Laser Lipo Ltd
Heath House, Crockham Hill
Edenbridge
United Kingdom, TN8 6ST
Telephone: +44 844 980 1820
e-mail: ian@strawberry-laser.com

510[k] Summary

as required by section 807.92(c)

Owner's Name

Laser Lipo Ltd	Address:	Heath House Crockham Hill Edenbridge Kent TN8 6ST United Kingdom
	Tel:	011 44 844 980 1820
	Mobile:	011 44 777 445 9611
	Fax:	011 44 1732 866 231
Contact Person:		Ian Cobley at Laser Lipo Ltd
	Tel:	011 44 844 980 1820
	Mobile:	011 44 777 445 9611
	Fax:	011 44 844 980 1820
	E-mail:	ian@strawberry-laser.com

SEP 06 2013

Date this summary was prepared: January 31, 2013

Classification name: Low Level laser system for aesthetic use,
21 CFR 878.5400
79 OLI

Common/Usual Name: Low Level laser system for aesthetic use

Proprietary Name: Laser Lipo Ltd will manufacture two devices:

- The Strawberry low level laser system model ILO, and,
- The Strawberry & Cream low level laser system model SC

Establishment Registration Number:

The Strawberry low level laser system and Strawberry & Cream low level laser system will be manufactured by:

Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
Kent TN8 6ST
United Kingdom

Telephone: 011 44 844 980 1820
Fax: 011 44 844 980 1820

Establishment Registration Number: To be applied for following clearance of this submission.

Substantial Equivalence: The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is substantially equivalent in design, use and materials to the: Chromogenex Technologies Ltd I-Lipo System – K111501

- They are made of the similar materials
- They have similar indications for use that are achieved through the same technology
- They are assembled from similar components
- They have similar user input and output interfaces and
- Have similar features.

In particular both the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd i-Lipo System:

- use laser diodes
  - of approximately 660 nm wavelength, and
  - less than 50 mW output
- incorporated into
  - multiple multi-diodes "paddles" attached to the subject with special straps
    Strawberry 4 to 10 paddles with 6 diodes each
    i-Lipo 4 paddles with 9 diodes each
  - and both have two probes with one diode each
- have a similar control unit
  - LCD subject display
  - membrane key pad inputs

- incorporated into display as a touch screen for strawberry and cream
  - microprocessor controlled through software
  - multi-range power supply (EU and US voltages and frequencies)
- have a similar range of connecting cables
- have the same laser protection goggles
  - different name printed on outside of frame

Description of Product:
The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system consists of a control unit, various connection leads up to 10 paddles, 2 probes, various "Velcro" attachment straps and other accessories. (A full list of system contents is included at the end of this section.)

A paddle is a device containing six cold red laser emitting diodes which is designed to be placed on the skin. The system can operate using 4, 6, 8 or 10 paddles that are connected to the control unit.

A probe is a device containing one cold red laser emitting diode which is designed to be placed on the skin to treat specific smaller areas of fat, where a usual flat paddle won't ergonomically fit.

The control unit is an electrically powered unit (100-240v, 50-60Hz auto-ranging), enabled by a main switch and key switch. Once enabled it is controlled using a button (Strawberry) or touchscreen (Strawberry and Cream) interface. The output of the diode (six per paddle) is limited to 40mW +/- 15% by a power limiting PCB from the central processing unit.

When the laser paddles are placed on the skin, the cold red laser beams penetrate the skin just deep enough to reach the layers of fat. When the light hits the fat cells, a rapid chain of events takes place. Firstly, pores form on the cells causing them to spill out. The water, Glycerol and fatty acids move into the interstitial space beneath the fatty layer in the skin. Then further water, fatty acids and Glycerol spill out. The adipocyte cells are therefore reduced in size.

Intended use:
The Low level Laser model Strawberry and Strawberry and Cream can be used for the non-invasive temporary reduction in waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.

Performance Data:
Laser wavelength and output has been demonstrated to be capable and substantially equivalent to the predicate device (Chromogenex i-Lipo, K 111051).

Test	Mean	Quantity	Sample Standard Deviation	Capability, Cp
Laser diode power output: Paddle Laser diode output is set to 40mw +/-15%.	39.35	1140	0.81	2.47
Probe Laser diode output is set to 40mw +/-15%.	39.02	40	0.72	3.49
EU portable appliance testing	100% pass	20		
Visual Inspection: • external components, cables, outer casings and the • General condition of all associated parts.	100% pass	20		100% inspection
Assembly tests	100% pass	20		100% inspection
Functionality tests	100% pass	20		100% inspection

Double blind clinical study: Laser Lipo Ltd, at the request of the CDRH, had a full double blind clinical study carried out using a total of 35 subjects. Of these, 22 subjects received active laser treatments, and the remaining 13 subjects received placebo treatments. (See section 20.)

Conclusions: At the conclusion of the study, it was clear that 95% of the actively treated subjects achieved, or met, the success criteria. The criteria was set as achieving a temporary reduction around the subjects abdomen (at the height of the iliac crest) of 1.6in (4cm). The average recorded loss was 3.68in (9.35cm) with the greatest loss at 5.6in (14.22cm). Out of the 22 treated subject one failed to met the criteria with a reduction of only 1.2in (3cm). Thus proving the efficacy of the Strawberry and Strawberry & Cream inch loss device.

Not one of the placebo subjects achieved more than 1.3in (3.3cm).

No adverse effects were experienced by any of the trial subjects.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 6, 2013

Laser Lipo Ltd
Mr. Ian Cobley
Heath House, Crockham Hill
Edenbridge, Kent
TN8 6ST
United Kingdom

Re: K130341
Trade/Device Name: Laser Lipo Ltd Strawberry Low Level Laser system and Strawberry and Cream Low level Laser system
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OLI
Dated: July 26, 2013
Received: July 29, 2019

Dear Mr. Cobley:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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

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

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

Sincerely yours,

Mark N. Melkerson -S

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

Enclosure

Indications for Use

510(k) Number (if known): K130341

Device Name: Laser Lipo Ltd Strawberry Low Level Laser system and Strawberry and Cream Low level Laser system

Indications for Use: The Low level Laser model Strawberry and Strawberry and Cream can be used for the non-invasive temporary reduction in waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.09.06 11:33:42 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K130341

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 6, 2013

Laser Lipo Ltd
Mr. Ian Cobley
Heath House, Crockham Hill
Edenbridge, Kent
TN8 6ST
United Kingdom

Re: K130341
Trade/Device Name: Laser Lipo Ltd Strawberry Low Level Laser system and Strawberry and Cream Low level Laser system
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OLI
Dated: July 26, 2013
Received: July 29, 2019

Dear Mr. Cobley:

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

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

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Sincerely yours,

Mark N. Melkerson -S

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

Enclosure

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

Full Submission Number:

For Office of Compliance Contact Information:

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

For Office of Surveillance and Biometrics Contact Information:

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

Digital Signature Concurrence Table	
Reviewer Sign-Off	Sankar P. Basu
Branch Chief Sign-Off	Neil R.P. Ogden
Division Sign-Off	Mark N. Melkerson -S 2013.09.06 15:57:32 -04'00'

f/t: SPB:dlm:9/6/13

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)..." Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe Janicki	Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful..." Replaced incorrect semicolon with a comma.

Indications for Use

510(k) Number (if known): K130341

Device Name: Laser Lipo Ltd Strawberry Low Level Laser system and Strawberry and Cream Low level Laser system

Indications for Use: The Low level Laser model Strawberry and Strawberry and Cream can be used for the non-invasive temporary reduction in waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.09.06 11:33:42 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K130341

3. 510(k) Cover Letter

K130341

Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
United Kingdom, TN8 6ST
Telephone: +44 844 980 1820
e-mail: ian@strawberry-laser.com

1L-92

February 15, 2013.

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring
Maryland 20993-0002
United States of America

Ref: **510(k) Premarket Notification**

Dear Document Control Clerk:

Pursuant to the requirements of section 510 (k) of the Food, Drug and Cosmetic Act, notification is made to manufacture and market the following new medical device:

Classification Name:
Low Level laser system for aesthetic use
79 OLI

Classification Regulation:
21 CFR 878.5400

Common/Usual Name:
Low level laser system for aesthetic use

Proprietary Name:

Laser Lipo Ltd will manufacture two devices:

- the Strawberry low level laser system model ILO, and,
- the Strawberry & Cream low level laser system model SC

Establishment Registration Number:

The Strawberry low level laser system and Strawberry & Cream low level laser system will be manufactured by:

Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
Kent TN8 6ST
United Kingdom
Telephone: 011 44 844 980 1820
Fax: 011 44 844 980 1820
Establishment Registration Number: To be applied for following clearance of this submission.

Classification:

The FDA has classified: Low level laser system for aesthetic use (79 OLI) as a Class II medical device under 21 CFR 878.5400.

Performance Standards:

None established under 514, however FDA has published "Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use".

The following international consensus standards, recognized by FDA, have been complied with:

IEC 62304:2006 – software life-cycle
IEC 60601-1:2006 – electrical safety
IEC 60601-1-2:2007 - electromagnetic compatibility
IEC 60601-2-22:1996 – laser products
IEC 60825-1:2007 – laser products
ISO 14971:2009 – risk management
ISO 10993-1:2009 - biocompatibility

The following additional standards have also been complied with, although not recognized by the FDA:

ISO 13485: 2003 – quality management system
EN 980:2008 – European symbols
(explanatory text included in US labeling)
EN 1041:2008 – requirements for information
(supplemented by FDA guidance listed below)

The following Guidance notes have been used extensively in the preparation of this submission:

- Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Format for Traditional and Abbreviated 510(k)s
- Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22

Labeling and Promotional Materials:

Draft labels, labeling (including the User Manual) and promotional materials for the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system are contained in Section 13.

Substantial Equivalence:

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is substantially equivalent in design, use and materials to the:

Chromogenex Technologies Ltd I-Lipo System – K111501

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is made of the similar materials as the Chromogenex Technologies Ltd I-Lipo System – K111501.

The Laser Lipo Ltd Strawberry and Strawberry & Cream low level laser systems has similar indications for use

The Low level Laser model Strawberry and Strawberry and Cream can be used for the non-invasive aesthetic treatment for the temporary reduction in waist circumference.

to the Chromogenex Technologies Ltd I-Lipo System.

The Chromogenex Technologies Limited i-lipo™ Low Level Laser System is indicated for non-invasive aesthetic treatment for the temporary reduction in circumference of the waist.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is made of the same materials as the Chromogenex Technologies Ltd I-Lipo System – K111501.

- thermoplastic control unit enclosure
  - proprietary components and assemblies used within the unit
- thermoplastic paddles and probes
- nylon covered "velcro" fixed straps
- nylon/polycarbonate goggles

Both the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd i-Lipo System:

- use laser diodes
  - of approximately 660 nm wavelength, and
  - less than 50 mW output
- incorporated into
  - various laser diode cluster probes and paddles attached to the subject with special straps
    Strawberry 4 to 10 paddles with 6 diodes each
    i-Lipo 4 paddles with 9 diodes each
  - and two probes with one diode each
- have a similar control unit
  - LCD subject display
  - membrane key pad inputs
    - incorporated into display as a touch screen for strawberry and cream
  - microprocessor controlled through software
  - multi-range power supply (EU and US voltages and frequencies)
- have a similar range of connecting cables
- have the same two pairs of laser protection goggles
  - different name printed on outside of frame

The Laser Lipo Ltd Strawberry low level laser system, Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd I-Lipo System have the same use achieved through the same technology, are assembled from similar components made from similar materials, have similar user input and output interfaces and have similar features.

All systems use laser emitting diodes of the similar wavelengths and powers: the Laser Lipo systems have the potential to use more paddles but with less

diodes in each paddle. All systems have two cluster probes with a single laser diode in each. In all systems the paddles and cluster probes are secured to the subject with nylon encased rubber straps secured with "velcro".

All control units have plastic enclosures, discrete power supply, microprocessor controlled electronics, controls, alarms and similar control software.

Laser Lipo Ltd concluded that the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system are substantially equivalent to the Chromogenex Technologies Ltd I-Lipo System, K111501

For a demonstration of equivalence, please see Section 12.

Promotional Material giving details of the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and Chromogenex Technologies Ltd I-Lipo System is compared in Section 12.

Previous Submission:
Laser Lipo Limited have previously submitted the Strawberry and Strawberry & Cream Low Level Laser system under K122354 and PRE Submission Q120359

Description of Product:
The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system consists of a control unit, various connection leads up to 10 paddles, 2 cluster probes, various "Velcro" attachment straps and other accessories. (A full list of system contents is included at the end of this section.)

A paddle is a device containing six cold red laser emitting diodes which is designed to be placed on the skin. The system can operate using 4, 6, 8 or 10 paddles that are connected to the control unit.

A probe is a device containing one cold red laser emitting diode which is designed to be placed on the skin to treat specific smaller areas of fat, where a usual flat paddle won't ergonomically fit.

The control unit is an electrically powered unit (100-240v, 50-60Hz auto-ranging), enabled by a main switch and key switch. Once enabled it is controlled using a button (Strawberry) or touch screen (Strawberry and Cream) interface. The output of the diode (six per paddle) is limited to 40mW +/- 15% by a power limiting PCB from the central processing unit.

When the laser paddles are placed on the skin, the cold red laser beams penetrate the skin just deep enough to reach the layers of fat. When the light hits the fat cells, a rapid chain of events takes place. Firstly, pores form on the cells causing them to spill out. The water, Glycerol and fatty acids move into the interstitial space beneath the fatty layer in the skin. Then further water, fatty acids and Glycerol spill out. The adipocyte cells are therefore reduced in size.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system contain the same control electronics and control software however the Strawberry and Cream has a menu driven touch screen interface while the Strawberry model has a liquid crystal display and (up, down, left, right and center/enter) push buttons. The outputs and functionality of the Strawberry and Strawberry and Cream models are identical, however displays, display drivers, interface electronics and software and power supply transformed are different. Full details are contained in Section 11.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is shipped in dedicated packaging to prevent damage and protected by a cardboard box.

The system as shipped contains:

- 1 low level laser system unit, either
  - Strawberry model, or
  - Strawberry & Cream model
- 1 user manual
- 1 power lead
- Paddle leads, for example for a 10 paddle system
  - 1 long paddle lead for connection to the device
  - 8 paddle standard leads
  - 1 long paddle lead
- 2 cluster Probes
- 1 Pair of goggles
- 2 Replacement fuses
- 2 Keys

Variants of the system will be available with 4, 6, 8 and 10 paddles.

number of paddles	number of paddle leads
3 standard and 1 end	3 standard
5 standard and 1 end	5 standard
7 standard and 1 end	7 standard
9 standard and 1 end	8 standard and 1 long (to connect two groups of five paddles)

Table 1 - Variants

A full list of the proposed variants and a schematic drawing showing the key design features are included in Section 11.

Engineering Drawings and Photographs of the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system can be found in Section 11.

Photographs, photo drawings and block diagrams showing the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd I-Lipo System are contained in Section 11 and comparison to the predicate Chromogenex Technologies Ltd I-Lipo System can be seen in Section 12.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system will be packaged in a cardboard box together with all components (instructions booklet, cables, paddles), software and accessories (diodes, goggles, fuse, straps and lead) within the scope of the 510(k). A shelf-life has been determined for 5 years based on the laser diodes.

Electrical Safety and Electromagnetic Compatibility is demonstrated through compliance with IEC 60601 part 1, part 1-2 and part 2-22 full test reports from a third party laboratory are included in Section 17.

The Guidance also states that there should be compliance with the IEC 60601-1-4 standard. Laser Lipo Ltd believes that compliance with IEC 62304:2006 life-cycle standard achieves at least the same level of assurance in the quality of the software used in the device.

A usability file detailing application of IEC 60601-1-6:2008 is contained in Section 11.

Table 2 - Product Release Testing Summary
Gives the results of bench testing of the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system which can be seen in section 18 and is confirmed by clinical reports in section 20.

Test	Mean	Quantity	Sample Standard Deviation	Capability, Cp
Laser diode power output: Paddle Laser diode output is set to 40mw +/-15%.	39.35	1140	0.81	2.47
Probe Laser diode output is set to 40mw +/-15%.	40.02	40	0.72	3.49
EU portable appliance testing	100% pass	20		
Visual Inspection: • external components, cables, outer casings and the • General condition of all associated parts.	100% pass	20		100% inspection
Assembly tests	100% pass	20		100% inspection
Functionality tests	100% pass	20		100% inspection

Table 2 - Product Release Testing Summary

Biocompatibility:

Biocompatibility assessment on the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system have been conducted following the ISO 10993-1 (FDA Recognized Consensus Standard), Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. Please see section 15.

Sterilization:

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system are supplied non-sterile.

Cleaning instructions are contained in the user manual included with each system.

Safety and Effectiveness:

A summary of safety and effectiveness information ("510(k) Summary" per 21 CFR 807.92) upon which an equivalence determination has been made is included as Section 5.

Indications for Use Statement:

A single sheet statement of "indications for use" as required by FDA for submissions after January 01, 1996, is included in Section 4.

Truthful and Accurate Statement:

The premarket notification "truthful and accurate" statement (per 21 CFR 807.87(k)), signed by the Group Director Ian Cobley of Laser Lipo Ltd is included as Section 6.

E Copy Statement:

The E Copy provided within our submission is an exact duplicate of the paper copy.

Owner:

This Pre-Market Notification is owned by Laser Lipo Ltd.

Submitter:

This Pre-Market Notification is submitted by
Ian Cobley
Group Director
For and on behalf of: Laser Lipo Ltd

Contact Persons:

The address and telephone number for **all** correspondence is:

Ian Cobley
Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
Kent TN8 6ST
United Kingdom
Tel: 011 44 844 980 1820
Mobile: 011 44 777 445 9611
Fax: 011 44 844 980 1820
e-mail: ian@strawberry-laser.com

As per your letter dated February 14, 2013 please find a replacement E copy of our submission.

If I can be of any further assistance, please do not hesitate to contact me.

Sincerely,

Ian Cobley
Group Director
Laser Lipo Ltd

1. Medical Device User Fee Cover Sheet (Form FDA 3601)

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Secret Process - Product
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/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

LASER LIPO LTD
Heath House
Crockham Hill
Edenbridge Kent TN8 6ST
GB

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Ian Cobley
2.1 E-MAIL ADDRESS
ian@strawberry-laser.com
2.2 TELEPHONE NUMBER (include Area code)
+44844-9801820
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/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER
3.2 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] 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?
[X] 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.)
[ ] 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/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] 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).
[ ] YES [X] 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) Trade 14-Dec-2012

"Close Window" Print Cover sheet

2. CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: December 31, 2013.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
17 December 2012	(b)(4) Trade Secret Process - Product Specs	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Laser Lipo Limited	To be applied for following clearance of this 510[k]		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	011 44 844 980 1820		
Street Address	FAX Number *(including area code)*		
Heath House, Crockham Hill	011 44 844 980 1820		
City	State / Province	ZIP/Postal Code	Country
Edenbridge	Kent	TN8 6ST	U.K.
Contact Name			
Ian Cobley			
Contact Title	Contact E-mail Address		
Group Director	ian@strawberry-laser.com		

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

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

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OLI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached

☐ 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K111501	1	I-Lipo System	1	Chromogenex Technologies Ltd
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Low Level laser system for aesthetic use

	Trade or Proprietary or Model Name for This Device		Model Number
1	Strawberry	1	ILO
2	Strawberry & Cream	2	SC
3		3	
4		4	
5		5	

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

1 K122354	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: OLI

C.F.R. Section *(if applicable)*: 21 CFR 878.5400

Classification Panel: General and plastic surgery devices

Device Class

☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Indications *(from labeling)*

The Low level Laser model Strawberry and Strawberry and Cream can be used for the non-invasive temporary reduction in waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

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

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number To be applied for following clearance of this 510[k]	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name Laser Lipo Limited		Establishment Registration Number To be applied for following clearance of this 510[k]			
Division Name *(if applicable)*		Phone Number *(including area code)* 011 44 844 980 1820			
Street Address Heath House, Crockham Hill		FAX Number *(including area code)* 011 44 1732 866 231			
City Edenbridge		State / Province Kent	ZIP/Postal Code TN8 6ST	Country U.K.	
Contact Name Ian Cobley	Contact Title Group Director		Contact E-mail Address ian@strawberry-laser.com		

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number			
Division Name *(if applicable)*		Phone Number *(including area code)*			
Street Address		FAX Number *(including area code)*			
City		State / Province	ZIP/Postal Code	Country	
Contact Name	Contact Title		Contact E-mail Address		

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number			
Division Name *(if applicable)*		Phone Number *(including area code)* ( )			
Street Address		FAX Number *(including area code)* ( )			
City		State / Province	ZIP/Postal Code	Country	
Contact Name	Contact Title		Contact E-mail Address		

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	62304	IEC	Medical Device Software, Software Life-cycle Processes		2006
	Standards No.	Standards Organization	Standards Title	Version	Date
2	60601	IEC	Medical Electrical Equipment, General Requirements for Safety	part 1	2006
	Standards No.	Standards Organization	Standards Title	Version	Date
3	60601	IEC	Medical Electrical Equipment, General Requirements for safety and essential performance, Collateral standard, Electromagnetic compatibility and tests	parts 1-2	2007
	Standards No.	Standards Organization	Standards Title	Version	Date
4	60601	IEC	Medical electrical equipment, Particular Requirements for safety. Specification for Diagnosis and Therapeutic Laser Equipment.	parts 2-22	1996
	Standards No.	Standards Organization	Standards Title	Version	Date
5	60825	IEC	Safety of laser products, Equipment classification and Requirements	part 1	2007
	Standards No.	Standards Organization	Standards Title	Version	Date
6	14971	ISO	Application of Risk Management to Medical Devices		2009
	Standards No.	Standards Organization	Standards Title	Version	Date
7	10993	ISO	Biological evaluation of Medical Devices, Evaluation and Testing	part 1	2009

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

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

Department of Health and Human Services
Food and Drug Administration
Office of the 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.

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
8	Standards No. 13485	Standards Organization ISO	Standards Title Quality Management Systems, Requirements for Regulatory Purposes	Version	Date 2003
9	Standards No.	Standards Organization	Standards Title	Version	Date
10	Standards No.	Standards Organization	Standards Title	Version	Date
11	Standards No.	Standards Organization	Standards Title	Version	Date
12	Standards No.	Standards Organization	Standards Title	Version	Date
13	Standards No.	Standards Organization	Standards Title	Version	Date
14	Standards No.	Standards Organization	Standards Title	Version	Date

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

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

Department of Health and Human Services
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Office of the 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.

3. 510(k) Cover Letter

Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
United Kingdom, TN8 6ST
Telephone: +44 844 980 1820
e-mail: ian@strawberry-laser.com

Thursday, 31 2013.

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring
Maryland 20993-0002
United States of America

Ref: **510(k) Premarket Notification**

Dear Document Control Clerk:

Pursuant to the requirements of section 510 (k) of the Food, Drug and Cosmetic Act, notification is made to manufacture and market the following new medical device:

Classification Name:
Low Level laser system for aesthetic use
79 OLI

Classification Regulation:
21 CFR 878.5400

Common/Usual Name:
Low level laser system for aesthetic use

Proprietary Name:

Laser Lipo Ltd will manufacture two devices:

- the Strawberry low level laser system model ILO, and,
- the Strawberry & Cream low level laser system model SC

Establishment Registration Number:

The Strawberry low level laser system and Strawberry & Cream low level laser system will be manufactured by:

Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
Kent TN8 6ST
United Kingdom
Telephone: 011 44 844 980 1820
Fax: 011 44 844 980 1820
Establishment Registration Number: To be applied for following clearance of this submission.

Classification:

The FDA has classified: Low level laser system for aesthetic use (79 OLI) as a Class II medical device under 21 CFR 878.5400.

Performance Standards:

None established under 514, however FDA has published "Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use".

The following international consensus standards, recognized by FDA, have been complied with:

IEC 62304:2006 – software life-cycle
IEC 60601-1:2006 – electrical safety
IEC 60601-1-2:2007 - electromagnetic compatibility
IEC 60601-2-22:1996 – laser products
IEC 60825-1:2007 – laser products
ISO 14971:2009 – risk management
ISO 10993-1:2009 - biocompatibility

The following additional standards have also been complied with, although not recognized by the FDA:

ISO 13485: 2003 – quality management system
EN 980:2008 – European symbols
(explanatory text included in US labeling)
EN 1041:2008 – requirements for information
(supplemented by FDA guidance listed below)

The following Guidance notes have been used extensively in the preparation of this submission:

- Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Format for Traditional and Abbreviated 510(k)s
- Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22

Labeling and Promotional Materials:

Draft labels, labeling (including the User Manual) and promotional materials for the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system are contained in Section 13.

Substantial Equivalence:

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is substantially equivalent in design, use and materials to the:

Chromogenex Technologies Ltd I-Lipo System – K111501

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is made of the similar materials as the Chromogenex Technologies Ltd I-Lipo System – K111501.

The Laser Lipo Ltd Strawberry and Strawberry & Cream low level laser systems has similar indications for use

The Low level Laser model Strawberry and Strawberry and Cream can be used for the non-invasive aesthetic treatment for the temporary reduction in waist circumference.

to the Chromogenex Technologies Ltd I-Lipo System.

The Chromogenex Technologies Limited i-lipo™ Low Level Laser System is indicated for non-invasive aesthetic treatment for the temporary reduction in circumference of the waist.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is made of the same materials as the Chromogenex Technologies Ltd I-Lipo System – K111501.

- thermoplastic control unit enclosure
    - proprietary components and assemblies used within the unit
- thermoplastic paddles and probes
- nylon covered "velcro" fixed straps
- nylon/polycarbonate goggles

Both the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd i-Lipo System:

- use laser diodes
    - of approximately 660 nm wavelength, and
    - less than 50 mW output
- incorporated into
    - various laser diode cluster probes and paddles attached to the subject with special straps
      Strawberry 4 to 10 paddles with 6 diodes each
      i-Lipo 4 paddles with 9 diodes each
    - and two probes with one diode each
- have a similar control unit
    - LCD subject display
    - membrane key pad inputs
        - incorporated into display as a touch screen for strawberry and cream
    - microprocessor controlled through software
    - multi-range power supply (EU and US voltages and frequencies)
- have a similar range of connecting cables
- have the same two pairs of laser protection goggles
    - different name printed on outside of frame

The Laser Lipo Ltd Strawberry low level laser system, Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd I-Lipo System have the same use achieved through the same technology, are assembled from similar components made from similar materials, have similar user input and output interfaces and have similar features.

All systems use laser emitting diodes of the similar wavelengths and powers: the Laser Lipo systems have the potential to use more paddles but with less

diodes in each paddle. All systems have two cluster probes with a single laser diode in each. In all systems the paddles and cluster probes are secured to the subject with nylon encased rubber straps secured with "velcro".

All control units have plastic enclosures, discrete power supply, microprocessor controlled electronics, controls, alarms and similar control software.

Laser Lipo Ltd concluded that the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system are substantially equivalent to the Chromogenex Technologies Ltd I-Lipo System, K111501

For a demonstration of equivalence, please see Section 12.

Promotional Material giving details of the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and Chromogenex Technologies Ltd I-Lipo System is compared in Section 12.

Previous Submission:
Laser Lipo Limited have previously submitted the Strawberry and Strawberry & Cream Low Level Laser system under K122354 and PRE Submission Q120359

Description of Product:
The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system consists of a control unit, various connection leads up to 10 paddles, 2 cluster probes, various "Velcro" attachment straps and other accessories. (A full list of system contents is included at the end of this section.)

A paddle is a device containing six cold red laser emitting diodes which is designed to be placed on the skin. The system can operate using 4, 6, 8 or 10 paddles that are connected to the control unit.

A probe is a device containing one cold red laser emitting diode which is designed to be placed on the skin to treat specific smaller areas of fat, where a usual flat paddle won't ergonomically fit.

The control unit is an electrically powered unit (100-240v, 50-60Hz auto-ranging), enabled by a main switch and key switch. Once enabled it is controlled using a button (Strawberry) or touchscreen (Strawberry and Cream) interface. The output of the diode (six per paddle) is limited to 40mW +/- 15% by a power limiting PCB from the central processing unit.

When the laser paddles are placed on the skin, the cold red laser beams penetrate the skin just deep enough to reach the layers of fat. When the light hits the fat cells, a rapid chain of events takes place. Firstly, pores form on the cells causing them to spill out. The water, Glycerol and fatty acids move into the interstitial space beneath the fatty layer in the skin. Then further water, fatty acids and Glycerol spill out. The adipocyte cells are therefore reduced in size.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system contain the same control electronics and control software however the Strawberry and Cream has a menu driven touch screen interface while the Strawberry model has a liquid crystal display and (up, down, left, right and center/enter) push buttons. The outputs and functionality of the Strawberry and Strawberry and Cream models are identical, however displays, display drivers, interface electronics and software and power supply transformed are different. Full details are contained in Section 11.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is shipped in dedicated packaging to prevent damage and protected by a cardboard box.

The system as shipped contains:

- 1 low level laser system unit, either
  - Strawberry model, or
  - Strawberry & Cream model
- 1 user manual
- 1 power lead
- Paddle leads, for example for a 10 paddle system
  - 1 long paddle lead for connection to the device
  - 8 paddle standard leads
  - 1 long paddle lead
- 2 cluster Probes
- 1 Pair of goggles
- 2 Replacement fuses
- 2 Keys

Variants of the system will be available with 4, 6, 8 and 10 paddles.

number of paddles	number of paddle leads
3 standard and 1 end	3 standard
5 standard and 1 end	5 standard
7 standard and 1 end	7 standard
9 standard and 1 end	8 standard and 1 long (to connect two groups of five paddles)

Table 1 - Variants

A full list of the proposed variants and a schematic drawing showing the key design features are included in Section 11.

Engineering Drawings and Photographs of the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system can be found in Section 11.

Photographs, photo drawings and block diagrams showing the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd I-Lipo System are contained in Section 11 and comparison to the predicate Chromogenex Technologies Ltd I-Lipo System can be seen in Section 12.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system will be packaged in a cardboard box together with all components (instructions booklet, cables, paddles), software and accessories (diodes, goggles, fuse, straps and lead) within the scope of the 510(k). A shelf-life has been determined for 5 years based on the laser diodes.

Electrical Safety and Electromagnetic Compatibility is demonstrated through compliance with IEC 60601 part 1, part 1-2 and part 2-22 full test reports from a third party laboratory are included in Section 17.

The Guidance also states that there should be compliance with the IEC 60601-1-4 standard. Laser Lipo Ltd believes that compliance with IEC 62304:2006 life-cycle standard achieves at least the same level of assurance in the quality of the software used in the device.

A usability file detailing application of IEC 60601-1-6:2008 is contained in Section 11.

Table 2 - Product Release Testing Summary
Gives the results of bench testing of the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system which can be seen in section 18 and is confirmed by clinical reports in section 20.

Test	Mean	Quantity	Sample Standard Deviation	Capability, Cp
Laser diode power output: Paddle Laser diode output is set to 40mw +/-15%.	39.35	1140	0.81	2.47
Probe Laser diode output is set to 40mw +/-15%.	40.02	40	0.72	3.49
EU portable appliance testing	100% pass	20		
Visual Inspection: • external components, cables, outer casings and the • General condition of all associated parts.	100% pass	20		100% inspection
Assembly tests	100% pass	20		100% inspection
Functionality tests	100% pass	20		100% inspection

Table 2 - Product Release Testing Summary

Biocompatibility:

Biocompatibility assessment on the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system have been conducted following the ISO 10993-1 (FDA Recognized Consensus Standard), Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. Please see section 15.

Sterilization:

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system are supplied non-sterile.

Cleaning instructions are contained in the user manual included with each system.

Safety and Effectiveness:

A summary of safety and effectiveness information ("510(k) Summary" per 21 CFR 807.92) upon which an equivalence determination has been made is included as Section 5.

Indications for Use Statement:

A single sheet statement of "indications for use" as required by FDA for submissions after January 01, 1996, is included in Section 4.

Truthful and Accurate Statement:

The premarket notification "truthful and accurate" statement (per 21 CFR 807.87(k)), signed by the Group Director Ian Cobley of Laser Lipo Ltd is included as Section 6.

E Copy Statement:

The E Copy provided within our submission is an exact duplicate of the paper copy.

Owner:

This Pre-Market Notification is owned by Laser Lipo Ltd.

Submitter:

This Pre-Market Notification is submitted by
Ian Cobley
Group Director
For and on behalf of: Laser Lipo Ltd

Contact Persons:

The address and telephone number for **all** correspondence is:

Ian Cobley
Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
Kent TN8 6ST
United Kingdom
Tel: 011 44 844 980 1820
Mobile: 011 44 777 445 9611
Fax: 011 44 844 980 1820
e-mail: ian@strawberry-laser.com

If I can be of any further assistance, please do not hesitate to contact me.

Sincerely,

Ian Cobley
Group Director
Laser Lipo Ltd

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Laser Lipo Ltd Strawberry Low Level Laser system and Strawberry and Cream Low level Laser system

Indications for Use:

The Low level Laser model Strawberry and Strawberry and Cream can be used for the non-invasive temporary reduction in waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page _1_ of _1_

5. 510(k) Summary

Laser Lipo Ltd
Heath House, Crockham Hill
Edenbridge
United Kingdom, TN8 6ST
Telephone: +44 844 980 1820
e-mail: ian@strawberry-laser.com

510[k] Summary

as required by section 807.92(c)

Owner's Name

Laser Lipo Ltd	Address:	Heath House Crockham Hill Edenbridge Kent TN8 6ST United Kingdom
	Tel:	011 44 844 980 1820
	Mobile:	011 44 777 445 9611
	Fax:	011 44 1732 866 231
Contact Person:		Ian Cobley at Laser Lipo Ltd
	Tel:	011 44 844 980 1820
	Mobile:	011 44 777 445 9611
	Fax:	011 44 844 980 1820
	E-mail: l	ian@strawberry-laser.com

Date this summary was prepared: January 31, 2013

Classification name: Low Level laser system for aesthetic use,
21 CFR 878.5400
79 OLI

Common/Usual Name: Low Level laser system for aesthetic use

Proprietary Name: Laser Lipo Ltd will manufacture two devices:

- The Strawberry low level laser system model ILO, and,
- The Strawberry & Cream low level laser system model SC

Establishment Registration Number:

The Strawberry low level laser system and Strawberry & Cream low level laser system will be manufactured by:

Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
Kent TN8 6ST
United Kingdom
Telephone: 011 44 844 980 1820
Fax: 011 44 844 980 1820

Establishment Registration Number: To be applied for following clearance of this submission.

Substantial Equivalence: The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is substantially equivalent in design, use and materials to the: Chromogenex Technologies Ltd I-Lipo System – K111501

- They are made of the similar materials
- They have similar indications for use that are achieved through the same technology
- They are assembled from similar components
- They have similar user input and output interfaces and
- Have similar features.

In particular both the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd i-Lipo System:

- use laser diodes
  - of approximately 660 nm wavelength, and
  - less than 50 mW output
- incorporated into
  - multiple multi-diodes "paddles" attached to the subject with special straps
    Strawberry 4 to 10 paddles with 6 diodes each
    i-Lipo 4 paddles with 9 diodes each
  - and both have two probes with one diode each
- have a similar control unit
  - LCD subject display
  - membrane key pad inputs

- incorporated into display as a touch screen for strawberry and cream
    - microprocessor controlled through software
    - multi-range power supply (EU and US voltages and frequencies)
- have a similar range of connecting cables
- have the same laser protection goggles
    - different name printed on outside of frame

Description of Product:
The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system consists of a control unit, various connection leads up to 10 paddles, 2 probes, various "Velcro" attachment straps and other accessories. (A full list of system contents is included at the end of this section.)

A paddle is a device containing six cold red laser emitting diodes which is designed to be placed on the skin. The system can operate using 4, 6, 8 or 10 paddles that are connected to the control unit.

A probe is a device containing one cold red laser emitting diode which is designed to be placed on the skin to treat specific smaller areas of fat, where a usual flat paddle won't ergonomically fit.

The control unit is an electrically powered unit (100-240v, 50-60Hz auto-ranging), enabled by a main switch and key switch. Once enabled it is controlled using a button (Strawberry) or touchscreen (Strawberry and Cream) interface. The output of the diode (six per paddle) is limited to 40mW +/- 15% by a power limiting PCB from the central processing unit.

When the laser paddles are placed on the skin, the cold red laser beams penetrate the skin just deep enough to reach the layers of fat. When the light hits the fat cells, a rapid chain of events takes place. Firstly, pores form on the cells causing them to spill out. The water, Glycerol and fatty acids move into the interstitial space beneath the fatty layer in the skin. Then further water, fatty acids and Glycerol spill out. The adipocyte cells are therefore reduced in size.

Intended use:
The Low level Laser model Strawberry and Strawberry and Cream can be used for the non-invasive temporary reduction in waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.

Performance Data

Laser wavelength and output has been demonstrated to be capable and substantially equivalent to the predicate device (Chromogenex i-Lipo, K 111051).

Test	Mean	Quantity	Sample Standard Deviation	Capability, Cp
Laser diode power output: Paddle Laser diode output is set to 40mw +/-15%.	39.35	1140	0.81	2.47
Probe Laser diode output is set to 40mw +/-15%.	39.02	40	0.72	3.49
EU portable appliance testing	100% pass	20		
Visual Inspection: • external components, cables, outer casings and the • General condition of all associated parts.	100% pass	20		100% inspection
Assembly tests	100% pass	20		100% inspection
Functionality tests	100% pass	20		100% inspection

Laser Lipo Ltd believes these demonstrate substantial equivalence, but have included clinical papers confirming similar performance from devices legally marketed within the European Union.

6. Truthful and Accuracy Statement

Laser Lipo Ltd
Heath House, Crockham Hill
Edenbridge
United Kingdom, TN8 6ST
Telephone: +44 844 980 1820
e-mail: ian@strawberry-laser.com

January 31, 2013

I certify that, in my capacity as Group Director of Laser Lipo Ltd, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____
(Signature)

Ian Cobley
_____
(Typed Name)

January 31, 2013
_____
(Date)

_____
(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.
Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

7. Class III Summary and Certification

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system products are class II medical devices hence no class III summary or certification is required.

8. Financial Certification or Disclosure Statement

No clinical trial data is presented in this submission and hence no Financial Certification or Disclosure Statement is required.

9. Declarations of Conformity and Summary Reports

SECTION 9 TABLE OF CONTENTS

9.1. Introduction

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system have been "CE Marked" for European distribution under the monitoring of the European Notified Body SGS; conformity to international and European standards is an important aspect of this process.

Where these international consensus standards have been recognized by the FDA, we have included the relevant test reports but we have also considered both the extent of FDA recognition and FDA's general and product specific guidance.

While we appreciate FDA does not recognize ISO 13485 (Quality System Standard for Medical Devices) and that this standard differs from FDA's current Good Manufacturing Practices (Quality System Regulation 21 CFR 820), we ask you to note that the Laser Lipo Quality management System has been accredited under this standard by their Notified Body SGS as part of the CE Marking process.

9.2. FDA Guidance Documents

The submission format and section numbering system has been based on FDA Guidance for the "Format of Traditional and Abbreviated 510[k]s Guidance", dated August 12, 2005.

The product specific guidance "Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use" has been used extensively in the preparation of this submission

In the development of the software for the Strawberry and Strawberry and Cream Low Level Laser systems, Laser Lipo has followed the IEC 62304 LifeCycle model and we have included a cross-reference table to the FDA Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

The FDA Guidance "Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22" has also been considered in the compilation of this submission and IEC 60601-2-22 has been considered together with electrical safety and electromagnetic compatibility in Section 17.

9.3. FDA Recognized Consensus Standards

IEC 62304:2006 Medical Device Software, Software Life-cycle Processes
FDA Recognition List Number: 13-8
Effective Date: 2006

IEC 60601-1:2006 Medical Electrical Equipment, General Requirements for Safety
FDA Recognition List Number: 5-4
The Laser Lipo products were originally tested to the second edition standard but have been retested to the third edition standard which we understand FDA now accepts as demonstrating electrical safety. The full test report is included in Section 16.

IEC 60601-1-2:2007 Medical Electrical Equipment, General Requirements for safety and essential performance, Collateral standard, Electromagnetic compatibility and tests
FDA Recognition List Number: 5-28
Effective Date: 2001

IEC 60601-2-22:1996 Medical electrical equipment, Particular Requirements for safety. Specification for Diagnosis and Therapeutic Laser Equipment.
FDA Recognition List Number: 12-197
Effective Date: 1995

IEC 60825-1:2007 Safety of laser products, Equipment classification and Requirements
FDA Recognition List Number: 12-168
Effective Date: 2007

ISO 14971:2009 Application of Risk Management to Medical Devices
FDA Recognition List Number: 5-70
Effective Date: 04/10/2007

ISO 10993-1:2009 Biological evaluation of Medical Devices, Evaluation and Testing
FDA Recognition List Number: 2-152
Effective Date: 01/2006

9.4. FDA Guidance Cross-Reference Tables

9.4.1. FDA Guidance to IEC 62304 Software Report

FDA Software in Submissions Guidance Item	Specifics: FDA Requirements for Moderate level of concern in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	Location, in the Software Development Report ,Section 16.3, unless otherwise stated.	Location in Additional Software Report, section 16.4
Level of concern	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	Section 16.1.2 of the 510k	N/A
Software Description	A summary overview of the features and software operating environment.	9.0 Development Plan >Background >Development Requirements (development process, programming environment, Strawberry, Strawberry & Cream)	N/A
Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigations.	6.0 Software Classification 3.0 Introduction >Risk Management 4.0 Purpose	16.4.1
Software Requirements Specification (SRS)	The complete SRS document.	7.0 Requirements 9.0 Development Plan >Development requirements	16.4.2

FDA Software in Submissions Guidance Item	Specifics: FDA Requirements for Moderate level of concern in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	Location, in the Software Development Report ,Section 16.3, unless otherwise stated.	Location in Additional Software Report, section 16.4
Architecture Design Chart	Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.	10.0 Software Performance and Functional Requirements 13.0 Annex A: Software Listing for Strawberry 14.0 Annex B: Software Listing for Strawberry & Cream	16.4.3
Software Design Specification (SDS)	Software design specification document.	10.0 Software Performance and Functional Requirements	16.4.4
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing.	9.0 Development plan >Verification Planning >validation 10.0 Software Performance and Functional Requirements >Software Verification	N/A
Software Development Environment Description	Summary of software life cycle development plan, including a summary of the configuration management and maintenance activities.	4.0 Purpose 7.0 Requirements 9.0 Development Plan 12.0 Software Modification and Maintenance Plan	N/A
Verification and Validation Documentation	Description of V&V activities at the unit, integration, and system level. System level test protocol, including pass/fail	5.0 Scope 9.0 Development Plan >Verification Planning >Validation 10.0 Software Performance and Functional Requirements	16.4.5

FDA Software in Submissions Guidance Item	Specifics: FDA Requirements for Moderate level of concern in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	Location, in the Software Development Report ,Section 16.3, unless otherwise stated.	Location in Additional Software Report, section 16.4
	criteria, and tests results.	>Software Verification	
Revision Level History	Revision history log, including release version number and date.	2.0 Document Revision History 3.0 Introduction >Revision 11.0 Software Release 12.0 Software Modification and Maintenance Plan	16.4.6
Unresolved Anomalies (Bugs or Defects)	List of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.	12.0 Software Modification and Maintenance Plan	N/A

9.4.2. Low Level Laser Guidance to this Submission

Low Level Laser Guidance Section	Item	Location in this 510[k]
1. Background 2. Introduction and 3. Scope		2. Cover Sheet 3. Cover Letter etc
4. Device Description	Device Components	11. Device Description
	Photographs or Drawing	11. Device Description
	Comparison to Predicate Device	12. SE Discussion
5. Risks to Health	Ocular Injury	11. Description (Goggles) 12. SE Discussion
	Electric Shock	16. IEC 60601 Testing
	Unintended Cell Damage	12. SE Discussion
	Use Error	13. Proposed labeling
6. Bench Testing	To design/performance specification	18. Performance Testing
	Laser Power Output	18. Performance Testing
	Targeting	18. Performance Testing
	Failure Simulation	18. Performance Testing
7. Software Validation	Software in Subs. Guidance	See table above section 9.4.1
	IEC 60601-1-4	17. IEC 62304 Report
8. Clinical Testing	Alternatives	12. SE Discussion 16. IEC Safety Testing 18. Bench Testing
9. Biocompatibility	ISO 10993-1	15. Biocompatibility
10. EMC	IEC 60601-1-2	16. IEC 60601-1-2 Testing
11. Elec and Mech Safety	IEC 60601-1	16. IEC 60601-1
12. Labeling:		13. Proposed Labeling
	Device User Manual	13. Draft User Manual
	Directions for Use	13. Draft User Manual
	Indications for Use	4. IFU Statement 12. SE Discussion 13. Draft User Manual
	Contraindications	13. Draft User Manual
	Storage Conditions	13. Draft User Manual
	Warnings	13. Draft User Manual
	Precautions	13. Draft User Manual

9.5. FDA Standard Forms, FDA 3654

FDA Standards Forms (FDA #3654) for each of the recognized consensus standards follow:

- ISO 10993
- ISO 14971
- IEC 60601-1-2
- IEC 60601-1-1
- IEC 60601-2-22
- IEC 60825
- IEC 62304

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

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]

ISO 10993-1:2009 Biological evaluation of Medical Devices, Evaluation and Testing

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	#2-152	
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: Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use

[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/sldsprog.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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-1:2009 Biological evaluation of Medical Devices, Evaluation and Testing

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

* 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971:2009 Application of Risk Management to Medical Devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	#5-70	
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: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

[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/sldsprog.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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14971:2009 Application of Risk Management to Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

* 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.

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Rockville, MD 20850

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FORM FDA 3654 (9/07) Page 2

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2:2007 Medical Electrical Equipment, General Requirements for safety and essential performance...

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	#5-28	
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.	☑	☐
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If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use

[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

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FORM FDA 3654 (9/07) Page 1

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SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1-2:2007 Medical Electrical Equipment, General Requirements for safety and essential performance...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1:2006 Medical Electrical Equipment, General Requirements for Safety

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	#5-4	
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.	☑	☐
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Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use

[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.

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1:2006 Medical Electrical Equipment, General Requirements for Safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
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DESCRIPTION		
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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-2-22:1996 Medical electrical equipment, Particular Requirements for safety. Specification for Diagnosis and..

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	#12-197	
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.	☑	☐
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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: Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22

[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.

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EXTENT OF STANDARD CONFORMANCE
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TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
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DESCRIPTION		
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☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60825-1:2007 Safety of laser products, Equipment classification and Requirements

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	#12-168	
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.	☐	☑
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Title of guidance: Laser Products – Conformance with IEC 60825-1 and IEC 60601-2-22;

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STANDARD TITLE
IEC 60825-1:2007 Safety of laser products, Equipment classification and Requirements

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JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62304:2006 Medical Device Software, Software Life-cycle Processes

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.	☑	☐
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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: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

[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/sldsprog.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 62304:2006 Medical Device Software, Software Life-cycle Processes

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
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10. Executive Summary

SECTION 10 TABLE OF CONTENTS

10.1. Description

Laser Lipo Ltd manufacture two devices:

- the 'Strawberry' with a liquid crystal display and membrane keypad and
- the 'Strawberry & Cream' with a touch screen display

These two low level laser systems are for the non-invasive temporary reduction in waist circumference by the disruption of adipocyte cells, within the fat layer, for the release of fat and lipids from these cells. This is done by anatomic redistribution, not weight loss. (21 CFR 878.5400 - 79 OLI)

The 'Strawberry' and the 'Strawberry & Cream' consist of a control unit, connection leads with up to 10 multi diode laser "paddles", 2 cluster probes, various "Velcro" attachment straps and other accessories.

The control units are electrically powered units (100-240v, 50-60Hz auto-ranging), enabled by a main switch and key switch. Once powered "ON", they are controlled using membrane buttons (Strawberry) and touch screen (Strawberry & Cream) interface. The output of the diodes is limited to 40mW +/- 15% by a power limiting PCB from the central processing unit.

When the laser paddles are placed on the skin, the cold red laser beams permeate the skin just deep enough to reach the layers of fat. When the light hits the fat cells, a rapid chain of events takes place. Firstly, pores form on the cells causing them to spill out. That is, the water, Glycerol and fatty acids move into the interstitial spaces beneath the fatty layer in the skin. Then further water, fatty acids and Glycerol spill out. The adipocyte cells with reduced content are therefore reduced in size.

10.2. Substantial Equivalence Tables

	Subject Device	Subject Device	Predicate Device
	Strawberry	Strawberry & Cream	I-Lipo
510(k)	THIS 510(k)	THIS 510(k)	K111501
Intended use	Indicated for non-invasive temporary reduction in waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.	same	indicated for Non-invasive treatment for the temporary reduction in Circumference of the waist.

	Subject Device	Subject Device	Predicate Device
	Strawberry	Strawberry & Cream	I-Lipo
510(k)	THIS 510(k)	THIS 510(k)	K111501
Enclosure	Plastic	Same	Same
Display	LCD	Same	Same
Laser type	Class 3b	Same	Same
Membrane Keypad	Yes	Touch screen	Same as Strawberry
Electronic technology	Yes	Same	Same
Fuses	Provided	Same	Same
Control electronics	Yes	Same	Same
Emergency stop	Provided	Same	Same
Key switch	Provided	Same	Same
Speaker	Provided	Same	Same
Adjustment	Keypad	Touch screen interface	Same as Strawberry
Power supply	100-240 v ac 50-60 Hz	Same	Similar 240 v ac 50 Hz 120 v ac 60 Hz
Transformer	Provided	Same	Same
Energy source	Laser Diode from 660 nm nominal	Same	Same
Energy output	up to 40 mW (50 mW probes)	Same	Similar up to 50 mW
Cooling requirements	Air cooled	Same	same
Paddle size	15.0 x 4.5 cm	Same	Similar 13 x 8.4 cm
Probe size	6 x 2.4 x 4.3cm	Same	Similar 2.7 x 3.6 x 2.6 cm
Environment Requirements	10°C to 30°C Non-condensing humidity's below 75%	Same	Same
Laser Output: wavelength output "paddles" laser diodes per "paddle" "cluster probes" laser diodes per "cluster probe" Laser class Laser Diode	 660 ± 15 nm up to 62 x 50 mW 4 , 6, 8 or 10 6 2 1 IIIb GaAlAs	 Same Same Same Same Same Same Same Same	 650 – 690 nm up to 38 x 50 mW 4 9 2 1 IIIb GaAlAs
Safety Features: Prevention of unauthorized use "Emergency" Stop	 Key switch "Stop" button	 Same Same	 Interlock Same

10.3. Summary of Performance Testing

Laser wavelength and output has been demonstrated to be capable and substantially equivalent to the predicate device (Chromogenex i-Lipo K111051).

Test	Mean	Quantity	Sample Standard Deviation	Capability, Cp
Laser diode power output: Paddle Laser diode output is set to 40mw +/-15%.	39.35	1140	0.81	2.47
Probe Laser diode output is set to 45mw +/-15%.	45.02	40	0.72	3.49
EU portable appliance testing	100% pass	20		
Visual Inspection: • external components, cables, outer casings and the • general condition of all associated parts.	100% pass	20		100% inspection
Assembly tests	100% pass	20		100% inspection
Functionality tests	100% pass	20		100% inspection

Laser Lipo Ltd has demonstrated substantial equivalence and have included a recent clinical paper conforming similar performance from devices legally marketed within the European Union.

11. Device Description

SECTION 11 TABLE OF CONTENTS

11.1. Summary Device Description

11.1.1. System Overview

The Laser Lipo Ltd 'Strawberry' low level laser system and 'Strawberry & Cream' low level laser system both consists of a control unit, multiple connection leads with up to 10 paddles, 2 cluster probes, various “Velcro” attachment straps and other accessories. (A full list of system contents is included at the end of this section.)

Each paddle is a device containing six cold red laser emitting diodes which are designed to be placed on the skin. The system can operate using 4, 6, 8 or 10 paddles that are connected to the control unit. These paddles are identical for both the 'Strawberry' and Strawberry & Cream' systems.

The control unit is an electrically powered unit (100-240v, 50-60Hz auto-ranging), enabled by a main switch and key switch. Once enabled it is controlled using a button (Strawberry) or touchscreen (Strawberry and Cream) interface. The output of the diode (six per paddle) is limited to 40mW +/- 15% by a power limiting PCB from the central processing unit.

The control unit is contained within a plastic enclosure weighing approximately 14 lbs. The dimensions of the unit are approximately 8” x 10” x 12”.

When the laser paddles are placed on the skin, the cold red laser beams permeates the skin just deep enough to reach the layers of fat. When the light reaches the fat cells, a rapid chain of events takes place. Firstly, pores form on the cells causing them to spill out water, Glycerol and fatty acids. These elements move into the interstitial space beneath the fatty layer in the skin. Due to these elements leaving the adipocyte cells, they are reduced in size.

The Laser Lipo Ltd 'Strawberry' system and 'Strawberry & Cream' low level laser systems contain the same control electronics and control software, however the 'Strawberry & Cream' has a menu controlled by a touch screen interface, whilst the 'Strawberry' model has a liquid crystal display and (up, down, left, right and center/enter) push buttons. The outputs and functionality of the 'Strawberry' and 'Strawberry & Cream' models are identical; however displays, display drivers, interface electronics and software differ. Full details are contained in Section 11.1.2.

The Laser Lipo Ltd ships both systems in dedicated packaging to prevent damage in transit. The systems are protected by cardboard boxes and polystyrene.

Each system is shipped with the following contents:

- 1 low level laser system unit, either
  - Strawberry model, or
  - Strawberry & Cream model
- 1 user manual
- 1 power lead
- Paddle leads, for example for a 10 paddle system
  - 1 long paddle lead for connection to the device
  - 8 paddle standard leads
  - 1 long paddle lead
- 2 Cluster Probes
- 1 Pair of goggles
- 2 Replacement fuses
- 2 Keys

Variants of the system will be available with 4, 6, 8 and 10 paddles.

number of paddles	number of paddle leads
3 standard and 1 end	3 standard
5 standard and 1 end	5 standard
7 standard and 1 end	7 standard
9 standard and 1 end	8 standard and 1 long (to connect two groups of five paddles)

Table 1 - Variants

Photographs are used in the following sections as a visual aide.

11.1.2. Control Unit Overview

Figure 11.1.2 a) - Strawberry Low Level Laser Control Unit

Figure 11.1.2 b) - Strawberry & Cream Low Level Laser Control Unit

The 'Strawberry' and the 'Strawberry & Cream' low level laser control units contain:

- Power supply of 100-240V ac 50-60Hz
- Key switch
- Emergency stop
- LCD display or Touch screen display
- Keypad
- 32-bits EISC with ISP Flash, USB and ADPCM Engine
- Mother board for S&C
- Fuse
- Digital PCB
- Wires
- Speaker
- Transformer
- Ribbon cable
- Hexagon bolts, nuts and washers
- Upper and lower case enclosure

Engineering Drawings of the 'Strawberry' and the 'Strawberry & Cream' low level laser systems can be found in Section 11.5.

IEC 60601 electrical safety and electromagnetic compatibility test reports and certificates can be seen in Section 17.

The Software Development Report following the IEC 62304 Life-cycle methodology is contained in Section 16.

11.1.3. Packaging

The Laser Lipo Ltd 'Strawberry' system and 'Strawberry & Cream' low level laser systems will be packaged in a cardboard case with polystyrene inserts.

11.1.4. Shelf-Life Overview

A shelf-life has been determined for 5 years based on the laser diodes. Bench test reports are contained in Section 18.

11.1.5. Laser

The Laser Lipo Ltd 'Strawberry' and 'Strawberry & Cream' low level laser systems are non-invasive class 3b cold red laser and uses 2 different laser LED configuration which are:

1. 660nm 40mW (+/- 15%), x 6 ea LD for paddles
2. 660nm 40mW (+/- 15%), x 1 ea LD for cluster probes

Both models have a GAAIAS & GAA1LnP Diode Source and use a continuous wave diode driver.

11.1.6. System Control

Figure 11.1.6 a)

The 'Strawberry' low level laser system is controlled using a membrane keypad as the user interface to set the treatment time.

Figure 11.1.6 b)

The 'Strawberry & Cream' uses a touch screen user interface to select treatment time.

Figure 11.1.6 c)

The i-Lipo LCD display screen with push buttons to set treatment time.

11.1.7. Laser Paddles

Laser Paddle Comparison between the Strawberry and i-Lipo paddles

Although there is a difference in the number of paddles, they actually equate to the same in terms of treatment power / energy applied to the skin.

<u>i-lipo treatment example;</u>

An abdomen treatment with the i-Lipo pads involves two 10 minute treatments. The size of the pads only covers half of an average abdomen. The pads therefore need to be placed on two areas to cover the abdomen.

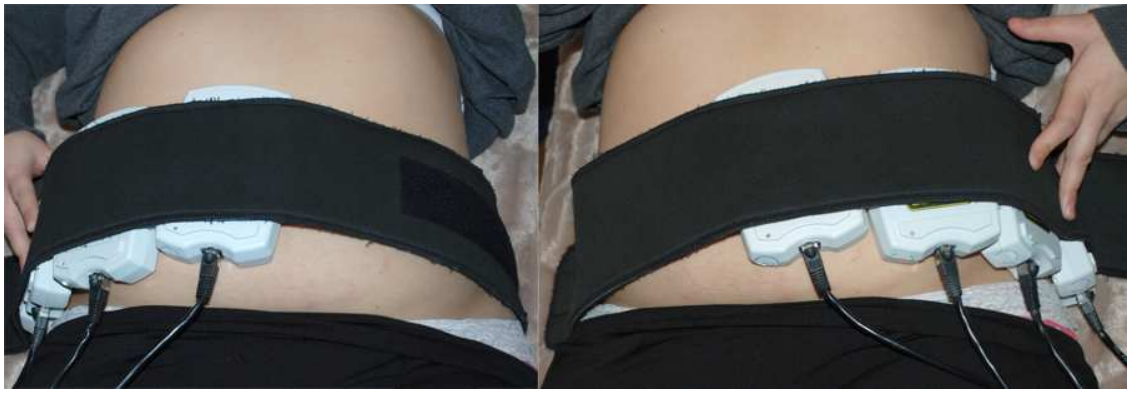


Fig. 11.1.7 a). i_lipo pad treating right side of the abdomen for 10 mins, then left side of the abdomen for 10 mins.

Image above show subjects right side being treated for 10 minutes. This is then followed with a second treatment of 10 minutes, with the pads placed on the subjects left side.

Therefore a treatment with the i-Lipo pads amount to two 10 minute treatments or 20 minutes of laser exposure time.

Strawberry treatment example;
The Strawberry paddles cover the entire abdomen area in one 10 minute treatment, without the need to move the paddles.

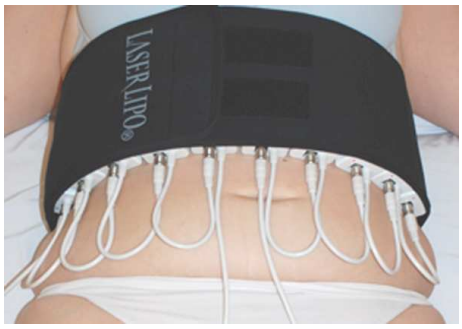


Fig. 11.1.7 b) Strawberry paddles placed for a treatment.

Physical size and number of diode comparison:

Fig. 11.1.7 c) Image of Strawberry paddles (x10) shown on the top, with i-Lipo pads (x4) shown beneath.

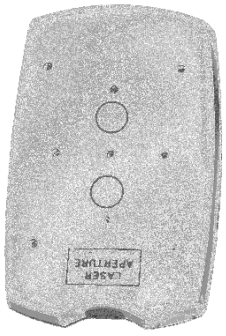


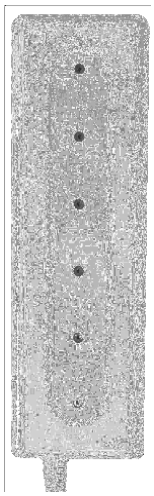
Fig. 11.1.7 d)

The i-Lipo laser treatment pads contain nine (9) laser diodes with a power output of 40mW and cover an active area of 84mm x 130mm.

When the four (4) laser pads are placed side by side the total skin area covered is 336mm x 130mm X 2 = 873.6 cm^2 for the entire treatment.

The pads are placed twice on the abdomen in order to treat the full abdomen area.

Joules are defined as Watts multiplied by the time in seconds, so Joules (J) = Watts × time (sec). Total energy given in Watts is calculated over an area as joules per centimeter squared (J/cm^2).



The Strawberry paddles contain six (6) laser diodes with a power output of up to 40mW and cover an active area of 45mm x 150mm.

When 10 paddles are placed side by side the total skin area covered is 450mm x 150mm = 675 cm^2 for one entire abdomen treatment.

Fig. 11.1.7 e). Strawberry paddle

Energy emitted per abdomen treatment is calculated as follows:

Single i-Lipo pad	40mW x 9 diodes	= 360mW or 0.36W
4 pads	4 laser paddles (0.36W x 4)	= 1.44w

The total energy emitted during a single treatment = 1.44W x 1200sec = 1,728 J.

Coverage of (4 pads x 2 placements) 8 pads area of 873.6 cm^2

The energy that reaches the skin is therefore 1,728 /873.6 cm^2= 1.98 J/cm^2

1x Strawberry paddle	40mW x 6 diodes	= 240mW or 0.24W
10 paddles	10 paddles (0.24W x 10)	= 2.40W.

The total energy emitted during a single treatment = 2.4W x 600sec = 1,440 J.
Coverage of (10 paddles each 450mm x 150mm is 675 cm^2

The energy that reaches the skin is therefore 1,440 /675SqCm = 2.13 J/cm$^{2.}$

(N.B. Calculations are based upon individual diode output being 40mW +/- 15%).

Optional number of paddles supplied with the 'Strawberry' and 'Strawberry & Cream' low level laser systems.

The 'Strawberry' and the 'Strawberry & Cream' low level laser systems have been designed to operate with up to 10 laser paddles. The systems can be purchased with 4, 6, 8 and 10 paddles.

The reason for this option is a financial one. Naturally a system with 4 paddles is sold at a lower price than a 6, 8 or 10 paddle system.

If a practitioner were to purchase a 4 paddle system, as with the i-Lipo system, it would be necessary to move the paddles a number of times to carry out an abdomen treatment. This results in a number of 10 minute treatments being necessary to complete a full abdomen treatment.

The treatment and results will be the same between treatments carried out with 4, 6, 8 or 10 paddles but will have taken longer to achieve. As a result practitioners will be able to treat fewer subjects in a working day.

