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Food and Drug Administration

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COMPANY: NEURO RESOURCE GROUP, INC. (NEURRESOGROU)
PRODUCT: STIMULATOR, NERVE, TRANSCUTANEOUS, FOR PAIN RELIEF (GZJ)
SUMMARY: Product: INTERX5000

DATE REQUESTED: Mar 7, 2016

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NEURO RESOURCE GROUP

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VIA OVERNIGHT MAIL

February 16, 2005

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Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

Re: K042912 – Additional Information

Enclosed is supplementary information to our response dated February 15.

A timely review of this information, and immediate feedback/interaction to ensure timely resolution of any remaining open issues, is very much appreciated.

Regards,

Krista Oakes
Vice President, Regulatory Affairs

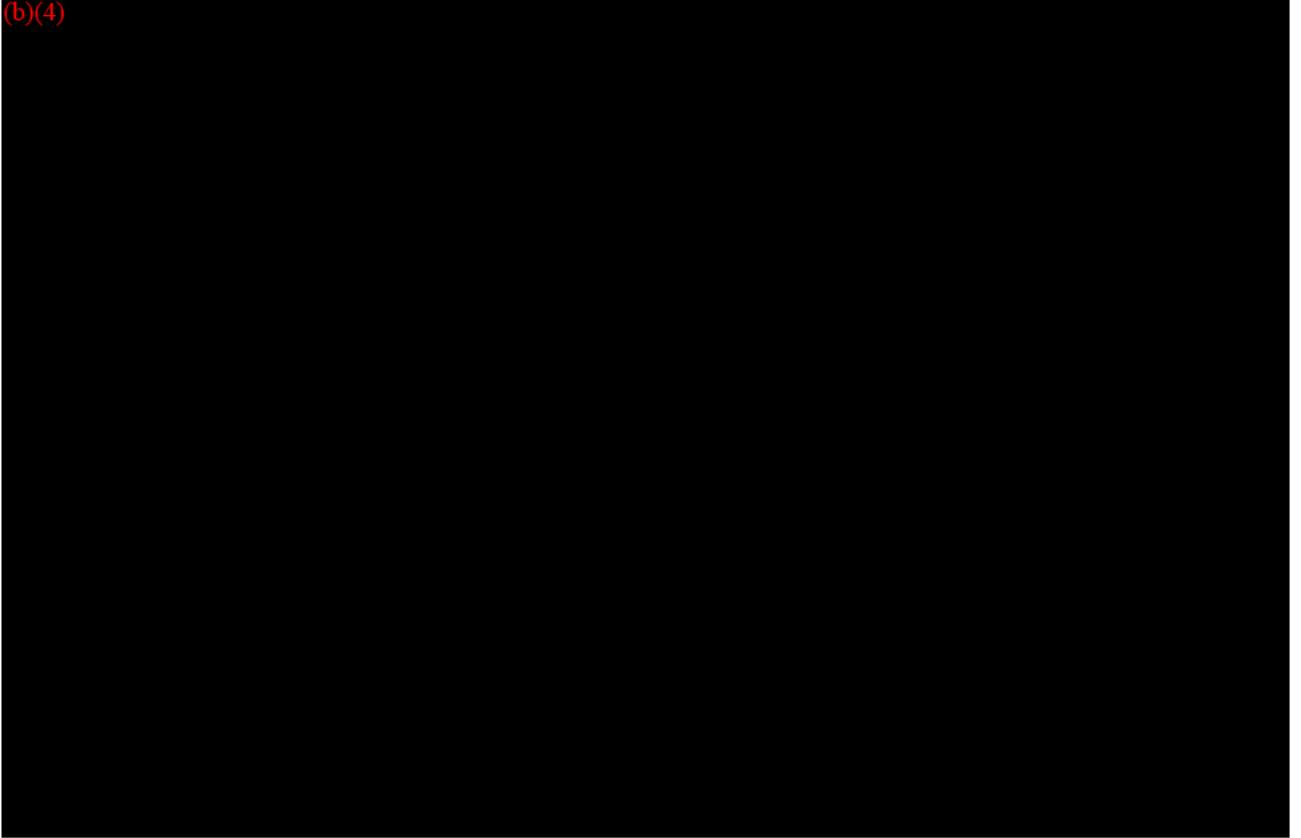
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Probe Testing in actual use

(b)(4)



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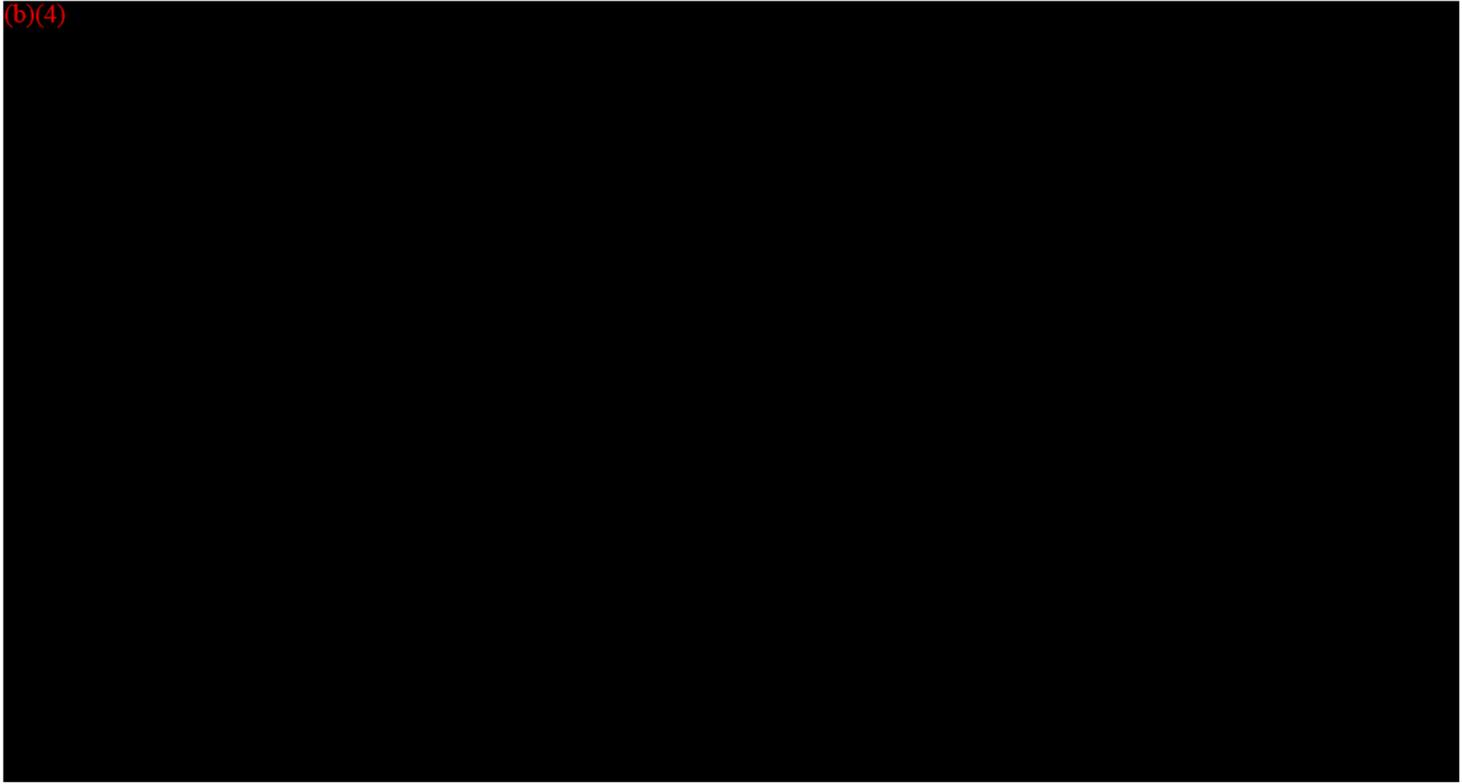


Figure 1 Peak stimulation current versus load impedance

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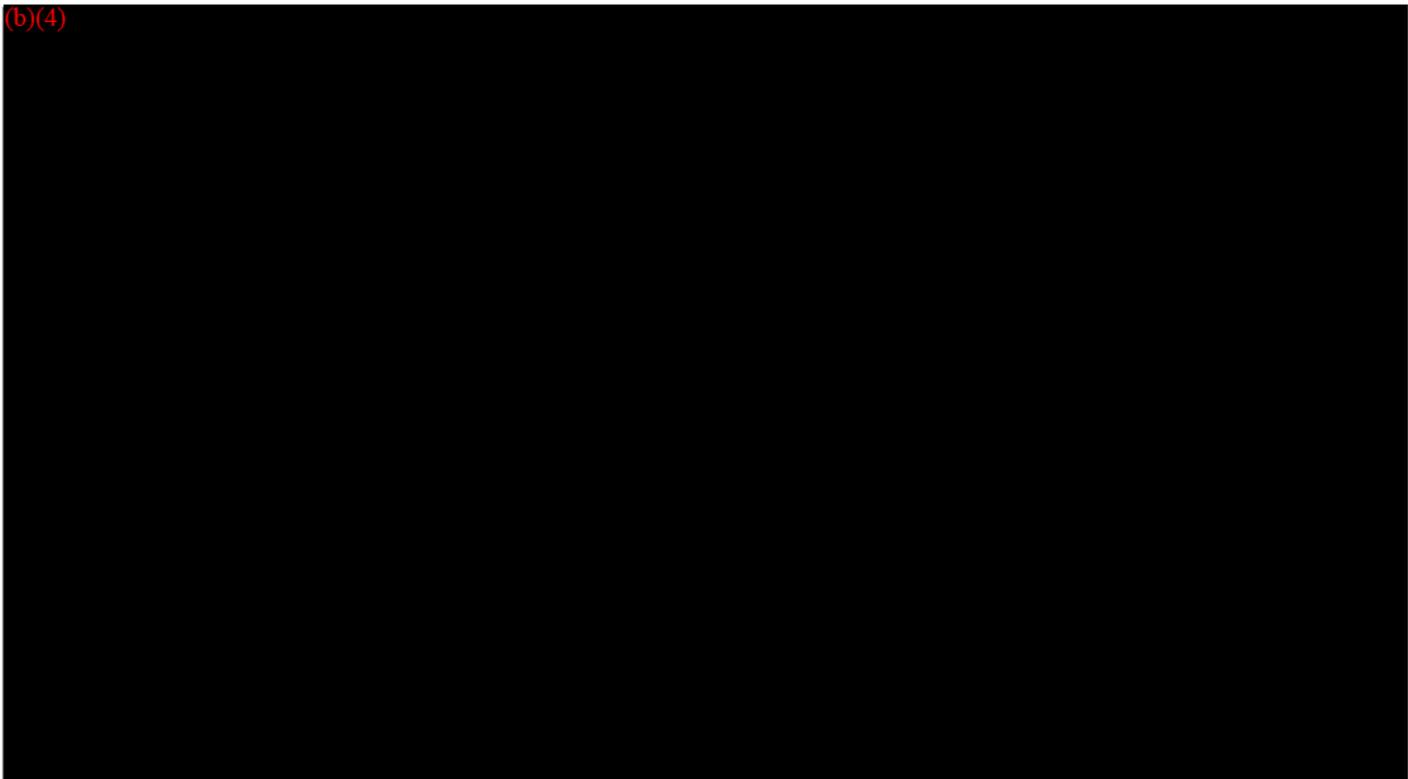


Figure 2 Peak output voltage versus power setting

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Figures 3 through Figure 6 Tissue impedance versus power setting for different body locations

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Figure 7 Tissue impedance versus power setting for different body locations

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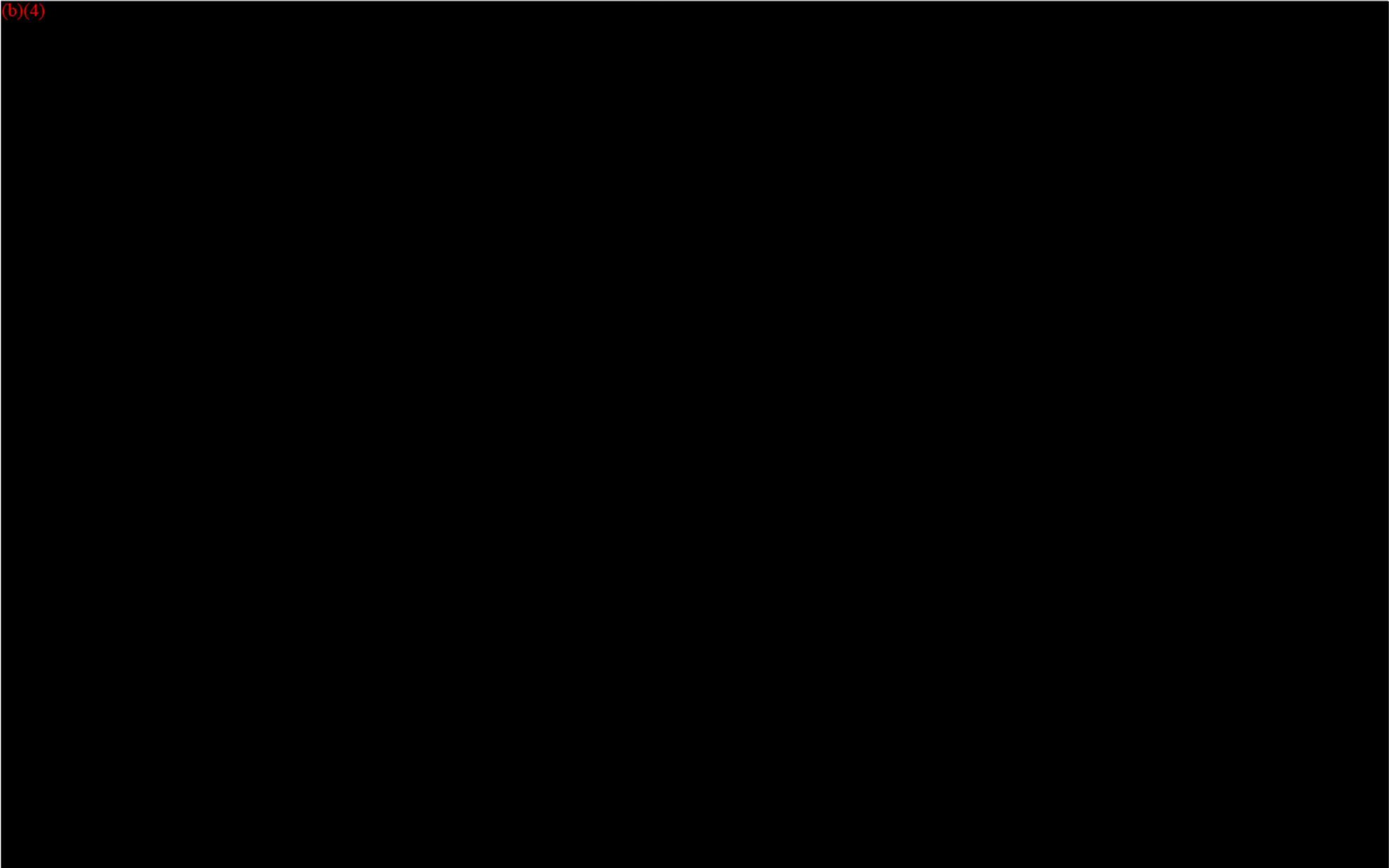


Figure 8 through Figure 11 Current density versus power setting for different body locations

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

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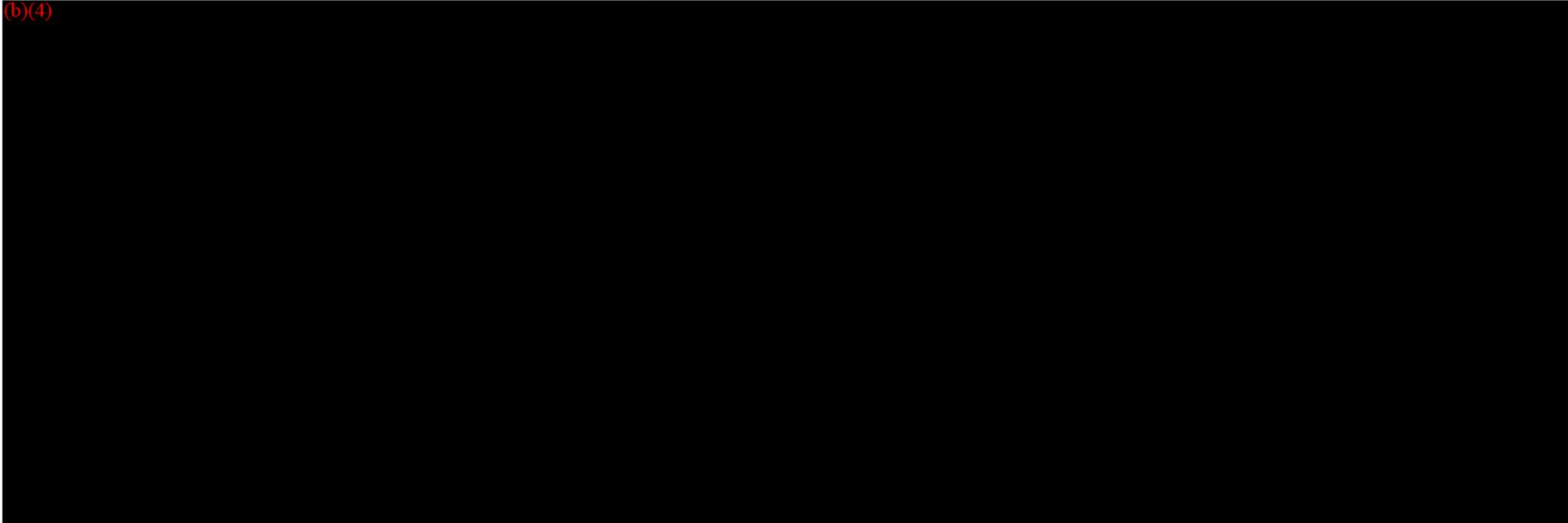


Figure 12 Current density versus power setting for different body locations

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Figure 13 through Figure 16 Power density versus power setting for different body locations

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Figure 17 Power density versus power setting for different body locations

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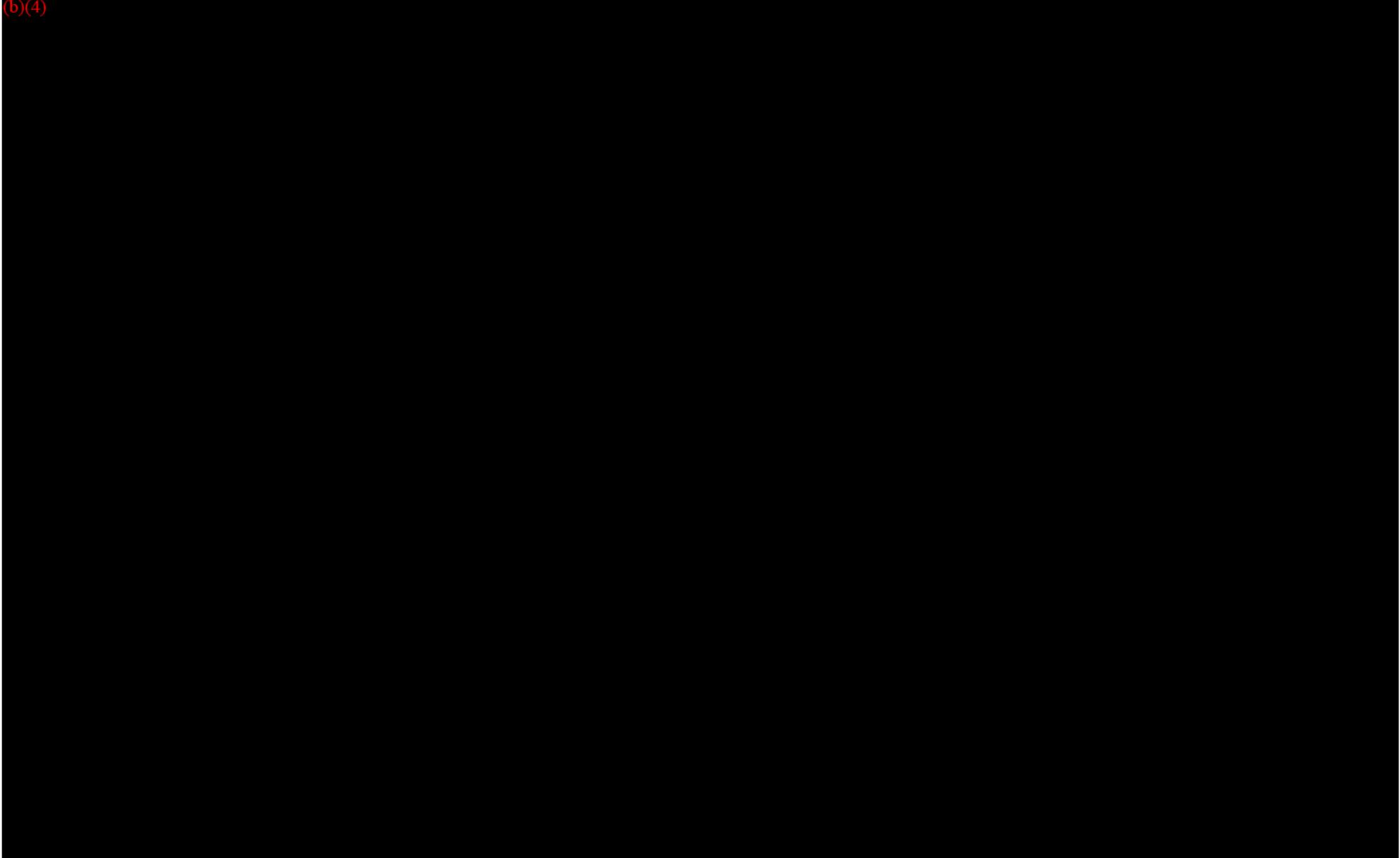


Figure 18 through Figure 21 Load current versus power setting for different body locations

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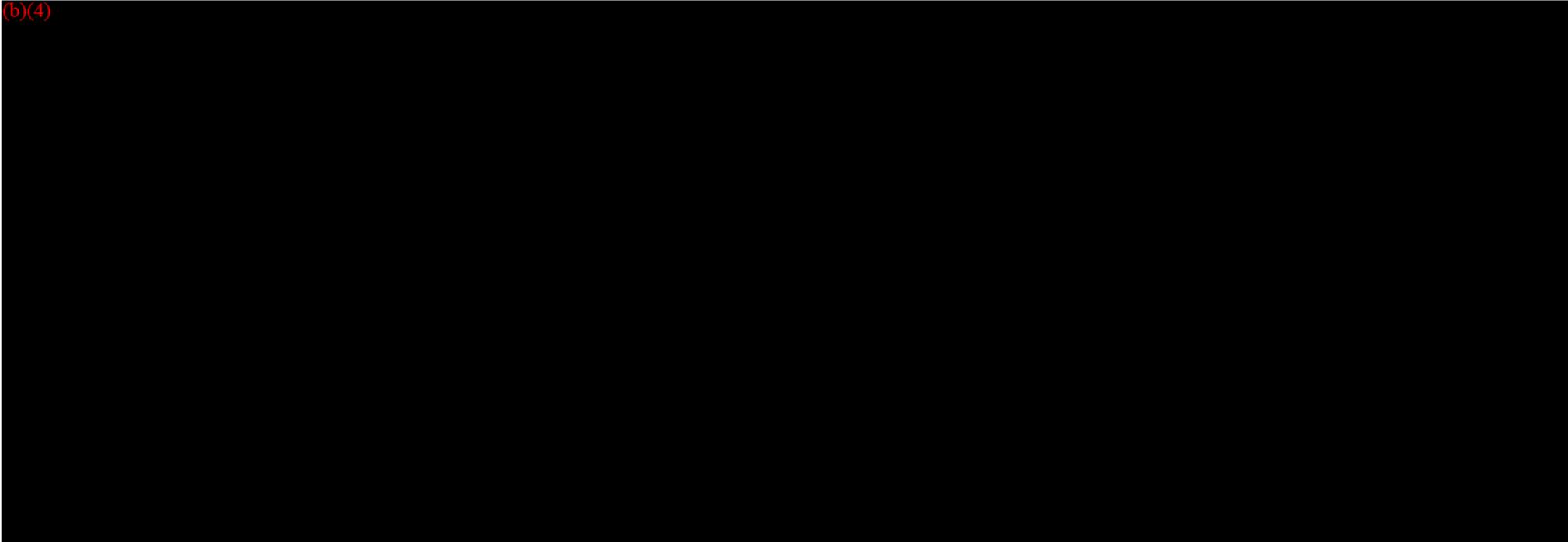


Figure 22 Load current versus power setting for different body locations

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ATTACHMENT 1

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CLINICAL INVESTIGATION

Head and Neck

PILOT STUDY OF IMPEDANCE-CONTROLLED MICROCURRENT THERAPY FOR MANAGING RADIATION-INDUCED FIBROSIS IN HEAD-AND-NECK CANCER PATIENTS

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Purpose: To evaluate the effectiveness of impedance-controlled microcurrent therapy for managing treatment sequelae in head-and-neck cancer patients.

Methods and Materials: Between January 1998 and June 1999, 26 patients who were experiencing late effects of radiotherapy were treated b.i.d. with impedance-controlled microcurrent therapy for 1 week. Objective range-of-motion measurements were made for cervical rotation, extension/flexion, and lateral flexion before therapy, at the end of each treatment day, and monthly for 3 months. In addition, each patient's subjective complaints were tabulated before treatment and reevaluated at the last follow-up visit. No additional physical therapy or electrical stimulation was permitted during the follow-up period.

Results: At the end of the course of microcurrent therapy, 92% of the 26 patients exhibited improved cervical rotation, 85% had improved cervical extension/flexion, and 81% had improved cervical lateral flexion. Twenty-two patients returned for the 3-month follow-up visit. Of these, 91% had maintained a cervical rotation range of motion greater than their pretherapy measurements. Eighty-two percent maintained improved cervical extension/flexion and 77% maintained improved lateral flexion. When the range-of-motion measurements were stratified by pretreatment severity (severe, moderate, mild, or asymptomatic), the degree of improvement directly correlated with the severity. Thus, patients who had more severe initial symptoms experienced a higher percentage of improvement than did those with milder symptoms. For these patients, the cervical rotation range of motion changed from a baseline of $59^\circ \pm 12^\circ$ to $83^\circ \pm 14^\circ$ at 3 months; flexion/extension improved from $47^\circ \pm 10^\circ$ to $73^\circ \pm 13^\circ$; and lateral flexion went from $31^\circ \pm 7^\circ$ to $48^\circ \pm 9^\circ$. Some patients also reported symptom improvement for tongue mobility, facial asymmetry, xerostomia, cervical/facial muscle spasms, trismus, and soft tissue tenderness. No adverse effects were observed.

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assembling the circular arcs and lasers used for measuring range of motion. The Electro-Myopulse 75F and the Electro-Acuscope 80L instruments were loaned to us by Advanced Biomedical Technologies.

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Conclusion: Impedance-controlled microcurrent therapy shows promise for remediation of range-of-motion limitations arising as late effects of radiotherapy for head-and-neck cancer. Additional studies are needed to validate these preliminary results and to optimize the microcurrent treatment protocol, particularly with respect to treatment schedules and combining microcurrent therapy with physical and/or drug therapy. © 2002 Elsevier Science Inc.

Microcurrent therapy, Neutrons, Radiation, Side effects, Head-and-neck cancer.

INTRODUCTION

As aggressive therapy with combination surgery, chemotherapy, and radiotherapy (RT) increases tumor control in head-and-neck neoplasms, posttreatment quality-of-life issues remain problematic (1). One area of concern is progressive fibrosis of soft tissue in the head, neck, and supraclavicular area. For many patients, palpation of the treated areas reveals hard, unyielding tissue that limits range of motion and/or leads to pain associated with movement.

The concept of investigating microcurrent therapy to treat radiation-induced fibrosis arose from the observation of a salivary gland patient who was receiving microcurrent therapy for the surgical scar at a family physician's office while receiving neutron therapy at Fermilab. The patient experienced significantly milder erythema and mucositis than would historically be expected for radical RT in the neck area. This serendipitous observation led to a hypothesis that microcurrent therapy could be beneficial in managing the effects of RT. A literature search revealed several case studies (2–4) from the 1980s suggesting that microcurrent therapy was effective for treating RT sequelae, but these studies lacked adequate statistics and did not include follow-up information on the long-term effectiveness. The reports also lacked information on the specific treatment instruments and precise treatment protocols used. This pilot study was designed to determine whether the suggested efficacy would be observed in a series of patients treated using a well-specified protocol.

METHODS AND MATERIALS

Twenty-six head-and-neck cancer patients who had completed RT and were experiencing tissue discomfort or limitations caused by fibrosis participated in the study. Because this was a pilot study to determine the efficacy of a new use of a standard therapeutic technique, it was important that all participants have quantifiable symptoms with no expectation of resolution without intervention. Hence, patients experiencing documented progressive fibrosis were targeted. The staff made objective range-of-motion measurements, and subjective complaints were solicited from the patients. The procedure and its possible lack of benefit were explained to the patients before they signed a document indicating informed consent. The Provena Saint Joseph Hospital Institutional Review Board approved the protocol.

Selection of study subjects

Eligible patients had finished either photon or neutron therapy at least 6 months before entering the study and had

no evidence of disease. They had mental alertness sufficient to understand, evaluate, and consent to the protocol, which included the availability for b.i.d. treatments daily for 1 week and the ability to return for scheduled follow-up visits. Exclusion criteria included the use of a pacemaker, use of calcium-channel blocker drugs, pregnancy, and a life expectancy of <6 months. Individuals who were unable to abstain from physical therapy to the affected area, routine use of antiinflammatory steroids, or nonsteroidal antiinflammatory drugs during the treatment and follow-up period were also excluded. Table 1 summarizes the baseline characteristics of the participants.

Choice of microcurrent technique and schedule

The use of electrical stimulation for pain relief is well established in physical therapy centers. Many commercial electrical stimulation devices are available, most of which are commonly referred to as transcutaneous electrical nerve stimulation units. Typical units emit electrical pulses with alternating positive and negative polarities in the 10–500-kHz range and currents in the milliamperage range. Microcurrent units are often incorrectly referred to as transcutaneous electrical nerve stimulation units, but microcurrent units deliver lower currents (microampere range) and lower frequencies (0.5 to several hundred hertz). In general, units using higher current and frequencies are more effective at blocking acute pain, but the pain relief is not lasting. Microcurrent therapy using lower frequencies requires longer treatment times to achieve pain relief, but the relief can endure for many hours after the treatment has terminated (5). Because the patients targeted for this study were experiencing chronic rather than acute symptoms, a microcurrent device was selected.

The costs of microcurrent devices range from several hundred to thousands of dollars. Some fraction of the cost is related to packaging, but most of it is associated with the degree of sophistication of the electronic circuits. It is well known that the body's impedance changes when electrical current passes through it. The more sophisticated devices contain circuitry that monitors impedance and adjusts the output current to compensate for changes. These devices also deliver fast rise time pulses that can affect voltage-sensitive sodium and calcium ion channels (6). The ElectroMyopulse and Electro-Acuscope instruments (Biomedical Design Instruments, Burbank, CA) chosen for this study deliver impedance-controlled, fast rise time pulses. Their retail price is about \$8500 each. Electrotherapy treatments are reimbursable under established billing codes. Typical charges to a patient are \$40–50 per 15-min treatment. However, patients in this study were not charged for the therapy.

Physical therapists use microcurrent therapy in a variety of ways, often in combination with massage, heat, and physical manipulation. Treatment schedules are not standardized, but are driven by insurance payment schedules and the patients' personal schedules. The treatment schedule for this study was established after informal discussions with a few physical therapists who had extensive experience using the Electro-Myopulse and Electro-Acuscope instruments for treating a variety of physical complaints. All agreed that noticeable improvement could be obtained most quickly if the patient were treated b.i.d. for 3 days. All agreed that lasting improvement tended to require several treatments per month for about 6 months and that some conditions could resolve completely if this long-term treatment schedule were followed, particularly if therapy started soon after the injury or symptom occurred. Given the advanced fibrosis of many of the study patients, it was decided to administer microcurrent treatments b.i.d. for 5 days and simply observe whether this therapy had any effect on severely fibrotic tissue. Any observed improvements were not expected to be lasting, because no follow-up treatments at more spread-out intervals were scheduled. Until measurable evidence of the treatment's effectiveness was observed, it did not seem reasonable to commit resources to a long-term treatment schedule.

Objective measurement techniques

As shown in Fig. 1, cervical rotation, extension/flexion, and lateral flexion were measured using two large protractors mounted in perpendicular planes. An elastic band with Velcro attachments was secured to the patient's head to permit the placement of a small laser that pointed to degree markings on circular scales used to measure range of motion in degrees. This laser was positioned relative to the points about which the patient's head pivots during rotation, extension/flexion, and lateral flexion. Stationary lasers were used to position the patient so that the movable laser was on a line that intersected the vertex of the large protractors. Figures 2 through 4 illustrate the setup for each angular measurement. Day-to-day patient positioning accuracy was ± 0.25 cm, which is small compared with the protractors' 112-cm radius. This choice of scale minimized the effect of day-to-day errors in positioning the patient's center of rotation at the vertex of the scale.

For each patient, the pretreatment data were used to classify each range of motion as asymptomatic or mildly, moderately, or severely limiting. If a patient's range was within 90% of the optimal range for a healthy young person, that patient was classified as asymptomatic for that measurement. Ranges between 70% and 90% of optimum were designated mildly limiting, and those of 50-70% were moderately limiting. Ranges <50% of optimum were considered severely limiting. By assigning a value of 0 to asymptomatic, 1 to mild, 2 to moderate, and 3 to severe, for each of the three range-of-motion measurements, it was possible to assign a number between 0 and 9 to each patient, with 0 corresponding to no practical limitations and 9 cor-

Table 1. Baseline characteristics of 26 patients in the pilot study

	Fast neutrons	Photons	Neutrons and photons
Gender (<i>n</i>)			
Male	3	9	2
Female	5	4	3
Race (<i>n</i>)			
White	8	13	3
Black	0	0	2
Age (y)	52 \pm 15	56 \pm 9.3	63 \pm 15
Radiation dose (Gy)	20.8 \pm 0.8	64 \pm 8.3	20.3 \pm 0.1 (n) 36 \pm 25 (γ)
Time from RT to start of therapy (mo)	67 \pm 61	30 \pm 27	42 \pm 38

Data presented as the average \pm standard deviation, unless otherwise noted.

Abbreviations: RT = radiotherapy; n = neutrons; γ = photons.

responding to significant limitations in all three measurements. Using these designations, the average pretreatment severity for the 13 patients treated with photons only was 5.6 ± 2.4 . For 8 patients receiving only fast neutrons, it was 4.0 ± 2.7 , and for 5 patients who were treated with neutrons after photon therapy, it was 2.4 ± 1.5 . The 3 patients who had a severity of 9 had received electrons in addition to photons. Table 2 lists all 26 cases in order of severity, along with information about the treatment site, tumor pathologic features, stage, type of radiation, and doses.

Treatment protocol

Alternating microampere current at frequencies ranging from 0.5 to 100 Hz was directed through the fibrotic area using one stationary and one moveable electrode. The current source was an Electro-Myopulse 75F instrument in mode 1 operated at the auto setting. The current was set as high as the patient could tolerate, typically at the maximal instrument setting of 600 μ A. Good electrical conductivity was obtained using CEL-0071 Conductive Electrolyte.

During the first 20 min of each treatment session, the fixed electrode was taped to the shoulder blade closest to the affected tissue. This electrode was a flat, square, conducting plate (area 5×5 cm²). The moveable electrode was a cylindrical roller, 7.6 cm in diameter and 7.6 cm long. The roller was repeatedly moved slowly from a region of healthy tissue just outside the fibrotic area into and across the region of scar tissue. For each patient, all the scar tissue related to RT was treated in this manner. Thus, if a supraclavicular RT field had been given in addition to the primary treatment fields, the supraclavicular area was included in the microcurrent treatment area.

During the next 10 min, the current source was the Electro-Acuscope 80L in mode 1 with settings of 10 Hz and 600 μ A. The single fixed electrode was replaced by two rectangular plates, each having an area of 10×27.2 cm², and connected to the current source through a preamplifier. The patient held one hand on each plate while the therapist treated the fibrotic

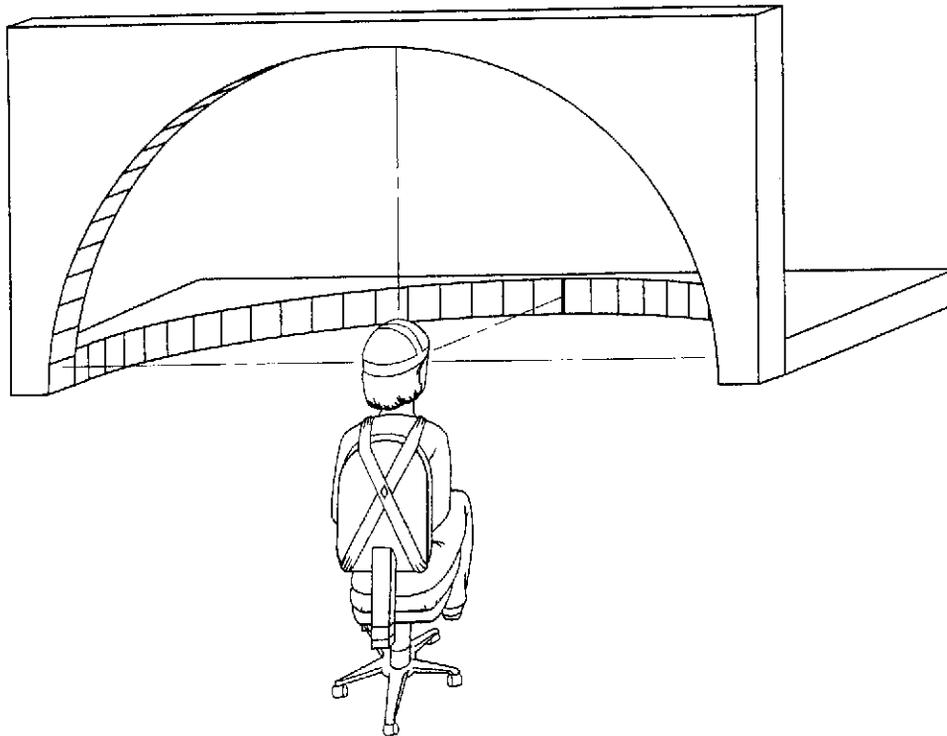


Fig. 1. Patient positioned at vertex of two mutually perpendicular protractors used to measure cervical range of motion.

area with the roller in the manner described above. Figure 5 shows the treatment technique. The session ended with a 1-min treatment using CRM-XR46 After Treatment Cream instead of the CEL-0071 Conductive Gel.

