CURLIN MEDICAL

Addendum to the *PainSmart*™ IOD

Ambulatory Infusion Systems

User Manual

360-9043-REV A

CURLIN MEDICAL, INC.
15751 Graham Street
Huntington Beach, CA 92649
Phone 714 893-2200
Fax 714 894-2602
www.curlinmedical.com

For 24-hour Clinical or Technical Support call toll free:
888-287-5999

THIS DOCUMENT REPLACES ALL PREVIOUS REVISIONS OF THIS ADDENDUM

Revision C
Re-order Number: 360-9043-ADD-02 Rev. C

Purpose of this Addendum

This addendum provides patients, technicians, and caregivers additional information important to the safe and effective use of the Curlin *PainSmart*™ IOD ambulatory infusion system.

The Curlin *PainSmart*™ IOD infusion system has been designed to meet/exceed all international standards for ruggedness and performance associated with an ambulatory medical product in normal use. In recent months, Curlin has seen an increase in the number of pumps involved in over-infusion or free-flow incidents where the pump has been dropped with the door open resulting in deformation of the door and a loss of delivery accuracy.

To help reduce the number of these incidents and to improve the prominence of cautionary statements already in the operator's manual, Curlin is making the following modifications to the operator's manual (P/N 360-9043).

In addition, the Volumetric Delivery Test in the User Manual has been improved to provide better test resolution in determining accuracy and the possibility of a free-flow condition. Therefore, this addendum also modifies the method for executing the Volumetric Delivery Test.

Page 5

Caution Bullet Number 2 on page 5 of the User Manual has been elevated to a Warning. The text has not been modified. It reads as follows.

- Visually inspect the pump, pumping chamber and administration set before use. Do not use any pump or administration set that appears to be damaged or tampered with or if there is any indication of improper function.

Caution Bullet Number 13 on page 5 of the User Manual has been elevated to a Warning. The text has been modified as follows:

- Do not subject the pump to dropping or hitting against a hard surface. If at any time the pump is dropped or hit, the pump must be checked for volumetric accuracy prior to reuse. The pump can only be brought back into service if the volumetric accuracy test passes per the user manual. If the pump fails volumetric accuracy it must be returned to Curlin Medical for evaluation.

Page 116

Replace the Purpose Statement with the following:

Procedure for Checking Pumps Between Patients

Purpose

This procedure is provided for use by caregivers to ensure pumps meet all critical performance specifications prior to use of the product on new patients. This procedure is for use by technicians to inspect, test, and prepare a pump for use by a new patient. The test checks for volumetric accuracy and all pump safety systems. Also, various parameters are initialized.

This procedure is intended to be used by technicians familiar with operation of the Curlin *PainSmart*™ IOD infusion pump.

Note: This procedure does not replace the recommended Annual Preventive Maintenance. The pump should receive preventive maintenance by a qualified technician at least annually.

Outpatient/Home Care/ Alternate Care Site Environment

If the pump is used in an outpatient, Home Care, or Alternate Care setting, the pump must be checked between patients using the following procedure.

Inpatient/Hospital Environment

Curlin Medical offers delivery sets with an anti-siphon valve for use in clinical situations where in between patient checks may not be practical.

Use of the supplied anti-siphon valve removes the recommendation for in between patient testing when determined by the institution to be impractical. In this event, Curlin recommends establishment, by the institution, of practical regular intervals for volumetric testing using the following procedure to ensure the pump continues to meet specifications.

Page 117

Replace the Volumetric Delivery Test with the following:

Refer to the picture below when executing the following instructions.

1 **Volumetric Delivery Test**:

a Install a new primed Administration Set in the pump and latch the door.

b Connect the up-stream side of administration set to a water source 12 inches +/-2 inches above the pump.

EPI		IV	
Pre Rx:		Pre Rx:	
UNITS:	ml	UNITS:	mg
Admin Rt:	EPI	CONC:	1 mg/ml
Load Dose:	0.0 ml	Admin Rt:	IV
MedLIMITS:	OFF	Load Dose:	OFF
NEXT?	YES	MedLIMITS:	OFF
		NEXT?	YES
Prescription:		Prescription:	
BAG VOL:	100 ml	BAG VOL:	100 ml
RATE:	0 ml/hr	RATE:	0 mg/ml
Pt Bolus:	9.9 ml	Pt Bolus:	9.9 mg
BOLS INT:	1 min	BOLS INT:	1 min
#BOLS/hr	1	#BOLS/hr	1
DONE?	YES	DONE?	YES

c Connect the downstream side of the administration set to a volumetric accuracy measurement device (i.e. a calibrated scale or burette) at the same level as the pump +/-2 inches.

d Program one of the following Infusions based on the default in the pump:

e Start the pump by pressing RUN button.

f Press the BOLUS key to start a bolus.

g When the 9.9 ml infusion is over, observe the amount volume infused as measured on the measurement device. Passing measurement is: 9.4 g to 10.4 g (9.4 ml to 10.4 ml).

h When Infusion complete occurs verify that the Audio Alarm beeps and that the Green LED is flashing.