



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: QMS118_09-F06

Original Date: 30Sep2016

Version Number: 4

Effective Date: 18Aug2017

CR Number: CMI-17-187

Checked By: AB 16Aug2017

Laser Serial Number: 28020 - 65620

Date: 24/05/19

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): Al Santa Maria

Under Warranty? ☐ Yes ☐ No

Customer Number:

Phone Number:

Contact Person:

Technician: Anna Yoder

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

If this Section does not apply check box ☒

Note any error code(s) that was present:

General Description of Issue:

Work Performed (Include Troubleshooting)

	Document Number: QMS118_09-F06	Quality Management System Instruction Form Laser Service Report	Version No.: 4
	Laser Serial Number: <u>29020-656726</u>		Date: <u>24/05/19</u>

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
+			Fi / two
-			

Defective Part Disposition: Disposed of _____

Returned to COOK Capital Equipment _____

Final Resolution

Equipo operativo 100%


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.

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

Laser Serial Number: 24020 - 65826

Date: 24/05/18

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		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	7.8 Hz	10 Hz	12 Hz	15 Hz	20 Hz
0.5 J	0.45 - 0.55	0.54	0.53	0.52	0.55	0.54	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					1.02	
1.2 J	1.08 - 1.32						
1.5 J	1.35 - 1.65				1.51	1.38	
2.0 J	1.80 - 2.20	2.02	2.05	2.08			
2.5 J	2.25 - 2.75						
3.0 J	2.70 - 3.30			2.88			
3.5 J	3.15 - 3.85						

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	7.8 Hz	10 Hz	12 Hz	15 Hz	20 Hz
0.5 J	0.45 - 0.55	0.52	0.54	0.53	0.55	0.55	
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					1.05	
1.2 J	1.08 - 1.32				1.28		
1.5 J	1.35 - 1.65		1.56	1.48		1.48	
2.0 J	1.80 - 2.20	2.06			2.00		
2.5 J	2.25 - 2.75						
3.0 J	2.70 - 3.30						

	Document Number:	Quality Management System Instruction Form		Version No.: 4
	QMSI18_09-F06	Laser Service Report		

Laser Serial Number: 29020-65626

Date: 24/05/19

If this Section does not apply check box <input checked="" 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: Andrew Turner

Date: 24/05/19

