



Quality Management System Instruction Form

Cook® Medical Incorporated

Title:

Laser Service Report

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Document Number: QMSI18_09-F06

Original Date: 30Sep2016

Version Number: 4

Effective Date: 18Aug2017

CR Number: CMI-17-187

Checked By: AB 16Aug2017

Laser Serial Number: CHT 02050217

Date: 06/11/2017

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):

Under Warranty? ☐ Yes ☐ No

Customer Number:

Phone Number:

Contact Person: Amos Yavel

Technician: Amos Yavel

Email: Amos.Yavel@CookMedical.com

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:

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:

General Description of Issue:

Work Performed (Include Troubleshooting)

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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		
	Gentec "Maestro" Target		
	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

Cook welcomes your feedback at 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 _{MIN}	E _{MAX}	PHD ADJ		E _{MIN}	E _{MAX}
RATE	LOW	HIGH			LOW	HIGH		
5 Hz			0.5	3.5			0.5	3.0
8 Hz			0.5	3.0			0.5	2.5
10 Hz			0.5	3.0			0.5	2.5
12 Hz			0.5	2.5			0.5	2.0
15 Hz			0.5	1.5			0.5	1.5
20 Hz			0.5				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 μ fiber.

ENERGY	TOLERANCE	REP. RATE: 5 Hz	8 Hz	10 Hz	12 Hz	15 Hz	20 Hz
0.5 J	0.45 - 0.55	0.44	0.48	0.46	0.47	0.45	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					0.90	
1.2 J	1.08 - 1.32						
1.5 J	1.35 - 1.65				1.31	1.32	
2.0 J	1.80 - 2.20	1.85	1.89	1.80			
2.5 J	2.25 - 2.75				2.22		
3.0 J	2.70 - 3.30		2.74	2.21			
3.5 J	3.15 - 3.85	3.21					

If this Section does not apply check box ☐

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

ENERGY	TOLERANCE	REP. RATE: 5 Hz	8 Hz	10 Hz	12 Hz	15 Hz	20 Hz
0.5 J	0.45 - 0.55	0.49	0.47	0.47	0.45	0.42	0.43
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					0.87	
1.2 J	1.08 - 1.32				1.08		
1.5 J	1.35 - 1.65		1.33	1.34		1.27	
2.0 J	1.80 - 2.20	1.83			1.77		
2.5 J	2.25 - 2.75		2.23	2.24			
3.0 J	2.70 - 3.30	2.73					

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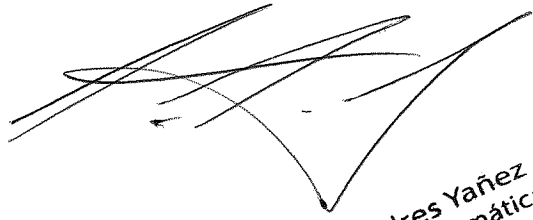
Date: 06/11/2017

If this Section does not apply check box <input type="checkbox"/>						
ELECTRICAL SAFETY TEST		UNITS	TOLERANCE	MEASURED	PASS	FAIL
Ground Resistance		OHMS	≤ 0.27			
Unit OFF	Forward Leakage	NA μ A	≤ 450			
	Reverse Leakage	NA μ A	≤ 450			
Unit ON	Forward Leakage	NA μ A	≤ 450			
	Reverse Leakage	NA μ A	≤ 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: 06/11/2017


Andres Yañez
Area Informática
CENCOMEX S.A.
06/11/17