The system is therefore designed to be upgradeable by purchasing additional paddles. This means that as demand for treatments increases, the practitioner can purchase additional paddles to reduce the treatment times down.

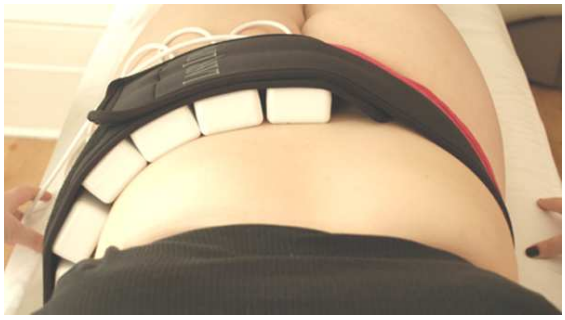


Fig. 11.1.7 f). Strawberry 6 paddle system fitted to abdomen.

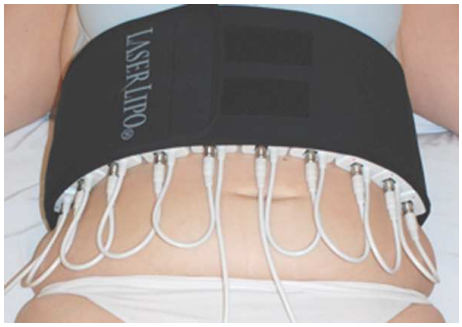


Fig. 11.1.7 g). Strawberry 10 paddles on abdomen.

The images below show (Fig.11.1.7 e) a 4 paddle system with probes and (Fig. 11.1.7.f) shows a set of 10 Strawberry paddles)

Fig. 11.1.7 e). Strawberry 4 paddle system.

Fig. 11.1.7 f). Strawberry 10 paddles.

11.1.8. Cluster Probes

The Cluster probes used with the i-Lipo system and the Strawberry Inch Loss systems are different in design (see Fig. 11.1.8 a) but substantially equivalent in power output and usage.

These probes are placed on the skin, in areas that are too small to fit laser paddles. The laser diodes are the same as those used in the larger laser paddles. They are used to assist the overall abdomen treatments to increase the treatment area.

Fig. 11.1.8 a) Strawberry Cluster probe on the left, i-Lipo cluster probe on the right.

Strawberry Cluster probe 40mW power output.

Fig. 11.1.8 b) Strawberry Cluster probe

i-Lipo cluster probe 40mW power output.

Fig. 11.1.8 c) i-Lipo Cluster probe

The cluster probes are used in conjunction with the laser paddles. Once the laser paddles have been attached to the Velcro belt and connected to the base unit, the probes are then connected to the base unit and positioned on to the skin.

There is one laser diode in each cluster probe and the cluster probes are supplied as a pair.

Fig. 11.1.8 d) i-Lipo Cluster probe

The 'Strawberry' and the 'Strawberry & Cream' low level laser systems are manufactured with 2 probes. The dimensions of the probes are approximately 2” x 1” x 1½”.

11.1.9. User safety Precautions

Prior to the device being switched on, the technician and subject need to wear protective goggles, see Section 11.1.16. Moreover a notice should be displayed on the door to the room, see section 13, showing the Laser Symbol and stating “Laser light, to avoid exposure to beam 3b laser product”.

11.1.10. Power Lead

Fig. 11.1.10 a) US Power Lead

11.1.11. Paddle leads

The Laser Lipo Ltd 'Strawberry' and the 'Strawberry & Cream' low level laser systems are manufactured with 3 types of paddle lead:

- 1 long lead for the connection between the unit and the first paddle
- 3, 5, 7 or 8 standard for the interconnection between paddles
- 1 longer interconnection lead between the 2 middle paddles when two straps are used.

number and type of paddles	number and type of paddle leads
3 standard and 1 end	3 standard
5 standard and 1 end	5 standard
7 standard and 1 end	7 standard
9 standard and 1 end	8 standard and 1 longer size to connect two sets of paddles

Fig. 11.1.11 a) Paddle Leads

11.1.12. Cluster Probe lead

The two cluster probes are connected to a dual wire "Y" type lead which connects with a single plug to the socket on the control unit.

Fig. 11.1.12 a) Probe "Y" type lead

11.1.13. Casing Screws

The top and bottom control unit moldings are held together with six casing screws.

Fig. 11.1.13. a) Casing Screws (set of 6)

11.1.14. 1 Amp Fuse

Fig. 11.1.14 a) Fuse - Fitting in lower housing

The 'Strawberry' and the 'Strawberry & Cream' low level laser systems are shipped with two spare fuses. Additional fuses are available as accessories.

The fuse is a Quick Acting F LBC Fuse, 1A 5x20mm andROHS Compliant.

11.1.15. Straps

The 'Strawberry' and the 'Strawberry & Cream' low level laser systems are manufactured with 3 different length straps:

- Large - (135 cmx17 cm)
- Medium - (75 cm x 17 cm)
- Small - (52 cm x17 cm)

Fig. 11.1.15 a) Velcro straps used to hold the paddles around the body.

The 'Strawberry' Velcro straps are made of the following materials:

External surface material:	Nylon
Internal material:	Neoprene (80%) + Nylon (20%)
Fitment:	Velcro pads on Nylon surface

11.1.16. Goggles

The 'Strawberry' and the 'Strawberry & Cream' low level laser systems are supplied with one pair of goggles in a protective case (for the subject) with a cleaning cloth (see Figure 11-2 - Photographs of goggles supplied as part of the system

Fig. 11.1.16 a) Laser protection goggles supplied with cleaning cloth.

The goggles are made of nylon and the lenses are made of Polycarbonate, with a luminous transmittance of 16% and designed as laser protection goggles for the appropriate wavelength.

The goggles are the same model from the same manufacturer as the goggles supplied with the predicate device. (see certification Fig.11.1.16 b)

Each pair of goggles is supplied with information regarding the glasses.
(See 11.1.16. b)

ECS GmbH - European Certification Service

CE

EC-type examination certificate

C7045.4NOIR

Applicant / manufacturer	NOIR Laser Company 6155 Pontiac Trail SOUTH LYON, MI 48178 USA
Identification of the manufacturer	NOIR
Product type	Laser protection filter
Model name	ML3 4base + 8base
Standard(s) / technical rules	DIN EN 207 : 2009 Annex II of the PPE-Directive 89/686/EEC
Test report	10313-ECS-07
Material and optical properties	Polycarbonate Luminous transmittance D65 16%
Marking	190 – 315 D LB7 + IR LB4 >315 – 395 D LB5 + IRM LB6 630 – 660 DIR LB3 >660 – 670 DIR LB2 780 – 920 DIR LB2 800 – 915 DIR LB3 NOIR CE

Herewith, ECS certifies that the named model complies with the basic requirements for health and safety as they are provided by the European Directive for Personal Protective Equipment 89/686/EEC. This certificate is based both / either on the test results as they are summarized in the named test reports, and/or on the technical documentation as it is delivered by the manufacturer. The applicant / manufacturer agrees to the General Business Rules of the ECS GmbH and to additional agreements as they are named in the application for conformity assessment.
The eye-protection device is to be marked as assigned. Either / both the frame and / or the ocular, spectacle, goggle or shield must be signed, as appropriate. If different marking has been assessed, the lowest marking must be applied, respectively.
The validity of this EC-type examination will expire, if the manufacturer modifies the safety-relevant properties of this product with comparison to the tested one or if the requirements in the standards or technical rules will be revised and/or tightened.
Name, address and identification number 1883 of the notified body ECS must be indicated in the information brochure of this product.

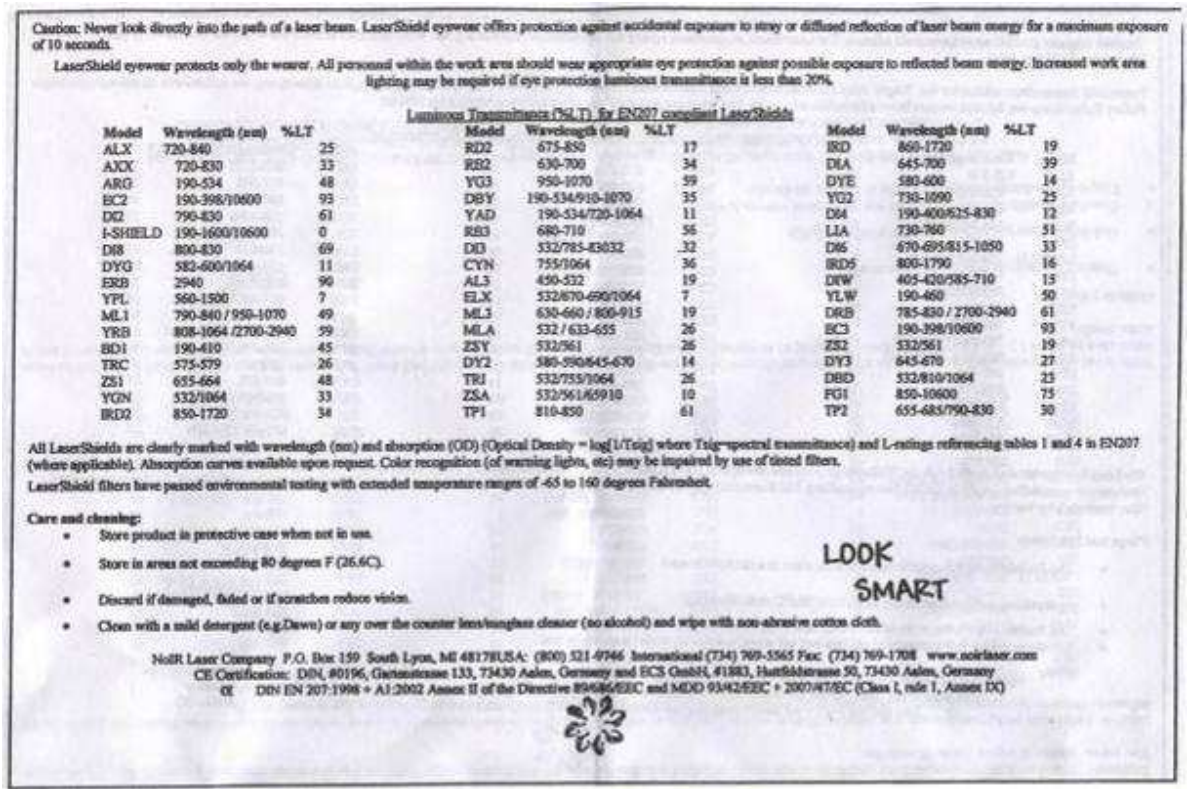
ECS GmbH
Notified Body 1883
13/10/10

Dipl.-Ing. Herbert Schäfer

European Certification Service ECS GmbH Aalen

ECS GmbH – European Certification Service
Augenschutz und Persönliche Schutzausrüstung
Laserschutz und Optische Messtechnik

Fig. 11.1.16 b) Laser Goggle Type Certificate



Caution: Never look directly into the path of a laser beam. LaserShield eyewear offers protection against accidental exposure to stray or diffused reflection of laser beam energy for a maximum exposure of 10 seconds.

LaserShield eyewear protects only the wearer. All personnel within the work area should wear appropriate eye protection against possible exposure to reflected beam energy. Increased work area lighting may be required if eye protection luminous transmittance is less than 20%.

Luminous Transmittance (%LT) for EN207 compliant LaserShields

Model	Wavelength (nm)	%LT	Model	Wavelength (nm)	%LT	Model	Wavelength (nm)	%LT
ALX	720-840	25	RD2	675-850	17	IRD	860-1720	19
AJX	720-830	33	RB2	630-700	34	DIA	645-700	39
ARG	190-534	48	YG3	950-1070	59	DYE	580-600	14
EC2	190-398/10600	93	DBY	190-534/910-1070	35	YG2	730-1090	25
DI2	790-830	61	YAD	190-534/720-1064	11	DI4	190-400/625-830	12
I-SHIELD	190-1600/10600	0	RB3	680-710	56	LIA	730-760	51
DI8	800-830	69	DID	532/785-85032	32	DI6	670-695/815-1050	33
DYG	582-600/1064	11	CYN	755/1064	36	IRD5	800-1790	16
ERB	2940	90	AL3	450-532	19	DIW	405-420/585-710	15
YPL	560-1500	7	ELX	532/670-690/1064	7	YLW	190-460	50
ML1	790-840 / 950-1070	49	ML3	630-660 / 800-915	19	DRB	785-830 / 2700-2940	61
YRB	808-1064 /2700-2940	59	MLA	532 / 633-655	26	EC3	190-398/10600	93
BD1	190-610	45	ZSY	532/561	26	ZS2	532/561	19
TRC	575-579	26	DY2	580-590/645-670	14	DY3	645-670	27
ZS1	655-664	48	TRJ	532/755/1064	26	DBD	532/810/1064	25
YGN	532/1064	33	ZSA	532/561/65910	10	FG1	850-10600	75
IRD2	850-1720	34	TP1	810-850	61	TP2	655-685/790-830	30

All LaserShields are clearly marked with wavelength (nm) and absorption (OD) (Optical Density = log[1/Tnig] where Tnig=spectral transmittance) and L-ratings referencing tables 1 and 4 in EN207 (where applicable). Absorption curves available upon request. Color recognition (of warning lights, etc) may be impaired by use of tinted filters.

LaserShield filters have passed environmental testing with extended temperature ranges of -65 to 160 degrees Fahrenheit.

Care and cleaning:

- Store product in protective case when not in use.
- Store in areas not exceeding 80 degrees F (26.6C).
- Discard if damaged, faded or if scratches reduce vision.
- Clean with a mild detergent (e.g.Dawn) or any over the counter lens/sunglass cleaner (no alcohol) and wipe with non-abrasive cotton cloth.

LOOK SMART

NoIR Laser Company P.O. Box 159 South Lyon, MI 48178USA: (800) 521-9746 International (734) 769-5565 Fax: (734) 769-1708 www.noirlaser.com
CE Certification: DIN, #0196, Gartenstrasse 133, 73430 Aalen, Germany and ECS GmbH, #1883, Huttfeldstrasse 50, 73430 Aalen, Germany
Of DIN EN 207:1998 + A1:2002 Annex II of the Directive 89/686/EEC and MDD 93/42/EEC + 2007/47/EC (Class I, rule 1, Annex IX)

Fig. 11.1.16.c) Information supplied with goggles

11.1.17. Keys

The 'Strawberry' and the 'Strawberry & Cream' low level laser systems are manufactured and supplied with 2 keys to help prevent accidental or unauthorized use.

The clinician must insert and turn the key in order to operate the unit.

Fig. 11.1.17 a) Keys

11.1.18. Presentation Box

Fig. 11.1.18 a) Cardboard Box with top tier removed to show control unit

Fig. 11.1.18 b) Top tier within cardboard box for cluster probes, paddles, leads etc

Fig. 11.1.18. c) Detail of individually packed items

11.2. Usability

The Following Usability file has been conducted using the 60601-1-6:2008 Standard

Doc No: UF/01/V1 Page: 1 of 4 Date : 03/04/2012	**Usability File Strawberry Medical Device**	

EN 60601-1-6: 2008
Documentation of Compliance

Author / Reviewer: Lisa Ormrod	Signed:

1. Application Specification

1.1 Medical Purpose

The Strawberry medical device is a non invasive class 3b cold red laser, the device is used for the purpose of Pain relief, inch loss and for the temporary reduction in the waist circumference.

1.2 Subject Population

The Strawberry Medical device is for use on adults only, and must not be used on people that suffer from any conditions listed as contraindications. (See Medical Questionnaire Document No. FRM-MED/001/Issue1)

1.3 Treatment areas

The Strawberry Medical device can be used on any area of the body with the exception of the middle and upper facial areas, due to the vulnerability of the retina in the eye.

1.4 User Profile

Therapists and clinicians can use the Strawberry Medical Devices, providing they have received training from the manufacturer or appointed distributors. (See Training schedule Document No. FRM 025 and certificate profile)

1.5 Operational environment

Treatments should be carried out in a closed area to protect the subject's modesty. The area should not be exposed to any people that are not aware of the need for protective eye protection. (See Eye protection specification Page 3 User Manual)

1.6 Operating Principle

The laser paddles need to be in contact with the skin, prior to the lasers being turned on. Once the laser paddles are in contact with the skin, the laser beams will be of no danger in the immediate proximity, and the beams will penetrate to a depth of no more than 13mm into the body. The treatment duration is selected by the technician and will not exceed 10 minutes in any single area. (See Training schedule Document No. FRM 025).

Doc No: UF/01/V1 Page: 2 of 4 Date : 03/04/2012	**Usability File Strawberry Medical Device**	"STRAWBERRY" The fastest growing International Beauty & Aesthetic Brand...

2. Operational procedures:

2.1 Check that the machine is connected to a 13amp wall socket and the switch is on.

2.2 Check that the laser paddles are correctly configured (See User Manual).

2.3 Ensure that the keys are in the back of the machine and press the power ON button, followed by turning the key to the ON position.

2.4 The machine will now carry out a 'self test function' and is then ready to be used.

2.5 Treatment protocols to follow those listed within the Training Schedule.

2.6 After use procedures are to carefully place the laser paddles so that they can not be damaged, turn off the power switches and after turning the key to the off position, the operator should remove the keys.

2.7 The machine is fitted with a standard 13amp fuse in the power lead and 2 additional 1amp fuses located at the back of the machine. These fuses are to protect against power surges or fluctuations.

3. Risk Analysis:

3.1 Intended Use/Intended Purpose

See 1.1

3.2 User Profile

See 1.4

3.3 Things that could go wrong

Sources: Clinical Evaluation Report, Risk Analysis Report, Risk Management file.

3.3.1 During Normal use:

a) Goggles MUST remain on subject and therapist's eyes at all times.

b) Therapist must stay in the room whilst treatment is being carried out.

3.3.2 Use Errors:

a) Dropping machine or parts

b) Exceeding user time (e.g. over 10 minutes in one area)

Doc No: UF/01/V1 Page: 3 of 4 Date : 03/04/2012	**Usability File Strawberry Medical Device**	

3.3.4 Hygiene

3.4 Protection protocol

- In the event that the operator or client's protective goggles should be dislodged the machine should be immediately switched off. This can be easily done by pressing the "LASER STOP" button clearly marked on the machine.
- The goggles MUST BE WORN AT ALL TIMES by the subject and therapist while the machine is turned on for treatments.

3.7 Resulting Hazardous situations and harms

- If the machine is dropped you could damage either the machine or laser paddles. This would be identified within the self check feature upon tuning on the machine.
- Ensuring that machine is thoroughly cleaned and sterilised between each client.

3.8 Preliminary review of the user interface concept

The user interface concept clearly identifies the potential risk of laser light to the eyes. The Risk assessment confirms this potential danger. Any person in possession of the keys to the device, without the proper training, could potentially do damage to their eyes or those around them. This is why the key system has been applied to this device.

- Removing goggles: Lasers are damaging hence why goggles must be worn, if clients and clinicians were to briefly look at the laser light it would cause blinking for a few seconds.

4. Strawberry medical device:

4.1 General

a) MEDICAL DEVICE
STRAWBERRY MEDICAL DEVICE

b) Basis

Intended use
possible use errors
hazardous situations or harms related to use
context of use
preliminary use scenarios

4.2 Use Scenarios

Worst case scenario to provide a basis for validation with subject and not the user:

a) Treatment potentially being carried out in an open, unprotected environment.
b) Untrained operator not providing the necessary eye protection goggles.

4.3 User actions related to Primary operating functions. (See Point 2)

4.4 User Interface requirements for the primary operating functions. (See point 2)

4.5 User Interface requirements for those use scenarios that are most frequent or related to safety.

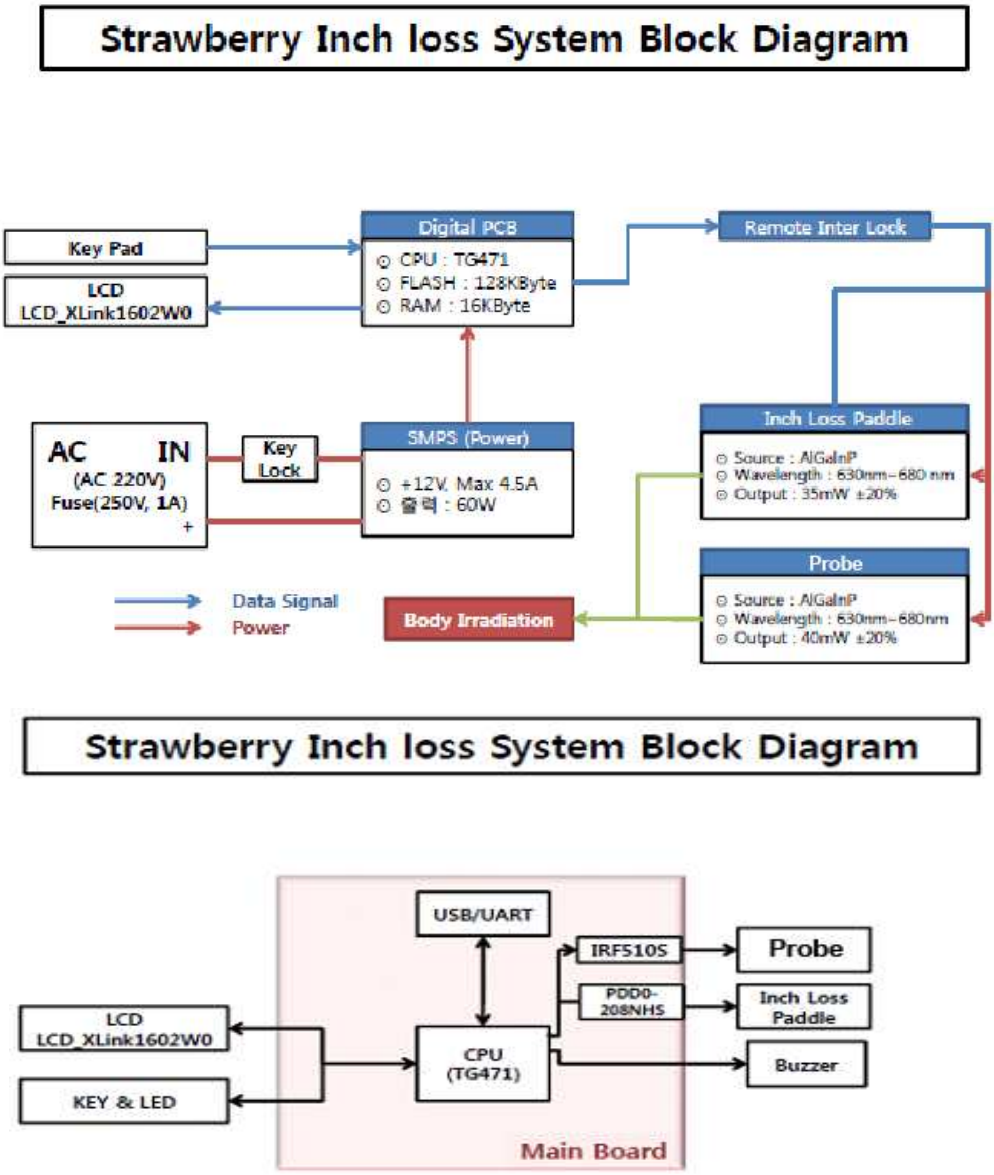
a) The whole procedure shall be easy to understand by reading the user manual.
b) Text: English and appropriate language for the country of use.
c) Font size 8pt Arial at a minimum
d) Symbols within the whole procedure should be based on international standards
e) Clearly understandable visuals are used within the User Manual.

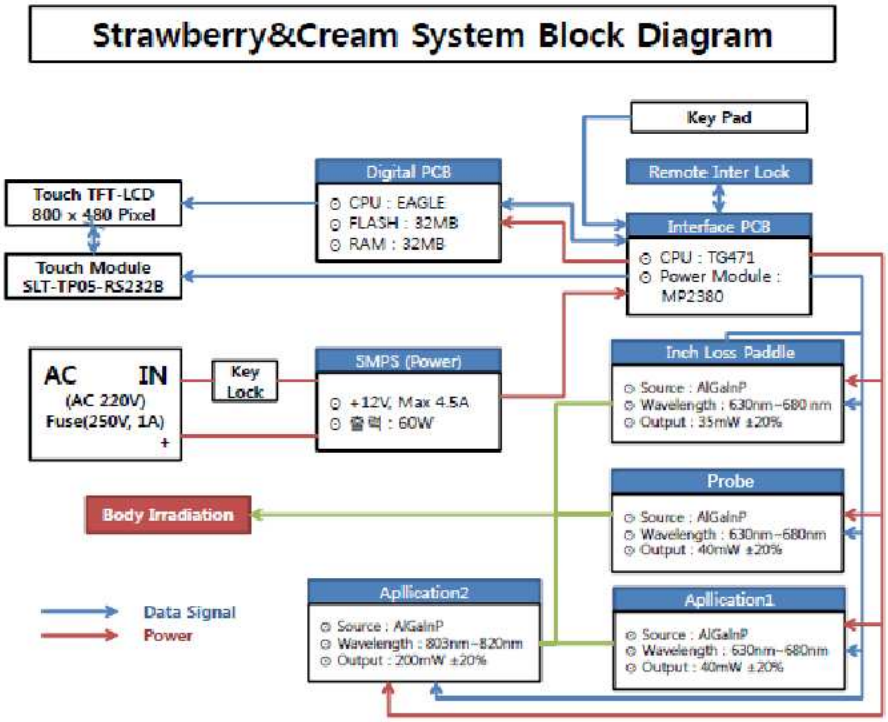
4.6 Requirements for determining whether the primary operating functions are easily recognisable by the user.

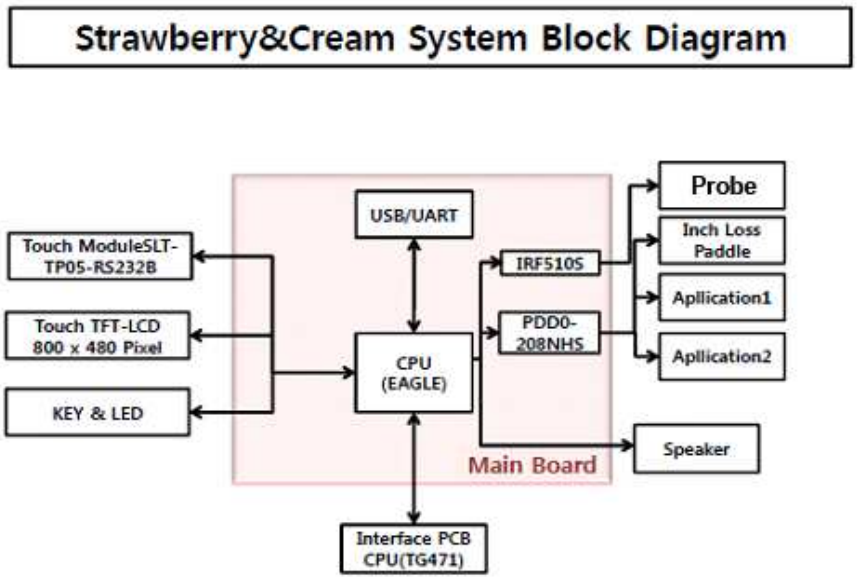
a) To protect against lack of understanding regarding the operating functions for the device, each potential operator undertakes a test to confirm that they have clearly understood the operating procedures, prior to receiving certification.

11.3. Systems Level Description

The 'Strawberry' and the 'Strawberry & Cream' low level laser systems are controlled by Digital PCBs, powered by a switched mode power supply (SMPS), input and output information are the keypad and LCD Display, and the energy is delivered to the paddles and cluster probes through a remote inter lock module or the PCB interface.




Strawberry&Cream System Block Diagram
Key Pad
Digital PCB
CPU : EAGLE
FLASH : 32MB
RAM : 32MB
Remote Inter Lock
Interface PCB
CPU : TG471
Power Module : MP2380
Touch TFT-LCD 800 x 480 Pixel
Touch Module SLT-TP05-RS232B
AC IN
(AC 220V)
Fuse(250V, 1A)
Key Lock
SMPS (Power)
+12V, Max 4.5A
출력 : 60W
Inch Loss Paddle
Source : AlGaInP
Wavelength : 630nm~680 nm
Output : 35mW ±20%
Probe
Source : AlGaInP
Wavelength : 630nm~680nm
Output : 40mW ±20%
Body Irradiation
Apllication2
Source : AlGaInP
Wavelength : 803nm~820nm
Output : 200mW ±20%
Apllication1
Source : AlGaInP
Wavelength : 630nm~680nm
Output : 40mW ±20%
Data Signal
Power


Strawberry&Cream System Block Diagram
Touch ModuleSLT-TP05-RS232B
Touch TFT-LCD 800 x 480 Pixel
KEY & LED
USB/UART
CPU (EAGLE)
IRF510S
PDD0-208NHS
Probe
Inch Loss Paddle
Apllication1
Apllication2
Speaker
Main Board
Interface PCB CPU(TG471)

11.4. Hardware

11.4.1 Laser

Operational rules to provide a safe environment of operation for the laser and other safety rules have been developed for using the Laser Lipo Ltd Strawberry and Strawberry and Cream models at "The Strawberry Clinic" which is co-located with their facility.

These rules identify the potential hazards and control measures used.

Laser Lipo Ltd appreciates that such rules have to be developed for each facility having due regard to the environment of use and is committed to providing appropriate training either directly or through their distributors to potential users to help them use the product safely.

11.4.2. LCD Display

Details of the touch screen display used follow, however we must stress these are confidential to the manufacturer or the component.

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(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

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(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

11.4.3. Subject Contact

Part Name	Details	Type of Subject Contact	Material
Enclosure for control unit	see section 11.1.2	The clinician touches the display for a few seconds	thermoplastic elastomer
strap	see section 11.1.15	The straps are pulled taught around the clients body and are kept on for the duration of the treatment time	Nylon
paddle	see section 11.1.7	Paddles are placed against the selected fatty area, pressed against the skin and held in place with Velcro straps.	thermoplastic elastomer
Cluster probe	see section **Error! Reference source not found.**	Cluster Probes are placed against the selected fatty area, and pressed against the skin.	thermoplastic elastomer
goggles	see section 11.1.16	goggles are kept on the clients face for the duration of the treatment	Plastic: Nylon Lenses: Polycarbonate
LCD Display	see section 0	The clinician touches the display for a few seconds	LCM Module Model AT070TN83 V.1 by InnoLux

11.3. Mechanical Drawings

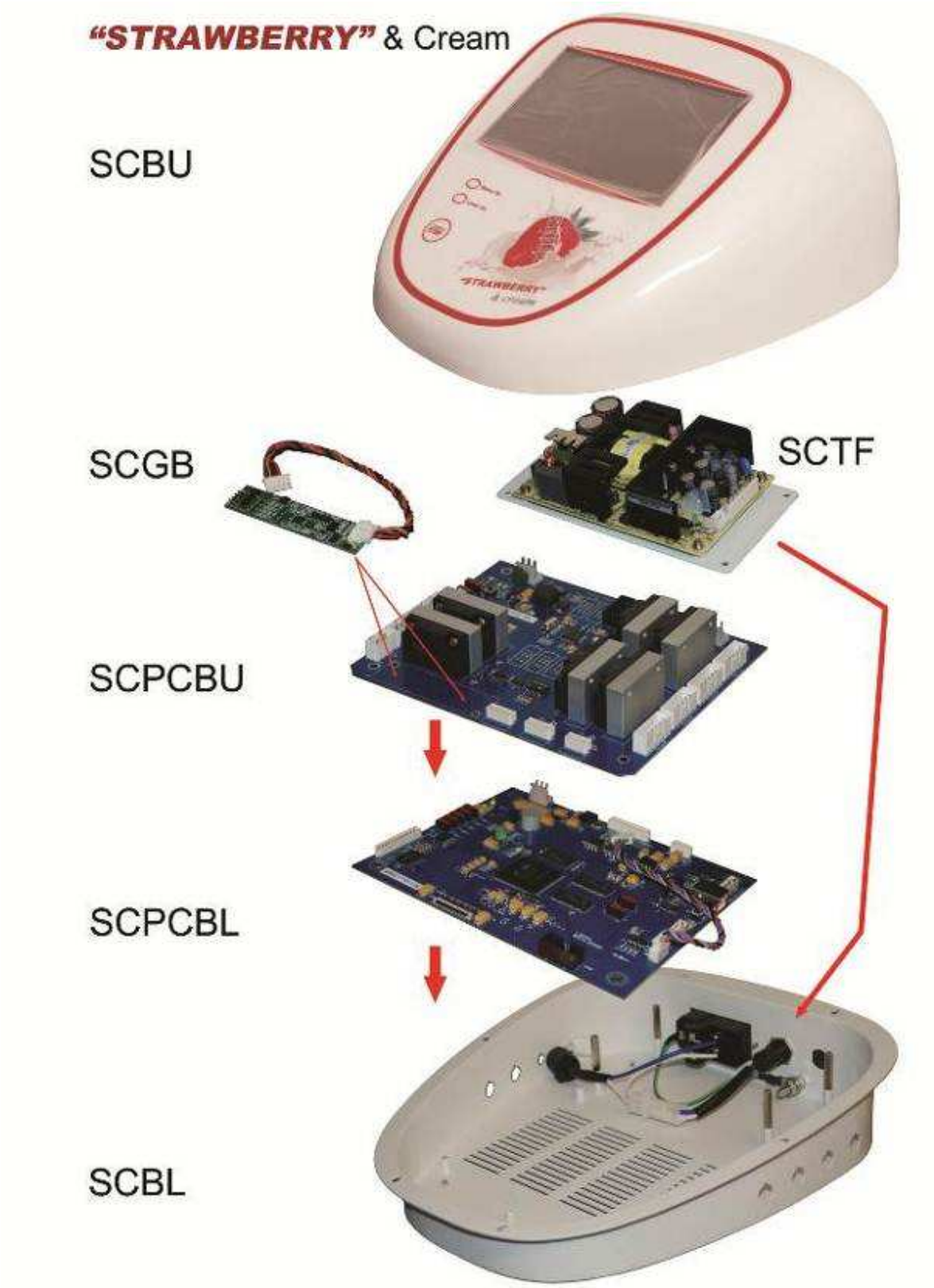
The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system control unit is contained within a plastic enclosure weighing approximately 14 lbs. The dimensions of the unit are approximately 8” x 10” x 12”.

Cut outs and holes are made in the plastic enclosure for the membrane keypad (except for the Strawberry & Cream low level laser system), the emergency stop, the key switch, the leads connections and the air cooling requirements.

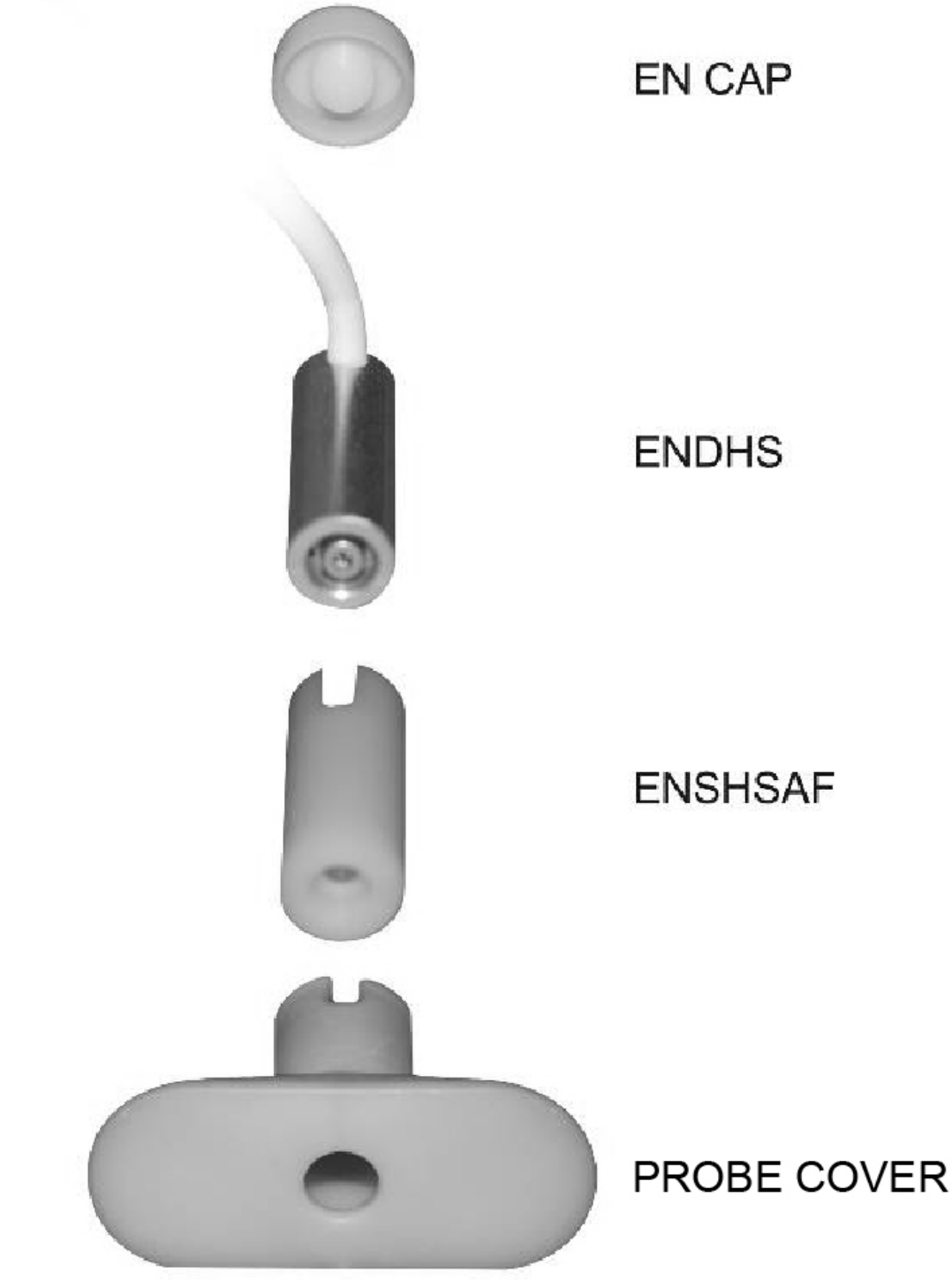
(b)(4) Trade Secret Process - Engineering Drawings

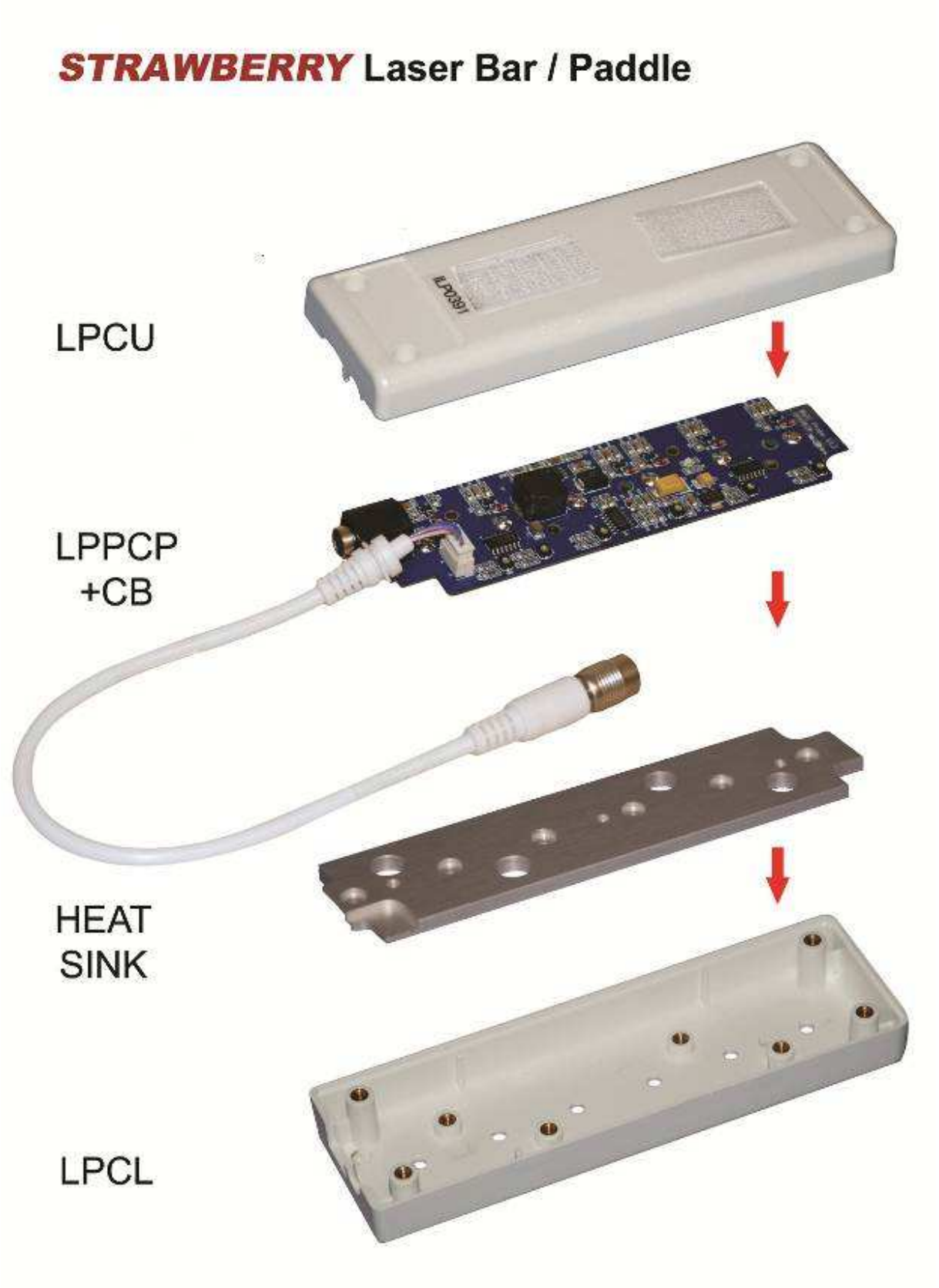
(b)(4) Trade Secret Process - Engineering Drawings

11.4. Photographs of Exploded Assemblies


"STRAWBERRY" & Cream
SCBU
SCGB
SCTF
SCPCBU
SCPCBL
SCBL

STRAWBERRY CLUSTER PROBE




STRAWBERRY Laser Bar / Paddle
LPCU
LPPCP
+CB
HEAT
SINK
LPCL

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

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

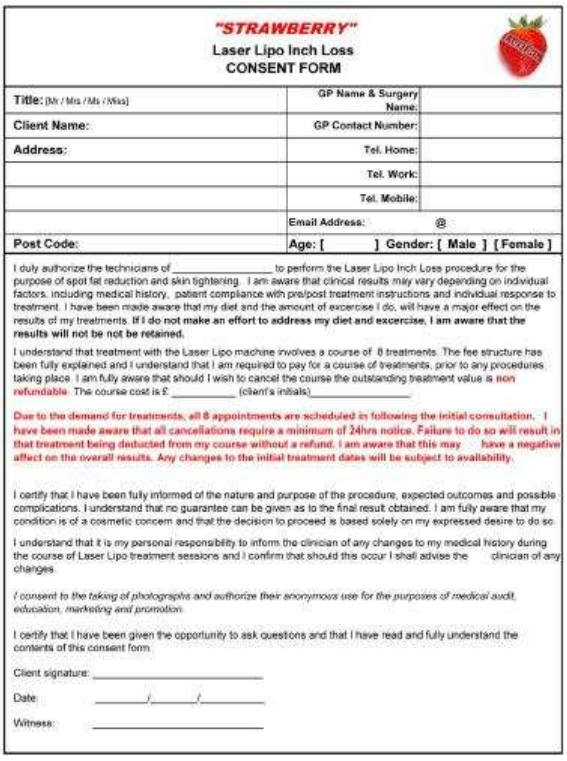
(b)(4) Trade Secret Process - Engineering Drawings

11.6. Training and Documentation

Laser Lipo Ltd is committed to offering training and supports either directly or through their US distributors. Part of this process will be to provide a set of forms to facilitate recording of treatment and results. These forms will be developed in co-operation with distributors and other marketing partners.

We include the type of documentation currently in use in the Europe.

11.6.1. Consent Form and Medical Questionnaire



"STRAWBERRY"
Laser Lipo Inch Loss
CONSENT FORM

Title: (Mr / Mrs / Ms / Miss)	GP Name & Surgery Name:	
Client Name:	GP Contact Number:	
Address:	Tel. Home:	
	Tel. Work:	
	Tel. Mobile:	
	Email Address: @	
Post Code:	Age: [ ] Gender: [Male] [Female]	

I duly authorize the technicians of _____ to perform the Laser Lipo Inch Loss procedure for the purpose of spot fat reduction and skin tightening. I am aware that clinical results may vary depending on individual factors, including medical history, patient compliance with pre/post treatment instructions and individual response to treatment. I have been made aware that my diet and the amount of excercise I do, will have a major effect on the results of my treatments. **If I do not make an effort to address my diet and excercise, I am aware that the results will not be not be retained.**

I understand that treatment with the Laser Lipo machine involves a course of 8 treatments. The fee structure has been fully explained and I understand that I am required to pay for a course of treatments, prior to any procedures taking place. I am fully aware that should I wish to cancel the course the outstanding treatment value is non refundable. The course cost is £ _____ (client's initials)_____

Due to the demand for treatments, all 8 appointments are scheduled in following the initial consultation. I have been made aware that all cancellations require a minimum of 24hrs notice. Failure to do so will result in that treatment being deducted from my course without a refund. I am aware that this may have a negative affect on the overall results. Any changes to the initial treatment dates will be subject to availability.

I certify that I have been fully informed of the nature and purpose of the procedure, expected outcomes and possible complications. I understand that no guarantee can be given as to the final result obtained. I am fully aware that my condition is of a cosmetic concern and that the decision to proceed is based solely on my expressed desire to do so.

I understand that it is my personal responsibility to inform the clinician of any changes to my medical history during the course of Laser Lipo treatment sessions and I confirm that should this occur I shall advise the clinician of any changes.

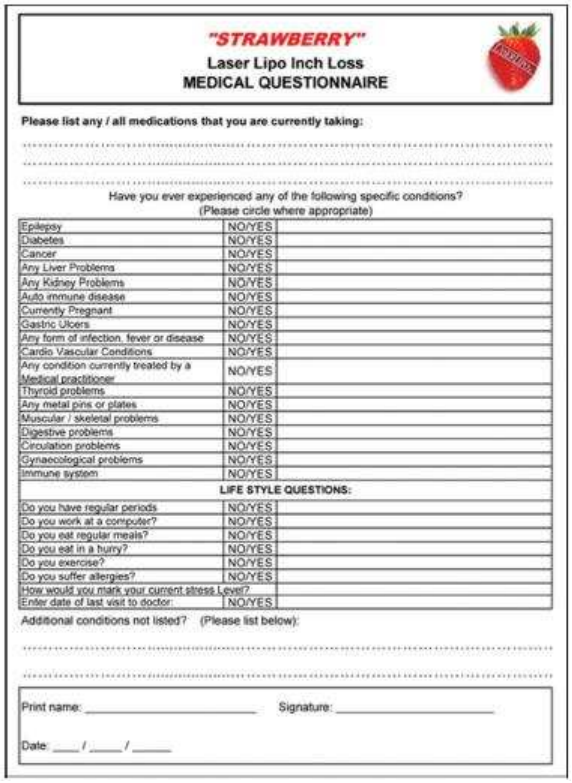
I consent to the taking of photographs and authorize their anonymous use for the purposes of medical audit, education, marketing and promotion.

I certify that I have been given the opportunity to ask questions and that I have read and fully understand the contents of this consent form.

Client signature: _____

Date: _____/_____/_____

Witness: _____



"STRAWBERRY"
Laser Lipo Inch Loss
MEDICAL QUESTIONNAIRE

Please list any / all medications that you are currently taking:

.....

.....

.....

Have you ever experienced any of the following specific conditions?
(Please circle where appropriate)

Epilepsy	NO/YES	
Diabetes	NO/YES	
Cancer	NO/YES	
Any Liver Problems	NO/YES	
Any Kidney Problems	NO/YES	
Auto immune disease	NO/YES	
Currently Pregnant	NO/YES	
Gastric Ulcers	NO/YES	
Any form of infection, fever or disease	NO/YES	
Cardio Vascular Conditions	NO/YES	
Any condition currently treated by a Medical practitioner	NO/YES	
Thyroid problems	NO/YES	
Any metal pins or plates	NO/YES	
Muscular / skeletal problems	NO/YES	
Digestive problems	NO/YES	
Circulation problems	NO/YES	
Gynaecological problems	NO/YES	
Immune system	NO/YES	
LIFE STYLE QUESTIONS:		
Do you have regular periods	NO/YES	
Do you work at a computer?	NO/YES	
Do you eat regular meals?	NO/YES	
Do you eat in a hurry?	NO/YES	
Do you exercise?	NO/YES	
Do you suffer allergies?	NO/YES	
How would you mark your current stress Level?		
Enter date of last visit to doctor:	NO/YES	

Additional conditions not listed? (Please list below):

.....

.....

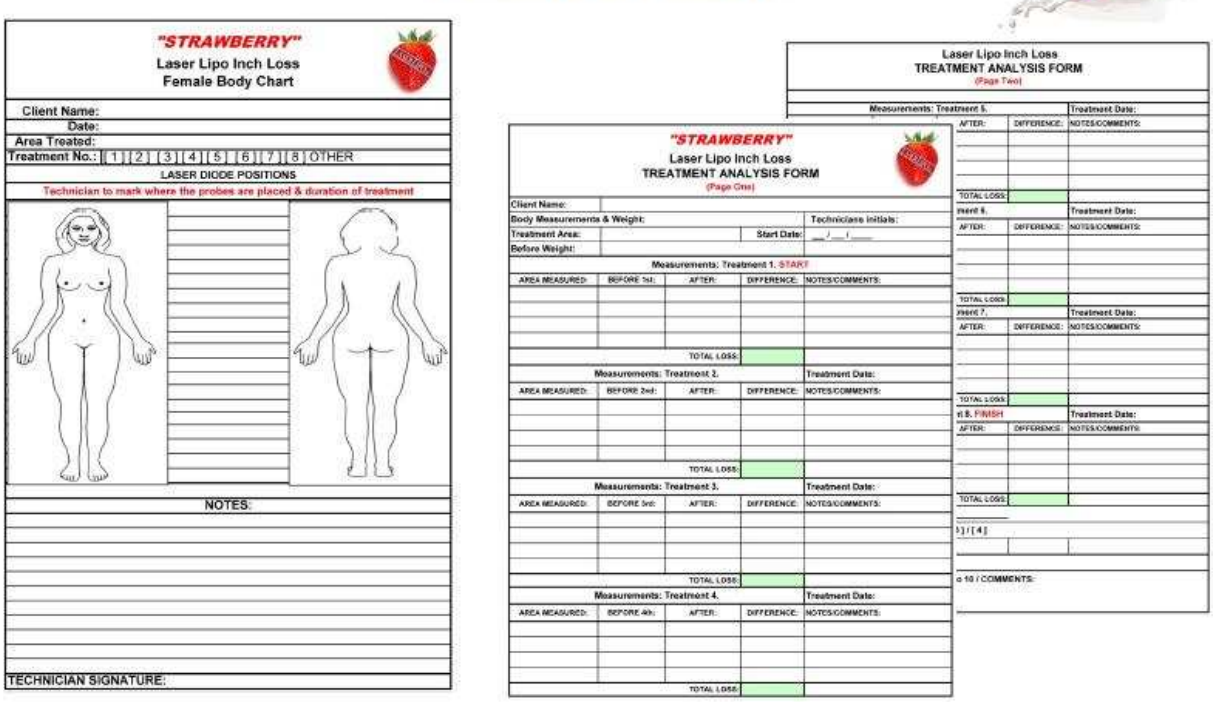
Print name: _____ Signature: _____

Date: ____ / ____ / _____

11.6.2. Treatment Forms

Inch Loss paper work

Treatment forms



"STRAWBERRY"
Laser Lipo Inch Loss
Female Body Chart

Client Name:
Date:
Area Treated:
Treatment No.: [1] [2] [3] [4] [5] [6] [7] [8] OTHER
LASER DIODE POSITIONS
Technician to mark where the probes are placed & duration of treatment

NOTES:

TECHNICIAN SIGNATURE:

"STRAWBERRY"
Laser Lipo Inch Loss
TREATMENT ANALYSIS FORM
(Page One)

Client Name:
Body Measurements & Weight:
Technicians Initials:
Treatment Area:
Start Date:
Before Weight:

Measurements: Treatment 1. START

AREA MEASURED:	BEFORE 1st:	AFTER:	DIFFERENCE:	NOTES/COMMENTS:
		TOTAL LOSS:		

Measurements: Treatment 2. Treatment Date:

AREA MEASURED:	BEFORE 2nd:	AFTER:	DIFFERENCE:	NOTES/COMMENTS:
		TOTAL LOSS:		

Measurements: Treatment 3. Treatment Date:

AREA MEASURED:	BEFORE 3rd:	AFTER:	DIFFERENCE:	NOTES/COMMENTS:
		TOTAL LOSS:		

Measurements: Treatment 4. Treatment Date:

AREA MEASURED:	BEFORE 4th:	AFTER:	DIFFERENCE:	NOTES/COMMENTS:
		TOTAL LOSS:		

Laser Lipo Inch Loss
TREATMENT ANALYSIS FORM
(Page Two)

Measurements: Treatment 5. Treatment Date:

AFTER:	DIFFERENCE:	NOTES/COMMENTS:
TOTAL LOSS:		

ment 6. Treatment Date:

AFTER:	DIFFERENCE:	NOTES/COMMENTS:
TOTAL LOSS:		

ment 7. Treatment Date:

AFTER:	DIFFERENCE:	NOTES/COMMENTS:
TOTAL LOSS:		

nt 8. FINISH Treatment Date:

AFTER:	DIFFERENCE:	NOTES/COMMENTS:
TOTAL LOSS:		

s) / [4]

e 10 / COMMENTS:

12. Substantial Equivalence Discussion

SECTION 12 TABLE OF CONTENTS

12.1. Substantial Equivalence Summary

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system are substantially equivalent in design, use and materials to the:

Chromogenex Technologies Ltd I-Lipo System – K111501

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system are made of the same materials as the Chromogenex Technologies Ltd I-Lipo System – K111501.

- thermoplastic control unit enclosure
    - proprietary components and assemblies used within the unit
- thermoplastic paddles and cluster probes
- nylon covered "velcro" fixed straps
- nylon/polycarbonate goggles

Both the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd i-Lipo System:

- use laser diodes
    - of approximately 660 nm wavelength, and
    - Up to 50 mW output
- incorporated into
    - multiple multi-diodes "paddles" attached to the patient with special straps
      Strawberry 4 to 10 paddles with 6 diodes each
      i-Lipo 4 pads (paddles) with 9 diodes each
    - and two cluster probes with one diode each
- have a similar control unit
    - lcd patient display
    - membrane key pad inputs
        - incorporated into display as a touch screen for strawberry and cream
    - microprocessor controlled through software
    - multi-range power supply (EU and US voltages and frequencies)
- have a similar range of connecting cables
- have the same laser protection goggles
    - different name printed on outside of frame

The key parts of the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd i-Lipo system are compared photographically in section 12.4. The systems compared in section 12.4 are both the European Systems however the US labeling for the Laser Lipo systems from Section 13 has been used.

The Laser Lipo Ltd Strawberry low level laser system, Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd I-Lipo System have the same intended use achieved through the same technology, are assembled from similar components made from similar materials, have similar user input and output interfaces and have similar features.

All systems use laser emitting diodes of similar wavelengths and powers: the Laser Lipo systems have the potential to use more paddles but with less diodes in each paddle. All systems have two cluster probes with a single laser diode in each. In all systems the paddles and cluster probes are secured to the subject with nylon encased rubber straps secured with "velcro".

All control units have plastic enclosures, discrete power supply, microprocessor controlled electronics, controls, alarms and similar control software.

Laser Lipo Ltd concluded that the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system are substantially equivalent to the Chromogenex Technologies Ltd I-Lipo System, K111501.

12.2. Tabular Comparison of Technical Specifications

Feature	Laser Lipo Strawberry Subject Device	Chromogenex i-Lipo Predicate Device K111501
Electrical Requirements: voltage frequency fuse rating Photographs in the user manual section 12.4.10	 100 – 240v 50 – 60 Hz 1A quick-blow fuse	 120 and 240 volt settings 60 and 50 Hz respectively 5A ceramic fuse
Laser Output: wavelength output *paddles laser diodes per paddle Photographs in section 12.4.2 probes laser diodes per probe Photographs in section 12.4.3 Laser class Laser Diode	 660 ± 15 nm Up to 62 x 40 mW (± 15%) 4 , 6, 8 or 10 6 2 1 IIIb GaAlAs	 650 – 690 nm up to 38 x 50 mW 4 9 2 1 IIIb
Physical Dimensions: control unit dimensions control unit weight Photographs in section 12.4.1	 275 x 185 x 315 mm 6 kg	 320 x 460 x 440 mm 10 kg
Environmental Conditions: Temperature Humidity IP rating Storage temperature Storage humidity Photographs in section 12.4.10	 50 -90°F (10 – 32 °C) 50 -90°F (10 – 32 °C)	 10 – 30 °C below 75% RH IPX0 5 – 30 °C 35 – 65% RH
Safety Features: Prevention of unauthorized use "Emergency" Stop Photographs in section 12.4.1	 Key switch "Stop" button on front panel	 Interlock "Stop" button on front panel

*Laser Lipo uses the term paddle, where i-lipo uses the term pad for the device that comes in to contact with the body.

Feature	Laser Lipo Strawberry Subject Device	Chromogenex i-Lipo Predicate Device K111501
Indications for Use Statement Strawberry, see Section 4 FDA Database K111501	The Low level Laser model Strawberry and Strawberry and Cream can be used for the Non-invasive aesthetic treatment for the temporary reduction in waist circumference.	The Chromogenex Technologies Limited i-lipo Tm Low Level Laser System is indicated for Non-invasive aesthetic treatment for the temporary reduction in Circumference of the waist.

12.3. Tabular Comparison of Features

	Subject Device	Subject Device	Predicate Device
	Strawberry	Strawberry & Cream	I-Lipo
510(k)	THIS 510(k)	THIS 510(k)	K111501
Intended use	Temporary reduction in waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.	same	same
Enclosure	Plastic	same	same
Display	LCD	same	same
Laser type	Class 3b	same	same
Membrane Keypad	yes	touch screen	same as Strawberry
Electronic technology	yes	same	same
fuses	provided	same	same
control electronics	yes	same	same
emergency stop	provided	same	same
key switch	provided	same	same
Speaker	provided	same	same
adjustment	Keypad	touchscreen interface	same as Strawberry
power supply	100-240 v ac 50-60 Hz	same	similar 240 v ac 50 Hz 120 v ac 60 Hz
transformer	provided	same	same
Energy source	Laser Diode from 658 nm	same	same
Energy output	up to 50± mW	same	Same up to 50 mW
cooling requirements	Air cooled	same	same
paddle size	15.2 x 4.7 cm	same	similar 15 x 9.6 cm
Cluster probe size	6 x 2.4 x 4.3cm	same	similar 2.7 x 3.6 x 2.6 cm
Environment Requirements	10°C to 30°C Non-condensing humidity below 75% RH	same	same

12.4. Detailed Comparison to Predicate Devices

12.4.1. Control Unit

Figure 12-1 - Strawberry & Cream Low Level Laser Control Unit

Figure 12-2 - I-lipo Control Unit

Figure 12-3 - Strawberry & Cream Low Level Laser Control Unit back side

Figure 12-4 - I-lipo Control Unit back side

Figure 12-5 - Strawberry & Cream Low Level Laser Control Unit underneath

Figure 12-6 - I-lipo Control Unit underneath

12.4.2. Paddles

Figure 12-7 – Strawberry/Strawberry and Cream paddles

Figure 12-8 - I-lipo paddles

12.4.3. Cluster probes

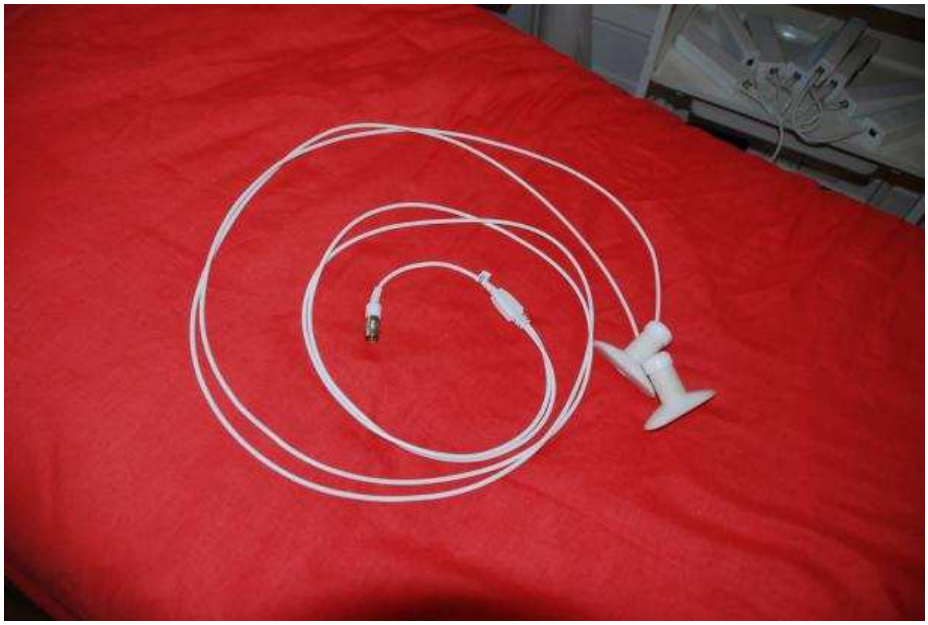


Figure 12-9 – Strawberry/Strawberry and Cream cluster probes

Figure 12-10 - I-lipo cluster probes

12.4.4. Paddle lead

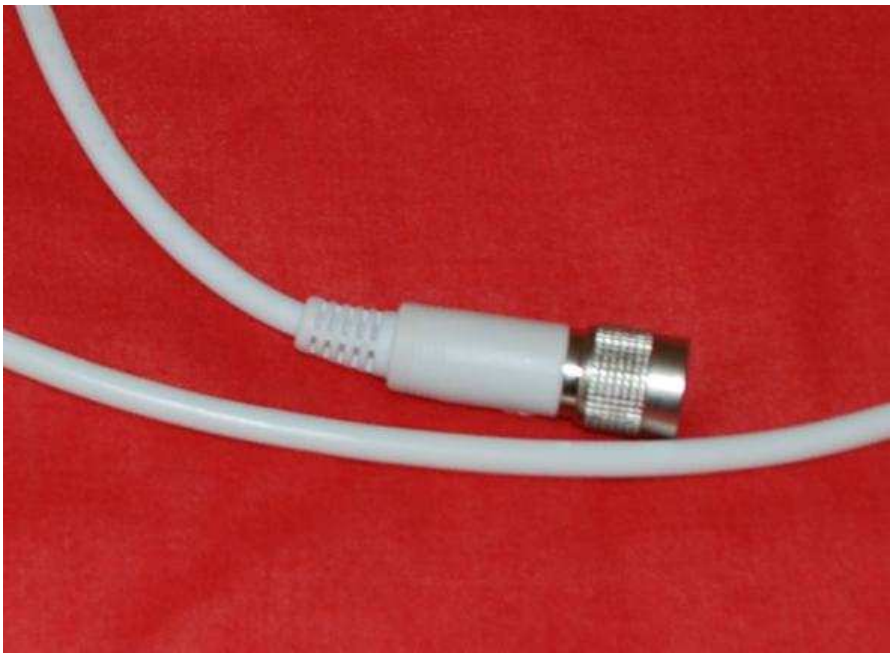


Figure 12-11 – Strawberry/Strawberry and Cream paddle lead

Figure 12-12 - I-lipo paddle lead

12.4.5. Cluster probe lead

Figure 12-13 – Strawberry/Strawberry and Cream cluster probe lead

Figure 12-14 - I-lipo cluster probe lead

12.4.6. Straps

Figure 12-16 – Strawberry/Strawberry and Cream straps

Figure 12-15 - I-lipo straps

12.4.7. Goggles

The goggles we have shown below are exactly the same model from the same supplier as those used by Laser Lipo Ltd. They have a different name printed on the frame.

