| COOK   | Quality Management System Instruction Form   |                                  |   |                    |                        |                          |             |  |
|--|--|----------------------------------|---|--------------------|------------------------|--------------------------|-------------|--|
| MEDICAL  | Cook® Medical Inco   |                                  |   |                    |                        |                          |             |  |
| Title:   | Laser Service Report   |                                  |   |                    |                        |                          |             |  |
|  | TIAL PROPRIETARY PROPERTY  Cook Medical. It contains confidential  | Document Num                     | her: OMSI18 00 E06  | Origin             | al Data:               | 2000=20                  | 16          |  |
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| document, the possessor expressly agrees to comply with these terms. "© COPYRIGHT Cook® Medical Incorporated 2016"   |  | CR Number: CMI-17-187            |   | Checked By: A      |                        | AB 16Au                  | 2017        |  |
| Laser Serial Numb  |  |                                  | 1317  |                    | Da                     | ate: <u>/ 4 /</u>        | 11/1        |  |
| Please fill out as muc<br>Seneral Information :  | ch information as possible   | n the form below.                |   |                    |                        |                          |             |  |
|  |  |                                  |   |                    |                        |                          |             |  |
| Laser System Type:   | Odyssey  | Ø H-30                           |   |                    |                        |                          |             |  |
|  | Owner (Hospital):  |                                  | Under Wa  | Under Warranty?    |                        | ○ No                     |             |  |
| C  | ustomer Number:  |                                  | Phone N   | lumber:            | •                      |                          |             |  |
|  | Contact Person:  |                                  |   | hnician:           | Duones                 | YANE                     | L           |  |
|  | Email:   |                                  | When was the laser last se                                  |                    |                        |                          |             |  |
| By whom was the las  |  |                                  | Under Service Co  | ontract?           | ○ Yes                  | ○ No                     |             |  |
| Current  | Service Location:  |                                  | Installatio   | Installation Date: |                        |                          |             |  |
|  | Plug Type:   |                                  |   |                    |                        |                          |             |  |
| ny information to re   |  |                                  | to illness or injury to patient o                           | or user?           | O Yes G                | √No If y                 | es, explair |  |
| Vas laser used for tre   | eatment or diagnosis? (  | ) Yes (No                        | to illness or injury to patient o                           |                    |                        |                          |             |  |
| Any information to reverse laser used for tred dditional comments: therwise leave blank of this Section does in  | eatment or diagnosis? ( (Note any recent issues :  not apply check box   | ) Yes (No                        |   |                    |                        |                          |             |  |
