EN

Diabecare dana-i

User Guide.

SOOIL

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1. Introduction

1. Diabecare DANA-i Insulin Pump Introduction

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

Warning The **Diabecare DANA-i** 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.

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.

3. Indications for Use

The **Diabecare DANA-i** Insulin Pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Diabecare DANA-i Insulin Pump is not intended for use with blood or blood products. The pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.
The pump is intended for single patient, home use and requires a prescription. The pump is indicated for use with NovoLog/NovoRapid U-100 Insulin. The pump is intended to be used both alone and in conjunction with digitally connected medical devices for the purpose of drug delivery.

4. Contraindication

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

5. Potential Risks

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

6. Precautions

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

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

3. The Diabecare DANA-i 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.

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

5. 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	0min
Maximum Daily Total	80u
Maximum Bolus	40u
Maximum Basal	3.3u/h

6. The pump is indicated for use with U-100 NovoLog insulin. The other insulin has not been tested and may not be compatible for use with the **Diabecare DANA-i** insulin pump.

7. Change the reservoir and the Infusion Set regularly, as recommended by your healthcare professional. DO NOT use for longer than the intended period.

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

9. 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.

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

11. Remove the battery for long-term storage.

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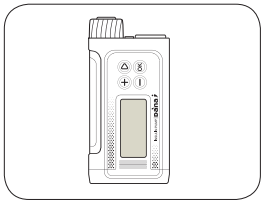
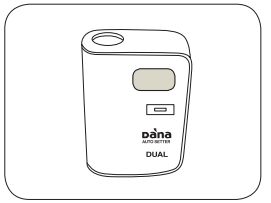
2. Getting Started

To make proper use of **Diabecare DANA-i** Insulin pump, the accessories and other components are required

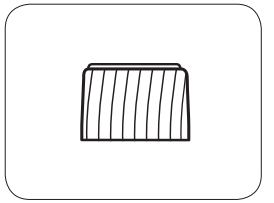
* Components of Diabecare DANA-i System



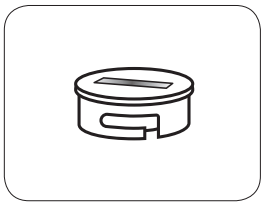
Insulin pump (1)



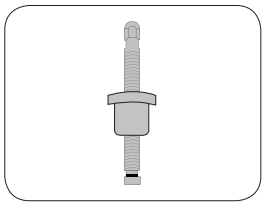
DANA Auto Setter (1)



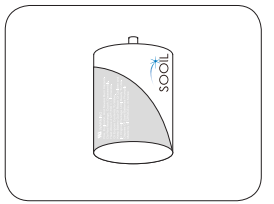
Syringe Cap (1)



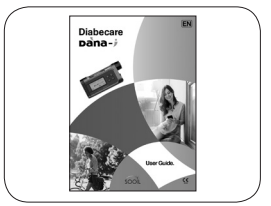
Battery Cap (1)



Linking Screw (2)



1/2AA Size Battery (1)



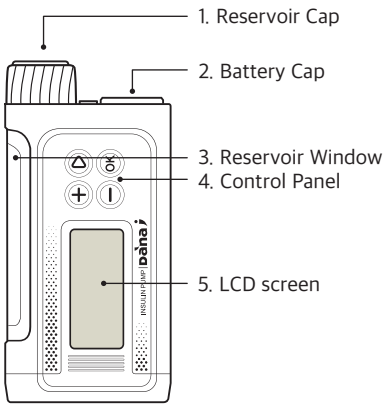
Manual (1)

Notice

- Additional accessories may be purchased separately.

1. Getting to know the DANA Insulin Pump

* Diabecare DANA-i Insulin Pump



1. Reservoir Cap
The reservoir and linking screw are inserted in this compartment. Turn the reservoir cap clockwise ¼ turn to open.

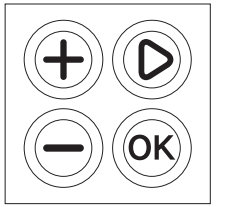
2. Battery Cap
The battery is inserted in this compartment. Turn the battery cap clockwise ¼ turn to open.

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.

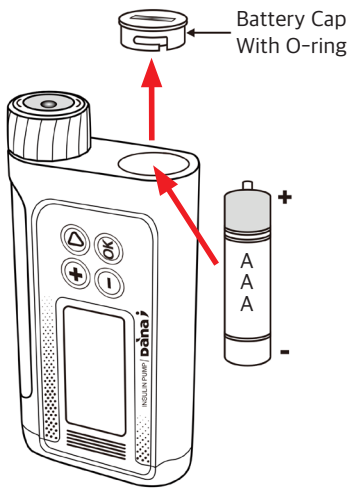
5. LCD screen
Displays the pump status, system features and system messages. This is the user interface for operation of the Insulin Pump. Lights automatically when buttons are pressed.

* Control Panel

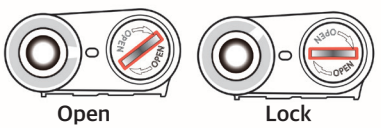


⊕ Press to increase values
⊖ Press to decrease values / return to previous screen
▷ Press to move to the next menu option
OK Press to select or confirm

2. Installing a battery



1. Open the battery cap and turning clock-wise 45 degrees.
2. Insert the battery with the positive (+) at top and insert the negative (-) into the Insulin Pump.
3. Replace the battery cap turning it counter clock-wise.
4. Completed when the cap is firmly locked with 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 with a push and 1/4 turn counter clock-wise to locked. This prevents water/ingress.

Caution The pump required one AAA 1.5V battery. Use a new AAA alkaline battery. Do not use a carbon zinc battery in your pump. Carbon zinc batteries are not compatible with this pump.

Caution Lithium batteries are not recommended as the battery level indicator may not be accurate.

Caution

- DO NOT attempt to change the battery while a bolus is in progress.
- Dispose of used batteries in an environmentally friendly way according to local disposal requirements or contact your local insulin pump distributor for disposal information.
- It is recommended to keep a spare battery as backup.
- For accurate reading of the remaining battery charge, check the battery display following the delivery of a bolus

Notice

- The Diabecare DANA-i Insulin Pump is powered by an external (AAA) Battery

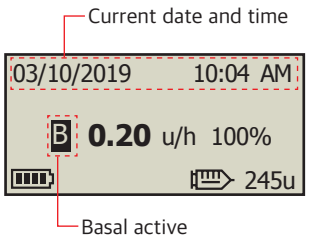
Notice

- SOOIL recommend using either a Duracell gold alkaline AAA battery or an 'Energizer Advanced' alkaline AAA battery.

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 adjust the time

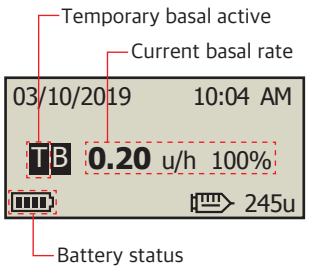
Notice When the time is set to '12', "AM/PM" will be shown.

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 Rates

*100% is normal basal delivery state.

*u/h = units/hour

Battery status

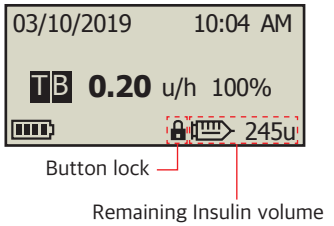
Displays remaining battery charge as,

100%, 75%, 50%, 25%, 0%

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

Notice Lithium batteries may not give an accurate battery level indicator.

Alkaline batteries are recommended.



Button lock

Appears on the screen when it is locked.

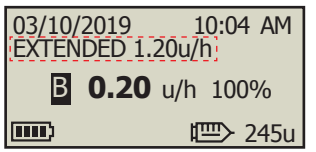
Refer 6.3 Button Lock

Remaining Insulin volume

Displays volume of insulin in the reservoir.

Notice Low Reservoir indicator will flash when insulin volume remaining is low.

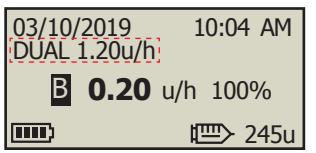
Refer to chapter 7. Alarms and Error messages.



Extended bolus status

This icon (EXTENDED x.xx u/h) will be displayed only when extended bolus is active.

Refer to 6.8 Extended Bolus



Dual bolus status

This icon (DUAL x.xx u/h) will be displayed only when a dual pattern bolus is active.

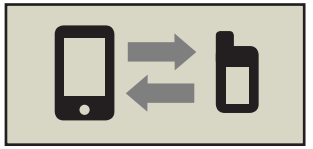
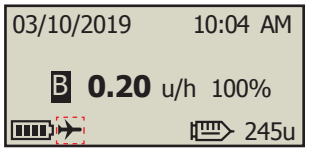
Refer to 6.9 Dual Pattern Bolus

No delivery

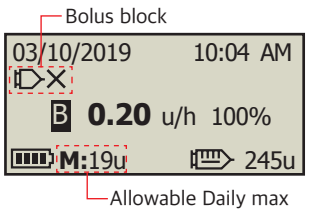
This screen will be displayed when pump does not deliver insulin.

Refer to chapter.7 Alarms and Error messages.

* Remote control mode

	**Remote control mode** When the smartphone with app installed is connected to the pump, the pump screen is displayed as shown in the figure. In this state, the button of the pump does not work. **Notice** You can disconnect by pressing the ⊖ key for more than 5 seconds.
	**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 ⊳X 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:XXu**) 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)")

4. Patient Education

Follow up education is recommended for all insulin pump users.

