510(k) Summary

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Manufacturer Submitting 510(k)

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Device Name

Trade Name:	Expanse Blood Bank
Common Name:	MEDITECH Blood Bank Software
Classification Name:	Blood Establishment Computer Software and Accessories-Automated Blood Grouping and Antibody Test System (21 CFR 864.9165, Product Code MMH) - Class II

Predicate Device

MEDITECH Client Server Blood Bank v5.6, cleared under **BK080037**

Device Description

MEDITECH's Blood Bank Software is a Blood Establishment Computer System (BECS) that tightly integrates donor, unit and patient history information with data in the Electronic Health Record (EHR). The software's significant performance characteristics are flagging abnormal test results, reporting test and transfusion results, minimizing product waste, utilizing expert rules when recording and performing error checks. It also generates turnaround time and workload statistics, compiles statistical reports, and automatically captures charges. Authorized users have the ability to view blood bank results from within the network or remotely. The MEDITECH Blood Bank Software is written in a

proprietary programming language which runs on industry standard tools and technology with respect to hardware and operating systems.

Intended Use / Indications for Use

The MEDITECH Blood Bank Software provides a variety of functionality for healthcare personnel. The software helps personnel, in both multiple and single facility organizations, manage their departments more efficiently by integrating donor, unit and patient information.

The MEDITECH Blood Bank Software assists with:

- Tracking of donor products from receipt to final disposition
- Specimen cross matching
- Specimen electronic crossmatching
- Determining the suitability of released products upon issuing
- Recording of transfusion information
- Tracking product disposition

The MEDITECH Blood Bank Software interfaces to the following Blood Bank Analyzer for the purposes of specimen resulting and transmitting the results to the MEDITECH Blood Bank Software:

- Galileo Echo

The software also allows online inquiries and permanent storage of:

- Donor history
- Crossmatch results
- Antigens/Antibodies
- Transfusion data
- Unit history
- Patient's comprehensive blood bank history

Intended Use Comparison

The intended use of MEDITECH Expanse Blood Bank is identical to MEDITECH Client Server Blood Bank version v5.6, and therefore is substantially equivalent.

Functional Characteristics Comparison

Following is a tabular comparison which lists functional characteristics between MEDITECH Expanse Blood Bank and MEDITECH Client Server Blood Bank v5.6.

Table 1

	MEDITECH	**MEDITECH**

Functional Characteristics	Expanse Blood Bank Functional Characteristics	Client Server Blood Bank v5.6 Functional Characteristics
Donor Management	• On-line database of donors detailing blood type, antigen profile, most recent donation date, and comments • On-line donor recruitment phone lists and letters • Donor appointment scheduling • On-line donor medical history questionnaires • Donor inquiries	• On-line database of donors detailing blood type, antigen profile, most recent donation date, and comments • On-line donor recruitment phone lists and letters • Donor appointment scheduling • On-line donor medical history questionnaires • Donor inquiries
Unit Inventory	Units and lot-specific products received from outside sources and donors are tracked from the time they are entered in the inventory through disposition. The application allows: • Unit receiving • Unit inquiries, transfers, pooling, edits, and quarantines • Compatible blood type searches • Bar coding capabilities • Inventory control • Automatic cancellation of product orders and reserve units for discharged patients. Inventory reports list expiring or contaminated units as well as those currently in stock.	Units and lot-specific products received from outside sources and donors are tracked from the time they are entered in the inventory through disposition. The application allows: • Unit receiving • Unit inquiries, transfers, pooling, edits, and quarantines • Compatible blood type searches • Bar coding capabilities • Inventory control • Automatic cancellation of product orders and reserve units for discharged patients. Inventory reports list expiring or contaminated units as well as those currently in stock.
Unit Processing	• Test result entry • Component and aliquot preparation with original unit data retention	• Test result entry • Component and aliquot preparation with original unit data retention
Patient Processing	Staff members order tests and assign collection categories with the application's requisition entry	Staff members order tests and assign collection categories with the application's requisition entry

	routines. Features include: • Demographic data entry for new patients • Label printing capability at order entry • Ordering of products and tests • View of related lab tests at time of product order • Duplicate order checking for tests and products • Instrument resulting of ABO/Rh Collection lists and labels expedite specimen collection. Features include: • User-definable specimen labels and collection lists • Ability to generate bar code labels for specimens • Multisite tracking of products • Most recent specimens display first in History Inquiry. Electronic worksheets can replace the manual worksheets now used to enter test results for specimens and units. Reports provide nurses and physicians with patients' test results and cumulative summaries.	routines. Features include: • Demographic data entry for new patients • Label printing capability at order entry • Ordering of products and tests • View of related lab tests at time of product order • Duplicate order checking for tests and products • Instrument resulting of ABO/Rh Collection lists and labels expedite specimen collection. Features include: • User-definable specimen labels and collection lists • Ability to generate bar code labels for specimens • Multisite tracking of products • Most recent specimens display first in History Inquiry. Electronic worksheets can replace the manual worksheets now used to enter test results for specimens and units. Reports provide nurses and physicians with patients' test results and cumulative summaries.
Blood Bank History	Patients' blood bank information is linked to their Medical Record Numbers. Patient records can include: • Demographic information • Antigens/Antibodies • Transfusion	Patients' blood bank information is linked to their Medical Record Numbers. Patient records can include: • Demographic information • Antigens/Antibodies • Transfusion

