

Dana Diabecare[®]

IIS

User Manual



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Chapter 1. Introduction

Warning Please note, US law restricts this device to use by or on order of physician.

Indications for Use

The DANA Diabecare® Insulin Infusion Pump is intended for the subcutaneous delivery of insulin for the treatment of diabetes mellitus. The DANA Diabecare® IIS Insulin Infusion Pump is not intended for use with blood or blood products.

Safety Precautions

1. Patients must not open the pump housing or handle any internal components.
2. The DANA Diabecare® IIS should not be used to diagnose diabetes or to test newborn.
3. The DANA Diabecare® IIS 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. If you experience any trouble with any system components, switch the pump off immediately and contact your healthcare provider or your sales representative.
5. Use the pad of your finger to press the buttons. DO NOT use your fingernails or any sharp objects to press the buttons.
6. Avoid the following conditions for safe storage and transport of the DANA Diabecare® IIS Insulin Pump:
 - a) Temperatures below 23°F-104°F (-0.5°C or above 40°C).
 - b) Atmospheric pressure below 500mmHg or above 1060mmHg.
 - c) Humidity above 95%.
 - d) Exposure to excessive dust or a salty environment.
 - e) Exposure to explosive gas.
 - f) Exposure to direct sunlight.
 - g) Environments where an electromagnetic field is generated by a medical device.
7. The 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.
8. The pump comes with factory default settings for alarms, maximum daily totals, basal and bolus doses. These settings may be modified by a healthcare professional.

Glucose Check Alarm	120 min
Maximum Daily Total	160 u
Maximum Bolus	40 u
Maximum Basal	3.3 u/h

9. Remove the battery for long-term storage.
10. The reservoir and infusion set are intended for single use only. Do not reuse either the reservoir or infusion set.
11. Change the reservoir and the infusion set regularly, as recommended by your healthcare professional. Do not use either for longer than 72 hours.

12. Please check the expiration dates regularly and dispose of any expired accessories.

Cleaning the Reusable Components

1. The outside of the Pump, Remote Controller and DANA Easy Setter should be cleaned monthly.
2. When cleaning, 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.

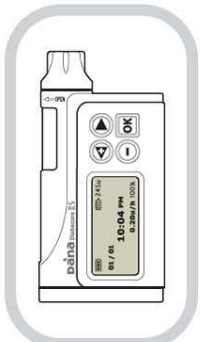
Explanation of “Warning”, “Caution” and “Notice” Symbols

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

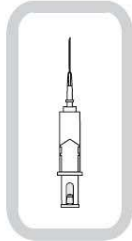
Caution indicates the presence of a hazard which will or can cause minor personal injury or property damage if the warning is ignored.

Notice advises the user of installation, operation or maintenance information which is important but not hazard related.

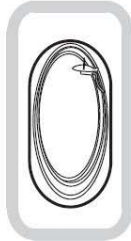
Contents of the DANA Diabecare® IIS System



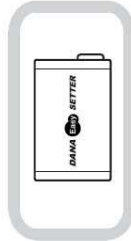
INSULIN PUMP



RESERVOIR (6)



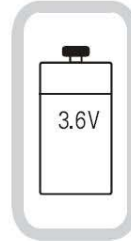
INFUSION SETS (6)



DANA EASY SETTER (1)



LINKING SCREW (2)



BATTERY (2)



ADHESIVE TAPE



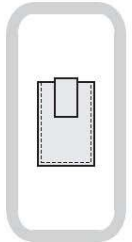
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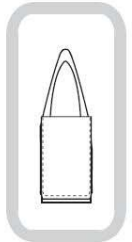
BATTERY KEY (2)



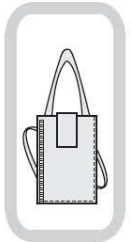
LEATHER CASE (2)



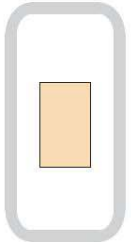
BRA POUCH



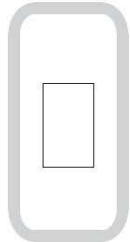
SHOWER POUCH



SHOULDER POUCH



TEGADERM

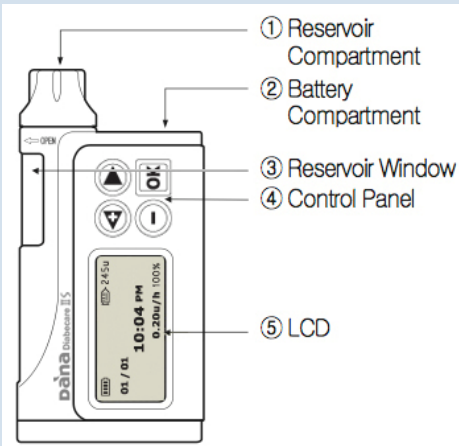


MEFIX

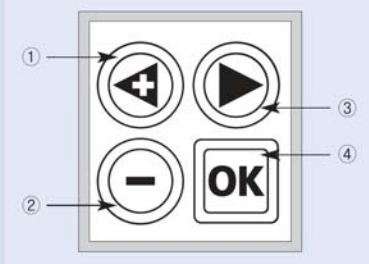
Notice Additional accessories may be purchased separately.

