CURLIN MEDICAL

Safely Managing Infusion ...and Information

Pump Recertification DFU

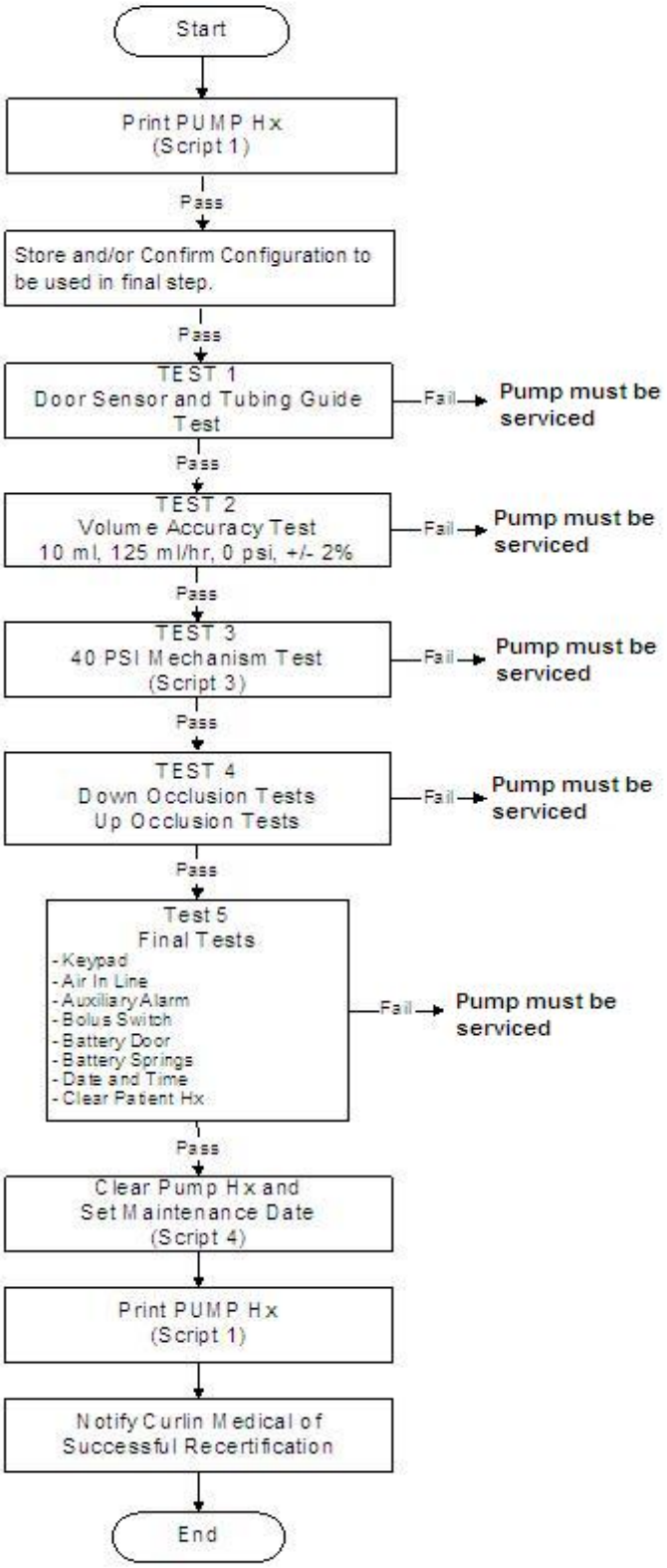

Figure 1: Self Recertification Procedure

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1.0 OVERVIEW

1.1 Purpose:

This document defines the procedure to be performed when a pump is being re-certified.
This procedure is intended to be executed on pumps that have exceeded or are within 2 months of their Maintenance date.

1.2 Scope:

This procedure is applicable to all 2000 Series (software revision R40), 4000 Series (software revision R5F through R5H, R6, R6B, and R6C), and 6000 Series (software revision 6R5, 6R7, 6R7A, and 6R9) Ambulatory Infusion Pumps being recertified.

1.3 Reference Documents:

Self Recertification Traveler 350-9256

1.4 Definitions:

PRU: The Pump Recertification Utility is a software program provided by Curlin Medical for use with this procedure. The PRU makes possible certain pump functions, which are necessary for recertification, that otherwise could not be executed by a Biomedical Technician.

Equipment:

- Self Recertification Kit (350-1107)

  Pump Recertification Utility (PRU) (350-7021)

  Tubing Guide gauge: (340-5056)

  Calibrated Test Set Non-Sterile (340-4038)

  4-Way Stopcock Valve (C74-19008)

  Pump-PC Data Interface Cable (340-2011)

  Instruction PC Data Interface Download Cable (340-9081)

  Non-DEHP Microbore Extention Set with M/F Luer (340-4109)

  Non-DEHP Microbore Set Non-Sterile (340-4023)

  Self Recertification Traveler (350-9256)

  Recerticiation DFU (350-9257)

  Dual Male Luer Lock Adapter (C74-14020)
- AC Adaptor 360-2022Kit or 2 C-cell Batteries
- Calibrated Pressure Gauge(s) capable of -10 PSI to 50 PSI

- Calibrated Scale capable of 250 Grams
- Bolus Switch: 340-2005
- Beaker capable of 200 ml
- Personal Computer with Microsoft Windows operating system: Windows 2000 or Windows XP.

Note: Necessary components for performing self recertification can be obtained from Curlin Medical. A self recertification kit 350-1107 is available from Curlin Medical. Copies of the latest revisions of travelers, COC's and DFU's can be printed from PRU's CD and/or Curlin Website.

1.5 Regulatory Requirements

Organizations performing this recertification are required, in compliance with FDA's QSR and JCAHO Standard of equipment maintenance to:

1. Assign competent employees and, qualified service personnel to assemble, test and/or maintain its infusion systems

2. Perform service and preventative maintenance in accordance with all applicable local, state, and federal requirements

3. Provide continuing education and technical training to its employees to assure competency levels are maintained. Education will include any changes or upgrades to equipment as well as notification of inherent problems, product alerts, or recalls that might be identified and published by Curlin Medical

4. Provide Curlin Medical with a completed traveler 350-9256, for each successful recertification performed.

2.0 SOFTWARE

Refer to flow chart (Figure 1) for an outline of this procedure.

