



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Litecure, LLC  
% Mr. Liang Lu  
Quality and Regulatory Manager  
250 Corporate Boulevard, Suite B  
Newark, Delaware 19702

May 13, 2013

Re: K123014  
Trade/Device Name: LiteCure Therapy System, Model LTS-1500  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and  
plastic surgery and in dermatology  
Regulatory Class: Class II  
Product Code: PDZ, ILY  
Dated: December 01, 2012  
Received: February 22, 2013

Dear Mr. Lu:

This letter corrects our substantially equivalent letter of March 29, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K123014

## Indications for Use

510 (k) Number (if known): K123014

Device Name: LiteCure Therapy System, Model L TS-1500

Indications for Use:

810 nm and 980nm wavelength:

LiteCure Therapy System, Model L TS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

980nm wavelength:

LiteCure Therapy System, Model L TS-1500 is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *Tmentagrophytes*, and/or yeasts *Candida albicans*, etc.).

Prescription Use X AND/OR Over-The-Counter Use \_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden

2013.03.28 15:26:31 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number   K123014



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Litecure, LLC  
% Liang Lu  
Quality and Regulatory Manager  
250 Corporate Boulevard, Suite B  
Newark, Delaware 19702

Letter dated: March 29, 2013

Re: K123014

Trade/Device Name: LiteCure Therapy System, Model LTS-1500  
Regulation Number: 21 CFR 890.5500, 878.4810  
Regulation Name: Infrared lamp, Laser surgical instrument for use in general and plastic surgery and in dermatology  
Regulatory Class: II  
Product Code: GEX  
Dated: December 01, 2012  
Received: February 22, 2013

Dear Liang Lu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K123014

## Indications for Use

510 (k) Number (if known): K123014

Device Name: LiteCure Therapy System, Model L TS-1500

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use \_\_\_

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden   
2013.03.28 15:26:31 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number \_\_\_K123014\_\_\_\_\_



K123014

DEPARTMENT OF HEALTH & HUMAN SERVICES

V.1 Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Litecure, LLC  
% Liang Lu  
Quality and Regulatory Manager  
250 Corporate Boulevard, Suite B  
Newark, Delaware 19702

Letter dated: March 29, 2013

Re: K123014

Trade/Device Name: LiteCure Therapy System, Model LTS-1500  
Regulation Number: 21 CFR 890.5500, 878.4810  
Regulation Name: Infrared lamp. Laser surgical instrument for use in general and plastic surgery and in dermatology  
Regulatory Class: II  
Product Code: GEX  
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Received: February 22, 2013

Dear Liang Lu:

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Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Concurrence & Template History Page  
 [THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number:

For Office of Compliance Contact Information:

[http://insideportlets.fda.gov:9010/portal/page?\\_pageid=197,415881&\\_dad=portal&\\_schema=PORTAL&org=318](http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318)

For Office of Surveillance and Biometrics Contact Information:

[http://insideportlets.fda.gov:9010/portal/page?\\_pageid=197,415881&\\_dad=portal&\\_schema=PORTAL&org=423](http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423)

<b>Digital Signature Concurrence Table</b>	
Reviewer Sign-Off	 <p>Kejing Chen  <small>Digitally signed by Kejing Chen                      DN: c=US, o=U.S. Government, ou=MHS,                      ou=FDA, ou=People, cn=Kejing Chen,                      0.9.2342.19200.100.1.1=200552696                      Date: 2013.03.27 10:09:37 -04'00'</small></p>
Branch Chief Sign-Off	 <p>Neil R Ogden                      2013.03.28 11:52:28 -04'00'</p>
Division Sign-Off	 <p>Mark N. Melkerson                      2013.03.29 09:18:08 -04'00'</p>

f:\KZC:kdm:3/27/13

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 <sup>st</sup> page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".

K123014

## Indications for Use

510 (k) Number (if known): K123014

Device Name: LiteCure Therapy System, Model L TS-1500

Indications for Use:

810 nm and 980nm wavelength:

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Prescription Use X AND/OR Over-The-Counter Use \_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden   
2013.03.28 15:26:31 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number     K123014



U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

December 12, 2012

LITECURE, LLC  
250 Corporate Blvd.  
Suite B  
NEWARK, DELAWARE 19702  
ATTN: LIANG LU

510k Number: K123014

Product: LITECURE THERAPY SYSTEM MODEL

Extended Until: 05/17/2013

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman  
Director, 510(k) Program  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and Radiological Health

Jones, Ashlee \*

---

**From:** Microsoft Outlook  
**To:** 'LIANGL@LITECURE.COM'  
**Sent:** Wednesday, December 12, 2012 2:13 PM  
**Subject:** Relayed: K123014 Extension Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

'LIANGL@LITECURE.COM' (LIANGL@LITECURE.COM) <mailto:LIANGL@LITECURE.COM>

Subject: K123014 Extension Letter

**510(k) Extension Request for K123014**

R 17

**510k Number: K123014**

**Product: LiteCure Therapy System Model LTS-1500**

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

FDA CDRH DMC  
DEC 12 2012  
Received

C/O Office of Device Evaluation  
Premarket Notification Section

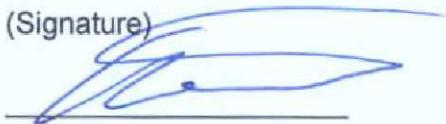
We received FDA's additional information request about Premarket Notification 510(k) review of our 510k.

We request for 180 days extension from the date of the additional information request according to FDA's policy.

We would greatly appreciate the Food and Drug Administration carrying out the above request immediate upon receipt of this communication,

LiteCure, LLC

(Signature)



(Typed Name)

LIANG LI

Date

12/10/2012

\* \* \* COMMUNICATION RESULT REPORT ( NOV. 20. 2012 2:09PM ) \* \* \*

FAX HEADER 1:  
FAX HEADER 2:

TRANSMITTED/STORED : NOV. 20. 2012 2:02PM  
F MODE OPTION

ADDRESS

RESULT

PAGE

1151 MEMORY TX

BWTEK

OK

3/3

REASON FOR ERROR  
E-1) HAND UP OR LINE FAIL  
E-3) NO ANSWER

E-2) BUSY  
E-4) NO FACSIMILE CONNECTION



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10901 New Hampshire Avenue  
Department Control Center - WO66-Q600  
Silver Spring, MD 20993-002

NOV 19 2012

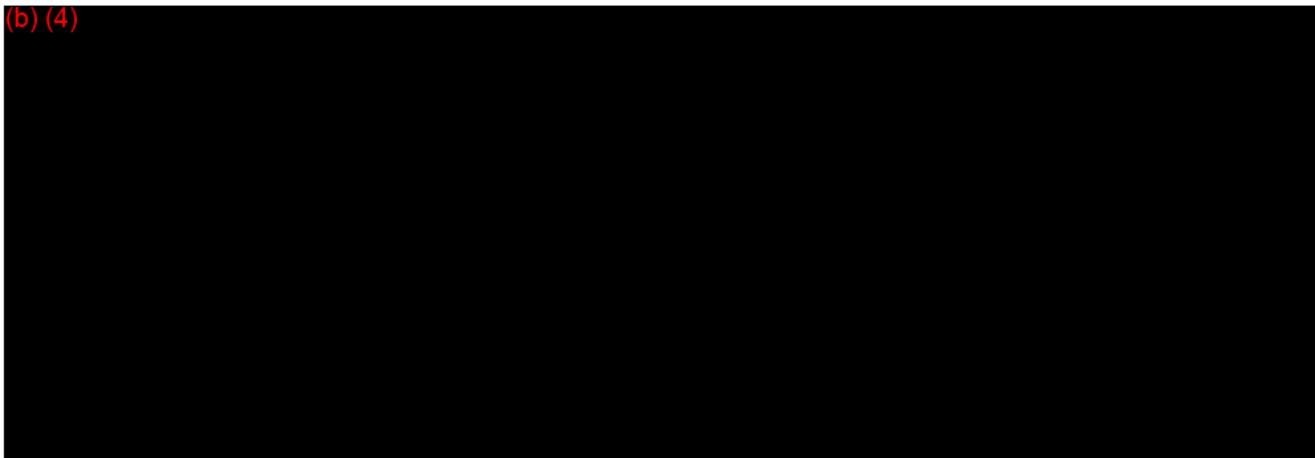
Litecure, LLC  
% Mr. M. Liang Lu  
Quality and Regulatory Manager  
250 Corporate Boulevard, Suite B  
Newark, Delaware 19702

Re: K123014  
Trade Name: Litecure Therapy System Model LTS-1500  
Dated: September 10, 2012  
Received: September 27, 2012

Dear Mr. Lu:

We have reviewed your Section 510(k) premarket notification of Intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following information:

(b) (4)



2. Software



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - W066-G609  
Silver Spring, MD 20993-002

NOV 19 2012

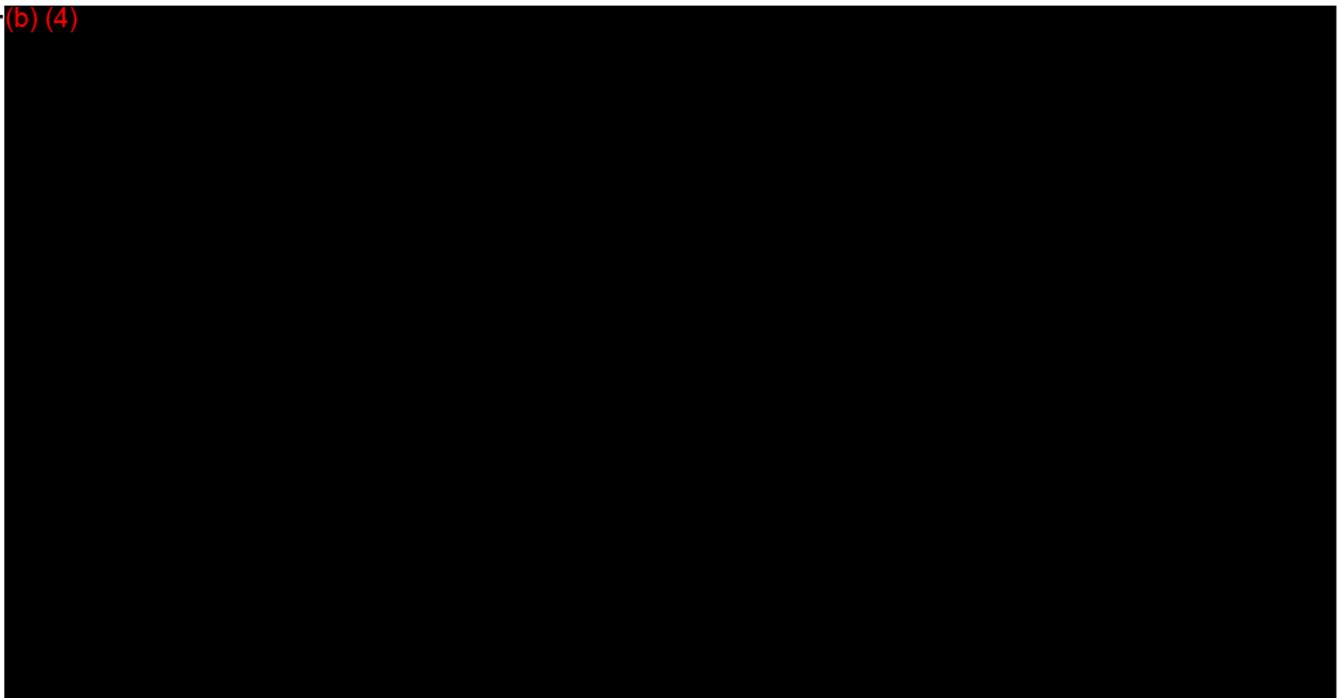
Litecure, LLC  
% Mr. M. Liang Lu  
Quality and Regulatory Manager  
250 Corporate Boulevard, Suite B  
Newark, Delaware 19702

Re: K123014  
Trade Name: Litecure Therapy System Model LTS-1500  
Dated: September 10, 2012  
Received: September 27, 2012

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(b) (4)



2. Software

(b) (4)



The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k) (21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at [www.fda.gov/cdrh/ode/guidance/1655.html](http://www.fda.gov/cdrh/ode/guidance/1655.html).

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-0609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Kejing Chen, Ph.D. at (301) 796-6390. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Neil R Ogden**

Neil Ogden, M.S.  
Chief, General Surgery Devices Branch II  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

**Concurrence & Template History Page**

[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

**Full Submission Number:**

For Office of Compliance Contact Information:

[http://insideportlets.fda.gov:9010/portal/page?\\_pageid=197,415881&\\_dad=portal&\\_schema=PORTAL&org=318](http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318)

For Office of Surveillance and Biometrics Contact Information:

[http://insideportlets.fda.gov:9010/portal/page?\\_pageid=197,415881&\\_dad=portal&\\_schema=PORTAL&org=423](http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423)

<b>Digital Signature Concurrence Table</b>	
<b>Reviewer Sign-Off</b>	
<b>Branch Chief Sign-Off</b>	
<b>Division Sign-Off</b>	

**Template Name:** K1(A) – SE after 1996

**Template History:**

<b>Date of Update</b>	<b>By</b>	<b>Description of Update</b>
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 <sup>st</sup> page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format

**Payne, Melissa T\***

---

**From:** Microsoft Outlook  
'liangl@litecure.com'  
**sent:** Monday, October 01, 2012 10:32 AM  
**Subject:** Relayed: K123014 Ack Letter/ E-Copy Attachment

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

'liangl@litecure.com' (liangl@litecure.com) <mailto:liangl@litecure.com>

Subject: K123014 Ack Letter/ E-Copy Attachment



U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

October 01, 2012

LITECURE, LLC  
250 Corporate Blvd.  
Suite B  
NEWARK, DELAWARE 19702  
ATTN: LI:ANG LU

510k Number: K123014

Received: 9/27/2012

Product: LITECURE THERAPY SYSTEM MODEL

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, “Format for Traditional and Abbreviated 510(k)s”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

**Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.**

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

## 510(k) Submission Package Checklist

Section	Descriptions
N/A	E-copy CD x 1
N/A	Letter to FDA for this 510k
1	MDUFMA Cover Sheet
2	CDRH Premarket Review Submission Cover Sheet
3	510(k) Cover Letter
4	Indications for Use Statement
5	510(k) Summary or 510(k) Statement
6	Truthful and Accuracy Statement
7	Class III Summary and Certification
8	Financial Certification or Disclosure Statement
9	Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)
10	Executive Summary
11	Device Description
12	Substantial Equivalence Discussion
13	Proposed Labeling
14	Sterilization/Shelf Life
15	Biocompatibility
16	Software
17	Electromagnetic Compatibility/Electrical Safety
18	Performance Testing – Bench
19	Performance Testing – Animal
20	Performance Testing – Clinical
21	Kit Certification

09/10/2012

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

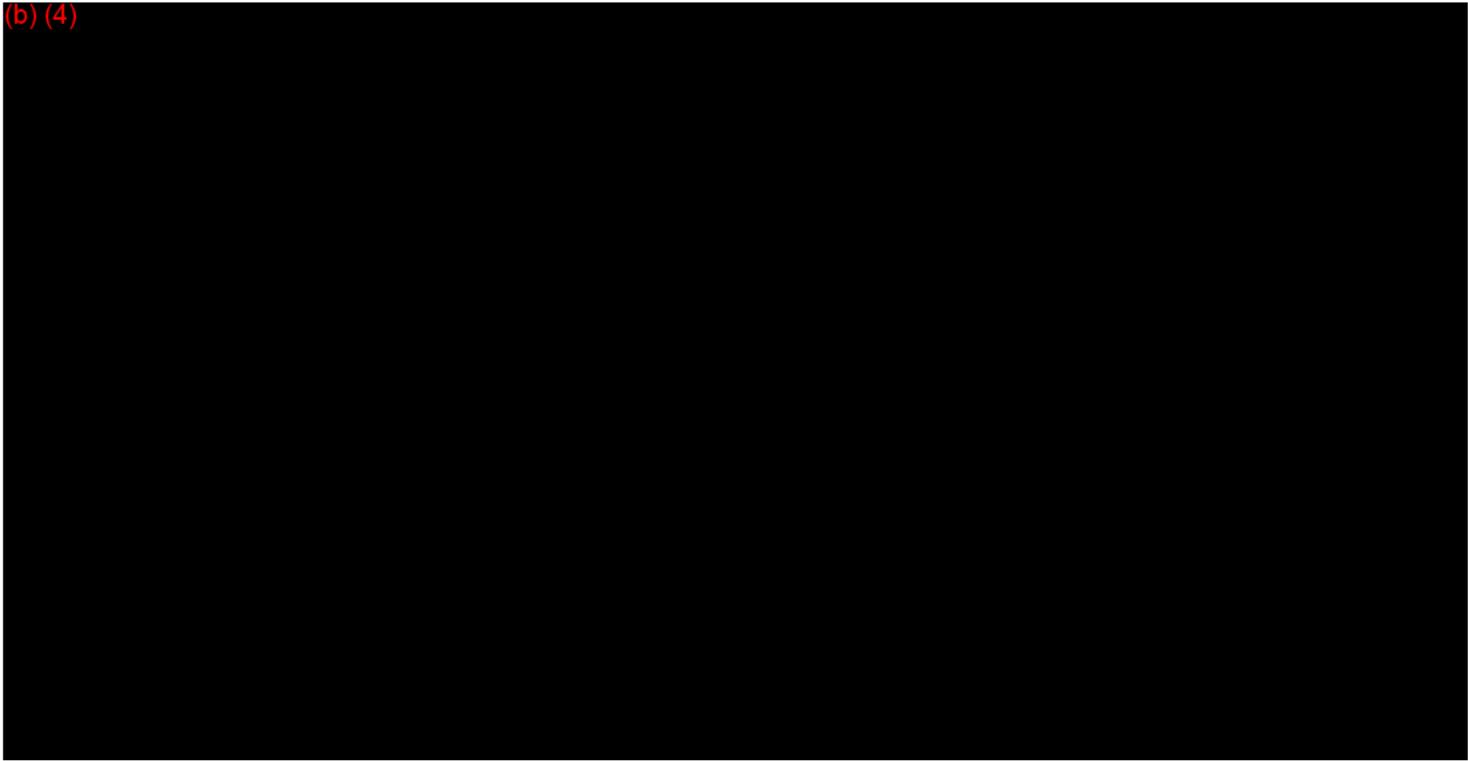
FDA CDRH DMC

SEP 27 2012

Received

Dear Madam/Sir:

(b) (4)



Sincerely,

Liang Lu

LiteCure, LLC  
Phone: (302) 709-0408 Ext: 1540  
Fax: (302) 709-3903  
Email: liangl@litecure.com

# SECTION /

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/coversheet.html">http://www.fda.gov/oc/mdufma/coversheet.html</a>		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  LITECURE LLC 250 Corporate Blvd., Suite B Newark DE 19702 US	2. CONTACT NAME Liang Lu 2.1 E-MAIL ADDRESS liangl@lifecure.com 2.2 TELEPHONE NUMBER (include Area code) 302-7090408 1540 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b) (4)		
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <a href="http://www.fda.gov/oc/mdufma">http://www.fda.gov/oc/mdufma</a> ) <u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		
3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)		
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <a href="http://www.fda.gov/cdrh/mdufma">http://www.fda.gov/cdrh/mdufma</a> for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates. <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only. <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially		
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.  Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b) (4)		11-Jun-2012

Form Approved: OMB No. 0916-511. See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/cover-sheet.html">http://www.fda.gov/oc/mdufma/cover-sheet.html</a>			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  LITECURE LLC 250 Corporate Blvd., Suite B Newark DE 19702 US  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b) (4)		2. CONTACT NAME Liang Lu 2.1 E-MAIL ADDRESS liangl@litechure.com 2.2 TELEPHONE NUMBER (include Area code) 302-7090408 1540 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <a href="http://www.fda.gov/oc/mdufma">http://www.fda.gov/oc/mdufma</a> ) Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice			
		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <a href="http://www.fda.gov/cdrh/mdufma">http://www.fda.gov/cdrh/mdufma</a> for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.  Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b) (4)		11-Jun-2012	

Form FDA 3601 (01/2007)

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# SECTION

2

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Date of Submission 9/1/2012	User Fee Payment ID Number (b) (4)	FDA Submission Document Number (if known)
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**SECTION A TYPE OF SUBMISSION**

<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Meeting</b> <input type="checkbox"/> Pre-510(k) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission?  Yes  No (If Yes, please complete Section I, Page 5)

**SECTION B SUBMITTER, APPLICANT OR SPONSOR**

Company / Institution Name LiteCure, LLC	Establishment Registration Number (if known) 3006268867		
Division Name (if applicable)	Phone Number (including area code) ( 302 ) 7090408 Ext 1540		
Street Address 250 Corporate Blvd, Suite B	FAX Number (including area code) ( 302 ) 7093903		
City Newark	State / Province Delaware	ZIP/Postal Code 19702	Country USA
Contact Name Liang Lu			
Contact Title Quality and Regulatory Manager		Contact E-mail Address liangl@litecure.com	

**SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)**

Company / Institution Name			
Division Name (if applicable)	Phone Number (including area code) ( )		
Street Address	FAX Number (including area code) ( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

**SECTION D1**

**REASON FOR APPLICATION - PMA, PDP, OR HDE**

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		

**SECTION D2**

**REASON FOR APPLICATION - IDE**

<input type="checkbox"/> New Device New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor  <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Reponse to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (specify):		

**SECTION D3**

**REASON FOR SUBMISSION - 510(k)**

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (specify):		

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	ILY	2	GEX	3	
-		6		7	
				<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K103511	1	LiteCure Therapy System, Model LTS-1500	1	LiteCure, LLC
2	K110375	2	Blueshine's GOLD series	2	Blueshine srl
3		3		3	
4		4		4	
5		5		5	
6		6		6	

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification  
 Infrared Lamp, Powered Laser Surgical Instrument

	Trade or Proprietary or Model Name for This Device		Model Number
1	LiteCure Therapy System	1	LTS-1500
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission  
 Laboratory Testing     Animal Trials     Human Trials

**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code ILY, GEX	C.F.R. Section (if applicable) 890.5500 890.4810	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Physical Medicine General and Plastic Surgery Devices		

Indications (from labeling)

810nm and 980nm wavelength:

LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

---  
nm wavelength:

LiteCure Therapy System, Model LTS-1500 is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *Tmentagrophytes*, and/or yeasts *Candida albicans*, etc.).

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

**SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 3006268867	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name LiteCure, LLC		Establishment Registration Number 3006268867		
Division Name (if applicable)		Phone Number (including area code) ( 302 ) 7090408 Ext 1540		
Street Address 250 Corporate Blvd., Suite B		FAX Number (including area code) ( 302 ) 7093903		
City Newark		State / Province Delaware	ZIP/Postal Code 19702	Country USA
Contact Name Liang Lu		Contact Title Quality and Regulatory Manager		Contact E-mail Address liangl@litecure.com

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name (if applicable)		Phone Number (including area code) (   )		
Street Address		FAX Number (including area code) (   )		
City		State / Province	ZIP/Postal Code	Country
Contact Name		Contact Title		Contact E-mail Address

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name (if applicable)		Phone Number (including area code) (   )		
Street Address		FAX Number (including area code) (   )		
City		State / Province	ZIP/Postal Code	Country
Contact Name		Contact Title		Contact E-mail Address

## SECTION I

## UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	IEC	Medical electrical equipment - Part 1:General requirements for safety (2nd Edition)	2nd Edition	12/30/1988
2	60601-1	IEC	Medical electrical equipment - Part 1:General requirements for safety (Amendment 1)	Amendment 1	11/13/1991
3	60601-1	IEC	Medical electrical equipment - Part 1:General requirements for safety (Amendment 2)	Amendment 2	3/7/1995
4	60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 2:2001)	Edition 2	1/1/2001
5	60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Amendment 1:2004)	Amendment 1	1/1/2004
6	60601-2-22	IEC	1995, 2nd Edition, Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment	Ed. 2.0	11/8/1995
7	60825-1	IEC	Ed. 2.0 (2007), Safety of laser products - Part 1: Equipment classification, and requirements	Ed. 2.0	3/30/2007

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration  
CDRH (HFZ-342)  
9200 Corporate Blvd.  
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

## SECTION I

## UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	10993-1	ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	Edition 4	10/13/2009
2	10993-5	ISO	Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity	Edition 3	5/20/2009
3	10993-10	ISO	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity	Edition 2	1/1/2002
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration  
CDRH (HFZ-342)  
9200 Corporate Blvd.  
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

# SECTION

3

**510(k) Notification****510(k) Notification Submitter:**

LiteCure, LLC  
250 Corporate Blvd., Suite B  
Newark, Delaware USA 19702

FDA CDRH DMC

SEP 27 2012

Received *K22***Official contact person authorized by the submitter:**

Liang Lu  
LiteCure, LLC  
250 Corporate Blvd., Suite B, Newark, Delaware 19702 USA  
Phone: (302) 709-0408 Ext 1540 Fax: (302) 709-3903 Email: liangl@litecure.com

**Type of 510(k) submission:** Traditional**Trade/Device Name:** LiteCure Therapy System, Model LTS-1500**Common Name of Device:** Infrared Lamp, Powered Laser Surgical Instrument**Recommended classification regulation:** 21 CFR 890.5500 and 21 CFR 890.4810**Class:** II**Panel:** Physical Medicine, General and Plastic Surgery Devices**Product code:** ILY, GEX**Basis for the Submission**

The basis for the 510(k) Notification is based on the special 510(k). The modification does not affect the intended use of the device or alter the fundamental scientific technology of the device.

**Design and Use of the Device**

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? *	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)? *		X
Does the device contain components derived from a tissue or other biologic source		X
Is the device provided sterile		X
Is the device intended for single use		X
Is the device a reprocessed single use device		X
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

\*A device may be intended for both prescription and over-the-counter use. If so, the answer to both of these questions is yes.

# SECTION

4



# SECTION

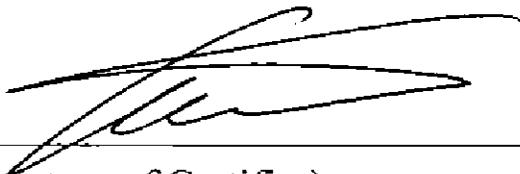
5

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## Premarket Notification 510(k) Statement

### (As Required By 21 CFR 807.93)

I certify that, in my capacity as Quality and Regulatory Manager of LiteCure, LLC I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.



\_\_\_\_\_  
(Signature of Certifier)

LIANG LU

\_\_\_\_\_  
(Typed Name)

9/10/2012

\_\_\_\_\_  
(Date)

NONE

\_\_\_\_\_  
\*(Premarket Notification [510(k)] Number)

# SECTION

6

## Section 6 Truthful and Accuracy Statement

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### Premarket Notification Truthful and Accurate Statement

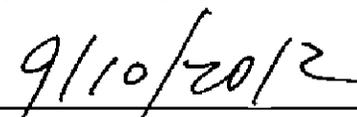
[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Quality and Regulatory Manager of LiteCure, LLC, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

  
\_\_\_\_\_  
(Signature)

Liang Lu

\_\_\_\_\_  
(Typed Name)

  
\_\_\_\_\_  
(Date)

  
\_\_\_\_\_  
\*(Premarket Notification [510(k)] Number)

## **Section 7 Class III Summary and Certification**

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### **Premarket Notification Class III Certification and Summary**

**[As Required by 21 CFR 807.94]  
(To be submitted when claiming equivalence to a Class III device)**

**NOT APPLICABLE**

**NOT APPLICABLE**

**Section 9 Declarations of Conformity and Summary Reports  
(Abbreviated 510(k)s)**

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**NOT APPLICABLE**

# SECTION

10

## Section 10 Executive Summary

### Concise description of the device

LifeCure Therapy System, Model LTS-1500 is a compact medical laser system (b)(4) Trade Secret Process -Product Specs

### Intended Use

810nm and 980nm wavelength:

LifeCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

980nm wavelength:

LifeCure Therapy System, Model LTS-1500 is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Tmentagrophytes, and/or yeasts Candida albicans, etc.).

### Concise Summary for Standard Compliance

- 1) Skin Temperature Measurement  
Refer to the Skin Temperature Measurement in Section 18 Performance Testing – Bench
- 2) Software Validation Test  
Refer to the DOC000100A Software Validation Test LTS-1500 in Section 16 Software
- 3) Risk Analysis LTS-1500  
Refer to the Risk Analysis LTS-1500 Report in Section 11 Device Description
- 4) IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995 (2nd Edition).  
Refer to the Report#100169008BOX-003 Section 18 Performance Testing – Bench

## Section 10 Executive Summary

- 5) IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004);  
Section 18 Performance Testing – Bench
- 6) IEC 60601-2-22 1995, 2nd Edition, "Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment"  
Section 18 Performance Testing – Bench
- 7) IEC 60825-1 Ed. 2.0 (2007), Safety of laser products - Part 1: Equipment classification, and requirements.  
Section 18 Performance Testing – Bench
- 8) ISO 10993-5: 2009. Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity  
Section 15 Biocompatibility
- 9) ISO 10993-10: 2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity  
Biocompatibility

### Product History

We got K103511 for our product "LiteCure Therapy System, Model LTS-1500". This submission is to add the following new intended use which is used by predicate device K110375 Blueshine's GOLD series.

980nm wavelength:

LiteCure Therapy System, Model LTS-1500 is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Tmentagrophytes, and/or yeasts Candida albicans, etc.).

Our LTS-1500 device can select dual wavelengths output (810nm and 980nm) or just a single wavelength (980nm).

When single wavelength (980nm) is selected then LTS-1500 has the same wavelength as predicate device and similar power.

For the LTS-1500 device, there is no design change.

### Comparison Table

## Section 10 Executive Summary

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Please refer to the Comparison Table in Substantial Equivalence Discussion in Section 12.

The proposed device is as safe and effective as the predicate devices. The proposed device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences between the proposed device and its predicate devices raise no new issues of safety or effectiveness. Thus, our device is substantially equivalent to its predicate devices.

**SECTION**

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## Section 11 Device Description

### Device Description

LiteCure Therapy System, Model LTS-1500 is a compact medical laser system. The laser light delivery system consists of a flexible optical fiber threaded through a lightweight handpiece. Activation occurs when the operator enables the laser and presses the foot/finger switch. Depending on laser system configuration, the foot/finger switch can function as on/off switch. A touch-screen display panel allows the operator to adjust or set laser output level. The laser can operate in continuous wave mode or controlled pulse mode.

#### NOTE:

**LTS-1500 treatment laser output has two wavelengths (810nm and 980nm). User can choose the either dual wavelength (810nm& 980nm) or single wavelength (980nm) by settings on touch screen display.**

### Intended Use

810nm and 980nm wavelength:

LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

980nm wavelength:

LiteCure Therapy System, Model LTS-1500 is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *Tmentagrophytes*, and/or yeasts *Candida albicans*, etc.).

## Main Unit

### Front View

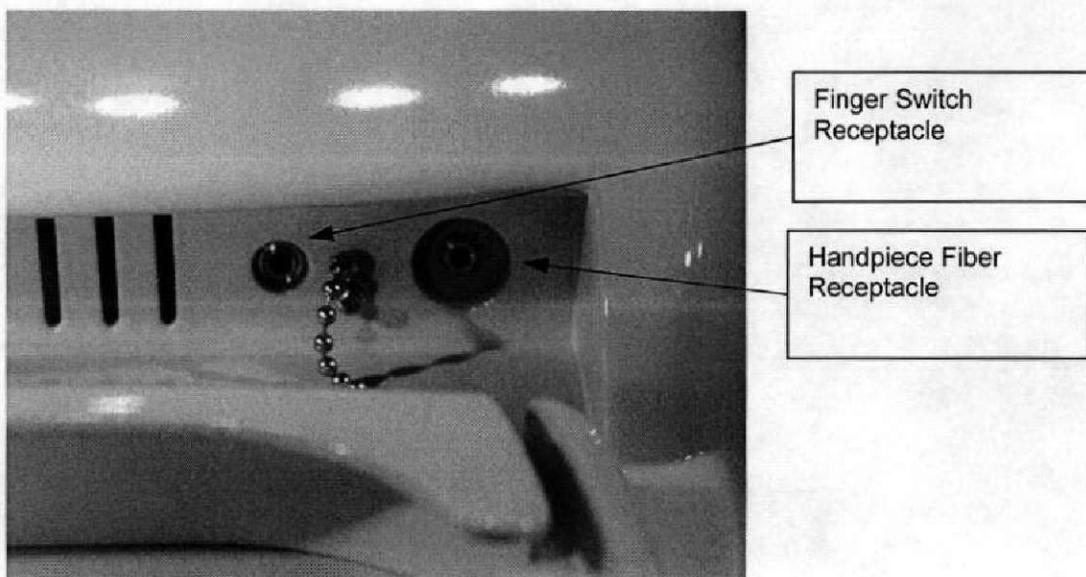
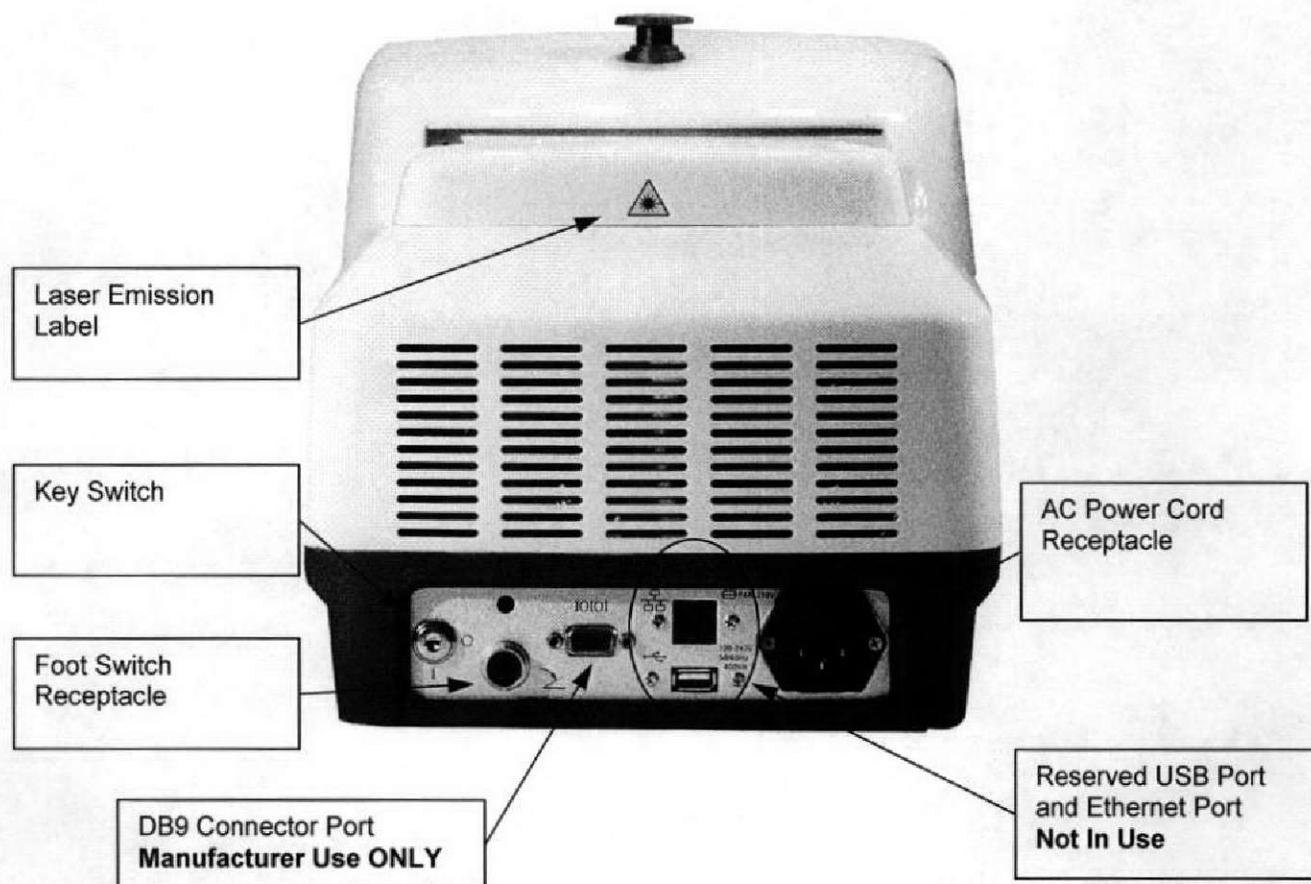


## Section 11 Device Description

<b>Model</b>	LTS-1500
<b>Laser type</b>	Solid State laser (Class IV)
<b>Treatment laser wavelength</b>	810+/-10nm, 980+/-10nm
<b>Aiming beam wavelength</b>	650+/-15nm
<b>Aiming beam power</b>	3.5mW+/-1.0mW
<b>Maximum output power</b>	15W @ aperture of hand piece
<b>Output port</b>	Hand piece
<b>Operating modes</b>	Continuous Wave (CW)
	Pulse Wave (50% duty cycle) 2, 10, 20, 100, 200, 500, 1000, 2500, 5000, 10000Hz
<b>Audio warning signal level</b>	45 to 65 dB
<b>Cooling</b>	Thermal Electrically Cooled with Forced Air
<b>Weight</b>	<30 lbs
<b>Dimensions</b>	413mm(L)x264mm(W)x257mm(H)
<b>Power requirement</b>	100-240V~ 50/60Hz 400VA
<b>Operation temperature</b>	10°C to 35 °C
<b>Storage temperature</b>	-20 °C to 70 °C

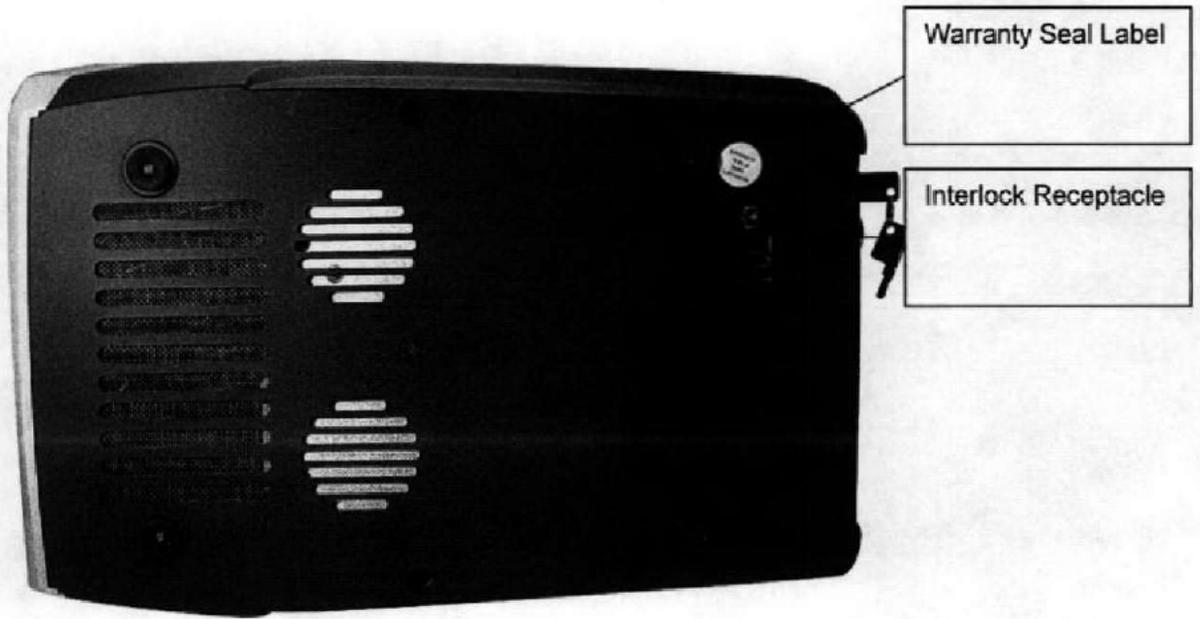
## Section 11 Device Description

### Rear View

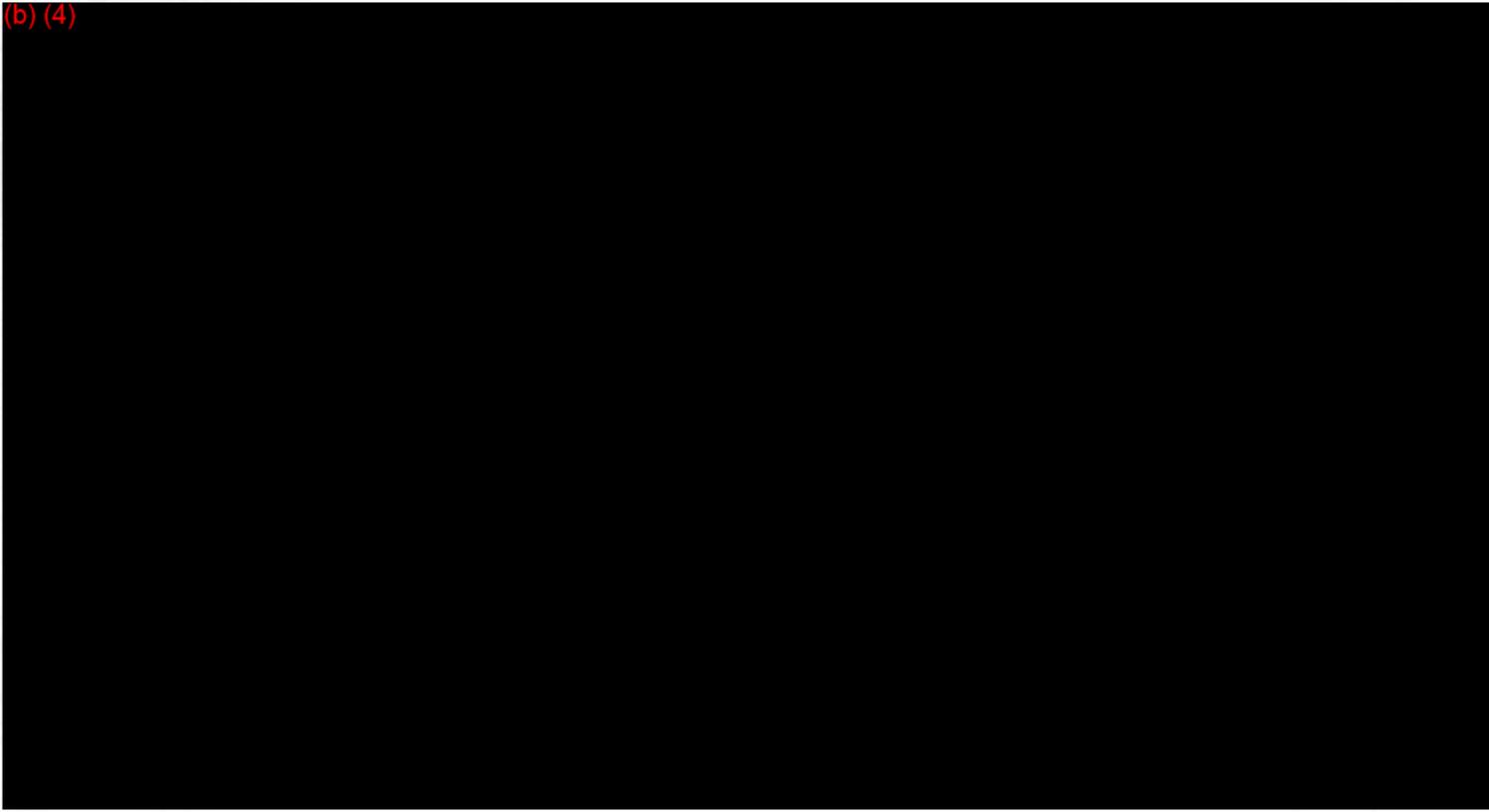


## Section 11 Device Description

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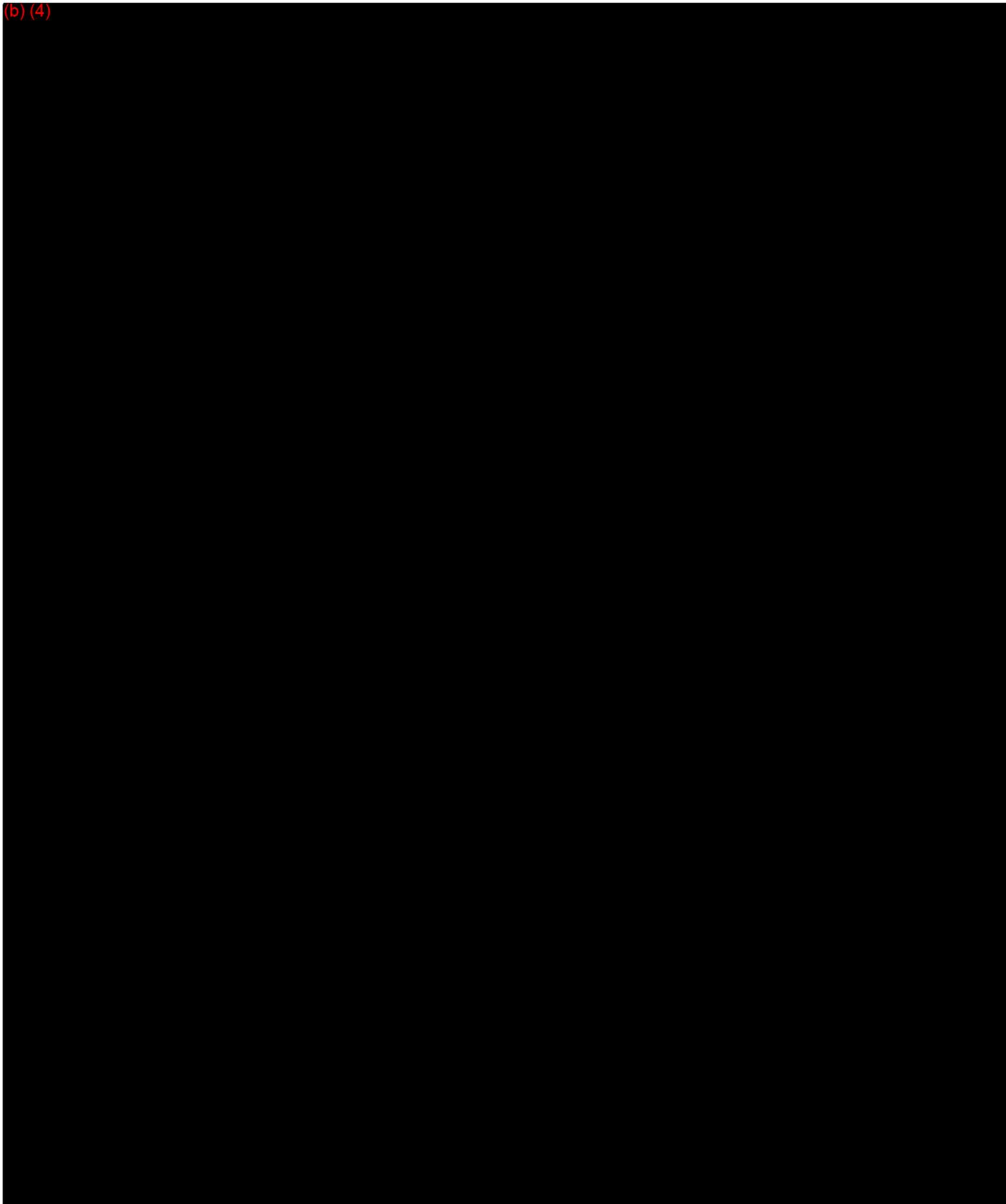
(b) (4)



## Section 11 Device Description

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(b) (4)



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**\*CONFIDENTIAL\***

## Section 11 Device Description

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1. Emergency Power Off Switch

This Emergency Power Off Switch shall stop the emission of laser output as fast as possible to prevent danger to any person.

2. Display LED Indicator

The LED provides a visual indication when the display is on.

3. Handpiece Fiber Receptacle

The handpiece fiber receptacle permits the fiber insertion.

4. Finger Switch Receptacle

The finger switch receptacle permits the finger switch connector insertion.

5. Key Switch

This switch uses a key to prevent unauthorized unit operation. The key will not be removable in the on position. It will be removable in the off position.

6. Safety Interlock

The unit will need a closed circuit to operate. This switch cuts off laser energy only. The power to the internal circuitry and displays will remain on.

7. Footswitch Receptacle

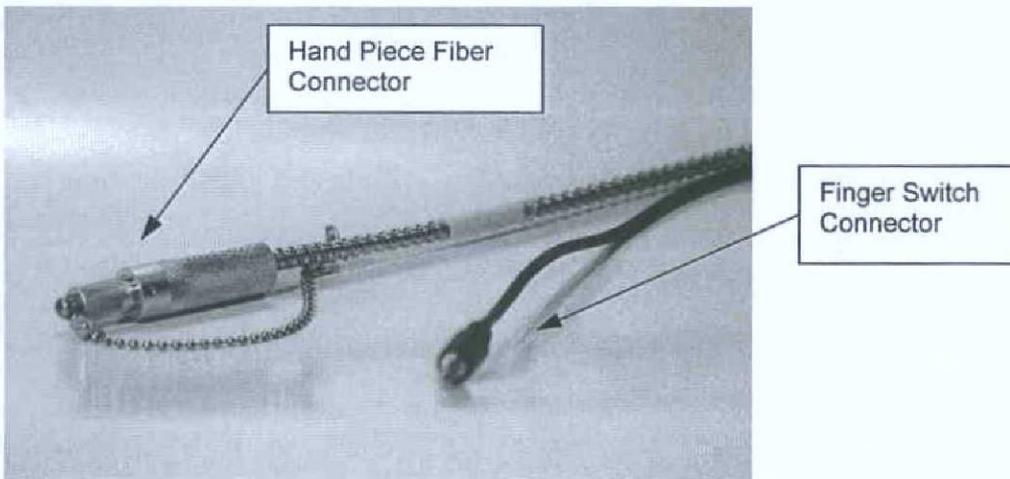
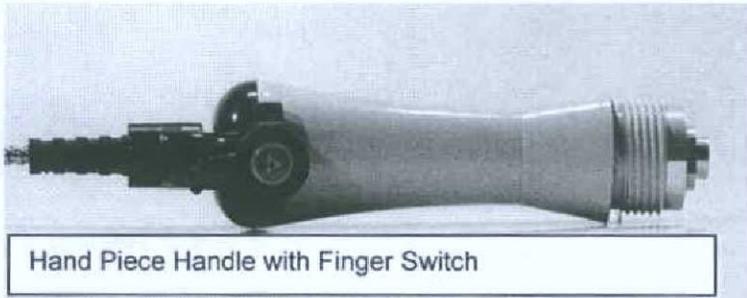
The footswitch receptacle permits the footswitch connector insertion.

8. AC Input Power Cord Receptacle

100-240 VAC/ 50-60Hz Power Cord connection.

## Accessories

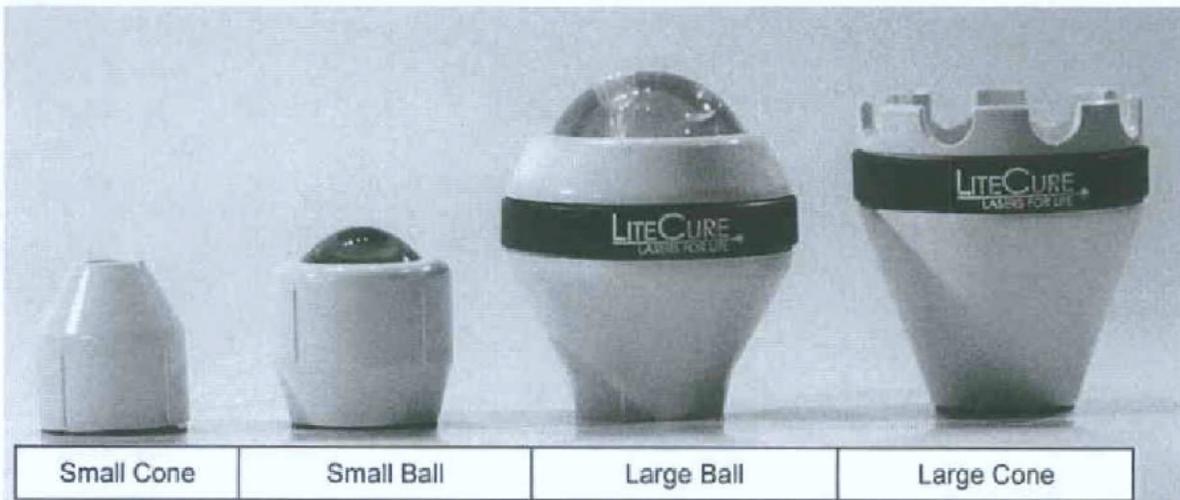
### Hand Piece



## Section 11 Device Description



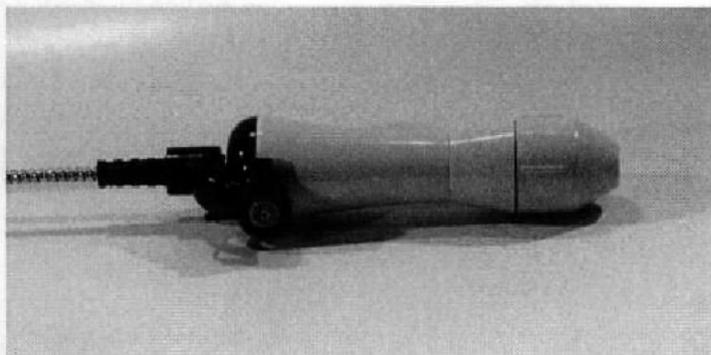
(b)(4) Trade Secret Process - Product Specifications



(b)(4) Trade Secret Process - Product Specifications

## Section 11 Device Description

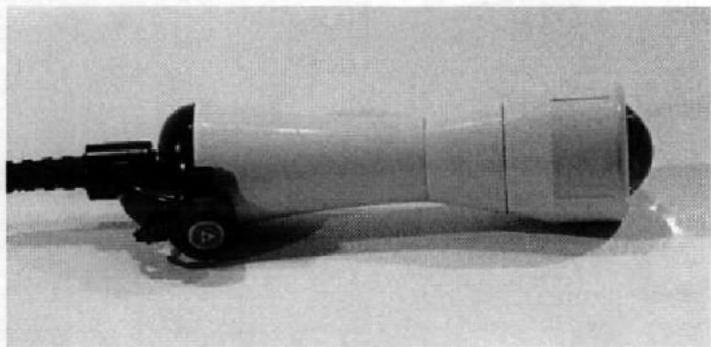
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Unit: mm

Hand Piece Handle + Finger Switch + Small Cone

(b)(4) Trade Secret Process - Product Specifications

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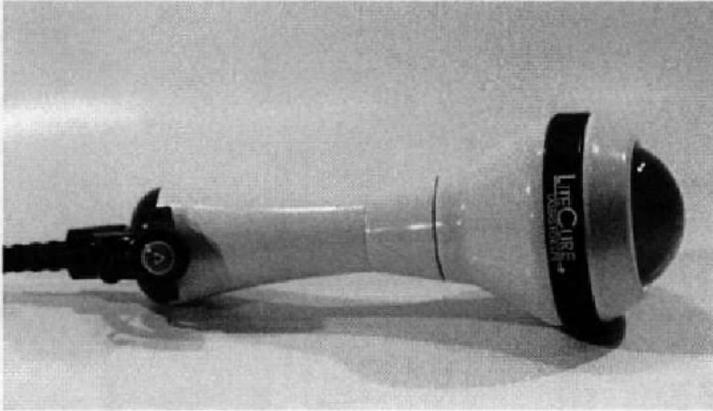
Unit: mm

Hand Piece Handle + Finger Switch + Small Ball

(b)(4) Trade Secret Process - Product Specifications

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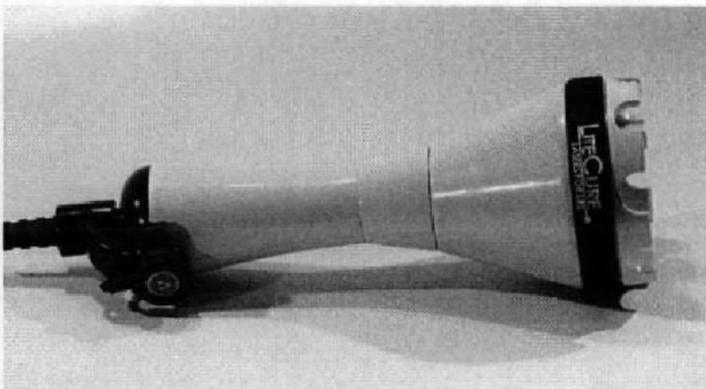
## Section 11 Device Description



Unit: mm

Hand Piece Handle + Finger Switch + Large Ball

(b)(4) Trade Secret Process - Product Specifications



Unit: mm

Hand Piece Handle + Finger Switch + Large Cone

(b)(4) Trade Secret Process - Product Specifications



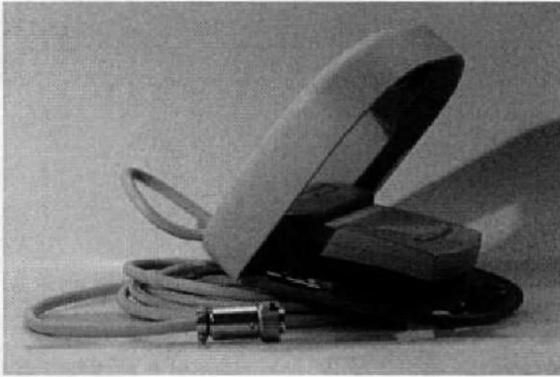
**\*CONFIDENTIAL\***

## Section 11 Device Description

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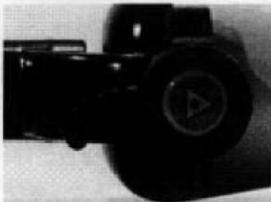
### Foot Switch

(b)(4) Trade Secret Process - Product Specifications

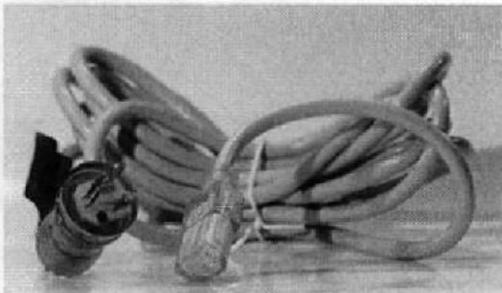


### Finger Switch

(b)(4) Trade Secret Process - Product Specifications



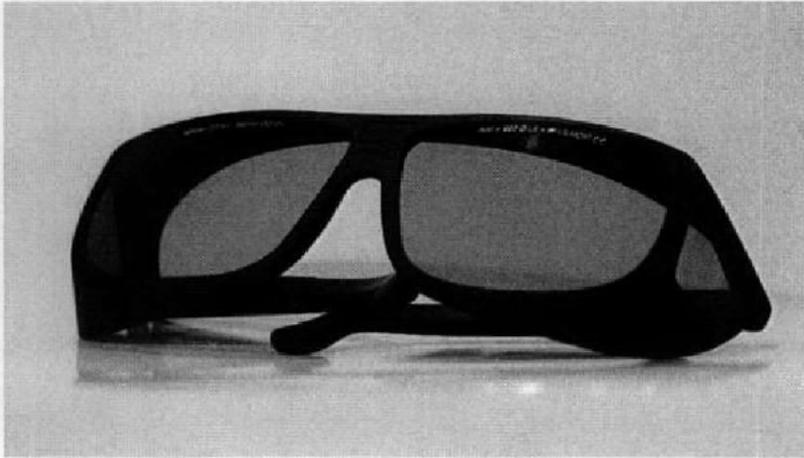
### Power Cord



## Section 11 Device Description

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### Laser Safety Eyewear



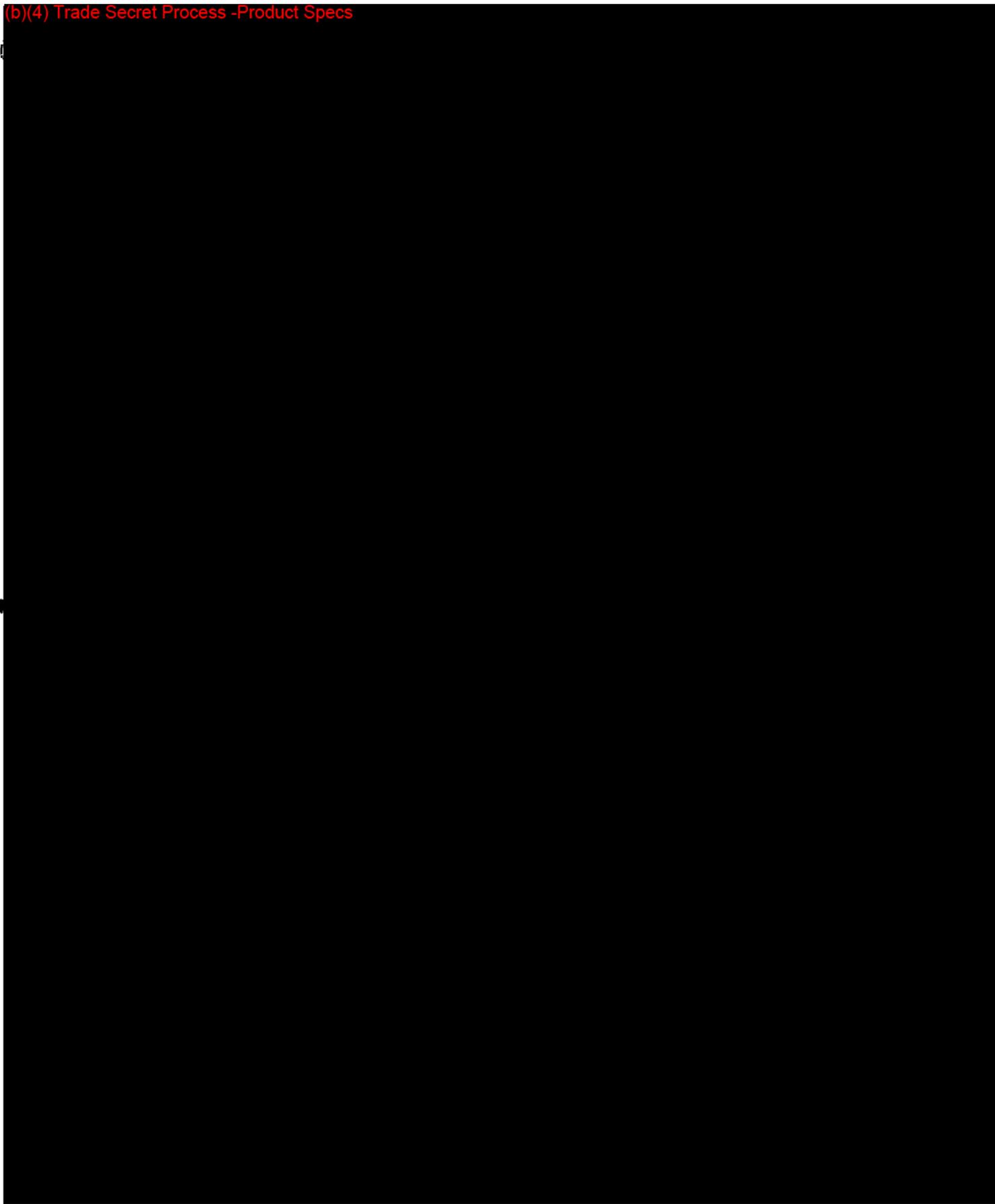
(b)(4) Trade Secret Process - Product Specifications