Chapter 2. The Basics

DANA Diabecare® IIS Insulin Pump



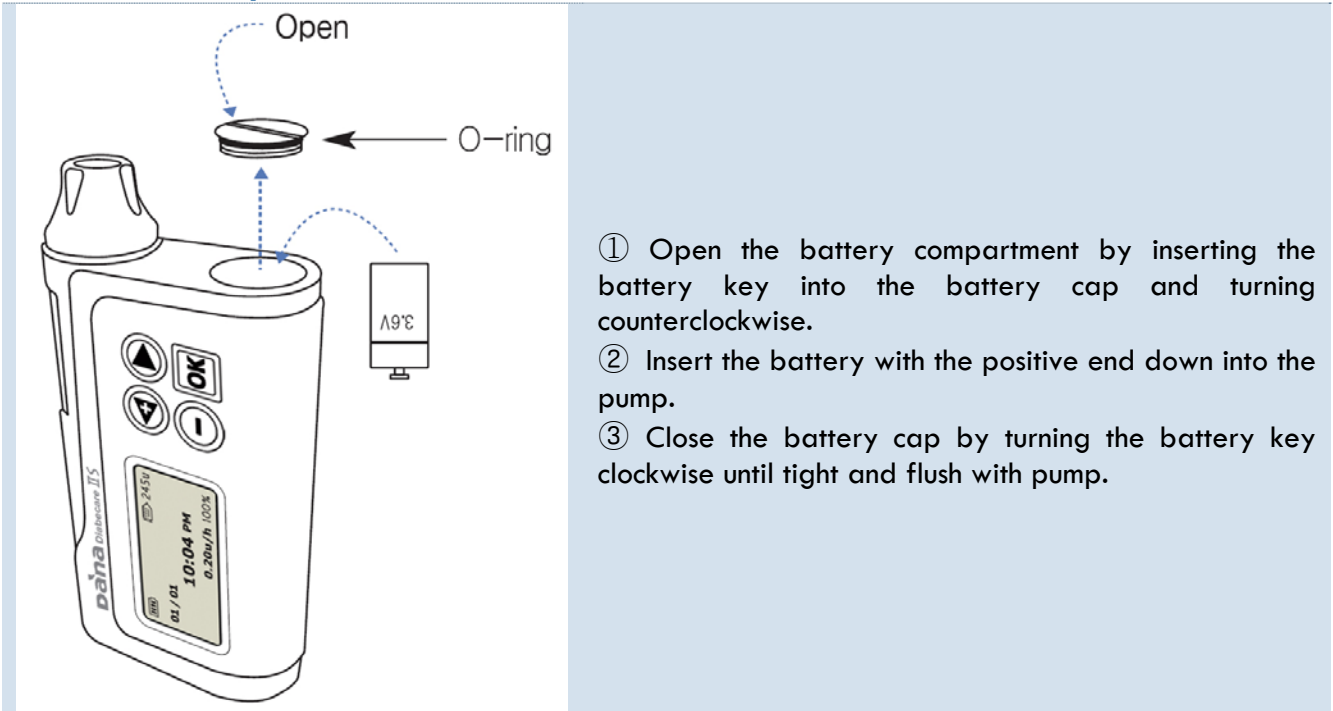
- ① Reservoir Compartment: The reservoir and linking screw are inserted in this compartment. Turn the reservoir cap clockwise to open.
- ② Battery Compartment: The battery is inserted in this compartment. Turn the battery cap counterclockwise to open.
- ③ Reservoir Window: Remaining insulin amount can be visually verified here.
- ④ Control Panel: Contains the four buttons which are used to increase and decrease settings, switch screens and select functions.
- ⑤ LCD: Displays status of system features and system messages and serves as the user interface with pump software. Lights automatically when any button is pressed.



Buttons

- ① button: Press to increase insulin dosages, time and date.
- ② button: Press to decrease insulin dosages, time and date Return to previous screen
- ③ button: Press to move to the next choice on the LCD.
- ④ button: Press to select the function highlighted on the LCD.

Install battery



Warning Change the battery in a dry environment to prevent water from entering the casing.

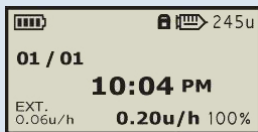
Caution Use of battery other than the 3.6V battery manufactured exclusively for SOOIL Development will result in the void of pump warranty.

Caution If the O-ring on the battery cover appears worn, frayed or torn, please contact your healthcare provider or your sales representative.

Caution Do not attempt to change the battery while a bolus is in progress.

Notice The battery cover is correctly inserted and tightened when the battery cover is level with the insulin pump casing.

Pump screen



Initial Display

	Displays remaining battery charge as 100%, 75%, 50%, 25%.
	Button lock
245u	Displays the amount of insulin remaining in the reservoir in units.
01/01 10:04 PM	Displays current time and date
0.20u/h 100%	Basal status (with temporary basal)
EXT. 0.06u/h	Extended bolus status (Dual bolus status)

Caution For accurate reading of the remaining battery charge, check the initial display immediately after delivering a bolus.

Notice The insulin pump LCD screen will automatically go blank after one minute to conserve battery power. Pressing any button will also activate the backlight for 10 seconds.

Infusion Sets



	Superline -Easy Release	Soft-Release-ST	Soft-Release-0
Needle gauge	27G	26G	24G
Needle type	Stainless Steel	Teflon	Teflon
Insertion angle	90°	0-30°	90°
Disconnect	Yes	Yes	Yes

Setting Bolus

Step or Normal Bolus rate Setting

<p>MAIN MENU SETTING</p>	<p>1) In the MAIN MENU screen press until SETTING icon is highlighted. Then press .</p>
<p>SETTING MENU BOLUS SETTING</p>	<p>2) The SETTING MENU screen will appear. Use to highlight to BOLUS SETTING icon and press .</p>
<p>BOLUS SETTING 10.00 u BOLUS</p>	<p>3) While in the BOLUS SETTING screen select the proper insulin dose by using and . After setting your bolus press to store the meal bolus. (Amount of the bolus)</p>
<p>SETTING SAVE? NO YES</p>	<p>4) Use to highlight 'YES' and press and you will be returned to the MAIN MENU screen.</p>

Caution Please talk to your health care professional if you wish to CONSULT your meal boluses.

Notice You may confirm your bolus settings by using the menu option.

Notice This setting is the amount of insulin that the pump will deliver the next time you bolus.

<p>BOLUS SETTING 10.00 u BREAKFAST</p>	<p>If you are using pre-set meal boluses, the following time periods correlate to the following schedule:</p>
<p>BOLUS SETTING 10.00 u LUNCH</p>	<ul style="list-style-type: none"> • Breakfast = 1:00 - 9:59 (1:00 am - 9:59 am)
<p>BOLUS SETTING 10.00 u DINNER</p>	<ul style="list-style-type: none"> • Lunch = 10:00 - 14:59 (10:00 am - 2:59 pm) • Dinner = 15:00 - 00:59 (3:00 pm - 12:59 am)
	<p>Notice The bolus screen will be separately displayed as Breakfast, Lunch and Dinner in case the device is set to pre-set bolus by your Healthcare professional.</p>

Setting Basal

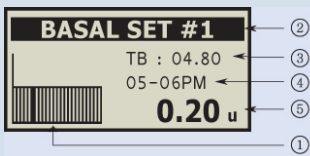
You must program your basal settings before you can deliver basal insulin. Basal insulin is required to maintain your target glucose values when you are not eating. You can set your insulin pump to change rates during the day to match your needs.



