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## 1.0 PURPOSE

*The Functional Requirements document serves many purposes. It is used to guide product development efforts. Descriptions of new features are actively added to this document as the software is created and improved.*

*It is the primary location where an explanation of the essential program functions can be found. Internally, programmers, testers, product managers, technical support, and other groups use the document to determine what the software should and should not do. Users also refer to this document as a source of functional requirement clarification, and as such, the basis for creating user requirements.*

*Functional requirements are tested via Operation-level testing (OQ). This document provides the necessary traceability (trace matrix) from the requirements to their associated MasterControl OQ tests. Each test's ultimate result and summarizations of deviations encountered during executions is also included. Additionally, result data is linked directly to associated objective evidence and detailed deviation data.*

*Lastly, regulated companies are expected to maintain documentation that describes what their regulated software does. This Functional Requirements Specification (FRS) may be adopted by companies using this software as part of their auditable set of specification and test documents.*

## 2.0 SCOPE

*Functional requirements are the basic, user-level features of an application. They describe the essential operations that the software is expected to perform. Functional Requirements do not explain design (such as character lengths or field position), nor do they present use cases or extensive user scenarios.*

*This document contains the functional requirements for the MasterControl Mobile module. It also presents the MasterControl tests (trace matrix) that exercise these requirements.*

*Summarizing results for OQ executions are presented in line with requirements throughout the document. Additional testing details are provided as hyperlinks within each result set.*

## 3.0 VALIDATION TEST HISTORY

Date	Execution ID	Build Number	Tests Executed
15 Apr 2022 11:42 AM	<a href="#">16579</a>	2022.2.0.184	37 (0 failed)

#### 4.0 TEST DEVIATION SUMMARY

Deviation Number	Affected Requirement	Deviation Type	Status
No deviations were found during the execution of this FRS.			

#### 5.0 APPLICATION OVERVIEW

*MasterControl Mobile allows remote access to MasterControl functionality from a wide variety of handheld devices. Key features of Mobile include:*

- A web interface optimized for the mobile device
- Accessibility to, and signing off of, tasks
- Viewing and filling out forms
- Usage of the collaboration workspace

##### 5.1 Dependencies

MasterControl Mobile requires cookies to be enabled to use MasterControl.

##### 5.2 Licensing

MasterControl Mobile is available to companies who have licensed the All Access, Documents, Process and Training products.

*Full details of MasterControl Mobile features and functionality follow.*

#### 6.0 FUNCTIONAL REQUIREMENTS AND TRACE

FRS ID	Description	Test #	Result
<b>1</b>	<b>MasterControl Mobile</b> <i>MasterControl Mobile allows users to access the functionality of MasterControl through their mobile device.</i>	---	---
1.1	MasterControl Mobile uses the same login information as the full MasterControl system.	S-02444_1	PASS <small>16579</small>
1.1.1	After logging in, the user's name and User ID are displayed on the Mobile home page.	S-02444_1	PASS <small>16579</small>
1.1.2	Users may save their User ID for future logins.	S-02444_1	PASS <small>16579</small>
1.2	If Mobile is configured in MasterControl, emails include a link to the Mobile site.	S-02444_2	PASS <small>16579</small>
1.2.1	The links in the email notifications allow access to the task on the Mobile site.	S-02444_2	PASS <small>16579</small>
1.2.1.1	If the user is not currently logged into the Mobile site, a login page displays requiring authentication.	S-02444_2	PASS <small>16579</small>
<b>2</b>	<b>My Tasks Page</b>	---	---