Figure 12-17 - Goggles

12.4.8. Display

Figure 12-18 - Displays: Strawberry (left) and Strawberry and Cream (right)

Figure 12-19 - i-Lipo Display

12.4.9. Treatment

Figure 12-20 Strawberry (left) and Strawberry and Cream (right) treatment mode displays

Figure 12-21 i-Lipo treatment mode display

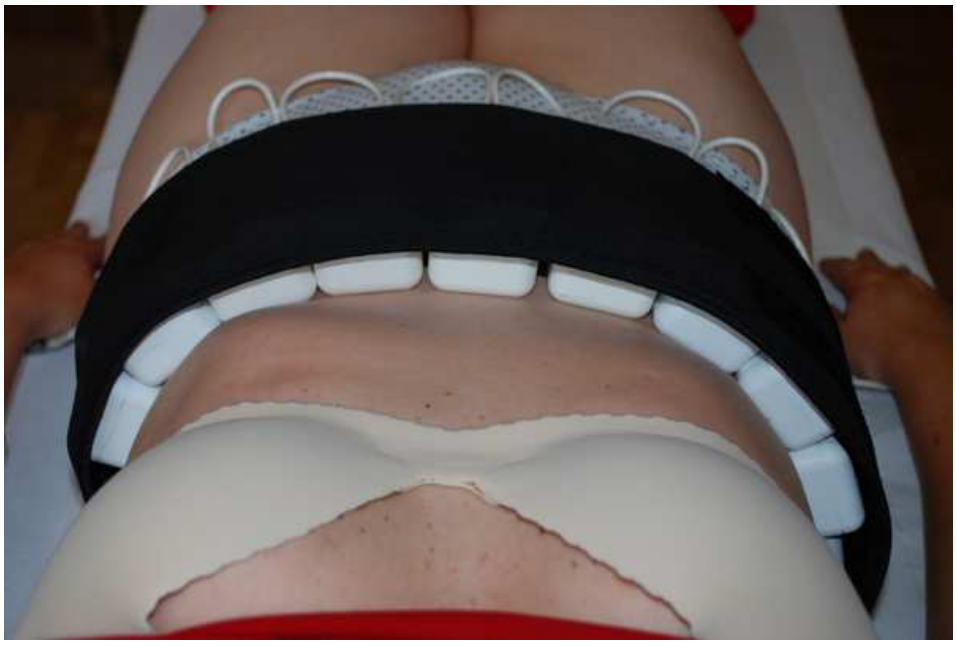


Figure 12-22 - Strawberry Abdomen treatment

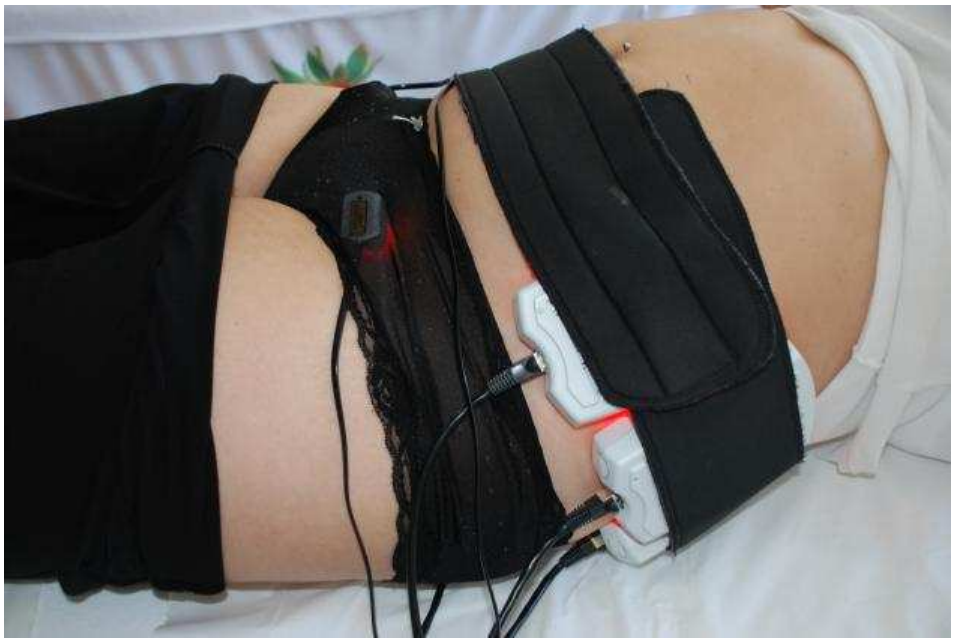


Figure 12-23 - I-lipo Abdomen treatment

12.4.10. User manual

Left hand side: Laser Lipo Ltd
Strawberry and Strawberry Cream
Low level Laser Systems

User Manual

For the

- Strawberry low level laser system model ILO, and,
- Strawberry & Cream low level laser system model SC

"STRAWBERRY" Model

"STRAWBERRY" & Cream Model

Right hand side: Chromogenex
i-Lipo K111501

ilipo

User Manual. *(Models: A00-1184 & A00-1200)*

CE
Low Voltage Directive 2006/95/EC

USER MANUAL INDEX

lipo chromogenex

Contents

5 Precautions

- Suitable protective eye-wear should be used at all times when the Low level Laser model Strawberry and Strawberry and Cream is in use
  - suitable goggles are supplied with the Low level Laser model Strawberry and Strawberry and Cream
  - Suitable "over-goggles" are available for those who wear prescription glasses.
- Keep the spare key secure to prevent unauthorized use
- Remove the operating key and store securely when not in use
- Access to and viewing of the treatment area should be limited while the laser is in operation to those wearing suitable protective eye-wear.
- Always check the device and leads for damage before use and if unsure consult a qualified electrician.

ilipo chromogenex

1 Safety Warnings.

The Chromogenex™ iLipo™ is a low level laser system intended to be used for body contouring.

Personnel operating and maintaining the iLipo™ system should be familiar with the safety information provided in this section.

Any laser light emitting device can cause injury if used improperly. Use of controls, adjustments or the performance of procedures other than those specified herein may result in hazardous exposure to light radiation.

No attempt should be made to operate the unit until the User Manual has been read and fully understood. In addition, a clear understanding of the biological effects of the interaction of laser light with tissue should be prerequisite to the use of this system.

When not in use the iLipo™ should be protected from unqualified use by removal of the key from the keyswitch.

IT IS STRONGLY RECOMMENDED THAT ALL OPERATORS OF THE iLipo™ ATTEND THE SUPPLIERS' APPROVED TRAINING COURSE PRIOR TO THE USE OF THIS SYSTEM.

FURTHER INFORMATION ON CHROMOGENEX™' PRODUCTS CAN BE VIEWED AT: -

http//: www.chromogenex.com

4 Warnings

The only adverse warning is that goggles must be worn throughout the duration of the treatment. As long as protocols are followed there is no danger.

Exposure of a class 3b laser directly to the eye can cause damage to the retina. This is the only Warning.

The following Laser Warning Signs are included with the Low level Laser model Strawberry and Strawberry and Cream:

ilipo chromogenex

1.1 Optical Safety

- Clearly identify the treatment room.
- The area around a laser light source must be secure to protect other persons while treatment is in progress. Entry must be restricted while the system is in use.
- Allow access to the treatment room only to personnel essential to the procedure and well trained in the required safety procedures.
- Ensure that all treatment room personnel are familiar with the system controls and know how to shut it down instantly.
- Appropriate protective eyewear must be worn by everyone within the controlled area whenever there is a risk of exposure to the light radiation.
- Never direct the light output at anything other than the intended treatment site, especially at reflective objects such as metal surgical instruments.
- Never look directly into the light emitted from the treatment pads or lymphatic stimulator probes even when wearing protective eyewear.

WARNING

IT IS THE RESPONSIBILTY OF THE USER TO ENSURE THAT THE PATIENTS EYES ARE PROTECTED DURING TREATMENT

Energy Output

The maximum energy output can be up to 38 x 50mW

Electromagnetic Compatibility

The Laser Lipo 'Strawberry' and 'Strawberry' & Cream systems Have been independently tested by BWS testing laboratory to Meet the following requirements.

Immunity to EN60601-1-2

- EN6100-3-2: Mains Harmonics
- EN6100-3-3: Voltage Fluctuations
- EN6100-4-2: Electrostatic Discharge
- EN6100-4-3: Radiated Immunity
- EN6100-4-4: Electrical fast transients
- EN6100-4-5: Surge Immunity
- EN6100-4-6: Conducted RF
- EN6100-4-11:Voltage Interuption

Emission to EN60601-1-2

- EN55011 Class B Radiated Emissions
- EN55011 Class B Conducted Emissions

The above shows that the systems have undergone vigorous testing to show the protection levels maintainable against harmful interference when the equipment is operated in a commercial environment.

Please contact Laser Lipo Limited directly if you require further guidance.

ilipo chromogenex

1.2 Electromagnetic Compatibility

The iLipo™ has been tested by an independent, accredited testing laboratory and found to meet the requirements of:

Immunity to EN60601-1-2

- EN 61000-3-2: Harmonic Distortion
- EN 61000-3-3: Voltage Fluctuations and Flicker
- EN 61000-4-2: Electrostatic Discharge (ESD)
- EN 61000-4-3: Radiated Immunity
- EN 61000-4-4: Fast Transients
- EN 61000-4-5: High Voltage (HV) Surges
- EN 61000-4-6: Conducted RF
- EN 61000-4-11: Voltage Interruption

Emission to EN60601-1-2

- EN55011 Class B Radiated Emissions
- EN55011 Class B Conducted Emissions

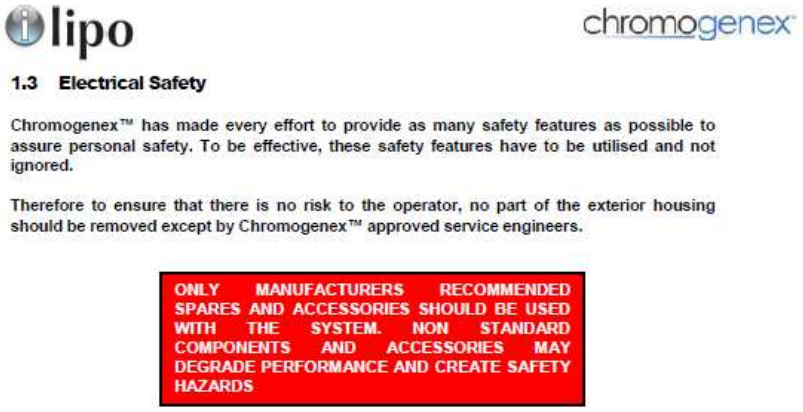
These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. Like all similar equipment, this product generates uses and can radiate radio frequency energy, which, if not installed and used in accordance with the User Manual, may cause interference to other equipment. If in doubt about possible interference to other equipment, please contact your distributor or Chromogenex™ direct for guidance.

Electrical Safety

The Laser Lipo 'Strawberry' and 'Strawberry' & Cream systems Has undergone rigorous testing to prove the safety and efficacy of the machines and are accredited to 60601-1-6

Laser Lipo Limited are proud of their accreditations and ensure that the best safety features are provided.

To ensure no risk to the operator the exterior housing should only be removed by a Laser Lipo approved service engineer.


lipo

chromogenex

1.3 Electrical Safety

Chromogenex™ has made every effort to provide as many safety features as possible to assure personal safety. To be effective, these safety features have to be utilised and not ignored.

Therefore to ensure that there is no risk to the operator, no part of the exterior housing should be removed except by Chromogenex™ approved service engineers.

ONLY MANUFACTURERS RECOMMENDED SPARES AND ACCESSORIES SHOULD BE USED WITH THE SYSTEM. NON STANDARD COMPONENTS AND ACCESSORIES MAY DEGRADE PERFORMANCE AND CREATE SAFETY HAZARDS

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7.5 Laser Machine Symbols and Specification

Symbols / Labels used on the Strawberry machine.	
Symbol	Description:
	Manufacturer date represented as YYYY-MM
	Type BF applied parts – provides degree of electrical protection against electric shock with isolated or floating applied parts
	Caution – there are specific warnings or precautions associated with the device
	Consult Operating Instructions

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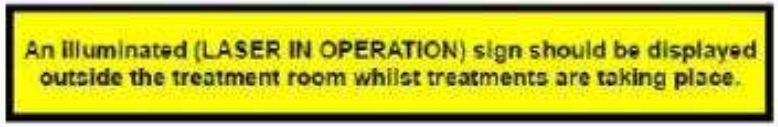
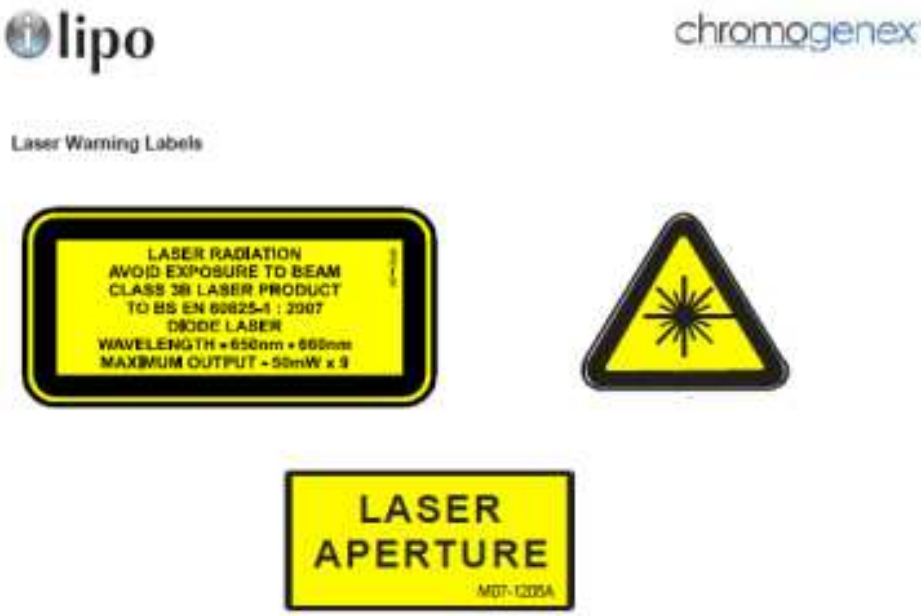
1.4 Labelling

Symbols Used

SYMBOL	DESCRIPTION	LOCATION
	Protective Earth (ground).	Internal
	IEC 471-5007. On (power: connection to the mains).	External – Top Moulding
	Off (only for part of equipment).	External – Top Moulding
	IEC 878-02-02. Type B Applied Part.	External – Manufacturer Label
	IEC 417-5016. Fuse Location.	External – Manufacturer Label
	IEC 417-5032. Alternating current.	External – Manufacturer Label
	IEC 348. Attention, consult accompanying documents.	External – Manufacturer Label
	IEC 471-5007. On (power: connection to the mains).	External – Rear panel
	IEC 471-5008. Off (power: disconnection from the mains.	External – Rear panel
T5H500V	Fuse Type. Timed 5 Amp ceramic fuse.	External – Manufacturer Label
	IEC 878-03-04. Non-ionising radiation	User Manual
	EN 50419. Separate collection for safe disposal.	External – Rear Panel
	**Emergency Stop** The Emergency Stop is the red button on the front of the iLipo™. When pressed it immediately disables the system. This button should be depressed only in the event of an emergency. The system can then be reset by rotating the button in the direction of the arrows.	External – Top Moulding

7.4 Laser Warning Signs and Safety





1 Indications for Use

The Low level Laser model Strawberry and Strawberry and Cream can be used for body contouring by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.

7 Understanding Your System

7.1 Laser Theory

The term laser is derived from:

L ight

A mplification by the

S timulated

E mission of

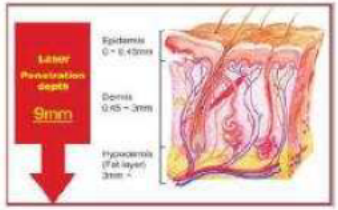
R adiation

The Low level Laser model Strawberry and Strawberry and Cream utilizes a semi-conductor diode to produce a coherent light source at a wavelength of 660nm in the "paddles" which lay on the patient's skin during treatment.

7.2 How It Works

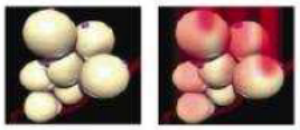
When the laser paddles are switched on, the laser light penetrates the skin and creates a reaction, see the diagram below.

"Strawberry" Penetration Depth



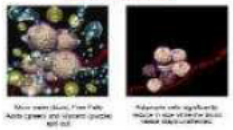
The Laser Beams have an active penetration of 9mm but continue deeper up to 13mm but with little or no effect.

Adipocyte Fat Cells



Adipocyte Fat Cells After Laser Treatment

Adipocyte Fat Cells After Laser Treatment



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2 Introduction

The iLipo™ is a state of the art laser device, intended to be used for lipolysis in order to achieve inch loss and body contouring. The system emits low levels of laser energy (wavelength 650nm - 660nm) to predetermined target sites resulting in disruption of fat cell membranes. Triglycerides spill out from the broken cell membranes and are released into the interstitial space where they are slowly transported through the body's natural metabolic functions.

The system is user friendly and utilises a membrane control panel with graphical LCD display and 3 control buttons which are used to scroll through the menus and select various options as detailed later in the manual.

The iLipo™ has been designed with user selectable software, ergonomic lightweight laser treatment pads and lymphatic stimulator probes.

6.2 Assembling Your System

1. Unpack the contents of the cardboard box and check no items are missing
2. Lay the Velcro straps on a table
3. Lay out the laser paddles on the Velcro straps. Make sure the "end paddle" is the last in line; it has only one socket so is easy to identify.
4. Connect the long lead between the front larger socket on the left hand side of the base of the unit and the first paddle
5. Connect the two sets of 5 paddles with the longer lead between paddles 5 and 6.
6. There is only one connection to the last paddle, paddle 10.

7. The 2 single diodes connect with dual lead to one plug. This fits into the second, smaller sockets on the left hand side of the base of the unit.

8. Connect the power lead between the rear of the base of the main unit and a suitable supply.
9. Insert the key into the lock at the rear of the base.
10. Give one final check that everything is securely connected and then if you are ready to power up the system for use, turn on the power switch at the rear of the base.

7 Understanding Your System

7.1 Laser Theory

The term laser is derived from:

L ight

A mplification by the

S timulated

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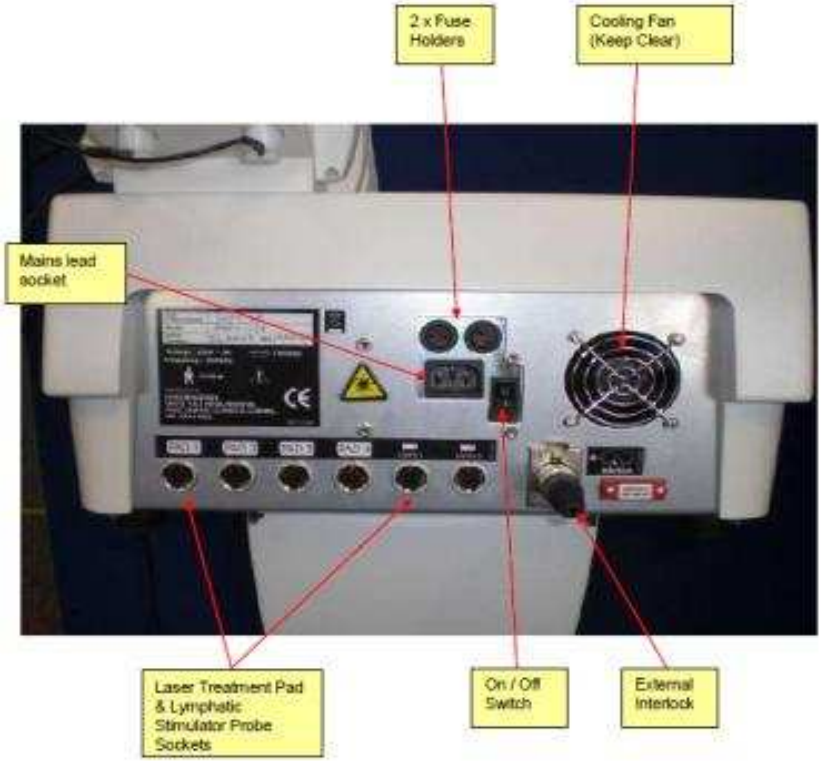
Rear of iLipo™ System



Technical Specifications

STRAWBERRY UNIT:

Power supply:	100—240 V~
Power consumption:	Max 60W Di-
mensions:	275 x 185 X
315 mm Weight:	6 kilos X 315
mm LCD Display	20 x 4 LCD

Red Laser Probe 660nn 40mW Visible

Output tolerance of Laser Diodes	<±15% Stated Probe Label Output Power
Measurement of uncertainty	5%
Increase in measured quantities	0%. Diodes are the main source for potential increases in measured quantities over time. Laser diodes suffer negligible obvious degradation until they fail.
Wavelength	660nm ±15 nm
Power Output	40mW
NOHD	120mm
Beam Divergence	9 x 38 degrees Typ
Laser Class	3B
Lasing Medium	GaAlAs

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2.2 Technical Specifications

Laser Type:	Laser Diode
Wavelength:	650nm - 660nm
Energy Output:	Up to 38 x 50mW
Mains Power Output:	100VA
Laser Treatment Pad Size:	15cm x 9.6cm
Lymphatic Stimulator Probe Size:	50cm x 18cm
Safety:	On board self-diagnostics
Classification:	Electrical Class 1, Type B Applied Part
Dimensions:	32cm x 46cm x 44cm
Weight:	10kg
Cooling Requirements:	Air Cooled
Electrical Requirements:	240V / 5A / 50Hz – *Model A00-1184* 120V / 5A / 60Hz – *Model A00-1200*
Fuses:	5A Ceramic Timed
Mode of Operation:	Continuous
System Status & Fault Diagnostics:	On board computer based self-diagnostics
Ingress Rating:	IPX0
Environmental Requirements:	10°C to 30°C Non-condensing humidities below 75% RH
Equipment Included:	2 x iLipo Keys 1 x User Manual *CD* 1 x Treatment Guidelines *CD* 1 x Mains Lead 4 x Laser Treatment Pads & Cables 2 x Lymphatic Stimulator Probes & Cables 2 x T5H500V Ceramic Fuses 1 x External Interlock 1 x Safety Glasses 10 x Laser Aid Eye Shields 1 x Treatment Pad Waist Belt (116cm) 2 x Treatment Pad Arm Belts (47cm) 2 x Treatment Pad Leg Belts (82cm) iLipo Stand

6.2 Assembling Your System

1. Unpack the contents of the cardboard box and check no items are missing
2. Lay the Velcro straps on a table
3. Lay out the laser paddles on the Velcro straps. Make sure the "end paddle" is the last in line; it has only one socket so is easy to identify.
4. Connect the long lead between the front larger socket on the left hand side of the base of the unit and the first paddle
5. Connect the two sets of 5 paddles with the longer lead between paddles 5 and 6.
6. There is only one connection to the last paddle, paddle 10.

7. The 2 single diodes connect with dual lead to one plug. This fits into the second, smaller sockets on the left hand side of the base of the unit.

8. Connect the power lead between the rear of the base of the main unit and a suitable supply.
9. Insert the key into the lock at the rear of the base.
10. Give one final check that everything is securely connected and then if you are ready to power up the system for use, turn on the power switch at the rear of the base.

7 Understanding Your System

7.1 Laser Theory

The term laser is derived from:

L ight

A mplification by the

S timulated

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3 Transportation and Installation

3.1 Transport Damage

The iLipo™ has been carefully packed and should arrive at its destination in perfect condition. Upon delivery, please check that the external packaging is not damaged. If signs of damage are present, please report them to the shipping carrier and your distributors Customer Service Department within 24 Hrs.

3.2 Environmental Transport & Storage Conditions

The transport and storage conditions for the iLipo™ are as follows:

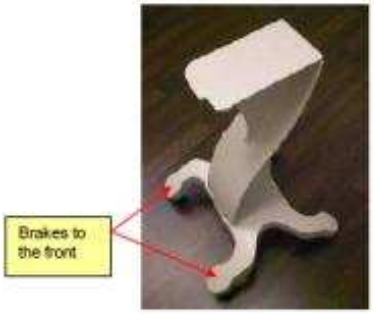
Temperature	+5°C to +40°C
Relative Humidity	35% to 65% Non-Condensing.
Atmospheric Pressure	500 – 1060 hPa

3.3 Installation

Carefully remove the packaging from around the unit and unpack the treatment pads and lymphatic stimulator probes. The iLipo™ is a compact portable system and has been designed for optimum cooling of the internal systems with a vented underside. It should be placed either on a firm surface allowing a passage of air underneath and a distance of approximately 20cm left clear around the unit to allow adequate ventilation or fitted to the iLipo™ stand. *(See Section 3.4)* Fit the laser treatment pads and lymphatic stimulator probes by plugging into the relevant connector sockets at the rear of the unit. Both the treatment pads and probes rest in the holster on the top of the unit when not in use. The system can then be plugged directly into a standard mains socket.

3.4 Fitting the Stand

The iLipo™ stand is fitted with 4 castors, the front 2 with brakes. Before fitting the iLipo™, ensure that the brakes are applied by pushing the lever downwards.



The Laser Lipo Ltd Strawberry and Strawberry and Cream low level laser systems are designed to be placed on a "table-top" and do not have a special stand.
Care must be taken not to strain the paddles main cable.

8 Instructions for Use

8.1 Strawberry Low Level Laser System

1. Set up the system as described in section 6.2
2. Switch on the unit by using key and power switch, see section 6.2
3. The screen will show the default treatment time of 10 minutes. You may use the up and down arrows on the front panel to alter this if desired.
4. The display "MENU>" indicates the menu can be accessed by the right arrow on the front panel. Follow the on-screen instructions to adjust the sound setting and total time.
5. Two indicator lights show that the power is connected and the laser is ready for use.
6. There is a "STOP" button in the middle of the front panel which will stop the unit when pressed at any time.

8.2 Strawberry and Cream Low Level Laser System

1. Set up the system as described in section 6.2
2. Switch on the unit by using key and power switch, see section 6.2
3. Adjust the treatment time using the touch screen, see below:

4. Adjust the alarm settings using the touch screen, see below:

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4 System Operation

4.1 Switch On Procedure

To operate the iLipo™ system, the following procedure must be followed:

1 Connect unit to wall supply and switch ON.

2 Switch mains power switch at the rear of the unit to the I (on) position. (See p.12)

3 Ensure the emergency stop button is released (rotate clockwise). (See p. 11)

4 Insert the key into the keyswitch and turn clockwise into the (•) (on) position.

5 After switch on, the screen will display the iLipo™ logo and run through a self-diagnostics check screen. (See Figures 1 & 2).

6 The software also provides the user with the option of an Initial System Set-Up.(See Section 4.3)

7 After the self diagnostics, the user will be presented with a treatment time selection screen. (See Section 4.2)

Fig.1

Fig.2

8 Instructions for Use

8.1 Strawberry Low Level Laser System

1. Set up the system as described in section 6.2
2. Switch on the unit by using key and power switch, see section 6.2
3. The screen will show the default treatment time of 10 minutes. You may use the up and down arrows on the front panel to alter this if desired.
4. The display "MENU>" indicates the menu can be accessed by the right arrow on the front panel. Follow the on-screen instructions to adjust the sound setting and total time.
5. Two indicator lights show that the power is connected and the laser is ready for use.
6. There is a "STOP" button in the middle of the front panel which will stop the unit when pressed at any time.

8.2 Strawberry and Cream Low Level Laser System

1. Set up the system as described in section 6.2
2. Switch on the unit by using key and power switch, see section 6.2
3. Adjust the treatment time using the touch screen, see below:

4. Adjust the alarm settings using the touch screen, see below:

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4.2 Setting Treatment Time

NOTE: EACH LASER TREATMENT PAD CONTAINS TWO SKIN SENSORS IN THE AREAS SHOWN IN FIG.3. THE iLipo UNIT MUST BE SWITCHED ON BUT NOT ARMED BEFORE THE PLACEMENT OF THE TREATMENT PADS IN ORDER FOR THE SKIN SENSORS TO CALIBRATE CORRECTLY. FAILURE TO DO THIS WILL RESULT IN THE DIODES NOT SWITCHING ON WHEN THE SYSTEM IS ARMED. IF THIS OCCURS, THE TREATMENT PADS MUST BE REMOVED FROM THE BODY AND RETURNED TO THE HOLSTER. THE MACHINE MUST BE SWITCHED OFF AT THE KEYSWITCH AND THEN BACK ON. THE TREATMENT PADS CAN THEN BE REPOSITIONED ON THE BODY BEFORE ARMING THE SYSTEM.

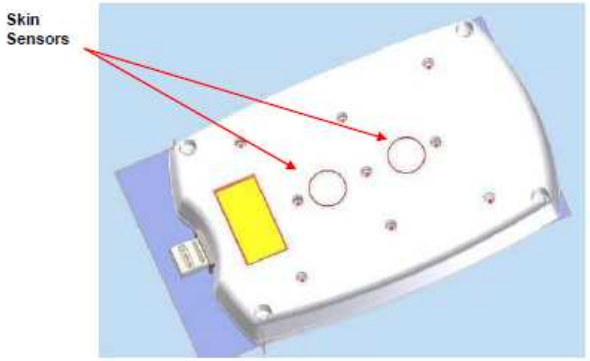

Fig.3

1 Position the laser treatment pads and the lymphatic stimulator (LS) probes as per treatment guidelines.

2 Use the ▲▼ arrows to select the required treatment time. Up to a maximum of 55 minutes. *(Fig.4.)*

Fig.4

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3 Press the ● button to arm the system. An audible alert will then be heard indicating that the iLipo™ is armed. This will be followed by a 2 second delay before treatment commences. The treatment time will then count down to zero which is when the laser pads and LS probes switch off. *(Fig.5.)*

Fig.5.

4 Treatment may be paused at any time by pressing the ● button *(Fig.6.)* and pressing it again to resume. Pressing either of the ▲▼ will terminate the treatment and reset the timer to the selected treatment time. *(Fig.7.)*

Fig.6.

Fig.7.

5 When treatment is complete, turn off the iLipo by turning the key anti-clockwise to the position and removing it from the system.

4.3 Initial System Set – Up & Service Information

The iLipo™ has been designed to be extremely user friendly whilst incorporating the latest technology, to this end; the following options have been made available to the user.
When the system is switched on, an audible 'beep' will be heard which lasts for 3 seconds. During this time, the operator can enter the system Set–Up Menu by holding down both arrow buttons on the control panel membrane at the same time.
NOTE: This option is an initial set–up and is not required each time the iLipo™ is switched on.

The following menu will be displayed: *(Fig.8)*

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- SETTINGS
- SERVICE
- EXIT

Fig.8.

The user can select any of the above options by scrolling up and down using the arrow buttons on the membrane panel. The selections available are as follows:

SETTINGS

- Volume. (User can select volume of the iLipo™ safety buzzer).
- Defaults. Resets factory defaults.
- The user can select either of the above settings by selecting the SAVE & EXIT function and pressing the ENTER button. This will return to the main menu screens as seen in Section 4.2

SERVICE

(In the unlikely event that the iLipo™ develops a fault, the user may be required to provide information from this function to the Service Engineer.)

- Shot Count
  Displays total time in minutes of treatments carried out.
- Temperature
  Displays the temperature inside the treatment pads and main unit.
- Software
  Displays the revision number of the software programmed into the iLipo™.

EXIT

- Selecting Exit will return to the main menu screen as seen in Section 4.2

9 Maintenance

9.1 Laser Servicing and Life

The machine should be serviced every 6 months or if only used infrequently maybe serviced annually

Like any light emitting device, the light output from each laser diode will decrease with time/use. It is important to service the equipment regularly so that compensating adjustments can be made.

Machines are set when new to achieve the specified output using approximately 60% of the maximum capacity; hence this utilization can be increased to compensate for the time-based reduction in light output. Machine life is thus anticipated to be between 3 and 5 years.

Laser Lipo will finalize service arrangements with their US distributors and include in the final manual.

9.3 Cleaning

We advise that after each use the paddles should be cleaned with a "sterile wipe" and that the probes are sterilized.

9.4 Routine Maintenance

There are no consumables needed and no routine maintenance is required.

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5 General Maintenance

5.1 Visual Inspection

The mains, treatment pad and LS probe cables should be inspected for damage and wear and tear on a regular basis.

Do not pull on the cables when removing from the treatment pads and probes, unplug by holding onto the connector.

In the unlikely event of damage to the treatment pads or LS probes, do not attempt to rectify the damage. Contact your Distributor for replacement parts.

5.2 Cleaning and Disinfecting

Before cleaning maintenance is carried out, please ensure the unit is disconnected from the mains supply.

Note that no disassembly of the iLipo™ unit or associated parts is required for cleaning and disinfecting.

The iLipo™ unit itself can be cleaned by dusting over with a clean, dry, soft, lint free cloth **ENSURING THAT NO FLUIDS ARE USED.**

The laser treatment pads and lymphatic stimulator probes should be carefully cleaned with an isopropyl wipe before each treatment and allowed to dry thoroughly before the system is switched on.

The treatment pads and probes are non-critical products as per the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC) Guidelines. Non-critical is defined as an item that comes in contact with intact skin but not with mucous membranes. Therefore cleaning with isopropyl wipes in between each client is all that is required by the APIC.

NOTE: DO NOT SUBMERGE THE TREATMENT PADS OR PROBES IN ANY SOLUTION. This may cause a hazardous condition for the operator and possibly the client and may also cause the system to malfunction.

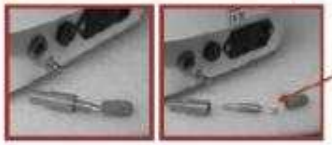
9.5 Changing the Fuses

9.5.1 Equipment Fuse

Grey Fuse unit located at the back of the machine.

PULL out the grey fuse holder from the machine. As shown.

Then holding the fuse assembly, unscrew the cap in an anti-clockwise direction.



Then pull out the fuse. 240v 1AMP.

Once you have replaced the fuse (Spares are supplied with each new machine) Re-assemble the fuse holder and carefully push back into the machine. Be careful of the two copper pins, when putting it back together. Align the component prior to inserting it.

9.5.2 Power Supply Fuse

The power supply fuse is located between the power switch and the power lead socket at the rear of the base unit. Consult a qualified electrician if this fuse has blown.

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5.3 Changing the Fuses

The iLipo™ is fitted with 2 external fuses, which can be easily replaced if required (replacement fuses are supplied). The fuse holders are located at the rear of the unit. (See page 11.)

Using a small flat head screwdriver, undo the fuse holder by unscrewing anticlockwise and remove from the recess as seen in *Figs.1&2*

Fig.1

Fig.2

Pull out the spent fuse from the holder *(Fig.3)* and replace with a new one of the correct rating.

Fig.3

Screw the fuse holder clockwise into the recess and tighten using the flat head screwdriver.

NOTE: The iLipo™ will only accept the following fuses: -

T5AH500V 32mm Ferrule Fuse Time Delay, High Breaking Capacity, Ceramic Body. (Size 6.3 x 32mm).

9.2 Error Messages

"CHECK PADDLE" on Strawberry ILO model LCD Screen only:

1. Turn off machine
2. Disconnect from power supply
3. Check all leads and connections to laser paddles and probes
4. Check laser paddles are connected in correct order
5. Reconnect to power supply
6. Turn on machine

No light or messages on screen when unit is switched on:

1. check power lead is fully inserted at socket on rear of machine
2. check power lead is fully inserted and turned on at wall socket
3. check that the power switch is turned on, the "1" position
4. if the above does not resolve the problem, turn off and disconnect from power supply then check the fuses, see section 9.5.

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6 Fault Diagnostics / Servicing

This section will help the Service Engineer to diagnose faults that may be experienced on the iLipo™. In the unlikely event that any of the following fault codes appear on screen, the user is advised to contact their Service Provider directly quoting the fault code displayed.

FAULT CODES	
F2	BASE OVER TEMPERATURE
F3	TREATMENT PAD OVERTEMPERATURE
F8	EEPROM CORRUPT, COMMUNICATIONS ERROR

NOTE: THER ARE NO USER SERVICABLE PARTS INSIDE THE iLipo™ SYSTEM. SHOULD ANY FAULT ARISE, PLEASE CONTACT YOUR SERVICE PROVIDER.

REMOVAL OF SECURITY SEALS, OPENING THE SYSTEM, OR THE USE OF LIQUIDS ON THE PRODUCT WILL RENDER THE WARRANTY INVALID.

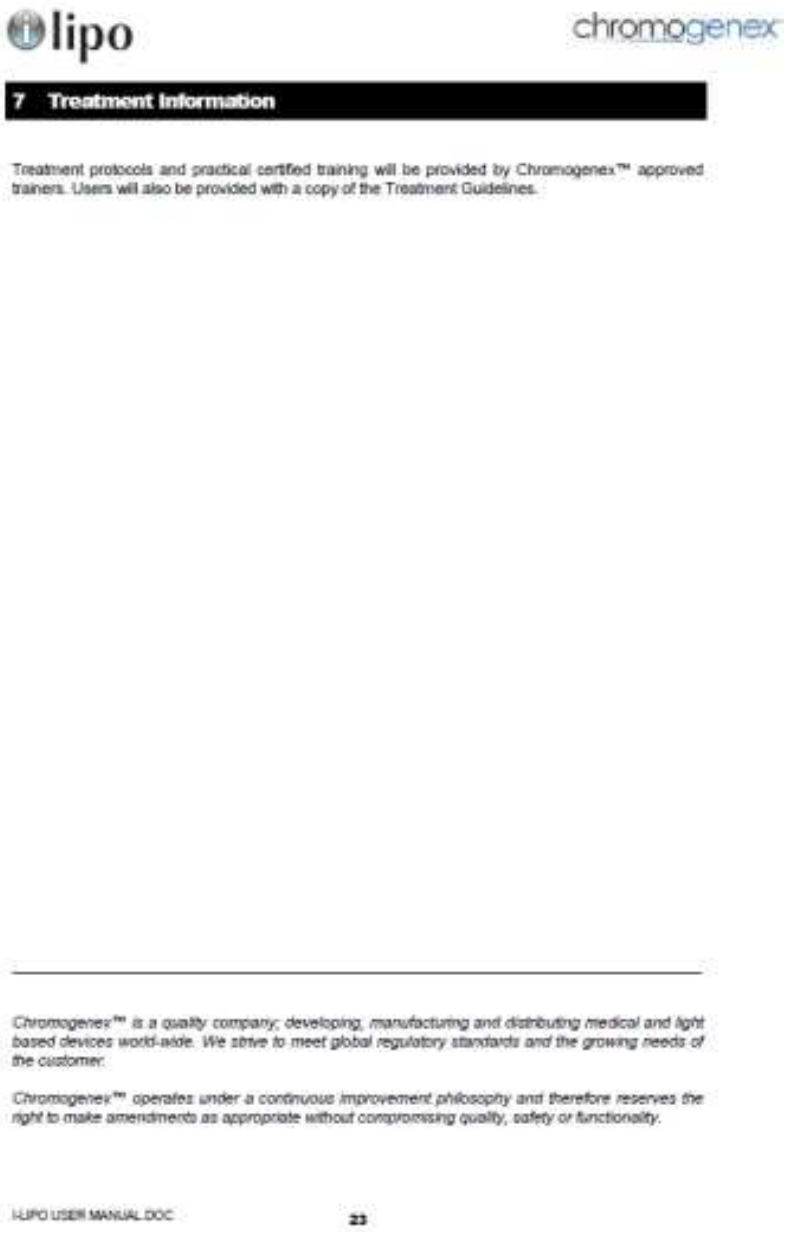
6.1 Safe Disposal

For safe disposal of the unit, please contact your Distributor.

Treatment Information

As part of Laser Lipo Ltd's protocols full practical certified training is provided by Approved 'Strawberry' trainers.

Manufactured by:	Distributed by:
Laser Lipo Ltd Heath House Edenbridge Kent. TN8 6ST. United Kingdom. strawberry-laser.com **2011-11**	



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7 Treatment Information

Treatment protocols and practical certified training will be provided by Chromogenex™ approved trainers. Users will also be provided with a copy of the Treatment Guidelines.

Chromogenex™ is a quality company; developing, manufacturing and distributing medical and light based devices world-wide. We strive to meet global regulatory standards and the growing needs of the customer.

Chromogenex™ operates under a continuous improvement philosophy and therefore reserves the right to make amendments as appropriate without compromising quality, safety or functionality.

I-LIPO USER MANUAL DOC 23

Distributed by:

Manufactured by:

Chromogenex Technologies Ltd. t/a Chromogenex™
Units 1 & 2 Heol Rhosyn,
Parc Dafen,
Llanelli,
Carmarthenshire,
S. Wales, UK.
SA14 8QG.
T: +44 (0) 1554 755444.
F: +44 (0) 1554 755333.
Registered in Wales: Number 2714095

12.4.11. Software

The Laser Lipo Ltd Strawberry low level laser system, Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd I-Lipo System are based on the same FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices and comply the following standards:

- ISO 13485
- ISO 14971
- IEC 62304
- IEC 60601-1-1
- IEC 60601-1-2
- IEC 60601-2-22

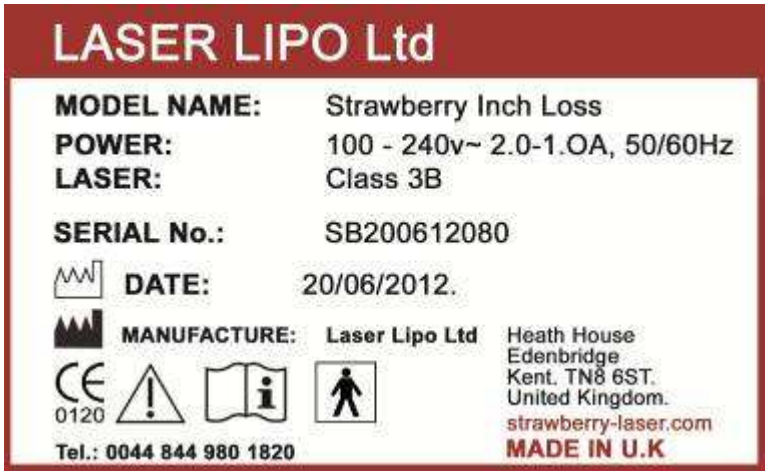
13. Proposed Labeling

SECTION 13 TABLE OF CONTENTS

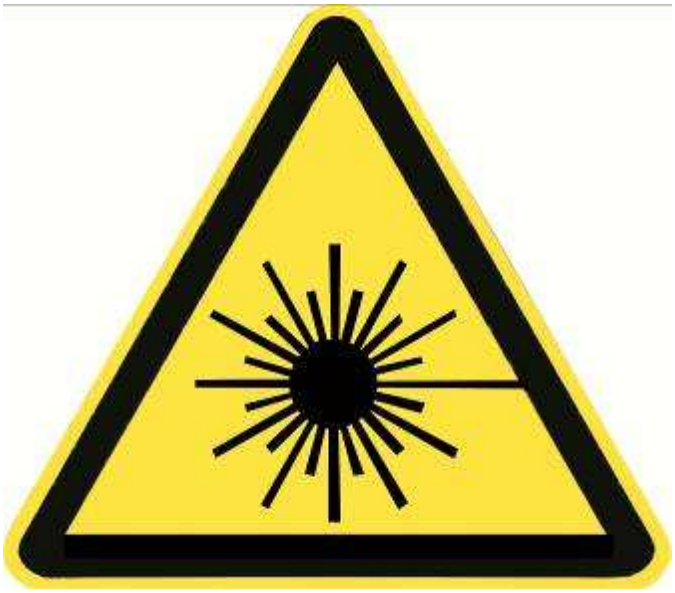
13.1. Draft Labels Attached to the Device

13.1.1. Draft Physical labeling

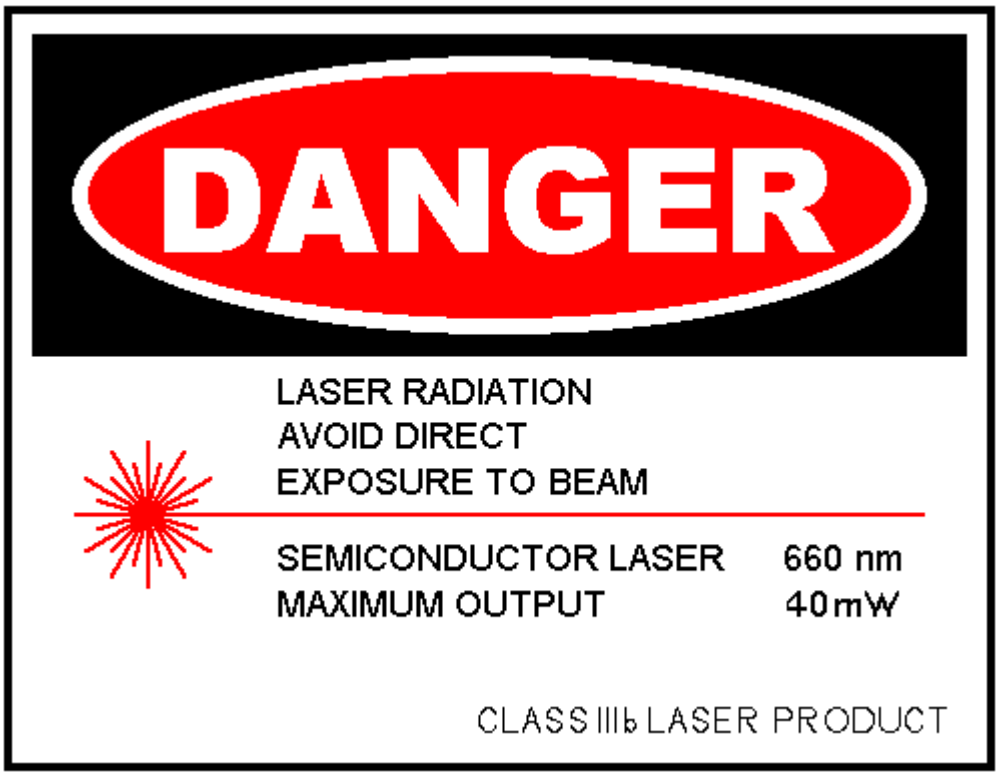
European labeling is shown here which form the draft for US labeling.



Descriptions will be added to EN 980 sysmbols e.g. “date of manufacture”, “manufacturer”, “consult users manual”.



Manufactured by:	Distributed by:
Laser Lipo Ltd Heath House Edenbridge Kent. TN8 6ST. United Kingdom. strawberry-laser.com 2011-11	



New US-style warning labels will be developed.

13.1.2. Laser warning sign for treatment room door

Figure 13-1 - Strawberry Laser warning sign for treatment room door

13.1.3. Draft Labeling in Software

Strawberry and Cream touch-screen version

Figure 13-2 - Strawberry & Cream Display Set time mode

Figure 13-3 - Strawberry & Cream Display Language settings mode

Language options and flags will be amended for the US product e.g. the "Stars and Stripes" will replace the "Union Flag" above "English".

Figure 13-4 - Strawberry & Cream Display Support mode

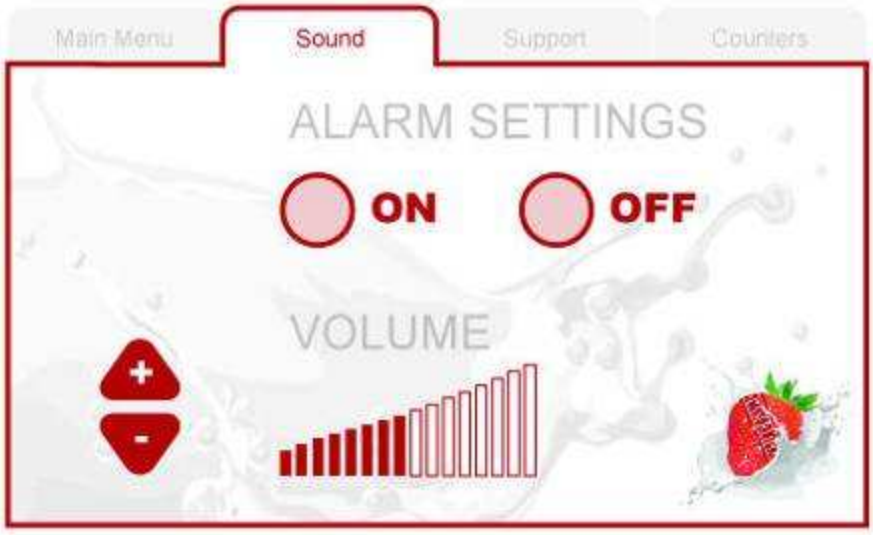


Figure 13-5 - Strawberry & Cream Display Alarm settings mode

Contact details will be amended to US details and/or US distributors once arrangements have been finalized.

13.2. Cardboard Presentation Box

Figure 13-6 – Packaging of the Strawberry unit

Figure 13-7 - Packaging of the Strawberry paddles, probes and leads

Note: photograph is of European paddles showing position of laser warning labels, but European rather than US labels.

13.3. Draft User Manual

User Manual

For the

- Strawberry low level laser system model ILO, and,
- Strawberry & Cream low level laser system model SC

"STRAWBERRY" Model

"STRAWBERRY" & Cream Model

USER MANUAL INDEX

Contents

1 Indications for Use

The Low level Laser model Strawberry and Strawberry and Cream can be used for body contouring by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.

2 Contraindications

The Low level Laser model Strawberry and Strawberry and Cream are contraindicated for use **in the vicinity of:**

- open wounds
- metallic implants
- active implants, such as a "pacemaker" or "implanted defibrillator"

Further, the Low level Laser model Strawberry and Strawberry and Cream are contraindicated for **patients suffering from:**

- epilepsy
- urinary infections
- diabetes
- cancer
- medical edema
- kidney problems
- auto immune disease
- gastric ulcers
- cardiovascular conditions, such as: thrombosis, phlebitis, hypertension, hypotension, heart conditions)
- any other infections, fever or disease

The Low level Laser model Strawberry and Strawberry and Cream are contraindicated for use when **pregnant**.

The Low level Laser model Strawberry and Strawberry and Cream are contraindicated for **minors (under the age of 21).**

3 Storage

The Low level Laser model Strawberry and Strawberry and Cream should be stored securely in a dry place where they will not be exposed to extremes of temperature (less than 50°F or more than 90°F) for prolonged periods.

4 Warnings

The only adverse warning is that goggles must be worn throughout the duration of the treatment. As long as protocols are followed there is no danger.

Exposure of a class 3b laser directly to the eye can cause damage to the retina. This is the only Warning.

The following Laser Warning Signs are included with the Low level Laser model Strawberry and Strawberry and Cream:

An illuminated (LASER IN OPERATION) sign should be displayed outside the treatment room whilst treatments are taking place.

5 Precautions

- Suitable protective eye-wear should be used at all times when the Low level Laser model Strawberry and Strawberry and Cream is in use
  - suitable goggles are supplied with the Low level Laser model Strawberry and Strawberry and Cream
  - Suitable "over-goggles" are available for those who wear prescription glasses.
- Keep the spare key secure to prevent unauthorized use
- Remove the operating key and store securely when not in use
- Access to and viewing of the treatment area should be limited while the laser is in operation to those wearing suitable protective eye-wear.
- Always check the device and leads for damage before use and if unsure consult a qualified electrician.

6 Preparation

6.1 Receiving and Opening

Your
"STRAWBERRY"
Will arrive carefully & safely boxed.

PLEASE KEEP THE BOX

Your machine will need to be serviced and the packaging will keep the machine safe during transport.

The "Strawberry" tm "Strawberry" & Cream" model low level laser system is delivered in a cardboard box. A top tray contains the "paddles", "diodes", "Leads" and other accessories while the main unit is securely packed underneath.

Contents:

- 1 - Strawberry or Strawberry & Cream model low level laser system unit.
- 1 - power lead
- 10 - paddles (9 standard and 1 end paddle)
- 2 - probes
- 10 - connecting leads
- 1 - long lead for first paddle
- 1 - longer lead to connect two sets of paddles
- 8 - short connecting leads
- 2 - Keys
- 2 - Replacement fuses
- 1 - pair of goggles
- 2 - Small straps
- 2 - Medium straps
- 1 - Large strap
- 1 - user manual

6.2 Assembling Your System

1. Unpack the contents of the cardboard box and check no items are missing
2. Lay the Velcro straps on a table
3. Lay out the laser paddles on the Velcro straps. Make sure the "end paddle" is the last in line; it has only one socket so is easy to identify.
4. Connect the long lead between the front larger socket on the left hand side of the base of the unit and the first paddle
5. Connect the two sets of 5 paddles with the longer lead between paddles 5 and 6.
6. There is only one connection to the last paddle, paddle 10.

7. The two diodes connect with dual lead to one plug. This fits into the second, smaller sockets on the left hand side of the base of the unit.

8. Connect the power lead between the rear of the base of the main unit and a suitable supply.
9. Insert the key into the lock at the rear of the base.
10. Give one final check that everything is securely connected and then if you are ready to power up the system for use, turn on the power switch at the rear of the base.

7 Understanding Your System

7.1 Laser Theory

The term laser is derived from:

L ight

A mplification by the

S timulated

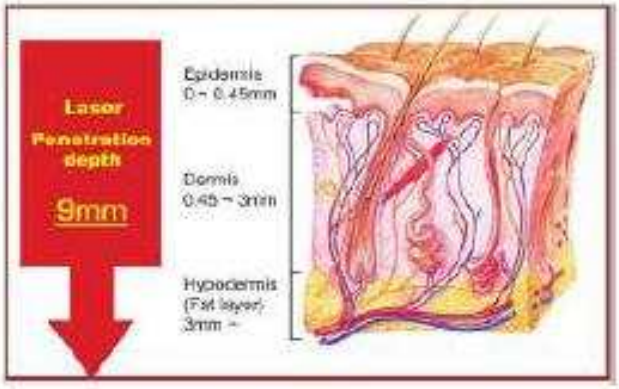
E mission of
R adiation

The Low level Laser model Strawberry and Strawberry and Cream utilizes a semi-conductor diode to produce a coherent light source at a wavelength of 660nm in the "paddles" which lay on the patient's skin during treatment.

7.2 How It Works

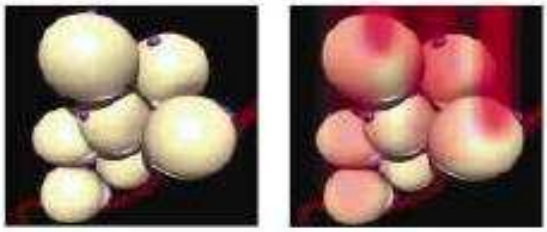
When the laser paddles are switched on, the laser light penetrates the skin and creates a reaction, see the diagram below:

"Strawberry" Penetration Depth



The Laser Beams have an active penetration of 9mm but continue deeper up to 13mm but with little or no effect.

Adipocyte Fat Cells



Adipocyte Fat Cells After Laser Treatment

Adipocyte Fat Cells After Laser Treatment

7.3 Training

Details to be finalized:

Free training will be available from Laser Lipo or its distributors in the United States, however details have yet to be confirmed.

A telephone support help line with a 1-800 number will also be provided.

7.4 Laser Warning Signs and Safety

7.5 Laser Machine Symbols and Specification

Symbols / Labels used on the Strawberry machine.	
Symbol:	Description:
	Manufacturer date represented as YYYY-MM
	Type BF applied parts – provides degree of electrical protection against electric shock with isolated or floating applied parts
	Caution – there are specific warnings or precautions associated with the device.
	Consult Operating Instructions

Technical Specifications

STRAWBERRY UNIT:

Power supply:	100—240 V~
Power consumption:	Max 60W Di-
mensions:	275 x 185 X
315 mm Weight:	6 kilos X 315
mm LCD Display	20 x 4 LCD

Red Laser Probe 660nn 40mW Visible

Output tolerance of Laser Diodes	<±15% Stated Probe Label Output Power
Measurement of uncertainty	5%
Increase in measured quantities	0%. Diodes are the main source for potential increases in measured quantities over time. Laser diodes suffer negligible obvious degradation until they fail.
Wavelength	660nm ±15 nm
Power Output	40mW
NOHD	120mm
Beam Divergence	9 x 38 degrees Typ
Laser Class	3B
Lasing Medium	GaAlAs

8 Instructions for Use

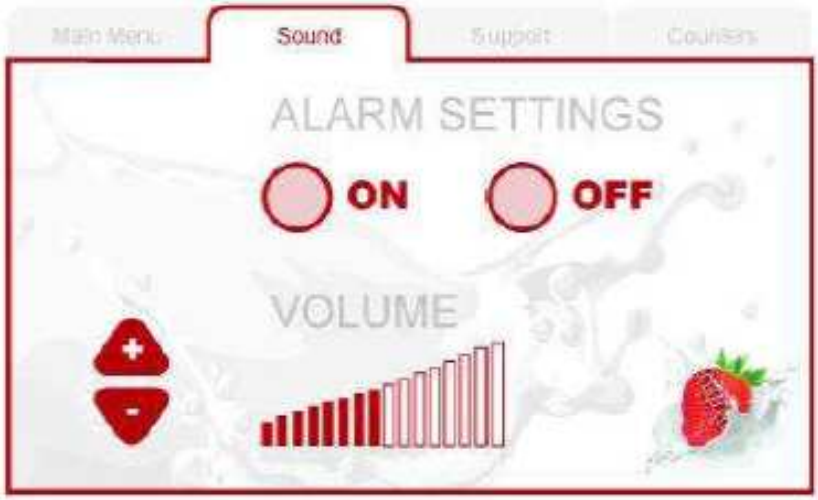
8.1 Strawberry Low Level Laser System

1. Set up the system as described in section 6.2
2. Switch on the unit by using key and power switch, see section 6.2
3. The screen will show the default treatment time of 10 minutes. You may use the up and down arrows on the front panel to alter this if desired.
4. The display "MENU>" indicates the menu can be accessed by the right arrow on the front panel. Follow the on-screen instructions to adjust the sound setting and total time.
5. Two indicator lights show that the power is connected and the laser is ready for use.
6. There is a "STOP" button in the middle of the front panel which will stop the unit when pressed at any time.

8.2 Strawberry and Cream Low Level Laser System

1. Set up the system as described in section 6.2
2. Switch on the unit by using key and power switch, see section 6.2
3. Adjust the treatment time using the touch screen, see below:

4. Adjust the alarm settings using the touch screen, see below:



9 Maintenance

9.1 Laser Servicing and Life

The machine should be serviced every 6 months or if only used infrequently maybe serviced annually

Like any light emitting device, the light output from each laser diode will decrease with time/use. It is important to service the equipment regularly so that compensating adjustments can be made.

Machines are set when new to achieve the specified output using approximately 60% of the maximum capacity; hence this utilization can be increased to compensate for the time-based reduction in light output. Machine life is thus anticipated to be between 3 and 5 years.

Laser Lipo will finalize service arrangements with their US distributors and include in the final manual.

9.2 Error Messages

"CHECK PADDLE" on Strawberry ILO model LCD Screen only:

1. Turn off machine
2. Disconnect from power supply
3. Check all leads and connections to laser paddles and probes
4. Check laser paddles are connected in correct order
5. Reconnect to power supply
6. Turn on machine

No light or messages on screen when unit is switched on:

1. check power lead is fully inserted at socket on rear of machine
2. check power lead is fully inserted and turned on at wall socket
3. check that the power switch is turned on, the "1" position
4. if the above does not resolve the problem, turn off and disconnect from power supply then check the fuses, see section 9.5.

9.3 Cleaning

We advise that after each use the paddles should be cleaned with a "sterile wipe" and that the probes are sterilized.

9.4 Routine Maintenance

There are no consumables needed and no routine maintenance is required.

9.5 Changing the Fuses

9.5.1 Equipment Fuse

Grey Fuse unit located at the back of the machine.

PULL out the grey fuse holder from the machine. As shown.

Then holding the fuse assembly, unscrew the cap in an anti-clockwise direction.

Then pull out the fuse. 240v 1AMP

Once you have replaced the fuse (Spares are supplied with each new machine) Re-assemble the fuse holder and carefully push back into the machine. Be careful of the two copper pins, when putting it back together. Align the component prior to inserting it.

9.5.2 Power Supply Fuse

The power supply fuse is located between the power switch and the power lead socket at the rear of the base unit. Consult a qualified electrician if this fuse has blown.

13.4. Training Materials

Laser Lipo Ltd will develop appropriate training materials for the United States with their distributors based on developing the European materials included as drafts in this section.

Photography for Abdomen

You **MUST** photograph every client before the start of the course and after the final treatment in order to show your client their before and after images.

DO NOT PHOTOGRAPH CLIENT'S FACES.

Front: Side:

You will need to take 4 pictures.

Back: Side:

Always make sure that the client has their hands on their head.

