

K132667

510(k) SUMMARY

**Topcon Medical Systems, Inc.
Synergy ODM**

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared**

Topcon Medical Systems, Inc.
111 Bauer Drive
Oakland, NJ 07436
Phone: (201) 599-5553
Facsimile: (201) 599-5240
Contact Person: Michael Gusel

OCT 09 2013

OR

Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864
Phone: (978) 207-1245
Facsimile: (978) 824-2541

Date Prepared: August 26, 2013

Name of Device and Name/Address of Sponsor

Synergy ODM
Topcon Medical Systems, Inc.
111 Bauer Drive
Oakland, NJ 07436

Common or Usual Name

System, image management, ophthalmic

Classification Name

21 C.F.R. 892.2050

Predicate Devices

Topcon Corporation Synergy (K093313)
Carl Zeiss Meditec AG Forum (K122938)

Intended Use / Indications for Use

Synergy ODM is a comprehensive software platform intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic instruments through either a direct connection with the instruments or through computerized networks.

Technological Characteristics

Synergy ODM is a software platform that collects, processes, measures, analyzes, stores, and manages patient data and clinical information. Synergy ODM is used together with a number of computerized digital imaging devices. In addition, Synergy ODM software collects and manages patient demographics, image data, and clinical reports from a range of medical devices. Synergy ODM enables a real-time review of diagnostic patient information at a PC workstation. Synergy ODM also includes an internet-browser-based user interface to allow authorized users to access, view, create reports, and analyze patient and examination data saved in a centralized database. The system utilizes dual level authentication and 128-bit encryption to ensure secure networking environment.

Performance Data

No performance data was required or provided. Software validation and verification demonstrate that the Synergy ODM performs as intended and meets its' specifications.

Substantial Equivalence

Synergy ODM is as safe and effective as the identified predicate devices including Topcon Corporation's Synergy (K093313) and Zeiss Forum (K122938). Synergy ODM has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. Both Synergy ODM and the predicate devices have similar technological characteristics. Synergy ODM and the identified predicate devices are software only devices.



October 9, 2013

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

Topcon Medical Systems
c/o Ms. Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K132667

Trade/Device Name: Synergy ODM
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system.
Regulatory Class: Class II
Product Code: NFJ
Dated: August 26, 2013
Received: August 27, 2013

Dear Ms. O'Connell:

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" (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,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132667

Device Name: Synergy ODM

Indications for Use:

Synergy ODM is a comprehensive software platform intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic instruments through either a direct connection with the instruments or through computerized networks.

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

AND/OR

Over-The-Counter
(21 C.F.R. 807

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Rahul K. Ram
-S (Affiliate)



October 9, 2013

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

Topcon Medical Systems
c/o Ms. Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K132667

Trade/Device Name: Synergy ODM
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system.
Regulatory Class: Class II
Product Code: NFJ
Dated: August 26, 2013
Received: August 27, 2013

Dear Ms. O'Connell:

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” (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,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132667

Device Name: Synergy ODM

Indications for Use:

Synergy ODM is a comprehensive software platform intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic instruments through either a direct connection with the instruments or through computerized networks.

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

AND/OR

Over-The-Counter
 (21 C.F.R. 807

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

 _____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Rahul K. Ram
-S (Affiliate)

K132667

FDA CDRO DMC

AUG 27 2013

Received

August 26, 2013

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Traditional 510(k): Topcon Medical Systems, Inc.'s Synergy Ophthalmic Data Management (ODM) System

Ladies and Gentlemen:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), Topcon Medical Systems, Inc. ("Topcon" or the "company") is submitting the attached traditional 510(k) premarket notification ("510(k)") for Synergy ODM. Synergy ODM is a comprehensive software platform intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic instruments through either a direct connection with the instruments or through computerized networks.

Synergy ODM is a Class II Ophthalmic Image Management System with a product code of NFJ (Picture archiving and communications system). As explained in more detail in the attached 510(k), Synergy ODM is substantially equivalent to Topcon's Synergy (K093313) and the Carl Zeiss Meditec AG Forum (K122938) ("the predicate devices") that FDA has already cleared for ophthalmic imaging.

There have been no formal regulatory submissions for Synergy ODM.

In accordance with the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Topcon has submitted the appropriate application fee electronically. A copy of the User Fee Cover Sheet is provided with the attached 510(k).

This premarket notification is provided in duplicate as required, with one paper and one identical electronic copy.

50

If you have any additional questions regarding the 510(k), please contact
Maureen O'Connell at (978) 207-1245 or Maureen@oconnellregulatory.com.
Upon clearance of the device, please fax the substantial equivalence letter to
(978) 824-2541.

Sincerely,



Michael Gusel
Manager, Regulatory Affairs and Quality Assurance

cc: Maureen O'Connell

Please wait...

If this message is not eventually replaced by the proper contents of the document, your PDF viewer may not be able to display this type of document.

You can upgrade to the latest version of Adobe Reader for Windows®, Mac, or Linux® by visiting <http://www.adobe.com/products/acrobat/readstep2.html>.

For more assistance with Adobe Reader visit <http://www.adobe.com/support/products/acrreader.html>.

Windows is either a registered trademark or a trademark of Microsoft Corporation in the United States and/or other countries. Mac is a trademark of Apple Inc., registered in the United States and other countries. Linux is the registered trademark of Linus Torvalds in the U.S. and other countries.

August 26, 2013

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Traditional 510(k): Topcon Medical Systems, Inc.'s Synergy Ophthalmic Data Management (ODM) System

Ladies and Gentlemen:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), Topcon Medical Systems, Inc. ("Topcon" or the "company") is submitting the attached traditional 510(k) premarket notification ("510(k)") for Synergy ODM. Synergy ODM is a comprehensive software platform intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic instruments through either a direct connection with the instruments or through computerized networks.

Synergy ODM is a Class II Ophthalmic Image Management System with a product code of NFJ (Picture archiving and communications system). As explained in more detail in the attached 510(k), Synergy ODM is substantially equivalent to Topcon's Synergy (K093313) and the Carl Zeiss Meditec AG Forum (K122938) ("the predicate devices") that FDA has already cleared for ophthalmic imaging.

There have been no formal regulatory submissions for Synergy ODM.

In accordance with the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Topcon has submitted the appropriate application fee electronically. A copy of the User Fee Cover Sheet is provided with the attached 510(k).

This premarket notification is provided in duplicate as required, with one paper and one identical electronic copy.

If you have any additional questions regarding the 510(k), please contact Maureen O'Connell at (978) 207-1245 or Maureen@oconnellregulatory.com. Upon clearance of the device, please fax the substantial equivalence letter to (978) 824-2541.

Sincerely,



Michael Gusel
Manager, Regulatory Affairs and Quality Assurance

cc: Maureen O'Connell

TOPCON MEDICAL SYSTEMS, INC.

510(k) Premarket Notification for Synergy ODM

Topcon Medical Systems, Inc.
111 Bauer Drive
Oakland, NJ 07436

TABLE OF CONTENTS

	Page
I. NAME OF DEVICE	4
II. ESTABLISHMENT REGISTRATION NUMBER	4
III. DEVICE CLASSIFICATION/FDA REVIEWING BRANCH	4
IV. PERFORMANCE STANDARDS	4
V. PROPOSED LABELING.....	5
VI. DEVICE DESCRIPTION	5
VII. SUBSTANTIAL EQUIVALENCE	7
VIII. SOFTWARE INFORMATION	13
IX. BIOCOMPATIBILITY INFORMATION.....	15
X. STERILIZATION / CLEANING / DISINFECTION / SHELF LIFE	15
XI. PERFORMANCE TESTING-BENCH.....	16
XII.PERFORMANCE TESTING-CLINICAL.....	16
XIII. FINANCIAL DISCLOSURES.....	16
XIV. 510(K) SUMMARY	16
XV. CONFIDENTIALITY	16
XVI. SUBMITTER'S NAME AND ADDRESS.....	16
XVII. CONTACT PERSON AND TELEPHONE/FACSIMILE NUMBERS.....	17
XVIII. MEDICAL DEVICE USER FEE.....	17
XIX. INDICATIONS FOR USE STATEMENT	17
XX. TRUTH AND ACCURACY STATEMENT.....	17

Attachments:

- Appendix 1 DICOM Conformance Statement
- Appendix 2 FDA Form 3654: DICOM
- Appendix 3 FDA Form 3654: IEC 62304 and Software Development Lifecycle QAP
- Appendix 4 User's Manual
- Appendix 5 Software Design Specification
- Appendix 6 Software Requirements Specification
- Appendix 7 Hazard Analysis
- Appendix 8 Traceability Analysis
- Appendix 9 Verification and Validation
- Appendix 10 Verification and Validation: DICOM File Import Protocol and Report
- Appendix 11 Verification and Validation: IMAGEnet 2000 CSI Import Protocol and Report
- Appendix 12 Verification and Validation: IMAGEnet SQL CSI Import Protocol and Report
- Appendix 13 Verification and Validation: 3D OCT 2000 CSI Import Protocol and Report
- Appendix 14 Verification and Validation: Template CSI Import Protocol and Report

Appendix 15 Revision Level History and Unresolved Anomalies
Appendix 16 510(k) Summary
Appendix 17 User Fee Cover Sheet
Appendix 18 Indications for Use
Appendix 19 Truthful and Accurate Statement

The following information is provided as required by 21 C.F.R. § 807.87 (2003) for Topcon Medical Systems, Inc.'s Synergy ODM 510(k) premarket notification:

I. NAME OF DEVICE

Trade Name:	Synergy ODM
Common Names:	System, Image Management, Ophthalmic
Classification Name:	Picture archiving and communication Systems

II. ESTABLISHMENT REGISTRATION NUMBER

Manufacturer:	2242863
---------------	---------

III. DEVICE CLASSIFICATION/FDA REVIEWING BRANCH

The Ophthalmic Branch has classified Ophthalmic Image Management Systems as Class II devices pursuant to 21 C.F.R. §892.2050.

IV. PERFORMANCE STANDARDS

We have reviewed the requirements of Sections 513 and 514 of the Act and are not aware of any requirements of either section applicable to this device. No performance standards or special controls have been developed under Section 514 of the FDC Act for Ophthalmic Image Management Systems. No special controls apply.

Synergy ODM complies with the following voluntary standards:

- DICOM (Digital Imaging and Communications in Medicine) - Developed by the American College of Radiology and the National Electrical Manufacturers Association. Specifies the format for the communication of digital images between individual devices and over networks. A DICOM Conformance Statement for the Synergy ODM DICOM Connection Module is provided in **Appendix 1**. This document confirms conformance to the DICOM 3.0 standard to allow the sharing of medical information and images with other Electronic Medical Record (EMR) systems that support DICOM standards.

The completed Standards Data Report Form (FDA Form 3654) is provided in **Appendix 2**.

- JPEG (Joint Photographic Experts Group) Standard - Specifies methods for the compression (reversible and irreversible) of digital medical images. References – ISO/IEC 10918-1 (1994-02) Digital Compression and Coding of Continuous-Tone Still Images (JPEG), G.K. Wallace, "The JPEG Still Picture Compression Standard", Communications of the ACM, Vol. 34, No. 4, April 1991.
- Medical device software-Software life cycle processes. IEC 62304. The Standards Data Report Form (FDA 3654) and Topcon's Software Development Lifecycle QAP are provided in **Appendix 3**.

V. PROPOSED LABELING

The User's Manual for Synergy ODM is provided in **Appendix 4** of this submission.

VI. DEVICE DESCRIPTION

Synergy ODM is a comprehensive software platform intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as for management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic instruments through either a direct connection with the instruments or through computerized networks.

Synergy ODM is used together with a number of computerized digital imaging devices, including:

- Optical Coherence Tomography devices
- Mydriatic retinal cameras
- Non-mydriatic retinal cameras
- Biomicroscopes (slit lamps)

In addition, Synergy ODM collects and manages patient demographics, image data, and clinical reports from a range of medical devices, including:

- Scanning Laser Ophthalmoscope images and videos
- Non Radiometric Ultrasound devices
- Video image sources
- TWAIN compliant imaging sources
- Compliant data sources placed in network accessible folders and directories
- Images of known format from digital cameras and scanners
- Printer files of known format from computerized diagnostic devices
- Electronic information complying to accepted DICOM formats
- Other devices connected in proprietary formats

The diagram of layout and interconnections between software components, and their technical characteristics and principles of operation are presented in the Software Design Specification in **Appendix 5**.

Operating Environment

Topcon Synergy ODM enables users to view images, manipulate images, and import exams all via a browser running on both Microsoft® Windows® and Mac® OS platforms. Below are the required specifications for the Synergy ODM Review Stations:

For Windows®:

- Operating System: Windows XP Service Pack 2 or above
- Memory (RAM): 2GB
- Processor (CPU): Dual processor running 2.33Ghz or faster
- Screen Resolution: 1440x900
- Monitor: Wide Screen format, 19” or larger

For Mac®:

- Operating System: OS X 10.5.8
- Memory (RAM): 1GB
- Processor (CPU): Dual processor running 2.4Ghz or faster
- Screen Resolution: 1440x900
- Monitor: Wide Screen format, 19” or larger

Topcon Synergy ODM must have the web pages generated by the application served by a computer acting as a web server. Below are the required specifications for the computer that will be used as the Topcon Synergy ODM Web Server.

- Operating System: Microsoft Windows Server 2008 R2 Standard Edition (64-bit) required
- Memory (RAM): Minimum of 8GB
- Storage (HDD): Minimum of 2TB of storage
- Processor (CPU): Minimum Intel Quad Core CPU with at least 2.26Ghz of speed
- Additional Software: Microsoft SQL Server 2008 R2 Standard Edition required.

Topcon Synergy ODM uses Capture System Gateway (CSG) computers to assist in the importing of information from approved medical devices. Below are the required specifications for CSG computers:

- Operating System: Microsoft Windows Server 2008 R2 Standard Edition (64-bit) required
- Memory (RAM): Minimum of 4GB (8GB recommended)
- Storage (HDD): Minimum of 1TB of storage (2TB recommended)

- Processor (CPU): Minimum Intel Dual Core CPU with at least 2.4Ghz of speed (Quad Core recommended)
- Imported Data from Approved Medical Devices: See List Above in Software Description

VII. SUBSTANTIAL EQUIVALENCE

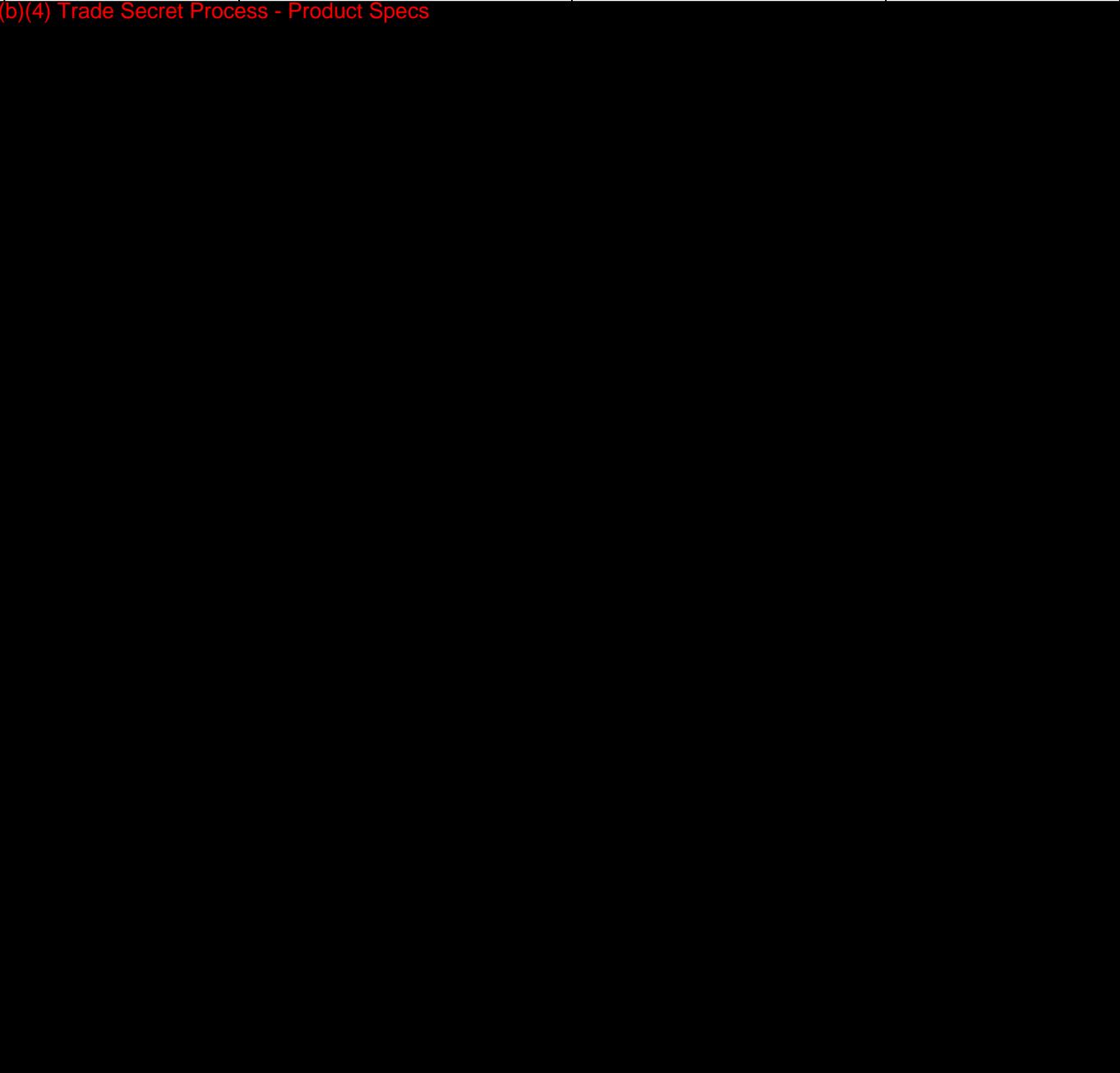
Topcon's Synergy ODM is substantially equivalent to Topcon's Synergy cleared in K093313 and Carl Zeiss Meditec AG's Forum cleared in K122938. As explained in more detail below, Synergy ODM has the same intended use and similar indications for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate devices. See **Table 1** for a substantial equivalence chart comparing the similarities and differences between Synergy ODM and its predicates. Thus, Synergy ODM is substantially equivalent to its predicates.

TABLE 1
TOPCON MEDICAL SYSTEMS, INC.
SYNERGY ODM
SUBSTANTIAL EQUIVALENCE CHART

	Topcon Synergy Ophthalmic Data Management (Synergy ODM) System	Topcon Synergy	Carl Zeiss Meditec AG Forum
510(k) Number	-	K093313	K122938
Product Code	NFJ	NFJ	NFJ
Indications for Use	Synergy ODM is a comprehensive software platform intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in the management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic instruments through either a direct connection with the instruments, or through computerized networks.	Synergy is a comprehensive software platform intended for use in acquisition or importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic instruments through either a direct connection with the instruments or through computerized networks.	FORUM is a software system intended for use in storage, management, processing, and display of patient, diagnostic, video and image data and measurement from computerized diagnostic instruments or documentation systems through networks. It is intended to work with other FORUM applications. FORUM is intended for use in review of patient, diagnostic and image data and measurement by trained healthcare professionals.
User Population	Trained professionals	Trained professionals	Trained professionals
Technological Characteristics	Software only	Software only	Software only
Standards with which the device complies	JPEG DICOM, HL7	JPEG DICOM	JPEG DICOM, HL7

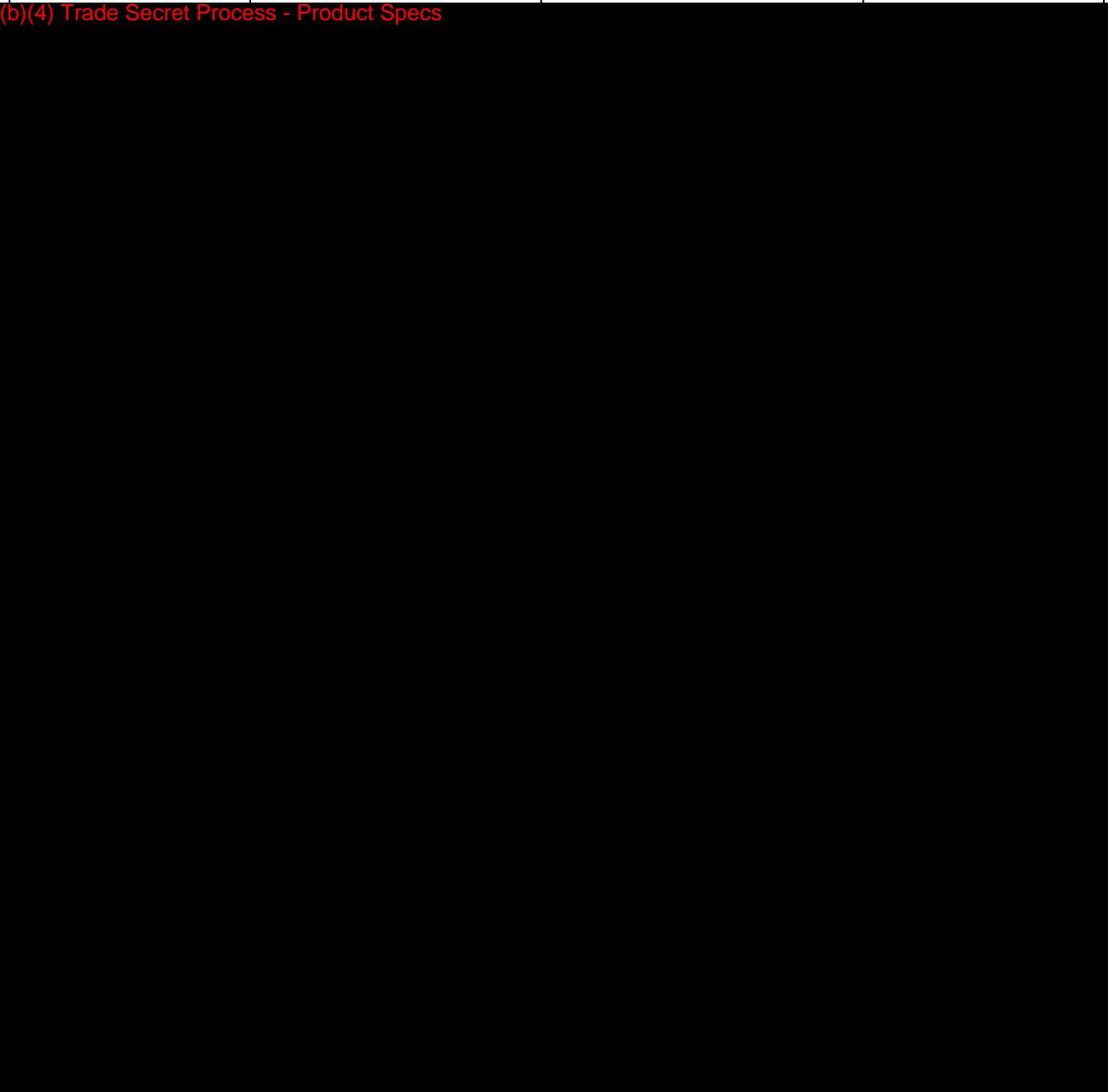
	Topcon Synergy Ophthalmic Data Management (Synergy ODM) System	Topcon Synergy	Zeiss Forum Archive and Viewer
--	---	-----------------------	---------------------------------------

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



	Topcon Synergy Ophthalmic Data Management (Synergy ODM) System	Topcon Synergy	Zeiss Forum Archive and Viewer
--	---	---------------------------	---

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



Substantial Equivalence Discussion for Synergy ODM per the Substantial Equivalence Decision-Making Process Flowchart

1. Does the new device have the same Indications Statement?

There is one minor difference between the indications for use statement for Synergy ODM compared with Synergy which is the removal of “acquisition”. Specifically, Synergy ODM does not include a capture component as Topcon now utilizes other software solutions to perform that task.

The indications for use statement for Forum is also very similar to Synergy ODM with only minor differences in the exact verbiage of the indications for use statement.

Synergy ODM, Synergy and Forum are all software platforms intended for use as ophthalmic image management systems and intended to be used by trained medical professionals. Therefore, Synergy ODM has the same intended use as Synergy and Forum and may be found substantially equivalent.

2. Does the new device have the same technological characteristics?

Synergy ODM has similar technological characteristics to Synergy and Forum. All of the devices are software only image management systems.

Regarding acquisition, Synergy ODM and Zeiss Forum (K122938) do not offer capture components while Synergy (K093313) does. Synergy ODM imports digital images, patient data, diagnostic data and clinical information from other software capture systems and directly from ophthalmic devices.

Regarding importing, Synergy ODM, Synergy (K093313) and Forum (K122938) all allow importing and management of files and images from a range of ophthalmic diagnostic devices including DICOM files, image files of known format, video images, and printer files.

Regarding viewing, Synergy ODM and Synergy (K093313) allow standard viewing operations such as zoom in/out, panning, etc. and standard image enhancements such as contrast and brightness adjustment, and drawing tools. Forum (K122938) also allows standard viewing operations including zooming, etc. but additional details regarding viewing options are not available.

Regarding measurement and analysis, Synergy ODM provides line and area measurement capabilities however, measurements of OCT retinal thickness and OCT retinal nerve fiber layer thickness that are available in Synergy (K093313) have not been implemented for the new (web) platform. Additionally, Synergy ODM provides two types of measurements not present in Synergy (K093313) including

Cup to Disc ratio and MPS (Macular Photocoagulation Study) measurements. Both types of new measurements are simple extensions of the area measurement capability of Synergy (K093313). Cup to Disc ratio is a quotient of two area measurements of image regions defined by the user and MPS measurement is an area of a circle specified in the image by the user. Forum (K122938) only provides line measurements.

Regarding network and security, Synergy ODM provides web-based access to all data files as does Synergy (K093313). Synergy ODM also provides DICOM communication with other PACS, as does Synergy (K093313) and Forum (K122938).

Regarding printing, Synergy ODM and Synergy (K093313) provide similar customizable print templates.

Regarding archiving and backup, Synergy ODM, Synergy (K093312) and Forum (K122938) all include archive and backup functionality. The operating system for review stations running each of the systems is Windows XP or above. Synergy ODM can also be executed on review stations with Mac OS X operating system as can Forum (K122938).

In conclusion, Synergy ODM shares similar technological characteristics with the predicate devices, both in terms of the manner in which images are imported, analyzed, and stored, as well as the operation of the device by the intended user. Any minor differences in operation do not raise new questions of safety and effectiveness. Synergy ODM raises the same issues of safety and effectiveness as the predicate devices.

3. Are the descriptive characteristics precise enough to ensure equivalence?

Yes, the descriptive characteristics are precise enough to ensure equivalence.

4. Conclusion

In summary, Topcon's Synergy ODM has the same intended use as all of the previously cleared predicate devices. In addition, Synergy ODM has very similar indications, technological characteristics, and principles of operation as its predicates. Although there are minor differences between the Synergy ODM and its predicate devices, those differences do not raise new questions of safety or efficacy. Thus, the Synergy ODM is substantially equivalent.

VIII. SOFTWARE INFORMATION

Level of Concern

Synergy ODM is a software based device which presents a Minor Level of Concern as defined in FDA's *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices* (May 11, 2005) (hereinafter Software Guidance Document).

Table 1 Major Level of Concern

If the answer to any <u>one</u> question below is Yes, the Level of Concern for the Software Device is likely to be Major.	
1. Does the Software Device qualify as Blood Establishment Computer Software?	NO
2. Is the Software Device intended to be used in combination with a drug or biologic?	NO
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?	NO
4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:	
a. Does the Software Device control a life supporting or life sustaining function?	NO
b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	NO
c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?	NO
d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such	

that if misapplied it could result in serious injury or death?
NO
e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?
NO

Table 2 Moderate Level of Concern

If the Software Device is not Major Level of Concern and the answer to any <u>one</u> question below is Yes, the Level of Concern is likely to be Moderate.
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?
NO
2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?
NO
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?
NO

Thus, the Synergy ODM software is considered to present a Minor Level of Concern. Documentation required for software with a Minor Level of Concern is the following:

Document	Appendix
Software Description	Appendix 6 (in SRS)
Software Requirements Specification	Appendix 6
Hazard Analysis	Appendix 7
Traceability Analysis	Appendix 8
Verification and Validation	Appendices 9-14
Revision Level History	Appendix 15

In addition to the overall Synergy ODM Verification and Validation results provided in Appendix 9, the test protocols and test reports listed below describe the

testing process of several Capture Station Interfaces (CSIs) used by Synergy ODM for particular devices/ software versions/interface types. The CSI concept is described in the SDS, section 13 as follows:

The Capture Station Interfaces (CSIs) allows Synergy to import exam data from ophthalmic devices. There are different CSIs for different classes of devices (DICOM-based, template-based, and database-based), which collect media data, retrieve patient data and generate meta-data (XML) description of patient demographics and exam information. The retrieved data are further processed by the Multi-Modality Interface (MMI) module.

The following test protocol and reports are being provided:

File Type	Appendix
Import of DICOM files	Appendix 10
Import of IMAGEnet 2000 files	Appendix 11
Import of IMAGEnet SQL files	Appendix 12
Import of 3D OCT 2000 files	Appendix 13
Import of Template CSI files	Appendix 14

Additionally, the following documents are being provided, although not required for a Minor Level of Concern software, to provide a full description of the software:

Document	Appendix
Architecture Design Chart	Appendix 5 (in SDS)
Software Design Specification	Appendix 5
Unresolved Anomalies	Appendix 15

IX. BIOCOMPATIBILITY INFORMATION

Synergy ODM is a software device and therefore, biocompatibility information is not applicable.

X. STERILIZATION / CLEANING / DISINFECTION / SHELF LIFE

Synergy ODM is a software device and therefore, this information is not applicable.

XI. PERFORMANCE TESTING-BENCH

No bench performance testing was required or performed.

XII. PERFORMANCE TESTING-CLINICAL

No clinical performance testing was required or performed.

XIII. FINANCIAL DISCLOSURES

Topcon is not submitting clinical data in support of this 510(k). For this reason, the regulations regarding clinical investigators financial interests in 21 C.F.R. § 54.4 do not apply. Thus, the company is not providing a disclosure or certification to the absence of any financial arrangements.

XIV. 510(K) SUMMARY

Appendix 16 of this submission contains the Company's 510(k) Summary.

XV. CONFIDENTIALITY

Topcon considers its intent to market the modified Synergy ODM as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore, requests FDA not to disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that you consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

XVI. SUBMITTER'S NAME AND ADDRESS

Topcon Medical System, Inc.
111 Bauer Drive
Oakland, NJ 07436
Phone: 201-599-5553

XVII. CONTACT PERSON AND TELEPHONE/FACSIMILE NUMBERS

Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Phone: (978) 207-1245
Facsimile: (978) 824-2541

XVIII. MEDICAL DEVICE USER FEE

The Company has electronically remitted the Medical Device User Fee of \$4,960.00 concurrent with this submission. A copy of the Medical Device User Fee Cover Page is provided in **Appendix 17**.

XIX. INDICATIONS FOR USE STATEMENT

The company's Indications for Use Statement for Synergy ODM is provided in **Appendix 18**.

XX. TRUTH AND ACCURACY STATEMENT

The company's signed Truth and Accuracy statement is included in **Appendix 19**.

Synergy ODM DICOM Conformance Statement

Revision 1.1

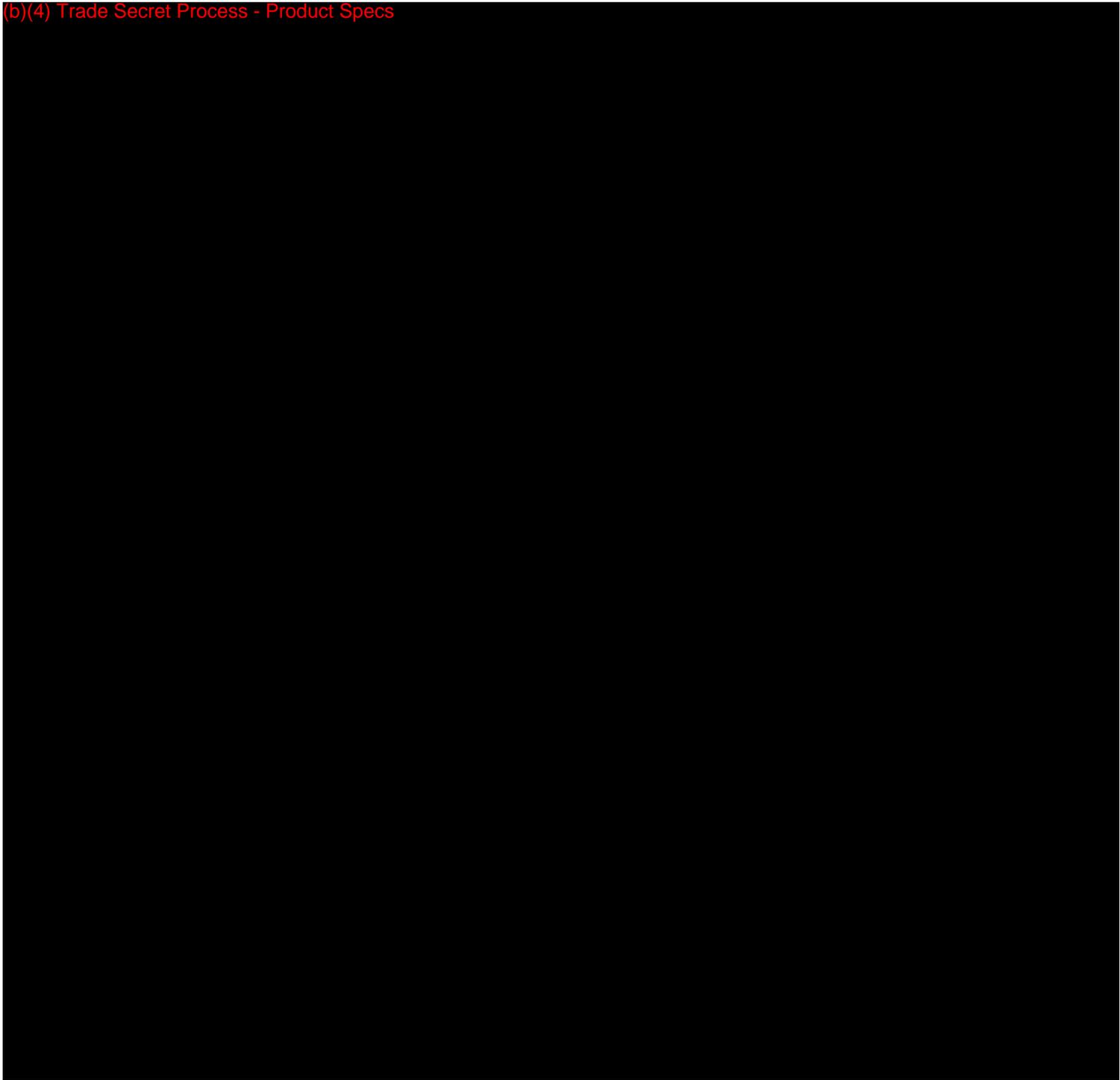
Topcon Medical Systems, Inc.

111 Bauer Drive, Oakland, NJ 07436, U.S.A.

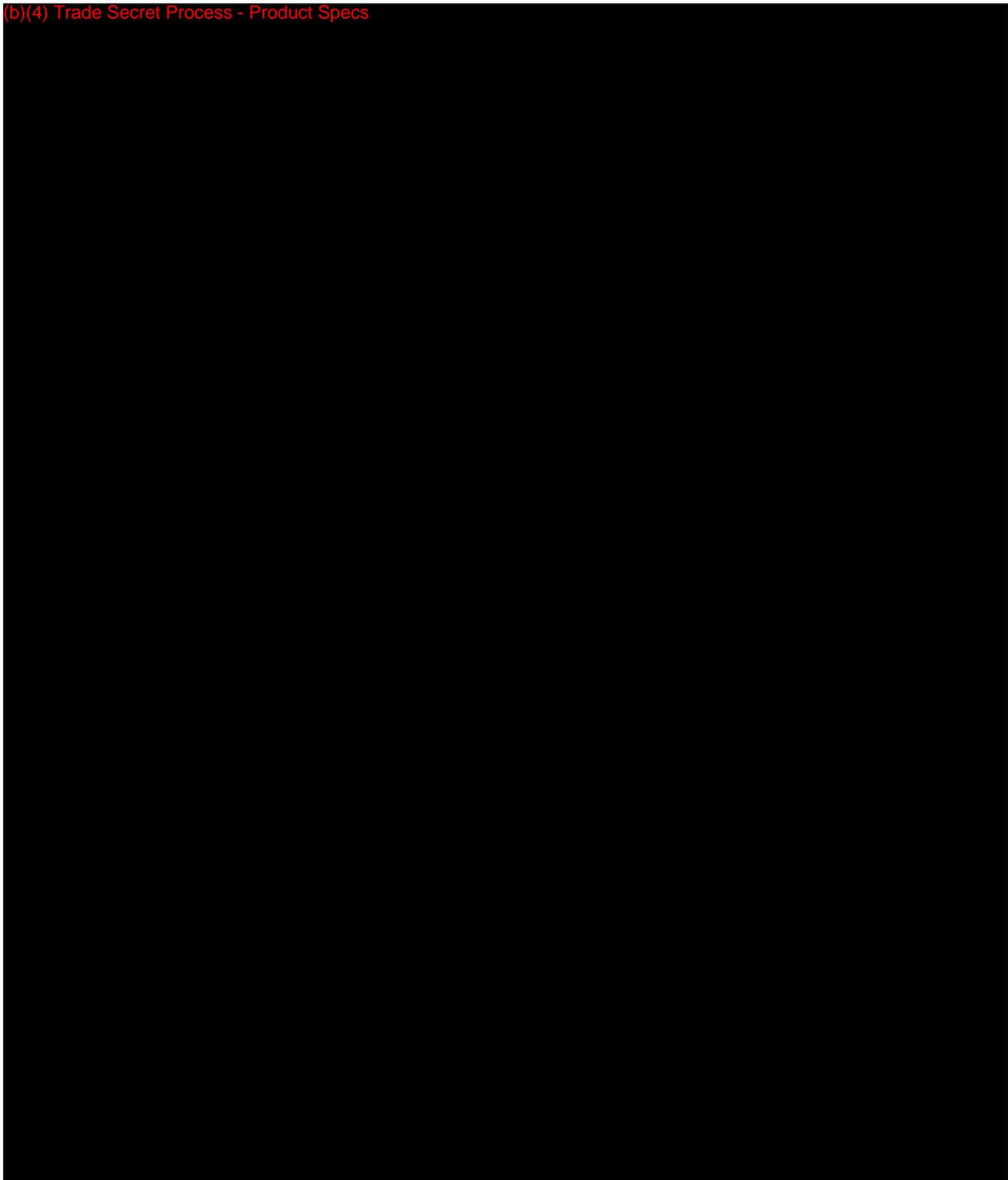
Phone: 201-599-5100 Fax: 201-599-5250 <http://www.topcon.com>

© 2013 Topcon Medical Systems, Inc., all rights reserved.

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

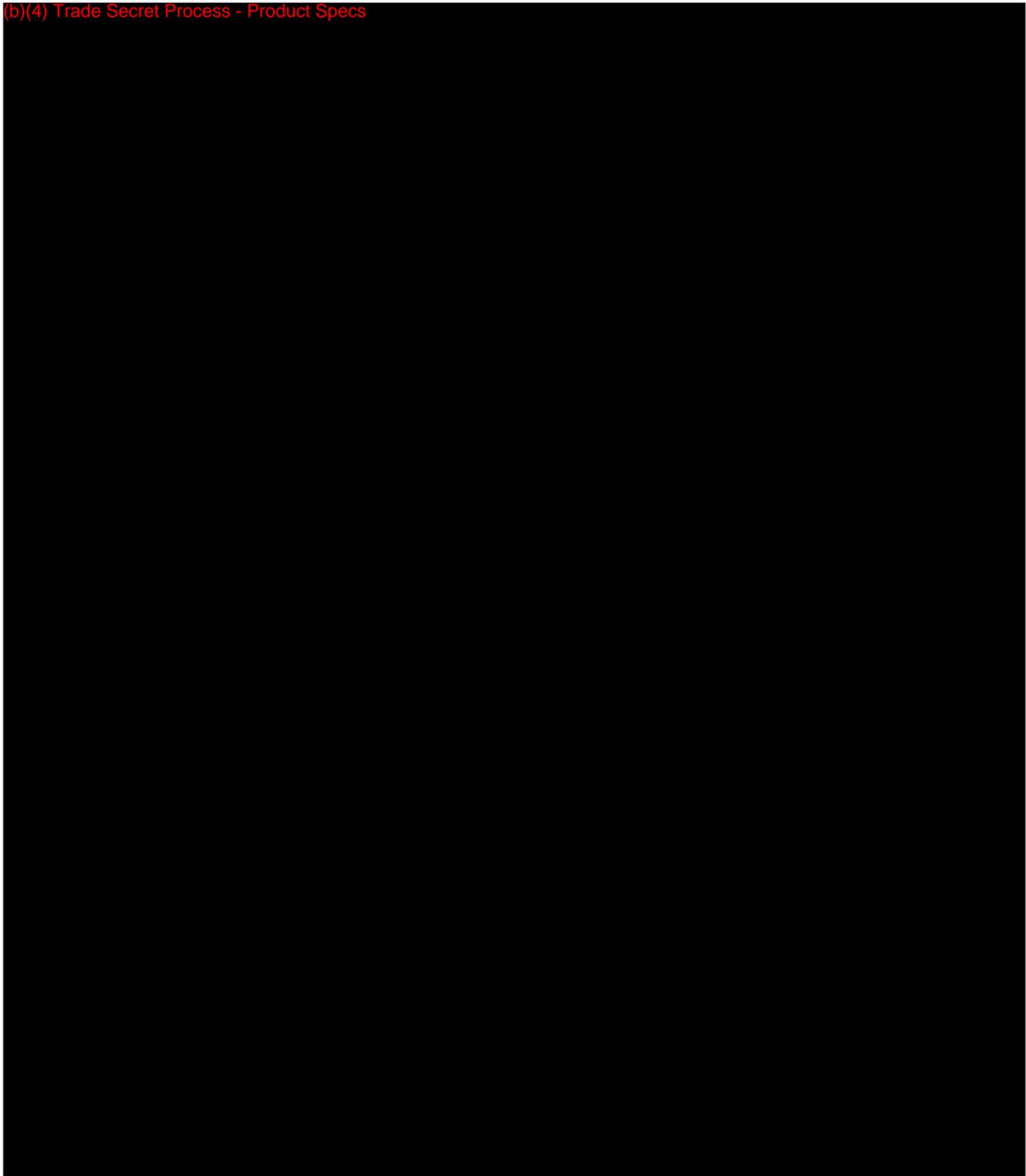


(b)(4) Trade Secret Process - Product Specs



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

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



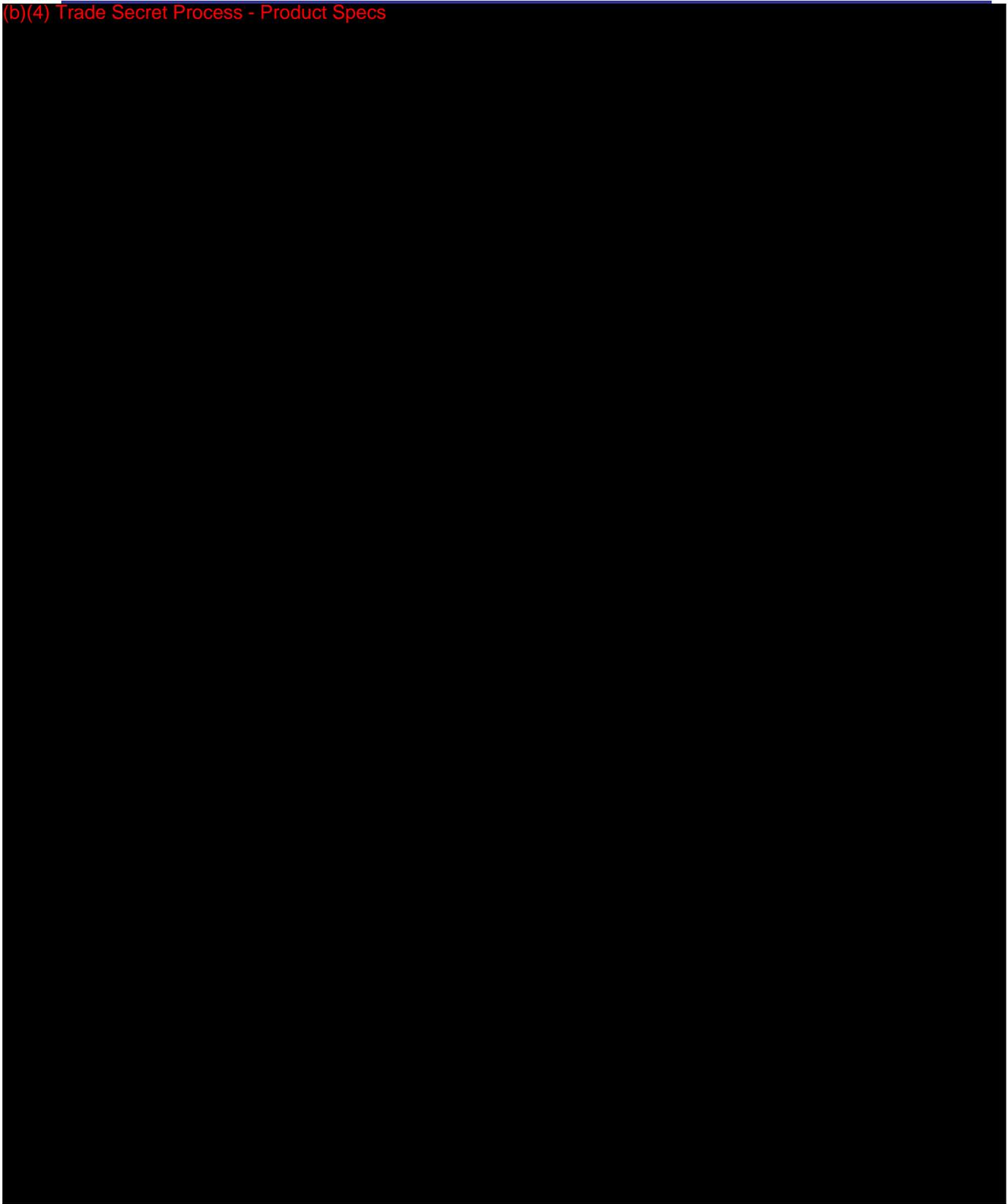
(b)(4) Trade Secret Process - Product Specs



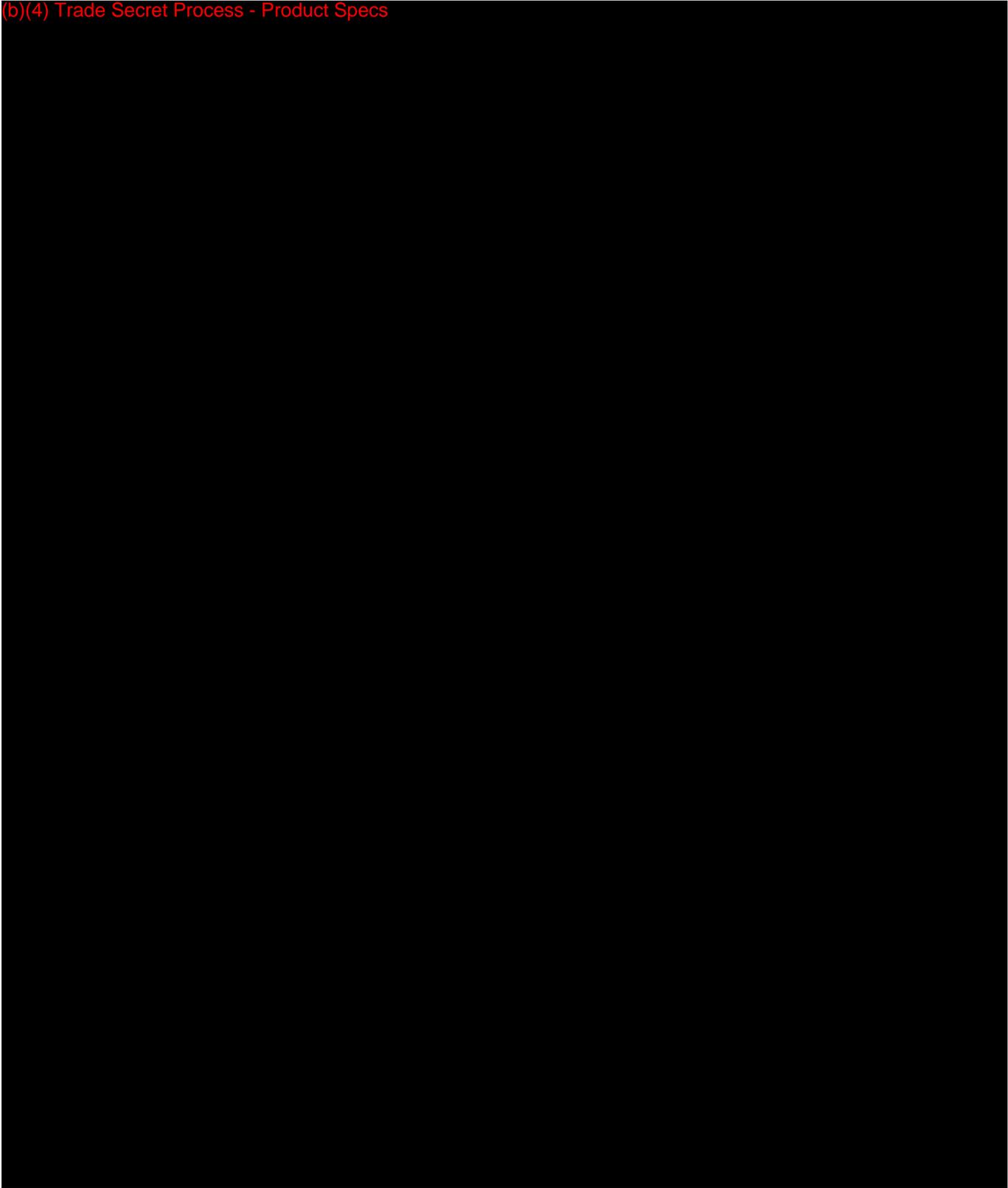
(b)(4) Trade Secret Process - Product Specs



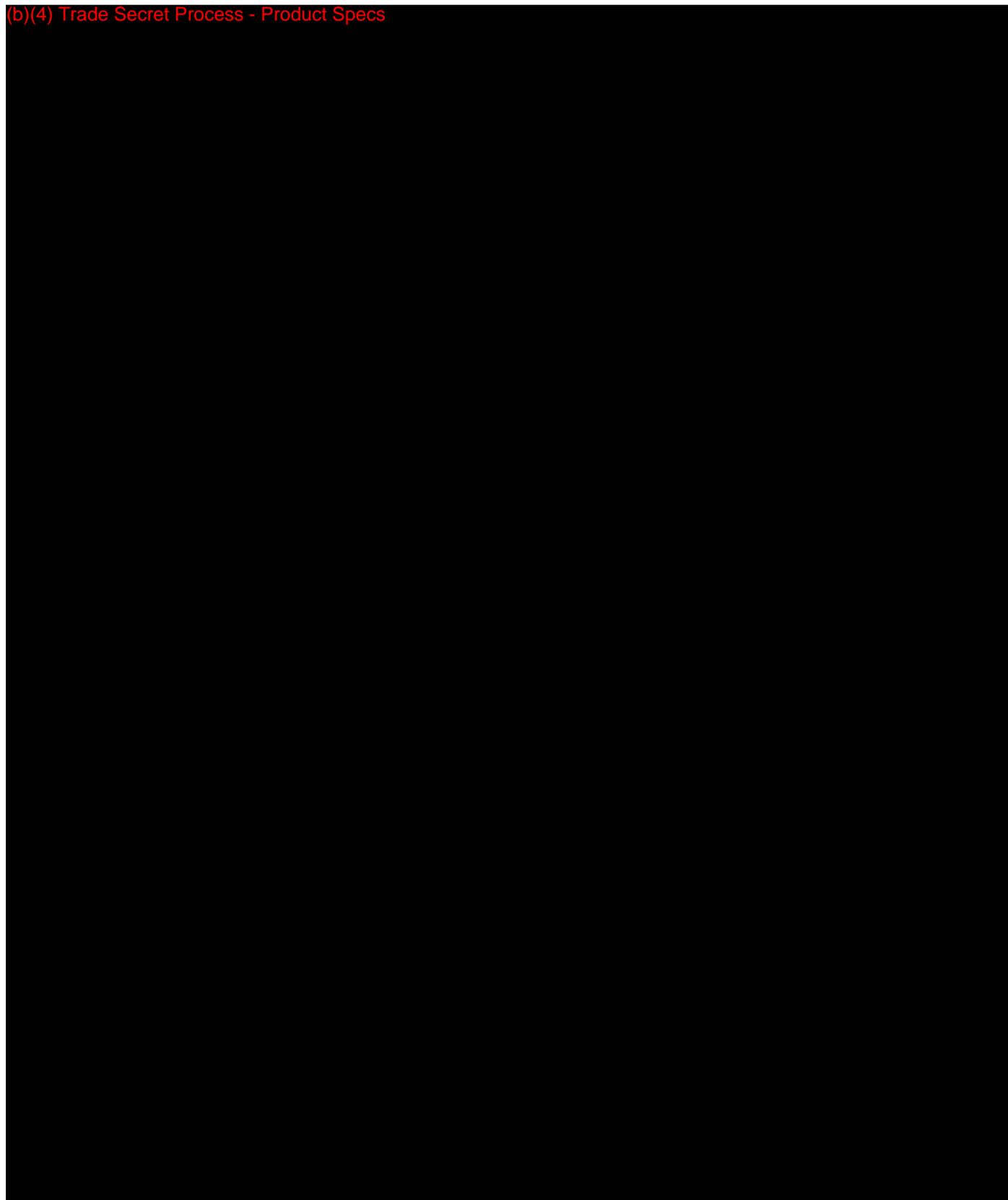
(b)(4) Trade Secret Process - Product Specs



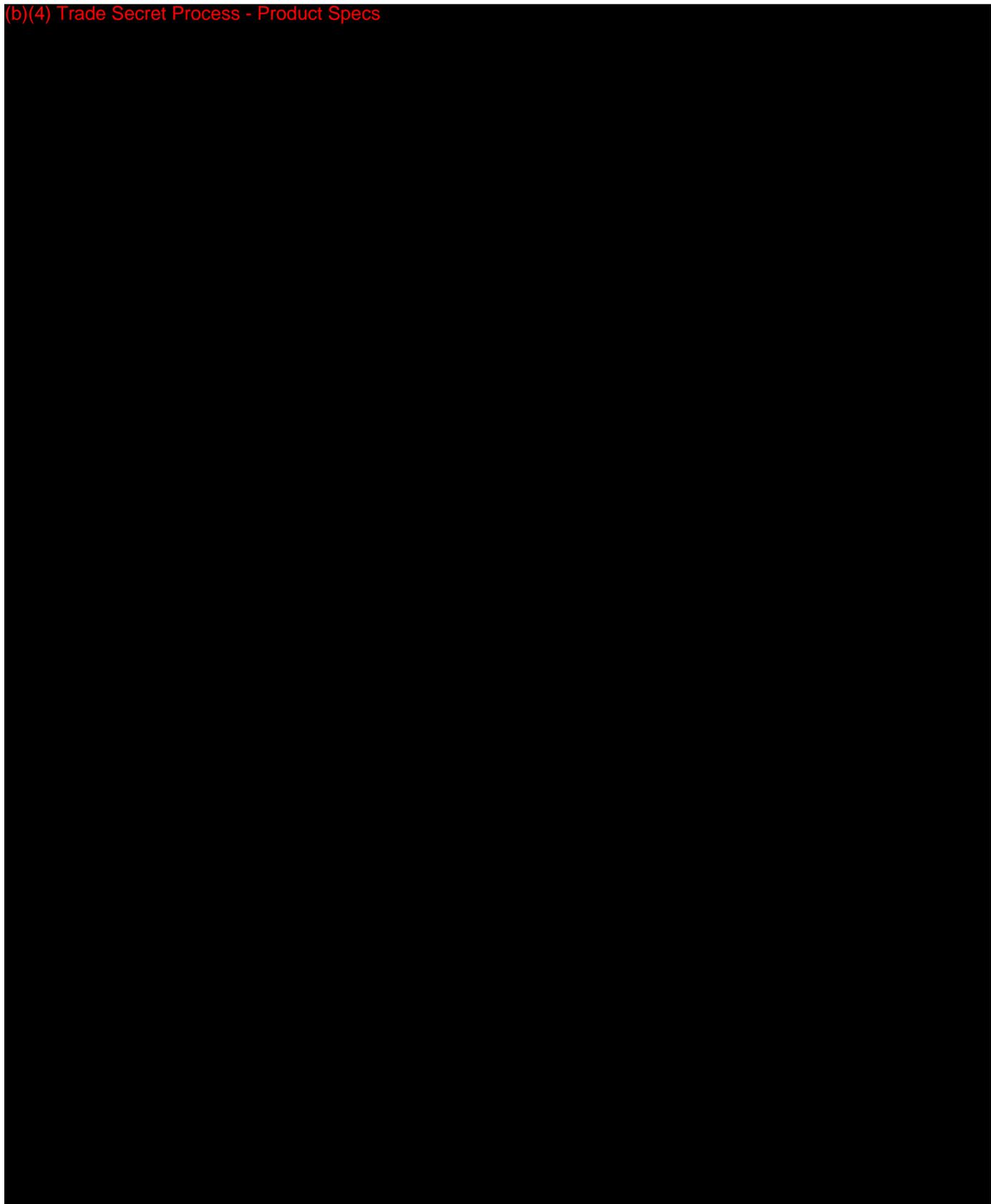
(b)(4) Trade Secret Process - Product Specs



