EN

Anydana

USER'S GUIDE

Ubiquitous InsulinPump System

Warning

Read this user's guide thoroughly before using the AnyDANA Application. The Application is designed to change the settings within the Insulin Pump and to control and administer bolus dosages. Incorrect or inappropriate usage could lead to adverse blood glucose levels. Thoroughly understand proper usage by reading the entire 'Manual' and consult with a healthcare professional before usage.

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1. Introduction

1.1 General Information

AnyDANA is a Mobile Phone Application paired with the DANA insulin pump. AnyDANA-A is for Android based device and AnyDANA-i is for iOS based device.

The main functions of AnyDANA:

1. Adjusting the settings within the **DANA Diabecare** insulin pump.

   - ✓ Basal profile
   - ✓ Bolus rates including CIR and CF rates
   - ✓ Personalizing the insulin pump User Options
   - ✓ Setting time

2. Review the data and history stored in the **DANA Diabecare** insulin pump

   - ✓ Bolus and Basal history, daily totals, Alarms, suspend history, etc.
   - ✓ BG history from within the insulin pump

1.2 Indications for Use

The **DANA Diabecare** Insulin Pump and AnyDANA Application are intended for the subcutaneous delivery of insulin for the treatment of diabetes mellitus.

Warning This software is to be used under the supervision of a healthcare professional. Any user should receive training from a certified diabetes educator and/or insulin pump trainer prior to using the AnyDANA Application.

Notice The insulin pump refill and prime function is only available from within the insulin pump menu. For safety reasons, the connection between the smart-phone and the insulin pump is temporarily disconnected during the refill and prime process.

1.3 Contradiction

Insulin Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms.

1.4 Potential Risks

- Discomfort
- Hypoglycemia
- Hyperglycemia
- Possible hypoglycemia(low blood glucose) from over-delivery of insulin due to a Mobile software error
- Hyperglycemia (high blood glucose) and ketosis have the potential to lead to diabetic ketoacidosis (DKA) due to a mobile software error, resulting in interrupted or under-delivered insulin delivery.

1.5 Explanation of Warning Symbols

Warning Indicates the presence of a hazard, which can cause severe personal injury, death or substantial property damage if the warning is ignored.

Caution Indicates the presence of a hazard, which will or can cause minor personal injury or property damage if the warning is ignored.

Notice Advises the user of installation, operation or maintenance information that is important but not hazards related.

1.6 Explanation of Universal Symbols

On the packaging and the type plate of AnyDANA, there are the following symbols:

	Medical Device
	Follow instructions for use.
	Caution; consult accompanying documents.
	Manufacturer.
	Authorized Representative in the European Community.
	CE Marking
	Importer

1.7 Precautions

1. AnyDANA can be downloaded from the **Google Play Store** or **App store**. Install AnyDANA on a compatible Device. As required or when prompted from the Google Play Store/App Store always update the software.
2. Before using this software, the insulin pump must be paired with the compatible device. After the initial pairing process, it does not need to be repeated unless the device is changed.
3. The insulin pump and device should be within a 5-meter range for reliable use. Ensure that the Bluetooth function on the device is working properly.
4. To maintain safety a password is required to connect AnyDANA. Take care not to reveal or forget this password.
5. Contact the local insulin pump distributor if any problems are noticed with the AnyDANA Application.
6. Any users of the AnyDANA Applications should have a good prior knowledge of insulin pump use before using the Application. If the device battery is low or in case of Bluetooth error, it will be necessary to resume usual function from the insulin pump menu.
7. Users require good vision and hearing to acknowledge any Application alarms.
8. The Application should be turned off when it is not in use.
9. Required Specification:

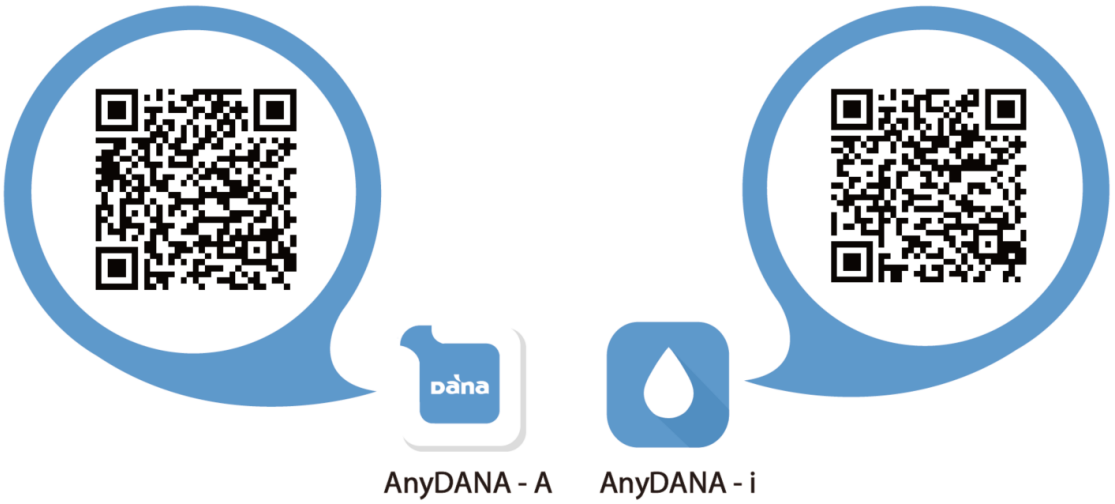
ENVIRONMENT	RECOMMENDED REQUIREMENT	
	AnyDANA-A	**AnyDANA-i**
Applied version	Version 3.0.X	Version 3.0.X
OS	Android 4.3 (Jelly Bean) or Later	iOS 9.0 or Later version
Resolution	xhdip, xxhdip, xxxhdip or higher	-
Memory	512MB or Higher	-
Interface	Touch screen	
Telecommunication	Bluetooth	

SOOIL has tested this software using a Samsung Galaxy Smart-Phone and iOS 9.0+ device.

2. The Paring and Connection

2.1 Download and Installation of Application

This application is available in the Google Play Store/App Store according to the device. Search for "AnyDANA-A/AnyDANA-i" or "AnyDANA" for installation on Devices. Also you can even download the application by scanning the following QR code. Once the download and installation has successfully finished, the icon below will appear on the device screen.



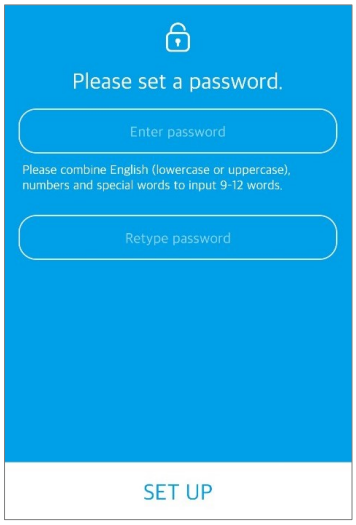
Notice Insulin pump and AnyDANA Mobile Application are connected via Bluetooth communication. Before using the AnyDANA Application, ensure that Bluetooth is enabled within the General Settings menu on the device.

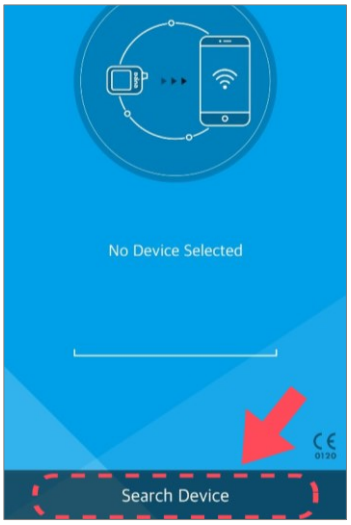
Settings > Bluetooth > "ON"

2.2 Pairing Procedure

The AnyDANA Application connects to the insulin pump using a Bluetooth connection.
BT devices must first be paired with cross checking.
Follow this process to pair devices for the first time.

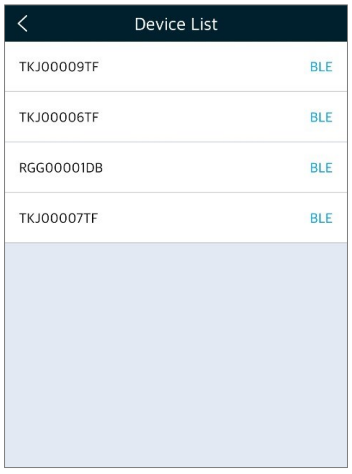
➢ Pairing to Diabecare DANA–i

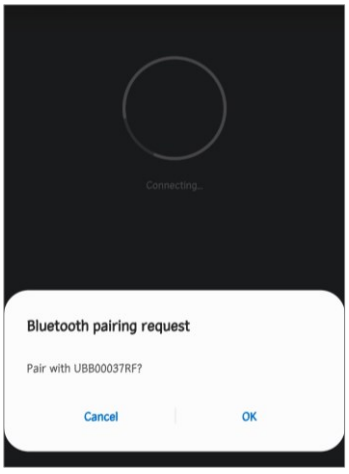




1. Open AnyDANA on the smart-phone. Set the password to run the application.

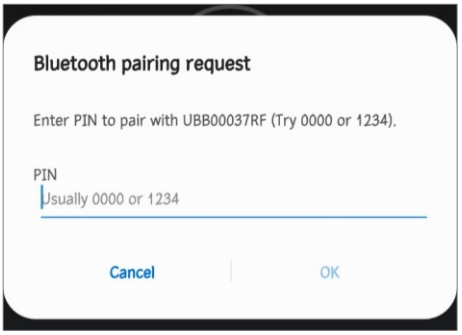
2. Press "Search Device" on the Initial screen.



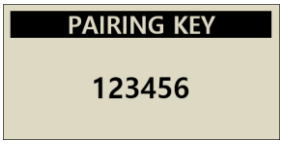


3. From 'Device List', select the pump serial number you want to connect.

4. Select "OK" to request the passcode. Press "OK" on the pump screen to confirm pairing.



5. Enter the pairing key shown on the pump screen.



Below Notes are common to DANA-i and RS.

Notice The 9~12-digit application password can include alpha, numerals, and special characters.

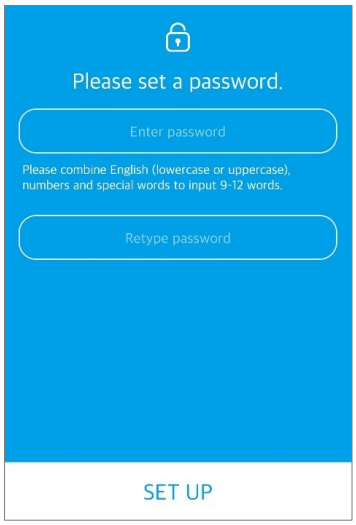
Notice The password entry screen appears at each connection.

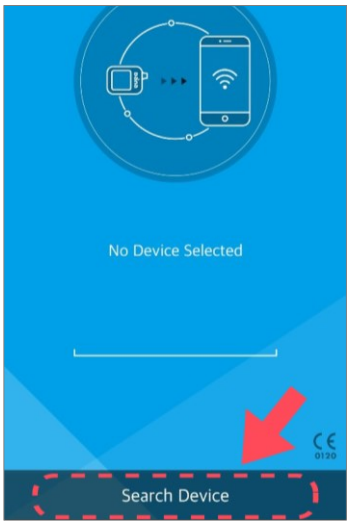
Notice The password entry screen appears by using another app on your smartphone and then running AnyDANA again.

Notice If you forget your password, you can reset your password by deleting and reinstalling the app.

Notice If the pairing is not possible when connecting through the device search button on the initial screen, click the icon to select a pump and connect. (Android version only)

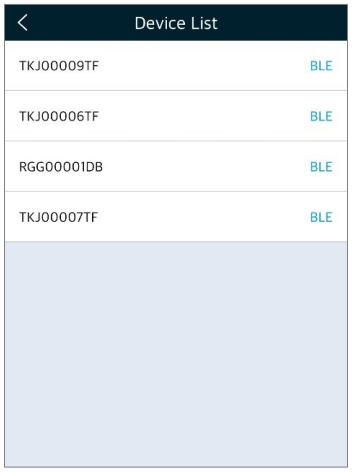
➢ Pairing to DANA Diabecare RS

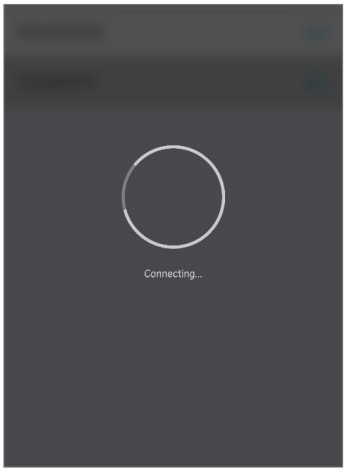




1. Open AnyDANA on the smart-phone. Set the password to run the application.

2. Press "Search Device" on the Initial screen.

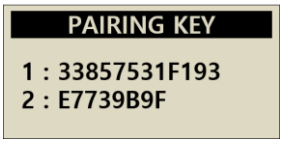




3. From 'Device List', select the pump serial number you want to connect.

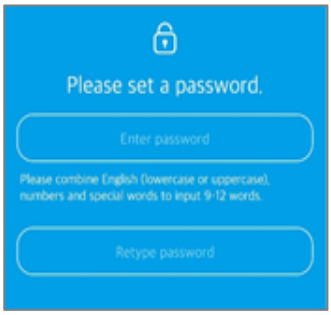
4. Select "Yes" to request the passcode. Press "Ok" on the pump screen to confirm pairing.

5. Enter the pairing key 1 and 2 shown on the pump screen.



➢ Pairing to DANA Diabecare R

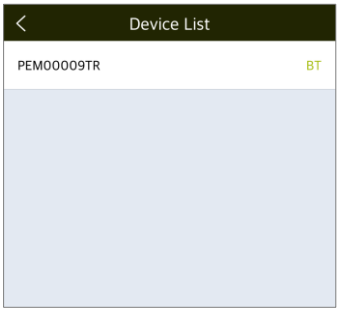
Notice Only AnyDANA-A (Android Device) can communicate with DANA Diabecare R Insulin Pump. AnyDANA-i (iOS Device) cannot connect with DANA R Pump.

