COVID-19 Clinical Considerations: Using extra-long extension sets with the BD Alaris™ Pump Module and Alaris™ Syringe Module

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BD understands some Alaris customers are connecting extra-long extension sets to the Alaris pump sets in order to keep the pumps outside the patient room. The information below addresses our customers' commonly asked questions related to this practice need.

I. Rate Accuracy

BD Alaris™ Pump Module

Rate accuracy of the Alaris™ Pump Module is +/-5% at rates between 1 and 999 mL/h, under certain conditions that include a standard Alaris dedicated IV set, source container head height of 20 inches above the top of the module, an 18 gauge needle, etc.

Alaris™ Syringe Module

Rate accuracy of the Alaris™ Syringe Module is +/- 2% but does not include syringe variation. The syringe size and running force, variations of back pressure or any combination of these can affect rate accuracy.

Any variations to the above rate accuracy conditions can affect the pump's accuracy. BD has done some informal, limited quantity testing with smallbore extra-long extension sets (108 inches long) and when one or two of the sets were attached to a pump primary set, the effect on device rate accuracy was minimal and the rate accuracy remained in the +/-5% specification. The Clinical Consideration sections below provide several ways to optimize pump performance.

Clinical Considerations for Rate Accuracy Performance

- **Head Height:** Attempt to hang the IV containers 20 inches above the top of the pump modules much as possible.

- **Catheter gauge:** A larger gauge catheter will decrease downstream resistance. This is particularly important when combining multiple infusions into the same IV line.
- **Management of IV Lines:** Any efforts to reduce unnecessary resistance in the line, e.g., extraneous loops of pump tubing, keeping the extension set additions as limited as possible, infusing through as large a catheter as possible, ensuring all clamps / connections are open when appropriate, can greatly help lower the resistance or working pressure in the IV line.
- **Prior to Starting the Infusion:** Consider pre-running the fluid/medication through the long extension sets prior to connecting to the patient to ensure the extension sets are fully primed with the medications to minimize risk of a delayed start.
- **IV Infusion of Critical Medications:** Once the infusion(s) are started, particularly if the long set is fully primed with medications well mixed, many critical medications are titrated to affect and continue to be titrated as needed. Although the rate accuracy due to these line setups may be affected related to volume over time infusions (e.g., hydration), the negative impact on rate accuracy for titratable medications should be minimal.

II. Occlusion Pressure Settings

Extra-long smallbore tubing may increase resistance downstream, which may lead to:

- Increased occlusion alarms at higher rates (higher volume is being forced through long narrow tubing)
- Increased time to alarm (takes longer for pressure to build in the line and reach limit threshold)

The BD Alaris™ Pump Module has two (2) **Occlusion Pressure Limit** programming modes.

Pump Pressure Mode: the occlusion pressure limit is a function of the flow rate and is automatically determined by the device. The downstream occlusion alarm threshold is 10.2 psi (~525 mmHg) for rates of 30 mL/h and above. For rates less than 10 mL/h, the alarm threshold is 3 psi (~150 mmHg). For rates between 10 and 30 mL/h, the occlusion pressure limit is rate-dependent for a faster response to occlusions.

Selectable Pressure Mode: The downstream occlusion alarm threshold can be adjusted in 25 mmHg increments, from 50 mmHg to the maximum occlusion pressure of 525 mmHg.

Clinical Considerations for Setting the Occlusion Pressure Limit:

BD Alaris™ Pump Module

If the infusion rates are above 30 mL/h, consider using the **Pump Pressure** mode, which automatically adjusts the occlusion pressure limit to 525 mmHg. This is particularly relevant if multiple infusions of higher rates are connected to one long extension line. This mode will reduce the number of nuisance occlusion alarms that may occur due to a higher resistance in the IV line setup.

If the infusion rates are less than 30 mL/h, and the pump is alarming for Downstream Occlusion without an apparent cause (nuisance alarms), consider changing to **Selectable Mode** to manually increase occlusion pressure limits to a higher setting.

How to change the Occlusion Pressure Limit for the BD Alaris™ Pump Module:

1. Press **CHANNEL SELECT** key
2. Press **OPTIONS** key
3. Press **Pressure Limit** soft key (Figure A)
4. Press either **Pump** or **Selectable** pressure soft key. (Figure B)
5. Press **Selectable** to change the occlusion pressure limit either Up or Down.