Time setting of pump should be set to 24-hour format. Refer to pump user manual for instructions.

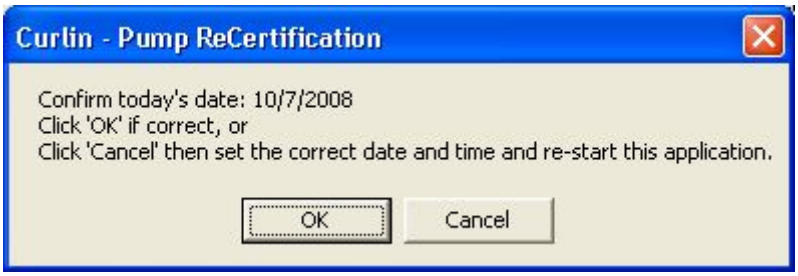
Pump may be powered using 2 C-cell Batteries or using the AC Adaptor 340-2004 / 340-2022.

2.1 Install the Pump Recertification Utility Software (PRU)

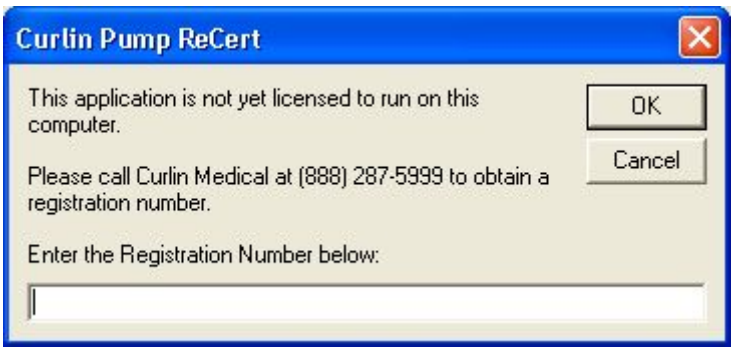
If the Pump Recertification (PRU) software has not been installed on the PC that will be used to assist in the recertification of Curlin pumps, obtain a copy of the PRU from Curlin Medical. Install the PRU program onto the PC.

2.2 Configure PRU

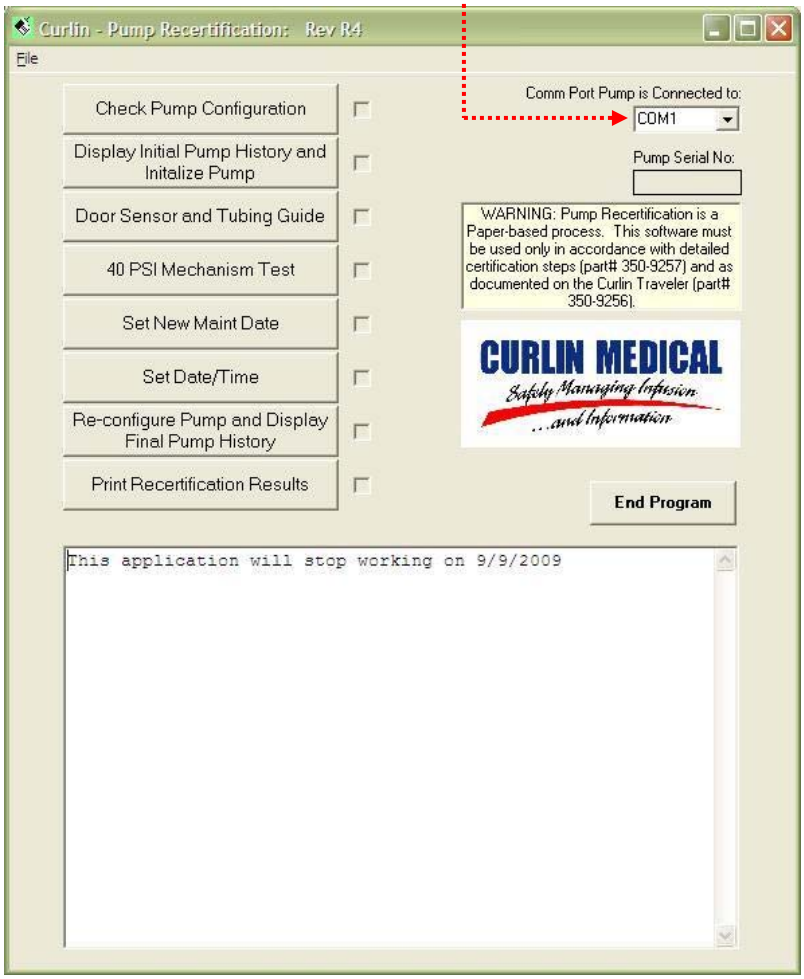
Start the PRU program by double clicking the icon. Verify the correct date and click OK.



Type in the registration code. The registration code can be obtained by calling Curlin Customer service. The code changes every day and is good for 1 year after installing.



Set the correct COM port.



