Operating Guidelines for the Medrad Stellant D Injector

Purpose: In order to minimize extravasations and maintain imaging quality the following guidelines and instructions shall be used.

Guidelines:

1. Use a 20 gauge or larger IV catheter over needle (a 22 gauge may be used with slower flow rates).
2. The preferred location for venipuncture is the medially located antecubital vein.
3. Have at least ½ inch of the catheter positioned in a good vein with rapid backflow.
4. Use a 60-96 inch coiled low pressure tube securely attached to the catheter. The coiled tubing reduces motion effect during table incrementation.
5. Instruct the patient to communicate immediately any pain or change in feeling during the injection.
6. If possible, instruct the patient to put his or her arm vertically above the shoulder with the palm of the hand on the ace of the gantry during injection. This allows for uninterrupted passage of injected contrast through the axillary and subclavian veins at the thoracic outlet.
7. A small volume test injection of contrast or saline may be utilized to confirm venous assess. A trained professional should remain by the patient during the initial stages of the injection palpating the venous access site to ensure proper placement of the I.V. catheter. If focal pain, swelling or signs of extravasation are noted, the injection should be stopped immediately.
8. Central lines and hep-locks should only be used in accordance with hospital policy guidelines.
9. Adhere to all instructions, warnings, and cautions listed for the specific products being used.

Injector Operation

DISPLAY CONTROL PANEL

1. INJECTION PHASES: First phase can be **Test Inject, Contrast, or Saline.** Test Inject parameters are programmable in the **SETUP SCREEN**. Six phases are available for programming. If more phases are required, press the triangle below the first phase, and Select **Contrast A, Flush B, Hold, or Pause.**

2. **Flow Rate** – 0.1 to 10 ml/sec, **Volume** – 1 to 20 ml, Pressure Limit – 50 to 325 PSI- Press **SET** to program.
3. **DELAY- programmable to 1 to 99 seconds. Press SET to program. Emits 5 beeps when delay is complete: Scan Delay, Inject Delay, No Delay**
4. **Programmed Volume and Total Duration is displayed on the screen.**
5. **Syringe icons indicate volume remaining in the syringes. A=Contrast - green, B+Saline-blue.**
6. **Press PROTOCOL LOCK on screen.**
7. **PROTOCOL LOCK must be ON to ARM from the injector head.**

SYRINGE INSTALLATION AND LOADING

1. Place the injector head in an upright position with the pistons fully retracted.
2. Syringes are sterile and for single use only. **Patient injury can result from leaks or ruptures during an injection. Use only MEDRAD disposable products, or use catheters and connectors with pressure ratings that are compatible with this system.** Inspect syringe packaging for expiration date and package integrity. Install syringes by inserting quickly and firmly in one motion. Installing the syringe slowly can result in an error message. Piston will automatically advance to the front of the syringe.

SETUP:

1. Using sterile technique, attach the sterile loading device and load the syringes by pressing **AUTOLOAD** and **FILL A** and/or **FILL B** within 10 seconds. The syringe will load the volume programmed at the **Main Screen**.
2. Increase or decrease the volume by pressing the +/- key.
3. Manually load the syringe by pressing MOVE PISTON to activate the forward and reverse load strips.
4. Expel any air from the syringes using the manual knobs or load strips.
5. Attach LPT with PRIME TUBE attached to the patient end of the tubing.
6. Select PRIME to fill the LPT with contrast or saline – configurable in the SETUP SCREEN or use manual knobs or load strips.
7. Patient injury can result from high contrast temperature. Do not use the syringe heat maintainer if the fault indicator light is on.
8. It is recommended that contrast be stored in a heater at 35° C before loading it in a syringe. Once contrast is loaded, snap the heat maintainer over the syringe to maintain contrast temperature.
9. Inspect the syringe, tubing, and FluiDots, confirming that all air is expelled, remove **PRIME TUBE**, turn injector head down, and connect LPT to patient ensuring an air-free connection.

10. **FluitDots:** View looking through the syringe jacket at a light source.