| Any information to re<br>Vas laser used for tre<br>dditional comments:<br>therwise leave blank<br>of this Section does in  | eatment or diagnosis? ( (Note any recent issues )  not apply check box   at Occurrence   | Yes No<br>and their resolutions. | ) Note: Only enter informatio                               |                    |                        |                          | es, explain |  |
| Any information to re  Vas laser used for tre  dditional comments:  therwise leave blank  f this Section does I  aser Use Information  Pulse Width Mod   | eatment or diagnosis? ( (Note any recent issues )  not apply check box   n at Occurrence e:  | Yes No<br>and their resolutions. | ) Note: Only enter informatio                               |                    | tional inform          |                          | eable,      |  |
| Any information to revolution  | eatment or diagnosis? (  (Note any recent issues  not apply check box   n at Occurrence e:  Short  Lor   | Yes No<br>and their resolutions. | Repetition Rate (Hz): Fiber Size(s) Used (μm):              | n if addii         | tional inform          | ation is appli           | eable,      |  |
| As laser used for tre  Idas laser used for tre  Idditional comments:  Itherwise leave blank  If this Section does is  Itaser Use Information  Pulse Width Mod  Pulse Energ  Total Energy Delivere  | eatment or diagnosis?  (Note any recent issues and apply check box  nat Occurrence e: Short Lory; d: Total 1   | Yes No and their resolutions.    | Repetition Rate (Hz):  Fiber Size(s) Used (µm):  150 200 27 | n if addin         | 8 10<br>5 550          | ation is appli           | 5 \( \) 20  |  |
| Vas laser used for tre dditional comments: therwise leave blank  f this Section does I aser Use Information Pulse Width Mod Pulse Energ Total Energy Delivere In what operational st   | not apply check box at Occurrence e: Short Lory: d: Total 1  | Yes No and their resolutions.    | Repetition Rate (Hz):  Fiber Size(s) Used (µm):  150 200 27 | n if addin         | 8 10<br>5 550          | ation is appli           | able,       |  |
| As laser used for tree diditional comments: therwise leave blank of this Section does a laser Use Information Pulse Width Mod Pulse Energy Total Energy Delivered In what operational states of this Section does in the section d | eatment or diagnosis?  (Note any recent issues  not apply check box  nat Occurrence e: Short Lor y: d: Total nate(s) was the laser when the  | Yes No and their resolutions.    | Repetition Rate (Hz):  Fiber Size(s) Used (µm):  150 200 27 | n if addin         | 8 10<br>5 550          | ation is appli           | 5 \( \) 20  |  |
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| Any information to real asser used for treal ditional comments: therwise leave blank of this Section does a leaser Use Information Pulse Width Mod Pulse Energy Total Energy Delivered In what operational states.   | eatment or diagnosis?  (Note any recent issues  not apply check box  nat Occurrence e: Short Lor y: d: Total nate(s) was the laser when the not apply check box  that was present: | Yes No and their resolutions.    | Repetition Rate (Hz):  Fiber Size(s) Used (µm):  150 200 27 | n if addin         | 8 10<br>5 550          | ation is appli           | 5 \( \) 20  |  |
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| As laser used for tree diditional comments: therwise leave blank of this Section does the leave blank of this Section does the leave leave blank of this Section does the leave leav | eatment or diagnosis?  (Note any recent issues  not apply check box  nat Occurrence e: Short Lor y: d: Total nate(s) was the laser when the not apply check box  that was present: | Yes No and their resolutions.    | Repetition Rate (Hz):  Fiber Size(s) Used (µm):  150 200 27 | n if addin         | 8 10<br>5 550          | ation is appli           | 5 \( \) 20  |  |



