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Test record

TEST PASSED

Test performed

Date: 07/07/2016
 Record: 13872572.mtr
 Plug-In: IDA4
 Plug-In: InfusionPump.m
 Template: tt
 Template version: 1.0.46

Components used

Ansur Version 3.0.0
 Plug-In: AVPI Version 2.4.11
 Version 1.0.1
 Plug-In: ESA620 Version 1.1.11

Test setup

Selections

Service events performed	Standards performed
	User defined AAMI/NFPA-99 (M)

Device under test

Serial Number	13872572	Type	Infusion Pump
Status	Certified	Model	Plum A+
Manufacturer	Hospira	Location	ElecoTek

MTI Data

Test instrument	Serial number	Firmware version
IDA-4 Plus #1	11960	2.10
ESA 620	9790056	v2.10

Signatures

ElecoTek INC

DD24E79E-2559-4948-BB7D-18CE363DE78D

Test result

Test element	Test type	Fail
<p>CLEANING AND SANITIZING</p> <p>Procedure: Inspect and clean the infuser after each use. In addition, establish a regular cleaning schedule for the device. Before cleaning, turn off the infuser and disconnect from AC power. Clean the exposed surfaces of the infuser with a soft, lint-free cloth moistened with one of the cleaning solutions recommended.</p> <p>Result:</p> <p>Confirm that the following labels are present:</p> <ul style="list-style-type: none"> - Close Lever Label (Lever Door Open) - Close Lever w/Arrow Label - Rear Caution Label - Battery Label (Internal) - Caution Label - Logo Label - Service Revision Level Label (Driver) - Product I.D. Label (Driver) - Product ID Label (Module) - Switchport Label - (2) MAC Address Labels (Wireless) - Push Label (Wireless) - Side Labels <p>Inspect the labels for legibility and peeling. To replace a label, contact Hospira</p>	<p>Checklist</p> <p>Recorded value</p> <p>Pass</p> <p>Pass</p>	
<p>LABELS INSPECTION</p> <p>Procedure: Preventive maintenance should be performed at least once every 12 months and each time the infuser is serviced. Replace components as required by visual inspection and test results.</p> <p>Result:</p> <p>Turn off the infuser and disconnect the device from AC power</p> <p>Remove the retainer and power cord as described.</p>	<p>Checklist</p> <p>Recorded value</p> <p>Pass</p> <p>Pass</p>	

Test element	Test type	Fail
<p>Result: Inspect the retainer for cracks, breaks, or missing parts of the retainer body. Inspect both ends of the power cord for any signs of electrical arcing, burn marks, or heat scorching or melting. Inspect the plug end of the power cord for bent blades or a bent or missing ground pin. Inspect the Velcro strap for damage. When inspections are completed, reassemble the power cord to the infuser as described. Connect the infuser to AC power and confirm the AC indicator is lit.</p>	<p>Recorded value Pass Pass Pass Pass Pass Pass</p>	
<hr/> <p>AC POWER CORD, RETAINER, AND VELCRO STRAP <i>Checklist</i></p>		
<p>Result: Turn off the infuser and disconnect the device from AC power Remove the retainer and power cord as described in Section 7.2.5 Inspect the retainer for cracks, breaks, or missing parts of the retainer body. Inspect both ends of the power cord for any signs of electrical arcing, burn marks, or heat scorching or melting. Inspect the plug end of the power cord for bent blades or a bent or missing ground pin. If any damage is observed, replace the power cord. Inspect the Velcro strap for damage. If any damage is observed, replace the strap. When inspections are completed, reassemble the power cord to the infuser as described in Section 7.2.5. Connect the infuser to AC power and confirm the AC indicator is lit.</p>	<p>Recorded value Pass Pass Pass Pass Pass Pass Pass</p>	
<hr/> <p>FRONT ENCLOSURE, REAR ENCLOSURE, CASSETTE <i>Checklist</i></p>		
<p>Result: Inspect the front and rear enclosures for cracks, chips, and gouges. Inspect the enclosures for stains and discolorations.</p>	<p>Recorded value Pass Pass</p>	

Test element	Test type	Fail
<p>Result: Inspect the rear enclosure for the presence and tightness of the six assembly screws. Inspect the cassette door for cracks and chips. Inspect the door lever for cracks. Move the door lever to the OPEN position. Confirm that the door opens smoothly. If the door does not open smoothly, check for debris or dried fluid buildup. Clean the mechanism as described Move the door lever to the CLOSED position. Confirm smooth operation as described</p>	<p>Recorded value Pass Pass Pass Pass Pass</p>	
<hr/>		
DOOR ROLLER INSPECTION AND TEST	<i>Checklist</i>	
<p>Result: Open the cassette door. Push the door release tab to the right to unlatch the door. Verify that the retaining ring that secures the roller wheel to the pin is seated properly and the pin is not bent Ensure the door roller spins smoothly with a finger touch.</p>	<p>Recorded value Pass Pass Pass Pass</p>	
<hr/>		
FLUID SHIELD INSPECTION	<i>Checklist</i>	
<p>Procedure: Equipment required for the fluid shield inspection is a 0.025 inch (0.65 mm) feeler gauge (plastic or metal). Result: Release the door so that it lays flat. Press the door release tab to the right and open the cassette door all the way. Attempt to insert the feeler gauge (held perpendicular to the fluid shield) into both gaps between the mechanism assembly and the fluid shield. If you are not able to insert the feeler gauge into the gaps between the mechanism assembly and the fluid shield, the fluid shield is in an acceptable condition.</p>	<p>Recorded value Pass Pass</p>	

