

MEDISHINE

Wireless Handy Type Filler Injector

User Manual

This is a medical device.

The absolute powerhouse
of filler injectors

MEDISHINE

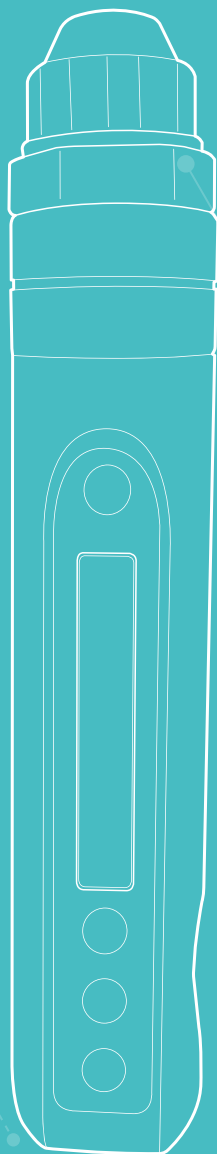


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1 About the user manual

1.1 Foreword

Please read this manual to the end and follow its instructions before using the product.

Note

- Some illustrations in this manual are provided to help understand how to use the product better. They may not be the exact representation of the actual product.
- Do not discard this manual. Keep it for later use.

1.2 Copyright

The copyright and intellectual property rights for the contents and illustrations in this manual all belong to SBMED, Inc.

Accordingly, any act of using, copying, disseminating, or distributing without prior written consent from SBMED, Inc. is strictly

prohibited as it constitutes an infringement of the intellectual property rights of SBMED, Inc.

Liability for any misuse or modifications of the patent rights of this product shall entirely lie with users.

Information covered in this manual is information that SBMED, Inc. can trust.

However, SBMED, Inc. is not liable for any situations arising from inaccurate contents or typographical errors.

2 Safety

This user manual uses the following safety signs.



Warning

This sign indicates warning. It is associated with the potential damage to the product or irreversible damage to patients.



Caution

This sign indicates caution. It is associated with the potential damage to the product or harm to patients.



Prohibition

This sign indicates prohibition. It is associated with the potential damage to the product or harm to patients.



Mandatory

This sign indicates “Refer to the user manual.”

2.1 Precautions for use



This product is a medical device that should be used only after fully understanding how to use it.



Precautions

- Use only the charging adaptors and wireless foot switches supplied by the manufacturer.
- Do not use the product for purposes other than its intended purpose. It may cause product failure and damage.

2.2 General warnings

Warnings

- Do not use or keep fire, combustibles, and flammables near the product. It may cause explosion or fire.
- Take safety precautions not to get pierced or punctured when attaching the needle to the syringe.
- Keep out of reach of children. The product may cause injury.

2.3 General prohibitions

Prohibitions

- Excessively high temperature, fire, or even explosion may occur due to improper replacement of lithium polymer battery by inexperienced persons.
- Users must not arbitrarily disassemble or alter the product. The product warranty will not cover damage caused by users' disassembly or alteration of the product.
- To avoid possible impact caused by high-frequency interference, such as electrosurgical and high-frequency surgical devices, do not use this product in combination with applicable high-frequency devices.
- Do not use this product on patients such as infants, toddlers, and pregnant women. If it is necessary to use this product under inevitable circumstances, do so only under the guidance of a physician.

3 Product description

3.1 Intended use

Infusion pump

MEDISHINE (SD-100) is an electric infusion pump that injects a specific drug dose into a patient.

3.2 Features

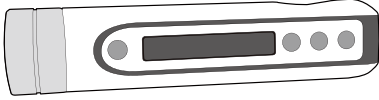
- MEDISHINE (SD-100) is used in hospitals and intended to be used by medical professionals.
- MEDISHINE (SD-100) can be operated by the wireless foot switch.
- MEDISHINE (SD-100) is an internally powered device with a rechargeable battery.