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

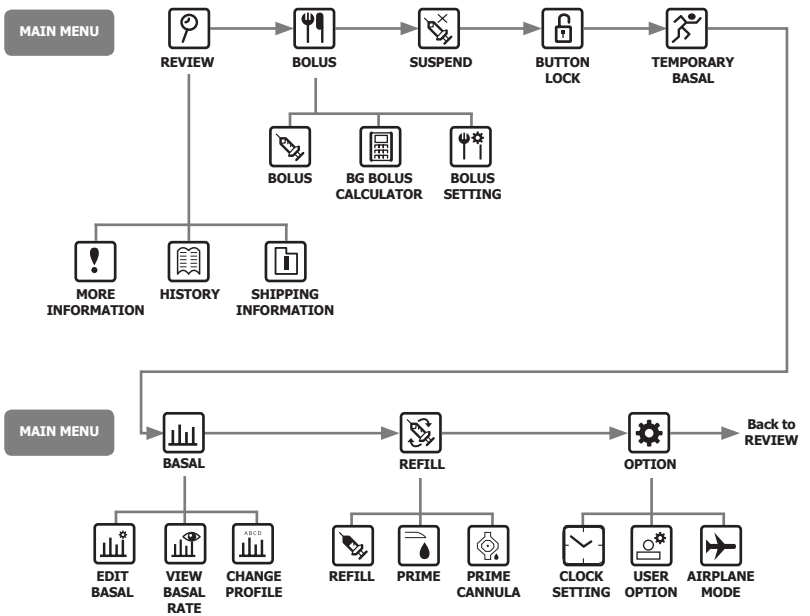
DOCTOR MODE is a configuration menu accessed only by healthcare professionals and certified insulin pump trainers. These settings are generally related to safety and to insulin dosages about individual patients.

- ✓ Preset Bolus
- ✓ Glucose Check alarm (min)
- ✓ Bolus Block
- ✓ Bolus Increment
- ✓ Basal Increment
- ✓ Ideal B.G level
- ✓ Active Insulin
- ✓ Insulin Decrese Ratio(%)
- ✓ Maximum Basal (u/h)
- ✓ Maximum Bolus (u)
- ✓ Maximum Total daily does(u)
- ✓ Safety Ratio (%)
- ✓ Block Sensitive
- ✓ Set UTC time (Date, Time)

Contact your healthcare professional in order to change these settings.

3. Programming the Insulin Pump

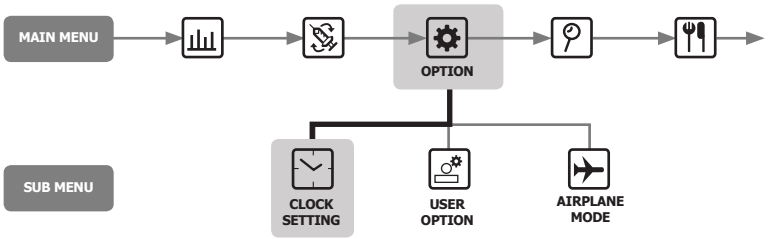
* Structure of DIABECARE DANA-i Menu:



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.

1. Adjust the time

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



TIMEZONE : 00
UTC TIME
01/01/2019 00:00:00
LOCAL TIME
01/01/2019 00:00:00

From within the Clock Setting menu - adjust the time using the (+) or (−) key. Press (OK) to save the setting.

UTC = 0	Greenwich mean
-1 hour	West Africa
-2 hour	Atlantic
-3 hour	Atlantic
-4 hour	US East
-5 hour	US Central / Chile
-6 hour	Canada
-7 hour	US Pacific
-8 hour	Alaska
-9 hour	South Pacific Ocean
-10 hour	Hawaii / Rarotonga
-11 hour	Samoa

+ 1 hour	UK / Portugal / Europe West
+ 2 hour	France / Germany / Italy
+ 3 hour	Europe East / Istanbul
+ 4 hour	Dubai
+ 5 hour	Asia / Uzbekistan
+ 6 hour	India
+ 7 hour	Thailand
+ 8 hour	West Coast Australia / China
+ 9 hour	Korea / Japan
+10 hour	East Coast Australia
+ 11 hour	Pacific / Noumea / Norfolk
+ 12 hour	New Zealand

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

Notice The Diabecare DANA-i Insulin Pump has UTC time. Setting the date and time is only completed within the Dr Mode.

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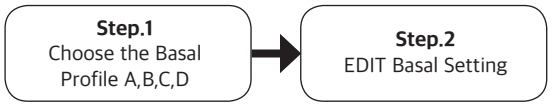
2. Setting the Basal Rate

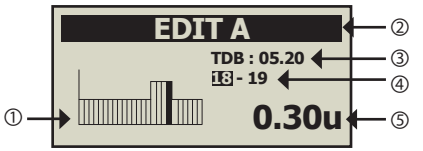
Basal settings must be programmed before using the insulin pump.
Basal insulin is required to maintain an ideal glucose level while fasting.

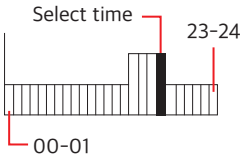
Basal insulin infusion rates are specific to individual patients. There are 24 hourly rates each day, these may increase or decrease to match personal insulin resistance and other factors. The healthcare professional will advise what the initial rates need to be set at the start.

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:

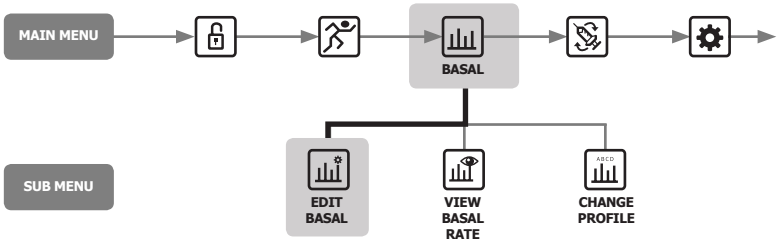


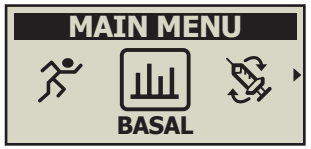
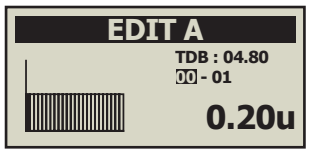
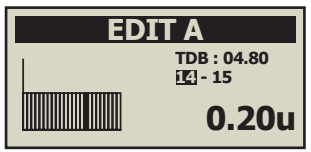
	**1. Basal rate bar graph per hour** The graph consists of 24 bars, and each bar represents each hourly basal rate. In the graph, this bar starts with 00 and display until 24 (12:00AM). When the specific time period is selected, the color of that bar changes to black.
EDIT A	**2. Basal Profile Letter** 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)
TDB : 05.20	**3. TDB (Total Daily Basal)** TDB is total insulin which will be delivered during 24 hours from the basal. Example, Total 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

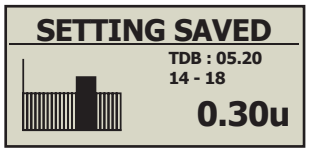
Notice

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

* How to edit the Basal Rate:

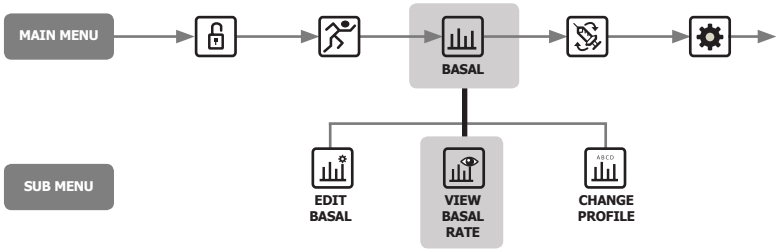


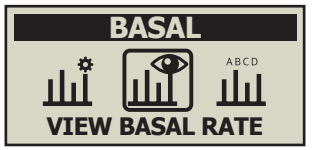
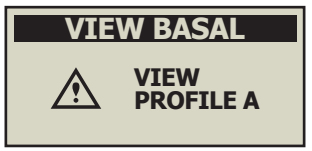
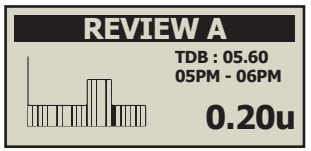
	1. Within **MAIN MENU** scroll through and select **BASAL** with OK.
	2. Select **EDIT BASAL** and press OK.
	3. The current Basal Profile is displayed, confirm the selection with OK.
	4. The edit basal screen is displayed. The default time is 00-01.
	5. Use the + and − to adjust the **start** time. 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. View Basal Rate

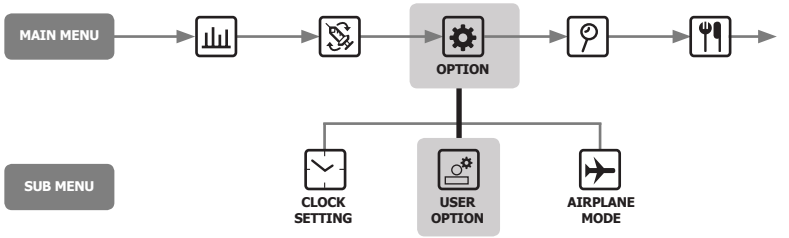
The view basal rate is used to view the current profile's time-specific settings.