## Section 11 Device Description

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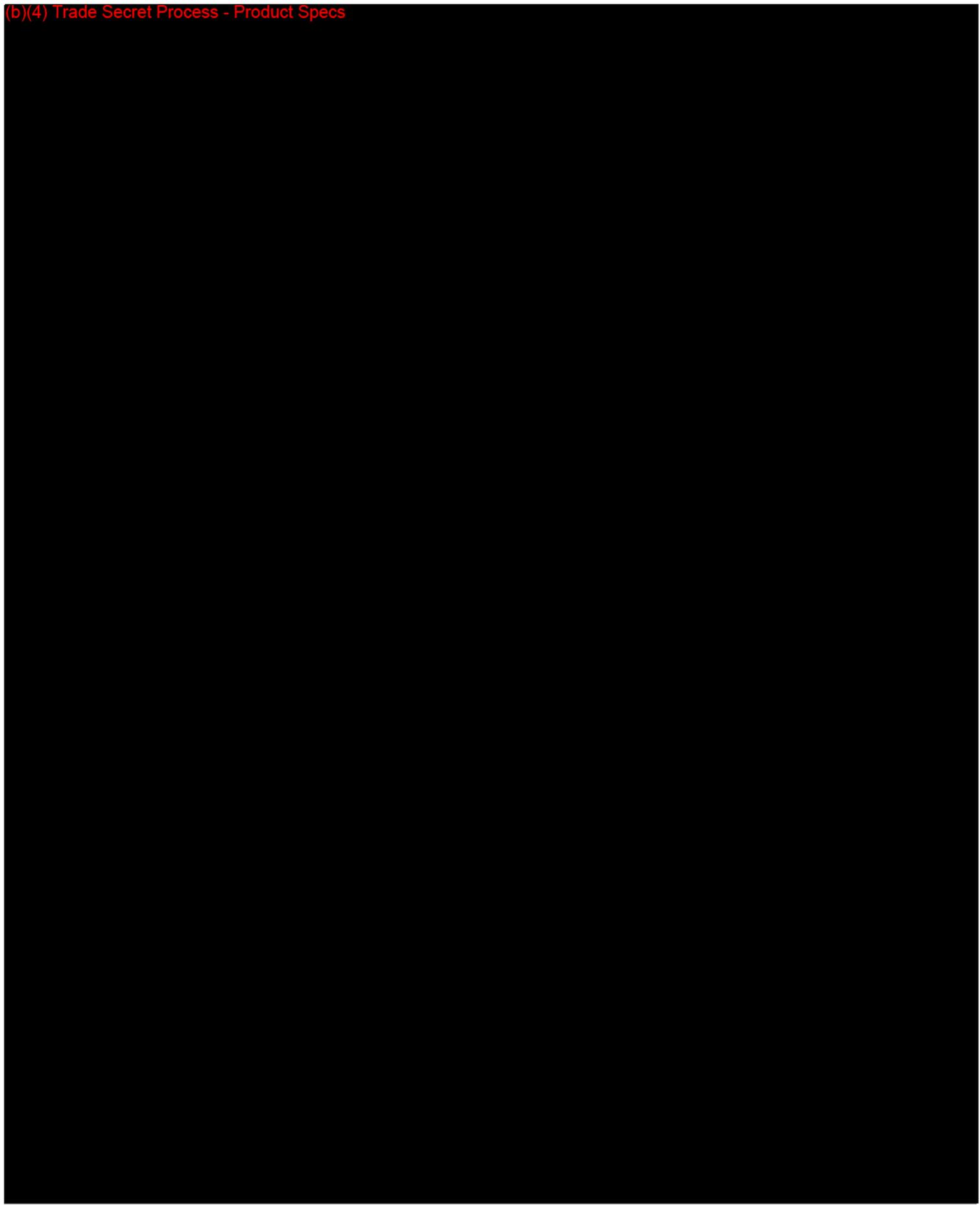
(b)(4) Trade Secret Process -Product Specs



## Section 11 Device Description

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(b)(4) Trade Secret Process - Product Specs



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**\*CONFIDENTIAL\***

## Section 11 Device Description

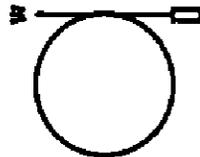
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### Warranty Seal Label

Labels are positioned on the underside of the laser device in such a way that any attempt to open



### Optical Fiber Applicator Label



### Laser Emissions Label



### Emergency Laser Off Label



### Finger/foot Switch Label

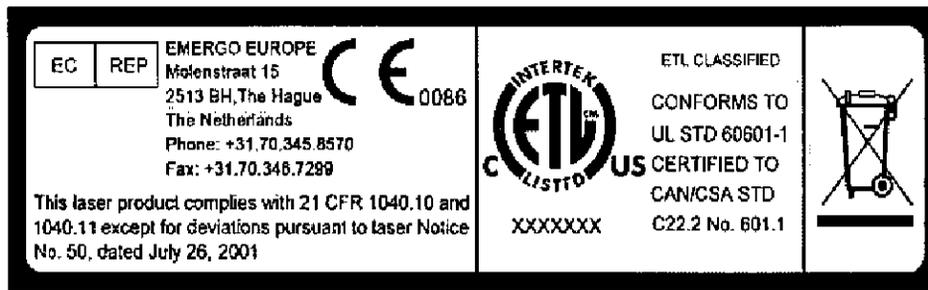


### Remote Interlock Connector Label



# Section 11 Device Description

## ETL Mark Label



## Fuse Label



## AC Power Input Label

100-240V~ 50/60Hz, 400VA

## Protective Earth (Ground) Label (Inside device)



## Mains ON Label



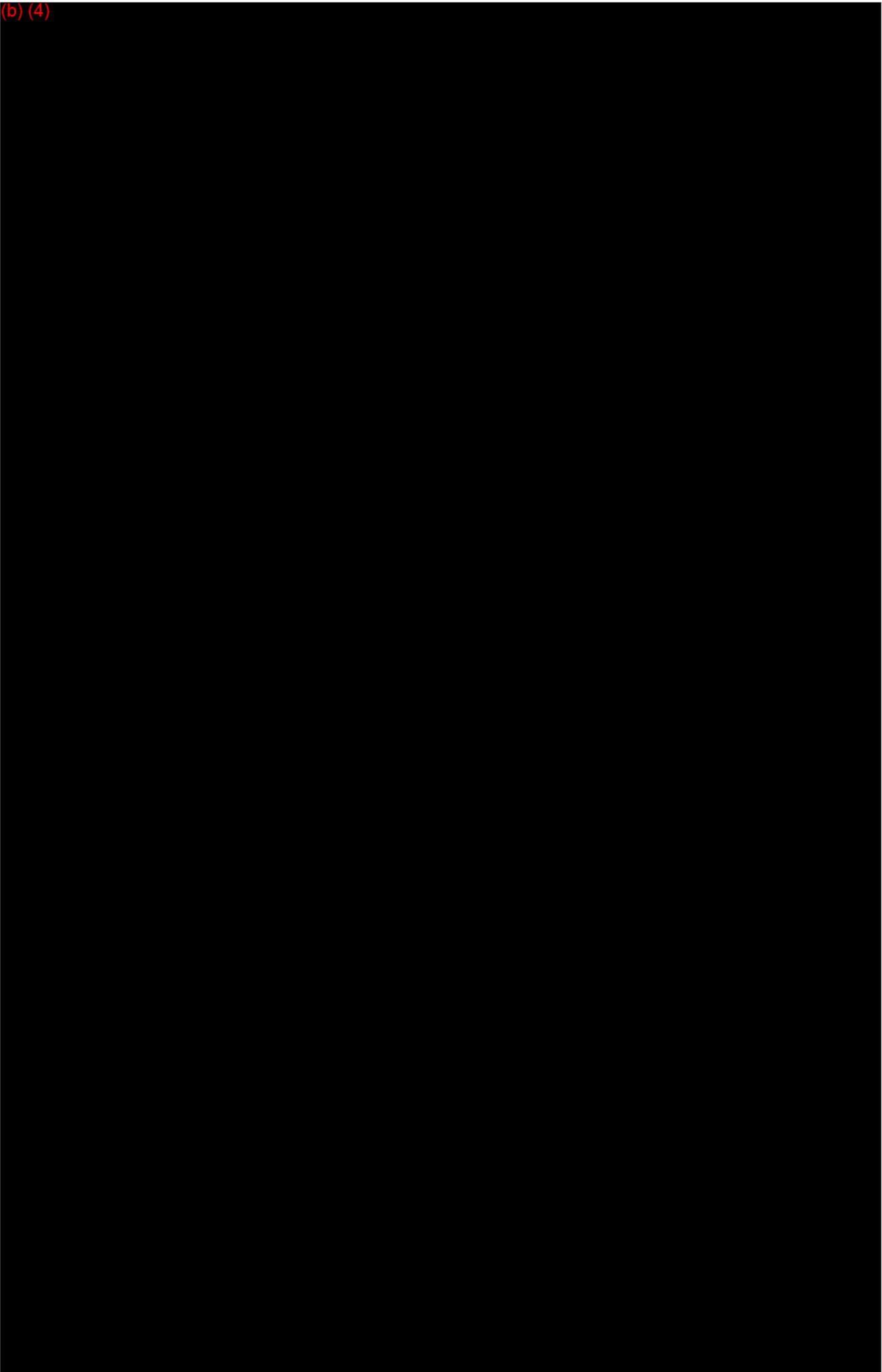
## Mains OFF Label



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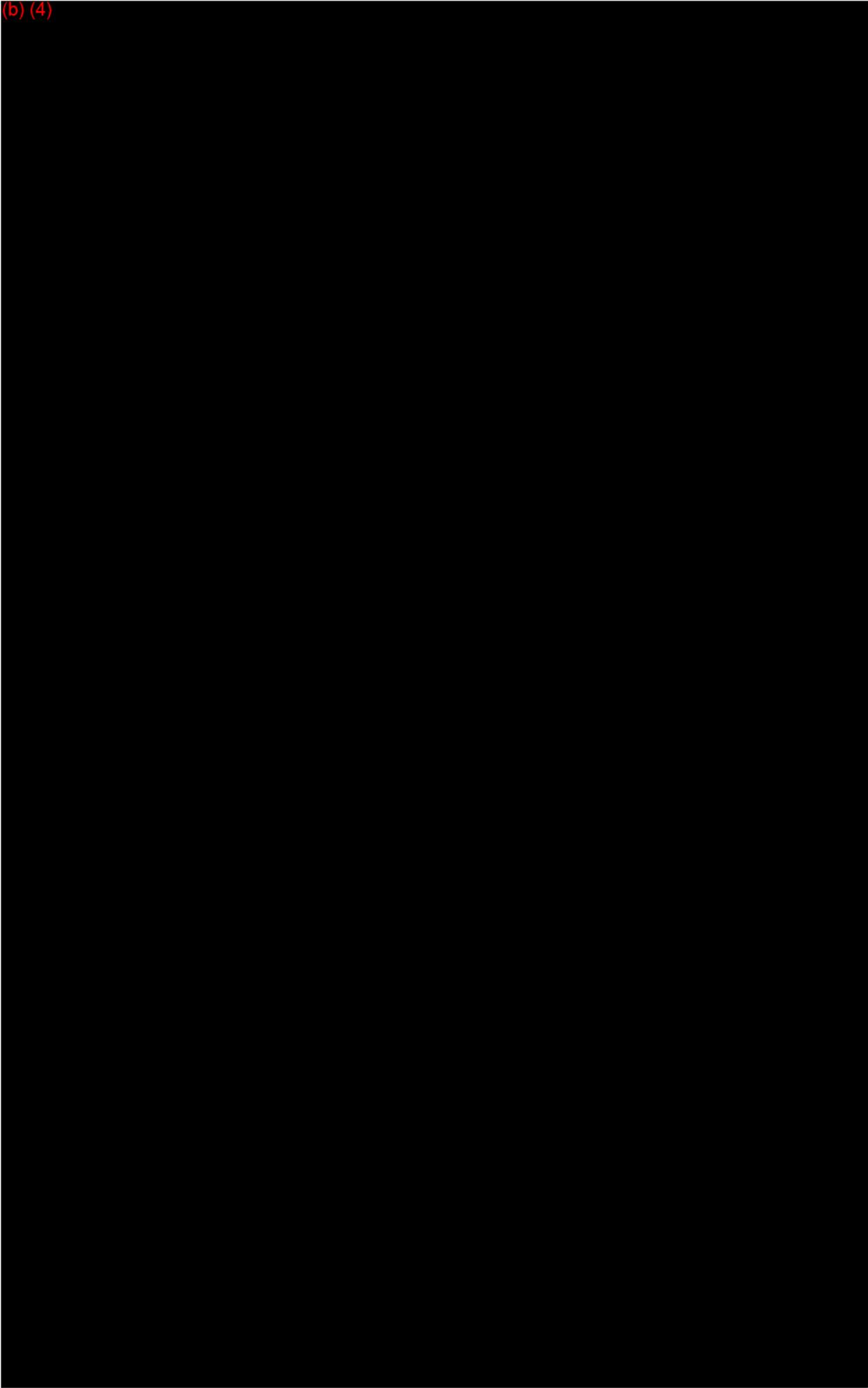
**Risk Analysis LTS-1500**

(b) (4)



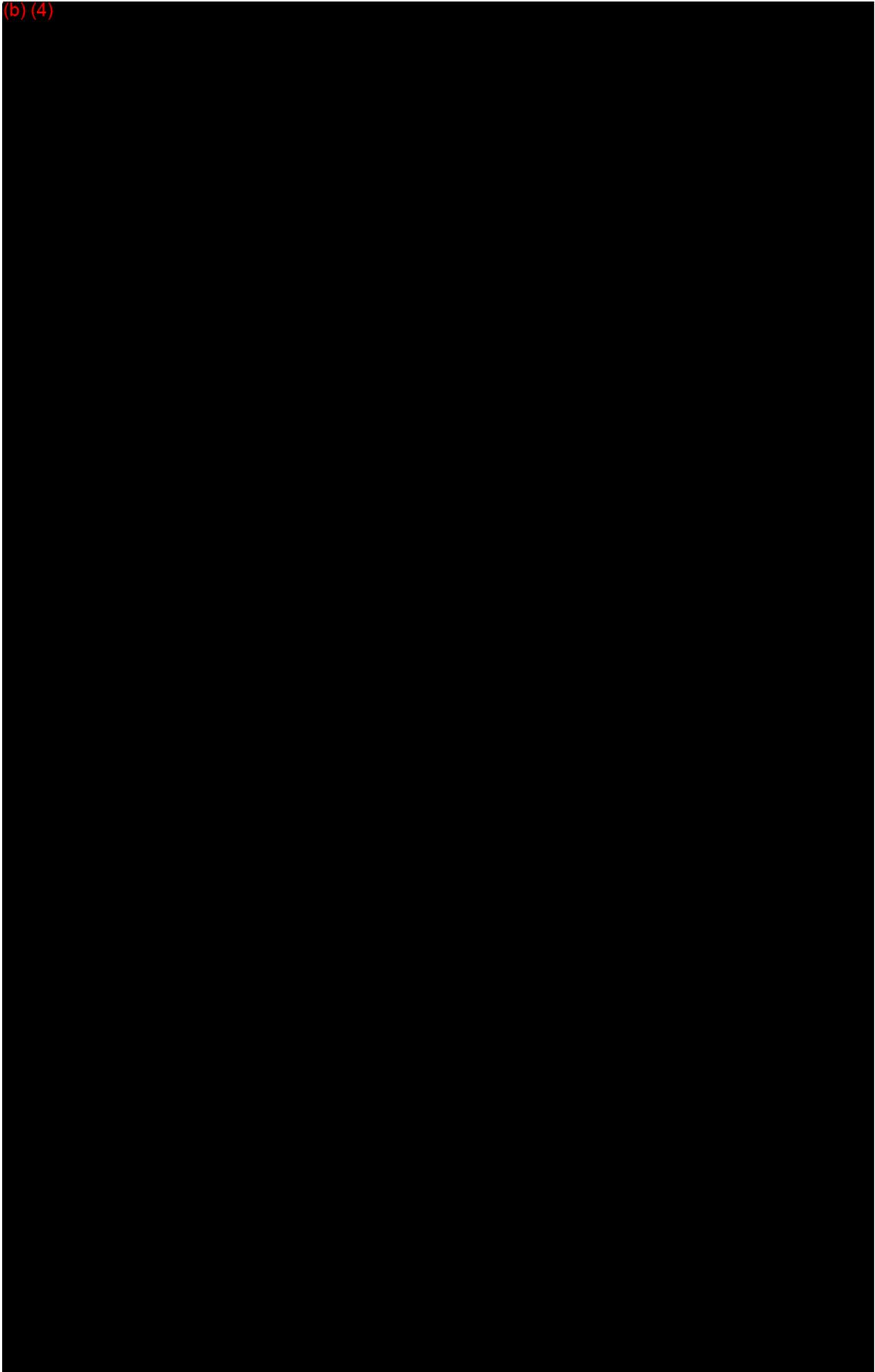
**Risk Analysis LTS-1500**

(b) (4)



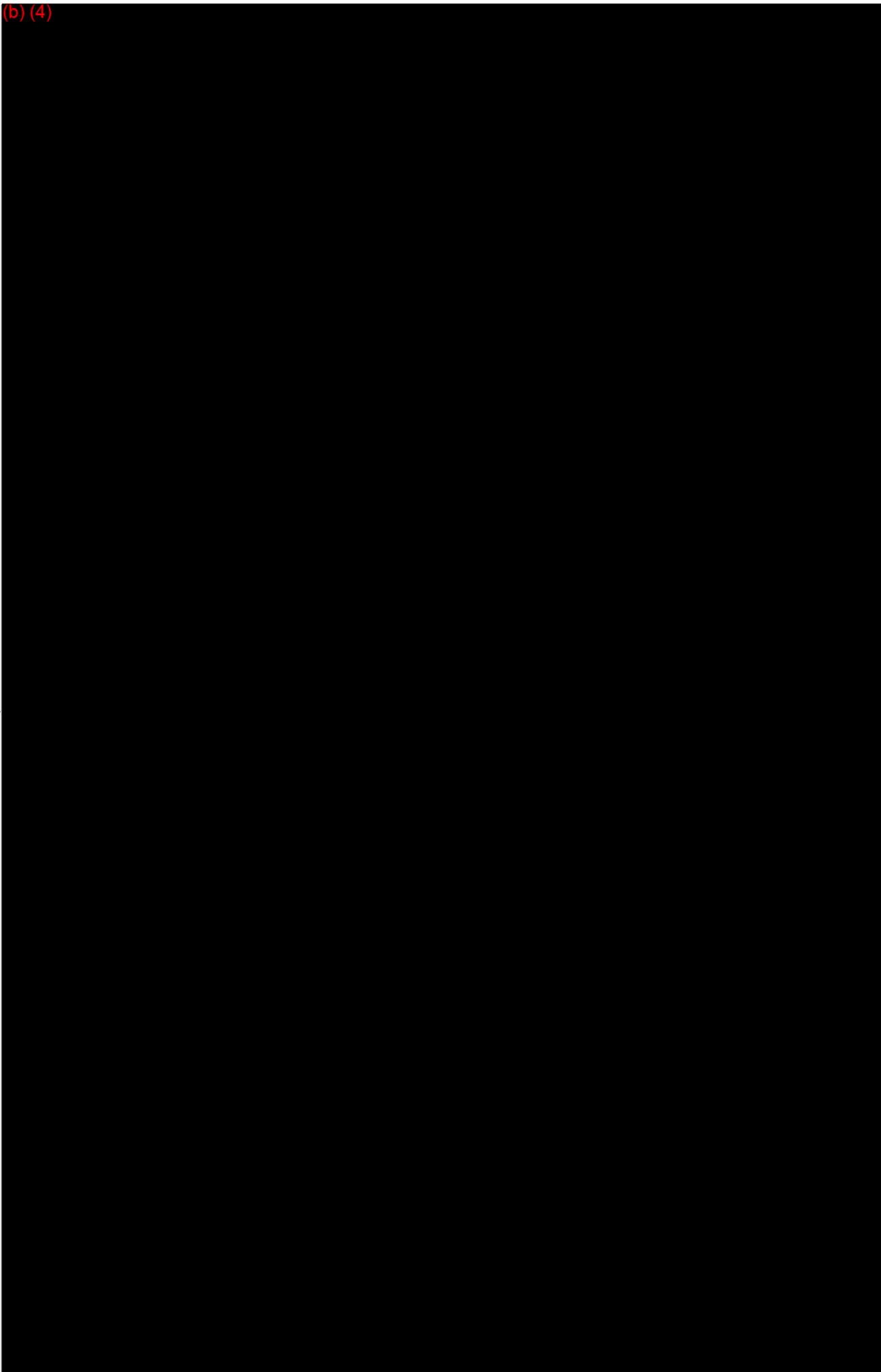
**Risk Analysis LTS-1500**

(b) (4)



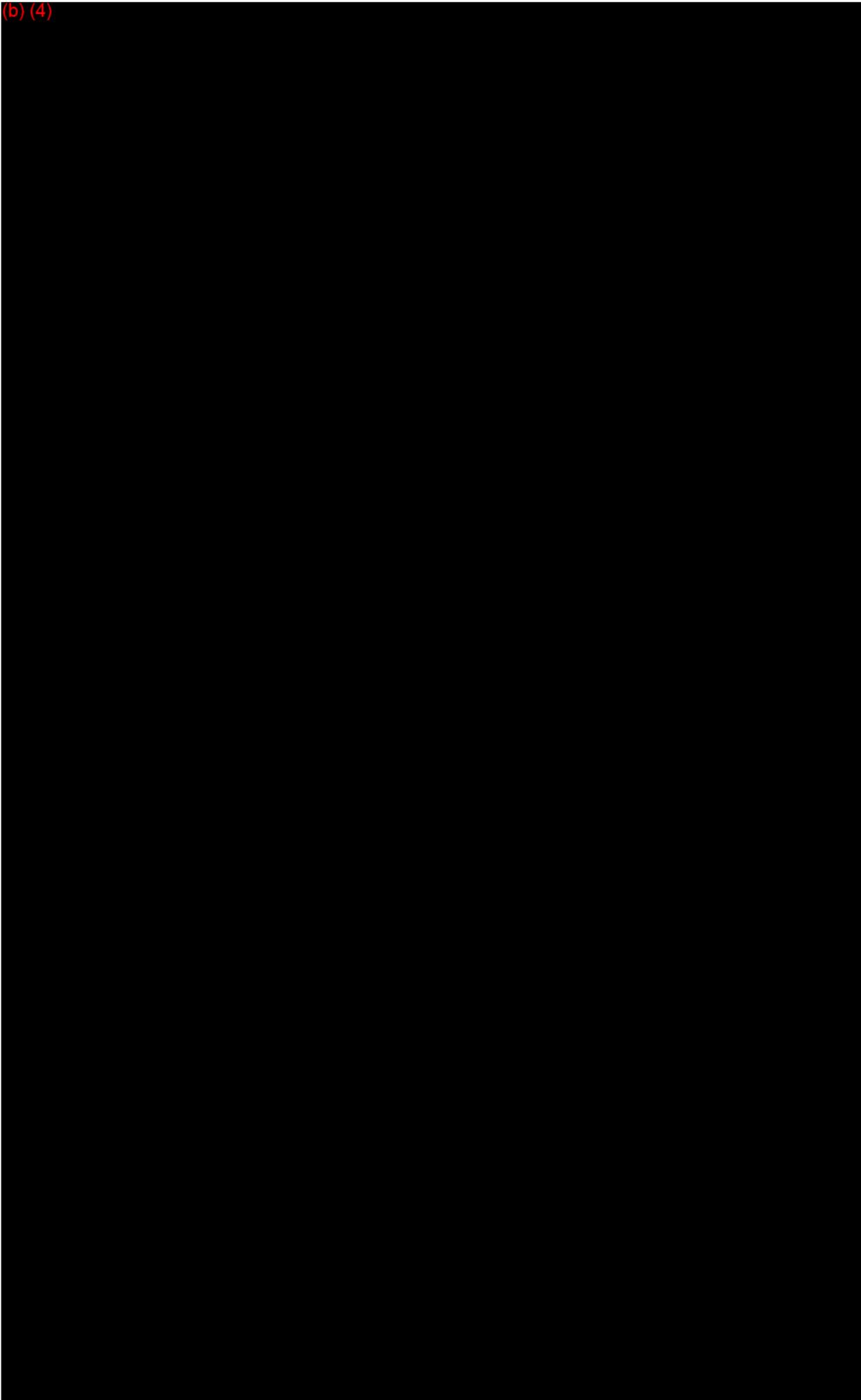
**Risk Analysis LTS-1500**

(b) (4)



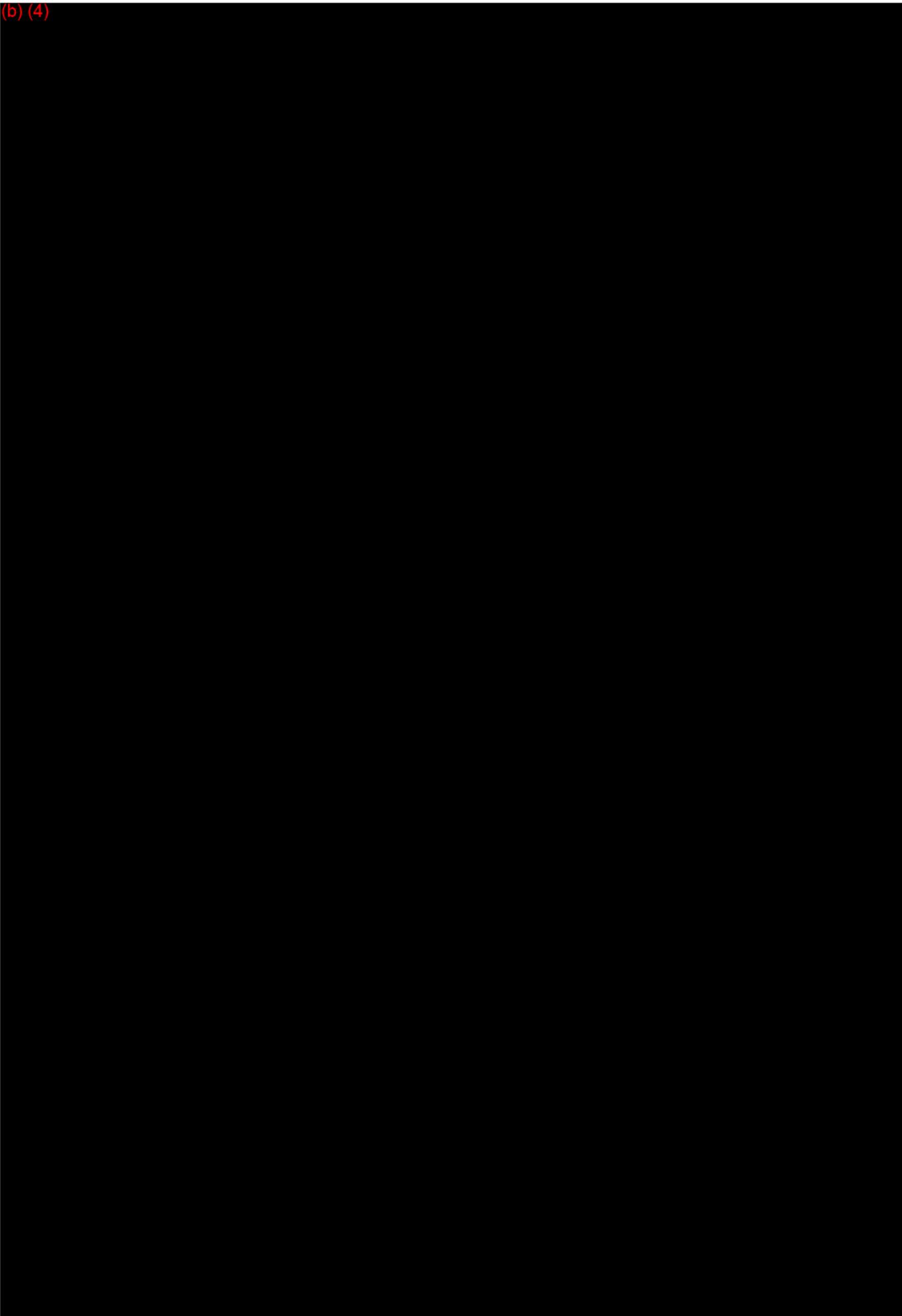
**Risk Analysis LTS-1500**

(b) (4)



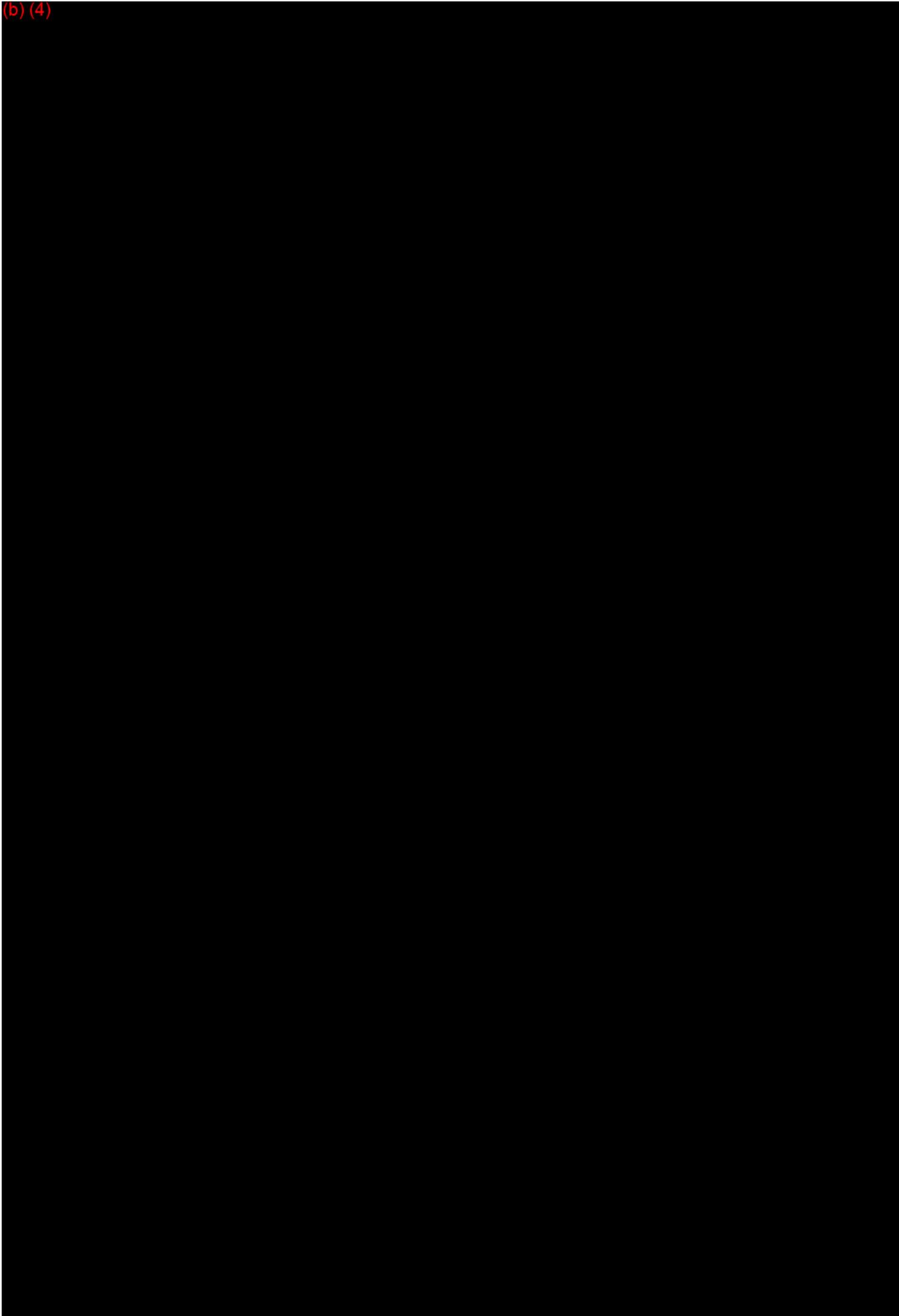
**Risk Analysis LTS-1500**

(b) (4)

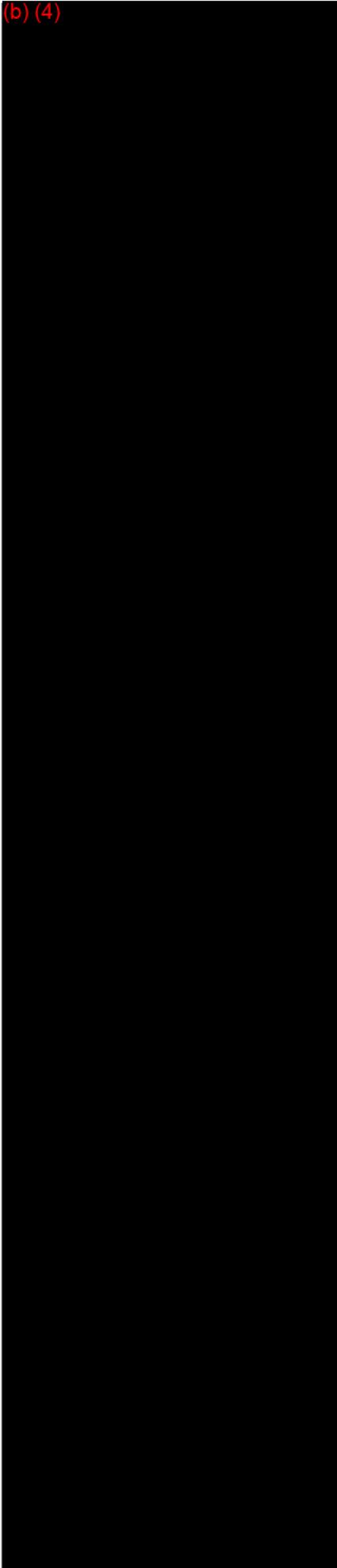


**Risk Analysis LTS-1500**

(b) (4)



**Risk Analysis LTS-1500**



(b) (4)

# **SECTION**

12

## Section 12 Substantial Equivalence Discussion

Substantial Equivalence is discussed as below.

Descriptive Information	Predicate Device#1 (Before Modifications)	Proposed Device (After Modifications)	Effectiveness & Safety Discussion
<b>510(k) Number</b>	K110375	NONE	N/A
<b>Manufacturer</b>	Blueshine srl	LiteCure, LLC	N/A
<b>Proprietary or Model Name</b>	Blueshine's GOLD series	LITECURE THERAPY SYSTEM, MODEL LTS-1500	Not affect effectiveness and safety
<b>Intended Use</b>	The GOLD series is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Tricentagrophytes, and/or yeasts Candida albicans, etc.).	<b>810nm and 980nm wavelength:</b> LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.  <b>980nm wavelength:</b> LiteCure Therapy System, Model LTS-1500 is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Tricentagrophytes, and/or yeasts Candida albicans, etc.).	The Intended Use of 980nm wavelength is SAME
<b>Labeling</b>	Refer to the labeling attached in the Section 12 Substantial Equivalence Discussion	Refer to the labeling attached in the Section 13 Proposed Labeling	Not affect effectiveness and safety.
<b>Laser Type</b>	Solid State laser	Solid State laser	Same

## Section 12 Substantial Equivalence Discussion

Treatment laser wavelength	980nm	980 +/- 10nm (When 810nm turned off)	Same
Aiming beam wavelength	Unknown	650 +/- 15nm	Not affect effectiveness and safety.
Aiming beam power	Unknown	3.5mW +/- 1.0mW	Not affect effectiveness and safety.
Maximum output power	25W	15W	Not affect effectiveness and safety.
Operating modes	Continuous Wave (CW) Pulse Wave up to 200Hz	Continuous Wave (CW) Pulse Wave (50% duty cycle) 2, 10, 20, 100, 200, 500, 1000, 2500, 5000, 10000Hz	Not affect effectiveness and safety.
Audio warning signal level	Unknown	45 to 65 dB	Not affect effectiveness and safety.
Cooling	Thermal Electrically Cooled with Forced Air	Thermal Electrically Cooled with Forced Air	Same
Weight	Unknown	<30 lbs	Not affect effectiveness and safety.
Dimensions	Unknown	413mm(L)x264mm(W)x257mm(H)	Not affect effectiveness and safety.
Power requirement	100-240V ~ 50/60Hz	100-240V ~ 50/60Hz 400VA	Not affect effectiveness and safety.
Operation temperature	Unknown	10°C to 35 °C	Not affect effectiveness and safety.
Storage temperature	Unknown	-20 °C to 70 °C	Not affect effectiveness and safety.
Materials of Patient Contact	Biocompatible	Plastic parts (PC+ABS blend), Glass Biocompatible	Materials are biocompatible. Not affect effectiveness and safety.

**Section 12 Substantial Equivalence Discussion**

Descriptive Information	Predicate Device#2	Proposed Device (After Modifications)	Effectiveness & Safety Discussion
<b>510(k) Number</b>	K103511	NONE	N/A
<b>Manufacturer</b>	LiteCure, LLC	LiteCure, LLC	N/A
<b>Proprietary or Model Name</b>	LITECURE THERAPY SYSTEM, MODEL LTS-1500	LITECURE THERAPY SYSTEM, MODEL LTS-1500	SAME
<b>Intended Use</b>	<p>LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.</p>	<p><b>810nm and 980nm wavelength:</b>                      LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.</p> <p><b>980nm wavelength:</b>                      LiteCure Therapy System, Model LTS-1500 is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Tmentagrophytes, and/or yeasts Candida albicans, etc.)</p>	<p>The Intended Use of 810nm and 980nm wavelength is SAME</p>
<b>Labeling</b>	NONE	Refer to the labeling of the LTS-1500 attached in the Section 13 Proposed Labeling.	SAME
<b>Skin Thermal Effectiveness</b>	Maintain a 40 – 45° C skin temperature for a minimum of 10 minutes	Maintain a 40 – 45° C skin temperature for a minimum of 10 minutes	SAME

## Section 12 Substantial Equivalence Discussion

Laser Type	Solid State laser	Solid State laser	Same
Treatment laser wavelength	810+/-10nm, 980+/-10nm	810+/-10nm, 980+/-10nm	SAME
Aiming beam wavelength	650+/-15nm	650+/-15nm	SAME
Aiming beam power	3.5mW+/-1.0mW	3.5mW+/-1.0mW	SAME
Maximum output power	15W	15W	SAME
Operating modes	Continuous Wave (CW) Pulse Wave (50% duty cycle) 2, 10, 20, 100, 200, 500, 1000, 2500, 5000, 10000Hz 45 to 65 dB	Continuous Wave (CW) Pulse Wave (50% duty cycle) 2, 10, 20, 100, 200, 500, 1000, 2500, 5000, 10000Hz 45 to 65 dB	SAME
Audio warning signal level	45 to 65 dB	45 to 65 dB	SAME
Cooling	Thermal Electrically Cooled with Forced Air	Thermal Electrically Cooled with Forced Air	SAME
Weight	<30 lbs	<30 lbs	SAME
Dimensions	413mm(L)x264mm(W)x257mm(H)	413mm(L)x264mm(W)x257mm(H)	SAME
Power requirement	100-240V~ 50/60Hz 400VA	100-240V~ 50/60Hz 400VA	SAME
Operation temperature	10°C to 35 °C	10°C to 35 °C	SAME
Storage temperature	-20 °C to 70 °C	-20 °C to 70 °C	SAME
Materials of Patient Contact	Plastic parts (PC+ABS blend), Glass	Plastic parts (PC+ABS blend), Glass	SAME

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### Conclusions:

The LiteCure Therapy System, Model LTS-1500 is as safe and effective as the predicate devices. The LiteCure Therapy System, Model LTS-1500 has the same intended uses and similar indications, technological characteristics (such as wavelength, laser safety class, etc), and principles of operation as its predicate device. The minor technological differences between the LiteCure Therapy System, Model LTS-1500 and its predicate devices raise no new issues of safety or effectiveness. Thus, the LiteCure Therapy System Model LTS-1500 is substantially equivalent to its predicate devices.

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## 510(k) SUMMARY

JAN 25 2011

<b>Applicant</b>	LiteCure, LLC 250 Corporate Blvd., Suite B Newark, Delaware 19702  Tel: 302-709-0408 Fax: 302-709-0409
<b>Date</b>	November 11, 2010
<b>Correspondent</b>	Liang Lu Quality and Regulatory Manager
<b>Device Name</b>	LiteCure Therapy System, Model LTS-1500
<b>Classification</b>	Infrared Lamp, 21 CFR 890.5500
<b>Predicate:</b>	<ul style="list-style-type: none"> <li>• K070400, LC THERAPY, MODEL LCT-1000, LiteCure, LLC</li> <li>• K091497, K-LASER K-1200, MODEL 12 W, ELTECH, S.R.L.</li> </ul>
<b>Description</b>	LiteCure Therapy System, Model LTS-1500 is a compact medical laser system. The laser light delivery system consists of a flexible optical fiber threaded through a lightweight handpiece. Activation occurs when the operator enables the laser and presses the foot/finger switch. Depending on laser system configuration, the foot/finger switch can function as on/off switch. A touch-screen display panel allows the operator to adjust or set laser output level. The laser can operate in continuous wave mode or controlled pulse mode.
<b>Intended Use</b>	LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.
<b>Contraindications</b>	<ul style="list-style-type: none"> <li>• Do not apply infrared light to abdominal or lumbosacral points in pregnant females.</li> <li>• Do not apply infrared light to the epiphyseal lines in children.</li> <li>• Do not apply infrared light to the thorax or over the pacemaker itself in patients with pacemakers.</li> <li>• Do not apply infrared light over the thyroid gland, ovaries and testicles.</li> <li>• Do not apply infrared light to patients who are taking drugs that have heat or light sensitive contraindications, such as but not Limited to certain types of steroids.</li> </ul>

<b>Warning</b>	<ul style="list-style-type: none"> <li>• <b>Warning:</b> Use carefully. May cause serious burns. Do not use over sensitive skin area or in the presence of poor circulation. The unattended use of this device by children or incapacitated persons may be dangerous.</li> <li>• <b>NEVER</b> look directly into the distal end of the optical fiber connected to an active laser device, direct the laser light directly into the eyes, or direct the laser beam at anything other than the area to be treated <b>WITH</b> or <b>WITHOUT</b> the appropriate laser-emission protective eyewear. Indirect or direct eye contact with the output beam or at scattered laser light from any reflective surfaces from the laser will cause serious damage, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes.</li> <li>• <b>DO NOT</b> allow any reflective object to fall into or obstruct the path of the laser energy produced by this device. Scattered or reflected laser energy can cause serious damage to eyes. The operator, all assistants, and the patient must remove all reflective objects (such as rings, metal watchbands, and jewelry) prior to treatment with this device. Indirect or direct eye contact with the output beam or at scattered laser light from any reflective surfaces from the laser will cause serious damage, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes.</li> <li>• <b>DO NOT</b> remove protective eyewear until the operator returns the laser device to Standby mode.</li> <li>• <b>DO NOT</b> use the System Controls or performance of procedures other than those specified in this manual may result in hazardous radiation exposure.</li> <li>• <b>DO NOT</b> attempt to gain access to any internal device component. <b>THERE ARE NO USER-SERVICEABLE COMPONENTS</b> inside this laser device. Doing so may cause serious and/or irreversible injury.</li> <li>• <b>AVOID THE USE</b> of flammable solvents, anesthetics, oxidizing gases such as nitrous oxide (N<sub>2</sub>O) and oxygen or endogenous gases. The high temperatures produced in normal use of the laser equipment may ignite some material, for example cotton or wool, when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.</li> <li>• <b>FAILURE TO COMPLY</b> with all safety instructions and warnings may expose all participants to harmful levels of laser radiation and/or dangerous levels of electrical current.</li> </ul>
<b>Cautions:</b>	<ul style="list-style-type: none"> <li>• Never allow untrained personnel to operate this advice unless directly supervised by a properly trained and experienced individual</li> <li>• The protective eyewear supplied with this device has an optical density rating &gt;5 in the 350nm~2000nm (see specification sheet) region. All personnel present during device operation must ware this eyewear. Contact LiteCure, LLC at 302-709-0408 to purchase additional sets of protective eyewear for this device.</li> </ul>

<p><b>Caution continued</b></p>	<ul style="list-style-type: none"> <li>• Select a secure, properly equipped, and well-ventilated location in which to install and operate the laser.</li> <li>• Place "Laser in use" signs at location entrances where people will use the LiteCure, LLC. laser device.</li> <li>• Always put the laser in Standby mode or switch the device off prior to adjusting or preparing the wand or fiber optic.</li> <li>• Never leave this device in the READY mode unattended. See the STANDBY to READY Mode in the Operations section of this manual.</li> <li>• Remove the key from the device's key switch when not in use to prevent unauthorized and/or unqualified use of the device as well as inadvertent laser emissions.</li> <li>• Turn the device off before relocating equipment in the same vicinity.</li> <li>• Never press the foot/finger switch without first verifying the safe orientation and proper positioning of the handpiece and distal end of the optical fiber and ensuring compliance to all safety precautions.</li> <li>• During any laser procedure, do not allow any nonessential personnel into the treatment area.</li> <li>• Never allow the untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual.</li> <li>• ALWAYS clean the SMA fiber tip before inserting into the SMA emission port. A dirty tip could result in damage to the unit.</li> <li>• Federal law (USA) restricts this device to sale by or on the order of a physician.</li> </ul>
<p><b>Substantial Equivalency Information</b></p>	<p>The LiteCure Therapy System, Model LTS-1500 is as safe and effective as the predicate devices. The LiteCure Therapy System, Model LTS-1500 has the same intended uses and similar indications, technological characteristics (such as wavelength, laser safety class, etc), and principles of operation as its predicate device. The minor technological differences between the LiteCure Therapy System, Model LTS-1500 and its predicate devices raise no new issues of safety or effectiveness. Thus, the LiteCure Therapy System, Model LTS-1500 is substantially equivalent to the device it was modified from, MODEL LCT-1000, and another predicate device, K-LASER K-1200.</p>
<p><b>Technological Characteristics</b></p>	<p>The device is subject to the following voluntary consensus standards:</p> <ul style="list-style-type: none"> <li>• IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995 (2nd Edition);</li> <li>• IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004);</li> <li>• IEC 60601-2-22 1995, 2nd Edition, "Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment";</li> <li>• IEC 60825-1 Ed. 2.0 (2007), Safety of laser products - Part 1: Equipment classification, and requirements.</li> </ul>



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

LiteCure, LLC  
% Mr. Liang Lu  
Quality and Regulatory Manager  
250 Corporate Boulevard, Suite B  
Newark, Delaware 19702

JAN 25 2011

Re: K103511

Trade/Device Name: LiteCure Therapy System, Model LTS-1500  
Regulation Number: 21 CFR 890.5500  
Regulation Name: Infrared lamp  
Regulatory Class: Class II  
Product Code: ILY  
Dated: December 28, 2010  
Received: January 03, 2011

Dear Mr. Lu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

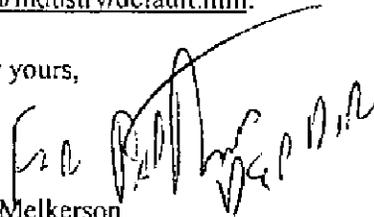
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
And Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K103511

Device Name: LiteCure Therapy System, Model LTS-1500

### Indications for Use:

LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

Prescription Use   X   AND/OR Over-The-Counter Use             
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)  
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Dodem for max  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K103511

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PAGE**

K11 0375  
Page 1 of 6

FEB 23 2012

**Title:** 510(k) SUMMARY  
Blueshine's GOLD series

**Submitter:** Blueshine srl via Querini,27 30171, Mestre Venezia  
Italy  
Contact person Chiara Ricci CEO +390415055847  
blueshine@blueshine.biz

**Contact:** Chiara Ricci  
C.E.O.

**Date Prepared:** Dec. 01, 2011

**Device Trade Name:** Blueshine's GOLD series

**Common Name:** Laser surgical instrument for use in general and plastic  
surgery and in dermatology

**Classification Name:** Instrument, surgical, powered, laser  
GEX  
21 C.F.R. 878.4810

**Predicate Devices:**

- Quanta System S.p.A. Diode Medical Laser Family (K072034)
- Osyris, Pharaon Lipo (K073617)
- Pinpointe, Pinpointe Footlaser (K093547)

**Summary of Onychomycosis Clinical data**

**Abstract:** A 6-month follow-up study was conducted on 48 patients who received laser treatment for onychomycosis with Gold Series 980 Diode Laser (BlueShine, Venice - Italy).

**Objective** To examine long-term cure and relapse rates after treatment with a 2 millisecond-pulse 980 nm near-infrared laser in onychomycosis.

**Setting** Two private practices in Padua and Venice, Italy.

**Subjects & Methods** The study population comprised 48 patients (31 male & 17 female) aged 23 to 79 years with a clinical and mycological diagnosis of onychomycosis.

The Laser treatment consisted of 3/4 sessions with 30 days interval. Each nail was treated with 2 alternating passes of laser pulses to cover the full nail, one pass applied vertically down each nail and the second applied

horizontally using defocused hand piece with 3 mm spot size.

The BlueShine Gold Series 980 Diode Laser has proven highly efficient against Onychomycosis. This protocol gives excellent results on almost all the nails treated and in a short time span.

The procedure is simple and quick with no noticeable side effects and complications.

Despite the high success rate, our laser treatment is not a definitive cure for onychomycosis. Therefore and because it can recur, preventative maintenance treatments might be recommended every 6 months.

The use of Blueshine Gold Series diode Laser on patients affected by Onychomycosis with different pathologies, has a significant, positive results.

On the 48 nails we found that , totally, 93,75 % have improved at least for 1/3 of the nail plate and no one was worse. 6,25 % were unchanged.

On the total eligible toenails (48) 45 presented some improvement and, much more important, 37 of these (77,09) showed complete clear nails, while just 8 presented middle or moderate clear.

First session % fungus

50-75	10(21%)
75-90	10 (21%)
>90	28 (58%)
Total	48 (100%)

All nails are checked visually and classified as:

1. Unchanged means there were no result or the nail were missed or  $< 1/3$ ;
2. Middle cleared means that the improvement was  $1/3$  to  $2/3$ ;
3. completely cleared means that the improvement was  $> 2/3$ .

Results

Unchanged	3 (6%)
Middle clear	8 (17%)
Complete clear	37 (77%)
Total	48 (100%)

**Intended Use /  
Indications for Use:**

**980nm Wavelengths**

The Blueshine GOLD series , (and the fiber delivery systems and accessories used to deliver laser energy), is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: gastroenterology, neurosurgery, general surgery, genitourinary surgery (urology), thoracic surgery, gynecology (GYN), pulmonology, ophthalmology, orthopedics, otolaryngology (ENT) and podiatry.

The Blueshine GOLD series Laser is indicated for use in the performance of specific surgical applications in gastroenterology, neurosurgery, general surgery, genitourinary surgery (urology), thoracic surgery, gynecology (GYN), pulmonology, ophthalmology, orthopedics, otolaryngology (ENT) and podiatry as follows:

**Gastroenterology**

The ablation, vaporization, excision, incision, and coagulation of soft tissue in gastroenterology procedures. Applications include: hemostasis of esophageal varices; palliation of malignant dysphagia; palliative ablation of obstructive neoplasms; hemostasis of colonoscopy.

**Neurosurgery**

The ablation, vaporization, excision, incision, and coagulation of soft tissue in neurosurgery procedures. Applications include: tumors adjacent to the spinal cord; tumors adjacent to the cortex.

**General Surgery**

Treatment of varicose veins and varicosities associated with superficial reflux of the greater saphenous vein. The ablation, vaporization, excision, incision, and coagulation of soft tissue in general surgery including endoscopic and open procedures. Applications include: Laparoscopic: appendectomy; cholecystectomy; bowel resection. Open: mastectomy; reduction mammoplasty; breast biopsy; rectal and anal hemorrhoidectomy; bowel resection; colectomy; cholecystectomy; liver resection; condyloma; thyroidectomy; thoracotomy; cavernous hemangioma.

**Genitourinary (Urology)**

The ablation, vaporization, excision, incision, and coagulation of soft tissue in genitourinary (urology) procedures. Applications include: Transurethral: transurethral incision of the prostate (TUIP); bladder

tumors; bladder neck incisions; urethral strictures; exterior sphincterotomy. Laparoscopic lymphadenectomy. Open: condyloma; circumcision; benign and malignant lesions of external genitalia

#### Thoracic Surgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in thoracic surgery including endoscopic and open procedures. Applications include: pulmonary resection; coagulation of blebs and bullae; adhesiolysis; pericardiectomy; mediastinal and thoracic lesions and abnormalities; mediastinal lymph node dissection; hemostasis; thoracotomy.

#### Gynecology (GYN)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in gynecology (GYN) procedures. Applications include: Laparoscopic excision/lysis of adhesions; endometrial lesions, including ablation of endometriosis; laparoscopic assisted hysterectomy (LAVH); laser uterosacral nerve ablation (LUNA); myomectomy; ovarian cystectomy; ovarian drilling; tubal fimbrioplasty; appendectomy. Open: conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia VIN, VAIN; condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosa (BP) lesions. Intrauterine: Fibroids/polyps/adhesions; Resection of septum.

#### Pulmonology

The ablation, vaporization, excision, incision, and coagulation of soft tissue in pulmonology procedures. Applications include: tracheal bronchial lesions.

#### Ophthalmology

The ablation, vaporization, excision, incision, and coagulation of soft tissue in ophthalmology procedures. Applications include: Oculoplastics; open DCR; endo-nasal DCR; tumor excision and biopsy; eyelid reconstruction; blepharoplasty.

#### Orthopedics

The ablation, vaporization, excision, incision, and coagulation of soft tissue in orthopedic surgery procedures. Applications include: Open: Dissect and coagulate.

#### Otolaryngology (ENT)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in otolaryngology procedures. Applications include: Nasal/Sinus: turbinectomy and

turbinate reduction/ablation; polypectomy of nose and nasal passages; ethmoidectomy; meatal antrostomy; Laryngo-tracheal: removal of vocal cord/fold nodules, polyps and cysts; arytenoidectomy; tracheal stenosis; Oropharyngeal: uvulopalatoplasty (LAUP, laser UTPP); tonsillectomy (including tonsillar cryptolysis, neoplasma) and tonsil; hemi glossectomy; Head & Neck: tumor resection on oral, subfacial and neck tissues; parathyroidectomy; thyroidectomy.

#### Podiatry

Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: Matrixectomy Periungual and subungual warts, Plantar warts, Neuromas. The Gold Series is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T mentagrophytes*, and/or yeasts *Candida albicans*, etc.).

In addition the Blueshine GOLD series Laser is intended for Laser Assisted Lipolysis

#### **Technological Characteristics:**

The GOLD series Laser is designed with 4 major subsystems: (1) an external structure; (2) power electronics; (3) display with control electronics, which controls the power electronics, the user interface and the laser source temperature via a thermostat board; and (4) the laser system with an opto-mechanical block composed of the laser source, the Peltier cooling system with dissipater and fans, the fiber launching system, the red diode aiming beam, and the power calibration system. The external accessories include separate optical fibers and hand pieces for dental, dermatological and surgical applications, or for endovascular applications. The fiber is connected to the system through an SMA 905 socket on the front panel. In addition to the four subsystems, the Diode Laser Family incorporates several safety features, including a remote interlock and a key switch..

The Blueshine laser was tested and conformed with the following standards:

- IEC 60601-1-1 Ed 2.0 Medical electrical equipment – Part 1-1: General requirements for safety –  
Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2 Ed 2.1 Medical electrical equipment – Part 1-2: General requirements for safety –  
Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60825-1 (2003-2): Safety of laser products – Part 1: Equipment classification, requirements and user's guide

**Substantial  
Equivalence:**

The Blueshine GOLD series Laser is as safe and effective as the predicate devices. The GOLD series Laser has the same intended uses, and similar indications for use, technological characteristics, and principles of operation as the predicates. The minor technological differences between the GOLD series Laser and its predicates raise no new issues of safety or effectiveness. Thus, the GOLD series Laser is substantially equivalent.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

FEB 23 2012

Blueshine Srl  
% Ms. Chiara Ricci  
Via Querini, 27 - 30171  
Mestre Venezia, Italy

Re: K110375

Trade/Device Name: Blueshine GOLD Series  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and  
plastic surgery and in dermatology  
Regulatory Class: Class II  
Product Code: GEX  
Dated: February 23, 2012  
Received: February 23, 2012

Dear Ms. Ricci:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



*fs* Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



urethral strictures; exterior sphincterotomy. Laparoscopic lymphadenectomy. Open: condyloma; circumcision; benign and malignant lesions of external genitalia

### **Thoracic Surgery**

The ablation, vaporization, excision, incision, and coagulation of soft tissue in thoracic surgery including endoscopic and open procedures. Applications include: pulmonary resection; coagulation of blebs and bullae; adhesiolysis; pericardiectomy; mediastinal and thoracic lesions and abnormalities; mediastinal lymph node dissection; hemostasis; thoracotomy.

### **Gynecology (GYN)**

The ablation, vaporization, excision, incision, and coagulation of soft tissue in gynecology (GYN) procedures. Applications include: Laparoscopic excision/lysis of adhesions; endometrial lesions, including ablation of endometriosis; laparoscopic assisted hysterectomy (LAVH); laser uterosacral nerve ablation (LUNA); myomectomy; ovarian cystectomy; ovarian drilling; tubal fimbrioplasty; appendectomy. Open: conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia VIN, VAIN; condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosa (BP) lesions. Intrauterine: Fibroids/polyps/adhesions; Resection of septum.

### **Pulmonology**

The ablation, vaporization, excision, incision, and coagulation of soft tissue in pulmonology procedures. Applications include: tracheal bronchial lesions.

### **Ophthalmology**

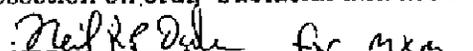
The ablation, vaporization, excision, incision, and coagulation of soft tissue in ophthalmology procedures. Applications include: Oculoplastics; open DCR; endo-nasal DCR; tumor excision and biopsy; eyelid reconstruction; blepharoplasty.

### **Orthopedics**

The ablation, vaporization, excision, incision, and coagulation of soft tissue in orthopedic surgery procedures. Applications include: Open: Dissect and coagulate.

### **Otolaryngology (ENT)**

The ablation, vaporization, excision, incision, and coagulation of soft tissue in otolaryngology procedures. Applications include: Nasal/Sinus: turbinectomy and turbinate reduction/ablation; polypectomy of nose and nasal passages; ethmoidectomy; meatal antrostomy; Laryngo-tracheal: removal of vocal cord/fold nodules, polyps and cysts; arytenoidectomy; tracheal stenosis; Oropharyngeal: uvulopalatoplasty (LAUP, laser UTPP); tonsillectomy (including tonsillar cryptolysis, neoplasma) and tonsil; hemi glossectomy; Head & Neck: tumor resection on oral, subfacial and neck tissues; parathyroidectomy; thyroidectomy.

  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K110375

**Podiatry**

Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: Matrixectomy Periungual and subungual warts, Plantar warts, Neuromas. The Gold Series is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T mentagrophytes*, and/or yeasts *Candida albicans*, etc.).

In addition the Blueshine GOLD series Laser is intended for Laser Assisted Lipolysis

Prescription Use:  X   
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use:       
(Part 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Blueshine srl via Querini,27 30171, Mestre Venezia Italy  
Contact person Chiara Ricci CEO +390415055847 blueshine@blueshine.biz

Neil R. Ozden for exam  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K110375

## Blueshine srl

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## Gold Series



The Gold Series is a break down in the device laser technology. It's extremely versatile and joins the high power (25 w on the fibres' tip) to a great security.

The Gold Series is an incredible machine, the only one with FDA certification and authorized with 11 different functions.

Gold Series most common applications are:

- Liposution
- Podiatry
- Orthopaedic
- Dental Surgery
- General Surgery
- Endovascular
- Vascular
- Ophthalmology
- Dermatology
- ENT

- Urology
- Gynaccology

Gold Series features are:

- Different and multiples applications
- The use of fibres from 200 to 1500 micron
- Calibration door to check the power delivered
- Personalized programs to make the machine more friendly
- Different modes (continuous, continuous-pulsed and pulsed) to manage the power in the best way
- Minimal recovery time and painless

The Gold Series is adaptable to many applications and every kind of patient and let you combine the maximum efficiency to a complete safety.

The quality is certified by CE 0476, ISO 13485:2004, ISO 9001:2008 and FDA clearance for 11 applications.

The Gold Series is available with different specifications:

808, 940, 980, 532, 808+532, 940+532, 980+532, 808+940, 808+980, 940+980

- Gold Lipo
- Gold Podos
- Gold Smile

## Related Items

- No Products or Application found

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Panese Web Design























# SECTION

13

## Section13 Proposed Labeling

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Please refer to the proposed labeling attached in this section.

LTS-1500 Labeling is comprised of the following

- 1) LTS-1500 Laser Device User Manual
- 2) Hand Piece Head User Manual

**USER MANUAL**

**LiteCure Therapy System**

**LTS-1500**

250 Corporate Blvd. Suite B  
Newark, Delaware 19702  
Tel: 302-709-0408  
Fax: 302-709-0409

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## 1. CONVENTIONS USED

Various Warnings, Cautions, Recommendations and Notes are presented throughout this document. Explanations and examples of each follow.

### 1.1. *Warning*

Call the reader's attention to a specific or potential danger in advance. If ignored or compromised, the situation could result in the possibility of injury, death or other serious adverse reaction associated with the use or misuse of the device

**WARNING!**

DO NOT direct the laser beam at anything other than the area to be treated.

### 1.2. *Caution*

Alert the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property.

**CAUTION**

DO NOT allow untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual.

### 1.3. *Recommendation*

Offers guidance that may be worthy of acceptance or trial within a specific area of LTS-1500 application and may serve to optimize overall utilization.

**RECOMMENDATION**

Designate at least one person at each facility that utilizes this device as laser safety supervisor, responsible for providing training on all operating and safety procedures.

### 1.4. *Note*

Describe the conditions or exceptions that may apply to the subject matter presented.

**NOTE**

The optical fiber must be properly inserted and secured into the laser emission port before the device's operational mode can change from standby to ready.

## 2. DEVICE DESCRIPTION

LiteCure Therapy System, Model LTS-1500 is a compact medical laser system. The laser light delivery system consists of a flexible optical fiber threaded through a lightweight handpiece. Activation occurs when the operator enables the laser and presses the foot/finger switch. Depending on laser system configuration, the foot/finger switch can function as on/off switch. A touch-screen display panel allows the operator to adjust or set laser output level. The laser can operate in continuous wave mode or controlled pulse mode.

### ***Classification***

According to the applicable standards, the LTS-1500 laser is classified as follows:

1. Class I Type B device according to EN/IEC 60601-1: +A1 +A2:1995
2. Class IIa according to Council Directive 93/42/EEC
3. Class II according to CMDR SOR/98-282
4. Class IV laser product according to IEC 60825-1
5. Degree of protection according to EN/IEC 60601-1 + A1+A2:1: diode laser unit; IPX 0 (enclosure not waterproof); foot control: at least IPX5
6. Ordinary protection against ingress of water
7. Continuous operation

### ***Regulatory Compliance***

1. The LTS-1500 laser complies with 21 CFR Chapter 1, Subchapter J, as administered by the Center for Devices and Radiological Health of the US Food and Drug Administration (FDA).
2. The LTS-1500 laser is manufactured in compliance with the provisions of Council Directive 93/42/EEC concerning medical device (MDD, EU) and CMDR SOR/98-282 (CAN).

### **Indication for Use**

LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

#### **810nm and 980nm wavelength:**

LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

#### **980nm wavelength:**

LiteCure Therapy System, Model LTS-1500 is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *Tmentagrophytes*, and/or yeasts *Candida albicans*, etc.).



### **Caution**

Federal law (USA) restricts this device to sale by or on the order of a physician.

### **Contraindications**

- Do not apply infrared light to abdominal or lumbosacral points in pregnant females.
- Do not apply infrared light to the epiphyseal lines in children.
- Do not apply infrared light to the thorax or over the pacemaker itself in patients with pacemakers.
- Do not apply infrared light over the thyroid gland, ovaries and testicles.
- Do not apply infrared light to patients who are taking drugs that have heat or light sensitive contraindications, such as but not Limited to certain types of steroids.



### **Warning**

Use carefully. May cause serious burns. Do not use over sensitive skin area or in the presence of poor circulation. The unattended use of this device by children or incapacitated persons may be dangerous.



### **Warning**

NEVER look directly into the distal end of the optical fiber connected to an active laser device, direct the laser light directly into the eyes, or direct the laser beam at anything other than the area to be treated WITH or WITHOUT the appropriate laser-emission protective eyewear. Indirect or direct eye contact with the output beam or at scattered laser light from any reflective surfaces from the laser will cause serious damage, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes.



### **Warning**

DO NOT allow any reflective object to fall into or obstruct the path of the laser energy produced by this device. The operator, all assistants, and the patient must remove all reflective objects (such as rings, metal watchbands, and jewelry) prior to treatment with this device. Indirect or direct eye contact with the output beam or scattered laser light from any reflective surface from the laser will

cause serious, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes.



**Warning**

DO NOT use the System Controls or performance of procedures other than those specified in this manual may result in hazardous radiation exposure.



**Warning**

DO NOT remove protective eyewear until the operator returns the laser device to Standby mode.



**Warning**

DO NOT attempt to gain access to any internal component. THERE ARE NO USER-SERVICEABLE COMPONENTS inside this laser device. Doing so may cause serious and/or irreversible injury.



