SYSTEM REVIEW SERIES

Blood bank information systems

The blood bank software of your dreams

Suzanne H. Butch, MA, CLDir(NCA)

We expect software to prevent ABO-incompatible blood from being issued and to tell us if a patient's blood type does not match what was listed previously, as well as perform a number of other tasks. But software should also capture all the steps in processing blood components and add significantly to the blood banker's ability to prevent errors.

Software should help laboratories meet the requirements of current good manufacturing practices and beyond. It should prevent mistakes or provide a means for detecting them before a unit of blood is issued. Some of these features are now available, such as electronic crossmatch, instrument interfaces, and ISBT 128 capabilities, but no system contains all of the necessary features. So what would the ideal software for the blood bank or transfusion service do?

✣ Use the error-checking features of ISBT 128 to detect data-entry and labeling errors. Much of today's software can use ISBT 128, but it fails to use the data-checking features of this symbology, such as reading the data identifiers to ensure that a blood type bar code is not entered for a donor identification number or reading the concatenate features of the symbology to ensure that the correct blood labels have been applied to the bag. Software should know the maximum length of a data stream expected for a field and be able to validate the contents of the input by comparing it to a table of acceptable values.

✣ Use bar coding from the time an empty bag is labeled until a blood component is transfused or discarded. This must be coupled with the use of an electronic means for identifying patients at specimen collection, generating specimen labels, and identifying patients prior to any treatment, including transfusion.

✣ Facilitate bar-code reading. For example, when dispensing a blood component, the component bar code should be read first and the information about the unit displayed rather than selecting the unit to be dispensed from a list of units available for a patient.

✣ Capture all "manufacturing" steps in the blood bank system. When adding a bag or syringe to a blood component, software should document all information about the lot numbers, unit identification, personnel identification, date, time, and weld inspection for that item.

✣ Allow the information from blood irradiators, apheresis equipment, and centrifuges to be added to the unit record automatically.

✣ Automatically display a patient's recent hemoglobin, platelet count, or coagulation test results when components are being reserved for a patient to assist with prospective review.

✣ Make it easier to generate visual and aural warnings for problems. For example, software should permit the end user to require an acknowledgement of a patient's special blood component needs each time a component is reserved for that patient, not just when a component is issued.

✣ Allow the user to determine what combinations of components should get a warning, need a password, or should not be issued to a patient.

✣ Offer full multi-facility and centralized transfusion service support.

✣ Provide a report writer that does not require a degree in programming to use. The report writer should ask: How many autologous units were ordered for the patient of Dr. X? One caveat is that for the system to find answers, data must be entered into the system. This task may be more than some blood bankers are willing to undertake, particularly if their systems don't interface to data repositories.

✣ Use the real estate on the screen effectively. Applications should be designed to fit the entire screen. Type fonts should be at least 12 points in size. Different fonts should be used to differentiate screen and background information from entered results or related information. Software should allow flexibility in how each person displays tests for result entry and that display setting should remain until it is intentionally reset.

✣ Reduce the paper used. Software should allow the review of all testing performed in the laboratory during the past days or weekend to be documented online rather than printing it so a signature can be shown to an assessor or investigator.

✣ Provide an online procedure manual for technical and computer operations. This would require an index containing such categories as "positive antibody screen," "broken bag," or "transfusion reaction," to simplify searches.

✣ Offer a secondary method for looking up special patient requirements, patient blood types, and transfusion reactions that does not involve printing a list on paper. This information could be stored on a CD, tape, or PC.

✣ Provide an audit trail for every entry or deletion for routine as well as utility programs. Software should include for all tasks and modules at least four levels of security—view; view and enter; view, enter, and modify; and view, enter, modify, and delete.

✣ Embody a method to modify, delete, or inactivate data or database parameters. For example, when the disposal method for blood components changes from incinerate to autoclave, the potential for selecting the wrong disposal method could be reduced if all the disposal options containing the method "incinerate" could be inactivated and only the options containing the word "autoclave" could be selected.

Flexibility, however, comes at a cost. The complexity of the system increases and the time to set up and validate the system rises almost exponentially. But if we want computer systems to do a better job of preventing errors, we need software that can be tailored to our needs. The future of the regulatory environment is focused on increased attention to process control. We expect our information systems to document and retrieve all the necessary information about patients and blood units quickly and accurately and in a manner that facilitates our use of the information.