	administration/reaction histories.	administration/reaction histories.
Blood Bank Analyzer Interface for ABO/Rh Resulting	Galileo Echo	Ortho Provue
Electronic Crossmatch	A user can initiate an electronic crossmatch. • If the patient or the unit do not meet pre-defined criteria, the user is prompted to result a serological crossmatch. Electronic Crossmatch criteria can be used to ensure: • a current patient specimen and blood type are available • two determinations of the patient's blood type are specified • patient and donor are ABO compatible • a check for positive antibody screens exists • no clinically significant antibodies are present • donor ABO group and Rh Type on the unit label is confirmed • Antigen/Antibody validation The system can also enforce a requirement for a second user to verify results on the current specimen.	A user can initiate an electronic crossmatch. • If the patient or the unit do not meet pre-defined criteria, the user is prompted to result a serological crossmatch. Electronic Crossmatch criteria can be used to ensure: • a current patient specimen and blood type are available • two determinations of the patient's blood type are specified • patient and donor are ABO compatible • a check for positive antibody screens exists • no clinically significant antibodies are present • donor ABO group and Rh Type on the unit label is confirmed • Antigen/Antibody validation The system can also enforce a requirement for a second user to verify results on the current specimen.

The functional characteristics of MEDITECH Expanse Blood Bank are substantially equivalent to MEDITECH Client Server Blood Bank v5.6.

Technological Characteristics

MEDITECH Expanse Blood Bank was designed to take advantage of and implement industry standard web architecture and security features to render output via a web browser or client based executable. MEDITECH Client Server

Blood Bank v5.6 was designed to output via a client based executable only. This technological difference requires design verification, design validation and user validation to ensure the performance of MEDITECH Expanse Blood Bank is comparable to the predicate device, MEDITECH Client Server Blood Bank v5.6. Evidence of the verification and validation is included in this 510(k) submission. This technological difference did not raise new questions of safety and effectiveness.

The difference in minimum recommended operating and hardware characteristics between MEDITECH Expanse Blood Bank and MEDITECH Client Server Blood Bank v5.6 are accounted for by improvements in industry standard technology. Inhouse and user validation of MEDITECH's recommendations ensures that the technology chosen by clients provides an adequate environment for the MEDITECH Expanse Blood Bank software to run.

Substantial Equivalence
Expanse Blood Bank was developed based on the predicate device, Client Server Blood Bank v5.6, cleared under BK080037. Software enhancements were added to the device to provide for customer needs. To show substantial equivalence with our own predicate device, comparisons have been drawn to the intended use and technical features of Client Server Blood Bank v5.6.

In-House Testing
The design and use of the software was evaluated for hazards, verified and validated at multiple phases throughout the development and implementation following MEDITECH's established procedures for software design and development. The objective of the testing is to ensure that the Blood Bank software fulfills its intended use and meets all safety critical requirements. Testing was performed at five levels:

- System level infrastructure testing
- Unit testing of individual changes
- Hardening sprints
- An integrated release test of all applications in the EHR
- The alpha in-house test for Blood Bank software

In-house verification and validation activities during design, development, and acceptance of MEDITECH Expanse Blood Bank demonstrated that the product is safe and effective when utilized within its intended use. No new issues of safety or effectiveness were raised.

Testing on Customer Equipment
The software was tested and validated by MEDITECH staff at one customer site, on the customer's hardware and operating systems, using the web browser user

interface. The objective of user-site testing is to provide objective evidence that the medical device could be used safely and effectively in the field on the equipment installed by the customer. The tests were designed to simulate blood banking activity using all major functional features of Expanse Blood Bank.

The user-site testing done by MEDITECH staff revealed a low number failures. Each failure was reviewed and evaluated in terms of impact on safety, effectiveness and intended use. All critical safety failures reported during user-site testing have been corrected. Verification and validation activities found that Expanse Blood Bank met the acceptance criteria. No new issues of safety or effectiveness were raised.

User Testing

The software was tested and validated using the web browser by Blood Bank personnel at 5 customer sites on their own equipment. User testing revealed a low number failures. Each failure was reviewed and evaluated in terms of impact on safety, effectiveness, and intended use of the Blood Bank application. Corrections were made and retested with no failures on retesting.

Conclusions of Testing

The results of in-house testing, testing on customer equipment, and user testing revealed a low number of initial failures. Each failure was reviewed and evaluated in terms of impact on safety, effectiveness and intended use. All critical safety failures reported have been corrected. Verification and validation activities met the acceptance criteria. No new issues of safety or effectiveness were raised.

Conclusions of Safety and Effectiveness

Based on the comparison of MEDITECH's Expanse Blood Bank functional and technological characteristics to MEDITECH's Client Server Blood Bank v5.6, cleared as BK080037, the results of validation testing, and use of controlled processes for design, development, configuration, verification, validation, and testing, the Expanse Blood Bank has met expectations for a safe and effective product, is fit for its intended use, and is substantially equivalent to its predicate device.