

URGENT MEDICAL DEVICE CORRECTION

July 17, 2025

Dear Director of Biomedical Engineering or Clinical Engineering and Director of Nursing

Baxter is issuing an Urgent Medical Device Correction for the **Novum IQ** large volume pump (LVP) due to the following two issues:

- 1) There is a potential for underinfusion when transitioning from a lower to a higher flow rate (e.g., rate change or bolus). Specifically, the risk occurs when the second flow rate is more than double the first flow rate. For example, an increase from a 30 mL/hr primary infusion over 12 hours to a 600 mL/hr flow rate for a bolus infusion. The level of underinfusion is variable and is based on the lower infusion rate, the duration the pump has been running at this flow rate, and the magnitude of the rate change. The longer duration the pump has been running at the lower infusion rate and the larger the magnitude of the rate change, the larger the underinfusion would be. In the worst case, no delivery may occur.

In addition to the corrections listed in the 'Actions to be Taken by Customers' section of this letter, Baxter is working to identify software and/or hardware corrections to address the issue and will contact customers with additional information when available.

- 2) Baxter has identified an increase in customer reports of over and underinfusion that may be due to set misloading. Failure to properly load the tubing into the pump channel may result in the pump infusing at a rate higher or lower than programmed. Consistent with the instructions for use, customers should ensure that:
 - a) The door is fully open before loading the set as pictured on page 5 of enclosed Attachment A.
 - b) The tubing is taut and loaded without slack in the pumping channel as pictured on page 8 of enclosed Attachment A, and in Figure 1 below.

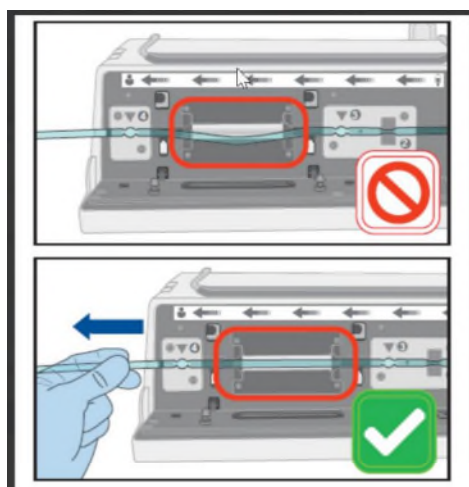


Figure 1

Baxter is developing a hardware change to reduce misloading of the set and will contact customers to update the pumps when the correction is available.

Customers may continue to use the **Novum IQ** LVP while following the instructions listed in the 'Actions to be Taken by Customers' section of this letter.

Affected Product

Product Code	Product Description	Serial Numbers
40700BAX	Novum IQ LVP	All

Hazard Involved

With respect to the first issue (flow rate change), this may lead to the pump delivering at a lower rate than intended (underinfusion). With respect to the second issue (set misloading), this may lead to non-delivery, underinfusion, or overinfusion of the intended solution/medication.

The adverse effects that may result from either issue range from minor or temporary harm to serious injury or death, depending on the patient, the condition being treated, and the fluid, drug, or other treatment being administered. High-risk and vulnerable patient populations may experience higher rates of serious adverse health consequences including hemodynamic instability, cardiac arrhythmias, insufficient sedation, hyperglycemia, and thromboembolic events, among others. From June 2023 through May 2025, Baxter has received 79 reports of serious injury, and two reports of death potentially related to overinfusion or underinfusion.

Actions to be Taken by Customers

1. Users should rely on their clinical judgment. When the delay associated with changing the pump and infusion set would **NOT** prove detrimental to the patient, users should change out the pump and infusion set prior to initiating a bolus infusion or a rate change of greater than 100%.
2. If the delay associated with changing the pump and/or infusion set would prove unacceptable, prior to initiating a bolus infusion or a rate change of greater than 100%, users should move the administration set downstream (towards the patient) approximately 1.3 cm (0.5 inches) by following steps A through C below.
 - A. Please follow the instructions for unloading the set in section 4.4, Unloading an Administration Set, of the **Novum IQ** LVP Operator's Manual (refer to enclosed Attachment A).