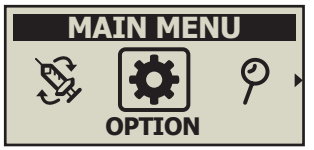
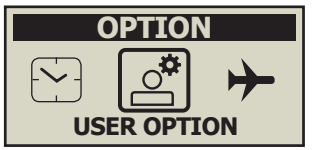


	1. Select **VIEW BASAL RATE** in BASAL's sub menu and press (OK).
	2. The current Basal Profile letter is displayed, confirm the selection with (OK).
	3. The cursor is positioned at the current time. Press (▷) to see the next time value. Press (−) to exit.

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

USER OPTION
1.TIME DISPLAY:12
2.BUTTON SCROLL:ON
3.BEEP:ON
4.ALARM:SOUND
5.LCD ON(S):60
6.BACKLIGHT ON(S):10
7.LANGUAGE:EN
8.GLUCOSE UNIT:MG
9.SHUTDOWN:0
10.LOW RESERVOIR:20
11.PASSWORD
12.CANNULA VOL.:0.4
13.ADJ. RES. VOL.:245U
14.IDEAL BG:100
15.EXIT

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.
Adjust time for backlight from 0 sec to 60

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

USER OPTION
1.TIME DISPLAY:12
2.BUTTON SCROLL:ON
3.BEEP:ON
4.ALARM:SOUND
5.LCD ON(S):60
6.BACKLIGHT ON(S):10
7.LANGUAGE:EN
8.GLUCOSE UNIT:MG
9.SHUTDOWN:0
10.LOW RESERVOIR:20
11.PASSWORD
12.CANNULA VOL.:0.4
13.ADJ. RES. VOL.:245U
14.IDEAL BG:100
15.EXIT

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 **(0)** to disable this auto off.

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

USER OPTION
10.LOW RESERVOIR:20
▶ 11.PASSWORD
12.CANNULA VOL.:0.4

USER OPTION
10.LOW RESERVOIR:20
▶ 11.PASSWORD:0000
12.CANNULA VOL.:0.4

PASSWORD
1 A 3 4

SAVE SETTING?
- :NO OK :YES

11. PASSWORD
Change the BUTTON LOCK password. Enter the current PASSWORD and OK.
From the PASSWORD screen enter the new password then 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

USER OPTION 11.PASSWORD ▶ 12.CANNULA VOL.:0.4 13.ADJ. RES. VOL.:245U	**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)
USER OPTION 12.CANNULA VOL.:0.4 ▶ 13.ADJ. RES. VOL.: 245U 14.IDEAL BG SAVE SETTING? - :NO OK :YES	**13. ADJ. RES. VOL:** 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.
USER OPTION 13.ADJ. RES. VOL.:245U ▶ 14.IDEAL BG:100 15.EXIT	**14. IDEAL BG:** This is the ideal or Target BG value from the 'BG Bolus Calculator' within the pump bolus menu. Use ⊕ and ⊖ key to adjust level OK.
USER OPTION 14.IDEAL BG:100 ▶ 15.EXIT 1.TIME DISPALY:12	**15. EXIT:** Press OK to exit and save settings.

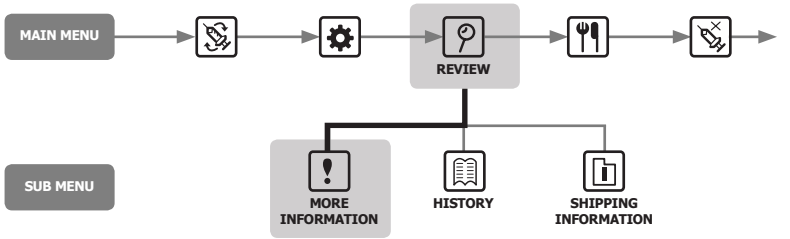
Notice

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

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.



REVIEW MORE INFORMATION	1. From the main menu select **REVIEW** press OK. 2. Select M**ORE INFORMATION**, press OK.
ACTIVE INSULINE: 4.2u DAILY TOTAL: 25.0u EXT. B:10.00u/00:30 PRE.BOLUS: 0h03m/3.5u	**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.

4. Loading Insulin into the Pump

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 Auto Setter
  ✓ Linking screw
  ✓ Alcohol swab (x 1)

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

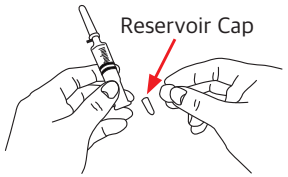
- Follow advice and recommended guidance from the healthcare professional and insulin pump trainer.

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.

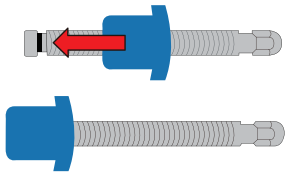
Notice Do not reuse parts or all of an old infusion set or reservoir.

Notice The room temperature in this manual is 15℃(59˚F) ~ 30℃(86˚F)

2. Filling the Reservoir with Insulin

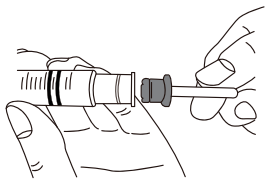


1. Remove the Reservoir cap at the backend of the reservoir plunger. A small white reservoir cap needs to be removed from the plunger-keep this cap for later use. Pull back on the plunger to the line marked with the 3 ml.



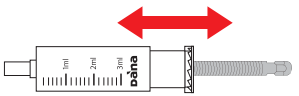
2. Loosen the linking screw until the shaft cap part is covered up by the head part (blue part). This is important to adjust the length accurately.

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

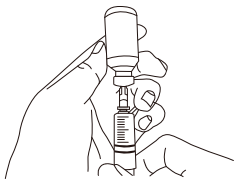


3. Insert and fit the plastic component of the linking screw into the end of the plunger/ reservoir.

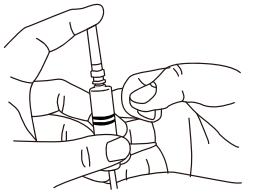
Notice The 'Blue' part needs to firmly engage and lock onto the reservoir plunger.



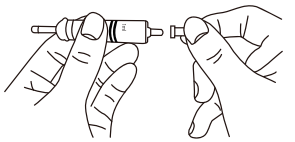
4. Push the plunger up and down 3-4 times to lubricate the reservoir.



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 properly.

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,

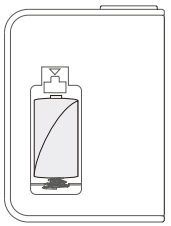
60 x 3 = 180u and extra +40u (suggest filling with 220 units).

3. Adjust the length of linking screw with Auto Setter

The DANA Auto Setter is intended for adjusting the length of linking screw, measuring the amount of insulin in the reservoir and sending it to the pump with the wireless communication.

DANA Auto Setter

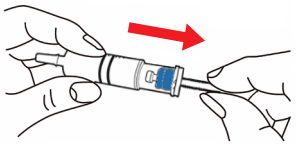
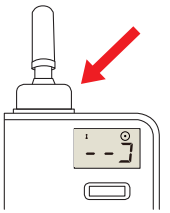
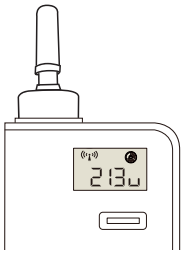
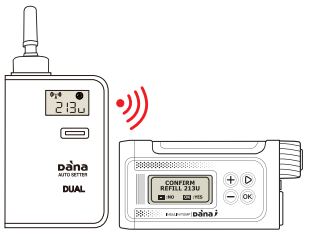
Insert a battery into Auto Setter

	Open the battery compartment. Insert a battery positive side up. Close battery compartment. **Notice** The DANA Auto Setter uses 1/2 AA size 3.6V battery.

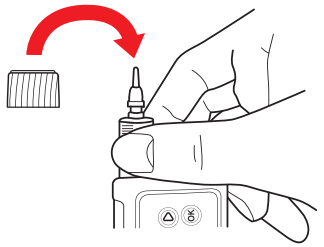
Caution

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

* Using DANA Auto 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 Auto Setter and turn on by pressing the button. **Caution** The end (hexagonal part) of the linking screw should be engaged with the hexagonal hole of DANA Auto Setter.
	3. Press the button again to start measuring. The reservoir will wind down and then count the volume. **Notice** When the button is held and the motor is operating you will notice the reservoir wind down into the device.
	4. The pump will automatically display correct refill volume. Press OK to save and go to Refill-PRIME Menu.

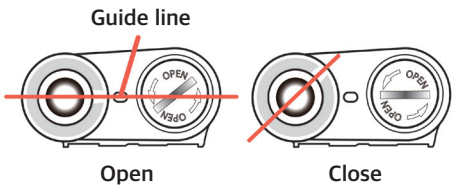
4. Inserting the Reservoir into the Insulin Pump



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. Position the reservoir cap stright line with the guide line, and turning clock-wise 45-degrees.



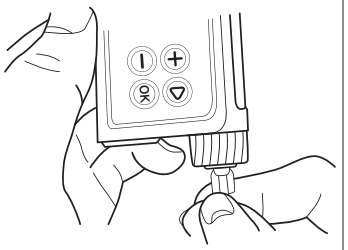
Caution

- DO NOT push or force the reservoir into the Insulin Pump as this could damage the Pump or force insulin from the reservoir.

Notice

- If repeated attempts to insert the reservoir fail, use another new reservoir.

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.