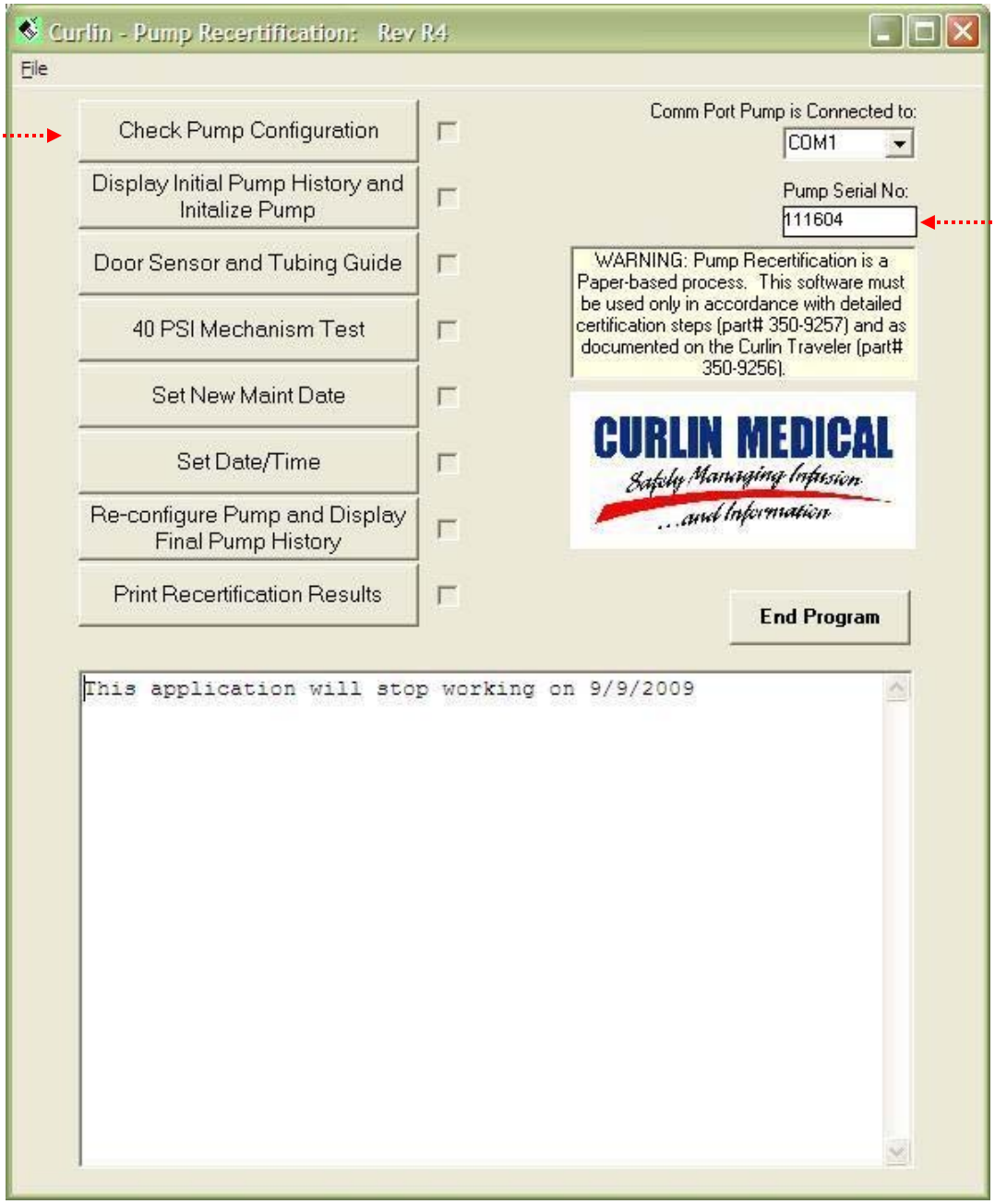
3.0 RECERTIFICATION PROCEDURE

3.1 Connect the Pump to the PC

Using the Data Interface cable for PC (340-2011), connects the PC Serial Port connector to the Pump Bolus/Data connector of the pump to be recertified. Turn the pump ON. The user must not disconnect the pump from the PC until commanded to do so by the PRU (normally at the end of this procedure.)

