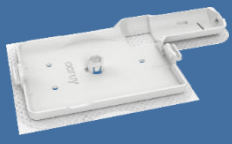


AR-C3012C

AR-C30A

Baseplate

AR-D30A (Portable)



AR-D30B (Paste Type)

AR-B200A/AR-B200B insulin pump with built-in catheter (Paste Type)

Paste Type Portable

AR-B200C/AR-B200D insulin pump with external catheter

Product Composition and Common Accessories of Insulin Pump System:

Insulin Pump: AR-B200A/AR-B200B/AR-B200C/AR-B200D

Insulin Pump Controller: AR-AN100 (applicable to Android system)

AR- iOS100 (applicable to iOS system)

Pump Battery: AR-BATB200

Pump Battery Charger : AR-ADP5V020

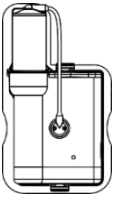
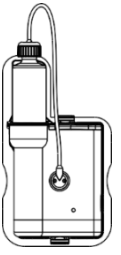
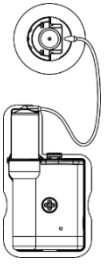
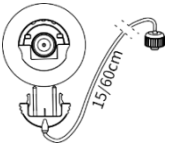
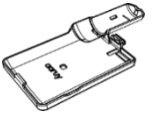
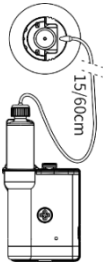
Functional Discrepancy of Insulin Pump:

Model	Type of Suitable Infusion Sets	Function
AR-B200A	Type A, Type B, Type C	Full function
AR-B200B	Type A, Type B, Type C	Functions except extended bolus and bolus guide
AR-B200C	Type A, Type C	Full function
AR-B200D	Type A, Type C	Functions except extended bolus and bolus guide

!CAUTION Make sure the insulin pump and reservoir are reliably fixed with the baseplate when in use.

Please be sure to use the reservoir and infusion set specified by our company. We will try our best to address any personal injury or pump failure inflicted by reservoirs or infusion sets made by other manufacturers, but we will not assume any legal liability arising therefrom.

Matching Consumables of Insulin Pump System:

Reservoir	Infusion Set	Baseplate	Assembly
Insulin Pump AR-B200A, AR-B200B			
 AR-C3006B	 AR-I06B, AR-I09B	 AR-D30B	
 AR-C30A	 AR-I0608B, AR-I0908B	 AR-D30B	
Insulin Pump AR-B200A, AR-B200B, AR-B200C, AR-B200D			
 AR-C3012C	 AR-I06C, AR-I09C	 AR-D30B	
 AR-C30A	 AR-I06015A, AR-I06060A AR-I09015A, AR-I09060A	 AR-D30A	

Important Safety Information Related to Insulin Pump

Do not immerse the pump in water!

The degree of protection provided by enclosures of the insulin pump is IP56, water damage won't occur if your pump is splashed or briefly dunked, you should avoid immersing your insulin pump in water. If you are bathing, swimming, or participating in other water activities, the delivery must be suspended and the pump must be removed. Only resume after you are out of water.

If you unintentionally immerse the pump in water, please remove the battery immediately, place it in a dry, ventilated place, then wipe it dry with a clean, soft towel. Install the battery after a period and perform self-test from genaral settings of the controller to confirm whether the pump is still working properly. If there is water in the pump or any abnormality in the pump function, please check your blood glucose (BG) and correct the hyperglycemia with other insulin delivery mode (if necessary). Symptoms of hyperglycemia include fatigue, excessive thirst, and nausea. If you feel that your BG reading is high or low, or if you have any questions about your condition, please contact healthcare professional.

Electrostatic Discharge (ESD)!

The insulin pump system can withstand normal levels of ESD, but excessively high levels of ESD may cause the pump software to reset, and the pump may stop infusing. Since ESD is more likely to be generated in a dry environment, using the pump in over-drying environment shall be avoided.

Contents

1 Introduction

Thank you for trusting aaruy insulin pump system to better control your diabetes. Your life quality will surely be enhanced with our product.

The aim of the instruction manual is to help you understand the insulin pump therapy and operation of aaruy insulin pump. We strongly suggest you to work closely with medical professionals to start insulin pump therapy safely and flawlessly.

1.1 How to use the manual

We suggest receiving trainings from doctors or other medical professionals before reading the manual.

Please read this manual carefully in order of the chapters. The text introduces the method of use of two insulin pump controller APPs: AR-AN100 and AR-iOS100. For the meaning of terms in the manual, please refer to *Appendix C.1 Glossary*.

Refer to the content for detailed information of each operation.

Please contact customer service for any support.

!CAUTION And the manual sets an example of the display screen which may be slightly different from the actual one in the pump controller.

1.2 Indications for use

The product is designed for continuous subcutaneous insulin delivery in patients with diabetes and is suitable for diabetics who require insulin pump therapy.

1.3 Contraindications

We do not recommend insulin pump therapy to patients who are unwilling or unable to have blood glucose tests at least four times a day and keep in touch with their doctor.

Successful insulin pump therapy requires good vision and hearing abilities to recognize pump signals and alarms.

1.4 Warnings

- Choose suitable short-/rapid-acting U100-insulin under the direction of doctors and obtain the active insulin time of the selected insulin from the doctor.
- Acquire the suitable delivery protocol from the doctor.
- Adjust the amount of insulin delivery according to your diet with the doctor's advice.
- If you choose to use the bolus guide to calculate the required bolus, obtain

your target blood glucose range (hereinafter called the 'target BG range'), insulin sensitivity, and carbohydrates ratio (hereinafter called the 'carbs ratio') from your doctor first.

- The first setup and operation of the insulin pump system must be performed under the guidance of a doctor or medical professional.

- The insulin pump system is intended only for insulin delivery and cannot be used for the delivery of other drugs or blood products.

- Make sure to use the reservoir and infusion set specified by our company. We will try our best to address any personal injury or pump failure inflicted by reservoirs or infusion sets made by other manufacturers, but we will not assume any legal liability arising therefrom.

1.5 Precautions

- Although there are several kinds of safety alarm conditions for the insulin pump, it cannot detect leakage in the infusion set, detachment of the soft cannula, or failure of insulin. Thus, the BG must be checked at least four times a day. If the BG exceeds the target range, check the insulin pump and infusion set to ensure that necessary dose of insulin is delivered.

- Avoid delivery at sites that may be stimulated by clothing or accessories, undergo strenuous stretching and movement frequently.

- The degree of protection provided by enclosures of the insulin pump is IP56, water damage won't occur if your pump is splashed or briefly dunked, you should avoid immersing your insulin pump in water. If you are bathing, swimming, or participating in other water activities, the pump must be removed.

- To ensure signal transmission, the distance between the insulin pump and the phone with insulin pump controller APP should be no more than two meters.

- It is forbidden to expose the insulin pump to an MRI device or other devices that will generate a strong magnetic field. The strong magnetic field can damage the pump motor and affect insulin delivery, which may lead to overinfusion and severe hypoglycemia.

- The pump must be removed and placed outdoors with the the phone with insulin pump controller APP during X-rays, CT scanning, MRI, or other radiological examinations.

- Excessive ESD may reset the pump's software, causing the delivery to stop. Please pay attention not to use this product in an environment with

humidity lower than 10 %.

- Insulin will freeze at around 0℃ and spoil at high temperatures, so when you go outside in cold weather, the insulin pump needs to be covered with warm clothing. In a warmer environment, measures must be taken to cool the pump and insulin.
- When using the pump, make sure to let the insulin pump and reservoir reliably fixed with the baseplate.
- One insulin pump controller can only be connected to one insulin pump at a time.
- When the insulin pump controller is disconnected from the insulin pump, the insulin pump continues to execute the last command sent by the insulin pump controller before the disconnection. For example, the insulin pump is in the basal/suspend/stop status when disconnected, the insulin pump is still in basal/suspend/stop status after disconnected; For example, the insulin pump is delivering bolus when disconnected, the insulin pump will still deliver bolus after disconnected, and then running basal when bolus is done.
- Keep the insulin pump and the phone with insulin pump controller APP well. Do not disclose the serial number of the insulin pump to others. If necessary, enable the password function of the insulin pump controller APP.
- If any unset bolus is found, stop the delivery immediately.
- If it is suspected that insulin pump controller parameters have been accidentally changed, monitor your BG, consult your doctor and set or change your insulin pump controller APP password
- If symptoms of severe hypoglycemia or diabetic ketoacidosis occur, check the settings of the parameters of the insulin pump controller and the infusion set, and consult your doctor for appropriate infusion specification.
- The insulin pump controller and the insulin pump transmit signals to each other via Bluetooth. Please make sure that the Bluetooth of the mobile phone is turned on. In addition, the location information also needs to be turned on when the insulin pump controller is applied to the Android system.
- This product adopts a private Bluetooth protocol and encrypts the transmitted data, among which the Bluetooth core protocol conforms to Bluetooth Core Specification V 5.0.
- The Bluetooth version of the mobile phone installed with the insulin pump controller APP must be 4.2 or above.
- Mobile phone hardware requirements for insulin pump controller APP:

CPU: Dual-Core or above.
Disk space: 1 GB or above.
RAM: 1 GB or above.
Network: Wide Area Network (WAN).

- Software requirements for the insulin pump controller APP:

  Android system version must be 11 or above;

- iOS system version must be 15.0 or above.

- The reminder signal/vibration of the insulin pump controller APP depends on the sound mode set in the mobile phone, so please set the phone to the ringtone/vibration mode to ensure the identification of the reminders and alarms.
- In order to identify the reminders and alarms of the insulin pump controller APP in time, the notification permission of the insulin pump controller needs to be enabled. Detailed setting method: On the mobile phone setting interface, click the "Notification" option, select "AR-B200" and allow notifications.
- Ensure that the mobile phone is set to the correct date and time. Only if you set the correct date and time can the basal be accurately delivered and the history be correct.
- Network connection is needed to log in to the APP, after the user enter the authorized mobile number, the verification code will be received. The verification code can only be obtained when connected to the Internet.

  Mobile number authorization and verification code delivery are conducted through the server, which communicates with the client portal through the HTTPS protocol. The server can process 1,500 user requests per minute. If you do not receive the verification code, please try again after 1 minute.

- A new password (face recognition/ fingerprint/number) can be set for the APP in the mobile phone's system settings. Users must enter their password every time they open the APP.
- The insulin pump provides important data for this product. When the APP fails or encounters errors, it will automatically restart and connect to the insulin pump. Upon the successful connection, the insulin pump will deliver the relevant information and status to the APP before the APP returns to the previous state.
- When the APP is running, it will consume no more than 250MB of the mobile phone's CPU capacity.
- Usage of this APP will not conflict with other APPs, such as Tik Tok, Netfile, Youtube, and Twitter.

1.6 Emergency kit

You should always carry an emergency kit to ensure necessary supplies are readily available. The following items should be included in the emergency kit

(user's own):

- Supplies for measuring BG
- Supplies for measuring ketone body
- Spare reservoir, infusion set, and baseplate
- Insertion device
- Power adapter
- Charging cable of the pump battery
- Pump battery charger
- Spare pump battery
- Fast-acting glucose tablets or other food that can give a quick boost of carbohydrates
- Insulin injector and rapid-acting insulin
- A card with emergency contacts, phone number of the attending physician, and the amount of insulin delivered.

2 Product composition

2.1 Insulin pump

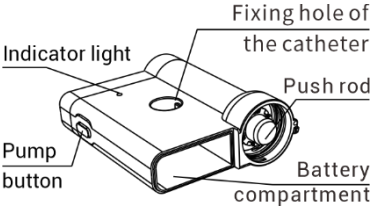


Figure 2.1 Diagram of insulin pump AR-B200A & AR-B200B

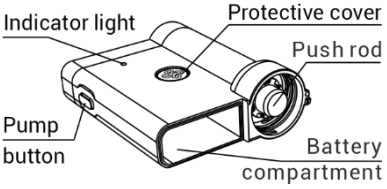


Figure 2.2 Diagram of insulin pump AR-B200C & AR-B200D

Pump button

The pump button can achieve the quick bolus and indicate the pump battery level.

(1) Quick bolus

When you need a bolus delivery but do not have the phone with insulin pump controller APP readily available, you can perform the delivery by pressing the pump button. For details, please refer to *15.3 Quick Bolus*.

!CAUTION The quick bolus function is off by default. To enable this function, please choose “More” - “Settings” - “Infusion Settings”.

(2) Pump battery level indicator

When there's no alarm occur, press the pump button and the indicator light will show pump battery level:

- Two green lights: Power is over 50 percent.
- One green light: Power is between 10 and 50 percent.
- One green flash: Power is under 10 percent.
- Indicator light off: Pump battery is power off.

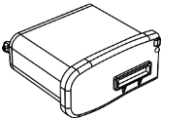
(3) When the pump is connected, pump button is used to confirm that the insulin pump controller is allowed to connect to the pump. For details, please refer to *3.5 Connecting the insulin pump*.

2.2 Accessories

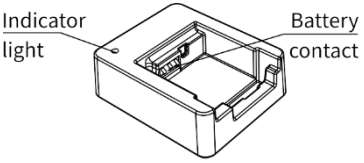
2.2.1 Power adapter

2.2.2 Charging cable of the pump battery

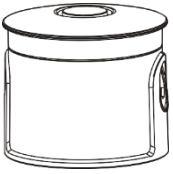
2.2.3 Pump battery



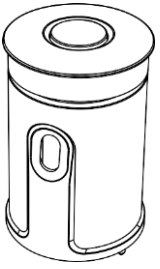
2.2.4 Pump battery charger



2.2.5 Insertion device



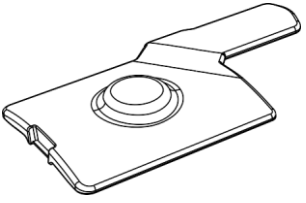
AR-Z200 Insertion device
(for infusion set type A and type C)



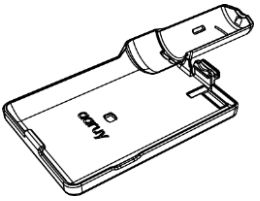
AR-Z210 Insertion device
(for infusion set type B)

2.2.6 Protective cover kit

The protective cover kit consists of a protective cover of infusion needle holder and a portable baseplate.



Protective cover of infusion needle holder



Portable baseplate

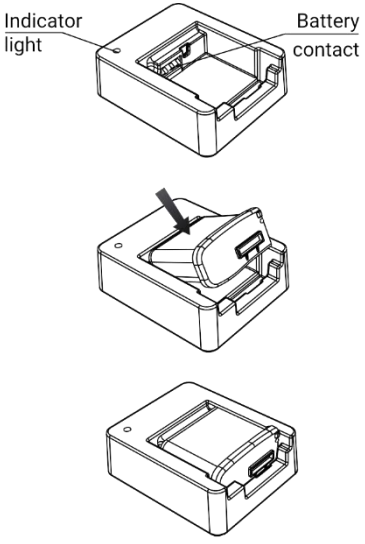
3 Prepare the pump before use

3.1 Battery charging

The new battery of the insulin pump must be fully charged before use. The charging method is as follows.

