EN

Dana Diabecare RS

USER'S GUIDE

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1. Introduction

1.1 DANA Diabecare RS Insulin Pump Introduction

The **DANA Diabecare RS** Insulin Pump herein after will be referred to as 'Insulin Pump' throughout the manual.

Warning The **DANA Diabecare RS** system is only to be used by patients who have received training from a certified diabetes educator and/or insulin pump trainer and by advice from a physician.
For safety and optimum benefits read the entire user manual before using the system.

Caution Read these instructions for use carefully and completely before using this device for the first time. Especially, users who have used other pumps should be cautious.

1.2 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 which is important but not hazard related.

1.3 Indications for Use

The **DANA Diabecare RS** Insulin Pump is intended for the subcutaneous delivery of insulin for the treatment of diabetes mellitus. The device is not intended for use with blood or blood products.

1.4 Contraindication

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

1.5 Potential Risks

- Infection
- Skin irritation or redness
- Bruising
- Discomfort or pain
- Bleeding
- Irritation
- Rash
- Hypoglycemia
- Hyperglycemia

- Possible hypoglycemia (low blood glucose) from over-delivery of insulin due to a hardware detect
- Hyperglycemia (high blood glucose) and ketosis possibly leading to Diabetic Ketoacidosis (DKA) due to pump failure resulting in cessation of insulin delivery due to either a hardware detect or software anomaly.

1.6 Precautions

1. Pump users need more than 4 blood glucose measurements per day, and vision and hearing to get the pump alarm.

2. Confirm regularly that the screen display turns on, you can hear audible beeps, and feel the vibrate. If these features are not working, discontinue use of the pump and contact a healthcare professional or technical support from the local Insulin Pump distributor.

3. Patients must not open the Pump housing or handle any internal components.

4. The **DANA Diabecare RS** Insulin Pump is intended for use with a proprietary Infusion Set, reservoir and other accessories specified in this booklet. DO NOT use the Pump with any other infusion system or accessories.

5. Press buttons with the pad of the finger. DO NOT use fingernails or any sharp objects.

6. The Insulin Pump comes with factory default settings and alarms, maximum daily totals, basal and bolus doses. These settings can be adjusted by a healthcare professional.

Glucose Check Alarm	120 min
Maximum Daily Total	80 u
Maximum Bolus	40 u
Maximum Basal	3.3 u/h

7. The reservoir and Infusion Set are supplied with sterile and intended for single use only. DO NOT reuse.

8. Change the reservoir and the Infusion Set regularly, as recommended by your healthcare professional. DO NOT use for longer than 72 hours.

9. Check the expiration dates and dispose of any expired accessories.

10. Avoid impact damage such as dropping. If there is any known damage of pump and accessory, contact your healthcare professional or technical support from the local Insulin Pump distributor.

11. For any trouble with any of the system components, turn off the Insulin Pump by removing the battery and contact your healthcare professional or your Insulin Pump trainer.

12. Remove the battery for long-term storage.

13. If remote control is not intended to be used, it is suggested to turn the BLE off by activating 'Airplane Mode' to prevent unintentional delivery.

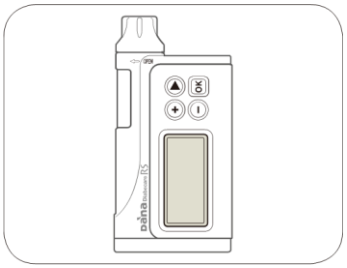
14. If you forgot pump password, contact technical support from the local Insulin Pump distributor.

15. Check your infusion site daily for proper placement and leaks. If you notice leaks around the site replace infusion set.

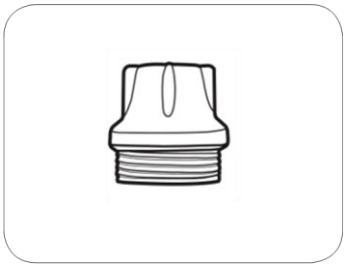
2. Getting Started

To make proper use of **Dana Diabecare RS** Insulin pump, the accessories and other devices are necessarily needed. And Components of DANA Diabecare RS KIT makes you feel a lot more comfortable when using Dana Insulin Pump.

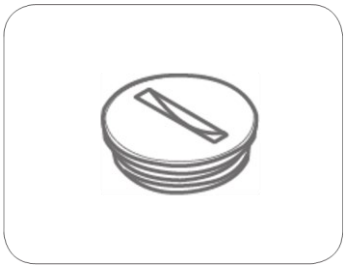
➢ Components of DANA Diabecare RS System



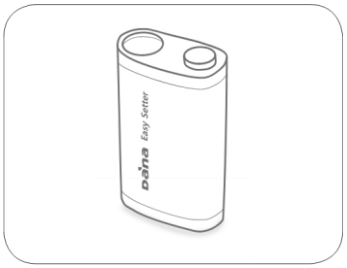
Insulin Pump (1)



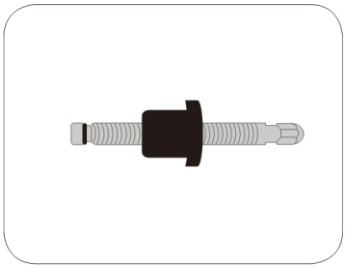
Reservoir Cap (2)



Battery Cap (2)

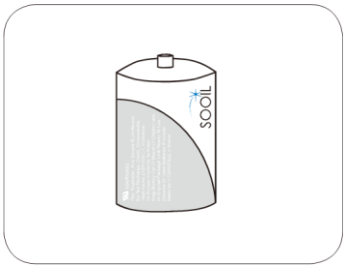


Easy Setter (1)

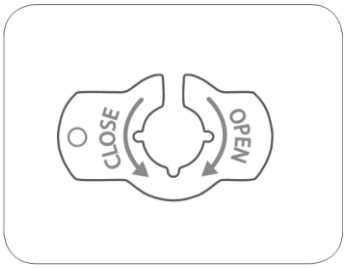


Linking Screw (2)

User Manual (1)



Battery (3)



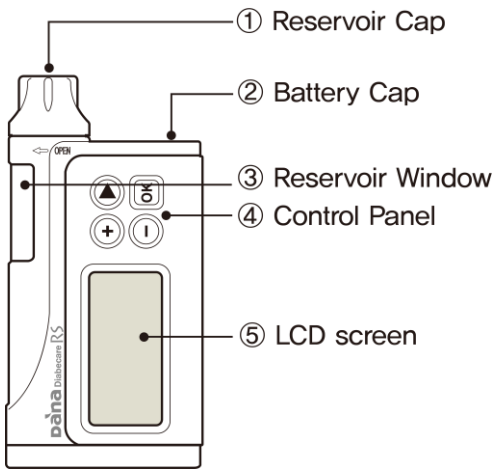
Battery Key (1)

Notice

- For Battery, Infusion set and Reservoir, please carefully check the expiration date before use.
- Additional accessories may be purchased separately.

2.1 Getting to know the DANA Insulin Pump

➢ DANA Diabecare RS Insulin Pump



① Reservoir Cap
The reservoir and linking screw are inserted in this compartment. Turn the reservoir cap clockwise to open.

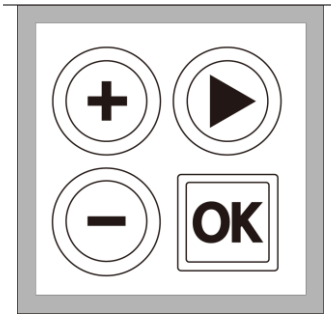
② Battery Cap
The battery is inserted in this compartment. Turn the battery cap counter-clockwise to open.

③ Reservoir Window
Reservoir volume can be visually verified here.

④ Control Panel
Includes the four buttons which are used to navigate the insulin pump menus, adjust settings and select functions.

⑤ LCD screen
Displays the pump status, system features and system messages. This is the user interface for operation of the Insulin Pump. Lights automatically when buttons are pressed.

➢ Control Panel



+	Press to increase values
−	Press to decrease values / return to previous screen
▶	Press to move to the next menu option
OK	Press to select or confirm

2.2 Installing a battery

Insulin Pump

① Open the battery cap by inserting the Battery key into the battery cap slot and turning counter clock-wise.

② Insert the battery with the positive end down into the Insulin Pump.

③ Replace the battery cap and press down whilst turning it clock-wise.

④ Completed when the cap is tight and flush with the top of the insulin pump.

Warning Change the battery in a clean dry environment to prevent water/ ingress from entering the pump case. The battery cap is correctly installed and tightened when the battery cover is level with the Insulin Pump case. This prevents water/ingress.

Caution Do not over tighten battery cap as the pump or cap could be damaged.

Notice

- Be careful about the opening direction of battery cap
- If the **O-ring** with battery cap is frayed, torn, or worn out, contact your healthcare professional or your insulin pump trainer to replace it. If it is damaged, its waterproof ability to prevent from inflow could be impaired.

➢ Check the DANA Battery:

Caution

- Use of battery other than the 1/2AA size 3.6V battery manufactured exclusively for the DANA Insulin pump will void the Insulin pump warranty.
- DO NOT attempt to change the battery while a bolus is in progress.
- Dispose of used batteries in an environmentally friendly way at a collection depot or through the insulin pump dealer.
- It is recommended to keep 2 spare batteries as backup.
- For accurate reading of the remaining battery charge, check the battery display following the delivery of a bolus

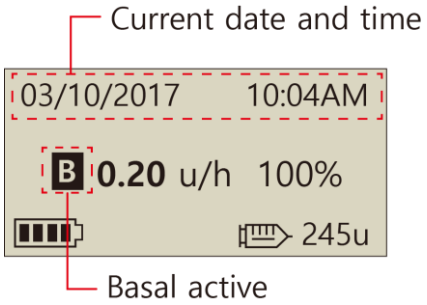
Notice

- More information of battery, refer to chapter 8.5 Battery for DANA Insulin Pump.

2.3 Display Screen

➢ Initial Screen

The initial screen is the first menu display. Enter by depressing any key from battery save mode

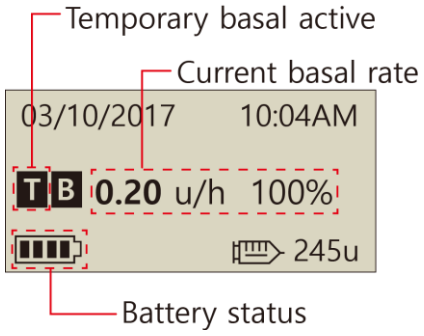


Current date and time
Time system option 12/24 available
Month/day/Year hh:mm am/pm
Refer to 3.1 Setting the time and date

Notice When the time is set to '12', "AM/PM" will be shown.

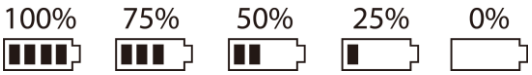
Basal active
This icon B symbol flashes when basal is active.

Temporary basal active
This icon T symbol flashes when a temporary basal is active.

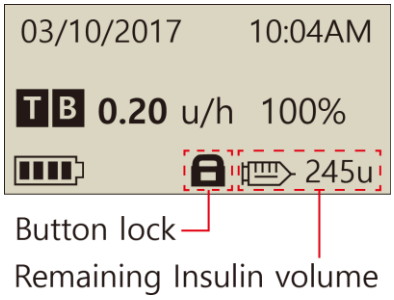


Current basal rate
Any number less than or greater than 100 indicates a temporary basal is active.
Refer to 6.1 Temporary Basal
*100% is normal basal delivery state.
*u/h = units/hour

Battery status
Displays remaining battery charge as,



Notice If 0% the battery icon will flash as a warning of low battery.

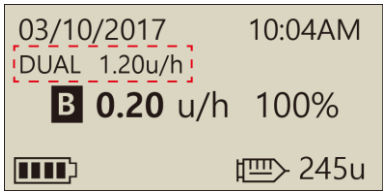


Button lock
Appears on the screen when it is locked.
Refer 6.3 Button Lock

Insulin remaining volume
Displays volume of insulin in the reservoir.

Notice Low Reservoir indicator will flash when insulin volume remaining is low.
Refer to chapter 7. Alarms and Error messages.

Extended bolus status
This icon (EXTENDED 1.20u/h) will be displayed only when extended bolus is active.
Refer to 6.8 Extended Bolus



Dual bolus status
This icon (DUAL 2.20u/h) will be displayed only when a dual pattern bolus is active.
Refer to 6.9 Dual Pattern Bolus

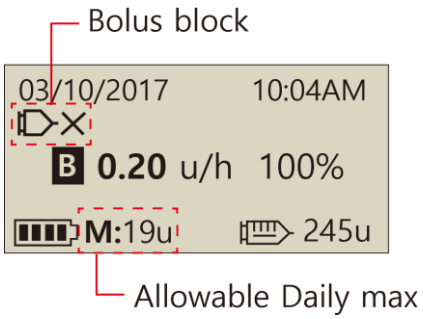
No delivery
This screen will be displayed when pump does not deliver insulin.
Refer to chapter.7 Alarms and Error messages.

➢ Airplane mode

Airplane mode

This icon ✈ will be displayed only when airplane mode is ON. The Bluetooth function is interrupted. Refer to 6.7 Airplane Mode.

➢ Additional Options



Bolus block

This icon ⊐✕ is displayed when bolus Block is active. This prevents a bolus repetition during the pre-set block time period.

Allowable Daily max

This icon (**M:19u)** is displayed when the total daily dose is high and nearing the allocated daily maximum set. Remaining units displayed from less than 20u (default) displayed.

Notice

- Additional options are configured by the Healthcare Provider or Insulin Pump Trainer.
- To save battery power the screen will automatically revert to blank after one minute without any button depressed. Pressing any button will illuminate the display and also activate the backlight for 10 seconds. (Refer to chapter 3.4 Setting User Options- "LCD on(s)" and "Backlight on(s)")

2.4 Patient Education

Follow up education is recommended for all insulin pump user.

1. When starting on insulin pump therapy, the patient should have daily contact with the pump trainer and/or medical professional.
2. Visit with the Endocrinologist, Diabetologist or Advanced Practice Nurse within 3-7 days.
3. At first schedule weekly/biweekly consults then periodically as needed and advised.
4. Visit specialist monthly until pump regimen is established and then at least once every three months or intervals advised by your medical professional.

➢ About Doctor Mode

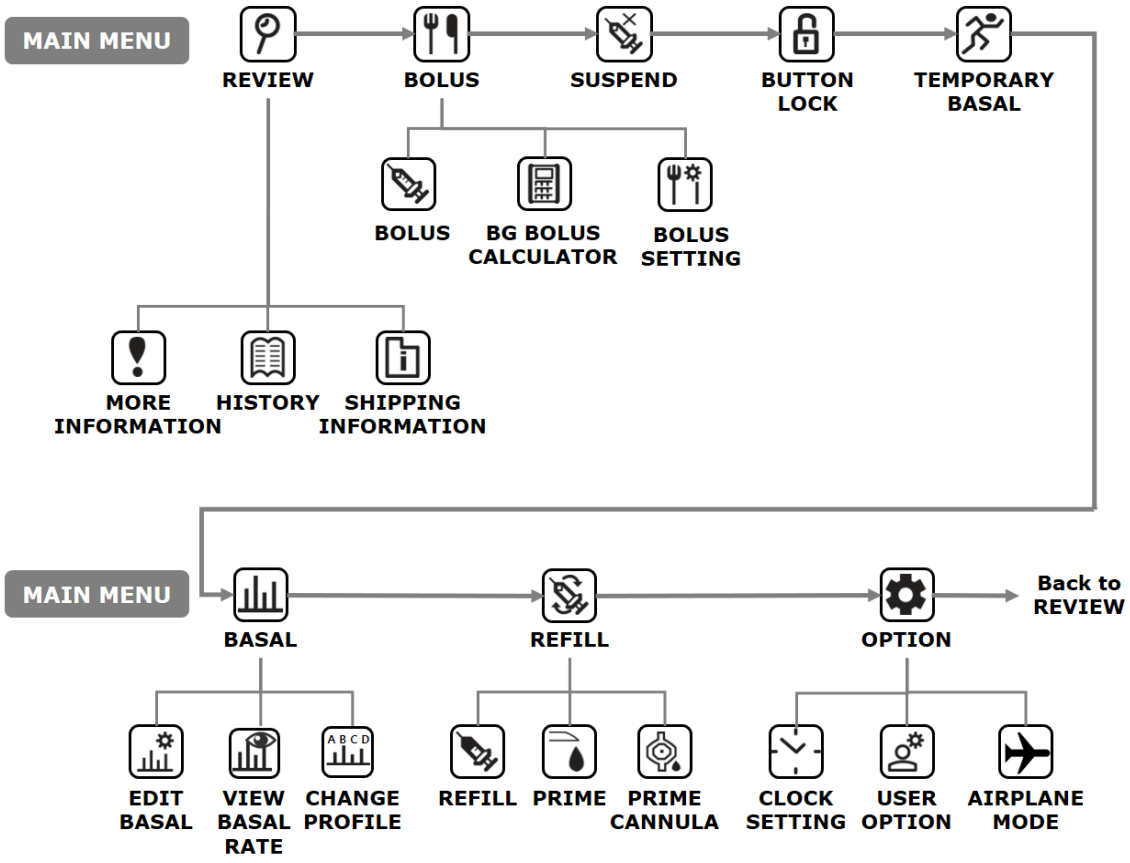
DOCTOR MODE is a configuration menu accessed only by healthcare professionals and certified insulin pump trainers. These settings are generally related to safety and to insulin dosages about individual patients.

- ✓ Preset Bolus
- ✓ Glucose Check Alarm
- ✓ Bolus Block
- ✓ Bolus Increment
- ✓ Basal Increment
- ✓ Ideal BG (Blood Glucose)
- ✓ Decrease Ratio (Active Insulin)
- ✓ Maximum Basal
- ✓ Maximum Bolus
- ✓ Maximum Daily Total
- ✓ Block Sensitive

You are required to contact your healthcare professional in order to change these settings.