To prevent free flow, ensure downstream roller clamp is fully closed.
 - B. Once unloaded, move the administration set downstream by moving the slide clamp toward the container by 1.3 cm (0.5 inches).
 - C. After moving the slide clamp, reload the administration set. Please follow the instructions for loading the set in section 4.3, Loading an Administration Set, of the **Novum IQ** LVP Operator's Manual and the additional diagrams and guidance in the enclosed Attachment A.

Once the tubing has been loaded, the door closed and the slide clamp has been ejected, ensure that the downstream roller clamp is fully open.
 - D. **Initiate replacement of the administration set at the first safe opportunity to do so, or check regularly to ensure the infusion proceeds at the expected rate.**
3. To prevent misloading, please follow the instructions for loading the set in section 4.3, Loading an Administration Set, of the **Novum IQ** LVP Operator's Manual and the additional diagrams and guidance in the enclosed Attachment A.
4. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form** and return it to Baxter by faxing it to 1-855-767-4572 or scanning and e-mailing it to fca_canada@baxter.com. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
5. If you purchased this product from a distributor or wholesaler, please note that responding on the Baxter customer reply form is not applicable. If a response is requested by your distributor or wholesaler, please respond to them according to their instructions.

6. Please forward a copy of this communication to the Chief Medical Officer, Medical Director, Director of Pharmacy, Facility Risk Manager, Director of Purchasing/Central Supply, Director of Anesthesia, and any other departments within your institution who use the affected product.
7. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Urgent Medical Device Correction in accordance with your customary procedures and **complete the applicable section on the reply form**.

Further Information and Support

If you have additional questions or experience quality problems, please contact your local Baxter representative.

Health Canada has been notified of this action.

We apologize for any inconvenience this Correction may cause you and your staff.

To provide a helpful and centralized resource for customers impacted by ongoing Novum IQ Large Volume Pump (LVP) field actions, Baxter has uploaded a summary of all current Novum IQ LVP field actions to our Novum IQ LVP Important Safety Updates website, including applicable remediation steps and links to associated customer letters. Please note that your facility would have previously received the official customer communication for all field actions that you are impacted by.

This page will be maintained and updated with any relevant information pertaining to Novum IQ LVP field actions, in addition to communication via our standard channels.

Please visit <https://www.baxter.ca/novum-iq-large-volume-pump-important-safety-updates> to view the information.

Sincerely,



Brandon Gingrich
Associate Director, Quality and Regulatory
Baxter Corporation – Canada

Enclosure: Baxter Customer Reply Form
Attachment A: **Novum IQ** LVP Operator's Manual Excerpt with Additional Guidance

Attachment A: NOVUM IQ LVP Operator's Manual Excerpt with Additional Guidance

4. Preparing the Pump

4.3 Loading an Administration Set

WARNING	
	Do Not Allow Uncontrolled Gravity Flow. - Before unloading a primed administration set, ensure that the roller clamp below the pump is in the closed position. - Do not open the slide clamp when the door is open or during and after administration set unloading. This can cause dangerous, uncontrolled free flow to occur. - Always close the set's roller clamp during administration set changes.
	Flow Rate Inaccuracy Rate accuracy can be affected by variations in head height, back pressure or any combination thereof. Fluid viscosity and ambient temperature contribute to this variation. In addition to administration set specific warnings, the following can cause flow rate inaccuracies and must be avoided: - Incompatible brand administration sets and compatible brand administration sets with unusually large or small diameters or unusually stiff materials. Refer to <i>Compatible Baxter Administration Sets</i> on page G-1 for administration sets approved for use with the NOVUM IQ large volume pump. - Non-vented administration sets with semi-rigid and rigid non-vented containers. - Leaving vents on sets or burettes closed when they should be open. - Infusing at flow rates above 300 mL/hr during a secondary infusion. See Section 4.5, <i>Secondary Infusion Setup</i> on page 4-31. - Using any administration set outside of its specifically labeled flow rate range, set change interval, operational environment range, or other labeled parameters.
	Prime Before Connection Prior to connecting to the patient, prime the administration set following the standard gravity priming instructions included with the administration set, remove all air, close the roller clamp and the slide clamp, load the administration set into the NOVUM IQ large volume pump, close the door, open the roller clamp, and make sure that the slide clamp is open. The pump is unable to detect any air that may be present in the additional administration set lines when another administration set or add-on is added to the existing infusion below the pump.
	Load Administration Set in the Correct Direction Load the administration set in the correct direction, from right to left, with Load Point 1 (slide clamp keyhole) closest to the container, as shown in Figure 4-10. Loading the administration set in the wrong direction will result in a failure to infuse and could cause patient injury.

