COOK	_	_	stem Instruction	n For	m				
MEDICAL	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 Num	Document Number: QMSI18_09-F06 O		Original Date: 30Sep2016				
		Version Numbe	Version Number: 4		Effective Date: 18Aug2017		7		
		CR Number:	CMI-17-187	Checked By: AB 16Aug201			2017		
Laser Serial Numb	oer: LHT 034	9-041	7	· · · · · · ·	Da	ate: / 丁 /	1/201		
Please fill out as mu	ich information as possible	in the form below.							
General Information	and Background								
Laser System Type	: Odyssey	Ø H-30							
	Owner (Hospital):		Under Wa	arranty?	() Yes	○ No			
	Customer Number:		Phone N						
	Contact Person:			hnician:					
	Email:		When was the laser last se		<u></u>				
By whom was the la	aser last serviced?		Under Service Co		○ Yes	○ No			
	t Service Location:		Installatio	on Date:					
	Plug Type:					***************************************			
			s.) Note: Only enter informatio	on if addit	ional inforn	nation is applic	able,		
If this Section does	s not apply check box 🖊								
Laser Use Informati	on at Occurrence								
Pulse Width M		ng	Repetition Rate (Hz):	5 (	8 🔾 10	O 12 O 1	5 🔾 20		
Pulse Ene	ergy:	T	Fiber Size(s) Used (µm):						
Total Energy Delive	red: Total	Time:	○ 150 ○ 200 ○ 27	/3 () 365 	550	940			
In what operational	state(s) was the laser when the	e issue occurred?	◯ Standby ◯ Trans	sition ()	Ready (	Preparatory	○ Lasing		
If this Section does	s not apply check box								
Note any error code	(s) that was present:								
General Description	of Issue:								
Work Performed (In	clude Troubleshooting)								