3. Programming the Insulin Pump

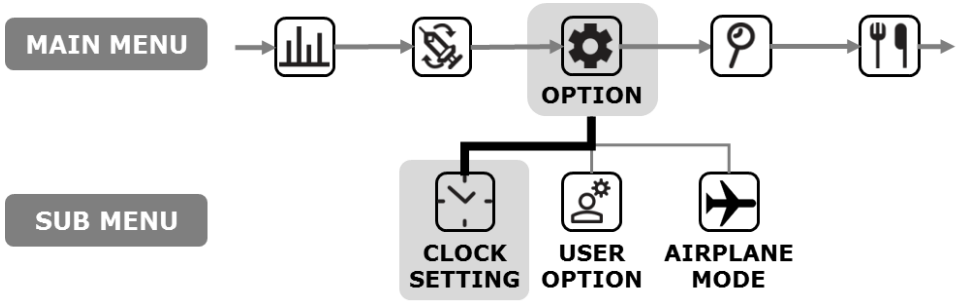
➢ **Structure of DANA DIABECARE RS Menu:**

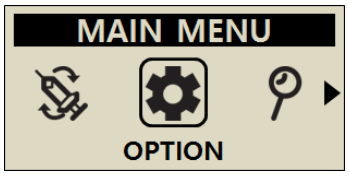
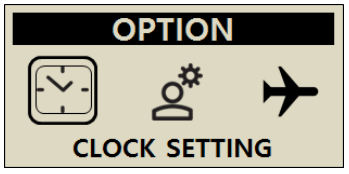
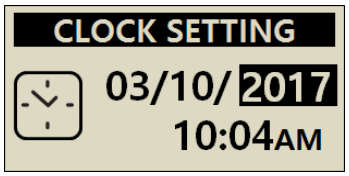
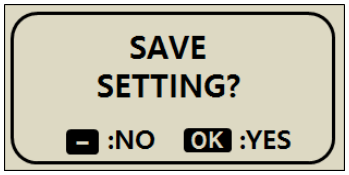


Warning Follow the training and advice of a pump specialist Healthcare professional and certified Insulin pump trainer whilst inputting the initial settings. Incorrect settings may cause serious harm.

3.1 Setting the time and date

Setting the correct date and time is necessary for accurate basal insulin delivery and for retaining an accurate record of all insulin delivery.



	1. Select **OPTION** in main menu and press OK
	2. Select **CLOCK SETTING**, press OK button.
	3. Use ▶ to move between month, day, year, hour and minute. Use + and − to make the changes. **Caution** Ensure 'AM' and 'PM' are correct.
	4. After making any changes, press OK to save.

Notice Changing 12 or 24hour clock format refer to 3.4 Setting User Options.

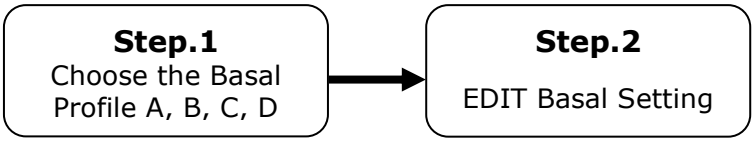
Warning If the battery was removed from the pump for a long time, the pump is asking to re-set the **Clock Setting**. Do not ignore Clock Setting screen.

3.2 Setting the Basal Rate

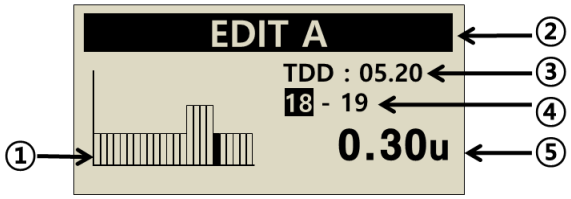
Basal settings must be programed before using the insulin pump.
Basal insulin is required to maintain an ideal glucose level while fasting.

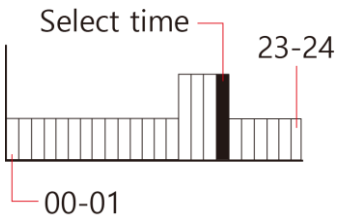
Basal insulin infusion rates are specific to individual patients. There are 24 hourly rates each day, these may increase or decrease to match personal insulin resistance and other factors. The healthcare professional will advise what the initial rates need to be set at the start.

Notice It is only possible to EDIT the current (selected) Basal Profile. Default profile is #A. (To change Basal Profile refer to 6.4 Basal Profile)



➢ Description of Basal Graph:

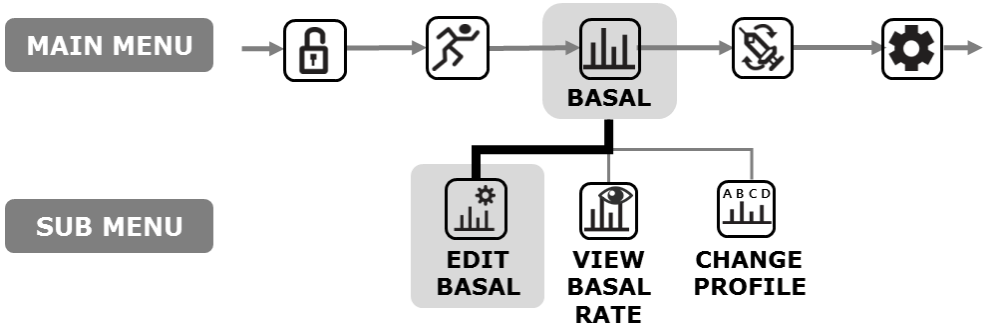


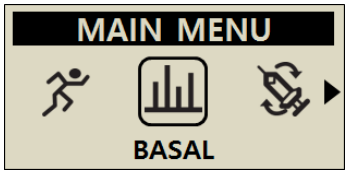
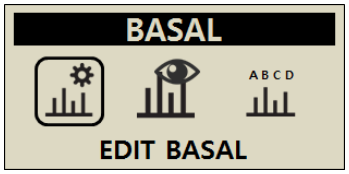
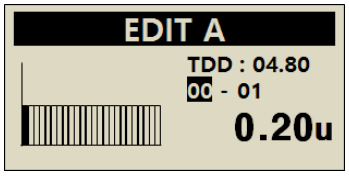
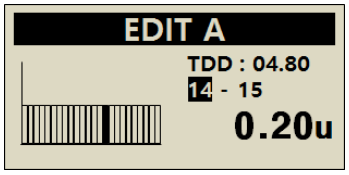
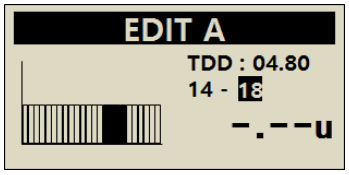
	① **Basal rate bar graph per hour** The graph consists of 24 bars, and each bar represents each hourly basal rate. In the graph, this bar starts with 00 and display until 24 (12:00AM). When the specific time period is selected, the color of that bar changes to black.
EDIT A	② **Basal Profile Letter** The active basal profile Letter# is in the title line. The example indicates that Basal Profile #A is selected. (Refer to 6.4 Basal Profile)
TDD : 05.20	③ **TDD (Total Daily Dose)** TDD is total insulin which will be delivered during 24 hours from the basal. Example, Total daily dose(basal) is 5.20 units.
18 - 19	④ **Starting and ending time** The first is starting time of each hourly basal delivery, and second is ending time. The example indicates the basal between 18 and 19 (06 PM-07 PM) is 0.3u.
0.30 u	⑤ **Basal Rate** In the example the basal rate between 18 and 19 (06 PM-07 PM) is 0.30 u/h

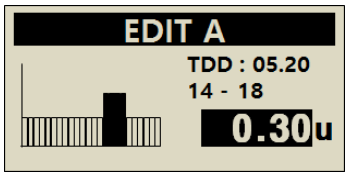
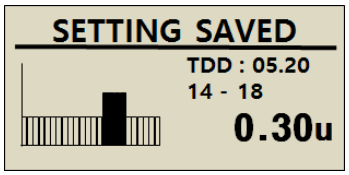
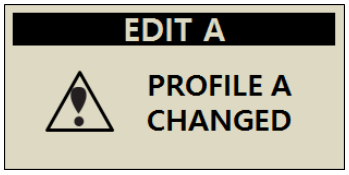
Notice

- Edit basal is only available in 24-hour format.
- Basal increments can be changed by the pump trainer.

➢ How to edit the Basal Rate:

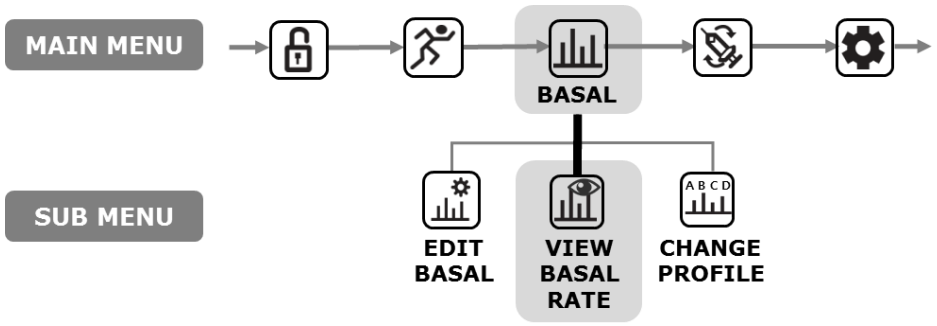


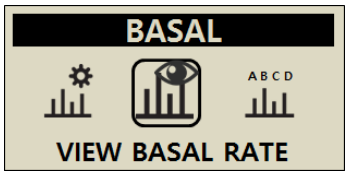
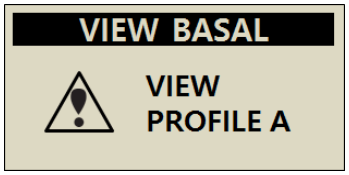
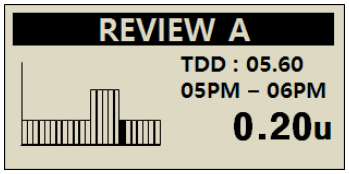
	1. Within **MAIN MENU** scroll through and select **BASAL** with OK.
	2. Select **EDIT BASAL** and press OK.
	3. The current Basal Profile is displayed, confirm the selection with OK.
	4. The edit basal screen is displayed. The default time is 00-01.
	5. Use the ⊕ and ⊖ to adjust the **start** time. press ▶ to move to the **End** time.
	6. Use the ⊕ and ⊖ to adjust the **End** time. press ▶ to move to the **Basal** rate.

	7. Use the ⊕ and ⊖ buttons to adjust the **Basal** rate for the selected time. Press OK to save the basal rate or press ▶ button to move to the start time(step.5).
	8. When press OK to save, a 'SETTING SAVED' screen appears. Press OK to finish the setting, or press ▶ to move to the start time to set next Basal rate.
	9. To save press OK. A confirmation message shows that the Basal Rate has changed. Press OK to confirm.

3.3 View Basal Rate

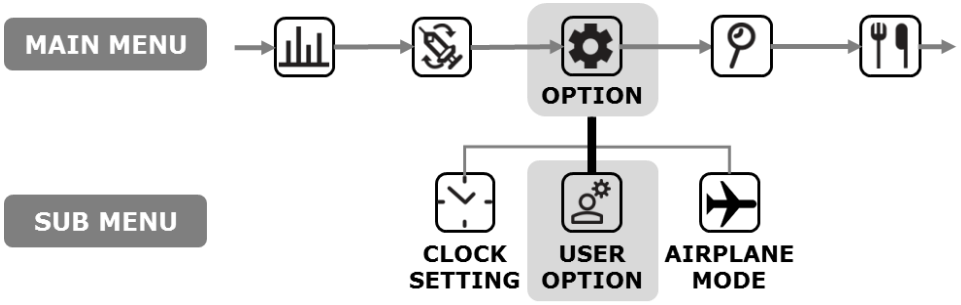
The view basal rate is used to view the current profile's time-specific settings.

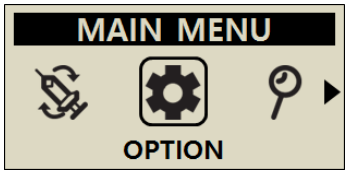
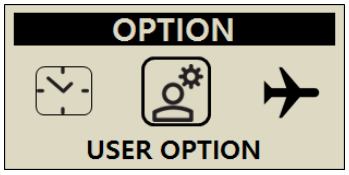
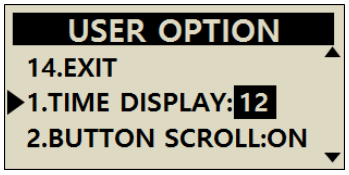


	1. Select **VIEW BASAL RATE** in BASAL's sub menu and press OK.
	2. The current Basal Profile letter is displayed, confirm the selection with OK.
	3. The cursor is positioned at the current time. Press ▶ to see the next time value. Press − to exit.

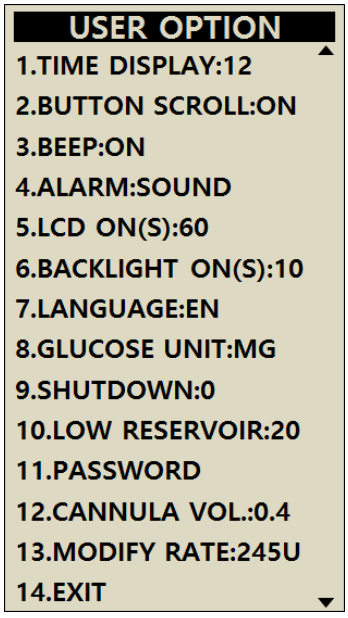
3.4 Setting User Options

The user can change the settings related to pump usage through the User option.



	1. Select **OPTION** in main menu and press OK
	2. Select **USER OPTION** in OPTION's sub menu and press OK
	3. Use the + and − buttons to set the user option. Use ▶ to move to next item.

➢ User Options



1. **TIME DISPLAY**
   Adjust the time display as 12hour or 24hour.

2. **BUTTON SCROLL**
   When **ON** holding the ⊕ or ⊖ buttons adjusts the value quickly.

3. **BEEP**
   Key Beep ON/OFF enables an audio tone when buttons are depressed.

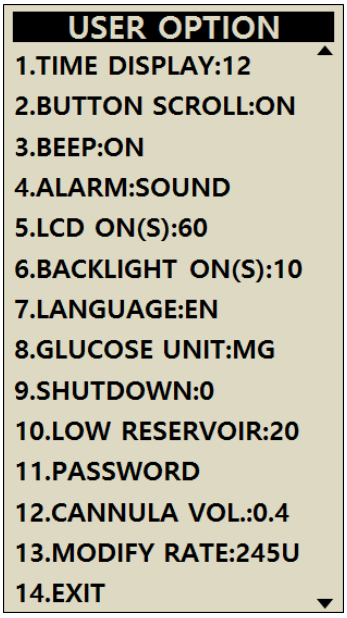
4. **ALARM**
   Change between **SOUND**, **VIBRATION** or **BOTH** for alerts and pump alarms.

   Notice for safety some important alarms will **SOUND** even though **VIBRATION** is selected.

5. **LCD ON(S)**
   Adjust the duration the LCD remains on before changing to Screen Saver Mode.
   Set between (5 – 240) seconds.

6. **BACKLIGHT ON(S)**
   Adjust the duration that the LCD backlight remains on between button presses.
   Set between (1 - 60) seconds.

7. **LANGUAGE**
   Change different language option set by Country / Region.



8. GLUCOSE UNIT

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

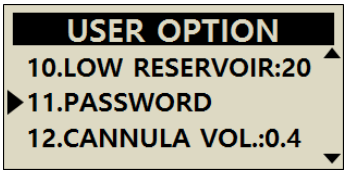
Warning Using wrong unit of measure could lead to Glucose results being misinterpret.

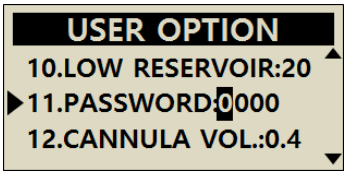
9. SHUTDOWN

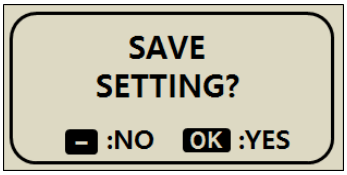
This is a safety setting, where if no buttons are depressed after the time set (0 – 24) the pump stops deliver and an alarm sounds.
Set the time to **(O)** to disable this auto off.

10. LOW RESERVOIR

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







11. PASSWORD

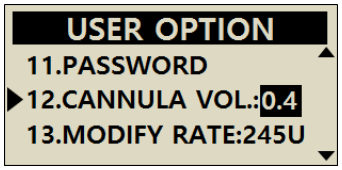
Change the BUTTON LOCK password. Enter the current PASSWORD and press OK.
From the PASSWORD screen enter the new password then press OK to save. The password can be set from 0 to 9 and A to F.

Notice Default password is derived from the manufacturing date and calculates as MMDD where MM are the month and DD are the days, the pump was producted. You can see the manufacturing date in the Shipping Information menu, refer to the chapter 6.6 Shipping information.

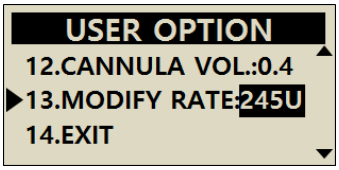
Caution Password "0000" is easily unlocked. This may be dangerous for children.

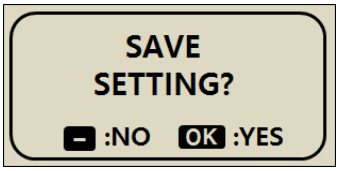
Notice If forget your password number, contact your dealer.

➢ User Options



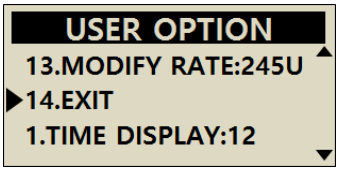
12. CANNULA VOLUME:
Soft needle cannula has a pre-assigned volume that needs to be filled with insulin before delivery. Set the pre-set the required volume here for the specific cannula used.
(Refer to 10.3 Prime Volume of infusion sets)





13. MODIFY RATE:
This is where the remaining reservoir volume in the pump can be adjusted.

Caution Changing the volume to an incorrect amount, may cause the pump to run out of insulin without alarm.



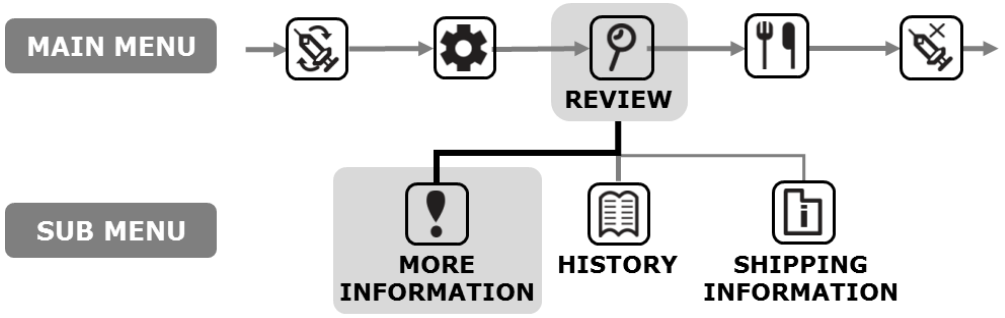
14. EXIT:
Press OK to exit

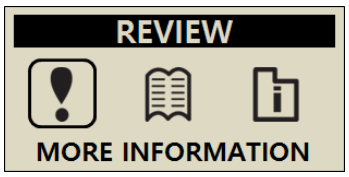
Notice When adjusting important USER OPTION settings like Language, Glucose Unit, or Shutdown, a confirmation YES/NO is required.

