
 edap tms Bringing New Horizons to Therapy	CHECKLIST	Réf : Version :	FMU-431 H
Focal One	PREVENTIVE MAINTENANCE		

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


1	PREVENTIVE MAINTENANCE 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				Installation date		
Probe 1 S/N			Probe 2 S/N			
						<input type="checkbox"/> NA
2.1	Subassemblies serial numbers and versions					
	Item	Reference	S/N		Version	
OR	IPO Computer (Global version)	(R) 236659		<input type="checkbox"/> NA if Ecrin		<input type="checkbox"/> NA if Ecrin
	Ecrin Computer (Global version)	(R) 233176		<input type="checkbox"/> NA if IPO		<input type="checkbox"/> NA if IPO
	MEP board (MEP_FOne)	(R) 235403				
	Extension board	(R) 228038			NA	
	MOT Probe Motorisation	(R) 901504				
	Cooling	(R) 901560				
	Amplifier	(R) 233360				
OR	Ultraview scanner	(R) 230885		<input type="checkbox"/> NA if EB		<input type="checkbox"/> NA if EB
	EB2300 scanner + Windows version	(R) 236150		<input type="checkbox"/> NA if UV		<input type="checkbox"/> NA if UV


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3	CONTROL TOOLS IDENTIFICATION			
Test Equipment	S/N	Validity	Comments	
Voltmeter				
Thermometer				
Inclinometer				
Current clamp				
Load bench		NA		


4	SITE INSTALLATION							<input type="checkbox"/> NA
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments	
4.1	Conform to installation recommendations (SPE-089)	-	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4.2	UPS is present. If YES, write its maxi power	-		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4.3	Circuit breaker (Type D or slow trip) is present. Write the value	-		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4.4	Earth leakage circuit breaker is present. Write the value	-		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4.5	Fuses							
4.5.1	If Main power supply = 100 / 120 VAC Check fuses 1, 2, 3 and 4	F1 = 20A	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
		F2 = 20A			<input type="checkbox"/>	<input type="checkbox"/>		
		F3 = 8A			<input type="checkbox"/>	<input type="checkbox"/>		
		F4 = 8A			<input type="checkbox"/>	<input type="checkbox"/>		
		F13 = 6.33 A			<input type="checkbox"/>	<input type="checkbox"/>		
4.5.2	If Main power supply = 200 / 230 VAC Check fuses 1, 2, 3 and 4	F1 = 10A	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
		F2 = 10A			<input type="checkbox"/>	<input type="checkbox"/>		
		F3 = 8A			<input type="checkbox"/>	<input type="checkbox"/>		
		F4 = 8A			<input type="checkbox"/>	<input type="checkbox"/>		
		F13 = 3.15 A			<input type="checkbox"/>	<input type="checkbox"/>		

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5	GENERAL AND MECHANICAL						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
5.1	Main power cable and connectors	Good condition	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
5.2	Main screen movement	Don't move itself and no noise	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
5.3	Secondary screen movement	Support 70° angles and no noise	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
5.4	Tablet displacement Locking system	No excessive noise Functional in release or retracted position	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
5.5	Ablasonic holder tightening	Stay in place at the vertical	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
5.6	Positions of breaking pedal	Three position functional	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
5.7	Hexagon's socket set screws	Tightened	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
5.8	Cable wipers	Set at 4mm from the ground (NA if mobile)	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.9	Labels	Good condition	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
5.10	Mönninghoff arm's locking system	No freeplay	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.11	Chassis fans	No noise	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
5.12	Accessories						
	Leg holder	Good condition	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Transport carriage	Good condition NA if not present	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Covers	Good condition	-		<input type="checkbox"/>	<input type="checkbox"/>	
5.13	Maintenance sticker	Filled NA if not in France	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	