Test element	Test type	Fail
<p>Result: Inspect the sensor and control pins for damage and built-up contamination around each pin. If any pins are broken or chipped, contact for repair. If there is accumulation of dried fluids around any pins, clean the area around the pin following the guidelines. Inspect the cassette presence detector boot for damage.</p>	<p>Recorded value Pass Pass</p>	
<hr/>		
DISTAL PRESSURE PIN INSPECTION	<i>Checklist</i>	
<p>Procedure: The distal pressure pin is the black pin. Result: Release the door so that it lays flat. Press the door release tab to the right and open the cassette door all the way Inspect the distal pressure pin to determine that it is not damaged or broken.</p>	<p>Recorded value Pass Pass</p>	
<hr/>		
PROXIMAL PRESSURE PIN INSPECTION	<i>Checklist</i>	
<p>Procedure: The proximal pressure pin is the white pin. Result: Release the door so that it lays flat. Press the door release tab to the right and open the cassette door all the way. Inspect the pin to determine that it is not damaged or broken</p>	<p>Recorded value Pass Pass</p>	
<hr/>		
RUBBER FOOT PAD INSPECTION (if available)	<i>Checklist</i>	
<p>Procedure: Some versions of the Plum A+ do not have rubber foot pads Result: Inspect for missing or loose rubber foot pads, and rubber foot pads that are starting to peel away from the enclosure.</p>	<p>Recorded value Pass</p>	
<hr/>		
POLE CLAMP INSPECTION AND TEST	<i>Checklist</i>	
<p>Result: Confirm that the pole clamp assembly is securely attached to the rear of the enclosure. Tighten the assembly if it is loose</p>	<p>Recorded value Pass</p>	

Test element	Test type	Fail
<p>Result: Confirm that the rubber pad (wireless devices only) is present on the inside surface of the pole clamp extrusion. If the pad is missing, replace the extrusion. Rubber pads are not present on non-wireless Plum A+ infusers. Confirm that the plastic shaft tip is present at the end of the threaded pole clamp shaft. Tighten and loosen the threaded pole clamp shaft so that it moves through the entire length of the threads. Confirm that the shaft moves smoothly and does not bind along its length. Mount the infuser on an IV pole and fully tighten the clamp. Ensure that the infuser is held firmly and does not slide on the IV pole. securely, replace the clamp.</p>	<p>Recorded value</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p>	

BATTERY INSPECTION AND REPLACEMENT *Checklist*

Procedure:

The sealed, lead-acid battery must be replaced at least once every 12 months. .

Result:

	Recorded value
<p>Turn off the infuser and disconnect the device from AC power. The Charge/Line indicator LED on the keypad will turn off. Wait five minutes for the microprocessor to save data and complete the turn off sequence before unplugging the battery.</p>	Pass
<p>remove the screw that attaches the battery door to the infuser, and remove the door.</p>	Pass
<p>Carefully pull the battery and wire harness assembly out of the enclosure and disconnect it from the infuser's internal wiring at the inline connector.</p>	Pass
<p>Inspect the battery compartment for any debris. If debris is present, wipe or brush the debris out of the compartment.</p>	Pass
<p>Inspect the battery door and replace, if damaged or cracked.</p>	Pass

Test element	Test type	Fail
<p>Result: Inspect the battery door pad on the battery door to ensure the pad is attached and is not damaged. If the pad is damaged, replace either the pad or the complete battery door assembly.</p>	<p>Recorded value Pass</p>	
<p>Inspect the battery door gasket on the battery door to ensure that the gasket is attached and is not damaged. The battery gasket may not be present on some versions of the infuser.</p>	<p>Pass</p>	
<p>Connect the replacement battery and wire harness assembly to the infuser's internal wiring harness at the inline connector. The inline connector is keyed so that the cables cannot be incorrectly connected.</p>	<p>Pass</p>	
<p>Carefully insert the battery and wire harness assembly into its compartment with the terminals facing upward. Confirm the battery harness is not pinched between the battery and the enclosure.</p>	<p>Pass</p>	
<p>Reinstall the battery door using the screw that was removed and return the infuser to its upright position</p>	<p>Pass</p>	
<p>Connect the device to AC power and verify that the Charge/Line indicator LED on the keypad is lit.</p>	<p>Pass</p>	
<p>Access the BIOMED SETTINGS screen and press the [CHANGE BATTERY] softkey. The infuser does not provide a confirmation message when the [CHANGE BATTERY] softkey is pressed.</p>	<p>Pass</p>	
<p>Verify that the battery charge level indicator on the LCD display shows at least one, but not more than three white bars. If the indicator shows more than three bars, press the [CHANGE BATTERY] softkey again. If the indicator still shows more than three bars or shows zero bars, repeat the steps in this section.</p>	<p>Pass</p>	
<p>Press [ON/OFF] to turn off the infuser.</p>	<p>Pass</p>	

KEYPAD INSPECTION

Checklist

Test element	Test type	Fail
<p>Result: Inspect the keypad for tears, cracks, or edges lifting away from the infuser. Inspect the keypad for worn or illegible numbers or letters. If letters or numbers are not readable Inspect the keypad domes by pressing each number, word, and symbol to confirm that the domes have mechanical strength and provide tactile feedback. Confirm that the green [START] button, red [STOP] button, and yellow [ON/OFF] button have retained their color.</p>	<p>Recorded value Pass Pass Pass Pass</p>	
DISPLAY AND INDICATORS INSPECTION <i>Checklist</i>		
<p>Result: Connect the power cord to the mains supply, and confirm that the CHARGE LED Rotate the infuser so that the rear of the device is facing to the front. Confirm that the keypad lockout switch is in the OFF (down) position Rotate the infuser back to its original position so that the display is facing forward Press the [ON/OFF] key to power on the infuser, and observe the infuser as it performs its self test Confirm that the two line flow LEDs flash, and that there are two audible sounds - one at the beginning of the self test and one at the end of the self test. If the audible sounds do not occur, replace the piezo alarm assembly Observe the display area. Confirm that the display is clear and readable.</p>	<p>Recorded value Pass Pass Pass Pass Pass Pass Pass Pass</p>	
KEYPAD LOCKOUT SWITCH INSPECTION <i>Checklist</i>		
<p>Result: Inspect for the presence of the keypad lockout switch and ensure the switch is not broken. Inspect for a loose or dislodged switch.</p>	<p>Recorded value Pass Pass</p>	
Preparing the Primary Line (Basic Test Setup) .1 <i>Checklist</i>		
<p>Procedure: The Basic test setup consists of Primed, primary and secondary lines attached</p>		