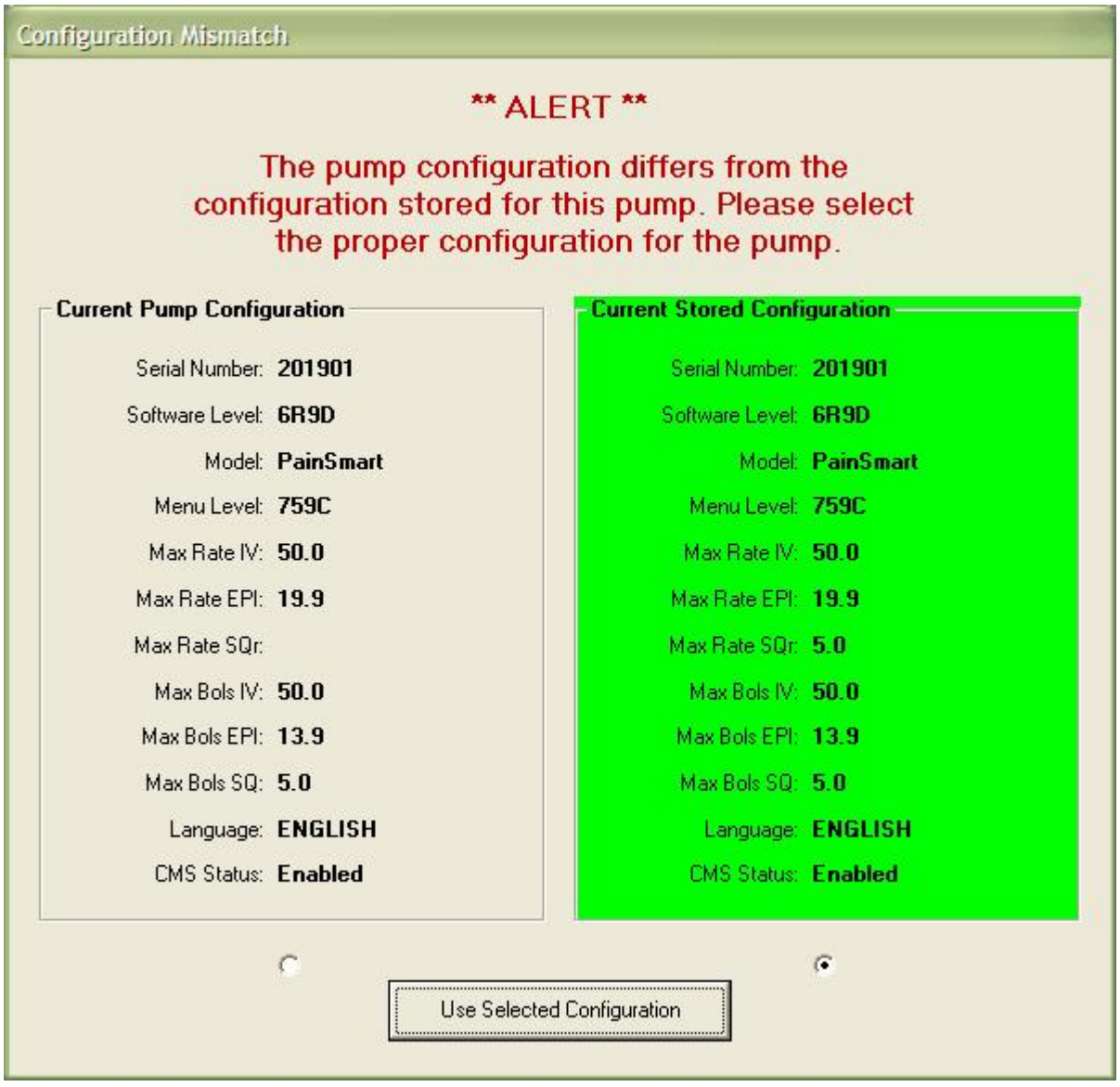
3.2 Check Pump Configuration

From the PRU, select "Check Pump Configuration". Observe the "Pump Serial Number" is displayed on the PRU screen. (Note: if pump is a 2000 Plus, the PRU will require technician to cause the pump to enter the BIOMED Setup menu by entering the Clinician Code. In addition, the technician must manually enter the pump Serial Number. If pump is a 4000 Plus, the PRU will require technician to cause the pump to enter the BIOMED Setup menu by entering the Clinician Code.) When the serial number of the pump is displayed, the pump is ready to be processed.



When the self-recertification process is executed, the pump is initialized in order to set it into a state where all tests can be run. In some cases, if the process is interrupted at critical moments, the pump will not go through the process to set it back to its original configuration. For this reason, the pump's initial configuration data is stored in a file and so the pump can be reconfigured even in the event of an interruption in the process.

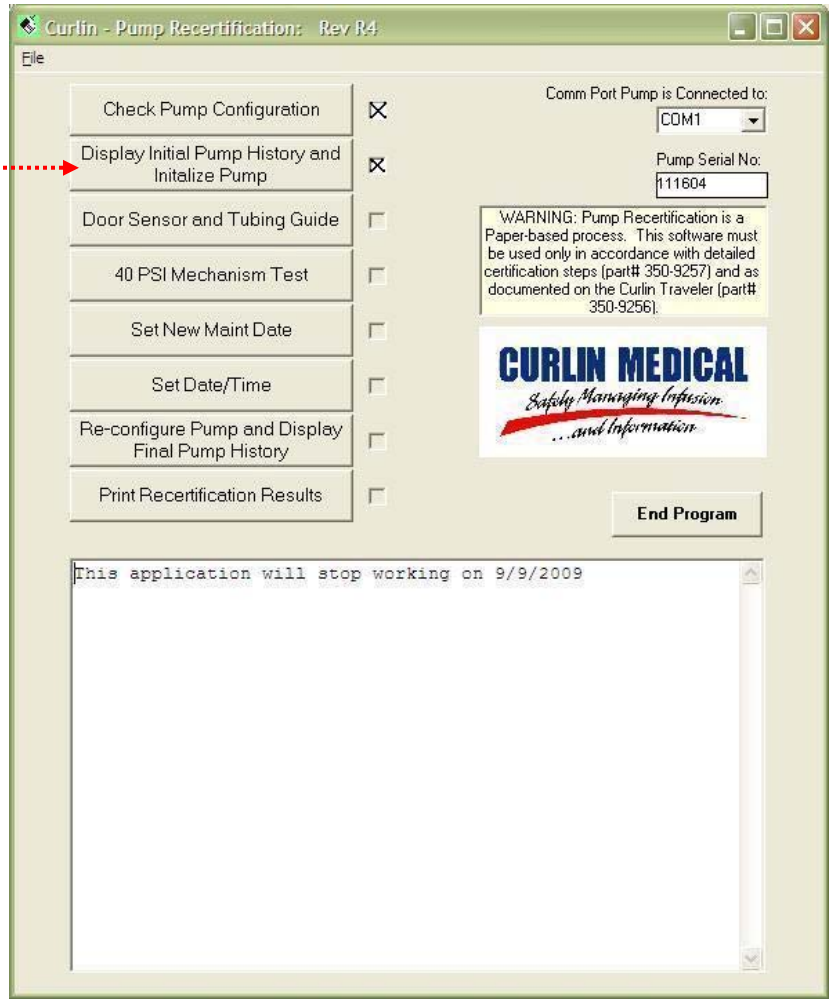
When the pump's current configuration differs from the file's configuration for the pump, a window will appear offering the option to choose the desired configuration (see below). All pertinent data will be presented to facilitate an informed decision regarding the intended final configuration of the pump.



3.3 Display Initial Pump History and Initialize Pump

From the PRU, select "Display Initial Pump History and Initialize Pump". Observe the Pump Hx being downloaded from the pump. Clear the alarm on the pump by pressing the 'Run/Pause' key when instructed by the PRU.

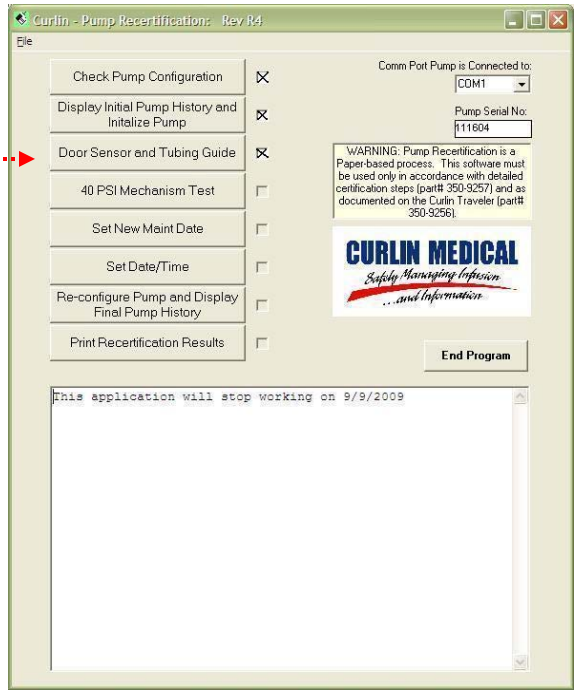
Note: If the pump is an E-Config (PainSmart), the PRU will initialize the pump. So wait until initializing has finished.