**Warning**

AVOID THE USE of flammable solvents, anesthetics, oxidizing gases such as nitrous oxide (N<sub>2</sub>O) and oxygen or endogenous gases. The high temperatures produced in normal use of the laser equipment may ignite some material, for example cotton or wool, when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.



**Warning**

FAILURE TO COMPLY with all safety instructions and warnings may expose all participants to harmful levels of laser radiation and/or dangerous levels of electrical current.



**Caution**

ALWAYS wear the protective eyewear supplied with this device, which is optically dense at the wavelength of operation (see specification sheet). All personnel present during device operation must wear this eyewear. Contact LiteCure, LLC at 302-709-0408 to purchase additional sets of protective eyewear for this device.



**Caution**

ALWAYS put the laser in Standby mode or turn the device OFF prior to adjusting or connecting / disconnecting the hand piece or fiber optic.



**Caution**

ALWAYS post Warning Signs for Class IV laser products.



**Caution**

ALWAYS post Warning Signs in the area of the laser beam to alert others.



**Caution**

ALWAYS Turn the device OFF before lifting, moving or relocating the device.



**Caution**

ALWAYS place "Laser In Use" signs at location entrances where people will use the laser



**Caution**

NEVER leave this device in the READY mode unattended. Reference the STANDBY and READY Mode in the Operations section of this manual.



**Caution**

NEVER allow untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual.



**Caution**

DO NOT leave key in device's key switch when not in use. Prevent unauthorized and/or unqualified use of the device. This will also prevent inadvertent laser emissions.



**Caution**

DO NOT allow any nonessential personnel into the treatment area during any laser procedure.



**Caution**

DO NOT press the finger/foot switch without first verifying the safe orientation and proper positioning of the hand piece and distal end of the optical fiber and ensuring compliance to all safety precautions.



**Caution**

If the laser fails to operate properly, please discontinue treatment and contact LiteCure, LLC at 302-709-0408.

**Recommendations**

1. Designate at least one person (e.g. Laser Safety Supervisor) responsible for providing training on all operating and safety procedures at each facility that utilizes this device.
2. Individuals planning to use the laser system should attend laser orientation and education sessions to achieve operational proficiency.



**Notice**

1. The key can only be inserted into and removed from the key switch when the key is in the vertical (OFF) position.
2. Pushing the red mushroom shaped Emergency Laser Off Switch down will terminate all electrical power to the laser device's microprocessor and laser-emitting components. Resetting the switch restores power. To release the Emergency Laser Off Switch, the user must twist and rotate in the direction indicated by the arrows, then release it as the switch pops out, returning it to its normal position.

### 3. MANUFACTURER'S DECLARATION ON ELECTROMAGNETIC COMPATIBILITY

<b>Guidance and Manufacturer's Declaration - Emissions</b>		
The LTS is intended for use in the electromagnetic environment specified below. The customer or user of the LTS should ensure that it is used in such an environment.		
<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic Environment – Guidance</b>
RF Emissions CISPR 11	Group 1	The LTS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Group 2	The LTS must emit Electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A or B	A
Harmonics IEC 61000-3-2	Class A,B,C,D or N/A	A
Flicker IEC 61000-3-3	Complies or N/A	Complies
		The LTS is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
		The LTS is suitable for use in all establishments, <b>other than</b> domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF Emissions CISPR 14-1	Complies	The LTS is not suitable for interconnection with other equipment.
RF Emissions CISPR 15	Complies	The LTS is not suitable for interconnection with other equipment.

**Guidance and Manufacturer's Declaration – Immunity**

The LTS is intended for use in the electromagnetic environment specified below. The customer or user of the LTS should ensure that it is used in such an environment.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD EN/IEC 61000-4-2	±6kV Contact ±8kV Air	As specified	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT EN/IEC 61000-4-4	±2kV Mains ±1kV I/Os	As specified	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	±1kV Differential ±2kV Common	As specified	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout EN/IEC 61000-4-11	>95% Dip for 0.5 Cycle  60% Dip for 5 Cycles  30% Dip for 25 Cycles  >95% Dip for 5 Seconds	As specified	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LTS requires continued operation during power mains interruptions, it is recommended that the 35700 be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field EN/IEC 61000-4-8	3A/m	As specified	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

**Guidance and Manufacturer's Declaration – Emissions**

The LTS is intended for use in the electromagnetic environment specified below. The customer or user of the LTS should ensure that it is used in such an environment.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
<p>Conducted RF EN/IEC 61000-4-6</p> <p>Radiated RF EN/IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>(V1)Vrms</p> <p>(E1)V/m</p>	<p>Portable and mobile communications equipment should be separated from the LTS by no less than the distances calculated/listed below:</p> <p><math>D=(3.5/V1)(\text{Sqrt } P)</math></p> <p><math>D=(3.5/E1)(\text{Sqrt } P)</math> 80 to 800 MHz</p> <p><math>D=(7/E1)(\text{Sqrt } P)</math> 800 MHz to 2.5 GHz</p> <p>where P is the max power in watts and D is the recommended separation distance in meters.</p> <p>Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).</p> <p>Interference may occur in the vicinity of equipment containing a transmitter.</p>

**Recommended Separations Distances for the LTS**

The LTS is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the LTS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the LTS as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz	Separation (m) 80 to 800MHz	Separation (m) 800MHz to 2.5GHz
	$D=(3.5/V1)(\text{Sqrt } P)$	$D=(3.5/E1)(\text{Sqrt } P)$	$D=(7/E1)(\text{Sqrt } P)$
0.01	.1166	.1166	.2333
0.1	.3689	.3689	.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

## 4. ADDITIONAL SAFETY AND HANDLING CONSIDERATIONS

### WIRELESS PHONE INTERFERENCE



#### **Caution**

To ensure the operational safety of medical electrical equipment, the use of mobile wireless cell phones in the vicinity of the laser or similar hospital environments must be prohibited.

### FIRE AND EXPLOSION HAZARDS

Healthcare professionals should be aware of the following safety considerations and potential fire hazards when using the laser:

1. The laser beam can ignite most nonmetallic materials.
2. A UL-approved or equivalent fire extinguisher should be readily available

This laser unit is not intended for operation in areas subject to explosion hazards such as flammable materials, gases or substances. A fire or explosion could occur.



#### **Warning**

The laser unit is not suitable for use in the presence of anesthetics that are flammable when in contact with air, oxygen, protoxide or nitrogen monoxide.



#### **Warning**

AVOID THE USE of flammable solvents, anesthetics, oxidizing gases such as nitrous oxide (N<sub>2</sub>O) and oxygen or endogenous gases. The high temperatures produced in normal use of the laser equipment may ignite some material, for example cotton or wool, when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Always be aware of the fire risk caused by flammable gases in close proximity to an operating laser. If you accidentally spill liquid on the unit, immediately stop treatment, disconnect the power supply cable and contact your local distributor, authorized service center or LiteCure customer service for assistance.



#### **Warning**

Never direct the laser beam toward paper, plastics or dark surfaces. These may catch fire or be damaged due to the high temperatures produced by the laser beam.



#### **Warning**

DO NOT treat through clothing or bandages. Possible damage or ignition may occur due to the high temperatures produced by the laser beam.

## 5. DISPOSAL

If you plan to discontinue the use of LTS-1500 laser and intended to dispose of it, make sure to observe the application legal provisions. Please contact your local distributor, authorized service center, or LiteCure customer service for the disposal of the LTS-1500 laser.

## 6. GLOSSARY AND ABBREVIATIONS

### *Glossary*

<b>Term</b>	<b>Definition</b>
CW, Continuous Emission, or Continuous Mode	Continuous laser emission
Pulse, Pulse Emission, or Pulsed Mode	Pulsed laser emission (pulsed mode)
Duty Cycle	Percentage of time in Pulsed Mode that laser energy is being generated during laser emission.
Frequency	Number of laser pulses per second
Hertz	Measuring unit for frequency
Remote Interlock	Safety device that stops laser radiation when the door of the treatment room is opened
Joule	Unit of measure for emitted energy
Watt	unit of measure for laser power
Stop	End of treatment or treatment break

### *Abbreviations*

<b>Abbreviation</b>	<b>Definition</b>
cm <sup>2</sup>	Square centimeter
Hz	Hertz
S	Second
W	Watt
mW	Milliwatt (one thousandth of a Watt)
J	Joule
nm	Nanometer
V	Volt
IR	Infrared diode
NOHD	Nominal Ocular Hazard Distance according to EN 60825-1

## 7. FEATURES

1. Emergency Laser Off Switch

This Emergency Laser Off Switch shall stop the emission of laser output as fast as possible to prevent danger to any person.

2. Display and Touch Screen

The display shows the user operation interface.

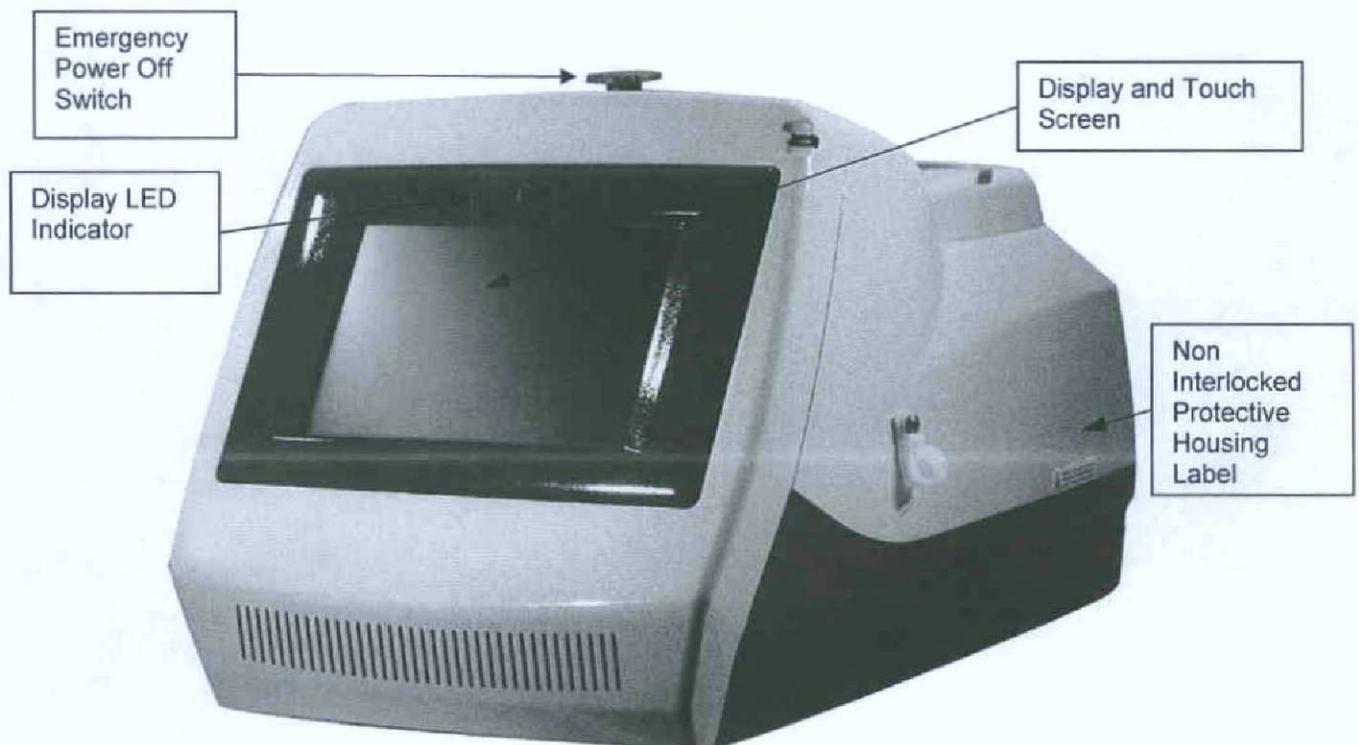
3. Handpiece Fiber Receptacle

The hand piece fiber receptacle permits the fiber insertion.

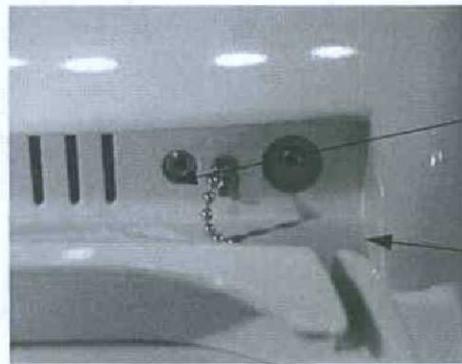
4. Key Switch

This switch uses a key to prevent unauthorized unit operation. The key will not be removable in the on position. It will be removable in the off position.

### Front View



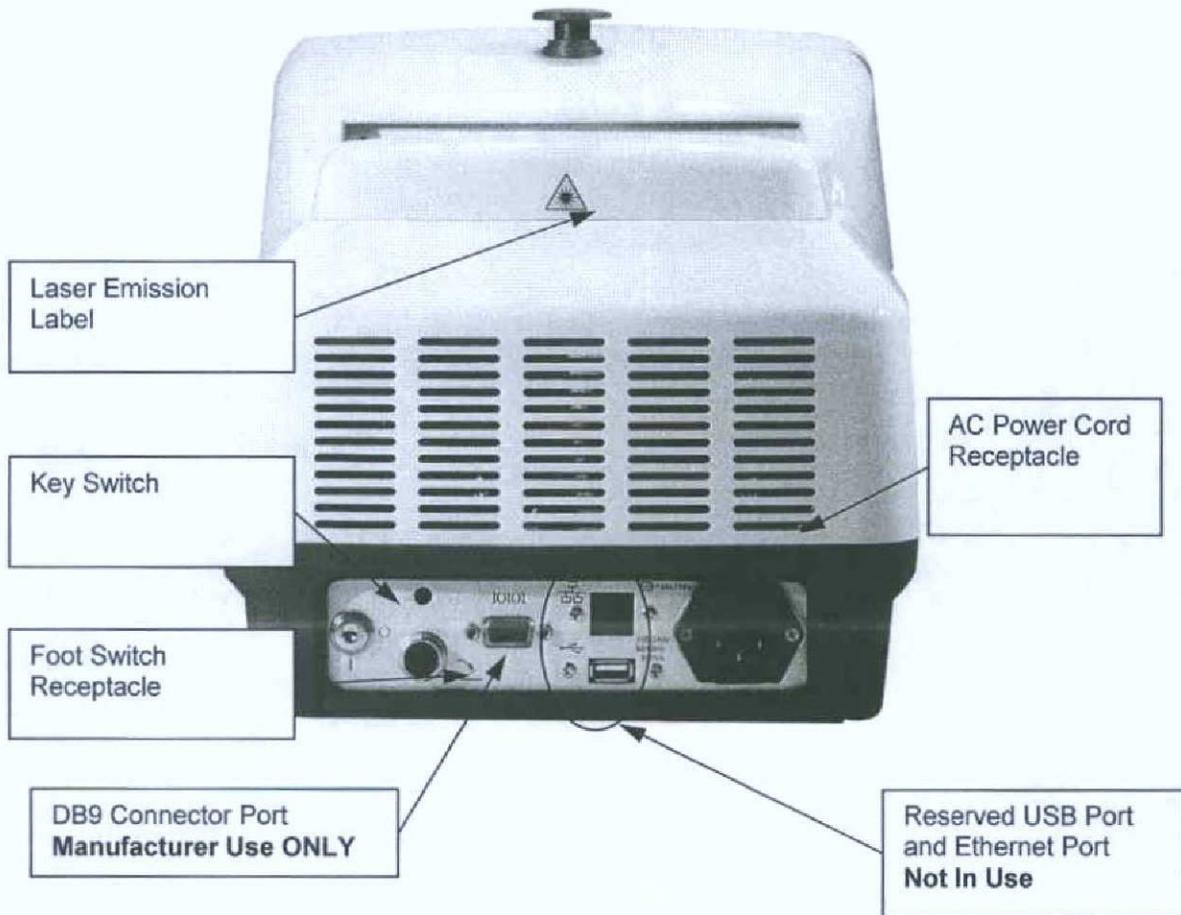
### Top View



Finger Switch Receptacle

Handpiece Fiber Receptacle

### Rear View



Laser Emission Label

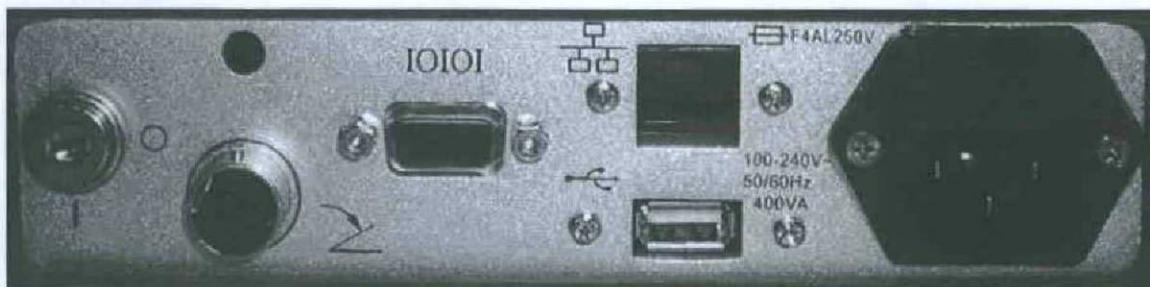
Key Switch

Foot Switch Receptacle

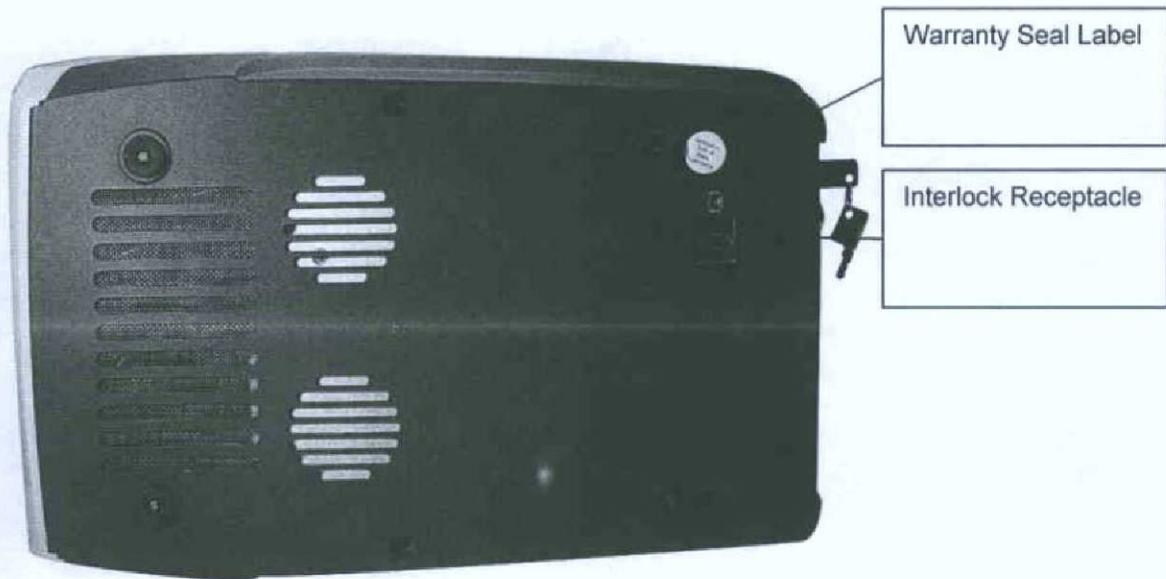
DB9 Connector Port  
Manufacturer Use ONLY

AC Power Cord Receptacle

Reserved USB Port and Ethernet Port  
Not In Use



## Bottom View



## 8. SYSTEM SET-UP

### 8.1. Receipt and Unpacking

Using LTS-1500 packing list, unpack the LTS-1500 and its accessories from the shipping carton. Check for missing parts and inspect the unit carefully for damage, such as cracks, dents or bent parts. If items are missing or any physical damage is apparent, please call LiteCure, LLC at 302-709-0408 for assistance. Notify the carrier if the damage appears to be the result of a shipping mishap.

If Warranty Seal Label is not found on device or is broken, please do not operate this device and call LiteCure, LLC at 302-709-0408 immediately for assistance.

### 8.2. Usage Prerequisites

#### RECOMMENDATION

Individuals planning to use the laser system should attend laser orientation and education sessions to achieve operational proficiency.

Every facility or institution utilizing this device is encouraged to adopt an ongoing training and safety program.

### 8.3. Set-Up / Location

1. Select a secure, properly equipped, and well-ventilated location in which to install and operate the laser device.
2. Ensure that the surface will properly support the entire device.
3. Place within 6 feet of an available 100-240V electrical outlet.
4. Ensure adequate airflow around the device. The laser device is air-cooled and designed for use in a well-ventilated environment.
  - 8.3.4.1. Select a flat hard surface (not a surface that will inhibit airflow through the bottom of the device).
  - 8.3.4.2. There must be a minimum 4" clearance around the rear of the device.
5. Locate and uncoil the AC power cord.
6. Plug the power cord into the AC input on the rear of the laser device.
7. Plug the male end of the AC power cord into a grounded electrical outlet.
8. Connect the finger/footswitch to the rear of the LTS-1500 laser device.
9. Press down on the footswitch cover then release; the spring loaded cover will open automatically.

#### CAUTION

Please do not remove the hand piece fiber from the emission port once it has been secured unless the device is being packaged or transported to another location. Constant insertion and removal of the hand piece fiber before and after every procedure will increase the chance of emission port and fiber tip contamination. If the emission port or the fiber tip is contaminated then the device might be damaged during beam emission.

The dust cap is installed by the manufacturer as a means to prevent dust and debris from contaminating the emission port during shipping and before device installation and is not intended as the primary means to protect the emission port connector during normal use.

We recommend the following procedure:

1. Before using the device for the first time, install and secure the hand piece fiber in accordance with the User Manual.
2. Use the device as required.
3. When done using the device, power off in accordance with the User Manual and leave the hand piece connected.

## 9. OPERATION

### 9.1. Fiber Installations

Take off the fiber cap. Make sure the fiber tip is clean prior to inserting into the hand piece fiber receptacle; secure by screwing the fiber locking collar onto the hand piece fiber receptacle.

### 9.2. Laser Safety Eyewear

ALWAYS wear the protective eyewear supplied with this device. All personnel present during device operation must wear this eyewear.

Laser safety eyewear must also be resistant to physical damage or photo-bleaching resulting from laser exposure.

All personnel who are within the NOHD are considered to be within the controlled area and must wear laser safety eyewear.

The NOHD and Beam Divergence for the LTS-1500 laser beams are:

Laser Hand Piece Style	NOHD (meter)	Beam Divergence
Small Cone	4.7 m	Full Angle (degree) 47
Large Cone	4.7 m	Full Angle (degree) 47
Small Ball	9.5 m	Full Angle (degree) 12
Large Ball	37 m	Full Angle (degree) 3

**MPE (W/cm<sup>2</sup>) =0.001514**

In addition to providing the required laser safety eyewear, take the following steps to secure the treatment room, or the controlled area:

1. To alert personnel before they enter the controlled area, place the included Laser Safety Sign, or its equivalent, on the outside of the treatment room door when the laser is in use.
2. Close the treatment room door during operation of the laser. Or, optionally, the Interlock Jack can be connected to the treatment room door through an interlock circuit so that laser emission is automatically disabled when the treatment room door is opened.

A blocking barrier, screen, or curtain capable of blocking or filtering the laser beam could be placed to create a controlled area inside a large treatment room. The barrier should be made of material that can withstand the power of the treatment beam for the maximum exposure time, relative to the configuration of the controlled area and the treatment parameters for the specific medical application.

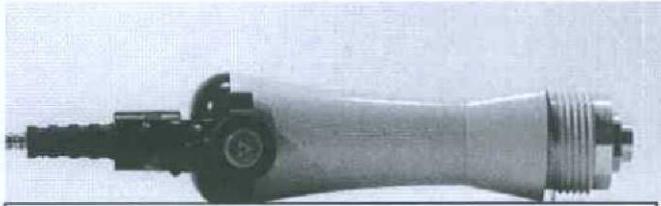


### **Caution**

ALWAYS wear the protective eyewear supplied with this device, which is optically dense at the wavelength of operation (see specification sheet). All personnel present during device operation must wear this eyewear. Contact LiteCure, LLC at 302-709-0408 to purchase additional sets of protective eyewear for this device.

### 9.3. Hand Piece

1. The hand piece is composed of hand piece handle and hand piece heads. The universal screw design is perfect for making the different heads interchangeable.



Hand Piece Handle + Finger Switch

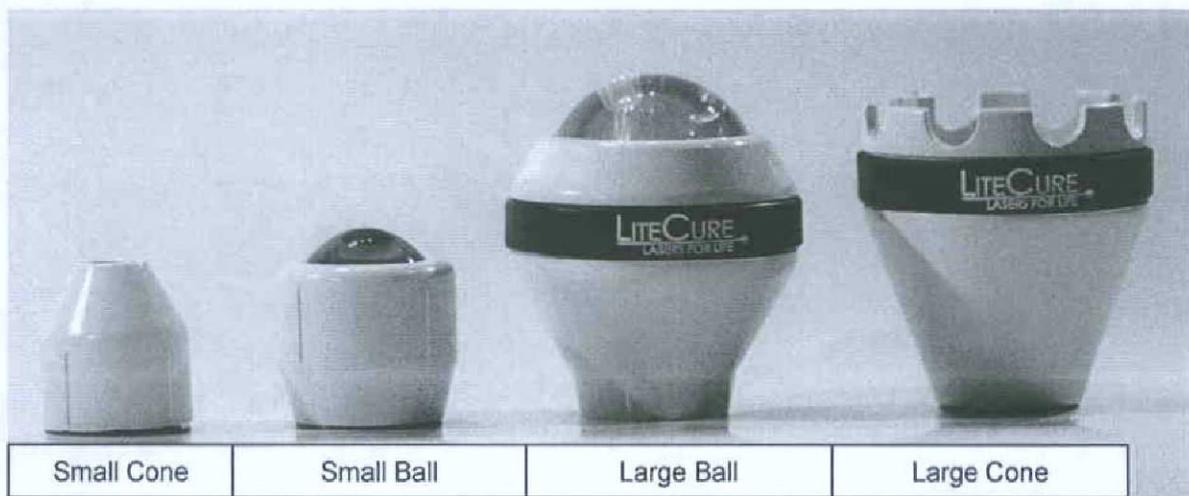
#### WARNING!



**DO NOT use Hand Piece without Hand Piece Head or inadequately secured Hand Piece Head on the Hand Piece Handle.**

**Doing so may cause serious and/or irreversible injury.**

2. Exchange Hand Piece Head.



#### Caution

Please read USER MANUAL HAND PIECE before using Hand Pieces.

## 9.4. Emergency Laser Off Switch and Key

Make sure the Emergency Laser Off Switch button pops out, otherwise rotate in the direction indicated by the arrows, then release it as the switch pops out. Insert key into the key-lock switch.

### NOTE

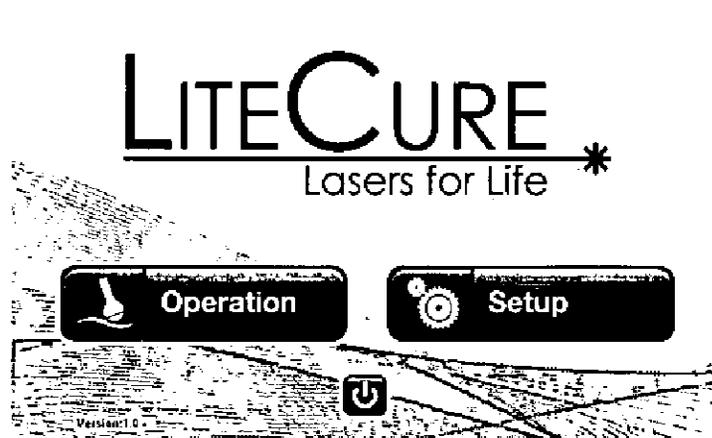
The key can only be inserted into and removed from the key switch when it is in the vertical (OFF) position.

Turn the key clockwise to the right one-quarter turn

1. The fan will start.
2. There will be an audible beep and the LCD panel will illuminate displaying the welcome (initial power-on) screen.

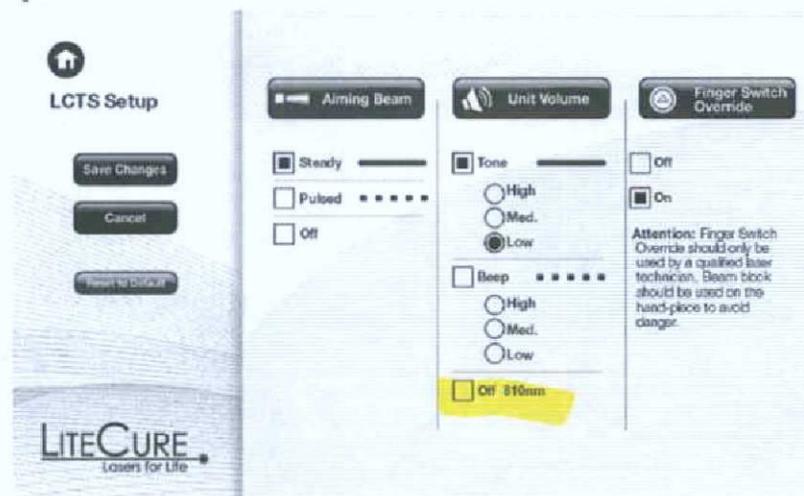
## 9.5. Power On

The initiation of the power-on sequence shall be accompanied by audible alerts, and then the Main Screen (below) presents.



- Press Operation button to enter Standby Mode.
- Press Setup button to enter Setup Screen.
- Press Power button to turn off the display.

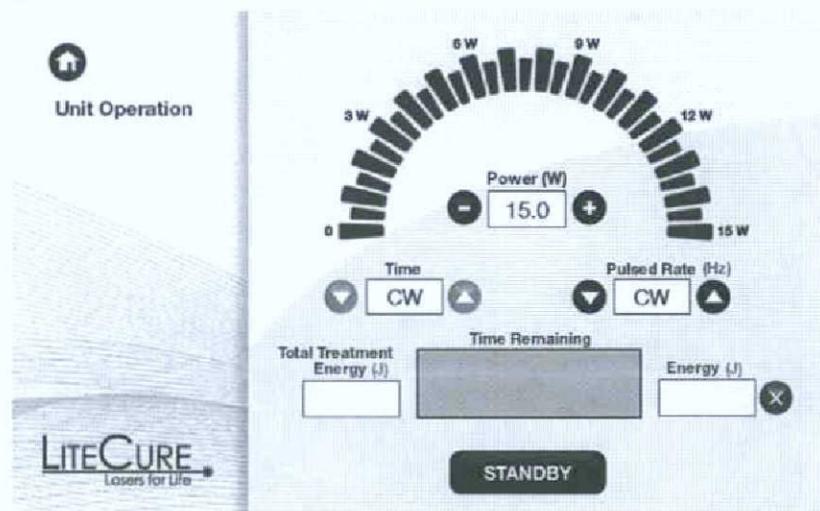
## 9.6. Setup



In Setup Screen, the software allows operators to change the Aiming Beam, Unit Volume and Finger (Foot) Switch Override settings.

- Aiming Beam: Steady, Pulsed, Off
  - a. 3.5+/-1.0mW
- Unit Volume: Tone (High, Med and Low)
  - a. 45-65dB at High
- Unit Volume: Beep (High, Med and Low)
- 810nm wavelength: Off
- Finger(Foot) Switch Override: On/Off
- Press Save Changes button to save the selected settings
- Press Cancel button to cancel the selected settings
- Press Reset to Default button to reset the settings to the default settings.

## 9.7. Standby Mode



In Standby Mode, the software allows operators to change the laser power, laser modulation frequency, laser emission timer, and energy reset in Standby mode.

- Standby button is active
- Modulation frequency display shows the selected modulation frequency
- Aiming beam is inactive
- Unit does not enter Ready Mode if finger/footswitch is closed – Create Error Message:
  - a. Operation Error, Foot/Finger switch is closed.
  - b. Produce audible beep – 3 times  
Press Exit button can return to Standby Mode.
- Unit does not enter Ready Mode if fiber is not inserted – Create Error Message:
  - a. Operation Error, Optic Fiber is not inserted.
  - b. Produce audible beep – 3 times  
Press Exit button can return to Standby Mode.
- Unit does not enter Ready Mode if safety interlock is not inserted – Create Error Message:
  - a. Operation Error, Interlock is not inserted.
  - b. Produce audible beep – 3 times  
Press Exit button can return to Standby Mode.
- Press the Power Setting Scale or the "+" / "-" button to set the laser power. The selected laser power will be shown at the Power Setting Window. To scroll to the desired power value, maintain pressure on the desired button. The laser power can be set from 0.5W to 15.0W
- Press the Pulsed Rate "+" / "-" button to set the laser modulation frequency. The selected laser frequency will be shown at the Pulsed Rate Window. To scroll to the desired frequency value, maintain pressure on the desired button. The laser frequency can be set from CW to 10000Hz
  - Note: The duty cycle in the Pulsed mode is 50%.
- Press the Time "+" / "-" button to set the laser treatment time. The selected laser treatment time will be shown at the Time Window. To scroll to the desired time value, maintain pressure on the desired button
- Press Energy Reset button to reset the energy monitor value to zero
- Press Home button in the upper-left corner to return to Main Screen

## 9.8. Ready Mode

The software has Ready Mode in which the laser will emit when the finger/footswitch is pressed. The purpose of Ready Mode is to wait for user(s) to press the finger/footswitch and start laser emission. The software produces 6 seconds delay (6 beeps) to warn the users during the transition from STANDBY to READY Mode. During the transition, the Standby button changes to Ready button and flashes. After 6 beeps, the aiming beam emits from the hand piece if the aiming setting is on.

In Ready Mode, the software allows operators to change the laser power level, laser modulation frequency, laser emission timer, and energy reset in Standby mode.

- Ready button is active
- Modulation frequency display shows the selected modulation frequency
- Aiming beam emits from the hand piece if the aiming setting is on.
- Unit exit from Ready Mode if fiber is not inserted correctly – Create Error Message:
  - a. Operation Error, Optic Fiber is not inserted.
  - b. Produce audible beep – 3 times  
Press Exit button can return to Standby Mode.
- Unit exit from Ready Mode if safety interlock is not inserted / attached to back of unit – Create Error Message:
  - a. Operation Error, Interlock is not inserted.
  - b. Produce audible beep – 3 times  
Press Exit button can return to Standby Mode.
- Press the Power Setting Scale or the "+" / "-" button to set the laser power. The selected laser power will be shown at the Power Setting Window. To scroll to the desired power value, maintain pressure on the desired button. The laser power can be set from 0.5W to 15.0W
- Press the Pulsed Rate "+" / "-" button to set the laser modulation frequency. The selected laser frequency will be shown at the Pulsed Rate Window. To scroll to the desired frequency value, maintain pressure on the desired button. The laser frequency can be set from CW to 10000Hz
 

Note: The duty cycle in the Pulsed mode is 50%.
- Press the Time "+" / "-" button to set the laser treatment time. The selected laser treatment time will be shown at the Time Window. To scroll to the desired time value, maintain pressure on the desired button.
- Press Energy Reset button to reset the energy monitor value to zero
- Unit returns to Standby Mode from Ready Mode if leaving unit alone for more than 3 minutes.
- Press Ready button to return to Standby Mode.

## 9.9. Emission Mode

The software monitors the laser output power in according to the parameter settings on the display to ensure the power is within +/-20% of power setting. During emission, the software does not allow users to change any settings on the display. The software displays the word EMISSION on the display. The device produces beeps, steady audible tone, or no audible tone during emission according to the audible settings.

- During emission, the software does not allow users to change any settings on the display
- The real laser output power is same as the power setting on the display within +/-20% deviation when the laser modulation frequency is CW.
- The real laser output power is 50% of the power setting on the display within +/-20% deviation when the laser modulation frequency is not CW
- Unit exit from Emission Mode if fiber is not inserted – Create Error Message:
  - a. Operation Error, Optic Fiber is not inserted.
  - b. Produce audible beep – 3 times

- c. Laser beam is disabled  
Press Exit button can return to Standby Mode.
- Unit exit from Emission Mode if safety interlock is not inserted – Create Error Message:
  - a. Operation Error, Interlock is not inserted.
  - b. Produce audible beep – 3 times
  - c. Laser beam is disabled  
Press Exit button can return to Standby Mode.
- Unit exit from Emission Mode if laser power exceeds +/-20% of power setting – Create warning message:
  - a. Laser power is out of range
  - b. Unit to produce audible beep – 3 times
  - c. No laser beam from hand piece  
Press Exit button can return to Standby Mode.
- Unit exit from Emission Mode if laser diode temperature is overheating – Create warning message:
  - a. Laser temperature is out of range
  - b. Unit to produce audible beep – 3 times
  - c. Laser beam is disabled.  
Press Exit button can return to Standby Mode.
- Laser emission is disabled when the timer counts down to zero if timer setting is not CW.
- Laser emission continues until emission is interrupted by finger/footswitch if timer setting is CW.
- If laser emission is interrupted during emission mode by finger/footswitch operation, the laser emission can be enabled again by finger/footswitch until the remaining time is over.

## 10. SAFETY

This section provides a collection of safety guidelines and safety-related statements relevant to the safe and effective operation of the LTS-1500 laser device. Additional statement and protocols regarding safety appear elsewhere in this document. Use this laser device according to all printed guidelines cautionary statements, and protocols.

### 10.1 Laser Safety Supervision

#### RECOMMENDATION

Designate at least one person (e.g. Laser Safety Supervisor) responsible for providing training on all operating and safety procedures at each facility that utilizes this device.

Individuals planning to use the laser system should attend laser orientation and education sessions to achieve operational proficiency.

1. Designate at least one person at each facility that utilizes this device as laser safety supervisor, responsible for providing training on all operating safety procedures.

### 10.2 Safety Devices

The following components have specific safety-related features. All individuals who use this laser device should be familiar with the purpose and the operation of these components.

**Emergency Laser Off Switch.** This switch is located on the top of the LTS-1500 device. Push the switch down to terminate all electrical power to the laser device's microprocessor and laser-emitting components. Resetting the switch restores power. To reset the Emergency Laser Off Switch, the user must twist and rotate in the direction indicated by the arrows, then release it as the switch button pops out, returning it to its normal position.



#### **Caution**

DO NOT leave key in device's key switch when not in use. Prevent unauthorized and/or unqualified use of the device. This will also prevent inadvertent laser emissions.

#### 1. Key Switch

- This switch is located on the rear panel of the LTS-1500 device. A key is required to activate the laser system. The user inserts one of the supplied keys into the key-switch and turns it 90 degree clockwise. When the key switch is in this position, it cannot be removed.

- After powering OFF the device using the key switch (a 90-degree, counter-clockwise turn), the user should remove the key and store it properly to prevent unauthorized or unexpected laser system operation.

## 2. Safety Interlock

This safety interlock located at the bottom of the device. If the interlock is not inserted into the connector jack, all electrical power to the controls and laser components is terminated. The safety interlock **MUST** be inserted before the laser emission.

## 10.3 Safety Strategy

### 1. Three Minutes Unattended Protection

If the laser device is left in Ready mode and does not receive any input for three minutes, the laser will switch back to Standby mode.

### 2. Internal Laser Energy Monitor

- This is an internal device that monitors the intensity of laser energy generated whenever laser emission occurs. This monitor aborts laser emission if the laser device is unable to maintain the laser energy output set by the user.

### 3. Laser Eye Protection

- The protective laser eyewear has an optical density rating  $> 5.0$  for 350nm~2000nm (see specification sheet) laser emission. All personnel present during device operation must wear this eyewear. Contact LiteCure, LLC at 302-709-0408 to purchase additional sets of 350nm~2000nm (see specification sheet) protective eyewear.

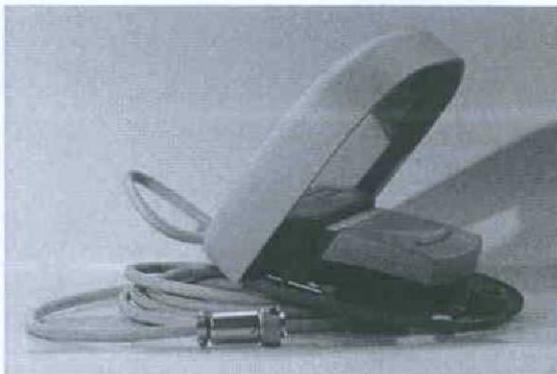
## 11. ACCESSORIES

### 11.1 Foot Switch

A single intensity footswitch comes with this laser device. The laser device treats the footswitch as a simple on/off device. When Override function is off, pressing down the footswitch produces 100% of the laser energy set by the operator. Fully releasing the pressed footswitch stops laser emission. When Override function is on, pressing down the footswitch one time produces 100% of the laser energy set by the operator, and pressing down again to stop the laser emission.

When closed, the cover of the foot switch is designed to prevent inadvertent foot pedal control surface depression. Always turn laser off when not in use.

When foot switch operation is desired, press down on the cover then release. The cover is spring loaded and will open automatically.

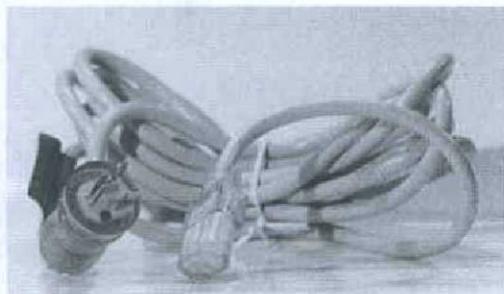


## 11.2 Finger Switch

A single intensity finger switch comes with the hand piece. The laser device treats the finger switch as a simple on/off device. When Override function is off, pressing down the finger switch produces 100% of the laser energy set by the operator. Fully releasing the pressed finger switch stops laser emission. When Override function is on, pressing down the finger switch one time produces 100% of the laser energy set by the operator, and pressing again stops the laser emission.



## 11.3 Power Cord



## 11.4 Laser Safety Eyewear



### Caution

ALWAYS wear the protective eyewear supplied with this device, which is optically dense at the wavelength of operation (see specification sheet). All personnel present during device operation must wear this eyewear. Contact LiteCure, LLC at 302-709-0408 to purchase additional sets of protective eyewear for this device.



All personnel who are within the NOHD are considered to be within the controlled area and must wear laser safety eyewear. ALWAYS wear the protective eyewear supplied with this device. All personnel present during device operation must wear this eyewear.

## 12. SPECIFICATIONS

<b>Model</b>	LTS-1500
<b>Laser type</b>	Solid State laser (Class IV)
<b>Treatment laser wavelength</b>	810+/-10nm, 980+/-10nm
<b>Aiming beam wavelength</b>	650+/-15nm
<b>Aiming beam power</b>	3.5mW+/-1.0mW
<b>Maximum output power</b>	15W @ aperture of hand piece
<b>Output port</b>	Hand piece
<b>Operating modes</b>	Continuous Wave (CW)
	Pulse Wave (50% duty cycle) 2, 10, 20, 100, 200, 500, 1000, 2500, 5000, 10000Hz
<b>Audio warning signal level</b>	45 to 65 dB
<b>Cooling</b>	Thermal Electrically Cooled with Forced Air
<b>Weight</b>	<30 lbs
<b>Dimensions</b>	413mm(L)x264mm(W)x257mm(H)
<b>Power requirement</b>	100-240V~ 50/60Hz 400VA
<b>Operation temperature</b>	10 °C to 35 °C
<b>Storage temperature</b>	-20 °C to 70 °C

## 13. CLEANING



### **Warning**

Always turn off the system and unplug the power cord from the wall outlet before cleaning.



### **Warning**

Always use protective eyewear and gloves when cleaning and disinfecting any equipment.



### **Caution**

**DO NOT use Hand Piece Head until alcohol solution used in cleaning procedure completely evaporates. Doing so may cause the laser to ignite alcohol solutions or vapors.**

LTS-1500 laser device uses solid-state laser technology. It is important to keep the unit and accessories free from dust. To clean the exterior surfaces on the unit or accessories:

- Wipe with a soft cloth moistened with isopropyl alcohol solution. Ensure the solution is only 70% alcohol or less. Solutions of more than 70% alcohol can cause product damage.

## 14. MAINTENANCE AND CALIBRATION

### **Calibration Procedure**

Regulatory agencies require that manufacturers of US FDA CDRH Class III and IV medical lasers supply their customers with power calibration instructions.

Calibration must be performed by the LiteCure-certified Service Personnel. Questions regarding this procedure should be referred to your local LiteCure representative. Units are recommended to be calibrated once a year.

### **DISCLAIMER WARNING**

Calibration is a service procedure to be done only by LiteCure-certified Service Personnel. Adjustment by anyone other than a certified LiteCure Service Personnel voids any existing manufacturer's warranty on the instrument.

### **Laser Power Calibration**

**TO PERFORM LASER CALIBRATION TEST PROCEDURE: WEAR LASER SAFETY GOGGLES WHEN PERFORMING THIS PROCEDURE**

Equipment Needed: Certified traceable power meter with appropriate wavelength and power measurement capabilities.

1. Turn off the laser.
2. Inspect and attach a LiteCure optical fiber, foot pedal and power cord as directed in the manual. Pay special attention to ensuring that both ends of the optical fiber are clean and free of any dust, fluid or other contaminants.
3. Turn on the LiteCure laser and enter standby mode as instructed in the manual.

4. Increase the power setting until the Digital and Analog Power Displays reach their maximum setting in CW (CONTINUOUS MODE).
5. Place the laser in ready mode.
6. Using the aiming beam, direct the distal end of the fiber into the active area of the power meter.
7. Enable the laser, fire the laser, and record the value in Watts from the power meter. Repeat 3 times and taken an average.
8. The average should be within 20% of power setting.
9. If the results are outside the 20% range, ensure that: all of the light from the fiber is entering the detector, the fiber is connected correctly, and the fiber is not damaged. Replace with a new fiber if necessary and repeat.
10. If the results are still outside the 20% range, discontinue this procedure and contact your local LiteCure representative.

## **15. SOURCES FOR ADDITIONAL INFORMATION AND ASSISTANCE ON LASER SAFETY**

### **Center for Devices and Radiological Health**

Office of Compliance

2098 Gaither Rd.

Rockville, MD 20850

Tel: 301-594-4654

Fax: 301-594-4672

<http://www.fda.gov/cdrh/index.html>

### **Laser Institute of America**

12424 Research Parkway, Suite 125

Orlando, FL 32826

Tel: 407 380 1553

Fax: 407 380 5588

<http://www.laserinstitute.org/>

## 16. WARRANTY INFORMATION

### 16.1 Terms and Conditions

1. LTS-1500 laser device is warranted to be free from defects in materials and workmanship for a period of 24 months, starting from the date of initial shipment. This warranty does not extend to incidental or consequential damages and to damage caused by negligent or improper handling in use, storage, nor to products from which the original identification markings or labels have been defaced, altered or removed.
2. LiteCure, LLC reserves the rights of determining cause or existence of defect and the options to repair the products, which proves to be defective during the warranty period. Products replaced under warranty will be warranted only for the balance of the warranty period starting from the date of the first shipment.
3. This warranty extends only to the original purchaser of the equipment from LiteCure, LLC. The purchaser must notify LiteCure, LLC within 15 days of first detecting the defect and promptly return the defective product before expiration of the warranty period.
4. Products claimed by purchaser to be defective shall be returned to LiteCure, LLC with transportation and insurance (if necessary) prepaid by purchaser. LiteCure, LLC will return repaired or replaced products to purchaser with FOB city destination within the Continental United States. Transportation fees insurance (if necessary) beyond this limit will be charged to purchaser.

### 16.2 Return Procedure

Please review terms of purchase and date of shipment to determine validity of warranty claim. Warranty claim should only be made for products within terms of warranty policy.

1. Call LiteCure, LLC at 302-709-0408 and obtain a Return Material Authorization number (RMA) and detailed return instructions. A form will be faxed and must be completed, signed and returned to LiteCure, LLC For customers where distributorship and/or a representative is not available, all claims should be addressed to:

Service  
LiteCure, LLC  
250 Corporate Blvd. Suite-B  
Newark, Delaware 19702

2. Be prepared to furnish:
  - Product Model number and Serial number
  - Purchase and Shipment Date
  - Reason for return
  - Name of person and phone number at your organization for further communication.
3. Adhere to LiteCure, LLC's complete return instructions for transportation and packaging and ship the product (freight and insurance prepaid) with proper documentation containing the RMA number and the information specified above.
4. LiteCure, LLC will advise the purchaser of its determination of warranty at the earliest possible time. Providing complete information as requested will expedite the procedure.







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# LITECURE

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Lasers for Life \*

## **USER MANUAL Hand Piece**

250 Corporate Blvd., Suite B  
Newark, DE 19702, USA  
Tel 302-709-0408  
Fax 302-709-0409  
<http://www.litecure.com>

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## SAFETY AND HANDLING CONSIDERATIONS



### **Warning**

NEVER look directly into the distal end of the hand piece connected to an active laser device. Never direct the laser light directly into the eyes, or direct the laser beam at anything other than the area to be treated. WITH or WITHOUT the appropriate laser-emission protective eyewear: indirect or direct eye contact with the output beam or scattered laser light from any reflective surface will cause serious irreparable corneal and/or retinal damage, and possible blindness to one or both eyes.



### **Warning**

DO NOT allow any reflective object to fall into or obstruct the path of the laser energy produced by this device. The operator, all assistants, and the patient must remove all reflective objects (such as rings, metal watchbands, and jewelry) prior to treatment with this device. Indirect or direct eye contact with the output beam or scattered laser light from any reflective surface from the laser will cause serious, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes.



### **Warning**

DO NOT remove protective eyewear until the operator returns the laser device to Standby mode.



### **Warning**

FAILURE TO COMPLY with all safety instructions and warnings may expose all participants to harmful levels of laser radiation and/or dangerous levels of electrical current.



### **Warning**

ALWAYS wear the protective eyewear (OD>5) supplied with this device, which is optically dense at the wavelength of operation. All personnel present during device operation must wear this eyewear. Contact LiteCure, LLC at 302-709-0408 to purchase additional sets of protective eyewear for this device.



### **Warning**

ALWAYS put the laser in Standby mode or turn the device OFF prior to adjusting or connecting / disconnecting the hand piece or fiber optic.



### **Warning**

ALWAYS post Warning Signs for Class IV laser products.



### **Warning**

ALWAYS post Warning Signs in the area of the laser beam to alert others.



### **Warning**

ALWAYS Turn the device OFF before lifting, moving or relocating the device.



***Warning***

ALWAYS place "Laser In Use" signs at location entrances where people will use the laser.



***Warning***

NEVER leave this device in the READY mode unattended.



***Warning***

NEVER allow untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual.



***Warning***

DO NOT leave key in device's key switch when not in use. Prevents unauthorized and/or unqualified personnel use of the device. This will also prevent inadvertent laser emissions. DO NOT allow any nonessential personnel into the treatment area during any laser procedure.



***Warning***

DO NOT press the foot/finger switch without first verifying the safe orientation and proper positioning of the hand piece and distal end of the optical fiber and ensuring compliance to all safety precautions.

If the laser fails to operate properly, please discontinue treatment and contact LiteCure, LLC at 302-709-0408.



***Warning***

Public legal provisions may include special safety regulations for the protection of personnel against laser radiation. Compliance with any special safety regulations is required.



***Warning***

Using controls or settings or performing procedures other than those specified in this Operator Manual may result in hazardous radiation exposure.



***Warning***

Do not attempt to disassemble the laser unit. This will void all warranties applicable to the unit and may result in hazardous radiation exposure.

## FIRE AND EXPLOSION HAZARDS

Healthcare professionals should be aware of the following safety considerations and potential fire hazards when using the laser:

1. The laser beam can ignite most nonmetallic materials.
2. A UL-approved or equivalent fire extinguisher should be readily available

This laser unit is not intended for operation in areas subject to explosion hazards such as flammable materials, gases or substances. A fire or explosion could occur.



### **Warning**

The laser unit is not suitable for use in the presence of anesthetics that are flammable when in contact with air, oxygen, protoxide or nitrogen monoxide.



### **Warning**

AVOID THE USE of flammable solvents, anesthetics, oxidizing gases such as nitrous oxide (N<sub>2</sub>O) and oxygen or endogenous gases. The high temperatures produced in normal use of the laser equipment may ignite some material, for example cotton or wool, when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Always be aware of the fire risk caused by flammable gases in close proximity to an operating laser. If you accidentally spill liquid on the unit, immediately stop treatment, disconnect the power supply cable and contact your local distributor, authorized service center or LiteCure customer service for assistance.



### **Warning**

Never direct the laser beam toward paper, plastics or dark surfaces. These may catch fire or be damaged due to the high temperatures produced by the laser beam.



### **Warning**

DO NOT treat through clothing or bandages. Possible damage or ignition may occur due to the high temperatures produced by the laser beam.

## PREPARATION OF PATIENT FOR LASER THERAPY TREATMENT

1. The area to be treated must be exposed
2. The treatment area should be clean and free of surface dirt or oils
3. Use rubbing alcohol for all instrument surfaces in contact with the patient

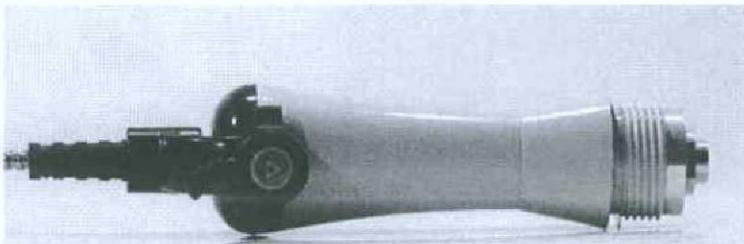


### **Caution**

**DO NOT use Hand Piece Head until alcohol solution used in cleaning procedure completely evaporates. Doing so may cause the laser to ignite alcohol solutions or vapors.**

## HANDPIECE DESCRIPTIONS

1. The hand piece is composed of hand piece handle and hand piece heads. The universal screw design is perfect for making the different heads interchangeable.



Hand Piece Handle + Finger Switch

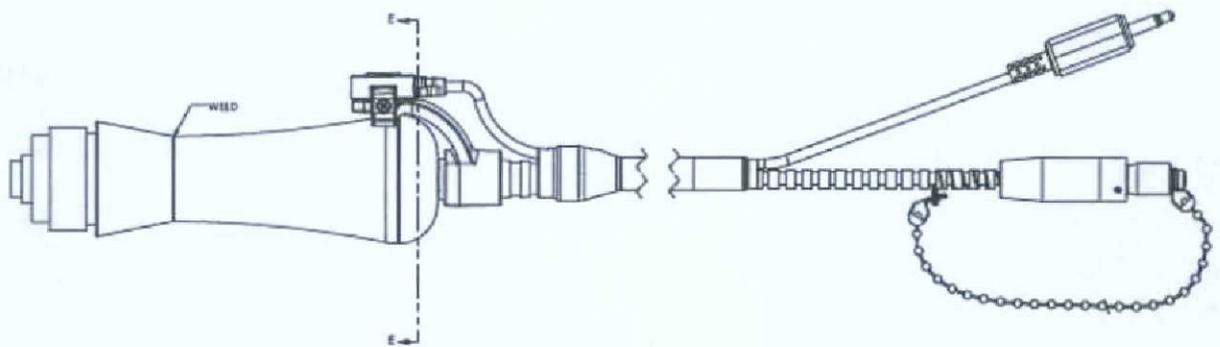
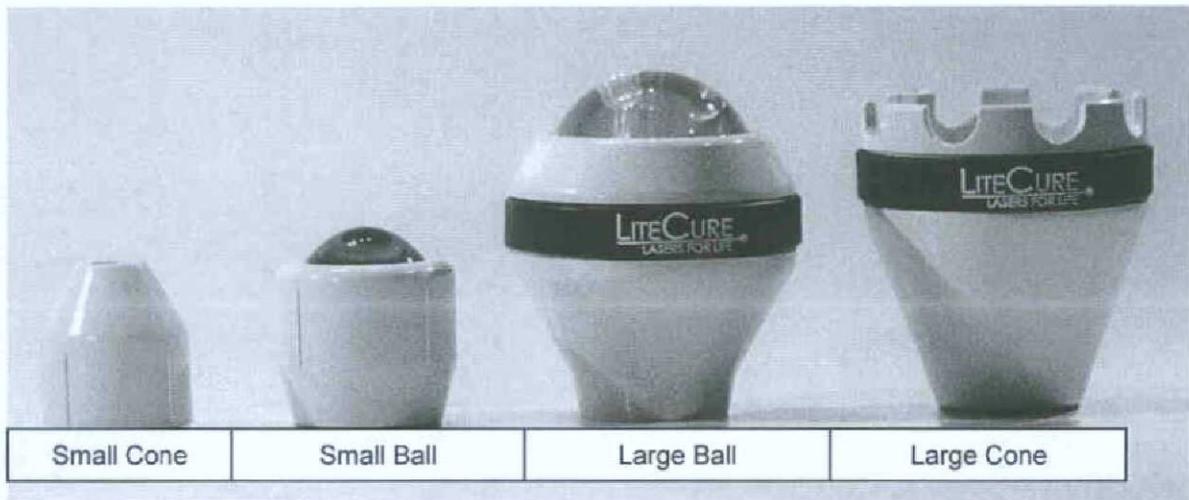
### WARNING!



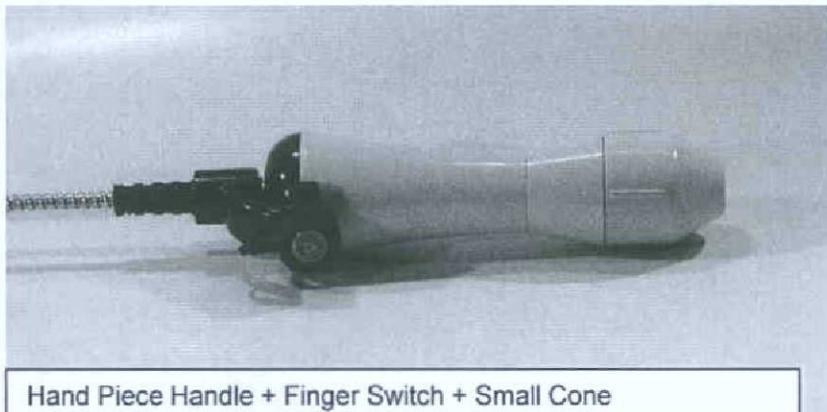
**DO NOT use Hand Piece without Hand Piece Head or inadequately secured Hand Piece Head on the Hand Piece Handle.**

**Doing so may cause serious and/or irreversible injury.**

2. Exchange Hand Piece Head.



Head Type	Spot Size (diameter)	Nominal Ocular Hazard Distance (NOHD)
Small Cone	100 mm with 10cm from the patient skin	4.7m
Small Ball	15mm	9.5m
Large Ball	30mm	37m
Large Cone	120mm with 8cm from the patient skin 140mm with 10cm from the patient skin	4.7m



Hand Piece Handle + Finger Switch + Small Cone

This head is for general use and applications where fine control with no contact or soft tissue manipulation during treatment is desired.

- For Intended Use:

**810nm and 980nm wavelength:**

LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

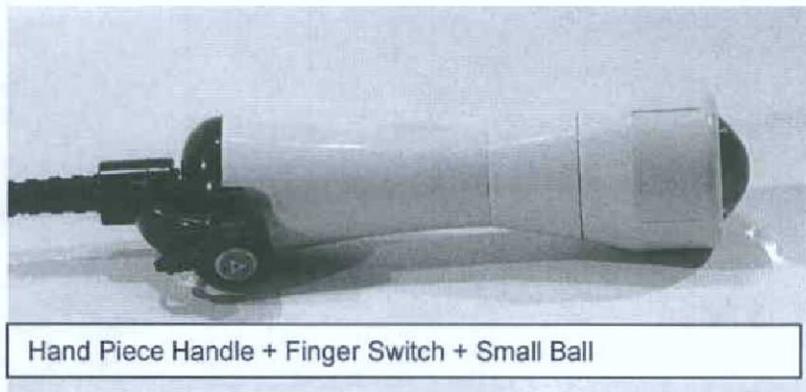
The Small Cone Head can be used at power settings up to **8W (810nm & 980nm)**, 10cm from the skin of the patient.

- For Intended Use:

**980nm wavelength:**

LiteCure Therapy System, Model LTS-1500 is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *Tmentagrophytes*, and/or yeasts *Candida albicans*, etc.).

The Small Cone Head can be used at power settings up to **15W (980nm)**, 10cm from the skin of the patient.

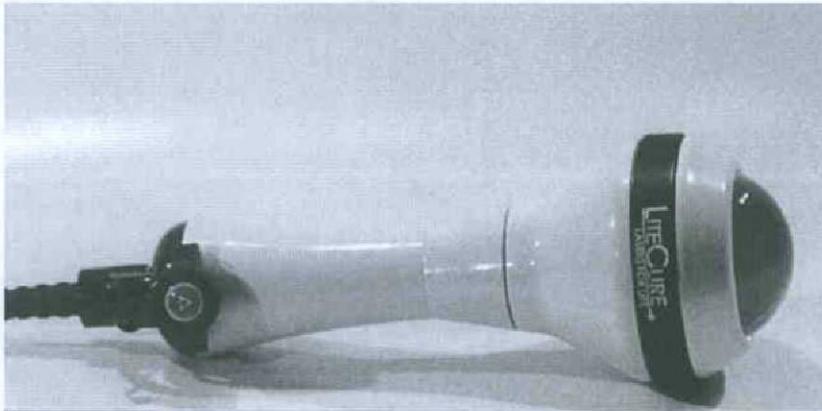


Hand Piece Handle + Finger Switch + Small Ball

This head is for use in applications where contact and soft tissue manipulation during treatment are desired. Examples of appropriate applications for the small ball are muscular or tissue injuries in tight spaces or near sensitive areas. The small ball is not recommended for use over bone, open wounds, non-intact skin or areas that would be sensitive to contact. This head should be

perpendicular to the skin and not approaching at an angle. The area to be treated and a significant surrounding margin should be covered evenly in a "painting" or "serpentine" motion.

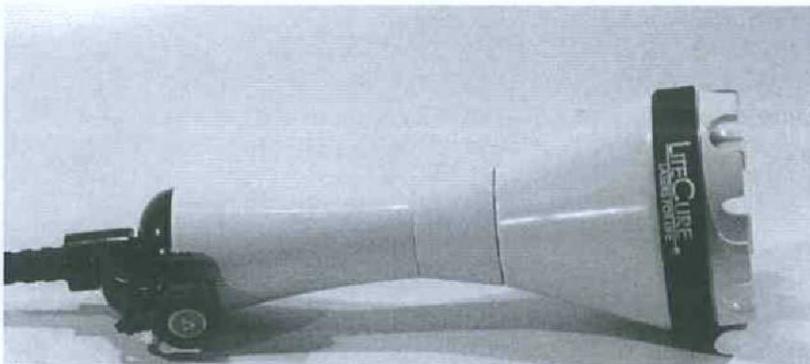
- The Small Ball can be used at power settings up to **8W (810nm & 980nm)**



Hand Piece Handle + Finger Switch + Large Ball

This head is for use in applications where contact and soft tissue manipulation during treatment are desired. Examples of appropriate applications for the large ball are muscular or deep soft tissue injuries. The large ball is not recommended for use over bone, open wounds, non-intact skin or areas that would be sensitive to contact. This head should be perpendicular to the skin and not approaching at an angle. The area to be treated and a significant surrounding margin should be covered evenly in a "painting" or "serpentine" motion.

- The Large Ball can be used at power settings up to **15W (810nm & 980nm)**



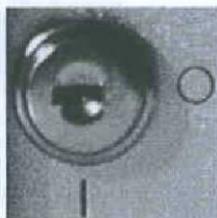
Hand Piece Handle + Finger Switch + Large Cone

This head is for general use and applications where no contact or soft tissue manipulation during treatment is desired.

- The Large Cone Head can be used at power settings up to **12W (810nm & 980nm)**, 8cm from the skin of the patient or power settings up to **15W (810nm & 980nm)**, 10cm from the skin of the patient.

**WARNING!**

**ALWAYS turn the device power OFF by using the key switch before changing Hand Piece Head.**



Remove Hand Piece Head from Hand Piece Handle, and **DO NOT** touch the distal end of the Hand Piece Handle.

Securely tighten the new Hand Piece Head to Hand Piece Handle.

**WARNING!**



**DO NOT use Hand Piece without Hand Piece Head or inadequately secured Hand Piece Head on the Hand Piece Handle.**

**Doing so may cause serious and/or irreversible injury.**

**WARNING!**

Wear Laser Safety Eyewear provided with the laser before operating the laser device.