3.5 More Information Screen

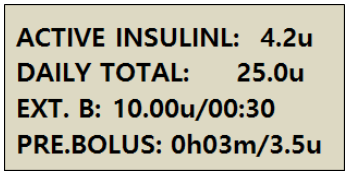
The More Information screen provides a quick review of:

- Active Insulin from a previous bolus.
- Extended bolus information (if active).
- The most recent bolus delivery information including how many minutes ago the bolus was delivery and the volume of the bolus.





1. From the main menu select **REVIEW** press OK.
2. Select **MORE INFORMATION**, press OK.



ACTIVE INSULIN
This is the Active Insulin sill working from previous boluses.

DAILY TOTAL
Displayed in units for the current day.

EXT.B (Extended bolus)
If an Extended Bolus is active, the Bolus amount and time remaining is displayed.

PRE. BOLUS (Previous bolus)
The most recent BOLUS is displayed as time since bolus and bolus amount.

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4. Loading Insulin into the Pump

4.1 Preparation

Loading and refilling the Insulin Pump with insulin is a technical process which involves medication (insulin) and sterile components.

It is recommended that:

- Retrieve the insulin vial from the refrigerator and let it warm up to room temperature before starting.

- Place all necessary components on a clean dry surface with good lighting.
  - ✓ DANA Insulin Pump
  - ✓ Analog insulin (room temperature)
  - ✓ DANA Reservoir (3ml)
  - ✓ DANA Infusion Set
  - ✓ DANA Easy Setter
  - ✓ Linking screw
  - ✓ Alcohol swab (x 1)

- Wash and dry hands before opening sterile packets and starting the refill process.

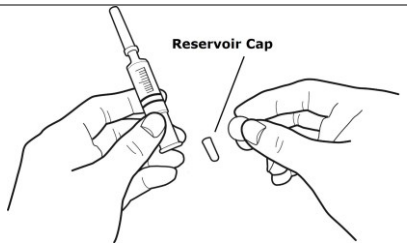
- Follow advice and recommended guidance from the healthcare professional and insulin pump trainer.

- The room temperature in this manual is 15℃ (59°F) ~ 30°C (86°F)

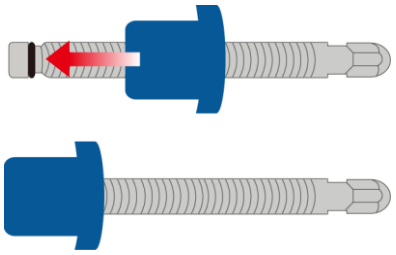
Warning Disconnect the insulin pump from the infusion set and body before opening or starting any of the refill procedure. Insulin could be unintentionally delivered if the pump is opened while still connected.

Notice Do not reuse parts or all of an old infusion set or reservoir.

4.2 Filling the Reservoir with Insulin

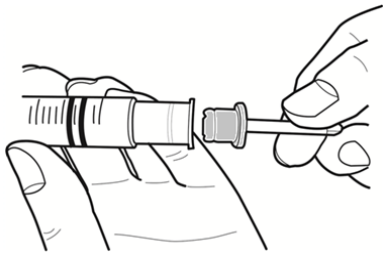


1. Remove the round cap at the backend of the reservoir plunger and discard. A small white reservoir cap needs to be removed from the plunger–keep this cap for later use. Pull back on the plunger to the line marked with the 3 ml.



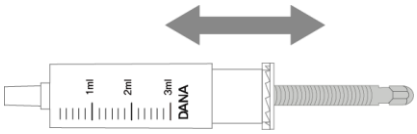
2. Loosen the linking screw until the shaft cap part is covered up by the head part (blue part). This is important to adjust the length accurately.

Caution If the linking screw is wound too far, the wrong way or tight so it cannot rotate the DANA Easy Setter may not operate properly.



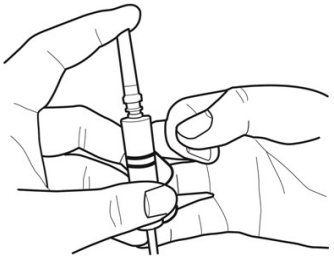
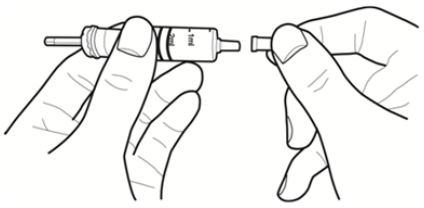
3. Insert and fit the plastic component of the linking screw into the end of the plunger/reservoir.

Notice The 'Blue' part needs to firmly engage and lock onto the reservoir plunger.



4. Push the plunger up and down 3-4 times to lubricate the reservoir.

5. Clean the lid of the insulin vial with an alcohol swab. Carefully remove the clear protective needle cover and draw up the desired amount of insulin.

	6. Place the clear needle protective cover back onto the needle. Gently tap the reservoir with your finger in order to make the air bubbles rise to the top of the reservoir. And push the plunger up gently to remove the air bubbles from the reservoir.
	7. Remove the needle from the reservoir and cover with the small white reservoir cap. Dispose of the needle as medical waste after a single-use.

Caution Using insulin directly from the fridge can cause micro air bubbles in the reservoir and tubing. Allow the insulin to reach room temperature before starting the refill process. When filling the reservoir, take care to remove all air bubbles.

Notice When refilling from a 10 ml Insulin vial, pull down the plunger until the volume of the reservoir matches the desired volume of insulin required. Insert the needle into the insulin vial and inject the air from the reservoir into the vial. Than draw down the desired volume of insulin.

Suggested fill amount formula:

(The usual daily requirement x 3 days) + Extra 40u.

※ For example, if a patient uses 60 units per day,

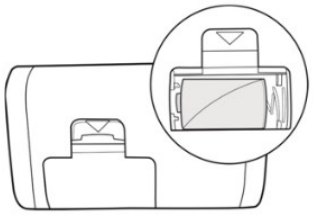
60 x 3 = 180u and extra +40u (suggest filling with 220 units).

4.3 Adjust the length of link-screw with Easy Setter

The DANA Easy Setter is intended for adjusting the length of linking screw ready for the reservoir to be loaded into the pump.

DANA Easy Setter

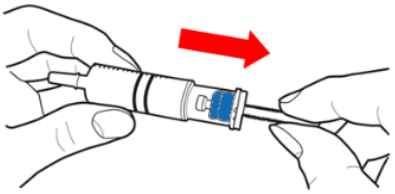
Insert a battery into Easy Setter

	Open the battery compartment. Insert a battery positive side up. Close battery compartment. **Notice** The DANA Easy Setter uses the same DANA 3.6V battery.

Caution

- The Easy Setter must be upright on a firm flat surface during usage.
- Cover the reservoir cap (with small white plastic cap) when using Easy Setter to prevent insulin leaking out.

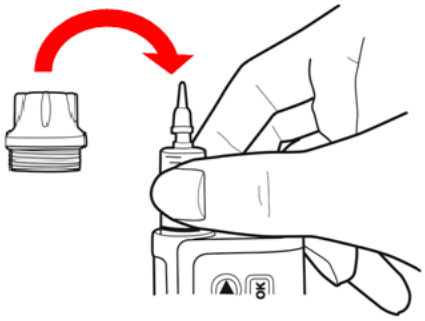
➢ Using DANA Easy Setter :

	1. Loosen the linking screw until the shaft cap part is covered by the head part (blue part). This is important to adjust the length accurately.
	2. Insert a reservoir filled with insulin into the DANA Easy Setter. **Caution** The end (hexagonal part) of the linking screw should be engaged with the hexagonal hole of DANA Easy Setter.
	3. Press and hold the button on the DANA Easy Setter. The reservoir will wind down, continue pressing the button for a further 3 seconds. Then retrieve the adjusted reservoir from the DANA Easy Setter. **Notice** When the button is held and the motor is operating you will notice the reservoir wind down into the device.

Notice

- Once removed read the reservoir volume from the indicators marked on the side of the reservoir (round the volume down to the nearest 20units).
- For more information on adjusting the connecting screws, see 4.2, 4.3

4.4 Inserting the Reservoir into the Insulin Pump



1. Insert the reservoir with linking screw into the Insulin Pump as shown.

TIP! When inserting the reservoir, rotate the reservoir 90 degrees until the notch on the side of the reservoir slide into place within the pump. Gently let the reservoir and linking screw fall into place.

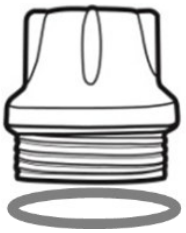
2. Turn (counterclockwise) the Insulin Pump Reservoir Cap so that it is firmly in place.

Caution

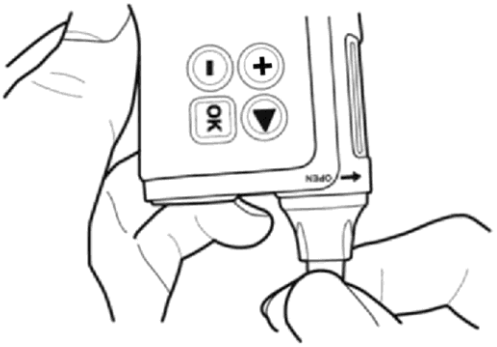
- DO NOT push or force the reservoir into the Insulin Pump as this could damage the Pump or force insulin from the reservoir.
- When reservoir cap is closed too tightly use the Battery Key to loosen it. Only close Reservoir cap firmly by hand (do not over tighten) as the pump or cap could be damaged.

Notice

- If repeated attempts to insert the reservoir fail, use another new reservoir.
- There is **O-ring** which protects the Reservoir Cap when it is closed. If it is not noticeable or in poor condition request a new one from the insulin pump provider.\



4.5 Connecting the Infusion Set to the Insulin Pump



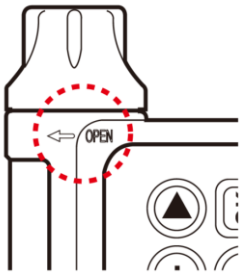
Attach the Infusion Set Tube counter clockwise into the reservoir compartment until it is firmly in place.

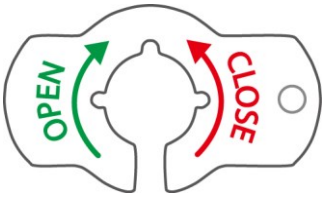
TIP! The DANA insulin pump uses a proprietary LH(Left Head) lure connection between the insulin pump and the Infusion Set tubing. Only DANA Infusion Sets will connect to the DANA insulin pump.

Notice Hold the Insulin Pump upside down while removing the white cap and connecting the tube to avoid insulin leaking into the Insulin Pump.

Warning DO NOT use an Infusion Set if the package is damaged, inadvertently opened or wet.

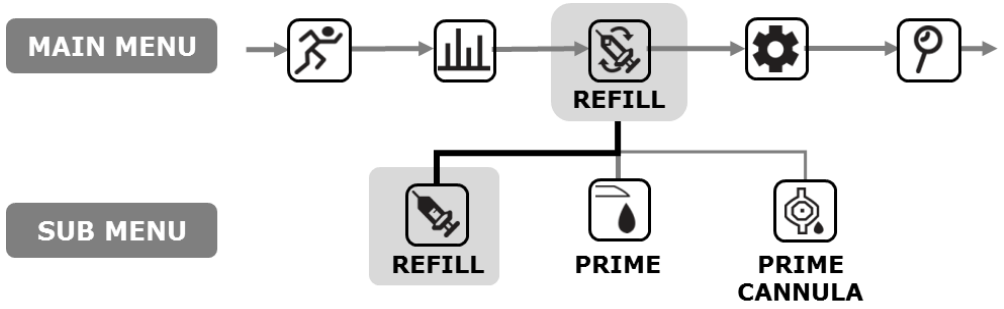
Caution Especially pay attention to follow correct direction which is marked on the Battery key and pump.

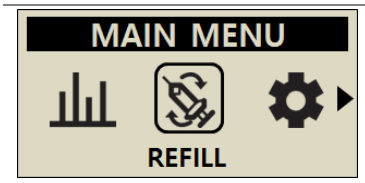
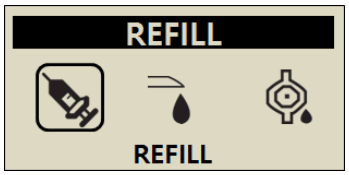




4.6 Refill

With the refill input, pump get to know exactly what the insulin amount is.



	1. Move to **REFILL**, press OK
	2. Select **REFILL** menu, press OK
	3. You can adjust the insulin amount directly using the ⊕ and ⊖ buttons.
	4. To confirm the insulin amount press OK button. **TIP!** Press and hold the ⊕ and ⊖ buttons to change the value to quickly.
	5. Press OK to save and go to Refill-PRIME Menu.

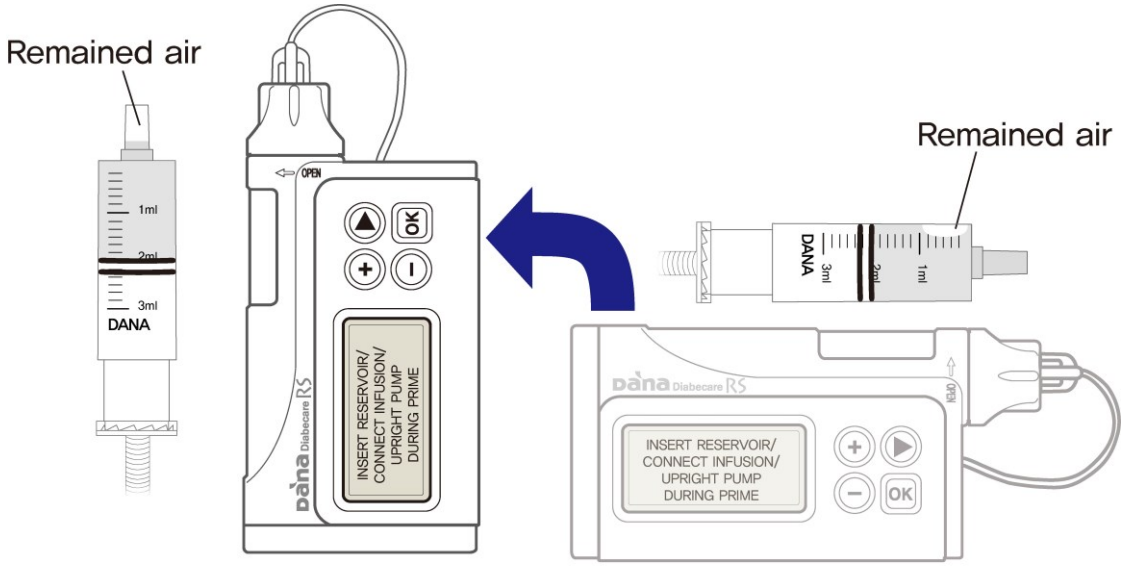
4.7 Prime the Infusion Set Tubing

Prime every new Infusion set tube to displace air from within the tubing. Visually confirm that all bubbles are primed from the Infusion Set tubing. Upon completion of refill process confirm the basal is active and correct.

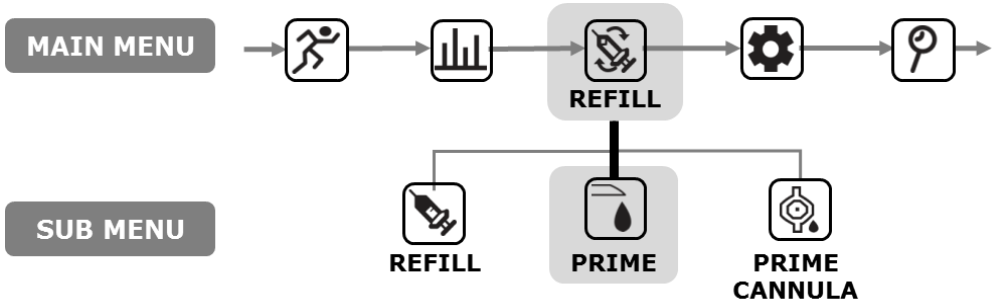
Warning It is important to properly prime the Tube and ensure all air is removed from the system. The pump may not properly deliver insulin without this.

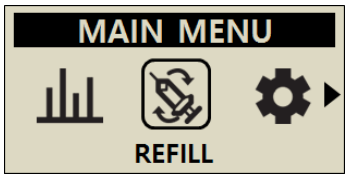
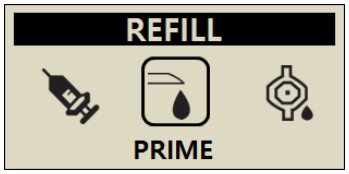
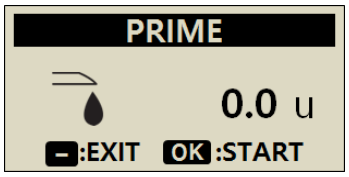
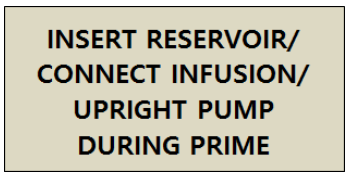
Caution PRIME is a very important process to ensure that the pump will deliver insulin accurately. Delivery problems often result due to air within the tube and occlusion alarms may be because of poor or insufficient PRIME. Patients are required to have good level understanding of how to properly PRIME and why the PRIME process is important.

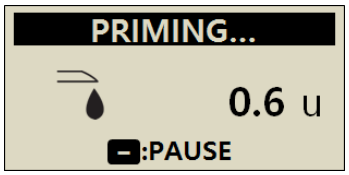
Notice Connect the infusion set tube then position the pump upright during priming for the perfect removal of any air in the reservoir and tube.