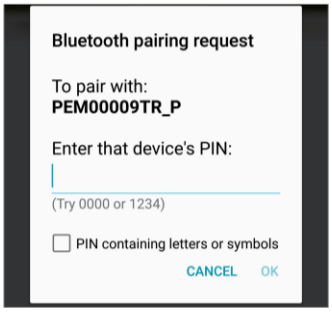


1. Open AnyDANA on the smart-phone.
   Set the password to run the application.

2. Press **"Search Device"** on the Initial screen.

3. At the same time as point 2, switch on the search mode **(main menu> Settings> Discovery)** on the Dana R pump.



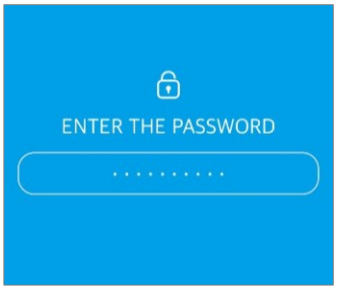


4. Check the device list within AnyDANA-A. Select the Dana R pump serial number.

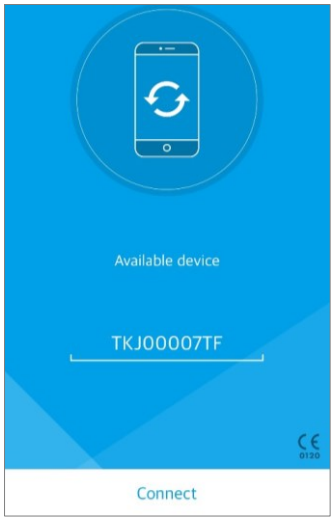
5. Bluetooth pairing request will open. Enter the 4-digit number ('0000' or '1234').

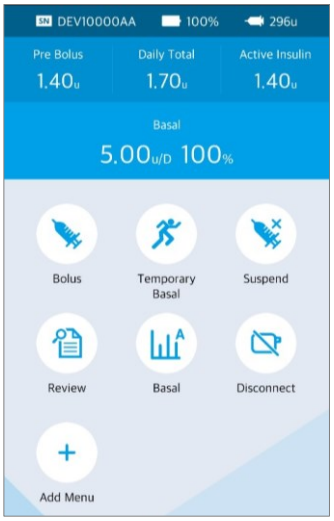
6. The AnyDana-A start screen is the displayed.

2.3 Connection Procedure



1. When the AnyDANA is opened, the ENTER THE PASSWORD screen will be shown.
2. Input the correct password.



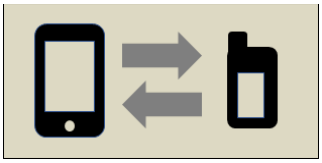


3. Press the "Connect" button.
4. Main menu is displayed.

Notice

- If the App password (Biometric) is wrong more than 5 times, password input restriction for 30 seconds occurs, and if it is wrong more than 5 times while connected to the pump, it is disconnected from the pump.
- If the above situation is repeated, the biometric function will be unlocked by entering the smartphone device password.

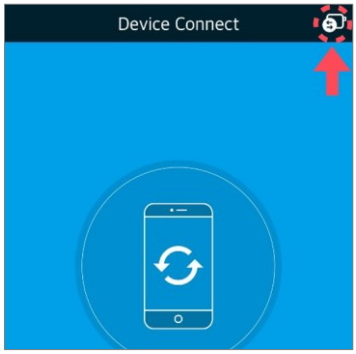
Notice While the pump connects to AnyDANA, the Insulin pump (except DANA R) shows the image below and all actions are only available from the application.

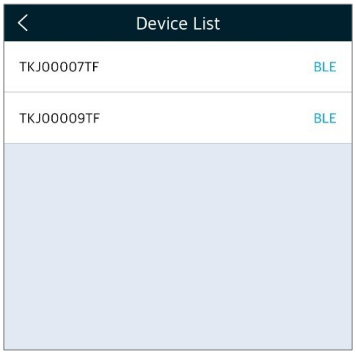


2.4 Change the Connection Pump

To connect to another pump, refer to the following procedure:

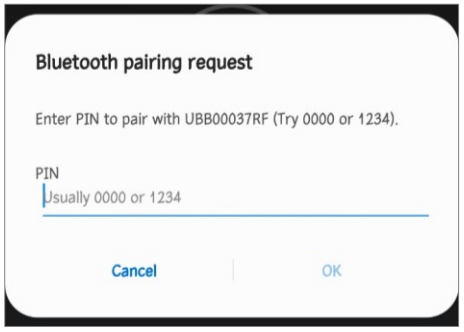
➢ Diabecare DANA-i





1. Press icon in the upper right corner of the initial menu to open the device list.

2. All pairable pumps are displayed within the device list. Select the desired pump.

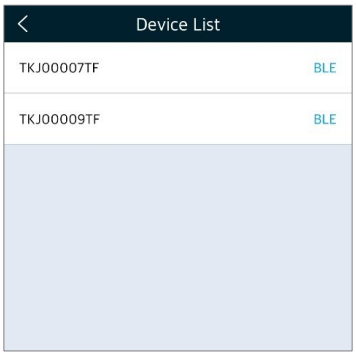


3. Press OK on the pump screen to confirm pairing.

4. If the pairing is confirmed within the pump, the pairing key screen will be displayed.

5. Enter the pairing key shown on the pump screen.

➢ DANA Diabecare RS



1. Press icon in the upper right corner of the initial menu to open the device list.

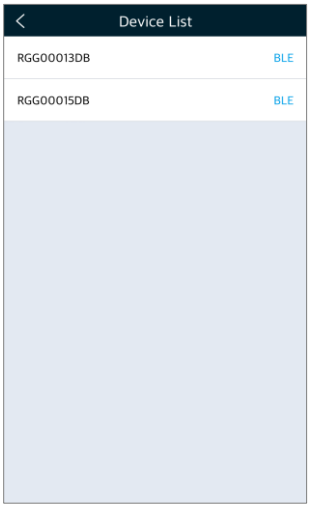
2. All pairable pumps are displayed within the device list. Select the desired pump.

3. Press OK on the pump screen to confirm pairing.

4. If the pairing is confirmed within the pump, the pairing key screen will be displayed.

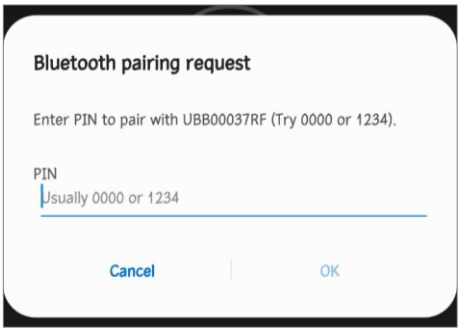
5. Enter the pairing key 1 and 2 shown on the pump screen.

➢ DANA Diabecare R



1. Press icon in the upper right corner of the initial menu to open the device list.

2. All pairable pumps are displayed within the device list. Select the desired pump.



3. If the pairing is confirmed with the pump, the pairing key input screen is displayed on the app.

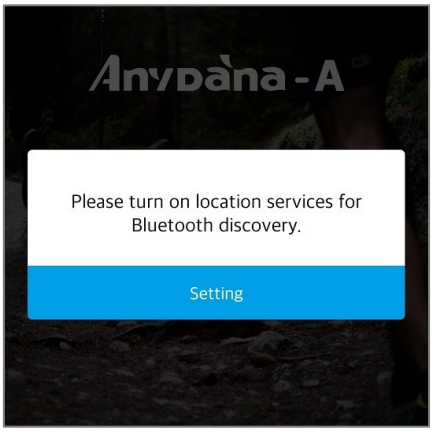
4. Enter AnyDANA password that is already set on the pump.

Caution Do not connect to any insulin pump other than the one intended to be controlled and accessed.

2.5 Solution for Connection errors

➢ Setting on Location (Android version 9 higher)

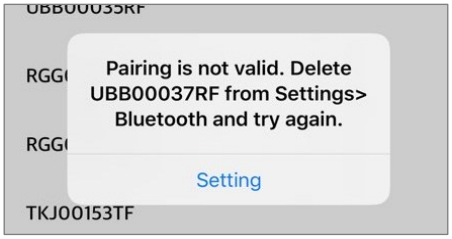
If the location service is off, the pump cannot be searched.

	1. If location service is off, the location service setting screen appears when running app 2. Press "Setting" on the Pop-up screen.
	3. Set location "on"

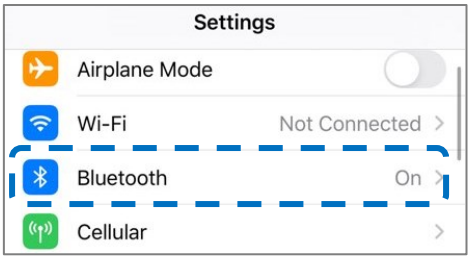
If the user turns off location service while using AnyDana-A, the location service setting window appears.

➢ Bluetooth Connection (iOS)

If an error occurs when connecting the insulin pump to a smartphone, you can solve it in the following ways.

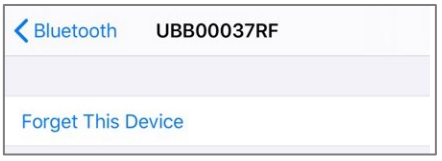


1. When selecting the serial number of the pump you want to connect from the device list, the following screen will appear. Press the set button.



2. When the smartphone's settings window opens, tap the Bluetooth button.

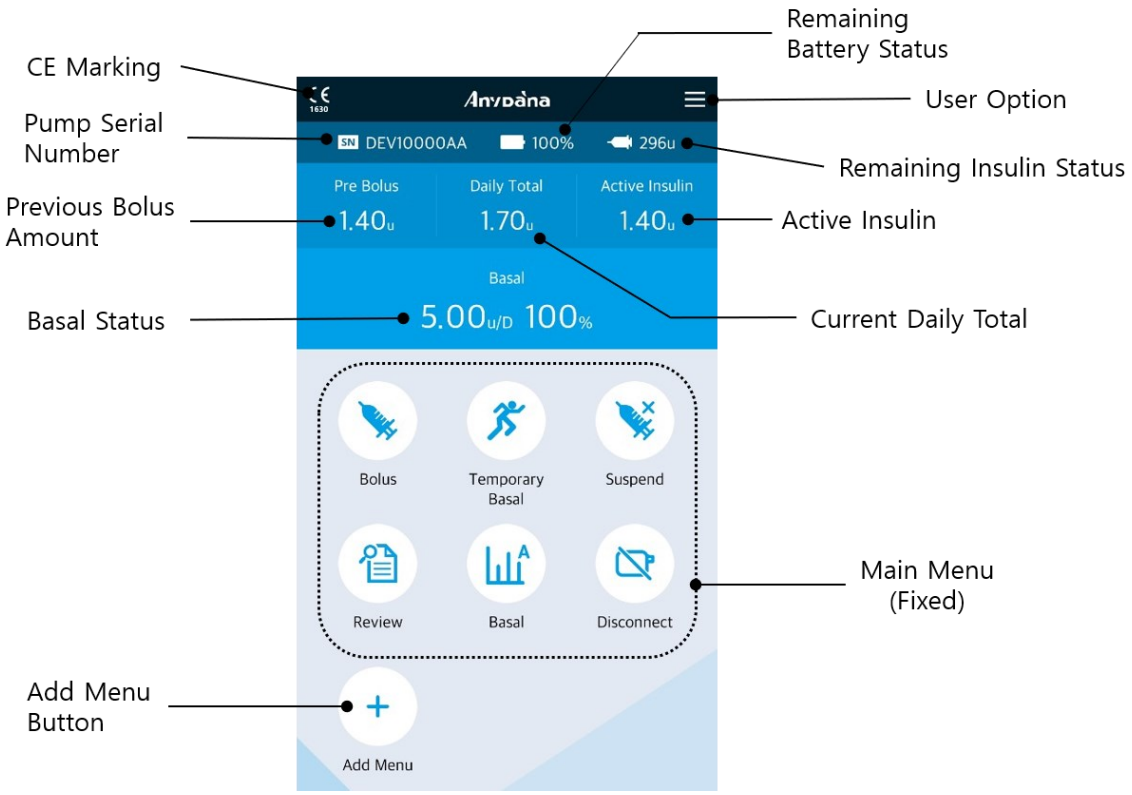
3. Select the serial number of the device you want to connect to from the Bluetooth device list.



4. After pressing the "Forget This Device" button, try to connect the pump from the beginning again.

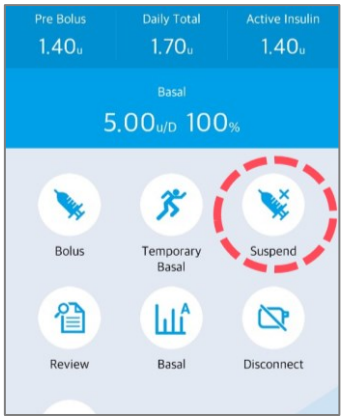
3. Main Menu

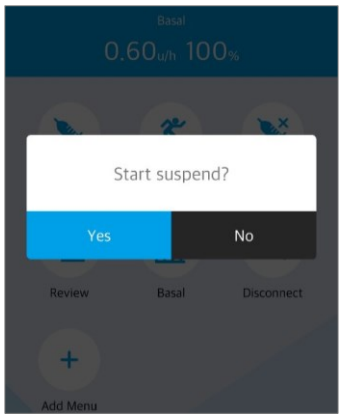
The Main Menu and Pump status screen of AnyDANA.



Notice To accurately read the remaining "pump battery" capacity, check the battery status in the main menu following a bolus delivery.

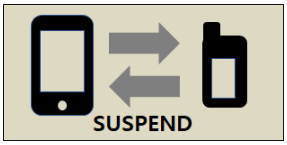
3.1 Suspend

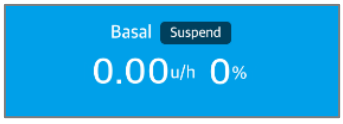


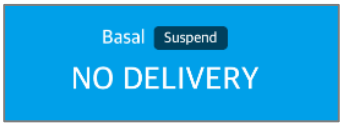


1. Press "SUSPEND" from within the main menu. Press "Yes" to confirm.

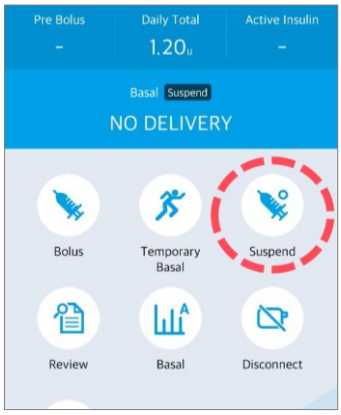
Notice The SUSPEND is also displayed on the Insulin pump (except DANA R).

