

DANA DIABECARE IISR



SOOIL

DANADIABECARE®

Thank you for choosing the DANA Diabecare IISR Insulin Pump.

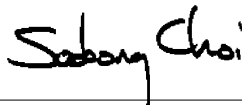
SOOIL Development Co., Ltd. has been committed to making scientific advancements in the development and production of innovative medical solutions for the management, treatment and cure of diabetes throughout the world since 1979. Your DANA Diabecare IISR has been designed and built with the most advanced technology available to create a high quality and very reliable device for the subcutaneous delivery of insulin. When used properly, your DANA Diabecare IISR will give you years of improved blood glucose control while enhancing your quality of life.

The welfare of the patient has been the cornerstone of our company's philosophy since 1979 when Dr. Soo - Bong Choi and his father, Dr. Hyun Choi, designed their first insulin pump for patients in their diabetes center. There are now more than 50,000 people throughout the world managing their diabetes with the DANA Diabecare line of insulin infusion pumps.

The DANA Diabecare IISR Insulin Pump is the only pump that adds simplicity to the complex technology of the device.

We welcome your comments and look forward to being key members of your diabetes team.

SOOIL Development Co., Ltd.



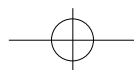
Soo - Bong Choi, M.D., Ph.D.
CEO
SOOIL Development Co., Ltd.

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

DANA DIABECARE IISR



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DANA DIABECARE IISR

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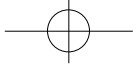
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1. Before using your DANA Diabecare IISR Insulin Pump, infusion set and reservoir

Indications for Use

The DANA Diabecare IISR insulin pump, infusion set and reservoir are intended for the continuous delivery of insulin for the management of diabetes mellitus. It is not intended for the delivery of blood or blood products.

Safety Precautions

1. Patients must not open the pump housing or handle any internal components.
2. The DANA Diabecare IISR 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.
3. If you experience any trouble with the pump, switch the pump off immediately and contact your healthcare provider or your sales representative.
4. Use the pad of your finger to press the buttons. DO NOT use your fingernails or any sharp objects to press the buttons.
5. Avoid the following conditions for safe storage and transport of the DANA Diabecare IISR:
 - 1) Temperatures below -0.5 °C or above 40 °C.
 - 2) Atmospheric pressure below 500mmHg or above 1060mmHg.
 - 3) Humidity above 95%.
 - 4) Exposure to excessive dust or a salty environment.
 - 5) Exposure to explosive gas.
 - 6) Exposure to direct sunlight.
 - 7) Environments where an electromagnetic field is generated by a medical device.
6. 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.
7. 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.
8. Remove the battery for long-term storage.
9. The reservoir and infusion set are intended for single use only. Do not reuse either the reservoir or infusion set.
10. Change the reservoir and the infusion set regularly, as recommended by your healthcare professional. Do not use either for longer than 72 hours.
11. The shelf life of the reservoir and the infusion set is 3 years. Please check the expiration dates regularly and dispose of any expired accessories.

1. Before using your DANA Diabecare IISR insulin pump, infusion set and reservoir

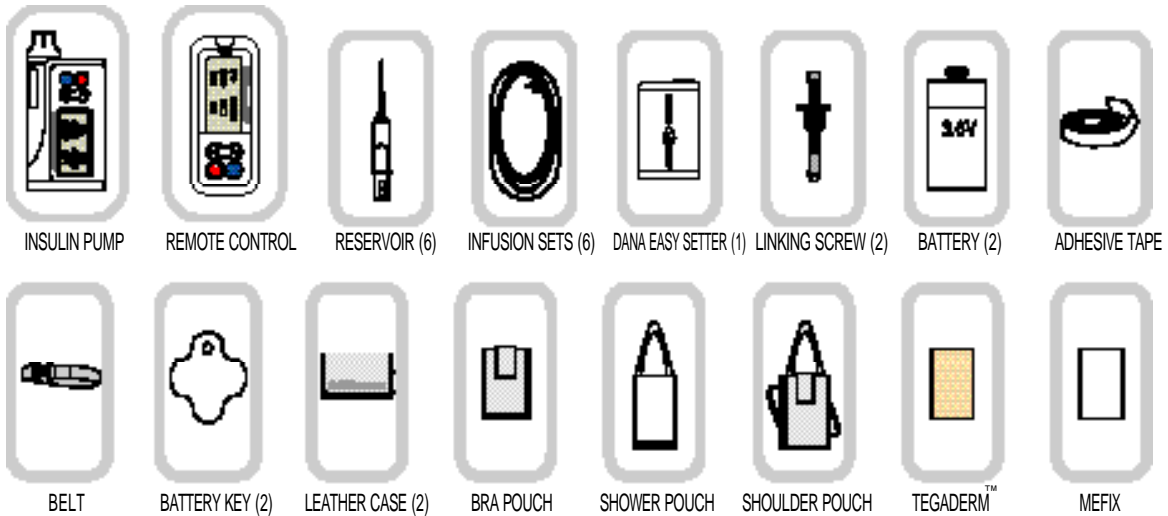
Cleaning your DANA Diabecare IISR insulin pump

1. The outside of the pump should be cleaned monthly.
2. When cleaning the pump, use a cloth moistened with water or a neutral pH detergent and wipe it with a dry cloth.
3. Do not use thinner, alcohol, benzene or similar solvents.

Explanation of "Warning", "Caution", and "Note" Symbols

1. **Warning** indicates the presence of a hazard which can cause severe personal injury, death or substantial property damage if the warning is ignored.
2. **Caution** Caution indicates the presence of a hazard which will or can cause minor personal injury or property damage if the warning is ignored.
3. **Note** Note advises the user of installation, operation or maintenance information which is important but not hazard-related.

Contents of the Dana Diabecare IISR Insulin Pump Kit

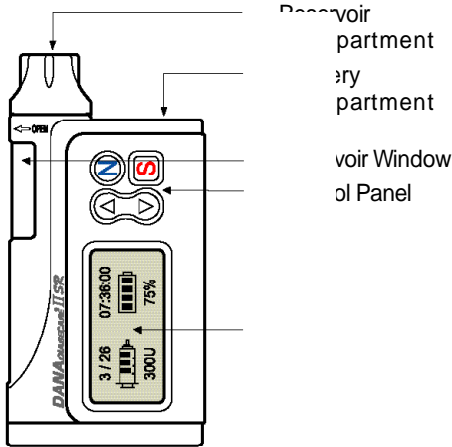


Note Additional accessories may be purchased separately

Note MEFIX is not available in Canada

Identification and Description of the DANA IISR

The DANA Diabecare IISR insulin pump, infusion set and reservoir are intended for the continuous delivery of insulin for the management of diabetes mellitus. It is not intended for the delivery of blood or blood products.



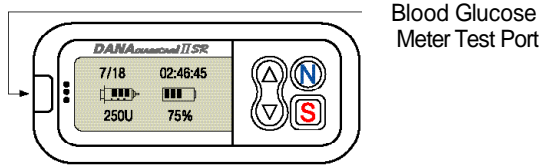
Reservoir Compartment: The reservoir and linking screw are inserted in this compartment. Turn cap clockwise to open.

Battery Compartment: The battery is inserted in this compartment. Turn cap counterclockwise to open.

Reservoir Window: Remaining insulin amount can be visually verified here.

Control Panel: Contains the four buttons which are used to increase and decrease settings, switch screens and select functions.

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.



Blood Glucose Meter Test Port: Test strips are inserted here for glucose monitoring.

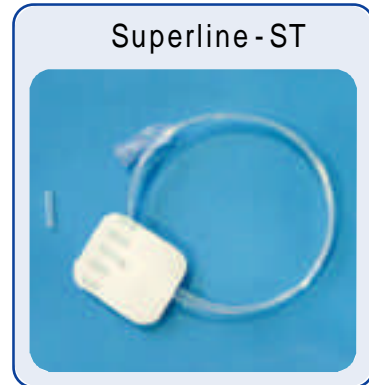
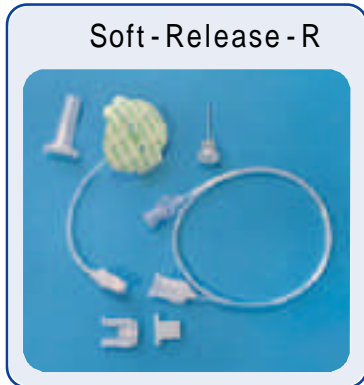
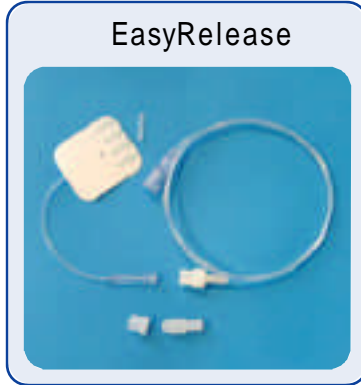
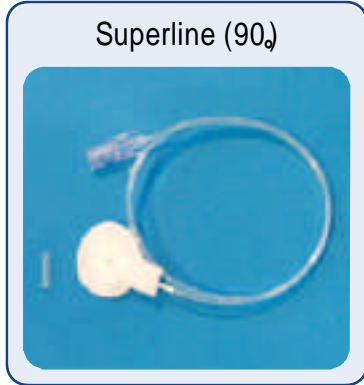
Battery Compartment: Push the cover of the battery to the arrow direction to open.

- ▲ Press to increase insulin dosages, time and date.
- ▼ Press to decrease insulin dosages, time and date.
- N Press to move to the next choice on the LCD.
- S Press to select the function highlighted on the LCD.

Note Buttons will beep when pressed.

1. Before using your DANA Diabecare IISR insulin pump, infusion set and reservoir

Infusion Sets



Note Product availability varies by country.

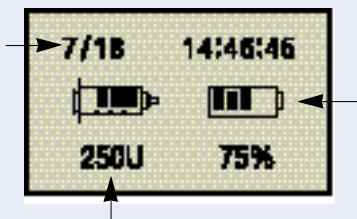
Note Infusion set specifications are as follows

	Superline (90)	EasyRelease	EasyReleasell	Soft - Release - R	Soft - Release - ST	Superline - ST
Needle gauge	27G	27G	27G	26G	26G	27G
Needle type	Stainless Steel	Stainless Steel	Stainless Steel	Polyurethane(Soft cannula)	Polyurethane(Soft cannula)	Stainless Steel
Insertion angle	90°	90°	90°	90°	0~30°	90°
Disconnect	No	Yes	Yes	Yes	Yes	No

2. Set - up and basic functions

Explanation of the display screens

Initial Display



Displays current time and date.

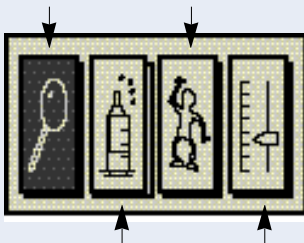
Displays remaining battery charge as 100%, 75%, 50%, 25%.

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

Displays the amount of insulin remaining in the reservoir in units. (1ml=100 units).

Note Push any button while viewing the initial display to bring up the basic display screen.

Basic Display



CHECK/REVIEW icon - Choose the first icon (magnifying glass) to check basal rates, previous bolus doses, last bolus, previous daily totals and prime history (see page 15 for reviewing the history).