Attachment A: NOVUM IQ LVP Operator's Manual Excerpt with Additional Guidance

4. Preparing the Pump

WARNING



Static Sensitive Equipment

- Wherever possible, eliminate any electrostatic producing materials or conditions (dry, low humidity, synthetic materials such as blankets, carpeting, drapes, etc.).
- Ensure surrounding medical equipment is appropriately grounded.
- If the floors of the rooms where the equipment is used are wood, concrete, or ceramic tile, ensure that relative humidity is greater than 10%, per the Operating Conditions. If the floors of the rooms are synthetic, ensure that the relative humidity is at least 30% per the recommendations of IEC standards.
- An electrostatic discharge event near door seams may trigger a momentary Door Open alarm and interrupt the therapy.
 1. Press  to resume therapy.
 2. Monitor visual indicators (beacon and display) to understand infusion status.
 3. The Inactivity alarm will sound in two minutes if you do not resume the infusion.
- An electrostatic discharge event in proximity to the load points may result in a System Error requiring a power cycle of the NOVUM IQ large volume pump to continue operation.

CAUTION



Accuracy

- Refer to Section B.3, *Accuracy Graphs* for flow rate accuracy as a function of short infusion durations.
- The upstream occlusion detector may not detect partially occluded tubing.
- Always check to ensure the infusion administration set's clamp is not closed above the pump and respond appropriately to all primary and secondary check flow prompts.
- The use of small bore catheters or needles at higher flow rates have impact on the flow rate accuracy and may cause excessive back pressure.
- Size the catheters according to expected flow rate and fluid viscosity.

Attachment A: NOVUM IQ LVP Operator's Manual Excerpt with Additional Guidance

4. Preparing the Pump

CAUTION	
!	Door Opening/Closing Visually inspect the top and front of the NOVUM IQ large volume pump, with the door fully open, for foreign material regularly during use at the point of care. Inspect for presence of surface contaminants such as colored deposits, corrosion, and cleaning residue deposits. If foreign material is present, or fluid exposure is suspected, remove any material using a compatible cleaning agent. See Section 9.2, <i>Cleaning and Disinfecting the Pump</i> for details about cleaning the NOVUM IQ large volume pump. Regular inspection and cleaning will help prevent unnecessary penetration of, or drying of foreign material, which could negatively impact the ability of the door to properly open or close.
!	Load the Administration Set without Slack Loading the administration set with slack may cause: ■ The tubing to be caught in the door resulting in a Door Not Fully Latched alarm. See <i>Door Not Fully Latched Alarm</i> on page 8-17 for a full description of this alarm. ■ The tubing to be loose in the pump, resulting in Non-Halting System Error alarms (code 20602). See non-halting system error alarm descriptions beginning on page 8-29.

NOTE: Follow all loading steps as stated when reloading an administration set.