!CAUTION Please make sure to use the special charger provided by our company. The company will not bear legal responsibility for any damage to the system or to the person caused by chargers from other suppliers.

(1) Insert the pump battery into the charger diagonally (as shown in Figure 3.2) and press down until you hear the “click” sound to confirm that it is in place.



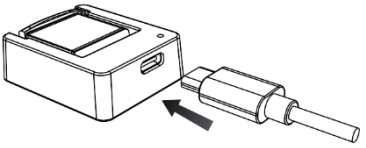


Figure 3.2 Diagram of pump battery charging

(2) The (smaller)Type-C end of the charging cable connects to the power port of the pump battery charger, and the (larger)Type-A end connects to the power input interface of the power adapter.

(3) Plug the power adapter into the 100-240 V power socket, the indicator light of the pump battery charger will turn on and stay green, indicating the battery is being charged; if the indicator light is off, it means that the charger is in no-load state. Please check whether the battery is properly installed.

(4) After the battery is fully charged, the indicator light will turn off, and the power adapter can be unplugged from the socket.

(5) Remove the pump battery.

!CAUTION After the battery is fully charged and disconnected from the power socket, take it out of the charger, otherwise it will lead to power loss..

3.2 Installation of the pump battery

The structure of the pump battery is shown in Figure 3.3. Please install it into the insulin pump according to the direction shown in Figure 3.4. If the direction is incorrect, the installation will fail.

Figure 3.3 Diagram of pump battery

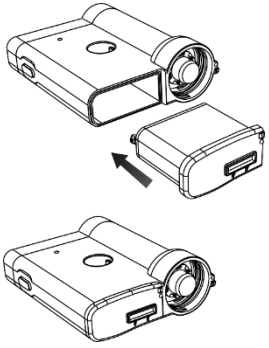


Figure 3.4 Diagram of installation

3.3 Downloading the APP

If your mobile phone uses an Android operating system, you can search for "AR-B200" in the mobile application market or scan the QR code as shown in Figure 3.4 to download and install the application "AR-B200".

Figure 3.4

If your mobile phone is an iOS operating system, you can search for "AR-B200" in the APP Store or scan the QR code as shown in Figure 3.5 to download and install the application "AR-B200".

Figure 3.5

3.4 Logging in to the application

Log in to the application for the first time and open the login interface (as shown in Figure 3.6). You need to enter the authorized mobile phone number, click "Get verification code" and then enter the verification code received to enter the APP.

Figure 3.6

After successfully logging in to the APP for the first time, subsequently, you can directly open the interface without the need to log in again.

!CAUTION If you have not used the APP for 15 days, you need to log in again to open the application.

!CAUTION Network connection is needed to log in to the APP. Otherwise, the verification code cannot be

obtained.

3.5 Connecting the insulin pump

After logging in to the APP for the first time, it will automatically open the Bluetooth connection interface. Click “Scan for Devices”, the Bluetooth will start to search for available devices, and the list of devices will appear (as shown in Figure 3.7).

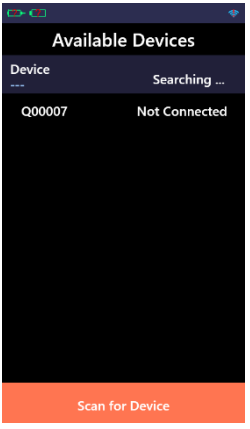


Figure 3.7

Click the serial number of the insulin pump to start the connection. If your mobile phone is Android operating system, the Bluetooth will automatically connect to the insulin pump; if your mobile phone is iOS operating system, please paste the password as reminded, then the Bluetooth will connect to the insulin pump.

When the insulin pump makes a “beep” sound with the green indicator light on, please press the pump button within 10 s to confirm the connection between the controller and the insulin pump. The “Not Connected” will be into “Connected” and the serial number of connected insulin pump will be displayed under “Device”.

4 Setup wizard

After successfully connecting the insulin pump, it will automatically open the setup wizard.

The setup wizard will guide you to open the following setting interface in turn to complete the basic settings, and you can also selectively enable and set some advanced functions.

Click “Next” to open the next interface for settings, or click “Back” to return to the previous interface to modify settings.

!CAUTION Click “ACT” to save the settings, or click“ESC" to exit without saving.

!CAUTION Upon starting the setup wizard for the first time, all settings must be completed in sequence at once. The system does not allow exiting in progress.

!CAUTION For detail of the setting range of parameters, please refer to *Appendix B*.

4.1 Setting basal

After opening the setup wizard, set the basal first (as shown in Figure 4.1).

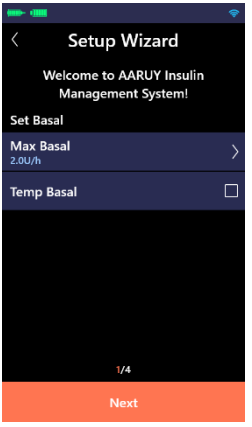


Figure 4.1

(1) Click “Max Basal” to open the setting interface (as shown in Figure 4.2). Click “+” or “-” to set the max basal.

Click “ACT” to save and exit, or click “ESC” to exit without saving.

Figure 4.2

!CAUTION Please set this value to the max basal you may use to reduce the risk of any faulty excessive delivery. Please consult your doctor for specific values.

!CAUTION The lower limit for the max basal is the maximum value in basal and temp basal. The default basal is set at 0.5 U/h. Therefore, the lower limit of the max basal is 0.5 U/h in the first-time use or when settings are reset to default.

(2) "Temp Basal" is disabled by default. You need to manually select it to enable this function.

The unit of temp basal is "U/h".

!CAUTION For the use of the temp basal, please refer to: *15.1 Temp basal*.

After setting, click "Next" to jump to the bolus setting interface.

4.2 Setting bolus

The basic setting interface of the bolus is shown in Figure 4.3.

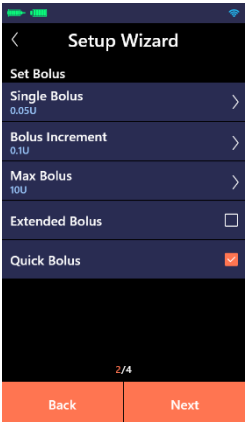


Figure 4.3

(1) Click "Single Bolus" to open the setting interface (as shown in Figure 4.4). Select the appropriate value. Click "ACT" to save and exit, or click "ESC" to exit without saving.

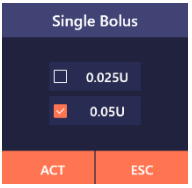


Figure 4.4

!CAUTION The single bolus is the amount of insulin injected every 2 s during bolus delivery, with 0.05 U by default.

Only when the single bolus is set to 0.025U can the bolus increment be set to 0.025 U.

(2) Click "Bolus Increment" to open the setting interface (as shown in Figure 4.5). Select the appropriate value. Click "ACT" to save and exit, or click "ESC" to exit without saving.

The bolus increment is the minimum increase when you setting bolus.

Figure 4.5

(3) Click "Max Bolus" to open the setting interface (as shown in Figure

4.6). Click “+” or “-” to set the appropriate value, Click “ACT” to save and exit, or click “ESC” to exit without saving.

Figure 4.6

!CAUTION Please set this value to the max bolus you may use to reduce the risk of faulty excessive delivery. Please consult your doctor for specific value.

(4) “Extended Bolus” is disabled by default. You need to manually select it to enable this function.

!CAUTION AR-B200B and AR-B200D insulin pump do not have extended bolus function.

!CAUTION For detail of extended bolus, please refer to *15.2 Extended bolus*.

(5) “Quick Bolus” is disabled by default. You need to manually select it to enable this function.

!CAUTION The function is disabled by default.

!CAUTION When you need a bolus delivery without taking the phone with insulin pump controller APP, you can enable the quick bolus function to complete the bolus delivery by pressing the pump button. For details, please refer to *15.3 Quick bolus*.

After setting, click “Next” to jump to the advanced setting interface of the bolus. To modify the previous settings, please click “Back”.

4.3 Setting advanced bolus

Advanced bolus setting interface is shown in Figure 4.7.

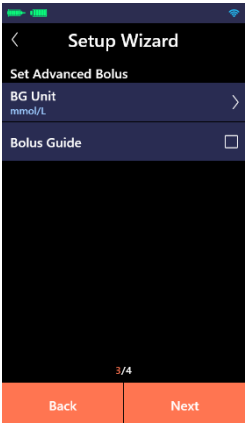


Figure 4.7

(1) Click “BG Unit” and the setting interface will pop up (as shown in Figure 4.8). Select “mmol/L” or “mg/dL” and then click “ACT” to save and exit or click “ESC” to exit without saving.

Figure 4.8

(2) "Bolus Guide" is disabled by default. You need to manually select it to enable this function.

!CAUTION AR-B200B and AR-B200D insulin pump do not have bolus guide function.

Select to enable “Bolus Guide” and then the related menu will be shown (as shown in Figure 4.9).

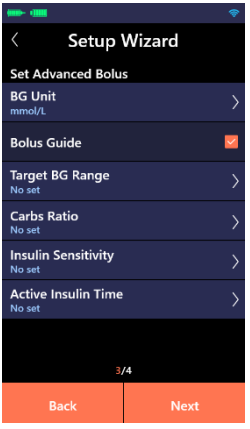


Figure 4.9

A. Setting target BG range

The option of “Target BG Range” is used to set BG targets. The bolus guide will calculate a correction bolus based on the target BG range. BG targets may vary at different time in a day, so the insulin pump allows up to eight target BG ranges to be set on the daily basis. If you want to set a specific BG target rather than a range, please simply set the lower and upper limits with the same value.

The insulin pump will remind you to set the start time and end time for each BG target. The end time is the end of the target BG range in the current period and also the beginning of that range in the next period.

Click “Target BG Range” to open the corresponding setting interface.

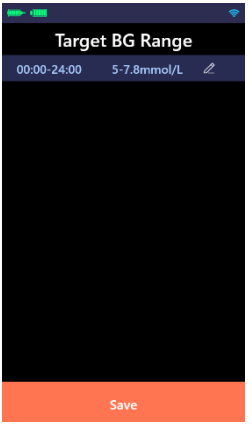


Figure 4.10

(a)Add/modify the target BG range: Click “Modify” to open the setting modification interface (as shown in Figure 4.10). Click “” on the right side of the data, and click “+” or “-” on the pop-up interface (as shown in Figure 4.11) to set start time, end time, lower and upper limits of the target BG range.

Click “ACT” to save and exit, or click “ESC” to exit without saving.

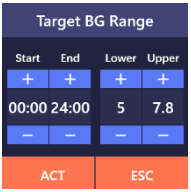


Figure 4.11

!CAUTION The first segment of target BG range always starts at 00:00 midnight. The last segment of target BG range always ends at 24:00 midnight.

!CAUTION If the start time of the first segment is not set at 00:00, a segment will be added automatically starting at 00:00, and the start time you set will be the end time.

!CAUTION If the end time of the last segment is not set at 24:00, a segment will be added automatically ending at 24:00 and the end time you set will be the start time.

If you modify the start time of a period in the middle:

- If the modified start time of this period is later than the end time of the previous one, a new period will be added.
- If the modified start time of this period is earlier than the end time of the previous one while later than the start time of that previous one, the end time of the previous period will be modified to the start time of this period.
- If the modified start time of this period is the same as or earlier than the start time of the previous one, it will be merged with the target BG range of the previous period.

!CAUTION If you modify the end time of a period in the middle:

- If the modified end time of this period is earlier than the start time of the next one, a new period will be added.
- If the modified end time of this period is later than the start time of the next one while earlier than the end time of that next one, the start time of the next period will be modified to the end time of this period.
- If the modified end time of this period is the same as or later than the end time of the next one, it will be merged with the target BG range of the next period.

Delete the target BG range: Please click "✖" on the right side of the data and it will be deleted, with the end time of the previous period modified to that of the deleted one.

After the setting is completed, click "Save", the confirmation interface will pop up. Click "ACT" to save and exit, or click "ESC" to return to the setting interface to continue the setting modifications.

B. Setting carbs ratio

The carbs ratio may change at different

time of the day, so the insulin pump allows up to eight carbs ratios to be set daily basis. But your doctor may only allow you to set one or two carbs ratios in the bolus guide.

The insulin pump will remind you to set the start time and end time of carbs ratio for each period. The end time marks the end of the carbs ratio in the current period and also its beginning in the next period.

Click "Carbs Ratio" to open the corresponding setting interface.

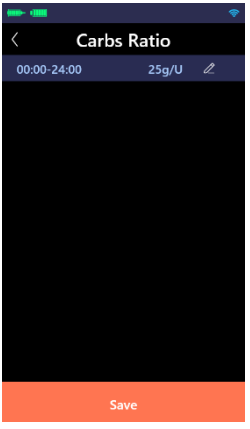


Figure 4.12

(a)Add/modify the carbs ratio: Click "Modify" to open the setting modification interface (as shown in Figure 4.12), please click "" on the right side of the data, then click "+" or "-" on the pop-up interface (as shown in Figure4.13) to set start time, end time and carbs ratio.

Click "ACT" to save and exit, or click "ESC" to exit without saving.

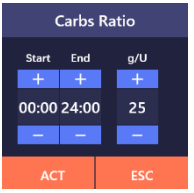


Figure 4.13

!CAUTION The first segment of carbs ratio always starts at 00:00 midnight. The last segment of carbs ratio always ends at 24:00 midnight.

!CAUTION If the start time of the first segment is not set at 00:00, a segment will be added automatically starting at 00:00. The start time you set previously will be the end time.

!CAUTION If the end time of the last segment is not 24:00, a segment will be added automatically ending at 24:00. The end time you set will be the start time.

!CAUTION If you modify the start time of a period in the middle:

- If the modified start time of this period is later than the end time of the previous one, a new period will be added.
- If the modified start time of this period is earlier than the end time of the previous one while later than the start time of the previous one, the end time of the previous period will

be modified to the start time of this period.

- If the modified start time of this period is the same as or earlier than the start time of the previous one, it will be merged with the carbs ratio of the previous period.

!CAUTION If you modify the end time of a period in the middle:

- If the modified end time of this period is earlier than the start time of the next one, a new period will be added.
- If the modified end time of this period is later than the start time of the next one while earlier than the end time of that next one, the start time of the next period will be modified to the end time of this period.
- If the modified end time of this period is the same as or later than the end time of the next one, it will be merged with the carbs ratio of the next period.

(b) Delete the carbs ratio: Please click "  " on the right side of the carbs ratio, then it will be deleted, with the end time of the previous period modified to that of the deleted one.

After the setting is completed, click "Save", the confirmation interface will pop up. Click "ACT" to save and exit, or click "ESC" to return to the setting interface to continue the setting modifications.

C. Setting insulin sensitivity

The insulin sensitivity refers to the BG level lowered by 1 unit of insulin for calculating correction. Insulin sensitivity may vary at different time in a day, so the insulin pump allows up to eight insulin sensitivities to be set, but your doctor may only set one or two insulin sensitivities for you.

The insulin pump will remind you to set a start and end time for the insulin sensitivity in each period. The end time is the end of the insulin sensitivity in the current period and the beginning of that in the next period.

Click "Insulin Sensitivity" to open the setting interface.

