













## Summary of Electromagnetic Compatibility Test

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
Electrostatic Discharge Immunity	EN 61000-4-2: 2009 IEC 61000-4-2: 2008	Injection mode	Enclosure	DC 3.6V	±8Kv/ Contact ±2, ±4, ±8, ±15Kv/Air
Radiated RF Electromagnetic Field Immunity	EN 61000-4-3: 2016+ A2:2010 IEC 61000-4-3: 2006+ A1:2007+A2:2010	Injection mode	Enclosure	DC 3.6V	10V/m 80MHz – 2.7GHz 80% AM at 1kHz
Immunity to Proximity Fields from RF wireless Communications Equipment	EN 61000-4-8: 2010 IEC 61000-4-8: 2009	Injection mode	Enclosure	DC 3.6V	Table 9 in IEC 60601-1-2:2014
Power Frequency Magnetic Field Immunity	EN61000-4-8: 2010 IEC 61000-4-8: 2009	Injection mode	Enclosure	DC 3.6V	30 A/m 50Hz & 60Hz

## Explanation of Universal Symbols

	Follow Instruction for Use		CE Marking
	Caution! Refer to safety-related notes in the manual accompanying this instrument		European Authorized Representative
	Manufacturer		Disposal (WEEE marking)
	Date of manufacture		Direct current
	Lot Number		International Protection code Dustproof degree: 2 Waterproof degree: 0
	Keep dry		Medical Device

IFU-390-EN (rev.9\_230313)



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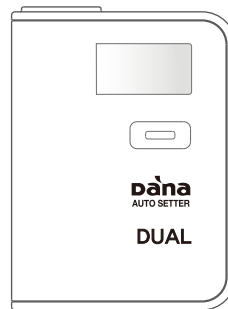


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EN

**dana**  
**AUTO SETTER DUAL**



**CE**  
1639


# Instructions for Use of DANA Auto Setter Dual

## Indication for Use

The DANA Auto Setter Dual is intended for adjusting the length of linking screw, measuring the amount of insulin in the reservoir and sending it to the pump. It must be used with DANA Diabecare Insulin Pump.

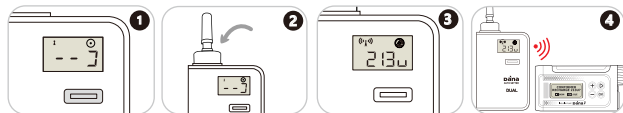
※The "DANA Auto Setter Dual" is referred to as "Auto Setter" in this Instructions for Use.

## Precaution

1. Read this instruction for use carefully and completely before using this device for the first time.
2. Auto Setter must be upright on a firm flat surface during usage.
3. Replace the battery when the low battery symbol  is displayed.
4. Auto Setter must not be used in the presence of intense electromagnetic fields, such as CT scan, MRI or X-ray.
5. Patients must not open the Auto Setter housing or handle any internal components.
6. The outside of the Auto Setter should be cleaned monthly with cloth moistened with water.
7. Auto Setter radiates radio frequency energy that may cause harmful interference to other devices.
8. Remove the battery for long-term storage.
9. Store and use the Auto Setter in a dry and dust-free environment.
10. Avoid direct sunlight when using AutoSetter.

## How to use

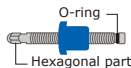
Refer to the Instructions for Use of the DANA Insulin Pump for detailed Refill process.



- ① Turn on Auto Setter by pressing the button.
- ② "Insert reservoir" mark like **1** will be shown on the screen.
- ③ Insert a reservoir filled with insulin and connected to linking screw into the Auto Setter like **2**.
- ④ Press the button to start measuring.
- ⑤ The measured amount **i** displayed on the screen like **3**.
- ⑥ The value will be transferred to the insulin pump while blinking the antenna icon, and the transferred value will be shown on the pump screen like **4**.

## Notice

1. Cover the reservoir cap when using Auto Setter to prevent insulin leaks out.
2. If there is no input for 10 seconds, the Auto Setter will go into the sleep mode to save the battery.
3. There could be a discrepancy of up to 2~5 U between the actual amount and measured amount.
4. Use the Linking Screw with an O-ring. If not, it may cause wide discrepancies in the refill volume.



## Trouble Shooting

Follow the troubleshooting depend on Error Code on your screen.

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

## Specification of the DANA Auto Setter Dual

Specification		
Size	73*54*25 mm	
Weight (g)	76 g (Including battery)	
Insulin Reservoir	3 mL(300 U) - DANA 3cc Syringe	
Power Supply	3.6 V DC (1/2AA Battery)	
Operating Current	60 mA	
Operation Time	1 minute	
Operation Condition	Temperature	- 5 °C ~ 40 °C
	Relative Humidity	30 % ~ 75 %
	Atmospheric Pressure	700 hPa ~ 1060 hPa
Transport and storage Condition	Temperature	- 20 °C ~ 50 °C
	Relative Humidity	0 % ~ 95 %
	Atmospheric Pressure	500 hPa ~ 1060 hPa
Measuring range	20 U ~ 300 U	
Accuracy	± 5 U	
Software Version	ASN-2.0.	