



# Quality Management System Instruction Form

Cook® Medical Incorporated

Title: **Laser Service Report**

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Original Date: 30Sep2016

Version Number: 4

Effective Date: 18Aug2017

CR Number: CMI-17-187

Checked By: AB 16Aug2017

Laser Serial Number: LHF1312-1215

Date: 06/11/18

Please fill out as much information as possible in the form below.

**General Information and Background**

Laser System Type: ☐ Odyssey ☒ H-30

Laser Owner (Hospital): CLC

Under Warranty? ☐ Yes ☐ No

Customer Number:

Phone Number:

Contact Person:

Technician: Arana Yara

Email:

When was the laser last serviced?

By whom was the laser last serviced?

Under Service Contract? ☐ Yes ☐ No

Current Service Location:

Installation Date:

Plug Type:

Any unusual environmental condition? ☐ Yes ☒ No If yes, explain:

Any information to reasonably suggest laser caused or contributed to illness or injury to patient or user? ☐ Yes ☒ No If yes, explain:

Was laser used for treatment or diagnosis? ☐ Yes ☒ No

Additional comments: (Note any recent issues and their resolutions.) Note: Only enter information if additional information is applicable, otherwise leave blank.

If this Section does not apply check box ☐

**Laser Use Information at Occurrence**

Pulse Width Mode: ☐ Short ☒ Long

Repetition Rate (Hz): ☐ 5 ☐ 8 ☐ 10 ☐ 12 ☐ 15 ☒ 20

Pulse Energy: 0.5 J

Fiber Size(s) Used (µm):

Total Energy Delivered:

Total Time:

☐ 150 ☐ 200 ☐ 273 ☐ 365 ☐ 550 ☐ 940

In what operational state(s) was the laser when the issue occurred?

☒ Standby ☐ Transition ☐ Ready ☐ Preparatory ☐ Lasing

If this Section does not apply check box ☐

Note any error code(s) that was present:


MPS

**General Description of Issue:**

Device operative

**Work Performed (Include Troubleshooting)**

Calibration

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List Calibrated Equipment, Tools or Test Equipment Used

	PART NUMBER/CPN	I.D. NUMBER	CALIBRATION DUE DATE
+	Gentec "Maestro" Power Meter	242057	2017
	Gentec "Maestro" Target	224533	2017
	BC Medical SA-2001 Safety Analyzer		
-			

Service Manual Revision Number: \_\_\_\_\_

Were replacement parts used? ☐ Yes ☒ No

	PART NUMBER/CPN	LOT NUMBER	DESCRIPTION
+			
-			

Defective Part Disposition: Disposed of \_\_\_\_\_

Returned to COOK Capital Equipment \_\_\_\_\_

Final Resolution

equipo operativo 100%.  
 SE CALIBRA PARA descartar error en herramienta.  
 Error indicado NO fue posible Replicarlo


Cook welcomes your feedback at [capitalservice@cookmedical.com](mailto:capitalservice@cookmedical.com)

If this Section does not apply check box ☒

Calibration

VALUE	INITIAL VALUE	E1	E2	FINAL VALUE	E1	E2
PHD OFFSET (10Hz, 0.5J)		MIN:	MAX:		MIN:	MAX:
PHD POTENTIOMETER/COARSE (10HZ, 3.0J)		INT:	EXT:		INT:	EXT:
PHD FULLSCALE/FINE (10 HZ, 3.0J)		INT:	EXT:		INT:	EXT:
PHD SHUTTER CLOSED		OPEN:	CLOSED:		OPEN:	CLOSED:

Notes (calibration, tuning, centration, alignment, etc.) Note: Only enter information if additional information is applicable, otherwise leave blank.

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PHD Calibration Verification (data can be replaced with external data sheets, if desired)

CAL	SHORT PW				LONG PW			
	PHD ADJ		E <sub>MIN</sub>	E <sub>MAX</sub>	PHD ADJ		E <sub>MIN</sub>	E <sub>MAX</sub>
	LOW	HIGH			LOW	HIGH		
5 Hz	-17	24	0.5	3.5	-22	21	0.5	3.0
8 Hz	-25	21	0.5	3.0	-21	17	0.5	2.5
10 Hz	-20		0.5	3.0	-16	20	0.5	2.5
12 Hz	-12	-3	0.5	2.5	-17	14	0.5	2.0
15 Hz	-18	-16	0.5	1.5	-16	-11	0.5	1.5
20 Hz	-4	-12	0.5		-22	-22	0.5	

#### Final Steps

Attach pictures of DAC values and plot from CAL menu, if voltage values changed.

If this Section does not apply check box ☐

Short PW Calibration Table (record average output values in User mode) with a 550  $\mu$  fiber.

ENERGY	TOLERANCE	REP. RATE: 5 Hz	8 Hz	10 Hz	12 Hz	15 Hz	20 Hz
0.5 J	0.45 - 0.55	0.47	0.49	0.50	0.49	0.51	0.45
0.6 J	0.54 - 0.66						
0.7 J	0.63 - 0.77						
0.8 J	0.72 - 0.88						
1.0 J	0.90 - 1.10					0.98	
1.2 J	1.08 - 1.32						
1.5 J	1.35 - 1.65				1.40	1.42	
2.0 J	1.80 - 2.20	1.71	1.74	1.92			
2.5 J	2.25 - 2.75				2.12		
3.0 J	2.70 - 3.30		2.17	2.50			
3.5 J	3.15 - 3.85	2.52					

If this Section does not apply check box ☐

Long PW Calibration Table (record average output values in User mode) with a 550  $\mu$  fiber.

ENERGY	TOLERANCE	REP. RATE: 5 Hz	8 Hz	10 Hz	12 Hz	15 Hz	20 Hz
0.5 J	0.45 - 0.55	0.48	0.49	0.50	0.49	0.47	0.46
0.6 J	0.54 - 0.66						
0.7 J	0.63 - 0.77						
0.8 J	0.72 - 0.88						
1.0 J	0.90 - 1.10					0.91	
1.2 J	1.08 - 1.32				1.04		
1.5 J	1.35 - 1.65		1.35	1.23		1.30	
2.0 J	1.80 - 2.20	1.50			1.48		
2.5 J	2.25 - 2.75		1.87	1.81			
3.0 J	2.70 - 3.30	2.22					



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ELECTRICAL SAFETY TEST		UNITS	TOLERANCE	MEASURED	PASS	FAIL
Ground Resistance		OHMS	$\leq 0.27$			
Unit OFF	Forward Leakage	NA $\mu$ A	$\leq 450$			
	Reverse Leakage	NA $\mu$ A	$\leq 450$			
Unit ON	Forward Leakage	NA $\mu$ A	$\leq 450$			
	Reverse Leakage	NA $\mu$ A	$\leq 450$			


**Note: If any item of Electrical Safety fail, contact service department immediately. Do not put H30 System back into operation mode. System may need to be returned to service department for service.**

Form Submitted By:

Andres Yañez

Date:

06/11/18

  
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06/11/18