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6	FOCAL ONE® SWITCH ON						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
6.1	Internal and external blue LEDs	Lights on	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
6.2	Switch ON Focal One®	Auto start run according to the version	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
6.3	Check power supply before F1 and after F2	Main power \pm 10%		-	<input type="checkbox"/>	<input type="checkbox"/>	
	Check power supply before F3 and after F4	217V – 253V			<input type="checkbox"/>	<input type="checkbox"/>	
	Check MEP power supply	22.8V – 25.2V			<input type="checkbox"/>	<input type="checkbox"/>	
	Check 12V power supply	11.4V – 12.6V			<input type="checkbox"/>	<input type="checkbox"/>	
6.4	LED tape	Colors change and all parts are lit	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
6.5	Patient movement detector	Stay in the same position	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
		Blue light and orange light indicators are lit			<input type="checkbox"/>	<input type="checkbox"/>	
6.6	External USB connectors	4 USB connectors works	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
6.7	Touch screen	Mouse moving	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
6.8	« Get init Status »	Status « OK »	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
6.9	MEP Analog input : “In7 - 3.3 Volts Power Supply”	3.13V – 3.47V		-	<input type="checkbox"/>	<input type="checkbox"/>	
	MEP Analog input : “In8 - 24 Volts Power Supply”	22.8V – 25.2V			<input type="checkbox"/>	<input type="checkbox"/>	


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6	FOCAL ONE® SWITCH ON						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
6.10	« Error » file	-	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
6.11	Emergency stop functions	Computer, US scanner and screens are ON Manual movments are unlocked Probe support keypad is OFF Manual movment locking after release	-		<input type="checkbox"/>	<input type="checkbox"/>	


7	COMPUTER						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
7.1	Image display	Centered and scaled	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
7.2	Free space on HDD	>10GB	C :	-	<input type="checkbox"/>	<input type="checkbox"/>	
			D :				
7.3	Number of patient treated since last maintenance	NA if installation		<input type="checkbox"/>	-	-	
7.4	Date of last maintenance	NA if installation		<input type="checkbox"/>	-	-	
7.5	Defrag analysis	NA if not necessary	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7.6	Date and time	Similar to local	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
7.7	Software versions	Status OK	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
7.8	Back up battery	>2.8Vdc NA if IPO PC		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7.9	Computer dust filter	Clean	-				

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8 PROBE HOLDER							
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
8.1	All axis						
8.1.1	Status after centering	« NoMotError »	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
8.1.2	Values of « Pos Mot »	0mm ± 0.2mm	X =	-	<input type="checkbox"/>	<input type="checkbox"/>	
			Y =	<input type="checkbox"/>	<input type="checkbox"/>		
			Z =	<input type="checkbox"/>	<input type="checkbox"/>		
		0° ± 1°	Θ =	<input type="checkbox"/>	<input type="checkbox"/>		
8.1.3	Keypad buttons	4 buttons are functional	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
8.1.4	Theta fan	Functional	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
8.2	X axis (longitudinal)						
	Record software value (1) for -50mm	Measure real value (2) for -50mm	Record software value (3) for +50mm	Measure real value (4) for +50mm			
	Calculate Software value : 1 + 3	100mm ± 2mm		-	<input type="checkbox"/>	<input type="checkbox"/>	
	Calculate measured value : 4 - 2	100mm ± 2mm		-	<input type="checkbox"/>	<input type="checkbox"/>	
8.3	Y axis (transversal)						
	Record software value (1) for -25mm	Measure real value (2) for -25mm	Record software value (3) for +25mm	Measure real value (4) for +25mm			
	Calculate Software value : 1 + 3	50mm ± 2mm		-	<input type="checkbox"/>	<input type="checkbox"/>	
	Calculate measured value : 2 - 4	50mm ± 2mm		-	<input type="checkbox"/>	<input type="checkbox"/>	

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N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments	
8.4	Z axis (actuator)							
	Record software value (1) for -40mm	Measure real value (2) for -40mm		Record software value (3) for +40mm			Measure real value (4) for +40mm	
	Calculate Software value : 1 + 3	80mm ± 2mm		-	<input type="checkbox"/>	<input type="checkbox"/>		
	Calculate measured value : 4 - 2	80mm ± 2mm		-	<input type="checkbox"/>	<input type="checkbox"/>		
8.5	Θ axis							
	Record software value (1) for -70°	Measure real value (2) for -70°		Record software value (3) for +70°			Measure real value (4) for +70°	
	Calculate Software value : 1 + 3	140° ± 2°		-	<input type="checkbox"/>	<input type="checkbox"/>		
	Calculate measured value : 4 + 2	140° ± 2°		-	<input type="checkbox"/>	<input type="checkbox"/>		
8.6	Manual Movements and panels collision check							
8.6.1	Probe holder leveled	0° ± 2° to the floor on X and Y axis	X = Y =	-	<input type="checkbox"/>	<input type="checkbox"/>		
8.6.2	Manual displacements	No hard point	-	-	<input type="checkbox"/>	<input type="checkbox"/>		
8.6.3	Displacement front right	No interference between motor board cables and frame	-	-	<input type="checkbox"/>	<input type="checkbox"/>		
	Displacement front left		-	-	<input type="checkbox"/>	<input type="checkbox"/>		
	Displacement back left	No collision with panel	-	-	<input type="checkbox"/>	<input type="checkbox"/>		
	Displacement back right	No friction with top panel	-	-	<input type="checkbox"/>	<input type="checkbox"/>		