(a)Add/modify the insulin sensitivity: Click "Modify" to open the setting modification interface (as shown in Figure 4.14), click "  " on the right side of the data, then click "+" or "-" on the pop-up interface (as shown in Figure 4.15) to set start time, end time and insulin sensitivity.

Click "ACT" to save and exit, or click "ESC" to exit without saving.

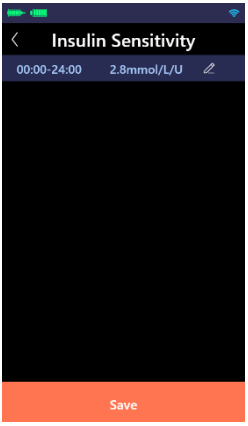


Figure 4.14

Figure 4.15

!CAUTION The first segment of Insulin sensitivity always starts at 00:00 midnight. The last segment of Insulin sensitivity always ends at 24:00 midnight.

!CAUTION If the start time of the first segment is not set at 00:00, a segment will be added automatically starting at 00:00 and the start time you set will be the end time.

!CAUTION If the end time of the last segment is not 24:00, a segment will be added automatically ending at 24:00. The end time you set previously will be the start time.

!CAUTION If you modify the start time of a period in the middle:

- If the modified start time of this period is later than the end time of the previous one, a new period will be added.
- If the modified start time of this period is earlier than the end time of the previous one while later than the start time of that previous one, the end time of the previous period will be modified to the start time of this period.
- If the modified start time of this period is the same as or earlier than the start time of the previous one, it will be merged with the Insulin sensitivity of the previous period.

!CAUTION If you modify the end time of a period in the middle:

- If the modified end time of this period is earlier than the start time of the next one, a new period will be added.
- If the modified end time of this period is later than the start time of the next one while earlier than the end time of that next one, the start time of the next period will be modified to the end time of this period.
- If the modified end time of this period is the same as or later than the end time of the next one, it will be merged with the insulin sensitivity of the next period.

(b) Delete the insulin sensitivity: Please click "✖" on the right side of the data, then it will be deleted, with the end time of the previous period modified to that of the deleted one.

After the setting is completed, click "Save", the confirmation interface will pop up. Click "ACT" to save and exit, or click "ESC" to return to the setting interface to continue the setting modifications.

D. Setting active insulin time

Active insulin refers to bolus insulin that have been delivered into the body and continues to lower BG levels.

Click "Active Insulin Time" to open the setting interface (as shown in Figure A.2.16), then click "+" or "-" to set the appropriate value.

Click "ACT" to save and exit, or click "ESC" to exit without saving.

Figure 4.16

After the setting is completed, click "Next" to jump to the alarm setting interface. To modify the previous settings, click "Back".

4.4 Setting alarm

Alarm parameter setting interface is as shown in Figure 4.17.

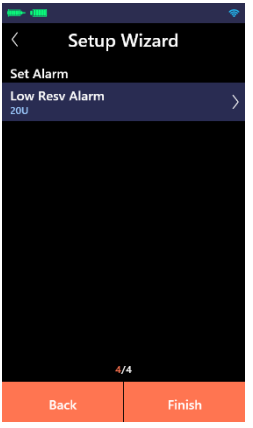


Figure 4.17.

Click "Low Resv Alarm" and the setting interface will pop up (as shown in Figure 4.18). Click "+" or "-" to set the appropriate value. Click "ACT" to save and exit, or click "ESC" to exit without saving.

When the remaining insulin in reservoir is lower or equal to set amount, the low reservoir alarm signal will be issued on the insulin pump and the insulin pump controller APP.

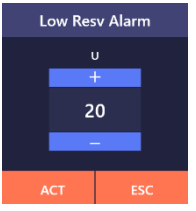


Figure 4.18

After setting, click "Finish" and it will

jump to the inferface of replacing the reservoir. To modify the previous settings, click “Back”.

4.5 Replacing reservoir

After completing the alarm settings, click “Finish” and the setup wizard will guide you through replacing the reservoir.

(1) Disconnect from body. click “ACT” to rewind, then the user can continue to replace the reservoir, or click “ESC” to return to the “More” interface (as shown in Figure 4.19).

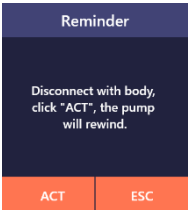


Figure 4.19

(2) Assemble the fully charged battery and the reservoir filled with insulin with the pump (as shown in Figure 4.20). After the assembly is completed, please click “Next”.

For the installation of the pump battery, please refer to *3.2 Installation of the pump battery*;

For the reservoir assembly, please refer to *8.3.1 Use method of the reservoir*.

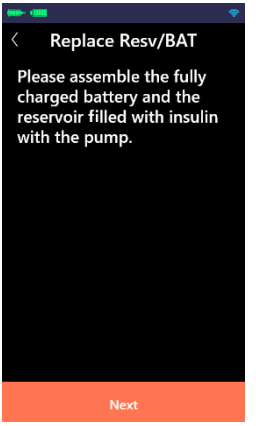


Figure 4.20

!CAUTION Subsequent operations not be performed without the reservoir installed.

!CAUTION Please make sure that the battery is fully charged, since the battery with insufficient power will not be able to support the insulin pump to run for more than three days.

(3) Prime. Press or click “Prime” until droplets discharge from the needle, then click “Next” (as shown in Figure 4.21).

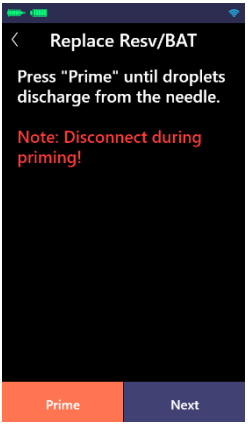


Figure 4.21

!CAUTION Please do not install the connector on the infusion needle holder until the prime is completed!

(4) Connect the infusion set with the body (as shown in Figure 4.22). When it is completed, click “Next”.

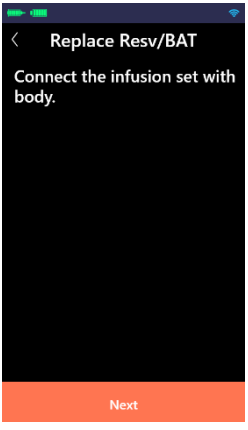


Figure 4.22

For the connection method, please refer to *8.4.3 Use method of the infusion set*.

(5) Exhaust. Select the length of the soft cannula you are using, and then click “Exhaust”, the insulin will fill the soft cannula (as shown in Figure 4.23).

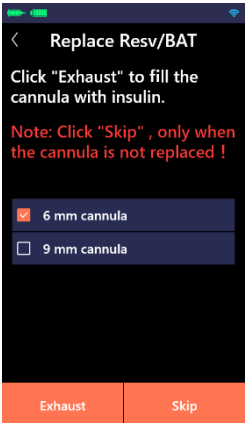


Figure 4.23

!CAUTION You can click “Skip” only when the infusion set is not to be replaced and there is no need to exhaust the soft cannula. Click “Exhaust” if it is your first time entering the setup wizard when using a new infusion set.

(6) Complete the replacement of the reservoir

!CAUTION After the setup wizard is completed, the basal will not run automatically, so please run it manually.

!CAUTION Before using the insulin pump, please read this manual carefully or attend relevant trainings.

After completing the setup wizard for the first time, you can click “More” -

“Settings” - “Setup Wizard” on the main interface to open the setup wizard again to modify the parameter settings.

5 Main interface

Click the “ACT” on the reminder interface to switch to the Main interface.

The main interface, as shown in Figure 5.1, includes the status bar, information display area and function buttons.

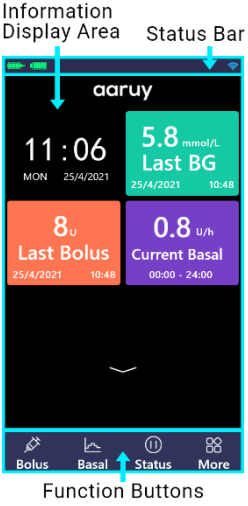


Figure 5.1

(1) Status bar:

The icons in the status bar indicate the current status of the system with the meanings as follows:

Remaining insulin:

From left to right, the reservoir of insulin goes from empty to full, with “  ” representing wireless disconnection.

Pump battery level

From left to right, battery power goes from empty to full, with “  ” representing wireless disconnection.

Alarm: 

This icon only appears when there is a high priority alarm.

AUDIO ALARM OFF:

This icon only appears when the audio alarm is turned off.

ACKNOWLEDGED:

The user has turned off the high priority alarm, but the alarm condition still exists, and this icon will appear.

BG test reminder: 

This icon only appears when the BG test reminder is turned on. For details, please refer to 13.*2 BG settings*.

Wireless network connection status:

From left to right, the signal strength of the wireless connection goes from weak to strong, with “  ” representing wireless disconnection.

Scroll down the status bar to extend it for details (as shown in Figure 5.2). In the detailed information interface, scroll up the screen to hide it.

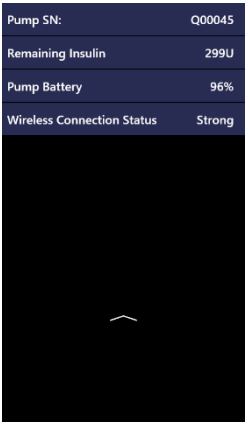


Figure 5.2

(2) Information display area

This area displays date and time, last BG, last bolus and current basal.

Function buttons

You can switch among the following function interfaces by clicking the function buttons.

- **Bolus:** Includes bolus and extended bolus.
- **Basal:** Includes basal and temp basal.
- **Status:** Displays the current operating status of the system.

More: Includes replacing resv/BAT, replacing pump, food database, input BG value, settings and history.

For details on how to use the above functions, please refer to the following chapters.

6 Basal rate settings and infusion

What is the basal?

The basal refers to the amount of insulin required without meals, simulating the trace amounts of insulin secreted by normal pancreas without meals to maintain the target BG.

Please get the suitable parameter from your doctor.

Click the “Basal” function button at the bottom of the main interface to open the basal interface (as shown in Figure 6.1). The basal switching (including basal 1, basal 2, and basal 3), the basal setting and browsing area, and the basal button are displayed from top to bottom, respectively.

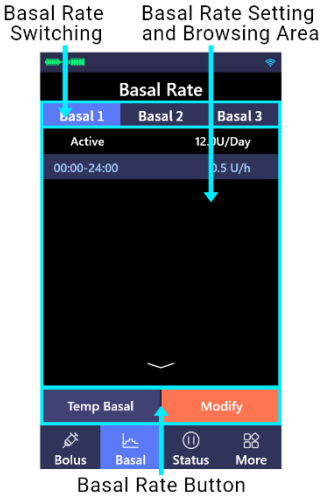


Figure 6.1

For detail of the setting range of parameters, please refer to *Appendix B*.

6.1 Switching and browsing basal

Click “Basal 1”, “Basal 2” or “Basal 3” on the basal switch tab bar, you will switch among the basal interfaces.

The setting of the basal can be browsed in the middle. If the number of set segments exceeds the display range of the browsing area, you can browse all settings by scrolling up and down.

6.2 Setting basal

By click “Basal 1”, “Basal 2” or “Basal 3” on the basal switching, you can switch to the basal interface. Click “Modify” to open the setting interface (as shown in Figure 6.2).

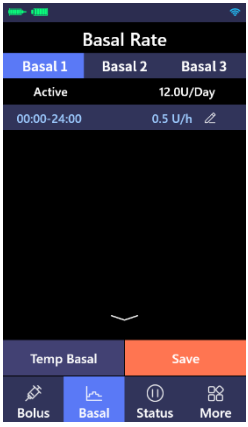


Figure 6.2

(1) Add/modify the basal: Click "" on the right side of the data, then click "+" or "-" in the pop-up interface (as shown in Figure 6.3) to set the start time, end time and basal (the upper limit is the max basal that has been set).

Click "ACT" to save and exit, or click "ESC" to exit without saving.

Figure 6.3

!CAUTION If the basal for a certain period of time is set to 0 U/h, then it is equivalent to suspending the delivery of insulin during this period of time.

!CAUTION The first segment of basal always starts at 00:00 midnight. The last segment of basal always ends at 24:00 midnight.

!CAUTION If the start time of the first segment is not set at 00:00, a segment will be added automatically starting at 00:00, and the start time you set previously will be the end time.

!CAUTION If you modify the start time of a period in the middle:

- If the modified start time of this period is later than the end time of the previous one, a new period will be added.
- If the modified start time of this period is earlier than the end time of the previous one while later than the start time of the previous one, the end time of the previous period will be modified to the start time of this period.
- If the modified start time of this period is the same as or earlier than the start time of the previous one, it will be merged with the basal of the previous period.

!CAUTION If you modify the end time of a period in the middle:

- If the modified end time of this period is earlier than the start time of the next one, a new period will be added.
- If the modified end time of this period is later than the start time of the next one while earlier than the end time of that next one, the start time of the next period will be modified to the end time of this period.
- If the modified end time of this period is the same as or later than the end time of the next one, it will be merged with the basal of the next period.

(2) Delete the basal: Please click "" on the right side of the data, and it will be deleted, with the end time of the previous period modified to that of the deleted one.

(3) After the setting is completed, click

“Save” and the confirmation interface will pop up. Click “ACT” to save and exit, or click “ESC” to return to the setting interface to continue the setting modifications.

6.3 Running basal

By click “Basal 1”, “Basal 2” or “Basal 3” on the basal switching, you can switch to the basal interface. Then click “Active” to open the confirmation interface. Then click “ACT” to run the basal, or click “ESC” to exit without running basal.

7 Bolus settings and infusion

What is bolus?

Diabetics' BG will rise after meals. In order to maintain the target postprandial BG, diabetics are required to receive bolus before meals.

The speed at which different food components are converted into BG varies greatly(as shown in Figure 7.1). You can choose normal bolus or extended bolus according to the food you have.

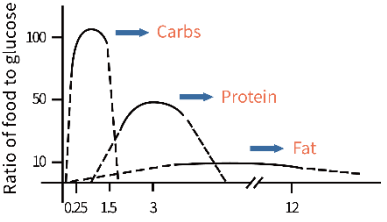


Figure 7.1

!CAUTION For detail of the setting range of parameters, please refer to *Appendix B*.

7.1 Normal bolus

Normal bolus refers to the delivery of bolus insulin in a short period of time according to the dose you set. It is the most common way for diabetics to control hyperglycemia.

(1) Click the "Bolus" at the bottom of the main interface to open the bolus interface (as shown in Figure 7.2).

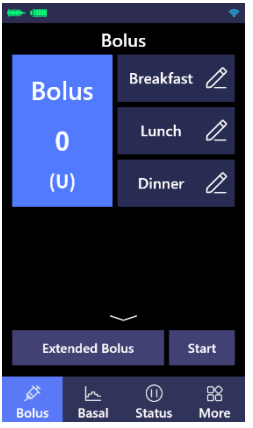


Figure 7.2

(2) Click the "Bolus" on the upper left to open the setting interface (as shown in Figure 7.3). Click "+" or "-" to set the bolus. The upper limit can be set to the max bolus that has been set. Click "ACT" to save and exit, or click "ESC" to exit without saving.

Figure 7.3

(3) When the value of bolus is greater than 0, the "Start" button (as shown in Figure 7.2) will turn orange. Click "Start" to open the confirmation interface, then click "ACT" for the

insulin pump controller to send a delivery instruction to the insulin pump. Click “ESC” to return to the Bolus interface.