FRS ID	Description	Test #	Result
	<i>MasterControl Mobile allows users to view and perform their active tasks, just as in the MasterControl application suite, with some limited functionality.</i>		
2.1	Executable tasks appear with an action icon.	S-08390_1	PASS <small>16579</small>
2.2	Collaboration tasks can be opened in Mobile.	S-08390_11	PASS <small>16579</small>
2.2.1	Mobile's collaboration workspace displays the latest redline of the document.	S-08390_11	PASS <small>16579</small>
2.2.2	The Collaboration files can be viewed.	S-08390_11	PASS <small>16579</small>
2.2.3	Collaboration members and comments can be viewed.	S-08390_3	PASS <small>16579</small>
2.2.3.1	Comments can be added.	S-08390_3	PASS <small>16579</small>
2.3	Document (Approval) Tasks can be opened in Mobile.	S-08390_2	PASS <small>16579</small>
2.3.1	Tasks can be approved.	S-08390_2	PASS <small>16579</small>
2.3.1.1	An Effective date can be specified using the following: <ul style="list-style-type: none"> <li>A calendar control</li> <li>Manual entry</li> </ul>	S-08390_2	PASS <small>16579</small>
2.3.1.2	An Expiration date can be specified using the following: <ul style="list-style-type: none"> <li>A calendar control</li> <li>Manual entry</li> </ul>	S-08390_2	PASS <small>16579</small>
2.3.2	Tasks can be rejected.	S-08390_4	PASS <small>16579</small>
2.3.2.1	A comment must be entered when a task is rejected.	S-08390_4	PASS <small>16579</small>
2.4	Users may sign off on documents sent in Advanced Packets.	S-08390_5	PASS <small>16579</small>
2.4.1	Users can view packet information.	S-08390_5	PASS <small>16579</small>
2.5	Documents linked to the packet can be viewed.	S-08390_5	PASS <small>16579</small>
2.6	When Documents are included in a multi-phase lifecycle, in which the document can move on to more than one phase, users are asked to select the desired phase during sign-off.	S-08390_7	PASS <small>16579</small>
2.7	Document Review tasks can be signed off in Mobile.	S-08390_8	PASS <small>16579</small>

FRS ID	Description	Test #	Result
2.7.1	Users may indicate either of the following on a Document Review task: <ul style="list-style-type: none"> <li>Needs Update</li> <li>Reviewed</li> </ul>	S-08390_8	PASS <small>16579</small>
2.8	<i>Process Form Tasks</i>	---	---
2.8.1	Form tasks can be launched in Mobile.	S-08390_6	PASS <small>16579</small>
2.8.2	HTML forms can be viewed.	S-08390_6	PASS <small>16579</small>
2.8.3	Data can be entered into form fields.	S-08390_6	PASS <small>16579</small>
2.8.4	Attachments can be added to the process task.	S-08390_12	PASS <small>16579</small>
2.8.5	Attachments can be removed from the process task.	S-08390_12	PASS <small>16579</small>
2.8.6	Attachments can be viewed in the process task.	S-08390_12	PASS <small>16579</small>
2.8.7	Task comments can be entered upon sign-off.	S-08390_13	PASS <small>16579</small>
2.8.8	<i>Users can sign-off on an HTML form with a status listed below:</i>	---	---
2.8.8.1	Work in Process	S-08390_13	PASS <small>16579</small>
2.8.8.2	Data Complete	S-08390_15	PASS <small>16579</small>
2.8.8.3	Data Approval	S-08390_15	PASS <small>16579</small>
2.8.8.4	Dual Sign Off	S-08390_18	PASS <small>16579</small>
2.8.8.5	Data Rejected	S-08390_18	PASS <small>16579</small>
2.8.8.5.1	If enabled on the route, users will be able to choose the workflow step the form should be rejected to.	S-08390_18	PASS <small>16579</small>
2.9	Training tasks can be opened in Mobile.	S-08390_16	PASS <small>16579</small>
2.9.1	Course materials can be viewed in Mobile.	S-08390_16	PASS <small>16579</small>
2.9.2	Course instructions can be viewed in Mobile.	S-08390_16	PASS <small>16579</small>
2.9.3	Users may sign off on training tasks.	S-08390_17	PASS <small>16579</small>
2.9.4	Files can be added to training tasks.	S-08390_17	PASS

