

December 18, 2013

To:

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

K133895
FDA CDRH DMC
DEC 20 2013
Received

REF : Traditional 510(k) Notification
DEKA SmartXide²

Dear Sir/Madam:

Attached please find in duplicate (a paper copy and an eCopy) the 510(k) Notification for the DEKA SmartXide² laser system.

The eCopy is an exact duplicate of the paper copy

Sincerely,



Paolo Peruzzi
Regulatory Affairs Manager & Official Correspondent
El.En. S.p.A.
Via Baldanzese, 17
50041 Calenzano (FI)
Italy

510(k) COVER LETTER

December 18, 2013

Food and Drug Administration
Office of Device Evaluation
Document Mail Center (WO66-G609)
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

K133895

FDA/CDRH/DCC
DEC 20 2013
RECEIVED

REF: Traditional 510(k) Notification
DEKA SmartXide² Laser

Dear Sir/Madam,

According to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, as amended (ACT), El. En. S.p.A. (El. En.) proposes to introduce into interstate commerce for commercial distribution a device described herein intended for human use and hereby reports to the Food and Drug Administration as required by law. This premarket notification report is being submitted in duplicate with a separate cover letter.

The following information on the device is provided in accordance with subpart E, 21 CFR Part 807.

a) DEVICE NAME

TRADE NAME	DEKA SmartXide ²
COMMON NAME	Laser for Surgery and Dermatology
CLASSIFICATION NAME	Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology

b) ESTABLISHMENT REGISTRATION NUMBER

El.En.'s Establishment Registration Number is 3001431138.

c) DEVICE CLASSIFICATION

This device has been classified under Section 513 of the ACT as a Class II (Performance Standards) device (21 CFR 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology) by the General Surgery Device Branch of the Division of General and Restorative Devices.

d) PERFORMANCE STANDARDS

El.En. believes that there have been no performance standards promulgated for this device. However, as a laser product, this device is required to conform and does conform with the Laser Performance Standard (21 CFR 1040).

e) LABELING

Labeling and Directions for Use. The proposed Operator's manual includes labeling, specifications, clinical indications, and directions for use. See Exhibit A.

Advertisements. Not available at this time.

f) SUBSTANTIAL EQUIVALENCE

The DEKA SmartXide² Laser is substantially equivalent to the DEKA SmartXide² Laser System and Delivery Accessories, manufactured by El.En. and cleared for commercial distribution by the FDA on February 1, 2013 under 510(k) notification No. K113504. The 510(k) device, DEKA SmartXide² Laser, is a modification of the predicate device by removing the two diode lasers. It only has the CO₂ laser with the power of 60Watts. The delivery system for both devices is an articulate arm attached with a scanner and handpieces. In addition to the micromanipulator that provides the delivery of the beam at various angle, the proposed device has an side firing hand piece to accomplish the same beam delivery but with ease for user-friendliness. In addition, the DEKA SmartXide² is also substantially equivalent to the Cynosure Affirm CO₂ Laser, K081424 for the Scanning Unit indicated for use for the ablative skin resurfacing. All the other indications for use for the three devices are the same. There were no prior submissions for the currently modified DEKA SmartXide² Laser.

Exhibit B contains the information for the predicate devices, the DEKA SmartXide² Laser System and Delivery Accessories, K113504 and The Cynosure Affirm CO₂ Laser, K081424.

A table of comparative features for the devices illustrating their similarities and differences is given in Exhibit C.

It is clearly demonstrated that the DEKA SmartXide² Laser is substantially equivalent to the two predicate devices.

The Truthful and Accurate Statements required by 21 CFR 807.87(k) is attached as Exhibit D.

The 510(k) summary of safety and efficacy information is attached as Exhibit E.

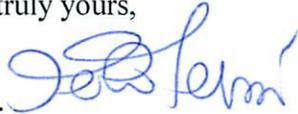
The Indications for Use Statement is attached, as Exhibit F.

Also attached is the Traditional 510(k) RTA Acceptance Checklist Summary as Exhibit G.

In accordance with the Medical Device User Fee and Modernization Act of 2002, the Medical Device User Fee Cover Sheet is attached as Exhibit H. The payment via credit card (mastercard) in amount of \$5,170.00 has been forwarded directly by internet on FDA website.

El.En. would appreciate FDA's efforts to expedite the review of this Notification. We look forward to your prompt reply.

Very truly yours,



Paolo Peruzzi
Regulatory Affairs Manager & Official Correspondent
El.En. S.p.A.
Via Baldanzese, 17
50041 Calenzano (FI)
Italy

Cc: George Cho, US Agent, El En S.p.A.
2 Jordan Road, Hopkinton, MA 01748, USA
Email: georgecho@verizon.net
Phone: 508-435-9140

EL.EN. SPA

**DEKA SMARTXIDE² LASER SYSTEM
510(K) PREMARKET NOTIFICATION**

**El.En. SpA
Via Baldanzese, 17
Calenzano (FI)
Italy 50041**

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ATTACHMENTS:

ATTACHMENT A: PROPOSED SMARTXIDE² OPERATOR’S MANUAL (104 PAGES)

ATTACHMENT B: PROPOSED MICROMANIPULATOR OPERATOR’S MANUAL (44 PAGES)

510(k) COVER LETTER

December 18, 2013

Food and Drug Administration
Office of Device Evaluation
Document Mail Center (WO66-G609)
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

REF: Traditional 510(k) Notification
DEKA SmartXide² Laser

Dear Sir/Madam,

According to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, as amended (ACT), El. En. S.p.A. (El. En.) proposes to introduce into interstate commerce for commercial distribution a device described herein intended for human use and hereby reports to the Food and Drug Administration as required by law. This premarket notification report is being submitted in duplicate with a separate cover letter.

The following information on the device is provided in accordance with subpart E, 21 CFR Part 807.

a) DEVICE NAME

TRADE NAME	DEKA SmartXide ²
COMMON NAME	Laser for Surgery and Dermatology
CLASSIFICATION NAME	Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology

b) ESTABLISHMENT REGISTRATION NUMBER

El.En.'s Establishment Registration Number is 3001431138.

c) DEVICE CLASSIFICATION

This device has been classified under Section 513 of the ACT as a Class II (Performance Standards) device (21 CFR 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology) by the General Surgery Device Branch of the Division of General and Restorative Devices.

d) PERFORMANCE STANDARDS

El.En. believes that there have been no performance standards promulgated for this device. However, as a laser product, this device is required to conform and does conform with the Laser Performance Standard (21 CFR 1040).

e) LABELING

Labeling and Directions for Use. The proposed Operator's manual includes labeling, specifications, clinical indications, and directions for use. See Exhibit A.

Advertisements. Not available at this time.

f) SUBSTANTIAL EQUIVALENCE

The DEKA SmartXide² Laser is substantially equivalent to the DEKA SmartXide² Laser System and Delivery Accessories, manufactured by El.En. and cleared for commercial distribution by the FDA on February 1, 2013 under 510(k) notification No. K113504. The 510(k) device, DEKA SmartXide² Laser, is a modification of the predicate device by removing the two diode lasers. It only has the CO₂ laser with the power of 60Watts. The delivery system for both devices is an articulate arm attached with a scanner and handpieces. In addition to the micromanipulator that provides the delivery of the beam at various angle, the proposed device has an side firing hand piece to accomplish the same beam delivery but with ease for user-friendliness. In addition, the DEKA SmartXide² is also substantially equivalent to the Cynosure Affirm CO₂ Laser, K081424 for the Scanning Unit indicated for use for the ablative skin resurfacing. All the other indications for use for the three devices are the same. There were no prior submissions for the currently modified DEKA SmartXide² Laser.

Exhibit B contains the information for the predicate devices, the DEKA SmartXide² Laser System and Delivery Accessories, K113504 and The Cynosure Affirm CO₂ Laser, K081424.

A table of comparative features for the devices illustrating their similarities and differences is given in Exhibit C.

It is clearly demonstrated that the DEKA SmartXide² Laser is substantially equivalent to the two predicate devices.

The Truthful and Accurate Statements required by 21 CFR 807.87(k) is attached as Exhibit D.

The 510(k) summary of safety and efficacy information is attached as Exhibit E.

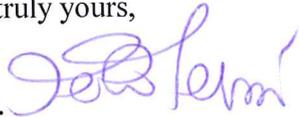
The Indications for Use Statement is attached, as Exhibit F.

Also attached is the Traditional 510(k) RTA Acceptance Checklist Summary as Exhibit G.

In accordance with the Medical Device User Fee and Modernization Act of 2002, the Medical Device User Fee Cover Sheet is attached as Exhibit H. The payment via credit card (mastercard) in amount of \$5,170.00 has been forwarded directly by internet on FDA website.

El.En. would appreciate FDA's efforts to expedite the review of this Notification. We look forward to your prompt reply.

Very truly yours,



Paolo Peruzzi
Regulatory Affairs Manager & Official Correspondent
El.En. S.p.A.
Via Baldanzese, 17
50041 Calenzano (FI)
Italy

Cc: George Cho, US Agent, El En S.p.A.
2 Jordan Road, Hopkinton, MA 01748, USA
Email: georgecho@verizon.net
Phone: 508-435-9140

EXHIBIT A - LABELING

The SmartXide² proposed Operator's manual is attached as Attachment A, and the Micromanipulator proposed Operator's Manual is attached as Attachment B.

EXHIBIT B - PREDICATE DEVICE INFORMATION

K 113504

510(k) Summary

FEB 01 2013

Submitter: El.En. S.p.A.
via Baldanzese, 17
50041 Calenzano (FI), Italy

Contact: Paolo Peruzzi
Regulatory Affairs Manager
Phone: +39.055.8826807
E-mail: standards@elen.it

Date Summary Prepared: January 30, 2013

Device Trade Name: DEKA SmartXide² laser system and delivery accessories

Common Name: CO₂ and Diode Laser System

Classification Name: Instrument, surgical, powered, laser
79-GEX, 21 CFR 878.4810

Equivalent Devices: Lumenis UltraPulse Surgitouch (**K030147**)
Quanta System Polysurge Diode Laser family (**K083613**)
Biolitec 100W Ceralas Diode 980 nm model D100
(**K050824**)

Device Description: The DEKA SmartXide² system is a medical laser system equipped with a 80W CO₂ laser source and an (optional) 980nm or 940nm 50W diode laser source.

The CO₂ laser radiation has a wavelength of 10600nm and is delivered to the treatment area through an articulated arm and a delivery accessory connected to its distal end.

The articulated arm is an optical assembly that delivers free beam laser radiation. It is made up of seven mirrors placed on rotating knuckles: the mechanical accuracy of the articulated arm allows the CO₂ laser beam to travel inside it and along its axis regardless of the arm orientation.

An air flow is provided by an internal pump in order to avoid dust and particles deposition on the optics during laser operations.

The DEKA SmartXide² CO₂ laser can be used with DEKA CO₂ scanning units and the DEKA EasySpot Hybrid micromanipulator.

The scanning units move the beam on the tissue with controlled velocity and defined patterns to optimize the laser ablation.

The CO₂ laser focalized on very little spots by the micromanipulator and moved by scanning systems is useful to fasten the surgical procedures and limit the thermal damage to the tissues surrounding the ablation.

The diode laser source can be provided in two alternative wavelengths: 940nm and 980nm.

The diode laser radiation is delivered to the treatment area through optical fibers, which are guided to the target tissue with the aid of handpieces. The spot size is effectively the diameter of the fiber being connected to the system.

Emission parameters are selected on the front panel while laser emission is activated by a footswitch. The on-off switch and emergency switch are also located on the front panel of the system.

A warning light is located on the top cover, close to the control panel. Light ON state indicates that the system is enabled and ready.

Overall weight of the device is 95 kg, and the size is 210 cm x 59 cm x 56 cm (H x W x D).

Electrical requirement is 100-120Vac 50/60Hz, 220-230Vac 50Hz, 16A.

Indications for Use:

The DEKA SmartXide² CO₂ laser is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery.

The DEKA SmartXide² 940nm diode laser is indicated for incision, excision, vaporization ablation and coagulation of soft tissues (open surgery), cutting, vaporization, ablation and coagulation of soft tissues (endoscopic surgery) in medical specialties including: plastic surgery, dermatology, ENT, gynaecology, urology, general surgery, gastroenterology and dental procedures.

The DEKA SmartXide² 980nm diode laser is indicated for incision, excision, vaporization ablation and coagulation of soft tissues (open and endoscopic surgery) in medical specialties including plastic surgery, dermatology, ear, nose and throat and oral surgery (otolaryngology), gynaecology, urology, neurosurgery, general and thoracic surgery, gastroenterology and dental procedures.

Comparison: The DEKA SmartXide² laser system with its delivery accessories is substantially equivalent to its predicate devices.
It shares same indication for use, same principle of operation and essentially same technological characteristics and performances.

Nonclinical Performance Data: Bench test data and literature data have been provided in order to demonstrate that DEKA SmartXide², despite some differences in emission parameters, behaves as well as, or better than, the predicate devices.
Several histological evaluations have been performed on three different animal tissues, in terms of ablation depth and lateral thermal damage; moreover literature data have been provided to support the DEKA SmartXide² safety and effectiveness for the claimed indications for use.

Clinical Performance Data: None

Conclusion: The tables of comparative features and the provided non clinical performance data show that the DEKA SmartXide² laser system with its delivery accessories is as safe and effective and performs as well as or better than the predicate devices, for the indications for use mentioned above.

Additional Information: None



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

EL.EN. Electronic Engineering SPA
% Mr. Paolo Peruzzi
Regulatory Affairs Manager and Official Correspondent
17 Via Baldanzese
Calenzano, Italy 50041

February 1, 2013

Re: K113504

Trade/Device Name: DEKA SmartXide² laser system and delivery accessories

Regulation Number: 21 CFR 878.4810

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

Regulatory Class: II

Product Code: GEX

Dated: January 08, 2013

Received: January 14, 2013

Dear Mr. Peruzzi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976; the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

Page 2 – Mr. Paolo Peruzzi

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

FOR

Peter D. Rumm -S

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

Enclosure

Indications For Use Statement

510(K) Number (if known): K113504

Device Name: DEKA SmartXide² laser system and delivery accessories

Indications for Use:

The DEKA SmartXide² CO₂ laser is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery.

The DEKA SmartXide² 940nm diode laser is indicated for incision, excision, vaporization ablation and coagulation of soft tissues (open surgery), cutting, vaporization, ablation and coagulation of soft tissues (endoscopic surgery) in medical specialties including: plastic surgery, dermatology, ENT, gynaecology, urology, general surgery, gastroenterology and dental procedures.

The DEKA SmartXide² 980nm diode laser is indicated for incision, excision, vaporization ablation and coagulation of soft tissues (open and endoscopic surgery) in medical specialties including plastic surgery, dermatology, ear, nose and throat and oral surgery (otolaryngology), gynaecology, urology, neurosurgery, general and thoracic surgery, gastroenterology and dental procedures.

Prescriptive Use (Part 21 CFR 801 Subpart D)

OR

Over-the-Counter Use _____ (Part 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
2013.01.31 15:41:15 -05'00'
(Division Sign-Off)
Division of Surgical Devices
510(k) Number K113504

(Optional Format 1-2-96)

510(K) Summary

K 081424

MAR 19 2009

Submitter: Cynosure, Inc.
5 Carlisle Road
Westford, MA 01886

Contact: George Cho
Senior Vice President of Medical Technology

Date Summary Prepared: May 16, 2008

Device Trade Name: Affirm CO₂ and Affirm CO₂ HP lasers

Common Name: Medical Laser System

Classification Name: Instrument, surgical, powered, laser
79-GEX
21 CFR 878.4810

Equivalent Device: Smart CO₂ laser and SmartXide CO₂ with DOT Scanner laser

Device Description: Affirm CO₂ and Affirm CO₂ HP lasers are CO₂ laser, having CO₂ gas as the lasing medium. It is a laser with a wavelength of 10.6 μm.

Laser activation is by foot switch. Overall weight of the laser is 25 Kg, and the size is 180x62x42 cm (HxWxD).

Electrical requirement is 110 VAC, 15A, 50-60 Hz, single phase.

Intended Use: Affirm CO₂ and Affirm CO₂ HP lasers are indicated for incision, excision, and coagulation of body soft tissue.

Comparison: The Affirm CO₂ and Affirm CO₂ HP lasers are substantially equivalent to the Smart CO₂ laser and the SmartXide CO₂ with DOT Scanner laser, with the same principle of operation, the same wavelength and essentially the same power range as the predicate devices for the same indications for uses.

Nonclinical Performance Data: none

Clinical Performance Data: none

Conclusion: The Affirm CO₂ and Affirm CO₂ HP lasers are another safe and effective device for body soft tissue applications.

Additional Information: none



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Cynosure, Inc.
% Mr. George Cho
Senior Vice President of Medical Technology
5 Carlisle Road
Westford, Massachusetts 01886

MAR 19 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Re: K081424

Trade/Device Name: Affirm CO₂ and Affirm CO₂ HP lassers

Regulation Number: 21 CFR 878.4810

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

Regulatory Class: II

Product Code: GEX

Dated: March 13, 2009

Received: March 16, 2009

Dear Mr. Cho:

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

Page 2 – Mr. George Cho

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 081424

Device Name: Affirm CO₂ and Affirm CO₂ HP lasers

Indications For Use:

The Affirm CO₂ and Affirm CO₂ HP lasers with SmartScan scanner are indicated for incision, excision, ablation, vaporization, and coagulation of body soft tissue including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otolaryngology (ENT), gynaecology, neurosurgery, dental, and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

Prescriptive Use X OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 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)

Michael P. ...
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K081424

EXHIBIT C - TABLE OF COMPARATIVE FEATURES

TABLE OF COMPARATIVE FEATURES

	Proposed 510(k) Device	Predicate Device 510(k) K113504	Predicate Device 510(k) K081424
Manufacturer	El En S.p.A.	El En S.p.A.	Cynosure, Inc.
Trade Name	DEKA SmartXide ² Laser	DEKA SmartXide ² Laser	Cynosure Affirm CO2 Laser
Indications	Indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.	Indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. (Other indications specific for the Diode Laser)	The Affirm CO2 laser with SmartScan scanner is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissue including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otolaryngology (ENT), gynaecology, neurosurgery, dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.
Device Type	CO ₂ Laser	CO ₂ Laser, (and Diode Lasers)	CO2 Laser
Wavelength (nm)	10600	10600 (and Diode -940 and 980)	10600
Max. Power Watts	60	60, 80	60
Spot Size (mm)	0.125 to 1.5	0.125 to 1.5	0.2 to 0.4
Pulse Width (ms)	0.04 to 1.5 + CW	0.04 to 1.5 + CW	0.2 – 800 + CW

Rep. Rate	Continuous, single, and repeat pulses (5 to 100 Hz)	Continuous, single, and repeat pulses (5 to 100 Hz)	Continuous, single, and repeat pulses (5 to 100 Hz)
Aiming Beam Wavelength,	635 nm	635 nm	635 nm
Aiming Beam Power, max	5 mW	5 mW	3 mW
Laser Delivery	Articulated Arm	Articulated Arm	Articulated Arm
Beam Delivery Handpiece	Handpieces or scanner with optional micromanipulator or, side firing handpiece	Handpieces or scanner with optional micromanipulator	Handpieces or scanner

EXHIBIT D - TRUTHFUL AND ACCURATE STATEMENT

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As required by 21 CFR 807.87(j))

I certify, in my capacity as Regulatory Affairs Manager of El.En. SpA, 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 of Certifier)

Paolo Peruzzi
(Typed Name)

18 DECEMBER, 2013

(Dated)

(Premarket Notification 510(k) Number)

EXHIBIT E - 510(k) SUMMARY

510(K) Summary

Submitter: El.En. S.p.A.
Via Baldanzese, 17
50041 Calenzano (FI), Italy

Contact: Paolo Peruzzi
Regulatory Affairs Manager
Phone: +39-055-882-6807
Email: p.peruzzi@elen.it

Date Summary Prepared: December 18, 2013

Device Trade Name: DEKA SmartXide² Laser System

Common Name: Medical Laser System

Classification Name: Instrument, Surgical, Powered, Laser
79-GEX
21 CFR 878.4810

Equivalent Device: DEKA SmartXide² Laser System (K113504) and Cynosure Affirm CO2 Laser (K081424)

Device Description: DEKA SmartXide² is a laser with a wavelength of 10600 nm having a maximal power of 60 Watts. The laser energy is delivered to the treatment area via an articulated arm and a delivery accessory connected to its distal end.

Laser activation is by footswitch. Overall weight of the laser is 95 Kg, and the size is 210 x 59 x 56 cm (H x W x D).

Electrical requirement is 100-120 Vac 15A, 50-60 Hz, single phase.

Intended Use: The SmartXide² laser is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

Comparison: The SmartXide² laser has the same indications for use, the same principle of operation, the same wavelength and the same pulse energy range as the predicate devices.

Nonclinical Performance Data: none

Clinical Performance Data: none

Conclusion: The SmartXide² laser is a safe and effective device for the intended uses

Additional Information: none

EXHIBIT F - INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): _____

Device Name: DEKA SmartXide² Laser System

Indications For Use:

It is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____
(Part 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)

**EXHIBIT G - TRADITIONAL 510(K) RTA ACCEPTANCE CHECKLIST
SUMMARY**

Traditional 510(k) RTA Acceptance Checklist Summary

Preliminary Questions:

1. **YES.** The proposed device is a device per section 201(h) of the Food, Drug and Cosmetic Act (FD&C).
2. **YES.** The 510(k) submission for the proposed device is appropriate for CDRH Office of Device Evaluation.
3. There is **no** Request for Designation (RFD) submitted for the proposed device.
4. **YES.** The proposed device is substantially equivalent to a legally commercialized medical device, thus eligible for a 510(k) submission.
5. **NO.** There is no pending PMA for this proposed device.
6. **NO.** The DEKA SmartXide² Laser is NOT the subject of an Application Integrity Police (AIP).

Organizational Elements:

- a) **YES.** A table of contents is included in the submission.
- b) **YES.** Each section of the submission is labeled.
- c) **YES.** Pages are numbered throughout the submission.
- d) **YES.** The 510(k) is identified as a 'Traditional' submission in both the cover letter and page 1 of the submission.

A. Administrative Questions:

1. **YES.** All content in this submission is in **English**.
2. **YES.** The submission cover letter identifies the proposed **device trade name, common name, device classification and device panel**.
3. **YES.** The submission contains the **Indication for Use Statement** with **Rx** designated. See Exhibit F.
4. **YES.** Submission contains a **510(k) Summary**. See Exhibit E.
5. **YES.** The submission contains a signed **Truth and Accuracy Statement**. See Exhibit D.
6. '**N/A**' The submission does NOT contain a **Class III Summary and Certification** because the proposed device is substantially equivalent to a legally commercialized class II medical device, thus is itself a class II device.
7. '**N/A**' Submission does NOT contain **clinical data**.
8. '**N/A**' The submission does NOT reference any national or international standard.
9. **YES.** The cover letter states that **'There were no prior submissions for the currently modified DEKA SmartXide² Laser**. The submission does NOT identify **Prior Submissions** for the device because there are no prior submissions for the subject device.

B. Device Description:

10. '**N/A**' Regarding Device Description, there are no device-specific regulations and/or device-specific guidance applicable to the DEKA SmartXide².
11. **YES.** Device descriptive information is included in the 510(k) Summary. See Exhibit E.

12. **'N/A'** The submission does NOT contain engineering drawings, schematics, illustrations, figures of the device. The **rationale** is because the proposed device is substantially unchanged from the (DEKA SmartXide² Laser) predicate device.
13. **YES.** The device is intended to be marketed with multiple components (Micromanipulator scanner and side firing handpiece).

C. Substantial Equivalence Discussion:

14. **YES.** Predicate devices have been identified by 510(k) number and trade name in the Substantial Equivalence section (Section (f) of the submission letter) and the 510(k) Summary (Exhibit E).
15. **YES.** The submission includes a comparative table of device features that includes Indications for Use and the Technology including features, materials, and principles of operation. (See Exhibit C).
16. **'N/A'** The submission does NOT include why any differences between the proposed device and predicate device does NOT render the device NSE. The proposed device technology is unchanged from the predicate device and there is no difference between the proposed device and predicate with respect to 'intended use'.

D. Proposed Labeling:

17. **YES.** Submission does include proposed labels and labeling that include description of the device, its intended use, and IFU. See Exhibit A, Attachments A and B.
18. **YES.** Proposed labeling includes the 'prescription use statement' in the IFU. See Exhibit A.
19. **YES.** The proposed IFU includes the name and place of business of the manufacturer and the device common name. See exhibit A.
20. **'N/A'** Regarding labeling, there are NO device-specific regulations, device-specific guidance, or special controls documents for the device
21. **'N/A'** The proposed device is NOT an in vitro diagnostic device and labeling requirements of 21 CFR 809.10 do NOT apply.

E. Sterilization: The proposed device is provided non-sterile but sterilized by the end user.

F. Shelf Life:

26. **'N/A'** The proposed device is NOT provided sterile.
27. **'N/A'** The proposed device is NOT provided sterile.
28. **'N/A'** The submission does NOT include a summary of methods used to establish that the proposed device performance is not adversely affected by aging. The proposed device is substantially unchanged from the predicate device. Therefore, the proposed device performance will remain the same as the predicate device.

G. Biocompatibility: There are direct patient-contacting components in the proposed device. See the IFU.

29. **YES.** The submission does include a list of patient contacting device components. In the IFU, the components that contact the patient are discussed and illustrated. See Exhibit A.
30. **YES.** The submission does identify contact classification of patient-contacting device components.
31. **YES.** The submission does include biocompatibility assessment of patient-contacting components and a

statement that biocompatibility testing is not needed with a rationale . See Exhibit I

H. Software: The proposed device DOES contain software.

32. 'N/A'. The Software used in the device is substantially the same as the predicate and the Level of Concern is the same.

33. 'N/A'. The submission does NOT include the software documentation. The Software used in the device is substantially the same as the predicate.

I. EMC and Electrical Safety: The proposed device DOES require EMC and Electrical Safety evaluation.

34. 'N/A'. The submission does NOT include the evaluation of electrical safety for the device. The proposed device is substantially unchanged from the predicate device. The information has been submitted to the FDA during the predicate device 510(k) review.

35. 'N/A'. The submission does NOT include an evaluation of electromagnetic compatibility (EMC) for the device. The proposed device is substantially unchanged from the predicate device. The information has been submitted to the FDA during the predicate device 510(k) review.

J. Performance Data-General:

36. 'N/A' The submission does NOT include performance data.

37. 'N/A' Regarding proposed device performance data, there are no device-specific regulations, device-specific guidance, or special controls document.

38. 'N/A' No reference literature is included in this submission.

39. 'N/A' No non-clinical studies are included in this submission.

K. In Vitro Diagnostic Devices Performance Characteristics: The proposed device IS NOT an in vitro diagnostic device. Items 40 & 41 are N/A.

CHECK LIST COMPLETE.

EXHIBIT H - MEDICAL DEVICE USER FEE COVER SHEET

Site: null

https://userfees.fda.gov/OA_HTML/mdufmaCScdCfgItemsPopup.j...

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/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm> for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

- | | |
|---|---|
| <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates | <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population |
| <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only | <input type="checkbox"/> The 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 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)

18-Dec-2013

REP: *****

["Close Window"](#) [Print Cover sheet](#)

Online Payment

<https://www.pay.gov/paygov/payments/authorizePlasticCardPayment...>

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: FDA User Fees

Pay.gov Tracking ID: (b)(4)

Agency Tracking ID: (b)(4)

Transaction Date and Time: 12/18/2013 03:37 EST

Payment Summary

Address Information

Account: (b)(4)

Holder Name: (b)(4)

Billing Address: (b)(4)

Billing

Address 2:

City: (b)(4)

State /

Province: (b)

Zip / Postal

Code: (b)(4)

Country: (b)(4)

Account Information

Card Type: (b)(4)

Card Number: (b)(4)

Payment Information

Payment Amount: (b)(4)

Transaction Date 12/18/2013 03:37
and Time: EST



EXHIBIT I - BIOCOMPATIBILITY

BIOCOMPATIBILITY

The device parts that may come in contact with the patient are the laser handpieces spacers, the smartcooler handpiece tip and the FT handpiece filters. They are all intended to be used on patient intact skin.

The parts that can get in contact with the patient are the handpieces and scanners terminals. They are made of the same materials used in the DEKA SmartXide², cleared with K113504, with same type of patient contact and same duration of patient contact:

- (b)(4)

According to FDA Guidance G95-1, Required Biocompatibility Training and Toxicology Profile for Evaluation of Medical Devices, following the flowchart in Attachment C:

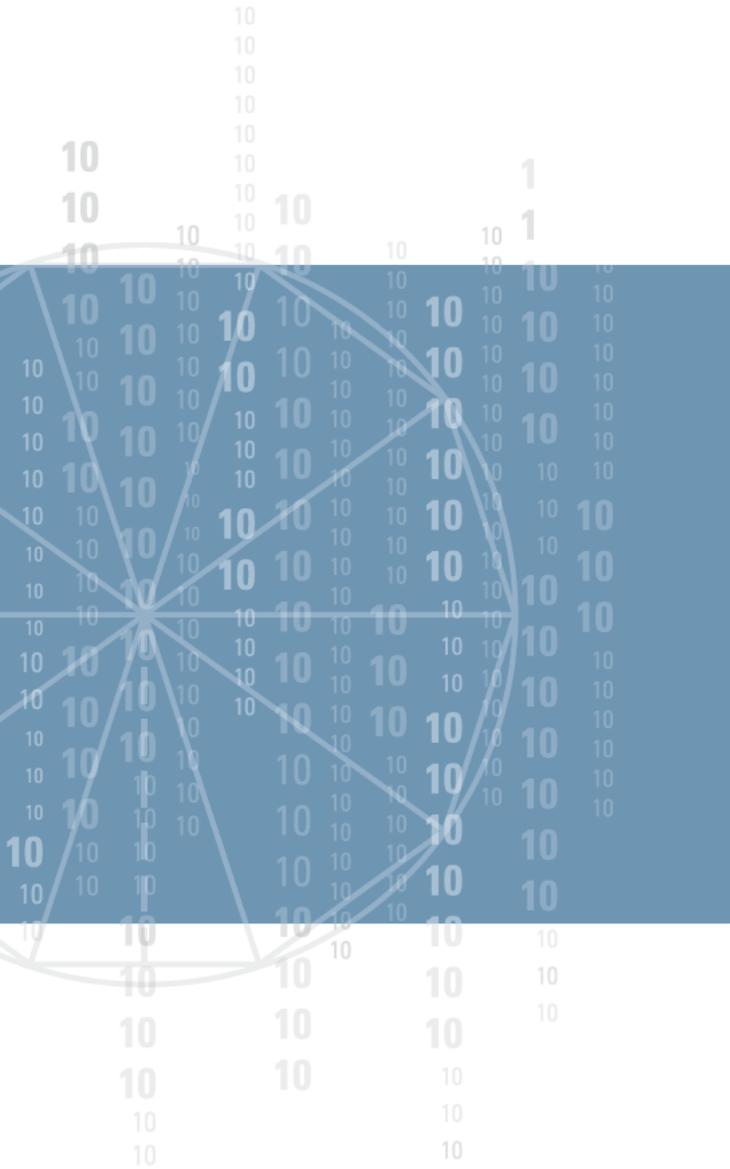
- Is the material same as in the marketed device? YES
- Same manufacturing process? YES
- Same chemical composition? YES
- Same body contact? YES
- Same sterilization method? YES

So, biocompatibility requirements are met and no testing is required.

ATTACHMENT A

PROPOSED SMARTXIDE² OPERATOR'S MANUAL

104 PAGES



OPERATOR'S MANUAL

SmartXIDE²

Code: OM103P1_G.V01

S/N:

Date: 14-Nov-2013



The Code of Excellence

www.dekalaser.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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GLOSSARY

GLOSSARY

The following symbols and abbreviations may be used on the SmartXide² system and/or in this manual.

	Symbol for "Manufacturer"
	Electrical protection degree type B
I	Electrical protection type
~	Symbol of alternating current
	Warning on system discarding (Directive 2002/96/EC)
NOHD	Nominal Ocular Hazard Distance
	Symbol of non ionizing radiation
J	joule - unit of energy
mJ	millijoule - 1000mJ=1J
nm	nanometer - unit of laser wavelength, 1000000nm=1mm
s	second - unit of time
μs	microsecond - 1000000μs=1s
min	minute - unit of time, 1min=60s
Hz	hertz (cycles per second) - unit of frequency
A	ampere - unit of electrical current
VA	volt ampere - unit of absorbed electrical power
V~	unit of alternating voltage
Pa	pascal - unit of measure of atmospheric pressure

Table 1 - Symbols and abbreviations

Table 2 - Units of measurement



GLOSSARY

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1. INTRODUCTION

1.1. The SmartXide² system

The SmartXide² system consists in a 10,600nm carbon dioxide laser (CO₂) laser with 60W of maximum power.

As scientifically entirely known, the 10,600nm wavelength is mostly absorbed by water; this characteristic makes this laser particularly suitable for soft tissue surgery.

CO₂ laser surgery is well recognized to be minimally invasive and highly effective, as proven by the hundreds of scientific articles written on this kind of laser in surgery and microsurgery in various disciplines and districts for more than 20 years.

The scanner technology (HiScan Surgical) can be used for surgical applications coupled with microspot micromanipulators for microsurgery applications in ENT, gynaecology and neurosurgery.

Another scanner, a miniaturized one, the EndoScan, is connectable with the SmartXide² system. This scanning unit is suited mainly for gynecological application both in colposcopic and laparoscopic procedures, but also for other surgical applications in which quick ablation is needed.

An additional scanner known as HiScan DOT can be connected to the system: this scanning unit is designed for ablative skin resurfacing and gynaecological applications.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician or other practitioner licensed by the law of the state in which he/she practices to use or order the use of the device.

Federal law and some international laws also require that this device be utilized under the direction of a physician. This device should only be used by healthcare professionals authorized under US state or international laws to treat patients.

All persons treating patients with this device should determine whether they are authorized healthcare professionals under the applicable US state or international laws.

INTRODUCTION

1.2. About the Manual

The SmartXide² Operator's Manual provides operators with the following information about the system:

- Indications for use
- Safety
- System description
- Installation
- Use of the system
- Scanning units
- Clinical Applications
- Faults and troubleshooting
- Maintenance
- Accessories

Before using the system for the first time, please familiarize yourself with the information and instructions of this manual. This is essential to ensure an effective and optimal use of the system, to avoid damage to people or to the device and to obtain good results of treatment.

In this manual we use different colours to highlight warnings:

- warnings on a grey background are remarks for a correct use of the system and of its accessories;
- warnings on a grey background and with a yellow triangle are remarks concerning safety.

Operators must read and follow all the remarks.

**CAUTION**

Possible risk for patient/operator

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

INDICATIONS FOR USE

2. INDICATIONS FOR USE

The SmartXide² system with its accessories is a medical device indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues, in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery, and genitourinary surgery. the use with scanning unit is indicated for ablative skin resurfacing.

The device is not indicated to be used for Prostate Ablation procedure.

The SmartXide² system must not be used for applications different from those specified above.

DEKA M.E.L.A. s.r.l. is not responsible for direct or collateral effects resulting from use of the system different from the intended use specified above.

**CAUTION**

Possible risk for patient/operator

DEKA M.E.L.A. s.r.l. is not responsible for the direct or indirect effects arising out of or in connection with, or resulting from the application or use of the system that are not a direct consequence of design or manufacturing defects of the device or parts thereof. The manufacturer shall not be responsible of the success of the treatment.

**CAUTION**

Possible risk for patient/operator



INDICATIONS FOR USE

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WARNINGS**3. WARNINGS**

This manual is not intended to be a complete guide to the use of the system.

DEKA M.E.L.A. s.r.l. recommends that all users first seek training that includes, but is not limited to, the following aspects of operation:

- Basic Laser Energy Physics
- Laser Safety
- Tissue Interaction
- Operating Procedures
- System Set-Up Procedures
- Potential Hazards

DEKA M.E.L.A. Srl shall not be liable nor responsible of the safety and performance in the following cases:

- if the system is not used in compliance with health and safety rules and regulations in force;
- if the precautions and instructions contained in the present manual are not observed;
- if the system is not used by qualified and trained personnel;
- if the installation, any modification, recalibration or maintenance are not performed by qualified personnel authorised by DEKA M.E.L.A. s.r.l.;
- if the environment in which the system is located and used does not conform with all electrical, laser, etc. safety prescriptions specified by the applicable international and local regulations and international guidelines in force.

DEKA M.E.L.A. s.r.l. reserves the irrevocable right to provide, upon written request, maintenance personnel authorised by the same, with electrical diagrams, components lists, adjustment instructions and any information relating to the parts of the system which are considered to be repairable.

WARNING

Do not modify this equipment without authorization of DEKA M.E.L.A. Srl.



WARNINGS

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PREMISES

4. PREMISES

The following instructions must be scrupulously observed.

4.1. Delivery – Inspection of goods received

Unless otherwise agreed between the manufacturer and the customer, the delivery of the goods shall be ex works (INCOTERMS 2000) even if it has been expressly agreed that the transport or part thereof shall be the responsibility of the manufacturer on the customer's behalf.

Upon delivery, all risks inherent to the system shall be transferred to the customer. Therefore, any damage to the system during transport shall be to the customer's account.

It shall be the customer's responsibility to inspect upon delivery and in the presence of the carrier, the integrity and condition of the goods received; to verify correspondence between the goods delivered and those described in the transport documentation; to immediately bring to the carrier's attention any divergence and/or damage noticed.

4.2. Working environment

The environment in which the device is located and operated must be suitable and comply with the relative legal requirements and regulations in force, applicable also to the associated systems, concerning the use and storage thereof in complete safety to persons and objects. The operation, workplace health and safety measures and any other activities shall be the exclusive responsibility of the relevant person(s) in charge and must be performed in compliance with local laws and Regulations and, where applicable, in compliance with European Directives (Council Directive 89/391/EEC and subsequent).

4.3. Responsibilities

The manufacturer shall guarantee the conformity of the product with EC safety and hygiene requirements according to the applicable Directives. The use of the system shall be the exclusive responsibility of the operator who shall be obliged to apply the necessary and adequate diligence and skills.

The manufacturer shall be responsible in terms of and within the exclusive scope of current regulations applicable to the production and marketing of medical devices.

The manufacturer shall not be responsible for unfavourable consequences resulting from installation, use or maintenance which does not comply with the instructions in the present manual or resulting from failure by the user to apply the care, precautionary measures and safety regulations necessary to avoid such consequences.

PREMISES

4.4. Laser Safety Officer

We recommend prior consultation of the IEC TR 60825-8 Safety of laser products, Part 8: Guidelines for the safe use of laser beams on humans (2006-12, Second edition), which is a guideline on how to apply laser safety in medical practices.

In accordance with Point 3.1 of the abovementioned guidelines, we recommend that a Laser Safety Officer be appointed and a precise definition of the relative responsibilities established.

SAFETY

5. SAFETY

This chapter provides a short description of the current safety standard taken in account while designing and manufacturing the SmartXide² system.

This section also covers specific safety features designed to minimize potential hazards.

5.1. General safety

The SmartXide² system is compliant with, but not limited to, the following standards:

- **Standard IEC 60601-1** - Medical electrical equipment Part 1: General requirements for safety
- **Standard IEC 60601-1-2** - Medical electrical equipment Part 1: General requirements for basic safety and essential performance - 2. Collateral standard: Electromagnetic compatibility - Requirements and tests
- **Standard IEC 60601-2-22** - Medical electrical equipment Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
- **Standard IEC 60825-1** - Safety of laser products - Part 1: Equipment classification and requirements

Classification:

- According to Standard IEC 60601-1, the SmartXide² system is classified as "**Class I**" with regard to the type of electrical protection, and "**type B**" for the degree of electrical protection.
- According to Standard IEC 60825-1, the SmartXide² system is in **Class 4**.

5.2. Optical hazard

The SmartXide² system emits a visible/invisible beam of intense energy that can cause serious eye and skin injury with direct or indirect beam contact. Please adhere to the following precautions to minimize optical damage to operators, assisting personnel and patients:

- All persons in the room during treatment must wear **protective eyewear**. See next paragraph for protective eyewear specifications.

- **Never look directly into the handpiece, into the fiber or into apertures labelled "laser aperture", even while wearing protective eyewear.**
- **Limit entry to the treatment room to only those who assist in treatment and are trained in the use of the equipment.**



CAUTION

Possible risk for patient/operator

SAFETY

- Mark treatment rooms clearly to avoid unexpected entry during treatment.
The label shown in Fig. 1 must be put on the external part of each entrance to these areas in order to point out the presence of a laser source inside.

Fig.1 - Door safety label



Two of these labels are provided with the SmartXide² accessories.



CAUTION

Possible risk for patient/operator

- **Direct the activated laser only at the intended area of treatment.**
- **Remove any metal object such as watches, rings, necklaces and similar items from the operating area and, if possible, do not use reflective instruments or materials.**

Reflective objects could intercept the laser beam causing a deflection to an area other than the intended treatment area. Many surfaces that may seem opaque can actually reflect the CO₂ laser emission wavelength.

- Put the system into the Standby mode when not in use (when in Standby mode, the beam cannot be inadvertently activated).
- Ensure that all trained staff assisting in the treatment know how to shut down the system in the case of an emergency.
- **Always remove the key from the switch when the system is switched off and keep it in a safe place.**

5.2.1. Protective eyewear specifications

Safety glasses must comply with the European regulation EN 207 "Personal eye-protectors. Filters and eye-protectors against laser radiation" and with the U.S. regulation ANSI Z136.7 "American National Standard for Testing and Labeling of Laser Protective Equipment".

They must have at least the following characteristics:

CO₂ aiming beam laser radiation:

OD• 0.4 at 630-670nm for beam intensity>60% (ANSI Z136.7)

CO₂ laser radiation:

OD• 4 at 10600nm (ANSI Z136.7)

D LB5 I LB5 at 10600nm (EN 207)

Contact your area agent or DEKA M.E.L.A. s.r.l. company for information on where to find this type of eyewear.

SAFETY

<p>As a safety precaution, eyes must not be exposed to direct laser radiation, even if protected by glasses.</p>	 <p>CAUTION <i>Possible risk for patient/operator</i></p>
--	---

<p>Safety glasses for CO₂ laser radiation are different from those for diode laser radiation and must not be exchanged. Always check you are wearing the right goggles: verify that the wavelength of the source you are using is marked on the lens or on the frame. See the example below for CO₂ glasses.</p> 	 <p>CAUTION <i>Possible risk for patient/operator</i></p>
--	---

5.3. Electrical Hazard

The SmartXide² system uses high voltages internally. Do not open the protective panels unless trained and authorized to do so.

<p>To avoid the risk of electric shock, this device must only be connected to a supply mains with protective earth.</p>	 <p>CAUTION <i>Possible risk for patient/operator</i></p>
---	---

5.4. Biological Hazard

<p>The laser smoke presents a possible biological hazard. Ablated tissue from the patient is present in the smoke. Laser smoke may contain viable particles. Use of a laser smoke evacuator is recommended.</p>	 <p>CAUTION <i>Possible risk for patient/operator</i></p>
---	---

5.5. Fire Hazard

When the light or the laser beam contacts an exterior surface, that surface absorbs energy. This raises the surface temperature, whether the surface is skin, hair, clothes, or any flammable substance. Operators should take the following precautions to prevent a fire:

- Use non-flammable substances for such uses as anesthesia, preparing soft tissue for treatment, and cleaning or disinfecting instruments.
- Be especially careful with the use of oxygen. Oxygen accelerates both

SAFETY

the severity and the extent of fire.

- Keep a minimum of combustible materials in the treatment room. If treatment requires the use of a combustible material, such as gauze, first soak it in water.
- Prevent singeing or burning when treating an area with hair by wetting the area with water or saline before beginning treatment.
- Always keep a small fire extinguisher and water in the treatment room.

**CAUTION**

Possible risk for patient/operator

Never use inflammable gas for gas shield.

The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N₂O) and oxygen should be avoided.

Some materials, for example cotton wool, when saturated with oxygen may be ignited by the laser equipment.

The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.

Attention should also be drawn to the danger of ignition of endogenous gases.

5.6. Radio frequency interference

The SmartXide² system complies with the EN 60601-1-2 standard.

It needs special EMC precautions and needs to be installed according to EMC information provided in this manual - see Appendix -.

Portable and Mobile communication equipment can affect the SmartXide² system.

The SmartXide² system should not be used near other equipment. If this is necessary, observe the SmartXide² to verify normal operation in the stacked configuration in which it will be used.

5.7. Essential performances

The following functions are Essential Performances, i.e. performances necessary to keep risk within acceptable limits:

- ability of the system to prevent any unwanted laser emission;
- ability of the system to stop laser emission as soon as footswitch is released;
- ability of the system to maintain laser output power during treatment within $\pm 20\%$ with respect to the set value.
- ability of the system to perform emission only from the selected source.

SAFETY

5.8. Safety labels

The SmartXide² system is provided with the safety labels shown in the following figure.

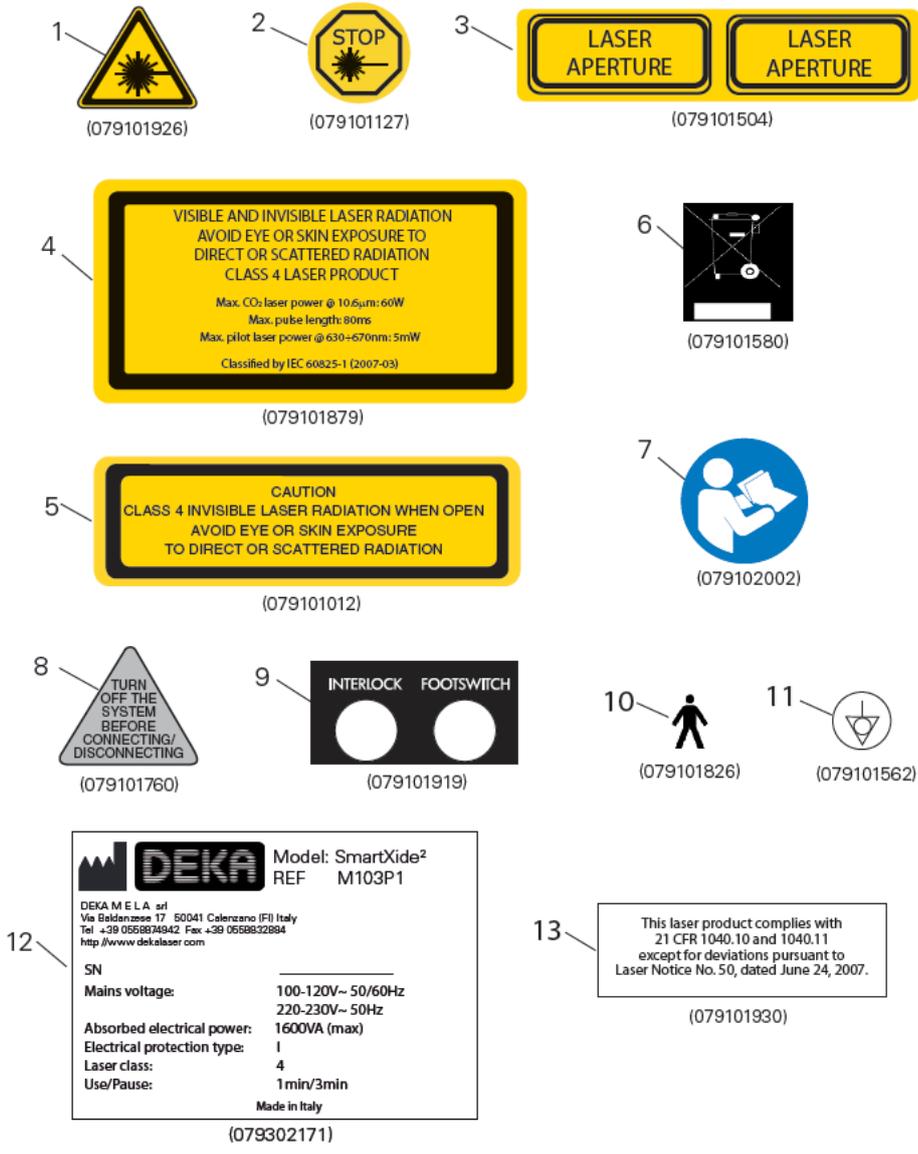


Fig.2 - Safety labels

SAFETY

5.8.1. Meaning of the safety labels

Table 3 gives the descriptions of the meanings of the safety labels shown in Fig. 2.

Table 3 - Meaning of the safety labels

Label Nr	Meaning
1	Emission of laser radiation.
2	Identification of the emergency switch for fast system turn off.
3	Identifies the aperture from which laser radiation comes out.
4	Warning on dangers related to the exposure to laser radiation. Specifications on the characteristics of CO ₂ laser radiation.
5	Warning on dangers related to the exposure to laser radiation in case of removal of panels of the chassis.
6	Warning on system discarding (Directive 2002/96/EC).
7	Warning. The operator is recommended to read carefully the operator's manual before using the system.
8	Warning on scanning unit connection/disconnection.
9	Identification of the rear panel's (interlock and footswitch) connections.
10	Electrical protection degree type B.
11	Potential equalization connector label.
12	System identification label.
13	CDRH certification label

NOTE

All the labels must be kept in their own position, in good condition and immediately replaced if damaged.

SAFETY

5.8.2. Positions of the safety labels

The safety labels shown in Fig. 2 are placed as shown in Fig. 3.

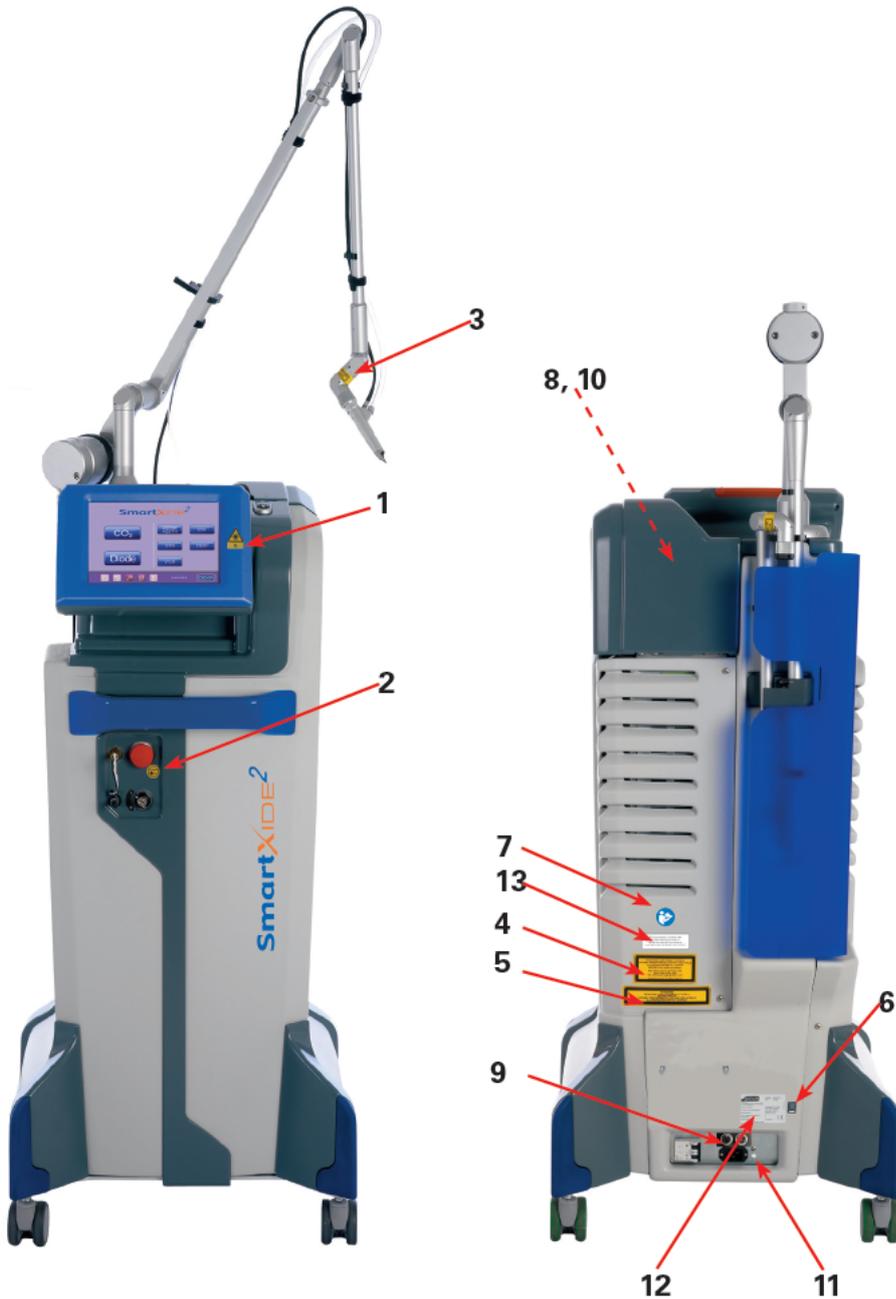


Fig.3 - Position of the safety labels



SAFETY

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6. SYSTEM DESCRIPTION

The operator interacts directly with the following external portions of the system.

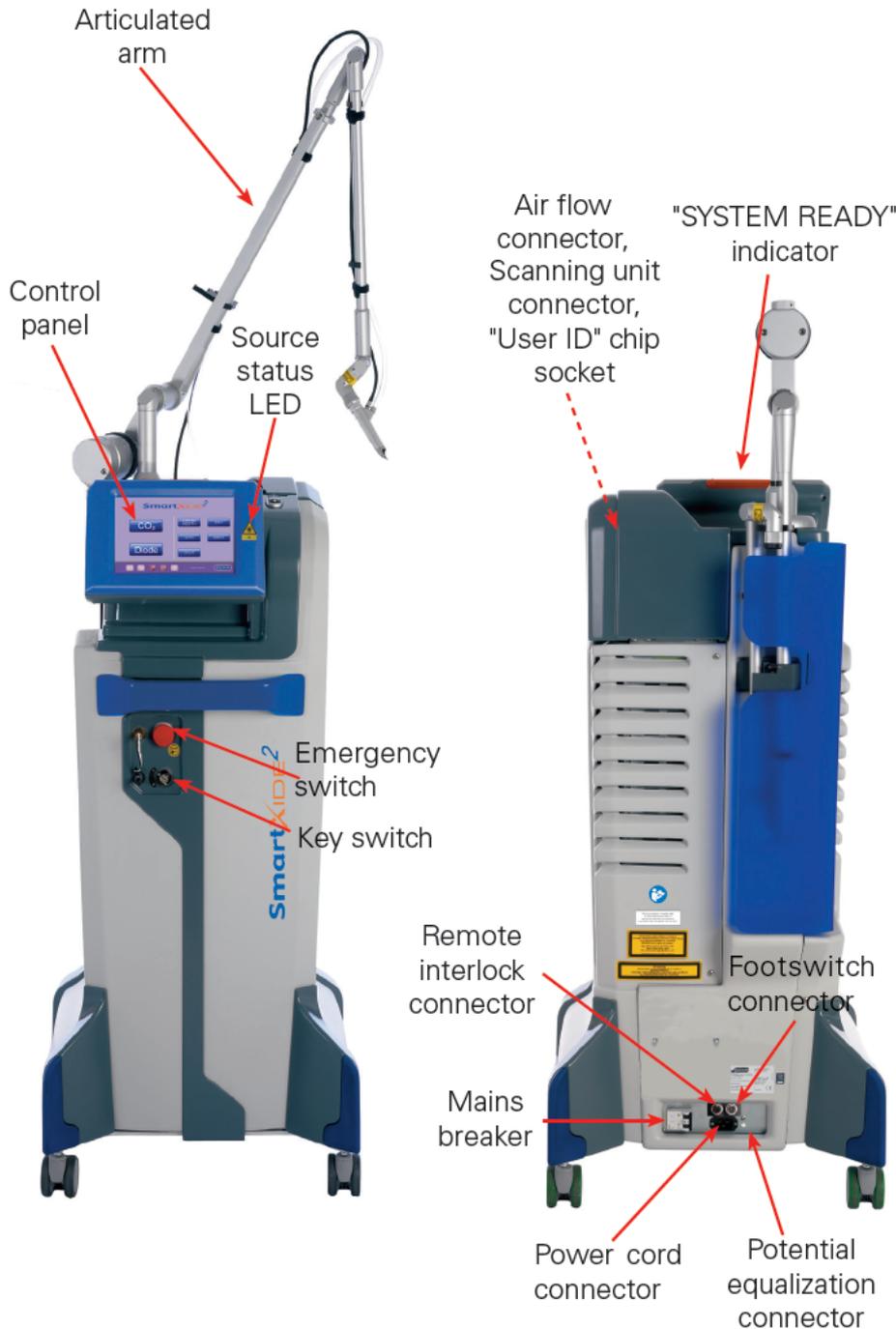


Fig.4 - System's main external components

SYSTEM DESCRIPTION

6.1. Control and signal devices

6.1.1. System switches

The system power controls are comprised of the switches described in detail below. Please refer to Fig. 5 for their position on the device.

Key Switch

To turn the system on and off use the key switch.

It is a double-throw switch (right-left) with removable (only if it is in the "O" position) safety key.

To turn the system on, insert the key and turn the key switch to "I"; to shut the system down normally, turn the key to "O".

The key switch works to turn on the system only if the emergency switch is not pushed in.



CAUTION

Possible risk for patient/operator

The key must always be removed when the system is turned off and must be kept only by authorized personnel.

Emergency Switch

The emergency switch shuts down the system immediately.

Use it only under emergency circumstances that is in case it is necessary for the operator to stop immediately emission.

To shut down the system, push in the switch button. To reset the switch, rotate the button and pull out.

ATTENTION

Possible equipment damage

Do not use the emergency switch to turn on and off the system under normal circumstances.

Mains breaker

This switch is located on the bottom side of the rear panel.

Move towards left the lever of the switch (position "I") to supply the system.

6.1.2. Footswitch

When the system is in READY mode, activate the emission by pressing the footswitch, which is an electrical switch intended to be located on the floor and actuated by foot.

6.1.3. Potential Equalization Connector

The potential equalization connector is provided on the lower portion of the rear panel.

Connecting a potential equalization cable from this connector to an appropriately grounded connection in the operating room offers additional grounding of the laser system (potential equalization).

SYSTEM DESCRIPTION

6.1.4. Internal buzzer

The system is equipped with an internal buzzer which produces an acoustic signal in the following cases:

- To warn the operator in case a wrong action has been performed - for instance, if footswitch is pressed when disabled -.
- If a laser treatment is in progress - CO₂ source switched on, footswitch enabled and pressed, shutter open, real power level correct - a sound is produced every 1s. This timed sound is intended to help the operator to 'measure' the treatment time.
- If a laser treatment is in progress - CO₂ source switched on, footswitch enabled and pressed, shutter open, power level mismatch - five sounds are produced every 1s. This faster timed sound is intended to warn the operator that a power mismatch has been detected, that is the real CO₂ output power level no more matches with the power level found by the power evaluation procedure. See also par. 8.7.

6.1.5. "SYSTEM READY" indicator

The "SYSTEM READY" indicator (see Fig. 5) is lighted when the emission is enabled.

6.1.6. Source status LED

This LED (see Fig. 5) is blinking when the start up procedure is in progress, it is orange lit when the "ON"/"READY" status is set; it is red lit during emission. When the system is in stand by, the LED is green lit.

6.1.7. Control panel

The control panel contains controls and displays for operating and monitoring the laser.

It contains a rear-lit touch-screen graphic display. All the functional controls of the device can be set by lightly pressing an area of the screen itself.

In order to have a better view, it is possible to adjust the display visual angle by pressing on the two keys next to the display itself (highlighted in Fig. 6).



Fig.5 - Display adjusting keys

Be very careful while the display is moving: do not keep your hands onto or near the display. *Danger of crushing!*



CAUTION

Possible risk for patient/operator

Please do not adjust the visual angle moving the display by hands!
Only electronic adjustment is allowed.

ATTENTION

Possible equipment damage

SYSTEM DESCRIPTION

6.2. Articulated arm and CO₂ handpieces

A wide range of handpieces can be provided with the SmartXide² system, having different spot sizes and high performances in specific application field. The system can be provided with a handpiece body which can house different lens assemblies (1.5", 2", 4", 7" and collimated, please refer to Fig. 8).

Moreover, a 5" handpiece and a 8" handpiece are available: each of them consists of the handpiece body (and lens assembly) with interchangeable handpiece spacers. These spacers are either straight, straight with backstop, 90° and 120° delivery for 5" handpiece; straight and straight with backstop for 8" handpiece (please refer to Fig. 9 and Fig. 10).

NOTE

If the 8" handpiece is connected to the EndoScan unit, the user has not to select scanning figures larger than 60%.

The term "spot size" identifies the diameter of the laser beam (and therefore the diameter of the circular area exposed to laser radiation) when the handpiece is hold perpendicularly to the surface to be treated and the laser beam is in focus.

The spot of the collimated handpiece is about 2.0mm (at 86% of output power).

The handpiece is attached to the distal end of the articulated arm.

The articulated arm is an optical assembly that delivers beam laser radiation. It is made up of seven mirrors placed on rotating knuckles: the mechanical accuracy of the articulated arm allows the CO₂ laser beam to travel inside it and along its axis however the arm is oriented.

The field of action of the articulated arm covers a radius of approximately 80 cm, the transfer efficiency of power is greater than 85%. The loss of 15% is balanced by a suitable calibration of the internal power meter.

An air flow is provided by an internal pump in order to avoid dust and particles deposition on the optics during laser operations.

The inlet connector on the handpiece is connected via a black plastic PVC tube to the proper output connector located on the rear side of the system. See par. 7.5 for details on the connections.

During system operation never disconnect the black tube.

Fig.6 - Laser handpiece



It is also possible to connect the handpiece to an external smoke evacuator via a flexible hose.

SYSTEM DESCRIPTION

In the lower part of the system side panel there is a suitable holder for the connection hose of an external smoke evacuator.

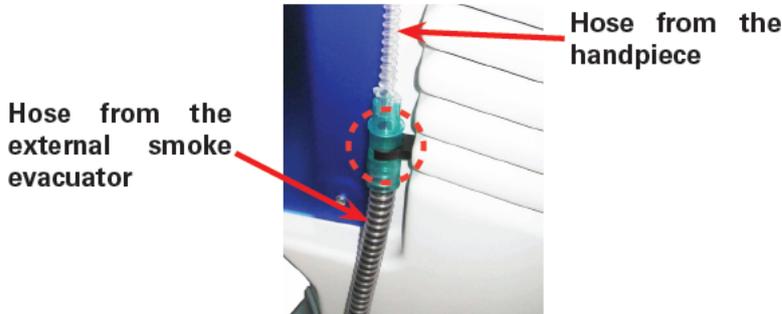


Fig.7 - Positioning of the smoke evacuator hose on the system

As the aiming beam passes down the same delivery system as the working beam it provides a good method of checking the integrity of the laser delivery system. If the aiming beam is not present at the distal end of the delivery system, its intensity is reduced, or it looks diffused, this is a possible indication of a damaged or not properly working system (EN 60601-2-22).



CAUTION

Possible risk for patient/operator

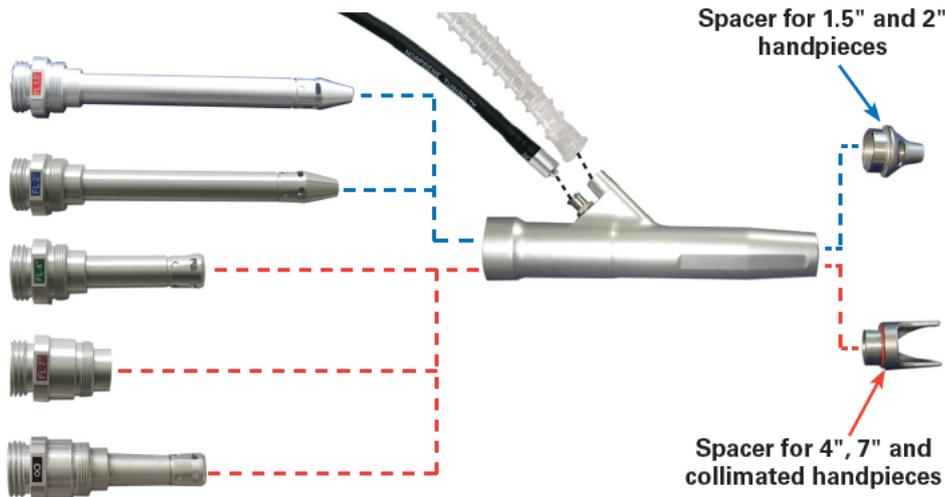
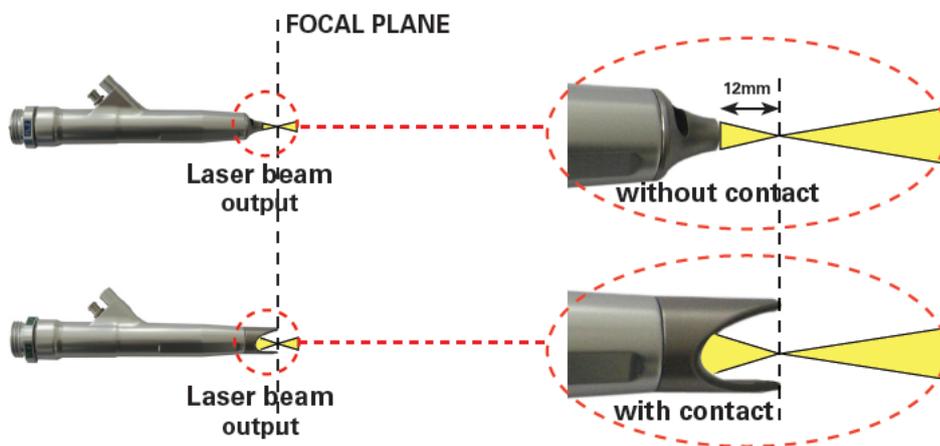


Fig.8 - Assembling the handpieces



SYSTEM DESCRIPTION

Fig.9 - 5" handpiece and spacers

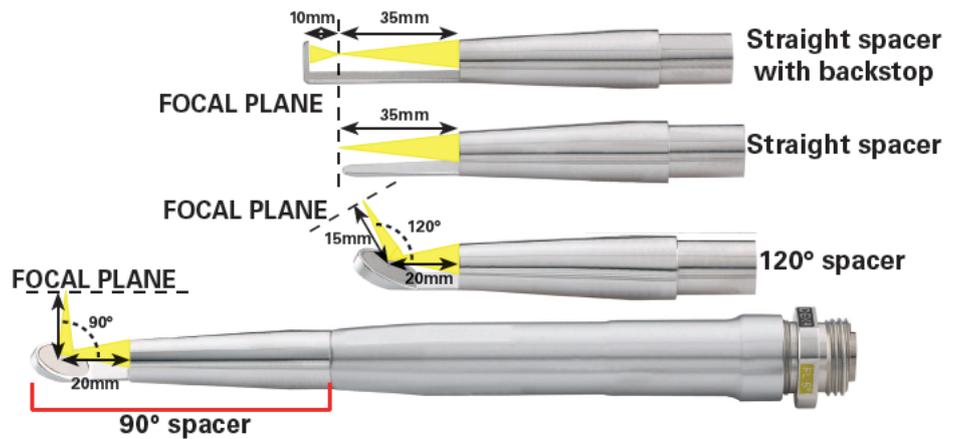
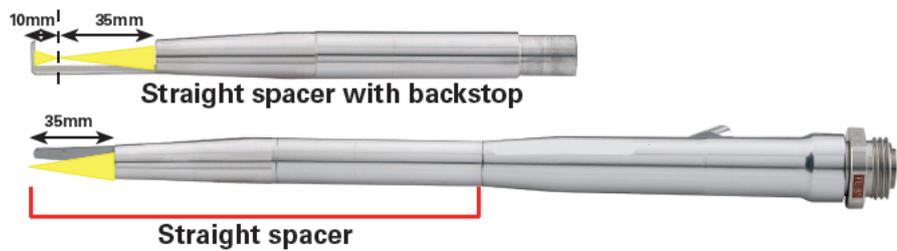


Fig.10 - 8" handpiece and spacers



Changing lens assembly

To change the lens assembly, disconnect the air pipes from the handpiece barrel, then unscrew the handpiece from the articulated arm. Extract the lens assembly currently screwed onto the handpiece and screw the one to be used. Connect again the air purge tubing and the smoke evacuator (if present).



CAUTION

Possible risk for patient/operator

Please pay attention to insert the lens assembly you want really to use: the focal length is marked on the holder itself!

Changing handpiece spacer

The handpiece spacer can be easily changed by removing the final part of the handpiece itself and inserting the new spacer. Use the narrow spacer for 1.5" and 2" handpieces, the open one for 4", 7" and collimated handpieces (please refer to Fig. 8). Use their own spacers for 5" and 8" handpieces.

SYSTEM DESCRIPTION

6.2.1. CO₂ handpieces for dental applications

The handpieces shown in Fig. 11 and Fig. 12 can be provided for the CO₂ laser source to be used for dental applications for the treatment of soft tissues.

The handpieces consist of the handpiece body and interchangeable handpiece apertures.

The 4" handpiece (Fig. 11) comes with four different apertures: a straight aperture and an open aperture to transmit the laser beam in line with handpiece's axis, and two apertures with mirror to deflect the laser of 75° or 120°. Moreover, the straight and 75° apertures can be used with removable ceramic tips to work in contact with the tissue.

The 2" handpiece (Fig. 12) includes two apertures: a straight aperture that transmits the laser beam in line with handpiece's axis, and an aperture with mirror to deflect the laser of 120°.

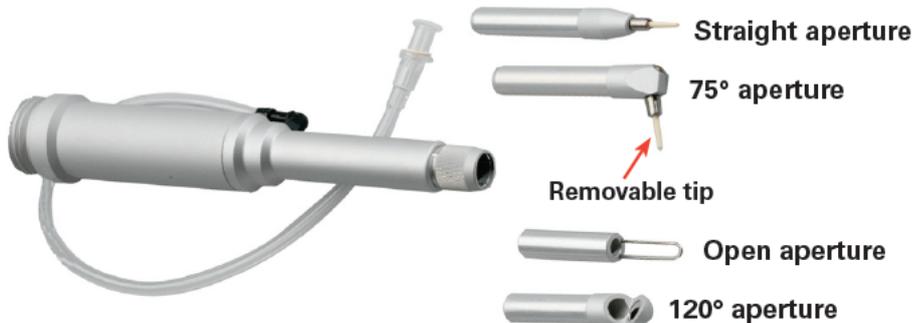


Fig.11 - 4" dental handpiece (N324A2)



Fig.12 - 2" dental handpiece (N377A1)

Changing 2" handpiece aperture

The 2" handpiece aperture is easily changed by unscrewing the final part of the handpiece itself and screwing the new aperture.

Changing 4" handpiece aperture

The 4" handpiece aperture is easily changed by loosening the ring nut located toward the end of the handpiece body. Pull the aperture out of the end of the body. Slide the new aperture into the end of the body until it stops and hand tighten the ring nut.

Changing contact tips

Pull on the tip to remove and push the new tip into the hole located at the end of the aperture until it stops.



SYSTEM DESCRIPTION

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INSTALLATION

7. INSTALLATION

Remove the device from its packaging, position it on a horizontal surface and lock the front wheels by using the locking system provided on them, so that it is stable.

Conserve the packaging in case it is necessary to repack the device for future transport or storage.

Check that the items listed in Section "Accessories" are included inside the box together with the device.

7.1. System requirements

7.1.1. Dimensions and weight

The SmartXide² system has the following dimensions and weight:

Height	210 cm 162 cm (with folded articulated arm)
Width	59 cm
Depth	56 cm
Weight	95kg

Table 4 - Dimensions and weight

7.1.2. Electrical requirements

Please consider the following electrical requirements before installing the system:

- the AC line power requirements for the SmartXide² system are:
100-120V~ 50/60Hz
220-230V~ 50Hz
16 A
- make sure the socket is efficiently earthed.
- the SmartXide² system unit should not share a power line with other heavy power-load equipment. The system should be on a separate power line with a separate circuit breaker.
- The SmartXide² should not be used near other equipment. If this is necessary, observe the SmartXide² to verify normal operation in the stacked configuration in which it will be used.

INSTALLATION

7.1.3. Environmental requirements

Follow these environmental requirements to properly maintain the system:

- Keep the air free of corrosive substances, such as salts and acids. These pollutants may damage electrical wirings;
- Keep dust particles to a minimum. Dust particles can cause damage to the system;
- Do not place system near heat sources.
- Observe the following temperature, humidity and pressure requirements:

Table 5 - Operating and environmental conditions

Operating temperature	From 15°C to 35°C
Operating humidity	From 20% to 80%
Atmospheric pressure	From 70,000Pa to 106,000Pa

Table 6 - Transport and storage conditions

Storage temperature	From 0°C to 50°C
Temperature during transport	From 0°C to 50°C
Operating humidity	From 10% to 90%
Atmospheric pressure	From 70000Pa to 106000Pa

7.1.4. System specifications

The SmartXide² system is equipped with a CO₂ laser source, emitting an infrared beam, and an aiming laser source, emitting a visible red beam. These two laser sources have the emission specifications listed in Table 7 and Table 8:

Table 7 - System specifications

Type	Value
Mains voltage	100-120V~ 50/60Hz 220-230V~ 50Hz
Absorbed electric power	1600 VA (max)
Circuit breaker	16A delayed
Electrical protection degree	
Electrical protection type	I
Laser class	4
Use/Pause	Intermittent: use 1min, pause 3min

INSTALLATION

Type	Value	
Wavelength	10.6 μ m	
Maximum output power	C60	60W
Method of Optical Output	7-mirror articulated arm	
Output mode	TEM ₀₀	
Divergence of laser beam (full angle d ₆₃ - handpiece's output)	1.5" handpiece	70 mrad
	2" handpiece	52 mrad
	4" handpiece	26 mrad
	5" handpiece	20 mrad
	7" handpiece	12 mrad
	8" handpiece	11 mrad
	Collimated handpiece	3.2 mrad
Diameter of laser beam (d ₆₃ - handpiece's output)	1.5" handpiece	0.125 mm
	2" handpiece	0.155 mm
	4" handpiece	0.267 mm
	5" handpiece	0.325 mm
	7" handpiece	0.489 mm
	8" handpiece	0.530 mm
	Collimated handpiece	1.5 mm
Power stability on 1 hour	≤20%	
Nominal Ocular Hazard Distance (NOHD)	29m 100m (with collimated handpiece)	
Emission	Controlled by footswitch	

Table 8 - CO₂ laser source emission features

Type	Value
Wavelength	635nm
Maximum output power (source output)	5mW
Output mode	Circular
Divergence (source output)	0.7mrad
Diameter (source output)	1.1mm
Laser class (source output)	3R
Relative position with CO ₂ source	Coaxial

Table 9 - Specifications for the aiming source of CO₂ laser

INSTALLATION

Table 10 - Operating characteristics

Type	Value
Aiming Beam	Visible. Intensity selectable between OFF and 100%; step: 2% between OFF and 10%, step: 10% between 10% and 100%.
Operating modes	<ul style="list-style-type: none"> • CW mode: the average output power can be selected from 0.5W to 60W. • UP mode: the average output power can be selected from 0.5W to maximum power. • SP mode: the average output power can be selected from 0.1W to 15W; the frequency from 5Hz to 100Hz. • DP mode: the average output power can be selected from 0.2W to 15W; the frequency from 5Hz to 100Hz. The selectable frequencies depend on the selected power value, as shown in Table 15. • HP mode: the average output power can be selected from 0.1W to 8W; the frequency from 5Hz to 100Hz.
Exposure modes	<p>Continuous exposure mode or timed exposure mode.</p> <p>The timed exposure mode allows both single exposure or repeated exposures. When timed exposure mode is selected, the exposure time can be selected between 0.01s and 0.9s.</p> <p>When the repeated exposures mode is selected the "T.OFF" time can be modified from 0.3s to 5s.</p>

7.2. Accuracy of values

The accuracy of all the values mentioned in this manual is reported in the outcome of the project for the SmartXide² system.

INSTALLATION

7.3. Installation

Proceed as follows:

- Insert the key into the key switch located on the front side: the key can be inserted only in the "O" position, so the system is still switched off. Do not turn the key to the "I" position.
- Make sure the emergency switch is pulled upwards and the mains breaker is in the "I" position.
- Connect the external interlock network to the socket marked "INTERLOCK"; if there is no external interlock chain, connect the interlock connector supplied with the accessories (see also par. 7.7 in this section).
- Connect the footswitch to the socket marked "FOOTSWITCH".

The contacts of the interlock and footswitch sockets must never be connected to the mains otherwise the system should be seriously damaged. Connect these sockets only as specified in this paragraph.

ATTENTION

Possible equipment damage

- Connect the mains cable provided with the system to the proper socket located on the rear side of the system.
- Connect the other side of the mains cable to a wall outlet.

ATTENTION!

- Make sure that the mains plug is always reachable.

- Make sure the wall outlet is properly grounded.
- Make sure that the mains specifications are met.

ATTENTION

Possible equipment damage

7.3.1. Installation of the articulated arm's counterweight

At system first installation, the counterweight of the articulated arm must be installed. Proceed as follows (please refer to Fig. 13):

- first assemble the heaviest component, **paying attention to put this first component on the opposite side of the articulated arm** (as shown in Fig. 13, step 21) and to insert the special washer of the

Be very careful while handling the counterweight because it is very heavy: in case of fall, it can damage the equipment or hurt someone!

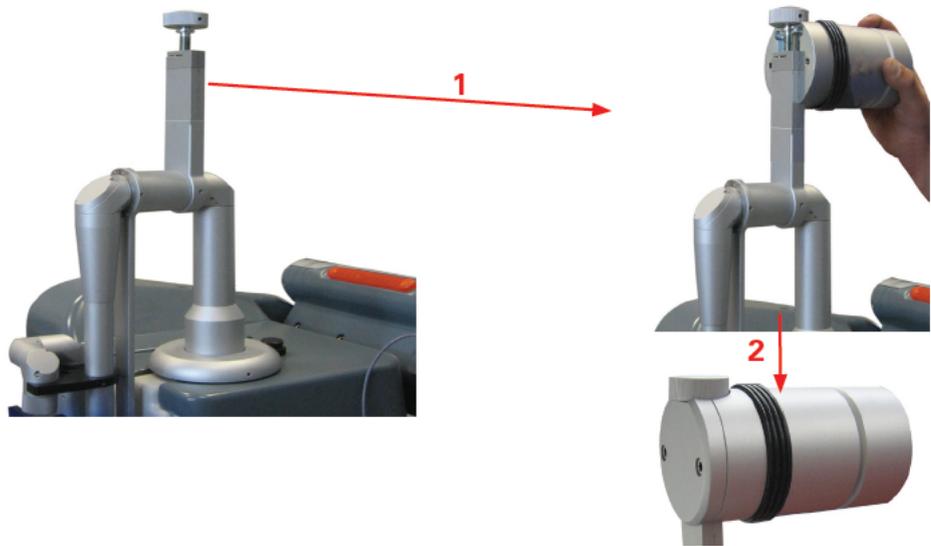
**CAUTION**

Possible risk for patient/operator

- install the second component which allows to fix the counterweight: insert the special washer of the articulated arm into its groove and screw it using the provided 5mm Allen wrench.

INSTALLATION

Fig.13 - Installation of the articulated arm's counterweight

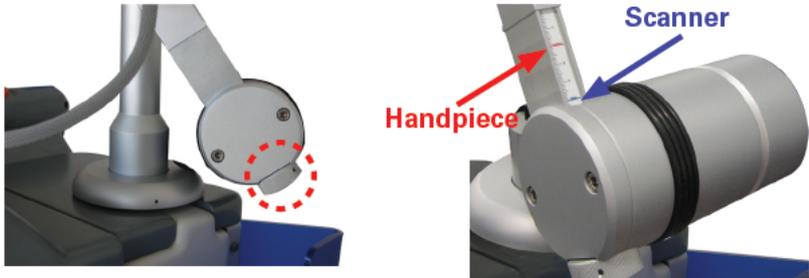


ATTENTION
Possible equipment damage

The counterweight has always to be removed for long distance transport. To remove it, put the articulated arm in its resting position and reverse the steps in this paragraph.

To move the articulated arm to the working position, remove it from its resting position and act on the adjusting knob in order to balance the counterweight according to the accessory connected to the articulated arm. Turn the knob up to reach a position around the mark "HiScan" if a scanner is connected, around the mark "Freehand" if a handpiece is connected.

Fig.14 - Counterweight



To place again the articulated arm in its resting position, rotate it slightly outwards and fold it so as to leave the counterweight upward. Secure the arm using the provided clamp on the system.

ATTENTION
Possible equipment damage

Avoid to apply any force to the support cantilever of the articulated arm. Do not hold the arm as shown in the picture below.

INSTALLATION

7.4. User ID chip

The SmartXide² system is provided with a "User ID" chip which allows the user to enter the "personal" database of user-defined treatments: see par. 8.5 for details.

Pull down the protection panel on the rear side of the system and insert the chip in its housing pushing it and paying attention to put its metallic face in the narrow side of the socket (highlighted in Figure, right side).

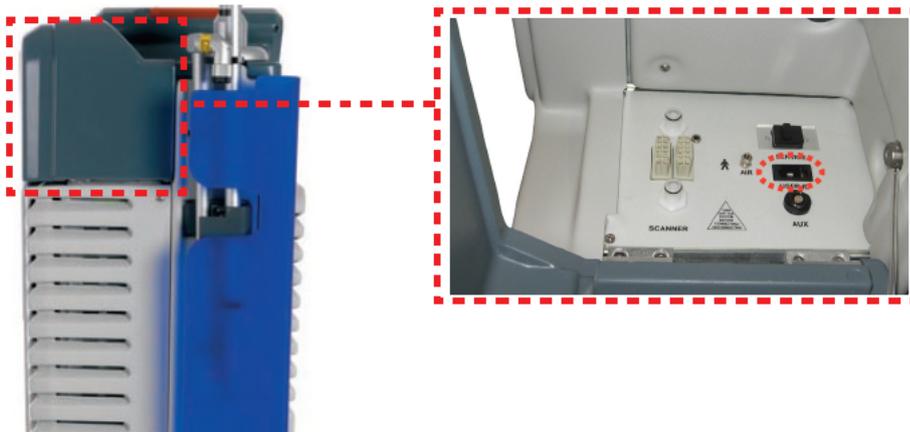


Fig.15 - "User ID" key socket

If the inserted "User ID" chip is recognized by the system, the icon highlighted in Fig. 16 is displayed in the User menu.



Fig.16 - "User ID" icon in the User menu

INSTALLATION

7.5. Air flow connections

The SmartXide² system is equipped with an internal pump which produces a continuous air flow which prevents dust and particles from depositing on the optics during laser operations.

Pull down the protection panel on the rear side of the SmartXide² system (Fig. 17) to access the air flow outlet connector (highlighted in Figure below): an internal connection links the air pump to this connector.

Fig.17 - Air flow connector on system



A black tube is provided to connect this outlet connector to the inlet connector located on the handpiece (see Fig. 7).

NOTE

Always verify that the black tube is properly connected to both connectors.

NOTE

Use the proper plastic holders placed on the articulated arm to position the air tube and, if present, the hose for the smoke evacuator; use the larger housing for the scanning unit cable. See the Figure below.

Fig.18 - Tubes holder on the articulated arm



INSTALLATION

7.6. Articulated arm working position

In order to move the articulated arm to its working position proceed as follows:

- move upwards the lock that blocks the articulated arm (see the enlarged detail in the Figure below);
- move the articulated arm away from its resting position rotating it as shown in the figures below.



Fig.19 - Articulated arm working position

NOTE

If the articulated arm has been properly taken out from its resting position, the tube holders on the articulated arm are placed externally as highlighted in Fig. 19. *The position shown below is not correct.*



INSTALLATION

7.7. Remote Interlock

The interlock socket can be used as an additional precautionary measure to stop emissions in case a specific external event occurs.

For instance, all the doors leading to the system operating area can be provided with series-connected microswitches (normally closed). In this case the opening of any of these doors results in an "INTERLOCK" alarm message (see the Section "Faults and troubleshooting") so the emission is immediately stopped.

To connect an external interlock chain, the interlock connector supplied with the accessories can be used.

Note that this connector has a jumper between contacts 1 and 2 (set by factory).

To use an external interlock chain, proceed as follows:

- remove the jumper between the contacts 1 and 2;
- connect these contacts to the external network. Note that the interlocks must be normally closed in order to let the system operate otherwise an INTERLOCK fault is stated and the system is stopped.

No voltage level should be applied to the contacts of the interlock connector.

If no external interlock chain is to be used, the interlock connector provided with the system (accessories) must be connected to the interlock socket in order to disable the interlock fault.

8. USE OF THE SYSTEM

8.1. Starting up the system

Insert the key into the key selector and turn to the "I" position. The system enters a self-test phase during which the introductory screen "System check" is displayed.

ATTENTION

During the self-test phase, the SYSTEM READY indicator on the top cover of the system and the LED on the control panel flash. This allows to verify its correct working. It is recommended to verify that the lamp is flashing during this phase. Otherwise call the Technical Assistance Service.

Once the internal check is over, if any problem is detected the system displays a "SYSTEM FAULT" menu: refer to the "Troubleshooting and solutions" section for possible solutions to the problem; otherwise an introductory warning is displayed.

The operator and all the personnel in the operating area are recommended to always wear protective eyewear when operating.

Never look directly into the handpiece or into apertures labelled "LASER APERTURE", even while wearing protective eyewear.



CAUTION

Possible risk for patient/operator

Once the "OK" key has been pressed, the system displays the Home menu:



Fig.20 - Home menu

The key on the left makes the operator enter the so called "User" mode as the operator himself has to select the emission characteristics (pulse number, pulse length, fluence) on his own experience.

Data can also be saved for future uses.

Key is shown with lighter colours if the related handpiece is not connected or it is not valid.

The keys on the right allow to select the application and enter the related user-defined database.

USE OF THE SYSTEM

The options described below are common to all system menus:

	This key goes to the Home menu
	This key goes to the previous displayed screen
	This key enters the database mode
	This key enters the Set-up menu
	This key displays an info screen

Keys are shown with lighter colours if the related option is temporarily disabled.

The system automatically selects the following status:

- "STAND BY" mode;
- Footswitch disabled.
- aiming source activated;
- exposure parameters previously saved;
- emission and scanning parameters previously saved.

8.2. Management of the selected source

'STAND BY'/'ON' key

The 'STAND BY'/'ON' key allows to switch off/on the selected source.

If it is green light coloured, it means that the key is disabled;

if it is green bright coloured, it means that the key is enabled to switch on the source;

if it is orange coloured, it means that the selected source is ON and it can be switched off by pressing the key itself.

'READY' key

The 'READY' key allows to enable footswitch in order to avoid unwanted emissions which might occur if it is accidentally pressed when the source is switched on.

The operator is suggested to use the READY option to disable footswitch while selecting the parameters as a precautionary measure.

Emission is enabled if both the READY key and the SYSTEM READY indicator on the system upper cover are permanently lit.

'EMISSION' LED

The "EMISSION" LED is under the "READY" key and, when lit, indicates that emission is in progress.

8.3. User mode for CO₂ source

The "User" mode allows to fully control emission parameters by "manually" selecting the emission mode, the pulse configuration and the power and/or frequency levels.

As the CO₂ area is pressed, a selection screen is displayed which allows to select the delivery system for the CO₂ source: handpiece ("Free hand" mode) or scanning system.

The key related to the scanning unit currently connected to the system is highlighted on the selection screen.

For the description of all the available scanning units, please refer to the relevant Section of this Operator's Manual (Section "Scanning units" on page 51).

8.3.1. CO₂ Free Hand mode



Fig.21 - CO₂ Free Hand mode

Power

The POWER selection keys increase or decrease and display power level. The range of available values changes according to the selected emission mode and according to the system model: please refer to the description of the exposure modes in this paragraph.

Frequency

The FREQUENCY area displays frequency of laser emission; the FREQUENCY selection keys increase or decrease it from 5Hz to 100Hz. *These keys appear only when the SP or DP emission mode has been selected.*

Emission mode

The area "EMISSION MODE" alternately selects and displays "CW", "SP", "UP", "DP" or "HP" emission mode.

In **CW mode**, laser emission is continuous: the CO₂ laser source is enabled to emission as long as it is switched on, so it provides a constant output power level whose value has to be selected by the operator according to the treatment to be performed.

USE OF THE SYSTEM

The POWER selection keys allow to change the power value from 0.5W to 60W.

In **SP mode** the CO₂ laser source is pulsed.

The operator can select the frequency - that is how many times per second the source is switched on and off - and the power value.

The FREQUENCY selection keys allow to change the frequency value between 5Hz and 100Hz; the POWER selection keys allow to change the power value between 0.1W and 15W.

In **DP mode** the CO₂ laser source is pulsed.

The operator can select the frequency - that is how many times per second the source is switched on and off - and the power value.

According to the selected power value, the allowed frequency range changes as shown in the Table below.

Table 11 - Power and Frequency selection in DP mode

Power	Available values for the "Frequency" parameter
0.2W ≤ P < 0.5W	up to 10Hz
0.5W ≤ P < 3W	up to 20Hz
3W ≤ P < 4W	up to 50Hz
4W ≤ P < 5W	up to 80Hz
5W ≤ P < 6W	up to 100Hz
6W ≤ P ≤ 15W	up to 100Hz

In **UP mode** the CO₂ laser source is pulsed.

The system sets an optimal frequency while the output power level has to be selected by the operator according to the treatment to be performed.

The POWER selection keys allow to change the power value from 0.5W to 60W.

In **HP mode** the CO₂ laser source is pulsed.

The operator can select the frequency - that is how many times per second the source is switched on and off - and the power value.

The FREQUENCY selection keys allow to change the frequency value between 5Hz and 100Hz; the POWER selection keys allow to change the power value from 0.1W to 8W.

Exposure

The SmartXide² system allows to control the exposure time during a laser treatment acting on the CO₂ shutter.

The selected exposure mode is displayed on the screen in the "Exposure mode" area. Touch this area to change the exposure mode.

Three exposure modes can be selected:

- continuous - "Contin." on the screen -;
- timed single exposure - "Single" on the screen -;
- timed repeated exposures - "Repeat." on the screen -.

USE OF THE SYSTEM

Note that the emission mode - CW/SP/UP/DP/HP - can be changed regardless of the selected exposure mode.

In **continuous exposure mode**, the exposure time is fully controlled by the operator acting on footswitch: as long as footswitch is kept pressed, the shutter is open and therefore laser emission occurs.

When the **single exposure mode** is enabled and footswitch is pressed, the system opens the shutter and keeps it open only for the selected exposure time. Once the selected exposure time is exhausted, the shutter is automatically closed regardless if footswitch is still pressed. If the operator wants to perform a new exposure, he has to release and then press again footswitch.

The system allows to select the exposure time between 0.01s and 0.9s acting on the two arrows next to the "T.ON" value. The minimum available "T.ON" value depends on the selected frequency as reported in the following Table.

Frequency	5Hz	10Hz	20Hz	50Hz	80Hz	100Hz	200Hz
Min.TON	0.30s	0.20s	0.10s	0.04s	0.04s	0.02s	0.01s

Table 12 - Minimum available TON according to selected frequency



Fig.22 - Exposure mode selection

When **timed repeated exposures mode** is enabled and footswitch is pressed, the SmartXide² system opens the shutter and keeps it open for the selected exposure time.

Once the selected exposure time is exhausted, the shutter is automatically closed then, if footswitch is still pressed, the system waits for the selected "T.OFF" time. Then the shutter is opened again and a new exposure is performed. This sequence is continuously repeated as long as footswitch is kept pressed.

The system allows to change the exposure time between 0.01s and 0.9s acting on the two arrows next to the "T.ON" value and to change the "T.OFF" time between 0.3s and 5s. The minimum available "T.ON" value depends on the selected frequency as reported in the Table 12.

Total Energy and Total Time

The system displays the energy delivered and the time elapsed since the last resetting.

USE OF THE SYSTEM

When the system is turned on, these counters are set to zero, then they increase during treatment.

If the "RESET" option is pressed, the "TOTAL ENERGY" and "TOTAL TIME" values are cleared.

Aiming source

The two icons "" and "" in the "Aiming" area adjust the intensity of the aiming beam from OFF to 100% (step: 2% between OFF and 10%, step: 10% for the other values).

It is also possible to switch off the aiming beam while lasing by pressing the "Dowl" ("Diode off while lasing") option.

Set the "Dowl" option ON to have a clear view of the operating field and well distinguish the tissue ablation planes while operating.



CAUTION

Possible risk for patient/operator

CO₂ aiming beam intensities higher than 60% require an optical protection as indicated in par. 5.2.1. The system displays a warning icon next to the selected value (if higher than 60%).

Scanning unit

Press the area displaying the type of the scanning unit currently connected to the system in order to activate it.

The screen displays a message warning the operator that the delivery system selection has been changed; moreover the operator is reminded to control the scanning unit connections.

8.4. Database mode

The "database" mode contains sets of stored user-defined treatments parameters (i.e., treatment description, delivery system, phototype, fluence and pulse configuration); it offers the convenience of storing important parameters that can be set automatically.

To enter this mode, press the area with the name of the treatment category you want to select in the Home menu or the  key common to all system menus.



Fig.23 - Database mode

For example, by pressing the "ENT" area, it is possible to display the list of all stored treatments for "ENT" category.

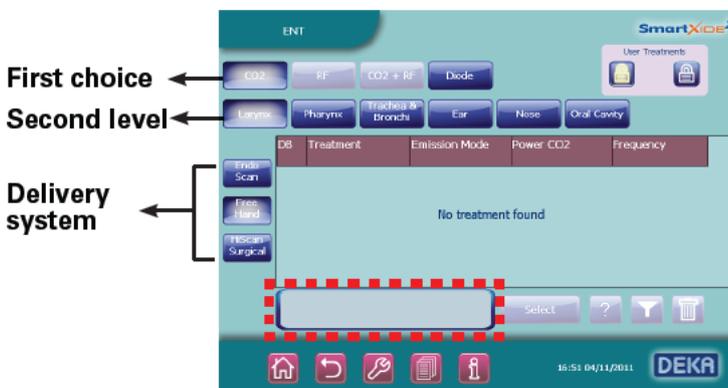


Fig.24 - ENT treatments

The system allows the user to save his own treatments both in a "public" database (identified by  icon) and in a "personal" database (identified by  icon).

The first one is always available both for displaying and modifying the stored treatments; the second type of user-defined database can be entered only if the "User ID" chip is inserted in the proper connector on the system (see par. 7.4.).

USE OF THE SYSTEM

Proceed as described below to display the treatments list.

The first choice to make is the database type: user-defined public or user-defined personal. Just press the related button to display the treatments: e.g. to display the personal treatments, press on the "📁" button.