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8	PROBE HOLDER						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
8.7	Random movements						
8.7.1	Mechanical origin	No motors errors	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Backlash value for X, Y and θ	<0.3mm	X =	-	<input type="checkbox"/>	<input type="checkbox"/>	
		<0.3mm	Y =		<input type="checkbox"/>	<input type="checkbox"/>	
		<0,6°	Θ =		<input type="checkbox"/>	<input type="checkbox"/>	
8.7.2	Time start	-		-	-	-	
	Time stop	-		-	-	-	
	Number of movements	-		-	-	-	
8.7.3	Analyze Random file	No error during displacement	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
8.7.4	Mechanical origin	No motors errors	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
8.7.5	Backlash value for X, Y and θ	<0.3mm	X =	-	<input type="checkbox"/>	<input type="checkbox"/>	
		<0.3mm	Y =		<input type="checkbox"/>	<input type="checkbox"/>	
		<0,6°	Θ =		<input type="checkbox"/>	<input type="checkbox"/>	
	Difference between before and after random	<0.3mm	X =		<input type="checkbox"/>	<input type="checkbox"/>	
		<0.3mm	Y =		<input type="checkbox"/>	<input type="checkbox"/>	
		<0,6°	Θ =		<input type="checkbox"/>	<input type="checkbox"/>	

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9	COOLING SYSTEM						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
9.1	Peltier consumption during regulation	27-38A		-	<input type="checkbox"/>	<input type="checkbox"/>	
9.2	Fans	No noise Air flow from user to patient	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
9.3	Pump	Turns clockwise, no noise and efficient No backlash on opening	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
9.4	Regulation	Temperature of PT100 1 & 2 decrease	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
		Temperature close to setpoint					
9.5	Peltier consumption between regulation	<0.2A		-	<input type="checkbox"/>	<input type="checkbox"/>	
9.6	Difference between the two PT100	<2°C		-	<input type="checkbox"/>	<input type="checkbox"/>	
9.7	Difference between thermometer and mean	<4.5°C		-	<input type="checkbox"/>	<input type="checkbox"/>	

10	ULTRASOUND						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
10.1	BK checklist (next page)	Completed	-	-	<input type="checkbox"/>	<input type="checkbox"/>	

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Customer Information :			
Name :	See part 1	Department :	See part 1
Address :	See part 1		

Scanner information :					
Type :	See part 2	Serial Number :	See part 2	SW Version :	NA
Customer Comments :	NA				
Installation Date :	See part 2	Previous Test Date :	NA	Service Contract Number :	NA

Mechanical Diagnostics	Pass	Replaced now	Replace next time	Adjusted	Cleaned	Comments :
Visual inspection:	NA			NA	NA	NA
Trackball friction:	NA	NA	NA	NA	NA	NA
Height Adjustment:	NA			NA		NA
Wheel movement:	NA	NA	NA		NA	NA
Monitor movement:	NA	NA	NA	NA	NA	NA
Cables:						
Connectors:						
Keyboard:	NA	NA	NA		NA	NA

Hardware Diagnostics	Pass	Replaced now	Replace next time	Adjusted	Cleaned	Comments :
Fans :						
Display :						
Board :						
Power supply :						

Software Diagnostics	Pass	Replaced now	Replace next time	Adjusted	Values	Comments :
Boot up time						
Monitor Checking :	NA	NA	NA	NA		NA
B-Mode :						
M-Mode :	NA					NA
Audio / Spectral Doppler	NA					NA
CFM	NA					NA
3D	NA					NA
Labels	NA					NA
Measurement	NA					NA
Touch Screen sensitivity	NA			NA		NA
Battery Support	NA	NA	NA	NA		NA
Image Storage	NA			NA		NA
Remaining disk space						
DVD / CD	NA	NA			NA	NA