1) In the MAIN MENU screen press until SETTING icon is highlighted. Then press .



2) The SETTING MENU screen will appear. Use to highlight to BASAL SETTING icon and press .



3) Use to move between the 24 rates. The corresponding chronological time will appear in the upper right corner. Use the and buttons to change the basal rate for the highlighted time period.

After basal rates are set, press to save the settings in the DANA memory.

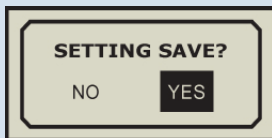
① Basal Profile - Shows basal rates in a graph from midnight to midnight.

② Basal Profile Number Saved.

③ Total basal amount programmed for delivery in a 24 hour period.

④ Chronological time which corresponds to the highlighted section of the basal profile.

⑤ Basal Rate for the time period shown in ④ (Chronological time)



4) Use to highlight 'YES' and press and you will be returned to the MAIN MENU screen.

Notice Basal rates can be adjusted in units per hour.

Notice Basal setting screen shows a basal profile that has been set in units per hour (u/h).

► Group Editing

When you want to change the basal rates for certain consecutive times.

① Press and hold the button for a few seconds once you place the cursor on to the blocks you want to adjust.

② Adjust the block while pressing button until the block covers the time frame you desire.

③ Press and hold the button for a few seconds to cancel the current block adjustment and to adjust different time frame.

④ Press button to save any changes.

Setting the time and date

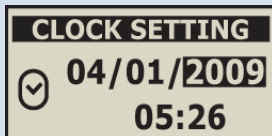
Setting the correct time and date in your pump is necessary for accurate basal insulin delivery and allows you to keep an accurate record of your insulin delivery and other pump functions.



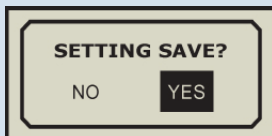
1) In the MAIN MENU screen press until SETTING icon is highlighted. Then press .



2) The SETTING MENU screen will appear. Use to highlight to CLOCK SETTING icon and press .



3) Use to move between the year and month and date, as well as hours and minutes. Use and to make the desired changes.



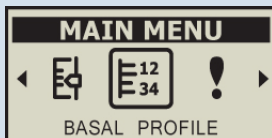
4) After making the changes press to save the setting and return to the MAIN MENU screen.

Caution You must set a.m. and p.m. correctly. If the clock shows 03:00 p.m. and you want 03:00 a.m. you must press until the screen reflects your desired change.

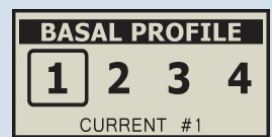
Notice The pump can be programmed in either 12 hour or 24 hour format.

Changing Basal Profile

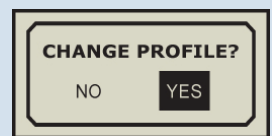
The adjusted basal rates can be saved as 4 different profiles.



1) In the MAIN MENU screen press until BASAL PROFILE icon is highlighted. Then press .



2) Choose a profile by using the button and press .



3) Press to highlight 'YES' then press to save.

Notice You can find the changed profile number in the Basal Setting menu.

Setting User Option

The user option settings allow you to save, restore and clear all pump settings.

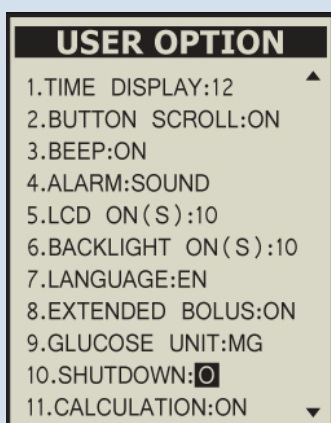


1) In the MAIN MENU screen press until SETTING icon is highlighted. Then press .



2) The SETTING MENU screen will appear. Use to highlight to USER OPTION icon and press .

3) The USER OPTION screen will appear. Use or to modify settings. Use to advance to the next settings.



1. TIME DISPLAY

You can adjust time display as 12 hour or 24 hour format.

2. BUTTON SCROLL

You can choose whether or not to utilize the button scroll function.

3.BEEP

You can choose Beep ON/OFF

4. ALARM

You can choose the method of alert among sound

- SOUND / VIBRATION / BOTH(Sound and Vibration)

5. LCD ON(S)

Adjust the duration of the LCD display by seconds (5-240).

6. BACKLIGHT ON(S)

Adjust the duration of the Backlight by seconds (1-60).

7. LANGUAGE

You can choose a language.

8. EXTENDED BOLUS

You can choose extend bolus menu ON/OFF

9. GLUCOSE UNIT : MG/MMOL

You can select mmol/L or mg/dL as your Blood Glucose Unit.

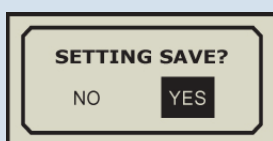
10.SHUTDOWN: 0-24

The pump will automatically shutdown if any of the buttons of the pump is pressed for the period that you set (from 1 to 24 hours). When the pump automatically shuts down, the delivery of insulin will stop and alarm will sound.

If you do not want to use the SHUTDOWN feature, make sure that the hour is set to zero (0).




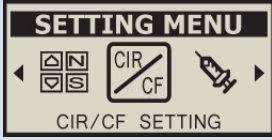


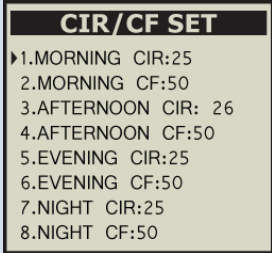



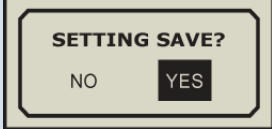


11. CALCULATION

You can choose the option between ON and OFF whether or not to use the Bolus Calculator after Blood Glucose Measurement.



Use to highlight 'YES' and press and you will be returned to the MAIN MENU screen.