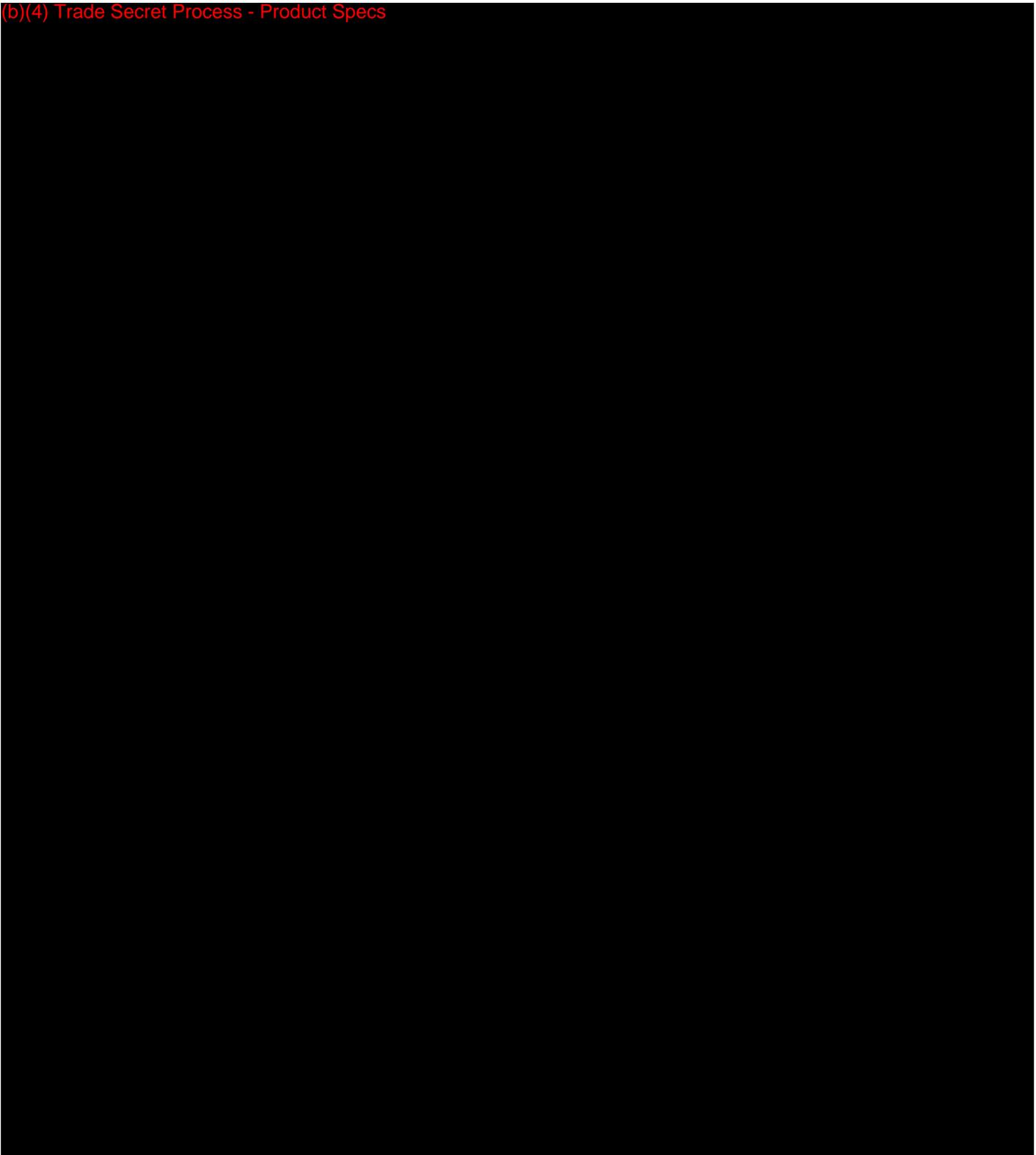
(b)(4) Trade Secret Process - Product Specs



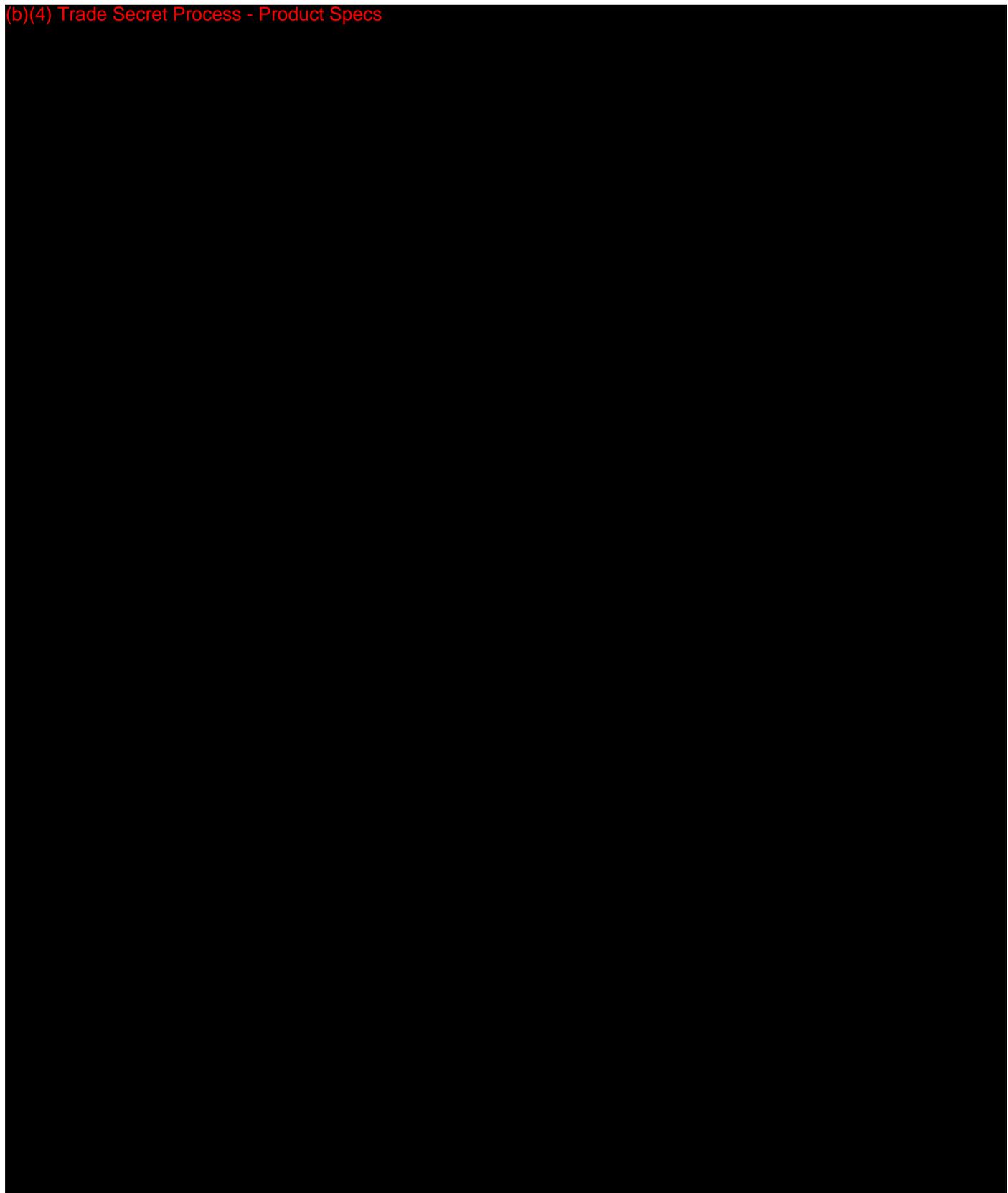
(b)(4) Trade Secret Process - Product Specs



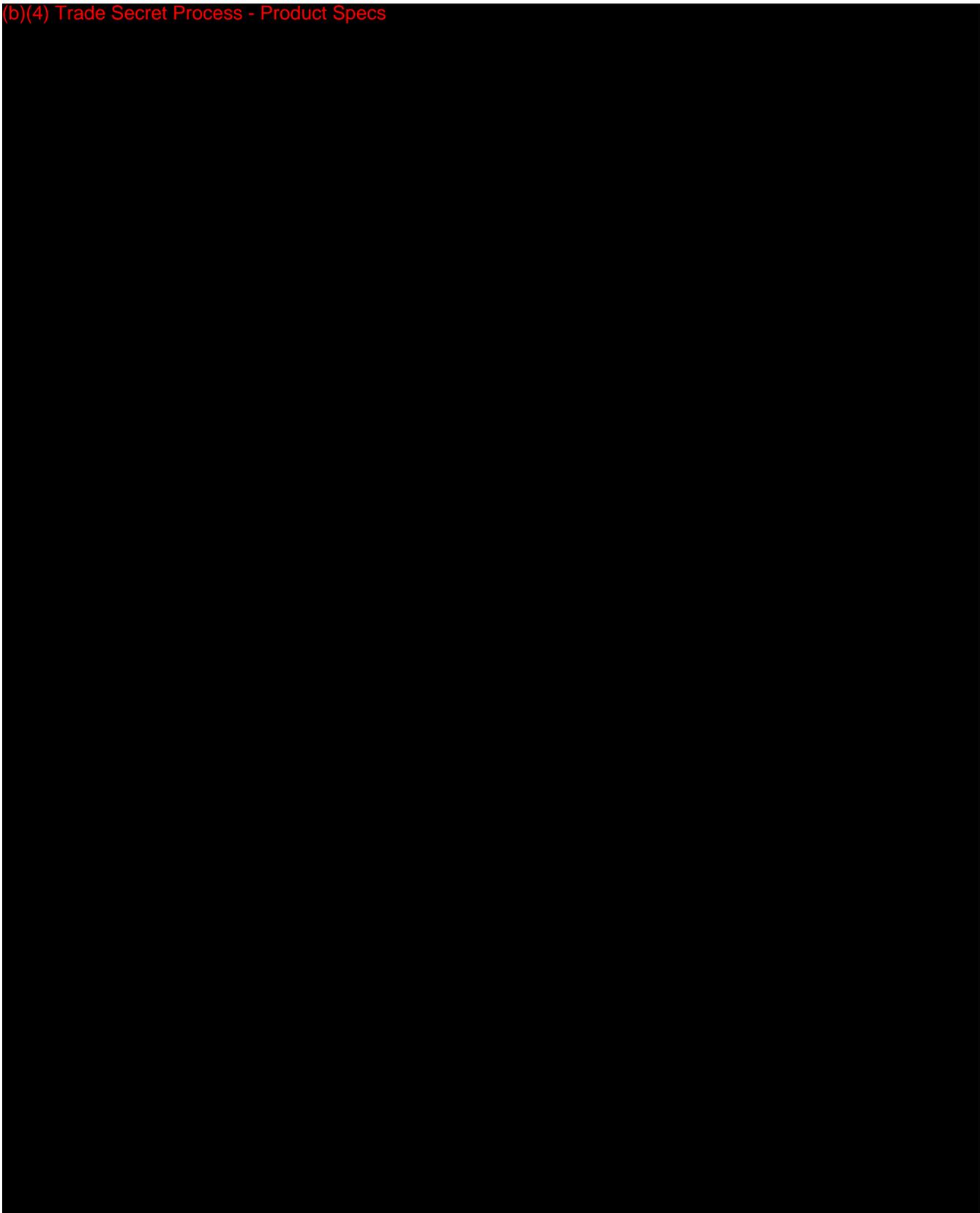
(b)(4) Trade Secret Process - Product Specs



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



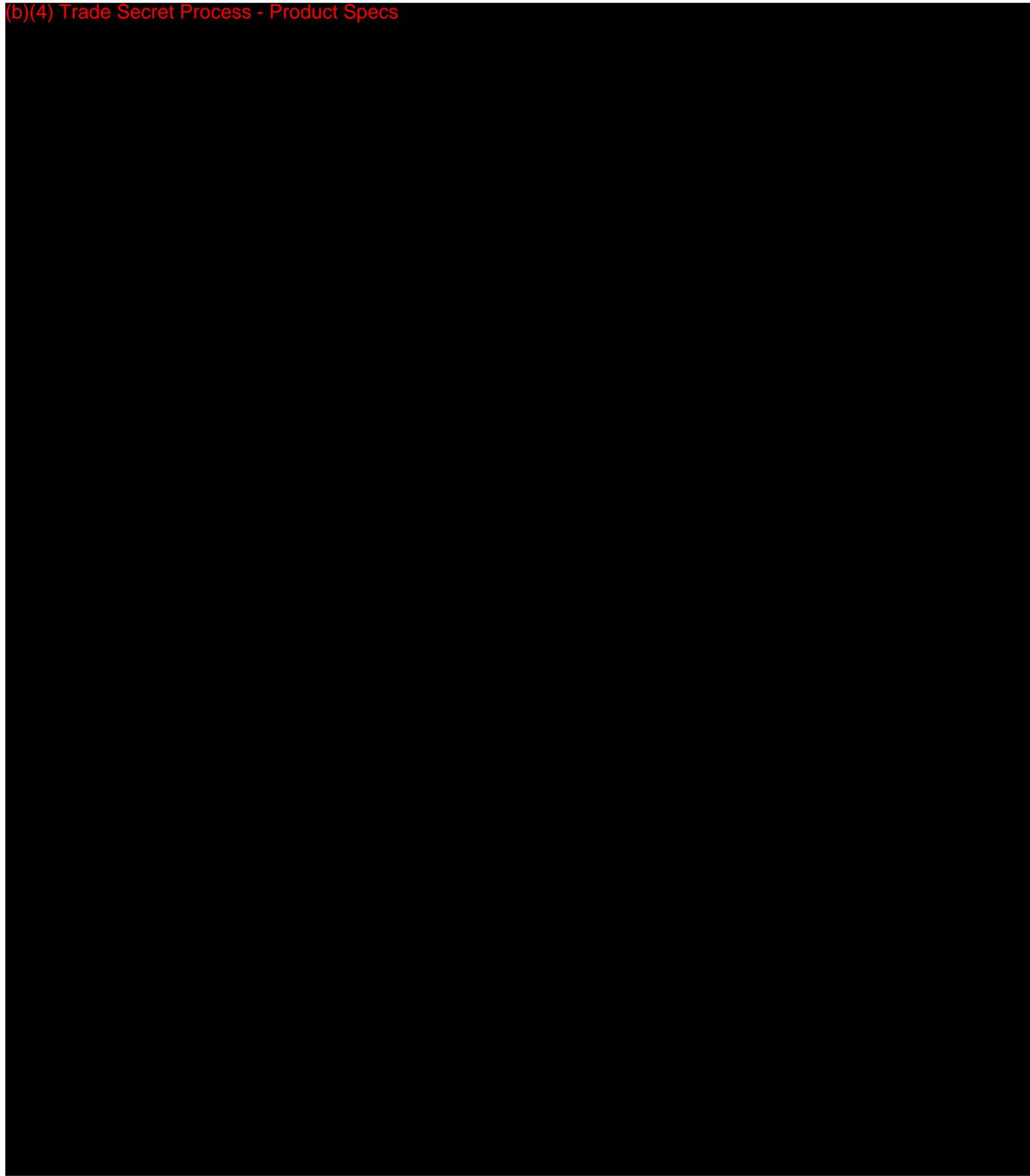
(b)(4) Trade Secret Process - Product Specs



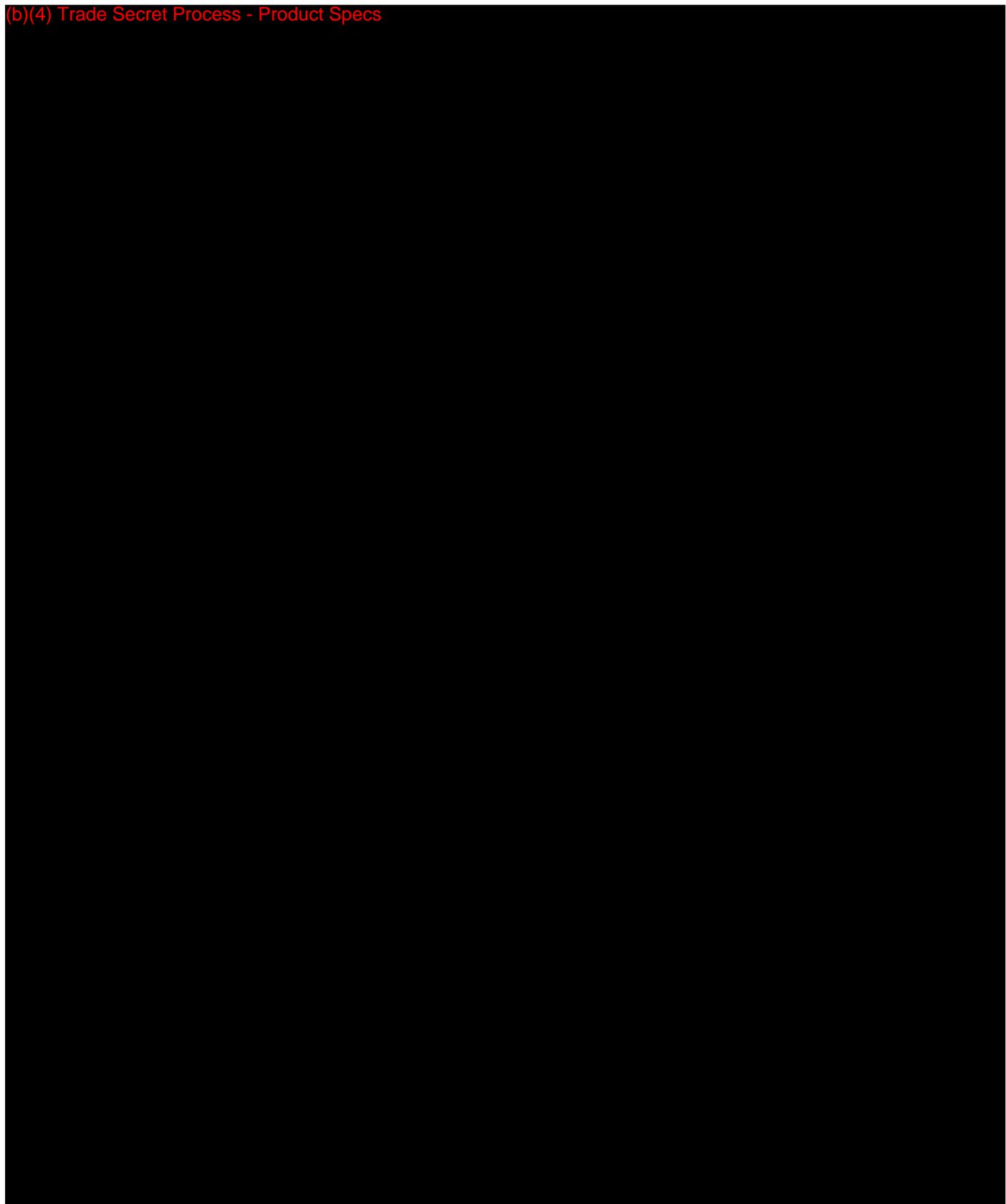
(b)(4) Trade Secret Process - Product Specs



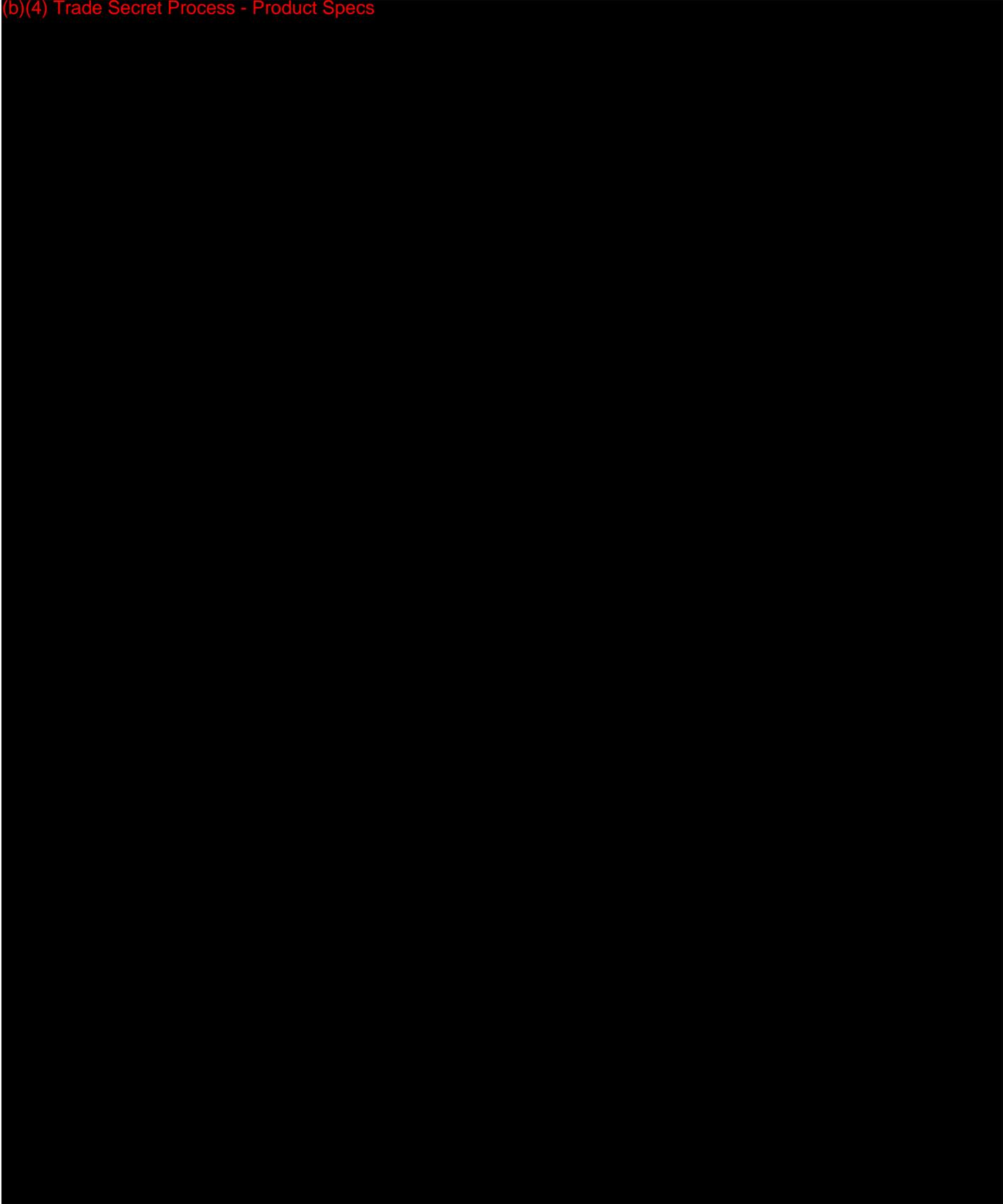
(b)(4) Trade Secret Process - Product Specs



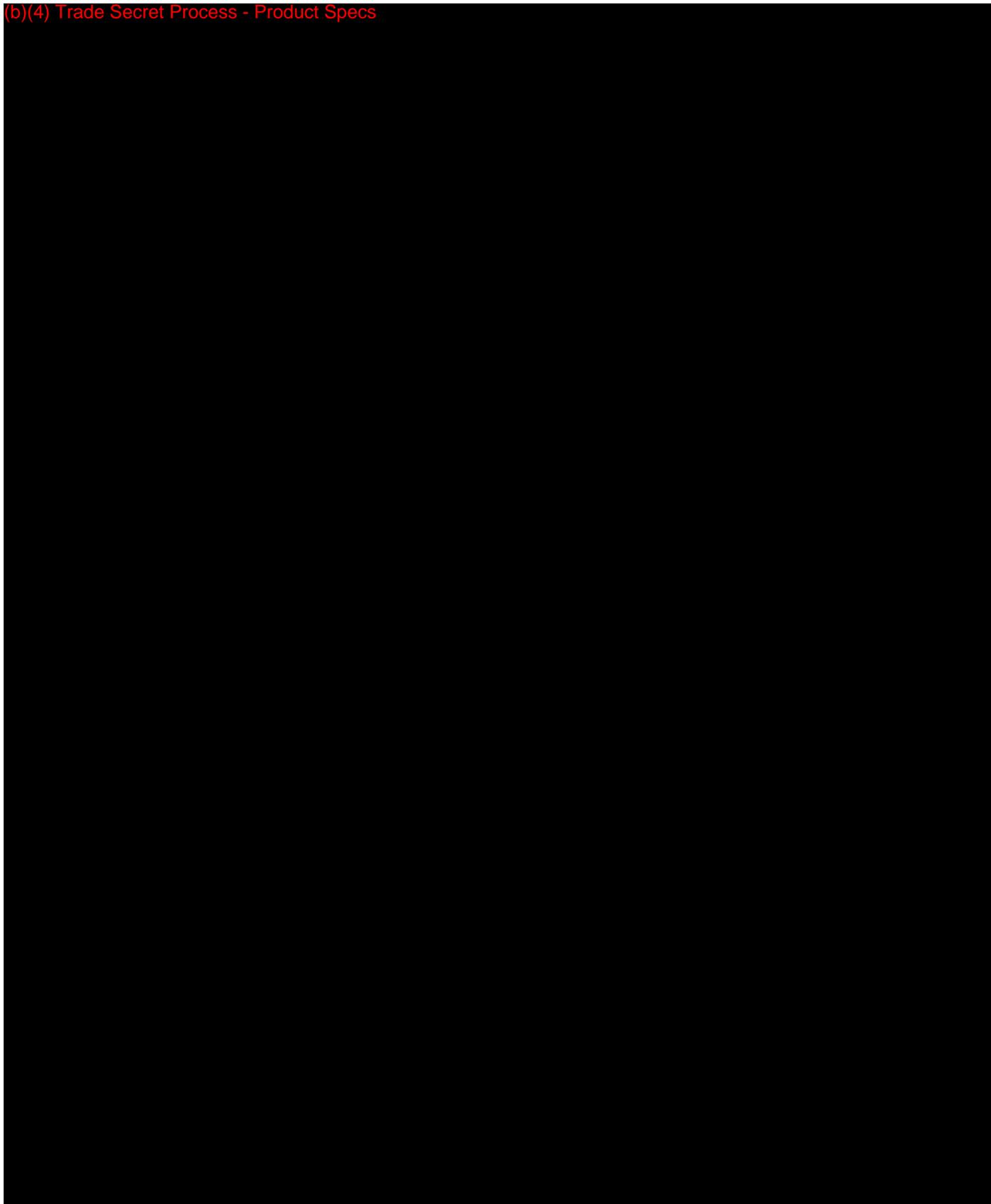
(b)(4) Trade Secret Process - Product Specs



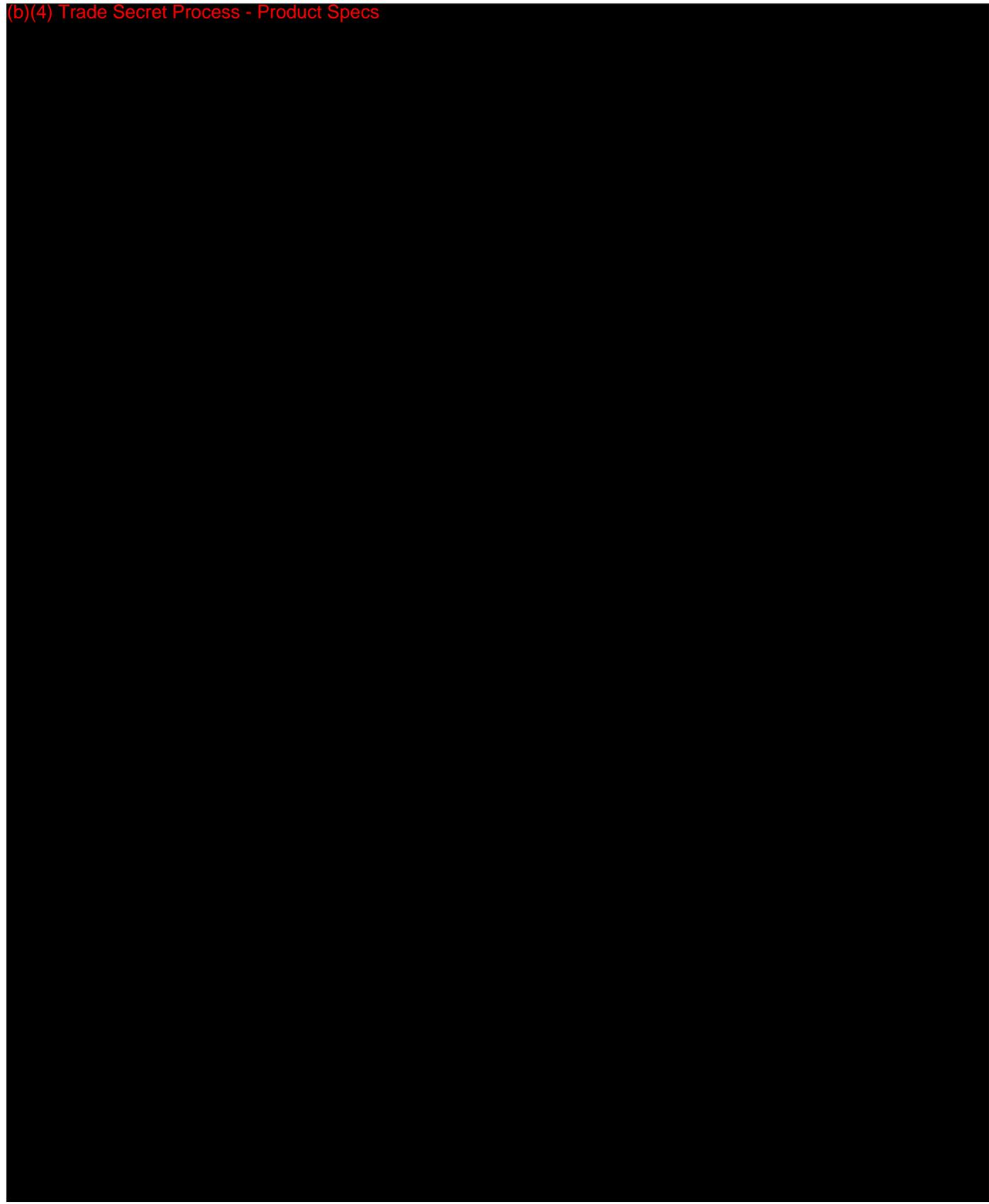
(b)(4) Trade Secret Process - Product Specs



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

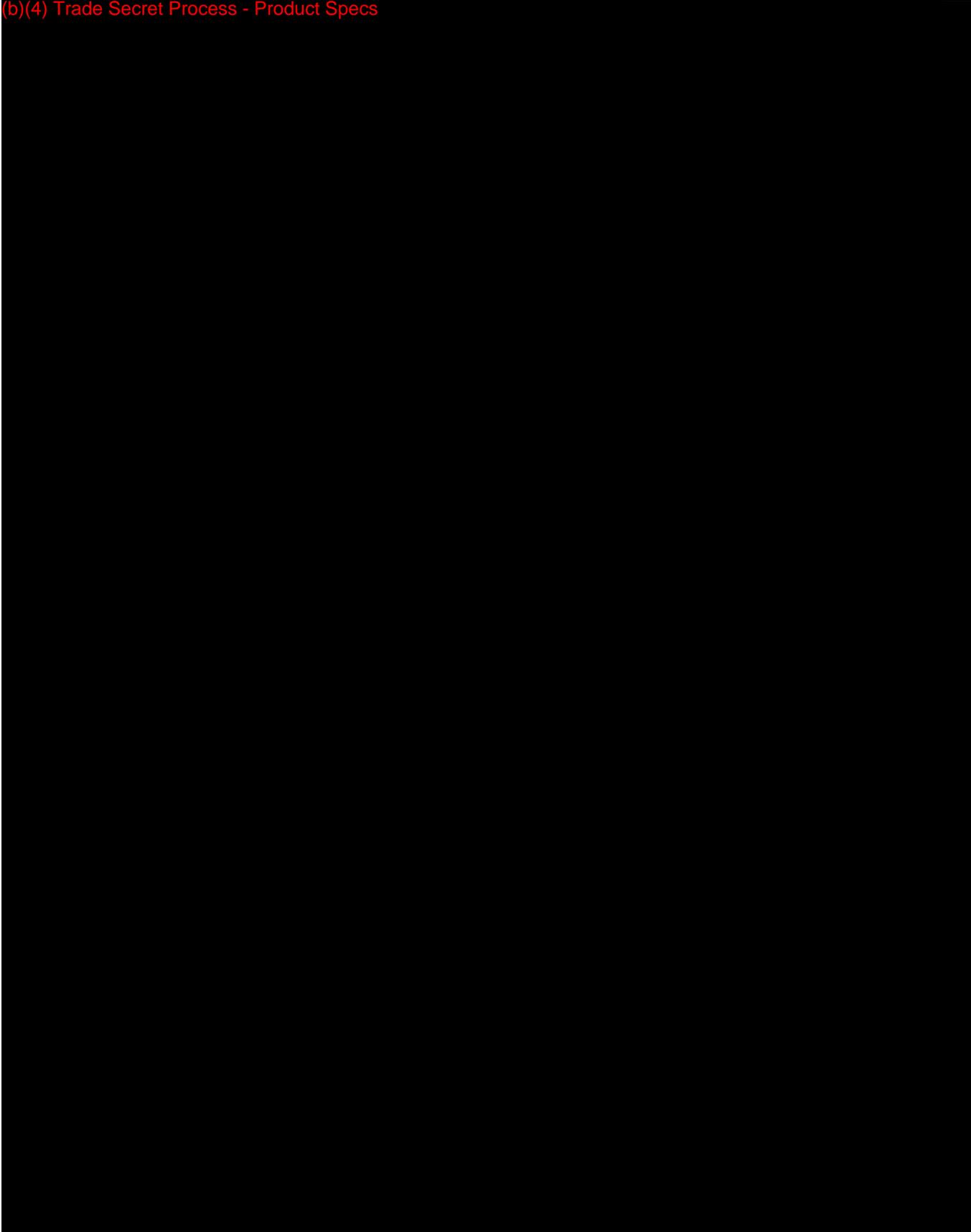


(b)(4) Trade Secret Process - Product Specs

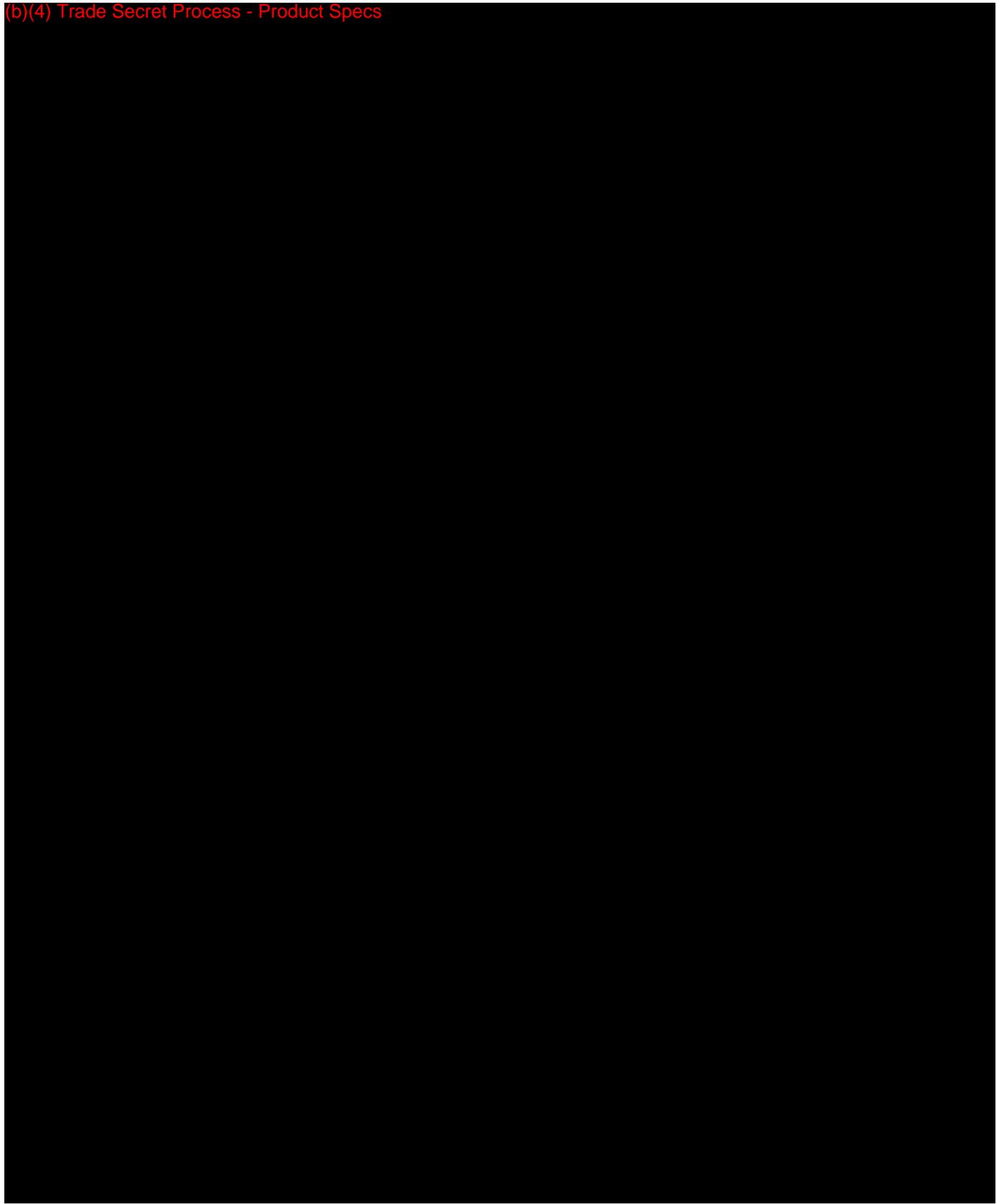




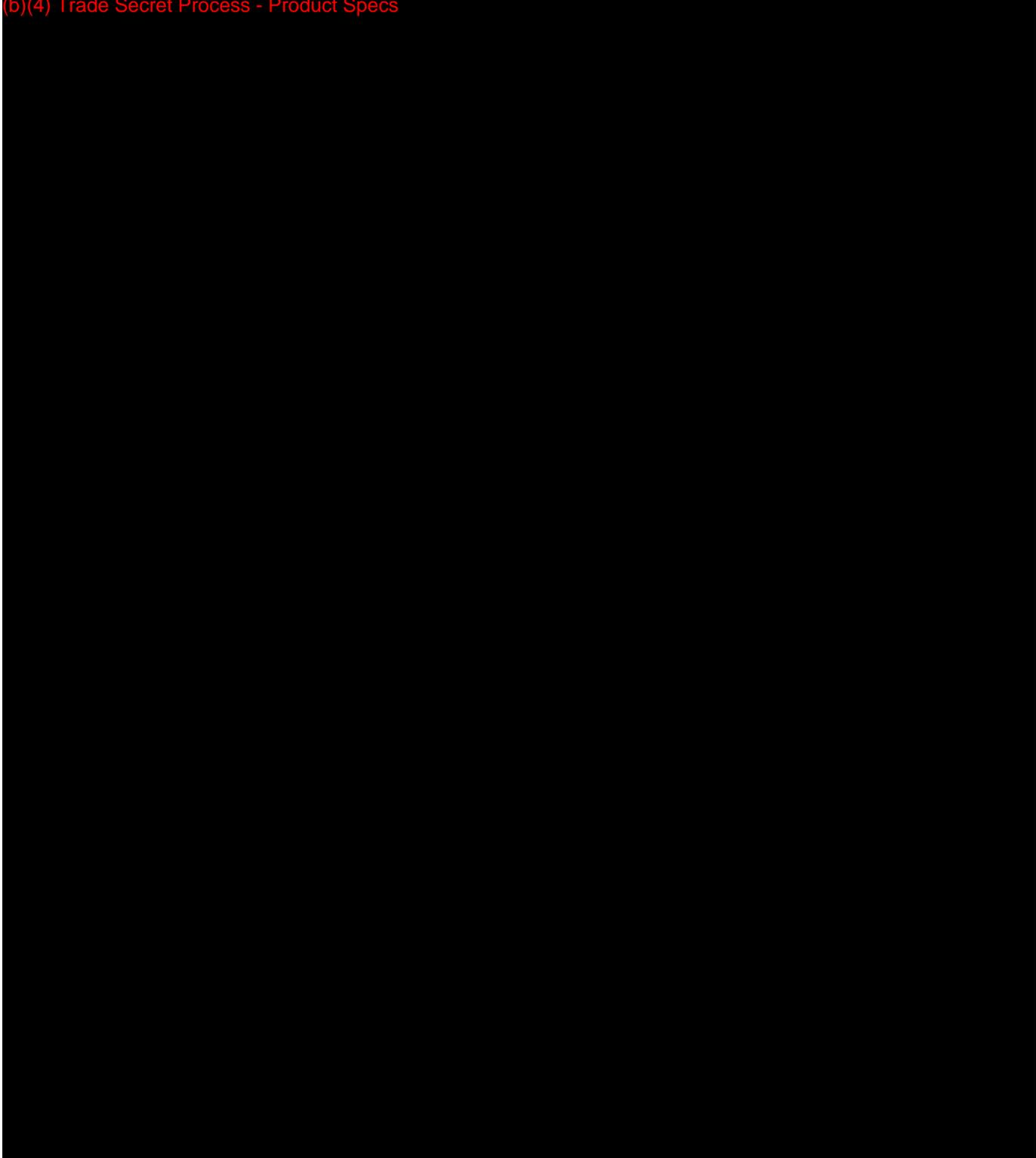
(b)(4) Trade Secret Process - Product Specs



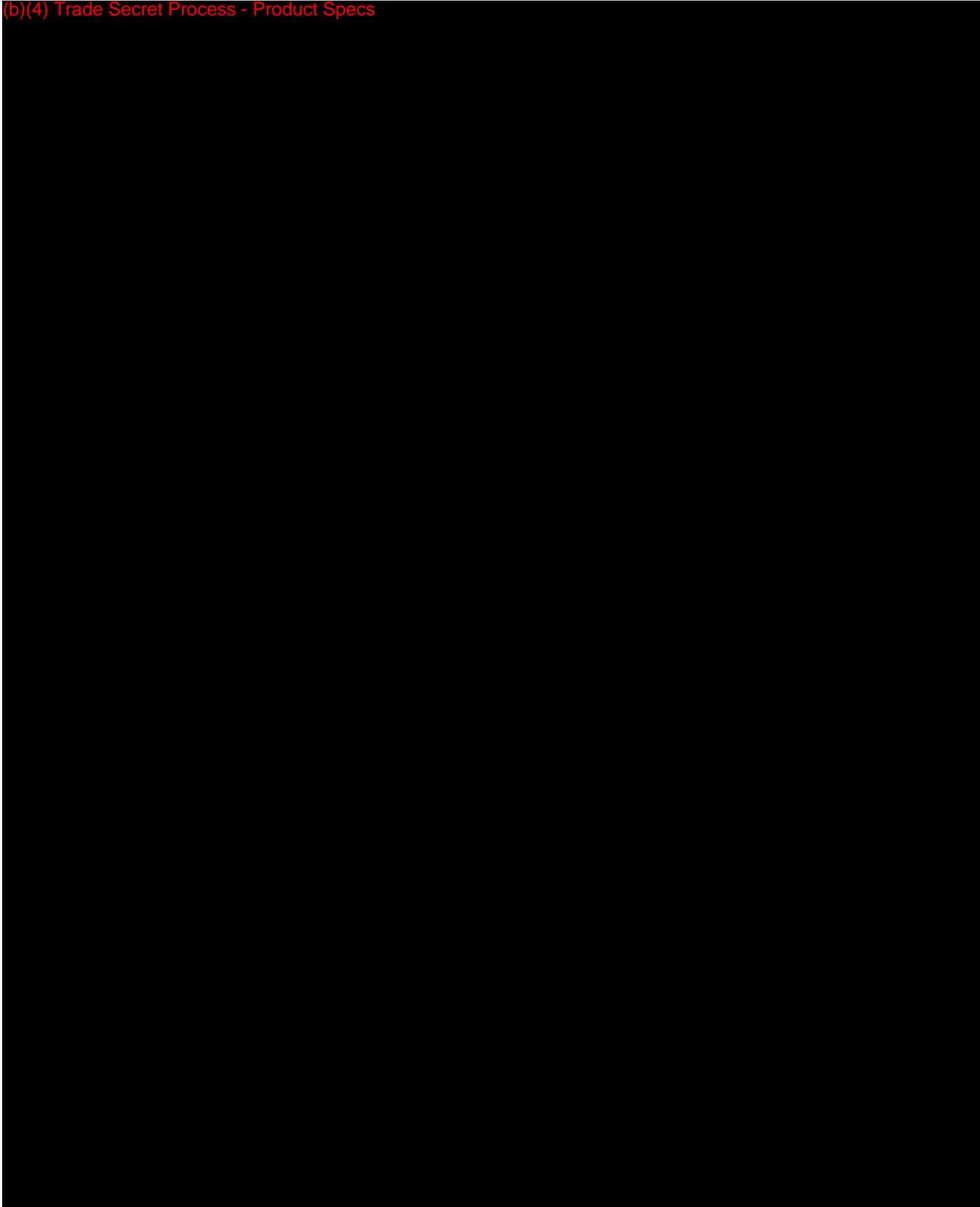
(b)(4) Trade Secret Process - Product Specs



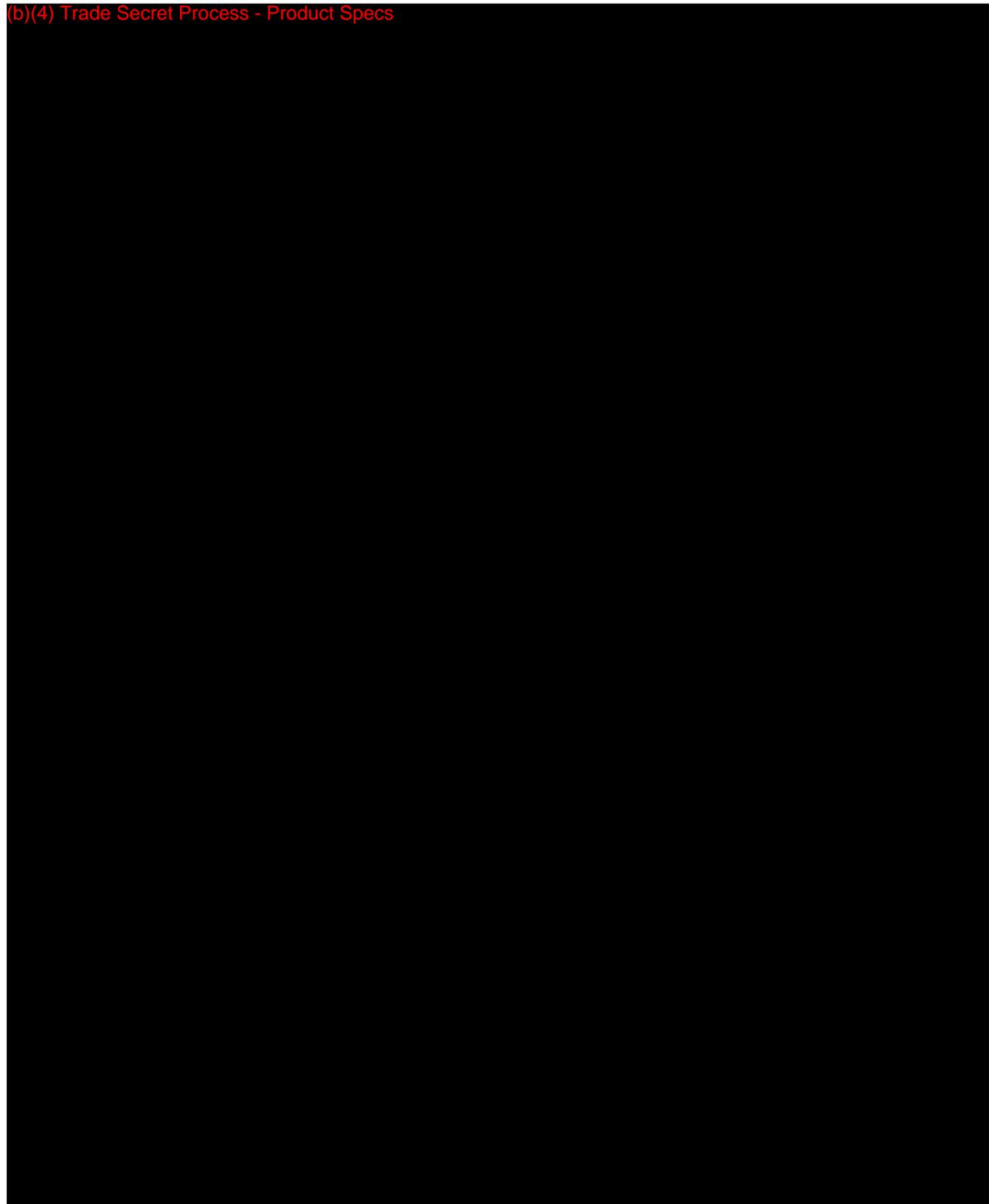
(b)(4) Trade Secret Process - Product Specs



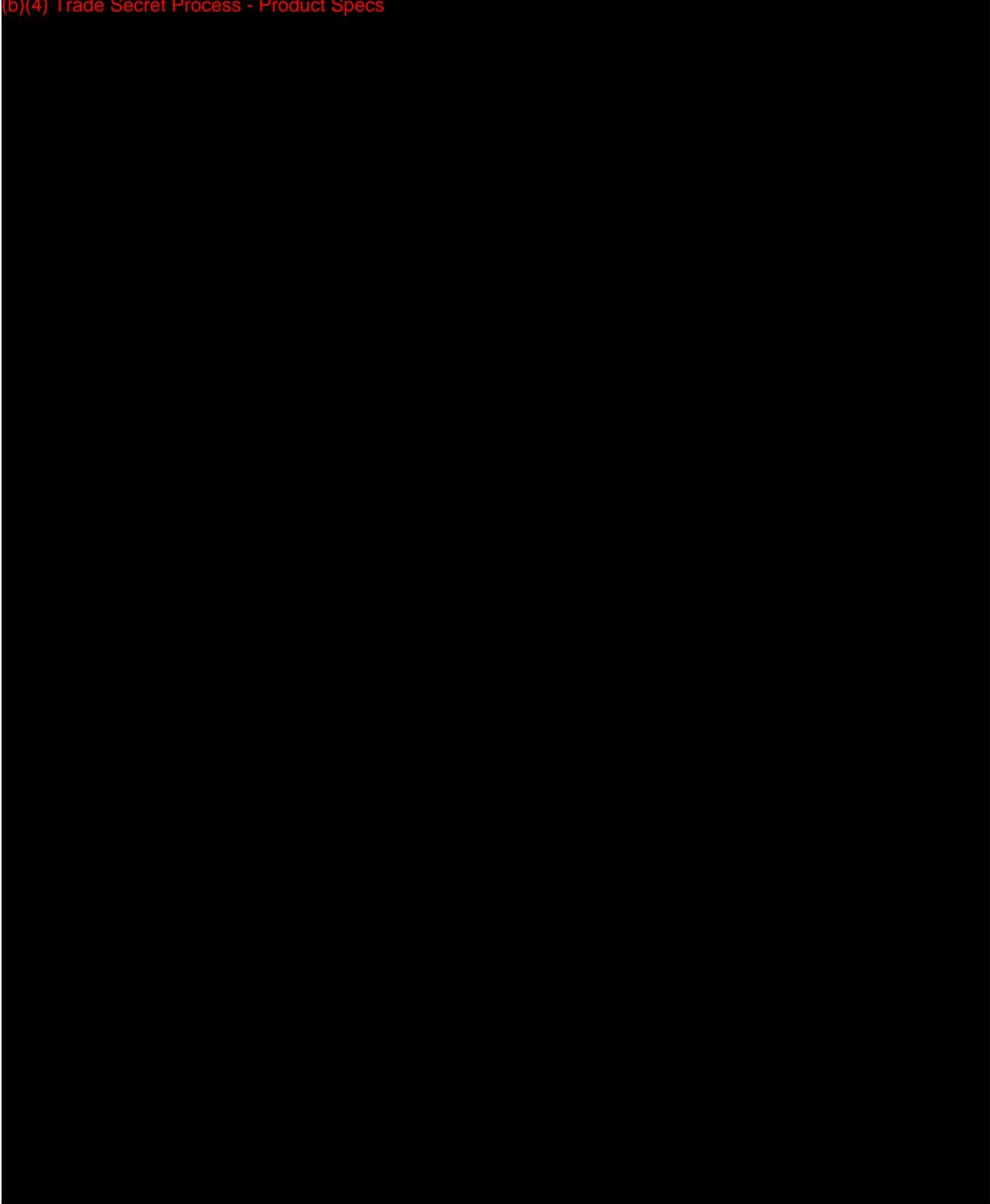
(b)(4) Trade Secret Process - Product Specs