➢ PRIME procedure:

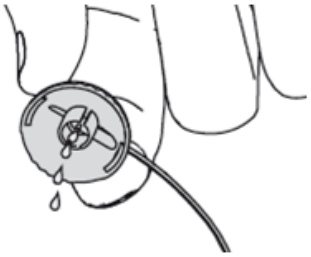


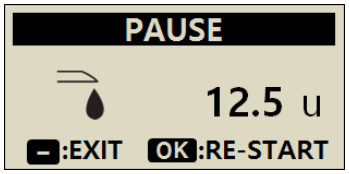
	1. From the main menu select **REFILL** and press OK
	2. Select **PRIME** from the REFILL's sub menu and press OK
	3. From the **PRIME** menu press OK to start. **Warning** It is very dangerous to start a Prime whilst the Infusion set is connected to the body.
	4. Stand PUMP **upright** during **PRIME,** press OK . Air moves upwards to top–standing pump upright helps displace all air bubbles.
	5. **START TUBE PRIME** confirmation menu, press OK to start **PRIME**



6. The **PRIMING** display will show the volume of insulin delivered.

Notice During PRIME the pump may BEEP or VIBRATE after every unit of Insulin is primed.



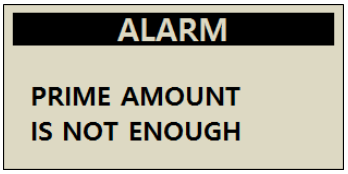


7. When droplets of Insulin appear at the end of the **TUBE** press to **PAUSE**. Check the entire length of **TUBE** for any bubbles. Press to finish the PRIME

Warning Ensure droplets of Insulin are clearly visible at the end of the tube / needle before stopping the prime

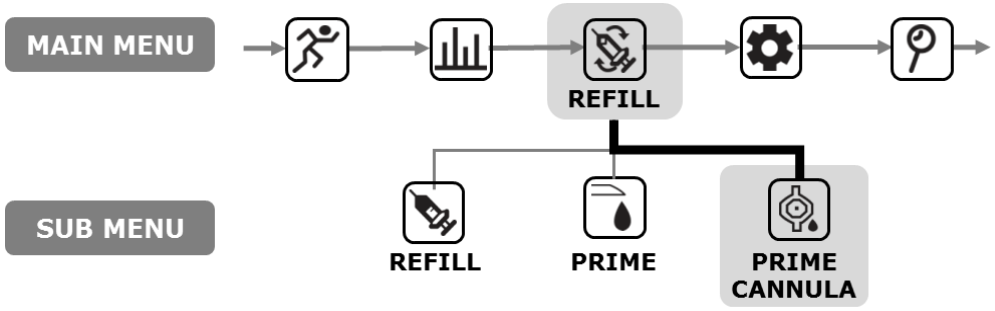
Notice Unless stopped already the PRIME will automatically stop after 25 units.

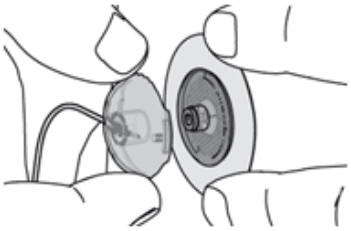
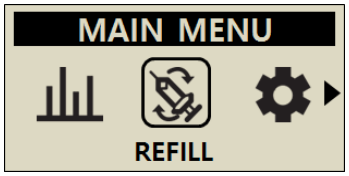
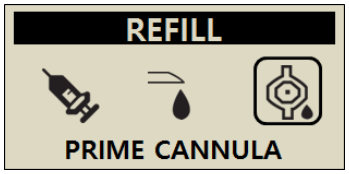
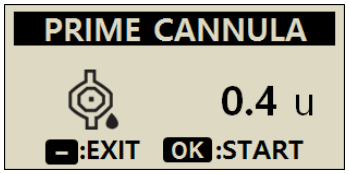
Notice If the prime amount is not enough (less than 7U), this alarm message will be displayed. Because, the minimum prime amount of the infusion set connected to the DANA pump is 7U. Refer to 10.3 Prime Volume of infusion sets and Chapter 7. Alarms and Error messages.

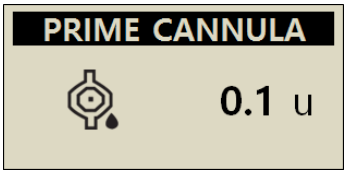


4.8 Prime the Cannula

When using an infusion set with a soft needle/cannula, the hollow area within the cannula requires PRIME CANNULA after completing tube prime.



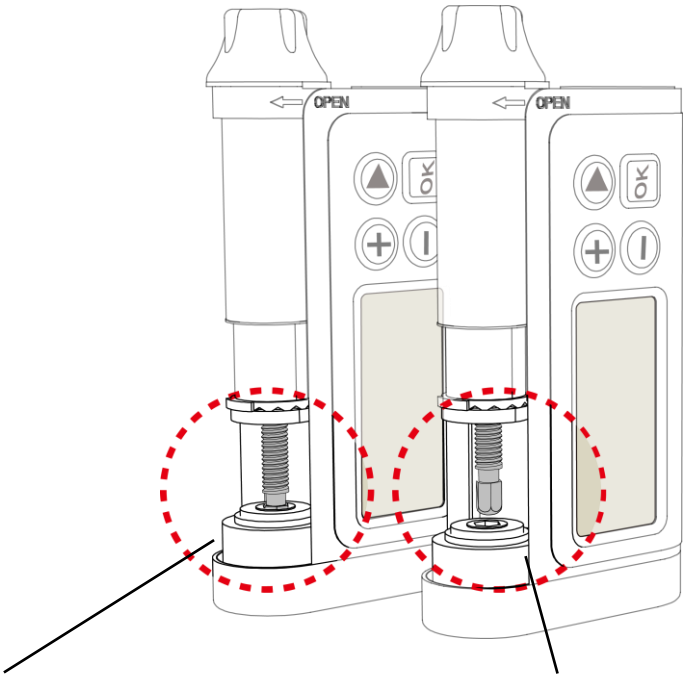
	1. After inserting the cannula into the body (following the cannula instructions) connect the infusion set tube to the infusion set after priming all bubbles out from the tube.
	2. Select **REFILL** menu from the **MAIN MENU** and press OK
	3. Select **PRIME CANNULA** from the **REFILL** menu press OK .
	4. Check the **PRIME CANNULA VOLUME** is correct? press OK to confirm.

	5. Press OK to confirm.
	6. The **PRIME CANNULA** window displays the delivery.

Notice Cannula fill volume is set in the USER OPTION menu. Cannula fill can be set between 0.1 – 0.9 units. Read cannula instructions to determine individual requirements for filling.

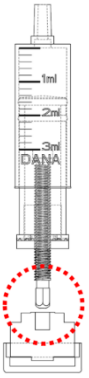
➢ Connection of Pump & Reservoir

The following is structure of pump and reservoir through linking screw.

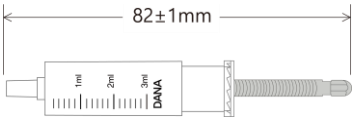


Connection Success
If after a new refill, insulin pump primes the tubing properly and insulin droplets appear at the end of the tubing, It confirms the successful mechanical connection of linking screw and gear pit of motor assembly.

Connection Fail
If the linking screw is too short, it won't engage with the pump motor and insulin delivery fails. If insulin does not come out even if you prime more than once, adjust the length of the linking screw again. Contact your healthcare professional or Pump Trainer if this occurs frequently.



Notice The insulin pump normally works if the length of adjusted reservoir including linking screw is 82±1 mm (3.2 inch).



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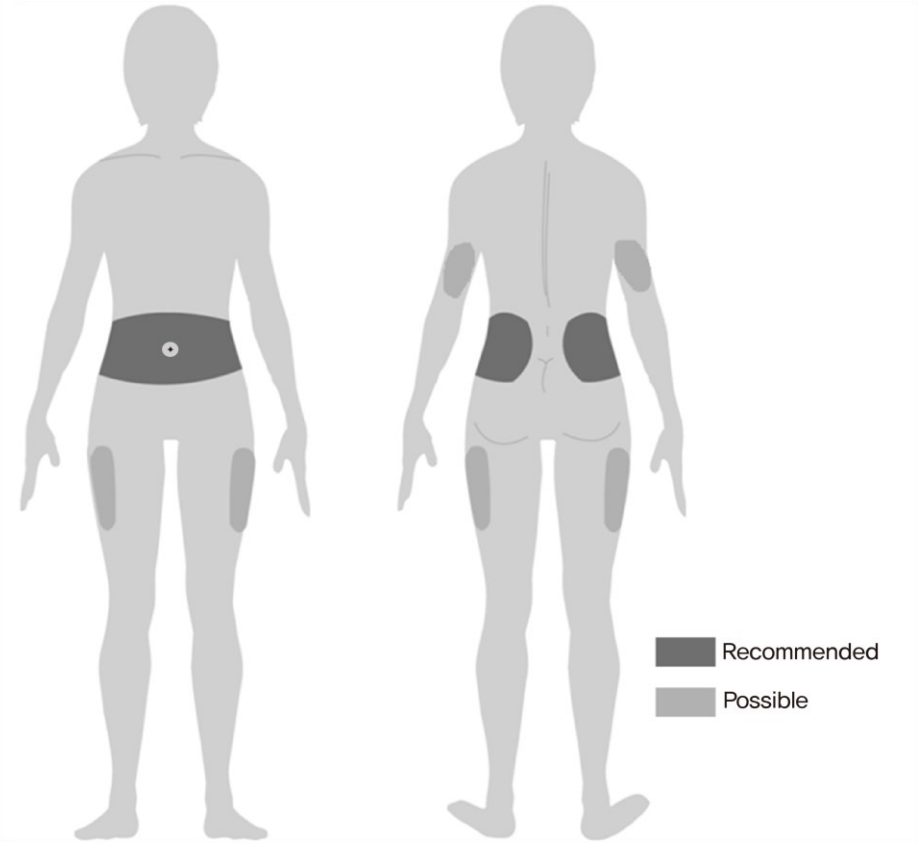
4.9 Inserting Infusion Set

Refer to instructions for the specific Infusion Set you (the patient) are using. Each Infusion Set/Cannula is made of different material and some have auto insertion tools to help with the Cannula insertion.

It is also recommended that cannula/infusion sites are inserted following a warm shower to ensure the area is clean and assist with adhesion.

Notice Your healthcare professional or certified Insulin Pump Trainer will be able to discuss the merits of each Infusion Set and assist you with choosing the most appropriate set and size for your insulin requirements.

➢ Recommending insertion site location



It is recommended to rotate the location of your Infusion Set sites to minimize skin damage and enable longer healing times. Consult your healthcare professional about the infusion site rotation. It is recommended that good rotation between 4 separate areas on the body – each area approximately the same size as the palm of the hand

Notice

- Avoid inserting Infusion Sets into any areas of recent insertion sites, scars, scar tissue or bruising.
- Infusion sites should not feel uncomfortable when touching near the insertion area after the cannula has been inserted. If discomfort is noticed it is likely the Infusion Set is not secured properly to the body.

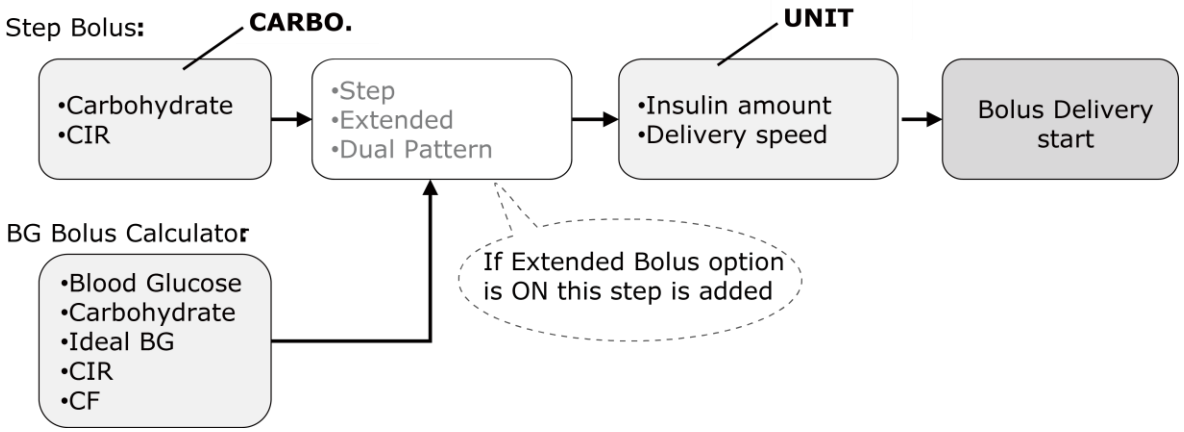
5. Delivering a Bolus

The DANA Insulin Pump can deliver a bolus of insulin using different user input parameters to calculate the bolus volume.

➢ Bolus calculation parameter

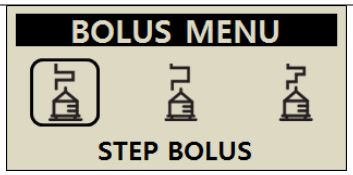
- **Step Bolus (Quick):** This standard bolus option can be calculated by either.
  - ✓ **CARBO.**: Inputting grams of carbohydrate to be consumed. The pump will estimate the dosage based on the CIR specific to the time of the day the bolus is being delivered.
  - ✓ **UNIT**: Specifying the dosage directly in units of insulin. By selection of dose in units of insulin below.

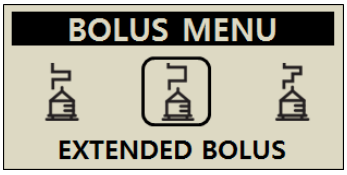
- **BG Bolus Calculator (Smart Bolus):** This smart bolus option uses the bolus calculator to calculate dosage based upon current BG level, grams of carbs to be consumed and uses the pre-set CIR, CF and Ideal BG levels set within the pump for the specific time of day.
  This Smart Bolus also factors in a bolus reduction for residual Active Insulin from previous boluses. Refer (5.3 Bolus Calculators) for detailed information.

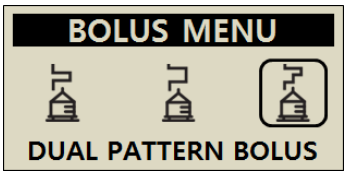


➢ Three type of Bolus Delivery

After selecting one of the options on previous page to assist with calculating the required dosage - the DANA Insulin Pump can deliver three types of bolus:





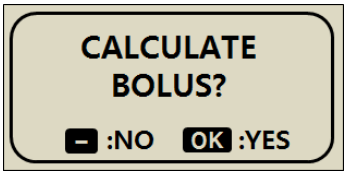


After a suggested bolus amount is shown press OK to select the bolus type:

- Step Bolus (Refer to chapter 5.1)
- Extended Bolus (Refer to chapter 6.8)
- Dual Pattern Bolus (Refer to chapter 6.9)

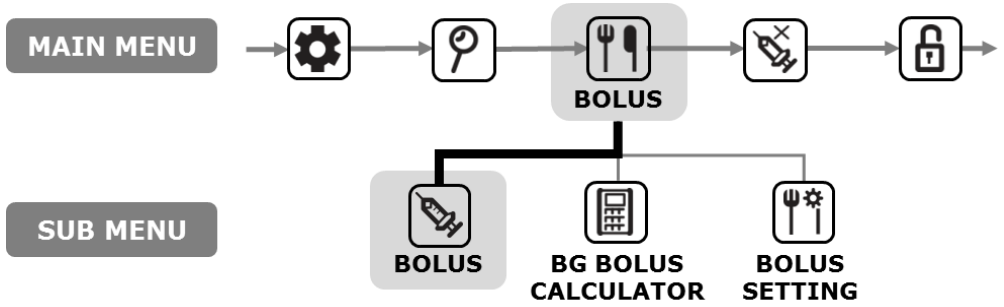
To enable the selection of bolus type, Extended Bolus must be set to ON
(Refer to 5.3 Bolus Setting - Extended Bolus).

Notice If Calculator setting is the "BOTH", this option you can choose whether to calculate your step bolus based on carbohydrates (CARBO.) or volume of insulin (UNIT) before bolus delivery.

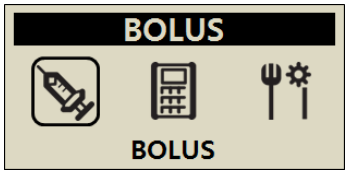
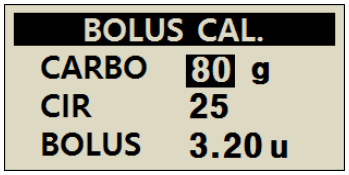
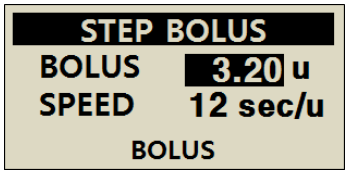
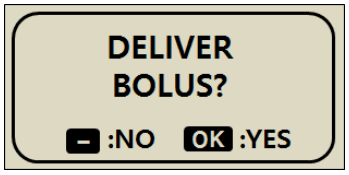


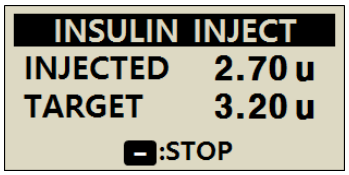
5.1 Bolus (Quick Bolus)

This bolus can be used to cover the carbohydrate in a meal or snack.

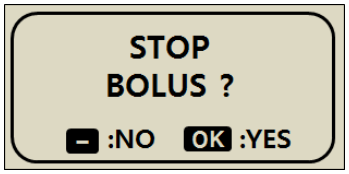


➢ **How to start the (Quick) bolus delivery:**

	1. Select **BOLUS** from the BOLUS Sub menu press OK
	2. Adjust the grams of carbohydrate with ⊕ or ⊖. Move down the menu using ▶ to adjust the CIR. Press OK for next step. **Notice** if BOLUS CALCULATION is set to "UNIT", this step has been skipped.
	3. Use ⊕ and ⊖ to increase/decrease the volume or speed of Bolus. Press OK.
	4. Press OK to start.

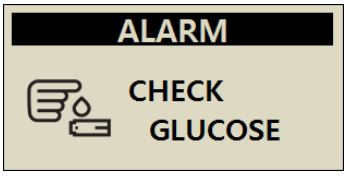
	5. The INSULIN INJECT screen displays during the delivery and you will hear the motor run as the bolus is being delivered. **Notice** You will hear the Insulin Pump beep or vibrate for every 1.0 unit while a bolus is being delivered.
	6. After the BOLUS has completed the delivery the DELIVERED BOLUS message displays the BOLUS amount. Press the OK button to return to the initial screen.

