Diabecare Dana-i

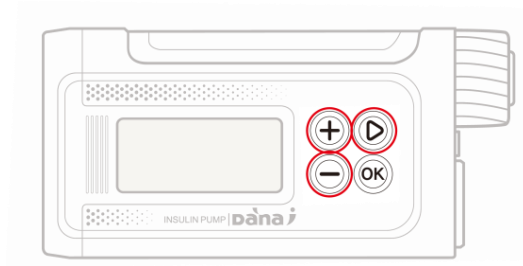## Professional Manual

Table of Contents

1.   Introduction

This manual is only to be used by certified DANA Insulin Pump trainers and healthcare professionals who manage patients on the DANA Diabecare Insulin Pump and are required to alter settings within the insulin pump configuration.   The information within this manual is supplementary to the IFU that is distributed with the DANA Insulin Pump.

Warning This is not for distribution to patients or end users.   This guide is intended only for pump trainers and diabetes educators.   The settings within DR MODE can adjust the safety parameters of the pump and must be changed carefully, as could lead to incorrect dose or delivery.
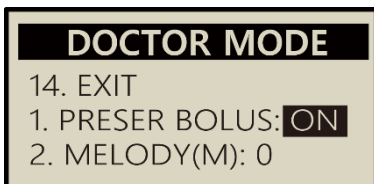
2. Doctor Mode

2.1 Accessing 'Doctor Mode'

1) Within **MAIN MENU,** press and hold ⊕,▶,⊖ three buttons at the same time.

2) The pump will request a PASSWORD, – enter **30XY** and press (OK).

Notice THE **XY** of 30**XY** is derived from the manufacturing day of the pumps. You can see the manufacturing date in the shipping Information menu on the pumps.

3) Unlocked - **DOCTOR MODE**
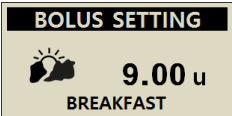
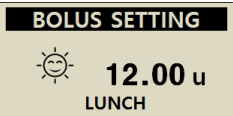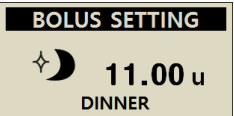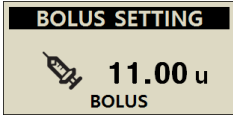## 2.2 What can be adjusted within 'Dcotor Mode'?

```
DOCTOR MODE
1.PRESET BOLUS: ON
2.MELODY(M): 120
3.BOLUS BLOCK(M): 0
4.BOLUS INC.: 1.00
5.BASAL INC.: 0.10
6.IDEAL BG: 100
7.ACTIVE INSULIN: 0.0
8. DEC.RATIO(%): 20
9.BASAL MAX(U/H): 3.3
10.BOLUS MAX(U)l: 40
11.DAILY MAX(U): 80
12.SAFETY RATIO: 100
13.BLOCK SENSITIVE: M
14.UTC SETTING
15.EXIT
```

1) PRESET BOLUS

Pre-set bolus feature is for a patient who has fixed-carbohydrate meals for breakfast, lunch and dinner.   Set and save 3 different insulin dosages for meal bolus of breakfast, lunch and dinner.

On – pre-set bolus is activated

Off – pre-set bolus is deactivated

Preset is ON			Preset is OFF
BOLUS SETTING 9.00 u BREAKFAST 01:00 - 09:59	**BOLUS SETTING** 12.00 u LUNCH 10:00 - 14:59	**BOLUS SETTING** 11.00 u DINNER 15:00 - 00:59	**BOLUS SETTING** 11.00 u BOLUS

(meal doses are set within the 'User Options' section)

2) MELODY
Melody feature is a reminder to check BG level post-prandial. Set the melody from 0-150 minutes in 10 minute intervals. Set the time to 0 (zero) to turn this reminder off.

3) BOLUS BLOCK
Bolus Block is a safety feature. Example if BOLUS BLOCK is set to 10 (minutes) it is impossible to enter a subsequent bolus for 10 minutes. When Bolus block is activated symbol (▷✕) will be shown on the initial screen.

Bolus Block can be set between 0 – 180 minutes in 10 minute intervals. To deactivate the bolus block feature set the time to 0 (zero).

4) BOLUS INC.
Bolus increment can be adjusted from 0.05, 0.1, 0.5, or 1.0 units.

(It is recommended to base the increments on TDD and how small the dose needs to be adjusted)

5) BASAL INC.
Basal increment can be adjusted to 0.01 or 0.1 u per hour.