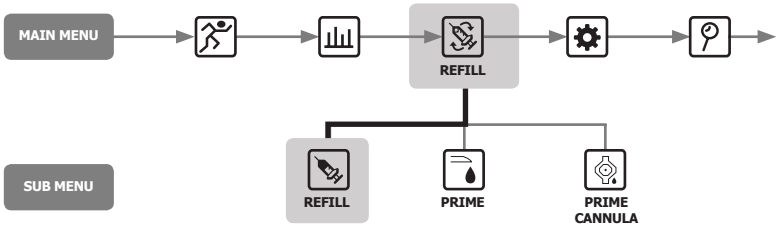
TIP! The DANA insulin pump uses a proprietary LH(Left Hand) lure connection between the insulin pump and the Infusion Set tubing. Only DANA Infusion Sets will connect to the DANA insulin pump.

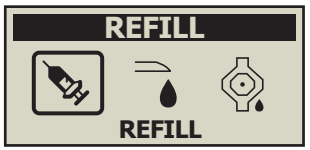
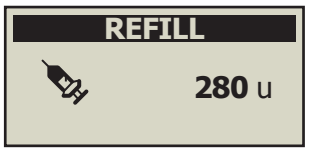
Notice Hold the Insulin Pump upside down while removing the white cap and connecting the tube to avoid insulin leaking into the Insulin Pump.

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

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.

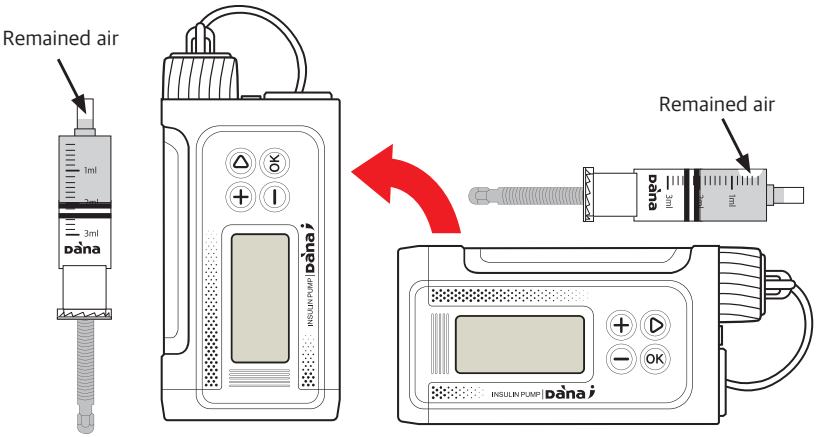
7. Prime the Infusion Set Tubing

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.

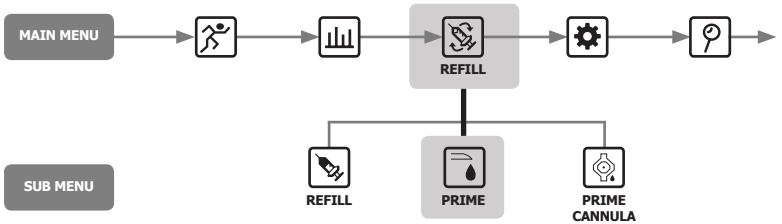
Warning It is important to properly prime the Tube and ensure all air is removed from the system. The pump may not properly deliver insulin without this.

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:



MAIN MENU REFILL	1. From the main menu select **REFILL** and press OK.
REFILL PRIME	2. Select **PRIME** from the REFILL's sub menu and press OK.
PRIME 0.0 u - :EXIT OK :START	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.
INSERT RESERVOIR/ CONNECT INFUSION/ UPRIGHT PUMP DURING PRIME	4. Stand PUMP **upright** during **PRIME**, press OK. Air moves upwards to top-standing pump upright helps displace all air bubbles.
START TUBE PRIME? - :NO OK :YES	5. **START TUBE PRIME** confirmation menu, press OK to start **PRIME**

12.3 u :PAUSE Priming...	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.
 PAUSE 12.5 u - :EXIT OK :RE-START	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.

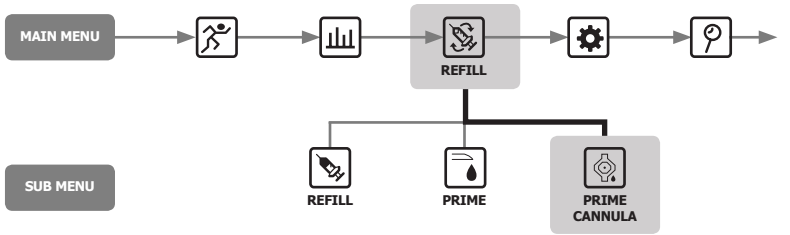
Notice If the prime amount is not enough (less than 7U), this message will be displayed. Because, the minimum prime amount of the infusion set connected to the DANA pump is 7U. Refer to 10.3 Prime Volume of infusion sets and Chapter 7. Alarms and Error messages.

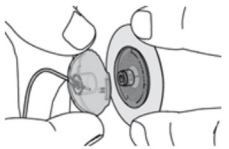
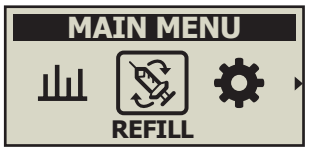
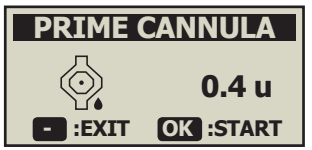
ALERT

PRIME AMOUNT IS NOT ENOUGH

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.



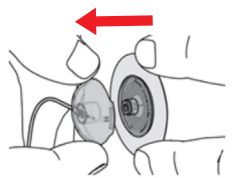
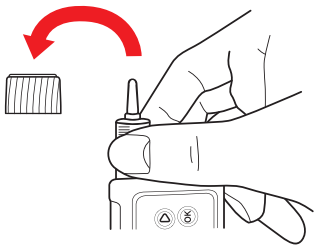
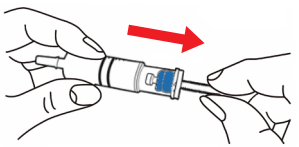
	1. After inserting the cannula into the body (following the cannula instructions) connect the infusion set tube to the infusion set after priming all bubbles out from the tube.
	2. Select **REFILL** menu from the **MAIN MENU** and press OK.
	3. Select **PRIME CANNULA** from the **REFILL** menu press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

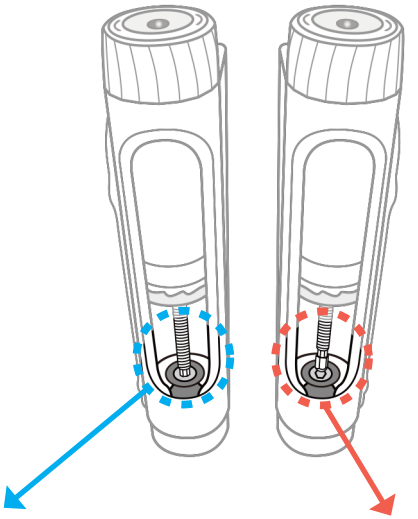
9. Reloading the pump

The previous instructions from (4.1 Preparation) provide details for loading the insulin pump. After usage - prior to loading it is necessary remove the old reservoir by opening the reservoir compartment.

	1. Disconnect the insulin pump tube at the infusion set. **Caution** Ensure the infusion site is disconnected from the pump tubing - before opening the Insulin Pump. Failure could cause unintended insulin delivery!
	2. Open the Insulin Pump reservoir compartment by turning the reservoir cap ¼ turn clockwise. Then remove the old reservoir by lifting out from the pump.
	3. Remove the Insulin Pump linking screw by firmly pulling from the reservoir (holding the reservoir barrel tightly. **Notice** The linking screw is part of the pump and is reused - keep this part each refill!

* Connection of Pump & Reservoir

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



Connection Success

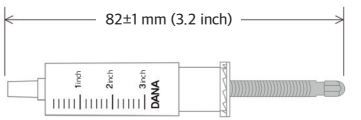
If after a new refill, insulin pump primes the tubing properly and insulin droplets appear at the end of the tubing, It confirms the successful mechanical connection of linking screw and gear pit of motor assembly.

Connection Fail

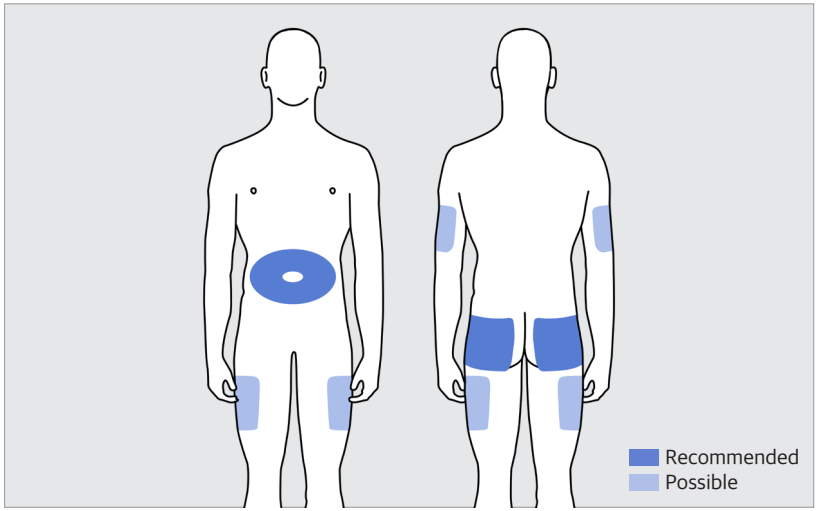
If the linking screw is too short, it won't engage with the pump motor and insulin delivery fails.

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).



* 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.

Notice Follow Infusion Set instructions for each specific infusion set used.