(4) After the insulin pump controller sends the delivery instruction to the insulin pump, the insulin pump will “beep” and start to perform bolus with delivery progress displayed in the status interface (as shown in Figure 7.4).

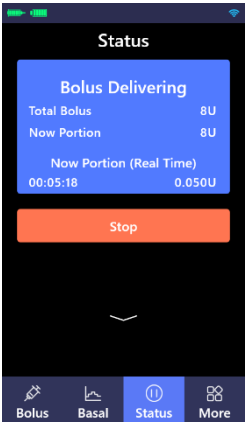


Figure 7.4

After the bolus delivery is completed, the pop-up interface will display the delivery time and total bolus.

7.2 Preset bolus

In the bolus interface, you can preset three groups of bolus for breakfast, lunch and dinner in the preset area (as shown in Figure 7.5). The default value of three preset bolus are 0 and users are required to set it before use.

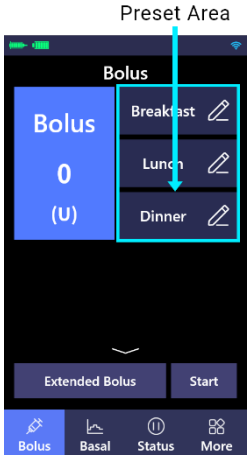


Figure 7.5

(1) Set preset bolus

Click “Breakfast”, “Lunch” or “Dinner” on the preset area, the icon will be highlighted, then click “ ” on the right, then click “+” or “-” in the pop-up interface to set the preset bolus, the upper limit can be set to the max bolus that has been set. If necessary, the characters of preset bolus can also be modified.

Click “ACT” to save and exit, or click “ESC” to exit without saving.

(2) Use the preset value

Click the preset bolus such as “Breakfast” on the preset area, the bolus icon on the upper left will display the preset bolus value. When the preset bolus value is not 0, the “Start” button will turn orange and you can deliver bolus. For details, please refer to: *A.5.1 Normal bolus*. If you have enabled the extended bolus function, the “Extended

Bolus" button will turn orange, and you can deliver extended bolus. For details, please refer to *15.2 Extended bolus*.

7.3 Emergency stopping bolus

If you notice an incorrect setting, meal interruption, or any changes to food during bolus delivery, please stop the bolus in progress.

Click “Stop" in the status interface (as shown in Figure 7.4), then click “ACT" in the pop-up confirmation interface to stop, or click “ESC" to continue.

!CAUTION Regardless of the mode, ongoing bolus delivery can be stopped by the above operations. You can view the bolus you have delivered in history.

!CAUTION After emergency stopping bolus, the basal will also be suspended. If you want to resume the basal delivery, click “ ” in the status interface.

8 Starting to use insulin pump

8.1 Preparing the insulin pump system

This insulin pump system is intended for short/rapid-acting U-100 insulin.

!CAUTION First-time setting and operation of this insulin pump system must be done under the guidance of the doctor or professional. Please consult your doctor for the parameters you need.

!CAUTION After you have completed the exercise and prepared to use your insulin pump, you must ensure the date and time set on the insulin pump controller are correct.

You will need the following items:

You will need the following items:

- Insulin pump
  (with fully charged battery)
- Mobile phone
  (fully charged)
- Short/rapid-acting U-100 insulin
- Baseplate
- Reservoir and its instruction manual
- Infusion set and its instruction manual

8.2 Connecting the insulin pump

After installing and logging in to the APP, you will be guided by the APP automatically to connect the insulin pump. For details, please refer to *3.5 Connecting the insulin pump*.

8.3 Setup wizard

The APP will automatically guide you to complete the basic settings. For details, please refer to *4 Setup Wizard*.

8.4 Use method of the insulin pump consumables

The first choice of infusion site is abdomen, followed by upper arm, lateral thigh, back waist, hip, etc.

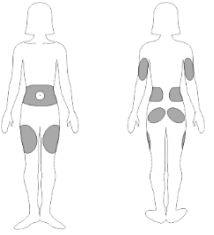


Figure 8.1 Diagram of infusion site

!CAUTION Cold insulin may create bubbles in the reservoir or tubing. If the insulin is stored in the refrigerator, please make sure it reach the room temperature before loaded into the reservoir. And be sure to remove bubbles when loading insulin into the reservoir.

!CAUTION Please use it immediately after loading insulin into the reservoir. Do not store it for a long time.

!CAUTION The reservoir, AR-D30B baseplate and infusion set should be

replaced every 48-72 h to ensure their safety and effectiveness.

!CAUTION The medical tape of the infusion set and the baseplate will contact with the intact skin. Please stop using immediately if sensitization occur and consult your doctor.

!CAUTION If the buckle is loose, please replace the AR-D30A baseplate immediately.

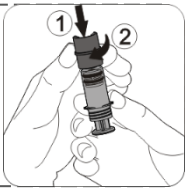
!CAUTION Ensure the insulin pump and reservoir are reliably fixed with the baseplate during application.

8.4.1 Method of use of the reservoir

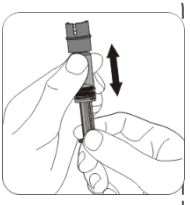
(1) AR-C30A Reservoir

❶ Wash your hands and open the package.

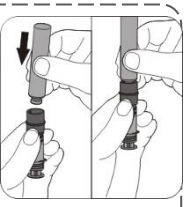
❷Attach the transfer guard to the reservoir and tighten it.



❸Push and pull the plunger back and forth to lubricate the reservoir, then push the plunger to the zero line.

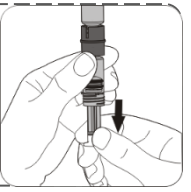


❹Disinfect the mouth of the insulin vial with alcohol before inserting it down into the transfer guard.

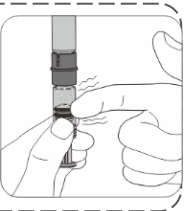


!CAUTION Please do not pull the plunger rod.

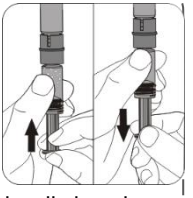
❺Slowly pull the plunger rod to draw the insulin into the reservoir.



❻Tap the side wall of the reservoir to rise bubbles, if any, to the top of the reservoir.

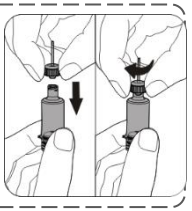


❼Slowly push the plunger rod to squeeze out the bubbles in the reservoir, and slowly pull the plunger rod to draw insulin into the reservoir; repeat this procedure until there is no bubble in the reservoir.

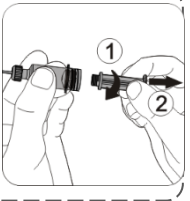


❽ Remove the insulin vial and transfer guard from the reservoir.

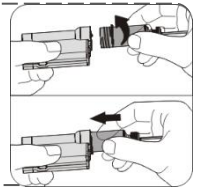
❾Attach the reservoir connector of the infusion set to the reservoir and tighten it.



❿Turn the plunger rod and remove it from the reservoir. Please do not pull the



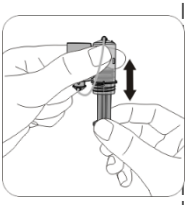
⓫Load the reservoir into the pump and tighten it until you hear a “click” sound.



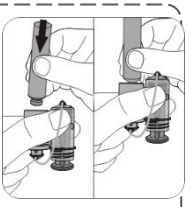
(2) AR-C3006B & AR-C3012C Reservoirs

❶ Wash your hands and open the package.

❷Push and pull the plunger back and forth to lubricate the reservoir, then push the plunger to the zero line.

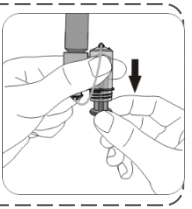


❸Disinfect the mouth of the insulin vial with alcohol before inserting it down into the transfer guard.

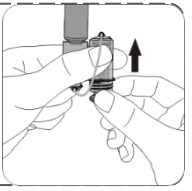


!CAUTION Please do not pull the plunger rod.

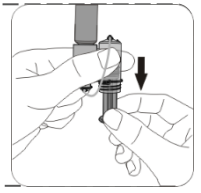
❹ With the insulin vial facing up, slowly pull the plunger rod to draw the insulin into the reservoir.



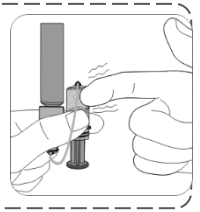
❺Slowly push the plunger rod to let bubbles in the reservoir rise to the top of insulin vial.



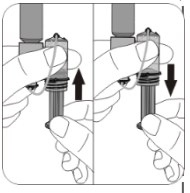
❻Slowly pull the plunger rod to draw the insulin into the reservoir.



❼Tap the side wall of the reservoir to rise bubbles, if any, to the top of the reservoir.

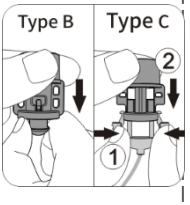


❽Slowly push the plunger rod to squeeze out the bubbles in the reservoir, and slowly pull the plunger rod to draw insulin into the reservoir; Repeat this procedure until there is no bubble in the reservoir.

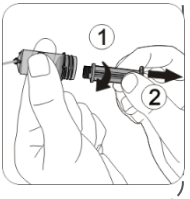


❾**Type B:** Pinch the connector and press your thumb against the transfer guard to pull out the connector.

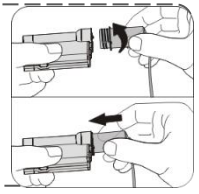
Type C: Pinch the buckles on both sides of the connector to separate them from the transfer guard.



❿Turn the plunger rod and remove it from the reservoir. Please do not pull the



⓫Load the reservoir into the pump and tighten it until you hear a “click” sound.



8.4.2 Method of use of baseplate

AR-D30A baseplate (portable)

To fix the insulin pump and reservoir on the baseplate:

- Install the insulin pump diagonally downwards into the bottom of the baseplate
- Press down the insulin pump until you hear a “click” sound;
- Press down the reservoir until you hear a “click” sound.

To separate the insulin pump and reservoir from the baseplate:

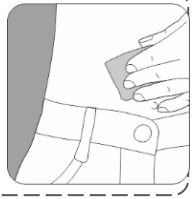
- Lightly press the buckle fixing the reservoir on the baseplate;
- Lightly press the buckle fixing the insulin pump on the baseplate;
- Remove the insulin pump.

8.4.3 Method of use of infusion set

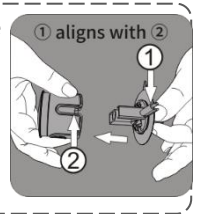
(1) AR-I06015A, AR-I09015A, AR-I06060A, AR-I09060A, AR-I06C and AR-I09C Infusion Sets

❶ Wash your hands and open the package.

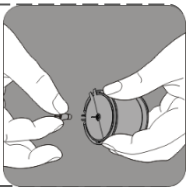
❷Use alcohol cotton to disinfect the infusion site in circular from inside to outside, and wait for it to be dry.



❸Align the needle assembly with the tubing slot of the insertion device, and press inward to put it in place.

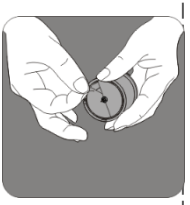


❹ Press down the tape to remove the puncture needle protector.

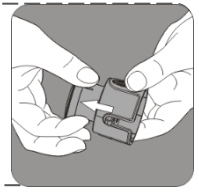


❺Press down the tape and remove the medical tape release paper.

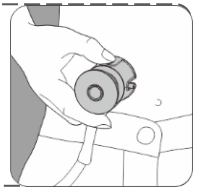
!CAUTION Please do not lift the needle assembly.



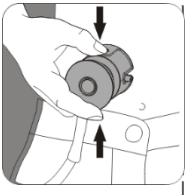
❻Pull up the cover of insertion device until you hear a “click” sound.



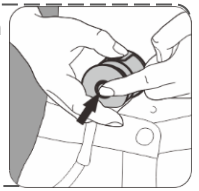
❼Place insertion device on disinfected and dried infusion site.



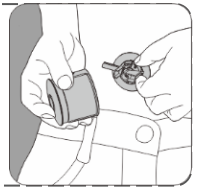
❽Press the buttons on both sides of the insertion device at the same time to implant the soft cannula subcutaneously.



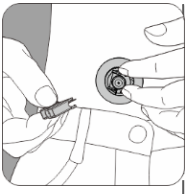
❾Press the button on the insertion device top to release the needle holder.



❿Remove the insertion device.

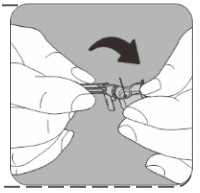


⓫Hold the medical tape with one hand to ensure that it fits smoothly with the infusion site, and Remove the puncture needle holder with the other hand.

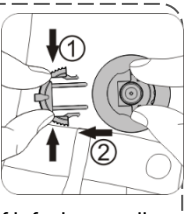


!CAUTION Please do not lift the soft cannula.

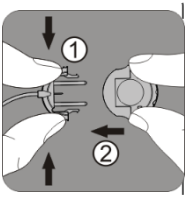
⓬Close the puncture needle holder to avoid getting hurt.



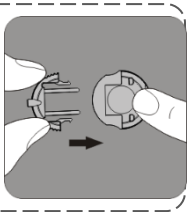
⓭Pinch the buckles on both sides of the protective cap of infusion needle holder, and remove the protective cap of infusion needle holder.



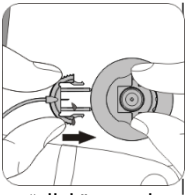
⓮Pinch the buckles on both sides of the connector to remove the protective cap of the connector.



⓯Insert the protective cap of the infusion needle holder into that of the connector and set aside.



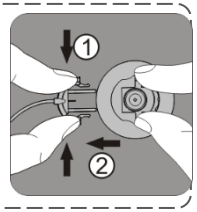
⓰Prime until droplets discharge from the connector needle, insert the connector into the infusion needle holder until you hear a “click” sound, and then exhaust the soft cannula.



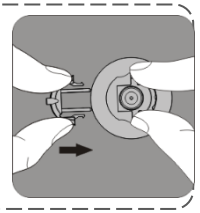
⓱ Now you can use the insulin pump for insulin delivery.

This product is a detachable infusion set that can be temporarily disconnected from the insulin pump without the need to remove the soft cannula from the body. To disconnect the connector:

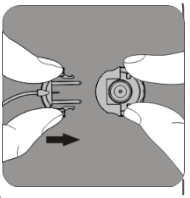
❶Pinch the buckles on both sides of the connector to remove the connector.



❷Insert the connector into its protective cap of connector until you hear a “click” sound.

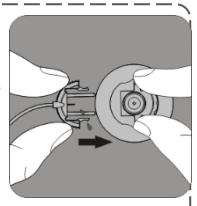


❸Insert the protective cap of the infusion needle holder into the infusion needle holder until you hear a “click” sound.

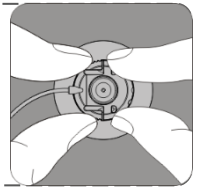


To reconnect the connector:

❶Prime until droplets discharge from the connector needle, insert the connector into the infusion needle holder until you hear a “click” sound.



