

Bar Code Expansion – Positive Patient Identification (BCE-PPI)

Increment II

***VISTA* Applications / VBECS Interfacing with a COTS Blood Administration Point of Care (BAPOC) System**

Requirements Specification Document



Version 1.0


September 2011

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Revision History

Date	Revision	Description	Author
05/04/10	0.1	Initial Draft	[REDACTED]
06/22/10		<u>Section 1.3.1:</u> Added VBECS system depiction diagram based on SMEs review	[REDACTED]
07/07/10		<u>Section 2.1:</u> Removed BAPOC functional requirements. Added VISTA & VBECS functional requirements	[REDACTED]
07/13/10		<u>Section 2.2:</u> Added VBECS & VISTA HL7 communications requirements for BAPOC	[REDACTED]
07/16/10		<u>Appendices:</u> Added HL7 Data Tables	[REDACTED]
07/20/10		<u>Section 1:</u> Added content to introduction	[REDACTED]
07/27/10		Updates based on review with SMEs: <u>Title Page:</u> Editing content <u>Section 1.1:</u> Editing content and verbiage <u>Section 1.2:</u> Editing content and verbiage <u>Section 2:</u> Editing content <u>Section 2.1.1:</u> Editing content and verbiage	[REDACTED]
07/29/10		Updates based on review with SMEs: <u>Section 1.2:</u> Editing content <u>Section 1.4.1:</u> Editing content <u>Section 2.1.2:</u> Editing VBECS functional requirements <u>Section 2.2.2</u> Editing VBCES HL7 communication content. <u>Section 2.10</u> Removed Diagram & edited content	[REDACTED]

Date	Revision	Description	Author
08/03/10		<u>A – Appendices</u> Removed Diagrams	[REDACTED]
		<u>Section 2.1.2.3</u> Edit content	[REDACTED]
		<u>A – Appendices</u> Removed Appendices	[REDACTED]
02/11/11		Formatting Changes	[REDACTED]
04/12/11		<u>Scope of Integration</u>	[REDACTED]
05/05/11		Formatted the entire document Added Requirements	[REDACTED]
05/09/11		Corrected BCE-PPI throughout document Use Pyxis® Transfusion Verification throughout document <u>Accessibility Specifications:</u> Added verbiage <u>Functional Requirement 34:</u> Added “allow entering” Corrected formatting problem	[REDACTED]
05/26/11	0.2	<u>1.2. Scope:</u> Bullets 1,3, & 4 – Accepted verbiage changes <u>1.3.2. Definitions:</u> Added SF-518 <u>2.2. Business Rules Specifications:</u> Accepted changes to 1 & 4 <u>2.3. Design Constraint Specifications:</u> Accepted changes to bullets 1 & <u>2.5. Document Specifications:</u> Accepted changes <u>2.6.1. Veterans Integrated Systems of Technological Architecture (VISTA):</u> Changed verbiage <u>2.6.2. Vital Signs NOTE:</u> Accepted changes <u>2.6.2.15. Functional Requirement 15:</u> Added via <u>2.6.2.16. Functional Requirement 16:</u> Accepted change <u>2.6.4.4. Functional Requirement 26:</u> Accepted change <u>2.6.4.26. Functional Requirement 48:</u> Accepted changes <u>2.8. MULTI-DIVISIONAL SPECIFICATIONS:</u> Changed verbiage <u>2.9. PERFORMANCE SPECIFICATIONS:</u> Changed verbiage <u>2.15. USABILITY SPECIFICATIONS:</u> Changed verbiage <u>4.2. HARDWARE SPECIFICATIONS:</u> “IS” Means Integrated Systems, added to 1.3.2. Definitions	[REDACTED]

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		6. PURCHASED COMPONENTS: Changed verbiage	
6/6/11	0.3	<p>1.0 Introduction Uncapitalize these words. The acronym is capitalized, but the terms do not need to be capitalized. Uncapitalize these words. Same comment as above</p> <p>1.2. Scope, 1st bullet Some acronyms are missing from this list.</p> <p>1.3.2 Definitions 2.0.2.</p> <p>2.2. Business Rules Specification</p> <p>2.3. Design Constraints Specifications Will another handheld device not work?</p> <p>2.4. Disaster Recovery Specifications What about the need for a SW disaster recovery plan? Will the SW work in a degraded mode?</p> <p>2.5. Documentation Specifications Suggest adding a better introductory sentence for this section. Suggest adding the dates and version for these documents Suggest adding the version and date for this document.</p> <p>2.6.1. VISTA Bold this word or not use any bold for the title. Add date and version Need to bold the entire title or not use bold type. Add data and version Why isn't this title underlined. Need to be consistent. Add data and version Suggest adding an introductory sentence and incorporate this information into the introduction for this section</p> <p>2.6.2. Vital Signs Suggest adding an introductory sentence and incorporate this information into the introduction for this section</p> <p>2.6.2.5. Functional Requirement 5</p> <p>2.6.2.12. Functional Requirement 12</p> <p>2.6.2.13. Functional Requirement 13</p> <p>2.6.2.15. Functional Requirement 15 This is a confusing requirement. If the BAPOC VS data are marked as an error, where are the new VS data coming from that are being recorded in Vista?</p> <p>2.6.2.16. Functional Requirement 16 How is this requirements different from 2.6.2.12?</p> <p>2.6.2.17. Functional Requirement 17 Duplicate of 2.6.2.8?</p> <p>2.6.3. VBECS</p> <p>2.6.3.1. Functional Requirement 18</p>	

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		<p>Replace “provide” with “send”</p> <p>2.6.3.2. Functional Requirement 19 If one of these element is missing, will the entire message fail? Same comment as #13 Same comment as #13</p> <p>2.6.3.3. Functional Requirement 20 Below requirements use the work processed? Which word is correct Processed or received? These requirements were extracted from the vendor User Guide to portray a complete picture. However, these ARE vendor requirements and they add no true significance to what has to be done on the VA side of the house.</p> <p>2.6.4.1. Functional Requirement 23 These words are unnecessary because an unsuccessful log in would not let the user get to this screen.</p> <p>2.6.4.3. Functional Requirement 25 This should be 2 requirements. This should be a separate requirement and not a note.</p> <p>2.6.4.4. Functional Requirement 26 This should be separate requirement. This comments is not needed.</p> <p>2.6.4.5. Functional Requirement 27 This should be a separate requirement: The system shall require the user to acknowledge the displayed patient name is the correct patient.</p> <p>2.6.4.7. Functional Requirement 29</p> <p>2.6.4.8. Functional Requirement 30 How is the system doing the scanning? Should this requirement be a user requirement? ...system shall require the user to scan the blood unit to start the transfusion process.</p> <p>2.6.4.10. Functional Requirement 32 This is vague wording. What does several really mean. What additional information?</p> <p>2.6.4.11. Functional Requirement 33 Each bullet should be a separate requirement.</p> <p>2.6.4.12. Functional Requirement 34</p> <p>2.6.4.14. Functional Requirement 36 Shall allow the user to edit or view. Requirement is not clear.</p> <p>2.6.4.15. Functional Requirement 37 If something is missing, will an error occur and prevent the unit from being transfused? Requirements 39 is the error requirement, but the requirement is out of sequence. Looks like the order should be #38, #37, then #39.</p> <p>2.6.4.16. Functional Requirement 38</p> <p>2.6.4.18. Functional Requirement 40</p>	

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		<p>Is the system doing the comparing or is a person doing a visual comparison? If it is a visual comparison, these word needs to be removed . If the system is doing this, suggest making this a separate requirement.</p> <p>2.6.4.19. Functional Requirement 41 Should this verb be changed to “require” can a facility choose not to configure a time for the transfusion?</p> <p>2.6.4.20. Functional Requirement 42</p> <p>2.6.4.21. Functional Requirement 43 Each item should be a separate requirement.</p> <p>2.6.4.23. Functional Requirement 45 Is this a required action? Is so, change the verb to require.</p> <p>2.6.4.24. Functional Requirement 46 If required by the application change the verb to require.</p> <p>2.6.4.25. Functional Requirement 47 Not sure what in normal flow means?</p> <p>2.6.4.26. Functional Requirement 48 This is requirements is not clear.</p> <p>2.9. Performance Specifications</p> <p>2.13. Security Specifications</p> <p>3. Applicable Standards</p> <p>4.1.2. VBECS HL7 Processing</p> <p>4.2. Hardware Interfaces</p> <p>4.3. Software Interfaces</p>	
6/7/11	0.4	<p>Concerns about clear separation of VistA and VBEC</p> <p>ADT subscription</p> <p>Division separation in a multidivisional environment</p> <p>No functional requirement to restrict access to “active” units with the Division of issue.</p> <p>OWNER to scan patient wristband</p> <p>Displays on handheld vs console.</p> <p>No outcome for the completed message</p> <p>TIU note</p> <p>1.0 Introduction, 1st ¶ applications ADT and Vitals as well as</p> <p>1.2. Scope, 1st ¶ Need to establish which of the specific other VistA applications this entails, including Vitals, ADT, and CPRS as applicable.</p> <p>1.3.2. Definitions when electronic documentation is not possible..</p> <p>1.3.2. Definitions obsolete</p> <p>1.3.2. Definitions VBECs</p> <p>1.4. References Is this applicable to this increment?</p> <p>11. (VAIS)</p>	<div style="background-color: black; width: 100px; height: 1.2em; margin-bottom: 2px;"></div> <div style="background-color: black; width: 60px; height: 1.2em;"></div>

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		<p>12. Carefusion For VA BarCode Expansion Project Section 2 for IRM</p> <p>13. Pyxis® Transfusion Verification 2.1, Patch 1, User Guide</p> <p>14. Bar Code Resource Office, Business Use Case Specification Positive Patient ID (PPID)</p> <p>2. Overall Specifications VISTA/VA system's 2. Overall Specifications to record the details of a transfusion episode 2.0.2. Scan patient wristband? 2.0.2. to record the details of a transfusion episode. 2.0.2. to record the details of a transfusion episode. 2.0.2. to record the details of a transfusion episode. 2.0.2. to record the details of a transfusion episode. 2.2. Business Rules Specifications BAPOC 2.2. Business Rules Specifications used 2.2. Business Rules Specifications Audit trails to determine the primary and secondary verifier for all data entry related to a transfusion episode. 2.2. Business Rules Specifications VBECS has nothing to do with this. What is the barcode language used by ADT now? I doubt it is Code 128 as the specimen labels are 39 or something. 2.2. Business Rule Specifications Both are quite actively used. 2.3. Design Constraints Specifications Isn't this that the WIR must be updated...but not all sites have to be complete to move forward? 2.3. Design Constraints Specifications impossible 2.3. Design Constraints Specifications I think you need to cite a specific as changes mid stream will affect project time lines and work. Updates addressed as current edition are released. 2.3. Design Constraints Specifications College 2.6.1. 2.6.2. Is this supposed to be a list available for view in vitals or the vitals collected to the transfusion? 2.6.2. 2.6.2.1. Functional Requirement 1</p>	