The blood bank software featured on pages 33 through 42 performs some of the aforementioned functions. The information provided is based on vendors' responses to a questionnaire. Readers should validate vendors' claims before making a purchase. □

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Name of blood bank system	Blood Bank Control System	PathNet	IDM Select Series for Blood Centers
First/most recent system installation	1987/2000	1985/2001	1991/2000
Total number of contracts for operational sites	25	267	7
•U.S. hospitals—donor and transfusion service	0	43	0
•U.S. hospitals—transfusion service only	0	205	0
•U.S. regional blood centers—donor service only	18	2	6
•U.S. regional blood centers—donor and transfusion service	7	2	0
•Centralized transfusion services in the U.S.	0	—	0
•Foreign hospitals/foreign regional blood centers	0	15	1 (Hong Kong)
Contracts signed but systems not installed as of 6/30/01 (hospitals/regional blood centers)	1 (0/1)	24 (24/0)	1 (0/1)
Total number of sites operational	23	389	7
Percentage of installations that are stand-alone systems	100%	5%	100%
Staff to develop/install/support/other*			
•In entire company/in blood bank systems	—/9-5-4-7	955-1,023-450-614/15-10-12-21	23-3-10-9/—
**other=sales, marketing, administration, other co. functions*			
No. of different versions of software installed in field	—	2	5
•Versions of product covered by FDA 510(k) clearance	v. 4.4	Classic, Millennium	—
•Versions of product that did not require FDA 510(k) clearance	n/a	n/a	DMIS 1.2.1, DMIS 1.2.2, CDIS 1.2.2, CDIS 1.1.2, InTouch 1.5
Home office inspected by FDA?	yes	yes	yes
No. of terminals/workstations in live sites (min.-max.; ave.)	10–200+; 50	2–40; 5–10	4–80; 30
•Central hardware	IBM AS/400	Compaq, IBM RISC/6000	HP NetServers, HP 9000 business servers
•Terminals/workstations	IBM-compatible workstations and PCs	VTs, PCs	Unix terminals/X-terminals, PCs, workstations
•Central hardware redundant/fault-tolerant?	yes	yes	yes
Software			
•Programming language(s)	RPG	Cobol, C++	Java, C++, C
•Operating system(s)	IBM OS/400	Open VMS, Unix	Unix
•Database platform	IBM DB2	Cerner proprietary, Oracle	Oracle
•Full transaction logging?	yes	yes	yes
Features (listed as a percentage of live installations, available but no installations, or not available)			
•Unit inventory	100%	100%	100%
•Autologous and directed unit tracking	100%	100%	100%
•Crossmatch results	15%	100%	not available
•Print donor unit labels—bar coded	not available	62%	100%
•Full support of ISBT 128 unit labeling	available in 2002	available in Jan. 2002	available in 2001
•Donor recruitment	100%	15%	100%
•Mobile scheduling	95%	15%	100%
•Interface with blood grouping machines	75%	available	available through IDM Surround
•Source/recovered plasma management	100%	available	100%
•Bar-code reading wherever donor number is entered	100%	100%	100%
•Ad hoc report writer	100%	100%	100%
•Accounts receivable	100%	20%	not available
•Management reports	100%	100%	100%
•Direct entry of test results	100%	100%	available in Oct. 2001
•Electronic crossmatch decision-making	15%	15%	not available
•Laptop-based mobile donor registration module	75%	10%	not available
•Track all steps in production of product	100%	100%	100%
•Antigen typing	100%	100%	100%
System provides standard ASTM/HL7 interface?	no	yes	no
Tools to help clients validate their systems	separate department dedicated to development of validation protocols, flow charts, 24/7 customer support	virtual and instructor-led education, R.F. Nozick and Associates Inc.	product users manuals; product validation guide; configuration workshops; automated testing tools; training classes and materials; more
Complete blood bank ASP solution?	no	yes	no
Method of charging for ASP service	n/a	fixed fee	n/a
Client software required	n/a	requires software be installed on client PC	n/a
ASP information conduit	n/a	requires use of private, dedicated circuit	n/a
Client contracts supported from data center not operated by client	n/a	2	n/a
How data center is operated	n/a	by vendor	n/a
System provides indexed field in each test definition for LOINC code	no	yes	no
Provide LOINC dictionary for each new installation?	no	no	no
HIS interfaces	—	HBOC, SMS	n/a
LIS interfaces	—	none	—
User group?	yes	yes	yes
Source code?	escrow	escrow	escrow
User programming in separate partition?	yes	yes	users can do SQL programming
Cost (hardware/software/monthly maintenance)			
•Smallest	$30k/$35k/$1k	—	—
•Largest	$200k/$500k/$10k	—	—
Distinguishing features (supplied by vendor)	• 24/7 customer support • customer support and software upgrades included in maintenance fee • real-time donor-to-patient integration	• fully integrated with laboratory information system • advanced decision-support tools • comprehensive automated/crossmatch features	• over two decades of experience in regulated software • 24/7 customer support services • large customer base; financial stability; continual research and development