CIR/CF Setting

 <p>MAIN MENU SETTING</p>	<p>1) In the MAIN MENU screen press  until SETTING icon is highlighted. Then press .</p>
 <p>SETTING MENU CIR/CF SETTING</p>	<p>2) In the SETTING MENU screen press  until CIR/CF SETTING icon is highlighted. Then press .</p>
 <p>CIR/CF SET</p> <ul style="list-style-type: none"> ▶1.MORNING CIR:25 2.MORNING CF:50 3.AFTERNOON CIR: 26 4.AFTERNOON CF:50 5.EVENING CIR:25 6.EVENING CF:50 7.NIGHT CIR:25 8.NIGHT CF:50 	<p>3) The CIR/CF SET screen will appear. Use  or  to modify settings. Use  to advance to the next settings.</p> <p>CF: Indicates Correction factor (1-100). CIR: Amount of carbohydrates capable of being processed by 1 unit of insulin (Insulin/Carb Ratio to Carbohydrate) (1-50)</p>
 <p>SETTING SAVE? NO YES</p>	<p>4) Press  to highlight 'YES' then press  to save.</p>

Notice Morning / 6:00 -10:59
 Afternoon / 11:00 -16:59
 Evening / 17:00 - 21:59
 Night / 22:00 - 5:59

Preparing

- 1) Retrieve the insulin vial from the refrigerator and let it warm up to room temperature for 15-30 minutes.
 - 2) Suspend the pump and remove the old infusion set.
 - 3) Remove the old reservoir.
 - 4) Place all materials on a clean dry surface.
- Materials: DANA Insulin Pump, fast acting insulin, reservoir, infusion set, DANA Easy Setter, linking screw, alcohol swab, etc.
- 5) Wash your hands

Caution Failing to warm the insulin sufficiently may result in air bubbles in the reservoir.

Filling the reservoir with insulin



1) Remove the round cap at the end of the reservoir plunger and discard. A thin white reservoir cap will fall out of the plunger – keep this cap for later use. Pull back on the plunger to the line marked with the number 3 and push up and down 3-4 times to properly lubricate the reservoir.



2) Insert and fit the plastic component of the linking screw into the cavity of the plunger.



3) Wipe the lid of the insulin vial with an alcohol swab. Carefully remove the clear needle protective cover and draw out the desired amount of insulin.



4) Place the clear needle protective cover back on the needle. Remove any bubbles from the inside of the reservoir by gently tapping on the sides, making the bubbles rise to the top of the reservoir. Gently push on the plunger to remove the bubbles at the top.

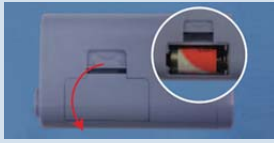


5) Remove the needle from the reservoir and cover with the thin white reservoir cap. Please dispose of the needle properly.

Notice Pull the plunger down until you are at the desired amount of insulin needed. Insert the needle into the insulin vial and inject the air from the reservoir into the vial. Draw out the desired amount of insulin.

Notice Total fill amount: (Daily requirement x 3-4 days) + extra 30u

Setting the reservoir with DANA Easy Setter



- 1) Insert a battery into Easy Setter as instructed below:
 - a. Open the battery compartment.
 - b. Insert a battery positive side up.
 - c. Close battery compartment.

Notice The DANA Easy Setter operates with the SOOIL 3.6V battery.



- 2) Insert a reservoir filled with insulin into the DANA Easy Setter.

Notice The end (hexagonal part) of the connecting screw should be placed into the hexagonal hole of DANA Easy Setter.



- 3) Press and hold the button on the DANA Easy Setter.

Notice When the button is held, you can see the reservoir slide in. Push 2-3 more seconds until the reservoir is fully inserted into the DANA Easy Setter

- 4) Retrieve the adjusted reservoir from the DANA Easy Setter.

Inserting the reservoir into the Pump



Insert the reservoir with linking screw into the insulin pump as shown. When inserting the reservoir, rotate the reservoir back and forth until the notch fittings on the side of the reservoir slide into place. Gently let the reservoir and linking screw fall into place. Next, screw (counterclockwise) the pump's reservoir compartment cap in place and remove the small white reservoir cap from the end of the reservoir.

Caution Do not push and/or force the reservoir into the pump. This could damage the motor drive and linking screw of the pump and could result in the loss of insulin from the reservoir.

Notice If attempts to reinsert the reservoir fail, try a new reservoir.

Connecting the infusion set to the Insulin Pump












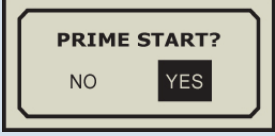





Screw the infusion set connector counter clock wise into the reservoir compartment until it is firmly in place.

Caution If the pump is not held upside down while removing the white cap and connecting the infusion set, insulin may drip down into the pump.

v

Refill Reservoir

Make sure to prime when you use a new infusion set or remove air from the tubing. Always check and confirm all basal and bolus settings after changing the insulin reservoir. Visually confirm there is no air in the infusion set tubing.

	<p>1) In the MAIN MENU screen press  until REFILL icon is highlighted. Then press .</p>
	<p>2) You will now see the REFILL screen display. Use  and  to adjust the amount of insulin (in cc's) in the new reservoir placed in the insulin pump. Then press .</p> <p>Notice Remember to adjust this setting up or down to the amount you have actually placed in the reservoir.</p> <p>Notice The 2.5 cc is a preset default setting.</p>
	<p>3) The PRIME screen will appear and press .</p> <p>Notice The insulin pump will allow 2 prime sequences every 12 hours (0:00 - 12:00, 12:00 - 24:00).</p>
	<p>4) Press  to highlight 'YES' then press  to start.</p>
	<p>5) The PRIMING screen will appear. You will see the insulin move towards the needle end of the infusion set.</p> <p>Notice You will hear the pump beep for every 1.0 unit while priming is in progress.</p>
	<p>6) When you see a drop of insulin appear at the end of the infusion set needle, press  to stop the priming sequence.</p>

Caution Make sure the needle is faced downwards so that insulin does not come in contact with the infusion set plaster.

Notice It is recommended that the pump be primed a minimum of 15 units

Inserting infusion set



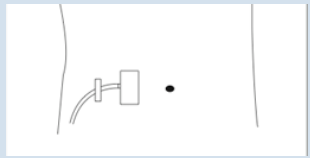
1) Choose an insertion site on your abdomen at least 5 cm away from the navel.
Clean the site with an alcohol swab and allow to dry.