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5. Delivering a Bolus

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

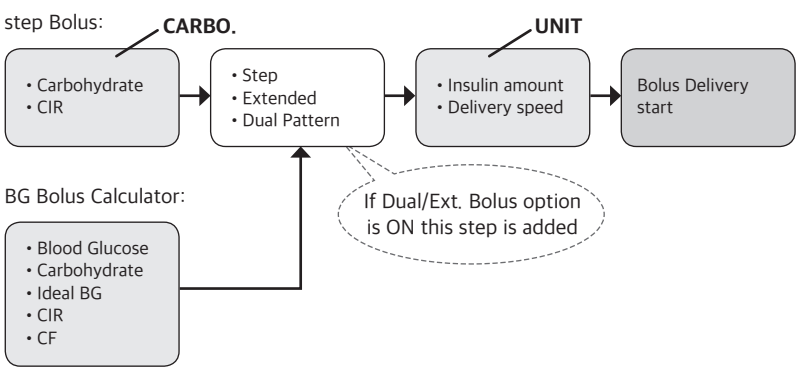
* Bolus calculation parameter

• **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.

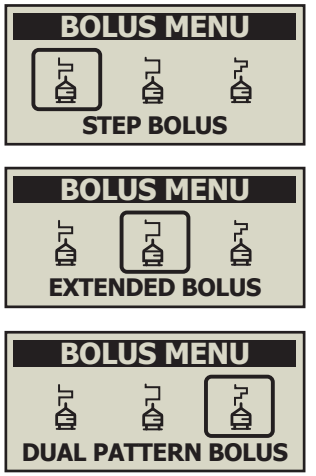
✓**UNIT :** Specifying the dosage directly in units of insulin. By selection of dose in units of insulin below.

• **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:



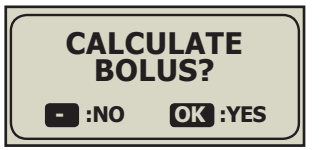
After a suggested bolus amount is shown press OK to select the bolus type:

- 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).

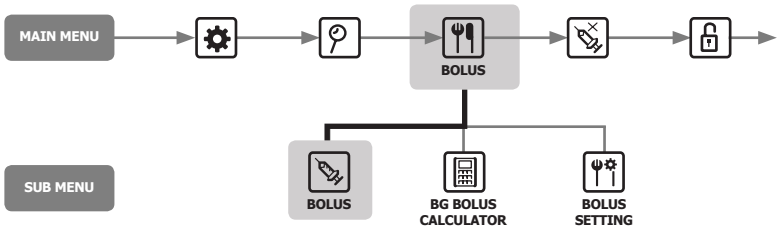
Notice

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.



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:

BOLUS BOLUS	1. Select **BOLUS** from the BOLUS Sub menu press OK.
BOLUS CAL. CARBO 80 g CIR 25 BOLUS 3.20 u	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.
STEP BOLUS BOLUS 3.20 u SPEED 12 sec/u BOLUS	3. Use + and − to increase/decrease the volume or speed of Bolus. Press OK.
DELIVER BOLUS? - :NO OK :YES	4. Press OK to start.

INSULIN INJECT INJECTED 2.70 u TARGET 3.20 u - :STOP	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.
STEP BOLUS 3.20U 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:

STOP BOLUS? - :NO OK :YES	1. During the BOLUS delivery press the − button. Confirm the STOP with OK.
STEP BOLUS 2.70U DELIVERED	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.

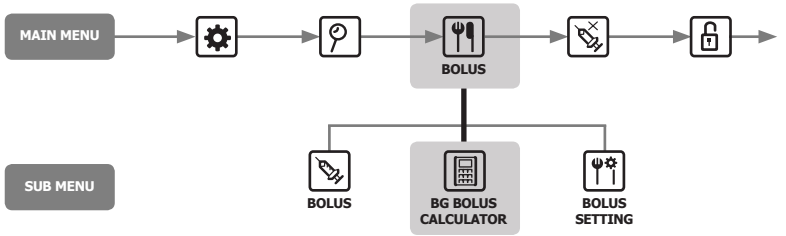
Notice

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.

ALERT
CHECK GLUCOSE

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.



BOLUS BG BOLUS CALCULATOR	1. From **BOLUS** select **BG BOLUS CALCULATOR** with OK button.
BG BOLUS CAL. BG 220 mg/dL CARBO 80 g IDEAL 100 mg/dL CIR 25 CF 50	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.
BG BOLUS CAL. G. 2.40 C.3.20 A.0.20 SUGGESTED BOLUS 5.40 u	3. The BOLUS review displays the suggested Bolus dose.

DELIVER BOLUS? - :NO OK :YES	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".

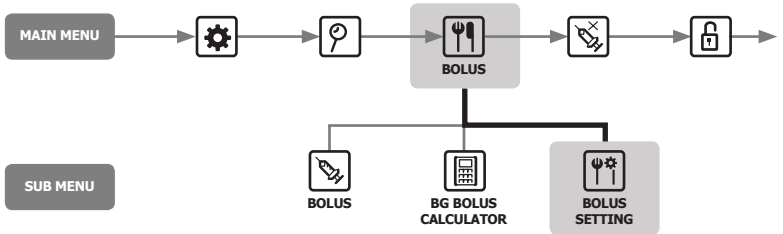
The suggested bolus is calculated by:
BOLUS = G + C - A
BOLUS = CORRECTION DOSE + MEAL DOSE - ACTIVE INSULIN

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.**

3. Bolus Setting

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



BOLUS BG BOLUS CALCULATOR	1. Select **BOLUS SETTING** from within the **BOLUS** MENU press (OK).
BOLUS SETTING 9.EXIT ▶ 1.CIR/CF SETTING 2.E+D BOLUS	2. The bolus setting menu is shown
BOLUS SETTING 1.CIR/CF SETTING 2.E+D BOLUS 3.BOLUS CAL.:CARB. 4.BOLUS RATE 5.MISSED BOLUS1:OFF 6.MISSED BOLUS2:OFF 7.MISSED BOLUS3:OFF 8.MISSED BOLUS4:OFF 9.EXIT	3. Press (+) and (−) buttons so adjust the **BOLUS SETTING.** The (▷) button move through the menu to next option.

* Bolus Setting

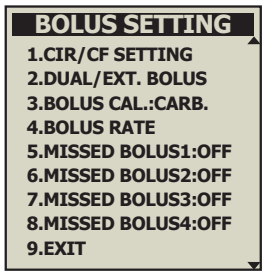
BOLUS SETTING 9.EXIT ▶ 1.CIR/CF SETTING 2.E+D BOLUS SELECT CIR OR CF - :CF OK :CIR CIR SET 23-24 CIR:20 00-01 CIR:20 01-02 CIR:20 02-03 CIR:20 03-04 CIR:20 04-05 CIR:20 05-06 CIR:20 ⋮ CF SET 23-24 CF:50 00-01 CF:50 01-02 CF:50 02-03 CF:50 03-04 CF:50 04-05 CF:50 05-06 CF:50 ⋮ SAVE SETTING? - :NO OK :YES	**1. CIR/CF SETTING** Select CIR or CF Press the (−) button to adjust the CF (correction factor) or press the (OK) button to adjust the CIR (carb to insulin ratio). From within the CIR or CF option, it is then necessary to adjust the ratio for every hour 00-01, 01-02, 02-03 etc for each hour to 23-24. After successfully changing the ratio to the personalized requirements. Press (OK) to save the settings.

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. DUAL/EXT. BOLUS

Adjust between extended and dual bolus ON/FF.

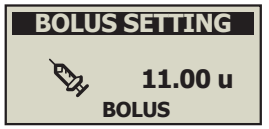
3. BOLUS CALCULATOR

Setting changes CARB, UNIT or BOTH

CARB = Bolus requests grams entered

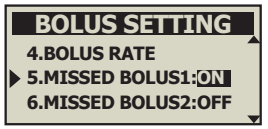
UNIT = Bolus by adjusting units entered

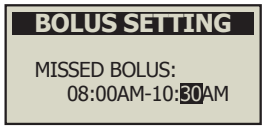
BOTH = every bolus asks which option



4. BOLUS RATE

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

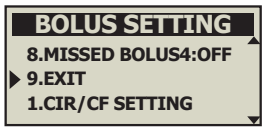




5. MISSED BOLUS 1-4

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".

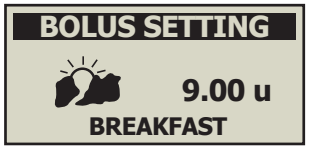


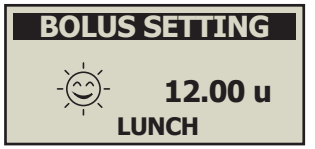
6. EXIT

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 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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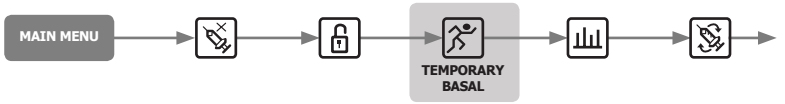
6. Advanced features within Pump

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.



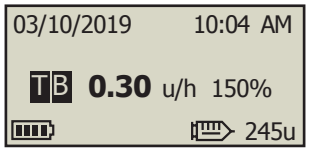
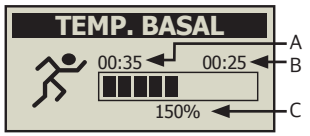
* Starting a Temporary Basal Rate

	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.

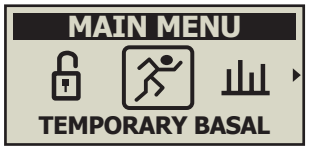
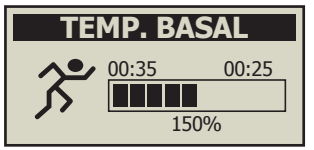
* Review Temporary Basal Rate Whilst in Operation

	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. A. Time Temporary rate has been running B. Time remaining for the Temporary Rate. C. 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.