FRS ID	Description	Test #	Result
			16579
2.9.5	Users may complete a training task exam.	S-08390_17	PASS
			16579
2.9.5.1	Users can complete an exam question of type True/False.	S-08390_9	PASS
			16579
2.9.5.2	Users can complete an exam question of type Multiple Choice.	S-08390_9	PASS
			16579
2.9.5.3	Users can complete an exam question of type "Matching".	S-08390_9	PASS
			16579
2.9.5.4	Users can complete an exam question of type Numeric.	S-08390_9	PASS
			16579
2.9.5.5	Users can complete an exam question of type Sequencing.	S-08390_9	PASS
			16579
2.9.5.6	Users can view the exam questions and whether each question was answered correctly or not.	S-08390_9	PASS
			16579
2.9.6	Users may complete a pre-exam before viewing the training materials.	S-08390_14	PASS
			16579
2.9.7	When the time limit is reached for a timed exam, the user will not be able to answer any more questions and the exam will be graded.	S-08390_10	PASS
			16579
2.9.8	When the number of retakes is reached, the user will no longer be able start the exam, but will be able to sign-off on the task.	S-08390_10	PASS
			16579
2.10	The Audit Workspace can be opened in Mobile.	S-08391_3	PASS
			16579
2.10.1	<i>Mobile supports the following task steps for all audit routes:</i>	---	---
2.10.1.1	Audit Step	S-08391_2	PASS
			16579
2.10.1.2	Peer Review Step	S-08391_1	PASS
			16579
2.10.2	<i>The following Audit task steps appear in a step user's My Tasks but are read-only:</i>	---	---
2.10.2.1	Approval step	S-08391_6	PASS
			16579
2.10.2.2	Response step	S-08391_14	PASS
			16579
2.10.3	The Mobile Audit Workspace consists of three tabs.	S-08391_3	PASS
			16579
2.10.3.1	All tabs display initially in view-only mode.	S-08391_3	PASS
			16579

FRS ID	Description	Test #	Result
2.10.3.2	Information within each tab can be edited.	S-08391_10	PASS <small>16579</small>
2.10.3.3	When in edit mode, the tab becomes locked.	S-08391_12	PASS <small>16579</small>
2.10.3.3.1	Other users are prevented from editing when a tab is in edit mode.	S-08391_12	PASS <small>16579</small>
2.10.3.4	The Scope can be entered.	S-08391_5	PASS <small>16579</small>
2.10.3.5	The Summary can be entered.	S-08391_5	PASS <small>16579</small>
2.10.3.6	The Conclusion can be entered.	S-08391_5	PASS <small>16579</small>
2.10.3.7	The Performed Start date can be entered.	S-08391_5	PASS <small>16579</small>
2.10.3.8	The Performed End date can be entered.	S-08391_5	PASS <small>16579</small>
2.10.3.9	The Finding Filter associated with Standard Text can be selected.	S-08391_8	PASS <small>16579</small>
2.10.3.10	A Standard Text option can be selected and inserted into a rich text field.	S-08391_8	PASS <small>16579</small>
2.10.3.11	A Rich Text Custom Field is supported.	S-08391_9	PASS <small>16579</small>
2.10.3.12	A Text Custom Field is supported.	S-08391_9	PASS <small>16579</small>
2.10.3.13	A Number Custom Field is supported.	S-08391_9	PASS <small>16579</small>
2.10.3.14	Custom Fields are displayed if they are associated with the current Audit InfoCard Type.	S-08391_9	PASS <small>16579</small>
2.10.3.15	Audit Entity information can be viewed.	S-08391_7	PASS <small>16579</small>
2.10.3.16	The Scheduled Start date can be viewed.	S-08391_7	PASS <small>16579</small>
2.10.3.17	The Scheduled End date can be viewed.	S-08391_7	PASS <small>16579</small>
2.10.3.18	Auditors can be viewed.	S-08391_7	PASS <small>16579</small>
2.10.3.19	The Standard Text Preview can be viewed.	S-08391_8	PASS <small>16579</small>
2.10.3.20	The Audit Reference can be entered.	S-08391_11	PASS <small>16579</small>
2.10.3.21	The Audit Categories can be entered.	S-08391_11	PASS <small>16579</small>



FRS ID	Description	Test #	Result
2.10.3.22	The Audit Findings can be entered.	S-08391_11	PASS <small>16579</small>
2.10.3.23	The Audit Rating can be entered.	S-08391_11	PASS <small>16579</small>
2.10.3.24	The Summary can be entered.	S-08391_11	PASS <small>16579</small>
2.10.3.25	The Recommendation can be entered.	S-08391_11	PASS <small>16579</small>
2.10.3.26	The Details can be entered.	S-08391_11	PASS <small>16579</small>
2.10.3.27	New observations/findings can be added to their associated criteria.	S-08391_13	PASS <small>16579</small>
2.11	Project simple tasks can be viewed.	S-08391_4	PASS <small>16579</small>
2.11.1	Users may sign off on Project simple tasks.	S-08391_4	PASS <small>16579</small>
<b>3</b>	<b>Simple Search</b> <i>The Simple Search behavior is similar to the "Simple" search in the MasterControl application.</i>	---	---
3.1	Simple search for documents is supported by Mobile.	S-08392_1	PASS <small>16579</small>
3.1.1	Documents can be viewed.	S-08392_1	PASS <small>16579</small>
3.1.2	Documents can be emailed.	S-08392_2	PASS <small>16579</small>
<b>4</b>	<b>Browse</b> <i>Users can access and view Organizers via Mobile using the same Explorer interface available in the MasterControl web GUI.</i>	---	---
4.1	Users can open the Explorer interface from Mobile.	S-08392_3	PASS <small>16579</small>

