



STEM CELL LABORATORY (STCL)



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Operation of Medfusion/Protege 3010/3010A Syringe Pumps

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STCL-EQUIP-020

OPERATION OF MEDFUSION/ PROTÉGÉ 3010/3010a SYRINGE PUMPS

1 PURPOSE

- 1.1 This procedure provides instruction to laboratory staff in the proper operation of the Medfusion/Protégé 3010/3010a syringe pump with orbital rocker. The delivery of cryoprotectant is critical to the quality of the product being prepared.

2 INTRODUCTION

- 2.1 The Medfusion/Protégé 3010/3010a syringe pump is an automated device that is used to deliver a controlled volume of DMSO over a specified time period, which is critical for the delivery of cryoprotectant to hematopoietic stem cells in preparation for cryopreservation.

3 SCOPE AND RESPONSIBILITIES

- 3.1 The procedure applies to the use of these syringe pumps for the infusion of DMSO into cord blood units prior to cryopreservation.
- 3.2 The STCL Medical Director, Laboratory Manager, and designated Stem Cell Laboratory staff are responsible for ensuring the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

- | | | |
|-----|------|----------------------|
| 4.1 | DMSO | Dimethyl Sulfoxide |
| 4.2 | STCL | Stem Cell Laboratory |
| 4.3 | CBU | Cord Blood Unit |
| 4.4 | mL | milliliter |

5 MATERIALS

- 5.1 Cryoprotectant containing 55% DMSO 5% Dextran 40 in vial or pre-filled syringe
- 5.2 Processing kit
- 5.3 Sepax CS-530 single-use kit DMSO line
- 5.4 10 mL Syringe

6 EQUIPMENT

- 6.1 Medfusion/Protégé 3010/3010a Syringe Pump
- 6.2 Orbital Rocker

7 SAFETY

- 7.1 Use all appropriate personal protective equipment when handling potentially hazardous blood and body fluids to include, but not limited to, gloves, lab coats, goggles, etc.

8 PROCEDURE

- 8.1 Secure the cellular/CBU product bag, wrapped in an ice pack, with rubber bands to the platform of the orbital rocker.
- 8.2 Turn orbital rocker switch on.
- 8.3 The platform should rock in an orbital pattern and should be free of any obstructions. Ensure the contents are secure before starting infusion.
- 8.4 To turn on the syringe pump, press and hold the power button until the dark screen appears.
- 8.5 The display screen should turn on and will automatically run a self-test.
- 8.6 Once the self-test is complete, the display will show "SELF TEST COMPLETED" indicating the successful completion of the system startup and self-test. If self-test is unsuccessful, a "system advisory" message will appear. Consult with the lab manager or senior staff before proceeding.

NOTE: System Advisory error messages require that maintenance be performed.

- 8.7 Next prompt will be to "**SELECT MODE SCREEN**".
- 8.8 Loading the Syringe onto the Pump:
 - 8.8.1 If closed, lift and swivel the syringe "Barrel Clamp" out of the way.
 - 8.8.2 Squeeze "Plunger Release Lever" on the syringe plunger driver and pull gently to extend it all the way.
 - 8.8.3 Load the 10 mL syringe onto the pump making sure the flange of the syringe barrel is pressed or rolled into "Flange Clip".
 - 8.8.4 Turn and lower "Barrel Clamp" onto the barrel of the syringe.
 - 8.8.5 Squeeze "Plunger Release Lever" on the end of the syringe plunger driver and slip the end of the syringe plunger into place, then release the lever to close it around the syringe.
 - 8.8.6 Ensure that the correct syringe size and manufacturer appear on the display. If not, remove syringe and reinstall it, display guide will appear to assist with identifying the problem. After install problem is corrected, display should show correct syringe size.
 - 8.8.7 Thread the tubing through the "Tubing Holder" on the top left side of the pump.
- 8.9 Selecting Delivery Mode:
 - 8.9.1 Press the button to select number 2 "**VOLUME/TIME**" delivery mode.
 - 8.9.2 Enter the volume amount and press enter.

- 8.9.3 Enter the length of time during which the solution will be infused, and then press **“ENTER”**.
- 8.10 Starting Infusion Delivery:
- 8.10.1 Ensure the clamp on the DMSO line and the cellular/CBU product bag is open.
- 8.10.2 The screen will display **“PRESS <START> TO BEGIN INFUSION”**. Press **“Start”**.
- 8.10.3 Pump will begin infusing.
- 8.10.4 Ensure that the **TVD** (Total Volume Delivered) and the **PVD** (Program Volume Delivered) begin increasing.
- 8.10.5 The timer will begin counting down from the time set.
- 8.11 Unloading the Syringe:
- 8.11.1 Following completion of the infusion, an alarm will sound. Ensure that infusion is complete and that volume delivery is accurate by looking at the syringe.
- 8.11.2 Press **“Stop”** button to end delivery.
- 8.11.3 Pump will stop infusing.
- 8.11.4 Close the blue clamps on the DMSO line and the cellular/CBU product bag.
- 8.11.5 Remove tubing from holding clip.
- 8.11.6 Lift and swivel the syringe **“Barrel Clamp”**, and squeeze **“Plunger Release Lever”** on the syringe plunger and remove the syringe.
- 8.11.7 Press and hold the **“Power”** button to turn OFF the pump.
- 8.12 Proceed to *STCL-PROC-045 Cryopreservation and Storage of CBU* for post DMSO sample removal and cryopreservation.

9 RELATED DOCUMENTS/FORMS

- 9.1 STCL-PROC-045 Cryopreservation and Storage of CBU
- 9.2 STCL-PROC-045 FRM1 CBU Cryopreservation

10 REFERENCES

- 10.1 Medex Part # G6000547 Revision 4-Operation Manual

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
03	B. Waters-Pick	Added document numbers to Section 9

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