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Survey editors: Raymond D. Aller, MD, and Suzanne Butch

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Name of blood bank system	Plasma Center Management System (PCMS)	Progesa	Trace Line
First/most recent system installation	1998/2000	1985/2001	1985/2001
Total number of contracts for operational sites	2 (plasma centers)	400	250
•U.S. hospitals—donor and transfusion service	—	0	0
•U.S. hospitals—transfusion service only	—	0	0
•U.S. regional blood centers—donor service only	—	3	0
•U.S. regional blood centers—donor and transfusion service	—	0	0
•Centralized transfusion services in the U.S.	—	0	0
•Foreign hospitals/foreign regional blood centers	—	397	250 (Canada)
Contracts signed but systems not installed as of 6/30/01 (hospitals/regional blood centers)	0	10 (5/5)	20 (20/0)
Total number of sites operational	2	—	—
Percentage of installations that are stand-alone systems	100%	100%	100%
Staff to develop/install/support/other*			
•In entire company/in blood bank systems	23-3-10-9/—	73-31-39-55/—	73-31-39-55/—
**other=sales, marketing, administration, other co. functions*			
No. of different versions of software installed in field	3	—	—
•Versions of product covered by FDA 510(k) clearance	PCMS 1.2, PCMS 2.0	4.4	not for the U.S. market
•Versions of product that did not require FDA 510(k) clearance	PCMS 1.3	—	not for the U.S. market
Home office inspected by FDA?	yes	yes	—
No. of terminals/workstations in live sites (min.-max.; ave.)	5–300; 150	10–500; 100	10–500; 100
•Central hardware	HP NetServers, HP 9000 business servers	no restriction (any hardware with Unix)	no restriction (central HW with Windows NT)
•Terminals/workstations	Unix terminals/X-terminals, PCs, workstations	Wyse, HP, IBM, DEC, PC	Wyse, HP, IBM, DEC, PC
•Central hardware redundant/fault-tolerant?	yes	yes	yes
Software			
•Programming language(s)	Java, C	C, C++, Pro/5	Delphi
•Operating system(s)	Unix	Unix	Windows NT
•Database platform	Oracle	Oracle, C-ISAM	Oracle, C-ISAM
•Full transaction logging?	yes	yes	yes
Features (listed as a percentage of live installations, available but no installations, or not available)			
•Unit inventory	100%	100%	100%
•Autologous and directed unit tracking	n/a	100%	—
•Crossmatch results	n/a	100%	100%
•Print donor unit labels—bar coded	100%	100%	—
•Full support of ISBT 128 unit labeling	available in 2002	2 sites	—
•Donor recruitment	n/a	100%	—
•Mobile scheduling	n/a	100%	—
•Interface with blood grouping machines	not available	100%	100%
•Source/recovered plasma management	100%	100%	—
•Bar-code reading wherever donor number is entered	100%	100%	100%
•Ad hoc report writer	100%	100%	100%
•Accounts receivable	not available	100%	—
•Management reports	100%	100%	100%
•Direct entry of test results	100%	—	100%
•Electronic crossmatch decision-making	n/a	—	100%
•Laptop-based mobile donor registration module	n/a	100%	—
•Track all steps in production of product	100%	—	—
•Antigen typing	100%	—	—
System provides standard ASTM/HL7 interface?	no	yes	yes
Tools to help clients validate their systems	product users manuals; product validation guide; configuration workshops; automated testing tools; training classes and materials; more	user guides; hazard analysis; training manuals; data conversion; validation scenario samples	user guides; hazard analysis; training manuals; data conversion; validation scenario samples
Complete blood bank ASP solution?	yes	no	no
Method of charging for ASP service	license support per site	—	—
Client software required	uses dumb terminals	—	—
ASP information conduit	VPN (virtual private network)	—	—
Client contracts supported from data center not operated by client	1	—	—
How data center is operated	by vendor (IDM)	—	—
System provides indexed field in each test definition for LOINC code	no	no	no
Provide LOINC dictionary for each new installation?	no	no	no
HIS interfaces	n/a	—	—
LIS interfaces	—	—	—
User group?	no	yes	yes
Source code?	escrow	escrow	escrow
User programming in separate partition?	users can do SQL programming	no	no
Cost (hardware/software/monthly maintenance)			
•Smallest	—	—	—
•Largest	—	—	—
Distinguishing features (supplied by vendor)	• over two decades of experience in regulated software • 24/7 customer support services • large customer base, financial stability, continual research and development	• Mak-System consists of blood bank professionals and physicians • modular, integrated application with extensive functionality • customized via parameters in compliance with regulatory requirements	• Mak-System consists of blood bank professionals and physicians • modular, integrated application with extensive functionality • customized via parameters in compliance with regulatory requirements