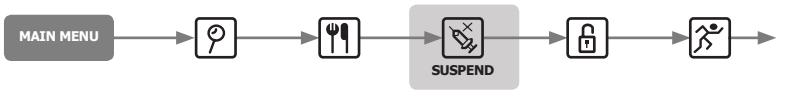
* Stopping a Temporary Basal Rate

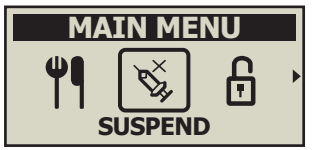
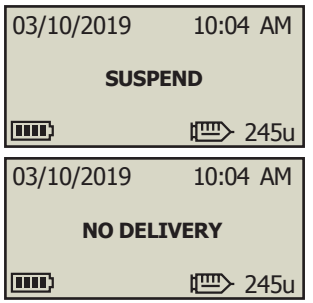
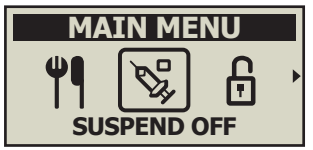
	1. Select **TEMPORARY BASAL** from the main menu.
	2. The **TEMP. STATE** screen is displayed, press OK to STOP the TEMPORARY RATE.
	3. Confirm the **STOP TEMP. RATE** with OK.

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

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 alert and the basal active status on initial screen.

Notice

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

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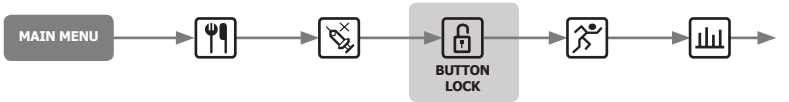
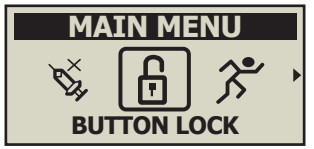
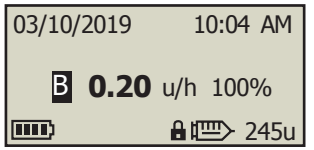
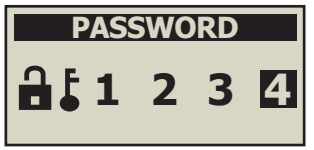
3. Button Lock

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.



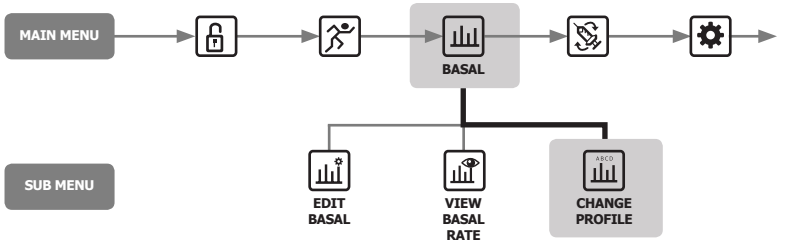
	1. Select **BUTTON LOCK** from the **MAIN MENU**.
	2. The BUTTON LOCK symbol is displayed on the Main Menu.
	3. Press any button from the Initial Screen and a PASSWORD request appears.
	4. The Correct **PASSWORD** must be entered correctly before any delivery menu can be accessed.

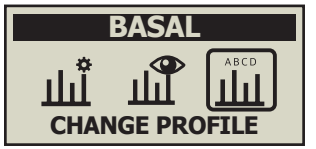
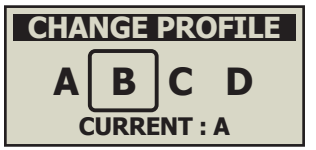
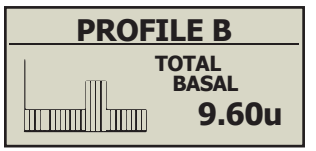
Notice

- 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.

4. 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.

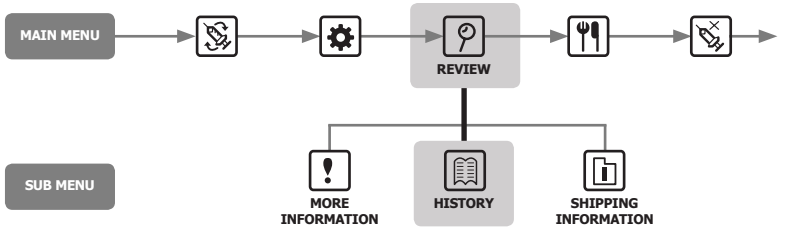


	1. Select **CHANGE PROFILE** from the **BASAL** sub menu.
	2. Select the Profile that is to be selected
	3. The PROFILE name is displayed confirm the change by pressing OK.
	4. Confirm the change with OK.

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

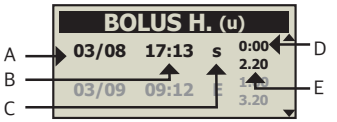
5. HISTORY : Displays all the Pump History

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



REVIEW HISTORY	1. Select **REVIEW** from the MAIN MENU then select **HISTORY** from the REVIEW sub menu.
BOLUS H. (u) 03/08 17:13 s 0:00 2.20 03/09 09:12 E 1:00 3.20	2. The ⊕ and ⊖ Use scroll up/down. ▷ button to next menu.

* Review Menu



1. BOLUS HISTORY

Record of the most recent 300 BOLUSES

A. DATE (mm/dd) B. TIME (hh:mm)

C. BOLUS Type

S = Step

E = Extended

DS = Dual **S**tep

DE = Dual **E**xtended

D. Duration of Bolus (hh:mm)

E. Bolus amount (units)

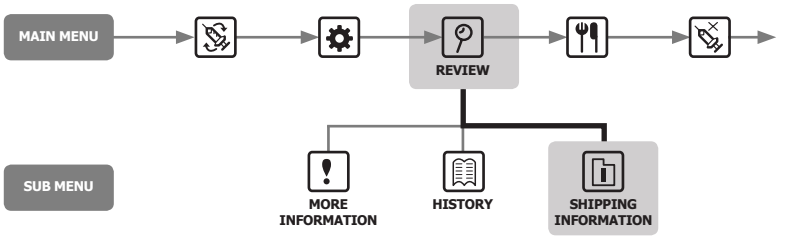
BOLUS AVG. (u) 03DAYS AVG 10.2 07DAYS AVG 12.3 14DAYS AVG 11.5	**2. BOLUS AVERAGE** Daily total average bolus for 3, 7 14 and 28 days displayed in units of insulin.
DAILY TOTAL. (u) 03/10 2.5/10.4 03/09 2.5/12.3 03/18 2.1/14.8	**3. DAILY TOTAL HISTORY** History of last 60 day's delivery totals Displayed as date with Basal / Basal +Bolus
REFILL H. (u) 03/08 09:02PM 240 03/05 05:32PM 220 03/02 11:55AM 210	**4. REFILL HISTORY** History of when pump has been refilled, time and volume of Insulin loaded.
PRIME H. (u) 03/08 09:06PM C0.4 03/08 05:34PM 15.2 03/05 05:35AM C0.4	**5. PRIME HISTORY** History of Pump Prime's, Date, Time, Volume **Notice** In volume, "C" means "Prime Cannula value"

* Review Menu

CARBO H. (u) 03/10 05:04PM 180 03/10 01:35PM 250 03/09 07:22AM 228	**6. CARBOHYDRATE HISTORY** History of carbohydrate used for bolus delivery calculations. Grams of CHO
B. GLUCOSE (mg/dL) 03/10 10:02AM 180 03/09 09:35PM 223 03/09 06:22PM 105	**7. BLOOD GLUCOSE HISTORY** History of Blood Glucose using the BG Bolus calculator. Date, Time, BG Result in mg/dL or mmol/L
ALARM CODE 03/03 11:20AM LOW BATTERY 209U REMAING	**8. ALARM CODE** History of DANA alarms and warnings • Date & Time • Type of alarm • Reservoir volume at time of alarm
SUSPEND H. 03/08 09:02PM OFF 03/08 08:55PM ON 03/05 05:30PM OFF	**9. SUSPEND HISTORY** History of Suspend Date, Time of when Suspend mode is started (ON) or stopped (OFF).
TEMP. BASAL 03/09 05:50PM OFF 03/09 05:04PM 150% 03/02 11:45AM OFF	**10. TEMP. BASAL** History of Temporary Basal rates Date, Time of when Temporary rate is started or stopped (OFF) and percentage of Temporary Basal rates.
BASAL H. 03/10/2019 05PM - 06PM 0.20u	**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. SHIPPING INFORMATION

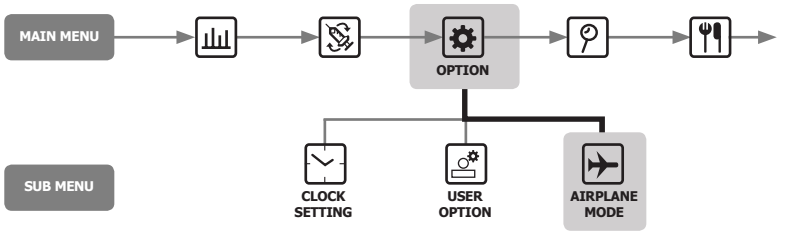
This displays the country that the pump was originally shipped to after manufacture. Also displayed is the date of manufacture, pump serial number and the software version installed.

