



# 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: LH 13111215

Date: 23/01/18

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): Cl. U. Los Andes

Under Warranty? ☐ Yes ☒ No

Customer Number:

Phone Number: +56 9 644 96402

Contact Person:

Technician: Andrés Yáñez

Email:

When was the laser last serviced? AYáñez @ Concorde 01

By whom was the laser last serviced? M. Juncos

Under Service Contract? ☒ Yes ☐ No

Current Service Location: Concorde

Installation Date:

Plug Type: 220 V.

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:

Equipo operativo. Problema +- 80% energía

## 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	2017/04
	Gentec "Maestro" Target	229533	2017/04
	BC Medical SA-2001 Safety Analyzer		
-			

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

Were replacement parts used? ☐ Yes ☐ No

+	PART NUMBER/CPN	LOT NUMBER	DESCRIPTION
	HCP-DIC	8E	Filter
-			

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

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

Final Resolution

Mantencao realizada equipo 100% operativo.  
 Alinhacao  
 combo de fibra, filtro y bast shield

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			
RATE	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			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	0.49	0.46	0.50	0.50	0.51	0.49
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				1.45	1.40	
2.0 J	1.80 - 2.20	1.91	2.04	1.93			
2.5 J	2.25 - 2.75				2.25		
3.0 J	2.70 - 3.30		2.73	2.70			
3.5 J	3.15 - 3.85	3.15					

 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	0.46	0.45	0.52	0.51	0.51	0.47
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					0.92	
1.2 J	1.08 - 1.32				1.25		
1.5 J	1.35 - 1.65		1.57	1.47		1.58	
2.0 J	1.80 - 2.20	2.00			1.80		
2.5 J	2.25 - 2.75		2.35	2.29			
3.0 J	2.70 - 3.30	2.72					

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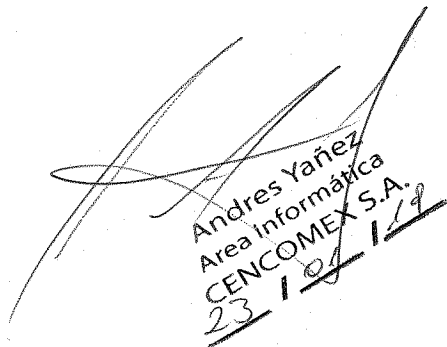
If this Section does not apply check box ☒

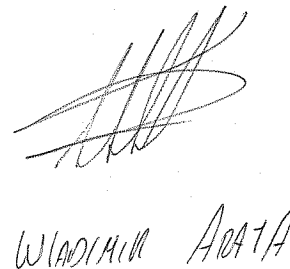
ELECTRICAL SAFETY TEST		UNITS	TOLERANCE	MEASURED	PASS	FAIL
Ground Resistance		OHMS	$\leq 0.27$			
Unit OFF	Forward Leakage	NAµA	$\leq 450$			
	Reverse Leakage	NAµA	$\leq 450$			
Unit ON	Forward Leakage	NAµA	$\leq 450$			
	Reverse Leakage	NAµA	$\leq 450$			

**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: 23/01/19

  
 Andres Yañez  
 Area Informática  
 CENCOMEX S.A.  
23/01/19

  
 Wladimir Arata