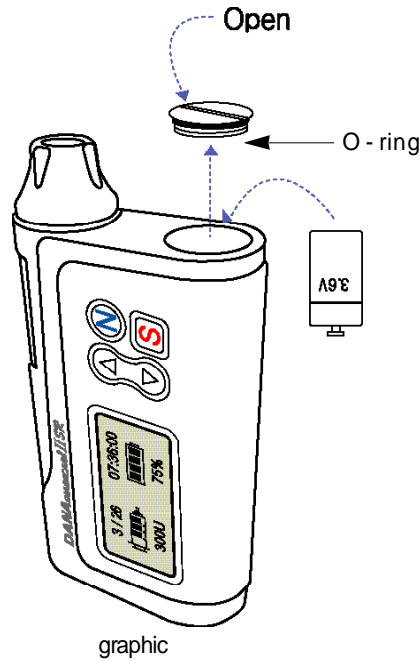
BOLUS icon - Choose the second icon (syringe) to deliver bolus doses.

TEMPORARY BASAL icon - Choose the third icon (person) for temporary changes in basal rates for exercising or other events.

SET/PROGRAM icon - Choose the fourth icon (sliding scale) to set basal rates, preset bolus doses and set clock.

Note The DANA Diabecare IISR LCD screen will automatically go blank after one minute to conserve battery power. Any button press will also activate the backlight for 10 seconds.

Inserting the Battery



Follow these steps

- 1) Open the battery compartment by inserting the battery key into the battery cap and turning counterclockwise.
- 2) Insert the battery with the positive end down into the pump.
- 3) Close the battery cap by turning the battery key clockwise until tight and flush with pump.

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

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

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

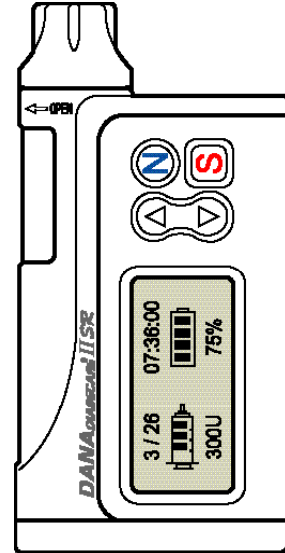
Warning Use of battery other than the 3.6V battery manufactured exclusively for SOOIL Development will result in the void of pump warranty.

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

Note The battery has a shelf life of 3 years. Please note 'best before date (xx/xxx)' before use

Setting bolus doses, basal rates and the clock

1) From the INITIAL DISPLAY screen, press any of the control buttons and the BASIC DISPLAY screen will appear.



2) In the BASIC DISPLAY screen, press **N** three times consecutively to highlight the **SET/PROGRAM** icon in figure 1.

Then press **S**.



(figure 1)

3) The SET/PROGRAM screen in figure 2 will appear. You can select

bolus or **basal** rate or **clock**.



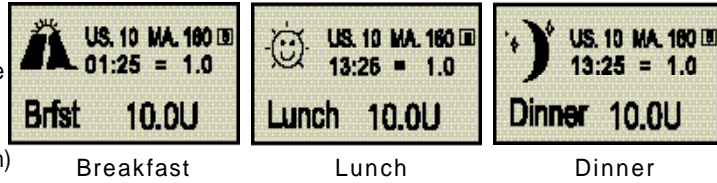
(figure 2)

Setting a Bolus

1. Pre - Setting Meal Boluses

If you pre - set meal boluses, the following time periods correlate to the following schedule:

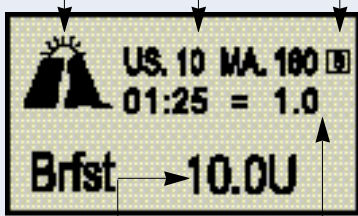
- Breakfast = 1:00 - 9:59 (1:00 am - 9:59 am)
- Lunch = 10:00 - 14:59 (10:00 am - 2:59 pm)
- Dinner = 15:00 - 00:59 (3:00 pm - 0:59 am)



- 1) From the BASIC DISPLAY screen, go to the SET/PROGRAM screen. In SET/PROGRAM press **S** when the **BOLUS** highlighted (figure 1). The bolus setting screen will appear as shown in figure 2.



(figure 1)



(figure 2)

Indicates that you are setting a bolus for Breakfast (Brfst), Lunch or Dinner.

US indicates the amount of insulin used since midnight. MA indicates the maximum amount of insulin allowed daily.

Time and amount of the previous bolus.

Amount of current bolus.

s indicates set mode.

- 2) While in the BREAKFAST BOLUS SETTING screen, select the proper insulin dose by using **▲** and **▼**. The insulin dose appears in units in the bottom right hand corner.

- 3) Press **N** to go to the LUNCH BOLUS screen and repeat step 2. Press **N** to advance to the DINNER BOLUS screen and repeat the step 2.

- 4) After setting all of your meal boluses press **S** to store the meal the meal bolus settings in the DANA memory.

Note Make sure to press **S** after the bolus dose is set to save the setting.

Note You may confirm your bolus settings by using the **CHECK/REVIEW** menu option (see page 15).

Note The settings are the amount of insulin that you will deliver each time you bolus during the time periods indicated above.

Note You may increase or decrease your bolus prior to delivery, but the preset bolus dose setting will not change unless you change it in the **SET/PROGRAM** screen.

2. Setting a Bolus

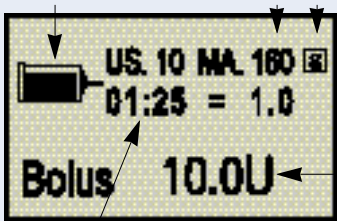
1) From the BASIC DISPLAY screen, go to the SET/PROGRAM screen.

In SET/PROGRAM press  when bolus icon is highlighted

(figure 1). The bolus setting screen will appear as shown in figure 2.



(figure 1)



(figure 2)



Indicates that you are setting a bolus.

US indicates the amount of insulin used since midnight. MA indicates the maximum amount of insulin allowed daily.


Time and amount refers to the previous bolus.

Amount of the bolus.

s indicates set mode.

2) While in the BOLUS SETTING screen select the proper insulin dose by using  and . The insulin dose appears in units in the bottom right hand corner.

3) After setting your bolus press  to store the preset meal bolus.

Note Make sure to press  after the bolus dose is set to save the setting.

Note You may confirm your bolus settings by using the **CHECK/REVIEW** menu option (see page 15).

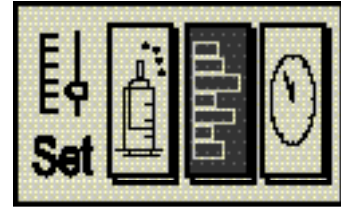
Note This setting is the amount of insulin that the pump will deliver the next time you bolus.

Note You may increase or decrease your bolus prior to delivery but the default bolus setting will not change unless you change it in the **SET/PROGRAM** screen.

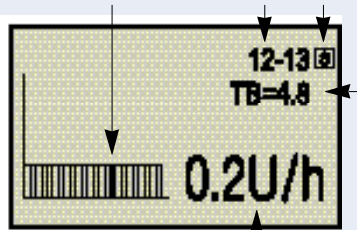
Note Please talk to your health care professional if you wish to preset your meal boluses.

Setting and Adjusting Basal Rates

1) From the BASIC DISPLAY screen, go to the SET/PROGRAM screen. Press **S** when the **BASAL** icon is highlighted (figure 1) in the SET/PROGRAM screen. The BASAL RATE SETTING screen will appear as in figure 2.



(figure 1)



(figure 2)

Basal Profile, which shows basal rates in a graph from midnight to midnight.

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

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

Basal Rate for the time period shown in .
s indicates set mode.

Note Basal rates can be adjusted in units per hour.

Note Figure 2 shows a basal profile that has been set in units per hour(u/h).



2) The Basal Profile appears in the lower left side of the screen. Use **N** 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.

3) After basal rates are set, press **S** to save the settings in the DANA memory.

Note You may confirm your basal settings by using the **CHECK/REVIEW** menu option (see page 15).




Setting the Clock

1) From the BASIC DISPLAY, go to the SET/PROGRAM screen. Press

 to highlight the CLOCK icon and press  (figure 1). The CLOCK SETTING screen will appear as shown in figure 2.





(figure 1)

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



(figure 2)

3) After making the changes press  to save the setting and return to the BASIC DISPLAY 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.

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

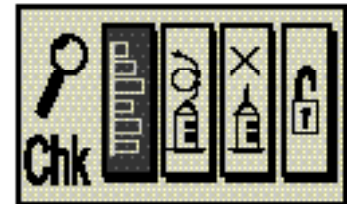
Checking Bolus Doses, Basal Rates and Reviewing Memory Data

1) In the BASIC DISPLAY screen press **N** until the CHECK/REVIEW icon is highlighted as in figure 1. Then press **S**.



(figure 1)

2) The Review icon will be highlighted as in figure 2 (if not, press **N** to change the highlighted icon). Then press **S**.



(figure 2)

Note The **CHK** icon is used for reviewing both basal rates and bolus settings.

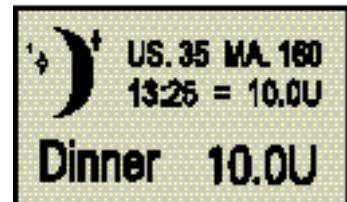
3) The BASAL PROFILE screen (figure 3) will appear. Press **N** to move between basal profiles and confirm settings. To review the previous meal bolus press **S**.



(figure 3)




Note ^c indicates check mode.

4) The MEAL BOLUS screen (figure 4) will appear. Press **N** to move from one meal period to the next. Press **S** to review the history of the previous 500 boluses.






(figure 4)

Note If your bolus and basal dose rate settings are incorrect please return to the BASIC DISPLAY and choose the SET/PROGRAM icon to make adjustments.

5) Use  and  to review the Bolus History including date, time and amount delivered (figure 5). Press  to review the 500 previous Daily Totals.




BOLUS HISTORY		
1: 1/4	13:00	4.5
2: 1/4	07:30	5.0

(figure 5)

6) Use  and  to review the Daily Total History including date and the total amount of insulin (figure 6). Press  to review the 500 previous Prime Amounts.




DAILY TOTAL HIST.	
1: 1/4	15.0U
2: 1/3	14.0U

(figure 6)

7) Use  and  to review the Prime History including date and amount (figure 7). Press  to review the 500 previous Carbohydrate amount.

PRIME HISTORY		
1: 1/4	10:00	235
2: 1/1	20:30	225

(figure 7)

8) Use  and  to review the Carbo History including date and amount (figure 8). Press  to review the Shipping info screen.

CARBO HISTORY		
1: 9/24	14:59	80
2: 9/13	12:09	72

(figure 8)

9) In the Shipping Info (figure 9) press  to return to the basic display.

SHIPPING INFO	
1. S/N	: AGJ00019GF
2. COUNTRY	: KOR
3. DATE	: 12/SEP, 2006

(figure 9)

- Note**
- Bolus History: Date, time and amount of past bolus deliveries.
 - Daily Total History: Total bolus and basal delivery amount for each day.
 - Prime History: Date and time of past primes, including the amount of insulin left in the reservoir following each prime.

Suspending the pump

1) In the BASIC DISPLAY screen press **N** to highlight the **CHECK/REVIEW** icon. Then press **S**.



(figure 1)

2) Press **N** to highlight the **SUSPEND** icon (figure 2). Then press **S**.

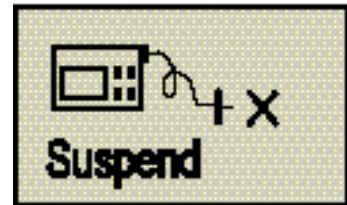


(figure 2)

3) The pump will give an audible tone and the screen will indicate the pump is suspended (figure 3).