Then select the type of source (only one selection at a time is possible). If a source is not available, the relevant key is "disabled".

When a source has been selected, the system enables the corresponding keys on the second level, that is the area to be treated or the treatment procedure (according to the selected database category) for which at least one treatment is available.

Depending on the selected option, the available delivery systems are enabled: select the one (by pressing the corresponding area) which you want to see the related treatments of.

The system displays all the available treatments for the selected parameters.

The arrows on the right side allows to page through the treatments list.

Each row of the table corresponds to an available treatment; for each of them the system provides the following information:

- the name of the treatment and the emission parameters: emission mode, power and/or frequency, scanning parameters (in case).
- it is possible to add notes about the selected treatment (both preset and user defined) by pressing the area highlighted in Fig. 24: an "ordinary" keyboard is displayed to allow typing.

Fig.25 - Keyboard



USE OF THE SYSTEM

Please note that the  key allows to switch from capital to small letters while the  key allows to insert special characters.

Press the  icon to save changes; press the  to close the window without saving.

- Moreover, it is possible to "search" along the database of treatments: press the  icon to filter the list of treatments and select the treatments you want to display.



Fig.26 - Database filter

How to select a treatment

- Press the row associated with the treatment to be selected: the row becomes yellow-highlighted.
- Press the **"Select"** key: it allows to set the selected treatment on the device. The type of database, the treatment category, treatment name and the phototype (if applicable) are displayed in the upper part of the User menu.

How to delete a treatment

- Press the row associated with the treatment to be deleted.
- Touch the  icon and confirm

How to save a treatment

- Enter the User mode and select the emission configuration that you want to store.
- Press the  icon: the system displays the menu shown in Fig. 27.



Fig.27 - How to save a treatment

USE OF THE SYSTEM

Fig.28 - Treatment name

- Select the treatment category, the type of user-defined database (public or personal) where you want to save the treatment and the kind of procedure.
- Press on the "Treatment" area to choose the treatment name. It is possible to choose the name among the ones already available or type a new name by pressing on the area highlighted in Fig. 28.



An "ordinary" keyboard, like the one shown in Fig. 25, is displayed to allow typing.

- it is also possible to add notes about the treatment by pressing the "Note" field.
- Press the "Save" icon to save: the new treatment parameters will be saved and displayed in the treatments database.

**CAUTION**

Possible risk for patient/operator

Once the selected treatment has been set on the User menu, if the user modifies a stored parameter, the system highlights with a "*" the modified parameter and allows to restore the stored value by pressing the "Restore" key (displayed in the upper part of the screen when a parameter is changed).

8.5. Set up menu

The Set up menu allows to set the system clock and date, to regulate the brightness of the screen, to select the language and other tasks.

To enter this menu, press the "🔧" area.



Fig.29 - "Set up" menu

From this menu the user can:

- choose between a 12h and 24h time format and a dd/mm/yy, mm/dd/yy, or yy/mm/dd date format; to change a parameter, touch the relative area and use the corresponding arrows.
- change the language.
- adjust the volume of the internal buzzer: press the "+" and "-" keys to adjust the level and the "TEST" key to test the selected level.
- select the time for automatic system switch off between 2 and 20 minutes by pressing "🕒": if the system is left unused for the selected amount of time, it will automatically switch off the laser source in order to extend the service life of the internal components.
- change the background colour.
- enable/disable the keys sound.
- choose an air flow mode for the handpiece by pressing "🌬️": continuous (i.e. the air flows continuously when the system is in READY status), and timed with emission (i.e. the air flows when the CO₂ laser source is operating).

If some parameters have been modified, the "💾" icon is displayed to allow to save changes.

USE OF THE SYSTEM

8.6. CO₂ power calibration procedure

The SmartXide² system is equipped with an internal power meter which allows to measure the real output power level of the CO₂ laser source. The power evaluation and calibration procedure is started and continuously performed as the CO₂ source is switched on.

As the CO₂ source is switched on and each time the power level is changed, the system starts flashing the message "POWER EVALUATION" on the screen in order to warn the operator that a power evaluation and calibration procedure for that power level is in progress.

During this procedure, footswitch is automatically disabled so no laser treatment can be started.

Note that if the READY mode was selected, the system will restore this mode only once the procedure will be completed.

The procedure is intended to verify the real power level provided by the CO₂ laser source and in case make it matching with the power level selected by the operator.

At the end of the procedure, the message "POWER EVALUATION" is cleared.

The following two conditions can occur:

- the real power level matches with the selected power level or the procedure succeeds in making them matching: no further message is displayed and the system is ready to operate;
- the real power level does not match with the selected power level AND the procedure fails in making them matching: in this case, a double warning sound is performed and the real power level currently available is flashed on the screen for about 5s to warn the operator.

After 5s, this value stops flashing and it is taken as the effective treatment power level.

Once the calibration procedure is completed, the SmartXide² system starts monitoring the real power level in order to detect power fluctuations. If the real power level changes so that it does not match anymore with the value displayed on the screen, the system acts as follows:

- if a laser treatment is in progress, that is if footswitch is pressed and as long as it is kept pressed, the new power level is displayed on the screen with black characters on white background and the internal buzzer produces 5 sounds per seconds - instead of 1 sound per second - in order to warn the operator; if the power mismatch is recovered, the old power level is displayed on the screen with standard characters and timed sound is again performed one time per second.
- If no laser treatment is in progress, a double warning sound is performed and the new power level is flashed on the screen for about 5s to warn the operator. After 5s, this value stops flashing and it is taken as the new effective treatment power level.
- if the detected output power is out of the regulatory limits on respect

to the nominal one, the emission is immediately stopped and the system states a HIGH POWER or a LOW POWER alarm - see Section "Troubleshooting" -.

8.7. System shutdown

To shut down the system in a normal (non-emergency) condition, proceed as follows:

- **press the "STAND BY" key on the control panel;**
- turn the key of the key switch to the "O" position.

In an emergency condition, press the emergency switch - see Section "System description" -.



USE OF THE SYSTEM

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SCANNING UNITS

9. SCANNING UNITS

The SmartXide² system can be provided with three different scanning units that can be connected to the articulated arm and that allow to achieve high performance in specific treatments.

The scanning units are listed below:

- "HiScan Surgical" for microsurgery applications.
- "Endoscan" for surgical endoscopic and microsurgical applications.
- "DOT" for ablative skin resurfacing and gynaecological applications.

9.1. Installation of the scanning unit

Proceed as follows to install a scanning unit: DOT

- **switch the system off;**
- remove the handpiece from the articulated arm, if connected;
- remove the protection cap (if present) and screw the scanning unit to the articulated arm;
- pull down the protection panel on the rear side of the system to access the connector for the scanning cable and connect it paying attention to make the plug of the cable enter the suitable hole (see Fig. 30);

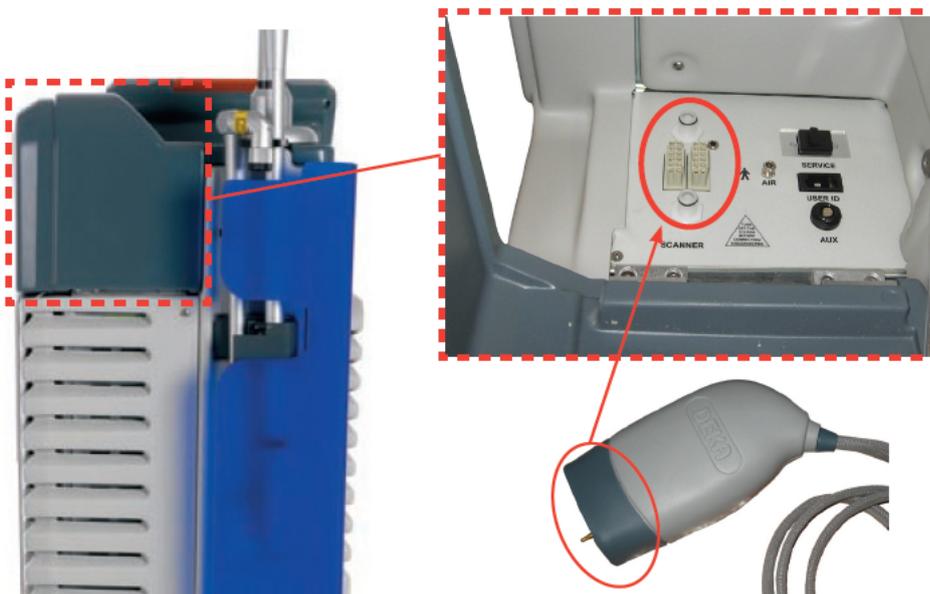
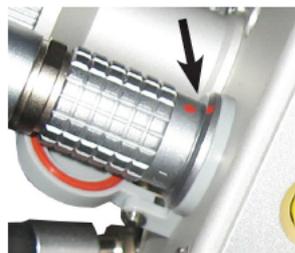


Fig.30 - Connection of the scanning unit

- **only if not already connected,** connect the other side of the cable to the scanning unit: insert the connector so that the red dot marked on it matches with the red dot on the unit connector, as highlighted in the example alongside.



SCANNING UNITS

NOTE

When the scanning unit is disconnected from the system, put again the protection cap on it.

Once a scanning unit is connected, the SmartXide² system automatically detects its presence and allows to activate it via the control panel. The area of the currently connected unit is highlighted on the CO₂ main menu.

ATTENTION

Possible equipment damage

- The connection/disconnection of the scanning cable has to be performed with the system switched off (key switch has to be in the 'O' position).
- **Do not disconnect the scanning head from its cable unless it is absolutely necessary: if you have to remove the scanner, disconnect its cable from the system.**



CAUTION

Possible risk for patient/operator

Each scanning unit has its own cable: be very careful not to exchange the cable with the one of another scanning unit. If possible, do not disconnect the cable from the scanning head.

SCANNING UNITS

9.2. Use of the HiScan Surgical unit

Another external scanning unit called HiScan Surgical is available among system accessories - optional - and shown in Fig. 31.

The external HiScan Surgical unit can be used either with micromanipulator or with long focal (4" or longer) handpieces. However the use together with the Deka EasySpot Hybrid micromanipulator or similar, is the best choice: please refer to the *Operator's Manual* of the micromanipulator for its description and use.



Fig.31 - HiScan Surgical unit

NOTE

HiScan Surgical is generally provided already connected to Deka micromanipulator: please do not disconnect the two units, if possible. If the two units are disconnected, screw the connector of the HiScan Surgical unit shown as (A) on the micromanipulator; connect the micromanipulator cable to its connector on the HiScan unit (B).

To verify that the two units are correctly assembled, perform an emission on a tongue depressor selecting the "hexagon" shape and verifying that the scanning is performed horizontally from top to bottom.

To activate the HiScan Surgical unit, if properly installed, press the "HiScan Surgical" area in the CO₂ main screen. The screen changes as shown in Figure:



Fig.32 - User menu when HiScan Surgical unit is activated

Shapes of the scanning pattern

The scanning unit can generate five types of pattern: line, spiral, ellipsoid motion on a circular surface, arc of a circle up to the complete circle, and hexagon (with "normal" or "interlaced" scan mode).

Touch the relevant icon in the **"Shape"** area to select a scanning shape.

SCANNING UNITS

NOTE

The HiScan Surgical unit moves the red aiming beam on the outline of the selected scanning area. This function allows to immediately check the characteristics - shape and dimensions - of the scanning area.

ATTENTION!

The ellipsoid motion on a circular surface does not have a uniform delivery of energy on the tissue. Therefore, the "depth" displayed on the screen is an average of the depths of ablated tissue in the whole scanning; moreover, it has to be used with high scanning speed and moving the laser beam on the tissue, to achieve the best result of ablation.

According to the selected shape, the system enables or not the parameters available in the User menu, as detailed in the following paragraphs.

In particular, **ONLY for the "hexagon" scanning shape**, it is possible to select two different types of scanning:

- **"Normal"** scan mode

When this scan mode is selected, the area is treated by scanning the lines from left to right and from right to left, starting at the first line from the top to the last line at the bottom.

- **"Interlaced"** scan mode

When this scan mode is selected, the area is treated by first scanning the odd lines and then the even lines. Once the scan of the odd lines has been completed from the top to the bottom the even lines are scanned from the bottom to the top.

The interlaced scan mode is advisable for reducing the thermal effects during treatment.

To select either one or the other scan mode, press the **"Scan Mode"** area (*this area is displayed only when the "hexagon" shape has been selected*).

Size of the scanning pattern

The **"Size"** option allows to change the dimension of the scanning area:

- the size is shown as percentage of the maximum available scanning area for all shapes except for spiral;
- the diameter of the spiral is shown in mm and can be selected from 0.3mm to 1.1mm (step: 0.1mm).

This parameter is available for all the scanning shapes and can be changed in one of the following ways:

- pressing the **"Size"** area of the User menu and acting on the arrows of the **"Select Dimension"** menu;
- by the **red key** located on the scanning head - see Fig. 31 -;
- by the remote command (central position) on the micromanipulator joystick. The change of the scanning area dimension occurs on releasing the remote command key. By keeping pressed this key for more than 4s, "SCAN OFF" mode is enabled.

See *Micromanipulator Operator's Manual*.

SCANNING UNITS

"Curving" parameter

If the "arc of circle" shape has been selected, the "Curving" parameter is enabled in the User menu.

The two arrows in this area allow to change this parameter, that is the extension of the selected arc.



Fig.33 - Curving parameter

Its value is expressed as ratio between the subtended arc and the maximum available extension - that is the circumference -.

The pictures below show, for example, the arcs resulting from some values of the "Curving" parameter.



Curving:

2/10

5/10

10/10

The "Curving" parameter is NOT available for the other scanning shapes.

Rotation of the scanning patterns

The selected scanning shape can be rotated in one of the following ways:

- by the two yellow keys located on the scanning head - see Fig. 31 -;
- by the rotation of the key of the remote command on the micromanipulator joystick. See *Micromanipulator Operator's Manual*.

Emission mode

The area "**Emission mode**" alternately selects and displays either **CW** or **UP** emission mode.

Please refer to par. 8.3.1 for details on these two emission modes.

Exposure

The selected exposure mode is displayed on the screen in the "**Exposure mode**" area; touch this area to enter the screen which allows to change the exposure mode.

Three exposure modes can be selected by touching the relevant area:

- continuous - "Contin." on the screen -;
- timed single exposure - "Single" on the screen -;
- timed repeated exposures - "Repeat. " on the screen -.

SCANNING UNITS

Fig.34 - Selection of the exposure mode

Note that the emission mode - CW/UP - can be changed regardless of the selected exposure mode.

In **continuous exposure mode**, the exposure time is fully controlled by the operator acting on the footswitch: as long as the footswitch is kept pressed, the shutter is open, the laser emission occurs and the scanning unit repeats the selected pattern.

When this mode is selected, it is also possible to select a finite number of scanings ("**Pass**" parameter on the screen, see Fig. 34): in this case, laser emission is stopped as soon as the selected number is reached.

It is possible to change the "**Pass**" parameter acting on the two arrows. The User menu displays the depth of ablated tissue for each scanning and the total depth once completed all the selected scanings.

When the **single exposure mode** is enabled and the footswitch is pressed, the system opens the shutter and keeps it open only for the time of one complete scanning. Once this time is exhausted, the shutter is automatically closed regardless if footswitch is still pressed.

If the operator wants to perform a new exposure, he has to release and then press again footswitch.

When **timed repeated exposures mode** is enabled and the footswitch is pressed, the system opens the shutter and performs scanning sequences until footswitch is kept pressed.

Once a single scanning is completed, the shutter is automatically closed then, if footswitch is still pressed, the system waits the selected "**Delay**" time; after this time the shutter is open again and a new scanning is performed. This sequence is continuously repeated as long as footswitch is kept pressed.

Use the arrow keys (Fig. 34) to change the "**Delay**" time between two scans from 0.3s to 3s.

Scanning modes

The HiScan Surgical system allows the operator to use two different working modes available in the "**MODE**" area of the User menu: the "Depth mode" and the "Power mode".

Using the "**Depth mode**", the operator can act directly on two parameters: the **emission power** and the **cutting depth**. According to the selected

SCANNING UNITS

values for these two parameters and according to the selected focal length, the system automatically calculates the required energy density (fluence).

The "Depth" parameter can be changed from 0.2mm to 2mm acting on the two arrows.

Using the "**Power mode**" (*please refer to the User menu shown in Fig. 32 where this mode is selected*), the operator can act directly on two parameters: the **emission power** and the **dwelt time** of the laser beam on a scanning point; according to the selected values for these two parameters and according to the selected focal length, the system automatically calculates the required energy density (fluence) and therefore the cutting depth on tissue: this last parameter is displayed on the User menu.

The "Dwell time" can be changed from 100 μ s to 45ms acting on the two arrows.

NOTE

If, according to the selected dwell time and power value, the resulting depth is higher than 2mm, the system does not declare this value and shows a warning icon next to the dwell time.

The tissue ablation depth is strictly connected to the type and characteristics of treated tissue, therefore the "Depth" parameter shown on the screen is purely as an indication.

**CAUTION**

Possible risk for patient/operator

Power selection

The "**Power**" selection keys allow to change the power value from 0.5W up to 60W.

Disabling the scanning

If an area is to be treated without scanning, select the "point" shape in the "SHAPES" area of the User menu (without unscrewing the scanning head).

The "point" becomes red highlighted and the selection of the scanning parameters is disabled: the operator can change only the power value, the emission mode and the focal length.

The scanning can be disabled also by keeping pressed for a few seconds the red key on the scanning head (or the central key of the remote command on the micromanipulator joystick) until the red aiming beam stops at the center of the area given by the spacer of the scanning head. The laser pulse will be performed on this point.

As the "**No Scan**" mode is set, the system displays a warning message to remind the operator that it is necessary to manually move the laser beam in order to avoid dangerous overexposures. For this reason the operator can enable an acoustic signal to warn that the "No Scan" status is set: this acoustic warning keeps on until the scanning mode is enabled again.

SCANNING UNITS

Fig.35 - "No Scan" mode



CAUTION
Possible risk for patient/operator

When the "No Scan" mode is selected, footswitch works in continuous way.

Aiming source

The intensity of the aiming beam from OFF to 100% (step: 2% between OFF and 10%, step: 10% for the other values).
It is also possible to switch off the aiming beam while lasing: press the "Aiming" area and select the "Dowl" ("Diode Off while Lasing") option.
Set the "Dowl" option on to have a clear view of the operating field and well distinguish the ablated tissues during treatment.

CAUTION
Possible risk for patient/operator

CO₂ aiming beam intensities higher than 60% require an optical protection as indicated in par. 5.2.1. The system displays a warning icon next to the selected value (if higher than 60%).

Scanning Info

The system displays further info about scanning, that is the total scanning time and energy according to the selected parameters.

"Free hand" mode

It is always possible to go back to the "Free Hand" mode by pressing the "Free Hand" area: the systems displays a message to warn the operator that the delivery system selection has been changed.
Press the "Confirm" key to go back to the User menu.

SCANNING UNITS

Settings

The "**Settings**" option allows to access two other options: the "Focal" and the "Centering correction" options.



Fig.36 - "Settings" option

The "**Focal**" option allows the operator to "inform" the system about the focal length set on the micromanipulator. Select the same focal length set on the micromanipulator and press "" area to confirm the choice.

Be careful to correctly select the focal length because this parameter is used by the system to calculate the scanning area and the cutting depth.

The selected focal length must be the same of the working focal length set on the microscope on which the focus of the micromanipulator was adjusted.

**CAUTION**

Possible risk for patient/operator

The "**Centering correction**" option allows to adjust the laser beam centering, if necessary.

This adjustment doesn't take the place of the alignment procedure of the articulated arm but it just helps when little adjustments are needed before treatment, in order to enter perfectly the most critical accessories like micromanipulators or laparoscopes.

Before starting the surgical procedure the operator has the responsibility to check the coaxiality between the red aiming and CO₂ beams.

In microsurgery procedures this check has to be performed through the microscope and the micromanipulator at the system's working setup; the operator has not to change it after this operation during the surgical procedure.

For further information, please refer to *Micromanipulator Operator's Manual*.

The arrow keys manage the horizontal and vertical motions of the laser beam along the two axes;

the "**Restore**" key allows to center the laser beam in the same position set by factory;

the "" icon confirms the selected centering.

NOTE

Assuming that the laser arm is correctly aligned, the "**Restore**" option is very important in order to come back to the initial position. It may be useful if the operator "loses" the beam during the centering procedures.

SCANNING UNITS

ATTENTION!

If you perform the centering correction procedure without saving the new settings (that is, if you switch off the system before exiting the "Centering correction" menu), at the next system start-up a warning message is displayed: the user has to perform again the centering procedure before using the scanning unit.

In order to check the accuracy of centering, the system allows to switch on the laser source and perform a laser emission on a target surface using preset parameters (UP, 5W). This operation can be done with the steady point or with the full circle pattern. To switch between the two modes, press the area highlighted in Fig. 36.

NOTE

It is possible to control the horizontal and vertical motion of the laser beam along the two axes also in the following ways:

- press the red key on the scanning head or the central key of the remote control on top of the micromanipulator joystick to select the horizontal or the vertical axes;
- press the two yellow keys on the scanning head or the right-left keys of the remote control on top of the micromanipulator joystick to move the beam.

9.2.1. HiScan Surgical alarms**Hi-Scan**

This fault condition concerns troubles with the HiScan Surgical unit.

Try to reset the fault condition. Call the technical assistance service if it persists.

HS KEYB

On the scanning head there are three keys. The system states a fault condition if one of these keys is pressed when the HiScan Surgical unit is activated. Try to reset the fault condition. If it persists call the technical assistance service.

HS galvo driver

The system states a fault condition if the mirrors inside the HiScan Surgical unit are not properly working. If this fault is stated on HiScan Surgical activation, check all the connections with the scanning unit.

Try to reset the fault condition. If it persists call the technical assistance service.

HS points maker

This fault condition concerns troubles with the software of the HiScan Surgical unit. Try to reset the fault condition. If it persists call the technical assistance service.

EEPROM Factory Centering/EEPROM User Centering

These fault conditions concern problems with the centering procedure data storing. In the first case, call the technical assistance service; in the second case, perform again the centering procedure and, if the problem is not solved, call the technical assistance service.

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9.3. Use of the EndoScan unit

Another external scanning unit called EndoScan is available among system accessories - optional - and shown in Fig. 37.

EndoScan can be used either via long focal handpieces (4" or longer), or via DEKA micromanipulator, or via laparoscope.



Fig.37 - EndoScan unit

NOTE

If present, screw the micromanipulator on the connector of the EndoScan unit shown as **(A)** and connect the remote control, if available, to the connector **(B)**.

To activate the EndoScan unit, if properly installed, press the "EndoScan" area in the CO₂ main screen. The screen changes as shown in Figure:



Fig.38 - User menu when the EndoScan unit is activated

Shapes

The scanning unit can generate two types of patterns:

Surface mode (red highlighted in Fig. 38)

A circular surface is covered, with a composed ellipsoid mode.

In this scanning modality, using the UP mode, more delicate ablations are obtained.

Perimeter mode

The focused laser beam moves in a circular mode. In this scanning modality the laser becomes a sort of "milling cutter" that ablates each passage a layer of tissue.

In any moment it is possible to stop the scanning movement to pass to the steady spot, just by pressing the dedicated button on the centre of the touch screen.

SCANNING UNITS

NOTE

The EndoScan unit moves the red aiming beam on the selected scanning figure. This function allows to immediately check the characteristics - shape and dimensions - of the scanning area.

Size of the scanning pattern

The "**Dimen.**" option allows to change the dimension of the scanning area (shown as percentage of the maximum available scanning area).

**CAUTION**

Possible risk for patient/operator

Once the power level has been set, the tissue ablation rate is higher for smaller scanning patterns.

Emission mode

The area "**Emission mode**" alternately selects and displays either CW or UP emission mode.

Please refer to par. 8.3.1 for details on these two emission modes.

Scan mode

The system allows to control the exposure time during a laser treatment. The selected exposure mode is displayed on the screen in the "Exposure" area; touch this area to enter the screen which allows to change the exposure mode.

Three exposure modes can be selected by touching the relevant area:

- continuous - "Contin." on the screen -;
- timed single exposure - "Single" on the screen -;
- timed repeated exposures - "Repeat." on the screen -.

Note that the emission mode - CW/UP - can be changed regardless of the selected exposure mode.

In **continuous exposure mode**, the exposure time is fully controlled by the operator acting on footswitch: as long as footswitch is kept pressed, the shutter is open, the laser emission occurs and the scanning unit repeats the selected pattern.

When the **single exposure mode** is enabled and footswitch is pressed, the system opens the shutter and keeps it open only for the time of one complete scanning. Once this time is exhausted, the shutter is automatically closed regardless if footswitch is still pressed.

If the operator wants to perform a new exposure, he has to released and then pressed again footswitch.

When **timed repeated exposures mode** is enabled and footswitch is pressed, the system opens the shutter and performs scanning sequences until footswitch is kept pressed.

Once a single scanning is completed, the shutter is automatically closed then, if footswitch is still pressed, the system waits the selected "Delay" time; after this time the shutter is opened again and a new scanning is performed. This sequence is continuously repeated as long as footswitch

SCANNING UNITS

is kept pressed. Use the arrow keys to change the "delay" time between two scans from 0.3s to 3s.

Power

The "**Power**" selection keys allow to change the power value from 0.5W up to 60W.

Dwell Time

Only if the circular scanning pattern is selected, the "Dwell Time" parameter, that is length of time that the laser beam stays on a scanning point, can be selected from 100 μ s to 1000 μ s.

"No Scan" scanning mode

Touch the "**No Scan**" option in the "Shapes" area to select this scanning mode: this area becomes red highlighted while all the scanning parameters are disabled except the emission mode.

The scanning can be disabled also by keeping pressed for a few seconds the central key on the scanning head (or the central key of the remote command on the micromanipulator joystick) until the red aiming beam stops at the center of the scanning area. The laser pulse will be performed on this point.

If the "No Scan" scanning mode is selected, the system emits a fixed laser beam, without scanning.

Aiming source

The intensity of the aiming beam from OFF to 100% (step: 2% between OFF and 10%, step: 10% for the other values).

It is also possible to switch off the aiming beam while lasing: press the "Aiming" area and select the "Dowl" ("Diode off while lasing") option.

Set the "Dowl" option on to have a clear view of the operating field and well distinguish the ablated tissues while operating.

CO₂ aiming beam intensities higher than 60% require an optical protection as indicated in par. 5.2.1. The system displays a warning icon next to the selected value (if higher than 60%).

**CAUTION**

Possible risk for patient/operator

"Free hand" mode

It is always possible to go back to the "Free Hand" mode by pressing the "**Free Hand**" area: the systems displays a message to warn the operator that the delivery system selection has been changed.

Press the "Confirm" key to go back to the User menu.

SCANNING UNITS

Adjusting of the laser beam centering

The "**Centering correction**" option allows to adjust the laser beam centering, if necessary.

This adjustment doesn't take the place of the alignment procedure of the articulated arm but it just helps when little adjustments are needed before treatment, in order to enter perfectly the most critical accessories like micromanipulators or laparoscopes.

Before starting the surgical procedure the operator has the responsibility to check the coaxiality between the red aiming beam and CO₂ beam.

In microsurgery procedures this check has to be performed through the microscope and the micromanipulator at the system's working setup; the operator has not to change it after this operation during the surgical procedure. For further information, please refer also to *Micromanipulator Operator's Manual*.

The arrow keys manage the horizontal and vertical motion of the laser beam along the two axes;

the "**Restore**" key allows to center the laser beam in the same position set by factory;

the "💾" icon confirms the selected centering.

Fig.39 - Endo Scan centering correction

**NOTE**

Assuming that the laser arm is correctly aligned, the "**Restore**" option is very important in order to come back to the initial position. It may be useful if the operator "loses" the beam during the centering procedures.

ATTENTION!

If you perform the centering correction procedure without saving the new settings (that is, if you switch off the system before exiting the "Centering correction" menu), at the next system start-up a warning message is displayed: the user has to perform again the centering procedure before using the scanning unit.

NOTE

It is possible to control the horizontal and vertical motion of the laser beam along the two axes also in the following ways:

- press the central key on the scanning head or the central key of the remote control on top of the micromanipulator joystick to select the horizontal or the vertical axes;

SCANNING UNITS

- move right-left the central key on the scanning head or the right-left keys of the remote control on top of the micromanipulator the joystick to move the beam.

In order to check the accuracy of centering, the system allows to switch on the laser source and perform a laser emission on a target surface using preset parameters (UP, 5W).

This operation can be done with the steady point or with the full circle pattern. To switch between the two modes, press the area highlighted in Fig. 39.

ATTENTION!

If you are performing the centering procedure with the scanning unit connected to a laparoscope, use the circle pattern: the laser beam is correctly centered only if you see the full circle (not an arc of circle) through the laparoscope (projecting the aiming beam on a perpendicular plane surface). The correct centering has to be verified every time the laparoscope is connected to the EndoScan unit.

Scanning Info

The system displays further info about scanning, that is the total scanning time and energy according to the selected parameters.

9.3.1. EndoScan alarm**EndoScan**

This fault condition is displayed by the "SYSTEM FAULT" menu if the SmartXide² system detects troubles about the EndoScan unit.

Make sure that the scanning unit is properly connected. Try to reset the fault condition; call the technical assistance service if the fault persists.

EEPROM Factory Centering/EEPROM User Centering

These fault conditions concern problems with the centering procedure data storing.

In the first case, call the technical assistance service; in the second case, perform again the centering procedure and, if the problem is not solved, call the technical assistance service.

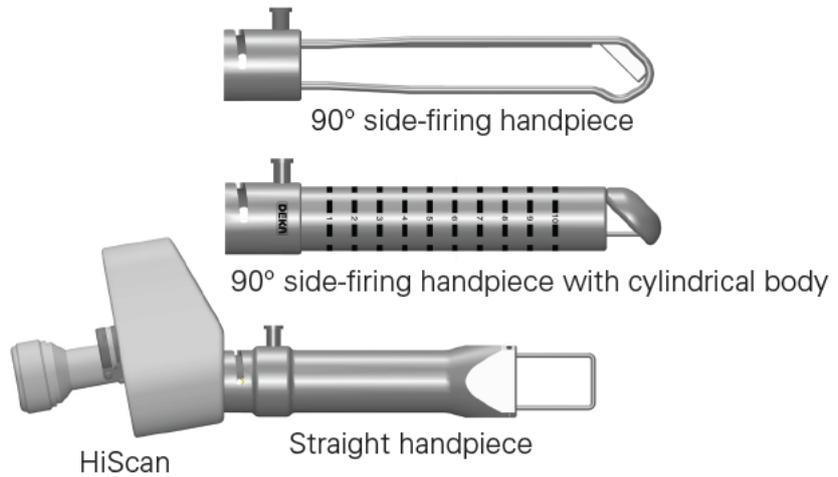
SCANNING UNITS

9.4. Use of the HiScan DOT

Another optional scanning unit for the SmartXide² system is the HiScan DOT unit which allows to achieve high performance in ablative skin resurfacing and gynaecological treatments.

Three handpiece are available for this HiScan unit:

Fig.40 - HiScan DOT unit



To turn the external HiScan DOT unit on, when installed correctly, press "DOT" on the CO₂ main menu. The screen will appear as below:

Fig.41 - User menu with HiScan DOT unit on



Power

The "Power" selection keys allow the user to change the power value up to 50W.

Dwell time

The scanning "dwell time", i.e. the length of HiScan emission, can be selected between 100µs and 2,000µs (at increments of 100µs).

Spacing

The "Spacing" parameter, i.e. the "distance" between scanning dots, can be selected between 0 and 2,000µm (at increments of 50µm).

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Shape and size of the scanning area

The **Size** area allows the user to change the size of the scanning area (shown as a percentage of the maximum available scanning area, i.e. 8mm x 8mm);

the **Ratio** area allows the user to change the height-width ratio of the scanning area.

NOTE

The HiScan DOT unit moves the red aiming beam along the outline of the selected scanning area. This function allows the user to immediately check the characteristics - shape and size - of the scanning area.

Aiming beam intensity

The intensity of the aiming beam can be set between OFF and 100% (increments of 2% between OFF and 10%, increments of 10% for the remaining values).

It is also possible to switch the aiming beam off during laser treatment: press "Aiming" and select the "Dowl" ("Diode off while lasing") option.

Set the "Dowl" option to ON to have a clear view of the treatment area and to clearly distinguish the treated tissues during the procedure.

CO₂ aiming beam intensities higher than 60% require an optical protection as indicated in par. 5.2.1. The system displays a warning icon next to the selected value (if higher than 60%).

**CAUTION**

Possible risk for patient/operator

Smart Stack

It is possible to select and edit the "**Smart Stack**" parameter which manages the number of pulses delivered consecutively by the system on the same "dot".

This value can be set between 1 to 5 by pressing "Smart Stack" by the number of pulses the user wishes to set.

For example, if value "1" is set, the system will perform only one pulse on every single dot, while a value of "3" will provide three pulses on a single dot, before moving onto another spot/dot. In theory, this scanning mode (i.e. Stack 3) should have the same effect on tissue as three consecutive scanning applications, however it has the advantage to ensuring greater overlapping by emitting three pulses over the same dot.

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Fig.42 - Example of "Normal" scan mode

Scan mode

It is possible to select a scan mode from Normal, Interlaced or SmartTrack, by simply touching the "**Scan mode**" area.

- **"Normal" scan mode**

When this scan mode is selected, the area is treated by scanning lines from left to right and from right to left, starting from the first line at the top, to the last line on the bottom.

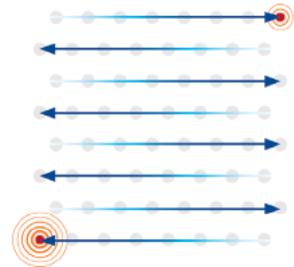


Fig.43 - Example of "Interlaced" scan mode

- **"Interlaced" scan mode**

When this scan mode is selected, the area is treated by scanning the odd numbered lines first, followed by the even numbered lines. Once the odd numbered lines have been scanned from the top to the bottom, the even lines are scanned from the bottom to the top. Use of the interlaced scan mode is advisable for reducing thermal effects during treatment.

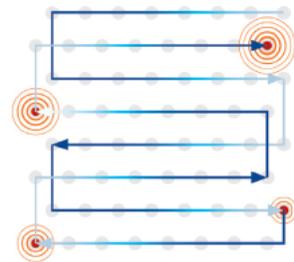
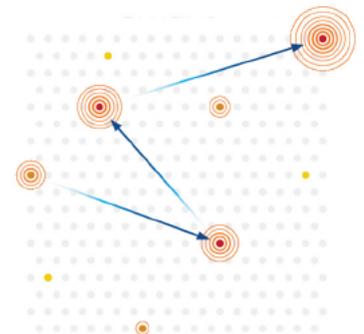


Fig.44 - Example of "SmartTrack" scan mode

- **"SmartTrack" scan mode**

When this scan mode is selected, the area is treated by scanning dots in random order: this minimizes the risk of tissue overheating, and therefore thermal damage.



Exposure mode

The system allows the user to control scanning exposure time.

Touch the "**Exposure mode**" area to open the screen where the exposure mode can be changed.

Two exposure modes are available by touching the relevant areas:

- single scanning ("Single" on the screen);
- timed repeated scanings ("Repeat." on the screen).

- **Single scanning**

When the single exposure mode is enabled and footswitch is pressed, the system opens the shutter and keeps it open only for the time of one complete scanning. Once this time is over, the shutter closes automatically, whether the footswitch is still down or not. If the operator wants to perform a new exposure he/she must release the footswitch and then press it down again.

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- **Timed repeated scanning mode**

When this mode is enabled and the footswitch is pressed down, the system opens the shutter and performs scanning sequences as long as the footswitch is held down. Once a single scanning is complete, the shutter closes automatically and then, if the footswitch is still down, the system waits out the selected "Delay" time; after this time the shutter opens again and a new scanning is performed. This sequence is repeated continuously as long as the footswitch is held down. Use the arrow keys to change the "Delay" time between scanings from 1s to 5s (increments of 0.5s).

Emission mode

An emission mode can be selected from **DP**, **HP** and **SP** modes: please refer to par. 8.3.1 for details on these emission modes.

For the same amount of time selected for pulse length, the amount of energy released by the system in DP mode is greater than the energy released in SP mode, because of a different pulse shape. Moreover, having equal power values, the energy released in HP mode is different (and can be much higher) from the other modes. Always check the value of the released energy as it is the indicator of the thermal effect on the tissue.



CAUTION

Possible risk for patient/operator

Scanning info

The system displays additional information about the scanning: the value, according to the selected parameters, of the energy released on each scanning point ("Pulse Energy"), the fluence (energy density) and the percentage of treated surface ("Density").

"Free hand" mode

It is always possible to go back to the "Free Hand" mode by pressing the "Free Hand" area: the systems will ask the operator to confirm this choice.

9.4.1. HiScan DOT alarms

Hi-Scan

This fault is related to problems with the HiScan DOT unit.

Try to reset the fault display.

Call the technical assistance service if the fault persists.

HS galvo driver

The system reports a fault if the mirrors inside the HiScan DOT unit are not working properly.

If this fault is reported when the HiScan DOT is switched on, check all the connections with the scanning unit.

Try to reset the fault display. If it persists call the technical assistance service.

SCANNING UNITS

HS points maker

This fault is related to problems with the software of the HiScan DOT unit.

Try to reset the fault display. If it persists call the technical assistance service.

10. CLINICAL APPLICATION

This section discusses the clinical application of the system in general terms; it is not intended to be an exhaustive clinical manual.

10.1. CO₂ laser clinical application

Laser applications and interventions evolved rapidly in the last three decades. Laser systems are nowadays being used extensively in all fields of surgery, and in particular of otorhinolaryngology, gynaecology and dermatology. Current developments are focused on modes of emission and intelligent laser power control as well as the application of laser energy with scanning technology.

The CO₂ is the election laser in most medical fields, thanks to its optical property of being absorbed mostly by water it has excellent tissue cutting properties with very little lateral tissue damage (about 50µm, with superpulsed systems and scanners).

The carbon dioxide (CO₂) emits at 10.6 µm, in the far invisible infrared region. As CO₂ radiation is invisible, a visible (typically red) aiming beam laser is accurately superimposed on to the path of the CO₂ beam.

The CO₂ radiation arrives to the accessory passing through an articulated arm with mirrors inside of it, better if 7.

The accessories for the CO₂ laser are always optical devices, single lens, groups of lenses (like zooms). This devices serve to focalize the beam on little spots. The more the spot is little, the more energy density (fluence) can be achieved even using low power, thus permitting a tissue ablation with minimal charring. The attachment with micromanipulators allows coaxial delivery of the energy for laser surgery with operating microscopes, thus extending its range of clinical application considerably, making its use more and more refined. With the zoom of the micromanipulator the focal point can change and be set on the surgical working plane. Thus the operator has to know how to focalize and work with it, specially with an electronic scanner that produces his best effects if working with a peectly focalized laser, in regime of photoablation.

Please refer also to *Micromanipulator Operator's Manual*.

10.1.1. Contraindications

There are no known contraindications for the use of the system, apart general contraindications as in standard surgery.

Generally, contraindications to using the carbon dioxide laser include an inability to visualize the area to be treated because of anatomic considerations (e.g., prolapsing lateral vaginal sidewall, larynx anatomic conformation) and inadequate physician training or experience.

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10.1.2. Side effects

Complications, though rare, can occur according to the anatomic district or the surgical procedure.

Generally speaking, they can be: blood spill, swelling, discomfort or moderate pain, abnormal cicatrization, adhesions.

The patient must understand the importance of pre-treatment and post-treatment instructions, and that failure to comply with these instructions may increase the probability of complications.

Both bacterial and viral infections are potential side effects if proper clinical precautions are not observed; these precautions are related to the kind of surgical procedure.

10.1.3. Precautions

 CAUTION <i>Possible risk for patient/operator</i>	<ul style="list-style-type: none"> • Beam alignment and focalization checks are extremely important for safe and correct operation: carefully check if the CO₂ laser beam is properly focused at the microscope's operative working distance and check the coaxiality between the red aiming beam and CO₂ beam. • Do not use the laser if aiming and treatment beams are not coincident.
--	--

 CAUTION <i>Possible risk for patient/operator</i>	<ul style="list-style-type: none"> • Spot size and laser energy are independently controlled. If a smaller spot size is used, as in excision procedures, the operator must remember that the energy density is higher. • Laser parameters should be employed with extreme caution until you understand the biological interaction between the laser energy and tissue.
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The beam should be moved manually or through the scanning system, if present, to control the ablation depth.

- Plastic instruments such as speculums or eye shields can melt when impacted by the laser beam. Use only stainless steel surgical instruments designed specifically for laser use.
- If necessary, the area around the target site can be protected with wet towels or gauze sponges or laser beam backstops. Ensure that sponges do not dry!
- Be especially careful with the use of oxygen. Oxygen accelerates both the severity and the extent of fire. Always refer to the protocols related to anaesthesia, in force in the hospital where the laser system is used.
- Use non-flammable substances for uses as anesthesia, preparing soft tissue for treatment, and cleaning or disinfecting instruments.
- The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.
- Keep a minimum of combustible materials in the treatment room. If treatment requires the use of a combustible material, such as gauze, first soak it in water.

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<ul style="list-style-type: none"> • Prevent singeing or burning when treating an area with hair by wetting the area with water or saline before beginning treatment. • Attention should also be drawn to the danger of ignition of endogenous gases. When procedures are performed in the perianal area, moistened sponges should be inserted into the rectum. 	 <p>CAUTION <i>Possible risk for patient/operator</i></p>
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<p>Always use laser-resistant, cuffed, and flexible stainless steel endotracheal tube. The endotracheal tube cuff can be inflated with saline to protect it from inadvertent penetration. The saline can be dyed with methylene blue so that evidence of cuff-penetration by the laser will readily appear on surrounding gauze sponge.</p>	 <p>CAUTION <i>Possible risk for patient/operator</i></p>
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10.1.4. Pretreatment Recommendations

At the time of the initial visit, the physician should determine the suitability of the laser treatment and inform patients about the treatment.

<p>If using the laser with micromanipulator, before starting starting the surgical procedure the physician has the responsibility to check if the CO₂ laser beam is properly focused at the microscope's operative working distance and to check the coaxiality between the red aiming beam and CO₂ beam. The physician has not to change the microscope's working distance after the focusing operation and/or during the surgical procedure.</p>	 <p>CAUTION <i>Possible risk for patient/operator</i></p>
---	--

10.1.5. Treatment Recommendations

<p>Adjust the appropriate maximum joystick's operating field using the dedicate adjustment screw before starting the procedure, in a way that the beam does not exceed the microscope's operating view.</p>	 <p>CAUTION <i>Possible risk for patient/operator</i></p>
--	---

This guarantees the laser beam will never get out of the visual field eventually being "lost" by the operator.

10.1.6. Posttreatment Recommendations

<p>After each treatment session, physicians should advise their patients on proper care of the treated area according to the surgical discipline or procedure.</p>	 <p>CAUTION <i>Possible risk for patient/operator</i></p>
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Patient has to contact the physician if there is any indication of infection (redness, tenderness or pus).



CLINICAL APPLICATION

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11. TROUBLESHOOTING

This sections describes the faults detected by the system and provides a troubleshooting of some problems that can be identified and solved by the operator.

11.1. Faults management

The SmartXide² system is able to detect fault conditions that may be dangerous for the subject under treatment and for the system itself. As soon as one of these conditions is detected, the system automatically switches to safety mode: shutter closed, source turned off (STAND BY), footswitch disabled.

The SYSTEM FAULT menu is immediately displayed on the screen.



Fig.45 - "SYSTEM FAULT" menu

The SmartXide² system displays only the currently detected fault conditions - i.e. in figure an INTERLOCK fault was detected -.

Moreover, once a fault is detected, the system keeps on displaying the label even if the fault is solved: this allows the operator to record the detected faults to eventually inform the technical assistance service.

11.2. Descriptions of Faults

The possible faults and the appropriate actions to take are detailed below.

11.2.1. Interlock

This fault is displayed if the INTERLOCK system detects an open circuit. If the INTERLOCK feature is attached to an external interlock device, check that the door is closed, that the external interlock device is functioning and that the cable from the external interlock device is properly attached to the INTERLOCK socket on the system.

If an external interlock device is not used, check that the INTERLOCK connector (provided with the system accessories) is properly attached to the INTERLOCK socket.

Reset the fault display. Call Technical Service if this fault persists.

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11.2.2. Temperature

This fault is displayed if the temperature of the cooling fluid inside the CO₂ laser source or the temperature of the high voltage power supply unit gets too high.

Do not turn off the system in order to let the cooling fluid cool down.

Wait approximately 2 minutes, and then press any key to reset the fault display. Call Technical Service if this fault persists.

11.2.3. Shutter

This fault condition is displayed if the shutter's detected position is not the same as the shutter's expected position. Press any key to reset the fault display.

Call Technical Service if this fault persists.

11.2.4. High voltage

This fault condition is displayed if the internal high voltage power supply unit is not properly working.

Press any key to reset this fault display, then switch on the laser source again. Call Technical Service if this fault persists.

11.2.5. Flow

This fault condition is displayed if low flow in the cooling circuit is detected. Press any key to reset the fault display.

Call Technical Service if this fault persists.

Only Deka technical assistance service or skilled personnel authorized by Deka may service the cooling circuit.

11.2.6. High power/Low power

These two fault conditions are stated if the power evaluation procedure detects a wrong output power level.

The "High power"/"Low power" label is displayed in the SYSTEM FAULT menu in the same location of "High current" alarm.

Carefully read par. 8.3..

Reset the fault condition, then try to switch on the laser source in order to perform once again the power evaluation procedure.

Call the technical assistance service if the fault persists.

11.2.7. EEPROM/Data Memory

These fault conditions are stated if an internal memory component does not work properly.

It can be stated at the start up of the system or when the CO₂ laser source is switched off - STAND BY key pressed -.

These faults are not critical as concerns the performances of the system but there might be problems with the management of the treatment programs that is the system might forget the changes made by the

operator to the treatment programs.

Try to reset the fault condition, if it persists call the technical assistance service.

11.2.8. CO₂ PSTEMP

This fault condition is stated if overheating of the CO₂ power supply temperature is out of the operating range.

Try to reset the fault condition. If the fault persists, call the technical assistance service.

11.2.9. CO₂ Power Supply

This fault condition is stated if the system detects problem with the CO₂ power supply.

Try to reset the fault condition, if it persists call the technical assistance service.

11.2.10. CO₂ DUTY

This fault condition is stated if the system detects an internal fault generated by the CO₂ power source.

Try to reset the fault condition, if it persists call the technical assistance service.

11.3. Warnings

If the system detects power fluctuations, the power level on the screen may be displayed with yellow characters instead of red characters once calibration is completed. If laser treatment is in progress when this occurs, the warning tone rate increases. These two conditions are warnings, not fault conditions. The system does not go into standby and the operator can continue with the laser treatment.

TROUBLESHOOTING

11.4. Troubleshooting

Following is a brief troubleshooting of some problems that can be identified and solved by the operator.

System does not turn on

- Make sure the mains cable is properly connected and the mains voltage/current values match with the specifications of the system.
- Check if the key switch, the emergency switch and the circuit breaker are correctly positioned.

Nothing happens as footswitch is pressed

- Make sure the system is in the OPERATE state - see the Section "System description" -.
- Make sure footswitch is properly connected to the suitable connector - see the Section "System description" -.

Poor laser emission or no laser emission from the handpiece

- Call for Technical Assistance Service.

Aiming beam and CO₂ beam not coaxial

- Make sure the articulated arm was properly installed.
- The problem may be due to a misalignment of the articulated arm: call Technical Assistance Service.

Power displayed after calibration is different from power selected.

- System cannot provide the selected power.
Read carefully par. 8.7.

System does not detect the scanning unit presence

- Make sure the scanning unit is properly connected.
Read carefully the relevant Sections.

For any further problem contact your agent or contact:

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Email: info@dekalaser.com

12. MAINTENANCE

12.1. Ordinary maintenance

12.1.1. Laser Care and Handling

Deka suggests that the operator periodically clean and disinfect the exterior of the laser system in the following manner:

- Clean the exterior of the laser with a mild soap and water.
- Use a soft cloth for both cleaning and disinfecting.
- When necessary, disinfect the exterior parts of the equipment with a hospital-grade disinfectant.
- Periodically, remove and vacuum the air filter located on the back of the unit (please refer to par. 12.1.7).

Precautions

- Take care that detergent does not penetrate cavities or apertures of the device;
- do not use chemical solvents and/or abrasive detergents;
- do not use alcohol to clean the surface of the display.

12.1.2. CO₂ reusable parts reprocessing

CO₂ handpieces have to be reprocessed after use. Proper handling and reprocessing of reusable parts for next patient has to be done by carefully adhering to reprocessing steps described below:

NOTE

Start cleaning of reusable parts as soon as possible after use.

A) Wear heavy-duty rubber gloves, a plastic apron, eye protection, and mask during reprocessing.

B) Precleaning at the point of use

Prior to thoroughly cleaning, remove visible soil.

A deep container, e.g. a bucket, containing a wire-mesh basket can be filled with tap water at 22°C to 43°C (72°F to 110°F) and enzymatic detergent (protease formula that dissolves proteins), such as Endozime® AW Triple Plus with APA.

This detergent has to be used in accordance with the detergent manufacturer's directions (e.g., dilution/concentration, temperature, water quality, soak time).

The parts are placed in the wire basket, agitated for 3-5 minutes, and then lifted out.

The basket is overturned onto a table or tray in order to separate the items prior to cleaning, packing and autoclaving.

C) Disassembling the reusable parts

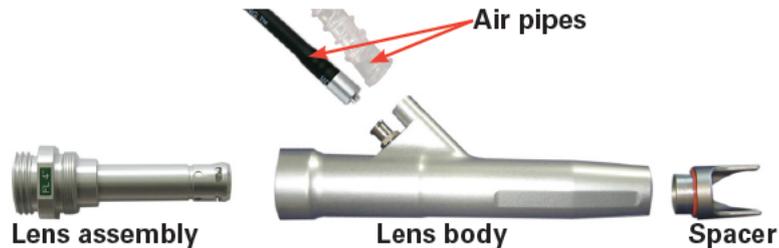
Disassemble the items as described below:

MAINTENANCE

Disassembling the CO₂ handpieces

1. disconnect the air pipes from the handpiece body
2. If connected, unscrew the handpiece from the articulated arm
3. Extract the lens assembly currently connected unscrewing it
4. Pull the spacer out

Fig.46 - Disassembling the CO₂ handpieces

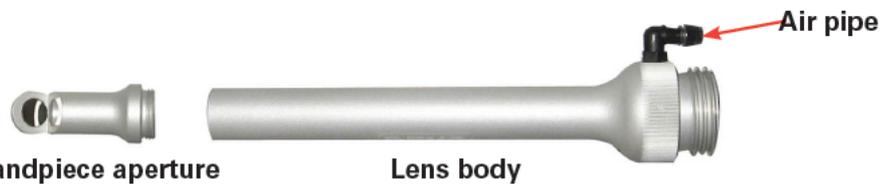


To reassemble the handpiece, reverse the steps.

Disassembling the CO₂ 2" dental handpiece

1. Disconnect the air pipe from the handpiece
2. If connected, unscrew the handpiece from the articulated arm
3. Unscrew the aperture currently connected

Fig.48 - Disassembling the CO₂ 2" dental handpiece



To reassemble the handpiece, reverse the steps.

Disassembling the CO₂ 4" dental handpiece

1. Disconnect the air pipe from the lens holder
2. If connected, unscrew the handpiece from the articulated arm
3. Remove the handpiece aperture by loosening the clamp nut and then sliding it out
4. Remove the clamp nut by turning it until it detaches
5. Unscrew the lens holder

Fig.49 - Disassembling the CO₂ 4" dental handpiece



To reassemble the handpiece, reverse the steps.

MAINTENANCE

D) Thorough cleaning

Thorough cleaning allows the removal of all foreign material (dirt and organic matter) from the parts being reprocessed and must always precede sterilization procedures.

If instruments and other items have not been cleaned, sterilization may not be effective because microorganisms trapped in organic material may survive sterilization.

Steps for thorough cleaning

1. Soak the instruments in a container deep enough for the number of items, filled with a solution of tap water at 22°C to 43°C (72°F to 110°F) and the same enzymatic detergent used for precleaning (**step C**).
2. Scrub items vigorously to completely remove all foreign material using the brushes provided with the accessories. Hold items under the surface of the water while scrubbing and cleaning to avoid splashing.
3. Be sure to brush in the grooves and joints where organic material can collect and stick.
4. Rinse items 2-3 minutes thoroughly with tap water to remove all detergent. Please adhere to the suggested rinse time as it ensures that residues remaining on the item do not exceed safe levels.
5. Inspect items visually to confirm that they are clean. If any visible debris remains, repeat steps 2-4.

E) Sterilization**For steam sterilization the following protocol is recommended:**

1. Package each component with self sealing pouches suitable for steam sterilisation made of medical paper (heavyweight 70 gsm) and transparent 2-ply laminate. Pouches are available in the following dimensions (they have to be large enough hold items without stressing the pouch seals):
 - 2¼" x 4" / 60mm x 100mm
 - 3½" x 8" / 90mm x 200mm
 - 5¼" x 14" / 135mm x 360mm
 - 7½" x 13" / 190mm x 330mm.
2. Arrange all wrapped items in the chamber of the autoclave in a way that allows the steam to circulate freely. DO NOT STACK.
3. Follow the manufacturer instruction for operating the autoclave. Set the autoclave parameters as follows, according to the autoclave type:
 - 1) Pre-vacuum cycle: 132°C, 4 minutes, minimum drying time: 5 minutes.
 - 2) Gravity cycle: 132°C, 10 minutes, minimum drying time: 5 minutes.

ATTENTION:

The autoclave should be checked each time it is used in order to make sure that it is functioning properly. Follow the manufacturer's instructions

MAINTENANCE

whenever possible since autoclave maintenance varies depending on the type of autoclave.

F) Post-processing handling

1. Do not store packs items until they cool to room temperature.
2. Store items using the following guidelines:
 - Store items in a closed, dry, cabinet with moderate temperature and low humidity in an area that is not heavily trafficked.
 - A wrapped pack can be considered sterile as long as it remains intact and dry. When in doubt about the sterility of a pack, consider it contaminated and re-sterilize the items.
3. Reassemble the items before use, reversing the steps previously described (phase **C**).

12.1.3. Inspect, clean and disinfect the scanning units

Before and after each use, inspect the scanning unit (HiScan Surgical, EndoScan) for dirt or damages. Failure to clean or improperly cleaning can alter the efficiency of the system.

Proceed as follows:

- **Switch the system off and disconnect the scanning unit from the laser system before inspection/cleaning/disinfecting.**
- To clean and disinfect the external surface of the scanning unit, use a cloth dampened with a hospital grade disinfectant.
- Dry with a clean cloth. Do not use the scanning unit until its surface is completely dry, that is the disinfectant solution is fully evaporated.
- Do not use disinfectants containing peracetic acid or chlorine.

12.1.4. Emergency switch and interlock

Check the correct working of the emergency switch and of the interlock network once a month.

MAINTENANCE

12.1.5. Air filters cleaning

This operation has to be performed once requested by the system.

Always disconnect the system from the mains before cleaning.



CAUTION

Possible risk for patient/operator

The filters are located in a proper housing in the bottom rear side of the system: pull out the housing as shown in Fig. 47 and remove the protection grid.

Blow away the dust on the filter, then put it back. These filters are washable: **be sure they are completely dry before putting them back.** Replace the filters, if necessary.

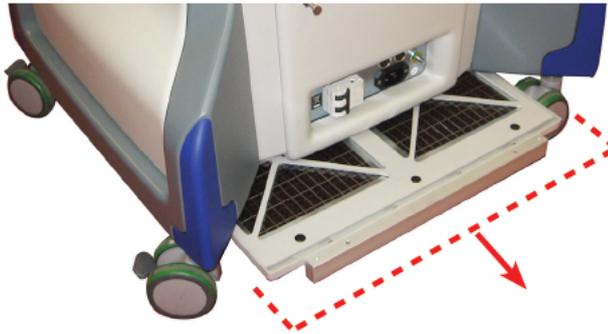


Fig.47 - Air filters replacing

MAINTENANCE

12.2. Disposal of system

To comply with European Commission Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) and other country and state regulations, please do not dispose of this equipment in any location other than designated locations.

You can also contact your local DEKA M.E.L.A. s.r.l. dealer to arrange the return of the equipment to the manufacturer.

NOTE

The fiber optic has a plastic sheath. The damaged fiber optics should be disposed according to national and local regulations.

12.3. Maintenance to be carried out by skilled personnel

The following maintenance procedures should be performed in order to assure system reliability:

- laser source inspection;
- footswitch/shutter check;
- internal power meter inspection and calibration;
- check of the electric insulation.
- check of the cooling circuit.

The cooling fluid of the SmartXide² system is bidistilled water.

All these maintenance procedures should be carried out at least once per year by qualified personnel authorized by DEKA M.E.L.A. s.r.l..

ACCESSORIES

13. ACCESSORIES

SmartXide² is provided with the accessories listed in the following table:

Name	Code	Quantity
Interlock connector	N21901	1
Footswitch	E094B1 E06301 (optional)	1
System key	041400050	2
Mains cable	-	1
Door safety labels	079101200	2
Operator's Manual	See code on the cover	1
CO ₂ laser safety glasses for physician	070100047	2
Aiming beam protection eyewear	070100056	2
Laser safety eyewear for patient	070100054	1
Flexible hose for smoke evacuator	070500027	1
Smoke evacuator accessories kit	070500028	1
"USER ID" chip	iBM103U	1
Air filters	020601021	2
5mm Allen wrench	041100082	1
Brush for probe internal cleaning	031001152	1
Brush for probe external cleaning	031001153	1
Accessories case	070400110	1
1.5" handpiece <i>including</i> 1.5" focal assembly Handpiece body Spacer Handpiece case	F26301 N76601 N77101 04370010A 070400108	optional
2" handpiece <i>including</i> 2" focal assembly Handpiece body Spacer Handpiece case	F26401 N76701 N77101 04370010A 070400108	optional
4" handpiece <i>including</i> 4" focal assembly Handpiece body Spacer Handpiece case	F26501 N76801 N77101 04370012A 070400108	optional

Table 13 - Accessories

ACCESSORIES

5" handpiece <i>including</i> 5" focal assembly Handpiece body Straight spacer Spacer with backstop 90° spacer 120° spacer	F28001 N77801 N78001 04370017A 04370018A 04370019A 04370020A	optional
7" handpiece <i>including</i> 7" focal assembly Handpiece body Spacer Handpiece case	F26601 N76901 N77101 04370012A 070400108	optional
8" handpiece <i>including</i> 8" focal assembly Handpiece body Straight spacer Spacer with backstop	F28101 N77901 N78401 04370022A 04370023A	optional
Collimated handpiece <i>including</i> Collimated focal assembly Handpiece body Spacer Handpiece case	F26701 N77001 N77101 04370012A 070400108	optional
HiScan Surgical unit <i>including</i> HiScan Surgical head HiScan cable	F27001 E165A1 N74801	optional
EndoScan unit <i>including</i> EndoScan Cable	F26801 N77501 N74901	optional
HiScan DOT unit <i>including</i> HiScan DOT head HiScan DOT cable 90° Side-firing handpiece with cylindrical body 90° Side-firing handpiece Straight handpiece	F34601 E109J1 N77601 N94601 N94701 N76001	optional
Micromanipulator EasySpot Hybrid	N183F1	optional

ACCESSORIES

Name	Code	Quantity
2" dental handpiece for CO ₂ source <i>including</i> 120° spacer straight spacer	N377A1 N66601 04255025A	optional
4" dental handpiece for CO ₂ source <i>including</i> straight spacer open spacer 120° spacer 75° spacer ceramic tip	N324A2 N47701 04255022A N47601 N47501 040218013	optional
Endonasal probes kit 80mm <i>including</i> Handpiece for endonasal probes Hollow flexible waveguide 80mm Straight endonasal probe 80mm 90° endonasal probe 80mm 120° endonasal probe 80mm	F27901 N34601 N76501 04283016A 04283018A 04283020A	optional 1 2 2 2 2
Accessories for laparoscopy: 400mm focal for laparoscope 300mm focal for laparoscope Direct coupler Connection for STORZ laparoscope*	N759A1 N75901 04366003A 04366004A	optional

*For other laparoscope models, please ask to the laparoscope's Manufacturer or to DEKA.

For other accessories, please contact your DEKA dealer or DEKA directly.

Table 14 - Optional accessories



ACCESSORIES

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14. APPENDIX

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSION		
<p>The system SmartXide²² is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartXide²² system should assure that it is used in such an environment.</p>		
Emission Test	Compliance	Electromagnetic environment
RF Emissions CISPR 11	Group 1	The SmartXide ²² system uses RF energy only for its internal function. Therefore, its RF emission are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The SmartXide ²² system is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supply buildings used for domestic purposes.
Harmonic Emissions CEI EN 61000-3-2	Class A	
Voltage fluctuation/ flicker emissions CEI EN 61000-3-3	Complies	

APPENDIX

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
The SmartXide ²² system is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartXide ²² system should assure that it is used in such an environment.			
Immunity test	Test level CEI EN 6001-1-2	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) CEI EN 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst CEI EN 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge CEI EN 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines CEI EN 61000-4-11	<5% U _T (>95% dip in U _T) for 0,5 cycles	<5% U _T (>95% dip in U _T) for 0,5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SmartXide ²² system requires continued operation during power mains interruptions, it is recommended that the SmartXide ²² system be powered from an uninterruptible power supply or a battery.
	40% U _T (60% dip in U _T) for 5 cycles	40% U _T (60% dip in U _T) for 5 cycles	
	70% U _T (30% dip in U _T) for 25 cycles	70% U _T (30% dip in U _T) for 25 cycles	
	<5% U _T (>95% dip in U _T) for 5s	<5% U _T (>95% dip in U _T) for 5s	
Power frequency (50/60Hz) magnetic field CEI EN 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

APPENDIX

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
The SmartXide ²² system is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartXide ²² system should assure that it is used in such an environment.			
Immunity test	Test level CEI EN 6001-1-2	Compliance level	Electromagnetic environment - recommended separation distance -
Conducted RF CEI EN 61000-4-6	3V _{RMS} 150kHz÷80MHz	3V _{RMS}	d=1,2√P
Radiated RF CEI EN 61000-4-3	3V/m 80MHz÷2.5GHz	3V/m	d=1,2√P from 80MHz to 800MHz
			d=2,3√P from 80MHz to 2.5GHz
<p>Portable and mobile RF communications equipment should be used no closer to any part of the system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance.</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^(a), should be less than the compliance level in each frequency range^(b). Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;"> </div>			
<p>Note:</p> <p>(1) At 80MHz and 800MHz, the separation distance for the higher frequency range applies.</p> <p>(2) The guidelines may not applied in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. to assess the electromagnetic environment due to fixed R transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SmartXide²² system is used exceeds the applicable RF compliance level above, the SmartXide²² system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the SmartXide²² system.</p> <p>(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			



APPENDIX

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE SmartXide²

The SmartXide² system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SmartXide² can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SmartXide² as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz÷80MHz $d=1,2\sqrt{P}$	80MHz÷800MHz $d=1,2\sqrt{P}$	800MHz÷2,5 GHz $d=1,2\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note:

- (1) At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
- (2) The guidelines may not applied in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



APPENDIX

CABLES AND ACCESSORIES WITH WHICH COMPLIANCE TO EN 60601-1-2 EMC REQUIREMENTS IS CLAIMED	
Interlock connector	N21901
Foot switch	E094B1
Mains cable	-
1.5" handpiece	F26301
2" handpiece	F26401
4" handpiece	F26501
5" handpiece	F28001
7" handpiece	F26601
8" handpiece	F28101
Collimated handpiece	F26701
HiScan Surgical cable	N74801
EndoScan cable	N74901
DOT	F34601
Micromanipulator	N183F1

NOTE

The use of accessories, transducers and cable other than those above specified may increase electromagnetic emission and decrease electromagnetic immunity.



APPENDIX

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ATTACHMENT B

PROPOSED MICROMANIPULATOR OPERATOR'S MANUAL

44 PAGES



OPERATOR'S MANUAL

EasySPOT
Hybrid

S/N:

Code: ON186F1U_G.V04

Date: 17/12/2013

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The Code of Excellence

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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GLOSSARY

The following symbols and abbreviations may be used on the EasySpot Hybrid system and/or in this manual.

	Symbol for "Manufacturer"
	Electrical protection degree
I	Electrical protection type
~	Symbol of alternating current
	Warning on system discarding (Directive 2002/96/EC)
NOHD	Nominal Ocular Hazard Distance
J	joule - unit of energy
mJ	millijoule - 1000mJ=1J
nm	nanometer - unit of laser wavelength, 1000000nm=1mm
s	second - unit of time
μs	microsecond - 1000000μs=1s
min	minute - unit of time, 1min=60s
Hz	hertz (cycles per second) - unit of frequency
A	ampere - unit of electrical current
VA	volt ampere - unit of absorbed electrical power
V~	unit of alternating voltage
Pa	pascal - unit of measurement of pressure

Table 1 - Symbols and abbreviations

Table 2 - Units of measurement

INTRODUCTION

1. INTRODUCTION

1.1. EasySpot Hybrid

EasySpot Hybrid is a new generation micromanipulator for CO₂ lasers.

EasySpot Hybrid has a single ring nut rapid focalization system that allows to focalize the beam to the same focal length of the microscope and fix the position with a mechanical block. In this way the micromanipulator "remembers" the focus position, still allowing eventually the surgeon to defocus the beam from the same ring nut.

Thanks to its joystick, it is possible to regulate the mechanical tension and the maximum work field in order to easily control and never "loose" the beam even inside small size laryngoscopes.

EasySpot Hybrid can mount on top of the joystick a remote control specially conceived to command top level scanning systems (HiScan Surgical/EndoScan/MiniScan Plus). It allows the surgeon to have under direct control the more useful electronic scanning functions (rotation and dimension of the figures, scan off-scan on, centering) without moving his eyes from the microscope.

DEKA M.E.L.A. s.r.l. recommends that all healthcare professionals who plan to use the micromanipulator read carefully all the information included in this manual and in the operator's manual of the laser system; familiarity with information and instructions is an essential requirement for ensuring an efficient and optimal use of the system, to avoid damage to people or devices and to obtain good results of treatment.

Only qualified medical personnel, trained in this particular technique, is allowed to use the micromanipulator EasySpot Hybrid.



CAUTION

Possible risk for patient/operator

1.2. Compatible laser systems

The micromanipulator EasySpot Hybrid can be used in conjunction with DEKA M.E.L.A. s.r.l. CO₂ laser systems.

The use of the EasySpot Hybrid with integrated scanning systems is possible with DEKA M.E.L.A. s.r.l. CO₂ SmartXide² and SmartXide HS/MS devices.

EasySpot Hybrid may also be used with CO₂ laser systems from other manufacturers. In this event, a preventive check of compatibility is mandatory.

For details, please contact DEKA M.E.L.A. s.r.l. or DEKA local dealer.



INTRODUCTION

1.3. About the Manual

The Operator's Manual provides operators with the following information about the system:

- Indications for use
- Safety
- Description
- Installation
- Use of the system
- Maintenance
- Faults and troubleshooting
- Accessories

Before using the system for the first time, please familiarize yourself with the information and instructions of this manual. This is essential to ensure an effective and optimal use of the system, to avoid damage to people or to the device and to obtain good results of treatment.

Note: Pictures in this manual are purely indicative and may be subject to changes.

In this manual we use different colors to highlight warnings:

- warnings on a grey background are remarks for a correct use of the system and of its accessories;
- warnings on a grey background and with a yellow triangle are remarks concerning safety.

Operators must read and follow all the remarks.

SAFETY

2. SAFETY

This chapter provides a short description of the current safety standards taken in account while designing and manufacturing the EasySpot Hybrid micromanipulator.

This section also covers specific safety features designed to minimize potential hazards.

2.1. Introduction

Before using the micromanipulator EasySpot Hybrid, users should be aware of potential hazards: optical, biological and fire.

This section of the manual covers the potential hazards, precautions and accident responses. It also points out some fundamental precautions which must be followed in order to minimize potential hazards.

DEKA M.E.L.A. s.r.l. is not responsible for the direct or indirect effects arising out of or in connection with, or resulting from the application or use of the system that are not a direct consequence of design or manufacturing defects of the device or parts thereof. The manufacturer shall not be responsible of the success of the treatment.



CAUTION

Possible risk for patient/operator

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.



CAUTION

Possible risk for patient/operator

2.2. Optical hazard

The micromanipulator is used in conjunction with a laser system which emits an invisible beam of intense energy that can cause serious eye and skin injury with direct or indirect beam contact.

Please adhere to the following precautions to minimize optical damage to laser operators, assisting personnel and patients:

- All persons in the room during treatment must wear protective eyewear. Protective eyewear must comply with the European regulation EN 207 "Personal eye-protectors. Filters and eye-protectors against laser radiation" and with the U.S. regulation ANSI Z136.7 "American National Standard for Testing and Labeling of Laser Protective Equipment". They must have at least the following characteristics:
OD• 5 at 10.6µm, 10600 D LB5 at 10.6µm
Contact DEKA M.E.L.A. s.r.l. or DEKA local dealer for information on where to find this type of eyewear.
- Mark treatment rooms clearly to avoid unexpected entry during treatment.



SAFETY



CAUTION

Possible risk for patient/operator

- Never look directly into the handpiece or into apertures labelled "laser aperture", even while wearing protective eyewear.
- Limit entry to the treatment room to only those who assist in treatment and are trained in the use of the equipment.



CAUTION

Possible risk for patient/operator

- Direct the activated laser only at the intended area of treatment.
- Remove any metal object such as watches, rings, necklaces and similar items from the operating area and, if possible, do not use reflective instruments or materials.

- Reflective objects could intercept the laser beam causing a deflection to an area other than the intended treatment area. Many surfaces that may seem opaque can actually reflect the 10.6µm CO₂ laser emission wavelength.
- Put the laser into the STAND BY mode when the laser is not in use. (When in Standby mode, the laser beam cannot be inadvertently activated.)
- Ensure that all trained staff assisting in the treatment know how to shut down the laser in the case of an emergency.
- Always verify that the micromanipulator is properly connected to the laser. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage might occur.
- Keep the laser start-up key in a safe place outside of the treatment room when the laser is not in use.

2.3. Biological Hazard



CAUTION

Possible risk for patient/operator

The laser smoke presents a possible biological hazard. Ablated tissue from the patient is present in the smoke. Laser smoke may contain viable particles. Use of a laser smoke evacuator is recommended.

Flow capability should be adequate to effectively remove the laser smoke; replace the filters of the smoke evacuator whenever it is necessary. Please refer to the relevant Operator's Manual.

2.4. Laser-induced fire hazard

When the laser beam contacts an exterior surface, the surface absorbs the laser energy, which raises the surface temperature, whether the surface is skin, hair, clothes, or any flammable substance. Operators should take the following precautions to prevent a laser-induced fire:

- Use non-flammable substances for such uses as anaesthesia, preparing soft tissue for treatment, and cleaning or disinfecting instruments.
- Be especially careful with the use of oxygen. Oxygen accelerates both

SAFETY

the severity and the extent of fire. Always refer to the protocols related to anaesthesia, in force in the hospital where the laser system is used.

- Keep a minimum of combustible materials in the treatment room. If treatment requires the use of a combustible material, such as gauze, first soak it in water.
- Prevent singeing or burning when treating an area with hair by wetting the area with water or saline before beginning treatment.
- Always keep a small fire extinguisher and water in the treatment room.
- The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.
- Attention should also be drawn to the danger of ignition of endogenous gases. When procedures are performed in the perianal area, moistened sponges should be inserted into the rectum.

2.5. Precautions in laryngeal microsurgery

Be especially careful with the use of oxygen. Oxygen accelerates both the severity and the extent of fire. Always refer to the protocols related to anaesthesia, in force in the hospital where the laser system is used. Always use laser-resistant, cuffed, and flexible stainless steel endotracheal tubes. The endotracheal tube cuff can be inflated with saline to protect it from inadvertent penetration. The saline can be dyed with methylene blue so that evidence of cuff-penetration by the laser will readily appear on the surrounding gauze sponge.

The endotracheal tube and the tissues behind the target area can be further protected by placement of wet sponges to absorb laser energy.

2.6. Further precautions

- Beam alignment checks are extremely important for the safe and correct operation.

Do not use the system if aiming and treatment beams are not coincident or if the spot size is not regular.

Carefully read the "TROUBLESHOOTING" Section.

- Spot size and laser energy are independently controlled. If a smaller spot size is used, as in excision procedures, the user must remember that the energy density is higher. Laser parameters should be employed with extreme caution until you understand the biological interaction between the laser energy and tissue.

The beam should be moved manually or through the scanning system, if present, to control the ablation depth.

- Plastic instruments such as speculums or eye shields can melt when impacted by the laser beam. Use only stainless steel surgical instruments designed specifically for laser use.
- If necessary, the area around the target site can be protected with wet towels or gauze sponges or laser beam backstops. Ensure that sponges do not dry!

3. SPECIFICATIONS

3.1. Description

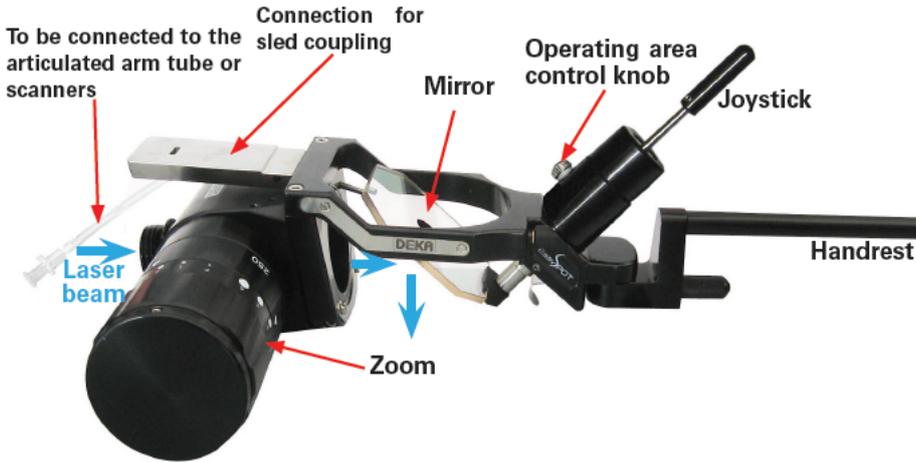


Fig.1 - Micromanipulator EasySpot Hybrid

The micromanipulator is composed of a metallic body which houses the optical system for focusing the laser beam - zoom -, a movable mirror driven by a precision joystick.

If the micromanipulator is used together with the scanning unit (HiScan Surgical, EndoScan), the final part of the joystick may be provided with a remote control shown in Fig. 2 having three different positions (left, right, central). It allows to set some scanning parameters acting in the same way as the keys located on the scanning head (see the relevant Operator's Manual for details).

In this way, it is possible for the user to control the main scanning functions without taking his eyes off the microscope.

The connection system with a retainer grain allows to easily switch from the joystick (Fig. 1) to the joystick with remote control (Fig. 2) and vice versa.

The remote control directly communicates with the scanning unit - thanks to the micromanipulator internal wiring - through a mini-jack connector: in this way, the remote control, if damaged, can be easily removed and replaced (code: N64501).

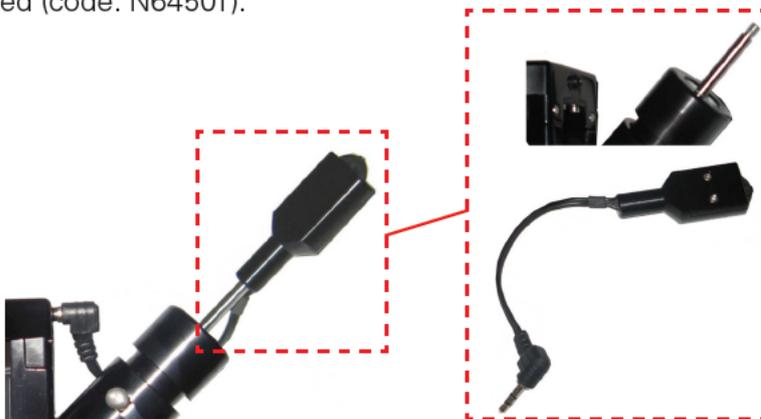


Fig.2 - Remote control (N64501)



SPECIFICATIONS

The optical system can be properly set, acting on the focusing zoom ring, in order to focus the laser beam on the focal plane of the microscope. The focus block prevents from having to perform this operation before each treatment, unless the working focus length of the microscope has been changed.

Once focused, the laser beam can be defocused, acting on the same ring, for coagulation or vaporization procedures.

The joystick acts on the movable mirror so it allows to easily move the laser beam in the microscope viewing area; tension of the joystick movement may be adjusted loosening or tightening the ring at the base of the joystick itself. The micromanipulator EasySpot Hybrid allows a very accurate mechanical adjustment of the maximum operating area - see par. 4.5 -.



CAUTION

Possible risk for patient/operator

Always test the focus of the CO₂ laser and the correspondence with the aiming beam (with the micromanipulator installed on the microscope in the working position and connected to the articulated arm) prior to surgery by shooting on a test surface. Never use the micromanipulator if the CO₂ beam does not match the spot of the aiming beam or if it produces figures different from a circular spot.

Moreover, the micromanipulator EasySpot Hybrid is provided with a PVC tube for air flow; this flow allows to keep the final mirror clean and cooled and has always to be connected to the tube on the articulated arm in the same way of the tube of the handpiece.

SPECIFICATIONS

3.2. Technical specifications

Type	Value
Focal range	From 200mm to 400mm
Operating area (at 400mm)	maximum 55x40mm
	minimum 20x18mm
Spot size of the laser beam on the focal plane	140µm at 200mm
	170µm at 250mm
	190µm at 300mm
	250µm at 400mm
Divergence of laser beam on the focal plane	56mrad at 200mm
	33mrad at 400mm
CO ₂ laser beam attenuation	≤20%
Lenses	Coated ZnSe (zinc selenide)
Joystick	Ambidextrous with tension control
Handrest	Ambidextrous, adjustable and removable
Connection to microscope	Easy and fast via the apposite adapter or the sliding coupler.
Focusing system	Continuously variable zoom with focal range depending from 200mm to 400mm. Can be used from either the right or left side.
Movement of the laser beam (and, in case, of the scanning figures)	Manual via precision joystick.
Dimensions (l x w x h)	30 x 14 x 10 cm (with handrest)
Weight	830g

Table 3 - Technical specifications



4. INSTALLATION AND USE

4.1. Microscopic adapters

The micromanipulator EasySpot Hybrid can be adapted to microscopes/colposcopes of the main manufacturing companies:

SLED AND RING ADAPTERS

- Zeiss;
- Wild/Leica;

RING ADAPTERS ONLY

- Olympus;
- Storz/Global;
- Jed Med/Kaps;
- Leisegang;
- etc.

For a complete list of models or for particular connections, please refer to the relevant vendor.

4.2. DEKA slide connection for microscopes

On request, DEKA M.E.L.A. s.r.l. can provide slide couplings for Zeiss and Leica microscopes.

For Leica microscopes, use the dedicated slide coupling adapter connecting it on the microscope by screwing four screws into the holes shown as **(A)** in Fig. 3. Once the adapter has been mounted on the microscope, just connect the micromanipulator to the microscope: the special groove on the micromanipulator (enlarged and highlighted in Fig. 3) makes an easier connection. Act on grain **(C)** to adjust the height of the micromanipulator compared to the microscope lens, then block it screwing the knob **(D)**.

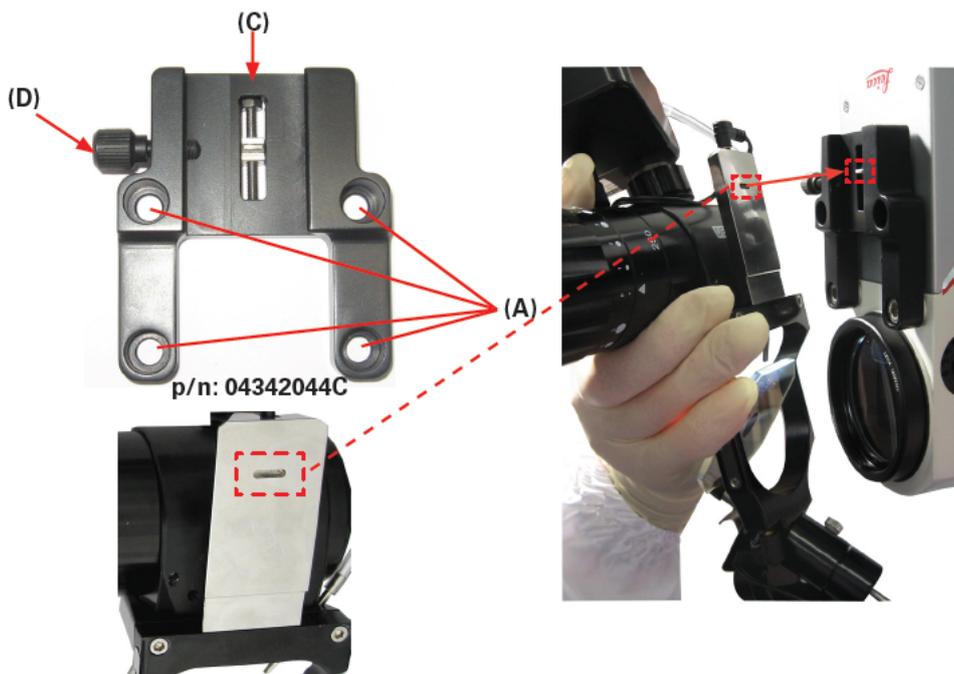
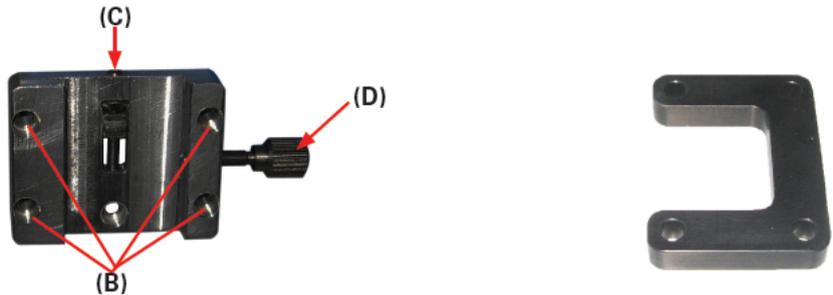


Fig.3 - Connection to Leica microscopes

INSTALLATION AND USE

For Zeiss microscopes, the adapter has to be mounted directly on the microscope (see Fig. 4): fix it on the microscope by screwing four screws into the holes shown as **(B)** (the grain shown as **(C)** has to be upward). Once the adapter has been mounted on the microscope, place the micromanipulator as previously described. In case of microscope with a prominent lens, use the adapter together with the shim shown on the right side of the figure. Act on the grain **(C)** to adjust the height of the micromanipulator as to the microscope lens, then block it screwing the knob **(D)**.

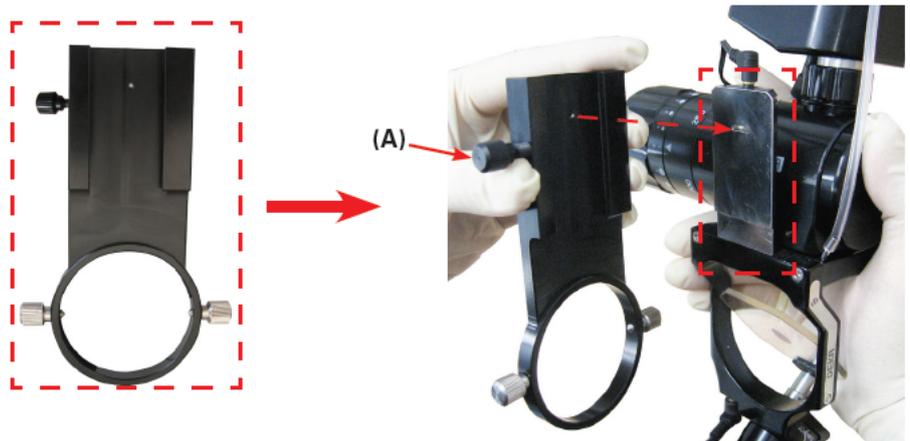
Fig.4 - Connection to Zeiss microscopes



4.2.1. Connection of the micromanipulator to the sled-ring adapter

- Connect the first adapter, shown below, to the micromanipulator by making it slide on the micromanipulator connection highlighted in Fig.5 and blocking it screwing the knob **(A)**. The groove on the micromanipulator has to match the special pin on the adapter (see the dotted arrow in Fig.5).

Fig.5 - Assembling the first adapter



INSTALLATION AND USE

- Once the first adapter has been connected, two screws allow to fix the micromanipulator to the ring adapter mounted on the microscope: both screws have to be unscrewed in order to make the ring enter completely inside its housing.
- Tight the screws to fix the micromanipulator to the microscope so that the screws enter into the special groove which is on all the adapters (this groove is highlighted in Fig.6 on the adapter for Leica microscopes).



Fig.6 - Adapter for microscope connection

While performing this operation, pay attention to hold the micromanipulator until you are sure the two knobs are well tightened in order to avoid accidental loss.

ATTENTION
Possible equipment damage

4.2.2. Connection of DEKA ring adapters to the microscope

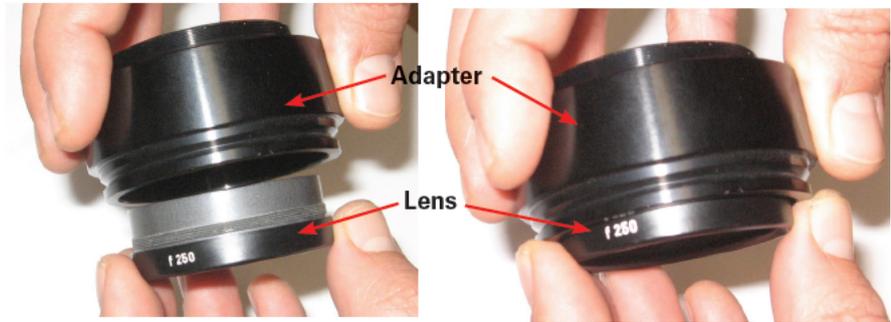
Special adapters allow to connect the microscope to the micromanipulator: the shape of this adapter and the way of connecting it depend on the microscope model so DEKA M.E.L.A. s.r.l. has to know which microscope is going to be connected in order to provide the correct adapter. For Zeiss and Leica microscopes, the company's sled adapters can be provided. For all other models, ring adapters must be used. Here is the description of the most common types of connection to the microscope:

Lens ring adapter for Zeiss objective OPMI 1 model (lens diameter: 48mm):

- remove the objective lens from the microscope;
- hold the rim of the objective lens in one hand and with the other hand screw the lens completely onto the adapter;
- screw the objective lens and adapter into the microscope.

INSTALLATION AND USE

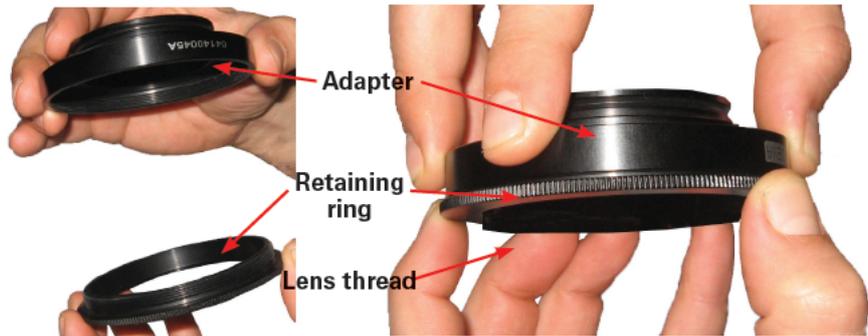
Fig.7 - Connection to the microscope - example 1 -



"Sandwich" ring adapter (for microscopes with fixed focal length):

- remove the objective lens from the microscope and drop it into the retaining ring;
- screw the retaining ring and lens into the adapter;
- screw the objective lens and adapter into the microscope by the thread of the lens.

Fig.8 - Connection to the microscope - example 2 -



Ring adapter connected with screws to the microscope/colposcope:

Screw the adapter (shown in Fig.9) into the microscope head.

This kind of adapter is suited, as an example, for autofocus Leica systems in which it is not required to change lens in order to change working distance.

For a complete list of models, please refer to the relevant vendor.

Fig.9 - Connection to the microscope - example 3 -



4.3. Adapter for sterile drapes

If the treatment to be performed requires absolute sterile conditions (e.g. ear surgery), it is suggested to cover the micromanipulator itself and the microscope with a sterile drape.

Sterile drapes are not provided with the device. The user is advised to use the original sterile drape for his specific microscope.

Alternatively, sterile drapes may be purchased from other manufacturers like 3M Health Care (Steri-Drape™ Fabric Surgical Drape). The user can select from 3M catalogue the suitable drape for their surgical microscope.

In order to use the sterile drape, the micromanipulator is provided with the two hooks highlighted in the figure below.



Fig.10 - Hooks for sterile drapes

Once the micromanipulator has been mounted onto the microscope, place the rubber ring of the sterile drape on the two hooks as shown in Fig. 11: to do this operation it is necessary to stretch lightly the rubber ring of the sterile drape.



Fig.11 - How to place the sterile drape

Then cover the micromanipulator and the microscope with the sterile drape (Fig. 12).



INSTALLATION AND USE

Fig.12 - Sterile drape placed on microscope



4.4. Connection to the laser system

Note that the micromanipulator should have already been connected to the microscope in the operating area. Proceed as follows:

- remove the handpiece - that is the final part which holds the focusing lens - from the laser articulated arm: see the operator's manual of the laser system for the description of the articulated arm;
- screw the articulated arm to the proper thread provided on the final part of the zoom of the micromanipulator EasySpot Hybrid (highlighted by the red arrow in Fig. 13).
- Connect the air flow tube to the other one on the system's articulated arm.

Fig.13 - Connection to the laser system



ATTENTION

Possible equipment damage

The operator is recommended to properly locate the laser system in order to avoid any mechanical stress on the articulated arm.

4.5. Operating area

The micromanipulator EasySpot Hybrid allows a very accurate mechanical adjustment of the operating area in order to guarantee that the laser beam remains inside the speculum or the laryngoscope, even if very small, or inside the operating area even if working using high magnifications.

To adjust the operating area dimension, unscrew the knob highlighted in Figure and rotate the cylinder placed at the joystick base moving the knob clockwise (to increase the dimension) or counterclockwise (to decrease the dimension). Once found the right adjustment, screw back the knob.



Fig.14 - Mechanical adjustment of the operating area

4.6. Focusing the laser beam

This operation has to be done the first time on the operating microscope or colposcope; once done, at a given focus length (e.g., in ENT 400mm for laryngeal surgery and 300mm for middle ear surgery), the block knob will prevent any other regulation in the future.

The beam has to be focused at the microscope maximum magnification.

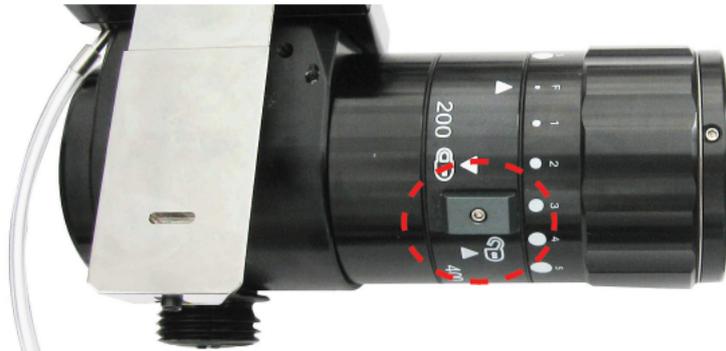
Proceed as follows:

1. turn on the laser system;
2. set the micro-colposcope at the maximum magnification;
3. Before moving the retainer to focus the laser beam, the focusing ring has to be up to the beat (that is the line has to match the "F" label, see the figure alongside).
4. loosen the focus block by moving the retainer towards the "open padlock" icon;



INSTALLATION AND USE

Fig.15 - Focus block retainer



5. focus the laser beam;
6. move the retainer towards the "closed padlock" icon.

NOTE

- The aiming beam focus is the same as the CO₂ laser beam focus; anyway, it is recommended to achieve a fine tuning of the CO₂ laser focus emitting single pulses on a target like a wooden tongue depressor or alumina.
- The labels of the focal distances marked on the micromanipulator show approximately the position to get that focal length because, according to the type of microscope, it may be a little bit distant from the point shown by the label.

Two different procedures to focus the laser beam are described.



CAUTION

Possible risk for patient/operator

- **Wear safety goggles!**
- **Place the target (alumina surface or tongue depressor) where there is no risk to expose people to laser radiation.**

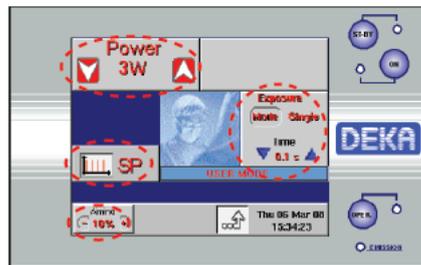
Fig.16 - Laser parameters (SmartXide²)

Procedure 1: focusing on a tongue depressor

- Attach the micromanipulator (with the scanner, if provided) onto the micro-colposcope;
- Turn ON the laser system and select 3W power value (increase to 6W, if necessary), UP emission mode (for SmartXide² systems), SP emission mode (for all other SmartXide systems) and a time of 0.1s. Set the aiming beam intensity at 10%.
- Set the micro-colposcope at the maximum magnification.
- Place the tongue depressor at a distance corresponding to the microscope working focal length.
- Make sure that the focusing ring is at the mechanical stop (the white arrow has to match the "F" label).
- Move the retainer towards the "open padlock" icon.
- **Preliminary focalization:** looking through the microscope, focus the red aiming beam by turning the focusing ring.



- **Fine focalization:** press ON and OPERATE keys and, turning slightly the focusing ring clockwise or counterclockwise, perform single pulses on the tongue depressor (better if slightly moist) and try to find the CO₂ minimum spot.
- Once focused, move the retainer towards the "closed padlock" icon. In this condition, rotating the focusing ring, you obtain defocused spots.



Be advised that in UP mode, the focused laser produces a typical "buzz" sound on the target. This is a very important feedback for the proper focalization during the surgical procedure.



DEFOCUSED LASER BEAM



FOCUSED LASER BEAM

Procedure 2: focusing on an alumina surface

A very good method to focus the laser beam is to use an alumina (Al₂O₃) surface (shown in Fig. 19 and provided with EasySpot Hybrid) as target: in fact the alumina becomes luminescent when hit by a focused laser beam.



