

Department of the Navy SBIR/STTR Transition Program

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ONR Approval #43-4388-18

Topic # N161-064

Inertial Microfluidics-based Platform for Portable Platelet Apheresis

CFD Research Corporation

WHO

SYSCOM: ONR

Sponsoring Program: Code 34

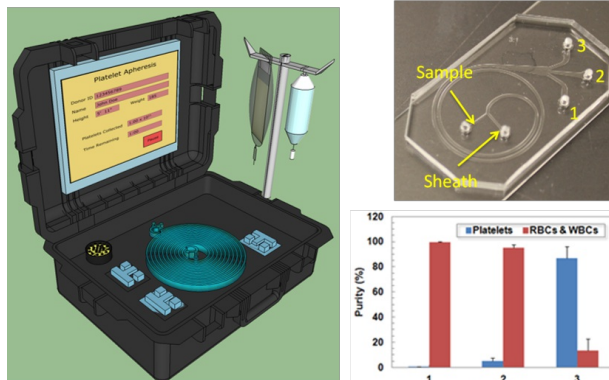
Transition Target: Expeditionary Resuscitative Surgical Systems (ERSS) / Expeditionary Trauma Team (ETT)

TPOC:

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Other transition opportunities:

Surface Warfare Medicine Institute / Operational / Supporter, Naval Medical Center San Diego/Portsmouth



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WHAT

Operational Need and Improvement: Hemorrhage is a leading cause of preventable deaths on the battlefield. Survivability is inversely related to the speed of receiving blood/blood components (red blood cells, platelets, plasma) following catastrophic wounding. Platelets are unavailable at forward operating naval medical facilities due to their short shelf life (3-5 days). Currently manufactured platelet apheresis devices (apheresis removes platelets while returning the other blood components back to the donor) exist in transfusion centers but are not designed for expeditionary use being large, heavy, bulky and have external components susceptible to breakage. Determination of lab values (blood type, platelet count, etc.) requires separate instruments and steps. A solution is the development of a portable, automated, platelet apheresis machine. Field apheresis will allow platelets to be collected from a single donor on site so they are available to the severely injured.

Specifications Required: Performance of the device must be equivalent to current FDA approved devices. It must be lightweight, ruggedized, have an effective platelet separation and leuko-reduction processes, simple operation and set up. The device must be able to receive and maintain the donor's personal info for tracking, and be able to print all stored data.

Technology Developed: CFD Research's portable platelet apheresis platform based on inertial microfluidics will provide fresh, leukocyte-reduced, platelets in the field. It is a single-person carry, ruggedized, battery operated, automated platelet apheresis device. The platform also includes relevant materials for pre-donation assessments including automated determination of platelet counts and serum calcium levels. The platform operates similar to current apheresis machines with only the inertial microfluidics cartridge replacing the centrifugation steps utilized in current machines.

Warfighter Value: Research has shown that the case fatality rates for hemorrhage patients can be reduced by decreasing the time interval between injury and treatment. Along with the increasingly dispersed battlefields, this has led to increasing reliance on Role 2 medical facilities for providing trauma care. Our portable platelet apheresis system will allow Role 2 facilities to utilize platelet units for trauma care, helping to improve outcomes for the injured warfighter.

WHEN

Contract Number: N00014-18-C-7004 **Ending on:** June 30, 2020

Milestone	Risk Level	Measure of Success	Ending TRL	Date
Wet Bench Platelet Separation Demonstration	High	Successfully produce one unit of apheresis platelets from whole blood samples	3	3rd QTR FY19
Bread-board Prototype Developed	Med	All sub-component systems identified and tested in bread-board format	4	1st QTR FY21
Alpha Prototype Development	Med	Fully assembled alpha prototype ready for third-party testing	4	1st QTR FY22
Clinical Testing & FDA 510(k) Approval	High	Successful testing of the alpha prototype and submission of FDA 510(k) application	5	1st QTR FY23
Ruggedized Beta Prototype Field Testing	High	Demonstration of ruggedized apheresis system in operation-equivalent environment	5	1st QTR FY25

HOW

Projected Business Model: CFD Research will license the technology to manufacturing partners for both military and civilian applications. Potential manufacturing partners include HDT Expeditionary Systems (military) and Fesenius-Kabi (civilian). Current apheresis systems range from \$60,000 to \$75,000 each. Since our systems will be portable and preferably less complex due to lack of the centrifuge components, we anticipate a 20-40% lower price point. Additional revenues would be linked to the sale of disposable cartridges used for platelet collection. We anticipate manufacturing this again by licensing to medical grade plastic manufacturing companies. Current kits cost between \$140 and \$160. We anticipate our kits to cost similar to the current kits.

Company Objectives: We aim to identify manufacturing and transition partners for the portable apheresis platform.

Potential Commercial Applications: Global apheresis equipment market share has been dominated by large corporations such as Terumo, Fresenius-Kabi, Haemonetics and B. Braun Melsungen. However, none of these entities have a portable and ruggedized platelet apheresis system which can be readily deployed in the field and used by both the DoD and civilian populations. The proposed apheresis system will establish a new era for point of care based treatments. It will be fully automated and self-sustained for ease of use in the field. Among DoD applications, the system will find wide uses in combat support systems, trauma, hemorrhage, wound healing, regenerative medicine and evaluation of therapeutics. Other than the immediate DoD needs, the technology will impact several established and emerging market sectors including hospital, healthcare, pharmaceutical and biotechnology, and clinical diagnostics that all work together for the management and control of hemorrhage.

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