Designation: ~~F1830 – 97 (Reapproved 2013)~~ F1830 – 97 (Reapproved 2017)

Standard Practice for Selection of Blood for *in vitro* Evaluation of Blood Pumps[1]

This standard is issued under the fixed designation F1830; 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.

1. Scope

1.1 This practice covers blood that will be used for *in vitro* performance assessments of blood pumps. These assessments include the hemolytic properties of the devices.

1.2 This practice covers the utilization of blood for the *in vitro* evaluation of the following devices:

1.2.1 Continuous flow rotary blood pumps (roller pumps, centrifugal pumps, axial flow pumps, and so forth) (see Practice F1841).

1.2.2 Pulsatile blood pumps (pneumatically driven, electromechanically driven, and so forth).

1.3 The source of blood utilized for *in vitro* evaluation of blood trauma (that is, hemolysis caused by the blood pumps, due to the pump design, construction, and materials used) substantially influences the results of the performance of these devices. Thus, a standardized blood source is required.

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F1841 Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps (Withdrawn 0)[3]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

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

3.1.2 *hemolysis*—one of the parameters of blood damage caused by a blood pump. This can be observed by a change in the plasma color and can be measured as an increase of free plasma hemoglobin concentration.

3.1.3 *pulsatile pump*—a blood pump that produces blood flow to mimic a natural heart.

4. Summary of Practice

4.1 For the experimental evaluation of blood pump designs and materials, an *in vitro* hemolysis test is recommended using fresh bovine or porcine blood. The donor animals should have normal body temperature, no physical signs of disease, including diarrhea and rhinorrhea, and an acceptable normal range of hematological profiles. The blood from a slaughterhouse should not be used because it may be contaminated with other body fluids, unless obtained by controlled venipuncture. However, for the preclinical studies, fresh human blood is recommended for use (see Practice F1841).

4.2 For the *in vitro* hemolysis test, fresh bovine or porcine blood is used within 48 h, including the time for transport. Fresh human blood should be used within 24 h after blood harvesting. The collected blood should be refrigerated at 2 to 8°C.

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[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 on Cardiovascular 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.

[3] The last approved version of this historical standard is referenced on www.astm.org.