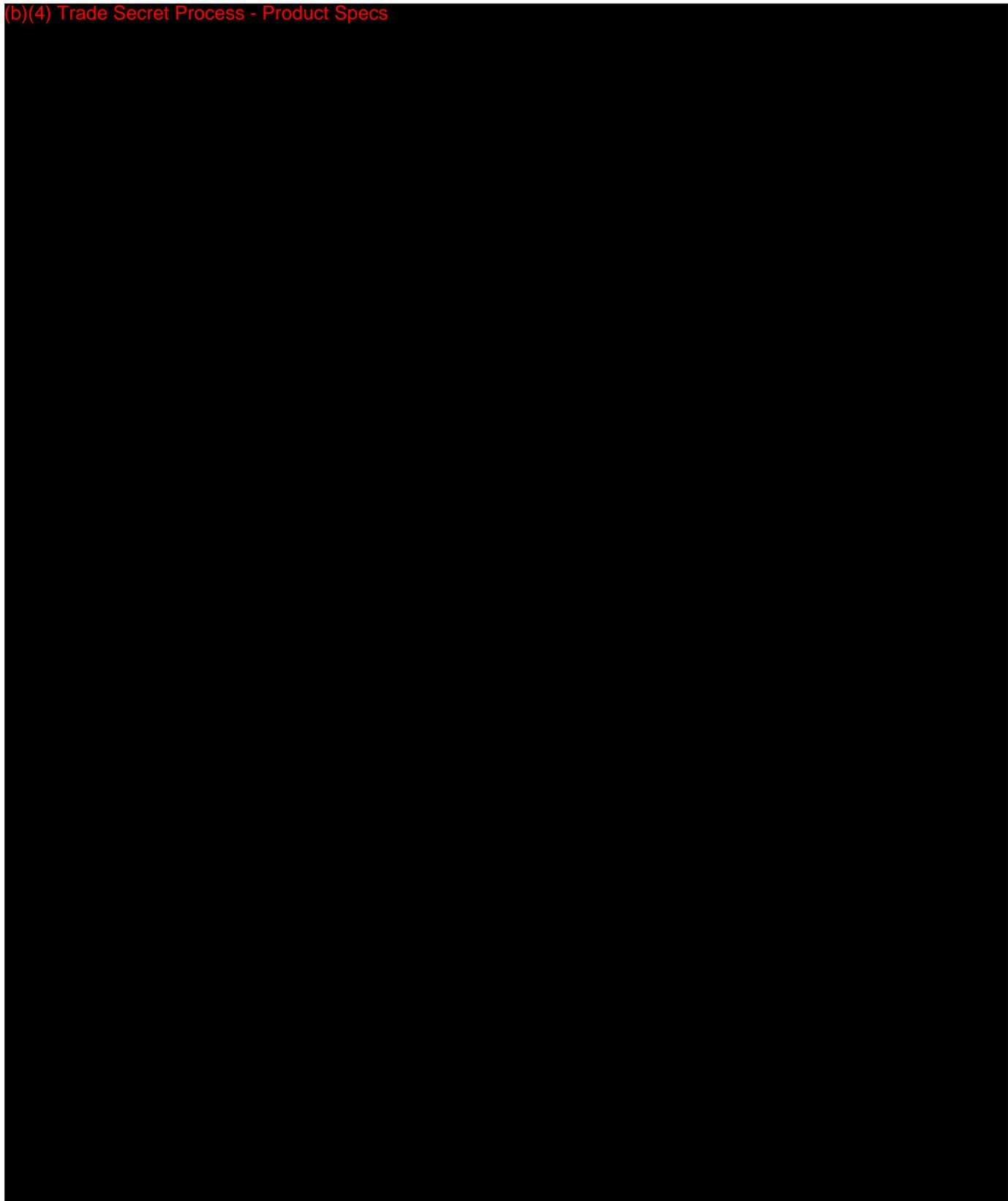
(b)(4) Trade Secret Process - Product Specs



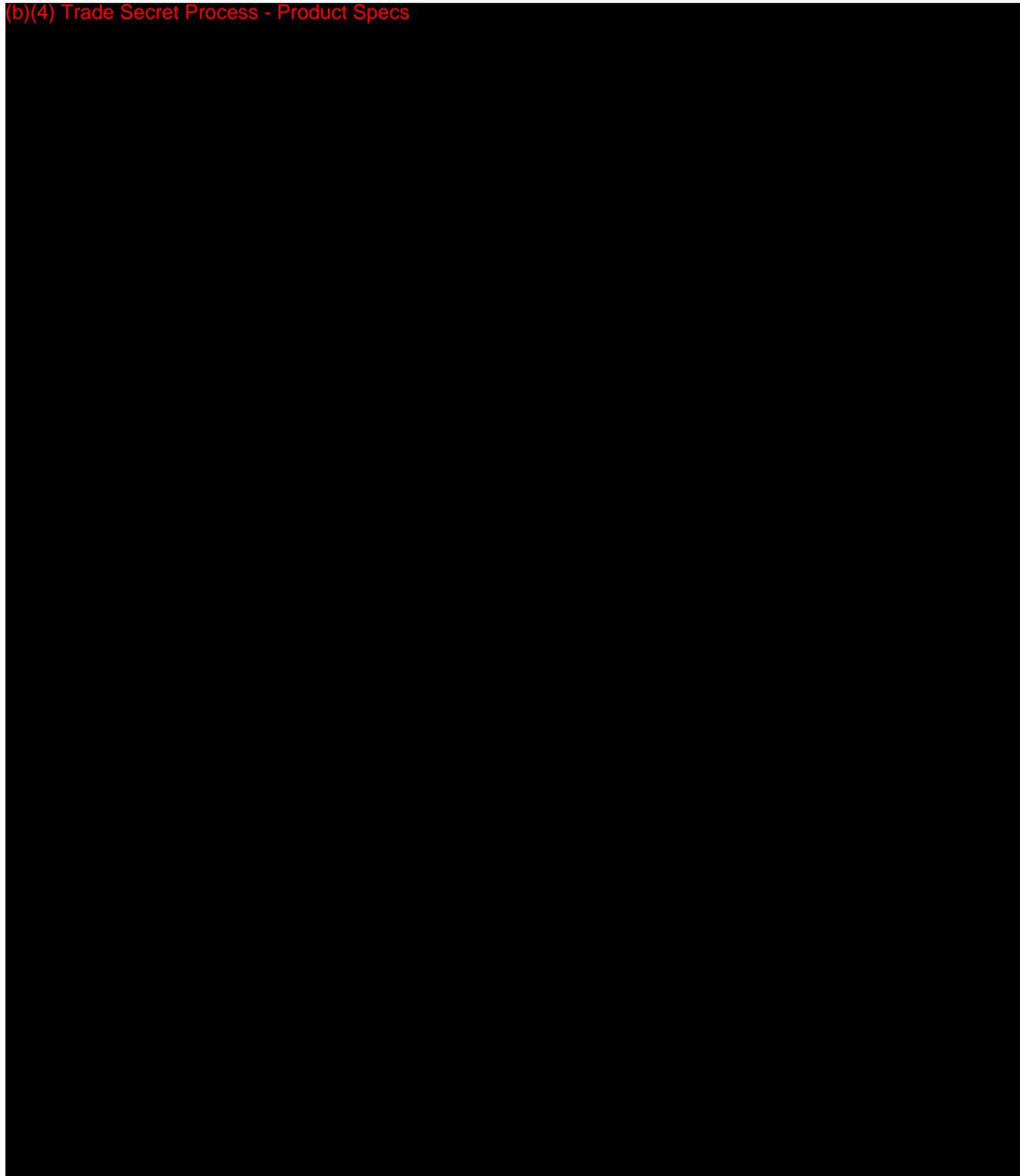
(b)(4) Trade Secret Process - Product Specs



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



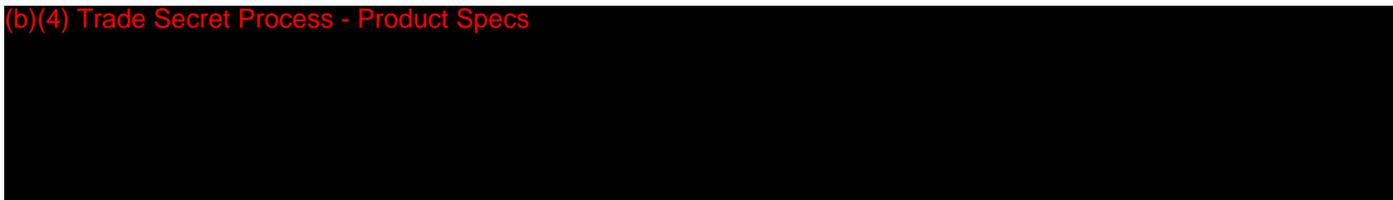
(b)(4) Trade Secret Process - Product Specs



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



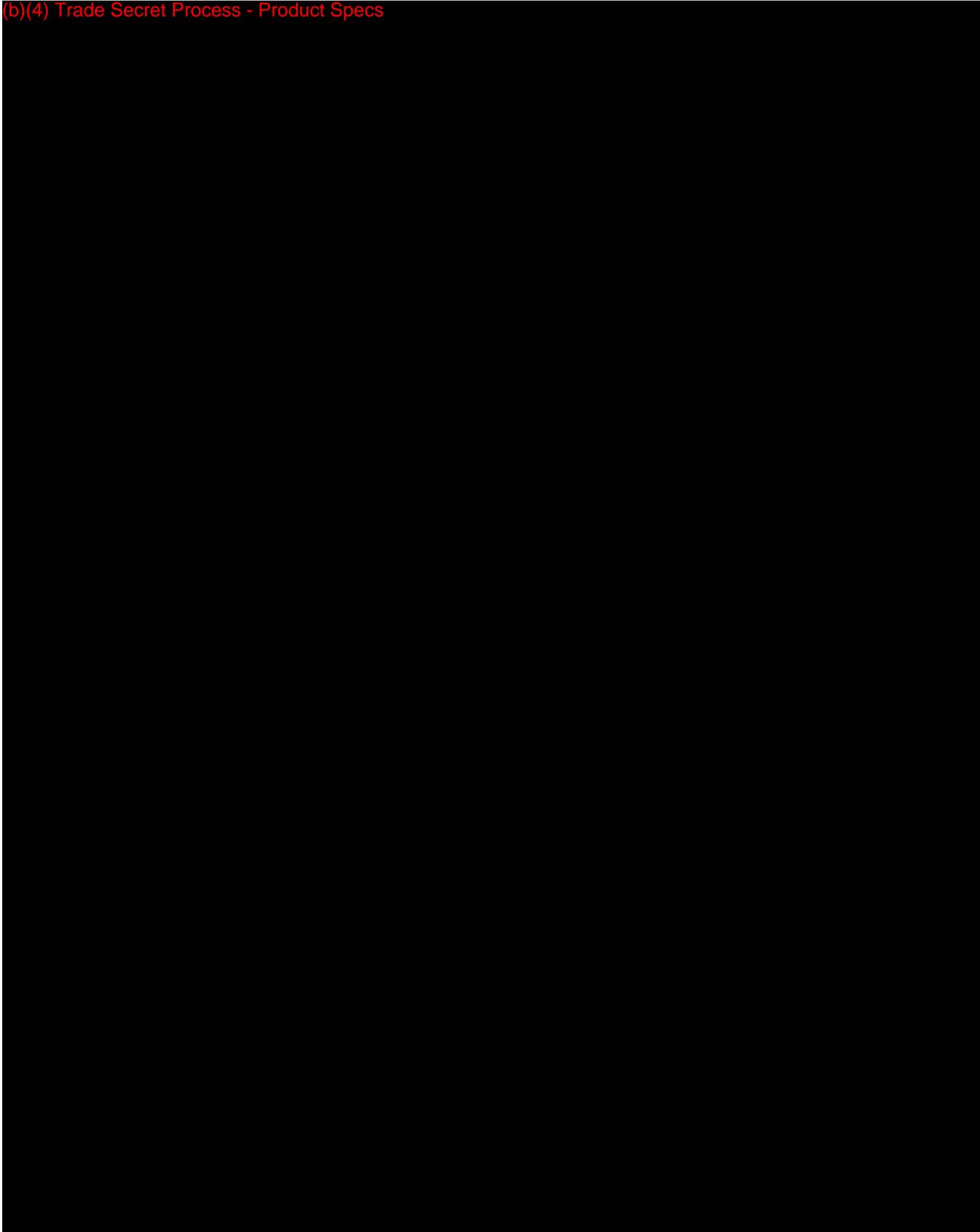
(b)(4) Trade Secret Process - Product Specs



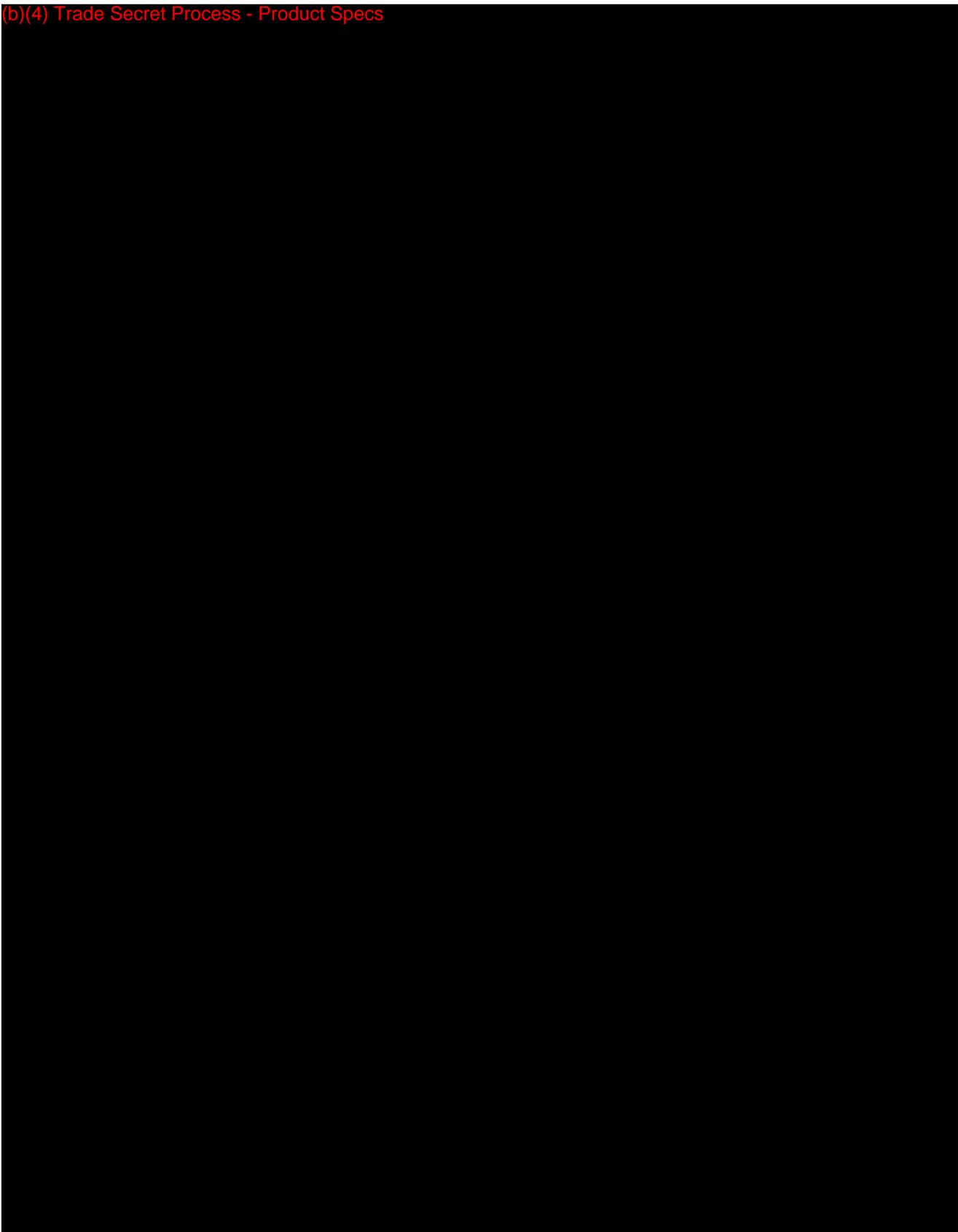
(b)(4) Trade Secret Process - Product Specs



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



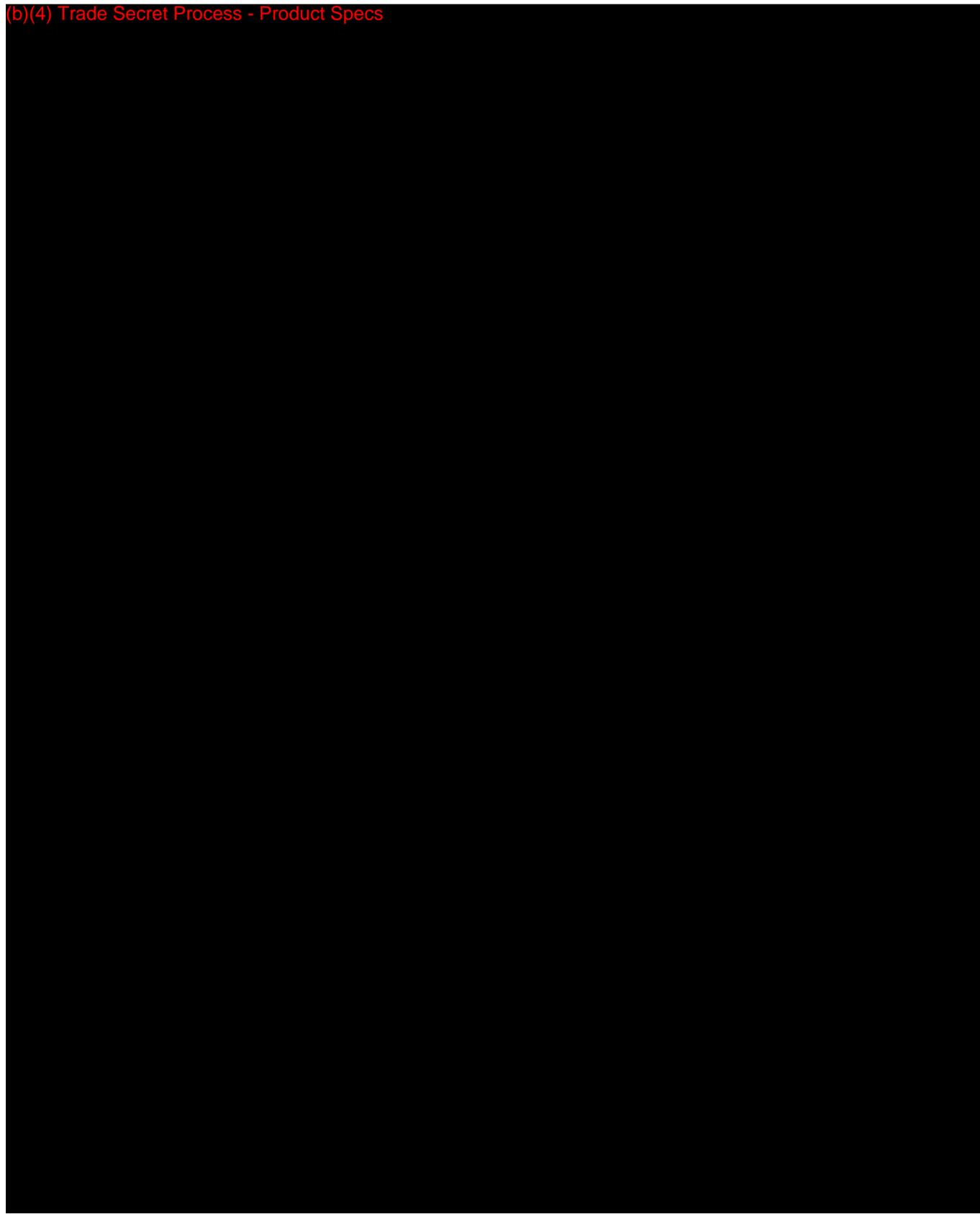
(b)(4) Trade Secret Process - Product Specs



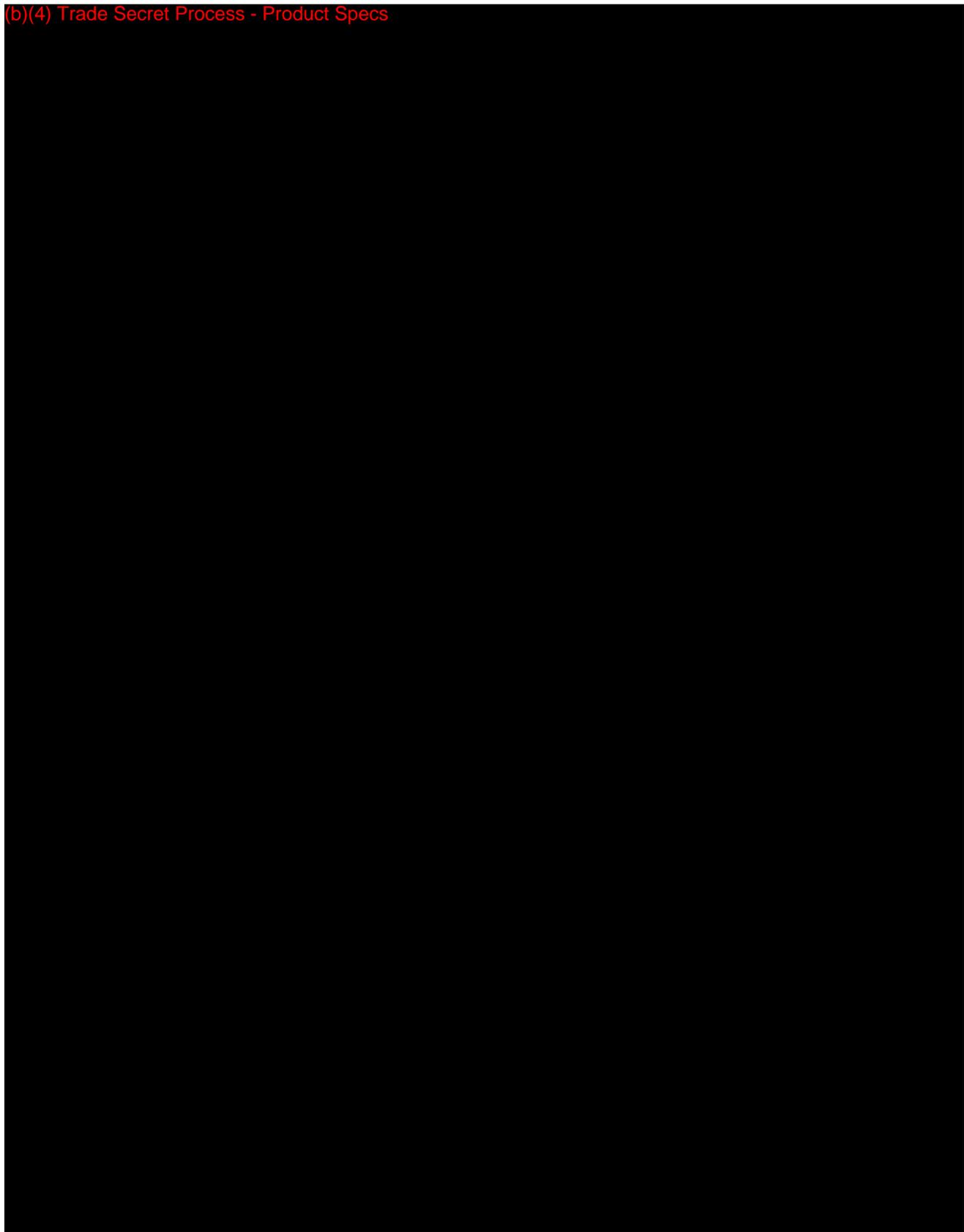
(b)(4) Trade Secret Process - Product Specs



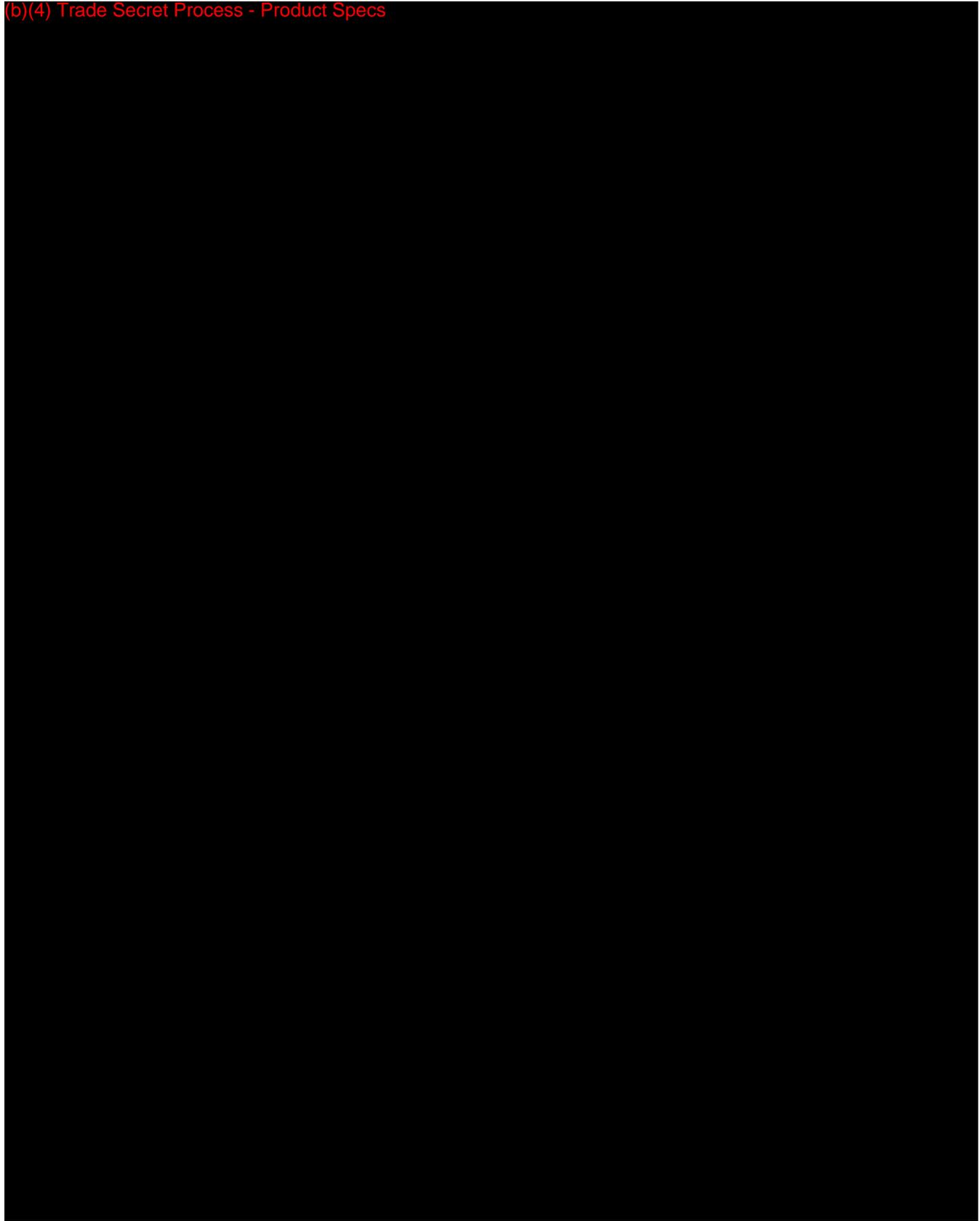
(b)(4) Trade Secret Process - Product Specs



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



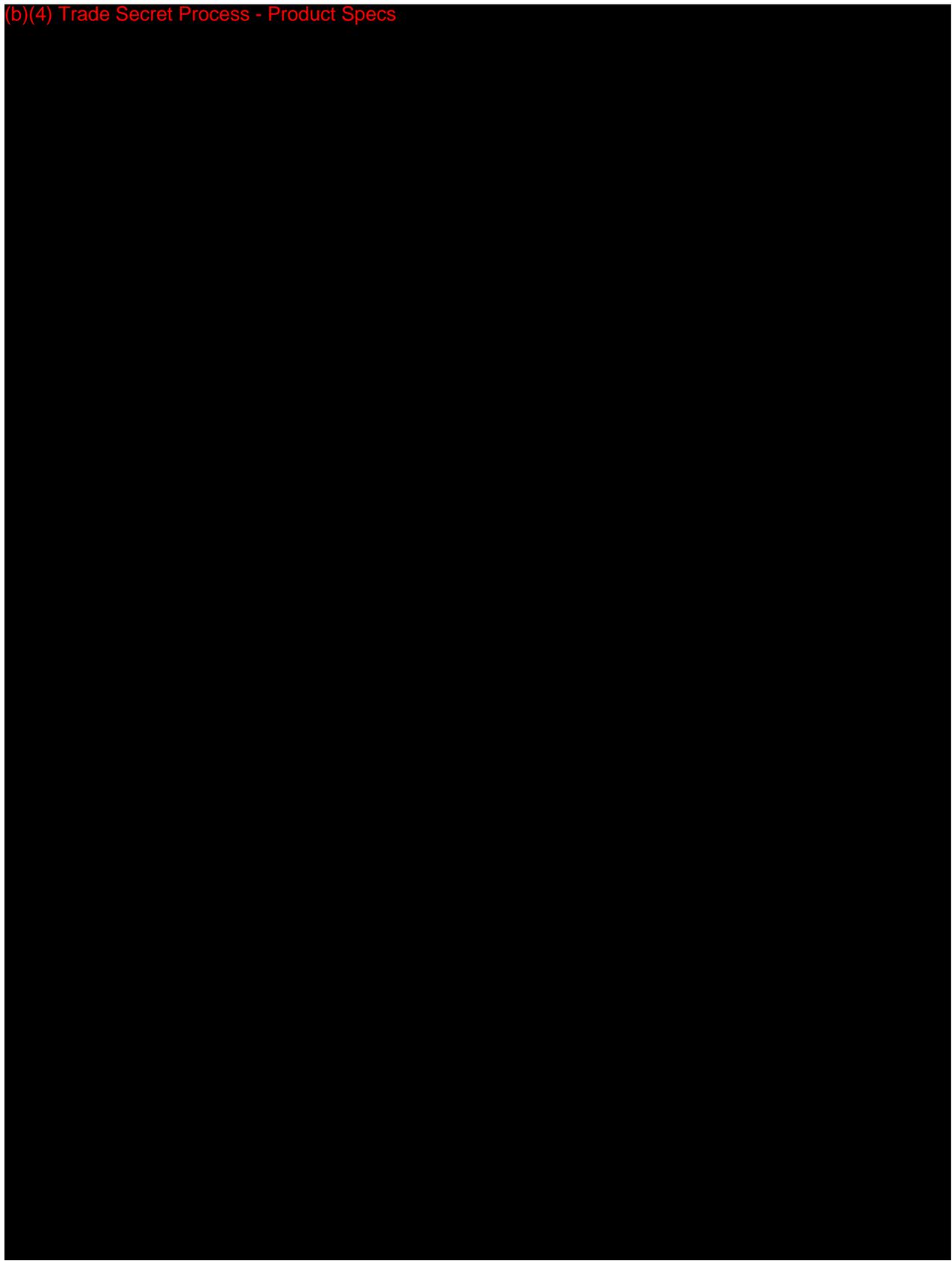
(b)(4) Trade Secret Process - Product Specs



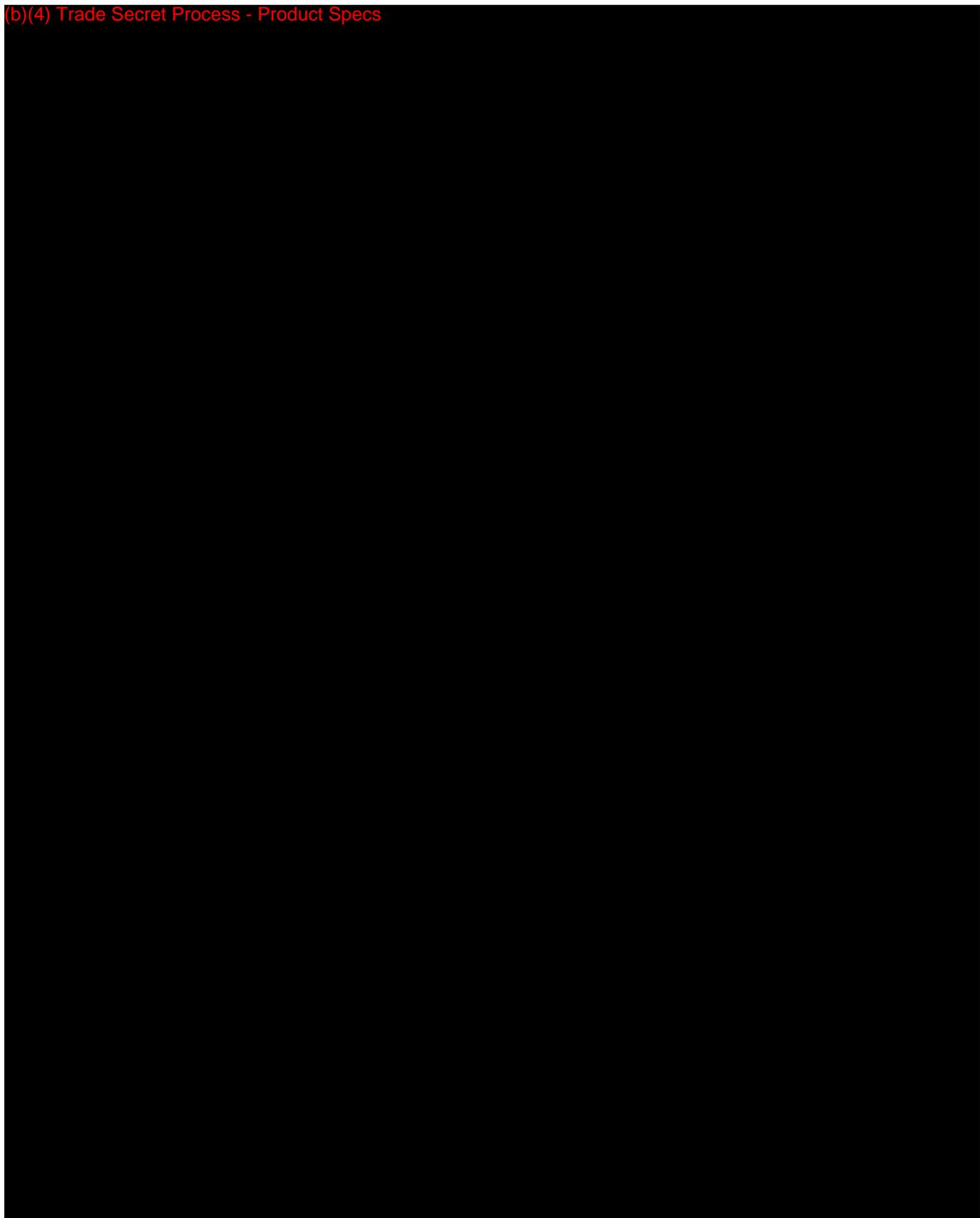
(b)(4) Trade Secret Process - Product Specs



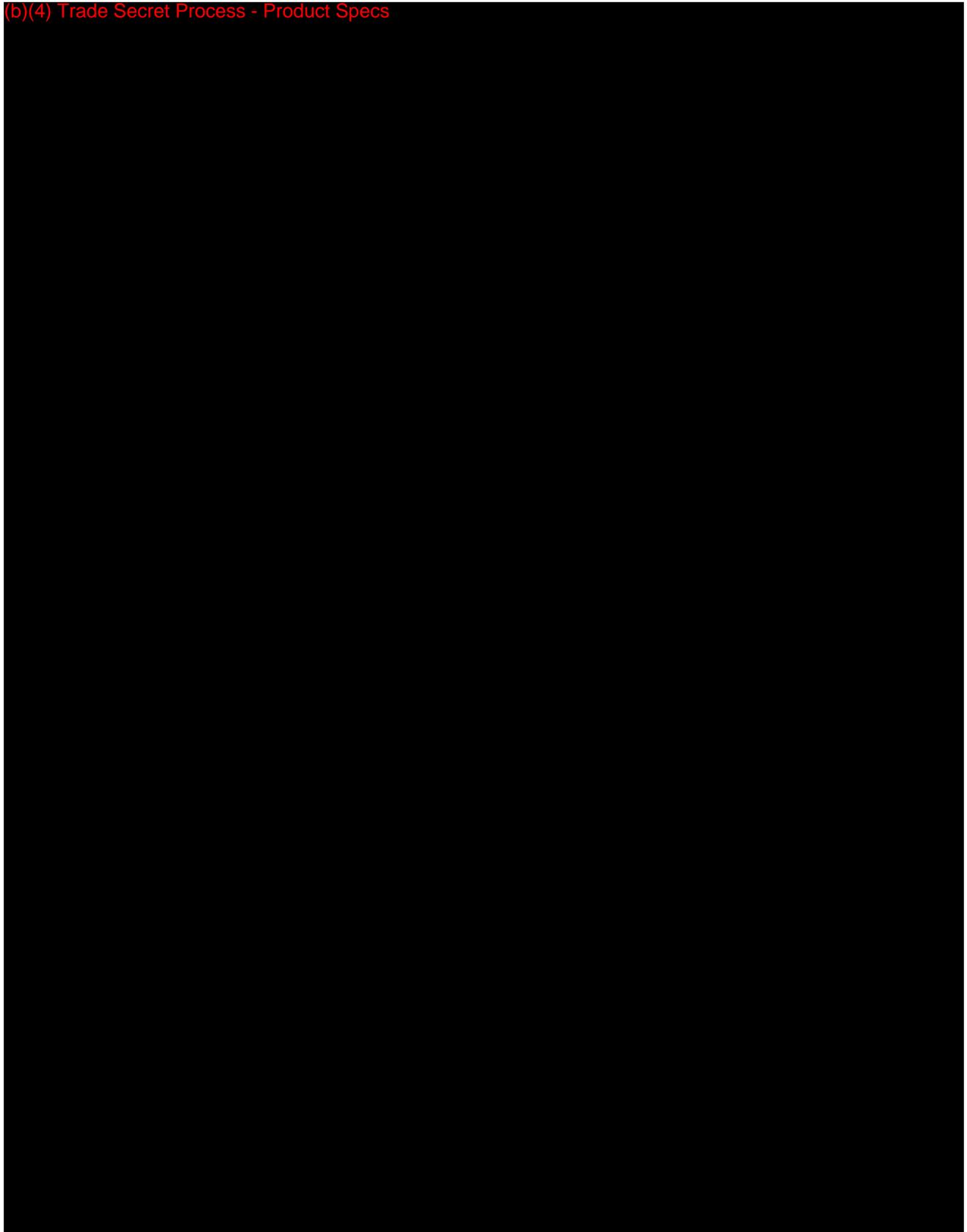
(b)(4) Trade Secret Process - Product Specs



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



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



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



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

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

NEMA PS 3.1 - 3.2 (2011), Digital Imaging and Communications in Medicine (DICOM) Set.

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 12-238

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

Is a summary report ⁴ 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 tests?
 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) ⁵?

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 ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

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

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

⁴ 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 and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
NEMA PS 3.1 - 3.2 (2011), Digital Imaging and Communications in Medicine (DICOM) Set.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER Part 4 Annex B	SECTION TITLE STORAGE SERVICE CLASS	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Service Class Specifications		
DESCRIPTION Conformance met		
JUSTIFICATION See Appendix 1 - DICOM Conformance Statement and Appendix 9 - Verification and Validation Procedure, and Test Report		

SECTION NUMBER Part 4 Annex C	SECTION TITLE QUERY/RETRIEVE SERVICE CLASS	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Service Class Specifications		
DESCRIPTION Conformance met		
JUSTIFICATION See Appendix 1 - DICOM Conformance Statement and Appendix 9 - Verification and Validation Procedure, and Test Report		

SECTION NUMBER Part 4 Annex K	SECTION TITLE BASIC WORKLIST MANAGEMENT SERVICE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Service Class Specifications		
DESCRIPTION Conformance met		
JUSTIFICATION See Appendix 1 - DICOM Conformance Statement and Appendix 9 - Verification and Validation Procedure, and Test Report		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
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 number.

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

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 62304 Ed. 1.0, Medical device software - Software life cycle processes, 2006

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #13-8

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

Is a summary report ⁴ 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 tests?
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) ⁵?

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 ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

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

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

⁴ 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 and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 62304 Ed. 1.0, Medical device software - Software life cycle processes, 2006

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 5, 6	SECTION TITLE 5 - Software development process, 6 - Software maintenance process	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
------------------------	---	--

TYPE OF DEVIATION OR OPTION SELECTED *
Classification of software development and maintenance process

DESCRIPTION
Conformance met

JUSTIFICATION
See Appendix 3 - Software Development Lifecycle

SECTION NUMBER 7, 8	SECTION TITLE 7 - Software risk management process, 8 - Software configuration process	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
------------------------	---	--

TYPE OF DEVIATION OR OPTION SELECTED *
Classification of software risk management process and software configuration management process

DESCRIPTION
Conformance met

JUSTIFICATION
See Appendix 7 - Hazard Analysis and Appendix 3 - Software Development Lifecycle

SECTION NUMBER 9	SECTION TITLE 9 - Software problem resolution process	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------	--	--

TYPE OF DEVIATION OR OPTION SELECTED *
Classification of software problem resolution process

DESCRIPTION
Conformance met

JUSTIFICATION
See Appendix 3 - Software Development Lifecycle

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
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 number.

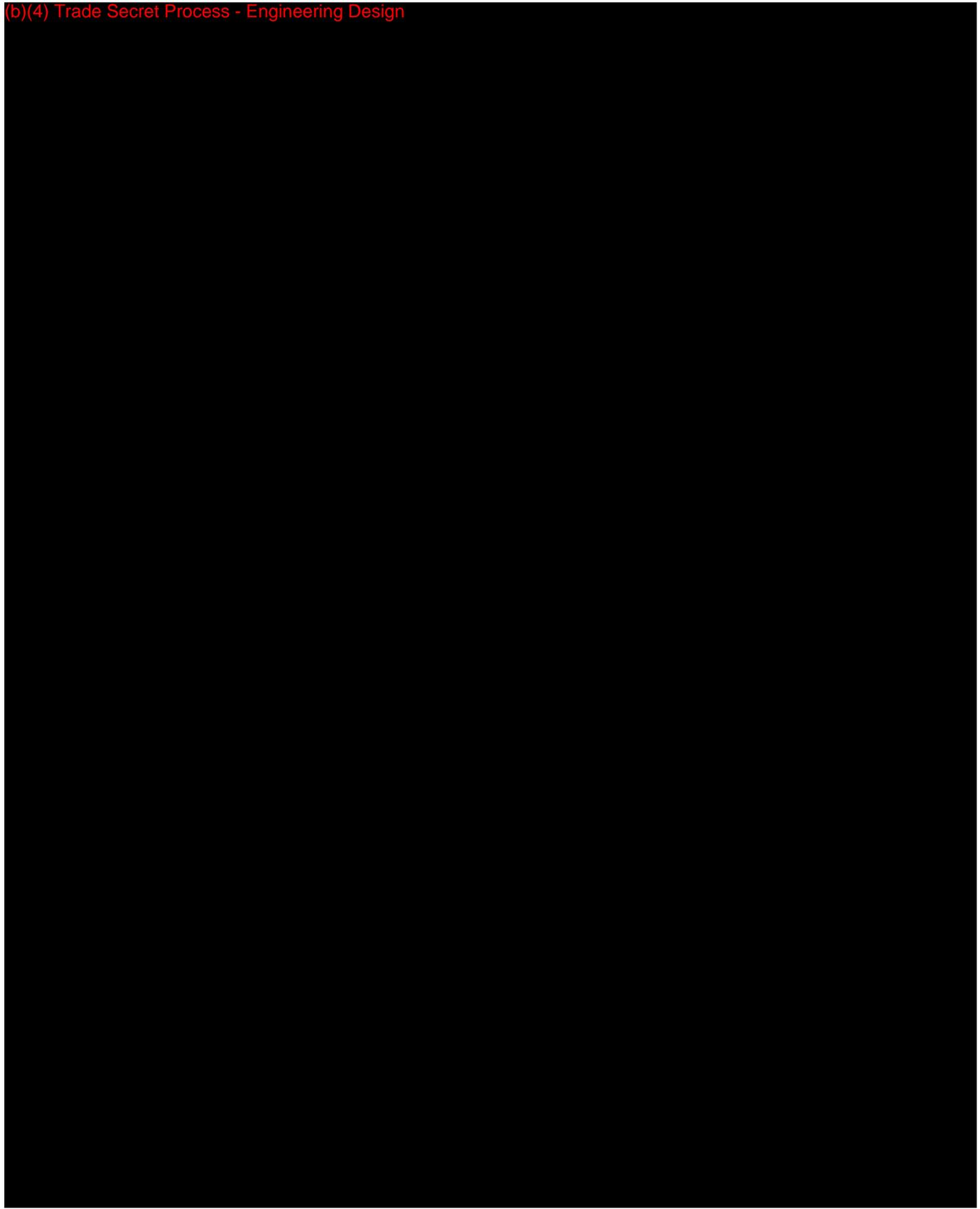
	Software Development Lifecycle	QSP-0302	
	Owner: Engineering	Rev. 1	Page 1 of 23

REVISION HISTORY			
Revision	Description of Change	Date	Changed By
	(b)(4) Trade Secret Process - Product Specs		

CONFIDENTIAL

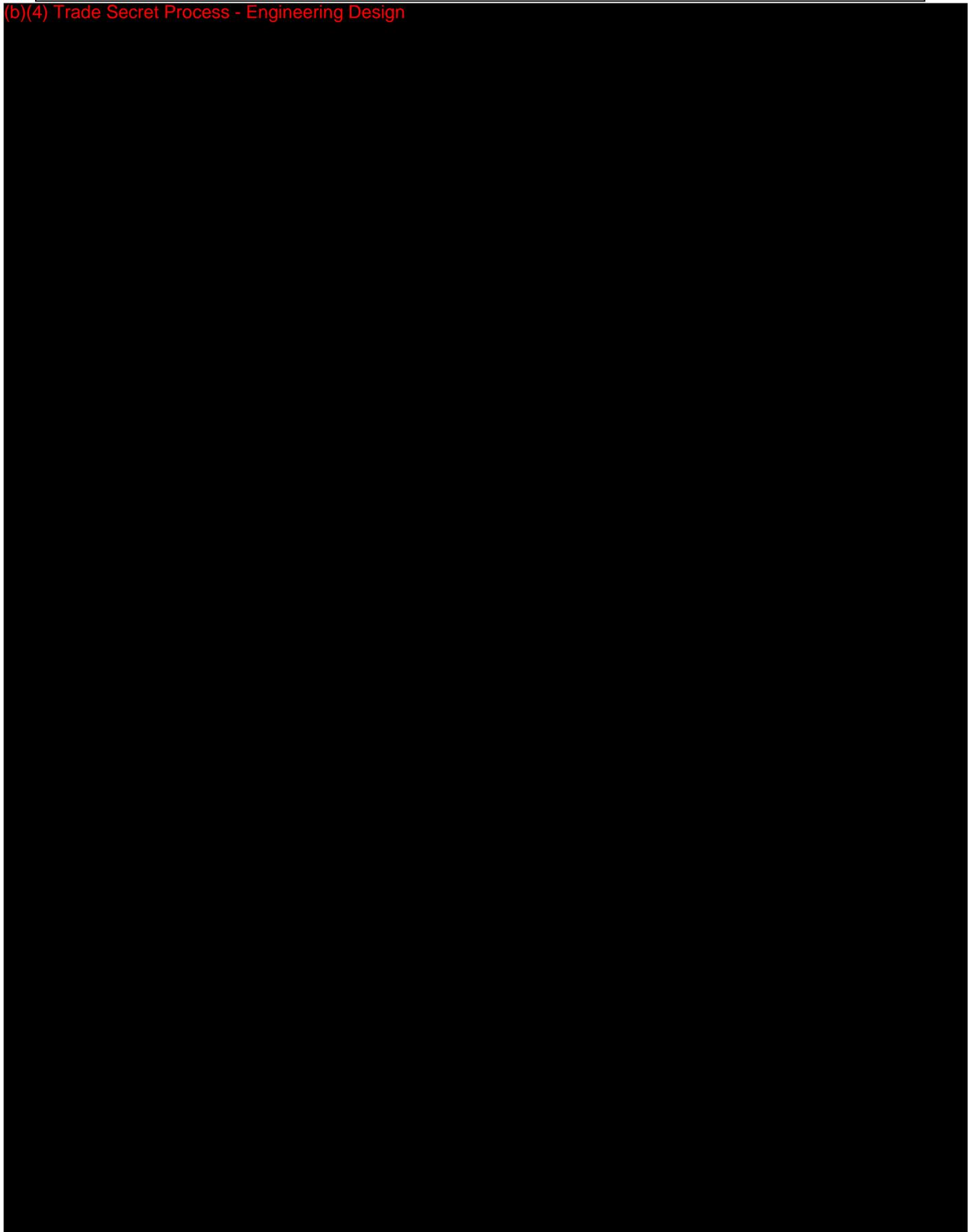


(b)(4) Trade Secret Process - Engineering Design



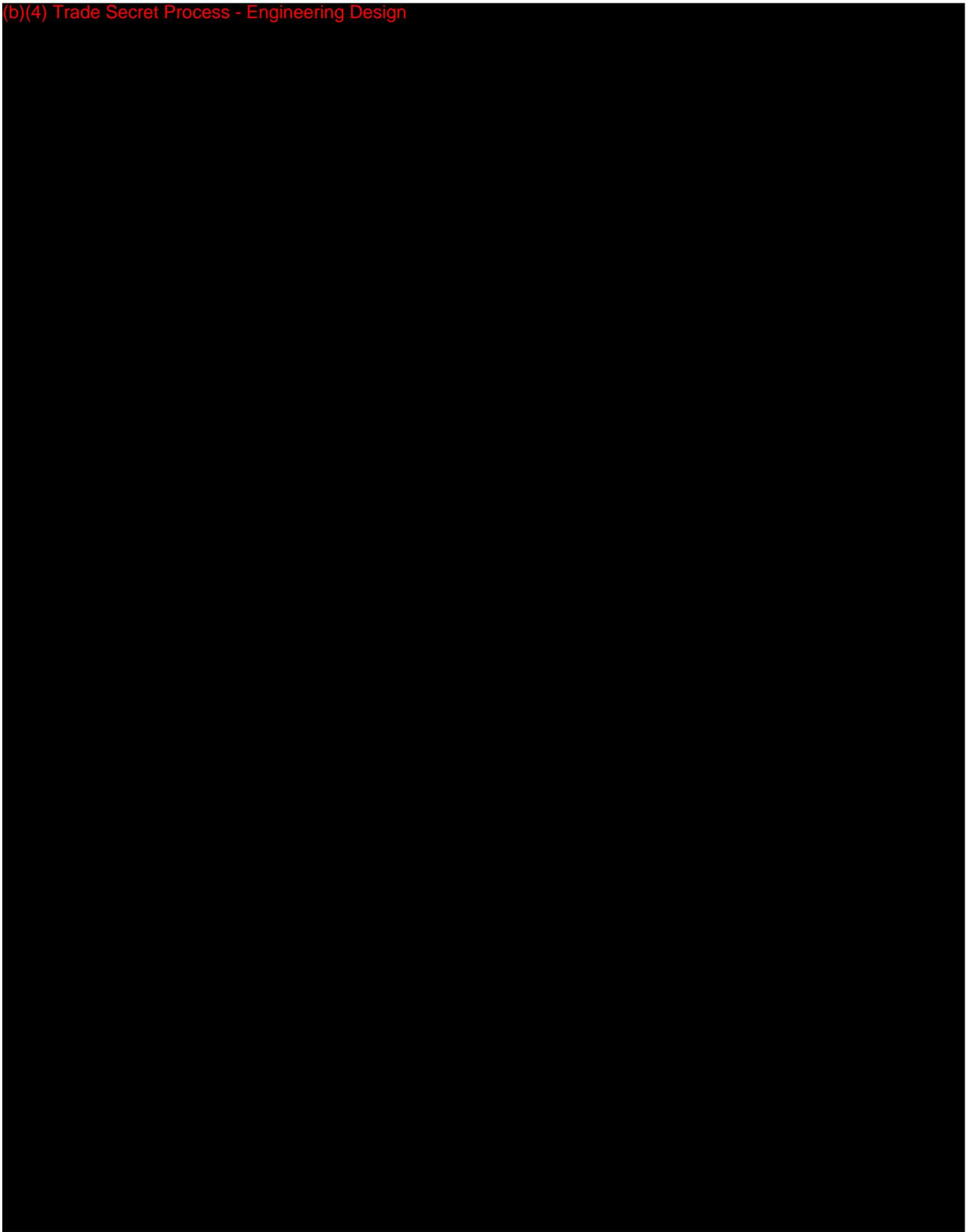


(b)(4) Trade Secret Process - Engineering Design



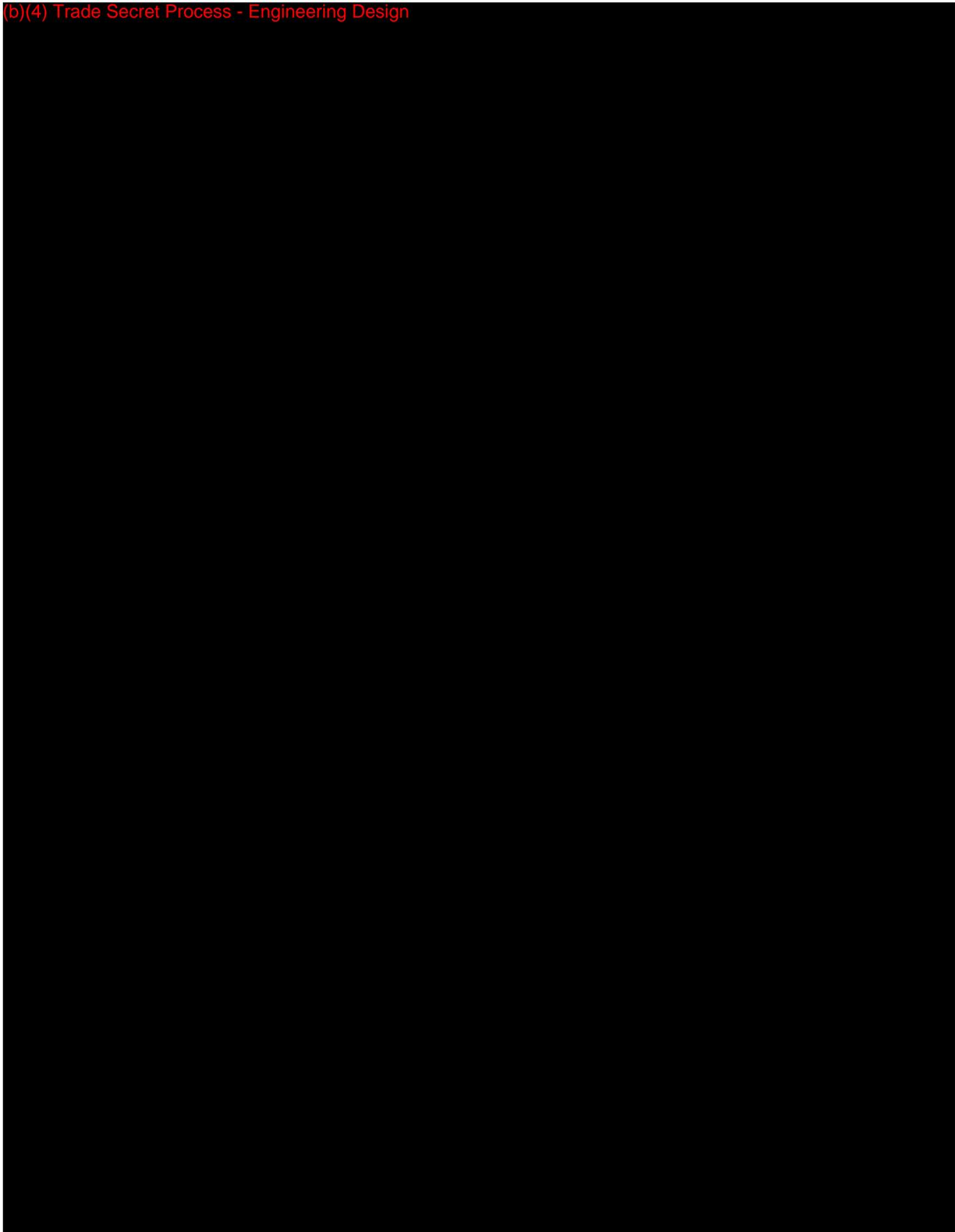


(b)(4) Trade Secret Process - Engineering Design



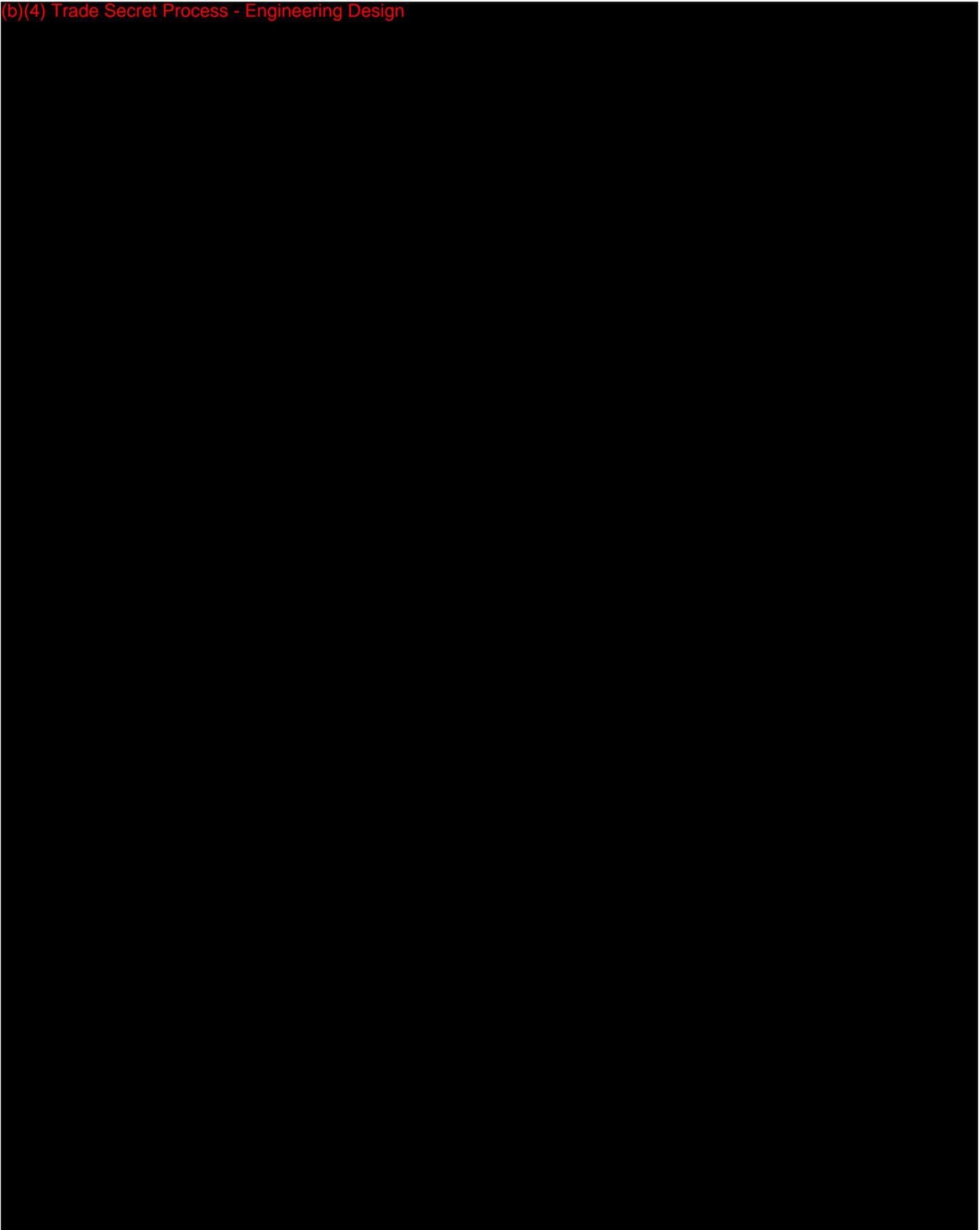
	Software Development Lifecycle	QSP-0302	
	Owner: Engineering	Rev. 1	Page 5 of 23