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		<p>Transmit ?</p> <p>Identify the subset for transfusion.</p> <p>2.6.2.2. Functional Requirement 2</p> <p>Do you mean the user may enter multiple qualifiers in one field? There has to be a limit.</p> <p>2.6.2.4. Functional Requirement 4</p> <p>successful</p> <p>2.6.2.5. Functional Requirement 5</p> <p>and results in an unsuccessful transmission.</p> <p>2.6.2.6. Functional Requirement 6</p> <p>Do you mean present a user readable error message to the user or turn off?</p> <p>2.6.2.7. Functional Requirement 7</p> <p>create a unique record</p> <p>2.6.2.9. Functional Requirement 9</p> <p>marked as</p> <p>logged on user</p> <p>2.6.2.10. Functional Requirement 10</p> <p>create a unique record</p> <p>2.6.2.11. Functional Requirement 11</p> <p>and store it as an unique record .</p> <p>2.6.2.14. Functional Requirement 14</p> <p>Error message or turn off?</p> <p>2.6.2.15. Functional Requirement 15</p> <p>replacement</p> <p>Do these need to be marked as corrected?</p> <p>2.6.4.</p> <p>2.6.4.1. Functional Requirement 19</p> <p>2.6.4.2. Functional Requirement 20</p> <p>from the component order or current VistA location information</p> <p>SI are not passed to TV</p> <p>electronic or serologic crossmatch, if available</p> <p>2.6.4.3. Functional Requirement 21</p> <p>this is all we need here. If they want more detail make a reference to the VAIS.</p> <p>2.6.4.4. Functional Requirement 22</p> <p>2.6.4.5. Functional Requirement 23</p> <p>Remove please – only applicable to VBECS</p> <p>I would also remove this – only applies to VBECS really</p> <p>VBECS Does not support this currently -</p> <p>Manual patient id entered override comment is captured, but not sent to VBECS. Where is this available for review on a management report?</p> <p>Manual unit ID entered override comment is sent and presented on the unit history report as configured.</p> <p>These are some vendor requirements extracted directly from their User Guide.</p> <p>2.6.5.4. Functional Requirement 28</p> <p>enter the patient identifier.</p> <p>2.6.5.6. Functional Requirement 30</p> <p>per local configuration settings.</p>	

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		<p>as required per local configuration settings. This comment is transmitted as part of the post transfusion message.</p> <p>2.6.5.7. Functional Requirement 31</p> <p>2.6.5.10. Functional Requirement 34 patient related</p> <p>2.6.5.11. Functional Requirement 35 WHAT is the ORDER LIST? My assumption is reflected in this change. Where and how? I didn't find this in their hand held app. Had to go to the management console.</p> <p>2.6.5.12. Functional Requirement 36</p> <p>2.6.5.13. Functional Requirement 37 Nursing transfusion orders? Optional based on local configuration Where are they getting this? VBECS nor VistA store this as a discreet field.</p> <p>2.6.5.14. Functional Requirement 38 Where? To the best of my knowledge this is not available for display on the handheld.</p> <ul style="list-style-type: none"> • Issue date/ Time <p>2.6.5.15. Functional Requirement 39 An active status to be transfused. The following information is scanned or manually entered per local configuration:</p> <ul style="list-style-type: none"> • Unit ID Barcode <p>2.6.5.16. Functional Requirement 40 start</p> <p>2.6.5.17. Functional Requirement 41 Allow the user to reenter? Or start over?</p> <p>2.6.5.18. Functional Requirement 42 There is only ONE scan of the unit ID in the handheld. This is not possible.</p> <p>2.6.5.20. Functional Requirement 44 as configured at the Facility.:</p> <p>2.6.5.22. Functional Requirement 46 continue to</p> <p>2.6.5.24. Functional Requirement 48 Does this calculate from the time the unit is issued or started? There are 2 separate issues to be reviewed as quality monitor, One is a delayed start... Other is prolonged transfusion.</p> <p>2.6.5.25. Functional Requirement 50 One of our concerns was correcting a record that was never administered at all but started incorrectly. Is this enough to correct that record?</p> <p>2.8. Multi-divisional Specifications VISNs do not necessarily share consolidated VistA databases and the records would need to be passed to national database</p> <p>2.9. Performance Specifications Define major</p>	

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		<p>2.11. Reliability Specifications</p> <p>2.12. Scope of Integration I encourage the addition of a multidivisional setup-</p> <p>I am not sure I understand how the RDC are depicted here. My understanding from CF is that there will be one of their servers pointed to the IP of a specific VistA institution...</p> <p>So for Heartland West: One VBECS with 5 divisions, with 5 CF servers each pointed to a different division in this instance.</p> <p>2.14. System Features Niki had a comment about these sections being about servers and connectivity. May want to include messing requirements/standards.</p> <p>2.15. Usability Specifications WHO is responsible for this orientation and training?</p> <p>3. Applicable Standards existing blood bank standards, standards of accrediting agencies, FDA regulations and VA policies.</p> <p>4. Interfaces We recommend deleting the VAIS reference here as this implies that VBECS is documenting all of the vista functionality too.</p> <p>4.1.2. VBECS Remove this whole section Refer to the VBECS Application Interface Specification Lose the for BCE as we have merged the documents into mainline of documents.</p> <p>4.2. Hardware Specifications What hardware? VistA servers?</p> <p>4.4. User Interfaces Really, I think they will be training in the use of... Handheld users will not be VBECS users. Suggest removal.</p> <p>6. Purchased Components Fragment and this is a vBECS internal requirement. Not new for this project. and the unit id is the only thing scanned other than patient wristband, so it can be tag less.</p> <p>7. User class Characteristics Customer support? Hardware support? For the COTS product. NOT VA or is it?</p>	
8/1/11	0.5	<p>1. Introduction The "s" “_“ In the interim of receiving approval for a new project name from the decision makers and for</p>	<div style="background-color: black; width: 100px; height: 1.2em; margin-bottom: 2px;"></div> <div style="background-color: black; width: 60px; height: 1.2em;"></div>

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		<p>the purpose of project planning, the formally known as Bar Code Expansion project will be referenced in this document as the Bar Code Expansion - Positive Patient Identification (BCE-PPI) Project. Now the Bar Code Expansion - Positive Patient Identification (BCE-PPI) Project has been permanently identified as the official name for the project.</p> <p>1.1. Purpose Enhancement Comma after applications Office of Nursing Service, Pathology & Laboratory Medicine Service, National Center for Patient Safety,</p> <p>1.2. Scope Removed “d” “match” point of care immediately</p> <p>1.3.1. Acronyms PPI OIT Federal Drug Administration</p> <p>1.3.2. Definitions BTRF SF 518</p> <p>1.3. References</p> <p>2.3. Design Constraints Specifications</p> <p>2.6.2.2. Functional Requirement 2</p> <p>2.6.2.6. Functional Requirement 6</p> <p>2.6.2.7. Functional Requirement 7</p> <p>2.6.2.12. Functional Requirement 12</p> <p>2.6.2.16. Functional Requirement 16</p> <p>2.6.3.1. Functional Requirement 18 I believe a more accurate representation of the original interface was capturing the Patient Transfusion Record in its entirety from the vendor software as a TIU Note.</p> <p>2.6.4.6. Functional Requirement 24 Recommend removal of requirement.</p> <p>2.6.5.1. Functional Requirement 25 through</p> <p>2.6.5.29. Functional Requirement 53</p> <p>2.9. Performance Requirements</p> <p>4.2. Hardware Interfaces</p> <p>4.3. Software Interfaces</p> <p>6. Purchase Components</p>	
8/05/11		<p>2.3. Design Constraints Specifications How is this a design constraint? This is acceptance criteria. How are these design constraints? Maybe project constraints, but these don’t affect the overall design.</p> <p>2.5. Document Specifications</p>	

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		<p>I don't understand. What are the specs for documentation? What documentation should be included? User manual, on-line help, etc</p> <p>2.6. Functional Specifications Where are these? Are they part of a repository?</p> <p>2.6.2.1. Functional Requirement 1 State which specific vital signs are for transfusion verification. This list could get reordered.</p> <p>2.6.3.1. Functional Requirement 18 How, in what format?</p> <p>2.7. Graphical User Interface (GUI) Specifications What about User Interface specifications on the hand held?</p> <p>2.9. Performance Specifications Not sure what this means?</p> <p>2.12. Scope of Integration What does this mean?</p> <p>2.15. Usability Specifications This is NOT usability specifications.</p> <p>4.2. Hardware Specifications Where are these servers?</p> <p>4.4. User Interfaces How can this be? This is a new product? Only Blood Bankers would be experts in VBECS. Many nurses and physicians/clinicians do not use VISTA, only CPRS.</p>	
8/09/11	0.6	<p>1.3.1. Acronyms Business Requirements Document? National Leadership board</p> <p>1.3.2. Definitions Will the SF-518 remain as a contingency for system downtime? BCE PPI and VBECS are not guaranteed to be operationa 100% of the time.</p> <p>2.01. Table 1 Correct font size</p> <p>2.02. Table 2 Correct font size Correct font size</p> <p>2.2. Business Rules Specifications It can only identify users who interact with the PDA, so unsure if this statement is accurate. Are there audit trails for any other data items?</p> <p>2.4. Disaster recovery Specifications Will there be support for/development of a national contingency plan for this technology?</p> <p>2.6.5.4. Functional Requirement 28 Manual entry of the patient identifier should be captured for audit? This became an important compliance indicator/measure of other system problems in BCMA use.</p> <p>2.6.5.7. Functional Requirement 31</p>	<div style="background-color: black; width: 100px; height: 1.2em; margin-bottom: 2px;"></div> <div style="background-color: black; width: 60px; height: 1.2em;"></div>

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		<p>Is this the intended information here?</p> <p>2.6.5.9. Functional Requirement 33 What is the content of these notifications?</p> <p>2.6.5.10. Functional Requirement 34 What specifically are these menus for?</p> <p>2.6.5.12. Functional Requirement 36 Should this be part of an audit trail as well to allow VHA to manage scanning failures?</p> <p>2.6.5.21. Functional Requirement 45 “to indicate the transfusion has been stopped.” (alternate wording)</p> <p>2.6.5.25. Functional Requirement 49 Normal flow of what? “normal completion of the transfusion.” ? please clarify.</p> <p>2.6.5.26. Functional Requirement 50 Should this specify the workflow/data entry, menus, etc., for documenting the rapid infusion?</p> <p>2.7. Graphical User Interface (GUI) Specifications What about no need for the user to horizontally scroll? Ensuring that auditory prompts and warnings remain on at all times?</p> <p>2.9. Performance Specifications VHA assesses nonfunctional in regards to patient safety in a different risk assessment framework than the vendor classifies risk purely in terms of software function. How do we harmonize here to ensure our safety risk assessment is the final decision standard on determining when the system is “nonfunctional?” This requirement may not be accurate. I thought that the vendor actually had to engage in significant customization to run on different handheld hardware platforms.</p> <p>2.15. Usability Specifications What documentation is available from the vendor regarding use error/use error mitigation? This should be part of the design file they presented for 510k approval to FDA.</p> <p>4.3. Software Interfaces If this RSD pertains to Transfusion , why is this sentence here? Only information/content pertinent to BAPOC should be in this document. Is this required? What information is in this information – is this all data entered by the nurse during the transfusion administration? Is there any intervening data transmission between VISTA and the PDA at the commencement of ID, and during administration? Should this section be parallel to section 2.01 at beginning of the document?</p> <p>4.4. User Interfaces It’s not clear what this section should contain.</p>	