2) Hold the infusion set in your fingers at the guide as shown.
Carefully remove the needle's protective cover and the paper backing from the adhesive dressing.



3) With your other hand pinch the tissue around the insertion site between your thumb and finger. Push the needle firmly into this tissue and secure with the adhesive dressing.
Notice Remove the introducer needle, if you use soft cannula infusion set.



4) Tape the infusion set to the body with adhesive tape 2-5 cm away from the insertion site.

Warning Make sure to prime when you use a new infusion set or remove air from the tubing.











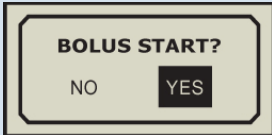



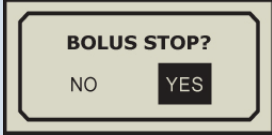



Warning Do not use the infusion set if the package has been damaged, inadvertently opened or wet.

Notice You should not feel pain when you touch the insertion area after the needle has been inserted.
You may feel some pain at the insertion site if the infusion set is not secured well to your body.



Notice Try to avoid any recent insertion sites, scars, scar tissue or bruising.

Step Bolus

Bolus can be used to cover the carbohydrate in a meal or snack and/or to correct a blood glucose that is higher than the target that was chosen for you.

	<p>1) In the MAIN MENU screen press  until BOLUS icon is highlighted. Then press .</p>
	<p>2) The BOLUS MENU screen will appear. Use  to highlight to STEP BOLUS icon and press .</p>
	<p>3) Confirm the amount of insulin to be delivered in the bottom right corner of the STEP BOLUS screen. If the insulin dose is not correct you may make the desired adjustments to the bolus setting by using  and  then press .</p> <p>Notice Remember the adjustment will not change the default bolus setting. It will only change the bolus that you are currently delivering.</p>
	<p>4) Press  to highlight 'YES' then press  to start.</p>
	<p>5) The DELIVERY screen will appear and you will hear the motor run as the bolus is being delivered. 6) The pump will make a beep and return to the INITIAL DISPLAY screen upon conclusion of bolus delivery.</p>
	<p>7) Press  to invoke the cancellation prompt. 8) Use  to highlight 'YES' and press . The Bolus sequence will be cancelled and you will be returned to the INITIAL DISPLAY screen.</p>

Warning You must eat your meal after the meal bolus has been delivered.




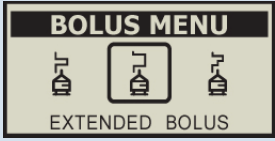


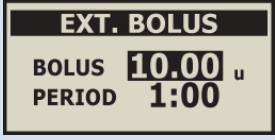




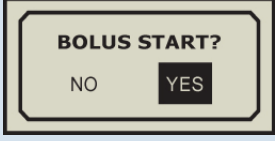


Notice Press  once and the word "BOLUS" (or BREAKFAST, LUNCH, DINNER) will be replaced by "SELECT" a second later. In order to commence the bolus sequence you must press  again while the screen is showing "SELECT".

Notice The Insulin Pump will deliver an audio reminder 2 hours after bolus begins. To stop the alert, push any button once.

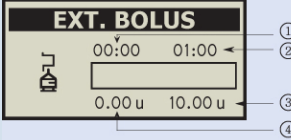
Extended Bolus

Extended Bolus can be used for insulin delivery when you have eaten a long meal with extended snacking. It can also be useful if you have delayed food digestion due to gastro paresis or meal high in fat.

Start Extended Bolus

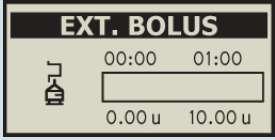

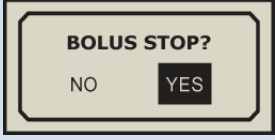


 <p>MAIN MENU BOLUS</p>	<p>1) In the MAIN MENU screen press  until BOLUS icon is highlighted. Then press .</p>
 <p>BOLUS MENU EXTENDED BOLUS</p>	<p>2) The BOLUS MENU screen will appear. Use  to highlight to EXTENDED BOLUS icon and press .</p>
 <p>EXT. BOLUS BOLUS 10.00 u PERIOD 1:00</p>	<p>3) Use  to toggle between Bolus amount and Bolus Period and make the necessary adjustments with  and  then press .</p>
 <p>BOLUS START? NO YES</p>	<p>4) Use  to highlight 'YES' and press  to start.</p>

Review Extended Bolus

 <p>EXT. BOLUS 00:00 01:00 0.00 u 10.00 u</p>	<p>The Extended Bolus Status screen will show how much time has elapsed since the start of the Extended Bolus(①), how much time is left until the completion of the Extended Bolus(②), amount left to be delivered(③) and amount delivered so far (④).</p>
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Caution Infusion occurs on 4 minutes past the hour, 8 minutes past the hour, 12 minutes past the hour, 16 minutes past the hour, and so on, in multiples of 4.

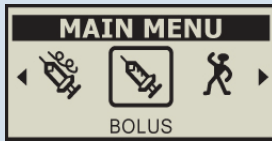
Stop Extended Bolus

 <p>EXT. BOLUS 00:00 01:00 0.00 u 10.00 u</p>	<p>1) Press  to invoke the cancellation prompt.</p>
 <p>BOLUS STOP? NO YES</p>	<p>2) Use  to highlight 'YES' and press . The current Extended Bolus sequence will be cancelled and you will be returned to the MAIN MENU screen.</p>

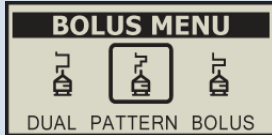
Caution Extended Bolus delivery is recorded in the bolus history. The time stamp of the entry corresponds to the date and time of Extended Bolus conclusion.

Dual Pattern Bolus

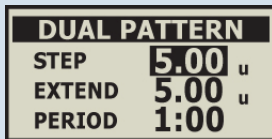
Dual Pattern bolus delivers a combination of an immediate step bolus followed by an extended bolus. A Dual Pattern bolus is useful for meals with both rapidly and slowly absorbed carbohydrates.