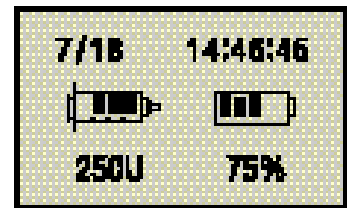
Note When you suspend the pump it will beep 3 times every 4 minutes to remind you insulin is not being delivered.

4) To take the pump out of SUSPEND, press **S**. You will hear an audible indicator and the BASIC DISPLAY will appear as shown in figure 4.



(figure 3)

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



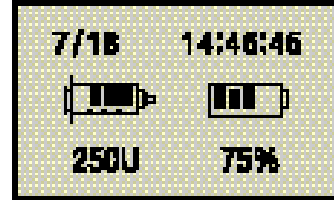
(figure 4)

User Setting

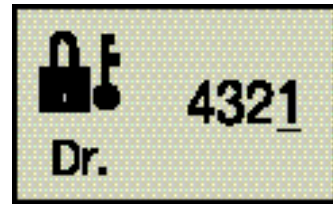
1) Press the three buttons (N + ▲ + ▼) at once to enter the PIN code screen for USER SETTING from the initial screen.

2) Input the PIN code '4321' by the use of ▲ and N buttons.

3) You can enter the USER SETTING mode by pressing S button once the PIN code is inputted.



(figure 1)



(figure 2)

Setting

1) Use ▲ or ▼ to modify settings. Use N to advance to the next settings.

USER SETTING	
1. HOUR DISPLAY TYPE	: 12
2. LOCK	: On
3. BUTTON SCROLL	: On
4. SOUND MODE	: RV
5. DISPLAY SET	
6. EXTENDED MENU	
7. STRIP CHECK	8. EXIT

(figure 1)

HOUR DISPLAY TYPE
- You can adjust time display as 12 hour or 24 hour format.

LOCK
- You can choose whether or not to utilize the key pad lock out function.
- How to unlock(see page 19)

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

SOUND MODE
- You can choose the method of alert among sound.

DISPLAY SET(see page 19)





EXTENDED MENU(see page 19)

STRIP CHECK (see page 20)

EXIT
- Saves adjustment and returns to the previous level.

Note How to unlock

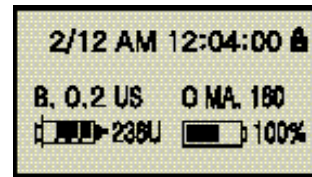
If the lock out feature is on, the following screen will appear.(figure 1)

To unlock the pump, in the exact order press  ,  .

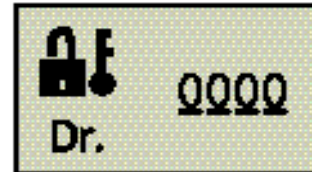
The following screen will appear(figure 2).

Enter 1, 2, 3, 4 by using the up arrow and next key.

The pump will return to the basic display.



(figure 1)



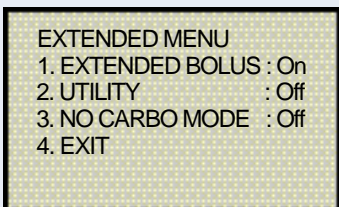
(figure 2)



(figure 3)

DISPLAY SET

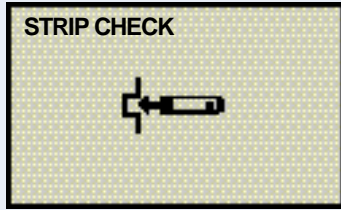
1. LCD on time
 - Adjust the duration of the LCD display by seconds.
2. EL on time
 - Adjust the duration of the Backlight by seconds.
3. Language
 - You can choose a language.
4. EXIT
 - Saves adjustment and returns to the previous level.



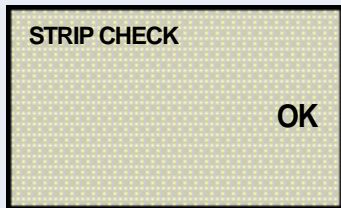
(figure 4)

EXTENDED MENU

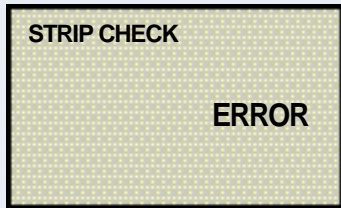
1. EXTENDED BOLUS
 - Choose whether or not to utilize the Extended Bolus function.
2. UTILITY
 - Choose whether or not to utilize the Utility function.
3. NO CARBO MODE
 - If the "NO CARBO MODE" was selected as "Off", a pop - up window will display to perform the carbohydrate counting function, once you checked your BG level by the DANA IISG pump. If the "NO CARBO MODE" was selected as "On", the pop - up window will not be activated after the checking BG level.
4. EXIT
 - Saves adjustment and returns to the previous level.



(figure 1)



(figure 2)



(figure 3)

STRIP CHECK

- This is the menu for check whether or not the glucose meter of DANA Diabecare IISG operates normally.

1. Insert the " Check Strip "into the Glucose Meter Port when the " Strip Check" displays (figure 1).
2. In case " OK " displayed, the meter is normal (figure 2).
3. In case " ERROR" displayed, the meter is abnormal (figure 3).

3. Filling and inserting a new reservoir

Changing the reservoir

Caution The reservoir must be changed every 3 days, regardless of the amount left in the reservoir.

Caution The reservoir must be changed when there is less than 20u remaining.

Caution Always remember to change the reservoir and infusion set at the same time.

Warning Use only fast acting insulin in your pump.

Preparation

1) Retrieve the insulin vial from the refrigerator and let it warm up to room temperature for 15 - 30 minutes.

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

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 Diabecare IISR Insulin Pump, fast acting insulin, reservoir, infusion set, DANA Easy SETTER, linking screw, alcohol swab, etc.

5) Wash your hands.

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 (figure 1). 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.



(figure 1)

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



(figure 2)

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 (figure 3).



(figure 3)

Note 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 syringe into the vial. Draw out the desired amount of insulin.

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

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 syringe. Gently push on the plunger to remove the bubbles at the top (figure 4).



(figure 4)

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



(figure 5)

Instructions for use of DANA Easy SETTER

1) Insert a battery into Easy SETTER as instructed below:

- Open the battery compartment.
- Insert a battery positive side up.
- Close battery compartment.

Note The DANA Easy SETTER operates with the SOOIL 3.6V battery

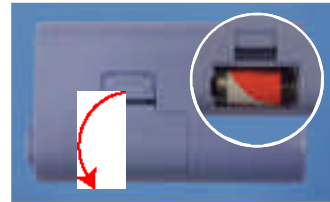
2) Insert a syringe filled with insulin into the DANA Easy SETTER (figure 2).

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

3) Push the button on DANA Easy SETTER.

Note When the button is pushed, you can see the syringe slide in. Push 2~3 more seconds until the syringe is fully inserted into the Easy SETTER(Figure 3).

4) Retrieve the adjusted syringe from the DANA Easy SETTER.



(figure 1)



(figure 2)



(figure 3)

Inserting the reservoir into the pump

1) Insert the reservoir with linking screw into the DANA Diabecare IISR insulin pump as shown in figure 1. 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 pumps' reservoir compartment cap in place and remove the small white reservoir cap from the end of the reservoir.

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



(figure 1)

Connecting the infusion set to the DANA IISR

- 1) Hold the pump upside down and remove the white cap. Screw the infusion set connector counterclockwise into the reservoir compartment until it is firmly in place.



(figure 1)

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.

Priming the infusion set

- 1) Press **S** to take the pump out of SUSPEND mode. The BASIC DISPLAY will appear.



(figure 1)

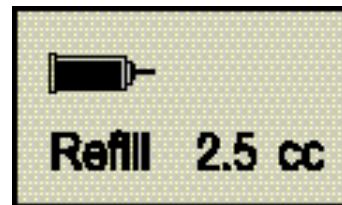
- 2) In the BASIC DISPLAY screen, highlight the **CHECK/REVIEW** icon and press **S** (figure 1).



(figure 2)

- 3) Press **N** in the **CHECK/REVIEW** screen to highlight the PRIME icon as shown in figure 2. Then press **S**.

- 4) You will now see the FILLING SCREEN display as shown in figure 3. Use **▲** and **▼** to adjust the amount of insulin (in ccs) in the new reservoir placed in the DANA pump. Then press **S**.




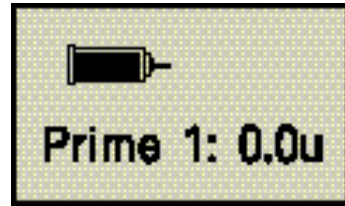
(figure 3)

Note Remember to adjust this setting up or down to the amount you have actually placed in the reservoir.



Note The 2.5 cc is a preset default setting.

3. Filling and inserting a new reservoir

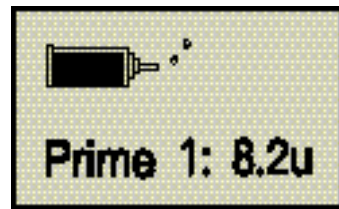
5) The prime screen will appear as in figure 4. Press  twice to begin priming the infusion set.



(figure 4)

Note Press  once and the word 'PRIME' will be replaced by "UP" a second later. The two words will flash back and forth every two seconds. In order to commence priming you must press  the second time while the screen displays the word 'UP'.


6) You will hear the pump begin to infuse insulin into the infusion set. The insulin amount on the PRIME screen will increase slowly and "bubbles" will appear at the end of the reservoir on the display as in figure 5. You will see the insulin move towards the needle end of the infusion set.



(figure 5)

Note You will hear the pump beep for every 1.0 unit while priming is in progress.

Note You may pause the prime temporarily by pressing . Press  twice to resume the priming sequence.

7) When you see a drop of insulin appear at the end of the infusion set needle, press  to stop the priming sequence.

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

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

Note The DANA Diabecare IISR insulin pump will allow 2 prime sequences every 12 hours (0:00 - 12:00, 12:00 -

Caution 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.

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

Inserting the infusion set

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

1) Choose an insertion site on your abdomen at least 5 cm away from the navel (figure 1).



(figure 1)

2) Clean the site with an alcohol swab and allow to dry (figure 1).



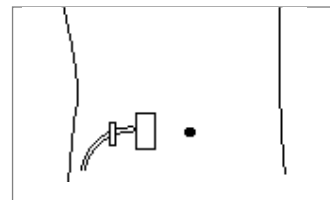
(figure 2)

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



(figure 3)

4) With your other hand pinch the tissue around the insertion site between your thumb and finger as in figure 3. Push the needle firmly into this tissue and secure with the adhesive dressing.



(figure 4)

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

Note 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.

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

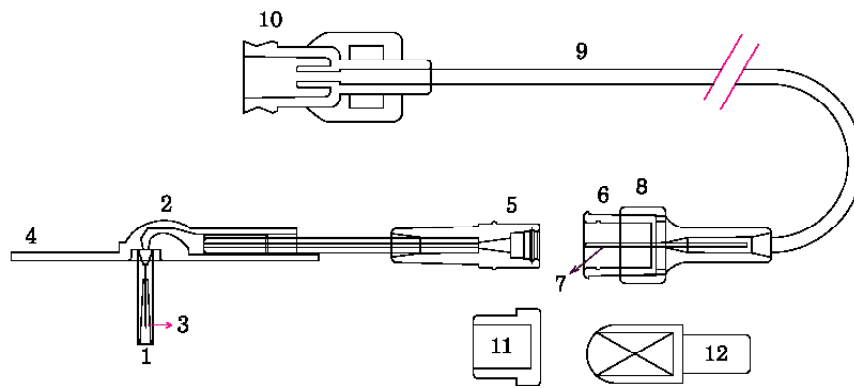
Note See page 32 for Soft - Release - ST inserting.