NOTE: The pump history will print during the last step "Print Recertification Results"

3.4 TEST 1 - Door Sensor and Tubing Guide

From the PRU, select "Door Sensor and Tubing Guide". Once the pump enters the Factory Menu, an Alert on the pump will occur. Execute the following key sequence on the pump:

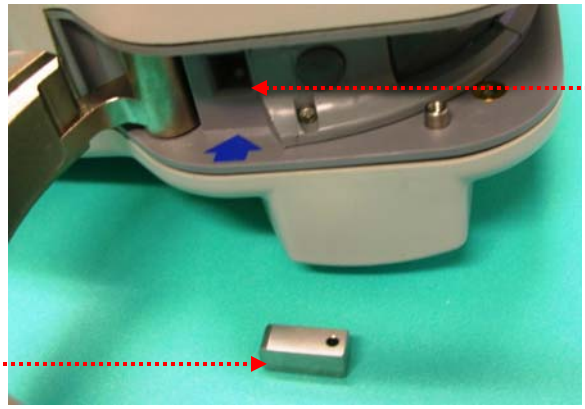


- Press the DOWN ARROW key once to arrive at the ACCEPT? field.
- Press the NO key once to arrive on the Factory Menu.

- Press the UP ARROW key approximately 4 times until DISP DOOR SEN is displayed in reverse video.

- Press the YES key once to display the door sensor status.

Insert the Tubing Guide Gauge (340-5056) into the pump tubing guide cavity. Close the pump door and latch.



Observe the LCD screen indicate “DOOR: CLOSED”.

Open the Latch and Door. Observe the LCD screen indicate “DOOR: OPEN”.

Remove the Tubing Guide Gauge from the pump and close the Door and Latch. Observe the LCD screen indicate “DOOR: OPEN”.

Document result on Traveler.

If the pump does not meet these criteria:

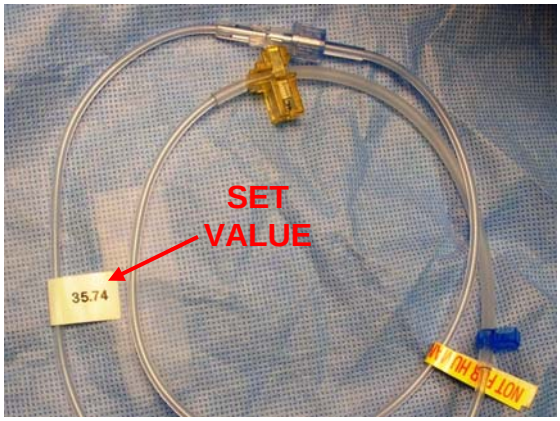
1. Did you test the DOOR: CLOSED with the Tubing Guide Gauge insert all the way into the pump tubing guide cavity and Latch closed? If no, retest with Tubing Guide Gauge fully inserted and Latch closed all the way.

If you answer yes for the above question and the pump still fail the test fail, it must be serviced by a trained service tech.

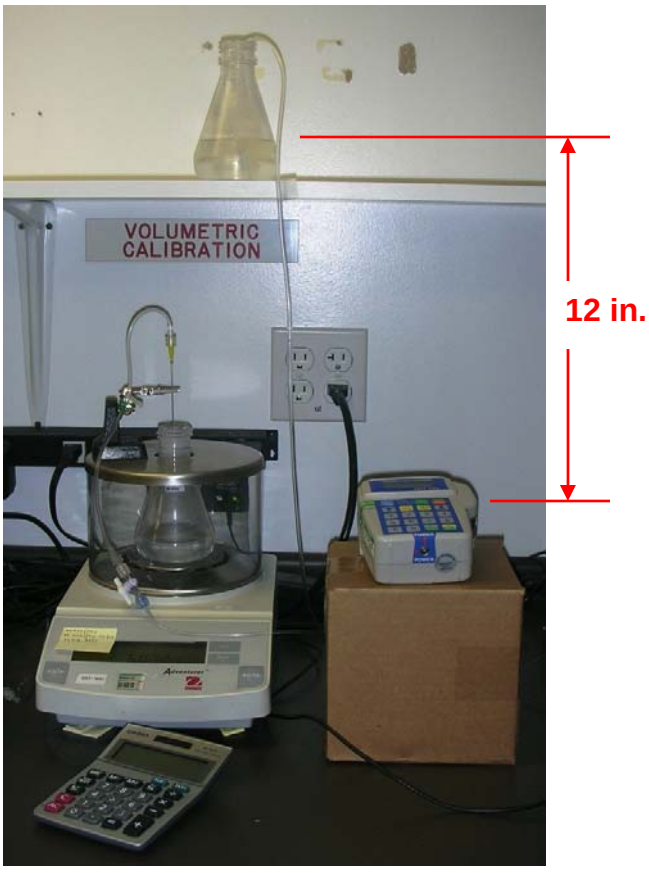
3.5 TEST 2 - Volume Accuracy Test

Turn the pump OFF and back ON.

Install a Calibrated Test set (340-4038) into the pump. (A Calibrated Test set can be used for no more than 20 times for the volume accuracy test. Do not leave the set in the pump when not using.) Place the inlet side of the administration set into a reservoir containing water (NOTE: The supply reservoir should be 12 inches above the pump head). Place the exit side of administration set in a collection reservoir which is place on the scale.



Note the tag on the Calibrated Test set includes the “Set Value” which will be used later in the procedure.



Program the pump to do the following Continuous infusion:

Pre Rx:

UNITS:	ml	
DELAY:	OFF	
Titrate:	OFF	
NEXT?	YES	

Prescription:

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	

Option:

AIL:	0.1	ml

Prime the administration set for 20 ml in order to prepare the set for volume accuracy test. (To prime 20 ml the technician must press and hold the prime key for 4 cycles. Note the maximum amount of prime per cycle is 6 ml.)

Zero the scale.

Start the continuous therapy running by pressing RUN button.

When the 10 ml infusion is over, obtain the Calculated Volume delivered according to the following equation:

Calculated Volume = Scale Value x 35.0 / Set Value

Record the Calculated Volume on the traveler. Passing measurement is: 9.80g <= Calculated Value <= 10.20g.