- Attach the micromanipulator (with the scanner, if provided) onto the micro-colposcope;
- Turn ON the laser system and select 3W power value (increase to 6W, if necessary), UP emission mode (for SmartXide² systems), SP emission mode (for all other SmartXide systems) and continuous exposure mode. Set the aiming beam intensity at 10%.
- Set the micro-colposcope at the maximum magnification.
- Place the alumina surface at a distance corresponding to the microscope working focal length.
- Make sure that the focusing ring is at the mechanical stop (the white arrow has to match the "F" label).
- Move the retainer towards the "open padlock" icon.
- **Preliminary focalization:** looking through the microscope, focus the red aiming beam by turning the focusing ring

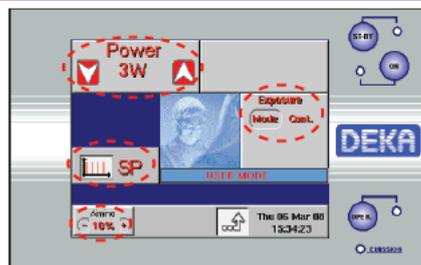


Fig.17 - Laser parameters (SmartXide systems)

Fig.18 - Focusing on a tongue depressor

Fig.19 - Alumina surface

Fig.20 - Laser parameters (SmartXide²)

Fig.21 - Laser parameters (SmartXide systems)

INSTALLATION AND USE

Fig.22 - Focusing the laser beam on alumina

- **Fine focalization:** press ON and OPERATE keys and, keeping the footswitch pressed, emit on the alumina turning slightly the focusing ring clockwise or counterclockwise. Go on until the red aiming beam disappears and the maximum luminescence shows up (if necessary, increase the selected power level up to 5W).
- Once focused, move the retainer towards the "closed padlock" icon. In this condition, rotating the focusing ring you obtain defocused spots.

Be advised that in UP mode, the focused laser produces a typical "buzz" sound on the target. This is a very important feedback for the proper focalization during the surgical procedure.



DEFOCUSED LASER BEAM
(you see only the aiming beam)



FOCUSED LASER BEAM

NOTE

- It is important to perform this procedure using low power values in order to identify the point of luminescence.
- Once the laser beam is focalized on the alumina surface, it is suggested to get confirmation on proper focalization on a tongue depressor (see procedure above).

ATTENTION!

The focal length of the microscope and the focus point of the laser has to be the same.

If microscopes with fixed focal length are used, just focus the laser on the working distance of the lens used.

If variable focus microscopes are used, once focused the laser on the working distance chosen (i.e. 400mm for laryngeal surgery), the microscope focal length has not to be changed (use the focus freezing option if available on the microscope, or don't touch the focus keys).

ATTENTION!

If the operator does not require corrective lenses or if the operator is wearing corrective lenses, set the eyepieces to zero.

If the operator requires visual correction and is not wearing corrective lenses, set the eyepieces to the operator's eye refraction, not to affect the working distance.

Do not use the eyepieces to focus the microscope.

Changing the working distance without focusing again the laser will cause the laser itself not to be effective, having the spot defocused.

INSTALLATION AND USE

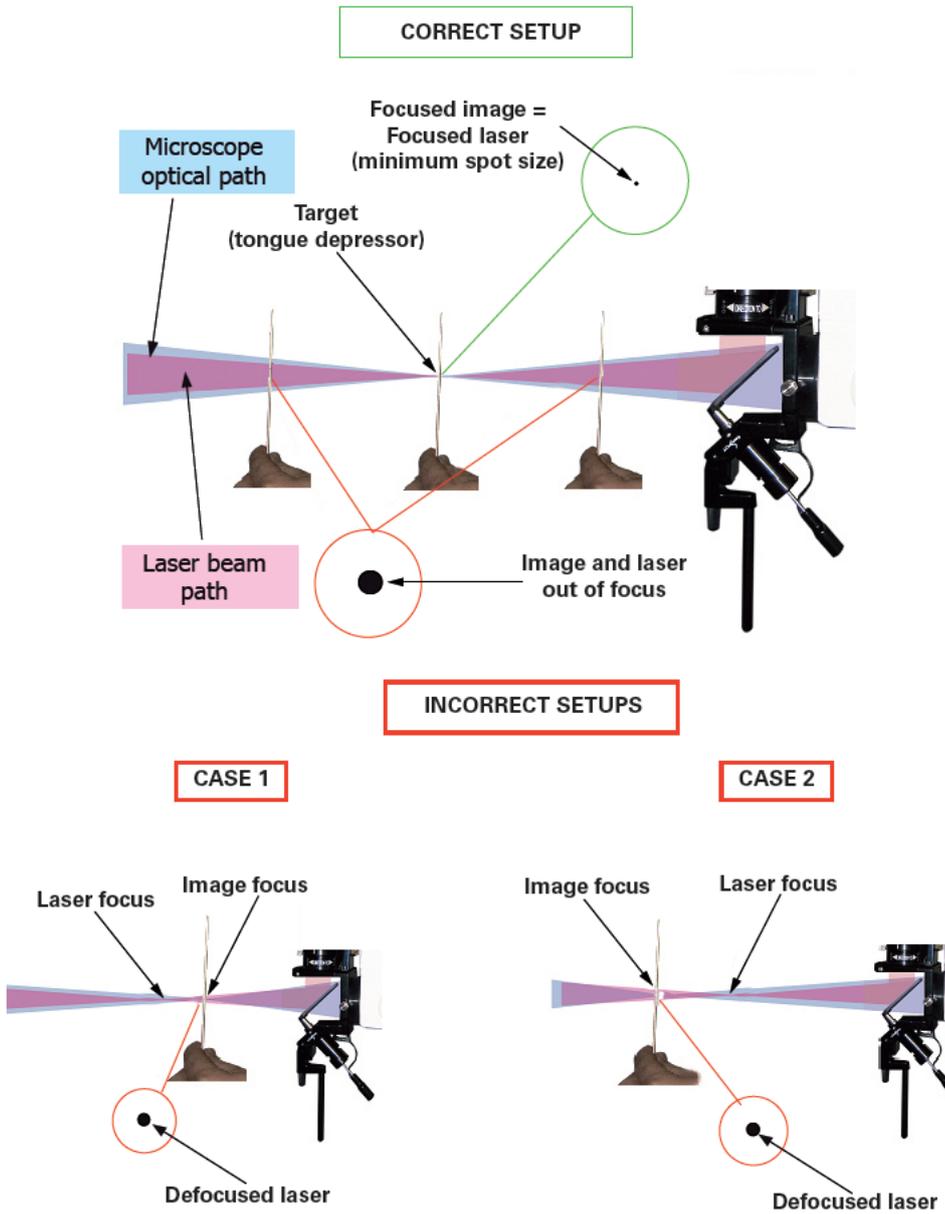


Fig.23 - Focusing the laser beam

INSTALLATION AND USE

4.7. Defocusing the laser beam

Once focused, the laser beam can be defocused for applications in coagulation and vaporization. If the procedure described in previous paragraph has been properly performed, use the focusing ring which can be rotated in only one direction to defocus the laser beam.

4.8. Laser beam centering

This adjustment allows to perform a fine tuning of the laser beam centering, if necessary. It doesn't take the place of the alignment procedure of the articulated arm but it just helps when little adjustments are needed before treatment, in order to enter perfectly the most critical accessories like micromanipulators or laparoscopes.

Before starting the surgical procedure the user has the responsibility to check the coaxiality between the red aiming beam and CO₂ beam and the correct delivery of laser radiation. In microsurgery procedures this check has to be performed through the microscope and the micromanipulator at the system's working setup; the user has not to change it after this operation during the surgical procedure.

- **Wear the safety goggles!**
- Attach the micromanipulator together with the scanner onto the micro-colposcope head and connect the assembly to the laser system.
- Turn ON the laser system.
- Check if the CO₂ beam spot and the aiming beam spot match (that is if they overlap).
 - If the two spots match, it is not necessary to perform this centering procedure.



OK

- If the two spots do not match or if the aiming beam produces clearly irregular shapes



KO



KO

proceed as follows:

- **For SmartXide² systems:** Press the "Settings" option in the "HiScan Surgical"/"EndoScan" user menu: the system will display the "Centering correction" area.

• **For all other SmartXide systems:**

Press the  key in the preliminary menu to enter the Setup menu, then press the "Center" area.

IMPORTANT: the green dots in the "Centering correction" area are not the absolute reference for centering (so they don't need to be always on the intersection of the axes to center the laser beam!) but they display just the amount of centering correction performed on the galvanometers.

- Control the motion of the laser beam along the two axes by the arrow keys in the "Centering correction" screen, by the remote command on the micromanipulator joystick or by the keys on the scanning head.

Press the central key of the remote command to select the horizontal or the vertical axes (a sound confirms the selection); then move right-left (yellow arrows in figure) to move the beam along the selected axis.

- In order to check the accuracy of centering, the system allows to switch on the laser source and perform a laser emission on a target surface using preset parameters (UP, 5W).

This operation can be done with the steady point or with the full circle pattern. To switch between the two modes, press the area highlighted in Fig.24.

- The centering can be checked looking at the gold-plated spot in the center of the final mirror.



Fig.24 - "Centering" option (SmartXide²)

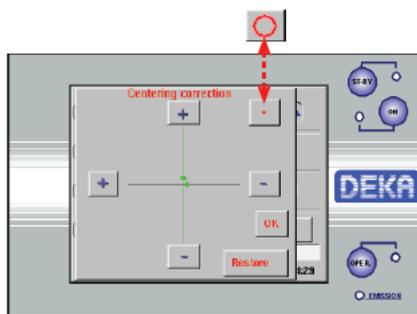


Fig.25 - Centering option (SmartXide systems)



Fig.26 - Joystick



Fig.27 - Laser beam centering on the final mirror

INSTALLATION AND USE

NOTE

- Please, be sure that the joystick is in the central position.
- The real position of the two axes on the final mirror depends on the position of the scanner on the system; for this reason, the laser beam movement and the direction of the key pressure on the remote command or on the "Centering correction" screen can be even in opposite directions.
- After laser beam centering, perform a pulse on a tongue depressor to check the result, then press the  icon (SmartXide² systems) or the "OK" key (SmartXide systems) in the "Centering correction" area to confirm.

4.9. Connection to the scanning unit

Proceed as follows to connect the scanning unit (both HiScan Surgical and Endoscan) to the micromanipulator. The procedure is the same for both the scanning units; we'll show, as an example, the connection to HiScan Surgical.

1. Connect the cable provided with the scanning unit to both the units as shown in the Figure below.



Fig.28 - Connection of the scanning unit

2. Screw the scanning unit to the micromanipulator.
3. If you want that the scanning with the "hexagon" shape is performed horizontally from top to bottom, perform an emission on a tongue depressor selecting this shape. If not, connect the two units in a slightly different position using two other grooves of the scanning unit connector until you have the "right" scanning.

Fig.29 - Scanning unit connector



5. MAINTENANCE

5.1. Inspecting, cleaning and disinfecting the micromanipulator

Before and after each use, inspect the micromanipulator for dirt or damages.

Failure to clean or improperly cleaning of the micromanipulator can cause damage to the optics and adversely alter the efficiency of the system.

- **Always disconnect the micromanipulator from the laser system before inspection/cleaning/disinfecting.**
- Do not touch any optical lens with your fingers because this may damage the delicate coatings.
- To clean and disinfect the external surface of the micromanipulator, use a cloth dampened with a hospital grade disinfectant or with methyl, ethyl or isopropyl alcohol.
- Dry with a clean cloth.
- Do not use the micromanipulator until its surface is completely dry that is: the disinfectant solution is fully evaporated.

Damage could occur if the disinfectant comes into contact with internal optics: therefore do not spray or pour the disinfectant directly on the micromanipulator.

ATTENTION

Possible equipment damage

5.2. Cleaning the lens

The final mirror and the lens need periodic cleaning.

For the lens, follow the procedure below.

- Soak several cotton-dipped applicators in distilled water and wrap each applicator in lens tissue;
- gently wipe the lens with circular movements from the center outwards;
- repeat the first steps except soak the wrapped applicators in reagent grade solution provided with the optics cleaning kit (see the Section "Accessories").

Do not use any solutions other than the one specified.

- if the lens is still not clean, repeat the cleaning procedure using new, clean applicators.
- Do not use the micromanipulator until the cleaning solution is fully evaporated.
- If the lens is still dirty or appears damaged, contact the DEKA Technical Assistance Service.

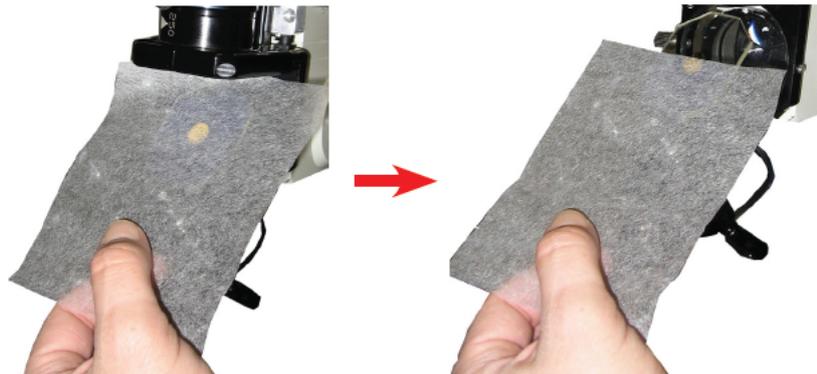
MAINTENANCE

5.3. Final mirror cleaning

If the final mirror appears dirty, clean as instructed below:

- Place a sheet of lens tissue-professional optical quality (Kodak® or equivalent) on top of the mirror so that one side of the tissue is positioned off-center on the mirror itself and one side is hanging over the edge. Leave enough tissue overhanging on the other side of the mirror to allow you to grasp the paper with your fingers when it is time to drag;
- Put one or two drops of the reagent grade solution provided with the optics cleaning kit (see the Section "Accessories") just enough to cover the mirror, on the section of the paper that rests on the mirror;
- Grasp the edge of the lens tissue and pull the tissue across the mirror surface so that the wet lens is replaced by a dry section of the lens tissue as it is "dragged" across (Figure below, right side);
- Repeat the previous two steps until the mirror is clean. Use a clean sheet of lens tissue for each "drag";
- Clean the other side of the mirror following the same procedure.

Fig.30 - Cleaning the final mirror



5.4. Sterilization

The micromanipulator EasySpot Hybrid is a precision instrument which contains delicate optical components and should be handled with care at all times. For this reason, avoid sterilization procedures. However, if sterility is required, cover the micromanipulator and microscope with sterile drapes as indicated in par. 4.3.

5.5. Final mirror replacement

If the final mirror is damaged, just unscrew the screw highlighted as **(A)** in Fig.31 to remove it and screw the new mirror.

The correct mounting of the mirror is forced by the presence of a lock-pin on the mirror holder arm, that has to fit in the hole of the final mirror base.

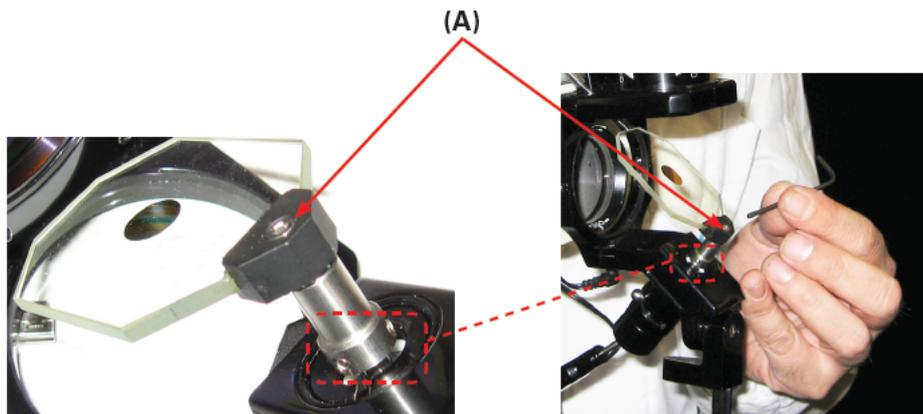


Fig.31 - Final mirror replacement

Never touch the micro-grain which allows a fine centering correction and which are placed at the bottom of the mirror-holder arm (see the enlarged detail in Fig.31).

If evident problems in the mirror alignment are noticed, please contact the technical assistance service.

TROUBLESHOOTING

6. TROUBLESHOOTING

The next table provides a troubleshooting of some problems that can be identified and solved by the operator.

If your problem is not listed below or if none of the suggestions resolve your problem, please contact the DEKA M.E.L.A. s.r.l. Technical Assistance Service.

Problem	Probable cause	Suggestion
Inadequate or no aiming beam	<ul style="list-style-type: none"> The aiming beam is on low intensity setting. 	<ul style="list-style-type: none"> Enter the system Set Up and adjust the aiming beam intensity.
	<ul style="list-style-type: none"> The accessory is not installed correctly on the articulated arm. 	<ul style="list-style-type: none"> Check connections and correct if indicated.
	<ul style="list-style-type: none"> The laser system articulated arm is out of alignment. 	<ul style="list-style-type: none"> Contact the Technical Assistance Service.
	<ul style="list-style-type: none"> The scanner unit (if present) is not centered. 	<ul style="list-style-type: none"> Perform the centering procedure as indicated in the laser system Operator's Manual.
Uneven burn spots	<ul style="list-style-type: none"> The final mirror or the zoom lenses are dirty. 	<ul style="list-style-type: none"> Inspect and if necessary clean the final mirror or the lenses as instructed in Chapter 4.
	<ul style="list-style-type: none"> The scanner unit (if present) is not centered. 	<ul style="list-style-type: none"> Perform the centering procedure as indicated in the laser system Operator's Manual.
	<ul style="list-style-type: none"> The laser system articulated arm is out of alignment. 	<ul style="list-style-type: none"> Contact the Technical Assistance Service.
Beam size abnormally large	<ul style="list-style-type: none"> The focusing ring is not set to focus position. 	<ul style="list-style-type: none"> Check the position of the focusing ring and ensure it is set in focus position.
	<ul style="list-style-type: none"> The focal distance on the micromanipulator does not match the focal distance of the microscope objective lens. 	<ul style="list-style-type: none"> Ensure that the focal distance on the micromanipulator matches the focal distance of the microscope objective lens: see par. 4.6.

Table 4 - Troubleshooting



TROUBLESHOOTING

Problem	Probable cause	Suggestion
Beam size abnormally large	<ul style="list-style-type: none"> The micromanipulator is not perpendicular to the intended target. 	<ul style="list-style-type: none"> Ensure that the micromanipulator is correctly mounted on the microscope and that the beam is perpendicular to the intended target.
	<ul style="list-style-type: none"> The microscope is not focused correctly. 	<ul style="list-style-type: none"> Check the focus of the microscope and correct it if necessary.
	<ul style="list-style-type: none"> Microscope eyepieces are not properly set for the operator's refractive error. 	<ul style="list-style-type: none"> Set the microscope eyepieces to the operator's refractive error.
Laser effect on tissue appears other than expected	<ul style="list-style-type: none"> The treatment parameters settings (power, frequency, etc.) are inappropriate for the intended application. 	<ul style="list-style-type: none"> Ensure that the treatment parameters settings are appropriate for the intended application.
	<ul style="list-style-type: none"> The focusing ring is not set to focus position. 	<ul style="list-style-type: none"> Check the position of the focusing ring and ensure it is set in focus position.
	<ul style="list-style-type: none"> The focal distance on the micromanipulator does not match the focal distance of the microscope objective lens. 	<ul style="list-style-type: none"> Ensure that the focal distance on the micromanipulator matches the focal distance of the microscope objective lens: see par. 4.6.
	<ul style="list-style-type: none"> The microscope is not focused correctly. 	<ul style="list-style-type: none"> Check the focus of the microscope and correct it if necessary.
	<ul style="list-style-type: none"> Microscope eyepieces are not properly set for the operator's refractive error. 	<ul style="list-style-type: none"> Set the microscope eyepieces to the operator's refractive error.
	<ul style="list-style-type: none"> The final mirror or the zoom lens are dirty. 	<ul style="list-style-type: none"> Inspect and if necessary clean the final mirror or the lenses as instructed in Chapter 4.
	<ul style="list-style-type: none"> The scanner unit (if present) is not centered. 	<ul style="list-style-type: none"> Perform the centering procedure as indicated in the system Operator's Manual.

TROUBLESHOOTING

Problem	Probable cause	Suggestion
Appearance of two beam spots	<ul style="list-style-type: none"> • Microscope eyepieces are not distanced appropriately for the operator's eyes. 	<ul style="list-style-type: none"> • Adjust the microscope eyepieces distance appropriately for the operator's eyes.
	<ul style="list-style-type: none"> • The scanner unit (if present) is not centered. 	<ul style="list-style-type: none"> • Perform the centering procedure as indicated in the system Operator's Manual.
	<ul style="list-style-type: none"> • The laser system articulated arm is out of alignment. 	<ul style="list-style-type: none"> • Contact the Technical Assistance Service.
The CO₂ spot does not match the aiming spot	<ul style="list-style-type: none"> • The aiming beam is out of alignment. 	<ul style="list-style-type: none"> • Contact the Technical Assistance Service.
A secondary satellite burn appears near the treatment burn	<ul style="list-style-type: none"> • The laser system articulated arm is out of alignment. 	<ul style="list-style-type: none"> • Contact the Technical Assistance Service.
	<ul style="list-style-type: none"> • The scanner unit (if present) is not centered. 	<ul style="list-style-type: none"> • Perform the centering procedure as indicated in the system Operator's Manual.



ACCESSORIES

7. ACCESSORIES

The EasySpot Hybrid system is provided with the accessories listed in the table below:

Name	Code	Quantity
Remote control	N64501	Provided with scanning unit
1.5 Allen wrench	041100063	1
2 Allen wrench	041100064	1
2.5 Allen wrench	041100067	1
3 Allen wrench	041100083	1
1.25 Allen wrench	041100101	1
Alumina	N69301	1
Optics cleaning kit <i>including</i> cotton-tipped applicators (100 pieces) Kodak optical paper (100 sheets) reagent grade solution (code: 030400030)	F22701	1
Case	070400112	1
Operator's Manual	ON186F1U_G.V04	1

Table 5 - Accessories



FDA CDRH DMC

MAR 28 2014

Received

K133895/S001

March 25, 2014

To:

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

REF : K133895 Response to RTA Checklist

Dear Sir/Madam:

We have just received a RTA Checklist, dated January 2, 2014 from Sankar Basu, lead reviewer of the afore mentioned 510(k) notification.

Please find attached in duplicate (1 eCopy and 1 paper copy) the response from El.En., addressing the elements identified as missing or inconsistent.

The eCopy is an exact duplicate of the paper copy.

Sincerely,



Paolo Peruzzi
Regulatory Affairs Manager & Official Correspondent
p.peruzzi@elen.it

El.En. S.p.A.
Via Baldanzese, 17
50041 Calenzano (FI)
Italy

RESPONSE FROM EL.EN. TO K133895 RTA CHECKLIST

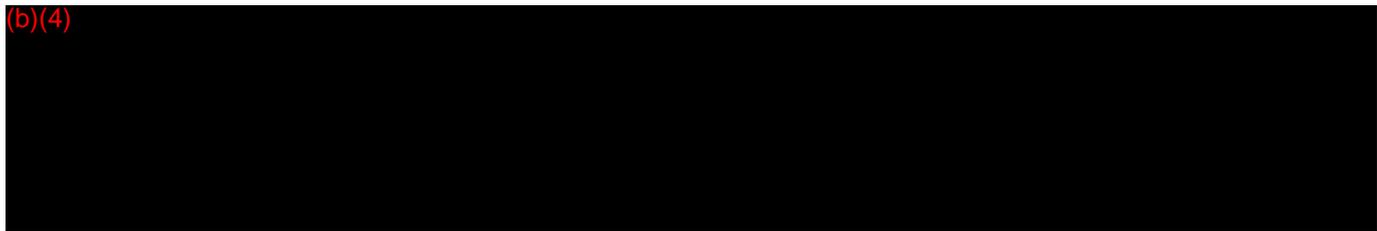
Item 1 of RTA Checklist

(b)(4)



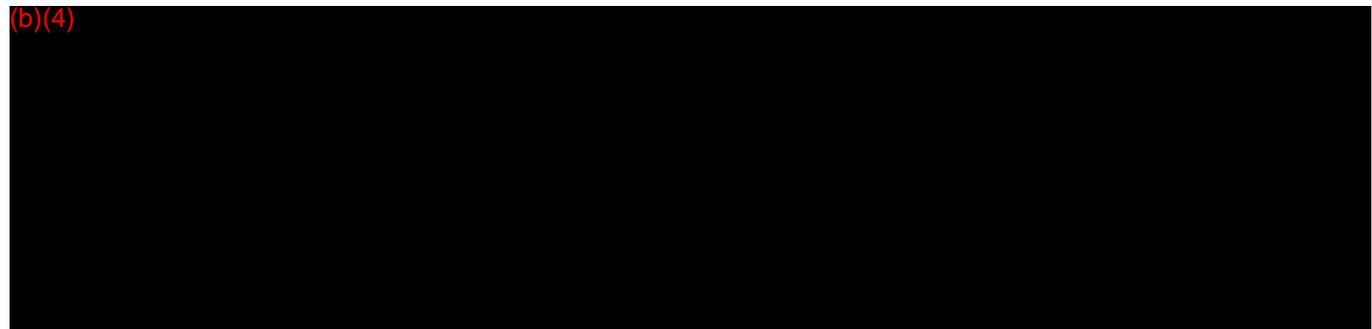
Response from El.En.:

(b)(4)



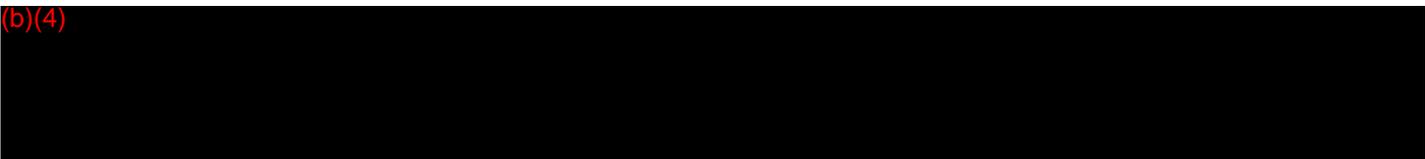
Item 2 of RTA Checklist

(b)(4)



Response from El.En.:

(b)(4)



Attachments:

Attachment A: Standards Data Report IEC 60601-1, IEC 60601-1-2

ATTACHMENT A

STANDARD DATA REPORTS

4 PAGES

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 <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ ANSI/AAMI ES 60601-1 :2005 Medical electrical Equipment - General requirements for basic safety and essential performance		
Please answer the following questions Yes No		
Is this standard recognized by FDA ² ?		<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³		#5-71
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
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 ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
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.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard?..... If yes, was the guidance document followed in preparation of this 510k?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____		
<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>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</p>	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. <p>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</p> <p>⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</p>	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
<p>* 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.</p> <p>♦ 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.</p>		
Paperwork Reduction Act Statement		
<p>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:</p> <p style="margin-left: 40px;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> <p style="margin-left: 40px;"><i>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.</i></p>		

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

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

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-1-2 Medical electrical equipment - Electromagnetic compatibility - Requirements and tests (Ed. 3:2007)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #5-53

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

Title of guidance: _____

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

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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

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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 SUMMARY REPORT TABLE		
STANDARD TITLE		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * [†]		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * [†]		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * [†]		
DESCRIPTION		
JUSTIFICATION		
<p>* 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.</p> <p>[†] 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.</p>		
Paperwork Reduction Act Statement		
<p>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:</p> <p style="margin-left: 40px;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> <p style="margin-left: 40px;"><i>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.</i></p>		

August 4, 2014

K133895/S002

To:

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

FDA CDRH DMC

AUG 06 2014

Received

**RE : K133895 - DEKA SMARTXIDE²
Additional Information**

Dear Sir/Madam,

as requested by Dr. Sankar Basu of CDRH/ODE in his email dated May 28, 2014, please find attached in duplicate (1 paper copy and 1 eCopy) the requested Additional Information for the afore-mentioned 510(k) notification.

The eCopy is an exact duplicate of the paper copy.

Sincerely,



Paolo Peruzzi

Regulatory Affairs Manager & Official Correspondent

El.En. S.p.A.

Via Baldanzese, 17

50041 Calenzano (FI)

ITALY

Phone: +39-055-882-6807

Fax: +39-055-883-2884

E-mail: p.peruzzi@elen.it

1-00

480

EL.EN. SPA

DEKA SMARTXIDE²

510(K) PREMARKET NOTIFICATION

K133895

RESPONSE TO 1ST REQUEST OF ADDITIONAL INFORMATION

**El.En. SpA
Via Baldanzese, 17
Calenzano (FI)
Italy 50041**

TABLE OF CONTENTS

ITEM 1 – DEVICE DESCRIPTION 3
ITEM 2 – STERILIZATION 4
ITEM 3 – SOFTWARE 5
ITEM 4 – SCANNING PARAMETERS FOR ABLATIVE SKIN RESURFACING..... 6
ITEM 5 – SAFETY AND EFFICACY DATA..... 7
ITEM 6 – TREATMENT GUIDELINES 8

ATTACHMENTS:

- ATTACHMENT A: Device Description (13 pages)
- ATTACHMENT B: Software Documentation (246 pages)
- ATTACHMENT C: Performance Data Report (14 pages)
- ATTACHMENT D: Treatment Guidelines (4 pages)

ITEM 1 – DEVICE DESCRIPTION

Records processed under FOIA Request # 2015-4016; Released by CDRH on 09-29-2015

FDA Question Q1 (from FDA email dated May 28, 2014)

(b)(4)



El.En. Answer to Q1 – August 4, 2014

(b)(4)

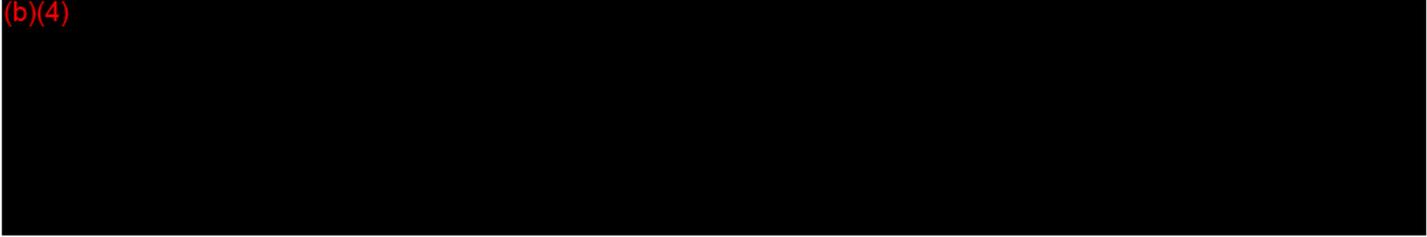


ITEM 2 – STERILIZATION

Records processed under FOIA Request # 2015-4016; Released by CDRH on 09-29-2015

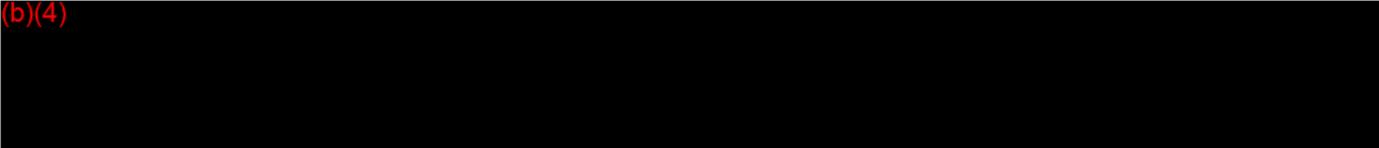
FDA Question Q2 (from FDA email dated May 28, 2014)

(b)(4)

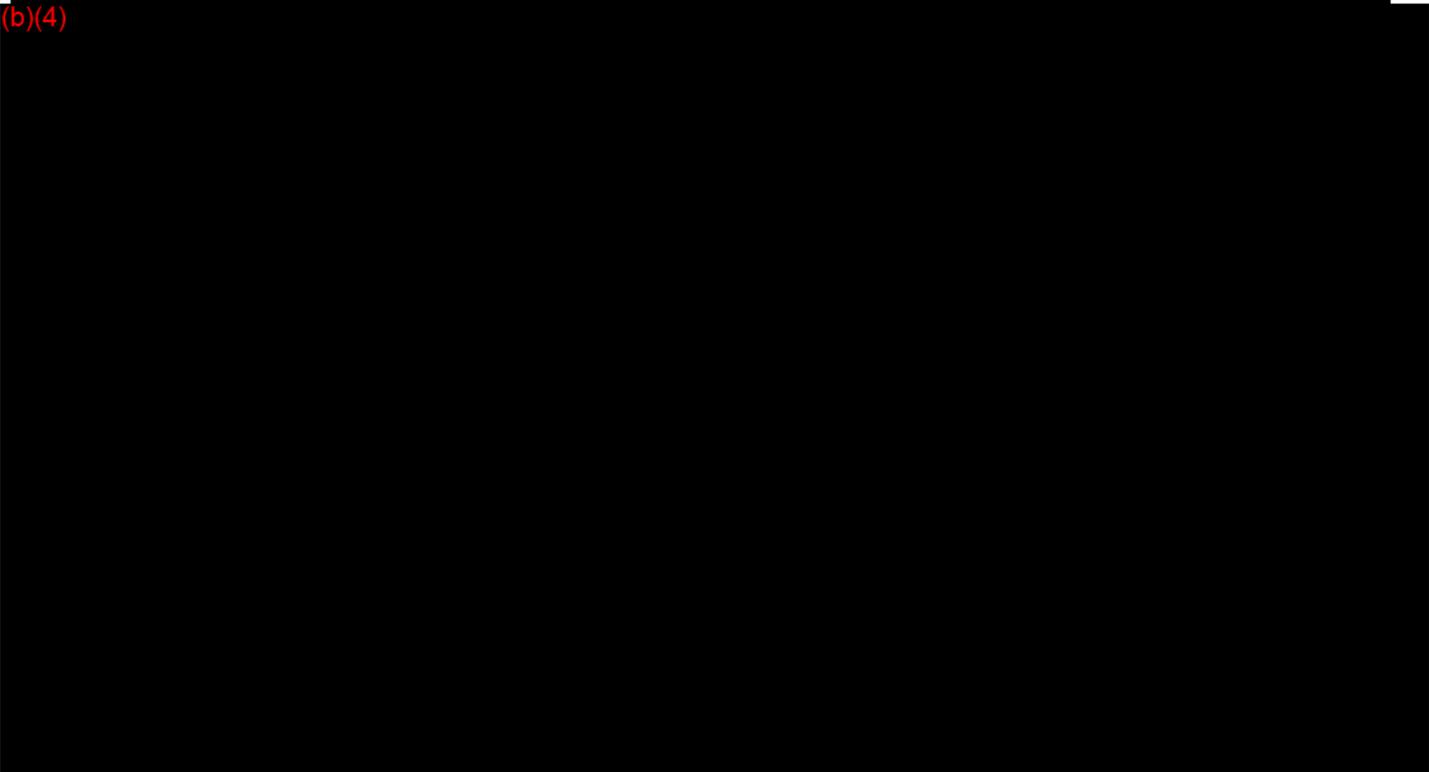
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El.En. Answer to Q2 – August 4, 2014

(b)(4)

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(b)(4)

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ITEM 3 – SOFTWARE

FDA Question Q.3 (from FDA email dated May 28, 2014)

(b)(4)



El.En. Answer to Q3 – August 4, 2014

(b)(4)



ITEM 4 – SCANNING PARAMETERS FOR ABLATIVE SKIN RESURFACING

FDA Question Q.4 (from FDA email dated May 28, 2014)

(b)(4)



El.En. Answer to Q4 – August 4, 2014

(b)(4)



FDA Question Q.5 (from FDA email dated May 28, 2014)

(b)(4)



El.En. Answer to Q5 – August 4, 2014

(b)(4)



ITEM 6 – TREATMENT GUIDELINES

FDA Question Q.6 (from FDA email dated May 28, 2014)

(b)(4)

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El.En. Answer to Q6 – August 4, 2014

(b)(4)

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ATTACHMENT A

DEVICE DESCRIPTION

13 PAGES

Device Description

1. The SmartXide² system

The SmartXide² family consists in 10,600nm carbon dioxide laser (CO₂) lasers with 60W of maximum power.

The wavelength of these lasers is 10.600nm. As scientifically entirely known, this wavelength is mostly absorbed by water; this characteristic makes these lasers particularly suitable for soft tissue surgery.

CO₂ laser surgery is well recognized to be miniminvasive and highly effective, as proven by the hundreds of scientific articles written on this kind of laser in surgery and microsurgery of various disciplines and districts for more than 20 years.

It's well known and scientifically proved, that transmitting heat to the organic tissues while cutting or destroying them guarantees hemostasis. In fact, an adequate amount of heat, causing the tissue to reach temperatures between 60°C and 100°C, generates in the tissue coagulative processes.

Several surgical techniques (electrosurgery, radiosurgery, ultrasound surgery, lasersurgery) coagulate thanks to heat generation in the tissues due to different kind of energies. Nevertheless the thermal damage due to this tissue heating, when excessive, causes delays and problems during the reparative processes, with not optimal aesthetic-functional results, specially on very delicate anatomic districts.

Maximum lateral thermal damage of CO₂ laser, even if used in the continuous mode (the most "thermal" modality of emission), doesn't reach 200-300µm: it's a lot lower compared to that of electrosurgery, but guarantees anyway, during cutting or vaporization of tissues, hemostasis and linfostasis of small vessels (less than 5mm of diameter).

CO₂ laser respects therefore the qualities of miniminvasive surgery: reduced postoperative oedema and pain, fast, plane and less evident cicatrisation, containment of the adherencial phenomenons and of the diffusion of cancerous cells in neoplastic surgery.

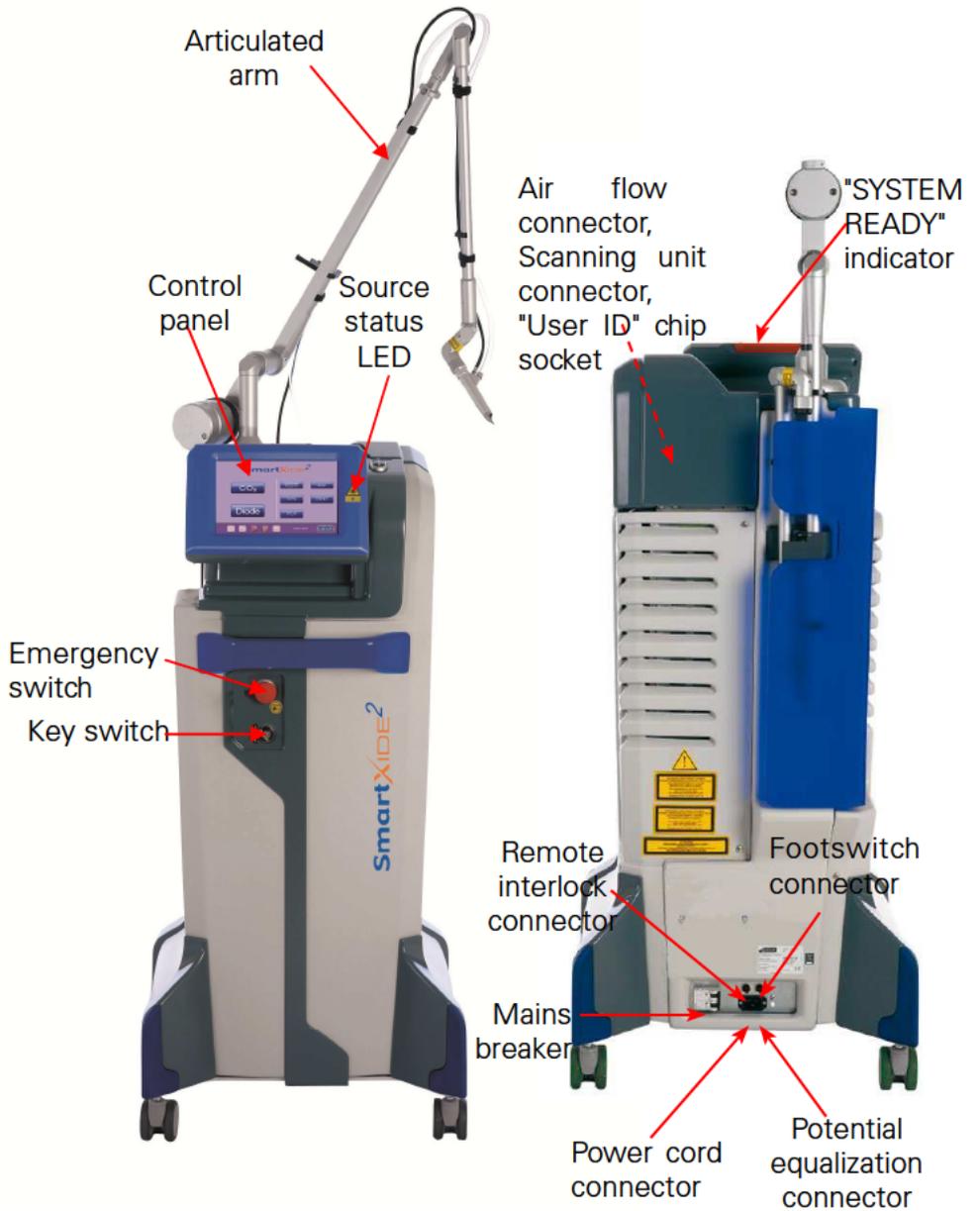
Moreover, the remarkable temporal thermal rising of the treated part and the absence of contact, guarantee an effective aseptic action.



Device Description

Fig.1 - System's main external components

The operator interacts directly with the following external portions of the system.



Device Description

The overall weight is approximately 95 kg and the size is 210x59x56 cm (HxWxD). Electrical requirements: 100-120V~ 50/60Hz 220-230V~ 50Hz, 16 A delayed.

The CO₂ laser radiation is delivered to the treatment area through the handpieces or the scanning units.

A wide range of handpieces can be provided with the SmartXide² system, having different spot sizes and high performances in specific application field. The system can be provided with a handpiece body which can house different lens assemblies (1.5", 2", 4", 7" and collimated), with a 5" handpiece and a 8" handpiece.



Fig.2 - Laser handpiece

The handpiece is attached to the distal end of the articulated arm.

The articulated arm is an optical assembly that delivers beam laser radiation. It is made up of seven mirrors placed on rotating knuckles: the mechanical accuracy of the articulated arm allows the CO₂ laser beam to travel inside it and along its axis however the arm is oriented.

The field of action of the articulated arm covers a radius of approximately 80 cm, the transfer efficiency of power is greater than 85%. The loss of 15% is balanced by a suitable calibration of the internal power meter. An air flow is provided by an internal pump in order to avoid dust and particles deposition on the optics during laser operations.

It is also possible to connect the handpiece to an external smoke evacuator via a flexible hose.

Device Description

Fig.3 - HiScan DOT



HiScan DOT is indicated for layer- by-layer ablation with char-free, enhancing the safety of the treatment with more uniform, accurate and controllable impact such as ablative skin resurfacing.

Fig.4 - HiScan Surgical



The scanner technology can be used for surgical applications coupled with microspot micromanipulators for microsurgery applications in ENT, gynaecology and neurosurgery. This is done with a second scanner: the HiScan Surgical.

Fig.5 - EndoScan



Another scanner, a miniaturized one, the EndoScan, is connectable with the SmartXide² system. This scanning unit is suited mainly for gynecological application both in colposcopic and laparoscopic procedures, but also for other surgical applications in which quick ablation is needed.

Both these two last scanning units can be used together with Deka micromanipulator EasySpot Hybrid.

Easyspot Hybrid has a single ring nut rapid focalization system that allows to focalize the beam to the same focal length of the microscope and fix the position with a mechanical block. In this way the micromanipulator "remembers" the focus position, still allowing eventually the surgeon to defocus the beam from the same ring nut.

Device Description

Thanks to its joystick, it is possible to regulate the mechanical tension and the maximum work field in order to easily control and never "loose" the beam even inside small size laryngoscopes.

On top of the joystick Easyspot Hybrid can mount a remote control specially conceived to command top level scanning systems (HiScan Surgical).

It allows the surgeon to have under direct control the more useful electronic scanning functions (rotation and dimension of the figures, scan off-scan on, centering) without moving his eyes from the microscope.



Fig.6 - EasySpot Hybrid micromanipulator

CO₂ laser surgery does not require the contact with the patient. Spacers and terminals are just a reference for the exact working distance and focus point. Anyway, the only parts that could come in touch with intact skin or mucosa are the handpiece terminals and the scanning spacer.

Specifically, the materials they are made of are:

(b)(4)

Device Description

2. Emission main parameters

The emission parameters are selected on the front touch-screen panel located on the front side of the system.

The USER menu contains controls and displays for changing the system's operating parameters.

The two keys on the left allow the selection of the source type to be used: these keys make the operator enter the so called "User" mode as the operator himself has to select the emission characteristics (pulse number, pulse length, fluence) on his own experience.

The keys on the right allow to select the application and enter the related user-defined database.

If the HiScan DOT has been activated, the User menu changes as shown in Figure:

Fig.7 - HiScan DOT scanning menu



Device Description

If the HiScan Surgical has been activated, the User menu changes as shown in Figure:



Fig.8 - HiScan Surgical scanning menu

If the EndoScan has been activated, the User menu changes as shown in Figure:



Fig.9 - Endo Scan scanning menu

For a detailed description of each menu please refer to Op. Manual.

Device Description

Table 1 - System specifications

3. Technical specifications

Type	Value
Mains voltage	100-120V~ 50/60Hz 220-230V~ 50Hz
Absorbed electric power	1600 VA (max)
Circuit breaker	16A delayed
Electrical protection degree	 with HiScan DOT
Electrical protection type	I
Laser class	4
Use/Pause	Intermittent: use 1min, pause 3min

Table 2 - CO₂ laser source emission features

Type	Value	
Wavelength	10.6mm	
Maximum output power	60W	
Method of Optical Output	7-mirror articulated arm	
Output mode	TEM ₀₀	
Divergence of laser beam (full angle d ₆₃ - handpiece's output)	1.5" handpiece	70 mrad
	2" handpiece	52 mrad
	4" handpiece	26 mrad
	5" handpiece	20 mrad
	7" handpiece	12 mrad
	8" handpiece	11 mrad
	Collimated handpiece	3.2 mrad
Diameter of laser beam (d ₆₃ - handpiece's output)	1.5" handpiece	0.125 mm
	2" handpiece	0.155 mm
	4" handpiece	0.267 mm
	5" handpiece	0.325 mm
	7" handpiece	0.489 mm
	8" handpiece	0.530 mm
	Collimated handpiece	1.5 mm

Device Description

Power stability on 1 hour	≤20%
Nominal Ocular Hazard Distance (NOHD)	29m 100m (with collimated handpiece)
Emission	Controlled by footswitch
Aiming beam specifications	
Wavelength	635nm
Maximum output power (source output)	5mW
Output mode	Circular
Divergence (source output)	0.7mrad
Diameter (source output)	1.1mm
Laser class (source output)	3R
Relative position with CO ₂ source	Coaxial
Type	Value
Aiming Beam	Visible. Intensity selectable between OFF and 100%; step: 2% between OFF and 10%, step: 10% between 10% and 100%.
Operating modes	<ul style="list-style-type: none"> • CW mode: the average output power can be selected from 0.5W to 60W • UP mode: the average output power can be selected from 0.5W to 60W. • SP mode: the average output power can be selected from 0.1W to 15W; the frequency from 5Hz to 100Hz. • DP mode: the average output power can be selected from 0.2W to 15W; the frequency from 5Hz to 100Hz The selectable frequencies depend on the selected power value. • HP mode: the average output power can be selected from 0.1W to 8W; the frequency from 5Hz to 100Hz.

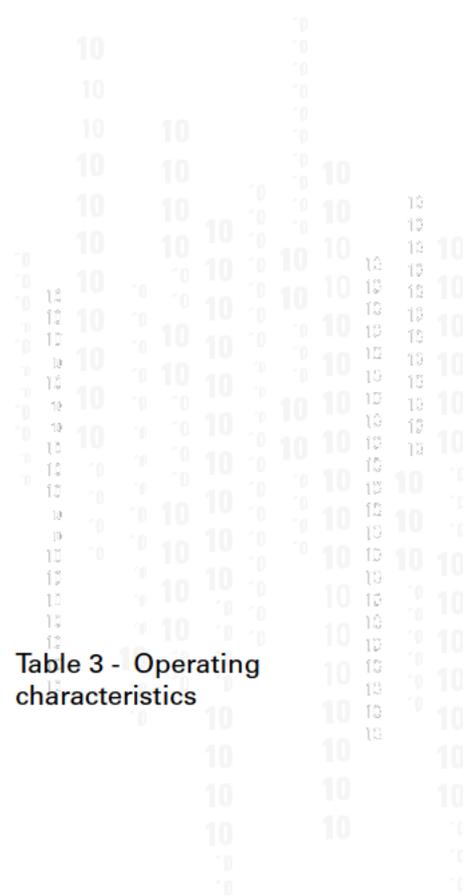


Table 3 - Operating characteristics



Device Description

Exposure modes

Continuous exposure mode or timed exposure mode.

The timed exposure mode allows both single exposure or repeated exposures. When timed exposure mode is selected, the exposure time can be selected between 0.01s and 0.9s.

When the repeated exposures mode is selected the "T.OFF" time can be modified from 0.3s to 5s.



Device Description

4. Accessories

SmartXide² is provided with the accessories listed in the following table:

Name	Code	Quantity
Interlock connector	N21901	1
Footswitch	E094B1 E06301 (optional)	1
System key	041400050	2
Mains cable	021300051	1
Safety labels	See Fig. 2	1 set
Door safety labels	079101200	2
Operator's Manual	See code on the cover	1
CO ₂ laser safety glasses for physician	070100047	2
Aiming beam protection eyewear	070100056	2
Laser safety eyewear for patient	070100054	1
Flexible hose for smoke evacuator	070500027	1
Smoke evacuator accessories kit	070500028	1
"USER ID" chip	iBM103U	1 2 for C80
Air filters	020601021	2
5mm Allen wrench	041100082	1
Accessories case	070400110	1
1.5" handpiece <i>including</i> 1.5" focal assembly Handpiece body Spacer Handpiece case	F26301 N76601 N77101 04370010A 070400108	optional
2" handpiece <i>including</i> 2" focal assembly Handpiece body Spacer Handpiece case	F26401 N76701 N77101 04370010A 070400108	optional

Table 4 - Accessories

Device Description

4" handpiece <i>including</i> 4" focal assembly Handpiece body Spacer Handpiece case	F26501 N76801 N77101 04370012A 070400108	optional
5" handpiece <i>including</i> 5" focal assembly Handpiece body Straight spacer Spacer with backstop 90° spacer 120° spacer	F28001 N77801 N78001 04370017A 04370018A 04370019A 04370020A	optional
7" handpiece <i>including</i> 7" focal assembly Handpiece body Spacer Handpiece case	F26601 N76901 N77101 04370012A 070400108	optional
8" handpiece <i>including</i> 8" focal assembly Handpiece body Straight spacer Spacer with backstop	F28101 N77901 N78401 04370022A 04370023A	optional
Collimated handpiece <i>including</i> Collimated focal assembly Handpiece body Spacer Handpiece case	F26701 N77001 N77101 04370012A 070400108	optional
HiScan DOT unit <i>including</i> HiScan DOT head HiScan DOT cable 90° Side firing handpiece with cylindrical body 90° side firing handpiece Straight handpiece	F34601 E109J1 N77601 N94601 N94701 N76001	optional
HiScan Surgical unit <i>including</i> HiScan Surgical head HiScan cable	F27001 E165A1 N74801	optional
EndoScan unit <i>including</i> EndoScan Cable	F26801 N77501 N74901	optional
Micromanipulator EasySpot Hybrid	N183F1	optional

Device Description

Name	Code	Quantity
2" dental handpiece for CO ₂ source <i>including</i> 120° aperture straight aperture	N377A1 N66601 04255025A	optional
4" dental handpiece for CO ₂ source <i>including</i> straight aperture open aperture 120° aperture 75° aperture ceramic tip	N324A2 N47701 04255022A N47601 N47501 040218013	optional
Endonasal probes kit 80mm <i>including</i> Handpiece for endonasal probes Hollow flexible waveguide 80mm Straight endonasal probe 80mm 90° endonasal probe 80mm 120° endonasal probe 80mm	F27901 N34601 N76501 04283016A 04283018A 04283020A	optional 1 2 2 2 2
Handpiece for endonasal probes	N34601	optional
Hollow flexible waveguide 80mm	N76501	optional
Hollow flexible waveguide 150mm	N765A1	optional
Straight endonasal probe 80mm	04283016A	optional
Straight endonasal probe 150mm	04283017A	optional
90° endonasal probe 80mm	04283018A	optional
90° endonasal probe 150mm	04283019A	optional
120° endonasal probe 80mm	04283020A	optional
120° endonasal probe 150mm	04283021A	optional
Accessories for laparoscopy: 400mm focal for laparoscope 300mm focal for laparoscope Direct coupler Connection for STORZ laparoscope*	N759A1 N75901 04366003A 04366004A	optional

Table 5 - Optional accessories

*For other laparoscope models, please ask to the laparoscope's Manufacturer or to DEKA.

For other accessories, please contact your DEKA dealer or DEKA directly.

ATTACHMENT B

SOFTWARE DOCUMENTATION

246 PAGES

	SOFTWARE DOCUMENTATION SMARTXIDE ²	Date: 23/04/2014 Rev: (b)(4)
(b)(4)		

SmartXIDE²

Software Documentation

	Name	Signature	Date
Issued by:	(b)(6)	(b)(6)	23/04/14
Checked by:			23/04/14
Approved by:			23/4/14

Revision history:

Rev.	Date	Brief change description
(b)(4)		

 (b)(4)	SOFTWARE DOCUMENTATION SMARTXIDE ²	Date: 23/04/2014 Rev (b)
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SOFTWARE DOCUMENTATION
SMARTXIDE²

Date: 23/04/2014

Rev. (b)

(b)(4)

INTRODUCTION

This document applies to the firmware resident in the microcontroller controlling the **SmartXide²**. This is the only operational software.

In the following the resident firmware will be equivalently called “firmware” or “software”.

The **SmartXide²** will be sometimes called “device” or “product”.

Applicable documents:

- U.S. Department of Health and Human Services, Food and Drug Administration: “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”, issued on May 11, 2005.



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SMARTXIDE²

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(b)(4)

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SUMMARY

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ENCLOSURE 2: SOFTWARE REQUIREMENTS SPECIFICATION

ENCLOSURE 3: SOFTWARE TECNICAL/FUNCTIONAL DESCRIPTION

ENCLOSURE 4: SOFTWARE DESIGN SPECIFICATION

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1 LEVEL OF CONCERN

1.1. LEVEL OF CONCERN STATEMENT

For the purpose of this submission El.En. believes that it is appropriate to classify SMARTXIDE² Software with **Moderate** Level of Concern.

1.2. SUMMARY OF DECISION RATIONALE

In accordance with section “Level of Concern” of the “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued May 11, 2005, El.En., provides the following tables summarizing the decision information:

Table 1

If the answer to any one question below is YES, the Level of Concern for the Software Device is likely to be Major.

1. <i>Question:</i> Does the Software Device qualify as Blood Establishment Computer Software? <i>Answer:</i> No.
2. <i>Question:</i> Is the Software Device intended to be used in combination with a drug or biologic? <i>Answer:</i> No.
3. <i>Question:</i> Is the Software Device an accessory to a medical device that has a Major Level of Concern? <i>Answer:</i> No.
4. <i>Question:</i> Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? <i>Examples of this include the following:</i> <ol style="list-style-type: none"> <li data-bbox="47 1675 1385 1825"> a. <i>Question:</i> Does the Software Device control a life supporting or life sustaining function? <i>Answer:</i> No. <li data-bbox="47 1825 1385 2000"> b. <i>Question:</i> Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators? <i>Answer:</i> No.

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c. <i>Question:</i> Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury? <i>Answer: No.</i>
d. <i>Question:</i> Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death? <i>Answer: No.</i>
e. <i>Question:</i> Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary? <i>Answer: No.</i>

Therefore, the Level of Concern is not Major.

Table 2

If the Software Device is not Major level of Concern and the answer to any one question below is YES, the Level of Concern is likely to be Moderate.

1. <i>Question:</i> Is the Software Device an accessory to a medical device that has a Moderate Level of Concern? <i>Answer: No.</i>
2. <i>Question:</i> Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device? <i>Answer: Yes.</i>
3. <i>Question:</i> Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury? <i>Answer: No.</i>

The answers to all of the questions in Table 1 are No, and an answer to a question in Table 2 is Yes, so the Level of Concern is **Moderate**.



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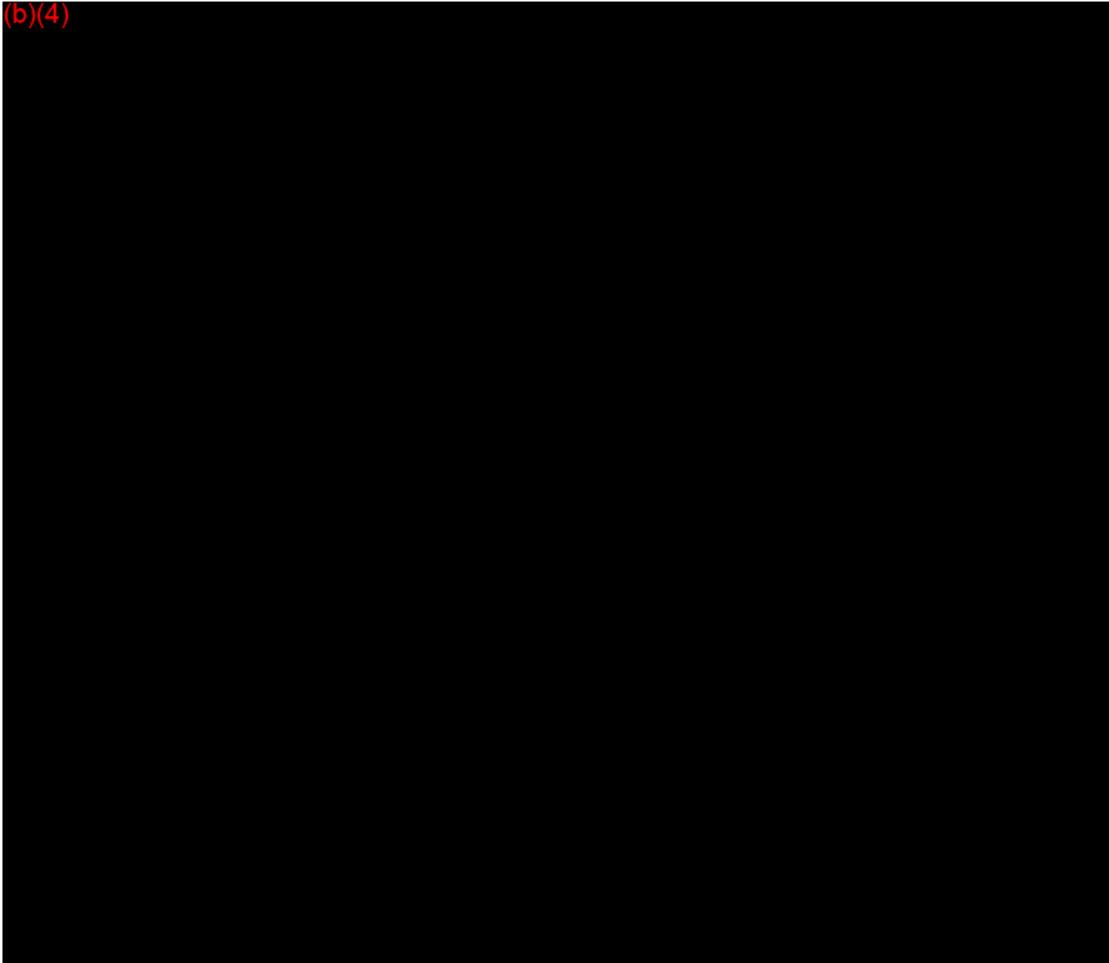
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2 SOFTWARE DESCRIPTION

This is an overview of the device features controlled by software. A more detailed description is included in the Software Requirements Specification, Architecture Design Chart and Software Design Specification.

Features Controlled By Software

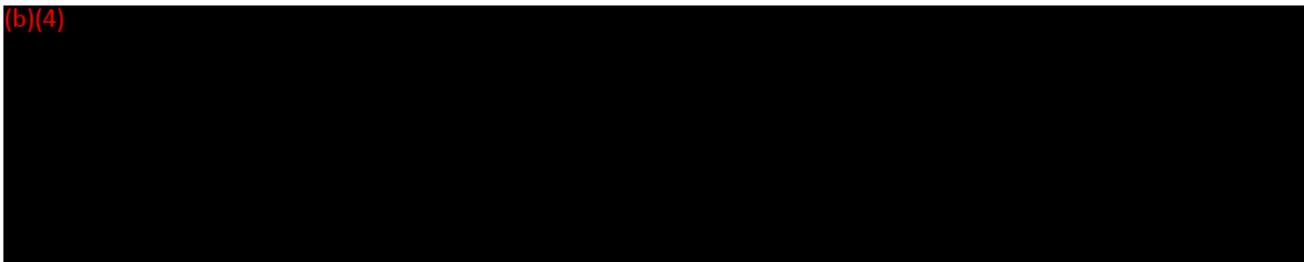
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h

Operational Environment

(b)(4)



Main user interactions:

(b)(4)





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3 DEVICE HAZARD ANALYSIS

For the device hazard analysis, see the Risk Management document (b)(4)

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4 SOFTWARE REQUIREMENTS SPECIFICATION

For software requirements specification, see the document (b)(4)

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5 ARCHITECTURE DESIGN CHART

For the Architecture Design Chart see the Software Technical and Functional Description - document

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6 SOFTWARE DESIGN SPECIFICATION

For the Software Design Specification see the document (b)(4)



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7 TRACEABILITY ANALYSIS (TA)

The document (b)(4) provides a hazard analysis in (b)(4), representing a (b)(4) (b)(4).

The traceability between requirements (SRS), specifications (SDS) and tests is included in the SW design specification and SW Verification documents: (b)(4)



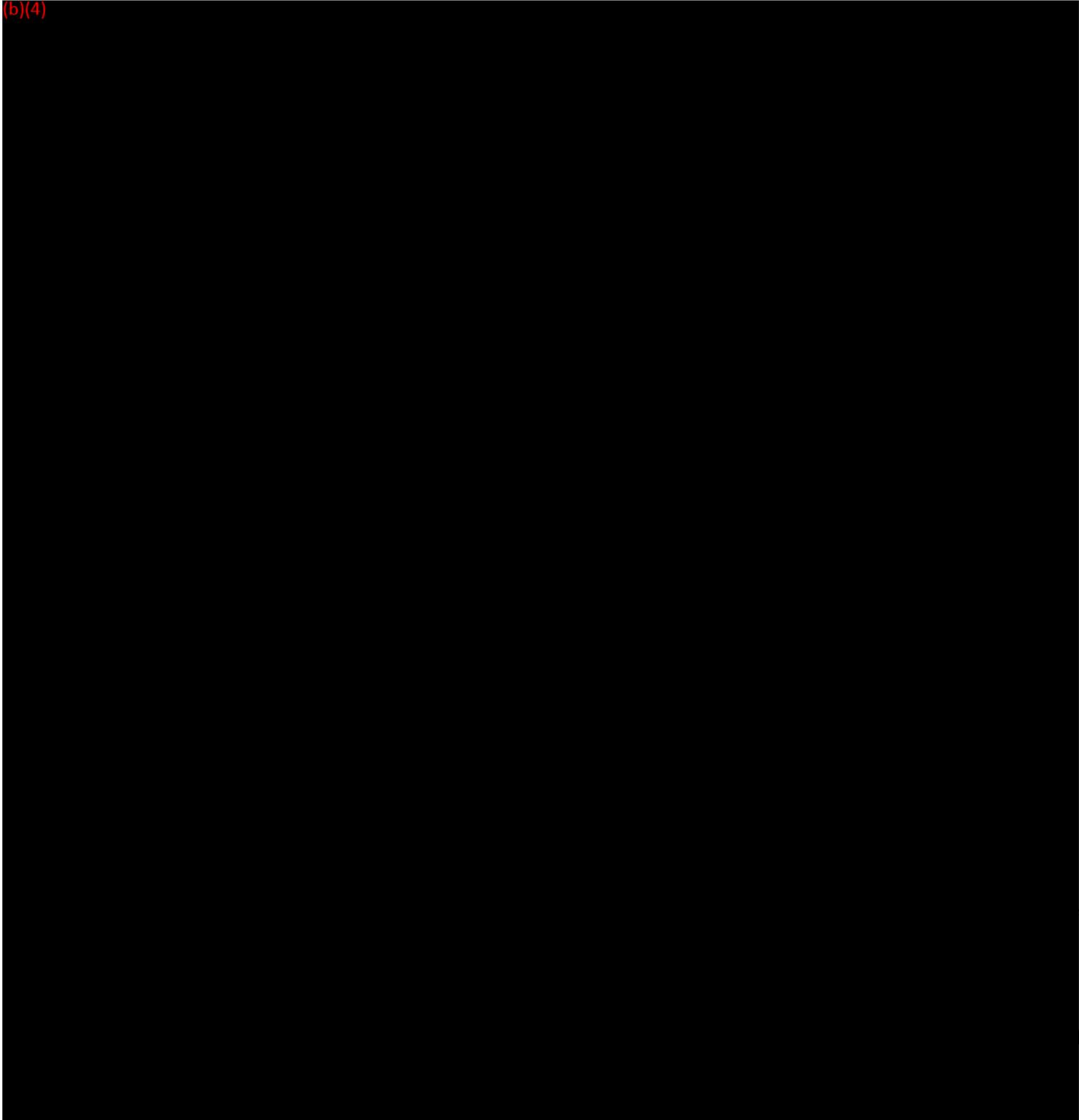
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8 SOFTWARE DEVELOPMENT ENVIROMENT DESCRIPTION

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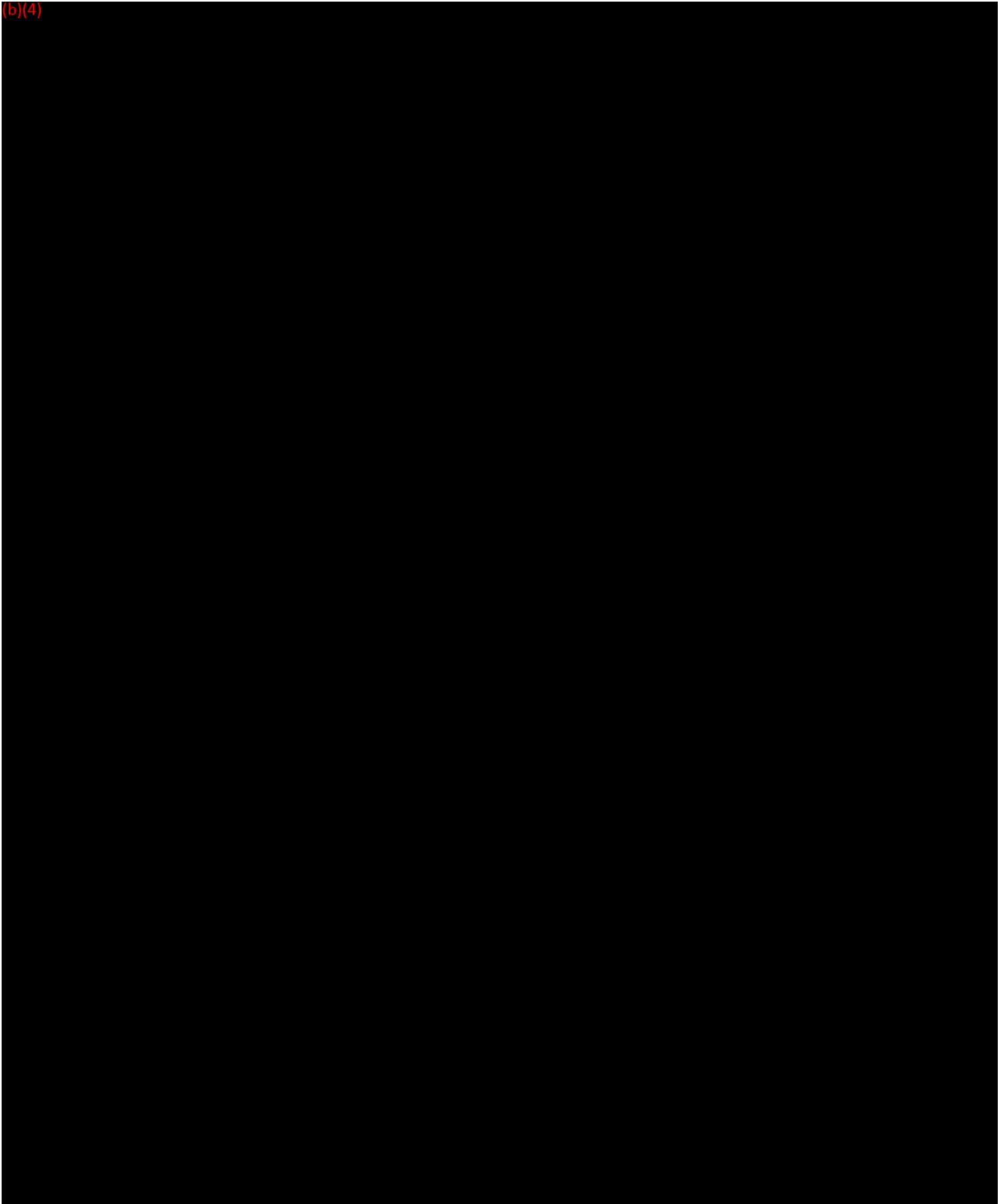
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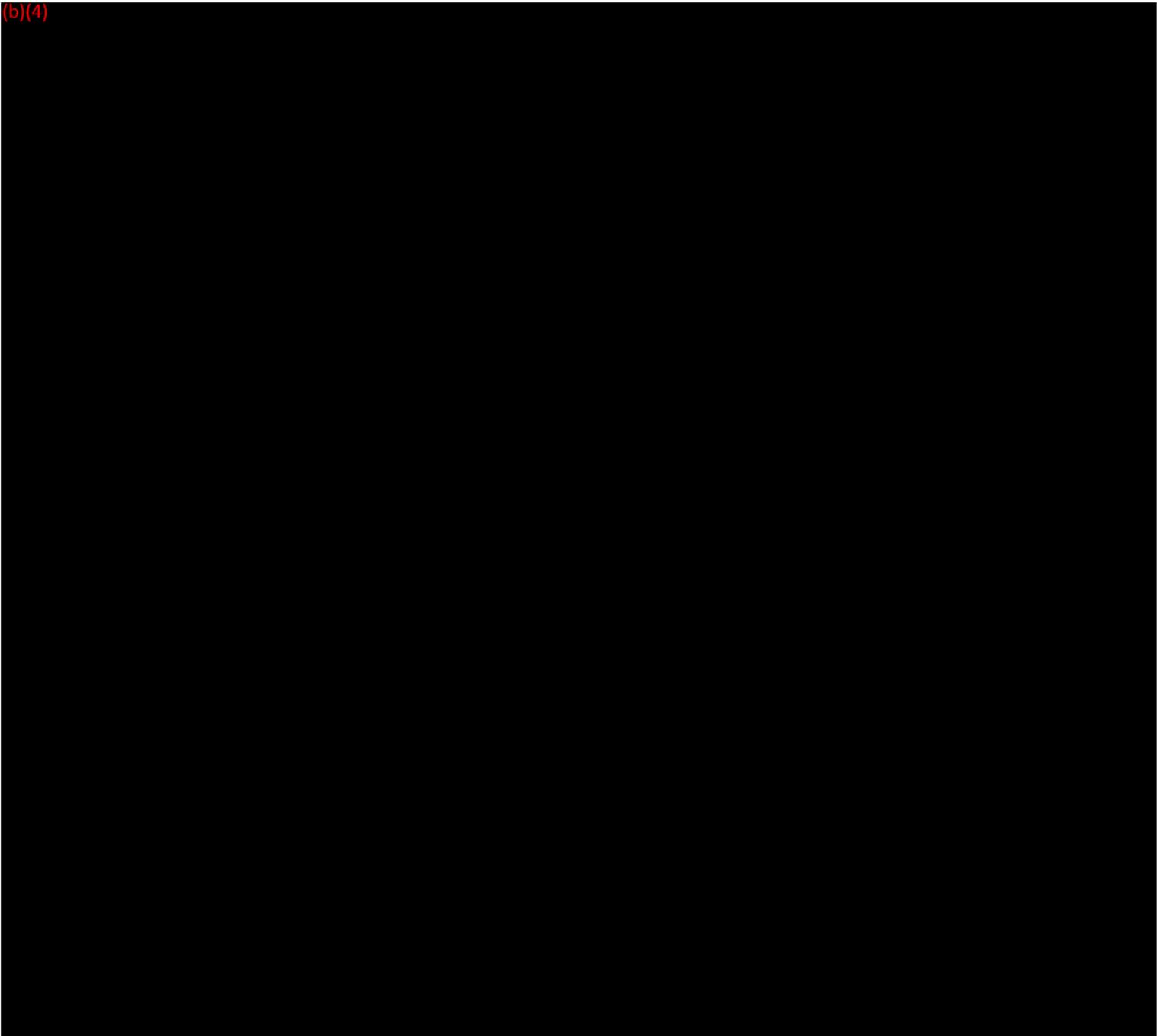
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9 VERIFICATION AND VALIDATION DOCUMENTATION

For the Software Verification and Validation see the documents (b)(4)

(b)(4)

The document (b)(4) is a Verification Report for software design specifications.

The document (b)(4) is a Validation Report which ensures that the software meets the needs of the user and all the requirements have been fulfilled.

Traceability among Software Requirements, Design specification, Verification and Validation is shown in the traceability matrix, reported in section 7.



SOFTWARE DOCUMENTATION
SMARTXIDE²

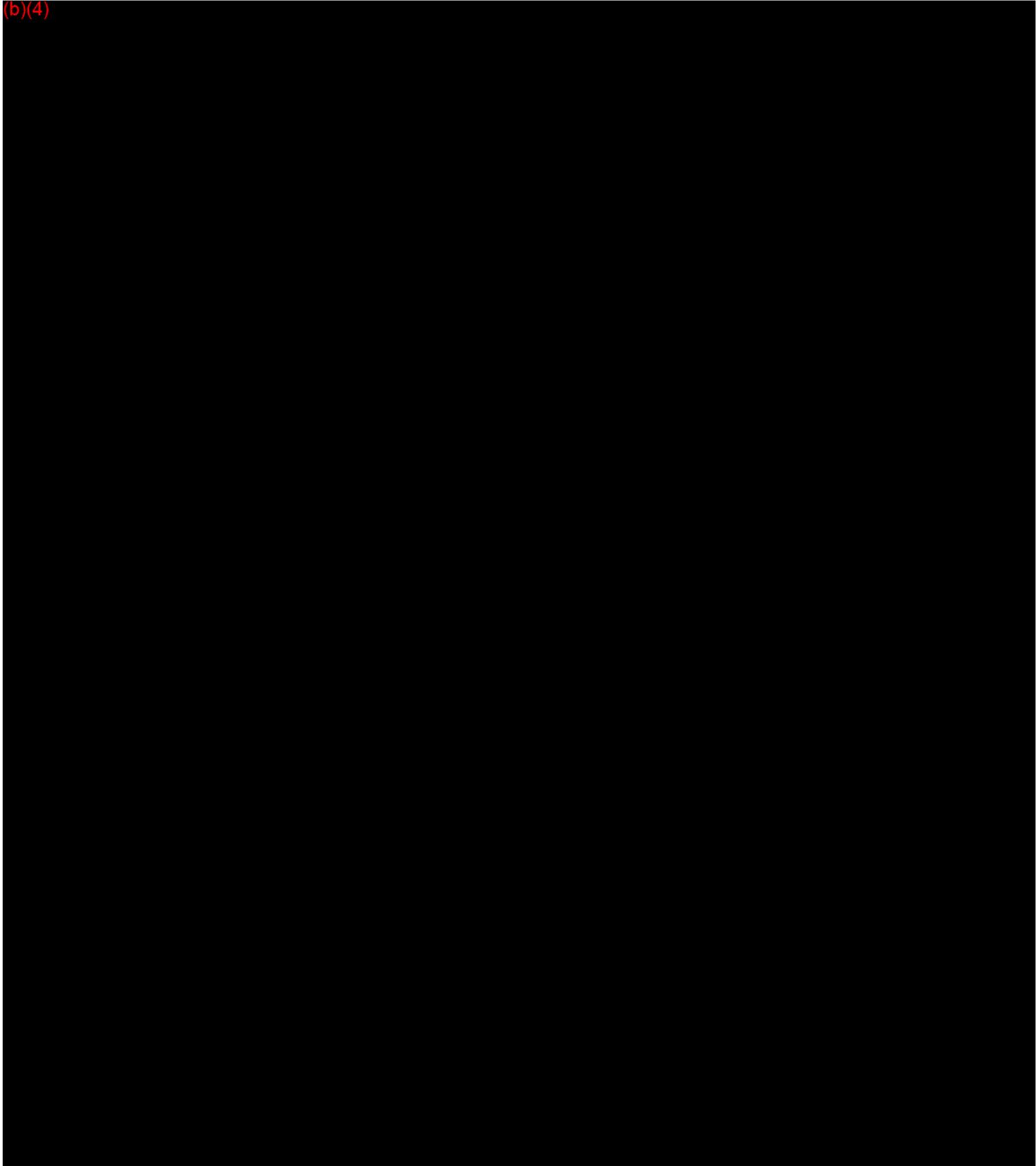
Date: 23/04/2014

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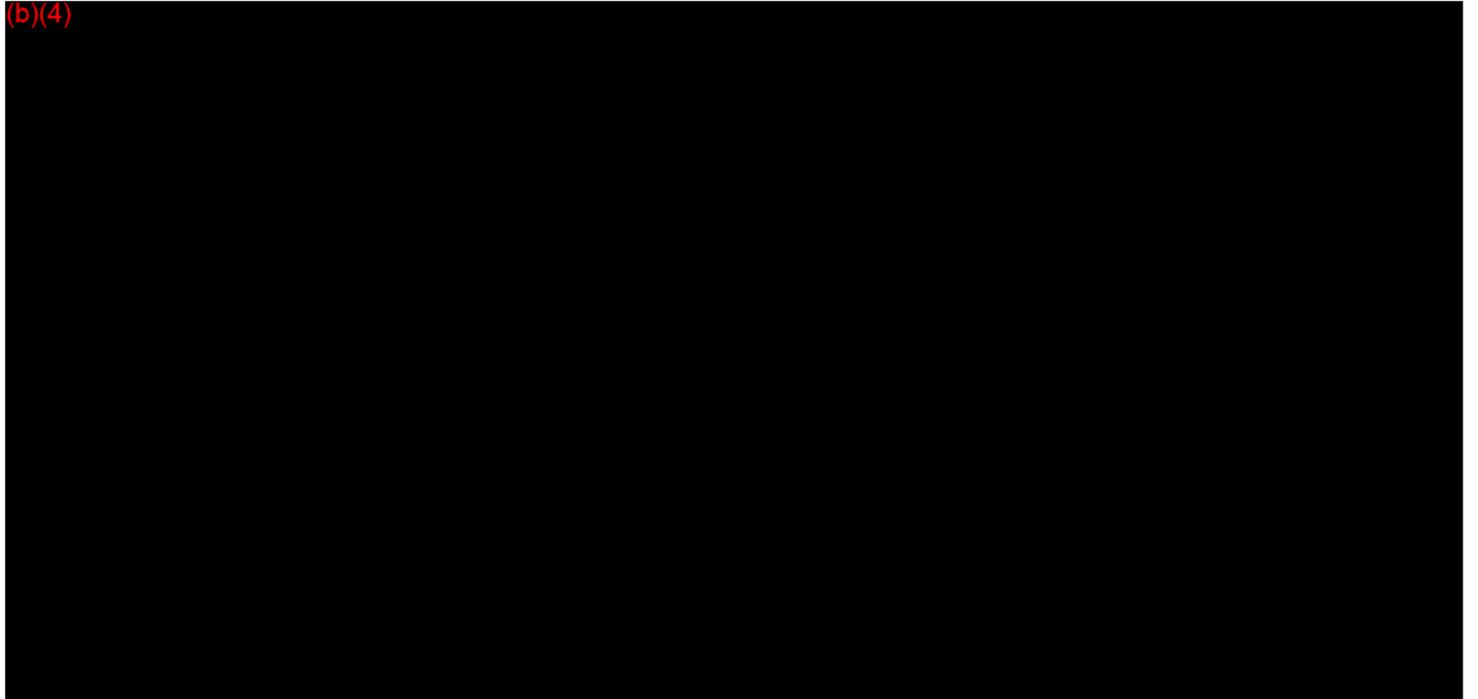
10 REVISION LEVEL HISTORY

(b)(4)



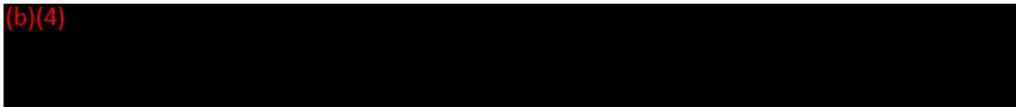
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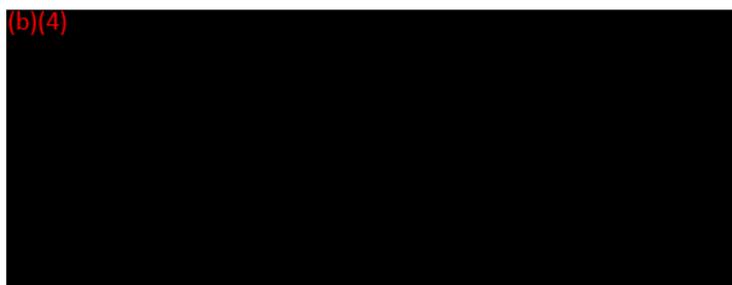
11 UNRESOLVED ANOMALIES (BUGS)

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12 RELEASE VERSION NUMBER

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ENCLOSURE 1

RISK MANAGEMENT REPORT

Document (b)(4)



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RISK MANAGEMENT

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	Name	Signature	Date
Prepared by	(b)(6)		08/04/14
Checked by			08/04/2014
Checked by			08/06/2014
Checked by			8/6/14
Checked by			8/04/14
Checked by			8/4/2014
Checked by			08/4/14
Checked by			08/4/14
Checked by			8/4/14
Approved by			08/4/2014



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Date: 08/04/2014

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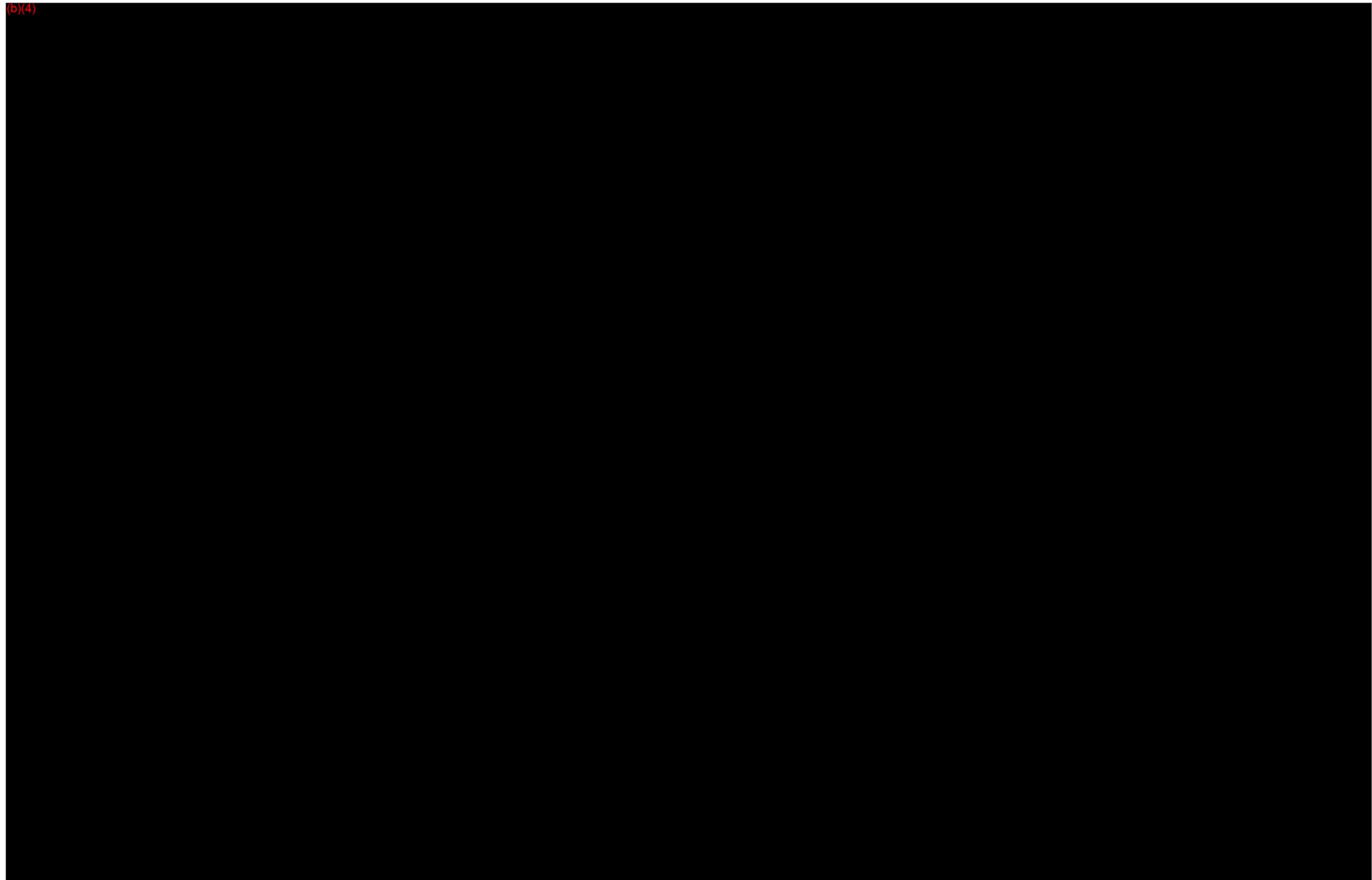
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RISK MANAGEMENT

Risk Analysis and evaluation

Risk control

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Risk Analysis and evaluation

Risk control

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Records processed under FOIA Request # 2013-2016-Release

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Risk Analysis and evaluation

Risk control

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Risk Analysis and evaluation

Risk control

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Risk Analysis and evaluation

Risk control

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Records processed under FOIA Request # 2013-2016-Rel

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Risk Analysis and evaluation

Risk control

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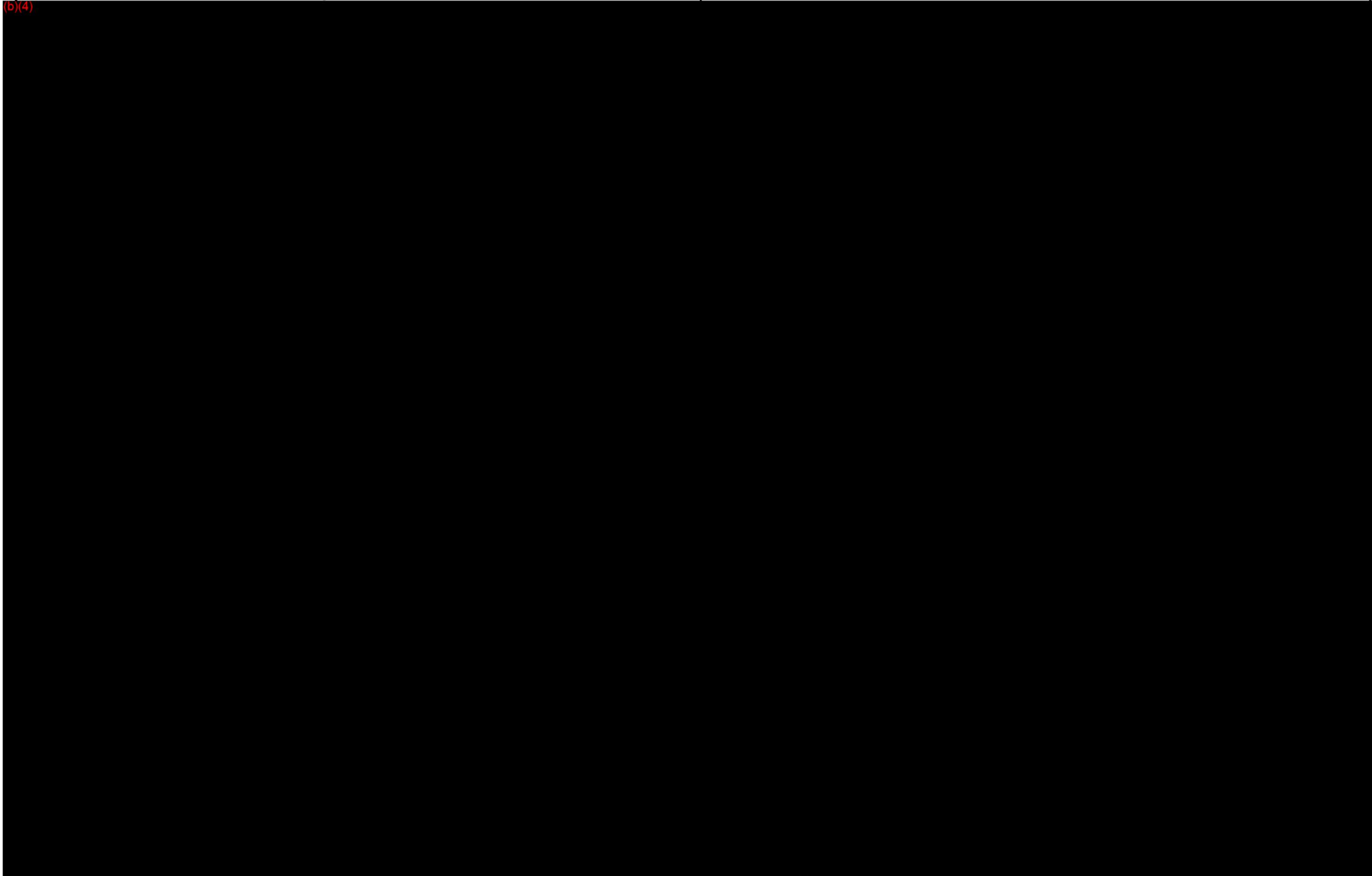
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RISK MANAGEMENT

Risk Analysis and evaluation

Risk control

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Risk Analysis and evaluation

Risk control

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Risk Analysis and evaluation

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RISK MANAGEMENT

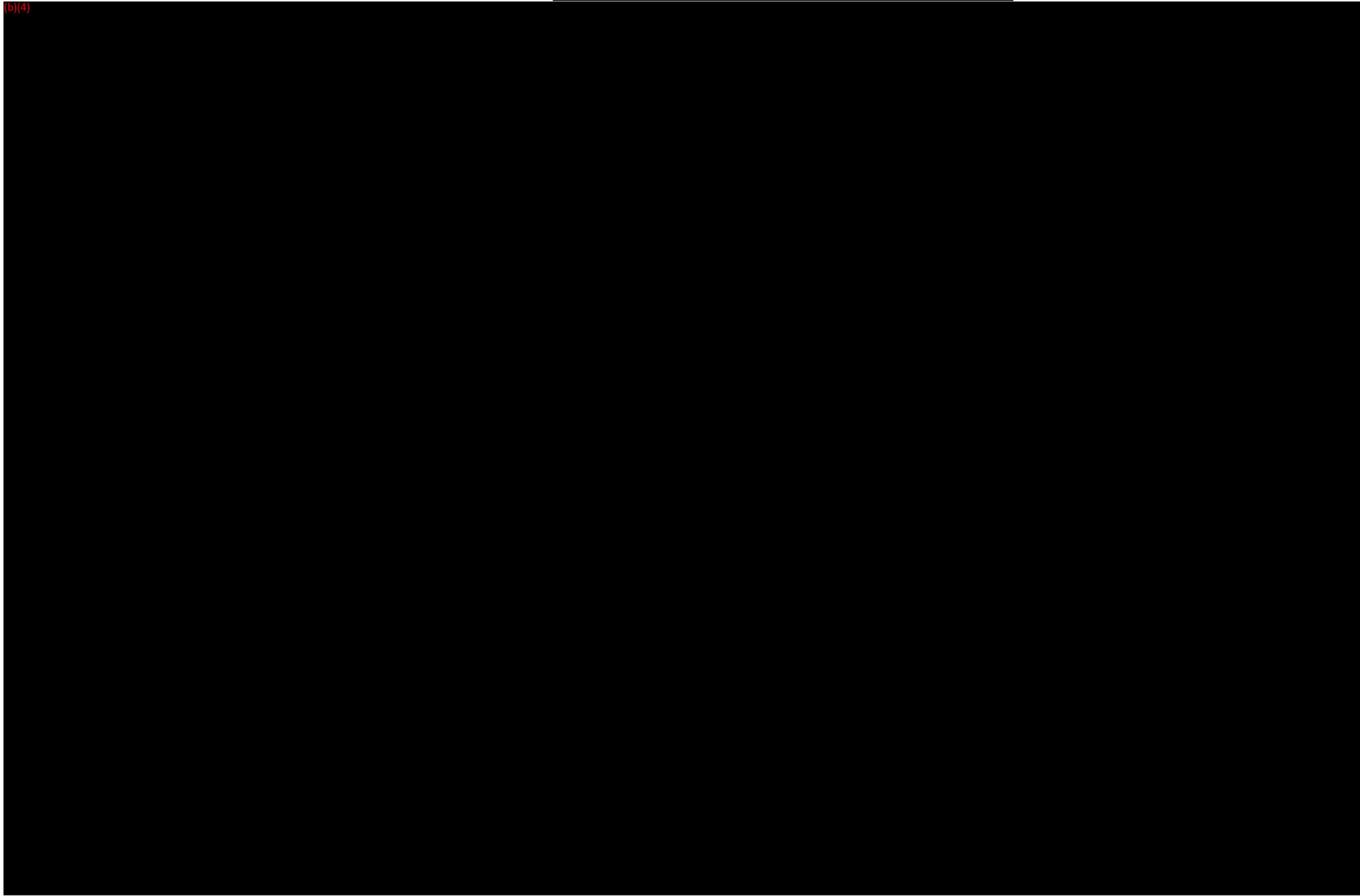
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SMARTXIDE²

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ENCLOSURE 2

SOFTWARE REQUIREMENTS SPECIFICATION

Document (b)(4)



Modulo (b)(4) ■ **Software Requirements Specification**

Records processed under FOIA Request # 2015-4016; Released by CDRH on 09-29-2015

Date 01/04/2014

Procedure (b)(4)

Rev (b)

Device name:

SmartXIDE²

(b)(4)

DESIGN SPECIFICATIONS/ RESULTS

VERIFICATION REPORT

(b)(4)