**CAUTION**

Please do not remove the hand piece fiber from the emission port once it has been secured unless it is unavoidable. Repeated insertion and removal of the hand piece fiber before and after every procedure will increase the chance of emission port and fiber tip contamination. If the emission port or the fiber tip is contaminated then the device might be damaged during laser beam output emission.

The dust cap is installed by the manufacturer as a means to prevent dust and debris from contaminating the emission port during shipping and before device installation and is not intended as the primary means to protect the emission port connector during normal use.

We recommend the following procedure:

1. Before using the device for the first time, install and secure the hand piece fiber into the laser emission port in accordance with the User Manual.
2. Use the device as required.
3. When done using the device, power off in accordance with the User Manual and leave the hand piece connected.

Bending Limits of the Hand Piece Cable:

The radiation transferred within the hand piece cable goes through a very small diameter glass rod (an optical fiber). It can be damaged if bent too sharply. The maximum permissible bending radius of optical fiber is 5 cm.

Laser Hand Piece Troubleshooting:

If the any part of the hand piece assembly is overheating or producing smoke, then immediately power off device and discontinue operation. And then call LiteCure, LLC at 302-709-0408 immediately for assistance.

## HAND PIECE HEAD CLEANING AND DISINFECTION



### **Warning**

Always turn off the system and unplug the power cord from the wall outlet before cleaning.



### **Warning**

Always use protective eyewear and gloves when cleaning and disinfecting any equipment.



### **Caution**

**DO NOT use Hand Piece Head until alcohol solution used in cleaning procedure completely evaporates. Doing so may cause the laser to ignite alcohol solutions or vapors.**

1. To clean the exterior surfaces on Hand Piece Head:

- Wipe with a soft cloth moistened with isopropyl alcohol solution. Ensure the solution is only 70% alcohol or less. Solutions of more than 70% alcohol can cause product damage.

2. To clean the Large Ball:

Always dampen the cloth and then clean.

- Before cleaning, turn off the system and unplug the power cord from the wall outlet.
- Avoid using gritty cloths.

3. If you have access to an Ultrasonic Cleaner, it can be used to deep clean the Large Ball.

The following recipe is recommended:

Mix 90% isopropyl alcohol with warm water at the volume ratio of 60:40 and add one drop of dish soap.

4. After cleaning the Hand Piece Head, wipe it with soft cloth. Then leave it on clean surface to dry. To expedite drying time of the Hand Piece Head, putting 70% or less isopropyl alcohol into the Hand Piece Head and pouring it out will be helpful.



### **Caution**

**DO NOT use Hand Piece Head until alcohol solution used in cleaning procedure completely evaporates. Doing so may cause the laser to ignite alcohol solutions or vapors.**



***Warning***

**DO NOT use anything to clean the lens inside the handpiece. Doing so may damage the lens when laser emission. Using compressed air to remove the dust, debris and hair is recommended.**

# SECTION

14

## Section14 Sterilization & Shelf Life

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Sterilization and shelf life is not applicable to our device and accessories.

# SECTION

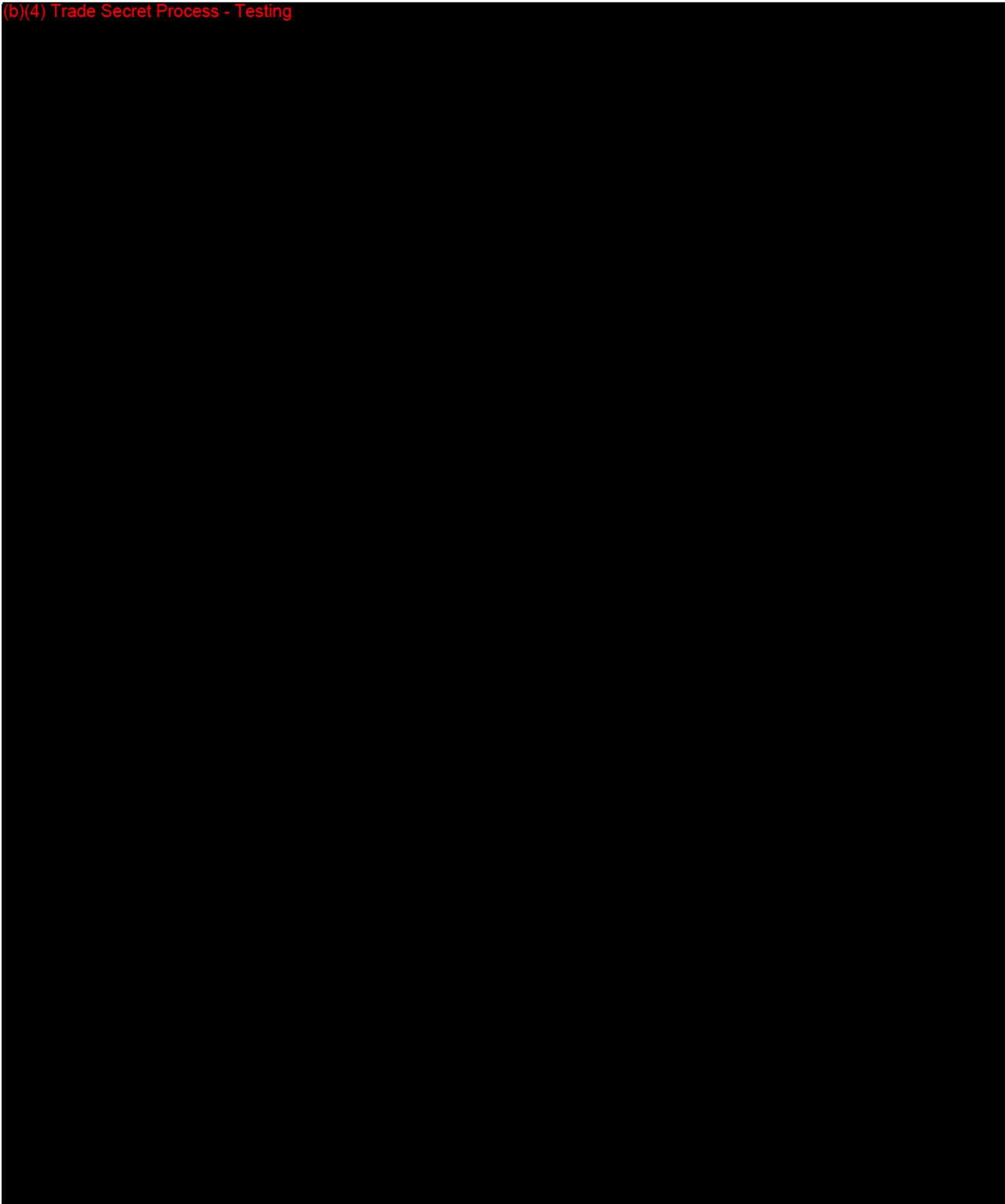
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15/001

## Section 15 Biocompatibility

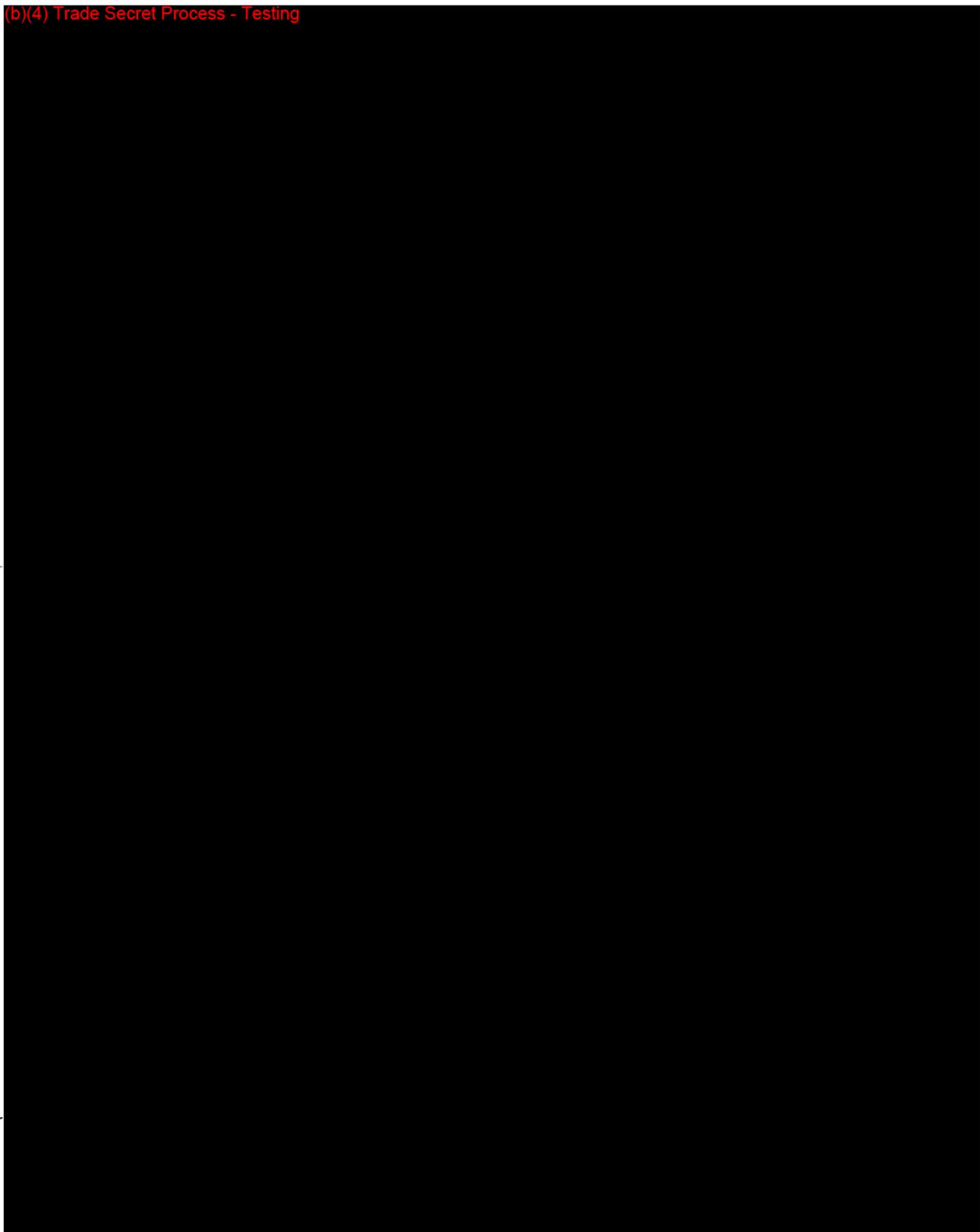
(b)(4) Trade Secret Process - Testing



## Section 15 Biocompatibility

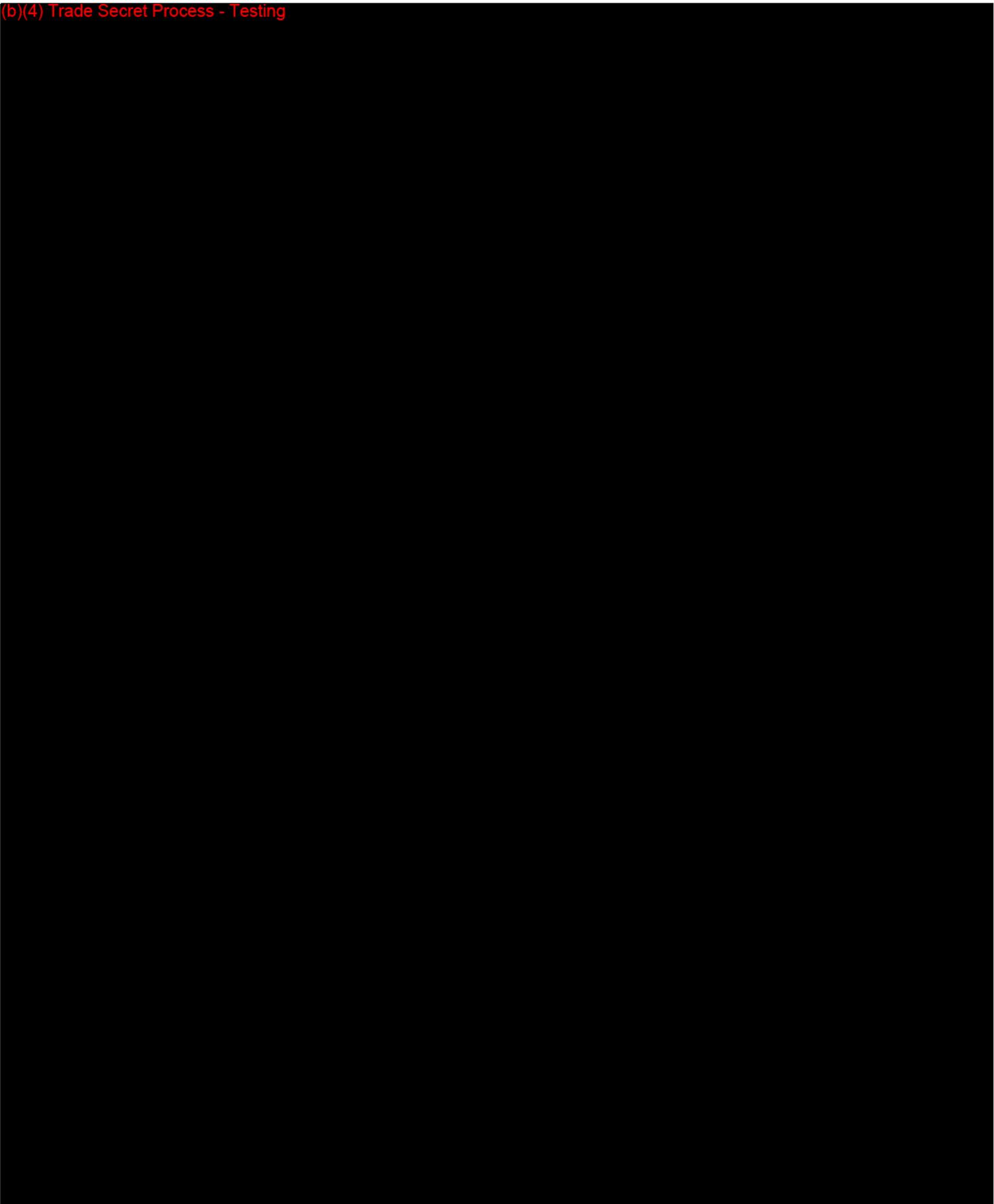
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(b)(4) Trade Secret Process - Testing



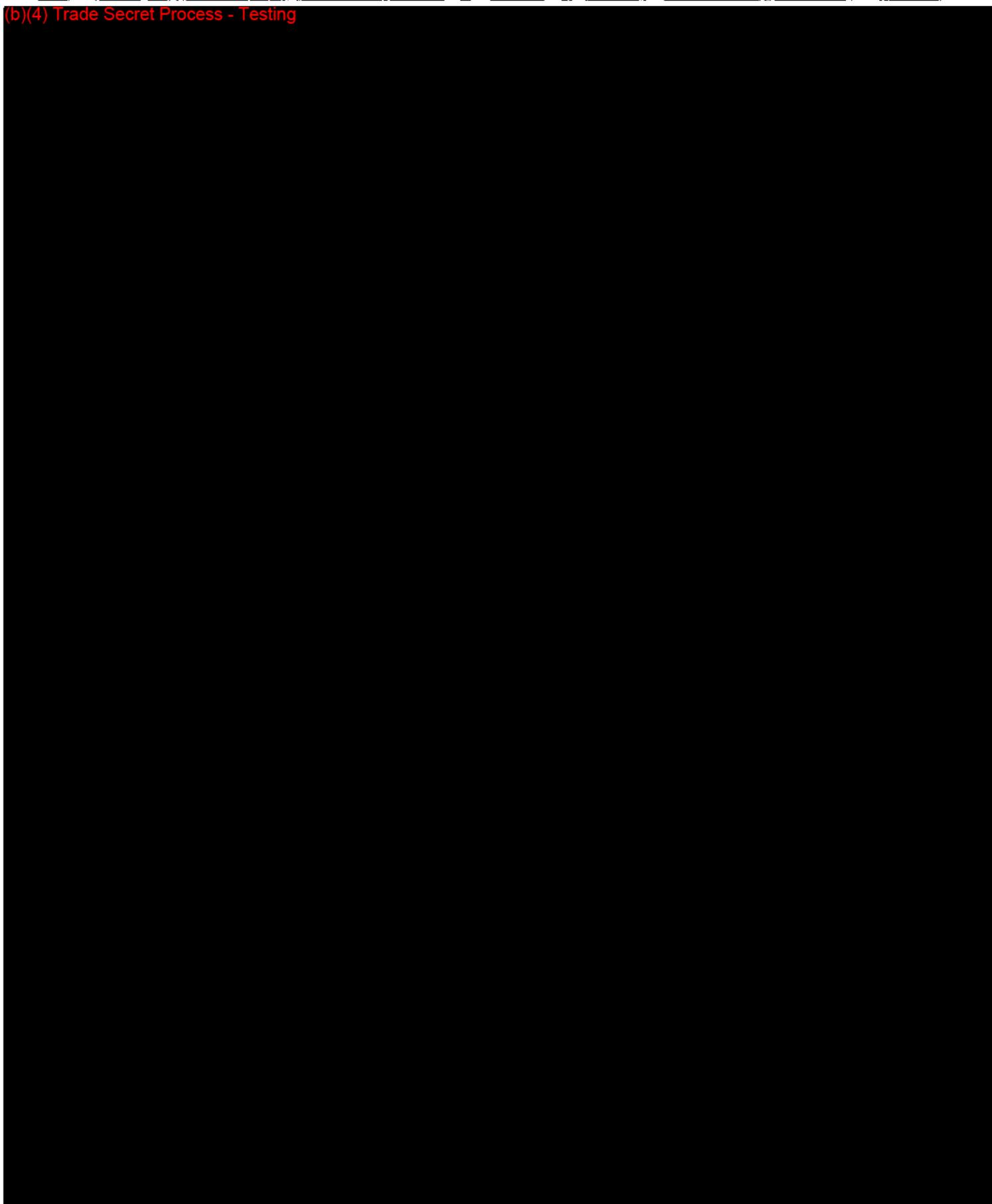
**Section 15 Biocompatibility**

(b)(4) Trade Secret Process - Testing



## Section 15 Biocompatibility

(b)(4) Trade Secret Process - Testing



Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(K)S**  
(To be filled in by applicant)

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**TYPE OF 510(K) SUBMISSION**

Traditional       Special       Abbreviated

**STANDARD TITLE<sup>1</sup>**

ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

*Please answer the following questions* Yes      No

Is this standard recognized by FDA<sup>2</sup>?      

FDA Recognition number<sup>3</sup> # 2-156

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?      

Is a summary report<sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)?         
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?      

Does this standard include acceptance criteria?         
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of the standard?         
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?         
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)<sup>5</sup>?      

Were deviations or adaptations made beyond what is specified in the FDA SIS?         
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?         
If yes, report these exclusions in the summary report table.

Is there an FDA guidance<sup>6</sup> that is associated with this standard?         
If yes, was the guidance document followed in preparation of this 510(k)?      

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'."

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]  
<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)  
<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>  
<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED\*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED\*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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DESCRIPTION

JUSTIFICATION

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**Paperwork Reduction Act Statement**

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>  
 ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity

*Please answer the following questions* Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 2-153

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....         
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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....      

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 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....      

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Were there any exclusions from the standard? .....         
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....         
 If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'."

<p><sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p><sup>2</sup> Authority [21 U.S.C. 360d], <a href="http://www.fda.gov/cdrh/stdsprog.html">www.fda.gov/cdrh/stdsprog.html</a></p> <p><sup>3</sup> <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a></p> <p><sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or</p>	<p>certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p><sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a></p> <p><sup>6</sup> The online search of CDRH Guidance Documents can be found at <a href="http://www.fda.gov/cdrh/guidance.html">www.fda.gov/cdrh/guidance.html</a></p>
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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED\*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

*Please answer the following questions*

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 2-87

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

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TYPE OF DEVIATION OR OPTION SELECTED\*

DESCRIPTION

JUSTIFICATION

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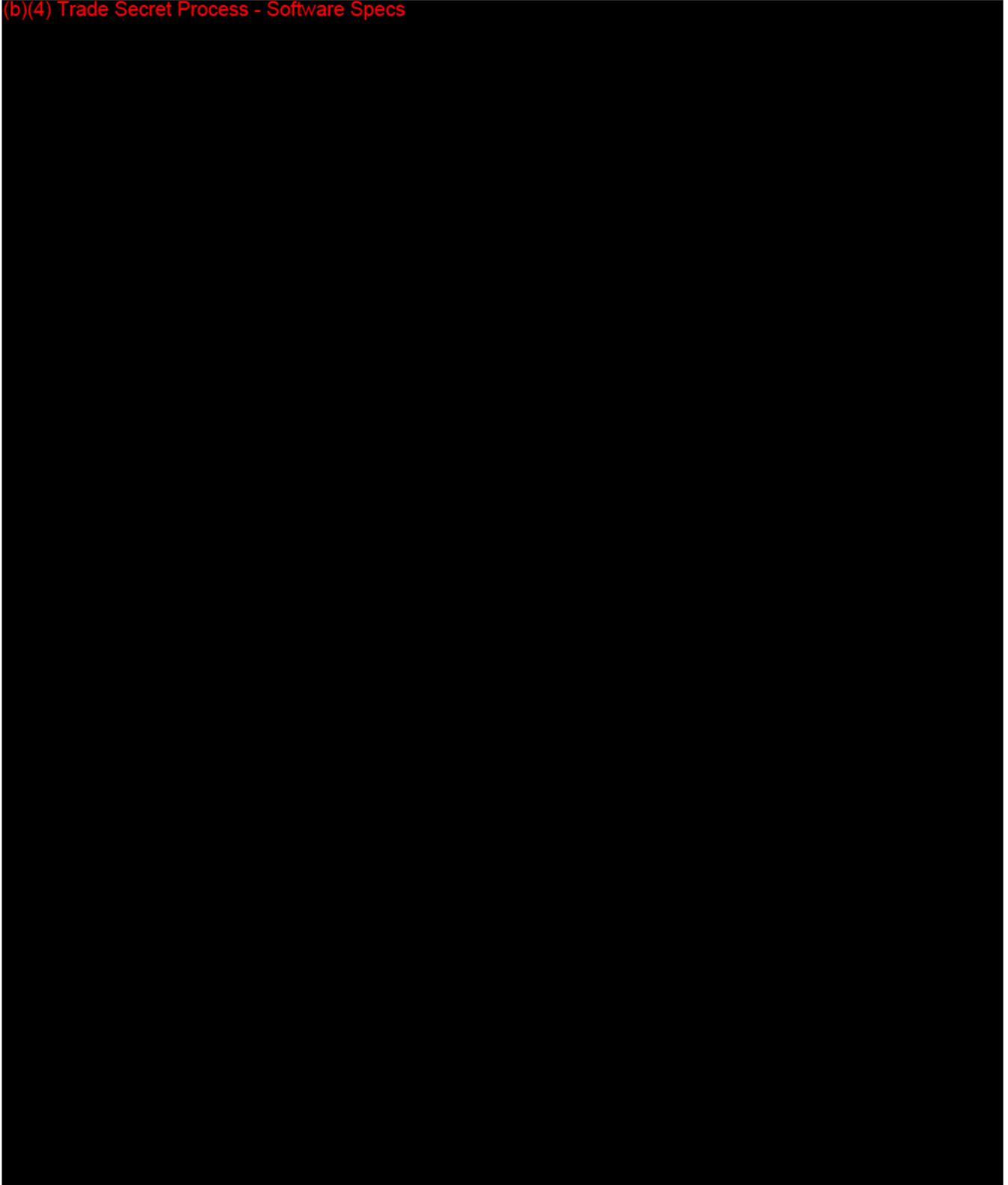




**Section16**  
**Software**

## Section16 Software

(b)(4) Trade Secret Process - Software Specs

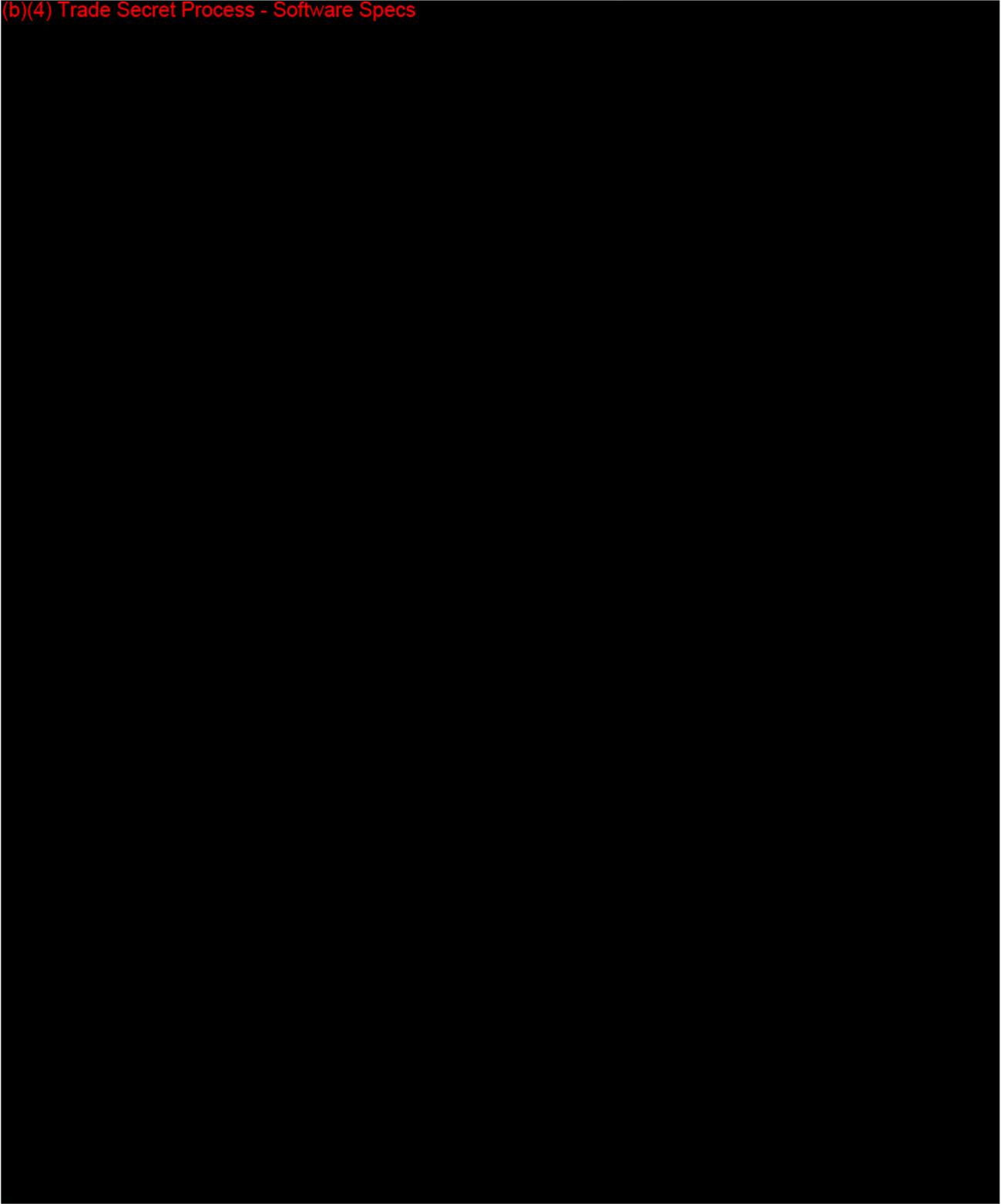


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Section16 Software

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(b)(4) Trade Secret Process - Software Specs

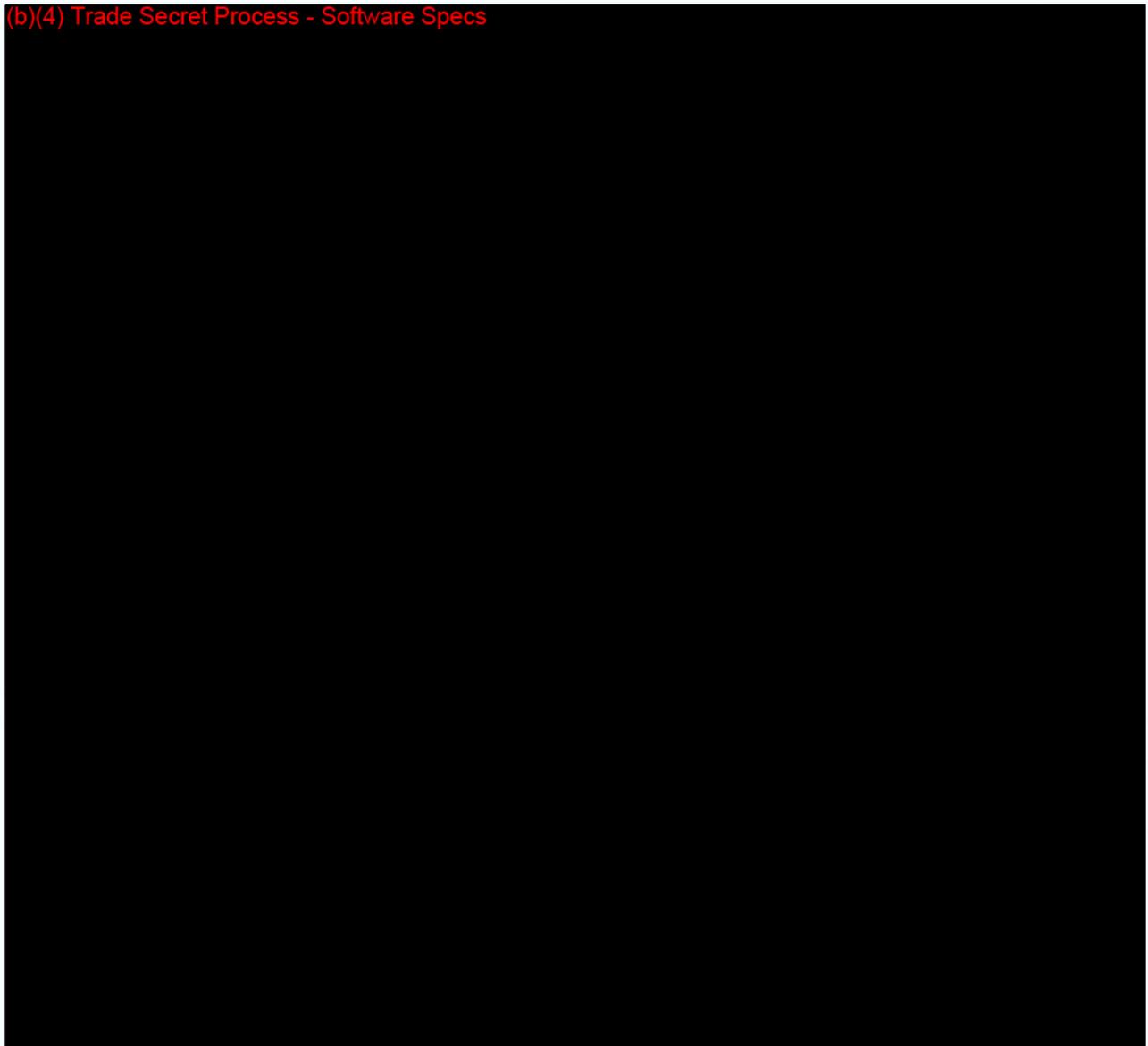


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## Section16 Software

(b)(4) Trade Secret Process - Software Specs



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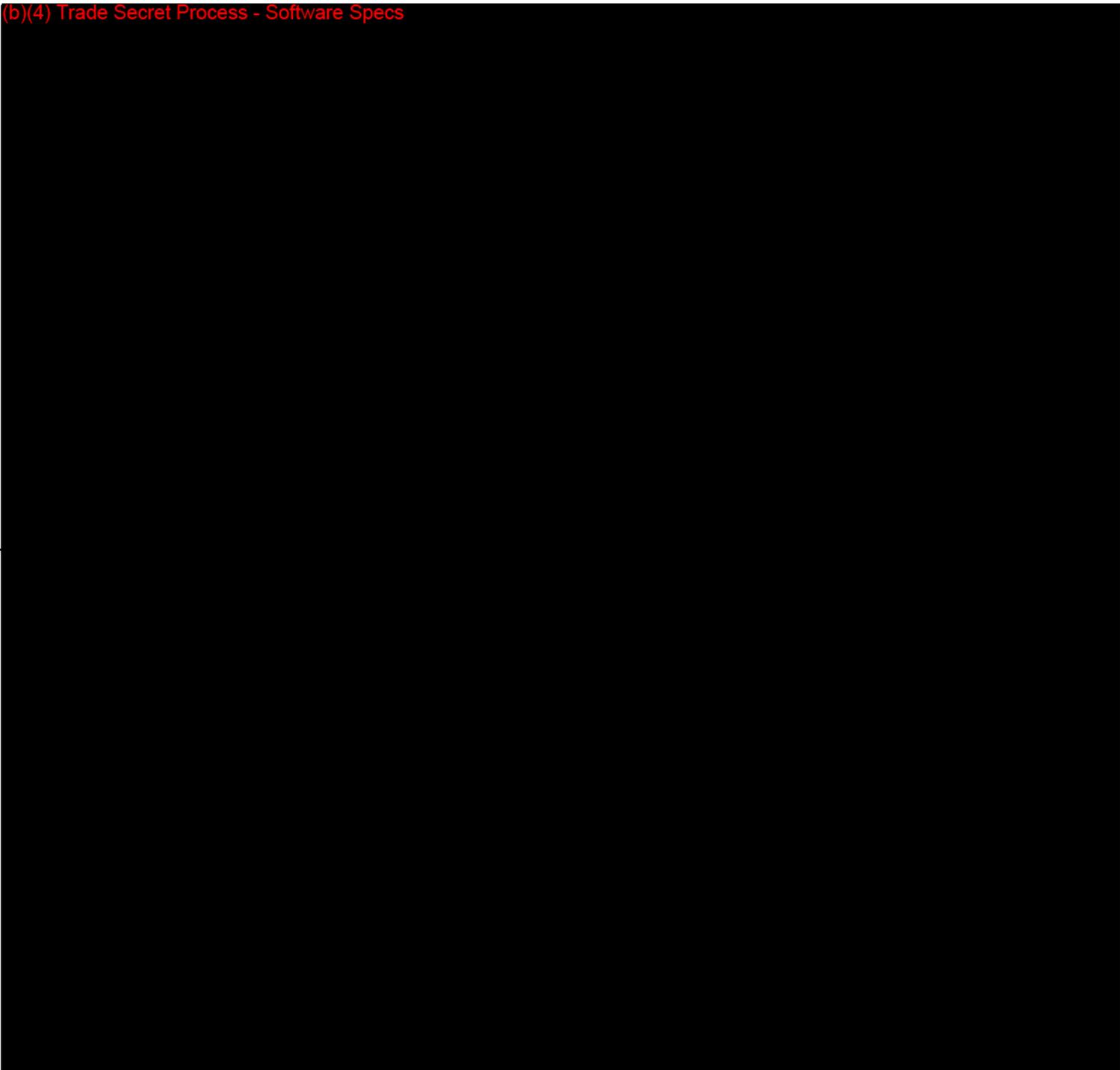
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Section 16 Software

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**SOFTWARE DESCRIPTION**

(b)(4) Trade Secret Process - Software Specs



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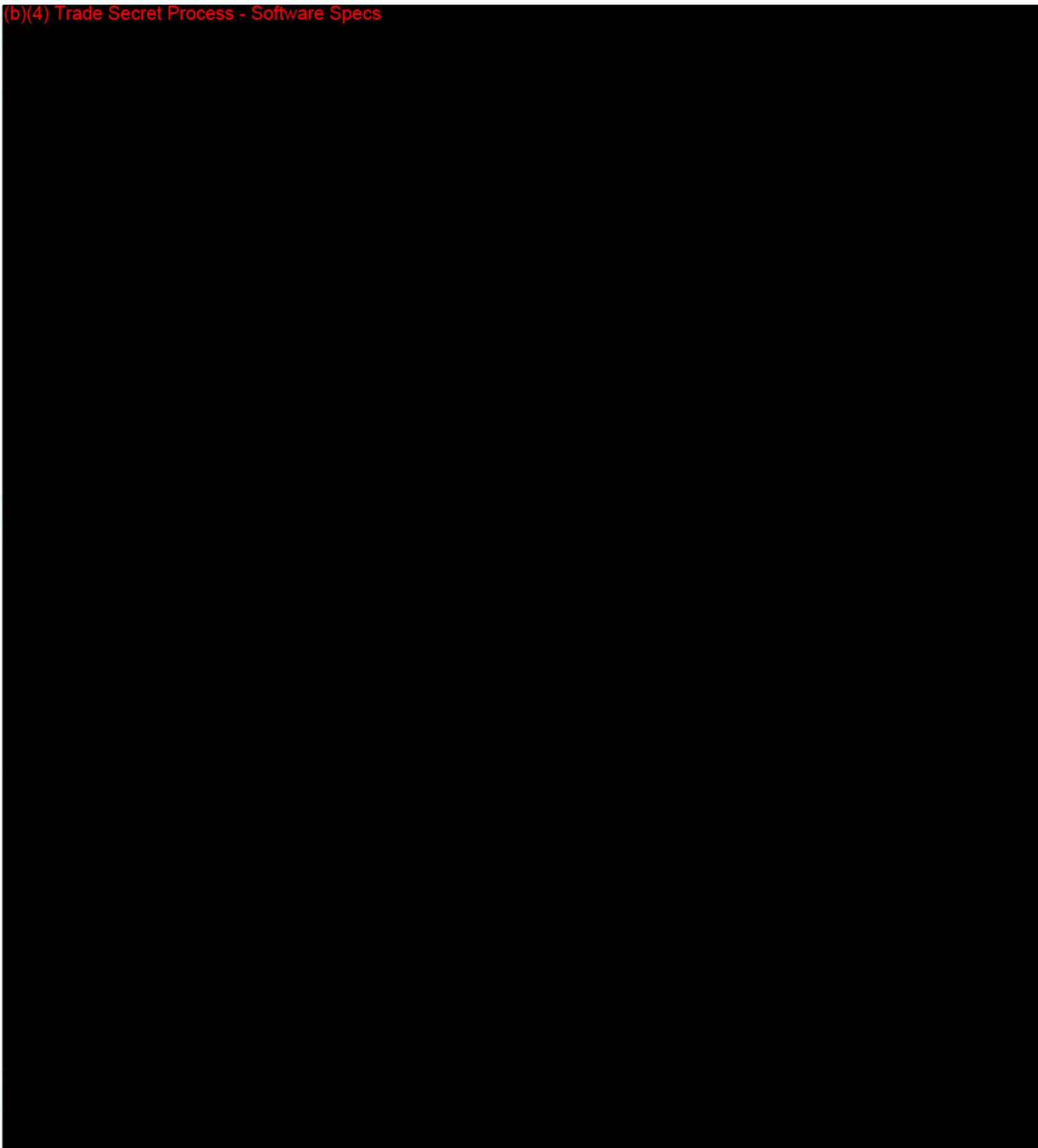
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Section16 Software

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**SOFTWARE REQUIREMENTS/SPECIFICATIONS (SRS)**

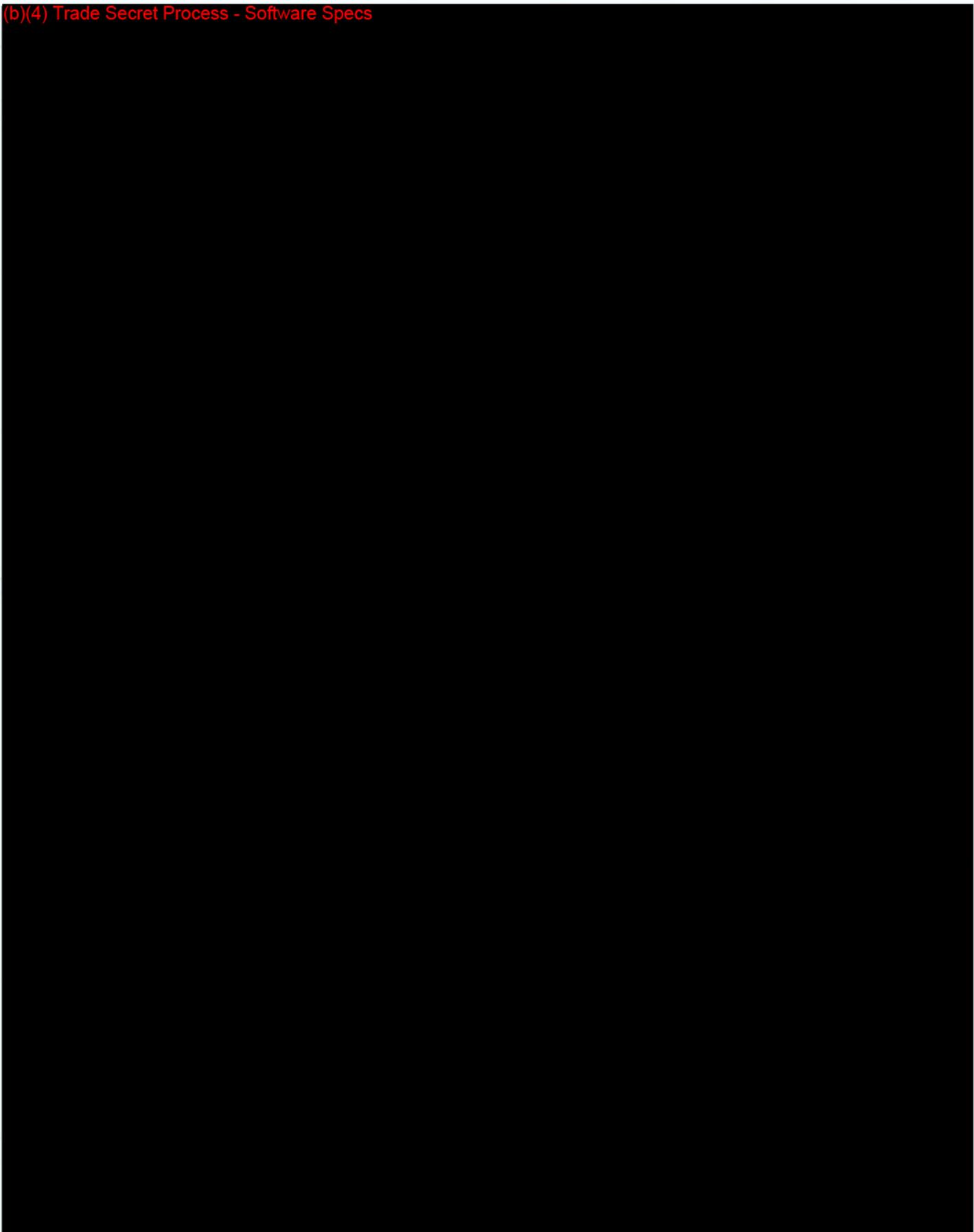
(b)(4) Trade Secret Process - Software Specs



## Section16 Software

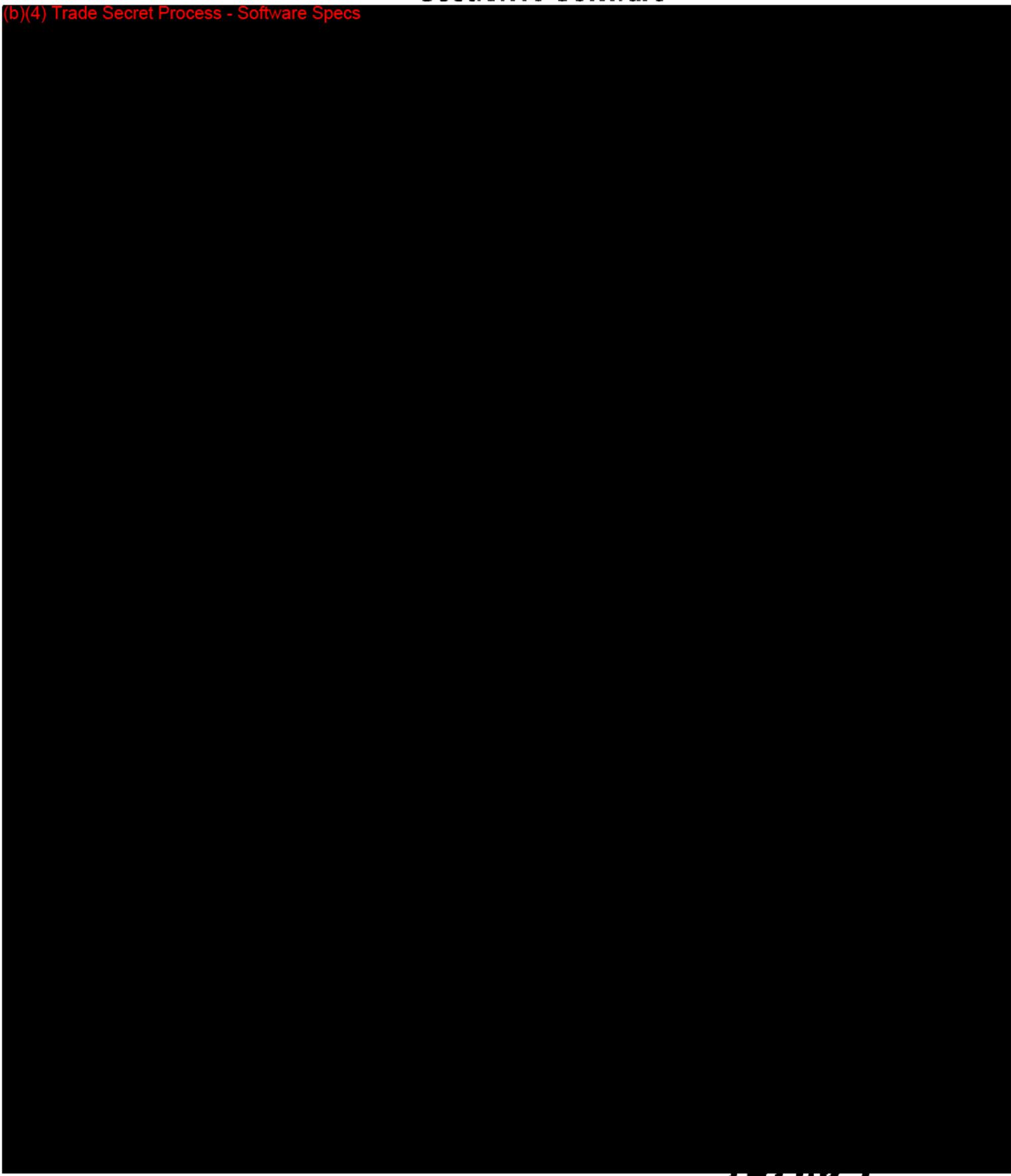
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(b)(4) Trade Secret Process - Software Specs



## Section 16 Software

(b)(4) Trade Secret Process - Software Specs

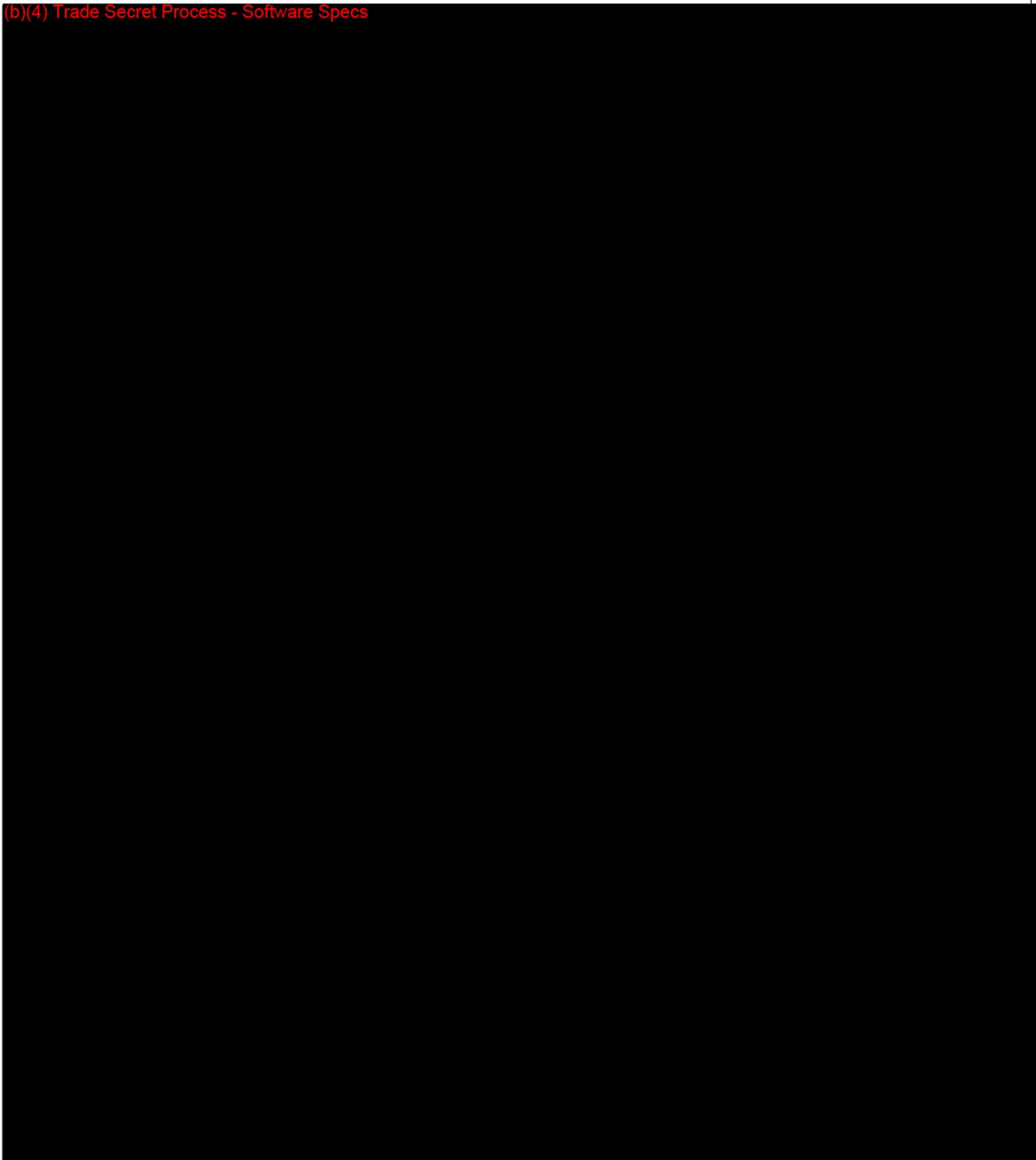


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## Section 16 Software

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(b)(4) Trade Secret Process - Software Specs

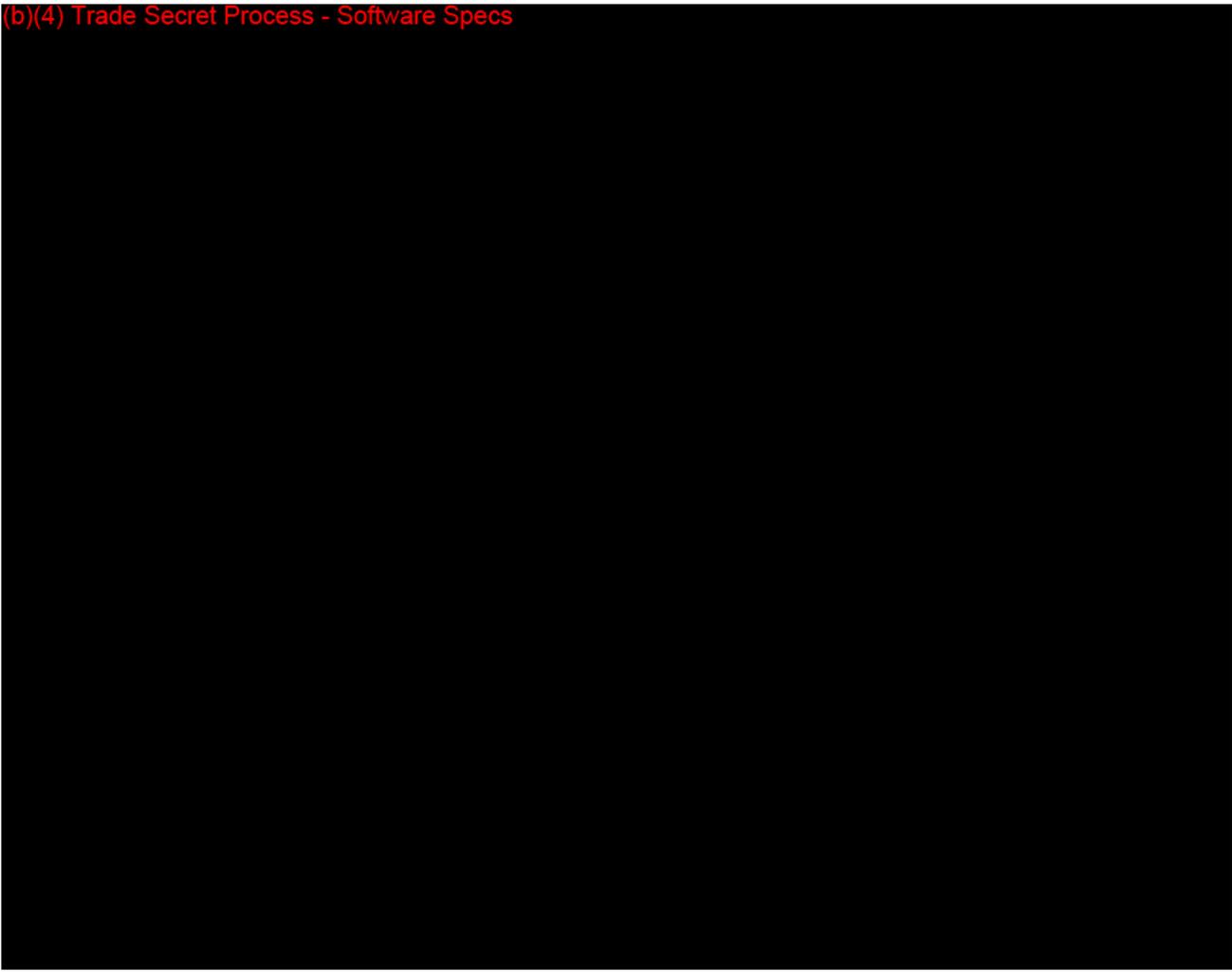


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## Section 16 Software

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(b)(4) Trade Secret Process - Software Specs



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16/009

## Section 16 Software

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(b)(4) Trade Secret Process - Software Specs

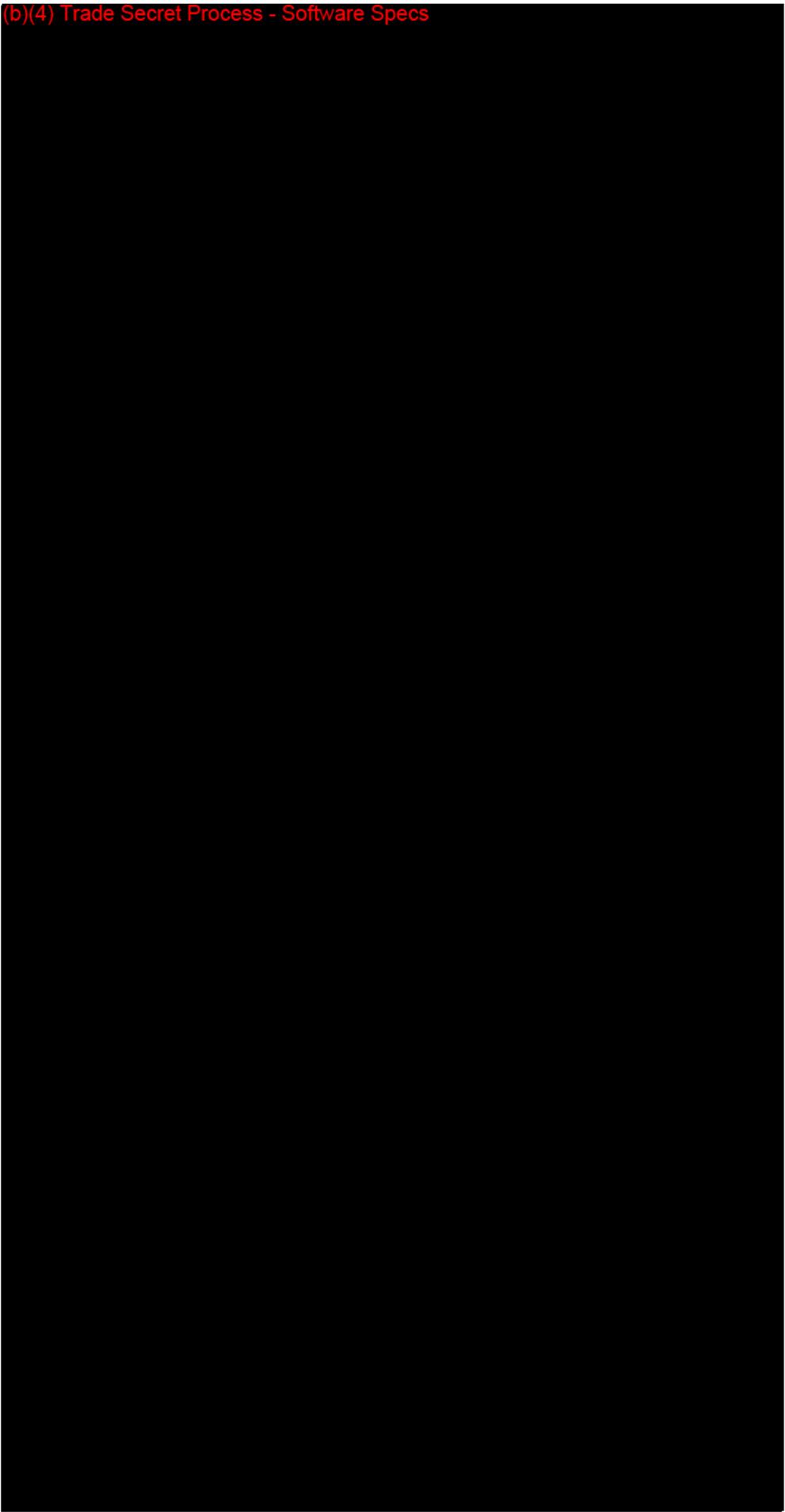


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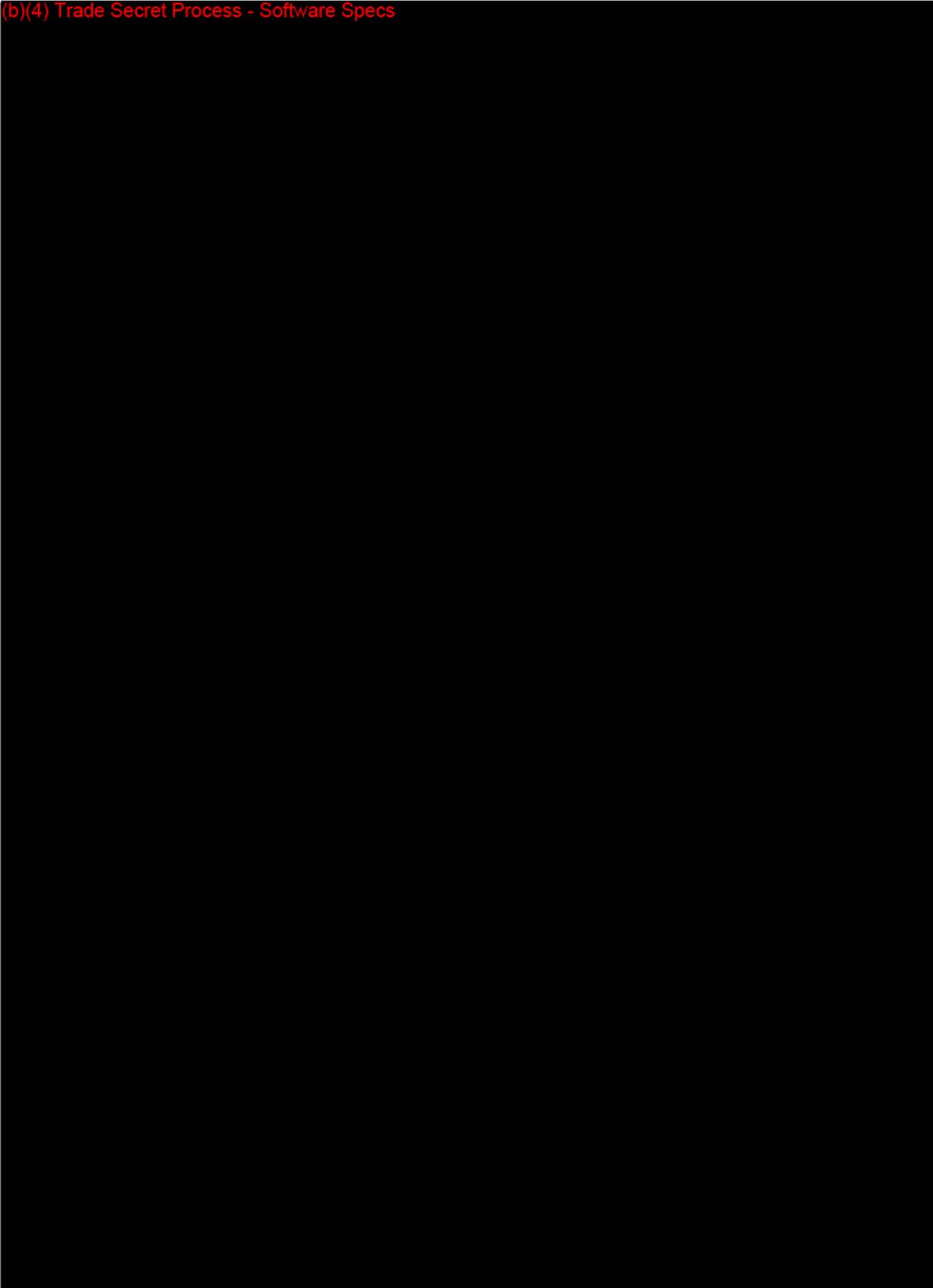
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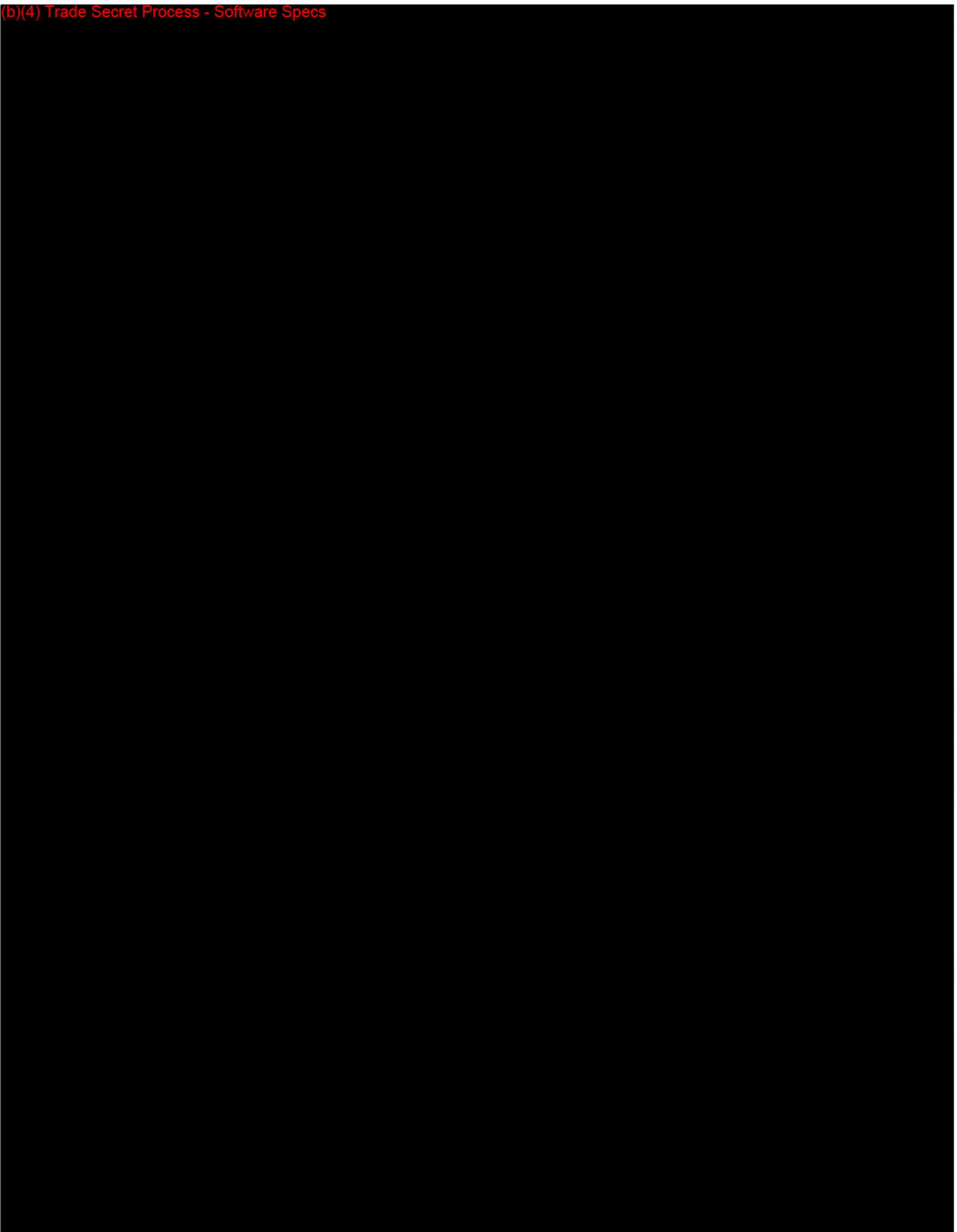
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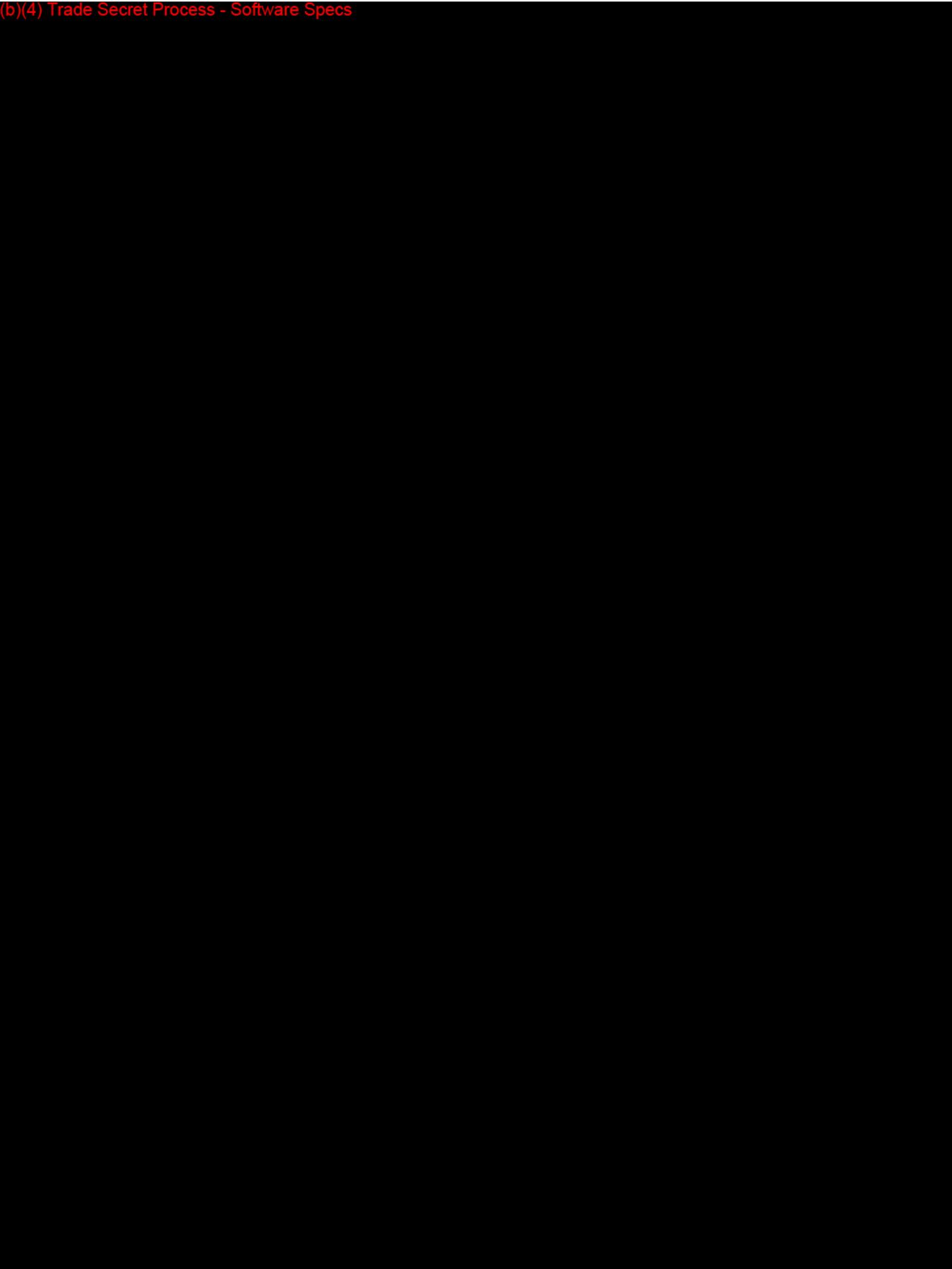
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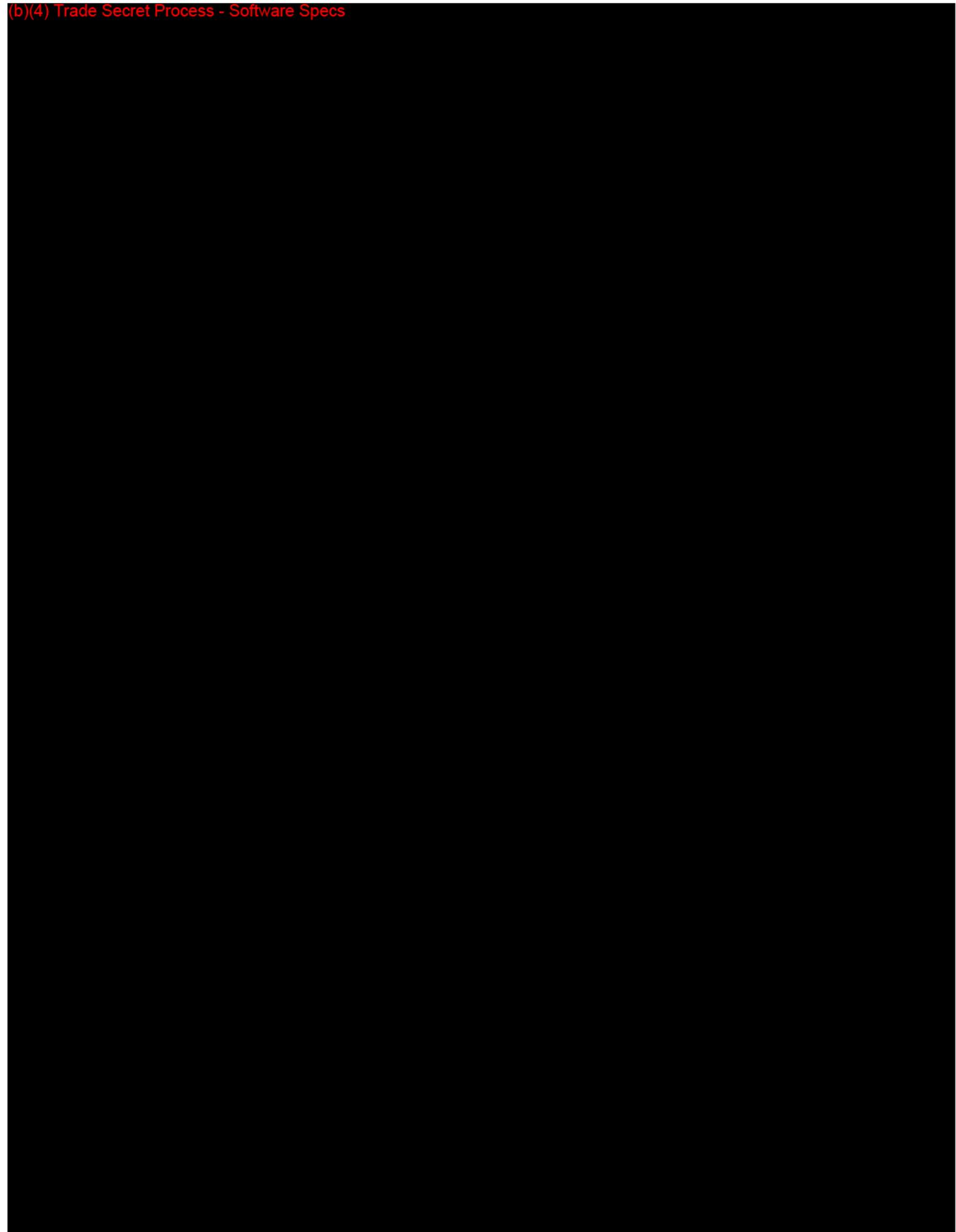