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SYSTEM REVIEW SERIES

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Name of blood bank system	Meditech Blood Bank LIS–client/server	Meditech Blood Bank LIS–Magic
First/most recent system installation	1997/2001	1980/2001
Total number of contracts for operational sites	90	792
•U.S. hospitals—donor and transfusion service	3	70
•U.S. hospitals—transfusion service only	86	692
•U.S. regional blood centers—donor service only	1	30
•U.S. regional blood centers—donor and transfusion service	0	0
•Centralized transfusion services in the U.S.	0	0
•Foreign hospitals/foreign regional blood centers	0	0
Contracts signed but systems not installed as of 6/30/01 (hospitals/regional blood centers)	5 (5/0)	12 (12/0)
Total number of sites operational	90	792
Percentage of installations that are stand-alone systems	0%	0%
Staff to develop/install/support/other*		
•In entire company/in blood bank systems	2,000 total/—	2,000 total/—
**other=sales, marketing, administration, other co. functions*		
No. of different versions of software installed in field	2	2
•Versions of product covered by FDA 510(k) clearance	Magic and client/server	Magic and client/server
•Versions of product that did not require FDA 510(k) clearance	—	—
Home office inspected by FDA?	yes	yes
No. of terminals/workstations in live sites (min.-max.; ave.)	—	—
•Central hardware	EMC, Dell, Compaq	EMC, Dell, Compaq
•Terminals/workstations	Dell, Compaq, various PC manufacturers	Dell, Compaq, various PC manufacturers
•Central hardware redundant/fault-tolerant?	yes	yes
Software		
•Programming language(s)	Windows NT	Magic
•Operating system(s)	Windows NT	Magic
•Database platform	SQL server	Magic
•Full transaction logging?	yes	yes
Features (listed as a percentage of live installations, available but no installations, or not available)		
•Unit inventory	100%	100%
•Autologous and directed unit tracking	100%	100%
•Crossmatch results	100%	100%
•Print donor unit labels—bar coded	40%	40%
•Full support of ISBT 128 unit labeling	available	available
•Donor recruitment	100%	100%
•Mobile scheduling	not available	not available
•Interface with blood grouping machines	available	available
•Source/recovered plasma management	100%	100%
•Bar-code reading wherever donor number is entered	100%	100%
•Ad hoc report writer	100%	100%
•Accounts receivable	100%	100%
•Management reports	100%	100%
•Direct entry of test results	100%	100%
•Electronic crossmatch decision-making	not available	not available
•Laptop-based mobile donor registration module	available	available
•Track all steps in production of product	100%	100%
•Antigen typing	100%	100%
System provides standard ASTM/HL7 interface?	yes	yes
Tools to help clients validate their systems	comprehensive manual; application consultants	comprehensive manual; application consultants
Complete blood bank ASP solution?	no	no
Method of charging for ASP service	—	—
Client software required	—	—
ASP information conduit	—	—
Client contracts supported from data center not operated by client	—	—
How data center is operated	—	—
System provides indexed field in each test definition for LOINC code	yes	yes
Provide LOINC dictionary for each new installation?	no	no
HIS interfaces	SMS, HBOC, Cerner, hundreds more	SMS, HBOC, Cerner, hundreds more
LIS interfaces	Sunquest, Citation, dozens more	Sunquest, Citation, dozens more
User group?	yes	yes
Source code?	no	no
User programming in separate partition?	no	no
Cost (hardware/software/monthly maintenance)		
•Smallest	—	—
•Largest	—	—
Distinguishing features (supplied by vendor)	• developed in-house by Meditech • supported by a 24/7 response staff • fully integrated applications	• developed in-house by Meditech • supported by a 24/7 response staff • fully integrated applications

