

#### **Ortho Clinical Diagnostics**

Because Every Test Is A Life™

#### **P-10**

# Safety and Effectiveness, Efficiency, and Satisfaction of Use for Data Management Software in the Transfusion Service

https://soundcloud.com/user-673204275/shot-p-10-safety-and-effectivenessefficiency-and-satisfaction-of-use-for-data-management

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## Introduction

#### Background

Data management plays a critical role in transfusion medicine

- Solutions which allow transfusion services to:
  - track individual samples and orders
  - clinical rules applied to ordered tests
  - Inkage of individual samples to results
- Data management software can be an effective, safe management tool.
- Usability assessment on human experience factors with a solution is important

## Introduction

#### Aims of the Study

- Study was designed to evaluate ORTHO CONNECT 3.0 a browser-based application
- Three areas of usability evaluated
  - Safety and effectiveness
  - Efficiency
  - Satisfaction
- Human factors usability evaluation plan
- Human factor scenario definition

## Method

- Validated simulation tool of application
- 20 Trained lab professionals tested the application
- 13 Task scenarios tested
- Human factors testing scenario template introduced lab setup and task overview
- Data files provided as required
- Observers captured testers on an observation documentation template
- Upon test completion, a system usability scale survey completed

## Results

#### **Table 1: Safety and Effectiveness**

Task Number	Scenario and Task	Number of Participants	Failure due to safety-related user error	Failure due to test assistance/ Incomplete result	Pass Rate (Effectiveness)
1	QC Samples Entered	19*	0	0	100%
2	Standard Result outcome	20	0	0	100%
3	Reflex Test	20	0	1	95%
4	Confirmation Result	20	0	0	100%
5	Result review with reaction result below expected threshold	20	0	1	95%
6	Check for incomplete sample information	20	0	0	100%
7	Specific test result triggers additional comment	20	0	1	95%
8	Special result condition	20	0	0	100%
9	Manual Result Entry	20	0	0	100%
10	Manual Result Entry Mismatch	19*	1	0	95%
11	Result review due to failing QC	19*	0	2	90%
12	Manual Order Entry Cross match	20	0	0	100%
13	Manual Result Entry for Cross match	20	0	1	95%

\*No Answer provided by one of the testers for the Scenario, and therefore not taken into account for the Pass Rate. In scenario 10, one tester failed to accurately file a result initially but later filed it correctly.

### Results

The System Usability Score (SUS) ranged from 52.5 -100. The average SUS score for all 20 testers was 80.5. The calculated score was above the industry average score of 68 (From, J. Usability Stud., 2013)

Participant number	SUS Score
1	52.5
2	80
3	80
4	72.5
5	87.5
6	82.5
7	75
8	85
9	97.5
10	70
11	100
12	100
13	67.5
14	75
15	70
16	77.5
17	85
18	100
19	77.5
20	75

## Conclusions

Human factors summative testing on ORTHO CONNECT<sup>®</sup> 3.0

- Found the data management SW solution to be safe and effective for the intended users, uses and use environments.
- Improvements have been identified in the training approach that will be adopted for future training sessions and deployment of the software solution and
- Graphic user interface screens shall be further reviewed and improved for usability awareness with future SW updates.



BioMedical Data Solutions developed ORTHO CONNECT 3.0

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