



Quality Management System Instruction Form

Cook® Medical Incorporated

Title: **Laser Service Report**

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Document Number: QMS118_09-F06

Original Date: 30Sep2016

Version Number: 4

Effective Date: 18Aug2017

CR Number: CMI-17-187

Checked By: AB 16Aug2017

Laser Serial Number: LH-1443-1116

Date: 10/10/2018

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):	<u>VICTORIA</u>	Under Warranty?	<input type="radio"/> Yes <input type="radio"/> No
Customer Number:		Phone Number:	
Contact Person:		Technician:	<u>Arnell Yader</u>
Email:		When was the laser last serviced?	
By whom was the laser last serviced?		Under Service Contract?	<input type="radio"/> Yes <input type="radio"/> 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:	<input type="radio"/> Short <input type="radio"/> Long	Repetition Rate (Hz):	<input type="radio"/> 5 <input type="radio"/> 8 <input type="radio"/> 10 <input type="radio"/> 12 <input type="radio"/> 15 <input type="radio"/> 20
Pulse Energy:		Fiber Size(s) Used (µm):	
Total Energy Delivered:		Total Time:	<input type="radio"/> 150 <input type="radio"/> 200 <input type="radio"/> 273 <input type="radio"/> 365 <input type="radio"/> 550 <input type="radio"/> 940
In what operational state(s) was the laser when the issue occurred?		<input type="radio"/> Standby <input type="radio"/> Transition <input type="radio"/> Ready <input type="radio"/> Preparatory <input type="radio"/> Lasing	


If this Section does not apply check box ☒

Note any error code(s) that was present:

General Description of Issue:

Equipment Operative 100%

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	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
	Cartridge	8E	Filter
-			

Defective Part Disposition: Disposed of

Returned to COOK Capital Equipment

Final Resolution

SE DEBE CARBON BLAST EFFECTS EN PROCESO MANTENIMIENTO Y CALIBRACION.


Cook welcomes your feedback at capital-service@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}
	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	0.47	0.46	0.47	0.48	0.52	0.50
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				1.48	1.51	
2.0 J	1.80 - 2.20	1.70	1.80	1.88			
2.5 J	2.25 - 2.75				2.40		
3.0 J	2.70 - 3.30		2.53	2.60			
3.5 J	3.15 - 3.85	2.66					

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	0.48	0.44	0.48	0.50	0.49	0.50
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				1.18		
1.5 J	1.35 - 1.65		1.35	1.29		1.47	
2.0 J	1.80 - 2.20	1.70			1.82		
2.5 J	2.25 - 2.75		2.10	2.09			
3.0 J	2.70 - 3.30	2.38					

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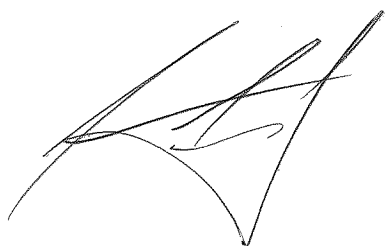
Laser Serial Number: LH 1443 - 1116

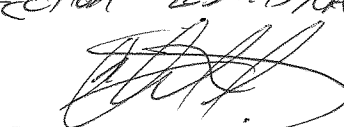
Date: 10/10/2018

If this Section does not apply check box <input type="checkbox"/>					
ELECTRICAL SAFETY TEST		UNITS	TOLERANCE	MEASURED	PASS
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: 10/10/2018


Hector Zumbado Novon


Andres Yañez
Area Informática
CENCOMEX S.A.
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