❷After the connector is reconnected, you can continue insulin infusion.



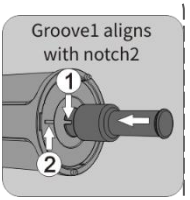
(2) AR-I0608B, AR-I0908B, AR-I06B and AR-I09B Infusion Sets

❶Wash your hands and open the package.

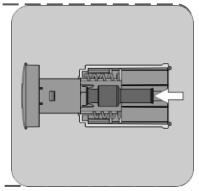
❷Disinfect the paste part with alcohol cotton and wait for it to be dry. Tear off the medical tape release

paper, and firmly paste the baseplate on the disinfected and dry part.

❸ Load the infusion set into the insertion device along the direction as shown in the picture.

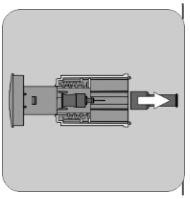


❹ Press the puncture needle protector inward until you hear a “click” sound.

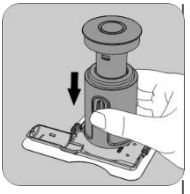


❺Remove the puncture needle protector and set aside.

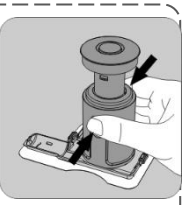
!CAUTION Please do not lift the needle assembly.



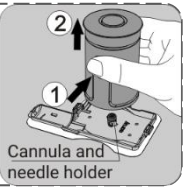
❻Align the lower round bump of the insertion device with the round hole in the baseplate, and then press down the insertion device until you hear a “click” sound.



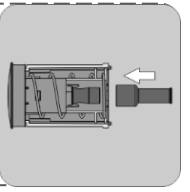
❼Press the buttons on both sides of the insertion device at the same time to implant the soft cannula subcutaneously.



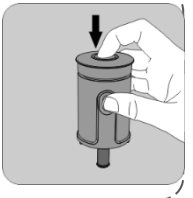
❽Remove the insertion device.



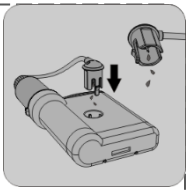
❾Reattach the puncture needle protector to the puncture needle.



❿Press the button on the insertion device top to release the puncture needle.

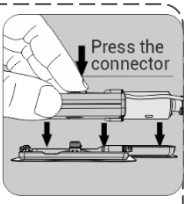


⓫Prime until droplets discharge from the connector needle, align the notch of the connector with the raised position of the middle hole of the insulin pump, and press the connector downward until you hear a “click” sound.



!CAUTION Please make sure to secure the connector to the pump before installing the pump into the

⓬Load the insulin pump into the baseplate according to the direction shown in the picture. Press both ends of the pump downward until you hear two “click” sounds. Press down the reservoir until you hear a “click” sound. Then exhaust the soft cannula.

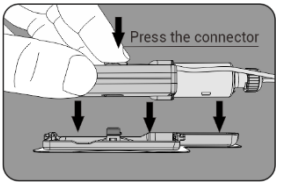


This product is a detachable infusion set that can be temporarily disconnected from the insulin pump without the need to remove the soft needle from the body. To disconnect the connector:

- Lightly press the buckle fixing the reservoir on the baseplate;
- Lightly press the buckle fixing the insulin pump on the baseplate;
- Remove the insulin pump.

To reconnect the connector:

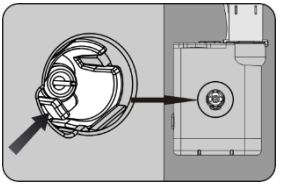
- Prime until droplets discharge from the connector needle;
- Install the insulin pump into the baseplate according to the direction as shown in the picture.



- Press down both ends of the insulin pump until you hear two “click” sounds;
- Press down the reservoir until you hear a “click” sound.

To separate the connector from the insulin pump when replacing the infusion set:

Light press the buckle of the connector to separate it from the insulin pump.



9 Suspending/stopping infusion by the insulin pump

In some case when you need to remove the insulin pump or the basal delivery is unnecessary, the suspend/stop mode will come in handy.

For example, when you need to shower, bathe, swim, participate in other water activities, or receive radiological examinations (such as MRI, CT, X-ray, etc.), it is required to disconnect the insulin pump, and that is when the suspension/stop mode will come in handy.

!CAUTION You can wear the insulin pump when you go through security checks to board planes, trains, etc.

!CAUTION The detachable infusion set allows you to temporarily disconnect the insulin pump without the need to remove the soft cannula from your body. For details, please refer to *8.4.3 Use method of the infusion set*.

9.1 Suspending delivery

When you need to suspend the delivery without replacing the reservoir or infusion set, please click "⏸" in the status interface (as shown in Figure 9.1) to open the suspend/stop pop-up interface (as shown in Figure 9.2).

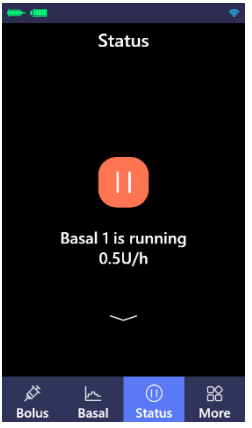


Figure 9.1

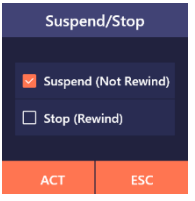


Figure 9.2

Click "Suspend (Not Rewind)", then click "ACT" to suspend the basal delivery, or click "ESC" to withdraw the suspend request and continue to run the basal.

After the suspension, the status interface will display "Suspended" and the suspended time (as shown in Figure 9.3).

!CAUTION If the bolus delivery is stopped, the basal delivery will be suspended as well.

!CAUTION After the delivery is suspended, there will be a suspension status reminder every 15 minutes until the status ends.

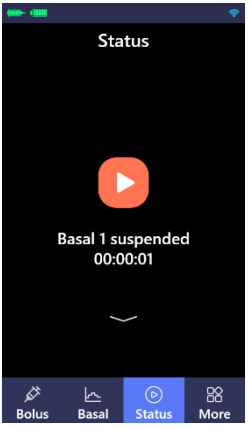


Figure 9.3

If you want to resume basal delivery, click "▶" to open the confirmation interface. Click "ACT" to resume basal delivery, or "ESC" to return to the status interface without any modifications to the suspension.

9.2 Stopping delivery

When you need to replace the reservoir or infusion set, please click "⏸" in the status interface to open the suspend/ stop interface (Figure 9.2).

Click "Stop (Rewind)", then click "ACT" to stop the basal delivery and the push rod will be rewound, or click "ESC" to withdraw the stop request and continue to run the basal.

After the stop, the running status interface will display "Stop (Rewind)" and the stop time (as shown in Figure 9.4).

!CAUTION The push rod will rewind when the delivery is stopped. If you need to resume the delivery, you will need to replace the reservoir.

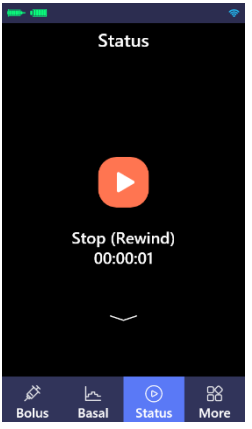


Figure 9.4

!CAUTION After the delivery is stopped, there will be a reminder every 15 minutes until the stop status ends.

10 Replacing the reservoir/battery

When you need to replace the reservoir or battery, click “More” - “Replace Resv/BAT" on the main interface, and follow the reminders to complete the operation. After completion, the system will automatically run the previous normal basal.

(1) Disconnect from body (as shown in Figure 10.1). Click “ACT” to rewind the push rod and the user can continue to replace the reservoir, or click “ESC” to return to the “More” interface.

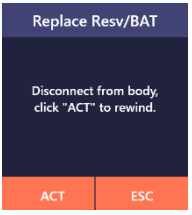


Figure 10.1

(2) Please assemble the fully charged battery and the reservoir filled with insulin with the pump (as shown in Figure 10.2). After the assembly is completed, please click “Next”.

For the installation of the pump battery, please refer to *3.2 Installation of the pump battery*;

For the use method of the reservoir, please refer to *8.4.1 Use method of the reservoir*.

!CAUTION Subsequent operations are not allowed without the reservoir installed.

!CAUTION Please make sure that the battery is fully charged, since the battery with insufficient power will not be able to support the insulin pump to run for more than three days.

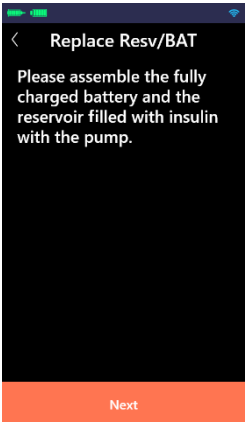


Figure 10.2

(3) Prime. Press or click “Prime" until droplets discharge from the needle and then click “Next” (as shown in Figure 10.3).

!CAUTION Please do not install the connector onto the infusion needle holder until prime is completed!

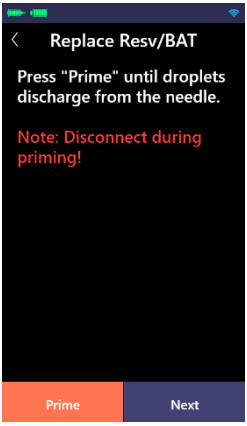


Figure 10.3

(4) Connect the infusion set with body (as shown in Figure 10.4). When it is completed, click "Next".

For the connection of the administration set to the infusion needle, please refer to *8.4.3 Use method of the infusion set*.

Figure 10.4

(5) Exhaust. Select the length of the soft cannula you are using and then click "Exhaust", the insulin will fill the soft cannula (Figure 10.5).

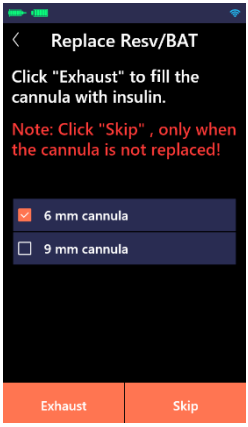


Figure 10.5

!CAUTION You can click "Skip" only when the infusion set is not to be replaced.

(6) After the soft cannula is exhausted, the normal basal before the replacement of the reservoir will be run.

!CAUTION When replacing the reservoir, if you encounter any abnormality, you can click "<" on the upper left corner of the interface to stop it.

!CAUTION If a low priority alarm (low reservoir, pump low power) occurs when replacing the reservoir, please click "ACT" in the alarm pop-up interface to continue the replacement.

!CAUTION If a high priority alarm (no reservoir, pump blocked, pump err, pump no power) occurs when replacing

the reservoir, please click “ACT” in the alarm pop-up interface to stop the replacement of the reservoir and return to the “More” interface.

11 Replacing the insulin pump

When you need to replace the insulin pump, click “More” - “Replace Pump” on the main interface and follow the reminders to complete the operation.

(1) Disconnect from body, click “ACT” to rewind the push rod then the user can continue to replace the pump, or click “ESC” to return to the “More” interface (as shown in Figure 11.1).

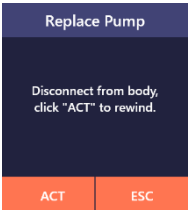


Figure 11.1

(2) Release the control over the pump (as shown in Figure 11.2). Click “ACT” to release the binding, or click “ESC” to return to “More” interface.

Figure 11.2

!CAUTION “Releasing the controller's control over the insulin pump” can only be completed when the controller is properly connected to the insulin pump.

!CAUTION Control can be released one-sidedly in special circumstances (such as pump failure), but doing so will cause usage or connection failure in the insulin pump. Please use this function with caution.

(3) Please assemble the fully charged battery and the reservoir filled with insulin with the pump (as shown in Figure 11.3). After the assembly is completed, please click “Next”.

For the installation of the pump battery, please refer to *3.2 Installation of the pump battery*;

For the use method of the reservoir, please refer to *8.4.1 Use method of the reservoir*.

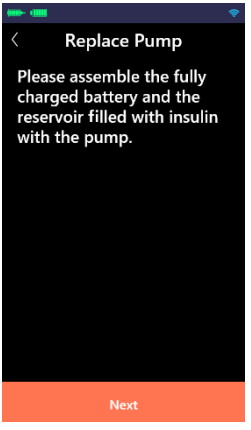


Figure 11.3

!CAUTION Subsequent operations

are not allowed without the reservoir installed.

!CAUTION Please make sure that the battery is fully charged, if not, the battery will not be able to support the insulin pump to run for more than three days.

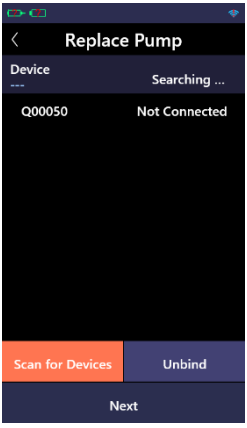


Figure 11.4

(4) Connect, Click “Scan for Devices”, the Bluetooth will automatically start to search for available devices, and a list of devices will be displayed (as shown in Figure 11.4).

Click the serial number of the insulin pump to start the connection. If your mobile phone is Android operating system, the Bluetooth will automatically connect to the insulin pump; if your mobile phone is iOS operating system, please paste the password as reminded and then the Bluetooth will connect to the insulin pump.

When the insulin pump makes a “beep” sound with the green indicator light on, please press the pump button within 10 s to confirm the connection between the controller and the insulin pump. After successful connection, the status of the insulin pump will be changed from “Not Connected” to “Connected” with the serial number of the connected insulin pump displayed below “Device Name”.

After successful connection, please click “Next”.

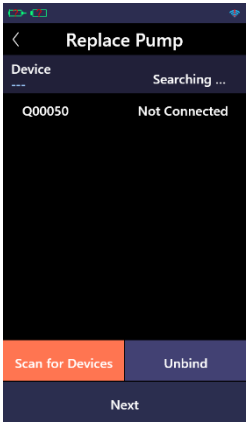


Figure 11.4

!CAUTION As required by some mobile phones, the user needs to clear the pairing information between the APP and the insulin pump to release the control of the old pump when replacing the insulin pump. In this case, please follow the interface reminders to clear the pairing information between the APP and the insulin pump.

(5) Prime, Press or click “Prime” until

droplets discharge from the needle and then click “Next” (as shown in Figure A.9.5).

!CAUTION Please do not install the connector onto the infusion needle holder until prime completed!

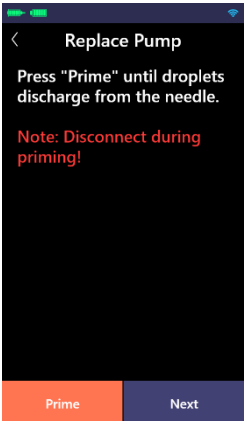


Figure 11.5

(6) Connect the infusion set with body (as shown in Figure 11.6). When completed, click “Next”.

Figure 11.6

For detail of connection of the administration set and the infusion needle holder, please refer to *8.4.3 Use method of the infusion set*.

(7) Exhaust, Select the length of the soft cannula you are using and then click “Exhaust”, the insulin will fill the soft cannula (Figure 11.7).

!CAUTION You can click “Skip” only when the infusion set is not to be replaced.