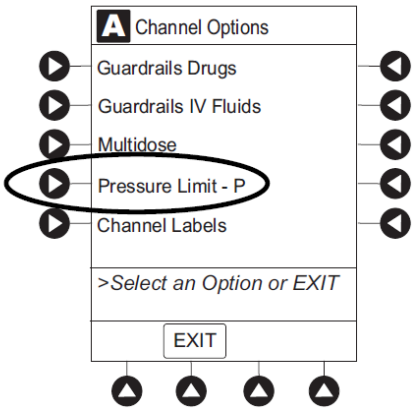


Figure A

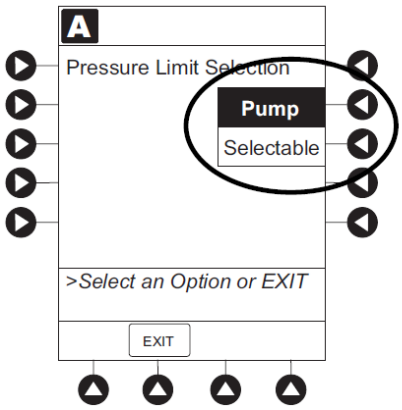


Figure B

Alaris™ Syringe Module

The Alaris™ Syringe Module can be used with or without a Pressure Sensing Disc.

Without a Pressure Sensing Disc: The occlusion pressure can be set to low (200 mmHg), medium (500 mmHg), high (800 mmHg).

With a Pressure Sensing Disc: The occlusion pressure can be set between 25–1000 mmHg in 1 mmHg increments. Customized limits can be set either manually, by reading the current pressure following stabilization and adding a margin, or by use of the Auto Pressure feature which, on activation, sets a margin of 30 mmHg for initial pressures under 100 mmHg or 30% of the initial pressure at higher initial values.

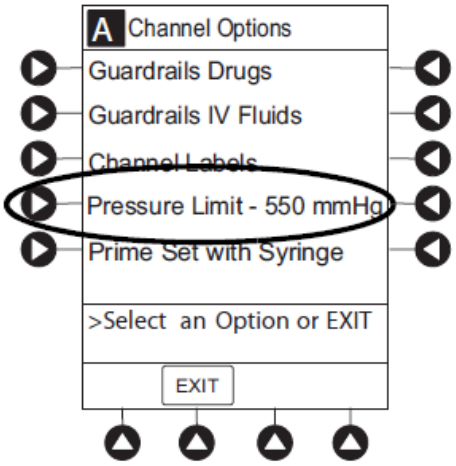
With or without a pressure sensing disc: use the lowest setting possible to decrease time to alarm, but if nuisance occlusion alarms are occurring consider raising the occlusion pressure setting.

How to change the Occlusion Pressure Limit for the Alaris™ Syringe Module:

1. Press **CHANNEL SELECT** key
2. Press **OPTIONS** key
3. Press **Pressure Limit** soft key

When using the pressure sensing disc:

Press the **Pressure Limit** soft key.

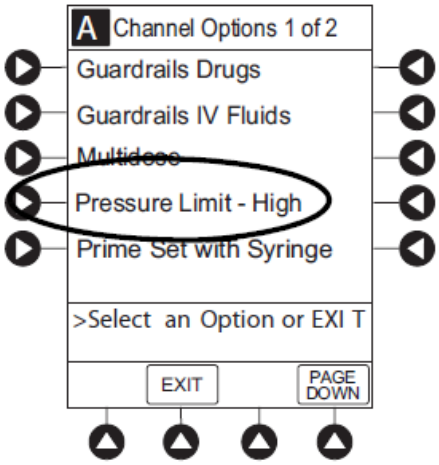


To enter a new pressure limit value, press the **Change Value** soft key, or

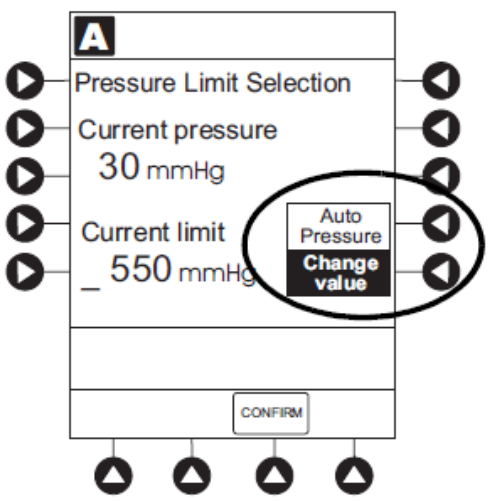
If Auto Pressure feature is enabled, press the **Auto Pressure** soft key.