3.3 Specifications

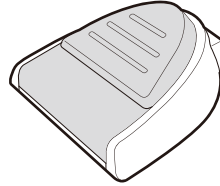
Manufacturer	SBMED, Inc. / Republic of Korea
Category	Infusion pump / Medical device
Item Name	MEDISHINE
Model No.	SD-100
Box Size	21cm * 14cm * 11cm
Gross Weight	900g
Components	Wireless hand-held main unit + wireless foot switch + main unit cradle + charging adaptor + syringe-retaining caps (2 types) + syringe size-converting heads (3 types)
Battery	Li-Polymer 400mAh (7.4V) 2EA
Charging Adaptor	Input : 100-240 Vac, 50/60 Hz, 20VA, Output : 12 Vdc, 1.0 A

3.4 Appearance

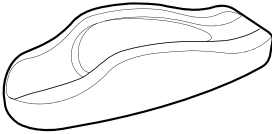
3.4.1 Components



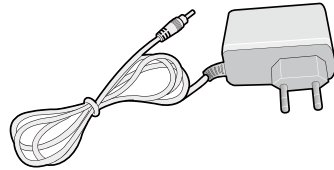
Main unit



Wireless foot button



Main unit cradle



Charging adaptor



1 cc



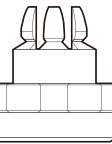
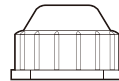
3 cc



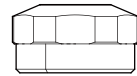
5 cc



10 cc (Option)



1~3cc



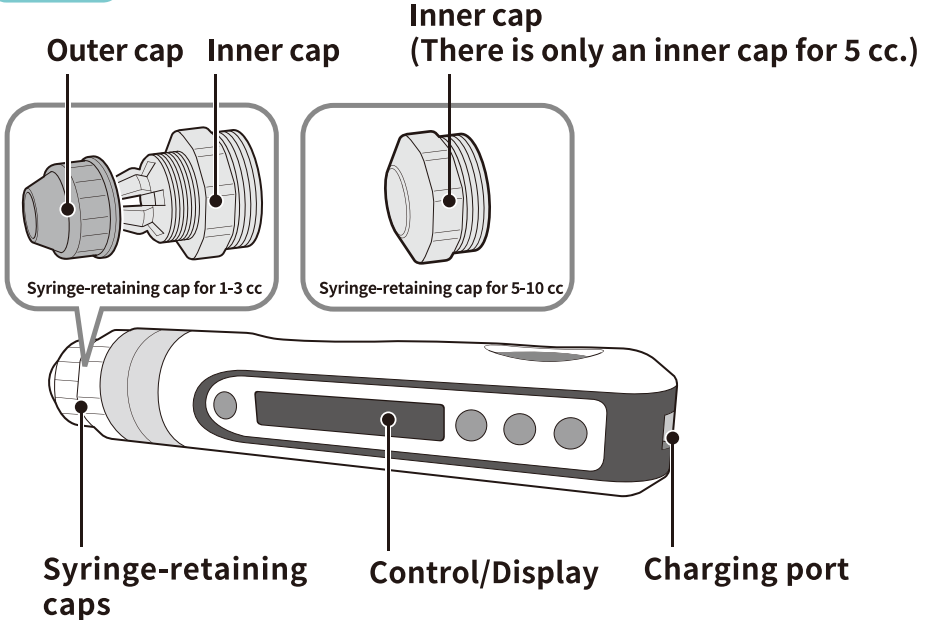
5~10cc

Syringe size-converting heads

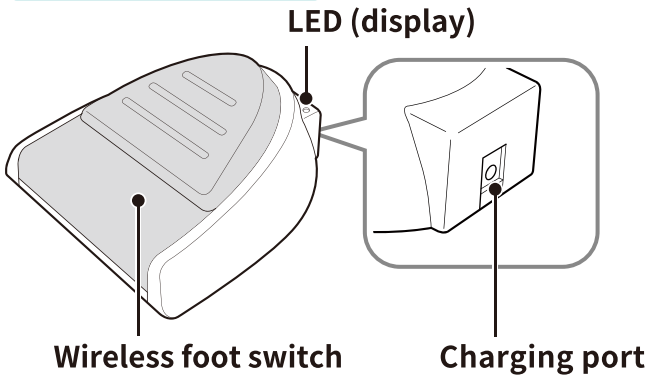
Syringe-retaining caps

3.4.2 Name of each part

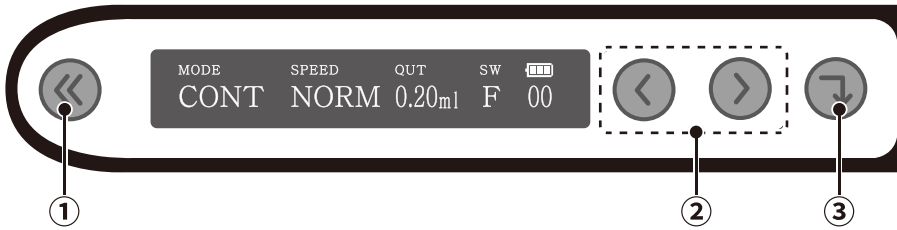
Main unit




Wireless foot switch



3.4.3 Control panel



①  **Hand injection button**

Inject filler (drug).

