



Quality Management System Instruction Form

Cook® Medical Incorporated

Title:

Laser Service Report

WARNING - CONFIDENTIAL PROPRIETARY PROPERTY

This document is owned by Cook Medical. It contains confidential proprietary trade secret information and must not be copied. The document and the information it contains can be used only by the recipient for the specific use for which it was requested. All other use is strictly prohibited. This document must be returned to Cook Medical immediately upon request by Cook Medical. By possession of this document, the possessor expressly agrees to comply with these terms.
© COPYRIGHT Cook® Medical Incorporated 2016

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: 247 0349 0412

Date: 22/09/2017

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): INDISA

Under Warranty? ☐ Yes ☐ No

Customer Number:

Phone Number: 9644 96402

Contact Person: ANITA YAJER

Technician: ANITA YAJER

Email: AYAJER@Cook.com

When was the laser last serviced? 23-12-2016

By whom was the laser last serviced? CLINICA

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:

Se realiza Mantenimiento Preventiva

Work Performed (Include Troubleshooting)

Cambio Filtro / Cambio de Agua
Limpieza Colador / Limpieza Blast Shield

COOK MEDICAL	Document Number: QMS118_09-F06	Quality Management System Instruction Form Laser Service Report	Version No.: 4
------------------------	-----------------------------------	--	----------------

Laser Serial Number: _____ Date: _____

List Calibrated Equipment, Tools or Test Equipment Used

+	PART NUMBER/CPN	I.D. NUMBER	CALIBRATION DUE DATE
	Gentec "Maestro" Power Meter	242057	
	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
	HLP-DIC/G34585	7766457	DI Cartridge
-			

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

Final Resolution

ESPERO LEVANTAR QUERIDO, SE DEBE CAMBIAR
Y CALIBRAR PARAMETROS BASES.

Prox. mantenimiento marzo 2018

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.



Document Number:
QMS18_09-F06

Quality Management System Instruction Form
Laser Service Report

Version No.: 4

Laser Serial Number: _____

Date: _____

If this Section does not apply check box ☐

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}
5 Hz			0.5	3.5
8 Hz			0.5	3.0
10 Hz			0.5	3.0
12 Hz			0.5	2.5
15 Hz			0.5	1.5
20 Hz			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	0.44	0.31	0.25	0.48	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					0.81	
1.2 J	1.08 - 1.32						
1.5 J	1.35 - 1.65				1.25	1.28	
2.0 J	1.80 - 2.20	1.97	1.94	1.78			
2.5 J	2.25 - 2.75				1.85		
3.0 J	2.70 - 3.30		2.78	2.62			
3.5 J	3.15 - 3.85	3.23					

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	0.41	0.40	0.41	0.42	0.38	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					0.78	
1.2 J	1.08 - 1.32				0.89		
1.5 J	1.35 - 1.65		1.19	1.20		1.03	
2.0 J	1.80 - 2.20	1.60			1.48		
2.5 J	2.25 - 2.75		2.01	1.94			
3.0 J	2.70 - 3.30	2.58					



Document Number:
QMS118_09-F06

Quality Management System Instruction Form
Laser Service Report

Version No.: 4

Laser Serial Number: _____

Date: _____

If this Section does not apply check box ☐

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: _____

Andrew Yaw

Date: _____

22/09/2017