(b)(4) Trade Secret Process - Engineering Design



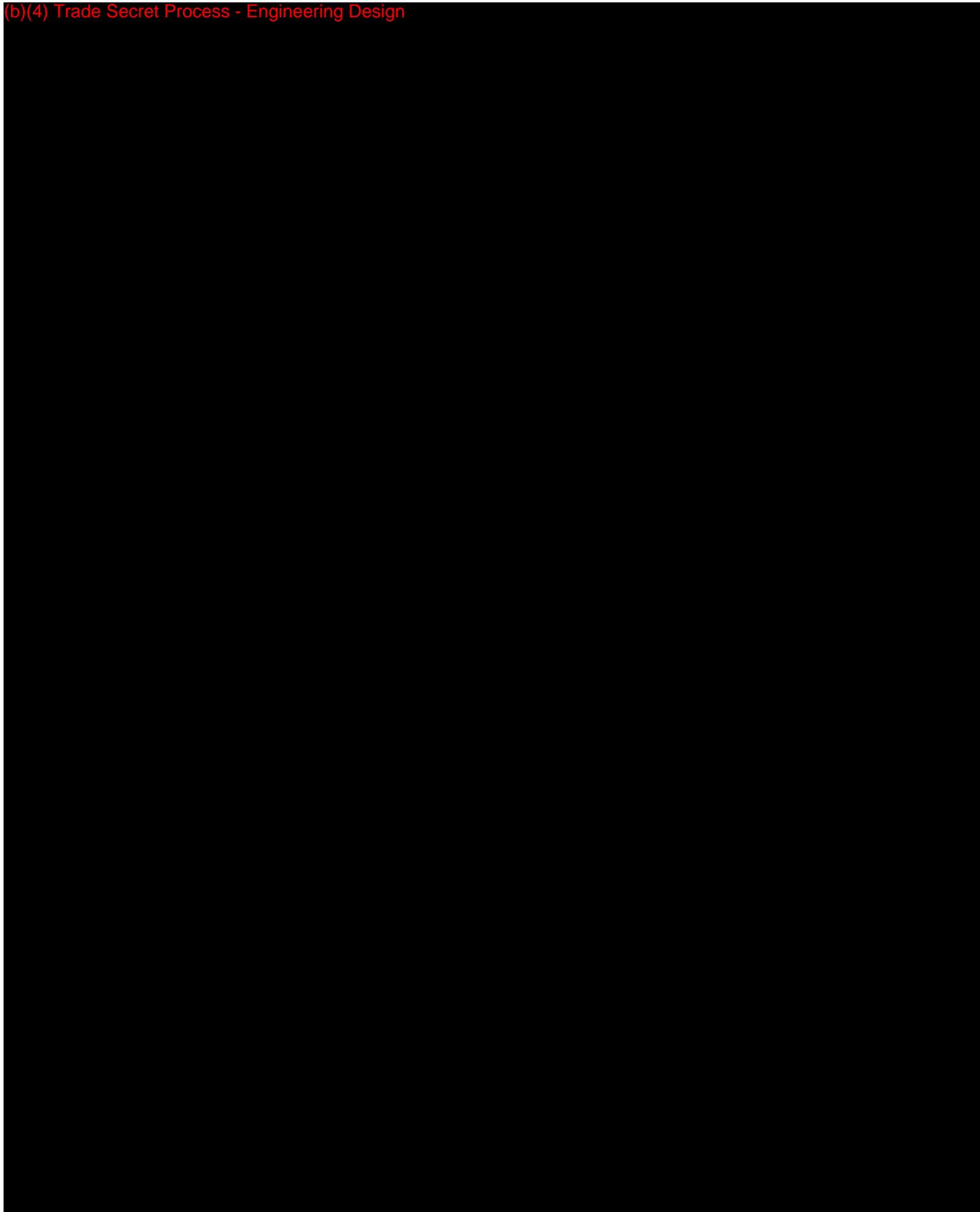


(b)(4) Trade Secret Process - Engineering Design



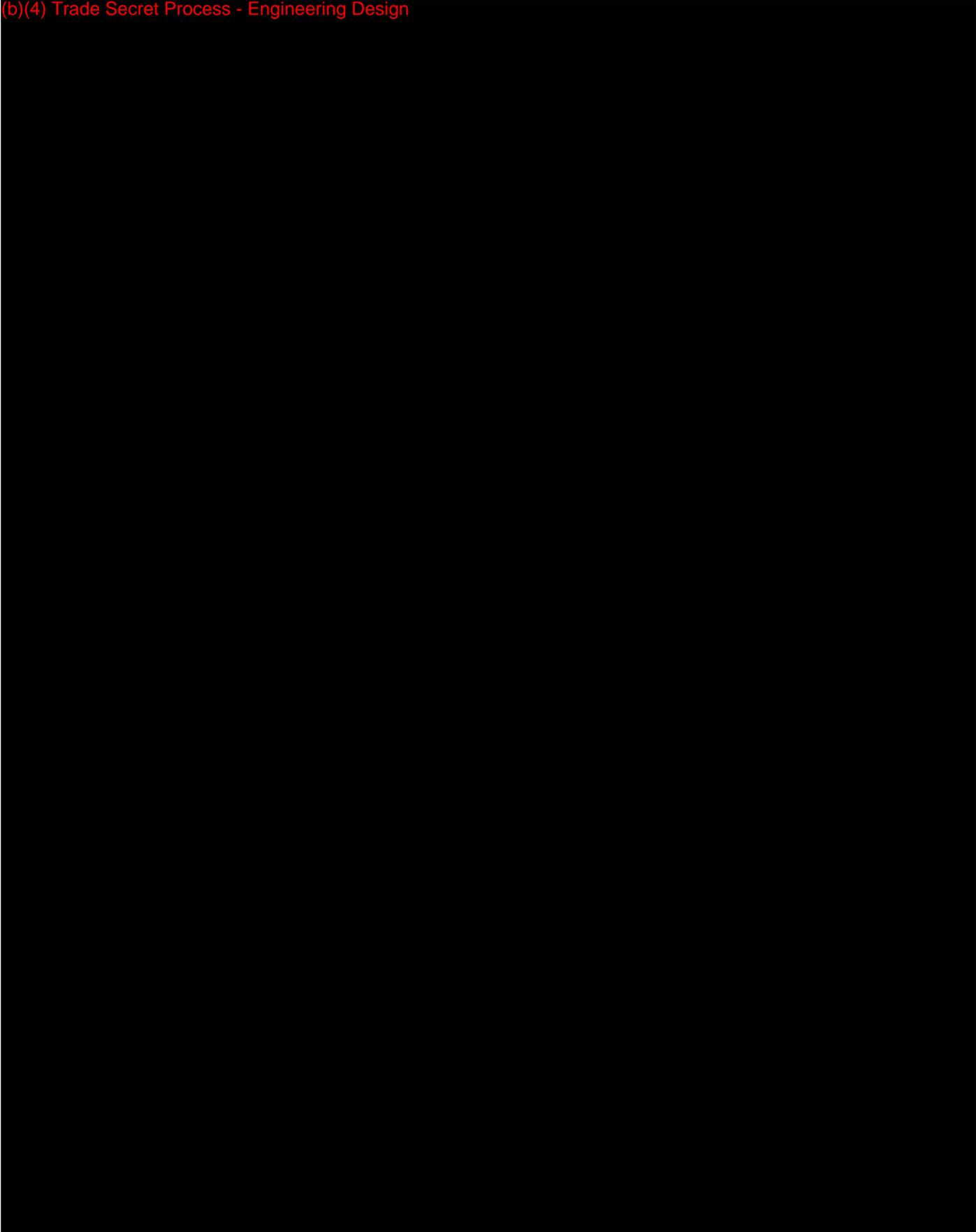


(b)(4) Trade Secret Process - Engineering Design



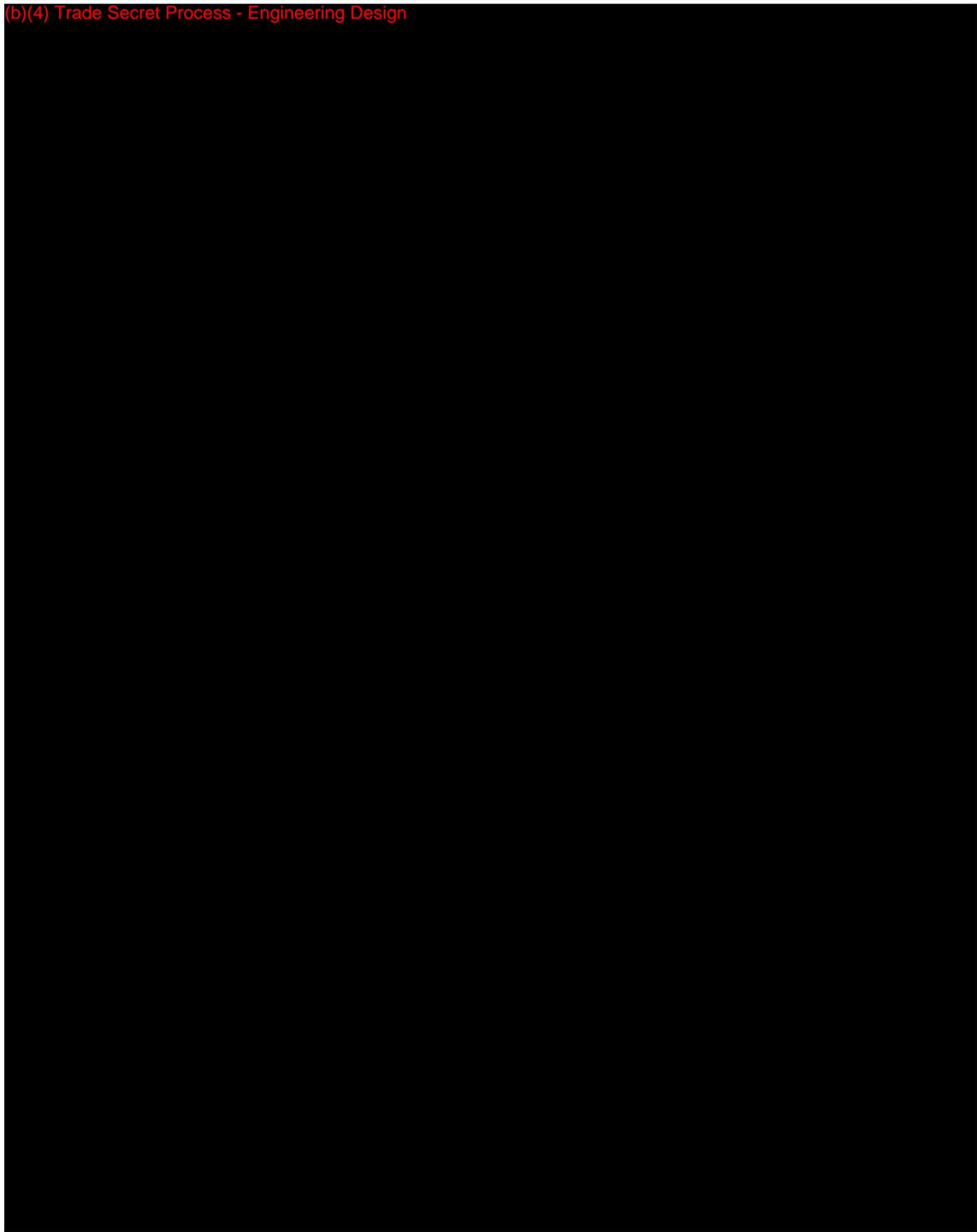


(b)(4) Trade Secret Process - Engineering Design



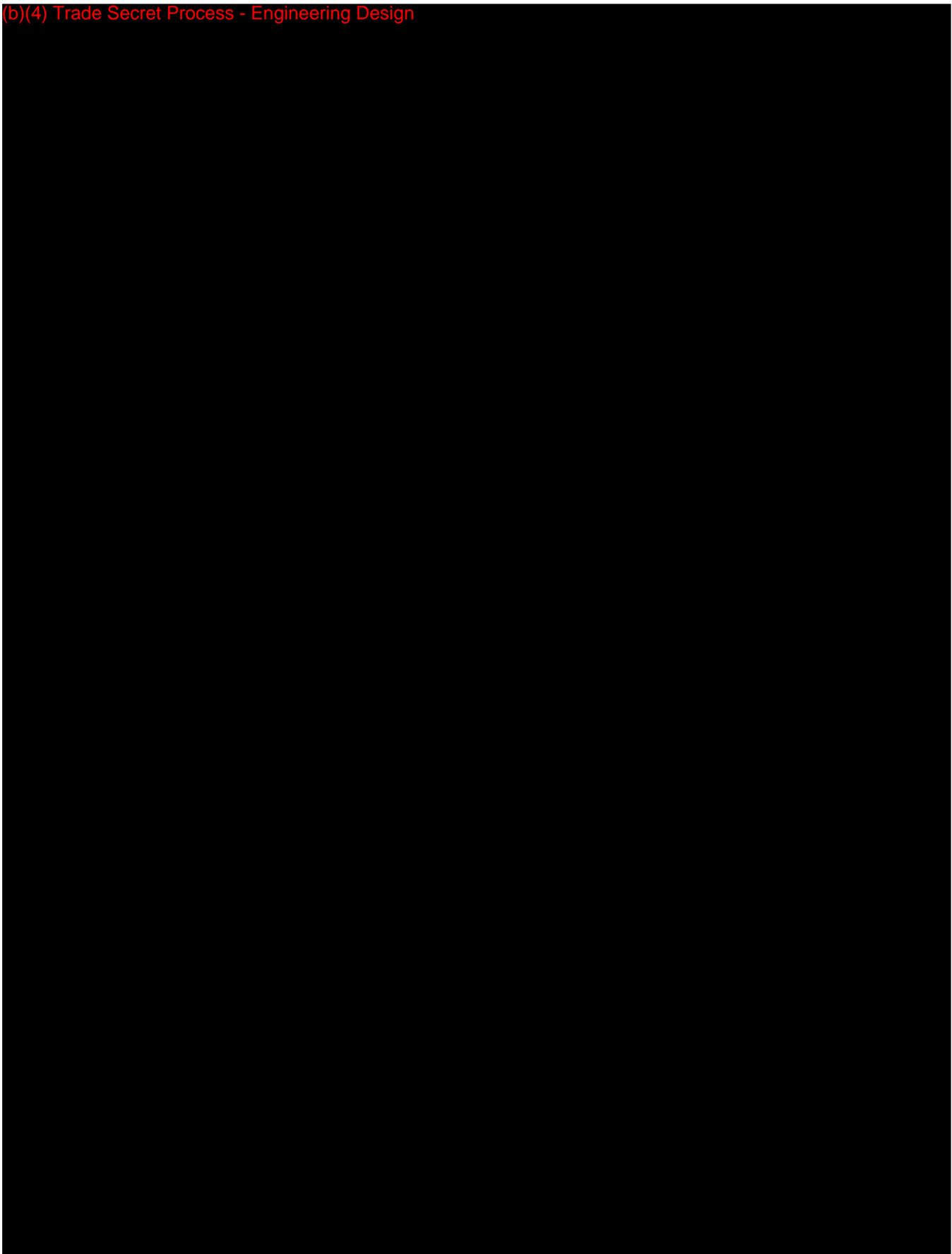


(b)(4) Trade Secret Process - Engineering Design



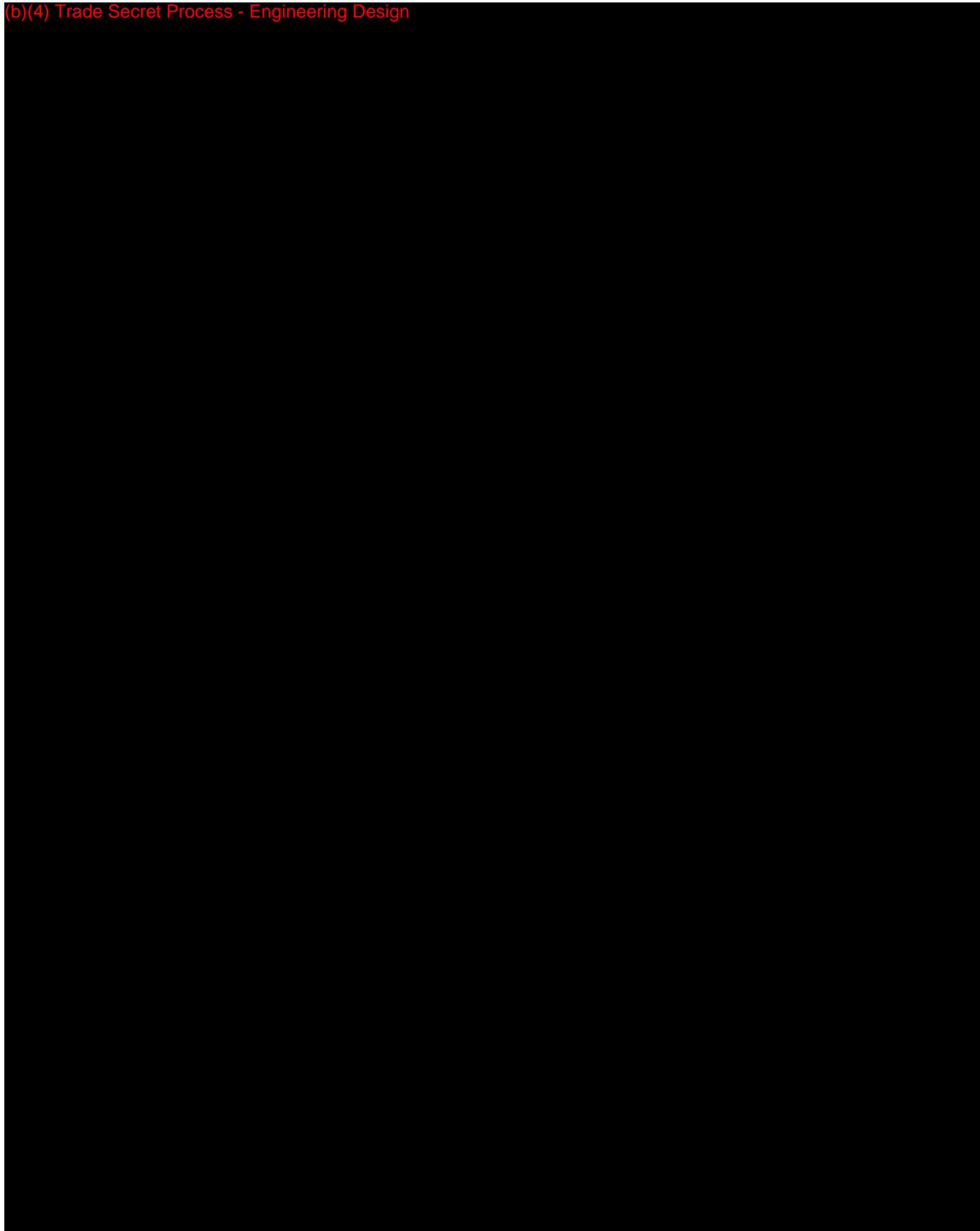


(b)(4) Trade Secret Process - Engineering Design



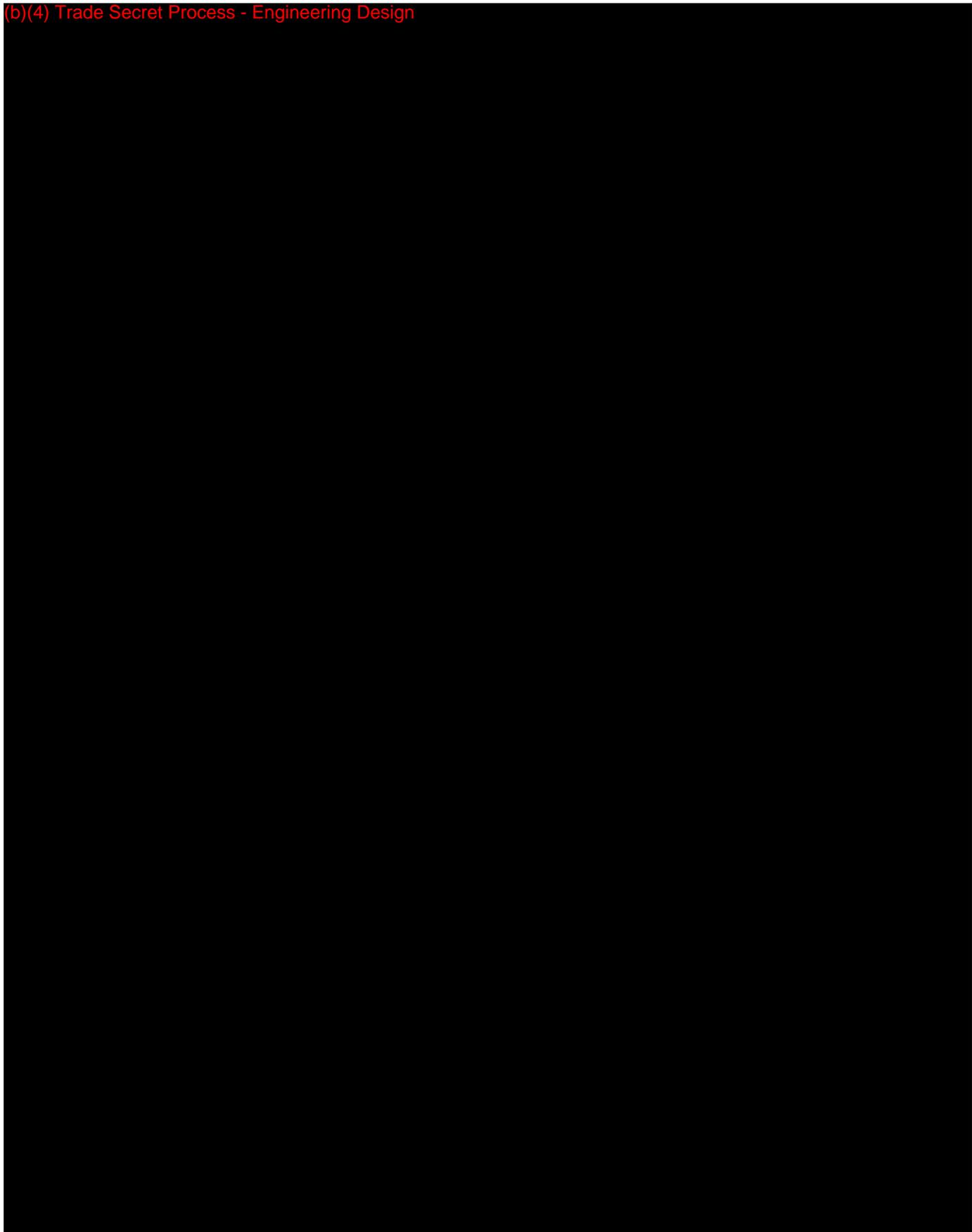


(b)(4) Trade Secret Process - Engineering Design





(b)(4) Trade Secret Process - Engineering Design



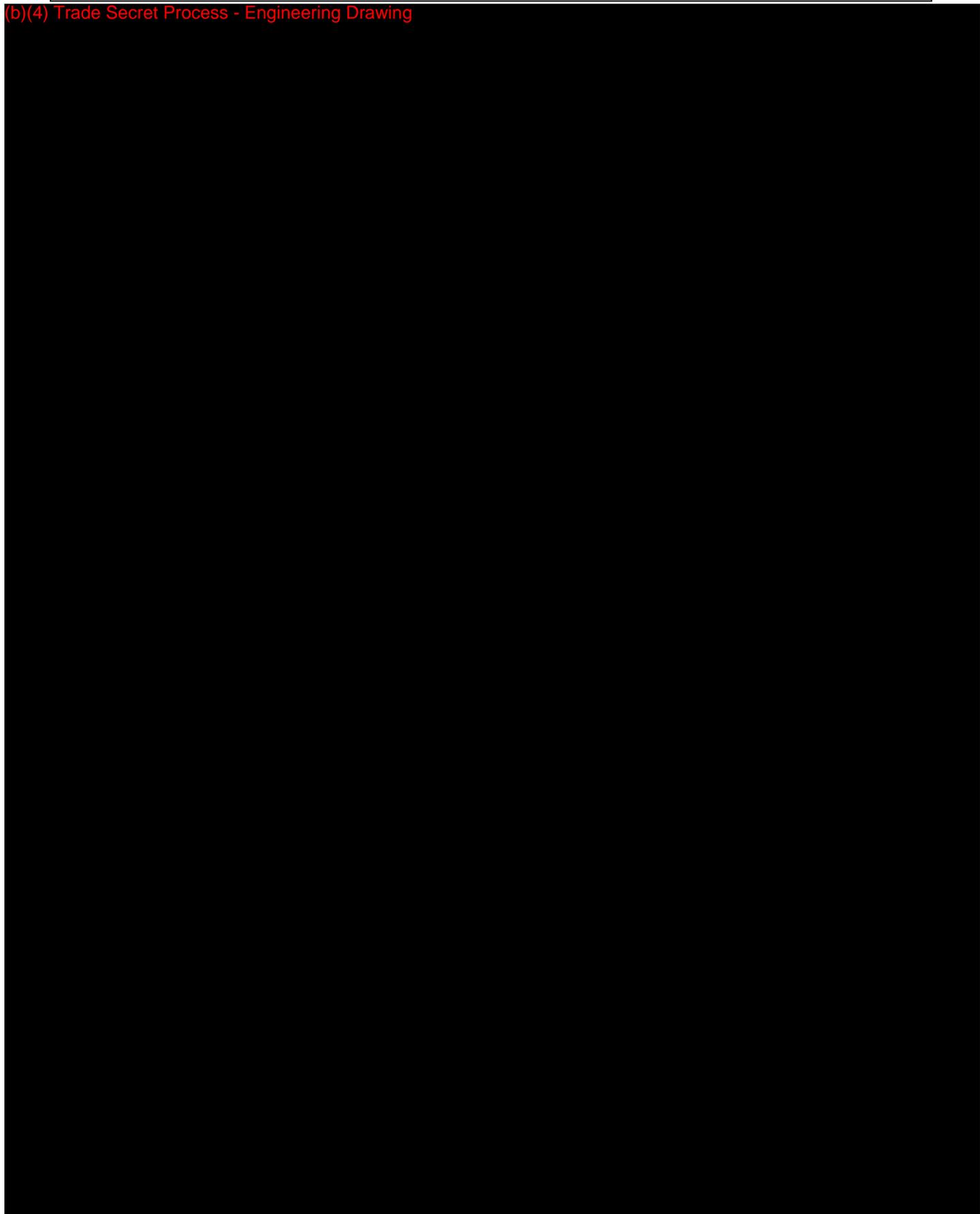
	Software Development Lifecycle	QSP-0302	
	Owner: Engineering	Rev. 1	Page 13 of 23

(b)(4) Trade Secret Process - Engineering Design



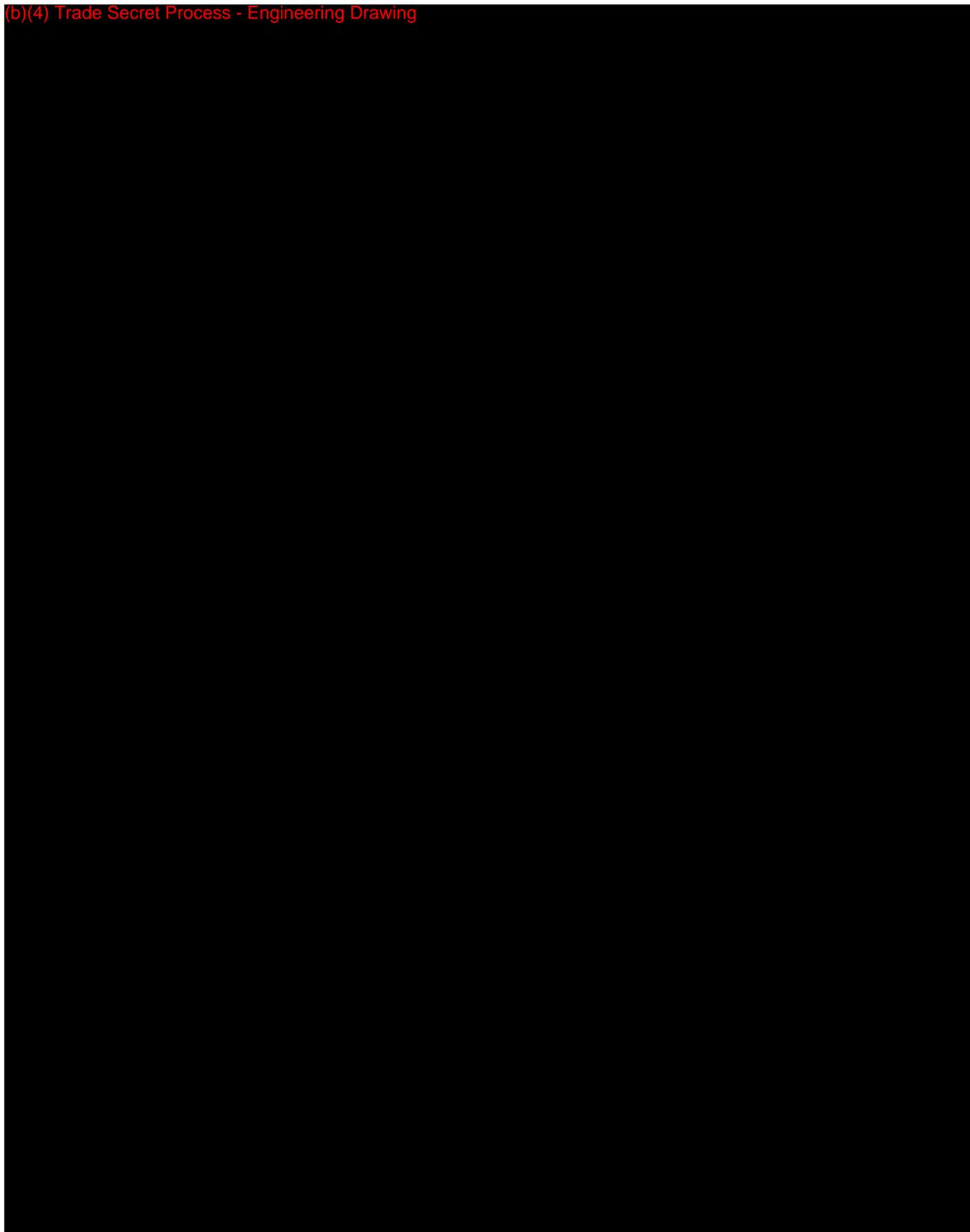


(b)(4) Trade Secret Process - Engineering Drawing



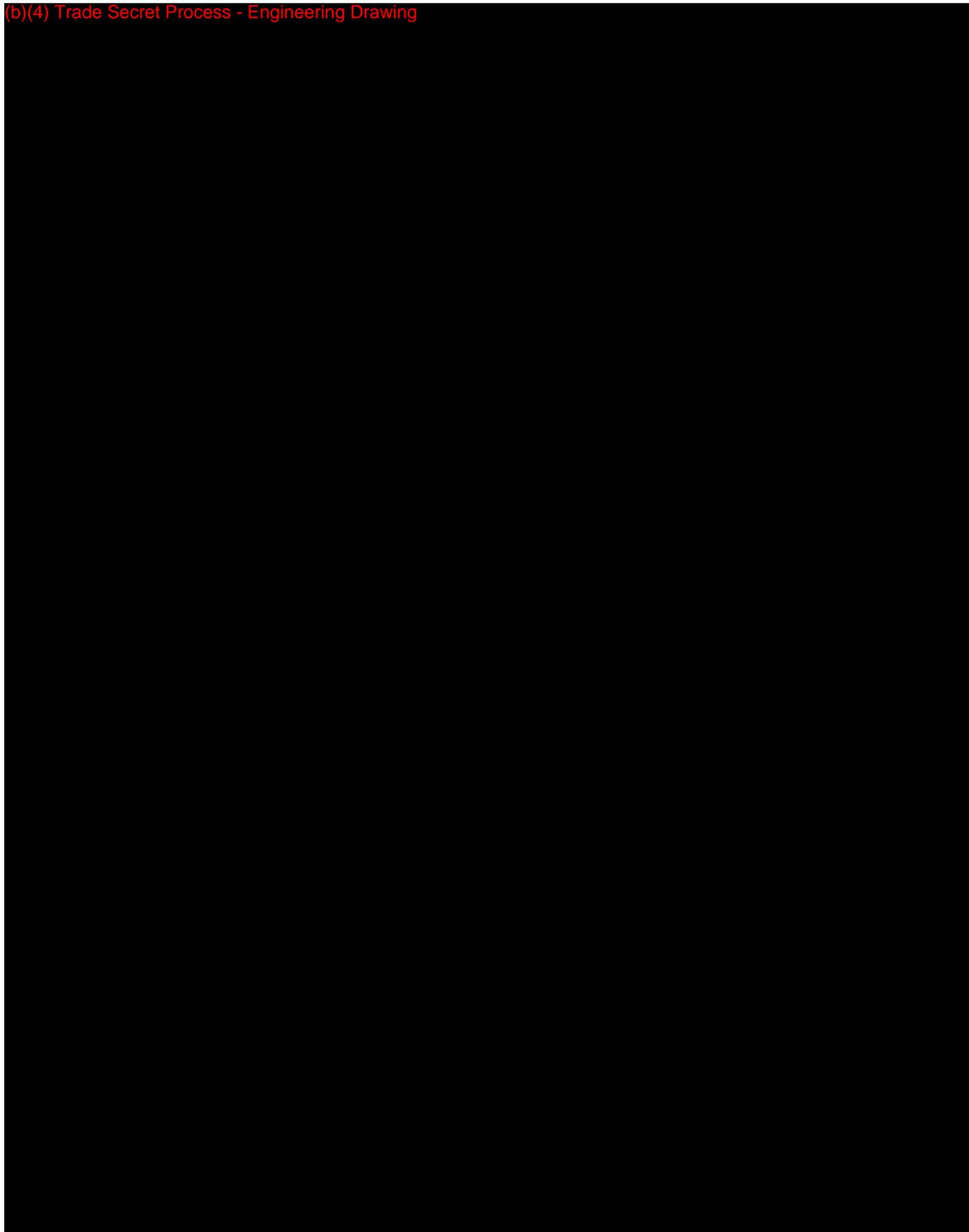


(b)(4) Trade Secret Process - Engineering Drawing



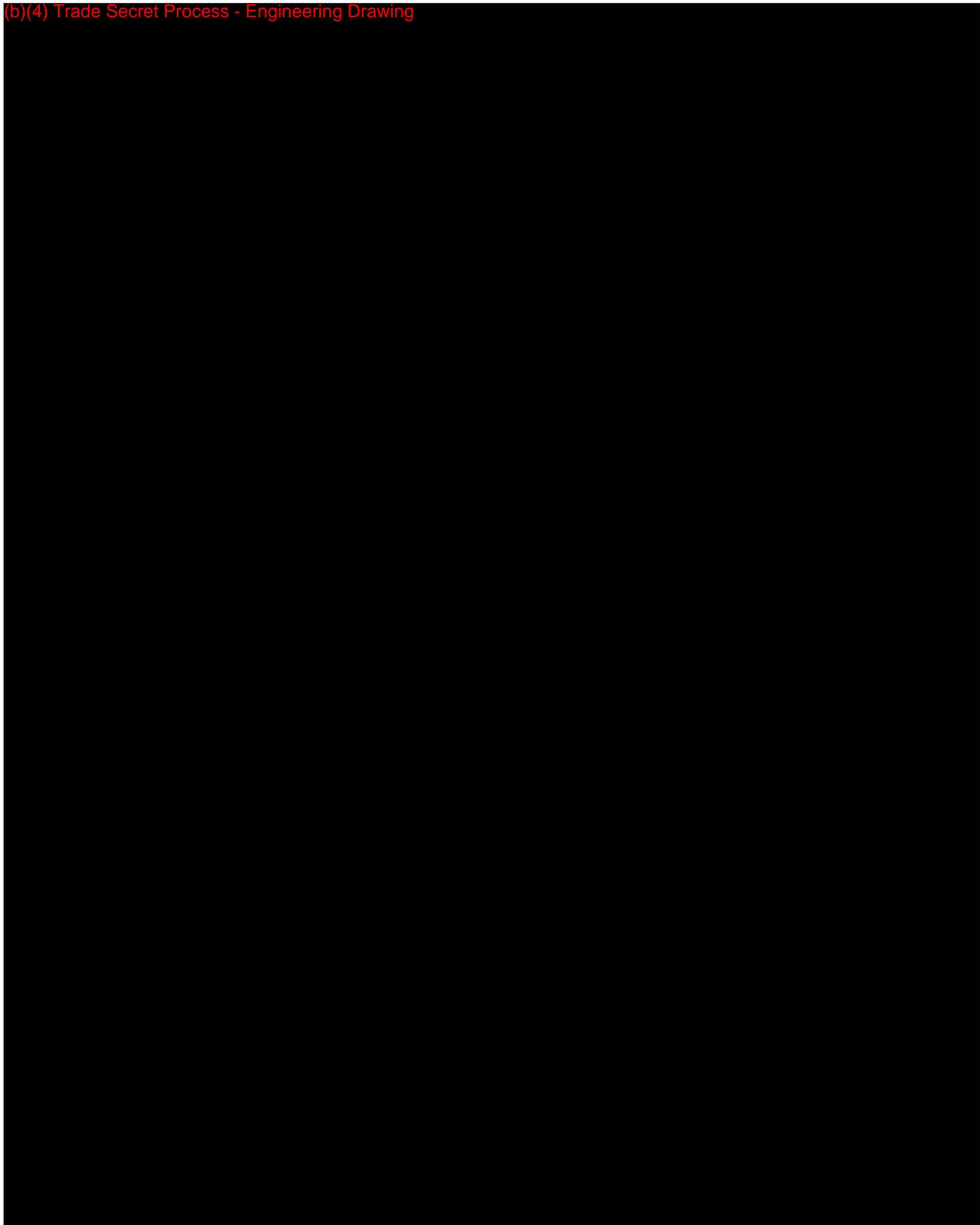


(b)(4) Trade Secret Process - Engineering Drawing



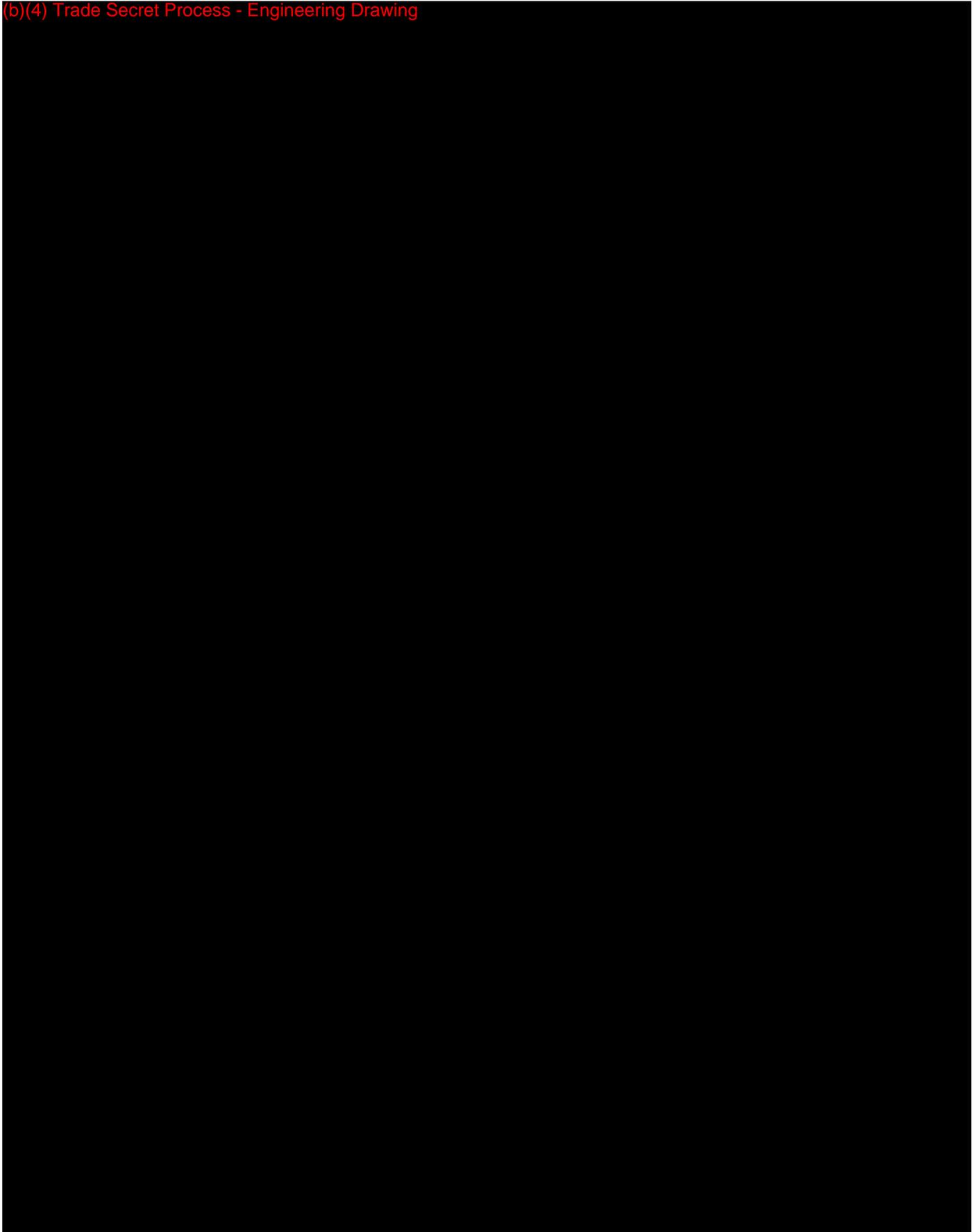
	Software Development Lifecycle	QSP-0302	
	Owner: Engineering	Rev. 1	Page 17 of 23

(b)(4) Trade Secret Process - Engineering Drawing



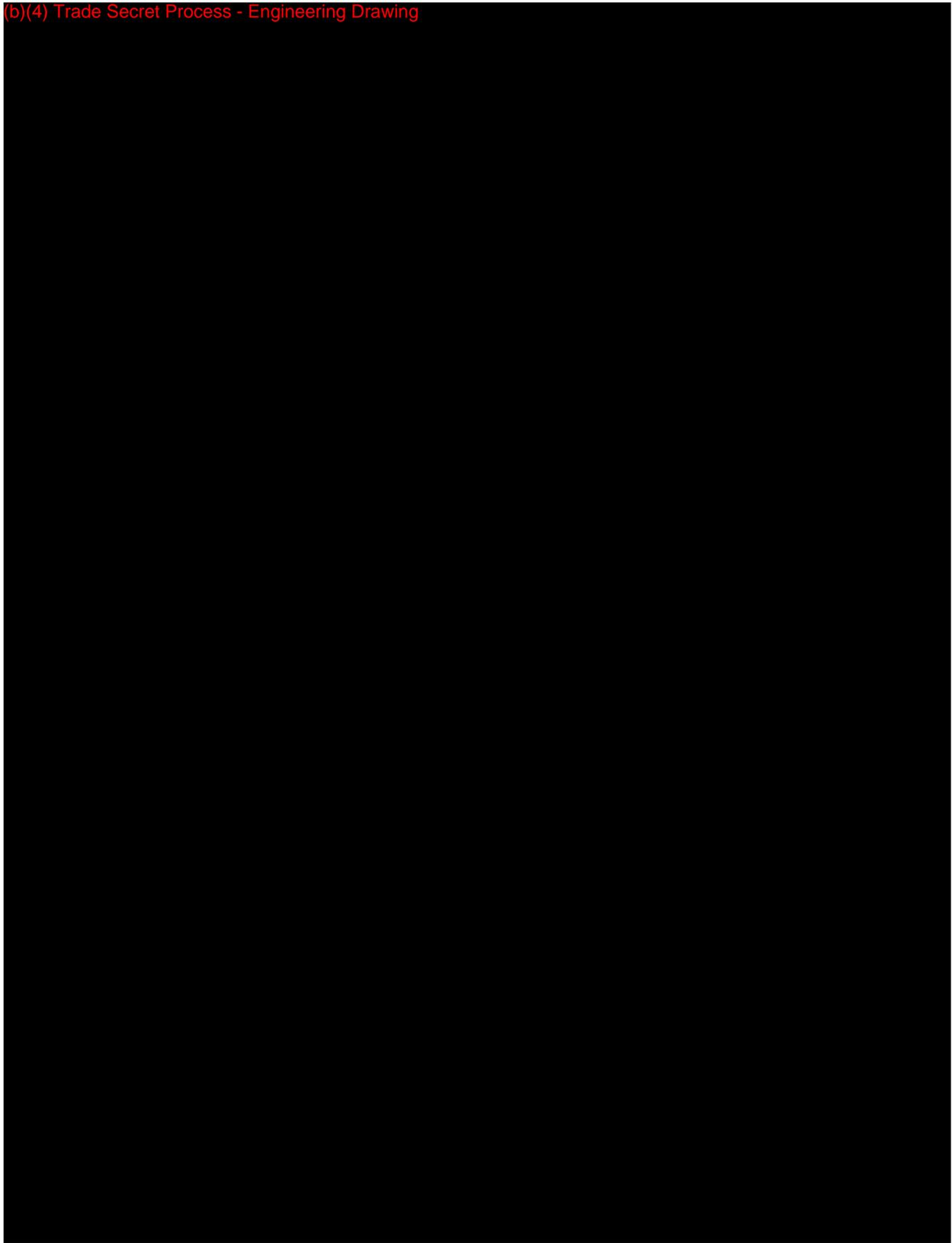


(b)(4) Trade Secret Process - Engineering Drawing



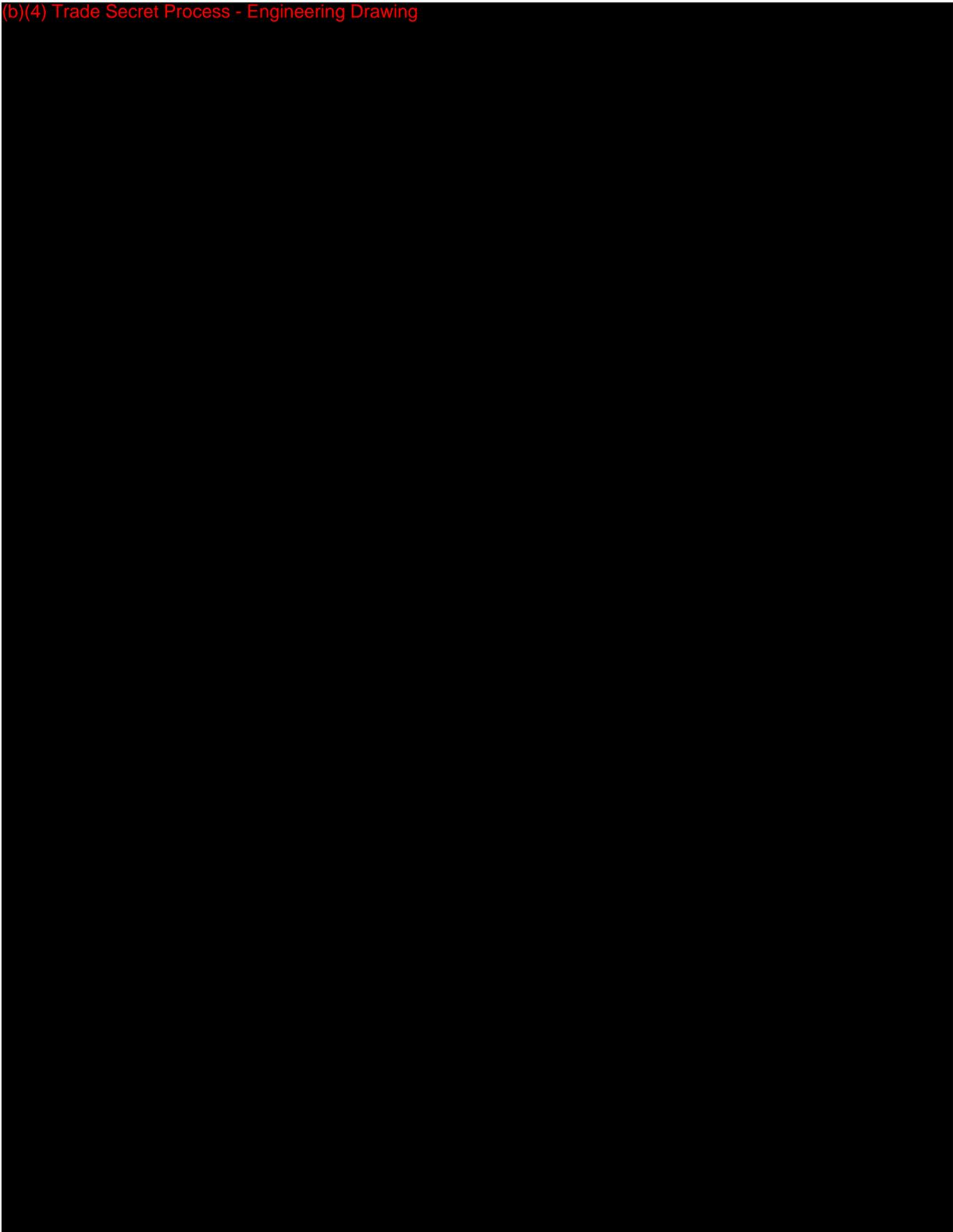


(b)(4) Trade Secret Process - Engineering Drawing



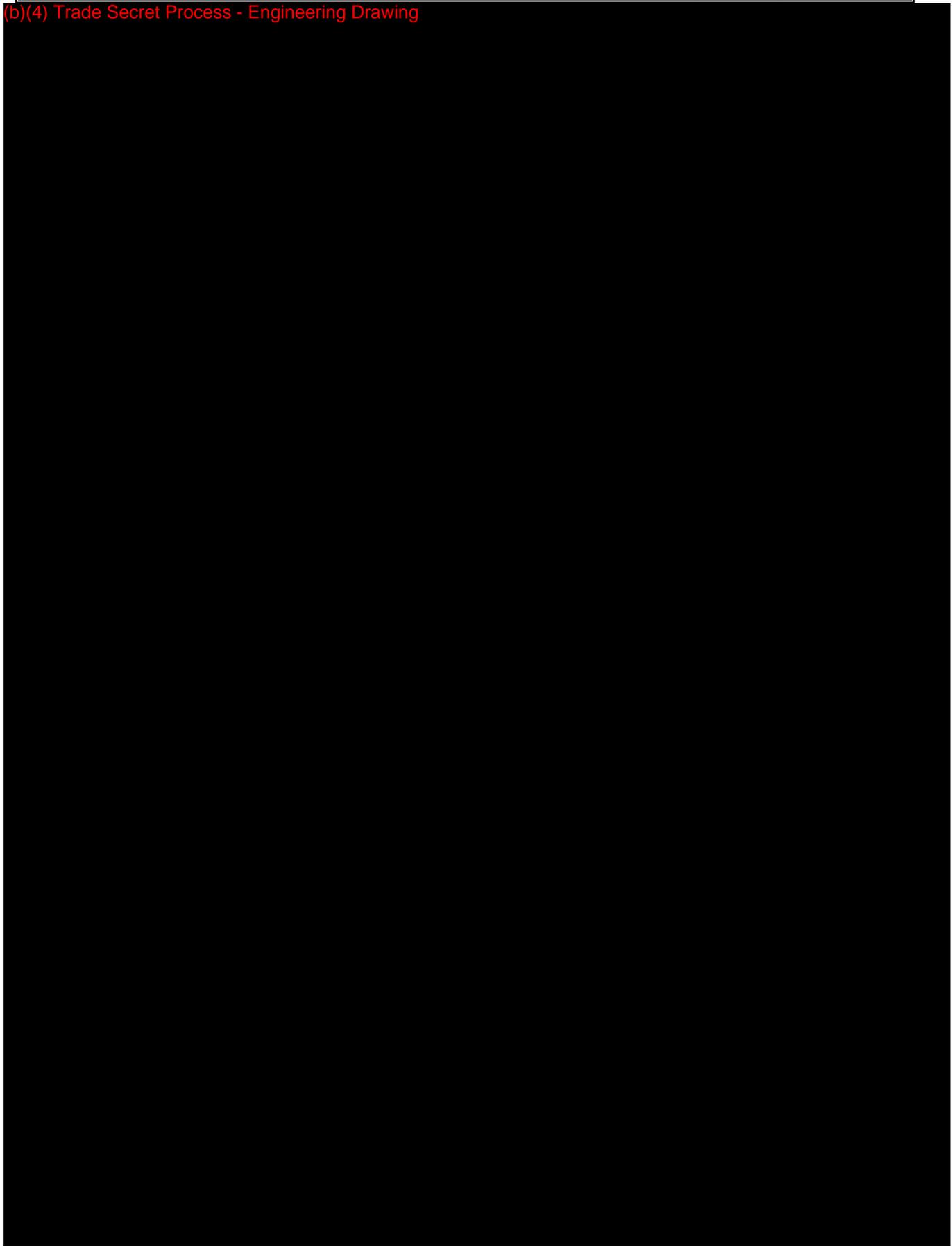
	Software Development Lifecycle	QSP-0302	
	Owner: Engineering	Rev. 1	Page 20 of 23

(b)(4) Trade Secret Process - Engineering Drawing



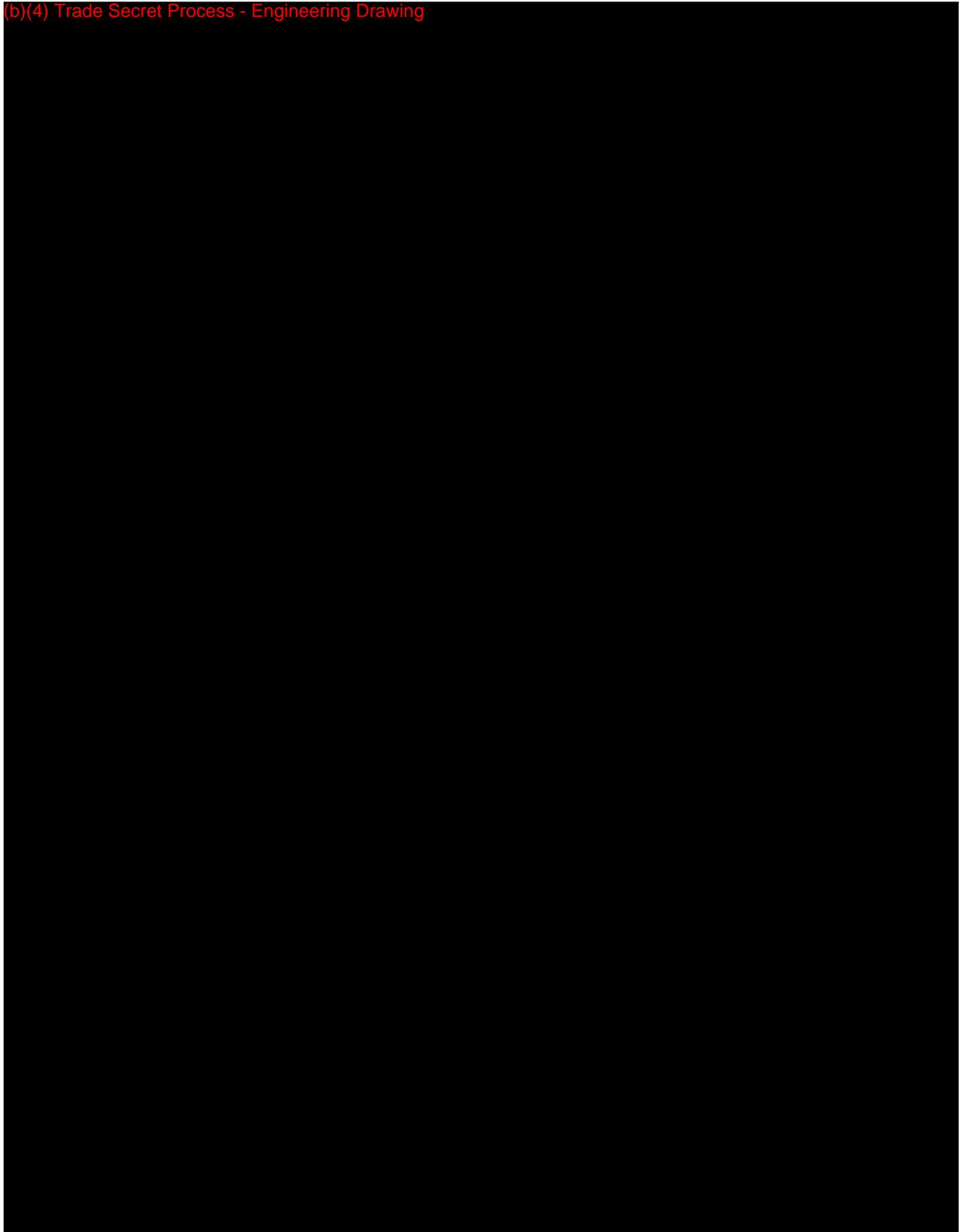


(b)(4) Trade Secret Process - Engineering Drawing



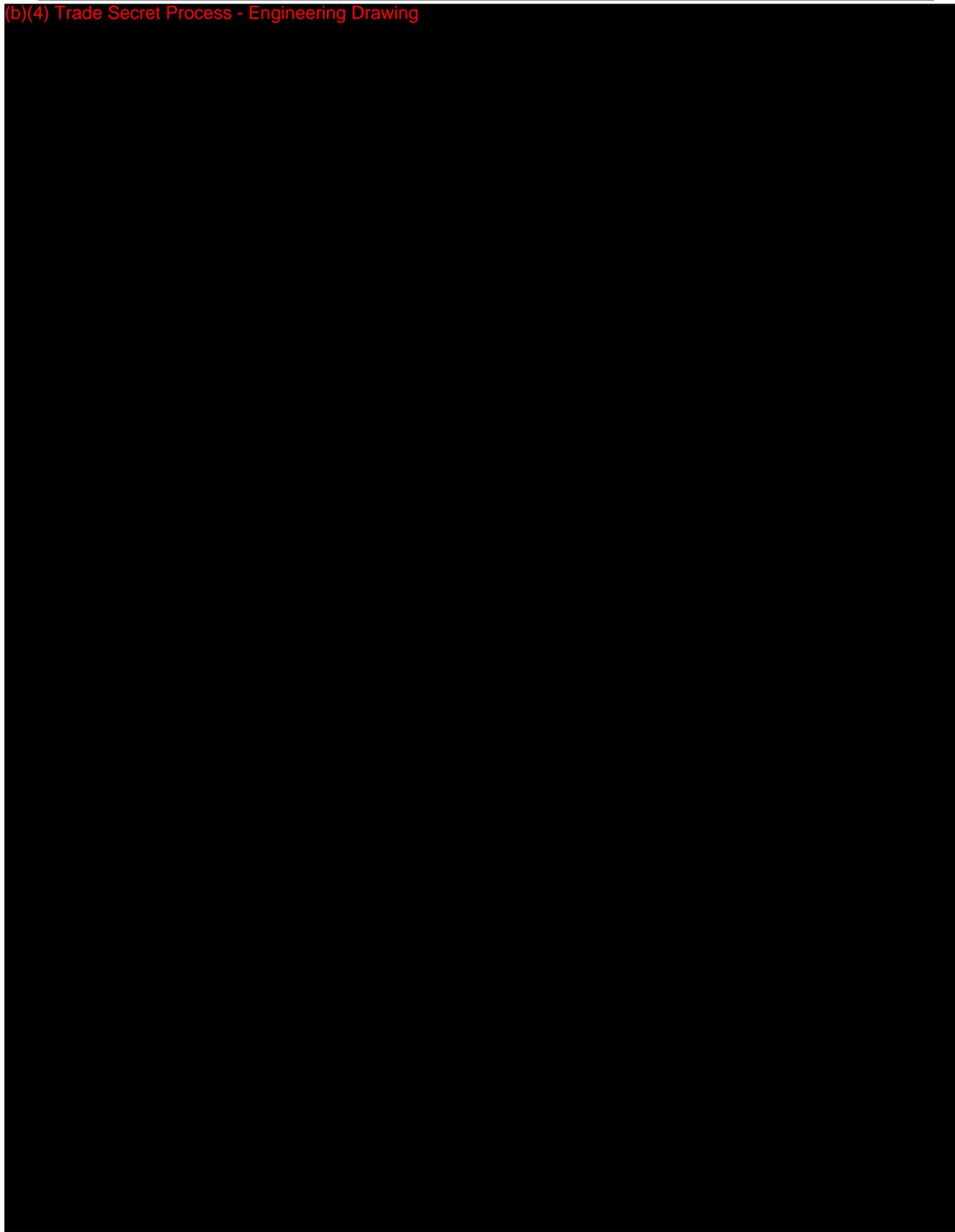
	Software Development Lifecycle	QSP-0302	
	Owner: Engineering	Rev. 1	Page 22 of 23

(b)(4) Trade Secret Process - Engineering Drawing





(b)(4) Trade Secret Process - Engineering Drawing



Topcon Medical Systems, Inc.



synergy™

Synergy ODM User's Manual Version 1.00

© 2013 Topcon Medical Systems, Inc., all rights reserved.