Test element	Test type	Fail
<p>to fluid bags. The cassette is inserted into the infuser and the distal (patient) end of the tubing is placed in a collection container. The Basic test setup is shown in Figure 5-18:</p>		
<p>Result:</p>	<p>Recorded value</p>	
<p>Prepare the primary line, proceed as follows to fill the cassette and tubing on the primary PlumSet with liquid (that is, prime it), eliminating all air, and then load the cassette into the infuser.</p>	<p>Pass</p>	
<p>Place the infuser on a bench or attach it to an IV pole.</p>	<p>Pass</p>	
<p>Press the cassette flow regulator in to make ensure it is closed</p>	<p>Pass</p>	
<p>If using a glass IV container, open the filter vent cover above the drip chamber. If using a plastic IV container, ensure that the filter vent cover is closed</p>	<p>Pass</p>	
<p>Using a twisting motion, insert the piercing pin into the outlet on a water container. Do not position the container above the infuser while inserting the piercing pin.</p>	<p>Pass</p>	
<p>Suspend the container on an IV pole.</p>	<p>Pass</p>	
<p>Check for leaks Squeeze the drip chamber to fill it about 1/2 full or to the score mark.</p>	<p>Pass</p>	
<p>Do not completely fill the drip chamber Invert the cassette so that the secondary port is pointing down</p>	<p>Pass</p>	
<p>Slowly open the flow regulator by turning it counter-clockwise (see Figure 5-24). When the first drop appears in the pumping chamber, turn the cassette upright.</p>	<p>Pass</p>	
<p>Tap and clear air from the cassette, Y-site, and tubing to remove all air from the remainder of the administration set</p>	<p>Pass</p>	
<p>Push in the flow regulator to close it (see Figure 5-26). Check the distal end of the tubing to confirm that there is no flow.</p>	<p>Pass</p>	
<p>Close all clamps on the proximal and distal lines</p>	<p>Pass</p>	
<p></p>	<p>Pass</p>	
<p>Loading the Cassette (Basic Test Setup) .2</p>	<p>Checklist</p>	

Test element	Test type	Fail
<p>Result: Lift the lever to open the cassette door Grasp the cassette by the finger grip Slide the cassette into the door guide Press the lever down to close the cassette door. Open all clamps Check the distal end of the tubing to confirm that there is no flow and that no kinks appear in the tubing. Ensure that the score mark on the drip chamber is 12 to 24 inches higher than the cassette. Place the distal end of the tubing in the collection container.</p>	<p>Recorded value Pass Pass Pass Pass Pass Pass Pass Pass</p>	
<hr/>		
<p>Preparing the Secondary Line (Basic Test Setup) .3</p>	<p><i>Checklist</i></p>	
<p>Result: Insert the piercing pin into the secondary container outlet using a twisting motion Do not position the container above the infuser while inserting the piercing pin. Suspend the container on an IV pole. Check the secondary container for leaks. Squeeze the drip chamber to fill it about 1/2 full or to the score mark. Do not completely fill the drip chamber. Slowly open the roller clamp to allow fluid to flow into the secondary tubing. After all air is removed, close the roller clamp If the cassette has a Clave secondary port: Insert the end of the secondary line into the Clave. Move the Option-Lok collar over the Clave and twist clockwise to secure the line to the port If the cassette has a capped secondary port: Confirm that the cassette door is closed, and then loosen and remove the white cap. Discard the cap. Insert the end of the secondary line into the port and twist clockwise to secure the line to the port</p>	<p>Recorded value Pass Pass Pass Pass Pass Pass Pass Pass</p>	

Test element	Test type	Fail
<p>Result: Open the cassette door to access to the white cap, first close all clamps on the primary and secondary lines to avoid spilling fluid when the cap is removed, and then lift the lever to open the cassette door. Remove and discard the cap, attach the secondary line, close the cassette door and then open all clamps. Arrange the fluid container so that the score mark on the drip chamber is 12 to 24 inches higher than the cassette. The secondary container does not need to be higher than the primary container for accurate delivery of a piggyback infusion.</p>	<p>Recorded value</p> <p>Pass</p> <p>Pass</p> <p>Pass</p>	
<hr/>		
<p>PROXIMAL AIR-IN-LINE TEST SETUP</p>	<p>Checklist</p>	
<p>Result: Cut to remove the proximal bubble sensor bulb tips as shown. Keep the knife parallel with the plastic to avoid cutting too far into the sensor bulb, which may cause leakage. permanent marker, write "Proximal" and the date on the drip chamber</p>	<p>Recorded value</p> <p>Pass</p> <p>Pass</p>	
<hr/>		
<p>DISTAL AIR-IN-LINE TEST SETUP</p>	<p>Checklist</p>	
<p>Result: Cut to remove the distal bubble sensor bulb tips as shown. Keep the knife parallel with the plastic to avoid cutting too far into the sensor bulb, which may cause leakage. permanent marker, write "Distal" and the date on the drip chamber</p>	<p>Recorded value</p> <p>Pass</p> <p>Pass</p>	
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<p>PRIMING A RUN-IN CASSETTE ASSEMBLY</p>	<p>Checklist</p>	
<p>Result: Primed run-in cassettes are required for Proximal Air-in-Line and Distal Air-in-Line tests. The run-in cassette has tubing that is arranged so that fluid is pumped in a continuous loop, as shown The proximal and distal portions of the run-in cassette must be primed separately, using two different procedures.</p>	<p>Recorded value</p> <p>Pass</p> <p>Pass</p>	

