

	<b>COOK MEDICAL MANAGEMENT SYSTEM (CMMS) DOCUMENT</b>			
	Information Technology			
	<b>Document Number:</b> RAVP-SID0186-C00170706	<b>Revision:</b> 000	<b>QMS Owner:</b> Cook Medical Holdings LLC	<b>Page:</b> 1 of 1
	<b>Title:</b> Risk Assessment and Validation Plan Form			

1. **Risk Probability**

☒ Low

☐ Moderate

☐ High

2. **Risk Severity**

☐ Low

☒ Moderate

☐ High

		PROBABILITY		
		LOW	MODERATE	HIGH
SEVERITY	HIGH	2	1	1
	MODERATE	3	2	1
	LOW	3	3	2

RISK LEVEL	
1 =	High Risk
2 =	Moderate Risk
3 =	Low Risk

3. **Risk Level**

☒ Low Risk ☐ Moderate Risk ☐ High Risk

4. **Required Validation Type**

☒ Minor ☐ Partial ☐ Full / New System ☐ COTS System

5. **Comments**

N/A

6. **Validation Plan:**

DELIVERABLE	VALIDATION TYPE					JUSTIFICATION FOR REMOVING DELIVERABLE FROM VALIDATION PLAN
	MINOR	PARTIAL	FULL / NEW SYSTEM	COTS	DELIVERABLES	
Requirements Phase						
User Requirements and Functional Specifications User Requirements Section (URFS)			X			
Software Validation Traceability Matrix (TM)			X			
Combined Form (CF) (Requirements Section)		X				
Software Qualification Protocol (SQP)				X		
Design Phase						
User Requirements and Functional Specifications Functional Design Section (URDS)			X			
Technical Specifications (TS)			X			
Combined Form (CF) (Design Section)		X				
Software Qualification Protocol (SQP)				X		
Development Phase						
Unit Test Report (UTR)	X		X			
System Acceptance Testing Phase						
System Acceptance Testing Protocol (SATP)			X			
System Acceptance Testing Report (SATR)			X			
User Acceptance Testing Phase						
User Acceptance Testing Protocol (UATP)			X			
User Acceptance Testing Report (UATR)			X			
Combined Form (CF) (Acceptance Testing Section)		X				
Software Qualification Protocol (SQP)				X		
Software Qualification Report (SQR)				X		

REVIEW AND APPROVAL			
JOB FUNCTION	PRINTED NAME	SIGNATURE	DATE
IT Risk Assessor	See C00170711 in PLM for Approval	See C00170711 in PLM for Approval	See C00170711 in PLM for Approval

Template used to generate current contents: D00243618, Rev 002

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