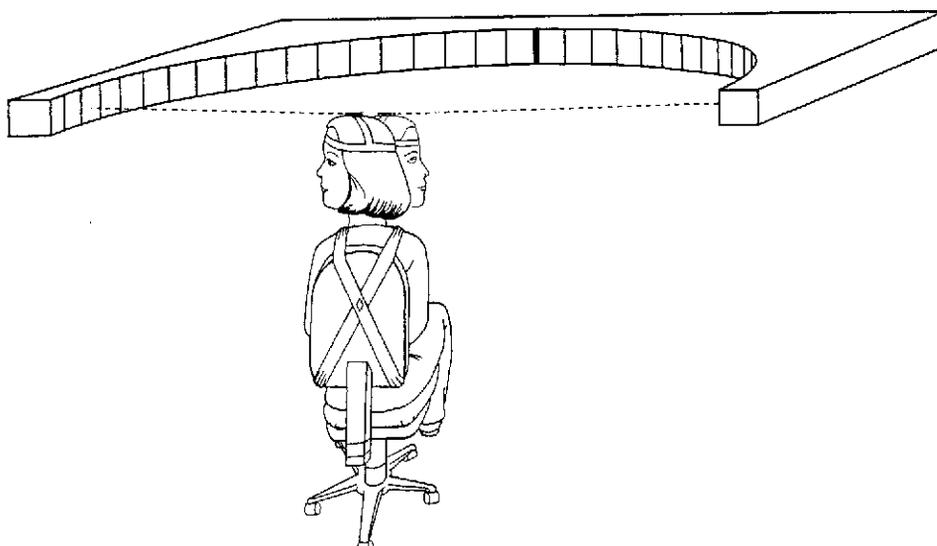
Patients were treated b.i.d., with a 4–5-h interval between treatment sessions. A total of 10 treatments was given during a 5-day period. Subjective symptoms were recorded and range-of-motion measurements made before the first treatment and at the end of each treatment day. Follow-up measurements and subjective assessments were made at

1-month intervals for a total of 3 months. No additional microcurrent or physical therapy was permitted until the end of the 3-month follow-up period.

RESULTS

Objective range-of-motion measurements

Tables 3 through 5 show the average pretreatment, post-treatment, and 3-month follow-up ranges for cervical rotation, extension/flexion, and lateral flexion measurements



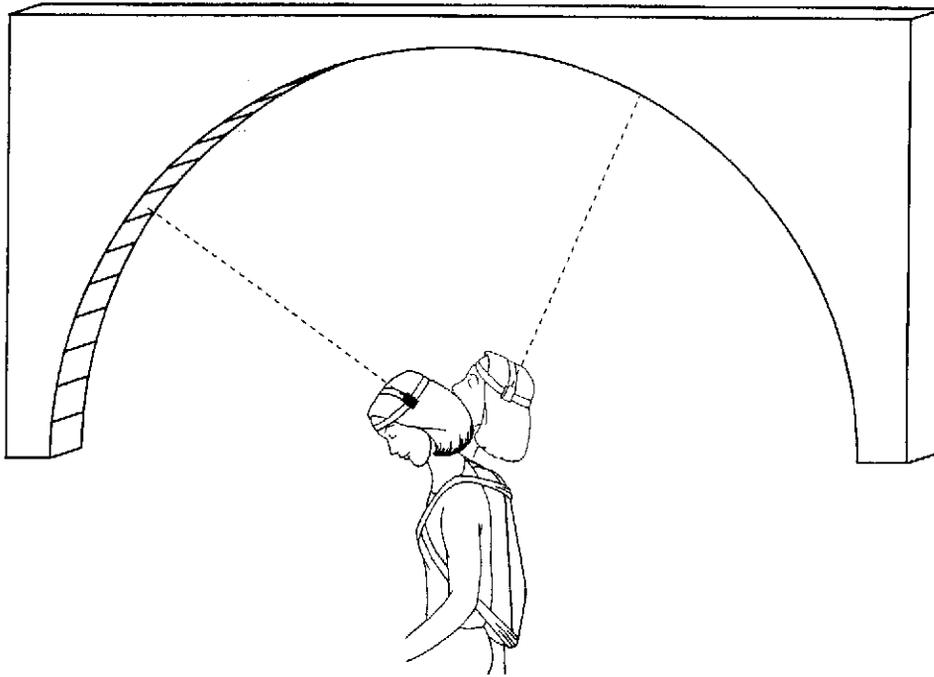


Fig. 3. Cervical extension/flexion measured using a laser affixed to the side of the head.

stratified by pretreatment severity and type of radiation given. For each type of motion, the degree of improvement was directly proportional to the pretreatment severity. Despite our expectations that any improvement observed at the end of the treatment week would be lost at the 3-month follow-up visit, most patients had better measurements at 3 months than they did before treatment. At the 3-month follow-up visit, the average severity score for the photon-

only patients was 3.9 ± 2.3 ; for the neutron-only patients, it was 1.2 ± 1.2 ; and for the neutron-following-photon patients, it was 2.0 ± 1.0 . No adverse side effects were observed. All the patients completed the treatments.

Cervical rotation

The range of right/left cervical rotation was compared with the nominal value of 170° , which is considered normal for a

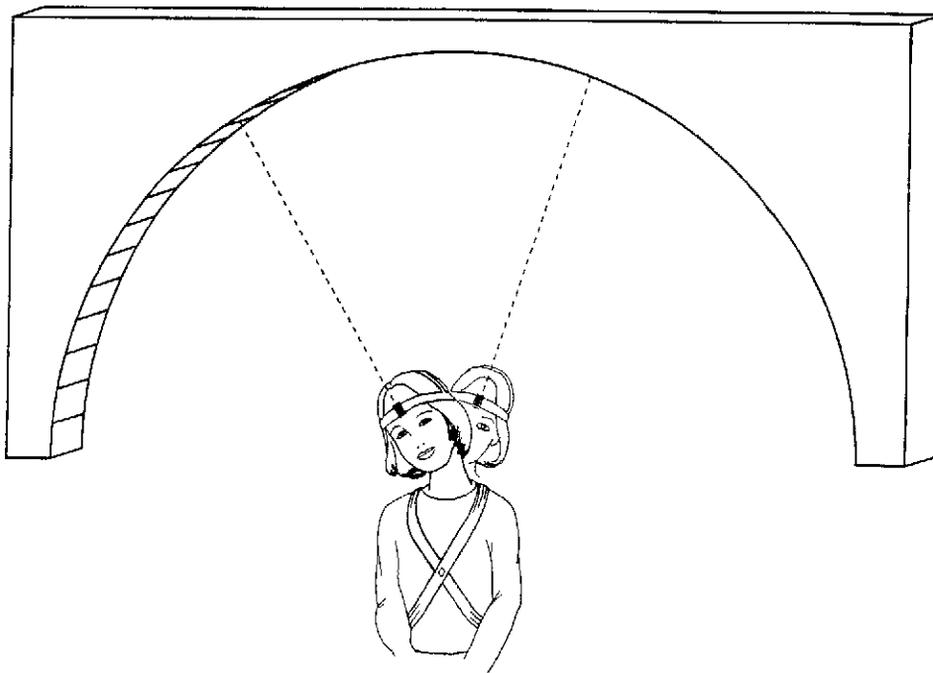


Table 2. Patient characteristics listed in order of greatest to least severe radiation-induced range-of-motion limitations before impedance-controlled microcurrent therapy

Severity	RT site	Dose (Gy)	Radiation	Pathologic features	Stage	Other therapy
9	Left thyroid	66	$\gamma + e$	Medullary carcinoma	T4N1bM0/Stage 3	Surgery
	Bilateral neck	66	$\gamma + e$			
	Supraclavicular nodes					
9	Oropharynx	63	$\gamma + e$	Squamous cell	T1N2bM0	Surgery
	Bilateral neck	50.4	$\gamma + e$			
	Supraclavicular nodes					
9	Left tonsil	74.4*	$\gamma + e$	Squamous cell	T3N2bM0	Surgery
	Bilateral neck	50.4				Chemotherapy
	Supraclavicular nodes					
8	Nasopharynx	22	n	Squamous cell	T2N2aM0/Stage 4	
	Supraclavicular nodes	14				
7	Maxillary sinus	20.4	n	Adenoid cystic	T4NxM0	Surgery
6	Supraglottic larynx	75*	$\gamma + e$	Squamous cell	T2N2bM0/Stage 4	Chemotherapy
	Supraclavicular nodes	51				
6	Nasopharynx	70	γ	Squamous cell	T2NbM0/Stage 4	Chemotherapy
	Bilateral neck	50				Surgery
	Supraclavicular nodes					
6	Right neck	58.7	γ	Colloidal carcinoma	Metastatic from breast	Chemotherapy
	Right supraclavicular nodes	45				
6	Nasopharynx and neck	45	γ	Malignant lymphoma	Recurrent/Stage 4	Chemotherapy
	Periaortic nodes					Surgery
6	Larynx	60.4	$\gamma + e$	Squamous cell	T4N0M0	Surgery
	Bilateral neck	50.4				
5	Right submaxillary	20.4	n	Adenoid cystic	Stage 1	Surgery
5	Left parotid	22	n	Adenoid cystic	T2N0M0/Stage 1	Surgery
4	Left parotid	59.2	γ	Melanoma	Metastatic from cheek	Surgery
4	Left parotid	30	γ	Benign mixed	Recurrent	Surgery
		20.4	n			
3	Right nasal ala	59.5	$\gamma + e$	Squamous cell	Recurrent	Surgery
	Bilateral neck					
	Supraclavicular nodes	50.4	γ			
3	Tongue	60	γ	Keratinizing	T2N1Mx	Surgery
	Left neck	62.8	$\gamma + e$	Squamous cell		
3	Base of tongue	20	n	Adenoid cystic	T1N0M0	Surgery
3	Right submandibular	7.2	γ	Adenoid cystic	T1N0Mx/Stage 1	Surgery
		20.4	n			
	Right supraclavicular nodes	14.0	n			
3	Left parotid	19	γ	Mucoepidermoid	T1N2bM0	Surgery
		20.1	n			
	Supraclavicular nodes	14	n			
3	Right tonsil	74.4*	$\gamma + e$	Squamous cell	T3N1M0	Surgery
2	Left parotid	20.8	n	Acinic cell	Recurrent	Surgery
	Left supraclavicular nodes	14.3	n			
2	Right tonsil	61	$\gamma + e$	Squamous cell	T1N2bM0/Stage 4	Surgery
	Bilateral neck	64	$\gamma + e$			
	Supraclavicular nodes	46	γ			
2	Left parotid	60	γ	Adenoid cystic	Recurrent	Surgery
		20.4	n			
1	Base of tongue	20.4	n	Mucoepidermoid	T3NxM0	
1	Base of tongue	20.4	n	Adenoid cystic	T4N1M0	
0	Left parotid	65	γ	Adenoid cystic	Recurrent	Surgery
		20.4	n			

Abbreviations: RT = radiotherapy; γ = photons; e = electrons; n = neutrons.

* b.i.d. treatment.



Fig. 5. Electrotherapy treatment technique. Patient's hands rest on large metal plates while impedance-controlled microcurrent therapy is delivered using a metal roller.

healthy, young individual (7). Of the 26 patients, 24 (92%) exhibited improved cervical rotation at the end of microcurrent therapy. Of the 22 who returned for the 3-month follow-up visit, 3 experienced continued improvement, and 17 had lost some of their range of motion, although their average mobility was somewhat better than it had been before microcurrent therapy. One patient in the mildly limited category experienced no improvement and one asymptomatic patient had measurements in the mildly limited category at the 3-month follow-up examination. Figure 6 illustrates the improvement for the 3 patients who started with severe limitations and completed all three follow-up visits on schedule.

Cervical extension/flexion

The range of cervical extension/flexion was compared with the nominal value of 120°, considered normal for a healthy, young individual (7). Of the 26 patients, 22 (85%) exhibited improved extension/flexion at the end of microcurrent therapy. Of the 22 who returned for the 3-month follow-up visit, 8 maintained or improved their end-of-treatment status. Ten of the 22 patients lost some range of motion but their mobility was still better than it had been before microcurrent therapy. The 4 patients who experienced no long-term improvement were already functioning within 80-90% of the nominal value at baseline. Figure 7 illustrates the

Table 3. Cervical rotation, stratified by severity of limitation, before, at the end, and 3 months after treatment

Patients (n)			Pretreatment rating	Pretreatment range (°)	Posttreatment range (°)	Change from pretreatment range (%)	3-mo follow-up range (°)	Change from pretreatment range (%)
Neutrons	Photons	Both						
1, 0	3, 3	—	Severe	59 ± 19 (n = 4)	97 ± 30 (n = 4)	64	83 ± 14 (n = 3)	41
2, 2	6, 5	2, 1	Moderate	101 ± 10 (n = 10)	131 ± 15 (n = 10)	30	119 ± 9 (n = 8)	18
4, 4	4, 4	2, 1	Mild	131 ± 8 (n = 10)	153 ± 16 (n = 10)	17	140 ± 13 (n = 9)	7
1, 1	—	1, 1	Asymptomatic	164 ± 1 (n = 2)	165 ± 9 (n = 2)	1	154 ± 22 (n = 2)	-6

Data presented as the average ± standard deviation, unless otherwise noted.

Optimal range-of-motion for a healthy young person is 170°. First 3 columns show type of radiation received by 26 patients who started the study, followed by the number of patients (total 22) who returned for the 3-month follow-up.

improvements for the 3 patients initially classified as most severely limited in extension/flexion.

Cervical lateral flexion

The range of cervical right/left lateral flexion was compared with the nominal value of 90°, considered normal for a healthy, young individual (7). Of the 26 patients, 21 (81%) exhibited improved range of lateral flexion at the end of microcurrent therapy. Of the 22 patients who returned for the 3-month follow-up visit, 8 had continued to improve their range of motion without any additional therapy. Nine patients experienced a decrease compared with their range of motion at the end of therapy, but their mobility was still better than their measurements before therapy. Five patients experienced no long-term improvement. Figure 8 illustrates the improvements for the 4 patients who started with severe limitations and completed all three follow-up visits on schedule.

Oral opening

Oral opening was measured using a Therabite scale (Fig. 9). The measurement was made for all 26 patients, even if trismus was not a complaint. Of the 26 patients, 21 (81%) exhibited improved oral opening after impedance-controlled

microcurrent therapy. Only 16 of the 26 patients stated that trismus was a problem. Four of the 16 had no improvement during the course of the study. One had no improvement at the end of the treatment week but had gained 3 mm in oral opening at the end of 3 months. For the 7 patients who maintained improvement in oral opening, the average increase was 4.6 ± 2.2 mm 3 months after the end of microcurrent therapy.

Subjective observations

Before starting microcurrent therapy, patients were asked to fill out a questionnaire regarding any symptoms they might be experiencing as a result of RT. During the treatment week, they turned in daily written observations of any changes in symptoms. Subjective observations were also recorded at the time of each follow-up visit. Table 6 lists the number of patients reporting various symptoms, along with the percentage of patients who said that the therapy had provided noticeable relief of the symptoms.

DISCUSSION

In head-and-neck cancer patients, radiation-induced fibrosis can lead to many different complaints, depending on

Table 4. Cervical extension/flexion, stratified by severity of limitation, before, at the end, and 3 months after treatment

Patients (n)			Pretreatment rating	Pretreatment range (°)	Posttreatment range (°)	Change from pretreatment range (%)	3-mo follow-up range (°)	Change from pretreatment range (%)
Neutrons	Photons	Both						
—	3, 3	—	Severe	47 ± 10 (n = 3)	70 ± 12 (n = 3)	49	73 ± 13 (n = 3)	55
2, 1	3, 3	—	Moderate	73 ± 9 (n = 5)	106 ± 9 (n = 5)	45	107 ± 20 (n = 4)	47
4, 4	5, 4	2, 1	Mild	96 ± 7 (n = 11)	114 ± 15 (n = 11)	19	110 ± 9 (n = 9)	15
2, 2	2, 2	3, 2	Asymptomatic	117 ± 6 (n = 7)	126 ± 15 (n = 7)	8	117 ± 14 (n = 6)	0

Data presented as the average ± standard deviation, unless otherwise noted.

Optimal range-of-motion for a healthy young person is 120°. First 3 columns show type of radiation received by the 26 patients who started the study, followed by the number of patients (total 22) who returned for the 3-month follow-up.

Table 5. Cervical lateral flexion, stratified by severity of limitation, before, at the end, and 3 months after treatment.

Patients (n)			Pretreatment rating	Pretreatment range (°)	Posttreatment range (°)	Change from pretreatment range (%)	3-mo follow-up range (°)	Change from pretreatment range (%)
Neutrons	Photons	Both						
1, 0	5, 4	—	Severe	31 ± 7 (n = 6)	51 ± 20 (n = 6)	65	48 ± 9 (n = 4)	55
2, 2	4, 4	1, 1	Moderate	53 ± 5 (n = 7)	76 ± 10 (n = 7)	43	79 ± 16 (n = 7)	49
3, 3	4, 4	1, 1	Mild	69 ± 5 (n = 8)	82 ± 17 (n = 8)	19	75 ± 12 (n = 8)	9
2, 2	—	3, 1	Asymptomatic	92 ± 22 (n = 5)	102 ± 25 (n = 5)	11	103 ± 30 (n = 5)	12

Data presented as the average ± standard deviation, unless otherwise noted.

Optimal range of motion for a healthy young person is 90°. First three columns show type of radiation received by the 26 patients who started the study, followed by the number of patients (total 22) who returned for the 3-month follow-up.

the size and placement of the treatment fields, the total dose, and whether the patient also underwent surgery. Limitations in neck range of motion are common and are quantifiable. Because this study was looking for objectively measured changes associated with microcurrent therapy, the protocol was designed to achieve improvement in the range of motion. Measurements were made on all patients in the study regardless of whether the patient considered range-of-motion limitations to be a problem. Most of the patients in the mildly and moderately limited groups had learned to compensate for the limitations and were surprised when the

measurements showed how much capability they had lost. The patients who were most severely limited received the greatest degree of benefit.

Patients also received relief from a number of complaints not directly targeted in the treatment protocol, the most significant of which were trismus and xerostomia. When the study was completed, some case studies were done using a different microcurrent protocol along with physical therapy for the relief of trismus. The results were encouraging and suggest that additional studies on the role of microcurrent therapy in treating trismus are warranted. Our xerostomia

Cervical Rotation

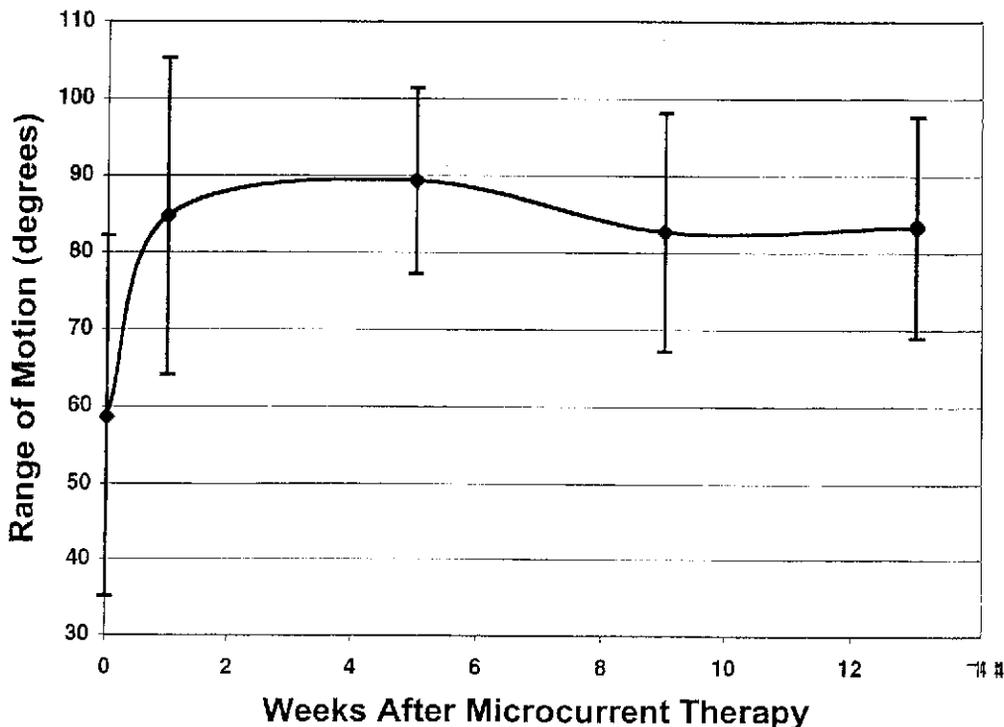


Fig. 6. Range of cervical rotation for 3 patients initially experiencing severe range-of-motion limitation. No microcurrent therapy was given after the first 14 weeks.

Cervical Extension-Flexion

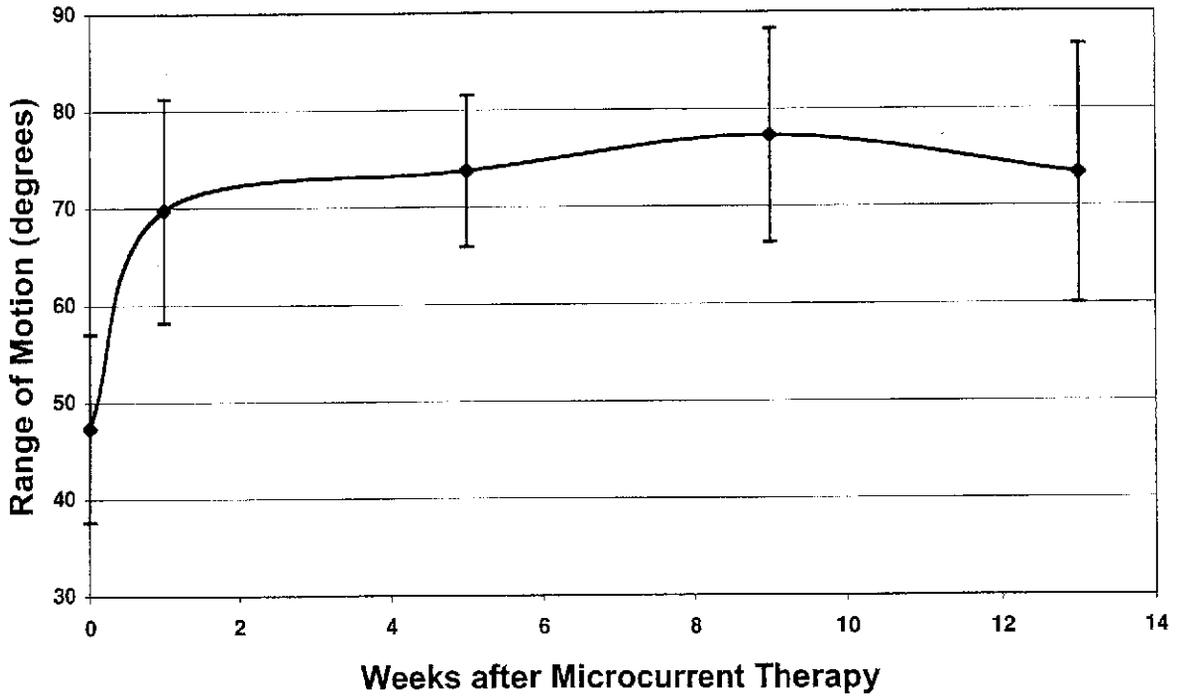


Fig. 7. Range of cervical extension/flexion for 3 patients initially experiencing severe range-of-motion limitation. No microcurrent therapy was given after the first week of treatment.

Cervical Lateral Flexion

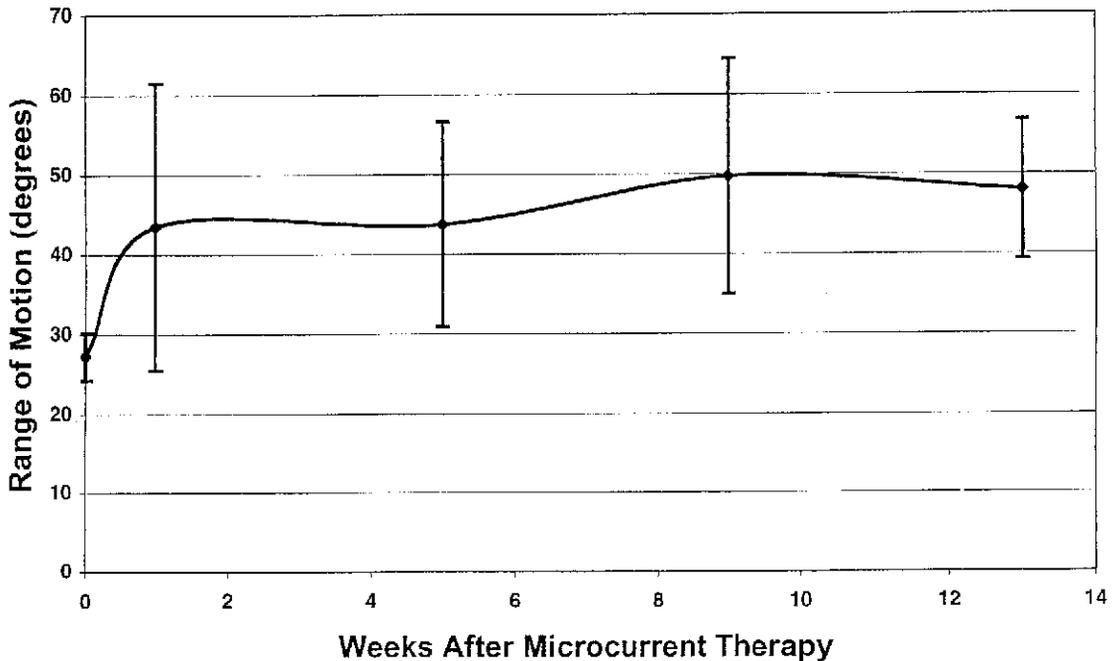


Fig. 8. Range of cervical lateral flexion for 4 patients initially experiencing severe range-of-motion limitation. No microcurrent therapy was given after the first week of treatment.



Fig. 9. Thera-bite scale used to measure oral opening.

data are currently being analyzed and will be published separately.

Perhaps the most encouraging outcome of this study was that many of the benefits observed at the end of the treatment week were sustained. In some cases, continued improvement occurred during the 3-month follow-up period, suggesting that the treatment had initiated tissue repair. The

beneficial effects of electric current for soft tissue repair have been described by Polk (8). The exact mechanisms for tissue repair are not completely understood, but one theory indicates that microcurrent stimulation influences the migration of extracellular calcium ions to penetrate the cell membrane. The higher level of intracellular calcium encourages increased synthesis of adenosine triphosphate. Protein synthesis is encouraged by affecting mechanisms that control DNA, thus encouraging cellular repair and replication (9). It is also believed that microvoltage may affect the cascade of reactions involved in a variety of inflammatory responses. Our data support the view that microcurrent therapy can initiate long-term benefit for patients with fibrosis.

At the onset of the study, it was expected that any improvement in symptoms would be transient, because no follow-up treatment was offered. The data indicate that this assumption was incorrect. Although the group size was small, the data shown in Figs. 6 through 8 suggest that improvement continued during the first and second months after microcurrent therapy. The treatment schedule needs to be optimized, perhaps delivering fewer treatments the first week followed by weekly and then monthly treatments to determine the maximal achievable benefit. For patients who are just beginning RT, it is possible that an optimal treatment schedule would include administering impedance-con-

Table 6. Patients with improvement in subjective complaints

Symptom	Patients reporting improvement (%)
Tongue immobility	3/8 (37)
Impaired speech	3/6 (50)
Stiffness/discomfort	24/26 (92)
Facial asymmetry	6/7 (86)
Soft tissue edema	11/17 (65)
Trismus	10/16 (62)
Dry mouth	15/20 (75)
Difficulty swallowing	4/10 (40)
Cervical/facial spasms	10/12 (83)
Fibrosis	12/20 (60)
Inability to purse lips	5/5 (100)
Difficulty breathing	3/3 (100)
Tenderness	10/15 (67)
Pain	9/13 (69)
Numbness	6/8 (75)

In designing the study, we deliberately excluded the use of any agent or activity that could contribute to the relief of symptoms associated with fibrosis. Because this study has shown benefits attributable to microcurrent therapy alone, it is appropriate to consider combining this therapy with other physical therapy techniques or medications such as pentoxifylline/vitamin E (10). Seven of the patients who benefited from microcurrent therapy indicated that they had received no benefit from previous physical therapy, but it is possible that the combination might be more effective than either modality alone.

CONCLUSION

Impedance-controlled microcurrent therapy shows promise in improving the range of motion and alleviating other symptoms associated with radiation-induced fibrosis. Studies should be done to validate our preliminary results and to optimize the treatment schedule to achieve longer lasting benefit. Protocols combining microcurrent therapy with physical therapy and/or promising medications could prove to be very beneficial in improving the quality of life for RT patients.

REFERENCES

1. Cooper JS, Fu K, Marks J, *et al*. Late effects of radiation therapy in the head and neck region. *Int J Radiat Oncol Biol Phys* 1995;31:1141-1164.
2. Bauer W. Electrical treatment of severe head and neck cancer pain. *Arch Otolaryngol* 1983;109:382-383.
3. Boswell NS, Bauer W. Noninvasive electrical stimulation for the treatment of radiotherapy side-effects. *Am J Electromed* 1985;1(3):5-6.
4. King GE, Jacob RF, Martin JW. Electrotherapy and hyperbaric oxygen: Promising treatments for postradiation complications. *J Prosthetic Dentistry* 1989;62:331-334.
5. Omura Y. Electro-acupuncture: Its electrophysiological basis and criteria for effectiveness and safety—Part 1. *Acupunct Electrother Res* 1975;1:157-181.
6. Biedebach M. Accelerated healing of skin ulcers by electrical stimulation and the intracellular physiological mechanisms involved. *Acupunct Electrother Res Int J* 1989;14:43-60.
7. Oslance J, Liebenson C. Outcomes assessment in the small private practice. In: Liebenson C, editor. *Rehabilitation of the spine*. Media, PA: Williams & Wilkins; 1996. p. 79.
8. Polk C. Electric and magnetic fields for bone and soft tissue repair. In: Polk C, Postow E, editors. *Handbook of biological effects of electromagnetic fields*. 2nd ed. Boca Raton: CRC Press; 1996. p. 231-246.
9. Cheng N, Van Hoof H, Bockx E, *et al*. The effects of electric currents on ATP generation, protein synthesis, and membrane transport in rat skin. *Clin Orthop* 1982;171:264-272.
10. Delanian S, Balla-Mekias S, Lefaix J. Striking regression of chronic radiotherapy damage in a clinical trial of combined pentoxifylline and tocopherol. *J Clin Oncol* 1999;17:3283-3290.



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WL 704 C641 1984

**Clinical transcutaneous electrical nerve stimulation
Mannheimer, Jeffrey S., 1942-**

Title: **Clinical transcutaneous electrical nerve stimulation /**

Other title: **Clinical T.E.N.S.**

Publication info: **Philadelphia : Davis, c1984.**

Physical description: **xxxiv, 636 p. : ill.**

Held by: **SOUTHLIB**

Medical Subject: **Electric Stimulation Therapy--methods**

Medical Subject: **Pain--therapy**

Personal author: **Mannheimer, Jeffrey S., 1942-**

Personal author: **Lampe, Gerald N., 1942-**

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(Numbers for: **SOUTHLIB**

1) WL 704 C641 1984 1 BOOK TOP-FLOOR



TOP

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As noted previously, slight adverse skin reactions may be caused by some factors, such as the electrical current, the composition of the electrodes, the substance of the coupling gel, the adhesives used to secure the electrodes in place, or more commonly, the techniques employed in fastening the electrodes in place. In other words, the skin problems associated with T.E.N.S. may be:

1. Electrical.
2. Chemical.
3. Allergic.
4. Mechanical.

ELECTRICAL REACTIONS

In addressing the electrical nature of possible trauma, consideration should be given to several factors.

1. Constant current versus constant voltage. Generators that are constant-current sources tend to be more effective than those with constant voltage because the constant-current stimulus supplies a greater amount of electrical charge to the underlying neurologic structures than does a constant-voltage source. The possibility of adverse skin reaction is minimized with a constant-current source. The waveform that is generated is grossly affected by the output impedance of the T.E.N.S. pulse generator when driving the impulses across the skin. It seems that the skin impedance appears as a resistor shunted by a capacitor. The skin and electrode-skin interface have significant capacitive components, and, therefore, constant-current sources tend to largely remove the possibility of skin burns from the electrical impulses. The electrical impulses are biphasic to further reduce the potential of injury secondary to the flow of electrical current both on the long- and short-term effects.

2. The potential for electrical burns exists if one or both of the following errors of application is made.

a. Skin burns may occur with excessive stimulation with small-area electrodes. The heat produced beneath the electrodes must be less than $250 \text{ mcal/cm}^2/\text{sec}^3$. This means that to ensure safety of stimulation, the electrode surface area must be equal to or greater than 4 cm^2 . Electrodes of this size will ensure safe current densities for clinical applications of T.E.N.S., and if applied correctly, skin burns will not result.

b. Care must be exercised to avoid placing electrodes too close to one another. If the distance between the electrodes is less than the cross-sectional diameter of the electrodes, then the current density between the electrodes is greater than that beneath either electrode. Thereby, the heat produced may exceed the safe limits and a skin burn may result.

3. Another type of clinical error may result in micropunctate burns. This may occur secondary to poor electrical contact between the skin and the stimulating electrode. Such burns may be observed when inadequate or improper "gelling" of the electrodes occurs or when electrodes are not properly conformed to the body contour. These clinical oversights result in a current distribution pattern that is not spread over the total, wide surface of the electrodes. Instead, the current may be concentrated in large volumes at small, punctate areas such as at the hair follicles. This may produce current densities within small areas sufficiently high to produce true thermal damage—burns to the skin.

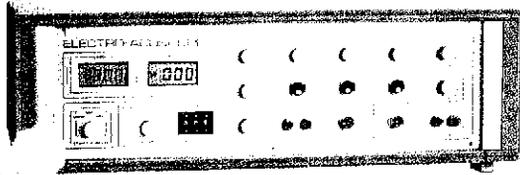
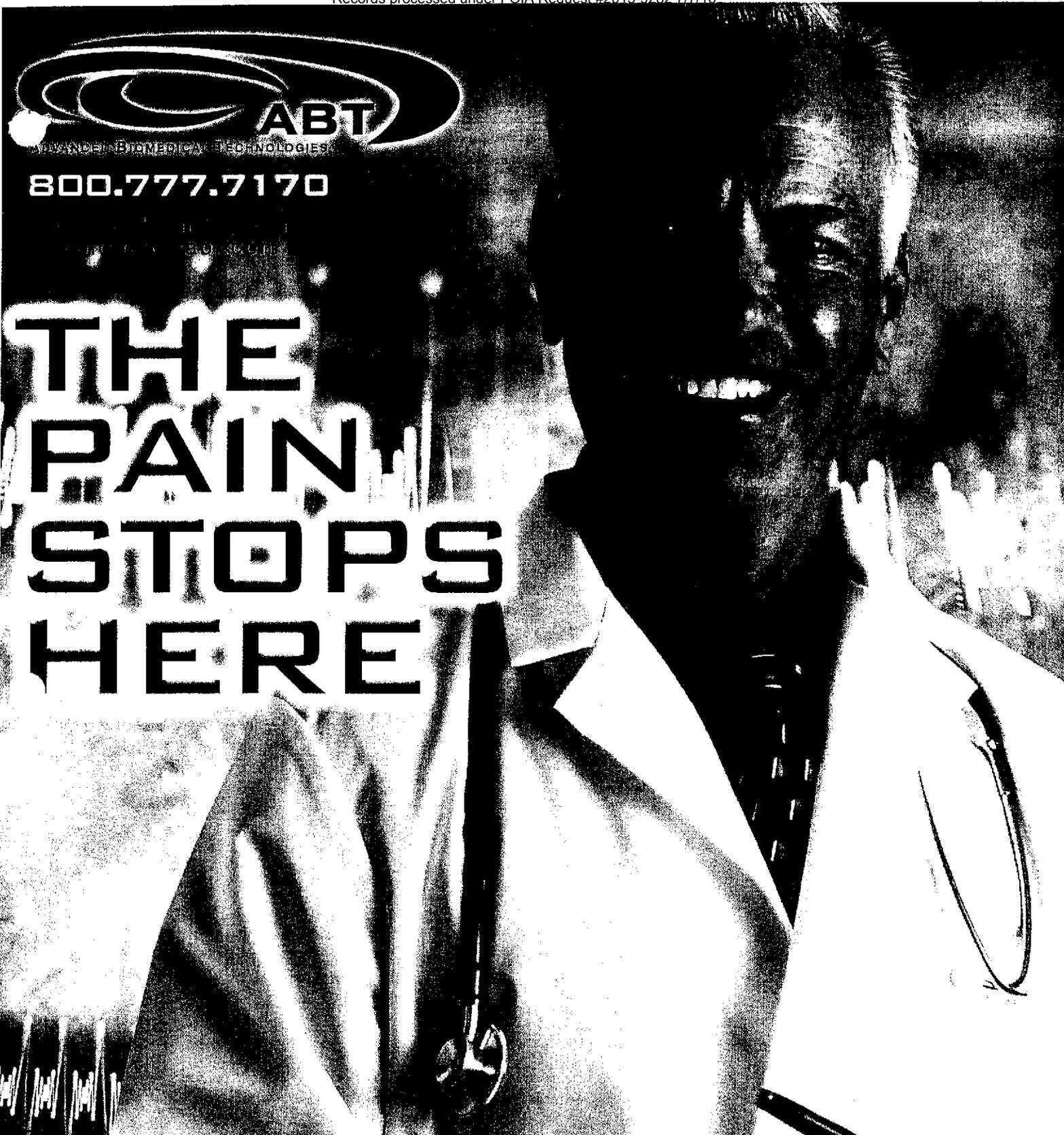
It is helpful to note that thermal damage as described is not necessarily an inherent complication of T.E.N.S. therapy. This thermal damage results instead from errors of application, and knowledge of these restrictions will prevent these complications.