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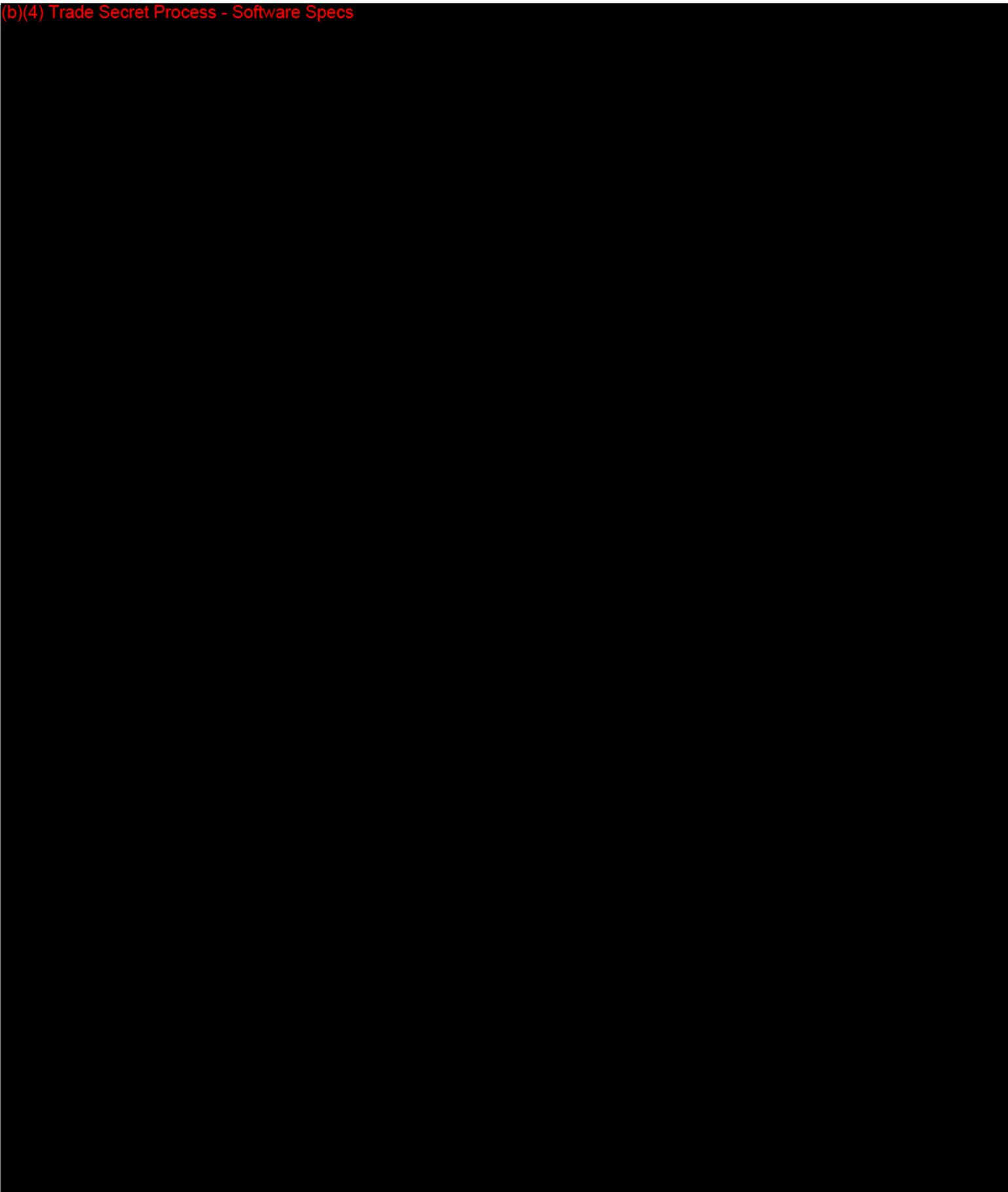


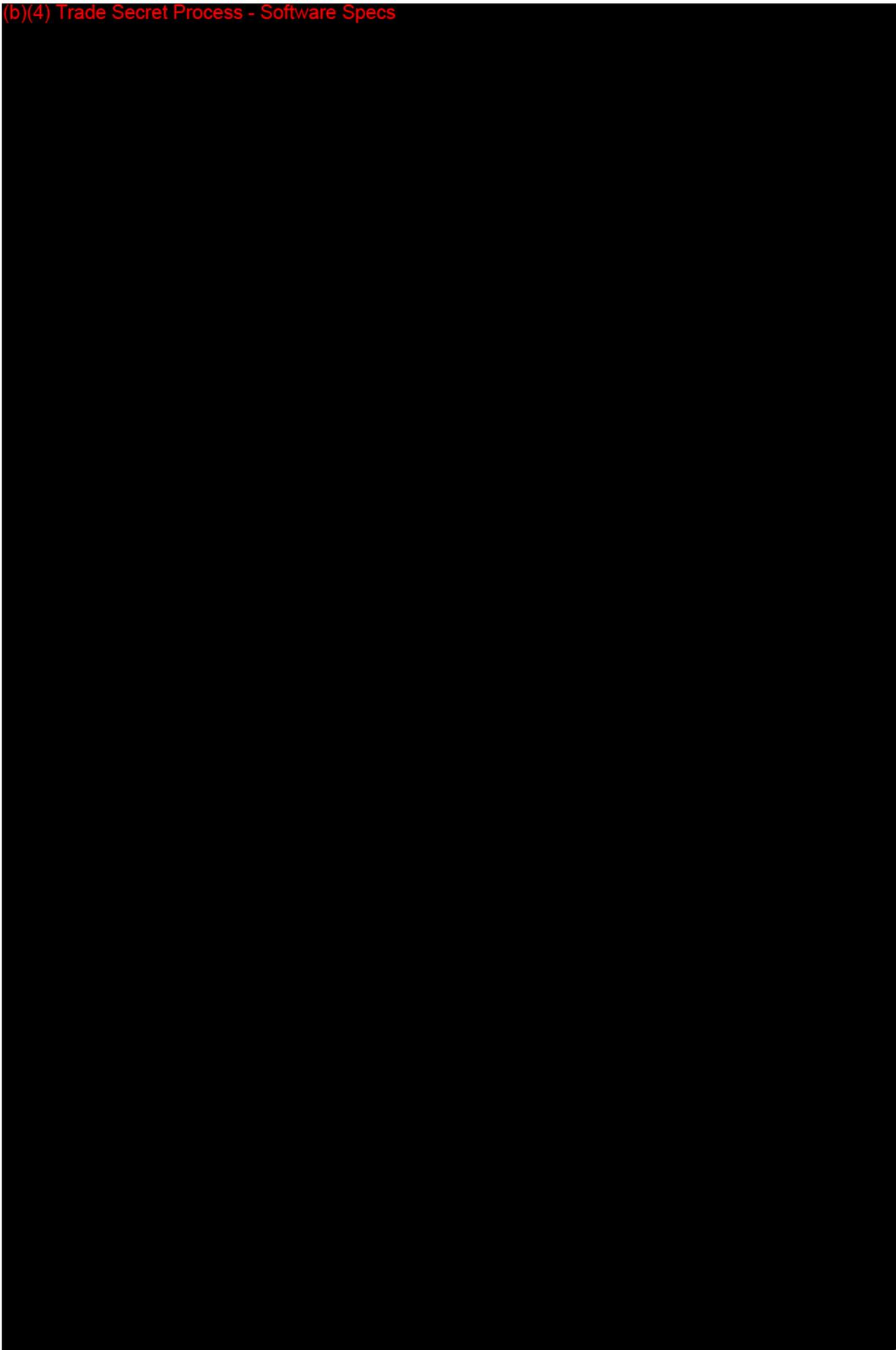


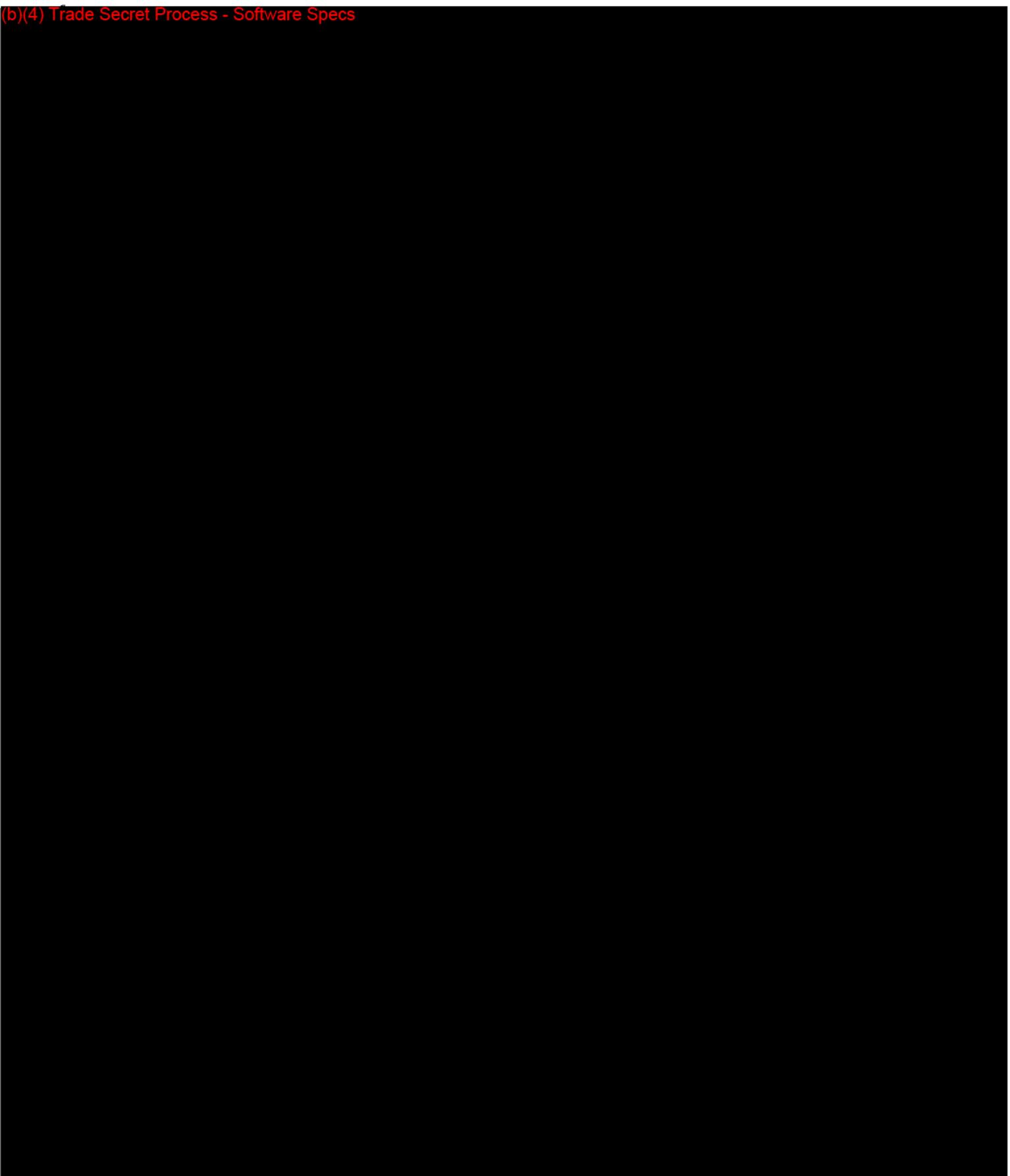




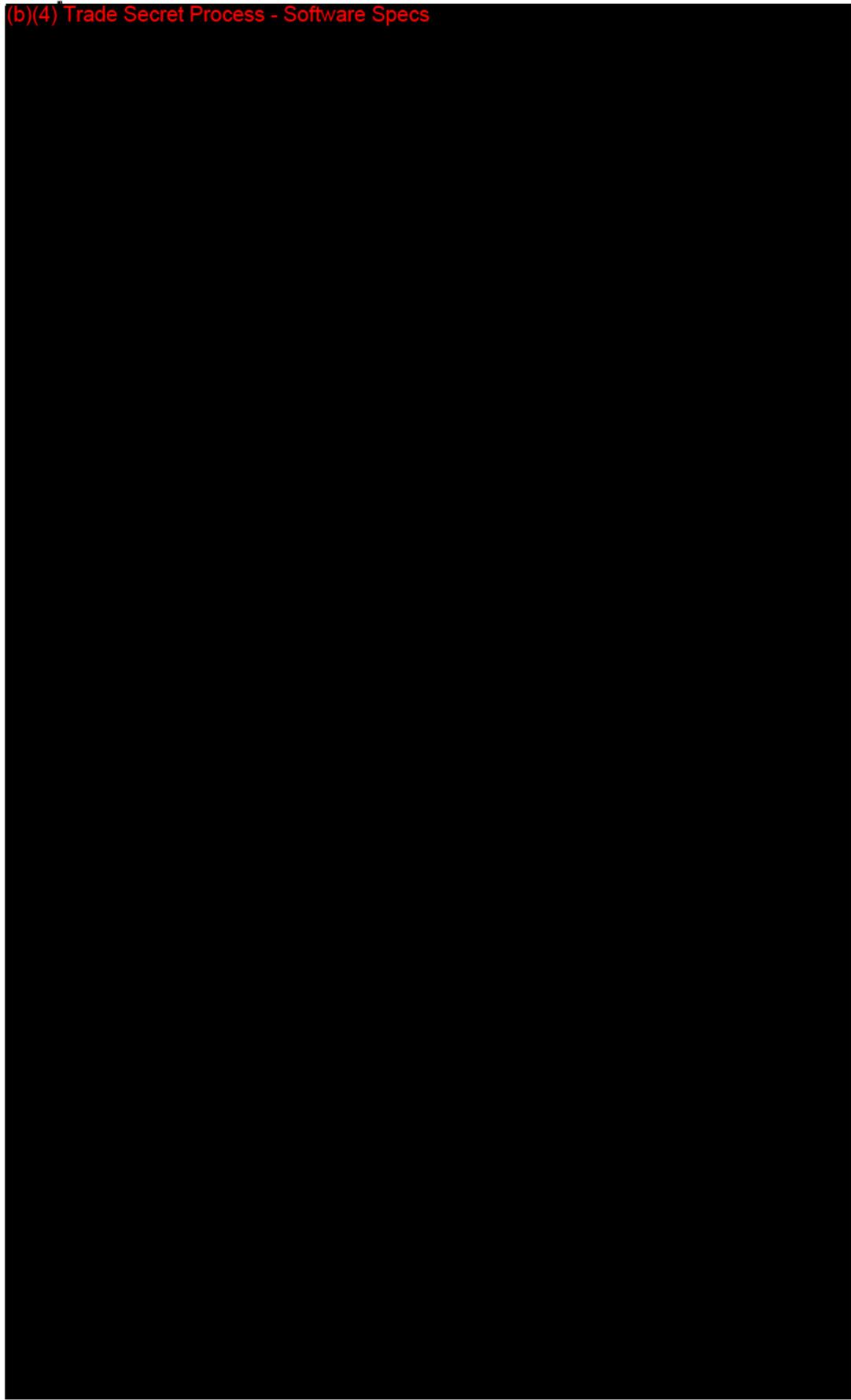




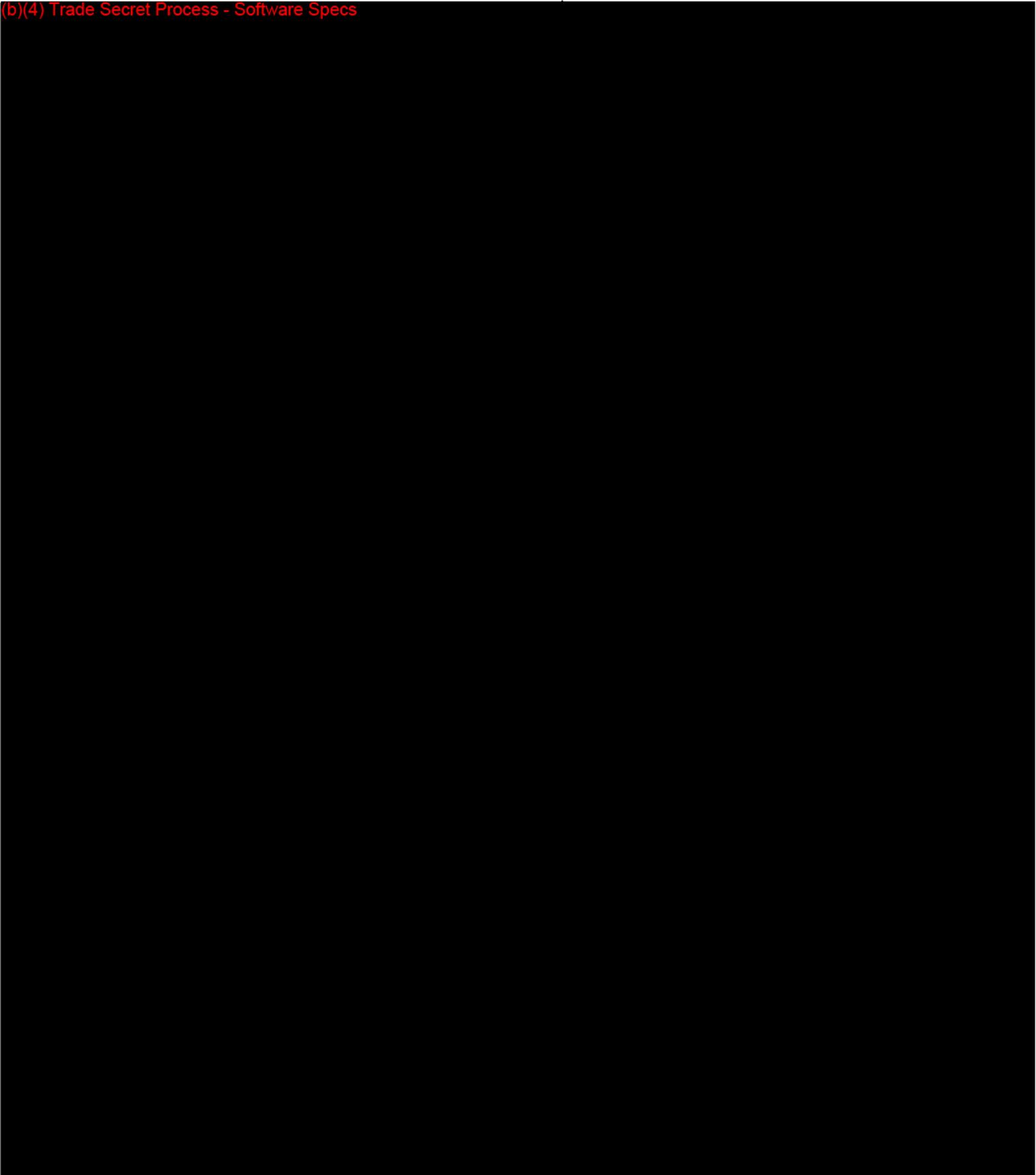




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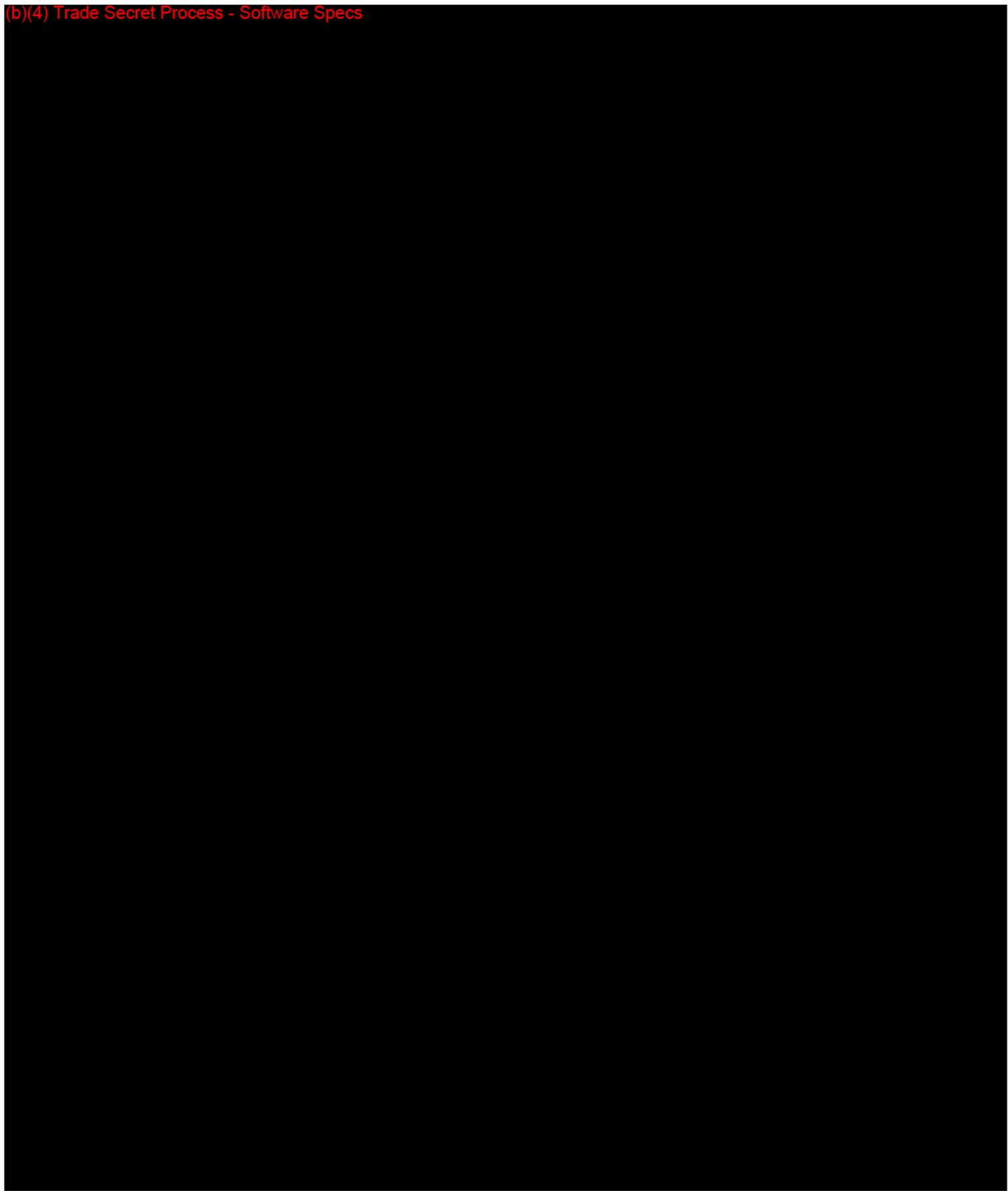


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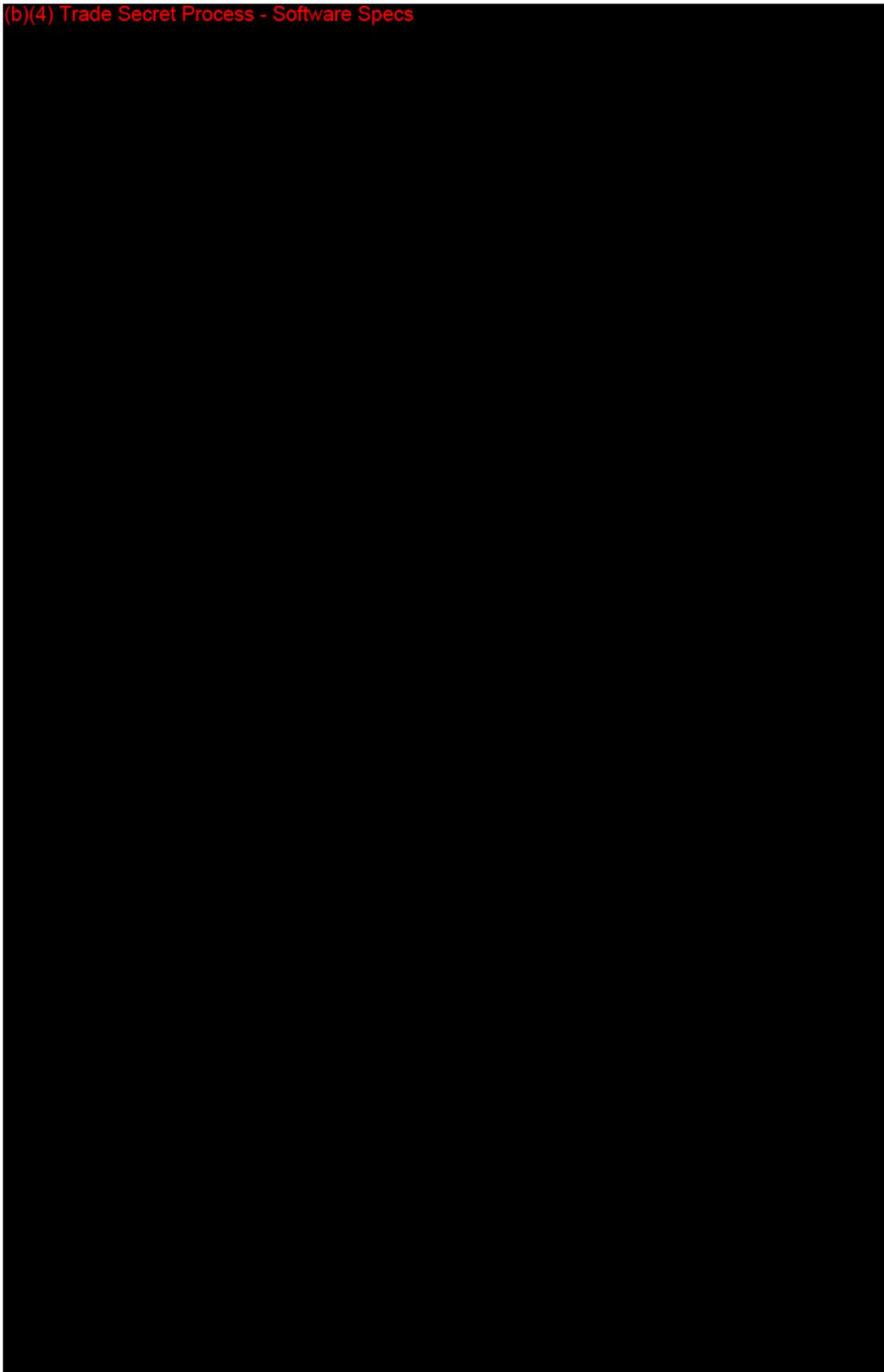




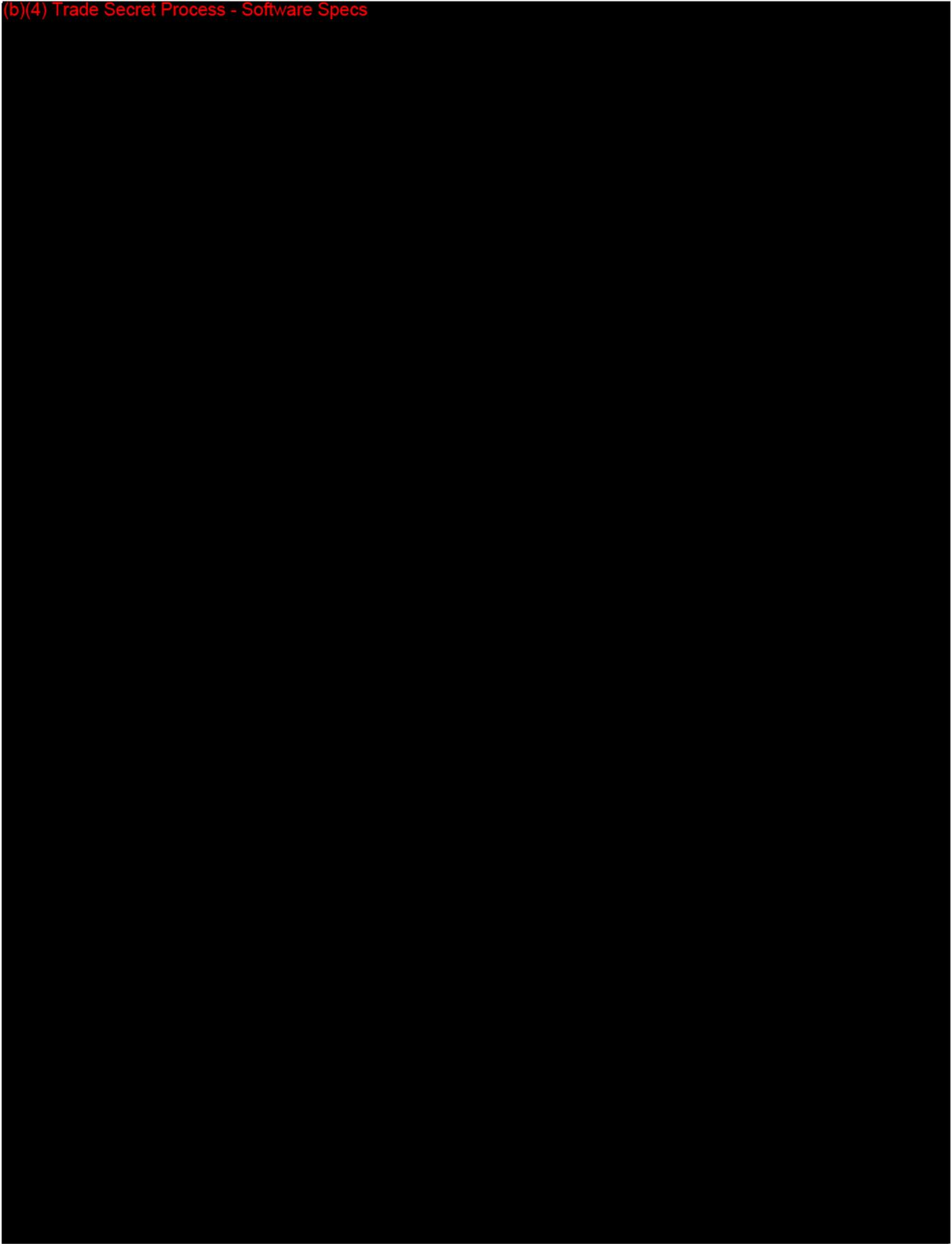
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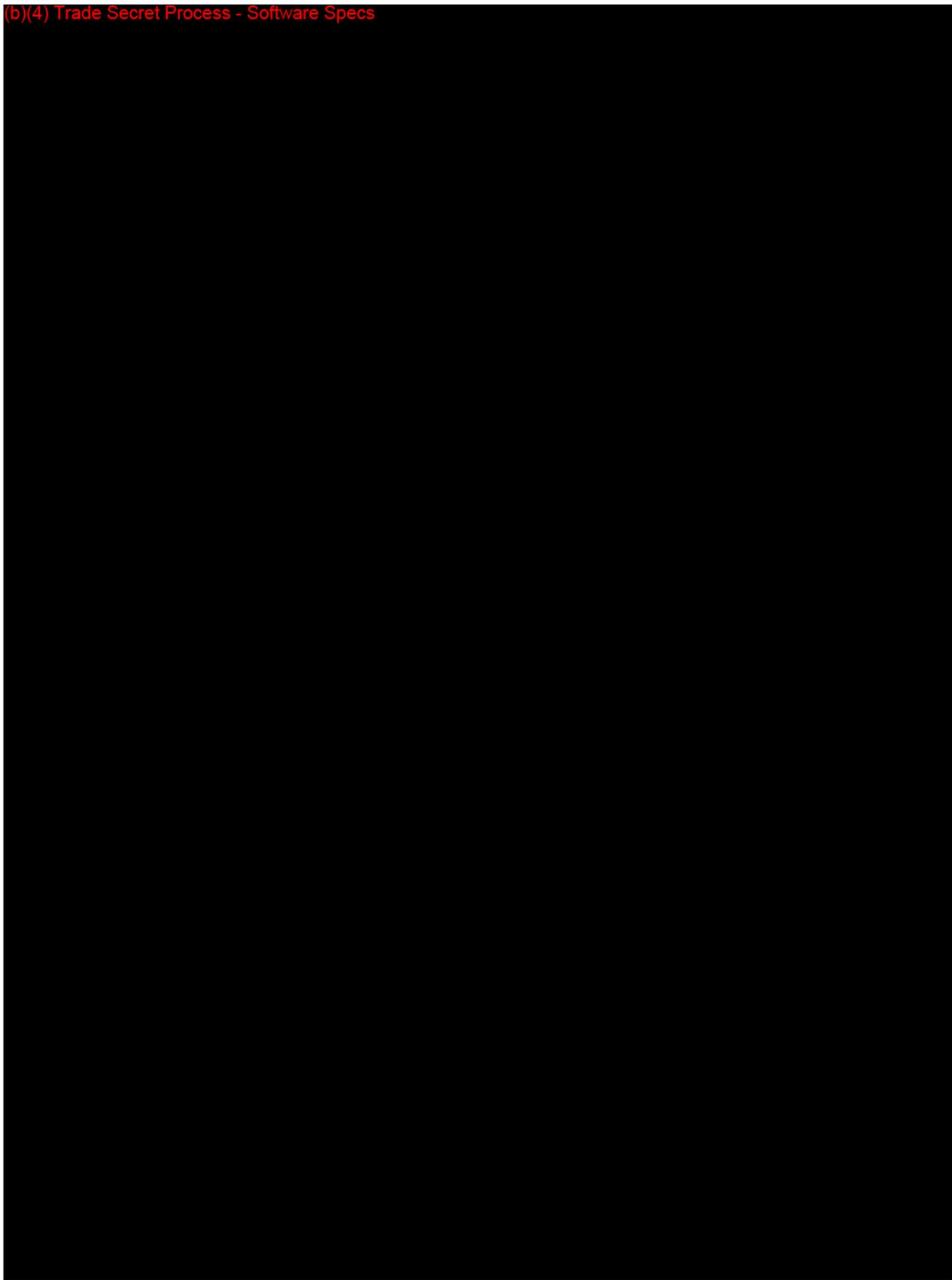


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(b)(4) Trade Secret Process - Software Specs



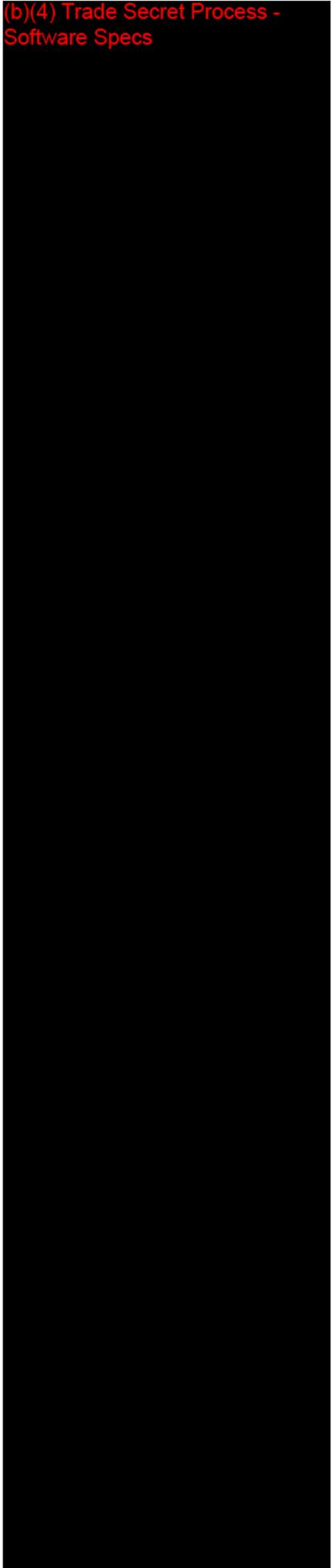




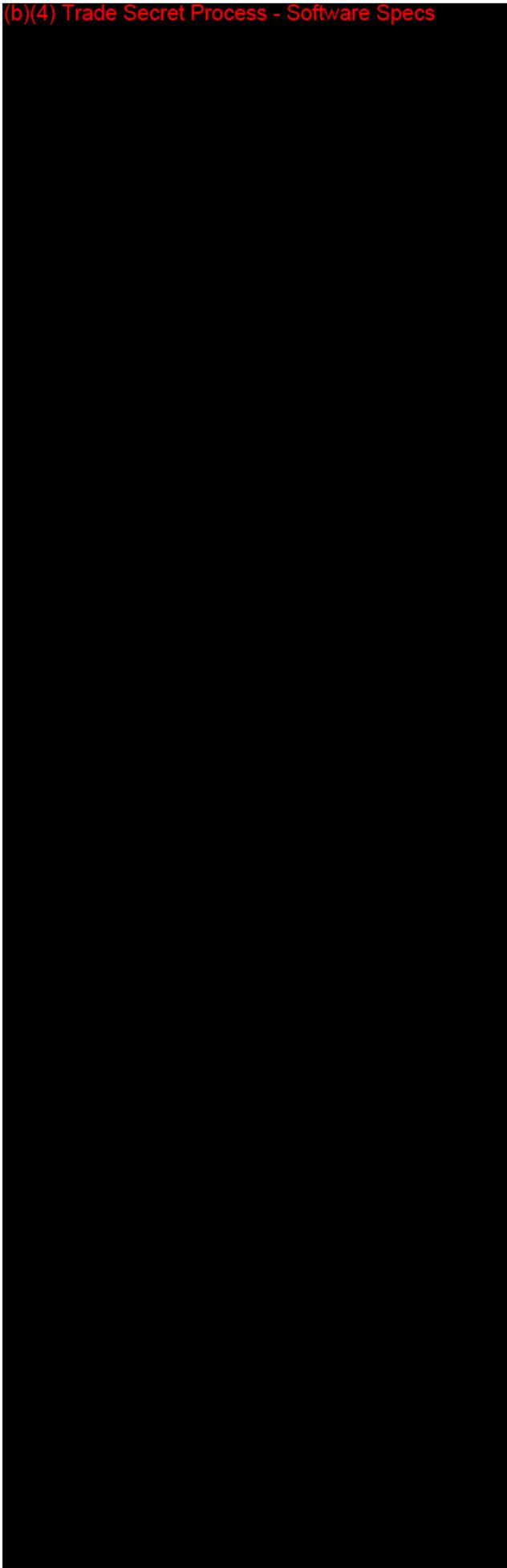


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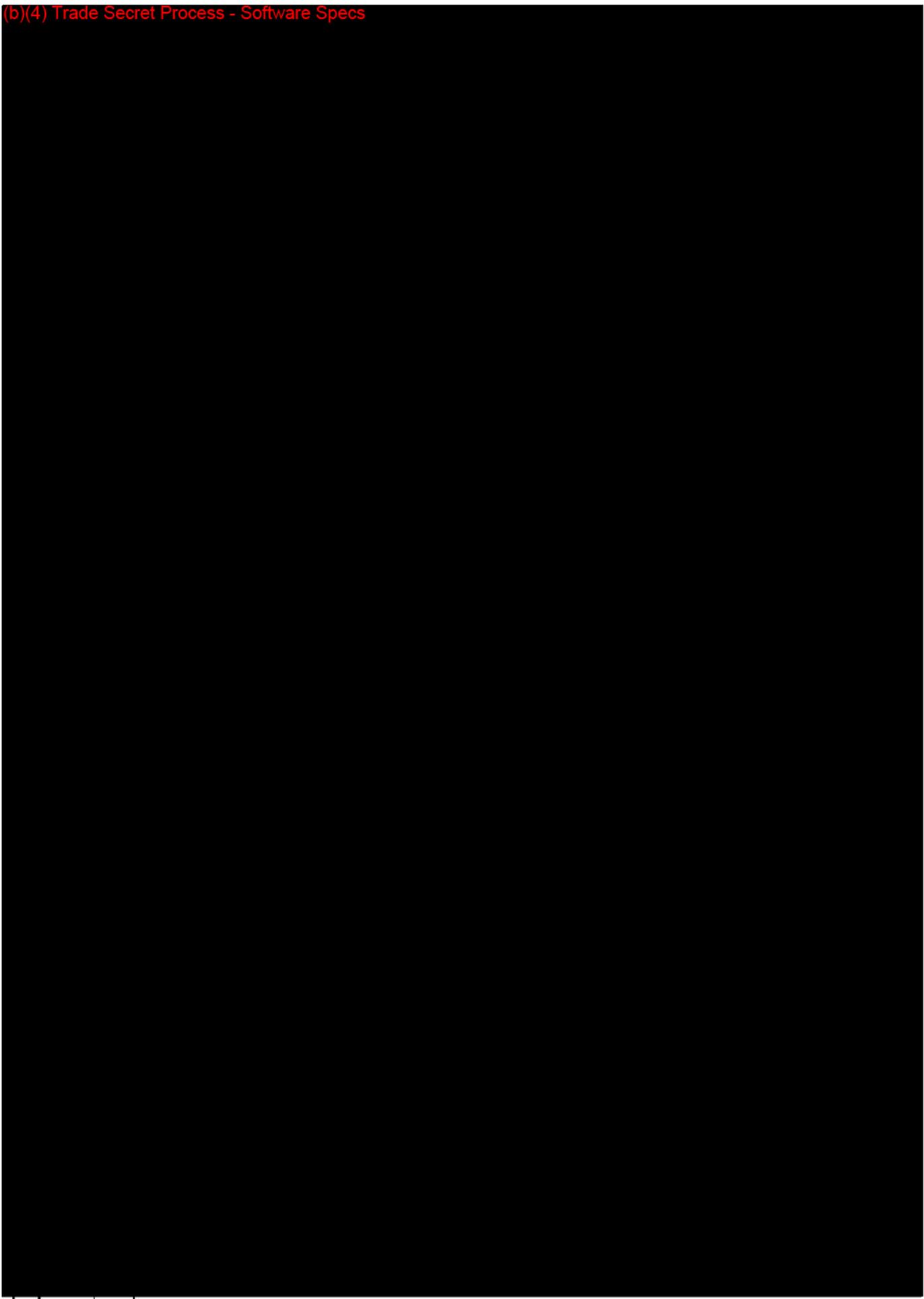
(b)(4) Trade Secret Process -  
Software Specs



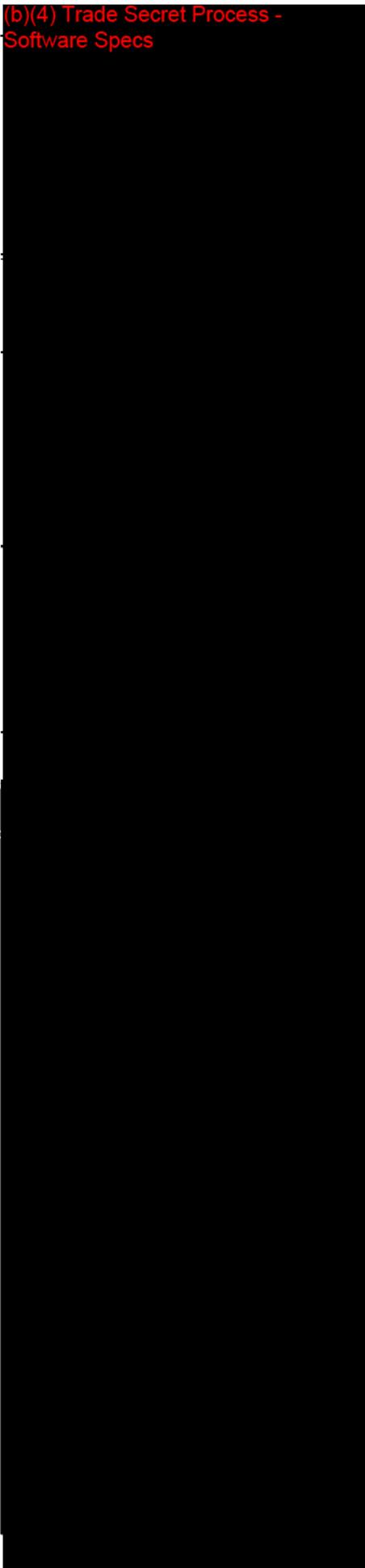
(b)(4) Trade Secret Process - Software Specs



(b)(4) Trade Secret Process - Software Specs

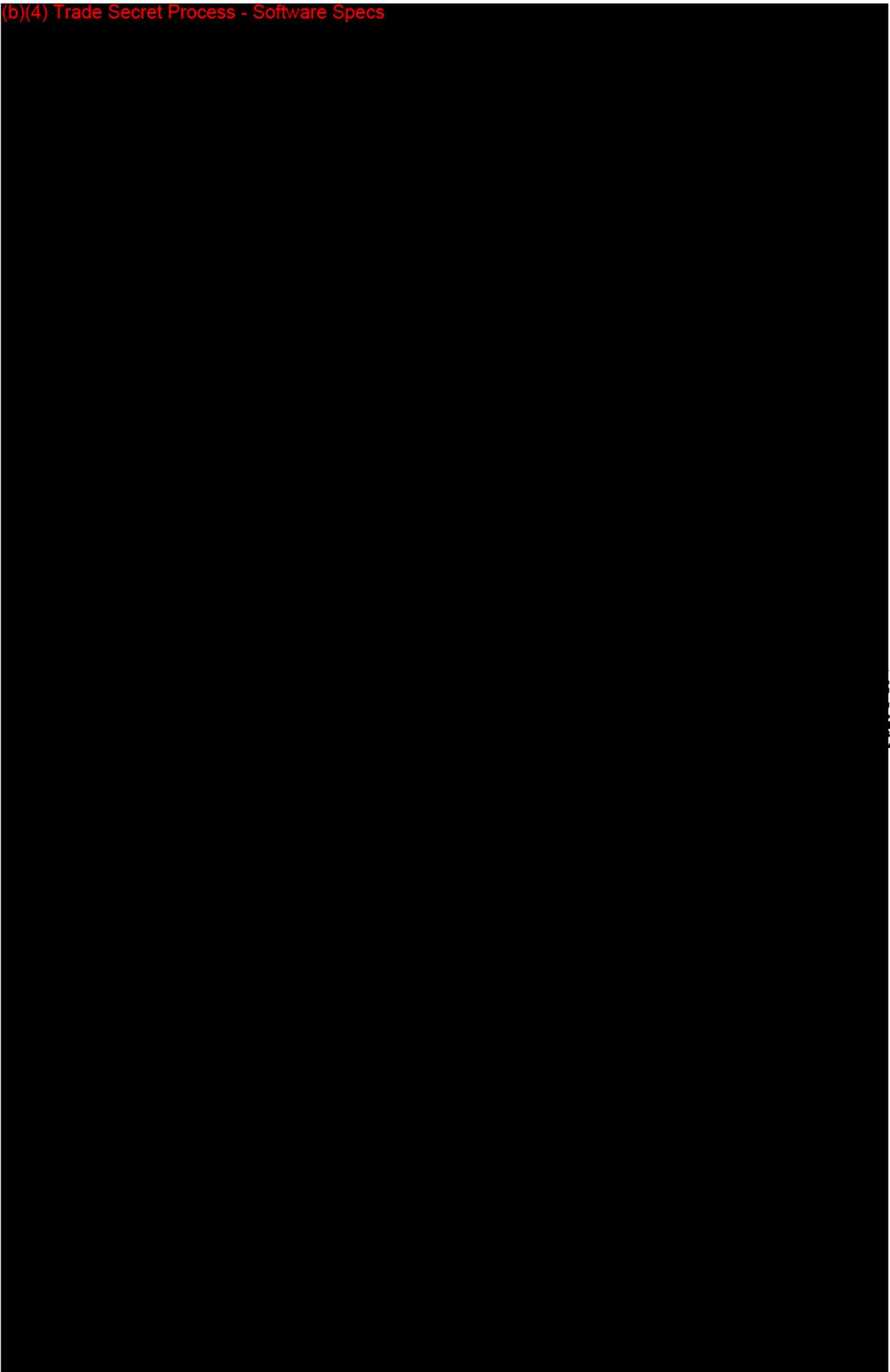


SOFTWARE TRACEABILITY MATRIX, RIX LITS-1500 Laser (Confidential)

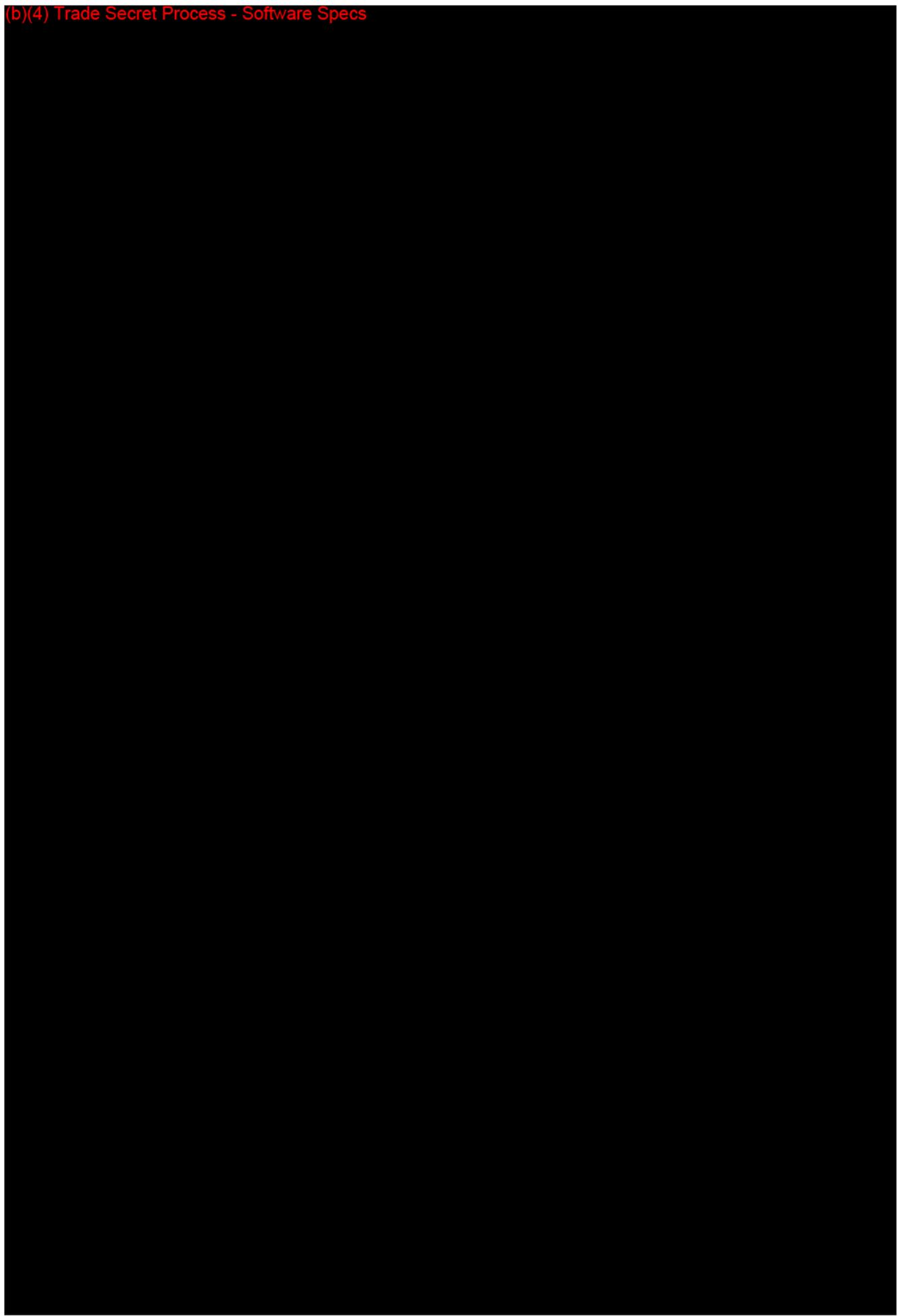


(b)(4) Trade Secret Process -  
Software Specs

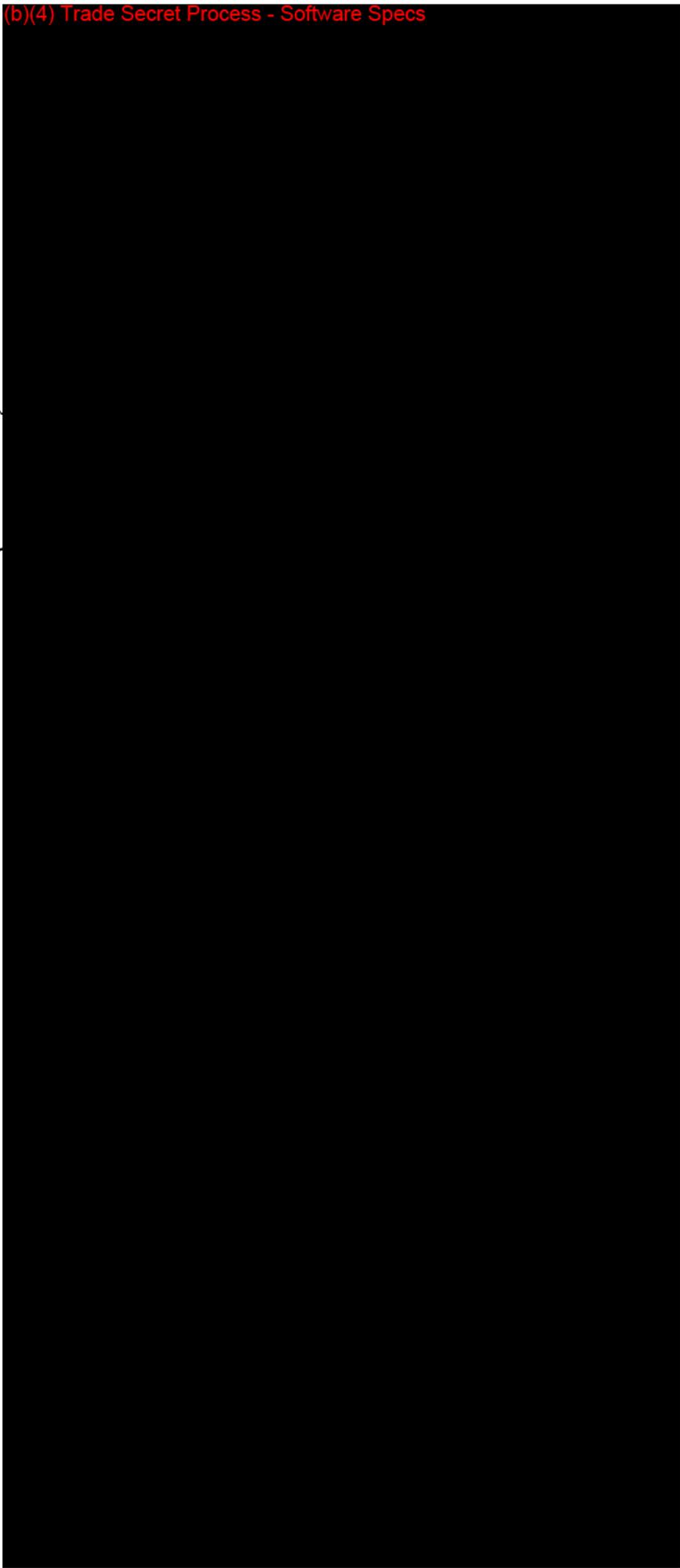
(b)(4) Trade Secret Process - Software Specs



SOFTWARE TRACEABILITY M<sub>A</sub>, RIX LTS-1500 Laser (Confidential)



**SOFTWARE TRACEABILITY M.A., RIX LTS-1500 Laser (Confidential)**



**Section17**  
**Electromagnetic Compatibility &**  
**Electrical Safety**

## Section 17 Electromagnetic Compatibility & Electrical Safety

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(b)(4) Trade Secret Process - Testing



**Section18**  
**Performance Testing – Bench**

## Section 18 Performance Testing – Bench

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(b)(4) Trade Secret Process - Testing