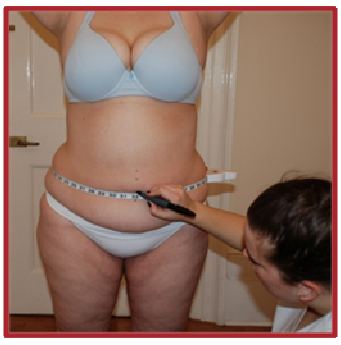
You will take the after pictures in the same way, at the end of the course. Make sure the client is wearing the SAME underwear.

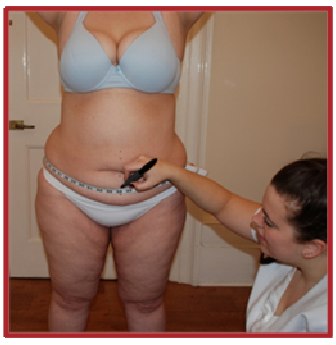
10 Minute Treatment For Lower Abdomen

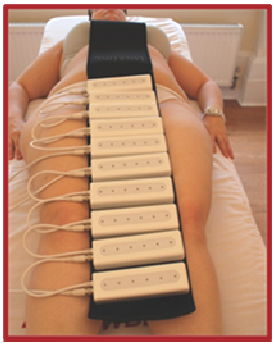
You must measure **EVERY** client **BEFORE** and **AFTER** every treatment. Below are images on where you measure for the abdomen treatment.

You will measure 3 areas when treating the client's lower abdomen.

You need to measure the **Waist, Belly button & Hips** on the client's abdomen.



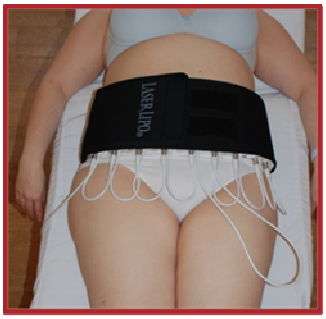




10 Treatment for Abdomen

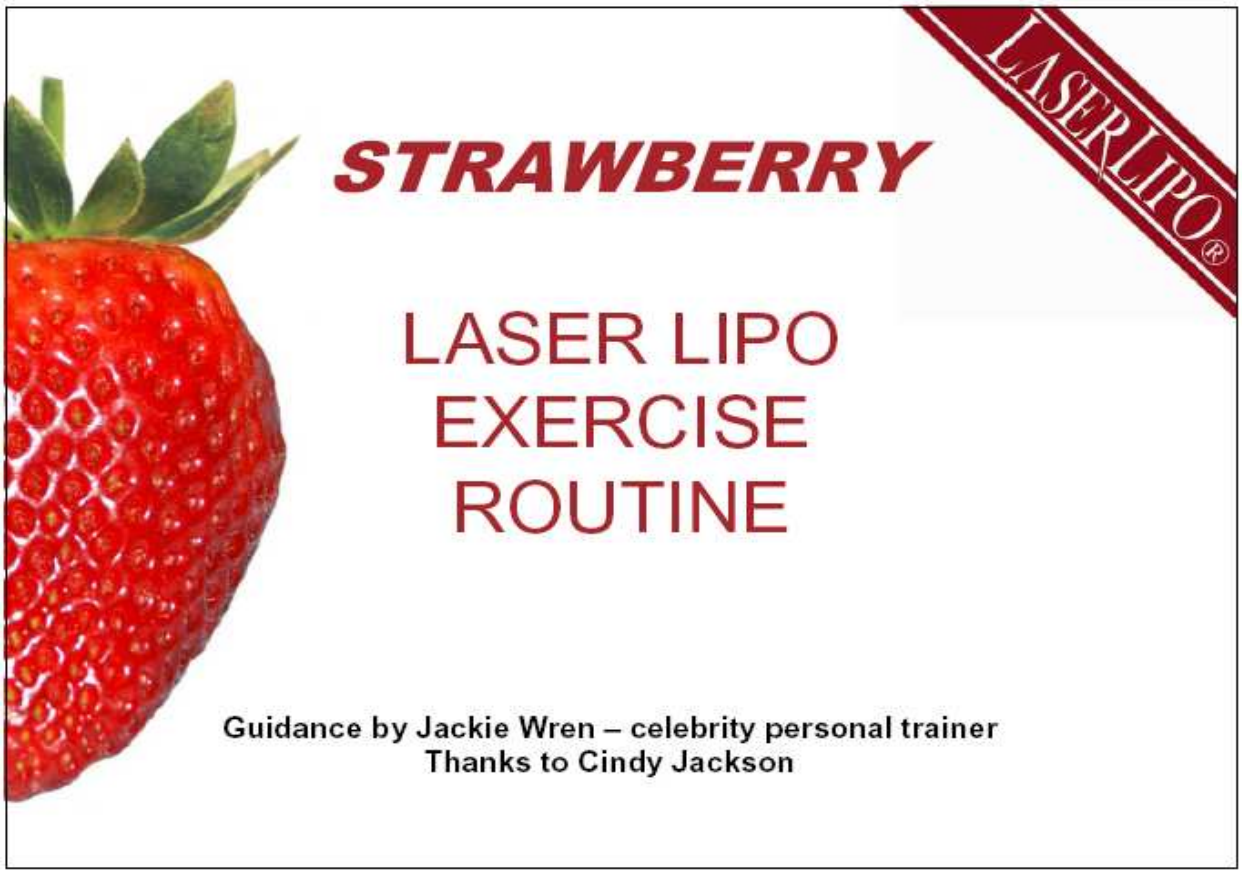
Step 1:

Ensure the machine is connected correctly (refer to user manual). All paddles should be placed on the abdomen strap to cover the area to be treated. Place safety goggles onto the clients eyes and the technicians.

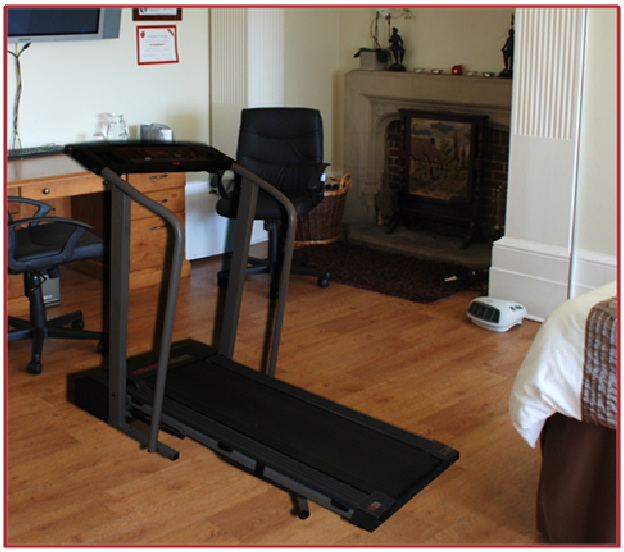


Step 2:

Place all of the 10 paddles on to the front of the clients abdomen. Ensure the timer is set to 10 minutes, and press start.



Running Machines



1) Use directly post treatment

2) Use the running machine as instructed. For 30 minutes only under the supervision of the technician.

3) For Cardio Vascular exercise you would programme the treadmill to the 'up-hill' setting.

Power Plate Machines

These machines may seem very simple but they can be very damaging to a person with existing injuries. It is **VITAL** that the client is made aware of any contra-indications prior to them using this type of device.

The power plate will help to speed up the body's metabolic rate and by doing so stimulate the body's natural lymphatic system. This in turn will stop the body from re-storing the fat that has been released from the laser treatment.

A 30 minute session on a standard setting will suffice.

13.5. Promotional Material

Promotional materials will be developed with US distribution partners based on the style of European materials under Labeling Control to ensure they do not exceed the scope of this 510[k].

13.6. Web-site and Other Electronic Media Materials

Laser Lipo Ltd will develop the domain name that it has purchased www.strawberry-laser.us. This will be a dedicated website to support the Strawberry and Strawberry and Cream low level laser systems in the United States, managed in partnership with its local distributors.

The website will be divided between information for potential users and potential patients and will include appropriate descriptions of the products, technologies, treatments and contact details.

14. Sterilization and Shelf Life

14.1. Sterilization

The Laser Lipo Ltd Strawberry and Strawberry & Cream is supplied non-sterile and is not designed to be sterilized.

14.2. Shelf Life

The Laser Lipo Ltd 'Strawberry' and 'Strawberry and Cream' low level laser systems use solid state diodes for the generation of laser light. All such diodes suffer degradation with time and use.

Having considered the length of use during treatment, number of treatments per day, the manufacturer's data on the laser diodes and Laser Lipo's own experience with products in the European Market, we conclude:

- if products are used intensively on a regular basis, best practice would be to service the unit every 6 months
    - counters are included to help the user make this determination
    - it is anticipated that even intensively used devices will be within specification, even if they are only serviced annually, but their performance could be less than optimal
- however for the majority of products, where treatments are few, or carried out infrequently, an annual service is recommended.

These servicing requirements are included in the user manual shipped with every system. At each service, the output of the control unit is reset and the output from the laser diodes measured, to ensure performance is still capable, and within specification. Data can be reviewed in section 18.

All laser diodes have an operational life before they are required to be re-calibrated or replaced, hence undertaking output measurements during a routine service by a qualified technician is the industry norm.

Laser Lipo Ltd aims to ensure the 'Strawberry' Laser systems shall be maintainable up to 5 years from the last manufacture, beyond this time availability of components may become difficult.

A shelf-life has been determined for 5 years based on the laser diodes.

Annunciation of failure alarms: if the system was to fail for any reason the system's alarm would sound
System Failure Probability – We have not had any system failure on either product.

14.2.1. Laser Diode Manufacturer's Specification

Environmental Variation Conditions –
Environmental Requirements:
10℃ to 30℃ Non-condensing
humidities below 75% RH

Output tolerance of Laser Diodes	<±15% Stated Probe Label Output Power
Measurement of uncertainty	5%
Increase in measured quantities	0%. Diodes are the main source for potential increases in measured quantities over time. Laser diodes suffer negligible obvious degradation until they fail.

660nn 40mW Visible Laser Probe

Wavelength	660nm ±15 nm
Power Output	40mW
NOHD	120mm
Beam Divergence	9 x 20 degrees Typ
Laser Class	3B
Lasing Medium	GaAlAs

Laser Beam profile and diode accuracy – Spread of 17 degrees, diffused.

15. Biocompatibility

15.1. Biocompatibility Summary

For the Laser Lipo Ltd 'Strawberry' and 'Strawberry' and Cream low level laser systems, an assessment of biocompatibility was made following the FDA recognized consensus standards ISO 14971 and ISO 10993-1 as amplified the FDA "Blue Book Memo #G95-1" and other FDA guidance.

The goggles are the same model from the same manufacturer as the predicate device the Chromogenex i-Lipo, K111501. The only difference is that they are printed on the outside surface with the"Strawberry-Laser" web address.

Figure 15-1 - Goggles showing arm printing

15.2. Assessment of Subject Contact

(Repeated from section 11.4.3)

Part Name	Details	Type of Subject Contact	Material
enclosure for control unit	see section 11.1.2	The clinician touches the display for a few seconds	thermoplastic elastomer
Strap	see section 11.1.15	The straps are pulled taught around the clients body and are kept on for the duration of the treatment time	Nylon
Paddle	see section 11.1.7	Paddles are placed against the selected fatty area, pressed against the skin and held in place with Velcro straps.	thermoplastic elastomer
Probe	see section 11.1.8	Probes are placed against the selected fatty area, pressed against the skin.	thermoplastic elastomer
Goggles	see section 11.1.16	goggles are kept on the clients face for the duration of the treatment	Plastic: Nylon Lenses: Polycarbonate
LCD Display	see section 11.4.2	The clinician touches the display for a few seconds	LCM Module Model AT070TN83 V.1 by InnoLux

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

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

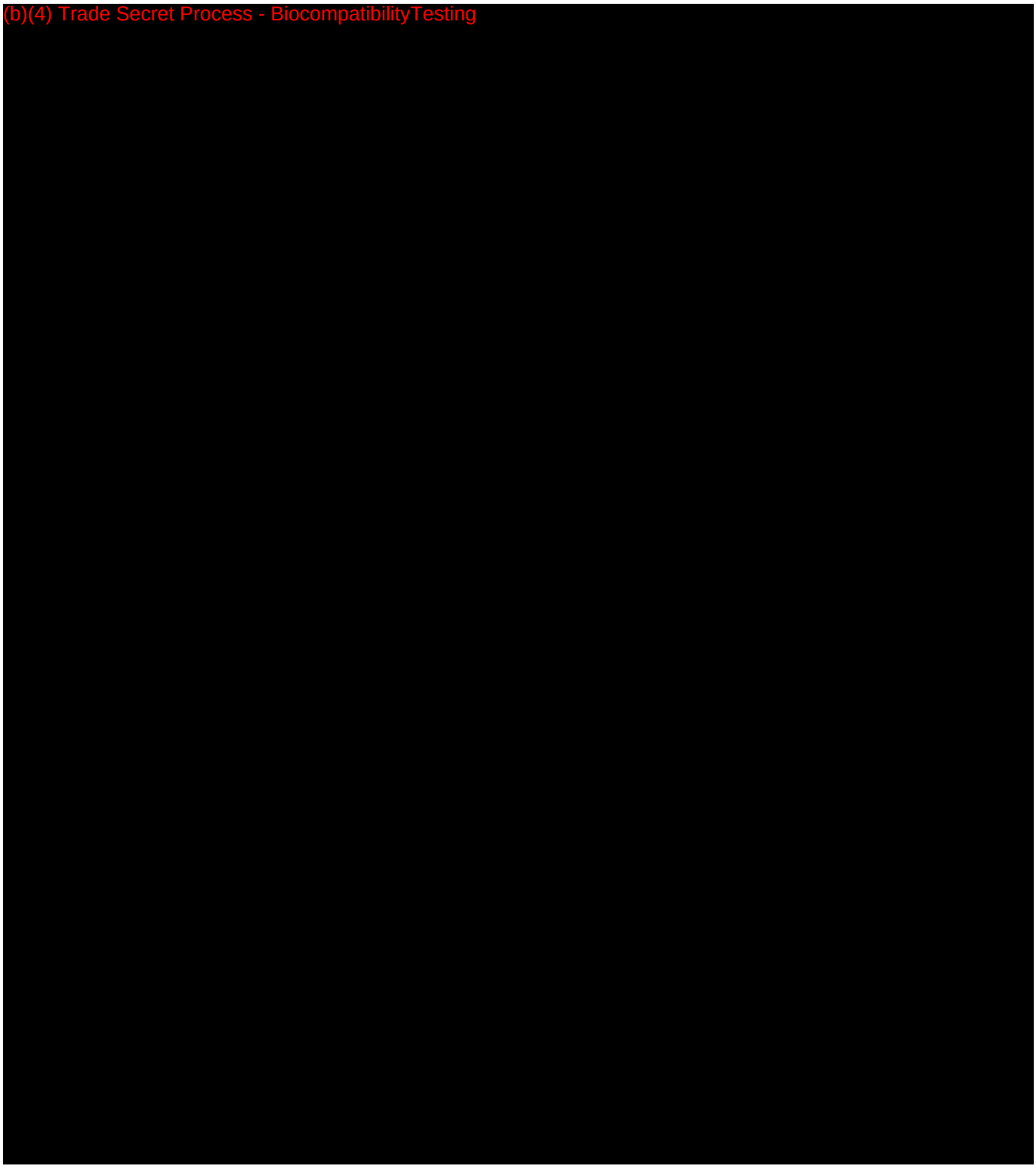
(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

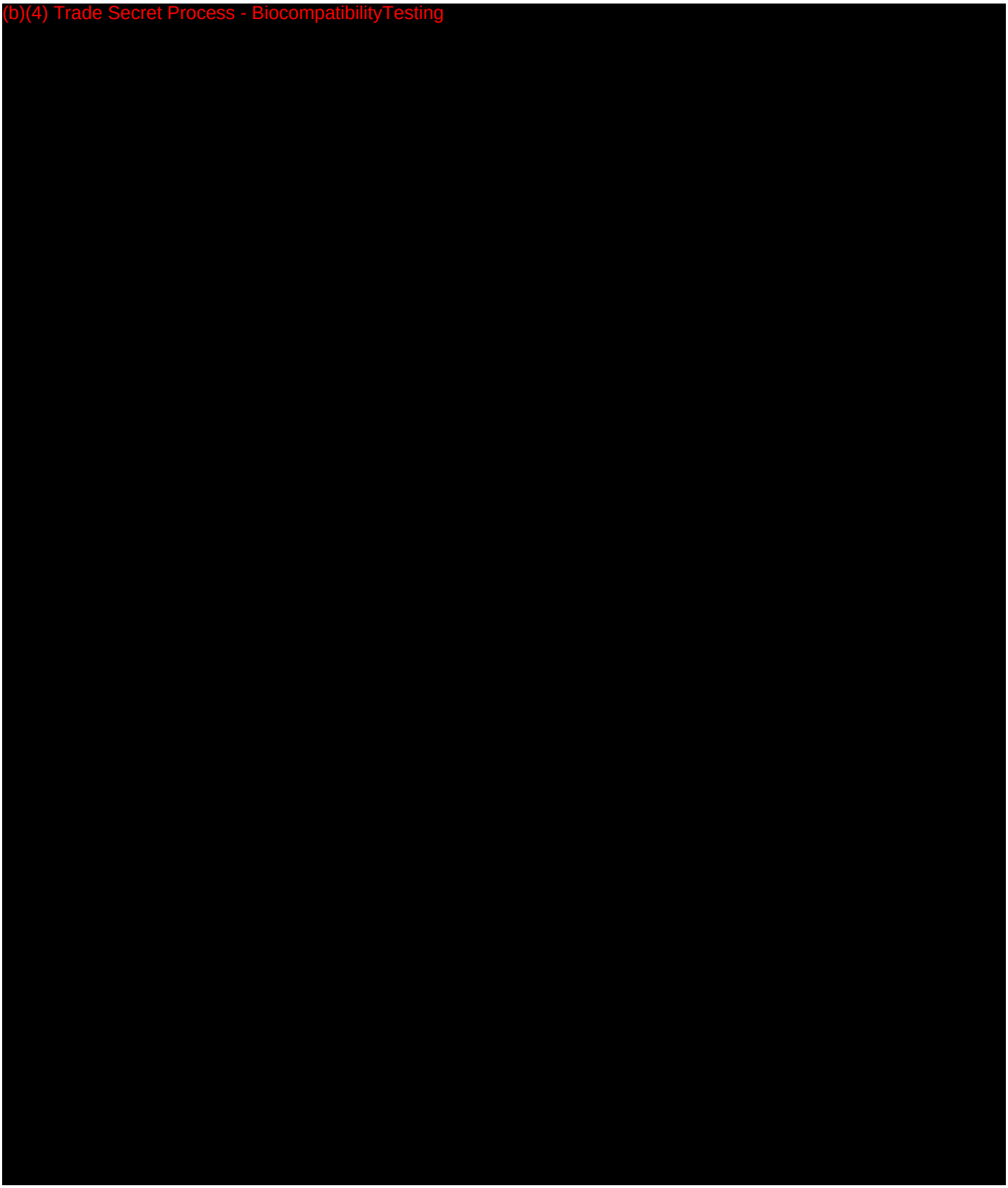
(b)(4) Trade Secret Process - Testing

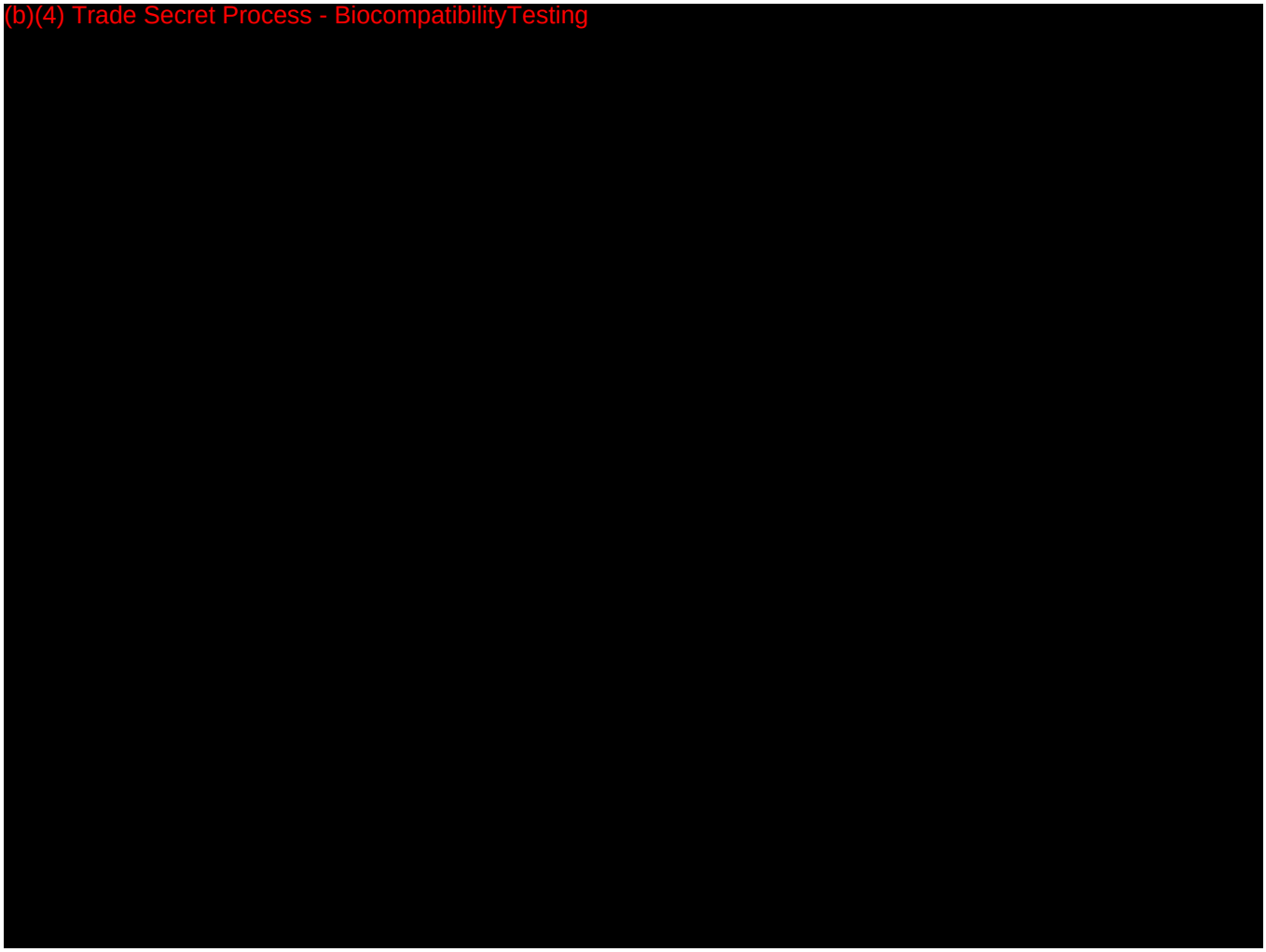
(b)(4) Trade Secret Process - Testing

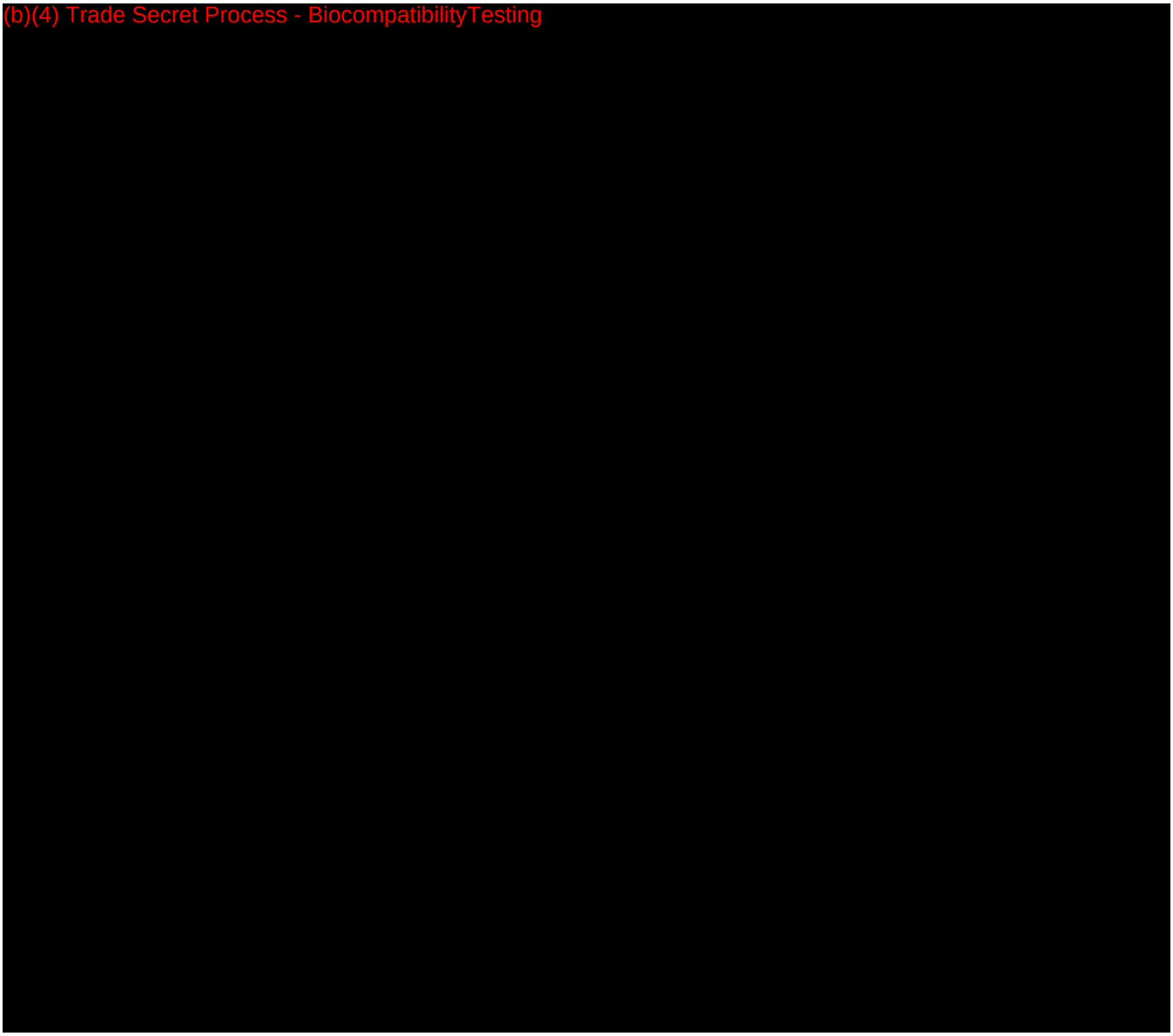
15.4. ISO 10993-1 Biocompatibility Assessment



(b)(4) Trade Secret Process - BiocompatibilityTesting

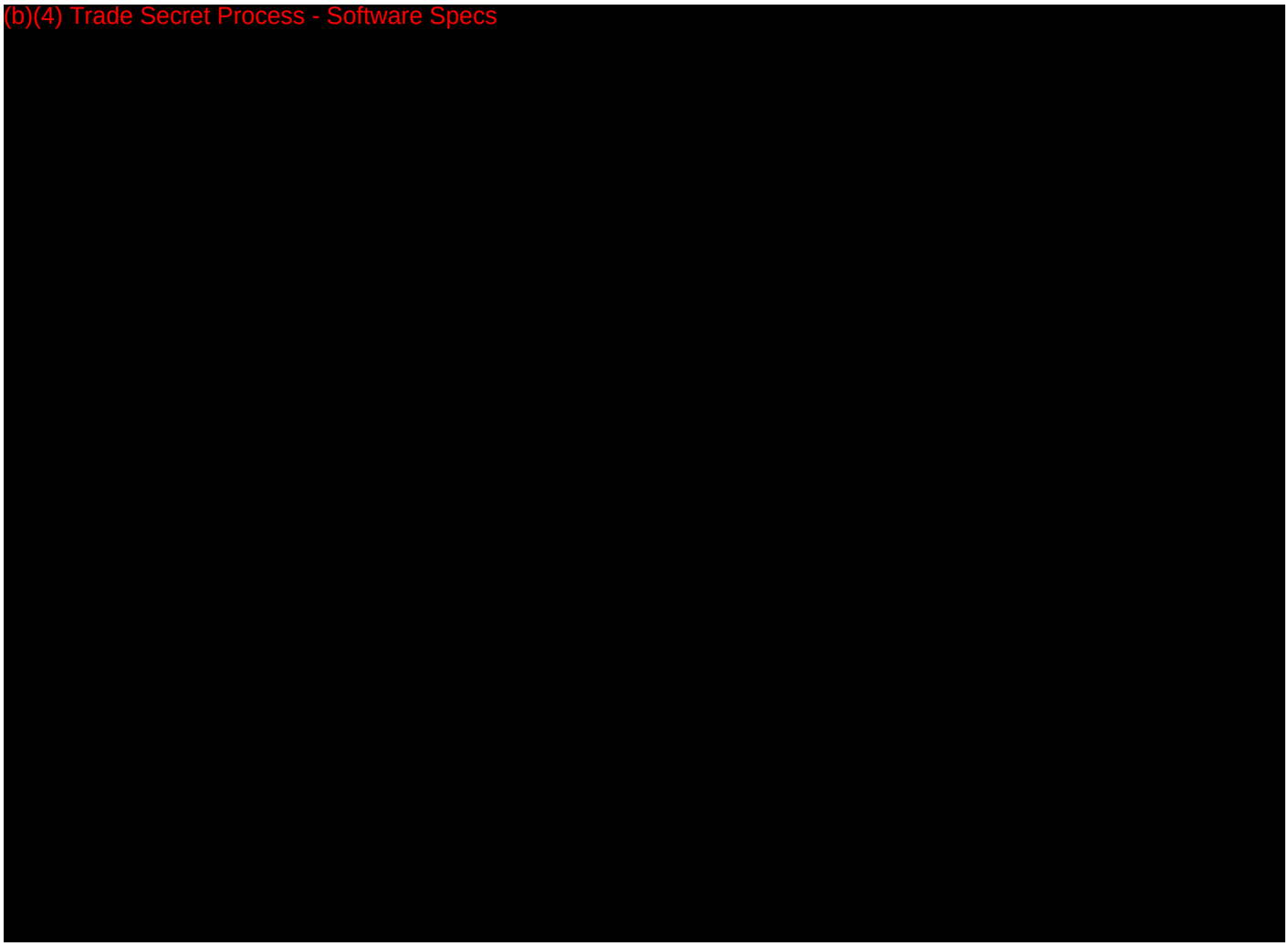


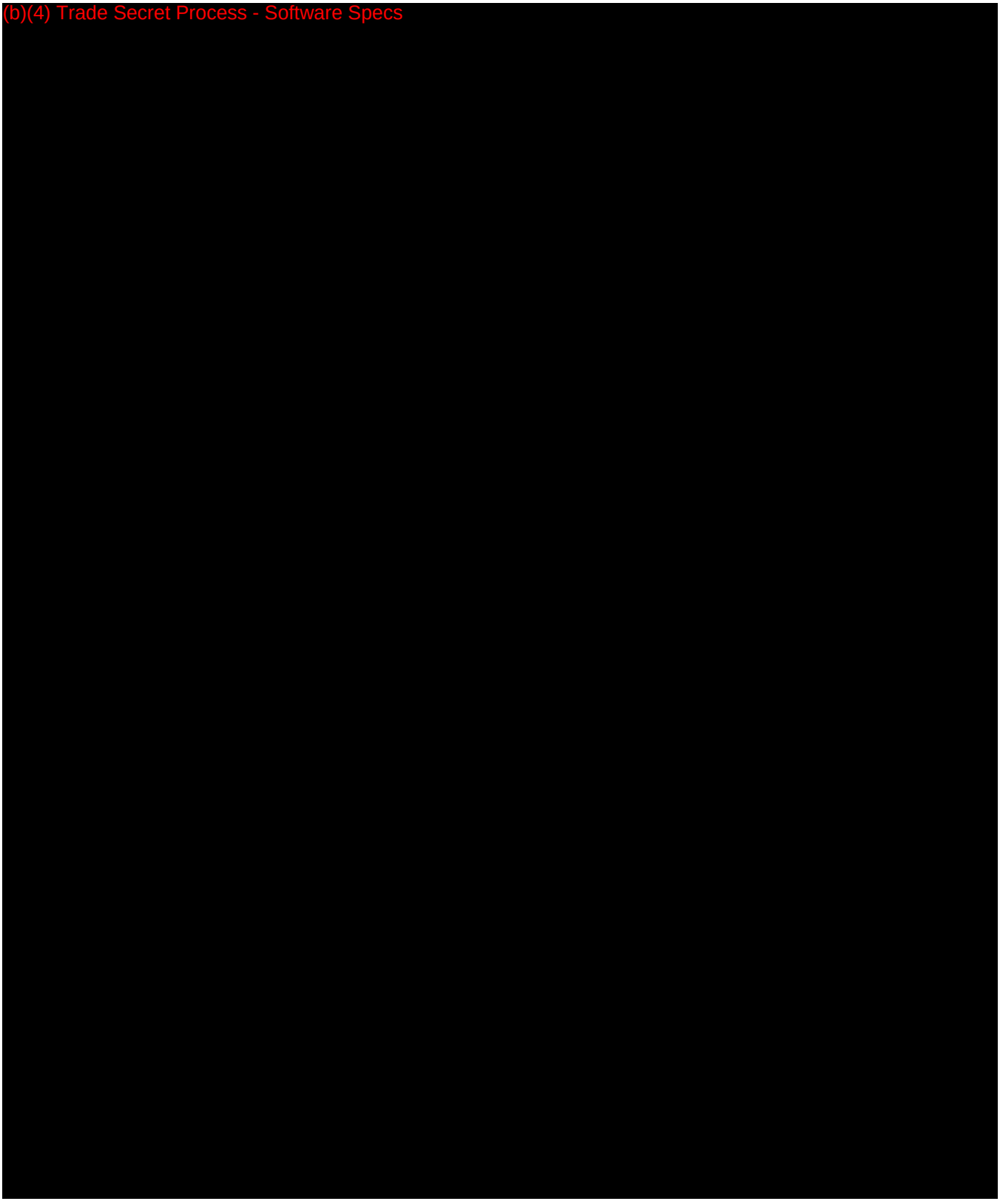

(b)(4) Trade Secret Process - BiocompatibilityTesting

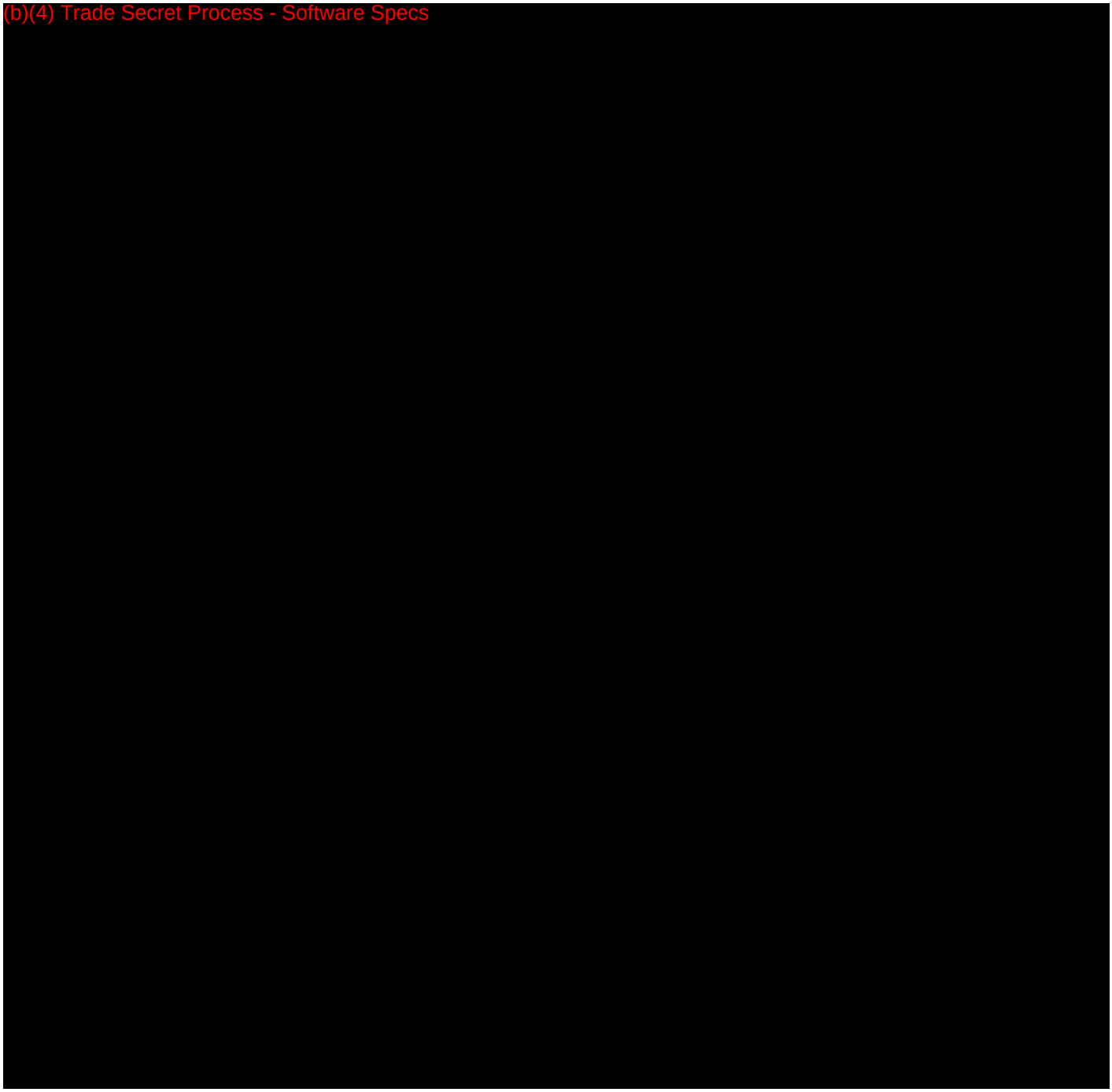

(b)(4) Trade Secret Process - BiocompatibilityTesting

16. Software

SECTION 16 TABLE OF CONTENTS


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


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


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


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

16.2. FDA Software in Submissions Requirements

16.2.1. Compliance with IEC and FDA requirements

There are differences in approach and level of documentation required between IEC 62304 and FDA's "Software on Submissions" Guidance, and a different method of classification (determining level of concern, explained below in Section 16.2.2). Hence, Laser Lipo Limited include first the IEC 62304 Software Development Report (as reviewed by our Notified Body SGS for the European CE Mark) as Section 16.3 and then additional items identified by FDA in Section 16.4.

16.2.2. Explanatory Note on Software Level of Concern

Based on the determination that the software is a moderate level of concern, the FDA Guidance for "software in submissions" has been compared against the requirements of the FDA recognized consensus standard IEC 62304 "Medical Device Software, Software Life-cycle Processes" in section 9 and the IEC 62304 Software Design Report is presented below, see section 16.3.

It may be noted that while the FDA Guidance on determining the level of concern associated with software is hazard-based, the IEC 62304 Life-cycle Standard is risk-based. Following the FDA hazard-based approach we agree the software should be considered a moderate level of concern because there is a hazard posed software control of laser light, however taking the ISO 14971 risk-based approach of IEC 62304 we see the probability of this hazard being realized as exceptionally low and hence conclude the software level of concern as Class A.

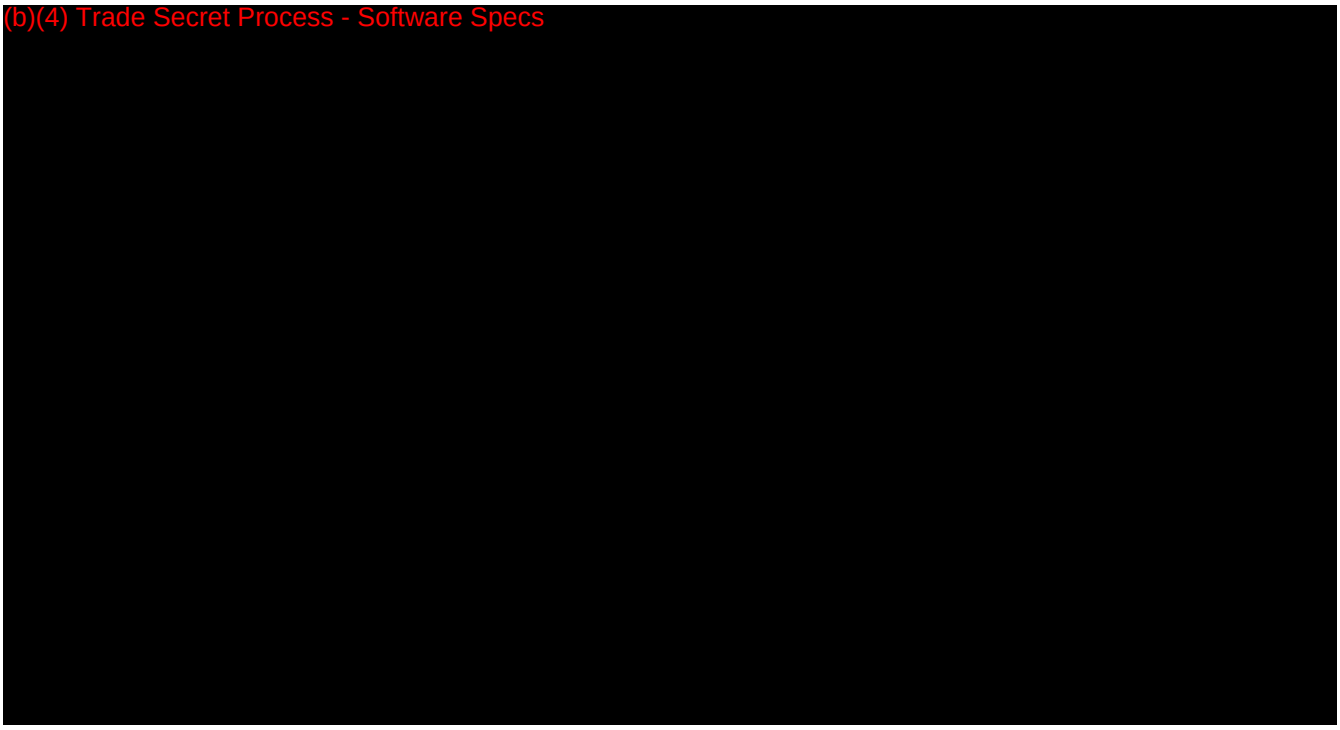
We do not see the above as inconsistent but as demonstrating the difference in taking a risk or hazard based approach.

16.3. IEC 62304 Software Development Report

Strawberry Laser & Strawberry & Cream

Software Development Report

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



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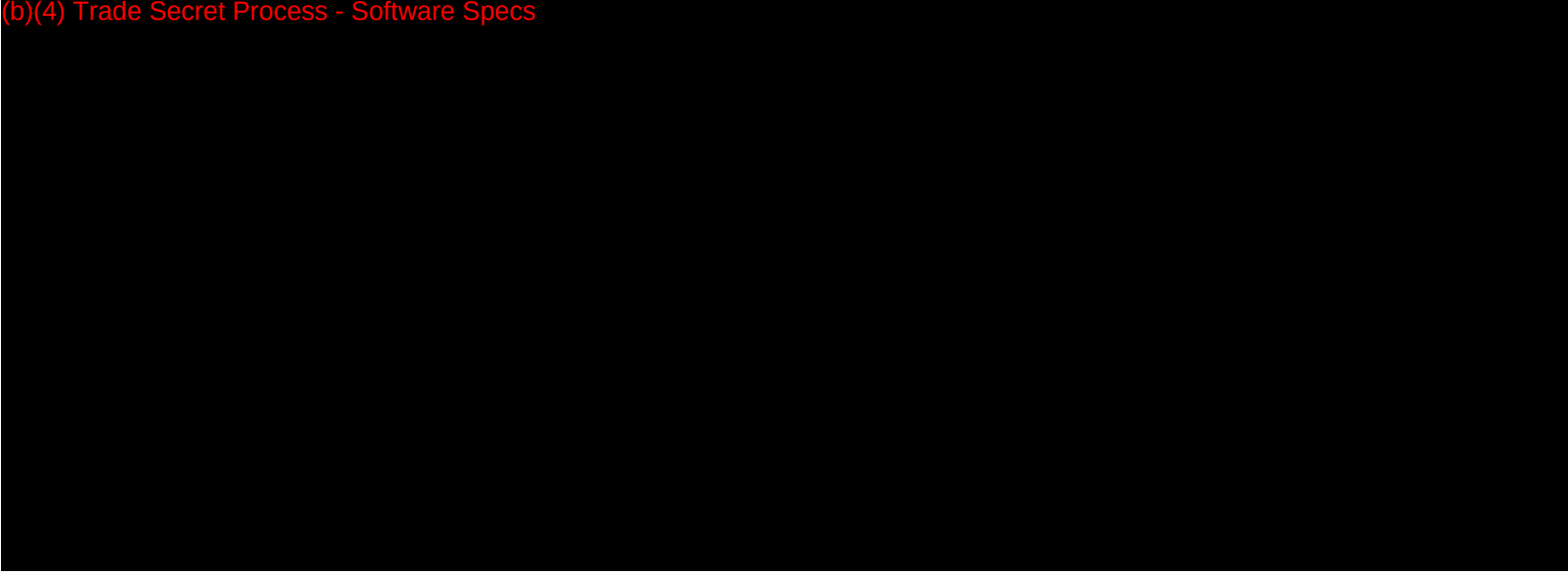

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16.4.4. Software Design Specification

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16.4.5. Verification and Validation Activities

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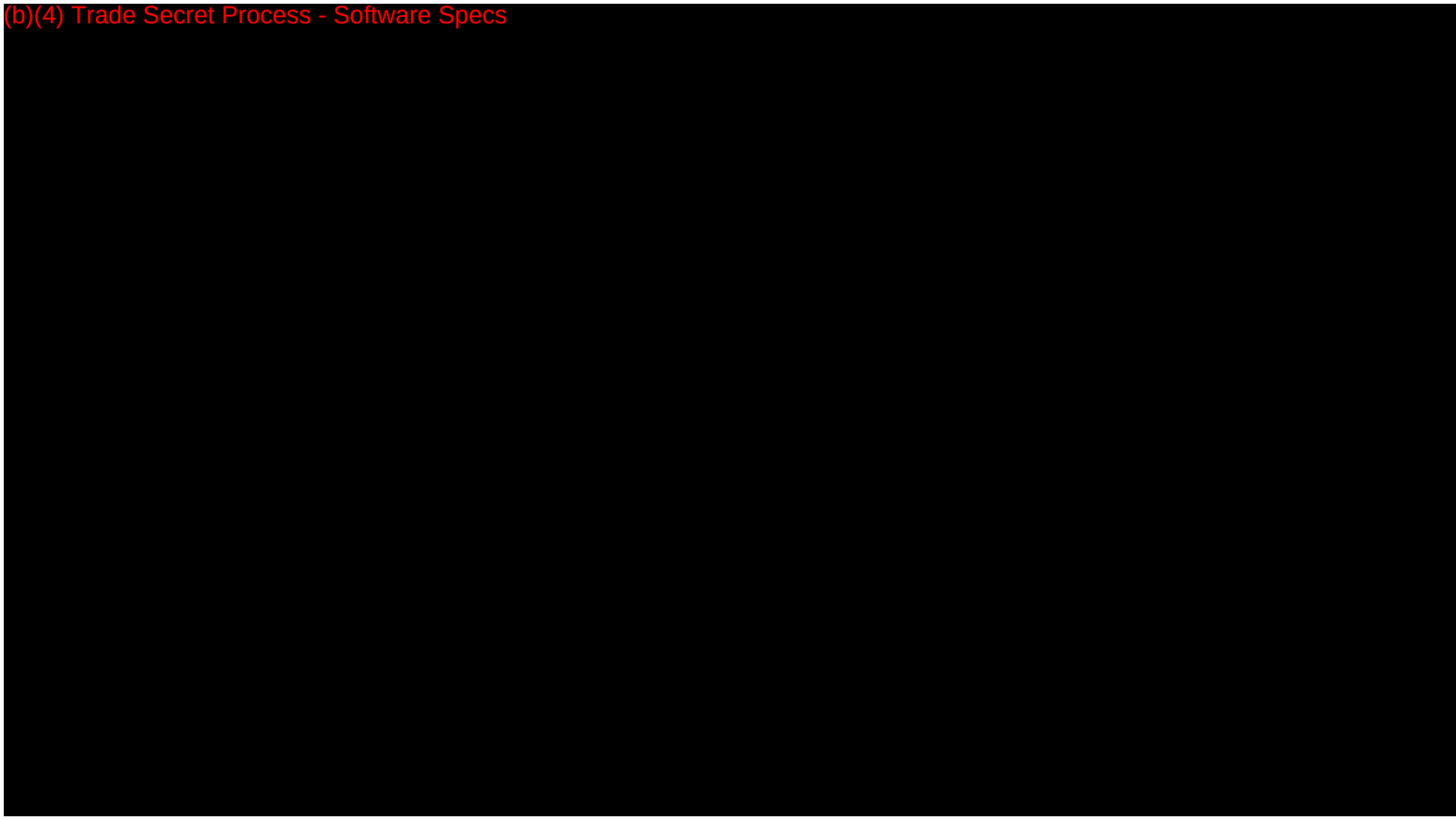

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17. Electromagnetic Compatibility and Electrical Safety

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17.1.2. Strawberry & Cream low level laser system

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17.2. Electrical Safety Test Report

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17.2.3. Reference to Usability Report

A Usability Report has been conducted to IEC 60601-1-6:2008 and can be seen in section 11.2.


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

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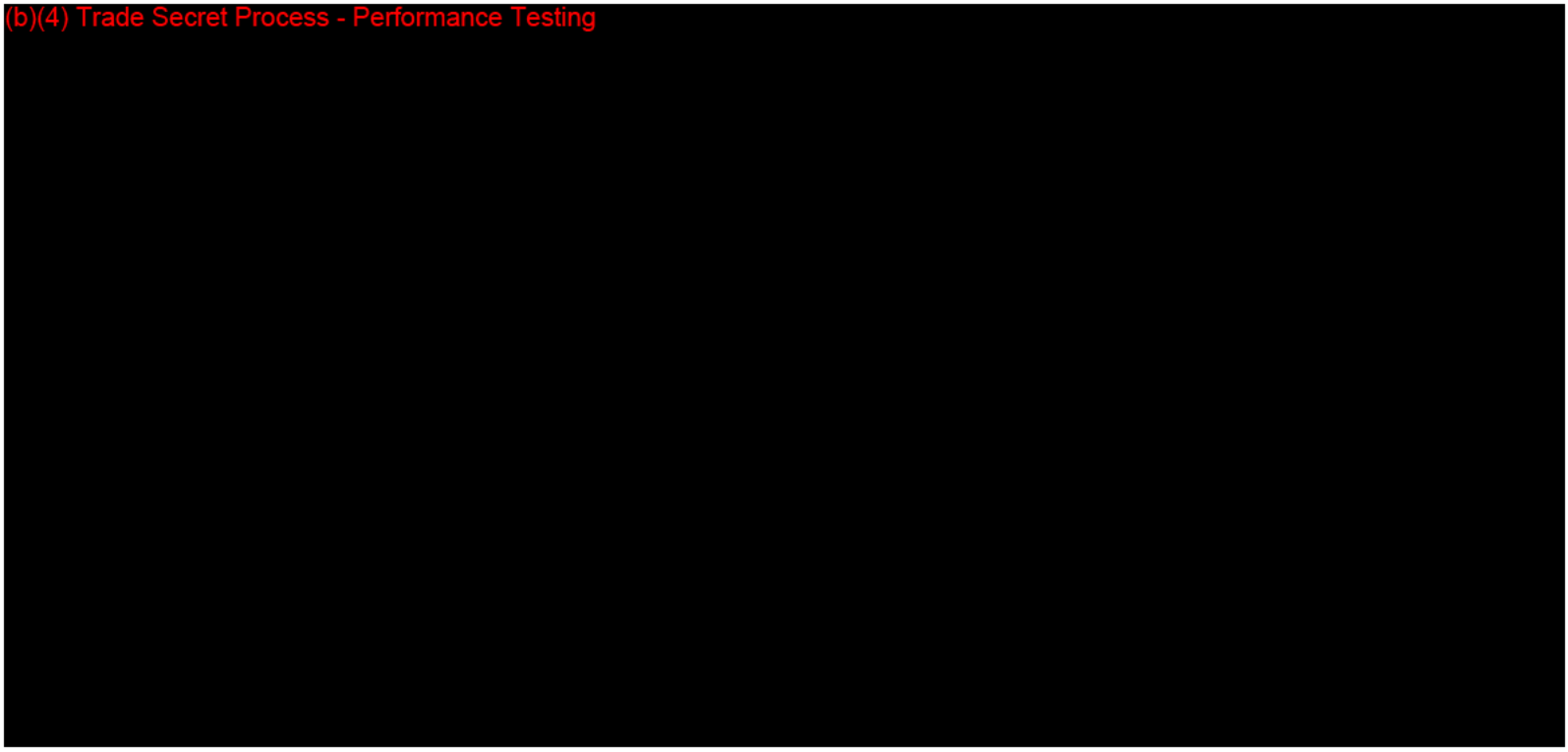

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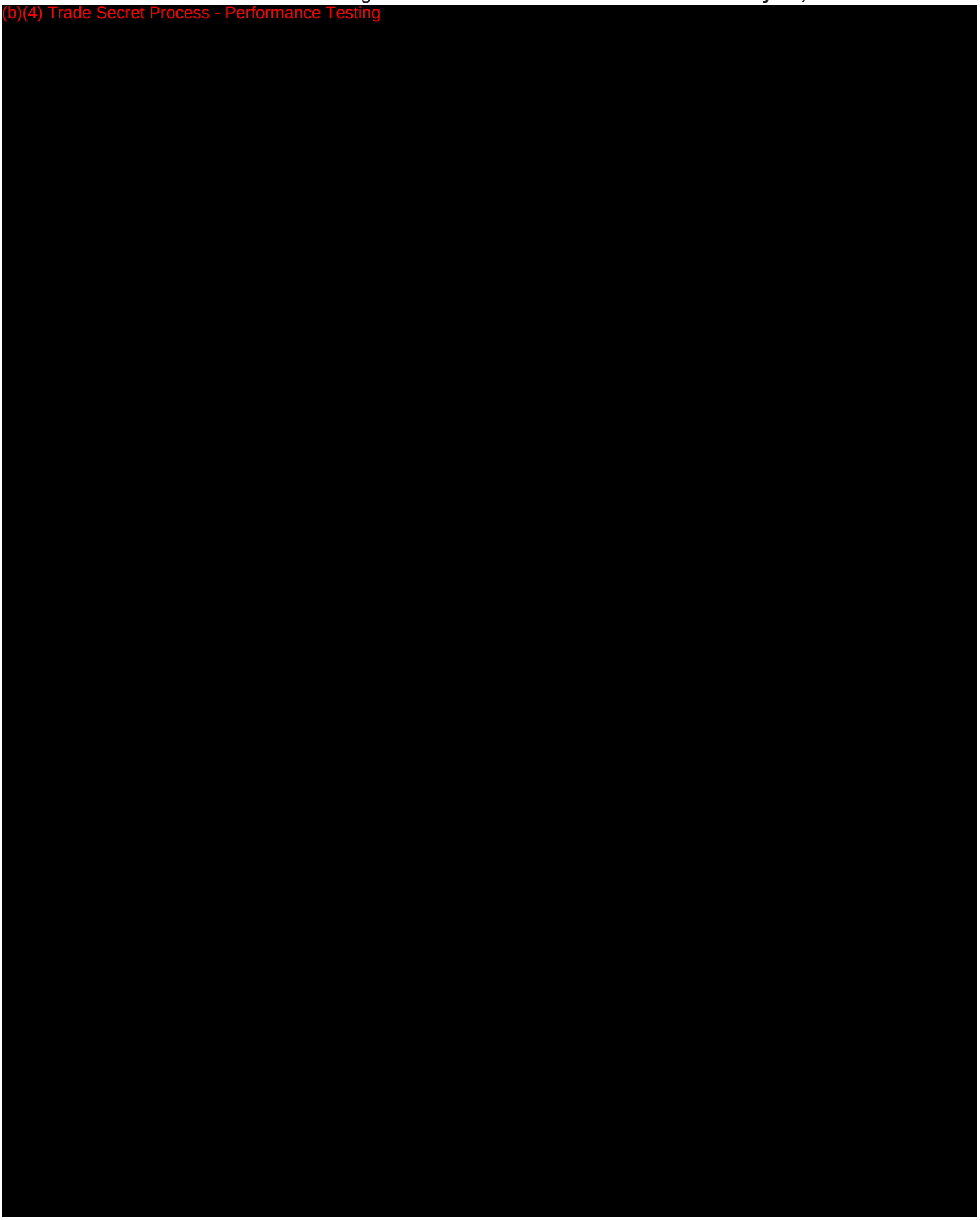

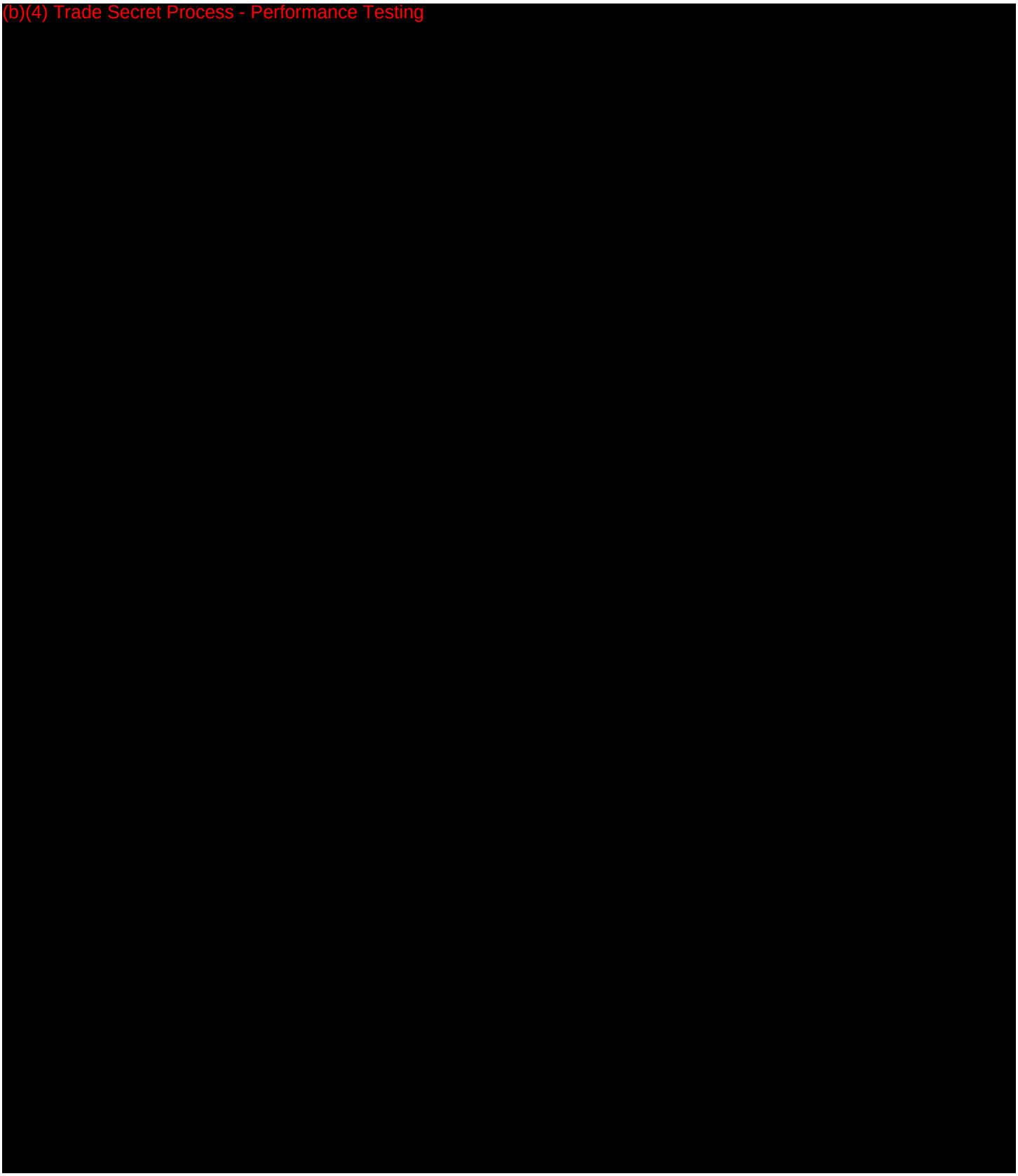
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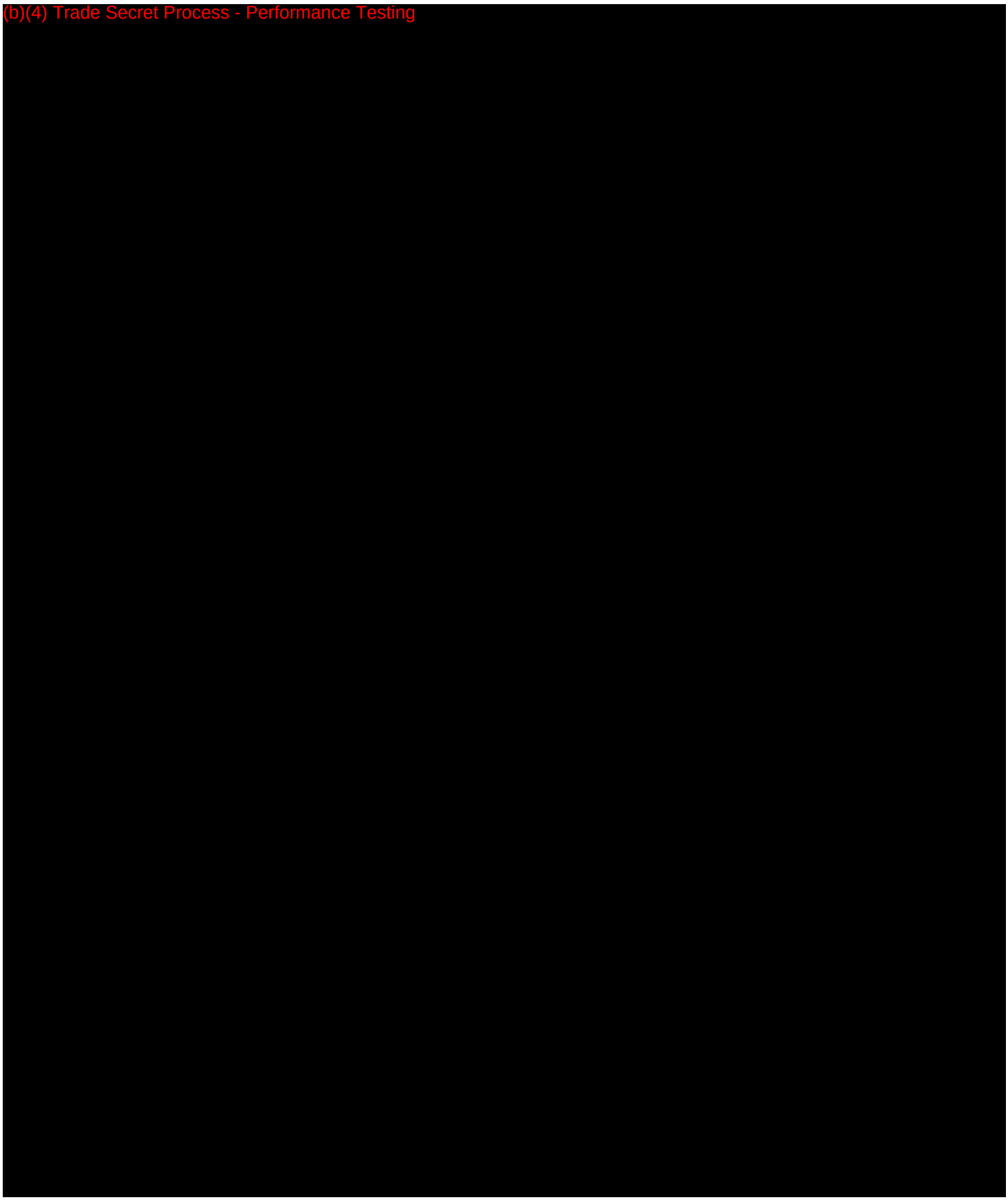

