edap tms
Bringing New Horizons to Therapy

TMS 511996 A
Focal One probe installation checklist

Focal·One

System S/N:	FO 023	Probe S/N:	UV 149
Installation site:	CLINICA SANTA MARIA	Call or service report #:	_____ ☐ NA

If needed, please refer to the procedure TMS 511991 for more details.

1. PROBE PARAMETERS.

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

2. POWER

N°§	CONTROL	PASS	FAIL	COMMENTS
13.5	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:

Firing number	Focal	Watts per channel	Total of watts	Total of Watts into "Pact_Load (W)" columns
1	32	1	16	16.23
2	37	2	32	32.05
3	42	3	48	47.43
4	47	4	64	64.19
5	52	5	80	79.62
6	57	6	96	95.46
7	62	7	112	111.34
8	67	8	128	129.01
9	72	9	144	146.36
10	NAT	10	160	160.03

13.6	Shots are within tolerance.	☑	☐	

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°§	CONTROL	VALUE	PASS	FAIL	COMMENTS
14.1	X real (apex – base) X measured	44/6 mm 33 mm(<1 mm)	☐	☐	
14.2	Y real (anterio – posterior) Y measured	624 mm 624 mm(<1 mm)	☐	☐	
14.3	Z real (left – right) Z measured	42 mm 41.5 mm(<1 mm)	☐	☐	
14.4	Software detects rectum automatically.		☑	☐	

4. TREATMENT SIMULATION

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

N°§	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.	☑	☐	
15.5	Lesions are correctly displayed.	☑	☐	
15.6	Endo-rectal probe moves to the next slice.	☑	☐	
15.7	Localization process is successfully completed.	☑	☐	
15.8	Endo-rectal probe moves from lesion to lesion.	☑	☐	
15.9	Treatment area is successfully completed.	☑	☐	
	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.	☑	☐	
15.11	Lesions are correctly displayed.	☑	☐	
15.12	Endo-rectal probe moves to the next slice.	☑	☐	
15.13	Localization process is successfully completed.	☑	☐	
15.14	Endo-rectal probe moves from lesion to lesion.	☑	☐	
15.15	Treatment area is successfully completed.	☑	☐	

Date: 24/09/2021	Date: 24/9/2021	Date: 24.09.2021
Signature:	Signature:	Signature:
CUSTOMER Cristina Lopez	FSE Jordi Fernandez	SERVICE MANAGER David Calvo

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.