Device name: **SmartXIDE²**

(b)(4)

1 - HARDWARE REQUIREMENTS

REQUIREMENTS SPECIFICATION	VERIFICATION REPORT				
	Verification Method	Used instruments	NOTES	Pass	Fail
(b)(4)					

2 - PROGRAMMING LANGUAGE REQUIREMENTS

REQUIREMENTS SPECIFICATION	VERIFICATION REPORT				
	Verification Method	Used instruments	NOTES	Pass	Fail
(b)(4)					



Device name:

SmartXIDE²

(b)(4)

REQUIREMENTS SPECIFICATION

VERIFICATION REPORT

(b)(4)

Verification Method	Used instruments	NOTES	Pass	Fail

5 - ALARMS AND SAFETY FEATURES

REQUIREMENTS SPECIFICATION

VERIFICATION REPORT

(b)(4)

Verification Method	Used instruments	NOTES	Pass	Fail



Module (b)(4) ■ Software Requirements Specification

Records processed under FOIA Request # 2015-4016; Released by CDRH on 09-29-2015

Date 01/04/2014

Procedure (b)(4)

Rev (b)

Device name:

SmartXIDE²

(b)(4)

REQUIREMENTS SPECIFICATION

VERIFICATION REPORT

(b)(4)

Verification Method	Used instruments	NOTES	Pass	Fail



Module (b)(4) processed under FOIA Request # 2015-4016; Released by CDRH on 09-29-2015

Procedure (b)(4)

Date 01/04/2014

Rev (b)(4)

Device name: **SmartXIDE²**

(b)(4)

PROJECT SPECIFICATIONS/VERIFICATIONS

VERIFICATION REPORT

(b)(4)

(b)(4)



(b)(4)

SOFTWARE DOCUMENTATION
SMARTXIDE²

Date: 23/04/2014

Rev (b)

ENCLOSURE 3

SOFTWARE TECHNICAL/FUNCTIONAL DESCRIPTION

Document (b)(4)

	Software technical/functional description	
	System: Code: SmartXIDE²	M103x1
	Software code: (b)(4) [REDACTED]	Sw Rev (b)(4) [REDACTED] Date 20/11/13 Rev (b)(4) [REDACTED] (16/04/14)

SOFTWARE TECHNICAL/FUNCTIONAL DESCRIPTION



Name	Signature	Date
Issued by: (b)(6) [REDACTED]	(b)(6) [REDACTED]	16/04/14
Checked by: (b)(6) [REDACTED]	[REDACTED]	16/4/14
Approved by: [REDACTED]	[REDACTED]	16/4/14

Software technical/functional description



System: Code: **SmartXIDE²**

M103x1

Software code: S (b)(4)
(b)(4)

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Rev (b) 16/04/14

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Software technical/functional description



System: Code: SmartXIDE²

M103x1

Software code: (b)(4)

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Software technical/functional description



System: Code: SmartXIDE²

M103x1

Software code: (b)(4)

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System: Code: **SmartXIDE²**

M103x1

Software code: (b)(4)

Sw Rev (b) Date 20/11/13

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I. Glossary

(b)(4)

Software technical/functional description



System: Code: **SmartXIDE²**

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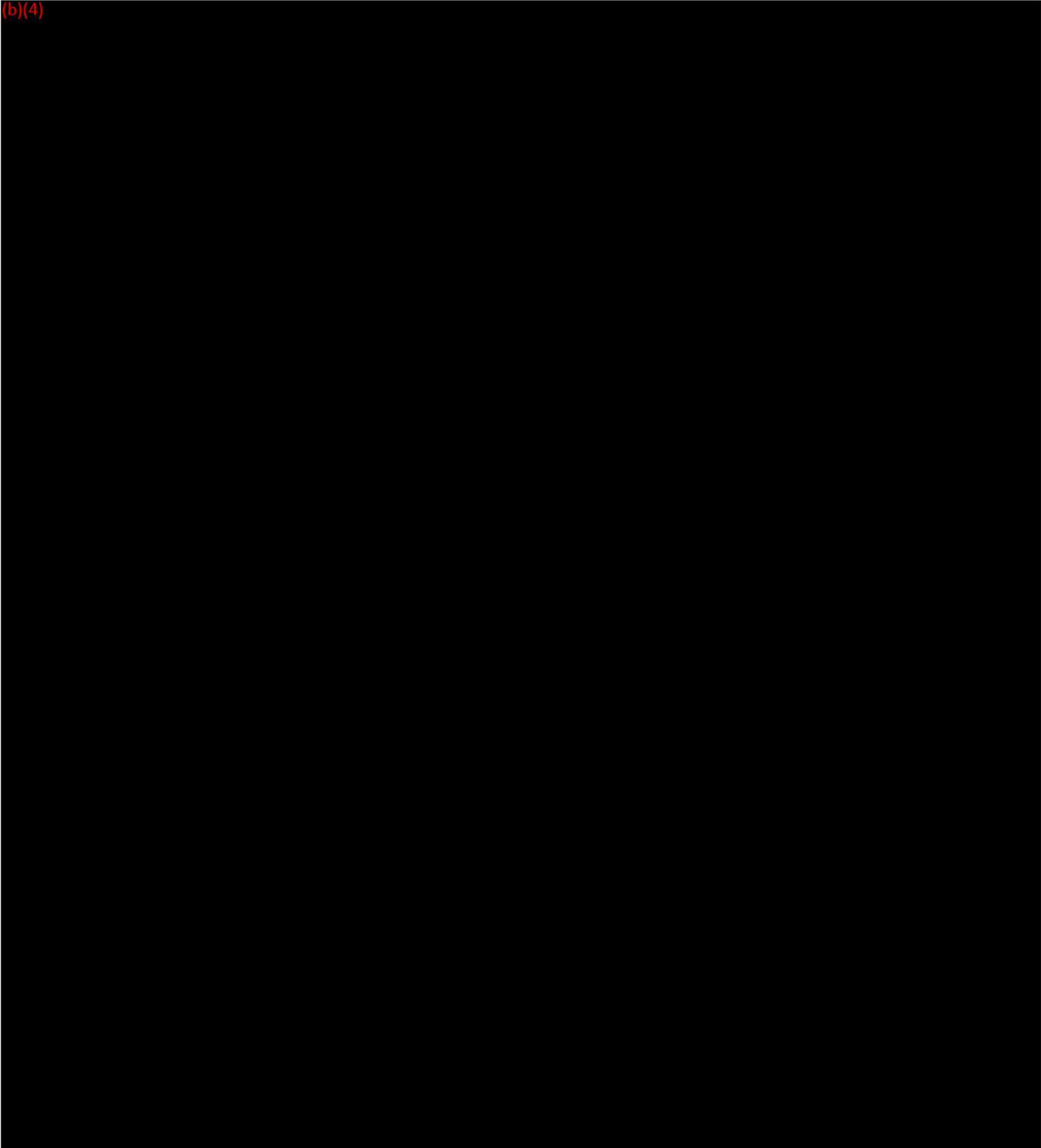
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Sw Rev (b) Date 20/11/13

Rev (b) 16/04/14

II. SYSTEM FUNCTIONAL DESCRIPTION

(b)(4)



Software technical/functional description



System: Code: **SmartXIDE²**

M103x1

Software code: (b)(4)

Sw Rev (b) Date 20/11/13

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Software technical/functional description



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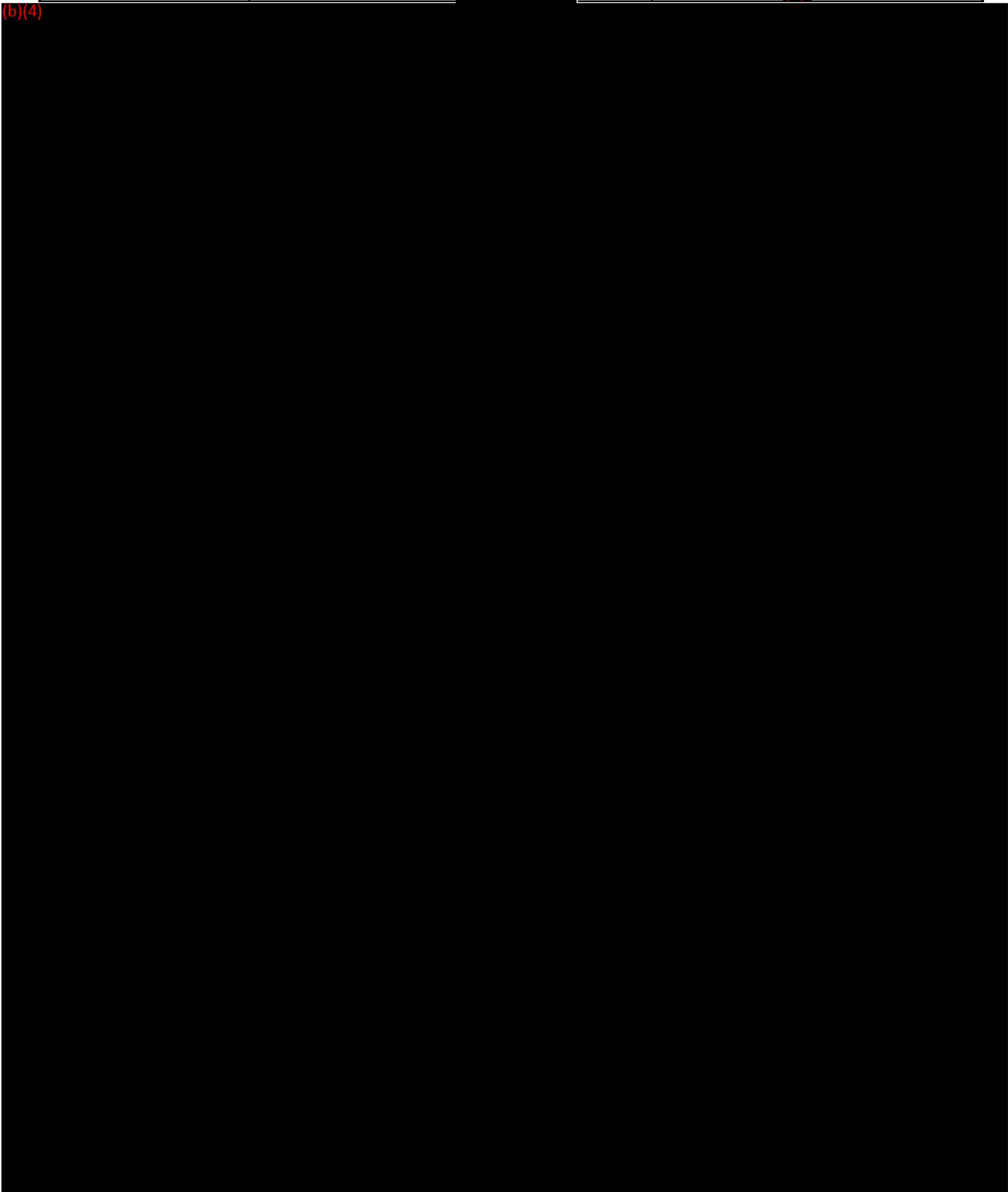
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Software technical/functional description



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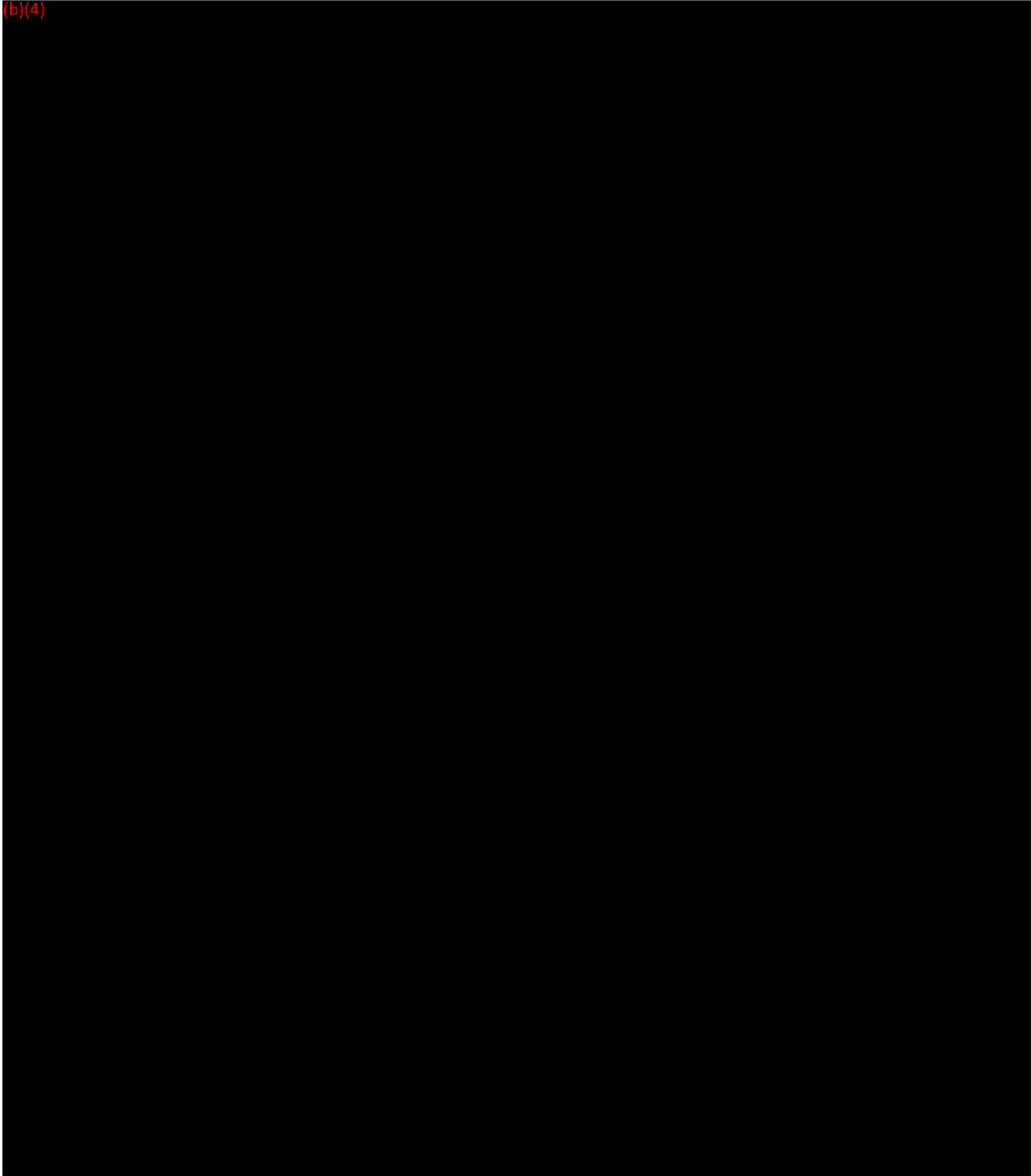
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Sw Rev (b) Date 20/11/13

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Software technical/functional description



System: Code: **SmartXIDE²**

M103x1

Software code: (b)(4)

Sw Rev (b) Date 20/11/13
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Software technical/functional description



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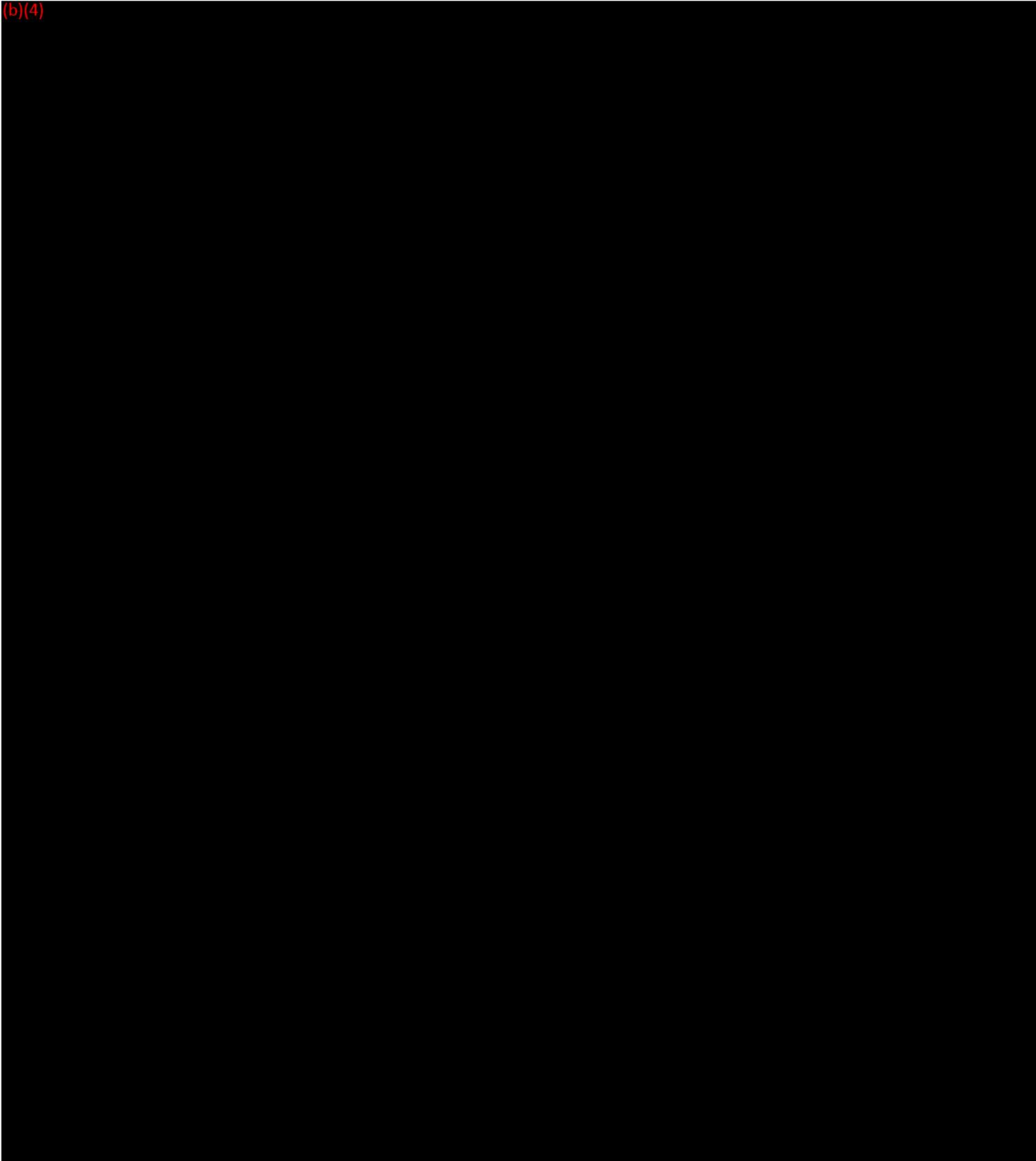
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Sw Rev (b) Date 20/11/13

Rev (b) (16/04/14)

(b)(4)



Software technical/functional description



System: Code: **SmartXIDE²**

M103x1

Software code: (b)(4)

Sw Rev (b)(4) Date 20/11/13
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Software technical/functional description



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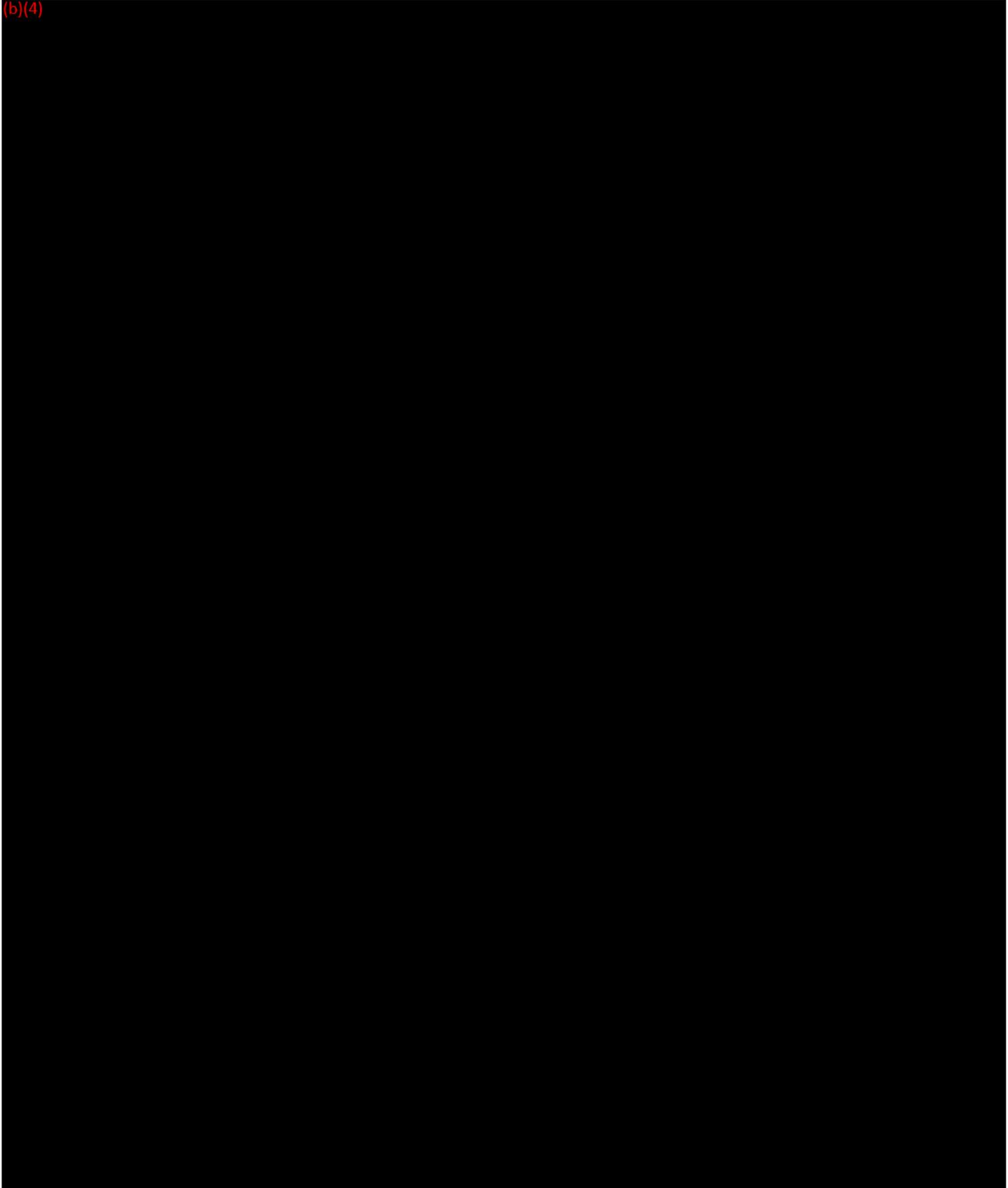
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Software technical/functional description



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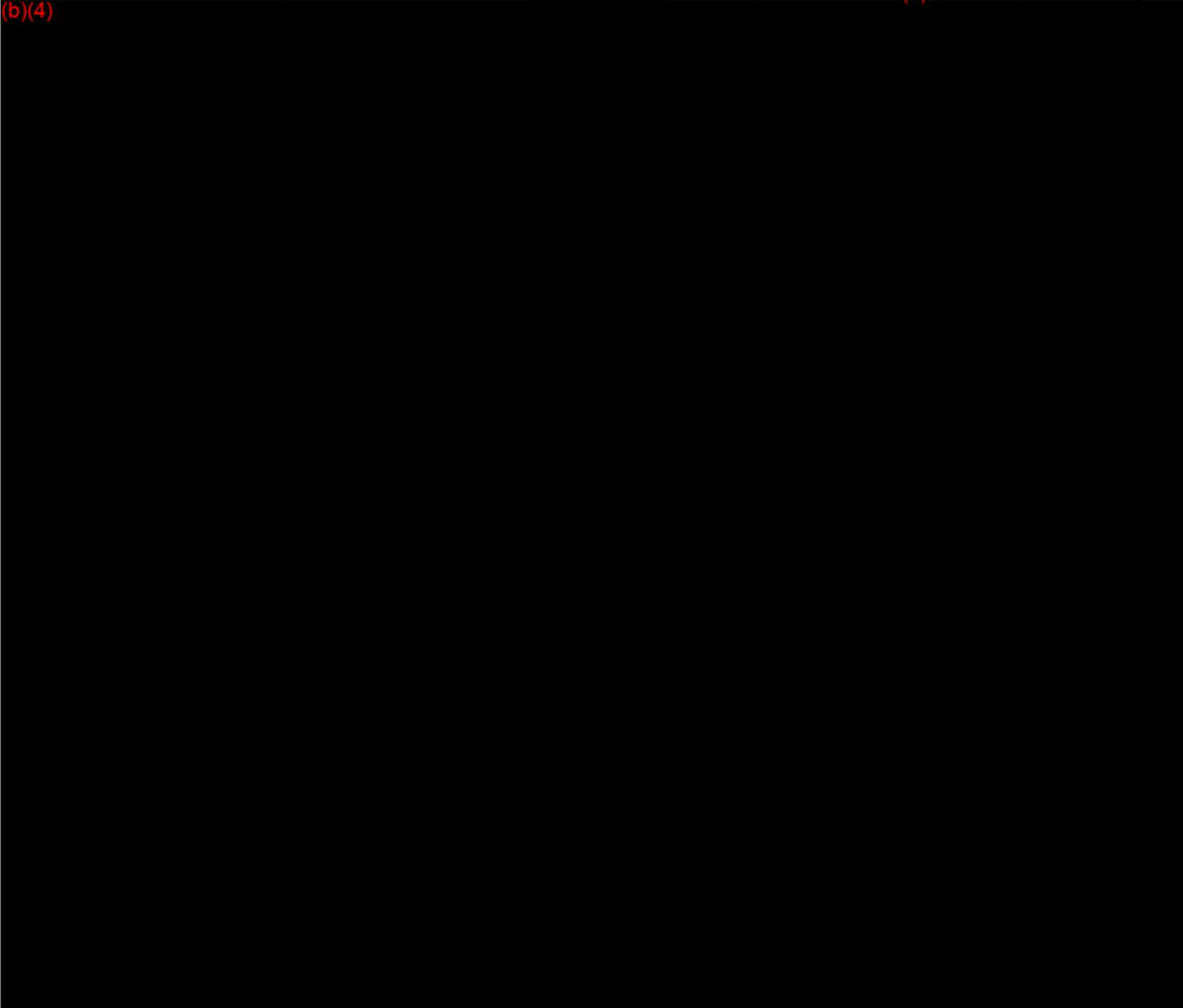
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Software technical/functional description



System: Code: **SmartXIDE²**

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Software technical/functional description



System: Code: **SmartXIDE²**

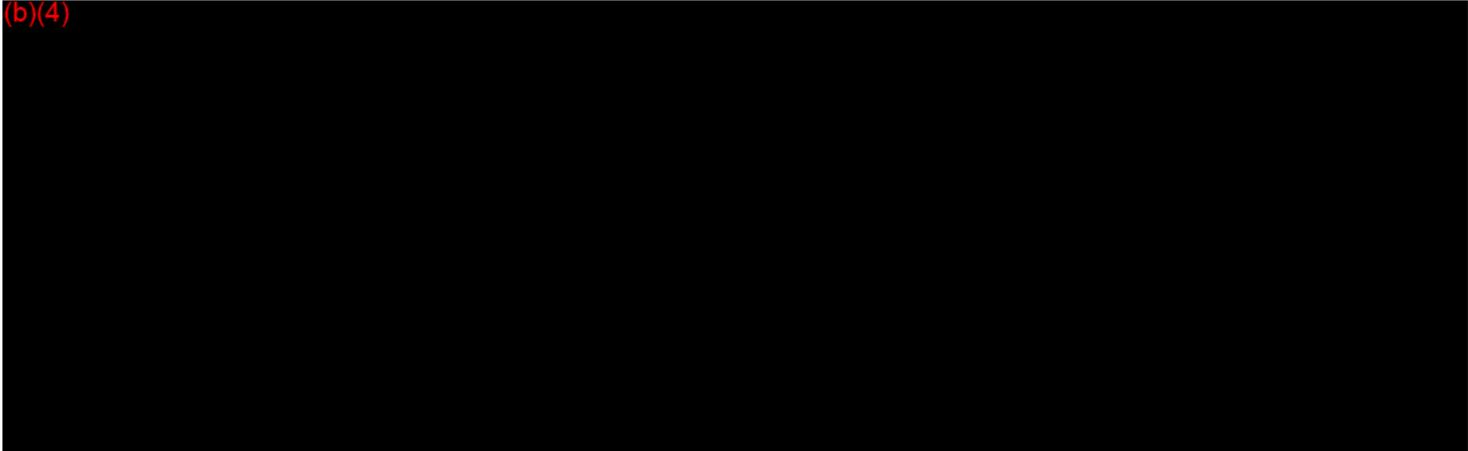
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Software technical/functional description



System: Code: **SmartXIDE²**

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III. FAULTS AND WARNINGS MANAGEMENT

(b)(4)

Software technical/functional description



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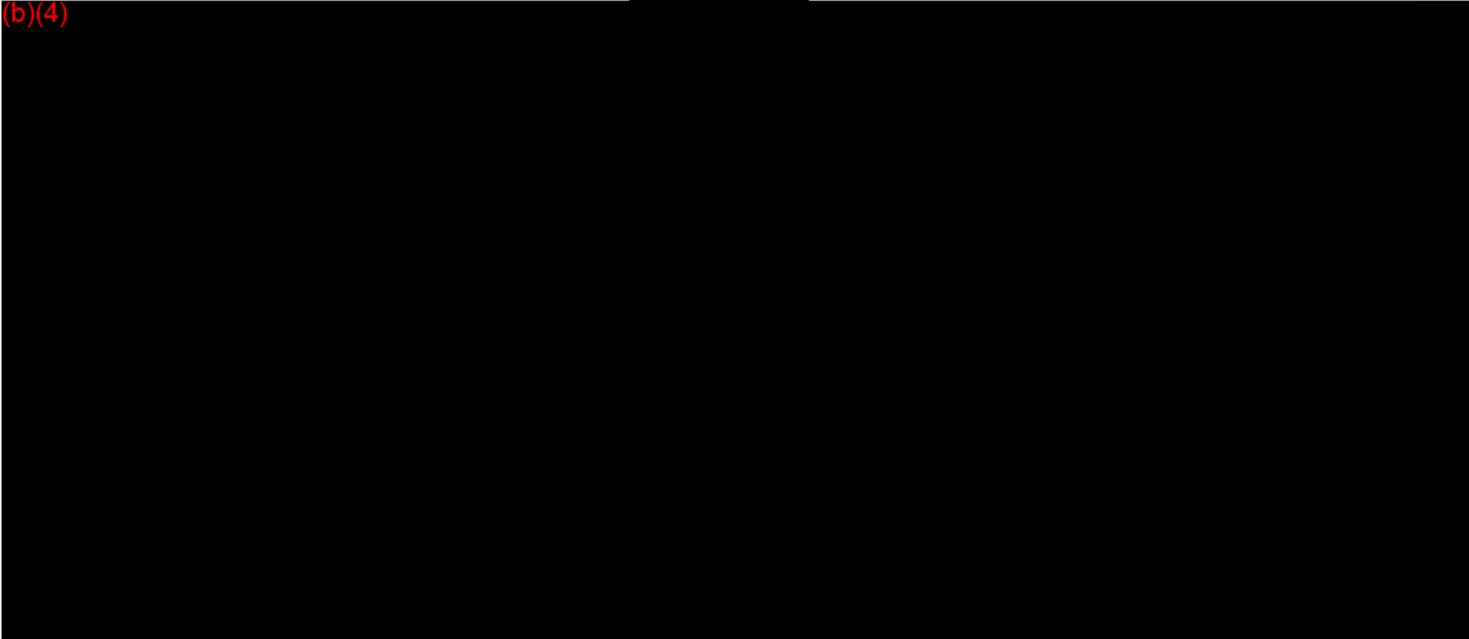
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Software technical/functional description



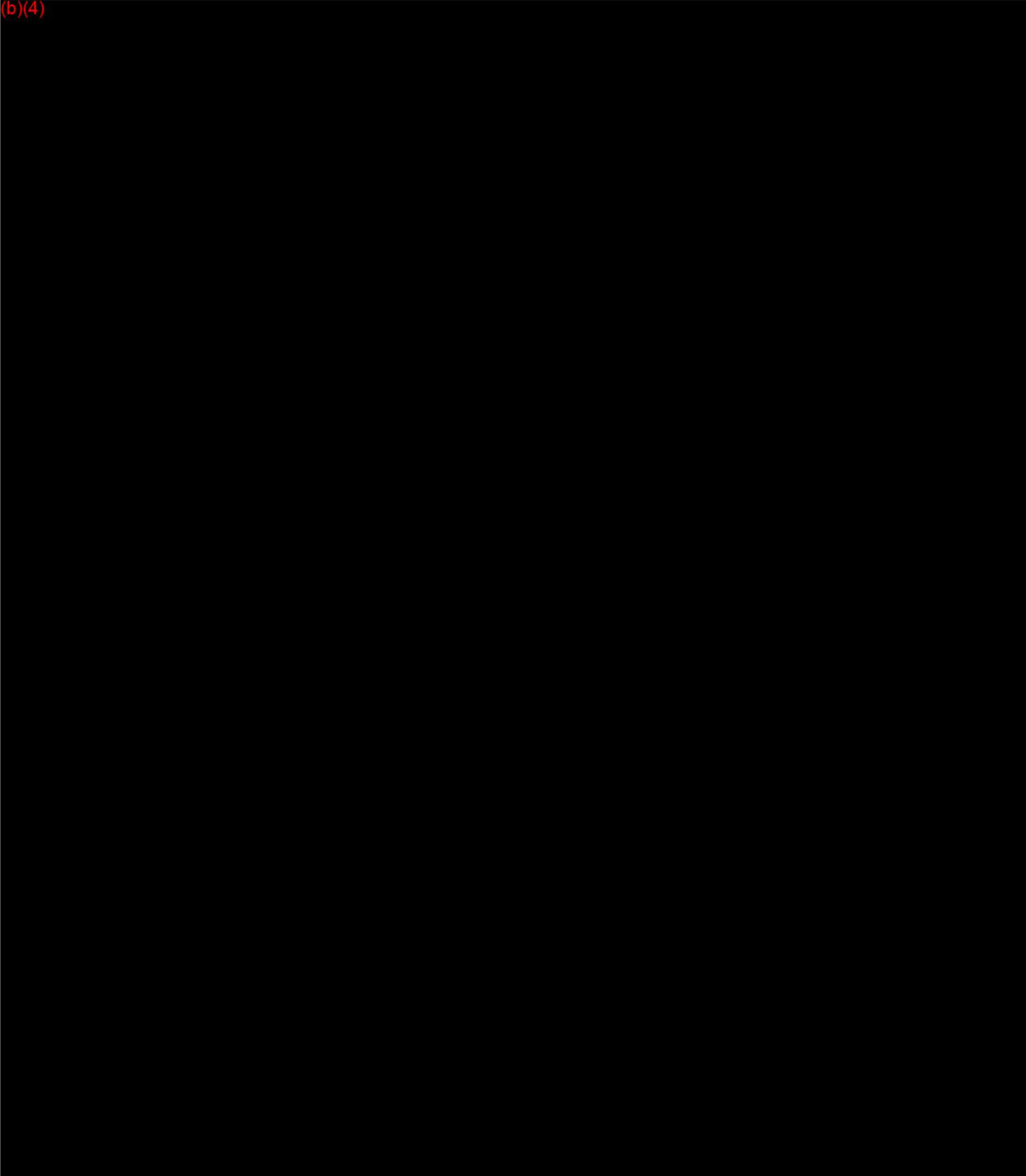
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Software code: (b)(4)

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Software technical/functional description



System: Code: **SmartXIDE²**

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(b)(4)

Software technical/functional description



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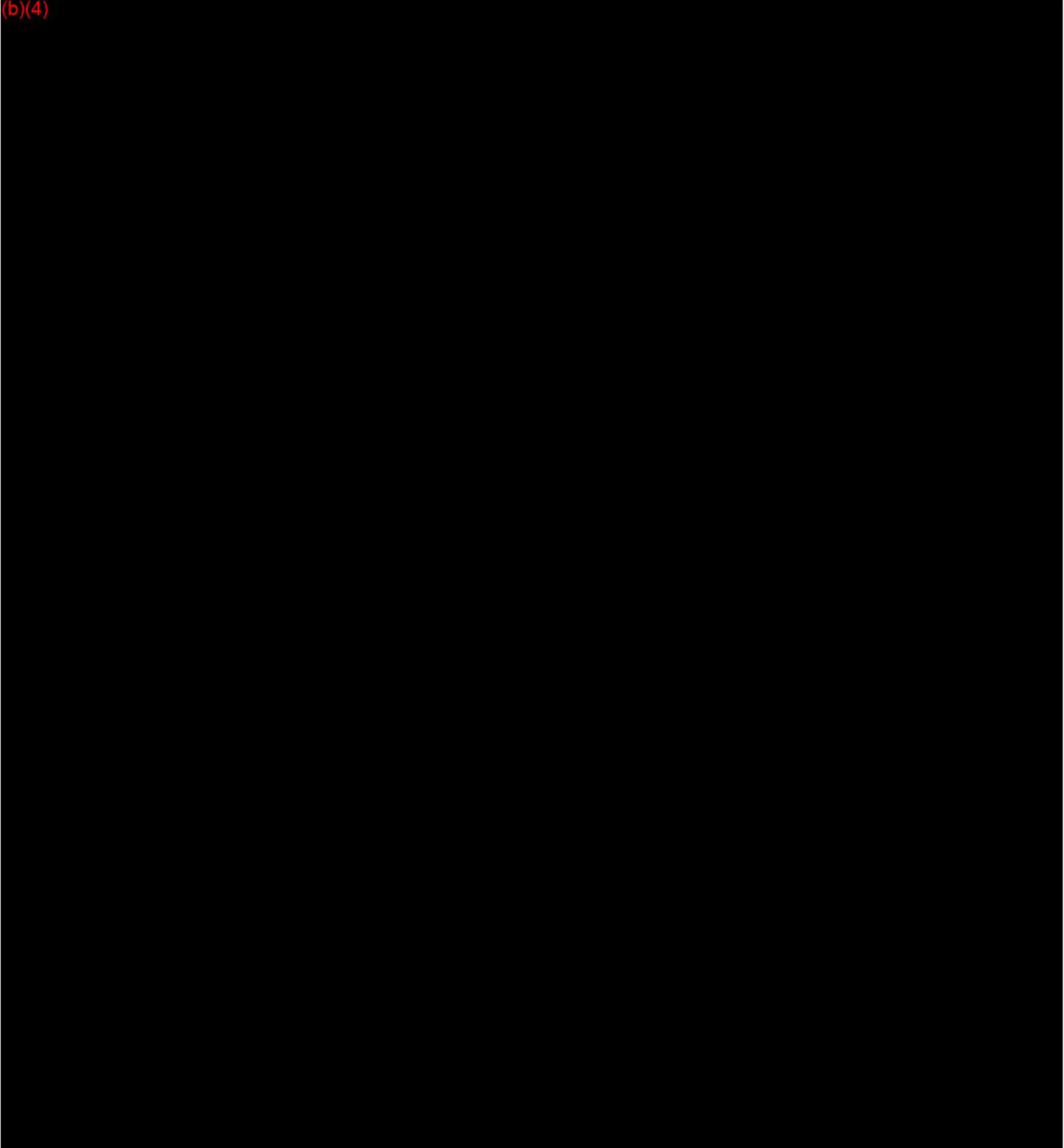
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Software code: (b)(4)

Sw Rev (b) Date 20/11/13

Rev (b) 16/04/14

IV. SW FLOW CHART



Software technical/functional description



System: Code: **SmartXIDE²**

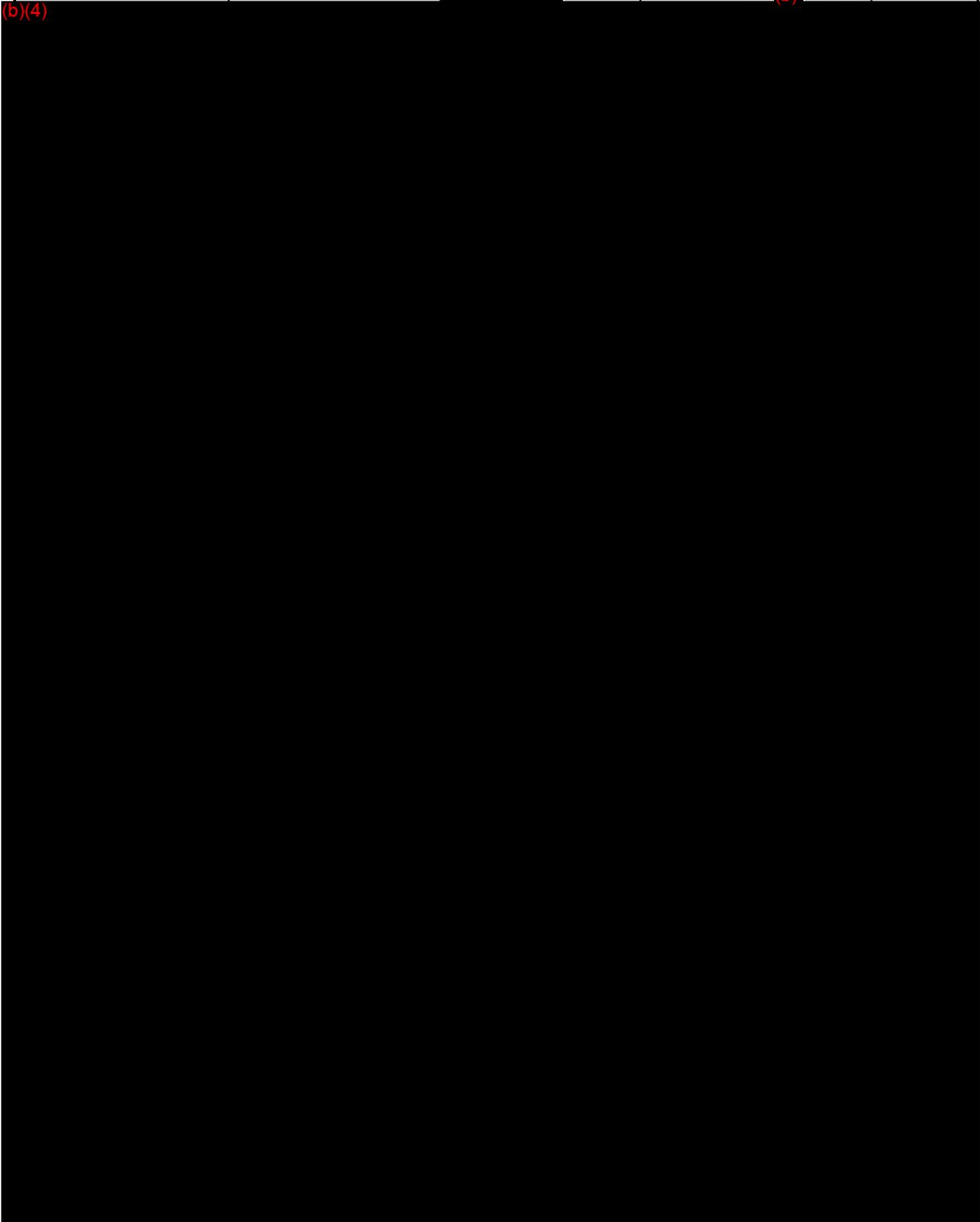
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(b)(4)



Software technical/functional description



System: Code: **SmartXIDE²**

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Software technical/functional description



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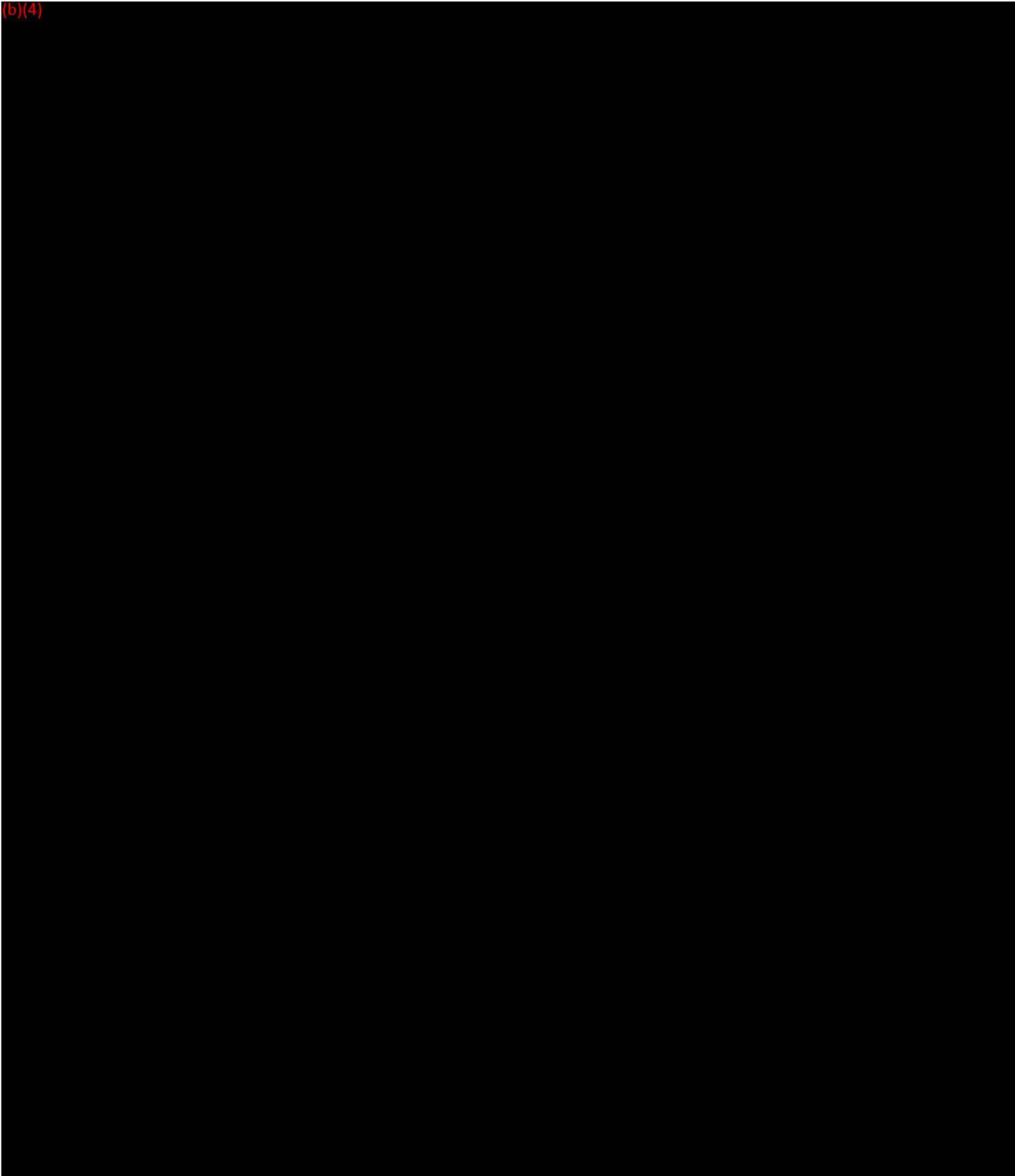
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Software technical/functional description



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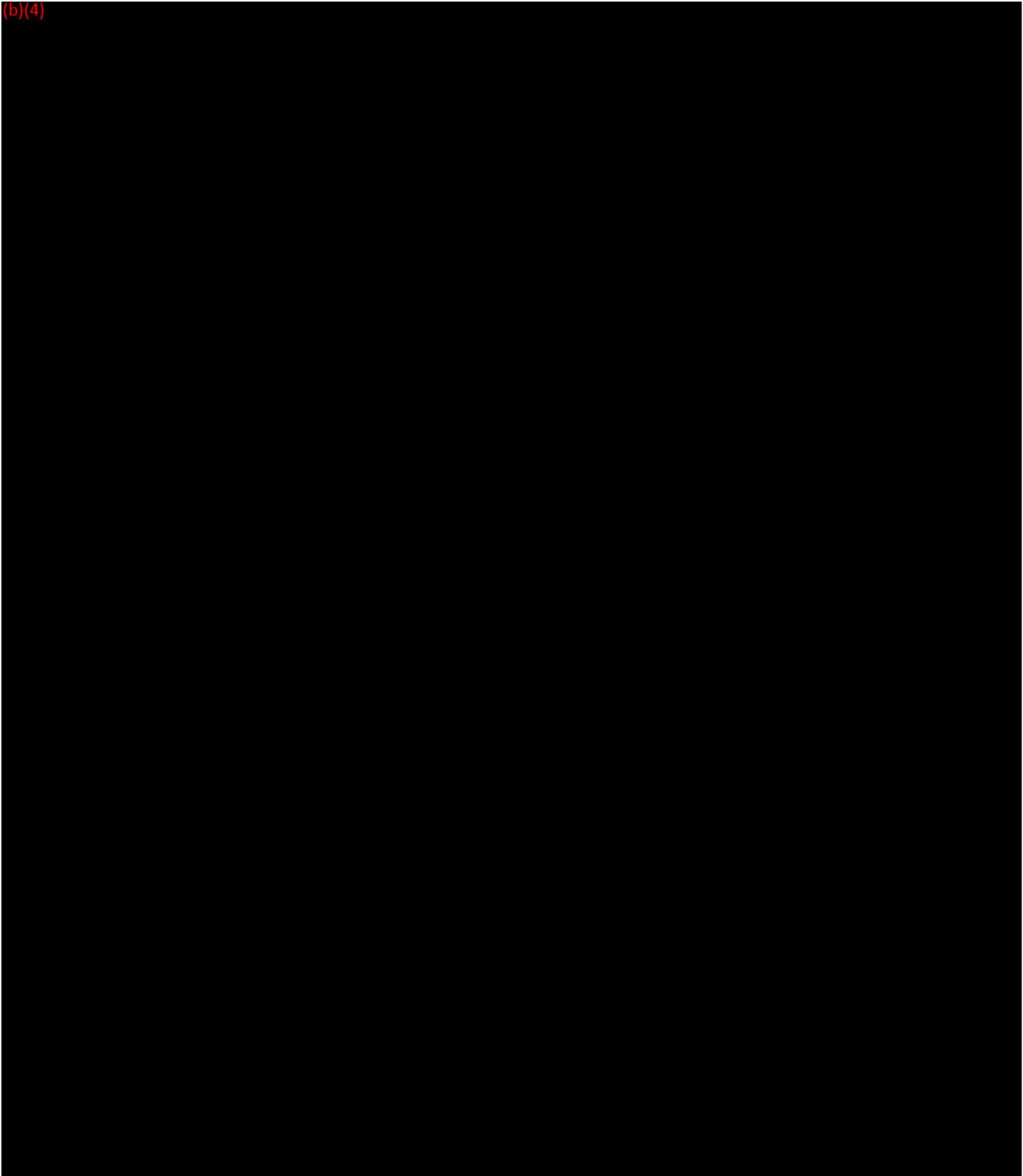
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Software technical/functional description



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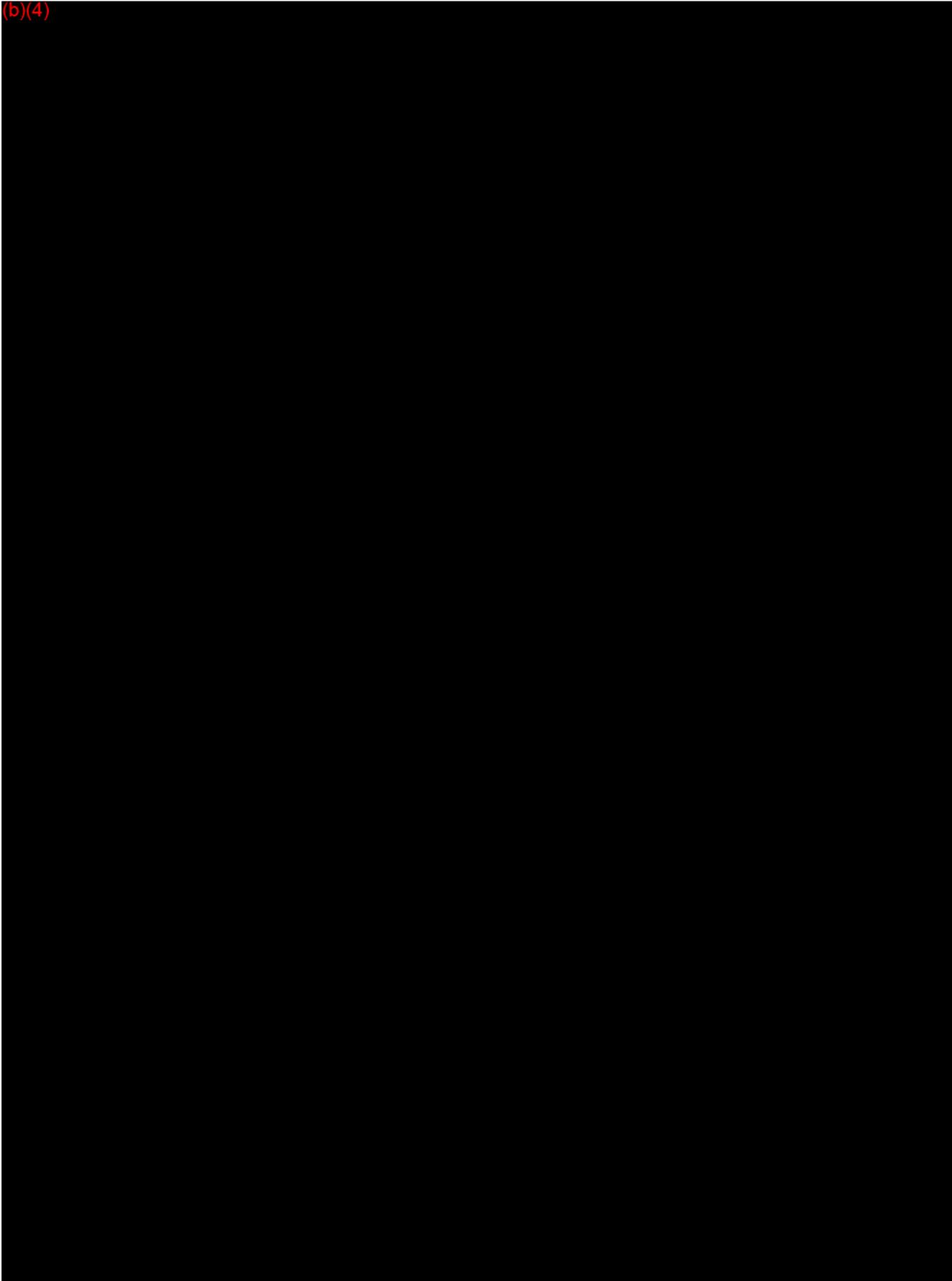
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Software technical/functional description



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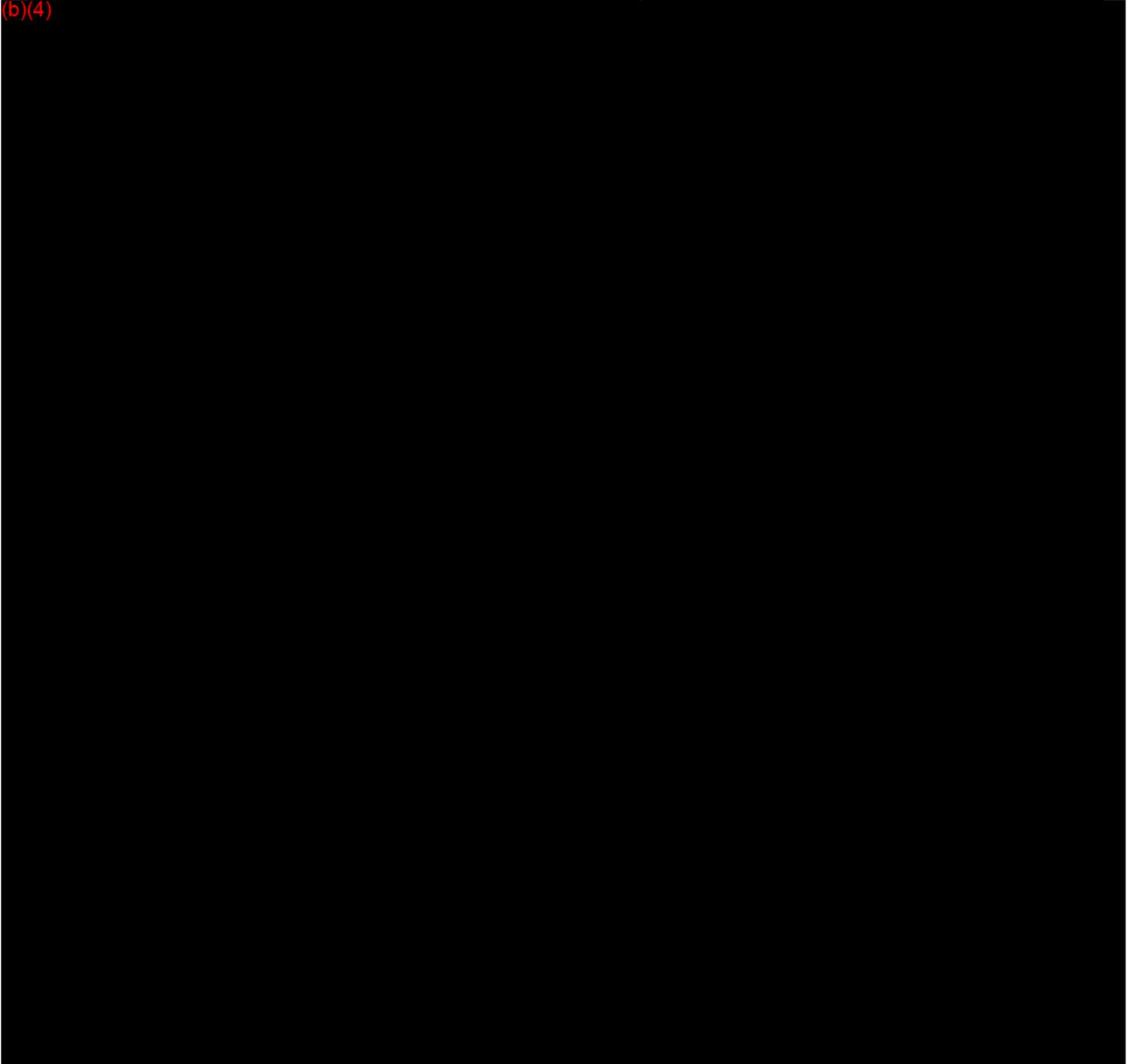
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Software technical/functional description



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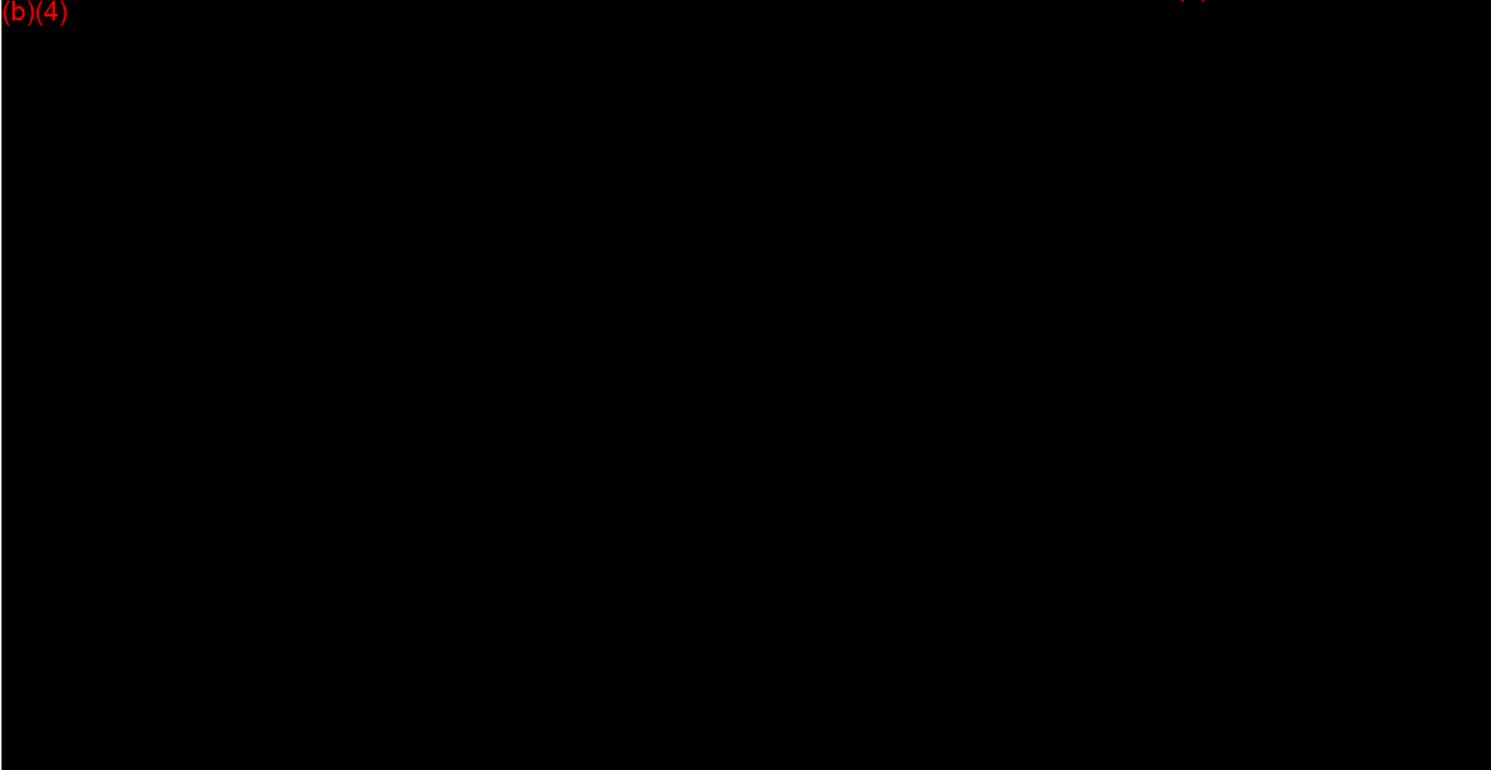
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Software technical/functional description



System: Code: **SmartXIDE²**

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Software technical/functional description



System: Code: **SmartXIDE²**

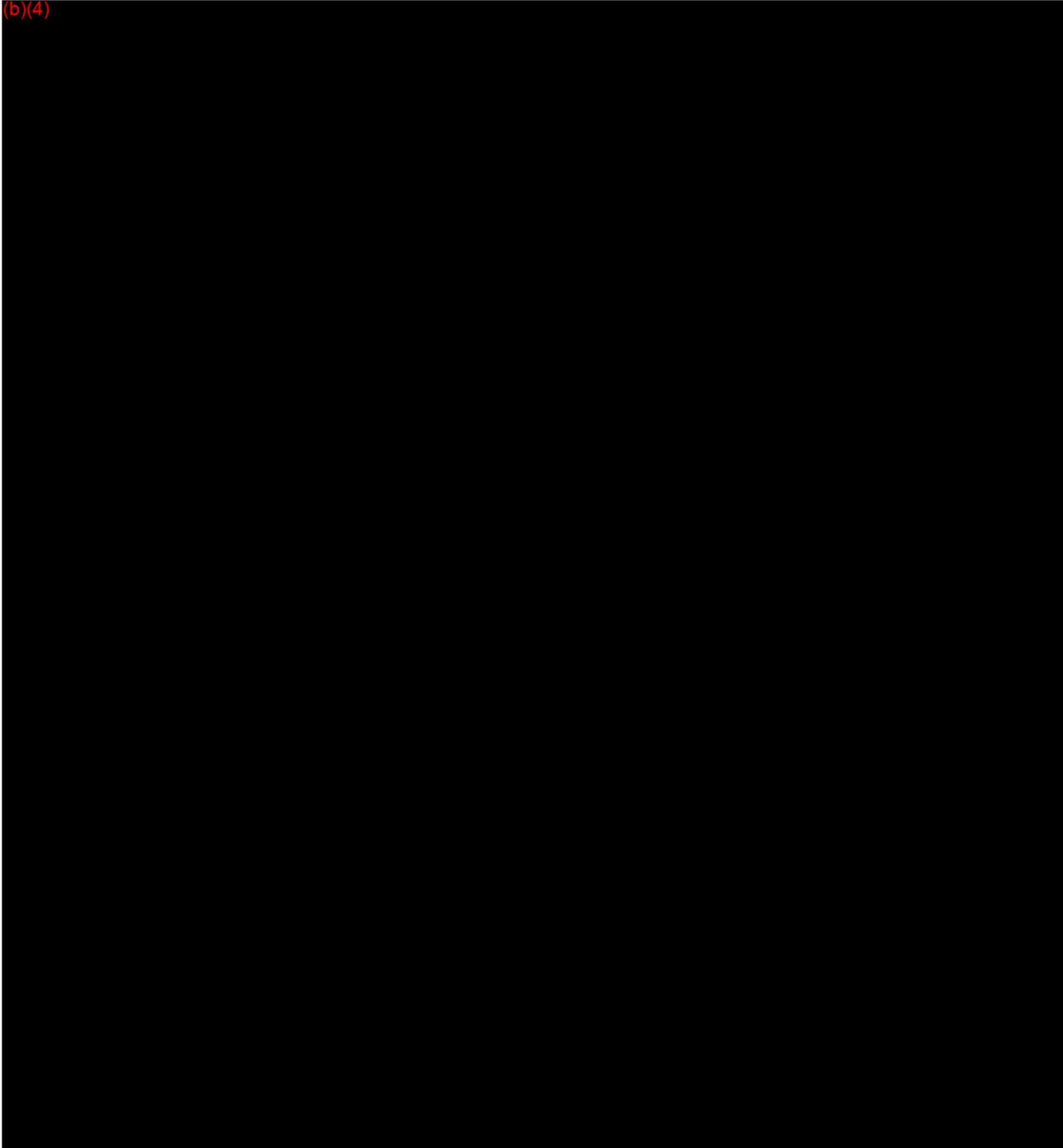
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Software code: (b)(4)

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(b)(4)



Software technical/functional description



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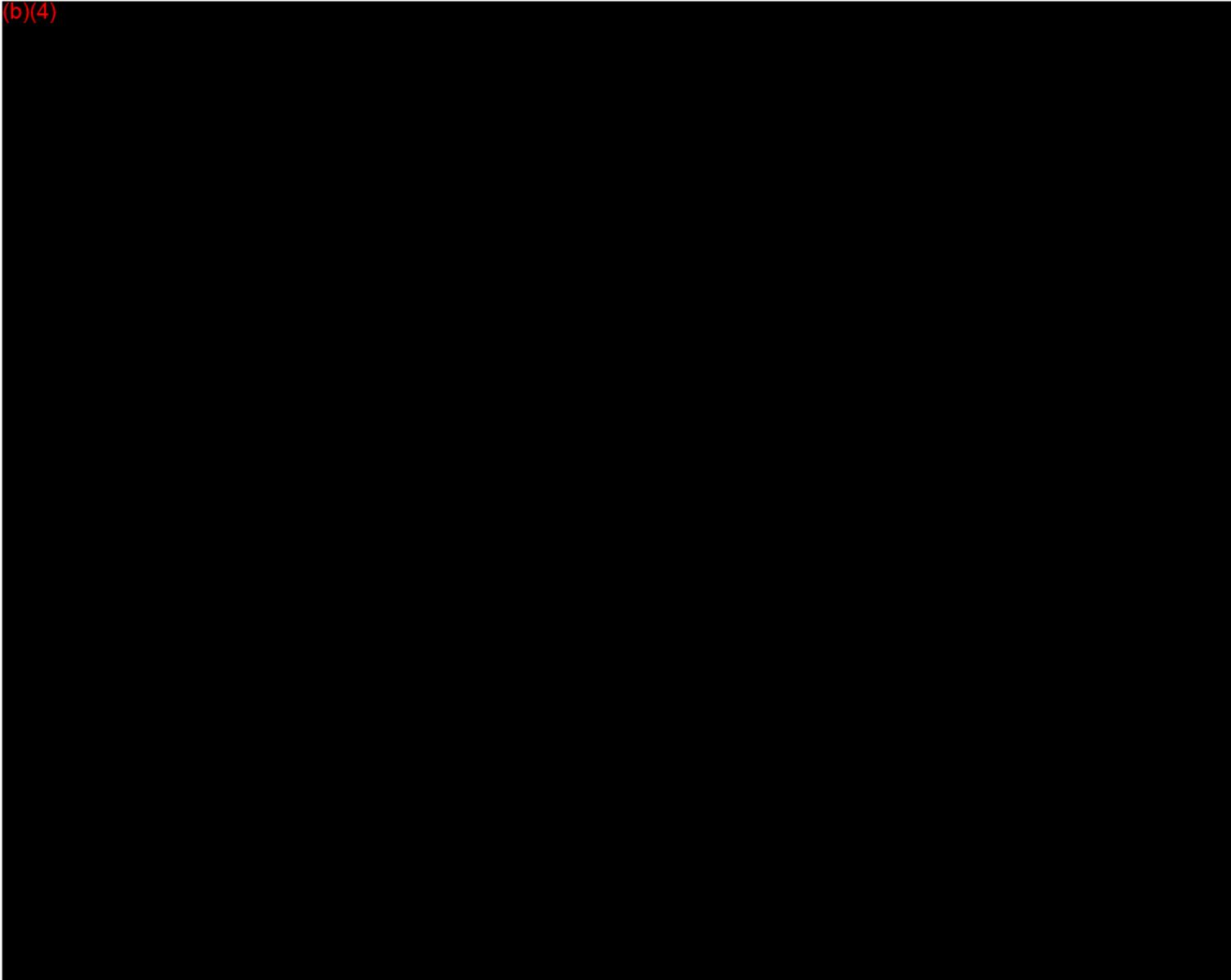
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Software technical/functional description



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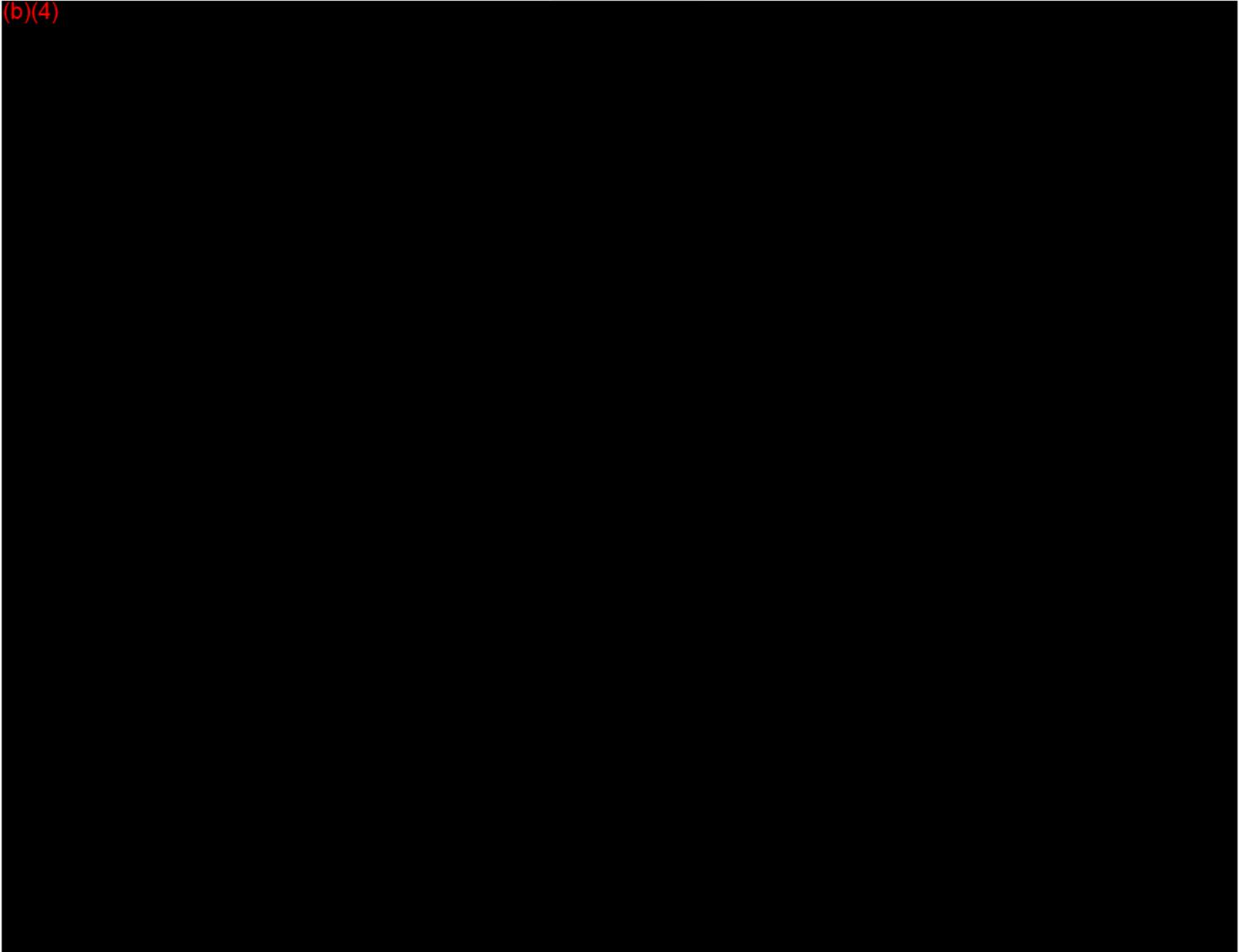
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Software technical/functional description



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System: Code: **SmartXIDE²**

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Software technical/functional description



System: Code: **SmartXIDE²**

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Rev (b)(4) /04/14

(b)(4)

Software technical/functional description



System: Code: **SmartXIDE²**

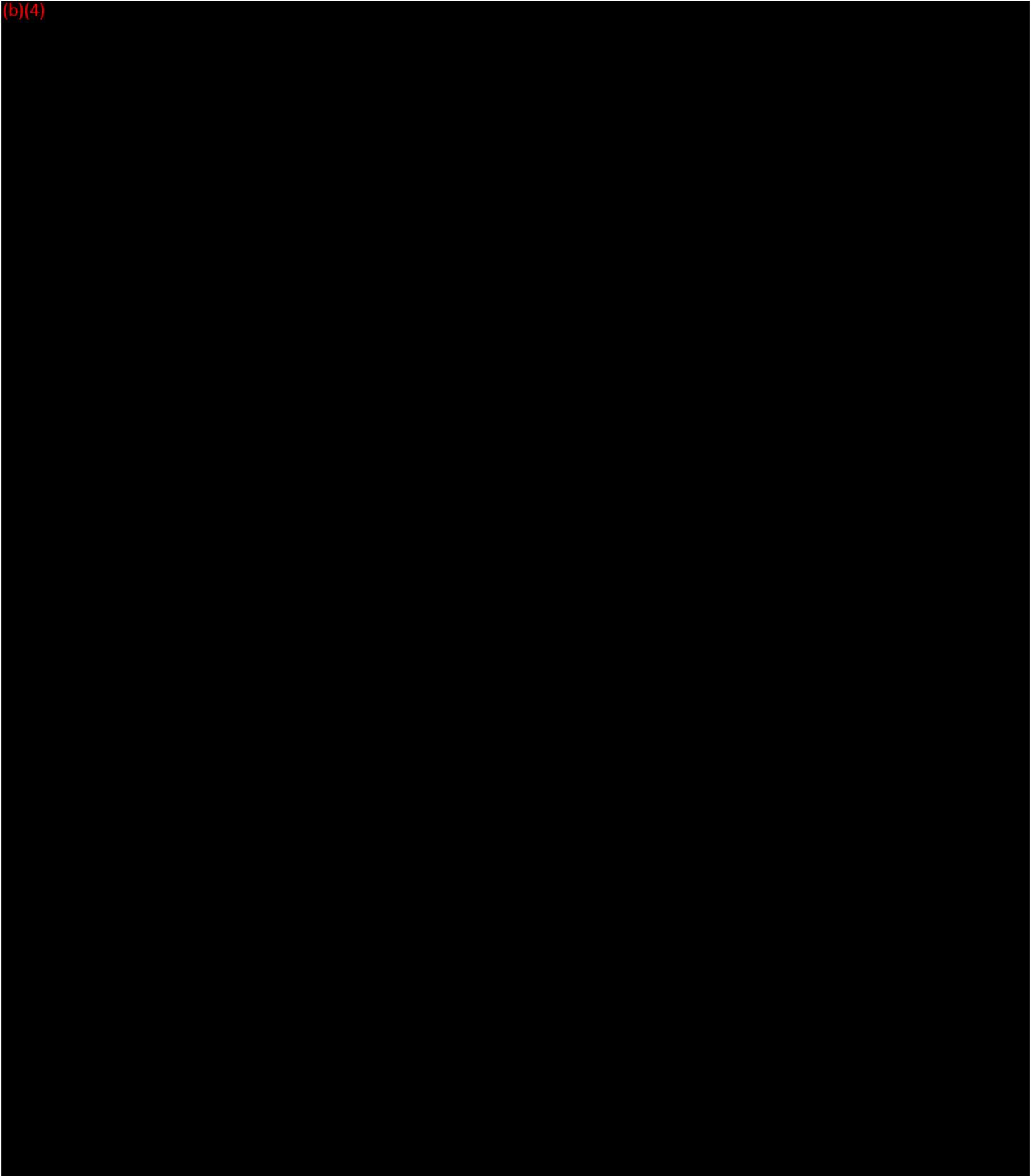
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Rev (b) (16/04/14)

(b)(4)



Software technical/functional description



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Software technical/functional description



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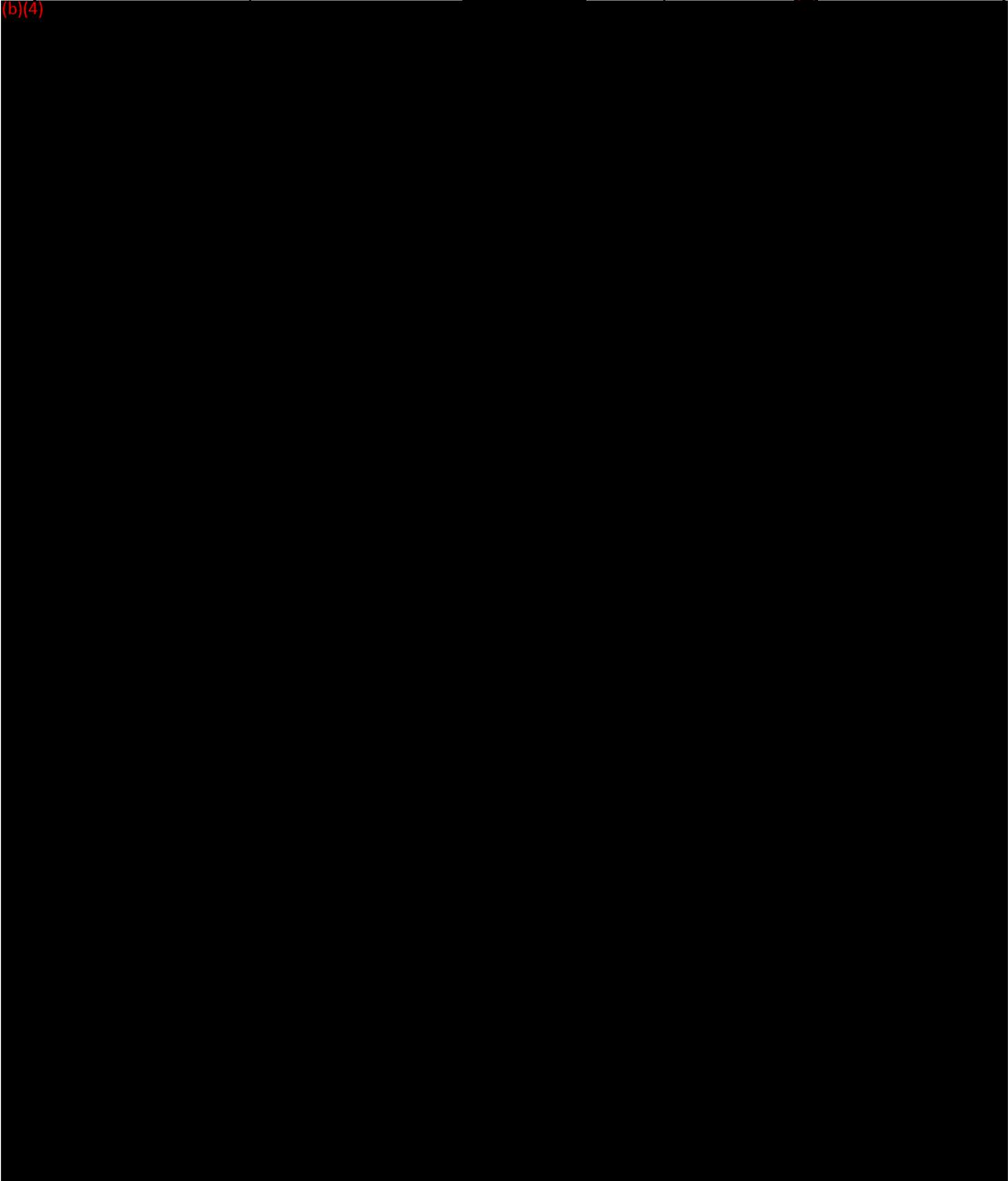
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Software code (b)(4)

Sw Rev (b) Date 20/11/13

Rev (b) (16/04/14)

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Software technical/functional description



System: Code: **SmartXIDE²**

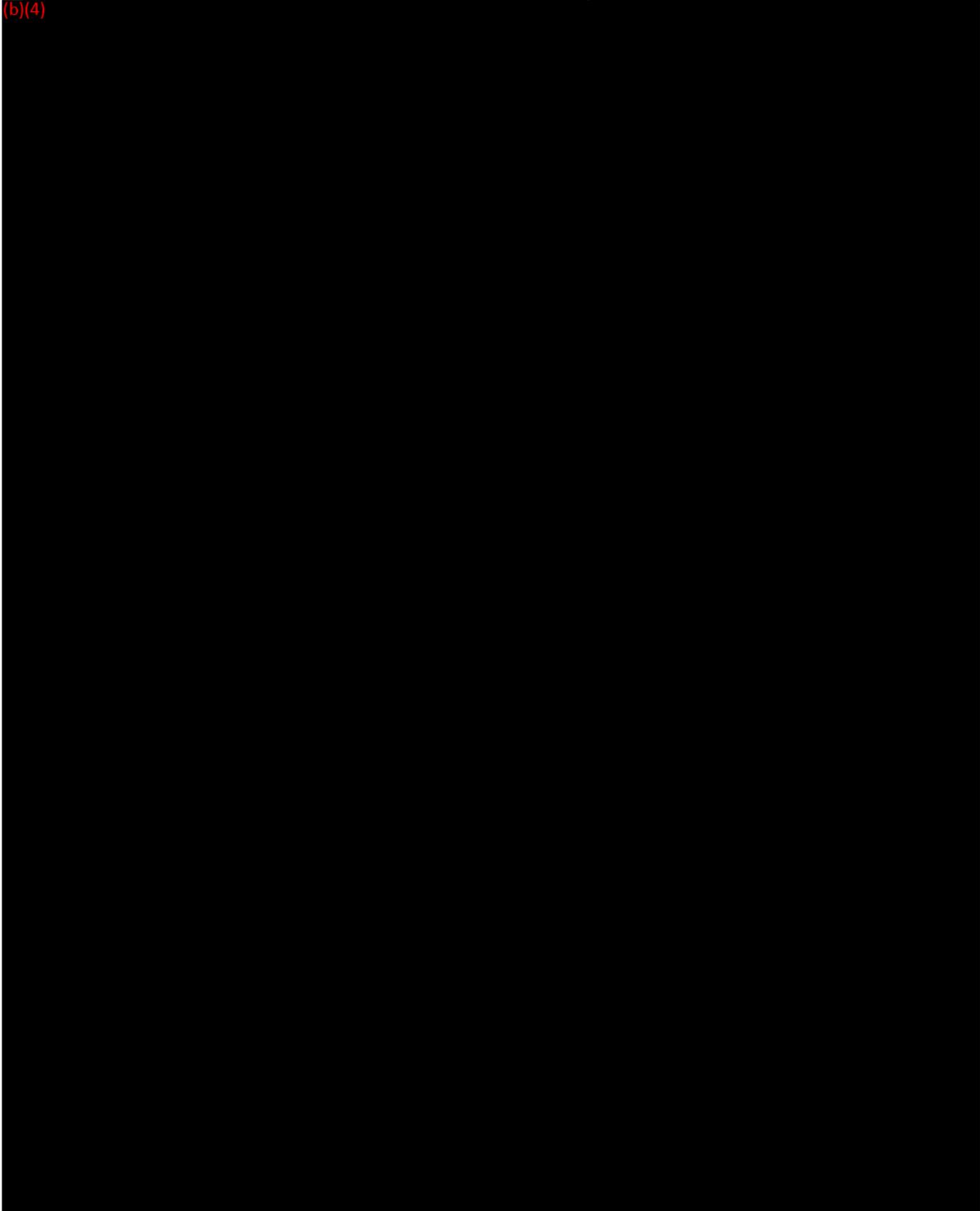
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Sw Rev (b) Date 20/11/13

Rev (b) (16/04/14)

(b)(4)



Software technical/functional description



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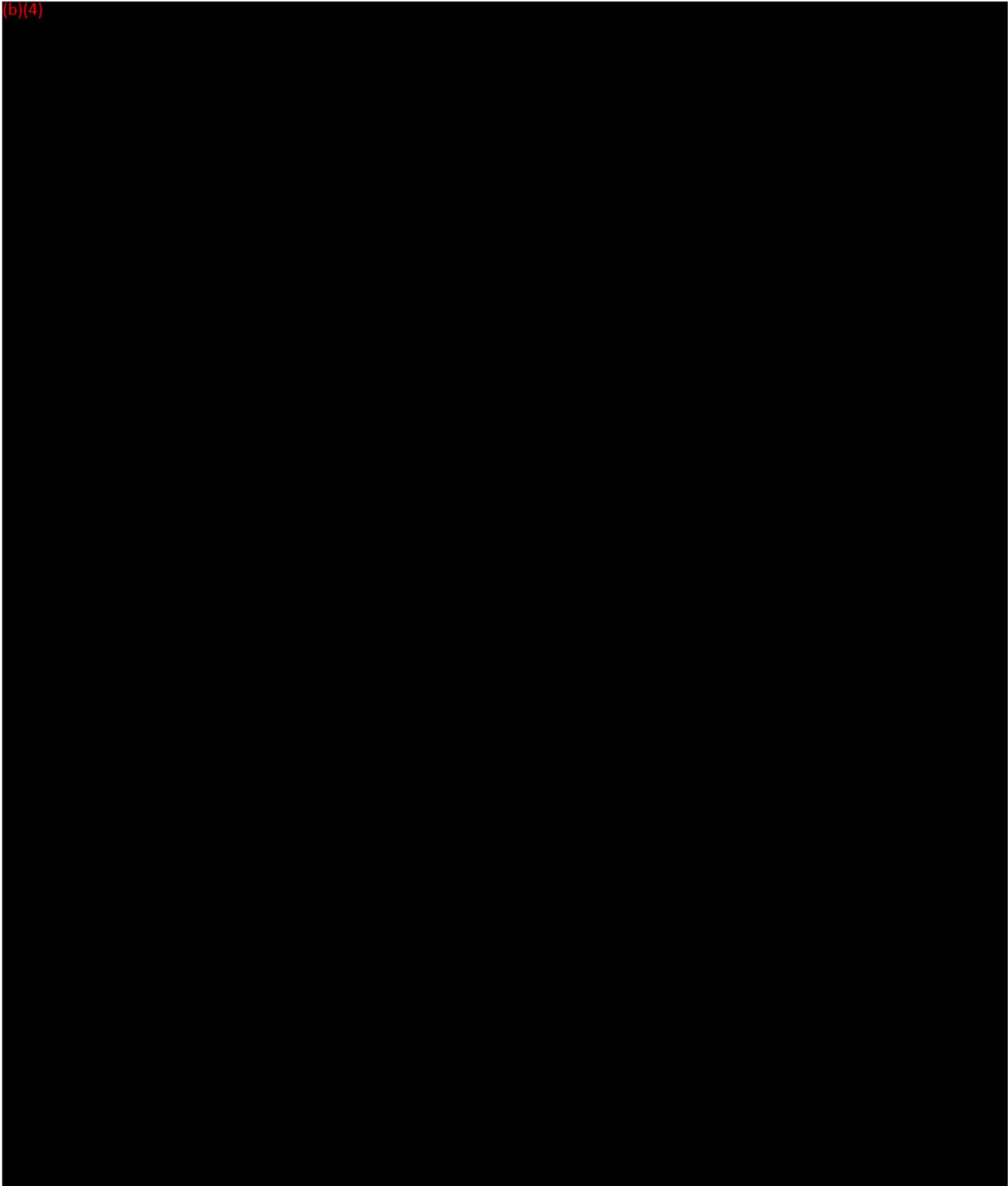
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Software code (b)(4)

Sw Rev (b) Date 20/11/13

Rev (b) 16/04/14

(b)(4)



Software technical/functional description



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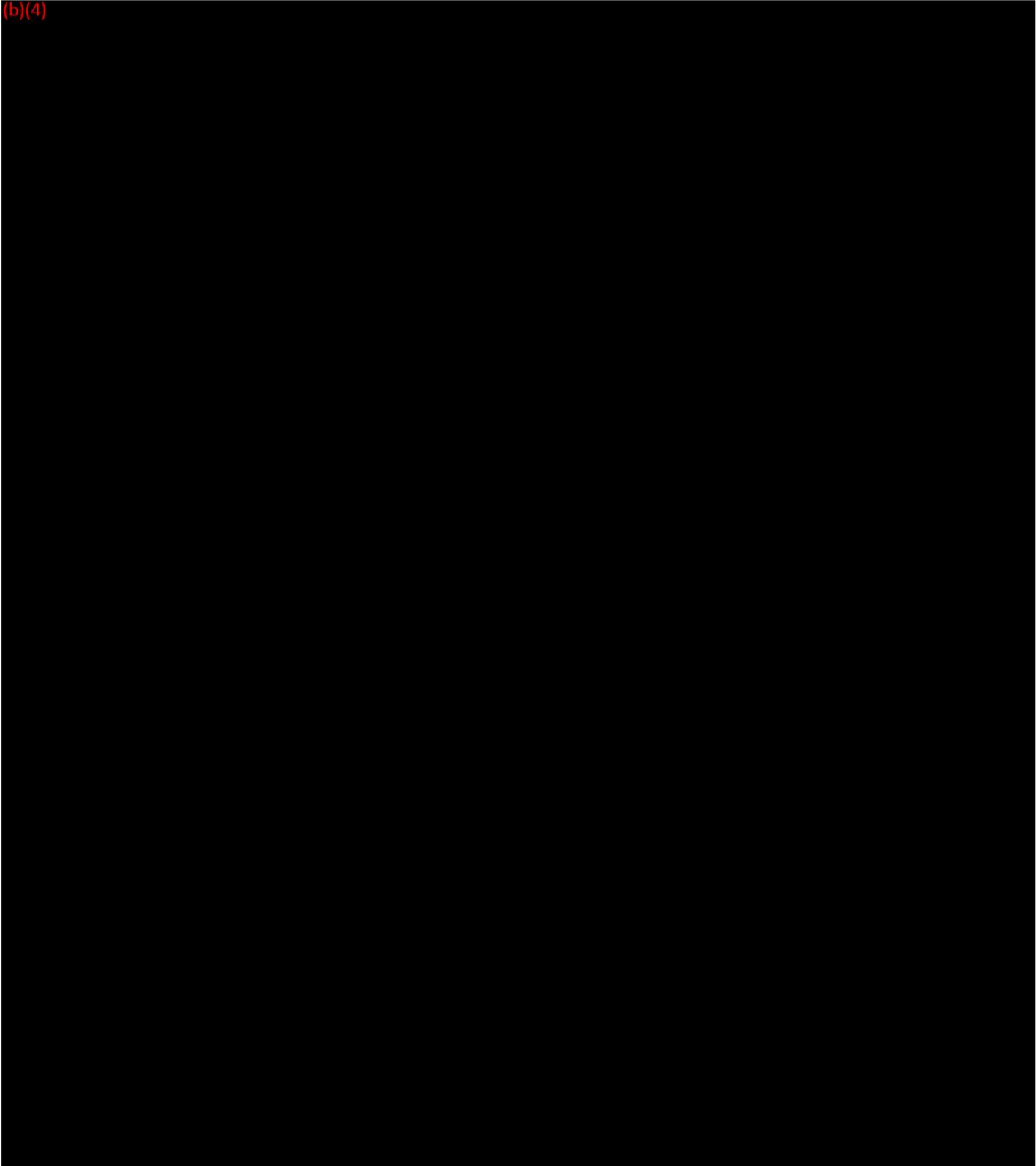
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Sw Rev (b) Date 20/11/13

Rev (b) (16/04/14)

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Software technical/functional description