Document Number: CH + O 4 9 O 4 12  CALIBRATION DUE DATE  Invaried Equipment, Tools or Test Equipment Used  CALIBRATION DUE DATE  I.D. NUMBER  CALIBRATION DUE DATE  L.D. NUMBER  DESCRIPTION  PART NUMBER/CPN  LOT NUMBER  DESCRIPTION  Returned to COOK Capital Equipment  Innal Resolution  COOK wellcomes your feedback at capital service@cookmadical.com  Returned to COOK Capital Equipment  Returned to COOK Capital Equipment  Cook wellcomes your feedback at capital service@cookmadical.com  Returned to COOK Capital Equipment  Returned to COOK Capital Equipment  Ann. MAX.  PRO PROPERTOR COOK CAPITAL VALUE  E1 E2 FINAL VALUE  PRO PROPERTOR COOK  Notes (calibration, buring, centration, alignment, etc.) Note: Only enter information if additional information is applicable, output vise leave  Notes (calibration, buring, centration, alignment, etc.) Note: Only enter information if additional information is applicable, output vise leave		mber:	Quality Ma	anagement System Laser Service I	m Instruction Form Report	Date:	vocality of the second
OMSTR JOSE CALIBRATION DUE DATE  PART NUMBER(OP)  Gentes "Meastro" Power Meter  Gentes "Meastro" Power Meter  Gentes "Meastro" Target  Centes "Meastro" Target  Condical SA-2001 Safety Analyzer  LOT NUMBER  PART NUMBER(OP)  LOT NUMBER  PART NUMBER(OP)  LOT NUMBER  PART NUMBER(OP)  LOT NUMBER  PART NUMBER(OP)  Returned to COOK Capital Equipment  Defective Part Disposition: Disposed of  Returned to COOK Capital Equipment  Cook welcomes your feedback at capitalservice@cookmedical.com  If this Section does not apply check box  Calibration  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 ownersex (powers)  NN: EXT: NT: EXT: EXT: NT: EXT: NT: EXT: EXT: NT: EXT: EXT: EXT: EXT: EXT: EXT: EXT: EX	Document Nu	mber. -F06				Date.	
PART NUMBERICPN  Gente "Maestro" Power Meter  Gente "Maestro" Target  C Medical SA-2001 Safety Analyzer  C Medical Sa-200	CAL QMSI18_09	-034	9 04	17			DUE DATE
PART NUMBERICPN  Gente "Maestro" Power Meter  Gente "Maestro" Target  C Medical SA-2001 Safety Analyzer  C Medical Sa-200	erial Number: 2 14 )	Tost Equipme	ent Used			CALIBRATION	TOOL -
PART NUMBER OF Meets Accepted to COOK Capital Equipment  Cook welcomes your feedback at capitalservice@cookmedical.com  If this Section does not apply check box  California Too  California Too  PhD presenter resources (104rc, 2001)  In this Section does not apply check box  PhD presenter resources (104rc, 2001)  PhD presenter re	orated Equipment, 10	Test = 1	1	.D. NUMBER		5/04/	2017
Gentec "Masstrd" Power Invest.  Gentec "Masstrd" Target  C. Medical SA-2001 Safely Analyzer  Ice Manual Revision Number:  Ter replacement parts used?	PART NUMBERICAN			057			·
Genter "Maestro" Target  C Medical SA-2001 Safety Analyzer  C Medical SA-2001 Safety Analyzer  Command Revision Number:  The replacement parts used?	Gentec "Maestro" Power Met	ter	721	1533			
Cook welcomes your feedback at capitalservice@cookmedical.com	Gentec "Maestro" Target						
Final Resolution  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 Despective Proposition of the proposit	Medical SA-2001 Safety Ar	nalyzer					
DESCRIPTION							888
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DESCRIPTION	- Lion Number						
PART NUMBERICPN    Cook welcomes your feedback at capitalservice@cookmedical.com	ce Manual Revision Number	? Yes C	No		<del></del>	DE	SCRIPTION
Defective Part Disposition: Disposed of	e replacement parts deci-					-15	- I M
Defective Part Disposition: Disposed of  Returned to COOK Capital Equipment  Returned to COOK Capital Equipment  Returned to COOK Capital Equipment  Final Resolution  If this Section does not apply check box  Calibration  VALUE INITIAL VALUE E1 E2 FINAL VALUE E1 E2  PHD orests (10Hz, 0.50)  PHD PROJECTIONAL ENTRY COORD INT: EXT: INT: EXT:  (10HZ, 3.01)  PHD PROJECTIONAL ENTRY COORD INT: EXT:  (10HZ, 3.01)  PHD SAUTTER CLOSED  OPEN: CLOSED: OPEN: CLOSED		N	80	09748	3	Est trans	suppr 1 1.111
Defective Part Disposition: Disposed of	HLP-MRF			30			
Defective Part Disposition: Disposed of  Final Resolution  Cook welcomes your feedback at capitalservice@cookmedical.com  If this Section does not apply check box  Catibration  VALUE   INITIAL VALUE   E1   E2   FINAL VALUE   E1   E2   PHD porset (10Hz, 0.5J)   MIN:   MAX:   MIN:   MAX:   PHD POTENTIOMETERCOARSE (10Hz, 0.5J)   INT:   EXT:   INT:   EXT:    PHD POULSCALEFINE (10 Hz, 3.0J)   PHD POULSCALEFINE (10 Hz, 3.0J)   OPEN:   CLOSED:    PHD SHUTTER CLOSED   OPEN:   CLOSED:   OPEN:   CLOSED:      Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2      Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.com   INT:   E2     Cook welcomes your feedback at capitalservice@cookmedical.c							
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Cook welcomes your feedback at capitalservice@cookmedical.com  If this Section does not apply check box   VALUE   INITIAL VALUE   E1   E2   FINAL VALUE   E1   E2    PHD orrset (10Hz, 0.5J)   MIN:   MAX:   MIN:   MAX:    PHD protriometercooase (10Hz, 3.0J)   INT:   EXT:   INT:   EXT:    PHD FULLSCALEFINE (10 HZ, 3.0J)   INT:   EXT:   INT:   EXT:    PHD shutter closed   OPEN:   CLOSED:   OPEN:   CLOSED:	Defective Part Disposition: Dispo	osed of					
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Calibration           VALUE         INITIAL VALUE         E1         E2         FINAL VALUE         E1         E2           PHD 0FFSET (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:			service@cookm	edical.com			
VALUE         INITIAL VALUE         E1         E2         FINAL VALUE         E1         L2           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:	Cook welcomes your feedl	back at capital		edical.com			
PHD offset (10Hz, 0.5J)	Cook welcomes your feedl	back at capital		edical.com			
(10Hz, 0.5J)   PHD POTENTIOMETER/COARSE (10Hz, 3.0J)	Cook welcomes your feedi If this Section does not a Calibration	back at capital	x 🔲		FINAL VALUE	E1	E2
NT:   EXT:   INT:   EXT:   I	Cook welcomes your feeding this Section does not a Calibration VALUE	back at capital	ox ☐	E2	FINAL VALUE		
PHD FULLSCALE/FINE	Cook welcomes your feedly lift this Section does not a Calibration  VALUE INTERPRET (10Hz, 0.5J)	back at capital	E1	E2 MAX:	FINAL VALUE	MIN:	MAX:
PHD SHUTTER CLOSED OPEN: CLOSED: OF LINE.	Cook welcomes your feedly If this Section does not a Calibration  VALUE  PHD OFFSET (10Hz, 0.5J)  PHD POTENTIOMETER/COARSE	back at capital	E1	E2 MAX:	FINAL VALUE	MIN:	MAX: EXT:
Notes (calibration, tuning, centration, alignment, etc.) Note: Only enter information if additional information is applicable, otherwise leav	Cook welcomes your feeds  If this Section does not a Calibration  VALUE  PHD offset (10Hz, 0.5J)  PHD POTENTIOMETER/COARSE (10Hz, 3.0J)  PHD FULLSCALE/FINE	back at capital	E1 MiN: INT:	MAX:	FINAL VALUE	MIN: INT:	MAX: EXT:
Notes (calibration, tuning, centration, alignment, etc.) Note. Only enter morning	Cook welcomes your feeds If this Section does not a Calibration  VALUE  PHD offset (10Hz, 0.5J)  PHD potentiometer/coarse (10Hz, 3.0J)  PHD fullscale/fine (10 Hz, 3.0J)	back at capital	E1 MIN: INT:	EXT:	FINAL VALUE	MIN: INT:	MAX: EXT:
	Cook welcomes your feeds If this Section does not a Calibration  VALUE  PHD offset (10Hz, 0.5J)  PHD POTENTIOMETER/COARSE (10HZ, 3.0J)  PHD FULLSCALE/FINE (10 HZ, 3.0J)  PHD SHUTTER CLOSED	back at capital	E1 MINT: INT: OPEN:	MAX: EXT: EXT: CLOSED:		MIN: INT: INT: OPEN:	MAX: EXT: EXT: CLOSED:
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## Quality Management System Instruction Form Laser Service Report