ATTACHMENT 2



800.777.7170

THE PAIN STOPS HERE



ELECTRO-ACUSCOPE



ELECTRO-MYOPULSE

Questions? Contact FDA/CDRH/OCE/DIV/CDR/FOIS/STATUS@fda.gov

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Power

*Experience unparalleled results with
Advanced Biomedical Technology,
the leader in Electro-Acuscope
and Electro-Myopulse
pain research*

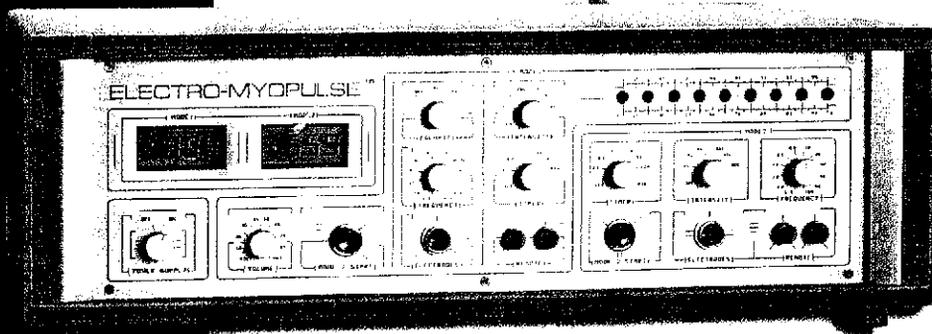
REDUCE PAIN



IMPROVE RANGE OF MOTION



ACCELERATE HEALING



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

To Speak with a Product Specialist please call **800 777 7170**

of Intelligence

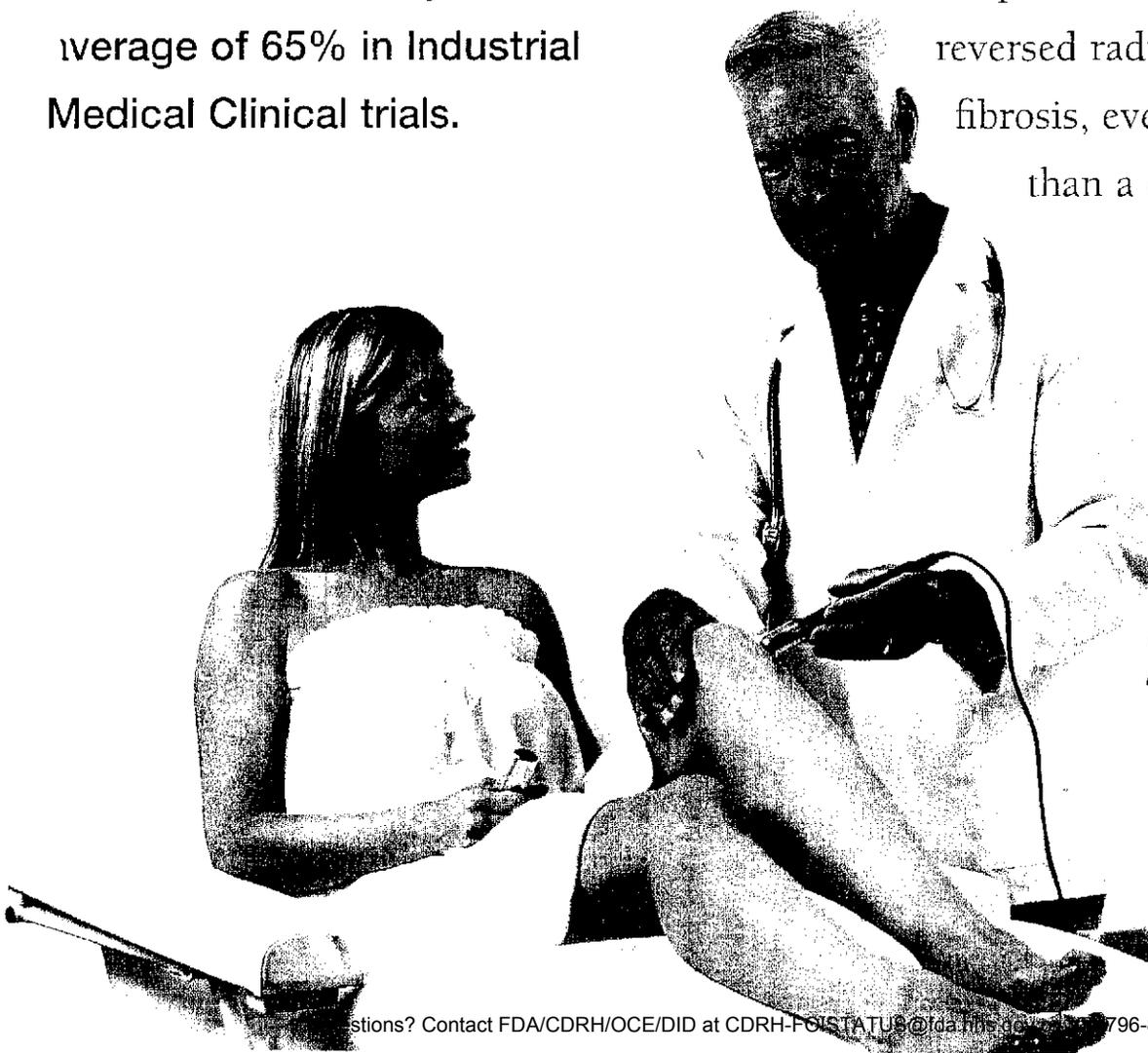
FOR YOUR PAIN PRACTICE

Capable of treating a wide variety of both acute and chronic conditions, the Electro-Acuscope and Electro-Myopulse System, has been **proven to reduce rehabilitation time by an average of 65% in Industrial Medical Clinical trials.**

Additionally, the Electro-Acuscope & Electro-Myopulse System produces results where **conventional therapies have failed.**

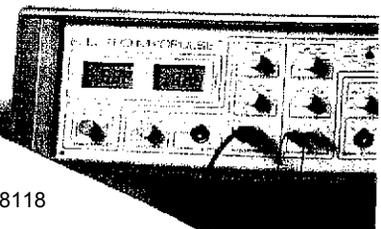


In particular, peer reviewed studies have proven that the system reversed radiation induced fibrosis, even after more than a decade!



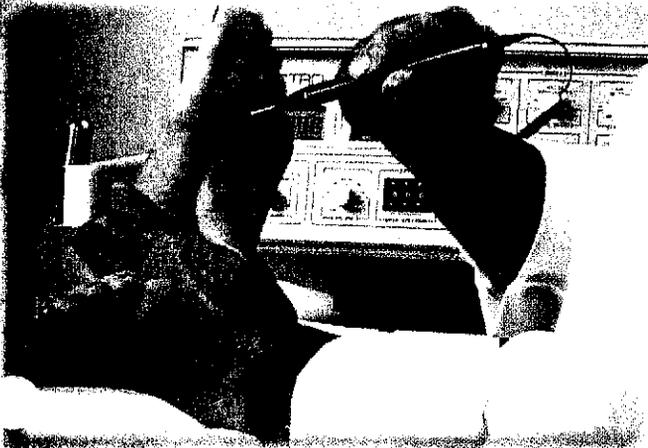
THE
"ABT SYSTEM"
offers the benefits of
*Electro-Acupuncture &
Electro-Acupressure using
non-invasive procedures*

146

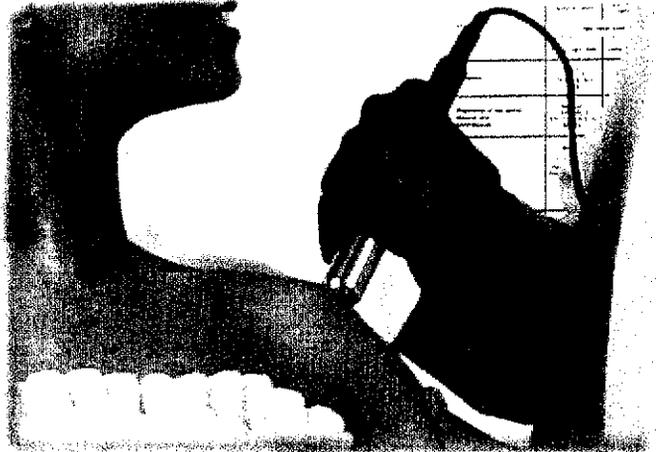


Relief for your patients

**THE "ABT SYSTEM" IS THE ONLY FULLY
COMPUTERIZED, FEED-BACK CONTROLLED,
ENERGY DELIVERY TECHNOLOGY.**



*allows for neurological treatment
using "foot reflexology".*



*reduces pain, improves range-of-motion
in myofacial & neurological injuries.*

THE "ABT SYSTEM"...



*provides stress management for
your patients. "C.E.S." Cranial
Electro-Stimulation for effective
stress reduction and relaxation.*

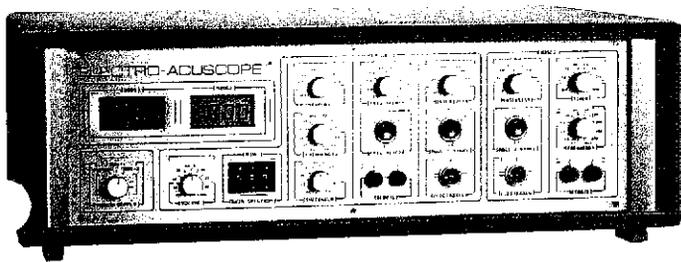


*can be used to
identify & stimulate
ear reflex points
(auricular therapy.)*

Freedom of Choice

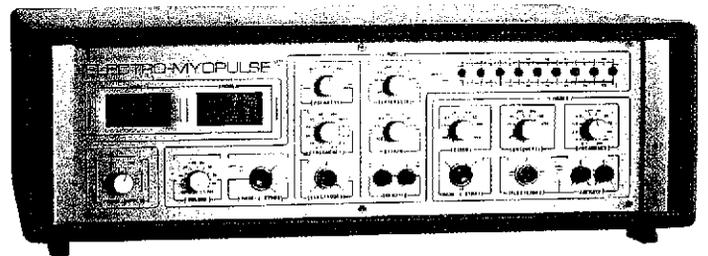
THIS STATE OF THE ART SYSTEM IS COMPRISED OF TWO SEPARATE PIECES OF EQUIPMENT WITH SIMILARITIES YET SIGNIFICANT DIFFERENCES BETWEEN THEM.

TOGETHER THEY COMPRISE A COMPLETE COMPUTERIZED LOW VOLTAGE / LOW AMPERAGE, FEEDBACK MODULATED TREATMENT SYSTEM OFFERING EXCEPTIONAL RESULTS.



The first component of this two part system is the **Electro-Acuscope**. This instrument acts upon subcutaneous tissues to reduce pain and inflammation. It also improves blood flow in circulatory impaired tissues.

The second component is the **Electro-Myopulse**, which is designed to treat connective tissue associated primarily with muscle.



WITH A VARIETY OF INTERCHANGEABLE TREATMENT COMPONENTS, EACH TAILORED TO MEET SPECIFIC NEEDS, THIS EXCEPTIONAL PACKAGE OFFERS CONTEMPORARY, NON-INVASIVE TREATMENT AND RELIEF TO MANY COMMON MALADIES INCLUDING:

- CARPAL TUNNEL
- TENDONITIS
- HEADACHE
- BACK PAIN
- MUSCLE SPASM
- EDEMA
- SCAR PAIN
- LIMITED ROM

Choice

of Healing

**ENERGY PRECISELY DOSED
BASED UPON TISSUE REQUIREMENTS.**

Accelerate healing

Measurable Pain Relief

Increase Range of Motion

Two decades clinical use

Non-invasive

Painless

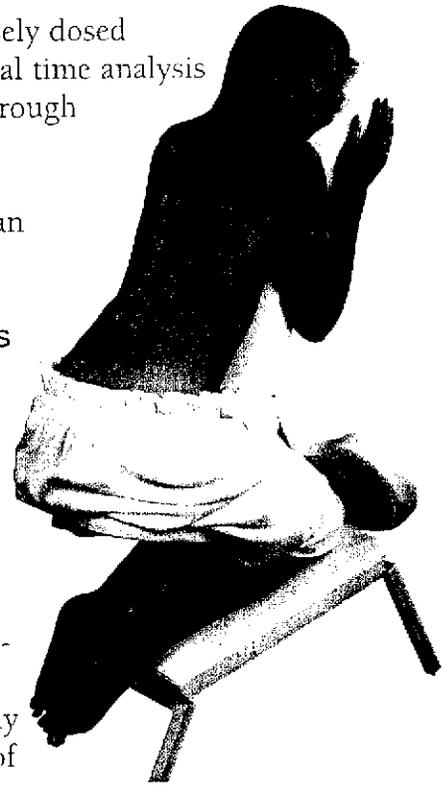
***No known
contra-indications
(vs. surgery, drugs, or pain)***

This revolutionary system directs precisely dosed energy to areas of bio-resistance with real time analysis and feedback to achieve homeostasis through transcutaneous stimulation.

With dynamic monitoring and more than 40,000 measurements and comparisons taken per second, the end result? **Significantly reduced recovery times and immediate, measurable pain relief.**

With more than two decades of clinical use, the Electro-Acuscope / Electro-Myopulse are FDA approved instruments that provide non-invasive, painless therapy, with no known contra-indications. Additionally, clinical and peer reviewed studies prove conclusively that rehab times are cut by an average of 65%. Perhaps even more astonishing, some conditions such as radiation induced fibrosis effects can be reversed even after more than a decade of non-response.

Our success is well documented. Evolve your practice the **Advanced Biomedical** way and experience unprecedented results in your pain practice. Call today to speak with a product specialist to see if your practice is a candidate for this cutting edge technology. **Your patients will thank you.**



*Additionally, the system has been **PROVEN** as a superior form of physical therapy and rehab for a wide variety of sporting and recreational injuries. With some of the top names in professional sports endorsing this product, we urge you to explore what this technology can do for your practice.*

"Isn't it amazing? I just love this Acuscope. I can use it on my elbow for fifteen minutes and virtually eliminate all pain." "...It's the Miracle Machine."

"...the Myopulse and Acuscope have become our number one modality choice for the treatment of our teams injuries."

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ELECTRO-ACUSCOPE 85

Instruction Manual

Revisions
8/11/89
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Page 2

To insure your complete satisfaction with this instrument, please follow these directions before testing or operating your new instrument:

1. EXAMINE FOR PHYSICAL DAMAGE:

If any damage is detected, file a claim with carrier immediately (and be sure to retain the shipping carton and packing materials). A carrier's report is required for settlement of all damage in shipment claims.

2. READ THE INSTRUCTION MANUAL:

An instruction manual with instruction for operation of the instrument is enclosed. Please read it thoroughly and carefully.

3. IF MALFUNCTION OCCURS:

First double check all connections, electrodes, and where applicable, related equipment. If the difficulty persists, immediately contact your local representative.

4. FILL OUT THE WARRANTY REGISTRATION CARD:

Return the warranty registration card within ten days of purchase to validate your warranty. Copy and retain all pertinent registration and receipts for your own records.

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Instrument Maintenance	12
Procedures	14
Theory and Applications of the Electro-Acuscope System	20
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Warranty Return Card

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INDICATIONS

The Electro-Acuscope '85' is used externally. It will not affect the sense of touch, temperature, or general awareness. It provides safe, comfortable, and effective relief from a variety of pain syndromes.

THE ELECTRO-ACUSCOPE '85' CAN BE USED:

- * For pre-and post-operative acute pain management.
- * As continuing treatment for relief and management of chronic pain disorders.
- * For temporary relief of pain with simultaneous treatment of the cause of the pain with another modality.

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CONTRAINDICATIONS

CONTRAINDICATIONS: Electro-Acuscope '85' can be contraindicated where analgesia may mask progressive pathology and should not be used where the physician would normally avoid the use of any other analgesia in order to retain beneficial aspects of pain, or until etiology is established.

TENS devices are contraindicated in the presence of demand type pacemakers.

WARNINGS: Electrical monitoring devices such as EKG Monitors may not operate properly when TENS Stimulator is in use.

The safety of TENS devices for use during pregnancy and delivery has not been established.

Electrical stimulation should not be applied over carotid sinus or trans-cranially.

The Electro-Acuscope '85' should be used under the continued supervision of a licensed clinician.

Do not use in an explosive atmosphere.

PRECAUTIONS: Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.

Transcutaneous electrical nerve stimulation devices are used for symptomatic relief only, and the use effectiveness is directly related to patient selection.

Transcutaneous electrical nerve stimulation is not effective for pain of central origin as compared to pain of peripheral origin.

Transcutaneous electrical nerve stimulation is of no curative value.

CAUTION: This device is restricted to sale and use by, or on the order of a physician.

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INTRODUCTION

The Electro-Acuscope is a complete pain management system equipped with outstanding capabilities and performance.

It was designed specifically for the clinician office or examination room. It is ideal for initial evaluation, screening of patients or clinical treatment, and post-operative pain management.

The Electro-Acuscope utilizes the finest electronic technology in transcutaneous electrical nerve stimulation. It incorporates solid state integrated circuitry to increase safe, precise, trouble-free operation. The front panel controls provide full versatility with maximum automated functions.

This manual was written to assist the clinician in using the Electro-Acuscope. The procedures are simplified and presented in outline form for convenience.

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SPECIFICATIONS Cont.

POWER REQUIREMENTS:

Power Supply 24 VDC, fully rechargeable lead-acid batteries. DC charging module with miniature coaxial power plug is supplied with instrument.

Charger Power ON LED Indicator

Hi Charge Mode LED Indicator

OTHER CHARACTERISTICS:

Included Accessories:

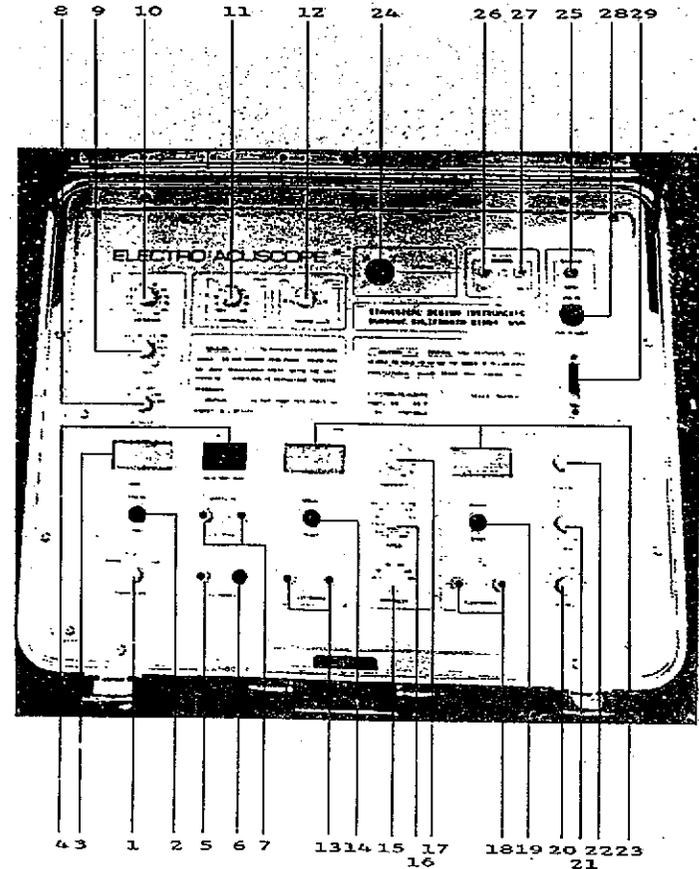
Operators Manual - Two sets placement Electrodes with leads - Two hand held remote Electrodes - Two Indifferent Electrodes - One set of four Probe Attachments - Y type Probe with 4 tips - Point Specific Probe with removable tip - Double Roller Electrode - Charging Module - Conductive Electrolyte.

DIMENSIONS:

20" long, 8" high, 16" deep,
Net weight 23 lbs.

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FRONT PANEL FUNCTIONS



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FRONT PANEL FUNCTIONS Cont.

1. Power OFF/ON Mode - 1 /ON Mode - 2
2. Mode - 1 Manual Cycle Start button
3. Mode - 1 Electrode Contact Display
4. Mode - 1 Gain Spectrum Control (Sensitivity of Display Level)
5. Mode - 1 Indifferent Electrode Output (Banana Jack)
6. Mode - 1 Control Electrode Output Jack (4pin AMP Jack)
7. Mode - 1 Remote Electrodes (Banana Jacks)
8. Mode - 1 Intensity Control (6 Positions)
9. Mode - 1 Timer Control (12 Positions)
10. Mode - 1 Frequency Control (12 Positions)
11. Mode - 1 Threshold Control Dial (For Control of Audio Response)
12. Mode - 1 Volume Control
13. Mode - 2 Ch 1 Electrode output Jacks (Banana Jacks)
14. Mode - 2 Ch 1 Manual Cycle Start button
15. Mode - 2 Ch 1 Intensity Control (6 Positions)
16. Mode - 2 Ch 1 Timer Control (12 Positions)
17. Mode - 2 Ch 1 Frequency Control (12 Positions)
18. Mode - 2 Ch 2 Electrode Output Jacks (Banana Jacks)
19. Mode - 2 Ch 2 Manual Cycle Start Button
20. Mode - 2 Ch 2 Intensity Control (6 Positions)
21. Mode - 2 Ch 2 Timer Control (12 Positions)
22. Mode - 2 Ch 2 Frequency Control (12 Positions)
23. Mode - 2 Ch 1 + 2 Intensity Level Display
24. Mode - 1 Audio Speaker
25. Charger Input Jack (Miniature Coaxial Jack)
26. On Charge LED Light
27. Hi Charge LED Light
28. Fuse (250mA Fast Blow)
29. Test signal output connector (Factory use only)

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INSTRUMENT MAINTENANCE

To insure your complete satisfaction with this instrument, please follow these simple instructions for maintaining your equipment.

If a malfunction occurs, first double check connections, electrodes and wires. If difficulty persists, communicate immediately with your local representative for technical or other assistance.

Do not leave or operate this unit in highly humid areas, such as steam room, as damage to some parts may occur. Do not spill water on the instrument.

Turn off the Electro-Acuscope after each use.

BATTERY RECHARGING

It is of utmost importance that you charge the unit when not in use. It will insure long and trouble free battery operation.

WHEN CHARGING THE BATTERIES, THE INSTRUMENT IS AUTOMATICALLY SWITCHED OFF.

A DC charger is supplied with the instrument. Plug the charger to the instrument's charger receptacle on the front panel and then to the wall outlet. Absolutely do not substitute by any other type of charging unit.

There are two LED lights on the front panel indicating the charging mode. The Charge On LED will light up and stay on during the entire charging period. The Hi Charge LED will light up only for a period of time when batteries are accepting high charging current. If any one of the LED's fails to light up after plugging in the charger, check the fuse. If bad, then replace it by 250mA Fast blow fuse. If fuse is not the problem, it may indicate a problem in the charging circuit.

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INSTRUMENT MAINTENANCE

The Hi Charge LED light will always come on after the use of the instrument. The period for which it will be On is determined by the level of discharge.

Deep discharge could result in permanent damage to the batteries.

The instrument is equipped with automatic voltage monitoring circuit, which will turn off the instrument at preset voltage level. At this point it is necessary to fully charge the batteries to prevent any damage. After shut off, the only battery power drain is by the monitoring circuit.

Do not close the top of the instrument while charging, as damage to the wires will occur, and gases escaping from the batteries are explosive in an air tight container.

If you are not certain of proper operation, please contact your local representative for further instructions or information.

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PROCEDURES

Have the patient complete a standard data collection form and carefully explore the cause of pain, previous treatments, current status with regard to activity, drug intake and pain.

Review elements of the patient's history questionnaire with the patient.

Keep in mind that for many long-term patients this modality may be the last and the best hope for pain relief. It should be given thorough and detailed evaluation.

Have the patient draw the pain areas on a form.

Have the patient rate their pain from one to ten. Ten would be the worst pain they have ever felt and one is almost no pain at all.

Determine specifics about the patient's pain: whether or not the pattern to the pain problem is worse in AM or PM, aggravated by activity, relieved by activity, constant, intermittent, sharp, burning, aching, shooting, etc.

Determine what methods and procedures patient may employ himself to help relieve the pain, such as rubbing, massaging, hot shower, etc.

Determine what activities the patient performs that aggravate the pain such as housework, stress, family tension, etc.

Ask if there is any numbness or lack of sensation associated with the pain.

Explain to the patient who is experiencing the Electro-Acuscope treatment for the first time what its purpose and function is and what reasonable expectations he may experience from it. It is important to explain the instrument in terms that will allay patient fears about its use.

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PROCEDURES Cont.

For easier explanation, can divide the procedures into four groups:

1. PATIENT PREPARATION
2. INSTRUMENT PREPARATION AND SETTINGS
3. ELECTRODE PLACEMENT
4. NOTE ON THE "PAIN GAME"

1) PATIENT PREPARATION

One of the most important aspects in the use of the Electro-Acuscope is the contact of electrode makes with the skin.

In general there are two types of electrodes which can be used with this instrument (a) placement carbon electrodes, or (b) hand-held remote control electrodes.

The carbon electrodes are electrolyte jelly activated. Use provided jelly for both electrodes before connecting electrodes to the instrument. Wash, rinse skin area thoroughly and remove excess hair where electrodes will be applied.

Blot skin area surface, leaving electrode site slightly moist.

The electrode must be applied securely to the skin surface to provide good contact between skin and electrode surfaces. This will help to avoid possible skin irritation. At any sign of irritation, a good quality lotion or cream should be applied to the affected areas, when stimulator is not in use.

When using remote control hand-held electrodes, clean with alcohol all areas to be treated. The remote control electrode is used for short term treatment, when several areas needs to be stimulated, or when selecting the proper electrode locations for optimum pain relief.

The remote control electrode assembly features a round ball applicators selectable from 2 sizes, 1/4 inch or 3/8 inch diameter. It is recommended to start with these electrodes, as it will be much simpler for you to establish the most effective locations, and also to stimulate the hard-to-getto areas.

The remote control electrode with its metal applicators are designed to be used in the Mode-1 only.

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PROCEDURES Cont.

2) INSTRUMENT PREPARATIONS AND SETTINGS

It is recommended to begin with the use of the hand held control electrode to determine the proper electrode placement and to select the best settings on the instrument for optimal pain relief. It is recommended that the following procedures be followed.

Before turning on the instrument:

- 1- Set the timer on 6 seconds. Use this setting throughout the effectiveness evaluation period.
- 2- Pulse width - frequency - start with 2Hz setting. Different patients will respond to different frequency.
- 3- Current should be set according to the area to be stimulated. In general, body areas start with 300 microamperes. When stimulating over sensitive areas start with 25 to 50 microampere setting. Current can be increased to patient tolerance.
- 4- Set volume to comfortable monitoring level. The audio tone follows the pulse frequency and varies in pitch according to the amplitude of pulse current.
- 5- The feedback threshold is an audio control in the conductance check mode. Audio turns on when preselected skin conductance has been reached. It is also used in conjunction with the gain spectrum.
- 6- The gain spectrum is a useful feature for determining the proper electrode contact. It is used with feedback threshold.
- 7- Once the optimum electrode placement is determined, and longer time stimulation is necessary, substitute the remote control electrodes for placement carbon electrodes. Turn the timer to "cont." on the front panel or to 10 or 15 minutes and trigger the treatment cycle on the front panel by pushing the manual cycle start button. Have the patient evaluate the pain at the end of treatment cycle and determine whether more stimulation is needed.

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PROCEDURES Cont.

8- Placement of the electrodes at or near the immediate painful area is usually the most suitable. If this does not produce the desired results, try placement of the electrodes over major nerve trunks in the area of the pain.

If you are using Electro-Acuscope as the only treatment modality for pain control and are not obtaining satisfactory results, consider testing all possible variables available on the ElectroAcuscope. The individual patient, may respond to different setting.

Carefully record all electrical settings and electrode locations and have the patient record the level of his pain on a daily basis as long as necessary to determine the ideal approach for the individual patient.

ELECTRODE PLACEMENT

The most desirable electrode placements are those that provide the best pain relief while maintaining a comfortable sensation with a minimum of muscle stimulation.

Place the electrode so that the sensation produced by the instrument occurs in the area of pain. This indicates that the appropriate peripheral neurons are being stimulated. Usually, this means placing the electrodes a) across the area of pain, b) over the nerves supplying the area, c) one electrode on a trigger point and the other in the referred area of pain, or d) any other combination that may produce sensation in the area of pain.

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PROCEDURES Cont.

SIX METHODS FOR ELECTRODE PLACEMENT

Method One: Place the electrodes so that the sensations produced by the instrument occurs in the area of pain. This can usually be accomplished by placing electrodes lateral to the area of pain, or one electrode proximal and the other electrode distal to the painful area.

Ask the patient if the tingling sensation exists where the pain is. Then determine if there is any place where there is pain that the tingling does not exist. Electrodes may then be supplemented to completely cover the area of pain so that tingling exists throughout the pain area.

Method Two: Place the electrodes across the nerves that supply the area of pain. Electrodes may be placed bilaterally to the target nerve or with the electrodes parallel to the neural pathway. For a causalgia in the ulnar distribution of the hand, for example, one electrode may be placed at the ulnar nerve near the elbow. The electrode polarity should be reversed, if necessary, to allow the major area of the tingling to match the pain.

Method Three: When trigger points exist*, place one electrode on the trigger area and the second electrode in the referred area of pain. When multiple trigger zones exist, both electrodes may be placed on the trigger areas.

Method Four: When the pain follows a dermatome of cutaneous innervation, the electrodes may be placed within the dermatome to allow integration to occur throughout the entire spinal of cutaneous innervation.

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PROCEDURES Cont.

Method Five: Determine the dermatome involvement by using dermatome charts indicating remaining sensibility (by Foerster). Do this by palpating both sides of the body simultaneously and note where the patient reports that one side feels different from the other. Then stimulate in the dermatome of cutaneous innervation (charts by Keegan). Stimulate on the contralateral side if the patient's pain was initially made worse by using TNS in the painful area.

Method Six: Use any other combination that may allow the patient to feel the sensation in the area of pain or that may be effective.

*) Trigger point - focus of hyperirritability in tissue that, when compressed, is locally tender and if sufficiently hypersensitive, gives rise to the referred pain and tenderness. Types include cutaneous, ligamentous and postural trigger point.

THEORY AND APPLICATIONS OF THE

ELECTRO-ACUSCOPE '35' SYSTEM

Application of Transcutaneous Nerve Stimulation:

Transcutaneous nerve stimulation is a non-invasive method of electrotherapy that employs a pulsed current biomedically designed to maximize stimulation of the large myelinated A beta neurons and minimize both muscle contraction and unmyelinated, C fiber response. When effective it provides electroanalgesia without muscle contraction and symptomatic relief of chronic intractable and acute pain syndromes.

TNS may be used clinically to mask pain so that a corrective therapy procedure previously considered too painful for the patient to tolerate may be initiated. TNS may be used to prevent the pain from destroying the effects of the therapy between the therapy sessions of a corrective program.

The theory which best describes the mechanism by which TNS controls pain is Melzack and Wall's gate control theory of pain. The theory explains the pain phenomena in terms of the sensory quality, temporal pattern, spacial organization and psychological significance of the stimulus.

Ideally, TNS provides elective stimulation of the large afferent A beta neurons. This causes hyperexcitation of interneurons in the substantia gelatinosa material which inhibits the transmission of C fiber information to the secondary afferent neurons by presynaptic inhibition.

When the spinal gating interneurons are hyperexcited due to TNS, the nerve patterns seen by the TNS may be affected for several hours after the therapy has stopped. Activity in the C fibers is presumed to exert an inhibitory influence on the spinal gating neurons which would tend to counteract the effects of TNS. TNS should be most effective in relieving pain when the pain results from loss of the normally present inhibitory influence of the afferent sensory neurons.

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THEORY and APPLICATIONS Cont.

The gate mechanism is made up of both peripheral and central mechanisms. The TNS modifies by both efferent control of sensory nerve response to physical stimuli, and by the interpretation of afferent information in terms of the meaning the stimulus has to the individual.

The physical cause of a stimulus cannot be separated from the interpretation it is given by the individual. The nervous system may become facilitated to a pattern of stimuli that are learned to be painful by the individual. The ability of TNS to relieve pain is a function of the ability of the stimulator to adequately modulate the appropriate neuron, the deep-seated psychological significance of the pain, and any psychological modulation that may exist because of the presence of the instrument.

EXPECTED RESULTS FROM THE TNS THERAPY

Skin electrodes are placed empirically over the painful area, over the nerves leading to the painful area, or on existing trigger points in the referred area of pain in such a way that the sensations caused by the caused by the ElectroAcuscope exist in the painful area. Each physician must determine the most effective electrode placement to benefit his patient's condition. In each case, a wide variety of electrode placements should be tried.

Electrotherapy produces a mild tingling sensation in the area that is described as pleasant by most persons. The sensations last only as long as the therapy sessions take place and is controlled by adjusting the controls of the instrument. The tingling sensations produced may either immediately replace the painful feeling, or relief may not be experienced for several minutes after a session. Of course, not every patient will experience 100% relief from therapy, and the amount and nature of relief will vary from patient to patient. Typically, a fifteen to thirty minute period of stimulation will provide relief for hours and in some cases days. Some individuals may obtain relief during the actual therapy session. A typical regimen would be a five to fifteen minute session of stimulation a day. The regimen that gives the best pain relief should be determined and varied according to individual requirements.

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THEORY and APPLICATIONS Cont.

The degree of success achieved with this form of therapy depends to a large extent on the patience of the doctor, testing for the most effective electrode sites.

Electro-Therapy will not interfere with the patient to experience other sensations. Proprioception, pressure, touch, and all other sensations are, for all practical purposes, unaffected. However, research has shown that the thresholds for touch sensations are slightly elevated by therapy and that increased threshold is only temporary.

Not enough is known about electrotherapy to give a definitive guide of the indications and recommended electrode placements. Remember, success or failure with electrotherapy is a function of a number of complex and ill-defined variables. The ability of the Electro-Acuscope to adequately modulate the appropriate neurons, the deep-seated psychological significance of the pain, the degree of unlearning the body must do to overcome pain, and any psychological modulation that may exist to the presence of the instrument are all factors that may affect the pain.

It should be understood that recommendation in this manual for specific electrode placement for indications are not a claim that Electro-Acuscope will be effective in the indications given and that the electrode placements suggested are not necessarily the correct ones to use. The success or failure of TNS, as is the problem of intractable pain, is a function of a large number of complex interacting variable.

Gate theory predicts that the device will be most effective when the pain results from a loss of normally present inhibitory influences of the large A beta neurons. The Electro-Acuscope is designed to maximize stimulation of this group of neurons which in turn excite interneurons in the substantia gelatinosa material that cause presynaptic inhibition of C fiber excitation of the secondary neurons.

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THEORY and APPLICATIONS Cont.

Many times a patient will describe a pain syndrome where there is a coincident loss of sensory response. He claims that a normally non-painful stimulus will aggravate the pain, whereas massaging or rubbing the area will afford some relief. The pain area may be ill-defined and the area itself may feel cold and clammy.

Gate theory predicts that the large afferent A beta neurons may not be supplying the normally present inhibitory influence to the smaller C fibers. The patient reports a loss of sensory response coincident with sensory nerve dysfunction. Stimuli that normally would excite predominantly sensory nerves, excite predominantly the smaller C fibers and pain results. Massaging the area increases the amount of sensory information present. Adequate sensory information causes enough presynaptic excitation of the C fibers to prevent excitation afferent neurons, and pain relief may result. The instrument ideally provides selective stimulation of the sensory neurons which will result in the inhibition of pain.

TNS is not the same as muscle stimulation therapy. The current use is not galvanic, faradic, or sine wave stimulation. In both modes an AC pulse is used so there will be no transfers of ions or resulting hyperemia. Muscle contraction is thereby minimized and ideally eliminated. The pulse has been biomedically engineered to provide a comfortable current for the patient.

Hyperexcitation of the SC interneurons may alter neural patterns seen by the Central Nervous System for hours after the therapy has terminated. Five to fifteen minutes of stimulation may relieve pain for hours. C fiber activity is presumed to exert an inhibitory influence on the spinal gating interneurons. The length of time that TNS can provide relief of pain is a function of the following:

- 1) The ability of the stimulator to adequately modulate the appropriate peripheral neurons, and
- 2) The amount of normally present C fiber activity. These two factors when considered in light of the psychological aspects of the pain problem will determine the amount and type of relief experienced.

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THEORY and APPLICATIONS Cont.

WAVEFORM TECHNOLOGY

Ideally, the TNS device selectively stimulates the large afferent A Beta neurons. In order to stimulate a sensory nerve as a result of TNS pulse, sufficient ions must respond to the TNS pulse so that the membrane potential of the nerve changes sufficiently to cause an action potential to occur. Ions move in response to the voltage generated by the instrument and the movement of those ions make up the current flow. Voltage and current flow and related by Ohms Law.

As the amplitude of the instrument pulse is brought from zero to threshold the first effects of the instrument can be felt as the sensory nerves respond. Sensory nerves are the most easily excited by the instrument as observed on the Electro-Myograph (EMG). As amplitude is raised to the point of discomfort, C fibers can be seen to respond on the EMG. There is no nerve response when the patient is not getting the stimulation. The correct amplitude is that which maximizes sensory nerve response while minimizing C fiber and muscle response.

The optimum frequency rate setting is that which is the most comfortable for the patient.

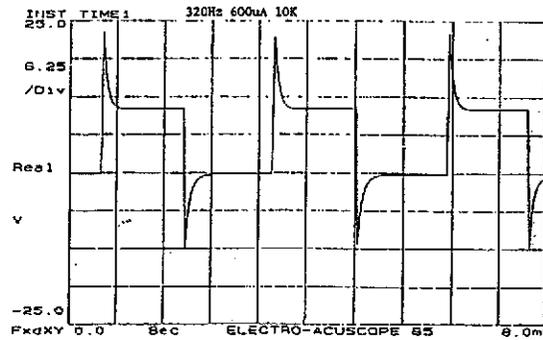
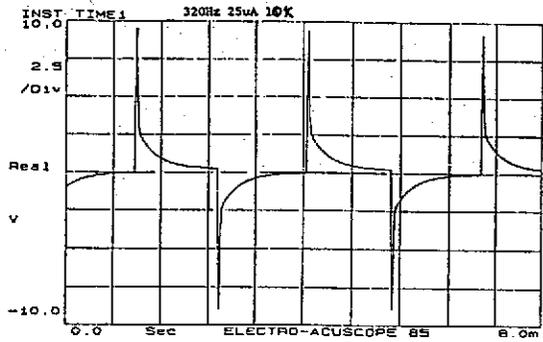
As the width control is increased, the amount of current that flows is unchanged. This means that the ions flow in response to the instrument pulse for a longer time. There is no more time for membrane potential to reach threshold levels as the ions have a longer time to respond to the instrument pulse. This will result in increased action potential in nerves farther away from the electrodes without increasing the amount of current flowing in the areas close to the electrodes. Increasing local current flow would tend to cause increase C fiber response. The effect of increasing pulse width is to feel the stimulation spread over a large area of the body as more and more action potentials are created farther and farther from the electrodes. A strength duration curve shows us that as the pulse width is increased, the change of motor response to the electrical stimulation increases.

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THEORY and APPLICATIONS Cont.

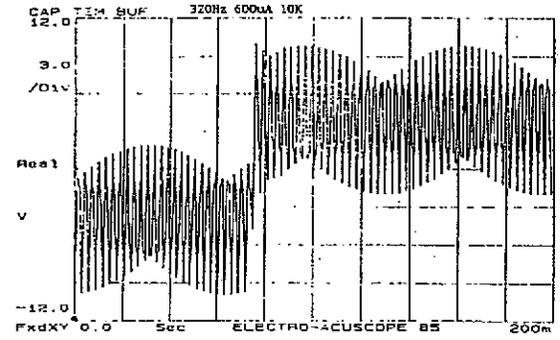
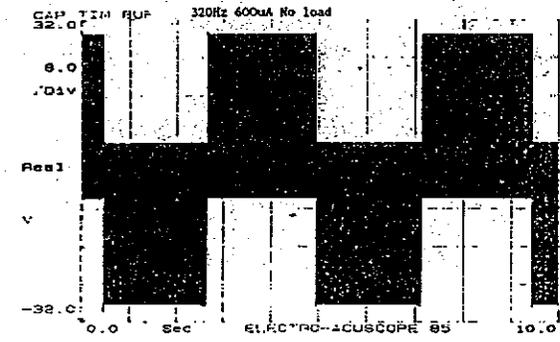
Electro-Acuscope Sample Stimulus Waveforms



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THEORY and APPLICATIONS Cont.

Electro-Acuscope Sample Stimulus Waveforms

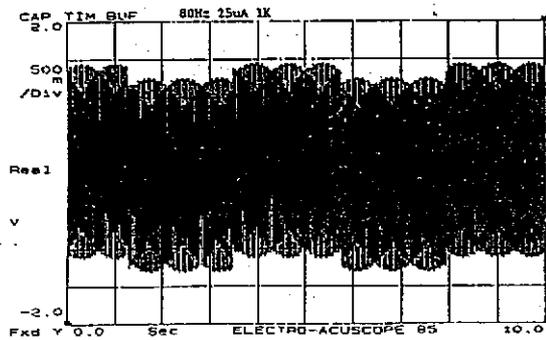
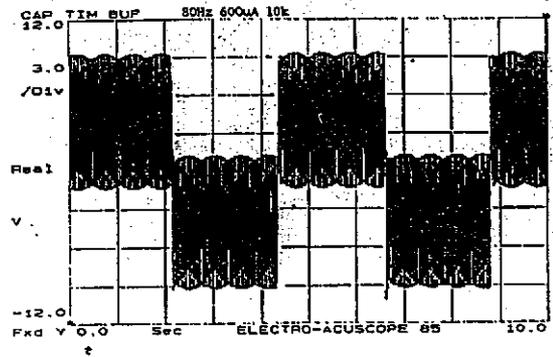


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Electro-Acuscope Sample Stimulus Waveforms

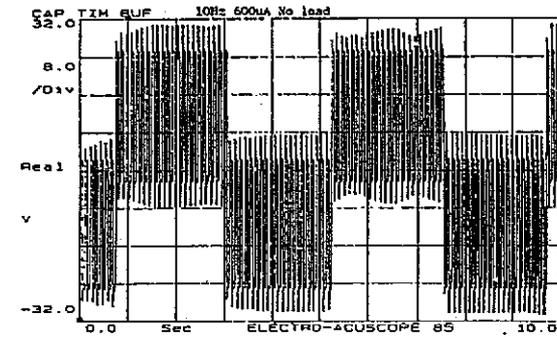
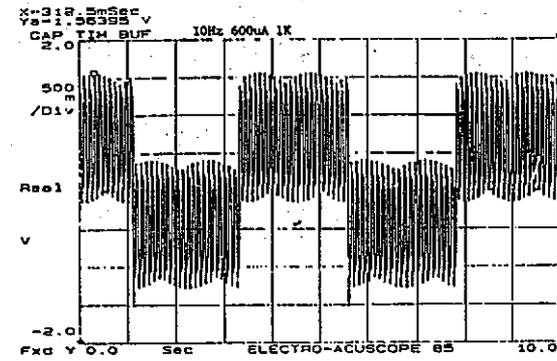


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THEORY and APPLICATIONS Cont.