    - **Empty syringe** – dots appear as narrow elipses
    - **Full syringe** – dots appear **larger** and **almost round**.

11. **Air embolism can cause death or serious injury to the patient. Patient injury could result from high flow-rate venous injections. Patient injury could result from inadvertent aspiration. Extravasation can cause injury to the patient.** Acknowledge that air inspection has occurred by pressing **CHECK FOR AIR.** If CHECK FOR AIR is not pressed at the injector head, the system will request confirmation that all air was expelled as part of the arming procedure.

INJECTION PROCEDURE

1. Press **ARM** on the injector head or the Main Screen.
2. Ensure there is sufficient volume to complete the protocol, insufficient volume is indicated with a message at the Display Console or flashing indication at the injector head.
3. Press ARM twice at the injector head to proceed with the remaining volume.
4. Armed Indication Lights – Contrast =green, Saline=blue, will flash when the injector is armed or on hold and will be solid when injecting.
5. Initiate the injection at the patient side.
6. **Injection View** – configurable at the Set-Up screen. Volume Remaining decrements and Delivered Volume increments.
7. **Phase** – as the phase is activated, it is highlighted, elapsed time and current
8. Phase is in status window.
9. **Pressure Graph** – displays the syringe pressure developed during an injection.
10. **ABORT:** Press any **button on the head or display except START/HOLD.** Pressing **START/HOLD** during an injection will hold an injection up to 20 minutes.
11. **Injection Complete** – summary of parameters selected and delivered are shown. Elapsed time will continue until **OK** is pressed.
12. **Syringe Removal** – twist syringe counterclockwise with tubing connected and discard following local guidelines. The piston will automatically retract.

STORE/RECALL/DELETE

1. **STORE-** enter desired parameters, press **STORE**. Title the protocol using keypad, press **ENTER**. 32 protocols can be stored in memory.
2. **RECALL** – press **RECALL**, press protocol title, press **OK**.
3. **DELETE**- press **RECALL**, press protocol title, press **DELETE**.

DISPLAY CONSOLE KEYS

1. **SETUP –** identifies configurable items and displays values.
2. **HELP –** information on system operation and service.
3. **RESET-** replaces all programmed phases, with factory default settings.

SYSTEM MALFUNCTION MESSAGES

If a system malfunction appears:

a. **Immediately remove power and disconnect the patient from the system.**
b. **If a fault message cannot be corrected, and/or the system is not Operating properly, DO NOT USE the system. Call MEDRAD Service.**
c. Routine inspections and maintenance will ensure continued performance and reduce equipment malfunction. MEDRAD, Inc. recommends complete calibration and performance check annually.

CLEANUP

1. **SHOCK HAZARD. Disconnect the system from line power when cleaning.**
2. **Do not immerse any part of the injector or allow liquid to enter the enclosure.**
3. Wipe the system with a soft cloth, warm water and a mild disinfectant. For all body-fluid spills, follow institutional decontamination procedures.

STELLANT PRESSURE MONITOR HELFUL HINTS – 203473 Rev. A.

CONDITION#	DESCRIPTION	POSSIBLE CAUSES	POSSIBLE ACTIONS
Condition #1	The graph is the typical shape, but the pressure is higher than normal.	The pressure required to push the contrast media through the disposable system is higher than normal, which means there is a greater restriction to fluid flow. Greater restriction can be caused by any of the following: * Higher viscosity of the contrast media (more grams of iodine/higher concentration, or lower temperature of of the contrast media/not heated. * A smaller gauge catheter is being used. * An additional disposable is in the fluid path causing a greater restriction to the flow of fluid (extension tube, stopcock, check valve, IV extension set). * Defective syringe (under lubricated).	Check to insure the syringe heater is functioning normally. As long as the "Possible Causes" listed are of no concern, then no action is necessary.
Condition #2	The graph is the typical shape, but the pressure is <u>lower</u> than normal	The pressure required to push the contrast through the disposable system is lower than normal, meaning there is less restriction to fluid flow. Lower restrictions can be caused by any of the following: * A lower visocity contrast media (less grams of iodine/lower concentration, or higher temperature of	As long as the "Possible Causes" listed are of no concern, then no action is necessary.