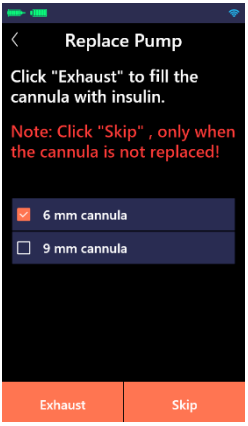


Figure 11.7

(8) Replacement has been completed.

!CAUTION After replacing the insulin pump, the basal will not automatically run, please run it manually.

!CAUTION When replacing the insulin pump, if you encounter any abnormality, you can click “ ” on the upper left corner of the interface to stop it.

!CAUTION If a low priority alarm (low reservoir, pump low power) occurs

when replacing the reservoir, please click “ACT” in the alarm pop-up interface to continue the replacement.

!CAUTION If a high priority alarm (no reservoir, pump blocked, pump err, pump no power) occurs when replacing the reservoir, please click “ACT” in the alarm pop-up interface to stop the replacement of the reservoir and return to the “More” interface.

12 Food database

The food database is an auxiliary function that mainly provides data on the carbohydrate content of various food. Click “More” - “Food Database” to browse the information.

!CAUTION You can click “  ” on the upper left corner of the interface to return to the previous interface.

Data Source: China Food Composition (2nd Edition)

Compiled by the National Institute for Nutrition and Health Chinese Center for Disease Control and Prevention

13 Settings

Click “More” – “Settings” in the main interface to open the setting interface, which includes setup wizard, BG settings, infusion settings, general settings, etc.

!CAUTION You can click “ ” on the upper left corner of the interface to return to the previous interface.

!CAUTION For detail of the setting range of parameters, please refer to *Appendix B*.

13.1 Setup wizard

Click “Setup Wizard” to modify the parameter settings. For details, please refer to *4 Setup wizard*.

13.2 BG settings

Click “BG Settings” to open the BG setting interface, which includes BG test reminder, BG unit and bolus guide.

(1) Click “BG Test Reminder” to open the test reminder interface, and then click “Modify” (as shown in Figure 13.1).

Click “Add” to open the setting interface (as shown in Figure 13.2), click “+” or “-” to set the reminder time. If you only need to be reminded once, please select “Single”; if you need to be reminded at the same time every day, please select “Repeat”. When the setting is completed, click “ACT” to save and exit, or click “ESC” to exit without saving.

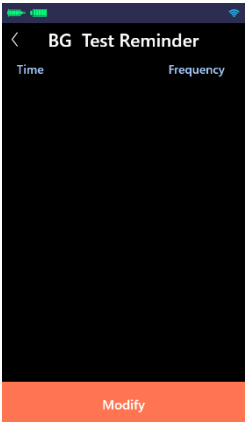


Figure 13.1

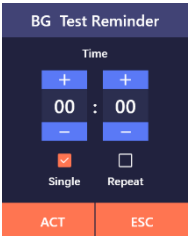


Figure 13.2

If you need to modify a reminder, click “ ” to modify it; if you need to delete a reminder, click “ ” to delete it.

After the setting is completed, click “Save” to open the confirmation interface. Click “ACT” to save and exit, or click “ESC” to return to the setting interface and you can continue

modifying the settings.

After setting the reminder, the BG test reminder interface will display your settings.

If you need to cancel the reminder, click "  " to unselect it;

(2) The setting methods of BG unit and bolus guide are the same as those of the setup wizard. For details, please refer to *4.3 Setting advanced bolus*.

13.3 Infusion settings

(1) **Audio prompt Off:** When the insulin pump starts bolus delivery, completes bolus delivery, suspends or stops bolus delivery, etc., there will be an audio prompt by default. If you don't need it, select the box next to "Audio Prompt Off", then the audio sound will be turned off.

(2) **AUDIO ALARM OFF:** When the insulin pump issues an alarm, there will be an audio alarm signal by default. If you don't need it, select the box next to "AUDIO ALARM OFF", the audio alarm will be turned off.

!CAUTION Please use this function with caution! If the audio alarm is turned off, please pay close attention to the status of the insulin pump to ensure timely identification of the alarm condition.

(3) **Pump auto-off**: Click "Pump Auto-off" to open the setting interface, click "+" or "-" to set the waiting time for auto-off.

The waiting time is zero by default, which means that this function is directly turned off.

Set the waiting time to turn on the function. If you do not operate the insulin pump controller or the insulin pump within the set waiting time, the controller will issue a reminder 15 minutes in advance. If the reminder is not confirmed and the set time is due, the insulin pump will automatically suspend the delivery, the pump and the controller will issue a high priority alarm singal.

!CAUTION The waiting time set by this function is the continuous delivery time of the insulin pump. If the insulin pump is suspended/stopped/not running, this time will not be counted into the set waiting time.

!CAUTION After the pump auto-off, click "  " on the suspended interface to resume basal delivery.

(4) The setting methods of other items are the same as those of setup wizard. For details, please refer to *4 Setup wizard*.

13.4 General settings

Click "General Settings" to open the interface.

(1) **User:**

A. Click “Factory Reset” could restore all settings of the insulin pump controller to the factory defaults.

!CAUTION Please use this function with caution. Once restored to factory defaults, all previous setting data will be lost (except for time and date) and the controller will release the control over the insulin pump. Please record all important settings before reset to factory settings.

B. Self-Check: Click “Pump Self-Test” to perform the insulin pump self- test function.

The self-test function is a safety tool to check whether the insulin pump is working properly. During the self-test, the pump will automatically run an internal test, which includes the checking of the indicator light, vibration and audio alarm.

If the self- test detects an abnormality, please contact the customer service.

!CAUTION The self-test function cannot be performed while running bolus delivery, replacing resv/BAT, and replacing pump.

!CAUTION During the self-test, when an alarm occurs, the self-test will stop immediately, and the alarm information will be displayed on the screen at the same time.

C. Click “More Records” to view the most recent 500 history records.

D. Click “Feedback”, you can feed back your comments or problems. We will contact you as soon as possible through the mobile phone number you entered during login or the mobile phone number/email address you reserved.

(2) About the system

Click “About the System” to view the detailed of the insulin pump and the insulin pump controller APP, including their product name, REF, SN, etc.

14 History record

Click “More” – “History” at the bottom of the main interface to open the history interface (as shown in Figure 14.1).

!CAUTION You can click “ ” on the upper left corner of the interface to return to the previous interface.

Click the arrow beside the date to select the date of the record you want to browse. You can browse the information from different time periods by scrolling up and down.

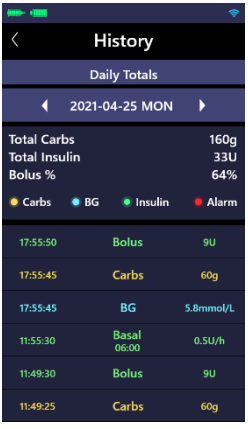


Figure A.12.1

In the middle of the screen, there are four options of “Carbs”, “BG”, “Insulin”, and “Alarm” to be chosen from. The item's information only be displayed if it has been selected. Four items are selected by default. The log is not maintained when the alarm system is powered down and the time of powering down is not captured in the log.

Click “Daily Totals” to browse the latest 30 daily total records.

15 Optimize pump therapy

After you have fully understood insulin pump therapy, you can consider optimizing the therapy with such functions as temp basal, extended bolus, quick bolus, and bolus guide.

The above functions are disabled by default.

!CAUTION AR-B200B and AR-B200D insulin pump do not have extended bolus and bolus guide functions.

!CAUTION For detail of the setting range of parameters, please refer to *Appendix B*.

15.1 Temp basal

When is it needed to set a temp basal?

Due to some special physical conditions, it is necessary to temporarily increase or decrease the basal.

Conditions that can temporarily increase the basal: Physical activity or labor volume greatly reduced compared to usual, gastric paralysis, ingesting food containing a lot of protein or fat, certain diseases, menstrual period, taking certain drugs, and high BG after meals.

Conditions that need to temporarily decrease the basal: Intense exercise, rapid weight loss, climate change, diarrhea, hot baths, sauna, and drinking alcohol.

!CAUTION All other basal are temporarily replaced during the temp basal. After the delivery at temp basal is over, the delivery rate returns to set normal basal. A temp basal can only be delivered once and cannot be repeated. If another is required, it must be reset.

!CAUTION After the reservoir/battery is replaced, the previous normal basal will be running automatically. If temp basal is required, please reset it.

(1) Click "Basal" at the bottom of the main interface to open the basal interface.

Click "Temp Basal" and then click "+" or "-" to set the temp basal (the upper limit is the max basal that has been set) and duration on the pop-up setting interface (as shown in Figure 15.1).

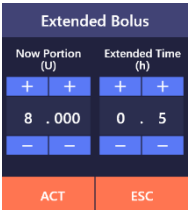


Figure 15.1

The latest temp basal is displayed at the bottom of the interface for your reference.

Click "ACT" to run the temp basal, or

click “ESC” to exit without running it.

!CAUTION If the temp basal is set to 0 U/h and starts running, it is equivalent to suspending the delivery.

!CAUTION Temp basal is off by default. If the “Temp Basal” button is gray, please go to “More” - “Settings” - “Infusion Settings” interface to enable this function.

!CAUTION Please set a suitable temp basal under the doctor's guidance.

(2) After the delivery at the temp basal starts, the status interface will display the current temp basal and the remaining delivery time (as shown in Figure 15.2).

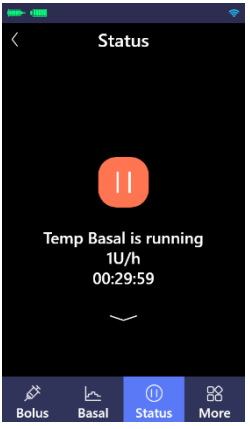


Figure 15.2

(3) If you need to suspend/stop/cancel the temp basal, please click “ ” on the status interface (as shown in Figure 15.2), you can choose to suspend/ stop/cancel the temp basal in the pop-up interface (as shown in Figure 15.3).

- Click “Suspend (Not Rewind)” to suspend the temp basal delivery, then click “ ” could resume it;
- Click “Stop (Rewind)” to stop the temp basal delivery, and it is required to replace the reservoir before automatically running the previous normal basal;
- Click “Cancel Temp Basal”, the pump will automatically run the previous normal basal.

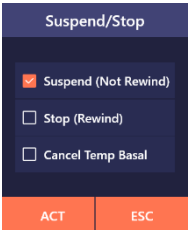


Figure 15.3

(4) After the delivery is completed, the pump will remind you with audio and vibration.

15.2 Extended bolus

What is an extended bolus?

The extended bolus refers to an even delivery of insulin after the now portion over a period of time for conditions of ingesting a mixture of fast-absorbed and slowly-absorbed food. See Figure A 15.4 for the difference between the extended bolus and normal bolus.

If you are only ingesting slowly-absorbed food or need to eat in small amounts over a long period of time, please set the now portion to zero and

deliver the extended portion only.

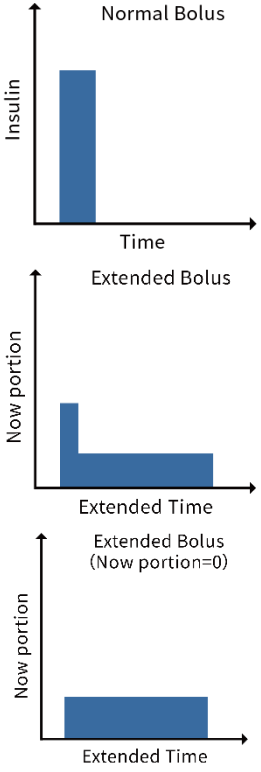


Figure 15.4

(1) Click the "Bolus" function button at the bottom of the main interface to open the bolus interface, then set the total bolus you need. The set method is the same as the bolus setting method, please refer to *7.1 Normal bolus*. When the value is not 0, the "Extended Bolus" button will turn orange.

!CAUTION The extended bolus is disabled by default. If the button is gray, please go to "More" - "Settings" - "Infusion Settings" to enable this function.

Using this function requires you to fully understand how fast the food you eat affects your BG. Please use this function under the guidance of professionals.

!CAUTION AR-B200B and AR-B200D insulin pump do not have extended bolus function.

(2) Click "Extended Bolus", click "+" or "-" to set now portion and extended time in the pop-up interface (as shown in Figure 15.5). Click "ACT" to save and exit, or click "ESC" to exit without saving.

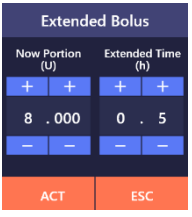


Figure 15.5

Now portion: The bolus value for an immediate delivery, which is related to how much fast-absorbed food you eat.

Extended portion= Total bolus - now portion

Extended time: The duration of extended portion delivery.

!CAUTION If you only take in slowly absorbed foods, or need to eat in small amounts over a long period of time, you can set the now portion to 0 and deliver

only the extended portion.

(3) After the now portion and extended time settings are completed. Click “Start”, the insulin pump controller will send a delivery instruction to the insulin pump and the pump will start delivery. The interface will display the progress of the extended bolus delivery (as shown in Figure 15.6).

(4) During the extended bolus delivery, if you find that the setting is wrong or the meal is interrupted or the food of the meal changes, you need to stop the ongoing extended bolus delivery.

Click “Stop” in the status interface (as shown in Figure 15.6), then click “ACT” in the pop-up confirmation interface to stop the delivery, or click “ESC” to continue the delivery.

!CAUTION After the emergency stop the extended bolus, the basal will also be suspended. To resume the basal delivery, please click “ ” on the status interface.

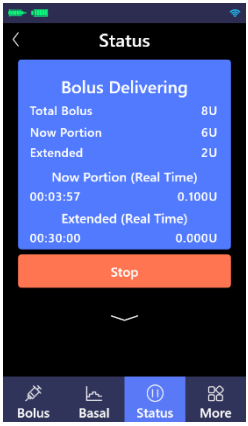


Figure 15.6

15.3 Quick bolus

When you need a bolus delivery without taking an insulin pump controller, you can enable the quick bolus function to complete the bolus delivery with pressing the pump button.

!CAUTION The quick bolus function is disabled by default. Please go to “More” - “Settings” - “Infusion Settings” to enable this function.

!CAUTION All types of bolus, including quick bolus, cannot be performed when the basal is not running.

(1) Press and hold the pump button for about 3 s, the insulin pump will emits an audio prompt (do-re-mi-fa-so), indicating that you can start to set a quick bolus.

(2) Set the bolus with the pump button. Each time the pump button is pressed,

it will play audios in different tones (five tones in total, which will be repeated when pressing for more than five times), indicating an increase of 1 U.

!CAUTION The max quick bolus can only be set to 10 U, and cannot exceed the max bolus you set.

(3) After the setting is completed, wait for 3 s, and the insulin pump will play the audios you set repeatedly. Please confirm whether the setting is correct according to the number of tones. After confirming that it is correct, you can press the pump button immediately, then the insulin pump will start the bolus delivery.

!CAUTION If you find that the setting is wrong, you can wait for 5 s without doing anything, and the insulin pump will automatically exit this quick bolus setting so that you can set it again.

(4) After the bolus delivery is completed, the pump will remind you with audio and vibration.

15.4 Bolus guide

What is bolus guide?

The bolus guide is designed to help keep your BG within a safe range by calculating the bolus you needed with the information you provide.