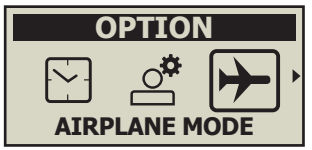
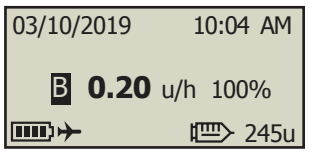
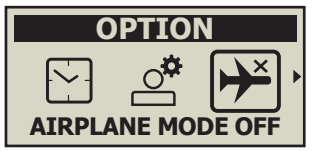


REVIEW SHIPPING INFORMATION	From **MAIN MENU** select **REVIEW** screen then open **SHIPPING INFORMATION** from the sub menu.
1. S/N : AAA00000AA 2. COUNTRY : KOR 3. DATE : 01/MAR 2019 4. VERSION : FPN X.X.X	Display includes: • Pump serial number • Country pump was originally distributed from • Date of manufacture • Pump software version number

7. Airplane mode

Diabecare DANA-i is designed for remote control in conjunction with smartphone app. However, 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.

Notice

- when not using the smartphone app, airplane mode helps save the battery.
- Refer to the app Manual for how to connect the smartphone app and the pump.

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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 a 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 DUAL/EXT. BOLUS refer 5.3 Bolus Setting

* Start Extended Bolus

Bolus using grams of carbohydrate Extended.

BOLUS BOLUS	1. From **MAIN MENU** select **BOLUS.** From BOLUS sub menu select **BOLUS** icon.
BOLUS CAL. CARBO 80 g CIR 25 BOLUS 3.20 u	2. Enter the grams of carbohydrate and confirm the CIR setting is correct. Press OK.
BOLUS CAL. EXTENDED BOLUS	3. Displays the three different bolus types. Select **EXTENDED BOLUS** press OK.
EXT. BOLUS BOLUS 3.20 u PERIOD 1:00	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.
DELIVER BOLUS? - :NO OK :YES	5. Confirm BOLUS start with OK.

* Start Extended Bolus

03/10/2019 10:04 AM EXTENDED 3.20u/h B 0.20 u/h 100% 245u	1. Extended state shown on the initial screen.
BOLUS MENU EXTENDED BOLUS	2. From **MAIN MENU** select **BOLUS.** From BOLUS sub menu select Bolus icon. The three bolus types are displayed, select Extended press OK.
EXT. BOLUS A 00:19 00:41 B C 1.10u 2.10u D	3. The **EXT. BOLUS** displays the current active Extended Bolus. A. Time since the Bolus started(hh:mm) B. Time remaining before Bolus is complete C. Bolus amount delivered already D. Bolus amount remaining Press - to exit.

* Stop an Extended Bolus

EXT. BOLUS 00:19 00:41 1.10u 2.10u	1. From **EXT BOLUS** status screen press OK.
STOP BOLUS? - :NO OK :YES	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.

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.

BOLUS BOLUS	1. From **MAIN MENU** select **BOLUS** From BOLUS sub menu select **BOLUS** icon.
BOLUS CAL. CARBO 80 g CIR 25 BOLUS 3.20 u	2. Enter the grams of carbohydrate and confirm the CIR setting is correct. Press OK.
BOLUS CAL. DUAL PATTERN BOLUS	3. The **BOLUS MENU** displays the three different bolus types. Select **DUAL PATTERN BOLUS** press OK.
DUAL PATTERN STEP 1.60 u EXTEND 1.60 u PERIOD 1:00	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.
DELIVER BOLUS? - :NO OK :YES	5. Confirm **BOLUS START** with OK.
INSULIN INJECT INJECTED 0.70u TARGET 1.60u - STOP	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.

03/10/2019 10:04 AM DUAL 1.60u/h B 0.20 u/h 100% 245u	1. Dual state shown on the initial screen.
EXT. BOLUS 00:19 00:41 0.50u 1.10u	2. From **EXT BOLUS** status screen press OK.
STOP BOLUS? - :NO OK :YES	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 "EXTENDED BOLUS DELIVERING" message is displayed.

EXTENDED BOLUS DELIVERING
- :NO OK :YES

7. Alarm, Error and Alert

This chapter describes insulin pump Alarm, Error, Alert messages and how to solve them.

Type	Message
ALARM (High Priority)	LOW BATTERY EMPTY RESERVOIR SHUTDOWN OCCLUSION CHECK ERROR SYSTEM ERROR PRIME INCOMPLETE BASAL MAX DAILY MAX
ERROR (Medium Priority)	LOW RESERVOIR SUSPEND DELIVERY LESS THAN BASAL SET RATE
ALERT (Low Priority)	MISSED BOLUS PRIME AMOUNT IS NOT ENOUGH CHECK GLUCOSE CONFIRM PAIRING NO DELIVERY

Notice

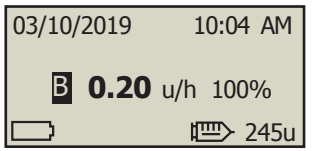
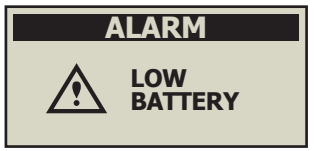
- **Alarm** is a critical alarm that can affect safety. Resolve an issue as soon as possible. In this case, the alarms will SOUND even though VIBRATION is selected.
- **Error** makes you know the problem of the insulin pump. An ERROR is less serious than an ALARM.
- **Alert** just informs you about the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

* ALARM Message

LOW BATTERY
The low battery screen will appear when the battery level is not sufficient to operate the pump and deliver insulin.

How to solve:
Silence the alarm by pressing any button and replace the new AAA battery as soon as possible.

Low Battery warning

	When battery energy is low, an empty battery symbol appears and blinks on the initial screen. BT Communication is interrupted to conserve the battery.
	Alarm will be activated with sound and repeat every 10 minutes or whenever the pump is awoken from the screen save mode until replace the battery.

Caution Always ensure you keep spare batteries near.

* ALARM Message

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:

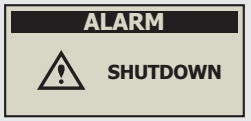
Silence the alarm by pressing any button. Immediately replace the reservoir and refill the pump

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 alarm 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.

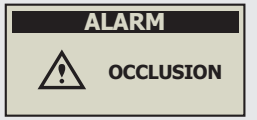


How to solve:

Silence by acknowledging the alarm and pressing any of the buttons.

OCCLUSION

This alarm occurs if the 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, it will be possible to 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.

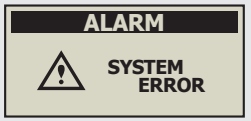
* ALARM Message

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:

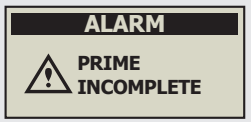
If/when either of these alarms, removal of the battery will silence the alarm. Reinsert the battery after 10 seconds and the pump will perform a full self-check procedure. DANA Insulin pump is monitoring all operation for safety. Any unusual noise may cause relevant alarms to prevent any further problems.
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 ALARM persists, contact technical support from your local Insulin Pump distributor.

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.

BASAL MAX

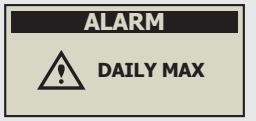
The Pump will automatically give an alarm sound when the total basal dose per hour reach to allocated basal maximum amount pre-set in Dr. Mode. When Warning is activated, the basal during that hour will be restricted.

How to solve:

Silence by pressing any of the buttons. The default is maximum 3.3u/h and can be adjusted by your health care professional in the Dr. Mode.

DAILY MAX

The Pump will automatically give an alarm sound when the Daily total dose reach to allocated Daily Maximum amount pre-set in Dr. Mode. When Warning is activated, the basal/bolus will be restricted for a day.



How to solve:

Silence by pressing any of the buttons. The default is maximum x.xu/day and can be adjusted by your health care professional in the Dr. Mode.

* ERROR Message

LOW RESERVOIR

When the reservoir volume is below the 'Low Reservoir' warning configured in the user options, this screen will be shown with either beep or vibrates.

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 The pump has a Low Reservoir alert. Depending upon dosage-the user can set this alert at 10, 20, 30, 40 or 50u threshold (See section 3.4 User option for changing the threshold). If set at 10 or 20u the pump will alert every half from when the threshold is reached. If set at 30, 40 or 50u the pump will alert very 1 hour after the threshold is reached.

SUSPEND

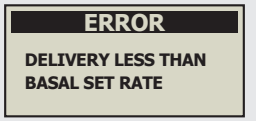
Select any menu related to infusion (insulin delivery) whilst the Insulin Pump is in Suspend Mode, you are alerted with this message.
Refer to 6.2 SUSPEND.

How to solve:

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

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.

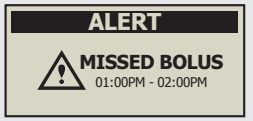
Size of **BASAL Rate** (u/hr)	BASAL **delivery interval**
≥ 0.1 U/h (Basal)	Every 4 minutes (1/15) of the hourly rate is delivered. 15 deliveries per hour.
Extended bolus	
≤ 0.09 U/h (Basal)	Basal delivery will occur once at 56min the hour. (hourly)

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

* ALERT Message

MISSED BOLUS

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



How to solve:

Silence the alert 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 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.

CHECK GLUCOSE

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

How to solve:

Silence the melody by depressing any button and check your blood glucose level.

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

CONFIRM PAIRING

Displayed when the pump receives a pairing signal.

How to solve:

To cancel / prevent pairing, press ⊖ NO.

Refer to Manual of Mobile application.