➢ Stop delivery during bolus:

	1. During the BOLUS delivery press the button. Confirm the STOP with OK
	2. After the BOLUS is stopped – the DELIVERED BOLUS message displays the amount delivered before being stopped.

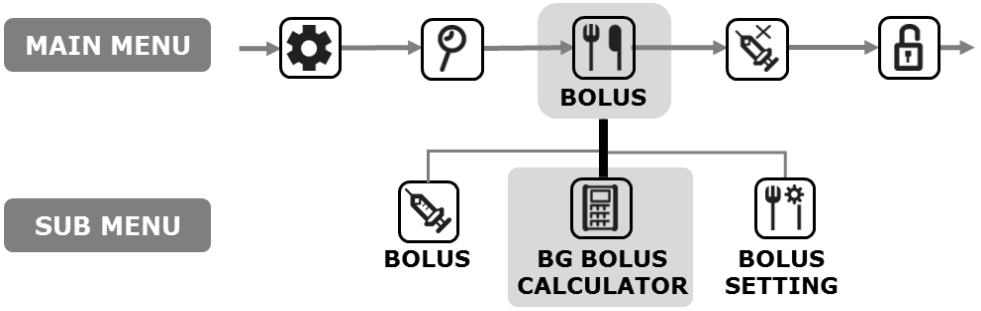
Warning Following a BOLUS delivered for carbohydrate – if the carbohydrate is not eaten, there is a risk of hypoglycemia.

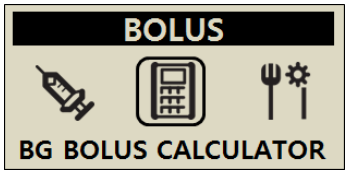
Notice The Insulin Pump will by default give an audio reminder (Glucose Check Alarm) 2 hours after bolus begins. To stop the alert, push any button once. This 2-hour Alarm can be amended or removed by your healthcare professional or certified Insulin Pump Trainer.



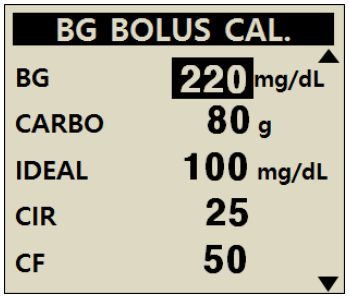
5.2 BG Bolus Calculator (Smart Bolus)

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. From **MAIN MENU** select **BG BOLUS CALCULATOR** with OK button.



2. Within the BOLUS CALULATOR menu, adjust the parameters displayed to match the settings for this BOLUS.

   BG the current BG level.

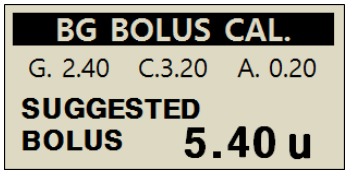
   CARBO the amount of carbohydrate in the meal.

   IDEAL the default target BG

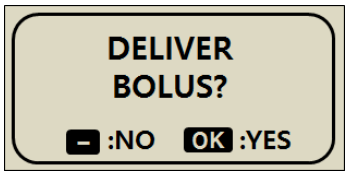
   CIR the carbohydrate to insulin ratio

   CF the correction factor

   ▶ to move the menu. Use ⊕ and ⊖ to make adjustments. Press OK.



3. The BOLUS review displays the suggested Bolus dose.



4. Start the BOLUS with OK button.

Within the BOLUS review display the following values are displayed

G Is the Bolus dose to adjust **G**lucose
= (BG-IDEAL)/CF

C Is the Bolus dose to cover **C**arbohydrate in the meal
= CARBO/CIR

A Is the residual Active insulin calculated from previous boluses. It is called "**A**ctive Insulin" or "Bolus on Board" or "Insulin on Board".

The suggested bolus is calculated by:

BOLUS = G + C – A

BOLUS = CORRECTION DOSE + MEAL DOSE – ACTIVE INSULIN

Example of Smart Bolus calculation.
Patient (A) has Ideal BG of 100 mg/dl, actual BG test prior to meal is 220 mg/dl. The meal/food contains 80 grams of carbohydrate. At the time of the calculation the set CIR is 1:25 and CF is 1:50. Patient (A) had 0.2u of active insulin at the time of the bolus.

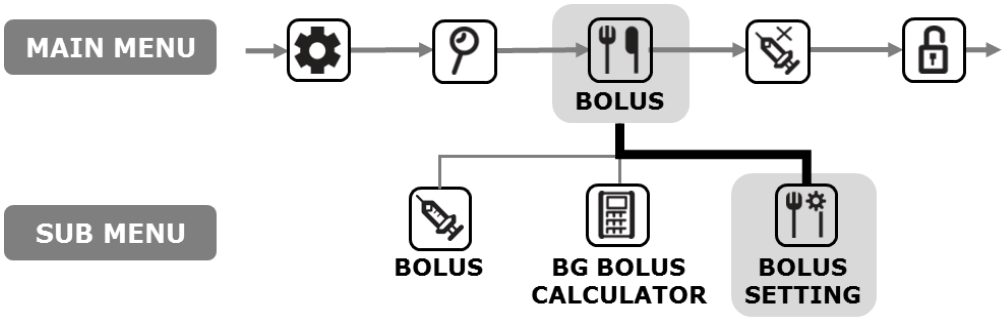
G = (220–100)/50 = 2.40
C = 80/25 = 3.20
A = 0.20

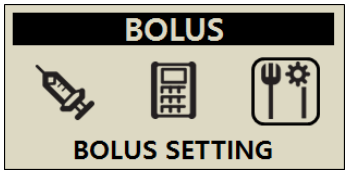
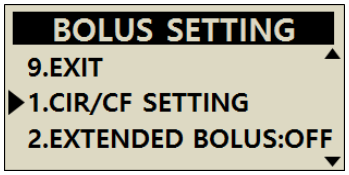
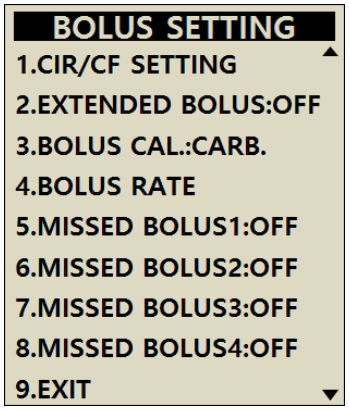
Suggested bolus = 2.40 + 3.20 – 0.20 = 5.40u

Notice If the actual BG is lower than the IDEAL BG the correction dose will be a reduction of Insulin required for the meal. Sometimes called a **Negative Correction**.

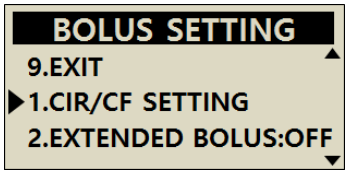
5.3 Bolus Setting

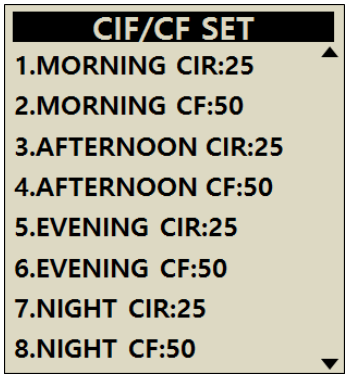
The Bolus Setting menu enables personalization of all Bolus features within the insulin pump.

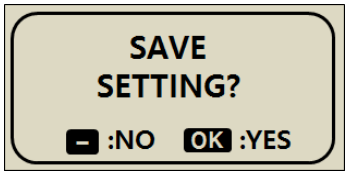


	1. Select **BOLUS SETTING** from within the **BOLUS** MENU press OK
	2. The bolus setting menu is shown
	3. Press ⊕ and ⊖ buttons so adjust the **BOLUS SETTING**. The ▶ button move through the menu to next option.

➢ Bolus Setting







1. CIR/CF SETTING

Used in the Bolus Calculator and the Bolus (Quick) menu (when calculation is selected) to accurately calculate the appropriate bolus to deliver.

Press ⊕ and ⊖ buttons so adjust the CIR and CF rates. The ▶ button will move through the menu to next setting option.

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

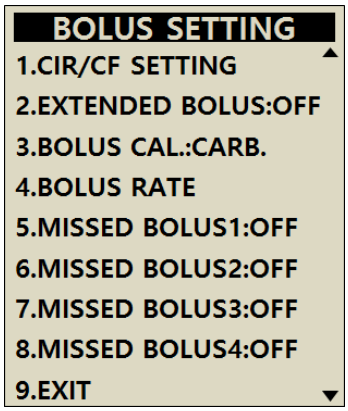
After each CIR/CF rate has been adjusted press OK to confirm changes. Save Setting with OK .

CIR = **C**arbohydrate to **I**nsulin **R**atio
CIR and CF are ratio's - so they each reflect how much 1u of insulin will cover. CIR is a setting based on the amount of carbohydrate in grams per 1u of insulin requirement.

CF = **C**orrection **F**actor
CF is a setting based on the expected change in Blood Glucose in mg/dl or mmol/L per 1u of insulin.

Notice Follow the advice and guidance from a Healthcare Professional, Nurse or Doctor when setting or changing CIR / CF ratio's.

➢ Bolus Setting

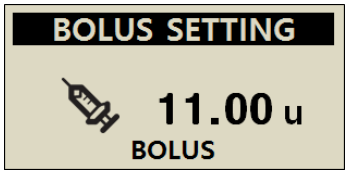


2. EXTENDED BOLUS

Adjust between extended and dual bolus ON/FF.

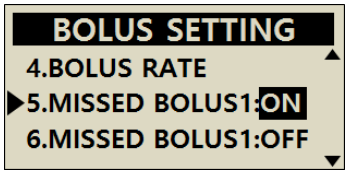
3. BOLUS CALCULATOR

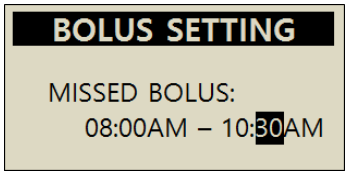
Setting changes CARB, UNIT or BOTH
CARB = Bolus requests grams entered
UNIT = Bolus by adjusting units entered
BOTH = every bolus asks which option?



4. BOLUS RATE

Enables the default bolus size to be adjusted to a personal amount.

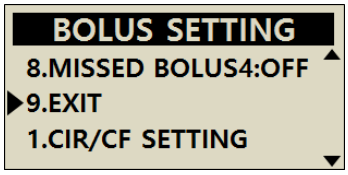




5. MISSED BOLUS 1-4

This is a safety reminder alarm. When turned on a time period can be set for regular meal bolus's. Once set an alarm will remind of a missed bolus if no bolus is delivered during the selected time period. Change the MISSED BOLUS to ON then the TIME SETTING option opens.

Notice If you do not want to use the MISSED BOLUS feature, make sure it set to "OFF".

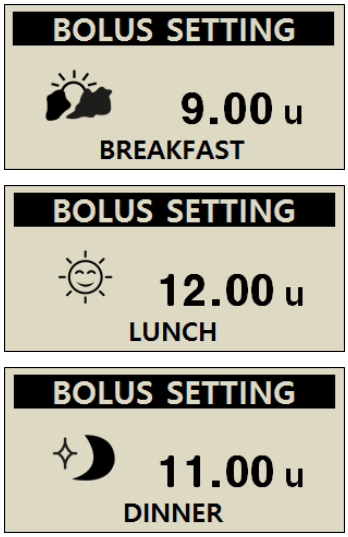


6. EXIT

Press OK, go back to BOLUS MENU.

➢ Pre-set Bolus

The value of pre-set bolus is a default value which will first appear in the bolus menu. Set the size for breakfast, lunch and dinner bolus's as an option within Bolus setting menu.



Pre-set meal boluses are set following by these time periods.

- BREAKFAST = 01:00 - 09:59 (1:00 am - 9:59 am)
- LUNCH = 10:00 - 14:59 (10:00 am - 2:59 pm)
- DINNER = 15:00 - 00:59 (3:00 pm - 12:59 am)

Notice BREAKFAST, LUNCH or DINNER will be displayed within the QUICK BOLUS menu when Pre-set Bolus is set to ON.

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

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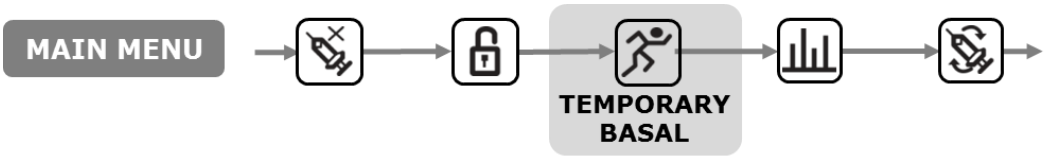
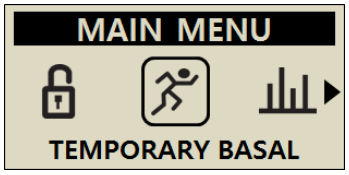
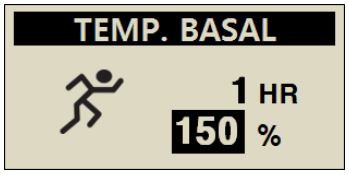
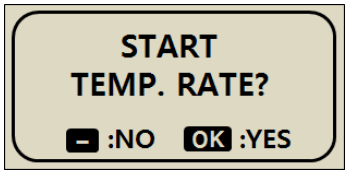
6. Advanced features within Pump

6.1 Temporary Basal Rates

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 to automatically revert to usual rates upon completion.



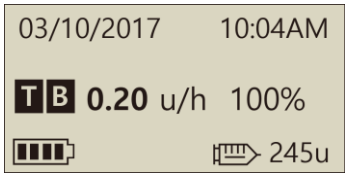
➢ Starting a Temporary Basal Rate

	1. Select **TEMPORARY BASAL** from within the **MAIN MENU**, press OK
	2. Press ▶ to toggle between **HR** and **%**. The ⊕ or ⊖ will adjust the selected rate.
	3. Confirm the Temporary Basal by selecting OK

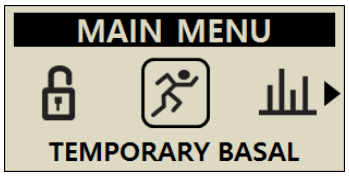
Notice

- Example: A temporary basal rate of 150% for 1 hour will increase the basal rate to one and a half of the regular basal rate for the next hour.
- The Temporary basal rate will not take effect if the HR is set to "0 HR" or the rate is set to "100%".
- Temporary Basal Rates can be set in 10% increments between 0 – 200% for between 0 – 24 hour in 1hr increments.

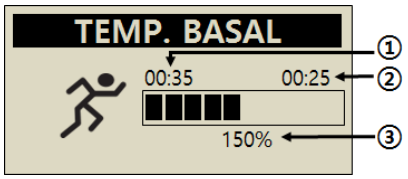
➢ Review Temporary Basal Rate Whilst in Operation



1. From the Home Screen a flashing **T** indicates that a Temporary Rate is active.



2. Select **TEMPORARY BASAL** from the **MAIN MENU**.



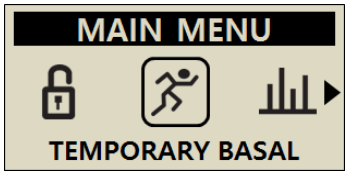
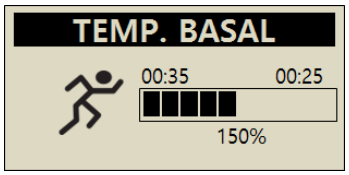
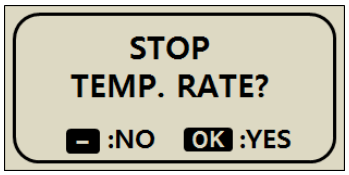
3. **TEMP. BASAL** is displayed.
   - ① Time Temporary rate has been running
   - ② Time remaining for the Temporary Rate.
   - ③ The % the Temporary Rate is set to.

   Press ⊖ to exit.

Notice Example:
Temporary basal rate: 150%
Temporary basal time: 1 hour (25 minutes remain)

Notice A second temporary rate cannot be started while one is active. The current active rate needs to finish or be stopped to start a new Temporary Basal rate.

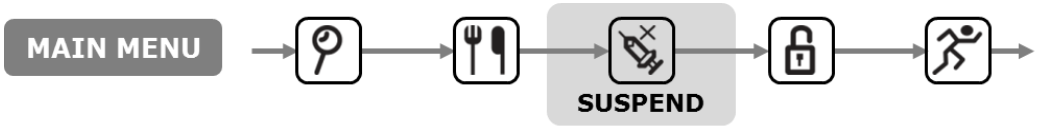
➢ Stopping a Temporary Basal Rate

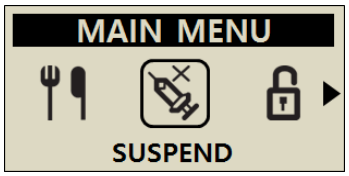
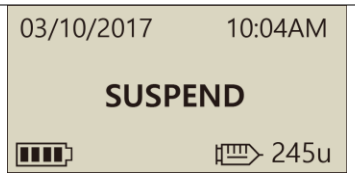
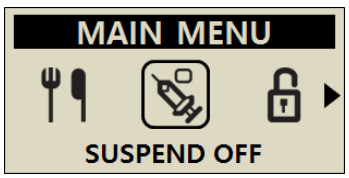
	1. Select **TEMPORARY BASAL** from the main menu.
	2. The **TEMP. STATE** screen is displayed, press OK to STOP the TEMPORARY RATE.
	3. Confirm the **STOP TEMP. RATE** with OK.

Caution Consult Healthcare Professional, Nurse or Doctor for advice about Temporary Basal rates prior to using them.

6.2 Suspend

To stop the Insulin Pump with the suspend function. Suspend stops all insulin delivery including basal and bolus. The Suspend must be off to resume basal delivery or to deliver a bolus.



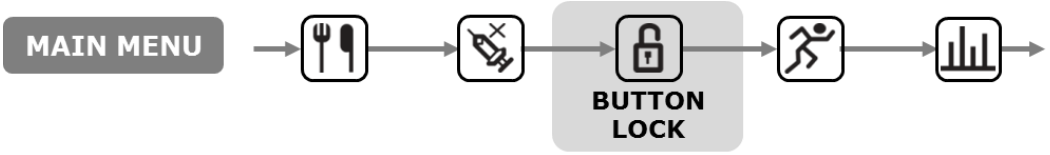
	1. Select **SUSPEND** from the **MAIN MENU**.
 	2. The display changes on the initial screen to alternate between SUSPEND and NO DELIVERY.
	3. To restart delivery select **SUSPEND OFF** from the main menu and confirm with OK. The pump will give an alarm and the basal active status on initial screen.