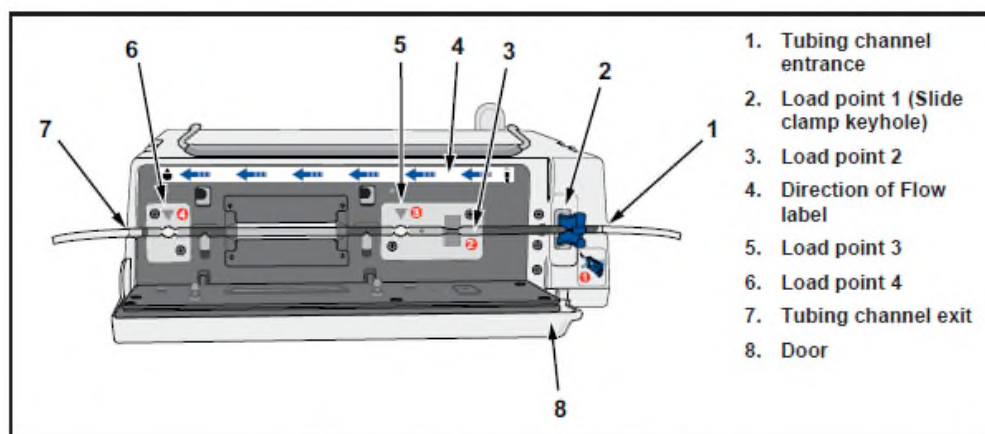


Figure 4-10. Pump Face with Door Open

Attachment A: NOVUM IQ LVP Operator's Manual Excerpt with Additional Guidance

4. Preparing the Pump

To load an administration Set:

1. Inspect the section of the administration set below the slide clamp that is to be loaded or reloaded into the pump. Make sure that the tubing is free of kinks, bends or creases.

WARNING



Do Not Reuse Tubing

Do not reload pumped-on tubing (the tubing segment previously used in the pumping channel) into the pumping channel. Doing so may cause alarms and adversely affect flow rate accuracy.

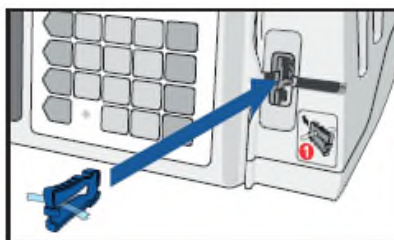


Retainer Clip

When loading the administration set, make sure the tubing is held by the retainer clip. Not using the retainer clip may result in a partial occlusion that may not be detected by the NOVUM IQ large volume pump or result in Non-Halting System Error alarms (code 21515). See non-halting system error alarm descriptions beginning on page 8-29.

Partial occlusions in the line may impact infusion accuracy and result in serious injury or death.

2. Press  to power on the pump.
3. Visually track the tubing from the drip chamber through the closed slide clamp.
4. Insert the slide clamp into the keyhole at the right side of the pump.
 - Inserting the slide clamp properly is the only way to open the pump door.
 - Do not grasp the top of the door and attempt to pry it open.



Load Point 1 is the keyhole. The slide clamp must remain in the keyhole during administration set loading and reloading.

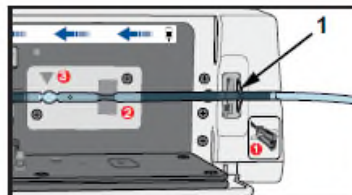
- If the slide clamp is removed during set loading, an alarm will sound. If this occurs, you will have to reload the administration set



Attachment A: NOVUM IQ LVP Operator's Manual Excerpt with Additional Guidance

4. Preparing the Pump

- Make sure the tubing is inside the retainer clip (1) on the right side of the keyhole.



5. Push in on the slide clamp until the door opens. When the slide clamp is properly inserted, the keyhole will light up and the door will be unlatched.
6. Open the door fully, so that it is horizontal. Tubing should now be in front of the loading channel and not underneath the door.

