COOK	Quality Management System Instruction Form								
MEDICAL	Cook® Medical Inco	orporated							
Title:	Laser Service	Report							
	ITIAL PROPRIETARY PROPERTY Cook Medical. It contains confidential	Document Numb	Document Number: QMSI18_09-F06 Origina			riginal Date: 30Sep2016			
proprietary trade secret information document and the information ecipient for the specific use for	rmation and must not be copied. The on it contains can be used only by the r which it was requested. All other use ment must be returned to Cook Medica	Version Number	: 4	Effecti	ve Date:	18Aug	2017	- Landan Company	
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Laser Serial Numb	er: L.H-+14	13-1116			D:	ate: <u>/</u> 0/	10/	20	
	ch information as possib	e in the form below.						t	
General Information	and Background				7			T	
Laser System Type	: Odyssey	Ø H-30						- Annual Control	
-			Under W	arranty?	○ Yes	○ No)	-	
	Customer Number:	ictoria		Number:				-	
Contact Person:			Teo	chnician:	Aume	2 YAU	P)	+	
Email:			When was the laser last serviced?						
By whom was the laser last serviced?			Under Service C	ontract?	○ Yes	O No	Ò	permonenta	
	Service Location:		Installati	on Date:				2000/00/00/00	
	Plug Type:							manage and a second	
		Yes No If y	T Decision						
Any unusual envir	onmental condition? () 100 (Ø NO ITY	es, explain:					1	
								-	
Any information to r	easonably suggest laser	caused or contributed	to illness or injury to patient	t or user?	○ Yes	∂ No	If yes, e	xpla	
								-	
		○Yes ⊘No				vari Brista			
						-antinu in	analiaable	+	
					itional intor	mation is a	аррисаріє	elecotion control	
Additional comment	s: (Note any recent issue	es and their resolutions	s.) Note: Only enter informat	ion it add	idonai imon			2	
Additional comment	s: (Note any recent issue	es and their resolutions	s.) Note: Only enter informat	ion if add				- Carrier Constitution of the	
Additional comment otherwise leave blad	s: (Note any recent issue nk.	es and their resolutions	s.) Note: Only enter informat	ion if add	nionar mion				
Additional comment otherwise leave blands	s: (Note any recent issuent) nk. s not apply check box	es and their resolutions	s.) Note: Only enter informat	ion if add	nona mo				
Additional comment otherwise leave bland If this Section does aser Use Informati	s: (Note any recent issuent). s not apply check box) 21	
Additional comment otherwise leave blad If this Section does Laser Use Informati	s: (Note any recent issuents: (Note any recent issuents.) s not apply check box ion at Occurrence		Repetition Rate (Hz):	O5 (0 0 12) 20	
otherwise leave blands If this Section does Laser Use Information	s: (Note any recent issuent). s not apply check box [sion at Occurrence] lode: Short [sion]			<u></u> 5 ()8 ()1) () 12) 2	

In what operational state(s) was the laser when the issue occurred?	○ Standby ○ Transition ○ Ready ○ Prep	aratory O Lasing
If this Section does not apply check box		
Note any error code(s) that was present:		OR STATE OF THE ST
General Description of Issue:		
EQUIDO OPERATIVO 100%.		
Work Performed (Include Troubleshooting)		