* ALERT Message

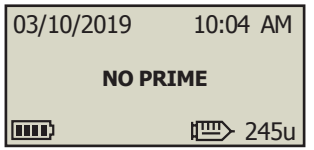
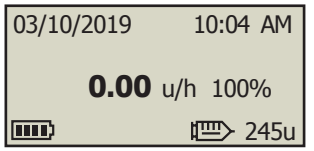
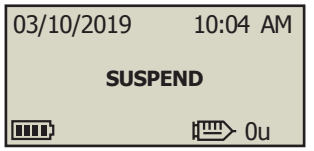
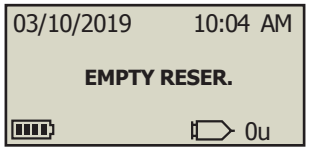
NO DELIVERY

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:

A detail message will blink alternately. Refer to following reason of NO DELIVERY.

※ Reason of NO DELIVERY

	If prime is not completed fill tube. 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.
	Pump has been suspended. 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.
	If the warning of BASAL MAX, DAILY MAX is activated, the delivery could be restricted for an hour/day

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8. Troubleshooting

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 occurs prior to a meal, consider a bolus delaying the bolus until during or after the meal, rather than before.
4. In cases of severe hypoglycemia, it is recommended to suspend delivery by disconnecting the Infusion Set.

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

* Hypoglycemia Troubleshooting

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

2. Hyperglycemia (hige 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 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 blood sugar level.
2. Check 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 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 bolus history and basal rates. Check with a healthcare professional to make sure Bolus, Time, CIR, CF, Target BG and Basal are correctly programmed.

3. Occlusion Alarm

The causes of occlusion alarms are very variety. The tubing 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 longer than intended usage.	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. Refer section 4.
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 alarm persists, contact technical support from local Insulin Pump distributor.

Caution Check blood glucose frequently following an occlusion.

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 to 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

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

5. Troubleshooting the Auto Setter

Error Code	PROBLEM	CORRECTIVE ACTION
E01	Can not transfer the value to the insulin pump.	Enter the"Refill"menu on your insulin pump to get the value from the Auto Setter.
E02	The hexagonal part of the linking screw does not engage with the hexagonal hole of DANA Auto Setter Dual.	Lengthen linking screw and reinsert it.
	Reservoir stuck inside the Auto Setter.	Slightly twist Reservoir to fit it in.
E12	Lost paring information.	Check the pump is On. If "On", try the paring procedure once again.
E13	Error on bluetooth.	Replace battery and retry. If the problem still exists, contact distributor.
E14	Communication error between Auto Setter and Insulin Pump.	
E20	Motor of the Auto Setter does not work.	
E21	Insulin amount is greater than 300 U.	
LO	Insulin amount is less than 20 U.	Fill the insulin more than 20 U.

9. Taking care of the System

1. Cleaning the System

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.

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, alcohol, benzene or similar solvents.

Notice The battery cap has a O-ring to seal the battery compartment. If it is damaged or missing replace the battery cap.

2. Disposing of Pump and System.

Consult a healthcare provider for instructions for disposal of devices containing electronic waste such as you pump and for instructions for disposal of potentially bio hazardous materials such as used cartridges, needles, syringes, and infusion sets.

3. Storing the System

For safe transport and storage of the **Diabecare DANA-i** Insulin Pump system 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

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.

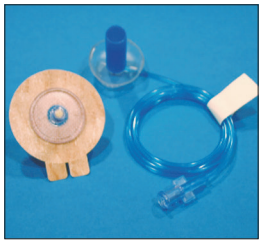
Caution The Insulin Pump must not be used in the presence of intense electromagnetic fields, such as those generated by certain electrically powered medical devices. The Pump should be removed prior to the user having a CT Scan, MRI or X-ray. The pump usage can generate and radiate radio frequency energy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

10. Specification

1. Insulin Pump

SPEC	INSULIN PUMP
Size	3.8× 1.8× 0.8 inch (97 × 47 × 22mm) **including reservoir cap
Net Weight	75g (without battery), 86g (including battery)
Insulin Reservoir	3mL(300 Units) insulin compatible reservoir
Meal Bolus Setting	0 - 80u
Basal Rate Setting	0, 0.04 ~ 16.0 u/h
Basal Profile	4 Types of 24 hours period
Minimum Basal Rate	0.04 u/h
Minimum Increment	0.01 unit
Motor	Swiss Micro DC motor (3V, 5.75mA)
Bolus Duration for 1 Unit	12 / 30 / 60 seconds (optional settings)
Power Supply	1.5V AAA size Battery
Energy Saver	Sleep Mode, Airplane Mode
Alarm	Alarm type: visual, audible and vibratory Audio Frequency: 300Hz to 3000Hz
Wireless	Bluetooth Specifications BLE 4.X (DANA-i4) BLE 5.X (DANA-i5)
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

2. Infusion Sets



Soft-Release-0

DANA Inset II

	Soft-Release-0	DANA Inset II
Needle gauge	26G	26G
Needle type	Teflon	Teflon
Insertion angle	90°	90°
Disconnect	Yes	Yes

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

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

Infusion Set	Tube length	Minimum required Insulin amount
Soft-Release-O	60cm	14 Units
	80cm	19 Units
DANA Inset II	60cm	15 Units
	110cm	22 Units

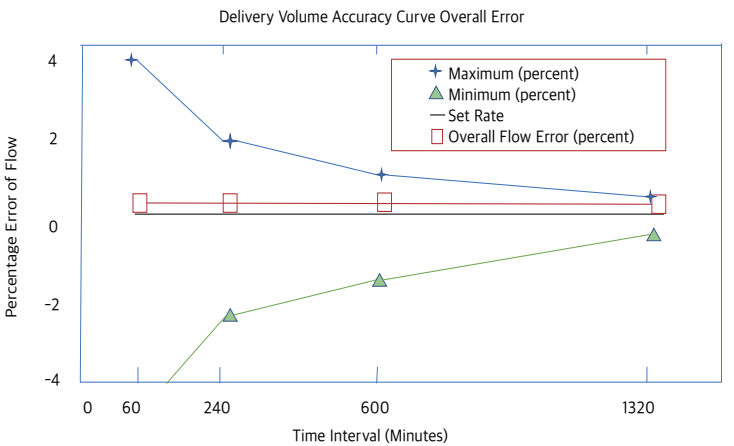
* Cannula prime

Infusion Set	Tube length	Minimum required Insulin amount
Soft-Release-O	6 mm needle with base	0.3 Units
	9 mm needle with base	0.4 Units
DANA Inset II	6mm needle with base	0.5 Units
	9mm needle with base	0.6 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.

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 (-1.4%) at the basal setting of 0.2u/h (the intermediate rate)



5. Classification and Compliance with Standards

- The Diabecare DANA-i 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.

6. Essential Performance

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

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7. Wireless communication

* DATA Security

The Diabecare DANA-i system ensure data security via proprietary means and ensure data integrity using error checking processes, such as cyclic redundancy checks.

* Declaration of EMC compatibility

The Diabecare DANA-i insulin pump is intended for use in the electromagnetic environment and comply with the United States Federal Communications Commission and international standards for electromagnetic compatibility.

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Electro
Radiated disturbance	EN 55011:2016+A1: 2017 CISPR11: 2015	Injection mode	Enclosure	DC 1.5V	Group1, Class B
Electrostatic Discharge Immunity	EN 61000-4-2: 2009 IEC 61000-4-2: 2008	Injection mode	Enclosure	DC 1.5V	±8Kv/ Contact ±2, ±4, ±8, ±15Kv/Air
Radiated RF Electromagnetic Field Immunity	EN 61000-4-3: 2016+ A2:2010 IEC 61000-4-3: 2006+A1:2007+A2:2010	Injection mode	Enclosure	DC 1.5V	10V/m 80MHz - 2.7GHz 80% AM at 1kHz
Immunity to Proximity Fields from RF wireless Communications Equipment	EN 61000-4-8: 2010 IEC 61000-4-8: 2009	Injection mode	Enclosure	DC 1.5V	Table 9 in IEC 60601-1-2:2014
Power Frequency Magnetic Field Immunity	EN61000-4-8: 2010 IEC 61000-4-8: 2009	Injection mode	Enclosure	DC 1.5V	30A/m 50Hz & 60Hz

8. Explanation of Universal Symbols

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

	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
Rx Only	Requires prescription in the United States.
	Do not reuse
SN	Serial Number
	Type BF applied part (protection from electrical shock)
EC REP	European Authorized Representative

IP68	International Protection Code. Dustproof degree: 6 / Waterproof degree:8
⎓	Direct current
	Disposal (WEEE marking)
	Keep dry
	Storage temperature range
	Do not use if package is damaged
	Storage humidity range
	Atmospheric pressure limitation

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12. Warranty

SOOIL Development Company Limited warrants that the Diabecare DANA-i 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 Diabecare DANA 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 Diabecare DANA System.
- Failure to follow the manufacturer's instructions, including those for storage, transport or cleaning for the Diabecare DANA System.
- This warranty does not cover batteries, Infusion Sets, cartridges or other accessories of the Diabecare DANA 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.

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Altenhofstrasse 80, 66386 St. Ingbert
Germany
Sales Representative:

FCC Information

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

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

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

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

WARNING
Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

"CAUTION : Exposure to Radio Frequency Radiation.
Antenna shall be mounted in such a manner to minimize the potential for human contact during normal operation. The antenna should not be contacted during operation to avoid the possibility of exceeding the FCC radio frequency exposure limit.

Diabecare Dana-i

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SOOIL DEVELOPMENT Co.,LTD