

ICU Medical, Inc.

Test Case CXXXXX - Records File

Product: CADD Solis Infuser

C983037: 'To verify that the infusion system provides an on screen visual indicator to indicate status the Standalone Rechargeable Battery in the infuser.' (CADD-SYSDI-234, CADD-SYSDI-750, CADD-HWDI-PWR-34).

GENERAL INFORMATION SECTION

Test Executor	Print Name	Sign Name / Date

Start Test	Date	Time

Completion Test	Date	Time

Environmental Conditions			
Condition	Temperature	RH%	Sign/Date
Initial			
Final			

Test Designation	Descriptions
Test Run ID:	
Test Case ID:	CXXXXX
Test ID:	

EQUIPMENT, MATERIAL AND DOCUMENTATION SECTION

Equipment and Material Description	Quantity	Part Number / List number / ID	Lot Number / SN / Cal_ID	Calibration Due Date / SW Version
CADD Solis Infuser				
CADD Consumable				
Extension set				
IV Bag				
CADD Key				
AA Alkaline Batteries				

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Equipment and Material Description	Quantity	Part Number / List number / ID	Lot Number / SN / Cal_ID	Calibration Due Date / SW Version
Temperature Meter				

Documents number	Documents description	Revision

TABLE 1. REQUIREMENTS CADD-SYSDI-73 AND CADD-SYSDI-75 CONDITIONS VERIFICATION

No.	Infuser Serial Number	The infuser stops the infusion	The infuser stops the infusion	The infuser provides an alarm	The infuser stops the infusion	The infuser provides an alarm	The infuser stops the infusion	Sign Name/Date
		Step 1 Sub-step 8	Step 1 Sub-step 16	Step 2 Sub-step 10	Step 2 Sub-step 12	Step 2 Sub-step 17	Step 2 Sub-step 20	
		CADD-SYSDI-73 (condition)	CADD-SYSDI-73 (condition)	CADD-SYSDI-75 (condition)	CADD-SYSDI-73 (condition)	CADD-SYSDI-75 (condition)	CADD-SYSDI-73 (condition)	
1		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
2		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
3		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
4		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	

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		Step 1 Sub-step 8	Step 1 Sub-step 16	Step 2 Sub-step 10	Step 2 Sub-step 12	Step 2 Sub-step 17	Step 2 Sub-step 20	
		CADD-SYSDI-73 (condition)	CADD-SYSDI-73 (condition)	CADD-SYSDI-75 (condition)	CADD-SYSDI-73 (condition)	CADD-SYSDI-75 (condition)	CADD-SYSDI-73 (condition)	
5		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
6		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
7		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
8		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
9		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
10		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
11		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
12		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
13		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
14		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
15		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
16		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
17		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	

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		Step 1 Sub-step 8	Step 1 Sub-step 16	Step 2 Sub-step 10	Step 2 Sub-step 12	Step 2 Sub-step 17	Step 2 Sub-step 20	
		CADD-SYSDI-73 (condition)	CADD-SYSDI-73 (condition)	CADD-SYSDI-75 (condition)	CADD-SYSDI-73 (condition)	CADD-SYSDI-75 (condition)	CADD-SYSDI-73 (condition)	
18		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
19		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
20		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
21		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
822		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
23		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
24		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
25		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
26		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
27		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
28		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
29		Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	

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TABLE 2. REQUIREMENTS CADD-SYSDI-XX AND CADD-SYSDI-XX VERIFICATION

Requirement	Verification Steps	Result	Signature/Date
CADD-SYSDI-XX	Texto requerimiento	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	
CADD-HWDI-XXX-XX	Texto requerimiento	Pass <input type="checkbox"/> / Fail <input type="checkbox"/>	

Comments: _____

Test Reviewer	Print Name	Sign Name / Date

END OF DOCUMENT

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