1) In the MAIN MENU screen press until BOLUS icon is highlighted. Then press .



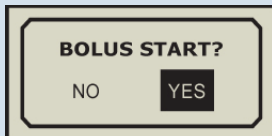
2) The BOLUS MENU screen will appear. Use to highlight to DUAL PATTERN BOLUS icon and press .



3) Use to toggle between Step Bolus and Extend Bolus and Bolus Period and make the necessary adjustments with and than press .

Notice If you want to deliver a certain amount of Bolus immediately then use the STEP BOLUS function.

If you want to a certain amount of Bolus over a period of time, then use the Extended Bolus function.



4) Use to highlight 'YES' then press to start.

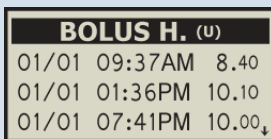
Notice The time may be adjusted in 30 minute increments within the range of 30 minutes - 8 hours.

Review

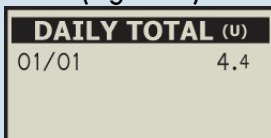
You can review the details for memory data History.



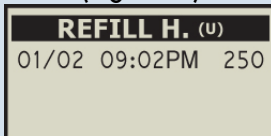
1) In the MAIN MENU screen press until REVIEW icon is highlighted. Then press .



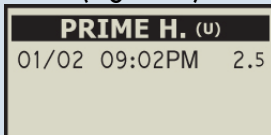
(figure 1)



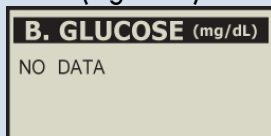
(figure 2)



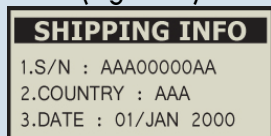
(figure 3)



(figure 4)



(figure 5)



(figure 6)

Use and to review the History. Press to move next menu.

- Bolus History: Date, time and amount of past bolus deliveries (figure 1).

- Daily Total History: Total bolus and basal delivery amount for each day (figure 2).

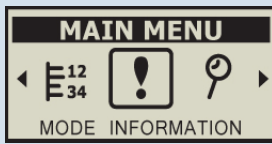
- Refill History: Refill insulin rate in the reservoir (figure 3).

- Prime History: Date and time of past primes (figure 4).

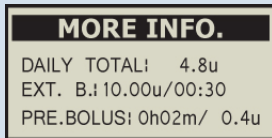
- Blood Glucose History: Reviewing the history of date, time and glucose level (figure 5).

- Shipping Info: Product information (figure 6).

More Information



1) In the MAIN MENU screen press  until MORE INFORMATION icon is highlighted. Then press .

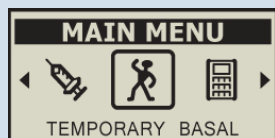


DAILY TOTAL : Total amount of insulin infused since midnight
EXT.B : Extended bolus status
PRE.BOLUS : Previous bolus

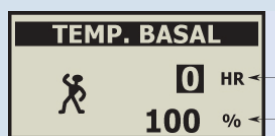
Temporary Basal

The temporary basal rate feature is useful to manage blood glucose levels during unusual short-term activities or conditions.

Start Temporary Basal



1) In the MAIN MENU screen press until TEMPORARY BASAL icon is highlighted. Then press .



2) Use to toggle between the number of hours and basal rate and make the necessary adjustments with and .

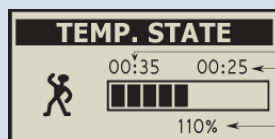
① This number indicates the number of hours during which the temporary basal rate will remain in effect.

② This number indicates the desired increase/decrease in basal delivery as a percentage of the regular basal rate.

Notice For instance, a temporary basal rate of “50%” for “1 hour” will change the basal rate to half of your regular basal rate for the next hour.

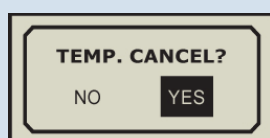
Notice Temporary basal rate will not take effect if you press while either the number of hours is set at “0”, or the rate is set at “100%”.

Review Temporary Basal



- ① Time elapsed
- ② Time remaining
- ③ Temporary basal rate

Stop Temporary Basal



1) To cancel a temporary basal rate currently in effect, press and a cancellation prompt will appear screen.

2) Press to highlight ‘YES’, then press if you would like to cancel temporary basal. The temporary basal rate in effect will be cancelled and you will be returned to the MAIN MENU screen.

Caution Please consult your healthcare professional about the temporary basal feature.

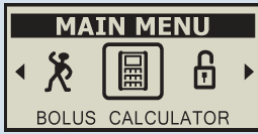
Notice Highlight ‘NO’ and press at the cancellation prompt to return to the MAIN MENU screen without cancelling temporary basal.

Notice Adjust the rate to ‘100%’ and time to ‘0 hours’ if you wish to return to your regular basal rate.

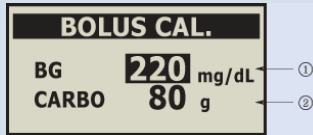
Notice The ratio may be adjusted between 0- 200% in increments of 10% for up to 12 hours.

Bolus Calculator

This feature can calculate an estimate of insulin you need for your correction bolus and/or your food bolus.



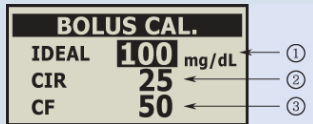
1) In the MAIN MENU screen press until BOLUS CALCULATOR icon is highlighted. Then press .



2) In the BOLUS CALCULATOR screen, Use to move the cursor on CARBO to adjust the amount of Carbohydrate with the use of or button. Then press .

① Displays current blood glucose level.

② Indicates the carbohydrate(g) to be consumed after bolus delivery.

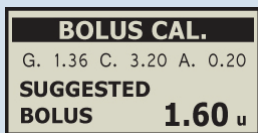


3) Use to move between “Ideal Blood Glucose”, “ CIR”, and ‘CF’, and use and to make the necessary adjustments. Then press .

① IDEAL: Indicates your target blood glucose level.

② CIR: Amount of carbohydrates capable of being processed by 1u (unit) of insulin. (Carbohydrate/insulin ratio)

③ CF: Indicates Correction factor.

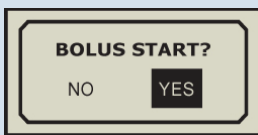


4) You can increase or decrease the suggested bolus amount by the using of or buttons what calculated through the bolus calculator. Press to take a bolus the suggested amount.

G: Indicates the amount of insulin required according to your present blood glucose level.

C: Indicates the amount of insulin required to process the amount of carbohydrates specified.

A: Indicates the amount of insulin remaining in your body you're your previous bolus amount. (Active insulin).

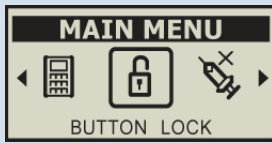


5) Press to highlight ‘YES’ then to start.

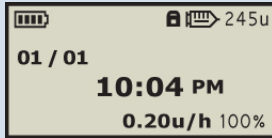
Notice You will hear the pump beep for every 1.0 unit while a bolus is being delivered. (You can choose beep to ON or OFF in the USER option)

Button Lock

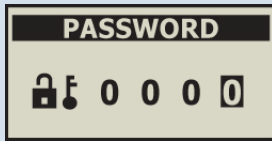
Button lock prevents accidental pump keypad presses.



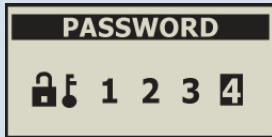
1) In the MAIN MENU screen press until BUTTON LOCK icon is highlighted. Then press .



2) If the lock out feature is on, the following screen will appear.



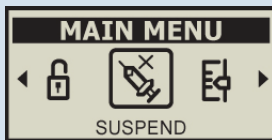
3) To unlock the pump, push any button PASSWORD screen will appear.



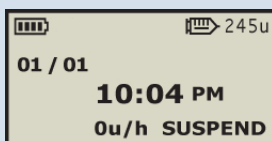
4) Enter 1, 2, 3, 4 by using the arrow and key.
5) The pump will return to the INITIAL DISPLAY.

Suspend

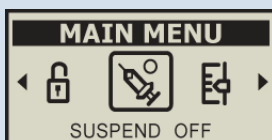
You can stop your pump with the suspend function. Suspend stops all insulin delivery including the current basal and any bolus or prime deliveries that are in progress. While in suspend, your pump will not deliver insulin until you release your pump from suspend mode.



1) In the MAIN MENU screen press until SUSPEND icon is highlighted. Then press .



2) The pump will give an audible tone and the screen will indicate the pump is suspended.







3) To release the pump from Suspend, in the INITIAL DISPLAY screen press until SUSPEND OFF icon is highlighted and then press . You will hear an audible indicator and the INITIAL DISPLAY will appear.

Caution Always keep at least one power kit (2 batteries) available for backup.



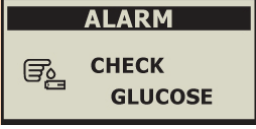
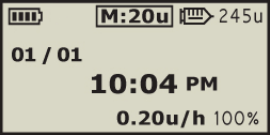

Notice When you suspend the pump it will beep 3 times every 4 minutes to remind you insulin is not being delivered.

Chapter 7. Alarms and Error Messages

Alarms and Error Message for Insulin Pump

SCREEN	PROBLEM	WHAT TO DO
 <p>WARNING LOW BATTERY</p>	The low battery screen will appear when the remaining battery charge is no longer sufficient for the pump to operate.	Please change the battery. Notice A continuous alarm will be activated with both sound and vibration.
 <p>WARNING LOW RESERVOIR</p>	The low reservoir screen will appear when there are approximately 20 units remaining. The pump will alarm every 30 seconds.	Make a visual confirmation of remaining insulin through the reservoir cavity window on the side of pump. After confirming the reservoir is low, insert a new reservoir filled with insulin. Warning For safety we recommend that you change the reservoir when there are 10 to 15 units of insulin remaining.
 <p>WARNING OCCLUSION</p>	This warning occurs if your pump detects a occlusion.	Suspend the pump, remove the infusion set and check your blood sugar, then check the reservoir amount. If less than 10 to 15 units of insulin remain in the reservoir, replace it. If this does not correct the error, check for occlusion of the infusion set. Visually check for any possible occlusion of the infusion set and take corrective measures (un-kink tubing, check for air bubbles, etc). If this does not resolve the problem change both the reservoir and infusion set. Warning If WARNING screen persists, contact technical support.
 <p>WARNING SHUTDOWN</p>	The pump will automatically shutdown with an alarm sound if any of the buttons on the pump Pump is pressed for the period that you had set (see page 13).	-

Chapter 7. Alarms and Error Messages

SCREEN	PROBLEM	WHAT TO DO
 <p>The screen displays the word "ERROR" in a black box at the top. Below it is a warning triangle icon and the text "CHECK ERROR".</p>	<p>This alarm occurs if your pump detects a check error.</p>	<p>If ERROR screen persists, contact technical support.</p>
 <p>The screen displays the word "ERROR" in a black box at the top. Below it is a warning triangle icon and the text "SYSTEM ERROR".</p>	<p>This alarm occurs if your pump detects a system error.</p>	<p>If ERROR screen persists, contact technical support.</p>
 <p>The screen displays the word "ALARM" in a black box at the top. Below it is a hand icon and the text "CHECK GLUCOSE".</p>	<p>Time to check your blood glucose level.</p>	<p>Notice A melody will play for 30 seconds.</p>
 <p>The screen shows a battery icon, "M:20u", and "245u" at the top. Below that is "01 / 01", "10:04 PM", and "0.20u/h 100%".</p>	<p>The daily remainder will appear if the amount different between Daily max and Daily infusion is less than 20u. For instance if the daily max is set to 100 units and the total infusion amount for one day exceeds 80 units the remainder will appear on the screen.</p>	<p>Contact your health care professional.</p>
 <p>The screen displays the word "ALARM" in a black box at the top. Below it is a warning triangle icon and the text "SUSPEND".</p>	<p>When you choose any of menus related to the injection like as bolus and basal while the pump and remote controller were suspend Mode.</p>	<p>You have to turn off the suspend mode to take a bolus.</p>

Chapter 8. Troubleshooting

When hypoglycemia (low blood sugar) occurs

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 main symptoms of hypoglycemia

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

What to do in case of hypoglycemia

- 1) Place the pump in SUSPEND mode.
- 2) Check your blood sugar level.
- 3) If the blood sugar level turns out to be low, treat with carbohydrates in accordance with the instructions of your diabetes professional.
- 4) Check your blood sugar level again in 15-20 minutes. If it returns to normal, no immediate action is needed and you may take the pump out of SUSPEND.
- 5) If not, refer to step 2 and retest in 15 minutes.
- 6) If hypoglycemia appears prior to a meal, consider a bolus while you consume your meal and not before.