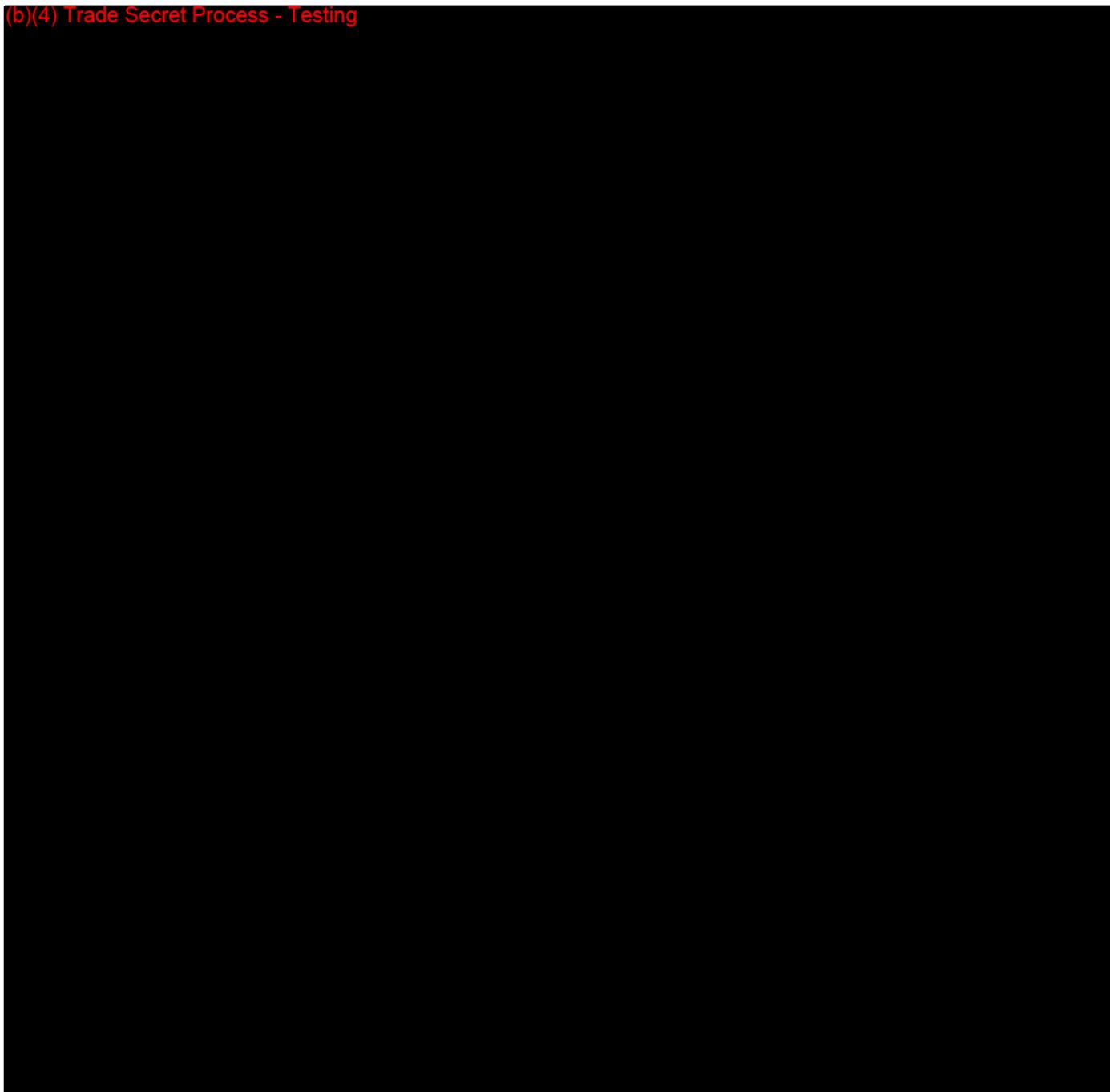


18/001

## Section 18 Performance Testing – Bench

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(b)(4) Trade Secret Process - Testing



18/002

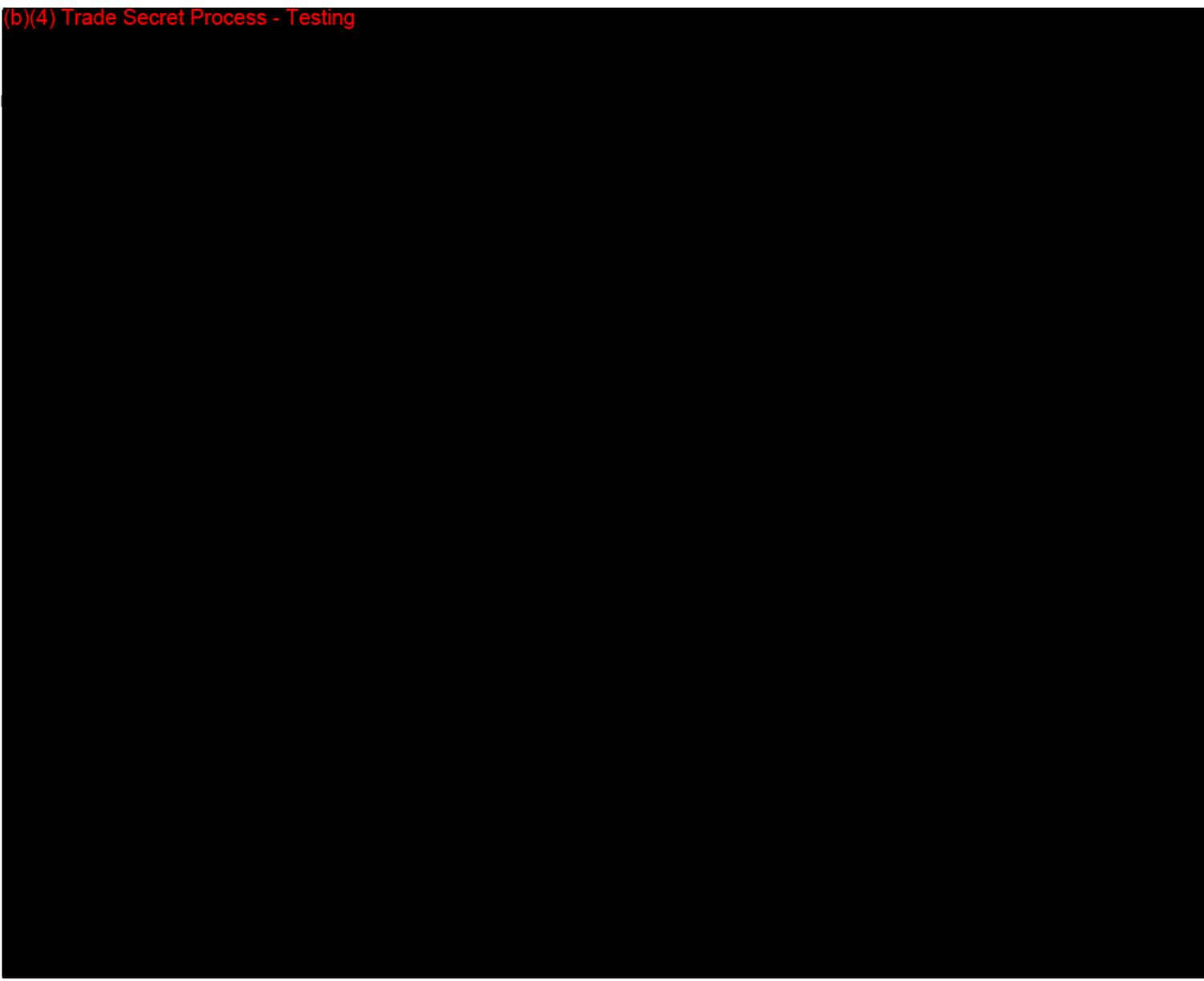
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CONFIDENTIAL

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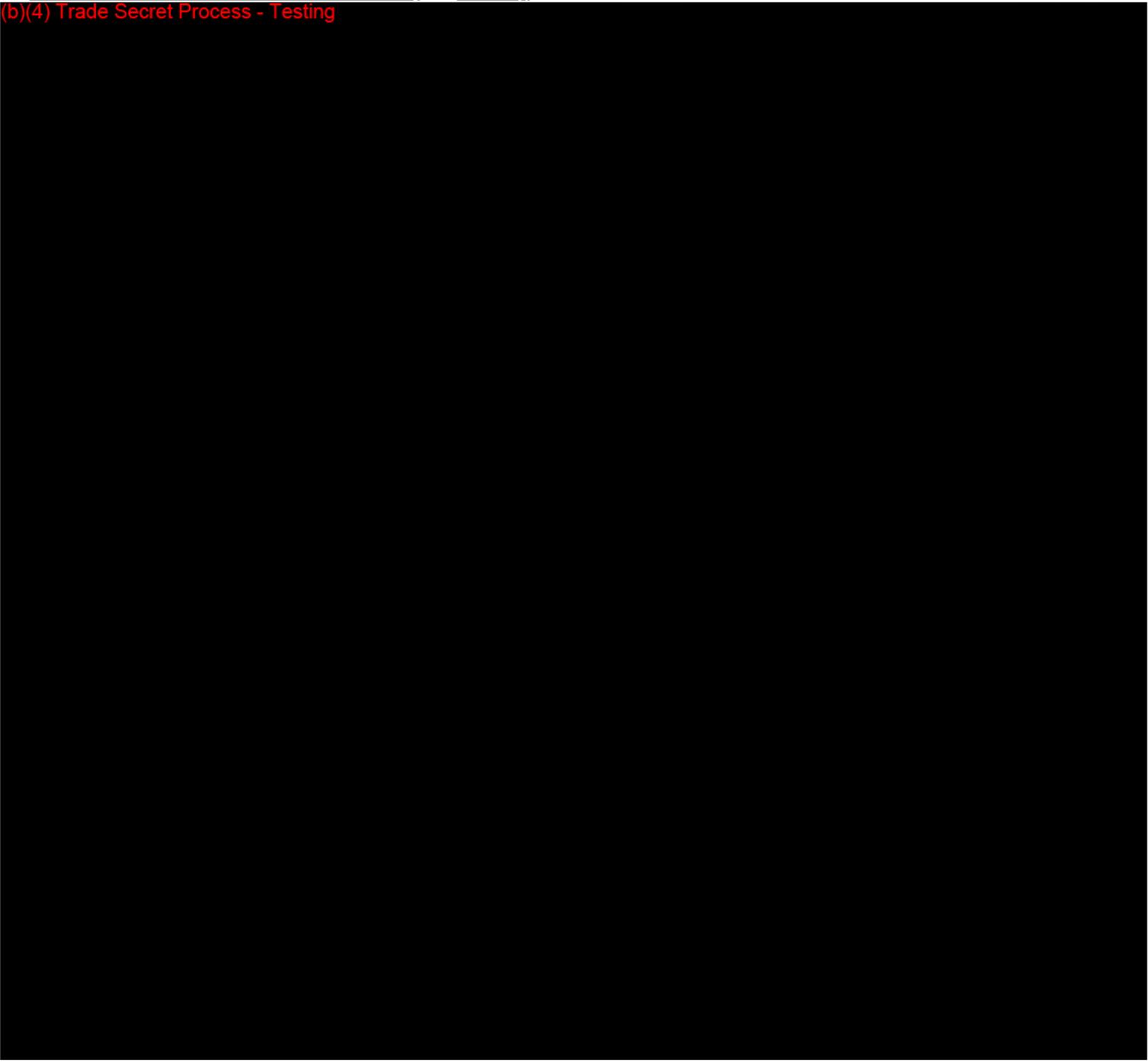
## Section 18 Performance Testing – Bench

(b)(4) Trade Secret Process - Testing



## Section 18 Performance Testing – Bench

(b)(4) Trade Secret Process - Testing



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CONFIDENTIAL

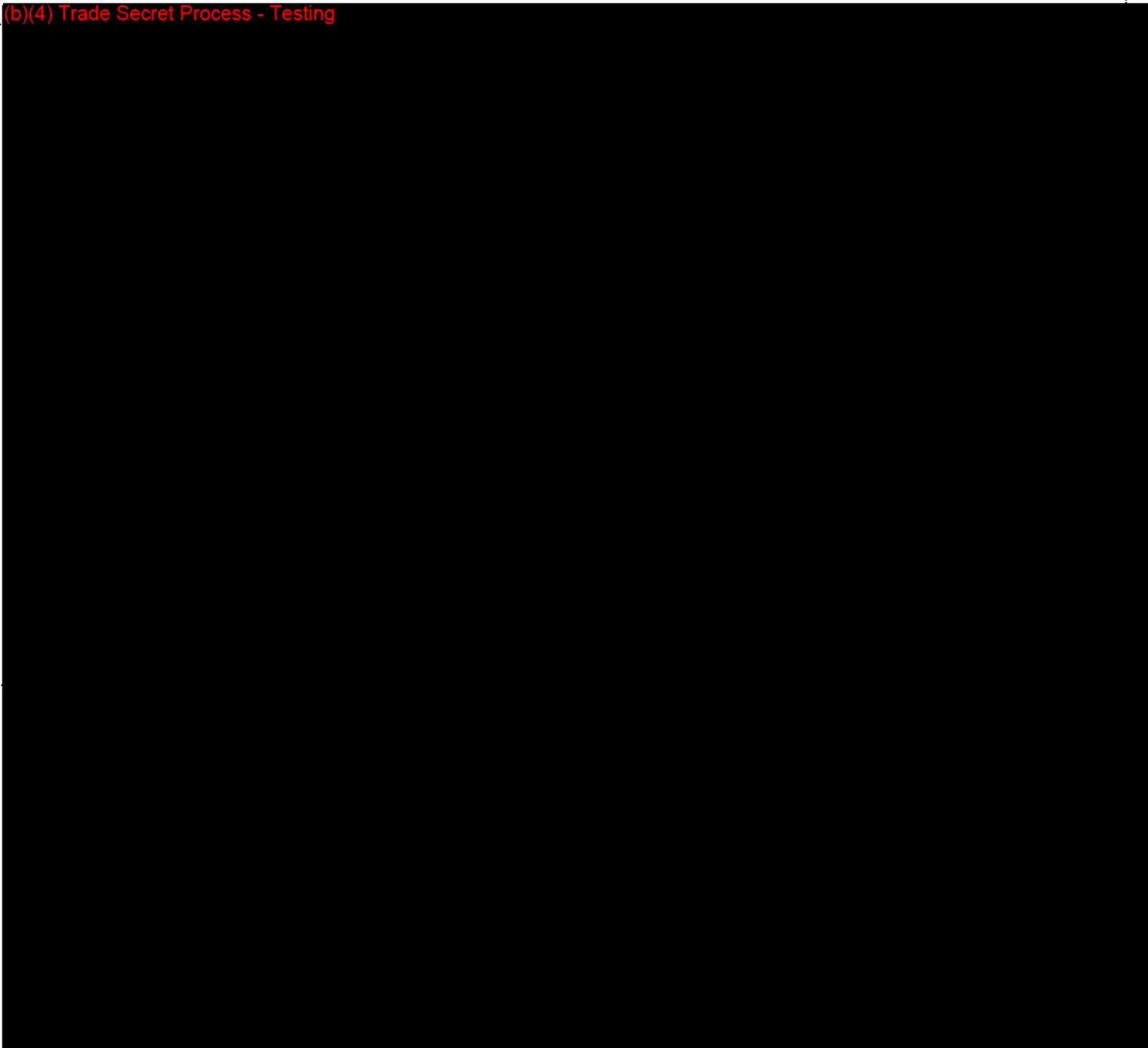
18/004

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## Section 18 Performance Testing – Bench

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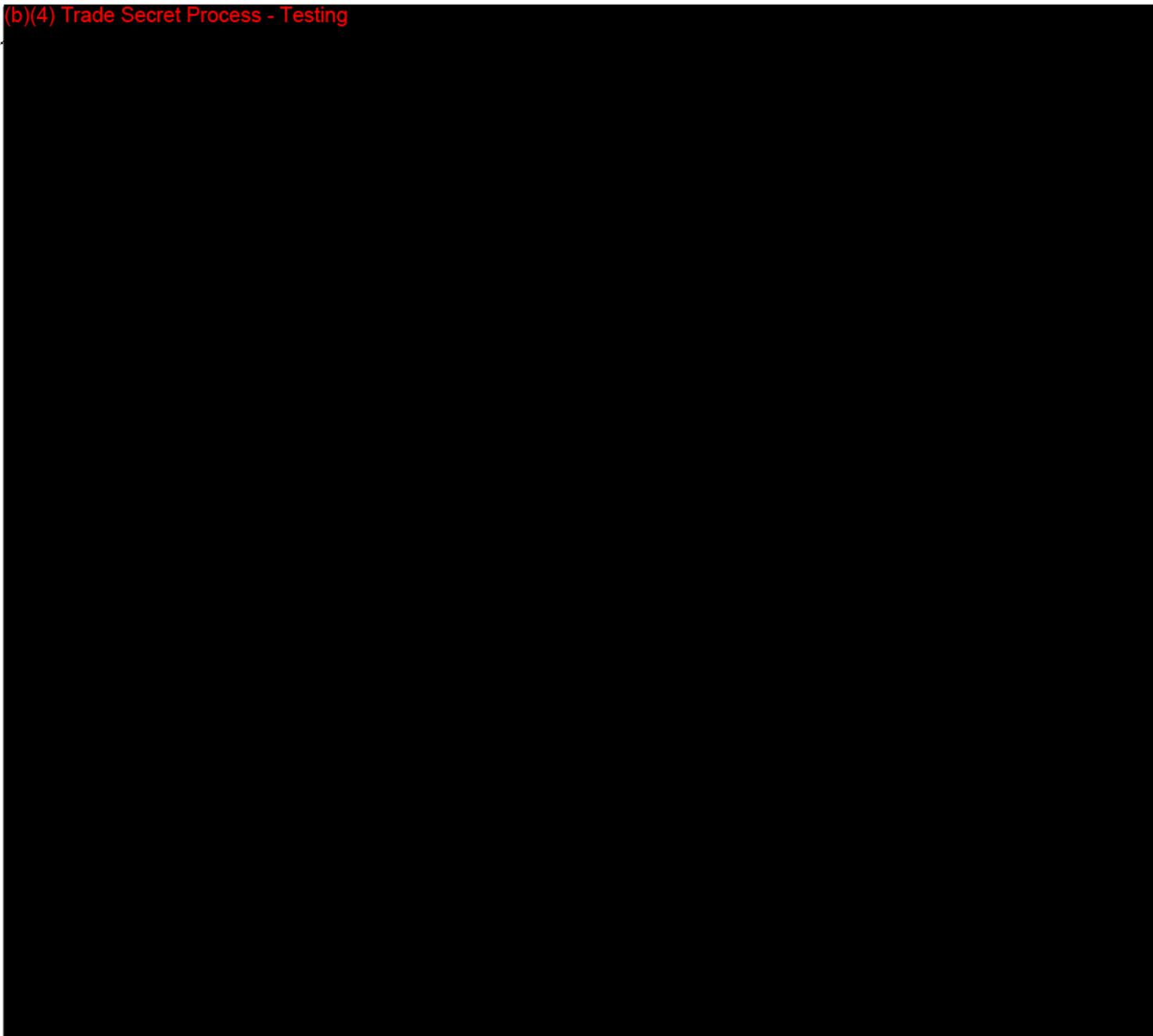
(b)(4) Trade Secret Process - Testing



## Section 18 Performance Testing – Bench

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(b)(4) Trade Secret Process - Testing



18/006

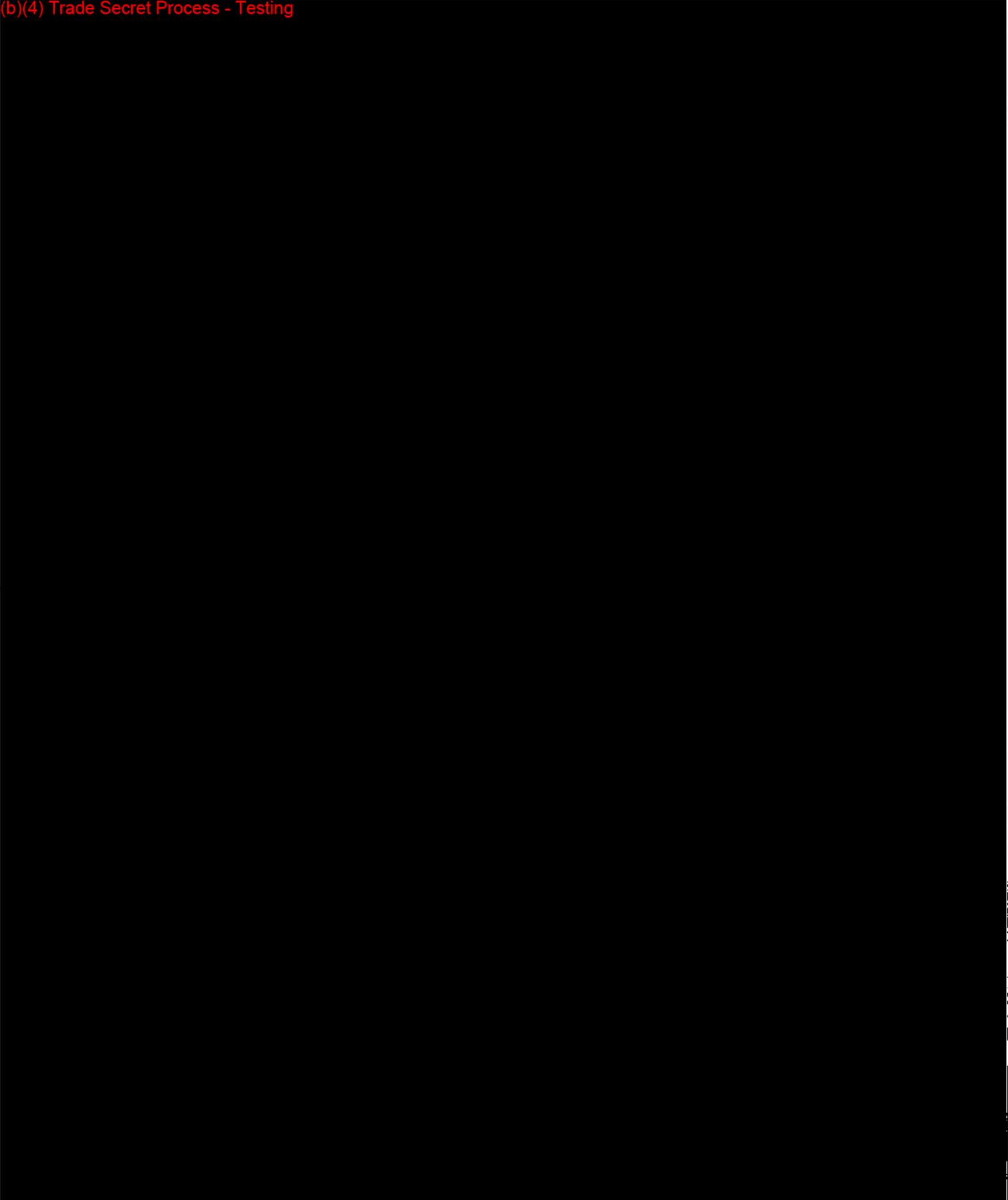
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CONFIDENTIAL

## Section 18 Performance Testing – Bench

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(b)(4) Trade Secret Process - Testing



CONFIDENTIAL

18/001

## Section 18 Performance Testing – Bench

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(b)(4) Trade Secret Process - Testing



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CONFIDENTIAL

18/008

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Department of Health and Human Services  
 Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(K)S**  
*(To be filled in by applicant)*

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995

<i>Please answer the following questions</i>	Yes	No
Is this standard recognized by FDA <sup>2</sup> ? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number <sup>3</sup> .....	# <u>5-4</u>	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of the standard? .....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard? .....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup> ? .....	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? .....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
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If yes, report these exclusions in the summary report table.		
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If yes, was the guidance document followed in preparation of this 510k? .....	<input type="checkbox"/>	<input type="checkbox"/>
Title of guidance: <u>N/A</u>		

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED\*

DESCRIPTION

JUSTIFICATION

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 Food and Drug Administration  
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TYPE OF 510(K) SUBMISSION  
 Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>  
 IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004)

*Please answer the following questions* Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 5-34

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....         
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....      

Does this standard include acceptance criteria? .....         
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Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....         
 If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: N/A

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]  
<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)  
<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>  
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<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED\*

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

IEC 60601-2-22 (1995), 2<sup>nd</sup> Edition, "Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment" 11/8/1995

*Please answer the following questions* Yes      No

Is this standard recognized by FDA <sup>2</sup>?      

FDA Recognition number <sup>3</sup> # N/A

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?      

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 If yes, was the guidance document followed in preparation of this 510k?      

Title of guidance: Guidance for Industry and FDA Staff - Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22; Guidance for Industry and FDA Staff (Laser Notice No. 50)

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d]. [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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device; and the name address of the test laboratory or

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

TANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED\*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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DESCRIPTION

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**TYPE OF 510(K) SUBMISSION**

Traditional       Special       Abbreviated

**STANDARD TITLE<sup>1</sup>**

IEC 60825-1 Ed. 2.0 (2007), Safety of laser products - Part 1: Equipment classification, and requirements. 3/30/2007

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... # 12-168

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED\*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
45.7g	No shut-off valve between a pressure-relief device and the parts intended to be protected		N/A
45.7h	Minimum number of cycles of operation: 100.000		N/A
<b>48</b>	<b>BIOCOMPATIBILITY</b>		—
	Parts of equipment and accessories intended to come into contact with biological tissues, cells or body fluids are evaluated in accordance with ISO 10993-1	Handpiece is not to come in contact with patient skin	N/A
<b>49</b>	<b>INTERRUPTION OF THE POWER SUPPLY</b>		—
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard	No such automatic resetting thermal cut-outs	N/A
49.2	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function	Disconnection only interrupts intended function	Pass
49.3	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure	No such constraints	N/A
<b>51</b>	<b>PROTECTION AGAINST HAZARDOUS OUTPUT</b>		—
51.4	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally	Equipment requires several steps to energize laser output. User must actively select desired power, and changing power settings requires an action for each level changed.	Pass
<b>52</b>	<b>ABNORMAL OPERATION AND FAULT CONDITIONS</b>		—
52.1	Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13)	(see appended table 52)	Pass
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4	Not part of this evaluation	N/A
52.5.2	Failure of thermostats presents no safety hazards	(see appended table 52)	Pass
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard	No such parts	N/A
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C	(see appended table 52)	Pass
52.5.6	Locking of moving parts presents no safety hazard	No such moving parts	N/A
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	No such parts	N/A
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8	No such parts	N/A
52.5.9	Failure of one component at a time presents no safety hazard	(see appended table 52)	Pass







































































































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IEC 60825-1			
Clause	Requirement + Test	Result - Remark	Verdict

<b>4</b>	<b>ENGINEERING SPECIFICATIONS</b>		
	General remarks		
	Modification	No modification	N/A
4.2	Protective housing		
4.2.1	General		Pass
4.2.2	Service	Tool Required	Pass
4.2.3	Removable laser system	Not a Removable Laser System	N/A
4.3	Access panels and safety interlocks		
4.3.1	Access panels of protective housing		
	Product Class .....	Class 4 Laser	Pass
	Accessible emission during removal of access panel .....	No access panel	N/A
	The removal of the panel gives access to laser radiation levels designated by "X" in the table		N/A
	Accessible emissions after removal .....		N/A
4.3.2	Deliberate override mechanism	None provided	N/A
4.4	Remote interlock connector	Open-circuit style interlock provided	Pass
4.5	Manual reset	Device requires entering 'ready' mode which entails a deliberate action and 7-second delay	Pass
4.6	Key control	Key control for mains provided	Pass
4.7	Laser radiation emission warning		
4.7.1	Class 3R ( $\lambda < 400$ nm; $\lambda > 700$ nm), 3B and 4		Pass
4.7.2	Audible or visible warning	Audible and visible provided	Pass
4.7.3	Operational control and laser aperture	Radiation warning indicator within 2m of entire product	Pass
4.7.4	Laser emission distributed through more than one output	Single output	N/A
4.8	Through	Multiple switch mechanisms provided for stopping emission	Pass
4.9	Controls	Access to controls does not require exposure to laser radiation	Pass
4.10	Viewing optics	None	
	a) Human access to laser radiation in excess of Class 1M prevented when the shutter is opened or attenuation varied		N/A























**Section19**  
**Performance Testing – Animal**

## Section 19 Performance Testing – Animal

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**NONE**

**Section20**  
**Performance Testing – Clinical**

**NONE**

**Section21**  
**Kit Certification**

## Section 21 Kit Certification

---

NONE

463

\* \* \* COMMUNICATION RESULT REPORT ( APR. 2. 2013 9:47AM ) \* \* \*

FAX HEADER 1:  
FAX HEADER 2:

TRANSMITTED/STORED : APR. 2. 2013 9:43AM  
MODE OPTION

ADDRESS

RESULT

PAGE

4140 MEMORY TX

BWTEK

OK

3/3

REASON FOR ERROR OR LINE FAIL  
E-1) HANG UP OR NO ANSWER

E-2) BUSY NO FACSIMILE CONNECTION



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - W066-G609  
Silver Spring, MD 20993-0002

Litecure, LLC  
% Liang Lu  
Quality and Regulatory Manager  
250 Corporate Boulevard, Suite B  
Newark, Delaware 19702

Letter dated: March 29, 2013

Re: K123014  
Trade/Device Name: LiteCure Therapy System, Model LTS-1500  
Regulation Number: 21 CFR 890.5500, 878.4810  
Regulation Name: Infrared lamp, Laser surgical instrument for use in general and plastic surgery and in dermatology  
Regulatory Class: II  
Product Code: GEX  
Dated: December 01, 2012  
Received: February 22, 2013

Dear Liang Lu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

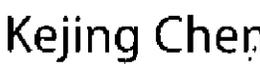
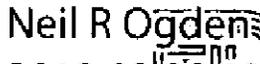
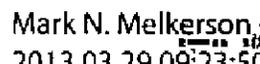
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.



For United States-based clinical studies only: Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank?</i> (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X
Mobile Application			X
MR Conditional			X
Device Contains Battery			X
Companion Diagnostic			X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <a href="http://www.fda.gov/cdrh/comp/guidance/169.html">http://www.fda.gov/cdrh/comp/guidance/169.html</a> )	Contact OC.		X

Regulation Number \_\_\_\_\_ Class\* \_\_\_\_\_ Product Code \_\_\_\_\_  
 21 CFR 878.4810, 21 CFR 890.5500 II GEX  
 (\*If unclassified, see 510(k) Staff)  
 Additional Product Codes: ILY

Digital Signature Concurrence Table	
Reviewer Sign-Off	 <small>Digitally signed by Kejing Chen            DN: cn=US, o=U.S. Government, ou=HHS,            ou=FDA, ou=People, cn=Kejing Chen,            0.9.2342.19200100.100.1.1=2000552696            Date: 2013.03.27 09:59:06 -0400</small>
Branch Chief Sign-Off	 Neil R Ogden 2013.03.28 11:3:53:42 -04'00'
Division Sign-Off	 Mark N. Melkerson 2013.03.29 09:23:50 -04'00'

**Napperli, Jesse \***

---

**m:** Garcia, Diane  
**Sent:** Tuesday, February 26, 2013 10:25 AM  
**To:** Napperli, Jesse \*  
**Subject:** RE: K123014/S1 ECOPY HOLD LETTER W/ ATTACHMENT

Jesse  
What did you find out?  
Diane

---

**From:** CDRH-eCopyinfo  
**Sent:** Monday, February 25, 2013 4:06 PM  
**To:** Napperli, Jesse \*  
**Subject:** FW: K123014/S1 ECOPY HOLD LETTER W/ ATTACHMENT

Hi Jesse  
Will you double check this cover sheet and send me a pdf of it so that we can show the firm that it was missing the signature.

Thanks  
Diane

---

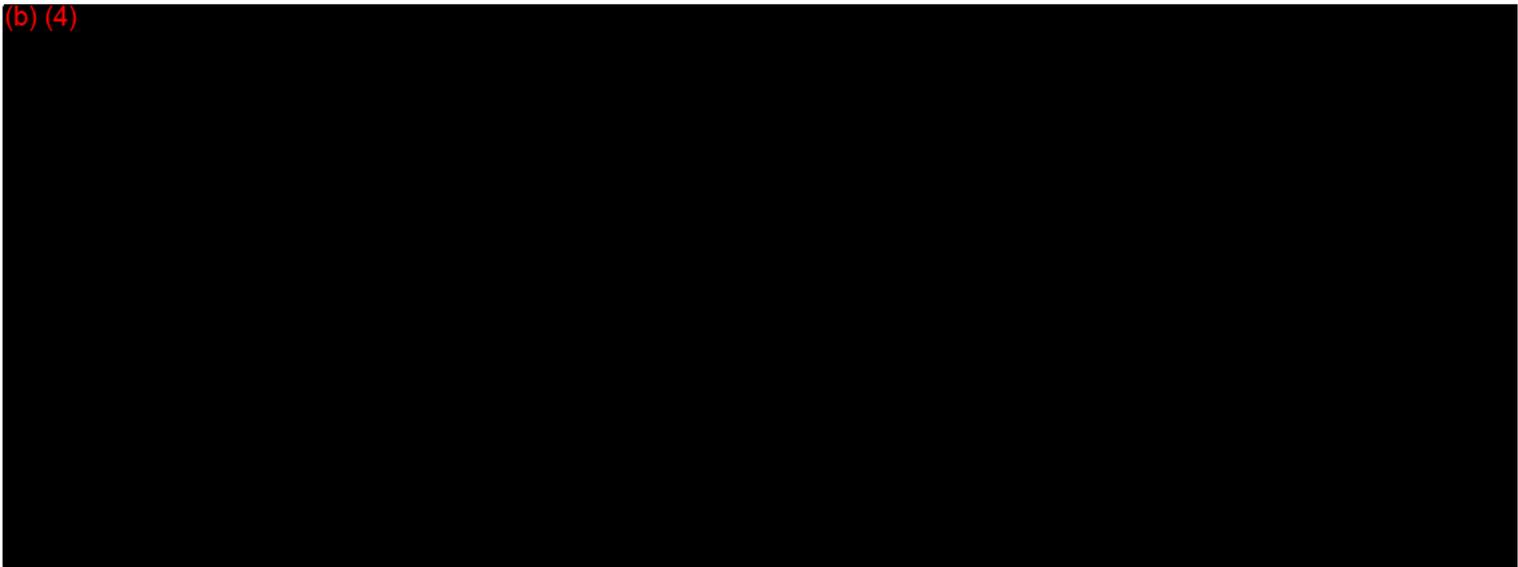
**From:** Leon Lu [<mailto:llangl@litecure.com>]  
**Sent:** Monday, February 25, 2013 2:27 PM  
**To:** Napperli, Jesse \*; Allen, Samie Niver  
**Cc:** DCCLetters; Leon Lu  
**Subject:** RE: K123014/S1 ECOPY HOLD LETTER W/ ATTACHMENT

Hello

(b) (4)



(b) (4)



Leon

\*\*\*\*\*Please consider the environment before printing this email\*\*\*\*\*

---

**From:** NapperIi, Jesse \* [<mailto:Jesse.NapperIi@fda.hhs.gov>]  
**Sent:** Monday, February 25, 2013 1:39 PM  
**To:** Leon Lu  
**Cc:** DCCLetters  
**Subject:** K123014/S1 ECOPY HOLD LETTER W/ ATTACHMENT

**Napperli, Jesse \***

---

**m:** Garcia, Diane  
**sent:** Tuesday, February 26, 2013 11:19 AM  
**To:** Napperli, Jesse \*  
**Subject:** RE: K123014/S1

(b) (5)



---

**From:** Napperli, Jesse \*  
**Sent:** Tuesday, February 26, 2013 11:15 AM  
**To:** Garcia, Diane  
**Subject:** K123014/S1

Hello Diane,

(b) (5)



-Jesse

**Napperli, Jesse \***

---

**From:** Garcia, Diane  
**Sent:** Tuesday, February 26, 2013 11:30 AM  
**To:** Napperli, Jesse \*  
**Subject:** RE: K123014/S1

Thanks Jesse.

Diane

*Diane Garcia  
Public Health Advisor  
510(k) Staff  
POS/ODE/CDRH/FDA  
301-796-6559*

---

**From:** Napperli, Jesse \*  
**Sent:** Tuesday, February 26, 2013 11:28 AM  
**To:** Garcia, Diane  
**Subject:** RE: K123014/S1

(b) (5)



---

**From:** Garcia, Diane  
**Sent:** Tuesday, February 26, 2013 11:19 AM  
**To:** Napperli, Jesse \*  
**Subject:** RE: K123014/S1

(b) (5)

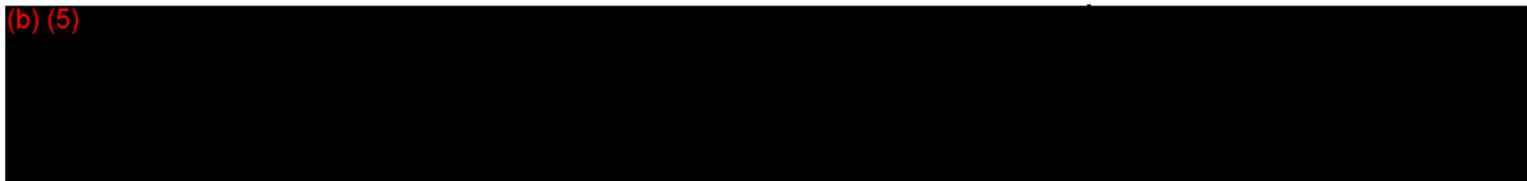


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**From:** Napperli, Jesse \*  
**Sent:** Tuesday, February 26, 2013 11:15 AM  
**To:** Garcia, Diane  
**Subject:** K123014/S1

Hello Diane,

(b) (5)



-Jesse



**COVER SHEET MEMORANDUM**

**From:** Reviewer Name Kejing Chen  
**Subject:** 510(k) Number K123014  
**To:** The Record

Please list CTS decision code AZ

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

**Not Substantially Equivalent (NSE) Codes**

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NM NSE requires PMA
- NS NSE no response
- NH NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )			✓
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			✓
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	
Is clinical data necessary to support the review of this 510(k)?		✓	
For United States-based clinical studies only: Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)		✓	
Does this device include an Animal Tissue Source?		✓	
All Pediatric Patients age<=21		✓	

Neonate/Newborn (Birth to 28 days)		✓
Infant (29 days -< 2 years old)		✓
Child (2 years -< 12 years old)		✓
Adolescent (12 years -< 18 years old)		✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		✓
Nanotechnology		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <a href="http://www.fda.gov/cdrh/comp/guidance/169.html">http://www.fda.gov/cdrh/comp/guidance/169.html</a> )	Contact OC.	✓

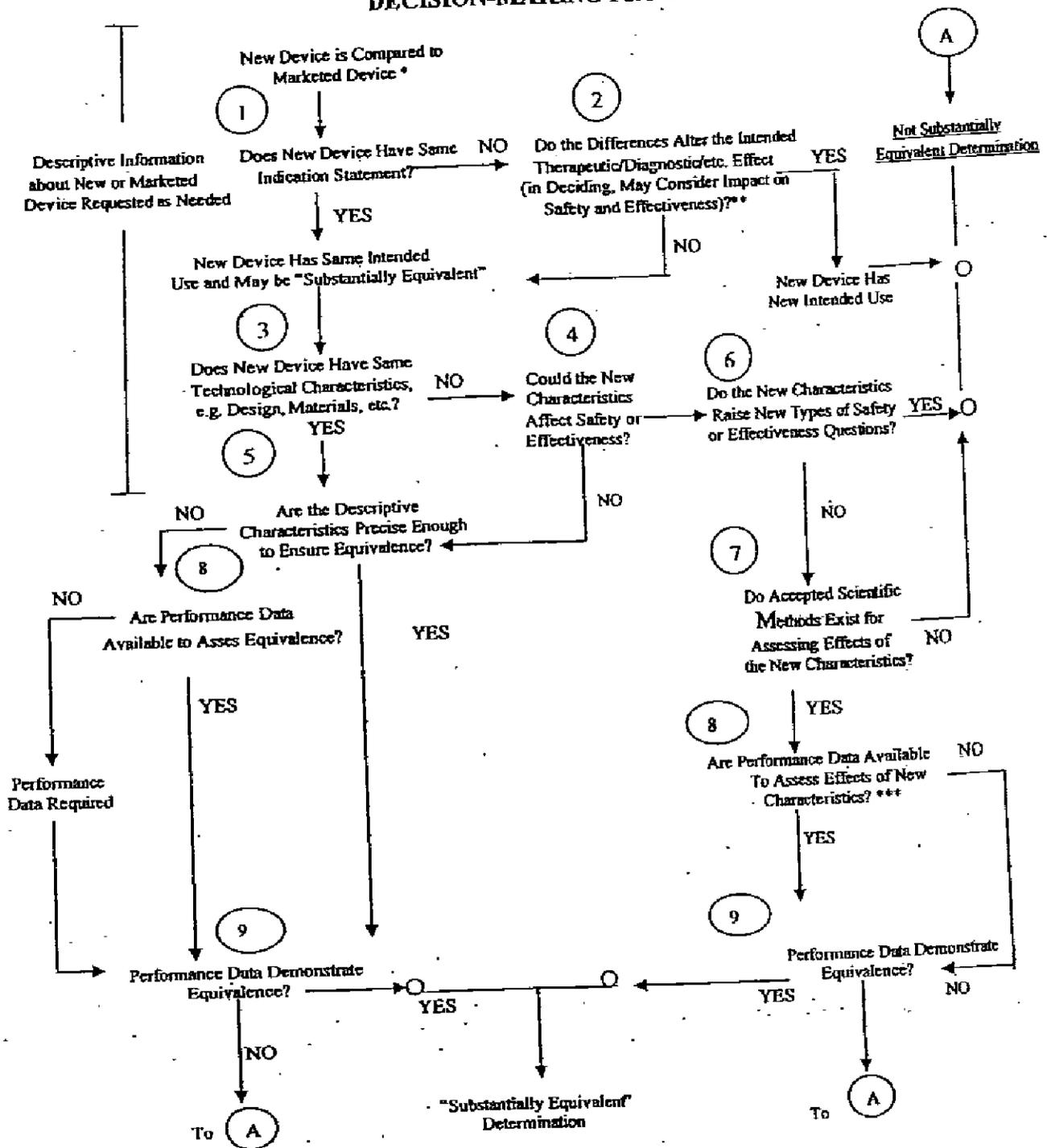
Regulation Number 21 CFR 890.4810 Class\* I Product Code GEX  
(\*If unclassified, see 510(k) Staff)

Additional Product Codes: LEX

Review: Neil R. Oades GEOB1 11/15/12  
(Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_  
(Division Director) (Date)

## 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



\* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

\*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

\*\*\* Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.



Food and Drug Administration  
Office of Device Evaluation  
WO Building 68  
Silver Spring, MD 20993

Premarket Notification [510(k)] Review  
Traditional

**K123014**

Date: November 9, 2012

To: The Record

From: Kejing Chen, Ph.D., Biomedical Engineer

Office: ODE

Division: DSORD/GSDB

510(k) Holder: Litecure, LLC

Device Name: Litecure

Contact: Mr. Liang Lu

250 Corporate Blvd.

Suite B

Newark, Delaware 19702

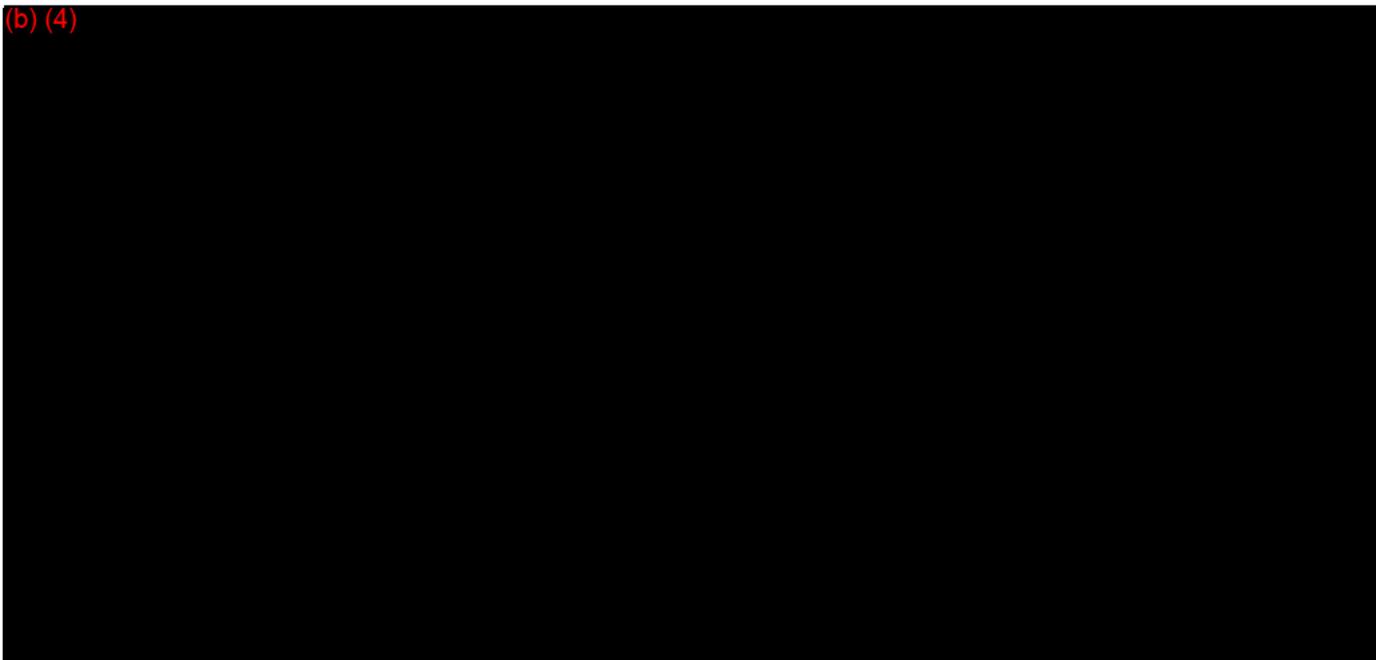
Phone: 302-709-0408 ext 1540

Fax: 302-709-3903

Email: [liangl@litecure.com](mailto:liangl@litecure.com)

I. Purpose

(b) (4)



**II. Administrative Requirements**

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Statement	X		
Standards Form	X		

**III. Device Description**

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

(b) (4)

**IV. Indications for Use**

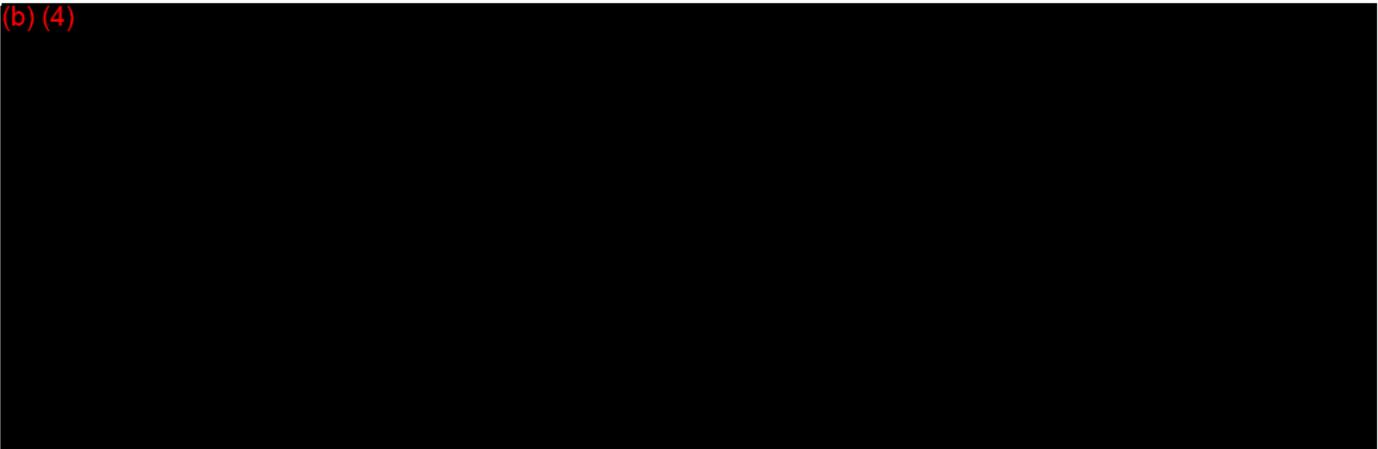
	Company	Indications for use
K123014 (subject)	Litecure	810 nm and 980 nm wavelength: LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevation tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.  980 nm wavelength: LiteCure Therapy System, Model LTS-1500 is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Tmentagrophytes, and/or yeasts Candida albicans, etc).
K103511	Litecure	LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle

		tissue and to temporarily increase local blood circulation.
K110375	Blueshine	<p>General indications</p> <p>Podiatry</p> <p>Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: Matrixectomy Periungual and subungual warts, Plantar warts, Neuromas.</p> <p>The Gold Series is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Tmentagrophytes, and/or yeasts Candida albicans, etc).</p>

The device is proposed for prescription use.

The proposed indications are the same as those when K103511 and K110375 are combined.

**V. Predicate Device Comparison**



**VI. Labeling**

Instructions for use are provided. (b)(4) Trade Secret Process - Product Specs

**VII. Sterilization/Shelf Life/Reuse**

(b)(4) Trade Secret Process - Product Specs d.

**VIII. Biocompatibility**

(b)(4) Trade Secret Process - Product Specs

**IX. Software**

Version:
Level of Concern:

	Yes	No
Software description:	x	
Device Hazard Analysis:		
Software Requirements Specifications:	x	
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:	x	
Development:		
Verification & Validation Testing:	x	
Revision level history:		
Unresolved anomalies:		

(b)(4) Trade Secret Process - Product Specs

**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

The sponsor declared conformance to the following standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-22
- IEC 60825-1
- ISO 10993-1
- ISO 10993-5
- ISO 10993-10

**XI. Performance Testing – Bench**

(b)(4) Trade Secret Process - Product Specs

**XII. Performance Testing – Animal**

N/A

**XIII. Performance Testing – Clinical**

N/A

#### XIV. Substantial Equivalence Discussion

	Yes	No	
1. Is Product A Device	X		If NO = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	X		If NO = Stop, see 510(k) staff
3. Same Indication Statement?	X		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
9. Accepted Scientific Methods Exist?			If NO = Stop NSE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: See [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_4147/FLOWCHART 510K DECISION.PDF](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4147/FLOWCHART%20510K%20DECISION.PDF) for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device:

It is a device.

2. Explain why not subject to 510(k):

It is subject to 510(k).

3. Explain how the new indication differs from the predicate device's indication:

Please refer to Section IV.

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

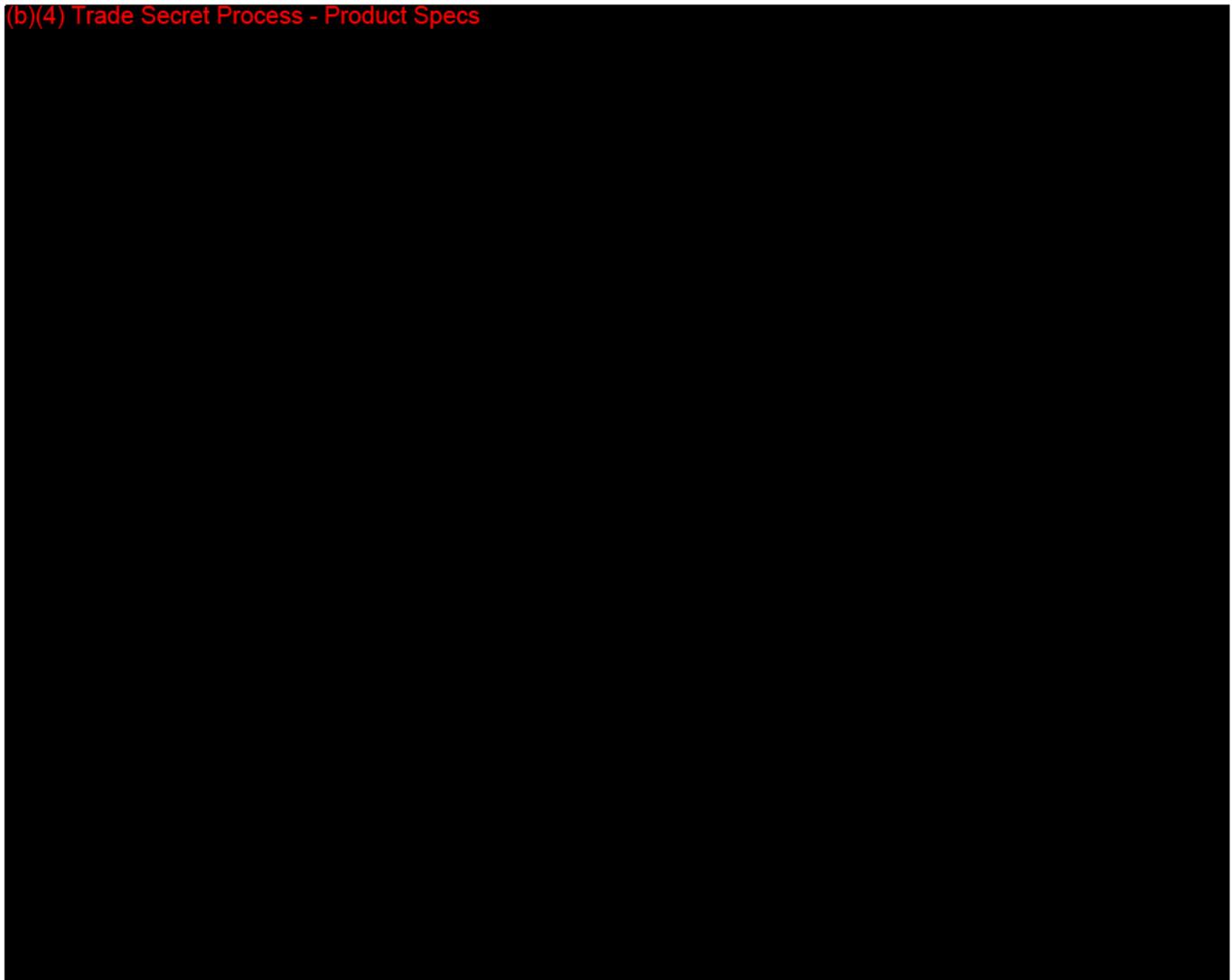
(b)(4) Trade Secret Process - Product Specs

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

(b)(4) Trade Secret Process - Product Specs



**XVI. Contact History**

**XVII. Recommendation**

I recommend that this submission be placed on hold pending receipt of the response to the above questions.

Regulation Number: 21 CFR 890.5500, 21 CFR 890.4810

Regulation Name: General and Plastic Surgery devices  
Regulatory Class: Class II  
Product Code: ILY, GEX

Digitally signed by Kejing Chen  
DN: cn=Kejing Chen, o=FDA, ou=FDA, email=kejing.chen@hhs.gov,  
c=US, ou=Product Development, ou=CDER, ou=FDA,  
ou=HHS, ou=US Government, ou=US  
**Kejing Chen**

---

Kejing Chen  
Lead Reviewer, GSDB/DSORD  
Neil R Ogdren  
2012.11.15 16:28:20 -05'00'  
Neil Ogdren  
Branch Chief, GSDB/DSORD

---

Date

---

Date

K123014/S1  
K123014

**Response to K123014, LiteCure Therapy System Model LTS-1500**

Kejing Chen, Ph.D.  
10903 New Hampshire Avenue W066-2566  
Silver Spring, Maryland 20993-0002  
Phone: (301) 796-6390

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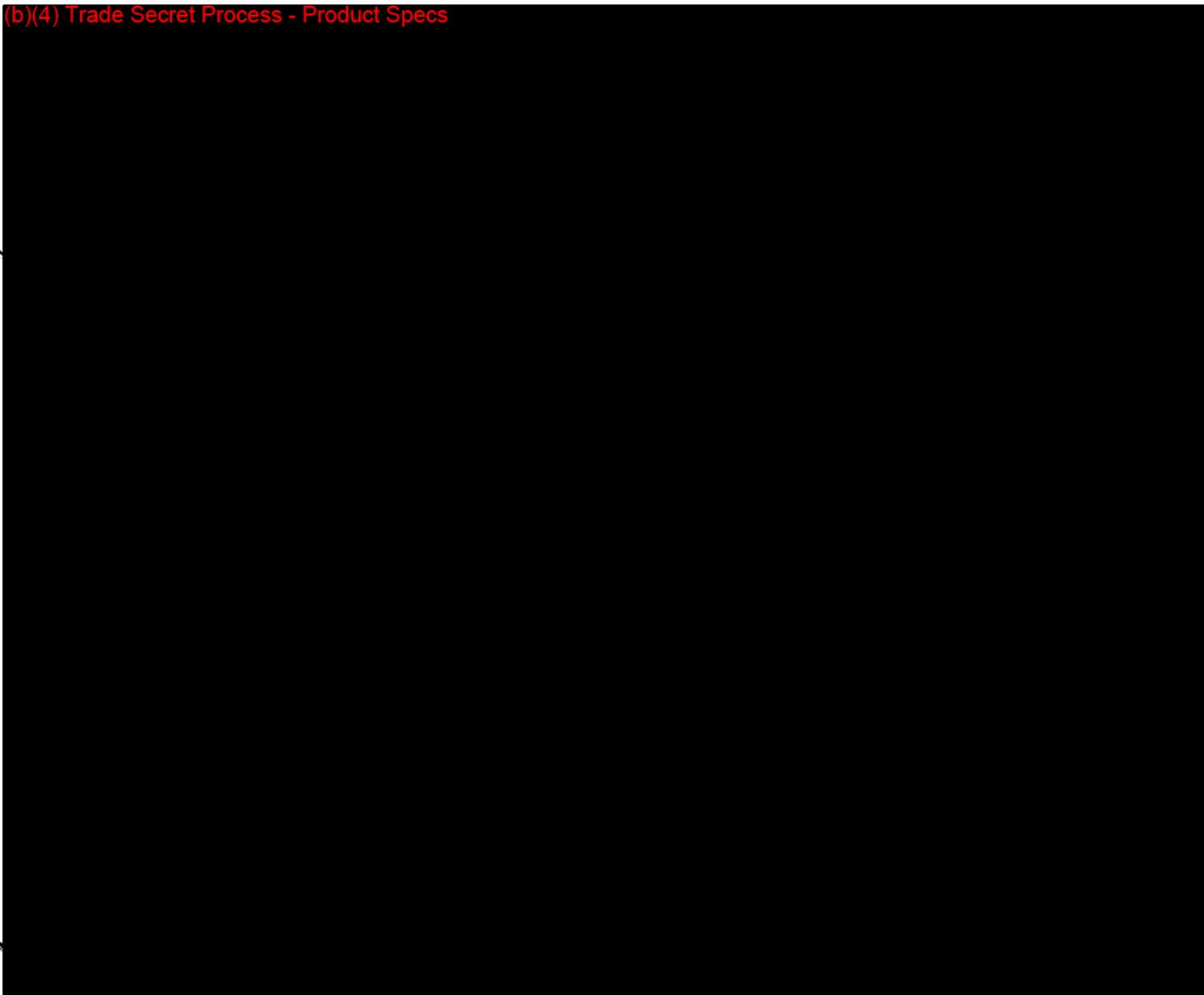
U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

FDA CDRH DMC  
FEB 22 2013  
Received

December 1, 2012

FDA 510(k): K123014, LiteCure Therapy System Model LTS-1500

(b)(4) Trade Secret Process - Product Specs

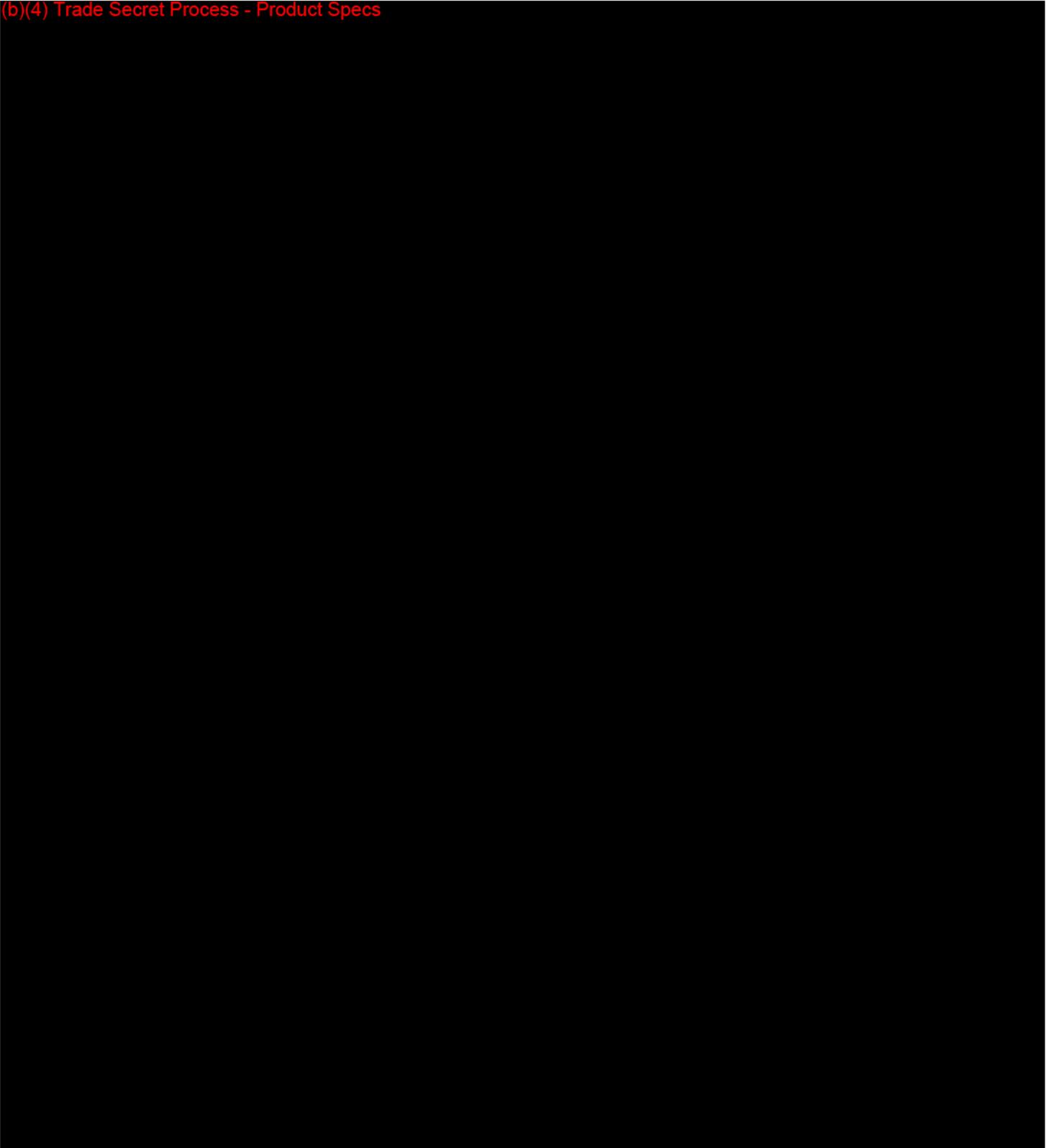


**Response to K123014, LiteCure Therapy System Model LTS-1500**



Kejing Chen, Ph.D.  
10903 New Hampshire Avenue W066-2566  
Silver Spring, Maryland 20993-0002  
Phone: (301) 796-6390

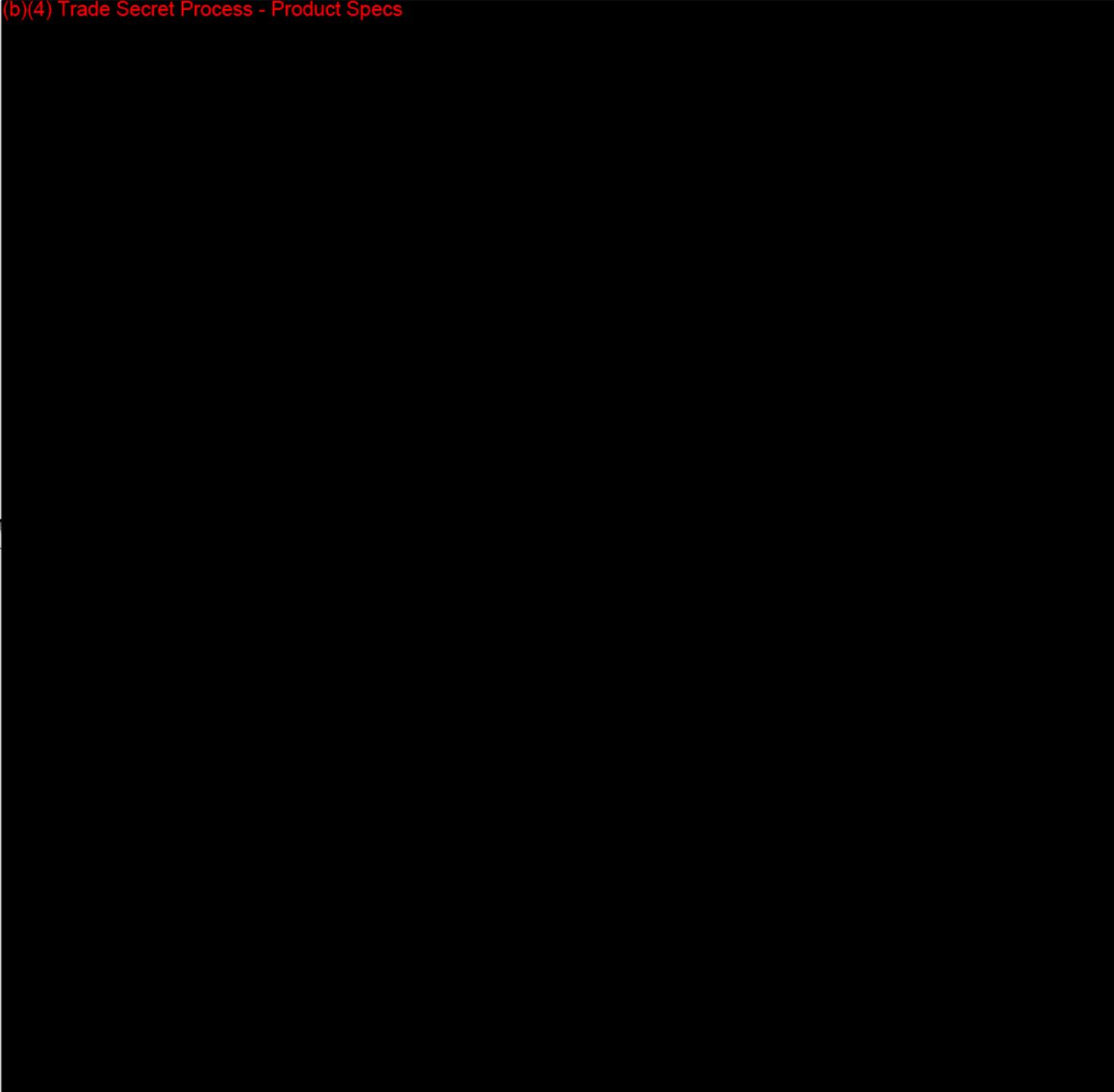
(b)(4) Trade Secret Process - Product Specs

A large, solid black rectangular redaction box covers the majority of the page, starting below the contact information and extending nearly to the bottom. The text "(b)(4) Trade Secret Process - Product Specs" is written in red at the top left corner of this redacted area.