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Blood bank information systems

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Mediware Information Systems–Hemocare
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112 N. Hatton St.
Lebanon, TN 37087
615-453-5200
www.mediware.com

Name of blood bank system	Hemocare Blood Bank Data Management
First/most recent system installation	1981/2001
Total number of contracts for operational sites	257
•U.S. hospitals—donor and transfusion service	55
•U.S. hospitals—transfusion service only	200
•U.S. regional blood centers—donor service only	0
•U.S. regional blood centers—donor and transfusion service	0
•Centralized transfusion services in the U.S.	0
•Foreign hospitals/foreign regional blood centers	2
Contracts signed but systems not installed as of 6/30/01 (hospitals/regional blood centers)	38 (34/4)
Total number of sites operational	257
Percentage of installations that are stand-alone systems	100%
Staff to develop/install/support/other*	
•In entire company/in blood bank systems	53-30-35-41/6-8-2-7
**other=sales, marketing, administration, other co. functions*	
No. of different versions of software installed in field	1
•Versions of product covered by FDA 510(k) clearance	5.2A
•Versions of product that did not require FDA 510(k) clearance	none
Home office inspected by FDA?	yes
No. of terminals/workstations in live sites (min.-max.; ave.)	1–60; 16
•Central hardware	IBM RS/6000, Intel Pentium
•Terminals/workstations	PCs, any ANSI/VT 100-compatible terminal
•Central hardware redundant/fault-tolerant?	yes
Software	
•Programming language(s)	C
•Operating system(s)	Unix
•Database platform	ISAM File Handler
•Full transaction logging?	yes
Features (listed as a percentage of live installations, available but no installations, or not available)	
•Unit inventory	100%
•Autologous and directed unit tracking	100%
•Crossmatch results	100%
•Print donor unit labels—bar coded	100%
•Full support of ISBT 128 unit labeling	available
•Donor recruitment	35%
•Mobile scheduling	not available
•Interface with blood grouping machines	not available
•Source/recovered plasma management	100%
•Bar-code reading wherever donor number is entered	100%
•Ad hoc report writer	60%
•Accounts receivable	100%
•Management reports	100%
•Direct entry of test results	100%
•Electronic crossmatch decision-making	75%
•Laptop-based mobile donor registration module	not available
•Track all steps in production of product	100%
•Antigen typing	not available
System provides standard ASTM/HL7 interface?	yes
Tools to help clients validate their systems	validation primer; validation templates; video validation
Complete blood bank ASP solution?	no
Method of charging for ASP service	n/a
Client software required	n/a
ASP information conduit	n/a
Client contracts supported from data center not operated by client	n/a
How data center is operated	n/a
System provides indexed field in each test definition for LOINC code	—
Provide LOINC dictionary for each new installation?	—
HIS interfaces	HBOC, SMS, HDS, TDS
LIS interfaces	HBOC, SMS, DHT, NLFC, CCA, others
User group?	yes
Source code?	escrow
User programming in separate partition?	no
Cost (hardware/software/monthly maintenance)	
•Smallest	$10k/$15k/$.4k
•Largest	$100k/$300k/$6k
Distinguishing features (supplied by vendor)	• all service, installation, and support conducted by blood banker • financial stability • over 20 years in market with large user base