System: Code: **SmartXIDE²**

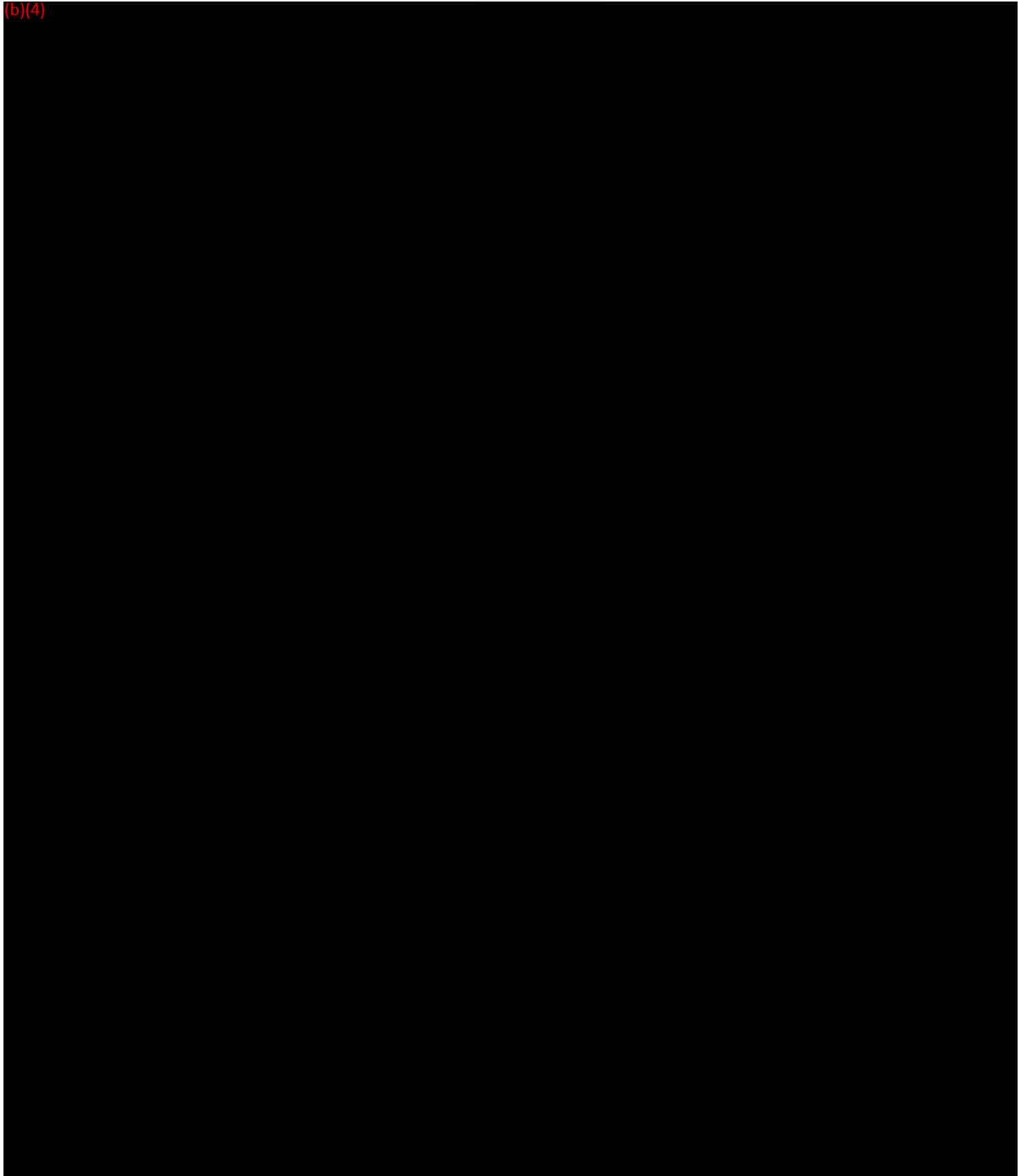
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Sw Rev (b) Date 20/11/13

Rev (b) (16/04/14)

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Software technical/functional description



System: Code: **SmartXIDE²**

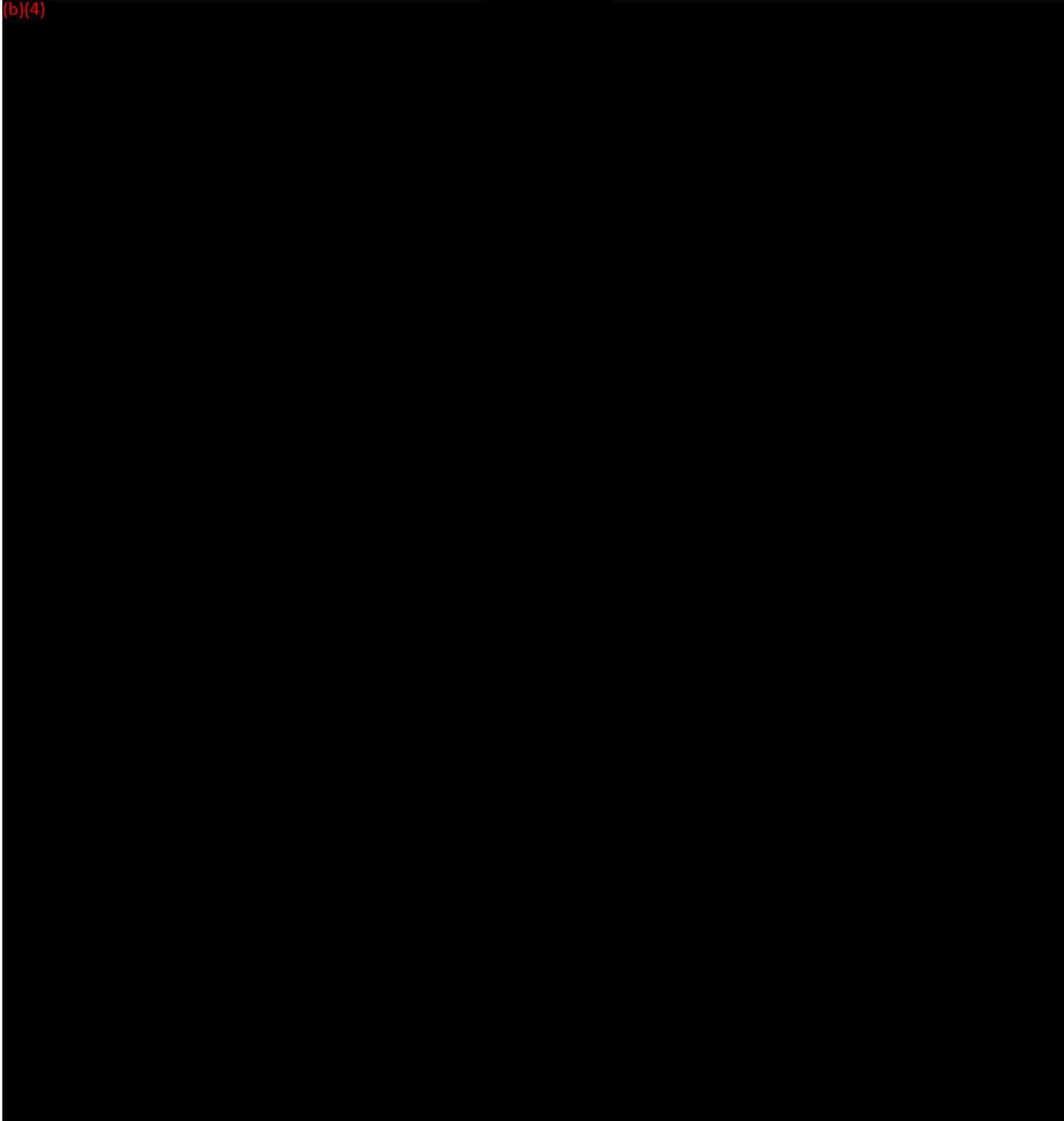
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Rev (b) 16/04/14

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Software technical/functional description



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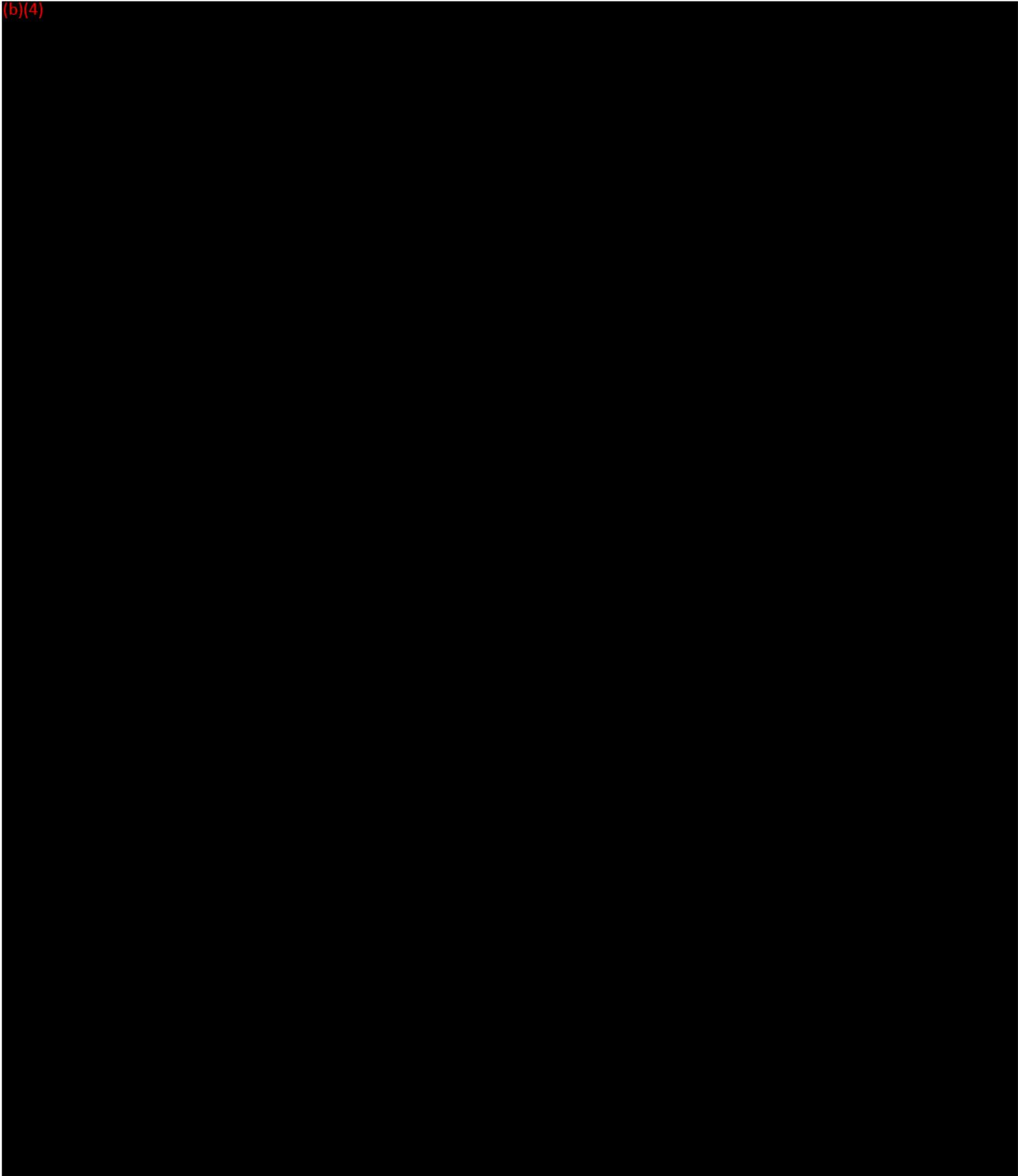
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Rev (b) (16/04/14)

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Software technical/functional description



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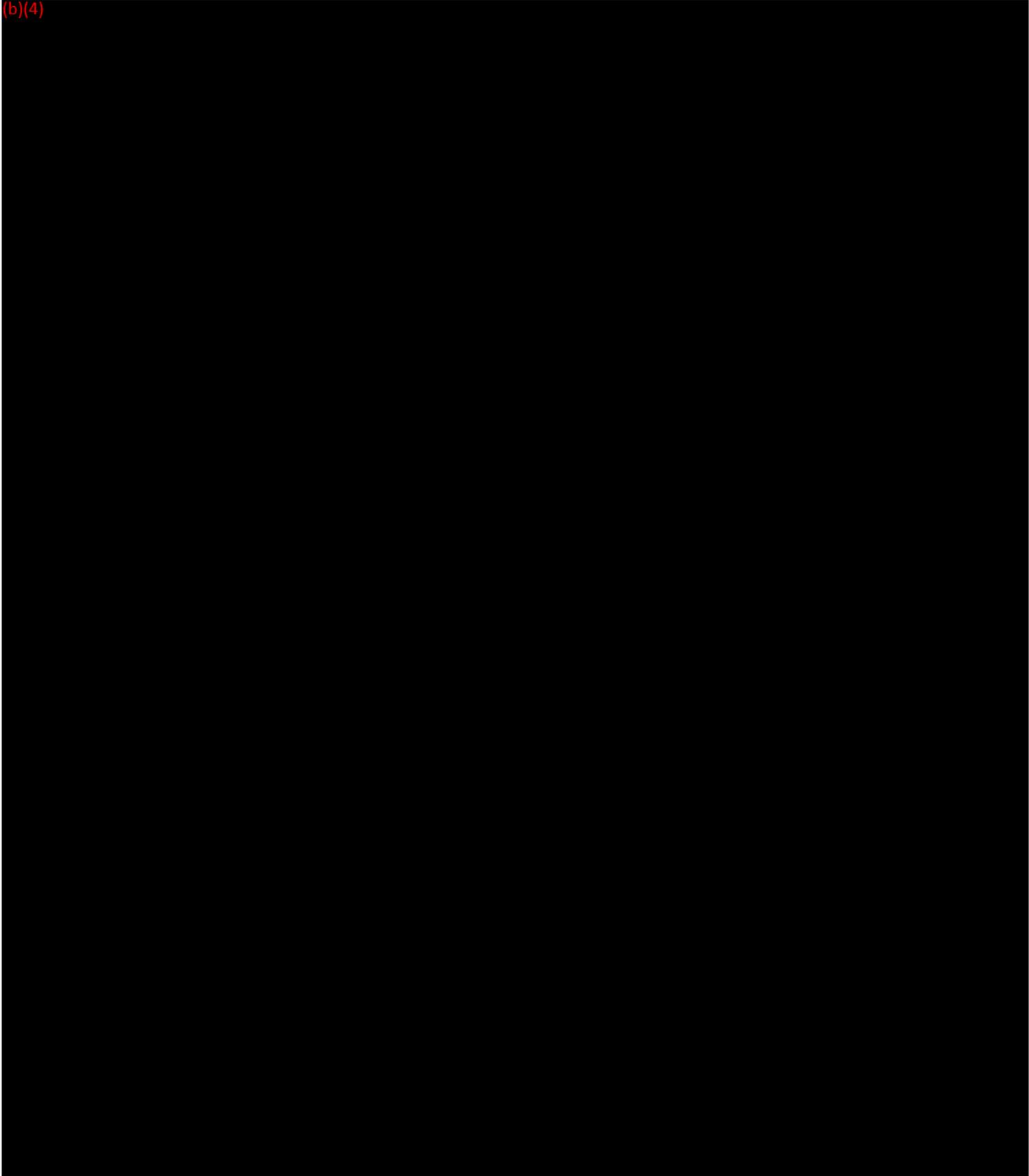
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Sw Rev () Date 20/11/13

Rev (b) (16/04/14)

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Software technical/functional description



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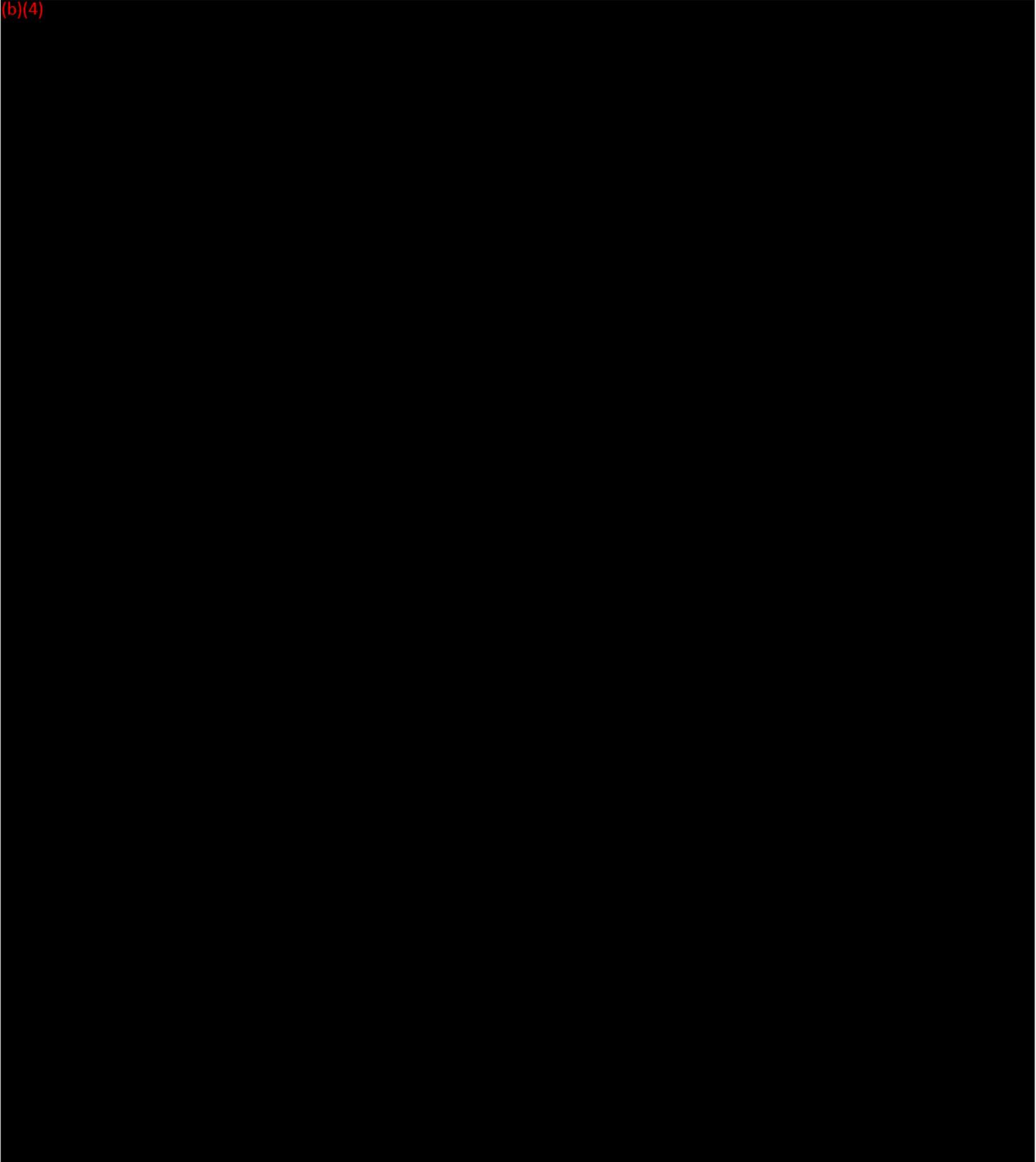
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Sw Rev (b) Date 20/11/13

Rev (b) 16/04/14

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Software technical/functional description



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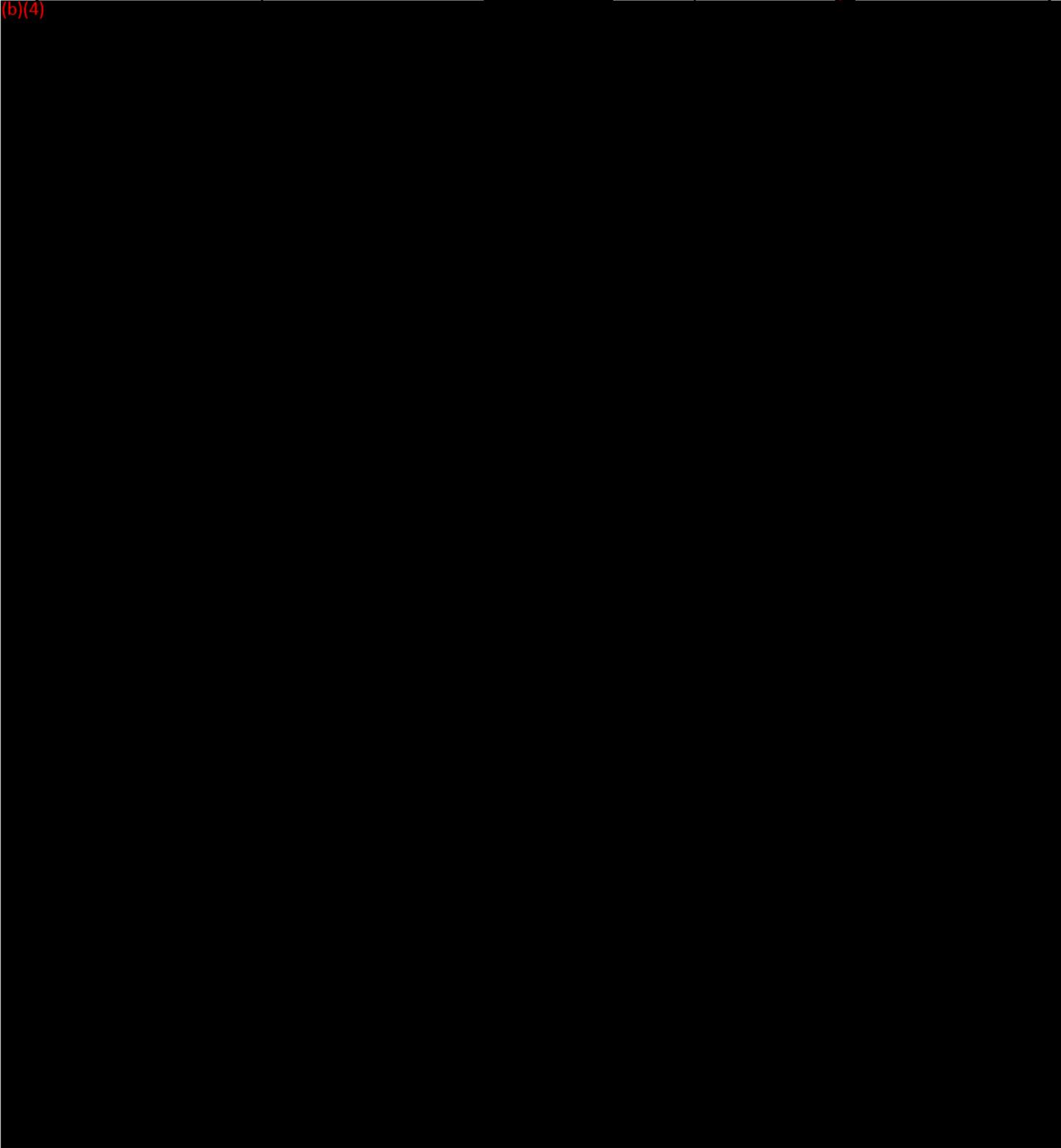
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Sw Rev (b) Date 20/11/13

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Software technical/functional description



System: Code: **SmartXIDE²**

M103x1

Software code: (b)(4)

Sw Rev (b) Date 20/11/13

Rev (b) (16/04/14)

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Software technical/functional description



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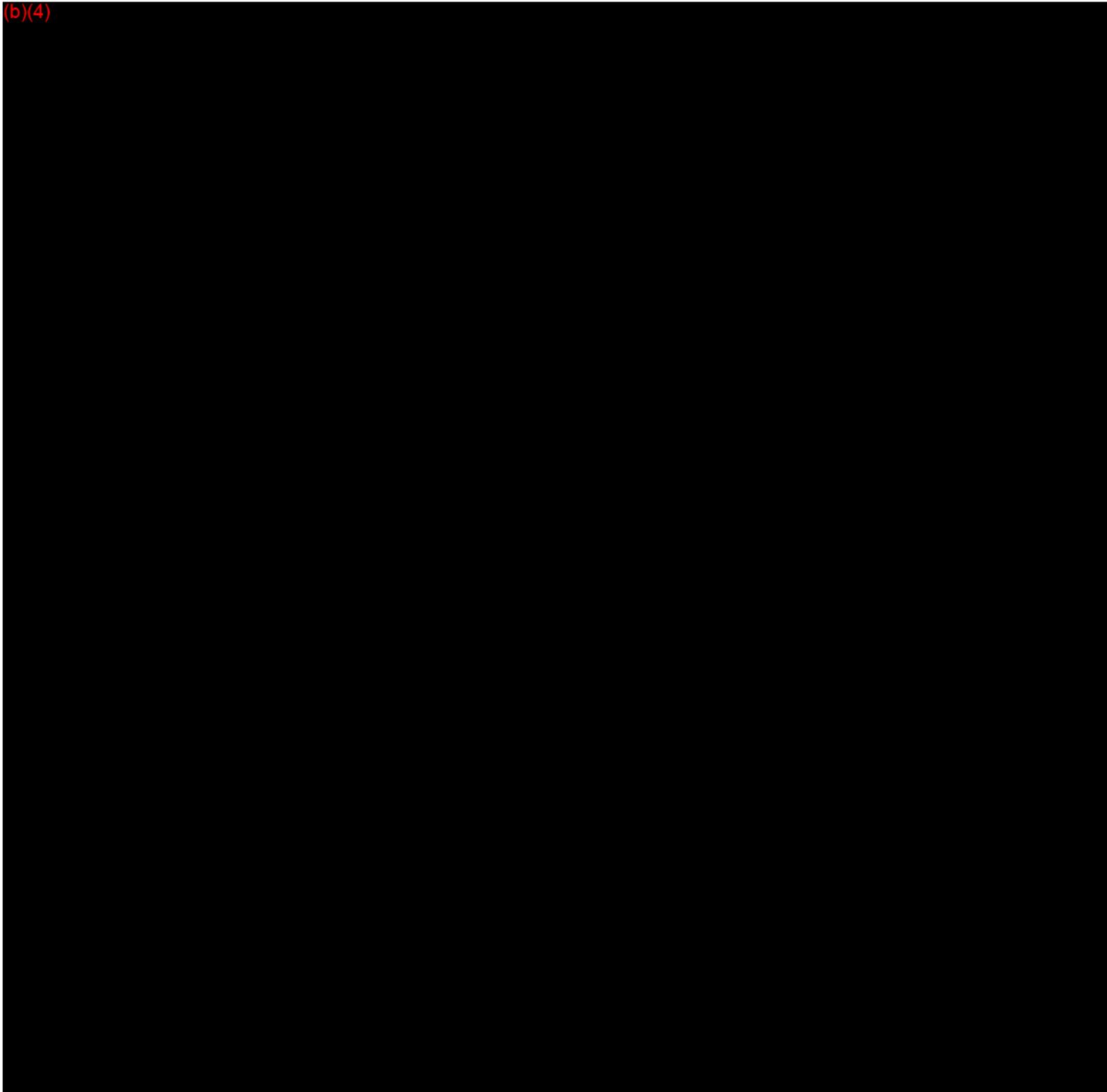
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Sw Rev (b) Date 20/11/13

Rev (b) (16/04/14)

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Software technical/functional description



System: Code: **SmartXIDE²**

M103x1

Software code: (b)(4)

Sw Rev (b) Date 20/11/13

Rev (b)(4) /04/14

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Software technical/functional description



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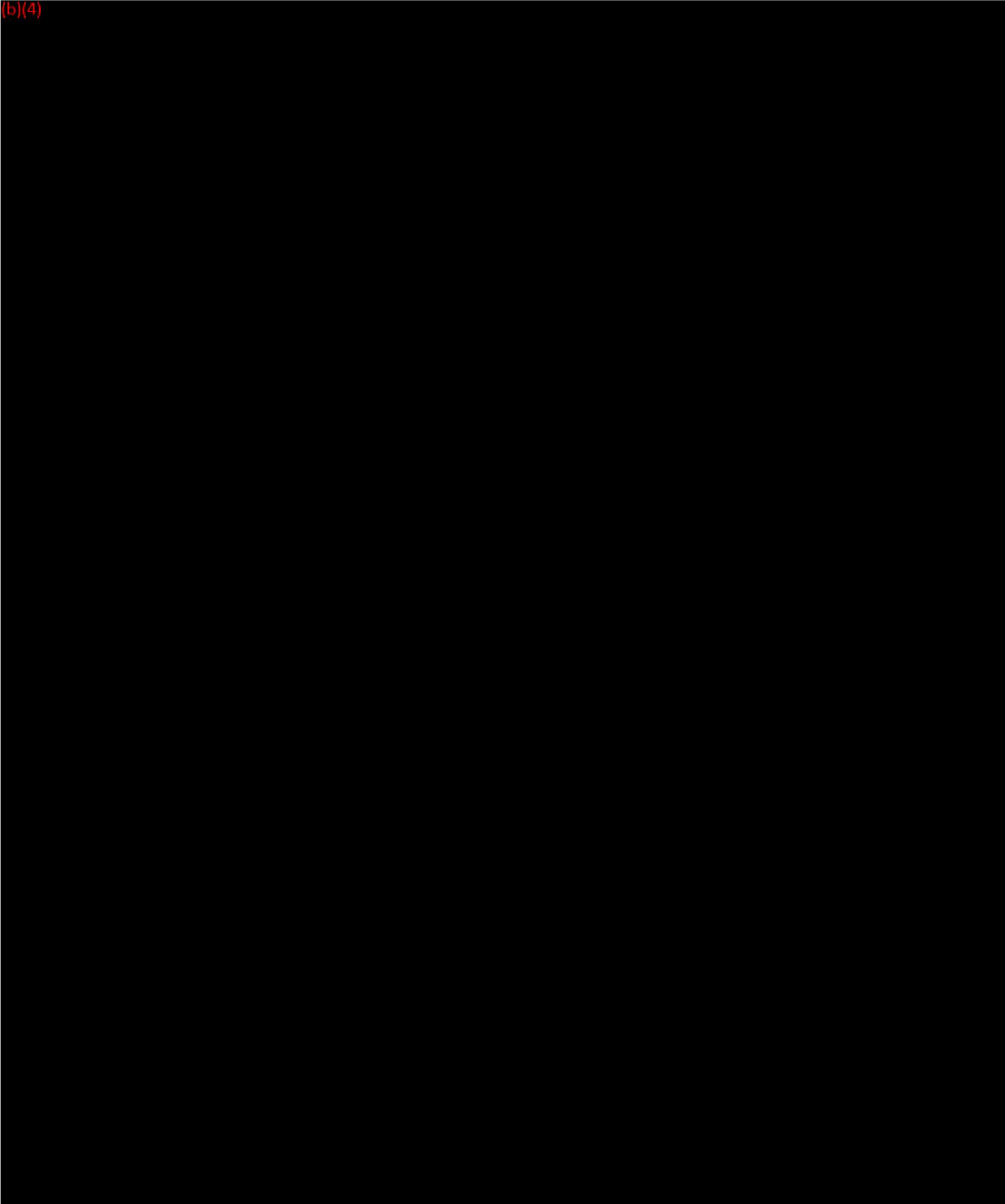
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Software code: (b)(4)

Sw Rev (b) Date 20/11/13

Rev (b) (16/04/14)

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Software technical/functional description



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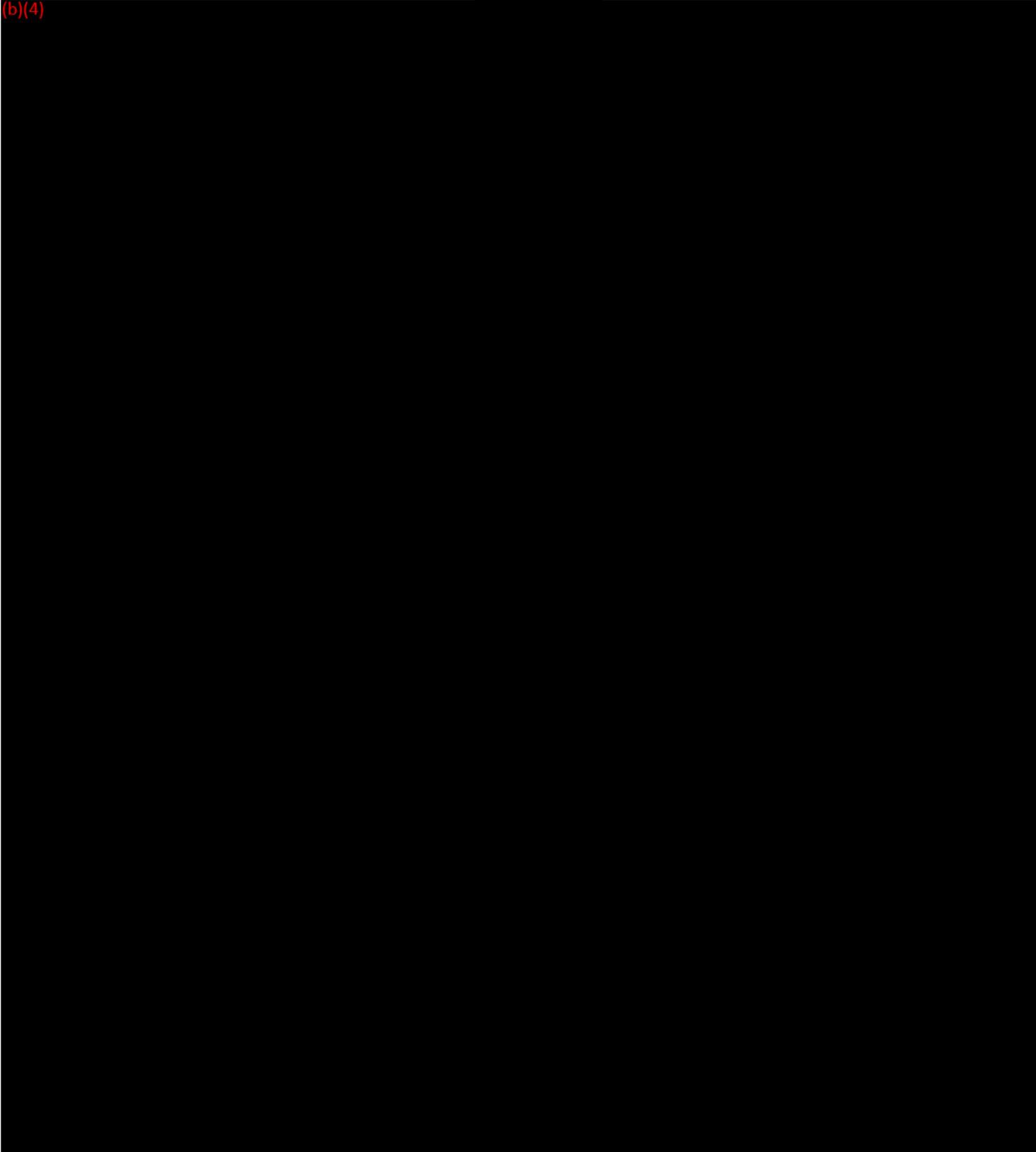
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Rev (b) (16/04/14)

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Software technical/functional description



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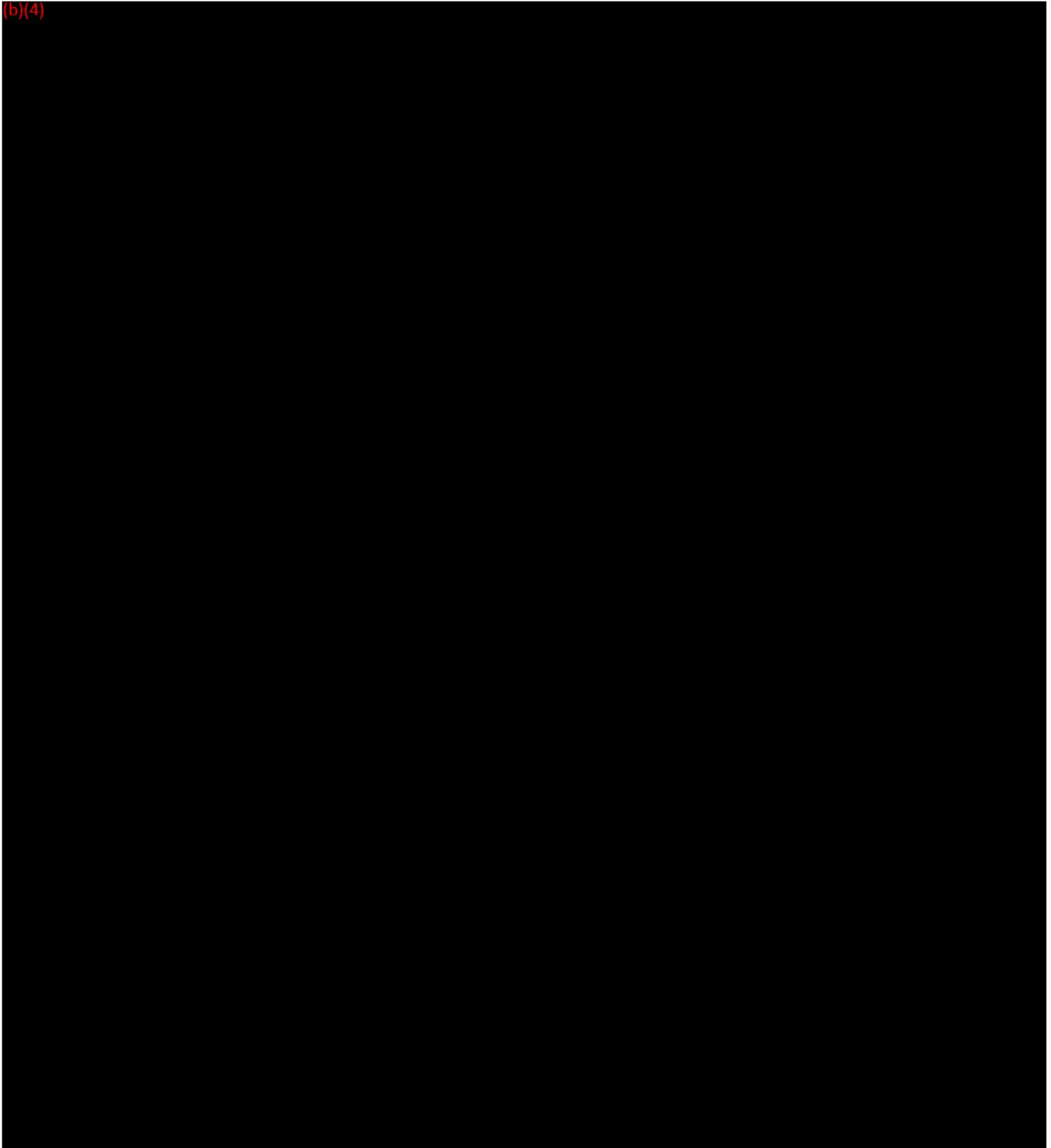
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Software code: (b)(4)

Sw Rev (b) Date 20/11/13

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Software technical/functional description



System: Code: **SmartXIDE²**

M103x1

Software code: (b)(4)

Sw Rev (b) Date 20/11/13

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Software technical/functional description



System: Code: **SmartXIDE²**

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Software code: (b)(4)

Sw Rev (b) Date 20/11/13
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Software technical/functional description



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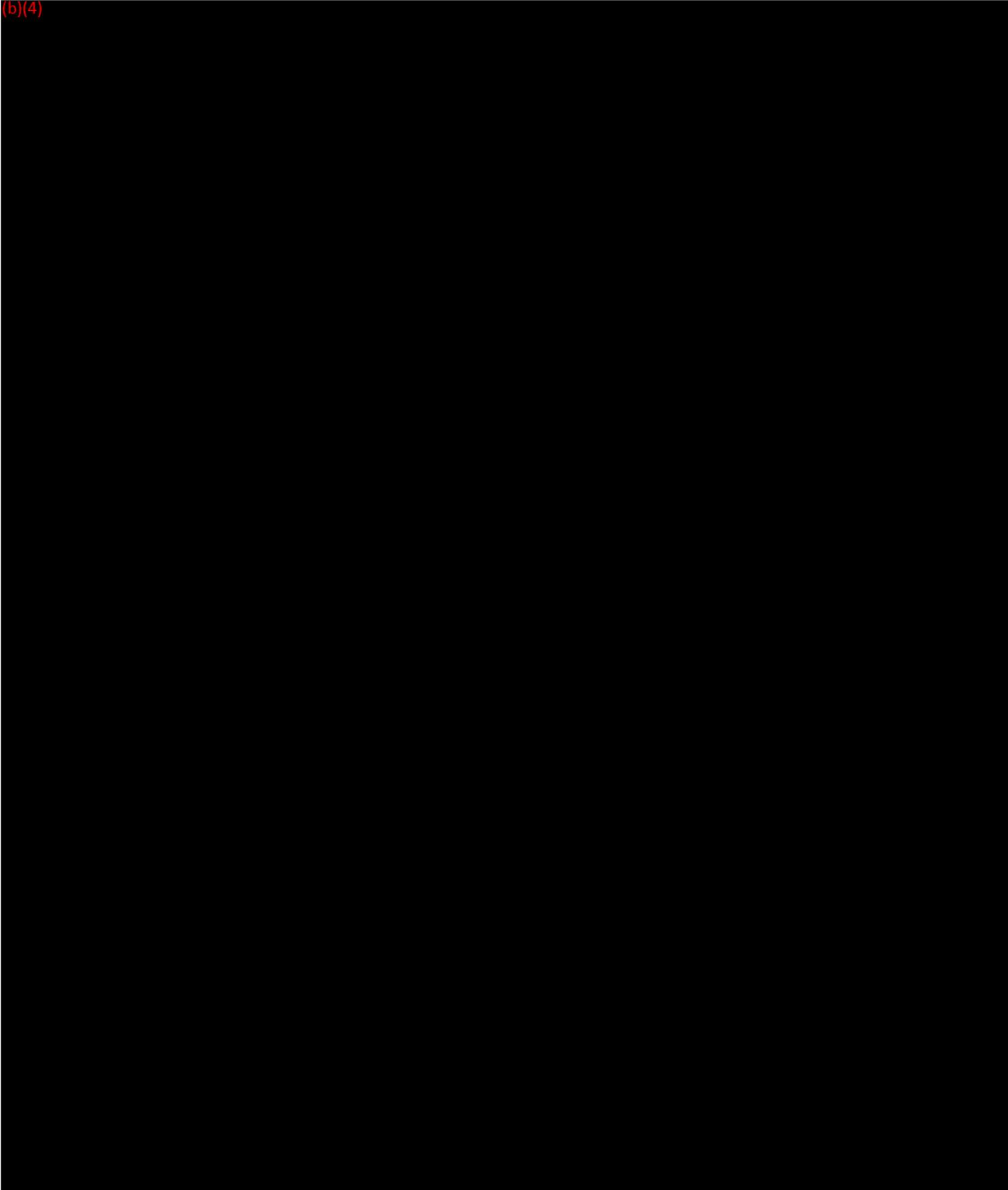
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Software code: (b)(4)

Sw Rev (b) Date 20/11/13

Rev (b) (16/04/14)

(b)(4)



Software technical/functional description



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M103x1

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Software technical/functional description



System: Code: **SmartXIDE²**

M103x1

Software code: (b)(4)

Sw Rev (b) Date 20/11/13

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SOFTWARE DOCUMENTATION
SMARTXIDE²

Date: 23/04/2014

Rev. (b)

ENCLOSURE 4

SOFTWARE DESIGN SPECIFICATION
Document([REDACTED]



Module (b)(4) SOFTWARE DESIGN SPECIFICATION

Date 02/04/2014

Rev (b)

Project name: **SmartXIDE²**

Project #: (b)(4)

DESIGN SPECIFICATIONS

VERIFICATION REPORT

(b)(4)

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(b)(4)



Module (b)(4) SOFTWARE DESIGN SPECIFICATION

Date 02/04/2014

Rev (b)

Project name: **SmartXIDE²**

Project #: (b)(4)

PART I: HARDWARE and PROGRAMMING LANGUAGE SPECIFICATIONS

(b)(4)



Module (b)(4) SOFTWARE DESIGN SPECIFICATION

Date 02/04/2014
Rev (b)

Project name: **SmartXIDE²**

Project #: (b)(4)

PART II: SYSTEM START UP AND GENERAL FUNCTIONAL SPECIFICATIONS

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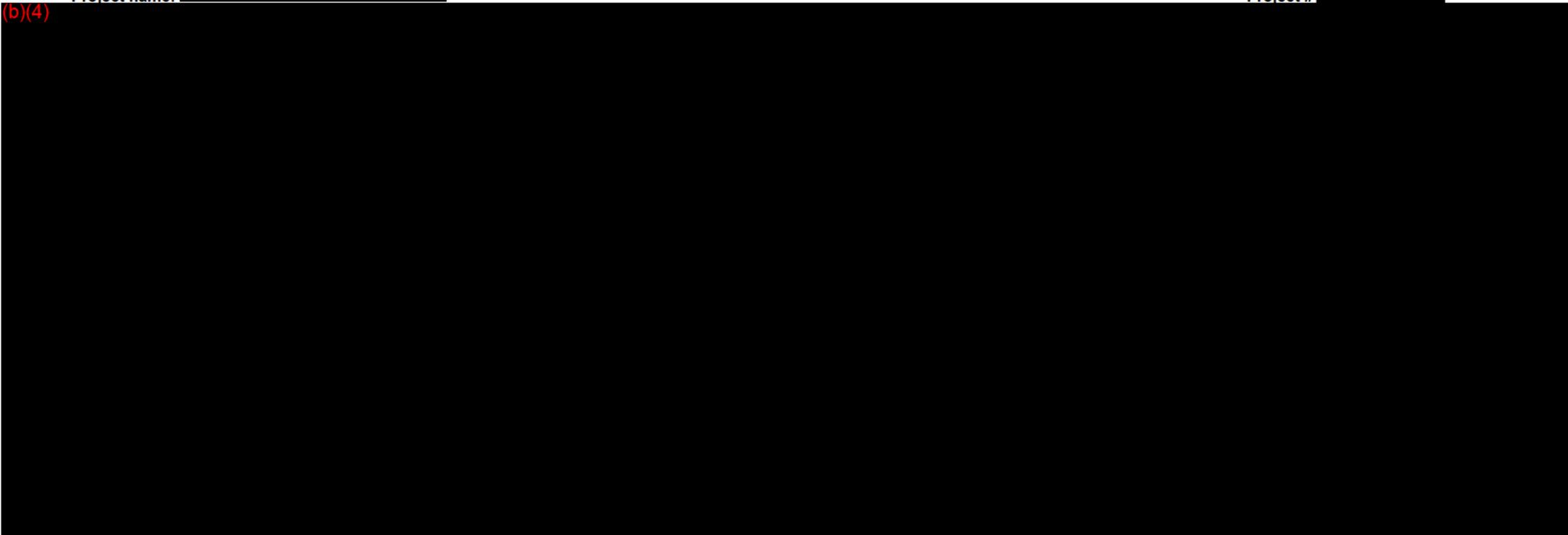
Module (b)(4) SOFTWARE DESIGN SPECIFICATION

Date 02/04/2014
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SmartXIDE²

Project name:

Project #



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Module (b)(4) SOFTWARE DESIGN SPECIFICATION

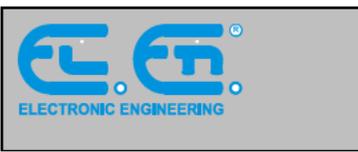
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Project name: **SmartXIDE²**

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PART III: USER ADJUSTABLE PARAMETERS SPECIFICATIONS

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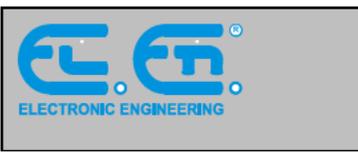
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Date 02/04/2014
Rev (b)

Project name: **SmartXIDE²**

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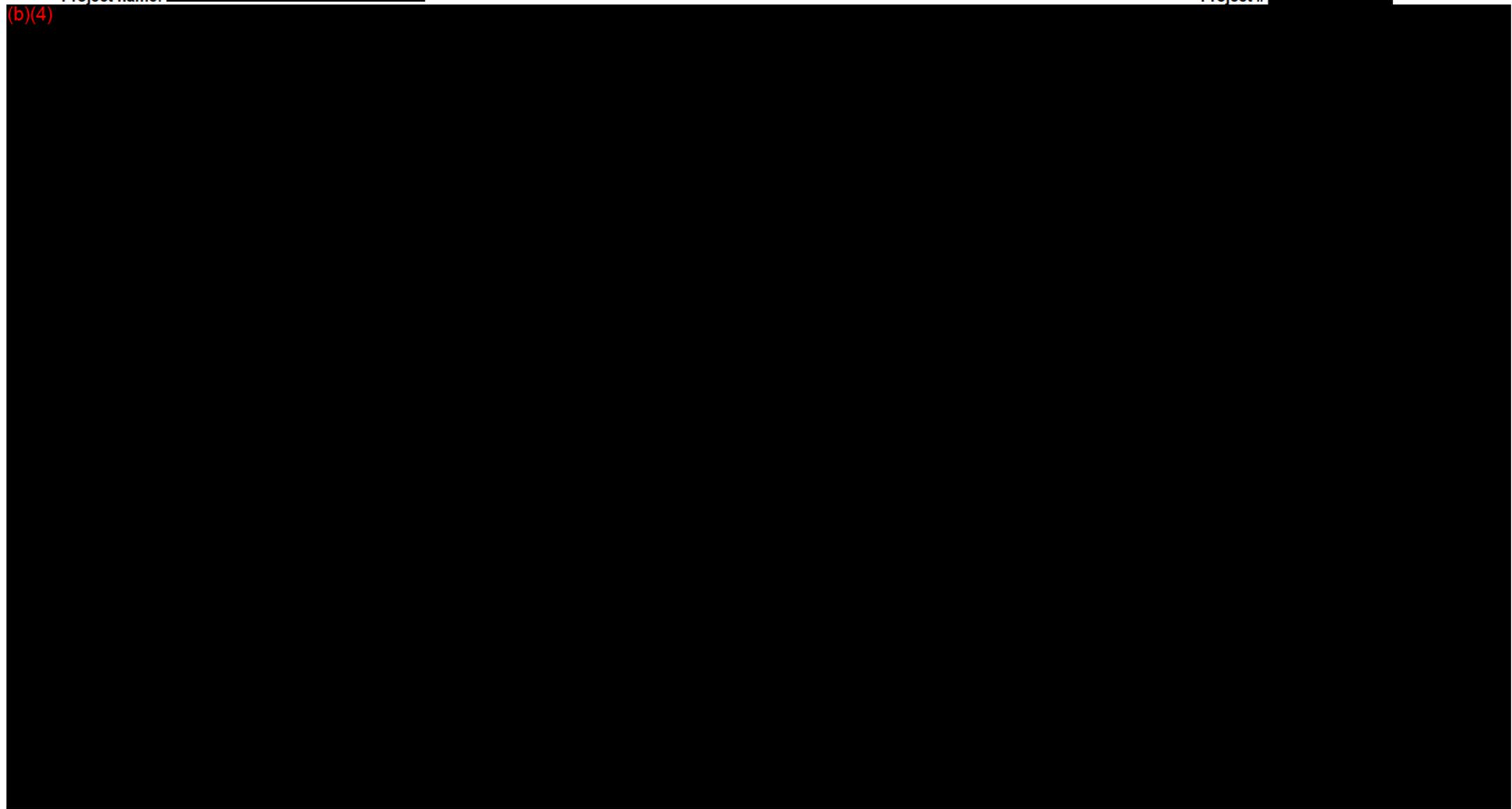


Module (b)(4) SOFTWARE DESIGN SPECIFICATION

Date 02/04/2014
Rev (b)

Project name: SmartXIDE²

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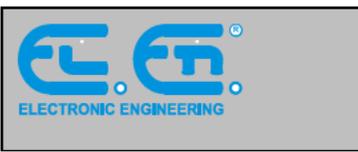
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Project name: **SmartXIDE²**

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Module (b)(4) SOFTWARE DESIGN SPECIFICATION

Date 02/04/2014
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Project name: SmartXIDE²

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PART IV: (b)(4) SPECIFICATIONS





Module (b)(4) SOFTWARE DESIGN SPECIFICATION

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Project name: SmartXIDE²

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Module (b)(4) SOFTWARE DESIGN SPECIFICATION

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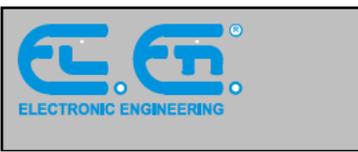
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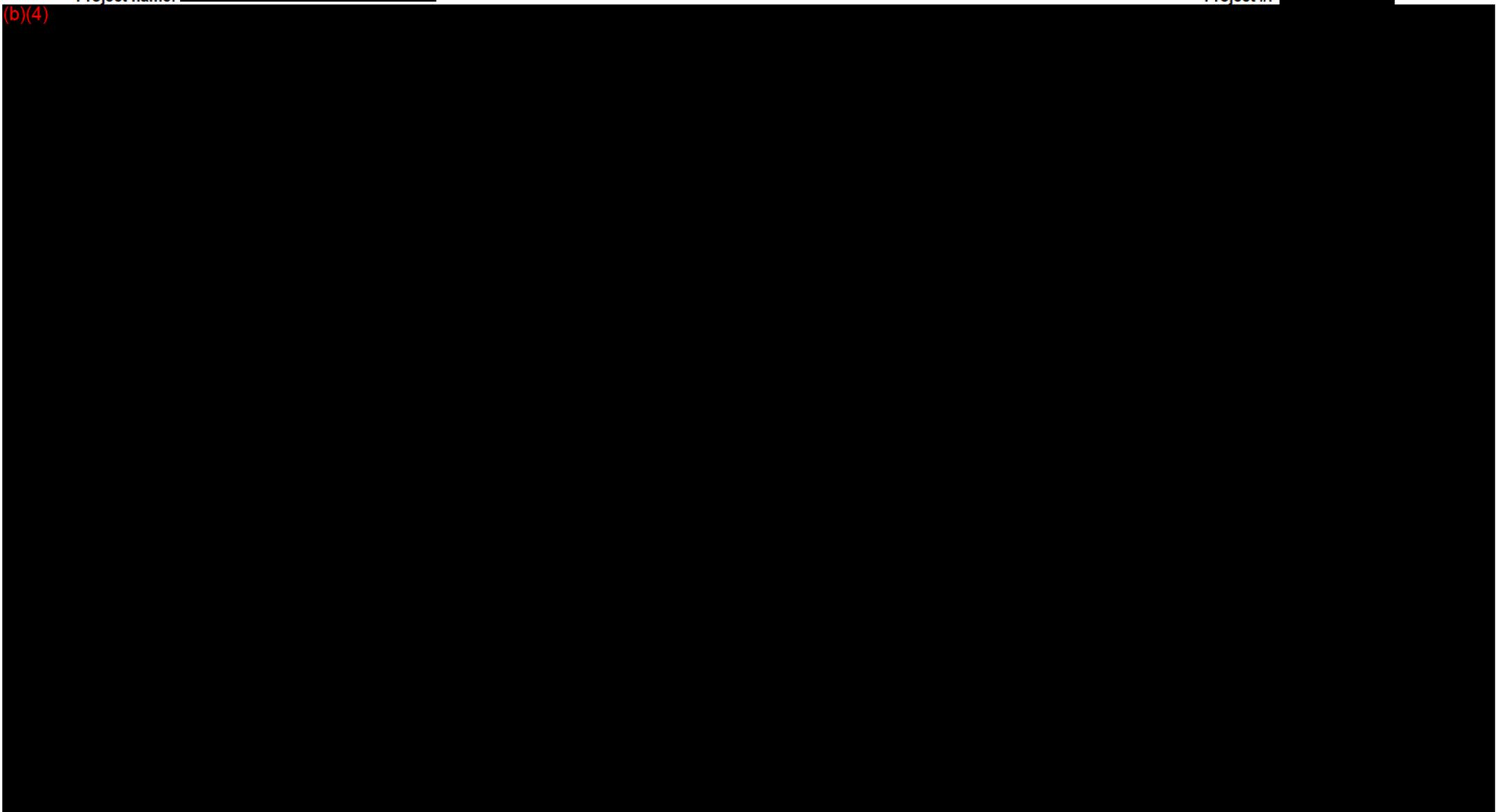


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PART V: USER INTERFACE SPECIFICATIONS

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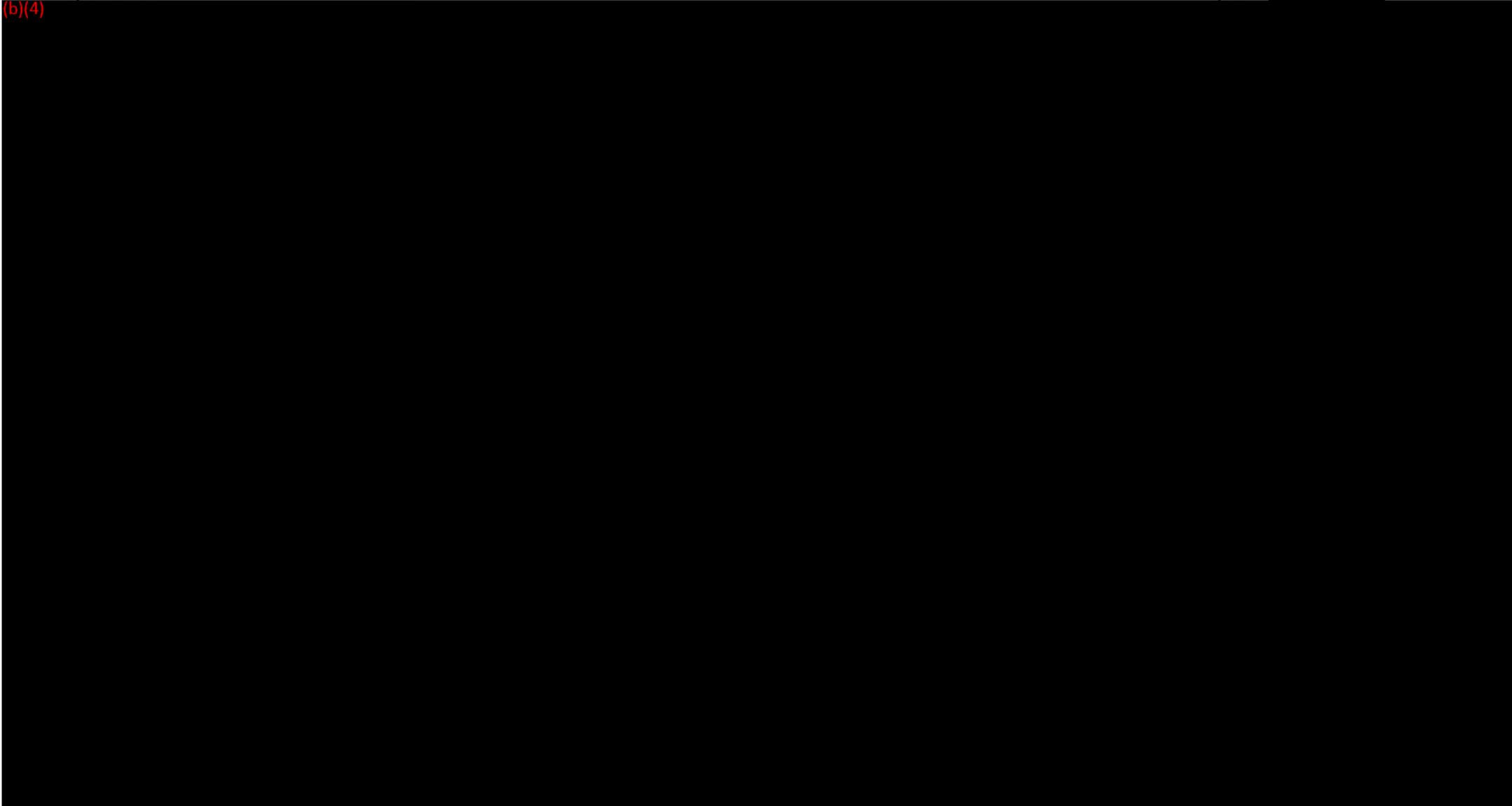


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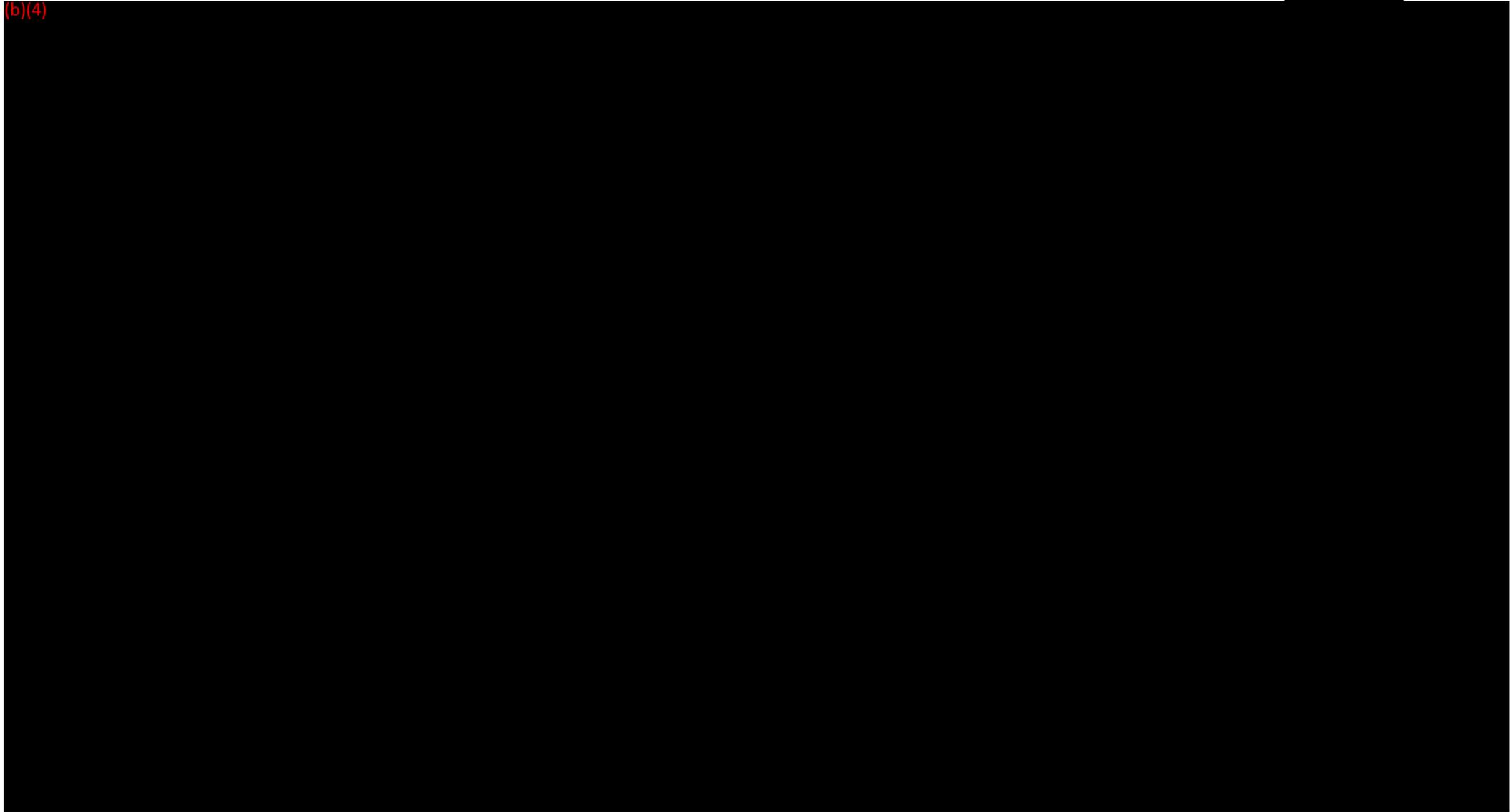
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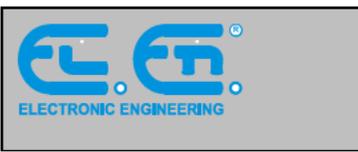
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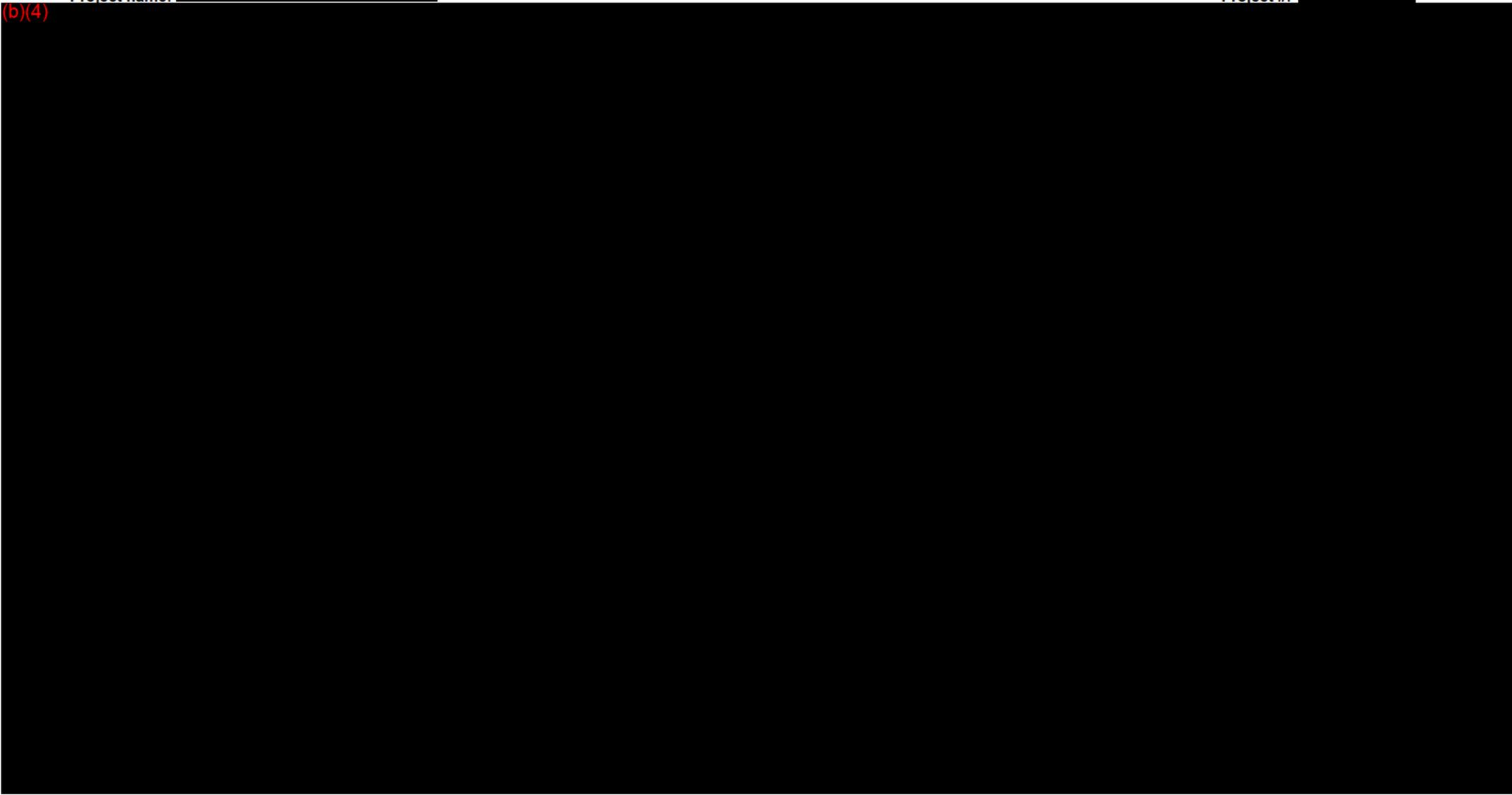
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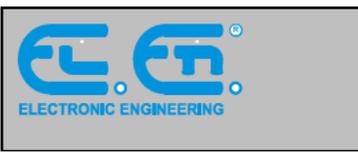
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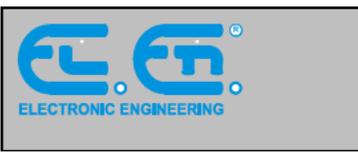
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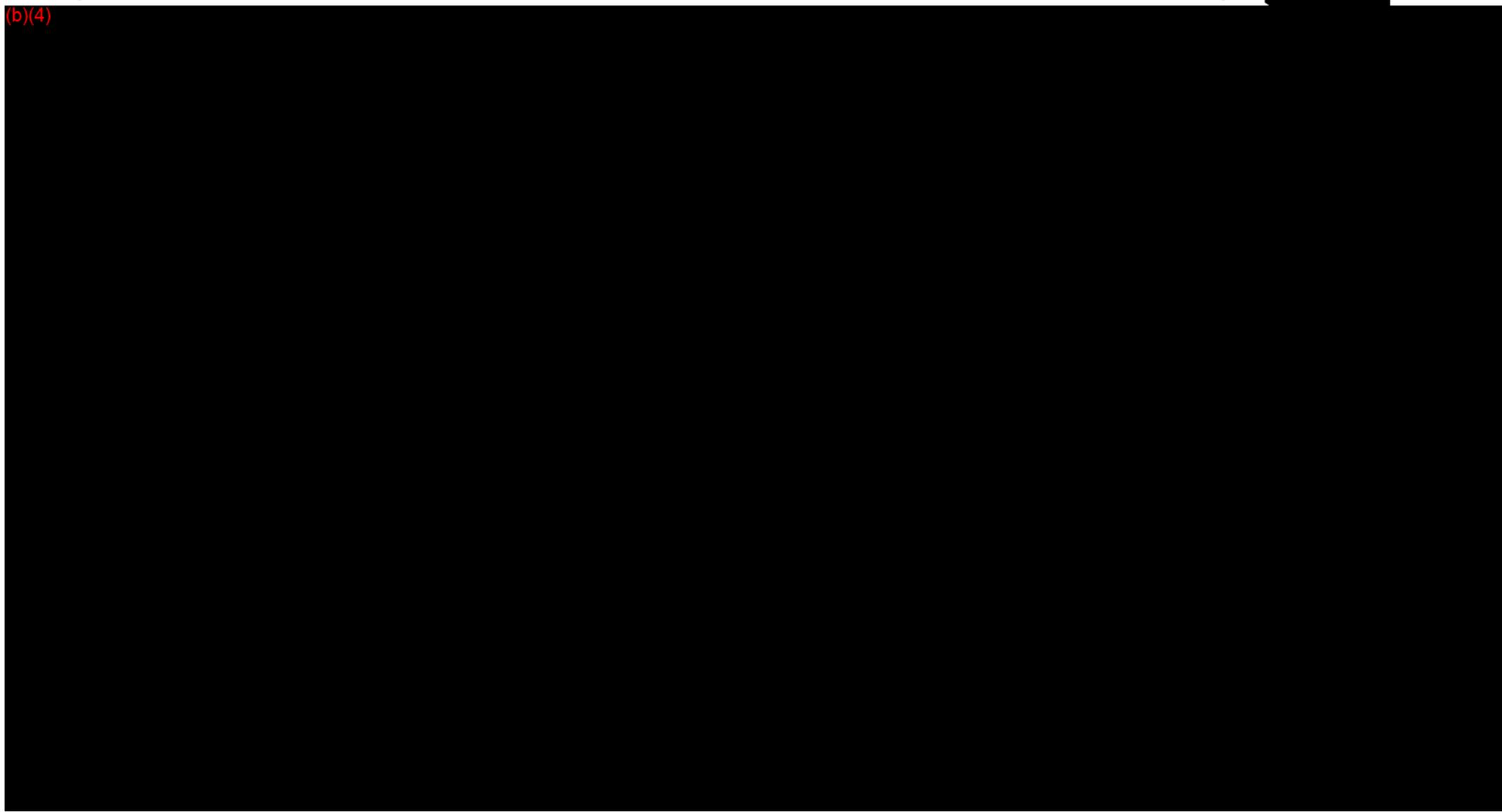


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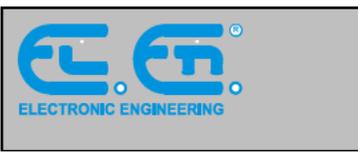
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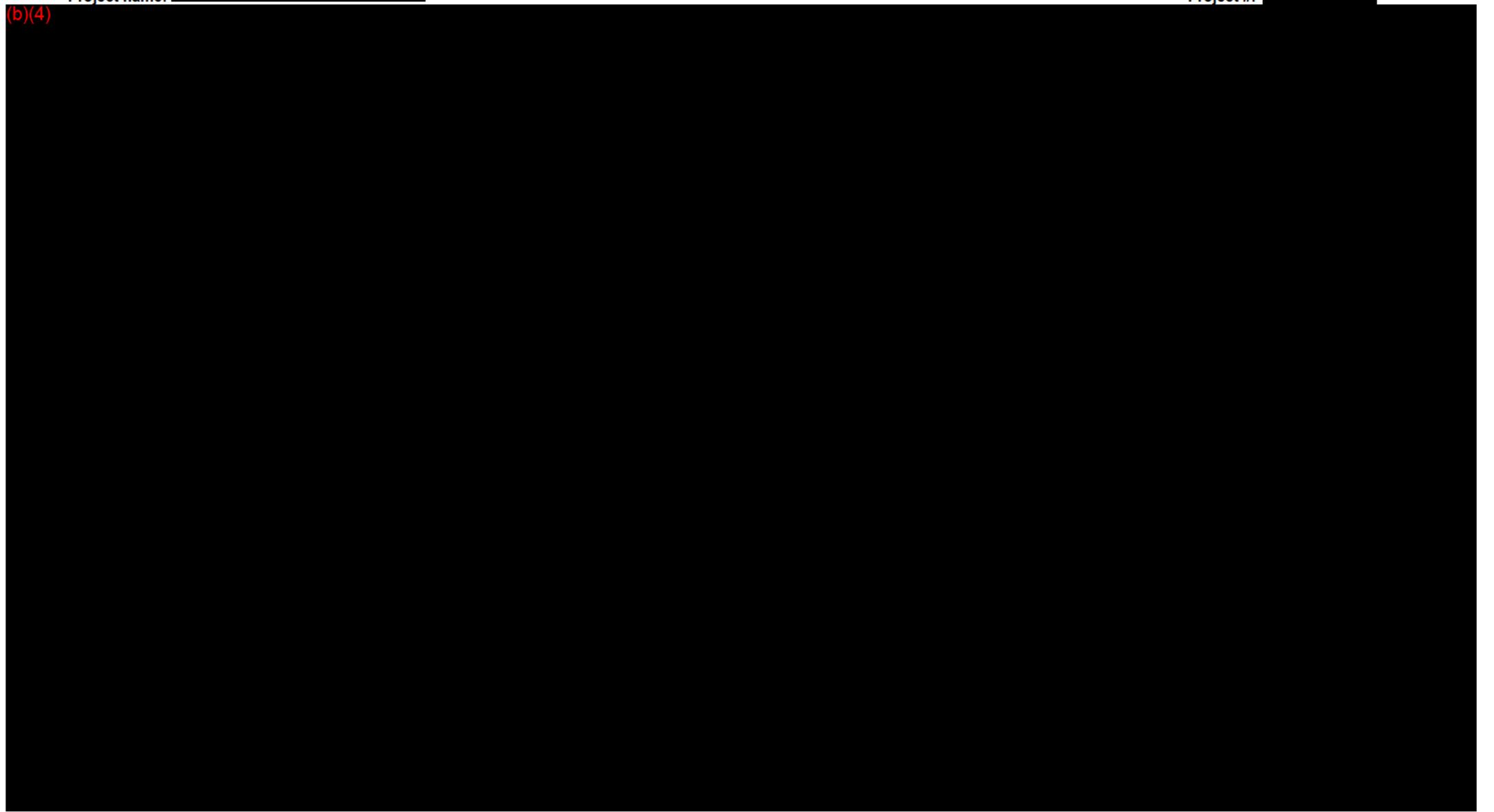


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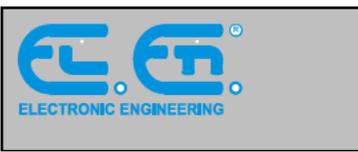
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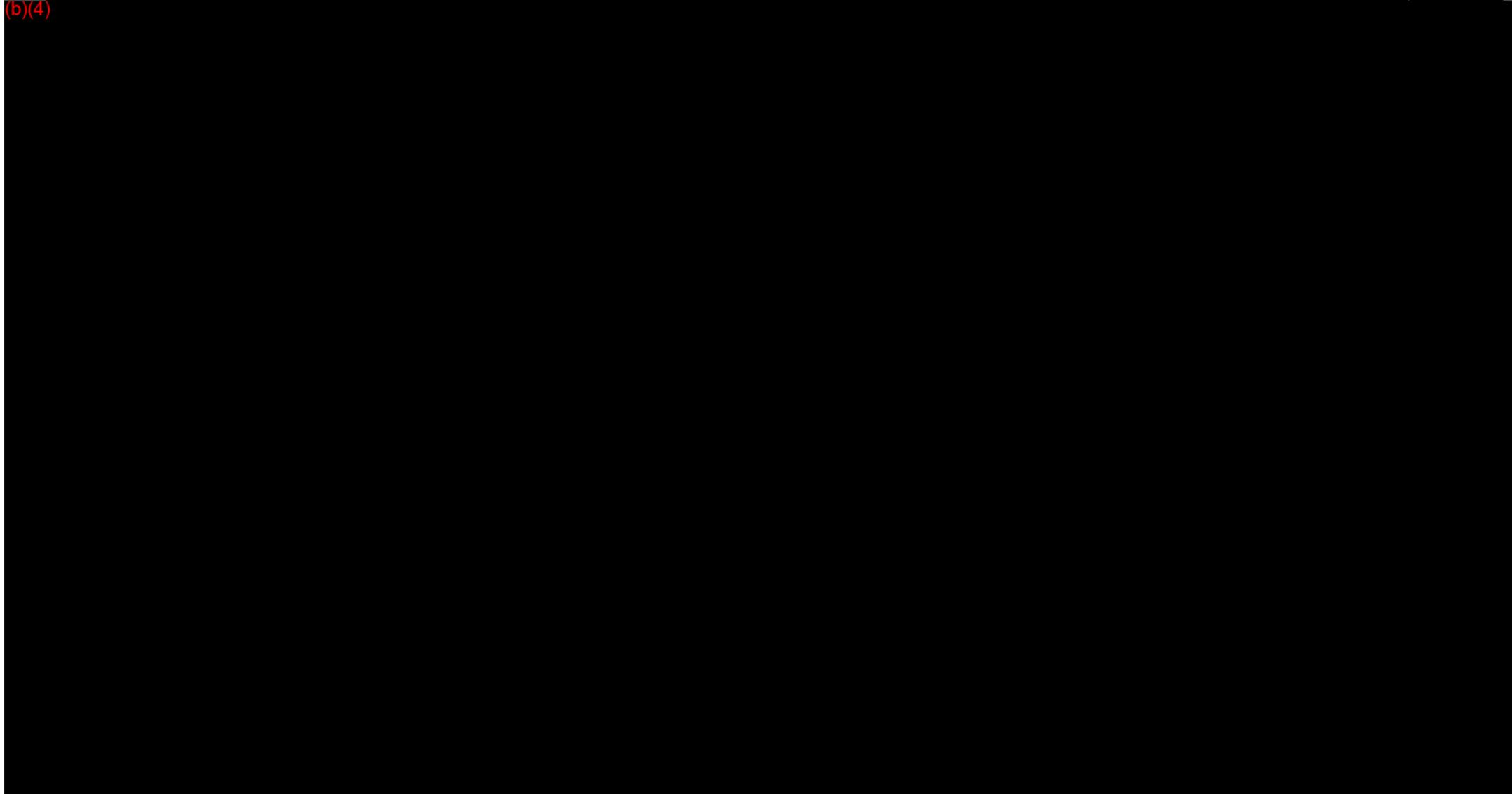
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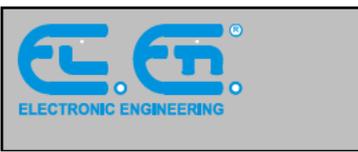
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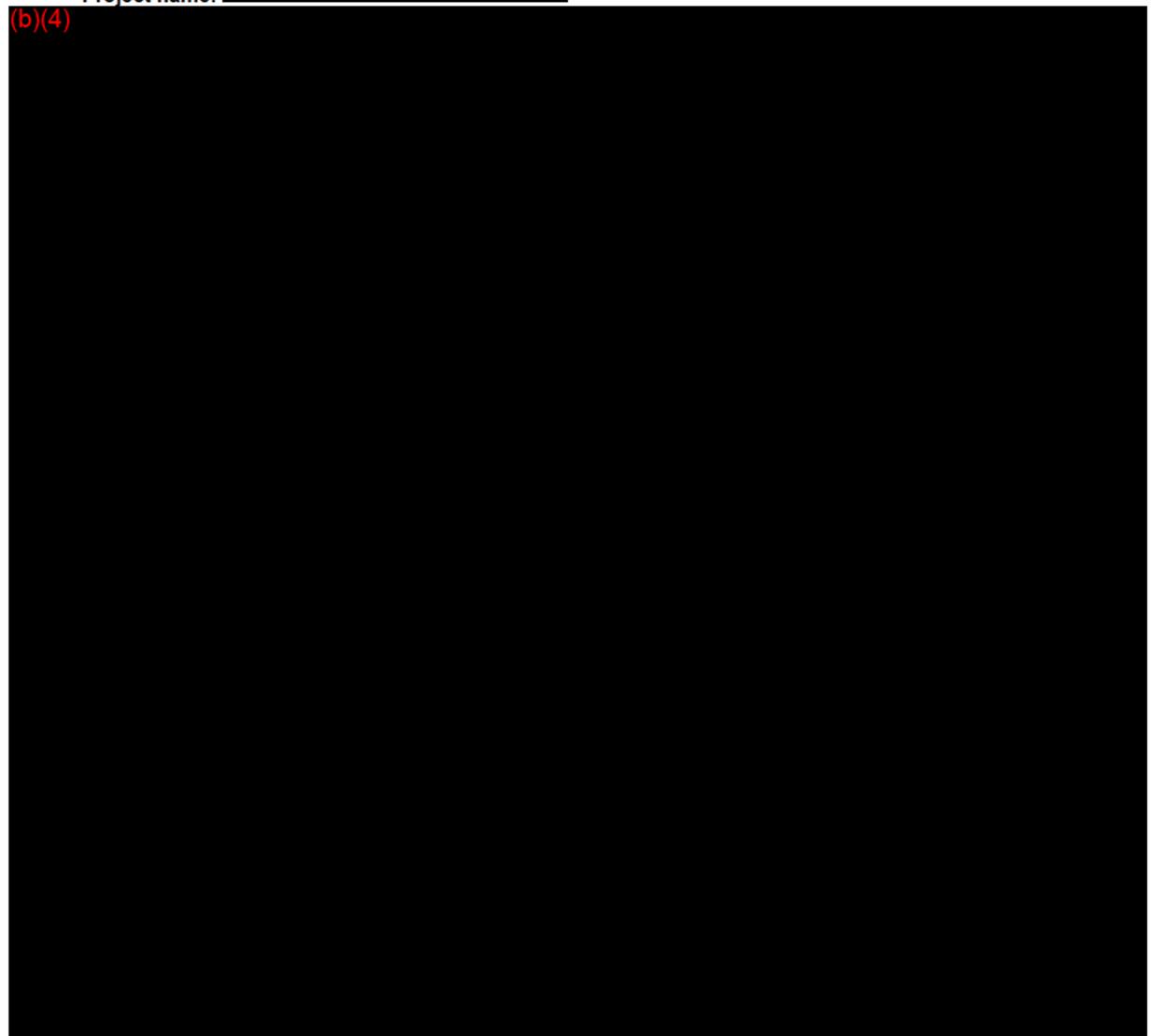


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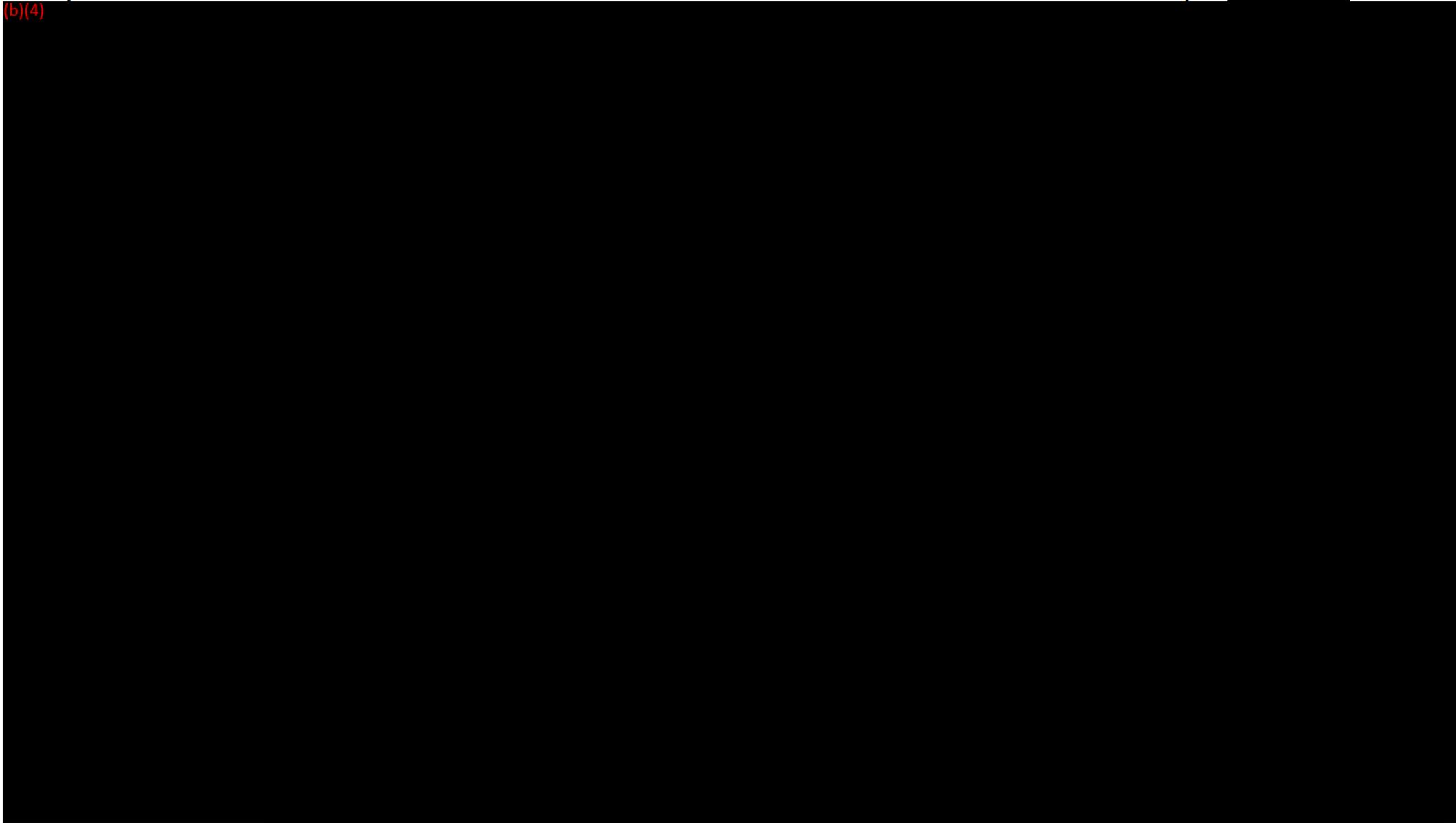


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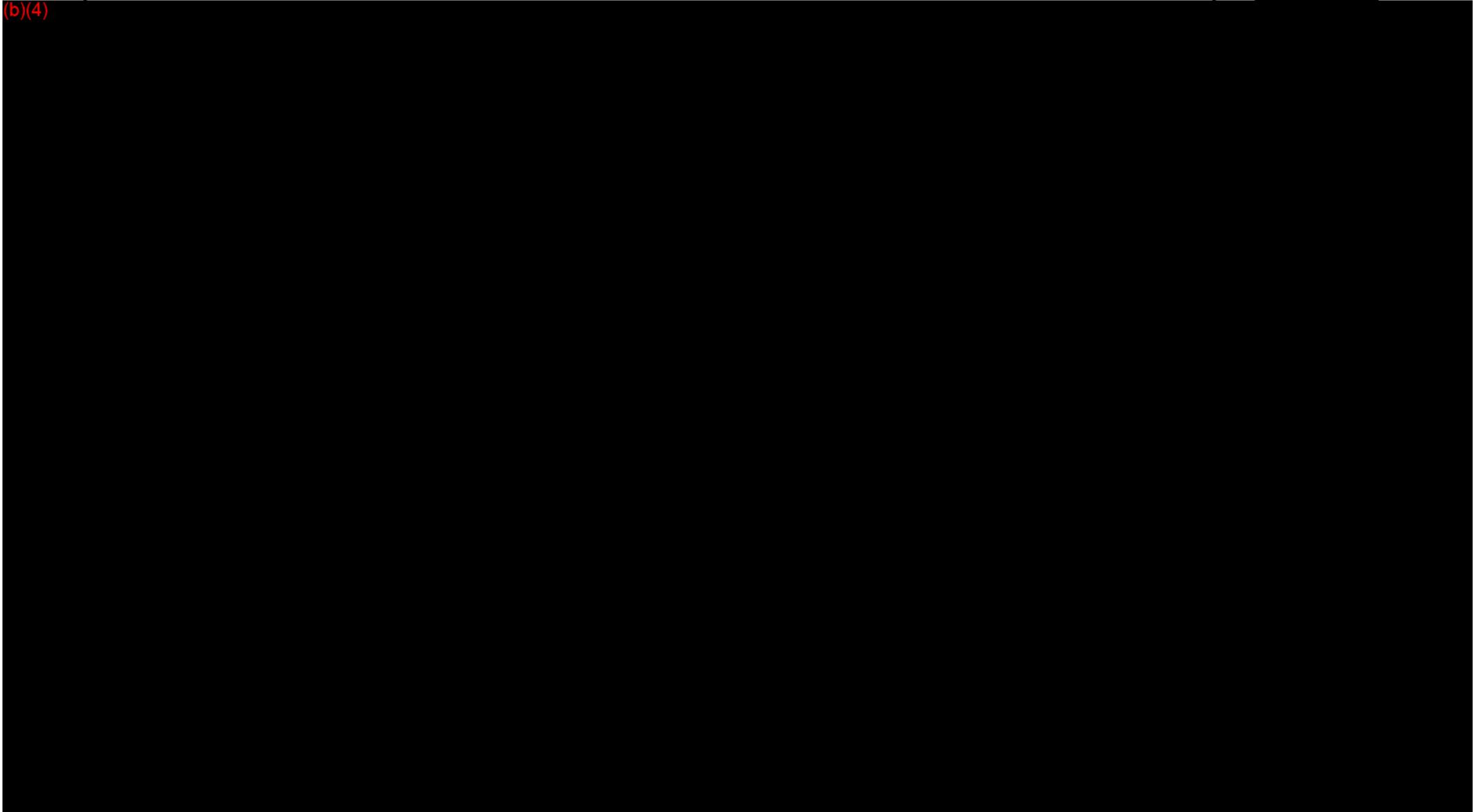
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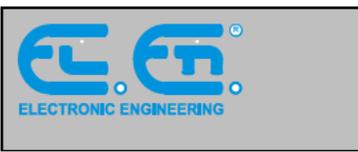
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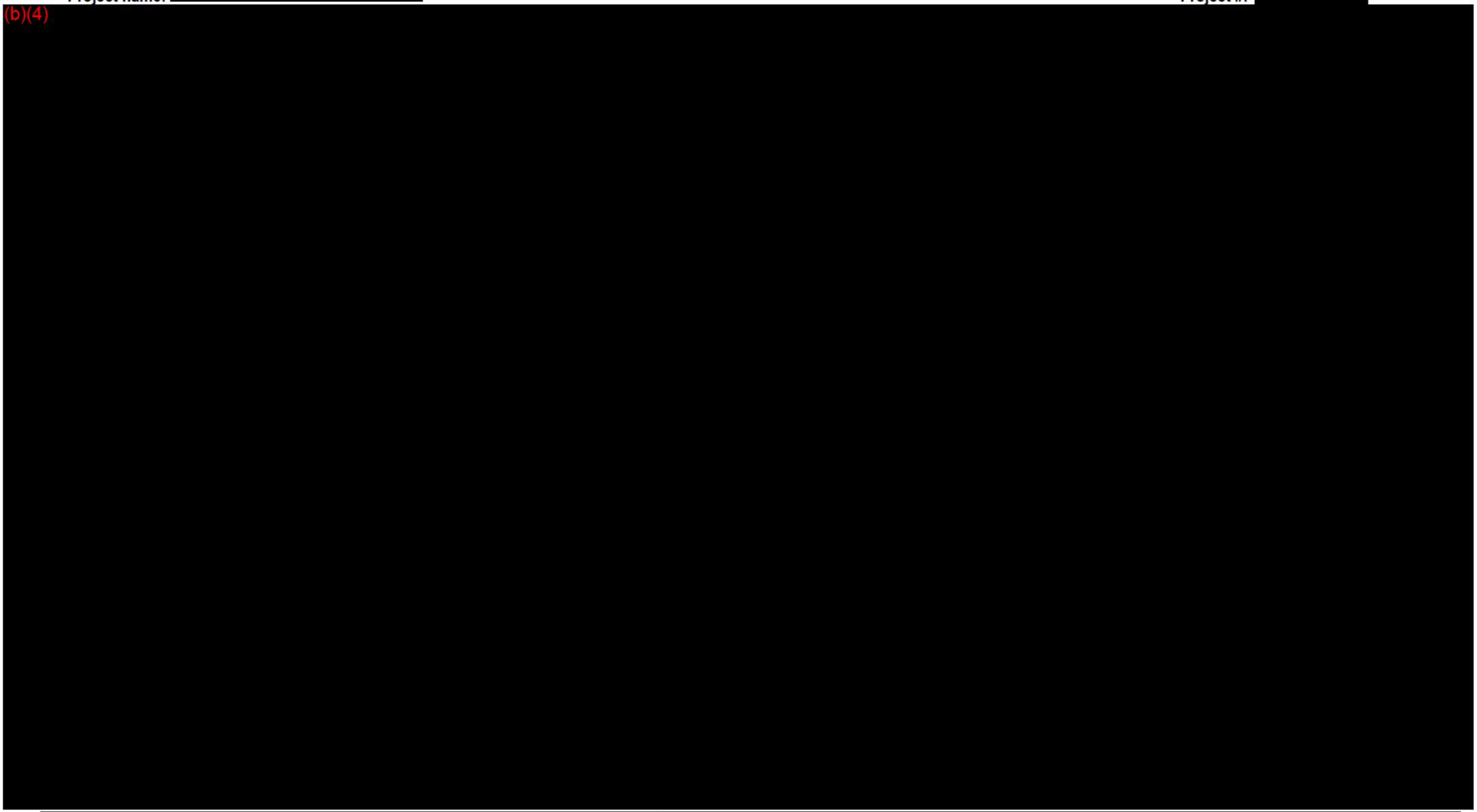