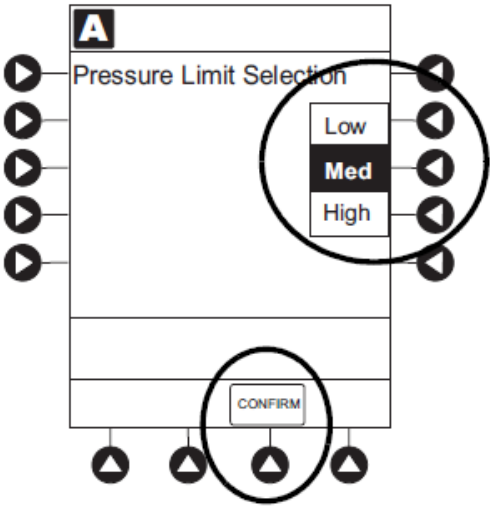
Without a pressure sensing disc:

Press **Pressure Limit** soft key.



To select a pressure limit, press appropriate soft key,
Press **CONFIRM** soft key.





Pharmacy

Consider setting the Pressure Mode Lock Status to Unlocked in the Guardrails™ Editor software. Unlocking the pressure mode configuration will allow nurses the ability to adjust the pump module between Pump Mode and Selectable Mode. Also review the Occlusion Pressure Limit options for the syringe module. Low, Medium and High settings are available without the pressure sensing disc tubing. If pressure sensing disc tubing is in use, additional configurations need to be enabled to set up to the max occlusion pressure of 1000 mmHg.

III. Intermittent Infusions

When running intermittent infusions with extra-long extension sets, consider the following to ensure all medication is delivered to the patient:

- Know the priming volume for the entire length of the tubing when programming infusion rates and flush volumes. With long tubing, consider priming the set with the medication to facilitate prompt delivery.
- If the extension line requires a flush, ensure the flush rate is the same as medication delivery rate so the medication infuses over ordered duration.
- If using secondary mode (sequential piggyback) to infuse a secondary medication at a rate different from the primary, check the rate of the primary infusion to ensure any medication remaining in the line is adequately flushed when the primary infusion resumes.

IV. Other Considerations

- If the BD Alaris™ System is placed outside patients' rooms, ensure that the power cord is plugged into an AC outlet. The AC indicator light (plug icon) will be lit up on the front of the PC Unit when it is plugged in and charging.
- There is no extension for the PCA button (dose request cord) when an Alaris™ PCA Module is placed outside the patient's room.
- If using a PCA extension set, be aware that it contains an anti-siphon valve near the proximal end. This valve requires higher pressure to be opened and therefore cannot be primed by gravity. The set can be primed by a manual syringe push or by running on the pump until a drop is seen at the distal end before connecting it to the patient.
- For the Alaris™ EtCO2 Module, Medtronic manufactures longer length Microstream disposables that are 13 feet long (e.g. part number 012463). They also offer an extender disposable that is 30 feet long, which can be added to the end of a standard Microstream disposable to allow the device to be outside the patient's room (part number 006325). The Microstream disposables contain a 0.2 micron hydrophobic filter to help reduce the risk of fluid ingress and biohazard contamination of the monitor. The filter is designed to filter particles that are larger than 0.2 microns, which aligns with the CDC protective guidelines for usage of the N95 face mask that is designed to filter particles larger than 0.3 microns.
- BD engineers have analyzed the potential effects and risks of utilizing 70% isopropyl alcohol to clean the outside of the polyvinyl chloride (PVC) tubing used in our extension sets. In reviewing independent studies and construction of Alaris extension set materials, our analysis of the data suggests that wiping down Alaris extension set tubing 2-3 times daily with a 70% isopropyl alcohol solution has minimal risk of changing tubing mechanical properties significantly enough to impact the functional performance of the PVC sets (i.e. kinking, flexibility, etc.). The risk of the isopropyl alcohol entering the fluid pathway is negligible. It is therefore expected that the PVC IV extension sets would still deliver their critical function with minimal risk to clinician or patient.
- The primary material risks of repeated disinfecting of PVC infusion and extension sets are as follows:
  - The exterior of the tubing could become slightly tacky.
  - Creation of visual defects in the outer tubing wall, but no impact to the bulk properties of the tubing as this would only affect the outer 10% of the tubing thickness.

For any additional questions related to this information, please visit www.bd.com/MMSCOVID, call 858-617-1316 or email GMB-AlarisMedSafetyProgram@bd.com.