Electro-Acuscope Sample Stimulus Waveforms



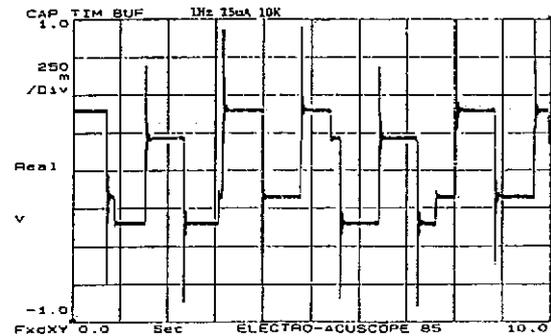
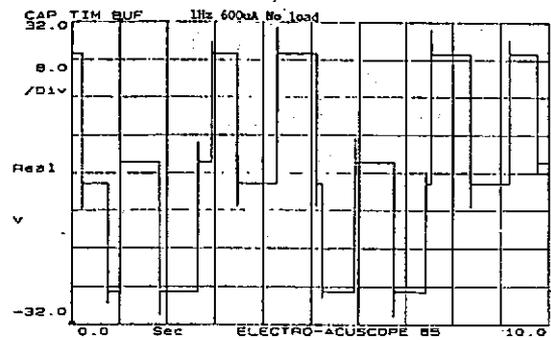
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THEORY and APPLICATIONS Cont.

Electro-Acuscope Sample Stimulus Waveforms



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STANDARD ACCESSORIES

ACCESSORIES DESCRIPTION AND USE.

There are several types of electrodes supplied with instrument. Remote control electrodes, Placement electrodes, and a Special design probes.

Remote control electrodes (Trigger electrodes) have screw on removable tips which can be changed according to application. Tips supplied are Two 1/4 inch diameter and two 3/8 inch diameter made from brass. The trigger electrodes are designed to be used in Mode One only, and due to the sizes of the tips, are for short term applications. The remote trigger switch built in the handle allows the operator to set the timer for short period, thus be able reposition electrodes frequently and activate treatment without returning to the instrument.

Trigger electrode is used with Indifferent electrode adapter (electrode without trigger switch) which also features removable screw on tips, for applications such as anterior and posterior contact on shoulder. The hand held metal bar replaces the adapter when only one electrode is used, such as in probing for a most painful area, for Placement electrode application.

The point specific probe has a 1/16 inch diameter metal tip, and is used for a hard to get areas and for applications on finger joints. It is used in conjunction with the hand held metal bar, or one placement electrode.

The hand held metal bar and the indifferent electrode attaches to the instrument via coil cord wire. The stretching capability of this wire allows the operator free movement around the patient.

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STANDARD ACCESSORIES

ACCESSORIES DESCRIPTION AND USE.

Double Roller probe has a two rollers freely spinning on its shaft, each roller being the opposite conductor. Each is 2 inch long and 1 inch in diameter. This probe makes large area application very simple. It is used in such applications as lower back pain treatment, and can be used in either mode.

It attaches to the instrument via two coiled cords.

Y Probe has its name from the position of its tips. Probe is self contained with cable and remote trigger switch. There are two sets of tips supplied with the probe. Each tip has a ball 1/2 inch in diameter. The two sets differ in shaft length, which creates different spread of the tips.

The tips are screw on, therefore easily exchangeable. As the Double Roller, each tip of the probe is the opposite conductor.

This probe is excellent for applications where a sliding motion is desired.

Placement electrodes - designed for longer term applications, can be used in both modes.

There are two types supplied with the instrument, each application depending on the operators preference.

All placement electrodes come with its removable interconnecting wires.

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WARRANTY

Biomedical Design Instruments, hereafter referred to as B.D.I. Guarantees each of its ELECTROACUSCOPE '85' Instruments to be free from all defects in workmanship and materials for a period of one year after original purchase. Repair or replacement (at factory option) will be made on any unit which is defective during this period at no charge for parts or labor.

REPLACEMENT OF BATTERIES AND OF THE ELECTRODES IS NOT INCLUDED IN THIS WARRANTY.

Defective equipment is to be returned to B.D.I. freight prepaid. Shipping costs to service center shall be borne by customer. Under this warranty, claims must be accompanied by the original sales invoice to establish date of purchase. Defects caused by shipping damage should be reported to the shipping carrier immediately. B.D.I. or its authorized agent must be also notified. Serviced equipment will be returned to the owner or user at the expense of B.D.I. or its authorized agent during the warranty period only. Goods returned by common carrier should be insured against loss or damage since such loss or damage is not covered by the B.D.I. warranty.

Damage because of misuse, neglect, fire, flood or other acts of God, or use in violation of the instructions supplied by B.D.I. or units which have been altered or repaired by other than authorized agent of B.D.I. or units having their serial numbers removed, defaced, or rendered illegible is not covered by this warranty.

All warranties implied by law, including implied warranties of merchantability and fitness, are hereby limited with respect to workmanship and parts to a period of one year (12 months) after date of original purchase and is valid only with the return of the warranty card within ten days of the purchase.

No other warranties, written or oral, are authorized by B.D.I. nor shall be binding except as expressly set forth herein.

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Burbank, California 91504

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PACKING LIST

Electro-Acuscope 85 Console	1
Remote Control Trigger Electrodes	2
Hand Held Indifferent Electrode Adapter	2
Coil Cord Lead Wire for Handle Electrodes	2
Ball Tip Attachments (Set of four)	1
Y Probe with 4 tips	1
Point Specific Probe	1
Double Roller Electrode	1
Hand Held Mass Electrode	1
Carbon Flex Electrode 2" x 2" (Pair)	2
Lead Wires for Flex Electrodes (Pair)	2
Brass Square Pad Electrodes 1" x 1" (Pair)	2
Lead Wires for Square Pad Electrodes (Pair)	2
Foam Socks for Electrode Tips (Bag of 10)	1
Foam Pads for Square Pads (Bag of 10)	1
Electrode Electrolyte Liquid	2
Charging Unit	1
Operating Manual	1

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ATTACHMENT 3

Neuro Research Group, Inc.

SPECIFICATION DOCUMENT

Title	InterX5000 Risk Assessment
Prepared by	M. Abbott
Date	September 7th, 2004

Specification #	RA1 - Launch
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4. DEFINITIONS, ACRONYMS AND ABBREVIATIONS

4.1 Glossary

Probability	The aggregate likelihood of a defined occurrence.
Risk	A combination of the probability of occurrence of harm and the severity of that harm
Hazard	A potential source of physical injury or damage to the health of people, or damage to property or the environment
Residual risk	The risk remaining after protective measures have been taken
Risk control	process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels
Severity	measure of the possible consequences of a hazard
Risk control	A process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels

4.2 Acronyms and Abbreviations

ALARP	As Low As Reasonably Practicable
BAR	Broadly Applicable Region
MDD	Medical Device Directive

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6. SAFETY ARCHITECTURE SUMMARY**6.1 Safety Architecture Overview**

The InterX5000 is a precision medical instrument used in biofeedback therapy for muscle re-education and relaxation training. The following activities have been conducted to assure the safe operation of the InterX5000:

- The system is designed to minimize the total level of energy that can be transmitted to the patient
- The system is designed to fail to a safe state in the case of any hardware failure
- The system is to be operated only by personnel that are trained and qualified for operation of the InterX5000
- The system has been certified as compliant with the medical safety requirements of IEC 60601 series standards

6.2 Safety Risk Approach

The following steps were followed in the identification of potential safety risks associated with the InterX5000:

- Analysis of potential risk due to failure of hardware components
- Analysis of potential risk due to software failures
- Analysis of potential risks due to operator use/misuse conditions
- Review of Essential Requirements from the Medical Device Directives (MDD) (results of this assessment are documented in the InterX5000 product design specification)
- Review of a safety risk list based on analyses conducted for other medical device companies
- The results of the safety risk analysis for the InterX5000 are listed in the following table.

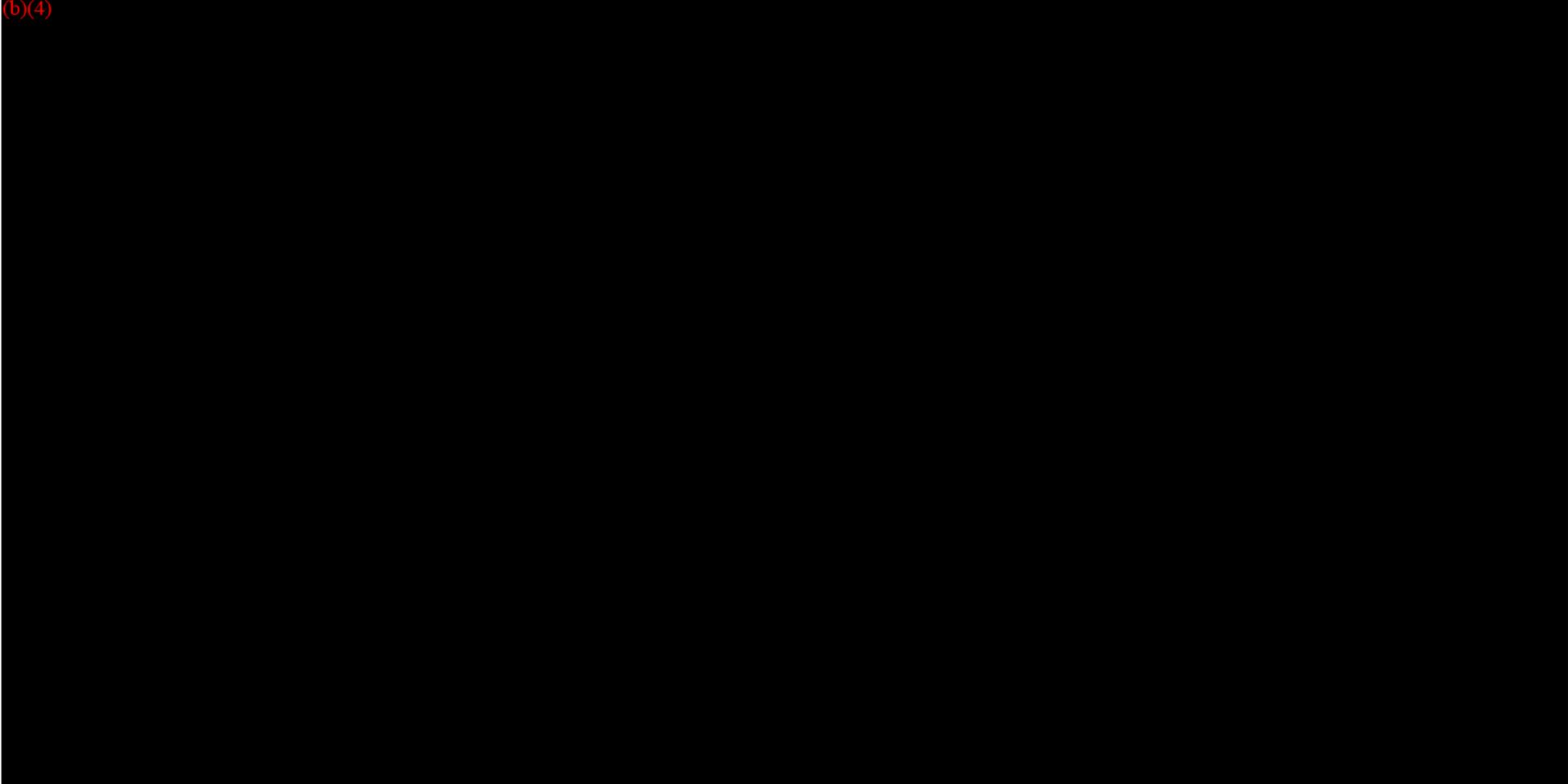
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Hazard	Clinical Effect	Severity	Initiating Causes	On	RPNa	Control/Detection Description	Req	Control/Detection Type	Of	RPNc
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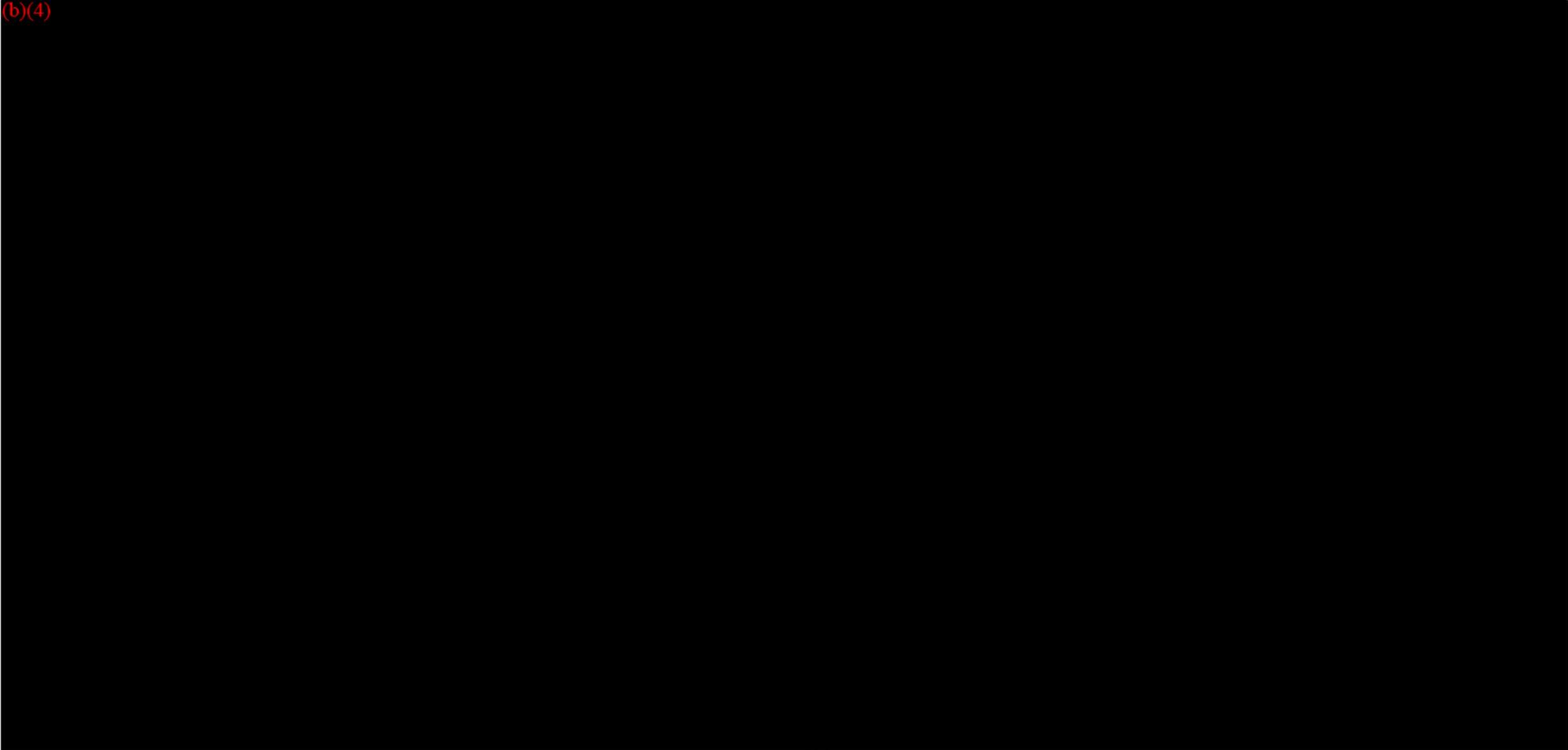
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Hazard	Clinical Effect	Severity	Initiating Causes	Qc	RPNa	Control/Detection Description	Req	Control/Detection Type	Oc	RPNe
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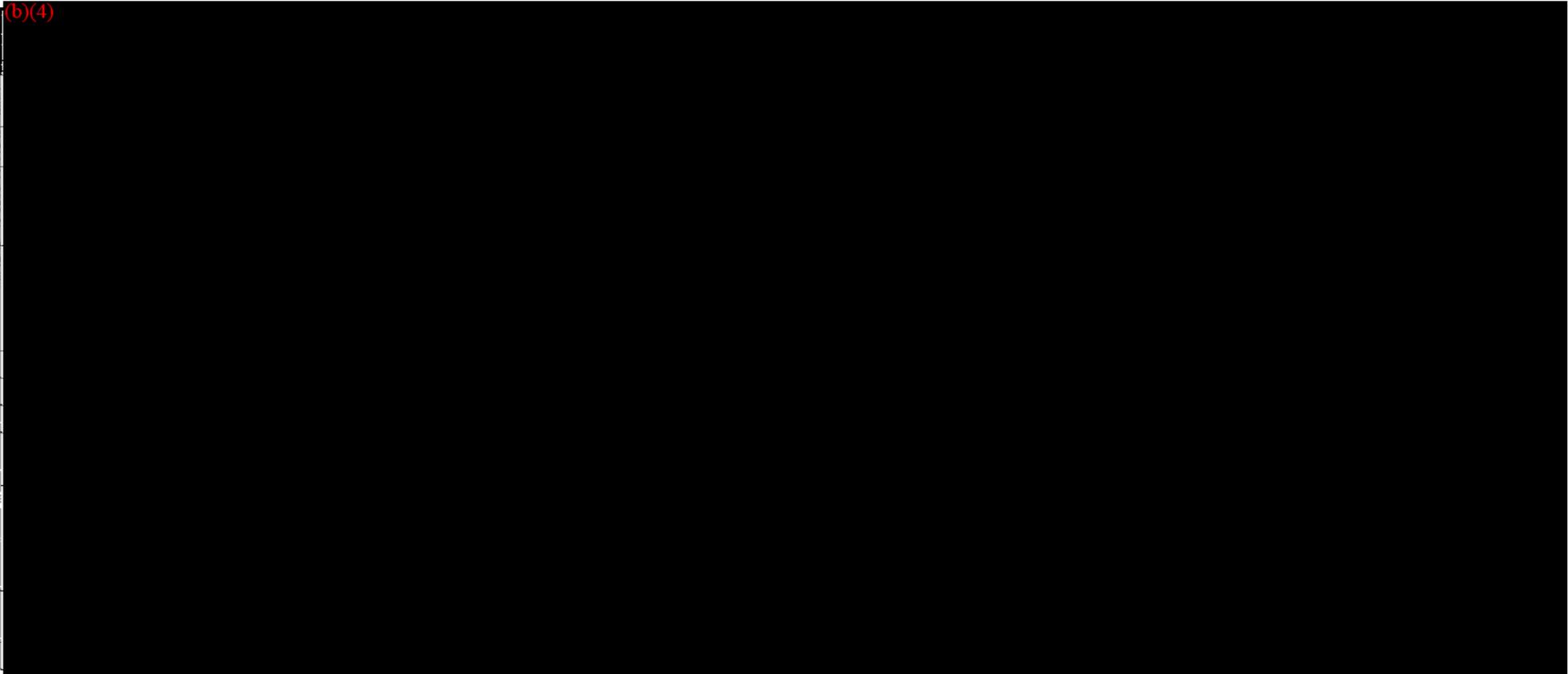
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7.3 Traceability of Safety Requirements to Verification Method

The following table traces each safety requirement to the verification method for risk mitigation:

No.	Verification Method	Safety Requirement	Ref.
1	(b)(4)		
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No.	Verification Method	Safety Requirement	Ref.
27	Labeling	Instructions for use shall indicate that electrodes shall be cleaned prior to use.	SAFE27
28	Labeling	Instructions for use shall indicate that stimulation output should be started at minimum and increased slowly to avoid unexpected pain	SAFE28
29	Labeling	Instructions for use shall indicate that the device should be kept away from children	SAFE29
30	Labeling	Instructions for use shall indicate that the device should never be used in transcerebral locations	SAFE30
31	Labeling	Instructions for use shall indicate that the device should never be used on infected or broken skin	SAFE31
33	Labeling	Instructions for use shall indicate that the device should never be used in the shower, immersed in water or with visible condensation on device	SAFE32
34	Labeling	Instructions for use shall indicate that use of device is contra-indicated for recipients with a cardiac pacemaker	SAFE33
35	Labeling	Instructions for use shall indicate that use of device is contra-indicated for recipients with cardiac arhythmias or circulatory impairment	SAFE34
36	Labeling	Instructions for use shall indicate that use of device is contra-indicated for recipients while receiving EEG or ECG monitoring	SAFE35
37	Labeling	Instructions for use shall indicate that use of device is contra-indicated for recipients prone to seizures.	SAFE36
38	Labeling	Instructions for use shall indicate that use of device is contra-indicated for recipients while driving or operating dangerous equipment	SAFE37
39	Labeling	Instructions for use shall indicate that use of device shall not be used for recipients undergoing dialysis as well as treatment in an MRI, xray, or other diagnostic machine	SAFE38
40	Labeling	Instructions for use shall state that device is not to be used in the presence of anesthetic or other flammable gases	SAFE39
41	Labeling	Instructions for use shall state that device shall only be	SAFE40

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9. REVISION HISTORY

Issue	Date	DRF No	Description
A	10/10/04	103	First Issue

K042912/AZ



NEURO RESOURCE GROUP

April 14, 2005

Document Mail Center (HFZ401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 USA
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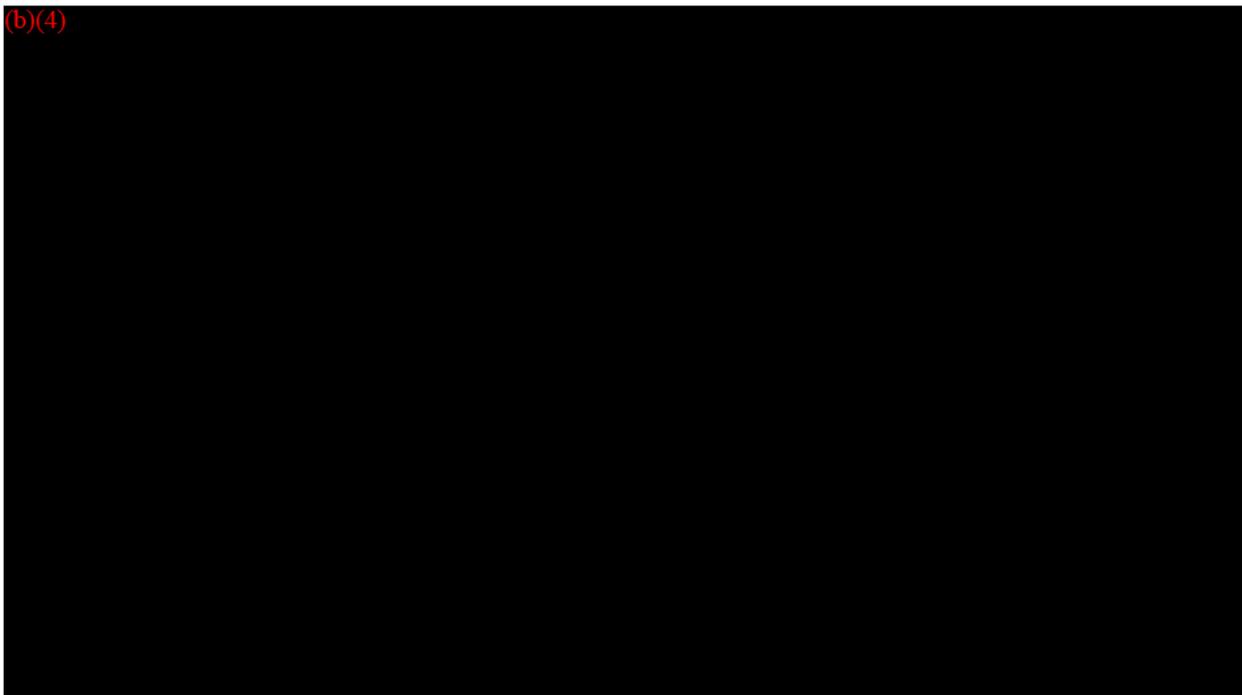
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FDA/CDRH/OCE/DID

Re: K042912 – Supplemental Information

Dear Mr. Stevens:

We appreciate the opportunity to meet with you, Miriam Provost, Heather Rosecrans, Les Weinstein, Steve Rhodes, Gladys Rodriguez, and Leslie Caster last week regarding the above-referenced submission. Based on our discussions, our firm has agreed to provide the supplemental information listed below.

1. Protocol and description of treatment application for Dr. Maale's clinical data.



JK04

1100 Jupiter Road, Suite 190 Plano, TX 75074 972-665-1810

K042912 Additional Information
April 14, 2005
Page 2 of 3

2. Revised labeling

We believe that the April 7 meeting was valuable in accurately characterizing the interactive nature of the InterX5000, and resolving previous misconceptions that this was an active function rather than a passive principle of operation. We agree with Dr. Provost's comments that some of the misconceptions may have been exacerbated by unclear labeling. As such, our firm will modify its user instructions to ensure a proper understanding of how the device operates. For example:

- (b)(4)
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-

A copy of the revised user manual draft is provided as an attachment to this letter.

3. Probe drawings

Please find attached to this letter copies of dimensional drawings of the accessory probes, as requested.

4. Maximum current density data

Our firm has re-examined the maximum current density data provided in our response dated February 15, and believes that it is the most appropriate approach to providing this information. Based on the practical application and use of our device, we believe that our approach best identifies the maximum current density based on a worst case, actual use environment, and provides appropriate context for evaluating safety. If CDRH believes that additional data is necessary, we would request a brief telephone meeting for the purpose of clarifying the additional data and the intended objectives for which this data is needed.

Also as discussed in our meeting, CDRH has agreed to review the patient lead/electrode performance standard for the purpose of clarifying any additional requirements, as our firm believes we have supplied adequate data to establish compliance with this standard. Additionally, CDRH has agreed to an approximate 30-day period to complete its review of our additional information, with earlier feedback as needed to resolve any additional deficiencies.

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Again, we appreciate having had the opportunity to discuss our submission in person, and to distill the open issues to these remaining items. We appreciate your earliest possible review and feedback to facilitate rapid progression toward an SE determination. Please do not hesitate to contact me as needed on my direct line at 972-849-5167, or via email at kristao@nrg-unlimited.com.

Regards,



Krista Oakes
Vice President, Regulatory Affairs
Neuro Resource Group, Inc.

/attachments

***The effects of the InterX 5000 on pain reduction
in the severe chronic orthopedic patient.***

Gerhard Maale, MD

Marcia Gamez, RN, CNS

Gretchen Thompson Wild, MHA, MBA

Janice Walker, OTR

Introduction

The base technology of the InterX 5000 has clinically been studied extensively in Russia, Europe and with limited use in the United States and Canada. The device, when applied to patients with acute and chronic pain has been shown to effectively reduce pain with serial treatments.^{1 2}

In addition, different site treatments have reduced pains in various areas of the body. The associated observation with serial use has been shown to increase circulation and reduce swelling in the orthopedic patient. The primary mechanism of action is thought to be through afferent C-filament stimulation of nerves breaking a pain arch. However decrease in swelling, increase in circulation, and warmth of the extremity, where the pain is secondary to orthopedic problems implicate possible autonomic nerve effects as seen in reflex sympathetic dystrophies.

The InterX 5000 is a handheld portable electrical neuro stimulator device, which provides electrical stimulation through two conductive electrodes, using skin as a conduit. The signal delivered is a damped, bi-phasic oscillatory waveform.

While the base frequency delivered is 59.3 cycles per second, the number of pulses delivered can be varied from 15 per second to 350 pulses per second. In addition, these pulses can be grouped into bursts of pulses. The power, frequency, pulse duration, pulse grouping and waveform damping can all be controlled by the user.³

For any specified user settings, the waveform shape and energy delivered to the body changes as a function of the skin and underlying tissue characteristics. There is an internal load circuit that is designed to create a sharing of the energy output between the device and the body. This interactive nature of the device is a key element to the effectiveness of the device.

The therapist applies the device to the patient's body by holding or moving the electrodes along a variety of locations. There are several techniques which must be learned by the clinician to define the optimum treatment protocol depending upon the patient's complaints and condition. The techniques are based upon an understanding of tissue differences or skin impedance. Changes in tissue impedance can be actively displayed by the InterX 5000 or identified through therapist's observations. Differences are observed as color changes and/or adherence of electrodes to the skin. This "sticky" adherence factor allows a therapist to localize and target the zone of treatment on each patient.

The treatment of severe chronic pain in orthopedic patients varies with the underlying pathologic conditions that cause it. Routinely opiates or derivatives with or without invasive technologies are used to decrease the pain. Opiates are associated with many side effects including; drug dependency, overdosing, insomnia, gastrointestinal side effects, hallucinations, and with overuse,

loss of mentation, depression of the central nervous system and often times even death. Invasive technologies such as spinal cord stimulation, sympathectomies, nerve blocks, and pumps, usually require anesthesia, with its inherent risk, to complete the procedure. If the patient requires surgical implants then the inherent additional surgical risks need also to be addressed. TENS units are currently being used by therapists, but have not been shown to be significantly more effective over placebo when addressing the chronic pain patient. There are no clinically available, "non-invasive" technologies that have been shown to be significantly effective in dealing with the chronic pain patient.

The search for other "non invasive" technologies is underway to reduce risk to patients when dealing with the chronic pain patient. The InterX 5000 has been clinically tested as a biofeedback mechanism and has no known side effects. ⁴

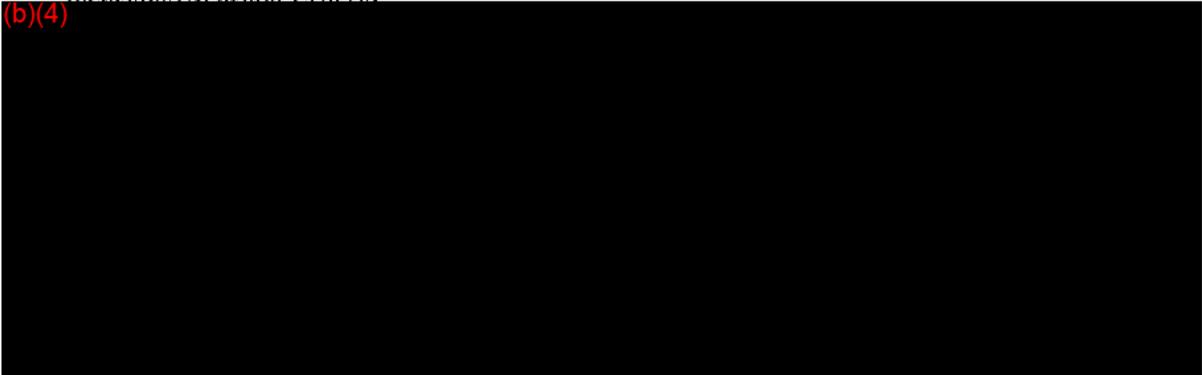
Materials and Methods (Study Protocol)

Objective:

The primary objective of the pilot study was to determine if focused short-term treatment (3 days) with the InterX 5000 would reduce pain levels, by three points or greater, on an 11-point numerical rating scale in a group of severe chronic orthopedic patients. Because of the severe chronic nature of the pain, patients actively receiving narcotics were accepted. Of secondary interest was whether or not patients would voluntarily reduce pain medication without increasing pain levels.

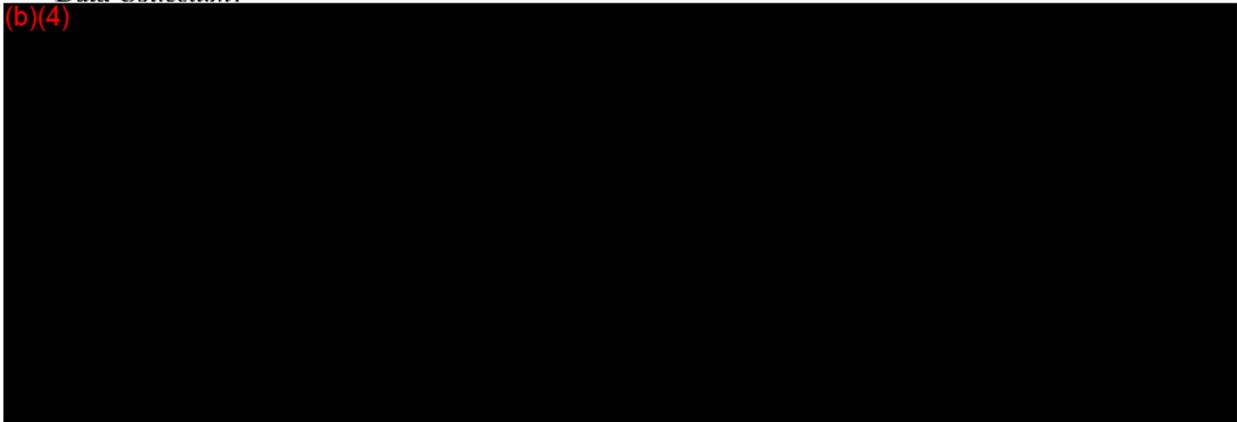
Inclusion/Exclusion Criteria:

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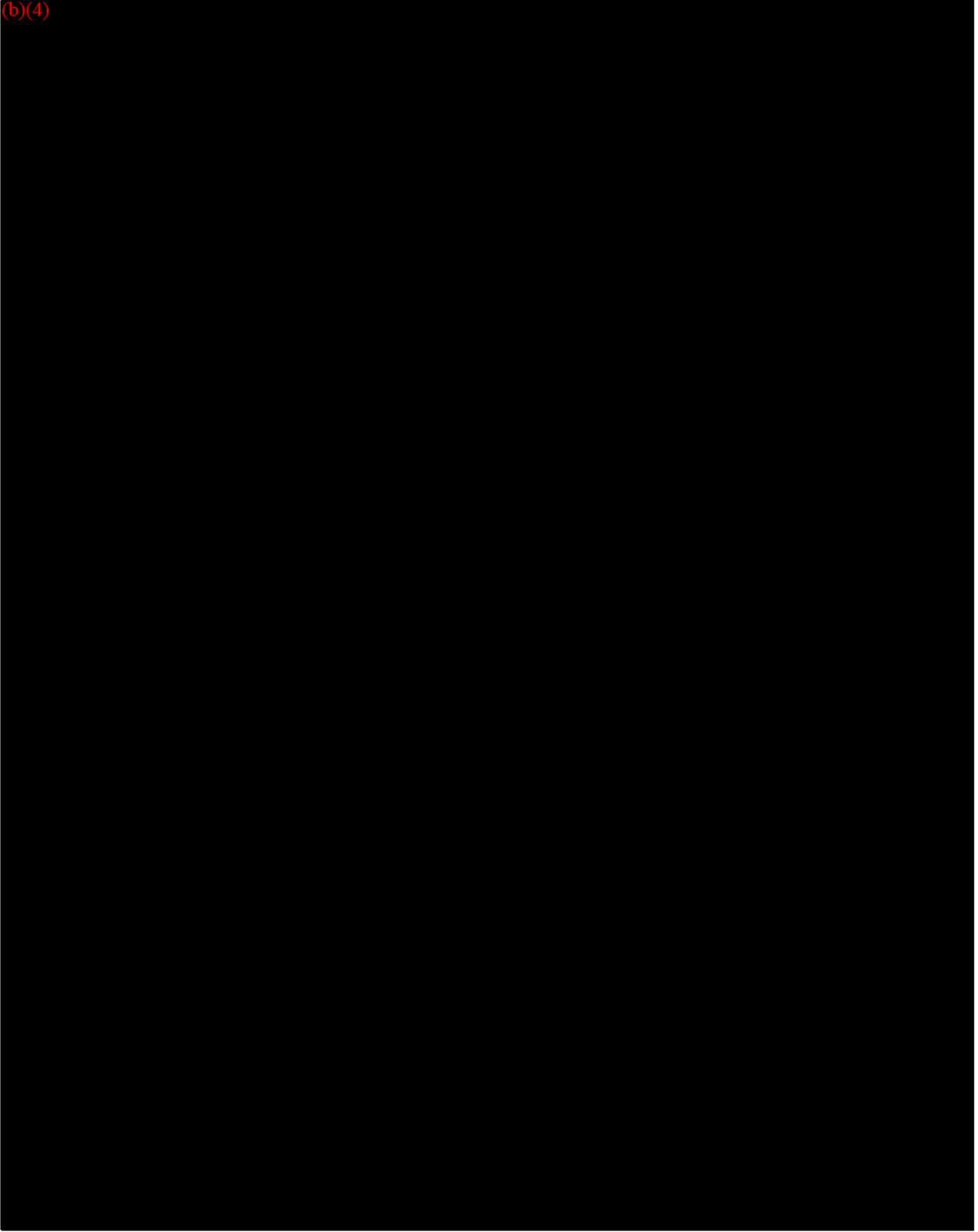
Data Collection:

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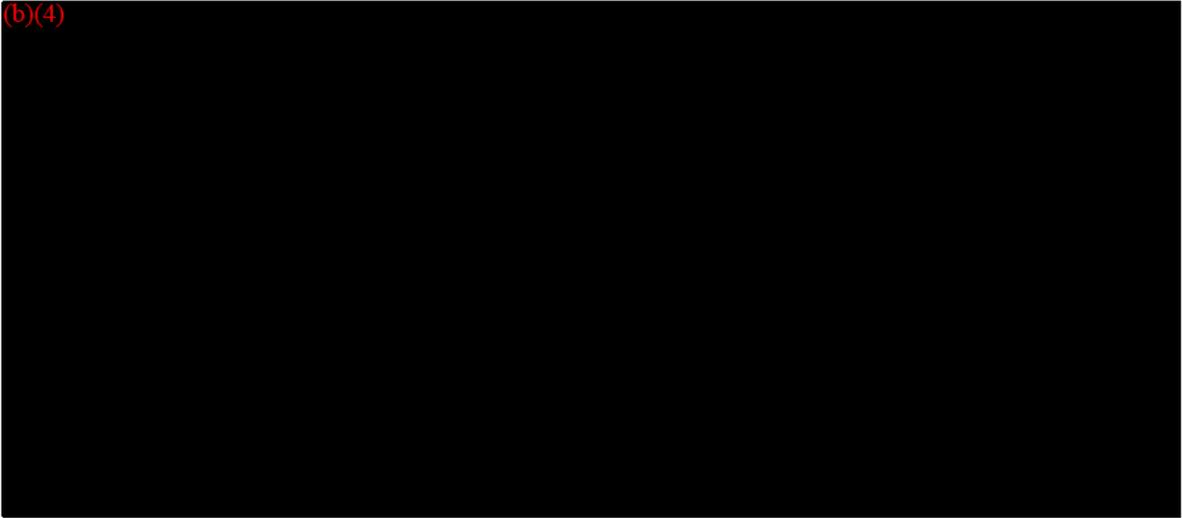
Results

