CURLIN 6000 TRAINING & QUICK REFERENCE GUIDE FOR BETWEEN PATIENT USE

This procedure should be followed prior to use on all patients who manage their own infusion therapy (typically referred to as Home Infusion Therapy) or when a pump has been reported as having been impacted on, (i.e. pump was dropped, something was dropped on the pump, or pump otherwise forcefully came in contact with another object). It is intended for use by clinicians/technicians who are responsible for the inspecting, testing, and/or preparing of pumps prior to patient use.

(Note: These procedures are for Curlin 6000 CMS and 6000 CMS IOD pumps only; PainSmart pumps will need to follow slightly different procedures.)

PUMP MAINTENACE

The full written procedure can be found in the Moog Curlin Infusion User Manual for the 6000 CMS™ and 6000 CMS™ IOD™ on pages 160-163. The purpose for checking pumps is to ensure pumps meet all critical performance specifications prior to use of the product on new patients. The test checks for volumetric delivery and all pump safety systems. Also, various parameters are initialized.

Required Equipment

The following equipment is required for this procedure:

- A NEW Administration Set (old or used sets are not suitable for the volumetric delivery and pressure measurements tests. If the set contains a filter, sterile saline or sterile water should be used).
- Volumetric measurement device (i.e. calibrated digital weight scale, burette or syringes.)
- Beaker with clean, fresh water or I.V. container.

Procedure

This procedure does not replace the recommended annual preventive maintenance. The pump should receive preventive maintenance by a qualified technician annually.

1. Clean the pump with a soft cloth dampened with a designated antiseptic, disinfectant solution or a solution of household bleach diluted 9:1 with water. Be sure to clean all surfaces, including the pumping chamber (full instructions can be found in the Moog Curlin Infusion User Manual for the 6000 CMS™ and 6000 CMS™ IOD™ on page 157).

   Inspect pump for physical damage. Check all case surfaces for cracks. Open the pumping chamber door. Examine the finger seal to confirm that no cuts or tears exist. Confirm that the door is well aligned by closing it with no unreasonable interference.

Verify that the Power and Bolus/Data connectors are securely mounted on the case (no loose nuts). Verify that all labels are legible and in good condition. Check that Keypad is securely attached to case and that no corners are pealing up. Verify that the Battery Door is in place and that the Battery Contacts in the Battery Compartment are not deformed.

(Note: if any damage is found during visual inspection of the pump, do not perform this procedure. Instead give the pump to a qualified Curlin Service technician for pump service).

2. Perform a volumetric delivery test:

   a. Install a new primed Administration Set in the pump and latch the door (the set should not have an Anti-Siphon Valve). Test sets are also acceptable (obtainable from Moog Medical Devices). A "primed" set is a set filled with fluid (in this case, de-ionized or distilled water). Refer to User Manual (P/N 360-9009) for instruction on priming the set.

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

   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 the following CONTINUOUS Infusion (see User Manual if programming instruction is needed):

      UNITS: mL
      DELAY: OFF
      Medlimit OFF
      NEXT? YES
      BAG VOL: 100 mL
      VOL TBI: 10.0 mL
      RATE: 125 mL/hr
      TIME: 0:04 HH:MM
      KVO Rate: 0.0 mL/hr
      DONE? YES

   e. Start the continuous therapy running by pressing the RUN button.

   f. When the 10 mL infusion is over, observe the volume infused as measured on the measurement device. Passing measurement is: 9.5 g to 10.5 g (9.5mL to 10.5mL).

   g. When "Infusion Complete" occurs verify that the Audio Alarm is beeping and that the Green and Red LEDs are flashing.

3. Check All Safety Systems:

   a. **Low Downstream Occlusion** - Repeat the same Continuous Infusion as above. Enter the Option Menu screen and confirm that the Down Occlusion level is set to LOW. Start the infusion and while the pump is running pinch off or close the downstream side of the administration set (between the pump and the distal end of the set). Confirm the pump goes into Down Occlusion alarm. Open or clear the downstream occlusion and confirm the pump resumes infusion.

   b. **High Downstream Occlusion** – Enter the Option Menu screen and change the Down Occlusion level to HIGH. Again, pinch off or close the clamp on the downstream side of the administration set. Confirm the pump goes into Down Occlusion. Open or clear the downstream occlusion and confirm the pump resumes infusion.