REVISION HISTORY

Date	Author	Document	Summary of Changes
10/19/2012	Artur J. Kowalski	Rev. 0.1	Synergy ODM User Manual draft, based on Synergy 1.xx and 2.xx User Manuals
11/20/2012	Artur J. Kowalski	Rev. 0.2	Formatting, footer correction, OCT Viewer section update
11/27/2012	Jim O'Brien	Rev. A	Initial Release – GDA 2034
07/19/2013	Alexander Kotchkin	Rev. B	Added Measurements section

Synergy is a trademark of Topcon Medical Systems, Inc.

Microsoft, MS and Windows are registered trademarks of Microsoft Corporation.

Windows XP is a trademark of Microsoft Corporation.

SQL Server is a trademark of Microsoft Corporation.

TABLE OF CONTENTS:

1	INTRODUCTION	6
1.1	Key Features	7
1.2	Document Conventions.....	7
2	GETTING STARTED	8
2.1	How to Access Synergy	8
2.2	Logging into Synergy from a Computer without a Shortcut	8
2.3	Setup an Synergy Shortcut.....	9
2.4	Login to Synergy.....	9
2.5	Multiple Logins.....	10
2.6	Changing User Passwords.....	10
2.6.1	To change your password, follow these steps:.....	10
2.6.2	To reset a forgotten password, follow these steps:	11
2.6.3	Changing or Resetting Passwords for Other Users.....	12
2.7	Setting Hints and Troubleshooting for Login	13
2.8	Logout.....	13
2.9	Session Expiration	13
3	APPLICATION CONVENTIONS	14
3.1	Help.....	14
3.1.1	Help Manual.....	14
3.1.2	FAQ	14
3.1.3	Support.....	14
3.1.4	About.....	14
3.2	Global Navigation Elements	15
3.2.1	Top Navigation Bar.....	15
3.2.2	My Account Menu	18
3.2.3	Procedure to Edit Account Information:.....	18
3.2.4	Procedure to Change Password.....	19
3.3	Indicators.....	19
3.3.1	The Message Center.....	20
3.3.2	Toolbar	20
3.3.3	Mail Folders.....	21
3.3.4	Procedure to Access Message Center:	21
3.3.5	Procedure to Send a Message.	22

3.3.6	Procedure to Reply to a Message:	22
3.3.7	Procedure to Forward a Message:	23
3.3.8	Procedure to Delete a Message:	24
3.4	Isolated Patients	25
3.4.1	Toolbar for Isolated Patients	25
3.4.2	Control Buttons:	26
3.4.3	Field Definitions for Isolated Patients	26
3.4.4	Procedure to Merge Patients	27
3.5	The Minimize Button	28
3.6	Search	28
3.7	Title Bar	29
3.8	Filtering	29
3.9	Drag and Drop	30
3.10	Scroll Bars	30
3.11	Toolbar	31
3.12	The Hover Effect	31
3.13	Input Validation	31
3.14	Alerts	32
3.15	Busy/Processing	32
4	SYNERGY FEATURE GUIDE	33
4.1	Home Page	33
4.1.1	User Information:	33
4.1.2	Procedure to Change User's Location	34
4.1.3	Quick Links	34
4.1.3.1	Definition of Quick Links:	35
4.2	Patients	35
4.2.1	Tool bar	35
4.2.2	Field Definitions for Patients:	36
4.2.3	Search	37
4.2.4	Patient Statistics	40
4.2.4.1	Procedure to Add a Patient:	40
4.2.4.2	Procedure to Edit a Patient:	44
4.2.5	The Patient Chart	46
4.2.6	Patient Details	47

4.2.7	Patient Exams.....	48
4.2.7.1	Sorting Patient Exams.....	48
4.2.7.2	Manual Import.....	48
4.2.7.3	Toolbars for Viewing Exams.....	51
4.2.7.4	The Viewing Area.....	54
4.2.8	Description of Actions.....	55
4.2.8.1	Viewing the Exam.....	55
4.2.8.2	Thumbnails.....	56
4.2.8.3	Thumbnail Strip.....	56
4.2.8.4	Proof Sheet View.....	58
4.2.8.5	Viewing the Proof Sheet View.....	58
4.2.8.6	Split (OD OS / OS OD) View.....	59
4.2.8.7	OCT Viewer.....	60
4.2.8.7.1	Toolbar.....	60
4.2.8.7.2	Using the OCT Viewer.....	61
4.2.8.8	Historical Comparison View.....	64
4.2.8.9	Toolbar for Historical Comparison.....	64
4.2.8.10	Viewing Historical Comparisons of Exams.....	65
4.2.8.11	Adding a Note to the Exam.....	67
4.2.8.12	Adding an Annotation to an Exam.....	67
4.2.8.13	Measurements.....	70
4.2.8.14	Interpretation Reports.....	72
4.2.8.15	DICOM COPY.....	74
4.2.8.16	Export an Exam.....	76
4.2.9	Exam Comparison.....	77
4.2.9.1	Toolbar for Comparing Exams.....	77
4.2.9.2	Comparing Exams.....	78
4.2.9.3	Compare Selected Media.....	80
4.2.10	Patient Journal.....	81
4.2.10.1	Locating and Sorting Journal Items.....	82
4.2.10.2	Viewing Journal Items.....	82
4.2.11	Discrete Data.....	83
4.2.11.1	Manually Entering Discrete Data.....	85
4.2.11.2	Trending Discrete Data.....	85

4.3	Statistics	88
4.3.1	Field Descriptions for Statistics:	88
4.3.2	Generating Statistics	89
4.4	Preferences	90
4.4.1	Toolbar for Preferences:	90
4.4.2	Profile List:	92
4.4.3	Options:	92
4.4.4	Setting Preferences	92
4.5	Administration	94
4.5.1	Management	94
4.5.1.1	Patients	94
4.5.1.1.1	Toolbar	94
4.5.1.1.2	Control Buttons:	95
4.5.1.1.3	Patient Fields:	95
4.5.1.1.4	Procedure to Merge Patients	96
4.5.1.1.5	Procedure to Add a Patient	96

1 INTRODUCTION

The purpose of this document is to serve as a reference for the Synergy Ophthalmic Data Management System (Synergy ODM). In this document, the application is simply called “the system” or “Synergy”.

Synergy ODM is a comprehensive software platform intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as for management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic instruments through either a direct connection with the instruments or through computerized networks.

Synergy is used together with a number of computerized digital imaging devices, including:

- Optical Coherence Tomography devices
- Mydriatic retinal cameras
- Non-mydriatic retinal cameras
- Biomicroscopes (slit lamps)

In addition, Synergy collects and manages patient demographics, image data, and clinical reports from a range of medical devices, including:

- Scanning Laser Ophthalmoscope images and videos
- Non Radiometric Ultrasound devices
- Video image sources
- TWAIN compliant imaging sources
- Compliant data sources placed in network accessible folders and directories
- Images of known format from digital cameras and scanners
- Printer files of known format from computerized diagnostic devices
- Electronic information complying to accepted DICOM formats
- Other devices connected in proprietary formats

Synergy enables users to view images, manipulate images, and import exams all via a browser running on both Microsoft® Windows® and Mac OS platforms. Below are the recommended specifications for the computers being used to access the Synergy application:

For Windows®:

- Operating System: Windows XP Service Pack 2 or above
- Memory (RAM): 2GB
- Processor (CPU): Dual processor running 2.33Ghz or faster
- Screen Resolution: 1440x900
- Monitor: Wide Screen format, 19” or larger
- Operating System: OS X 10.5.8
- Memory (RAM): 1GB
- Processor (CPU): Dual processor running 2.4Ghz or faster
- Screen Resolution: 1440x900
- Monitor: Wide Screen format, 19” or larger

For Mac®:

- Operating System: OS X 10.5.8
- Memory (RAM): 1GB

- Processor (CPU): Dual processor running 2.4Ghz or faster
- Screen Resolution: 1440x900
- Monitor: Wide Screen format, 19" or larger

Synergy provides fluent workflow efficiency and helps the transition to a paperless environment. The browser based system allows for rapid access to patient data, anytime, from virtually anywhere, including workstations and remote computers. Designed as a scalable and flexible solution, Synergy integrates with most EMR's, is fully standards compliant and scalable to fit any size practice.

1.1 Key Features

- Store, manage and review data from different ophthalmic devices
- Communicate and share information with your co-workers, in real time, through Synergy Messaging
- Compare current and historical exams fast and efficiently
- Enhanced workflow for ease of access to the data you need
- Complete interoperability between Ophthalmic devices and EMRs/EHRs

1.2 Document Conventions

- Page names and Field names appear with their first letter capitalized.
- Keyboard keys and "buttons" that appear on a page appear inside brackets - [].
- Titles and exact text descriptions will appear in quotation marks - "".
- Tab names will appear inside vertical bars or pipes - | |.

2 GETTING STARTED

2.1 How to Access Synergy

Each Synergy system has its unique URL for web access. Refer to your clinic's *Connecting to Synergy Web Interface* document for your specific URL link, user name, and password. Consult your local Synergy Web Interface administrator if you are missing this information.

2.2 Logging into Synergy from a Computer without a Shortcut

Synergy provides two-level user authentication for logging in: the window system log in and the Synergy log in.

1. Open your browser and enter your Synergy link: (e.g. www.topconsynergy.com).
2. You may be prompted to enter a User name and Password to access the server. If you are, enter the user name and password.

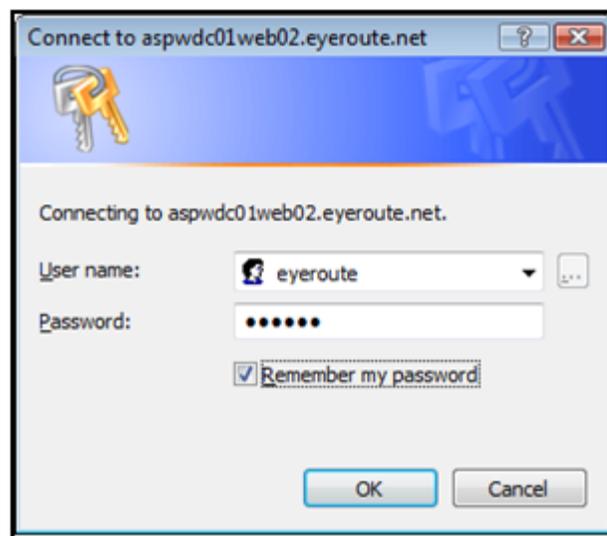


Figure 1: Windows' User Authentication

3. Check "Remember my password", if you do not want to be prompted to enter this information each time a user logs in to Synergy. NOTE: some Operating System versions will not offer to save the password.
4. Click the [OK] button.
5. The Synergy login screen should display.

2.3 Setup an Synergy Shortcut

Users can create a shortcut icon on the desktop to easily access Synergy.

1. Follow the steps above to get to the Synergy login screen.
2. In Internet Explorer's menu bar click on Favorites, then "Add to Favorites"... to add Synergy to your list of Favorite websites.
3. Find the small Internet Explorer icon in-between the words "Address" and "https://" in the address bar of Internet Explorer (see Figure 4).
4. Drag and drop this icon to your desktop.
5. Drag that icon onto your desktop to create a shortcut. You may also drag the icon to your quick launch bar to create a shortcut.

2.4 Login to Synergy

Synergy may be accessed either by entering the appropriate URL address in the browser or selecting a shortcut. The following screen is displayed and the user may begin the login process:

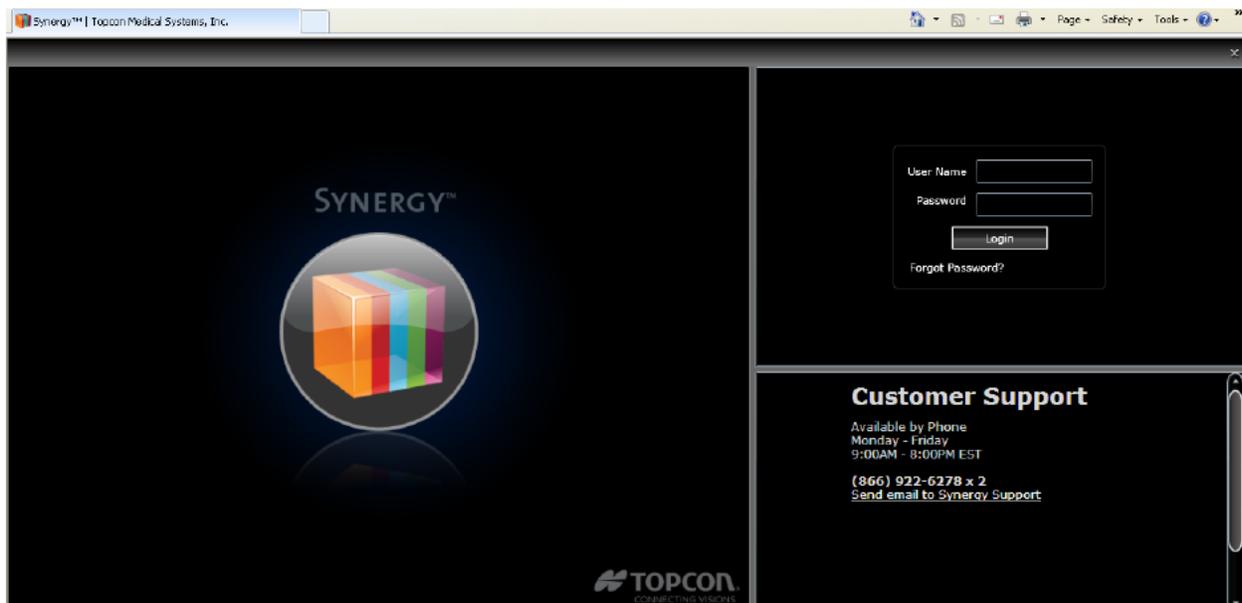


Figure 2: The Login Screen

1. Enter your username in the "User Name" field.
2. Enter your password in the "Password" field.
3. Click on the [Login] button or simply press the [Enter] key.

NOTES:

1. If an account is not created, please contact your local Synergy administrator.
2. When your user account is created, a temporary one-time password will be e-mailed to your e-mail account. Upon your first login, you will be prompted to change your password

2.5 Multiple Logins

Users logged into Synergy are concurrent hence a license is consumed for each login. This could cause others users not to be able to login. When a user attempts to login more than once, the following prompt appears:

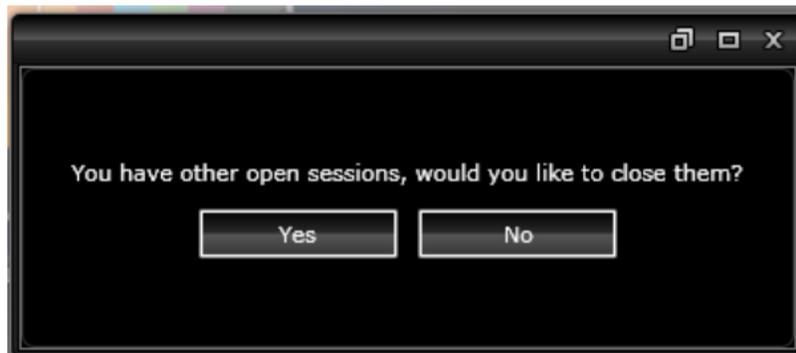


Figure 3: Multiple Sessions Prompt

1. Click on the [Yes] button to close the other session(s) thereby freeing the license(s).
2. Click [No] to keep the other session(s) open and consuming licenses.

2.6 Changing User Passwords

Users have an option to change their own password at any time. The parameters for the user's password and the frequency with which passwords expire are global settings for each clinic defined by the Synergy administrator.

2.6.1 To change your password, follow these steps:

1. Navigate to the "Home Page".
2. Click on the quick link [Change Password](#).
The following pop-up screen will appear:



Figure 4: Reset Password

3. Enter your old password.
4. Enter your new password.

NOTE: Passwords need to conform to the specifications defined by the system administrator.
5. In the “Confirm Password” field re-enter your new password.
6. Click on the [Save] button to save the new password else Click on [Cancel] to disregard the new password and return to the “Home” screen.
7. If the password change is successful, the message “Password changed successfully...” is displayed.
8. If the new password does not conform to the password settings defined by the system administrator, a popup window displays the rules for defining a password.

2.6.2 To reset a forgotten password, follow these steps:

1. Click on the [Forgot Password](#) link on the login screen.
2. A pop-up screen with a hint for the user’s password is displayed.

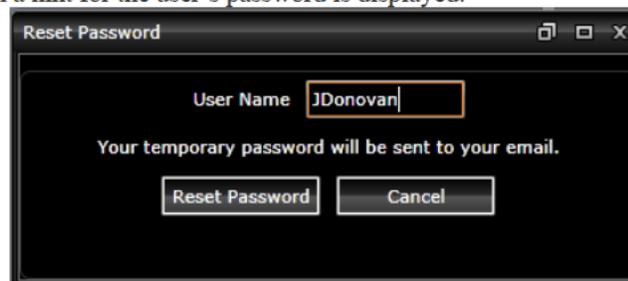


Figure 5: Forgotten Password

3. If the user remembers his/her password, the user enters their password in the password field.

4. If the user does not remember his/her password and wants to reset their password, he/she enters their username and Click on [Reset Password].
5. A temporary password is sent to his/her e-mail.
6. Once the temporary password is retrieved, the user may login and change their password.

2.6.3 Changing or Resetting Passwords for Other Users.

Users who have access to the “Users and Physicians” under the “Administration” menu may change passwords of users other than themselves.

1. Click on Administration > Management > Users Physicians. The following screen appears:

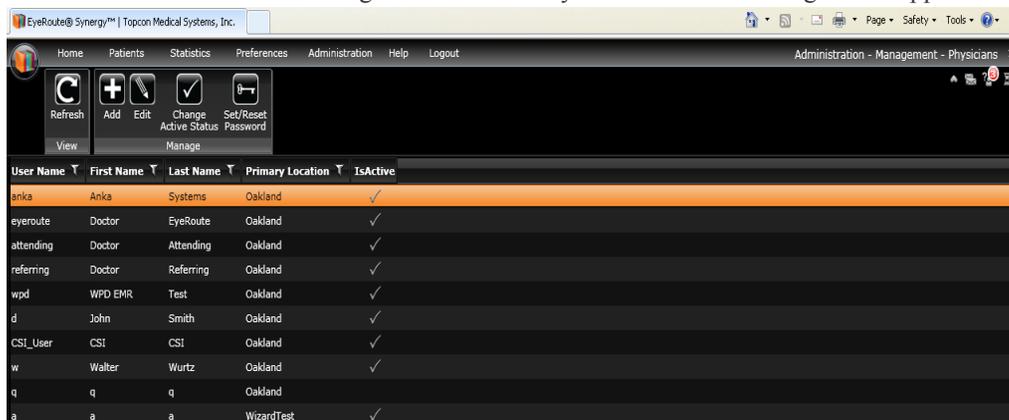


Figure 6: Users and Physicians Screen

2. Click on the [Set/Reset Password] button. The following screen appears:



Figure 7: Change or Reset Password

3. The user’s password may both be reset and sent to the user’s e-mail or a new password may be created on this screen.
4. To reset the user’s password, click on the [Reset Password] button. The temporary password will be sent to the e-mail address of the user.

5. To change the user's password:
 - Enter a new password in the "New Password" field.
 - Confirm the password by entering it again in the "Confirm Password" field.
 - Click on the [Save] button.

2.7 Setting Hints and Troubleshooting for Login

Here are few things to check:

- If you see "The page cannot be found" error message for the web page, please check and make sure that the URL address is correct.
- Check the security settings for Internet Explorer. Please consult your IT Department.
- Make sure that pop-up blockers have been disabled for the Synergy website. You might have multiple pop-up blockers installed.

2.8 Logout

The [Logout] menu button,  on the global menu bar may be clicked on from any screen. When the user clicks on the [Logout], the user is taken to the Login screen.

2.9 Session Expiration

If the Synergy application is idle for a certain period of time, the system will automatically log the user out. The default timeout is determined by the system administrator. A message will appear indicating that the session has expired and the user is returned to the "Login" screen.

3 APPLICATION CONVENTIONS

3.1 Help

The “Help” feature in Synergy provides four options for the user to find information about the system. The four options are: the User Manual, Frequently Asked Questions (FAQ), Support and About. The information found under each option is current with the version of the user’s system.

3.1.1 Help Manual

This manual, which may be found as a sub-menu under the Help menu is also available as a printed document. It contains documentation on the features and use of Synergy.

3.1.2 FAQ

FAQs (Frequently Asked Questions) may be found as a sub-menu under the Help menu. It provides questions and answers to commonly asked questions. For additional questions, comments or assistance Topcon Customer Support may be contacted.

3.1.3 Support

Support information may be found as a sub-menu under the Help menu. It provides the e-mail address and telephone number for Topcon customer support.

3.1.4 About

About may be found as a sub-menu under the Help menu. It provides the user with system information.

3.2 Global Navigation Elements

3.2.1 Top Navigation Bar

The navigation menu appears at the top left of the page, next to the Synergy application icon. It is available from every screen in Synergy. It contains top level and secondary level menus and fly open menus. The navigation menu is used to navigate to the main modules of the system, such as Patients, Statistics, etc.

Table 1: Menu Tabs

Tabs	Descriptions
Home	When the user clicks on the Home menu, the “Home” screen appears. It contains user and location information, quick links, the user’s exams for the day and three broadcast content areas. Depending upon how the user preferences are set, the Home screen may be the landing page.
Patients	When the user clicks on the Patients menu, the “Patients” screen is displayed. The Patient screen is the window where patient information and exams may be viewed and accessed.
Statistics	When the user clicks on the Statistics menu, the “Statistics” screen is displayed. The Statistics screen is the window where the statistical data may be displayed or printed.
Preferences	When the user clicks on the Preferences menu, the “Preferences” screen is displayed. The Preferences screen is the window where the user may specify their preferences for how their screens will appear.
Administration	When the user clicks on the Administration menu, the “Administration” screen is displayed. The sub-menus and subsequent fly open menus under Administration are used for maintaining Synergy.
Management	When the user clicks on the sub-menu Management, fly-open menus are displayed. The menus are: Patients, User & Physicians and User Roles
Patients	When the user clicks on the sub menu Patients, records containing patient information become available to the user based upon the user’s user role. Patient records can be retrieved, created, updated, merged or imported in this maintenance screen.
User & Physicians	When the user clicks on the sub menu, User & Physicians, records containing user and physician information become available. These records can be retrieved, created, updated, merged or deactivated depending upon the user’s user role. The user-physician account records contain demographic as well as role information for the user-physician. User roles and access to locations are assigned in the User & Physician in this menu selection.

User Roles	When the user clicks on the sub menu, User Roles, records containing user role information become available. These records can be retrieved, created, updated, copied or deleted. User access to modules and the ability to add, modify and delete records in Synergy is determined by user roles.
Monitoring	When the user clicks on the sub-menu, Monitoring, fly-open menus used for monitoring Synergy are displayed. The menus are: Open Sessions, System Log and Audit Trail. System data regarding users logged in, servers, CSGs and CSIs and system processes and transactions may be found among these menus.
Open Sessions	When the user clicks on the fly open menu, Open Sessions, records regarding usernames, location and date and time logged into Synergy are displayed.
CSGS	When the user clicks on the fly open menu, CSGS, a tab for "Hosts" and "CSIs" become available.
System Log	When the user clicks on the fly open menu, System Log, records regarding the servers, CSGs and CSIs are displayed.
Audit Trail	When the user clicks on the fly open menu, Audit Trail, records regarding the events in Synergy are displayed.
Jobs	When the user clicks on the fly open menu, Jobs, tabs for Dicom and MMI jobs become available.
Configuration	When the user clicks on the sub menu, Configuration, a list of fly-open menus used for configuring/setting up Synergy is displayed. The menus are: Security Settings, Regional Settings, System Settings, and Activation.
Security Settings	When the user clicks on the fly open menu, "Security Settings", a screen displaying password and expiration settings is displayed. These settings may be defined or modified.
System Settings	When the user clicks on the fly open menu, "System Settings", the default preferences for the appearance of Synergy screens is displayed. These settings may be defined or modified.
Site Configuration	When the user clicks on the fly open menu "Site Configuration", the user is able to add to or modify any of the following tabs: Locations, Hosts, Services, Capture Systems, Devices or CSIs.
Report Settings	When the user clicks on the fly open menu, "Report Settings", the user is able to define the configuration for reports.
Connectivity Settings	When the user clicks on the fly open menu, "Connectivity Settings", the user is able to define Dicom Servers, Services Selection and Dicom Image Encoding.
Activation	When the user clicks on the sub-menu "Activation", the user is able to enter a 25-character encrypted code that activates Synergy.

Help	When the user clicks on the Help menu, sub menus appear. These sub-menus are used for accessing information about Synergy. They are: Manual, FAQs, Support and About.
Manual	When the user clicks on the sub menu Manual, on-line documentation becomes available.
FAQs	When the user clicks on the sub menu FAQs, a listing of frequently asked questions and answers are displayed.
Support	When the user clicks on the sub menu Support, a screen with an e-mail link and the customer support telephone number are displayed.
About	When the user clicks on the sub-menu, About sub-menu, information regarding the version of Synergy, activated modules, commercial libraries, patents, FDA approval, and contact information shall be displayed.
Logout	When the user clicks on the Logout menu button, the user is logged out of Synergy.

3.2.2 My Account Menu



When the My Account Menu [] is selected, the details of the user's account information is displayed as show in the figure below.

A screenshot of the 'My Account' screen. It features a dark background with white text and input fields. The fields are: User ID (DDonovan), First Name (Dean), Last Name (Donovan), and Email (ddonovan@eyeinstitute.com). At the bottom, there are two buttons: 'Edit Account Information' and 'Change Password'.

Figure 8: My Account

The user may edit their account information or change their password.

3.2.3 Procedure to Edit Account Information:

- 1, Click on the [Edit Account Information] button.
The following popup window is displayed:

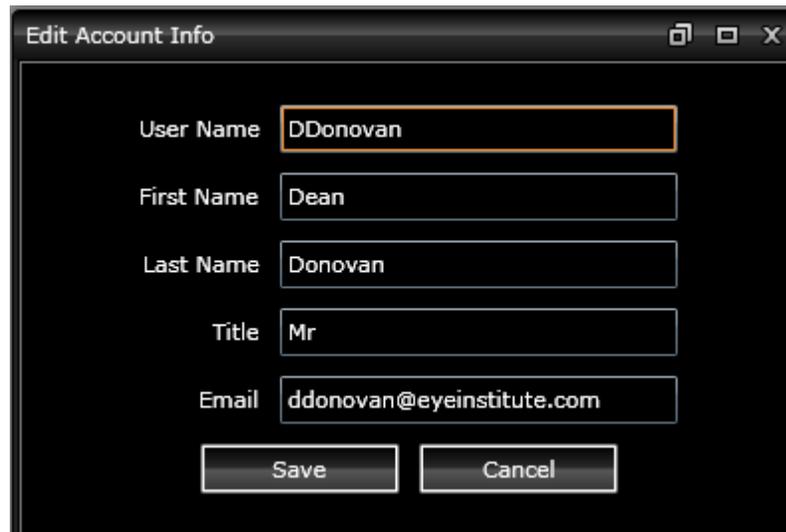
A screenshot of the 'Edit Account Info' popup window. It has a dark background with white text and input fields. The fields are: User Name (DDonovan), First Name (Dean), Last Name (Donovan), Title (Mr), and Email (ddonovan@eyeinstitute.com). At the bottom, there are two buttons: 'Save' and 'Cancel'.

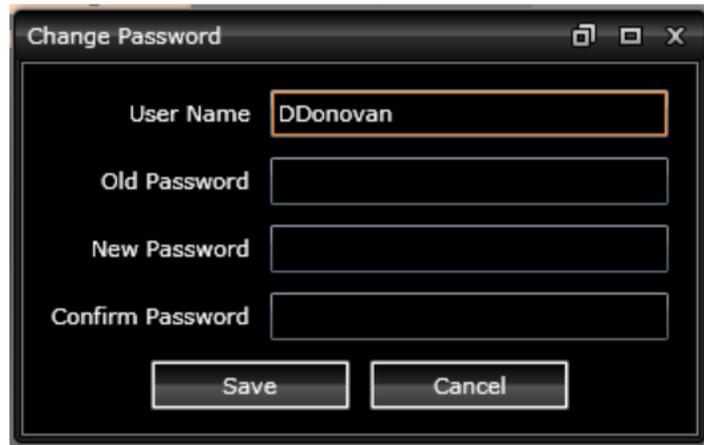
Figure 9: Edit Account Information

2. Edit the appropriate field(s).
- 3, Click on [Save] to update the changes or Click on [Cancel] to disregard any changes made on the screen.

3.2.4 Procedure to Change Password.

1. Click on the [Change Password] button.

The following popup window is displayed:



A screenshot of a 'Change Password' dialog box. The dialog has a title bar with 'Change Password' and standard window controls. It contains four text input fields: 'User Name' (with 'DDonovan' entered), 'Old Password', 'New Password', and 'Confirm Password'. At the bottom are 'Save' and 'Cancel' buttons.

Figure 10: Change Password

2. Enter the user's old/existing password.
3. Enter a new password.
4. Confirm the new password.
5. Click on [Save] to change the password or Click on [Cancel] to disregard any changes entered.

3.3 Indicators

“Indicators” for the “Message Center” and “Isolated Patients” appear on the right side of the “Title” bar. The number of messages and isolated patients overlays the icon for each indicator. The “Title bar” is visible on every screen within Synergy. They appear as follows:

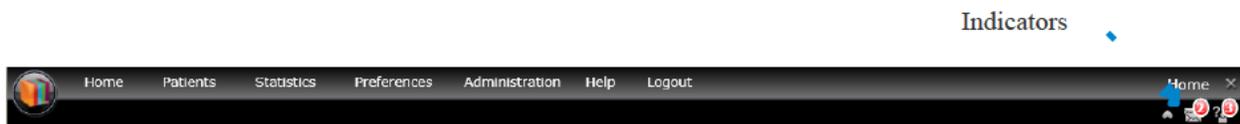


Figure 11 Indicators

3.3.1 The Message Center



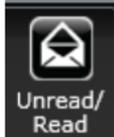
The Message Center can be accessed by clicking the Message indicator, , in the upper right-hand corner of the screen. It is next to the minimize/maximize button for the toolbar and accessible from any location within Synergy. The message indicator displays the number of unread messages so that the user knows if there are waiting messages. The Synergy Message Center enhances communication among users by providing internal users the ability to communicate within Synergy. It allows the user to send, receive and draft messages. Messages may include attachments or links which allow the user to transmit important data quickly and easily.

3.3.2 Toolbar



The following buttons appear in the toolbar for the Message Center:

Name	Button/Icon	Description
Refresh	 Refresh	The [Refresh] button updates the screen with the latest messages.
New Message	 New Message	A pop-up window for creating a new message appears when the [New Message] button is selected.
Reply	 Reply	The [Reply] button launches a new message within the same window. The selected message is copied into the window along with the sender's name in the "To" field. It provides the user with an efficient means of responding to the message.
Reply All	 Reply All	The [ReplyAll] button launches a new message within the same window. The selected message is copied into the window along with the sender's and recipients' names in the "To" field. It provides the user with an efficient means of responding to the message.
Forward	 Forward	The [Forward] button launches a new message within the same window. The "To" field is blank and the original message is copied into the window. It provides the user with an efficient means of forwarding the message.
Delete	 Delete	When selected, the message is deleted.

Unread/Read	 <p>Unread/Read</p>	When selected, the message that had been highlighted for reading is de-selected.
-------------	--	--

3.3.3 Mail Folders

The following mail folders appear in the Message Center:

Folder	Description
Inbox	The “Inbox” folder contains messages that have been sent to the user and not deleted.
Drafts	The “Drafts” folder contains messages that have not yet been sent.
Sent Items	The “Sent Items” folder contains messages that have been sent by the user.
Deleted Items	The “Deleted Items” folder contains messages that have been deleted by the user but not purged from their mailbox.

3.3.4 Procedure to Access Message Center:

1. Click on the icon for Messages.
2. The messages in the user’s Inbox are displayed:

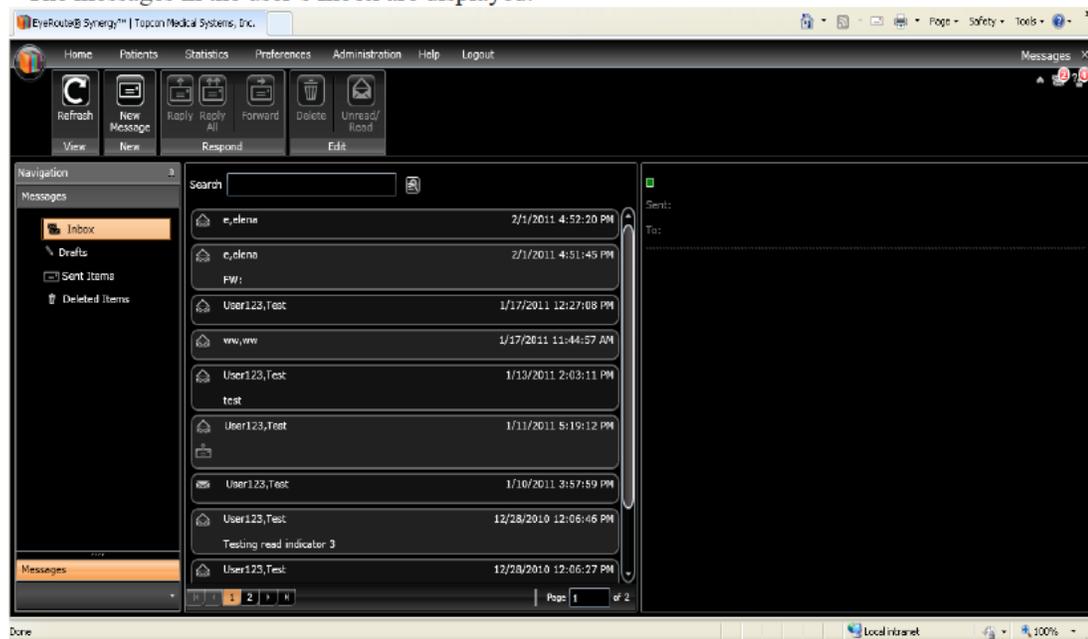


Figure 12: The Message Center

3. Highlight the message you wish to view.

4. The message appears in the content area for viewing messages.
5. Click on the [Unread/Read] button to remove the message details from the content viewing area.

3.3.5 Procedure to Send a Message.

1. Access the Message Center.
2. Click on the [New Message] button on the toolbar.
3. A pop-up window appears.

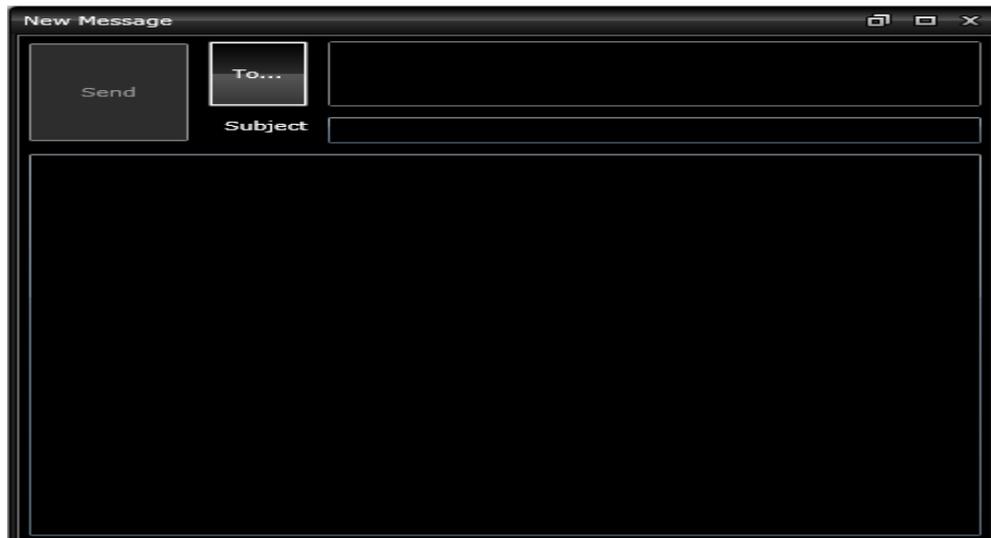


Figure 13: New Message

4. Click on the [To] button to select the user(s) to whom the message is to be sent.
5. Select the username from the list of users displayed.
6. Click on the [To...] buttons to populate the “To” field with the names.
7. Click on [Ok] to accept the recipients or Click on [Cancel] to disregard the names.
8. Enter the Subject of the message.
9. Enter the text of the message.
10. Click on the [Send] button.

3.3.6 Procedure to Reply to a Message:

1. Access the Message Center.
2. Highlight the message to which you want to reply.

3. Click on the [Reply] or [Reply All] button on the toolbar.
4. The following pop-up window will appear.



Figure 14: Reply Message

5. The name of the sender and recipients of the message, if the [Reply All] button is selected, appear in the "To" field.
6. Enter the text of the message.
7. Click on the [Send] button.

3.3.7 Procedure to Forward a Message:

1. Access the Message Center.
2. Highlight the message you want to forward.
3. Click on the [Forward] button on the toolbar.
4. The following pop-up window will appear.



Figure 15: Forward Message

5. Click on the [To...] button to select the user(s) to whom the message is to be sent.
6. Click on the username from the list of users displayed.
7. Click on the [To...] button to populate the “To” field with the names.
8. Click on [Ok] to accept the recipients or Click on [Cancel] to disregard the names.
9. Optional: Enter the Subject of the message.
10. Enter the text of the message.
11. Click on the [Send] button.

3.3.8 Procedure to Delete a Message:

1. Access the Message Center.

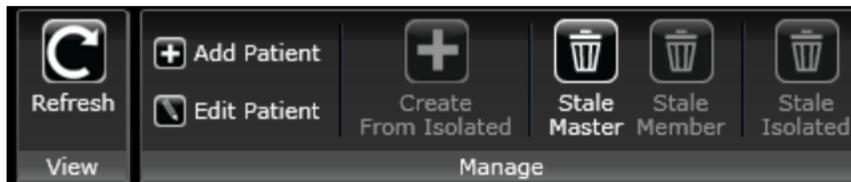
2. Highlight the message you want to delete.
3. Click on the [Delete] button on the toolbar.
4. The message is deleted.

3.4 Isolated Patients

"Isolated Patients" is used to identify patient exam data that was sent to Synergy from a capture station, but did not

match an existing have a patient record within the Synergy database. A button, , which allows the user to navigate to isolated patients appears in the upper right hand corner next to the Message Center. The button displays the number of isolated patients. It is accessible from any location within Synergy. Isolated Patients may also be accessed in the "Patients" menu option under the "Administration" menu screen or by clicking on the [Isolated Patients](#) link on the "Home" screen.

3.4.1 Toolbar for Isolated Patients



The following buttons appear in the toolbar for Isolated Patients:

Button	Icon	Description
Refresh	 Refresh	The [Refresh] button updates the screen with the latest patients.
Add Patient		A pop-up window for creating a new patient appears when the [Add Patient] button is selected.
Edit Patient		A pop-up window for editing the patient data appears when the [Edit Patient] button is selected.
Create from Isolated	 Create From Isolated	When an isolated patient is selected, this button becomes available. When the button is clicked, a pop-up window for updating the patient data appears. When the data has been modified, the isolated patient becomes a master patient.
Stale Master	 Stale Master	The [Stale Master] button deactivates the master patient. The patient record is denoted as "Staled".
Stale Member	 Stale Member	The [Stale Member] button deactivates the selected member patient. The patient record is denoted as "Staled".

Stale Isolated		The [Stale Isolated] button deactivates the selected isolated patient. The patient record is denoted as “Staled”.
----------------	---	---

NOTE: “Staled” information is considered inactive. Once the data is “staled”, it no longer appears on normal user screens. The information is not deleted from Synergy and can be restored by users who have permission to view “staled” data.

3.4.2 Control Buttons:

Button	Description
	Moves records from the isolated patient list to the master patient list.
	Moves records from the master patient list to the isolated patient list.

3.4.3 Field Definitions for Isolated Patients

Field	Description
Master Patients	
ID	Unique Id code for the patient record.
Last Name	The surname of the patient.
First Name	The first name of the patient.
Birth Date	The date of birth of the patient.
Gender	The gender of the patient. “F” is displayed for female and “M” is displayed for male.
Last Visit	The date of the patient’s last visit. This is calculated by finding the most recent exam date for the patient.
Isolated Patients	
ID	Unique Id code for the patient record.
Last	The surname of the patient.
First	The first name of the patient.
Birth Date	The date of birth of the patient.
Gender	The gender of the patient. “F” is displayed for female and “M” is displayed for male.
Capture System	Capture station type used for this exam (e.g. MRP, OCT, Topcon, Import, OIS, Heidelberg, ULI3, etc.).
Last Visit Date	The date of the patient’s last visit. This is calculated by finding the most recent exam date for the patient.

3.4.4 Procedure to Merge Patients

1. Locate the patient record. This may be done by using the search feature or scrolling through the list of patients.
2. Select the patient record to be moved to the master list and click on the left arrow, the record is moved to the master list of patients.
3. Instead of using the left arrow, the [Create from Isolated] button. A pop-up window with patient data appears.

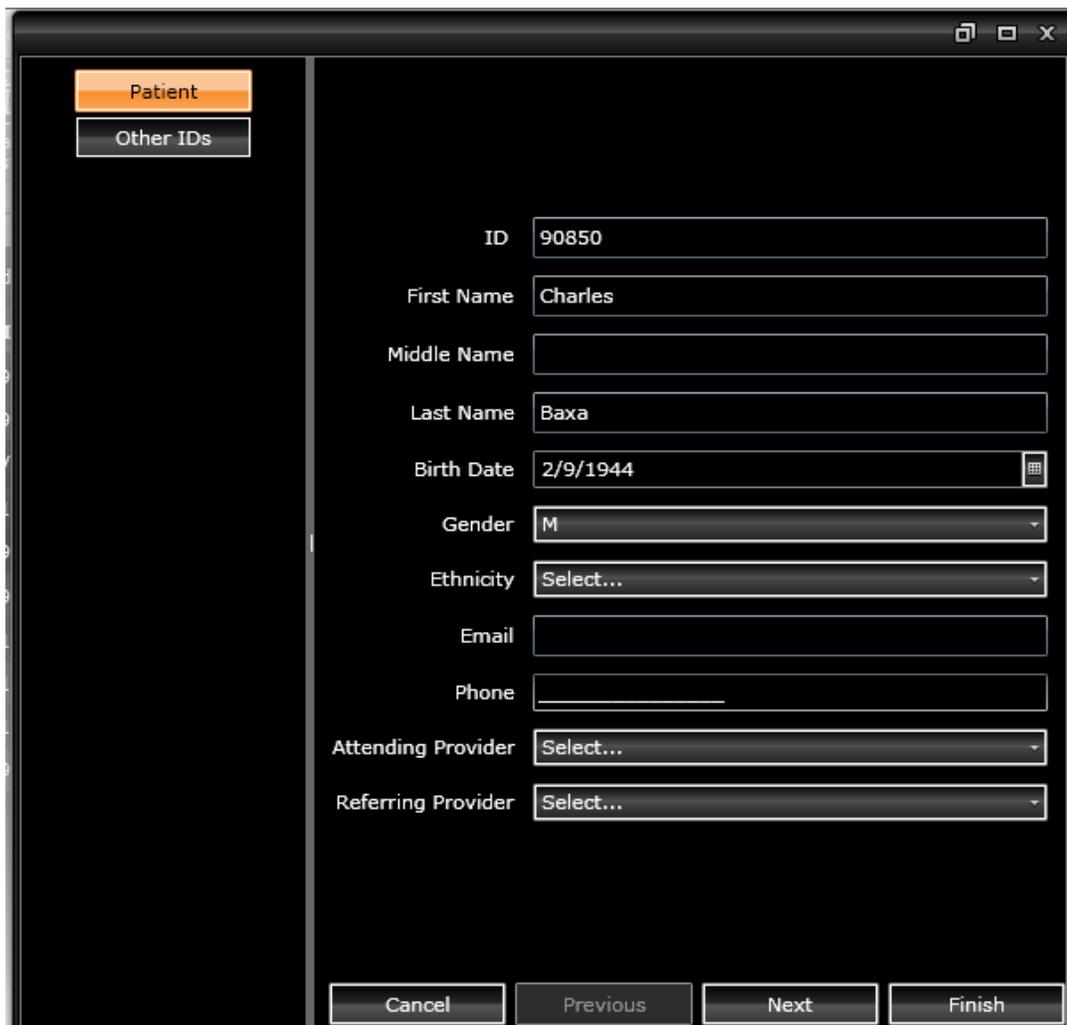


Figure 16: The Patient Edit Screen

4. Update the data as necessary.
5. When finished, the isolated patient will be moved to the master list.
6. If a patient in the master table needs to be moved to the isolated table, highlight the patient. The exams for the patient appear.

7. Select the appropriate record and click on the right arrow. The record is moved to the isolated list of patients.

3.5 The Minimize Button

The icons on a toolbar may be hidden to provide more space on the screen by clicking on the [Minimize]  button located on the right side of the toolbar next to the indicators. The button functions as a toggle button. To maximize the toolbar re-select the button.



Figure 17: Minimized Toolbar



Figure 18: Maximized Toolbar

3.6 Search

Records may easily be retrieved by invoking the search feature. The user has the option of retrieving all records, retrieving records by date, or retrieving records associated with a specific criterion. To search by date, the user has the option of searching all records, the last 7 days or the current date.

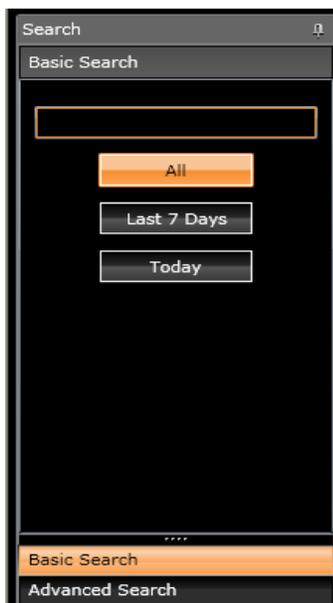


Figure 19: Basic Search



Figure 20: Advanced Search

If the user would like to search by a specific criterion, he/she may click on the [Advanced Search] button and choose one of the following criteria: First name, Last Name, ID, Modality, Device, Physician, From to Date.

3.7 Title Bar

A title bar will appear on every screen. This screen contains the global menu, name of the screen, the minimize/maximize button and indicators.

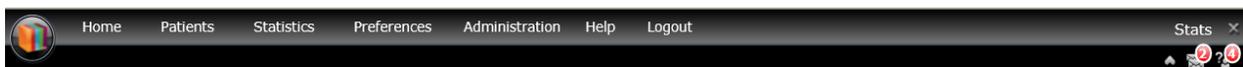


Figure 21 Title Bar

3.8 Filtering

The user has the option of filtering records by clicking on the filter icon . When the filter icon is selected, the user is presented with options on how he/she would like the data filtered.

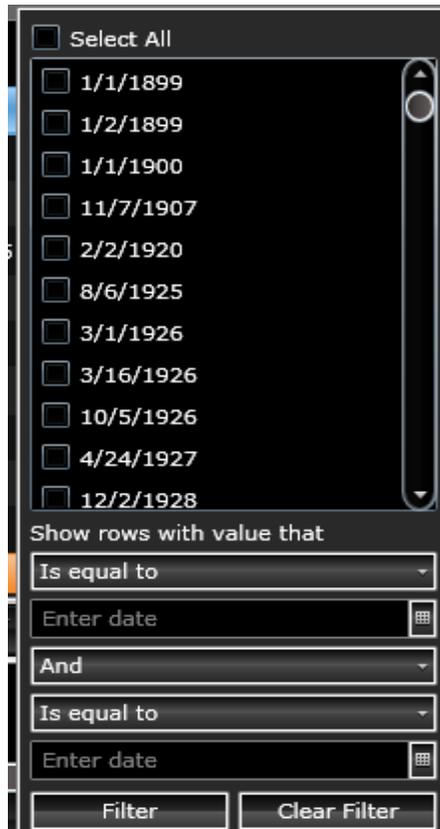


Figure 22: Filtering

3.9 Drag and Drop

Column headers and exams may be repositioned by dragging and dropping them to the desired position. To do this, highlight the column to be repositioned. The column label turns blue. Now drag the column to the desired position and drop it in place. The column now appears in the specified position.