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Name of blood bank system	LifeLine	LifeTrak
First/most recent system installation	1984/2000	1999/2001
Total number of contracts for operational sites	235	4
•U.S. hospitals—donor and transfusion service	—*	0
•U.S. hospitals—transfusion service only	—*	0
•U.S. regional blood centers—donor service only	—*	1
•U.S. regional blood centers—donor and transfusion service	—*	2
•Centralized transfusion services in the U.S.	—*	1
•Foreign hospitals/foreign regional blood centers	—*	0
Contracts signed but systems not installed as of 6/30/01 (hospitals/regional blood centers)	0	4 (0/4)
Total number of sites operational	235	2 (and 1 testing center)
Percentage of installations that are stand-alone systems	100%	100%
Staff to develop/install/support/other*		
•In entire company/in blood bank systems	53-30-35-41/5-2-2-3	53-30-35-41/7-2-3-2
**other=sales, marketing, administration, other co. functions*		
No. of different versions of software installed in field	1	1
•Versions of product covered by FDA 510(k) clearance	1	2.03
•Versions of product that did not require FDA 510(k) clearance	none	none
Home office inspected by FDA?	yes	yes
No. of terminals/workstations in live sites (min.-max.; ave.)	1–35; 12	12–60; 30
•Central hardware	PCs	HP, Intel product
•Terminals/workstations	PCs	PCs
•Central hardware redundant/fault-tolerant?	yes	yes
Software		
•Programming language(s)	Basic	Oracle Developer 2000
•Operating system(s)	Novell	HP Unix–Linux
•Database platform	Btrieve	Oracle 8I
•Full transaction logging?	no	yes
Features (listed as a percentage of live installations, available but no installations, or not available)		
•Unit inventory	100%	available
•Autologous and directed unit tracking	100%	available
•Crossmatch results	100%	not available
•Print donor unit labels—bar coded	100%	not available
•Full support of ISBT 128 unit labeling	—	available
•Donor recruitment	40%	available
•Mobile scheduling	30%	available
•Interface with blood grouping machines	10%	available
•Source/recovered plasma management	—	available
•Bar-code reading wherever donor number is entered	100%	available
•Ad hoc report writer	75%	available
•Accounts receivable	not available	not available
•Management reports	100%	available
•Direct entry of test results	75%	available
•Electronic crossmatch decision-making	—	not available
•Laptop-based mobile donor registration module	—	not available
•Track all steps in production of product	60%	available
•Antigen typing	100%	available
System provides standard ASTM/HL7 interface?	yes	no
Tools to help clients validate their systems	validation template	validation template
Complete blood bank ASP solution?	—	no
Method of charging for ASP service	—	—
Client software required	—	—
ASP information conduit	—	—
Client contracts supported from data center not operated by client	—	—
How data center is operated	—	—
System provides indexed field in each test definition for LOINC code	no	no
Provide LOINC dictionary for each new installation?	no	no
HIS interfaces	SMS, HBOC, Sunquest, CHC	none
LIS interfaces	SMS, HBOC, Sunquest, CHC	none
User group?	yes	yes
Source code?	escrow	no
User programming in separate partition?	no	yes
Cost (hardware/software/monthly maintenance)		
•Smallest	$8k/$20k/$.4k	$50k/$45k/$1.2k
•Largest	$18k/$100k/$2k	$250k/$700k/$10k
Distinguishing features (supplied by vendor)	• no downtime backup • QC module • on-line patient, unit/donor history	• telerecruitment • mobile scheduling • focus on cGMPs