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57

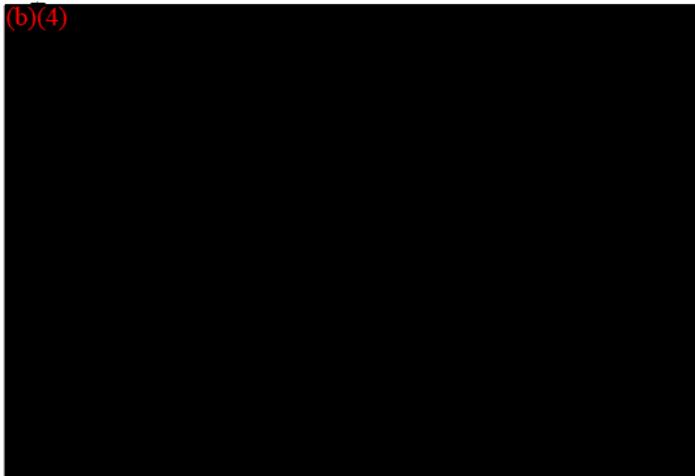
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Mean Numeric Pain Scale Readings

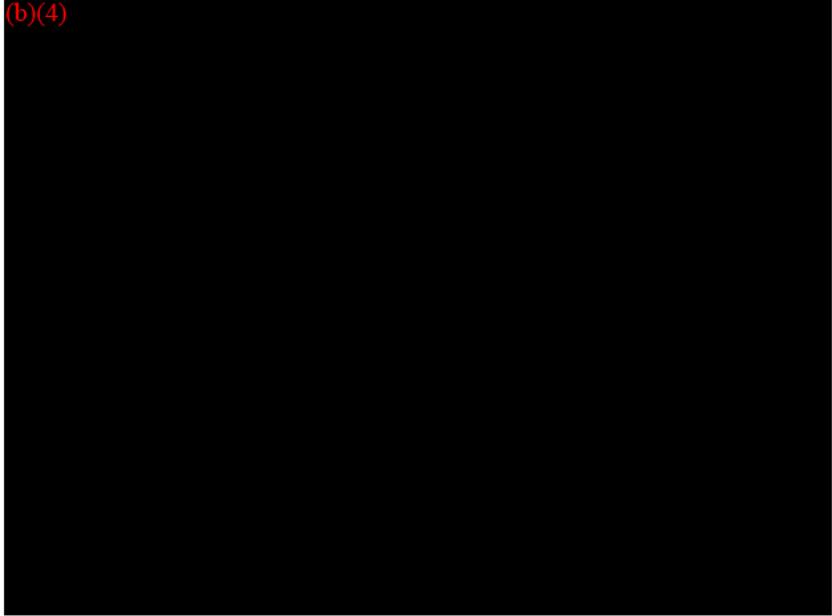
■ Pre-Treatment Score ■ Post-Treatment Score

(b)(4)



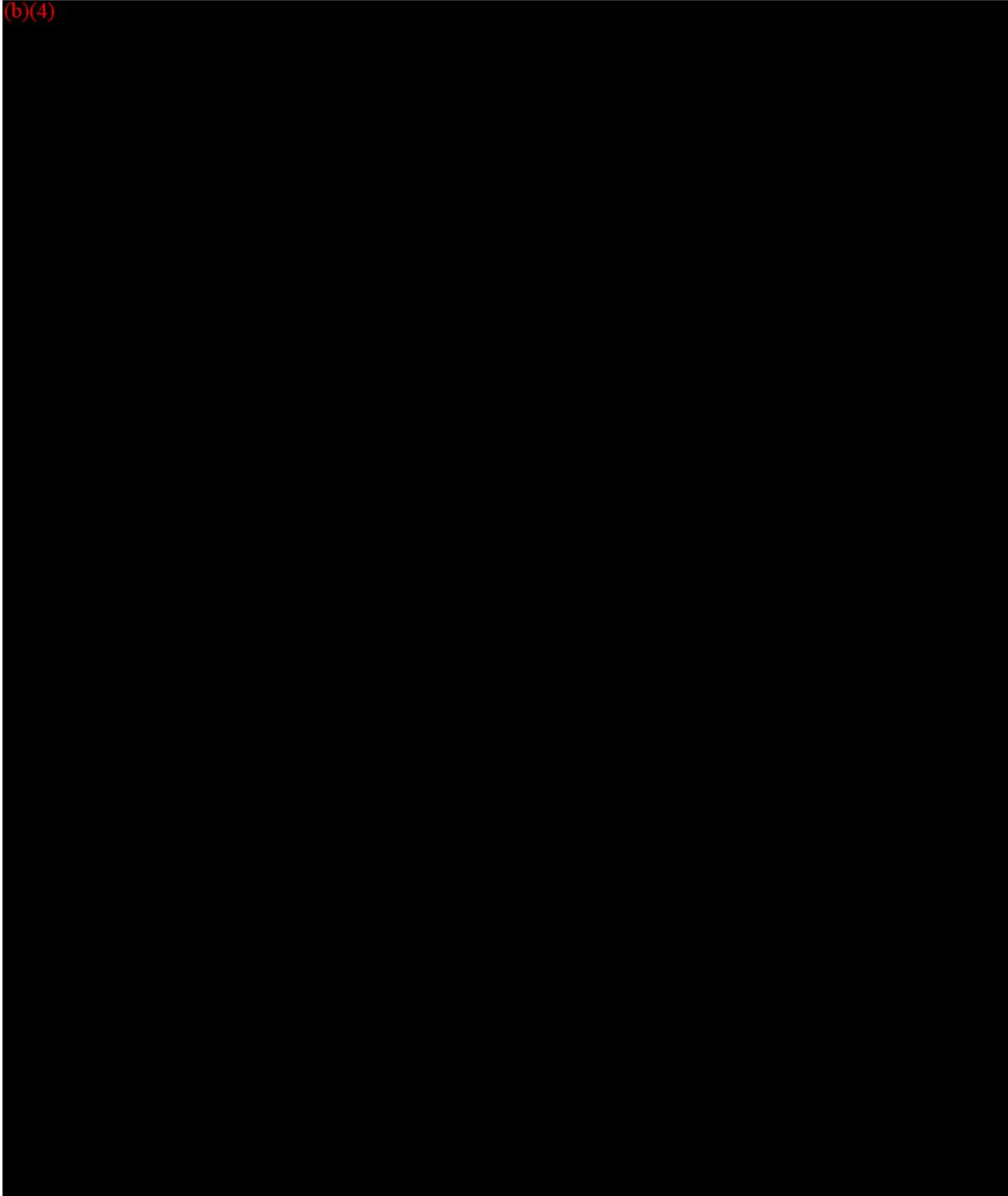
Median Numeric Pain Scale Readings

(b)(4)



Discussion

(b)(4)



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Summary

(b)(4)

Table 1: Patient Histories

Patient Number	Description	Condition
(b)(4)	(b)(4)	



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Table 2: Day 1 – Numeric Pain Scale Ratings

Patient ID #	Before Treatment			After Treatment		
	AV	PAS	Illicit	AV	PAS	Illicit
(b)(4)	(b)(4)					

Table 3: Day 2 – Numeric Pain Scale Ratings

Patient ID #	Before Treatment			After Treatment		
	AV	PAS	Illicit	AV	PAS	Illicit
(b)(4)	(b)(4)					

Table 4: Day 3 – Numeric Pain Scale Ratings

Patient ID #	Before Treatment			After Treatment		
	AV	PAS	Illicit	AV	PAS	Illicit
(b)(4)	(b)(4)					

Table 5: Overall Change in Numeric Rating Scale

(b)(4)

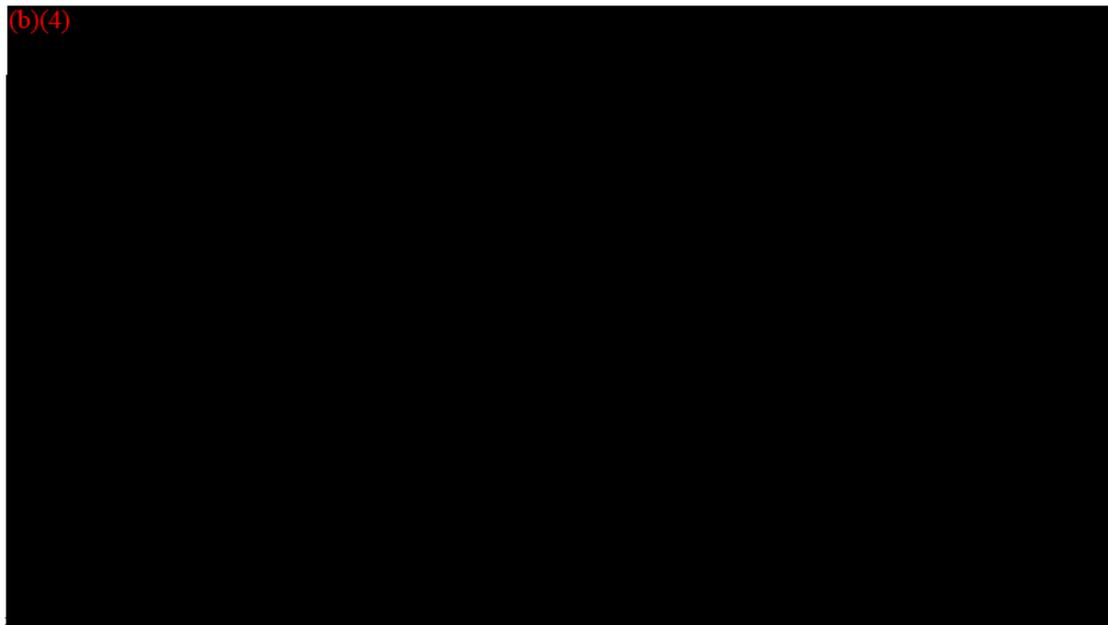


Table 6: Medication History

ID #	Before Study (Daily Intake)	Day 1	Day 2	Day 3
(b)(4)				

(b)(4)

References:

¹ Coleman, S, *Knee Injuries – InterX Therapy to Solve Unsolved Sports Injuries*, presented at the International Congress on Sports Rehabilitation and Traumatology, Bologna, Italy, 2005.

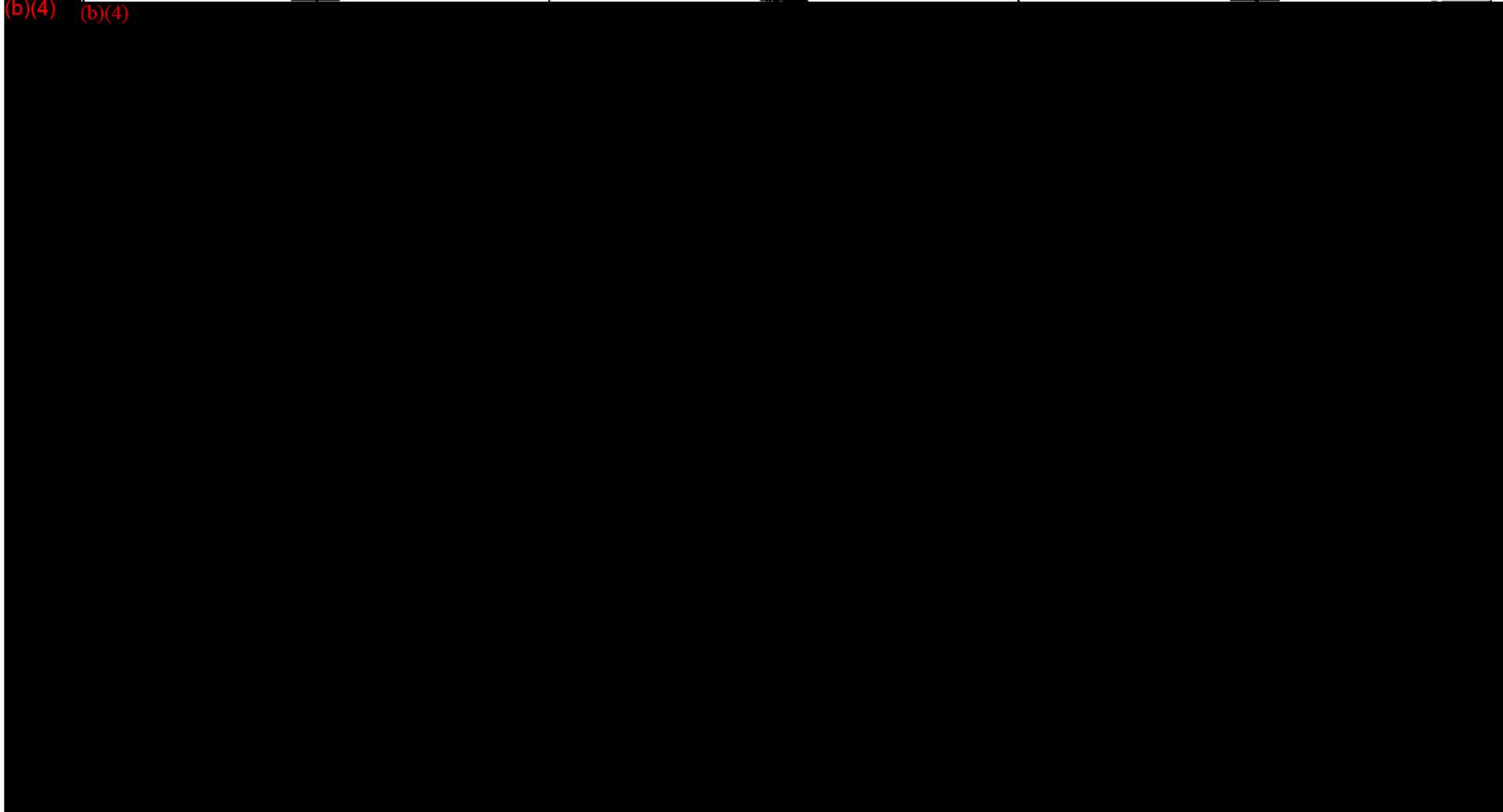
² Neuro Resource Group, Inc., *Clinical Investigation – InterX 5000 Technical File*, 2004.

³ Neuro Resource Group, Inc., *510(k) Submittal #K042912*, October 20, 2004.

⁴ OKB RITM, *SCENAR-Expertise, Issue #8* ISBN 5-8327-0011-2, 2002.

**Non-invasive Treatment for Severe Chronic Pain
Patient Specific Treatment Protocols**

Pt #	Day 1	Day 2	Day 3
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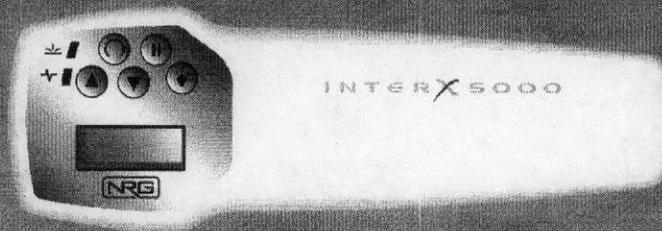


Painting: InterX 5000 may be in Diag 0 or 1. The device is moved over the area of patient complaint. Any of the various device setting can be changed individually or together to modify the waveform for increased effectiveness.

Point of Pain: InterX 5000 "IR" readings (Diag 1) are compared on and around the patient point of complaint. Based upon a defined protocol, specific points are taken to "Dose (*)" and "Zero (@)".

3 Pathways: Treatment along the spine, right and left pathway to work at and around the CNS. InterX 5000 may be in Diag 0 or 1.

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INTERX5000

Interactive Neuro Stimulation Device

European Authorized Representative and Distributor:

Neuro Resource Group, Inc.
Maple House
Bayshill Rd.
Cheltenham
GL50 3AW, UK

Manufactured by:
Neuro Resource Group, Inc.
1100 Jupiter Rd., Suite 190
Plano, TX 75074 • USA
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InterX 5000 Operations Manual

This manual provides information regarding the controls and functions of the InterX 5000. The InterX 5000 must be used strictly in accordance with these instructions. Further training is required to fully use the device and obtain optimal patient outcomes.

Warnings and Cautions

Definition – Warning: A warning message contains special safety emphasis and must be observed at all times. Failure to observe a WARNING message could result in serious personal injury.

Definition – Caution: Failure to observe a CAUTION associated with use could result in minor injury or product damage. Such problems include device malfunction, device failure, damage to the device or damage to other property

Warnings

Federal (U.S.A.) law restricts this device to sale by, or on the order of a practitioner licensed by the law of the State in which he/she practices to use, or order the use of the device.

Use and supervision of the InterX 5000 is limited to professionals who have received certified training from the manufacturer.

Federal (U.S.A.) law requires the InterX 5000 be used only by a trained healthcare practitioner or under the continued supervision of a licensed healthcare practitioner. The InterX 5000 must be used only by the person for whom it is prescribed. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner

Safe use of the InterX 5000 is the primary responsibility of the user. The user is responsible for the monitoring of the product. Contact clinical/technical support if the InterX 5000 appears to be operating incorrectly.

The user must keep this device out of reach of children.

The InterX 5000 is not effective for pain of central origin including headaches.

The InterX 5000 is symptomatic treatment and as such could suppress the sensation of pain which would otherwise serve as a protective mechanism.

The safety of the use of InterX 5000 has not been established during pregnancy or childbirth.

Do not operate the InterX 5000 before verifying that other medical devices will not be adversely affected by the electrical impulses generated.

Stimulus delivered by this device may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax or carotid sinus nerves because it may cause a cardiac arrhythmia or interfere with cardiac function.

Use caution in applying the InterX 5000 over areas which are swollen, infected, inflamed as it may result in a worsening of the symptoms. In particular, caution should be taken when electrodes are placed over areas associated with phlebitis, thrombophlebitis and varicose veins as these conditions have an increased risk of forming blood clots which could become dislodged during stimulation.

Use caution in applying the InterX 5000 to patients suspected of having heart disease.

If the display becomes blank or inoperative discontinue use.

The InterX 5000 is contraindicated for:

- Undiagnosed pain (until etiology is established)
- Electrode placement over malignant tumors
- Transcerebral and/or carotid sinus electrode placement
- Use over mucous membranes
- Patients who are prone to seizures (i.e. patients with epilepsy).
- Use over pharyngeal or laryngeal muscles, the electrical impulses generated may cause muscle spasm resulting in difficulty in breathing.
- Patients that have a demand-type cardiac pacemaker

Do not make contact with the InterX 5000 electrodes on wet skin. Natural bodily fluids, including sweat, are acceptable.

Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when InterX 5000 stimulation is in use.

Do not use on patients that are undergoing dialysis or are being treated in an MRI, X-ray, or with other diagnostic equipment that may be impacted by the electrical impulses. Remove all jewelry before treatment.

The InterX 5000 is not to be used in the presence of anesthetic or other flammable gases.

The InterX 5000 has no curative value.

Avoid placing the device on the skin when turning ON or returning from PAUSE to avoid electrical signal.

Treatments with the InterX 5000 should not exceed 1 hour in any specific area of the body and there should be a minimum of 2 hours between treatment sessions, to avoid isolated cases of skin irritation.

Skin irritation, electrode burns, dizziness, nausea, and headaches are potential adverse reactions.

Cautions

InterX 5000 should be used only with manufacturer approved electrodes and accessories. Built-in device electrodes and external electrodes should not be used in combination transcranially.

Avoid spilling fluids on the device. If the InterX 5000 is immersed in any liquid it must be replaced with a new device. This equipment has an IP rating of IPX0, ordinary equipment.

Do not sterilize the InterX 5000.

Do not expose any part of the InterX 5000 to chemical solvents or harsh cleaning fluids. Follow cleaning instructions in this manual.

Effectiveness of the InterX 5000 is highly dependent upon patient selection by a person qualified in the management of pain patients.

The InterX 5000 should not be used while driving, operating machinery, or during any activity in which may put the user at undue risk of injury.

Do not open the InterX 5000 case. Opening or removing covers may expose you to dangerous voltage or other hazards and damage operating circuits. Opening the case will void the manufacturer's warranty. If the device needs repair or service contact your distributor or an authorized service representative.

Turn main switch OFF before replacing batteries to avoid unexpected electrical signal. Only the battery cover may be removed when changing batteries. Do not attempt to connect the InterX 5000 to any other power source.

Definitions and Symbols:

Regulatory Symbols used on the device



This CE symbol certifies that the product complies with the essential requirements of the Medical Device Directive



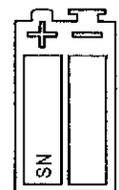
The "NRTL/C" indicator adjacent to the CSA (Canadian Standards Association) Mark signifies the product has been evaluated to the applicable ANSI/UL and CSA standards for use in the U.S. and Canada. NRTL (Nationally Recognized Testing Laboratory) is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.



This stimulator is internally powered only. The symbol indicates the device was manufactured according to the degree of protection against electrical shock for this type BF protection class equipment.



DO NOT use this device without adequate training in its function and purpose. This manual provides information regarding the controls and functions of the InterX 5000, further training is required.



The Serial Number and the manufacturing date is located on the battery label inside the battery compartment. To view label information gently press, in the direction indicated by the arrows, on the serrated area of the battery compartment to remove the battery cover, remove battery if in place and label should now be visible.

Definitions used throughout this manual

Coefficients (X and Y) – Displays the ratio of change of the body's ongoing response to the treatment. The coefficients are readings of tissue impedance visible in Diag 1 and Diag 2 mode.

Damping (Dmpf) – Damping controls the shape of the waveform generated by the InterX 5000, settings include SK1 to SK4 and VAR.

Diag – Operating modes of the InterX 5000 – Diag 0 is the InterX 5000 default or basic mode. Other modes are Diag 1 and Diag 2, any or all of the modes may be used during one InterX 5000 treatment.

Dose (*) –A signal to the operator that the rate of tissue impedance change has reduced significantly.

Frequency (F) – Frequency is the number of pulses per second measured in hertz (Hz). When Intensity is greater than one (1) the frequency is constant at 59,3Hz. Throughout the InterX 5000 Instruction Manual frequency is represented in the International manner of 59,3, which is equivalent to 59.3.

Frequency Modulation Variable – A setting of the device where the frequency is varied between 29,3 Hz to 121 Hz and the damping (Dmpf) varies through settings.

Impedance – Measure of the body's combined physical characteristics which impact its ability to absorb the energy generated by the InterX 5000.

Initial Reaction (IR) – The relative measure of the tissue impedance. High initial reaction (IR) readings, combined with patient input are an indication of where treatment with the InterX 5000 may be focused. Visible in Diag 1 and Diag 2 mode.

Intensity (Intens) – The number of pulses in a complete cycle. (For example: Frequency of 59,3Hz, is the number of impulses that occur in a second.)

Modulation (Mod) – The ratio of time that the device is sending impulses into the skin, for example a Mod setting of 3:1 indicates the device is transmitting impulses for 3 seconds and then sends no impulse for 1 second.

Nobody – Appears on the display screen when operating in Diag 1 or Diag 2 mode and the electrodes of the InterX 5000 are not in good contact with a patient's skin or when indicates a particular area of the body is outside an acceptable range for the device (either too high or too low).

Note – Highlights information that acts as a reminder or helps explain a concept or procedure

Power – The strength of the impulse on the patient's skin – the higher the setting the stronger the tingling sensation felt by the patient

Swing Variable (Sw1) – Intensity is constant at 3 pulses/cycle and the Z (pulse delay) and Dmpf (damping) are automatically varied.

Z – Delay between the peaks of each pulse in the cycle being delivered to the patient. This can only be used when the Intensity (Intens) setting is 2 or greater.

Zero (@) – A signal to the operator that the tissue impedance readings have stopped changing. Active in Diag 1 and Diag 2 mode.

******* – Indication on display screen that attribute setting is in Var.

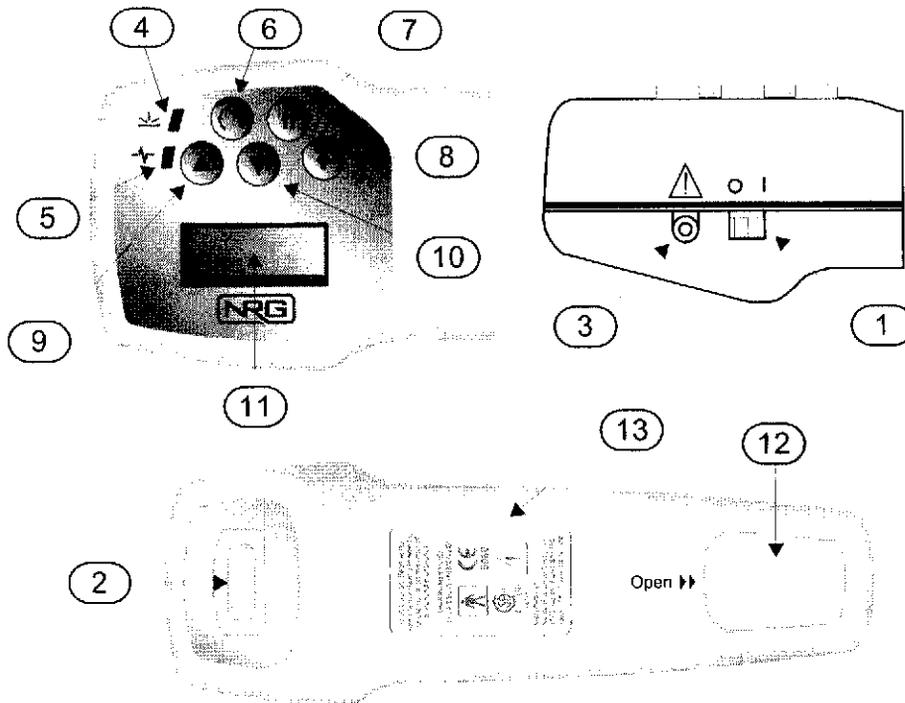


Indications for Use

The InterX 5000 is indicated for:

- Symptomatic relief and management of chronic intractable pain
- Adjunctive treatment in the management of post surgical and post traumatic pain
- Relaxing muscle spasms
- Increasing local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Preventing or retarding disuse atrophy

Overview of the InterX 5000 Controls and Functions



Item	Feature or Control	Description/Use
1.	Main Power Switch (ON/OFF Switch)	Slide the switch to the right to turn the InterX 5000 ON. Slide the switch to the left, to turn the device OFF.
2.	Built-in Electrodes	The two active electrodes that are applied to the skin.
3.	Accessory Port	Used for the attaching of accessory probes to the InterX 5000. Only manufacturer approved accessories should be used.
4.	Dose/Low Battery Indicator Light	Visual indicator of dose level. When a dose level has been achieved while operating in Diag1 or Diag 2 an amber light will appear and you will hear an audible beep. This light will blink when entering Pause if the battery is low.

Item	Feature or Control	Description/Use
5.	ON/OFF Indicator Light	Indicator that the InterX 5000 has been turned ON, a green light will glow when the device is ON. This light will blink on and off indicating the frequency of impulses being delivered, at higher frequencies it appears to be glowing continuously. The intensity of the light will increase as the energy/power delivered increases.
6.	ON/MENU SCROLL BUTTON	Button will allow the user to scroll through the various operational menus (Diag) and impulse attributes (Mod, Dmpf, Intens, Z, Freq). User may also press to resume InterX 5000 operation after it has been placed in pause.
7.	PAUSE BUTTON	Press to pause the operation of the InterX 5000. The device will retain the settings while in use prior to PAUSE. Caution should be used when returning to ON from PAUSE.
8.	SCREEN BACKLIGHT BUTTON	Press to turn display screen backlight ON. Backlight will remain on for a period of 3 seconds after the button is released.
9.	INCREASE BUTTON	Press to increase the power of the InterX 5000 and to scroll up through operational settings in the device.
10.	DECREASE BUTTON	Press to decrease the power of the InterX 5000 and to scroll down through operational settings in device.
11.	Screen	Displays the various settings and operating modes of the InterX 5000.
12.	Battery Compartment	Location for one (1) 9V alkaline battery, product serial number and manufacturer date.
13.	Product Label	States manufacturer information and regulatory cautions. Do not remove. Removal of label will void manufacturer's warranty.

Battery Operation and Replacement

The InterX 5000 operates by battery power only. Use only quality 9 Volt alkaline batteries for longer life and optimum performance of the device. The InterX 5000 is rated for continuous operation.

Low Battery Condition

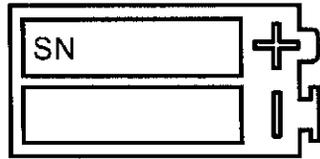
Battery life is highly dependent on how often the device is used and the specific settings that are utilized for treatments. However, under normal use (approximately 5 hours per day at varying degrees of power and with periodic use of the backlight) battery life of the device is estimated to be approximately 1 – 2 weeks.

When the battery is low the amber Dose/Low Battery light will blink when the device enters Pause and you will hear a descending audible sound. It is advisable to keep extra 9 Volt alkaline batteries in a convenient place where the InterX 5000 therapy is provided.

Replacing batteries *(see Controls and Functions Item 12)*

To replace the battery, press firmly with both thumbs on the smooth upward slope of the battery door (not the serrated area) and slide the cover away from the electrodes, towards the rear of the InterX 5000. Pull up on the battery removal ribbon to remove the old battery.

NOTE: *Please note the "locking tab" on the inside rear of the battery door. This tab will slide and lock into the molded area on the main case. To replace the battery door, gently rest the battery door flat on the main case and slide forward into the locked position. This should occur in a single sliding motion. Caution should be taken not to break the "locking tab" when replacing the battery door.*



Remove and properly dispose of old battery and replace with a new 9 Volt Alkaline battery in the orientation indicated, taking care to lay part of the battery extraction ribbon under the new battery. Securely place the battery cover back on the device by sliding it until it snaps in place. The device will not function if the battery is placed in the compartment incorrectly.

Operation Modes of the InterX 5000

There are three operating modes of the InterX 5000. A standard InterX 5000 treatment will last from 20 to 40 minutes. Electrode placement is determined by multiple factors, including patient complaint, practitioner experience, tissue response and InterX 5000 readings (Diag 1 and 2 modes only). The most desirable electrode placements are those that provide the best relief of symptoms while maintaining a comfortable sensation. Experienced practitioners often use multiple features of Diag 0 (Mod, Dmpf, Intens, Z, and Freq) and Diag 1 (Dose and Zero) during an InterX 5000 treatment.

- **Diag 0** – is the default or base mode of operation. In Diag 0 you can provide impulses to the patient, increase and decrease the power of those impulses, and change all of the attributes of the impulse signals.
- **Diag 1** – In Diag 1 you can obtain various readings relative to changes in the patient's tissue. You can also change other impulse variables with the exception of DMPF. Key treatment parameters include Dose (*) and Zero (@). Recommended Frequency (F) is 59,3Hz.
- **Diag 2** – Diag 2 operates in a similar fashion to Diag 1 with the exception that the dose (*) and zero (@) indications are arrived at simultaneously and their calculation is performed differently and faster than when operating in Diag 1 mode.

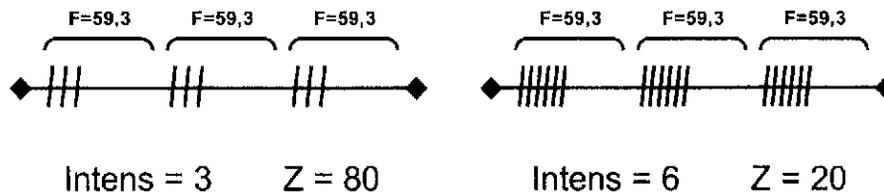
Impulse Signal Attributes

Depending on which of the above three modes the InterX 5000 is operating in you can vary some or all of the following attributes of the impulse signals being delivered by the InterX 5000:

- **Power** – Strength of the electronic impulse which can vary from a minimum of one to a maximum of 250.
Note: The comfortable level of power may vary significantly from patient to patient.
- **Mod** – Modulation is the ratio of time that the device is sending impulses into the skin to the time that there is no impulse. For example, a Mod setting of 3:1 indicates the device is transmitting impulses for 3 seconds and then no signal for 1 second.
- **Dmpf** – Damping controls the shape of the waveform of the signal generated by the InterX 5000. VAR consists of a combination of the all the damping setting (SK1, SK2, SK3, and SK4) in a cycle.
- **Intens** – Intensity is the number of pulses in each cycle being delivered to the patient.

NOTE: While operating the device in Intens 2-8 the Frequency is constant at 59,3Hz and the Mod is off.

Example of relationship between Intens and Z:



- **Z** – Delay between the peaks of each pulse in the cycle being delivered to the patient. 10 is the shortest amount of delay between pulses and 80 is the longest

NOTE: This can only be used when the Intens setting is 2 or greater.

- **Freq** – Frequency is the number of impulses per second. For example at a frequency setting of 59,3Hz the InterX 5000 would deliver 59.3 impulses per second to the patient.

Table of Attribute Default and Menu Options:

Attribute	Default	Options
Power	1	1 – 250
Diag	0	1; 2
Mod	Off	1:1; 2:1; 3:1; 4:1; 5:1; FM; Sw1
Dmpf	Off	Sk1; Sk2; Sk3; Sk4; Var
Intens	1	2; 3; 4; 5; 6; 7; 8
Z	20	10 up to 80
F	59,3Hz	15,3Hz up to 351Hz

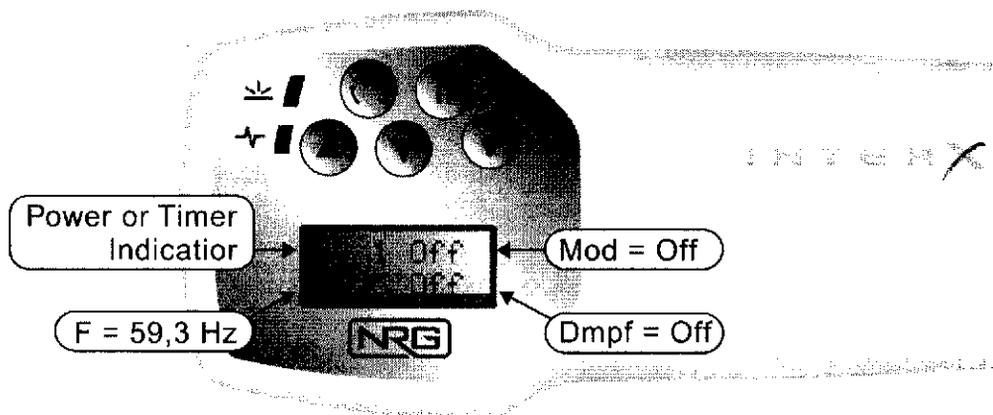
Instructions for Use

Turning ON the InterX 5000 (see Controls and Functions Item 1)

Once you have examined your patient and are ready to begin InterX 5000 therapy, turn the device to the ON position by sliding the ON/OFF switch to the right. The Green ON/OFF indicator (see Controls and Functions Item 4) will glow.

NOTE: *At low frequency levels the light will blink on and off; at higher levels it will appear to be glowing continuously.*

Upon startup the instrument goes through a short self test and then the display screen will show the current programming of the device, and a short audible beep will be heard.



The display will show the BASE SCREEN which will identify the current power setting, the current frequency, and that Mod and Dmpf attributes are OFF.

NOTE: Always confirm that the device has been returned to default settings between patients, to ensure that the device is reset from PAUSE settings press buttons UP and DOWN simultaneously.

Once the unit has been ON for 3 seconds the screen will automatically change from displaying the current power setting to displaying a time clock indicating the length of time the equipment has been ON. All other information on the screen will remain unchanged.

To return the display the Power settings press either the INCREASE or DECREASE BUTTON once.

NOTE: The power setting is changed in increments of 1 when you press either the INCREASE or DECREASE BUTTON.

NOTE: Every 30 seconds that the InterX 5000 is operating an audible beep will sound. To reset the device programming while in use, hold both the INCREASE and DECREASE BUTTON,s simultaneously for 3 seconds. When you release them you will hear a short audible beep, the device will have reset to the default settings.

To pause the operation of the InterX 5000 (see *Controls and Functions Item 7*)

To pause the operation of the InterX 5000 press the PAUSE BUTTON once.

To restart the operation of the device, press the ON/SCROLL BUTTON.

NOTE: *If the patient or the patient's programming has changed since you paused the device it is important to reset the the InterX 5000 when returning from PAUSE (see Controls and Functions Item 7). The device maintains the programming that was set when it was paused.*

To turn the InterX 5000 OFF (see *Controls and Functions Item 1*)

To turn the InterX 5000 OFF slide the ON/OFF Switch to the left.

NOTE: *If you do not press a button on the InterX 5000 for a period of 5 minutes the device will automatically go into PAUSE.*

To establish Electrode contact

When beginning treatment with the InterX 5000 ensure that the device is in default settings and that Power is set at 1. Identify area of electrode placement as directed in InterX 5000 training. Place both electrodes firmly on clean and dry patient skin.

NOTE: *To achieve best results it is recommended that the skin remain in a "natural" condition, the patient should not shower or bathe for two hours prior to and after the treatment.*

The InterX 5000 should only be used with manufacturer approved accessories/probes.

To Change Power

In the BASE SCREEN press the INCREASE or DECREASE BUTTON to set the Power from a minimum of one (1) to a maximum of 250.

Obtain a comfortable level of power by placing the electrodes on the patient's skin and slowly increasing the power until the patient tells you that they feel a tingling sensation. The patient should experience a slight tingling and vibration, but no pain as the InterX 5000 is moved on the skin.

NOTE: Refer to training manuals for indications of use at higher levels of Power to achieve desired treatment results.

If the power is increased to a level that makes the patient uncomfortable, press the DECREASE BUTTON until a more comfortable power level is obtained.

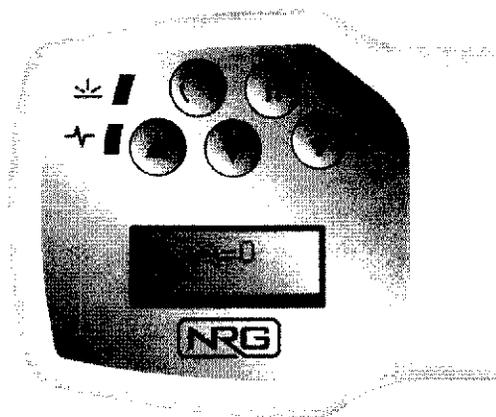
The setting of the InterX 5000 power level should always be started at a minimum level and gradually increased with patient feedback.

NOTE: The treatment power level will vary from patient to patient based upon their individual sensitivity to the electrical impulse.

Using the InterX 5000 in Diag Mode

The InterX 5000 is not intended to diagnose any medical condition. The "Diag" mode functions assist the practitioner to determine optimal electrode placement.

To Change Operation Mode (Diag)



From the BASE SCREEN press the ON/SCROLL BUTTON until the following screen appears:
Once in this screen, press INCREASE or DECREASE to set the Diag operating mode.

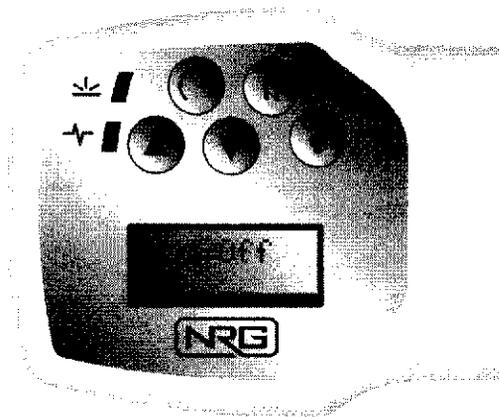
NOTE: *If you do not press the INCREASE or DECREASE BUTTON within 3 seconds of entering the DIAG SCREEN the device will revert back to the BASE SCREEN. To return to the DIAG SCREEN press the ON/SCROLL BUTTON once.*

- Diag 0 is the default operation mode. When treating a patient in Diag 0 you may change the attributes; Modulation, Damping, Intensity, and Frequency to vary the electronic output achieving different treatment results. Further training is required to fully use the device and obtain optimal attribute settings for different patient conditions.