Test element	Test type	Fail
Priming the Run-In Cassette and Proximal Tubing	<i>Checklist</i>	
Result:	Recorded value	
Prime the cassette and proximal tubing parts of the run-in cassette assembly using the Backprime feature of the infuser. During backpriming, the white cap is off to allow air to escape as fluid fills the cassette and tubing.	Pass	
Remove the top from the run-in cassette, fill the drip chamber about 2/3 full, and then put the top back on. Do not fill the drip chamber any more than 2/3 full or water may spill out the top of the cassette during backpriming.	Pass	
Insert the run-in cassette into the infuser and close the door.	Pass	
Remove the white cap on the run-in cassette, taking care not to spill any water into the infuser. The run-in cassette is now installed in the infuser with the white cap off.	Pass	
Turn on the infuser. During the self test, the infuser will issue a cassette test failure alarm.	Pass	
Press and hold [BACKPRIME] to pump water from the drip chamber into the proximal lines and cassette.	Pass	
When bubbles are no longer being pushed into the drip chamber, release the [BACKPRIME] key. The cassette test will proceed.	Pass	
When the cassette test completes with no alarms, replace the white cap.	Pass	
Pass	Pass	
Priming the Distal Tubing Loop	<i>Checklist</i>	
Procedure:		
After the cassette and proximal tubing are primed, the cassette test will succeed. A distal air alarm may occur the first time a test infusion is run, however, because Backprime only affects tubing that is proximal to the cassette. The following procedure describes how to manually pump air out of the distal tubing.		
Result:	Recorded value	
Open the cassette door and remove the run-in cassette. Close the cassette door.	Pass	

Test element	Test type	Fail
<p>Result: Remove the top of the run-in cassette and add water to bring the level in the drip chamber to about 2/3 full. Replace the top. Check the run-in cassette for leaks, especially around the sensor bulbs that were cut. If there is any leakage, replace the run-in cassette. Keeping the cassette upright, remove the white cap. Pull out the flow regulator Press in firmly on the pumping chamber to pump air out of the chamber Continue to press on the pumping chamber as you use your other hand to push the flow regulator closed. This prevents the air from returning to the pumping chamber Release the pumping chamber and flow regulator Repeat steps until all distal air is pumped out of the tubing. Replace the cap. The run-in cassette is now ready for use Remove the cassette from the infuser.</p>	<p>Recorded value</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p>	
<hr/>		
Distal Occlusion Test Setup	<i>Checklist</i>	
<p>Procedure: Add a three-way stopcock and Digital Pressure Meter (DPM) to the distal tubing on the Basic test setup.</p> <p>Result: Attach the pressure sensor connector on the DPM to a compatible port (male or female) on the three-way stopcock Insert the distal tubing on the Basic test setup into a female port on the three-way stopcock and turn the Option-Lok connector clockwise to secure the tubing to the port Place the DPM connector at a height of 0 +/- 12 inches from the midline of the pumping chamber on the cassette</p>	<p>Recorded value</p> <p>Pass</p> <p>Pass</p> <p>Pass</p>	
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SELF TEST	<i>Checklist</i>	
<p>Procedure: Use the Basic test setup and proceed</p>		

Test element	Test type	Fail
<p>Result: Plug the power cord into a grounded AC outlet. Verify that the charge/line indicator is lit and an alarm sounds Without a cassette installed, press [ON/OFF] to turn on the infuser. The LCD screen briefly displays the SELF TEST screen. If MedNet is installed, an Area Selection or CCA Selection screen appears. Choose a care area and press [ENTER]. (If MedNet is not installed, skip this step.) After the self test is complete, the message INSERT PLUM SET CLOSE LEVER appears. Open the cassette door and insert the primed cassette from the Basic test setup Close the cassette door. The infuser will begin a cassette test. If a NEW PATIENT? or CLEAR SETTINGS? message appears, press [YES]. When the CASSETTE TEST IN PROGRESS message disappears from the DELIVERY screen, the self test is complete. Open the door and remove the cassette. If an alarm condition occurs during the self test, cycle the power and repeat the self test.</p>	<p>Recorded value</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p>	
<hr/>		
CASSETTE ALARM TEST	<i>Checklist</i>	
<p>Procedure: Use an empty (not primed) run-in cassette and proceed</p>	<p>Recorded value</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p>	
<p>Result: If the infuser is not on, press [ON/OFF] to turn it on. If an Area Selection or CCA Selection screen appears, choose a care area and press [ENTER]. Insert the empty run-in cassette and close the cassette door. The CASSETTE TEST IN PROGRESS message appears. After the cassette test is complete, verify that CASSETTE TEST FAILURE is flashing on the display and that the alarm sounds. Open the door and remove the cassette</p>		

Test element	Test type	Fail
<p>UNRESTRICTED FLOW TEST</p> <p>Procedure: Use the Basic test setup and proceed</p> <p>Result:</p> <p>Insert the primed cassette into the infuser and close the cassette door</p> <p>If an Area Selection or CCA Selection screen appears, choose a care area and press [ENTER]. Otherwise, skip this step.</p> <p>With the cassette door closed, check the distal end of the tubing for fluid flow. Verify that no fluid is flowing or that fluid stops after a few drops (maximum) are released from the end of the distal tubing.</p> <p>Clamp the secondary line and open the cassette door and check the distal end of the tubing for fluid flow. Verify that no fluid is flowing or that fluid stops after a few drops (maximum) are released from the end of the distal tubing.</p> <p>Close the cassette door.</p>	<p><i>Checklist</i></p> <p>Recorded value</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p>	
<p>DISPLAY TEST</p> <p>Procedure: Use the Basic test setup and proceed</p> <p>Result:</p> <p>Verify that the LCD backlight is illuminated and the display is clearly legible at eye level from approximately 18 inches.</p> <p>On the DELIVERY screen, press [OPTIONS/VOL INF] to select the OPTIONS screen</p> <p>Select LIGHTING/CONTRAST, and press [CHOOSE].</p> <p>Use the [DECREASE SETTING] and [INCREASE SETTING] softkeys to change BACKLIGHT INTENSITY. Verify that the backlight intensity decreases and increases.</p> <p>Select DISPLAY CONTRAST</p> <p>Press [DECREASE SETTING] and [INCREASE SETTING] to change display contrast. Verify that the display contrast decreases and increases.</p> <p>Press [CANCEL/BACK] to return to the OPTIONS screen.</p> <p>Press [BACK] to return to the DELIVERY screen.</p>	<p><i>Checklist</i></p> <p>Recorded value</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p>	

