

Medfusion® 3500/4000 Operator's Manual Insert

AFFECTED MODELS:

Medfusion® 3500 (Version 6.0.0); Medfusion® 4000 (Version 1.5.0, 1.5.1, 1.6.0, 1.6.1, 1.7.0)

WARNING

THE PROGRAMMING SEQUENCE DESCRIBED BELOW MAY LEAD TO INAPPROPRIATE DELIVERY

Programs a Bolus or Loading Dose

1. Programs the Bolus or Loading Dose
2. Initiates the Bolus or Loading Dose
3. Interrupts the Bolus or Loading Dose
4. Primes Using the Pump
5. Resumes the Bolus or Loading Dose **instead of beginning a new infusion**

INSTRUCTIONS TO CLINICIANS

For any reason, when a bolus or loading dose delivery is interrupted and mechanically primed using the PRIME FUNCTION, cancel the bolus or loading dose and begin a new infusion to avoid potential inappropriate delivery.

Users of the Affected Devices listed above must not resume an interrupted bolus dose or loading dose if mechanical priming using the PRIME FUNCTION has been performed during bolus dose or loading dose interruption. After priming, when prompted to continue the interrupted bolus dose or loading dose, only continue medication delivery by beginning a new infusion.

This Operator's Manual Insert has been prepared as a supplemental communication to customers impacted by Smiths Medical's voluntary Recall of Affected Models listed above to highlight steps taken when a bolus or loading dose is interrupted to avoid **potential under-delivery or over-delivery of infused medication, which could potentially result in serious injury or death.**

Scenario Description:

A Continuous infusion is programmed, and either:

1. A Loading dose is programmed and started, **OR**
2. A Bolus dose is programmed and started.

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