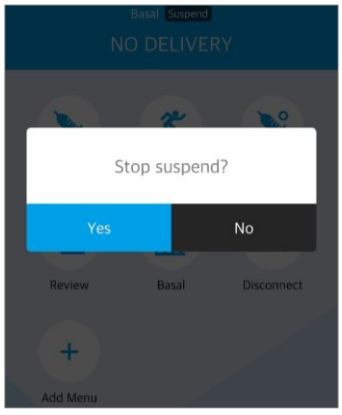






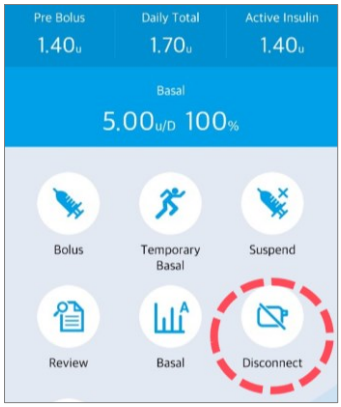
2. During 'SUSPEND', '0.0u/h 0%' and 'NO DELIVERY' are displayed alternately within the Basal status.

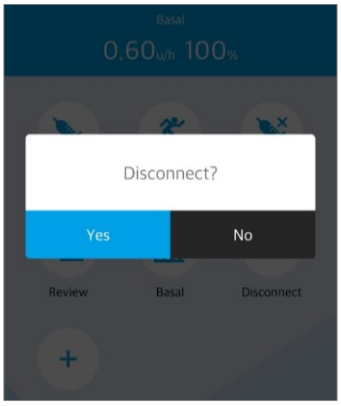




3. To turn off SUSPEND press "SUSPEND". Press "YES" to confirm restarting delivery.

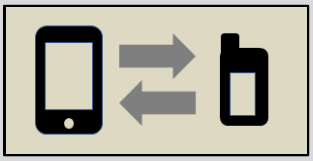
3.2 Disconnect



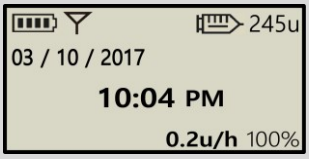


Press the "Disconnect" button from within the main menu.
Press "Yes" to confirm disconnect.

Caution The pump can also disconnect AnyDANA. From the 'pump connection screen' shown below press and hold the minus (-) button on the insulin pump until the pop-up are shown.

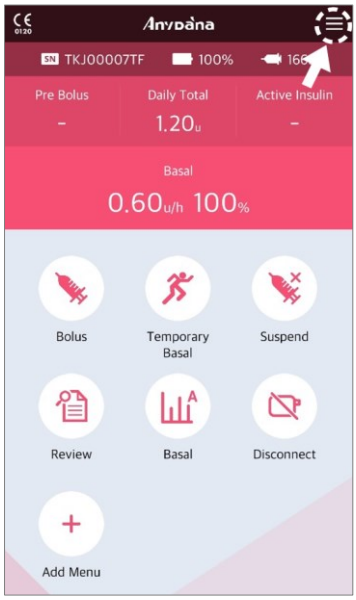


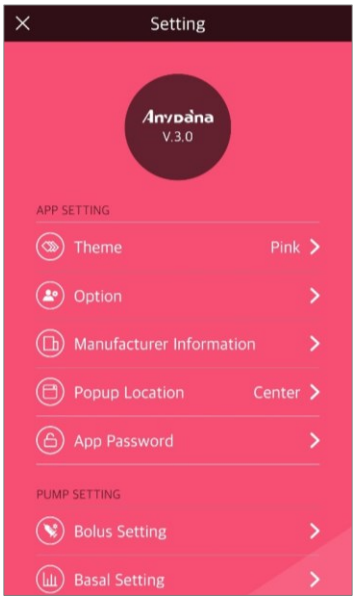
From the **DANA R** pump 'Main Menu', select the "Disconnect" icon to disconnect.



3.3 User Option

The ‘User Option’ allows for personalization of the settings within the insulin pump.

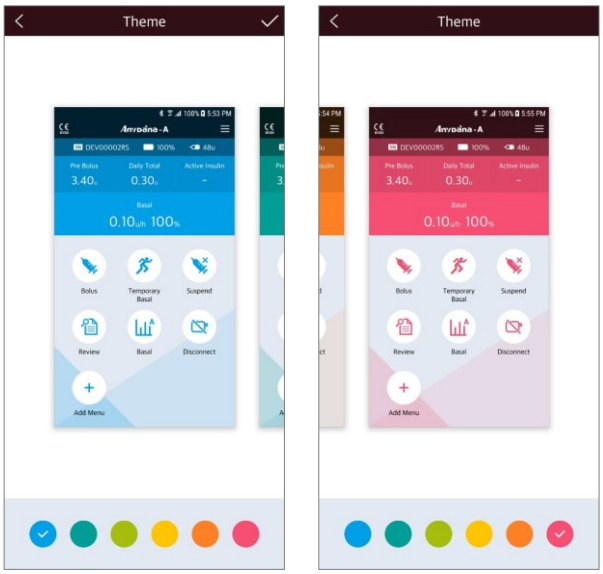




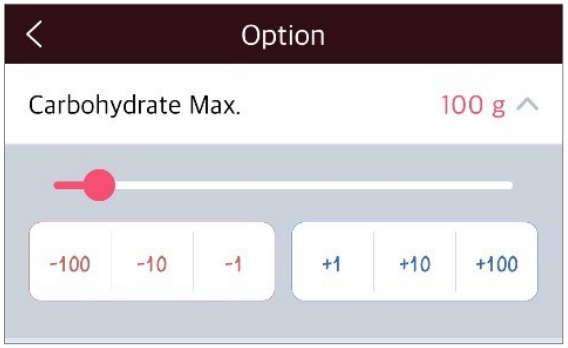
Select ‘≡’ icon from the top right corner of the AnyDANA application. The insulin pump ‘User Option’ menu will open enabling changes to be made.

Caution Consult with a healthcare professional prior to adjusting the User Options.

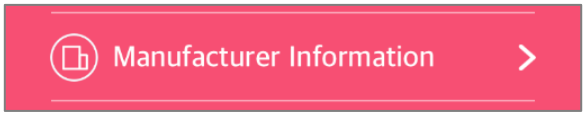
➢ Application Setting



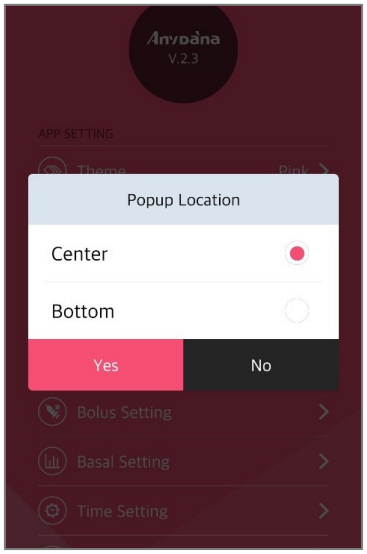
Theme:
6 different color themes are available.

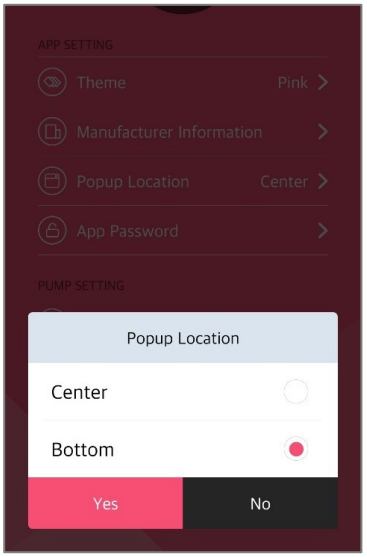


Option:
Can set the maximum carbohydrate.

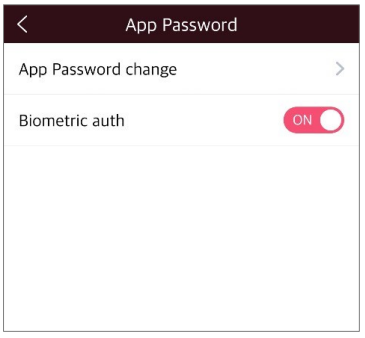


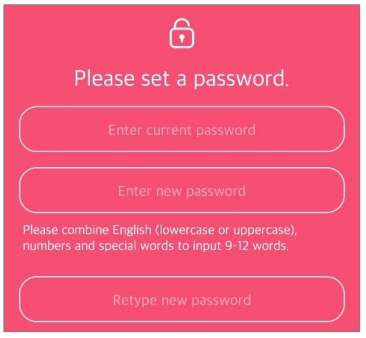
Manufacturer Information:
Review the manufacturer information stored within the insulin pump.





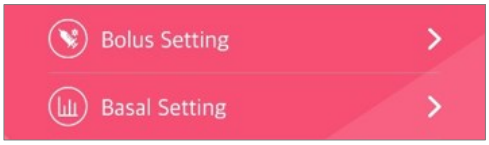
Popup Location:
Adjust the position of the 'Popup Location'





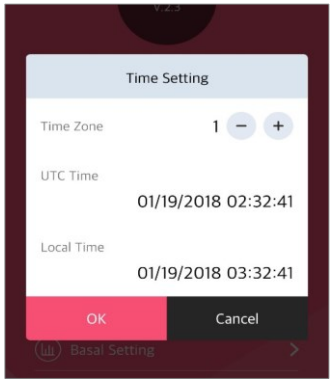
App Password:
Can change the app password or set biometrics.

➢ Pump Setting



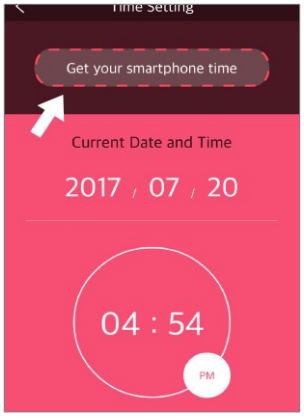
Bolus setting:
Refer to 5.3 bolus setting.

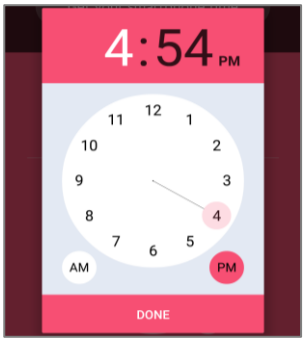
Basal setting:
Refer to 4.0 basal setting.

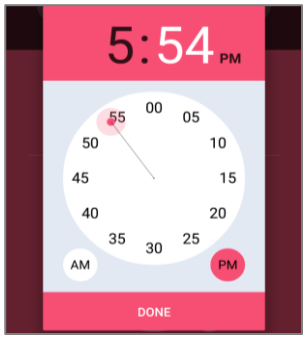


Date and Time setting
For DANA-i pump:

Change the time zone by pressing − , + button. And save with the OK button.







Date and Time setting
For DANA-R and RS pump:

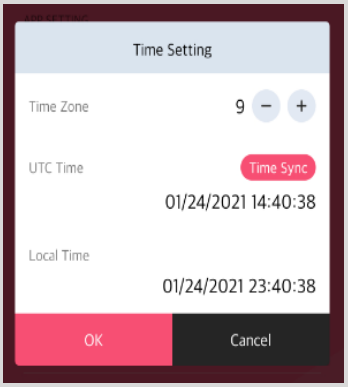
1) **Sync to the smart-phone**
   Select the option 'Get your Smartphone Time' to set the current time automatically within the pump.

2) **Manually**
Select each date and time section and adjust as required to set.

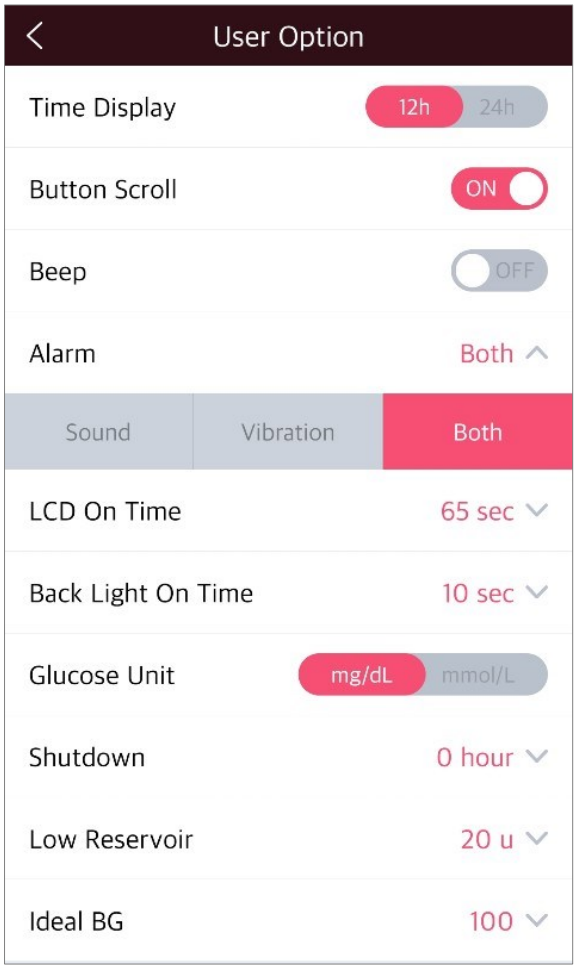
Notice The method for changing the time and date may differ depending on the smartphone.

Notice Time Setting may need to be changed if you travel to a different time zone. It is important to set the current time and date accurately to ensure the correct basal insulin delivery and to keep an accurate record of pump functions.

Warning If there is a difference of more than 1 minute between the **UTC time** of the smartphone and DANA-i pump, the "Time Sync" button appears. Users can synchronize the time on their smartphone with the DANA-i pump. Do not ignore this button.