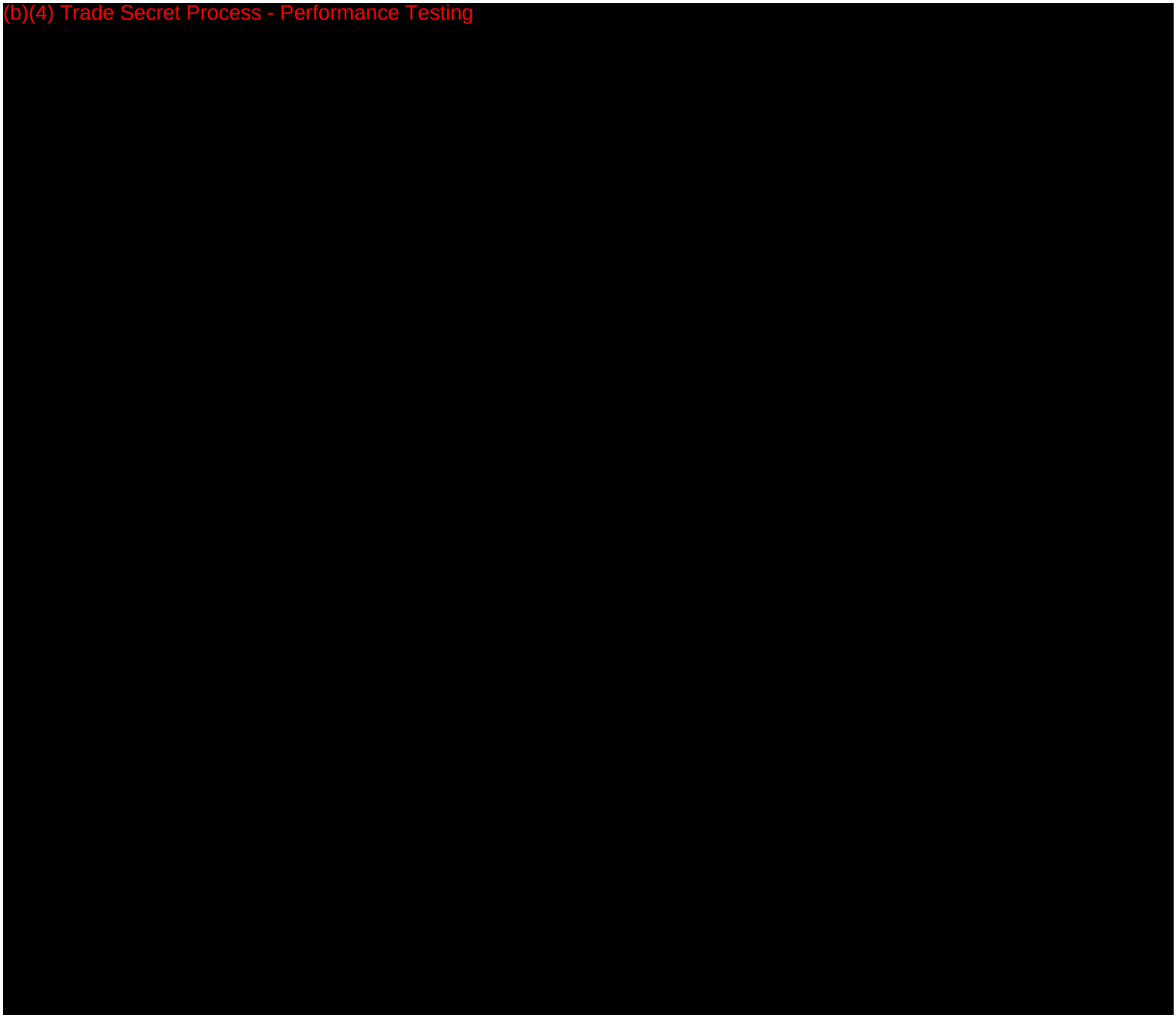
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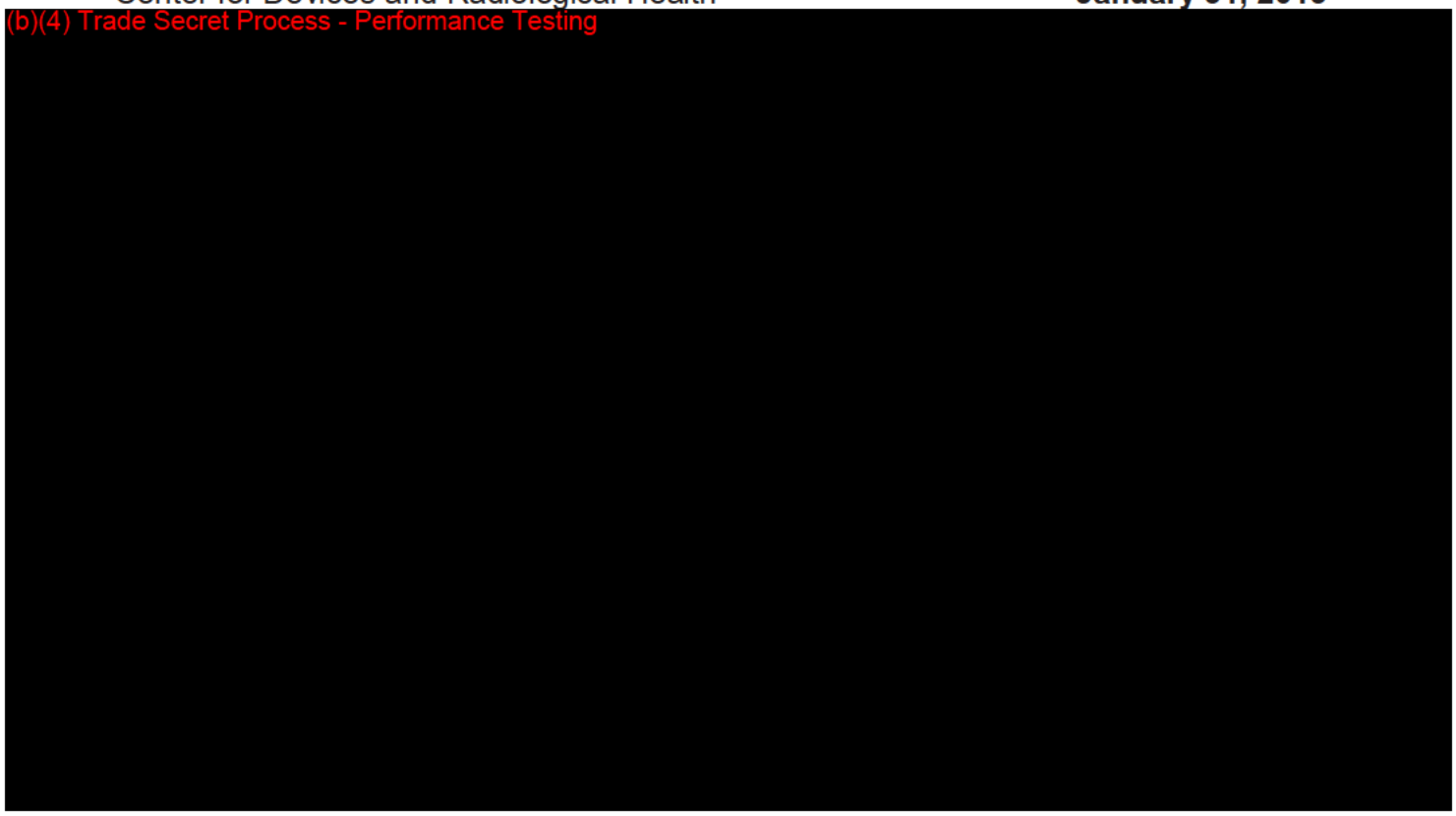

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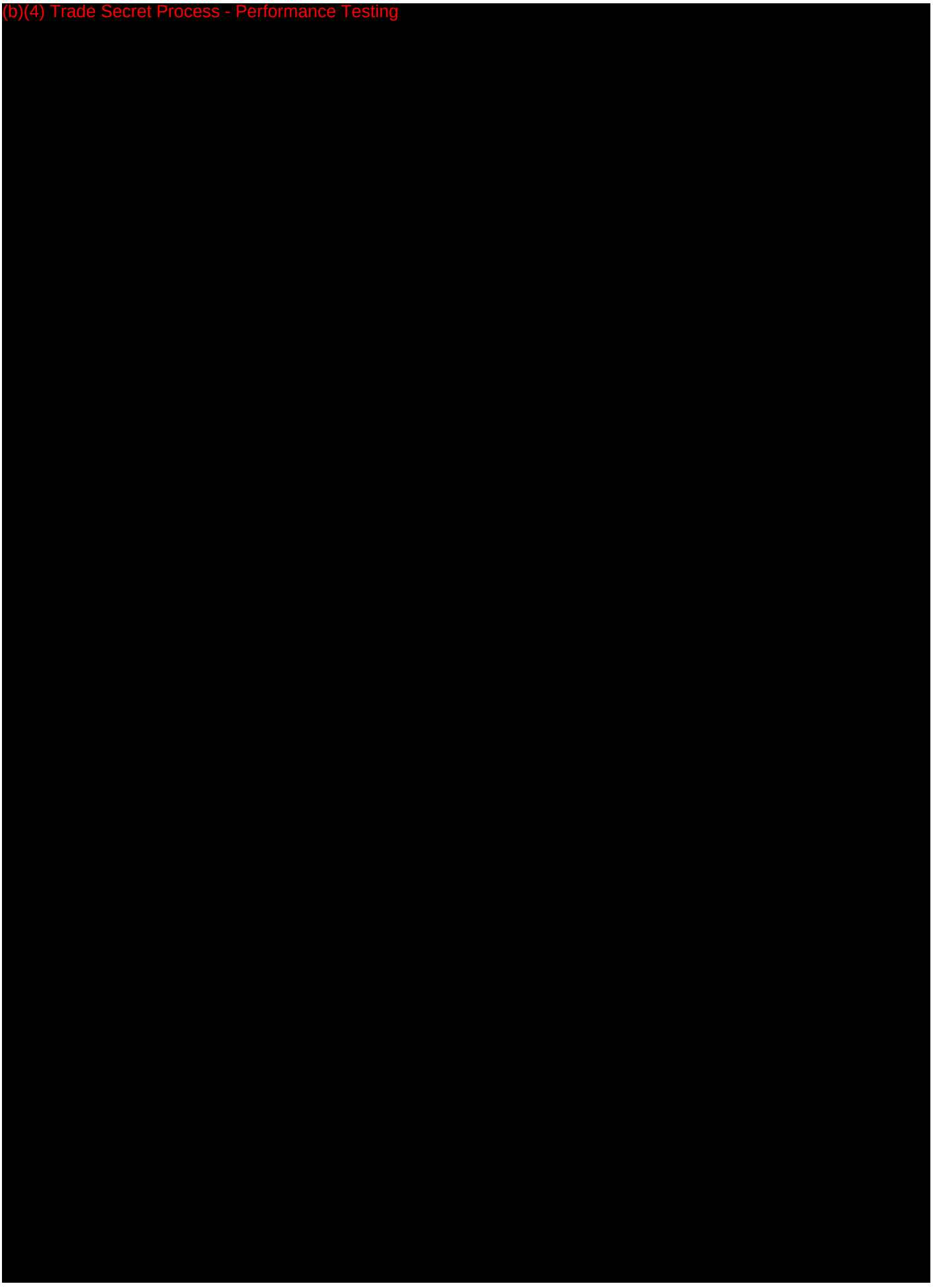

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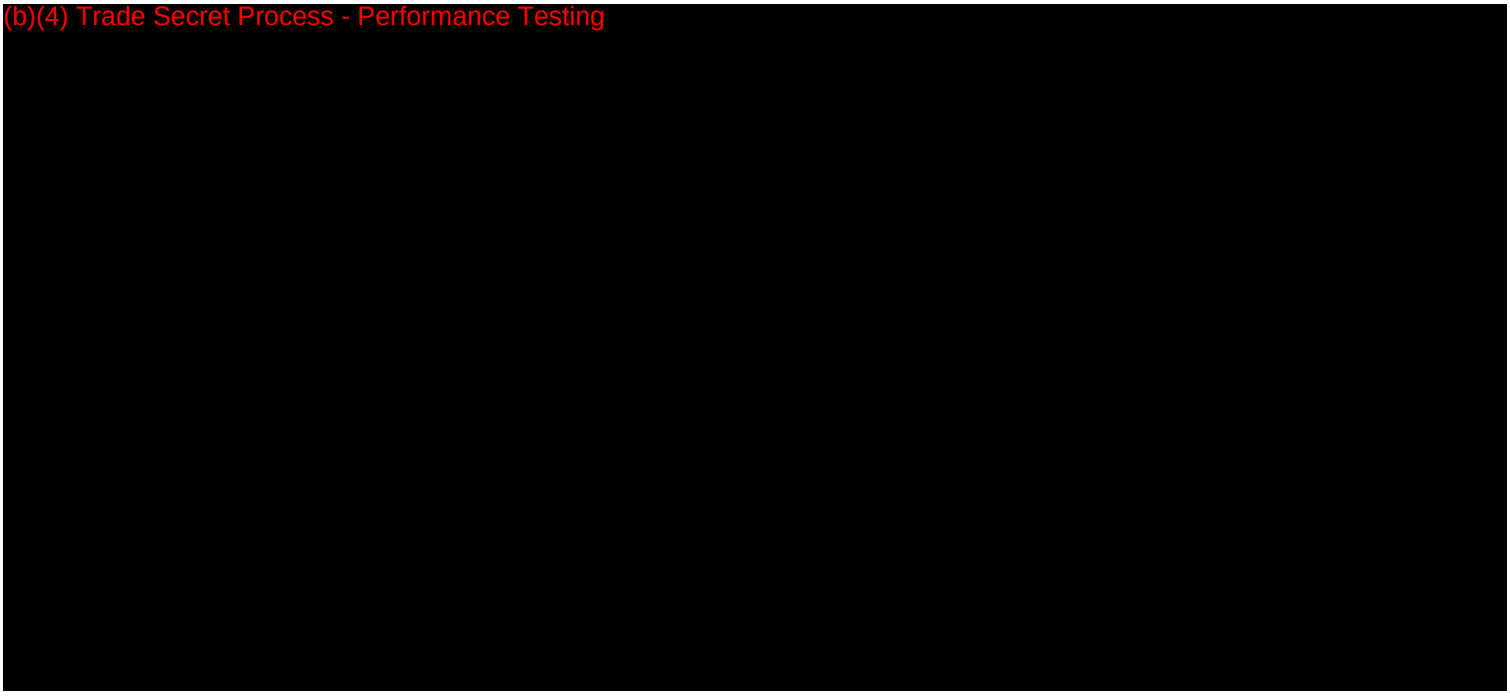

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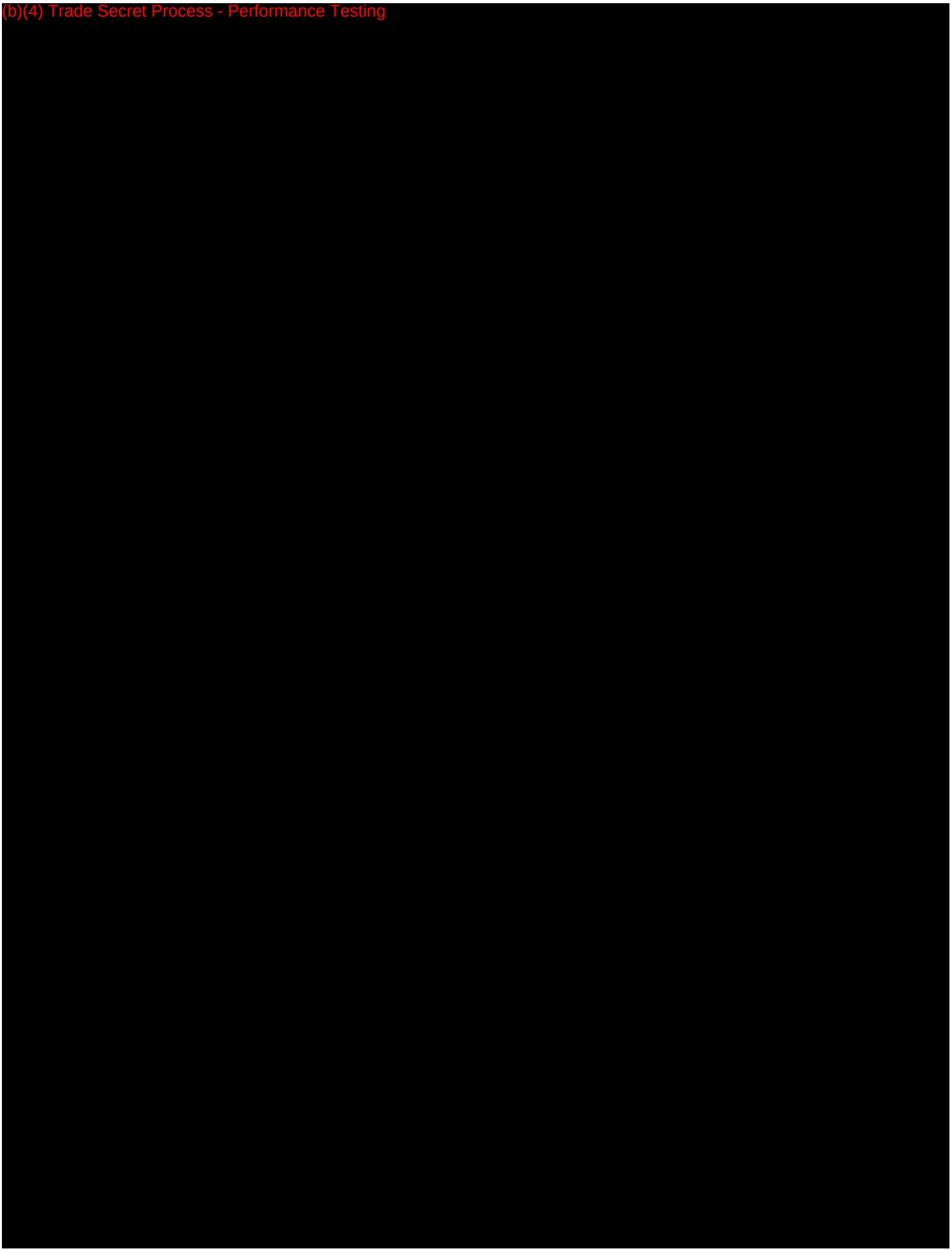

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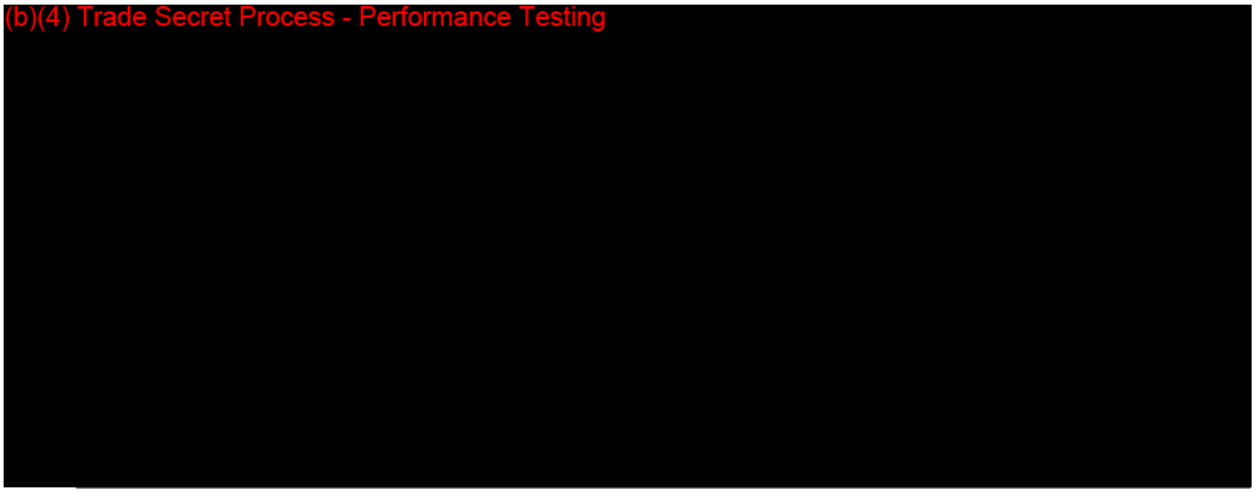

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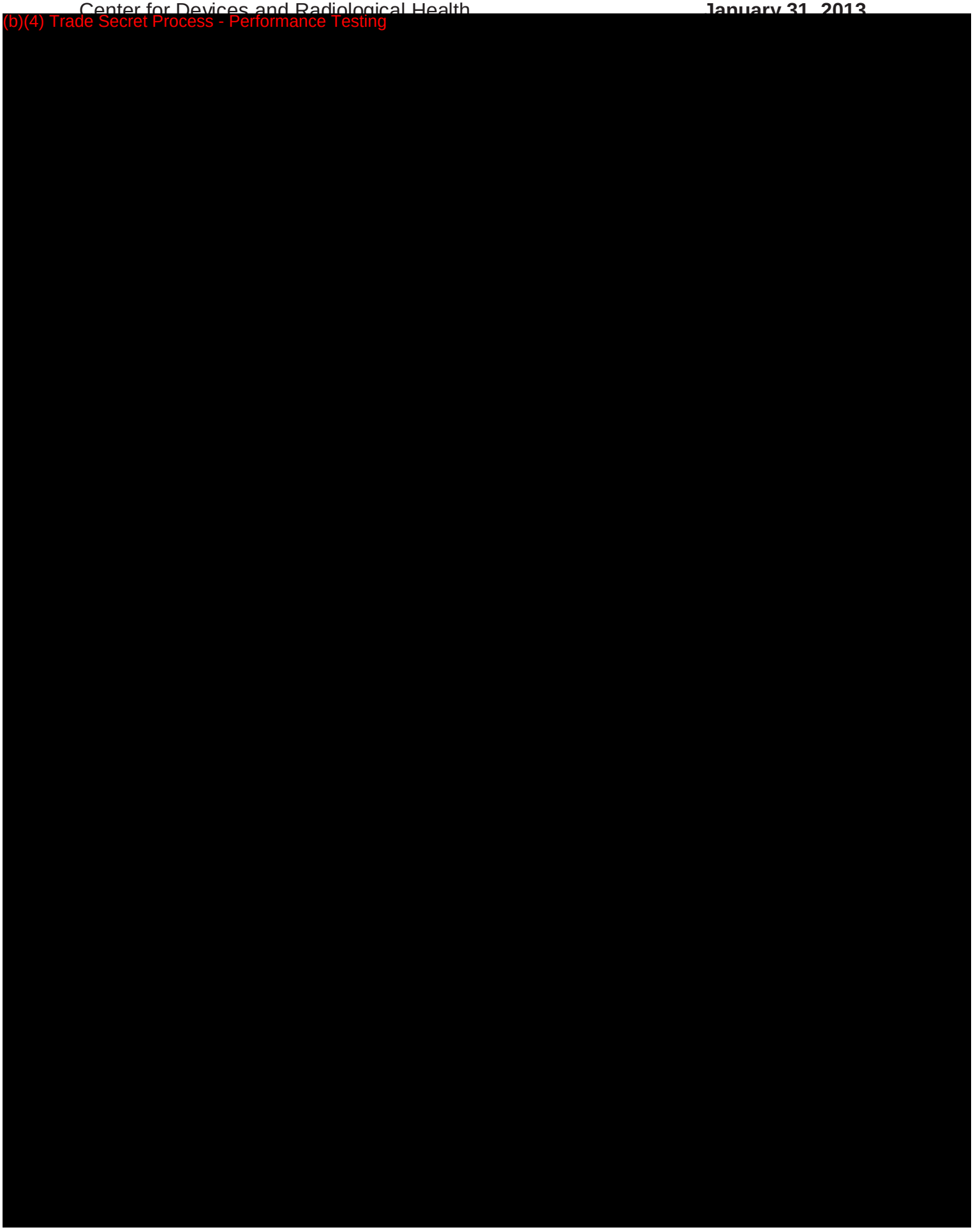

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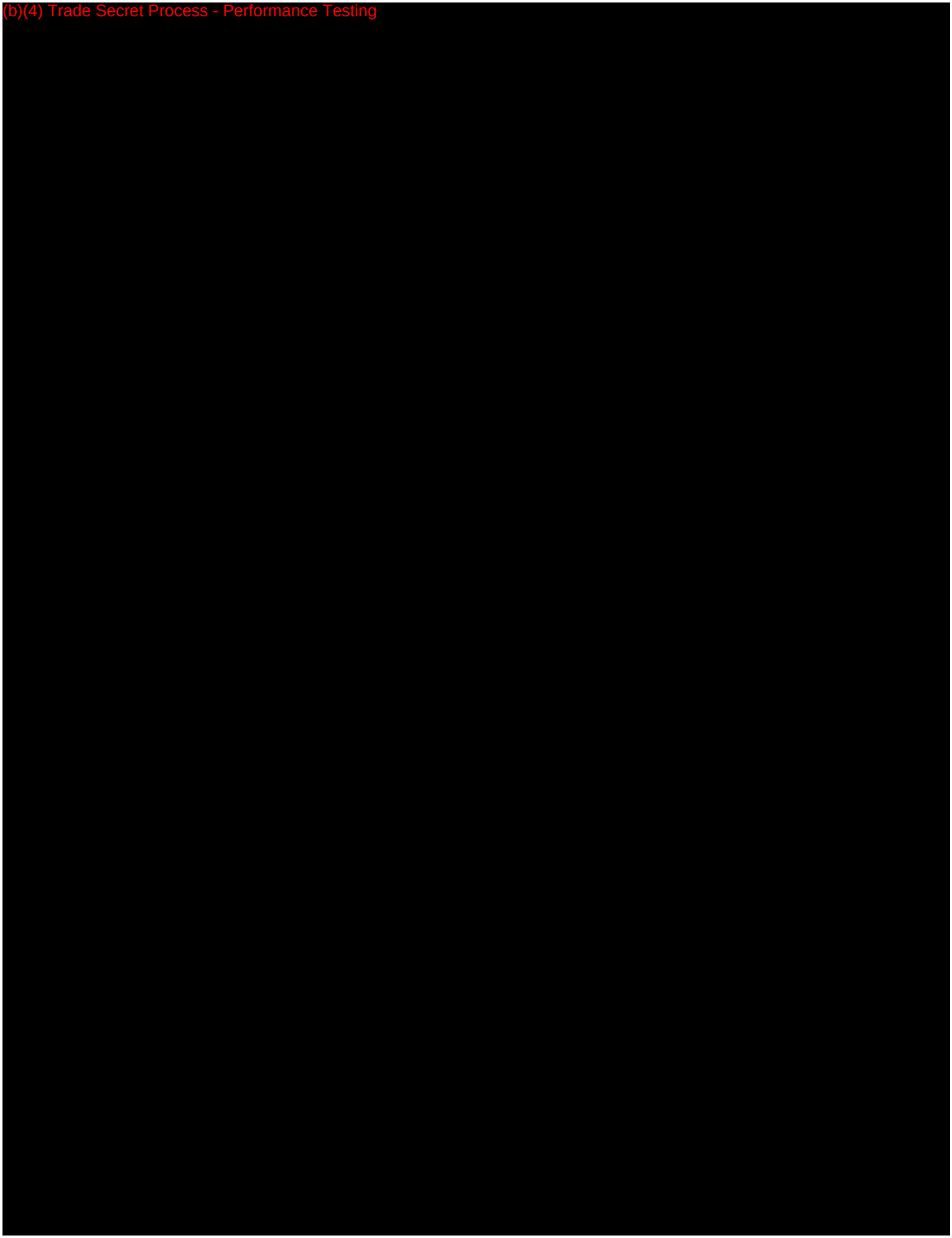

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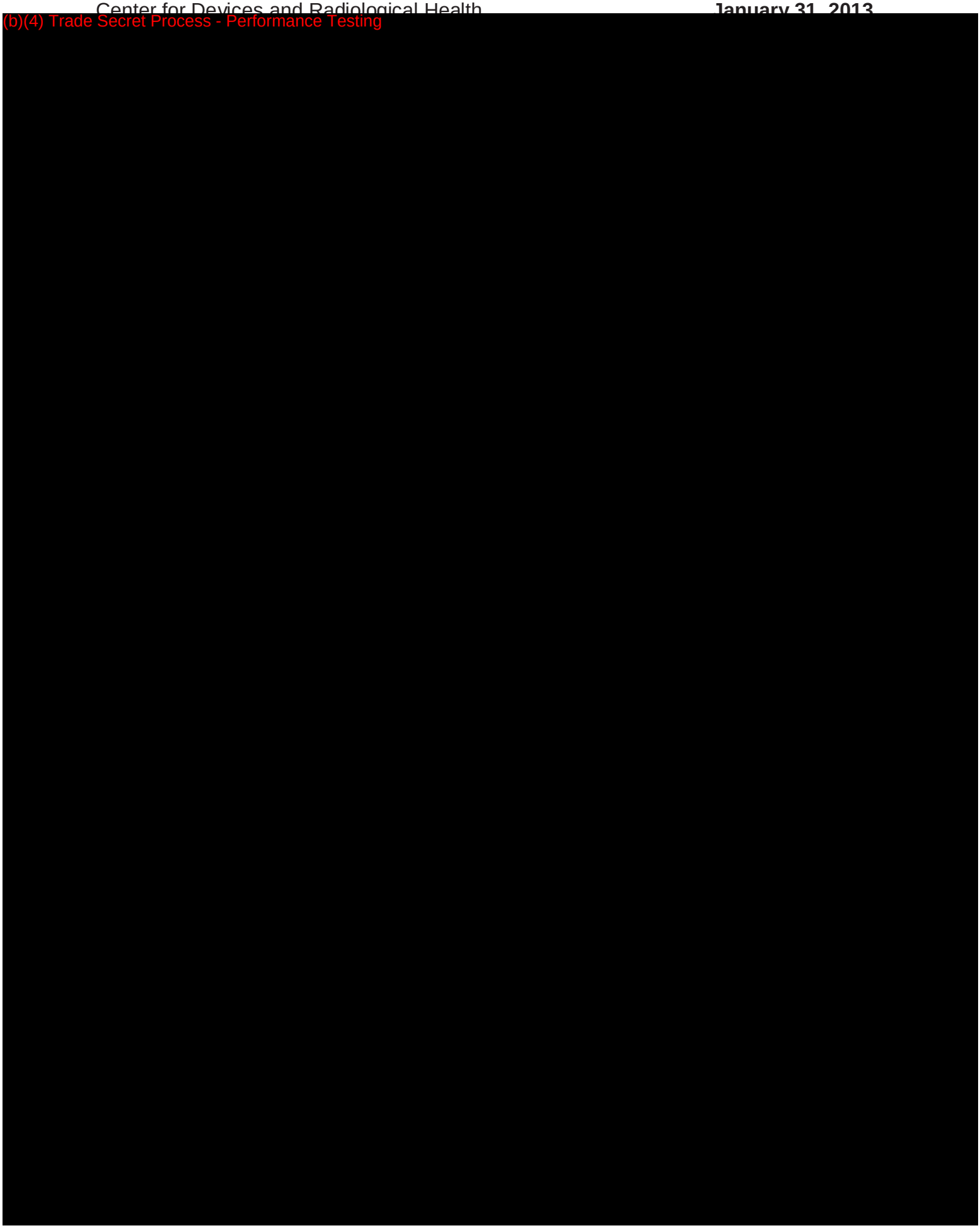

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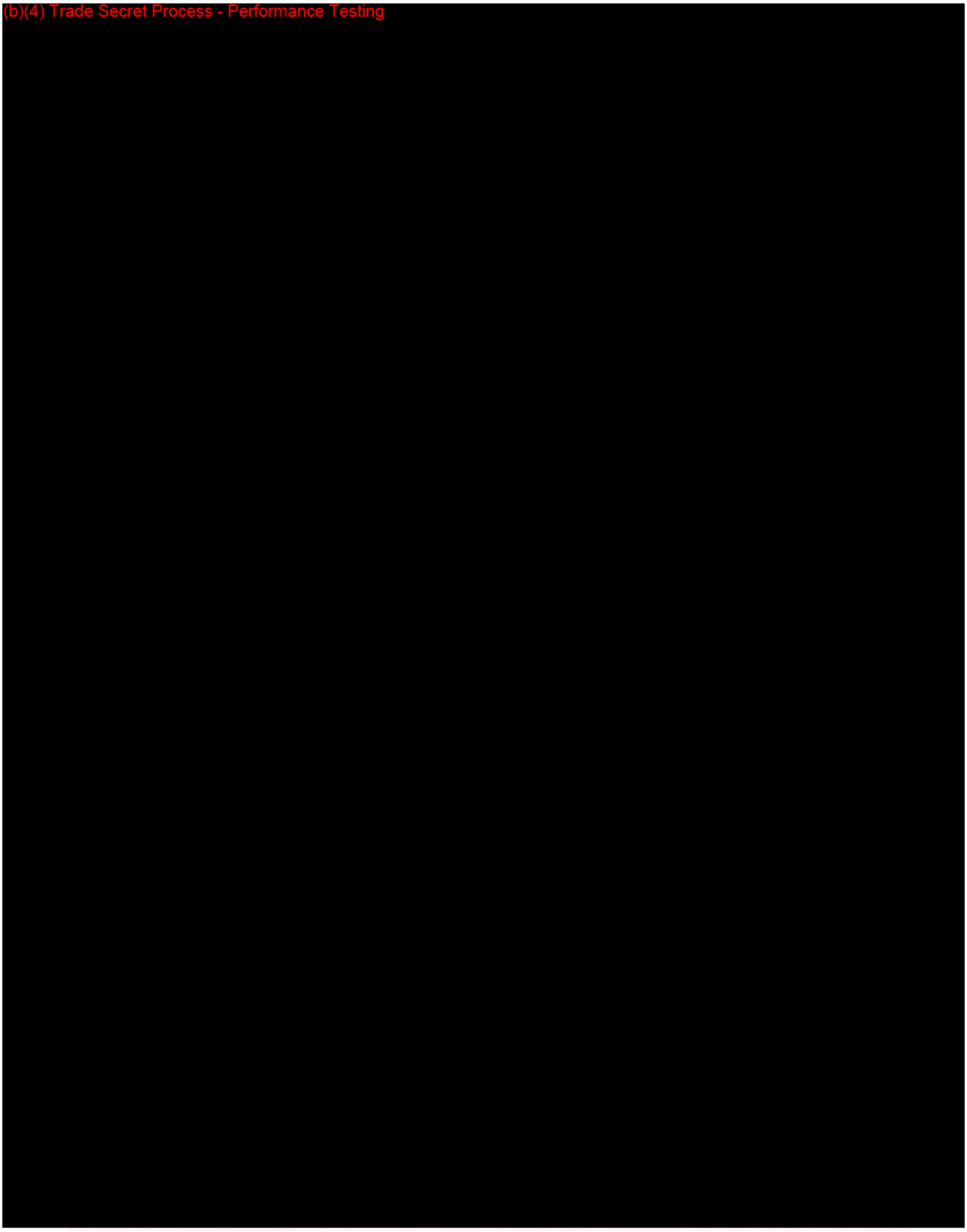

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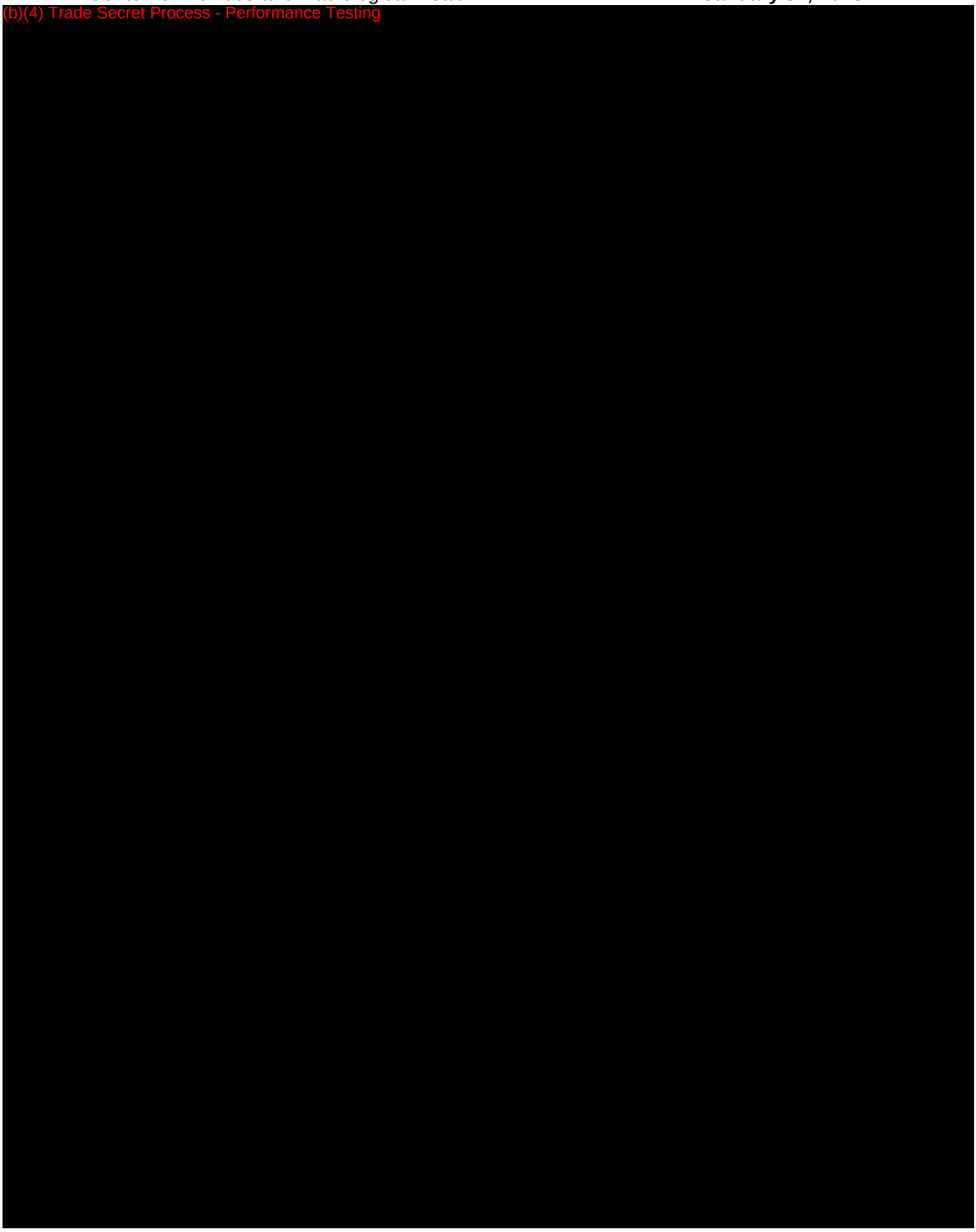

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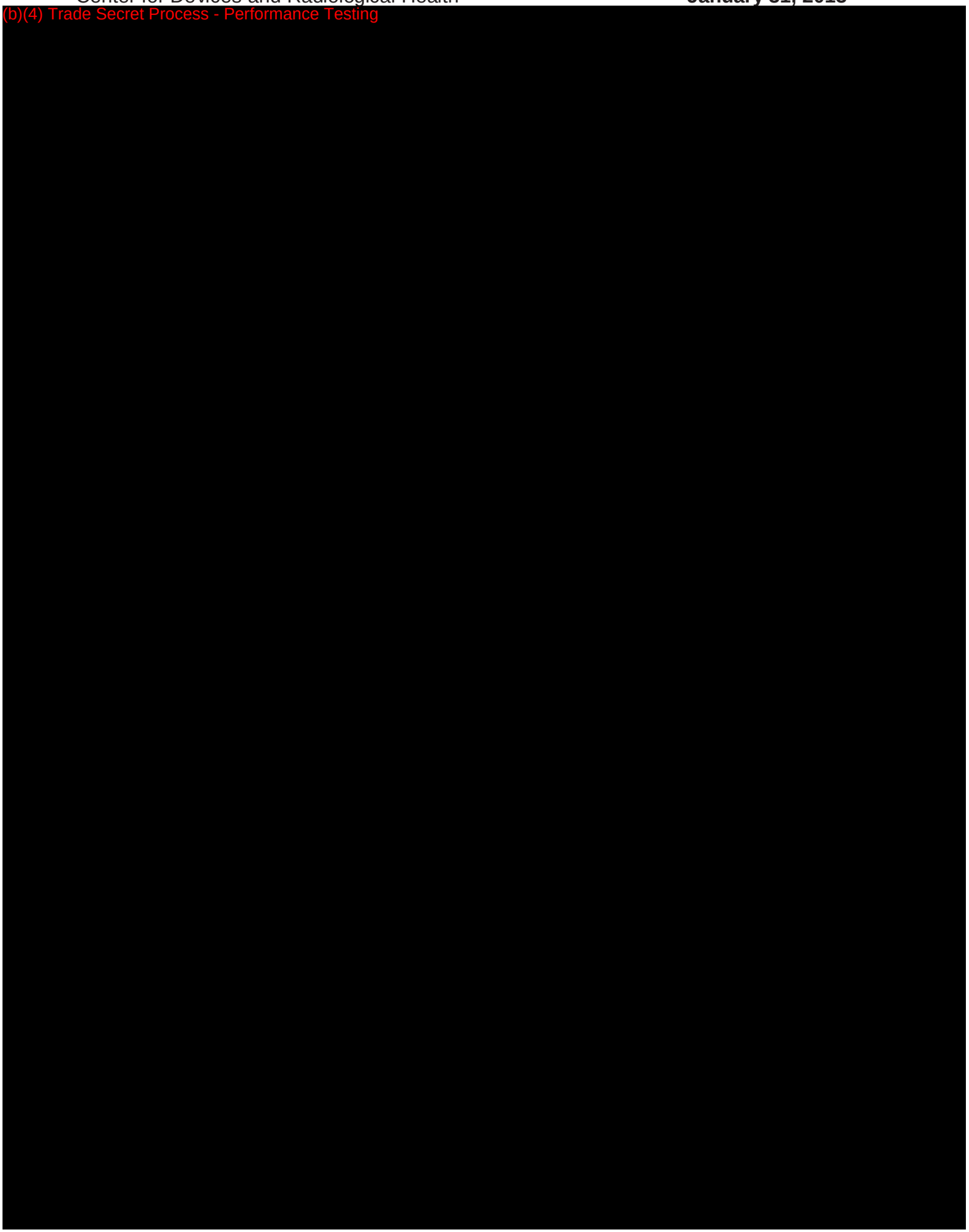

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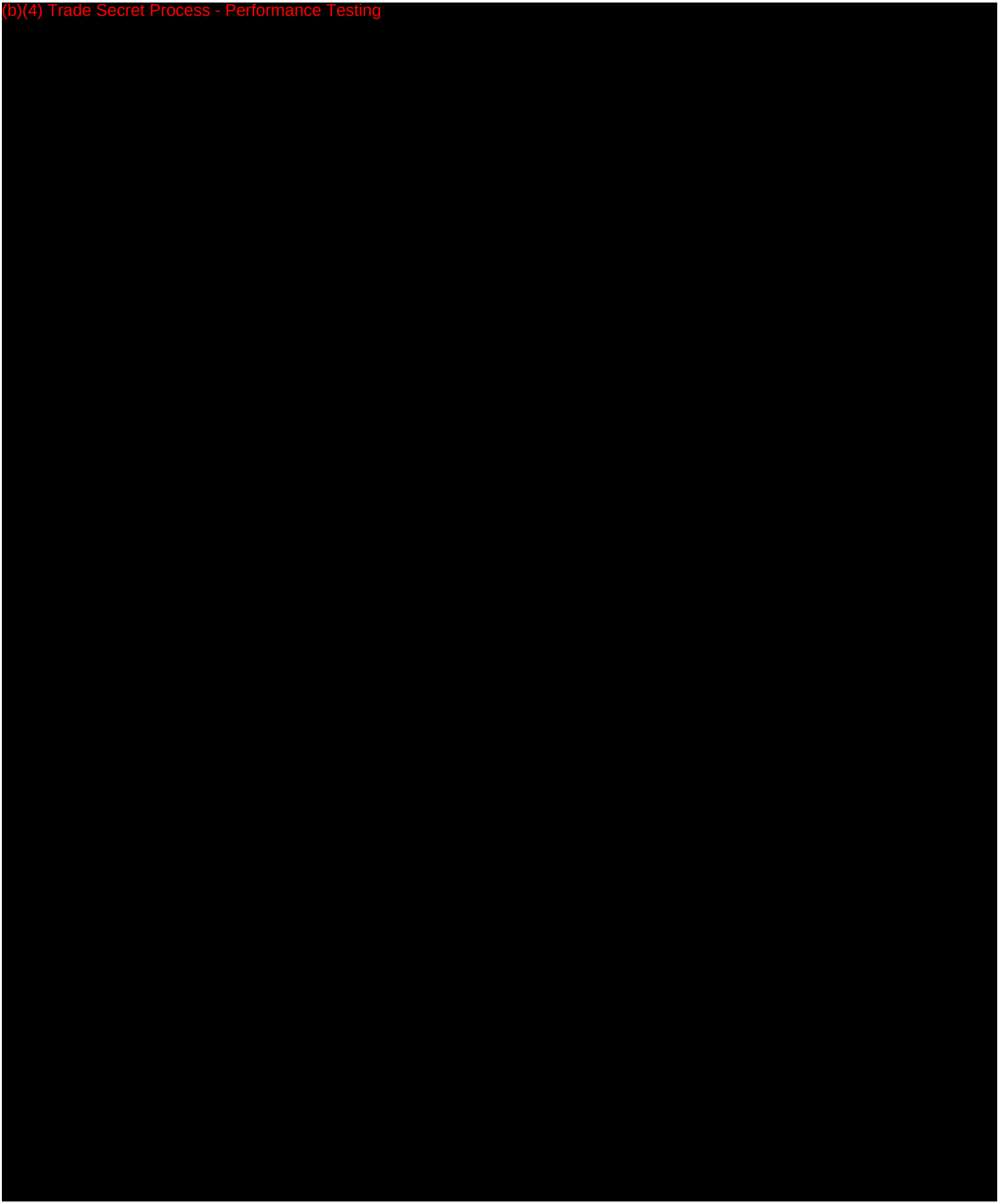

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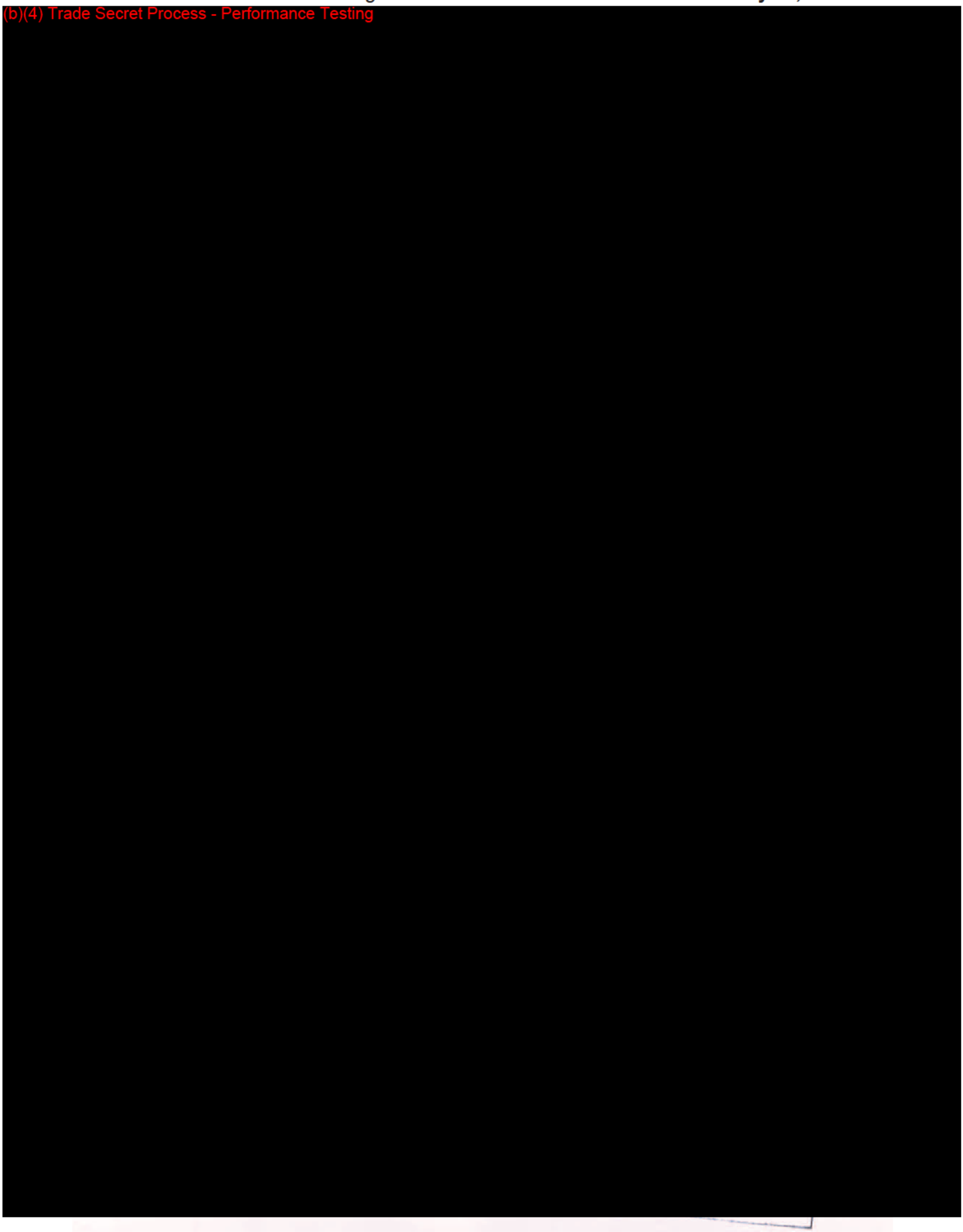

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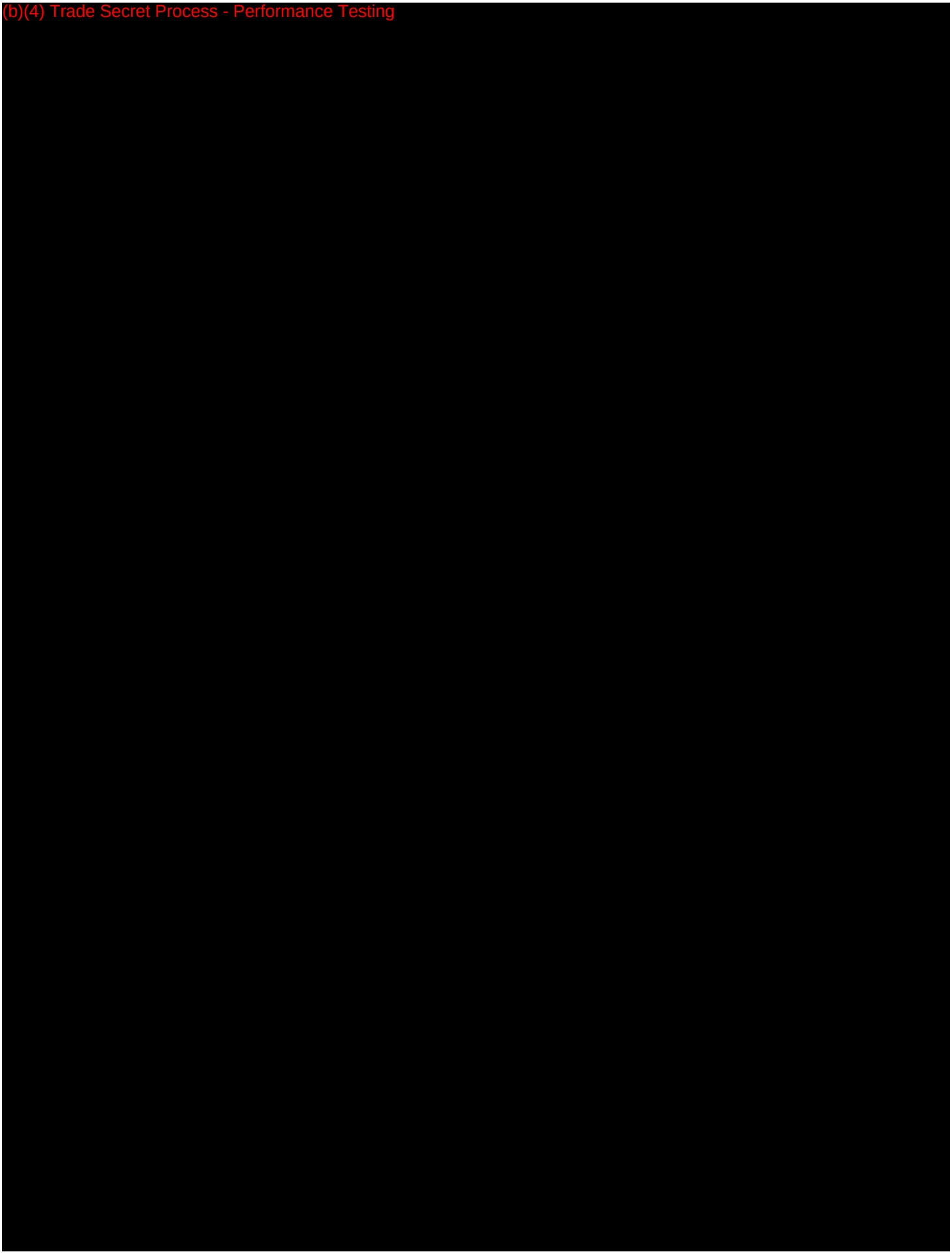

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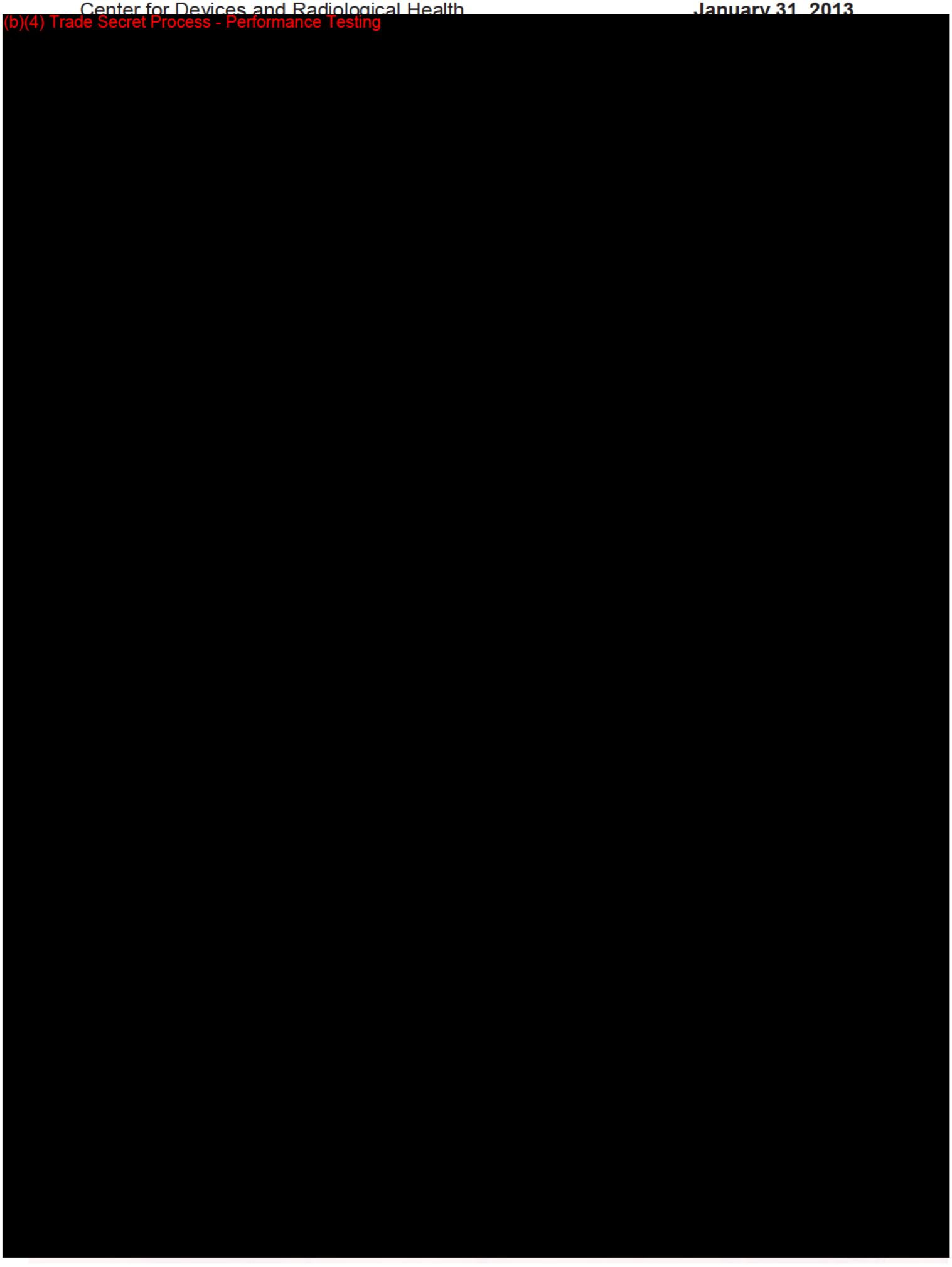

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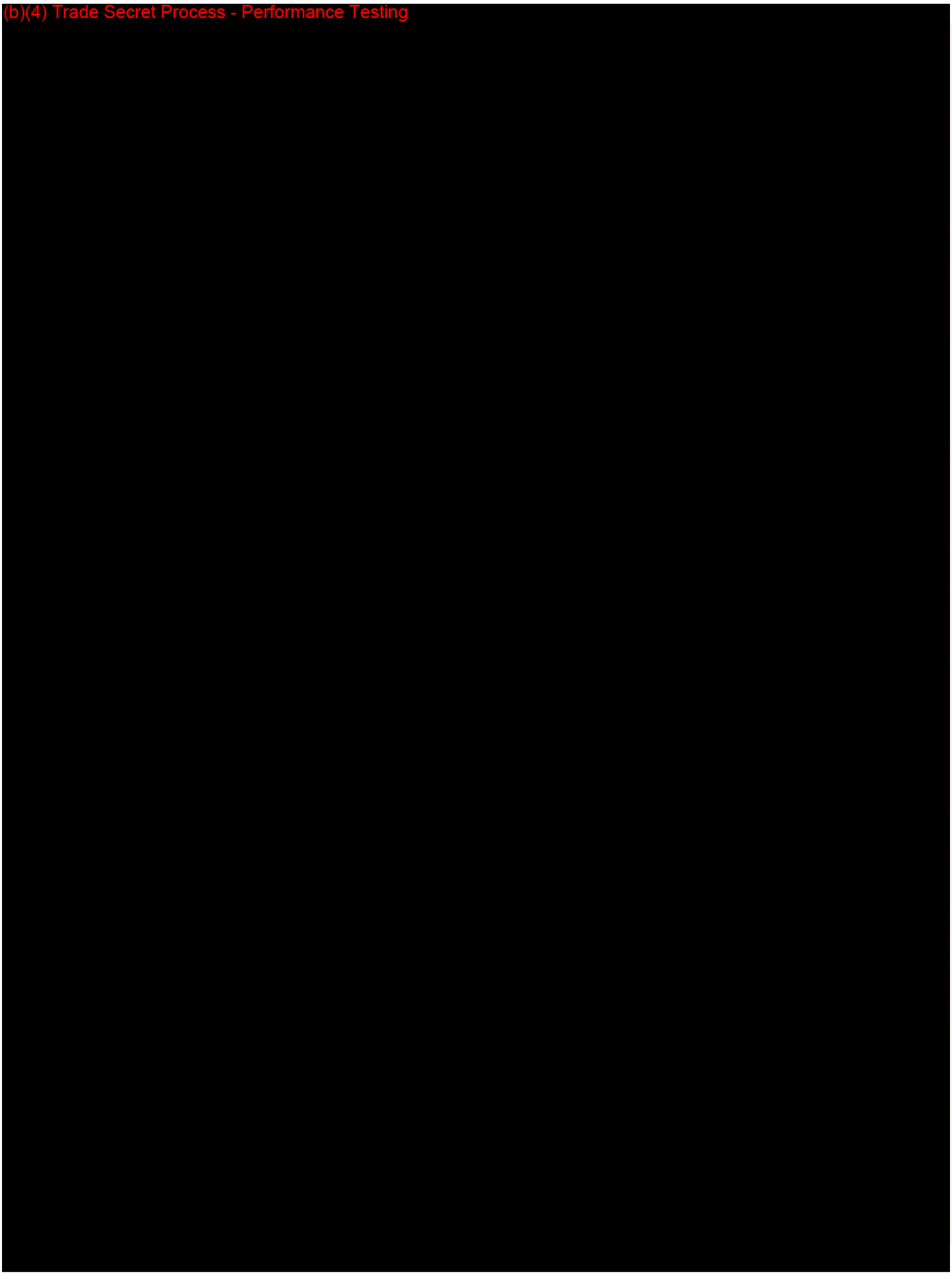