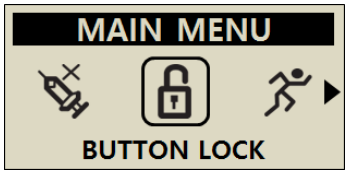
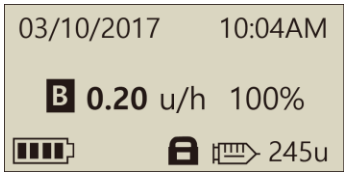
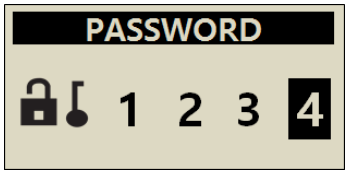
Notice When suspended, the insulin pump alarm will ring every 4 minutes. This is to advise that no insulin is being delivered.

6.3 Button Lock

Button lock prevents accidental Insulin Pump keypad presses.
It is particularly useful for:

- Pediatric patients who are not able to program their own pump.
- Patients whilst sleeping.



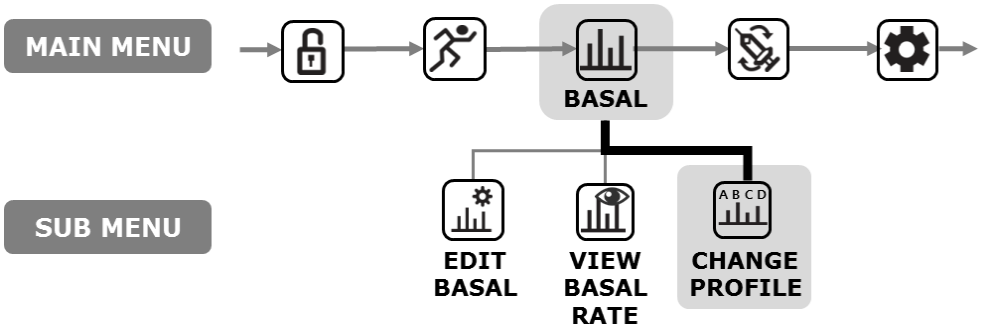
	1. Select **BUTTON LOCK** from the **MAIN MENU**.
	2. The BUTTON LOCK symbol is displayed on the Main Menu.
	3. Press any button from the Initial Screen and a PASSWORD request appears.
	4. The Correct **PASSWORD** must be entered correctly before any delivery menu can be accessed.

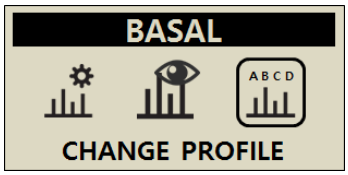
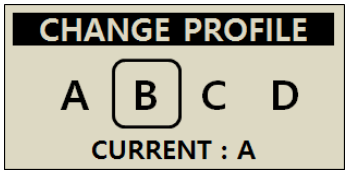
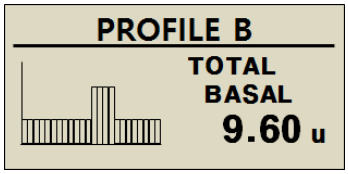
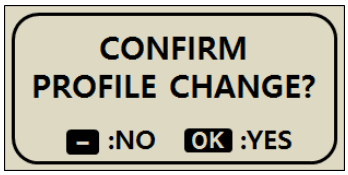
Notice

- Default password is derived from the manufacturing date and calculates as MMDD where MM are the month and DD are the days, the pump was producted. You can see the manufacturing date in the Shipping Information menu, refer to the chapter 6.6 Shipping information.
- The PASSWORD can be changed within the USER OPTION menu.

6.4 Change Basal Profile

The adjusted basal rates can be saved as 4 different profiles. These are useful for sport days, sick days or specific events that may affect your insulin sensitivity.

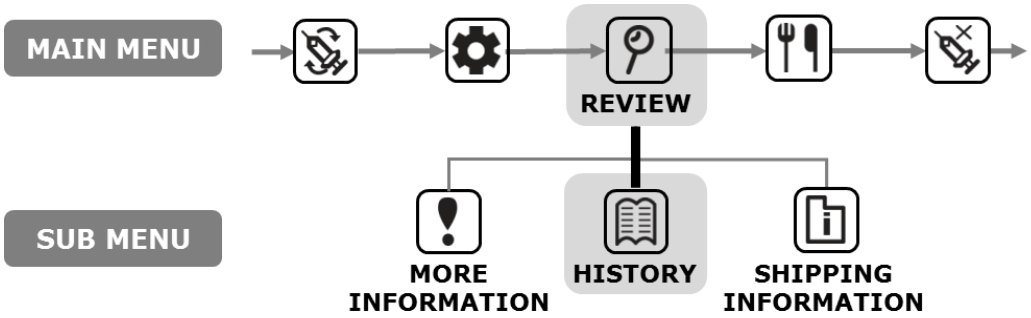


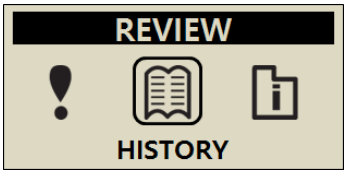
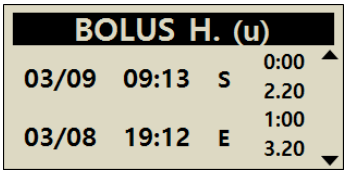
	1. Select **CHANGE PROFILE** from the **BASAL** sub menu.
	2. Select the Profile that is to be selected
	3. The PROFILE name is displayed confirm the change by pressing OK.
	4. Confirm the change with OK.

Notice Default Basal profile #A is 0.2 u/h and profile (#B, #C, #D) are 0 u/h.

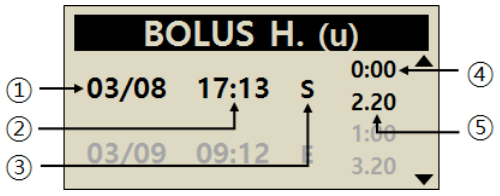
6.5 HISTORY : Displays all the Pump History

History and pump memory can be viewed either on the Insulin Pump

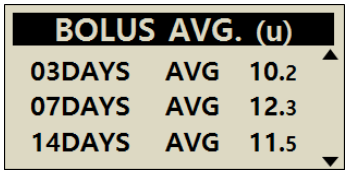
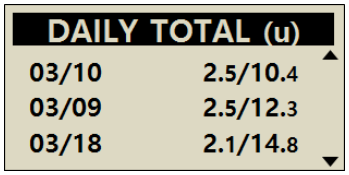
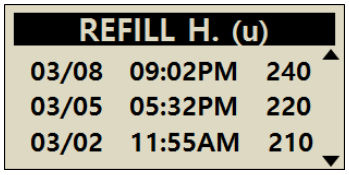
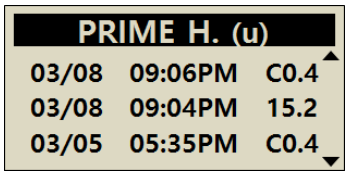
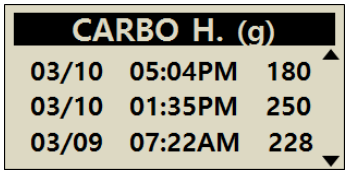
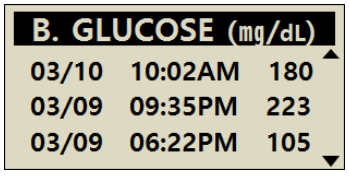
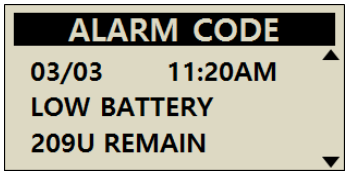
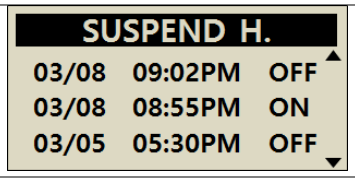


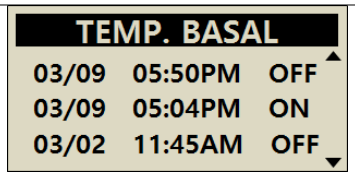
	1. Select **REVIEW** from the MAIN MENU then select **HISTORY** from the REVIEW sub menu.
	2. The ⊕ and ⊖ Use scroll up/down. ▶ button to next menu.

➢ Review Menu

	**1. BOLUS HISTORY** Record of the most recent 300 BOLUSES ① DATE (mm/dd) ② TIME (hh:mm) ③ BOLUS Type **S = S**tep **E = E**xtended **DS** = **D**ual **S**tep **DE** = **D**ual **E**xtended ④ Duration of Bolus (hh:mm) ⑤ Bolus amount (units)

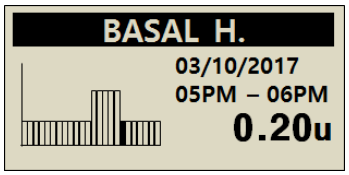
➢ Review Menu

	**2. BOLUS AVERAGE** Daily total average bolus for 3, 7, 14 and 28 days displayed in units of insulin.
	**3. DAILY TOTAL HISTORY** History of last 60 day's delivery totals Displayed as date with Basal / Basal +Bolus
	**4. REFILL HISTORY** History of when pump has been refilled, time and volume of Insulin loaded.
	**5. PRIME HISTORY** History of Pump Prime's, Date, Time, Volume **Notice** In volume, "C" means "Prime Cannula value"
	**6. CARBOHYDRATE HISTORY** History of carbohydrate used for bolus delivery calculations. Grams of CHO
	**7. BLOOD GLUCOSE HISTORY** History of Blood Glucose using the BG Bolus calculator. Date, Time, BG Result in mg/dL or mmol
	**8. ALARM CODE** History of DANA alarms and warnings • Date & Time • Type of alarm • Reservoir volume at time of alarm
	**9. SUSPEND HISTORY** History of Suspend Date, Time of when Temporary rate is started (ON) or stopped (OFF).



10. TEMP. BASAL

History of Temporary Basal rates Date, Time of when Temporary rate is started (ON) or stopped (OFF).



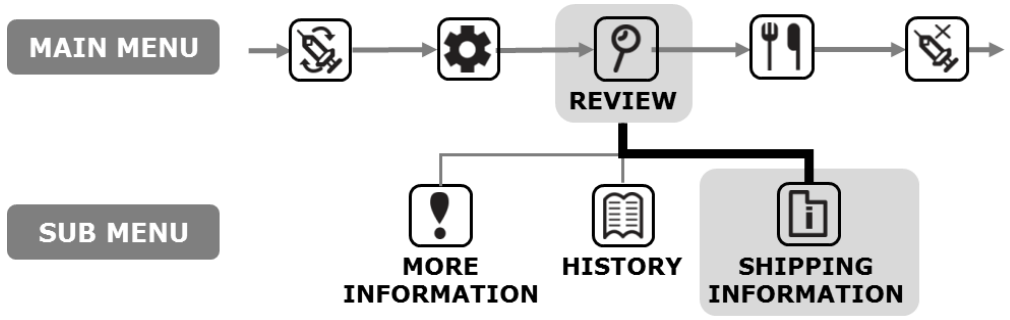
11. BASAL HISTORY

Review of hourly basal delivery. Scrolling back hour by hour of delivered basal up to 60days history.

Press ⊕ and ⊖ to move the time.

6.6 SHIPPING INFORMATION

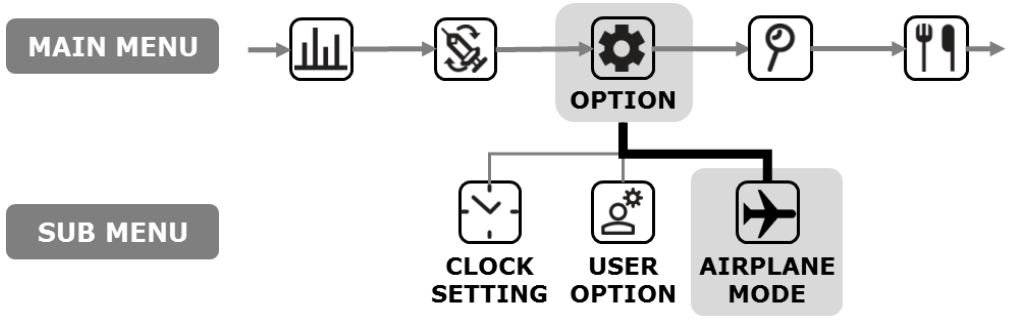
This displays the country that the pump was originally shipped to after manufacture. Also displayed is the date of manufacture, pump serial number and the software version installed.

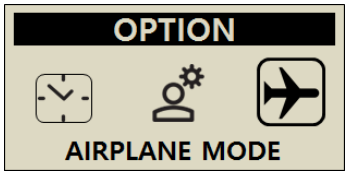
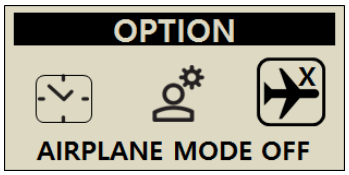


	From **MAIN MENU** select **REVIEW** screen then open **SHIPPING INFORMATION** from the sub menu.
	Display includes: • Pump serial number • Country pump was originally distributed from • Date of manufacture • Pump software version number

6.7 Airplane mode

Since it always transmits Bluetooth signal, it is necessary to switch to airplane mode when it is necessary to turn off the electronic signals such as when boarding on an airplane.



	1. Select **OPTION** from the **MAIN MENU** then select **AIRPLANE MODE** from the OPTION's sub menu.
	2. The airplane symbol is displayed on the initial screen.
	3. To turn off the airplane mode, select **AIRPLAME MODE OFF** from the OPTION's sub Menu.

A

6.8 Extended Bolus

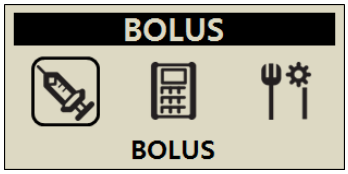
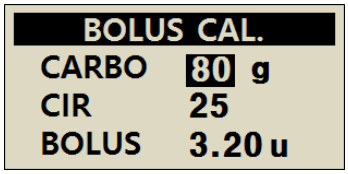
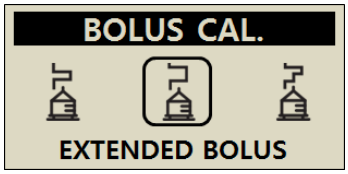
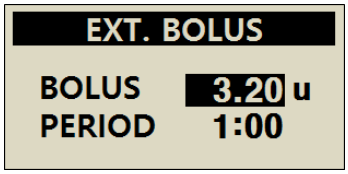
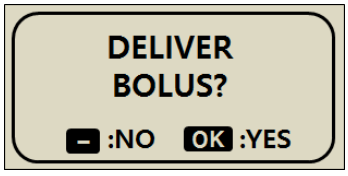
Extended or Dual bolus can be used for:

- Meals with slow absorption (high fat) i.e. pizza or lasagne
- Insulin Pump users who have other conditions such as gastroparesis which can delay/slow the absorption of carbohydrate. Refer to your Healthcare Professional about this condition and treatment.
- Insulin delivery where a meal has been eaten over a long period of time or with extended snacking.

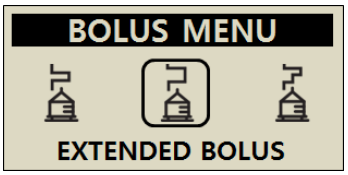
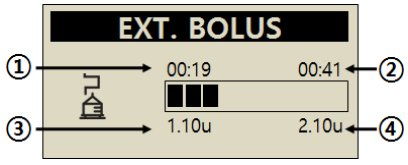
Notice to enable EXTENDED BOLUS refer 5.3 Bolus Options.

➢ Start Extended Bolus (Quick Bolus)

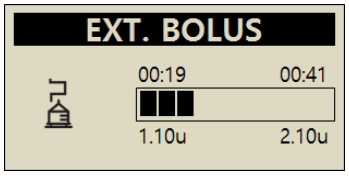
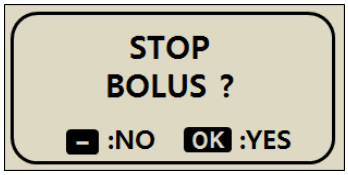
Bolus (Quick Bolus) using grams of carbohydrate Extended.

	1. From **MAIN MENU** select **BOLUS.** From BOLUS sub menu select **Bolus** icon.
	2. Enter the grams of carbohydrate and confirm the CIR setting is correct. Press OK
	3. Displays the three different bolus types. Select **EXTENDED BOLUS** press OK
	4. The **EXT. BOLUS** menu displays the Bolus amount in units of insulin and enables the time to be adjusted. The time can be adjusted in 30 minute increments up to 8 hours.
	5. Confirm BOLUS start with OK

➢ Review Extended Bolus

	1. Extended state shown on the initial screen.
	2. From **MAIN MENU** select **BOLUS.** From BOLUS sub menu select Bolus icon. The three bolus types are displayed, select Extended press OK
	3. The **EXT. BOLUS** displays the current active Extended Bolus. ① Time since the Bolus started(hh:mm) ② Time remaining before Bolus is complete ③ Bolus amount delivered already ④ Bolus amount remaining Press − to exit.

➢ Stop an Extended Bolus

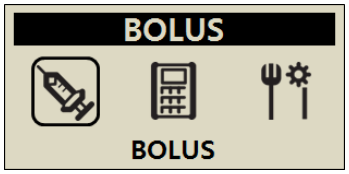
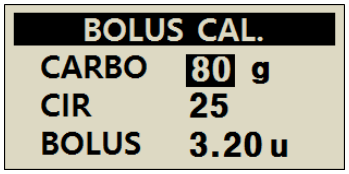
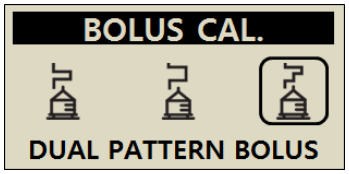
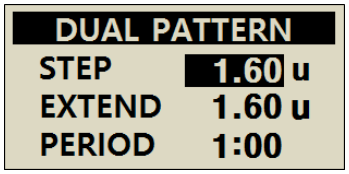
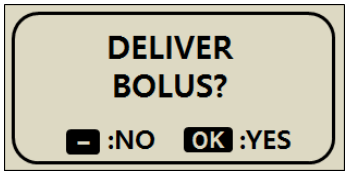
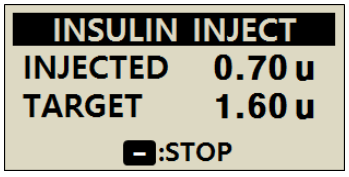
	1. From **EXT BOLUS** status screen press OK.
	2. Confirm the **BOLUS STOP** with OK.