➢ Pump Setting (Continue)



Time Display:
Change between 12 and 24 hour time format.

Button Scroll:
Button scroll on or off.

Beep:
Key Beep ON/OFF enables an audio tone when the insulin pump buttons are depressed.

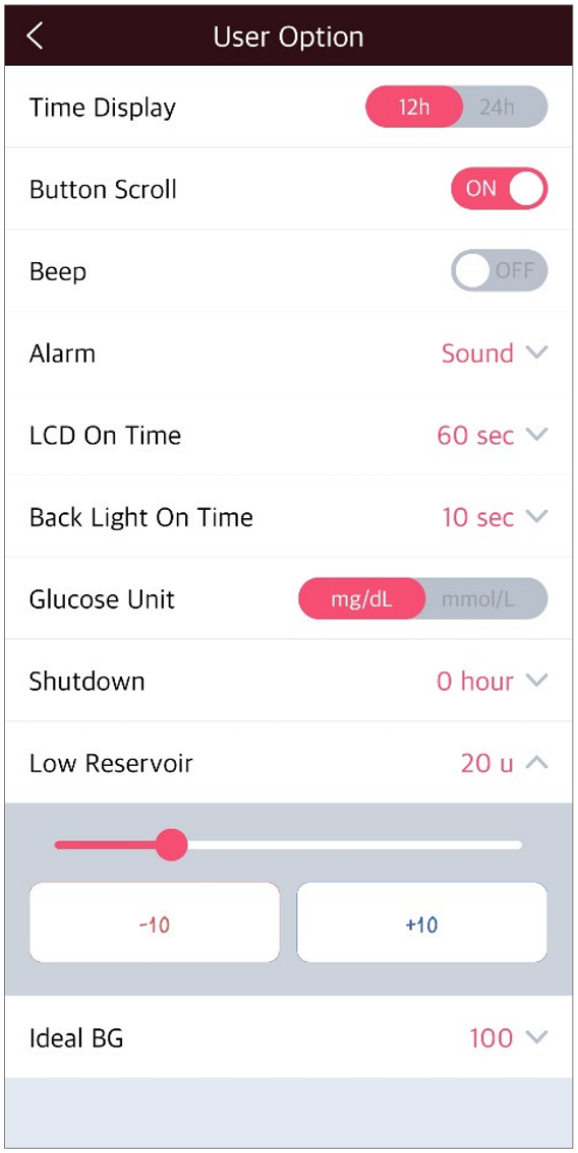
Alarm:
Change among **SOUND**, **VIBRATION** or **BOTH** for alerts and pump alarms.

LCD On:
Adjust the duration the LCD remains on before changing to Sleep Mode. Setting (5 – 240) seconds

Backlight On:
Adjust the duration that the LCD backlight remains on between button presses. Setting (1 - 60) seconds. However, you can set it (0-60) seconds at DANA-i.

Glucose Unit:
Adjust the unit of measure for Glucose results between **ML** (mmol/L) and **MG** (mg/dL).

Warning Using wrong unit of measure could lead to Glucose results being misinterpreted.



Shut Down:
This is a safety setting, where if no buttons are depressed after the time set (0 – 24hr) the pump stops delivery and an alarm sounds. Set the time to **(0)** to disable this auto off.

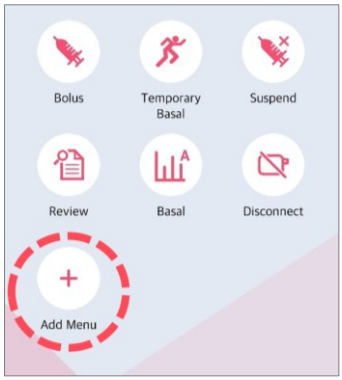
Low Reservoir:
Adjust the LOW RESERVOIR warning alarm threshold (10, 20, 30, 40, 50) units of insulin remaining.

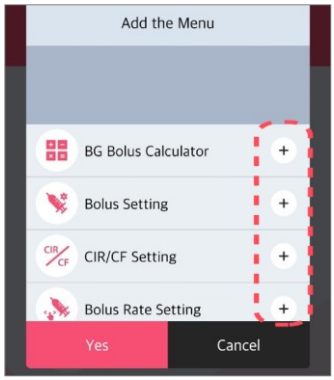
Ideal BG (only DANA-i) :
Set the Ideal BG.

3.4 Add Menu into Main Menu

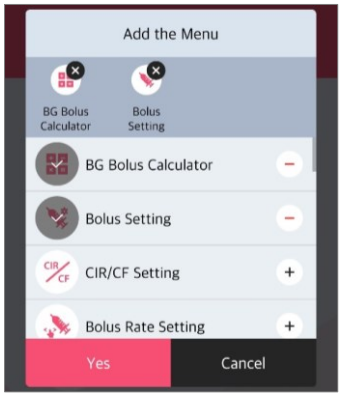
The AnyDANA menu can be personalized to suit common features that are preferred.

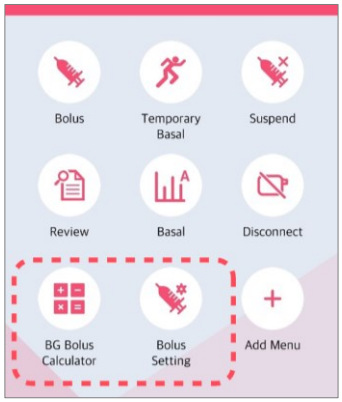
➢ Adding a Menu





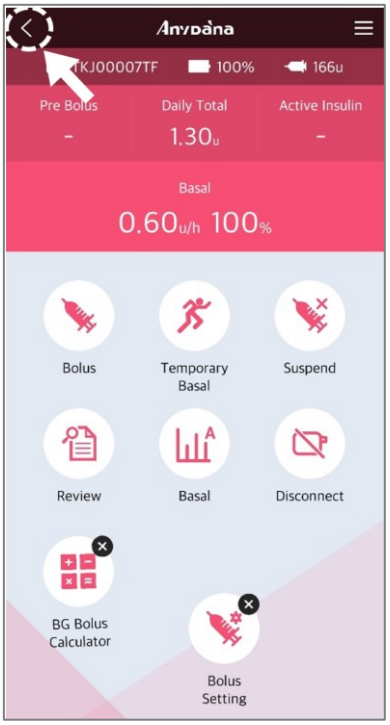
1. Select "Add Menu" from the Main Menu.
2. The 'Add the Menu' options are displayed. Press ⊕ for adding preference options.





3. Press "Yes" to confirm changes to the 'Main Menu'

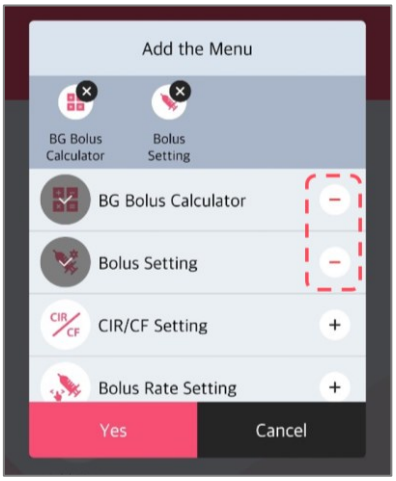
➢ Moving or Deleting Menu Icons



Move the Menu:

1. Touch and hold any menu icon until the icons wiggle. Move the icon to the new location.

2. Press the Back button at the top to complete the menu movement.



Delete the Menu:

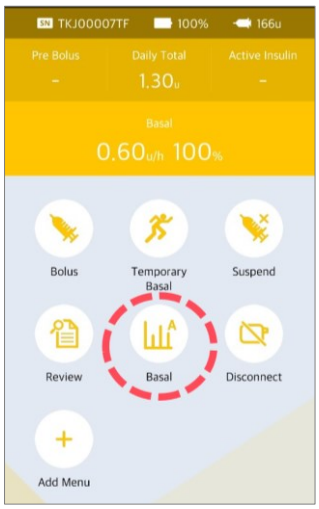
Press to delete Icon's from the 'Add the Menu' option.

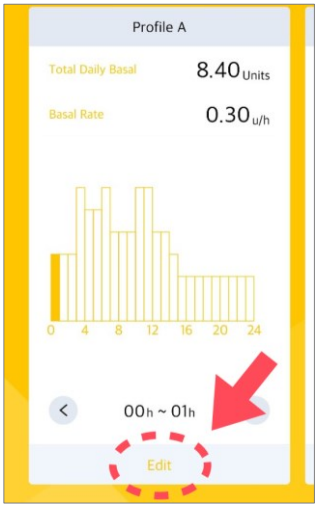
Notice Main Menu Icons (Bolus, Temporary Basal, Suspend, Review, Basal, Disconnect) cannot be deleted or moved.

4. Basal Setting

Basal settings must be programmed before using the insulin pump. Basal insulin is required to maintain an ideal BG level while fasting.

4.1 Setting the Basal Profile

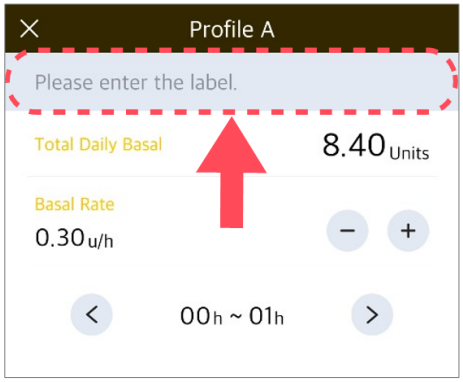




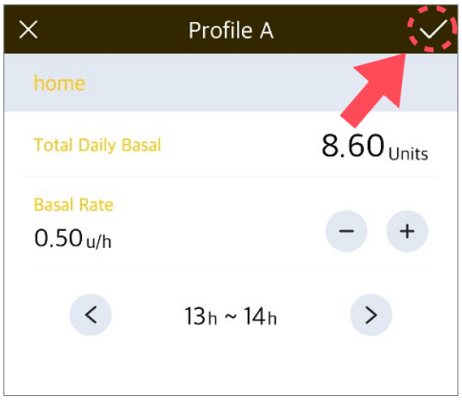
1. Select "Basal" icon at the main menu.

2. The Basal Profile menu is displayed. Change to the preferred profile by sliding the screen sideways. Press "Edit" to make changes to the selected profile.

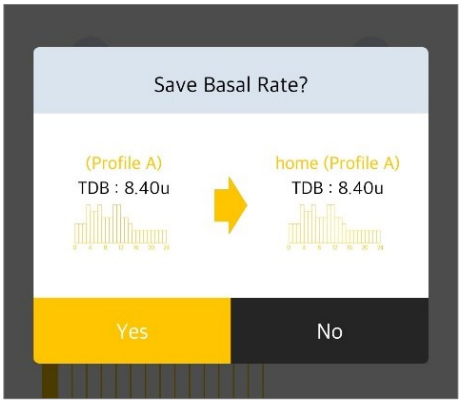
Notice
R, RS pump : TDD(Total Daily Dose)
i pump : TDB(Total Daily Basal)



3. Press the "Please enter the label" at the top of the screen to personalize the profile name.



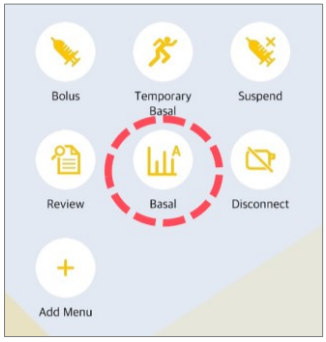
4. To change the hourly basal rate, move left (<) or right (>) to adjust the time. Set the basal rate with plus (+) or minus (-).

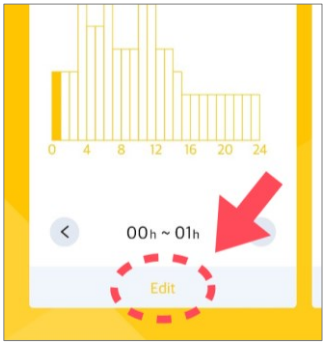


5. When changes are completed, press ✓ button at the top of the right then press “Yes” to save the Basal Tate changes.

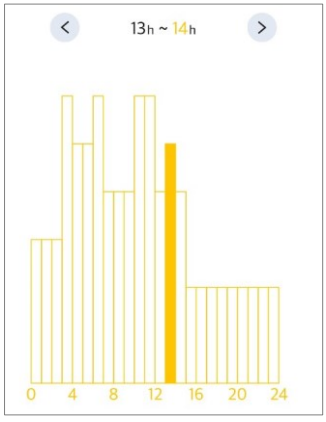
4.2 Change basal rates with time blocks greater than 1hr

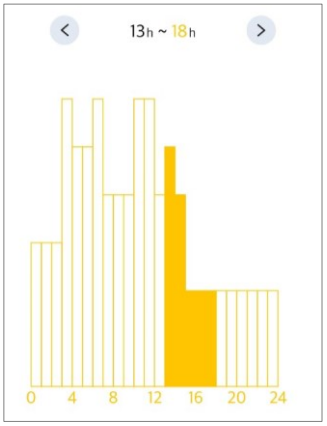
The basal rate is usually set in blocks/periods of time greater than 1 hour. For example, a basal rate maybe set from 21:00 to 06:00 at the same u/hr rate. AnyDANA help achieve this easily using following methods:



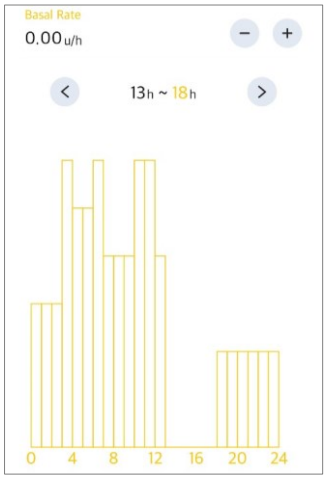


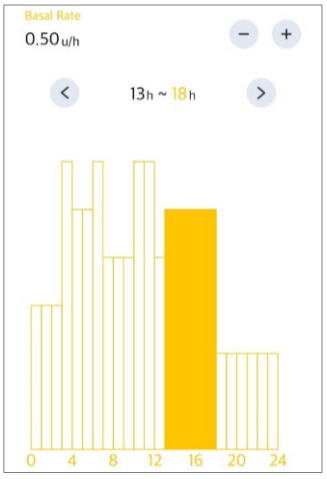
1. Select "Basal" then press "Edit" for the appropriate basal profile.



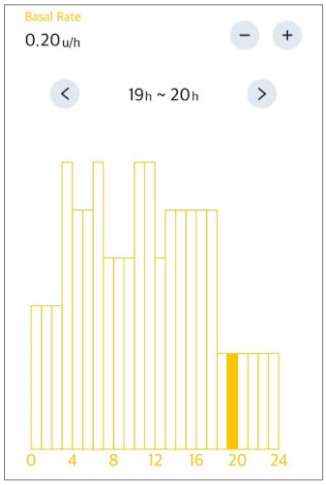


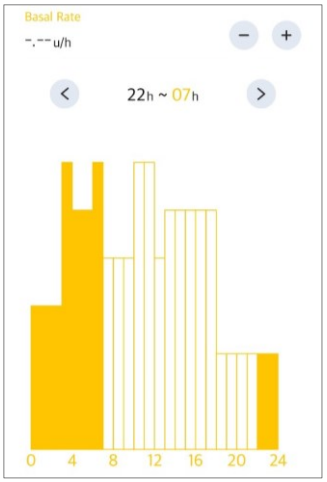
2. Move to the desired time. Select the start or end time you want to select multiple, and then adjust using the (< & >) arrows. The color of the selected time will be highlighted within the graph.





3. Adjust the basal rate using plus (+) and minus (-).

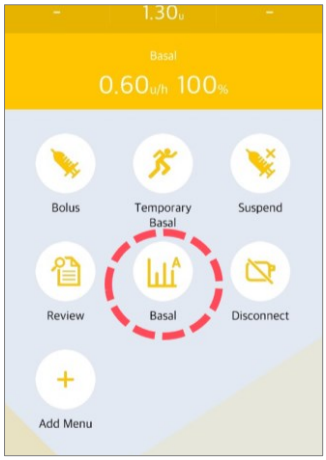


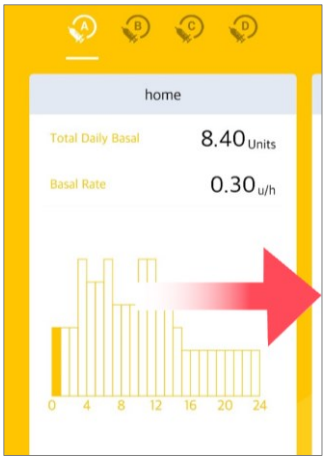


4. Press and hold the arrow (< or >) to release the multiple selection.

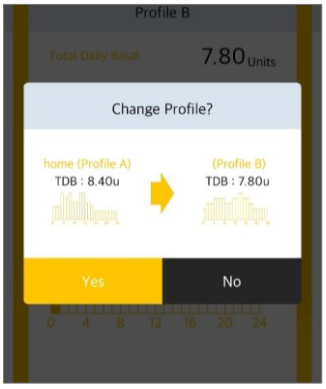
4.3 Change Basal Profiles

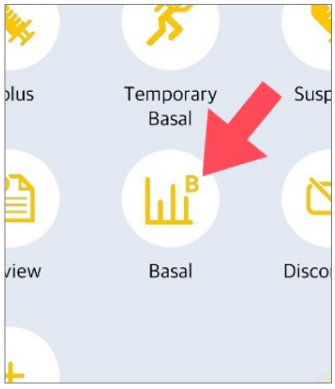
The DANA Diabecare insulin pump provides 4 different basal profiles. Change profiles if necessary after setting each profile. For instance 'Exercise Profile' or 'Sick-day Profile'.





1. Select Basal from the Main Menu.
2. Change profile by sliding the screen from side to side.





3. Touch the ✓ icon at the top of the right to change profile. Press "Yes" on the confirmation message to apply the changed profile.
4. The basal icon on the main menu shows the current Profile. (A, B, C, or D)

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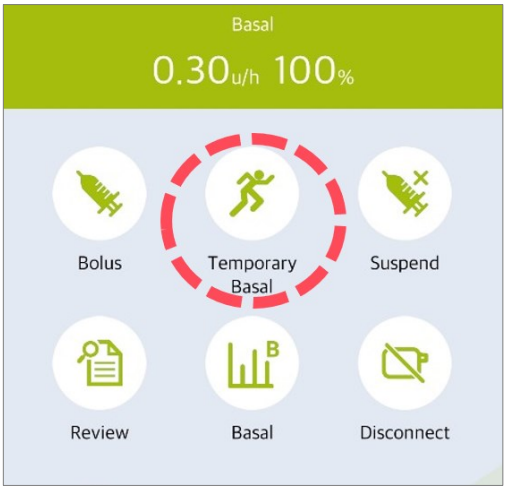
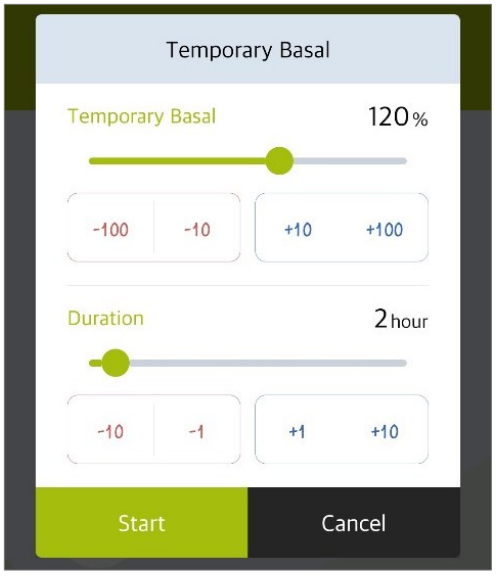
4.4 Start Temporary Basal

The temporary basal rate feature is useful to manage blood glucose levels during unexpected and unusual short-term activities (sport or exercise) or conditions of illness or stress. Using the temporary basal rate enables changes to be temporary and automatically revert to usual rates upon completion.

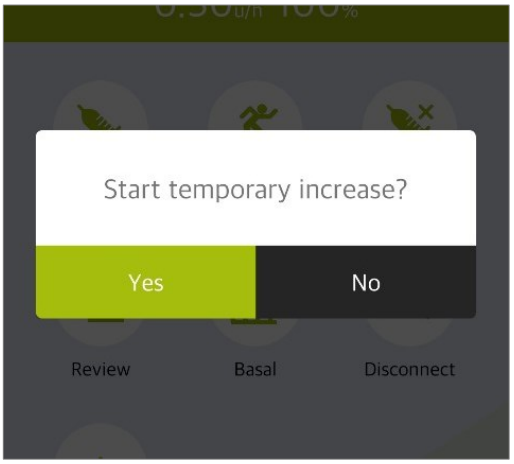


1. Select "Temporary Basal" from the main menu.

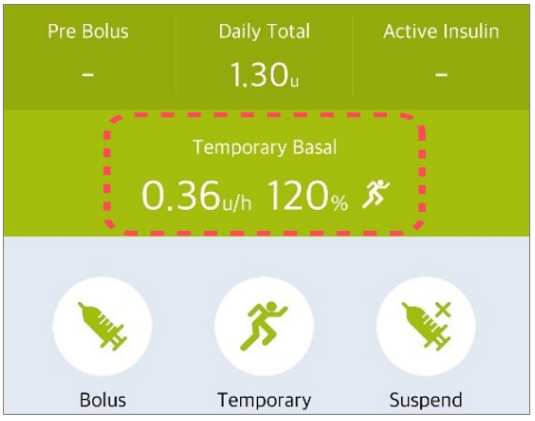


2. Adjust the rate to more or less than 100% as required.

3. Adjust the duration for the temporary rate in hours. Press "Start".



4. Confirm start “Yes”

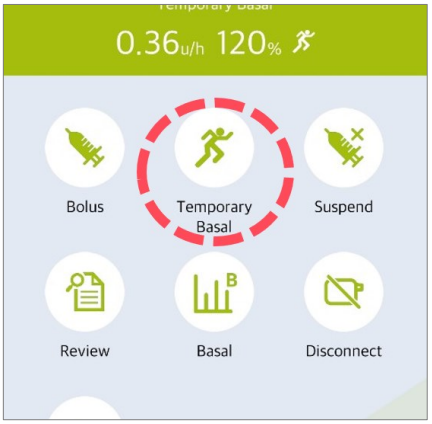


5. Basal status screen displays the temporary basal status.

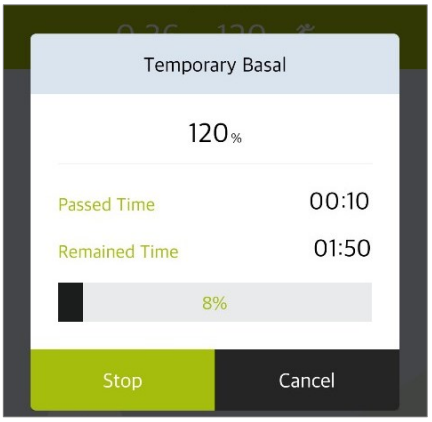
Notice

- The Temporary basal rate will not take effect if the duration is set to “0 hour” or the rate is set to “100%”.
- Temporary Basal Rates can be set in 10% increments from 0% to 200%. Temporary Basal time can be set in 1-hour increments from 1 to 24 hours.

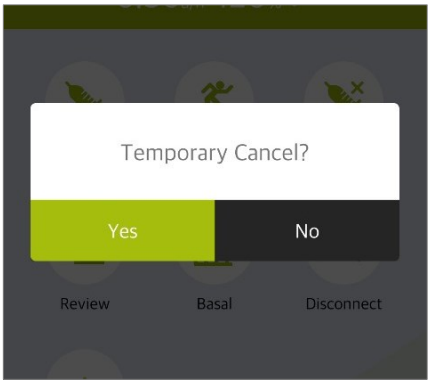
4.5 Review or Stop Temporary Basal



1. Select “Temporary Basal” from the main menu.



2. Review the temporary basal status.



3. To cancel the temporary basal, select “Stop”. Confirm “Yes” to cancel the Temporary Basal rate.

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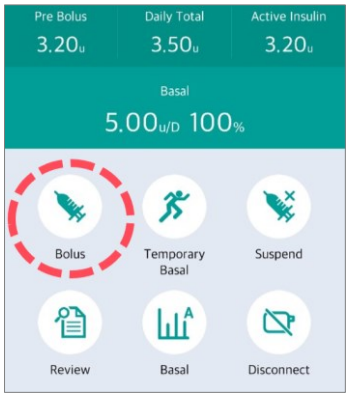
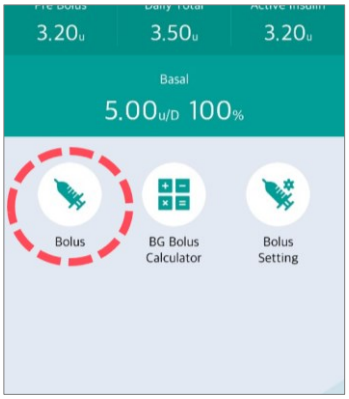
5. Bolus Delivery

Bolus delivery can be used to cover the carbohydrate in a meal or snack.

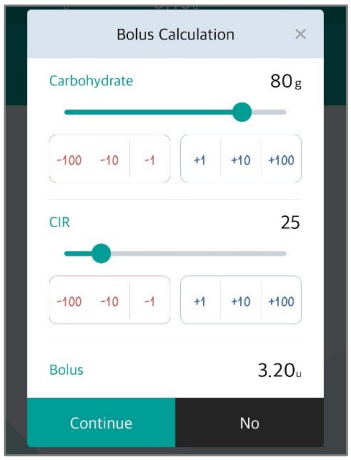
5.1 Suspend (Quick Bolus)

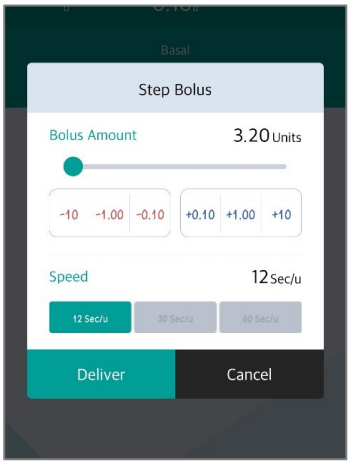




1. Select "Bolus" from the main menu.

2. Select "Bolus" icon from the Bolus menu.

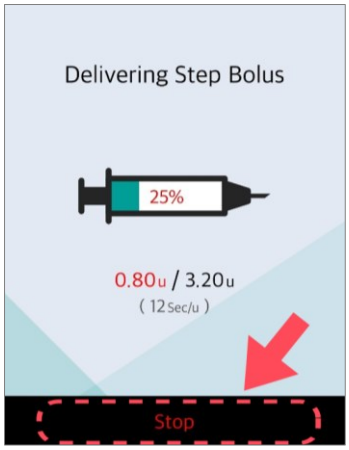


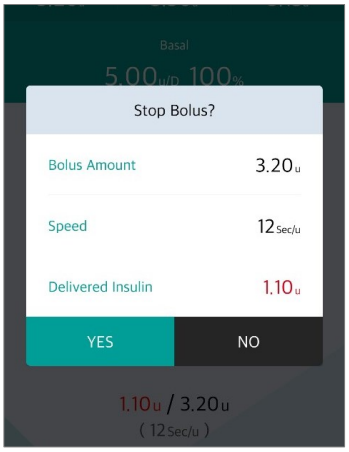


3. Enter Carbohydrate using plus (+) and minus (–). The CIR ratio can also be adjusted if required. Press "Continue".

CIR = **C**arbohydrate to **I**nsulin **R**atio

4. Adjust the delivery speed if required. Select "Deliver".





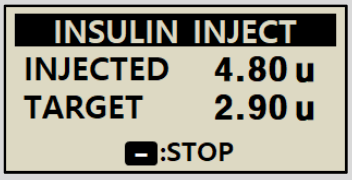
5. The pump will start the bolus delivery.

6. To stop the Bolus press "Stop" and confirm the stop by selecting "Yes".

Warning Following a BOLUS delivered for carbohydrate – if the carbohydrate is not eaten, there is a risk of hypoglycemia.