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		<p>6. Purchased Components Please specify what these are bar code printers will be used to label -- Blood component? For Labels for blood components? Chargers for which equipment – PDAs, printers? Are the WIR upgrade hardware components a cost to this project? Unsure what the last sentence means; is it a blanket statement to cover omissions? Or does it refer to the WIR and what it supports? The WIR does not support the desktop versions of the software; these are wired onto the network.</p>	
09/14/11	0.7	<p>2.2. Business Rules Specifications is intended to</p> <p>remove entire administration of blood products portion of the</p> <p>2.6.2.1. Functional Requirement 1 Does this technically make sense? CPRS and VistA options do not send data. RPC calls send data. Please clarify or possibly delete this phrase, as this is a functional requirement and not a technical requirement.</p> <p>2.6.2.5. & 6. Functional requirements 5 & 6 Is there a definition for the error messages? This can be a raw string that makes no sense to the end user or it can be a meaningful message. Please clarify.</p> <p>2.6.2.10. Functional Requirement 10 crossed out using the Vitals/ Measurements GUI Application [GMV V/M GUI] option.</p> <p>2.6.2.14. Functional Requirement 14 Please clarify what is meant by “error out”.</p> <p>2.6.2.15. Functional Requirement 15 Please clarify? Does this mean the user of the BAPOC system has to log into the VistA GUI Vitals client to enter data?</p> <p>2.6.3.1. Functional Requirement 16 Please clarify. What is the title and construct of this note? What RPCs are used? Does this vary from facility to facility? Will this note need an electronic signature? This needs clarification. Are there Joint Commission or other requirements for what data needs to be documented for the transfusion in the patient’s medical record?</p> <p>2.6.4. VISTA Blood Establishment Computer Software (VEBCS) Please provide the specific name of this vendor server, unless any vendor server that meets the requirements is allowed.</p> <p>2.6.4.2. Functional Requirement 20 Please provide whether this is in compliance</p>	

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		<p>with VHA Identity Management Enterprise requirements.</p> <p>2.6.4.3. Functional Requirement 21</p> <p>2.6.4.5. Functional Requirement 23</p> <p>Functional Requirements 25-53</p> <p>These requirements were extracted from the vendor User Guide to portray a more thorough picture. However, these ARE vendor requirements and they add no true significance to what has to be done on the VA side of the house.</p> <p>2.6.5.1. Functional Requirement 25</p> <p>hours,</p> <p>2.6.5.5. Functional Requirement 29</p> <p>Please clarify the difference between Functional Requirements 29 and 31.</p> <p>Added initially and additionally</p> <p>2.6.5.8. Functional Requirement 32</p> <p>What is the connection between this note and functional requirement #32.</p> <p>2.6.5.10. Functional Requirement 34</p> <p>Please clarify. This is a vague requirement.</p> <p>2.6.5.13. Functional Requirement 37</p> <p>Where is this data obtained? Is this for the person transfusing the blood to confirm?</p> <p>2.6.5.14. Functional Requirement 38</p> <p>If this is not in the VA settings, then it should not be in the VA Requirements document. Is there not a CPRS order number associated with the request?</p> <p>2.6.5.15. Functional Requirement 39</p> <p>Please clarify. Are 7 barcodes scanned? Or are 7 pieces of data obtained from a scanning a singled unit barcode?</p> <p>2.6.5.20. Functional Requirement 44</p> <p>Does the transfusing user even know what this number is?</p> <p>2.6.5.49. Functional Requirement 49</p> <p>Please clarify what is meant by normal flow. Editing a record is not usually normal flow.</p> <p>2.6.5.27. Functional Requirement 51</p> <p>Please specify VistA ADT messages.</p> <p>Added VISTA</p> <p>2.7. Graphical User Interface (GUI) Specifications</p> <p>Are there any User Interface specifications? Is this a character based interface (ie. CHUI or Roll&Scroll). Please indicate type of user interface.</p> <p>2.9. Performance Specifications</p> <p>What does this mean? I don't recall where "SOLUTION" was defined. Is this referring to a</p>	

Date	Revision	Description	Author
		<p>product?</p> <p>2.12. Scope of Integration Has this architecture been approved by OI&T?</p> <p>2.12. Scope of Integration Please clarify. Why is this statement in the Requirements Specification Document?</p> <p>Comment removed for now.</p> <p>2.13. Security Specifications Please see previous comment regarding "SOLUTION"</p> <p>2.15. Usability Specifications This is NOT a usability specification. This is a training specification. If you are not going to execute best practices for evaluating usability, then state such. Usability specifications usually have a measured method to determine whether the product is acceptable to use. Training is used to mitigate when there are problems with usability.</p> <p>4.1.1. VISTA Is there any intent to make the end user aware of issues with communication between VistA and BAPOC? Specifically, how will the end user know that the 2 systems are not communicating? A</p> <p>4.1.1. VISTA Please complete this statement.</p> <p>4.1.2. VBECS This is not clear how the following is relevant to this particular increment. Do you simply mean that BAPOC will comply with VBECS defined HL7 messaging? IS BAPOC communication directly with VBECS or via VistA to VBECS? Please clarify.</p> <p>4.2. Hardware Software If this can be run on "hospital hardware", then why are there separate servers? Please clarify.</p> <p>4.3. Software Interfaces 4.3. Software Interfaces What is relevance to this increment?</p> <p>4.4 User Interfaces How can the users be experts if the product is not yet delivered?????</p> <p>6. Purchased Components What is the plan for purchasing?</p> <p>8. Estimation Is this a required element for delivery? If so, when will this be updated? Is this intentionally left unanswered?</p>	
09/29/11	0.8	<p>2.15. Usability Specifications There will be adequate orientation and training provided for the BCE-PPI Blood Administration/Pyxis® Transfusion Verification</p>	<div style="background-color: black; width: 100px; height: 1.2em; margin-bottom: 2px;"></div> <div style="background-color: black; width: 140px; height: 1.2em;"></div>

Date	Revision	Description	Author
		<p>system. <u>However, there are no statistical usability specifications at this time.</u></p> <p>4.4. User Interfaces The intended users of this product are expected to be <u>experienced</u> in the use of <u>VISTA</u>, VBECS, and the <u>blood transfusion process</u>. These users may include but are not limited to physicians, nurses, and other trained authorized medical professionals.</p> <p>2.15. Usability Specification There are no usability specifications at this time.</p> <p>4.4. User Interfaces The intended users of this product are expected to be experienced in the use of CPRS, VBECS, and the blood transfusion process as appropriate for their role(s). These users may include but are not limited to physicians, nurses, medical technologists and other trained authorized medical professionals.</p> <p>2.15. Usability Specification In regard to the COTS Blood Administration Point of Care (BAPOC) System, VA has requested documentation from the vendor concerning previous work performed pertaining to use error/usability (such as, but not limited to, the vendor's 510K submission, usability data, use error risk analysis and mitigation responses, etc). VHA will review the information provided to determine the need for risk mitigation plans, i.e., VHA operating procedures, implementation and maintenance processes, training.</p>	
09/29/11	1.0	Approved	IPT

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1. Introduction

The Bar Code Expansion (BCE) Project was approved by the National Leadership Board (NLB) in May 2004 to improve patient safety by enabling providers to utilize the same bar code scanning technology for specimen collection and blood administration that has decreased medication errors in the Veterans Health Administration (VHA). Subsequently, BCE was funded in 2005 for the acquisition of a commercial off-the-shelf (COTS) technology solution for laboratory specimen collection and blood administration.

The National Center for Patient Safety has identified labeling of patient blood, Anatomic Pathology (AP) specimens, and laboratory samples as a persistent cause of adverse events in VHA facilities. A total of 227 Root Cause Analysis (RCA) cases of patient misidentification events were examined. Over 80% of these reports were directly related to mislabeled specimens for the clinical laboratory, anatomic pathology, or blood bank. Patients were harmed in every one of these cases which resulted in unnecessary surgical procedures, unnecessary treatment such as radiation therapy, chemotherapy, antibiotics, blood transfusions, and cardiac catheterizations. Other patients experienced extensive delays in treatment for cancer and other medical conditions, repeat phlebotomy procedures, and repeat biopsies.

In Oct 2009, the Veterans Affairs (VA) Chief Information Officer (CIO) communicated to the Under Secretary for Health the need to stop the Bar Code Expansion (BCE) project and plan to deliver its requirements under a new project name.

In the interim of receiving approval for a new project name from the decision makers and for the purpose of project planning, the formally known as Bar Code Expansion project will be referenced in this document as the Bar Code Expansion - Positive Patient Identification (BCE-PPI) Project. Now the Bar Code Expansion - Positive Patient Identification (BCE-PPI) Project has been permanently identified as the official name for the project.

1.1. Purpose

The purpose of this Requirement Specification Document (RSD) is to describe in detail the Bar CodeExpansion-Positive Patient Identification (BCE-PPI) Blood Administration requirements necessary to interface with the Veterans Health Information System and Technology Architecture (**VISTA**) applications, Vitals, and other applications such as Admission Discharge Transfer (ADT), a front-end Graphical User Interface (GUI) Computerized Patient Record System (CPRS) as well as **VISTA** Blood Establishment Computer Software (VBECS) with the Pyxis® Transfusion Verification system to perform the transfusion process at the point of care.

The intended audience of this RSD includes but is not limited to Office of Information & Technology (OIT) Development Team, Bar Code Resource Office (BCRO), Office of Nursing Service, Pathology & Laboratory Medicine Service, National Center for Patient Safety, and other business owners, subject matter experts (SMEs), any development team associated with Blood Bank Administration and any individual or group associated with the success of this project.

1.2. Scope

The scope of this project is to document the functionality and interface between the VISTA Applications (Vitals, ADT, CPRS GUI, VBECS) and the Pyxis® Transfusion Verification system to perform transfusion at the point of care.

Benefits of this activity include:

- Enhance the ability of the Department of Veterans Affairs (VA) Veterans Health Administration's (VHA) to deliver quality transfusion services to meet the needs of the VA community.
- Positively identify the patient and the blood product typed for that patient at the point of care (bedside, transfusion chair, etc) immediately prior to transfusion.
- Improve the safety of blood component transfusions by decreasing the risk of errors through effective use of technology, such as barcode scanning, retrieval of previous records to be used for comparison, and detection of inconsistencies in data input.
- Provide comprehensive reporting capabilities for quality monitoring of transfusion activities.

1.3. Acronyms and Definitions

This section will provide the definitions of all terms, acronyms, and abbreviations required to properly interpret the RSD. This information may be provided by reference to other documents.

1.3.1. Acronyms

Term	Definition
AABB	American Association of Blood Banks
ADT	Admit Discharge Transfer
BCE	Bar Code Expansion
BDET	Business Detailed Requirements
BAPOC	Blood Administration Point of Care System
ACK	General Acknowledgement Message
BR	Business Rule
BRD	Business Requirements Document
BTRF	Blood Transfusion Record Form
BUC	Business Use Case
CAP	College of American Pathologists
CE	Commit Error
CIO	Chief Information Officer

Term	Definition
CPRS	Computerized Patient Record System
COTS	Commercial Off-The-Shelf
CR	Commit Reject
FDA	Food and Drug Administration
GUI	Graphical User Interface
HHD	Hand Held Device
HL7	Health Level 7
ID	Identification
IRM	Information Resource Management
IS	Integrated Systems
ISBT	International Society of Blood Transfusion
TJC	The Joint Commission
MSH	Message Header
NLB	National Leadership Board
OIT	Office of Information and Technology
OR	Operating Room
PMAS	Project Management & Accountability System
PPI	Positive Patient Identification
PPID	Positive Patient Identification
RCA	Root Cause Analysis
RDPC	Remote Data Processing Center
RDC	Remote Data Center
RPC	Remote Procedure Call
RSD	Requirements Specification Document
SME	Subject Matter Expert
SRS	Software Requirements Specification
TCP/IP	Transmission Control Protocol/Internet Protocol
TIU	Text Integration Utility
TV	Transfusion Verification
UC	Use Case
VA	Department of Veterans Affairs
VBECS	VISTA Blood Establishment Computer Software

Term	Definition
VHA	Veterans Health Administration
VISN	Veterans Integrated Services Network
VISTA	Veterans Health Information Systems and Technology Architecture
WLAN	Wireless Local Area Network
WIR	Wireless Infrastructure Replacement

1.3.2. Definitions

Term	Definition
BPS 029	Blood Product Dispense Status Message
BPS 031	Blood Product Transfusion/Disposition Message
BTRF	A form used to record the product info, testing results, and transfusion administration data when electronic documentation is not possible.
Caution Tag	A tie tag attached to the blood component bag that contains patient and unit identification with testing results and is to be used during the pre-transfusion verification process.
MSH	A message header segment present in every HL7 message type and defines the message's source, purpose, destination, and certain syntax specifics like delimiters (separators characters) and character sets.
SF-518 obsolete	The blood or blood component form, used in VA hospitals, is manually sent to the laboratory with specimens to order a type and screen or a type and crossmatch. The SF-518 has three sections: Requisition, Pre-transfusion Testing, and Record of Transfusion. However, the type and crossmatch order has been replaced by the type and screen order and is orderable via CPRS/VBECS.
Shared Disk Array	A disk subsystem that is connected to two or more computers typically via Small Computer Systems Interface (SCSI).
Tethered	Attached to a data or power source by a wire or fiber.
Tetherless	A style of computing where smart mobile devices communicate over heterogeneously administered wireless networks.
VISTA	Veterans Health Information System and Technology Architecture (VISTA) of the Veterans Health Administration (VHA), Department of Veterans Affairs (VA).
WIR	Wireless Infrastructure Replacement is a project to upgrade and standardize the wireless network across the VA.

1.4. References

1. Blood Administration Master Requirements Document
2. *VISTA* Blood Establishment Computer Software (VBECS) Application Architecture
3. BCE Architecture Description Draft 012908 v02
4. BUC36_Transfusion Activity
5. BUC37_Transfusion Monitoring
6. BUC39_Transfusion Initiation
7. BUC54_Obtain Vitals
8. BUC55_Transfusion Stop
9. VBECS_UC_109 BCE COTS Pre-Transfusion Interface
10. VBECS_UC_69 Enter Post-Transfusion Details
11. VBECS Application Interface (VAIS)
12. CareFusion For VA Bar Code Expansion Project Section 2 for IRM
13. Pyxis® Transfusion Verification 2.1, Patch 1, User Guide
14. Bar Code Resource Office, Business Use Case Specification Positive Patient ID (PPID)

2. Overall Specification

2.01. Table 1 - Illustrates the VA system's overall specifications that pertain to the interface with Blood Administration Point of Care (BAPOC) COTS application.

Need #	Need	Feature #	Feature
242	Customer needs the VA System to communicate with the BAPOC system to record the details of a transfusion episode	OWNR 436.0	Send Requested Data to the BAPOC system
		OWNR 419.0	Receive Vitals Change Data from BAPOC system
		OWNR 421.0	Receive Vital Signs Data from the BAPOC system
		OWNR 422.0	Receive Data Confirmations
		OWNR 435.0	Receive Data requests from the BAPOC system

Table 1: VA Blood Administration System

2.02. Table 2 - Illustrates BAPOC system overall specifications that will be included in the vendor requirements.

Need #	Need	Feature #	Feature
236	Customer needs the BAPOC system to communicate with the VA System to record the details of a transfusion episode.	OWNR 417.0	Receive blood product identification data from the VA System.
		OWNR 418.0	Receive patient vital signs data from the VA System.
		OWNR 437.0	Send requests for data to the VA System.
		OWNR 444.0	Send gathered vital signs data to the VA System.
		OWNR 452.0	Send confirmation data to the VA System.
237	Customer needs the BAPOC system to display blood product and patient data to record the details of a transfusion episode.	OWNR 424.0	Display patient identification data from the VA systems.
		OWNR 438.0	Display Blood Product data received from the VA System.
		OWNR 446.0	Display patient vital signs records received from the VA system.
		OWNR 454.0	Support functions enumerated in the detailed requirements.
		OWNR 455.0	Display informative messages to the user.

		OWNR 459.0	Display patient information, associated patient vital sign records, transfusion comments, and transfusion details.
238	Customer needs the BAPOC System to enable interactive data entry to record the details of a transfusion episode.	OWNR 427.0	Allow confirmation of displayed data received from the VA system.
		OWNR 429.0	Allow entry of patient vital signs.
		OWNR 430.0	Allow pre-transfusion checklist management.
		OWNR 433.0	Scan bar coded IDs and labels.
		BDET 315	Scan Consumable Lot used in transfusion process
		OWNR 434.0	Accept manual data entry.
		OWNR 442.0	Record the reason for a bar code scan failure.
		OWNR 447.0	Allow the selection of a displayed vital signs record.
		OWNR 450.0	Accept entry of transfusion observation.
		OWNR 451.0	Accept an entry that indicates start/stop of a transfusion.
		OWNR 456.0	Allow selection of optional actions.
		OWNR 457.0	Capture the reason when a transfusion is not infused at the point of care.
		OWNR 458.0	Allow entry of transfusion comments.
		OWNR 460.0	Accept indications of the status of the transfusion.
244	Customer needs the BAPOC system to process data values and determine logical results (computations) to record the details of a transfusion episode.	OWNR 439.0	Validate blood product to patient matching.
		OWNR 440.0	Determine the appropriate next step in the blood administration process for a specific administration.
		OWNR 441.0	Identify and track all manual entry of blood product ID.
		OWNR 445.0	Record the current local time for time sensitive data entry.

Table 2: Blood Administration Point of Care System

2.1. Accessibility Specifications

The accessibility specifications established for this software patch are in accordance with all government mandates, rules, regulations, and standards.

2.2. Business Rules Specifications

1. This BAPOC system is intended to reduce transfusion errors, enhance patient safety, track and record the administration of blood products and maximize the efficiency and productivity of the administration of blood products portion of the transfusion process.
2. The data received from the BAPOC System shall be used for but not limited to patient record updates, transfusion reports, vital signs reports, and management reports.
3. There will be audit trails to determine who was the primary user, the secondary user or verifier or anyone that is physically involved with the transfusion process.
4. The bar codes that are expected to be scanned while using the Transfusion Verification (TV) application include;
 - patient identifier on a wristband, recommended to be Code 128
 - blood product-related bar codes on the unit(s) to be transfused, ISBT Code 128 and/ or Codabar label types.

2.3. Design Constraints Specifications

- The Pyxis® Transfusion Verification product handheld device (MC75A) is dependent upon WIR completion.
- The Pyxis® Transfusion Verification product must be able to function from a wired or wireless workstation if the MC75A is unavailable.
- All increment releases will be appropriately tested and approved at multiple field test sites.
- The Pyxis® Transfusion Verification product must meet 100% of the documented requirements for each increment release.
- The project is dependent upon VA Technical Resources. This may impact project schedule, scope and budget.
- The project schedule, scope, and budget are dependent on the Project Management & Accountability System (PMAS) submission, review and approval process.
- The Pyxis® Transfusion Verification product interfaces must be developed as part of a quality system as defined by Part 820 of the CFR, Quality System Regulation.
- All functionality in the Pyxis® Transfusion Verification product software shall be fully compliant with the following:
 - The American Association of Blood Banks (AABB) Standards for Blood Banks and Transfusion Services, current edition.
 - The College of American Pathologists (CAP) Laboratory Accreditation Program checklists current edition.
 - The Joint Commission (TJC), current standard edition.

- The Food and Drug Administration.

2.4. Disaster Recovery Specifications

Every facility is responsible for Disaster Recovery Specifications.

2.5. Documentation Specifications

There is a:

- CareFusion For VA Bar Code Expansion Project Section 2 for IRM, Adding the Motorola MC75 to Your Network and loading the Image, version 1.0, September 22, 2010
- CareFusion, Pyxis® Transfusion Verification 2.1, Patch 1, Handheld Device User Guide, For the Symbol MC70/MC75A Enterprise Digital Assistant, December 2010
- BUC 36 Transfusion Activity
- BUC 37 Transfusion Monitoring
- BUC 39 Transfusion Initiation
- BUC 55 Transfusion Stop
- Bar Code Resource Office, Business Use Case Specification Positive Patient ID (PPID), version 1.0036, August 2009

2.6. Functional Specifications

2.6.1. Veterans Integrated System of Technological Architecture (VISTA)

The following **VISTA** system functional specifications pertain to communication with BAPOC system only and do not represent the functional specifications of the entire **VISTA** application system. Furthermore, it is assumed that the users of the BAPOC system are familiar with the hand-held device (HHD) and they know how to power on, log on, access the appropriate application, identify themselves, identify the confirming personnel, and then scan the patient's wristband for positive patient identification (PPID). For more information on setting up the HHD and preparing it for use, personnel should refer to the **Carefusion For VA Bar Code Expansion Project Section 2 for IRM, Adding the Motorola MC75 to Your Network and loading the Image**, version 1.0, September 22, 2010. For information on using the HHD, users can reference the **Pyxis® Transfusion Verification 2.1, Patch 1, User Guide, For the Symbol MC70/MC75A Enterprise Digital Assistant**, December 2010. For more information on the positive patient identification (PPID) process, refer to the **Bar Code Resource Office, Business Use Case Specification Positive Patient ID (PPID)**, version 1.0036, August 2009.

2.6.2. Vital Signs

NOTE: For certain diseases and patients in critical condition, the vital signs are taken at more frequent intervals as opposed to 30 minutes during transfusions.

2.6.2.1. Functional Requirement 1

The **VISTA** system shall send the most recent patient's vital signs via CPRS using the Vitals/Measurements GUI Application [GMV V/M GUI] option to the BAPOC. The vital signs include:

- blood pressure
- temperature
- pulse
- respiration
- pain
- height
- weight
- pulse oximetry
- central venous pressure
- Circumference/girth

NOTE: Only blood pressure, temperature, pulse, and respiration are used in transfusion verification.

2.6.2.2. Functional Requirement 2

The **VISTA** system shall transmit the vital sign information to the BAPOC by RPC. The information is as follows:

a. Required:

- (#.01) DATE/TIME VITALS TAKEN [1D]
- (#.02) PATIENT [2P:2]
- (#.03) VITAL TYPE [3P:120.51]
- (#.04) DATE/TIME VITALS ENTERED [4D] current date/time
- (#.05) HOSPITAL LOCATION [5P:44]
- (#.06) ENTERED BY [6P:200]] logged on user (#1.2)
RATE [8F]

b. Optional

- (#1.4) SUPPLEMENTAL O2 [10F] ← used for Pulse Oximetry only
- (#5) QUALIFIER ← can be a multiple value

c. Used only when a record is marked as error:

- (#2) ENTERED IN ERROR [1S]
- (#3) ERROR ENTERED BY [2P:200] logged on user
- (#4) REASON ENTERED IN ERROR

2.6.2.3. Functional Requirement 3

The **VISTA** system shall store the vital signs and the date and time in FILE 120.5 – GMRV VITAL MEASUREMENT.

2.6.2.4. Functional Requirement 4

The **VISTA** system shall receive an acknowledgement from the BAPOC system to end a successful transmission.

2.6.2.5. Functional Requirement 5

The **VISTA** system shall receive an error message when a data element(s) is incorrect from the BAPOC system and results in an unsuccessful transmission.

2.6.2.6. Functional Requirement 6

The **VISTA** system shall error out the current incorrect vital signs received from the BAPOC via RPC.

2.6.2.7. Functional Requirement 7

The **VISTA** system shall create a unique record from current vital signs received from the BAPOC via RPC.

2.6.2.8. Functional Requirement 8

The **VISTA** system shall store new vital signs information in File 120.5 – GMRV VITAL MEASUREMENT.

2.6.2.9. Functional Requirement 9

The **VISTA** system shall capture and store as an audit trail, the following when vitals data is marked as entered in error.

a. Used only when a record is marked as error

(#2) ENTERED IN ERROR [1S]

(#3) ERROR ENTERED BY [2P:200] logged on user

(#4) REASON ENTERED IN ERROR

2.6.2.10. Functional Requirement 10

The **VISTA** system shall create a unique record for patients with no previous record in the Vital Signs package using the Vitals/Measurements GUI Application [GMV V/M GUI] option.

2.6.2.11. Functional Requirement 11

The **VISTA** system shall receive a set of vitals from the BAPOC and store it as an unique record.

2.6.2.12. Functional Requirement 12

The **VISTA** system shall receive the vital signs information from the BAPOC via Remote Procedure Calls (RPCs).

2.6.2.13. Functional Requirement 13

The **VISTA** system shall store the vital signs information received from the BAPOC in

File #120.5 – GMRV VITAL MEASUREMENT.

2.6.2.14. Functional Requirement 14

The **VISTA** system shall error out and delete existing patient vital signs from the BAPOC system that require updating.

2.6.2.15. Functional Requirement 15

The **VISTA** system shall enter replacement vital signs data via the Vitals/Measurements GUI Application [GMV V/M GUI] option when the existing vital sign data from the BAPOC have been marked as an error.

2.6.2.16. Functional Requirement 16

The **VISTA** system shall receive the updated vital signs information via RPCs.

2.6.2.17. Functional Requirement 17

The **VISTA** system shall store the updated vital signs information in File #120.5 – GMRV VITAL MEASUREMENT.

2.6.3. Computerized Patient Record System (CPRS)

2.6.3.1. Functional Requirement 18

The **VISTA** CPRS system shall pull information from the information to construct a Text Integration Utilities (TIU) note that will serve as the patient's permanent record. (See example of a TIU note in Appendix B)

2.6.4. VISTA Blood Establishment Computer Software (VBECS)

The following VBECS functional specifications pertain to communication with BAPOC system only and do not represent the functional specifications of the entire VBECS application system. VBECS provides information in HL7 messages to the BCE-PPI COTS server.

2.6.4.1. Functional Requirement 19

VBECS shall send the following:

- a. VBECS shall send patient and blood component information to the BAPOC system via HL7 BPS 029 Blood Product Dispense Status message (*see VBECS_WBC-BPS_029 – HL7 message profile*) for the following unit status change events:
 - Blood Products Assigned to Patient
 - Issued Blood Products
 - Blood Products Released from Patient Assignment

VBECS shall communicate patient and blood component information to the BAPOC system for the following unit status change events:

- b. VBECS shall send the BAPOC system with **Blood Units that are assigned to a patient**.
 - The message shall be sent with a status of 'RS' (Reserved – ordered and product allocated for patient) to the BAPOC system.
- c. VBECS shall send the BAPOC system with **Blood Units that are Issued** to the selected patient.
 - The message shall be sent with a status of 'DS' (Dispensed to patient location) to the BAPOC system.
- d. VBECS shall send the BAPOC system with **Blood Units that have been released from patient assignment** or for assigned units which have been discarded. VBECS may not release patient assignment for discarded units due to circumstances requiring discard.
 - The message shall be sent with a dispense status of 'RE' (Released – no longer allocated to patient).

2.6.4.2. Functional Requirement 20

VBECS shall transmit selected blood unit with patient details to the BAPOC system via a HL7 message.

- a. VBECS shall include the following patient information to the BAPOC:
 - Patient ID (SSN and VISTA ID)
 - Patient Last Name
 - Patient First Name
 - Inpatient or Outpatient indicator (from the component order)
 - Patient Middle Name (optional),
 - Patient ICN (optional)
 - Patient Date of Birth (optional)
 - Patient Gender (optional)
 - Issued to Location (from Issue Unit processing when applicable)
 - Treating Specialty Code (from the component order) (optional)
 - Patient ABO and Rh interpretation from the most recent test result only (not historic or database conversion), associated with the selected unit(s) (if available)
 - Patient Transfusion Requirements and Antigen Negative Requirements for the selected patient
 - Patient Antibody Screen Interpretation (if available)
 - Crossmatch Interpretation (if available as electronic crossmatch)
- b. VBECS shall send the following patient location (current) details to the BAPOC (if available)
 - Point of Care
 - Room Bed IEN (Internal Entry Number for Point of Care)
 - Division Code
 - Division Name
- c. VBECS shall send the following unit information details to the BAPOC:
 - Component Class Name

- Required Unit Quantity (from original order)
- Unit ID (Codabar or ISBT 128 eye-readable number)
- Unit Product code (full eye-readable number in Codabar or ISBT 128)
- Unit ABO and Rh type
- Blood Unit GUID (unique identifier)

2.6.4.3. Functional Requirement 21

VBECS shall receive and record data processing message statuses from BAPOC system via HL7 message.

- a. VBECS shall receive an ‘acknowledgement accept’ (AA) message when the original message is successfully received by the BAPOC system.
 - The VBECS application shall not attempt to resend the message when a successful data processing message is received from the BAPOC system.
- b. VBECS shall receive an ‘error acknowledgement’ (AE) message when the original message was not successfully processed by the BAPOC system.
- c. VBECS shall record that the message was unsuccessfully processed and attempt to resend the message to BAPOC system.
 - VBECS shall attempt re-transmission of messages up to a configurable number of attempts until a success or reject acknowledgement message is received from the BAPOC system.
 - If after re-transmission up to the maximum number of attempts the message still cannot be processed, VBECS shall e-mail the administrator that the message was rejected.
- d. VBECS shall receive a ‘reject acknowledgement’ (AR) message when the original message sent is rejected by the BAPOC system.
 - VBECS shall record that the received message was rejected
 - VBECS shall e-mail the administrator that the message was rejected.
 - VBECS shall not attempt to resend the message when an application reject acknowledgement message is received from the BAPOC system.

2.6.4.4. Functional Requirement 22

VBECS shall acknowledge HL7 BTS_031 blood product transfusion disposition message (*see VBECS_WBC-BTS_031 - HL7 message profile*) when the BAPOC completes the transfusion record for a patient.

2.6.4.5. Functional Requirement 23

VBECS shall receive the following data from the BAPOC system when a transfusion is statused “completed”:

- Transfusionist confirmation of Blood Product and Patient Identification data

- 2nd Verifier confirmation for Blood Product and Patient Identification data
- Transfusion Disposition Status
- Transfusion Start Time
- Date/time transfusion completed or interrupted
- Patient location at transfusion (required), default to the issue-to location
- Transfusion completed (Optional)
- Transfusion Interrupted (Optional), display the option to enter volume transfused
 - a. 1/4
 - b. 1/2
 - c. 3/4
 - d. The user may edit the amount to a value from “1” to the maximum volume of the unit.
- Transfusion Reaction Noted (Yes/No) (Optional)
- Reaction symptoms noted (free text) (Optional)
- Option to enter an explanatory comment (free text) (Optional)

2.6.4.6. Functional Requirement 24

VBECS shall subscribe to ADT for patient updates.

2.6.5. Blood Administration POC System

2.6.5.1. Functional Requirement 25

The Pyxis® Transfusion Verification system shall display a screen called the Nursing Units List screen with patients that have active transfusion orders when login is successful.

NOTE : Facility specific configuration determines the number of hours, patients and the corresponding orders display.

2.6.5.2. Functional Requirement 26

The Pyxis® Transfusion Verification system shall display the following message if login is unsuccessful:

- Incorrect User ID/Password – Please re-enter

2.6.5.3. Functional Requirement 27

The Pyxis® Transfusion Verification system shall allow one or more units in the Nursing Units List screen to be selected and then select patients to access a list of patients.

NOTE: The patient location, priority (stat (*) or routine (R)) and patient name display for review.

2.6.5.4. Functional Requirement 28

The Pyxis® Transfusion Verification system shall allow the user to scan the patient's wristband or enter the patient identifier.

2.6.5.5. Functional Requirement 29

The Pyxis® Transfusion Verification system shall allow the user to initially confirm the patient by displaying the following and asking if this is the correct patient:

- Patient's name
- Patient's ID or Alternate ID
- Location
- DOB
- Sex
- Age
- Race
- Provider

2.6.5.6. Functional Requirement 30

The Pyxis® Transfusion Verification system shall allow manual entry of patient's record per local configuration settings.

NOTE: The user must enter the reason for manual entry as required per local configuration settings. This comment is transmitted as part of the post transfusion message.

2.6.5.7. Functional Requirement 31

The Pyxis® Transfusion Verification system shall allow the user to additionally confirm the following:

- Patient Demographics
- Allergy Confirmation or any potential adverse drug reaction

2.6.5.8. Functional Requirement 32

The Pyxis® Transfusion Verification system shall scan the blood unit to start the transfusion process.

NOTE: This is an optional configuration at the Facility and shall display a message if it is the user's first time accessing the orders screen.

2.6.5.9. Functional Requirement 33

The Pyxis® Transfusion Verification system shall display notifications throughout the transfusion process.

2.6.5.10. Functional Requirement 34

The Pyxis® Transfusion Verification system shall provide the user with several menus that provide additional patient related information.

2.6.5.11. Functional Requirement 35

The Pyxis® Transfusion Verification system shall have the ability to do the following:

- a. Refresh orders through the Refresh Order List
- b. Obtain a unit history report
- c. Enter Patient Vitals

2.6.5.12. Functional Requirement 36

The Pyxis® Transfusion Verification system shall allow entering blood product ID manually per local configuration settings.

NOTE: The user must enter the reason for manual entry as required per local configuration settings. This comment is transmitted as part of the post transfusion message.

2.6.5.13. Functional Requirement 37

The Pyxis® Transfusion Verification system shall display the following from the orders screen:

- a. Screen name
- b. User identification number
- c. Patient name and Identification number
- d. Blood type
- e. Blood bank number
- f. Order List
- g. Status Type Selection

2.6.5.14. Functional Requirement 38

The Pyxis® Transfusion Verification system shall allow the following when viewing of Transfusion Activities:

- Unit ID
- Order Number (N/A in VA settings)
- Status
- Priority
- Donor Blood Type
- Product
- Product Code
- Transfusion Requirements
- Issue Time
- Expiration Date
- Ordering Provider
- Antibody Screen
- Crossmatch Compatibilities
- Transfusing Time
- Stop Time

- Stop Reason
- Stop

2.6.5.15. Functional Requirement 39

The Pyxis® Transfusion Verification system shall allow the blood unit with active orders to be transfused. The following information is scanned:

- Production Date
- Time Barcode
- Unit ID Barcode
- Product Code Barcode
- ABO/Rh Barcode
- Collection Date/Time Barcode
- Expiration Date/Time Barcode
- Special Testing Barcode

2.6.5.16. Functional Requirement 40

The Pyxis® Transfusion Verification system shall allow the user to select the transfusion.

2.6.5.17. Functional Requirement 41

The Pyxis® Transfusion Verification system shall display an error message when any of the scanned information does not match any transfusion on the list.

2.6.5.18. Functional Requirement 42

The Pyxis® Transfusion Verification system shall allow a second scan for the user to scan the Unit ID bar code on the blood tag/label and compare it against the Unit ID barcode that is imprinted on the unit bag itself.

2.6.5.19. Functional Requirement 43

The Pyxis® Transfusion Verification system shall allow the facility to configure an allowable time frame for the transfusion of an issued blood product.

2.6.5.20. Functional Requirement 44

The Pyxis® Transfusion Verification system shall allow the following which are optional entries:

- a. Infusion Device and Number
- b. Admin Set and Filter Entry option
- c. Lot Number
- d. Indication for Transfusion drop-down
- e. Entry for Primary Blood Bank Number
- f. Enter Vital Signs
- g. Warning Message for a Suspected Transfusion

- Reaction
- h. Pre-Transfusion Checklist
 - i. Witness Verification
 - j. Transfusion Begin Time Capture, if system not configured for Match Confirmation

NOTE: These are configurable entries at the Facility.

2.6.5.21. Functional Requirement 45

The Pyxis® Transfusion Verification system shall allow the user to enter the stopped transfusion.

- a. Enter Vital Signs for Stopped Transfusion
- b. Record Volume Infused For Stopped Transfusion

NOTE: The Stop Action drop-down list is populated by the Facility through the Pyxis Point of Verification console.

2.6.5.22. Functional Requirement 46

The Pyxis® Transfusion Verification system shall allow the user to continue to transfuse stopped blood unit.

2.6.5.23. Functional Requirement 47

The Pyxis® Transfusion Verification system shall allow the user to document the volume infused.

2.6.5.24. Functional Requirement 48

The Pyxis® Transfusion Verification system shall allow documenting exceeding the maximum time transfused.

2.6.5.25. Functional Requirement 49

The Pyxis® Transfusion Verification system shall allow a user to edit a transfusion record in normal flow.

2.6.5.26. Functional Requirement 50

The Pyxis® Transfusion Verification system shall allow working with Rapid Infusion.

NOTE: Rapid infusion is designed to provide a more flexible workflow for use in the Operating Room (OR) and emergent environments.

2.6.5.27. Functional Requirement 51

The Pyxis® Transfusion Verification system shall subscribe to **VISTA** ADT for patient updates.

2.6.5.28. Functional Requirement 52

The Pyxis® Transfusion Verification system shall recognize the different divisions in a multi-divisional medical center.

2.6.5.29. Functional Requirement 53

The Pyxis® Transfusion Verification system shall restrict access to active units and other parameters from other divisions in a multi-divisional setup.

2.7. Graphical User Interface (GUI) Specifications

There are no graphical user interface (GUI) specifications.

2.8. Multi-Divisional Specifications

The BCE-PPI Blood Administration/Pyxis® Transfusion Verification system shall allow data to be captured, reported, and shared at the division and consolidated VistA as configured. (VBECS patient testing and blood availability information and records are division specific).

2.9. Performance Specifications

1. The BCE-PPI Blood Administration/Pyxis® Transfusion Verification system shall be free of any major defects that will render the system disabled or non-functional.
2. The BCE-PPI Blood Administration/Pyxis® Transfusion Verification system shall operate on various devices; is not restricted to how the platform is identified, are upgradeable and sustained overtime.
3. The BCE-PPI Blood Administration/Pyxis® Transfusion Verification system shall provide opportunities to reduce the total number of SOLUTION instances needed to support all medical centers, provides any requirements for proximity to end users, and describe tools included for remote management of the system.

2.10. Quality Attributes Specifications

All functionality shall be compliant with existing blood bank standards, standards of accrediting agencies, FDA regulations and VA policies.

2.11. Reliability Specifications

When data is entered or updated from the BAPOC system, there shall be an acknowledgement from the VBECS system of receipt of that data.

2.12. Scope of Integration

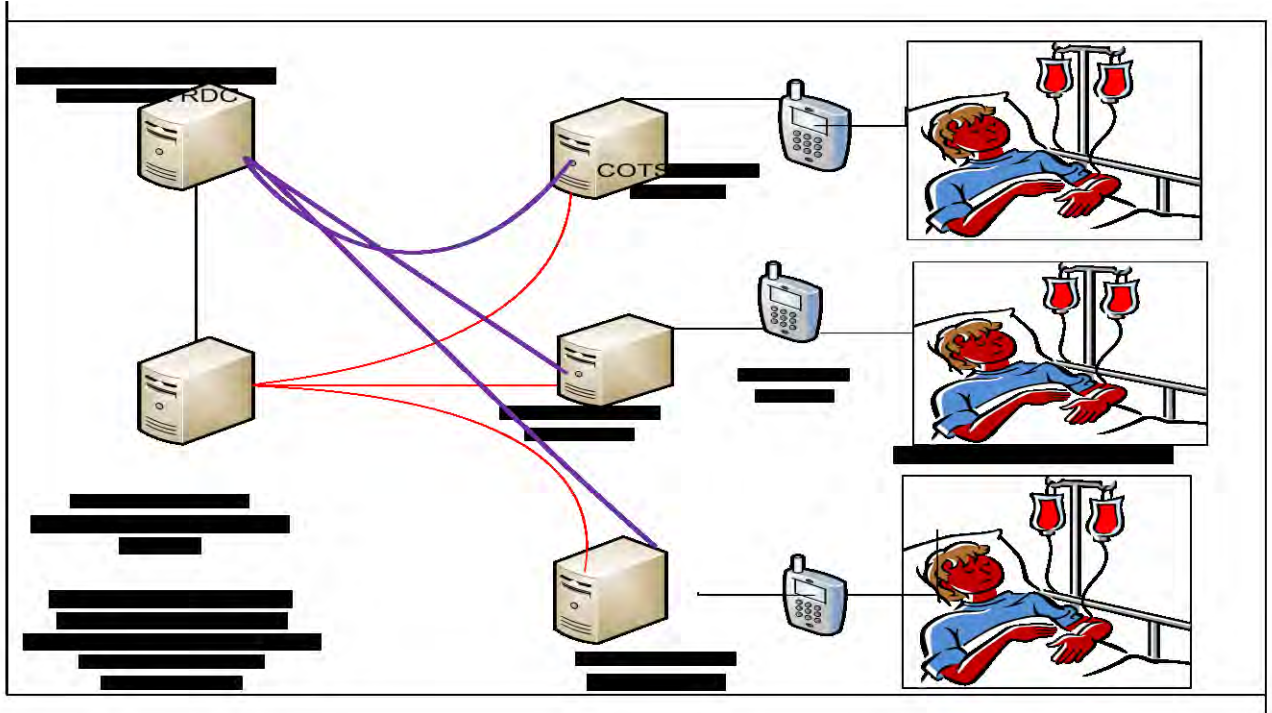


Illustration 1.1

This illustrates a multidivisional architecture with each COTS server representing a separate division.

For example, VBECS and VistA may contain multiple blood banks, Heartland East has 3: St Louis, Marion and Poplar Bluff. All 3 have separate instances in VBECS as defined by their institution number.

2.13. Security Specifications

1. The BCE-PPI Blood Administration/Pyxis® Transfusion Verification system shall provide role-based security to restrict access to information as established for the user in the **VISTA** system.
2. The BCE-PPI Blood Administration/Pyxis® Transfusion Verification system provides secure authentication to the **VISTA** system.
3. The BCE-PPI Blood Administration/Pyxis® Transfusion Verification system shall describe tools provided with the SOLUTION to enable VA to fully manage VA patient and security data stored within the SOLUTION.

2.14. System Features

Refer to sections 2.01 & 2.02 of this RSD.

2.15. Usability Specifications

In regard to the COTS Blood Administration Point of Care (BAPOC) System, VA has requested documentation from the vendor concerning previous work performed pertaining to use error/usability (such as, but not limited to, the vendor's 510K submission, usability data, use error risk analysis and mitigation responses, etc). VHA will review the information provided to determine the need for risk mitigation plans, i.e., VHA operating procedures, implementation and maintenance processes, training.

3. Applicable Standards

All functionality shall be compliant with existing blood bank standards, standards of accrediting agencies, FDA regulations and VA policies.

4. Interfaces

Refer to VBECS Application Interface Specification for BCE, version 2.0.

- ADT subscription
- Vitals
- TIU note

4.1. Communications Interfaces

4.1.1.VISTA

This section specifies the requirements necessary to establish and maintain communications between **VISTA** and the BAPOC system. It includes requirements to be satisfied by each system when sending or receiving a message. The interface between **VISTA** and the BAPOC system is established via a persistent or a transient (non-persistent) TCP/IP connection. Two TCP sockets provide bi-directional communications between the systems. Within the context of the TCP socket, each system will connect as the client when it initiates a message. The other system will connect as the server to receive messages from the listen state.

1. If **VISTA** detects a remote end disconnect, it shall attempt to reconnect to the BAPOC system TCP Server Socket for a locally defined number of Retry Attempts.
2. If **VISTA** detects a remote end disconnect and is unable to reconnect to the BAPOC system after locally defined number of Retry Attempts, it shall log an error.
3. If the BAPOC system detects a remote end disconnect, it shall close that channel of its TCP Server Socket and wait **VISTA** reconnection.
4. The Receiving system shall return an Accept Acknowledgement with a Commit Accept (CA) status to the Sending System for each incoming HL7 message in which the Message Header Segment (MSH) conforms to the following criteria:
 - The first segment is a Message Header Segment (MSH).

- The Field Separator (MSH-1) is valued.
 - The Encoding characters (MSH-2) are valued.
 - The Sending Application field (MSH-3) contains the values LA7LAB or LA7POCn as appropriate.
 - The Sending Facility field (MSH-4) contains the VA stations number of the primary VA facility hosted on the VA system.
 - The Receiving Application field (MSH-5) contains the values LA7LAB or LA7POCn as appropriate.
 - The Receiving Facility field (MSH-6) contains the VA stations number of the primary VA facility hosted on the VISTA system.
 - The Date/time Message (MSH-7) is valued.
 - The Message Type Field (MSH-9) contains a valid message and event (when appropriate) type.
 - The Message Control ID Field (MSH-10) contains an ID.
 - The Processing ID (MSH-11) contains a valid ID.
 - The Version ID (MSH-12) contains 2.5.
 - The Accept Acknowledgment Type (MSH-15) indicates a valid acknowledgment condition.
 - The Application Acknowledgment Type (MSH-16) contains a valid acknowledgment condition.
5. The Receiving system shall return an Accept Acknowledgement with a Commit Reject (CR) status to the Sending System for each incoming HL7 Message in which the Message Header Segment (MSH) fails to conform to the criteria in #4 above.
 6. The Receiving system shall return an Accept Acknowledgement with a Commit Error (CE) status to the Sending System for each incoming HL7 Message that it has not accepted for any reasons other than those requiring a Commit Reject.
 7. Upon receipt of an Accept Acknowledgment with a Commit Error (CE) status from the Receiving System, the Sending System shall institute appropriate notification actions.
 8. The Receiving System shall return an Application Acknowledgement to the Sending System for each incoming HL7 Message in which the Application Acknowledgement Type Field of the MSH Segment (MSH-16) is set to "AL".

4.1.2.VBECS

VBECS uses HL7 messaging to share information with other applications and services. These subsections describe the HL7 interfaces used by VBECS and the steps required to configure these interfaces for use. (Refer to the VBECS Application Interface Specification)

These HL7 interfaces use the VBECS INTERFACE ADMIN mail group on the

VistA system to receive notifications when problems arise with delivery of messages to VBECS from VistA.
Refer to VBECS Application Interface Specification for BCE, version 2.0.

Implementation Details: Multi Listener Service and Single Listener Services (Messages Inbound to VBECS)

All VBECS Windows listener services are based on a core set of logic in the abstract class SimpleListener. Each listener inherits the core functionality. The VBECS HL7 Multi Listener Service is automatically started when the server is rebooted, or can be started manually. This service is designed to handle inbound data from all supported HL7 interfaces for VBECS.

Optionally, VBECS may be configured to use single-mode listener services, for example, if there is a problem with one of the interfaces and more in-depth trouble-shooting is required. A VBECS HL7 Listener Windows Service (single listener mode – each listener will use a unique IP address and port number as configured in the VBECS Administrator (refer to *SDD VBECS Administrator*) is automatically started when the server is rebooted, or can be started manually.

The listener receives an HL7 message, determines the type of message received and sends to appropriate parser for processing. All VBECS supported inbound messages are saved to the MessageLog table except ADT messages for patients not in VBECS.

See table below for VBECS HL7 Processing overview.

VBECS HL7 Processing

Listener determines the type of message	Is message type supported by VBECS?	Listener determines validity of message	HL7 manager determines correct parser	VBECS Processing	Response
VistA PING message	Yes	Valid	N/A	N/A	PING response is sent immediately (if service is available).
All message types	No	N/A	N/A	N/A	Negative acknowledgement with an error message indicating the sending and/or receiving application(s) in the message are not supported by VBECS.
ADT	Yes	Validates message type and patient exists in VBECS	Patient Update HL7 Parser	Patient demographic data and/or location data is updated if VBECS does not have the most recent information.	<p>Success: An application accept (AA) acknowledgement message is generated and returned to the sending application.</p> <p>Failure: Negative acknowledgement (AR) with an error message is returned to sending application.</p> <p>The AR response message will contain detailed information regarding any invalid or missing required data in the HL7 message received by VBECS.</p>

Listener determines the type of message	Is message type supported by VBECS?	Listener determines validity of message	HL7 manager determines correct parser	VBECS Processing	Response
ADT	Yes	Validates message type and patient DOES not exist in VBECS	Patient Update HL7 Parser	N/A	<p>Success: An application accept (AA) acknowledgement message is generated and returned to the sending application.</p> <p>Failure: Since no in-depth processing is done on the message content (only enough to validate the patient is not in VBECS), an error here would result in no return message to the sending application. However, an email message is sent to the interface administrator (as defined in VBECS Administrator [refer to <i>SDD VBECS Administrator</i>]).</p>
ADT	Yes		Patient Merge HL7 parser	The Patient Merge HL7 parser updates the VBECS database with the patient merge event. Both patients must be in VBECS, if either the merge-from or merge-to patients do not exist in VBECS then the merge event cannot be processed.	<p>Success: An application accept (AA) acknowledgement message is generated and returned to the sending application.</p> <p>Failure: Negative acknowledgement (AR) with an error message is returned to sending application.</p>
CPRS New Order or Cancel Order or Process Previous Lab Results	Yes	Validates message type and patient exists in VBECS	CPRS HL7 Parser	The CPRS HL7 Parser determines if the message is for a new order, cancel order or lab results. The message is then processed and the VBECS DB is updated.	<p>Success: An application accept (AA) acknowledgement message is generated and returned to the sending application.</p> <p>Failure: Negative acknowledgement (AR) with an error message is returned to sending application.</p>

Listener determines the type of message	Is message type supported by VBECS?	Listener determines validity of message	HL7 manager determines correct parser	VBECS Processing	Response
BCE Post-Transfusion Information	Yes	Validates message type and patient exists in VBECS	BCE HL7 Parser	The patient transfusion data is parsed and saved to the VBECS DB (if valid). If not valid, a negative acknowledgment message is returned to the BCE COTS application indicating the source of the problem and an email sent to the interface administrator (see <i>SDD VBECS Administrator</i>).	<p>Success: An application accept (AA) acknowledgement message is generated and returned to the sending application.</p> <p>Failure: Negative acknowledgement (AE or AR) with an error message is returned to sending application. AE is sent if a transfusion record was updated but another user is currently editing the record (locked). The AR code is sent for all other errors encountered.</p> <p>The AR response message will contain detailed information regarding any invalid or missing required data in the HL7 message received by VBECS.</p>

VBECS HL7 Processing

Listener determines the type of message	Is message type supported by VBECS?	Listener determines validity of message	HL7 manager determines correct parser	VBECS Processing	Response
Vista PING message	Yes	Valid	N/A	N/A	PING response is sent immediately (if service is available).
All message types	No	N/A	N/A	N/A	Negative acknowledgement with an error message indicating the sending and/or receiving application(s) in the message are not supported by VBECS.
ADT	Yes	Validates message type and patient exists in VBECS	Patient Update HL7 Parser	Patient demographic data and/or location data is updated if VBECS does not have the most recent information.	<p>Success: An application accept (AA) acknowledgement message is generated and returned to the sending application.</p> <p>Failure: Negative acknowledgement (AR) with an error message is returned to sending application.</p> <p>The AR response message will contain detailed information regarding any invalid or missing required data in the HL7 message received by VBECS.</p>

Listener determines the type of message	Is message type supported by VBECS?	Listener determines validity of message	HL7 manager determines correct parser	VBECS Processing	Response
ADT	Yes	Validates message type and patient DOES not exist in VBECS	Patient Update HL7 Parser	N/A	<p>Success: An application accept (AA) acknowledgement message is generated and returned to the sending application.</p> <p>Failure: Since no in-depth processing is done on the message content (only enough to validate the patient is not in VBECS), an error here would result in no return message to the sending application. However, an email message is sent to the interface administrator (as defined in VBECS Administrator [refer to <i>SDD VBECS Administrator</i>]).</p>
ADT	Yes		Patient Merge HL7 parser	The Patient Merge HL7 parser updates the VBECS database with the patient merge event. Both patients must be in VBECS, if either the merge-from or merge-to patients do not exist in VBECS then the merge event cannot be processed.	<p>Success: An application accept (AA) acknowledgement message is generated and returned to the sending application.</p> <p>Failure: Negative acknowledgement (AR) with an error message is returned to sending application.</p>
CPRS New Order or Cancel Order or Process Previous Lab Results	Yes	Validates message type and patient exists in VBECS	CPRS HL7 Parser	The CPRS HL7 Parser determines if the message is for a new order, cancel order or lab results. The message is then processed and the VBECS DB is updated.	<p>Success: An application accept (AA) acknowledgement message is generated and returned to the sending application.</p> <p>Failure: Negative acknowledgement (AR) with an error message is returned to sending application.</p>

Listener determines the type of message	Is message type supported by VBECS?	Listener determines validity of message	HL7 manager determines correct parser	VBECS Processing	Response
BCE Post-Transfusion Information	Yes	Validates message type and patient exists in VBECS	BCE HL7 Parser	The patient transfusion data is parsed and saved to the VBECS DB (if valid). If not valid, a negative acknowledgment message is returned to the BCE COTS application indicating the source of the problem and an email sent to the interface administrator (see <i>SDD VBECS Administrator</i>).	<p>Success: An application accept (AA) acknowledgement message is generated and returned to the sending application.</p> <p>Failure: Negative acknowledgement (AE or AR) with an error message is returned to sending application. AE is sent if a transfusion record was updated but another user is currently editing the record (locked). The AR code is sent for all other errors encountered.</p> <p>The AR response message will contain detailed information regarding any invalid or missing required data in the HL7 message received by VBECS.</p>

4.2. Hardware Interfaces

Pyxis® Point of Care Verification is a software solution that can be run on hospital hardware. There are three primary components to the Pyxis® Point of Care Verification System:

- PDA/Handheld with built in scanner; laptop, desktop or Workstations On Wheels(WOWs) with wired/wireless scanners
- Server/Interface Engine
- Pyxis® Point of Care Verification Console(CFMC) thin-client application

There are basic hospital infrastructure components required to implement any of the Pyxis® Point of Care Verification applications. Integrated Systems (IS) specific tasks/requirements include a wired and wireless network, interfaces (HL7), server configuration and installation, back-ups, anti-virus protection, patching, remote access, network printing.

Interfacing between the hospital clinical systems and Pyxis® Point of Care Verification is done through the Pyxis® Interface Engine (CFIE) – an application that resides on the Pyxis® Point of Care Verification server(s). Interfaces conform to the HL7 standard (version 2.5) using a TCP/IP

socket-to-socket connection (9800 and above) and can be point-to-point and/or through a hospital interface engine. Data transmission is real-time and message traffic should be unsolicited.

The BCE-PPI, Increment II VISTA Applications/VBECS interfacing with a COTS BAPOC system is also dependent of WIR installation at the facility supported by the WIR.

4.3. Software Interfaces

The VISTA/VBECS system is interfaced with the BAPOC system. Each Pyxis[®] Point of Care Verification application has different interface requirements (listed below) and application specific HL7 interface specifications can be provided upon request. The common thread for all applications, however, is an inbound, real-time ADT interface required for PPID. In instances where Pyxis[®] Medstation RX is installed, some existing interfaces/capabilities may be used to satisfy Pyxis[®] Point of Care Verification interface requirements. Specific interface requirements for each application are listed below.

- ***Pyxis[®] Transfusion Verification***
 - Inbound ADT messages from the hospital admissions system for real-time patient census, allergy, and height/weight information* (required)
 - Inbound ORU (blood order) messages from the hospital's blood bank system showing patient transfusion assignment, disposition/release from blood bank to patient, and/or release back to inventory or waste (required)
NOTE: THIS IS NOT THE NURSING ORDER TO ADMINISTER.
 - Post transfusion completion information

4.4. User Interfaces

The intended users of this product are expected to be experienced in the use of CPRS, VBECS, and the blood transfusion process as appropriate for their role(s). These users may include but are not limited to physicians, nurses, medical technologists and other trained authorized medical professionals.

5. Legal, Copyright, and Other Notices

There are no legal disclaimers, warranties, copyright notices, patent notice, word mark, 508 disclaimer, or trademark logo compliance issues for the BCE-PPI Blood Administration project.

6. Purchased Components

The purchased components are the PDAs, chargers, and/or batteries that are required. Servers that house the vendor software require purchasing. The WIR upgrade needs to be in place at all the sites intending to install the BCE-PPI Blood Administration/Pyxis[®] Transfusion Verification software. This will include all other products purchased for the system.

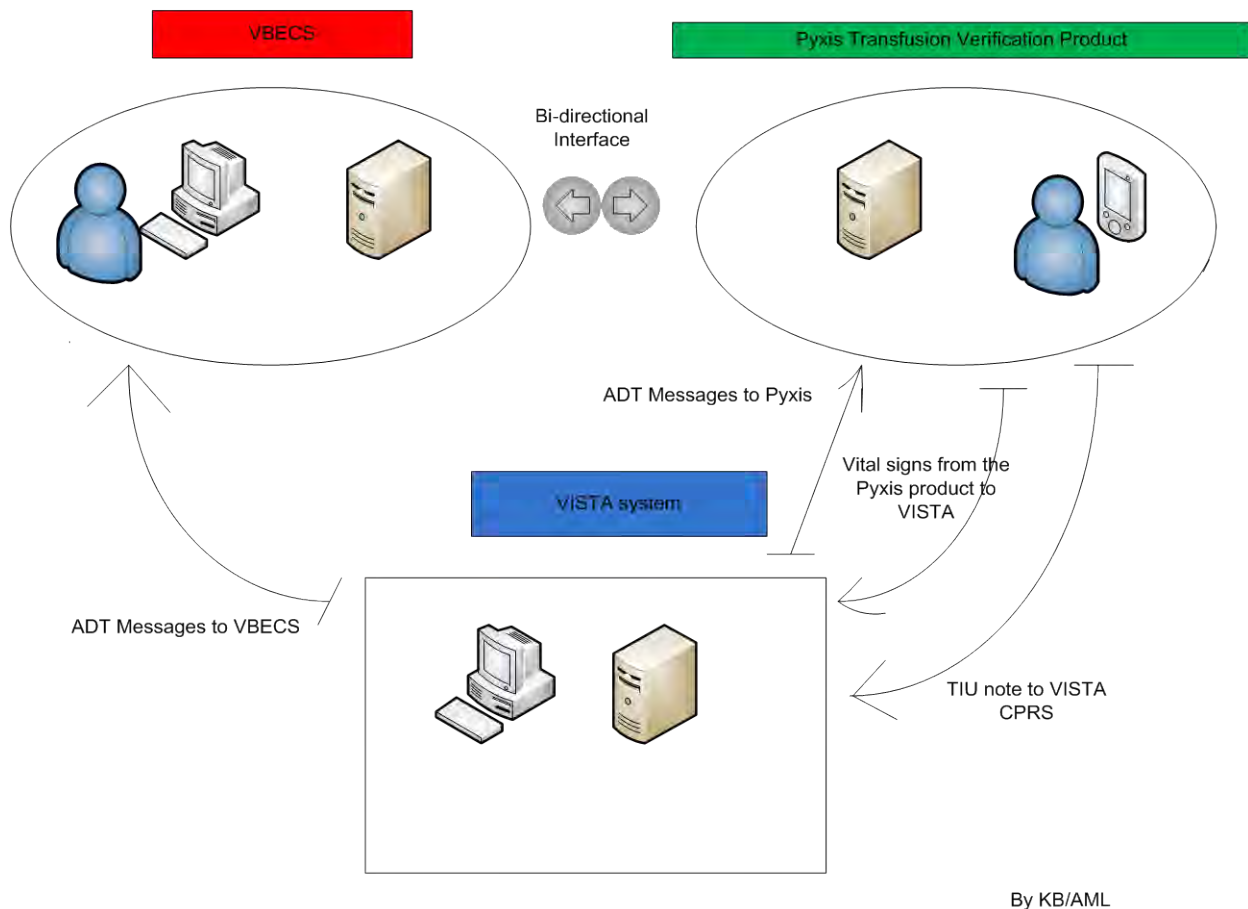
7. User Class Characteristics

The user class characteristics shall include medical professionals who are trained and authorized to use this medical equipment and software.

8. Estimation

Function Point Analysis = 0

9. Appendix A – An Overall Diagram depicting the VISTA/VBECS Blood Administration – Pyxis Transfusion Verification System



10. Appendix B – TIU Note with Vital Signs

Example 1 (with VS):

LOCAL TITLE: TRANSFUSION RECORD REPORT
DICT DATE: MAY 18, 2007@17:22 ENTRY DATE: MAY 18, 2007@17:22:05
DICTATED BY: MANAGER,SYSTEM EXP COSIGNER:
URGENCY: STATUS: COMPLETED
SUBJECT: Unit Id: BC00000

PATIENT INFORMATION:

Patient Name: [REDACTED]
Patient Location: [REDACTED]
Patient ID: 12 [REDACTED]
Patient Blood: [REDACTED]
Attending Physician: [REDACTED]

ORDER INFORMATION:

Order Number: 938
Ordering Provider: PVNA
Blood Product Components: LIQUID PLASMA, CPD
Blood Product Transfusion Requirement: Please check SF518 for special requirements
Transfusion Priority: Routine
Donor Blood Type: A NEG
Unit Issued From Blood Bank Date/Time: 05/18/2007 13:00:22
Blood Product Unit Id: BC00000
Expiration Date: 06/17/2007 13:00:22
Issue Location: BLOOD BANK
Transfusion Status: Completed
Product Code: 18401

TRANSFUSION INFORMATION:

User ID of Administering Personnel: AGER
User ID of Witnessing Personnel: [REDACTED] (2007-05-18 17:21:25.427)
Transfusion Begin Date/Time: 2007 [REDACTED] 17:21:25.427
Indication For Transfusion: Elective Surgery
Expired Override Reason: Issued to Remote Monitored Storage
Admin Set/Filter Type: Alaris Blood Tubing (Pump) Latex Free
Admin Set/Filter Lot Number:

Transfusion Stopped Date/Time: 05/18/2007 17:21:38
Transfusion Stopped By User: SMANAGER
Transfusion Stopped Reason(s): Fever (>1C or 2F increase with temp >= 100F)
: Other interruption reason

Stop Reason Comments:
Transfusion Stopped Action Taken: Blood Bank and Provider Notified
Stopped Volume (ml): 66
Transfusion Completed Date/Time: 05/18/2007 17:22:01
Completed Volume (ml): 1000
User ID of Completing Personnel: SMANAGER

VITAL SIGNS INFORMATION:


Vitals Taken: 05/18/2007 17:19:51
Entered By: SMANAGER
Temp: 99
Pulse: 100
Resp: 90
Systolic BP: 100
Diastolic BP: 90
Rate in ml/hr:
Pt Condition:
S/S Reaction:

Vitals Taken: 05/18/2007 17:21:44
Entered By: SMANAGER
Temp: 99
Pulse: 100
Resp: 90
Systolic BP: 100
Diastolic BP: 90
Rate in ml/hr:
Pt Condition:
S/S Reaction:

/es/ SYSTEM MANAGER

Signed: 05/18/2007 17:22

11. Appendix C – Blood Transfusion Record Form

Blood Transfusion Record Form			
 VA HEARTLAND - WEST, VISN 15, Fort Myers, FL		Transfusion Requirements COMPONENT REQS: Irradiated cellular products	
Patient Name: [REDACTED]			
Patient ID: 666-66-6666	Patient Blood Type: O Pos	Blood Component Information Blood Component: PLATELETS/CPDA-1/500mL/20-24C/Irradiated	
Unit/Pool ID: W0429 00 000004	Unit Blood Type: O Pos	Component Expiration Date/Time: 04/30/2011 23:59 Number of units/pool: 0	
Compatibility Interpretation: Not required		Additional Patient Information Specimen UID: Location: VBEC KANSAS CITY INPT	
Assigned Date/Time: 04/29/2011 12:43	Technologist initials: DM		
Remarks <div style="height: 100px;"></div>			
Pretransfusion Data			
Inspected and issued by:			
Issued to:		Issued to location:	
I have verified and compared, AT THE BEDSIDE, the transfusion recipient's identity (i.e., wristband), the unit ID tag, the blood component container label, and this form. I verify that all information matches and is consistent ITEM for ITEM. I verify that the intended recipient is the same person named on this form and on the unit ID tag. Furthermore, I verify that there is a current, valid INFORMED CONSENT, and a PHYSICIAN'S ORDER for this transfusion.			
<input type="checkbox"/> Verified informed consent for transfusion	First identifier (signature):	Second identifier (signature):	

Transfusion Data					
	Date/Time	Temperature	Pulse	Blood Pressure	Respiration
Start					
15 minutes					
Mid (optional)					
Stop					
Amount given (mL): _____ <input type="checkbox"/> Completed <input type="checkbox"/> Interrupted <input type="checkbox"/> No reaction <input type="checkbox"/> Reaction suspected (Complete Transfusion Reaction Data section)					
Other difficulties (equipment, clots, etc.): <input type="checkbox"/> No <input type="checkbox"/> Yes (specify) _____ Transfusion Data section completed by (signature) _____					
Transfusion Reaction Data					
Patient identity match with unit compatibility tag and this form reverified by (initials): _____					
Description of reaction: <input type="checkbox"/> Urticaria <input type="checkbox"/> Chill <input type="checkbox"/> Pain <input type="checkbox"/> Fever <input type="checkbox"/> Dyspnea <input type="checkbox"/> Other (specify) _____					
Transfusion Reaction Data section completed by (signature): _____					
Suspected Transfusion Reaction: Immediate Response					
If a reaction is suspected, IMMEDIATELY: 1. Interrupt the transfusion. Give emergency treatment. Keep the intravenous line open. 2. Reverify patient and blood product identification. 3. Notify physician and Transfusion Service. 4. Follow transfusion reaction procedures. 5. Do NOT discard the component. Return the blood component bag, filter set, and attached solutions to Transfusion Service. Collect patient specimens as required. 6. Order a Transfusion Reaction Workup.					
Patient name: _____ Patient ID: _____ DOB: 5/28/1989 Blood Transfusion Record Form, Version, 1.0					

Function Point Analysis Results Table

Project Software Functional Size and Size-based Effort and Duration Estimate						
	Application					
Item	A	B	C	D	E	Total
Counted Function Points						
Estimated Scope Growth						
Estimated Size At Release						
Size-based Effort Estimates					Labor Hours	Probability
Low Effort estimate – with indicated probability, project will consume no more than:						
High Effort estimate -- with indicated probability, project will consume no more than:						
Size-based Duration Estimates					Work Days	Probability
Low Duration estimate – with indicated probability, project will consume no more than:						
High Duration estimate -- with indicated probability, project will consume no more than:						

[Insert Cumulative Probability (“S-curve”) Charts here]

Attachment A - Approval Signatures

This section is used to document the approval of the Requirements Specification Document. The Chair of the governing Integrated Project Team (IPT), Business Sponsor, IT Program Manager, and the Project Manager are required to sign. Please annotate signature blocks accordingly.

REVIEW DATE: *<date>*

SCRIBE: *<name>*



RE Approval of Increment II RSD.msg

Signed:

Date:


, *BCE-PPI Senior Project Manager*



RE Approval of Increment II RSD.msg

Signed:

Date:

, *(NCPS), Patient Safety Physician*



RE Approval Signatures for RSD.msg

Signed:

Date:

, *MBA, CISM, CRISC, GSLC, CNDA, SDE PAO Project Manager*



RE Approval of Increment II RSD.msg

Signed:

Date:

[Redacted Signature]

Director, Bar Code Resource Office, VHA OIA Health Informatics