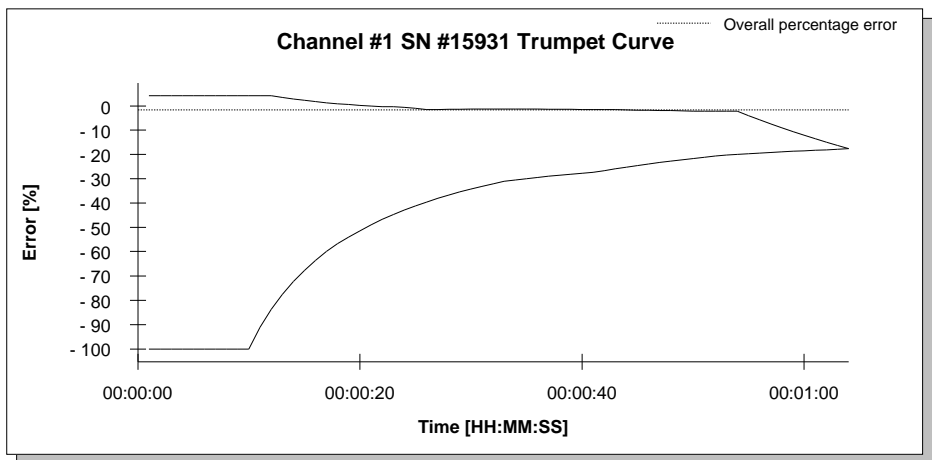
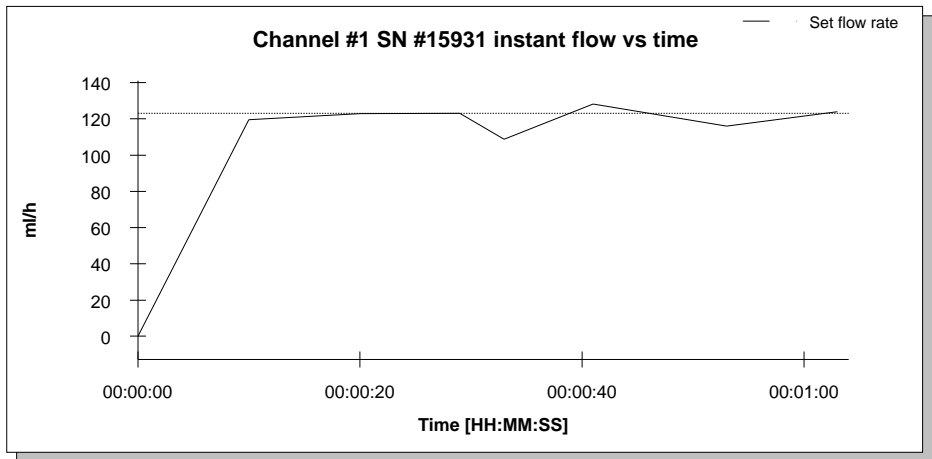
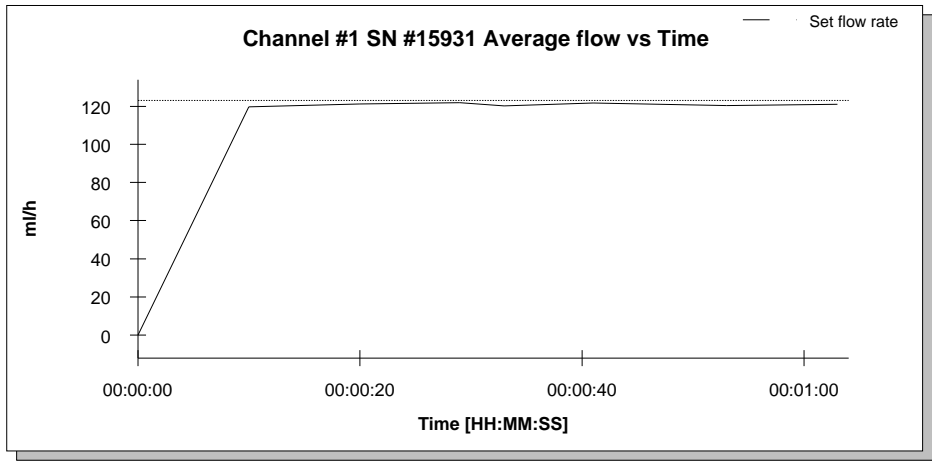
Test element	Test type	Fail
KEYPAD VERIFICATION/FUNCTIONAL TEST	Flow test	
.1		
<p>Procedure: Use basic test setup. -While the infuser displays the DELIVERY screen, press [A] to select Line A. -Verify that the PROGRAM screen is displayed. Enter a rate of 123 mL/hr and VTBI of 4567. -Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES]. -Verify that fluid is pumping, the message PUMPING is displayed in the Line A status bar, and the LED over Line A flashes. -Press [STOP]. -Press and hold [BACKPRIME]. Verify that the BACKPRIMING and RELEASE BACKPRIME TO STOP messages are displayed, and confirm that the infuser is actually backpriming. -Release the [BACKPRIME] softkey. Wait for cassette test to finish, before continuing to next step. -Press [START], and verify that Line A is pumping again. -Press [B]. -Verify that PIGGYBACK is the displayed delivery mode. If necessary, change the delivery mode by pressing [CHANGE MODE].</p>		

Configuration:

