COOK*	Quality Management System Instruction Form Cook® Medical Incorporated						
Title:	Laser Service Report						
WARNING - CONFIDENTIAL PROPRIETARY PROPERTY			Document Number: QMSI18_09-F06 Original Date: 30Sep20			30Sep2016	
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		ledical of this	CR Number: CMI-17-187		Checked By:	18Aug2017	7
Laser Serial Number	k® Medical Incorporated 2016"	17	17 15			AB 16Aug2017	·
	ch information as pos) / C = sible in th	e form below.		L	Date: 06/11/	18
General Information							
Logor System Type	Odvasov						
Laser System Type:			H-30	<u> </u>			
	Owner (Hospital):	· LAS (0000	Under Wa		○ No	
C	ustomer Number:			Phone N	Number:	No constraints	
	Contact Person:			Tec	hnician: Long	1 Yaza	
·	Email:			When was the laser last se	erviced? O4/	18	
By whom was the las	ser last serviced?			Under Service Co	ontract? O Yes	○ No	
Current	Service Location:			Installatio	on Date:	- Contraction	
	Plug Type:						
				to illness or injury to patient o	or user? O Yes	⊘ Ño If yes, exp	olai
Was laser used for tra	eatment or diagnosis'	? () Yes	s ⊘(No	to illness or injury to patient of the control of t	or user:		blaii
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Document Number:

Quality Management System Instruction Form

Version	No.:	4
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Gentec "Maestro" Power Meter Gentec "Maestro" Target Quidade SA-2001 Safety Analyzer BC Medical SA-2001 Safety Analyzer BC Medical SA-2001 Safety Analyzer BC Medical SA-2001 Safety Analyzer Divice Manual Revision Number: BC Medical SA-2001 Safety Analyzer Divice Manual Revision Number: BC Medical SA-2001 Safety Analyzer Divice Manual Revision Number: BC Medical SA-2001 Safety Analyzer DESCRIPTION Descripti	st Calibrated Equip	ment, Tools or Te	st Equipment Used					
Gentec "Maestro" Target BC Medical SA-2001 Safety Analyzer BC Medical SA-2001 Safety Analyzer Provice Manual Revision Number: Bro replacement parts used? O Yes O No PART NUMBER/CPN LOT NUMBER DESCRIPTION Returned to COOK Capital Equipment al Resolution All Resolution WALUE INTIAL VALUE E1 E2 FINAL VALUE E1 E2 Description NIT: EXT: NIT: EXT: PPID MASSCAPREE NIT: EXT: NIT: EXT: PPID MASSCAPREE NIT: EXT: NIT: EXT: PPID MASSCAPREE NIT: EXT: OPEN: CLOSED: OPEN: CLOSED:	PART NUN	IBER/CPN		I.D. NUMBER		CALIBE	RATION DUE DA	ΤE
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Document Number: QMSI18 09-F06

Quality Management System Instruction Form Laser Service Report

Version No.: 4

Laser Serial Number: 1312-1215 Date: 06 If this Section does not apply check box [PHD Calibration Verification (data can be replaced with external data sheets, if desired) SHORT PW LONG PW CAL **PHD ADJ** PHD ADJ RATE LOW HIGH EMIN EMAX LOW HIGH EMIN EMAX 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 2.5 0.5 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 - 0.550.49 0.47 0.48 0.70 0.51 0.45 0.6 J 0.54 - 0.66 0.7 J 0.63 - 0.77 0.8 J 0.72 - 0.881.0 J 0.90 - 1.10 0.88 1.2 J 1.08 - 1.32 1.5 J 1.35 - 1.65 40 1.42 2.0 J 1.80 - 2.20 71 . 74 2.0 2.5 J 2.25 - 2.75 2 3.0 J 2.70 - 3.30 2.50 3.5 J 3.15 - 3.85 .52 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 0.48 O. 49 0.50 0.46 0.49 0.47 0.6 J 0.54 - 0.66 0.7 J 0.63 - 0.770.8 J 0.72 - 0.881.0 J 0.90 - 1.10 0.81 1.2 J 1.08 - 1.32 04 1.5 J 1.35 - 1.65 1.35 .30 2.0 J 1.80 - 2.20 50 .48 2.5 J 2.25 - 2.75 87 . B. 3.0 J 2.70 - 3.30



Document Number: QMSI18_09-F06

Quality Management System Instruction Form Laser Service Report

Version No.: 4

Laser Serial Number: LH+1312-1215

Date: 06/11/18

	not apply check box					
ELECTRIC	ELECTRICAL SAFETY TEST Ground Resistance		TOLERANCE	MEASURED	PASS	FAIL
Grou			≤0.27			I ALL
Unit	Forward Leakage	NAµA	≤450			
OFF	Reverse Leakage	NAµA	≤450			
Unit	Forward Leakage	NAµA	≤450			
ON	Reverse Leakage	ΝΑμΑ	≤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: And Source Yours

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Andres Yahez Andres Yahez Andres Yahez Area Informatica CENCOMEX S.A. 3