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

Infusion Sets

The EasyRelease Infusion Set

The EasyRelease Infusion Set is a stainless steel needle set. A needle is inserted at 90° into the skin. The adhesive of the EasyRelease allows the needle to be fixed firmly in place.



- | | | |
|----------------------------|------------------------|------------------------------|
| Needle Cover | Site Connector | Tubing |
| Needle Hub | Infusion Set Connector | Pump Connector |
| Needle | Connection Needle | Site Connector Cover |
| Needle Guide with Adhesive | Collar | Infusion Set Connector Cover |

Instructions

1. Prior to Inserting the EasyRelease Infusion Set

- 1) Wash your hands before handling the infusion set.
- 2) Take out the EasyRelease Infusion Set from its package. Be careful not to touch the connector to any object that would breach its sterility.
- 3) Screw the Pump Connector counterclockwise into the reservoir compartment until it is firmly in place.
- 4) Push the Set Connector firmly into the Site Connector and pull the Collar back to secure the connection (figure 1).



(figure 1)



(figure 2)

2. Inserting the EasyRelease 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 (figure 2).
- 2) Prime the infusion set by following the instructions on page 23. Air removal is complete when a drop of insulin appears at the end of the needle (figure 3).
- 3) Carefully remove the needle's protective cover (figure 4), and the paper backing from the adhesive dressing (figure 5).
- 4) With your other hand pinch the tissue around the insertion site between your thumb and finger. Push the needle firmly into the tissue (figure 6).
- 5) Secure the needle with the adhesive dressing (figure 7).
- 6) Tape the infusion set to the body with adhesive tape 2~5 cm away from the insertion site (figure 8).



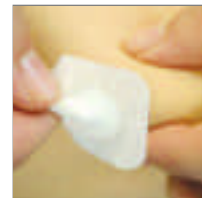
(figure 3)



(figure 4)



(figure 5)



(figure 6)



(figure 7)



(figure 8)

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

3. Disconnecting the EasyRelease Infusion Set

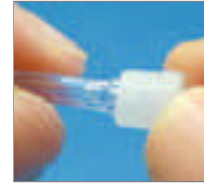
- 1) Place the pump in SUSPEND (see page 17).
- 2) Push the Collar forward and pull the Infusion Set Connector out of the Site Connector (figure 9).
- 3) Push the Infusion Set Connector Cover onto the Connection Needle (figure 10). Make sure that this is done without bending the Connection Needle. This prevents insulin from dripping out at the release site and keeps the Connection Needle clean.
- 4) Insert the Site Connector Cover into the Site Connector (figure 11).
- 5) Put your pump in a clean and safe place until you are ready to reconnect.



(figure 9)



(figure 10)



(figure 11)

4. Reconnecting the EasyRelease Infusion Set

- 1) Wipe the tip of the Site Connector with an alcohol swab after removing the Site Connection Cover (figure 12).
- 2) Remove the Infusion Set Connector Cover from the Infusion Set Connector (figure 12).
- 3) Take pump out of SUSPEND (see page 17).
- 4) Before reconnecting, program the pump to bolus 0.5~1 unit of insulin (see page 39) and watch to ensure that a drop is visible from the Connection Needle tip (figure 14).
- 5) Gently slide the Infusion Set Connector into the Site Connector, and pull the Collar back to secure the connection (figure 15).



(figure 12)



(figure 13)



(figure 14)



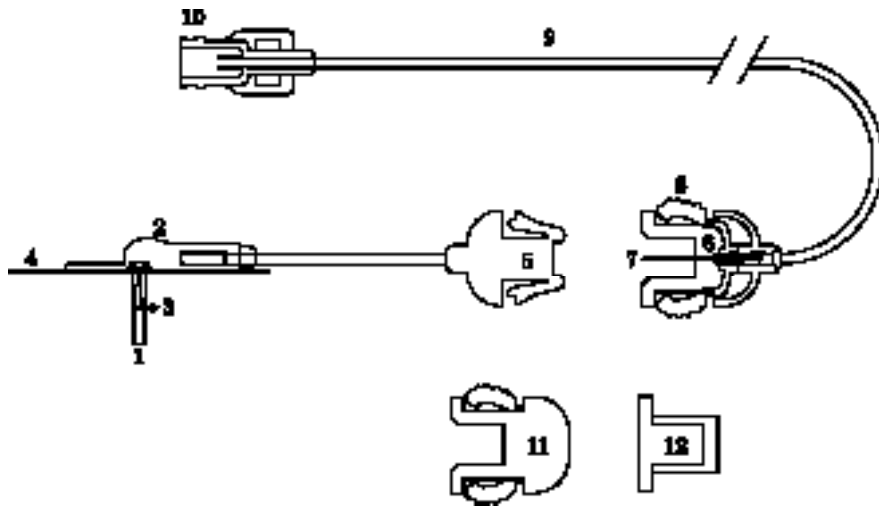
(figure 15)

5. Removing the EasyRelease Infusion Set

- 1) Place the pump in SUSPEND (see page 17).
- 2) Carefully remove the adhesive tape from the Tubing and needle insertion site.
- 3) Grab the Needle Guide in the same manner as if you were inserting it. Use your other hand to apply slight pressure on the tissue around the insertion area. Gently pull out the needle.
- 4) Remove the infusion set from the pump by turning the Pump Connector clockwise and pulling upwards.

The EasyRelease II Infusion Set

The EasyRelease II Infusion Set is a stainless steel needle set. A needle is inserted at 90° into the skin. The adhesive of the EasyRelease II allows the needle to be fixed firmly in place.



Needle Cover

Needle Hub

Needle

Needle Guide with Adhesive

Site Connector

Infusion Set Connector

Connection Needle

Spring Clip

Tubing

Pump Connector

Site Connector Cover

Infusion Set Connector Cover

Instructions

1. Prior to Inserting the EasyRelease II Infusion Set

- 1) Wash your hands before handling the infusion set.
- 2) Take out the EasyRelease II Infusion Set from its package. Be careful not to touch the connector to any object that would breach its sterility.
- 3) Screw the Pump Connector counterclockwise into the reservoir compartment until it is firmly in place.
- 4) Push the Set Connector firmly into the Site Connector and pull the Collar back to secure the connection (figure 1).



(figure 1)



(figure 2)

2. Inserting the EasyRelease II 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 (figure 2).



(figure 3)



(figure 4)

- 2) Prime the infusion set by following the instructions on page 23. Air removal is complete when a drop of insulin appears at the end of the back side of needle (figure 3).

- 3) Carefully remove the needle's protective cover (figure 4), and the paper backing from the adhesive dressing (figure 5).



(figure 5)



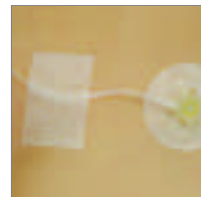
(figure 6)

- 4) With your other hand pinch the tissue around the insertion site between your thumb and finger. Push the needle firmly into the tissue (figure 6).

- 5) Secure the needle with the adhesive dressing (figure 7).



(figure 7)



(figure 8)

- 6) Tape the infusion set to the body with adhesive tape 2~5 cm away from the insertion site (figure 8).

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

3. Disconnecting the EasyRelease II Infusion Set

- 1) Place the pump in SUSPEND (see page 17).
- 2) Grasp each side of the Infusion Set Connector, pressing gently on the Spring Clips. Pull the Infusion Set Connector out of the Site Connector (figure 11).
- 3) Push the Infusion Set Connector Cover onto the Connection Needle (figure 12). Make sure that this is done without bending the Connection Needle. This prevents insulin from dripping out at the release site and keeps the Connection Needle clean.
- 4) Insert the Site Connector Cover into the Site Connector (figure 13).
- 5) Put your pump in a clean and safe place until you are ready to reconnect.



(figure 9)



(figure 10)



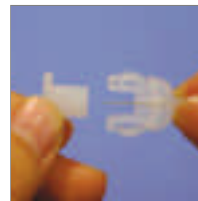
(figure 11)



(figure 12)

4. Reconnecting the EasyRelease II Infusion Set

- 1) Wipe the tip of the Site Connector with an alcohol swab after removing the Site Connection Cover (figure 14).
- 2) Remove the Infusion Set Connector Cover from the Infusion Set Connector (figure 15).
- 3) Take the pump out of SUSPEND (See page 17).
- 4) Before reconnecting, program the pump to bolus 0.5~1 unit of insulin (see page 39) and watch to ensure that a drop is visible from the Connection Needle tip (figure 16).
- 5) Gently slide the Infusion Set Connector into the Site Connector, by pressing lightly on the Spring Clips on either side of the Infusion Set Connector (figure 17).



(figure 13)



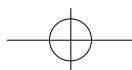
(figure 14)



(figure 15)

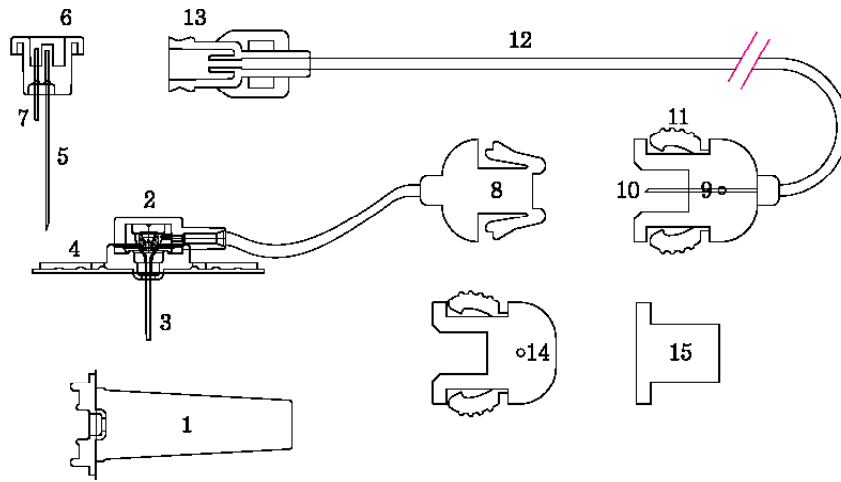
5. Removing the EasyRelease II Infusion Set

- 1) Place the pump in SUSPEND (see page 17).
- 2) Carefully remove the adhesive tape from the Tubing and needle insertion site.
- 3) Grab the Needle Guide in the same manner as if you were inserting it. Use your other hand to apply slight pressure on the tissue around the insertion area. Gently pull out the cannula.
- 4) Remove the infusion set from the pump by turning the Pump Connector clockwise and pulling upwards.



The Soft - Release - R Infusion Set

The Soft - Release - R is a soft cannula infusion set and is inserted at a 90° angle. The needle is removed after insertion and only the cannula remains under the skin.