(It is recommended to base the increments on TDD and how accurate basal adjustments are required.)

6) IDEAL BG

Ideal BG stands for 'Ideal Blood Glucose' – often referred to as target BG. Ideal BG can be set between 40 – 400 mg/dl (2.2 to 22.2 mmol). The number set is used within the BOLUS CALCULATOR to calculate the correction dose required to reach this target.

7) ACTIVE INSULIN

Active Insulin cannot be adjusted.

8) DEC. RATIO (%)

DEC ratio means decrement ratio of insulin. Often referred to as an hourly absorption ratio for insulin. For the DANA insulin pump to calculate for residual active insulin, the DEC RATIO to suit the individual patient needs to be set.

The DEC RATIO can be set from 5 – 50% in 5% increments. The default is set at 25% - which indicates that the normal rapid acting analog insulin (insulin lispro or aspart) is absorbed over 4hour duration.

(DEC RATIO equates to duration of Insulin Action)

9) BASAL MAX

This is a safety feature to set maximum limits of delivery for individual patients.

BASAL MAXIMUM can be set from 0.0units/hour to a maximum delivery of 16u/hr.

10) BOLUS MAX

This is a safety feature to set maximum limits of delivery for individual patients.

BOLUS MAXIMUM can be set from 0 u to a maximum single delivery of 80 units.

11) DAILY MAX

This is a safety feature to set maximum limits of delivery for individual patients.

The DAILY MAXIMUM can be set between 0u to 300u in 1u increments.

12) Safety Ratio

This is a safety feature to prevent over-dose of insulin from wireless commands (BT enabled devices). When the bolus is administrated more than the value of average of 3days bolus amount, the alarm will occur.

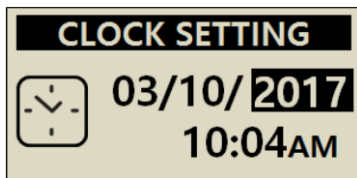The Safety Ration can be set OFF or 100 to 300 in 10 intervals.

If the Safety Ratio is set to 150, the pump will allow up to 150% of bolus amount of 3 days average from the remote enabled devices.

13) BLOCK SENSITIVE

Is a variable sensitivity for any occlusion within the pump or infusion sets. Occlusions occur due to crystallization, blood or infusion set kink age. The Block sensitivity can be adjusted between H(high) 2-3u, M(medium) 3-5u, or L(low) 5-8u of blocked delivery and is usually adjusted for total daily dose.

14) UTC SETTING

Set default UTC Time (Date and time) used in the [OPTION] – [CLOCK SETTING].
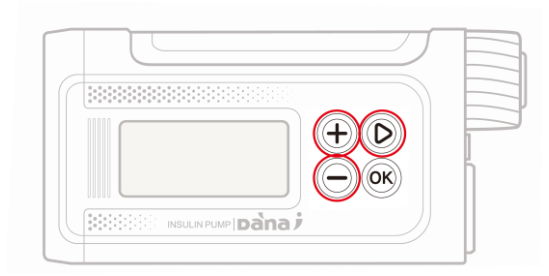

15) EXIT

Save all setting and exit the menu.

It is necessary to exit from the Dr. Mode to ensure that all/any changes are saved. When exit is selected a pop up screen appears with a question "SAVE SETTING?" – select YES to save changes, select NO to revert to the main patient user section of the pump without saving any changes made within the Dr. Mode settings.

3. Password Mode

3.1 Accessing 'Password Mode'

1) Within **MAIN MENU,** press and hold the ⊕,▶,⊖ three buttons at the same time.
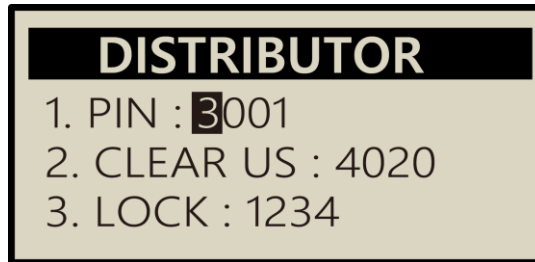

2) The pump will request a PASSWORD, – enter **3571** as the following sequence (1→ 3→5→7) and press (OK).

Notice Must input the last number (1) first, if not - cannot access 'Distributor Mode'.