   c. **Upstream Occlusion** - Resume the infusion (press Pause, then YES to Resume then RUN). Pinch off or close the upstream side of the administration set (between the pump and the fluid source). Confirm that the pump goes into an Up Occlusion alarm. Open or clear the upstream occlusion, press Pause then Resume the infusion.

   d. **Door Sensor** - With infusion in progress open the door latch and observe ALARM DOOR OPEN OR SET NOT INSTALLED.

   e. **Set Sensor** – Remove the administration set from the pump and reinstall it so that the flow stop and tubing guide are not in the pumping chamber. Close the door latch and start an infusion by pressing the RUN key. Observe "***ALERT*** DOOR OPEN or SET NOT INSTALLED" will occur. Reinstall the set properly and close the door latch.

   f. **Air In Line Sensor** - Resume the infusion. Enter the Option Menu screen and set the AIL SENS (AIR IN LINE sensitivity) to 0.1mL. With the pump running introduce an air bolus of approximately 0.5mL into the fluid path at the input side of the pump. Once approximately 0.1mL of air has past the AIL detector, an ALARM AIR IN LINE will occur. Press pause, Yes to Resume, then enter the Prime Screen. Prime the air bolus past the AIL sensor, press Yes to exit, then resume the infusion.

   g. **Auxiliary Alarm** - With the pump running observe the Vol INF (volume infused on the run screen) and disconnect the pump from all power sources (unplug the AC Adapter eliminator and remove one C-Cell battery.) Observe that the Auxiliary Alarm System is activated, with the Red LED and Beeper on constant (not intermittently beeping). With the battery still out of the pump, press the ON/OFF button to turn off the auxiliary alarm. Replace the battery in the battery compartment and turn on the pump. Resume the therapy and confirm that the infusion continues where it stopped due to Auxiliary Alarm occurrence.

CLEARING THE PUMP

Clearing the pump (as well as verifying/resetting the date/time) MUST be performed PRIOR to programming the pump for each patient's use. The Curlin 6000 pump can be used for multiple

therapies on a single patient and retains these therapies until removed. Therefore, it is an important safety feature to remove/clear all previous Rx from the pump before programming. Clearing previous Rxs will ensure that only the current patient's Rx is in the pump. Patients will then only have access to the Rx programmed for them and will not have to choose a Therapy Mode when hanging new medication containers when they have only one Rx programmed for them.

Also, having the correct date and time in the pump is important. All infusion data is recorded based upon the date and time set in the pump. Therefore, initial date and time validation should be performed as well as when any other factors affect the date and time (ex. Daylight Savings Time).

Procedure

1. Turn the pump Off and back On (The Biomed Setup Menu can only be accessed from the opening screen).

2. While pump is performing Self Tests confirm that the pump is set to the correct Date and Time. Setting the correct date and time when needed is covered in this procedure.

3. Press the down arrow key to cursor downward until Biomed Setup is highlighted (it is not visible on the opening screen).

4. Press the Yes key to enter or confirm. An access code is required to enter the biomed menu; enter the access code and you are now in the biomed setup menu.

5. Observe the Pump Maintenance Date at the top of the Biomed Menu to ensure adequate time for the next patient use.

6. Set the Lock Level to OFF in the CHANGE LOCK Menu

7. To clear all previous and current Rx from the pump, press the down arrow key until "CLEAR Pt DATA/RX" is highlighted and press YES. NOTE: The difference between CLEAR RX and CLEAR Pt DATA/RX is CLEAR RX will clear all previous and current Rx including the lock level. CLEAR Pt DATA/RX will do the same except it will not clear the lock level.

8. Press YES again to confirm to clear.

9. When the date/time is **correct,** exit the Biomed Setup Menu by pressing the down arrow key until Yes is highlighted in the DONE? field, press YES to exit and the pump is ready for patient use.

10. When the date/time is **incorrect,** set the date/time by pressing the down arrow key until "DATE and TIME" is highlighted and press YES. It is important to note that you must clear all previous RX from the pump *before* the pump will allow you to change the date and time.

    a. Set the pump clock to a 12- or 24-hour clock. (Press NO to change and YES

to confirm each data field).

b. Set the correct time and press Yes to confirm.

c. Set the correct date (if needed) and press Yes to confirm. The date is six digits in the format of MM/DD/YY.

d. Press YES to accept.

e. If you are ready to exit the Biomed Menu, press Yes to the DONE? field to exit and the pump is ready for patient use.