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: 29020 - GHGRD Date: 24/10/17

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):	COPIAPO	Under Warranty?	○ Yes ○ No
Customer Number:		Phone Number:	
Contact Person:	ANDRES YAÑEZ	Technician:	
Email:	AYANEZ@CENCOSUD.CL	When was the laser last serviced?	05/2017
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):	○ 150 ○ 200 ○ 273 ○ 365 ○ 550 ○ 940
Total Energy Delivered:	Total Time:		

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 CALIBRADO, LIMPIEZA FILTRO AIRE.
EQUIPO FUNCIONANDO 100%.

Work Performed (Include Troubleshooting)

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

Laser Serial Number: 29020 – 6HG12D Date: 24/04/2017

List Calibrated Equipment, Tools or Test Equipment Used

+	PART NUMBER/CPN	I.D. NUMBER	CALIBRATION DUE DATE
	Gentec "Maestro" Power Meter	242057	25/04/2017
	Gentec "Maestro" Target	224533	25/04/2017
	BC Medical SA-2001 Safety Analyzer		
-			

Service Manual Revision Number:

Were replacement parts used? ○ Yes ✓ No

+	PART NUMBER/CPN	LOT NUMBER	DESCRIPTION
-			

Defective Part Disposition: Disposed of Returned to COOK Capital Equipment

Final Resolution

Equipo 100% operativo
Limpieza de filtro Aire
Cambio de Agua.
Calibracion. Completa.

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.

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

Laser Serial Number: 29020 - GHG2D Date: 24/10/2017

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}	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	0.514	—	0.503	0.512	—	—
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					—	
1.2 J	1.08 - 1.32						
1.5 J	1.35 - 1.65				—	—	
2.0 J	1.80 - 2.20	2.12	—	—			
2.5 J	2.25 - 2.75				—		
3.0 J	2.70 - 3.30		—	—			
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	8 Hz	10 Hz	12 Hz	15 Hz	20 Hz
0.5 J	0.45 - 0.55	0.521	—	0.529	0.503	—	—
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					—	
1.2 J	1.08 - 1.32				—		
1.5 J	1.35 - 1.65		—	—		—	
2.0 J	1.80 - 2.20	1.90			—		
2.5 J	2.25 - 2.75		—	—			
3.0 J	2.70 - 3.30	—					

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

Laser Serial Number: 29020 - GHG2D Date: 24/10/2017

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	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: Andres Yanez Date: 24/10/2017