Caution During the Bolus delivery the pump screen also provides Bolus delivery information.

<DANA R>



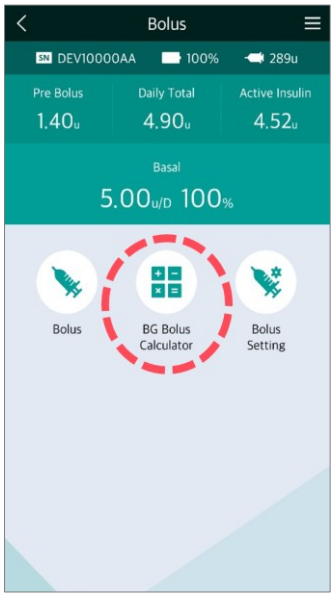
<DANA RS/ DANA-i>

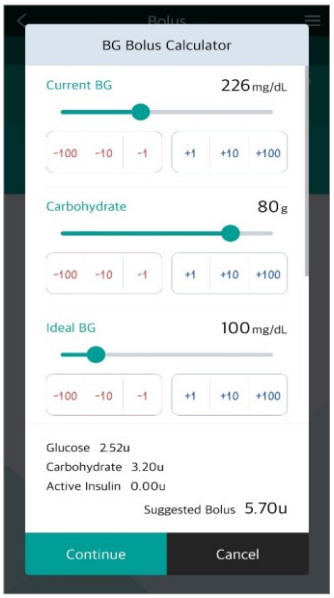
Notice

- The Bolus Speed adjustment is very useful for large boluses. Slowing the delivery can reduce discomfort and increase insulin absorption.
- If 'Extended Bolus' is enabled within the 'Bolus Setting', it is necessary to select among (Step bolus, Extended bolus or Dual pattern bolus) Refer to 5.3 Bolus Setting – Extended Bolus.

5.2 BG Bolus Calculator (Smart Bolus)

This type of BOLUS will calculate an estimate of insulin required for a correction bolus and/or food bolus and adjusts the suggested dose to compensate for residual Active Insulin from previous Bolus delivery.

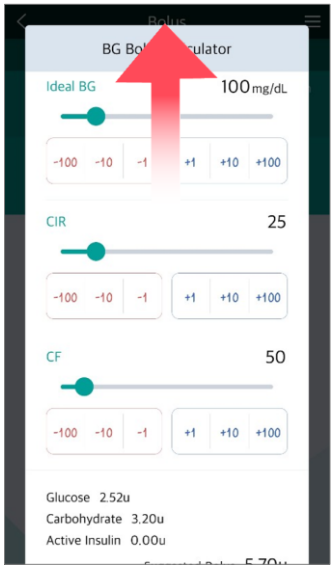


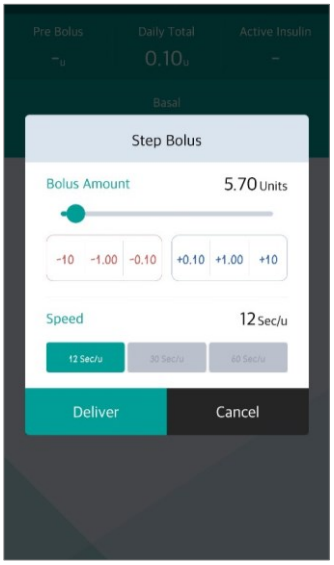


1. Select "BG Bolus Calculator" from bolus menu.

2. Adjust:
   - Current BG
   - Carbohydrate

3. If required, adjust:
   - Ideal BG
   - CIR
   - CF



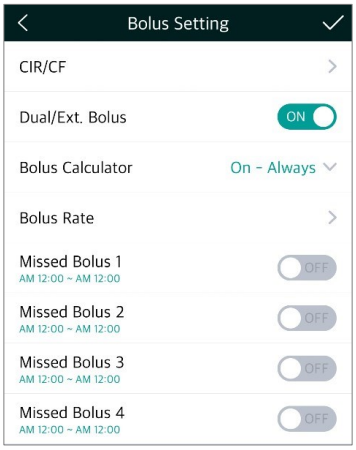


4. Drag the window upward to see CIR and CF.

5. Press "Continue" button to deliver Bolus.

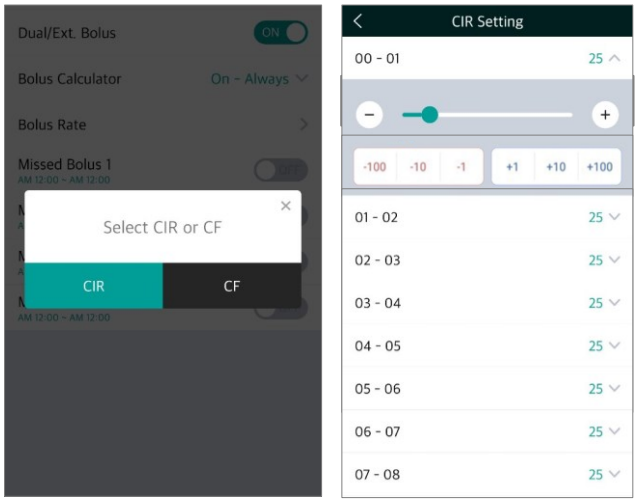
5.3 Bolus Setting

The Bolus Setting menu enables personalization of all Bolus features.

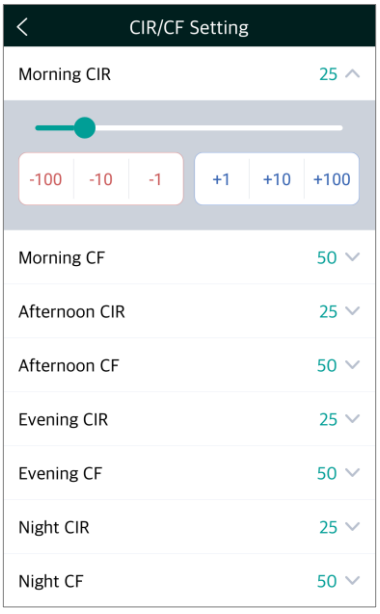


Select “Bolus Setting” from the bolus menu.

➢ Bolus Setting Menu



<DANA-i>

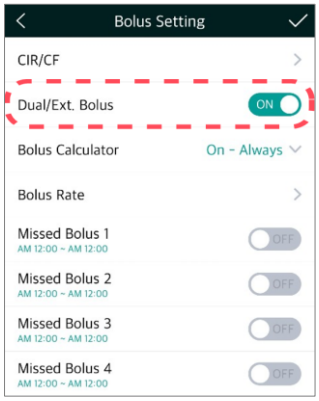


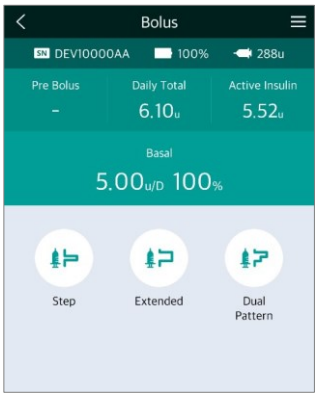
<DANA RS and DANA R>

1. CIR/CF Setting

Adjust CIR/CF ratios used in Bolus calculations. CIR and CF can be set for different times of the day, Morning, Afternoon, Evening, and Night at DANA R, RS pump. However, DANA-i pump can be set each hour.

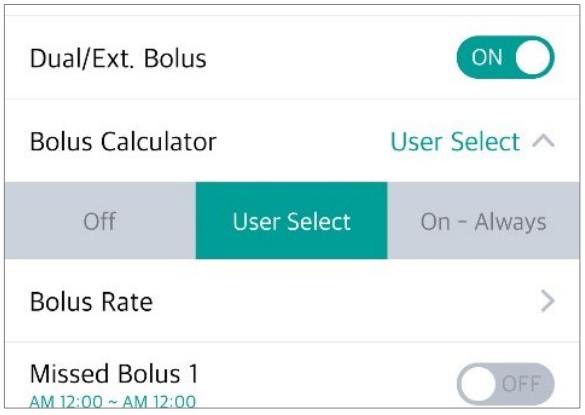
Morning	06:00 - 10:59
Afternoon	11:00 - 16:59
Evening	17:00 - 21:59
Night	22:00 - 05:59





2. Dual/Ext.Bolus (Extended Bolus)

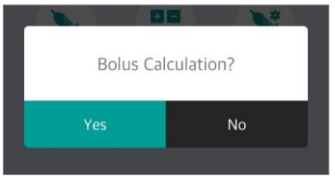
Adjust the extended bolus and Dual bolus 'on' or 'off'.



3. Bolus Calculator

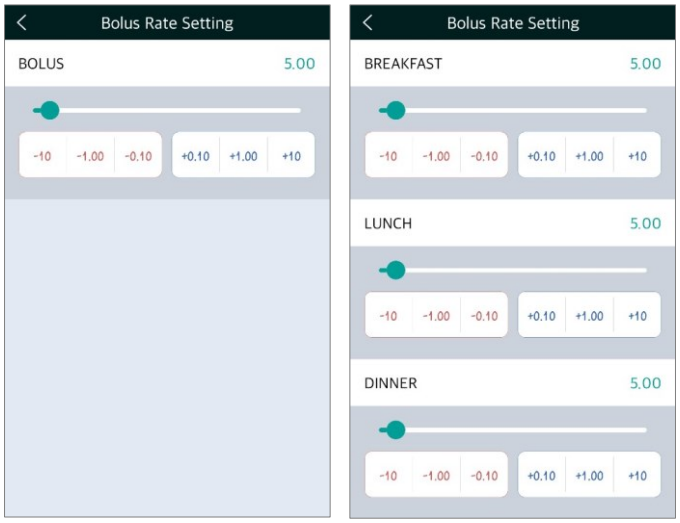
Off: Users will input in units (u) of insulin to deliver.

User Select: All Boluses require a choice calculation Yes/No.



On-Always: Users will input in gram of carbohydrate and CIR to calculate amount of insulin to deliver.

➢ Bolus Setting Menu

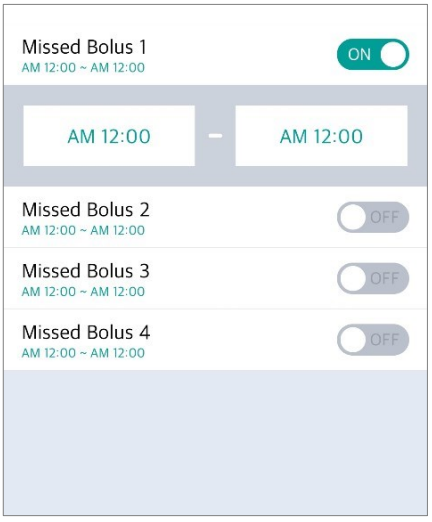


4. Bolus Rate Setting

This is a pre-set bolus amount for regular daily meals.

Breakfast 01:00 ~ 09:59
Lunch 10:00 ~ 14:59
Dinner 15:00 ~ 00:59

Notice PRESET BOLUS is activated from in Doctor Mode, only a Healthcare Professional or Insulin Pump Trainer can enable this option.

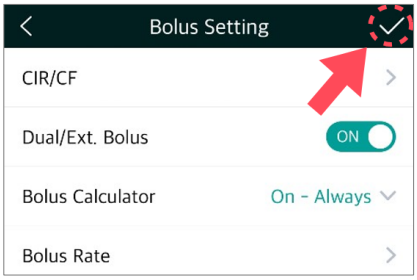


5. Missed Bolus (1 - 4)

This is a safety alarm.
When turned on, a time period can be set for regular meal boluses.
If a bolus is not delivered during the selected time, an alarm will remind the pump user to bolus.
To enable select “On” and adjust the time period.

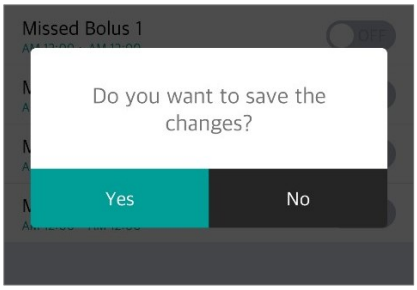
Notice If the MISSED BOLUS alarm is not desired, select “OFF”.

➢ Saving Bolus Setting



Bolus Setting exit

1. Select ✓ at the top of the right.

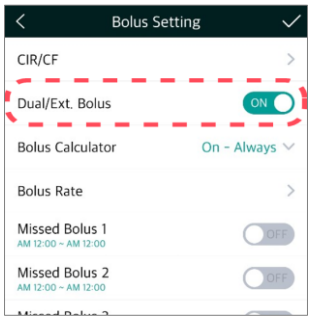


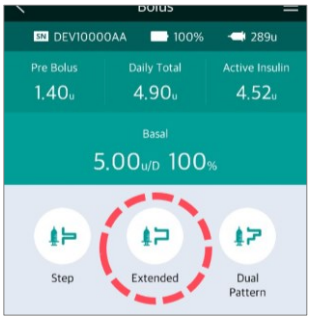
2. Select “Yes” to save the settings.

5.4 Extended Bolus

An 'Extended Bolus' can be used for insulin delivery when planning a long meal with extended snacking or slowly absorbed carbohydrate. It also can be useful for delayed food absorption due to gastroparesis.