NOTE: *The InterX 5000 will beep every 30 seconds to signal active treatment.*

- In Diag mode 1 or 2 the word NOBODY may appear on the screen. This indicates that the electrodes are not in proper contact with the patient's skin. Once you correctly apply the electrodes to the skin the screen will begin to display the impulse attribute readings.

To Change the Modulation (Mod)



From the BASE SCREEN press the ON/SCROLL BUTTON until the following screen appears:
Once in this screen, press INCREASE or DECREASE to set the Mod setting:

- 1:1 (creates impulses for 1 second and no signal for 1 second)
- 2:1 (creates impulses for 2 seconds and no signal for 1 second)

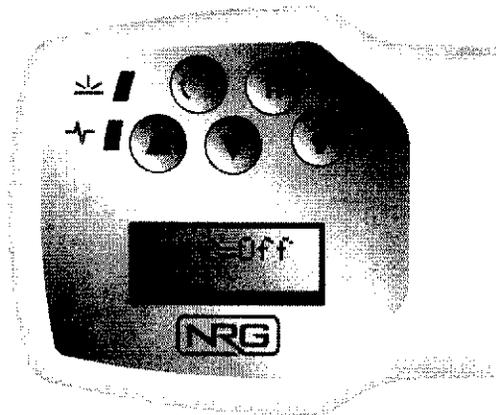
- 3:1** (creates impulses for 3 seconds and no signal for 1 second)
- 4:1** (creates impulses for 4 seconds and no signal for 1 second)
- 5:1** (creates impulses for 5 seconds and no signal for 1 second)
- FM** (frequency modulation) – this setting varies the frequency automatically between 29,3 to 121 Hz
- Sw1** (frequency swing) – Intensity is constant at 3 pulses/cycle and the Z (pulse delay) and Dmpf (damping) are automatically varied.

NOTE: *If you do not press the INCREASE or DECREASE BUTTON within 3 seconds of entering the MOD SCREEN the device will revert back to the BASE SCREEN. To return to the MOD SCREEN press the ON/SCROLL BUTTON once.*

To Change Waveform Damping (Dmpf)

You can only program damping settings when you are operating in the Diag 0 mode.

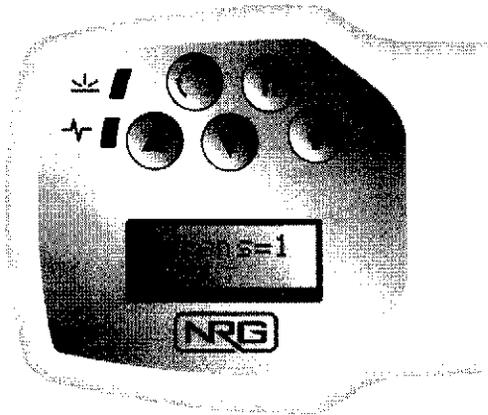
To apply damping to the impulse wave form from the BASE SCREEN press the ON BUTTON until the following screen appears:



Once in this screen, press INCREASE or DECREASE to set the Dmpf setting from SK1 – SK4. In addition, you can set the damping in VAR mode which will scroll through all 4 SK settings during each cycle, with a cycle being 2 minutes in length.

NOTE: *If you do not press the INCREASE or DECREASE BUTTON within 3 seconds of entering the Dmpf SCREEN the device will revert back to the BASE SCREEN. To return to the Dmpf SCREEN just press the ON/SCROLL BUTTON once.*

To change the Intensity (Intens)



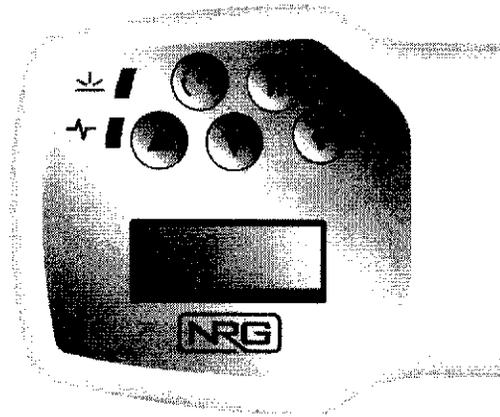
From the BASE SCREEN press the ON/SCROLL BUTTON until the following screen appears: Once in this screen, press INCREASE or DECREASE to set the Intens operating mode from 1–8 pulses/cycle.

NOTE: *If you do not press the INCREASE or DECREASE BUTTON within 3 seconds of entering the DIAG SCREEN the device will revert back to the BASE SCREEN. To return to the DIAG SCREEN press the ON/SCROLL BUTTON once*

When setting the intensity level you will hear an audible beep when you program the device at level 8 and when you decrease it back to level 1 from a higher setting (to indicate that you cannot program the device any higher or lower).

To change the Pulse Delay (Z)

To program a pulse delay (Z) you must have the InterX 5000 set at an Intensity level of 2 or greater.



To program a pulse delay into InterX 5000 from the BASE SCREEN press the ON/SCROLL BUTTON until the following screen appears:

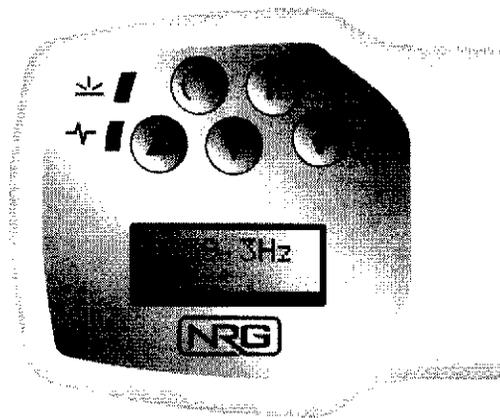
Once in this screen, press INCREASE or DECREASE to set the

Z operating mode from 10–80, with 10 being the shortest amount of delay and 80 being the longest.

NOTE: *If you do not press the INCREASE or DECREASE BUTTON within 3 seconds of entering the Z SCREEN the device will revert back to the BASE SCREEN. To return to the Z SCREEN just press the ON/SCROLL BUTTON once.*

To Change the Frequency (F)

From the BASE SCREEN press the ON/SCROLL BUTTON until the following screen appears:



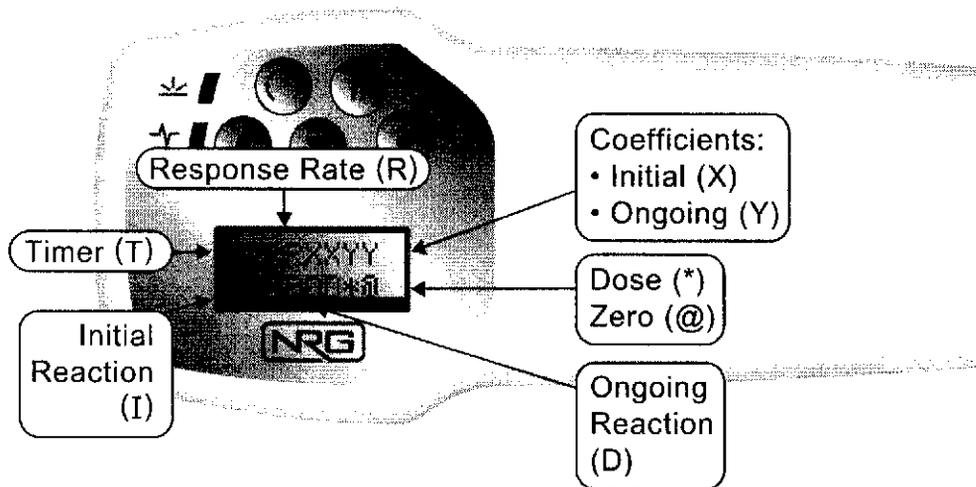
Once in this screen, press INCREASE or DECREASE to set the Frequency (F) operating mode from 15,3 Hz to 351 Hz.

NOTE: *Once you are in the Frequency Screen if you do not press a BUTTON within 3*

seconds the device will return to the base screen. To return to the Frequency Screen just press the ON/SCROLL BUTTON once.

Explanation of Diag 1 Mode

In Diag 1 and 2 Mode the InterX 5000 provides you with additional readings that relate to tissue impedance. When you place the InterX 5000 electrodes correctly on the patient's skin the screen will reflect the tissue impedance at the point of electrode placement. The display below illustrates the relative positions of each reading present on the screen in Diag 1 and 2 mode:

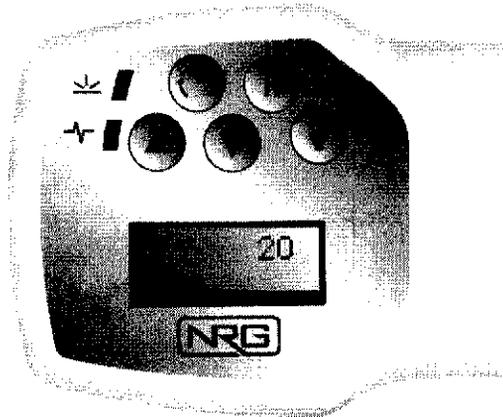


NOTE: Remember you must have the electrodes in proper contact with the patient's skin to have the screen display the above information. In Diag mode 1 or 2 the word **NOBODY** may appear on the screen. This indicates that the electrodes may not be in proper contact with the patient's skin. Once you correctly apply the electrodes to the skin the screen will begin to display the impulse attributes. On very rare occasions the word **NOBODY** can appear on the screen while the InterX 5000 has good skin contact. This indicates a particular area of the body is outside an acceptable range for the device (either too high or too low).

During the treatment in Diag 1 or Diag 2 if you do not have the electrodes on the patient's skin for a period of 30 seconds the InterX 5000 will go into pause and the screen will go blank. In Diag 0 mode the InterX 5000 will pause

and the screen will go blank after 5 minutes of inactivity. In either of these situations to turn the device back ON press the ON/SCROLL BUTTON once.

Initial Reaction (I) – A relative measure of the body's impedance. High initial reaction (IR) readings, combined with patient input are an indication of where treatment with



the InterX 5000 may be focused. The IR will change each time you remove the device from the patient's skin and then place it back on the patient's skin.

NOTE: Once the device is in Diag 1 or 2 mode,

the word NOBODY will appear. Place the electrodes firmly on the treatment area, two numbers will appear. For example, the number on the upper row reflects the X coefficient (X=20) and the number on the bottom row (I=23) reflects the IR.

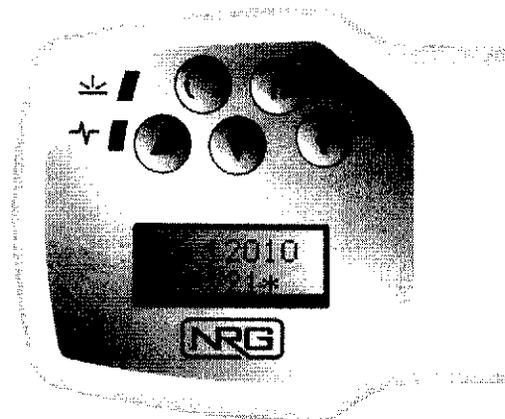
Coefficients – The two coefficients displayed are initial (X) and ongoing (Y). These indications are the ratio of change of the body's ongoing response to the treatment. The following three coefficient relationships (X:Y) can be present while giving treatment to a patient (the ratio must be calculated):

- A ratio of X:Y, where $X=Y$, indicates there is no dynamic change and the body needs more treatment at that area because it is not responding to stimulus.
- A ratio of X:Y, where $X>Y$, indicates there is low dynamic change and the body still needs attention to sufficiently respond to the treatment.

- A ratio of X:Y, where $X < Y$, indicates there is dynamic change and the body is approaching satisfactory response to the treatment.

Timer – Indicates how long the device was in contact with the patient's skin. When the treatment extends over 99 seconds, the first digit becomes an asterisk (The device will display *5 to indicate 115 seconds or 215 seconds). The length of time required to successfully achieve Dose (*) and Zero (@) are indications to the therapist that they may move to another area for further treatment. These features of the InterX 5000 enhance treatment, but do not replace therapist judgement.

Dose (*) – Indicates that the body is responding to the stimulation and the InterX 5000 is no longer recording



significant changes in the tissue. An audible sound will be heard, the amber Dose light will flash (see Features and Controls, Item 4), and an (*) will appear immediately to the right of the ongoing reading

(D). The InterX 5000 will automatically continue to treat the patient and calculate the Response Rate (R).

Response Rate (R) – Indicates how fast or slowly the tissue is responding to InterX 5000. When the tissue impedance has stopped changing, the Response Rate will register that "0" Zero (@) has been achieved.



Zero (@) – After the Dose occurs, hold the device on the treatment area until a second audible sound occurs to signal Zero (@). The (@) symbol will appear next to Dose on the display screen.

Because the body is a dynamic system, the number visible in Response Rate (R) may fluctuate after signaling “0”.

Explanation of Diag 2 Mode

The use and various readings of the InterX 5000 in Diag 2 modes is identical to its use in Diag 1 mode, with the exception that the Dose (*) and Zero (@) indications are arrived at simultaneously and their calculation is performed differently and faster than when operating in Diag 1 mode.

Description of Accessory Probes

The accessory probes plug into the accessory port of the InterX 5000 system located on the side of the device. Use care when you plug in and unplug the lead wire from the device. Jerking the lead wire instead of holding its insulated connector may cause damage. Do not attempt to plug other devices or accessories into the accessory port of the InterX 5000.

Only manufacturer approved probes may be used with the InterX 5000. All instructions in this manual apply to user placement of built-in and external electrodes. The probe package contains instructions for care and replacement of accessory probes.

Apply external electrode firmly to indicated patient treatment area. Turn ON the InterX 5000 and adjust power as described on page 23 of this manual. InterX 5000

attributes may be adjusted during use of external probes in the same manner as described while using the built-in electrodes.

General Care Instructions

Warning: Do not disassemble the InterX 5000. Dangerous voltages could be present. The InterX 5000 does not contain any user-serviceable components. If the device needs repair or service, contact your distributor or an authorized service representative.

Caution: Do not expose any part of the InterX 5000 to chemical solvents or harsh cleaning fluids. Do not sterilize or immerse the InterX 5000 in any fluid.

Storage and Cleaning

Remove the battery when storing the InterX 5000 for an extended period of time (more than one month).

Always use the carrying case to transport the InterX 5000. When not in use the InterX 5000 should be stored in its carrying case.

Clean the InterX 5000 periodically. With the main power OFF, gently wipe the surface with a damp cloth. Use mild soap and water, if necessary. Use of other cleaning solutions may damage the case. Never spray cleaners directly on the device.

The InterX 5000 is a non-critical patient contact device indicated only for contact between the electrodes and intact skin. Between patient treatments thoroughly clean the electrodes and surrounding device area with 70% isopropyl alcohol wipes.

Service and Warranty

If the InterX 5000 needs service

The InterX 5000 is not user-serviceable. Never attempt to open the case as this device contains high voltages during operation.

To obtain service, first contact NRG Customer Service at 972-665-1810, or your distributor for a Returned Goods Authorization (RGA) number. Send the entire unit, with all accessories, packed in the original carrying case, freight and insurance prepaid to the address provided to you by NRG. Include in the package a copy of your original invoice and a note describing the problem. Be sure to include your return address, phone number, fax number and/or an email address, if available.

NRG will not be responsible for damage due to improper packaging or shipment.

One-Year Limited Warranty

NRG warrants to the original purchaser that each new InterX 5000 and probe are free of defects in workmanship and materials under normal use for a period of one year from original purchase date, except for the battery and carrying case. The warranty registration card must be completed and returned to NRG to validate the warranty.

During the warranty period, NRG's sole obligation shall be, at NRG's option, to repair or replace the InterX 5000 without charge. If the InterX 5000 is outside the warranty coverage period any requested repairs or replacement charges will be invoiced to the customer.

If NRG determines there is a defect covered by this warranty, the repaired or replaced product will be shipped back, freight and insurance prepaid. If NRG determines, in its judgment,

that the product does not contain defective workmanship or materials, NRG will return the product and invoice the customer for the return freight and insurance charges.

The warranty is voided immediately if the product has been subjected to abuse, accidental damage, damage in transit, negligence, acts of nature, or damage resulting from failure to follow operating instructions, or alteration/disassembly by anyone other than NRG. Opening of the InterX 5000 case will void the warranty.

NRG shall not be liable for any direct, indirect, special, incidental, or consequential damages, lost profits or medical expenses caused by any defect, failure, malfunction, or otherwise of the product, regardless of the form in which any legal or equitable action may be brought against NRG (such as contract, negligence, or otherwise). In no event shall NRG's liability under any cause of action relating to the product exceed the purchase price of the product. Repair or replacement of the device under this warranty will not extend the original warranty time period.

Batteries and carrying cases, are excluded from the warranty and are sold as is.

Product Specifications

Size	2.5 X 7.75 X 1.5 inches; 6.5 X 20.0 X 4.0 cm
Weight	6.5 ounces; 185 grams without battery
Operating Temperature	15 – 40°C
Operating Humidity	5% - 85% relative humidity (non-condensing)
Storage Temperature	-40 - 60°C
Storage Humidity	5% - 85% relative humidity (non-condensing)
Power Source	9v DC Alkaline battery
Pulse Duration	68 – 668 ms
Pulse Frequency	15 – 350 Hz
Output Voltage Range	20 – 450 V
Output Current Range	2 - 90mA
Electrodes	Stainless Steel
Waveform	Damped bi-phasic



MAY 17 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Krista Oakes
Vice President, Regulatory Affairs
Neuro Resource Group, Inc.
1100 Jupiter Road, Suite 190
Plano, Texas 75074

Re: K042912
Trade/Device Name: InterX5000
Regulation Numbers: 21 CFR 882.5890
Regulation Names: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: April 14, 2005
Received: April 18, 2005

Dear Ms. Oakes:

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.

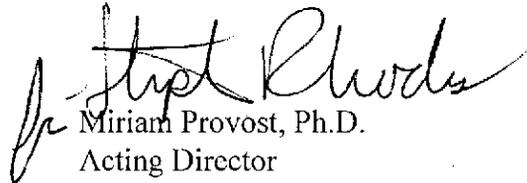
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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) 276-0120 . 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam Provost", is written over the typed name.

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) # (if known): K042912

Device Name: InterX5000

Indications for Use:

The InterX5000 is indicated for symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain.

Prescription Use x
(21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(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)


(Division Sign-Off)

**Division of General, Restorative
and Neurological Devices**

510(k) Number K042912

3

Rosecrans, Heather S.

From: Tommy Thompson [tommyt@nrg-unlimited.com]
Sent: Thursday, March 24, 2005 4:15 PM
To: hsr@cdrh.fda.gov
Subject: RE: Chronology of events re: K042912

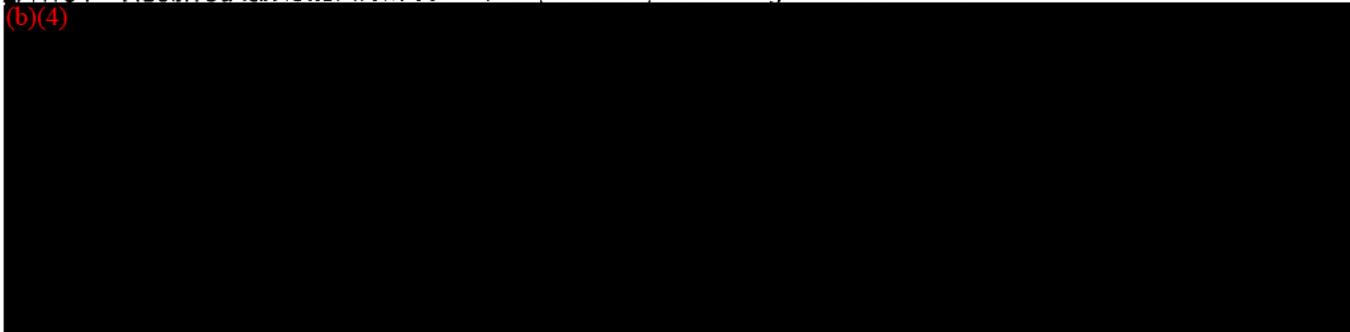
Heather - This is a brief review of our history relative to this filing. There have numerous attempts to communicate on issues although if you only considered when we had responses, it would be a much shorter list. Our file # is above.

Tommy Thompson
(972) 665-1810

10/20/04 – Submitted 510k based on FDA guidance documents and data found in recently cleared Fenzian System summary of safety & effectiveness (including comparison matrix), as well as other predicate device 510k submissions.

12/17/04 – Received fax letter from Jeff Rossi (reviewer) containing 14 issues. These included:

(b)(4)



12/17/04 – Telephone conversation with Jeff Rossi

- Jeff Rossi identified our concerns as relating to “least burdensome” and “level playing field”, and recommended that we proceed to a supervisor meeting. Recommended that we send a written request, outlining the key issues of concern.

12/17/04 – Emailed request for supervisor meeting with outlined issues of concern.

12/21/04 – Jeff Rossi attempted to set up a supervisor meeting during week of 12/21, as supervisor would be out the following week. Our company requested more time in order to provide additional background information to facilitate a constructive meeting.

12/22/04 – Jeff Rossi contacted Greg Wood to request the scheduling of a supervisor meeting after the first of the year.

1/6/05 – Followed up with Greg Wood via email to request meeting schedule. No response received to email or subsequent telephone messages.

1/10/05 – Emailed informational letter to Jeff Rossi in preparation for supervisor meeting. Letter addressed all fourteen items raised in additional information request. Mentioned having received no response from Greg Wood.

1/10/05 – Received email responses from Jeff Rossi:

- Greg Wood would contact us in the next day or so – he is very busy with post-holiday activity.
- They would not likely be able to review our entire letter prior to the supervisor meeting; please highlight specific issues/reiterate points from our original meeting request.

1/12/05 – Emailed Jeff Rossi and Greg Wood with proposed agenda and the following discussion points for which we sought agreement/resolution:

- The validity of predicate devices, including the EMPI focus, which was successfully used as a predicate to the Fenzian system without the need for clinical data
- The specificity of information necessary to reach a determination of substantial equivalence, as compared to other recent 510k submissions
- Appropriate labeling modifications to clarify the (b)(4) [REDACTED] as an alternative to redesign
- Appropriate bench data and predicate information for the accessory probes

1/12/05 – Jeff Rossi sent an email confirming that he and Ted Stevens would be able to meet with us the following week on the discussion points that we outlined.

1/12/05 – Submitted 30-day extension for submitting additional information, citing time needed to schedule supervisor meeting. Extension was granted until February 16.

1/19/05 – Telephone meeting with Jeff Rossi and Ted Stevens.

- Neither Mr. Rossi nor Mr. Stevens was well prepared to discuss the discussion points; neither had substantively reviewed the background information we provided on 1/10 (and to date, we have no information to suggest that any subsequent review of this information has ever taken place)
- Justification for differences in approach between our device and predicates was exclusively confined to speculation about what might be in the Fenzian System 510k, although neither had familiarized themselves with the Fenzian 510k in preparation for the meeting
- Our company offered to provide additional technical data regarding impedance in response to one of the questions raised
- Ted Stevens committed to conducting a review of the Fenzian System 510k and providing commentary regarding SE approach
- Other than the two actions/commitments identified, no progress was made toward resolving the issues

(The ineffectiveness of this meeting in reaching any agreement or plan was a major factor in the subsequent loss of key investors for our company.)

1/19/05 – Emailed follow-up to Jeff Rossi & Ted Stevens to confirm action items & requested estimated timeframe for completion of Ted Stevens' review of Fenzian submission. Emphasized importance of this information in order for us to prepare an adequate response by February 16th. No acknowledgement or response received.

1/28/05 – Emailed second follow-up to Ted Stevens & requested reply with estimated timeframe for completion. No acknowledgement or response received.

2/2/05 – Contacted Marjorie Schulman re: least burdensome dispute resolution guidance; she recommended contacting Les Weinstein (ombudsman). Called Les Weinstein and left a message.

2/3/05 – Les Weinstein returned call & left message; we played some phone tag; I sent an email summary of our situation.

2/4/05 – Les Weinstein called in response to email; arranged phone meeting on 2/8/05

2/4/05 – Emailed and faxed third follow-up to Ted Stevens, requesting reply with estimated timeframe for completion. No acknowledgement or response received.

2/8/05 – Telephone meeting with Les Weinstein:

- Reviewed situation.
- Mentioned Linda Kahan's request to Mark Leahey for specific examples of non-responsiveness.
- Requested assistance in obtaining response to promised action item, as time is of the essence.
- Requested assistance in pursuing "least burdensome" and "level playing field" issues, and reaching agreement on appropriate data to be submitted, so that our company would not have to go through multiple 90-day reviews.
- Les Weinstein acknowledged that the lack of response and the lack of preparation for the supervisor

meeting were "wrong", and acknowledged an appearance of inconsistency based on our description of events.

- Les Weinstein recommended attempting to resolve directly with Ted Stevens rather than going over his head at this point. Expressed a willingness to possibly involve deputy division director, if needed.
- Les Weinstein initially committed to exploring this and responding by 2/11. When I explained the 2/16 deadline for our additional information response, he agreed to try to accelerate his efforts, and invited me to follow up with him the next day.

2/9/05 – Called Les Weinstein to follow up on previous day's conversation. He had been unable to reach Ted Stevens throughout the day, and would continue to try.

2/10/05 – Les Weinstein called to report his conversation with Ted Stevens:

- Stated 'Ted Stevens' reason for no reply is that Fenzian System 510k is over 300 pages long, and he has not had time to review it.
- New plan is to have a staff member familiar with the Fenzian System 510k perform the review (no timeframe commitment). We offered to provide a focused list of questions to narrow the review effort.
- Ted Stevens did not comment that their role is not as a consultant – "But he could have."
- Les Weinstein has elected not to escalate further at this point, in the hopes of resolving at Ted Stevens' level.
- We should contact Ted Stevens regarding this review and contact Les Weinstein next week to report on progress.
- We will not likely resolve these issues in time for the 2/16 submission deadline, but Les Weinstein is willing to assist us in pursuing our concerns to help avoid another 90-day cycle before receiving feedback.
- We should send Les Weinstein another list of highlighted issues, and he will coordinate meetings with appropriate persons.

2/10/05 – Emailed Ted Stevens with focused questions & copied Les Weinstein.

2/11/05 – Received email acknowledgement from Ted Stevens, but no commitment for completion timeframe.

2/11/05 – Contacted Mark Leahey and requested contact with Linda Kahan.

2/15/05 – Linda Kahan responded to Mark Leahey to report having met with Les Weinstein; committed to having Les work with the managers to reach a resolution. Received acknowledgement from Les re: his conversation with Celia Whitten (Director of the Division of General, Restorative and Neurological Devices (DGRND)) and her intent to have an internal meeting followed by a phone conference with NRG. Les requested that we check back with him on 2/23.

2/23/05 – Followed up with Les & received reply that Celia's promotion to a new assignment had been announced, so the meeting had not happened.

2/25/05 – Sent status to Mark Leahey. Les called in the afternoon to check in and report that Celia intended to address our situation before leaving for her new assignment at the end of the following week.

3/1/05 (attempted 2/28/05) – Ayanna Hill (interim project manager) called to request 3/2 conference meeting with NRG and CDRH managers/reviewer + Les Weinstein. We requested an agenda, and also requested answers to the focused questions sent to Ted Stevens on 2/10 in advance of the meeting. Response was "We plan to discuss the predicate 510(k) and the review of your submission, to include our established policies and procedures. We are not prepared to send you answers to these questions prior to the meeting. Please follow-up with Ted Stevens to discuss when you may receive a response to your questions as listed in your 2-10-05 email."

3/1/05 – Relayed above response to Les Weinstein, who agreed to try and get some response to the focused questions prior to the telephone conference.

3/2/05 – Conference call held with NRG and CDRH (Celia Whitten, Ted Stevens, Jeff Rossi, Mark Melkersen, Les Weinstein). CDRH maintained that the InterX and Fenzian are not the same because of interactive feedback. Melkersen and Stevens both referred to SE as NOT whether new safety & effectiveness questions were involved, but rather whether the device is within the "window of predicates" that they had seen before. Rossi said that there was no technological justification for a comb probe for the indications we claim. Whitten committed to a follow-up phone call but only after the additional information had been reviewed, and she maintained the policy of allowing 60 days from the time of receipt of the official submission (not January 10, when most of the information had been

informally provided to the reviewer). Whitten refused NRG's request for an interim progress call, and would not comment on whether anything we had provided previously had been reviewed yet.

3/3/05 – Reviewed conference call with Les Weinstein. Requested pressing for expedited review considering delay due to Ted Stevens' non-responsiveness. Requested clarification of communication points. Per Les, he had briefed Linda Kahan after the phone meeting, and she decided to have a meeting with him and with Celia Whitten's successor during week of 3/7. We also discovered the Fenzian US website and forwarded this information to Les.

3/9/05 – Received call from Miriam Provost (Celia's successor), who wanted a general overview of our concerns from our perspective. She has agreed to get involved, and requested that we contact her in 1 week for feedback. Forwarded Fenzian US website link to Miriam for review.

3/16/05 – Called Miriam Provost as arranged; left voice mail message including cell phone number (to ensure callback availability at any time).

3/18/05 – No reply received yet; emailed Miriam Provost to follow up.

3/21/05 – No reply received yet; called Miriam Provost and left voice mail message including cell phone number. Received email from Miriam Provost 30 minutes later:

"I wanted to let you know that I did speak with Ted Stevens and I also looked into our files myself regarding the Fenzian device. I also reviewed the web site link that you provided. I have asked Ted to make sure that the review staff carefully compares the features of your device with the Fenzian predicate. Although this review is still underway, I can tell you that from my brief review of the 510(k) files, it is not clear that the device that is being advertised on the website is the same device that we cleared. Once we have had the chance to do a thorough review of your response and a comparison to the Fenzian predicate as described in our files, we will be in touch. Thank you and let me know if you have any questions. - Miriam"

Thanks again.

*Krista Oakes, Principal
Amica Solutions
2300 McDermott Road, # 200-207
Plano, TX 75025
Phone: 972-849-5167
Fax: 214-291-5383
E-mail: koakes@amicasolutions.com
www.amicasolutions.com
"Business-friendly" Compliance Solutions for the Medical Device Industry*

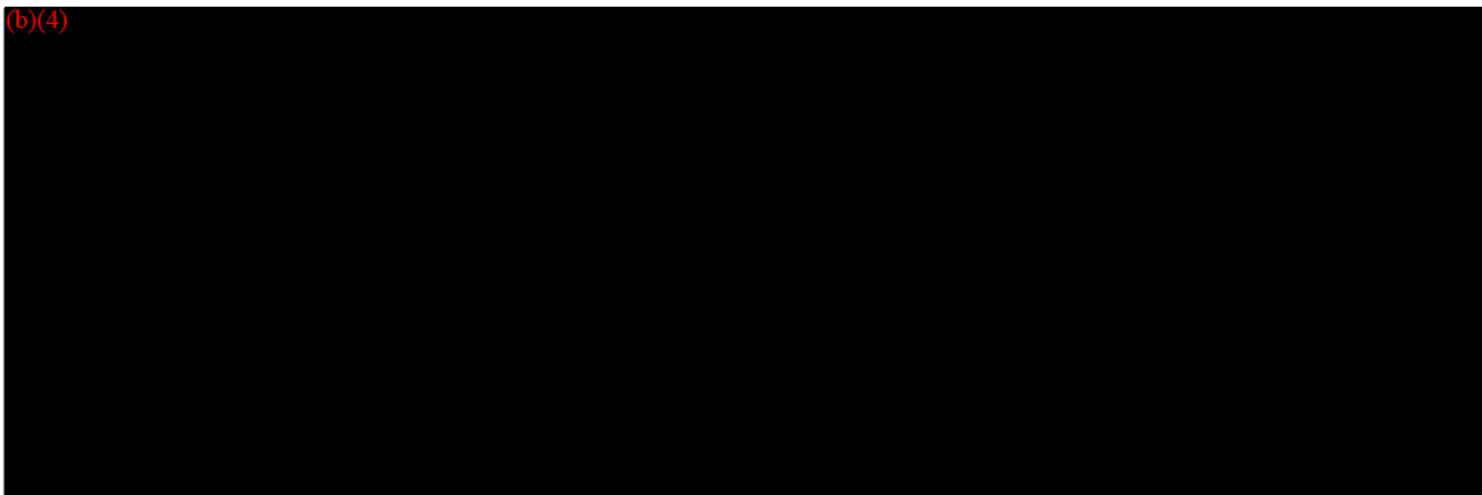
This email may contain material that is confidential and for the sole use of the intended recipient. Any review, reliance or distribution by others or forwarding without express permission is strictly prohibited. If you are not the intended recipient, please contact the sender and delete all copies.

Rosecrans, Heather S.

From: Tommy Thompson [tommyt@nrg-unlimited.com]
Sent: Thursday, March 31, 2005 8:29 PM
To: hsr@cdrh.fda.gov
Cc: john.manthei@lw.com; kristao@nrg-unlimited.com; Gretchen Wild; gmaale@sbcglobal.net
Subject: Meeting Thursday, April 7, 2005

Hello Heather - Attached to this Email is the Orthopedic Oncologist CV that set up the preliminary study on 16 of the most difficult pain patients in his practice. These patients were treated initially over a three day period and continued to be followed. The objective of the study was to determine if it is possible to bring pain relief to patients, that everything else had failed, using the InterX 5000. Furthermore, a number of the patients were asked to reduce or eliminate some or all of their multiple pain meds during and after the initial treatments. Most of these patients are continuing to be treated with an InterX 5000 at home or by an outside therapist.

(b)(4)



We look forward to this meeting and again, we appreciate your efforts in setting up this very important meeting.

Tommy Thompson
(972) 665-1810

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This e-mail and any attachments contain information from Neuro Resource Group, Inc. and are intended solely for the use of the named recipient or recipients. Any dissemination of this e-mail by anyone other

than an intended recipient is strictly prohibited. If you are not a named recipient, you are prohibited from any further viewing of the e-mail or any attachments or from making any use of the e-mail or attachments. If you believe you have received this e-mail in error, notify the sender immediately and permanently delete the e-mail, any attachments, and all copies thereof from any drives or storage media and destroy any printouts of the e-mail or attachments.

Rosecrans, Heather S.

From: Krista Oakes [koakes@amicasolutions.com]
Sent: Thursday, March 03, 2005 5:47 PM
To: Weinstein, Les S
Subject: Talking points for meeting

Les, thank you for your time again today to discuss yesterday's meeting with Tommy and me. As requested, here are some talking points that we would appreciate being brought forward during your meeting next week with Linda Kahan and Celia Whitten's successor.

1. We believe that the additional information submitted on 2/15 should receive priority/expedited review for the following reasons:

- (b)(4)

-
2. We wish to clarify the division's policies with regard to ongoing communication during the review process. In our March 2 telephone meeting, Celia Whitten offered to schedule another call after the AI review had taken place (potentially 60 days from now, absent any prioritized review). Ms. Whitten refused my request for some kind of interim phone meeting, which we are interpreting as "don't call us – we'll call you... in a couple of months". We believe there is value in interactive discussions during the review process.
 3. We wish to clarify the division's intent with regard to review timeframe, especially since the March 2 meeting did result (finally) in some specific clarifications and suggestions for additional information beyond what has already been provided. Assuming we provide this supplemental information, will CDRH start the review clock yet again when this supplement is received? Will any consideration be given to the fact that these specific suggestions could/should have been offered in either the original AI letter or at least during the supervisor meeting on January 19?
 4. We have discovered a new source of information for our predicate device (specifically, the US Fenzian website). It has information that describes the interactive feedback functioning of the device. (Until now, CDRH has insisted that the Fenzian device does not operate with interactive feedback, and this has been the basis of much of the AI request.) We feel that it would be valuable to discuss this development as soon as possible, as it may impact the course of our review. What would be our options for bringing this forward and preventing any further delay?

Krista Oakes, Principal
Amica Solutions
 2300 McDermott Road, # 200-207
 Plano, TX 75025
 Phone: 972-849-5167
 Fax: 214-291-5383
 E-mail: koakes@amicasolutions.com
 www.amicasolutions.com
 "Business-friendly" Compliance Solutions for the Medical Device Industry

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (BFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 21, 2005

NEURO RESOURCE GROUP, INC.
2220 CHEMSEARCH BLVD.
SUITE 108
IRVING, TX 75062
ATTN: KRISTA OAKES

510(k) Number: K042912
Product: INTERX5000

Extended Until: 16-FEB-2005

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

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health



NEURO RESOURCE GROUP

FDA/CDRH/ODE

JAN 12 2005 3:51

January 12, 2005

Document Mail Center (HFZ401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

Re: K042912 – Request for Time Extension

Our firm hereby requests an extension of 30 days to provide requested additional information relating to the above-referenced premarket notification. The primary reason for delay is that our firm is attempting to schedule time to speak with CDRH about our response.

Regards,

A handwritten signature in black ink, appearing to read 'K. Oakes'.

Krista Oakes
Vice President, Regulatory Affairs

cc: Jeffrey Rossi, ODE

SK-33

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

3

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 17, 2004

NEURO RESOURCE GROUP, INC.
2220 CHEMSEARCH BLVD.
SUITE 108
IRVING, TX 75062
ATTN: KRISTA OAKES

510(k) Number: K042912
Product: INTERX5000

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

October 22, 2004

NEURO RESOURCE GROUP, INC.
2220 CHEMSEARCH BLVD.
SUITE 108
IRVING, TX 75062
ATTN: KRISTA OAKES

510(k) Number: K042912
Received: 21-OCT-2004
Product: INTERX5000

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

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

October 21, 2004

Food and Drug Administration
 Center for Devices and
 Radiological Health
 Office of Device Evaluation
 Document Mail Center (HFZ-401)
 9200 Corporate Blvd.
 Rockville, Maryland 20850

NEURO RESOURCE GROUP, INC.
 2220 CHEMSEARCH BLVD.
 SUITE 108
 IRVING, TX 75062
 ATTN: KRISTA OAKES

510(k) Number: K042912
 Received: 21-OCT-2004
 Product: INTERX5000
 User Fee ID Number: 15649

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail

 Food and Drug Administration
 P.O. Box 956733
 St. Louis, MO 63195-6733.

By Private Courier (e.g., Fed Ex, UPS, etc.)