Caution Within the Pump History Extended Bolus history is recorded at the date and time the Bolus is finished.

6.9 Dual Pattern Bolus

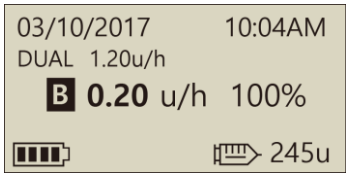
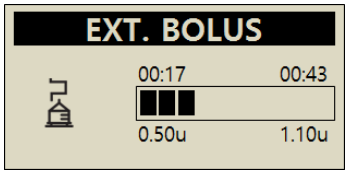
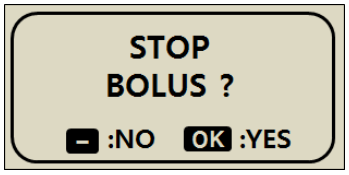
Dual Pattern bolus delivers a combination of a Step Bolus followed by an Extended Bolus. A Dual Pattern bolus is useful for meals with a combination of fast and slow absorbed carbohydrate.

➢ Starting a Dual Pattern Bolus

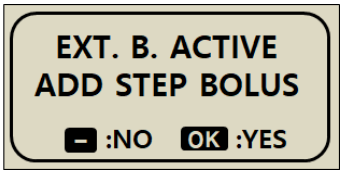
	1. From **MAIN MENU** select **BOLUS** From BOLUS sub menu select **Bolus** icon.
	2. Enter the grams of carbohydrate and confirm the CIR setting is correct. Press OK
	3. The BOLUS MENU displays the three different bolus types. Select **DUAL BOLUS** press OK
	4. The **DUAL PATTERN** menu displays the Bolus amount in units of insulin. Half is STEP and half is EXTEND. Each Bolus amount can be adjusted. The time can be adjusted in 30 minute increments up to 8 hours.
	5. Confirm **BOLUS START** with OK
	6. The step bolus is injected immediately, and the remaining amount is deliver by Ext. Bolus.

➢ Stopping a Dual Pattern Bolus

To stop the extended part of a Dual Bolus from the EXT Bolus status menu.

	1. Dual state shown on the initial screen.
	2. From **EXT BOLUS** status screen press OK.
	3. Confirm the **BOLUS STOP** with OK.

Notice If Step Bolus is selected while an Extended Bolus or Dual Pattern Bolus is being delivered an "EXT. B. ACTIVE ADD STEP BOLUS" message is displayed.



7. Alarms and Error Messages

This chapter describes insulin pump alarms and error messages and how to solve them. **DANA Diabecare RS** alarms and error messages are as follows.

Type	Alarm and Error Message
WARNING (High Priority)	LOW BATTERY LOW RESERVOIR EMPTY RESERVOIR SHUTDOWN OCCLUSION
ERROR (Medium Priority)	CHECK ERROR SYSTEM ERROR
ALARM (Low Priority)	SUSPEND MISSED BOLUS PRIME AMOUNT IS NOT ENOUGH PRIME INCOMPLETE DELIVERY LESS THAN BASAL SET RATE CHECK GLUCOSE NO DELIVERY

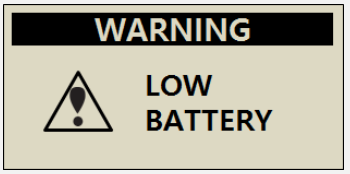
Notice

- **WARNING** is a critical alarm that can affect safety. Resolve an issue as soon as possible. In this case, the alarms will SOUND even though VIBRATION is selected.
- **ERROR** makes you know the problem of the insulin pump. An ERROR is less serious than an WARNING. In this case, the alarms will SOUND even though VIBRATION is selected.
- **ALARM** just informs you about the status of the insulin pump.

➢ WARNING Message

LOW BATTERY

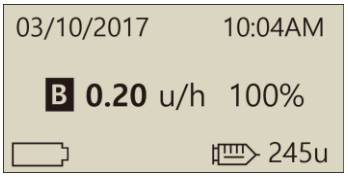
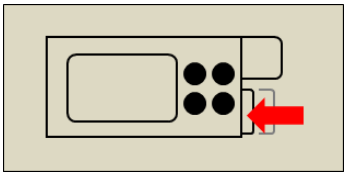
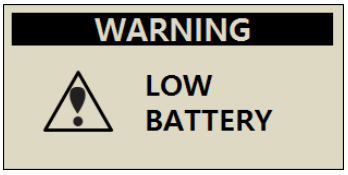
The low battery screen will appear when the battery level is not sufficient to operate the pump and deliver insulin. A continuous alarm will be activated with both sound and vibration.



How to solve:

Remove the battery from the Insulin Pump and replace with a new battery.

Low Battery warning step

<table>
<tr>
<td> 
</td>
<td>Step.1 Recommended to change:
When battery energy is below 5%, an empty battery icon ▭ appears and blinks. BT communication is interrupted to conserve the battery.</td>
<td rowspan="2">Notice
Insulin Delivery is not affected</td>
</tr>
<tr>
<td>  </td>
<td>Step.2 Required to change soon:
when the Insulin Pump battery is 1%, this repeats every 10 minutes or is displayed whenever the pump is awoken from screen saver.</td>
</tr>
<tr>
<td> 
</td>
<td colspan="2">Step.3 Warning – Low Battery
When a battery has insufficient energy to operate the pump 'Low Battery' warning is displayed with a continuous alarm.
Warning Insulin Delivery is STOP at the LOW BATTERY warning.</td>
</tr>
</table>

Notice

- If spare battery is not available, use the battery from the Easy Setter. Always ensure you keep spare batteries near.
- Refer to 8.5 Battery for DANA Insulin Pump.

➢ WARNING Message

LOW RESERVOIR

When the reservoir volume is below the 'Low Reservoir' warning configured in the user options, this screen will be shown with an alarm.

How to solve:

The pump will revert to the Initial Display and the reservoir icon will blink/flash. After checking the actual remaining insulin volume of the reservoir in your pump, replace the reservoir and refill the pump if necessary.

Notice This alert/alarm message will start depending on the 'Low Reservoir' set on the User Option. Unless the pump is refilled, the Low Reservoir alarm will repeat every hour for over 20U and every 30 minutes for 20U or less. Refer to 3.4 Setting User Options and 4. Loading Insulin into the Pump.

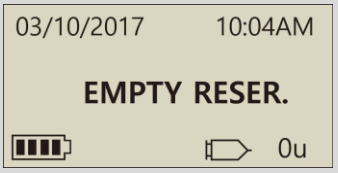
EMPTY RESERVOIR

When the reservoir volume is zero (0u), all delivery is stopped and this screen will be shown with a sound alarm.

How to solve:

Silence the alarm by pressing any button. Immediately replace the reservoir and refill the pump

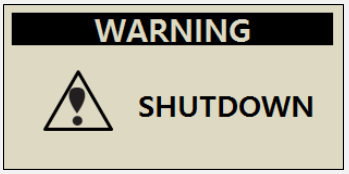
Warning The pump displaying "NO DELIVERY/EMPTY RESERVOIR" is unable to not only deliver basal and bolus but access to any delivery function.



Notice This alert/alarm message will repeat every 5 minutes until a complete refill is completed. Refer to chapter 4. Loading Insulin into the Pump.

SHUTDOWN

The Pump will automatically give an alarm sound if no buttons are pressed after the pre-set shutdown period is exceeded. If no acknowledgment of the alarm is received (button press) following the audible alarm - the pump will suspend all insulin delivery.

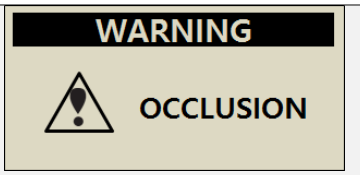


How to solve:
Silence by acknowledging the alert and pressing any of the buttons.

Notice To disable the auto off alarm refer to 3.4 Setting User Options – "SHUT DOWN" and set the time to 0 zero.

OCCLUSION

This warning occurs if your Insulin Pump has an occlusion or a problem which disturbs insulin delivery.



How to solve:
An occlusion alarm will occur when the Insulin Pump detects a blockage and cannot deliver insulin. Check for blocked or folded areas and replace the reservoir or infusion set if necessary.

Caution Even after resolution of the problem - check your blood glucose frequently to ensure the pump is delivering insulin properly.

Self-check Procedures for Occlusion Alarm Occurrence
Implement self-check procedures in the case of the following:

- An occlusion alarm occurs during replacement of the infusion set or reservoir.
- The occlusion alarm occurs frequently.

Step.1 Safety first - check BG levels (could be Hyperglycemia)
Step.2 Visually check if there is any area of the tubing that is folded or blocked.
Step.3 To determine of the occlusion is in the pump or body/consumable:

a. Disconnect infusion set from the body.
b. Deliver a BOLUS of 5 - 6 units.
c. If there is no occlusion alarm or blockage you will visually notice/see a puddle of insulin at the end of the Infusion Set tubing. This has now determined that the occlusion was in the cannula or body. Replace cannula or insertion site to resolve.

➢ ERROR Message

CHECK ERROR

This alarm occurs if the Insulin Pump suspects an internal signal defect.

SYSTEM ERROR

This alarm occurs when the Insulin Pump detects any unusual movement of the controller.

How to solve:

If/when either of these alarms, removal of the battery will silence the alert. Reinsert the battery after 10 seconds and the pump will perform a full self-check procedure. DANA Insulin pump is monitoring all operation for safety. Any unusual noise may cause relevant alarms to prevent any further problems.
However, if it does not occur again after resetting the pump, the pump has no problem.

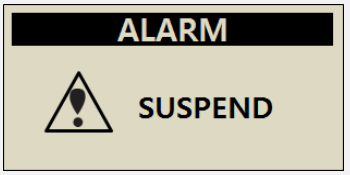
Warning When the errors occur, all the delivery is stopped. Check the insulin delivery following restart when these errors occur.

Caution If WARNING persists, contact technical support from your local Insulin Pump distributor.

➢ ALARM Message

SUSPEND

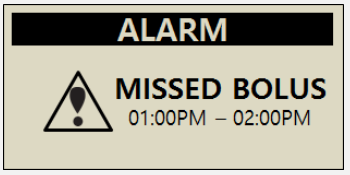
When you try to select any menu related to infusion (insulin delivery) whilst the Insulin Pump is in Suspend Mode, you are alerted with this message.
Refer to 6.2 SUSPEND.



How to solve:
Turn the Suspend Mode off prior to continuing in any of the infusion (insulin delivery) menu's.

MISSED BOLUS

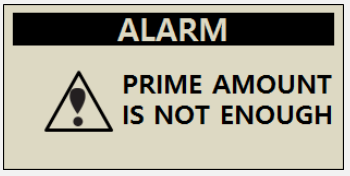
If you missed a bolus during the time period you had set, the Insulin Pump will give you an alarm together with an alarm message.
Refer to 5.3 Bolus Setting-MISSED BOLUS



How to solve:
Silence the alarm by pressing any button.
Follow the prompt by determining if a food bolus was missed and administer if necessary.

PRIME AMOUNT IS NOT ENOUGH

This alarm/alert message will be displayed if the volume delivered for tubing prime is less than 7 units.

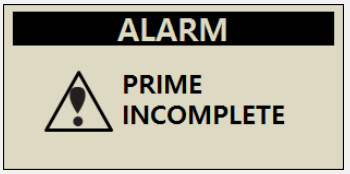


How to solve:
Properly priming the infusion set tube is necessary to ensure all air is displaced and insulin is ready for infusion. Even the shortest infusion set tube will require more than 7 units to properly prime - so for safety the Insulin Pump has a minimum required Prime volume of 7 units. Refer to 10.3 Prime Volume of infusion sets for suggested minimum prime amount for each infusion set.

➢ ALARM Message

PRIME INCOMPLETE

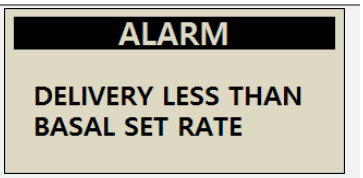
If the prime process is not correctly completed following a refill the "PRIME INCOMPLETE" alarm occurs every 5 minutes and message will be displayed with a beep sound.



How to solve:
Silence the alarm by pressing any button. In this case, insulin is not delivered until prime is properly completed. Refer to 4.7 Prime the infusion set tubing.

DELIVERY LESS THAN BASAL SET RATE

If the basal is skipped and delivered less than 80% of the basal setting, this alarm will be generated.



How to solve:
Silence the alarm by pressing any button. If you operate the pump at basal delivery interval, the basal may occasionally skip. For a stable basal delivery, avoid long-time pump button operation.

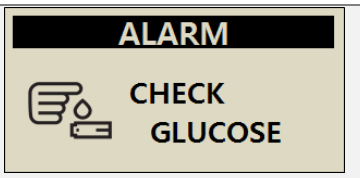
※ Basal Insulin delivery intervals very based on the size of the set basal rates.

Size of **BASAL Rate** (u/hr)	BASAL **delivery interval**
≥ 0.1 U/h (Basal)	Every 4 minutes (1/15) of the hourly rate is delivered. 15 deliveries per hour.
Extended bolus	
≤ 0.09 U/h (Basal)	Basal delivery will occur once at 56min the hour. (hourly)

Warning The individual small basal delivery increments maybe interrupted during Bluetooth pairing or during changes being made to configuration or pump settings. These increments of basal delivery in very low basal delivery rates such as ≤ 0.09 U/h patients need to be monitored carefully to avoid unexpected hyperglycemia which it could lead to ketoacidosis

CHECK GLUCOSE

This alarm is to remind you to check your blood glucose level after a bolus.



How to solve:

A melody will play for 30 seconds. You can silence by depressing any button.

Notice The default is 2 hours and can be adjusted by your health care professional in the Dr. Mode.

➢ ALARM Message

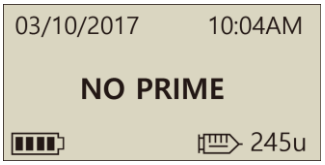
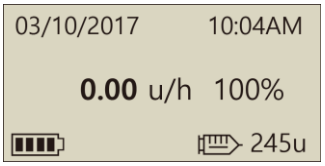
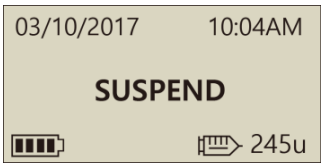
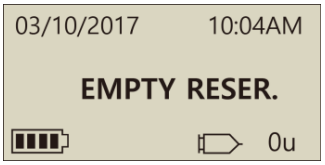
NO DELIVERY

The pump cannot deliver insulin for one or more of different reasons. This message is shown on initial display and may blink/flash with additional information

How to solve:

Detail message is blink alternately. Refer to follow Reason of NO DELIVERY.

※ Reason of NO DELIVERY

	If do not prime, the pump does not delivery insulin. Refer to 4.7 Prime the infusion set tubing.
	If basal setting is 0.0 u/h, NO DELIVERY is displayed during that time. Refer to 3.2 Setting the Basal rate.
	Suspend mode is on. Refer to 6.2 suspend
	If there is no insulin in the reservoir, EMPTY RESERVOIR is displayed and insulin is not injected. Refer to 4. Loading Insulin into the Pump.

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8. Troubleshooting

8.1 Hypoglycemia (low blood sugar)

➢ What is hypoglycemia (low blood sugar)?

Hypoglycemia occurs when the blood sugar 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 your blood sugar level.
2. If the blood sugar level is low, treat with fast acting carbohydrates in accordance with the instructions of your diabetes professional. Recheck BG level as advised.
3. If hypoglycemia appears prior to a meal, consider a bolus while you consume your 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 your health care professional.

➢ Hypoglycemia Troubleshooting

POSSIBLE CAUSE	SUGGESTED RESPONSE
Increased physical activity	Consult with your healthcare professional to make adjustments for increased physical activity. You may choose to use or modify temporary basal rates or decrease meal boluses prior to activity.
Eating less	Consult with your healthcare professional to adjust basal rates or meal boluses to more accurately reflect your current intake.
Alcohol consumption	Caution required when consuming alcohol, as the liver metabolizes alcohol making you vulnerable to hypoglycemia.
User setting error	Check and review your bolus history and basal rates. Check with your healthcare professional to make sure your Bolus, Time, CIR, CF, Target BG and Basal are correctly programmed.

8.2 Hyperglycemia (high blood sugar)

➢ What is hyperglycemia (high blood sugar)?

Hyperglycemia (high blood sugar) can occur due to any interruption in the delivery of insulin. It is important to know that if there is no insulin delivery you may experience an increase in your blood sugar which, if undetected or untreated, may cause DKA (diabetic ketoacidosis). The symptoms are:

- 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
- Disruption of insulin delivery from the pump

➢ What to do in case of High Blood Sugar

1. Check your blood sugar level.
2. Check your Pump even if it does appear to be in good order. If the insulin pump and linking screw are not connected, even though pump is seen normally to be working, insulin is not delivered. Refer to chapter 4. Loading Insulin into the Pump.
3. If your blood sugar remains high, treat as prescribed by your healthcare professional and /or contact your healthcare professional immediately.

➢ Troubleshooting for Hyperglycemia

POSSIBLE CAUSE	SUGGESTED RESPONSE
Empty reservoir	Visually check display screen for remaining insulin and also visually check reservoir in Pump. Replace 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 Set to the Pump and the Infusion Set connector. **Notice** Insulin has a strong pungent smell – if you smell insulin anywhere it may be leaking.
Pinched or obstructed Infusion Set	Change the Infusion Set.
User setting error	Check and review your bolus history and basal rates. Check with your healthcare professional to make sure your Bolus, Time, CIR, CF, Target BG and Basal are correctly programmed.

8.3 Occlusion Alarm

An occlusion is a blockage or interruption in insulin delivery from the DANA Diabecare Insulin Pump. If the pump detects an occlusion, the 'Occlusion Alarm' occur.