- The wireless foot switch is disabled when the hand injection button is enabled.
- The hand injection button is disabled when the wireless foot switch is enabled.

②   **Syringe plunger adjustment & menu navigation buttons**

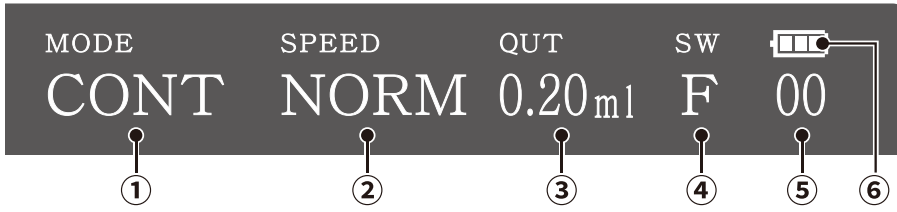
- Move the syringe plunger forward or backward.
 - ◀ : Move the syringe plunger forward
 - ▶ : Move the syringe plunger backward
- Navigate through menus or select options.

③  **Settings button**

Set values for the menu.

- Press and hold the Settings button for 3 seconds to reset the number of shots.
- Press and hold the Settings button for 6 seconds to return to the initial screen.
- Switch to use screen by pressing the Settings button in power saving mode.

3.4.4 Display



- ① **MODE menu**
 - **DOSE** : Automatically inject the amount set in the **QUT** menu when pressing the hand injection button or wireless foot switch.
 - **CONT** : Inject continuously while pressing the hand injection button or wireless foot switch.

- ② **SPEED menu**
 - **SLOW** : Set the injection speed to slow.
 - **NORM** : Set the injection speed to normal.
 - **FAST** : Set the injection speed to fast.

- ③ **QUT menu**
 - It applies only when using **DOSE** mode.
 - The injected dose can be set between **0.01 mL** and **1.00 mL**.
 - The settings in the **QUT** menu are the reference values tested by SBMED, Inc.

Test Conditions : Non Cross-Linked Hyaluronic Acid(2ml), 30G 2/1 needle
 - The injected dose may vary depending on the preparations of the product used for injection, syringe size, and thickness of the injection needle or filler cannula. Please use after conducting sufficient testing and setting a dose to inject.
 - The RPM of linear motor per shot when setting the dose mode is the same. That is, a consistent amount is injected per shot.

- ④ **SW menu**
 - **H** : Set this when injecting using the hand injection button.
 - **F** : Set this when injecting using the wireless foot switch.

- ⑤ **Display cumulative shot count**

It displays the shot count.

















- ⑥ **Display remaining battery**

It displays the amount of the remaining battery.

- ⑦ **RECHARGING**

When this message appears, use the product after charging it for over an hour.

3.5 Symbols

Symbol	Description	Symbol	Description
	Follow the user manual. (safety sign)		Prohibited (safety sign)
	General precautions, warning (safety sign)		Recommendation
	Manufacturer		MFG. Date
	Serial No.		Electromagnetic radiation
	Temperature range		Protection against vertically falling water drops
	Humidity range		Disposal
	Atmospheric pressure range		Moisture warning
	Class 2 device		Mounting type B

4 How to Use

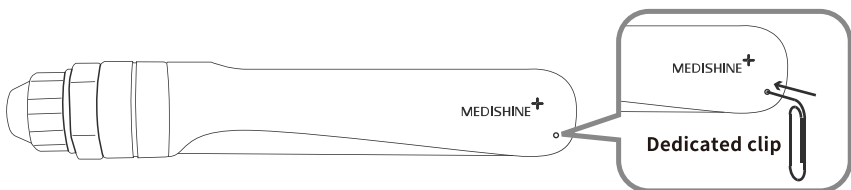
4.1 Turn on the product using the power cut-off switch

- 1) Open the product box.
- 2) Check for a dedicated clip in the box.

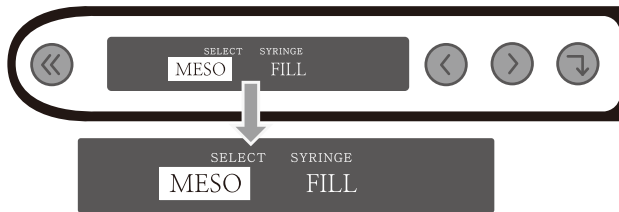


Dedicated clip

- 3) Insert the straight part of the dedicated clip all the way into the small hole under the MEDISHINE logo on the main unit to turn on the power cut-off switch.



