



April 23, 2003

**RE: Administration and Aspiration of Blood through the CLC2000®**

Dear Clinician:

Thank you for your interest in the CLC2000 by ICU Medical, Inc. This letter describes the attributes of the CLC2000 when used with blood or blood components.

Various studies have been performed to validate the use of the CLC2000 including an administration and aspiration study to demonstrate that no significant hemolysis occurs, and a flush analysis which demonstrates that following the travel of blood through the device, the CLC2000 can be flushed clean. Following are the specified reports which have evaluate these attributes.

1. Se60-00010 Rev: Nov. 1997. Hemolysis Study of the CLC2000.
2. SE60-00009 Rev: Nov. 1997. CLC2000 Flow Rate and Flush Analysis Using Whole Citrated Bovine Blood.
3. 01-040T Rev: Aug 2001. Hemolysis Blood Draw Study for the CLC2000.

ICU Medical recommends that the CLC2000 be changed in accordance with validated facility protocols. We also recommend flushing the CLC2000 after each use with normal saline or in accordance with facility protocols. The intent of the studies completed by ICU Medical is to provide guidance for the Healthcare Provider in determining what appropriate use protocols are. ICU Medical is aware that the majority of more than 1,000 facilities using the CLC2000 regularly administer or aspirate blood through the device and do not change it after such use.

If you have any further question or concerns related to the CLC2000 please feel free to contact ICU Medical at your convenience.

Best regards,

Alison Burcar  
ICU Medical, Inc.