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Gentec "Maestro" Power Meter Q 4 2057 Gentec "Maestro" Target 22 4533 BC Medical SA-2001 Safety Analyzer Prvice Manual Revision Number: ere replacement parts used?	<u> </u>	Date: / O			1	QMSI18_09-F0	MEDICAL		
PART NUMBER/CPN I.D. NUMBER CALIBRAT Gentec "Maestro" Power Meter 2 4 2057 Gentec "Maestro" Target 2 2 4 5 3 3 2019 BC Medical SA-2001 Safety Analyzer Vice Manual Revision Number: ere replacement parts used? Yes	<u> </u>	Serial Number: 4# 1443 = 1116 Date: 10/10/							
Gentec "Maestro" Power Meter Q Q 2057 Gentec "Maestro" Target 22 Q 333 BC Medical SA-2001 Safety Analyzer Vice Manual Revision Number: Ure replacement parts used? Yes	<u> </u>				Equipment Used	ent, Tools or Test	Calibrated Equipm		
Gentec "Maestro" Target 22 4533 BC Medical SA-2001 Safety Analyzer vice Manual Revision Number: ere replacement parts used?		CALIBRATION I	PART NUMBER/CPN I.D. NUMBER						
Gentec "Maestro" Target 22 US33 BC Medical SA-2001 Safety Analyzer vice Manual Revision Number: are replacement parts used?		2017		242057			Gentec "Maestro" Power Meter		
vice Manual Revision Number: per replacement parts used?		2017				stro" Target	Gentec "Maes		
ere replacement parts used? Yes No						1 Safety Analyzer	BC Medical SA-200		
re replacement parts used?									
re replacement parts used? O Yes O No	Optorior -								
re replacement parts used?									
						CONTRACTOR CONTRACTOR			
PART NUMBER/CPN LOT NUMBER DE		T			○ No	ts used? O ^{res}	re replacement par		
	SCRIPTION	DESCRIP	LOT NUMBER			PART NUMBER/CPN			
Contribute 8E Fil-	0	Filter	8 <i>E</i>			Con trider			
	######################################								
refective Part Disposition: Disposed of Returned to COOK Capital Equipment			, .			on: Disposed of	efective Part Disposition		
				lical com					
Ook welcomes your feedback at capitalservice@cookmedical.com				ilical.com					
CA (NON C.) book welcomes your feedback at capitalservice@cookmedical.com this Section does not apply check box				nca.com			this Section does		
CA (NON C.) book welcomes your feedback at capitalservice@cookmedical.com this Section does not apply check box	E2	<u> </u>	FINAL VALUE)x 🗹	not apply check bo	this Section does		
This Section does not apply check box VALUE INITIAL VALUE E1 E2 FINAL VALUE E1 HD OFFSET MINI- MAX.	E2 MAX:			E2	x	not apply check bo	this Section does		
This Section does not apply check box WALUE INITIAL VALUE E1 E2 FINAL VALUE E1 HD offset OHz, 0.5J) HD POTENTIOMETER/COARSE INT. EVT. INT.		MIN: MA		E2	E1	not apply check bo	this Section does libration VALUE HD OFFSET OHZ, 0.5J) HD POTENTIOMETER/COARSE		
Ook welcomes your feedback at capitalservice@cookmedical.com This Section does not apply check box Alibration VALUE INITIAL VALUE E1 E2 FINAL VALUE E1 HD offset OHz, 0.5J) MIN: MAX: MIN: HD potentiometerscoarse INT: EXT: INT: PHD FULLSCALEFINE INT: FXT: INT: INT:	MAX:	MIN: MA INT: EX		MAX:	E1 MIN: INT:	not apply check bo	this Section does alibration VALUE HD offset OHz, 0.5J) HD POTENTIOMETER/COARSE OHZ, 3.0J) PHD FULLSCALEFINE		
PHD offset (10Hz, 0.5J) PHD potentiometer/coarse (10Hz, 3.0J) INT: EXT: INT:	MAX: EXT:	MIN: MA INT: EX INT: EX		MAX: EXT: EXT:	E1 MIN: INT:	not apply check bo	this Section does alibration VALUE HD OFFSET OHZ, 0.5J) HD POTENTIOMETERICOARSE OHZ, 3.0J) PHD FULLSCALE/FINE O HZ, 3.0J)		



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1443-1116 Date: Laser Serial Number: If this Section does not apply check box PHD Calibration Verification (data can be replaced with external data sheets, if desired) SHORT PW CAL PHD ADJ **PHD ADJ** HIGH EMAX LOW EMIN LOW HIGH EMIN EMAX **RATE** 0.5 3.0 0.5 3.5 5 Hz 2.5 0.5 0.5 3.0 8 Hz 2.5 0.5 0.5 3.0 10 Hz 0.5 2.0 0.5 2.5 12 Hz 1.5 0.5 0.5 1.5 15 Hz 0.5 0.5 20 Hz 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. 20 Hz 15 Hz REP. RATE: 5 Hz 8 Hz 10 Hz 12 Hz **TOLERANCE ENERGY** 0.48 2.0 0.00 0.46 47 0.47 0.5 J 0.45 - 0.55 0.54 - 0.66 0.6 J 0.7 J 0.63 - 0.77 0.72 - 0.88 0.8 J 0.99 0.90 - 1.10 1.0 J 1.2 J 1.08 - 1.32 48 1.51 1.5 J 1.35 - 1.65 1.88 1.90 1.80 - 2.20 10 2.0 J 2.5 J 40 2.25 - 2.75 2,53 60 3.0 J 2.70 - 3.30 2.66 3.5 J 3.15 - 3.85If this Section does not apply check box Long PW Calibration Table (record average output values in User mode) with a 550 μ fiber. 20 Hz 15 Hz 10 Hz 12 Hz REP. RATE: 5 Hz 8 Hz **ENERGY** TOLERANCE 0.50 0.44 0.48 50 0.44 0.48 0.45 - 0.55 0.5 J 0.54 - 0.66 0.6J0.7 J 0.63 - 0.77 0.72 - 0.88 0.8 J0.82 0.90 - 1.10 1.0 J 13 1.08 - 1.32 1.2 J 47 1.35 1.28 1.35 - 1.65 1.5 J 82 2.0 J 1.80 - 2.20 7-0 2.5 J 00 7,10 2.25 - 2.75 3.0 J 2.70 - 3.30



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Laser Serial Number: LH+ 1443 - 1116

Date: 10/10/2018

If this Section does	not apply check box [
ELECTRIC/	ELECTRICAL SAFETY TEST		TOLERANCE	MEASURED	PASS	FAIL
Grou	nd Resistance	OHMS	≤0.27			·
Unit	Forward Leakage	NAμA	≤450		The Control	
OFF	Reverse Leakage	NAµA	≤450			
Unit	Forward Leakage	NAµA	≤450			
ON	Reverse Leakage	NAµA	≤450			0.00

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:

S YAJEZ

Date:

Andres yañez Andres yañez Area Informática CENCOMEX S.A.