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Connectivity	Pass	Adjusted	Comments :
External monitor	NA	NA	NA
Picture in Picture	NA	NA	NA
Video input	NA	NA	NA
Video output	NA	NA	NA
Sony printing	NA	NA	NA
Office printing	NA	NA	NA
Remote control	NA	NA	NA

Connectivity	Pass	Adjusted	Comments :
Dicom	NA	NA	NA
Variseed / Vitesse	NA	NA	NA
Histoscanning	NA	NA	NA
Dornier	NA	NA	NA
Network Drive	NA	NA	NA

Transducer Type & Serial number.	Visual Check		Functional Test*		Button Test		Pressure Test		Comments :
See part 1 and 12	<input type="checkbox"/> P	<input type="checkbox"/> F	<input type="checkbox"/> P	<input type="checkbox"/> F	<input type="checkbox"/> P	<input type="checkbox"/> F	<input type="checkbox"/> P	<input type="checkbox"/> F	NA
NA	<input type="checkbox"/> P	<input type="checkbox"/> F	<input type="checkbox"/> P	<input type="checkbox"/> F	<input type="checkbox"/> P	<input type="checkbox"/> F	<input type="checkbox"/> P	<input type="checkbox"/> F	NA
NA	<input type="checkbox"/> P	<input type="checkbox"/> F	<input type="checkbox"/> P	<input type="checkbox"/> F	<input type="checkbox"/> P	<input type="checkbox"/> F	<input type="checkbox"/> P	<input type="checkbox"/> F	NA
NA	<input type="checkbox"/> P	<input type="checkbox"/> F	<input type="checkbox"/> P	<input type="checkbox"/> F	<input type="checkbox"/> P	<input type="checkbox"/> F	<input type="checkbox"/> P	<input type="checkbox"/> F	NA
NA	<input type="checkbox"/> P	<input type="checkbox"/> F	<input type="checkbox"/> P	<input type="checkbox"/> F	<input type="checkbox"/> P	<input type="checkbox"/> F	<input type="checkbox"/> P	<input type="checkbox"/> F	NA


*B-mode, M-Mode, Doppler/power mode, and crystal movement when available.

ConnectivityElectrical Safety Test Record			
Performed by:	See EST checklist	Performed date:	See EST checklist
Comments:	See EST checklist		


Software handling	Done	Comments :
Check Hard disk	NA	NA
Defragment Hard disk	NA	NA
Check Log files	NA	NA
Clean up	NA	NA

Upgrades	Done	New versions				Comments :
Check Hard diskHotline upgrades	NA	NA	NA	NA	NA	NA
Software patches	NA	NA	NA	NA	NA	NA
Software upgrades	NA	NA				NA

Overall					
Performed by:	See part 1				Signature: See part 20
Date:	See part 1	Start Time:	NA	End time:	NA
Comments:	NA				


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10	ULTRASOUND						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
10.2	Offset	-	X =	-	-	-	
		-	Y =				
	Size	-	X =	-	-	-	
		-	Y =				
	Active area	Ticked	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Yellow box	Present	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Exclusion circle coordinates	-	X =	-	-	-	
		-	Y =				
		-	Radius =				
	IP adress	169.254.42.25	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Port number	7915	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Delay	OFF : 30s	OFF :	-	<input type="checkbox"/>	<input type="checkbox"/>	
		ON : 100s	ON :		<input type="checkbox"/>	<input type="checkbox"/>	
10.3	Date and time	Correct	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Mi	Ultraview: 1.39/1.50 EB2300 : 1.2/1.2	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	TIS	0.3/4.0Hz	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Gain	50%	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Dyn Range	62dB	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Pers	Ultraview : 1 EB2300 : NA	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Resolution	1 focal point at 25mm	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Imaging cell	Ultraview: 6030 EB2300 : X12C3E	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Frequency	7.5MHz	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Depth	7.8cm or 8cm	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
	Size	Version F : 75% Version G : 100%		-	<input type="checkbox"/>	<input type="checkbox"/>	

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11	AMPLIFIER						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
11.1	Serial number			-	<input type="checkbox"/>	<input type="checkbox"/>	
	COM number			-	<input type="checkbox"/>	<input type="checkbox"/>	
11.2	Wires	Connected			<input type="checkbox"/>	<input type="checkbox"/>	

12	PROBE N°1						
12.1	Probe serial number						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
12.2	Power connector VPC	Insert easily	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.3	Ultrasound connector	Pins good Lock smooth	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.4	Probe adaptation	Insert easily	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.5	Holding pin	Correctly locks	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.6	Luer connections	Connect easily	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.7	Image orientation	Upper part of the cell is on the right of the image			<input type="checkbox"/>	<input type="checkbox"/>	
12.8	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°1
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WARNING

- Probe should be fully immersed into water and the temperature must be $13 \pm 1^{\circ}\text{C}$
- 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.