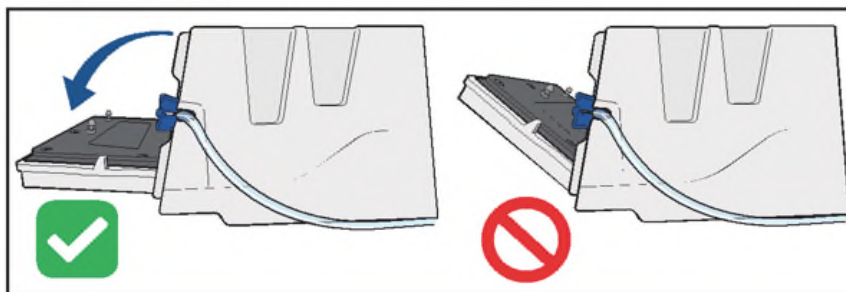
Inspect the tubing channel to make sure it is free of dirt and debris. See Section 9.2, *Cleaning and Disinfecting the Pump*.

CAUTION



Fully Open the Door to Properly Load the Administration Set

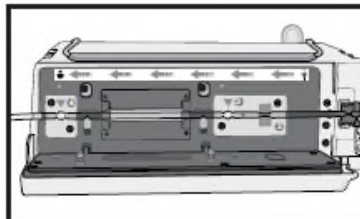
Opening the door fully is the only way to properly load the administration set into the pumping channel. Failure to do so may result in difficulty closing the door, set loading alarms, and the pump infusing at rate other than programmed.



Attachment A: NOVUM IQ LVP Operator's Manual Excerpt with Additional Guidance

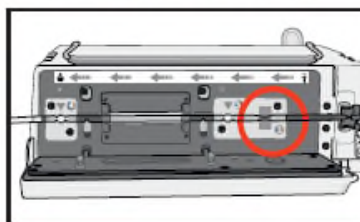
7. Load the primed administration set tubing from right to left in the tubing channel.

- Make sure that the tubing follows the Direction of Flow label.
- Make sure that the tubing is routed from the slide clamp directly into the tubing channel.
- Load the tubing without slack. This prevents the tubing from getting caught in the door or from being loose in the pump.
- Do not use excessive force when inserting the administration set into the channel.



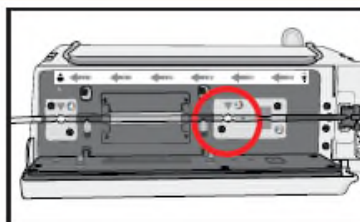
8. Push the tubing into Load Point 2.

- Run a thumb or finger as you load to eliminate slack.



9. Push the tubing into Load Point 3. When the tubing is correctly loaded the triangle over Load Point 3 will light green and an audible tone will sound.

NOTE: If the pump is actively alarming, the loading tones will not sound.

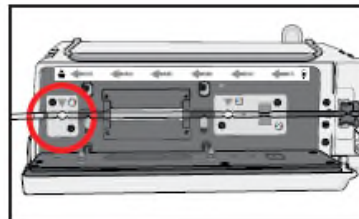


Attachment A: NOVUM IQ LVP Operator's Manual Excerpt with Additional Guidance

4. Preparing the Pump

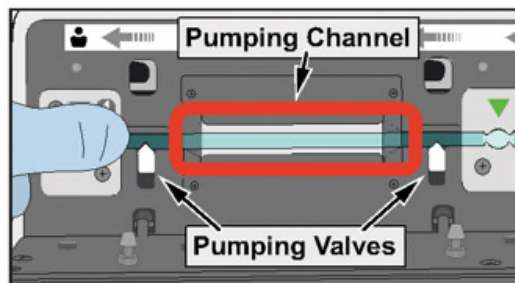
10. Lead the tubing from Load Point 3 to Load Point 4 without slack.
11. Push the tubing into **Load Point 4**. When the tubing is correctly loaded the triangle over Load Point 4 will light green and an audible tone will sound.

NOTE: If the pump is actively alarming, the loading tones will not sound.



12. Lead the tubing out the left side of the pump via the tubing channel exit.

Confirm that the tubing is seated into the white pumping valves.