## 7.0 VIDEO REVIEW/ANALYSIS LOG

This table summarizes any videos that the validation team reviewed/analyzed as required per the MasterControl Validation Video Review Methodology MEMO. It includes the test ID number, the test run ID(s), the FRS ID numbers, and references the video review notes that were logged for each.

Test ID	Run ID(s)	FRS ID Steps(s)	Validation Video Review Analysis Notes(s)
N/A			

**8.0 REVIEWER NOTES**

No Reviewer Notes generated. There were no issues found during this Review.

**9.0 REVISION AND APPROVAL HISTORY**

*All approvals are maintained and controlled in the MasterControl™ electronic system.*

## Signature Manifest

**Document Number:** FRS-0955

**Revision:** 01

**Title:** Mobile FRS v2022.2

**Effective Date:** 19 Apr 2022

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### Mobile FRS v2022.2

#### Protocol Collaboration

Name/Signature	Title	Date	Meaning/Reason
Kirsty Massman (KMASSMAN)	Validation Engineer III	30 Mar 2022, 02:52:35 PM	Complete

#### Protocol Approval

Name/Signature	Title	Date	Meaning/Reason
Nghi Tran (NTRAN)	Validation Engineer I	15 Apr 2022, 11:27:11 AM	Approved

#### Execution Analysis

Name/Signature	Title	Date	Meaning/Reason
Nghi Tran (NTRAN)	Validation Engineer I	15 Apr 2022, 02:52:30 PM	Complete

#### Tech Review

Name/Signature	Title	Date	Meaning/Reason
Kirsty Massman (KMASSMAN)	Validation Engineer III	18 Apr 2022, 09:52:18 AM	Complete

#### Quality Review

Name/Signature	Title	Date	Meaning/Reason
Michelle Leckie (MLECKIE)	Validation Engineer	19 Apr 2022, 04:51:39 PM	Complete

#### Validation Approval

Name/Signature	Title	Date	Meaning/Reason
Brent Page (BPAGE)	Director of Engineering	19 Apr 2022, 05:19:15 PM	Approved

#### Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Michelle Leckie (MLECKIE)	Validation Engineer	19 Apr 2022, 04:51:59 PM	Approved

#### Notification

Name/Signature	Title	Date	Meaning/Reason
Scott Dickey (SDICKEY)	Validation Engineer III	19 Apr 2022, 05:19:15 PM	Email Sent
Jonathan LeBaron (JCLEBARON)	Quality Engineer	19 Apr 2022, 05:19:15 PM	Email Sent
David Baldwin (DBALDWIN)	Vice President of Engineering	19 Apr 2022, 05:19:15 PM	Email Sent

Colman Lloyd (CLLOYD)	Validation Engineer I	19 Apr 2022, 05:19:15 PM	Email Sent
Jeff Peterson (JVPETERSON)	Quality Manager	19 Apr 2022, 05:19:15 PM	Email Sent
Jake Walton (JWALTON)	Director, Quality & Compliance	19 Apr 2022, 05:19:15 PM	Email Sent
Brent Page (BPAGE)	Director of Engineering	19 Apr 2022, 05:19:15 PM	Email Sent
Adam Berrio (ABERRIO)	Director, Engineering	19 Apr 2022, 05:19:15 PM	Email Sent
Nghi Tran (NTRAN)	Validation Engineer I	19 Apr 2022, 05:19:15 PM	Email Sent
Kirsty Massman (KMASSMAN)	Validation Engineer III	19 Apr 2022, 05:19:15 PM	Email Sent
Michelle Leckie (MLECKIE)	Validation Engineer	19 Apr 2022, 05:19:15 PM	Email Sent