 U.S. Bank
 956733
 1005 Convention Plaza
 St. Louis, MO 63101
 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at <http://www.fda.gov/oc/mdufma>.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-free number (800)638-2041, or contact them at their Internet address <http://www.fda.gov/cdrh/dsmamain.html>, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 10/8/2004	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known) K042912
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SECTION A		TYPE OF SUBMISSION		
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (120 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Neuro Resource Group, Inc.		Establishment Registration Number (if known)	
Division Name (if applicable)		Phone Number (including area code) (972) 438-5202	
Street Address 2220 Chemsearch Blvd, Suite 108		FAX Number (including area code) ()	
City Irving	State / Province TX	ZIP/Postal Code 75062	Country USA
Contact Name Krista Oakes		Contact E-mail Address kristao@nrg-unlimited.com	
Contact Title Vice President, Regulatory Affairs			

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

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

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (<i>specify</i>):					

SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final			
<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing					
<input type="checkbox"/> Other Reason (<i>specify</i>):					

SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason (<i>specify</i>):					

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GZJ	2	IPF	3		4	
		6		7		8	

Summary of, or statement concerning, safety and effectiveness information
 510 (k) summary attached
 510 (k) statement

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K04175	1	Fenzian Treatment System	1	Eumedic
2	K951951	2	EMPI Focus 795	2	EMPI
3	K971437	3	Bionicare Stimulator System	3	Bionicare
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Transcutaneous Electrical Nerve Stimulator

	Trade or Proprietary or Model Name for This Device		Model Number
1	InterX5000	1	
2		2	
3		3	
4		4	
5		5	

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

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

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code GZJ	C.F.R. Section (if applicable) 882.5950	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Neurology		

Indications (from labeling)
 The InterX5000 is indicated for symptomatic relief and management of chronic, intractable pain, adjunctive treatment in the management of post-surgical and post-traumatic pain, relaxing muscle spasms, increasing local blood circulation, immediate post surgical stimulation of calf muscles to prevent venous thrombosis, muscle reeducation, maintaining or increasing range of motion, and preventing or retarding disuse atrophy

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

FDA Document Number (if known)

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

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

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

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

SECTION I

UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

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

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

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification Number on your check.
Completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:	
1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a . You are responsible for paying all fees associated with wire transfers. 6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.	
1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code) NEURO RESOURCE GROUP, INC. 2220 CHEMSEARCH BLVD SUITE 108 IRVING, TX 75062	2. CONTACT NAME KRISTA OAKES 2.1 E-MAIL ADDRESS kristao@nrg-unlimited.com 2.2 TELEPHONE NUMBER (Include Area Code) 972-438-5202 2.3 FACSIMILE (FAX) NUMBER (Include Area Code) 972-401-9161
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma)	
Select an application type: <input checked="" type="checkbox"/> Premarket notification (510(k)); except for third party reviews Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)	3.1 Select one of the types below: <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:	
5. 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, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005) (b)(4)	

Form FDA 3601 (08/2003)

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Appendices:

- Appendix A – Summary of Safety and Effectiveness
- Appendix B – Statement of Indications for Use
- Appendix C – Labeling
- Appendix D – Substantial Equivalence Matrix
- Appendix E – Drawings, Photos, and Schematics
- Appendix F – Performance Testing
- Appendix G – Electrical Safety/Electromagnetic Compatibility Data
- Appendix H – Software Documentation

Premarket Notification Truthful and Accurate Statement

[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as Vice President of Regulatory Affairs for Neuro Resource Group, Inc., 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.



Krista Oakes

10/20/04
Date

Device Name

Common Name(s): Transcutaneous Electrical Nerve Stimulator
Trade Name: InterX5000

Facility Information

Neuro Resource Group, Inc.
2220 Chemsearch Blvd.
Suite 108
Irving, TX 75062

This facility has not yet been registered with FDA. The facility will be registered within 30 days of initiating activities that require facility registration as per 21 CFR 807 Subpart B.

Device Classification

Classification Regulation: 882.5950
Panel: Neurology
Product Code: GZJ

510(k) Summary

This summary, required by 513(I)(3)(A) of the Act and defined by 21 CFR 807.3, is provided as Appendix A.

Reason for Submission

This is a device to be marketed for the first time in the US by Neuro Resource Group.

Performance Standards

There are no applicable performance standards for this device.

Statement of Indications for Use

This statement is provided as Appendix B.

OCT 21 2004
DMC

Executive Summary

The InterX5000 is an interactive electrostimulation device intended for:

- symptomatic relief and management of chronic, intractable pain
- adjunctive treatment in the management of post-surgical and post-traumatic pain
- relaxing muscle spasms
- increasing local blood circulation
- immediate post surgical stimulation of calf muscles to prevent venous thrombosis
- muscle reeducation
- maintaining or increasing range of motion
- preventing or retarding disuse atrophy

The InterX5000 is not life-supporting or life-sustaining.

The InterX5000 is not invasive or implanted. Materials intended for contact with intact skin are either stainless steel, or are biocompatible according to EN/ISO 10993.

The InterX5000 includes software with minor level of concern. Information regarding software verification and validation is provided in this submission.

The InterX5000 is not a sterile device.

This premarket notification includes a Summary of Safety and Effectiveness, as required per 21 CFR 807.92.

This premarket notification contains comparative data establishing substantial equivalence to the following legally-marketed devices:

- K041575 – Fenzian Treatment System
- K951951 – EMPI Focus 795
- K971437 – Bionicare Stimulator System

Product labeling bears a prescription legend per 21 CFR 801.109 and contains applicable warnings, cautions, and contraindications as recommended in relevant FDA guidance documents for TENS units.

Labeling

The InterX5000 is labeled for the indications identified in Appendix B. This device is intended to be a prescription device, with labeling in accordance with 21 CFR Section 801.109. Both the device and its labeling bear the prescription legend.

Draft labeling and copies of predicate device labeling are provided as Appendix C.

Predicate Device(s)

The predicate devices listed are indicated for the device using the flow chart in the reference document "Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program", the InterX5000 is substantially equivalent to the predicate devices listed below:

K041575 – Fenzian Treatment System
K951951 – EMPI Focus 795
K971437 – Bionicare Stimulator System

Substantial Equivalence Comparison

A comparison matrix is provided as Appendix D.

Does the Device have the same Indication Statement?

Yes. The InterX5000 is indicated for:

- symptomatic relief and management of chronic, intractable pain
- adjunctive treatment in the management of post-surgical and post-traumatic pain
- relaxing muscle spasms
- increasing local blood circulation
- immediate post surgical stimulation of calf muscles to prevent venous thrombosis
- muscle reeducation
- maintaining or increasing range of motion
- preventing or retarding disuse atrophy

These indications are consistent with defined indications for TENS units and powered muscle stimulators, and are also consistent with predicate device indications.

Does the new Device have the same Technological Characteristics?

Yes. As demonstrated in the comparison matrix, the InterX5000 has the same technical characteristics as the predicate devices.

Are Descriptive Characteristics precise enough to ensure Equivalence?

Yes. The comparison matrix establishes that the device is equivalent to predicate devices in terms of safety and effectiveness. In addition, this premarket notification refers to industry standards to which the device complies.

Are Performance Data available to assess Equivalence?

Yes. Performance bench testing was performed to demonstrate product equivalence to published predicate device performance data.

Performance Data Demonstrate Equivalence?

Yes. The performance data provided in Appendix F and the comparison matrix provided in Appendix D establish the equivalence of the InterX5000 to the stated predicate devices.

Substantial Equivalence Determination

The conclusion of this premarket notification is that the InterX5000 is substantially equivalent to the stated predicate devices.

Product Description

Product drawings, schematics, and photographs are provided as Appendix E.

General/Functional Characteristics

InterX means "Interactive". InterX technology is designed to work by introducing very brief pulses of electricity into the tissue and immediately monitoring impedance changes as the tissue responds. Stimulation and sensing take place via a concentric electrode system that is moved over the skin surface, and a digital display enables the operator to follow the course of the treatments and adjust the output.

The InterX 5000 consists of a small handheld device in a plastic case. It is powered by one nine-volt alkaline battery. On the upper face of the machine there are two LED's, an LCD display and 5 control buttons. The underside of the machine contains two metal surfaces that form the poles of a treatment electrode. The electrodes are placed directly on the unbroken skin and do not use any conductive material or gel.

On the side of the machine is one socket for a standard 3.5mm stereo jack socket that connects to the main electrodes of the machine to an optional external electrode accessory. The device's electrodes are disabled when the optional external electrode accessory is attached. The optional external electrode accessories only serve as an extension and allow the user to apply treatment in areas which may not be accessible by the main unit electrodes. None of the three electrode accessories intended for use with the InterX 5000 have any active electrical components.

The waveform is a high amplitude, short-duration bi-polar pulse (circuitry in the device integrates time and dosage delivered). A digital display monitors the biofeedback process in relation to the starting point, enabling the operator to track changes in the tissues being treated and make appropriate adjustments to the output characteristics if necessary. This interaction and human adjustment continues throughout the length of the InterX treatment. The result is that the body experiences a conditioned training process that enhances the body's ability to effectively reduce and manage the level of pain.

The InterX 5000 is designed to continuously modify its output as the device encounters changes in tissue properties. The device emits a damped, bi-phasic small electrical pulse which changes damping shape and amplitude as it encounters differing tissue impedance.

The device provides the option to the user to choose variations of waveform. In addition, the device has:

- Pulsing ability with on: off ratios available from 1:1 to 5:1
- Variable frequency choices from 15Hz to 351Hz
- The grouping of multiple pulses can be made to output pulses in bursts of 2 to 8 pulses.
- When pulses have been grouped together in bursts, there is the choice to be able to vary the time between the consecutive pulse peaks between 200 – 1600 microseconds.
- Two multiple sweeping modes:
 - FM: continually sweeps through a range of frequencies from 29-121Hz
 - SW: continually sweeps through the range of distance between groups of three peaks (Z), while the peaks are continually changing between the five available waveforms.

Controls

In addition to a separate on/off switch, there are five buttons for the user to control the device. They are:

Screen Backlight BUTTON

Pressing this button turns on a display screen backlight. The backlight will remain on for a period of 3 seconds after the button is released.

ON/MENU SCROLL BUTTON

Pressing this button will allow the user to scroll through the various operational menus and impulse attributes. The user may also press to resume InterX 5000 operation after it has been placed in pause.

INCREASE BUTTON:

Pressing this button increases the power of the InterX 5000 and scrolls the device up through its operational settings.

DECREASE BUTTON:

Pressing this button decreases the power of the InterX 5000 and scrolls the device down through its operational settings.

PAUSE BUTTON:

Pressing this button pauses the operation of the InterX 5000

Accessory Electrodes (Probes)

Currently there are three approved designs of optional electrode accessories. The optional external electrode accessory only serves as an extension and allows the user to apply treatment in a variety of areas on the body which may not be accessible with the device electrodes. None of the three electrode accessories which are approved for use with the InterX 5000 have any active electrical components. None of the accessory electrodes use any conductive material or gel.

The three approved accessories are:

Comb Probe

This accessory has a connector which inserts into the accessory socket on the side of the InterX 5000, a cable approximately three feet long containing two wires and a molded electrode configuration capable of contacting a person's scalp.

Pencil Probe

This accessory has a connector which inserts into the accessory socket on the side of the InterX 5000, a cable approximately three feet long containing two wires and a molded electrode configuration slightly larger than a pencil which is capable of reaching specific local treatment areas.

Ball Probe

This accessory has a connector which inserts into the accessory socket on the side of the InterX 5000, a cable approximately three feet long containing two wires and an electrode configuration resembling two stainless steel balls in a "V" configuration capable of reaching between a person's fingers or toes.

Electrical Output

Electrical outputs are described and reported in the performance test report included as Appendix F. This report also includes diagrams depicting waveform for each simulated load, across frequency range at the maximum power setting.

Performance

Performance bench testing was conducted to characterize the electrical performance of the InterX5000 as compared to published data of predicate devices.

The performance factors of particular interest are electrical stimulation waveshape, voltage, current, energy and frequency. Test information, including protocols, results, analysis, and conclusions, has been provided as Appendix F.

Electrical & Thermal Safety

This device is powered by a 9 volt, disposable alkaline battery. It is not line-powered, and does not employ a line-powered battery charger. There is also no interface that enables the device to be powered with a line-powered charger.

This device conforms with industry standards relating to electrical safety and electromagnetic compatibility (EN 60601-1 and EN 60601-1-2).

Average power density was calculated by dividing the average power per pulse by the area of the smaller electrode (1.67 cm²). The maximum value obtained was 0.115 W/cm² over a 500-ohm purely resistive load.

Electrical safety and electromagnetic compatibility data is provided as Appendix G.

Environmental Testing

This device has been tested to EN 60601-1-2 standards for electromagnetic compatibility and EN 60601-1 standards for electrical safety.

Electrical safety and electromagnetic compatibility reports are provided as Appendix G.

Materials

The following components are intended for contact with unbroken patient skin:

Component	Material Description
Machine Case external electrodes	(b)(4)
Optional Accessory external electrodes	
Machine Case Plastic	
External Electrode sealant	

Plastic materials and sealant comply with biocompatibility requirements of ISO 10993-1/EN 30993-1 relating to sensitization, irritation, and cytotoxicity.

Software

The device software has been determined to have a "minor" level of concern, according to FDA's "Reviewer Guidance Document for Computer Controlled Medical Devices". The following rationale provides the basis for this determination:

- The device software does not control a life-supporting or life-sustaining device.
- The device software does not control the delivery of potentially harmful energy which could result in death or serious injury.
- The device software does not control treatment delivery, such that an error or malfunction with the delivery could result in death or serious injury.

- The device software does not provide diagnostic information on which treatment or therapy is based.
- The device software does not provide vital signs monitoring and alarms for potentially life threatening situations in which intervention is necessary.

Software information is provided as Appendix H.

APPENDIX A

**SUMMARY OF SAFETY AND
EFFECTIVENESS**

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NEURO RESOURCE GROUP

510(k) Summary

Submitter Information:

Contact:

Krista Oakes
Tel: 972-438-5202
Fax: 972-401-9161

Date Prepared:

September 30, 2004

Product Name & Classification:

Classification Regulation: 882.5950, 890.5850,
Panel: Neurology, Physical Medicine
Product Code: GZJ, IPF
Trade Name(s): InterX5000

Predicate Device:

K041575 – Fenzian Treatment System
K951951 – EMPI Focus 795
K870947 – Dynatron 500 Electrical Muscle Stimulator

Description:

InterX means “Interactive”. InterX technology is designed to work by introducing very brief pulses of electricity into the tissue and immediately monitoring impedance changes as the tissue responds. Stimulation and sensing take place via a concentric electrode system that is moved over the skin surface, and a digital display enables the operator to follow the course of the treatments and adjust the output.

The InterX 5000 consists of a small handheld device in a plastic case. It is powered by one nine-volt alkaline battery. On the upper face of the machine there are two LED's, an LCD display and 5 control buttons. The underside of the machine contains two metal surfaces that form the poles of a treatment electrode. The electrodes are placed directly on the unbroken skin and do not use any conductive material or gel.

On the side of the machine is one socket for a standard 3.5mm stereo jack socket that connects to the main electrodes of the machine to an optional external electrode accessory. The device's electrodes are disabled when the optional external electrode accessory is

attached. The optional external electrode accessories only serve as an extension and allow the user to apply treatment in a areas which may not be accessible by the main unit electrodes. None of the three electrode accessories intended for use with the InterX 5000 have any active electrical components.

The waveform is a high amplitude, short-duration bi-polar pulse (circuitry in the device integrates time and dosage delivered). A digital display monitors the biofeedback process in relation to the starting point, enabling the operator to track changes in the tissues being treated and make appropriate adjustments to the output characteristics if necessary. This interaction and human adjustment continues throughout the length of the InterX treatment. The result is that the body experiences a conditioned training process that enhances the body's ability to effectively reduce and manage the level of pain.]

Intended Use:

The InterX5000 is indicated for:

- symptomatic relief and management of chronic, intractable pain
- adjunctive treatment in the management of post-surgical and post-traumatic pain
- relaxing muscle spasms
- increasing local blood circulation
- immediate post surgical stimulation of calf muscles to prevent venous thrombosis
- muscle reeducation
- maintaining or increasing range of motion
- preventing or retarding disuse atrophy

Comparison to Predicate Devices:

- *Does the new Device have the same indications for use? Yes*
- *Does the new Device have the same Technological Characteristics? Yes*
- *Are Descriptive Characteristics precise enough to ensure Equivalence? Yes.*
- *Are Performance Data available to assess Equivalence? Yes*
- *Performance Data Demonstrate Equivalence? Yes*

A comparison matrix has been provided as part of this premarket notification.

Performance Data & Conclusions:

Performance bench testing was conducted to characterize the electrical performance of the InterX5000 as compared to published data of predicate devices.

APPENDIX B

**STATEMENT OF INDICATIONS FOR
USE**

Indications for Use

510(k) # (if known):

Device Name: InterX5000

Indications for Use:

The InterX5000 is indicated for:

- symptomatic relief and management of chronic, intractable pain
- adjunctive treatment in the management of post-surgical and post-traumatic pain
- relaxing muscle spasms
- increasing local blood circulation
- immediate post surgical stimulation of calf muscles to prevent venous thrombosis
- muscle reeducation
- maintaining or increasing range of motion
- preventing or retarding disuse atrophy

Prescription Use x
(21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(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)

APPENDIX C

PRODUCT LABELING AND PREDICATE DEVICE LABELING

InterX 5000

Interactive Electro-Stimulation Device

Instruction Manual

Part # 001002-10/04

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InterX 5000 Operations Manual

This manual provides information regarding the controls and functions of the InterX 5000. The InterX 5000 must be used strictly in accordance with these instructions. Further training is required to fully use the device and obtain optimal patient outcomes.

Warnings and Cautions

Definition - Warning: *A warning message contains special safety emphasis and must be observed at all times. Failure to observe a WARNING message could result in serious personal injury.*

Definition - Caution: *Failure to observe a CAUTION associated with use could result in minor injury or product damage. Such problems include device malfunction, device failure, damage to the device or damage to other property*

Warnings

Federal (U.S.A.) law restricts this device to sale by, or on the order of a practitioner licensed by the law of the State in which he/she practices to use, or order the use of the device.

Use and supervision of the InterX 5000 is limited to professionals who have received certified training from the manufacturer.

Federal (U.S.A.) law requires the InterX 5000 be used only by a trained healthcare practitioner or under the continued supervision of a licensed healthcare practitioner. The InterX 5000 must be used only by the person for whom it is prescribed. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner

Safe use of the InterX 5000 is the primary responsibility of the user. The user is responsible for the monitoring of the product. Contact clinical/technical support if the InterX 5000 appears to be operating incorrectly.

The user must keep this device out of reach of children.

The InterX 5000 is not effective for pain of central origin including headaches.

The InterX 5000 is symptomatic treatment and as such could suppress the sensation of pain which would otherwise serve as a protective mechanism.

The safety of the use of InterX 5000 has not been established during pregnancy or childbirth.

Do not operate the InterX 5000 before verifying that other medical devices will not be adversely affected by the electrical impulses generated.

Stimulus delivered by this device may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax or carotid sinus nerves because it may cause a cardiac arrhythmia or interfere with cardiac function.

Use caution in applying the InterX 5000 over areas which are swollen, infected, inflamed as it may result in a worsening of the symptoms. In particular, caution should be taken when electrodes are placed over areas associated with phlebitis, thrombophlebitis and varicose veins as these conditions have an increased risk of forming blood clots which could become dislodged during stimulation.

Use caution in applying the InterX 5000 to patients suspected of having heart disease.

If the display becomes blank or inoperative discontinue use

InterX 5000 is contraindicated for:

- *Undiagnosed pain (until etiology is established)*
- *Electrode placement over malignant tumors*
- *Transcerebral and/or carotid sinus electrode placement*
- *Use over mucous membranes*
- *Patients who are prone to seizures (i.e. patients with epilepsy).*
- *Use over pharyngeal or laryngeal muscles, the electrical impulses generated may cause muscle spasm resulting in difficulty in breathing.*
- *Patients that have a demand-type cardiac pacemaker*

Do not make contact with the InterX 5000 electrodes on wet skin. Natural bodily fluids, including sweat, are acceptable.

Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when InterX 5000 stimulation is in use.

Do not use on patients that are undergoing dialysis or are being treated in an MRI, X-ray, or with other diagnostic equipment that may be impacted by the electrical impulses. Remove all jewelry before treatment.

The InterX 5000 is not to be used in the presence of anesthetic or other flammable gases.

The InterX 5000 has no curative value.

Avoid placing the device on the skin when turning ON or returning from PAUSE to avoid electrical signal.

Treatments with the InterX 5000 should not exceed 1 hour in any specific area of the body and there should be a minimum of 2 hours between treatment sessions, to avoid isolated cases of skin irritation.

Skin irritation, electrode burns, dizziness, nausea, and headaches are potential adverse reactions.

Cautions

InterX 5000 should be used only with manufacturer approved electrodes and accessories. Built-in device electrodes and external electrodes should not be used in combination transcerebrally.

Avoid spilling fluids on the device. If the InterX 5000 is immersed in any liquid it must be replaced with a new device.

Do not sterilize the InterX 5000.

Do not expose any part of the InterX 5000 to chemical solvents or harsh cleaning fluids. Follow cleaning instructions in this manual.

Effectiveness of the InterX 5000 is highly dependent upon patient selection by a person qualified in the management of pain patients.

The InterX 5000 should not be used while driving, operating machinery, or during any activity in which may put the user at undue risk of injury.

Do not open the InterX 5000 case. Opening or removing covers may expose you to dangerous voltage or other hazards and damage operating circuits. Opening the case will void the manufacturer's warranty. If the device needs repair or service contact your distributor or an authorized service representative.

Turn main switch OFF before replacing batteries to avoid unexpected electrical signal. Only the battery cover may be removed when changing batteries. Do not attempt to connect the InterX 5000 to any other power source.

Definitions and Symbols:

Regulatory Symbols used on the device



This CE symbol certifies that the product complies with the essential requirements of the Medical Device Directive.



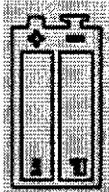
Signifies the product has been evaluated to the applicable ANSI/UL and CSA standards



This stimulator is internally powered only, the symbol indicates the device was manufactured according to the degree of protection against electrical shock for this type BF protection class equipment.



DO NOT use this device without adequate training in its function and purpose. This manual provides information regarding the controls and functions of the InterX 5000, further training is required.



The Serial Number and the manufacturing date is located on the battery label inside the battery compartment. To view label information gently press, in the direction indicated by the arrows, on the serrated area of the battery compartment to remove the battery cover, remove battery if in place and label should now be visible.

Definitions used throughout this manual

Coefficients (X and Y) – Display the ratio of change of the body’s ongoing response to the treatment. The coefficients are readings of the body’s reaction visible in Diag 1 and Diag 2 mode.

Damping (Dmpf) - Damping controls the shape of the waveform generated by the InterX 5000, settings include SK1 to SK4 and VAR.

Diag – Operating modes of the InterX 5000 – Diag 0 is the InterX 5000 default or basic mode of operation. Other modes of operation are Diag 1 and Diag 2.

Dose (*) – Is a signal to the operator that the first aspect of the treatment has been successfully completed

Frequency (F) – Frequency is the number of pulses per second measured in hertz (Hz). When Intensity is greater than one (1) the frequency is constant at 59,3Hz. Throughout the InterX 5000 Instruction Manual frequency is represented in the International manner of 59,3, which is equivalent to 59.3.

Frequency Modulation Variable – A setting of the device where the frequency is varied between 29,3 Hz to 121 Hz and the damping (Dmpf) varies through settings.

Impedance – Measure of the body's combined physical characteristics which impact its ability to absorb the energy generated by the InterX 5000.

Initial Reaction (IR) – The relative measure of the body's impedance. High initial reaction (IR) readings are an indication of where treatment with the InterX 5000 should be focused. Visible in Diag 1 and Diag 2 mode.

Intensity (Intens) – The number of pulses in a complete cycle. (For example: Frequency of 59,3Hz, is the number of impulses that occur in a second.

Modulation (Mod) – Modulation is the ratio of time that device is sending impulses into the skin, for example a Mod setting of 3:1 indicates the device is transmitting impulses for 3 seconds and then sends no impulse for 1 second.

Nobody – appears on the display screen when operating in Diag 1 or Diag 2 mode and the electrodes of the InterX 5000 are not in good contact with a patient's skin or when indicates a particular area of the body is outside an acceptable range for the device (either too high or too low).

Note - highlights information that acts as a reminder or helps explain a concept or procedure

Power – the strength of the impulse on the patient's skin – the higher the setting the stronger the tingling sensation felt by the patient

Swing Variable (Sw1) – Intensity is constant at 3 pulses/cycle and the Z (pulse delay) and Dmpf (damping) are automatically varied.

Z – Delay between the peaks of each pulse in the cycle being delivered to the patient. This can only be used when the Intensity (Intens) setting is 2 or greater.

Zero (@) – Is a signal to the operator that the second aspect of the treatment has been successfully completed (Dose being the first aspect of the treatment). Active in Diag 1 and Diag 2 mode.

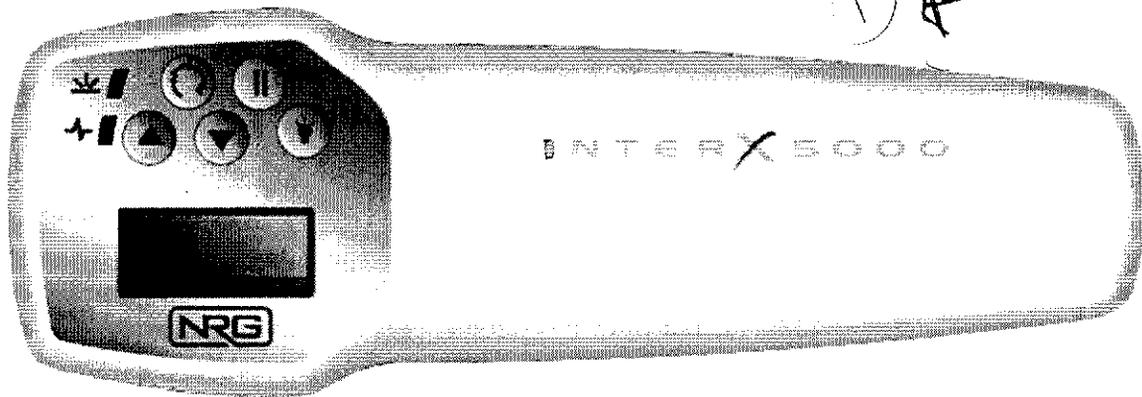
******* - Indication on display screen that attribute setting is in Var.

2.11.14 @ 10:14

Introduction

The InterX 5000 is a light weight hand held electro-stimulation device that when applied to the skin transmits electrical impulses into the body. InterX technology is designed to work by introducing very brief pulses of electricity into the tissue which vary as the device encounters changes in the tissue's impedance.

The InterX 5000 is unique in the way it is designed to continuously modify its output as it senses changes in tissue properties. In comparison to other types of currently available electro-stimulation devices, the InterX 5000 is unique in the way it works interactively with the body, by modifying its signal in response to the changing impedance of the tissue in contact with its electrodes.

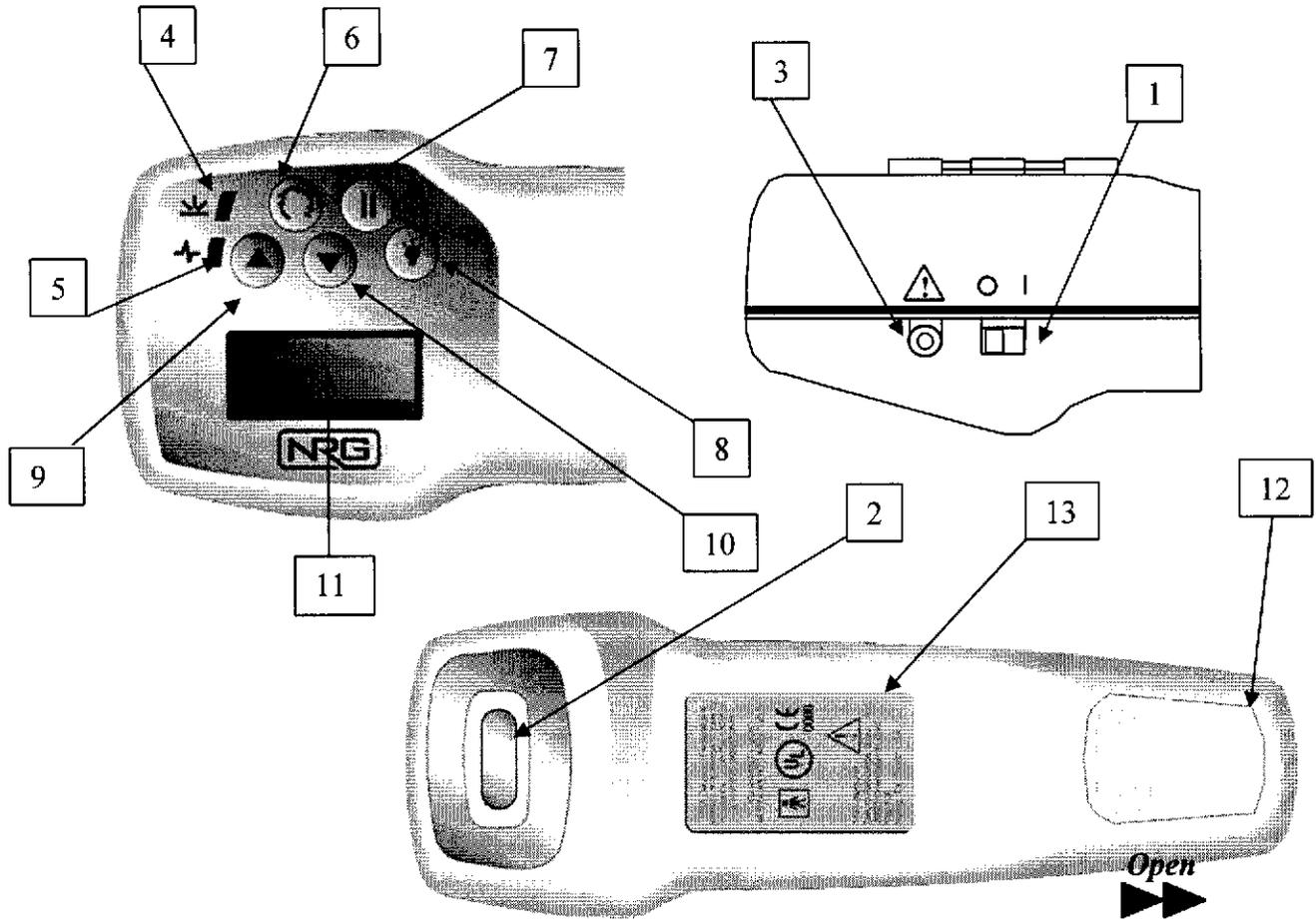


Indications for Use

The InterX 5000 is indicated for:

- Symptomatic relief and management of chronic intractable pain.
- Adjunctive treatment in the management of post surgical and post traumatic pain
- Relaxing muscle spasms
- Increasing local blood circulation
- Immediate post surgical stimulation of calf muscles to prevent venous thrombosis
- Muscle re-education
- Maintaining or increasing range of motion
- Preventing or retarding disuse atrophy

Overview of the InterX 5000 Controls and Functions



Item	Feature or Control	Description/Use
1.	Main power switch (ON/OFF Switch)	Slide the switch to the right to turn the InterX 5000 ON. Slide the switch to the left, to turn the device OFF.
2.	Built-in electrodes	The two active electrodes that are applied to the skin
3.	Accessory port	Used for the attaching of accessory probes to the InterX 5000. Only manufacturer approved accessories should be used.
4.	Dose/Low battery Indicator Light	Visual indicator of dose level. When a dose level has been achieved while operating in Diag1 or Diag 2 an amber light will appear and you will hear an audible beep. This light will blink when entering Pause if the battery is low.

Item #	Feature or Control	Description/Use
5.	ON/OFF Indicator Light	Indicator that the InterX 5000 has been turned ON, a green light will glow when the device is ON. This light will blink on and off indicating the frequency of impulses being delivered, at higher frequencies it appears to be glowing continuously. The intensity of the light will increase as the energy/power delivered increases.
6.	ON/MENU SCROLL BUTTON	Button will allow the user to scroll through the various operational menus (Diag) and impulse attributes (Mod, Dmpf, Intens, Z, Freq) User may also press to resume InterX 5000 operation after it has been placed in pause.
7.	PAUSE BUTTON	Press to pause the operation of the InterX 5000. The device will retain the settings while in use prior to PAUSE. Caution should be used when returning to ON from PAUSE.
8.	Screen Backlight BUTTON	Press to turn display screen backlight ON. Backlight will remain on for a period of 3 seconds after the button is released.
9.	INCREASE BUTTON	Press to increase the power of the InterX 5000 and to scroll up through operational settings in the device
10.	DECREASE BUTTON	Press to decrease the power of the InterX 5000 and to scroll down through operational settings in device
11.	Screen	Displays the various settings and operating modes of the InterX 5000.
12.	Battery compartment	Location for one (1) 9V alkaline battery, product serial number and manufacturer date.
13.	Product label	States manufacturer information and regulatory cautions. Do not remove. Removal of label will void manufacturer's warranty.

Battery Operation and Replacement

The InterX 5000 operates by battery power only. Use only quality 9V alkaline batteries for longer life and optimum performance of the device.

Low Battery Condition

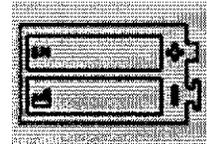
Battery life is highly dependent on how often the device is used and the specific settings that are utilized for treatments. However, under normal use (approximately 5 hours per day at varying degrees of power and with periodic use of the backlight) battery life of the device is estimated to be approximately 1 - 2 weeks.

When the battery is low the amber Dose/Low Battery light will blink when the device enters Pause and you will hear a descending audible sound. It is advisable to keep extra 9V alkaline batteries in a convenient place where the InterX 5000 therapy is provided.

Replacing batteries (see Controls and Functions Item 12):

To replace the battery gently press on the serrated area of the battery compartment in the direction indicated by the arrows. Pull up on the battery removal ribbon to remove the old battery.

Discard old battery and replace with a new 9 Volt Alkaline battery in the orientation indicated, taking care to lay part of the battery extraction ribbon under the new battery. Securely place the battery cover back on the device by sliding it until it snaps in place. The device will not function if the battery is placed in the compartment incorrectly.



Operation Modes of the InterX 5000

There are three operating modes of the InterX 5000.

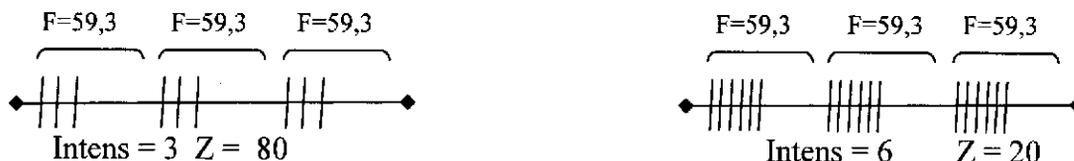
- **Diag 0** – is the default or base mode of operation. In Diag 0 you can provide impulses to the patient, increase and decrease the power of those impulses, and change all of the attributes of the impulse signals.
- **Diag 1** - In Diag 1 you can obtain various readings relative to changes in the patient's tissue. You can also change other impulse variables with the exception of DMPF. Key treatment parameters include Dose (*) and Zero (@). Recommended Frequency (F) is 59,3Hz.
- **Diag 2** – Diag 2 operates in a similar fashion to Diag 1 with the exception that the dose (*) and zero (@) indications are arrived at simultaneously and their calculation is performed differently and faster than when operating in Diag 1 mode.

Impulse Signal Attributes

Depending on which of the above three modes the InterX 5000 is operating in you can vary some or all of the following attributes of the impulse signals being delivered by the InterX 5000:

- **Power** – Strength of the electronic impulse which can vary from a minimum of one to a maximum of 250. Note: The comfortable level of power may vary significantly from patient to patient.
- **Mod** –Modulation is the ratio of time that the device is sending impulses into the skin to the time that there is no impulse. For example, a Mod setting of 3:1 indicates the device is transmitting impulses for 3 seconds and then no signal for 1 second.
- **Dmpf** –Damping controls the shape of the waveform of the signal generated by the InterX 5000. VAR consists of a combination of the all the damping setting (SK1, SK2, SK3, and SK4) in a cycle.
- **Intens** –Intensity is the number of pulses in each cycle being delivered to the patient. **NOTE:** While operating the device in Intens 2-8 the Frequency is constant at 59,3Hz and the Mod is off.

Example of relationship between Intens and Z:



- **Z** – Delay between the peaks of each pulse in the cycle being delivered to the patient. 10 is the shortest amount of delay between pulses and 80 is the longest **NOTE:** This can only be used when the **Intens** setting is 2 or greater.
- **Freq** – Frequency is the number of impulses per second. For example at a frequency setting of 59,3Hz the InterX 5000 would deliver 59.3 impulses per second to the patient.

Table of Attribute Default and Menu Options:

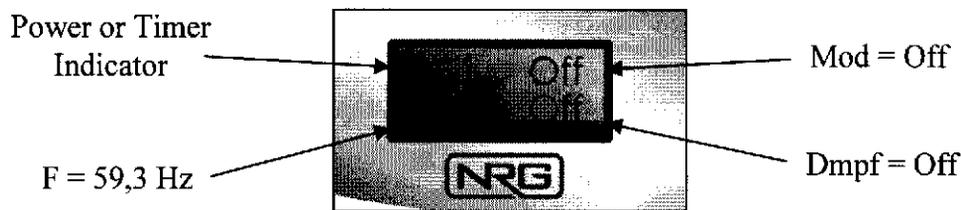
<i>Attribute</i>	<i>Default</i>	<i>Options</i>
Power	1	1 - 250
Diag	0	1; 2
Mod	Off	1:1; 2:1; 3:1; 4:1; 5:1; FM; Sw1
Dmpf	Off	Sk1; Sk2; Sk3; Sk4; Var
Intens	1	2; 3; 4; 5; 6; 7; 8
Z	20	10 up to 80
F	59,3 Hz	15,3 Hz up to 351Hz

Instructions for Use

Turning ON the InterX 5000 (see Controls and Functions Item 1)

Once you have examined your patient and are ready to begin InterX 5000 therapy, turn the device to the ON position by sliding the ON/OFF switch to the right. The Green ON/OFF indicator (see Controls and Functions Item 4) will glow. **NOTE:** At low frequency levels the light will blink on and off; at higher levels it will appear to be glowing continuously.

Upon startup the instrument goes through a short self test and then the display screen will show the current programming of the device, and a short audible beep will be heard.



The display will show the BASE SCREEN which will identify the current power setting, the current frequency, and that Mod and Dmpf attributes are OFF. **NOTE:** Always confirm that the device has been returned to default settings between patients, to ensure that the device is reset from PAUSE settings press buttons UP and DOWN simultaneously.

Once the unit has been ON for 3 seconds the screen will automatically change from displaying the current power setting to displaying a time clock indicating the length of time the equipment has been ON. All other information on the screen will remain unchanged.

To return the display the Power settings press either the INCREASE or DECREASE BUTTON once. **NOTE:** The power setting is changed in increments of 1 when you press either the INCREASE or DECREASE BUTTON.

NOTE: Every 30 seconds that the InterX 5000 is operating an audible beep will sound. To reset the device programming while in use, hold both the INCREASE and DECREASE BUTTON's simultaneously for 3 seconds. When you release them you will hear a short audible beep, the device will have reset to the default settings.

To pause the operation of the InterX 5000 (see Controls and Functions Item 7)

To pause the operation of the InterX 5000 press the PAUSE BUTTON once.

To restart the operation of the device, press the ON/SCROLL BUTTON. **NOTE:** If the patient or the patient's programming has changed since you paused the device it is important to reset the the InterX 5000 when returning from PAUSE (see Controls and Functions Item 7). The device maintains the programming that was set when it was paused.

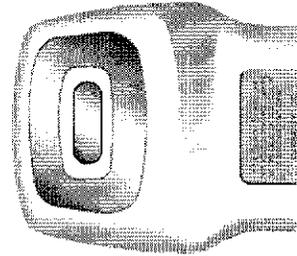
To turn the InterX 5000 OFF (Controls and Functions Item 1)

To turn the InterX 5000 OFF slide the ON/OFF Switch to the left.

NOTE: If you do not press a button on the InterX 5000 for a period of 5 minutes the device will automatically go into PAUSE.

To establish Electrode contact

When beginning treatment with the InterX 5000 ensure that the device is in default settings and that Power is set at 1. Identify area of electrode placement as directed in InterX 5000 training. Place both electrodes firmly on clean and dry patient skin.



NOTE: To achieve best results it is recommended that the skin remain in a “natural” condition, the patient should not shower or bathe for two hours prior to and after the treatment.

The InterX 5000 should only be used with manufacturer approved accessories/probes.

To Change Power

In the BASE SCREEN press the INCREASE or DECREASE BUTTON to set the Power from a minimum of one (1) to a maximum of 250.