If the pump does not meet these criteria:

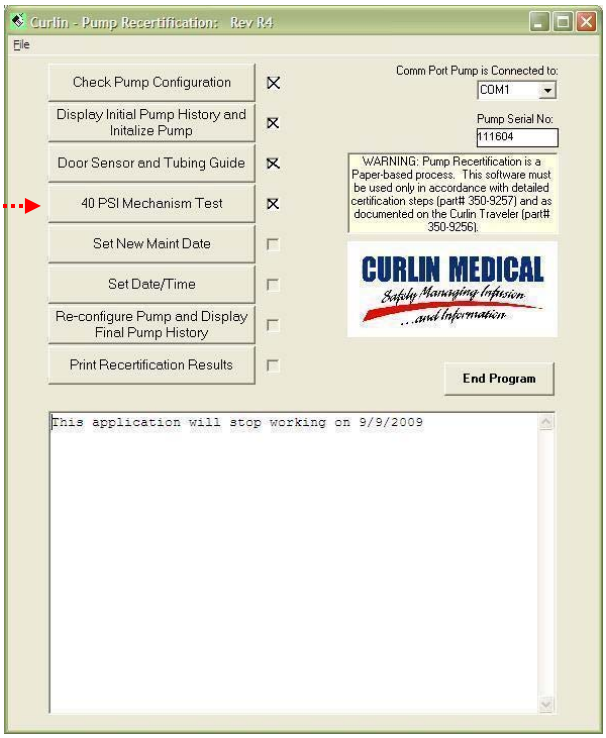
1. Did you use a qualified calibration set 340-4038 for the test? If no, retest with qualified calibration set.
2. Was the test set used less than 20 times and less than 3 days old? If no, retest with new qualified calibration set.
3. Did you prime the set for 20 ml? If no, prime the set for 20 ml.
4. Did you use the set value with the conversion equation? If no, recalculate with conversion equation.

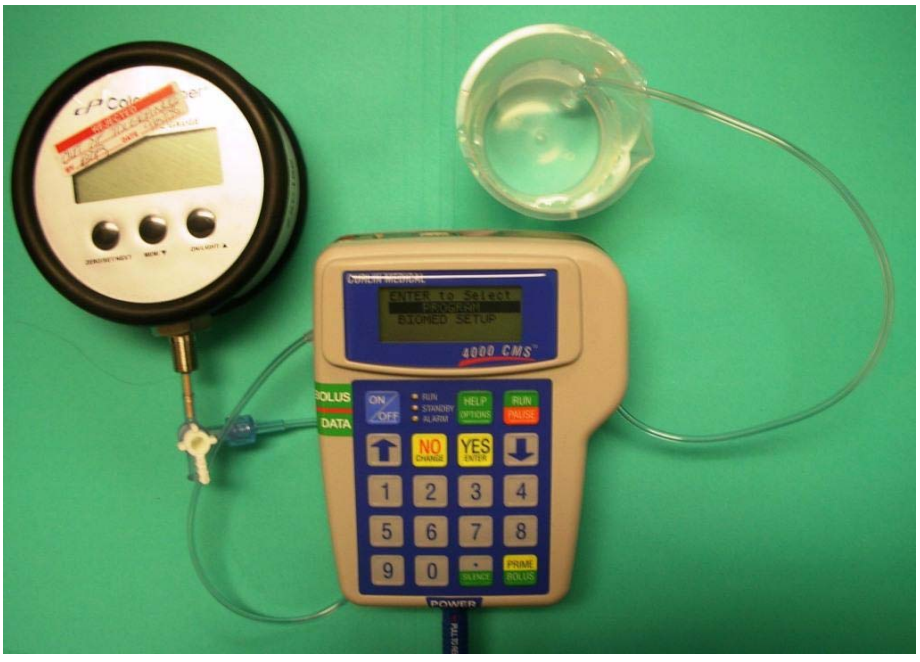
If you answer yes on the above questions and the pump still fails the test a second time, it must be serviced by a trained service tech.

3.6 TEST 3 - Forty (40) PSI Mechanism Test

Connect a pressure gauge capable of measuring 50 PSI to the output/patient side of a primed administration set 340-4023. (*Note: this administration set does not need to be a new set; however, once used for the 40 PSI Mechanism Test, this set may only be used hereafter for subsequent 40 PSI Mechanism Tests*.)

From the PRU, select "40 PSI Mechanism Test" to disable the alarms and malfunctions on the pump.





Place the set into the pump. When the check mark appears next to the 40 PSI Mechanism Test check box, program the pump with the following Continuous infusion:

Pre Rx:		
UNITS:	ml	
DELAY:	OFF	
Titrate:	OFF	
NEXT?	YES	
Prescription:		
BAG VOL:	200	ml
VOL TBI:	100.0	ml
RATE:	20	ml/hr
TIME:	5:00	HH:MM
KVO Rate:	0.0	ml/hr
DONE?	YES	
Option:		
AIL:	0.1	ml

Place the inlet side of administration set into a water reservoir and prime the administration set.

Occlude the output/patient side of the set past the pressure gauge. (Gauge will measure pressure in the output side of the administration set.)

Start the infusion running. While the pump is running observe the pressure gauge. Pressure will build with each peristaltic. Pump must be able to pump more than 40 PSI. In addition, prior to reaching 40 PSI, pumping pressure shall not drop more than -10 PSI. Stop the infusion after 40 PSI pressure has been attained.

Document result on Traveler.

If the pump does not meet these criteria:

1. Did you set up the test so that the pressures gauge measures the downstream pressure? If no, refer to Fig 3 for test setup.
2. Did you prime the set? If no, prime the set until there is no air bubble inside the test set.

If you answer yes for the above questions and the pump still fails to attain specified pressure or suffering more drops in pressure than specified must be serviced by a trained service tech .

3.7 TEST 4 - Down and Up Occlusion Test:

Turn the pump OFF and back ON.