WARNING

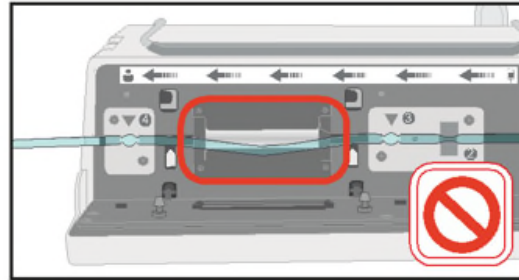


Properly Load Tubing into Pumping Valves

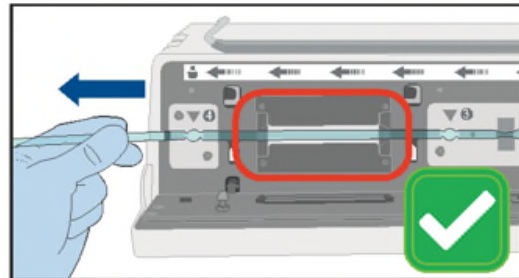
Failure to properly seat the tubing into the pumping valves may result in the pump infusing at a rate higher or lower than programmed, resulting in serious injury or death.

Attachment A: NOVUM IQ LVP Operator's Manual Excerpt with Additional Guidance

Make sure there is no slack in the tubing before closing the door.



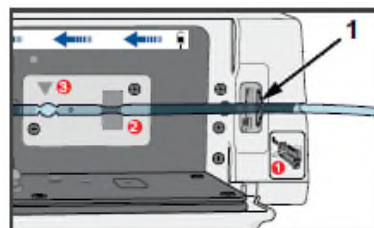
If there is slack in the line, gently pull the tubing to the left to eliminate the slack.



Attachment A: NOVUM IQ LVP Operator's Manual Excerpt with Additional Guidance

13. Make sure that the tubing is inside the retainer clip (1) on the right side of the keyhole.

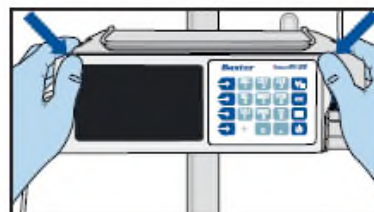
NOTE: If the tubing is not held by the retainer clip, when the door closes and the slide clamp ejects, the tubing may still be occluded by the slide clamp. An Upstream Occlusion alarm will occur if the tubing is still fully occluded by the slide clamp.



14. Close the door.

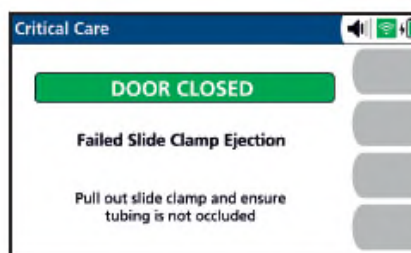
NOTE: Avoid pinching your fingers by pressing on the front corners of the door and grasping the finger grips.

NOTE: Do not press on the display when closing the door.



15. The slide clamp will be ejected when the administration set is properly loaded and the door is closed. Make sure that the clamp is fully open.

If the slide clamp fails to automatically eject, the Failed Slide Clamp Ejection message appears. Manually remove the slide clamp from Load Point 1 and unocclude the line to clear this message.



