
 edap tms Bringing New Horizons to Therapy	CHECKLIST	Réf : Version :	FMU-231 C
Focal One	PROBE INSTALLATION		

This document is linked with the Preventive Maintenance Instruction INS-367

1	PROBE INSTALLATION INFORMATION					
Call number		Date		Engineer		
DISTRIBUTOR INFORMATION						<input type="checkbox"/> NA
Name		Phone n°		Mail		
CUSTOMER INFORMATION						<input type="checkbox"/> NA (if mobile)
Installation Site						
Address				Country		


2	FOCAL ONE® IDENTIFICATION		
Focal One® S/N		Probe S/N	

12	PROBE PARAMETERS						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
12.1	Power connector VPC	Insert easily	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.1	Ultrasound connector	Pins good Lock smooth	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.1	Probe adaptation	Insert easily	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.1	Holding pin	Correctly locks	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.1	Luer connections	Connect easily	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.1	Image orientation	Upper part of the cell is on the right of the image			<input type="checkbox"/>	<input type="checkbox"/>	
12.1	Correspondence between software and data sheet	Same value	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Last maintenance date	-		<input type="checkbox"/>	-	-	
	Number of treatment since last maintenance	-		<input type="checkbox"/>	-	-	

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13	CALIBRATION PROBE						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
<p style="text-align: center;">WARNING</p> <ul style="list-style-type: none"> - Probe should be fully immersed into water and the temperature must be 13 ±1°C - No other object is in the test tank. - Transducer has to be moved away 10cm from test tank edge on transversal axis and in the middle of the tank on longitudinal axis. - Probe should not be aligned with the tank but with a slight angle to avoid any reflection back to the transducer. - Cooling has to be started with a complete FocalPak and balloon in good conditions. - No bubbles are present into and onto the balloon and into test tank. 							
13.1	Probe calibration	Done without red value Refl Rate lower than 5% on each channel and each focal	-	-	<input type="checkbox"/>	<input type="checkbox"/>	

14	POWER TEST PROBE						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
14.1		Firing number	Focal	Watts per channel	Total of watts	Total of Watts into "Pact_Load (W)" columns	
		1	32	1	16	_____	
		2	37	2	32	_____	
		3	42	3	48	_____	
		4	47	4	64	_____	
		5	52	5	80	_____	
		6	57	6	96	_____	
		7	62	7	112	_____	
		8	67	8	128	_____	
		9	72	9	144	_____	
		10	NAT	10	160	_____	
14.2	Shoots into tolerances	No red values	-	-	<input type="checkbox"/>	<input type="checkbox"/>	

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15	FUNCTIONAL TESTS PROBE						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
15.1	3D Measurements						
15.1.1	X axis real measure	-	X =	-	-	-	
	X axis software measure	< 2mm of real measure	X =	-	<input type="checkbox"/>	<input type="checkbox"/>	
15.1.2	Z axis real measure	-	Z =	-	-	-	
	Z axis software measure	< 2mm of real measure	Z =	-	<input type="checkbox"/>	<input type="checkbox"/>	
15.1.3	Y axis real measure	-	Y =	-	-	-	
	Y axis software measure	< 2mm of real measure	Y =	-	<input type="checkbox"/>	<input type="checkbox"/>	
15.2	Rectum detection functions						
15.2.1	Detection	Automatic	-	-	<input type="checkbox"/>	<input type="checkbox"/>	


16	TREATMENT SIMULATION PROBE						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
<p style="text-align: center;">WARNING</p> <ul style="list-style-type: none"> - Probe should be fully immersed into water and the temperature must be 13 ±1°C - No other object is in the test tank. - Transducer has to be moved away 10cm from test tank edge on transversal axis and in the middle of the tank on longitudinal axis. - Probe should not be aligned with the tank but with a slight angle to avoid any reflection back to the transducer. - Cooling has to be started with a complete FocalPak and balloon in good conditions. - No bubbles are present into and onto the balloon and into test tank. 							
16.1	Initialization	Without error message	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
		Motors centering done	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
16.2	For the 4 blocks	Treatment area is correctly defined	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
		Lesions are correctly displayed	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
		Endo-rectal probe moves to the next slice	-	-	<input type="checkbox"/>	<input type="checkbox"/>	

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16	TREATMENT SIMULATION PROBE						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
16.2	For the 4 blocks	Localization process is successfully completed	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
		Endo-rectal probe moves from lesion to lesion	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
		Treatment area is successfully completed	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Treatment duration		-	-	-	-	

17	FINAL CHECKING						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
17.2	Files backup and retrieve	Copied	-	-	<input type="checkbox"/>	<input type="checkbox"/>	

19	COMMENTS / DOCUMENTS	
List documents associated with this checklist		
Title	Description	
Add comments if necessary		

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20	APPROVALS		
Send by mail all documents completed and files saved (ZIP format) to your local referent technical engineer and to ccc@edap-tms.com			
Function	Name	Date	Signature
Support Engineer			
Customer			
Service Manager			