	<h2 style="margin: 0;">Quality Management System Instruction Form</h2> <p style="margin: 0;">Cook® Medical Incorporated</p>		
Title:	<h3 style="margin: 0;">Laser Service Report</h3>		
<p>WARNING - CONFIDENTIAL PROPRIETARY PROPERTY</p> <p>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.</p> <p>© COPYRIGHT Cook® Medical Incorporated 2016</p>			
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: <u>LAT 0348-0412</u>		Date: <u>15/11/2017</u>	
Please fill out as much information as possible in the form below.			
General Information and Background			
Laser System Type: <input type="radio"/> Odyssey <input checked="" type="radio"/> H-30			
Laser Owner (Hospital):		Under Warranty? <input type="radio"/> Yes <input type="radio"/> No	
Customer Number:		Phone Number:	
Contact Person:		Technician:	
Email:		When was the laser last serviced?	
By whom was the laser last serviced?		Under Service Contract? <input type="radio"/> Yes <input type="radio"/> No	
Current Service Location:		Installation Date:	
Plug Type:			
Any unusual environmental condition? <input type="radio"/> Yes <input checked="" type="radio"/> No If yes, explain:			
Any information to reasonably suggest laser caused or contributed to illness or injury to patient or user? <input type="radio"/> Yes <input checked="" type="radio"/> No If yes, explain:			
Was laser used for treatment or diagnosis? <input type="radio"/> Yes <input checked="" type="radio"/> 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 <input checked="" type="checkbox"/>			
Laser Use Information at Occurrence			
Pulse Width Mode: <input type="radio"/> Short <input type="radio"/> Long		Repetition Rate (Hz): <input type="radio"/> 5 <input type="radio"/> 8 <input type="radio"/> 10 <input type="radio"/> 12 <input type="radio"/> 15 <input type="radio"/> 20	
Pulse Energy:		Fiber Size(s) Used (µm):	
Total Energy Delivered:	Total Time:	<input type="radio"/> 150 <input type="radio"/> 200 <input type="radio"/> 273 <input type="radio"/> 365 <input type="radio"/> 550 <input type="radio"/> 940	
In what operational state(s) was the laser when the issue occurred?		<input type="radio"/> Standby <input type="radio"/> Transition <input type="radio"/> Ready <input type="radio"/> Preparatory <input type="radio"/> Lasing	
If this Section does not apply check box <input checked="" type="checkbox"/>			
Note any error code(s) that was present:			
General Description of Issue:			
Work Performed (Include Troubleshooting)			



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If this Section does not apply check box ☐

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

CAL	SHORT PW	PHD ADJ		E _{MIN}	E _{MAX}	LONG PW		E _{MIN}	E _{MAX}
		LOW	HIGH			LOW	HIGH		
RATE									
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	0.46	0.47	0.48	0.45	0.48	0.40
0.6 J	0.54 - 0.66						
0.7 J	0.63 - 0.77						
0.8 J	0.72 - 0.88					0.87	
1.0 J	0.90 - 1.10						
1.2 J	1.08 - 1.32				1.28	1.15	
1.5 J	1.35 - 1.65			1.60			
2.0 J	1.80 - 2.20	1.66	1.64		1.88		
2.5 J	2.25 - 2.75		2.34	2.33			
3.0 J	2.70 - 3.30						
3.5 J	3.15 - 3.85	2.70					

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						
0.6 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						
2.5 J	2.25 - 2.75						
3.0 J	2.70 - 3.30						

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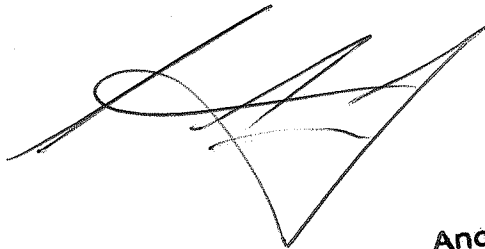
Laser Serial Number: _____ Date: _____

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: Andres Yañez Date: 15/11/2017



Andres Yañez
Area Informática
CENCOMEX S.A.
____/____/____