

System S/N:	<u>FO 023</u>	Probe S/N:	<u>UV 108</u>
Installation site:	<u>CLINICA SANTA MARIA</u>	Call or service report #:	_____ <input type="checkbox"/> NA

If needed, please refer to the procedure INS-367 for more details.

1. PROBE PARAMETERS				
N°S	CONTROL	PASS	FAIL	COMMENTS
12.2	Power connector 'VPC' inserts easily in the socket. Lock is smooth and easy.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.3	Ultrasound connector inserts easily in the socket. Lock is smooth and easy.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.4	Treatment probe adapts correctly without forcing onto its support.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.5	Holding pin correctly locks the probe each time.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.6	Focal Pak connectors are easy to connect.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.7	Go to technical file, all values between software and data sheet are the same.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
WARNING: The probe temperature must be at 13°C (+/- 1°C) during the whole calibration process.				
12.14	Probe is correctly calibrated.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

2. POWER																																																											
N°S	CONTROL	PASS	FAIL	COMMENTS																																																							
13.6	Go to Maintenance, Firings and Power tab. Click on Open trajectory and select PM trajectory.prm file. Click on Use Probe Power coeffs and then, click on Send trajectory to generator . Click on Start Cooling and once the probe temperature is lower than 13.5°, Execute the trajectory . Once the trajectory is complete, fill the following table:																																																										
	<table border="1"> <thead> <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> </thead> <tbody> <tr><td>1</td><td>32</td><td>1</td><td>16</td><td><u>16.09</u></td></tr> <tr><td>2</td><td>37</td><td>2</td><td>32</td><td><u>32.01</u></td></tr> <tr><td>3</td><td>42</td><td>3</td><td>48</td><td><u>48.02</u></td></tr> <tr><td>4</td><td>47</td><td>4</td><td>64</td><td><u>64.52</u></td></tr> <tr><td>5</td><td>52</td><td>5</td><td>80</td><td><u>79.81</u></td></tr> <tr><td>6</td><td>57</td><td>6</td><td>96</td><td><u>95.03</u></td></tr> <tr><td>7</td><td>62</td><td>7</td><td>112</td><td><u>111.82</u></td></tr> <tr><td>8</td><td>67</td><td>8</td><td>128</td><td><u>128.08</u></td></tr> <tr><td>9</td><td>72</td><td>9</td><td>144</td><td><u>144.39</u></td></tr> <tr><td>10</td><td>NAT</td><td>10</td><td>160</td><td><u>159.22</u></td></tr> </tbody> </table>				Firing number	Focal	Watts per channel	Total of watts	Total of Watts into "Pact_Load (W)" columns	1	32	1	16	<u>16.09</u>	2	37	2	32	<u>32.01</u>	3	42	3	48	<u>48.02</u>	4	47	4	64	<u>64.52</u>	5	52	5	80	<u>79.81</u>	6	57	6	96	<u>95.03</u>	7	62	7	112	<u>111.82</u>	8	67	8	128	<u>128.08</u>	9	72	9	144	<u>144.39</u>	10	NAT	10	160	<u>159.22</u>
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13.8	Shots are within tolerance.	<input checked="" type="checkbox"/>	<input type="checkbox"/>																																																								

3. 3D MEASUREMENT

Start FOneTherapy software. Connect to EDAP hospital.

Use protocol 91 and FocalPak number 223Y T5N5.

Use the circle tool with lead balls and membrane. When U/S image is available, do all the measurement.

N°S	CONTROL	VALUE	PASS	FAIL	COMMENTS
14.1	X real (apex – base) X measured	34.6 mm 33.9 mm (<2 mm)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
14.2	Y real (anterio – posterior) Y measured	64.2 mm 64.5 mm (<2 mm)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
14.3	Z real (left – right) Z measured	42 mm 42.1 mm (<2 mm)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
14.4	Software detects rectum automatically.		<input checked="" type="checkbox"/>	<input type="checkbox"/>	

4. TREATMENT SIMULATION

WARNING: The probe temperature must be less than 13.5°C during the whole treatment simulation.

N°S	CONTROL	PASS	FAIL	COMMENTS
Area 1 Block 1 slices 1 to 5: 12 lesions, focal 32 & 37 only. Area 1 Block 2 slices 6 to 10: 12 lesions, focal 32, 37, 42 & 47 only.				
15.4	Treatment area is correctly defined.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
15.5	Lesions are correctly displayed.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
15.6	Endo-rectal probe moves to the next slice.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
15.7	Localization process is successfully completed.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
15.8	Endo-rectal probe moves from lesion to lesion.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
15.9	Treatment area is successfully completed.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Area 2 Block 1 slices 1 to 5: 12 lesions, focal 32, 37, 42, 47, 52 & 57 only. Area 2 Block 2 slices 6 to 10: 12 lesions, all focal points.				
15.10	Treatment area is correctly defined.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
15.11	Lesions are correctly displayed.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
15.12	Endo-rectal probe moves to the next slice.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
15.13	Localization process is successfully completed.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
15.14	Endo-rectal probe moves from lesion to lesion.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
15.15	Treatment area is successfully completed.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

Date: 1/4/2022	Date: 1/4/2022	Date: 01/04/2022
Signature: 	Signature: 	Signature: 
Cristian López Jil Rut: 9.876.831-9 Supervisor de Radiación Clínica Santa María	FSE	SERVICE MANAGER

Once complete, please send this document to ccc@edap-tms.com
 with all documents and data which might be helpful:
all txt calibration files + ProbeCalibListing.txt + Tech File.