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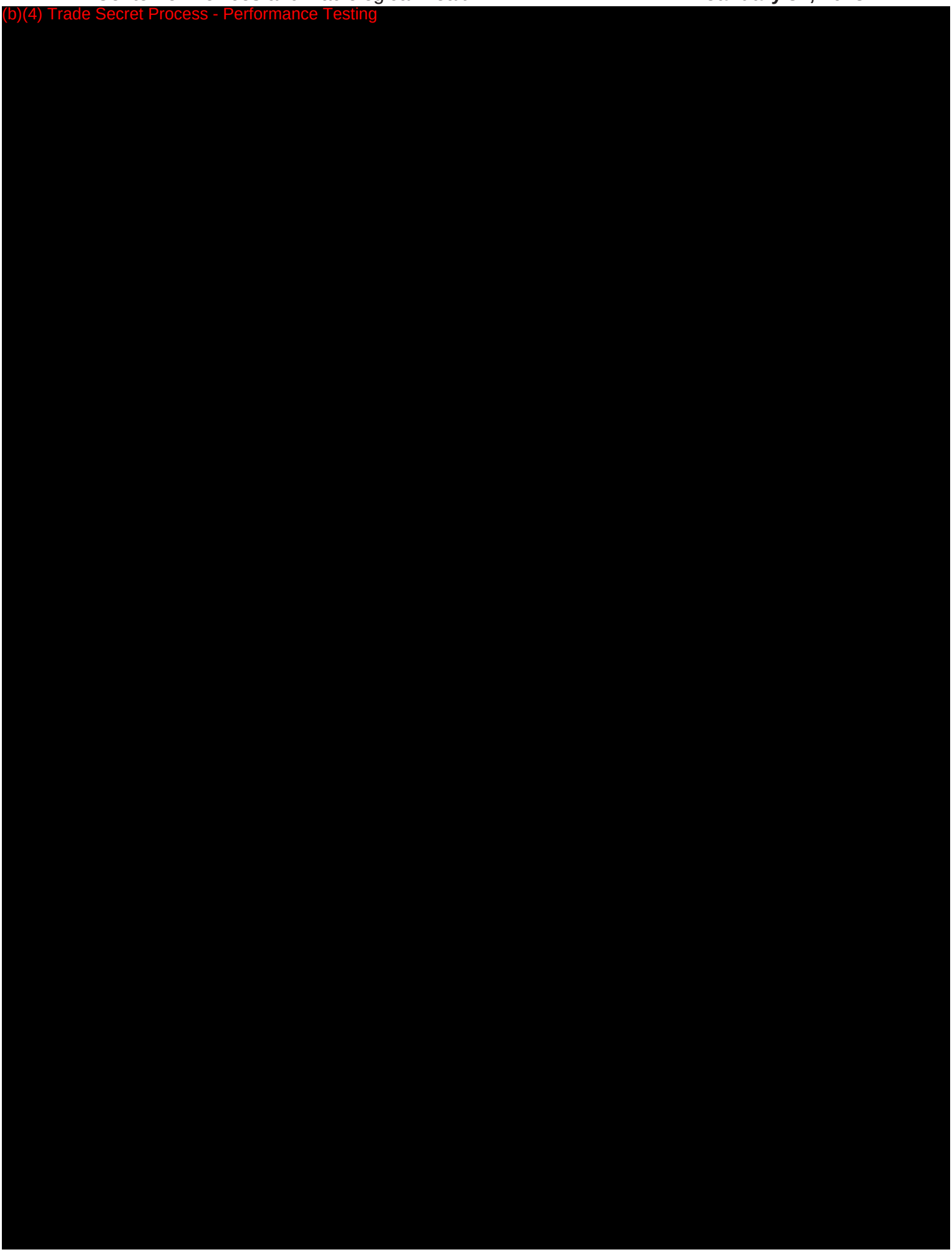

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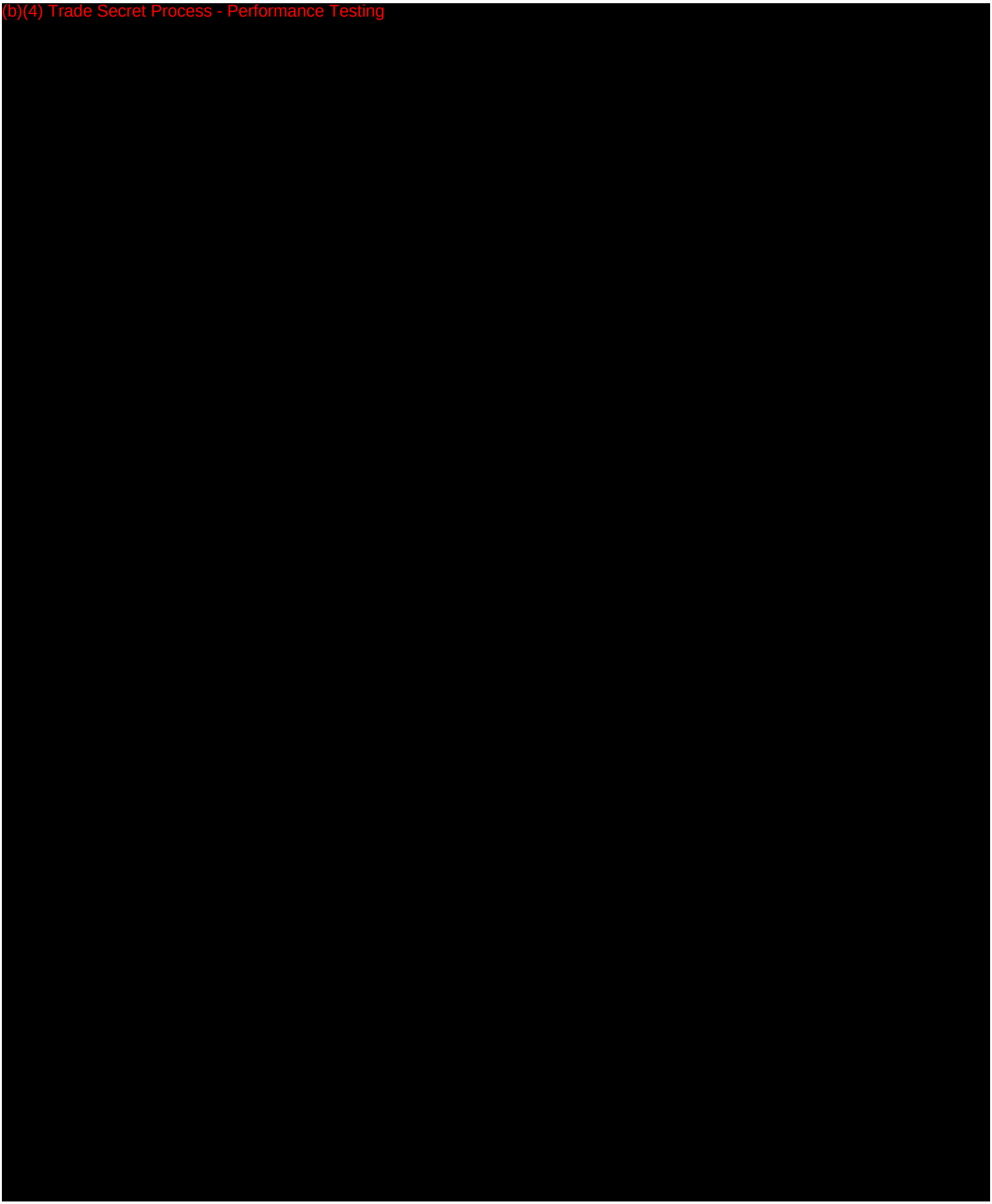

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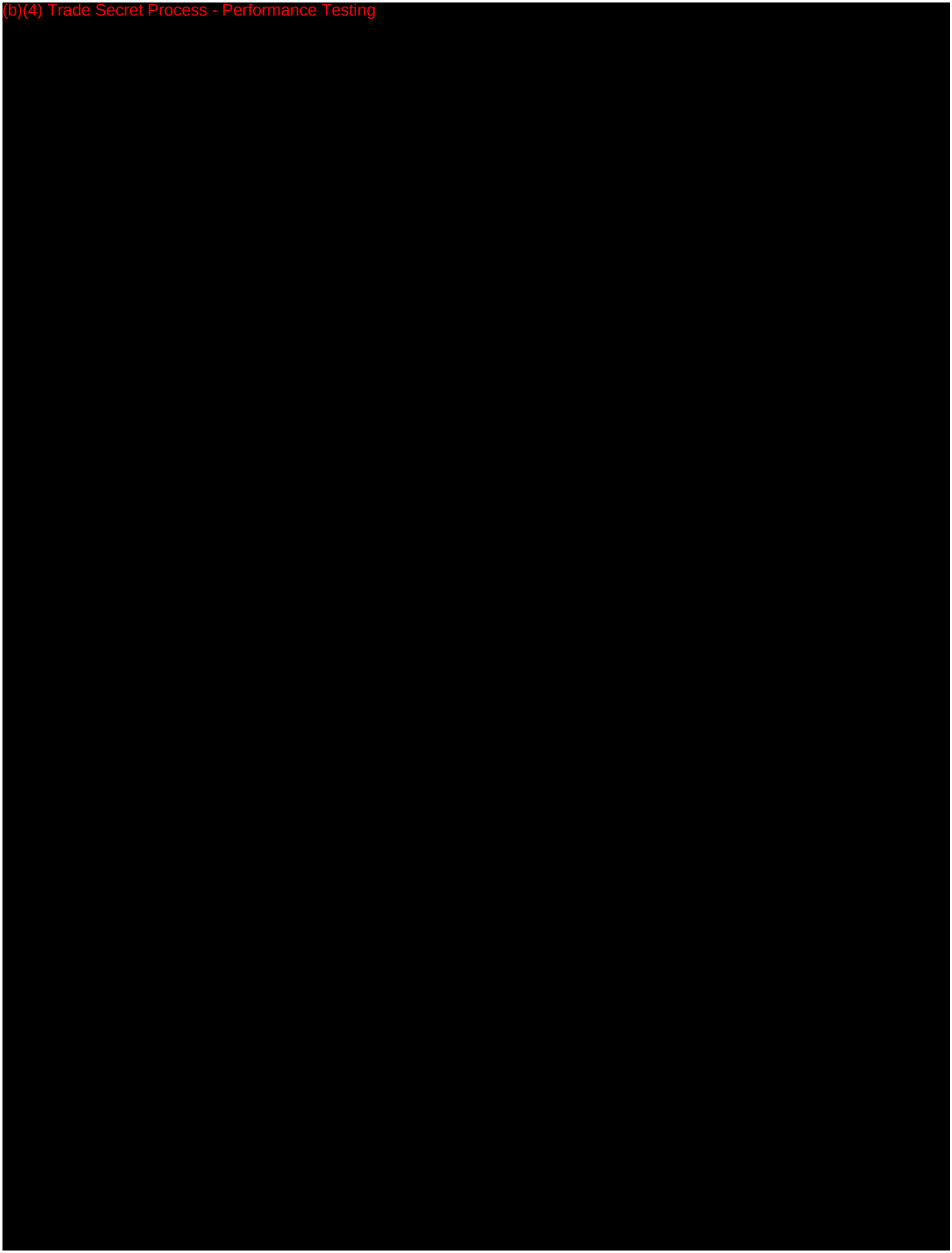

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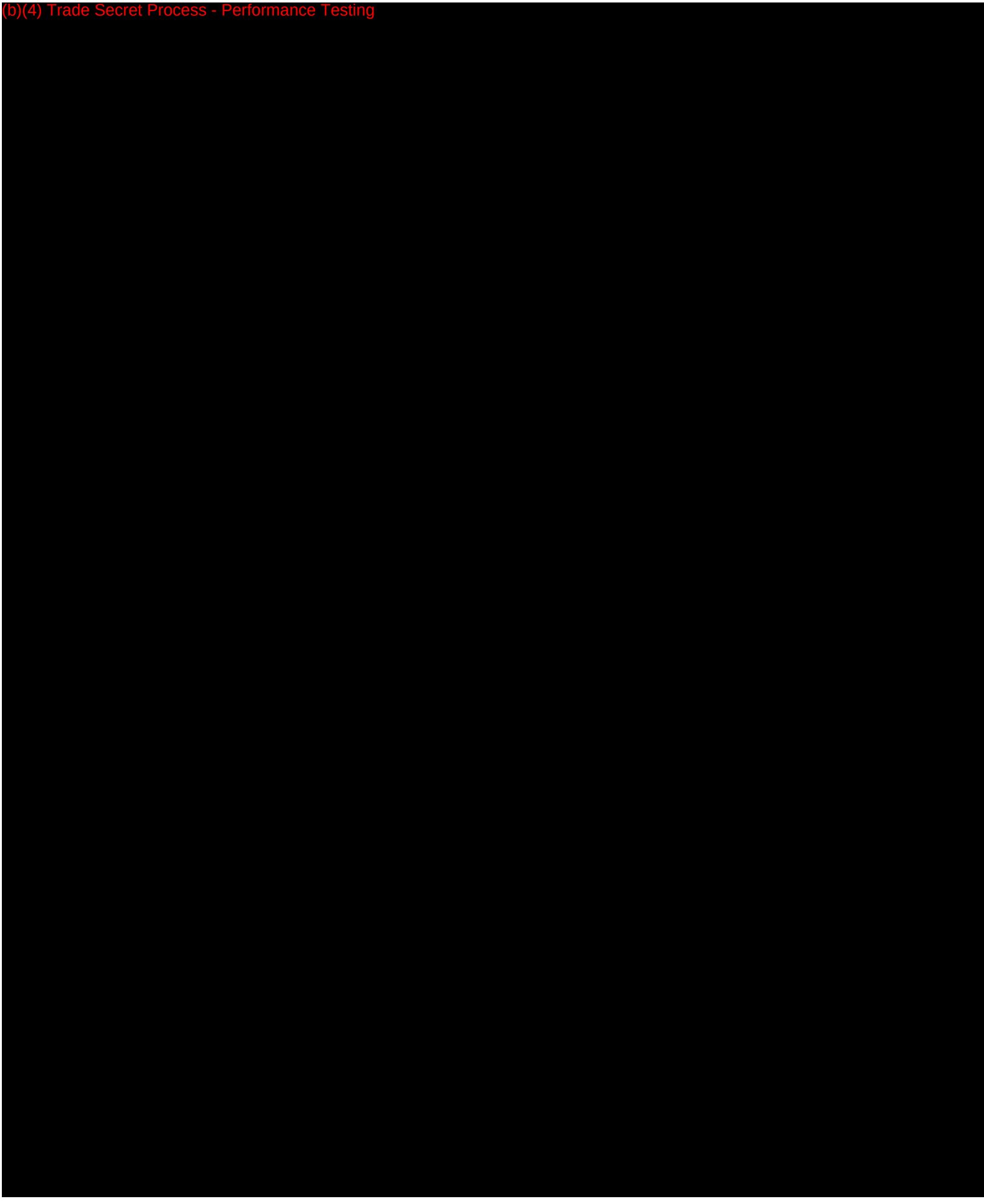

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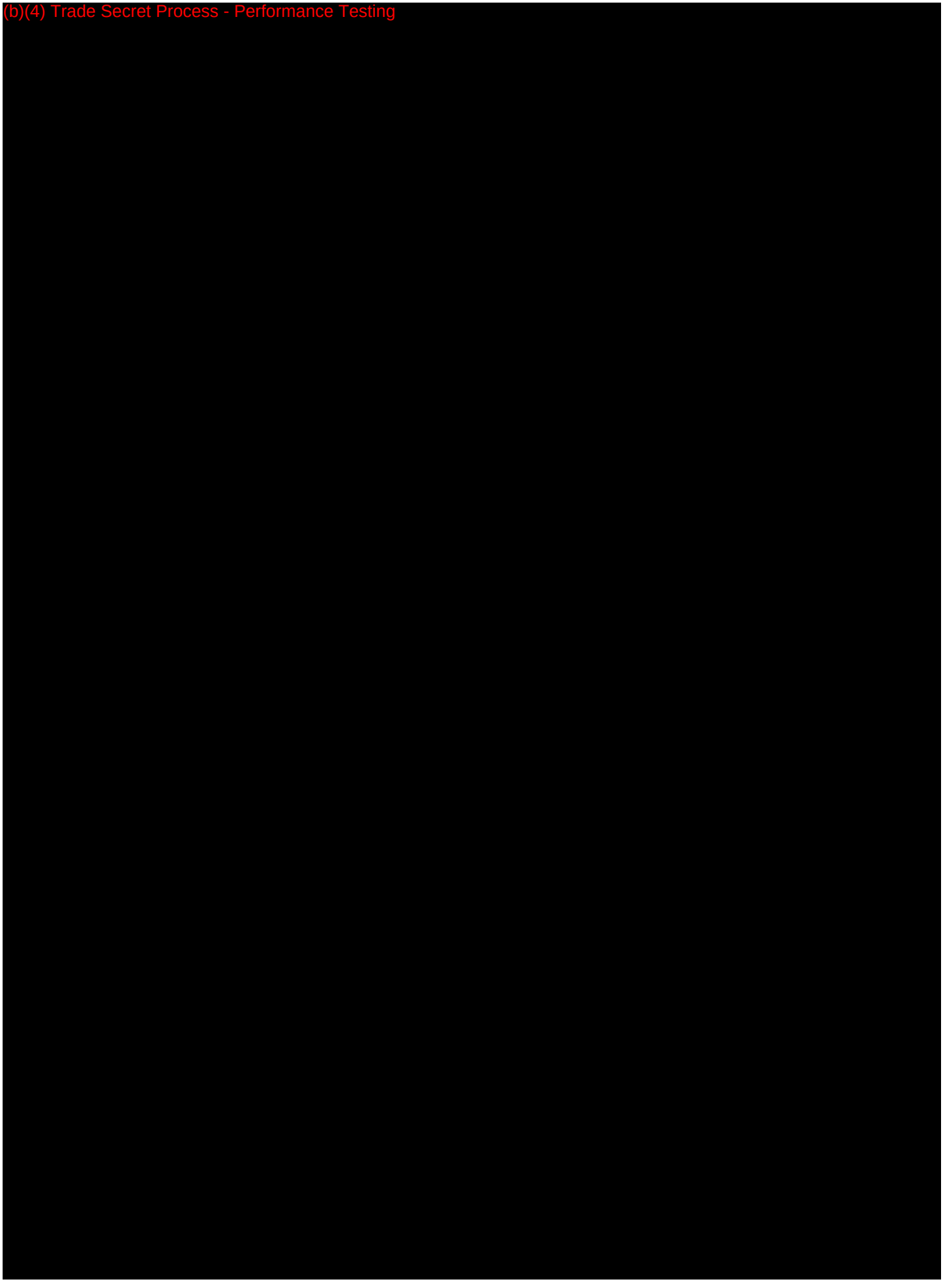

19. Performance Testing – Animal

No animal testing has been conducted with the Laser Lipo 'Strawberry' and 'Strawberry' and Cream low level laser systems.

20. Performance Testing – Clinical

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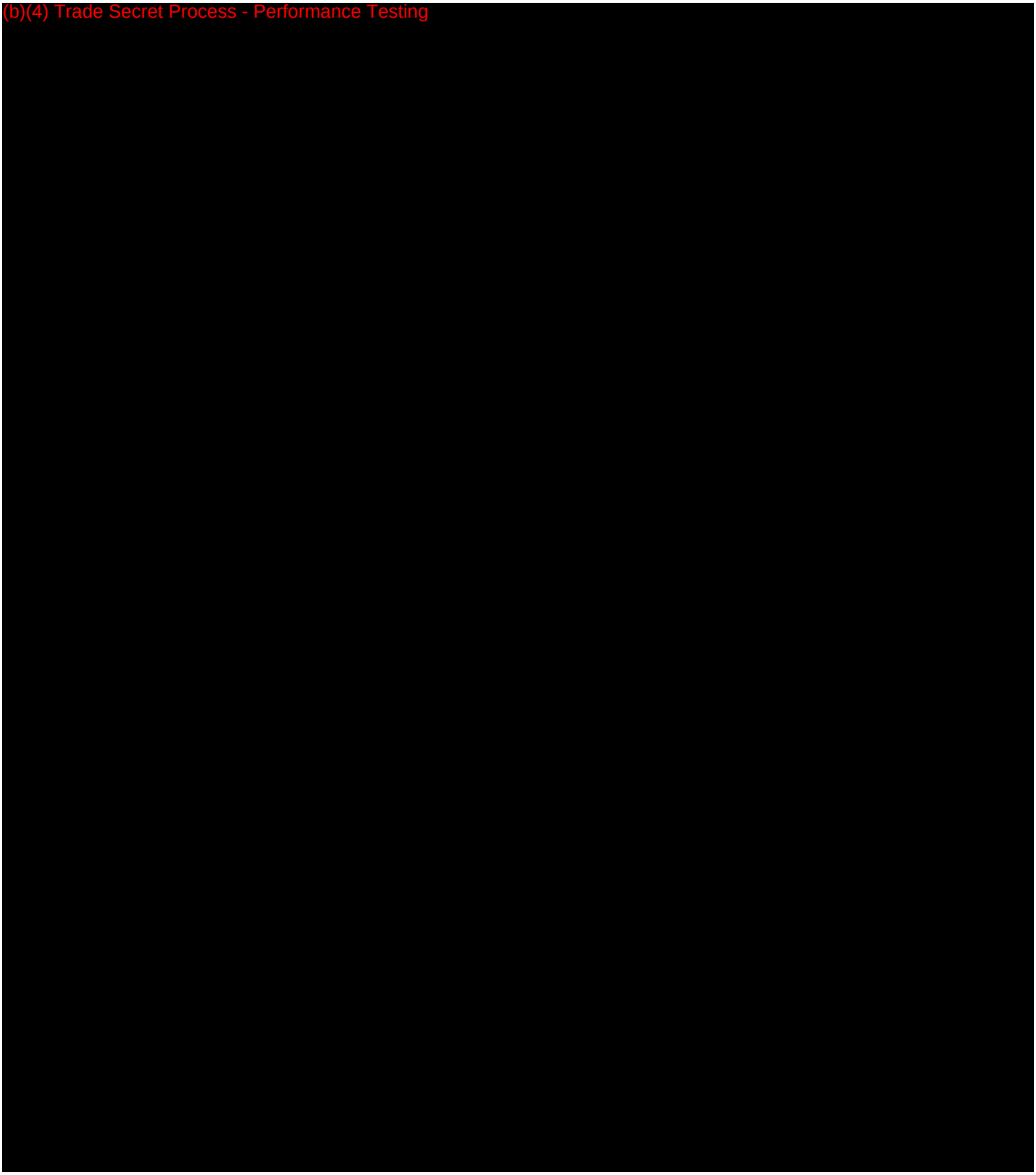

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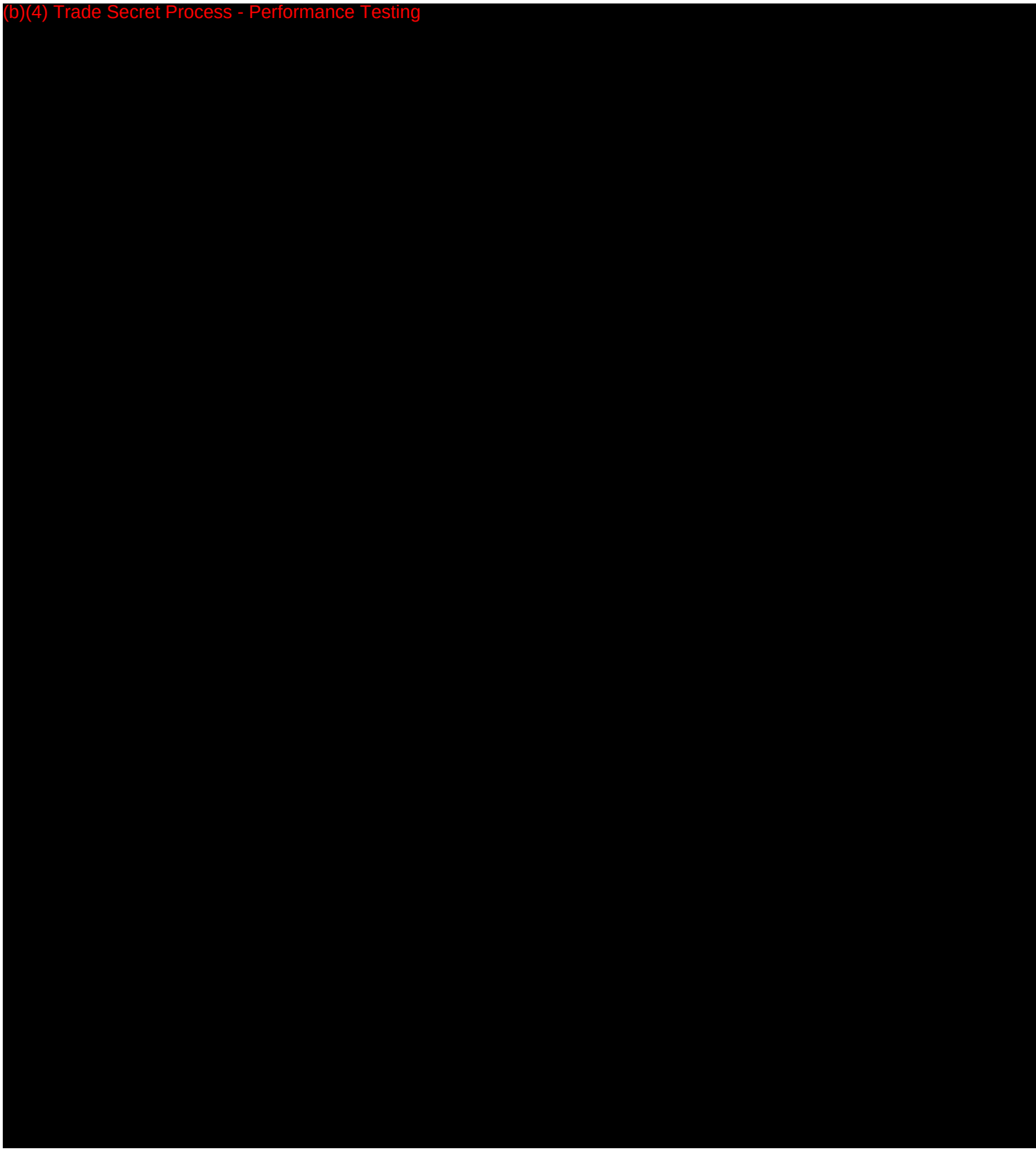

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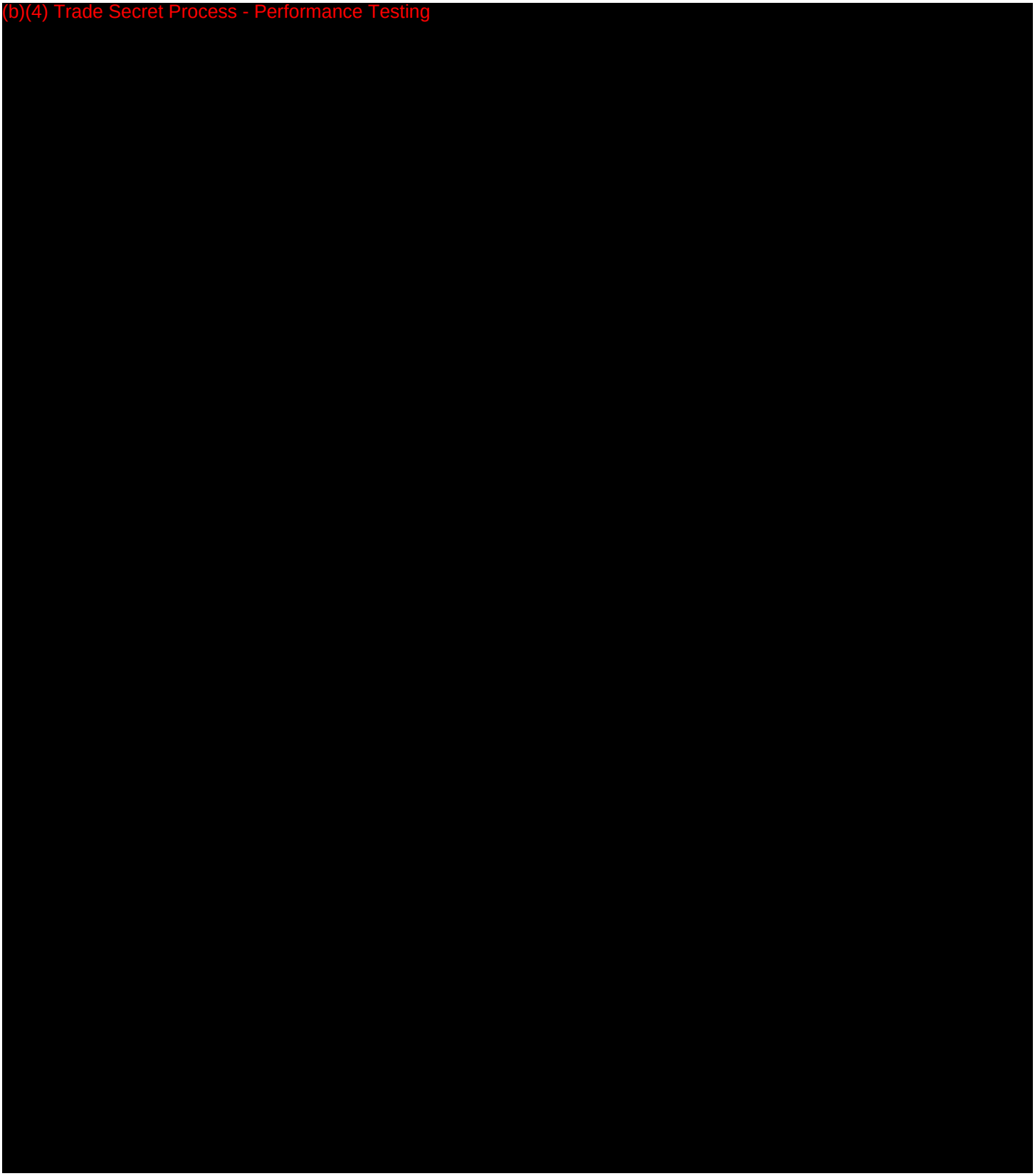

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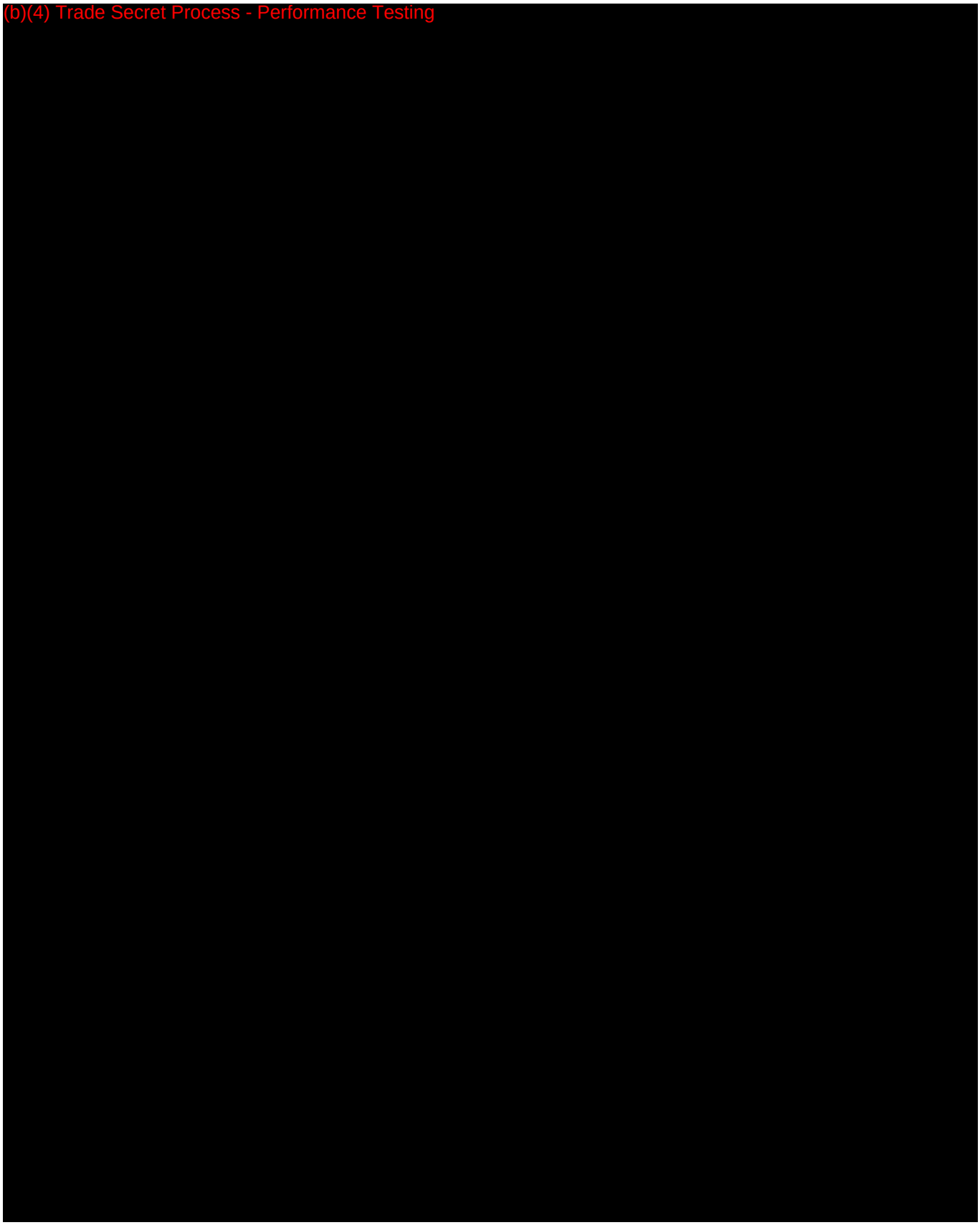

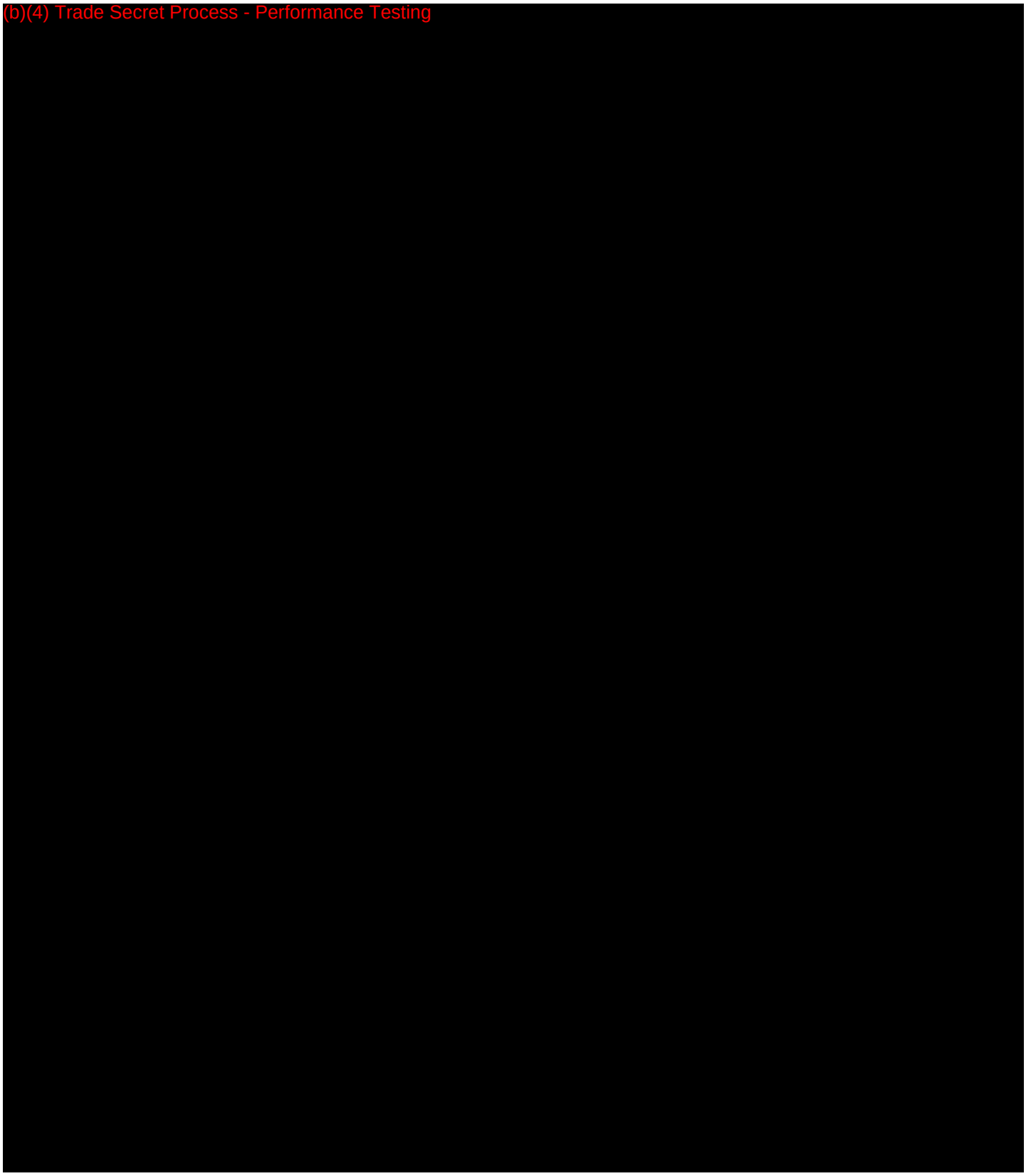
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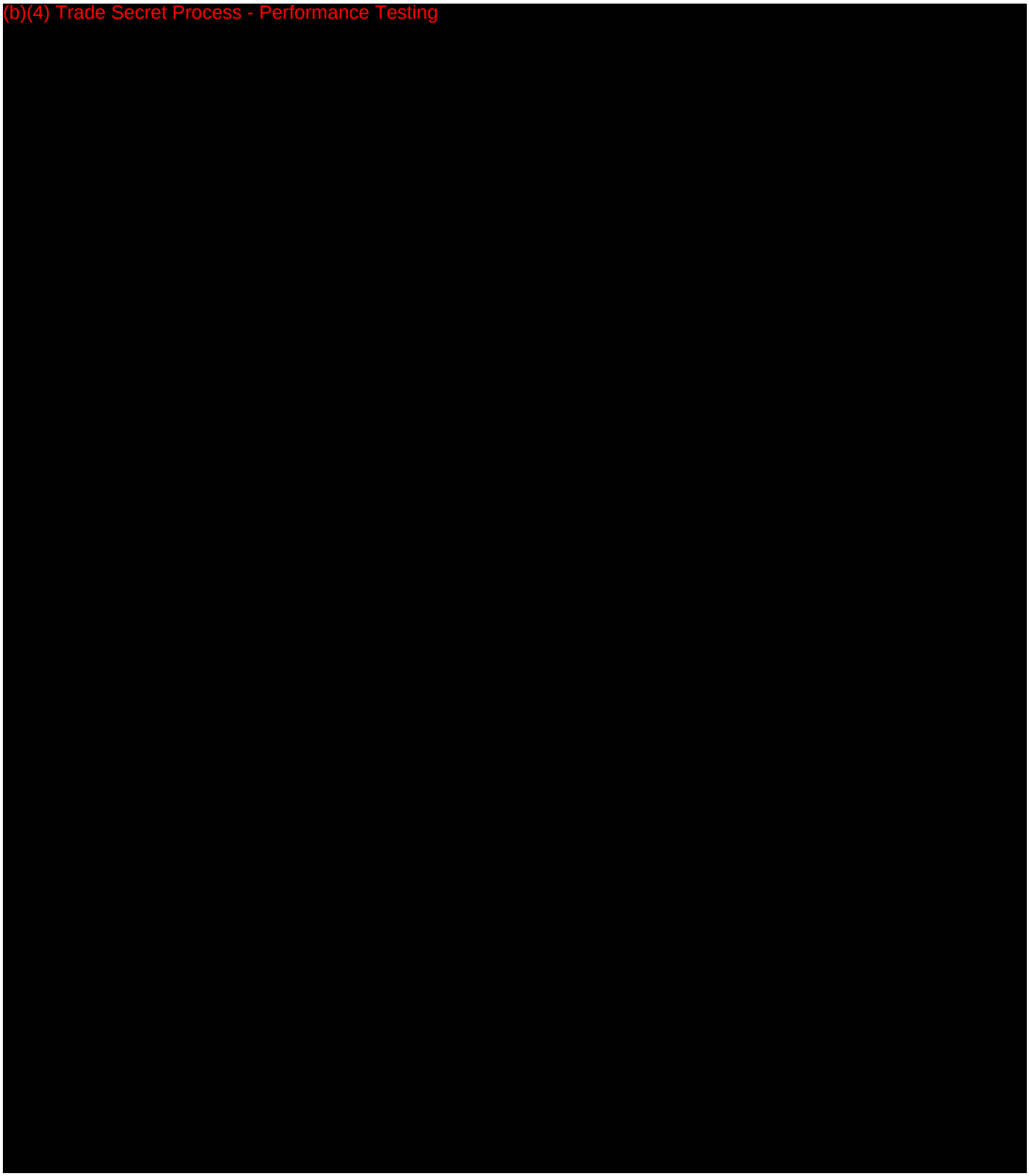

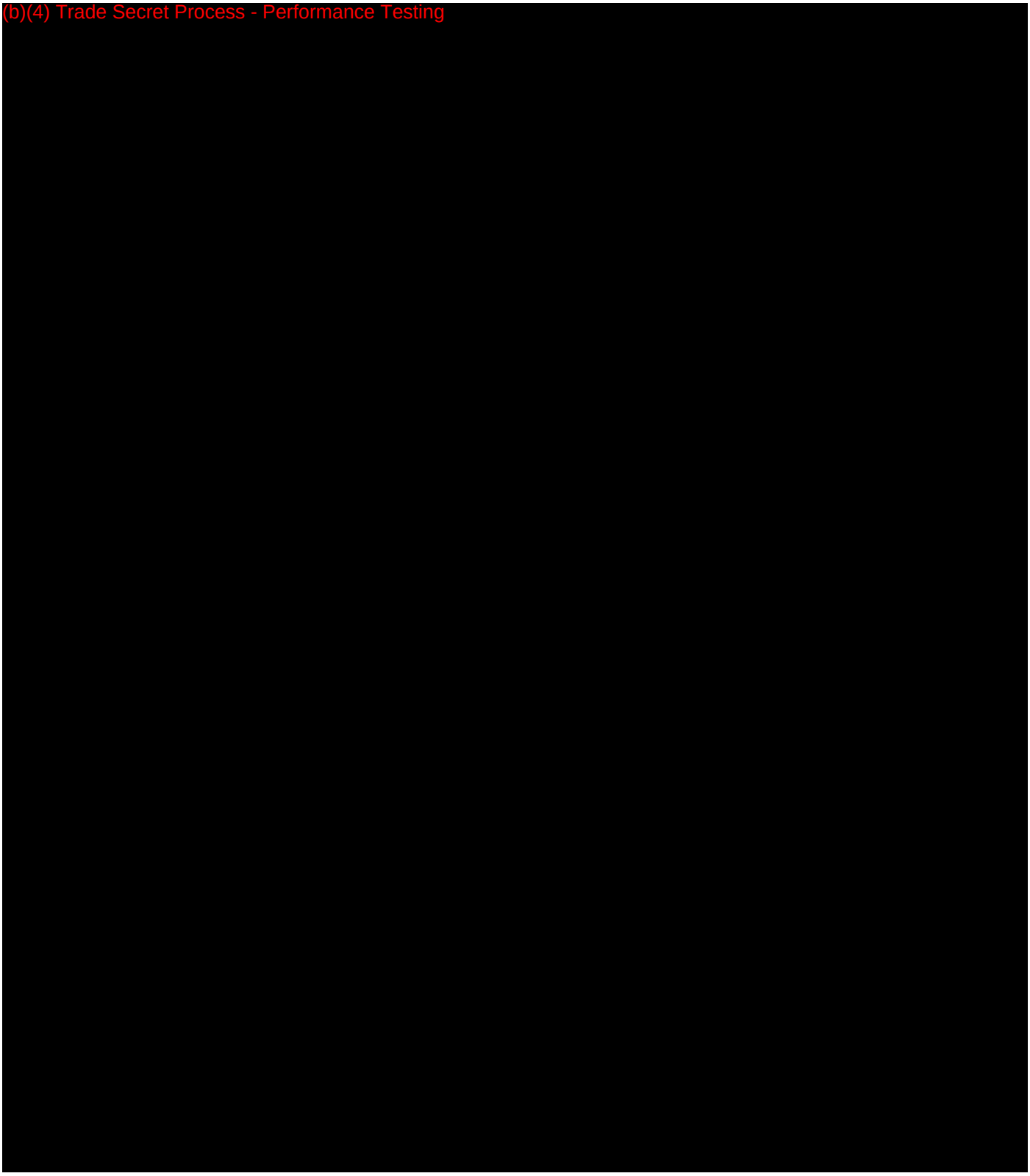
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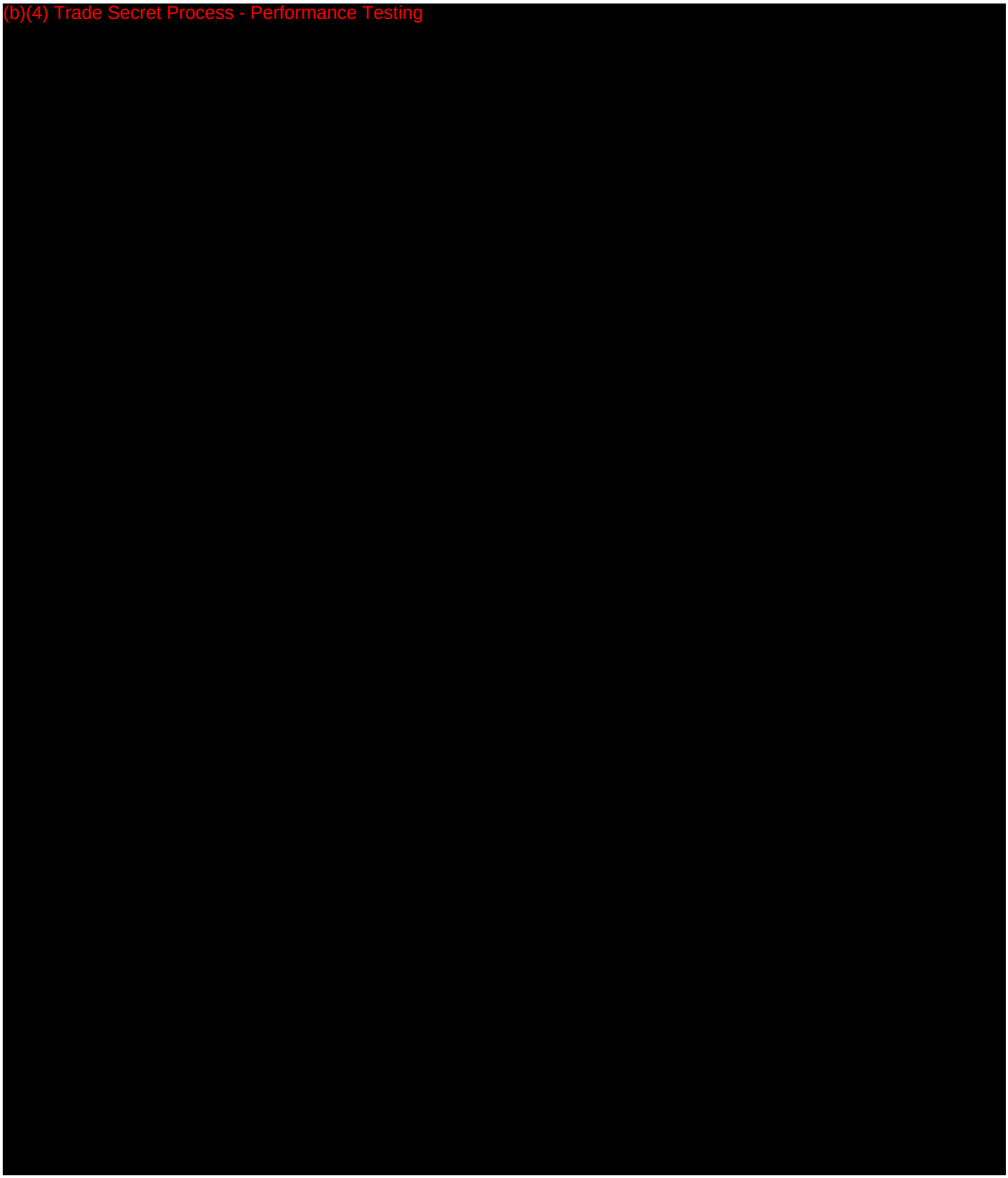

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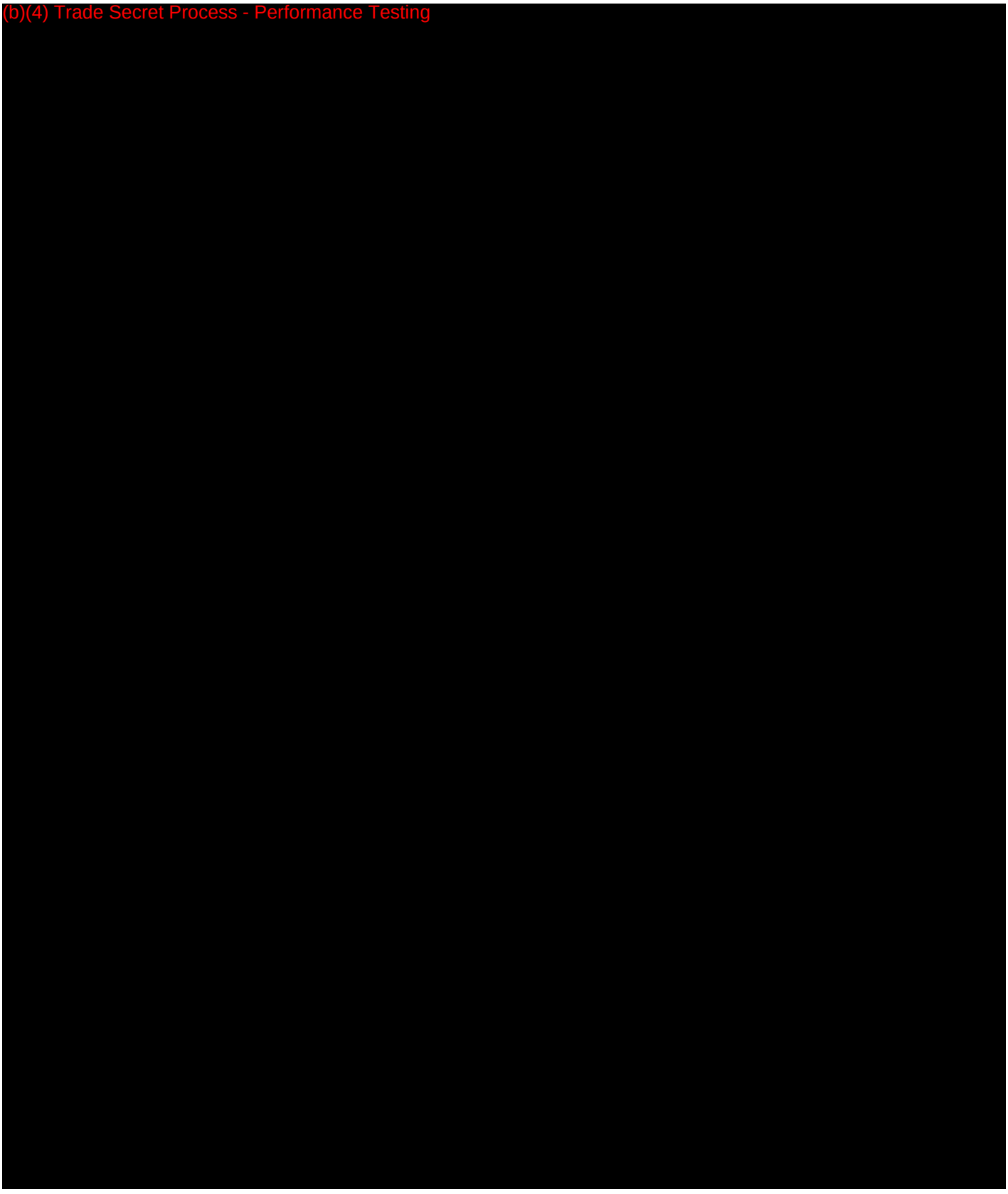

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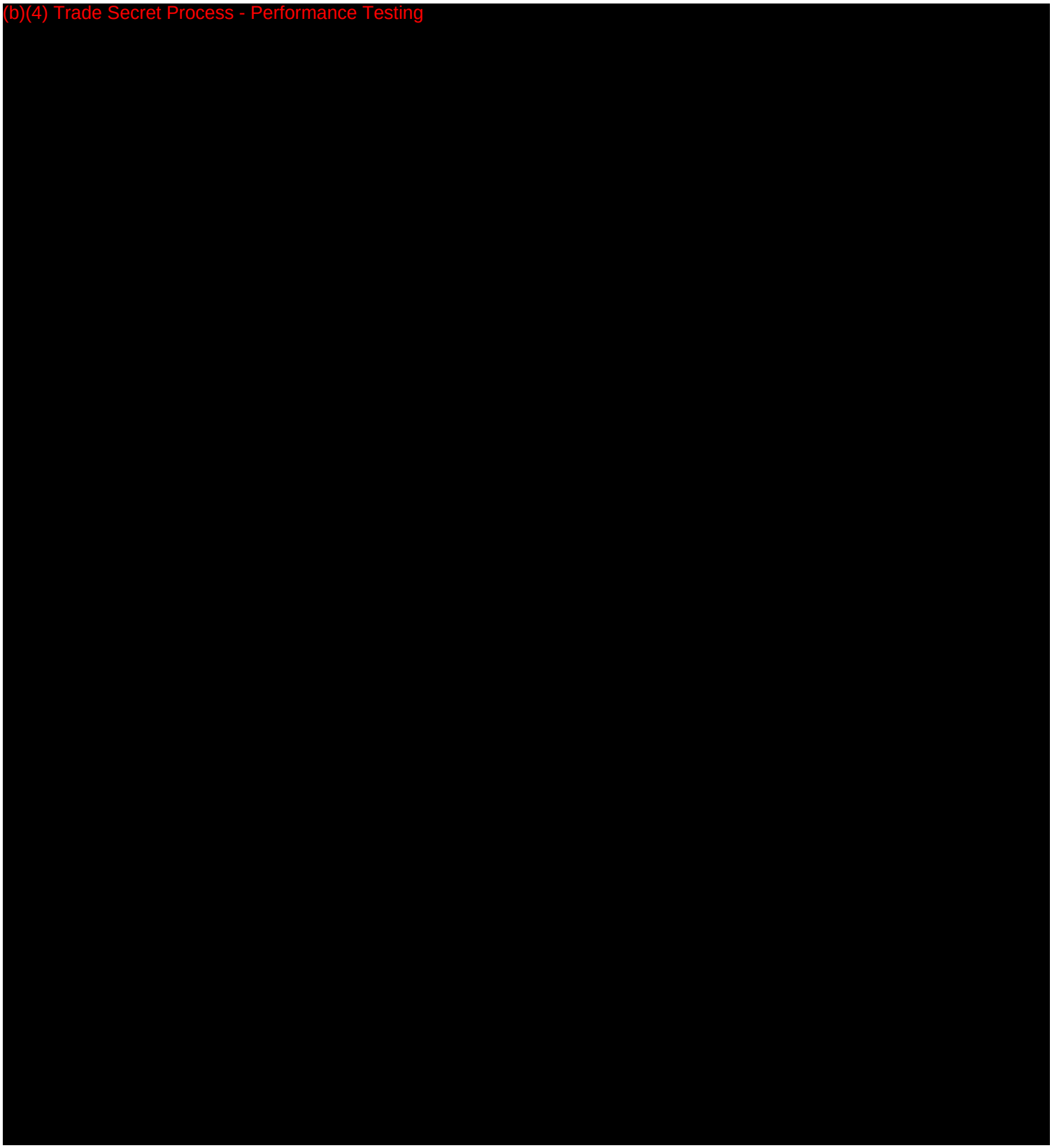

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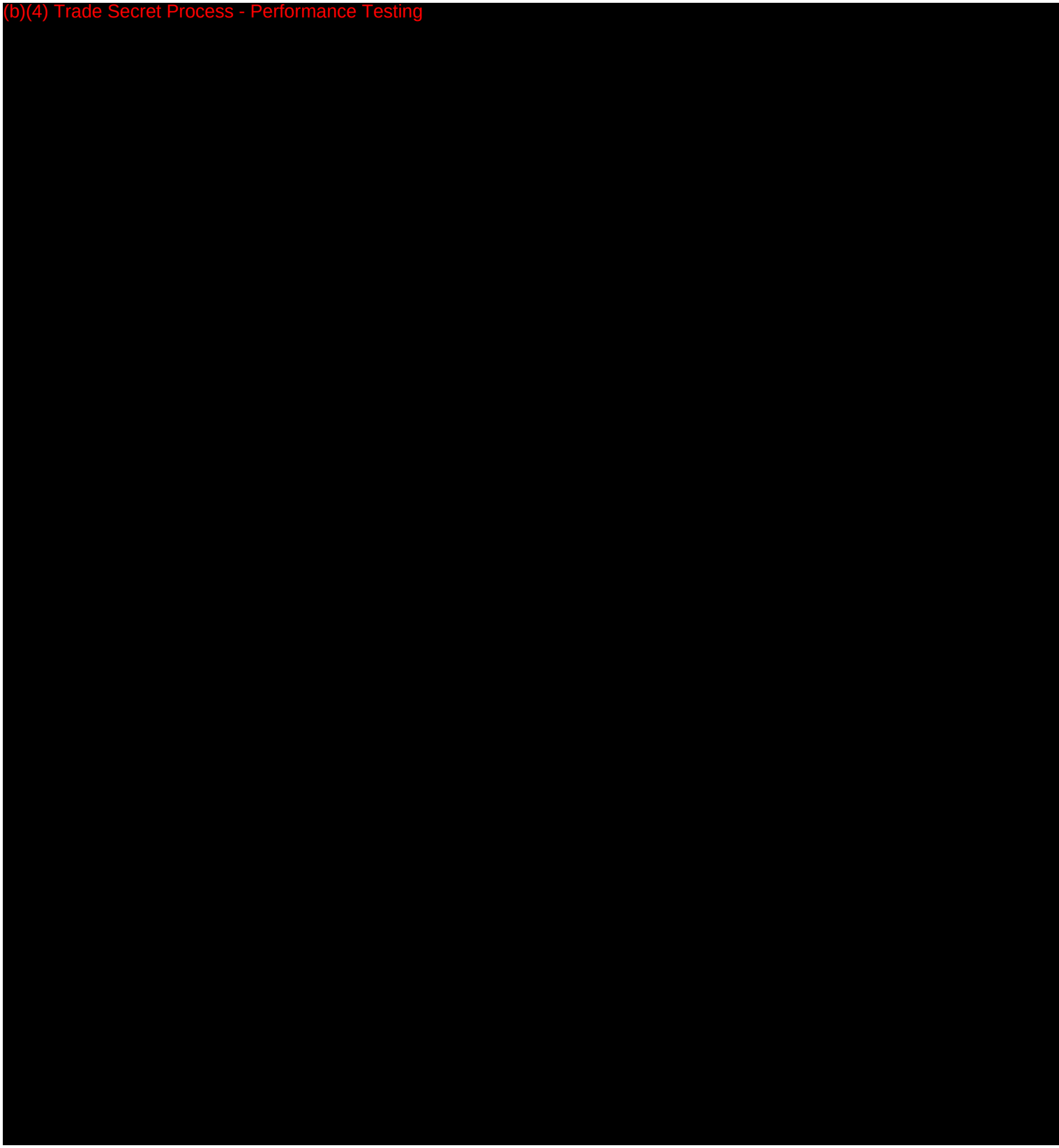