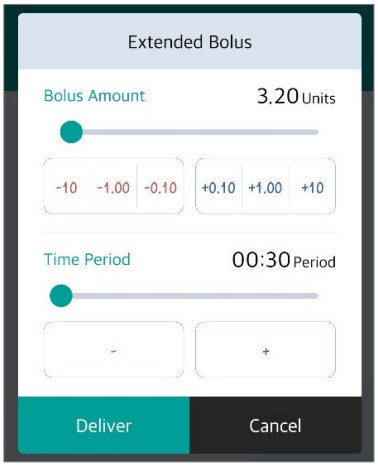
➢ Start Extended Bolus



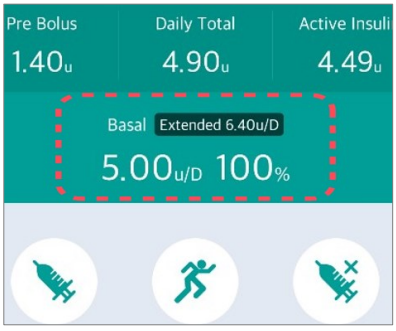


1. Ensure "Dual/Ext.Bolus(Extended Bolus)" is enabled within the Bolus Setting menu.

2. Select "Extended" from the bolus delivery menu.

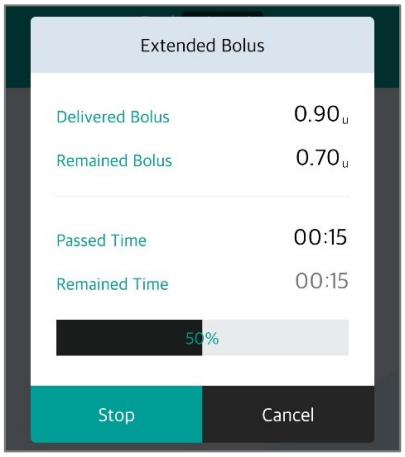


3. Check/adjust the Bolus Amount and Delivery period in the Extended Bolus menu then press "Deliver".



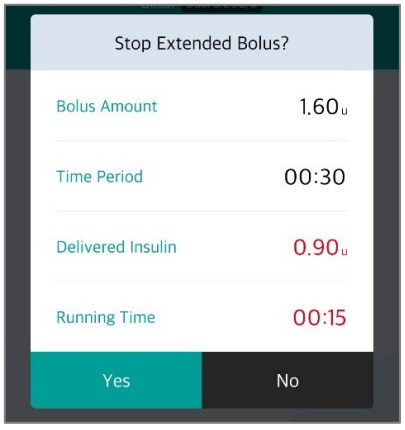
4. Extended Bolus is delivered. Basal status displays the Extended Bolus progress.

➢ Review or Stop Extended Bolus



Review Extended Bolus:

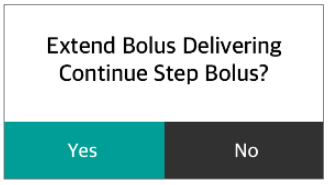
Press "Extended" from the basal status menu.



Stop Extended Bolus:

Press "Stop" from the 'Extended Bolus' menu.
Press "Yes" to confirm.

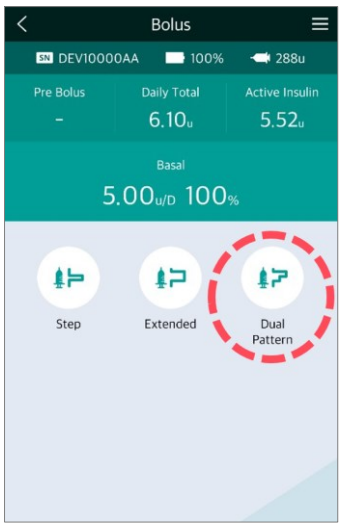
Notice If a Step Bolus is added during the Extended Bolus delivery, the following confirmation message appears for safety. The Extended Bolus is interrupted during the Step Bolus delivery.

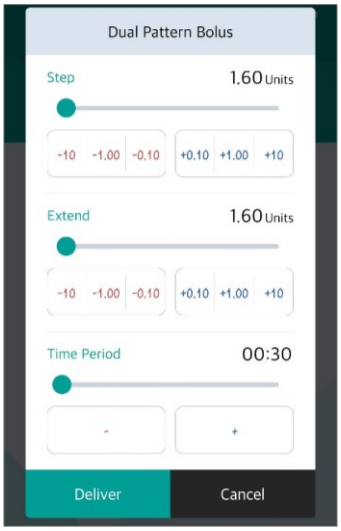


5.5 Dual Pattern Bolus

Dual Pattern bolus delivers a combination of a step bolus and an extended bolus. Dual Pattern bolus is useful for meals containing both rapidly absorbed and slowly absorbed carbohydrate.

➢ Start Dual Pattern Bolus

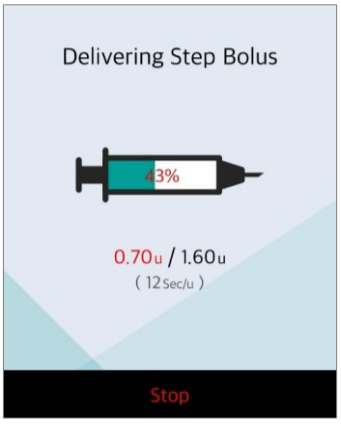


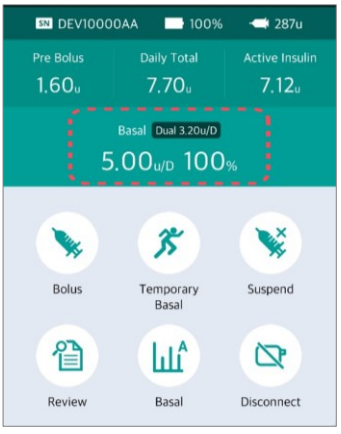


1. Select "Dual Pattern" within the Bolus screen.

2. Review and adjust the parameters. Press "Deliver" to start Dual Bolus.

Step - Insulin amount for Step Bolus.
Extend - Insulin amount for Extended Bolus.
Period - Time period for Extended Bolus.



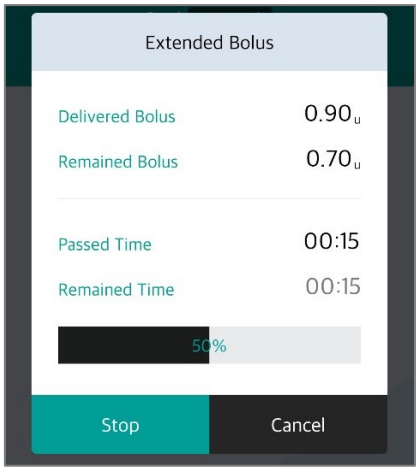


3. The Step Bolus is delivered first.

4. The Basal Status displays the Extended Bolus progress.

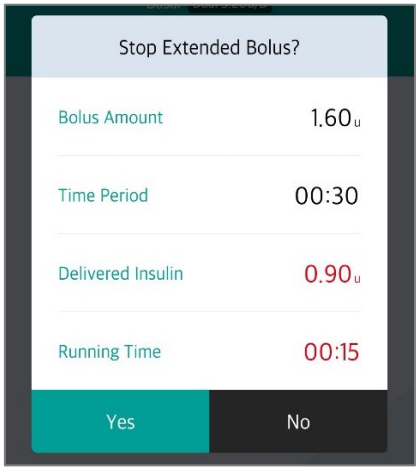
➢ Review or Stop Dual Pattern Bolus

The review and stopping of a Dual Pattern Bolus are the same as the Extended Bolus. **Notice** The first part of a Dual Pattern Bolus can only be stopped during the initial delivery.



Review Dual Pattern Bolus:

Press "Extended" from the basal status menu.

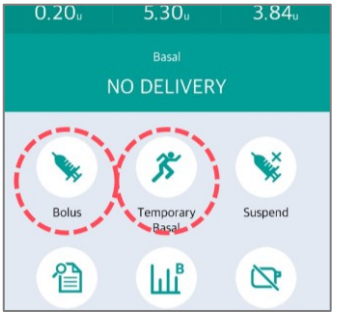


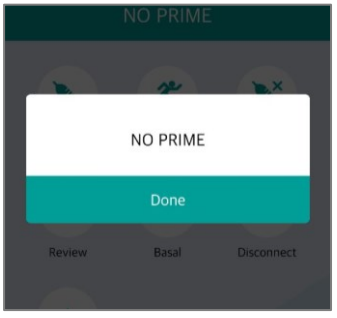
Stop Dual Pattern Bolus:

Press "Stop" from the 'Extended Bolus' menu.
Press "Yes" to confirm.

5.6 Refill and Prime

Insulin refills and prime must be performed via a pump.
If you do not prime after refill the insulin, the words “NO PRIME” and “NO DELIVERY” will appear alternately on the AnyDANA main screen.





Without prime the pump, if you select “Bolus”-“Bolus” or “Temporary Basal” on AnyDANA main screen, a 'NO PRIME' pop-up window will appear.

Notice. When the message “NO PRIME” is displayed in the AnyDANA app, disconnect the pump from AnyDANA, and priming through the pump, and then reconnect with AnyDANA.

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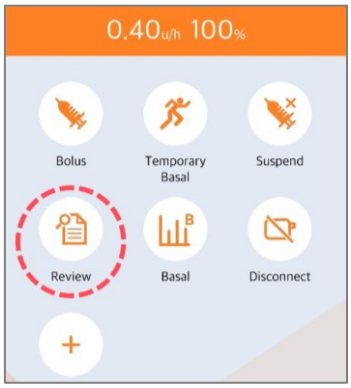
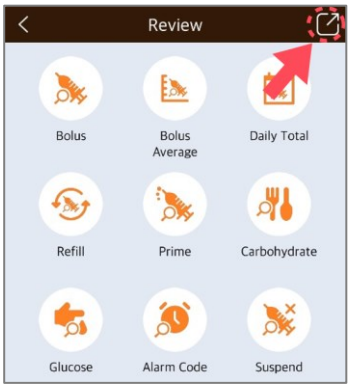
6. Review

All Delivery histories from the insulin pump are clearly displayed on the smart-phone screen.

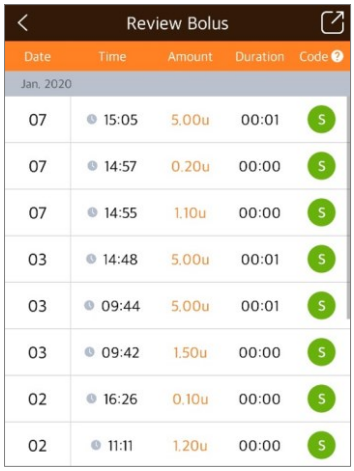


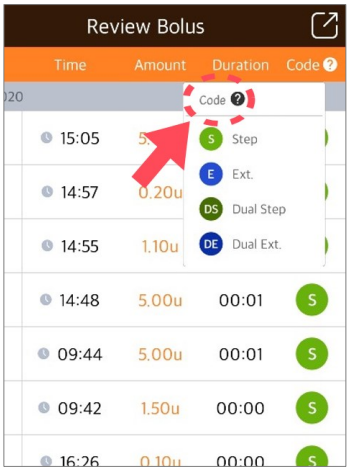


1. Select "Review" from the main menu.
2. Can export the history by selecting the icon on the top right of the application

Notice Retrieving the data may cause a short delay.

➢ Review the History





Bolus:
Displays date, time, amount, duration and type of Bolus.

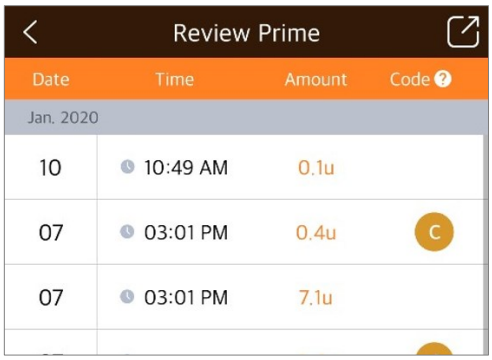
Notice Select 'Code?' for full explanation.

Bolus Average:
Daily average for bolus for last 3, 7, 14, 21 and 28 days.

Daily Total:
Date and Basal/Total delivery in units.

Refill:
Date, time and refill volume amount.

➢ Review the History

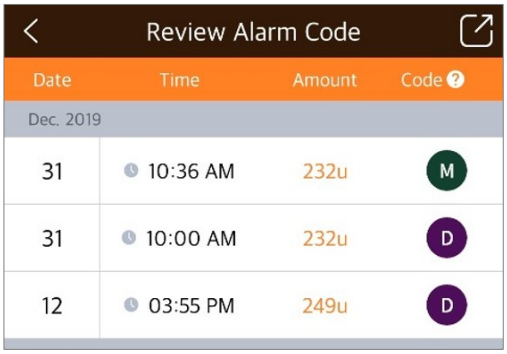


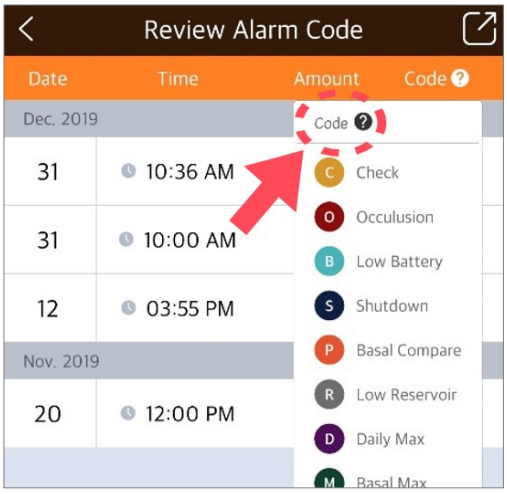
Prime:
Date, time and prime volume in units.

Notice 'C' indicates cannula prime.
Press "Code?" for details.

Carbohydrate:
Date, time and entered grams of carbohydrate.

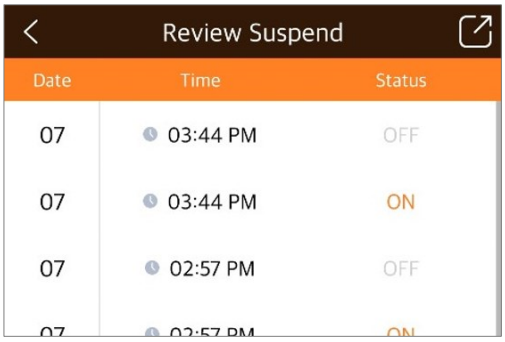
Glucose:
Date, time and blood glucose value used for Bolus.





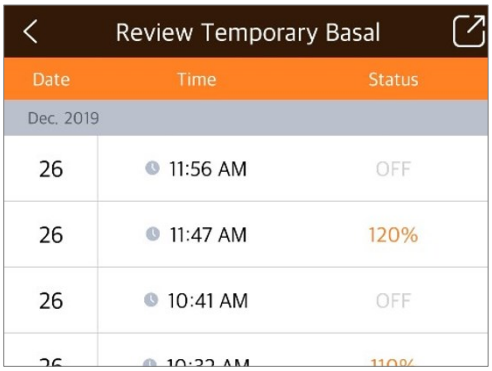
Alarm Code:
Date, time, the amount of remaining insulin and the type of alarm occurred.