Needle Protective Cover for disposal	Introducer Needle	Spring Clip
Cannula Hub	Bypass Needle	Tubing
Teflon (Soft Cannula)	Site Connector	Pump Connector
Needle Guide with Adhesive	Infusion Set Connector	Site Connector Cover
Needle Hub	Connection Needle	Infusion Set Connector Cover

1. Prior to Inserting the Soft -Release -R Infusion Set

- 1) Wash your hands before handling the infusion set.
- 2) Take out the Soft - Release - R Infusion Set from its package. Be careful not to touch the connector to any object that would breach its sterility.
- 3) Screw the Pump Connector counterclockwise into the reservoir compartment until it is firmly in place.
- 4) Connect the Infusion Set Connector with the Site Connector (figure 1).



(figure 1)



(figure 2)

2. Inserting the Soft -Release -R 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 (figure 2).
- 2) Prime the infusion set by following the instructions on page 23. Air removal is complete when a drop of insulin appears at the end of the back side of needle (figure 3).
- 3) Hold the infusion set in your fingers at the Needle Guide and carefully remove the needle's protective cover (figure 4), and remove the paper backing from the adhesive dressing (figure 5).
- 4) With your other hand pinch the tissue around the insertion site between your thumb and finger. Insert the needle quickly, at a 90 ° angle straight into the infusion site (figure 6). Watch the Teflon (soft cannula) during insertion to assure that it goes in smoothly without kinking or crimping.
- 5) Before withdrawing the Introducer needle, you may want to ensure that the cannula is firmly taped (figure 7).
- 6) To remove the Introducer Needle, place one finger on each side of the Needle Guide with Adhesive and one on either side of the Introducer Needle. Pull the needle straight out (figure 8).
- 7) Dispose of the Introducer Needle in a safe manner by using the needle Protective Cover (figure 9).
- 8) Tape the infusion set to the body with adhesive tape 2~5 cm away from the insertion site (figure 10).



(figure 3)



(figure 4)



(figure 5)



(figure 6)



(figure 7)



(figure 8)



(figure 9)

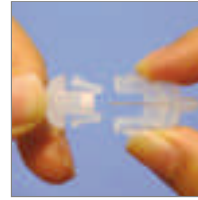


(figure 10)

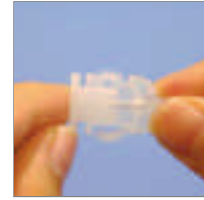
Note Try to avoid any recent insertion sites, scars, scar tissue or bruising.

3. Disconnecting the Soft-Release-R Infusion Set

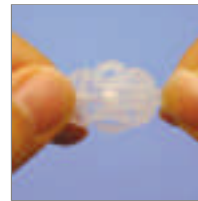
- 1) Place the pump in SUSPEND (see page 17).
- 2) Grasp each side of the Infusion Set Connector, pressing gently on the Spring Clips. Pull the Infusion Set Connector out of the Site Connector (figure 11).
- 3) Push the Infusion Set Connector Cover onto the Connection Needle (figure 12). Make sure that this is done without bending the Connection Needle. This prevents insulin from dripping out at the release site and keeps the Connection Needle clean.
- 4) Insert the Site Connector Cover into the Site Connector (figure 13).
- 5) Put your pump in a clean and safe place until you are ready to reconnect.



(figure 11)



(figure 12)



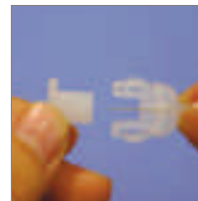
(figure 13)



(figure 14)

4. Reconnecting the Soft-Release-R Infusion Set

- 1) Wipe the tip of the Site Connector with an alcohol swab after removing the Site Connection Cover (figure 14).
- 2) Remove the Infusion Set Connector Cover from the Infusion Set Connector (figure 15).
- 3) Take the pump out of SUSPEND (See page 17).
- 4) Before reconnecting, program the pump to bolus 0.5~1 unit of insulin (see page 39) and watch to ensure that a drop is visible from the Connection Needle tip (figure 16).
- 5) Gently slide the Infusion Set Connector into the Site Connector, by pressing lightly on the Spring Clips on either side of the Infusion Set Connector (figure 17).



(figure 15)



(figure 16)



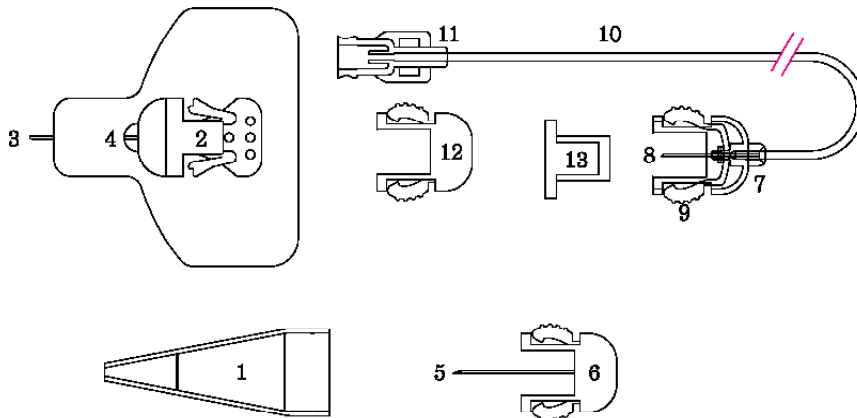
(figure 17)

5. Removing the Soft-Release-R Infusion Set

- 1) Place the pump in SUSPEND (see page 17).
- 2) Carefully remove the adhesive tape from the Tubing and needle insertion site.
- 3) Grab the Needle Guide in the same manner as if you were inserting it. Use your other hand to apply slight pressure on the tissue around the insertion area. Gently pull out the cannula.
- 4) Remove the infusion set from the pump by turning the Pump Connector clockwise and pulling upwards.

The Soft-Release-ST Infusion Set

The Soft - Release - ST is a soft cannula infusion set. It may be inserted at any angle between 15° and 30° depending on your body type, comfort and instructions from your healthcare professional. The needle is removed after insertion and only the cannula remains under the skin.



Needle Cover	Introducer Needle	Pump Connector
Site Connector	Infusion Set Connector	Site Connector Cover
Teflon (Soft Cannula)	Connection Needle	Infusion Set Connector Cover
Needle Guide with Adhesive	Spring Clips	
Needle Hub	Tubing	

1. Prior to Inserting the Soft -Release -ST Infusion Set

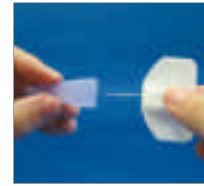
- 1) Wash your hands before handling the infusion set.
- 2) Take out the Soft - Release - ST Infusion Set from its package. Be careful not to touch the connector to any object that would breach its sterility.
- 3) Screw the Pump Connector counterclockwise into the reservoir compartment until it is firmly in place.

2. Inserting the Soft -Release -ST Infusion Set

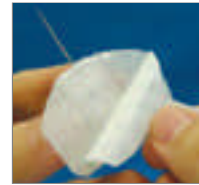
- 1) Choose an insertion site on your abdomen at least 5 cm away from the navel. Clean the site with an alcohol swab and allow to dry (figure 1).
- 2) Hold the infusion set in your fingers at the Site Connector and carefully remove the needle's protective cover (figure 2), and remove the bottom portion of the paper backing from the adhesive dressing (figure 3).
- 3) With your other hand pinch the tissue around the insertion site between your thumb and finger. Insert the needle quickly, at a 15°-30° angle straight into the infusion site (figure 4). Watch the Teflon (soft cannula) during insertion to ensure that it goes in smoothly without kinking or crimping.
- 4) Once the bottom portion of the adhesive has been fixed, remove the top portion of the paper backing and apply the entire dressing. Ensure that the cannula is firmly taped (figure 5).
- 5) To remove the Introducer Needle, place one finger on each side of the Site Connector and one on either side of the Spring Clips of the Needle Hub. Pull the needle straight out (figure 6).
- 6) Dispose of the Introducer Needle in a safe manner by using the needle Protective Cover (figure 7).
- 7) Prime the infusion set by following the instructions on page 23. Air removal is complete when a drop of insulin appears at the end of the Connection Needle (figure 8).
- 8) Gently slide the Infusion Set Connector into the Site Connector so that the two units firmly snap together (figure 9).
- 9) Tape the infusion set to the body with adhesive tape 2-5 cm away from the insertion site (figure 10).



(figure 1)



(figure 2)



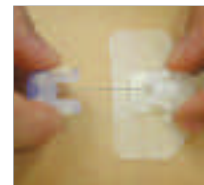
(figure 3)



(figure 4)



(figure 5)



(figure 6)



(figure 7)



(figure 8)



(figure 9)



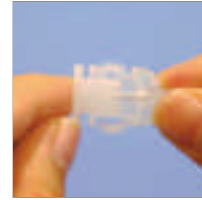
(figure 10)

3. Disconnecting the Soft-Release-ST Infusion Set

- 1) Place the pump in SUSPEND (see page 17).
- 2) Grasp each side of the Infusion Set Connector, pressing gently on the Spring Clips. Pull the Infusion Set Connector out of the Site Connector (figure 11).
- 3) Push the Infusion Set Connector Cover onto the Connection Needle (figure 12). Make sure that this is done without bending the Connection Needle. This prevents insulin from dripping out at the release site and keeps the Connection Needle clean.
- 4) Insert the Site Connector Cover into the Site Connector (figure 13).
- 5) Put your pump in a clean and safe place until you are ready to reconnect.



(figure 11)



(figure 12)



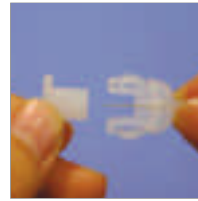
(figure 13)



(figure 14)

4. Reconnecting the Soft-Release-ST Infusion Set

- 1) Wipe the tip of the Site Connector with an alcohol swab after removing the Site Connection Cover (figure 14).
- 2) Remove the Infusion Set Connector Cover from the Infusion Set Connector (figure 15).
- 3) Take the pump out of SUSPEND (see page 17).
- 4) Before reconnecting, program the pump to bolus 0.5~1 unit of insulin (see page 39) and watch to ensure that a drop is visible from the Connection Needle tip (figure 16).
- 5) Gently slide the Infusion Set Connector into the Site Connector, by pressing lightly on the Spring Clips on either side of the Infusion Set Connector (figure 17).



(figure 15)



(figure 16)

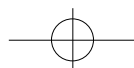


(figure 17)

5. Removing the Soft-Release-ST Infusion Set

- 1) Place the pump in SUSPEND (see page 17).
- 2) Carefully remove the adhesive tape from the Tubing and needle insertion site.
- 3) Grab the Needle Guide in the same manner as if you were inserting it. Use your other hand to apply slight pressure on the tissue around the insertion area. Gently pull out the cannula.
- 4) Remove the infusion set from the pump by turning the Pump Connector clockwise and pulling upwards.

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



General Precautions for All Infusion Sets

1. Change the reservoir and the infusion set regularly as recommended by your healthcare professional. Do not use either for longer than 72 hours.
2. The reservoir and infusion set are intended for single use only. Do not reuse either the reservoir or infusion set.
3. Do not use the reservoir or infusion set if the package has been damaged, inadvertently opened or wet.
4. The shelf life of the reservoir and the infusion set is 3 years. Please check expiration dates regularly and dispose of any expired accessories.
5. Do not disconnect from your pump for more than one hour without discussing with your healthcare professional on how you should compensate for missed insulin. Please remember that while disconnected from the pump, no insulin is being infused. Carefully monitor blood glucose levels during periods of disconnection and after reconnection.
6. Check the infusion site often for redness, irritation and inflammation.
7. Remember to prime at least 15 units when you change your reservoir and infusion set to permit the pump to perform an additional series of safety checks.

