

USAMMDA INFORMATION PAPER

PRODUCT: THAWED BLOOD PROCESSING SYSTEM

DESCRIPTION: The Thawed Blood Processing System (TBPS) consists of a blood processor and related components that will replace the existing frozen blood system. The current system does not meet military requirements because it is labor-intensive, limits production to 1-blood unit per hour per technician, and limits shelf life of processed thawed blood to only 1-day. The new system is an automated, closed-loop blood-processing system capable of increasing production and shelf life (of processed blood) from the current 1-day to 14-days. The TBPS also includes a bar code reader for automated data collection, a printer, a newly designed dry thawing device to reduce thaw time from the current 50 minutes in a conventional water bath to less than 10 minutes, and a new blood bag to eliminate the current 20 percent to 50 percent leakage rate. The TBPS processing device is a compact tabletop design. Currently there are two competing candidate devices: the Mission Medical Model 1000 and the Haemonetics Model APC 215.

PROGRAM RELEVANCE to the ARMY: This product supports both the core mission of the Army and the Army Campaign Plan. Of the Army's core competencies, this product supports "Sustained Land Dominance," and "Support of Civil Authorities." The TBPS does this by reducing manpower requirements, increasing production rate of blood units, and increasing shelf life of processed blood. Frozen blood is important in emergency casualty care, and often the only blood available. This is especially true in Korean military blood depots, aboard ships, and in remote locations. It is becoming more important, because blood reserves are in short supply. Also, the Food and Drug Administration (FDA) is increasing restrictions on donations outside the U.S. due to: HIV, mad cow disease, malaria, and different donation standards in different countries. As a result, consideration is being given to shipping frozen blood to foreign countries for U.S. citizens rather than collecting donations in those countries. This product supports Future Operational Capabilities: MD-02-002 Hospitalization, MD-02-003 Medical Force Protection, and MD-02-004 Combat Health Logistics.

ISSUES/ACTIONS:

- The major issue of this program is to attain Food and Drug Administration (FDA) approval. That is the top priority and the focus of resources. The company has established contracts with three clinical laboratories recognized by the FDA.
- Mission Medical, Inc. (MMI) received an Investigational Device Exemption (IDE) from the FDA and has conditional approval from the Fort Detrick Human Use Review Board.
- The conditions imposed by the Human Use Board are being worked out with the blood research laboratories contracted by MMI to conduct the clinical trials.
- Independent testing of the device is currently being conducted at the Walter Reed Army Institute of Research (WRAIR).
- Efforts to develop a new blood bag continue in order to eliminate the current 20 to 50 percent breakage.
- Parallel work also continues on a new Blood Dry Thawing Device with a 10-minute thaw time to replace the current cumbersome water-bath that requires approximately 45 minutes to thaw a frozen unit of blood.
- Development continues on an automated data acquisition system that is bar code based.

ADDITIONAL INFORMATION:

BPL # 317

DA PROJECT/TASK: Trauma Management –
PE/PROJ 643807/836BQ; 6543807/832BQ

MAMP RANK: 36/36

ARMY ORD: Approved, 16 June 2000, CARDS
#14034

SCHEDULE:

MS I/II	4QFY00
MS C	4QFY04

For additional information, contact: Applied Medical Systems, DSN 343-7582, Comm. 301-619-7582