**Response to K123014, LiteCure Therapy System Model LTS-1500**

Kejing Chen, Ph.D.  
10903 New Hampshire Avenue W066-2566  
Silver Spring, Maryland 20993-0002  
Phone: (301) 796-6390

(b)(4) Trade Secret Process - Product Specs



# COVER LETTER

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*#123014*

*[Signature]*  
*12/15/2012*

K15201A

# COVER LETTER

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12/15/2012

Kejing Chen, Ph.D.  
10903 New Hampshire Avenue W066-2566  
Silver Spring, Maryland 20993-0002  
Phone: (301) 796-6390

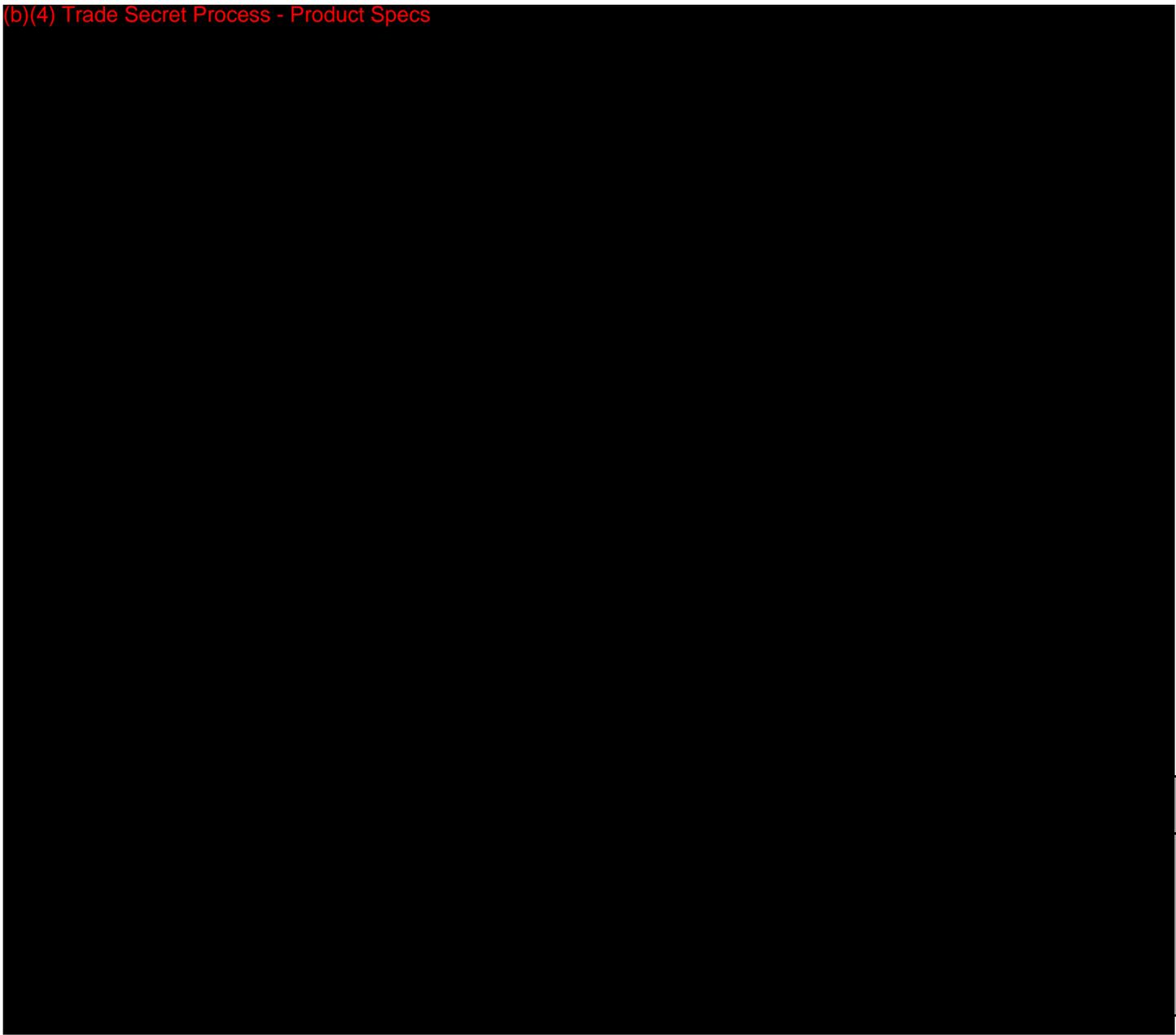
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U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

December 1, 2012

FDA 510(k): K123014, LiteCure Therapy System Model LTS-1500

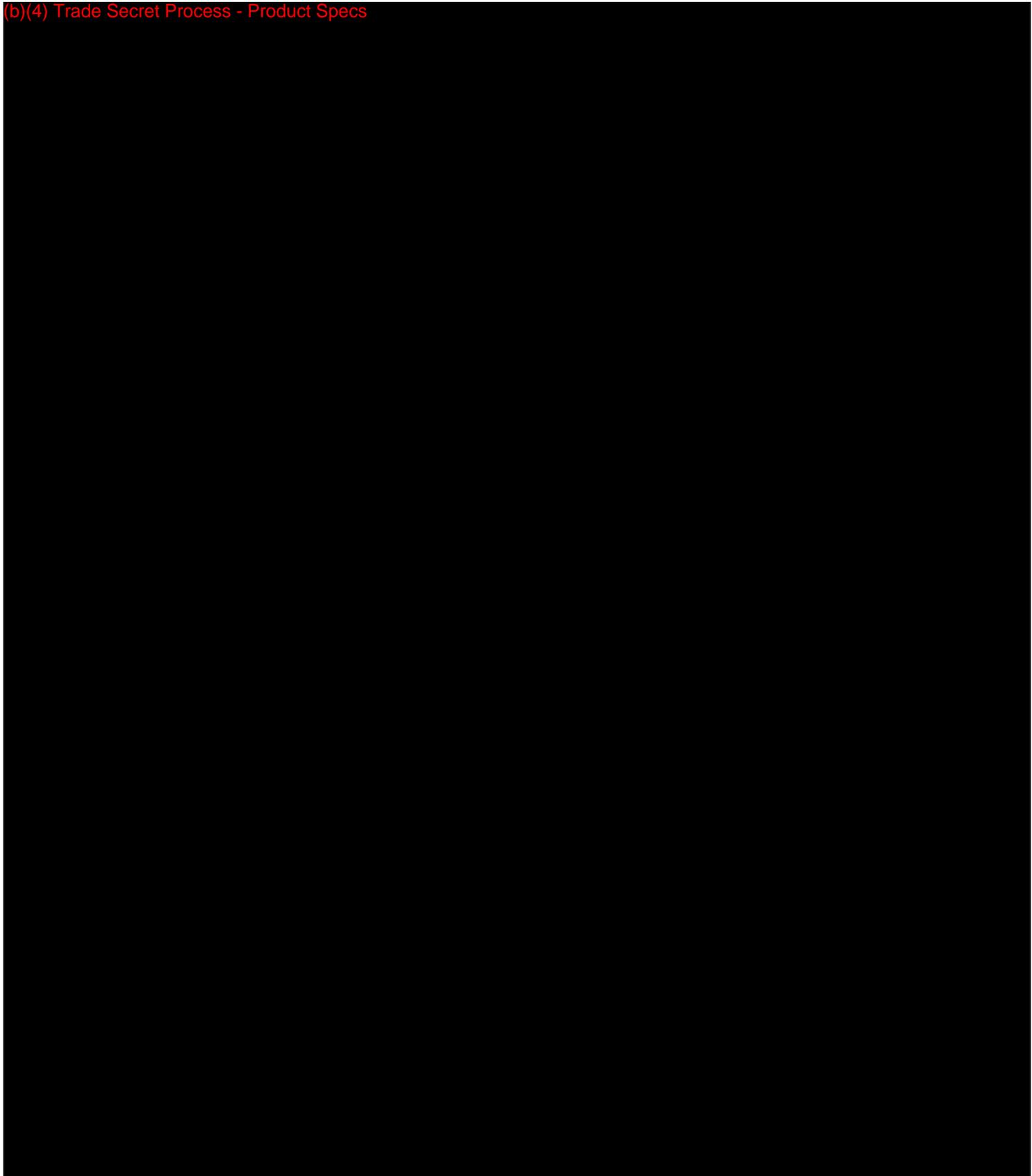
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**Response to K123014, LiteCure Therapy System Model LTS-1500**

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Phone: (301) 796-6390

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**Response to K123014, LiteCure Therapy System Model LTS-1500**

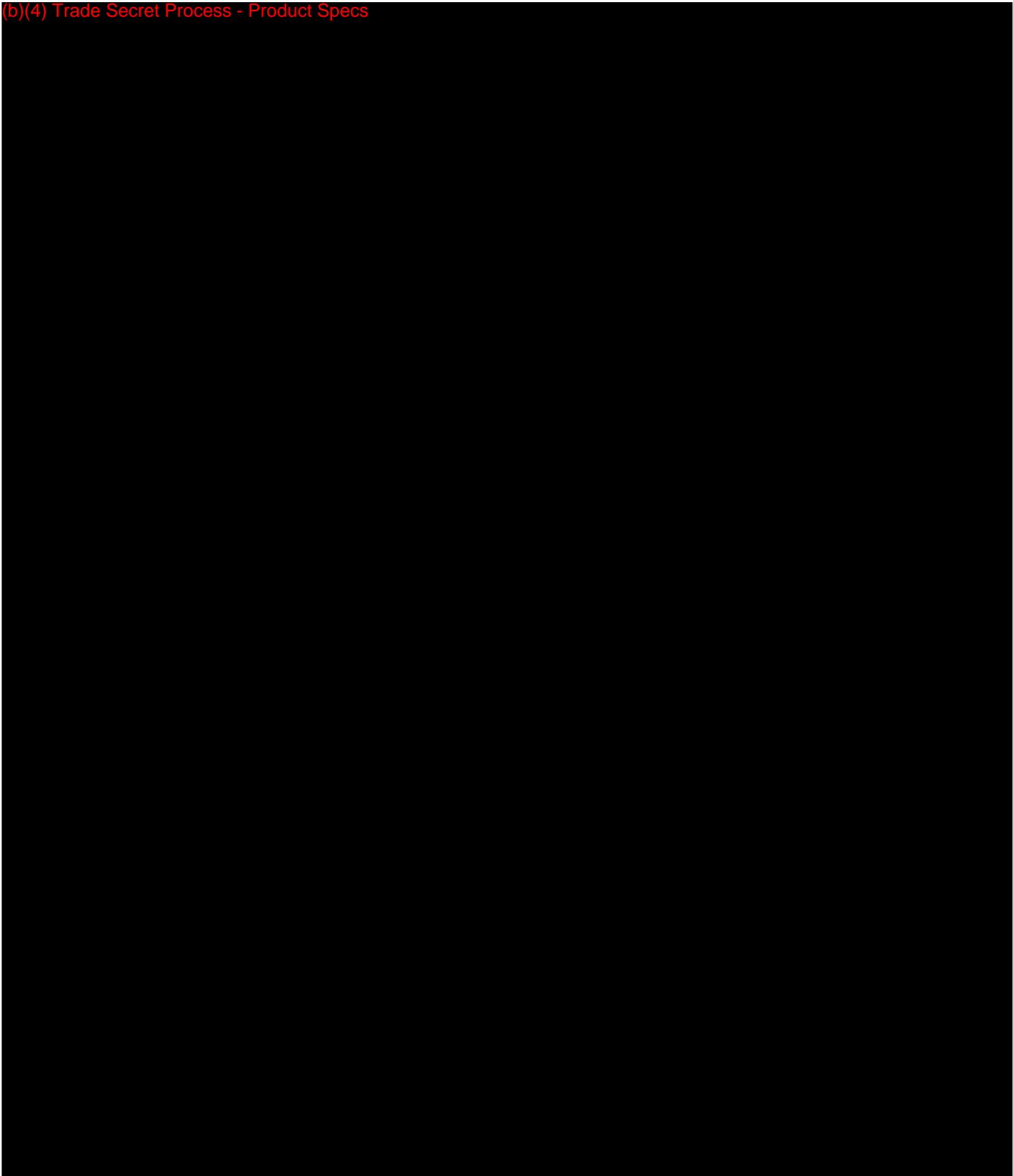
Kejing Chen, Ph.D.  
10903 New Hampshire Avenue W066-2566  
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**Section16 Software**

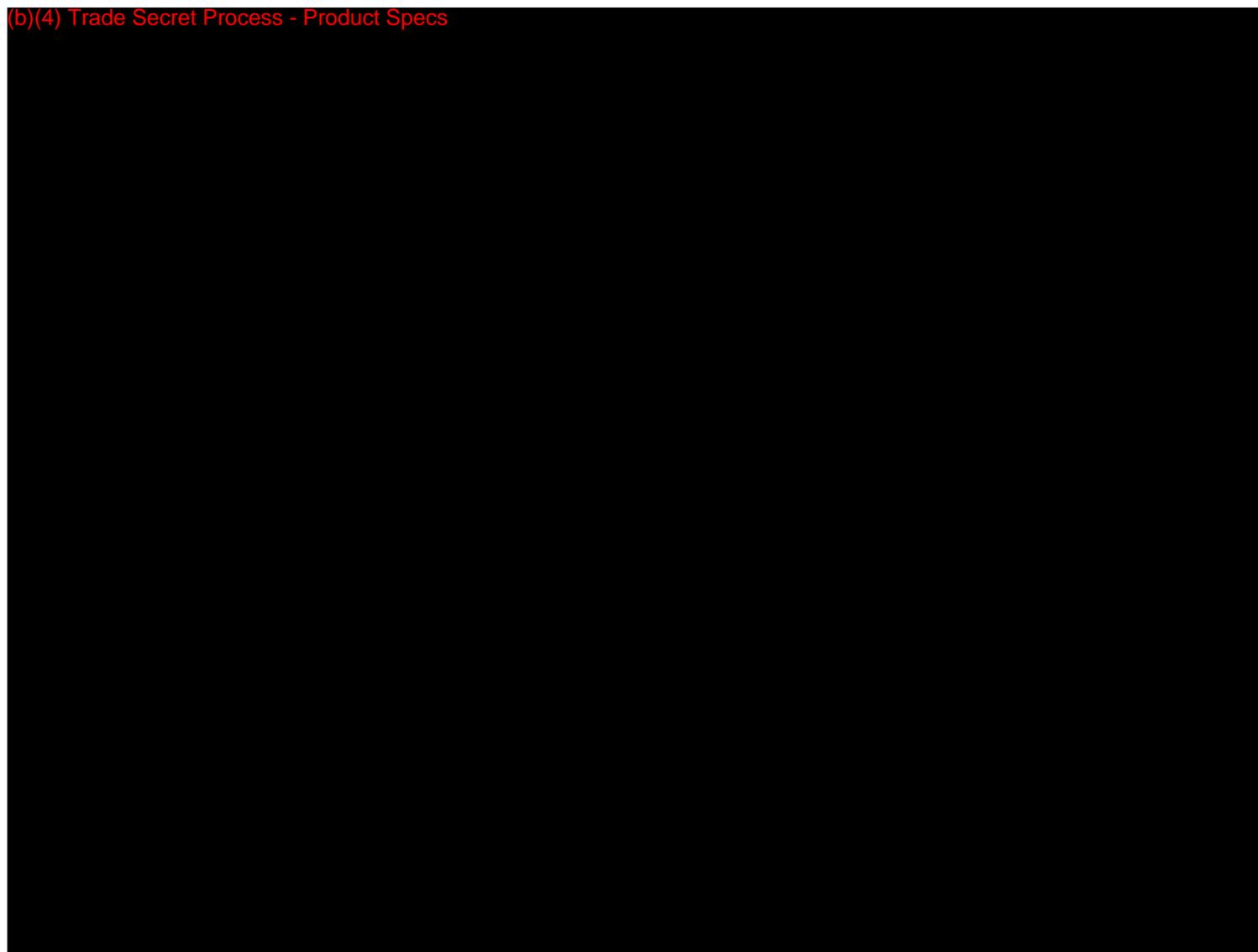
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## Section16 Software

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## Section16 Software

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### SOFTWARE DESCRIPTION

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## Section16 Software

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### SOFTWARE REQUIREMENTS/SPECIFICATIONS (SRS)

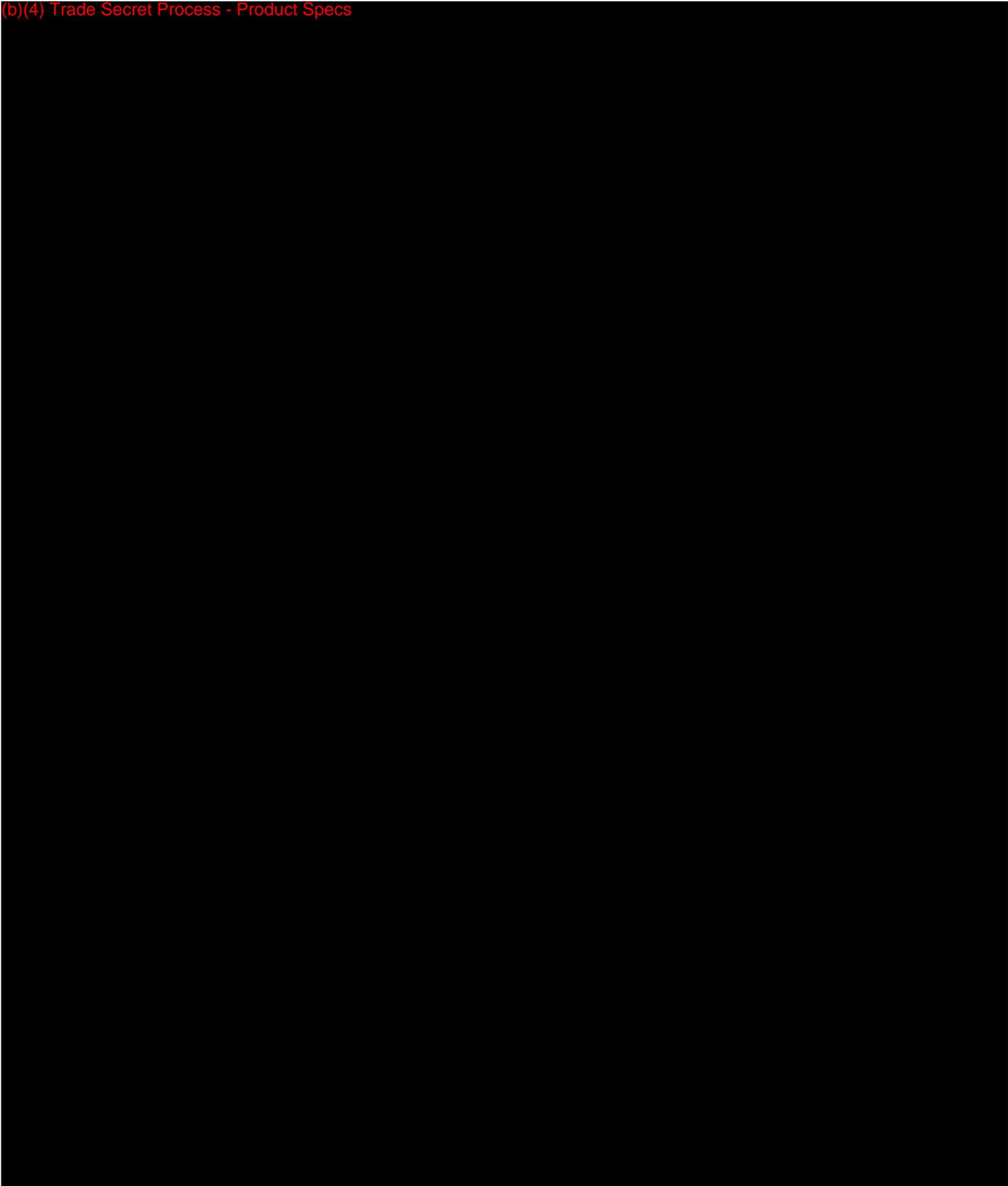
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# Section16 Software

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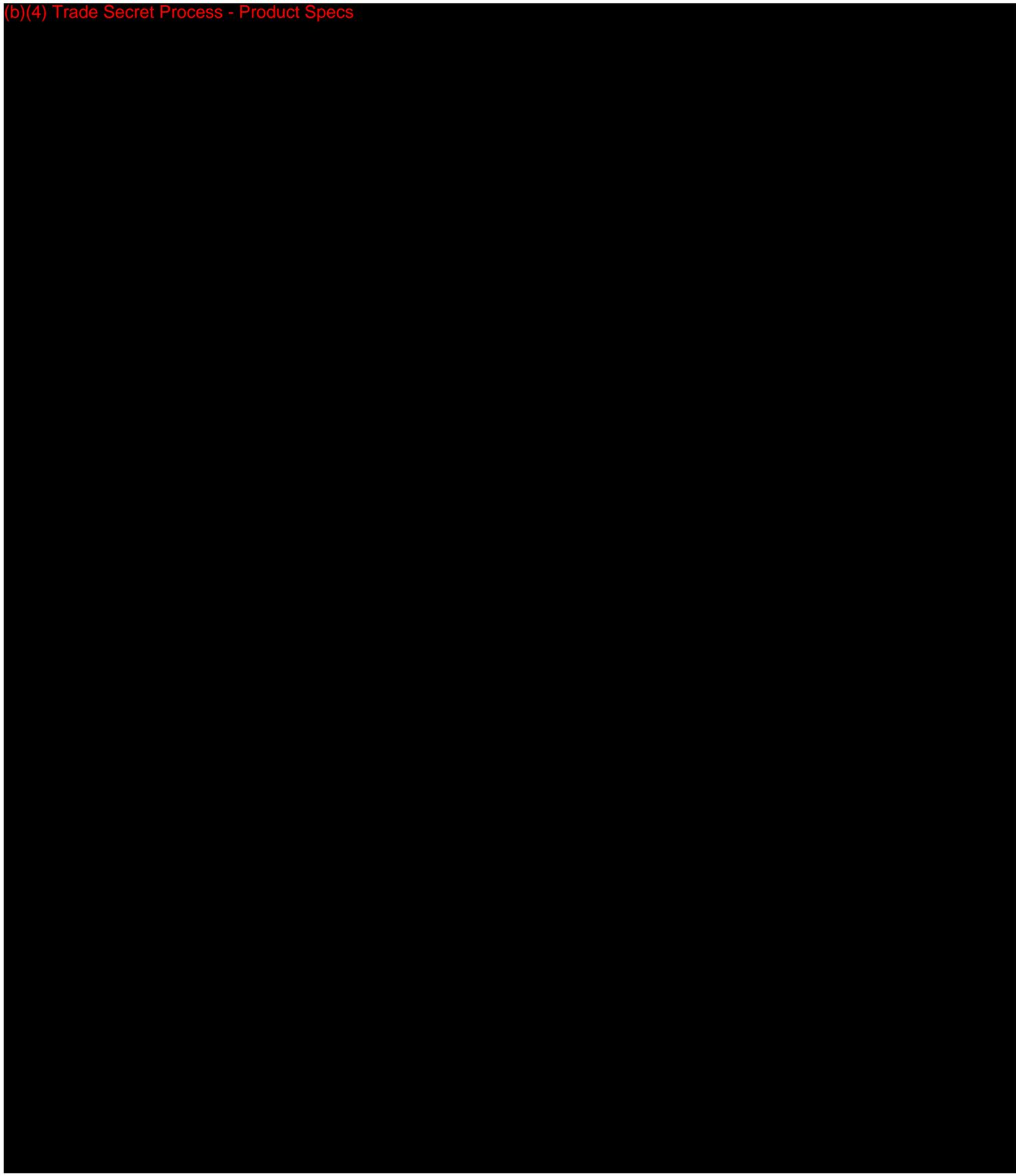
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## Section16 Software

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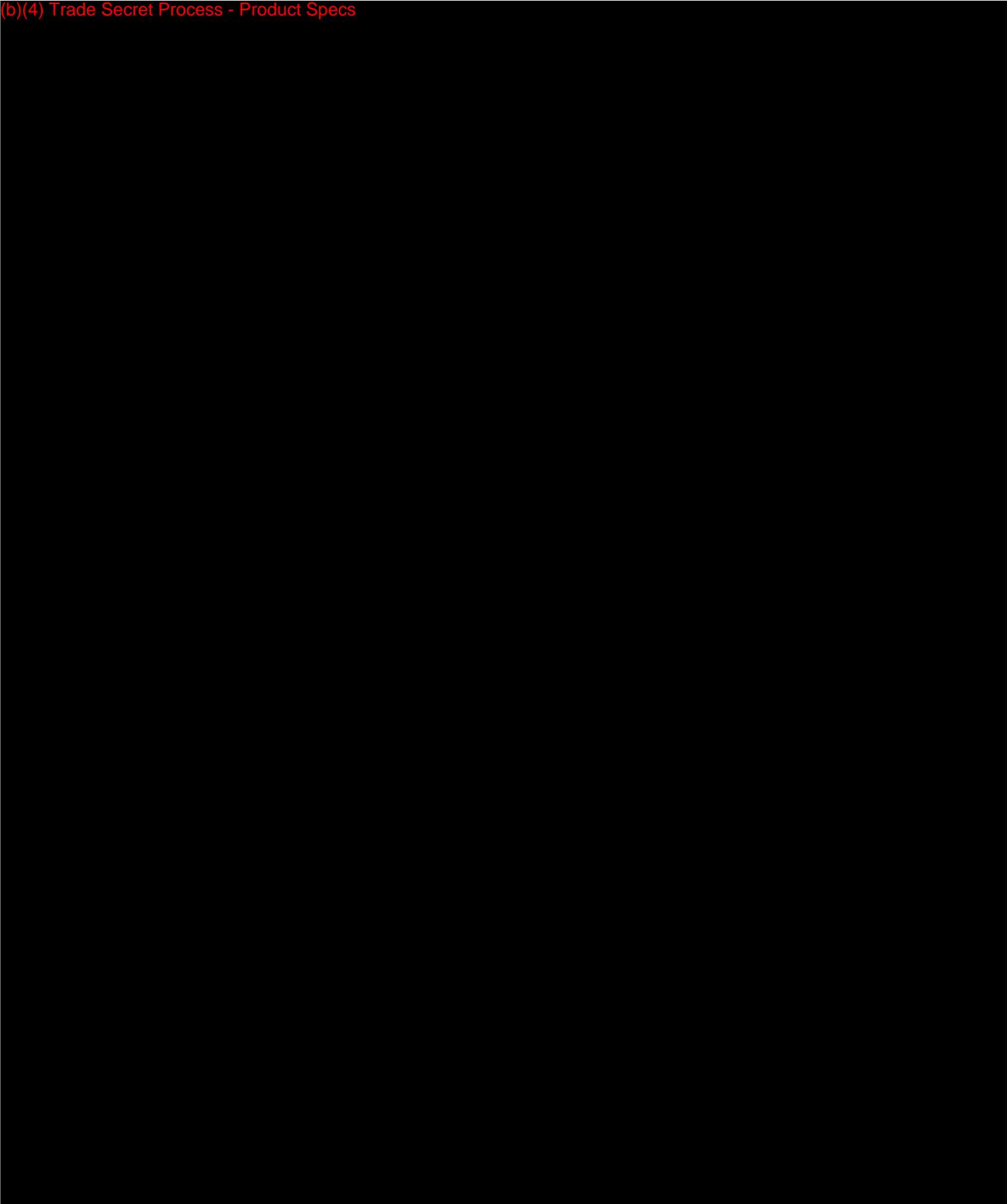
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# Section16 Software

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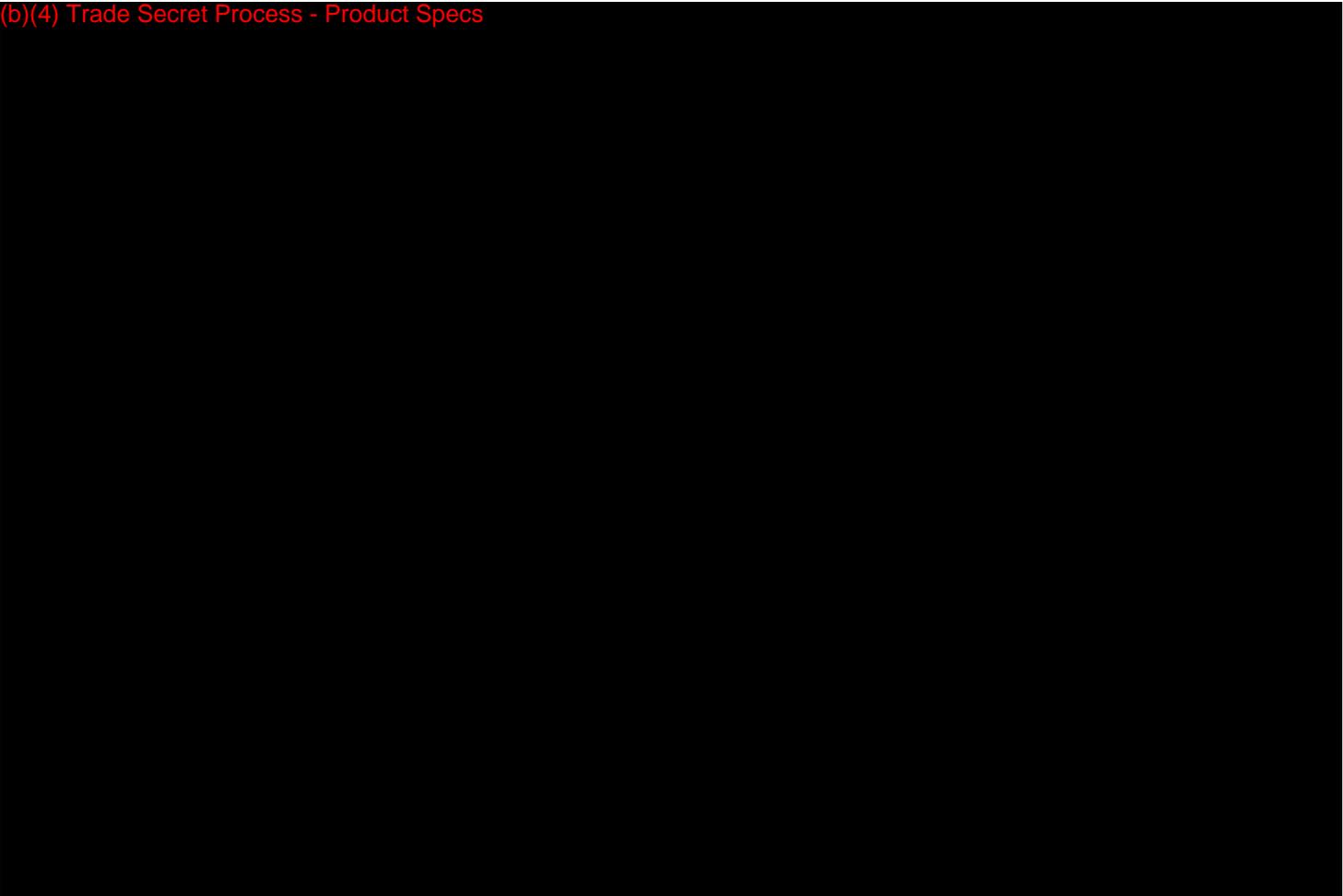
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**Section16 Software**

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(b)(4) Trade Secret Process - Product Specs



# Section16 Software

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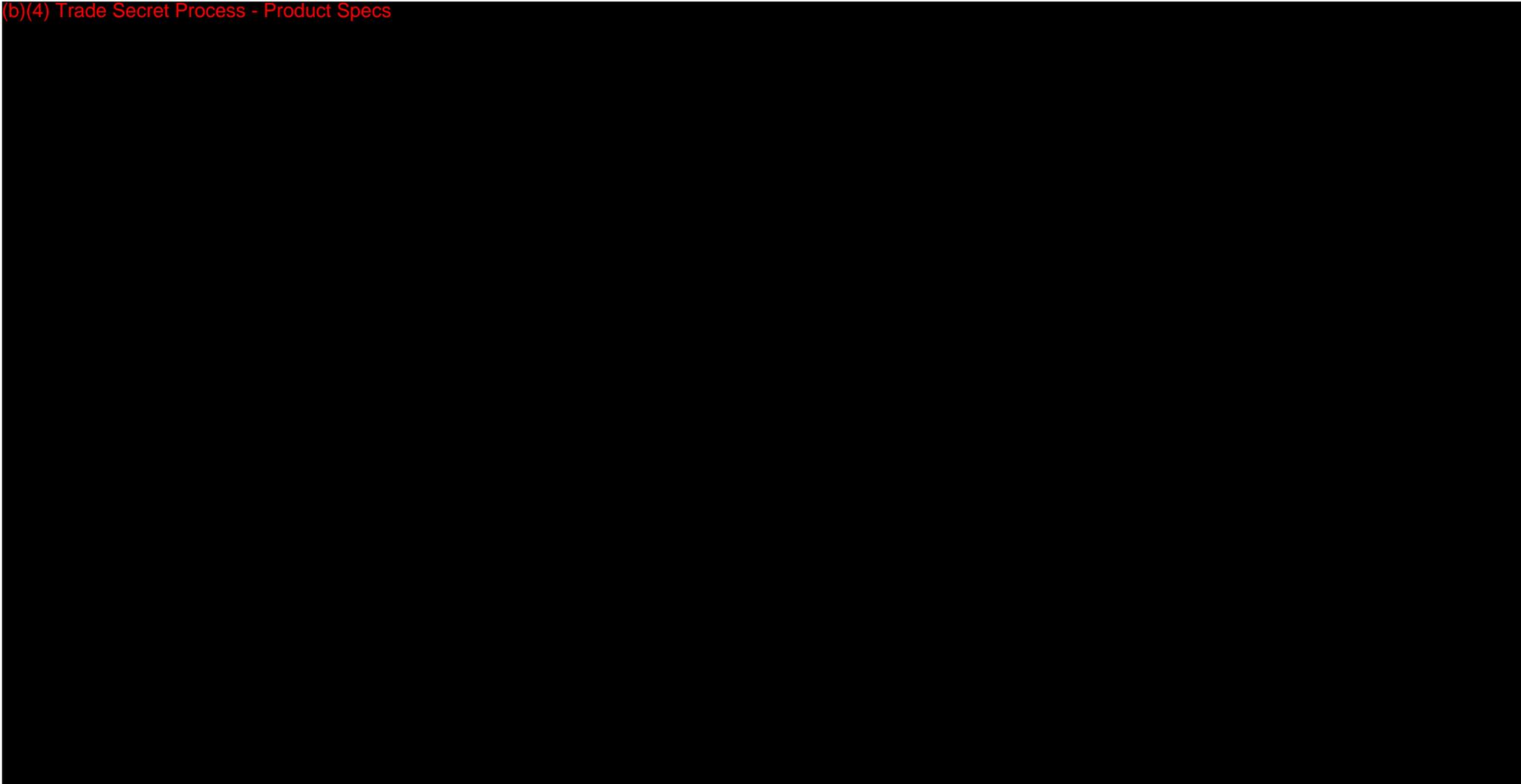
# Risk Analysis LTS-1500

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# Risk Analysis LTS-1500

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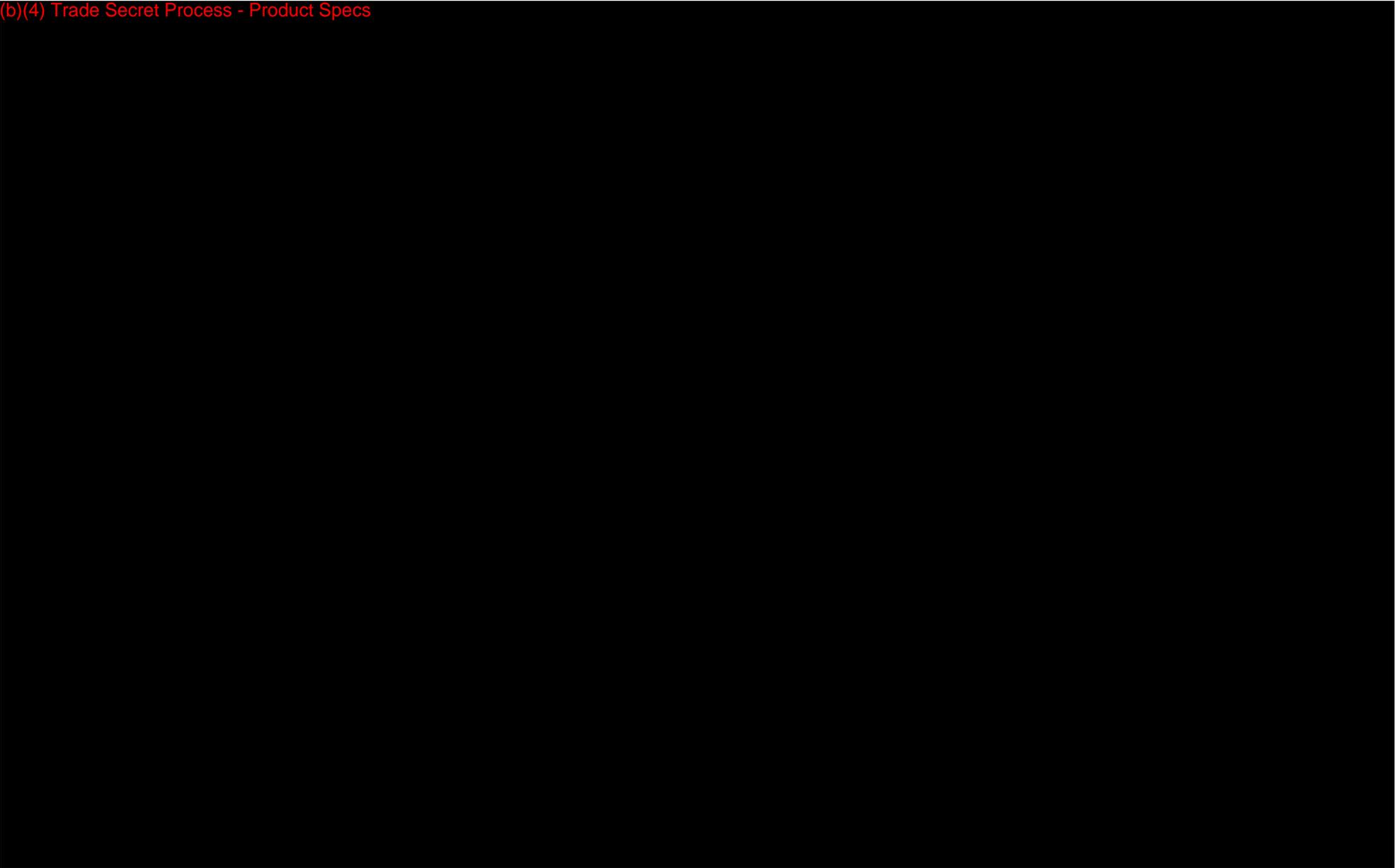
# Risk Analysis LTS-1500

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# Risk Analysis LTS-1500

(b)(4) Trade Secret Process - Product Specs



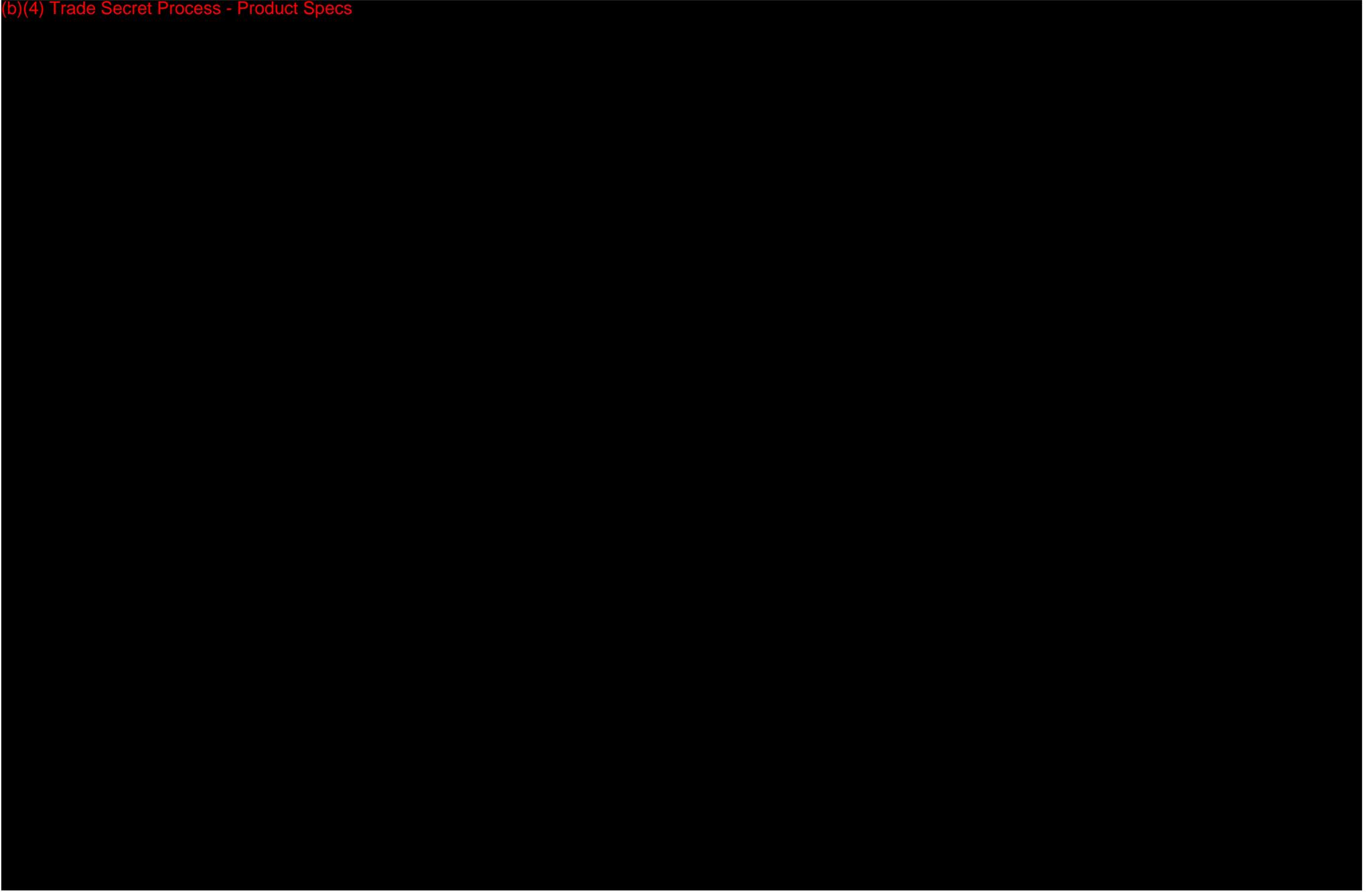
# Risk Analysis LTS-1500

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# Risk Analysis LTS-1500

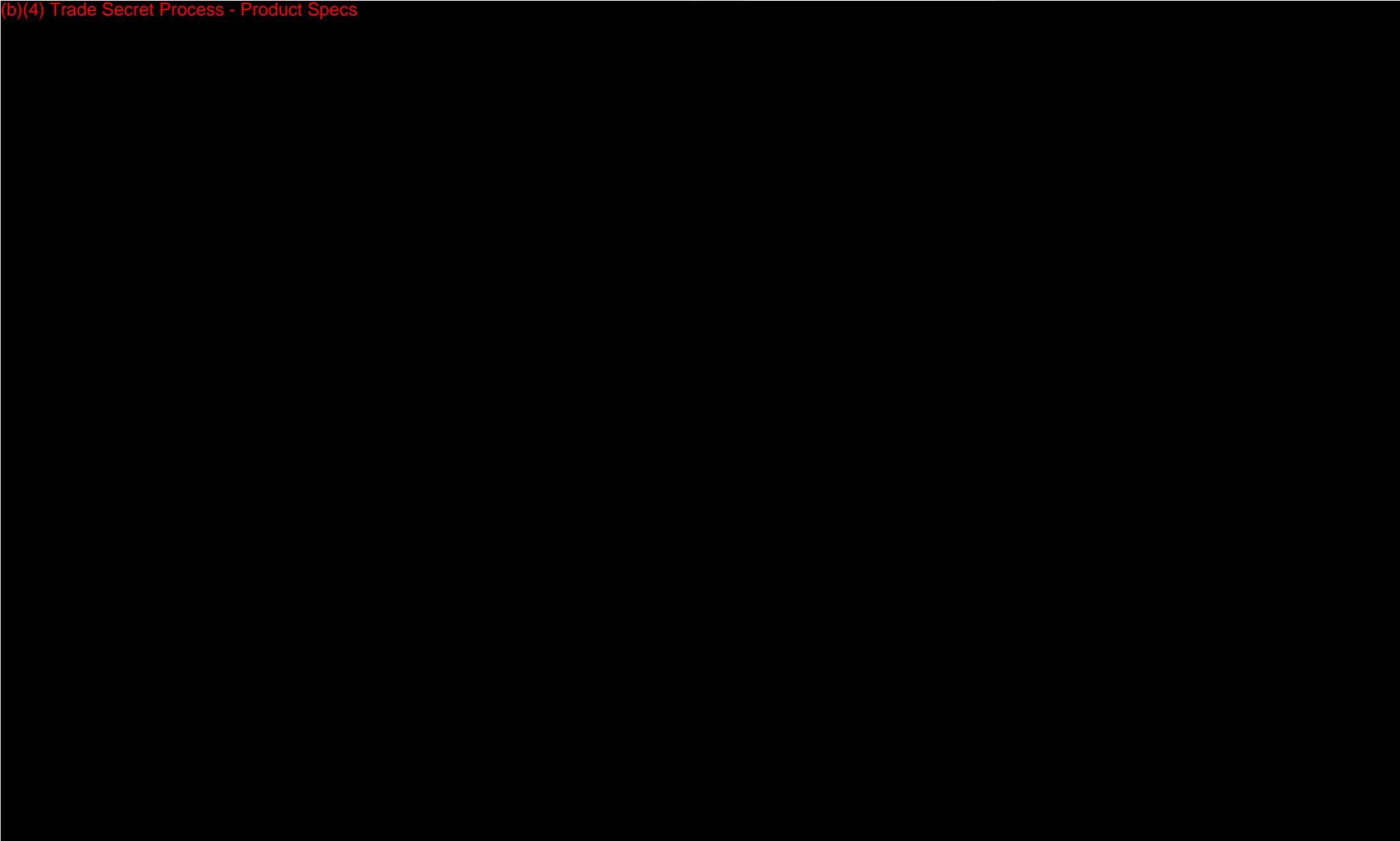
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# Risk Analysis LTS-1500

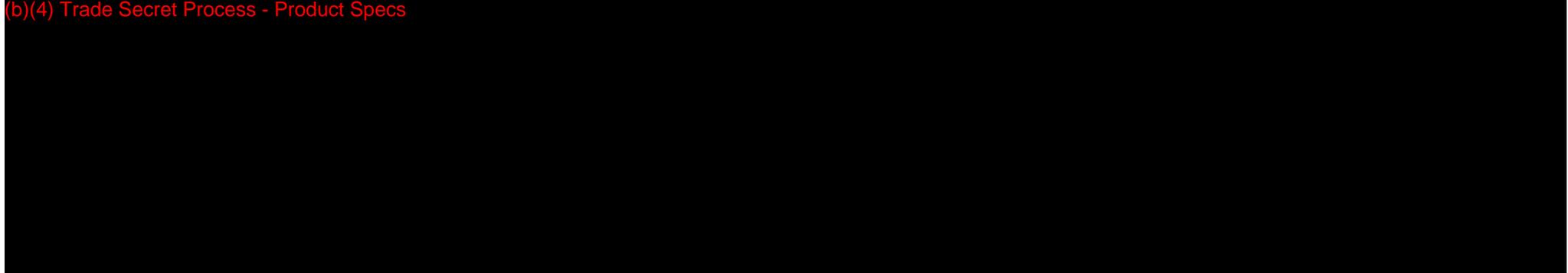
## Risk Assessment Summary of Device Modifications

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# Risk Analysis LTS-1500

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Doc. Title: **Software Requirements Specification for  
LiteCure Therapy System Model LTS-1500**

**Software Requirements Specification (SRS)  
For  
LiteCure Therapy System Model LTS-1500**





















LTS-1500  
Laser Architecture Design Chart











**Software Design Specification (SDS)  
For  
LiteCure Therapy System Model LTS-1500**







































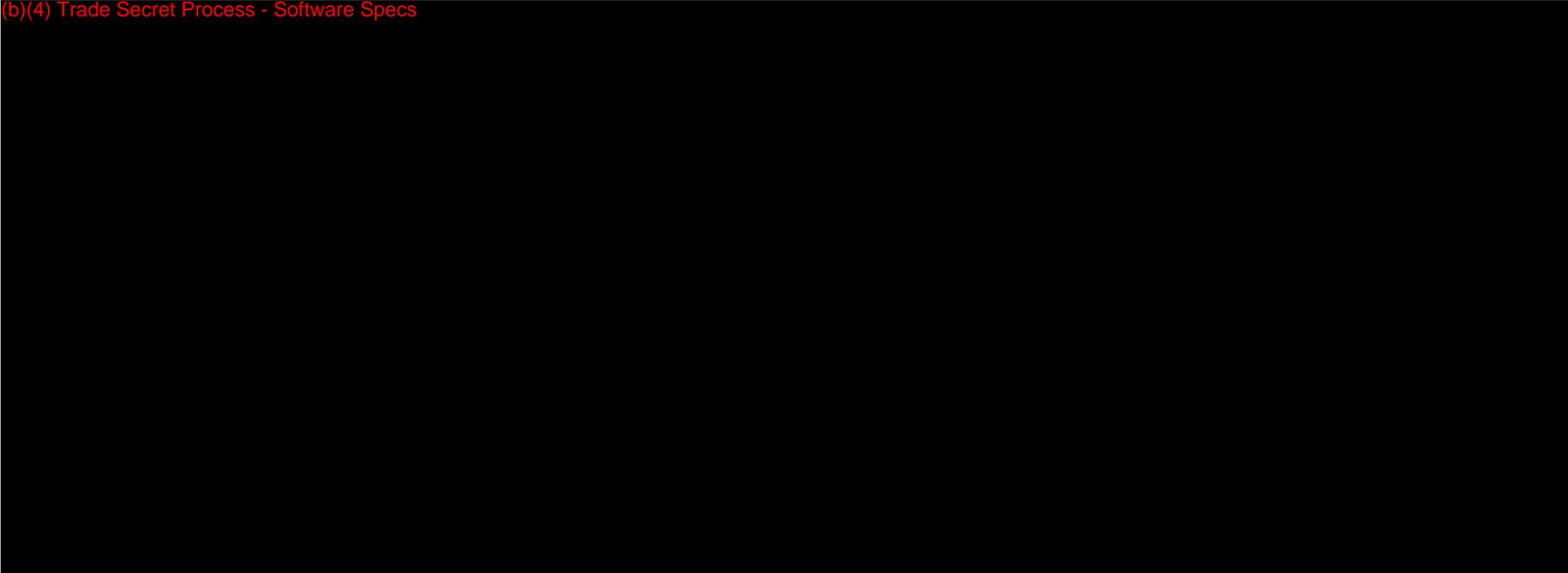
**SOFTWARE TRACEABILITY MATRIX LTS-1500 Laser (Confidential)**

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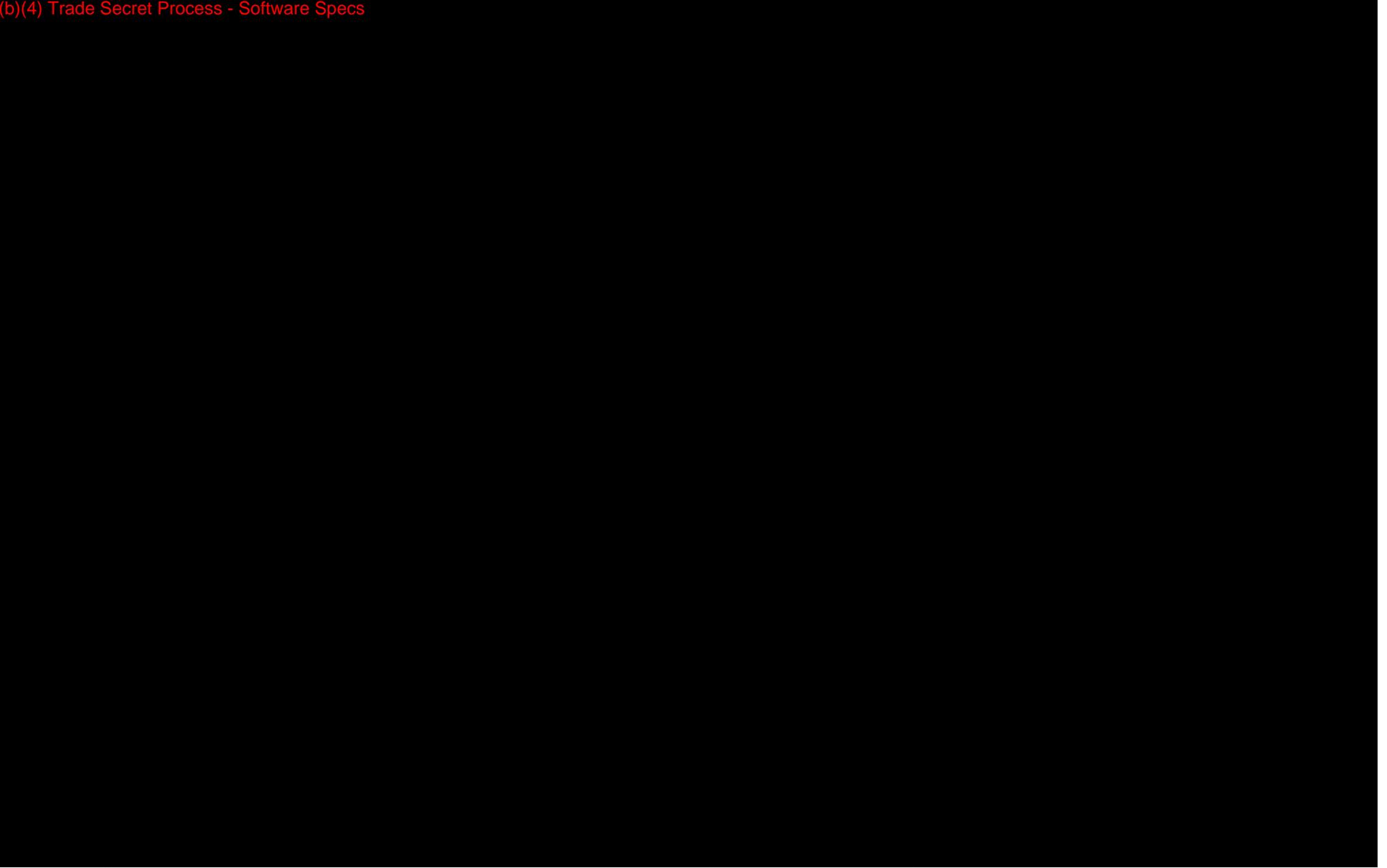
**SOFTWARE TRACEABILITY MATRIX LTS-1500 Laser (Confidential)**

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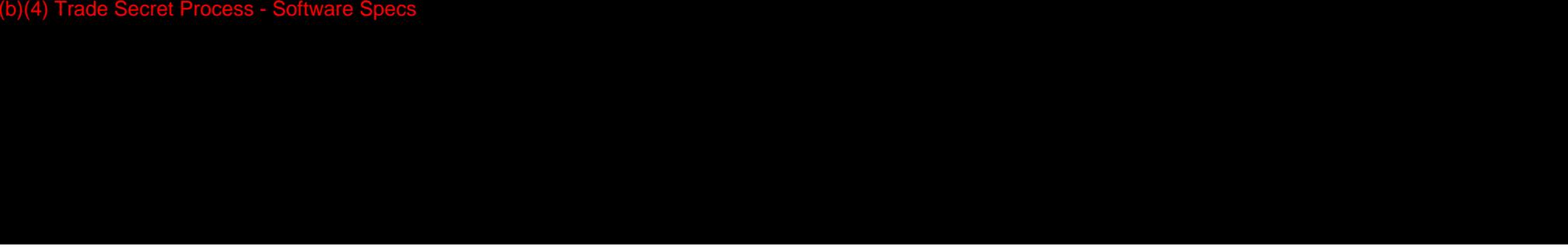
**SOFTWARE TRACEABILITY MATRIX LTS-1500 Laser (Confidential)**

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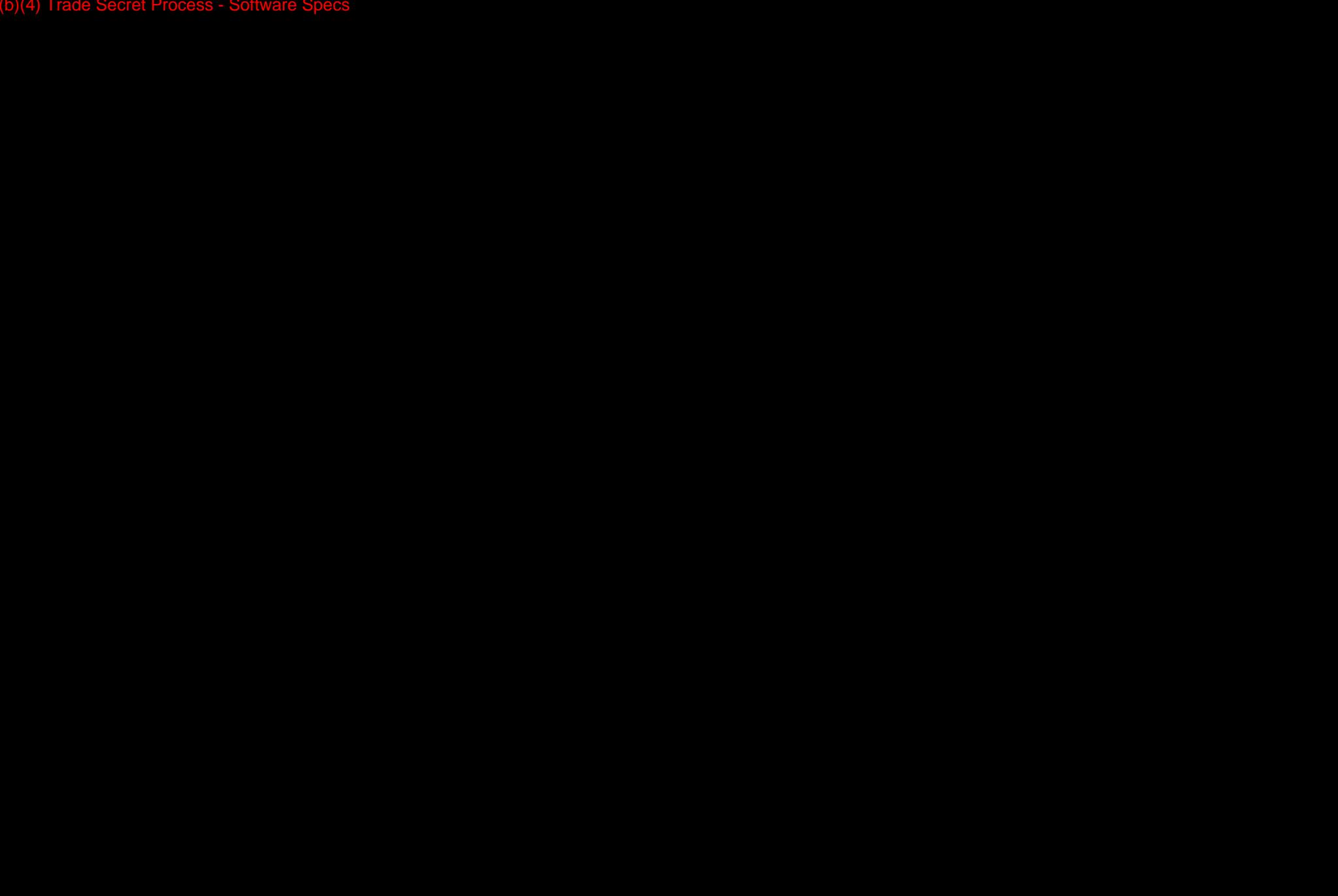
**SOFTWARE TRACEABILITY MATRIX LTS-1500 Laser (Confidential)**

(b)(4) Trade Secret Process - Software Specs



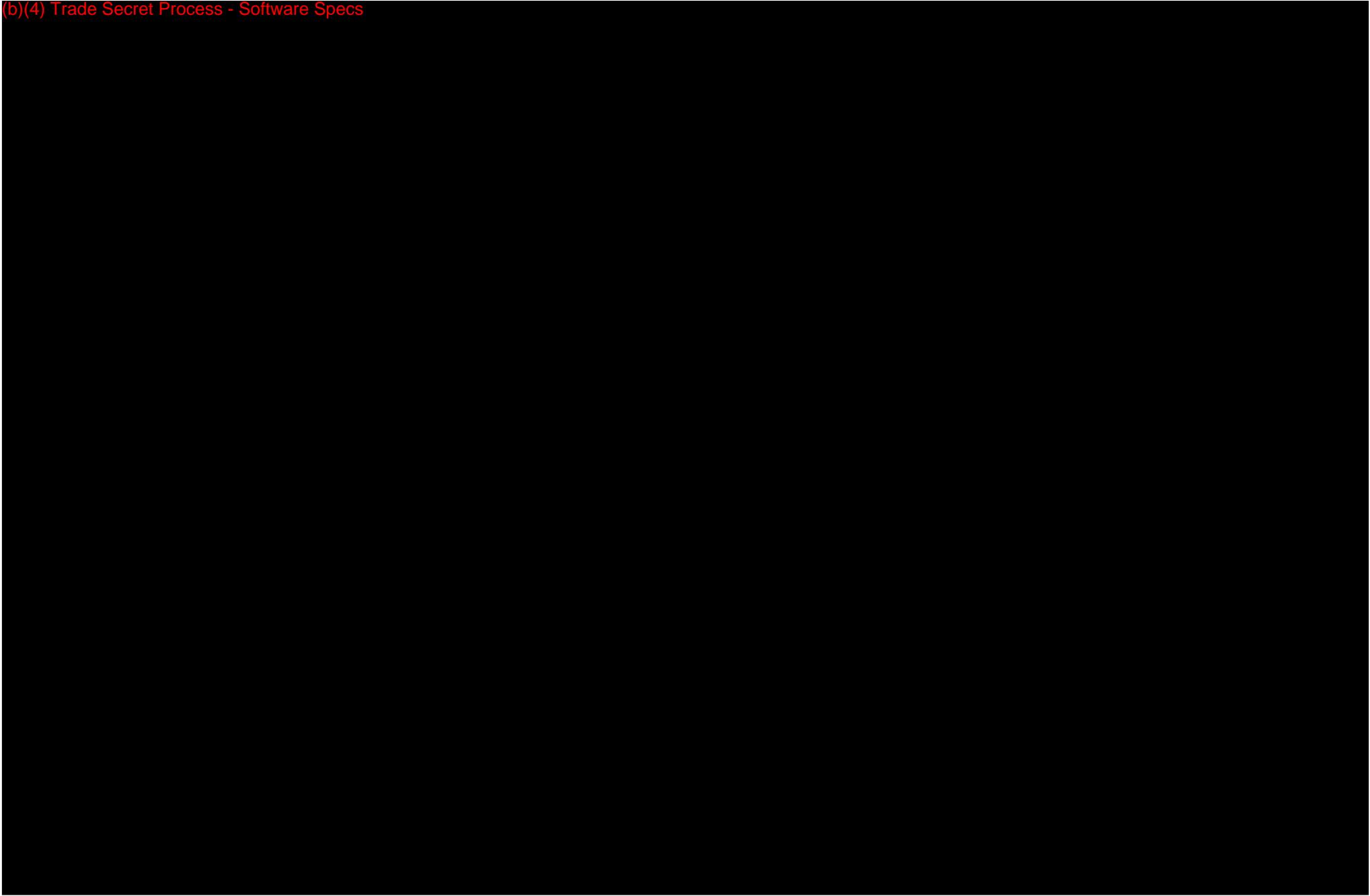
**SOFTWARE TRACEABILITY MATRIX LTS-1500 Laser (Confidential)**

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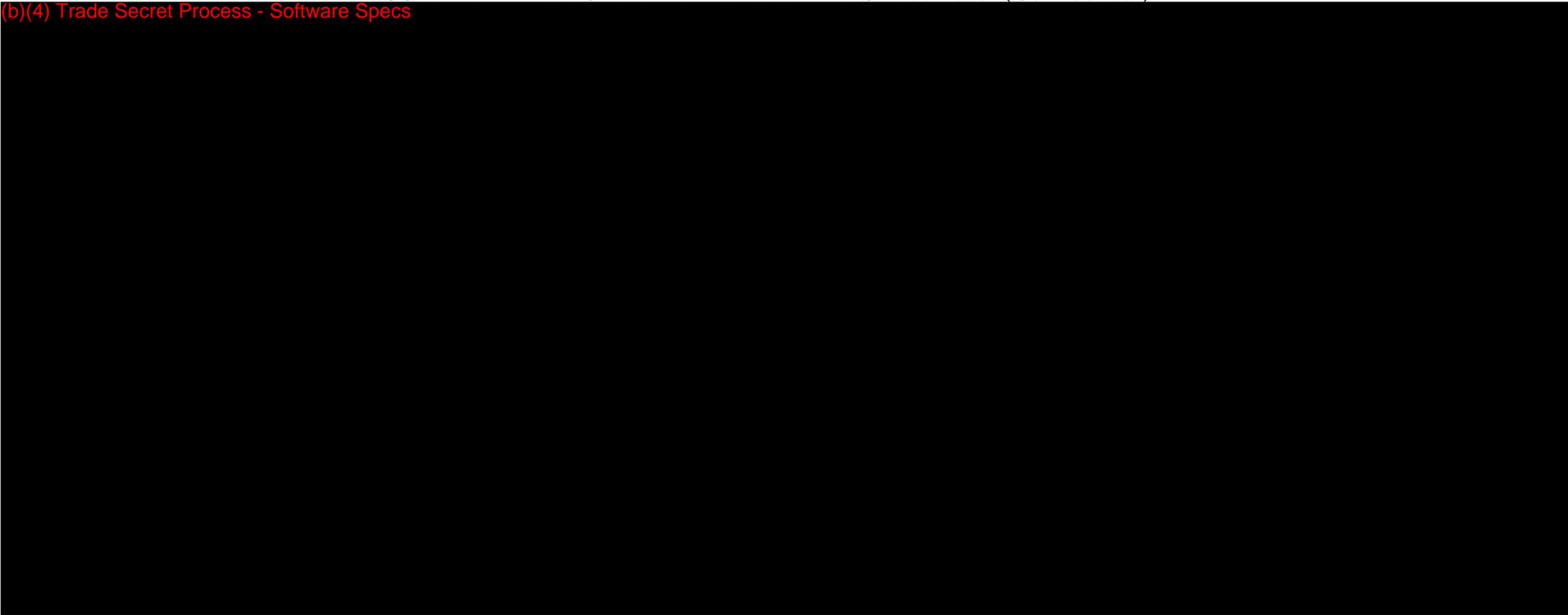
**SOFTWARE TRACEABILITY MATRIX LTS-1500 Laser (Confidential)**

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**SOFTWARE TRACEABILITY MATRIX LTS-1500 Laser (Confidential)**

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# **SOFTWARE DEVELOPMENT ENVIRONMENT DESCRIPTION**

**FOR**

**LTS-1500 LASER**

LiteCure, LLC  
250 Corporate Blvd, Suite B  
Newark, Delaware 19702















































































































































































# **USER MANUAL**

## **Hand Piece**

250 Corporate Blvd., Suite B  
Newark, DE 19702, USA  
Tel 302-709-0408  
Fax 302-709-0409  
<http://www.litecure.com>

## **SAFETY AND HANDLING CONSIDERATIONS**



### ***Warning***

NEVER look directly into the distal end of the hand piece connected to an active laser device. Never direct the laser light directly into the eyes, or direct the laser beam at anything other than the area to be treated. WITH or WITHOUT the appropriate laser-emission protective eyewear: indirect or direct eye contact with the output beam or scattered laser light from any reflective surface will cause serious irreparable corneal and/or retinal damage, and possible blindness to one or both eyes.