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## Quality Management System Instruction Form Laser Service Report

Version No.: 4

|                                   | QMS118_09-1                           |  | ······································ | Service I                              | Report       |                     |                     |          |  |
|-----------------------------------|---------------------------------------|--|--|--|--------------|---------------------|---------------------|----------|--|
| aser Serial Numbe                 |                                       | ////////////////////////////////////// | -0217                                  |  |              | Da                  | ate: <u>/ 4 / /</u> | 1/1      |  |
| t Calibrated Equipr               |                                       | est Equipment Use                      |  |  |              | T                   |                     |          |  |
| PART NUM                          | IBER/CPN                              |  | I.D. NUMBER                            |  |              | CALIE               | BRATION DUE         | DATE     |  |
| Gentec "Maestro                   |                                       |  | 242057                                 |  |              | 25/04/201           |                     |          |  |
| Gentec "Mae                       |                                       |  | 22453                                  | 3                                      |              |                     | 277                 |          |  |
| BC Medical SA-200                 | 11 Safety Analyzer                    |  |  |  |              |                     |                     |          |  |
| 4                                 | · · · · · · · · · · · · · · · · · · · |  |  | ······································ |              |                     |                     |          |  |
|                                   |                                       |  |  |  |              |                     |                     | :        |  |
| ice Manual Revision N             | lumber:                               |  |  |  |              |                     |                     |          |  |
| re replacement par                | rts used? O Ye                        | s & No                                 |  |  |              |                     |                     |          |  |
| PART NUMBER/CPN                   |                                       | LOT NUMBER                             |  |  | DESCRIPTION  |                     |                     |          |  |
|                                   |                                       |  |  |  |              |                     |                     |          |  |
| f                                 |                                       |  |  |  |              |                     |                     |          |  |
|                                   |                                       |  |  |  |              |                     |                     |          |  |
| efective Part Dispositio          | n: Disposed of                        |  | Re                                     | turned to COC                          | K Capital Eq | uipment             |                     |          |  |
| al Resolution                     |                                       |  |  |  |              |                     |                     |          |  |
| ok welcomes your fe               | eedback at capita                     | alservice@cookm                        | edical.com                             |  |              |                     |                     |          |  |
| nis Section does n                | nt annly check h                      | <u> </u>                               |  |  |              |                     |                     |          |  |
| bration                           | ot apply officiend                    | υ <b>λ</b>                             |  |  |              |                     |                     |          |  |
| VALUE                             | INITIAL VALUE                         | E1                                     | E2                                     | FINAL                                  | VALUE        | E1                  |                     | E2       |  |
| O OFFSET<br>Hz, 0.5J)             |                                       | MIN:                                   | MAX:                                   |  |              | MIN:                | MAX:                | ·        |  |
| POTENTIOMETER/COARSE<br>HZ, 3.0J) |                                       | INT:                                   | EXT:                                   |  |              | INT:                | EXT:                |          |  |
| PHD fullscale/fine<br>HZ, 3.0J)   |                                       | INT:                                   | EXT:                                   |  |              | INT:                | EXT:                |          |  |
| HD SHUTTER CLOSED                 |                                       | OPEN:                                  | CLOSED:                                |  |              | OPEN:               | CLOSED              |          |  |
| es (calibration, tunir            | ng, centration, ali                   | gnment, etc.) Note                     | e: Only enter informat                 | ion if additio                         | nal informa  | ition is annlicable | e otherwice l       | nava bla |  |
|                                   |                                       |  |  |  | indi mornie  | пеот в аррисари     | e, ourerwise i      | eave Dia |  |
|                                   |                                       |  |  |  |              |                     | - CONTRACTOR        |          |  |
|                                   |                                       |  |  |  |              |                     |                     |          |  |
|                                   |                                       |  |  |  |              |                     |                     |          |  |
|                                   |                                       |  |  |  |              |                     |                     |          |  |



3.0 J

2.70 - 3.30

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## Quality Management System Instruction Form Laser Service Report

Version No.: 4

Laser Serial Number: LHT 03/7 Date: 14/11/ 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 LOW RATE HIGH EMIN LOW EMAX 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 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 0.40 0.57 0.51 0.52 0.52 0.51 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 1.03 1.2 J 1.08 - 1.32 1.5 J 1.35 - 1.65 1.48 1.54 2.0 J 2.06 2.08 1.80 - 2.20 1.95 2.5 J 2.25 - 2.75 47 3.0 J F P 2.70 - 3.30 2.90 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. **ENERGY** TOLERANCE REP. RATE: 5 Hz 8 Hz 10 Hz 12 Hz 15 Hz 20 Hz 0.5 J 0.45 - 0.55 0.49 0.45 0.425 0.45 0.43 0.52 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 - 1.101.00 1.2 J 1.08 - 1.32 1.08 1.5 J 1.27 1.35 - 1.65 1.47 2.0 J 1.79 1.80 - 2.20 2.5 J 2.25 - 2.75 35 2.39



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## Quality Management System Instruction Form Laser Service Report

Version No.: 4

Laser Serial Number: 24+0385 - 0317

Date: 14/11/17

| Ground Resistance |                 | UNITS | TOLERANCE       | MEASURED | PASS | FAIL     |
|-------------------|-----------------|-------|-----------------|----------|------|----------|
|                   |                 | OHMS  | <u>&lt;0.27</u> |          |      |          |
| Unit              | Forward Leakage | NAµA  | ≤450            |          | 100  |          |
| OFF               | Reverse Leakage | NAµA  | <450            |          |      |          |
| Unit              | Forward Leakage | NAµA  | ≤450            |          |      | <u> </u> |
| 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: ADDRES ASEZ

Date: 14/11/17

Andres yañez Area Informática CENCOMEX S.A.