Quality Management System Instruction Form

Cook® Medical Incorporated

Title:	**Laser Service Report**

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: **LHT1311-1215**   Date: **22/06/2018**

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): **Clinical U de los Andes**		Under Warranty?	◯ Yes ◯ No
Customer Number:		Phone Number:	
Contact Person:		Technician:	**Andrés Yáñez**
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:		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

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If this Section does not apply check box ☑

Note any error code(s) that was present:

General Description of Issue:

Equipo en buen estado y sin aparentes daños físicos.

Work Performed (Include Troubleshooting)

Laser Serial Number: __LHT V311 - 1215__   Date: __22/06/2018__

List Calibrated Equipment, Tools or Test Equipment Used

+	PART NUMBER/CPN	I.D. NUMBER	CALIBRATION DUE DATE
	Gentec "Maestro" Power Meter	242057	04/2017
	Gentec "Maestro" Target	224533	04/2017
	BC Medical SA-2001 Safety Analyzer		
−			

Service Manual Revision Number:

Were replacement parts used? ○ Yes ○ No

+	PART NUMBER/CPN	LOT NUMBER	DESCRIPTION
	HLP-WF	5510876	Filtro de Agua.
−			

Defective Part Disposition: Disposed of _____   Returned to COOK Capital Equipment _____

Final Resolution

Se Realiza calibración del equipo; mantención preventiva donde, se efectúa Cambio de Filtro de agua y el cambio de agua.

Verificar estado de blastshield en la próxima mantención, Reemplazar de ser necesario.

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.

Laser Serial Number: LHT 1311-1215 **Date:** 22/06/2018

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

CAL	SHORT PW				LONG PW			
	PHD ADJ				PHD ADJ			
RATE	LOW	HIGH	E_{MIN}	E_{MAX}	LOW	HIGH	E_{MIN}	E_{MAX}
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	0.51	0.51	0.50	0.51	0.49	0.51
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					0.97	
1.2 J	1.08 - 1.32						
1.5 J	1.35 - 1.65				1.44	1.49	
2.0 J	1.80 - 2.20	1.82	1.92	1.84			
2.5 J	2.25 - 2.75				2.30		
3.0 J	2.70 - 3.30		2.43	2.53			
3.5 J	3.15 - 3.85	2.63					

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	0.49	0.47	0.51	0.49	0.48
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					0.94	
1.2 J	1.08 - 1.32				1.16		
1.5 J	1.35 - 1.65		1.40	1.43		1.42	
2.0 J	1.80 - 2.20	1.71			1.85		
2.5 J	2.25 - 2.75		2.10	2.12			
3.0 J	2.70 - 3.30	2.50					

Laser Serial Number: LHT 1311 – 1215   Date: 22/06/2018

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ELECTRICAL SAFETY TEST		UNITS	TOLERANCE	MEASURED	PASS	FAIL
Ground Resistance		OHMS	≤ 0.27			
Unit OFF	Forward Leakage	NAµA	≤450			
	Reverse Leakage	NAµA	≤450			
Unit ON	Forward Leakage	NAµA	≤450			
	Reverse Leakage	NAµA	≤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: _Audrey Yawer_   Date: 22/06/18

[signature]

[signature] WLADIMIR ANAYA