Channel selected	Set flow rate[ml/h]	Total volume[ml]	Stop test when time reached[hh:mm]
Channel #1 SN #15931	123	4567	00:01

Result:	Preset Value	Measurement	Unit	High Limit	Low Limit	Standard
IDA4 Plus #1						
Channel #1 SN #15931						
Average flow	123.00	120.88	ml/h			User defined
Min instant flow	123.00	108.66	ml/h			User defined
Max instant flow	123.00	128.16	ml/h			User defined
Volume	4 567.00	2.10	ml			User defined
Overall percentage error		- 1.7	%			User defined

Test element	Test type	Fail
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ALARM LOUDNESS TEST

Checklist

Procedure:

Use the Basic test setup and proceed

Result:	Recorded value
Press [A] to select Line A.	Pass
If the message CLEAR LINE A SETTINGS appears, press [YES].	Pass
Enter a rate of 400 mL/hr and VTBI of 1 mL	Pass

Test element	Test type	Fail
<p>Result: Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES]. Verify that fluid is pumping, the message PUMPING is displayed in the Line A status bar, and the LED above Line A flashes Verify that the alarm sounds and the message LINE A VTBI COMPLETE appears when the dose has been delivered. Turn the volume control knob on the back of the infuser clockwise and counterclockwise. Verify that the alarm loudness changes. Press the [SILENCE] key, and verify that the alarm is paused. Press [STOP].</p>	<p>Recorded value Pass Pass Pass Pass Pass Pass</p>	
<p>KEYPAD LOCKOUT SWITCH TEST <i>Checklist</i></p>		
<p>Procedure: Use the Basic test setup and proceed</p> <p>Result: Press [A] to select Line A. If the message CLEAR LINE A SETTINGS appears, press [YES]. Enter a rate of 400 mL/hr and VTBI of 50 mL. Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES]. Verify that fluid is pumping, the message PUMPING is displayed in the Line A status bar, and the LED above Line A flashes Move the keypad lockout switch on the back of the infuser to the up (ON) position to disable the keypad Press any key except [STOP], and verify that an invalid key press audio alert is generated and the HARD LOCK ENABLED message is displayed. Confirm that the infuser continues to operate. Press [STOP]. Verify that an alarm sounds, the HARD LOCKOUT VIOLATION message appears, and pumping stops.</p>	<p>Recorded value Pass Pass Pass Pass Pass Pass</p>	

Test element	Test type	Fail
<p>Result: Move the keypad lockout switch to the down (OFF) position. Verify that the HARD LOCKOUT VIOLATION message disappears and the alarm stops. Press [START]. Open the cassette door and verify that an alarm sounds and the DOOR OPEN WHILE PUMPING message is displayed. Close the cassette door. Press [NO] at the NEW PATIENT? or CLEAR SETTINGS? prompt.</p>	<p>Recorded value Pass Pass Pass Pass Pass Pass Pass Pass Pass</p>	

PROXIMAL OCCLUSION TEST	Flow test	
<p>Procedure: -Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES]. -Verify that the LED above Line A flashes -After several pumping cycles, clamp the Line A tubing proximal to the cassette. -Verify that the PROXOCCL A/AIR message flashes and the alarm sounds before three pumping cycles are completed. -Press [SILENCE] and verify that the alarm stops while the message on the display continues to flash. -Unclamp the proximal line and press [START]. Verify that pumping resumes. -Press [STOP]. -Open the cassette door and remove the cassette.</p>		

Configuration:						
Channel selected	Set flow rate[ml/h]	Total volume[ml]	Stop test when time reached[hh:mm]			
Channel #1 SN #15931	400	50	00:03			
Result:	Preset Value	Measurement	Unit	High Limit	Low Limit	Standard
IDA4 Plus #1 Channel #1 SN #15931						
Average flow	400.00	361.59	ml/h			User defined
Min instant flow	400.00	16.21	ml/h			User defined
Max instant flow	400.00	410.49	ml/h			User defined
Volume	50.00	18.99	ml			User defined
Overall percentage error		- 9.6	%			User defined

Test element	Test type	Fail

PROXIMAL AIR-IN-LINE TEST

Checklist

Procedure:

Proximal Air-in-Line test uses the Proximal Air-in-Line test setup and the programming from the Proximal Occlusion test. (If performing this section as a standalone test, insert the test cassette prepared in Section 5.3.2.2, select Line A, and enter a rate of 400 mL/hr and a VTBI of 50 mL. Go to Step 4)

Result:

Recorded value

Insert the proximal test cassette into the infuser and close the cassette door.

Pass

Test element	Test type	Fail
<p>Result: If a NEW PATIENT? or CLEAR SETTINGS? message appears, press [NO]. Make a note of the Volume Infused (Vol Inf mL) displayed on the Main Delivery screen for Line A. You will need this value for Step 6. Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES]. Verify that fluid is pumping, the message PUMPING is displayed in the Line A status bar, and the LED above Line A flashes. Before 1 mL of fluid is delivered, verify that pumping stops, the alarm sounds, and the N232 PROX AIR A, BACKPRIME message is flashing on the display. Open the cassette door and remove the test cassette.</p>	<p>Recorded value Pass Pass Pass Pass Pass</p>	