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

 edap tms Bringing New Horizons to Therapy	CHECKLIST	Réf : Version :	FMU-431 H
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15	FUNCTIONAL TESTS PROBE N°1						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
15.1	3D Measurments						
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"/>	
15.2.2	Transverse correction	Move between 1 and 4mm Treatment doesn't stop	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
15.2.3	Error message	When >4mm	-	-	<input type="checkbox"/>	<input type="checkbox"/>	

16	TREATMENT SIMULATION PROBE N°1						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
WARNING <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"/>	

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16	TREATMENT SIMULATION PROBE N°1						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
16.2	4 first blocks and 4 last 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"/>	
	4 first blocks and 4 last 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			-	-	-	

12	PROBE N°2						<input type="checkbox"/> NA
12.1	Probe serial number						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
12.2	Power connector VPC	Insert easily	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.3	Ultrasound connector	Pins good Lock smooth	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.4	Probe adaptation	Insert easily	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.5	Holding pin	Correctly locks	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.6	Luer connections	Connect easily	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.7	Image orientation	Upper part of the cell is on the right of the image	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
12.8	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°2						<input type="checkbox"/> NA
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N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
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WARNING

- Probe should be fully immersed into water and the temperature must be $13 \pm 1^{\circ}\text{C}$
- 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"/>	
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14	POWER TEST PROBE N°2						<input type="checkbox"/> NA
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N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
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14.1	<table border="1"> <tr> <th>Firing number</th> <th>Focal</th> <th>Watts per channel</th> <th>Total of watts</th> <th>Total of Watts into "Pact_Load (W)" columns</th> </tr> <tr><td>1</td><td>32</td><td>1</td><td>16</td><td>_____</td></tr> <tr><td>2</td><td>37</td><td>2</td><td>32</td><td>_____</td></tr> <tr><td>3</td><td>42</td><td>3</td><td>48</td><td>_____</td></tr> <tr><td>4</td><td>47</td><td>4</td><td>64</td><td>_____</td></tr> <tr><td>5</td><td>52</td><td>5</td><td>80</td><td>_____</td></tr> <tr><td>6</td><td>57</td><td>6</td><td>96</td><td>_____</td></tr> <tr><td>7</td><td>62</td><td>7</td><td>112</td><td>_____</td></tr> <tr><td>8</td><td>67</td><td>8</td><td>128</td><td>_____</td></tr> <tr><td>9</td><td>72</td><td>9</td><td>144</td><td>_____</td></tr> <tr><td>10</td><td>NAT</td><td>10</td><td>160</td><td>_____</td></tr> </table>					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	_____
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14.2	Shoots are into tolerances	No red values	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
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15	FUNCTIONAL TESTS PROBE N°2						<input type="checkbox"/> NA
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"/>	
15.2.2	Transverse correction	Move between 1 and 4mm Treatment doesn't stop	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
15.2.3	Error message	When >4mm	-	-	<input type="checkbox"/>	<input type="checkbox"/>	

16	TREATMENT SIMULATION PROBE N°2						<input type="checkbox"/> NA
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"/>	

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16	TREATMENT SIMULATION PROBE N°2						<input type="checkbox"/> NA
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
16.2	Firing test for 4 first blocks and 4 last 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"/>	
		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
17.1	Print treatment report	Functional	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
17.2	Files backup and retrieve	Copied	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
17.3	Wheels	Don't touch panels or chassis	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
17.4	Panels	In good condition Easily removed	-	-	<input type="checkbox"/>	<input type="checkbox"/>	
17.5	Panels ground cables	Firmly attached NA for system with plastic panels	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

18	ELECTRICAL SAFETY TEST						
N°	Control	Expected Results	Observed Results	NA	Pass	Fail	Comments
18.1	FMU-224	Checklist completed and compliant	-	-	<input type="checkbox"/>	<input type="checkbox"/>	

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

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			