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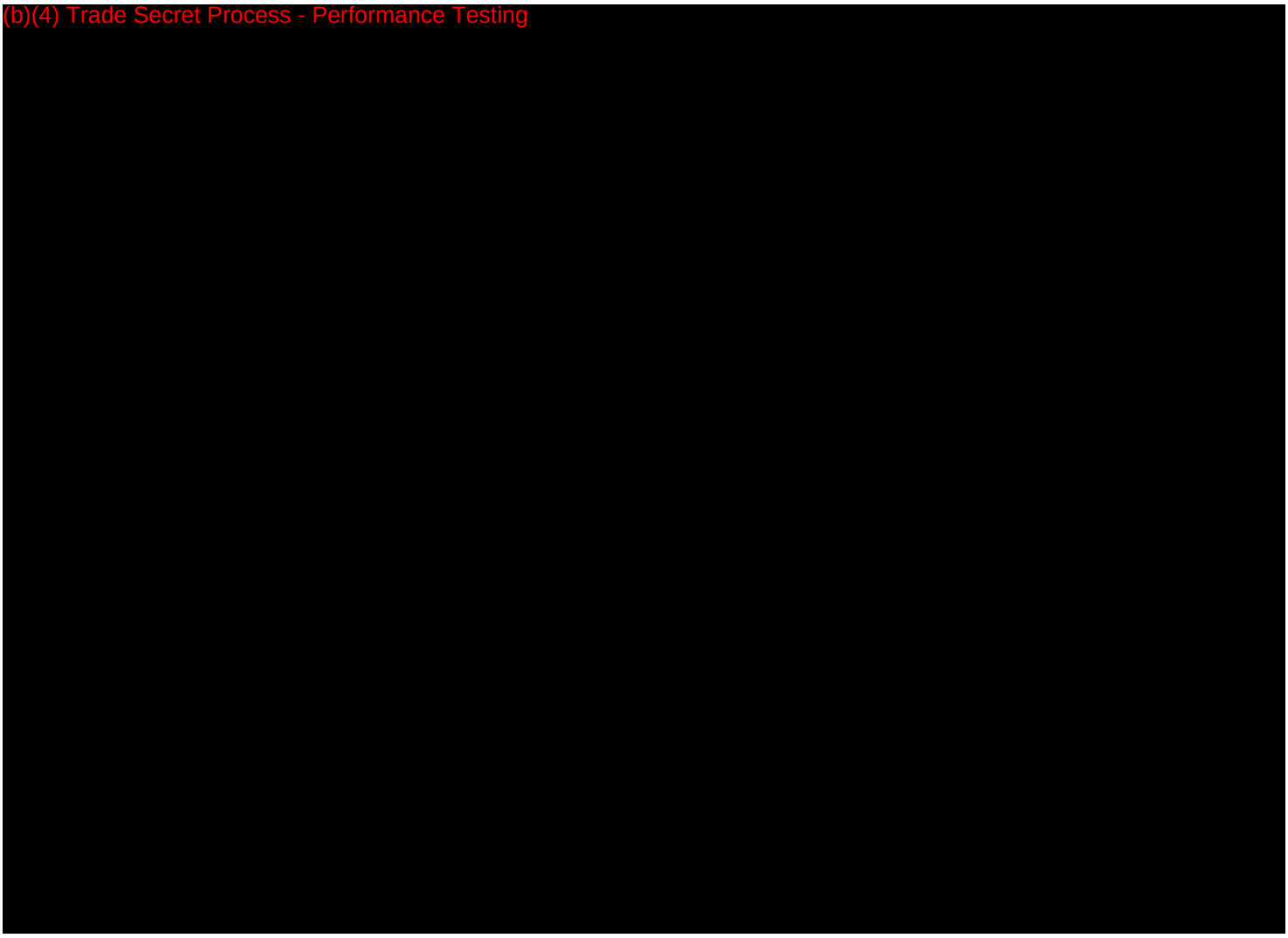

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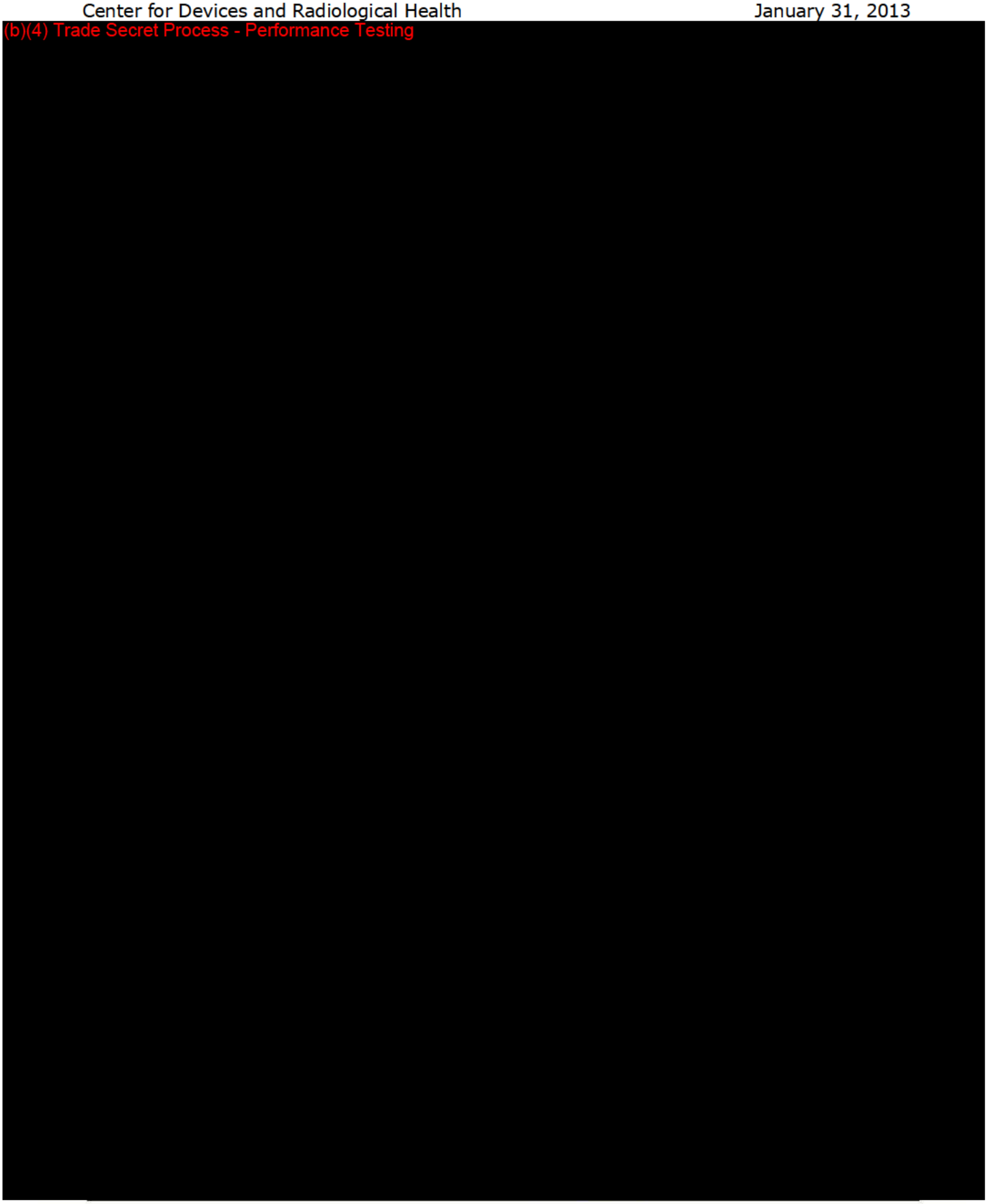

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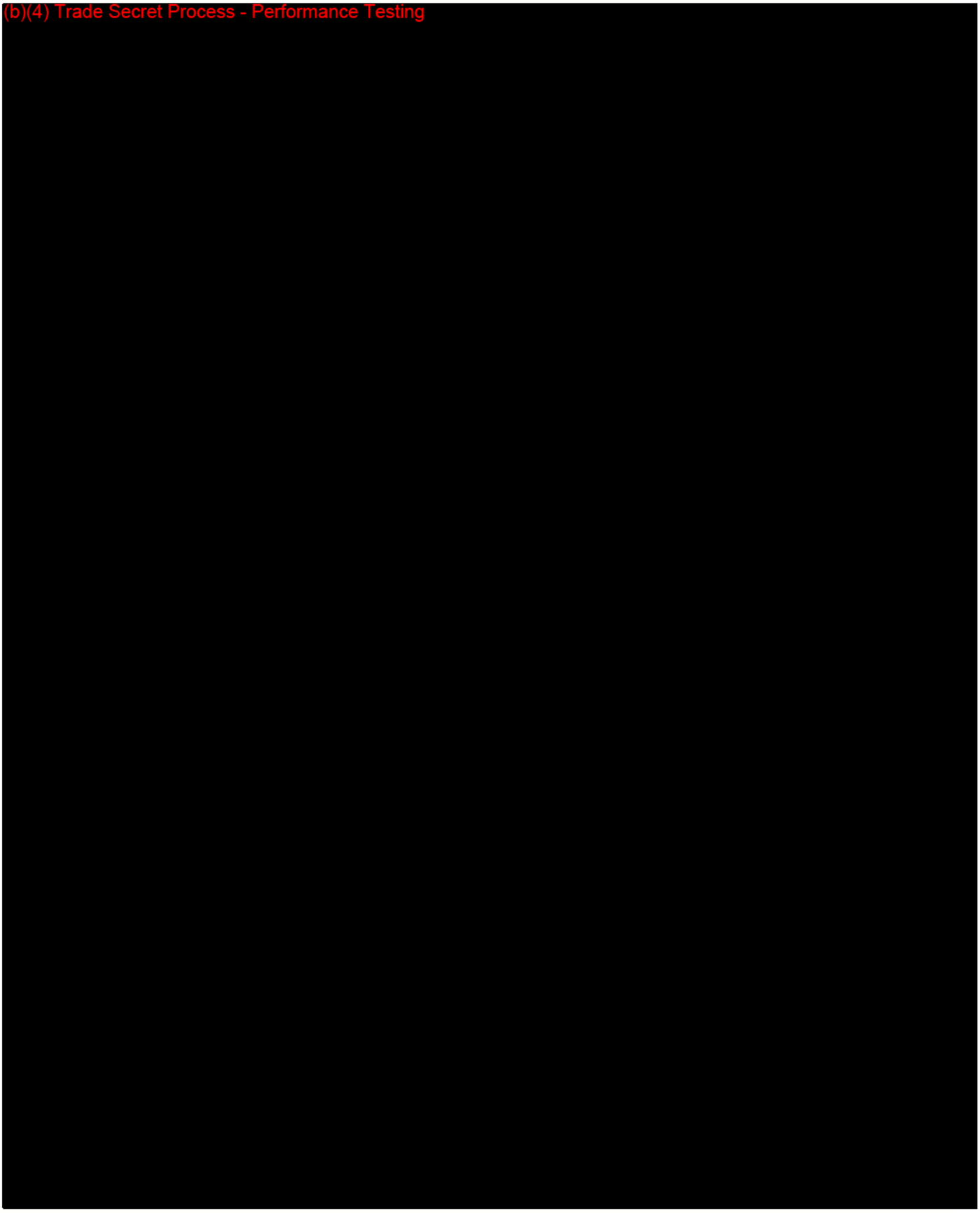

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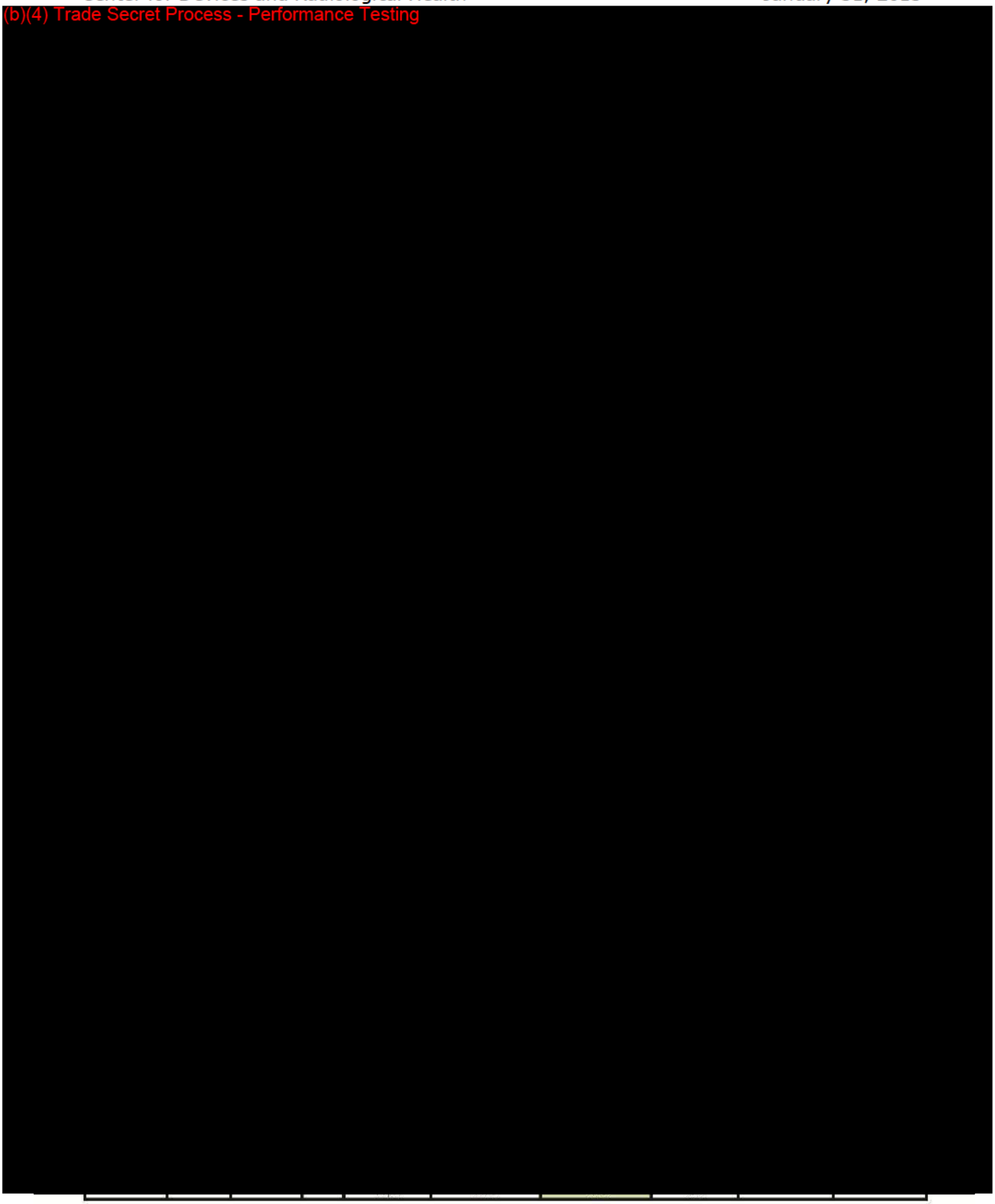

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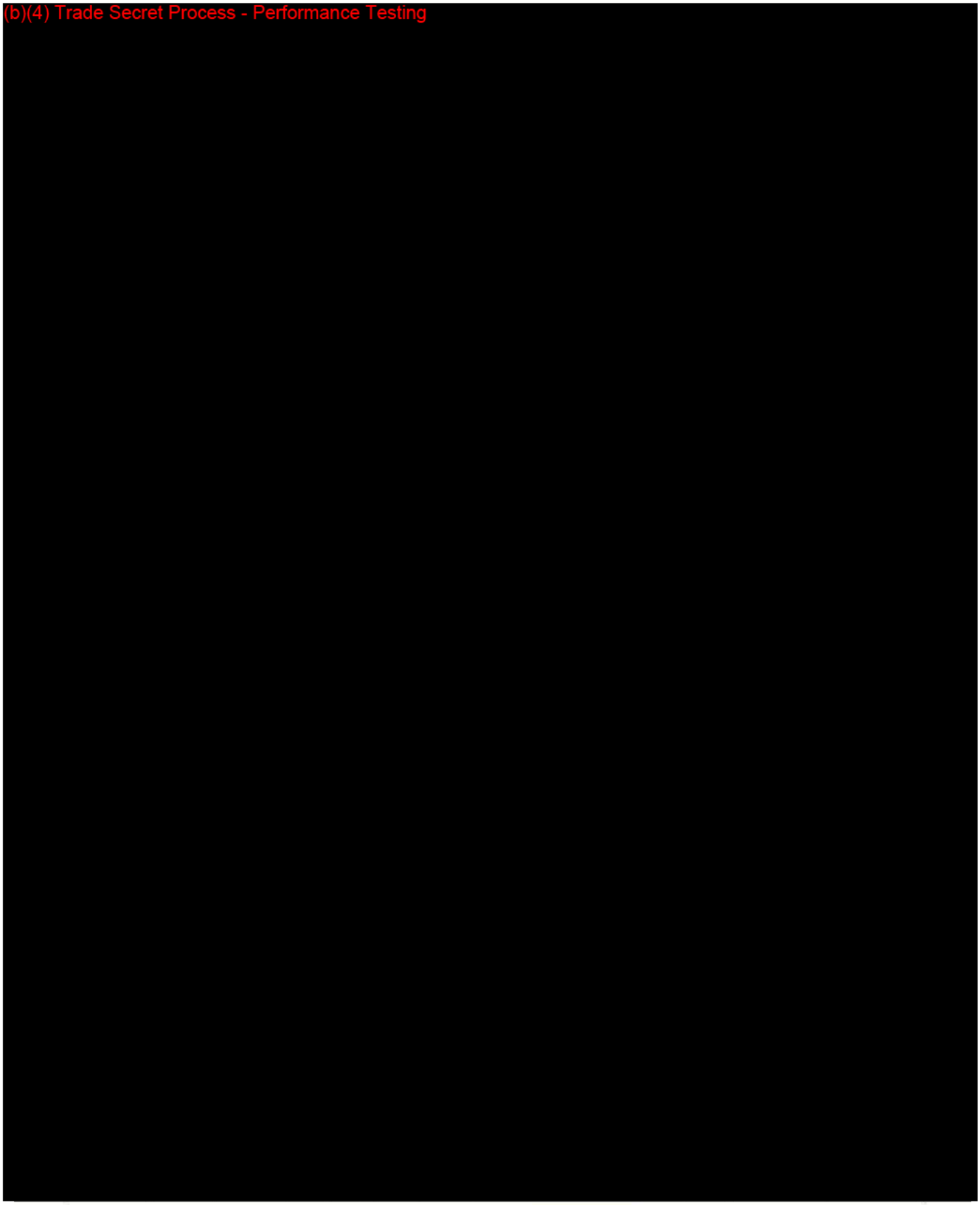

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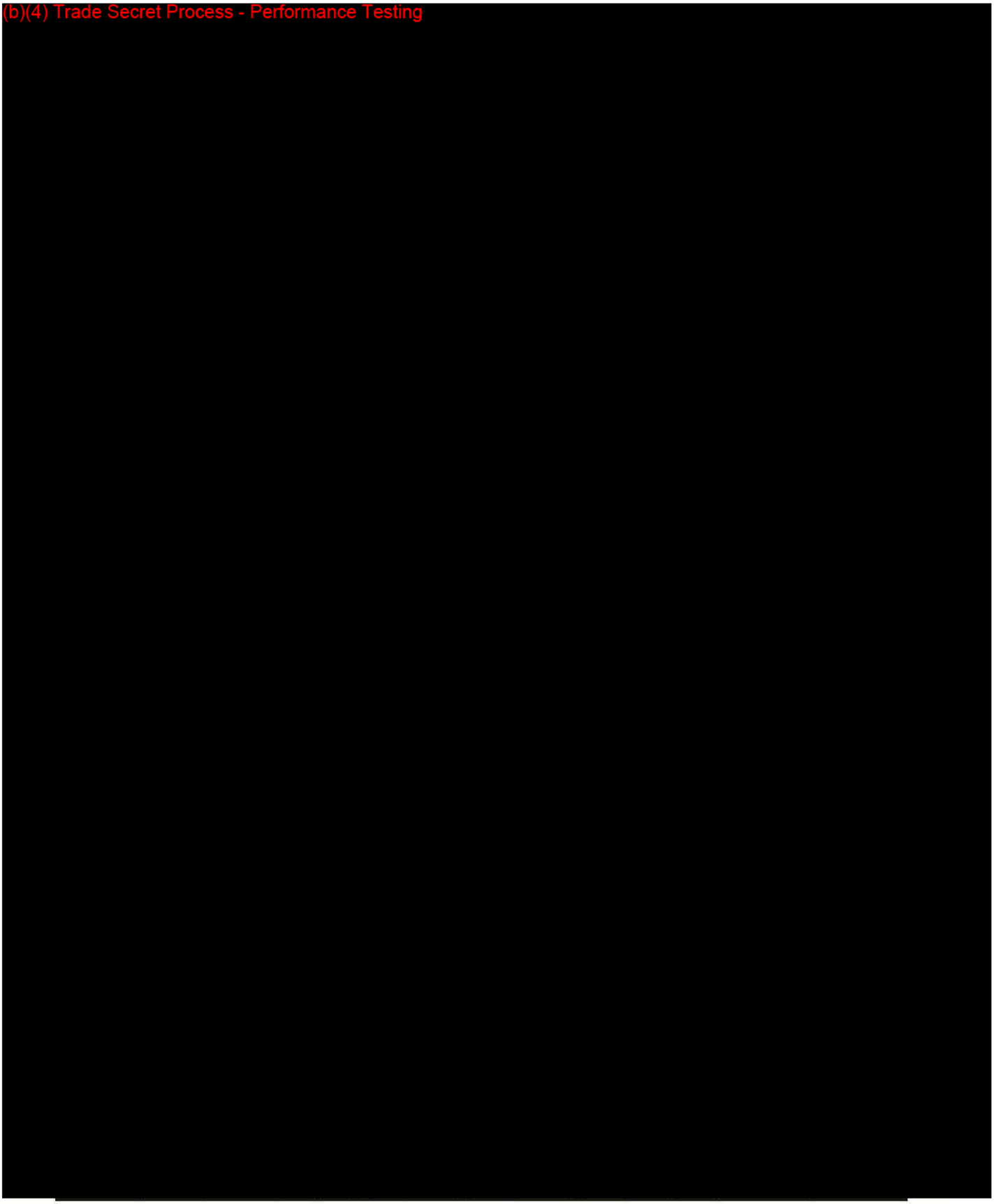

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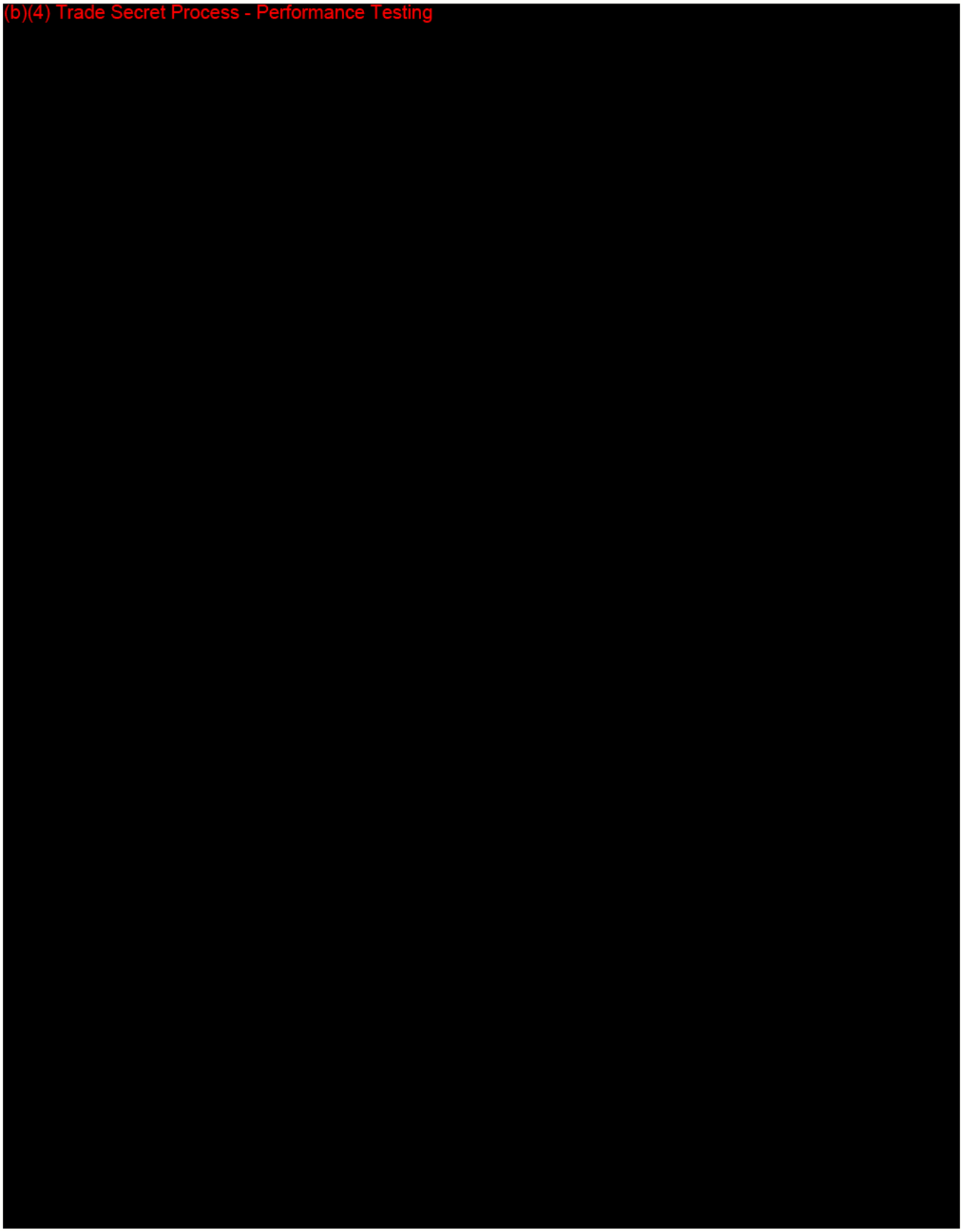

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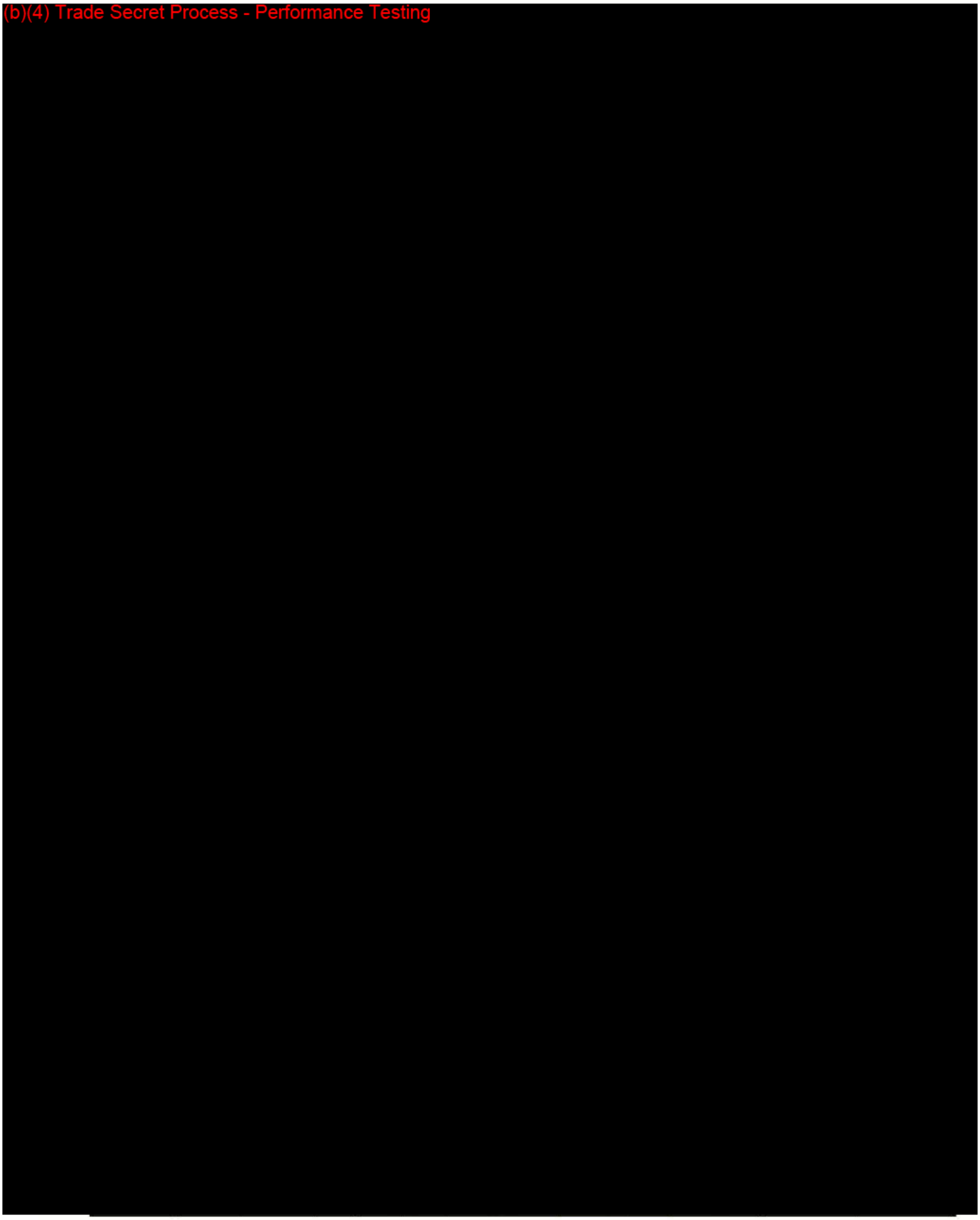

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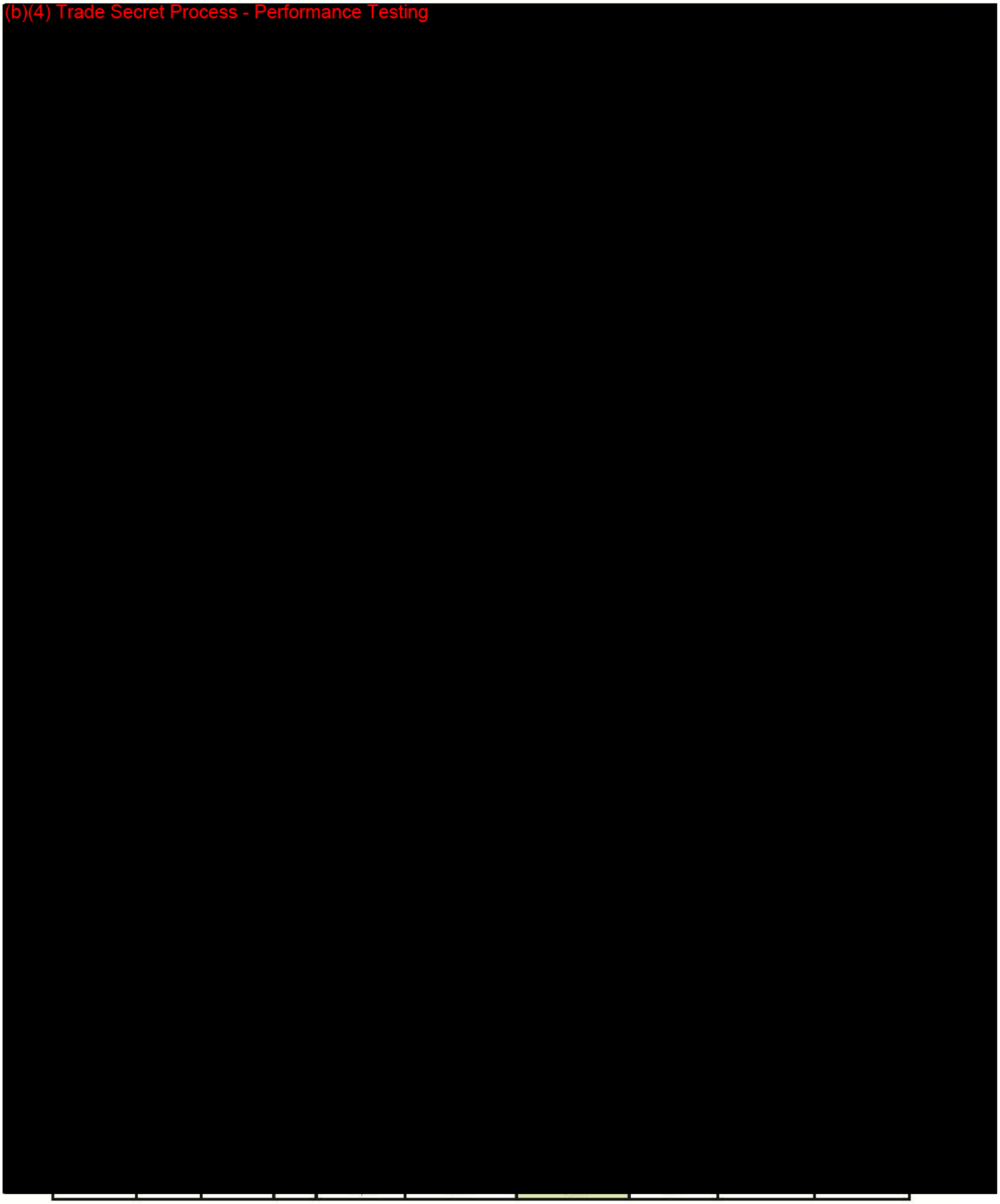

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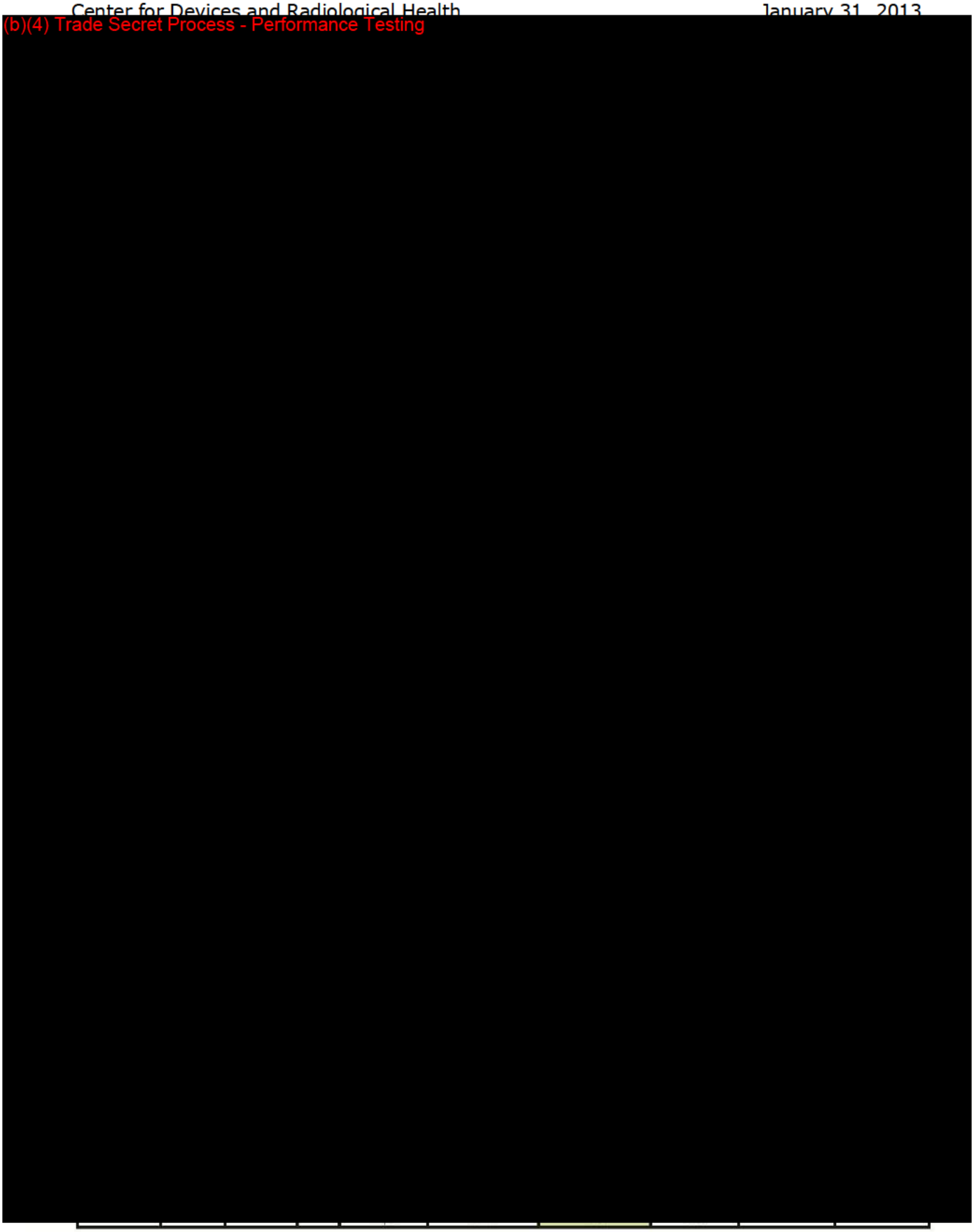

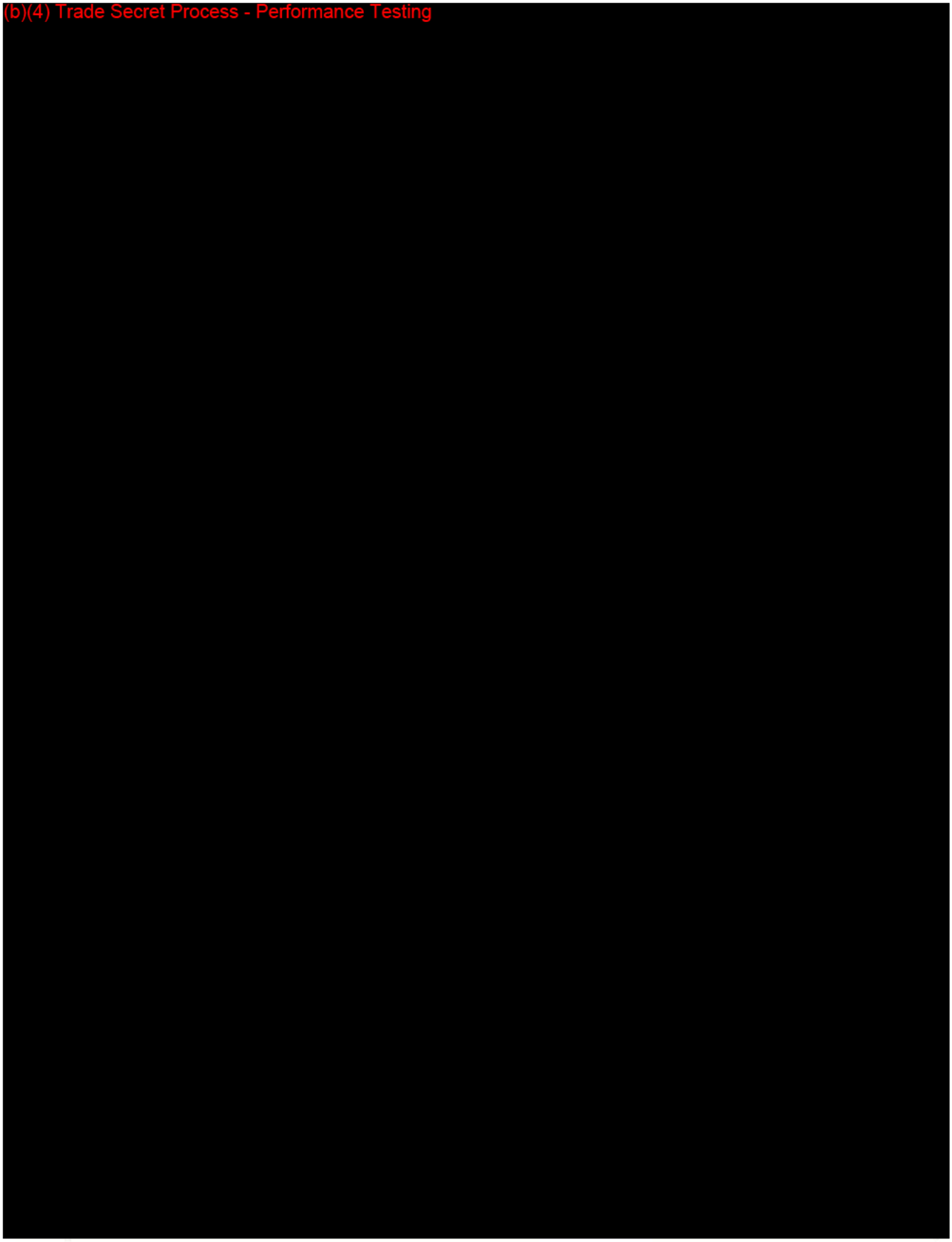
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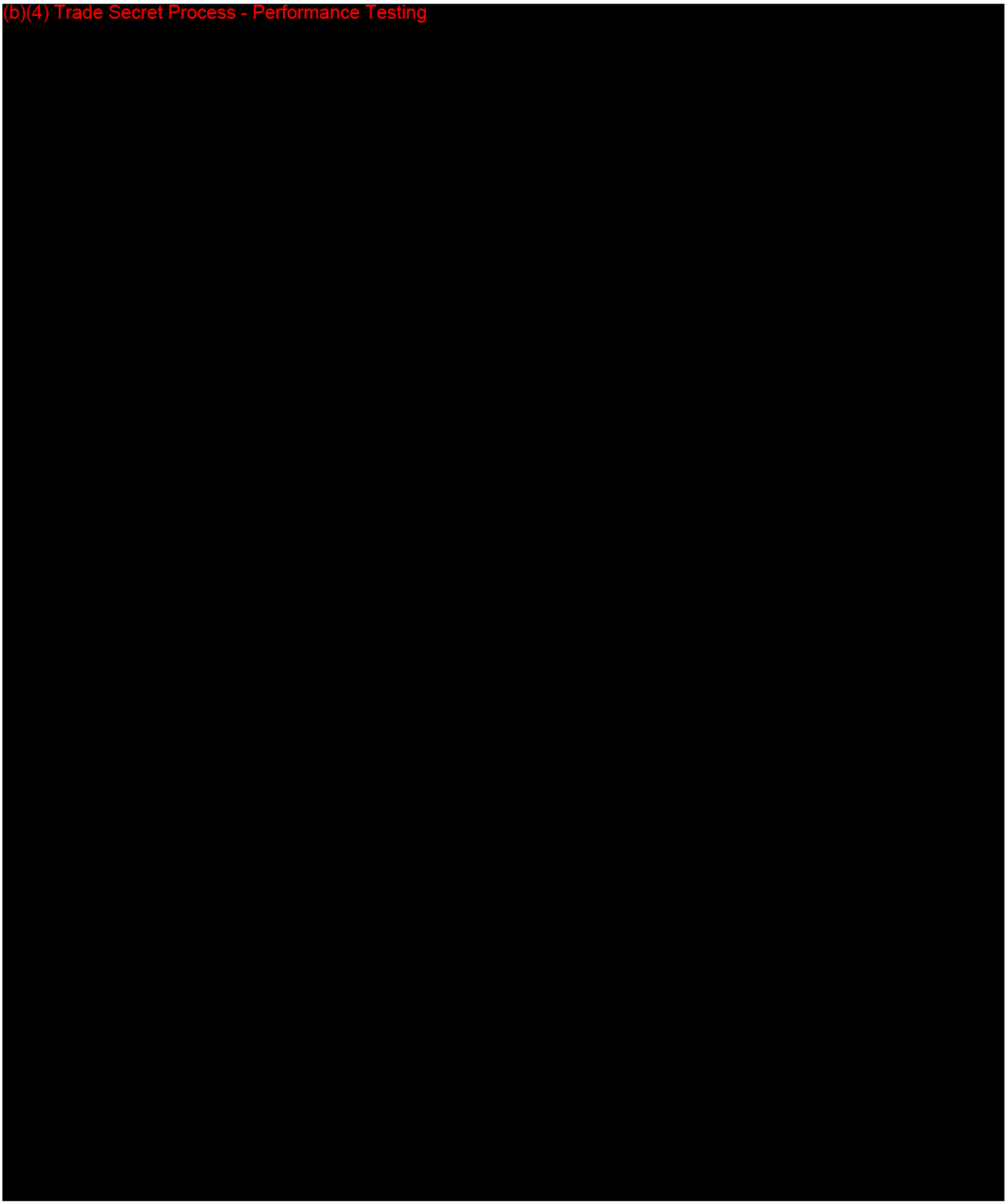

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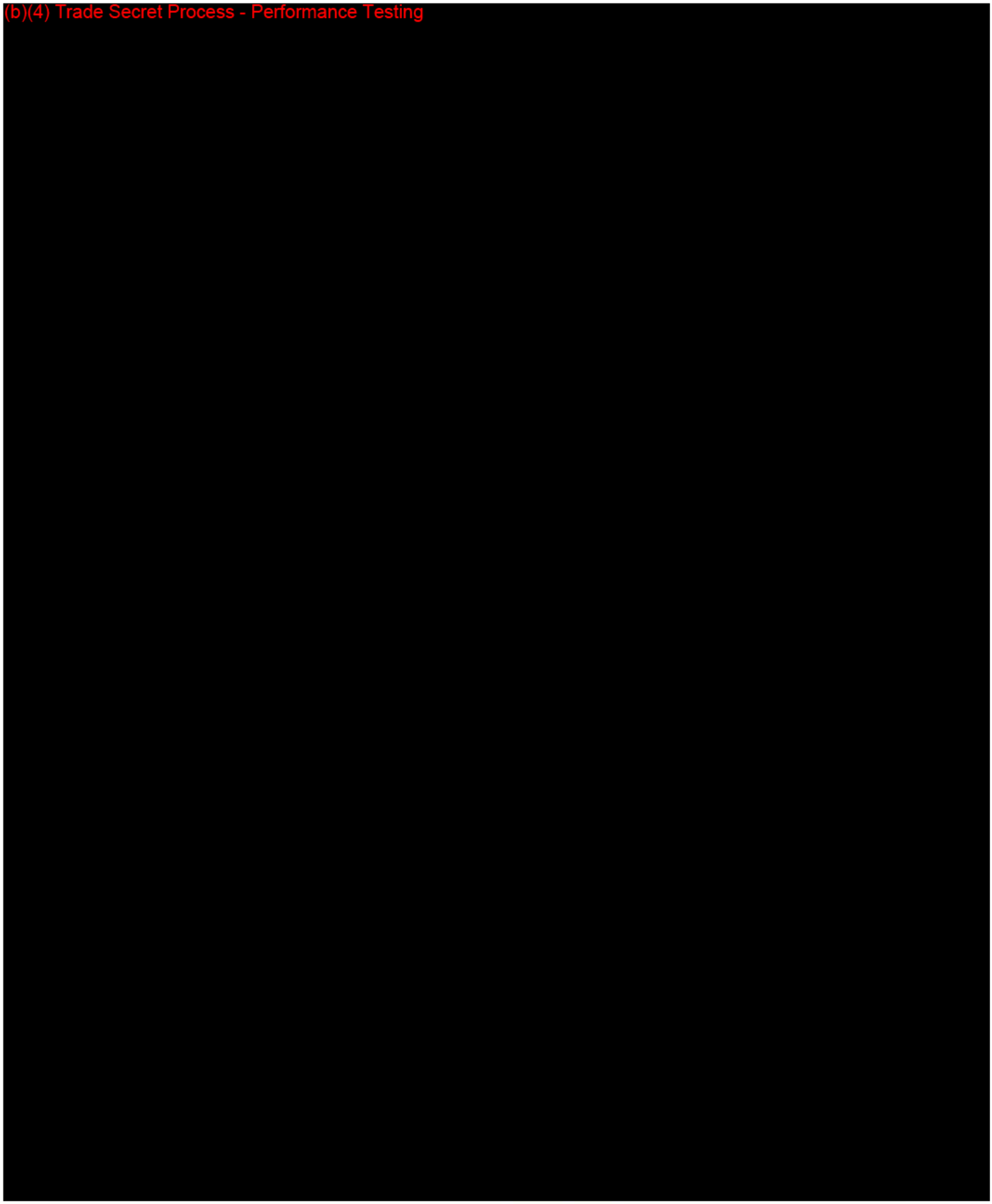

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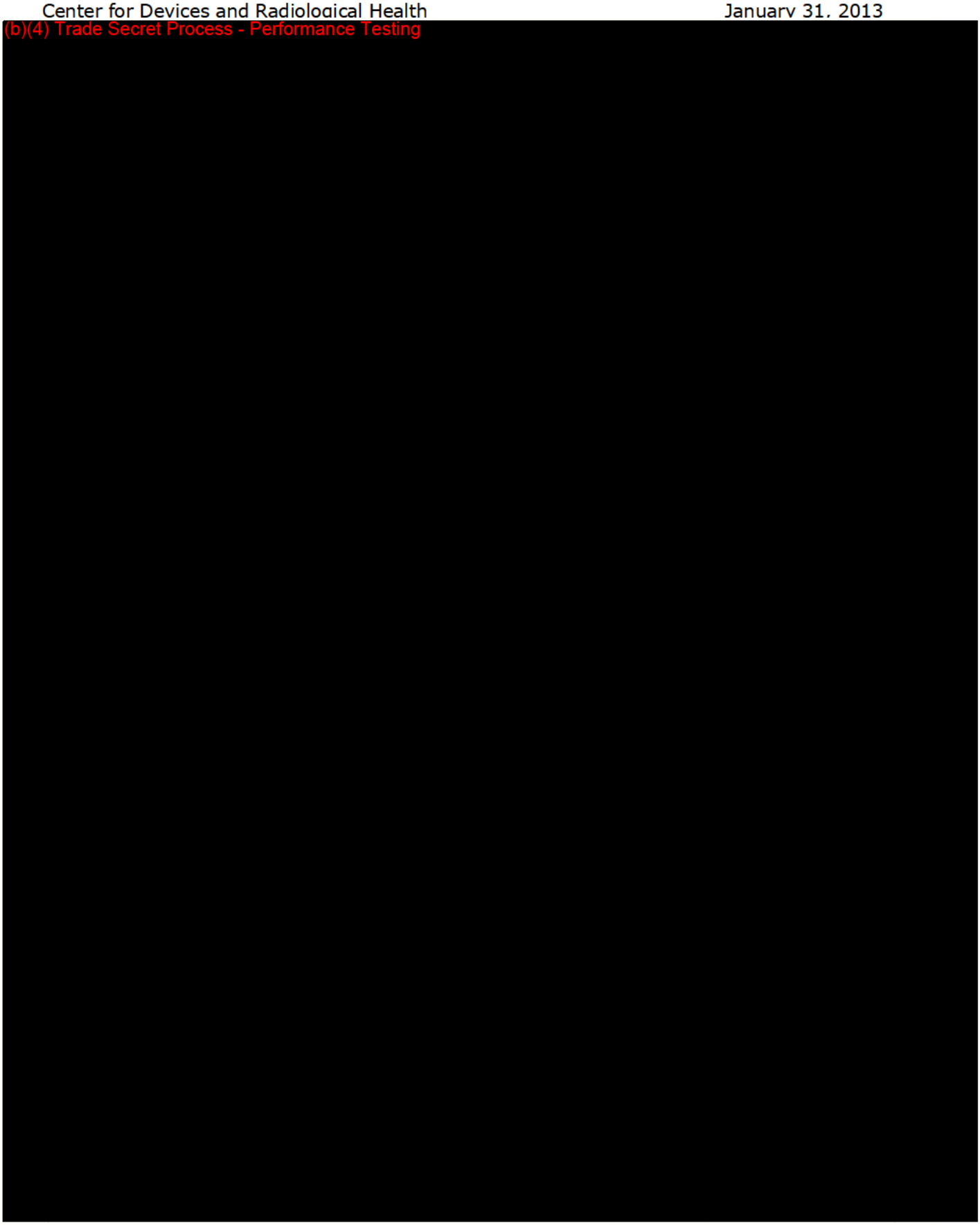
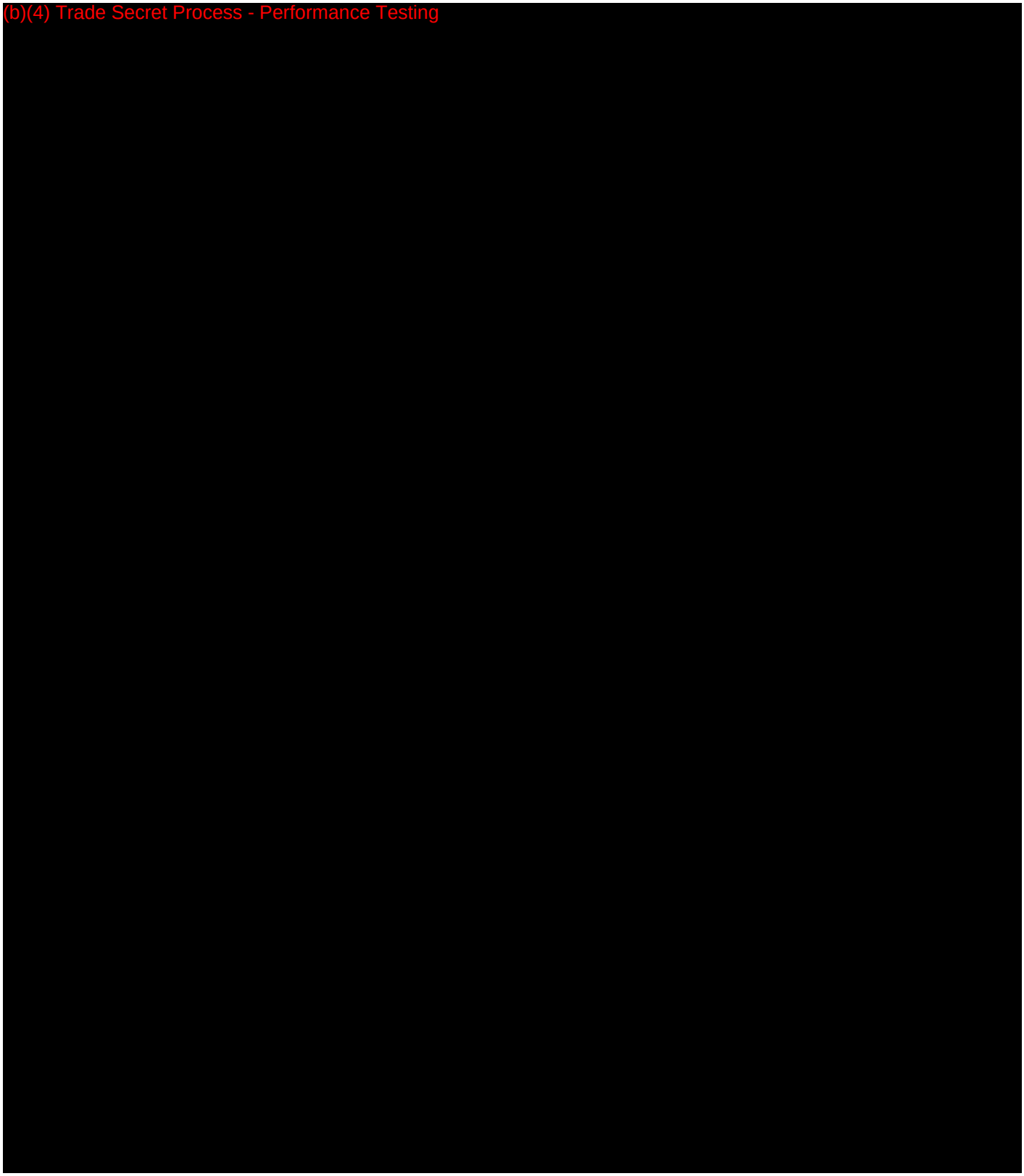


(b)(4) Trade Secret Process - Performance Testing



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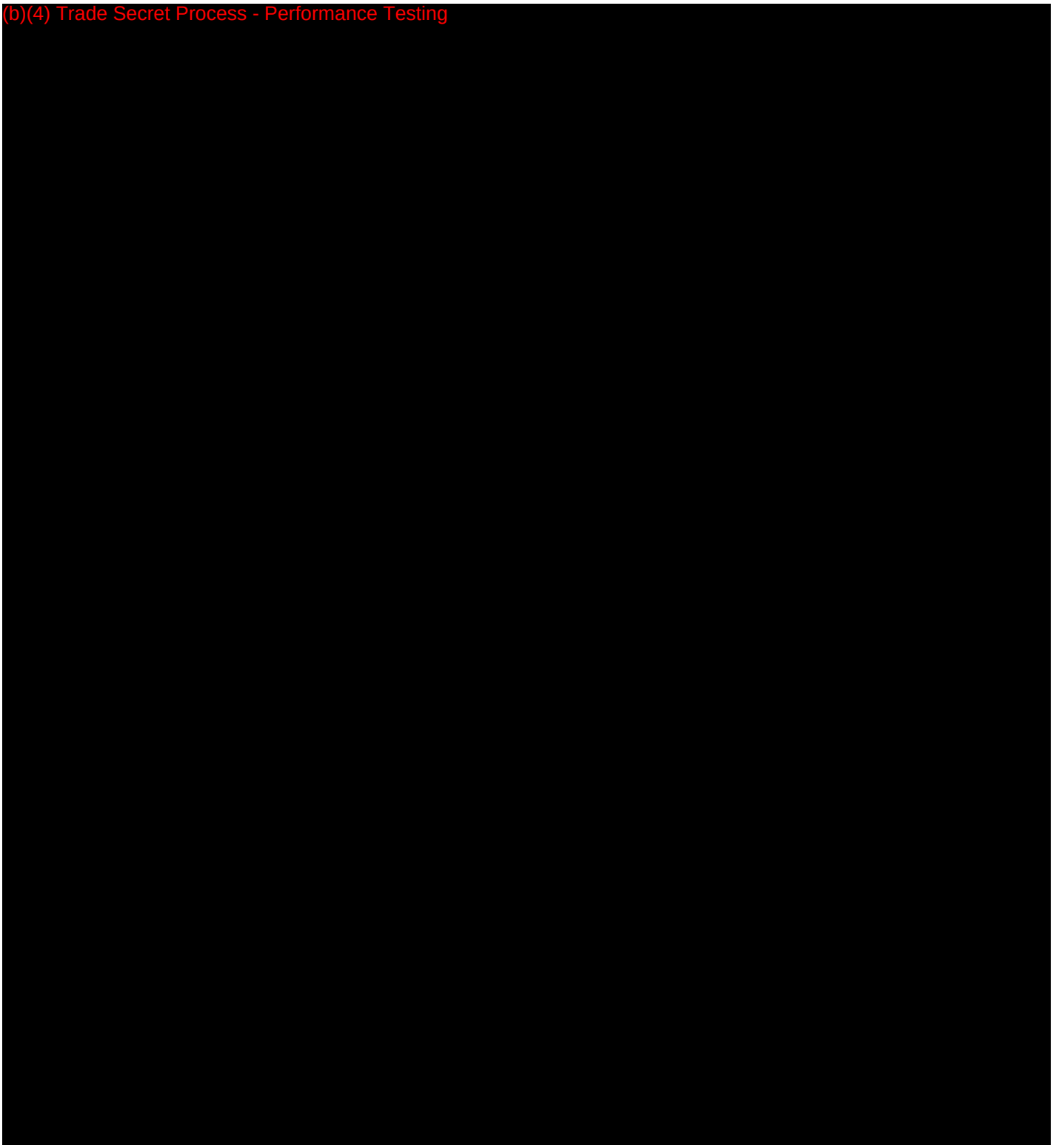
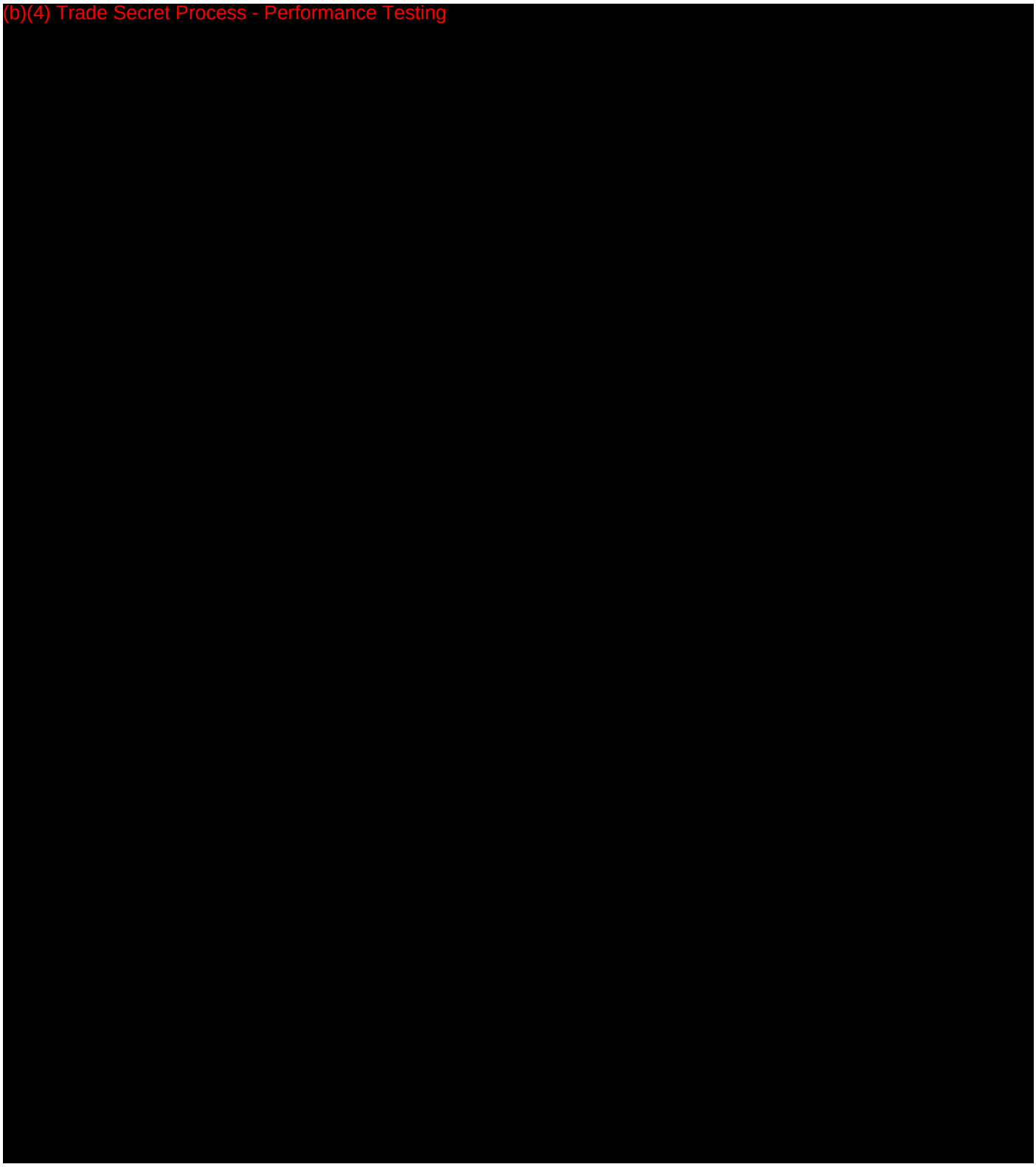
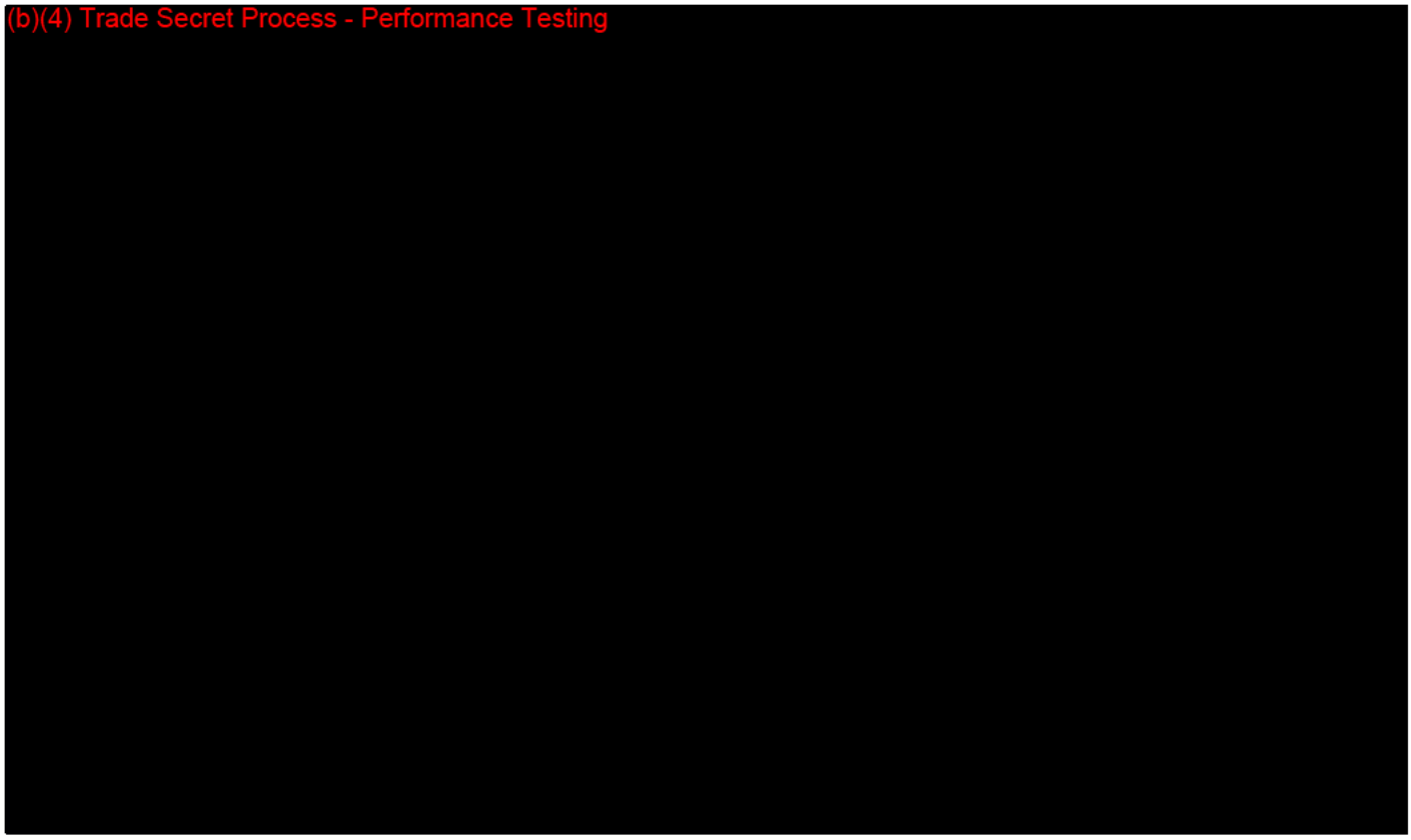