3) Unlocked - **PASSWORD MODE**

3.2 What can be adjusted within 'Password Mode'?

```
┌─────────────────────────────────┐
│ ████ DISTRIBUTOR ███████████████ │
│ 1. PIN : █001                    │
│ 2. CLEAR US : 4020               │
│ 3. LOCK : 1234                   │
└─────────────────────────────────┘
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1)   PIN : 3001

This is a password to enter the Doctor Mode. *(not recommended to change).* The password is derived from the manufacturing day of the pumps. Refer to the Chapter 2.1
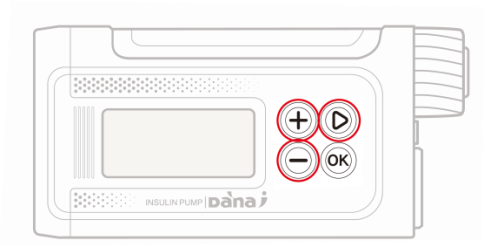
2)   CLEAR US : 4020

This is a password to delete the history of the day total dose. Useful to reset or clear the already delivered daily dose, input 4020 on the password screen after press the three buttons (⊕, ▶,⊖) at the same time.
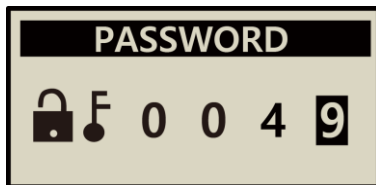
3)   LOCK : 1234

This is the personalized user password set within the pump. The password is derived from the manufacturing date of the pumps. Refer to the User Manual of the DANA-i pump.

4. Distributor Mode

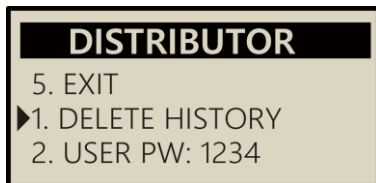## 4.1 Accessing 'Distributor Mode'

1) Within **MAIN MENU,** press and hold the ⊕, ▶, ⊖ three buttons at the same time.
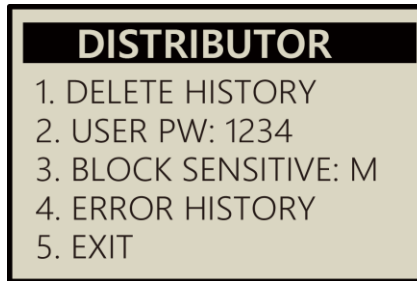

2) The pump will request a PASSWORD, – enter **8949** as the following sequence (4→9→8→9) and press (OK).

   Notice Must input the third number (**4**) first, or cannot access the 'Distributor Mode'.

3) Unlocked - **DISTRIBUTOR MODE**

4.2 What can be adjusted within 'Distributor Mode'?

```
┌─────────────────────────────┐
│ DISTRIBUTOR                 │
│ 1. DELETE HISTORY           │
│ 2. USER PW: 1234            │
│ 3. BLOCK SENSITIVE: M       │
│ 4. ERROR HISTORY            │
│ 5. EXIT                     │
└─────────────────────────────┘
```

1)   **DELETE HISTORY**
This is a function to delete all history within the pump.

2)   **USER PW**
This is a function to check the personalized user password set within the pump. In case of forgetting the password, the distributor can review and/or reset the password here.

3)   **BLOCK SENSITIVE**
Is a variable sensitivity for any occlusion within the pump or infusion sets. Occlusions occur due to crystallization, blood or infusion set kink age. The Block sensitivity can be adjusted between **H**(high) 2-3u, **M**(medium) 3-5u, or **L**(low) 5-8u of blocked delivery and is usually adjusted for total daily dose.

4)   **ERROR HISTORY**
This is a function to review the history of error. The distributor can check the detailed error history within the pump.

5)   **EXIT**
Save all settings and exit the menu.

5. Pump Silence Option

The DANA Insulin Pump is a popular pump used within clinical trials for closed loop or artificial pancreas systems. Some of these advanced algorithms deliver many boluses (referred to as SMB or Small Micro Bolus). The Audio tune that the DANA Insulin pump announces at the finish of a bolus / could be considered annoying.   Within the ENGINEERING MODE of the DANA Insulin pump – it is therefore possible to adjust the bolus audio tone from melody to beep or silence.

Warning This is not for distribution to patients, end users or diabetes educators.   Access to ENGINEER MODE is restricted to Aftersales Technicians and DANA pump Certified Engineers only.   The settings within ENGINEER MODE can adjust the safety parameters of the pump and must be changed carefully, as could lead to incorrect dose or delivery.

For access to ENGINEER MODE, please contact SOOIL Development Co Limited or an authorized DANA distributor.

MEMO

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