4) Check whether the OLED on the main unit display is turned on.



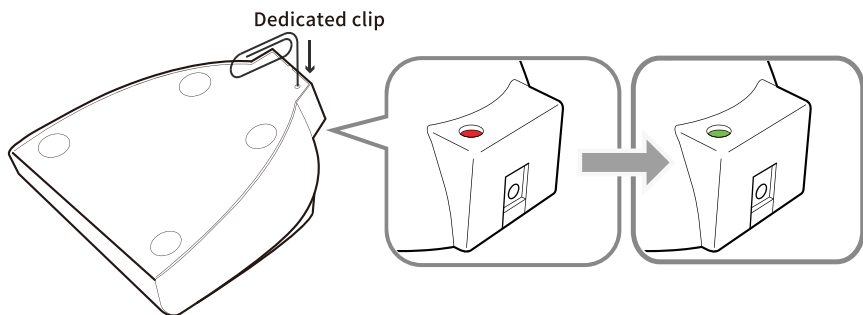
MESO : Use for general drug injection

FILL : Use for filler injection

5) It indicates that the product is working properly when the OLED on the main unit display turns on. If the OLED on the display does not turn on, repeat the step described in 3).

TIP See Page 14 for information on how to set up the initial screen.

6) Insert the straight part of the dedicated clip all the way into the small hole on the bottom of the wireless foot switch to turn on the power cut-off switch.



7) The product works properly when the LED on the top of the wireless foot switch lights up sequentially in red and green.

TIP The product works properly if the top LED lights up in green upon pressing the wireless foot switch.

8) When the wireless foot switch does not work properly, repeat the step described in 6).

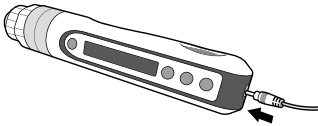
4.2 What to prepare before use

4.2.1 Charging

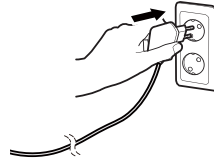


It may not work properly if the charge level is not enough. Be sure to check the charge level when charging the product before use.

1 Plug the charging cable into the charging port of the product.



2 Plug the charger into an outlet.



It will not charge when the power cut-off switch is off.

TIP The display turns on when connected to the charger, even if the power cut-off switch is off.

However, the display turns off as soon as it is disconnected from the charger. (Not charging)

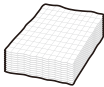
4.2.2 Syringe assembly

What you need

Items you need to prepare other than the product are as follows :



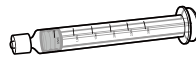
Gauze



alcohol swab



gloves



drug to be injected



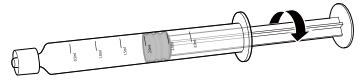
1-pin needle or cannula for filler

(*The items above are not included in the product.)



SBMED, Inc. is not liable for assembly issues due to errors in syringe types and sizes. Please check the compatibility before use.

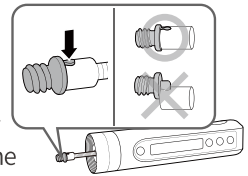
- 1** Turn the plunger counterclockwise to remove it from the syringe.



- 2** Insert the 1 cc, 3 cc, or 5 cc syringe size-converting head into the product according to the syringe size.



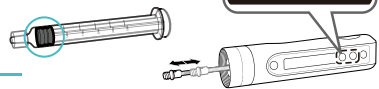
- Insert the size-converting head after pushing the syringe plunger forward at a sufficient distance.
- When assembling the size-converting head, hold the syringe plunger on the main unit with both hands to avoid wobbling. It may lead to main unit failure.



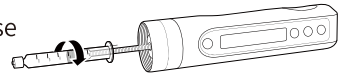
- 3** Use the plunger adjustment button to adjust it to an appropriate length.



- Adjust it similarly to the position of the rubber part inside the syringe.



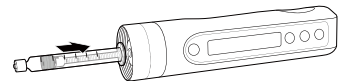
- 4** Turn the rubber inside the syringe and the syringe size-converting head counterclockwise to connect.



- 5** Push the syringe in until the tip is tightly in contact with the main unit.