Attachment A: NOVUM IQ LVP Operator's Manual Excerpt with Additional Guidance

4. Preparing the Pump

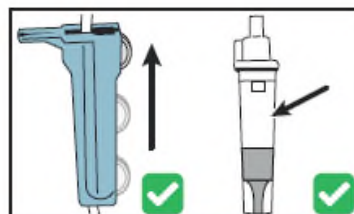
WARNING	
	Bolus When the administration set is loaded, the door is closed and the slide clamp is ejected, a fluid bolus will occur (maximum of 0.3 mL).
	Special Considerations for Use in the Neonatal Population ■ Use 60 drop/1 mL administration sets. ■ Consider whether the infusate is appropriate and can be delivered safely to the neonate patient via the pump, given the flow rate volumetric accuracy specification (See Table A-1, Pump Specifications in Appendix A). ■ Bolus accuracy is of particular importance for neonates, where adverse effects will be more deleterious with little time for reversal. See the bolus accuracy specification in Table C-1 of Appendix C to ensure bolus use is appropriate. ■ Configure the pump with appropriate flow rate, VTBI (Volume To Be Infused), patient weight, occlusion alarm sensitivity, air-in-line limits, and KVO settings, etc., for the neonate patient. See Table A-1, Pump Specifications in Appendix A for available settings. ■ Ensure that if a drug library care area is used, that the care area is appropriate for use in neonates. ■ The volumetric accuracy may deviate outside the accuracy specification when used at Non-Standard environmental conditions, as described in Section B4, Effect of Environmental Conditions. ■ Air Infusion of <50 µL can result in under infusion when assessing instantaneous flow rate accuracy for rates <3 mL/hr. When higher accuracy is required for instantaneous flow rate, consider an alternate infusion device. ■ Refer to Table A-1, Pump Specifications for unintended bolus volumes related to disposable loading, occlusion and single fault. Please ensure that this bolus volume of infusate is appropriate for the neonate patient. ■ Prior to connecting to the patient: 1. Prime the administration set following the standard gravity priming instructions included with the administration set. 2. Close the roller clamp. 3. Load the administration set. 4. Open the slide clamp and the roller clamp to avoid a possible bolus (0.3 mL) that would result from a door opening/set loading event. ■ If the pump door is opened while the administration set is connected to a patient, bolusing at door closing must be avoided. Before closing the door, clamp the set below the lower Y injection site. Connect a syringe to the lower Y injection site, close the door, open the slide clamp, collect bolus in the syringe and unclamp the set below the Y injection site. ■ Use an air eliminating filter to prevent air embolisms in susceptible patients.

Attachment A: NOVUM IQ LVP Operator's Manual Excerpt with Additional Guidance

4. Preparing the Pump

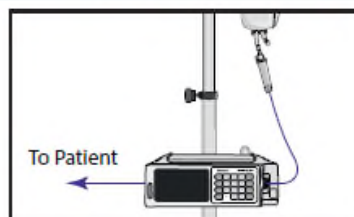
16. Open the lower roller clamp and confirm that no drops are flowing within the drip chamber.

NOTE: Close the roller clamp and remove the pump from service if drops are flowing in drip chamber.



17. Trace the administration set line from the container to the pump and from the pump to the patient to confirm correct route.

NOTE: When using multiple pumps, make sure that the administration set lines are correctly traced from the container to the pump and from the pump to the patient.



NOTE: Follow your facility's procedure for labeling administration set tubing.

18. Connect the administration set to the patient access site.

WARNING



Prime Before Connection

Prior to connecting to the patient, prime the administration set following the standard gravity priming instructions included with the administration set, remove all air, close the roller clamp and the slide clamp, load the administration set into the Novum IQ large volume pump, close the door, open the roller clamp, and make sure that the slide clamp is open.

The pump is unable to detect any air that may be present in the additional administration set lines when another administration set or add-on is added to the existing infusion below the pump.

19. Prime all additional administration sets or add-ons prior to attaching to the existing infusion.

NOTE: Make sure that drugs using the same administration set are compatible with one another.

Attachment A: NOVUM IQ LVP Operator's Manual Excerpt with Additional Guidance

4. Preparing the Pump

4.4 Unloading an Administration Set

WARNING



Do Not Allow Uncontrolled Gravity Flow.

- Before unloading a primed administration set, ensure that the roller clamp below the pump is in the closed position.
- Do not open the slide clamp when the door is open or during and after administration set unloading. This can cause dangerous, uncontrolled free flow to occur.
- Always close the set's roller clamp during administration set changes.

To unload an administration set:

1. Press  to stop the infusion when the pump is running.
2. Close the roller clamp to prevent free flow.
3. Push the slide clamp into the keyhole until the door opens.

WARNING



Use only the slide clamp on the administration set loaded into the pump, to prevent free flow. Use of a slide clamp from another administration set can cause dangerous uncontrolled free flow to occur when the door is opened.

4. Unload the tubing out from the left side of the pump towards the right. Make sure that the slide clamp is not inadvertently opened when removing tubing.