➢ Occlusion Alarm threshold

	Typical time and delivered insulin to occlusion detection		
Block sensitive	L	M	H
At minimum basal rate (0.04 u/h)	256h 33m (10.26U)	144h 18m (5.77U)	53h 16m (2.13U)
At medium basal rate (2 u/h)	4h 34m (9.13U)	2h 58m (5.93U)	2h 02m (4.07U)
Bolus (10 units)	1m 13s	46s	11s

The test is conducted with the SUPERLINE SU201 model in the infusion set.
Specifications: Needle length 6.5mm, Tube length 550mm.

Notice
The data in the table above may vary depending on the infusion set used and the environment of use.

The causes of occlusion alarms are very variety. The tube may be blocked by uncertain materials or may be caused by other external factors. The various causes of occlusion are described as follows.

- **Real Occlusion (Usually within the Cannula or tube)**

OCCLUSION CAUSES	WHAT TO DO
Use of the reservoir or Infusion Set for more than 72 hours.	Replace Infusion Set and reservoir, complete refill and prime.
Infusion Sets or reservoir is re-used.	
Skin cell tissue or tiny substance in flow.	
Bent, folded or damaged Cannula.	Insert new Infusion Set Cannula, in new location.
Bent, folded or distorted tubing.	Straighten to allow easy flow.
Denatured insulin (crystallized, changed color) This is more common in hot climates! Sometimes it is best to only partly fill reservoir and replace more frequently to prevent Insulin deterioration.	Change insulin from new vial. Refill pump replacing the tubing, reservoir and Infusion Set Cannula.

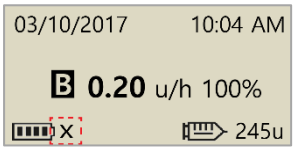
➢ Occlusion caused by external factor

OCCLUSION CAUSES	WHAT TO DO
Linking screw has previously been affected by insulin leakage. (seldom)	Wash linking screw in warm water with mild detergent, thoroughly dry then reinstall the linking screw into the pump.
The end of insulin delivery. (The correct linking screw placement)	Adjust and fully loosen the linking screw to the end, then complete refill of pump with a new reservoir.
Cold insulin used during refill. (Air-bubbles in reservoir or tubing could occur when Insulin warms to room temperature)	Let the insulin adjust to room temperature for 30 minutes, then complete refill and prime.
Lumpy fat or stiff muscle. Improper sites to inject. Needle-subtracted area, chapped skin, wrinkled area or frequently inserting at the same site location causing lipohypertrophy.	Frequently change site locations Massage to smooth skin.
Not good angle to insert Cannula according to the sort/length of Cannula	Consult medical professional or Insulin Pump Trainer for guidance for the best Infusion Set type and size and how to properly insert the Cannula.

Warning If Occlusion Warning persists, contact technical support from your local Insulin Pump distributor.

Caution You should to check your blood glucose frequently following an occlusion.

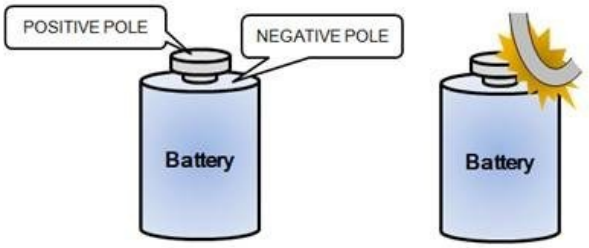
8.4 Troubleshooting the Insulin Pump

PROBLEM	CORRECTIVE ACTION
Abnormal LCD	An abnormal LCD can occur when the battery charge is low. Check the remaining battery charge after you administer a bolus dose. The life span of the battery is between 3-6 weeks, but varies among users. Some batteries are known to still show a full charge after two months. To avoid any battery mishaps we recommend that you change the battery every two months, when the pump alerts to low battery reserve or whenever there is a display problem with your screen.
Insulin Pump does not function following CT or MRI scan	It is possible that the pump is damaged by CT or MRI scan. contact technical support
Abnormal BLE Module	If the "X" mark is displayed on the screen, your pump has problems in the Bluetooth module. After removing the battery from the pumps, reinsert it after 10 seconds. If the "X" mark persists, contact technical support from your local Insulin Pump distributor. 

Warning In case of device malfunction, stop using the Insulin Pump immediately and contact your local distributor for technical support.

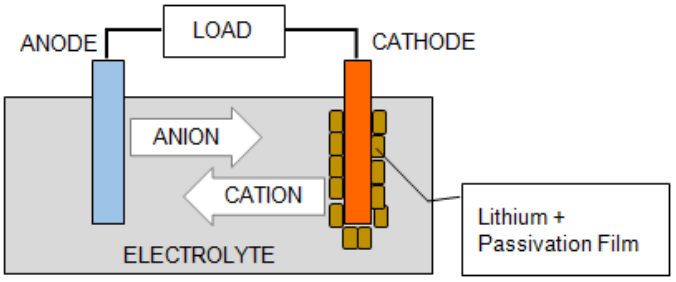
8.5 Battery for DANA Insulin Pump

DANA Insulin Pump Battery is a Lithium ½ AA size.



Caution Do not store or transport the unpackaged battery with any conductor such as coin, metal key or metal clip. The Battery has a high-risk of starting a fire if the battery poles are shorted.

Passivation film: In physical chemistry and engineering, "passive" refers to a material that is less affected by environmental factors such as air and water. Passivation involves the shielding outer-layer of base material, which can be applied as a micro-coating, or which occurs spontaneously in nature.



The passivation film is naturally generated on the DANA insulin pump's Lithium Battery as time proceeds. The Passivation film is not related to the battery capacity and will not reduce the discharge rate, but it might cause the pump to display less than 100% capacity when a new battery is first inserted.

When first installing a new battery within the DANA insulin pump, the pump draws a higher than usual current whilst performing self-checks. This should break any passivation film. If however the battery doesn't immediately display 100%, removing the battery and repeating the installation 2-3 times will successfully break the passivation film and enable the battery to display the expected 100% battery capacity.

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9. Maintenance of Pump & Accessory

9.1 Caring for the Insulin Pump

Use a soft cloth or tissue to wipe the exterior of the Insulin Pump. If necessary, a small amount of mild alcohol on a soft cloth or tissue may be used. Organic solvents such as benzene, acetone and household industrial cleaners can cause irreparable damage to the Insulin Pump.

It's important to

- Not expose the Insulin Pump to direct sunlight or heat for an extended period of time.
- Not drop the Insulin Pump.
- Not try to fix, open or alter the Insulin Pump in any way.
- Avoid acid or alkali environment.
- Keep the Insulin Pump away from strong electromagnetic fields such as cell phone and microwave ovens.

Caution The Insulin Pump must not be used in the presence of intense electromagnetic fields, such as those generated by certain electrically powered medical devices. The Pump should be removed prior to the user having a CT Scan, MRI or X-ray. The pump usage can generate and radiate radio frequency energy which may cause harmful interference to other devices nearby.

➢ Transport and Storage Condition

For safe transport and storage of the **DANA Diabecare RS** Insulin Pump kit avoid the following conditions:

- Storage Temperatures below -20°C (-4°F) or above 50°C (122°F).
- Operation Temperatures below 1°C (34°F) or above 40°C (104°F).
- Humidity above 95%.
- Exposure to excessive dust or a salty environment.
- Exposure to explosive gas.
- Exposure to direct sunlight.
- Environments where an intense electromagnetic field is generated.
- Atmospheric pressure below 500 hPa or above 1060 hPa.

500 hPa =	500 mbar,	50 kPa,	375 mmHg,	7.3 psi
1060 hPa =	1060 mbar,	106 kPa,	795 mmHg,	15.4 psi

➢ Cleansing the pump & accessories

1. The outside of the Insulin Pump and Accessory should be cleaned monthly.
2. When cleansing, use a cloth moistened with water or a neutral pH detergent and afterwards wipe, with a dry cloth.
3. **DO NOT USE** thinner, acetone, benzene or similar solvents.

Notice It is recommended to wipe and clean the rubber O-ring of the battery cap each time a new battery is fitted to the Insulin Pump. During normal usage small amounts of lint and dirt can accumulate around this O-ring.

10. Specification

10.1 Insulin Pump

SPEC	INSULIN PUMP
Product Name Model Name	DANA Diabecare DANA Diabecare RS
Size Net Weight Insulin Reservoir	3.6× 1.8× 0.8inch (91× 45.5× 20mm) **including reservoir cap 53g (without battery), 62g (including battery) 3mL(300 Units) insulin compatible reservoir
Meal Bolus Setting Basal Rate Setting Basal Profile Minimum Basal Rate Minimum Increment	0 - 80u 0, 0.04 ~ 16.0 u/h 4 Types of 24 hours period 0.04 u/h 0.01 unit
Motor Bolus Duration for 1 Unit	Swiss Micro DC motor (3V, 5.75mA) 12 / 30 / 60 seconds (optional settings)
Power Supply	3.6V DC Lithium 1/2AA size Battery
Energy Saver	Sleep Mode, Airplane Mode
Alarm	Alarm type: visual, audible and vibratory Audio Frequency: 300Hz to 3000Hz
Wireless	Bluetooth Specifications V4.X BLE
Operation Condition	Temperature: 1 - 40°C / 34 - 104°F Relative Humidity: 10-90 % Atmospheric Pressure: 700 - 1060 hPa
Transport and storage Condition	Temperature: -20 - 50°C / -4 - 122°F Relative Humidity: 0 - 95 % Atmospheric Pressure: 500 - 1060 hPa
Unique Device Identification	Kit set: 08809220582981 Bulk type: 08809220582998

10.2 Infusion Sets

	Soft-Release-O	Soft-Release-ST	Super Line	Easy Release	DANA Inset Ⅱ
Needle gauge	26G	26G	27G	27G/29G	27G
Needle type	Teflon	Teflon	Stainless Steel	Stainless Steel	Teflon
Insertion angle	90°	15-30°	0°, 90°	90°	90°
Disconnect	Yes	Yes	No	Yes	Yes

Notice Each type of Infusion Set is unique. Healthcare Professional and your Insulin Pump Trainer will help provide assistance with the most appropriate Infusion Set to use.

10.3 Prime Volume of Infusion Sets

New unopened Infusion Sets are sterile and the tubing is filled with air/empty. Once connected to the Insulin Pump it is necessary to prime the tubing (fill it with insulin and remove the air) before the tube is connected to the Cannula or patient.

The following shows the estimated volume of insulin required to fill tubing for each of the Infusion Sets below:

Notice Volumes are approximate

➢ Prime tube

Infusion Set	Tube length	Minimum required Insulin amount
SUPER LINE	550 mm	10 Units
Easy Release Soft Release ST	700 mm	15 Units
	1,100 mm	20 Units
Soft-Release-O	300 mm	7 Units
	600 mm	14 Units
	800 mm	19 Units
	1,000 mm	22 Units
DANA Inset II	450 mm	12 Units
	600 mm	15 Units
	800 mm	18 Units
	1100 mm	22 Units

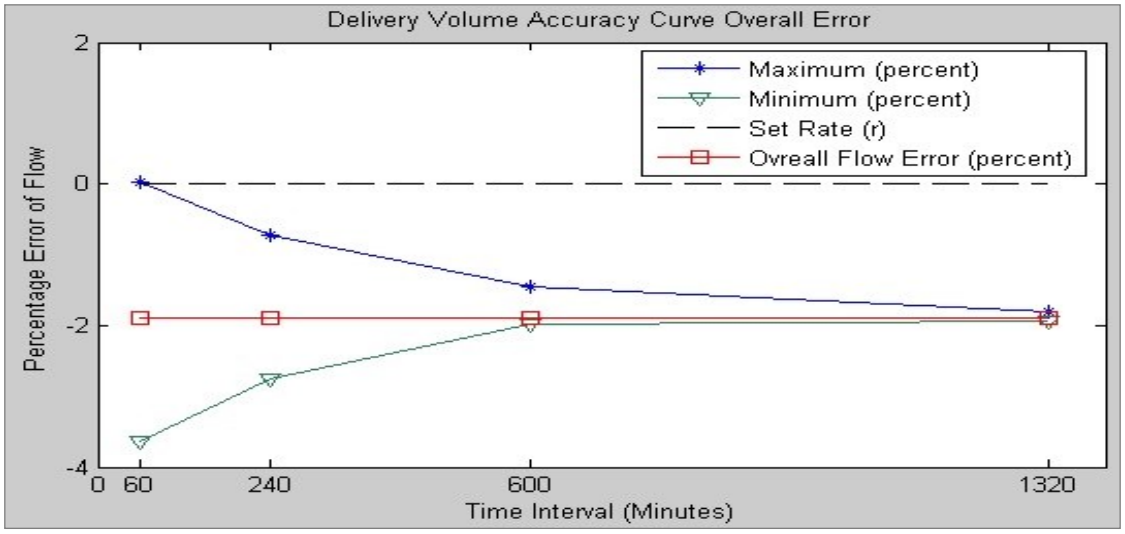
➢ Cannula prime

Infusion Set	needle length	Minimum required Insulin amount
Soft Release ST	19mm needle with base	0.6 Units
Soft-Release-O	6 mm needle with base	0.3 Units
	9 mm needle with base	0.4 Units
DANA Inset II	6 mm needle with base	0.1 Units
	9 mm needle with base	0.2 Units

Notice Because the air is lighter than insulin, the insulin pump should be kept in an upright position during the priming process. This can help displace any air in the tubing.

10.4 Delivery accuracy

Delivery Intervals: 4 minutes when a basal setting is not lower than 0.1u/h
60 minutes when basal delivery setting is 0.04 - 0.09u/h
Delivery Accuracy: ± 4%
Trumpet Curve for Delivery Accuracy (-1.94 %) at the basal setting of 8u/h (the intermediate rate)



10.5 Classification and Compliance with Standards

- The **DANA Diabecare RS** is classified as an internal powered equipment BF type under the standard of IEC 60601-1
  (Medical Electrical Equipment, General Requirements for Safety).
- It is not suitable for use in the presence of a flammable anesthetic mixture by the standard of IEC 60601-1.
- The System will continuously operate according to the user defined settings.

10.6 Essential Performance

The Insulin infusion pump maintains insulin delivery accuracy in the specified environmental conditions.

10.7 Cyber Security

The DANA Diabecare RS insulin pump encrypts all BLE communication.

If you do not want to use remote control, it is suggested to turn the BLE off by activating 'Airplane Mode' in the Main Menu. Refer to chapter 6.7 Airplane Mode.

To prevent unintentional delivery of insulin from cyber-security hacking, 'Bolus Block' and 'Safety Ratio' can be turned on in Doctor Mode. Additionally, the DANA RS Insulin Pump includes safety limits to bolus size, Basal rate, and Daily total Dose. These should be personalized by your healthcare professional in Doctor Mode.

The DANA Diabecare RS Insulin Pump only allows pairing with one device at a time.

10.8 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.

10.9 Declaration of EMC compatibility

The DANA Diabecare RS insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of the DANA Diabecare RS insulin pump should assure that it is used in such an environment.

Electromagnetic emissions		
Emissions test	Compliance	Electromagnetic environment
RF emissions EN 55011	Group 1	The DANA Diabecare RS insulin pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions EN 55011	Class B	The DANA Diabecare RS insulin pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	
NOTE The preceding statement is required by IEC 60601-1-2 for Group 1, Class B devices. However, since the DANA Diabecare RS insulin pump is battery powered, its emissions will not be affected by the establishment power supply.		

Electromagnetic immunity – for all ME equipment and ME systems			
Emissions test	IEC 60601 test level	Compliance	Electromagnetic environment
Electrostatic discharge(ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	The DANA Diabecare RS should not be affected by electrostatic discharge that might occur under normal conditions of use.
Electric fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in U_T) For 0, 5 cycles 40% UT (60% dip in U_T) For 5 cycles 70% UT (30% dip in U_T) For 25 cycles <5% UT (>95% dip in U_T) for 5 seconds	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Emissions test	IEC 60601 test level	Compliance	Electromagnetic environment
			Portable and mobile RF communications equipment should be used no closer to any part of the DANA Diabecare RS insulin pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	**Recommended separation distance** $d = [\frac{3,5}{3}]\ \sqrt{P}$ $d = [\frac{3,5}{3}]\ \sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = [\frac{7}{3}]\ \sqrt{P}$ 800 MHz to 2.7 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE.1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE.2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DANA Diabecare RS insulin pump is used exceeds the applicable RF compliance level above, the DANA Diabecare RS insulin pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DANA Diabecare RS insulin pump.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the DANA Diabecare RS

The DANA Diabecare RS insulin pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DANA Diabecare RS insulin pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DANA Diabecare RS insulin pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]	
	80 MHz to 800 MHz $d = [\frac{3,5}{3}] \sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{3}] \sqrt{P}$
0.01	0.117	0.233
0.1	0.369	0.738
1	1.167	2.333
10	3.689	7.379
100	11.667	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE.1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE.2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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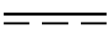
10.10 Explanation of Universal Symbols

On the packaging and on the type plate of **DANA Diabecare RS** System you may encounter the following symbols shown here with their meanings:

MD	Medical Devices
	Follow instructions for use
	Caution. Refer to safety-related notes in the manual accompanying this instrument
	Date of manufacture
	Manufacturer
REF	Catalogue or model number
LOT	LOT Number (Batch Code)
	Expiration Date (Use by date)
CE 1639	CE Marking
	Do not reuse
SN	Serial Number
	Type BF applied part (protection from electrical shock)
EC REP	European Authorized Representative
STERILE EO	Sterilized with ethylene oxide
IP28	International Protection Code. Dustproof degree: 2 / Waterproof degree:8
	Direct current

	Disposal (WEEE marking)
	Non-Pyrogenicity
	Keep dry
	Storage temperature range
	Do not use if package is damaged
	Storage humidity range
	Atmospheric pressure limitation
	Importer
RxOnly	Requires prescription in the United States.

11. Index

12. Warranty

SOOIL Development Company Limited warrants that the DANA Diabecare System 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 the DANA Diabecare System 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 the System by the user or any other person including but not limited to physical abuse of the product such as dropping or otherwise damaging the DANA Diabecare System.
- Failure to follow the manufacturer's instructions, including those for storage, transport or cleaning for the DANA Diabecare System.
- This warranty does not cover batteries, Infusion Sets, cartridges or other accessories of the DANA Diabecare System.

WARNING: Use of Infusion Sets, cartridges and batteries not specifically indicated by the manufacturer may result in harm or injury to the user or the device.
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.

CE 1639

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Sales Representative:

Dana Diabecare RS

IFU-120-EN (rev.11.1_230110)

SOOIL DEVELOPMENT Co.,LTD