Commissioning requirements for Trophon ultrasound disinfection system

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Commissioning Requirements for Trophon ultrasound probe disinfection System

Note: - the manufacturer should provide the Trust AE (DA) & AP (D) with all relevant type test data PRIOR to commissioning of below equipment. Type test data should conform to OEM recommendations (To be approved by Trust AE (DA) & AP (D))

Trophon ultrasound probe disinfection System

Installation, operational and performance qualification (OP, IQ & PQ) - Contractor / CP (D)

Confirmation shall be provided by the OEM that commissioning engineer[s] have received OEM certified training on the equipment to be installed. Certificates of competency to be provided along with commissioning report.

Test No:	Description of test	OEM Recommendations	Comments
	Installation qualification		
1	Record model number		
2	Record Serial number		
3	Record Software version		
4	Record printer serial number		
5	Provide technical documents		User documents and technical documents if applicable
6	Check storage conditions for consumables		
	Operational Qualification		
7	Electrical safety test to be carried out on site and prior to commencement of OQ & PQ tests		Calibration certificate for all electrical safety test equipment to be provided. Certified training certificates to be provided for person conducting electrical safety tests.
8	Visual inspection including lights, indicators and touchscreen displays		

Test No:	Description of test	OEM Recommendations	Comments
9	Initial setup		
10	AcuTrace check		(Only applicable to Trophon 2)
11	Disinfection cycle Automatic Control Test		Cycle pass indicated. Indicated temperatures within specification during cycle. Label printed and information correct.
12	Verification of calibration		Control and measured temperatures taken during load probe stage.
13	Fault test – door lock		
14	Fault test – power failure	Error code DFP07	
15	Fault test – nebuliser disk failure	Error code DFV0008	
16	Fault test – dose sensor failure	Error code DFV0004	
17	Fault test – rear chamber temperature sensor failure	Error code DFP02	
18	Check electronic data logging		
19	Label printout – failed cycles		
	Performance qualification		
20	Biological indicator test – cycle 1		Biological indicator test results to be included in report
21	Biological indicator test – cycle 2		
22	Biological indicator test – cycle 3		
24	Biological indicator test – positive control		
25	Residual safety test		
	Appendices		
	Electrical safety test report shall be included in report		
	Calibration certificates for all test equipment including electrical safety tester used to be included with commissioning report		
	Process printouts for all tests ran to be included with commissioning report		

	Electronic datalog for all test cycles to be included in the report		
	Biological indicator test results to be included in the report		
	Training certificates / competency evidence of commissioning engineer to be included in the report		
	User training to be completed and a list of trained users signed off to operate the Trophon to be completed.		
	Confirmation of Trust oversight responsibilities for commissioned equipment.		