Figure 23: Drag and Drop

3.10 Scroll Bars

Horizontal and vertical scroll bars may be used to view additional data within a content area. By moving the scroll bar across or up and down the screen additional data becomes available for viewing.



Figure 24: Vertical Scroll Bar



Figure 25: Horizontal Scroll Bar

3.11 Toolbar

The Synergy Tool Bar contains buttons specific to the screen displayed. Each button is represented with an icon and paired with a description below it. It has a custom minimize button on the right that can be selected to save screen real estate. The minimize button can be toggled to display the tool bar again. When the user moves the mouse over a button, a hover effect takes place.

3.12 The Hover Effect

The purpose of the hover effect is to communicate to the user that their mouse pointer is now pointing to a particular object on the screen. This is particularly helpful for functions which require the use of a mouse. The hover effect changes both the foreground and the background of the controls as follows:

1. The foreground text and/or icon figure color changes from light to dark.
2. The background color changes from dark to blue shade.



Figure 26: Before Hover



Figure 27: After Hover

3. When the button is selected it changes to orange.



Figure 28: Selected

3.13 Input Validation

In Synergy, if the input entered into a field has an error, the error message displays on a red background and the field with the error gets a red border as in the following snap shot.

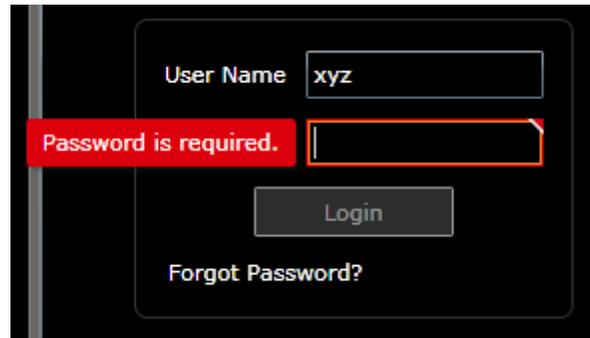


Figure 29: Input Validation

3.14 Alerts

In case of an alert a dialog box with the appropriate message and icon will pop up as in the following snap shot.

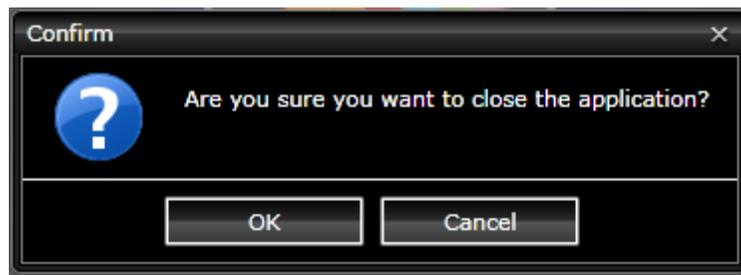


Figure 30: Sample Alert

3.15 Busy/Processing

The circular circles as shown in the figure below indicate that the system is busy or processing.

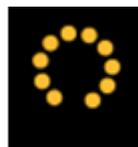


Figure 31: The Busy Indicator

4 SYNERGY FEATURE GUIDE

4.1 Home Page

The Home page contains user and location information, and quick links. Depending upon how the user preferences are set, the “Home” screen may be the landing page. From this page the user may change their location, access the message center and isolated patients, change their password and edit their account information. The user may select any of the menu options on the global menu to exit the screen.

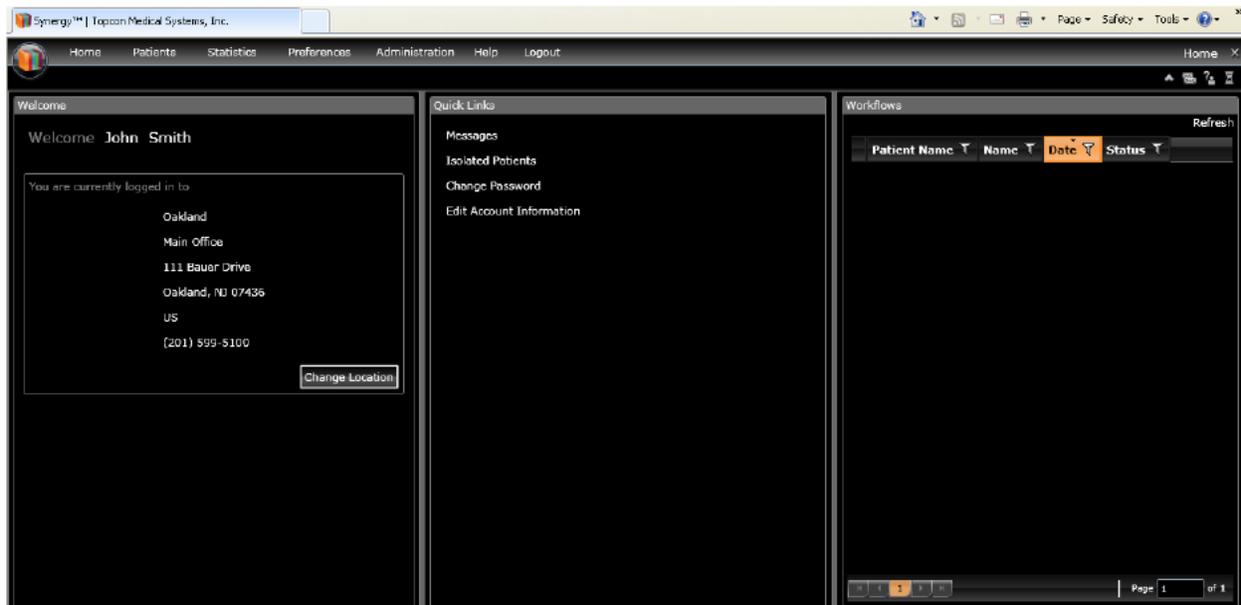


Figure 32: The Home Page

4.1.1 User Information:

A welcome greeting and the following user information is displayed in the user information content area.

Field	Description
Location Name	The primary office location of the user is displayed. This location can be changed by clicking on the [Change Location] button.
Address	Three lines are provided for the address of the location. The street address along with any suite or floor number, city, state and zip are displayed.
Phone Number	The phone number of the location is displayed.
Main Fax Number	The primary fax number of the location is displayed.
Last Login	Date and time the user last logged in.

Last Failed Login	Date and time of the last failed login.
-------------------	---

4.1.2 Procedure to Change User's Location.

1. Click on the button [Change Location].
2. The following pop-up window appears:

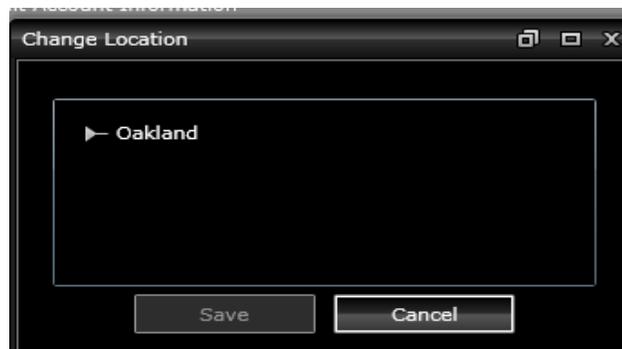


Figure 33: Changing location

3. Click on the appropriate location from the list displayed on the pop-up window.
4. Click on the [Save] button to update your account with the modifications entered on the screen otherwise click on the [Cancel] button to disregard any modifications entered on the screen.
Note: The user will be able to access the location based upon the privileges set for his/her role.

4.1.3 Quick Links

“Quick Links” provide the user with quick access to other screens within Synergy. They appear as follows on the “Home” page:

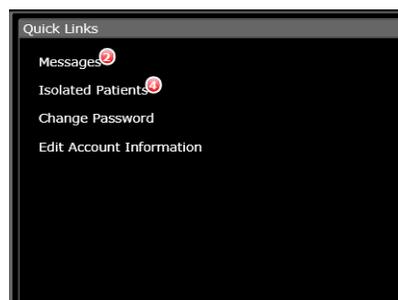


Figure 34 Quick Links

4.1.3.1 Definition of Quick Links:

Link	Description
Messages	A link that takes the user to their message box.
Isolated Patients	A link that takes the user to patients that have been not been updated in the patient file.
Change Password	A link that allows the user to change his/her password.
Edit Account Information	A link that allows the user to update his/her accounts information.

4.2 Patients

The *Patients* module is used to view patient information and their exams. Patient information along with their exams is available for viewing, updating, annotating, and creating reports. This module may be accessed from the global menu. Access to patient records is determined by the user's user role.

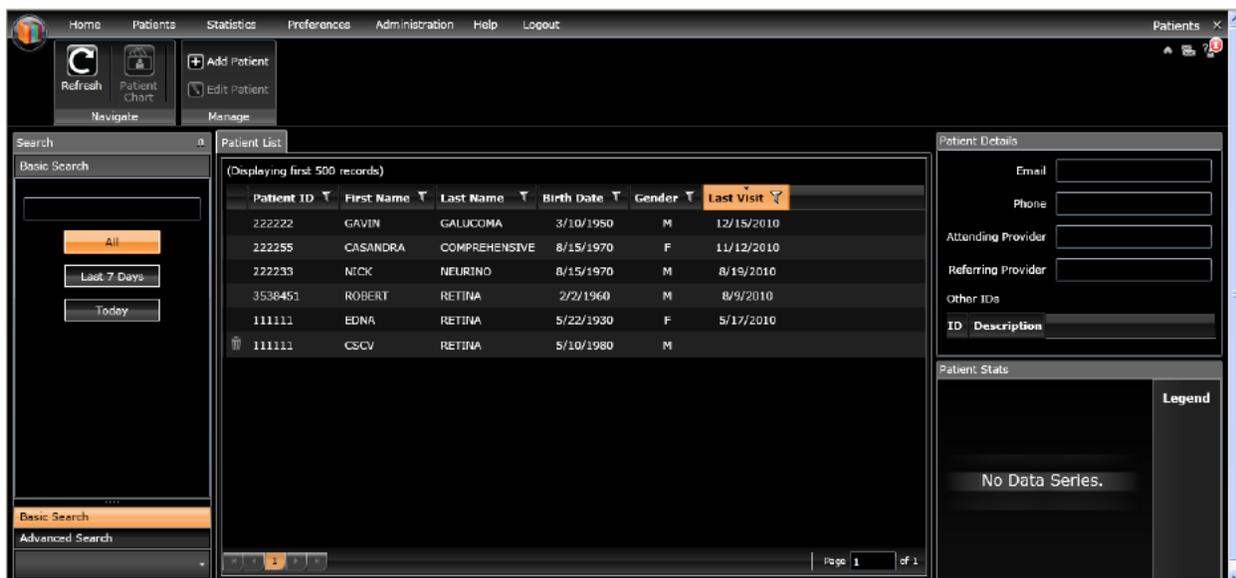
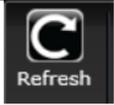
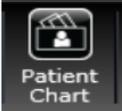


Figure36: The Patient Screen

4.2.1 Tool bar

Name	Button/Icon	Description
Refresh		The [Refresh] button updates the screen with the latest patients.

Patient Chart		A listing of the patient's exams is displayed. The exams may be viewed. The user also has the option to view patient details and the patient journal.
Add Patient		A pop-up window for creating a new patient appears when the [Add Patient] button is selected.
Edit Patient		A pop-up window for editing the patient data appears when the [Edit Patient] button is selected.

4.2.2 Field Definitions for Patients:

The following fields are contained in the patient list:

Field	Description
Patient ID	The unique id for the patient is displayed.
Last Name	The last name of the patient.
First Name	The first name of the patient.
DOB	The patient's date of birth is displayed.
Gender	The gender of the patient is displayed. F=Female; M=Male.
Last Visit	The date the patient was last seen in the office.

The following fields are contained in the patient details:

Field	Description
Email	The patient's e-mail address
Phone	The patient's phone number.
Attending Provider	The physician responsible for the patient's care.
Referring Provider	The physician from whom the patient originated.

ID Description	In the event that the patient has more than one ID, the ID number and description of the id appears in this field.
----------------	--

4.2.3 Search

Patient records may easily be retrieved by invoking the search feature. There is a [Basic Search], an [Advance Search] and a [Dicom Search]. The “Basic Search” allows the user to search by a text string, all records for the patients who have been seen in the last 7 days or in the current date. The “Advance Search” allows the user to search by specific criterion and/or date range. The “Dicom Search” allows the user to search by patient, physician or study criterion.

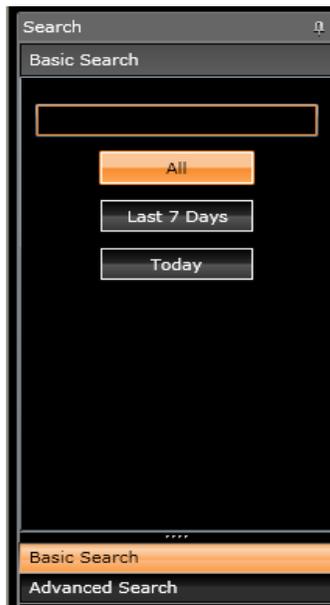


Figure 35: Basic Search



Search

Advanced Search

First Name

Last Name

ID

Modality

Device

Physician

From 3/2/2011

To 3/2/2011

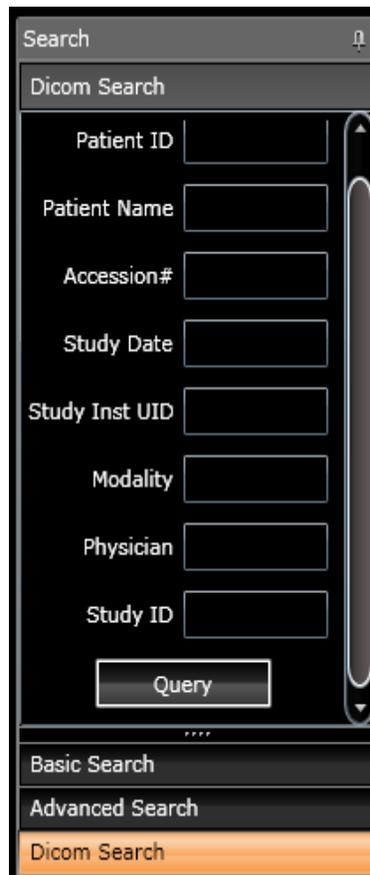
Search

....

Basic Search

Advanced Search

Figure 36: Advanced Search



The screenshot displays a mobile application interface for a search function. At the top, there is a header labeled "Search" with a search icon. Below this is a sub-header "Dicom Search". The main area contains several input fields for search criteria: "Patient ID", "Patient Name", "Accession#", "Study Date", "Study Inst UID", "Modality", "Physician", and "Study ID". A "Query" button is positioned below these fields. At the bottom of the screen, there is a navigation menu with three options: "Basic Search", "Advanced Search", and "Dicom Search". The "Dicom Search" option is currently selected and highlighted in orange.

Figure 37: Dicom Search

4.2.4 Patient Statistics

A graphical presentation of the patient's exams is presented in the form of a pie chart in the lower right-hand corner of the screen. The patient's exams appear color coded by modality and include the number of exams per modality. The legend for each device appears to the right of the pie chart.

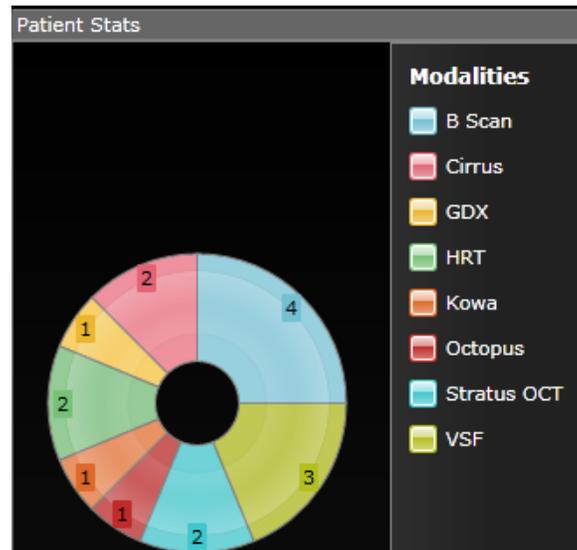


Figure 38: Patient Statistics

The pie chart is interactive, and allows an end user to quickly jump to a patient's examination, within the respective patient's chart. Hovering over an individual modality with the mouse pointer will highlight the examination to be selected, and dim out all other modalities. Clicking on the modality will bring the end user directly into the patient's chart, viewing the latest images captured for the modality type selected.

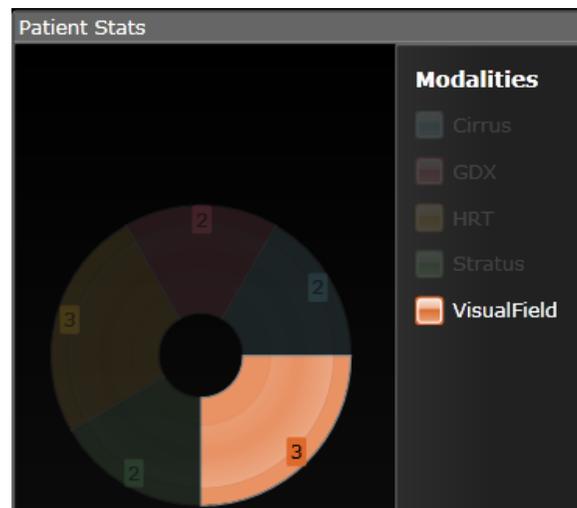


Figure 40: Interactive Patient Statistics

4.2.4.1 Procedure to Add a Patient:

1. Click on the [Add Patient] button.

A pop-up window with the following fields appears:

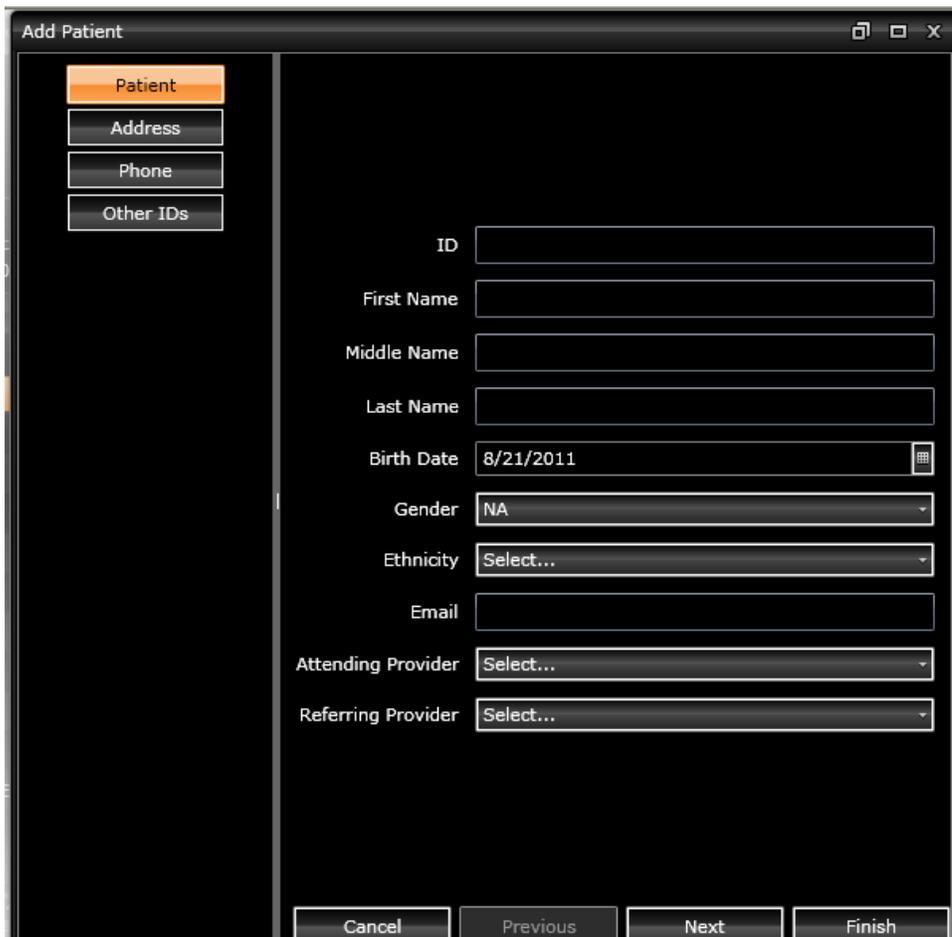
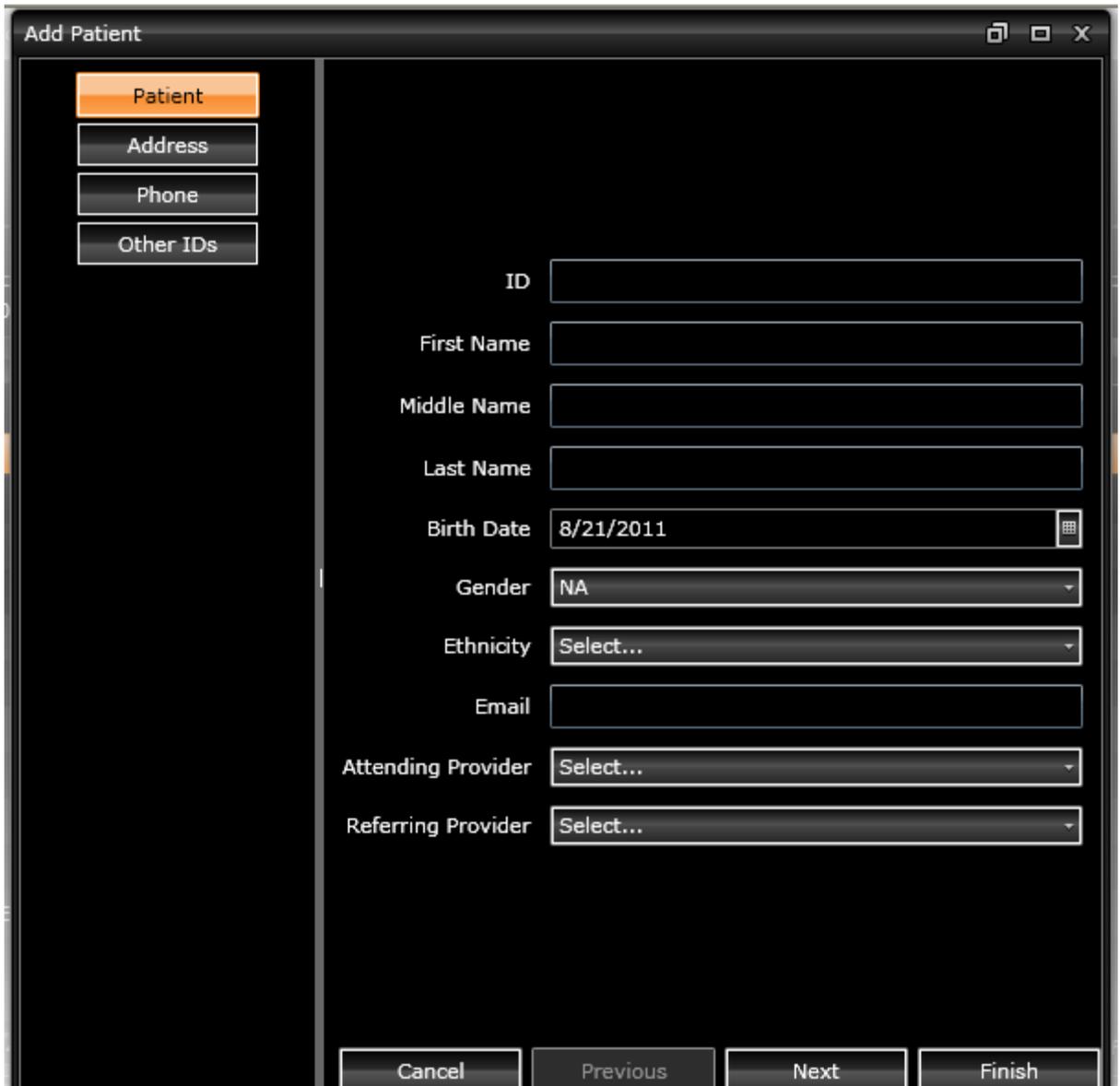


Figure 39: Add a Patient

2. Enter the appropriate data in each of the fields.
3. Click on the Next button.
The following screen appears:



4. Enter the patient's street address in Address 1 and Address 2.
5. Enter the city for the address.
6. Enter the state for the address.
7. Enter the country for the address.
8. Enter the zip code for the address.
9. Click on the [Next] button or the [Phone] button to enter the patient's phone number.
The following screen appears:



Figure 40: Phone Number Screen

10. Multiple phone numbers may be entered for the patient by clicking on the add button.
11. Click on the [Next] or [Other Ids] button if the patient has multiple ids otherwise click on the [Finish] button to add the patient. The following screen appears:



12. Click on the [Add] button to enter additional ids for the patient.
13. Click on the [Finish] button when all ids have been entered. The patient is added to the database.

4.2.4.2 *Procedure to Edit a Patient:*

1. Click on the [Edit Patient] button.
2. A pop-up window with the following fields appears:

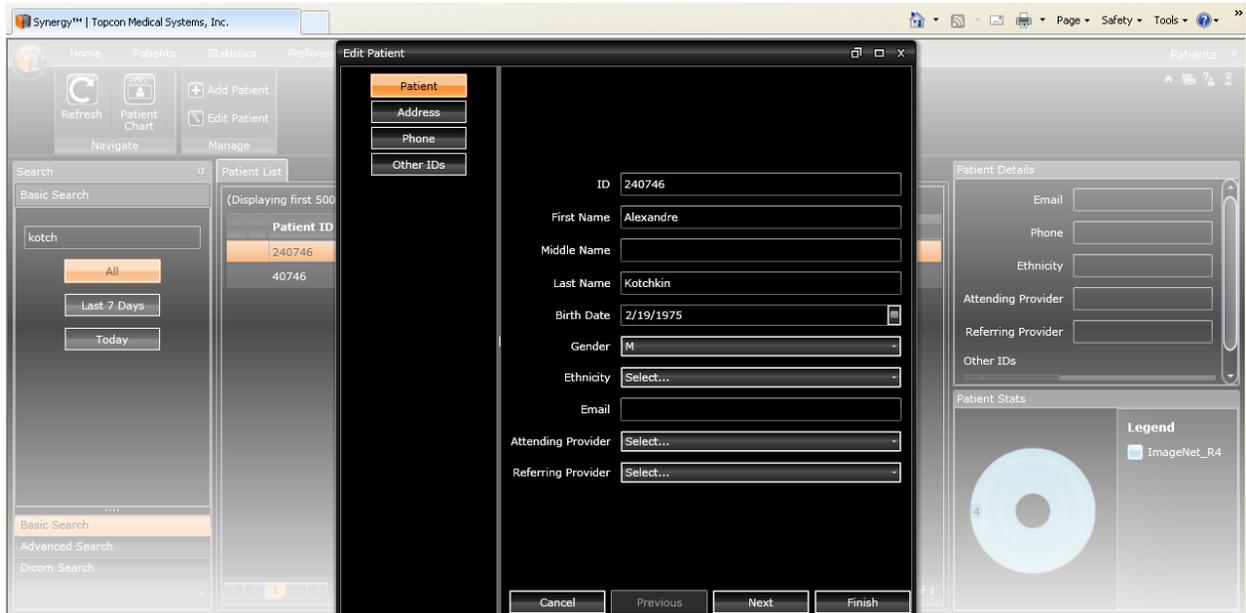


Figure 41: Editing a Patient

3. Modify the appropriate data in each of the fields.
4. Click on the [Next] button.
The following screen appears:

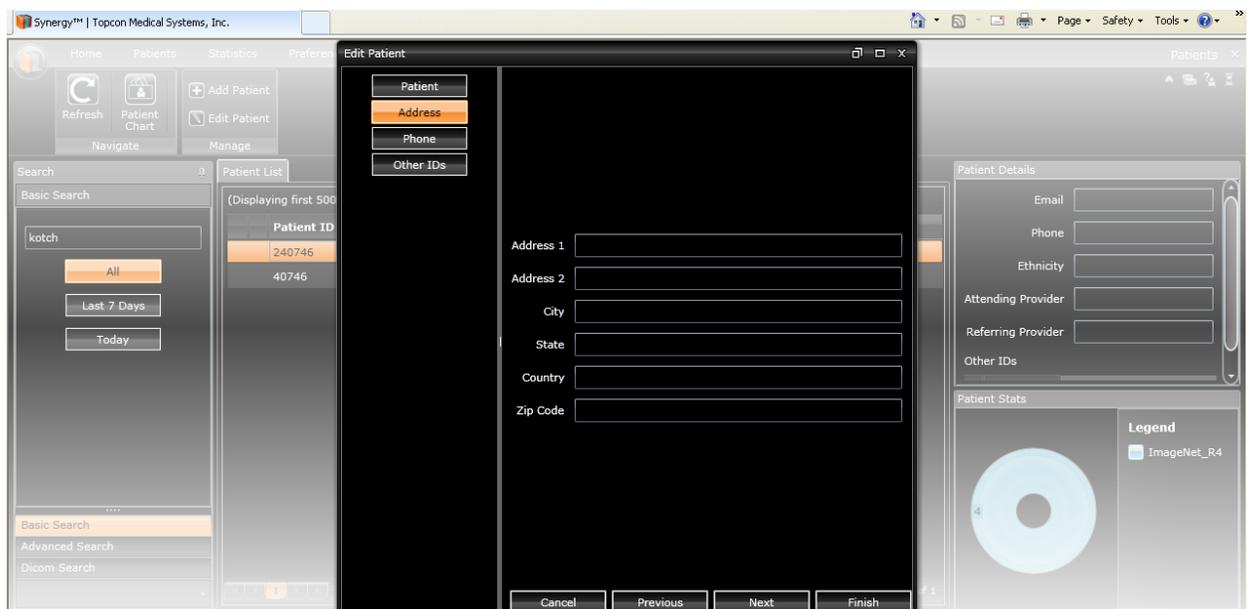
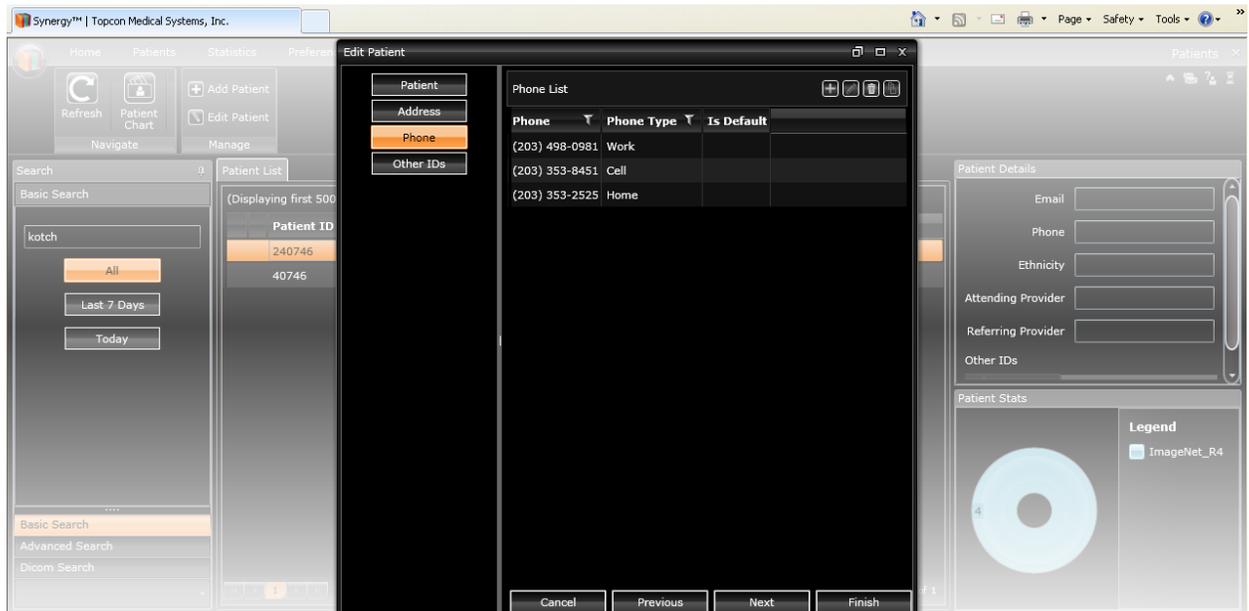
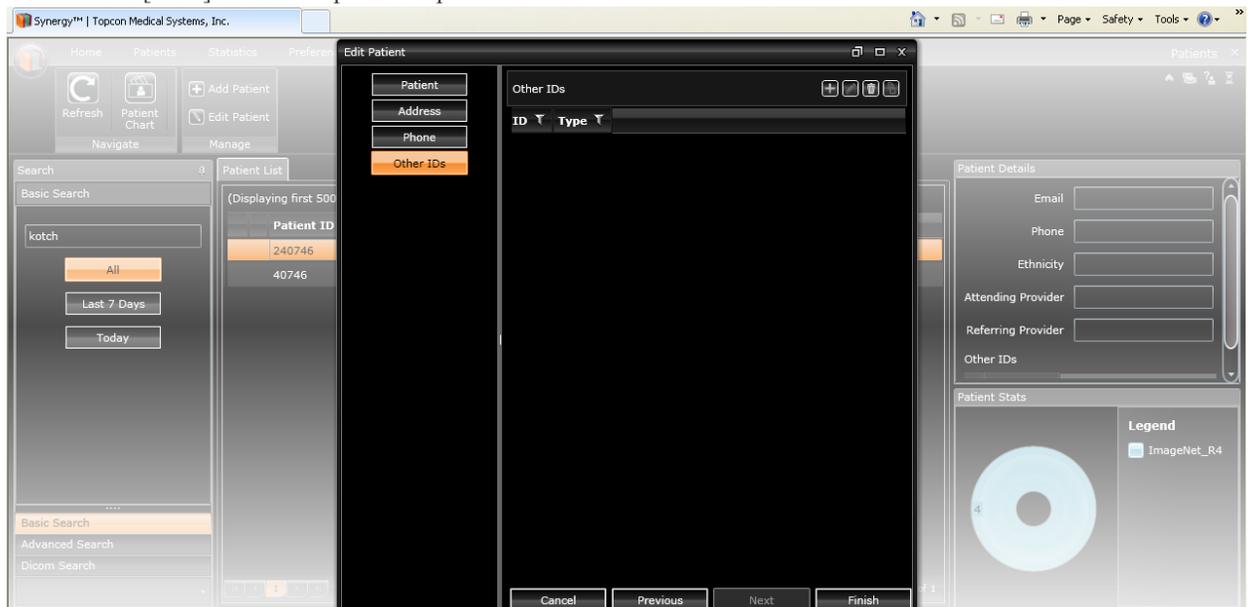


Figure 42: Editing Patient Address

5. Add or modify the patient's address, if appropriate.
6. Click on the [Next] button or [Phone] button to modify the phone number.



- Click on the [Next] button to update the patient's IDs.



- Click on the [Finish] button when completed. The patient information is updated.

4.2.5 The Patient Chart

The "Patient Chart" contains the "Patient's Exams", "Patient Details" and the "Patient Journal". The "Patient Chart" may be accessed by highlighting the patient record and clicking on the [Patient Chart] button on the "Patient List" screen. It may also be accessed by double clicking on the patient record.

The name of the patient, patient id and patient’s date of birth appear in the title bar for the screen. The left pane contains the Patient Details, Patient Exams, and Patient Journal. Upon hovering on the Patient Journal, the list of journal types is displayed. They are: ALL, Note, and Annotation.

The right pane holds the media viewing area. This is where all images, videos, reports and other patient media are displayed. The media viewport is split into tabs, one per modality, and additional tabs for exam comparison and journal items.

4.2.6 Patient Details

When “Patient Details” is selected, the following details are displayed.

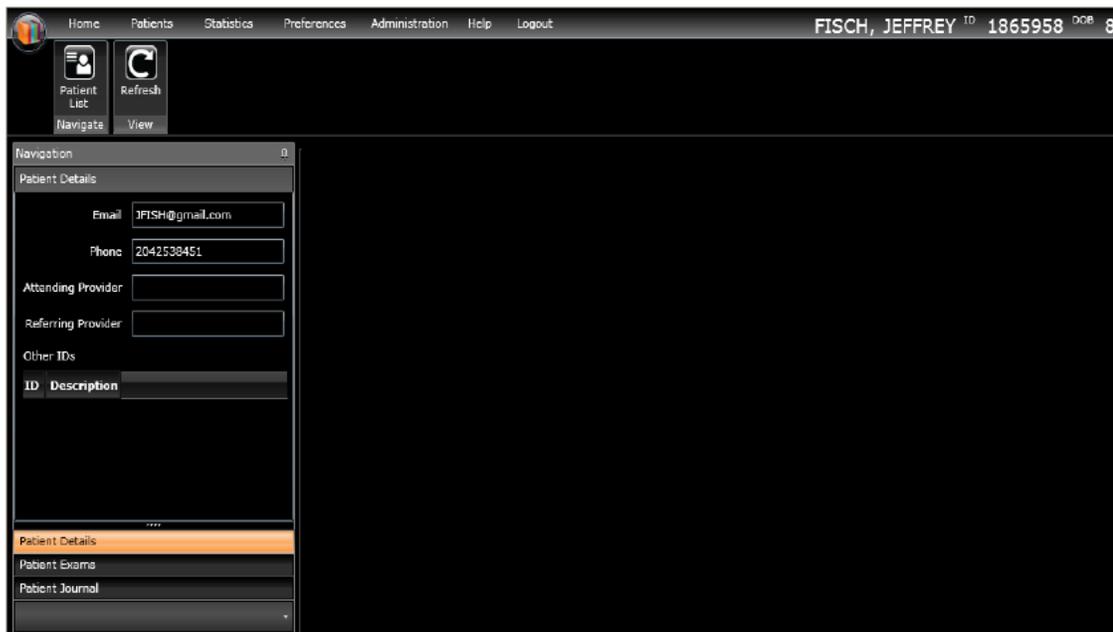


Figure 43: Patient Details

The following fields are contained in the patient details:

Field	Description
Email	The patient’s e-mail address
Phone	The patient’s phone number.
Attending Provider	The physician responsible for the patient’s care.
Referring Provider	The physician from whom the patient originated.
ID Description	In the event that the patient has more than one ID, the ID number and description of the id appears in this field.

4.2.7 Patient Exams

Patient exams are listed in the left pane they may be grouped by date, modality or device. They may be opened or dragged into the viewing area for comparison.

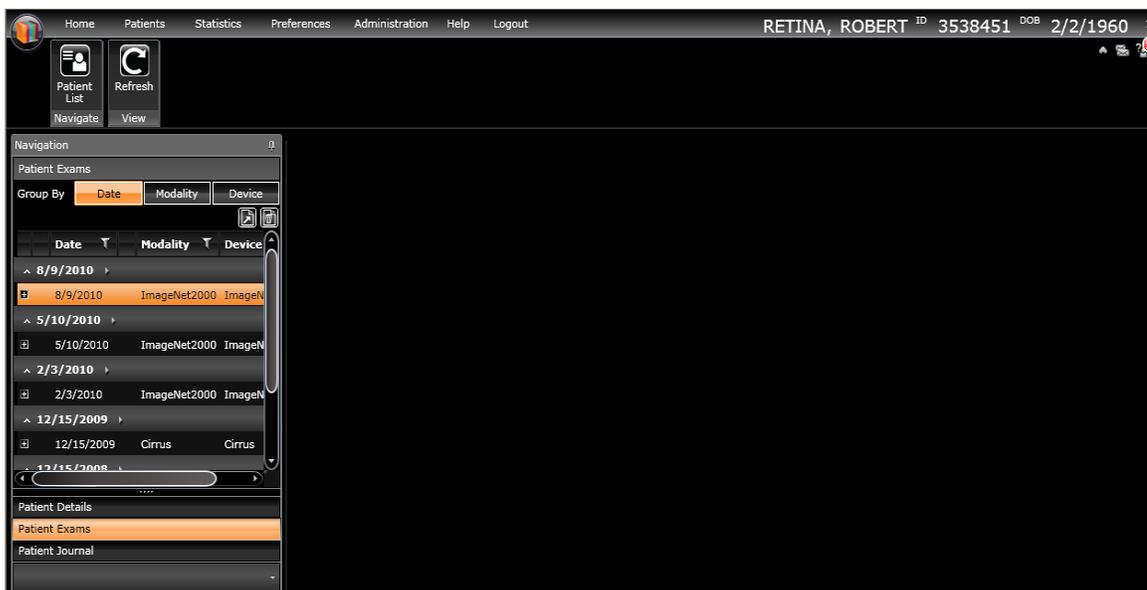


Figure 44: Patient Exams and Viewport

4.2.7.1 *Sorting Patient Exams*

1. The “Exams” list may be sorted by date, modality or device by clicking on the corresponding button in the “Group By” field.
2. To view the individual exams within the group, click on the Open Selected Exam  button.

4.2.7.2 *Manual Import*

Local media files may be imported into Synergy

1. Choose the patient from the patients list by double clicking on the selected patient or clicking on the [Patient Chart] button.
2. When the patient chart appears an additional button will be added for importing exam images from the local PC. To start the import job double click on the [Import] button on the tool bar.
3. When the [Import] button is clicked the Import tab appears with exam information such as the exam date and device, to be filled for the imports.

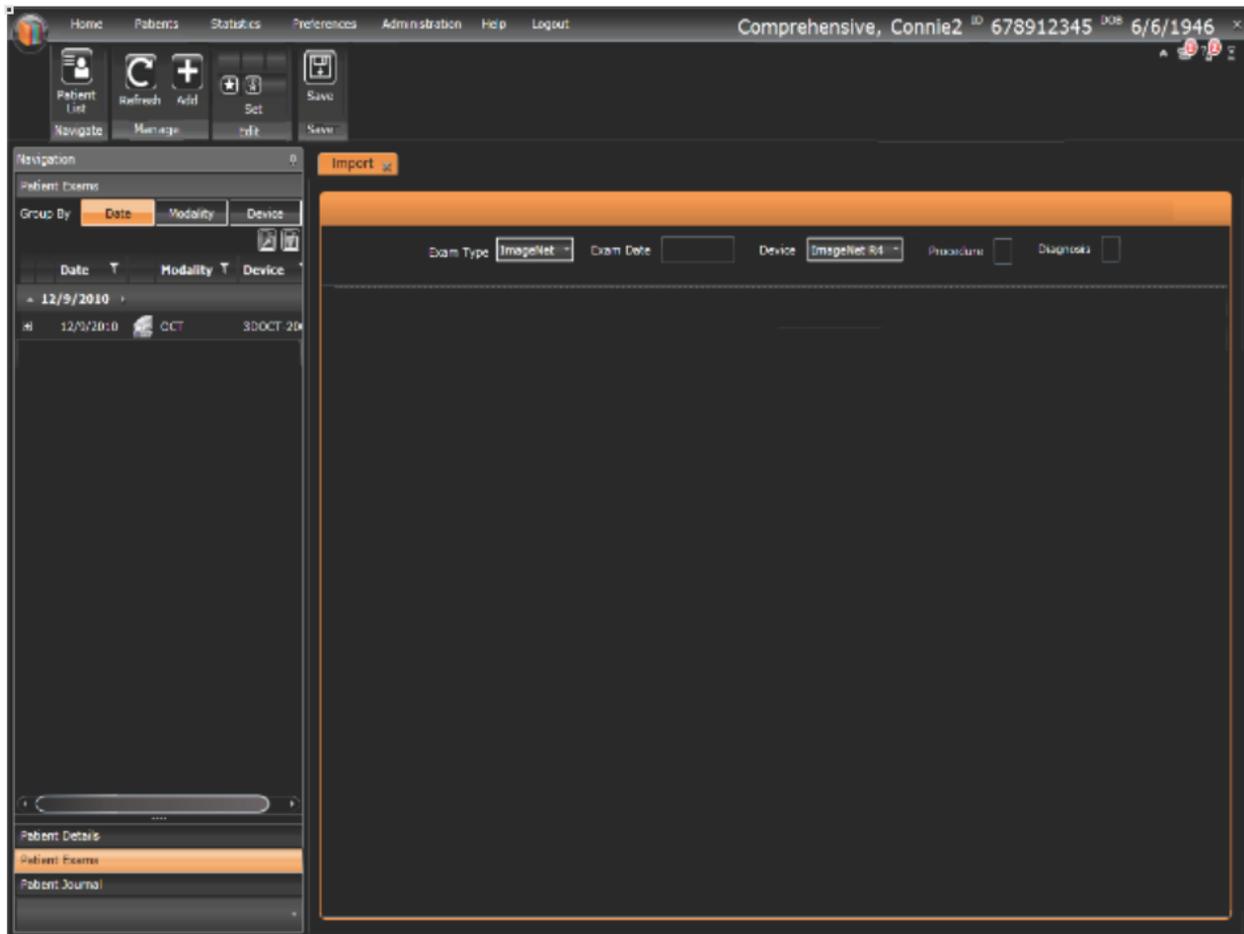


Figure 45: Manual Import

4. To select images for import, click on the [Add] button on the tool bar.
5. After selecting the images for import using Open File Dialog, they will appear within the Import tab, similar to the existing Proof Sheet format. At this point, they can be set as OD, OS, etc as well as their procedure.

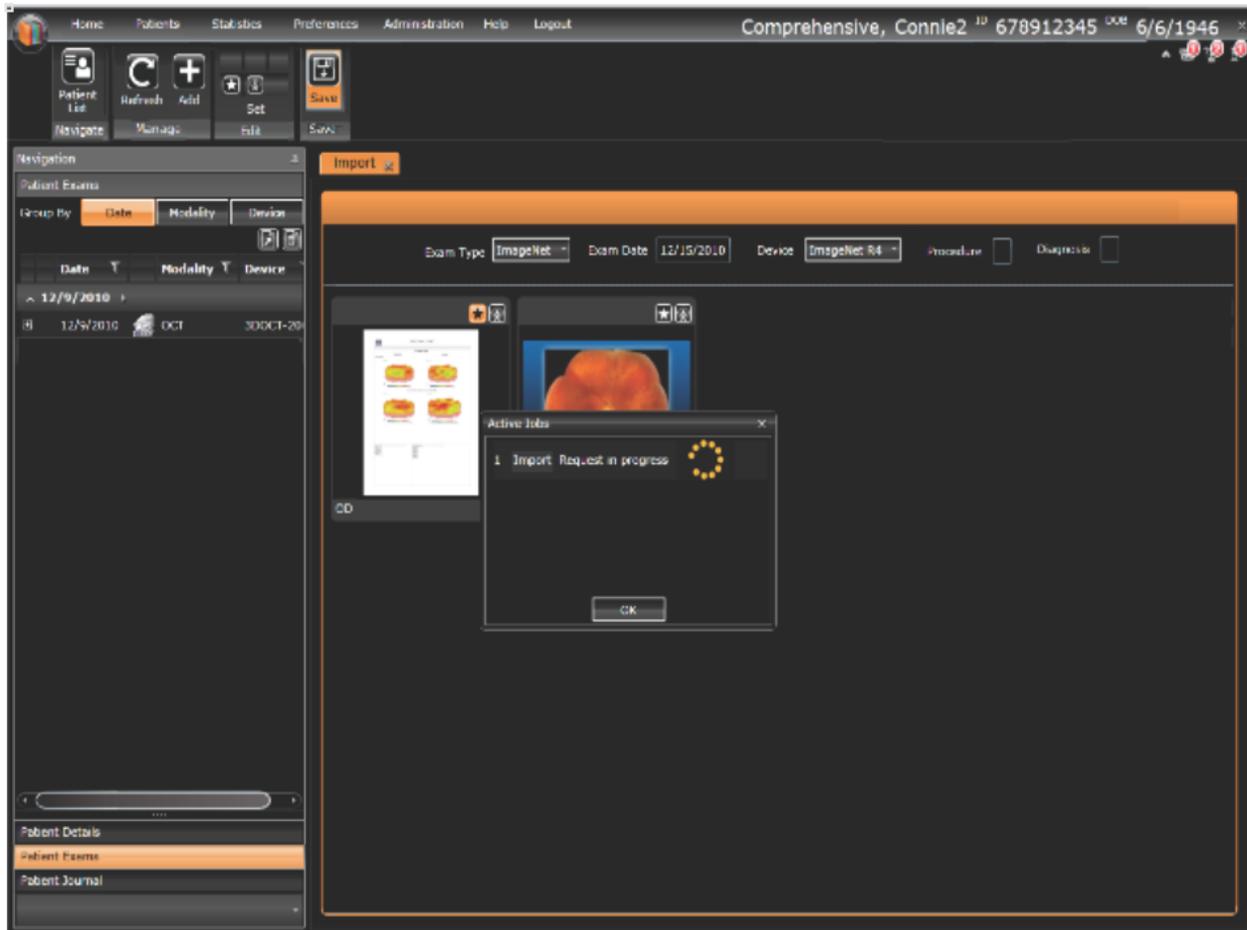


Figure 46: Save Imports

6. To save or upload the imported media to the Media Server, click on the [Save] button. Some of the exam details need to be validated such as exam type (modality), date and device before saving.

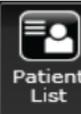
Note: Saving or uploading process will be done asynchronously by adding it as a job.

4.2.7.3 Toolbars for Viewing Exams

The toolbar for viewing exams is dynamic. It is based upon the modality that is selected and if exams are being compared. When there are additional buttons available, a right bar appears at the end. By clicking on this bar, additional buttons are displayed. To return to the previous set of buttons, click on the left bar.



Figure 47: Toolbars for Viewing Exams

Button	Icon	Description
Navigate		
Patient List		Displays the “Patient List” screen. The “Patient List” screen displays a list of patients.
View		
Refresh		Refreshes the screen
Full View		The media is displayed on the full screen. To exit the full screen mode, click on the [Esc] button.
Historical Comparison		Compares the selected media with previous exams.
Select		
Select All		Selects all media
UnSelect All		De-selects the media
Edit – Filter		
OD (Right Eye)		Sets the value of the eye as OD (Right eye)
OS (Left Eye)		Sets the value of the eye as OS (Left eye)
OU (Both Eyes)		Sets the value of the eye as OU (Both eyes)
Key		Marks the media as key media

Hide/Show		Hides/shows
Edit – Sort		
Eye Value		Sorts the media by eye value.
Key		Sorts the media by key value
Procedure		Sorts the media by procedure
Timer		Sorts the media by timer
Print		
Print	 Print	Prints the media
Journal		
Note	 Note	Presents a pop-up window allowing text to be entered for an exam.
Export		
Export	 Export	Allows the media to be exported to a local disk.
DICOM Copy	 DICOM Copy	Displays the Modality Work List (MWL)
Interpretation Report	 Interpretation	Presents a pop-up window of the interpretation report. The report may be created, signed or viewed.

Image Tools		
Save		Saves the data on the screen
Size		Displays the image or report in the original size.
		Fits the image or report to the container
		Fits the image or report to the width of the container.
iMode		Sets the interactive mode to pan.
		Sets the interactive mode to magnify.
Annotate		Allows a note to be entered at a specific place on the media.
		Allows free drawing on the media and a note to be entered on the media.
Hide Registration Box		Hides the registration box
Show Thickness Map		Displays the thickness
Levels		Sets the brightness, contrast and intensity level of an image or report.
Channels		Filters the RGB (Red, Green, Blue) channels of an image.

4.2.7.4 *The Viewing Area*

The viewport has a header, a footer, an auto-collapsible slider and the media viewer pane. It appears as follows:

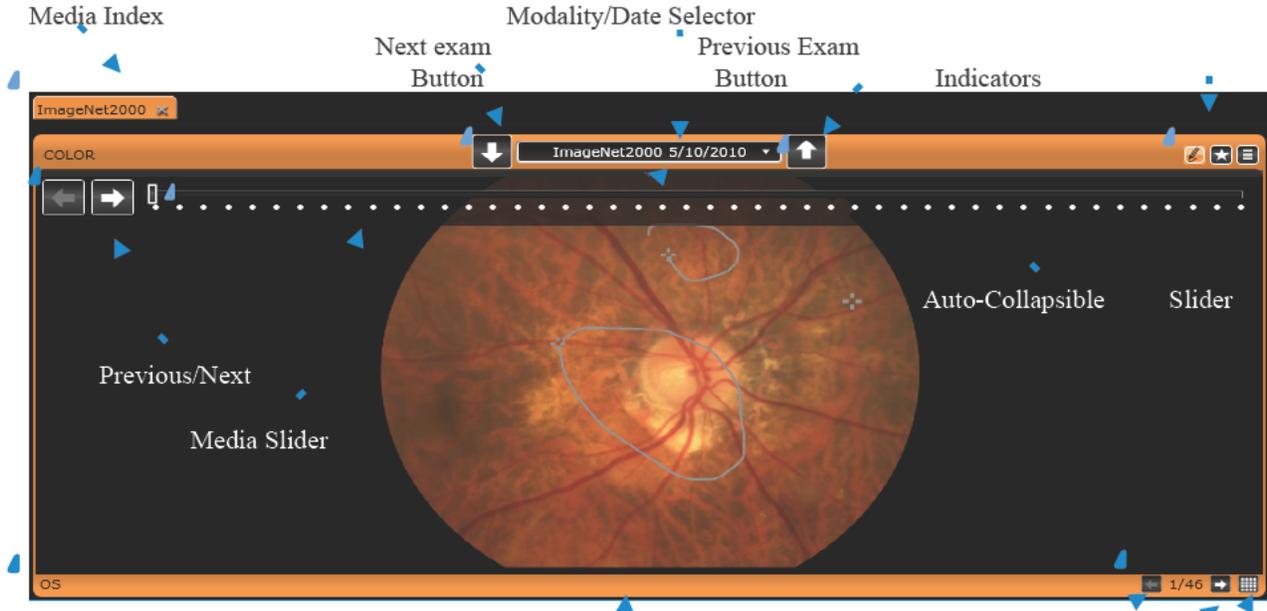


Figure 48: The Viewing Area

Eye Indicator Timer if applicable Previous/Next Buttons Viewport

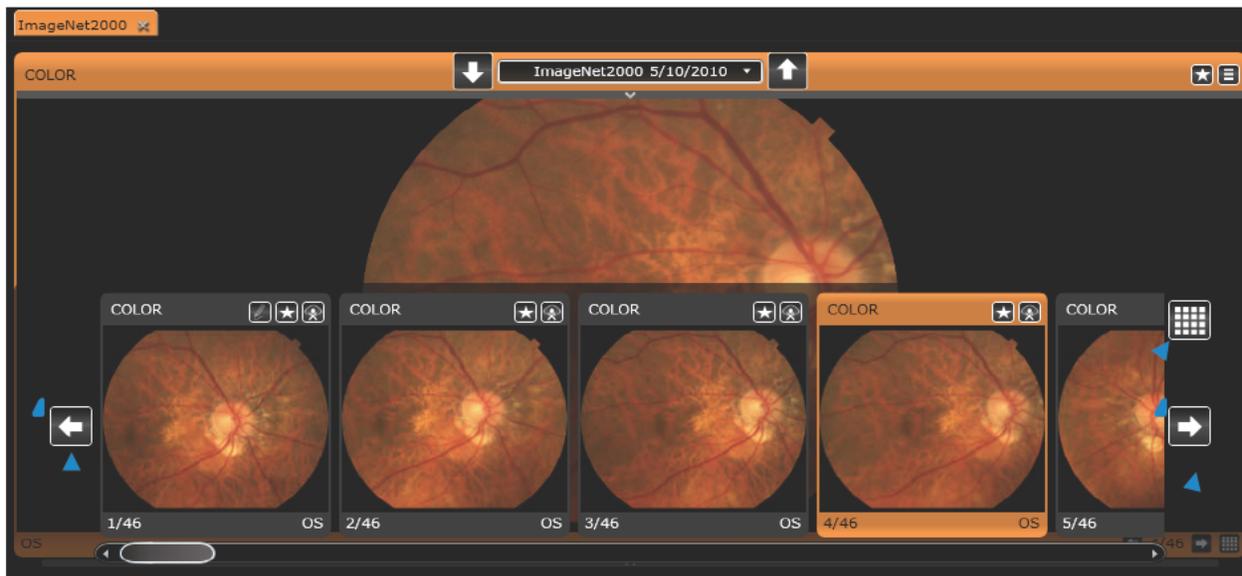


Figure 49: Bottom Auto-Collapsible Slider

Previous Button Media Thumbnails Proof Sheet Next Button

4.2.8 Description of Actions

4.2.8.1 Viewing the Exam

1. Highlight the exam in the Exam list to be viewed.
2. Clicking on the [Open Selected Exam] button , or double clicking on the row in the “Exams” list opens the selected exam images in the corresponding modality tab in the viewing area.