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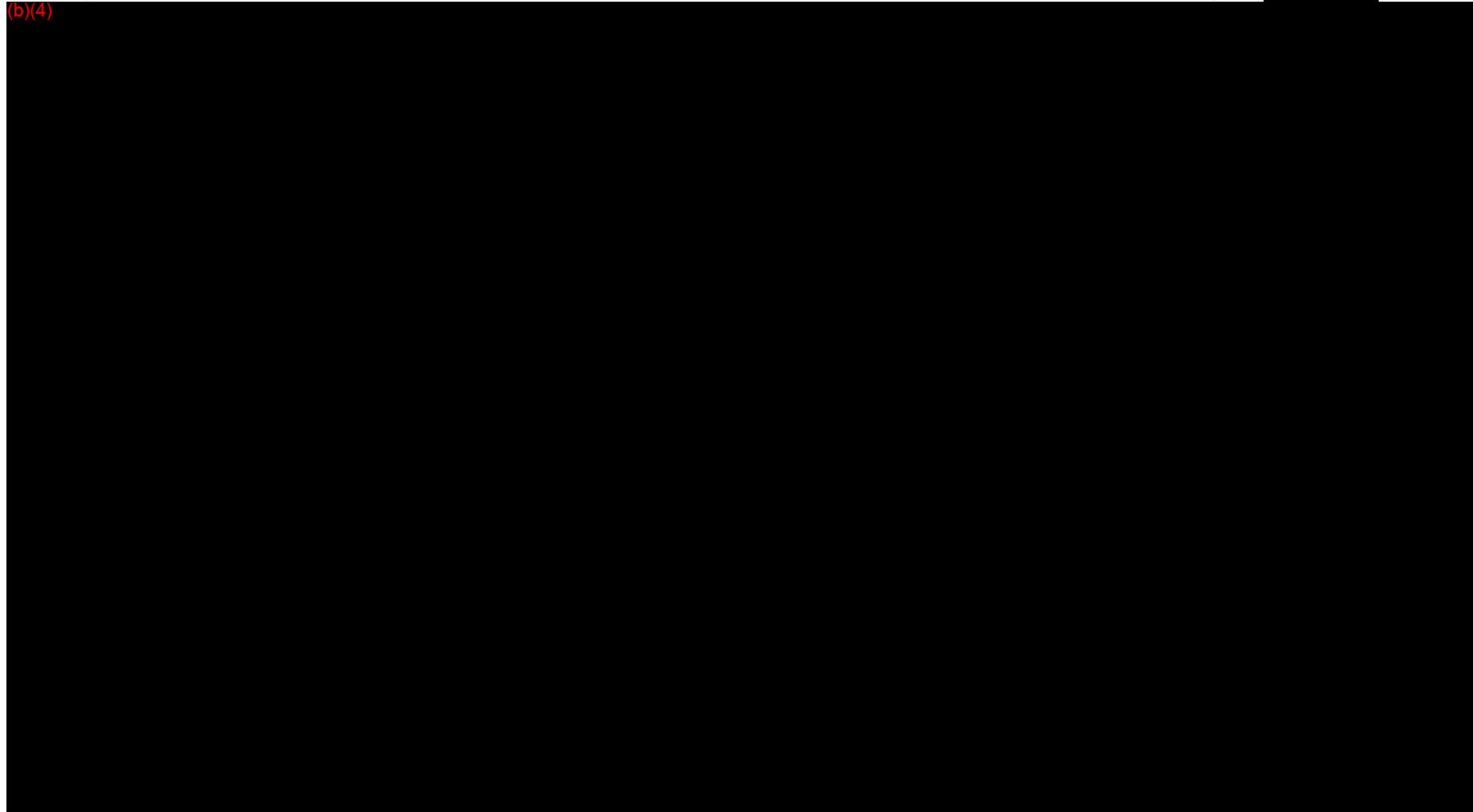


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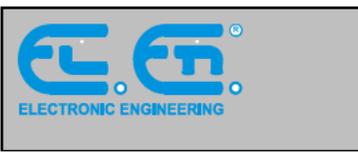
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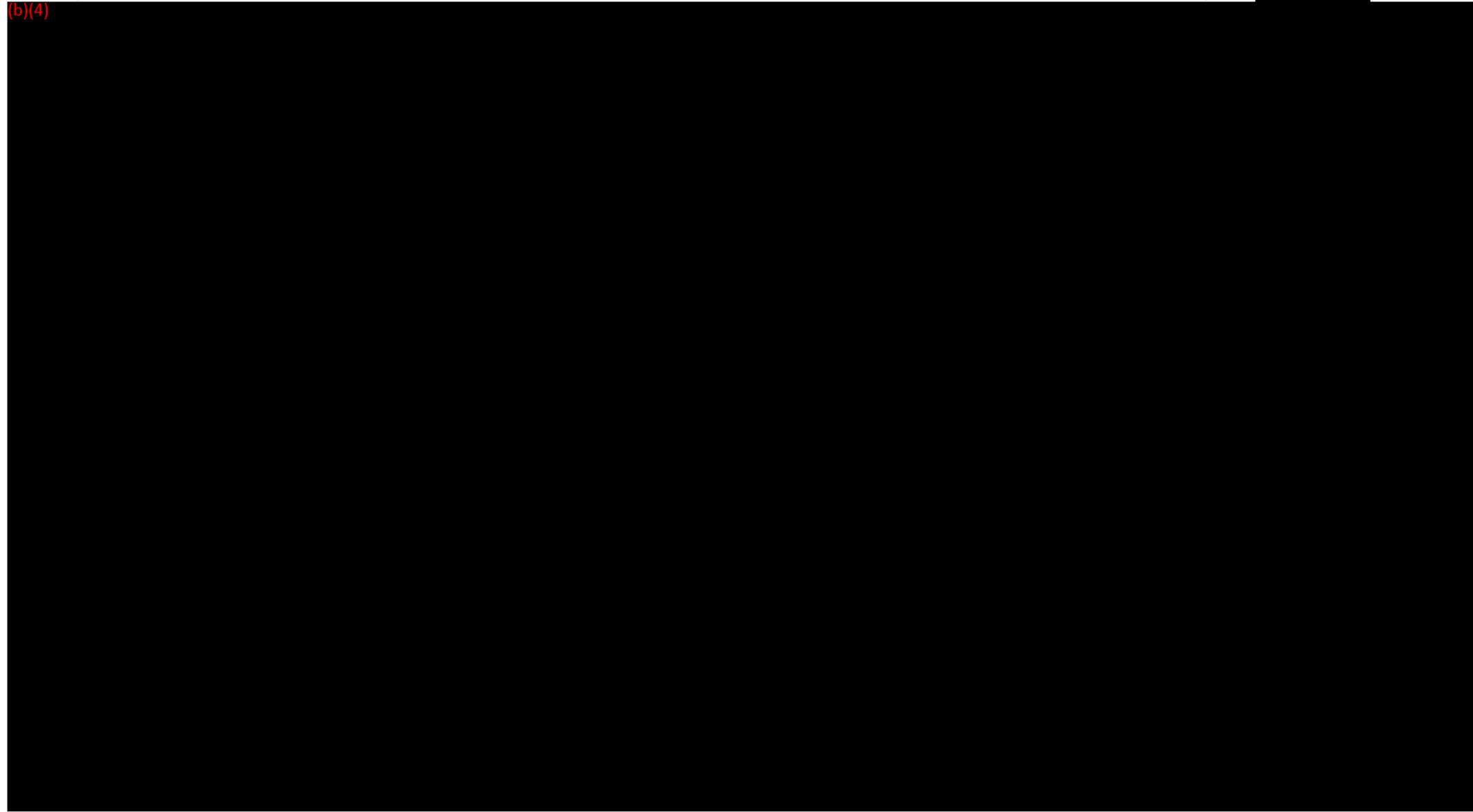


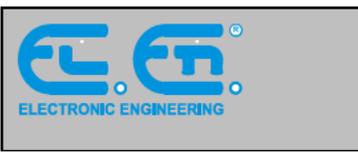
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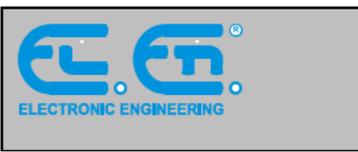
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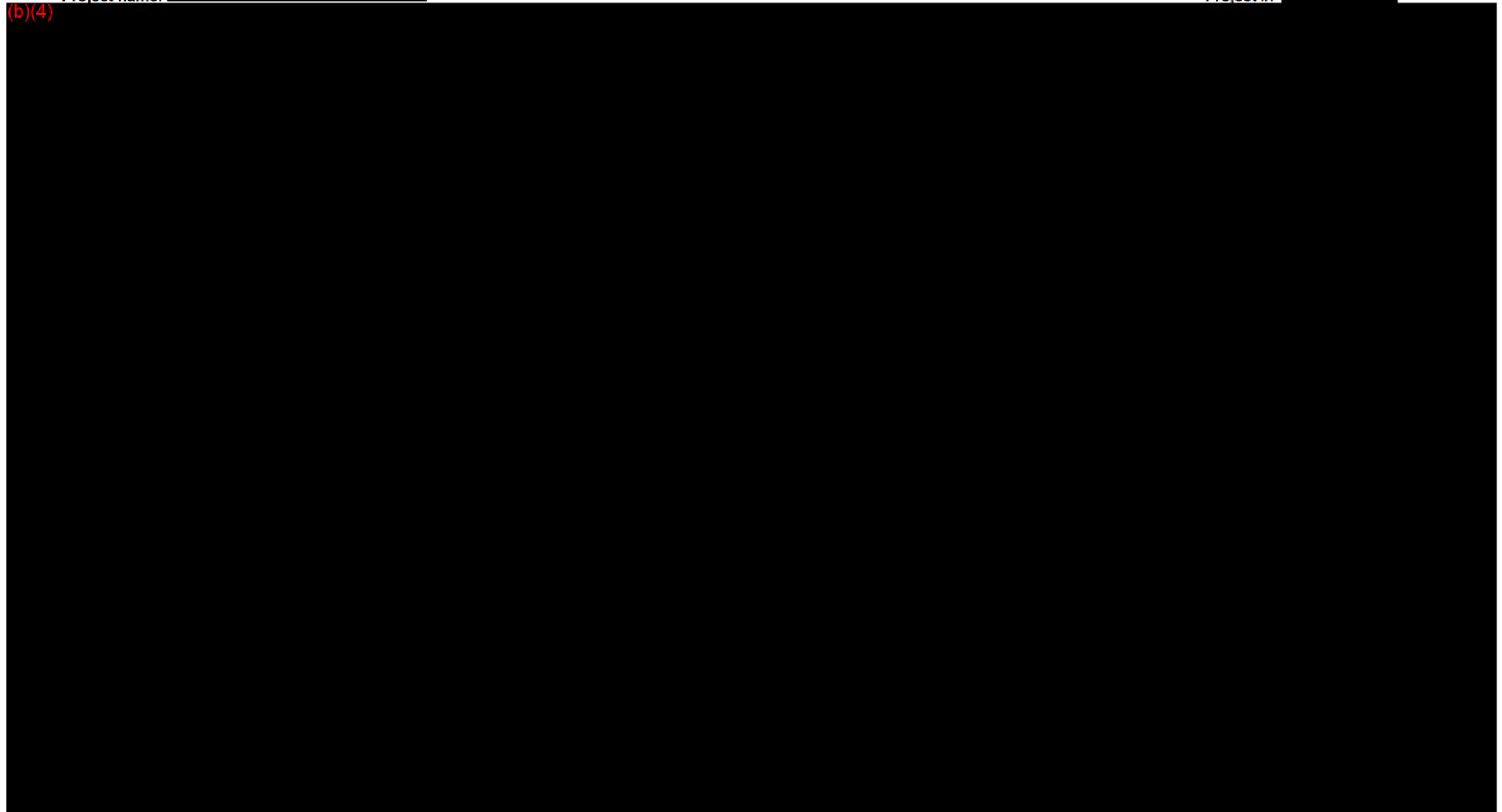


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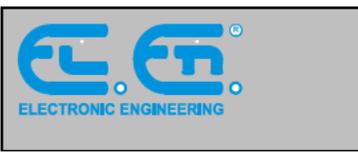
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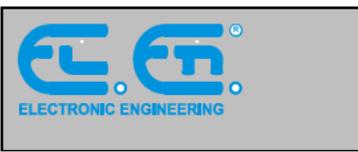
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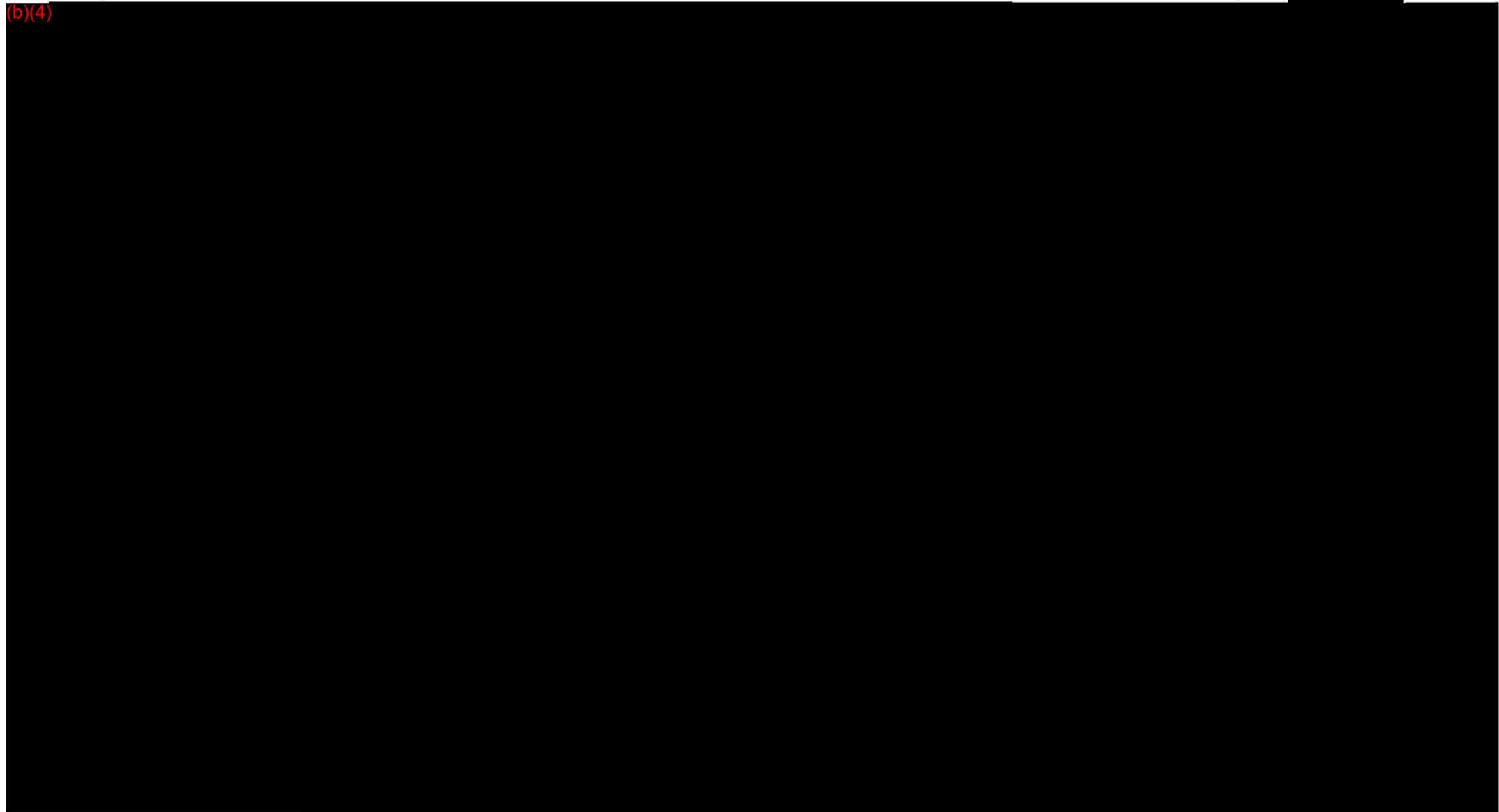


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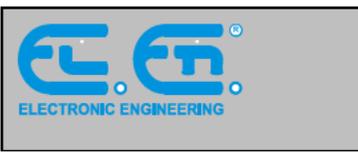
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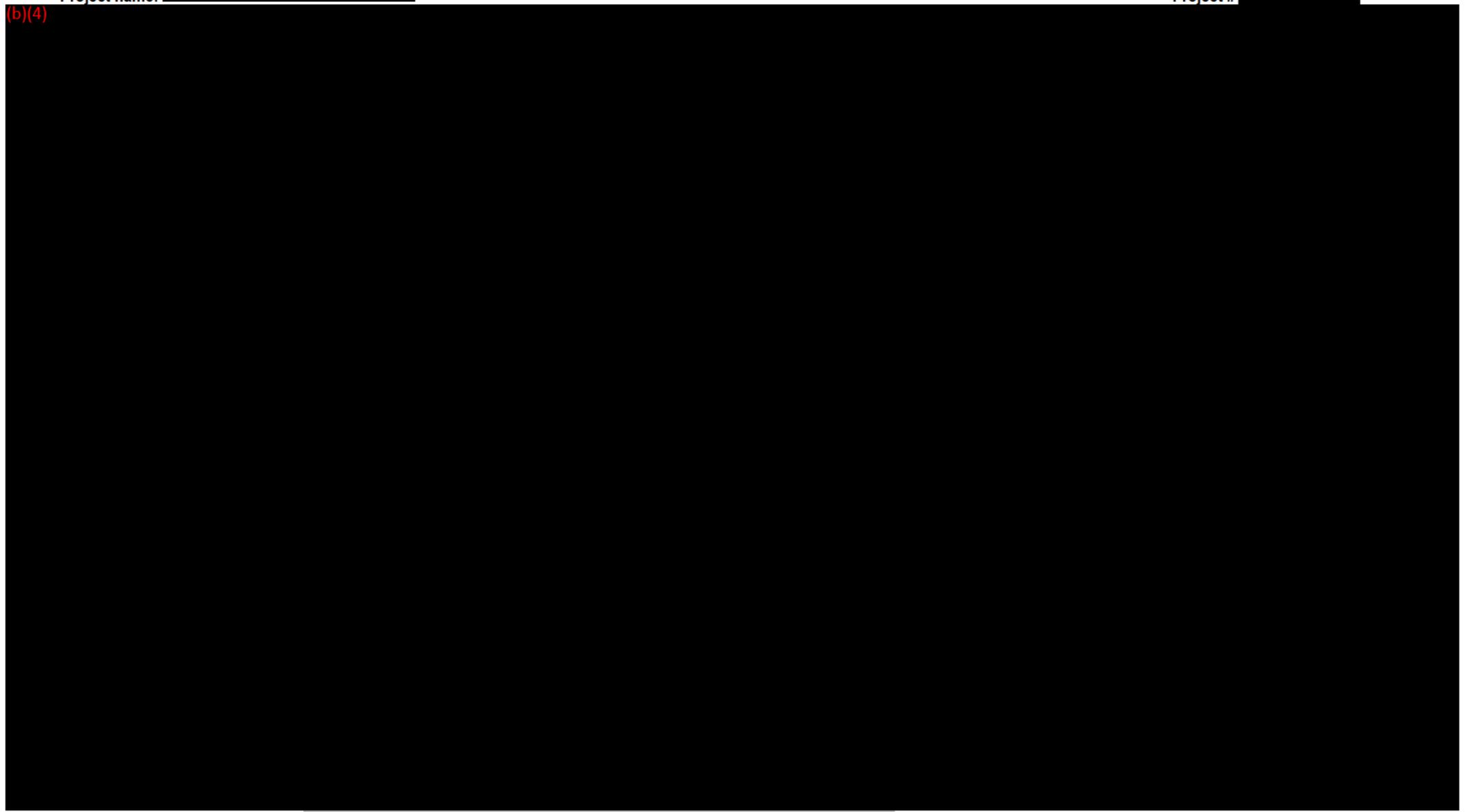


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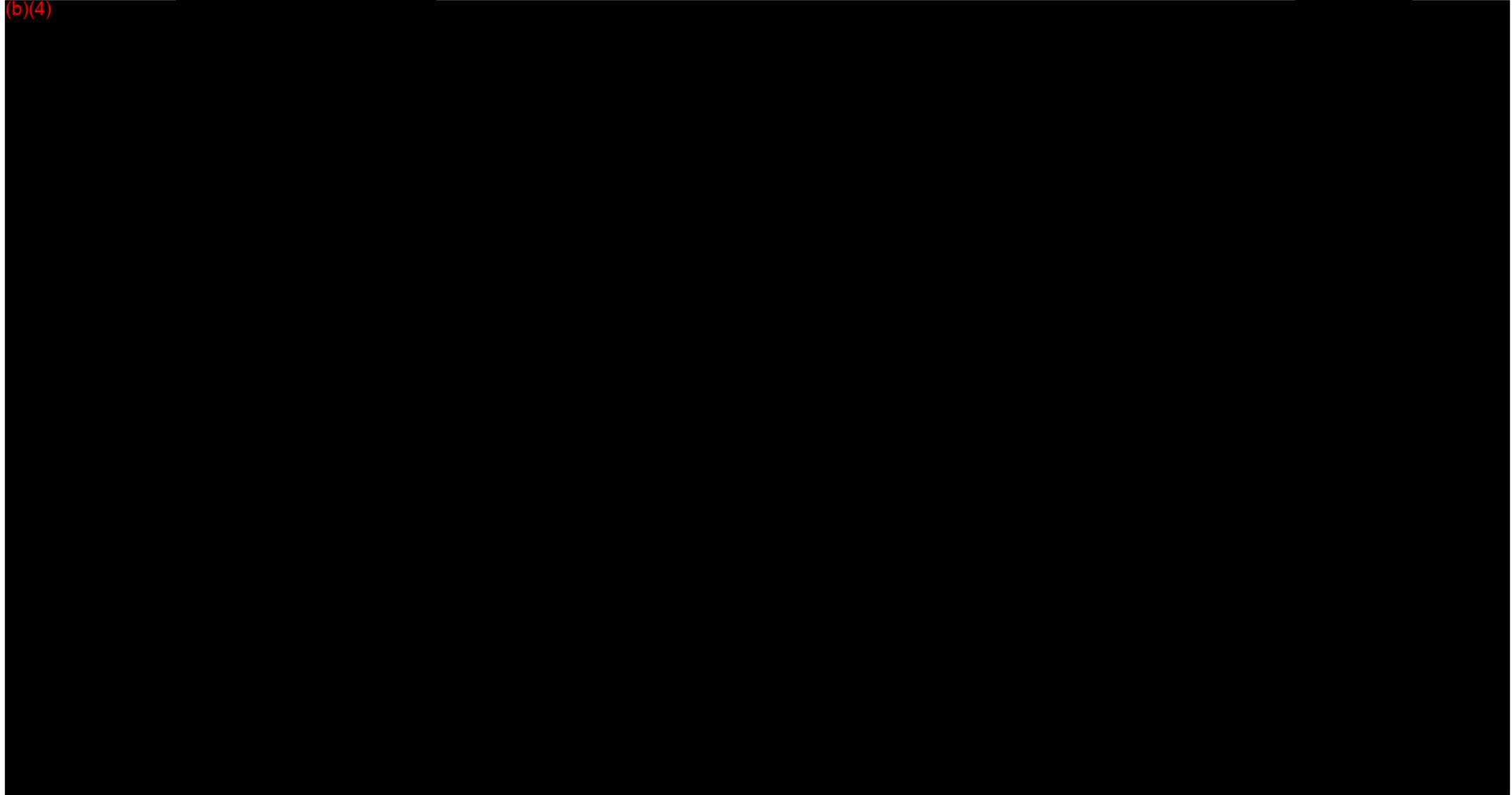
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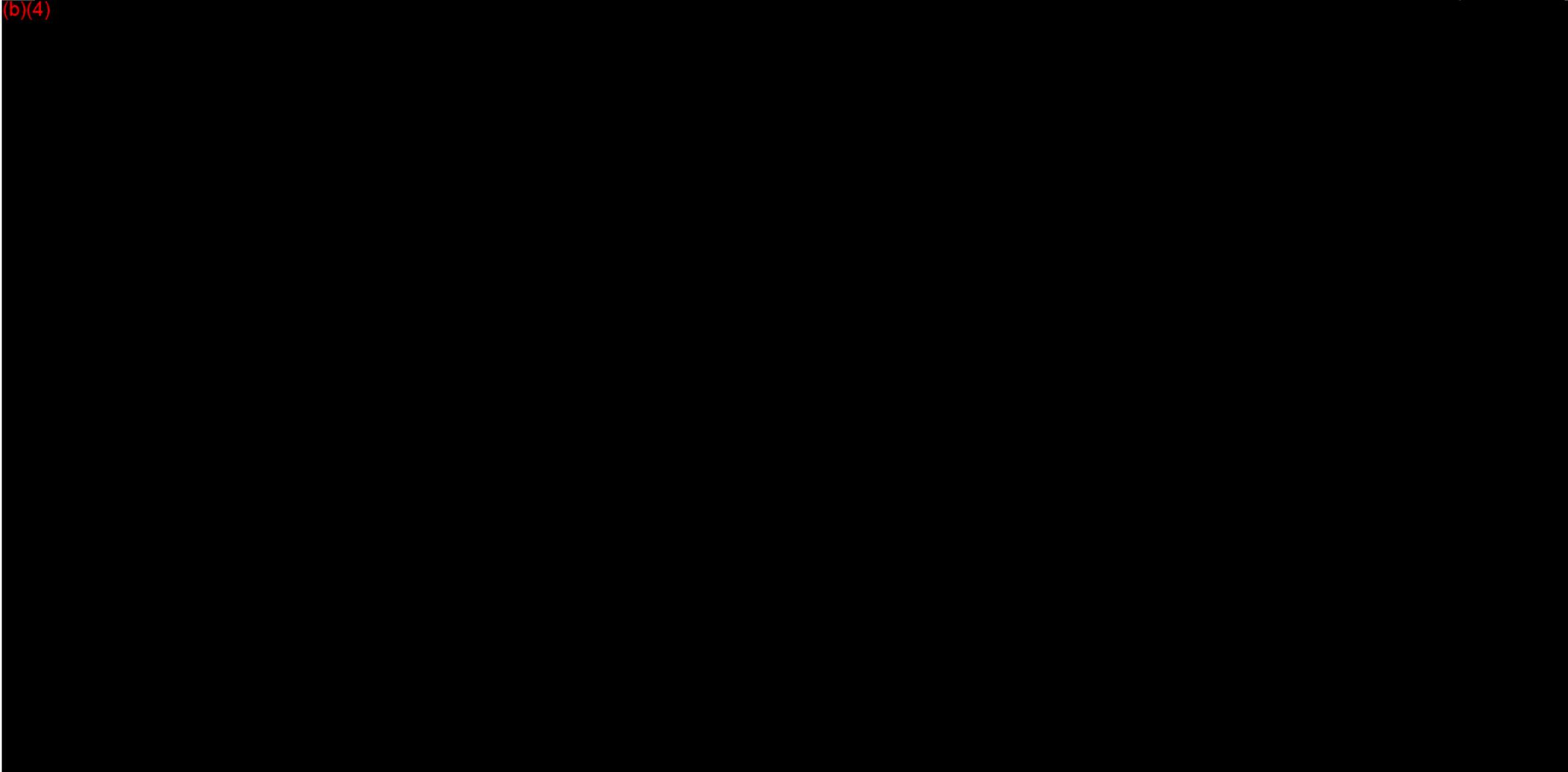
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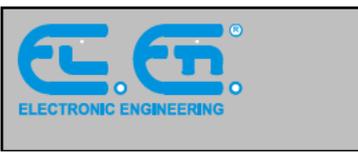
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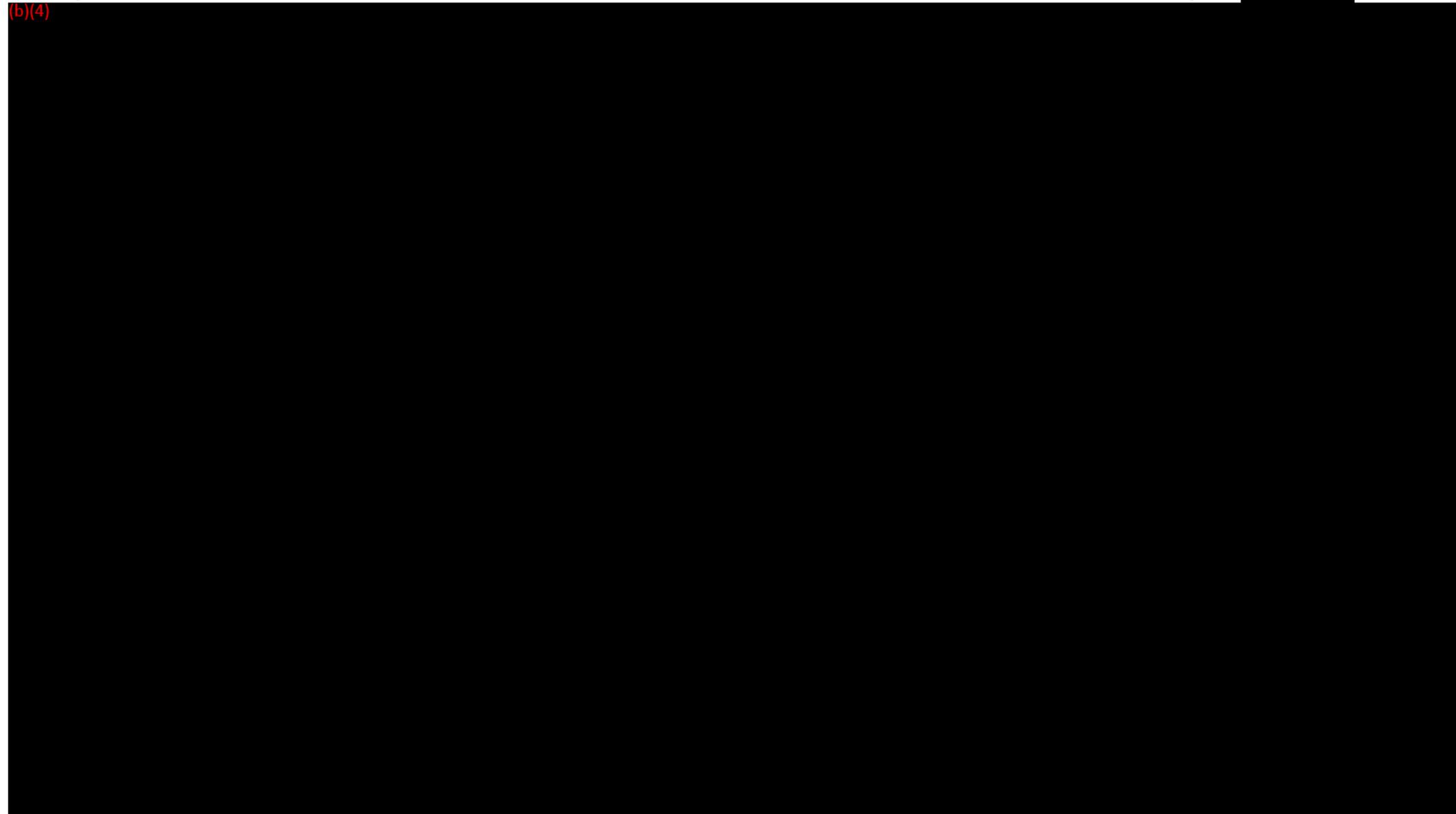


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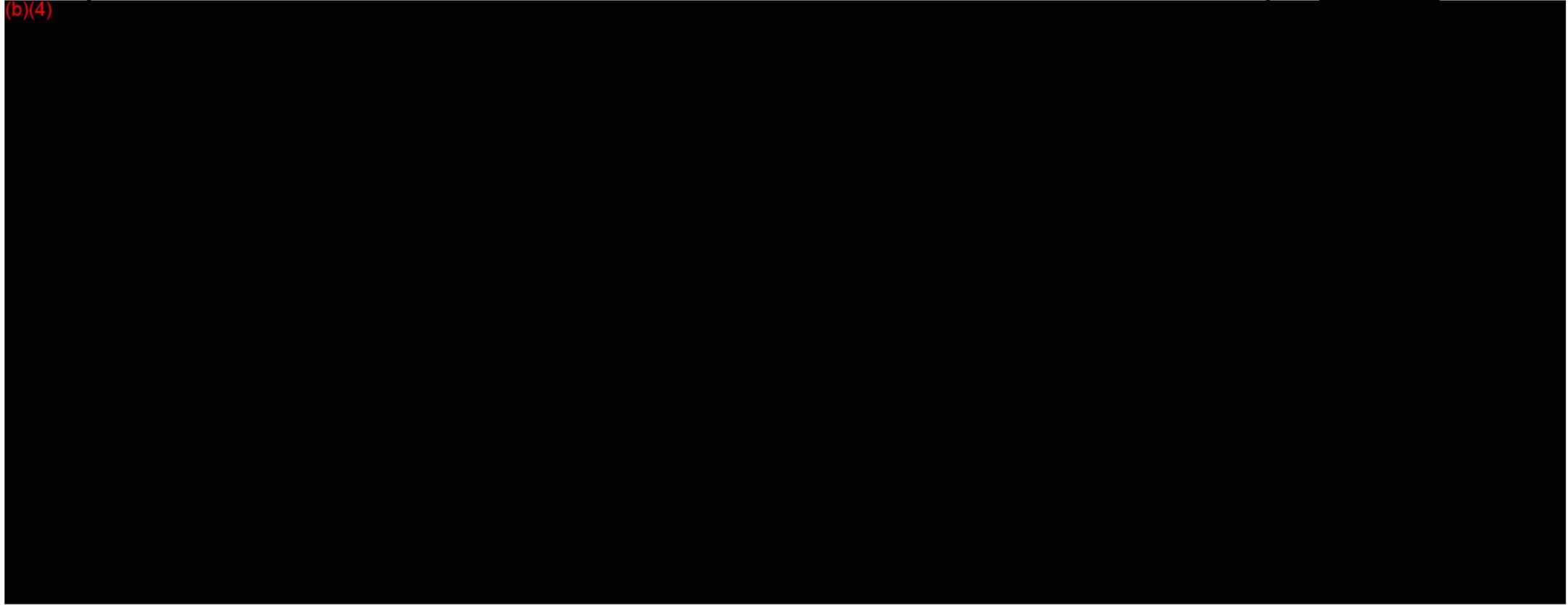
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PART VI: (b)(4) **SOFTWARE SPECIFICATIONS**

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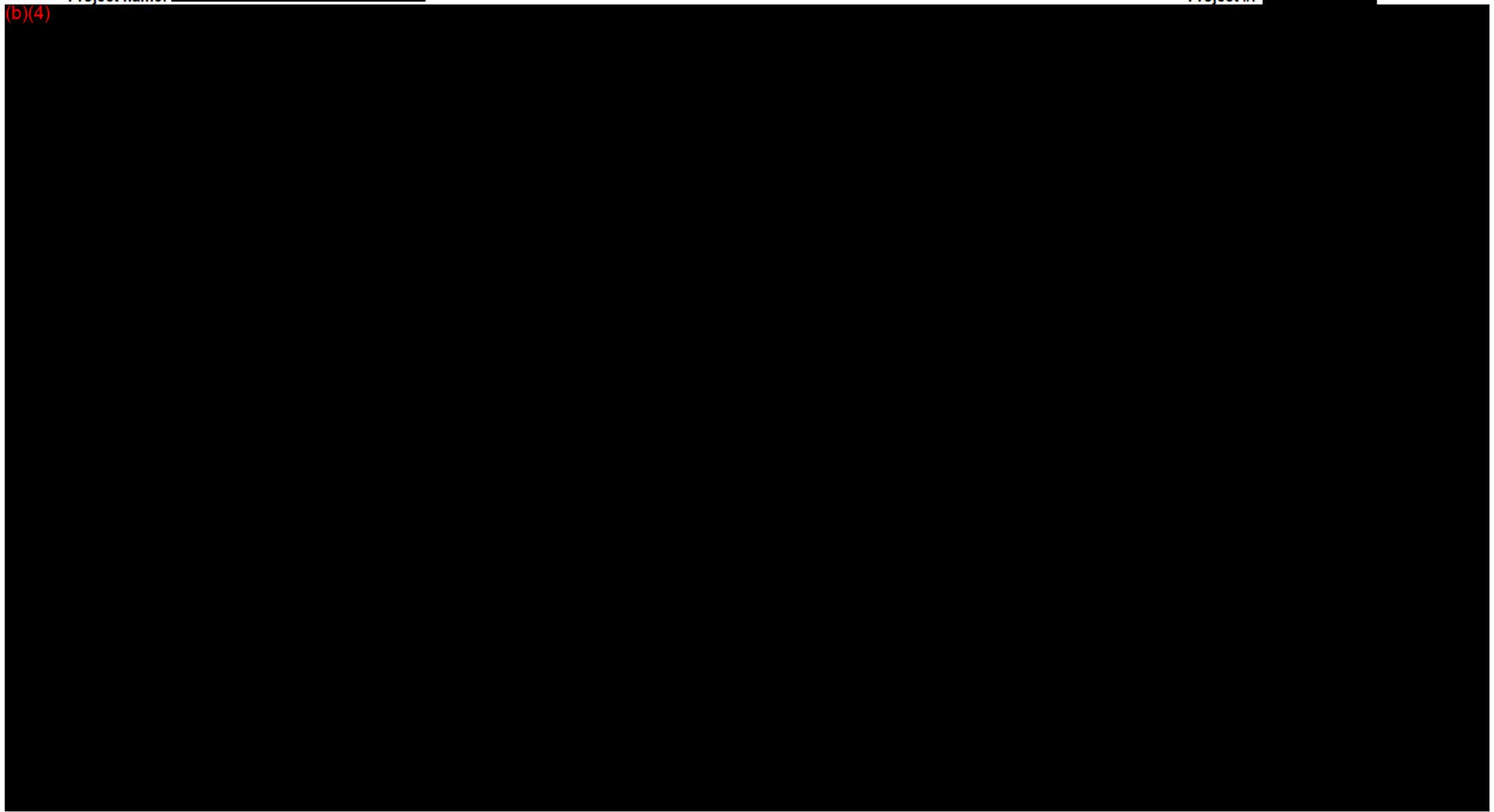


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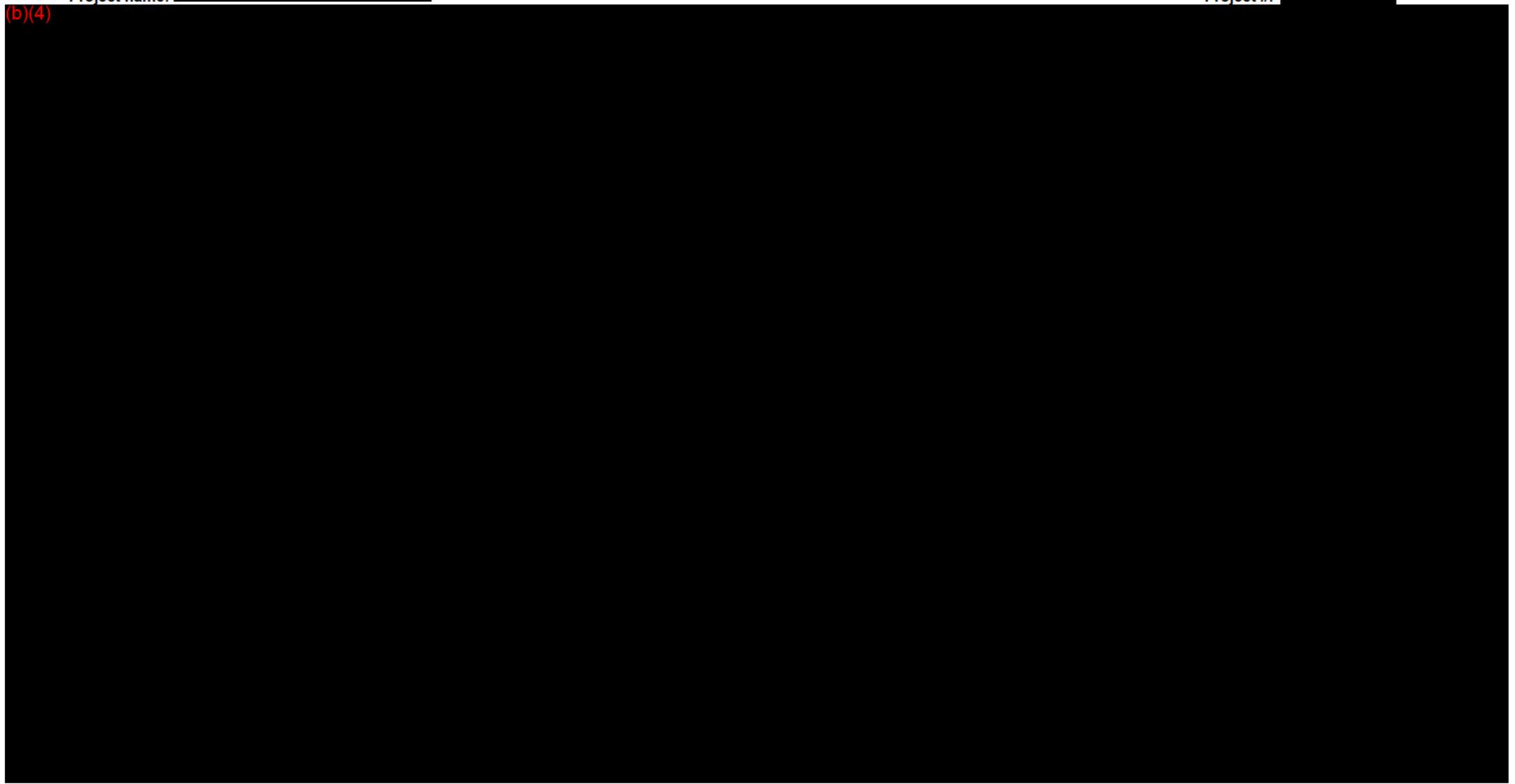


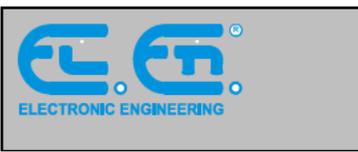
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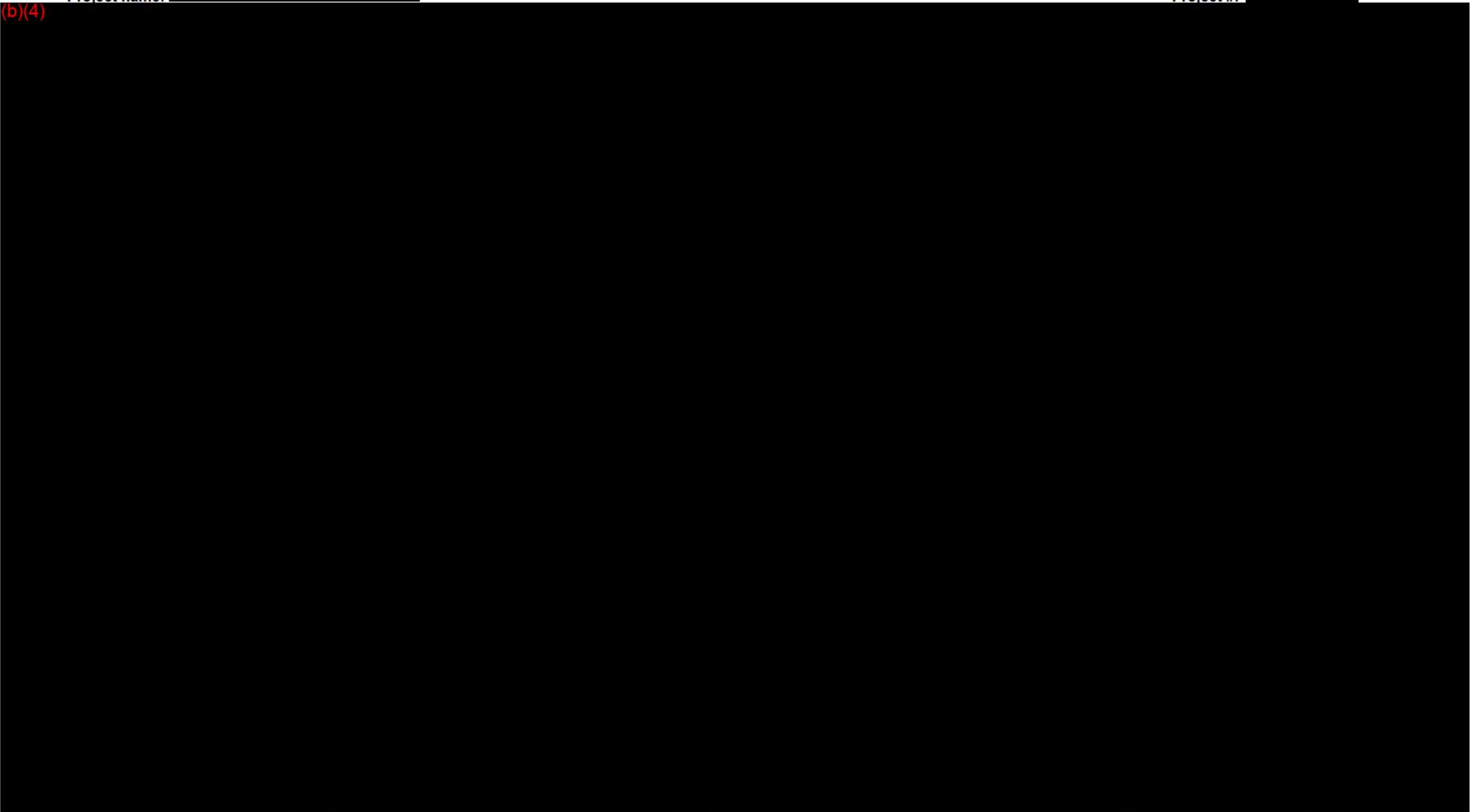


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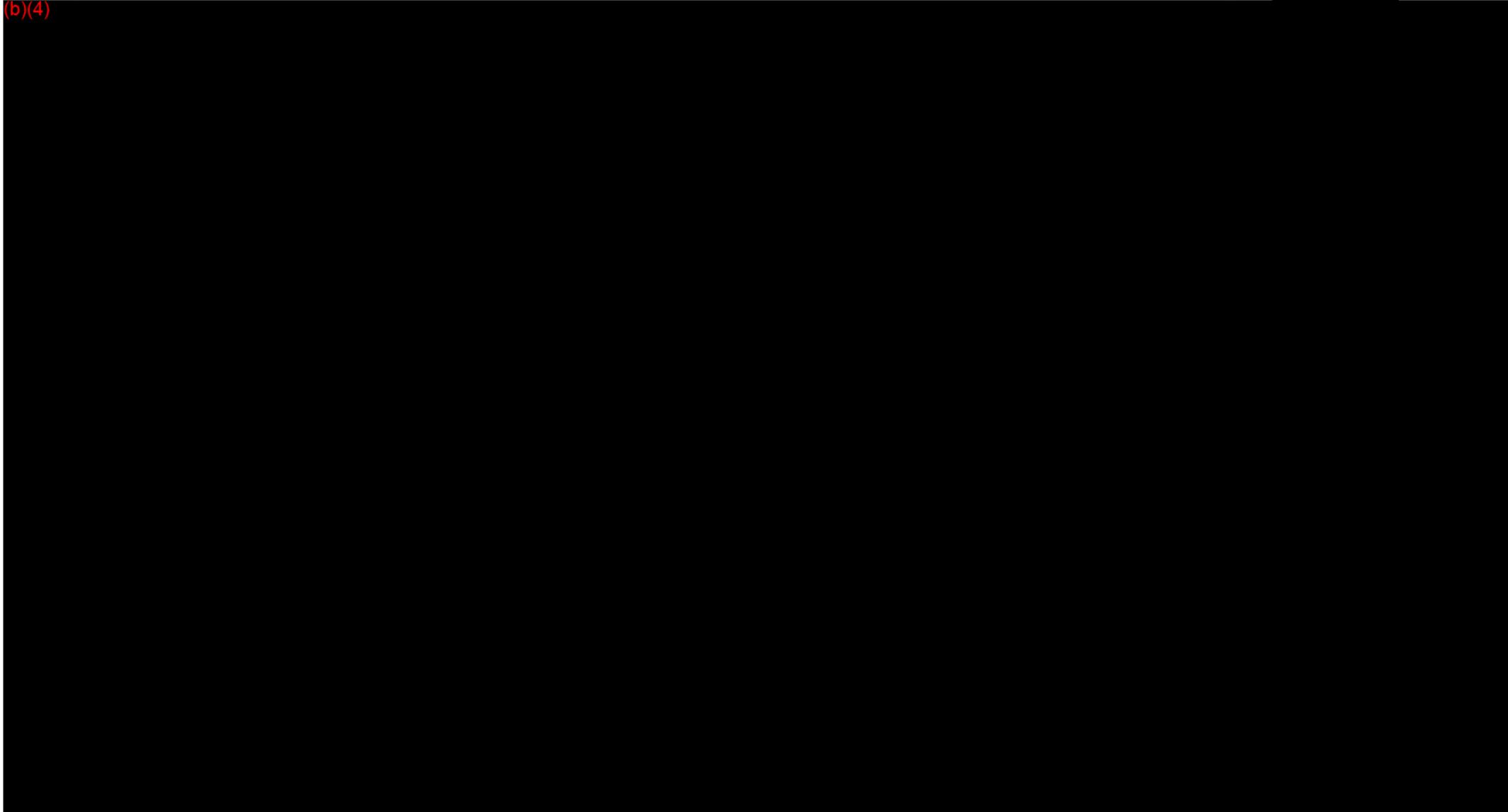
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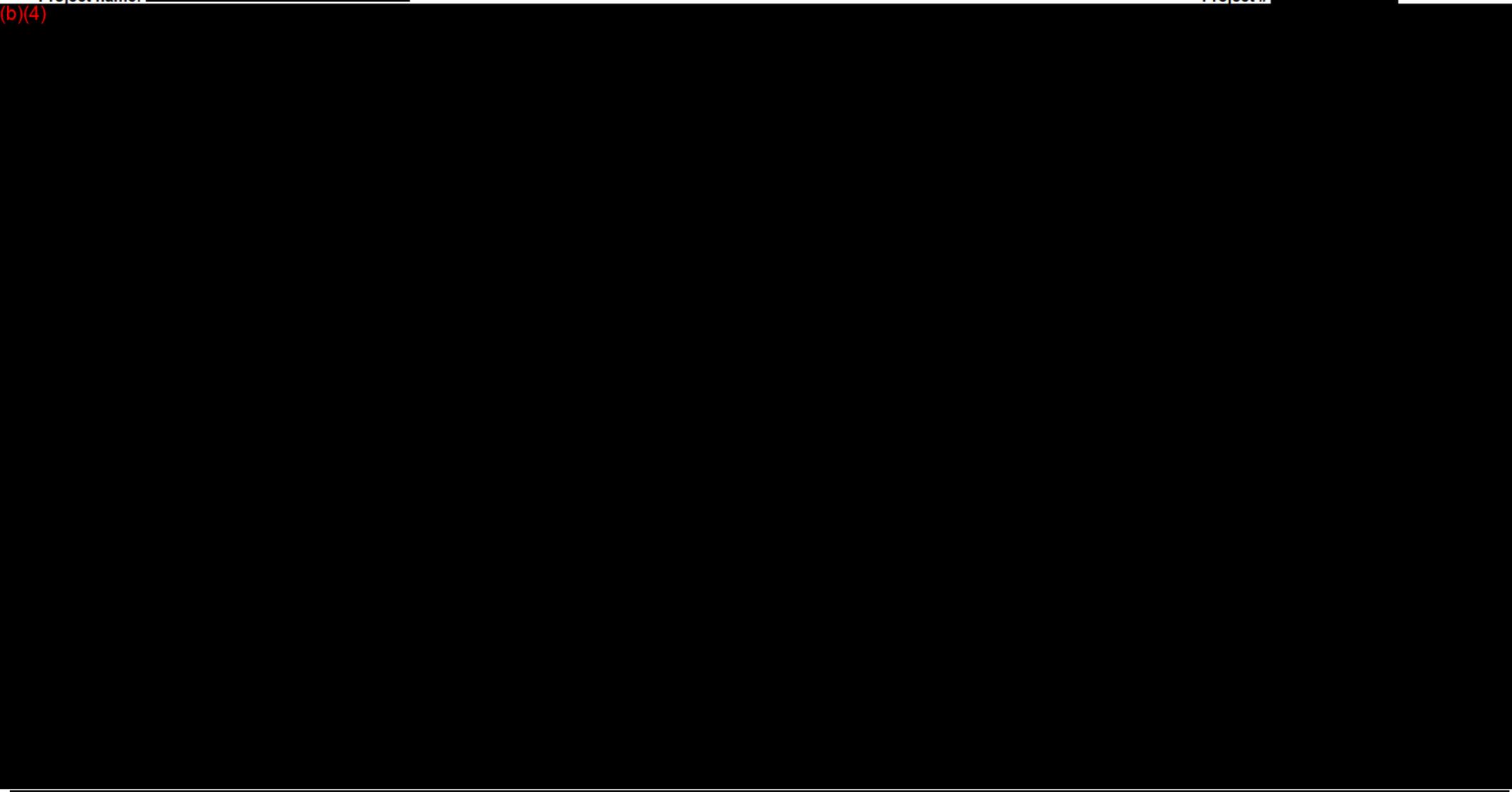


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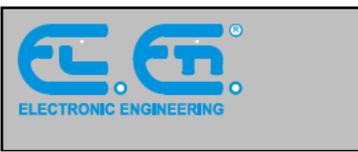
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SOFTWARE VERIFICATION

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Module (b)(4) SOFTWARE VERIFICATION

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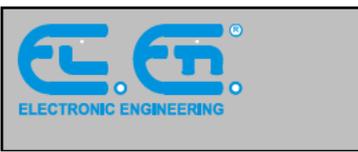
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DESIGN SPECIFICATIONS

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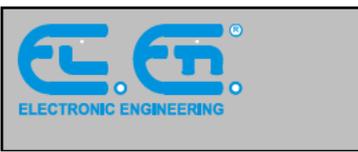
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PART I: HARDWARE and PROGRAMMING LANGUAGE SPECIFICATIONS

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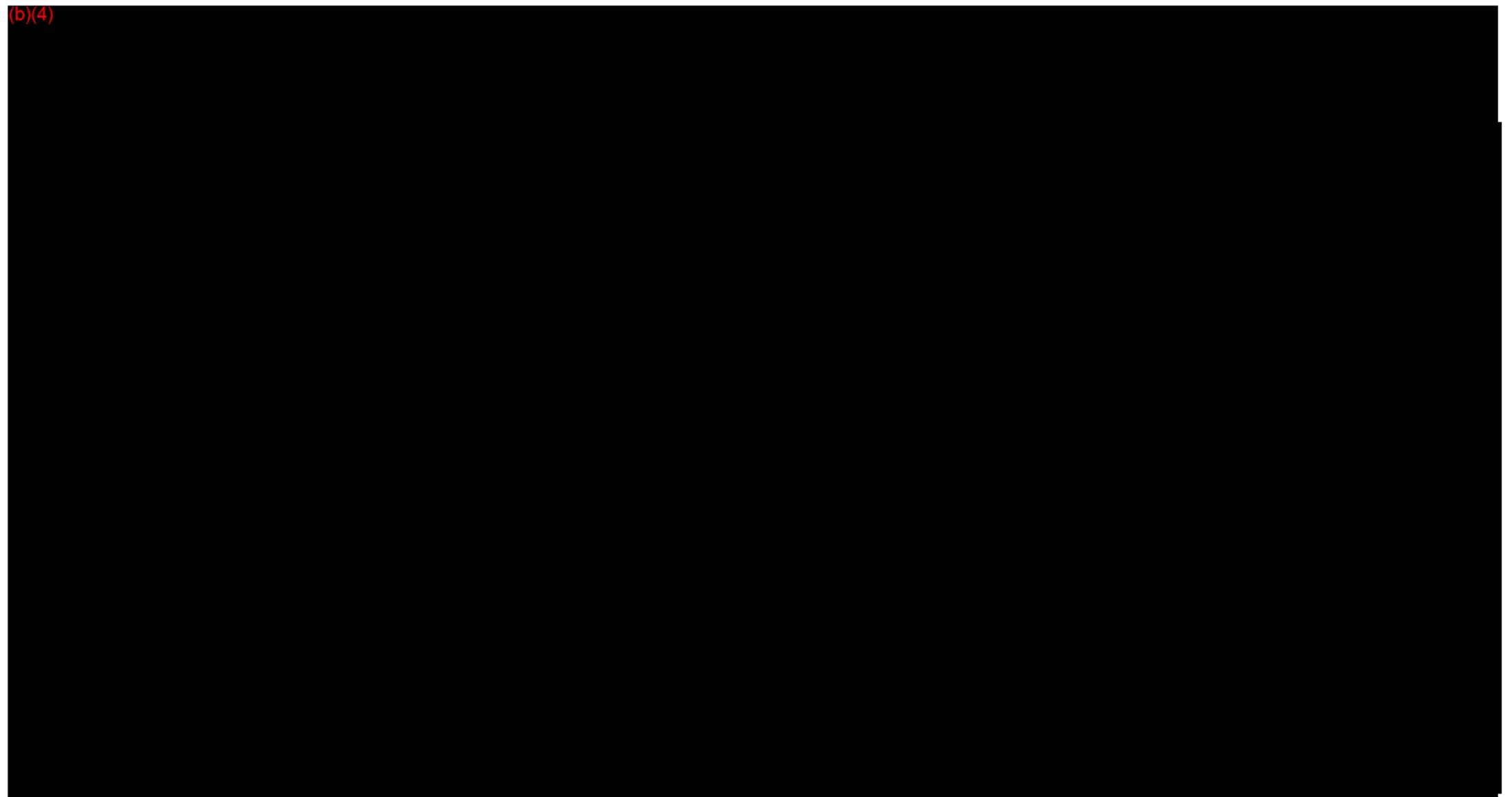


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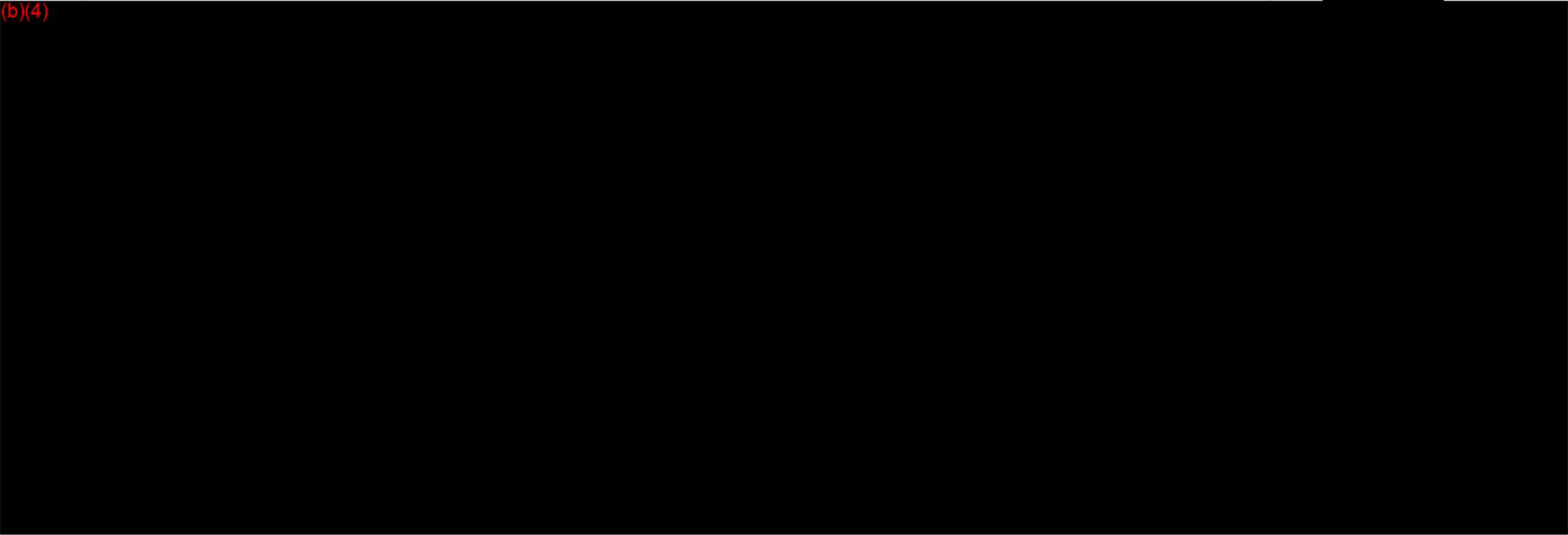


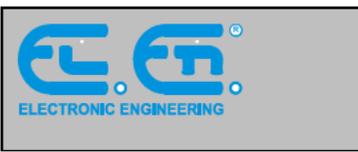
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Date 16/04/2014
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Project name: SmartXIDE²

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Rev (b)

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PART III: (b)(4) PARAMETERS SPECIFICATIONS

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Module (b)(4) SOFTWARE VERIFICATION

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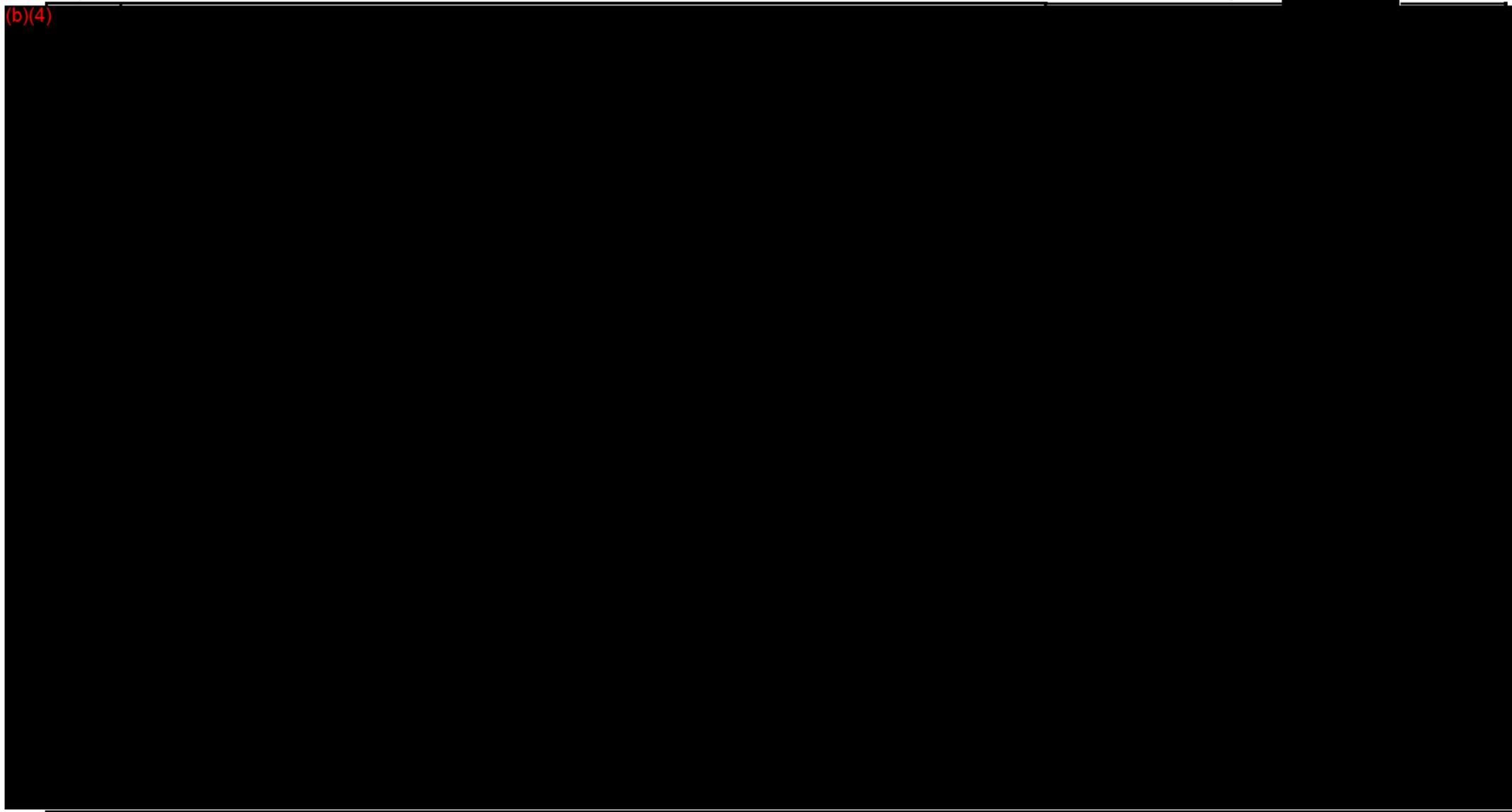


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Date 16/04/2014
Rev (b)

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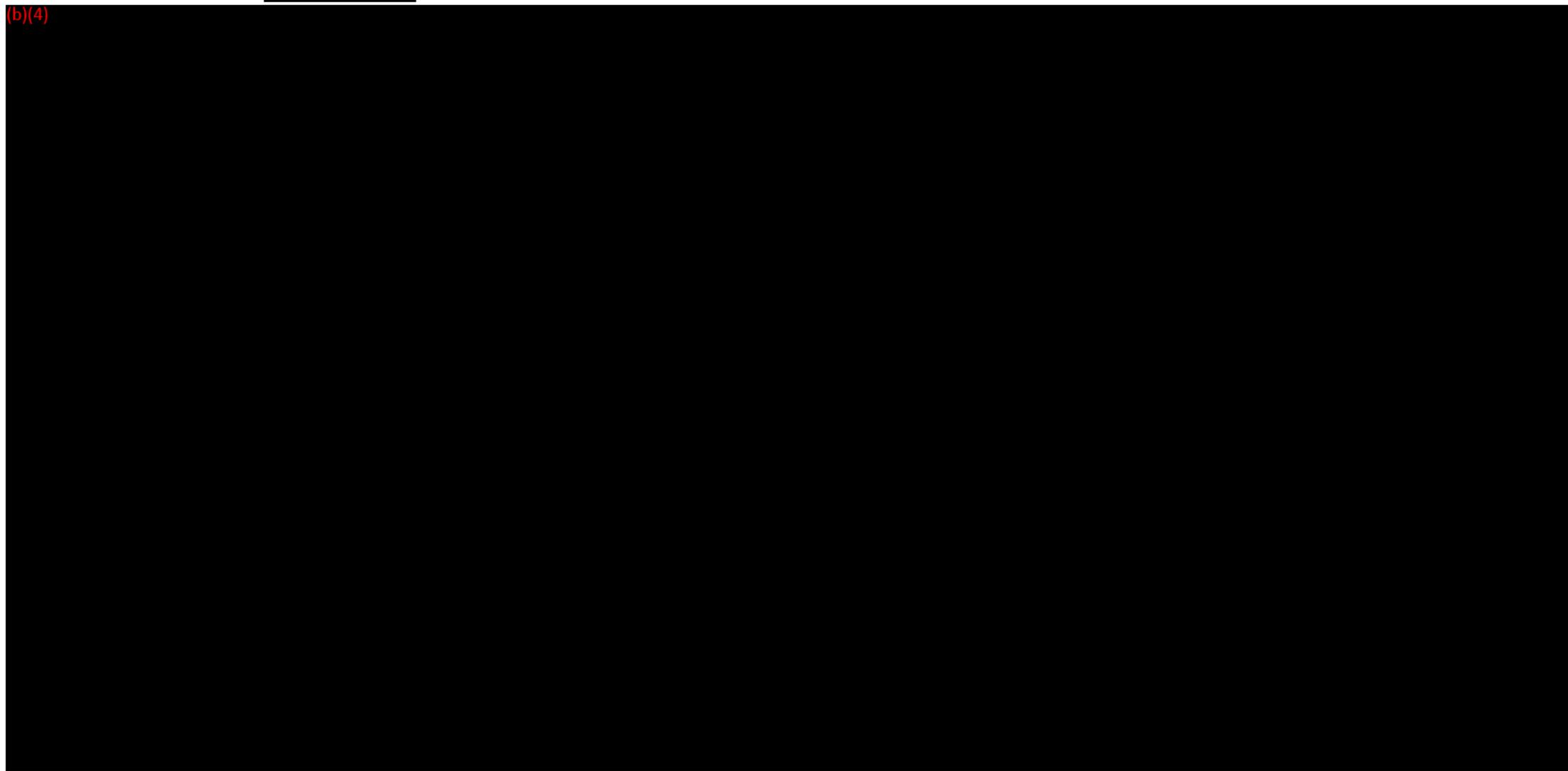
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Date 16/04/2014
Rev (b)

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PART IV: (b)(4) SPECIFICATIONS



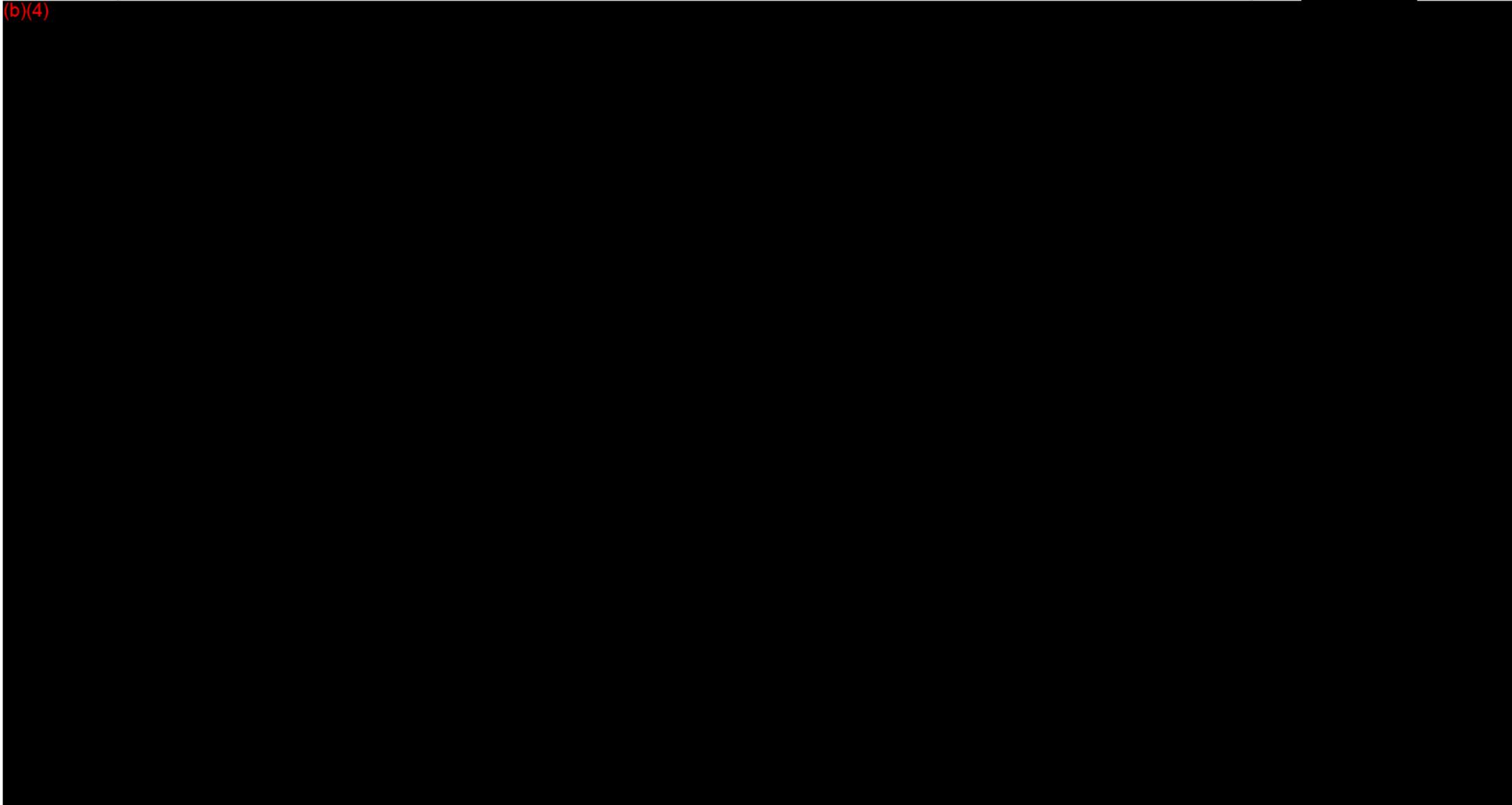


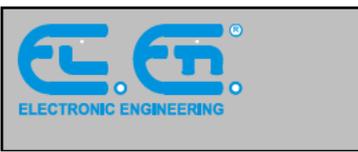
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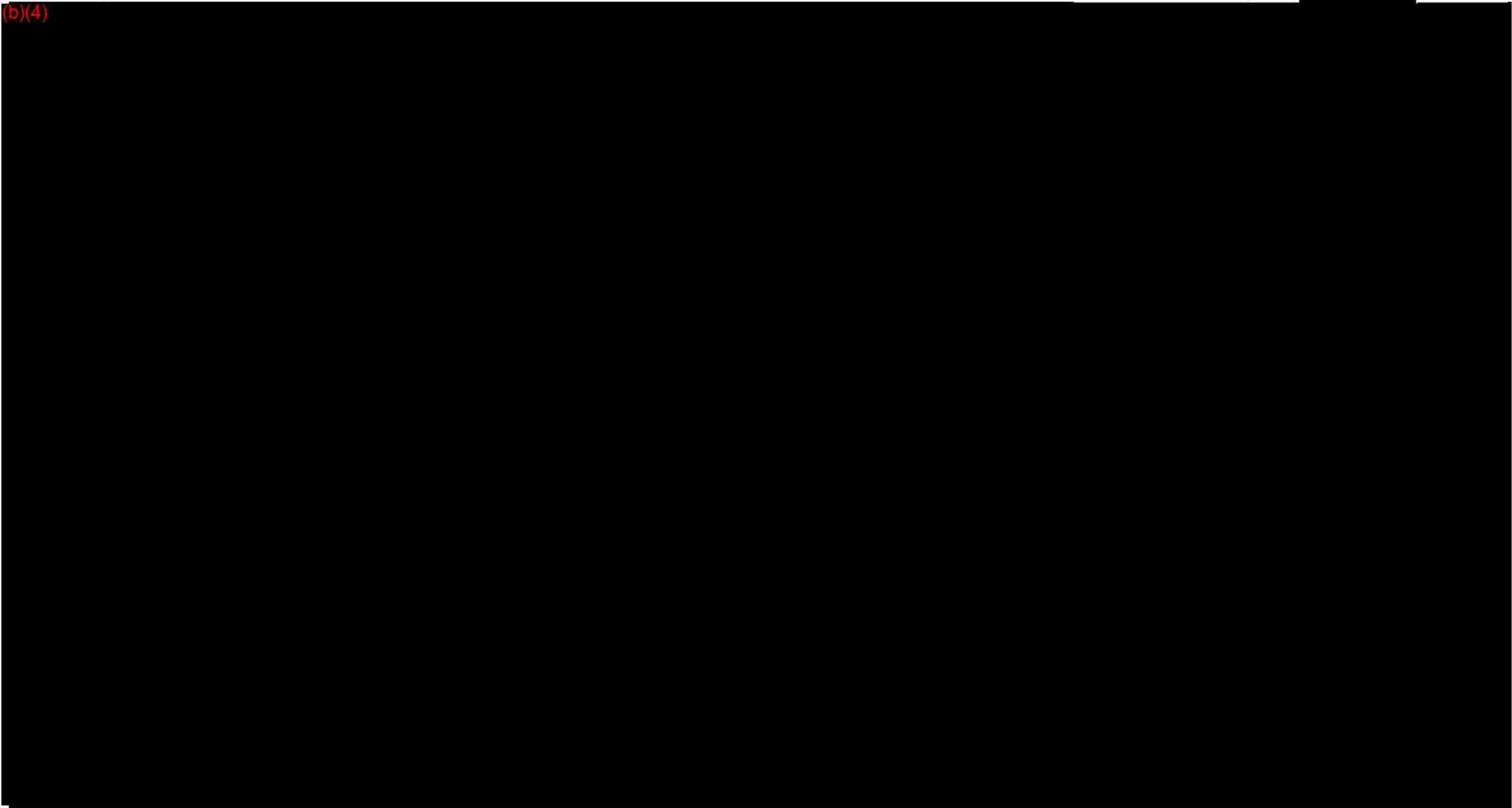


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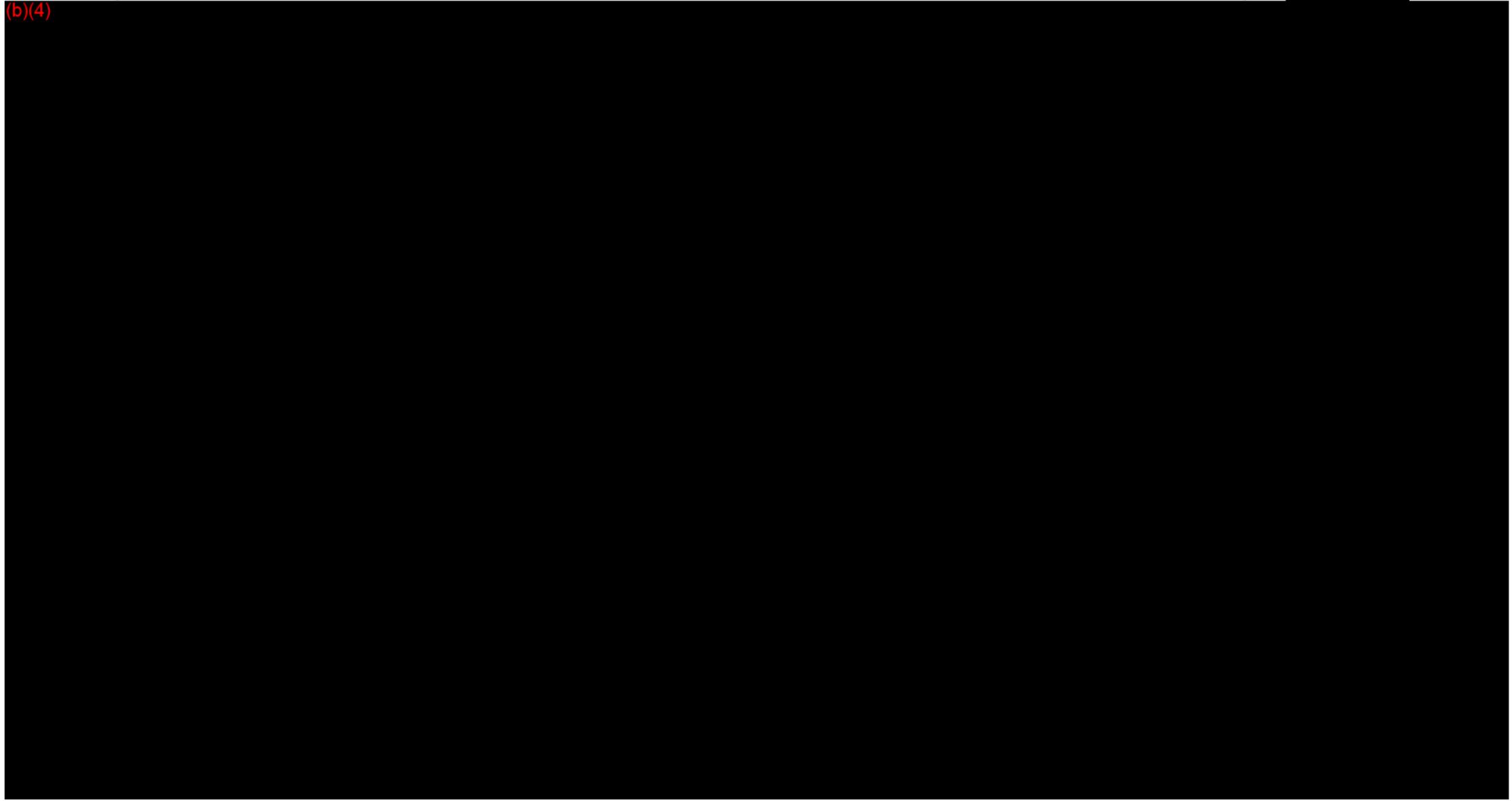


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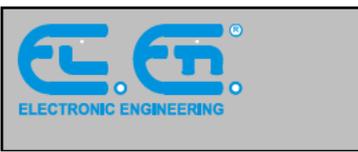
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PART V: USER INTERFACE SPECIFICATIONS

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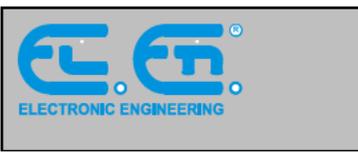
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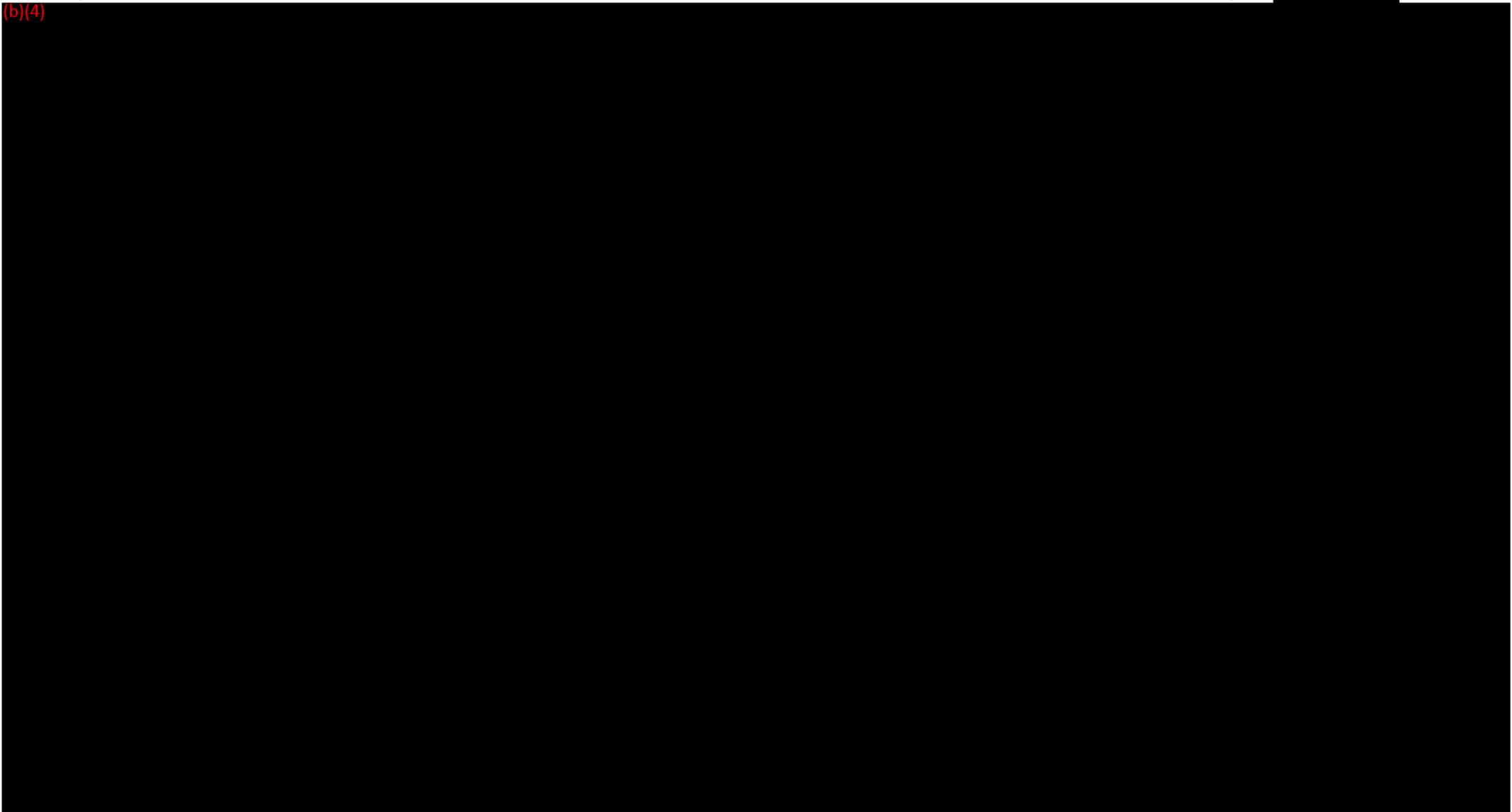


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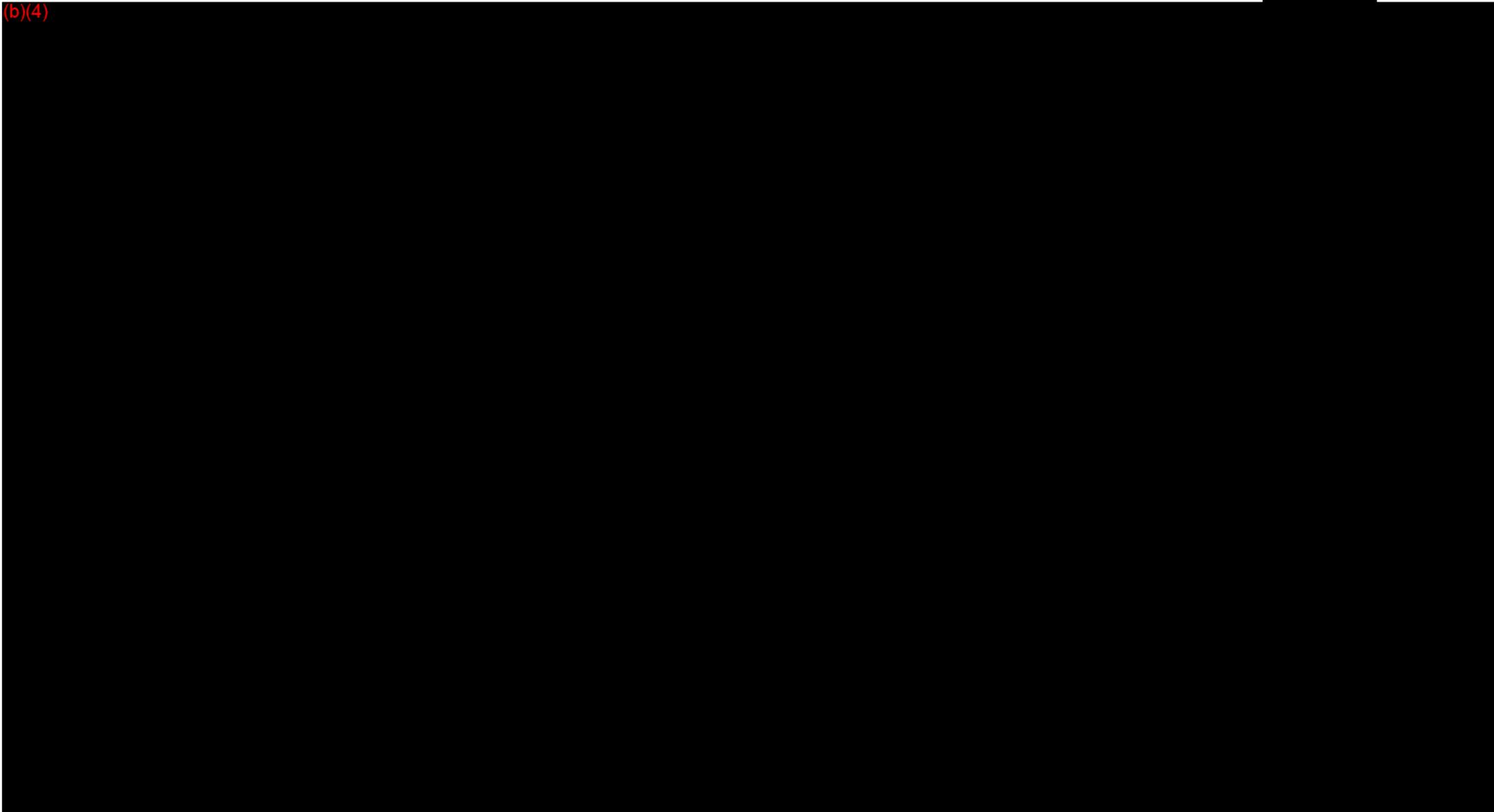


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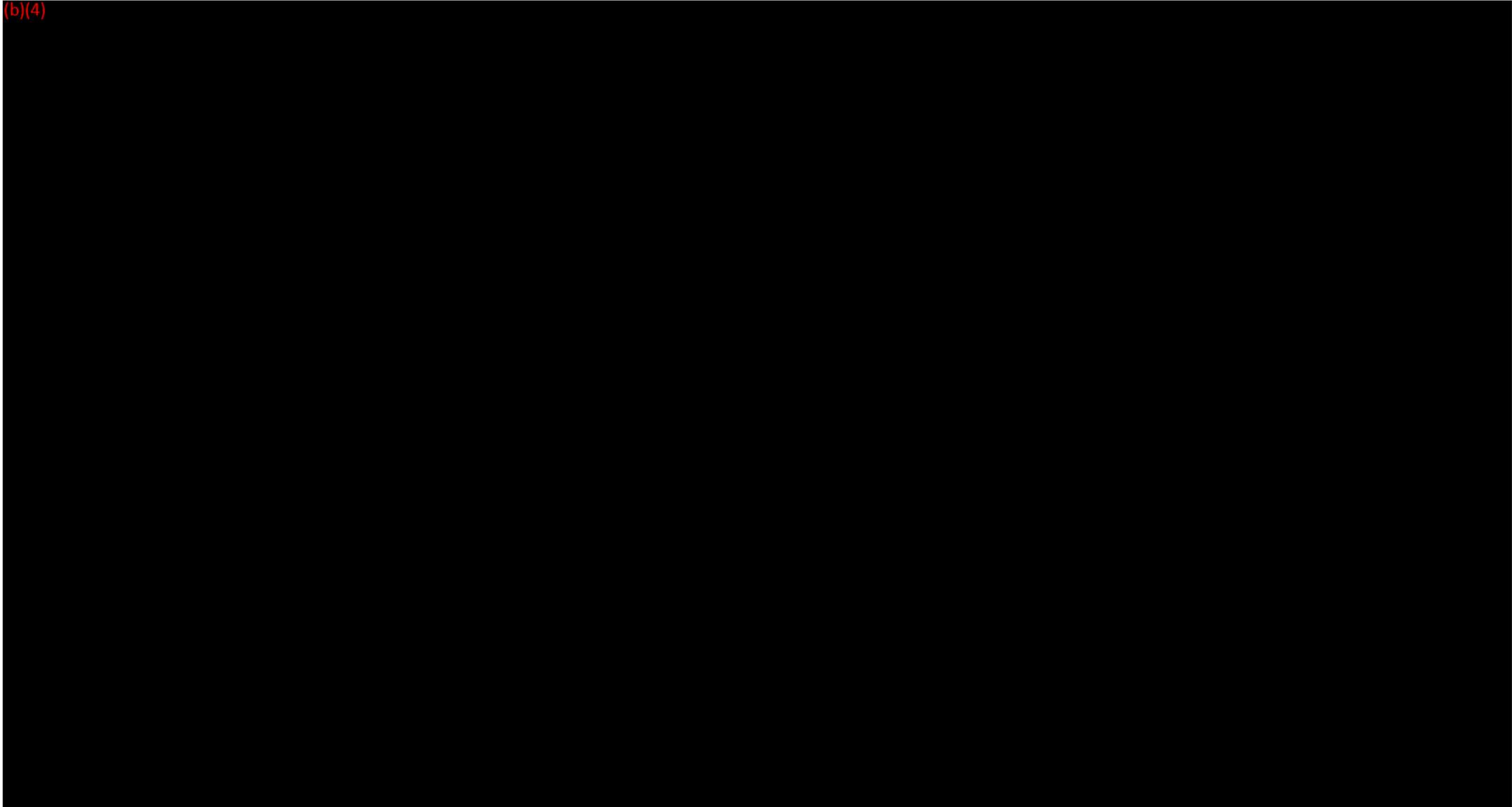
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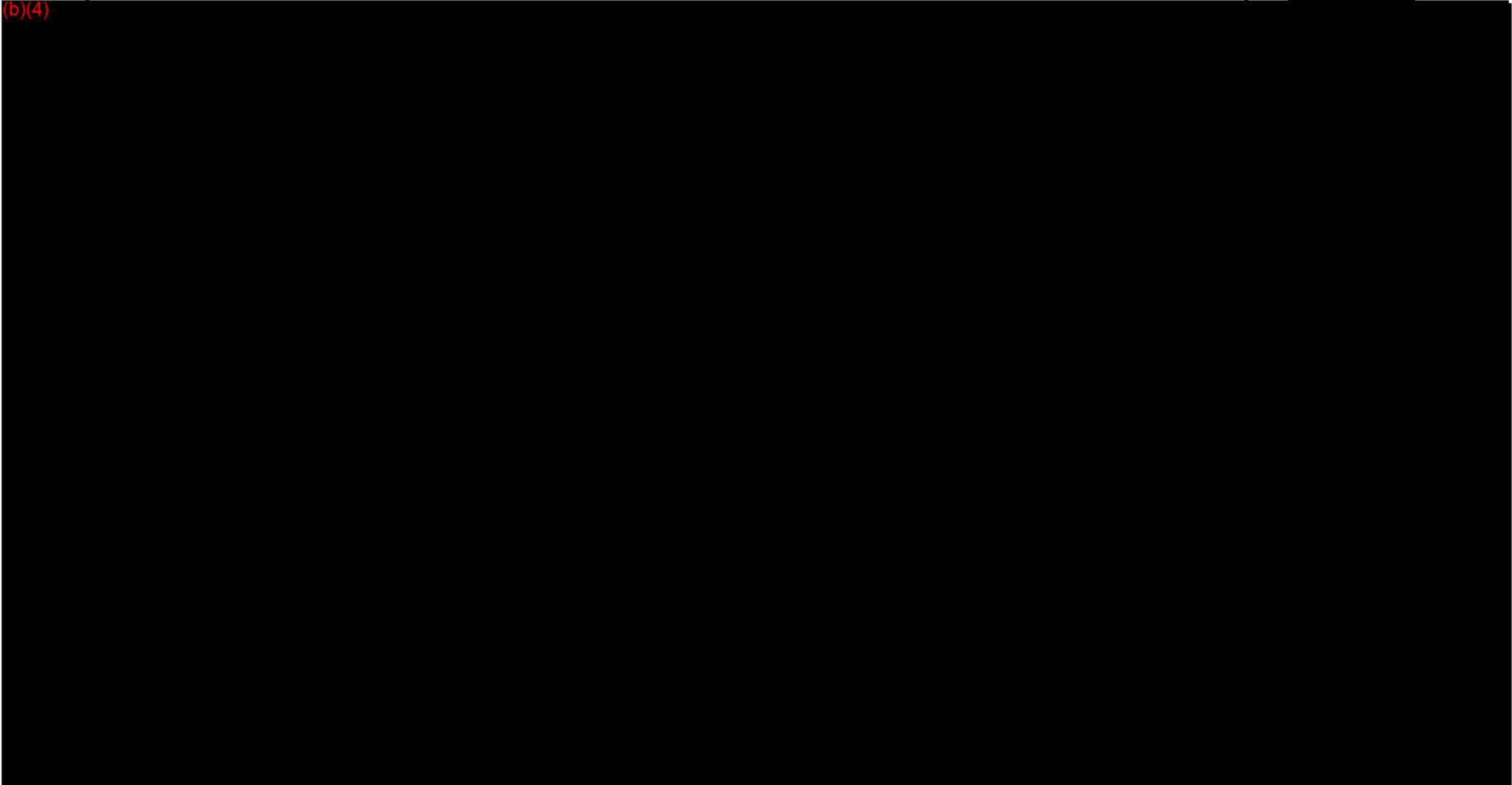