Notice Select 'Code?' for detailed explanation about the Alarm type.

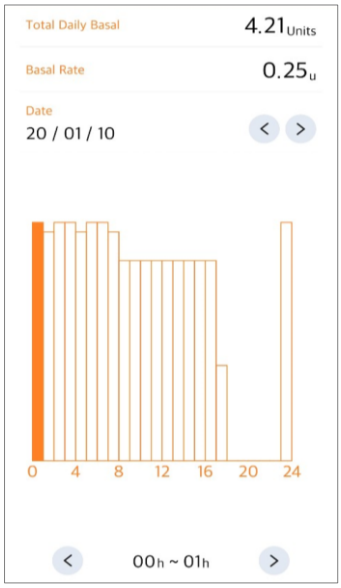


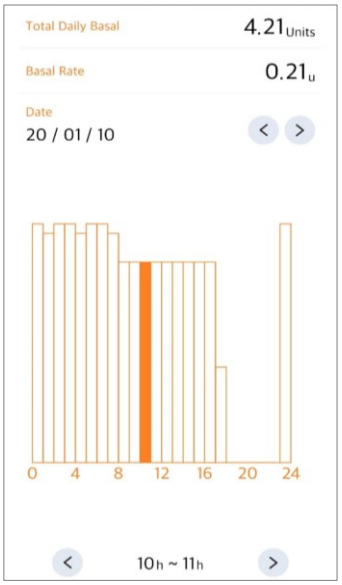
Suspend:
Date and time for each ON and OFF for suspend.

➢ Review the History



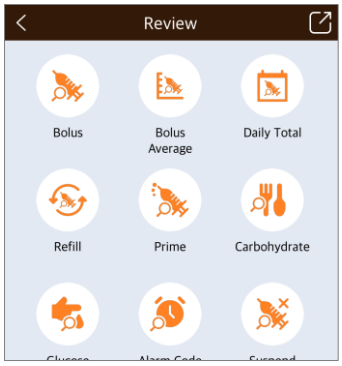
Temporary Basal:
Date and time of starting (--%) and finishing (OFF) at DANA-i pump.
Date and time of starting (ON) and finishing (OFF) at DANA R and RS pump.

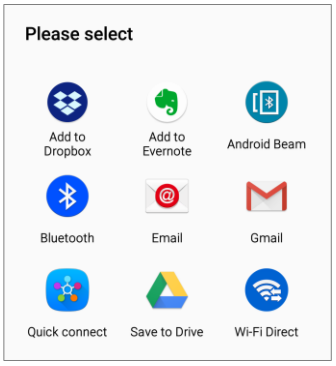




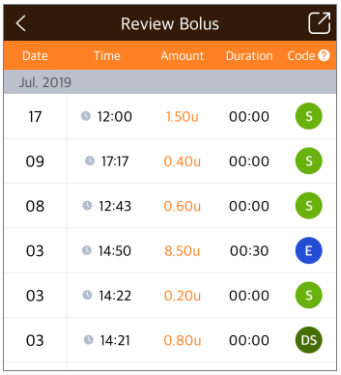
Basal:
Basal insulin amount delivered hourly.
Press left (<) or right (>) to scroll through previous records.
Press the date arrow to change to a specific date.

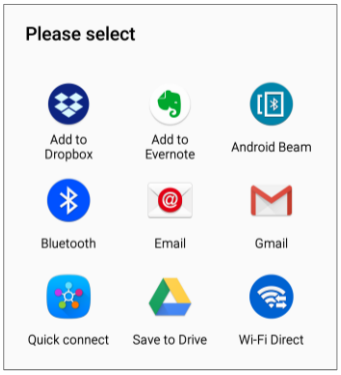
➢ Export History





Export all history
Export the history by selecting the icon on the top right of the history view screen, you can export a total of 11 histories at once.





Export bolus history
If export a history by selecting the icon in the upper right corner of the bouls history screen, can export the bolus history.

Notice Can export your desired history out of a total of 11 reviews.

7. Troubleshooting

7.1 Alarm and Error

➢ Insulin Pump Error Message

If the Insulin Pump incurs an error, the following messages may appear within AnyDANA. Check the Insulin Pump immediately.

Message	Problems	What To Do
Low battery pump Replace the battery	The Insulin Pump battery is very low.	Replace the Insulin Pump battery immediately.
Error occurred Restart the pump	An internal error is detected within the insulin pump.	Remove the insulin pump battery for 10sec, then reinsert to restart the pump.
Occlusion Insulin flow blocked	Insulin delivery is stopped due to an occlusion.	Follow the Insulin Pump instructions. (Occlusion Alarm)

Notice If above mentioned messages occur, AnyDANA is disconnected with pump.

Message	Problems	What To Do
Low reservoir Check your reservoir	The reservoir volume is less than the Low Reservoir level within user options.	Check the reservoir level and replace if necessary.
Empty reservoir Immediately Replace the reservoir	The remaining insulin reservoir level is zero (0u)units.	Check the reservoir level and replace, refill the insulin pump. **Notice** In this case, AnyDANA will be disconnected with pump.

Message	Problems	What To Do
Less delivery than basal set rate	Basal delivery is skipped. Less than 80% basal rate is delivered.	Check BG level. (refer to the Chapter7. Alarms and Error Messages in the DANA insulin pump IFU)
Check your blood glucose	Post Bolus BG check alarm.	Check BG level.
Missed Bolus 11:00 -12:00	Missed meal bolus.	Check the insulin pump history and deliver Bolus if necessary.
Notification Disconnect with pump	BT disconnection between AnyDANA app and pump.	Reconnect the application and pump.
Bolus Block Try again in a few minutes	'Bolus Block' is not allowing an additional bolus.	Try again after bolus block is released.
Daily Maximum Insulin delivery has reached daily maximum	Insulin Pump maximum limits cannot be exceeded.	Refer to a healthcare professional to review the maximum settings within the insulin pump.
Basal Max	Insulin Pump maximum limits cannot be exceeded.	Refer to a healthcare professional to review the maximum settings within the insulin pump.
NO PRIME	The pop-up appears when the pump is not prime.	Disconnect the pump from AnyDANA, and priming through the pump.

Notice For detailed solutions, refer to instruction for use of the insulin pump.

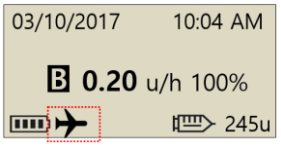
➢ AnyDANA Error Message

The following table lists error messages that can occur during the connection between AnyDANA and Insulin Pump.

Message	Problem	What To Do
Bluetooth permission request Application is requesting permission to turn on Bluetooth. Allow?	The Bluetooth within Android/iOS device is off.	Select 'Yes' to allow AnyDANA to access Bluetooth settings.
Password does not match. Try again.	Wrong password used.	Correct the password. If the password is forgotten – you can reset it by reinstalling the application.
Not Connectable. Pump Busy.	In case of Bolus / Prime mode.	Retry after Bolus / Prime is completed.
Speed specified incorrectly. Please try again.	Injection speed is incorrectly entered into the pump.	Adjust the speed to try the injection again.

7.2 BT Connection Issues

To resolve any BT connection problems between the Android/iOS device and the insulin pump, refer to details below:

Case	What To Do
Android/iOS device cannot locate insulin pump from BT search.	Airplane mode within the insulin pump prevents all BT communication. Airplane mode must be turned off within the insulin pump 'Options' menu. 
Application install trouble	Delete the APP from the Android/iOS device. Re-install the APP and restart the "Paring" process. Contact the local insulin pump distributor for further technical support.
Repeated display of password screen	For security, the AnyDANA App requires a password to reconnect. This occurs 5 sec after Android/iOS screen turns off or another App is opened.
Repeated turn on Bluetooth message	If the Bluetooth is on, try connecting with another Bluetooth device. If the issue continues, contact the local insulin pump distributor for further assistance.

7.3 Hypoglycemia (low blood glucose)

What is hypoglycemia (low blood glucose)?

Hypoglycemia occurs when the blood glucose level is low. Anyone using insulin should be familiar with the symptoms and treatment of hypoglycemia.

The symptoms are:

- Headache and dizziness
- Sweating
- Shaking
- Hunger
- Tingling / numbness
- Nausea or vomiting
- Fast heart rate
- Confusion

Reasons for hypoglycemia

- Not enough food
- Too much insulin
- More exercise than usual
- Drinking alcoholic beverages

What to do in case of hypoglycemia

1. Check Blood Glucose level.
2. If the blood glucose level is low, treat with fast acting carbohydrates in accordance with the instructions of a healthcare professional.
3. If hypoglycemia occurs prior to a meal, after a bolus. Try delaying the meal bolus until during the meal rather than before.
4. In cases of severe hypoglycemia, it is recommended to suspend delivery by disconnecting the Infusion Set.

Notice If hypoglycemia occurs frequently, or is difficult to resolve, contact a health care professional for assistance.

➢ Troubleshooting for hypoglycemia

POSSIBLE CAUSE	SUGGESTED RESPONSE
Increased physical activity	Consult a healthcare professional to make adjustments for increased physical activity. Temporary basal rates or decrease meal boluses prior to activity may be useful.
Eating less	Consult a healthcare professional to adjust basal rates and meal boluses accurately.
Alcohol consumption	Caution required following the consumption of alcohol as the liver metabolizes alcohol increasing vulnerability for hypoglycemia.
Programming or User error	Check and review bolus history and basal rates. Consult with a healthcare professional to review Bolus, Time, CIR, CF, Target BG and Basal Rates are correctly programmed.

7.4 Hyperglycemia (high blood glucose)

What is hyperglycemia (high blood glucose)?

Hyperglycemia (high blood glucose) can occur due to any interruption in the delivery of insulin. It is important to know that when there is no insulin delivery an increase in blood glucose (BG) is possible. If undetected or untreated, may cause DKA (diabetic ketoacidosis).

The symptoms of hyperglycemia may include:

- Nausea
- Vomiting
- Increased drowsiness
- Difficulty breathing
- Dehydration
- Fruity odor to the breath
- Dry cracked lips, mouth or tongue

Reasons for hyperglycemia

- Too much food
- Not enough insulin
- Loss of insulin strength/effectiveness
- Non-diabetes illness causing insulin resistance
- Disruption of insulin delivery from the pump or infusion set

What to do in case of hyperglycemia

1. Check blood glucose level.
2. Check the Pump even if it does appear to be in good order. If the insulin pump and linking screw are not connected - then even though pump is appears to be working, insulin is not delivered (refer to insulin pump IFU – *Connection of Pump & Reservoir*).
3. If blood glucose remains high, treat as prescribed by a healthcare professional and/or contact a healthcare professional immediately.

➢ Troubleshooting for hyperglycemia

POSSIBLE CAUSE	SUGGESTED RESPONSE
Empty reservoir	Visually check display screen for remaining insulin and visually view the reservoir in Pump. Replace the reservoir if required.
Insulin leakage at infusion site, disconnection at the site or connection to Pump	Examine infusion site to make sure that there is no leakage. Examine the connection of the Infusion Site to the Pump and the Infusion Site connector. **Notice** Insulin has a strong pungent smell – if insulin can be smelt anywhere, it is likely to be leaking.
Pinched or obstructed Infusion Set	Change the Infusion Set.
Programming or user error	Check and review the bolus history and basal rates. Check with a healthcare professional to make sure Bolus, Time, CIR, CF Target BG and Basal are correctly programmed.

8. Specification

8.1 Mobile Application

Information	Mobile Application
Product Name	AnyDANA
Model Name	AnyDANA-A (Android based) AnyDANA-i (iOS based)
Unique Device Identification	AnyDANA-A : 08809220583506 AnyDANA-i: 08809220583513

8.2 Cyber Security

The AnyDANA mobile application encrypts all BLE communication between the DANA insulin pump and the AnyDANA mobile application.

In order to prevent insulin delivery due to unintended connection due to cybersecurity hacking, AnyDANA mobile application requests connection approval from the pump, and the connections are only connected to the approved pump. In addition, to prevent illegal connection, security is maintained by connecting to the network and authentication when running AnyDANA mobile application once every 10 days. If the authentication is not valid, the app cannot be used.

The AnyDANA mobile application only allows pairing with one device at a time.

9. Adverse Event Reporting

If you experience any malfunction or deterioration in the characteristics and/or performance of a device which, directly or indirectly might lead to the death of a patient, or to a serious deterioration in their state of health, report to the manufacturer and the competent authority of the Member state in which the user and/or patient is established.

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11. Warranty

SOOIL Development Company Limited warrants that the AnyDANA is free from defects in material and workmanship under normal use and conditions and will warrant this for a period of four (4) years from the date of purchase by the original purchaser. This limited warranty extends only to the original purchaser.

Should the System fail to operate properly due to defect in material or workmanship during the warranty period, it may be returned to SOOIL Development Co. Ltd., by shipment to its designated Distributor. The System will be repaired or replaced at SOOIL's option without charge to the purchaser. Freight and other charges, where applicable, incurred in shipping a System for repair date is covered under this warranty. The warranty period shall not be extended from the original purchase.

This limited warranty is valid only if AnyDANA is used in accordance with all of the manufacturer's instructions. Note that this warranty does not extend to damage as a result of the following:
• Service or repairs performed by any person or entity other than a SOOIL authorized technician.
• Modifications or changes to the System by the user or any other person after the date of manufacture.
• A force majeure or other event beyond the control of SOOIL or acts of negligence, misuse, or mishandling of AnyDANA by the user or any other person including but not limited to physical abuse of the product such as dropping or otherwise damaging AnyDANA.
• Failure to follow the manufacturer's instructions.

Except as expressly set forth in this limited warranty, all other warranties are expressly disclaimed and excluded including, without limitation, any warranties of fitness or merchantability for a particular purpose.

The remedies provided herein are the exclusive remedies available in the event of any breach hereof. Except for such remedies, SOOIL Development Co. Ltd., its distributors, suppliers and agents shall not be liable for any losses, liabilities, claims, or damages of any kind or nature whatsoever including, without limitation any indirect, consequential, incidental or special damages caused by or arising from a defect of the System.

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AnyDANA

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