PROXIMAL AIR-IN-LINE TEST

Flow test

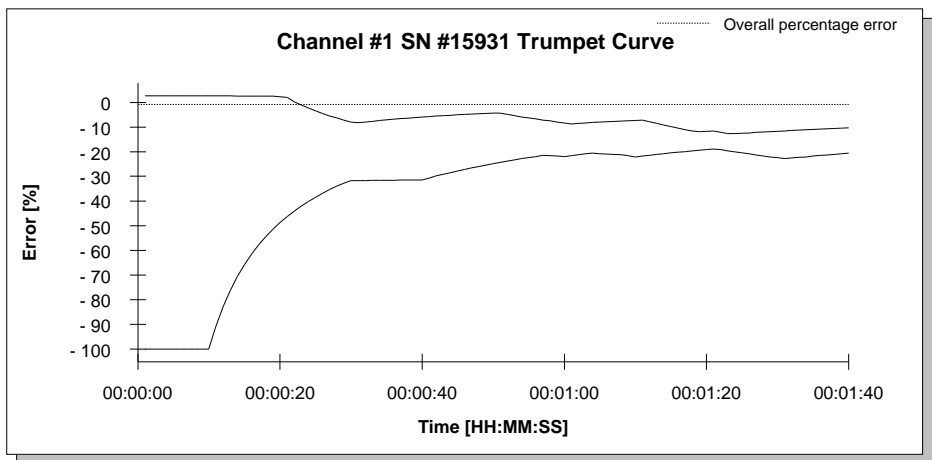
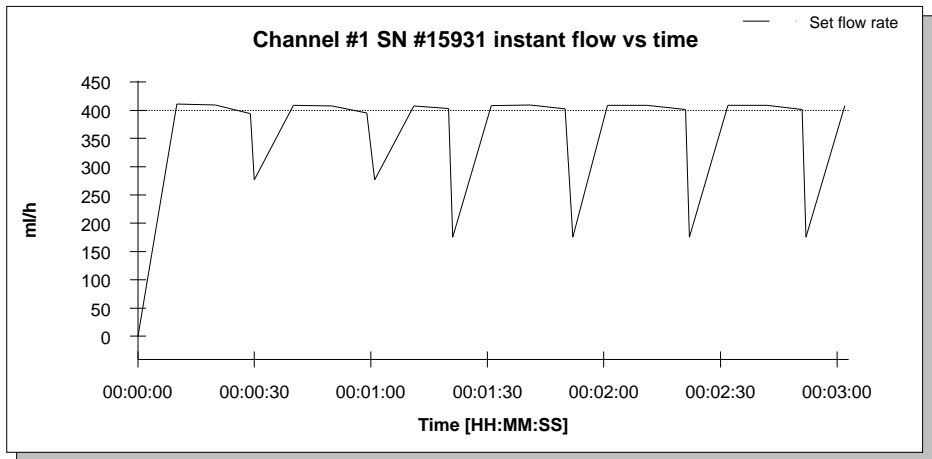
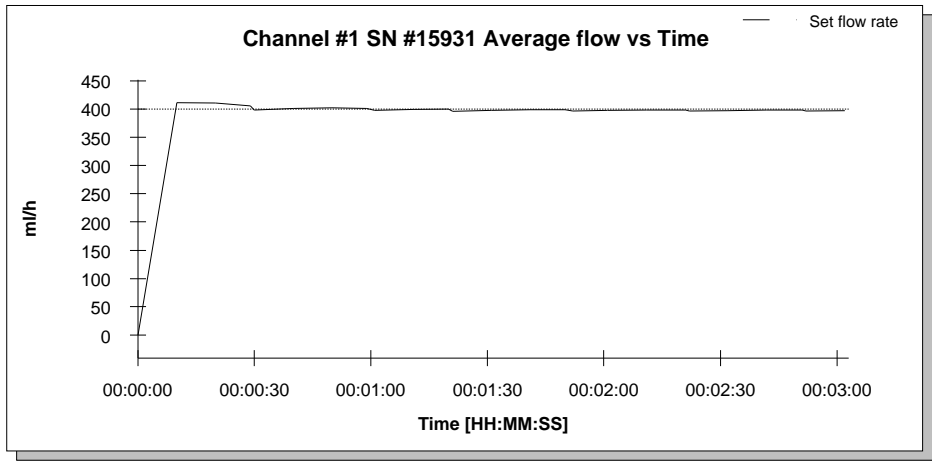
Procedure:

- Insert the proximal test cassette into the infuser and close the cassette door.
- If a NEW PATIENT? or CLEAR SETTINGS? message appears, press [NO].
- Make a note of the Volume Infused (Vol Inf mL) displayed on the Main Delivery screen for Line A. This value is for Step 6.
- Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES].
- Verify that fluid is pumping, the message PUMPING is displayed in the Line A status bar, and the LED above Line A flashes.
- Before 1 mL of fluid is delivered, verify that pumping stops, the alarm sounds, and the N232 PROX AIR A, BACKPRIME message is flashing on the display.
- Open the cassette door and remove the test cassette.

Configuration:

Channel selected	Set flow rate[ml/h]	Total volume[ml]	Stop test when time reached[hh:mm]			
Channel #1 SN #15931	400	50	00:03			
Result:	Preset Value	Measurement	Unit	High Limit	Low Limit	Standard
IDA4 Plus #1						
Channel #1 SN #15931						
Average flow	400.00	397.00	ml/h			User defined
Min instant flow	400.00	175.66	ml/h			User defined
Max instant flow	400.00	410.99	ml/h			User defined
Volume	50.00	20.11	ml			User defined
Overall percentage error		- 0.8	%			User defined

Test element	Test type	Fail
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DISTAL OCCLUSION TEST .1

Checklist

Procedure:

Use basic test setup

Result:

Insert the cassette from the Basic test setup into the infuser and close the cassette door. The infuser will proceed with the cassette test.

Recorded value

Pass

Test element	Test type	Fail
<p>Result: Attach the stopcock and DPM to the distal end of the tubing as shown in the Distal Occlusion test setup. Position the collection container beneath the stopcock to catch water that is released during the test. Turn the DPM on. When the CLEAR SETTINGS? or NEW PATIENT? message appears on the infuser display, press [YES]. Press [OPTIONS/VOL INF] to select the Options screen. Select Pressure/Post Infusion Rate, and press [CHOOSE]. Verify that the distal pressure limit is set at 6 psi. If the pressure limit is not 6 psi, highlight the Distal Pressure Limit and enter 6. Press [ENTER]. Press [A] to select Line A.</p>	<p>Recorded value</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p>	

DELIVERY ACCURACY TEST (for Verification Purposes only) .1 *Checklist*

Procedure:
 The Delivery Accuracy Test uses the Basic test setup with the following changes: a blunt cannula is attached to the end of the distal tubing, and a 25 mL graduated cylinder is used in place of the collection container.