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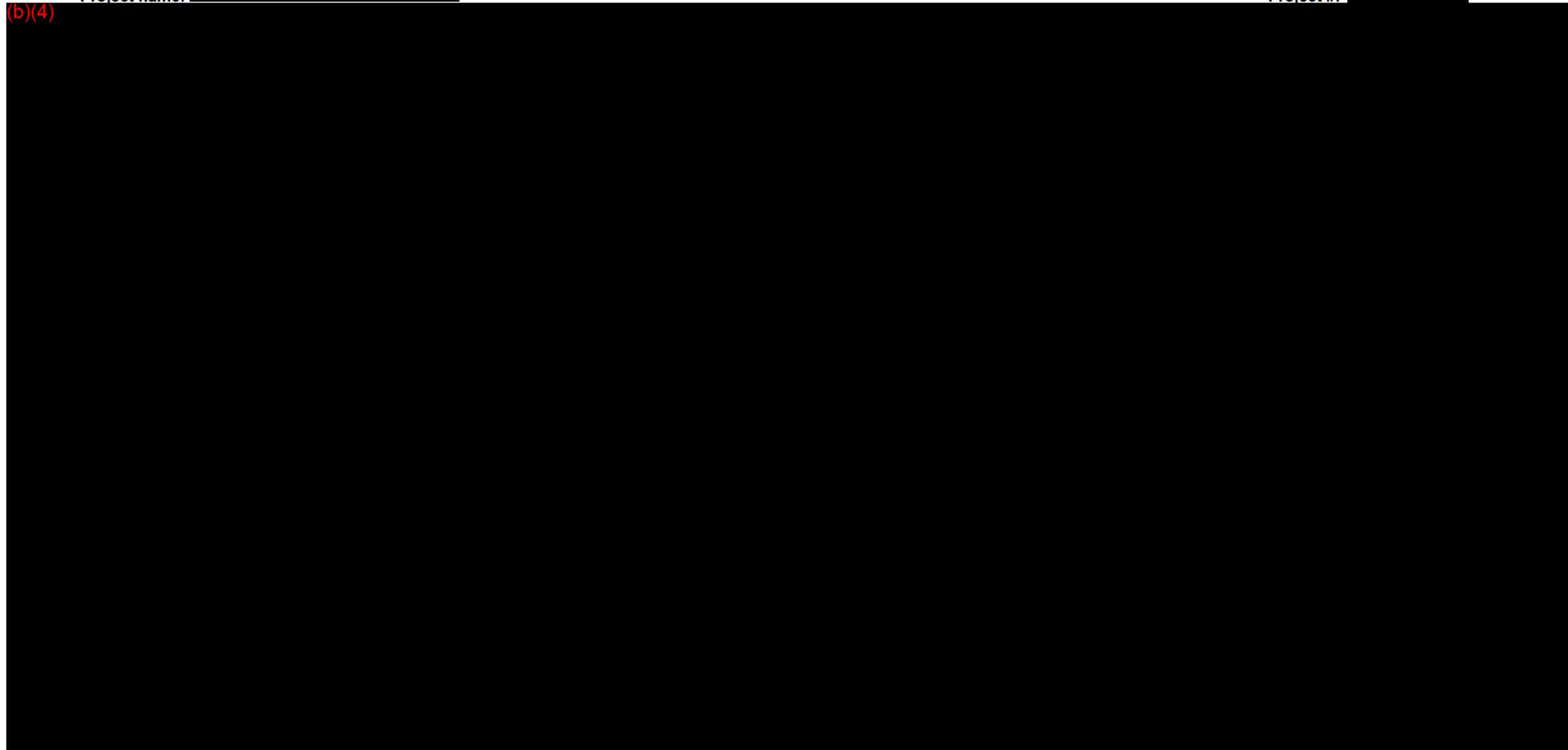
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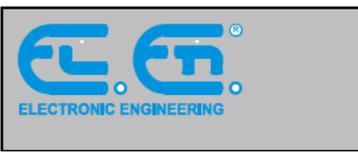
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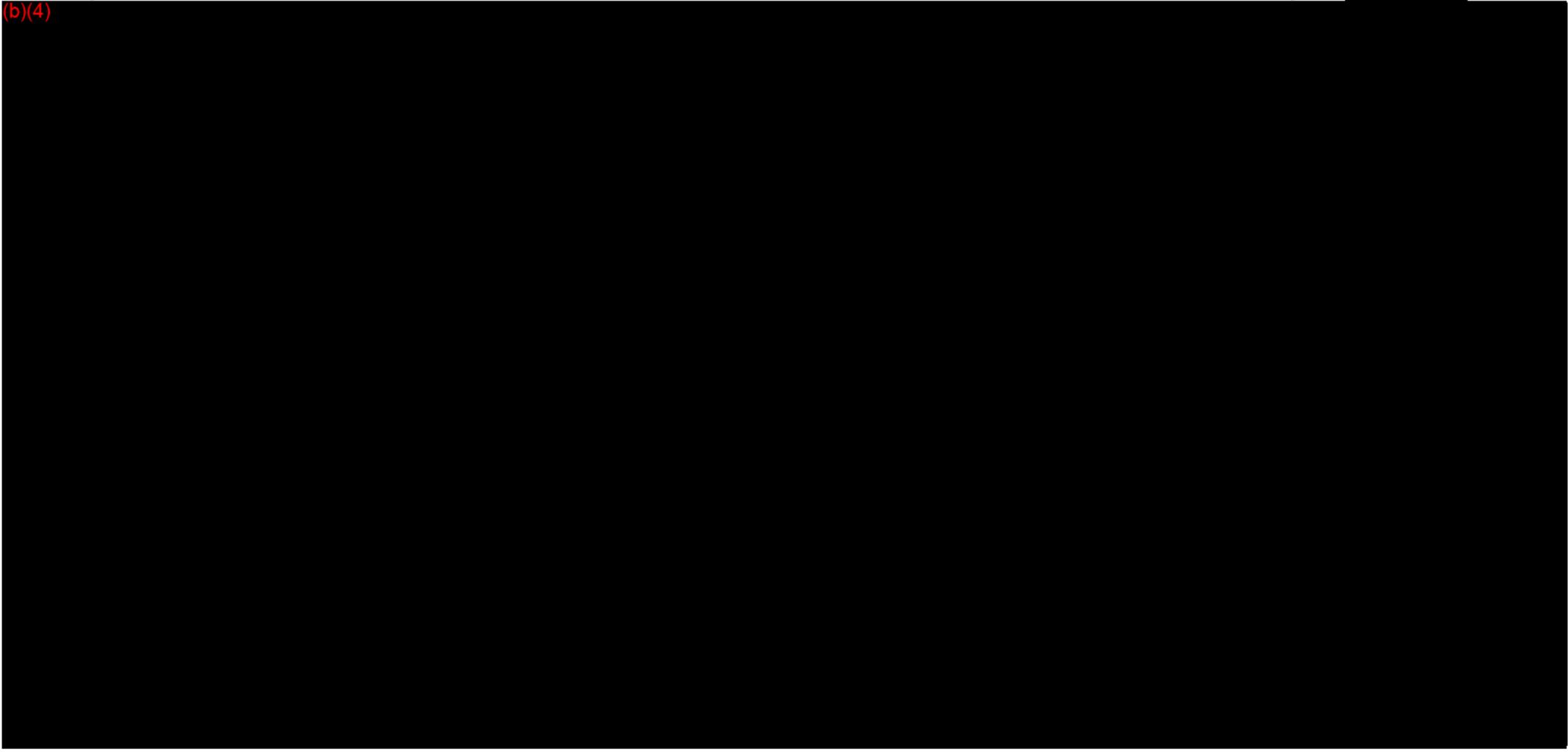
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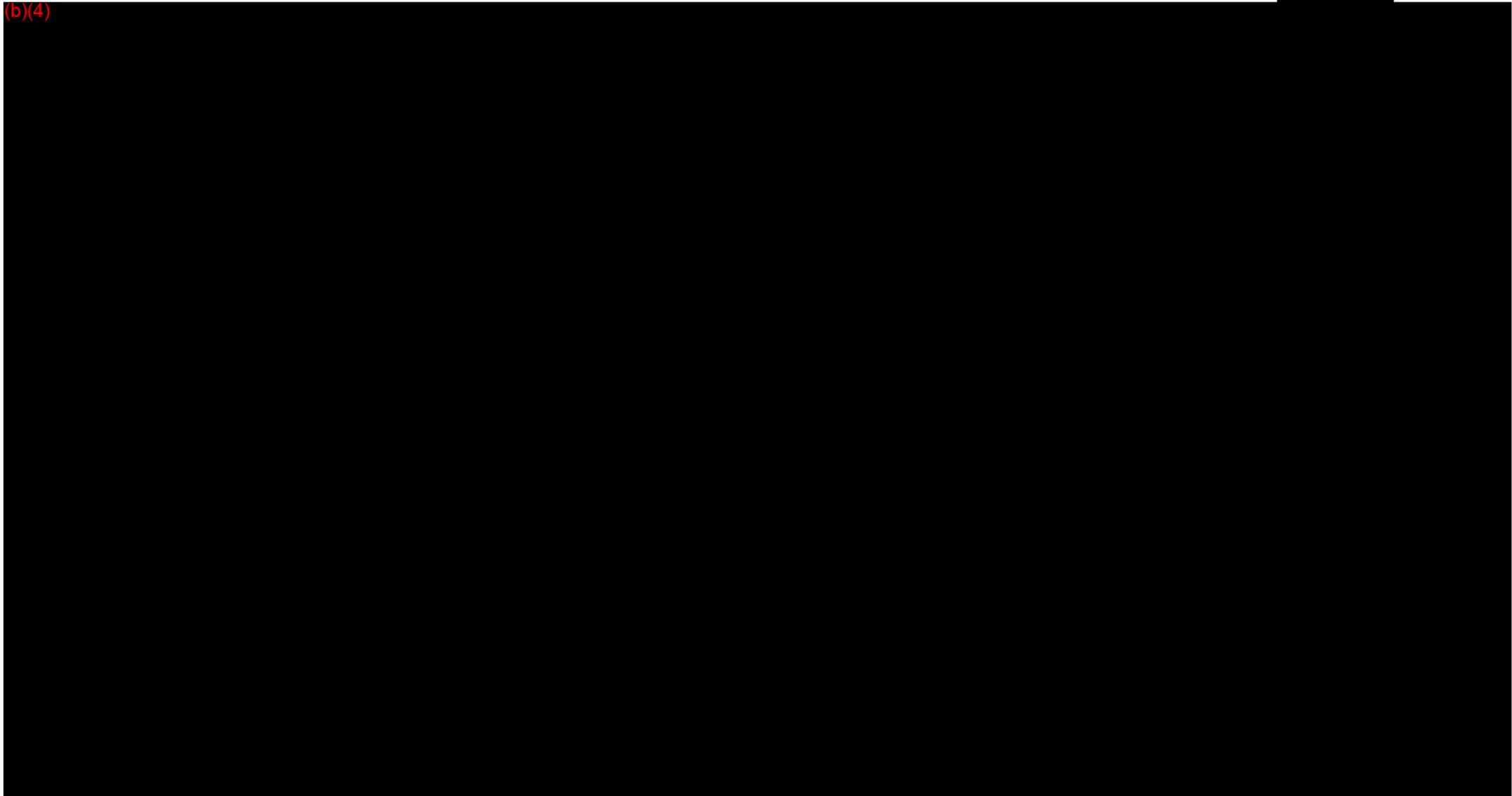
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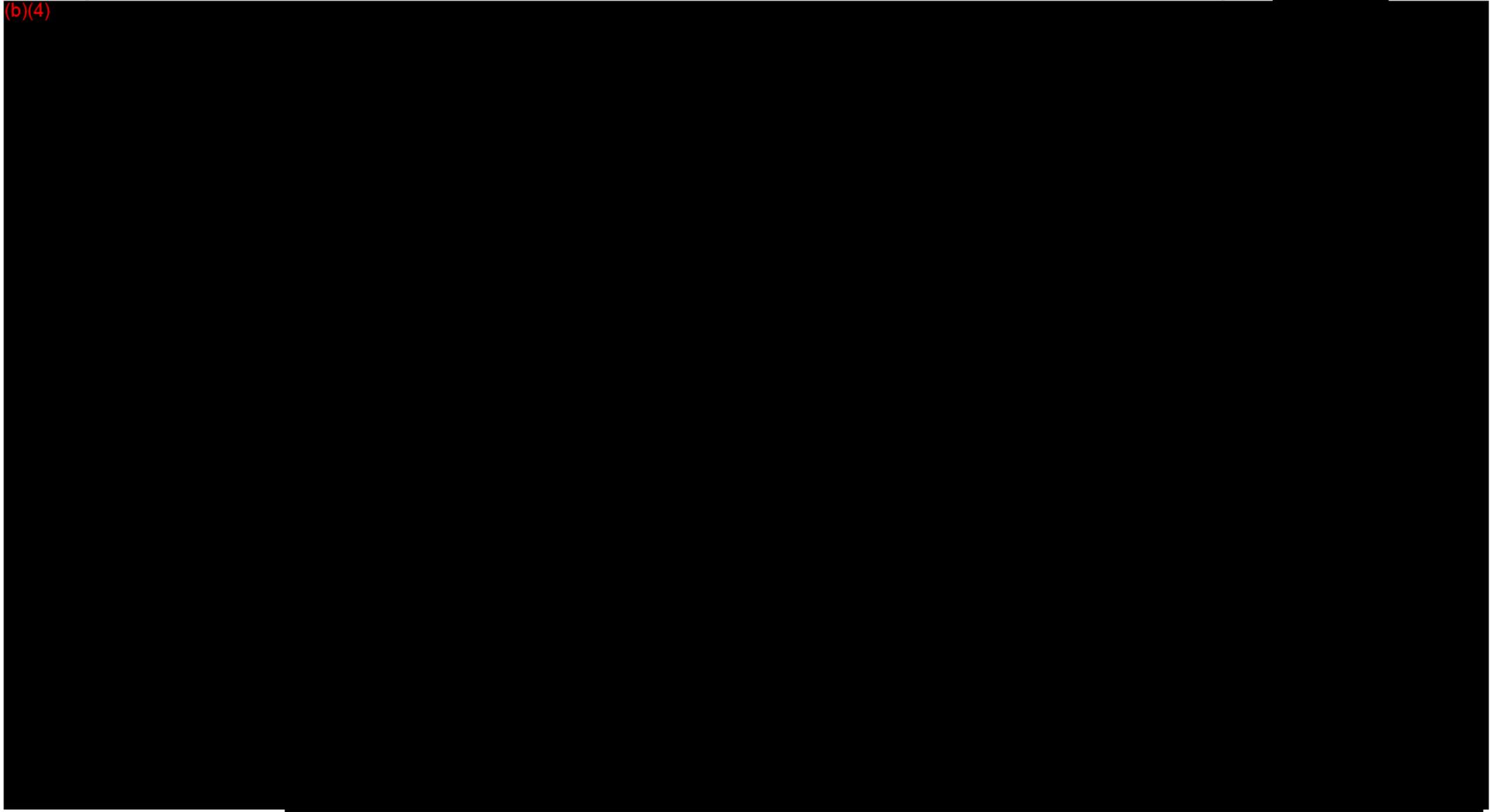


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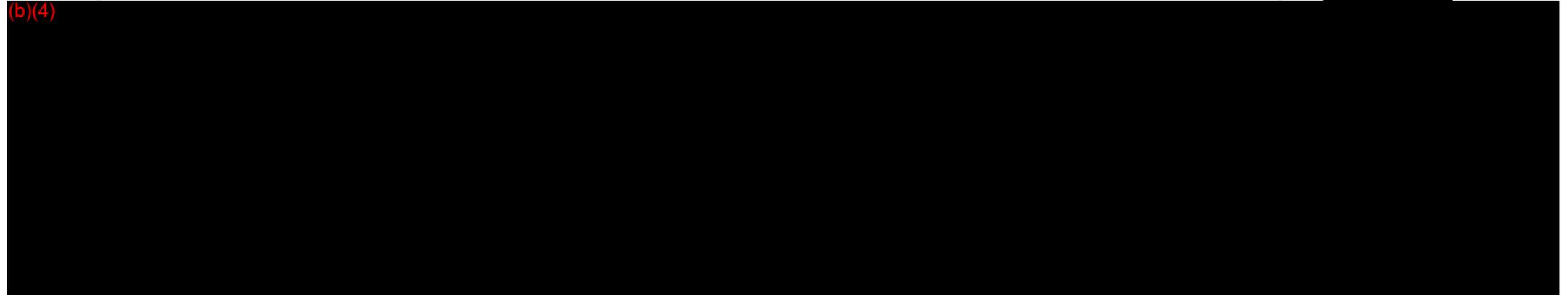


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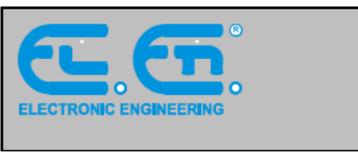
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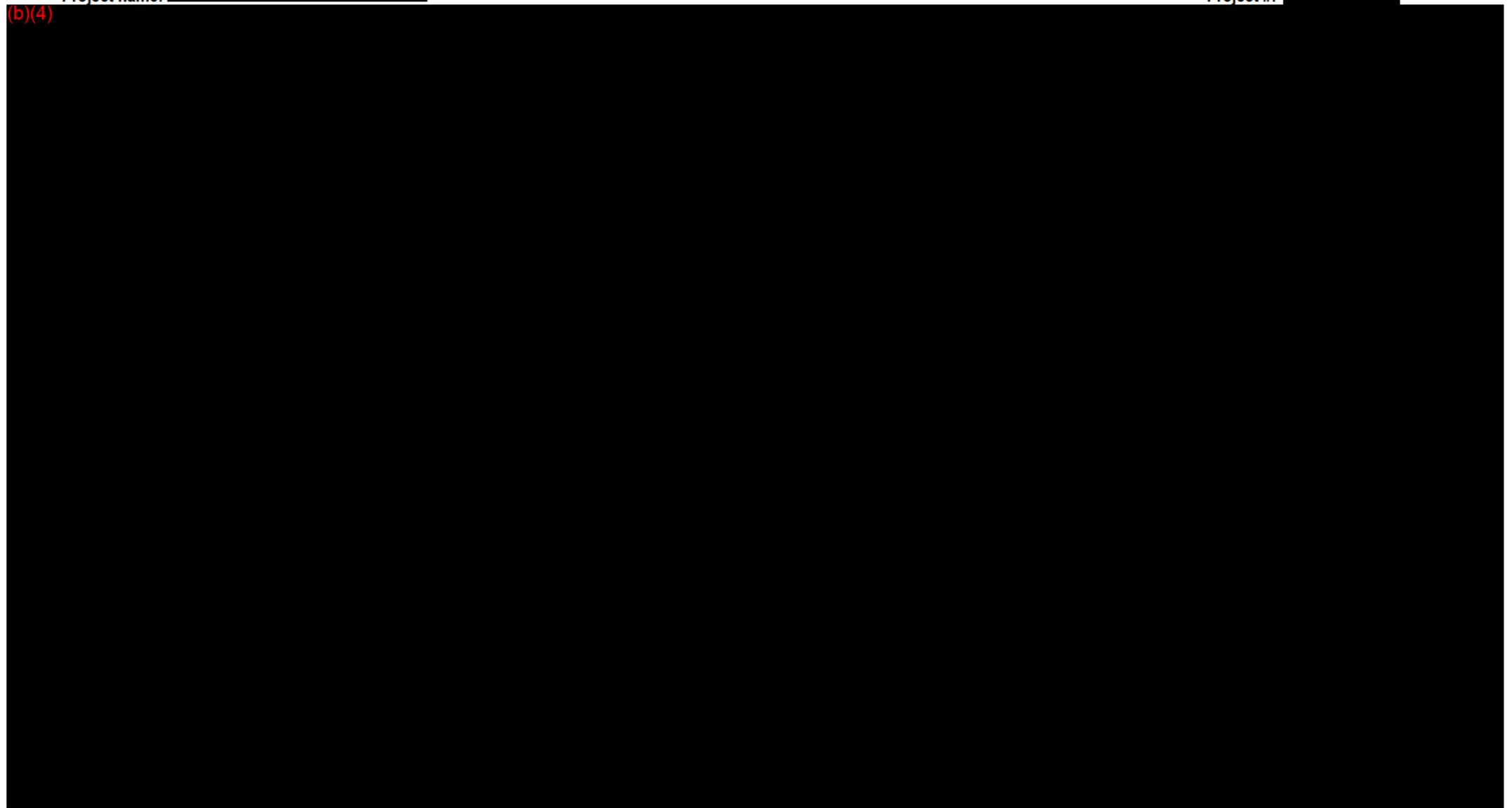


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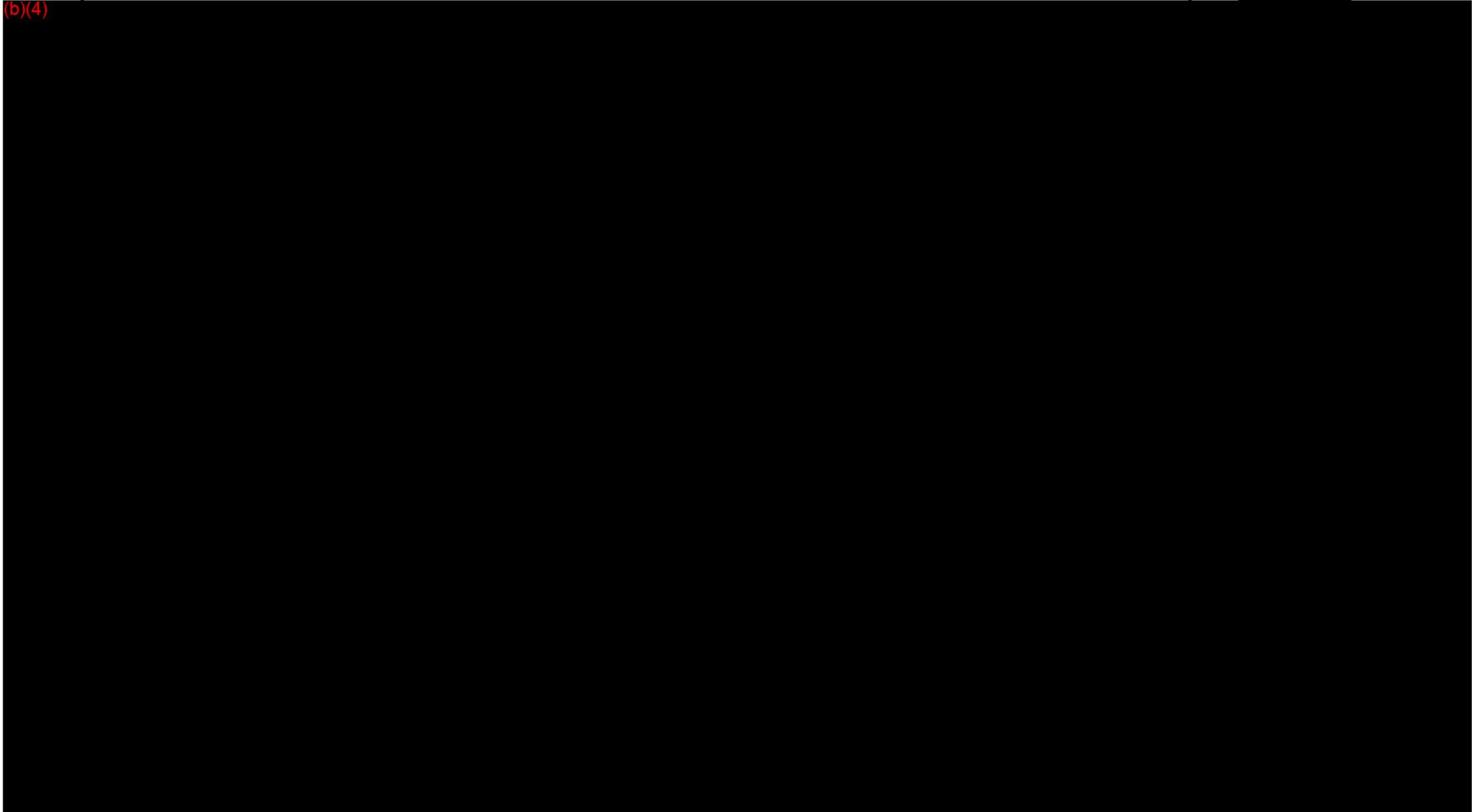
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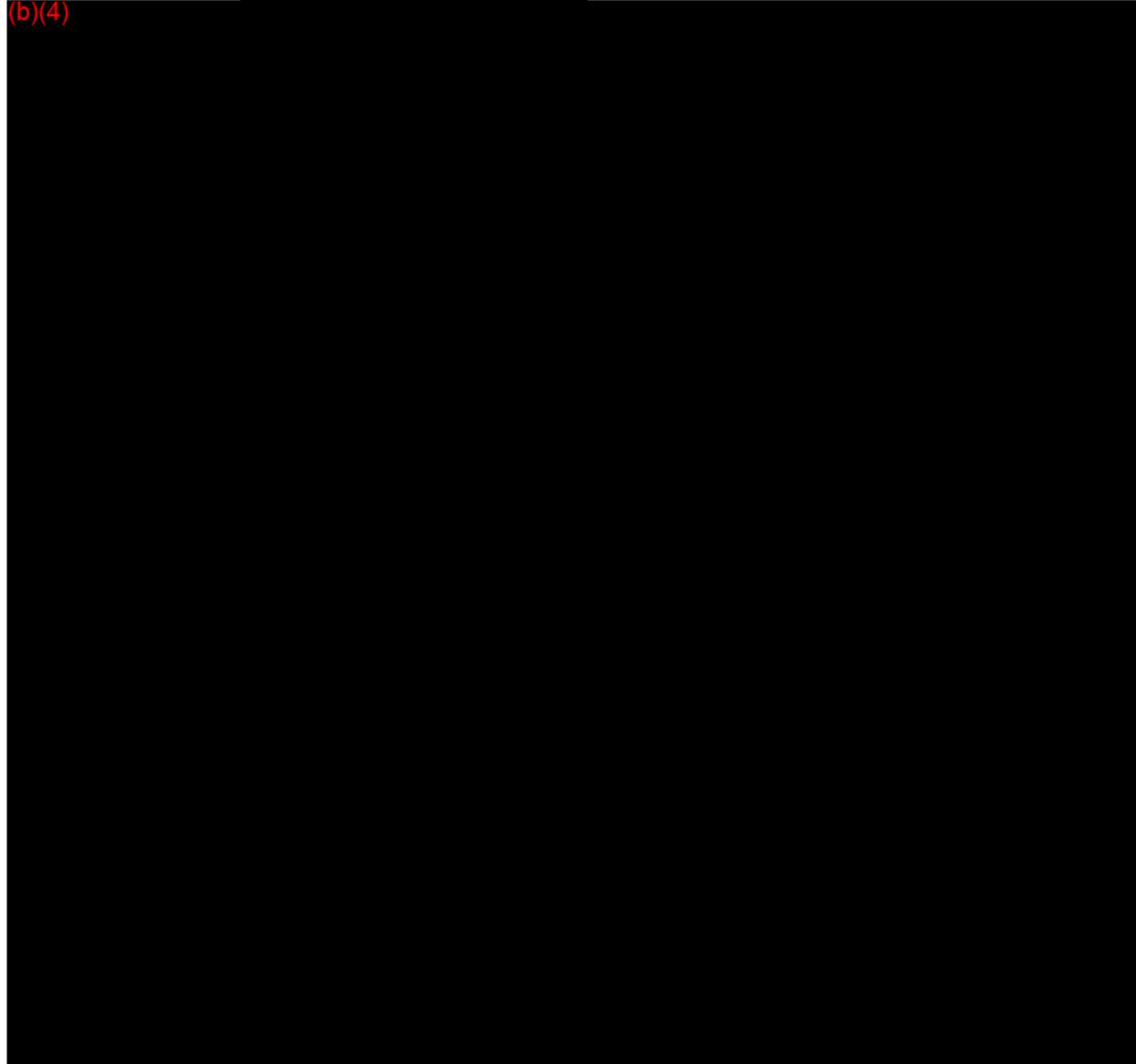
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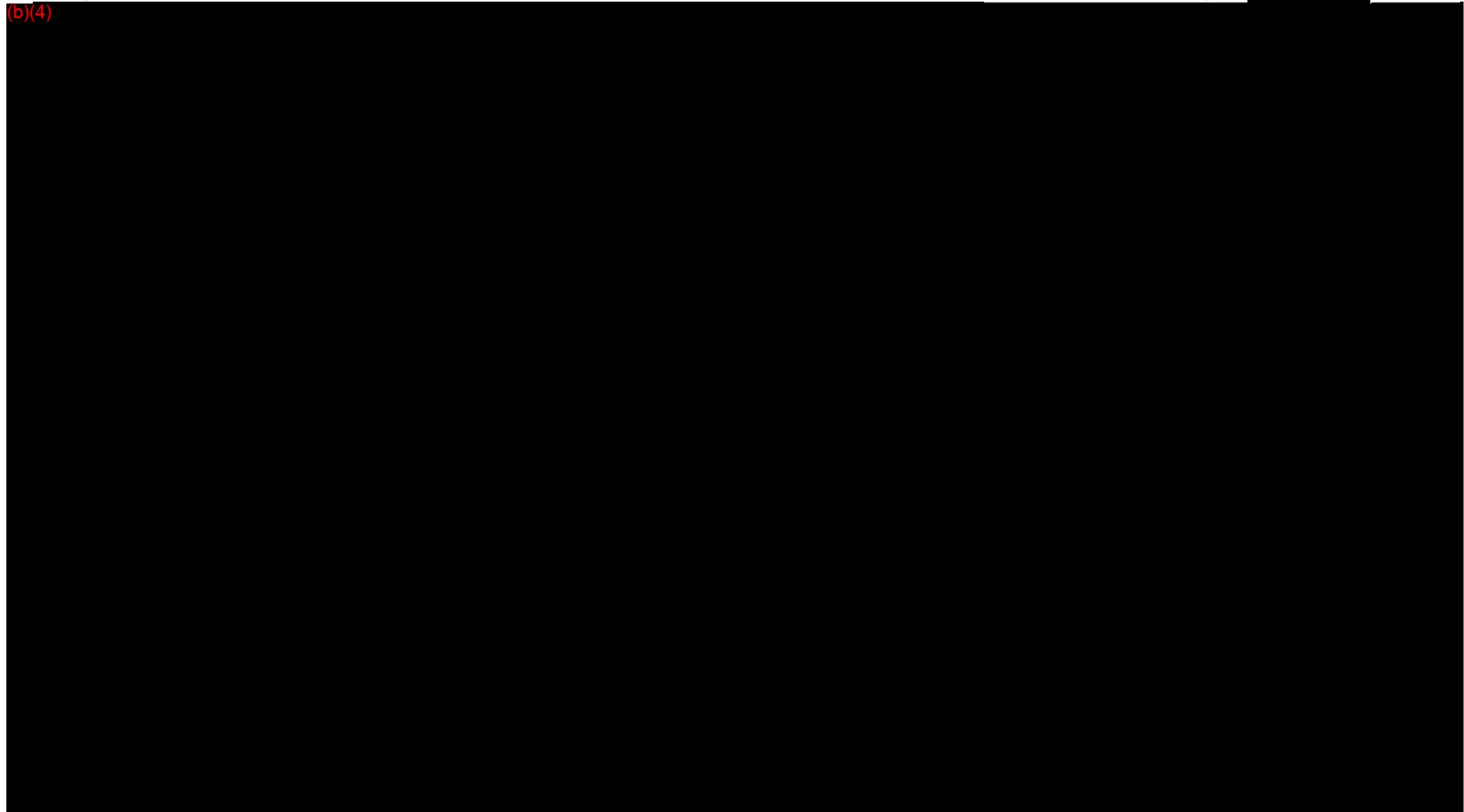


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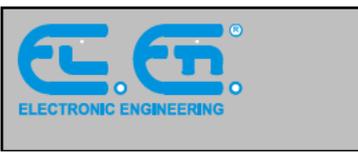
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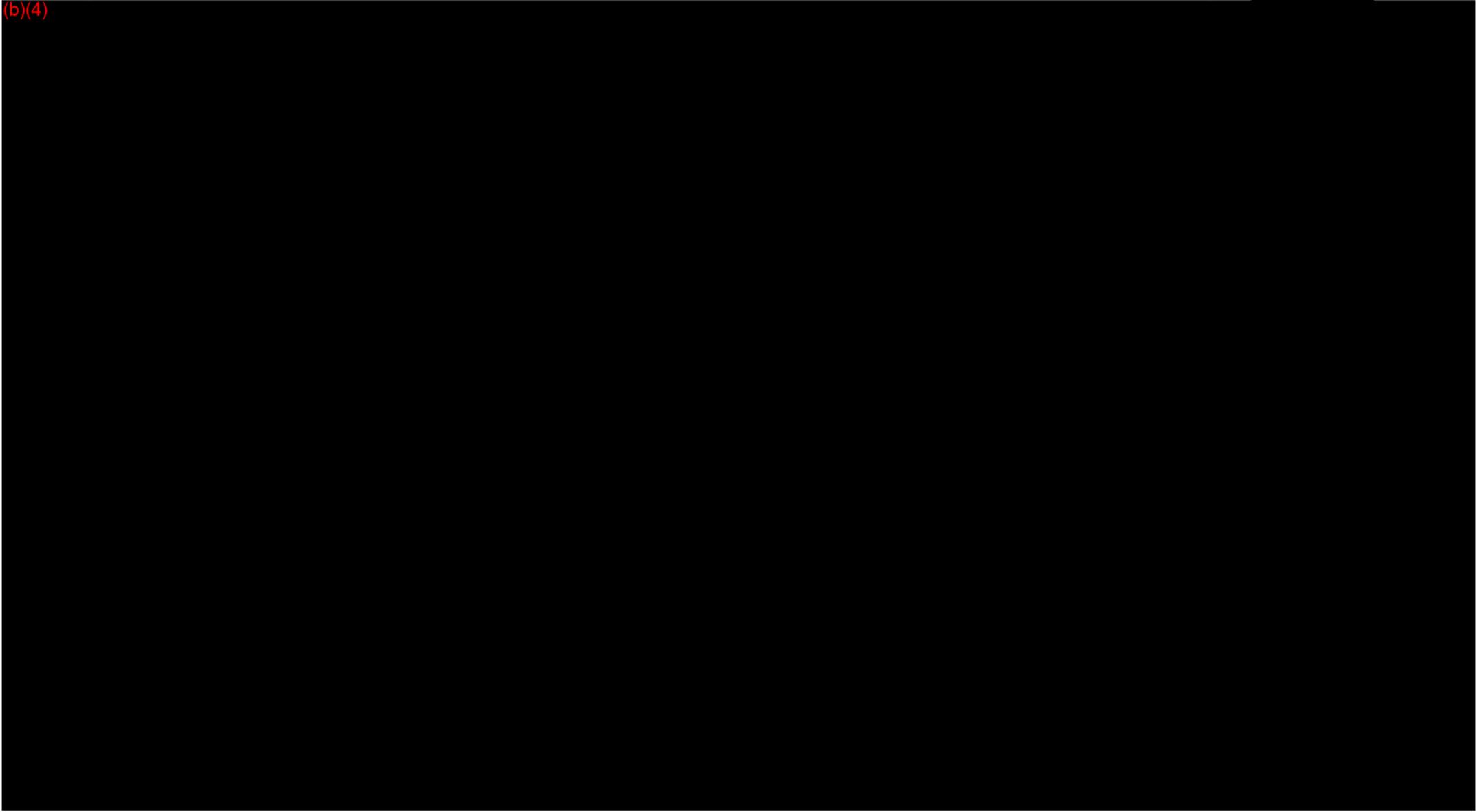
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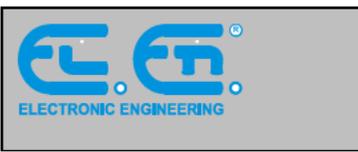
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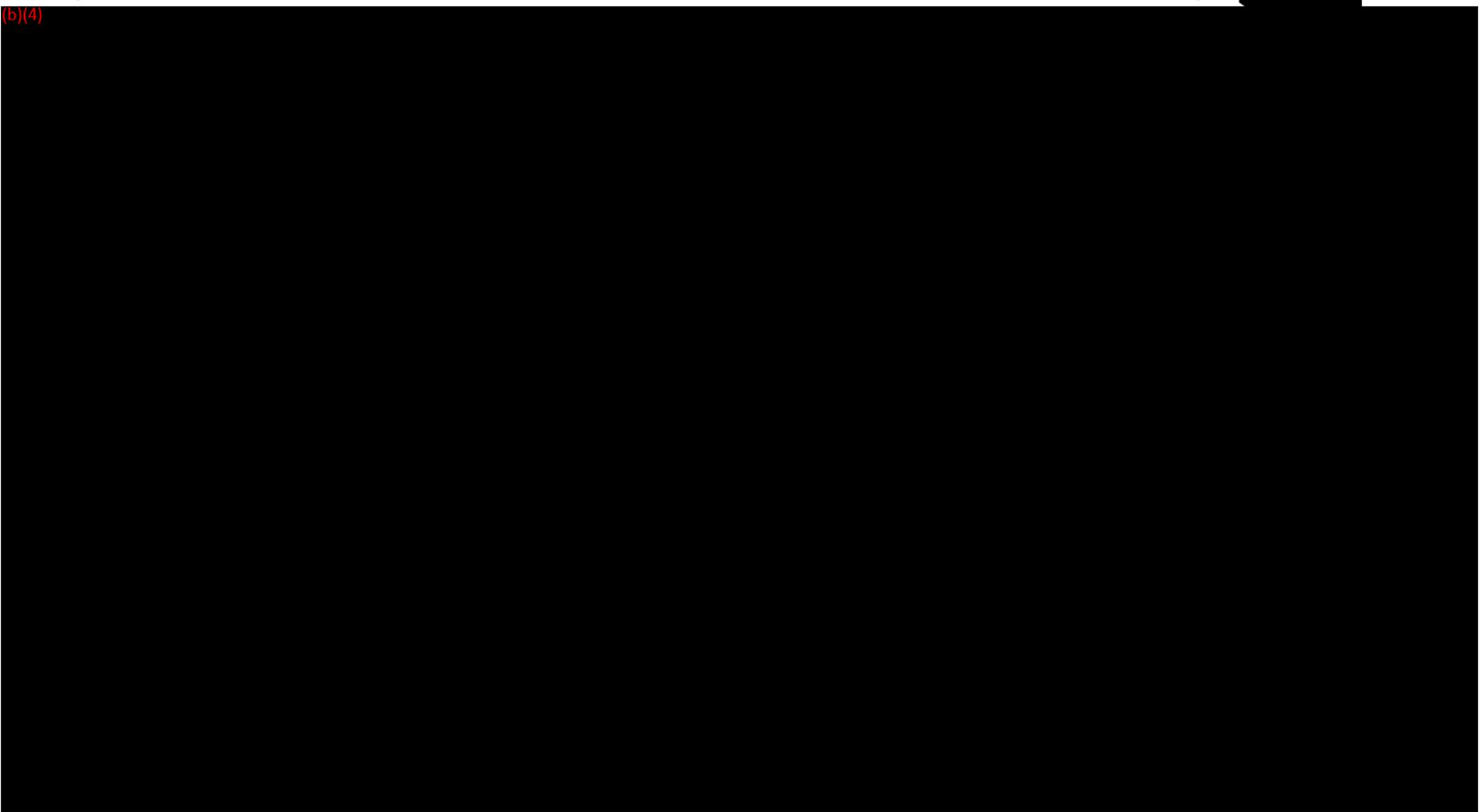


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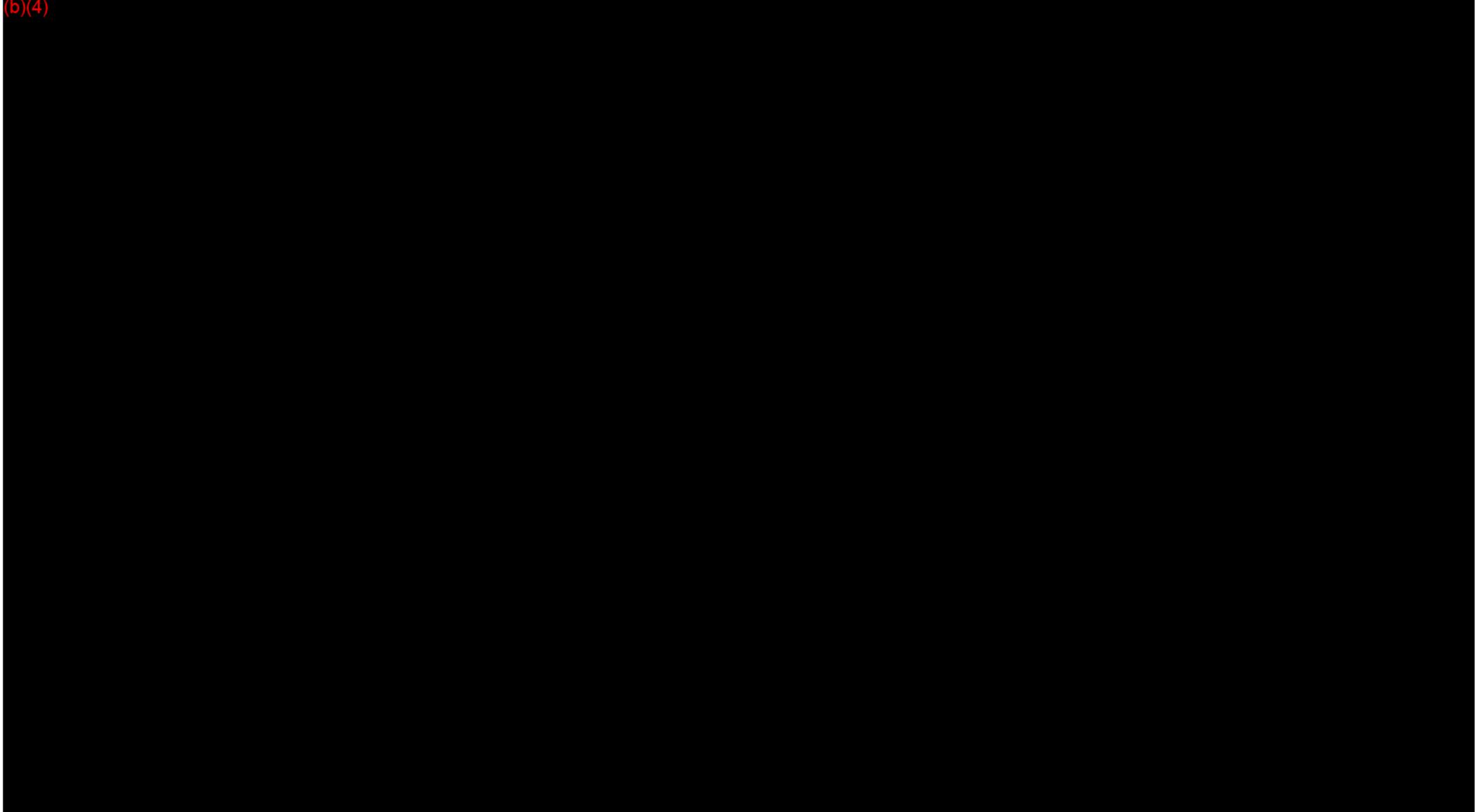


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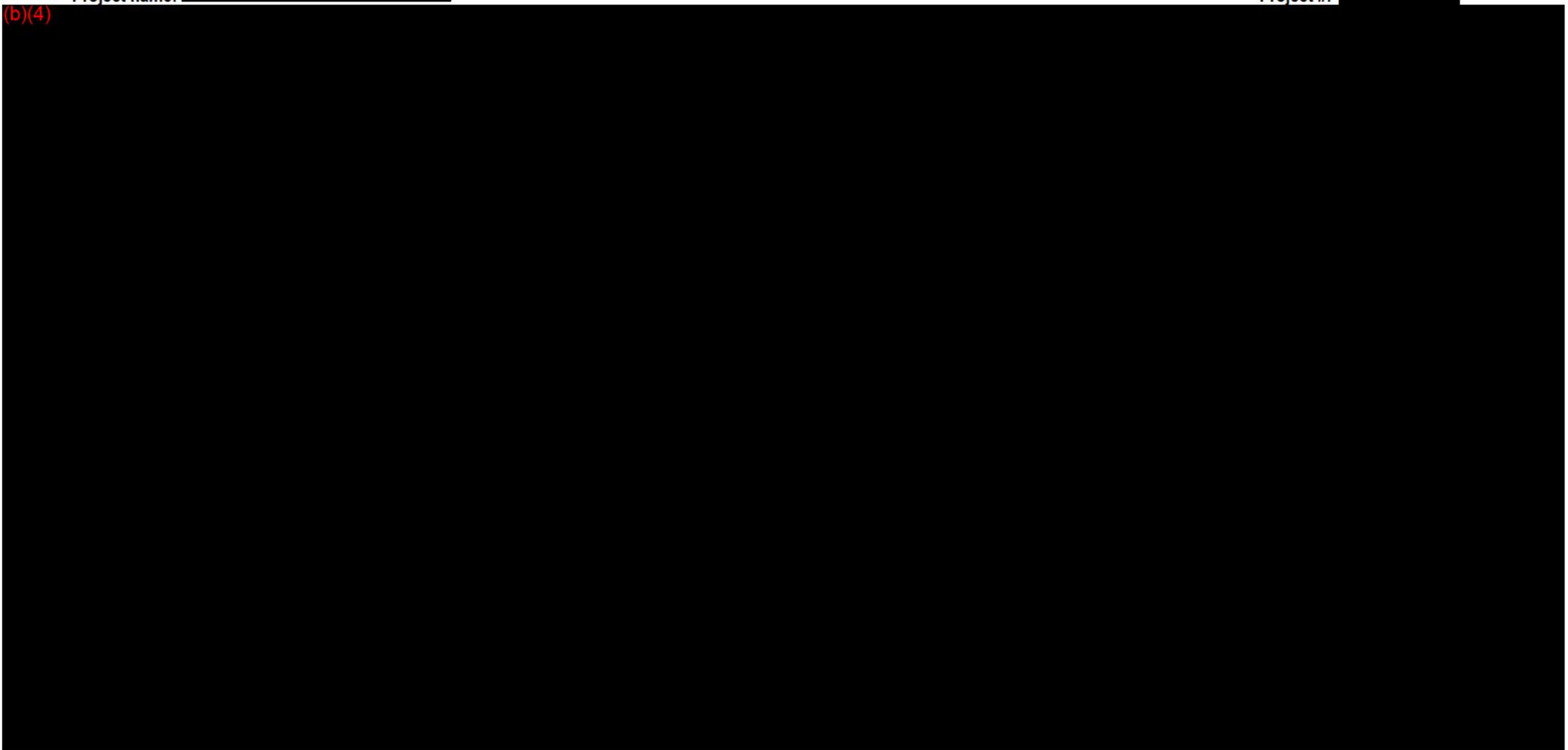


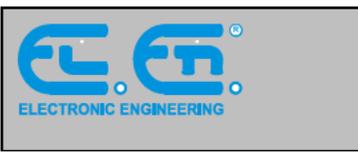
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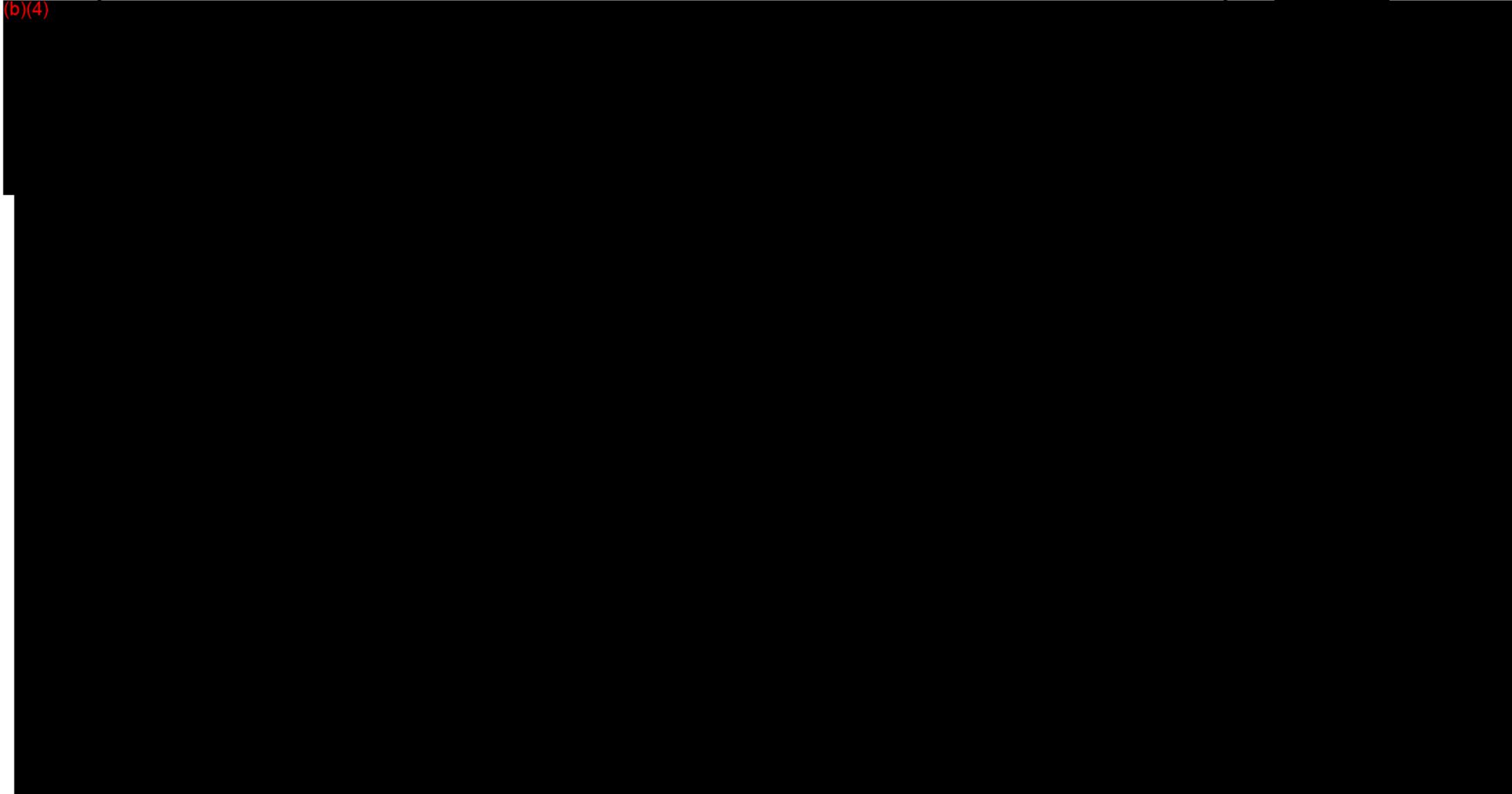
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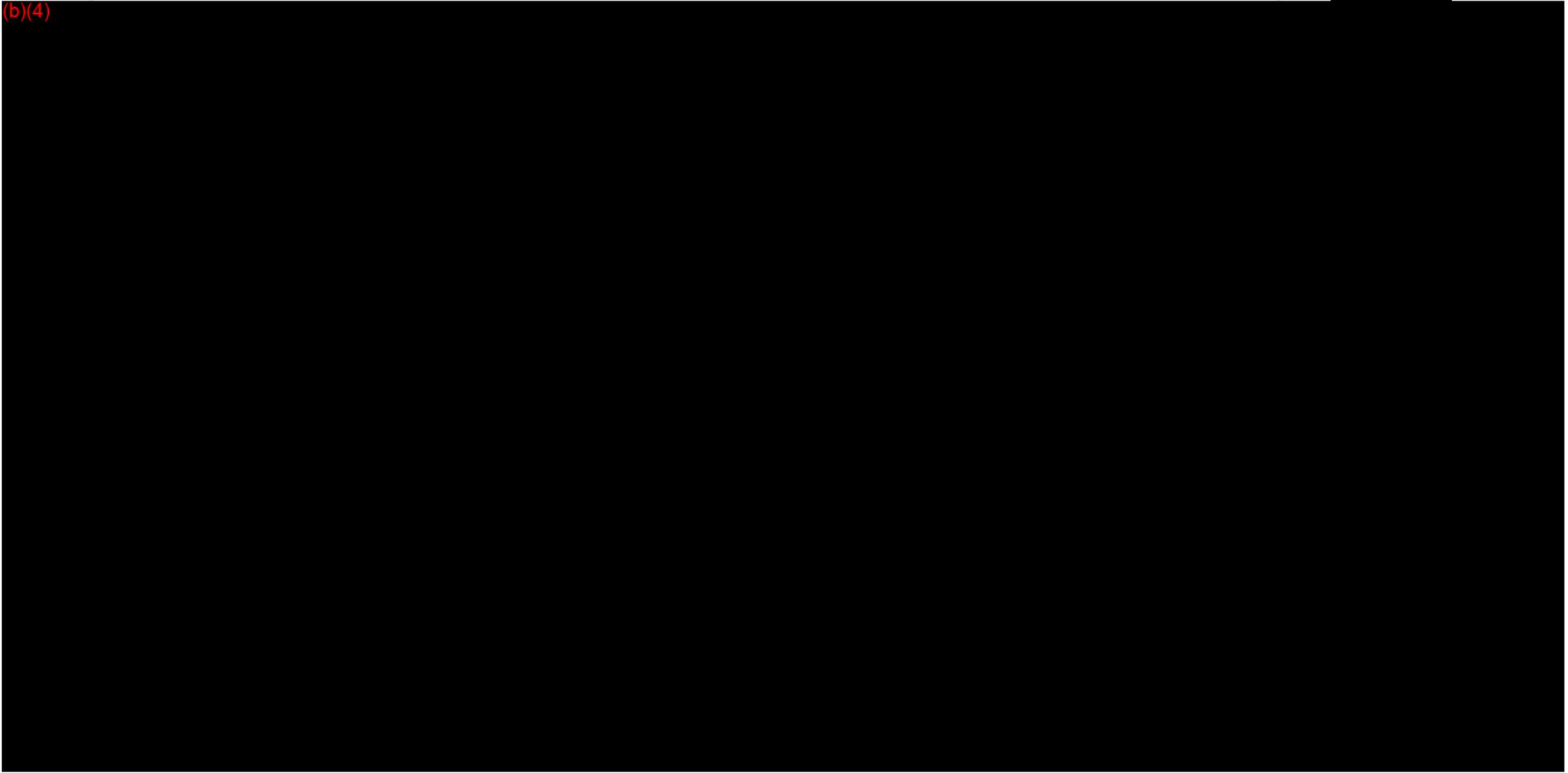


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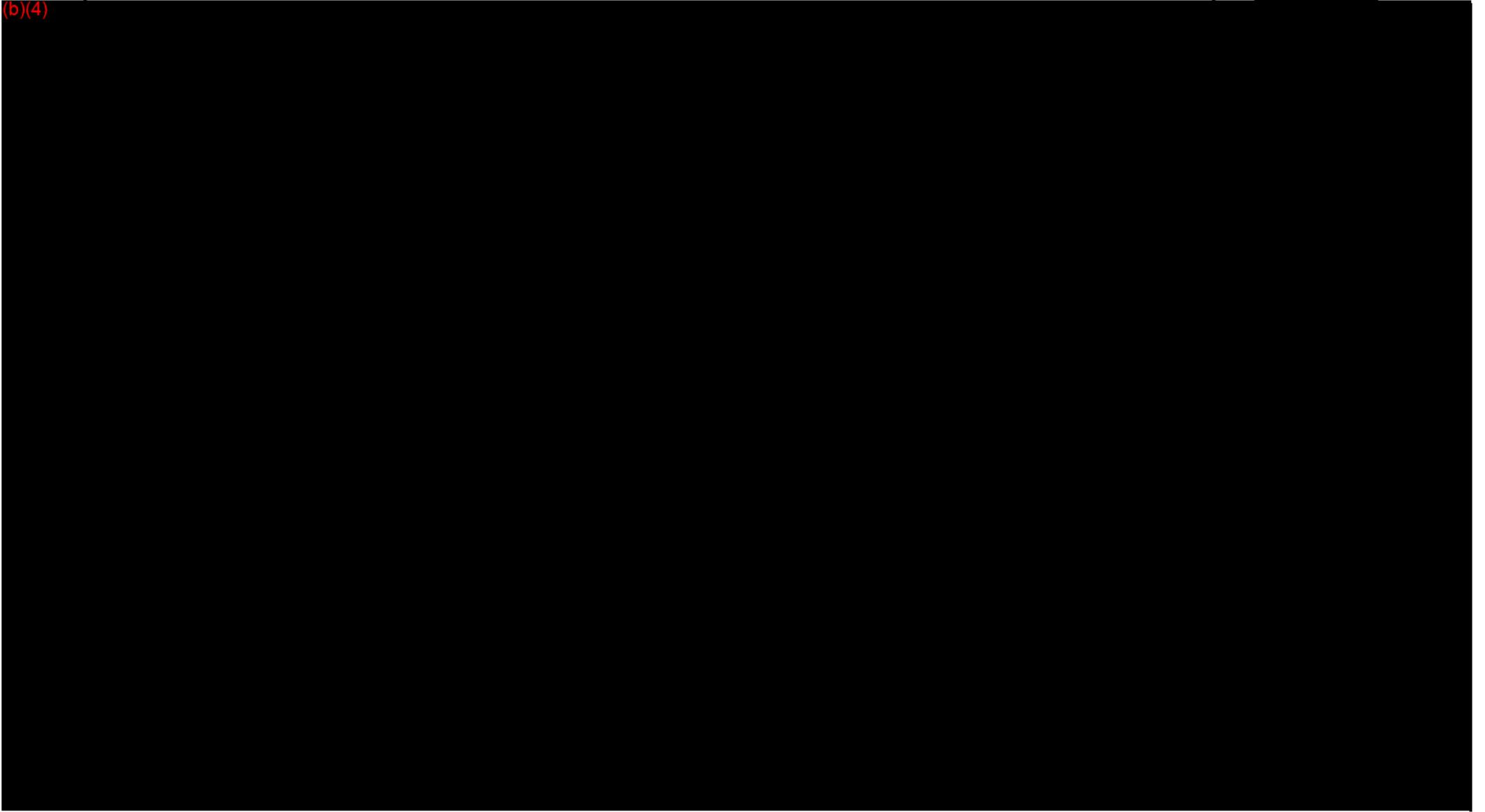
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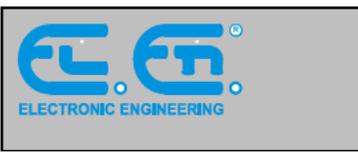
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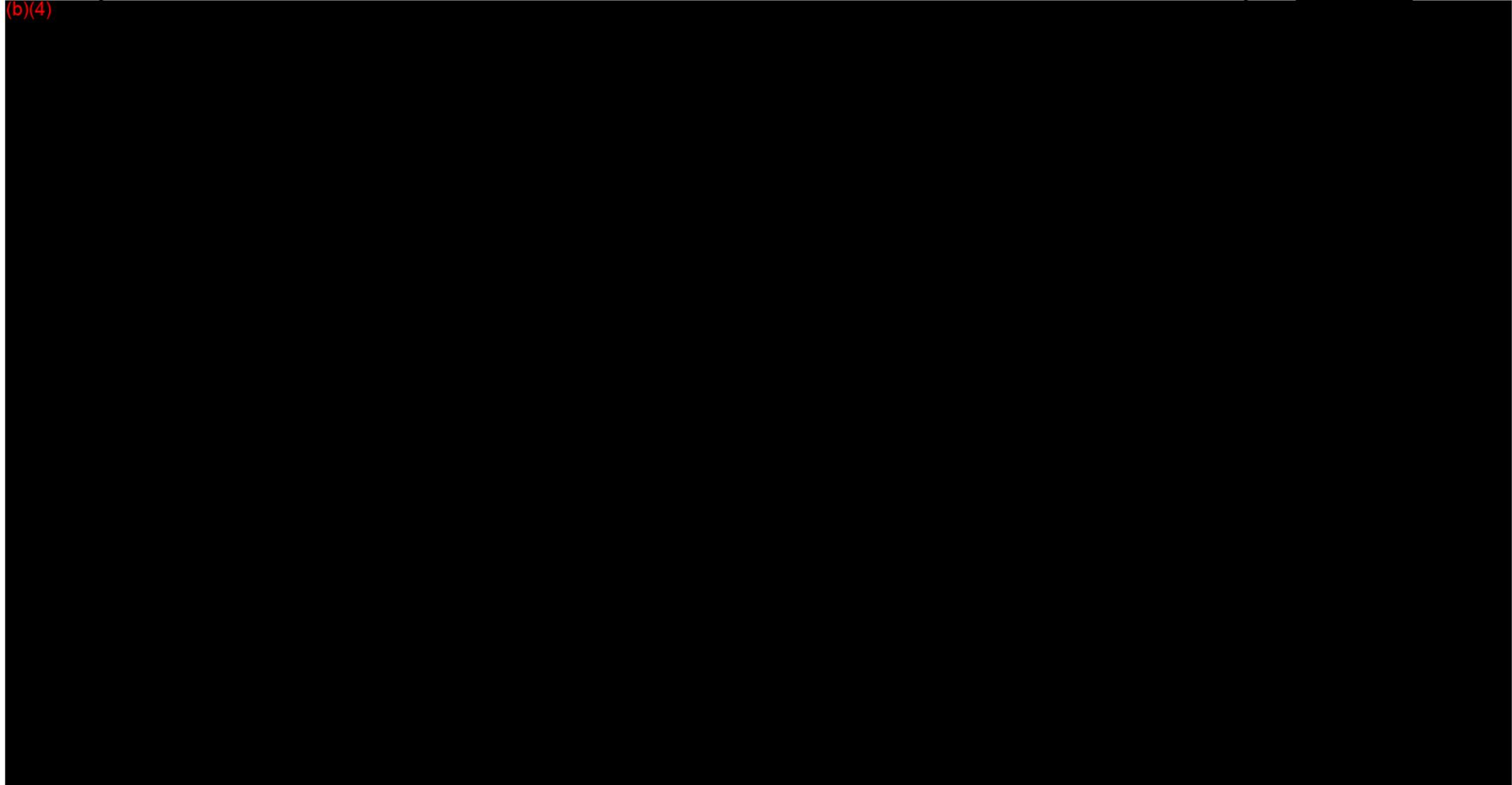
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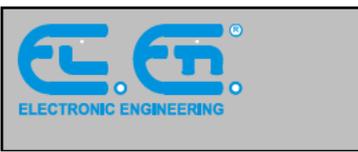
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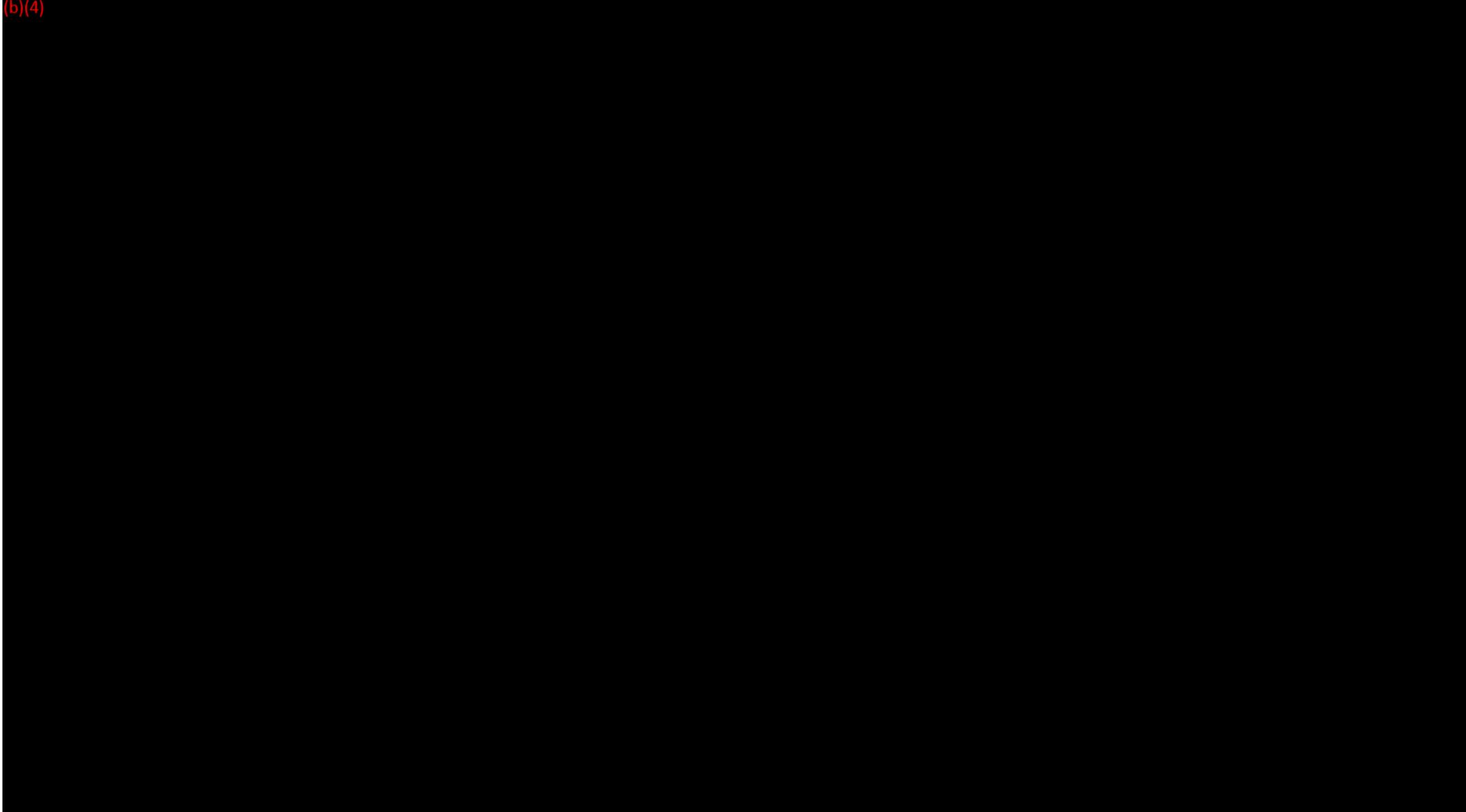
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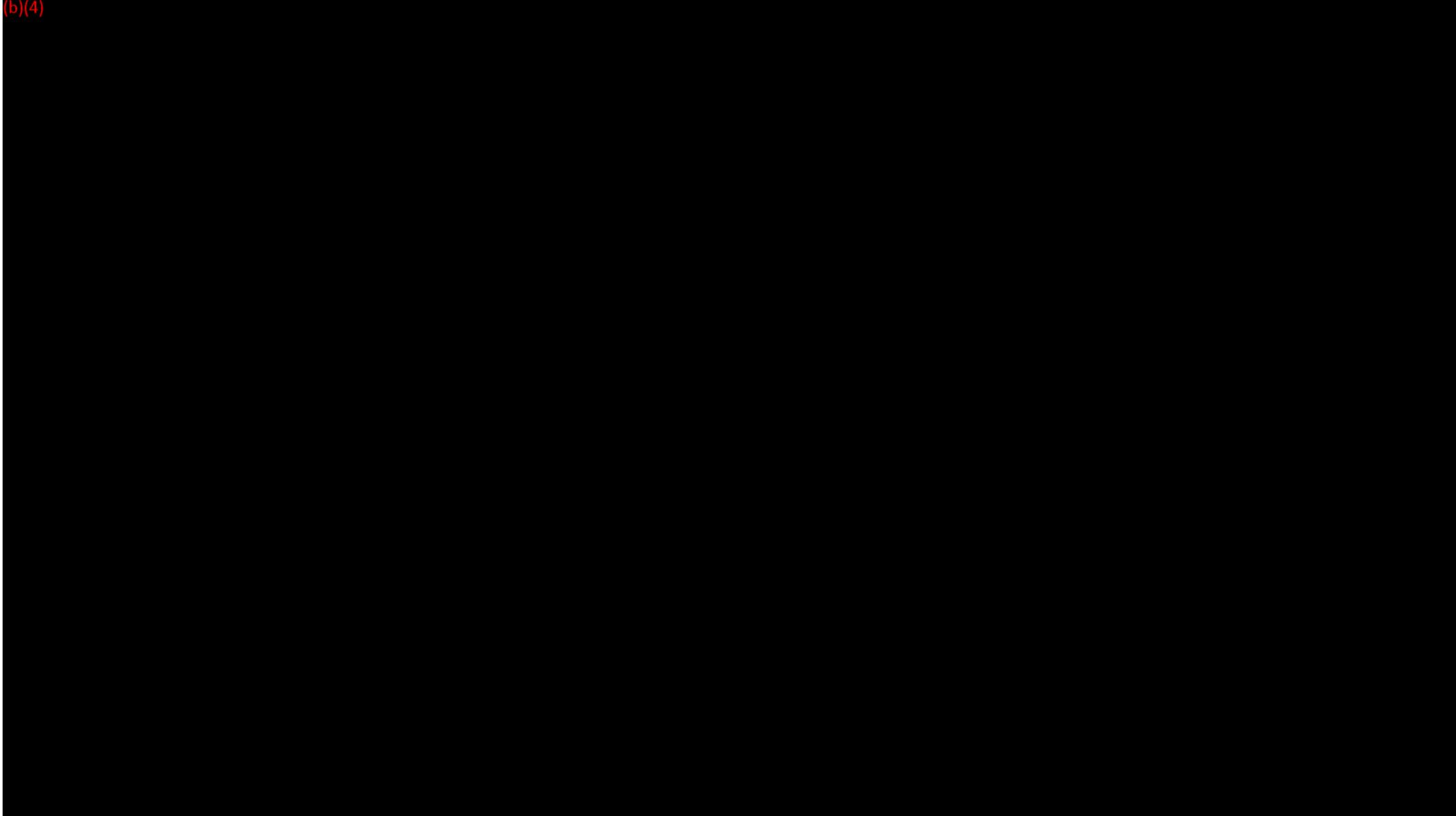
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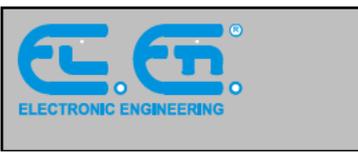
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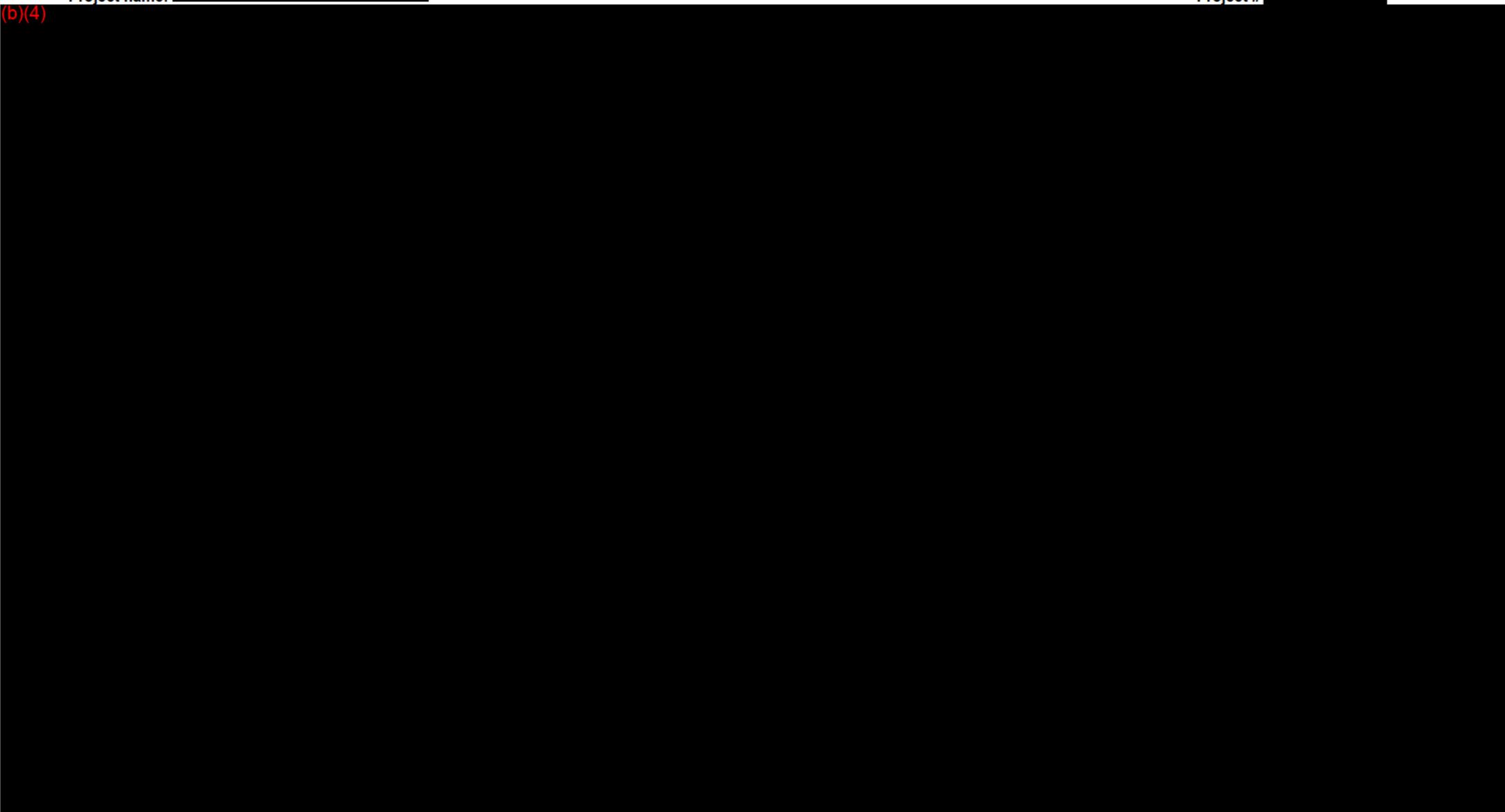


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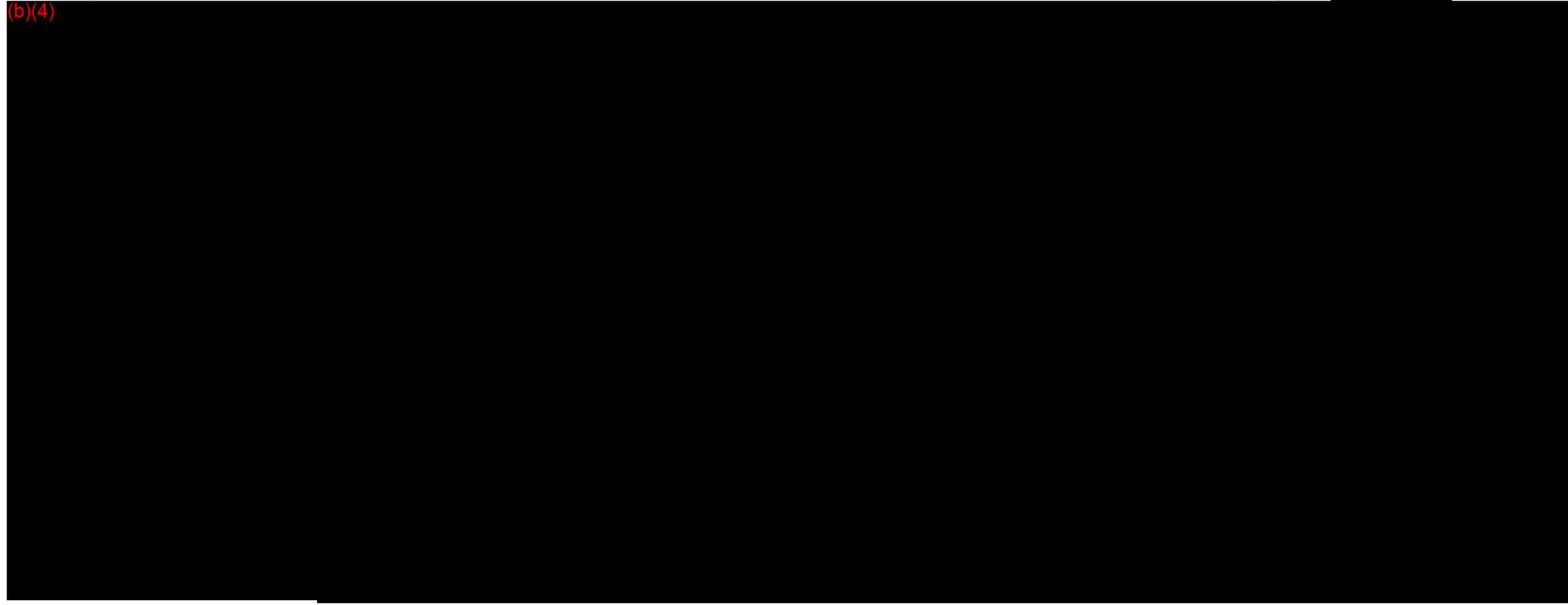


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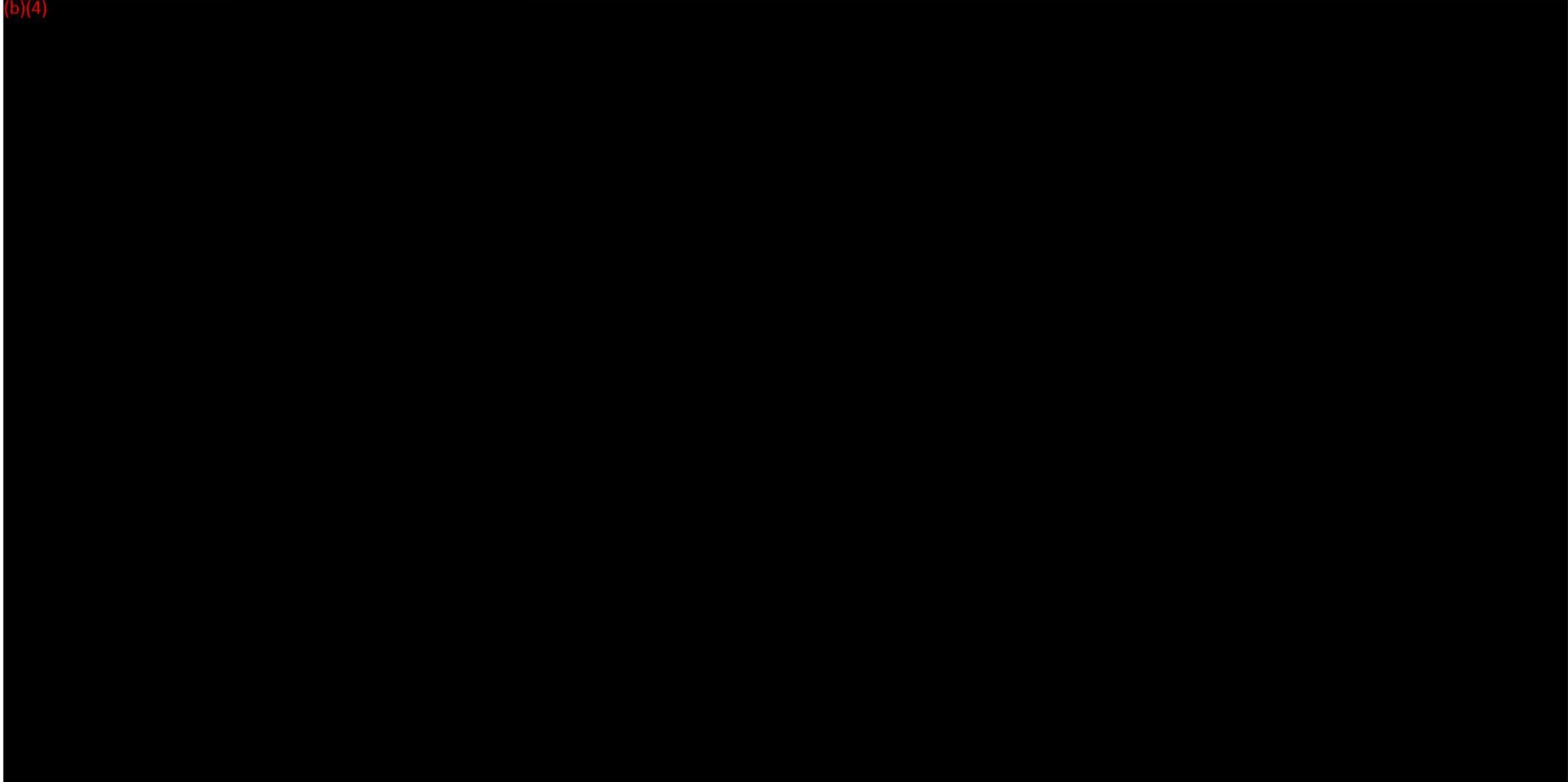
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PART VI: (b)(4) **SOFTWARE SPECIFICATIONS**

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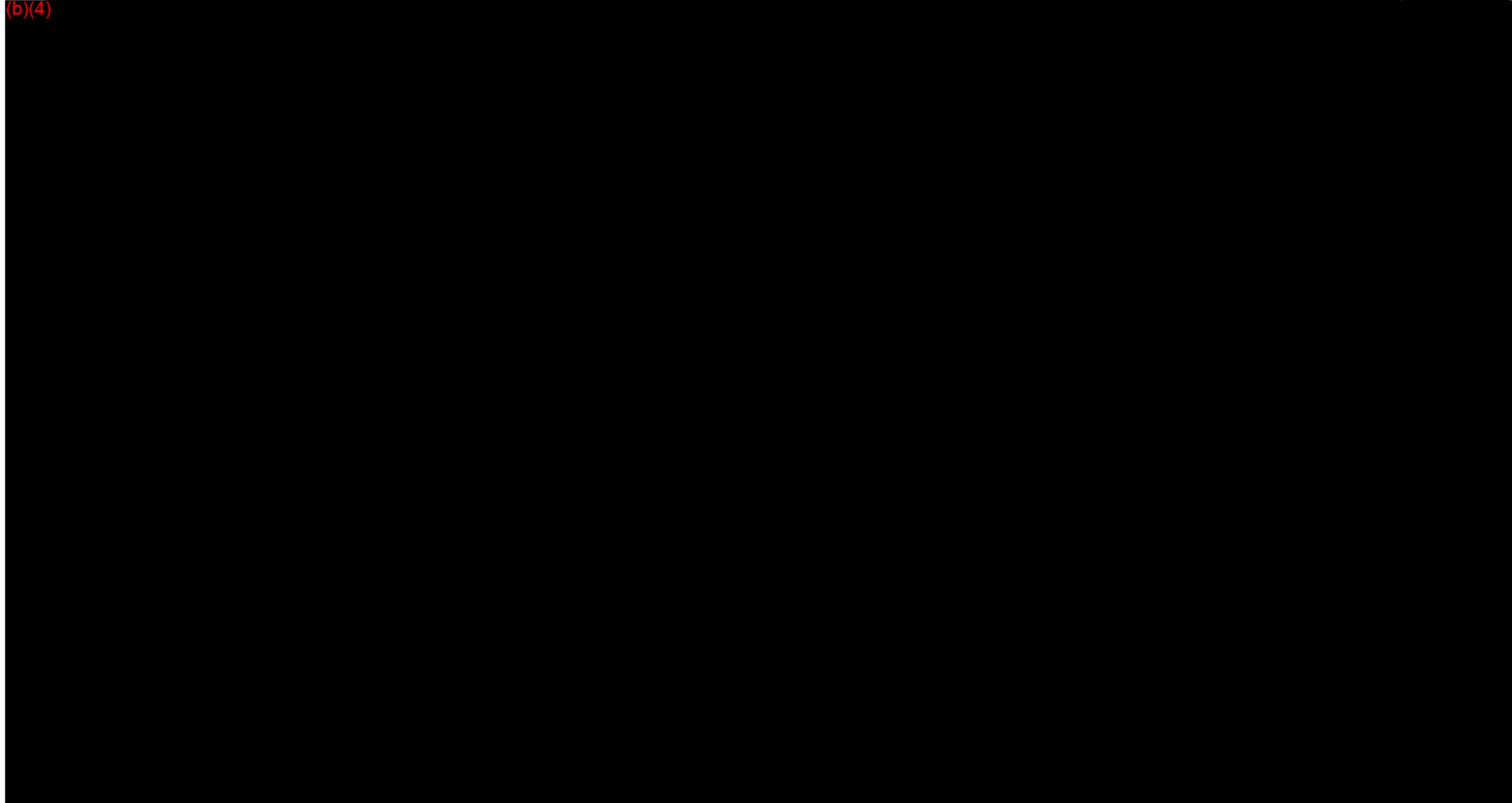
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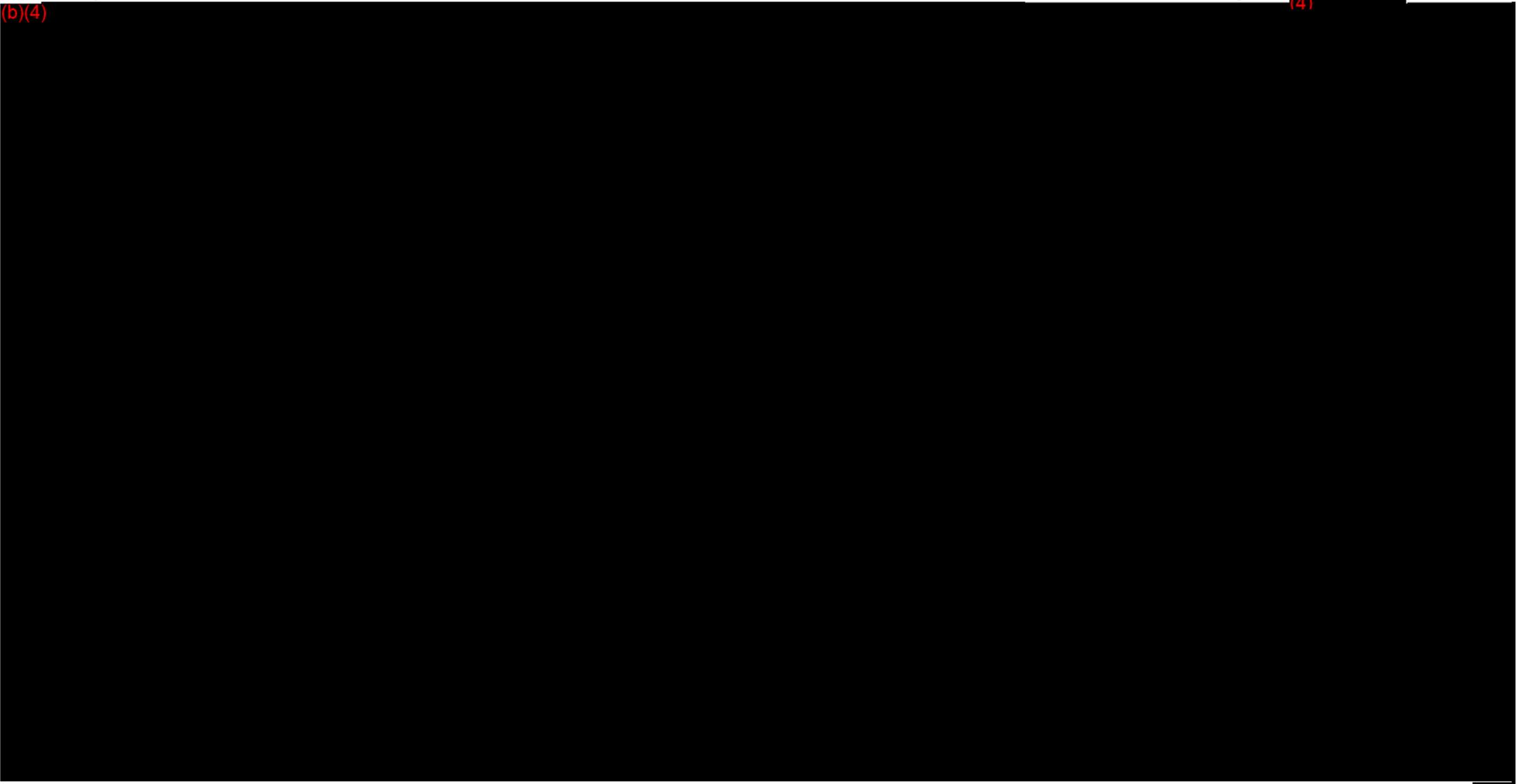


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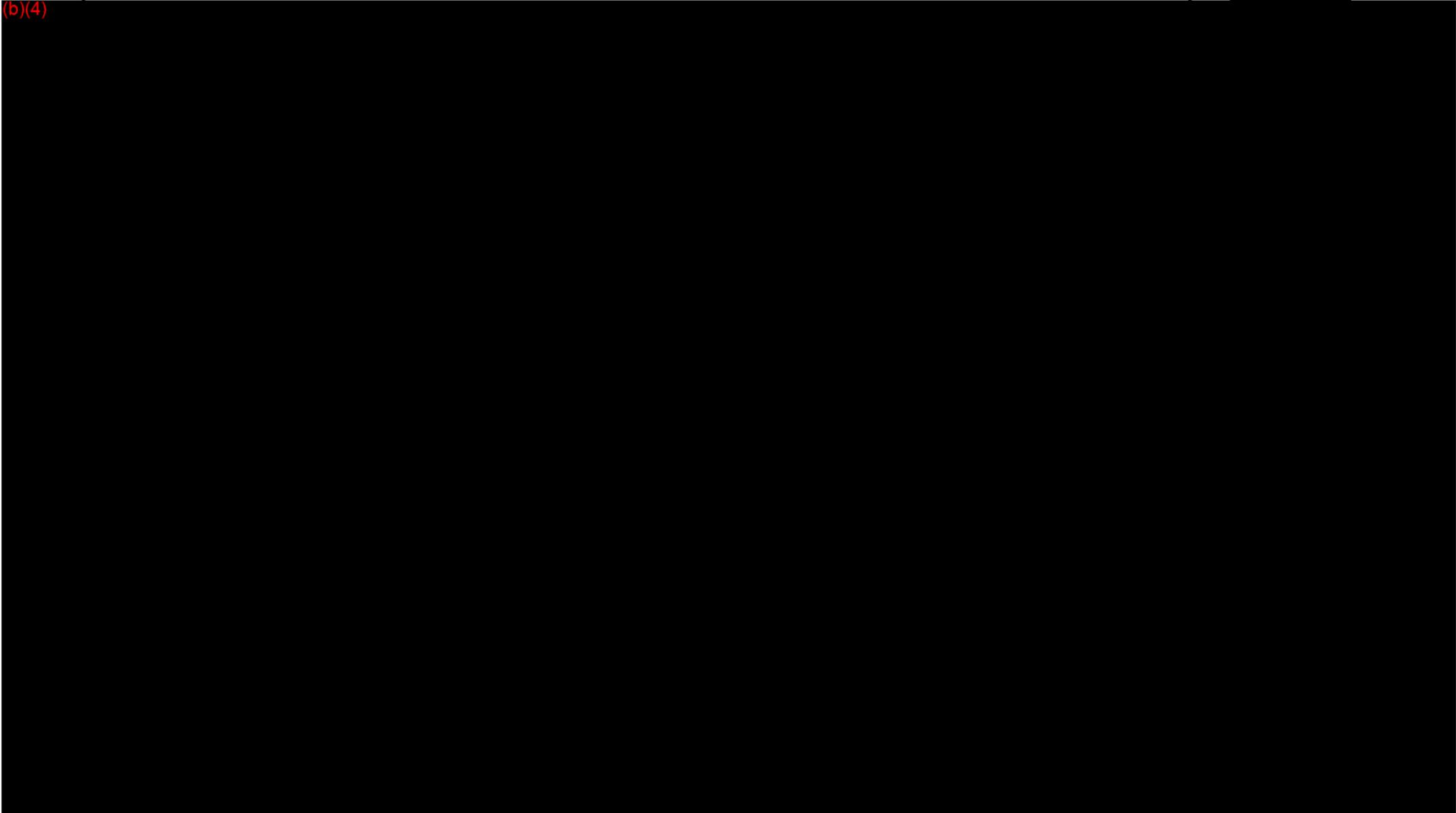
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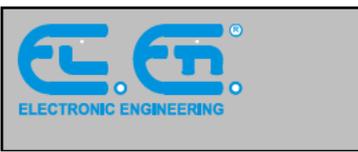
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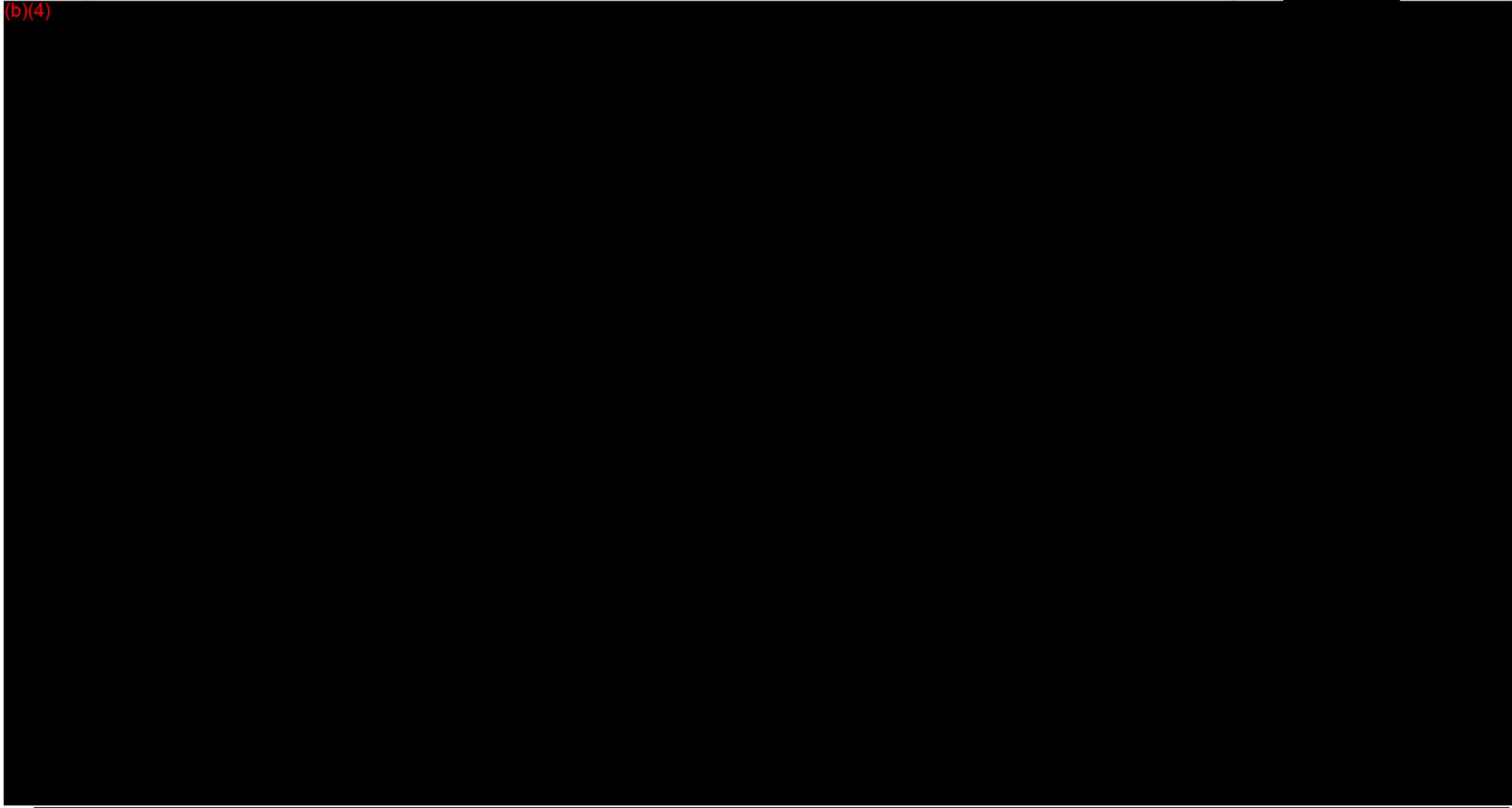