* company does not break down this data for this product

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Psyché Systems Corp.
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Name of blood bank system	LabWeb–SBB	SoftBank II	FlexiLab Blood Bank Transfusion
First/most recent system installation	1998/2001	1992/2001	1985/2001
Total number of contracts for operational sites	5	95	450
•U.S. hospitals—donor and transfusion service	0	0	—
•U.S. hospitals—transfusion service only	5	84	—
•U.S. regional blood centers—donor service only	0	0	—
•U.S. regional blood centers—donor and transfusion service	0	0	—
•Centralized transfusion services in the U.S.	0	0	—
•Foreign hospitals/foreign regional blood centers	0	11	—
Contracts signed but systems not installed as of 6/30/01 (hospitals/regional blood centers)	0	12 (12/0)	28 (25 hospitals/3 blood donor sites)
Total number of sites operational	5	114	500+
Percentage of installations that are stand-alone systems	0%	2.1%	0%
Staff to develop/install/support/other*			
•In entire company/in blood bank systems	9-15-10-6/4-8-5-3	338-75-205-83/23-16-23-23	195-150-242-193/8-4-3-2
**other=sales, marketing, administration, other co. functions*			
No. of different versions of software installed in field	1	—	3
•Versions of product covered by FDA 510(k) clearance	SBB v. 6.4	SoftBank II v. 19.1, v. 21.2	v. 5.2
•Versions of product that did not require FDA 510(k) clearance	none	0	v. 5.23, v. 5.3
Home office inspected by FDA?	no	yes	yes
No. of terminals/workstations in live sites (min.-max.; ave.)	2–20; 6	1–70+; 4	4–500+; 15–20
•Central hardware	Compaq Alpha	IBM pSeries-F620 model 6F1	Compaq Alpha, IBM RS/6000
•Terminals/workstations	Windows compatible	PCs or ASCII terminals	PCs, terminals
•Central hardware redundant/fault-tolerant?	yes	yes	on request
Software			
•Programming language(s)	Fortran	C	Open M, C, C++
•Operating system(s)	Open VMS	Unix	DEC Unix, Open VMS, AIX
•Database platform	Oracle/SQL server	Centura's Raima db-Vista	InterSystems M, Caché
•Full transaction logging?	yes	yes	yes
Features (listed as a percentage of live installations, available but no installations, or not available)			
•Unit inventory	100%	100%	100%
•Autologous and directed unit tracking	100%	100%	100%
•Crossmatch results	100%	100%	100%
•Print donor unit labels—bar coded	100%	100%	not available
•Full support of ISBT 128 unit labeling	100%	available in Nov. 2001	100%
•Donor recruitment	not available	available in Nov. 2001	15%
•Mobile scheduling	not available	available in Nov. 2001	not available
•Interface with blood grouping machines	not available	available in Nov. 2001	available in 2002
•Source/recovered plasma management	not available	available in Nov. 2001	100%
•Bar-code reading wherever donor number is entered	100%	100%	100%
•Ad hoc report writer	100%	100%	100%
•Accounts receivable	not available	—	100% (charge capture)
•Management reports	100%	100%	100%
•Direct entry of test results	100%	100%	100%
•Electronic crossmatch decision-making	100%	available in Nov. 2001	available in 2002
•Laptop-based mobile donor registration module	not available	available in Nov. 2001	not available
•Track all steps in production of product	100%	100%	100%
•Antigen typing	100%	100%	100%
System provides standard ASTM/HL7 interface?	yes	yes	yes
Tools to help clients validate their systems	documentation, training	validation guidelines, examples, validation forms	validation protocol and guideline for each SW release; Balance View Consulting for valid. assist.
Complete blood bank ASP solution?	yes	yes	future release
Method of charging for ASP service	fixed fee	fixed fee	—
Client software required	browser-based, requires software be installed on client PC, uses dumb terminals	requires software be installed on client PC, uses dumb terminals	—
ASP information conduit	requires use of private, dedicated circuit	requires use of private, dedicated circuit	—
Client contracts supported from data center not operated by client	0	1	—
How data center is operated	by vendor	by vendor	—
System provides indexed field in each test definition for LOINC code	yes	no	no
Provide LOINC dictionary for each new installation?	no	no	no
HIS interfaces	Sunquest, Meditech, SMS, Cerner, HBOC, others	Meditech, McKessonHBOC, IDS, CPSI, many others	HBOC, SMS, Meditech, IDX, Phamis, Cerner, many others
LIS interfaces	LabWeb	SCC, McKessonHBOC, Meditech, Sunquest, Cerner, many others	n/a
User group?	yes	yes	yes
Source code?	yes	escrow	escrow
User programming in separate partition?	no	no	yes
Cost (hardware/software/monthly maintenance)			
•Smallest	$10k/$10k/$.15k	$30k/$50k/15% annually	$50k/$100k/$1.5k
•Largest	$100k/$50k/$.5k	$100k/$200k/15% annually	$100k+/$250k+/$4k+
Distinguishing features (supplied by vendor)	• complete ASP solution for all lab departments • customizable browser user interface • different levels of ASP support for varying levels of resources	• unit recall documentation • electronic crossmatch • multi-site inventory	• integration with general lab • No. 1 in installs/support according to KLAS survey • proactive utilization reports