4. Bolusing, temporary basal rates, calculating your bolus dosage and dose automation



Bolus

When Extended Bolus is set to OFF

-Delivering a Bolus

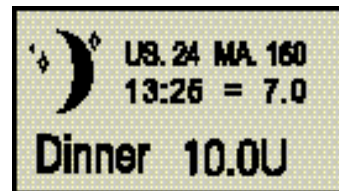
1) Press any button while in the INITIAL DISPLAY screen to bring up the BASIC DISPLAY screen.

2) In the BASIC DISPLAY screen press **N** until the BOLUS icon is highlighted as in figure 1. Then press **S**. The BOLUS screen will appear as in figure 2.

3) Confirm the amount of insulin to be delivered in the bottom right corner of the BOLUS screen. If the insulin dose is not correct you may make the desired adjustments to the bolus setting by using  and .



(figure 1)

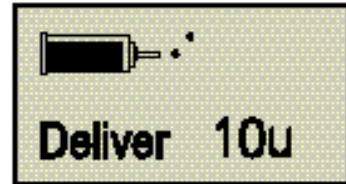


(figure 2)

Note Remember the adjustment will not change the default bolus setting. It will only change the bolus that you are currently delivering.

4. Bolusing, temporary basal rates, calculating your bolus dosage and dose automation

4) Press **S** twice to begin delivery. The screen in figure 3 will appear and you will hear the motor run as the bolus is being delivered.



(figure 3)

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

Note You will hear the pump beep for every 1.0 unit while a bolus is being delivered.

Note Press **▲** or **▼** once to stop a bolus during delivery.

Note Press **N** to return to Basic Display screen.

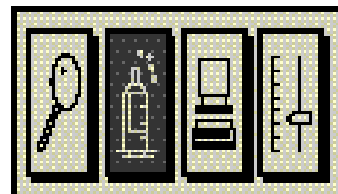
5) The pump will make a beep and return to the INITIAL DISPLAY screen upon conclusion of bolus delivery.

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

When Extended Bolus is set to ON

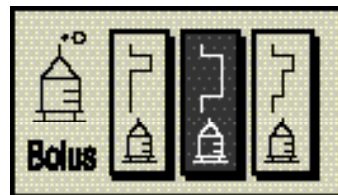
- The BOLUS OPTION Screen

1) In the BASIC DISPLAY screen press **N** until the BOLUS icon is highlighted as in figure 1. Then press **S**.



(figure 1)

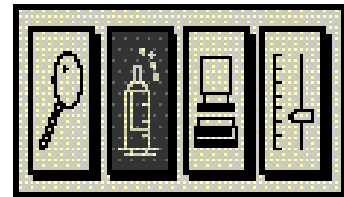
2) Choose the first icon to access the **NORMAL BOLUS** screen, the second icon to access the **EXTENDED BOLUS** screen, and the third icon to access the **DUAL PATTERN BOLUS** screen.



(figure 2)

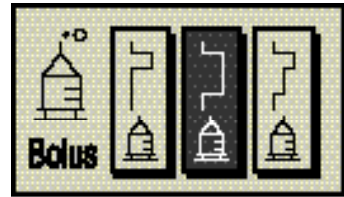
- Extended Bolus

1) In the BASIC DISPLAY screen press **N** until the BOLUS icon is highlighted as in figure 1. Then press **S**.



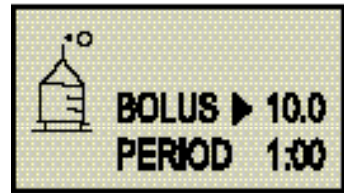
(figure 1)

2) Use **N** to highlight the middle icon and press **S**.



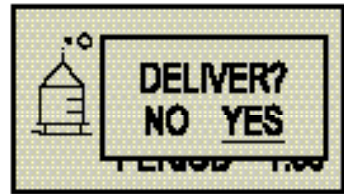
(figure 2)

3) Use **N** to toggle between BOLUS amount and BOLUS Period and make the necessary adjustments with **▲** and **▼** then press **S**.



(figure 3)

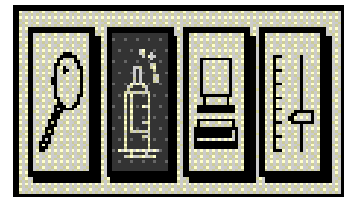
4) Use **N** to highlight 'YES' and press **S**.



(figure 4)

- Dual Bolus

1) In the BASIC DISPLAY screen press **N** until the BOLUS icon is highlighted as in figure 1. Then press **S**.



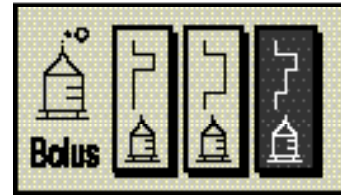
(figure 1)

4. Bolusing, temporary basal rates, calculating your bolus dosage and dose automation

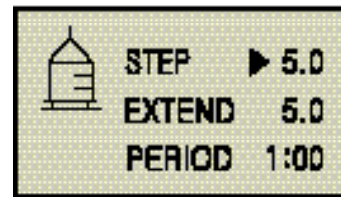
2) Use **N** to highlight the rightmost icon and press **S**.

3) Use **N** to toggle between STEP BOLUS and EXTEND BOLUS and BOLUS Period and make the necessary adjustments with **▲** and **▼** than press **S**.

4) Use **N** to highlight 'YES' and press **S**.

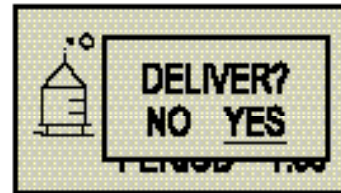


(figure 2)



(figure 3)

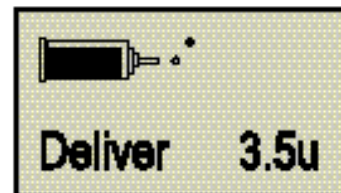
Note To verify that Extended Bolus is in effect, while in the BASIC DISPLAY screen use **N** to highlight the BOLUS icon and press **S**. The EXTENDED BOLUS STATUS screen will appear.



(figure 4)

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

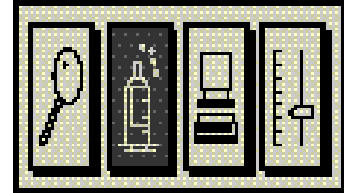
Note The bolus amount may be set to any amount within the range of 0 - bolus max.



(figure 5)

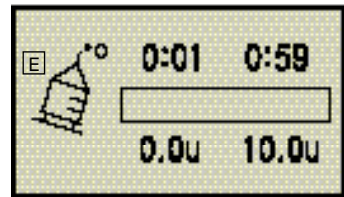
- Extended Bolus Status

1) In the BASIC DISPLAY screen press **N** until the BOLUS icon is highlighted as in figure 1. Then press **S**.



(figure 1)

2) The screen will show how much time has elapsed since the start of the Extended Bolus, how much time is left until the completion of the Extended Bolus, amount delivered so far, and amount left to be delivered.

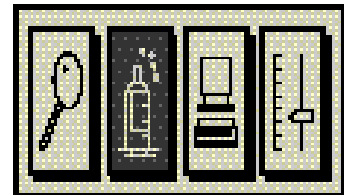


(figure 2)


Note E means Extended Bolus.

-Extended Bolus Cancellation

1) In the BASIC DISPLAY screen press **N** until the BOLUS icon is highlighted as in figure 1. Then press **S**.



(figure 1)

2) Press  to invoke the cancellation prompt.

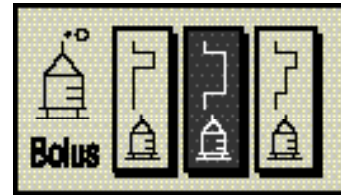
3) Use **N** to highlight 'YES' and press **S**. The current Extended Bolus sequence will be cancelled and you will be returned to the BASIC DISPLAY screen.



(figure 2)

4. Bolusing, temporary basal rates, calculating your bolus dosage and dose automation

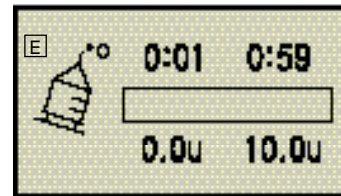
Note To verify the Extended Bolus has been cancelled, while in the BASIC DISPLAY screen, use **N** to highlight the BOLUS icon and press **S**. You will see the BOLUS OPTION screen if Extended Bolus was successfully cancelled (figure 3).



(figure 3)

Note If cancellation was not successful, the EXTENDED BOLUS STATUS screen will appear as in figure 4.

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.



(figure 4)

Note Insulin is delivered every four minutes when the Dana IISR utilizes the extended bolus feature. While in extended bolus mode, insulin delivery will be halted during the following four events:

- 1) Start of a bolus
- 2) Delivery of a bolus
- 3) Priming the infusion set
- 4) Delivery of basal rates

Therefore, the actual delivered amount displayed in the extended bolus status screen may differ from the actual delivered amount.

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.

Temporary Basal

When Utility is set to OFF

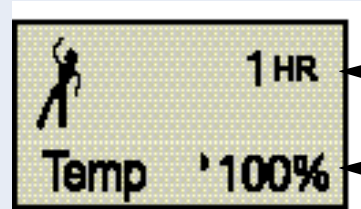
- Programming Temporary Basal Rates

1) Press any button while in the INITIAL DISPLAY screen to bring up the BASIC DISPLAY screen.



(figure 1)

2) In the BASIC DISPLAY screen press **N** until the TEMPORARY BASAL icon is highlighted as in figure 1. Then press **S**. The TEMPORARY BASAL screen will appear as in figure 2.

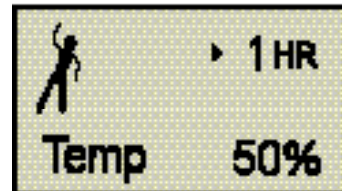


(figure 2)

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

This number indicates the desired increase/decrease in basal delivery.

3) Use **N** to toggle between the number of hours and basal ratio and make the necessary adjustments with **▲** and **▼**.



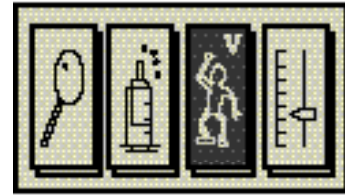
(figure 3)

Note 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.

Note No temporary basal rate will take effect if you press **S** while either the number of hours is set at 0, or the rate is set at 100%.

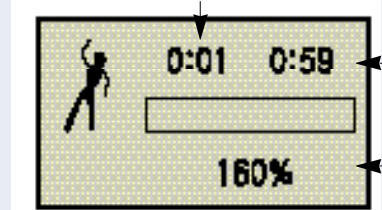
4. Bolusing, temporary basal rates, calculating your bolus dosage and dose automation

4) Press **S** after making the desired adjustments to commence temporary basal. Upon pressing **S** you will be returned to the BASIC DISPLAY screen and a v mark will appear in the TEMPORARY BASAL icon to indicate that the temporary basal rate is in effect.



(figure 4)

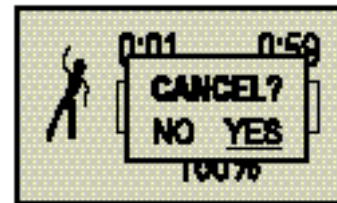
5) If you would like to check the status of a temporary basal rate that is currently in effect, use **N** to highlight the TEMPORARY BASAL icon with a v mark in the BASIC DISPLAY screen and press **S**. The TEMPORARY BASAL STATUS screen will appear as in figure 5.