3.7.1 Up Occlusion Test

Use a beaker with water as the reservoir. Connect a pressure gauge to the input side of the administration set using the male to male adapter 340-4039, and a Stopcock 4 way valve. Use an extension set from the pressure gauge to the beaker. Install the administration set into the pump. (See Figure 2)

Figure 2

Program the pump with the following Continuous prescription:

Pre Rx:

UNITS:	ml	
DELAY:	OFF	
Titrate:	OFF	
NEXT?	YES	

Prescription:

BAG VOL:	100	ml
VOL TBI:	50.0	ml
RATE:	9.9	ml/hr
TIME:	5:03	HH:MM
KVO Rate:	0.0	ml/hr
DONE?	YES	

Option:

AIL:	0.1	ml
DN Occl:	LOW	

Prime the administration set. Start the continuous therapy running by pressing RUN button. While running, occlude the input side by closing the 4 way valve toward the reservoir (handle points to the beaker). Observe the inlet pressure falls and pump will go into ALARM UP OCCLUSION

when pressure reaches -6 PSI (-12.2 inHg). Valid pressure range is -8 < up occlusion pressure < -4 PSI (-16.3 <up occlusion pressure< -8.1 inHg). Pumps failing these criteria may be tested a second time. If pump fails a second time it must be serviced by a trained service tech. Record results on traveler. Press the Run/Pause key to clear the Up Occlusion alarm.

3.7.2 Down Occlusion Test 8 PSI

Modify setup from the previous step (see figure 3). Remove the pressure gauge from the input side of administration set and connect it to the output side of the administration set. Use an extension set from the pressure gauge to the beaker.

Figure 3

Observe the prescription from the previous step has the Down Occlusion sensitivity level set to LOW.

Execute a REPEAT RX, prime the set, and start the infusion. While the pump is running occlude the output by closing the 4 way valve for the return to the beaker (handle of valve points to beaker). Observe pressure buildup on the pressure gauge. Pump will go to ALARM DOWN OCCLUSION when pressure reaches 8 PSI. Valid pressure range for low occlusion is 6.0 < occlusion pressure < 10.0 PSI. Pumps failing these criteria may be tested a second time. If pump fails a second time it must be serviced by a trained service tech. Release the pressure by opening the 4 way valve (handle does not point to any tube connector). Observe pump automatically restarts infusion when pressure is released. Record results on the traveler.

3.7.3 Down Occlusion Test 18 PSI

Leave pumping system in same configuration as described in Down Occlusion Test 8 PSI. (See figure 3.) Execute a REPEAT Rx and change the DN OCCLU to HIGH on the Options menu. Start the infusion running. After running the infusion for one minute occlude the output by closing the 4 way valve for the return to the beaker (handle of valve points to beaker). Observe pressure buildup on the pressure gauge. Pump will go into ALARM DOWN OCCLUSION when pressure reaches 18 PSI. Valid pressure range for high occlusion is 16.0 < occlusion pressure < 20.0 PSI. Pumps failing these criteria may be tested a second time. If pump fails a second time it must be recalibrated by a trained service tech. Release the pressure by opening the 4 way valve (handle does not point to any tube connector). Observe pump automatically restarts infusion when pressure is released. Record results on the traveler.

If the pump does not meet these criteria:

1. Did you use a new set? If no, use a brand new set.
2. Did you prime the set? If no, prime the set until there is no air bubble inside the test set.
3. Did you turn off/on the pump after Test 3? If no, turn pump off then on.
4. Did you set up the test so that the pressures gauge measures the upstream pressure during occlusion? If no, refer to Fig. 2 for test setup.
5. Did you set up the test so that the pressures gauge measures the downstream pressure during occlusion? If no, refer to Fig. 3 for test setup.
6. Did you record the pressure reading on the gage as soon as you hear the occlusion alarm? If no, redo test and record pressure reading on the gage as soon as occlusion alarm sounded. Since digital pressure gage is very sensitive, we should record the pressure on the gage as soon as we hear the occlusion alarm.

If you answer yes for the above questions and the pump still fails to meet specifications, then the pump must be serviced by a trained service tech.

3.8 TEST 5 - Final Tests:

Note: if a pump fails any of the following tests, it may be tested a second time for that failing test. However, a pump that fails the same test a second time must be serviced by a trained service tech.

Results for the following tests must be recorded on the traveler.

3.8.1 Keypad Test:

Enter the following Continuous prescription:

Pre Rx:

UNITS:	ml
DELAY:	OFF
Titrate:	OFF
NEXT?	YES

Rx:

BAG VOL:	8765	ml
VOL TBI:	42.1	ml
RATE:	390	ml/hr
TIME:	0:06	HH:MM
KVO Rate:	0.1	ml/hr
DONE?	YES.	

If any of the keys fails to operate properly, then the pump must be serviced by a trained service tech.

3.8.2 Air In Line Test:

Install a primed administration set properly into the pump. Place the ends of the administration set into a beaker of water. Set the AIR SENS on the Options menu to 0.1 ml. Execute the Continuous Infusion programmed in the previous step. With the pump infusing, lift the inlet side of the administration set out of the reservoir and allow air to be infused. Once a sufficient amount of continuous air passes the AIL detector an ALARM AIR IN LINE will occur. (Approximately 1 to 2 inches of continuous air exiting the pump.)

Place the tubing inlet back in the reservoir. Press the Pause key to clear the AIL alarm and select Resume. Prime the air out of the set and resume the infusion.

3.8.3 Auxiliary Alarm Test:

While the pump is infusing, observe the Vol INF (volume infused on the run screen) and remove all power from the pump. To remove all power from the pump, remove one of the C-Cell batteries and unplugging the AC Battery eliminator. Observe the Auxiliary Alarm System is activated (Alarm LED is on and audio alarm is sounding.) With all power removed from the pump, press the On/Off button to turn off the alarm.

Connect an energized AC Adaptor (340-2004 / 340-2022) to the pump. (Connect the AC Adaptor's blue cable connector to the POWER connector on the bottom of the pump). Turn the pump ON. Resume the therapy and confirm that the infusion continues (observing the Vol INF) where it stopped due to Auxiliary Alarm occurrence.