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SYSTEM REVIEW SERIES

Blood bank information systems

Part 7 of 7

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Name of blood bank system	LifeTec	SafeTrace	SafeTrace Tx
First/most recent system installation	1983/2000	1996/2001	1999/2001
Total number of contracts for operational sites	6	28	15
•U.S. hospitals—donor and transfusion service	0	2	2
•U.S. hospitals—transfusion service only	0	0	9
•U.S. regional blood centers—donor service only	5	22	n/a
•U.S. regional blood centers—donor and transfusion service	1	4	2
•Centralized transfusion services in the U.S.	0	0	2
•Foreign hospitals/foreign regional blood centers	0	0	0
Contracts signed but systems not installed as of 6/30/01 (hospitals/regional blood centers)	0	6 (2/4)	27 (26/1)
Total number of sites operational	6	117+	62+
Percentage of installations that are stand-alone systems	100%	100%	100%
Staff to develop/install/support/other*			
•In entire company/in blood bank systems	3.5-1-7.25-2/3.5-1-1.5-1	17-8-5-22/—	17-8-5-22/—
**other=sales, marketing, administration, other co. functions*			
No. of different versions of software installed in field	2	4	4
•Versions of product covered by FDA 510(k) clearance	revisions 2.10, 2.20	all	all
•Versions of product that did not require FDA 510(k) clearance	0	none	none
Home office inspected by FDA?	yes	yes	yes
No. of terminals/workstations in live sites (min.-max.; ave.)	10–200; 40	3–200; 45	1–75; 8
•Central hardware	DG (rev. 2.10), Intel Pentium server (rev. 2.20)	HP, IBM, Sun	Intel-based servers
•Terminals/workstations	DG or PC (rev. 2.10), Intel PC (rev. 2.20)	PCs or Wyse terminals	PCs
•Central hardware redundant/fault-tolerant?	—	yes	yes
Software			
•Programming language(s)	Universal Business Basic (rev. 2.10), Transoft UBL (rev. 2.20)	C, Cobol, SQL	Delphi, SQL
•Operating system(s)	Unix (rev. 2.10), Windows NT (rev. 2.20)	Unix	Windows NT, Windows 2000
•Database platform	SQL server (rev. 2.10, 2.20)	Oracle RDBMS	Oracle
•Full transaction logging?	no	yes	yes
Features (listed as a percentage of live installations, available but no installations, or not available)			
•Unit inventory	100%	100%	100%
•Autologous and directed unit tracking	100%	100%	100%
•Crossmatch results	0%	15%	100%
•Print donor unit labels—bar coded	100%	100%	100%
•Full support of ISBT 128 unit labeling	available	100%	100%
•Donor recruitment	100%	100%	40%
•Mobile scheduling	100%	100%	40%
•Interface with blood grouping machines	100%	100%	100%
•Source/recovered plasma management	100%	100%	40%
•Bar-code reading wherever donor number is entered	100%	100%	100%
•Ad hoc report writer	100%	100%	100%
•Accounts receivable	100%	100%	100%
•Management reports	100%	100%	100%
•Direct entry of test results	100%	100%	100%
•Electronic crossmatch decision-making	0%	15%	100%
•Laptop-based mobile donor registration module	100%	30%	40%
•Track all steps in production of product	100%	100%	100%
•Antigen typing	100%	100%	100%
System provides standard ASTM/HL7 interface?	no	yes	yes
Tools to help clients validate their systems	validation plans provided based on user group requests; automated scripts	validation test plans for all safety critical checks; sample test cases	validation guide; templates; validation test plan for all safety critical control checks
Complete blood bank ASP solution?	no	yes	yes
Method of charging for ASP service	—	transaction-based	transaction-based
Client software required	—	software installed on client PC	software installed on client PC
ASP information conduit	—	requires private, dedicated circuit	requires private, dedicated circuit
Client contracts supported from data center not operated by client	—	0	0
How data center is operated	—	—	—
System provides indexed field in each test definition for LOINC code	no	no	no
Provide LOINC dictionary for each new installation?	no	no	no
HIS interfaces	—	n/a	SMS, McKessonHBOC, Keane, Phamis, Meditech, homegrown
LIS interfaces	—	n/a	Triple G, SMS, Sunquest, Citation, CCA, Meditech, SCC, Cerner
User group?	yes	yes	yes
Source code?	yes	yes	escrow
User programming in separate partition?	yes	yes	yes
Cost (hardware/software/monthly maintenance)			
•Smallest	varies/$50k/$9k	$7.5k/$15k/$.5k	$5k/$12k/$.24k
•Largest	varies/$100k/$19k	—	$50k/$200k/$4k
Distinguishing features (supplied by vendor)	• flexible—operates in a manner unique to each user • vendor-provided validation support • annual maintenance fees set by user group	• complete Vein-to-Vein solution • superior service, safety, and compliance record	• patent pending for advanced CTS/transfusion functionality • complete Vein-to-Vein solution • superior service, safety, and compliance record

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