(b)(4) Trade Secret Process - Performance Testing




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

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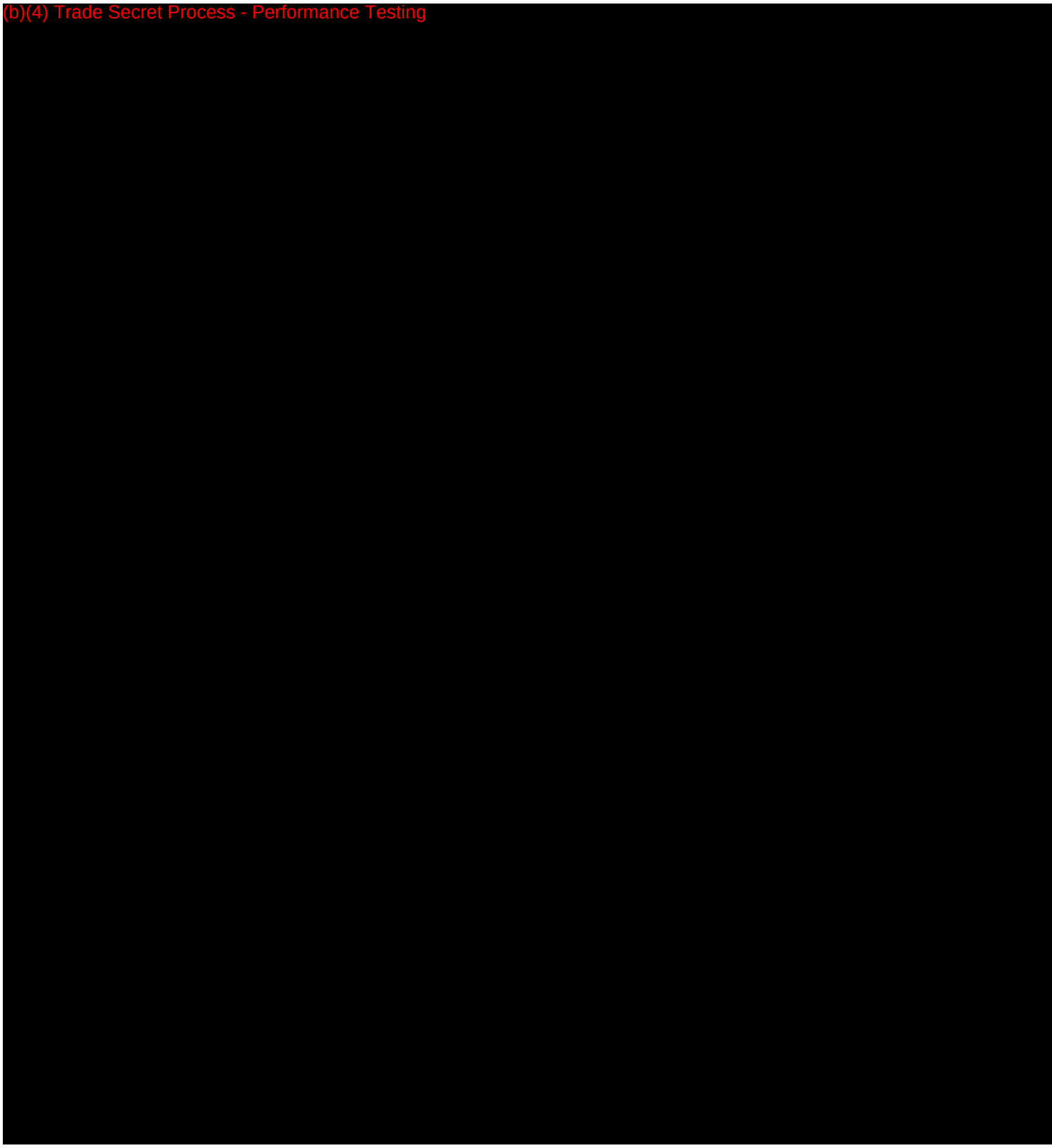

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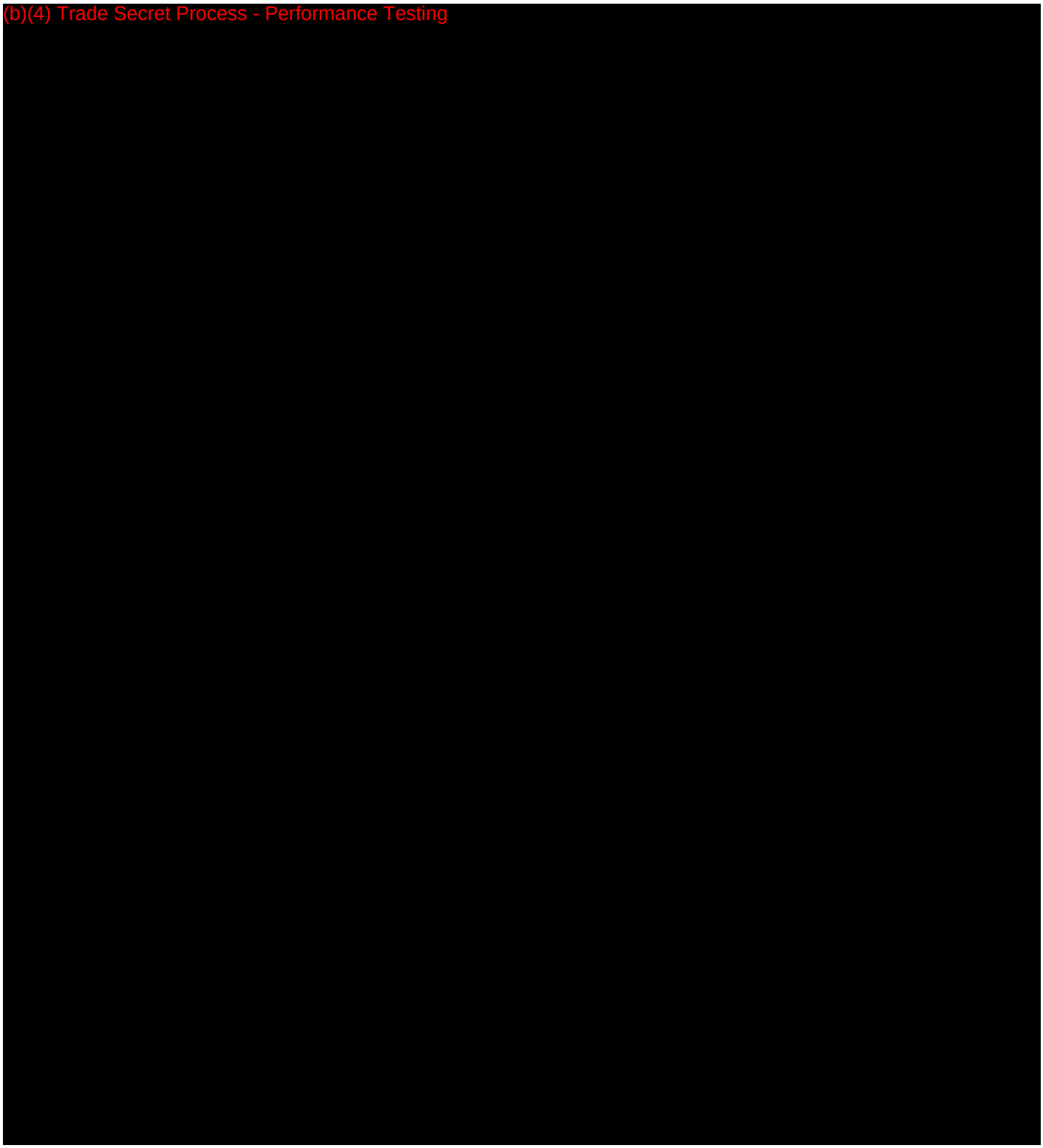

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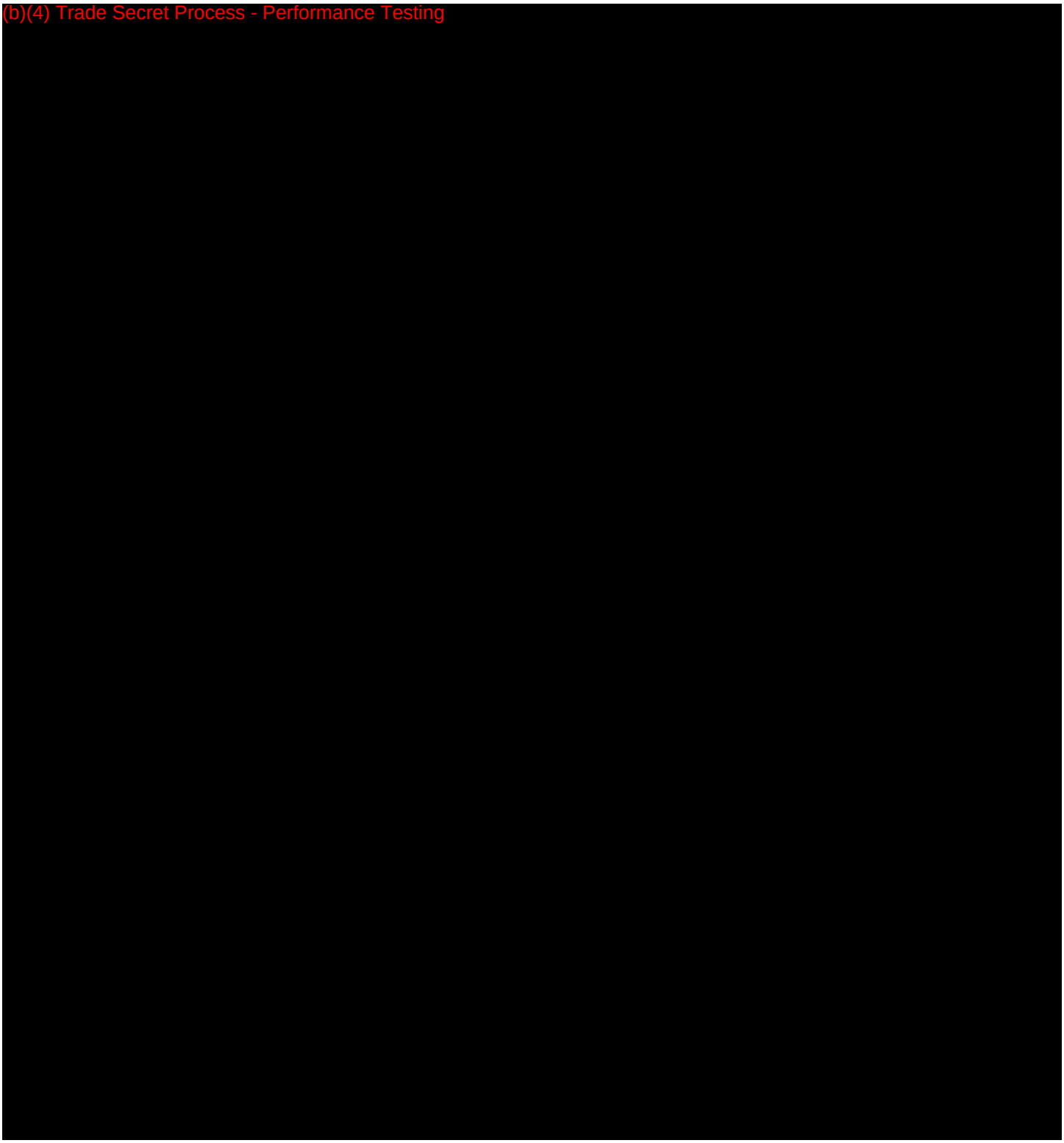

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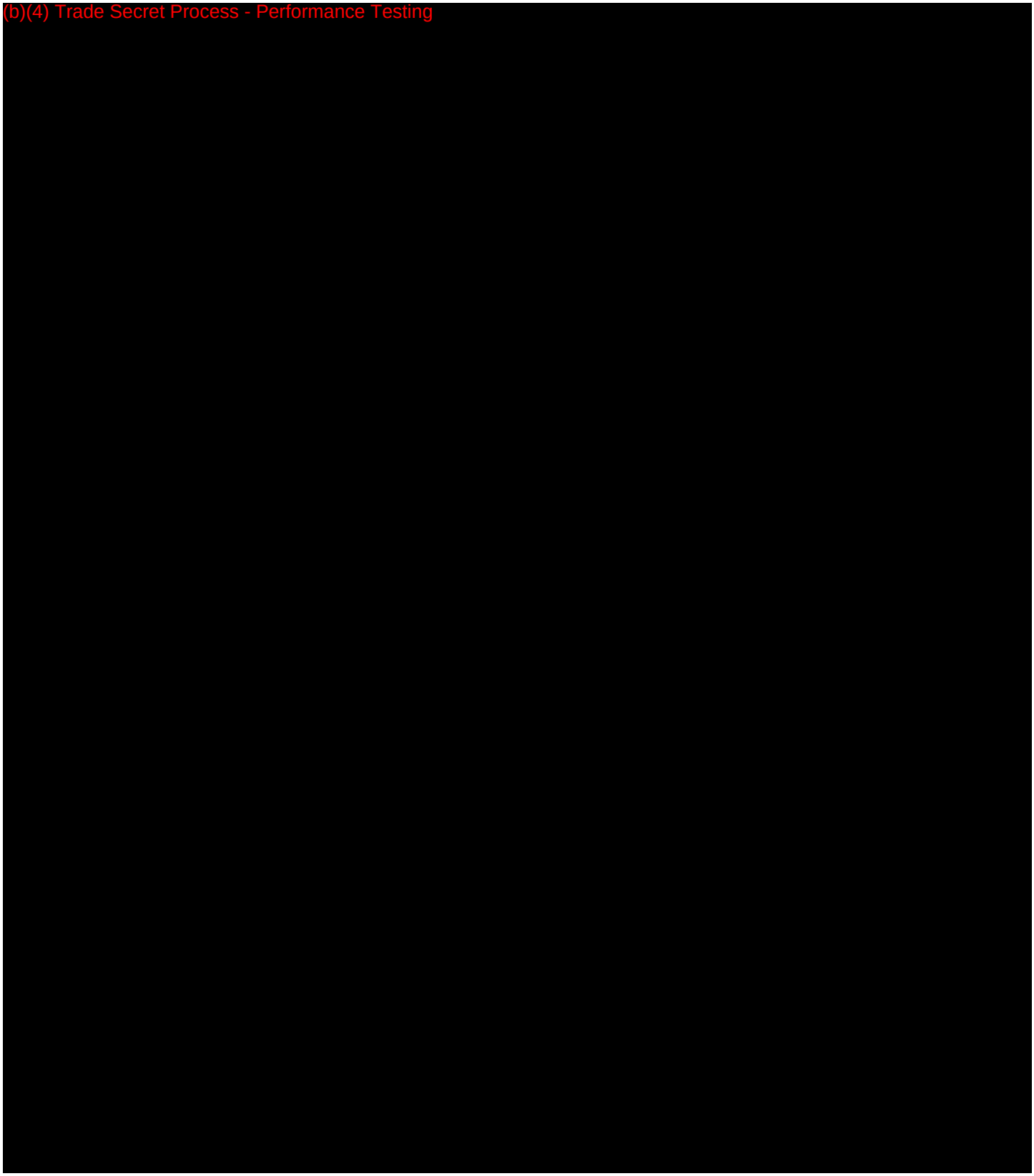

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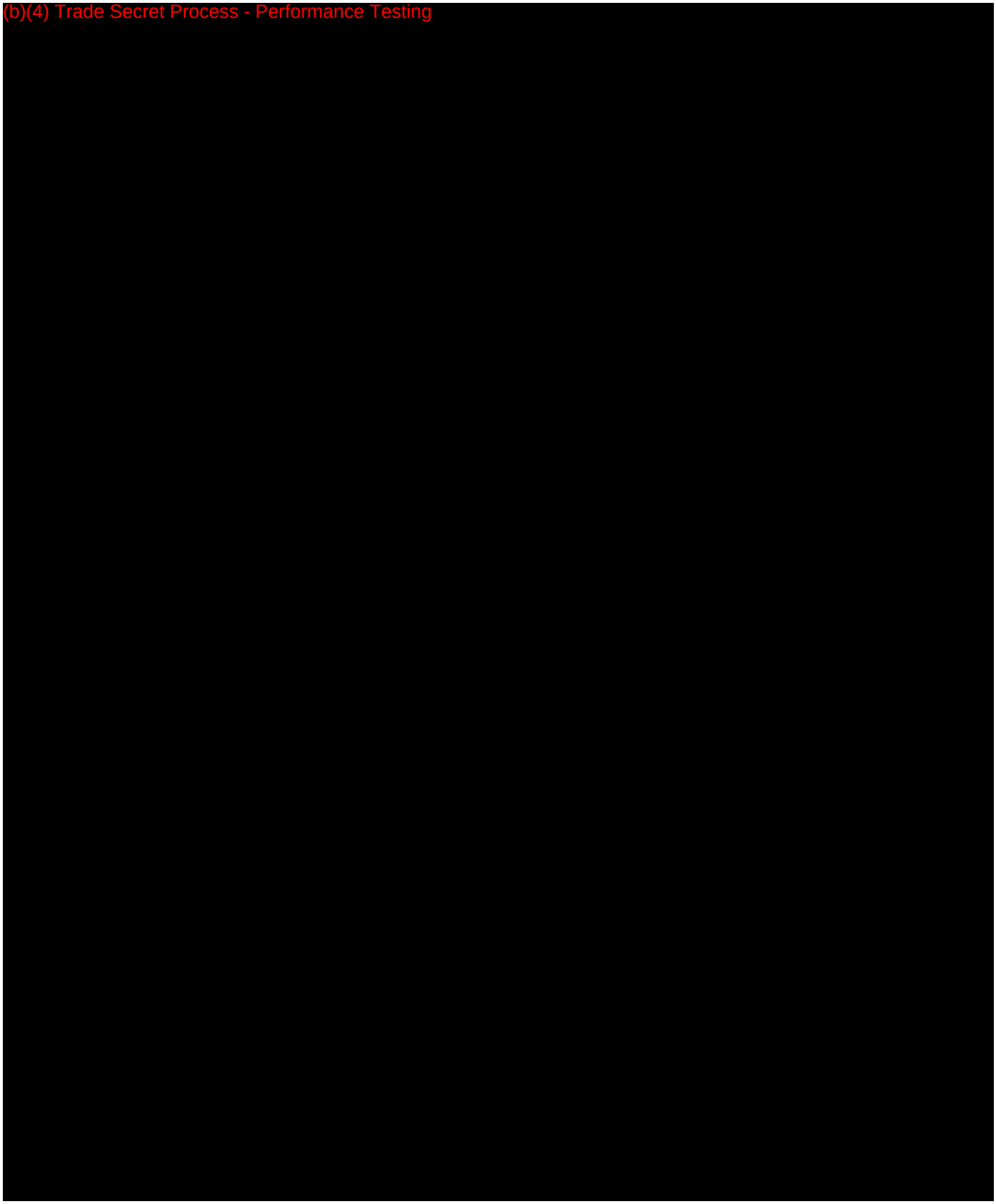

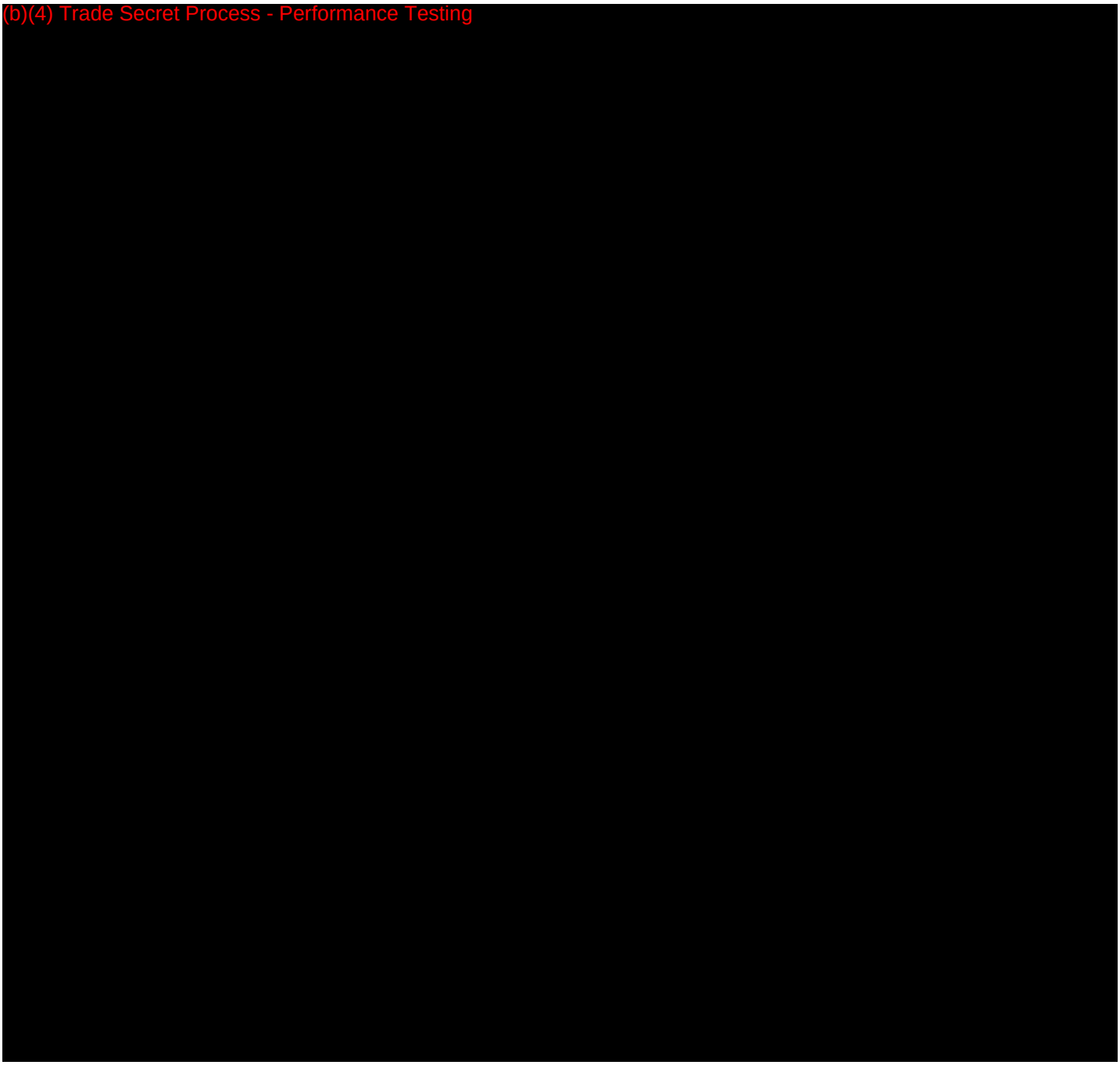
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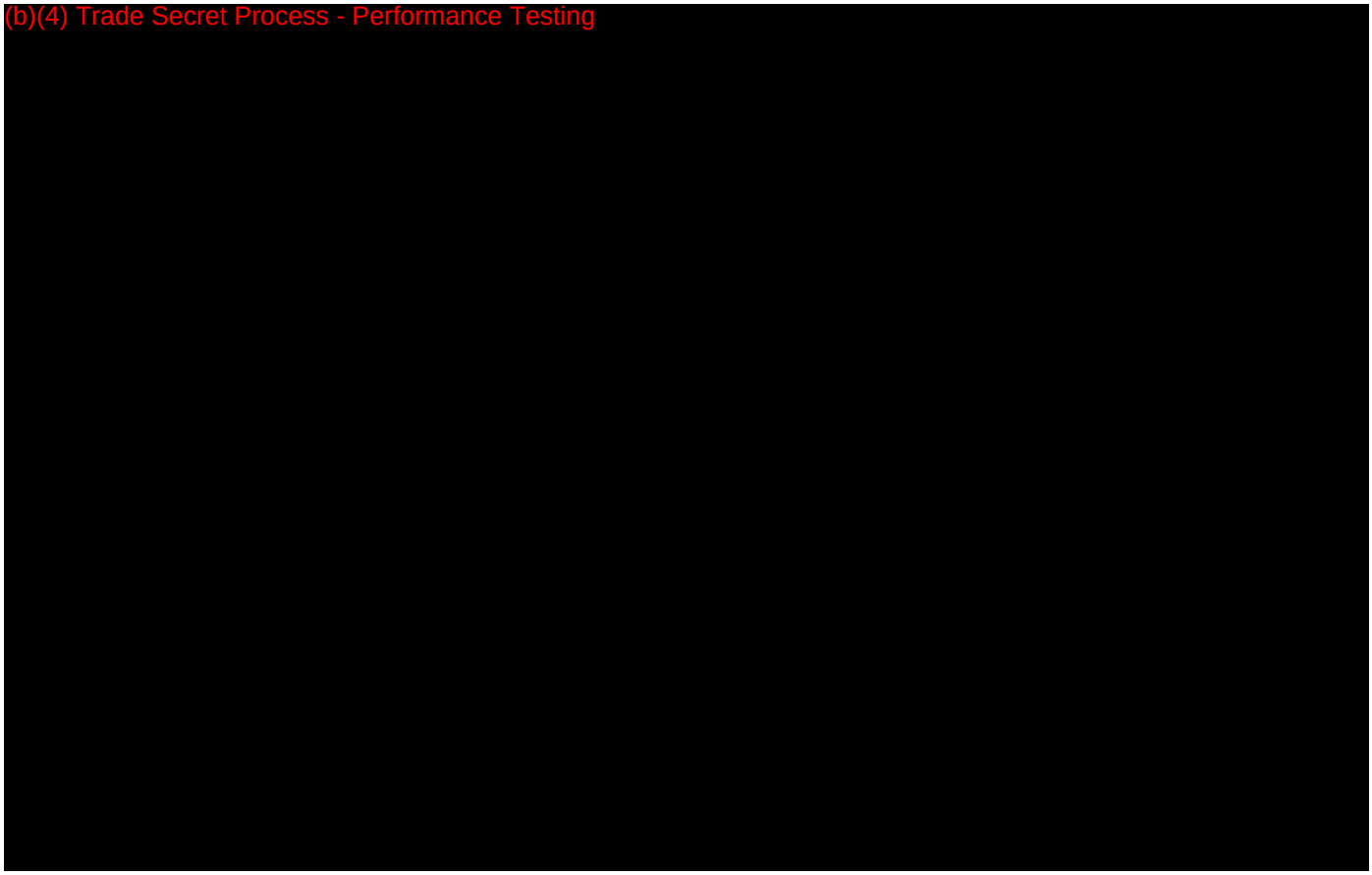
(b)(4) Trade Secret Process - Performance Testing

21. Other

Laser Lipo Ltd do not wish to present any further information at this time and feel they have determined substantial equivalence of the 'Strawberry' and 'Strawberry and Cream' low level laser systems to the Chromogenex i-Lipo system K111501 based on the information in the preceding sections.

Barlow, Lenny *

From:	Barlow, Lenny *
Sent:	Friday, September 13, 2013 2:04 PM
To:	'ian@strawberry-laser.com'
Cc:	DCCLetters
Subject:	k130341 Correspondence
Attachments:	k130341.pdf

COVER SHEET MEMORANDUM

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

From: Reviewer Name Sankar Basu

Subject: 510(k) Number K130341

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 *(Attach IFU)*	X	
510(k) Summary or 510(k) Statement *(Attach Summary or Statement)*	X	
Truthful and Accurate Statement *(Must be present for a Final Decision)*	X	
Is the device Class III?		X
firm reference standards? (If yes, please attach Form 3654.)	X	
Is this a combination product?		X
Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices.)		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.)		
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 's age >= 21 (different device design or tesating, different protocol procedures, etc.)		X
sitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X

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

Regulation Number:	21CFR 878.4810
Class:	II
Product Code:	OLI
Additional Product Codes:	

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

Branch Chief Sign-Off	Neil R Ogden -S 2013.09.06 11:31:01 -04'00'
Division Sign-Off	Mark N. Melkerson -S 2013.09.06 15:59:59 -04'00'

Dr. Sankar Basu, PHD
U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Control Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Ref. K130341.

March 01, 2013

Dear Dr. Basu,

In reference to your email dated February 28, 2013 I can confirm that we have addressed the following elements that were identified as missing or inconsistent within the Acceptance checklist for Traditional 510(k)s.

A. Administrative
Section 7 a
Form 3454 Certification: Financial Interests and arrangements of clinical investigators has been completed.

Section 7 b
Form 3674 Certification of compliance has been completed.

Section 9
The submission identifies prior submissions for the same device details of this can be found within section 3 of our 510(k) Cover letter, and also in section 2 of our 510(k) application CDRH Premarket Review Submission Cover Sheet within section (F)

Section 9 a
We have identified in Appendix A where we identified previous submission issues and how these where resolved.

Please do let me know if I can be of further assistance.

Yours Sincerely

Ian Cobley
Director.

179

3. 510(k) Cover Letter

Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
United Kingdom, TN8 6ST
Telephone: +44 844 980 1820
e-mail: ian@strawberry-laser.com

March 05, 2013.

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring
Maryland 20993-0002
United States of America

Ref: **510(k) Premarket Notification**

Dear Document Control Clerk:

Pursuant to the requirements of section 510 (k) of the Food, Drug and Cosmetic Act, notification is made to manufacture and market the following new medical device:

Classification Name:
Low Level laser system for aesthetic use
79 OLI

Classification Regulation:
21 CFR 878.5400

Common/Usual Name:
Low level laser system for aesthetic use

Proprietary Name:

Laser Lipo Ltd will manufacture two devices:

- the Strawberry low level laser system model ILO, and,
- the Strawberry & Cream low level laser system model SC

Establishment Registration Number:

The Strawberry low level laser system and Strawberry & Cream low level laser system will be manufactured by:

Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
Kent TN8 6ST
United Kingdom
Telephone: 011 44 844 980 1820
Fax: 011 44 844 980 1820
Establishment Registration Number: To be applied for following clearance of this submission.

Classification:

The FDA has classified: Low level laser system for aesthetic use (79 OLI) as a Class II medical device under 21 CFR 878.5400.

Performance Standards:

None established under 514, however FDA has published "Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use".

The following international consensus standards, recognized by FDA, have been complied with:

IEC 62304:2006 – software life-cycle
IEC 60601-1:2006 – electrical safety
IEC 60601-1-2:2007 - electromagnetic compatibility
IEC 60601-2-22:1996 – laser products
IEC 60825-1:2007 – laser products
ISO 14971:2009 – risk management
ISO 10993-1:2009 - biocompatibility

The following additional standards have also been complied with, although not recognized by the FDA:

ISO 13485: 2003 – quality management system
EN 980:2008 – European symbols
(explanatory text included in US labeling)
EN 1041:2008 – requirements for information
(supplemented by FDA guidance listed below)

The following Guidance notes have been used extensively in the preparation of this submission:

- Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Format for Traditional and Abbreviated 510(k)s
- Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22

Labeling and Promotional Materials:

Draft labels, labeling (including the User Manual) and promotional materials for the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system are contained in Section 13.

Substantial Equivalence:

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is substantially equivalent in design, use and materials to the:

Chromogenex Technologies Ltd I-Lipo System – K111501

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is made of the similar materials as the Chromogenex Technologies Ltd I-Lipo System – K111501.

The Laser Lipo Ltd Strawberry and Strawberry & Cream low level laser systems has similar indications for use

The Low level Laser model Strawberry and Strawberry and Cream can be used for the non-invasive aesthetic treatment for the temporary reduction in waist circumference.

to the Chromogenex Technologies Ltd I-Lipo System.

The Chromogenex Technologies Limited i-lipo™ Low Level Laser System is indicated for non-invasive aesthetic treatment for the temporary reduction in circumference of the waist.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is made of the same materials as the Chromogenex Technologies Ltd I-Lipo System – K111501.

- thermoplastic control unit enclosure
  - proprietary components and assemblies used within the unit
- thermoplastic paddles and probes
- nylon covered "velcro" fixed straps
- nylon/polycarbonate goggles

Both the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd i-Lipo System:

- use laser diodes
  - of approximately 660 nm wavelength, and
  - less than 50 mW output
- incorporated into
  - various laser diode cluster probes and paddles attached to the subject with special straps
    Strawberry 4 to 10 paddles with 6 diodes each
    i-Lipo 4 paddles with 9 diodes each
  - and two probes with one diode each
- have a similar control unit
  - LCD subject display
  - membrane key pad inputs
    - incorporated into display as a touch screen for strawberry and cream
  - microprocessor controlled through software
  - multi-range power supply (EU and US voltages and frequencies)
- have a similar range of connecting cables
- have the same two pairs of laser protection goggles
  - different name printed on outside of frame

The Laser Lipo Ltd Strawberry low level laser system, Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd I-Lipo System have the same use achieved through the same technology, are assembled from similar components made from similar materials, have similar user input and output interfaces and have similar features.

All systems use laser emitting diodes of the similar wavelengths and powers: the Laser Lipo systems have the potential to use more paddles but with less

diodes in each paddle. All systems have two cluster probes with a single laser diode in each. In all systems the paddles and cluster probes are secured to the subject with nylon encased rubber straps secured with "velcro".

All control units have plastic enclosures, discrete power supply, microprocessor controlled electronics, controls, alarms and similar control software.

Laser Lipo Ltd concluded that the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system are substantially equivalent to the Chromogenex Technologies Ltd I-Lipo System, K111501

For a demonstration of equivalence, please see Section 12.

Promotional Material giving details of the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and Chromogenex Technologies Ltd I-Lipo System is compared in Section 12.

Previous Submission:
Laser Lipo Limited has previously submitted the Strawberry and Strawberry & Cream Low Level Laser system under K122354 and PRE Submission Q120359. The reasons that the Strawberry and Strawberry & Cream devices were not considered being substantially equivalent to the predicate device can be found in Appendix A - Administrative section with a summary of the corrective action taken.

Description of Product:
The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system consists of a control unit, various connection leads up to 10 paddles, 2 cluster probes, various "Velcro" attachment straps and other accessories. (A full list of system contents is included at the end of this section.)

A paddle is a device containing six cold red laser emitting diodes which is designed to be placed on the skin. The system can operate using 4, 6, 8 or 10 paddles that are connected to the control unit.

A probe is a device containing one cold red laser emitting diode which is designed to be placed on the skin to treat specific smaller areas of fat, where a usual flat paddle won't ergonomically fit.

The control unit is an electrically powered unit (100-240v, 50-60Hz auto-ranging), enabled by a main switch and key switch. Once enabled it is

controlled using a button (Strawberry) or touch screen (Strawberry and Cream) interface. The output of the diode (six per paddle) is limited to 40mW +/- 15% by a power limiting PCB from the central processing unit.

When the laser paddles are placed on the skin, the cold red laser beams penetrate the skin just deep enough to reach the layers of fat. When the light hits the fat cells, a rapid chain of events takes place. Firstly, pores form on the cells causing them to spill out. The water, Glycerol and fatty acids move into the interstitial space beneath the fatty layer in the skin. Then further water, fatty acids and Glycerol spill out. The adipocyte cells are therefore reduced in size.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system contain the same control electronics and control software however the Strawberry and Cream has a menu driven touch screen interface while the Strawberry model has a liquid crystal display and (up, down, left, right and center/enter) push buttons. The outputs and functionality of the Strawberry and Strawberry and Cream models are identical, however displays, display drivers, interface electronics and software and power supply transformed are different. Full details are contained in Section 11.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is shipped in dedicated packaging to prevent damage and protected by a cardboard box.

The system as shipped contains:

- 1 low level laser system unit, either
  - Strawberry model, or
  - Strawberry & Cream model
- 1 user manual
- 1 power lead
- Paddle leads, for example for a 10 paddle system
  - 1 long paddle lead for connection to the device
  - 8 paddle standard leads
  - 1 long paddle lead
- 2 cluster Probes
- 1 Pair of goggles
- 2 Replacement fuses
- 2 Keys

Variants of the system will be available with 4, 6, 8 and 10 paddles.

number of paddles	number of paddle leads
3 standard and 1 end	3 standard
5 standard and 1 end	5 standard
7 standard and 1 end	7 standard
9 standard and 1 end	8 standard and 1 long (to connect two groups of five paddles)

Table 1 - Variants

A full list of the proposed variants and a schematic drawing showing the key design features are included in Section 11.

Engineering Drawings and Photographs of the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system can be found in Section 11.

Photographs, photo drawings and block diagrams showing the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd I-Lipo System are contained in Section 11 and comparison to the predicate Chromogenex Technologies Ltd I-Lipo System can be seen in Section 12.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system will be packaged in a cardboard box together with all components (instructions booklet, cables, paddles), software and accessories (diodes, goggles, fuse, straps and lead) within the scope of the 510(k). A shelf-life has been determined for 5 years based on the laser diodes.

Electrical Safety and Electromagnetic Compatibility is demonstrated through compliance with IEC 60601 part 1, part 1-2 and part 2-22 full test reports from a third party laboratory are included in Section 17.

The Guidance also states that there should be compliance with the IEC 60601-1-4 standard. Laser Lipo Ltd believes that compliance with IEC 62304:2006 life-cycle standard achieves at least the same level of assurance in the quality of the software used in the device.

A usability file detailing application of IEC 60601-1-6:2008 is contained in Section 11.

Table 2 - Product Release Testing Summary
Gives the results of bench testing of the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system which can be seen in section 18 and is confirmed by clinical reports in section 20.

Test	Mean	Quantity	Sample Standard Deviation	Capability, Cp
Laser diode power output: Paddle Laser diode output is set to 40mw +/-15%.	39.35	1140	0.81	2.47
Probe Laser diode output is set to 40mw +/-15%.	40.02	40	0.72	3.49
EU portable appliance testing	100% pass	20		
Visual Inspection: • external components, cables, outer casings and the • General condition of all associated parts.	100% pass	20		100% inspection
Assembly tests	100% pass	20		100% inspection
Functionality tests	100% pass	20		100% inspection

Table 2 - Product Release Testing Summary

Biocompatibility:

Biocompatibility assessment on the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system have been conducted following the ISO 10993-1 (FDA Recognized Consensus Standard), Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. Please see section 15.

Sterilization:

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system are supplied non-sterile.

Cleaning instructions are contained in the user manual included with each system.

Safety and Effectiveness:

A summary of safety and effectiveness information ("510(k) Summary" per 21 CFR 807.92) upon which an equivalence determination has been made is included as Section 5.

Indications for Use Statement:

A single sheet statement of "indications for use" as required by FDA for submissions after January 01, 1996, is included in Section 4.

Truthful and Accurate Statement:

The premarket notification "truthful and accurate" statement (per 21 CFR 807.87(k)), signed by the Group Director Ian Cobley of Laser Lipo Ltd is included as Section 6.

E Copy Statement:

The E Copy provided within our submission is an exact duplicate of the paper copy.

Owner:

This Pre-Market Notification is owned by Laser Lipo Ltd.

Submitter:

This Pre-Market Notification is submitted by
Ian Cobley
Group Director
For and on behalf of: Laser Lipo Ltd

Contact Persons:

The address and telephone number for **all** correspondence is:

Ian Cobley
Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
Kent TN8 6ST
United Kingdom
Tel: 011 44 844 980 1820
Mobile: 011 44 777 445 9611
Fax: 011 44 844 980 1820
e-mail: ian@strawberry-laser.com

As per your email dated March 4, 2013 please find a copy of our response to the acceptance review notification, for K130341

If I can be of any further assistance, please do not hesitate to contact me.

Sincerely,

Ian Cobley
Group Director
Laser Lipo Ltd

510(k) Cover Letter

K130341/S001

K52

FDA CDRH DMC
MAR 4 2013
Received

Dr. Sankar Basu, PHD
U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Control Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 01, 2013

Dear Dr. Basu,

In reference to your email dated February 28, 2013 I can confirm that we have addressed the following elements that were identified as missing or inconsistent within the Acceptance checklist for Traditional 510(k)s.

A. Administrative
Section 7 a
Form 3454 Certification: Financial Interests and arrangements of clinical investigators has been completed.

Section 7 b
Form 3674 Certification of compliance has been completed.

Section 9
The submission identifies prior submissions for the same device details of this can be found within section 3 of our 510(k) Cover letter, and also in section 2 of our 510(k) application CDRH Premarket Review Submission Cover Sheet within section (F)

Section 9 a
We have identified in Appendix A where we identified previous submission issues and how these where resolved.

Please do let me know if I can be of further assistance.

Yours Sincerely

Ian Cobley
Director.

Laser Lipo Ltd. "Heath House" Crockham Hill Edenbridge Kent. TN8 6ST. United Kingdom.
T. 0044 844 980 1820. W. strawberry-laser.com Co. Reg. No. 06308992. VAT Reg. No. 891 7315 01

Dr. Sankar Basu, PHD
U.S. Food and Drug Administration
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Document Control Center - WO66-0609
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Yours Sincerely

Ian Cobley
Director.

Laser Lipo Ltd. "Heath House" Crockham Hill Edenbridge Kent. TN8 6ST. United Kingdom.
T. 0044 844 980 1820. W. strawberry-laser.com Co. Reg. No. 06308992. VAT Reg. No. 891 7315 01

3. 510(k) Cover Letter

Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
United Kingdom, TN8 6ST
Telephone: +44 844 980 1820
e-mail: ian@strawberry-laser.com

February 28, 2013.

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring
Maryland 20993-0002
United States of America

Ref: **510(k) Premarket Notification**

Dear Document Control Clerk:

Pursuant to the requirements of section 510 (k) of the Food, Drug and Cosmetic Act, notification is made to manufacture and market the following new medical device:

Classification Name:
Low Level laser system for aesthetic use
79 OLI

Classification Regulation:
21 CFR 878.5400

Common/Usual Name:
Low level laser system for aesthetic use

Proprietary Name:

Laser Lipo Ltd will manufacture two devices:

- the Strawberry low level laser system model ILO, and,
- the Strawberry & Cream low level laser system model SC

Establishment Registration Number:

The Strawberry low level laser system and Strawberry & Cream low level laser system will be manufactured by:

Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
Kent TN8 6ST
United Kingdom
Telephone: 011 44 844 980 1820
Fax: 011 44 844 980 1820
Establishment Registration Number: To be applied for following clearance of this submission.

Classification:

The FDA has classified: Low level laser system for aesthetic use (79 OLI) as a Class II medical device under 21 CFR 878.5400.

Performance Standards:

None established under 514, however FDA has published "Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use".

The following international consensus standards, recognized by FDA, have been complied with:

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IEC 60825-1:2007 – laser products
ISO 14971:2009 – risk management
ISO 10993-1:2009 - biocompatibility

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EN 980:2008 – European symbols
(explanatory text included in US labeling)
EN 1041:2008 – requirements for information
(supplemented by FDA guidance listed below)

The following Guidance notes have been used extensively in the preparation of this submission:

- Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Format for Traditional and Abbreviated 510(k)s
- Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22

Labeling and Promotional Materials:

Draft labels, labeling (including the User Manual) and promotional materials for the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system are contained in Section 13.

Substantial Equivalence:

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is substantially equivalent in design, use and materials to the:

Chromogenex Technologies Ltd I-Lipo System – K111501

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is made of the similar materials as the Chromogenex Technologies Ltd I-Lipo System – K111501.

The Laser Lipo Ltd Strawberry and Strawberry & Cream low level laser systems has similar indications for use

The Low level Laser model Strawberry and Strawberry and Cream can be used for the non-invasive aesthetic treatment for the temporary reduction in waist circumference.

to the Chromogenex Technologies Ltd I-Lipo System.

The Chromogenex Technologies Limited i-lipo^{Tm} Low Level Laser System is indicated for non-invasive aesthetic treatment for the temporary reduction in circumference of the waist.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is made of the same materials as the Chromogenex Technologies Ltd I-Lipo System – K111501.

- thermoplastic control unit enclosure
  - proprietary components and assemblies used within the unit
- thermoplastic paddles and probes
- nylon covered "velcro" fixed straps
- nylon/polycarbonate goggles

Both the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd i-Lipo System:

- use laser diodes
  - of approximately 660 nm wavelength, and
  - less than 50 mW output
- incorporated into
  - various laser diode cluster probes and paddles attached to the subject with special straps
    Strawberry 4 to 10 paddles with 6 diodes each
    i-Lipo 4 paddles with 9 diodes each
  - and two probes with one diode each
- have a similar control unit
  - LCD subject display
  - membrane key pad inputs
    - incorporated into display as a touch screen for strawberry and cream
  - microprocessor controlled through software
  - multi-range power supply (EU and US voltages and frequencies)
- have a similar range of connecting cables
- have the same two pairs of laser protection goggles
  - different name printed on outside of frame

The Laser Lipo Ltd Strawberry low level laser system, Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd I-Lipo System have the same use achieved through the same technology, are assembled from similar components made from similar materials, have similar user input and output interfaces and have similar features.

All systems use laser emitting diodes of the similar wavelengths and powers: the Laser Lipo systems have the potential to use more paddles but with less

diodes in each paddle. All systems have two cluster probes with a single laser diode in each. In all systems the paddles and cluster probes are secured to the subject with nylon encased rubber straps secured with "velcro".

All control units have plastic enclosures, discrete power supply, microprocessor controlled electronics, controls, alarms and similar control software.

Laser Lipo Ltd concluded that the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system are substantially equivalent to the Chromogenex Technologies Ltd I-Lipo System, K111501

For a demonstration of equivalence, please see Section 12.

Promotional Material giving details of the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and Chromogenex Technologies Ltd I-Lipo System is compared in Section 12.

Previous Submission:
Laser Lipo Limited have previously submitted the Strawberry and Strawberry & Cream Low Level Laser system under K122354 and PRE Submission Q120359. The reasons that the Strawberry and Strawberry & Cream devices were not considered to be substantially equivalent to the predicate device these can be found in Appendix A - Administrative section with a brief summary of the corrective action taken.

Description of Product:
The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system consists of a control unit, various connection leads up to 10 paddles, 2 cluster probes, various "Velcro" attachment straps and other accessories. (A full list of system contents is included at the end of this section.)

A paddle is a device containing six cold red laser emitting diodes which is designed to be placed on the skin. The system can operate using 4, 6, 8 or 10 paddles that are connected to the control unit.

A probe is a device containing one cold red laser emitting diode which is designed to be placed on the skin to treat specific smaller areas of fat, where a usual flat paddle won't ergonomically fit.

The control unit is an electrically powered unit (100-240v, 50-60Hz auto-ranging), enabled by a main switch and key switch. Once enabled it is

controlled using a button (Strawberry) or touch screen (Strawberry and Cream) interface. The output of the diode (six per paddle) is limited to 40mW +/- 15% by a power limiting PCB from the central processing unit.

When the laser paddles are placed on the skin, the cold red laser beams penetrate the skin just deep enough to reach the layers of fat. When the light hits the fat cells, a rapid chain of events takes place. Firstly, pores form on the cells causing them to spill out. The water, Glycerol and fatty acids move into the interstitial space beneath the fatty layer in the skin. Then further water, fatty acids and Glycerol spill out. The adipocyte cells are therefore reduced in size.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system contain the same control electronics and control software however the Strawberry and Cream has a menu driven touch screen interface while the Strawberry model has a liquid crystal display and (up, down, left, right and center/enter) push buttons. The outputs and functionality of the Strawberry and Strawberry and Cream models are identical, however displays, display drivers, interface electronics and software and power supply transformed are different. Full details are contained in Section 11.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is shipped in dedicated packaging to prevent damage and protected by a cardboard box.

The system as shipped contains:

- 1 low level laser system unit, either
  - Strawberry model, or
  - Strawberry & Cream model
- 1 user manual
- 1 power lead
- Paddle leads, for example for a 10 paddle system
  - 1 long paddle lead for connection to the device
  - 8 paddle standard leads
  - 1 long paddle lead
- 2 cluster Probes
- 1 Pair of goggles
- 2 Replacement fuses
- 2 Keys

Variants of the system will be available with 4, 6, 8 and 10 paddles.

number of paddles	number of paddle leads
3 standard and 1 end	3 standard
5 standard and 1 end	5 standard
7 standard and 1 end	7 standard
9 standard and 1 end	8 standard and 1 long (to connect two groups of five paddles)

Table 1 - Variants

A full list of the proposed variants and a schematic drawing showing the key design features are included in Section 11.

Engineering Drawings and Photographs of the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system can be found in Section 11.

Photographs, photo drawings and block diagrams showing the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd I-Lipo System are contained in Section 11 and comparison to the predicate Chromogenex Technologies Ltd I-Lipo System can be seen in Section 12.

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system will be packaged in a cardboard box together with all components (instructions booklet, cables, paddles), software and accessories (diodes, goggles, fuse, straps and lead) within the scope of the 510(k). A shelf-life has been determined for 5 years based on the laser diodes.

Electrical Safety and Electromagnetic Compatibility is demonstrated through compliance with IEC 60601 part 1, part 1-2 and part 2-22 full test reports from a third party laboratory are included in Section 17.

The Guidance also states that there should be compliance with the IEC 60601-1-4 standard. Laser Lipo Ltd believes that compliance with IEC 62304:2006 life-cycle standard achieves at least the same level of assurance in the quality of the software used in the device.

A usability file detailing application of IEC 60601-1-6:2008 is contained in Section 11.

Table 2 - Product Release Testing Summary
Gives the results of bench testing of the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system which can be seen in section 18 and is confirmed by clinical reports in section 20.

Test	Mean	Quantity	Sample Standard Deviation	Capability, Cp
Laser diode power output: Paddle Laser diode output is set to 40mw +/-15%.	39.35	1140	0.81	2.47
Probe Laser diode output is set to 40mw +/-15%.	40.02	40	0.72	3.49
EU portable appliance testing	100% pass	20		
Visual Inspection: • external components, cables, outer casings and the • General condition of all associated parts.	100% pass	20		100% inspection
Assembly tests	100% pass	20		100% inspection
Functionality tests	100% pass	20		100% inspection

Table 2 - Product Release Testing Summary

Biocompatibility:

Biocompatibility assessment on the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system have been conducted following the ISO 10993-1 (FDA Recognized Consensus Standard), Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. Please see section 15.

Sterilization:

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system are supplied non-sterile.

Cleaning instructions are contained in the user manual included with each system.

Safety and Effectiveness:

A summary of safety and effectiveness information ("510(k) Summary" per 21 CFR 807.92) upon which an equivalence determination has been made is included as Section 5.

Indications for Use Statement:

A single sheet statement of "indications for use" as required by FDA for submissions after January 01, 1996, is included in Section 4.

Truthful and Accurate Statement:

The premarket notification "truthful and accurate" statement (per 21 CFR 807.87(k)), signed by the Group Director Ian Cobley of Laser Lipo Ltd is included as Section 6.

E Copy Statement:

The E Copy provided within our submission is an exact duplicate of the paper copy.

Owner:

This Pre-Market Notification is owned by Laser Lipo Ltd.

Submitter:

This Pre-Market Notification is submitted by
Ian Cobley
Group Director
For and on behalf of: Laser Lipo Ltd

Contact Persons:

The address and telephone number for **all** correspondence is:

Ian Cobley
Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
Kent TN8 6ST
United Kingdom
Tel: 011 44 844 980 1820
Mobile: 011 44 777 445 9611
Fax: 011 44 844 980 1820
e-mail: ian@strawberry-laser.com

As per your letter dated February 14, 2013 please find a replacement E copy of our submission.

If I can be of any further assistance, please do not hesitate to contact me.

Sincerely,

Ian Cobley
Group Director
Laser Lipo Ltd

Appendix A

A. Administrative section

9) Laser Lipo Ltd identified our prior submission K122354 within our new application K130341 within 'Section 2 CDRH Pre Market Review Coversheet'.

a) The reasons that the Strawberry and Strawberry & Cream devices were not considered to be substantially equivalent to the predicate device are listed below with the action taken to address these issues.

i) The original application contained data in two studies using two lymph probes for causing lymphatic drainage. The removal of these lymphatic probes required new study data to be supplied.

A new study is contained within Section 20 Performance Testing - Clinical within our new submission K130341.

ii) The previous submission did not include a cardiovascular exercise program post-laser treatment.

This can be found Within the treatment protocol and the clinical studies in Section 20 Performance Testing - Clinical in our new submission K130341.

iii) The Indication for Use (IFU) statement submitted originally included generic fat reduction and body contouring without specifying the anatomical area.

The new submission clarifies that the IFU is for the temporary reduction in waist circumference.
This is listed within K130341 in Section 4, Indications for use statement.

ix) The labeling did not make it clear as to the number of laser paddles (containing 6 laser diodes) should be used on each patient.

Direct comparisons between the Strawberry laser paddles and the predicate laser paddles, including the number of paddles to be used and the amount of energy provided is contained within Section 11 Device Description of K130341

2. CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: December 31, 2013.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
17 December 2012	(b)(4) Trade Secret Process	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Laser Lipo Limited	To be applied for following clearance of this 510[k]		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	011 44 844 980 1820		
Street Address	FAX Number *(including area code)*		
Heath House, Crockham Hill	011 44 844 980 1820		
City	State / Province	ZIP/Postal Code	Country
Edenbridge	Kent	TN8 6ST	U.K.
Contact Name			
Ian Cobley			
Contact Title	Contact E-mail Address		
Group Director	ian@strawberry-laser.com		

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

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

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OLI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached

☐ 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K111501	1	I-Lipo System	1	Chromogenex Technologies Ltd
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Low Level laser system for aesthetic use

	Trade or Proprietary or Model Name for This Device		Model Number
1	Strawberry	1	ILO
2	Strawberry & Cream	2	SC
3		3	
4		4	
5		5	

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

1 K122354	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: OLI

C.F.R. Section *(if applicable)*: 21 CFR 878.5400

Classification Panel: General and plastic surgery devices

Device Class

☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Indications *(from labeling)*

The Low level Laser model Strawberry and Strawberry and Cream can be used for the non-invasive temporary reduction in waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

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

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number To be applied for following clearance of this 510[k]	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name Laser Lipo Limited		Establishment Registration Number To be applied for following clearance of this 510[k]			
Division Name *(if applicable)*		Phone Number *(including area code)* 011 44 844 980 1820			
Street Address Heath House, Crockham Hill		FAX Number *(including area code)* 011 44 1732 866 231			
City Edenbridge		State / Province Kent	ZIP/Postal Code TN8 6ST	Country U.K.	
Contact Name Ian Cobley	Contact Title Group Director		Contact E-mail Address ian@strawberry-laser.com		

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number			
Division Name *(if applicable)*		Phone Number *(including area code)*			
Street Address		FAX Number *(including area code)*			
City		State / Province	ZIP/Postal Code	Country	
Contact Name	Contact Title		Contact E-mail Address		

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number			
Division Name *(if applicable)*		Phone Number *(including area code)* ( )			
Street Address		FAX Number *(including area code)* ( )			
City		State / Province	ZIP/Postal Code	Country	
Contact Name	Contact Title		Contact E-mail Address		

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	62304	IEC	Medical Device Software, Software Life-cycle Processes		2006
	Standards No.	Standards Organization	Standards Title	Version	Date
2	60601	IEC	Medical Electrical Equipment, General Requirements for Safety	part 1	2006
	Standards No.	Standards Organization	Standards Title	Version	Date
3	60601	IEC	Medical Electrical Equipment, General Requirements for safety and essential performance, Collateral standard, Electromagnetic compatibility and tests	parts 1-2	2007
	Standards No.	Standards Organization	Standards Title	Version	Date
4	60601	IEC	Medical electrical equipment, Particular Requirements for safety. Specification for Diagnosis and Therapeutic Laser Equipment.	parts 2-22	1996
	Standards No.	Standards Organization	Standards Title	Version	Date
5	60825	IEC	Safety of laser products, Equipment classification and Requirements	part 1	2007
	Standards No.	Standards Organization	Standards Title	Version	Date
6	14971	ISO	Application of Risk Management to Medical Devices		2009
	Standards No.	Standards Organization	Standards Title	Version	Date
7	10993	ISO	Biological evaluation of Medical Devices, Evaluation and Testing	part 1	2009

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

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

Department of Health and Human Services
Food and Drug Administration
Office of the 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.

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
8	Standards No. 13485	Standards Organization ISO	Standards Title Quality Management Systems, Requirements for Regulatory Purposes	Version	Date 2003
9	Standards No.	Standards Organization	Standards Title	Version	Date
10	Standards No.	Standards Organization	Standards Title	Version	Date
11	Standards No.	Standards Organization	Standards Title	Version	Date
12	Standards No.	Standards Organization	Standards Title	Version	Date
13	Standards No.	Standards Organization	Standards Title	Version	Date
14	Standards No.	Standards Organization	Standards Title	Version	Date

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

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

Department of Health and Human Services
Food and Drug Administration
Office of the 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

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: August 31, 2012

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		
	(b) (6)	

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
IAN COBLEY	DIRECTOR
FIRM/ORGANIZATION: LASER LIPO LTD	
SIGNATURE: [signature]	DATE *(mm/dd/yyyy)*: 28/02/2013

Paperwork Reduction Act Statement

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. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 2-28-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
LASER LIPO LTD

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
JANUARY 31, 2013

3. ADDRESS *(Number, Street, State, and ZIP Code)*
HEATH HOUSE, CROCKHAM HILL, EDENBRIDGE. KENT. TN8 6ST. U.K.

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 0044 844 980 1820
(Fax)

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

STRAWBERRY	ILO
STRAWBERRY and CREAM	SC

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*
K130341 K122354

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☒ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF ~~SPONSOR~~/APPLICANT/~~SUBMITTER OR AN AUTHORIZED REPRESENTATIVE~~ (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) IAN COBLEY
(Title) DIRECTOR

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
HEATH HOUSE, CROCKHAM HILL, EDENBRIDGE. KENT. TN8 6ST. U.K

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 0044 844 980 132
(Fax)

15. DATE OF CERTIFICATION
28/02/2013

PSC Publishing Services (301) 443-6740 EF

K130341/S002

FDA CDRH DMC
JUL 29 2013
Received

Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
United Kingdom, TN8 6ST
Telephone: +44 844 980 1820
e-mail: ian@strawberry-laser.com

July 26, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring
Maryland 20993-0002
United States of America

Ref: **Additional Information - K130341/S1**

Dear Document Control Clerk:

In reference to our ongoing application for a 510k we would like to provide additional information to our application K130341/S1

Additional information comprises of our study protocol.

E Copy Statement:

The E Copy provided within our submission is an exact duplicate of the paper copy.

Owner:

This **Additional Information - K130341/S1** is owned by Laser Lipo Ltd.

Submitter:

This Additional Information is submitted by
Ian Cobley
Group Director
For and on behalf of: Laser Lipo Ltd

Contact Persons:

The address and telephone number for **all** correspondence is:

Ian Cobley
Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
Kent TN8 6ST
United Kingdom
Tel: 011 44 844 980 1820
Mobile: 011 44 777 445 9611
e-mail: ian@strawberry-laser.com

Please find enclosed our E copy submission, along with one paper copy.

If I can be of any further assistance, please do not hesitate to contact me.

Sincerely,

Ian Cobley
Group Director
Laser Lipo Ltd

1. Additional Information (S1) Cover Letter

Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
United Kingdom, TN8 6ST
Telephone: +44 844 980 1820
e-mail: ian@strawberry-laser.com

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This Additional Information is submitted by
Ian Cobley
Group Director
For and on behalf of: Laser Lipo Ltd

Contact Persons:

The address and telephone number for **all** correspondence is:

Ian Cobley
Laser Lipo Ltd
Heath House
Crockham Hill
Edenbridge
Kent TN8 6ST
United Kingdom
Tel: 011 44 844 980 1820
Mobile: 011 44 777 445 9611
e-mail: ian@strawberry-laser.com

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If I can be of any further assistance, please do not hesitate to contact me.

Sincerely,

Ian Cobley
Group Director
Laser Lipo Ltd

Dr Sankar Basu, Ph.D
Senior Physicist
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring
Maryland 20993-0002

Re: Response for K130341/S1

26th July 2013.

Dear Dr Basu

(b)(4) Trade Secret Process - Testing

[redacted]

Yours sincerely

Ian B. Cobley
Director.

(b)(4) Trade Secret Process - Testing

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