

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

pmda No. 21 January, 2011

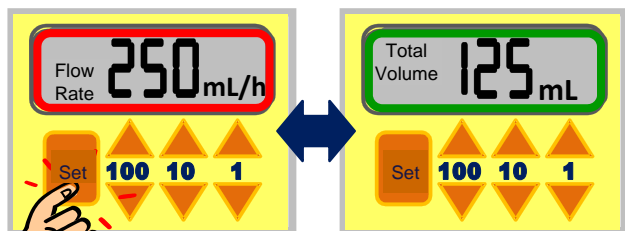
Precautions in flow rate programming of infusion pumps

POINT Key points for safe use

(Case 1) The order was to give the patient 250 mL of anticancer drug at a flow rate of 125 mL/h (for 2 hours) using an infusion pump. However, the drip infusion was completed after 30 minutes.

1 Precautions when using an infusion pump

- Reconfirm the contents of programmed "Flow Rate" and "Total Volume" displayed on the infusion pump and in medication orders.



Please be careful of misprogramming!
For types of machine where displays of "Flow Rate" and "Total Volume" are switched over with a button, data are liable to be entered incorrectly!

Medication order
for drip infusion
Total volume: 250mL
Flow rate: 125mL/h



**No, Wait!
Check the display
one more time!**



Make sure to double check the letters and numbers you've entered as "Flow Rate" and "Total Volume" after programming. Medication orders may not always be written in the same order as the infusion pump programming.



Built-in Safeguards to prevent misprogramming of flow rates

Separate screen displays

The flow rate and total volume are displayed simultaneously on the two display screens.



Total Volume

Alarm to remind reconfirmation

Beep!

The flow rate value is greater than the total volume's!

Flow Rate

Products equipped with safeguards against medication errors has safety features to remind reconfirmation of the pump programming, such as alarms that goes off when the programmed flow rate value is greater than the total volume's.



Examples of products equipped with built-in safeguards for medication errors

TECTRON CO., INC.



Infusion Pump
FP-970



Infusion Pump
FP-1200s

JMS Co., Ltd.



JMS Infusion Pump
OT-808

Med-Tech Inc.



Otsuka Infusion Pump
OT-707

Top Corporation



Top Infusion Pump
TOP-2300



Top Infusion Pump
TOP-3300



Top Infusion Pump
TOP-2200



Top Infusion Pump
TOP-7100

Atom Medical Corporation



Atom Infusion Pump AS-700

Terumo Corporation



Terufusion® Infusion Pump TE-261



Terufusion® Infusion Pump TE-161S



Terufusion® Infusion Pump TE-131

Daiken Medical Co., Ltd.



Coopdech Infusion Pump

Please consider switching to products equipped with built-in safeguards against medication errors such as tubing guide, free flow protection, and battery status indicator in addition to safeguards against misprogramming.