(figure 5)

Time elapsed
Time remaining
Temporary basal rate

6) To cancel a temporary basal rate currently in effect, press **▼** and a cancellation prompt will appear as in figure 6.



(figure 6)

7) Press **N** to highlight "YES", then press **S** if you would like to cancel temporary basal. The temporary basal rate in effect will be cancelled and you will be returned to the BASIC DISPLAY screen.

Note Highlight "NO" and press **S** at the cancellation prompt to return to the BASIC DISPLAY screen without canceling temporary basal.

Note Adjust the rate to "100%" and time to "0 hours" if you wish to return to your regular basal rate.

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

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

When Utility is set to ON

-UTILITY MENU screen

1) In the BASIC DISPLAY screen, use **N** to highlight the Utility icon (Computer). Then press **S**.

2) If Temporary Basal is not activated your UTILITY MENU screen will appear as in figure 2.

3) If Temporary Basal is in effect your UTILITY MENU screen will appear as in figure 3.

Note Select the leftmost icon for the Bolus Calculator, middle icon for Temporary Basal, and rightmost icon for Dose Automation.

-Bolus Calculator

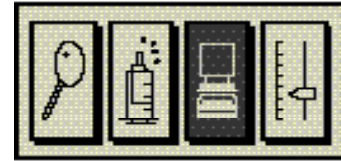
1) In the BASIC DISPLAY screen, use **N** to highlight the UTIL icon. Then press **S**. (figure 1)

2) While in the UTILITY MENU screen, press **S** to access the BOLUS CALCULATOR screen. (figure 2)

3) In the BOLUS CALCULATOR screen, Use **N** to move the cursor on CARBO to adjust the amount of Carbohydrate with the use of **▲** or **▼** button. (figure 3)

Displays current blood glucose level.

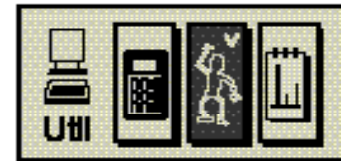
Indicates the carbohydrate to be consumed after Bolus delivery.



(figure 1)



(figure 2)



(figure 3)



(figure 1)



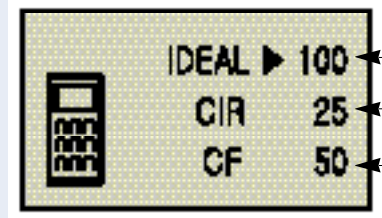
(figure 2)



(figure 3)

4. Bolusing, temporary basal rates, calculating your bolus dosage and dose automation

4) Use **N** to move between " Ideal Blood Glucose ", " CIR", and " CF "; and use **▲** and **▼** to make the necessary adjustments. Then press **S**. The BOLUS CALCULATOR RESULTS screen will appear as in figure 4.



(figure 4)

Indicates your target blood glucose level.

Amount of carbohydrates capable of being processed by 1u (unit) of insulin. (Carb/insulin ratio)

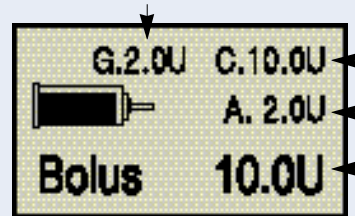
Indicates Correction factor.

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

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

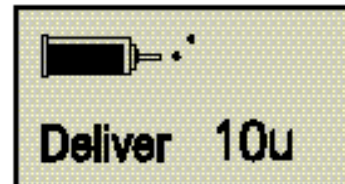
Indicates the amount of insulin remaining in your body from your previous bolus amount(active insulin).

Indicates the calculated bolus amount.



(figure 5)

5) Press **S** twice to commence bolus delivery. You will hear the motor run and the screen will show that a bolus is being delivered.



(figure 6)

Note You will hear the pump beep for every 1.0 unit while a bolus is being delivered.

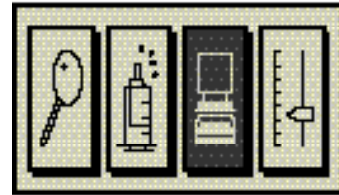
Note Press **S** once and the word 'BOLUS' will be replaced by 'SELECT' a second later. The two words will flash back and forth every two seconds. In order to commence the bolus sequence you must press **S** again while the screen is showing 'SELECT'.

Note Press **▲** or **▼** once to stop a bolus during delivery.

- Temporary basal

1) In the BASIC DISPLAY screen, use **N** to highlight the UTIL icon.

Then press **S**.



(figure 1)

2) While in the UTILITY MENU screen, use **N** to highlight the

TEMPORARY BASAL ICON. Then press **S**.



(figure 2)

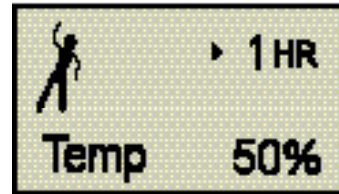
3) Use **N** to toggle between the number of hours and basal rate,

and make the necessary adjustments with **▲** and **▼**.

4) Once temporary basal has been set, a 'v' mark will appear in the

TEMPORARY BASAL icon at the UTILITY MENU screen to indicate

a temporary basal rate is in effect.



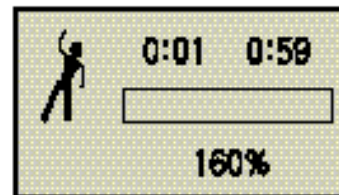
(figure 3)

Note To confirm that temporary basal is in effect, use **N** in the UTILITY MENU screen to highlight the TEMPORARY BASAL icon and press **S**. The TEMPORARY BASAL STATUS screen will appear.



(figure 4)

Note The percentage rate shown in figure 5 corresponds to the rate at which basal infusion will occur while temporary basal is active. The percentage calculation is based on your regular basal rate. For instance, if your regular basal rate is 4 units per hour and the percentage rate is set to 150%, the temporary basal rate would be 6 units per hour.

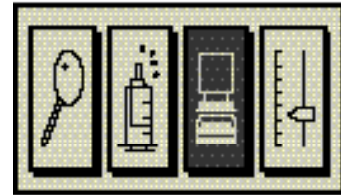


(figure 5)

4. Bolusing, temporary basal rates, calculating your bolus dosage and dose automation

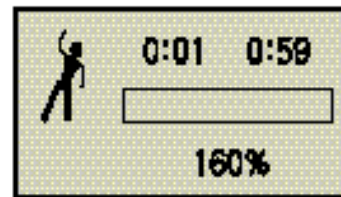
- Temporary Basal Cancellation

1) In the BASIC DISPLAY screen, use **N** to highlight the UTIL icon (Computer) and press **S**. The UTILITY MENU screen will appear.



(figure 1)

2) Use **N** to highlight the TEMPORARY BASAL icon and press **S** to access the TEMPORARY BASAL STATUS screen.



(figure 2)

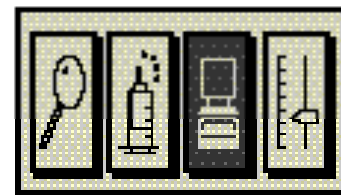
3) Press **▼** to invoke the cancellation prompt.



(figure 3)

4) Use **N** to highlight "YES" and press **S** to cancel temporary basal. You will be returned to the BASIC DISPLAY screen upon pressing **S**.

Note If you do not wish to cancel, choose "NO" and press **S** at the cancellation prompt. You will be returned to the BASIC DISPLAY screen upon pressing **S**.



(figure 4)

- Dose Automation

1) In the BASIC DISPLAY screen, use **N** to highlight the UTIL icon and press **S**.

2) Use **N** to highlight the rightmost icon and press **S** to access the DOSE AUTOMATION screen.

3) Use **N** to toggle between Daily total and Bolus and Basal and make the necessary adjustments with **▲** and **▼** then press **S**.

4) Use **N** to confirm the time and rates. Use **▲** and **▼** to choose the desired basal pattern and press **S**.

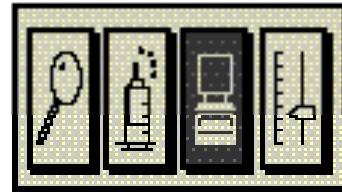
5) Use **N** to highlight "YES" and press **S**.

Note 1 indicates pattern number. 4 different basal profiles are available for selection.

Note You may verify your bolus and basal rates through the CHECK/REVIEW menu option.

Note The Daily Total can be set to any value within the range of 0 - Daily Max.

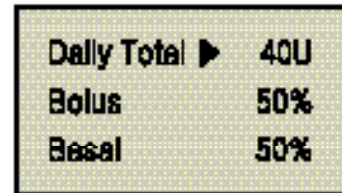
Note The percentage rate can be adjusted within the range of 0 - 100%.



(figure 1)



(figure 2)



(figure 3)



(figure 4)

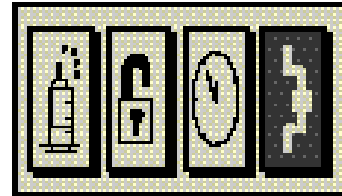


(figure 5)

5. Remote Control

Synchronize the Remote Control with the Pump

1) Select the menu of **connect** icon at the basic menus display to synchronize the remote control with the pump (figure 1).



(figure 1)

Note An icon with four antennas will be displayed on the remote control while the synchronization is attempting.

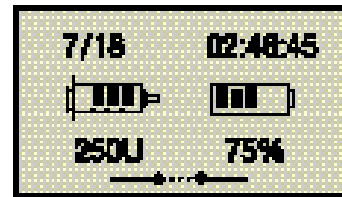


(figure 2)

Note An icon with six antennas will be displayed on the remote control once the synchronization is completed.

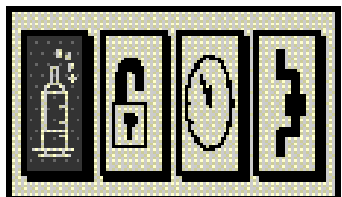
Bolus

1) In the BASIC DISPLAY screen press **N** until the **BOLUS** icon is highlighted as in figure 1. Then press **S**. Then press **S**.



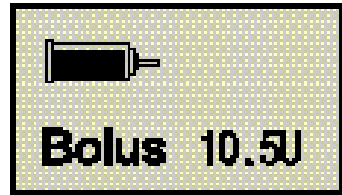
(figure 3)

2) While in the BOLUS SETTING screen, select the proper insulin dose by using **▲** and **▼**. The insulin dose appears in units in the bottom right hand corner.



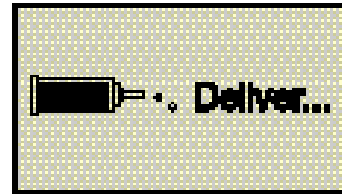
(figure 1)

3) Press **S** twice to begin delivery. The screen in figure 2 will appear and you will hear the motor run as the bolus is being delivered.



(figure 2)

Note Press **S** once and the word 'BOLUS' will be replaced by 'SELECT' a second later. In order to commence the bolus sequence you must press **S** again while the screen is showing 'SELECT' (figure 3)

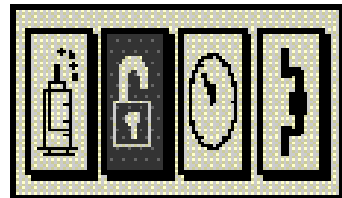


(figure 3)

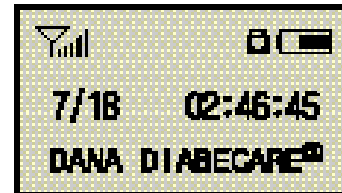
Note Press **▲** or **▼** once to stop a bolus during delivery.