Notice If hypoglycemia does not resolve contact your health care professional.

Troubleshooting for hypoglycemia

POSSIBLE CAUSE	SUGGESTED RESPONSE
Increased physical activity	Consult with your healthcare professional to make adjustments for increased physical activity. You may choose to use or modify temporary basal rates or decrease meal boluses prior to activity.
Eating less	Consult with your healthcare professional to adjust basal rates or meal boluses to more accurately reflect your current intake.
Alcohol consumption	Please refrain from consuming alcohol.
User error or Programming error	Check and review your bolus history and basal rates. Check with your healthcare professional to make sure your bolus is properly calculated as well as your basal rates.
Incorrect settings	Check your blood sugar regularly and check with your healthcare professional to make sure that your bolus is properly calculated as well as your basal rates.

When Hyperglycemia (high blood sugar) occurs

What is hyperglycemia (high blood sugar)?

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

- Nausea
- Vomiting
- Increased drowsiness
- Difficulty breathing
- Dehydration
- Abdominal pain

What to do in case of high blood sugar

- 1) Check your blood sugar level.
- 2) Check your pump for any problems.
- 3) If your blood sugar remains high, treat as prescribed by your healthcare professional and /or contact your healthcare professional immediately.

Troubleshooting for hyperglycemia

POSSIBLE CAUSE	SUGGESTED RESPONSE
Empty reservoir	Visually check display screen for remaining insulin and also visually check reservoir in pump. Replace reservoir immediately.
Insulin leakage at infusion site, disconnection at the site or connection to pump	Examine infusion site to make sure that there is no leakage. Also examine the connection of the infusion set to the pump and the infusion set connector.
Pinched or obstructed infusion set	Change the infusion set.
Programming or user error	Check to see if the pump is in SUSPEND or if there is enough insulin in the reservoir. Check your bolus/basal settings, history, and time. Check the remaining battery charge and replace if necessary.
Incorrect settings	Check your blood sugar regularly and check with your healthcare professional to make sure that your bolus is properly calculated as well as your basal rates.

Notice Possible cause could be a high blood sugar level due to improper result/test strip. Suggested response should be re-testing the blood sugar level with a new test strip.

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 usually 1 or 2 months, but varies among users. Some batteries are known to still show a full charge after two months even though they are low on charge. To avoid any battery mishaps we recommend that you change the battery every two months or whenever there is a display problem with your screen.
Cannot change bolus/basal settings	Contact technical support.
Pump does not function following CT or MRI scan	Contact technical support.
Pump will not prime	Contact technical support. Notice The DANA Diabecare® IIS insulin pump will allow 2 prime sequences every 12 hours (0:00 - 12:00, 12:00 - 24:00).

Warning In case of device malfunction, stop using the pump immediately and contact technical support.

Chapter 9. Specification

SPEC	INSULIN PUMP
Size Net Weight Insulin Reservoir	77×45×20mm(3.1×1.8×0.8in) 62.2g (including battery) 3mL(300 Units), Insulin compatible reservoir
Meal Bolus Setting Basal Rate Setting Basal Profile	0-80u 0-16.0 u/h 24 Settings
Motor Bolus Duration for 1 Unit Power Supply	Swiss Micro DC motor 12 seconds 3.6V DC
Energy Saver Basal Delivery Increments	Sleep Mode, Screen Saver 4 minute intervals
Basal & Bolus Insulin Delivery accuracy	±4%

Classification and compliance with standards

- The DANA Diabecare® IIS is classified as an internal powered equipment BF type under the standard of IEC 60601 (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 pump will continuously operate according to the user defined settings.











Summary of EMI emission test results

Application	Test method	Test result
Conducted emission	EN 55011:2007, Class B	N/A
Radiated emission – DC 3.6V	EN 55011:2007, Class B	Complied
Harmonics	EN 61000-3-2:2006	N/A
Flicker	EN 6100-3-3/A2:2005	N/A

Summary of immunity test results

Items	Application	Test method	Test result
Electrostatic discharge	Enclosure	EN 61000-4-2:1955+A1+1988+A2:2001	Complied
Radiated RF immunity	Enclosure	EN 61000-4-3:2006	Complied
Fast transient	DC 3.6 V	EN 61000-4-4:2004	Complied
Surge	DC 3.6 V	EN 61000-4-5:1995+A1:2001	N/A
Conducted RF immunity	DC 3.6 V	EN 61000-4-6:1995+A1:2001	N/A
Magnetic field immunity	Enclosure	EN 61000-4-8:1993+A1:2001	Complied
Voltage dip/interruption	DC 3.6 V	EN 61000-4-11:2004	N/A

Universal Symbols

SYMBOL	DEFINITION
	Read instructions for use.
	Manufacture data
	Lot number
	Expiration date (Use by date)
	CE Marking
	Do not re- Use
	Adhesive plaster
	Serial number
	Isolated patient connection
	Tubing length (43inch, 27inch/ 1100mm, 700mm)

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WARRANTY

SOOIL Development Company Limited warrants that the DANA Diabecare® insulin pump 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 pump 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 pump and remote control unit will be repaired or replaced at SOOIL's option without charge to the purchaser. Freight and other charges, where applicable, incurred in shipping a pump for repair date is covered under this warranty. The warranty period shall not be extended from the original purchase.

This limited warranty is valid only if the DANA Diabecare® insulin pump 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 pump and remote control unit 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 pump by the user or any other person including but not limited to physical abuse of the product such as dropping or otherwise damaging the DANA Diabecare® insulin pump.
- Failure to follow the manufacturer's instructions, including those for storage, transport or cleaning for the DANA Diabecare® insulin pump.
- This warranty does not cover batteries, infusion sets, cartridges or other accessories of the DANA Diabecare® insulin pump.

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 insulin pump.

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