3. Clicking on the [Previous Exam] button jumps to the previous exam of the same modality.
Note: With the focus on the media, the left and right arrow keys on the keyboard may be used as “hot” keys to move to the previous media or next media.
4. Clicking on another exam from the “Modality/Date drop down” jumps to the corresponding exam.
Note: With the focus on the media, the up and down arrow keys on the keyboard may be used as “hot” keys to move to the earlier media or later media.
5. Clicking on the [Next Exam] button jumps to the next exam of the same modality.
6. Clicking on the [Key] button/indicator toggles the media as key.
7. Clicking on the [Hide/Show] button toggles the visibility of the corresponding annotation on the media.
8. On the auto-collapsible slider,:
 - Clicking on the [Previous] button displays the previous media in the media viewer.
 - Clicking on the [Next] button displays the next media in the media viewer.
 - Dragging the slider displays the corresponding media in the media viewer.
 - Clicking on the “Slide Show” split button starts the slide show.
9. On the auto-collapsible slider on media container footer:
 - The thumbprints are displayed
 - Clicking on the [Previous] button displays the previous media in the media viewer.

- Clicking on the [Next] button displays the next media in the media viewer.
- Clicking on the [Proof Sheet] button displays the proof sheet.

4.2.8.2 *Thumbnails*

The Media Thumbnail has a header and footer. The left side of the header contains the procedure. The right side contains the buttons for key, notes and annotations. The left side of the footer contains the media index. The center contains the media timer if applicable and to the right of the footer is the eye indicator.

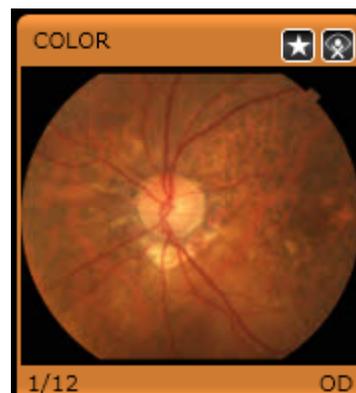


Figure 50: Thumbnail

1. Clicking on the “Key” button/indicator toggles the media as key.
2. Clicking on the “Eye” indicator displays a drop down list of possible eye type values to select.
3. Clicking on the “Procedure” indicator displays a drop down of possible procedure values for the corresponding modality to select.

4.2.8.3 *Thumbnail Strip*

The thumbnail strip, a horizontally scrollable list of “Media Thumbnails”, can be accessed by clicking on the bottom of the media where the auto-collapsible thumb-strip container is displayed. The container has a “Previous” and “Next” buttons on each side of the scrollable list and a “Proof-sheet” button in the top-right corner.



Figure 51: Thumbnail Strip

1. Clicking on the “Previous” button displays the previous media in the media viewer.

2. Clicking on a thumbnail displays the corresponding media in the media viewer.
3. Clicking on the “Next” button displays the next media in the media viewer.
4. Clicking on the “Proof-sheet” button displays the exam in proof-sheet mode and changes the tab name to [Compare].
5. Clicking on the “Key” button/indicator toggles the media as key.

4.2.8.4 *Proof Sheet View*

The proof-sheet view consists of a wrap panel of “Media Thumbnails”. Clicking on the “Proof-sheet” button displays the exam in proof-sheet mode and changes the tab name to [Compare].

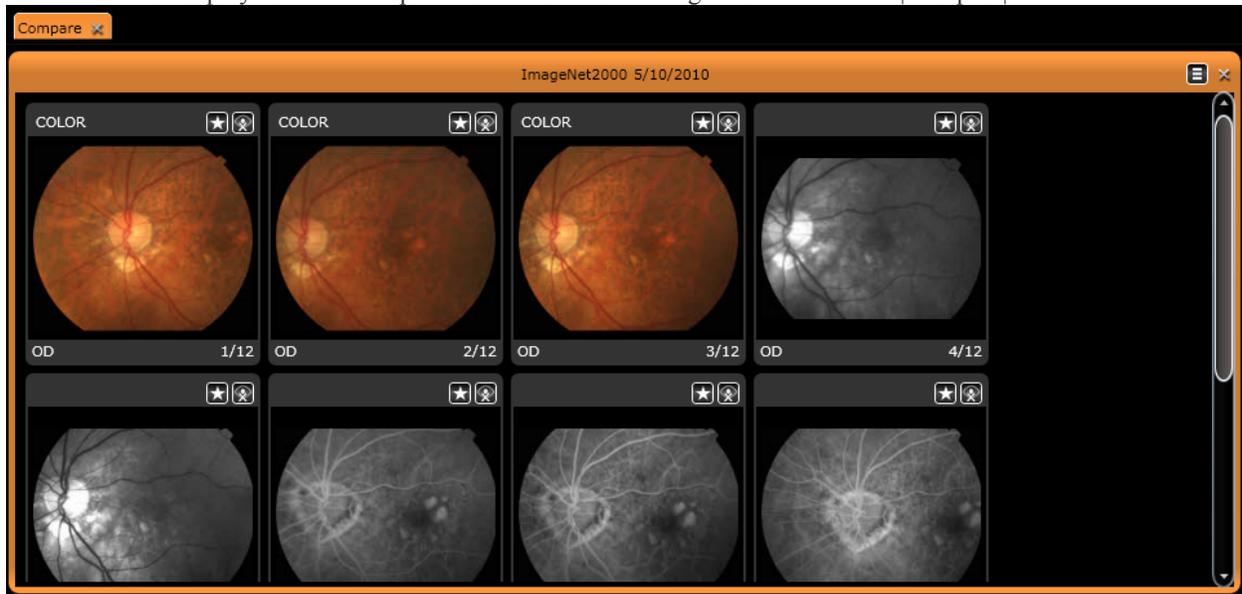


Figure 52: Proof Sheet View

4.2.8.5 *Viewing the Proof Sheet View*

1. Clicking on the [Proof-sheet] button  displays the exam in proof-sheet mode and changes the tab name to [Compare].
2. Clicking on a thumbnail displays the corresponding media in the media viewer.
3. Clicking on the [Details] button displays the details of the exam.

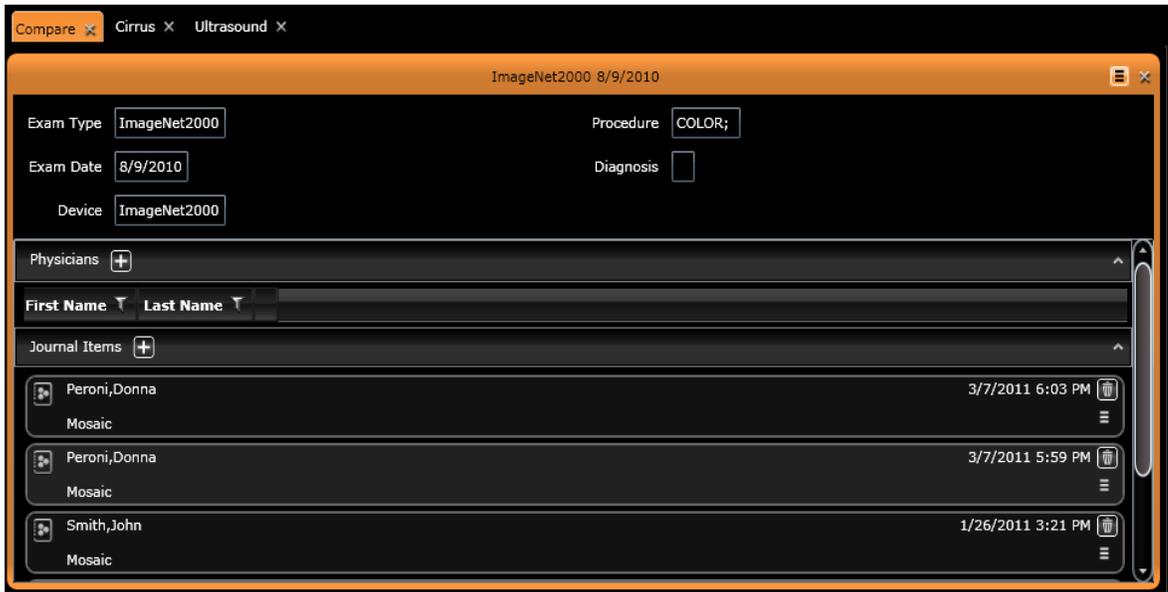


Figure 53: Details

4. Clicking on the “Key” button/indicator toggles the media as key.

4.2.8.6 *Split (OD|OS / OS|OD) View*

The patient exam can be viewed in a split view whereby both the right eye and the left eye are displayed side by side on the screen. Each eye has a single media view. The Exam (Type/Date) indicators are synchronized. The A split view of the exam is displayed when the user clicks on the user clicks the [OD|OS] button.

The icon for the OD/OS view is 

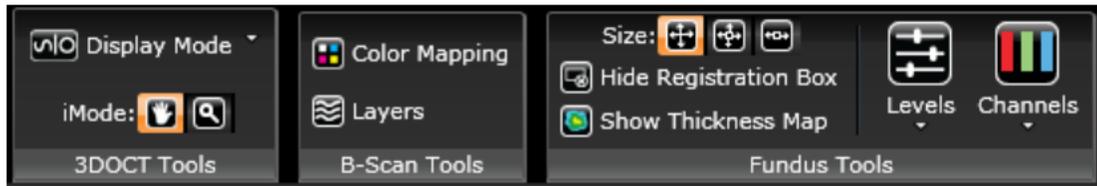


Figure 54: Split View GUI

4.2.8.7 OCT Viewer

This viewer applies for 3DOCT and Spectralis data. The OCT Viewer is hosted in a Single Media View. To the left it displays the OCT B-Scan Viewer and to the right it displays the OCT Fundus Viewer. Some Toolbar options (B-Scan Tools, Hide Registration Box, Show Thickness Map) are available only for 3DOCT data.

4.2.8.7.1 Toolbar



Button	Icon	Description
Display Mode		Click on this button to set the display mode for the exam. The options are: <ul style="list-style-type: none"> Registration (displays both Fundus and B-Scan) Fundus Only B-Scan Only
iMode		Sets the interactive mode to pan.
		Sets the interactive mode to magnify.
Color Mapping		Applies color mapping to the B-scan image (only for 3DOCT exams).
Layers		Applies layers to the B-scan image (only for 3DOCT exams).
Size		Displays the Fundus image in the original size.
		Fits the Fundus image to the container
		Fits the Fundus image to the width of the container
Hide Registration Box		Removes the registration box from the Fundus image (only for 3DOCT exams).
Show Thickness Map		Displays a thickness map on the Fundus image (only for 3DOCT exams).
Levels		Sets the brightness, contrast and intensity level of the image or report.

Channels		Filters the RGB (Red, Green, Blue) channels of the Fundus image.
----------	---	--

4.2.8.7.2 Using the OCT Viewer

1. Highlight an OCT exam in the Exam list to be viewed.
2. Clicking on the [Open Selected Exam] button  or double clicking on the row in the “Exams” list opens the selected exam images in the corresponding modality tab in the viewing area.

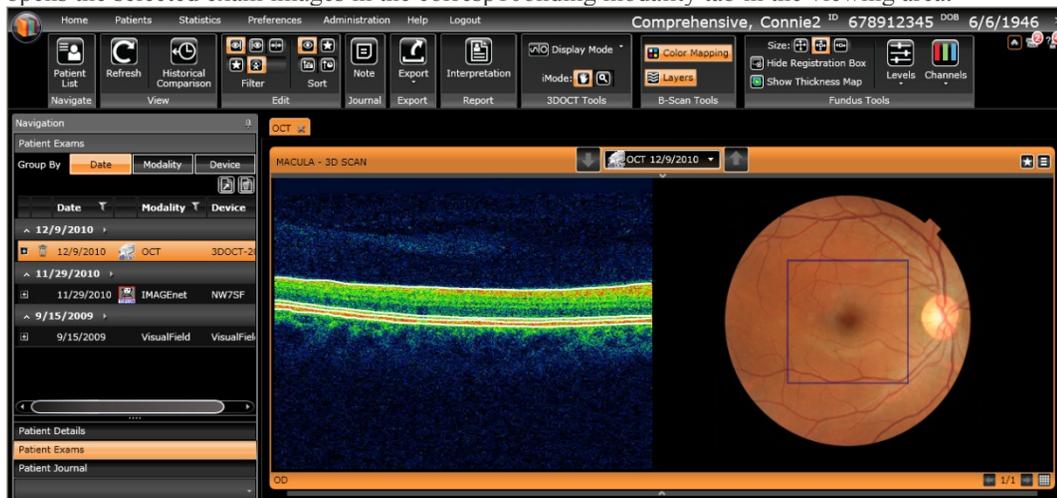


Figure 55 The OCT Viewer

3. The OCT B-Scan Viewer appears on the left while the OCT Fundus Viewer appears on the right.
4. Click on the [iMode interactive pan]  button to set the interactive mode to pan.
5. Click on the [iMode interactive magnify]  button to set the interactive mode to modify.
6. To change the view, click on the [Display Mode] button. This button displays 3 options as shown below.

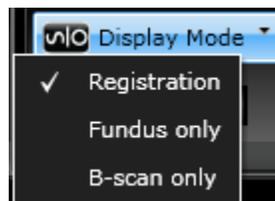


Figure 56: Display Mode Options

7. The “Registration” mode shows both the “OCT B-Scan Viewer” and the “OCT Fundus Viewer”.

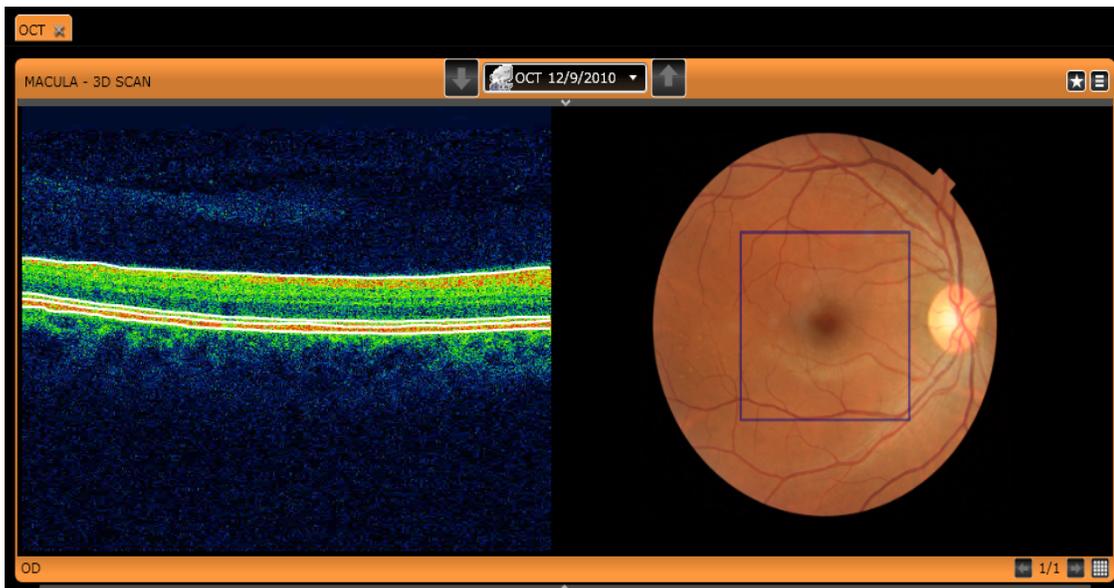


Figure 57: The OCT Registration Mode

8. “The Fundus Only” shows the “OCT Fundus Viewer” and hides the “OCT B-Scan Viewer”.

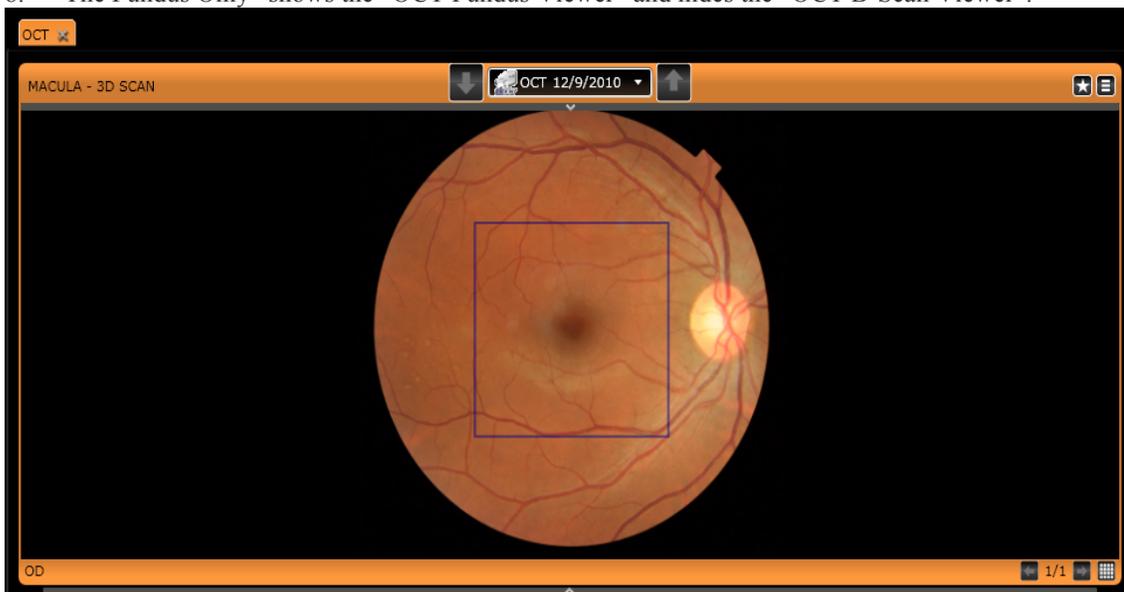


Figure 58: The OCT B-Fundus Only View

9. “The Scan Only” shows the “OCT B-Scan Viewer” and hides the “OCT Fundus Viewer”.

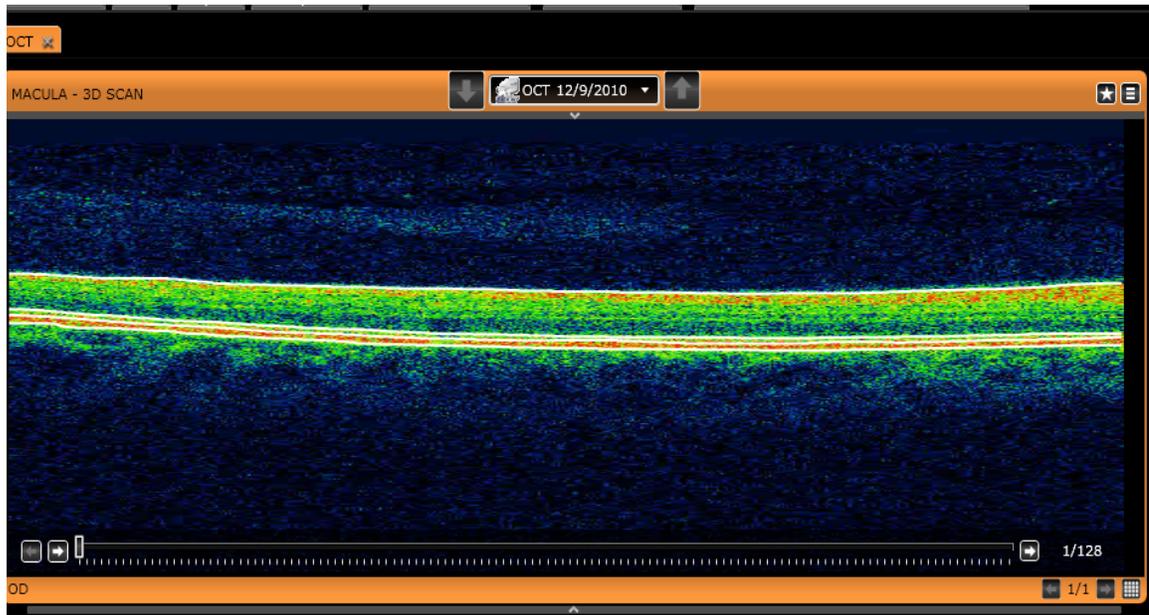


Figure 59: The OCT B-Scan Only Viewer

1. Clicking on the “Next” or “Previous” buttons or moving the “Slider” moves to the corresponding OCT scan displays the corresponding line on the “Registration Box” in the “OCT Fundus Viewer”.
2. Clicking on the “Slide Show” activates a loop to jump through the OCT scans and also displaying the corresponding line on the “Registration Box” in the “OCT Fundus Viewer”.
3. Clicking on the [Key]  button marks the media as key.
4. Clicking on the [Details]  button displays the details as shown below:

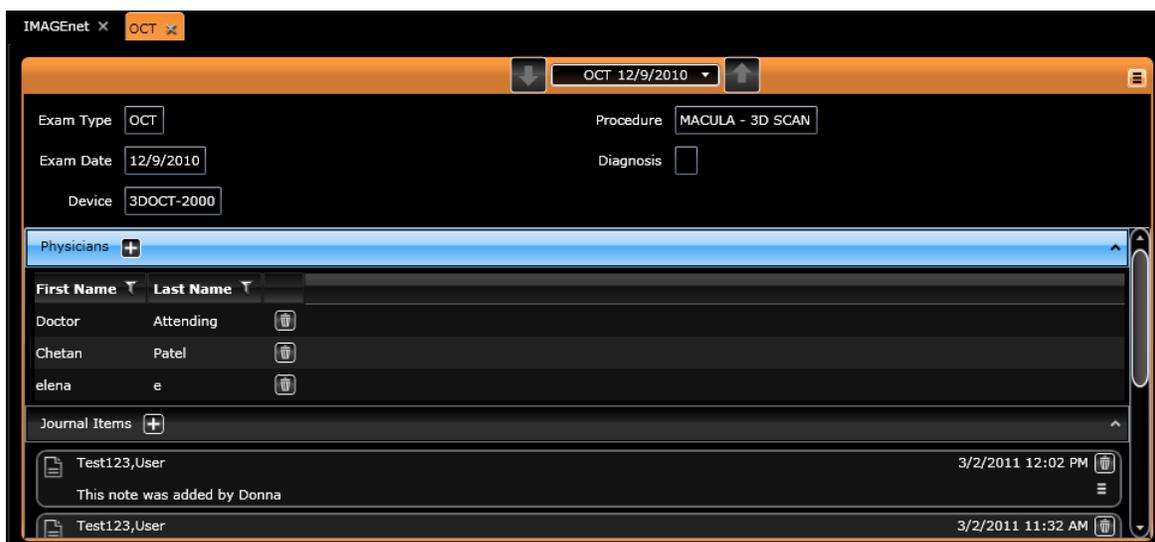


Figure 60: The Details Screen

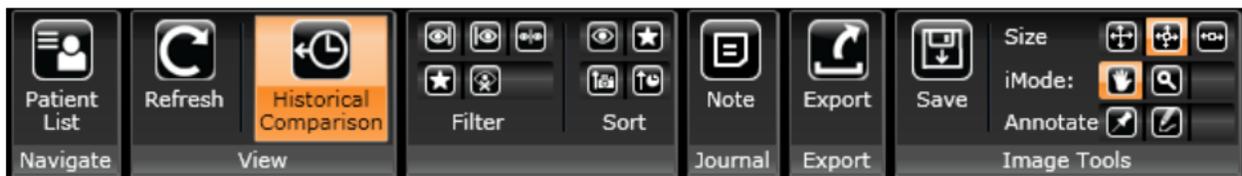
4.2.8.8 *Historical Comparison View*

Exams taken at different times can be viewed together by clicking on the [Historical Comparison] button as shown below:



Figure 61: Historical Comparison View

4.2.8.9 *Toolbar for Historical Comparison*



Button	Icon	Description
Navigate		
Patient List		Displays the “Patient List” screen. The “Patient List” screen displays a list of patients.
View		
Refresh		Refreshes the screen
Historical Comparison		Compares the selected media with previous exams.
Filter		

OD (Right Eye)		Sets the value of the eye as OD(Right eye)
OS (Left Eye)		Sets the value of the eye as OS(Left eye)
OU (Both Eyes)		Sets the value of the eye as OU(Both eyes)
Key		Marks the media as key media
Hide/Show		Hides/shows
Sort		
Eye Value		Sorts the media by eye value.
Key		Sorts the media by key value
Procedure		Sorts the media by procedure
Timer		Sorts the media by timer
Journal		
Note	 Note	
Export		
Export	 Export	
Image Tools		
Save	 Save	Saves the data on the screen
Size		Displays the image or report in the original size.
		Fits the image or report to the container
		Fits the Fundus image to the width of the container.
iMode		Sets the interactive mode to pan.
		Sets the interactive mode to magnify.
Annotate		Allows a note to be entered at a specific place on the media.
		Allows free drawing on the media and a note to be entered on the media..

4.2.8.10 *Viewing Historical Comparisons of Exams*

1. Highlight the exam in the Exam list to be viewed.
2. Clicking on the [Open Selected Exam] button  or double clicking on the row in the “Exams” list opens the selected exam images in the corresponding modality tab in the viewing area.

3. If applicable, click on additional exams from different modalities.
4. Click on the [Historical Comparison] button to view exams taken at different times.
5. Click on the [Historical Comparison] button to exits the historical comparison view.

4.2.8.11 *Adding a Note to the Exam*

1. Click on the exam.
2. Click on the [Note] button to add a note.

The following popup window appears:

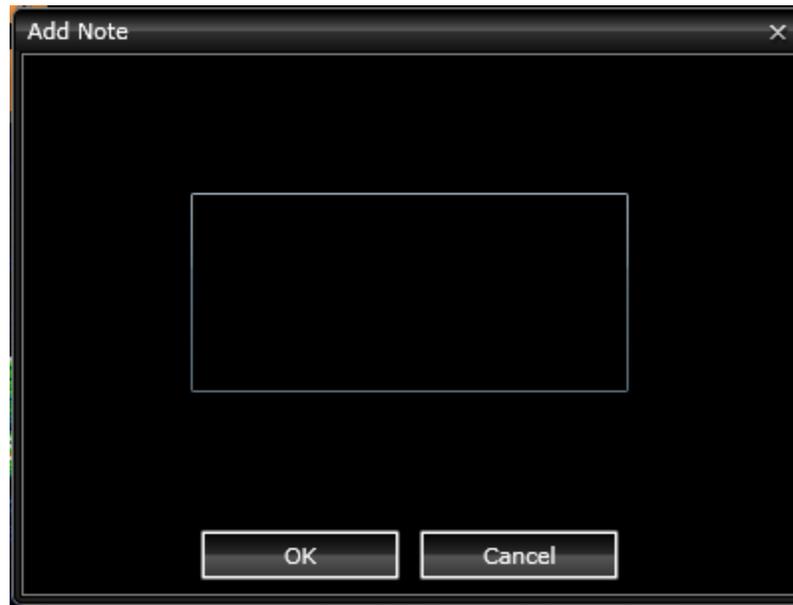


Figure 62: Add a Note

3. Enter the note in the text box.
4. Click on the [OK] button to save the note otherwise click on [Cancel] to disregard the note and return to the exam screen.

4.2.8.12 *Adding an Annotation to an Exam*

1. Highlight the exam in the Exam list to be viewed.
2. Clicking on the [Open Selected Exam] button  or double clicking on the row in the “Exams” list opens the selected exam images in the corresponding modality tab in the viewing area.

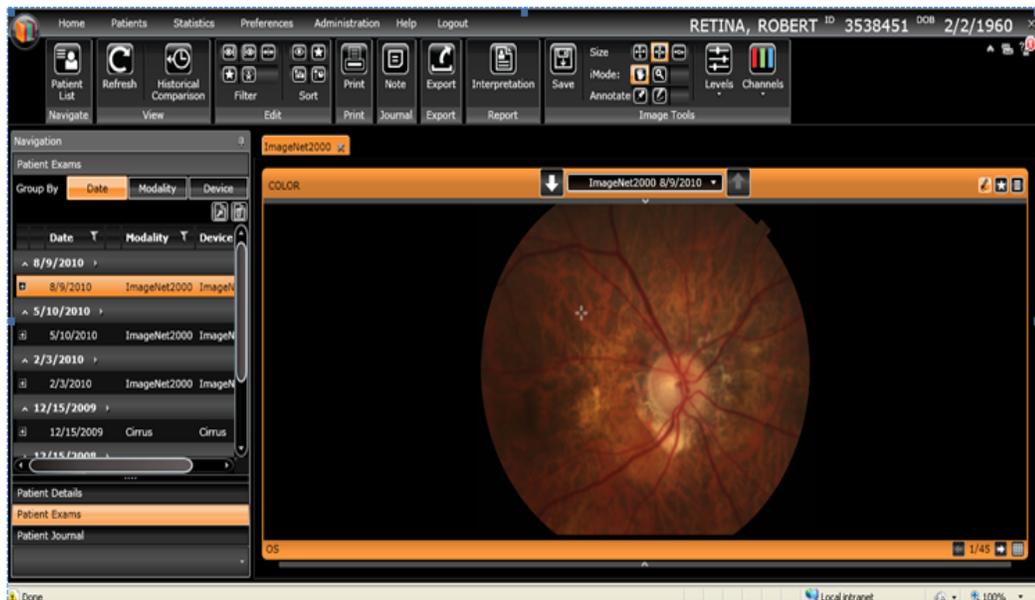


Figure 63: Viewing an Exam

3. Click on the annotate push pin button, , to enter a note at a specific location on the image.
4. When the cursor is moved to the viewing area, the cursor will change to . Move the cursor to the place on the image where the note is to be entered.
5. Mouse click to enter an annotation. A text box appears as follows:



Figure 64: Text box for Annotation

6. Enter the annotation and click on [Save] to save the annotation.

7. Click on the annotate free drawing button, , for free-hand drawing at a specific location on the drawing.
8. When the cursor is moved to the viewing area, the cursor will change to . Move the cursor to the place on the image where the note is to be entered.
9. Mouse click to annotate the image. When the mouse button is released, a text box appears as follows:

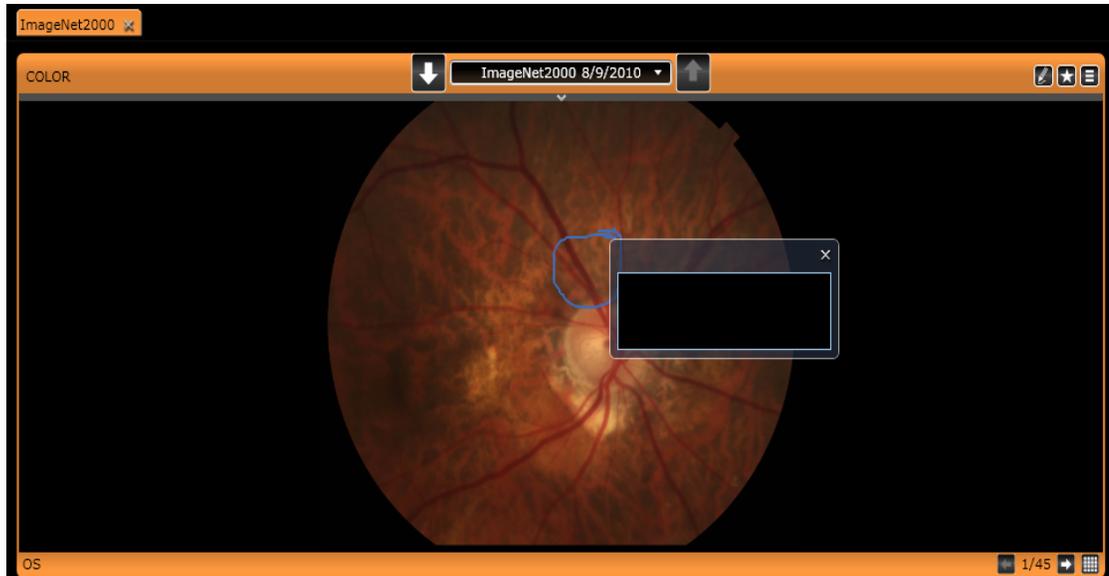


Figure 65: Annotate Image

10. Enter the annotation and click on [Save] to save the annotation
11. If the [Save] button is not selected, the following prompt appears when closing the media viewer:



Figure 66: Save Changes Prompt

12. Click on [OK] to save the annotation otherwise click on [Cancel] to not save the annotation.

13. Annotations appear as  on the image. To hide annotations, click on the Hide/Show button in the header of the viewing area

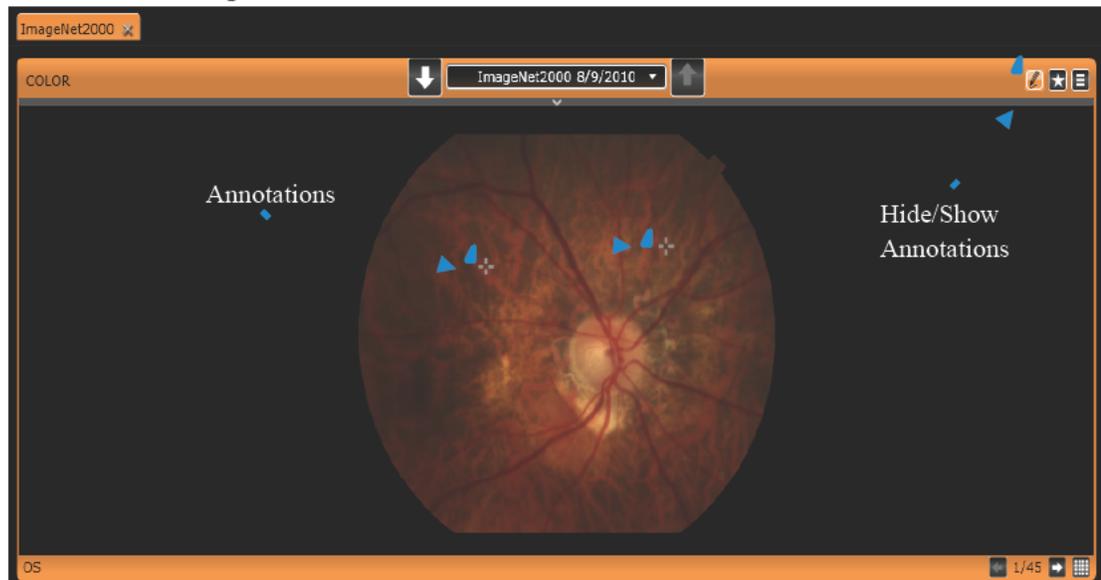


Figure 67: Annotations

4.2.8.13 *Measurements*

Measurement is a special type of annotation that in addition to its location has one or more numeric values calculated by the software. If an image's scale factor is provided by a manufacturer, measurements are calculated in microns and millimeters otherwise in pixels. The following measurements are currently supported by the software:

- Line Measurement
 1. Choose Line Measurement from the Toolbar.
 2. Mouse click to start drawing a line.
 3. Drag the mouse to create a line from the initial to the current location of the mouse.
 4. Release the mouse to finish creating a Line Measurement.
 5. When mouse is released, a text box will appear with the line's length calculated.

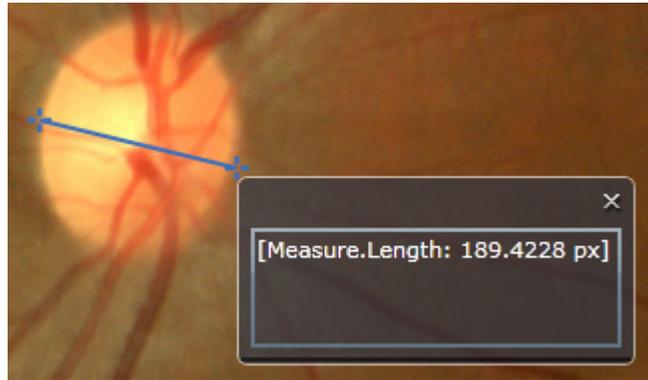


Figure 68: Line Measurement

- Area Measurement
 1. Choose Area Measurement from the Toolbar.
 2. Mouse click to start a free-hand drawing.
 3. Drag the mouse to enclose the area in question.
 4. Release the mouse to finish creating an Area Measurement.
 5. When mouse is released the last point will be connected to the first one to create a closed area and a text box will appear with an area value calculated.

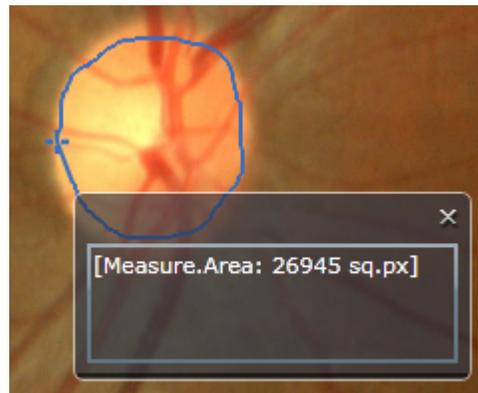


Figure 69: Area Measurement

- Cup-to-Disc Ratio
 1. Choose Cup-to-Disc Ratio from the Toolbar.
 2. Draw two areas when one is enclosed inside the other one.
 3. When the second area is finished, a text box will appear with a ratio of two areas calculated.
Note: the order in which areas are created is irrelevant; - the ratio is always calculated from the smaller area to the bigger one.

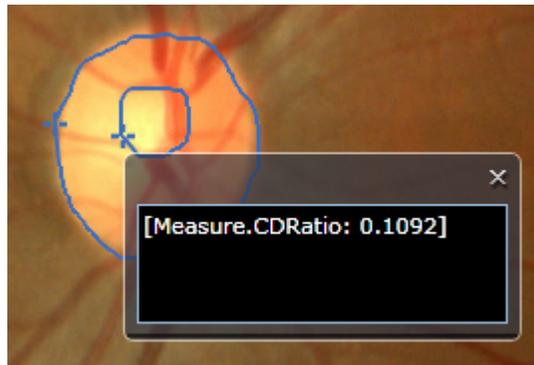


Figure 70: Cup-to-Disc Measurement

- MPS [Macular Photocoagulation Study]
 1. Choose MPS of desired radius from the Toolbar.
 2. Mouse click to indicate the center of the circle.
 3. Drag the mouse to move the center of the circle.
 4. Release the mouse to finish creating an MPS Measurement.
 5. When mouse is released, a text box will appear with area value of that circle in DA units.
Note: MPS Measurement is available only when a scale factor is provided by device's manufacturer.

4.2.8.14 *Interpretation Reports*

A variety of Interpretation Reports are available. More than one report of each type may be created.

1. Click on the exam.
2. Click on the [Interpretation Report] Button to create or view an Interpretation Report.
3. The report appears to the right of the media as shown below:

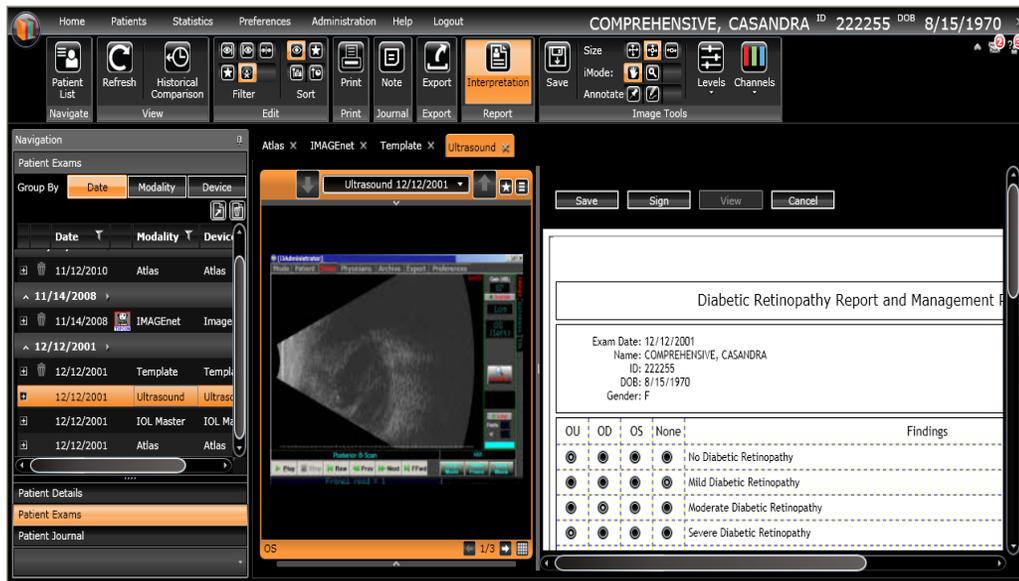


Figure 71: Interpretation Reports

- The report may be completed by selecting the appropriate radio buttons, checkboxes and entering text.
- After making the appropriate entries on the report, click on the [Save] button. The following message appears:

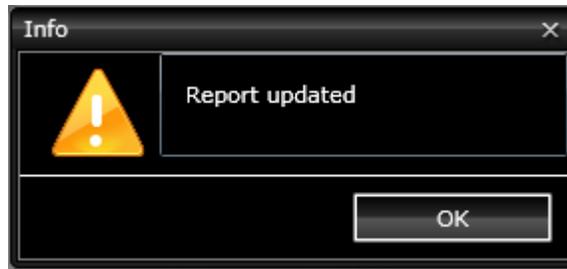


Figure 72: Report Updated Message

- The interpretation report may be signed by clicking on the [Sign] button. The following message appears:

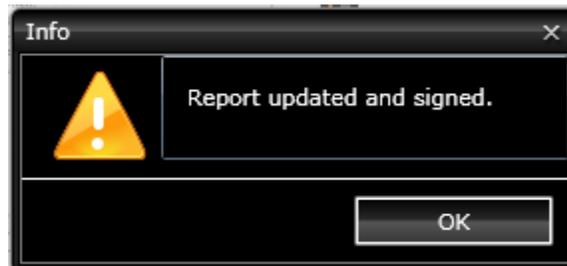


Figure 73: Report Updated and Signed Message

- Note: Updates to the report are not allowed after the report has been signed.

- To view the report in full view, click on the [View] button.

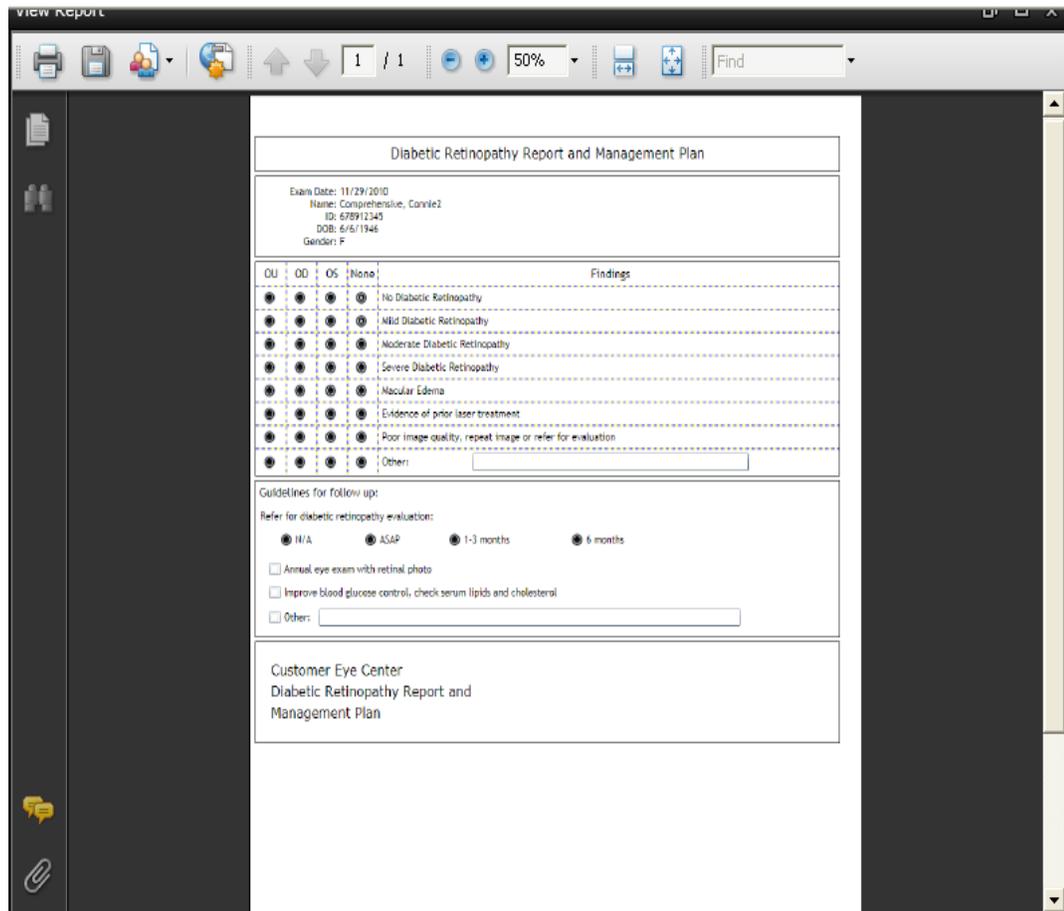


Figure 74: Full View Interpretation Report

- Click on [Cancel] to close the window.

4.2.8.15 *DICOM COPY*

- Click on the [DICOM Copy] button to view the Modality Work List.



Patient ID	Patient Name	Accession#	<input type="checkbox"/> Scheduled Date	Requested Procedure
			8/3/2011	

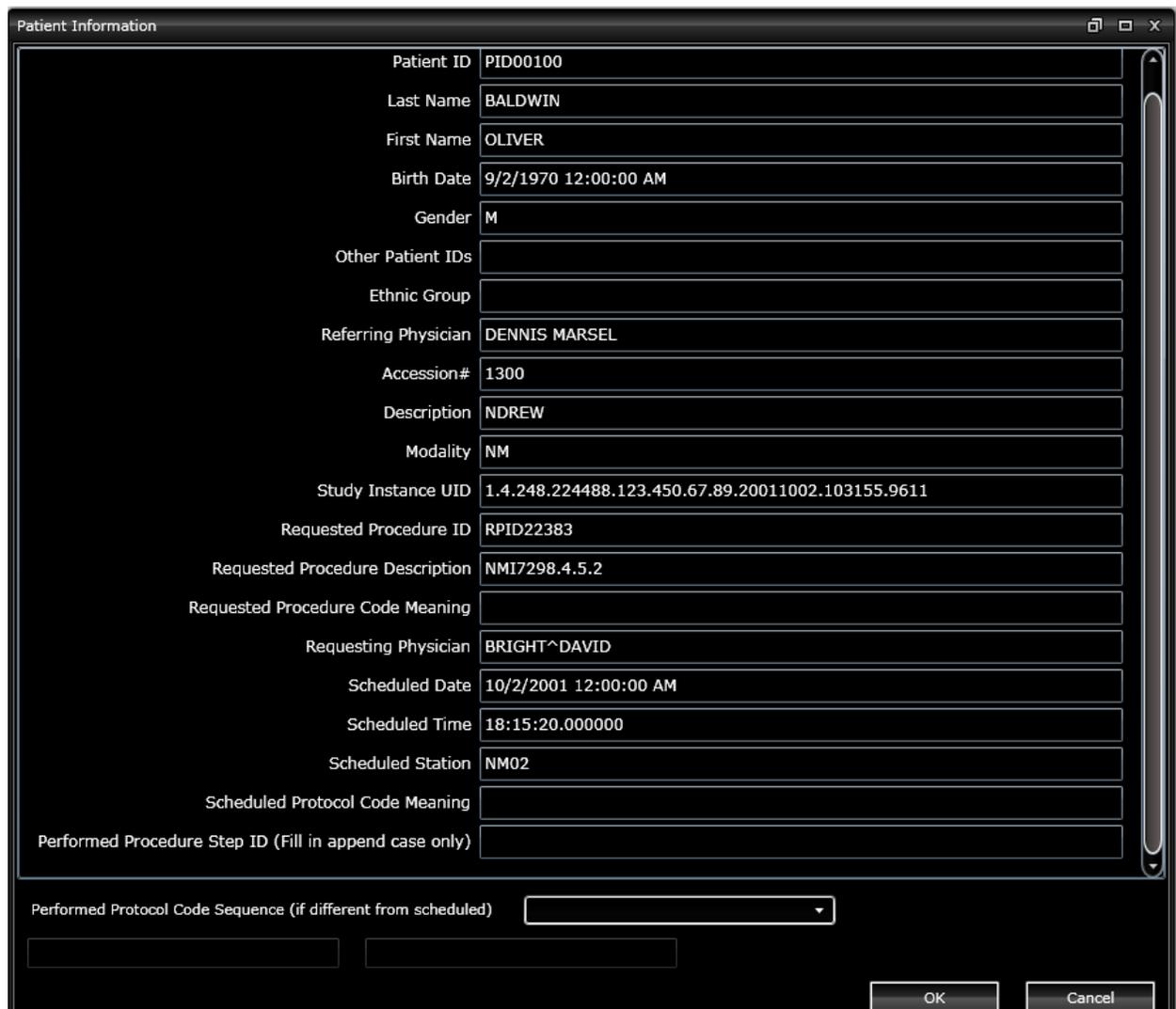
Query Info Copy Close

Patient ID	Last Name	First Name	Birth Date	Gender	Accession#	Sch
[Empty Table]						

2. Check the checkbox next to the “Scheduled Date” field to retrieve records for a date. The “Schedule Date” field defaults to the current date. To select records from another date, click on the calendar icon and modify the date.

Note: If the checkbox for the “Scheduled Date” field is not checked, records will not be retrieved by date.

3. Enter applicable search criteria and click on the [Query] button.
4. To view the details for a particular patient, highlight the record and click on the [Info] button. The following popup window is displayed:



Patient ID	PID00100
Last Name	BALDWIN
First Name	OLIVER
Birth Date	9/2/1970 12:00:00 AM
Gender	M
Other Patient IDs	
Ethnic Group	
Referring Physician	DENNIS MARSEL
Accession#	1300
Description	NDREW
Modality	NM
Study Instance UID	1.4.248.224488.123.450.67.89.20011002.103155.9611
Requested Procedure ID	RPID22383
Requested Procedure Description	NMI7298.4.5.2
Requested Procedure Code Meaning	
Requesting Physician	BRIGHT^DAVID
Scheduled Date	10/2/2001 12:00:00 AM
Scheduled Time	18:15:20.000000
Scheduled Station	NM02
Scheduled Protocol Code Meaning	
Performed Procedure Step ID (Fill in append case only)	

Performed Protocol Code Sequence (if different from scheduled)

OK Cancel

5. Click on the [OK] button to return to the MWL.
6. When the appropriate patient record in the MWL is identified, highlight the record and click on the [Copy] button. This moves the failed job to the patient record.

4.2.8.16 *Export an Exam*

1. Images can be exported in jpeg format one at a time.
2. While exporting 3D OCT images, there is an option to export a fundus or B-scan image.

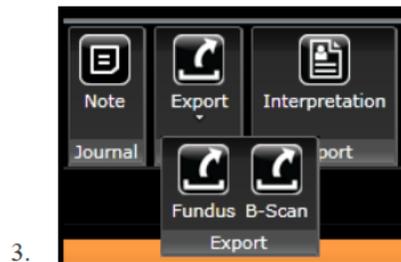


Figure 75: Export buttons

4. Click on the exam.
5. Click on the [Export] Button to export the media to local disk.
6. Enter the location where the media should be saved.

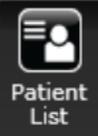
4.2.9 Exam Comparison

Exams may be compared by selecting exams and dropping and dragging them into the viewing area. The dropped exams are displayed in proof-sheet view. They are sized proportionally in the scrollable area. Up to 4 exams are visible at the same time. If more than 4 exams are opened, the user must scroll to view the other exams.

4.2.9.1 Toolbar for Comparing Exams

The following toolbar becomes available when comparing exams:



Button	Icon	Description
Navigate		
Patient List	 Patient List	Displays the “Patient List” screen. The “Patient List” screen displays a list of patients.
View		
Refresh	 Refresh	Refreshes the screen
Compare Selected	 Compare Selected	Opens the selected media

Edit - Filter		
OD (Right Eye)		Displays only media with the designation of OD
OS (Left Eye)		Displays only media with the designation of OS
OU (Both Eyes)		Displays only media with the designation of the eye as OU(Both eyes)
Key		Marks the media as key media
Hide/Show		Hides/shows
Edit - Sort		
Eye Value		Sorts the media by eye value.
Key		Sorts the media by key value
Procedure		Sorts the media by procedure
Timer		Sorts the media by timer
Edit - Set		
Note		Add a note
OS		Identifies the selected media as OS (Left Eye)
OD		Identifies the selected media as OD (Right Eye)
OU		Set Identifies the selected media as OU (Both Eyes)
Key		Identifies selected media as key
Hide/Show		A toggle key for hiding or showing media
Print		
Print		Prints the exam
Journal		
Note		Opens a text box to add a note to the exam.

4.2.9.2 *Comparing Exams*

1. Highlight the exam in the Exam list to be viewed.
2. Drag a single exam, all exams of a specific date or all exams of the same type into the viewport.

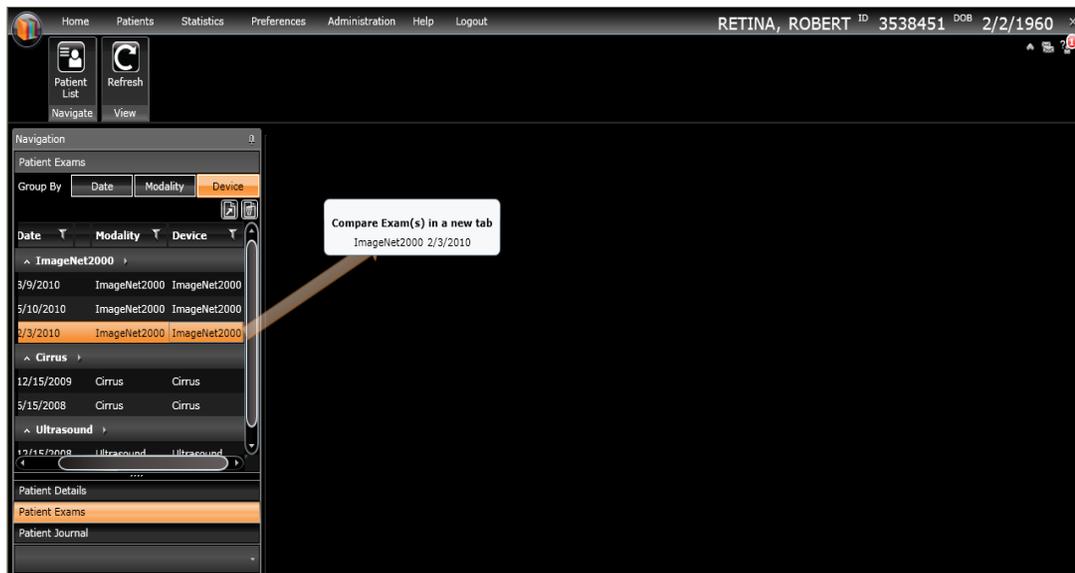


Figure 76: Compare Exams

3. The dropped exams are sized proportionally in the scrollable area. Up to 4 exams are visible at the same time within the same viewing area. If more than 4 exams are opened, the user must scroll to view the other exams. All dropped exams display in proof-sheet view



Figure 77: Proof-Sheet View

4. Different functions can be performed by clicking on the appropriate button on the tool bar.
 - Media may be selected and compared
 - Filtering may be done. Filtering will display only the media for that matches the criteria selected. The options are: Right Eye Only (OD), Left Eye Only (OS), a split view (OD/OS), key media only or show/hide images.
 - Sorting will sort the media by the criteria selected. The options are eye value, key, procedure or timer.

- The attribute of the eye can be set by selecting the media and clicking on the appropriate attribute. The options are: Right Eye (OD), Left Eye Only (OS), Both eyes (OU).
- The image may be denoted as key media.
- Show/hide images.
- Printing will print the media to the designated printer
- A note may be added to the media.