Lock Setting

1) Move to the program setting screen from the basic screen (figure 1), press **S** button once an icon of LOCK is displayed, and then the **LOCK** icon will be displayed like figure 2.



(figure 1)



(figure 2)

2) To unlock, press in order of **▲**, **S**, **N**, **▼** and then, a display like figure 3 will be displayed. Input PIN code 1234 by use of **▲** or **▼** buttons.

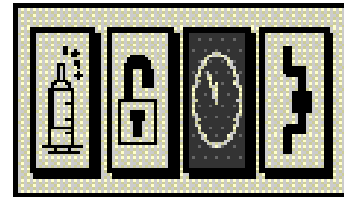


(figure 3)

Setting the Clock

1) From the BASIC DISPLAY, go to the SET/PROGRAM screen. Press

N to highlight the CLOCK icon and press **S** (figure 1). The CLOCK SETTING screen will appear as shown in figure 2.



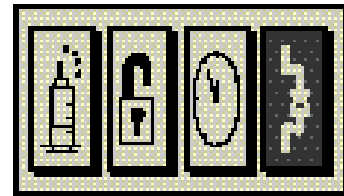
(figure 1)

2) Use **N** to move between the year and month and date, as well as hours and minutes. Use **▲** and **▼** to make the desired changes.



(figure 2)

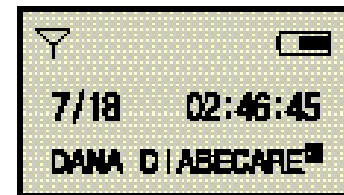
3) After making the changes press **S** to save the setting and return to the BASIC DISPLAY screen.



(figure 1)

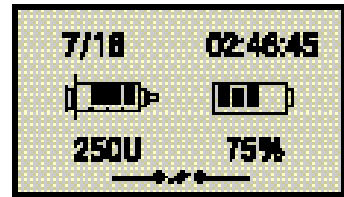
Disconnect Remote Control and Insulin Pump

1) Select the menu of disconnect icon at the basic menus display to disconnect remote control.



(figure 2)

Note The antenna icon will be disappeared once the remote control disconnected.



(figure 3)


Note A disconnect icon will be displayed on the pump.

Checking your blood glucose level

1) After washing your hands, insert a DANA blood glucose strip into the blood glucose meter test port (figure 1).



(figure 1)

2) The STRIP CODE SETTING screen will appear as in figure 2. Set the STRIP CODE and press .



(figure 2)

Note The STRIP CODE range is between 0 and 49. You must use the code indicated on the DANA glucose strip packaging for accurate results.

Note If the strip is removed from the test port while the display screen appears as in figure 1 or figure 2, you will be returned to the BASIC DISPLAY screen.



(figure 3)

Caution Please leave the DANA Diabecare IISG insulin pump and its test strips for 30 minutes in room temperature before use.

3) Verify that the display shows the OBTAIN BLOOD screen as in figure 3.



(figure 4)

4) Clean your fingertip with an alcohol swab. Obtain a blood sample with a blood sampling needle (figure 4).

5) Apply the sample blood on the end of the strip (figure 5).



(figure 5)

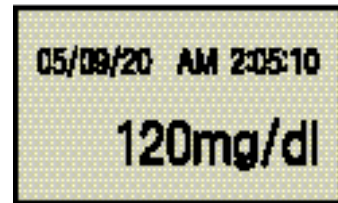
6) A 5 second countdown will appear as in figure 6. Once the countdown concludes the BLOOD GLUCOSE TEST RESULT screen will appear (date, time, blood glucose level) as in figure 7.



(figure 6)

Calculating your bolus dosage

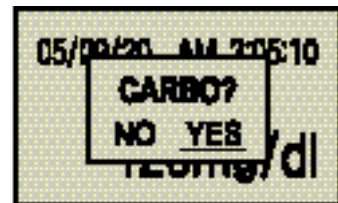
1) While in the BLOOD GLUCOSE TEST RESULT screen, press **S** and the CARB COUNTER prompt will appear as in figure 8.



(figure 7)

Note If you press **N**, you will be returned to the BASIC DISPLAY screen.

2) If you would like to calculate your bolus dosage, use **N** to highlight 'YES' and press **S**. The initial BOLUS CALCULATION screen will appear as in figure 9.



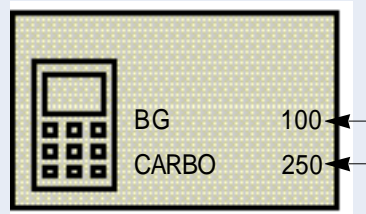
(figure 8)

Note If you press **S** while 'NO' is highlighted, you will be returned to the BASIC DISPLAY screen.

3) Use **N** to move between 'Blood Glucose' and 'Carbos', and use **▲** and **▼** to make the necessary adjustments. Press **S** to move to the next screen (figure 10).

Indicates your present blood glucose test result.

Indicates the amount of carbohydrates to be consumed prior to bolus delivery.



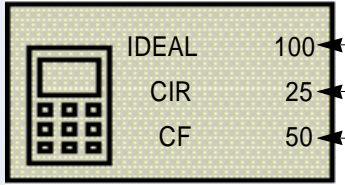
(figure 9)

4) Use **N** to move between 'Target Blood Glucose', 'CIR', and 'CF', and use **▲** and **▼** to make the necessary adjustments. Then press **S**. The CARB COUNTER RESULTS screen will appear as in figure 11.

Indicates your target blood glucose level.

Amount of carbohydrates capable of being processed by 1u of insulin.

Indicates insulin action rate



(figure 10)

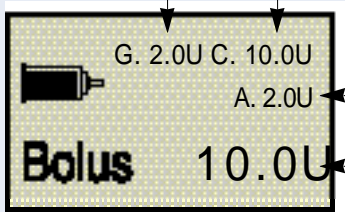
5) Press **S** twice to commence bolus delivery. You will hear the motor run and the screen will show that a bolus is being delivered.

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

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

Indicates the amount of insulin remaining in your body from your previous bolus amount.

Indicates the calculated bolus amount.



(figure 11)

Note Press **S** once and the word 'BOLUS' will be replaced by 'SELECT' a second later. The two words will flash back and forth every two seconds. In order to commence the bolus sequence you must press **S** the second time while the screen is showing 'SELECT'.

Note You will hear the pump beep for every 1.0 unit while a bolus is being delivered.

Note Press **▲** or **▼** twice to stop a bolus during delivery.

6) The pump will make a beep and return to the INITIAL DISPLAY screen upon conclusion of bolus delivery.

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

Note The DANA Diabecare IISG insulin pump will deliver an audio reminder 30 minutes after bolus delivery. To stop the alert, push any button once.

Glucose meter related error messages and troubleshooting

Note Please refer to the following in the event of a measurement error.

SCREEN	PROBLEM	CORRECTIVE ACTION
ERROR 1	Strip has been used more than once.	Retest with a new strip.
ERROR 2	Blood was applied prior to being prompted.	Retest with a new strip.
ERROR 3	Test environment is not within the allowed temperature range.	Retest with new strip in 30 minutes in adequate temperature.
ERROR 4	Blood viscosity is exceedingly high or blood sample size is not sufficient for testing.	Retest with a new strip. If the same error message repeatedly appears, contact your healthcare professional.

Warning Blood Glucose meter precautions

- Do not use a bent or damaged strip.
- Blood must not be applied to the strip prior to being prompted by the OBTAIN BLOOD screen.
- The blood sample size must be sufficiently large to ensure an accurate reading.
- Used strips cannot be reused.
- Glucose testing must be conducted within the allowed temperature range (10~40 C, 00 - 00F). In the event of a sudden temperature change, allow at least 30 minutes for the device to adjust to the ambient temperature.
- Test result may not be accurate if the viscosity of the blood sample is exceedingly high or the sample size is too small.

6. 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 bolusing while you consume your meal.

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

POSSIBLE CAUSE	SUGGESTED RESPONSE
Increased physical activity	Consult with your diabetes 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 diabetes 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 diabetes professional to make sure that your bolus is properly calculated as well as your basal rates.
Incorrect settings	Check your blood sugar regularly and check with your diabetes 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).

The main symptoms of DKA:

- 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, take an injection of fast - acting insulin and contact your diabetes professional.

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 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 diabetes professional to make sure that your bolus is properly calculated as well as your basal rates.

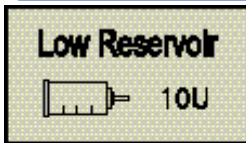
Problem / Correction Action

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	The DANA Diabecare IISR 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.

7. List of alarms and audible signals

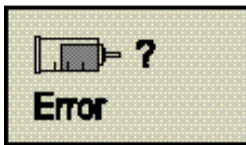
LOW RESERVOIR screen appears



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 that 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.

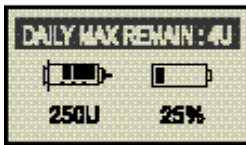
ERROR screen appears



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 (unkink tubing, check for air bubbles, etc.). If this does not resolve the problem change both the reservoir and infusion set.

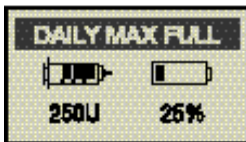
Warning If ERROR screen persists, contact technical support.

Daily Remainder



The daily remainder will appear if (Daily max - Daily infusion amount) < 10u. For instance if the daily max is set to 100 units and the total infusion amount for one day exceeds 90 units the remainder will appear on the screen.

Daily Max



Appears when the total infusion amount for one day has reached the daily max setting. If you require more insulin per day, please consult your healthcare professional to extend the daily max setting.

Low Battery



The low battery screen will appear when the remaining battery charge is no longer sufficient for the pump to operate. Please change the battery.

Note A continuous alarm will sound.

Check Glucose



Time to check your blood glucose level.

Note A melody will play for 30 seconds.

8. Specifications, symbols, warranty

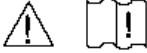










DANA Diabecare IISR Insulin Pump General Specifications

Size	3.04x 1.78x 0.79inch (77 x45x 20mm)
Net Weight	61g (including battery)
Insulin Syringe	3 mL (300 Units), insulin compatible reservoir
Meal Bolus Setting	0 - 80u
Basal Rate Setting	0 - 16.0 u/h
Basal Profile	24 Settings
Motor	Swiss Micro DC motor
Bolus Duration for 1 Unit	12 seconds
Power Supply	3.6V DC
Energy Saver	Sleep Mode, Screen Saver
Basal Delivery Increments	4 minute intervals
Integrated Circuit	Dual microprocessors for continuous cross checking

Classification and compliance with standards

- The DANA Diabecare IISR 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 pump will continuously operate according to the user defined settings.
- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
 - (1) this device may not cause harmful interference, and
 - (2) this device must accept any interference received, including interference that may cause undesired operation.
 Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Universal Symbols

SYMBOL	DEFINITION
	Read instructions for use.
	Sterilized with ethylene oxide
	Manufacture date
	Lot number
	Expiration date (Use by date)
	CE Marking (SGS UK)
	Do not re - use
	Adhesive plaster
	Serial number
	Isolated patient connection (IEC 60601 - 1 BF type)
	Tubing length (43 inch, 27 inch / 1100 mm, 700 mm)

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 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 manufacturers' 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 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 pump.
- Failure to follow the manufacturers' 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. Please consult owners' manual for full instructions.

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

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

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DANA *DIABECARE[®] II SR*

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