Version No.: 4

Date:

Laser Serial Number:

is Section does no	ot apply check box cation (data can be r	eplaced with ext	ernal data shoo	LONG PW		EMAX
Calibration Verific	PW			PHD AD.	HIGH EMIN	
CAL	PHD ADJ		EMAX	LOW	0.5	3.0
1	OW HIGH	EMIN	3.5		0.5	2.5
RATE LI		0.5				2.5
5 Hz		0.5	3.0		0.5	2.0
8 Hz		0.5	3.0		0.5	
10 Hz		0.5	2.5		0.5	1.5
12 Hz		0.5	1.5		0.5	
15 Hz		0.5				
20 Hz		10.0		BANKANAN BERKETERA (BANKAN)		

Attach pictures of DAC values and plot from CAL menu, if voltage values changed. Final Steps

ort PW Calibr	loes not apply che ation Table (recor	J average -	8 Hz	10 Hz	12 Hz	15 Hz	0.40
ENERGY	TOLERANCE	REP. RATE: 5 Hz	0.47	0.48	0.45	0.90	
0.5 J	0.45 - 0.55	10.46	<u> </u>				
0.6 J	0.54 - 0.66						
0.7 J	0.63 - 0.77					0)	
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		164	1.60			
2.0 J	1.80 - 2.20	1.66	1.64	1.00	1.88		
2.5 J	2.25 - 2.75		2.34	2.33			
3.0 J	2.70 - 3.30	3-5-	2.34	12.00			
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  $\mu$  fiber. 20 Hz 15 Hz 10 Hz 12 Hz REP. RATE: 5 Hz 8 Hz TOLERANCE **ENERGY** 0.45 - 0.55 0.5 J 0.54 - 0.66 0.6 J 0.63 - 0.77 0.7 J 0.72 - 0.880.8 J 0.90 - 1.10 1.0 J 1.08 - 1.32 1.2 J 1.35 - 1.65 1.5 J 1.80 - 2.20 2.0 J 2.5 J 2.25 - 2.75 2.70 - 3.30 3.0 J



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If this Section does	not apply check box 🔲					
ELECTRIC	AL SAFETY TEST	UNITS	TOLERANCE	MEASURED	PASS	FAIL
Grou	nd Resistance	OHMS	≤0.27	<u> 1995 olympia kalistoly y propinski kali</u>		244
Unit	Forward Leakage	NAµA	≤450			
OFF	Reverse Leakage	NAµA	≤450			
Unit	Forward Leakage	NAµA	≤450			
ON	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: Andrew Yare	Form Submitted By:	Ausner	YADER
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Date: 15/11/2017

Andres Yañez Area Informática CENCOMEX S.A.