4.2.9.3 Compare Selected Media

1. Click on the media to be compared.

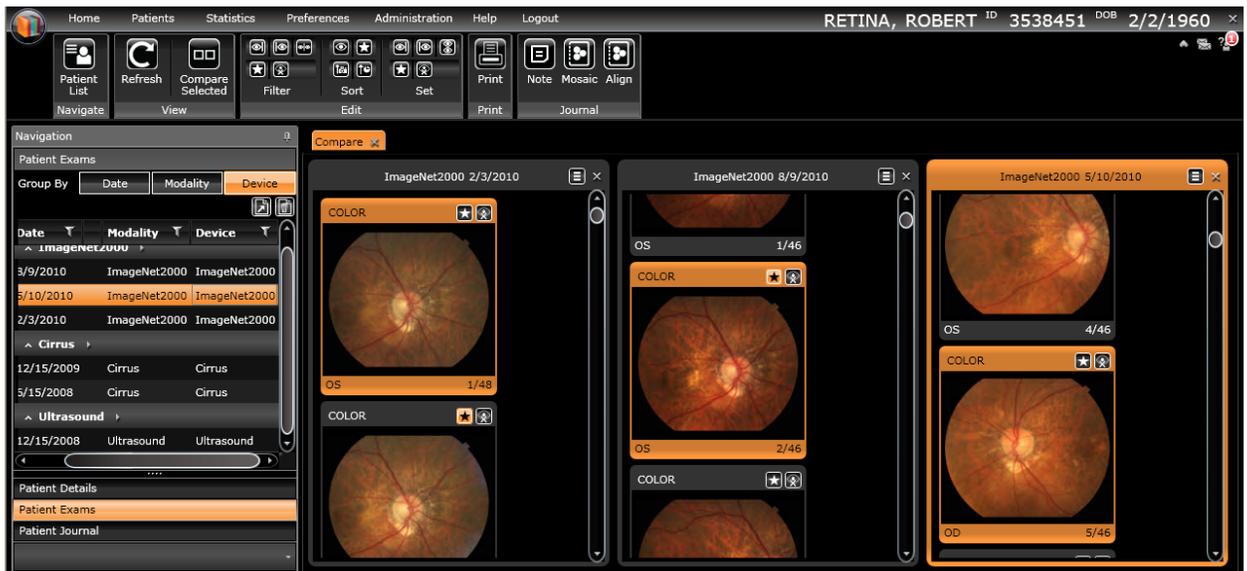


Figure 78: Selected Media



2. Click on the [Compare Selected] button in the top tool bar to open the selected media in the Compare Media View.



Figure 79: Compare Media View

3. Different functions can be performed by clicking on the appropriate button on the tool bar.
 - Filtering may be done. Filtering will display only the media for that matches the criteria selected. The options are: Right Eye Only (OD), Left Eye Only (OS), a split view (OD/OS), key media only or show/hide images.
 - Sorting will sort the media by the criteria selected. The options are eye value, key, procedure or timer.
 - Printing will print the media to the designated printer
 - A note may be added to the media.
 - The comparative view may be saved.
 - The fundus images may be re-sized. The options are: Original size, fit to the container or fit the width of the container.
 - Pan the image. There are two options: Interactive and magnify.
 - Annotate the image.

4.2.10 Patient Journal

The “Patient Journal” contains the notes, annotations, and/or reports of the patient exams(s). It is displayed when the user clicks on the [Patient Journal] button in the left pane. The hover menu for the “Patient Journal” displays the available journal types. Each journal item displays the date and time, the user, an icon for the journal type and the note. When the journal item is selected the journal is displayed in the viewing area. Journals may be grouped by date and type and filtered by any of the journal types.

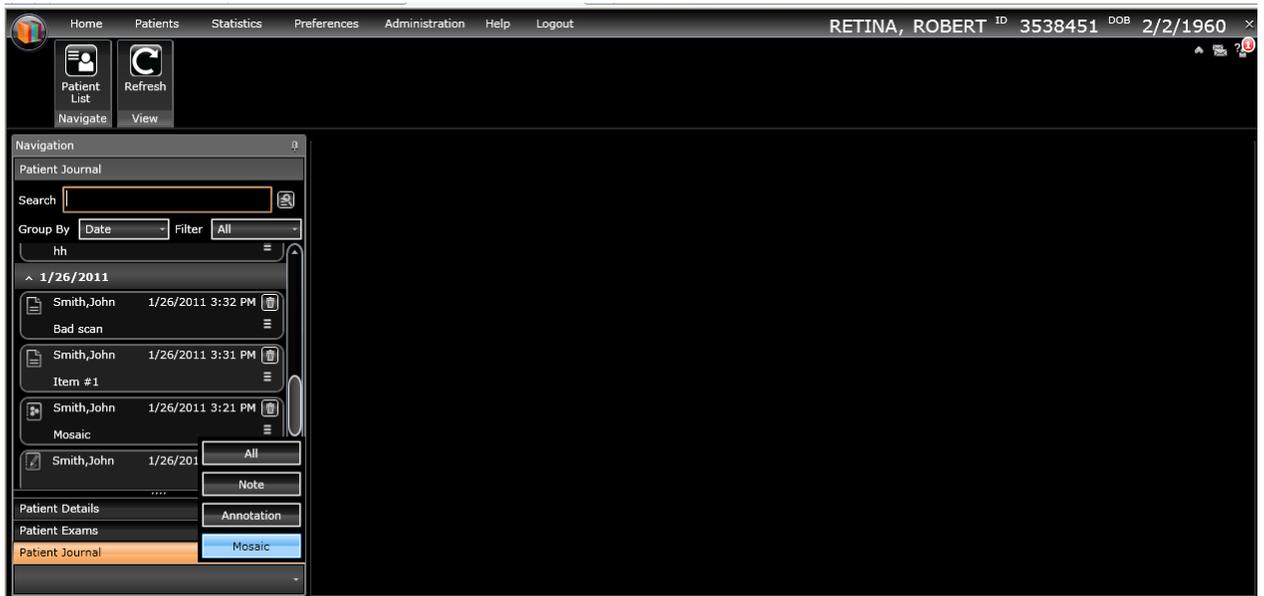


Figure 80: Patient Journal

4.2.10.1 *Locating and Sorting Journal Items*

1. A “Journal Item” may be located by entering a string of text in the “Search” field or scrolling through the list of items.
2. The journal list may be grouped by date or type by selecting the appropriate option from the dropdown list for the “Grouped By” field.
3. The list may be further defined by clicking on a filter option. The options for filtering the list are: All (all types of journal items will be displayed), Report, Note, or Annotation.

4.2.10.2 *Viewing Journal Items*

1. Highlight the journal item you wish to view and double click on it. The note and corresponding exam is displayed in the viewport. If there is not any associated image, such as in the case of just a note, nothing will appear in the item viewer

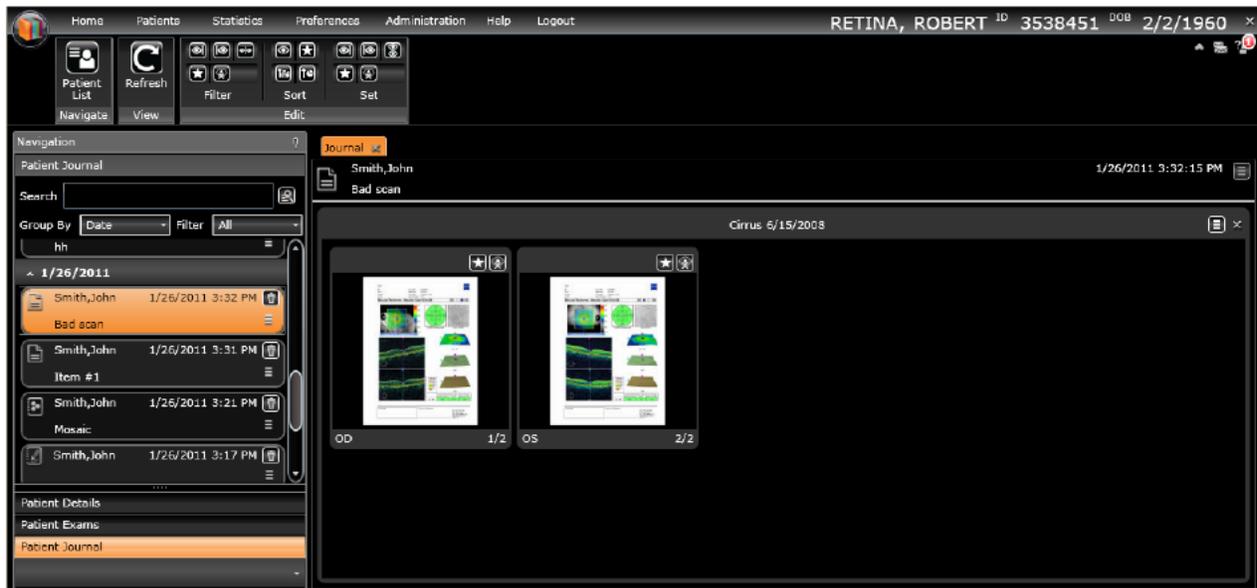


Figure 81: Viewing Journals

2. Different functions can be performed by clicking on the appropriate button on the tool bar.
 - Media may be selected and compared
 - Filtering may be done. Filtering will display only the media for that matches the criteria selected. The options are: Right Eye Only (OD), Left Eye Only (OS), a split view (OD/OS), key media only or show/hide images.
 - Sorting will sort the media by the criteria selected. The options are eye value, key, procedure or timer.
3. The Eye value can be set by selecting the media and clicking on the appropriate value. The options are: Right Eye (OD), Left Eye Only (OS), Both eyes (OU), key media, or show/hide images
4. The details of the exam can be viewed by clicking the [Details] button.

4.2.11 Discrete Data

Discrete data can be captured manually into a patient's chart within Synergy. Discrete Data is made up of:

Discrete Data Point	Description	Measurement Values
Intraocular Pressure	IOP	mmHg
Visual Acuity	Best Visual Acuity – BVA	BVA – LogMAR,
	Unaided Visual Acuity – UVA	UVA – LogMAR, ETDRS
Kerato	Horizontal – KRT_H	KRT_H – Diopters, MM, Axis
	Vertical – KRT_V	KRT_V – Diopters, MM, Axis
	Average – KRT_AVE (D,mm)	KRT_AVE – Diopters, MM

	Cylinder – KRT_Cyl	KRT_Cyl – MM, Axis
Refractive	Rx	Rx – Sphere, Cylinder, Axis
	Manifest	Manifest – Sphere, Cylinder, Axis
Anatomical	Pupil Distance – PD	PD – MM
	Vertex Distance – VD	VD – MM

The latest discrete data is displayed as a “Summary” at the top of the Navigation pane, on the left hand side. Historical discrete data may be viewed by selecting the [Discrete Data] button in the left pane. Each discrete data item displays the date and time of entry, the value for the data entered (as noted above), and the method for capturing the values displayed.

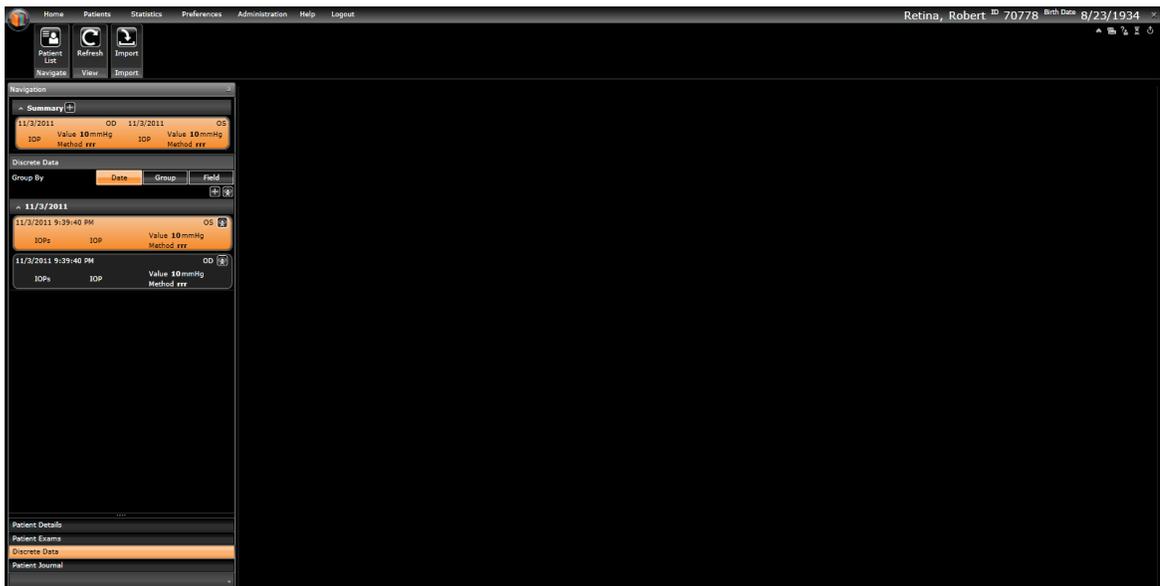


Figure 87: Viewing Discrete Data

4.2.11.1 *Manually Entering Discrete Data*

1. Under the [Discrete Data] menu, select the [+] symbol to display the manual entry window.

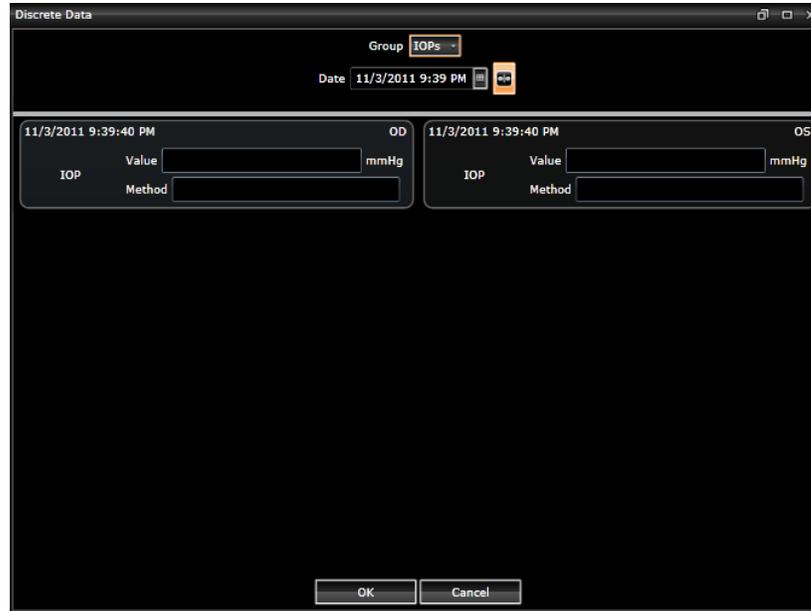


Figure 88: Discrete Data Manual Entry

2. Select from the [Group] pull down menu the item you would like to enter.
3. Enter the required data within the displayed fields.
4. Click 'OK' when complete.
5. Discrete Data will automatically be updated and displayed in the Patient Chart summary, and Discrete Data history.

4.2.11.2 *Trending Discrete Data*

1. Double click on the one of the discrete data points from the Summary, or within the Discrete Data list.
2. A graph for that data selected will be displayed on the right hand side.

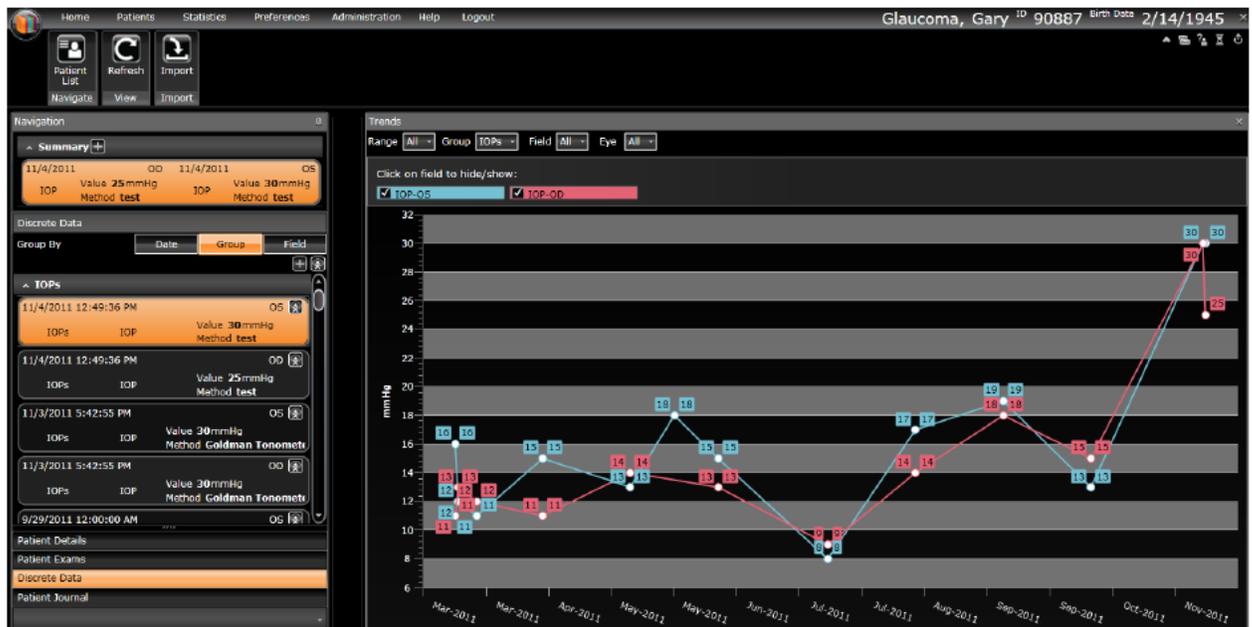


Figure 91: Trending Discrete Data

Trending Data Controls	Description
Range	Select a date range to show values over time.
Group	Select which type of data to view.
Field	Select which type of sub data to view. Ex: UVA or BVA.
Eye	Select which eye (OD, OS) to view.

3. Hovering over any point on the graph will show the details of that data point, as well as dim all other data that may be displayed at the same time.

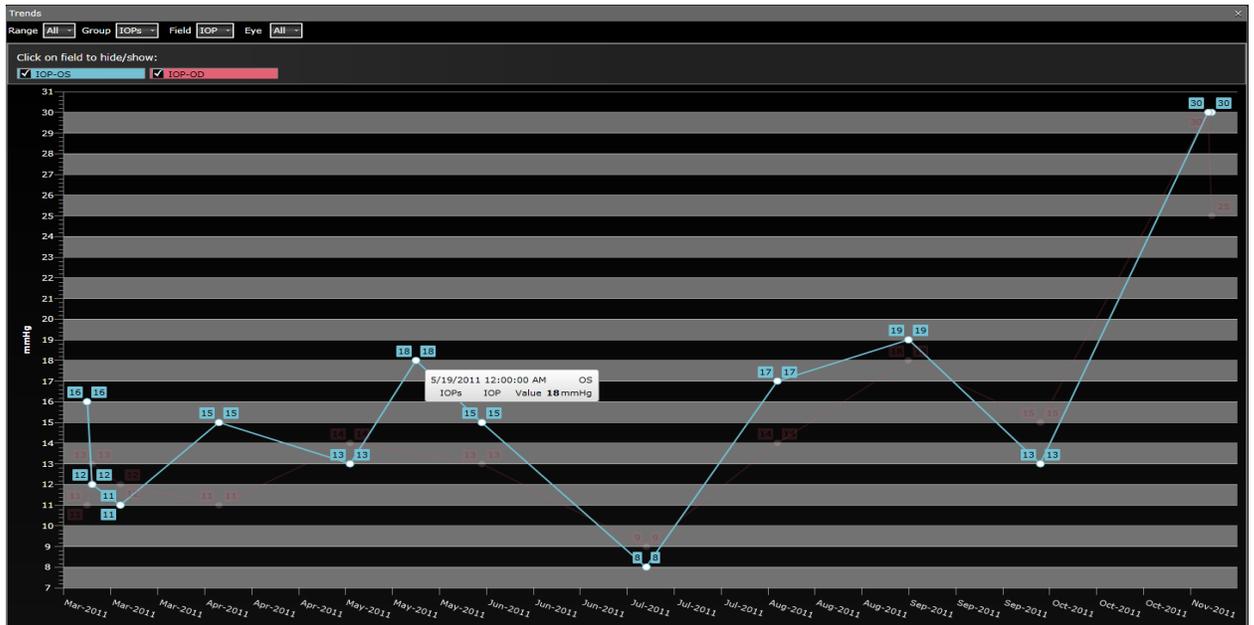


Figure 92: Viewing Discrete Data Point Details in Graph

- By hovering over the desired field for the graph (ex: IOP-OS, IOP-OD), will highlight the selected item, and dim out the non-selected item.

4.3 Statistics

Statistics for the practice are available in a chart or pie view. The statistics are generated based upon criterion defined by the user. The criterion for generating statistics on patient exams are: Date range, location, and device model. The user will also be able to identify an option for slicing the statistics. The attribute for slicing will be color coded in the presentation and a legend shall appear to the right of the statistics. The user may access the “Statistics” page by clicking the “Statistics” menu.

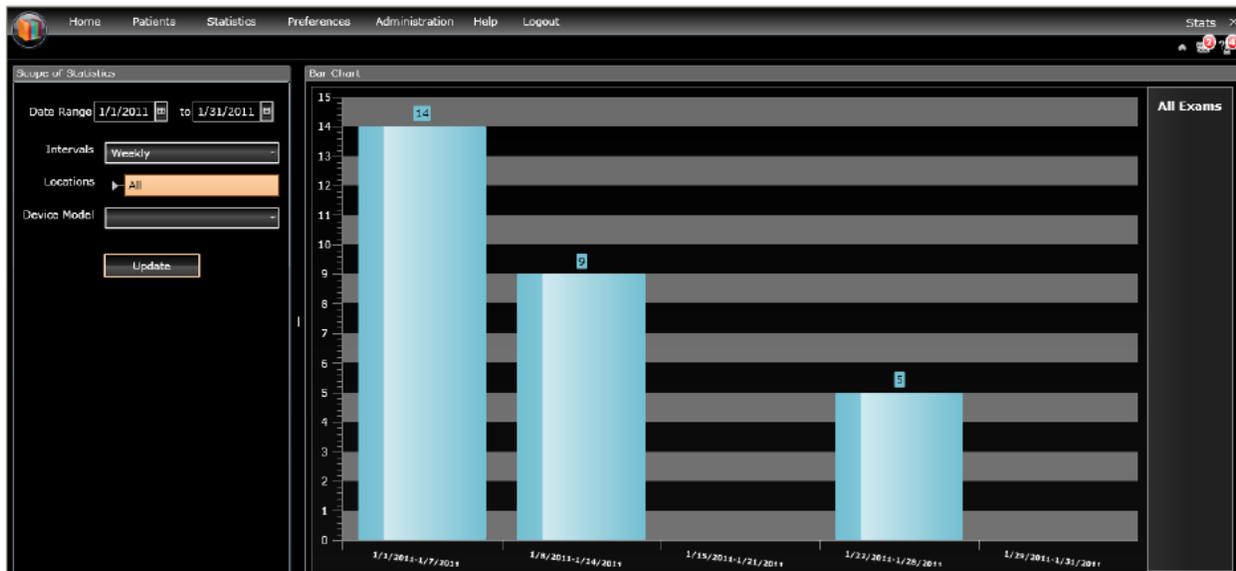


Figure 93: Statistics Screen

4.3.1 Field Descriptions for Statistics:

Field	Description
Date Range	The from date field and to date field of the date range for the statistics. The first date field on the screen is the “from” date. The second date field is the “to” date. Next to each date field is a [calendar] button. When the calendar button is selected, a calendar appears from which a date may be selected.
Interval	The interval is the unit of time for which the statistics will be calculated. The interval may be selected from the dropdown for this field. The possible values are: day, week, month, or year. The statistics will be calculated for each interval within the date range specified.
Location	The location name of the practice or office. The location may be selected from a dropdown field listing the locations for the practice. The locations will appear in hierarchically. Statistics will be generated for the location selected. When “All” is selected, the statistics will be generated for all locations of the practice.
Device Model	The instrument or device for which the statistics are to be calculated. The device model may be selected from a dropdown listing of the device models. The device

	models will appear in alphabetical order. Statistics will be generated for the device model selected. When “All” is selected, the statistics will be generated for all device models.
Slicing	A dropdown listing of the options for slicing the data presented. Values are: Device model, physician, procedure type. If no slicing is selected, each bar in the chart represents a total number of exams in the selected interval, without splitting into categories. Slicing will be color coded with a legend appearing to the right of the presentation.

4.3.2 Generating Statistics

1. Enter the start date for the date range in the first date field.
2. Enter the end date for the date range in the second date field.

NOTE: The [calendar] button may be used to select the date.

3. From the dropdown listing for the interval field, select the interval for the statistics.
4. From the dropdown listing for the location field, select the location for the statistics.
5. From the dropdown listing for the device-model field, select the device model for the statistics.
6. From the dropdown listing for slicing, select the method of slicing the data. Note: slicing will be color coded and a legend for each color will appear to the right of the chart.
7. Click on the [Update] button to generate the statistics for the criterion specified.

4.4 Preferences

User preferences contain the user's preferred default settings. The initial value of the user preferences are set to the system defaults. If the user does not change the settings, the system default settings will be in used. The settings selected by the user are in effect for the user's login until changed by the user. Any changes made to the user's preferences will take place the next time the user logs in. The user may access the "Preferences" screen by clicking on the "Preferences" menu.

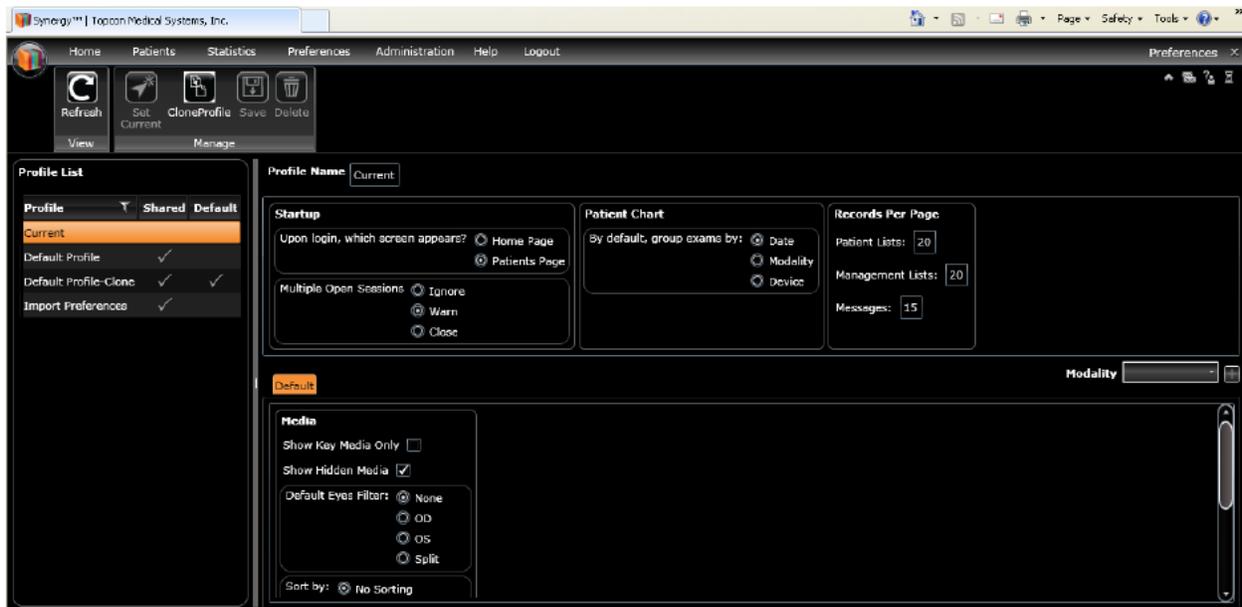


Figure 94: Preferences

4.4.1 Toolbar for Preferences:



Name	Button/Icon	Description
Refresh		When the user clicks on the [Refresh] button, the data is updated.

Set Current		When the user clicks on the [Set Current] button, the preferences displayed on the screen take effect after the next login.
Clone Profile		When the user clicks on the [CloneProfile] button, a copy is made of the preferences displayed on the screen.
Save		When the user clicks on the [Save] button, the data on the screen is saved and the following message is displayed: “Updated preferences will take effect after next login.” [OK]
Delete		When the user clicks on the [Delete] button, the profile displayed on the screen is deleted. Note: The profile may not be deleted if it is designated as a default or current.

4.4.2 Profile List:

Available profiles are displayed in the profile list. A checkmark next to the profile indicates whether or not the profile is shared by multiple users and if it is a default profile.

4.4.3 Options:

Option	Description
Upon Login Which Screen appears	The user may select a radio button for either "Home Page" or "Patients". Whichever screen is selected becomes the landing screen upon login for the user.
Default Grouping for Exams	The user may select a radio button for "Date", Modality or "Device". Whichever option is selected becomes the default grouping for patient exams appearing on the patient's chart.
Records Per Page	The user may enter the number of records per page for Patient Lists, Management Lists and Messages. The number entered in the field will be the number of records displayed per page of the screen.
Modality	Defaults may be defined for each modality by selecting the modality from a dropdown and clicking on the [+] button..
Media	The user may select a checkbox for key images. The options are: "Show Key Media Only" and "Show Hidden Media". When the checkbox is selected, the option will be displayed. When the checkbox is not selected, the option will not be displayed.
Default Eyes Filter	The user may select a radio button to identify their preference for default Eyes Filter. The options are: "None", "OD", "OS", "Split"
Sort by	The user may select a radio button to identify their preference for sorting. The options are: "No sorting", "Eye", "Key", "Procedure" or "Time".
Default Image Size	The user may select a radio button to identify their preference for the default image size. Options are: Normal, Fit Size, Fit Width.

4.4.4 Setting Preferences

- Click on the [Preferences] menu option.
- Click on the radio button for the screen that will be displayed immediately upon login. There are two choices: Home Page or Patient Page.
- Click on the radio button for the default grouping of exams on the patient chart. The options are: Date, Modality or Device.
- Enter the number of pages that will be listed at a single time for each of the following:

- Patient Lists
- Management Lists
- Messages

- Check the checkbox for whether or not to show key media only.
- Check the checkbox for whether or not to show hidden media.
- Click on the default eyes filter. The options are:
 - None
 - OD
 - OS
 - Split
- Click on how the media is to be sorted. The options are:
 - No sorting
 - Eye
 - Key
 - Procedure
 - Time
- Click on the default image size. The options are:
 - Normal
 - Fit Size
 - Fit Width
- Click on the [Save] button to save the user's preferences.

4.5 Administration

The sub-menus and fly open menus under the administration menu are used for setting up and maintaining Synergy. Access to these menu items are determined by the user's role.

4.5.1 Management

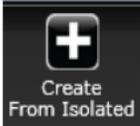
The sub-menu "Management" contains three fly open menus. They are: Patients, User and Physicians and User Roles.

4.5.1.1 Patients

Patient records are created, updated and merged in the menu item "Patients". The user may access "Patients" by clicking on Administration > Management > Patients.

4.5.1.1.1 Toolbar

The following buttons appear in the toolbar for Isolated Patients:

Name	Button	Description
Refresh	 Refresh	The [Refresh] button updates the screen with the latest patients.
Add Patient		A pop-up window for creating a new patient appears when the [Add Patient] button is selected.
Edit Patient		A pop-up window for editing the patient data appears when the [Edit Patient] button is selected.
Create from Isolated	 Create From Isolated	When an isolated patient is selected, this button becomes available. When the button is selected, a pop-window for updating the patient data appears. When the data has been modified, the isolated patient becomes a master patient.
Stale Master	 Stale Master	The [Stale Master] button deactivates the selected master patient. The patient record is denoted as "Staled".
Stale Member	 Stale Member	The [Stale Member] button deactivates the selected member patient. The patient record is denoted as "Staled".
Stale Isolated	 Stale Isolated	The [Stale Isolated] button deactivates the selected isolated patient. The patient record is denoted as "Staled".

4.5.1.1.2 Control Buttons:

Button	Description
	Moves records from the isolated patient list to the master patient list.
	Moves records from the master patient list to the isolated patient list.

4.5.1.1.3 Patient Fields:

Field	Description
Master Patients	
ID	Unique Id code for the patient record.
Last Name	The surname of the patient.
First Name	The first name of the patient.
Birth Date	The date of birth of the patient.
Gender	The gender of the patient. "F" is displayed for female and "M" is displayed for male.
Last Visit	The date of the patient's last visit. This is calculated by finding the most recent exam date for the patient.
Isolated Patients	
ID	Unique Id code for the patient record.
Last	The surname of the patient.
First	The first name of the patient.
Birth Date	The date of birth of the patient.
Gender	The gender of the patient. "F" is displayed for female and "M" is displayed for male.
Capture System	Capture station type used for this exam (e.g. MRP, OCT, Topcon, Import, OIS, Heidelberg, ULI3, etc).
Last Visit Date	The date of the patient's last visit. This is calculated by finding the most recent exam date for the patient.

4.5.1.1.4 Procedure to Merge Patients

1. Locate the patient record. This may be done by using the search feature or scrolling through the list of patients.
2. Click on the patient record to be moved to the master list and click on the left arrow, the record is moved to the master list of patients.
3. Instead of using the left arrow, the [Create from Isolated] button. A pop-up window with patient data appears.

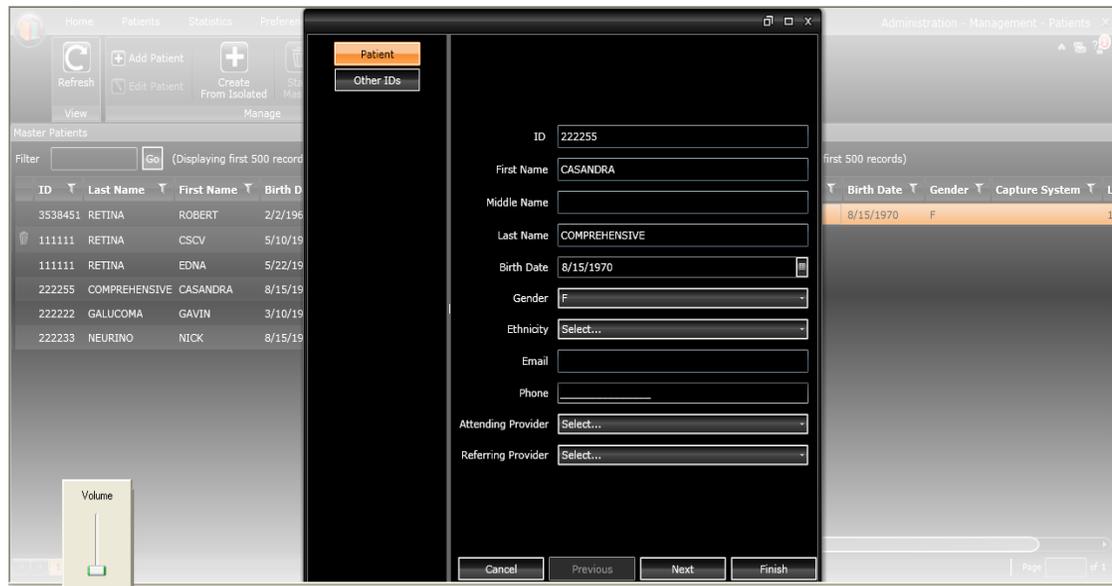


Figure 95: Create Patient from Isolated Patient

4. Update the data as necessary.
5. When finished, the isolated patient will be moved to the master list.
6. If a patient in the master table needs to be moved to the isolated table, highlight the patient. The exams for the patient appear.
7. Click on the appropriate record and click on the right arrow. The record is moved to the isolated list of patients.

4.5.1.1.5 Procedure to Add a Patient

1. Click on the [Add Patient] button.

The following pop-up window appears:

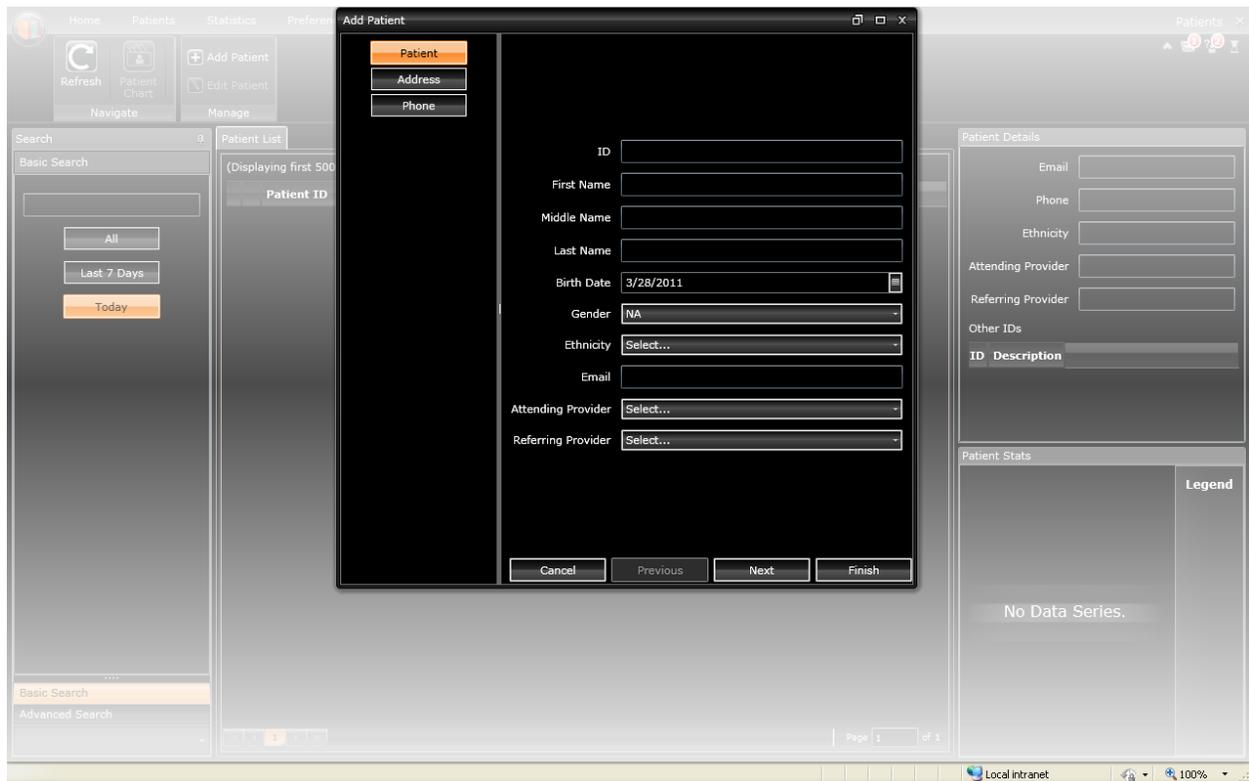


Figure 96: Adding a Patient

2. Enter an identification number for the patient in the “ID” field.
3. Enter the patient’s first name in the “First Name” field.
4. Enter the patient’s middle name in the “Middle Name” field.
5. Enter the patient’s last name in the “Last Name” field.
6. Enter the patient’s date of birth in the “Birth Date” field.
7. Click on the gender of the patient from the dropdown list for the “Gender” field.
8. Click on the patient’s ethnic background from the dropdown list for the “Ethnicity” field.
9. Enter the patient’s e-mail address in the “E-Mail” field.
10. Enter the patient’s telephone number in the “Phone” field.
11. Click on the attending provider for the patient from the dropdown list for the “Attending Provider” field.
12. Click on the referring provider for the patient from the dropdown list for the “Referring Provider” field.
13. Click on the [Next] button to proceed to the “Address” screen.

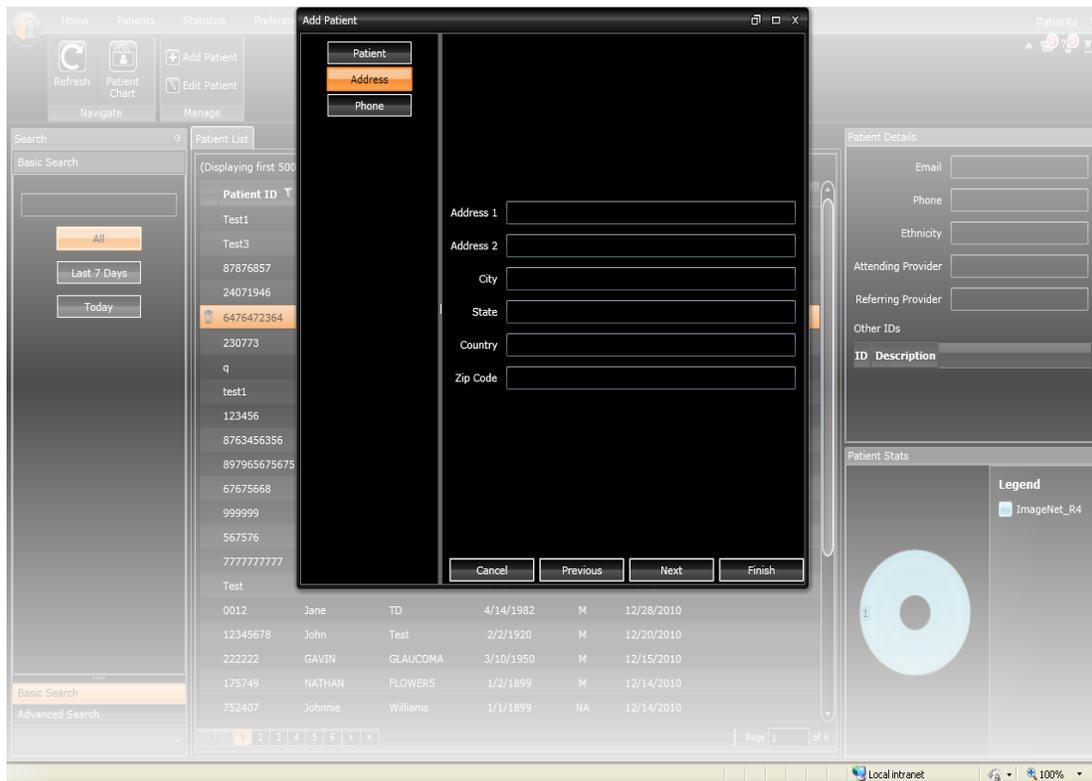


Figure 97: Patient Address Screen

14. Enter the patient's address information.
15. Click on the [Next] button or [Phone] to enter phone information on the next screen.

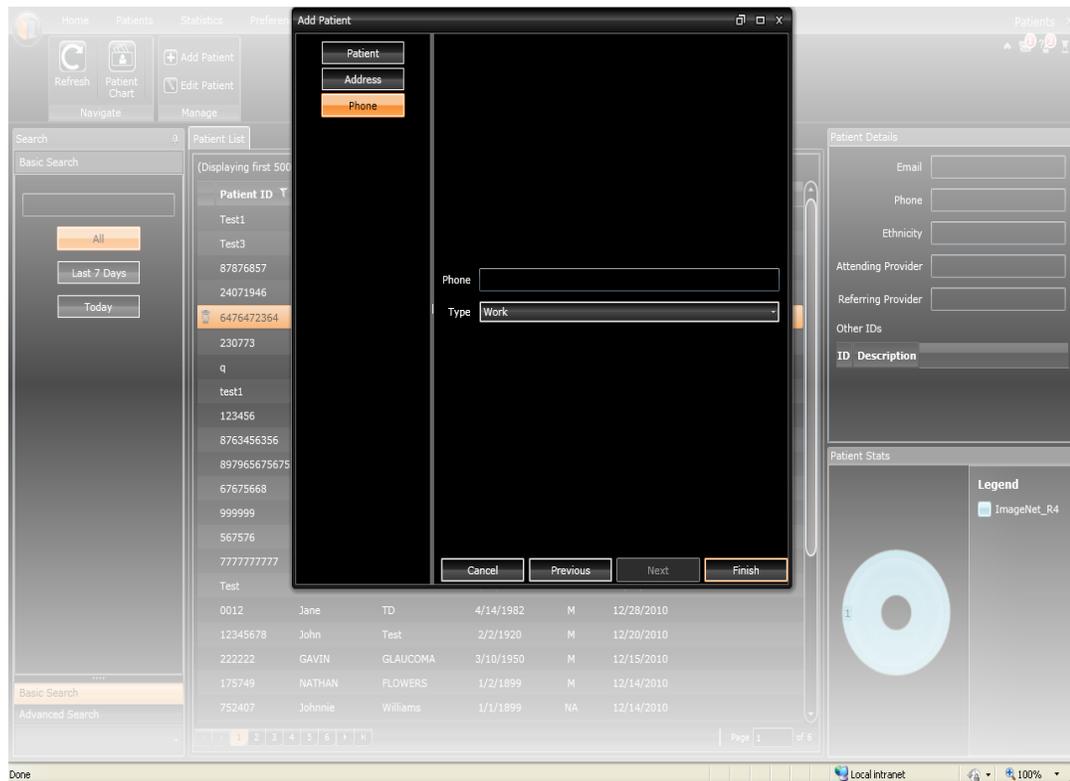


Figure 98: Patient Phone Number Screen

16. Enter the phone number and select the phone type.
17. Click on the [Finish] button to add the patient and return to the “Patient List”.

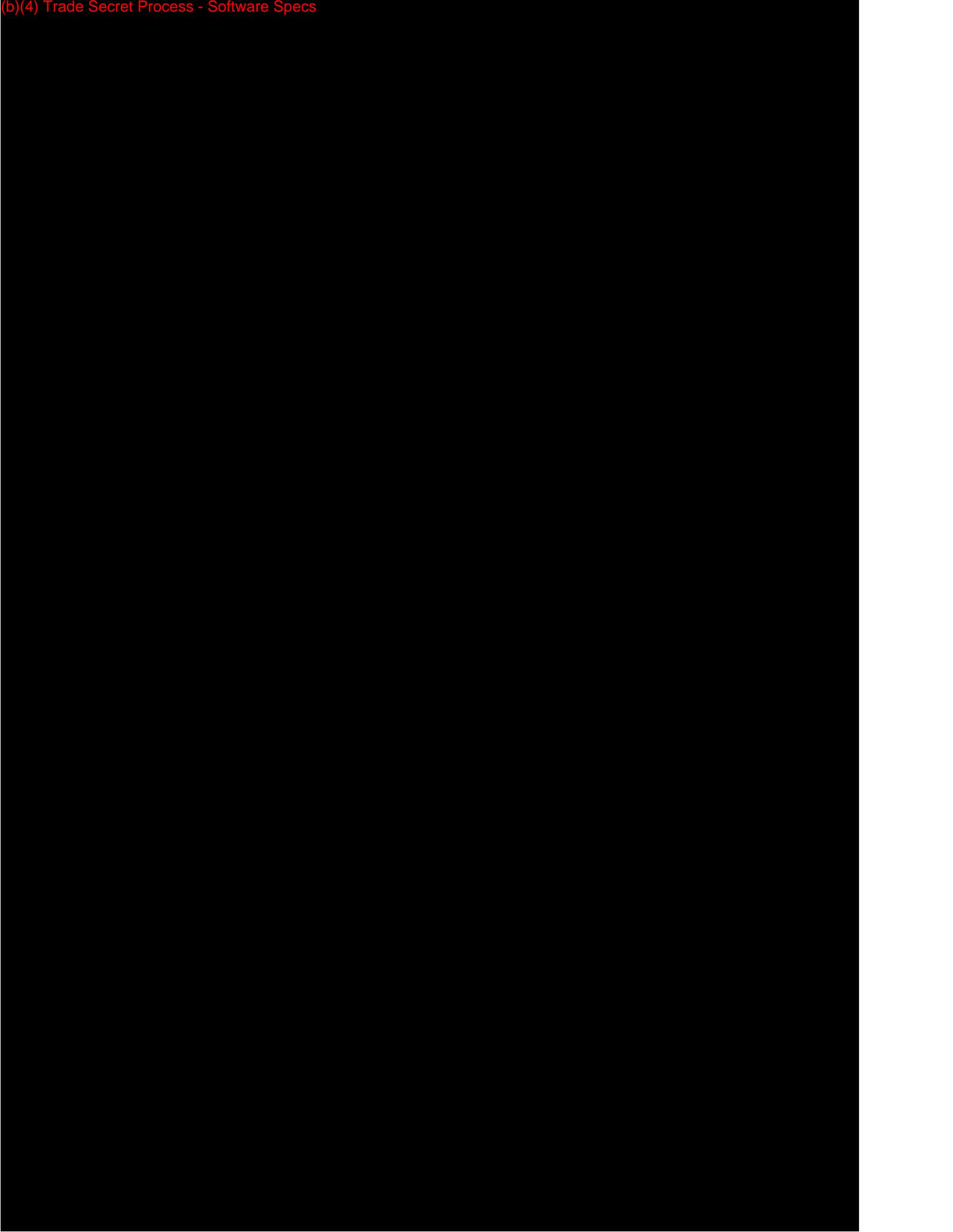


Topcon Synergy ODM

Software Design Specification (SDS)

07/19/2013

Synergy ODM v. 1.00 SDS	SD-PDR1017_0002
CONFIDENTIAL & PROPRIETARY. ALL INFORMATION CONTAINED HEREIN IS THE EXCLUSIVE PROPERTY OF TOPCON MEDICAL SYSTEMS, INC.	Rev. BB.3
	Page 1 of 89





Topcon Synergy ODM

Software Requirement Specification (SRS)

07/19/2013

Topcon Synergy ODM v. 1.00 SRS	SD-PDR1017_0001
CONFIDENTIAL & PROPRIETARY. ALL INFORMATION CONTAINED HEREIN IS THE EXCLUSIVE PROPERTY OF TOPCON MEDICAL SYSTEMS, INC.	Rev. B
	Page 1 of 16



Topcon Synergy ODM

Traceability Analysis

07/19/2013

Topcon Synergy Software Documentation	SD-PDR2001_0001
CONFIDENTIAL & PROPRIETARY. ALL INFORMATION CONTAINED HEREIN IS THE EXCLUSIVE PROPERTY OF TOPCON MEDICAL SYSTEMS, INC.	Rev. A.4
	Page 1 of 8

Topcon Synergy

Validation & Verification

Revision A

11/27/2012

V&V - Synergy ODM	SD-PDR1017_006
THIS DOCUMENT IS TOPCON MEDICAL SYSTEMS COMPANY CONFIDENTIAL. ALL INFORMATION CONTAINED HEREIN IS THE EXCLUSIVE PROPERTY OF TOPCON MEDICAL SYSTEMS.	Rev. A
	Page 1 of 22

(b)(4) Trade Secret Process -
Testing Report

(b)(4) Trade Secret Process - Testing
Report

Testing Protocol

(b)(4) Trade
Secret Process

(b)(4) Trade
Secret

(b)(4) Trade Secret Process - Testing Report

(b)(4) Trade Secret Process - Testing Report

(b)(4) Trade Secret Process - Testing Report

Testing Protocol

(b)(4) Trade Secret Process - Testing Report

(b)(4) Trade Secret Process - Testing Report

(b)(4) Trade Secret Process - Testing Report

(b)(4) Trade Secret Process - Testing Report

Testing Protocol

(b)(4) Trade Secret Process - Testing Report

(b)(4) Trade Secret Process - Testing Report

(b)(4) Trade Secret Process - Testing Report

(b)(4) Trade Secret Process - Testing Report

Testing Protocol

(b)(4) Trade Secret Process - Testing Report

(b)(4) Trade Secret Process - Testing Report

(b)(4) Trade Secret Process - Testing Report

(b)(4) Trade Secret Process - Testing Report

Testing Protocol

(b)(4) Trade Secret Process - Testing Report

(b)(4) Trade Secret Process - Testing Report

510(k) SUMMARY

Topcon Medical Systems, Inc. Synergy ODM

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Topcon Medical Systems, Inc.
111 Bauer Drive
Oakland, NJ 07436
Phone: (201) 599-5553
Facsimile: (201) 599-5240
Contact Person: Michael Gusel

OR

Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864
Phone: (978) 207-1245
Facsimile: (978) 824-2541

Date Prepared: August 26, 2013

Name of Device and Name/Address of Sponsor

Synergy ODM
Topcon Medical Systems, Inc.
111 Bauer Drive
Oakland, NJ 07436

Common or Usual Name

System, image management, ophthalmic

Classification Name

21 C.F.R. 892.2050

Predicate Devices

Topcon Corporation Synergy (K093313)
Carl Zeiss Meditec AG Forum (K122938)

Intended Use / Indications for Use

Synergy ODM is a comprehensive software platform intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic instruments through either a direct connection with the instruments or through computerized networks.

Technological Characteristics

Synergy ODM is a software platform that collects, processes, measures, analyzes, stores, and manages patient data and clinical information. Synergy ODM is used together with a number of computerized digital imaging devices. In addition, Synergy ODM software collects and manages patient demographics, image data, and clinical reports from a range of medical devices. Synergy ODM enables a real-time review of diagnostic patient information at a PC workstation. Synergy ODM also includes an internet-browser-based user interface to allow authorized users to access, view, create reports, and analyze patient and examination data saved in a centralized database. The system utilizes dual level authentication and 128-bit encryption to ensure secure networking environment.

Performance Data

No performance data was required or provided. Software validation and verification demonstrate that the Synergy ODM performs as intended and meets its' specifications.

Substantial Equivalence

Synergy ODM is as safe and effective as the identified predicate devices including Topcon Corporation's Synergy (K093313) and Zeiss Forum (K122938). Synergy ODM has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. Both Synergy ODM and the predicate devices have similar technological characteristics. Synergy ODM and the identified predicate devices are software only devices.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade 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: http://www.fda.gov/oc/mdufma/cover-sheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city, state, country, and post office code) TOPCON MEDICAL SYSTEMS INC 111 Bauer Drive Oakland NJ 07436 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	2. CONTACT NAME Michael Gusel 2.1 E-MAIL ADDRESS mgusel@topcon.com 2.2 TELEPHONE NUMBER (include Area code) 201-599-5553 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: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm) <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"/> 30-Day Notice		
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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm 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)		22-Aug-2013

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Synergy ODM

Indications for Use:

Synergy ODM is a comprehensive software platform intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic instruments through either a direct connection with the instruments or through computerized networks.

Prescription Use <input checked="" type="checkbox"/>	AND/OR	Over-The-Counter
Use _____		
(Part 21 C.F.R. 801 Subpart D)		(21 C.F.R. 807
Subpart C)		

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 C.F.R. § 807.87(k))

I certify that, in my capacity as Manager, Regulatory Affairs and Quality Assurance of Topcon Medical Systems, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification for the Synergy ODM are truthful and accurate and that no material fact has been omitted.



(Signature)

Michael Gusel
Manager, Regulatory Affairs and Quality Assurance

8/23/13
(Date)

Barlow, Lenny *

From: Barlow, Lenny *
Sent: Wednesday, October 16, 2013 11:41 AM
To: 'Maureen@oconnellregulatory.com'
Cc: DCCLetters
Subject: k132667 Correspondence
Attachments: k132667.pdf



COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

From: Reviewer Name Rahul Ram
Subject: 510(k) Number K132667
To: The Record

Please list CTS decision code: SE - Substantially Equivalent

- Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)
- Hold (Additional Information or Telephone Hold)
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page (<i>Attach IFU</i>)	X	
510(k) Summary or 510(k) Statement (<i>Attach Summary or Statement</i>)	X	
Truthful and Accurate Statement (<i>Must be present for a Final Decision</i>)	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach <u>Form 3654</u> .)	X	
Is this a combination product?		X
Is this a reprocessed single use device? (See <u>Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices</u> .)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
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 was incomplete, then applicant must be contacted to obtain completed form.)		X
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 to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); 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 years to <21 years); No special considerations compared to adults >= 21 years)		X

Nanotechnology		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Regulation Number: 21 CFR 892.2050
Class: II
Product Code: NFJ
Additional Product Codes:

Digital Signature Concurrence Table
 (Not all signatures may be required)

Branch Chief Sign-Off	Bradley S. Cunningham -S 2013.10.09 15:29:55 -04'00'
Division Sign-Off	Kesia Y. Alexander -S 2013.10.09 16:08:26 -04'00'