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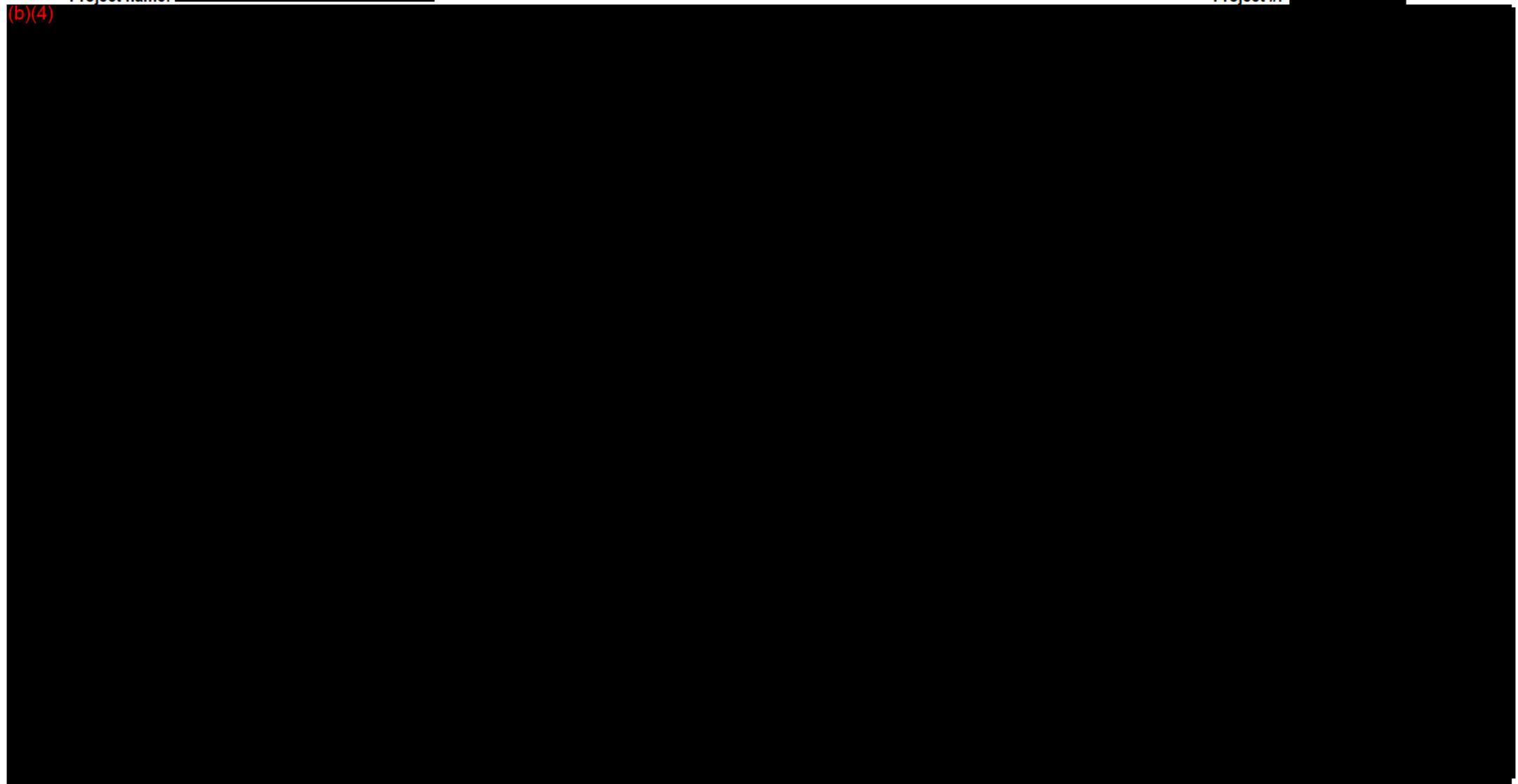


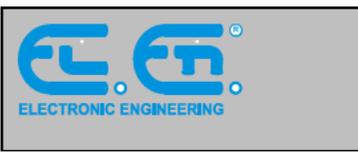
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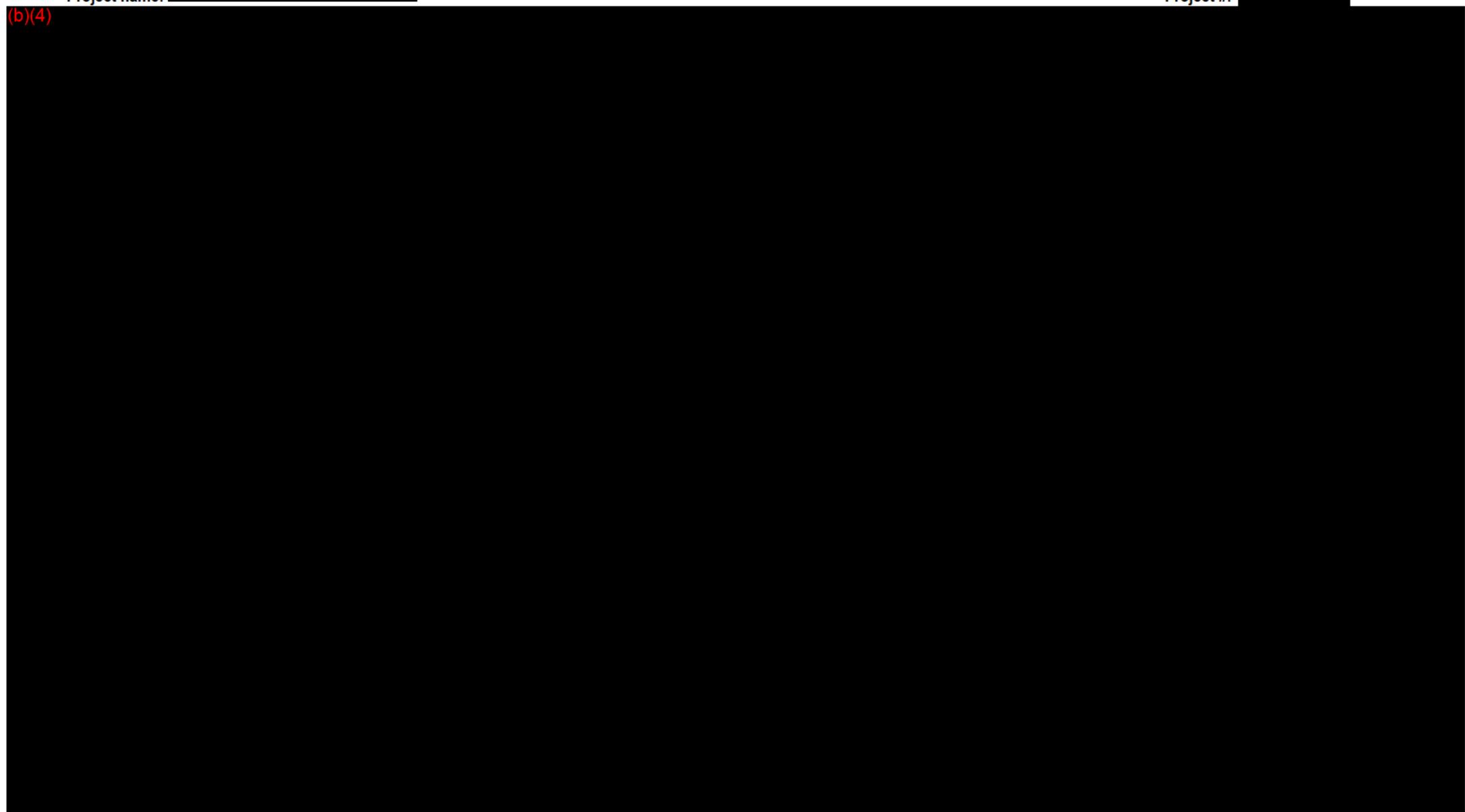


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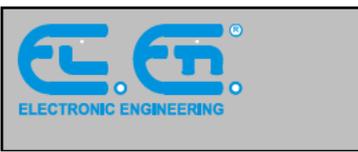
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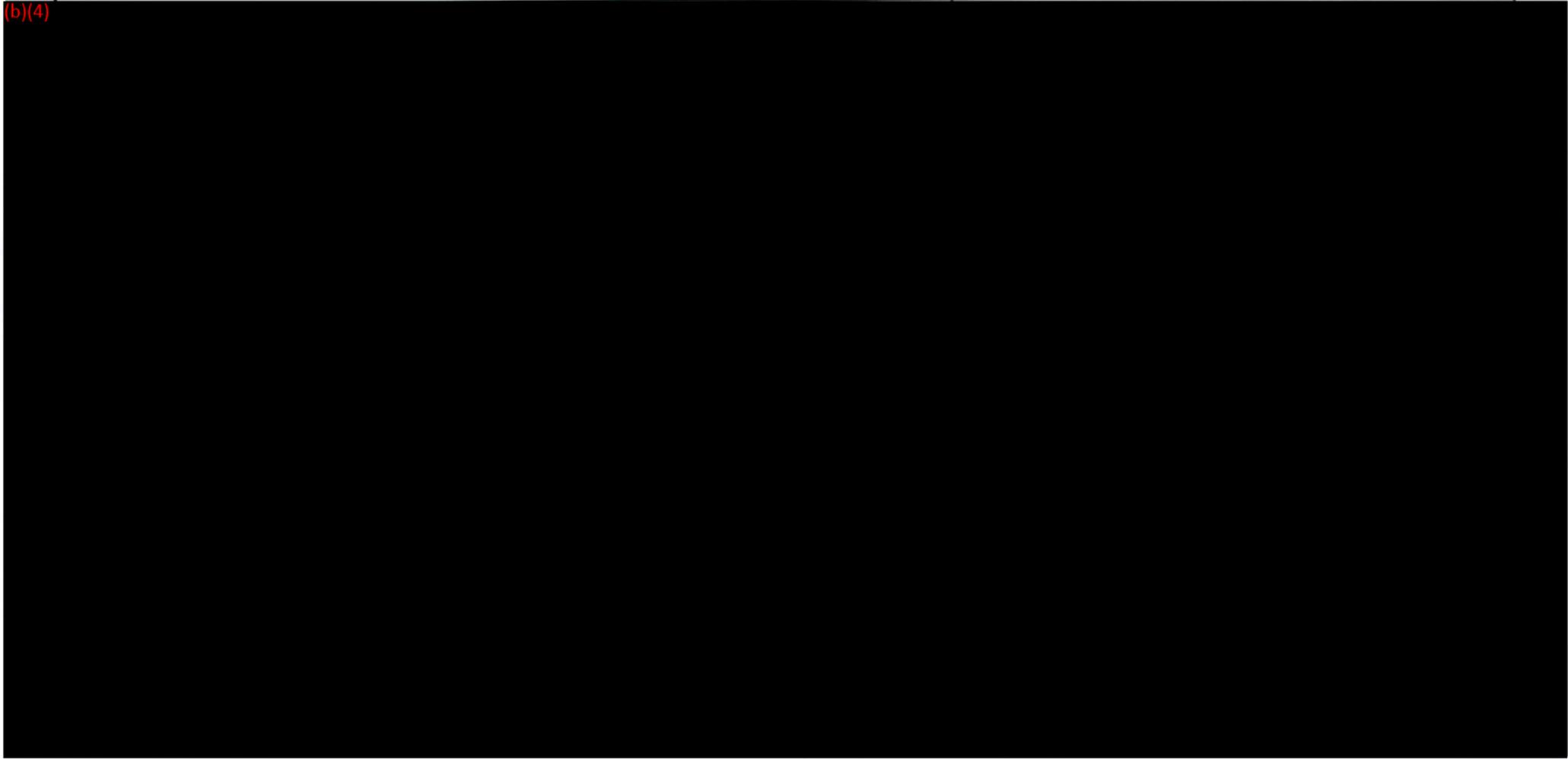
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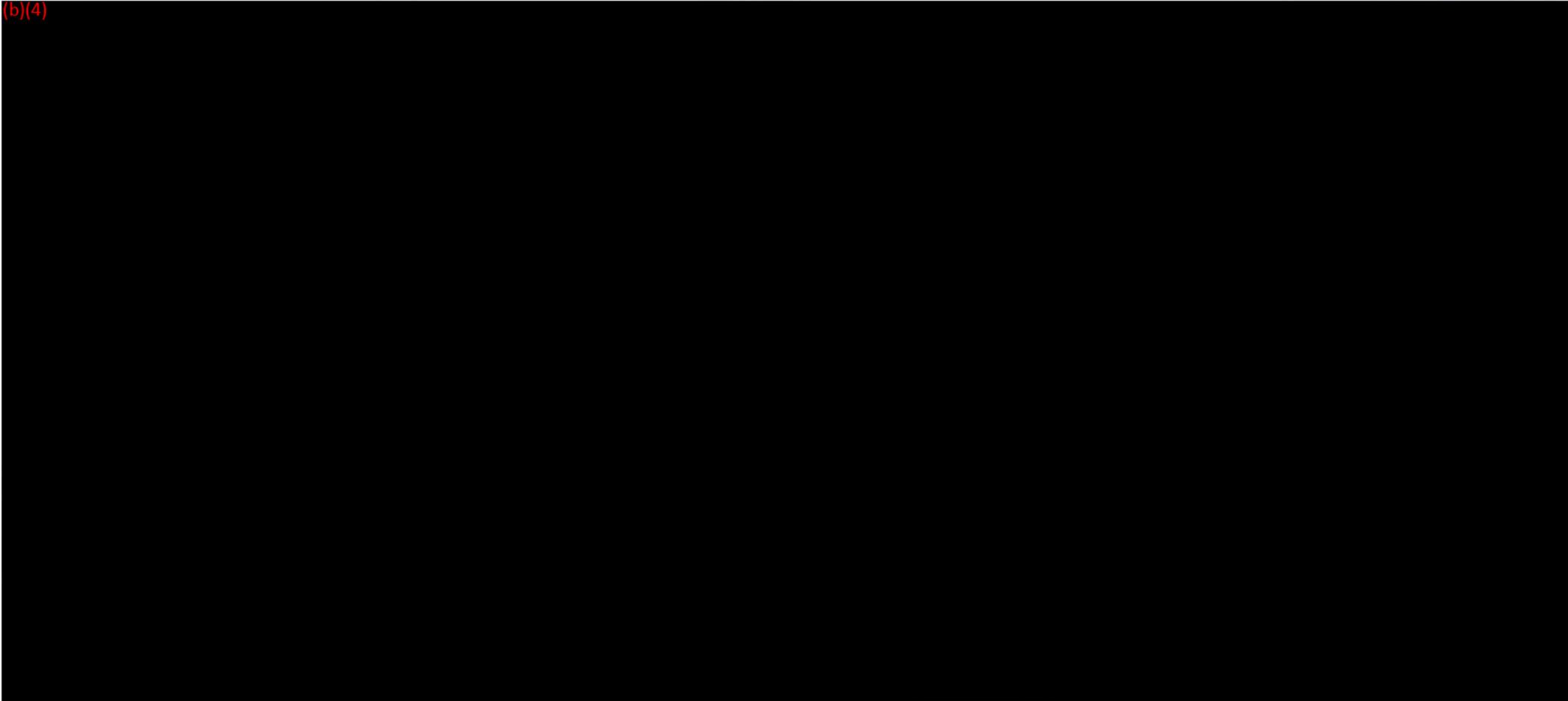
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SOFTWARE DOCUMENTATION
SMARTXIDE²

Date: 23/04/2014
Rev (b)

(b)(4)

ENCLOSURE 6

SOFTWARE VALIDATION
document (b)(4)



Modulo (b)(4) ■ **Software Validation**

Records processed under FOIA Request # 2015-4016; Released by CDRH on 09-29-2015

Date 16/04/14

Procedure (b)(4)

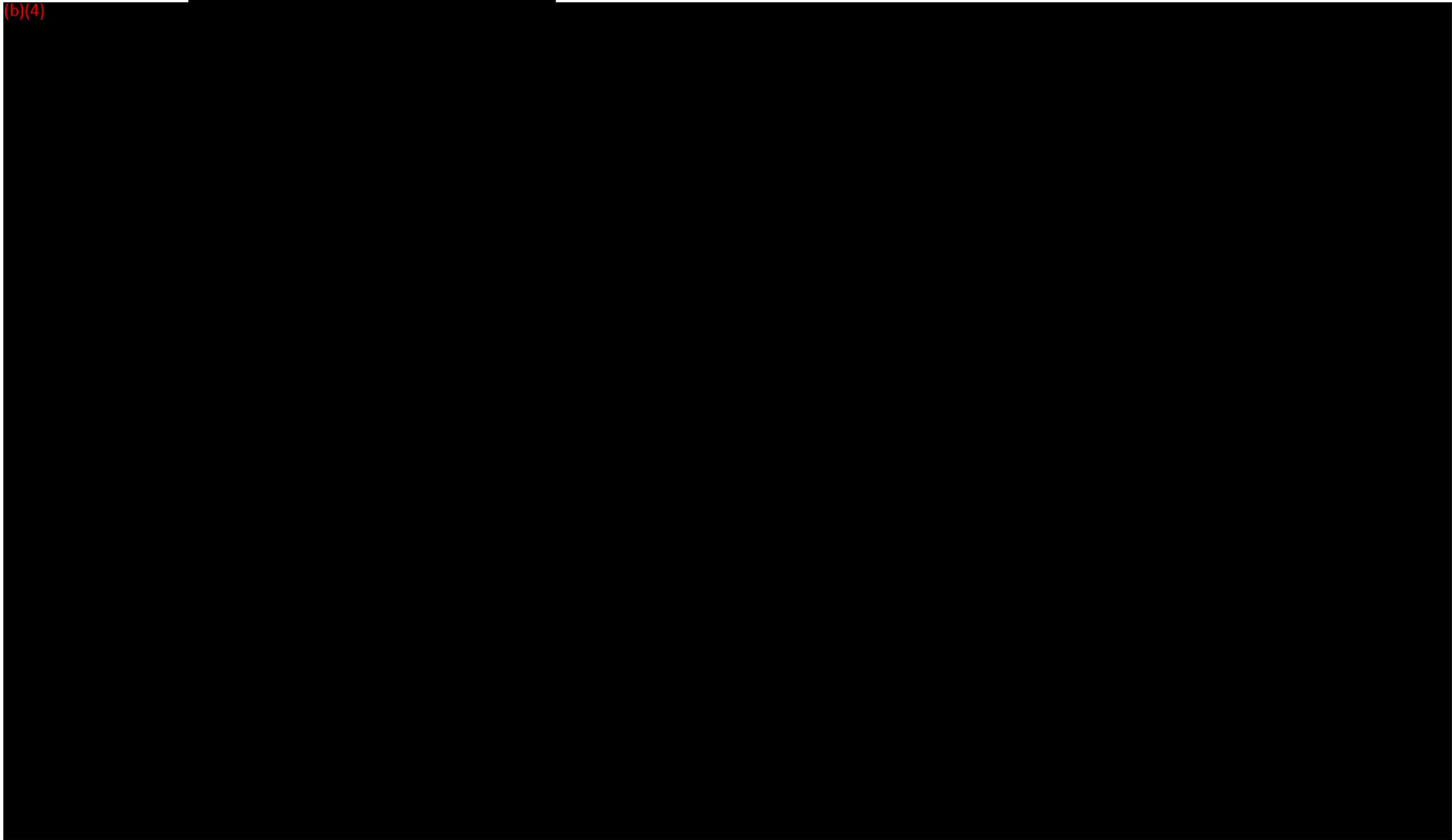
Rev (b)

Device name:

SmartXIDE²

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Modulo (b)(4) (b) ■ **Software Validation**

Records processed under FOIA Request # 2015-4016; Released by CDRH on 09-29-2015

Date 16/04/14

Procedure (b)(4)

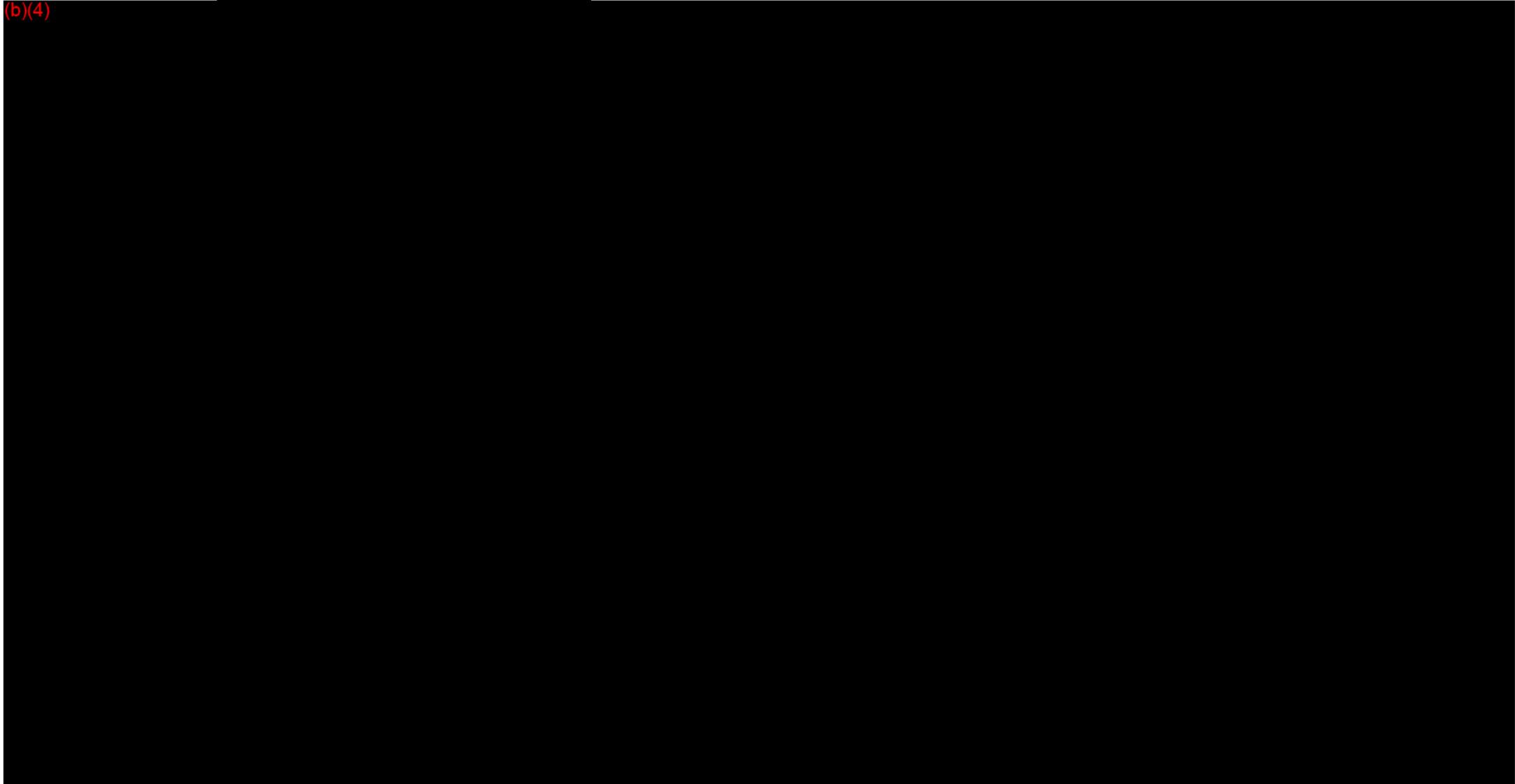
Rev (b)

Device name:

SmartXIDE²

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Modulo (b)(4) ■ **Software Validation**

Records processed under FOIA Request # 2015-4016; Released by CDRH on 09-29-2015

Date 16/04/14

Procedure (b)(4)

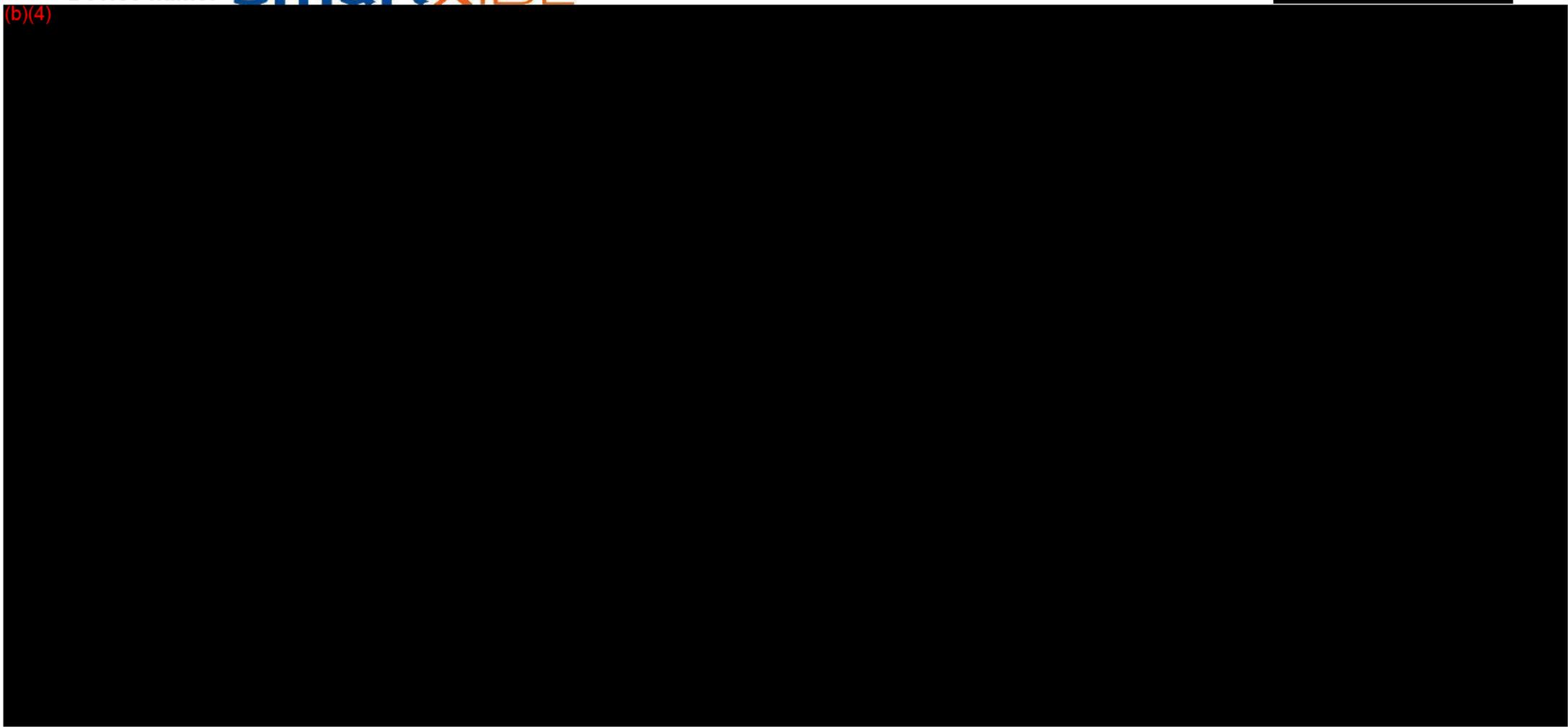
Rev (b)

Device name:

SmartXIDE²

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(b)(4)



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Modulo (b)(4) ■ **Software Validation**

Records processed under FOIA Request # 2015-4016; Released by CDRH on 09-29-2015

Date 16/04/14

Procedure (b)(4)

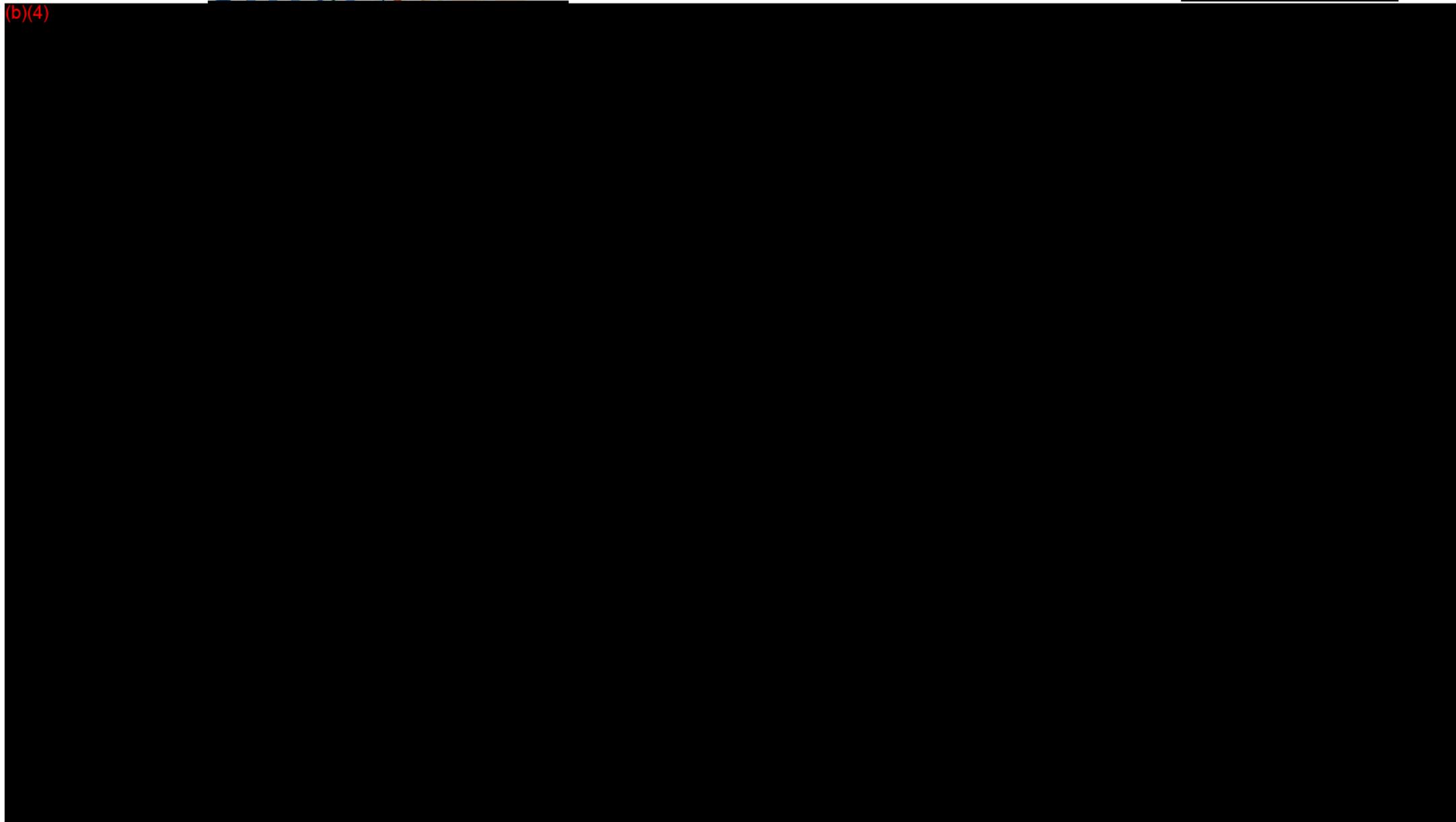
Rev (b)

Device name:

SmartXIDE²

(b)(4)

(b)(4)



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Modulo (b)(4) ■ **Software Validation**

Records processed under FOIA Request # 2015-4016; Released by CDRH on 09-29-2015

Date 16/04/14

Procedure (b)(4)

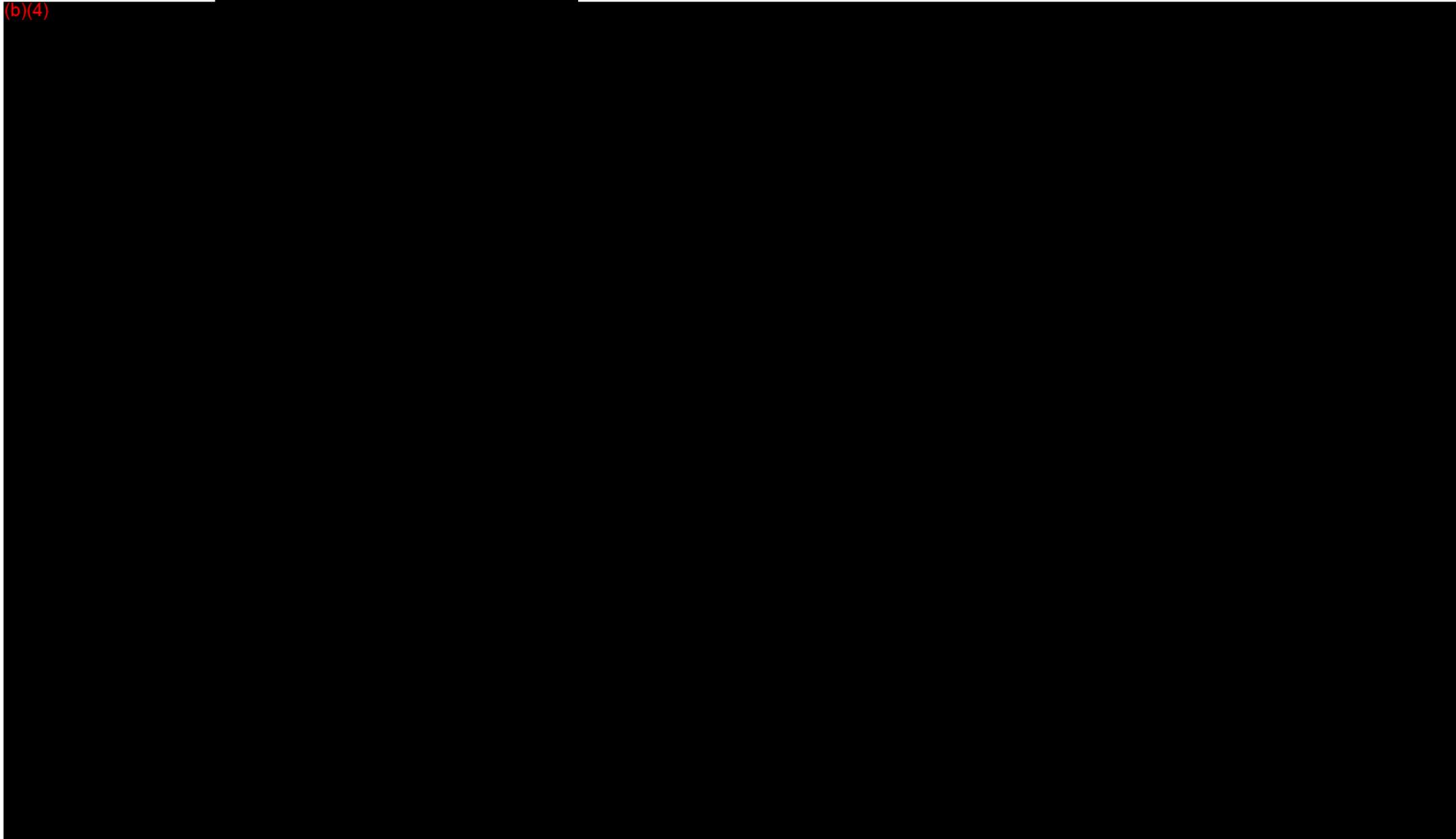
Rev (b)

Device name:

SmartXIDE²

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Modulo (b)(4) ■ Software Validation

Records processed under FOIA Request # 2015-4016; Released by CDRH on 09-29-2015

Date 16/04/14

Procedure (b)(4)

Rev (b)

Device name:

SmartXIDE²

(b)(4)

(b)(4)

(b)(4)



Modulo (b)(4) ■ **Software Validation**

Records processed under FOIA Request # 2015-4016; Released by CDRH on 09-29-2015

Date 16/04/14

Procedure (b)(4)

Rev (b)

Device name:

SmartXIDE²

(b)(4)

(b)(4)



Module (b)(4) Software Validation

Procedure (b)(4)

Records processed under FOIA Request # 2015-4016; Released by CDRH on 09-29-2015

Date 16/04/14

Rev (b)(4)

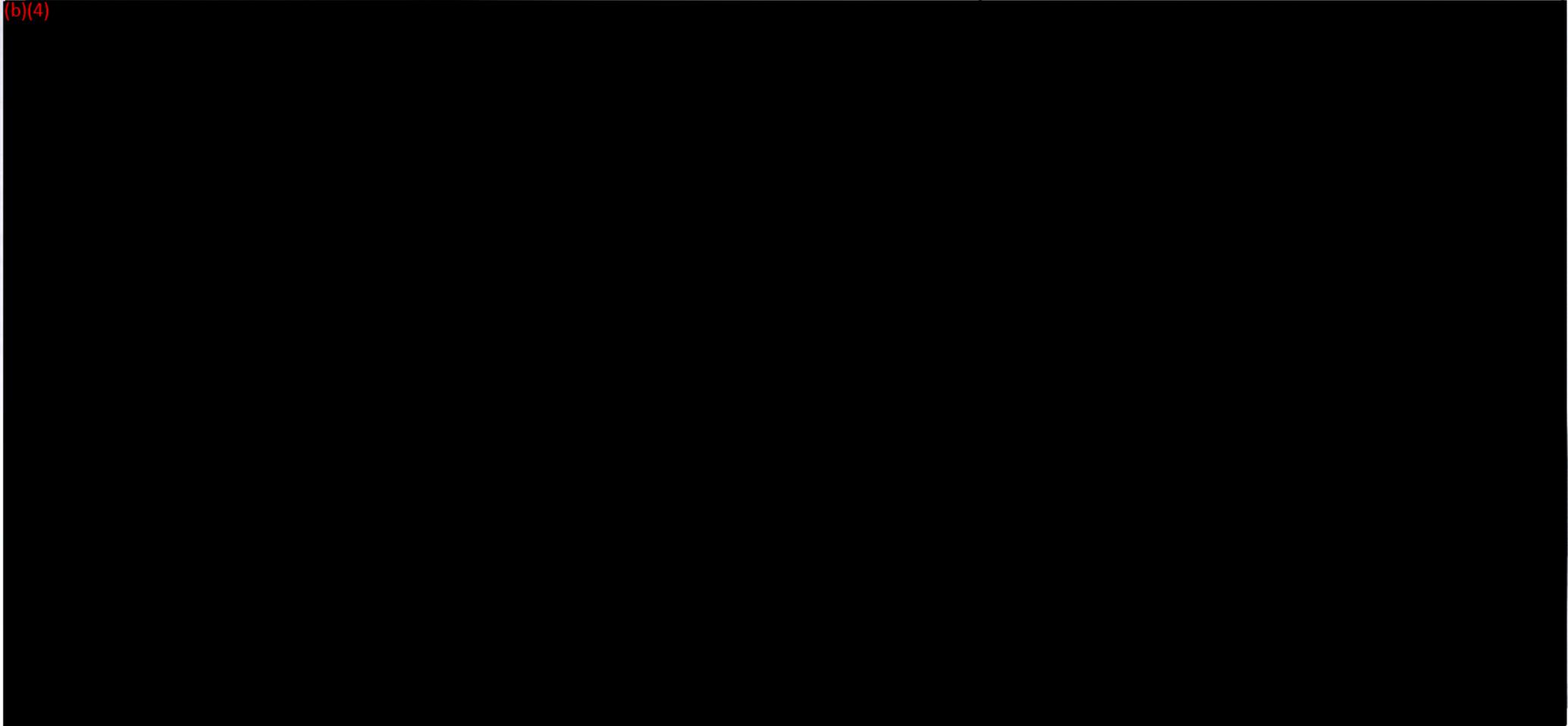
Device name: **SmartXIDE²**

(b)(4)

PROJECT SPECIFICATIONS/VERIFICATIONS

VERIFICATION REPORT

(b)(4)



(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

ATTACHMENT C

PERFORMANCE DATA REPORT

14 PAGES

	DEKA SmartXide² Performance Data Report	Date 22/07/2014 REV. (b)(4) Page 1 of 14
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DEKA SmartXide² Performance Data Report

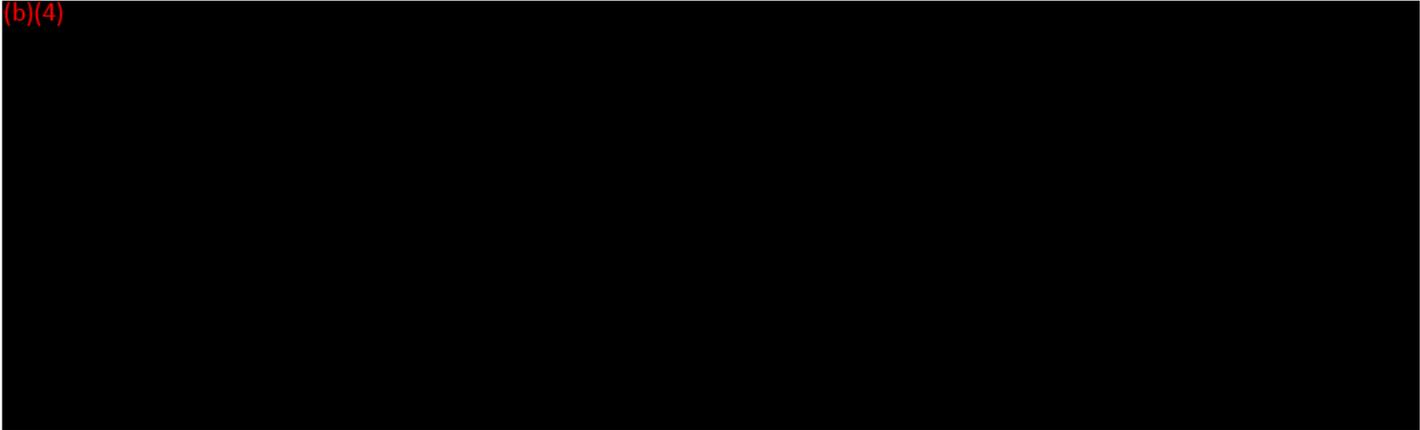


Name	Signature	Date
<i>Prepared by:</i> (b)(6)	(b)(6)	22/7/14
<i>Approved by:</i> (b)(6)	(b)(6)	22/7/14

 <p>ELECTRONIC ENGINEERING</p>	<p style="text-align: center;">DEKA SmartXide² Performance Data Report</p>	<p>Date 22/07/2014 REV (b) Page 2 of 14</p>
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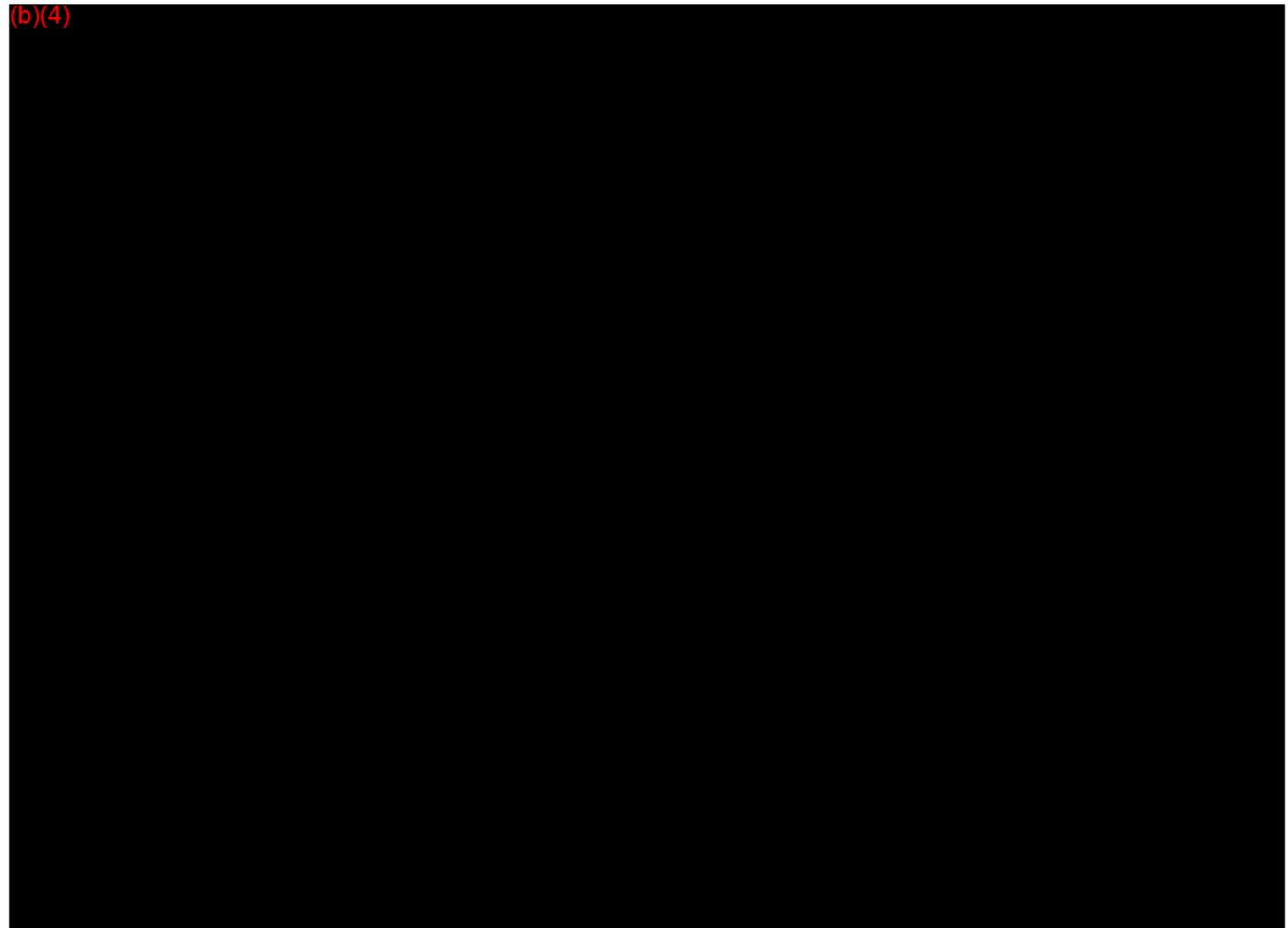
Introduction

(b)(4)



Test data setup

(b)(4)



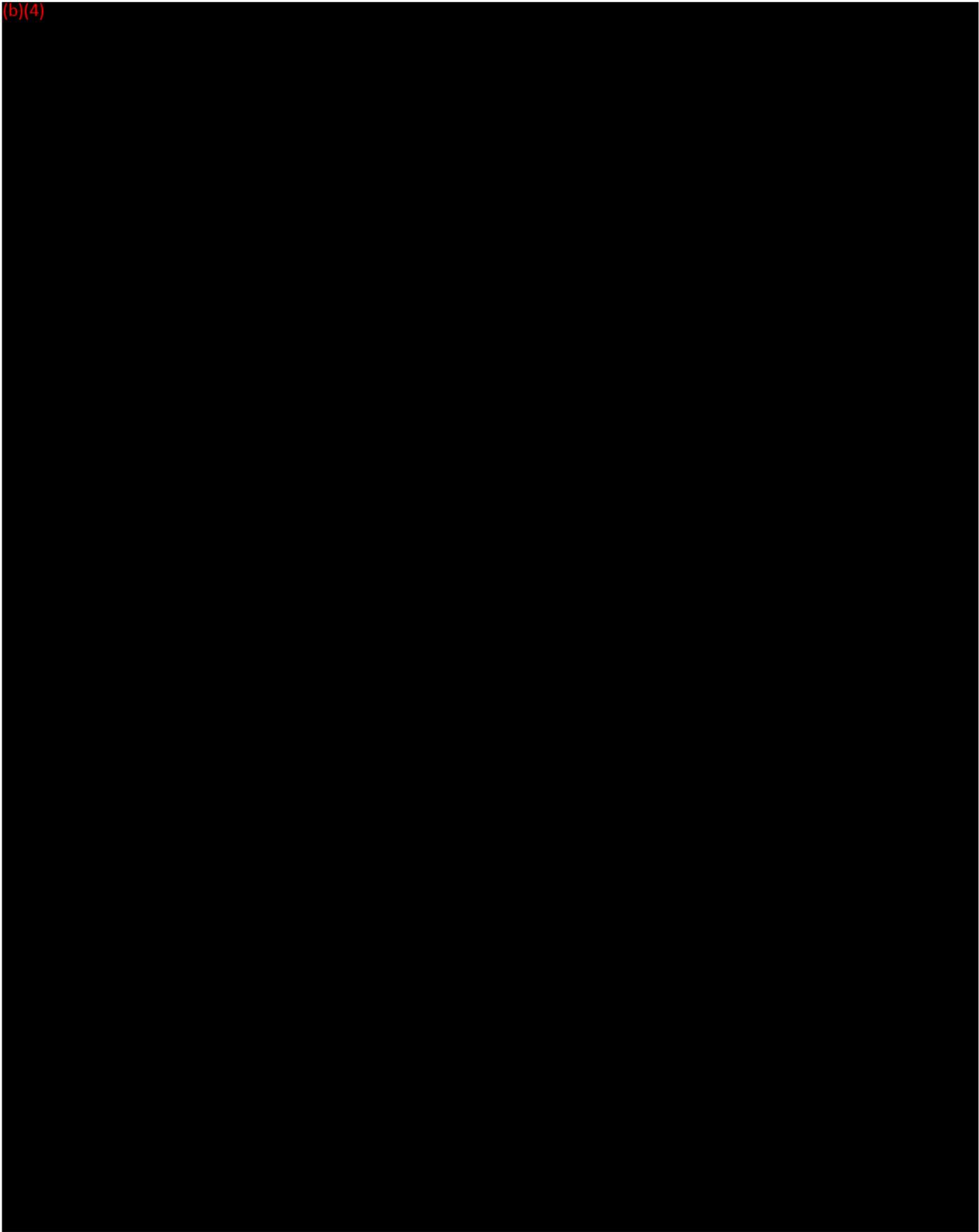
	DEKA SmartXide² Performance Data Report	Date 22/07/2014 REV. (b) Page 3 of 14
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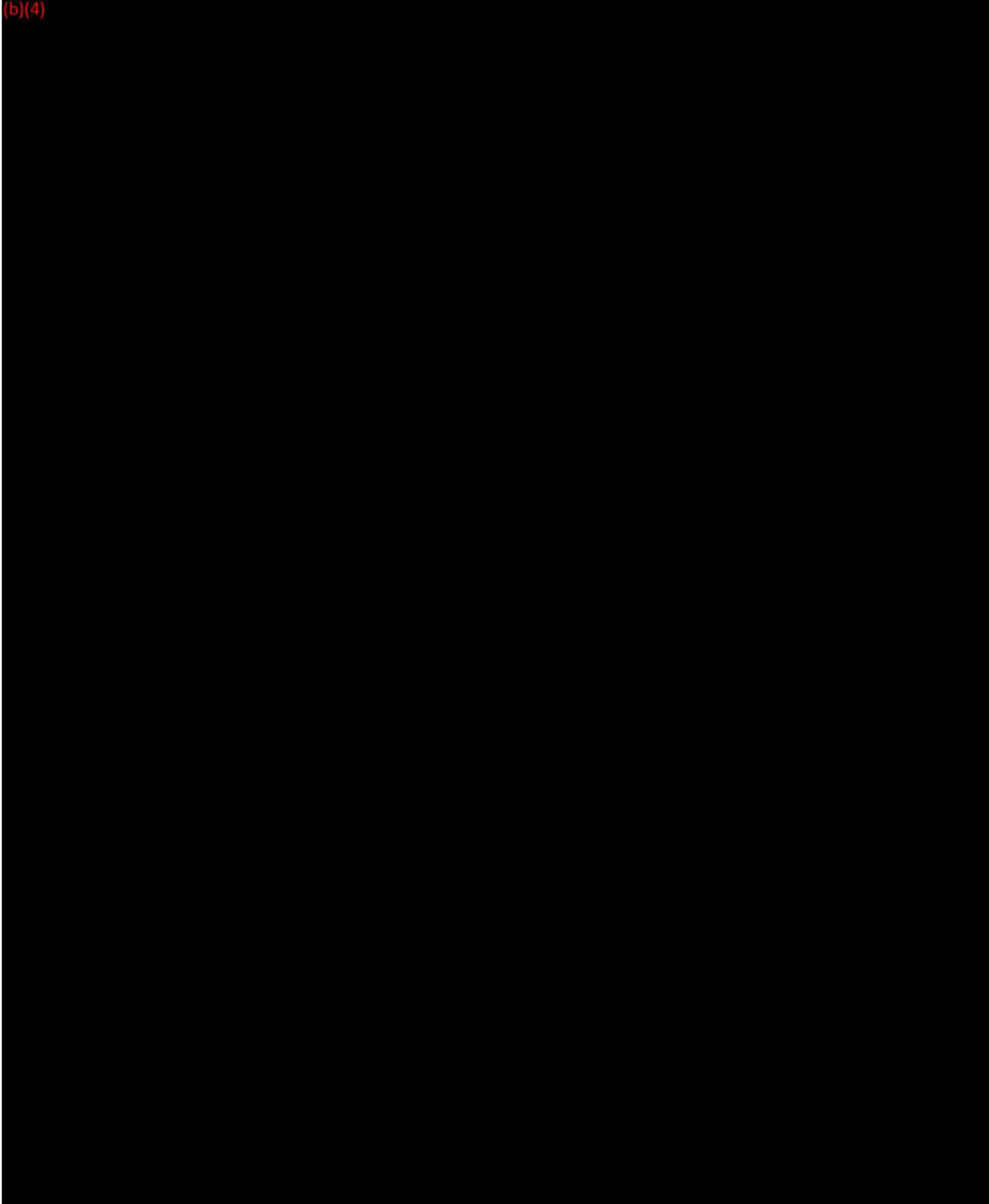
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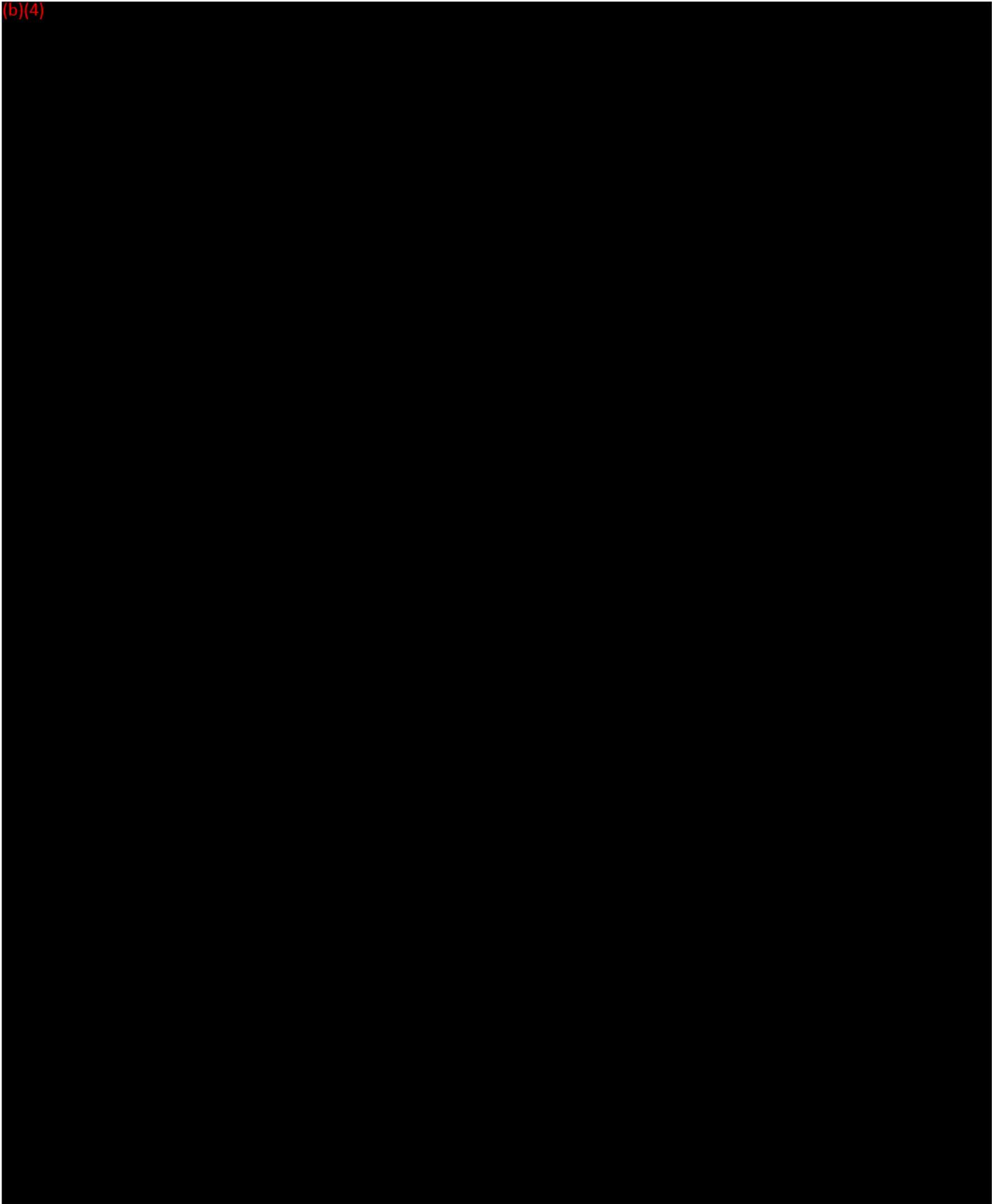
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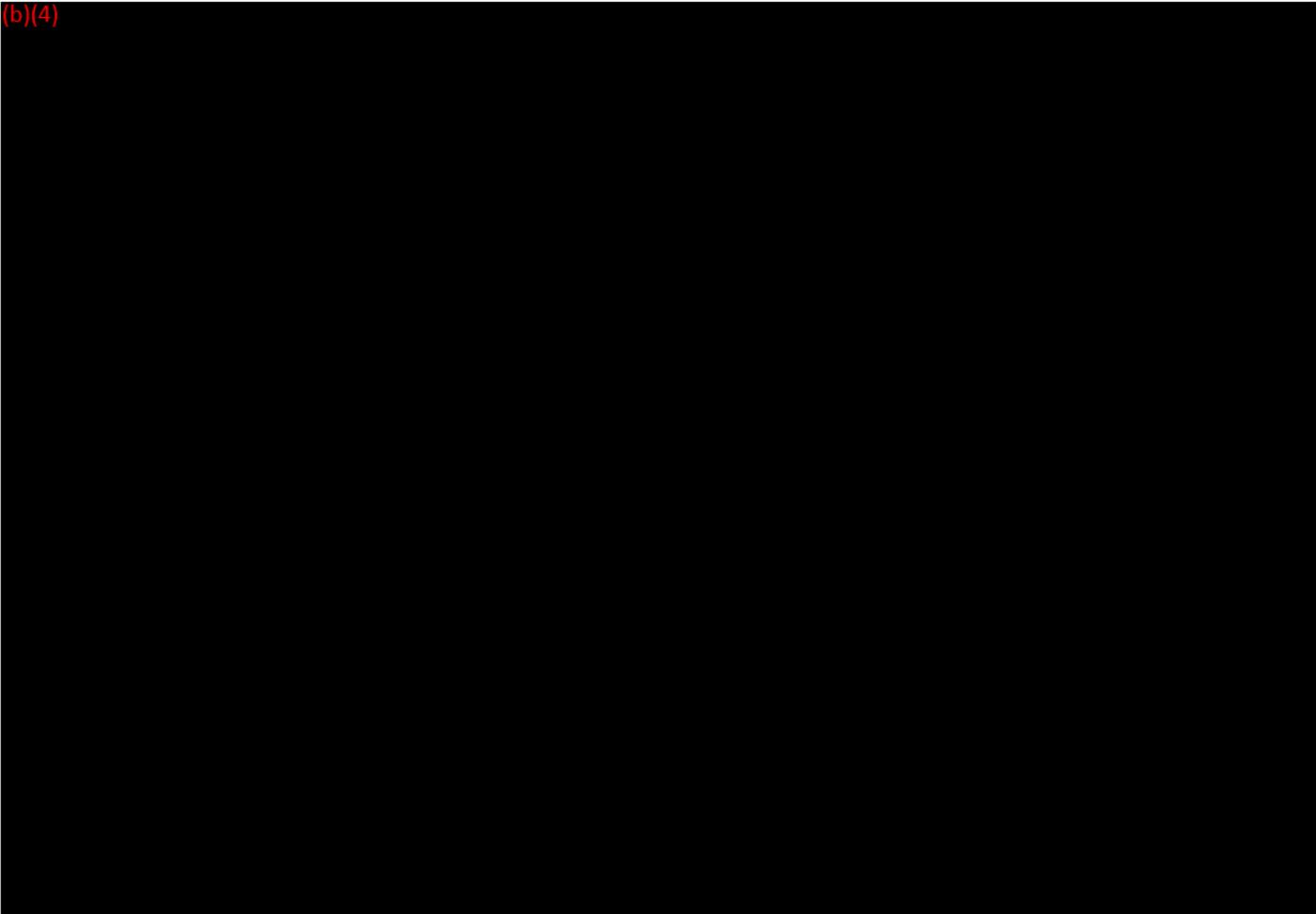
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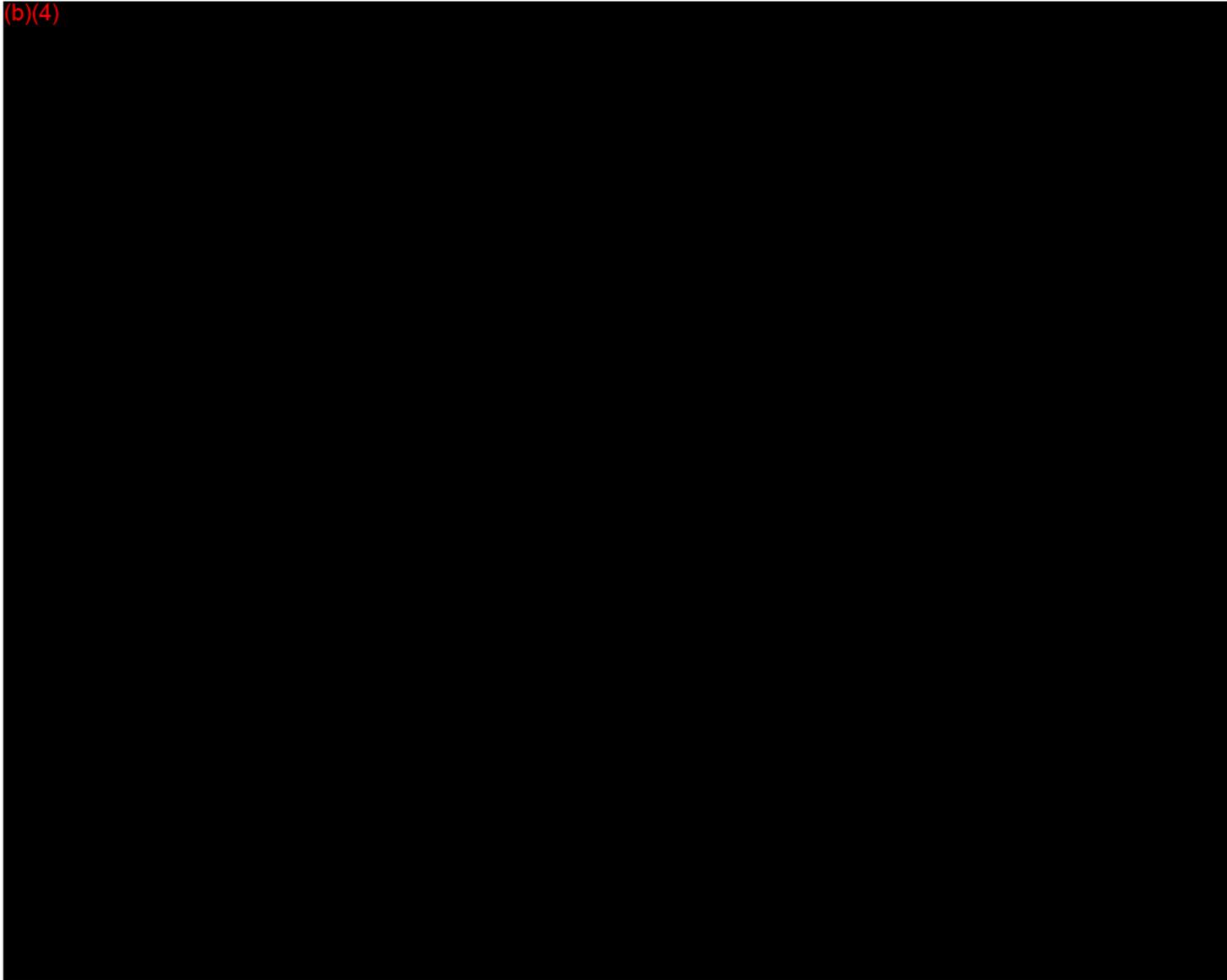
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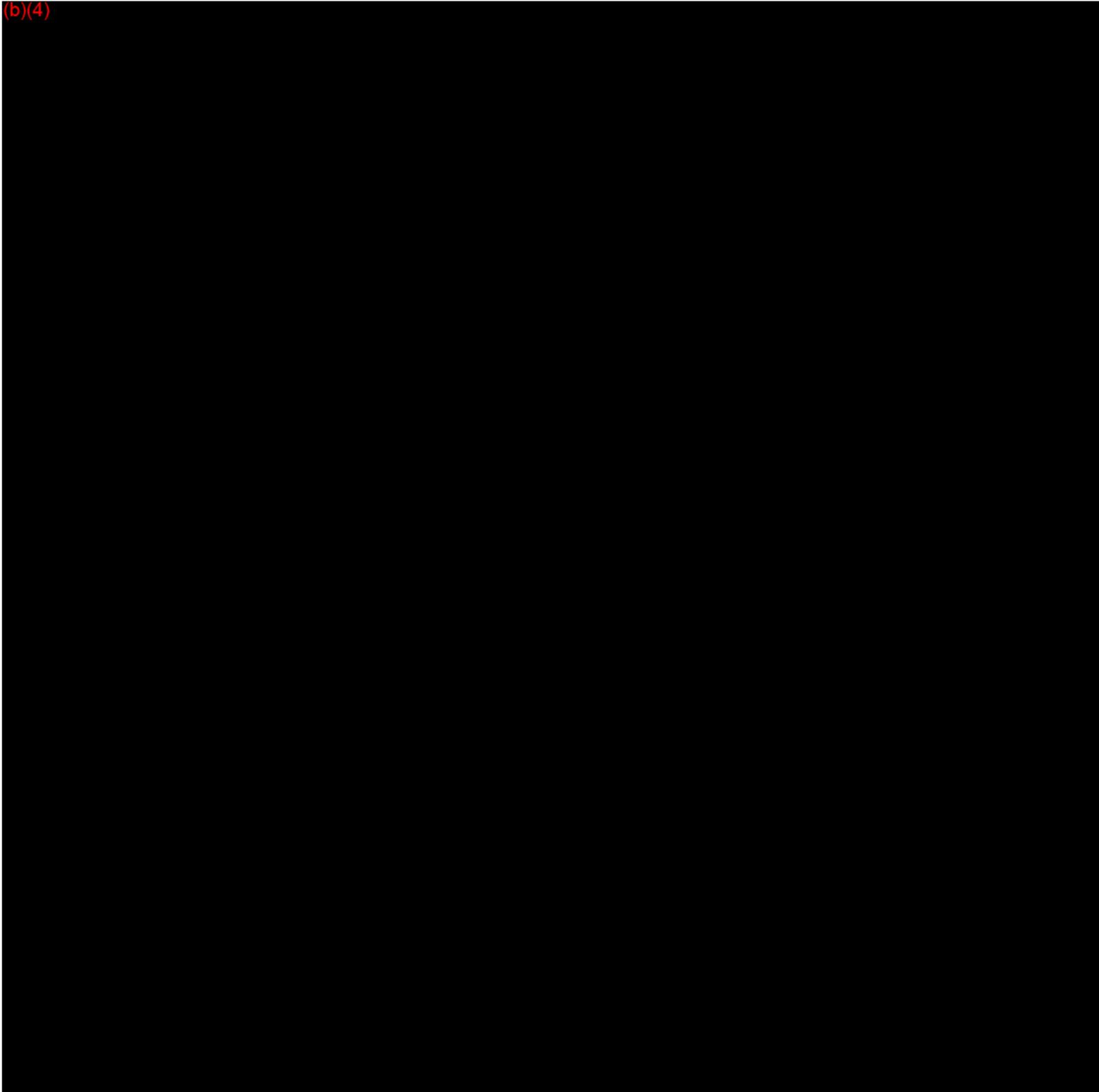
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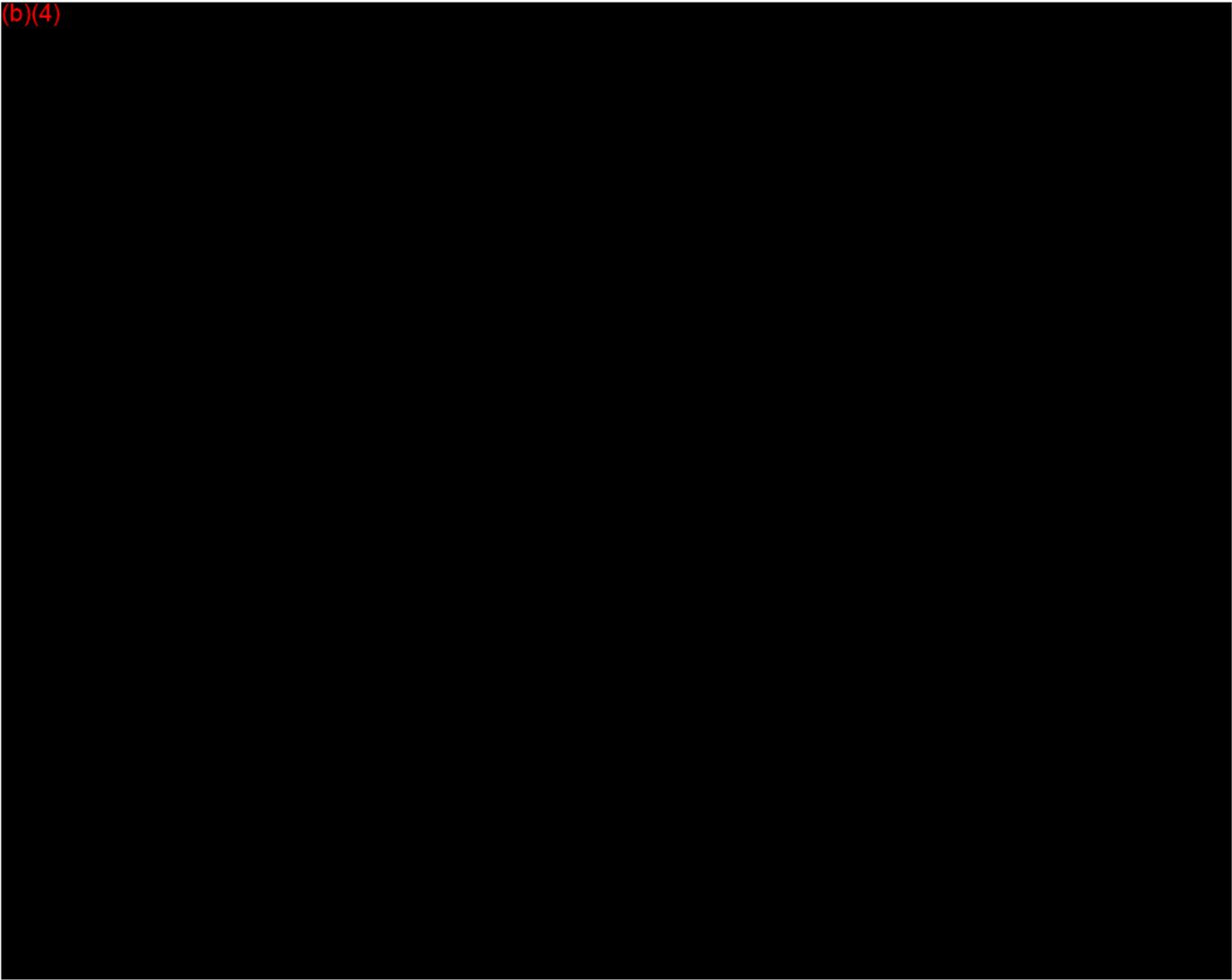
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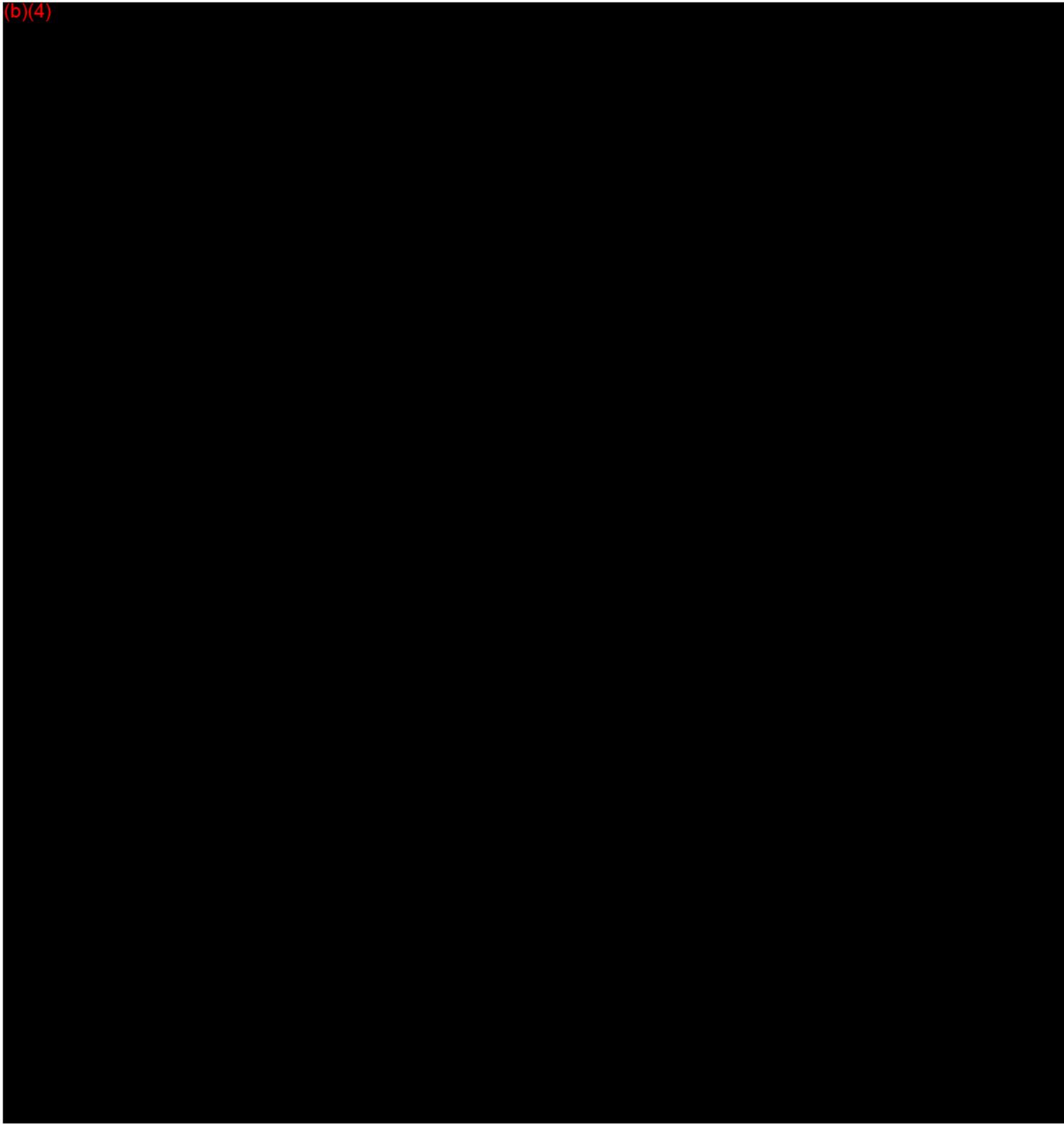
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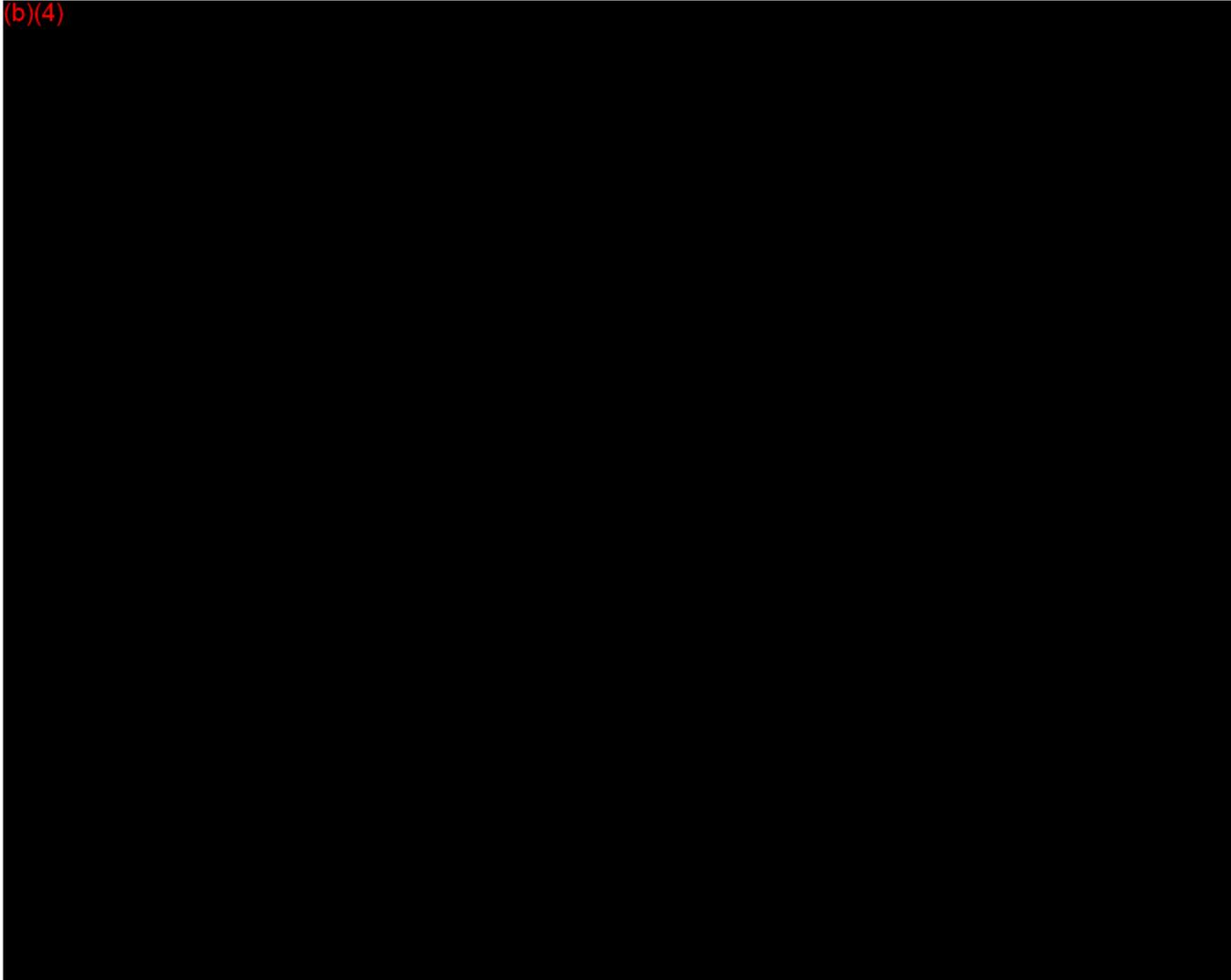
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(b)(4)



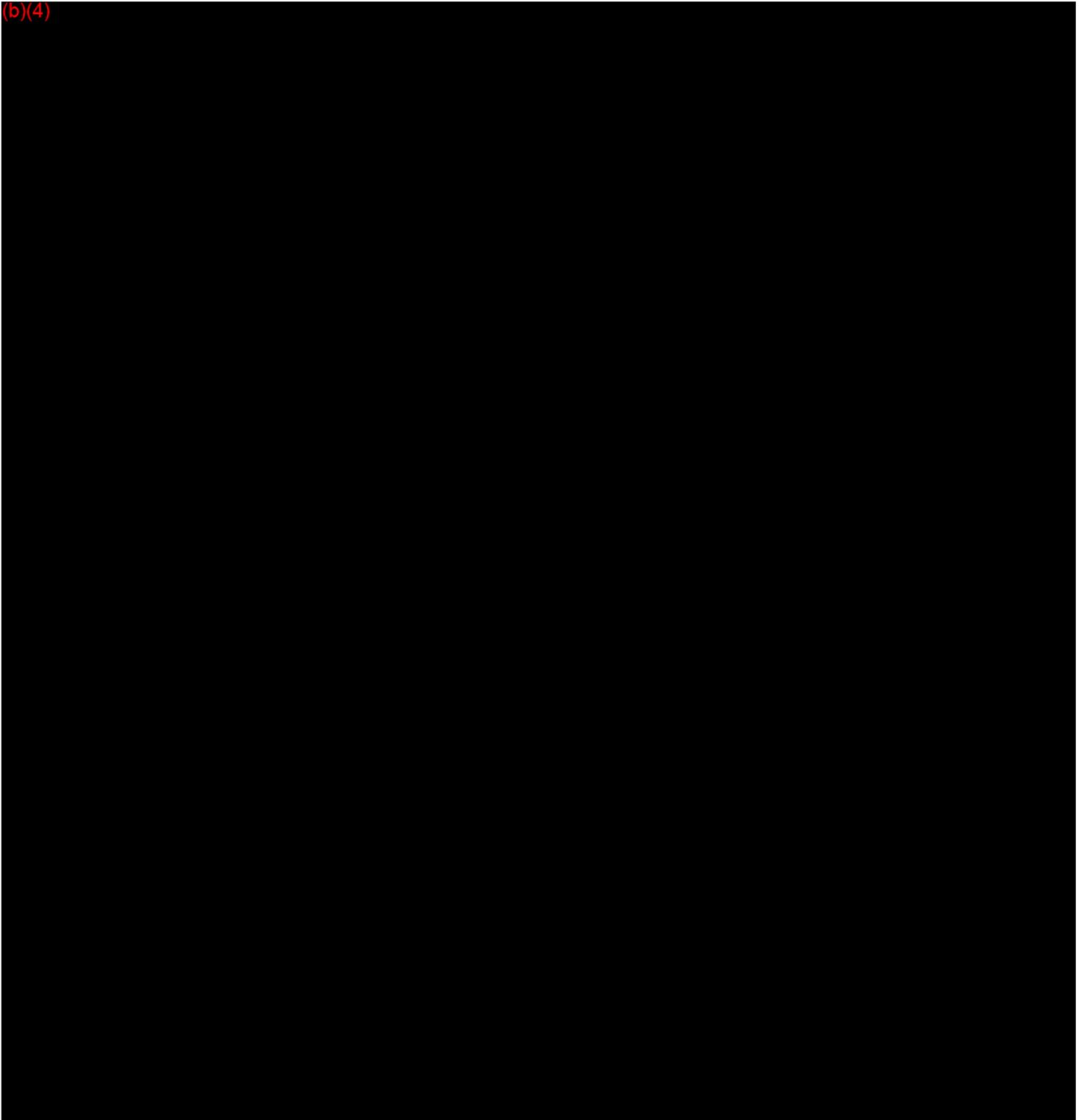
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(b)(4)



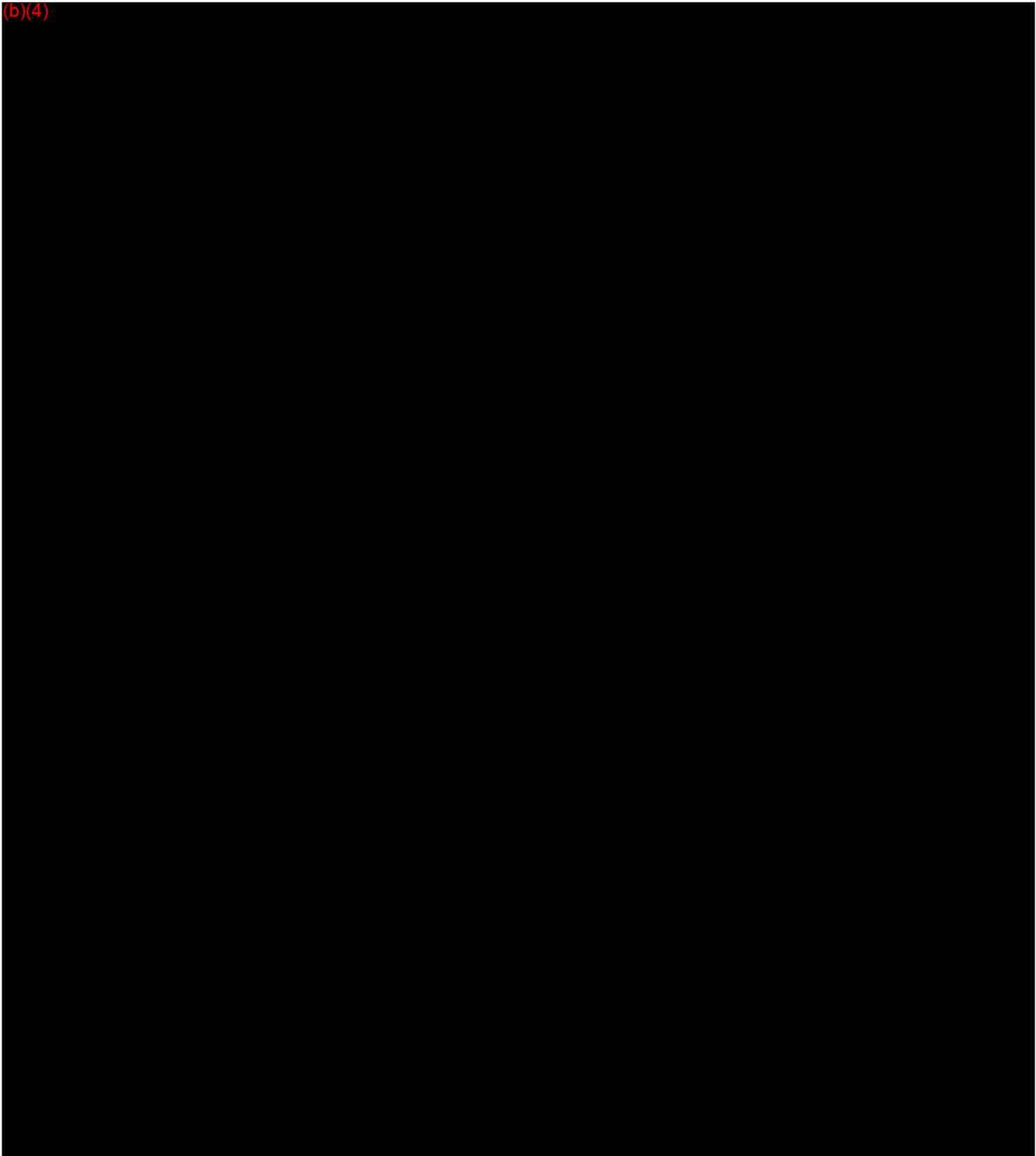
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 <p>EE ELECTRONIC ENGINEERING</p>	<p style="text-align: center;">DEKA SmartXide² Performance Data Report</p>	<p>Date 22/07/2014 REV (b) Page 14 of 14</p>
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ATTACHMENT D

TREATMENT GUIDELINES

4 PAGES

11. TREATMENT GUIDELINES

As with any dermatosurgical modality, the doctor must have a complete understanding of the indication and limitation of a given laser procedure.

11.1. Pre-Treatment Care

11.1.1. Patient Examination

First of all it is important to proceed with the visit and the anamnesis of the patient. During the initial consultation, the doctor should evaluate the patient's expectation of the treatment. A person's history should be compiled by establishing the following:

- Sun and UV lamp exposure: avoid them before (at least 1 month), during and after treatment. Apply SPF50 sunblock before and after the treatment.
- Be careful in case the patient is taking following types of drugs (suspend the administration according to the specific drug so that its effect is expired before the treatment):
 - Anticoagulants (as acetylsalicylic acid, heparin, etc),
 - Retinoids – these drugs can cause problems in the healing process with possible scar results - (as isotretinoin, etc),
 - Photo-sensitizers (as tetracycline [antibiotic], naproxen [NSAD], auranofin [antirheumatic], estrogens and progestins [oral contraceptive], cloroquine [antimalarial], etc.)
- Recent exfoliation treatment (peels, scrubs, retin-A, previous laser resurfacing or dermabrasion) and surgical treatment (as lifting, etc.), because the procedure could potentially delay the wound healing response due to the presence of inflammation or fibrosis.
- Past skin disorders and keloid formation.
- History of herpes virus infection.

In order to ensure a positive outcome with laser treatment, the patient must strictly follow a pre-operative protocol to help prevent the two main possible complications: Post-Inflammatory Hyperpigmentation (PIH) and infection.

11.1.2. PIH prevention

Especially with darker phototypes (III, IV, V and VI) and Asian phototypes, it is recommended to apply a topical cream every day for four weeks before the treatment for inhibiting melanin production. It is possible to use cream containing hydroquinone or, as alternative lighteners, arbutin, azelaic acid, kojic acid or stabilized vitamin C. This procedure is highly recommended with darker and Asian skin types, while for photo type I and II it is just a suggestion.

TREATMENT GUIDELINES

11.1.3. Infection prevention

The drugs used fall into two main categories:

- **Antiviral drugs** (aciclovir, valaciclovir, etc). It is suggested to start the antiviral prophylaxis 6 days before the treatment in subjects with a positive anamnesis of herpes virus infections history. The antiviral treatment can start 2 days before the treatment in subjects without previous experience of herpes infections. It is recommended to continue the antiviral drugs at routine doses for 5-15 days after the intervention.
- **Antibiotic drugs** (macrolides, cephalosporins, etc). The doctor may consider prescribing antibiotic drugs for 7-8 days after the procedure. Remark: It is not necessary to prescribe antibiotic drugs in all cases. It is often enough the application of a topical antibiotic cream or ointment (like gentamicin) after the procedure.

11.1.4. Cleaning the Skin

Before treatment clean the relevant area, removing all impurities that could interact with the light radiation (make-up, lotions, deodorants, ointments etc.). Use a mild soap and rinse well with water. As a precaution the patient should be advised not to use cosmetics for 48 hours prior to treatment.

11.1.5. Classification of the Phototypes

Before starting treatment it will be necessary to evaluate the patient's phototype.

Type	Hair colour	Skin colour	Eye colour	Reaction to the Sun
I	Red	Fair	Blue-grey	Goes red, does not tan
II	Blonde	Fair	Blue	Goes red, does not tan
III	Brown	Medium	Brown	Goes red, then tans
IV	Dark Brown	Light Brown	Dark Brown	Tans
V	Black	Dark Brown	Black	Tans
VI	Black	Black	Black	Tans

11.1.6. Photographic Monitoring

Taking pictures that document the patient during the various treatment phases helps to monitor the effectiveness of the treatment. For ensuring the best photographic quality it is necessary to standardise the shots in order to reproduce the same position of the patient and the same lighting conditions.

11.1.7. Anaesthesia

Dermal treatments with laser may give rise to a painful sensation described as similar to an elastic band being pinged against the skin, or the pain caused by burns.

The anaesthetic protection for CO₂ laser skin therapies becomes necessary in specific cases, such as:

- Traditional CO₂ laser skin resurfacing;
- The treatment of extensive skin areas;
- The treatment of deep lesions;
- Patients with a low pain threshold;
- Non-compliant patients;
- Paediatric patients.

11.1.8. Suggested Treatment Parameters

Treatment parameters are for reference only. Many variables exist which may dictate higher or lower settings. There is no substitute for training and consultation.

USE OF SCANNER FOR ABLATIVE SKIN RESURFACING

Treated area	Power	Pulse Width	Downtime	No. of treatments	
Rhytides-forehead, perioral, nose and chin	Mild	15-20W	600-800µs	1-3 days	3-5
	Moderate	20-25W	800-1000µs	3-5 days	2-3
	Aggressive	25-30W	1000-1500µs	5-7 days	1-2
Rhytides-periocular	Mild	12-15W	500-600µs	1-3 days	3-5
	Moderate	15-20W	600-700µs	3-5 days	2-3
	Aggressive	20-25W	800-1000µs	5-7 days	1-2
Rhytides-eyelids NOTE: one pass only	Mild	15-18W	600-700µs	2-3 days	2-4
	Moderate	18-20W	800-1000µs	4-6 days	1-2
Rhytides-neck, and hands	Mild	12-15W	600-800µs	1-3 days	3-5
	Moderate	15-20W	800-1000µs	3-5 days	2-3
	Aggressive	20-25W	800-1000µs	5-7 days	1-2

GENERAL SOFT TISSUE VAPORIZATION

Treatment	Power	Pulse Width	Downtime
Soft tissue vaporization	20-30W	200µs	7-10 days

TREATMENT GUIDELINES

HANDPIECE MODE

Treatment	Mode	Power	Pulse Width
Soft tissue surgery	Continuous wave (CW)	2-30W	n/a

NOTES:

1) Based on the speed of treatment and the tissue targeted for treatment, power can be adjusted.

2) Test spots should be done prior to treatment.

11.2. Post Treatment care

Operations carried out with CO₂ laser devices generate thermal injury, abrasion or ablation of the skin which makes daily care of the wound essential. Therefore, side effect are expected and must be differentiated from complication.

The aim is to achieve healing, preventing the formation of scabs in the middle and on the inner edges of the area treated, and thus guaranteeing an adequate cleanliness and softness.

Nearly all patient encounter minor side effects ranging from postoperative pain and edema to pruritis and tightness. In order to reduce the swelling and the inflammation that may occur after the procedure of skin resurfacing, we recommend applying on the skin, just after the treatment, cool compression or wet gauzes cooled using the Cryo6 air jet. A mild serous (watery) discharge could be seen, which subsides spontaneously after 2/3 days.

For post-treatment care, apply skin cleansing, cold packs compression which must always be carried out with sterile gauze and saline solution. Patient must re-applies every time emollient and/or antibiotic and enzymatic ointments, especially after cleaning and showers. This procedure has to be performed 3-4 times per day until the clinical healing is observed (4-7 days typically). After this time, apply a normal skin-care moisturizer and a sunblock protection (for 2-5 months according to the skin phototype and the environmental conditions).

It is suggested to wait for 1 day before having a shower (avoid hot water on the treated area until healing is complete). Avoid sun exposure for at least 2-4 weeks.

The use of moisturizing and emolient lotions is suggested without time limitation: it helps in maintaining the uniform and compact aspect of the new skin.

NOTE: The patient must immediately call the physician in the event of any side effects such as excessive reddening, infections or blistering. The physician will judge whether it is necessary to use antibiotic creams.