Before using the bolus guide, you need the following information:

Current BG value: Please test the BG within 10 minutes before the insulin delivery, otherwise the calculation error will be relatively significant.

Target BG range: the BG you need to maintain as determined by the doctor.

Carbs ratio: the number of grams of carbohydrates covered by one unit of insulin, which is adopted to calculate the meal bolus. Please obtain the suitable parameters from the doctor.

Insulin sensitivity: the amount that BG is reduced by one unit of insulin, which can help calculate the insulin that needs to be supplemented in hyperglycemia. Please obtain the suitable parameters from the doctor.

Active insulin time: The bolus guide calculates the active insulin inside your body based on the set active time of insulin. Please obtain this parameter from the doctor.

What is active insulin?

Active insulin refers to bolus insulin that have been delivered into the body and continues to lower BG levels.

Most insulin will be active and available in the body for 4-6 hours, but a small amount of insulin will still remain active for longer. The bolus guide automatically calculates the Active insulin based on the last bolus, time after delivery and active insulin time, and subtracts the corresponding amount from the correction bolus.

!CAUTION The bolus guide is disabled by default. Please go to “More” - “Settings” - “BG Settings” to enable this function, and set the relevant parameters before using the bolus guide.

!CAUTION The bolus guide calculates the estimated bolus according to the parameters you set. Please be sure to set those under the doctor's guidance.

!CAUTION AR-B200B and AR-B200D insulin pump do not have bolus guide function.

(1) Click “More” – “Input BG Value” at the bottom of the main interface to open the input BG value interface (as shown in Figure 15.7), then record the measured BG value through “ ”, “ ”. Click “Save”, the bolus guide function will be activated.

Figure 15.7

!CAUTION Please test the BG within 10 minutes before the delivery of insulin. Otherwise, the calculation error will be relatively significant.

!CAUTION When the BG is lower than 3.9 mmol/L, the body enter a state of hypoglycemia. The insulin pump will display a reminder. You should read the message, then click “ACT” to exit the “Bolus Guide” and monitor BG. Bolus delivery is prohibited before the BG returns to normal.

!CAUTION When the BG is higher than 13.9 mmol/L, the body enter a state of hyperglycemia. The insulin pump will display a reminder. You should read the message, then click “ACT” to continue the bolus guide.

(2) Click “Bolus Guide”, click “+” or “-” to set the amount of carbs in the pop-up interface (as shown in Figure 15.8), then click “ACT”, the system will automatically estimate the bolus, or click “ESC” to stop the bolus guide. The BG value you input will be saved to the history.

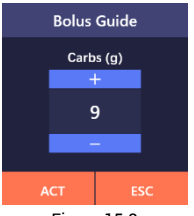


Figure 15.8

!CAUTION You can look up the amount of carbs in food through the food packaging information, books, or the food database that comes with the insulin pump controller.

!CAUTION The amount of food and way to cook can have much effect on its carbs. Knowing the carbs of the food that is frequently ingested is a great help for using this function accurately.

(3) After the settings of the BG value and carbs, the system will automatically estimate the bolus (as shown in Figure 15.9). The information area will display the BG value and carbs you input, as well as the active insulin and estimated bolus calculated by the system. You can click "Details" on the lower right corner to view the calculation process.

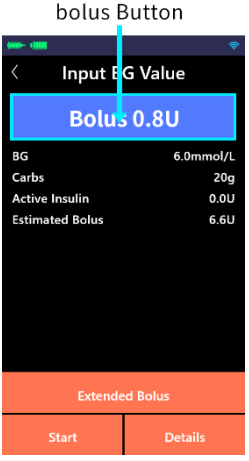


Figure 15.9

Meal bolus = carbs / carbs ratio

A. The BG value is higher than the upper limit of the target BG range:

Estimated bolus = meal bolus + correction bolus - active insulin

Where: correction bolus = (current BG value - upper limit of target BG range) / insulin sensitivity

!CAUTION If (correction bolus - active insulin) is negative, it is calculated as zero.

B. The BG value is within the target BG range:

Estimated bolus = meal bolus

C. The BG value is lower than the lower limit of the target BG range:

Estimated bolus = meal bolus + correction bolus

Where: correction bolus = (current BG value - lower limit of target BG range) / insulin sensitivity

In the Bolus calculation result interface (as shown in Figure 15.9), click "Start" to perform normal bolus delivery. For details, please refer to: 7.*1 Normal bolus*; If you have enabled the extended bolus function, you can also click "Extended Bolus" to perform extended bolus delivery. For details, please refer to: 15.*2 Extended bolus*.

!CAUTION If you believe the estimated bolus is biased, you can click the bolus button on the interface to make changes in the pop-up interface.

16 Alarms and troubleshooting

The insulin pump system has a complete safety inspection mechanism. If any abnormality that needs immediate attention is detected, the system will notify you with audio and vibration, and an alarm interface will pop up on the insulin pump controller.

The insulin pump alarm system indicated technical alarm condition only, without physiological or other alarm condition.

The insulin pump system is a distributed alarm system. The insulin pump controller is the receiving end of the alarm and the insulin pump is the sending end of the alarm.

According to risk analysis, the insulin pump system has high priority alarms and low priority alarms.

A high priority alarm occur means that the delivery of the insulin pump has stopped, requiring the user to operate the pump, replace the pump or take other measures to deliver insulin to control BG; this alarm condition will only occur on the insulin pump, and the pump controller will simultaneously display the alarm after receiving the alarm signal from the insulin pump.

A low priority alarm occur means that the delivery of the insulin pump is not affected in the short term, but the user still needs to pay attention to such information and take relevant measures or preparations in advance to ensure that the pump could be running reliably.

!CAUTION The system cannot issue alarm signal under insulin inactivation or insulin leakage. In such circumstances, user control and observation are required.

!CAUTION If the self-test does not issue alarm signal after starting the insulin pump and the controller, the entire alarm system can be considered as working properly.

!CAUTION The data for all alarms and related settings of this system will be retained after power-off (removal of the battery), and the data will also be retained even the device runs out of power for more than 30 s.

!CAUTION There is only one alarm preset in the alarm system, and the user can restore to factory default settings by operating the insulin pump controller; the

default settings cannot be modified by the user.

16.1 Alarm signals of the insulin pump

Table 16.1 Insulin pump alarm signals

Alarm category	Audio alarm signal	Sound pressure level (dB)
High priority	✓ (Ten consecutive short beeps, repeated every 15 s)	45–85
Low priority	✓ ("Beep, beep". Two continuous short beeps, not repeated)	45–85
Note: (1) The high priority audio alarm signal will continue until the user turns off the alarm. (2) The low priority audio alarm signal will not be repeated. (3) There will be vibration at the same time when the alarm signal is generated to remind the user.		

Table 16.2 Insulin pump alarm list and solutions

Alarm condition	Alarm category	Alarm Signal	Solutions
No reservoir	High priority	Audio	The delivery has stopped. Please replace the reservoir and test the BG in time.
Pump blocked	High priority	Audio	
Pump ERR	High priority	Audio	The delivery has stopped. Please contact customer service and test the BG in time.
Pump no power	High priority	Audio	The delivery has stopped. Please replace a battery that fully charged.
Low reservoir	Low priority	Audio	The remaining reservoir is lower than the set low resv alarm (10-50 U, increment: 1U, default: 20 U). Please have a new reservoir and insulin on hand.
Pump low power	Low priority	Audio	The battery power not great than 10%. Please have a battery that fully charged on hand.

16.2 Alarm signals of the insulin pump controller

Table 16.3 Insulin pump controller alarm signals

Alarm category	Alarm signal
High priority	Vibration
Low priority	Vibration
Note: (1) Please enable vibration function of your phone to ensure identification of the alarm signal of the insulin pump controller. (2) At the same time as the alarm is generated, the interface of the insulin pump controller will display the alarm condition reminder. (3) Please enable the notification permission of the insulin pump controller APP, so that the insulin pump controller can pop up alarm notifications when running in the background.	

Table 16.4 Insulin pump controller alarm list and solutions

Alarm condition	Alarm category	Alarm Signal	Solutions
No reservoir	High priority	Vibration	The delivery has stopped. Please replace the reservoir and test the BG in time.
Pump blocked	High priority	Vibration	
Pump ERR	High priority	Vibration	The delivery has stopped. Please contact customer service and test the BG in time.
Pump no power	High priority	Vibration	The delivery has stopped. Please replace a battery that fully charged.
Low reservoir	Low priority	Vibration	The remaining reservoir is lower than the set low resv alarm (10-50 U, increment: 1U, default: 20 U). Please have a new reservoir and insulin on hand.
Pump low power	Low priority	Vibration	The battery power not great than 10%. Please have a battery that fully charged on hand.

16.3 Multiple alarm condition rules

When multiple alarm conditions occur, the alarm signals are issued according to the following rules:

(1) When multiple alarm conditions of different priority presented at the same time, the alarm signal is consistent with the highest priority.

(2) When multiple alarm conditions of different priority presented at the same time, there will be a pop-up interface for high priority alarm item. The pop-up interface for low priority alarm item will only be displayed after clicking “ACT” to close the current interface.

(3) When multiple alarm conditions of same priority presented at the same time, there will be a pop-up interface for most recent alarm item. The pop-up interface for previous alarm item will only be displayed after clicking “ACT” to close the current interface.

16.4 Alarm handling rules

Under normal working conditions, when an alarm occurs, all the alarm signal of the insulin pump will display corresponding reminders according to the alarm category.

When a high priority alarm occurs, the insulin pump will stop all delivery-related activities. When a low priority alarm occurs, the delivery will not be affected in the short term.

When a high/low priority alarm occurs, the content of the alarm condition will be displayed in the pop-up interface on the screen of the insulin pump controller. When the Bluetooth connection is normal, click “ACT” or tap the pump button to turn off the alarm. If the Bluetooth is disconnected, click “ACT” to turn off the alarm of the insulin pump controller only; tap the pump button to turn off the alarm of the insulin pump only.

16.5 Alarm system delays

Alarm systems has inherent delays.

(1) The delay caused by alarm system processing and averaging is ≤ 0.1s.

(2) The delay caused by the communication time between the alarm system of the insulin pump to the alarm signal generating device is ≤ 0.1s.

(3) The wireless transmission delay from the insulin pump sending an alarm to the insulin pump controller receiving the complete alarm is ≤ 4s.

(4) The delay caused by the communication between the alarm system of the insulin pump controller and the signal generating device is ≤ 0.1s.

This system is a distributed alarm system, where the delay time from the onset of

the alarm condition to the point that the representation of the alarm condition leaves the signal output part is ≤ 0.2s, and the maximum delay of the controller receiving the remote alarm condition from the insulin pump is ≤ 4s.

17 Quality Features

Quality	Features
Functional Suitability	According to the Instruction Manual, you can deliver basal, temp basal, normal bolus and extended bolus, suspend/stop delivery, use settings function, bolus guide, and food database, as well as view alarm information and history.
Performance Efficiency	The server can process 1,500 user login requests per minute. After you turn on the Bluetooth on the mobile phone with the insulin pump controller installed, the maximum delay of data transmission between the phone and the insulin pump will not be no more than 4 s if there are no obstacles (such as walls, floors, metal plates or human bodies) and the distance is not farther than 2 meters.
Compatibility	When the APP is running, it will not consume more than 250MB of the mobile phone's CPU. When the APP is running, it does not affect any normal use of Twitter, Youtube, Tiktok and other APPs. The historical records can be exported to the mobile phone after the customer service staff enters the maintenance password.
Usability	The instruction manual features texts supplemented by graphics and is well-hierarchized and easy to understand. The colorful interface, clear writing, and reasonable logic will allow users to quickly find common operating buttons. Contraindications are specified in the Instruction Manual. When the APP is activated, “Insulin Pump Controller” will be displayed at the bottom of the interface. The instruction manual has fully considered most possible application scenarios of the user. For some operations, such as deleting a basal or performing factory reset, there will be a pop-up window to remind the user, and the user can click “ESC” to cancel the operation if there is any mistake. When the Bluetooth connection times out or fails, there will be a pop-up window to reminder the user.
Reliability	If the insulin pump alarms when the Bluetooth is disconnected, the insulin pump controller APP will display the alarm interface

	after reconnection. For some risky operations, such as deleting a basal or performing factory reset, there will be a pop-up window to reminder the user and the operation will be executed only after the confirmation from the user. If the insulin pump controller APP crashes, the software data can be restored after the insulin pump is re-connected.
Security	Unauthorized mobile numbers will not be able to receive verification codes. APP login access will be denied if an incorrect or expired verification code is entered. History record cannot be altered or edited.
Maintainability	The “About the System” interface will display details about the insulin pump and the insulin pump controller APP. When an abnormality such as an alarm condition or Bluetooth disconnection occurs, the interface will display relevant information. After the insulin pump controller release its control over the old pump, other insulin pumps can be connected. The insulin pump controller includes four functional modules: basal, bolus, status, and more.
Portability	The APP can be installed and upgraded only when the software and hardware of the mobile phone meet the requirements.

18 Cybersecurity information

18.1 Limit access

Limit access to devices through the authentication of users (Authorized phone number and verification code)

18.2 Date interfaces

Date interfaces: Bluetooth version 4.2 or above.

The data protocol of the communication is a private protocol, and encrypt the transmitted data.

18.3 Operating environment

(1) iOS

Hardware:

CPU: Dual-Core or above

Disk space: 1GB or above.

RAM: 1GB or above.

Network: WAN

Software: the version of the iOS system is 15.0 or above.

(2) Android

Hardware:

CPU: Dual-Core or above.

Disk space: 1GB or above.

RAM: 1GB or above.

Network: WAN

Software: the version of the Android system is 11 or above.

Appendix A Maintenance

The insulin pump is a precision instrument. Improper use or storage will lead to reduced accuracy or even malfunction. Please read this chapter carefully and maintain your insulin pump according to the methods mentioned in this chapter.

A.1 Cleaning

Insulin pump cleaning

- Use a soft cotton ball soaked in an appropriate mild detergent solution to clean the exterior surface. If necessary, wipe off the excessive detergent with a dry cloth.
- Use medicinal alcohol to wipe and disinfect.
- Do not use lighter oil, nail polish remover, or paint thinner to wipe the surface.
- Keep your insulin pump dry and avoid getting wet.
- Do not use any lubricant.
- It is recommended to clean once every two months, and increase the maintenance frequency when necessary.
- This product is intended for individual patients when used in the housing environment. When used in medical institutions, it may be used for multiple patients, but before the next patient uses the product, it needs to be cleaned and disinfected with medical alcohol.

A.2 Avoiding extreme temperatures

Avoid placing the insulin pump or the controller in an environment with temperatures above 40℃ or below 0℃.

Insulin will freeze at around 0℃ and spoil at high temperatures, so when you go outside in cold weather, the insulin pump needs to be covered with warm clothing. In a warmer environment, measures must be taken to cool the pump and insulin.

A.3 Avoiding immersing the insulin pump in water

The pump' protection against the ingress of water is classified IP56. Do not immerse it in water during bathing, swimming, or other water activities. If the insulin pump is immersed in water, it may malfunction.