Result:	Recorded value
Attach the 18-gauge blunt cannula to the distal end of the tubing and place the cannula into the graduated cylinder. Make sure the score marks on the Line A and Line B drip chambers are 12 to 24 inches above the cassette and that all lines are unclamped	Pass
Turn on the infuser.	Pass
If an Area Selection or CCA Selection screen appears, choose a care area and press [ENTER].	Pass
Press [YES] at the CLEAR SETTINGS? or NEW PATIENT? prompt.	Pass
Press [A] to select Line A.	Pass
Enter a rate of 200 mL/hr and VTBI of 10 mL.	Pass
Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES].	Pass

Test element	Test type					Fail
<p>Result: Verify that fluid is pumping, the message PUMPING is displayed in the Line A status bar, and the LED over Line A flashes. Press [B] to select Line B. Verify that Piggyback delivery mode is selected. If necessary, press [CHANGE MODE] to change the delivery mode. Enter a rate of 200 mL/hr and a VTBI of 10 mL. Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES]. Verify that fluid is pumping, the message PUMPING is displayed in the Line B status bar, and the LED over Line B flashes. Line A will be stopped (DELAYED) while Line B is pumping, and will resume pumping when Line B delivery is complete. When total delivery is complete on Line A, verify that the KVO message flashes on the display and an audible alarm sounds. Press [STOP] and verify that the volume delivered into the graduated cylinder is 20 mL +/- 1 mL. The pumping chamber in a test cassette can become fatigued after repeated tests are run. If an infuser fails the delivery accuracy test, run the test again with a new primary administration set, to ensure that the issue is with the infuser, not the test setup.</p>	Recorded value					
	Pass					
	Pass					
	Pass					
	Pass					
	Pass					
	Pass					
	Pass					
Protective Earth Resistance	Protective Earth Resistance					
<p>Procedure: If the infuser does not have a ground test screw/post, connect the analyzer ground lead to one of the screws that secures the power cord retainer. Configuration Test Current: Low</p>						
<p>Result: PE Resistance1</p>	Value	Unit	High limit	Low limit	Standard	
	0.168	Ohm	0.2		User defined	
Enclosure Leakage Current	Enclosure Leakage Current					
<p>Configuration Unused Applied Parts: Floating</p>						
Normal Condition	Enclosure Leakage Current Normal Condition					
<p>Result: Normal Condition</p>	Value	Unit	High limit	Low limit	Standard	
	1.4	uAAC+DC	100	0	User defined	

Test element	Test type					Fail
Open Neutral	<i>Enclosure Leakage Current</i> <i>Open Neutral</i>					
Result: Open Neutral	Value 1.4	Unit uAAC+DC	High limit 300	Low limit 0	Standard User defined	
Open Earth	<i>Enclosure Leakage Current</i> <i>Open Earth</i>					
Result: Open Earth	Value 21.2	Unit uAAC+DC	High limit 300	Low limit 0	Standard User defined	
Normal Condition, Reversed mains	<i>Enclosure Leakage Current</i> <i>Normal Condition, Reversed mains</i>					
Result: Normal Condition, Reversed mains	Value 1.4	Unit uAAC+DC	High limit 100	Low limit 0	Standard User defined	
Open Neutral, Reversed Mains	<i>Enclosure Leakage Current</i> <i>Open Neutral, Reversed Mains</i>					
Result: Open Neutral, Reversed Mains	Value 1.4	Unit uAAC+DC	High limit 300	Low limit 0	Standard User defined	
Open Earth, Reversed Mains	<i>Enclosure Leakage Current</i> <i>Open Earth, Reversed Mains</i>					
Result: Open Earth, Reversed Mains	Value 21.8	Unit uAAC+DC	High limit 300	Low limit 0	Standard User defined	
Earth Leakage Current Configuration Unused Applied Parts: Floating	<i>Earth Leakage Current</i>					
Normal Condition	<i>Earth Leakage Current</i> <i>Normal Condition</i>					
Result: Normal Condition	Value 23.4	Unit uAAC+DC	High limit 500	Low limit 0	Standard User defined	
Open Neutral	<i>Earth Leakage Current</i> <i>Open Neutral</i>					
Result: Open Neutral	Value 37.1	Unit uAAC+DC	High limit 1000	Low limit 0	Standard User defined	
Normal Condition, Reversed mains	<i>Earth Leakage Current</i> <i>Normal Condition, Reversed mains</i>					
Result: Normal Condition, Reversed mains	Value 25.6	Unit uAAC+DC	High limit 500	Low limit 0	Standard User defined	
Open Neutral, Reversed Mains	<i>Earth Leakage Current</i> <i>Open Neutral, Reversed Mains</i>					
Result: Open Neutral, Reversed Mains	Value 37.1	Unit uAAC+DC	High limit 1000	Low limit 0	Standard User defined	
END OF THE PVT	<i>Checklist</i>					
Procedure: If the infuser passed all performance verification tests, follow these instructions to clear all programming and prepare the device to be put back into service:						
Result: Turn on the infuser.	Recorded value Pass					

Test element	Test type	Fail
<p>Result: If an Area Selection or CCA Selection screen appears, choose a care area and press [ENTER].</p>	<p>Recorded value Pass</p>	
<p>In response to the NEW PATIENT? or CLEAR SETTINGS? prompt, press [YES].</p>	<p>Pass</p>	
<p>Remove the cassette and close the cassette door.</p>	<p>Pass</p>	
<p>Turn off the infuser.</p>	<p>Pass</p>	
<p>Make sure the keypad lockout switch on the back of the infuser is in the DOWN position (lockout disabled).</p>	<p>Pass</p>	
<p>Return the infuser to service.</p>	<p>Pass</p>	