### ***Warning***

DO NOT allow any reflective object to fall into or obstruct the path of the laser energy produced by this device. The operator, all assistants, and the patient must remove all reflective objects (such as rings, metal watchbands, and jewelry) prior to treatment with this device. Indirect or direct eye contact with the output beam or scattered laser light from any reflective surface from the laser will cause serious, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes.



### ***Warning***

DO NOT remove protective eyewear until the operator returns the laser device to Standby mode.



### ***Warning***

FAILURE TO COMPLY with all safety instructions and warnings may expose all participants to harmful levels of laser radiation and/or dangerous levels of electrical current.



### ***Warning***

ALWAYS wear the protective eyewear (OD>5) supplied with this device, which is optically dense at the wavelength of operation. All personnel present during device operation must wear this eyewear. Contact LiteCure, LLC at 302-709-0408 to purchase additional sets of protective eyewear for this device.



### ***Warning***

ALWAYS put the laser in Standby mode or turn the device OFF prior to adjusting or connecting / disconnecting the hand piece or fiber optic.



### ***Warning***

ALWAYS post Warning Signs for Class IV laser products.



### ***Warning***

ALWAYS post Warning Signs in the area of the laser beam to alert others.



### ***Warning***

ALWAYS Turn the device OFF before lifting, moving or relocating the device.



***Warning***

ALWAYS place "Laser In Use" signs at location entrances where people will use the laser.



***Warning***

NEVER leave this device in the READY mode unattended.



***Warning***

NEVER allow untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual.



***Warning***

DO NOT leave key in device's key switch when not in use. Prevents unauthorized and/or unqualified personnel use of the device. This will also prevent inadvertent laser emissions. DO NOT allow any nonessential personnel into the treatment area during any laser procedure.



***Warning***

DO NOT press the foot/finger switch without first verifying the safe orientation and proper positioning of the hand piece and distal end of the optical fiber and ensuring compliance to all safety precautions.

If the laser fails to operate properly, please discontinue treatment and contact LiteCure, LLC at 302-709-0408.



***Warning***

Public legal provisions may include special safety regulations for the protection of personnel against laser radiation. Compliance with any special safety regulations is required.



***Warning***

Using controls or settings or performing procedures other than those specified in this Operator Manual may result in hazardous radiation exposure.



***Warning***

Do not attempt to disassemble the laser unit. This will void all warranties applicable to the unit and may result in hazardous radiation exposure.

## **FIRE AND EXPLOSION HAZARDS**

Healthcare professionals should be aware of the following safety considerations and potential fire hazards when using the laser:

1. The laser beam can ignite most nonmetallic materials.
2. A UL-approved or equivalent fire extinguisher should be readily available

This laser unit is not intended for operation in areas subject to explosion hazards such as flammable materials, gases or substances. A fire or explosion could occur.



### ***Warning***

The laser unit is not suitable for use in the presence of anesthetics that are flammable when in contact with air, oxygen, protoxide or nitrogen monoxide.



### ***Warning***

AVOID THE USE of flammable solvents, anesthetics, oxidizing gases such as nitrous oxide (N<sub>2</sub>O) and oxygen or endogenous gases. The high temperatures produced in normal use of the laser equipment may ignite some material, for example cotton or wool, when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Always be aware of the fire risk caused by flammable gases in close proximity to an operating laser. If you accidentally spill liquid on the unit, immediately stop treatment, disconnect the power supply cable and contact your local distributor, authorized service center or LiteCure customer service for assistance.



### ***Warning***

Never direct the laser beam toward paper, plastics or dark surfaces. These may catch fire or be damaged due to the high temperatures produced by the laser beam.



### ***Warning***

DO NOT treat through clothing or bandages. Possible damage or ignition may occur due to the high temperatures produced by the laser beam.

## **PREPARATION OF PATIENT FOR LASER THERAPY TREATMENT**

1. The area to be treated must be exposed
2. The treatment area should be clean and free of surface dirt or oils
3. Use rubbing alcohol for all instrument surfaces in contact with the patient



### ***Caution***

**DO NOT use Hand Piece Head until alcohol solution used in cleaning procedure completely evaporates. Doing so may cause the laser to ignite alcohol solutions or vapors.**

## HANDPIECE DESCRIPTIONS

1. The hand piece is composed of hand piece handle and hand piece heads. The universal screw design is perfect for making the different heads interchangeable.



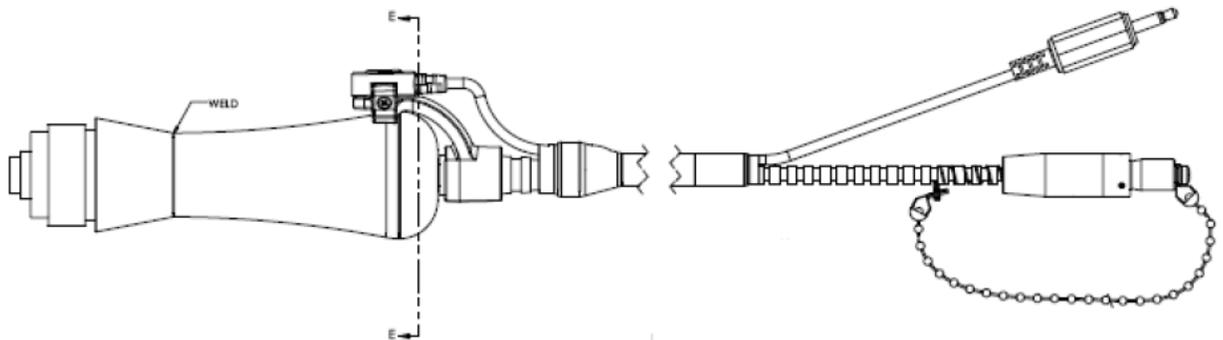
### **WARNING!**



**DO NOT use Hand Piece with inadequately secured Hand Piece Head on the Hand Piece Handle.**

**Doing so may cause serious and/or irreversible injury.**

2. Exchange Hand Piece Head.



Head Type	Spot Size (diameter)	Nominal Ocular Hazard Distance (NOHD)
Small Cone	100 mm with 10cm from the patient skin	4.7m
Small Ball	15mm	9.5m
Large Ball	30mm	37m
Large Cone	120mm with 8cm from the patient skin 140mm with 10cm from the patient skin	4.7m
Handpiece Handle (without Head)	3mm	4.7m

**For Intended Use:  
810nm and 980nm wavelength:**

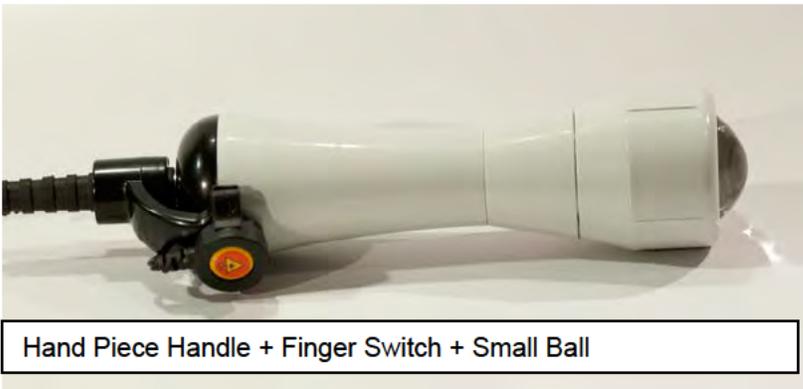
LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of

minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.



This head is for general use and applications where fine control with no contact or soft tissue manipulation during treatment is desired.

- The Small Cone Head can be used at power settings up to **8W (810nm & 980nm)**, 10cm from the skin of the patient.



This head is for use in applications where contact and soft tissue manipulation during treatment are desired. Examples of appropriate applications for the small ball are muscular or tissue injuries in tight spaces or near sensitive areas. The small ball is not recommended for use over bone, open wounds, non-intact skin or areas that would be sensitive to contact. This head should be perpendicular to the skin and not approaching at an angle. The area to be treated and a significant surrounding margin should be covered evenly in a “painting” or “serpentine” motion.

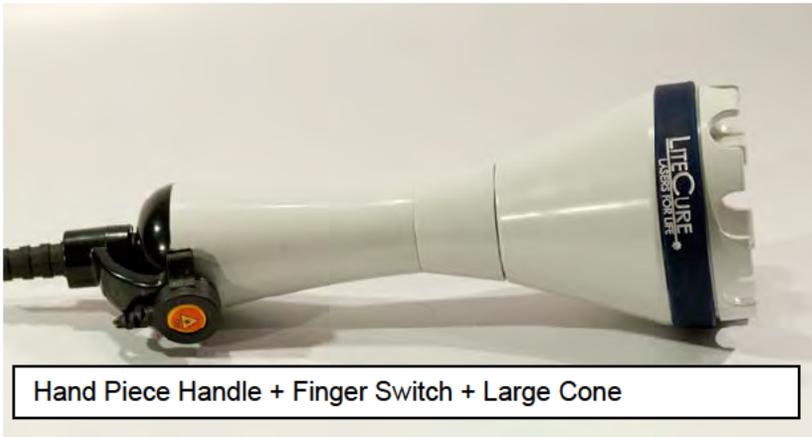
- The Small Ball can be used at power settings up to **8W (810nm & 980nm)**



Hand Piece Handle + Finger Switch + Large Ball

This head is for use in applications where contact and soft tissue manipulation during treatment are desired. Examples of appropriate applications for the large ball are muscular or deep soft tissue injuries. The large ball is not recommended for use over bone, open wounds, non-intact skin or areas that would be sensitive to contact. This head should be perpendicular to the skin and not approaching at an angle. The area to be treated and a significant surrounding margin should be covered evenly in a "painting" or "serpentine" motion.

- The Large Ball can be used at power settings up to **15W (810nm & 980nm)**



Hand Piece Handle + Finger Switch + Large Cone

This head is for general use and applications where no contact or soft tissue manipulation during treatment is desired.

- The Large Cone Head can be used at power settings up to **12W (810nm & 980nm)**, 8cm from the skin of the patient or power settings up to **15W (810nm & 980nm)**, 10cm from the skin of the patient.

### **For Intended Use: 980nm wavelength:**

LiteCure Therapy System, Model LTS-1500 is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *Tmentagrophytes*, and/or yeasts *Candida albicans*, etc.).



- The Handpiece Handle (without Head) can be used at power settings up to **25W (980nm)**, contact the treatment area of the patient.

### **TREATMENT METHODS**

*WAVELENGTH:* 980 nm

*MAX POWER DELIVERY:* 25W

*REPETITION RATE:* 200 Hz

*FIBER OPTIC DIAMETER/SIZE:* 600 µm

*SPOT SIZE:* 3 mm

Each nail of the given subject's involved toes was targeted with 2 alternating passes of laser pulses to cover the full nail, one pass applied vertically down each nail and the second applied horizontally using defocused hand piece with 3mm spot size. Subjects returned for a total of 3 treatments with each session spaced 30 days apart.

### **TREATMENT PROTOCOLS**

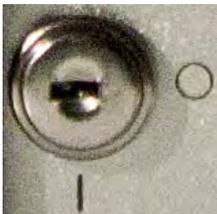
Laser treatment consisted of 3 sessions with 30 days interval. Before the treatments the toes were debrided.

Time taken to treat each nail was approximately 1-2 minutes. Patients were treated without using anesthesia and only lamented small discomfort and the occasional sensation of a "hot spot" throughout the treatment.

Follow-ups took place 3, 4 and 6 months after the first treatment and every 6 months up to one year after the initial treatment. Comparative photographs were taken during the last follow-up.

#### **WARNING!**

**ALWAYS** turn the device power OFF by using the key switch before changing Hand Piece Head.



Remove Hand Piece Head from Hand Piece Handle, and DO NOT touch the distal end of the Hand Piece Handle.

Securely tighten the new Hand Piece Head to Hand Piece Handle.

**WARNING!**



**DO NOT use Hand Piece with inadequately secured Hand Piece Head on the Hand Piece Handle.**

**Doing so may cause serious and/or irreversible injury.**

**WARNING!**

Wear Laser Safety Eyewear provided with the laser before operating the laser device.

**CAUTION**

Please do not remove the hand piece fiber from the emission port once it has been secured unless it is unavoidable. Repeated insertion and removal of the hand piece fiber before and after every procedure will increase the chance of emission port and fiber tip contamination. If the emission port or the fiber tip is contaminated then the device might be damaged during laser beam output emission.

The dust cap is installed by the manufacturer as a means to prevent dust and debris from contaminating the emission port during shipping and before device installation and is not intended as the primary means to protect the emission port connector during normal use.

We recommend the following procedure:

1. Before using the device for the first time, install and secure the hand piece fiber into the laser emission port in accordance with the User Manual.
2. Use the device as required.
3. When done using the device, power off in accordance with the User Manual and leave the hand piece connected.

Bending Limits of the Hand Piece Cable:

The radiation transferred within the hand piece cable goes through a very small diameter glass rod (an optical fiber). It can be damaged if bent too sharply. The maximum permissible bending radius of optical fiber is 5 cm.

Laser Hand Piece Troubleshooting:

If the any part of the hand piece assembly is overheating or producing smoke, then immediately power off device and discontinue operation. And then call LiteCure, LLC at 302-709-0408 immediately for assistance.

## HAND PIECE HEAD CLEANING AND DISINFECTION



### **Warning**

Always turn off the system and unplug the power cord from the wall outlet before cleaning.



### **Warning**

Always use protective eyewear and gloves when cleaning and disinfecting any equipment.



### **Caution**

**DO NOT use Hand Piece Head until alcohol solution used in cleaning procedure completely evaporates. Doing so may cause the laser to ignite alcohol solutions or vapors.**

1. To clean the exterior surfaces on Hand Piece Head:

- Wipe with a soft cloth moistened with isopropyl alcohol solution. Ensure the solution is only 70% alcohol or less. Solutions of more than 70% alcohol can cause product damage.

2. To clean the Large Ball:

Always dampen the cloth and then clean.

- Before cleaning, turn off the system and unplug the power cord from the wall outlet.
- Avoid using gritty cloths.

3. If you have access to an Ultrasonic Cleaner, it can be used to deep clean the Large Ball.

The following recipe is recommended:

Mix 90% isopropyl alcohol with warm water at the volume ratio of 60:40 and add one drop of dish soap.

4. After cleaning the Hand Piece Head, wipe it with soft cloth. Then leave it on clean surface to dry. To expedite drying time of the Hand Piece Head, putting 70% or less isopropyl alcohol into the Hand Piece Head and pouring it out will be helpful.



### **Caution**

**DO NOT use Hand Piece Head until alcohol solution used in cleaning procedure completely evaporates. Doing so may cause the laser to ignite alcohol solutions or vapors.**



### **Warning**

**DO NOT use anything to clean the lens inside the handpiece. Doing so may damage the lens when laser emission. Using compressed air to remove the dust, debris and hair is recommended.**



# **USER MANUAL**

## **LiteCure Therapy System**

### **LTS-1500**

250 Corporate Blvd. Suite B  
Newark, Delaware 19702  
Tel: 302-709-0408  
Fax: 302-709-0409

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## 1. CONVENTIONS USED

Various Warnings, Cautions, Recommendations and Notes are presented throughout this document. Explanations and examples of each follow.

### 1.1. *Warning*

Call the reader's attention to a specific or potential danger in advance. If ignored or compromised, the situation could result in the possibility of injury, death or other serious adverse reaction associated with the use or misuse of the device

**WARNING!**

DO NOT direct the laser beam at anything other than the area to be treated.

### 1.2. *Caution*

Alert the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property.

**CAUTION**

DO NOT allow untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual.

### 1.3. *Recommendation*

Offers guidance that may be worthy of acceptance or trial within a specific area of LTS-1500 application and may serve to optimize overall utilization.

**RECOMMENDATION**

Designate at least one person at each facility that utilizes this device as laser safety supervisor, responsible for providing training on all operating and safety procedures.

### 1.4. *Note*

Describe the conditions or exceptions that may apply to the subject matter presented.

**NOTE**

The optical fiber must be properly inserted and secured into the laser emission port before the device's operational mode can change from standby to ready.

## 2. DEVICE DESCRIPTION

LiteCure Therapy System, Model LTS-1500 is a compact medical laser system. The laser light delivery system consists of a flexible optical fiber threaded through a lightweight handpiece. Activation occurs when the operator enables the laser and presses the foot/finger switch. Depending on laser system configuration, the foot/finger switch can function as on/off switch. A touch-screen display panel allows the operator to adjust or set laser output level. The laser can operate in continuous wave mode or controlled pulse mode.

### ***Classification***

According to the applicable standards, the LTS-1500 laser is classified as follows:

1. Class I Type B device according to EN/IEC 60601-1: +A1 +A2:1995
2. Class IIa according to Council Directive 93/42/EEC
3. Class II according to CMDR SOR/98-282
4. Class IV laser product according to IEC 60825-1
5. Degree of protection according to EN/IEC 60601-1 + A1+A2:1: diode laser unit; IPX 0 (enclosure not waterproof); foot control: at least IPX5
6. Ordinary protection against ingress of water
7. Continuous operation

### ***Regulatory Compliance***

1. The LTS-1500 laser complies with 21 CFR Chapter 1, Subchapter J, as administered by the Center for Devices and Radiological Health of the US Food and Drug Administration (FDA).
2. The LTS-1500 laser is manufactured in compliance with the provisions of Council Directive 93/42/EEC concerning medical device (MDD, EU) and CMDR SOR/98-282 (CAN).

## **Indication for Use**

LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

### **810nm and 980nm wavelength:**

LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

### **980nm wavelength:**

LiteCure Therapy System, Model LTS-1500 is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *Tmentagrophytes*, and/or yeasts *Candida albicans*, etc.).



### **Caution**

Federal law (USA) restricts this device to sale by or on the order of a physician.

## **Contraindications**

- Do not apply infrared light to abdominal or lumbosacral points in pregnant females.
- Do not apply infrared light to the epiphyseal lines in children.
- Do not apply infrared light to the thorax or over the pacemaker itself in patients with pacemakers.
- Do not apply infrared light over the thyroid gland, ovaries and testicles.
- Do not apply infrared light to patients who are taking drugs that have heat or light sensitive contraindications, such as but not Limited to certain types of steroids.



### **Warning**

Use carefully. May cause serious burns. Do not use over sensitive skin area or in the presence of poor circulation. The unattended use of this device by children or incapacitated persons may be dangerous.



### **Warning**

NEVER look directly into the distal end of the optical fiber connected to an active laser device, direct the laser light directly into the eyes, or direct the laser beam at anything other than the area to be treated WITH or WITHOUT the appropriate laser-emission protective eyewear. Indirect or direct eye contact with the output beam or at scattered laser light from any reflective surfaces from the laser will cause serious damage, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes.



### **Warning**

DO NOT allow any reflective object to fall into or obstruct the path of the laser energy produced by this device. The operator, all assistants, and the patient must remove all reflective objects (such as rings, metal watchbands, and jewelry) prior to treatment with this device. Indirect or direct eye contact with the output beam or scattered laser light from any reflective surface from the laser will

cause serious, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes.



**Warning**

DO NOT use the System Controls or performance of procedures other than those specified in this manual may result in hazardous radiation exposure.



**Warning**

DO NOT remove protective eyewear until the operator returns the laser device to Standby mode.



**Warning**

DO NOT attempt to gain access to any internal component. THERE ARE NO USER-SERVICEABLE COMPONENTS inside this laser device. Doing so may cause serious and/or irreversible injury.



**Warning**

AVOID THE USE of flammable solvents, anesthetics, oxidizing gases such as nitrous oxide (N<sub>2</sub>O) and oxygen or endogenous gases. The high temperatures produced in normal use of the laser equipment may ignite some material, for example cotton or wool, when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.



**Warning**

FAILURE TO COMPLY with all safety instructions and warnings may expose all participants to harmful levels of laser radiation and/or dangerous levels of electrical current.



**Caution**

ALWAYS wear the protective eyewear supplied with this device, which is optically dense at the wavelength of operation (see specification sheet). All personnel present during device operation must wear this eyewear. Contact LiteCure, LLC at 302-709-0408 to purchase additional sets of protective eyewear for this device.



**Caution**

ALWAYS put the laser in Standby mode or turn the device OFF prior to adjusting or connecting / disconnecting the hand piece or fiber optic.



**Caution**

ALWAYS post Warning Signs for Class IV laser products.



**Caution**

ALWAYS post Warning Signs in the area of the laser beam to alert others.



**Caution**

ALWAYS Turn the device OFF before lifting, moving or relocating the device.



**Caution**

ALWAYS place "Laser In Use" signs at location entrances where people will use the laser



**Caution**

NEVER leave this device in the READY mode unattended. Reference the STANDBY and READY Mode in the Operations section of this manual.



**Caution**

NEVER allow untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual.



**Caution**

DO NOT leave key in device's key switch when not in use. Prevent unauthorized and/or unqualified use of the device. This will also prevent inadvertent laser emissions.



**Caution**

DO NOT allow any nonessential personnel into the treatment area during any laser procedure.



**Caution**

DO NOT press the finger/foot switch without first verifying the safe orientation and proper positioning of the hand piece and distal end of the optical fiber and ensuring compliance to all safety precautions.



**Caution**

If the laser fails to operate properly, please discontinue treatment and contact LiteCure, LLC at 302-709-0408.

**Recommendations**

1. Designate at least one person (e.g. Laser Safety Supervisor) responsible for providing training on all operating and safety procedures at each facility that utilizes this device.
2. Individuals planning to use the laser system should attend laser orientation and education sessions to achieve operational proficiency.



**Notice**

1. The key can only be inserted into and removed from the key switch when the key is in the vertical (OFF) position.
2. Pushing the red mushroom shaped Emergency Laser Off Switch down will terminate all electrical power to the laser device's microprocessor and laser-emitting components. Resetting the switch restores power. To release the Emergency Laser Off Switch, the user must twist and rotate in the direction indicated by the arrows, then release it as the switch pops out, returning it to its normal position.

### 3. MANUFACTURER’S DECLARATION ON ELECTROMAGNETIC COMPATIBILITY

<b>Guidance and Manufacturer’s Declaration - Emissions</b>		
The LTS is intended for use in the electromagnetic environment specified below. The customer or user of the LTS should ensure that it is used in such an environment.		

<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic Environment – Guidance</b>
RF Emissions CISPR 11	Group 1	The LTS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Group 2	The LTS must emit Electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A or B	A
Harmonics IEC 61000-3-2	Class A,B,C,D or N/A	A
Flicker IEC 61000-3-3	Complies or N/A	Complies
		The LTS is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
		The LTS is suitable for use in all establishments, <b>other than</b> domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF Emissions CISPR 14-1	Complies	The LTS is not suitable for interconnection with other equipment.
RF Emissions CISPR 15	Complies	The LTS is not suitable for interconnection with other equipment.

**Guidance and Manufacturer’s Declaration – Immunity**

The LTS is intended for use in the electromagnetic environment specified below. The customer or user of the LTS should ensure that it is used in such an environment.

<b>Immunity Test</b>	<b>EN/IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment – Guidance</b>
ESD EN/IEC 61000-4-2	±6kV Contact ±8kV Air	As specified	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT EN/IEC 61000-4-4	±2kV Mains ±1kV I/Os	As specified	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	±1kV Differential ±2kV Common	As specified	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout EN/IEC 61000-4-11	>95% Dip for 0.5 Cycle  60% Dip for 5 Cycles  30% Dip for 25 Cycles  >95% Dip for 5 Seconds	As specified	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LTS requires continued operation during power mains interruptions, it is recommended that the 35700 be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field EN/IEC 61000-4-8	3A/m	As specified	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

**Guidance and Manufacturer's Declaration – Emissions**

The LTS is intended for use in the electromagnetic environment specified below. The customer or user of the LTS should ensure that it is used in such an environment.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
<p>Conducted RF EN/IEC 61000-4-6</p> <p>Radiated RF EN/IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>(V1)Vrms</p> <p>(E1)V/m</p>	<p>Portable and mobile communications equipment should be separated from the LTS by no less than the distances calculated/listed below:</p> <p><math>D=(3.5/V1)(\text{Sqrt } P)</math></p> <p><math>D=(3.5/E1)(\text{Sqrt } P)</math> 80 to 800 MHz</p> <p><math>D=(7/E1)(\text{Sqrt } P)</math> 800 MHz to 2.5 GHz</p> <p>where P is the max power in watts and D is the recommended separation distance in meters.</p> <p>Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).</p> <p>Interference may occur in the vicinity of equipment containing a transmitter.</p>

**Recommended Separations Distances for the LTS**

The LTS is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the LTS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the LTS as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz	Separation (m) 80 to 800MHz	Separation (m) 800MHz to 2.5GHz
	$D=(3.5/V1)(\text{Sqrt } P)$	$D=(3.5/E1)(\text{Sqrt } P)$	$D=(7/E1)(\text{Sqrt } P)$
0.01	.1166	.1166	.2333
0.1	.3689	.3689	.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

## 4. ADDITIONAL SAFETY AND HANDLING CONSIDERATIONS

### WIRELESS PHONE INTERFERENCE



#### **Caution**

To ensure the operational safety of medical electrical equipment, the use of mobile wireless cell phones in the vicinity of the laser or similar hospital environments must be prohibited.

### FIRE AND EXPLOSION HAZARDS

Healthcare professionals should be aware of the following safety considerations and potential fire hazards when using the laser:

1. The laser beam can ignite most nonmetallic materials.
2. A UL-approved or equivalent fire extinguisher should be readily available

This laser unit is not intended for operation in areas subject to explosion hazards such as flammable materials, gases or substances. A fire or explosion could occur.



#### **Warning**

The laser unit is not suitable for use in the presence of anesthetics that are flammable when in contact with air, oxygen, protoxide or nitrogen monoxide.



#### **Warning**

AVOID THE USE of flammable solvents, anesthetics, oxidizing gases such as nitrous oxide (N<sub>2</sub>O) and oxygen or endogenous gases. The high temperatures produced in normal use of the laser equipment may ignite some material, for example cotton or wool, when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Always be aware of the fire risk caused by flammable gases in close proximity to an operating laser. If you accidentally spill liquid on the unit, immediately stop treatment, disconnect the power supply cable and contact your local distributor, authorized service center or LiteCure customer service for assistance.



#### **Warning**

Never direct the laser beam toward paper, plastics or dark surfaces. These may catch fire or be damaged due to the high temperatures produced by the laser beam.



#### **Warning**

DO NOT treat through clothing or bandages. Possible damage or ignition may occur due to the high temperatures produced by the laser beam.

## 5. DISPOSAL

If you plan to discontinue the use of LTS-1500 laser and intended to dispose of it, make sure to observe the application legal provisions. Please contact your local distributor, authorized service center, or LiteCure customer service for the disposal of the LTS-1500 laser.

## 6. GLOSSARY AND ABBREVIATIONS

### ***Glossary***

<b>Term</b>	<b>Definition</b>
CW, Continuous Emission, or Continuous Mode	Continuous laser emission
Pulse, Pulse Emission, or Pulsed Mode	Pulsed laser emission (pulsed mode)
Duty Cycle	Percentage of time in Pulsed Mode that laser energy is being generated during laser emission.
Frequency	Number of laser pulses per second
Hertz	Measuring unit for frequency
Remote Interlock	Safety device that stops laser radiation when the door of the treatment room is opened
Joule	Unit of measure for emitted energy
Watt	unit of measure for laser power
Stop	End of treatment or treatment break

### ***Abbreviations***

<b>Abbreviation</b>	<b>Definition</b>
cm <sup>2</sup>	Square centimeter
Hz	Hertz
S	Second
W	Watt
mW	Milliwatt (one thousandth of a Watt)
J	Joule
nm	Nanometer
V	Volt
IR	Infrared diode
NOHD	Nominal Ocular Hazard Distance according to EN 60825-1

## 7. FEATURES

1. Emergency Laser Off Switch

This Emergency Laser Off Switch shall stop the emission of laser output as fast as possible to prevent danger to any person.

2. Display and Touch Screen

The display shows the user operation interface.

3. Handpiece Fiber Receptacle

The hand piece fiber receptacle permits the fiber insertion.

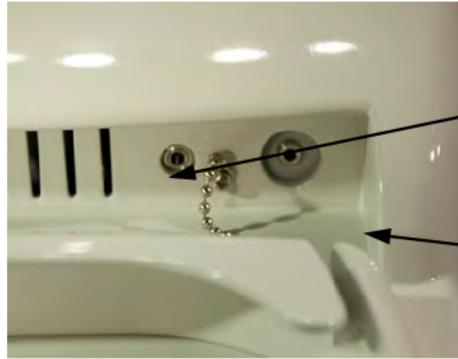
4. Key Switch

This switch uses a key to prevent unauthorized unit operation. The key will not be removable in the on position. It will be removable in the off position.

### Front View



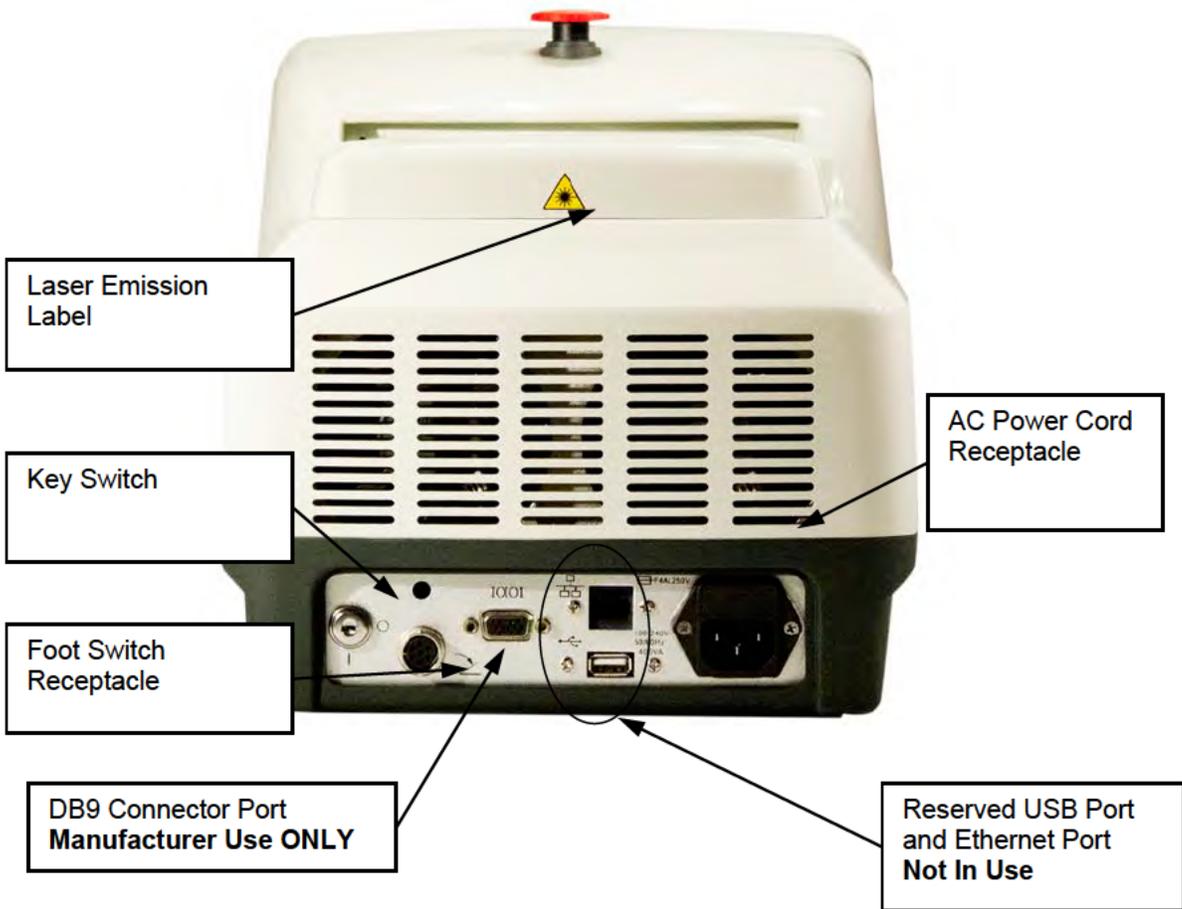
### Top View



Finger Switch Receptacle

Handpiece Fiber Receptacle

### Rear View



Laser Emission Label

Key Switch

AC Power Cord Receptacle

Foot Switch Receptacle

DB9 Connector Port  
Manufacturer Use ONLY

Reserved USB Port  
and Ethernet Port  
Not In Use



## Bottom View



## 8. SYSTEM SET-UP

### 8.1. Receipt and Unpacking

Using LTS-1500 packing list, unpack the LTS-1500 and its accessories from the shipping carton. Check for missing parts and inspect the unit carefully for damage, such as cracks, dents or bent parts. If items are missing or any physical damage is apparent, please call LiteCure, LLC at 302-709-0408 for assistance. Notify the carrier if the damage appears to be the result of a shipping mishap.

If Warranty Seal Label is not found on device or is broken, please do not operate this device and call LiteCure, LLC at 302-709-0408 immediately for assistance.

### 8.2. Usage Prerequisites

#### RECOMMENDATION

Individuals planning to use the laser system should attend laser orientation and education sessions to achieve operational proficiency.

Every facility or institution utilizing this device is encouraged to adopt an ongoing training and safety program.

### 8.3. Set-Up / Location

1. Select a secure, properly equipped, and well-ventilated location in which to install and operate the laser device.
2. Ensure that the surface will properly support the entire device.
3. Place within 6 feet of an available 100-240V electrical outlet.
4. Ensure adequate airflow around the device. The laser device is air-cooled and designed for use in a well-ventilated environment.
  - 8.3.4.1. Select a flat hard surface (not a surface that will inhibit airflow through the bottom of the device).
  - 8.3.4.2. There must be a minimum 4" clearance around the rear of the device.
5. Locate and uncoil the AC power cord.
6. Plug the power cord into the AC input on the rear of the laser device.
7. Plug the male end of the AC power cord into a grounded electrical outlet.
8. Connect the finger/footswitch to the rear of the LTS-1500 laser device.
9. Press down on the footswitch cover then release; the spring loaded cover will open automatically.

#### CAUTION

Please do not remove the hand piece fiber from the emission port once it has been secured unless the device is being packaged or transported to another location. Constant insertion and removal of the hand piece fiber before and after every procedure will increase the chance of emission port and fiber tip contamination. If the emission port or the fiber tip is contaminated then the device might be damaged during beam emission.

The dust cap is installed by the manufacturer as a means to prevent dust and debris from contaminating the emission port during shipping and before device installation and is not intended as the primary means to protect the emission port connector during normal use.

We recommend the following procedure:

1. Before using the device for the first time, install and secure the hand piece fiber in accordance with the User Manual.
2. Use the device as required.
3. When done using the device, power off in accordance with the User Manual and leave the hand piece connected.

## 9. OPERATION

### 9.1. Fiber Installations

Take off the fiber cap. Make sure the fiber tip is clean prior to inserting into the hand piece fiber receptacle; secure by screwing the fiber locking collar onto the hand piece fiber receptacle.

### 9.2. Laser Safety Eyewear

ALWAYS wear the protective eyewear supplied with this device. All personnel present during device operation must wear this eyewear.

Laser safety eyewear must also be resistant to physical damage or photo-bleaching resulting from laser exposure.

All personnel who are within the NOHD are considered to be within the controlled area and must wear laser safety eyewear.

The NOHD and Beam Divergence for the LTS-1500 laser beams are:

Laser Hand Piece Style	NOHD (meter)	Beam Divergence
Small Cone	4.7 m	Full Angle (degree) 47
Large Cone	4.7 m	Full Angle (degree) 47
Small Ball	9.5 m	Full Angle (degree) 12
Large Ball	37 m	Full Angle (degree) 3
Handpiece Handle	4.7 m	Full Angle (degree) 47

#### **MPE (W/cm<sup>2</sup>) =0.001514**

In addition to providing the required laser safety eyewear, take the following steps to secure the treatment room, or the controlled area:

1. To alert personnel before they enter the controlled area, place the included Laser Safety Sign, or its equivalent, on the outside of the treatment room door when the laser is in use.
2. Close the treatment room door during operation of the laser. Or, optionally, the Interlock Jack can be connected to the treatment room door through an interlock circuit so that laser emission is automatically disabled when the treatment room door is opened.

A blocking barrier, screen, or curtain capable of blocking or filtering the laser beam could be placed to create a controlled area inside a large treatment room. The barrier should be made of material that can withstand the power of the treatment beam for the maximum exposure time, relative to the configuration of the controlled area and the treatment parameters for the specific medical application.



### **Caution**

ALWAYS wear the protective eyewear supplied with this device, which is optically dense at the wavelength of operation (see specification sheet). All personnel present during device operation must wear this eyewear. Contact LiteCure, LLC at 302-709-0408 to purchase additional sets of protective eyewear for this device.

### 9.3. Hand Piece

1. The hand piece is composed of hand piece handle and hand piece heads. The universal screw design is perfect for making the different heads interchangeable.



**WARNING!**



**DO NOT use Hand Piece without Hand Piece Head or inadequately secured Hand Piece Head on the Hand Piece Handle.**

**Doing so may cause serious and/or irreversible injury.**

2. Exchange Hand Piece Head.



### Caution

Please read USER MANUAL HAND PIECE before using Hand Pieces.

## 9.4. Emergency Laser Off Switch and Key

Make sure the Emergency Laser Off Switch button pops out, otherwise rotate in the direction indicated by the arrows, then release it as the switch pops out. Insert key into the key-lock switch.

### NOTE

The key can only be inserted into and removed from the key switch when it is in the vertical (OFF) position.

Turn the key clockwise to the right one-quarter turn

1. The fan will start.
2. There will be an audible beep and the LCD panel will illuminate displaying the welcome (initial power-on) screen.

## 9.5. Power On

The initiation of the power-on sequence shall be accompanied by audible alerts, and then the Main Screen (below) presents.



- Press Operation button to enter Standby Mode.
- Press Setup button to enter Setup Screen.
- Press Power button to turn off the display.

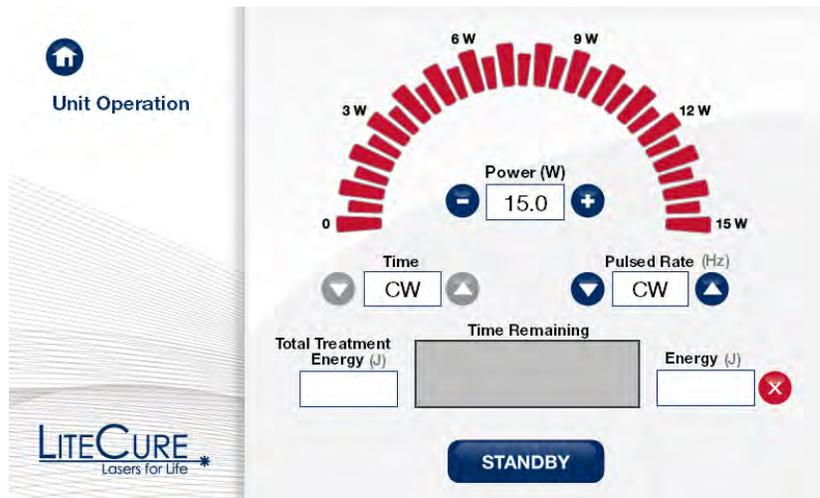
## 9.6. Setup



In Setup Screen, the software allows operators to change the Aiming Beam, Unit Volume and Finger (Foot) Switch Override settings.

- Aiming Beam: Steady, Pulsed, Off
  - a. 3.5+/-1.0mW
- Unit Volume: Tone (High, Med and Low)
  - a. 45-65dB at High
- Unit Volume: Beep (High, Med and Low)
- 810nm wavelength: Off
- Finger(Foot) Switch Override: On/Off
- Press Save Changes button to save the selected settings
- Press Cancel button to cancel the selected settings
- Press Reset to Default button to reset the settings to the default settings.

## 9.7. Standby Mode



In Standby Mode, the software allows operators to change the laser power, laser modulation frequency, laser emission timer, and energy reset in Standby mode.

- Standby button is active
- Modulation frequency display shows the selected modulation frequency
- Aiming beam is inactive
- Unit does not enter Ready Mode if finger/footswitch is closed – Create Error Message:
  - a. Operation Error, Foot/Finger switch is closed.
  - b. Produce audible beep – 3 times  
Press Exit button can return to Standby Mode.
- Unit does not enter Ready Mode if fiber is not inserted – Create Error Message:
  - a. Operation Error, Optic Fiber is not inserted.
  - b. Produce audible beep – 3 times  
Press Exit button can return to Standby Mode.
- Unit does not enter Ready Mode if safety interlock is not inserted – Create Error Message:
  - a. Operation Error, Interlock is not inserted.
  - b. Produce audible beep – 3 times  
Press Exit button can return to Standby Mode.
- Press the Power Setting Scale or the “+” / “-” button to set the laser power. The selected laser power will be shown at the Power Setting Window. To scroll to the desired power value, maintain pressure on the desired button. The laser power can be set from 0.5W to 15.0W
- Press the Pulsed Rate “+”/ “-” button to set the laser modulation frequency. The selected laser frequency will be shown at the Pulsed Rate Window. To scroll to the desired frequency value, maintain pressure on the desired button. The laser frequency can be set from CW to 10000Hz
 

Note: The duty cycle in the Pulsed mode is 50%.
- Press the Time “+” / “-” button to set the laser treatment time. The selected laser treatment time will be shown at the Time Window. To scroll to the desired time value, maintain pressure on the desired button
- Press Energy Reset button to reset the energy monitor value to zero
- Press Home button in the upper-left corner to return to Main Screen

## 9.8. Ready Mode

The software has Ready Mode in which the laser will emit when the finger/footswitch is pressed. The purpose of Ready Mode is to wait for user(s) to press the finger/footswitch and start laser emission. The software produces 6 seconds delay (6 beeps) to warn the users during the transition from STANDBY to READY Mode. During the transition, the Standby button changes to Ready button and flashes. After 6 beeps, the aiming beam emits from the hand piece if the aiming setting is on.

In Ready Mode, the software allows operators to change the laser power level, laser modulation frequency, laser emission timer, and energy reset in Standby mode.

- Ready button is active
- Modulation frequency display shows the selected modulation frequency
- Aiming beam emits from the hand piece if the aiming setting is on.
- Unit exit from Ready Mode if fiber is not inserted correctly – Create Error Message:
  - a. Operation Error, Optic Fiber is not inserted.
  - b. Produce audible beep – 3 timesPress Exit button can return to Standby Mode.
- Unit exit from Ready Mode if safety interlock is not inserted / attached to back of unit – Create Error Message:
  - a. Operation Error, Interlock is not inserted.
  - b. Produce audible beep – 3 timesPress Exit button can return to Standby Mode.
- Press the Power Setting Scale or the “+” / “-” button to set the laser power. The selected laser power will be shown at the Power Setting Window. To scroll to the desired power value, maintain pressure on the desired button. The laser power can be set from 0.5W to 15.0W
- Press the Pulsed Rate “+” / “-” button to set the laser modulation frequency. The selected laser frequency will be shown at the Pulsed Rate Window. To scroll to the desired frequency value, maintain pressure on the desired button. The laser frequency can be set from CW to 10000Hz
  - Note: The duty cycle in the Pulsed mode is 50%.
- Press the Time “+” / “-” button to set the laser treatment time. The selected laser treatment time will be shown at the Time Window. To scroll to the desired time value, maintain pressure on the desired button.
- Press Energy Reset button to reset the energy monitor value to zero
- Unit returns to Standby Mode from Ready Mode if leaving unit alone for more than 3 minutes.
- Press Ready button to return to Standby Mode.

## 9.9. Emission Mode

The software monitors the laser output power in according to the parameter settings on the display to ensure the power is within +/-20% of power setting. During emission, the software does not allow users to change any settings on the display. The software displays the word EMISSION on the display. The device produces beeps, steady audible tone, or no audible tone during emission according to the audible settings.

- During emission, the software does not allow users to change any settings on the display
- The real laser output power is same as the power setting on the display within +/-20% deviation when the laser modulation frequency is CW.
- The real laser output power is 50% of the power setting on the display within +/-20% deviation when the laser modulation frequency is not CW
- Unit exit from Emission Mode if fiber is not inserted – Create Error Message:
  - a. Operation Error, Optic Fiber is not inserted.
  - b. Produce audible beep – 3 times

- c. Laser beam is disabled  
Press Exit button can return to Standby Mode.
- Unit exit from Emission Mode if safety interlock is not inserted – Create Error Message:
  - a. Operation Error, Interlock is not inserted.
  - b. Produce audible beep – 3 times
  - c. Laser beam is disabled  
Press Exit button can return to Standby Mode.
- Unit exit from Emission Mode if laser power exceeds +/-20% of power setting – Create warning message:
  - a. Laser power is out of range
  - b. Unit to produce audible beep – 3 times
  - c. No laser beam from hand piece  
Press Exit button can return to Standby Mode.
- Unit exit from Emission Mode if laser diode temperature is overheating – Create warning message:
  - a. Laser temperature is out of range
  - b. Unit to produce audible beep – 3 times
  - c. Laser beam is disabled.  
Press Exit button can return to Standby Mode.
- Laser emission is disabled when the timer counts down to zero if timer setting is not CW.
- Laser emission continues until emission is interrupted by finger/footswitch if timer setting is CW.
- If laser emission is interrupted during emission mode by finger/footswitch operation, the laser emission can be enabled again by finger/footswitch until the remaining time is over.

## 10. SAFETY

This section provides a collection of safety guidelines and safety-related statements relevant to the safe and effective operation of the LTS-1500 laser device. Additional statement and protocols regarding safety appear elsewhere in this document. Use this laser device according to all printed guidelines cautionary statements, and protocols.

### 10.1 Laser Safety Supervision

#### RECOMMENDATION

Designate at least one person (e.g. Laser Safety Supervisor) responsible for providing training on all operating and safety procedures at each facility that utilizes this device.

Individuals planning to use the laser system should attend laser orientation and education sessions to achieve operational proficiency.

1. Designate at least one person at each facility that utilizes this device as laser safety supervisor, responsible for providing training on all operating safety procedures.

### 10.2 Safety Devices

The following components have specific safety-related features. All individuals who use this laser device should be familiar with the purpose and the operation of these components.

**Emergency Laser Off Switch.** This switch is located on the top of the LTS-1500 device. Push the switch down to terminate all electrical power to the laser device's microprocessor and laser-emitting components. Resetting the switch restores power. To reset the Emergency Laser Off Switch, the user must twist and rotate in the direction indicated by the arrows, then release it as the switch button pops out, returning it to its normal position.



#### Caution

DO NOT leave key in device's key switch when not in use. Prevent unauthorized and/or unqualified use of the device. This will also prevent inadvertent laser emissions.

#### 1. Key Switch

- This switch is located on the rear panel of the LTS-1500 device. A key is required to activate the laser system. The user inserts one of the supplied keys into the key-switch and turns it 90 degree clockwise. When the key switch is in this position, it cannot be removed.

- After powering OFF the device using the key switch (a 90-degree, counter-clockwise turn), the user should remove the key and store it properly to prevent unauthorized or unexpected laser system operation.

## 2. Safety Interlock

This safety interlock located at the bottom of the device. If the interlock is not inserted into the connector jack, all electrical power to the controls and laser components is terminated. The safety interlock **MUST** be inserted before the laser emission.

## 10.3 Safety Strategy

### 1. Three Minutes Unattended Protection

If the laser device is left in Ready mode and does not receive any input for three minutes, the laser will switch back to Standby mode.

### 2. Internal Laser Energy Monitor

- This is an internal device that monitors the intensity of laser energy generated whenever laser emission occurs. This monitor aborts laser emission if the laser device is unable to maintain the laser energy output set by the user.

### 3. Laser Eye Protection

- The protective laser eyewear has an optical density rating  $> 5.0$  for 350nm~2000nm (see specification sheet) laser emission. All personnel present during device operation must wear this eyewear. Contact LiteCure, LLC at 302-709-0408 to purchase additional sets of 350nm~2000nm (see specification sheet) protective eyewear.

## 11. ACCESSORIES

### 11.1 Foot Switch

A single intensity footswitch comes with this laser device. The laser device treats the footswitch as a simple on/off device. When Override function is off, pressing down the footswitch produces 100% of the laser energy set by the operator. Fully releasing the pressed footswitch stops laser emission. When Override function is on, pressing down the footswitch one time produces 100% of the laser energy set by the operator, and pressing down again to stop the laser emission.

When closed, the cover of the foot switch is designed to prevent inadvertent foot pedal control surface depression. Always turn laser off when not in use.

When foot switch operation is desired, press down on the cover then release. The cover is spring loaded and will open automatically.



## 11.2 Finger Switch

A single intensity finger switch comes with the hand piece. The laser device treats the finger switch as a simple on/off device. When Override function is off, pressing down the finger switch produces 100% of the laser energy set by the operator. Fully releasing the pressed finger switch stops laser emission. When Override function is on, pressing down the finger switch one time produces 100% of the laser energy set by the operator, and pressing again stops the laser emission.



## 11.3 Power Cord



## 11.4 Laser Safety Eyewear



### Caution

ALWAYS wear the protective eyewear supplied with this device, which is optically dense at the wavelength of operation (see specification sheet). All personnel present during device operation must wear this eyewear. Contact LiteCure, LLC at 302-709-0408 to purchase additional sets of protective eyewear for this device.



All personnel who are within the NOHD are considered to be within the controlled area and must wear laser safety eyewear. ALWAYS wear the protective eyewear supplied with this device. All personnel present during device operation must wear this eyewear.

## 12. SPECIFICATIONS

<b>Model</b>	LTS-1500
<b>Laser type</b>	Solid State laser (Class IV)
<b>Treatment laser wavelength</b>	810+/-10nm, 980+/-10nm
<b>Aiming beam wavelength</b>	650+/-15nm
<b>Aiming beam power</b>	3.5mW+/-1.0mW
<b>Maximum output power</b>	25W @ aperture of hand piece
<b>Output port</b>	Hand piece
<b>Operating modes</b>	Continuous Wave (CW)
	Pulse Wave (50% duty cycle) 2, 10, 20, 100, 200, 500, 1000, 2500, 5000, 10000Hz
<b>Audio warning signal level</b>	45 to 65 dB
<b>Cooling</b>	Thermal Electrically Cooled with Forced Air
<b>Weight</b>	<30 lbs
<b>Dimensions</b>	413mm(L)x264mm(W)x257mm(H)
<b>Power requirement</b>	100-240V~ 50/60Hz 400VA
<b>Operation temperature</b>	10°C to 35 °C
<b>Storage temperature</b>	-20 °C to 70 °C

## 13. CLEANING



### **Warning**

Always turn off the system and unplug the power cord from the wall outlet before cleaning.



### **Warning**

Always use protective eyewear and gloves when cleaning and disinfecting any equipment.



### **Caution**

**DO NOT use Hand Piece Head until alcohol solution used in cleaning procedure completely evaporates. Doing so may cause the laser to ignite alcohol solutions or vapors.**

LTS-1500 laser device uses solid-state laser technology. It is important to keep the unit and accessories free from dust. To clean the exterior surfaces on the unit or accessories:

- Wipe with a soft cloth moistened with isopropyl alcohol solution. Ensure the solution is only 70% alcohol or less. Solutions of more than 70% alcohol can cause product damage.

## 14. MAINTENANCE AND CALIBRATION

### ***Calibration Procedure***

Regulatory agencies require that manufacturers of US FDA CDRH Class III and IV medical lasers supply their customers with power calibration instructions.

Calibration must be performed by the LiteCure-certified Service Personnel. Questions regarding this procedure should be referred to your local LiteCure representative. Units are recommended to be calibrated once a year.

### ***DISCLAIMER WARNING***

Calibration is a service procedure to be done only by LiteCure-certified Service Personnel. Adjustment by anyone other than a certified LiteCure Service Personnel voids any existing manufacturer's warranty on the instrument.

### ***Laser Power Calibration***

**TO PERFORM LASER CALIBRATION TEST PROCEDURE: WEAR LASER SAFETY GOGGLES WHEN PERFORMING THIS PROCEDURE**

Equipment Needed: Certified traceable power meter with appropriate wavelength and power measurement capabilities.

1. Turn off the laser.
2. Inspect and attach a LiteCure optical fiber, foot pedal and power cord as directed in the manual. Pay special attention to ensuring that both ends of the optical fiber are clean and free of any dust, fluid or other contaminants.
3. Turn on the LiteCure laser and enter standby mode as instructed in the manual.

4. Increase the power setting until the Digital and Analog Power Displays reach their maximum setting in CW (CONTINUOUS MODE).
5. Place the laser in ready mode.
6. Using the aiming beam, direct the distal end of the fiber into the active area of the power meter.
7. Enable the laser, fire the laser, and record the value in Watts from the power meter. Repeat 3 times and taken an average.
8. The average should be within 20% of power setting.
9. If the results are outside the 20% range, ensure that: all of the light from the fiber is entering the detector, the fiber is connected correctly, and the fiber is not damaged. Replace with a new fiber if necessary and repeat.
10. If the results are still outside the 20% range, discontinue this procedure and contact your local LiteCure representative.

## **15. SOURCES FOR ADDITIONAL INFORMATION AND ASSISTANCE ON LASER SAFETY**

### **Center for Devices and Radiological Health**

Office of Compliance

2098 Gaither Rd.

Rockville, MD 20850

Tel: 301-594-4654

Fax: 301-594-4672

<http://www.fda.gov/cdrh/index.html>

### **Laser Institute of America**

12424 Research Parkway, Suite 125

Orlando, FL 32826

Tel: 407 380 1553

Fax: 407 380 5588

<http://www.laserinstitute.org/>

## 16. WARRANTY INFORMATION

### 16.1 Terms and Conditions

1. LTS-1500 laser device is warranted to be free from defects in materials and workmanship for a period of 24 months, starting from the date of initial shipment. This warranty does not extend to incidental or consequential damages and to damage caused by negligent or improper handling in use, storage, nor to products from which the original identification markings or labels have been defaced, altered or removed.
2. LiteCure, LLC reserves the rights of determining cause or existence of defect and the options to repair the products, which proves to be defective during the warranty period. Products replaced under warranty will be warranted only for the balance of the warranty period starting from the date of the first shipment.
3. This warranty extends only to the original purchaser of the equipment from LiteCure, LLC. The purchaser must notify LiteCure, LLC within 15 days of first detecting the defect and promptly return the defective product before expiration of the warranty period.
4. Products claimed by purchaser to be defective shall be returned to LiteCure, LLC with transportation and insurance (if necessary) prepaid by purchaser. LiteCure, LLC will return repaired or replaced products to purchaser with FOB city destination within the Continental United States. Transportation fees insurance (if necessary) beyond this limit will be charged to purchaser.

### 16.2 Return Procedure

Please review terms of purchase and date of shipment to determine validity of warranty claim. Warranty claim should only be made for products within terms of warranty policy.

1. Call LiteCure, LLC at 302-709-0408 and obtain a Return Material Authorization number (RMA) and detailed return instructions. A form will be faxed and must be completed, signed and returned to LiteCure, LLC For customers where distributorship and/or a representative is not available, all claims should be addressed to:

Service

LiteCure, LLC

250 Corporate Blvd. Suite-B

Newark, Delaware 19702

2. Be prepared to furnish:
  - Product Model number and Serial number
  - Purchase and Shipment Date
  - Reason for return
  - Name of person and phone number at your organization for further communication.
3. Adhere to LiteCure, LLC's complete return instructions for transportation and packaging and ship the product (freight and insurance prepaid) with proper documentation containing the RMA number and the information specified above.
4. LiteCure, LLC will advise the purchaser of its determination of warranty at the earliest possible time. Providing complete information as requested will expedite the procedure.

## 17 APPENDIX - LABELS

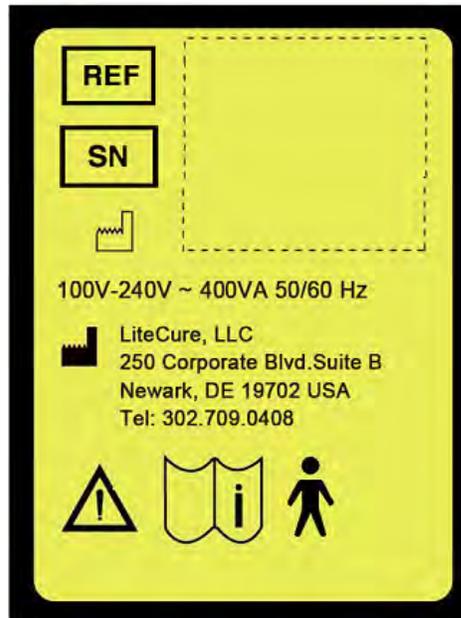
### 17.1 Warning Label

This label indicates the laser classification. It warns of the radiation exposure hazard potential to eyes and skin.

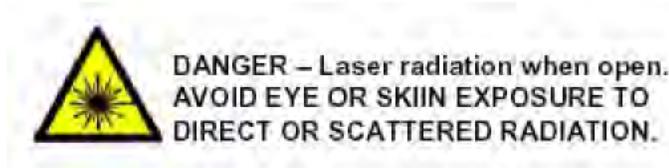


### 17.2 Manufacture Label

The label displays the manufacturer, model number, serial number, and regulatory compliance declarations



### **17.3 Non Interlocked Protective Housing Label**

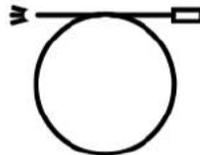


### **17.4 Warranty Seal Label**

Labels are positioned on the underside of the laser device in such a way that any attempt to open



### **17.5 Optical Fiber Applicator Label**



### **17.6 Laser Emissions Label**



### **17.7 Emergency Laser Off Label**



### **17.8 Finger/foot Switch Label**



### 17.9 Remote Interlock Connector Label



### 17.10 ETL Mark Label



### 17.11 Fuse Label



### 17.12 AC Power Input Label

100-240V~ 50/60Hz 400VA

### 17.13 Protective Earth (Ground) Label (Inside device)



### 17.14 Mains ON Label



### 17.15 Mains OFF Label