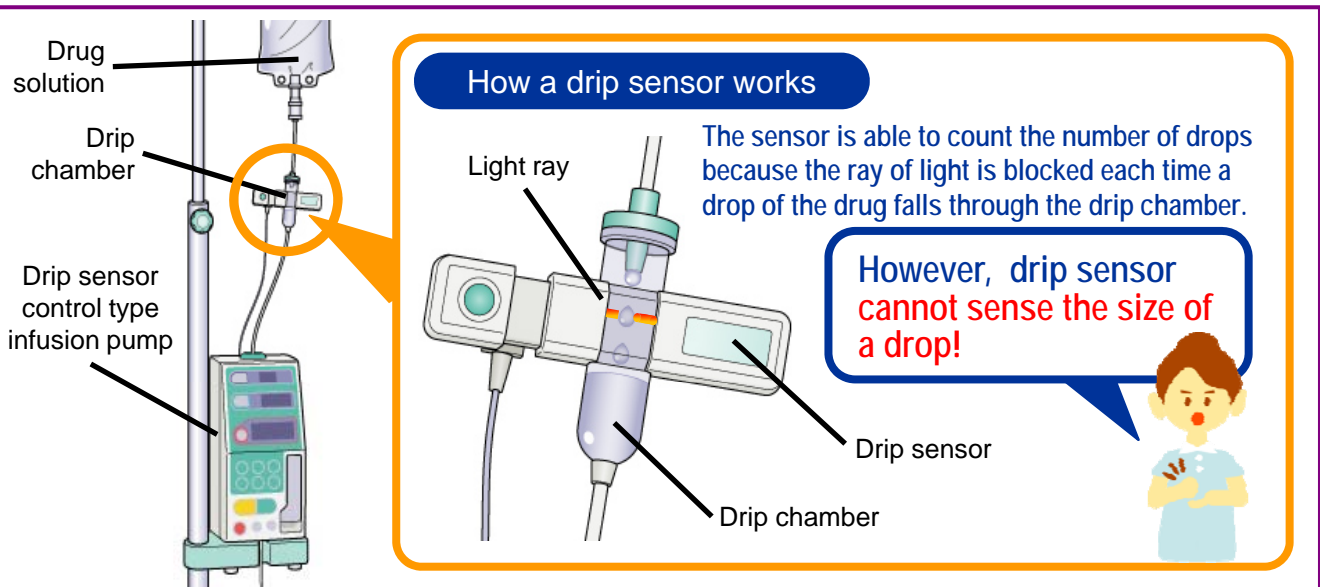


* A list of infusion pumps that meet the criteria for products with built-in safeguards against medication errors is available at the Japan Medical Devices Manufacturers Association website <http://www.jmed.jp/jp/ikiko/safety-use/index.php> (Japanese only).

(Case 2) 250 mg of cyclosporine injection containing surfactant was mixed into 250 mL of physiological saline solution. It was administered at a flow rate of 10 mL/h. However, some of the drug solution still remained even at the planned time of completion.

2 Precautions when using a drip sensor control type infusion pump

- For some drugs, the size of drop differs because of the influence of excipients such as surfactants, so adjust (correct) the flow rate when using drip sensor control type infusion pumps.

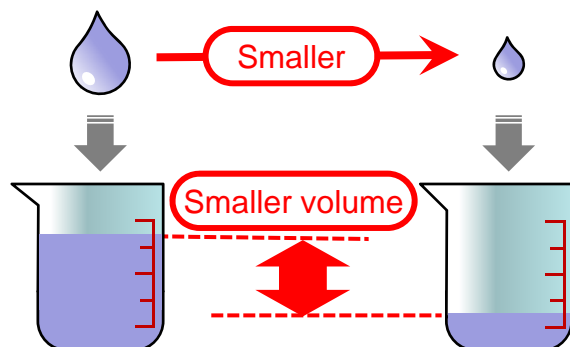


The cause of the underdose

The drops from drug solutions containing surfactant, etc. are small, so, even if the drugs are administered at the ordered flow rate, the actual volume of drip infusion ends up being smaller.

Planned infusion volume

Actual infusion volume



When using drip sensor control type infusion pump, **consult a pharmacist about the characteristics of the drug.** Also, please consider using flow rate control type infusion pump.



[Precautions]

4. When using drip sensor control type infusion pumps

When drip sensor control infusion pump is used, the actual infusion volume becomes smaller than the programmed value. To administer the drug accurately, there is a need to correct it to the proper flow rate. (Because of the surfactant effects of polyoxyethylene castor oil that is an excipient of this drug, the size of a drop inside the drip chamber is believed to become smaller.)

**This part is indicated in Japanese.*

Precautions such as shown on the left are described in package inserts of cyclosporine injections.

(Excerpts from the package insert of Sandimmun for i.v. infusion 250mg (Novartis Pharma K.K.))

The Ministry of Health, Labour and Welfare (MHLW) has issued notifications that are related to the issues in this PMDA Medical Safety Information No. 21.

- "Preventive Measures against Medication Errors Related to Infusion Pumps, etc." PMSB Notification No. 0318001 dated on March 18, 2003

Information on this notification is available at the Pharmaceuticals and Medical Devices Information website (in Japanese)

<http://www.info.pmda.go.jp/iryujiko/file/20030318.pdf>

About this information

* PMDA Medical Safety Information is issued by the Pharmaceuticals and Medical Devices Agency for the purpose of providing healthcare providers with clearer information from the perspective of promoting the safe use of pharmaceuticals and medical devices. The information presented here has been compiled, with the assistance of expert advice, from cases collected as Medical Accident Information Reports by the Japan Council for Quality Health Care, and collected as Adverse Drug Reaction and Malfunction Reports in accordance with the Pharmaceutical Affairs Law.

* We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future.

* This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals.