Certificate of Accreditation

Blood Bank Computer Systems, Inc. (BBCS) certifies that the following is true and correct:

BBCS and Fenwal, Inc. (Vendor)

worked together to ensure:

The DXT Relay System developed by the vendor can interface with the ABO Wheels Application, Version 1.1.0 when the Fenwal Interface developed by BBCS is used.

BBCS tested over 40 transactions for the Alyx procedure types during which data that was sent on the Fenwal Interface was verified by BBCS and was able to be properly retrieved, transmitted, and loaded for display using the Alyx device, the DXT Relay System, BBCS's Fenwal DXT Relay Interface, and the ABO Wheels Application together.

After passing the test, BBCS certifies that the DXT Relay System is compatible with the ABO Wheels Application, Version 1.1.0. When used together pursuant to the respective operating instructions for each, the DXT Relay System and the ABO Wheels Application are capable of retrieving, transmitting and loading for display the intended and correct data.

This certification is limited to the software versions identified herein, and is not applicable to any modified or later version tested, except as expressly provided herein.

BBCS Accreditation Program: Device Certification



Certificate of Accreditation

Outbound Data Elements

Outbound data elements are sent to the DXT Relay System in preparation to receivie data from the collection device. Because it is not end result data, outbound data elements are not subject to the same level of testing as inbound data elements.

Table 1: Data sent to the DXT Relay System for Alyx

Data Elements	Data E
Unit Number	Sex
Donor Number	Diastolic Pressure
Donor Weight	Systolic Pressure
Weight Unit of Measure	Pulse Rate
Donor Height	Donor Temperature
Height Unit of Measure	Temperature Unit of N
Hematocrit*	Donor Confirmation C
Hemoglobin*	Donor Confirmation A
Donor Blood Type	
* Only one test type (HGB or HCT) may be used	

Elements Measure Question [◊] Answer [◊]



Only one test type (HGB or HCT) may be used.

[♦] Donor Confirmation Question is hard-coded as "What is your date of birth?" Donor Confirmation Answer will display the Donor's date of birth for the Phlebotomist's reference.

Certificate of Accreditation

Certified Inbound Data Elements

Table 2: Inbound Data Elements

Data Elements	Included in Interface
Unit Number	Certified
Donor Number	Certified
Phlebotomy Start Time	Certified
Phlebotomy Stop Time	Certified
Phlebotomist ID – Start	Certified
Phlebotomist ID – Stop	Certified
Product Category	Certified
Arm Used	Certified

Data Elements	Included in Interface
Draw Volume	Certified
Plasma Loss	Certified
Red Blood Cell Loss	Certified
Anticoagulant Volume	Certified
Device Type	Certified
Device Serial Number	Certified
Bag Lot ID Number	Certified