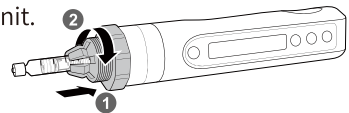
- Injecting medication won't go smoothly if the tip of the syringe is not tightly in contact with the main unit.



- 6** Insert the inner cap into the syringe and turn it clockwise to secure it onto the main unit.



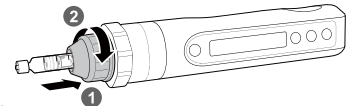
- Only the inner cap is provided for 5 cc.



- 7** Insert the outer cap into the syringe and turn it clockwise to fix it onto the inner cap.



- Do not tighten too much. Turning the cap too much may damage the mounted syringe.



- 8** Remove the protective cap of the syringe to attach the needle.

4.3 How to use

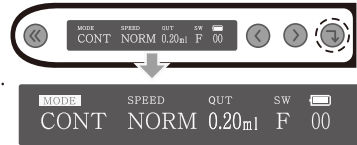
In power saving mode (the OLED screen on the display is turned off), press the Settings button to enter the standby mode to finish the settings in the following procedure



The display screen turns off and enters the power saving mode after 3 minutes of inactivity.

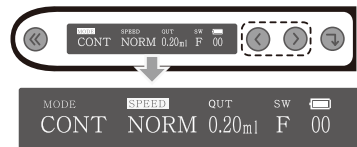
1 Press the Settings button.

- A cursor appears in the menu when pressing the Settings button in standby mode.
- The previously used settings are memorized when switching to standby mode from sleep mode.



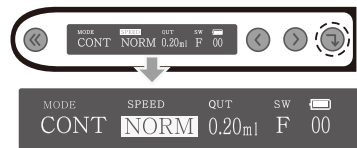
2 Use the forward or backward button to choose the menu.

- Refer to Page 8 for a detailed explanation of each menu.



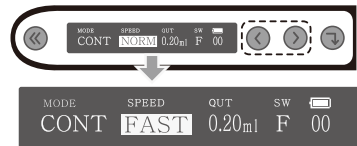
3 Press the Settings button.

- Pressing the Settings button while a cursor is on the menu will move the cursor to the settings value item.



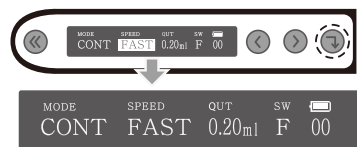
4 Use the forward or backward button to set the options for the corresponding menu.

- Refer to Page 8 for details about the options in each menu.



5 Press the Settings button to finish the settings.

- Repeat steps 1 to 5 to edit the values of other menus.



4.4 How to return to the initial screen while in use

4.4.1 Return to the initial screen while in use

1 Press and hold the Settings button for over 6 seconds.

2 Select MESO or FILL using the forward or backward button.



- Switch to FILL when injecting filler.
- Switching to FILL increases the motor power, but it will increase the noise and reduce the injection speed.

4.5 Precautions for use

- 1) Read the user manual before using the product.
- 2) Do not alter the product arbitrarily.
- 3) Contact the manufacturer when the product breaks down without arbitrarily attempting to repair it.
- 4) Use the product with safety in mind at all times.
- 5) Use only the charging adaptors and wireless foot switches supplied by the manufacturer.
- 6) Stop using the product immediately if it breaks down.
- 7) If the product works abnormally or does not work properly while in use, contact the customer service of SBMED, Inc. so that the necessary measures can be taken.

5 Maintenance

5.1 How to clean and store

- 1) Store the product at room temperature, avoiding places with high temperature and humidity.
- 2) Do not store the product in places susceptible to atmospheric pressure, temperature, humidity, wind, etc.
- 3) Store the product in places safe from vibration or impact.
- 4) Do not store the product in places where chemicals are stored or gases are generated.

5.1.1 Cleaning



Do not immerse the product in water or spray water on it for cleaning.

- Wipe the product with a soft, dry cloth if contaminated with drugs or impurities.
- If severely contaminated, wipe the product with a slightly damp cloth.

5.1.2 Storing



- Do not use or store the product at high temperatures above 60 °C. It may cause product failure.
 - When storing the product for an extended period without using it (over 100 days), make sure that the batteries are not completely discharged. Lithium polymer batteries are damaged if completely discharged.
-

5.2 Product disposal



This product contains batteries. The product must be disposed of following the applicable laws and regulations of the subject country.

The absolute powerhouse
of filler injectors

MEDISHINE

MEDISHINE

Wireless Handy Type Filler Injector



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