		contrast media/heated). * A larger gauge catheter is being used. * Fewer disposables in the fluid path (lack of extension tube, stopcock, checkvalve, IV extension set).	
Condition #3	The graph and injection start out normal, but level off to a less than expected peak pressure.	An inappropriate pressure limit may be selected. If a lower pressure is selected than what is required to deliver the flow rate, the injection will start out normally for the first few seconds. However, as soon as the pressure limit value is achieved, the flow rate will automatically decrease to keep the system from exceeding the selected pressure limit.	Check to see if the Pressure Graph is approaching the dotted horizontal line (pressure limit setting). If it is, the injector is pressure limiting and causing this condition. See Pressure Limiting" in the Operation Manual for a thorough discussion of causes and resolution.

Note: Medrad makes no claims about the information on the Pressure Monitor Graph other than it is a graphic representation of the force required to move the syringe plunger, which closely approximates the pressure developed in the syringe.

CONDITION#	DESCRIPTION	POSSIBLE CAUSES	POSSIBLE ACTIONS
Condition #4	At the start of the injection, the Pressure Garph signal immediately rises straight up and hits the pressure limit setting (dotted horizontal line).	The fluid path may be occluded (after reaching a "High Pressure Disarm". Stellant will automatically terminate the injection). Total occlusions may be caused by one of the following: * A closed stopcock * An IV extension set with the clamp closed off * A defective disposable (fluid will not flow through it).	Consider putting the injector on hold and investigating. There is a high probability that no contrast media is being injected into the patient.

Condiiton #5	The injection is proceeding perfectly normal, but during the injection, with no programmed decrease in flow rate, the Pressure Graph sharply drops to baseline, but no error messages appear on the screen. Note: If a multilevel injection is programmed, and the flow rate is programmed to decrease, then the pressurewill also drop at that time.	If the injector is still armed and injecting at a constant flow rate, but the Pressure Graph drops sharply to baseline: **Stop the injector immediately and investigate**. The pressure in the syringe has sharply dropped and through the piston is moving forward and should be developing pressure. Possible causes: * The Low Pressure Connector Tubing, extension set, or catheter has burst or disconnected from the fluid path (fluid is running on the floor). * The syringe may have failed. Fluid is being forced around the syringe plunger instead of out the end of the syringe (fluid is running on the floor).	If the injector is still injecting (arm light solid and manual knob on the back of the head turning), consider aborting the injection. There is a high probability that fluid is running on the floor.
Condition #6	The pressure buildup to the expected peak is taking longer than typical, even thought he injector is injecting normally.	Due to operator error, the syringe may contain a large amount of air (example: half air, half fluid). It is easier to compress air, than to push fluid through a CT disposable system, so the injector is initially developing less pressure as it compresses the air.	Stop the injector immediately and investigate. Check the fluid path for air.

Condition #7	When the injection starts, <u>almost no pressure buildup is witnessed, when a buildup was expected.</u>	Due to operator error, there may be no fluid in the syringe (you could be injecting air). The injector will experience almost no resistance to moving the syringe plunger forward with an empty syringe. **Note**: Very slow injections through large disposable sets will require and display very little pressure. This is normal. What is being described above is a condition where a buildup of pressure was expected, and none was witnessed. OR: You may have two syringes on the injector, only performing a single syringe injection, and the LPCT may be connected to the wrong syringe.	Stop the injector immediately and investigate. Check the fluid path for air.
Condition #8	At the end of a normal injection, the pressure graph <u>does not immediately drop to zero</u>.	Stellant is designed to inject all of the contrast in the syringe to help minimize contrast waste. Sometimes in the process of doing this, the piston pushes against the front of the syringe as it squeezes out the last drops of fluid. This in turn generates pressure, which is displayed by the Pressure Graph. This pressure reading should drop to baseline after about 50 seconds.	No action. This is normal operation.

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