3.8.4 Bolus Switch Test:

Program the pump with the following PCA prescription:

Pre Rx:
- UNITS: mg
- CONCEN: 1.0 mg/ml
- ADMIN Rt: IV
- LOAD DOSE: 0.0 mg
- Titrate: OFF
- NEXT? YES

Prescription:
- BAG Vol: 100 ml
- BASL RATE: 25 mg/hr
- BOLUS: 1 mg
- BOLS INT: 1 min
- #BOLS/hr: 5
- DONE? YES

Start the infusion running. Connect a Bolus Cable (340-2005) to the connector on the side of the pump marked BOLUS/DATA. Press the Bolus Switch on the Bolus Cable. Observe the word BOLUS appears on the top line of the LCD display (flashing).

Pause the infusion and turn the pump OFF.

3.8.5 Battery Door Check:

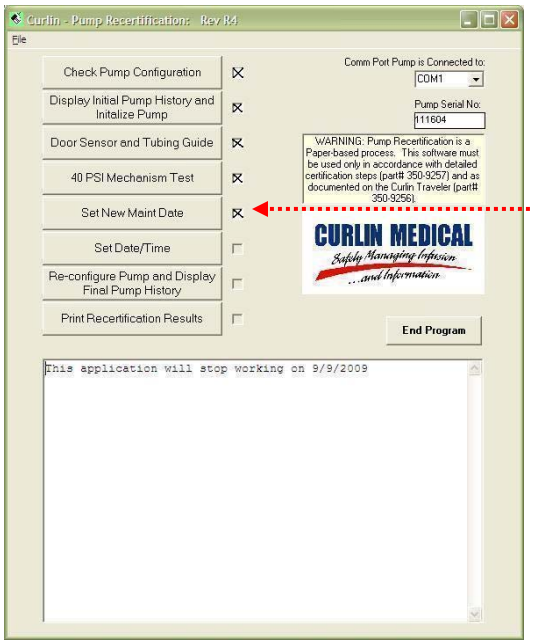
Open the battery compartment to check for smooth opening of the battery door. If battery door sliding is tight, have the sliding sides of the door sanded slightly.

3.8.6 Battery Spring Check:

Remove the C cell batteries and check for proper battery contact springs position, and check for any damage to the coil spring contacts.

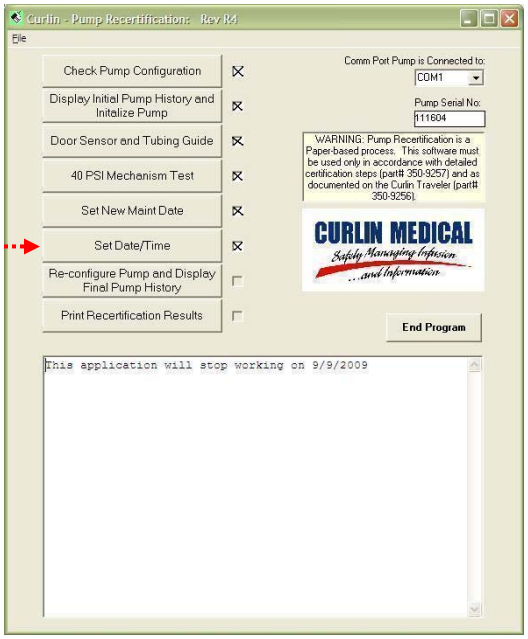
3.9 Set new Maintenance Date

Turn the pump on and allow it to finish booting (displays the PROGRAM / BIOMED SETUP screen.) From the PRU, select "Set New Maint Date". After the pump has been programmed with the new maintenance date, turn the pump OFF and back ON. Select BIOMED SETUP and enter the Clinician code. Observe that the maintenance date is set one year from today's date.



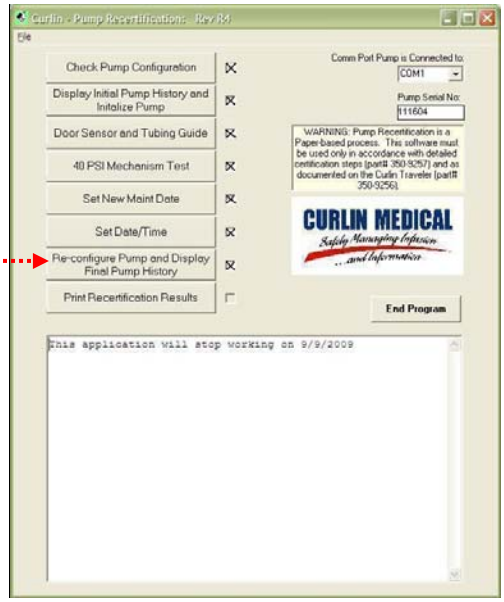
3.10 Set Date and Time

From the PRU, select "Set Date/Time". After the date and time have been set, turn the pump off and on and observe the startup screen indicate the correct date and time.



3.11 Reconfigure Pump and Display Final Pump History

From the PRU, select "Re-configure Pump and Display Final Pump History". Observe the Pump Hx being downloaded from the pump. Clear the alarm on the pump as instructed by the PRU.



Note: If the pump was an E-Config pump, the PRU will set the E-Config back to what it was before (including Lock Level, Max Basal Rate / Bolus Dose, and IOD).

3.12 Print Recertification Results

Finish the pump testing by selecting the "Print recertification Results" button on the PRU on the same PC which the recertification process begins with. Continue the print process by selecting the appropriate printer and pressing the Print button. You must see the words "pump recertification completed at" followed by the date and time. If the above is not visible, you are not done. Repeat this step. If the problem persists, return the pump to Curlin Medical.

Make sure to use the same PC that you start the Recertification process with. If the PC crash during recertification, reboot the PC and restart the recertification on the same PC. If the PRU reports a mismatch between the calibration data in the pump, or the pump ends up in an unexpected configuration, the pump must be returned to Curlin Medical for re-calibration.

3.13 Notify Curlin Medical of Successful Self Recertification

After a successful recertification a copy of the completed traveler and the pump history printout must be sent to Curlin Medical. This allows Curlin Medical to update its Device History List for the pump just recertified. Please mail a copy of the completed traveler and the pump history printout to:

Curlin Medical, Inc.
Attn: Self Recertification
15751 Graham St.
Huntington Beach, CA 92649
Or
FAX (714) 894-2602

If a pump fails the recertification, please call Curlin Medical Customer Support at (888) 287-5999 to obtain a RMA number prior to returning the pump.