A.4 X-rays, MRIs, and CT scans

If X-rays, MRIs, CT scans, or radiographic inspection of other types are required, the insulin pump must be removed from the body, and the pump and controller must be kept outside the radiation field.

A.5 Precautions

Although there are several kinds of safety alarms for the insulin pump, it cannot detect leakage in the infusion set, detachment of the soft cannula, or failure of insulin. Thus, the BG must be checked at least four times a day. If the BG exceeds the target range, check the insulin pump and infusion set to ensure that necessary dose of insulin is delivered.

A.6 Wireless connection

In this system, the insulin pump and the insulin pump controller communicate wirelessly. When the insulin pump controller APP sends new commands to the insulin pump or transmit data, the distance between the insulin pump and the insulin pump controller should be no more than two meters.

The distance for wireless communication is closely related to the environment. In actual use, please pay attention to the following points to ensure a long-distance and reliable wireless connection.

- The insulin pump is properly installed with battery charged.
- There are no obstacles between the phone with the insulin pump controller APP and the insulin pump, such as walls, floors, metal plates, human bodies, etc.
- Clothes near the insulin pump should have less metal objects.
- Stay away from areas with strong electromagnetic radiation.
- Try not to place portable or mobile RF communication devices close to the insulin pump controller or the insulin pump. Even if other devices meet the emission requirements of the corresponding national standards, the pump system may still be interfered by other devices.

The signal strength of the wireless connection can be seen through the status bar of the insulin pump controller. The stronger the signal strength, the faster the command or data transmission will be, and the shorter the waiting time. Before using the insulin pump controller to set or control the insulin pump, please observe whether the wireless signal is good. Weak or no signal may cause command transmission to fail.

!CAUTION If the signal is weak or there is no connection, please check according to the above five items, and try to shorten the distance between the insulin pump and the mobile phone installed with the insulin pump controller APP. If the signal is still weak or there is no signal, please contact the customer service.

A.7 Environmental protection

When you replace it with a new insulin pump or its accessories, please do not throw away the old product or

accessories at will. Please refer to the local waste recycling requirements to recycle the waste, and do not treat the device waste as unsorted municipal waste.

When the battery reaches its service life, it should be scrapped. Scrapped batteries cannot be discarded at will. Improper disposal may cause the danger of fire or chemical burns. Please hand them over to a specialized recycling company in accordance with local laws, regulations, and environmental protection requirements.

A.8 Transportation

Please avoid heavy pressure, direct sunlight, and rain during transportation.

A.9 Storage

If the pump is not used for a short while, please store it in a cool, dry, clean, well-ventilated, and corrosion-free environment.

If the pump is not used for a long time, in addition to the above conditions, please store the battery separately from other components.

A.10 Circuit diagram and component list

This product is a precision instrument. If it fails, it can only be returned to the manufacturer for repair. Third-party individuals or institutions are not allowed to repair it. The circuit diagram and key components list are not provided in the manual.

A.11 APP upgrade

The user will be contacted by customer service personnel for guided application upgrade. The software upgrade uses the https protocol to send requests to the server and receive the file transport stream; the file format is apk.

- Android operating system: Click “More” - “Settings” - “System Maintenance” at the bottom of the main interface, enter the maintenance password (provided by customer service personnel), and open the system maintenance interface. Click “Software upgrade” to open the software upgrade interface, then click “Check for upgrade”. The interface will remind “New Version Found” when a new version is detected. Click “Download and Install” to complete the application upgrade.
- iOS operating system: Search for “AR-B200” in the APP Store; download the “AR-B200” application and install it.

A.12 Battery

If the rechargeable battery is idle for a long time, the battery will be damaged due to low power. Make sure to fully charge it at least every three months.

If the lithium battery is idle for long time, the battery will be damaged. Please unload the pump battery and store it separately and make sure to fully charge it at least every three months.

Appendix B Specifications

B.1 General Specifications

Specifications	Insulin Pump
Model	AR-B200A, AR-B200B AR-B200C, AR-B200D
Dimensions	51.0*40.1*18.0 mm
Weight	26 g (without battery and insulin)
Reservoir volume	3 mL
Operating temperature	3-40℃(37-104℉)
Operating humidity	10-95%(non-condensing)
Operating atmospheric pressure	700-1060 hPa
Temperature for storage and transportation (Ex-factory packaging)	-40~55℃
Humidity for storage and transportation (Ex-factory packaging)	5-95%(non-condensing)
Temperature for storage and transportation (Non-factory packaging)	-25~55℃ Note: Before storage and transportation, the push rod should be rewound and the battery should be removed, then seal the pump with anti-impact materials such as foam cotton. Before use again, device must reach 3 to 40 ° C. The time required for the device to warm from -25° C until the device is ready for its intended use is 1 h when the ambient temperature is 20 °C; The time required for the device to cool from 55° C until the device is ready for its intended use is 1 h when the ambient temperature is 20 °C;
Humidity for storage and transportation (Non-factory packaging)	5~90% (non-condensing)
IP code	IP56
Alarm signal	Audio, vibration
Memory storage	With built-in memory storage

	(The earliest record is automatically overwritten when the memory is full)
Display screen	No
Battery capacity	120 mAh
Service life	5 years
Pump battery life	The battery life of a fully charged new pump battery is ⩾ 12 days when the insulin pump is running at 1U/h The battery life of a fully charged new pump battery is ≥24 h when the insulin pump is running at 35U/h.
Threshold of low resv alarm	10-50 U, increment: 1 U,20 U by default
Waiting time for pump auto-off	0-24 hours, increment: 1 hour, 0 by default, meaning this function is disabled.
Electronic memory retention time after shutdown	All records and settings of this system will not be lost in the event of power failure.
Frequency band and bandwidth for wireless receiver	Frequency band: 2400~2483.5 MHz Bandwidth: 1 MHz
Modulation type for wireless transmission	GFSK
Effective radiated power for wireless transmission	⩾20dBm

B.2 Infusion specifications

Specifications	Parameters
Basal	0-35 U/h, increment: 0.025 U/h
Basal preset	Three presets, each with up to 48 periods to be set.
Max basal	0.1-35 U/h, 2.0 U/h by default
Temp basal	Turn-on and turn-off, turn-off by default
Bolus	0.025-25 U
Bolus increment	0.025/0.05/0.1/0.5/1 U, 0.1 U by default
Single bolus	0.025/0.05 U available, 0.05 U by default
Max bolus	1-25 U, increment: 1 U, 10 U by default
Extended bolus (Only for AR-B200A and	Turn-on and turn-off, turn-off by default Extended time: 0.5-8 h, increment: 0.5 h

AR-B200C insulin pump)	
Quick bolus	Turn-on and turn-off, turn-off by default
Quick bolus increment	1 U by default

B.3 Bolus guide specifications (only for AR-B200A & AR-B200C insulin pumps)

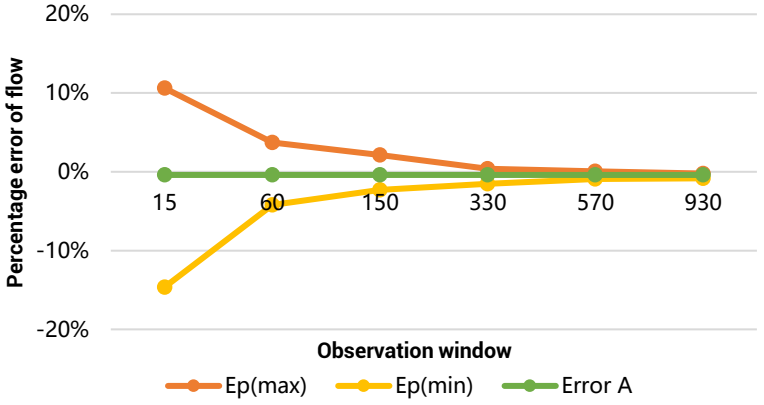
Bolus guide	Turn-on and turn-off, turn-off by default
Target BG range	4.4-8.9 mmol/L, increment: 0.1 mmol/L
Carbs ratio	3-75 g/U, increment: 1 g/U
Insulin sensitivity	0.5-13.9 mmol/L/U, increment: 0.1 mmol/L/U
Active insulin time	2-8 hours, increment: 1 hour
Bolus guide	Turn-on and turn-off, turn-off by default

B.4 Bolus delivery

Insulin delivery increment	The interval between stroke deliveries/strokes
0.025/0.05 U, 0.05 U by default	2 s

B.5 Delivery accuracy

At a set rate of 1 U/h, the measured overall percentage error is -0.4%, as shown below:



B.6 Infusion pressure

Maximum Infusion pressure and occlusion pressure levels at 130kPa.

B.7 Occlusion

When an occlusion is detected, a pump blocked alarm will be issued. The length of the infusion set will affect the time and infusion volume for activation of the occlusion alarm. In general, if the infusion set is longer, the time for activation of the occlusion alarm will be slightly longer and the infusion volume for activation of the occlusion alarm will be slightly larger. The infusion volume for activation of the occlusion alarm reaches an average of 2.3 U.

The table below illustrates three kinds of time for activation of the occlusion alarm in using U-100 insulin.

Speed	Typical Alarm Time	Maximum Alarm Time
Bolus (1.5 U/min)	92 s	140 s
Basal (1 U/h)	138 min	3.8 h
Basal (0.025 U/h)	92 h	154 h

The unintended bolus is not more than 0.25 U under the delivery rate of 1 U/h.

B.8 Overinfusion and underinfusion

This system is designed with dual protection measures to prevent overinfusion or underinfusion. An encoder is set on the insulin pump motor, which can accurately count the number of revolutions of the motor. When a single fault leads to the number of revolutions of the motor being greater or less than the set value, the insulin pump system will issue an alarm signal and stop the delivery automatically. In addition, the insulin pump has a built-in sensor to detect the pressure. The pressure will automatically trigger an alarm and stop the delivery when the pressure exceeds a preset value. The above two methods can effectively avoid Overinfusion or underinfusion.

The maximum volume that may be infused under SINGLE FAULT CONDITIONS is 0.25 U.

B.9 Electromagnetic compatibility specifications

This device needs special precautions regarding electromagnetic compatibility

(EMC) and must be used according to the EMC instructions provided in the manual. The device may be subject to the impacts of portable and mobile RF communication equipment.

The cables and accessories provided with this device must be used, of which the cable information is as follows:

Name	Length	Shielded or Not	Remark
Charging cable of the pump battery	0.6 m	Yes	EUT DC 5 V

The use of accessories and cables (transducers) other than those specified, with the exception of cables (transducers) sold by the manufacturer as spare parts for internal components, may result in increased emissions or decreased immunity of the device or system.

The device or system should not be used adjacent to or stacked with other equipment. If so, this device and the other equipment should be observed to verify that they can work properly under the configuration.

The essential performance:

In bolus infusion mode, the infusion accuracy is within the range of ±5%. Its essential performance can meet the requirement, the occlusion and alarm function is normal.

Table C.9.1 EMC Test Results Summary

Test Items	Compliance Level
Conducted Disturbance	CISPR 11 Group 1 Class B
Radiated disturbance	CISPR 11 Group 1 Class B
Harmonic current	IEC 61000-3-2 Class A
Flicker	IEC 61000-3-3
ESD Immunity	±8kV contact discharge, ±2,±4,±8,±15kV air discharge
Radiated Electromagnetic Field Immunity	80 MHz – 2,7 GHz, 10V/m, 1 kHz, 80% AM Table 9 of IEC 60601-1-2:2014+AMD1:2020
EFT Immunity	±2kV for power supply lines ±1kV for signal lines and control lines
Surge Immunity	±0.5,±1kV differential mode ±0.5,±1,±2kV common mode
Conducted Immunity	3V 6V at ISM bands
Voltage dips and interruptions Immunity	0% U_T for 0.5 cycle At 0°,45°,90°,135°,180°,225°,270° and 315°
	0% U_T for 1 cycle Single phase: at 0°
	70% U_T for 25 cycles Single phase: at 0°
	0% U_T for 250 cycles
Power Frequency Magnetic Field	30A/m
ME EQUIPMENT and ME SYSTEMS identification, marking and documents	clause 5

B.10 FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.
—Increase the separation between the equipment and receiver.
—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
—Consult the dealer or an experienced radio/TV technician for help.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference
(2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

!CAUTION Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Appendix C Reference

C.1 Glossary

Terms	Definitions
U100-insulin	It refers to insulin of 100 units per milliliter, where 1 unit means 1 U.
Active insulin	Active insulin refers to bolus insulin that have been delivered into the body and continues to lower BG levels.
Active insulin time	The bolus guide will calculate the active insulin based on the set active insulin time. Please obtain the parameter from the doctor.
Basal	It refers to the amount of insulin required without meals, simulating the trace amounts of insulin secreted by normal pancreas without meals to maintain the target BG. Please get the suitable parameter from your doctor.
Max basal	It is used to limit the maximum basal value that can be set to reduce any faulty excessive delivery.
Temp basal	It is used when the basal needs to be temporarily increased or decreased. Please set a suitable temp basal under the doctor's guidance.
Bolus	It refers to the single rapid insulin delivery before a meal maintains the target postprandial BG range.
Max bolus	It is used to limit the maximum bolus value that can be set to reduce any faulty excessive delivery.
Extended bolus	It refers to an even delivery of insulin after the now portion over a period of time for conditions of ingesting a mixture of fast-absorbed and slowly-absorbed food.
Now portion	It refers to the bolus value immediately delivered in extended bolus mode, which is related to the amount of fast-absorbed food you ingest.
Extended portion	It refers to an even delivery of insulin over a period of time in extended bolus mode. Extended portion= Total bolus - Now portion
Extended time	It refers to the duration of extended portion delivery in extended bolus mode.
Quick bolus	When you need to deliver bolus without taking the insulin pump controller, you can enable the quick bolus function and then

	complete the bolus delivery with pressing the pump button.
Bolus guide	It refers to the function of the insulin pump that adopts the information you enter to calculate the bolus you need for supporting meals or correcting hyperglycemia.
Target BG range	It refers to the blood glucose level you need to maintain as determined by your doctor.
Carbs ratio	It refers to the number of grams of carbohydrates covered by one unit of insulin, which is adopted to calculate the meal bolus. Please obtain the suitable parameters from the doctor.
Insulin sensitivity	It refers to the amount that BG is reduced by one unit of insulin, which can help calculate the insulin that needs to be supplemented in hyperglycemia. Please obtain the suitable parameters from the doctor.

C.2 Symbols

	Catalogue number
	Date of manufacture
	Manufacturer
	Use-by date
	Batch code
	Serial number
	Authorized representative in the European Community
	Marking of conformity
	Indicates the item is a Medical Device
	Prescription only (United States only)
	Caution, with reference to the attached documents
	General warning sign

	Non-ionizing radiation
	Please refer to User Manual
	Follow instructions for use
	Type BF device (protection against electric shock)
IP56	Insulin pump is dust-proof and resistant to strong water spray.
	Fragile, handle with care.
	Upward
	Recyclable
	Do not discard at will.
	Keep dry.
	Protect from heat and radioactive sources
	Do not re-use (Suitable for insulin pump consumables)
	Magnetic Resonance (MR) Unsafe: keep away from magnetic resonance imaging (MRI) equipment
	Recycle: Electronic Equipment
	For Indoor Use Only (Applicable to Receiver Charger)
	Class II Equipment
	Input

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