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Standard Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps[1]

This standard is issued under the fixed designation F1841; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

The goal of blood pump development is to replace or supplement the function of the human heart. As a result, continuous flow blood pumps, including roller pumps and centrifugal pumps, are commonly used in clinical extracorporeal circulation. They are used not only for cardiopulmonary bypass in routine cardiac surgery but also for ventricular assist, percutaneous cardiopulmonary support, and extracorporeal membrane oxygenation.

Many investigators have attempted to develop an atraumatic blood pump. Hemolysis is one of the most important parameters of blood trauma induced by blood pumps. However, comparative *in vitro* evaluation of the reported results of hemolysis are difficult due to the lack of uniformity of the test methods employed. Thus, it is necessary to standardize the method of performing *in vitro* hemolysis tests for the evaluation of continuous flow blood pumps.

1. Scope

1.1 This practice covers a protocol for the assessment of the hemolytic properties of continuous flow blood pumps used in extracorporeal or implantable circulatory assist. An assessment is made based on the pump's effects on the erythrocytes over a certain period of time. For this assessment, a recirculation test is performed with a pump for 6 h.

1.2 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F1830 Practice for Selection of Blood for ***in vitro*** Evaluation of Blood Pumps

3. Terminology

3.1 *Definitions:*

3.1.1 *continuous flow blood pump*—a blood pump that produces continuous blood flow due to its rotary motion.

3.1.2 *free plasma hemoglobin*—the amount of hemoglobin (iron or heme-containing protein) in plasma.

3.1.3 *hemolysis*—damage to erythrocytes resulting in the liberation of hemoglobin into the plasma.

3.1.4 *Index of Hemolysis*

3.1.4.1 *normalized index of hemolysis*—added grams of plasma free hemoglobin per 100 L of blood pumped, corrected for plasma volume using hematocrit and normalized by flow rate and circulation time.

3.1.4.2 *normalized milligram index of hemolysis*—normalized index of hemolysis expressed by milligram value of free plasma hemoglobin.

[1] This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.30 onCardiovascular Standards.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

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