Obtain a comfortable level of power by placing the electrodes on the patient’s skin and slowly increasing the power until the patient tells you that they feel a tingling sensation. The patient should experience a slight tingling and vibration, but no pain as the InterX 5000 is moved on the skin. **NOTE:** Refer to training manuals for indications of use at higher levels of Power to achieve desired treatment results.

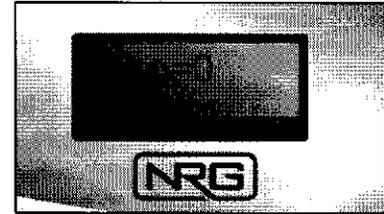
If the power is increased to a level that makes the patient uncomfortable, press the DECREASE BUTTON until a more comfortable power level is obtained.

The setting of the InterX 5000 power level should always be started at a minimum level and gradually increased with patient feedback. **NOTE:** The treatment power level will vary from patient to patient based upon their individual sensitivity to the electrical impulse.

Using the InterX 5000 in Diag Mode

To Change Operation Mode (Diag)

From the BASE SCREEN press the ON/SCROLL BUTTON until the following screen appears:



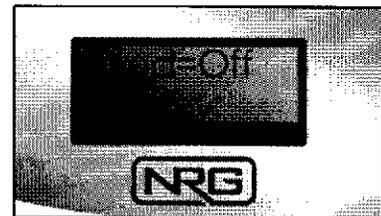
Once in this screen, press INCREASE or DECREASE to set the Diag operating mode. (**NOTE:** If you do not press the INCREASE or DECREASE BUTTON within 3 seconds of entering the DIAG SCREEN the device will revert back to the BASE SCREEN. To return to the DIAG SCREEN press the ON/SCROLL BUTTON once).

- Diag 0 is the default operation mode. When treating a patient in Diag 0 you may change the attributes; Modulation, Damping, Intensity, and Frequency to vary the electronic output achieving different treatment results. Further training is required to fully use the device and obtain optimal attribute settings for different patient conditions. **Note:** The InterX 5000 will beep every 30 seconds to signal active treatment.
- In Diag mode 1 or 2 the word NOBODY may appear on the screen. This indicates that the electrodes are not in proper contact with the patient's skin. Once you correctly apply the electrodes to the skin the screen will begin to display the impulse attribute readings.

To Change the Modulation (Mod)

From the BASE SCREEN press the ON/SCROLL BUTTON until the following screen appears:

Once in this screen, press INCREASE or DECREASE to set the Mod setting:



- 1:1 (creates impulses for 1 second and no signal for 1 second)
- 2:1 (creates impulses for 2 seconds and no signal for 1 second)
- 3:1 (creates impulses for 3 seconds and no signal for 1 second)
- 4:1 (creates impulses for 4 seconds and no signal for 1 second)
- 5:1 (creates impulses for 5 seconds and no signal for 1 second)
- FM (frequency modulation) – this setting varies the frequency automatically between 29,3 to 121 Hz

Sw1 (frequency swing) – Intensity is constant at 3 pulses/cycle and the Z (pulse delay) and Dmpf (damping) are automatically varied.

NOTE: If you do not press the INCREASE or DECREASE BUTTON within 3 seconds of entering the MOD SCREEN the device will revert back to the BASE SCREEN. To return to the MOD SCREEN press the ON/SCROLL BUTTON once.

To Change Waveform Damping (Dmpf)

You can only program damping settings when you are operating in the Diag 0 mode.

To apply damping to the impulse wave form from the BASE SCREEN press the ON BUTTON until the following screen appears:

Once in this screen, press INCREASE or DECREASE to set the Dmpf setting from SK1 – SK4. In addition, you can set the damping in VAR mode which will scroll through all 4 SK settings during each cycle, with a cycle being 2 minutes in length.



NOTE: If you do not press the INCREASE or DECREASE BUTTON within 3 seconds of entering the Dmpf SCREEN the device will revert back to the BASE SCREEN. To return to the Dmpf SCREEN just press the ON/SCROLL BUTTON once.

To change the Intensity (Intens)

From the BASE SCREEN press the ON/SCROLL BUTTON until the following screen appears:

Once in this screen, press INCREASE or DECREASE to set the Intens operating mode from 1-8 pulses/cycle.



NOTE: If you do not press the INCREASE or DECREASE BUTTON within 3 seconds of entering the DIAG SCREEN the device will revert back to the BASE SCREEN. To return to the DIAG SCREEN press the ON/SCROLL BUTTON once

When setting the intensity level you will hear an audible beep when you program the device at level 8 and when you decrease it back to level 1 from a higher setting (to indicate that you cannot program the device any higher or lower).

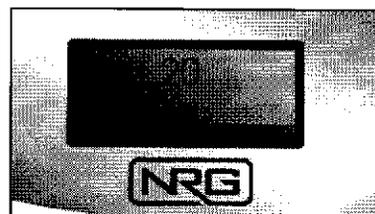
To change the Pulse Delay (Z)

To program a pulse delay (Z) you must have the InterX 5000 set at an Intensity level of 2 or greater.

To program a pulse delay into InterX 5000 from the BASE SCREEN press the ON/SCROLL BUTTON until the following screen appears:

Once in this screen, press INCREASE or DECREASE to set the Z operating mode from 10-80, with 10 being the shortest amount of delay and 80 being the longest.

NOTE: If you do not press the INCREASE or DECREASE BUTTON within 3 seconds of entering the Z SCREEN the device will revert back to the BASE SCREEN. To return to the Z SCREEN just press the ON/SCROLL BUTTON once.

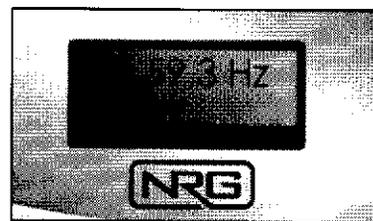


To Change the Frequency (F)

From the BASE SCREEN press the ON/SCROLL BUTTON until the following screen appears:

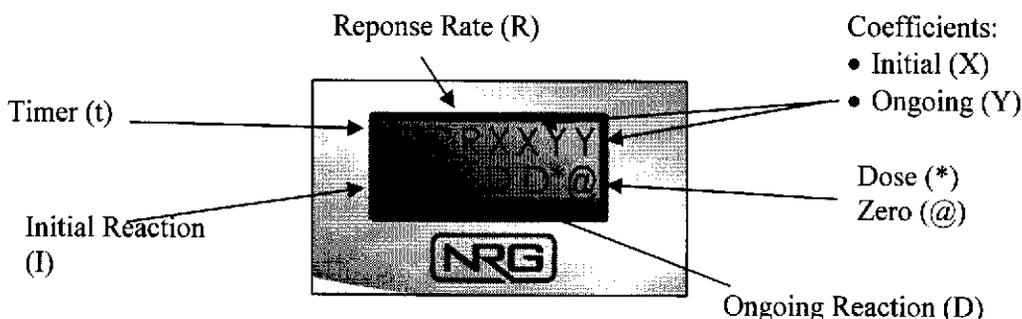
Once in this screen, press INCREASE or DECREASE to set the Frequency (F) operating mode from 15,3 Hz to 351 Hz.

NOTE: Once you are in the Frequency Screen if you do not press a BUTTON within 3 seconds the device will return to the base screen. To return to the Frequency Screen just press the ON/SCROLL BUTTON once.



Explanation of Diag 1 Mode

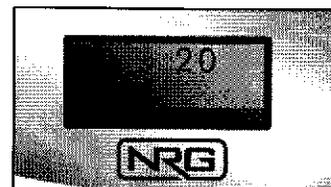
In Diag 1 and 2 Mode the InterX 5000 provides you with additional readings that relate to the interactive features of the device. When you place the InterX 5000 electrodes correctly on the patient's skin the screen will reflect the body's reaction to the impulses in real time. The display below illustrates the relative positions of each reading present on the screen in Diag 1 and 2 mode:



NOTE: Remember you must have the electrodes in proper contact with the patient's skin to have the screen display the above information. In Diag mode 1 or 2 the word NOBODY may appear on the screen. This indicates that the electrodes may not be in proper contact with the patient's skin. Once you correctly apply the electrodes to the skin the screen will begin to display the impulse attribute readings. On very rare occasions the word NOBODY can appear on the screen while the InterX 5000 has good skin contact. This indicates a particular area of the body is outside an acceptable range for the device (either too high or too low).

During the treatment in Diag 1 or Diag 2 if you do not have the electrodes on the patient's skin for a period of 30 seconds the InterX 5000 will go into pause and the screen will go blank. In Diag 0 mode the InterX 5000 will pause and the screen will go blank after 5 minutes of inactivity. In either of these situations to turn the device back ON press the ON/SCROLL BUTTON once.

Initial Reaction (I) – is a relative measure of the body's impedance. High initial reaction (IR) readings are an indication of where treatment with the InterX 5000 should be focused. The IR will change each time you remove the device from the patient's skin and then place it back on the patient's skin.



Note: Once the device is in Diag mode, the word NOBODY will appear. Place the electrodes firmly on the treatment area, two numbers will appear. For example, the number on the upper row reflects the X coefficient (X=20) and the number on the bottom row (I=23) reflects the IR.

Coefficients – The two coefficients displayed are initial (X) and ongoing (Y). These indications are the ratio of change of the body’s ongoing response to the treatment. The following three coefficient relationships (X:Y) can be present while giving treatment to a patient (the ratio must be calculated):

- A ratio of X:Y, where X=Y, indicates there is no dynamic change and the body needs more treatment at that area because it is not responding to stimulus.
- A ratio of X:Y, where X>Y, indicates there is low dynamic change and the body still needs attention to sufficiently respond to the treatment.
- A ratio of X:Y, where X<Y, indicates there is dynamic change and the body is approaching satisfactory response to the treatment.

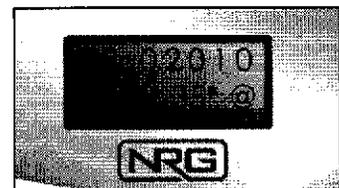
Timer – Indicates how long the device was in contact with the patient’s skin. When the treatment extends over 99 seconds, the first digit becomes an asterisk (The device will display *5 to indicate 115 seconds or 215 seconds). The length of time required to successfully achieve the treatment aspects of Dose (*) and Zero (@) may vary significantly between patients, from a few seconds to over 10 minutes.

Dose (*) – indicates that the body has now responded to the stimulation and the InterX 5000 is no longer sensing changes in the impulse. The ongoing reading (D) has achieved the first aspect of the treatment. An audible sound will be heard, the amber Dose light will flash (see Features and Controls, Item 4), and an (*) will appear immediately to the right of the ongoing reading (D). The InterX 5000 will automatically continue to treat the patient and calculate the Response Rate (R).



Response Rate (R) – Indicates how fast or slowly the body is responding to InterX 5000 impulses. A higher response rate indicates a more active local process. When the treatment has completed, the Response Rate will register a “0” indicating the second aspect of treatment Zero (@) has been achieved.

Note: Zero (@) – is the indication to the operator that the second aspect of the treatment has been successfully completed (Dose * being the first aspect of the treatment). After the Dose occurs, hold the device on the treatment area until a second audible sound occurs to signal Zero (@). The (@) symbol will appear next to Dose on the display screen. Because the body is a dynamic system, the number visible in Response Rate (S) may fluctuate after signaling “0”.

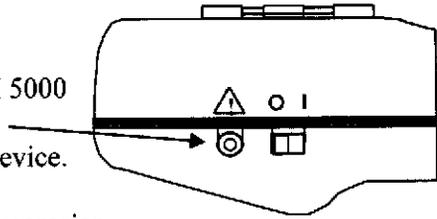


Explanation of Diag 2 Mode

The use and various readings of the InterX 5000 in Diag 2 modes is identical to its use in Diag 1 mode, with the exception that the dose (*) and zero (@) indications are arrived at simultaneously and their calculation is performed differently and faster than when operating in Diag 1 mode.

Description of Accessory Probes

The accessory probes plug into the accessory port of the InterX 5000 system located on the side of the device. Use care when you plug in and unplug the lead wires from the electrodes and the device. Jerking the lead wire instead of holding its insulated connector may cause damage. Do not attempt to plug other devices or accessories into the accessory port of the InterX 5000.



Only manufacturer approved probes may be used with the InterX 5000. All instructions in this manual apply to user placement of built-in and external electrodes. The probe package contains complete instructions for care and replacement of accessory probes.

Applying external electrode firmly to indicated patient treatment area. Turn ON the InterX 5000 and adjust power as described on page 14 of this manual. InterX 5000 attributes may be adjusted during use of external probes in the same manner as described while using the built-in electrodes.

General Care Instructions

Warning: Do not disassemble the InterX 5000. Dangerous voltages could be present. The InterX 5000 does not contain any user-serviceable components. If the device needs repair or service, contact your distributor or an authorized service representative.

Caution: Do not expose any part of the InterX 5000 to chemical solvents or harsh cleaning fluids. Do not sterilize or immerse the InterX 5000 in any fluid.

Storage and Cleaning

Remove the battery when storing the InterX 5000 for an extended period of time (more than one month).

Always use the carrying case to transport the InterX 5000. When not in use the InterX 5000 should be stored in its carrying case.

Clean the InterX 5000 periodically. With the main power OFF, gently wipe the surface with a damp cloth. Use mild soap and water, if necessary. Use of other cleaning solutions may damage the case. Never spray cleaners directly on the device.

The InterX 5000 is a non-critical patient contact device indicated only for contact between the electrodes and intact skin. Between patient treatments thoroughly clean the electrodes and surrounding device area with 70% isopropyl alcohol wipes.

Service and Warranty

If the InterX 5000 needs service

The InterX 5000 is not user serviceable. Never attempt to open the case as this device contains high voltages during operation.

To obtain service, first contact NRG Customer Service at 972-438-5205, or your distributor for a Returned Goods Authorization (RGA) number. Send the entire unit, with all accessories, packed in the original carrying case freight and insurance prepaid to the address provided to you by NRG. Include in the package a copy of your original invoice and a note describing the problem. Be sure to include your return address, including your phone number and if you have them a fax number and/or an email address.

NRG will not be responsible for damage due to improper packaging or shipment.

One-Year Limited Warranty

NRG warrants to the original purchaser that each new InterX 5000 is free of defects in workmanship and materials under normal use for a period of one year from original purchase date, except for accessories (batteries and carrying case). The warranty registration card must be completed and returned to NRG to validate the warranty.

During the warranty period, NRG's sole obligation shall be, at NRG's option, to repair or replace the InterX 5000 without charge. If the InterX 5000 is outside the warranty coverage period any requested repairs or replacement charges will be invoiced to the customer.

If NRG determines there is a defect covered by this warranty, the repaired or replaced product will be shipped back, freight and insurance prepaid, as soon as reasonably possible. If NRG determines, in its sole judgment, that the product does not contain defective workmanship or materials, NRG will return the product and invoice the customer for the return freight and insurance charges.

The warranty is voided immediately if the product has been subjected to abuse, accidental damage, damage in transit, negligence, acts of nature, or damage resulting from failure to follow operating instructions, or alternation/disassembly by anyone other than NRG.

NRG shall not be liable for any direct, indirect, special, incidental, or consequential damages, lost profits or medical expenses caused by any defect, failure, malfunction, or otherwise of the product, regardless of the form in which any legal or equitable action may be brought against NRG (such as contract, negligence, or otherwise). In no event shall NRG's liability under any cause of action relating to the product exceed the purchase of the product.

Accessories, such as batteries and carrying case, are excluded from the warranty and are sold "as is".

Product Specifications

Size	2.5 X 7.75 X 1.5 inches
Weight	185 grams without battery
Environment:	
Operating Temperature	15 – 40°C
Operating humidity	5% - 85% relative humidity (non-condensing)
Storage Temperature	-40 - 60°C
Storage humidity	5% - 85% relative humidity (non-condensing)
Power Source	9v DC Alkaline battery
Pulse Duration	68 – 668 ms
Pulse Frequency	15 – 350 Hz
Output voltage	45V @ 500 ohms 51V @ 2K ohms 90V @ 10K ohms
Output Current	51.4 mA @ 500-ohms 12.8 mA @ 2k-ohms 5.1 mA @ 10k-ohms
Electrodes	Stainless Steel
Waveform	Damped bi-phasic

InterX 5000

Interactive Electro-Stimulation Device

European Authorized Representative and Distributor:

Neuro Resource Group, Inc.
Maple House
Bayshill Rd.
Cheltenham
GL50 3AW, UK

Manufactured by:

Neuro Resource Group, Inc.
2220 Chemsearch Blvd., Suite 108
Irving, TX 75062
972/438-5202



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InterX 5000 – Accessory Electrodes

Instructions For Use

Use Accessory Electrodes only with the InterX 5000 manufactured by Neuro Resource Group, Inc.

Only manufacturer approved electrodes may be used with the InterX 5000.

All instructions in the *InterX 5000 Instruction Manual* apply to accessory electrodes.

Regulatory Symbols used



This CE symbol certifies that the product complies with the essential requirements of the Medical Device Directive.



Signifies the product has been evaluated to the applicable ANSI/UL and CSA standards



DO NOT use this product without adequate training in its function and purpose.

Cautions and Warnings

Federal (U.S.A.) law restricts this device to sale by, or on the order of a practitioner licensed by the law of the State in which he/she practices to use, or order the use of the device.

Safe use of the InterX 5000 and accessory electrodes is the primary responsibility of the user. The user is responsible for the monitoring of the product. Contact clinical/technical support if the InterX 5000 appears to be operating incorrectly.

Do not make contact with the InterX 5000 electrodes on wet skin. Natural bodily fluids, including sweat, are acceptable.

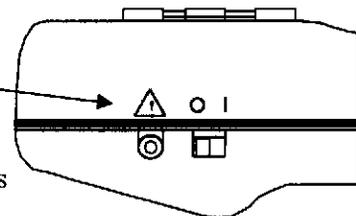
Avoid placing the device on the skin when turning ON or returning from PAUSE to avoid electrical signal.

Built-in device electrodes and external electrodes should not be used in combination trans-cerebrally.

Do not use any damaged electrodes

Instructions

Accessory electrodes plug into the accessory port of the InterX 5000 system located on the side of the device. Use care when you plug in and unplug the lead wires from the electrodes and the device. Jerking the lead wire instead of holding its insulated connector may cause damage. Do not attempt to plug other devices or accessories into the accessory port of the InterX 5000.



Apply the accessory electrode firmly to prescribed treatment area. Turn ON the InterX 5000 and adjust power according to the manufacturer's or a medical professional's instructions.

Care and Storage

The InterX 5000 and accessory electrodes are non-critical patient contact devices indicated only for contact between the electrodes and intact skin. Between patient treatments thoroughly clean the electrodes and surrounding device area with 70% isopropyl alcohol wipes.

Customer: *Neuro Resource / NRG*

Attn: *Dave Turner*

Your account manager is: *Teresa Caputo*

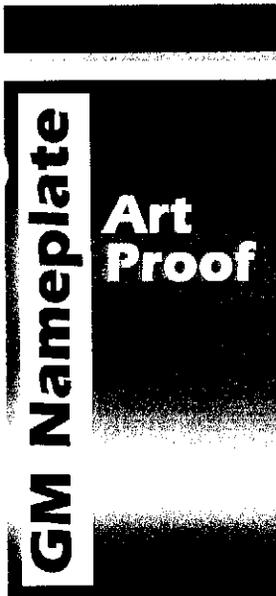
Please check design, copy, critical placements and specifications carefully.

Take note of our "Warranty and Limited Liability" statement below.

Check appropriate box below, sign and return so we may proceed with your order.

- Print as is
- Print with corrections marked
- Submit corrected proof

Your signature:



SPECIFICATIONS

Part Number: 1014

P.O. Number: 126

Qty Ordered: 200

GM Number: 039394

Finished Size: 1.250" x 2.125"

NOTES

PMS 431U graphics
PMS 427U background
.094" radius corners
dieline does not print
Please notify your account manager
immediately if there are any changes.

Approval of this proof is required by
 to maintain your scheduled ship date. *10-4-04*
 Save time in contacting **GM Nameplate, Inc.**
Phone: 408-435-1666 Fax: 408-435-8121

Customer alterations of original design are not included in quotation. Changes made at this point in production may result in additional charges.

We cannot proceed with production on this job until you obtain UL approval on your art. Please contact your account manager with any questions.

Please Note:

The colors shown are not for color matching purposes.

They are for reference only.

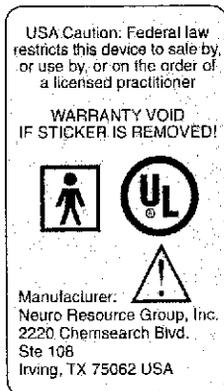


= PMS 431U Gray



= PMS 427U Gray

= Dieline



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Attn: *Dave Turner*

Your account manager is: *Teresa Caputo*

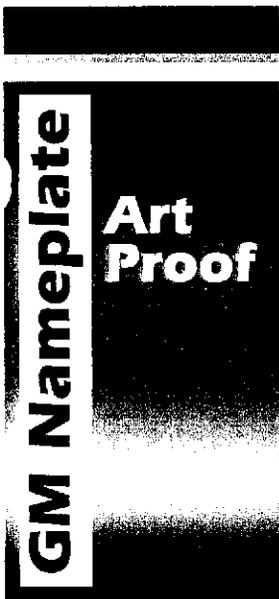
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P.O. Number: *127*

Qty Ordered: *2300*

GM Number: *039396*

Finished Size: *1.250" x 2.125"*

NOTES

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SPECIFICATIONS

Part Number: *1013 Rev B*

P.O. Number: *12B*

Qty Ordered: *2500*

GM Number: *039476*

Finished Size: *.910" x 1.200"*

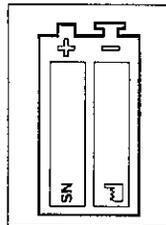
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NMS

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FOEUS-

FOEUS-

INSTRUCTION MANUAL

Empi.

Empi.
 Empi, Inc.
 1275 Grey Fox Road
 St. Paul, Minnesota 55112
 612-636-6600; 800-328-2536

Your authorized representative:

360146 Rev. E

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Instruction Manual for the Empi® FOCUS™ NMS Device

The FOCUS NMS system is designed and manufactured to conform to the "Standard for Transcutaneous Electrical Nerve Stimulation," as published by the Association for the Advancement of Medical Instrumentation, ANSI/AAMI NS4-1985.

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

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FOCUS™ NMS

Introduction

Introduction

The FOCUS™ NMS System

The Empr[®] FOCUS™ Neuromuscular Stimulation (NMS) system produces an electrical stimulus that, when properly applied, activates specific muscles or muscle groups in patients who will not, or cannot, contract these muscles voluntarily.

The FOCUS may also be used as a Transcutaneous Electrical Nerve Stimulator (TENS) for the symptomatic relief and management of chronic, intractable pain and as an adjunctive treatment for post-surgical and post-trauma acute pain.

The FOCUS has eight custom preprogrammed regimens, two independent intensity controls, continuous or cyclical stimulation capability, three rate settings, and adjustable ON and OFF time controls. A timing control allows selection of treatment duration. In addition, the device may be set for either symmetric or asymmetric biphasic waveforms.

How Does NMS Work?

The stimulator produces a mild electrical current that is transmitted via leads to electrodes placed on the skin in areas predetermined by the clinician. Stimulation of motor end plates causes nerve depolarization and subsequent activation of muscle fibers. The resulting muscle contraction persists as long as the electrical stimulus is present and stops upon cessation of the stimulus.

When applied as a TENS device, the electrodes are placed on the skin over cutaneous nerves. The stimulus travels through the cutaneous nerves to the deeper afferent nerves and then to the spinal cord and brain.

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Directions for Use

Getting Started

Your NMS kit includes:

- FOCUS NMS device
- electrodes and leads
- electrode gel (if carbon electrodes are used)
- 9-volt alkaline batteries (2)
- belt clip

1. You should be familiar with the locations of the intensity controls, indicator lights and timing control, as shown in Figure 1, and rate setting switch, cycling mode switch, ON time setting control, OFF time setting control, jack for remote switch and battery, which are located under the front panel cover, before continuing.

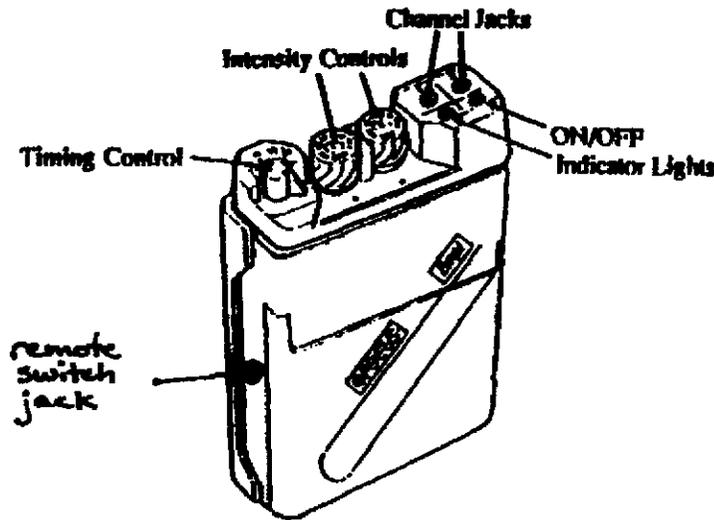


Figure 1. Review the location of the controls and indicator lights before using your NMS device.

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2. Carefully remove the NMS device from the carrying case. If the battery has not been inserted, see the "Changing the Battery" section in this manual.

3. Turn the channel 1 and channel 2 intensity controls clockwise until you hear a click or until the controls move freely. The **red ON/OFF indicator light** should come on. If not, replace the battery. If the **red light is slowly blinking on and off**, you may need to replace the battery.

4. Turn the device off by turning the channel 1 and channel 2 intensity controls counterclockwise until they click off (no longer move freely).

CAUTION: Always turn the device off before connecting the electrodes to your body and when changing the battery.

5. Prepare the electrode placement site by thoroughly washing and rinsing the skin. Your clinician will tell you where to place the electrodes.

NOTE: Repeated use of alcohol or other solutions may cause dryness and skin irritation.

6. Attach the electrodes to the lead wires.

7. Plug the leads into the channel jacks. If only one lead will be used, plug it into the channel 1 jack (Figure 2).

8. Place the electrodes on the skin.

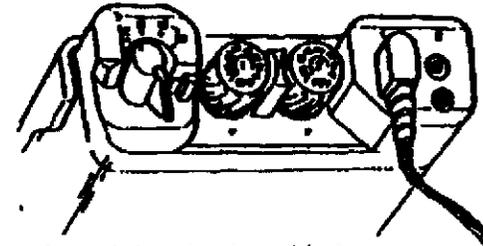


Figure 2. Plug the leads into the channel jacks.

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Directions for Use

FOCUS™ NMS

Operation

1. Follow your clinician's instructions. Mode of operation, regimen, waveform, rate, and ON and OFF times have been set by your clinician. Do not alter these, as your clinician has selected the most effective settings for your treatment.
2. Set the timing control to the N (Normal operation) position, unless you are using the 15- or 30-minute timing options (Figure 1).
3. Turn the channel 1 intensity control to the desired setting. The red indicator light will come on. Turn the control until you achieve the same response as in the clinic. If both channels are being used, turn the channel 2 intensity control to the appropriate setting.
4. When the session is complete, turn the intensity controls counterclockwise to OFF. Remove the electrodes from the skin or leave them in place for use in your next treatment session.

Changing the Battery

Empl recommends a 9-volt non-rechargeable alkaline battery for use in your FOCUS NMS device. Alkaline batteries are available at retail stores.

NOTE: Use only major brands. Carbon and mercury type batteries are usable, but will not last as long.

1. Unlatch the front panel cover by pressing on the bottom edge of the device. Pull the cover up toward you (Figure 3).

If you pull up too far on the cover, the cover will snap off the hinges. Snap the cover back on by aligning the hinges and pressing firmly.

If you attempt to change the battery without turning the device to OFF, the high amplitude shutdown will be activated and there will be no output until the device is turned OFF and ON again.

FOCUS™ NMS

Directions for Use

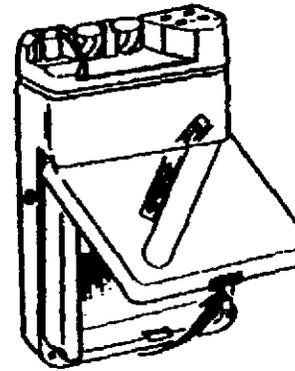


Figure 3. To open the front panel, press on the bottom edge of the device and pull the cover up toward you.

2. Remove the discharged battery from the unit by lifting the bottom of the battery and sliding it out of the battery compartment.
3. Place the new battery into the space provided (Figure 4). Be sure the terminals are in proper alignment.

Do not force the battery. If force is required, you may be putting the battery in backwards. Check the "+" and "-" markers.

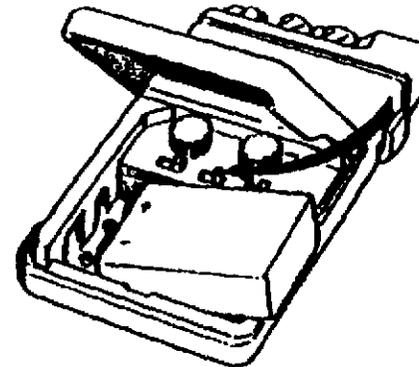


Figure 4. Place the battery in the compartment. Align the "+" and "-" marks on the battery with the labels in the battery compartment.

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Directions for Use **FOCUS™ NMS**

Using the Belt Clip

The FOCUS is supplied with a simple clip that will fit comfortably over a belt or pants top. The belt clip can be used to hold the device horizontally or vertically.

With the back of the stimulator facing you, insert one end of the clip onto the small slots located on either side of the stimulator just below the top control area. Snap the device into the belt clip. The device can be worn vertically or horizontally on a belt by slipping the belt between the belt clip and the device.

To remove the belt clip push it down the stimulator.

For Your Safety

Do NOT use the stimulator for conditions other than those for which the device was prescribed by your physician. The pain relieving capabilities of the FOCUS system could mask an injury or disease that requires professional treatment.

Do NOT use any electrodes or accessories with the system other than those obtained from, or recommended by, your clinician or Empl representative.

Do NOT use while bathing.

Do NOT use the stimulator while operating potentially dangerous equipment, such as automobiles, power lawn mowers, or large machinery.

Skin irritation and burns beneath electrodes have been reported with the use of TENS/NMS. The safety and efficacy of TENS/NMS depends on the proper use and handling of the device and accessories. Electrodes should not be left in place for long periods of time without checking or cleaning the skin underneath them. Electrode sites should be rotated with long term use when possible. During use, the electrodes and lead wires should be secured to prevent inadvertent detachment and potential shocks or burns. **DO NOT CONTINUE STIMULATION OVER IRRITATED SKIN.** Consult your clinician if any skin irritation or reaction develops at the electrode sites following use of the stimulator. Your clinician may recommend a different type of electrode.

FOCUS™ NMS Directions for Use

The use of heat- or cold-producing devices, such as electric blankets, heating pads, or ice packs, may adversely affect the electrode or your circulation. Consult with clinician before using these devices with stimulation.

Consult your clinician if there is any change in an existing condition or if any new condition develops.

Troubleshooting and Maintenance

Troubleshooting

If the FOCUS NMS device does not function, perform the following.

1. Check the battery for proper positioning. Only minimal force is required to insert the battery; if excessive force is necessary, the battery may be in backwards.
2. If unit appears to be functioning but there is no stimulation, try new leads or electrodes.
3. If the unit continues to be inoperable, return it to your local Empl representative. For assistance, call the Empl Repair Department, toll-free, at 800-328-2536. (In Minnesota 612-636-6600.)

Ⓐ A.A.A. Maintenance

The FOCUS stimulator is designed for minimal maintenance. To clean the stimulator, use a cloth moistened with a soap and water solution. **NEVER IMMENSE** the stimulator in water or other liquids.

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If there is no output, the unit may need to be turned off and reinserted due to high amplitude shutdown.

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Clinical Information

FOCUS™ NMS

Clinical Information

The Empr FOCUS is a dual channel NMS. Its features include:

- two independent intensity controls
- timed therapy sessions
- continuous or cycled stimulation
- three rates settings
- two waveforms
- eight ON settings
- eight OFF settings
- synchronous or alternate cycling of the two channels
- normal/high output switch (60 or 100 mA)
- eight preprogrammed regimens

Patient Selection and Precautions

Indications for use

Neuromuscular Stimulation (NMS) is indicated for:

- relaxation of muscle spasm
- prevention or retardation of disuse atrophy
- increasing local blood circulation
- muscle re-education
- prevention of venous thrombosis immediately after surgery
- maintaining or increasing range of motion

① Add

Transcutaneous Electrical Nerve Stimulation (TENS) is indicated for:

- symptomatic relief and management of chronic, intractable pain
- adjunctive treatment for post-surgical and post-trauma acute pain

Contraindications for use

TENS/NMS is contraindicated for patients with:

- undiagnosed pain (until the etiology is established)
- cardiac pacemakers (demand type)
- transcranial and/or carotid sinus electrode placement

In addition, NMS is contraindicated for electrode placement over malignant tumors or across the thoracic region.

② Add

FOCUS™ NMS

Clinical Information

Warnings

- Stimulation on or around the throat may cause potentially dangerous spasms of the larynx or changes in blood pressure.
- The safety of TENS/NMS for use during pregnancy or delivery has not been established.
- TENS is a symptomatic treatment with no known curative value and, as such, may suppress the sensation of pain that would otherwise serve as a protective mechanism.
- TENS has not been proven effective for pain of central origin.
- TENS devices should only be used under the medical supervision of a physician or referred clinician.
- Keep this device out of the reach of children.
- The use of TENS/NMS may interfere with electronic sensing such as ECG monitoring of patients.
- The effects of long-term chronic electrical stimulation are unknown.
- NMS should not be used on areas where there are symptoms of thrombosis, such as swelling, inflammation and pain.

Precautions

- The effectiveness and safety of TENS/NMS is dependent upon proper patient selection. Treatment outcome will be influenced by drug use and/or the patient's psychological state.

Special precautions should be taken when the following situations exist concurrently with NMS therapy:

- history of, or potential for, hemorrhage
- menstruation when electrode placement is over the abdomen
- post-surgery when muscle contraction may disrupt the healing process.
- sensory nerve damage or loss of normal skin sensation
- pre-existing conditions such as epilepsy or heart disease

1. stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide function of the foot and thus improve the patient's gait.

2. NMES is contraindicated for assisting paraplegic patients into the stance phase (standing).

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How ON and OFF Time is Determined

Synchronous Mode (S)

Both channels are identical. ON time begins after ramp up and ends when ramp down starts. OFF time begins after ramp down and ends before ramp up (Figure 6). ON and OFF times are set with the ON and OFF time setting controls.

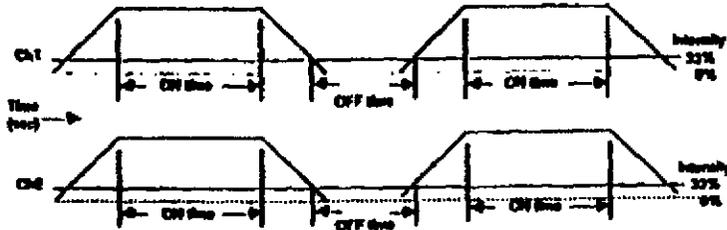


Figure 6. The output pattern for synchronous modes.

Alternate Mode (A)

For cases where ON time ≤ OFF time, alternate mode timing differs from synchronous mode timing only in that channel 2 is delayed from channel 1 by the set ON time (Figure 7).

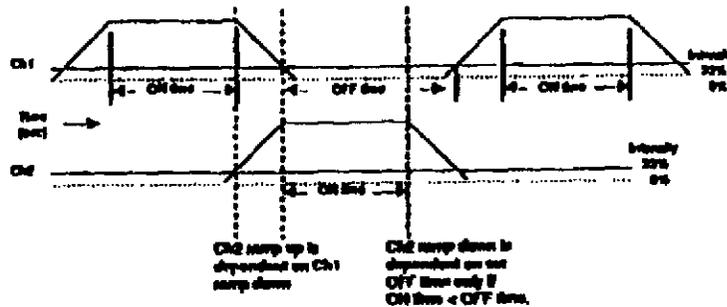


Figure 7. Alternate mode when ON time ≤ OFF time.

For cases where ON time > OFF time, channel 2 ON time is reduced in relation to the difference between the channel 1 ON and OFF time. Channel 2 ON time will equal channel 1 OFF time (Figure 8). However, even if channel 2 ON time is zero, both ramp up and ramp down will occur.

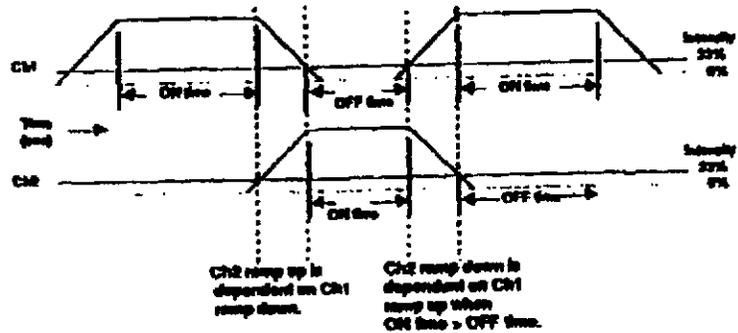


Figure 8. Alternate mode when ON time > OFF time.

NOTE: Figures 6, 7 and 8 are schematic diagrams and do not represent actual output.

The FOCUS NMS

The following are descriptions of the controls and switches on the FOCUS device. Be thoroughly familiar with these controls before using the device.

Channel Jacks

There are two Channel Jacks; one for channel 1, which is controlled by the channel 1 intensity control, and one jack for channel 2, which is controlled by the channel 2 intensity control (Figure 9) These channels are independently operated. If only one lead is used, insert the lead wire into the channel 1 jack.

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Clinical Information FOCUS™ NMS

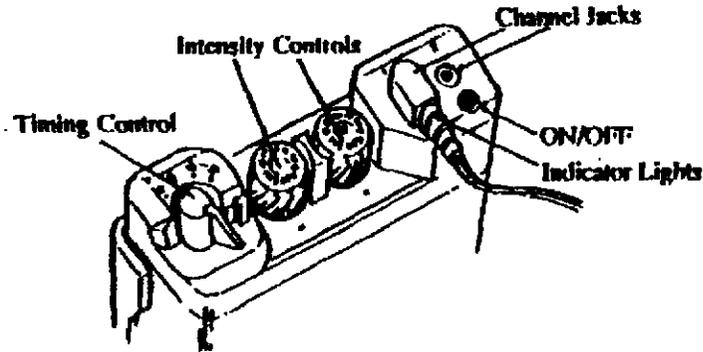


Figure 9. The top of the NMS device has the channel jacks, the ON/OFF indicator lights, the intensity control, and the timing control.

ON/OFF Indicator Lights

The ON/OFF indicator lights are located below their respective channel jacks (Figure 9). Whenever stimulation is being sent through a lead, the respective red indicator light will flash. The light will flash at the set rate of stimulation. (Above 35 pulses per second (pps) the flash will not be perceived by the human eye.)

When the battery reaches low voltage, both LEDs will flash at about 0.5 pps (significantly slower than the ON/OFF indicator light flashes). During use, if the battery reaches the power down threshold, the device will shut off. In addition, if the battery power is below the power up threshold, the device will not turn on.

Intensity Controls

The Channel 1 and Channel 2 Intensity Controls are used to turn their respective channels on and off and to adjust the intensity of the stimulation (Figure 9). Turning the intensity control clockwise activates the channel and increases the intensity of the stimulation. (Turning either control will turn the device on; both channels must be off for the device to be off.)

① Add

FOCUS™ NMS Clinical Information

Timing Control

The Timing Control, also located on the top panel of the device, allows the stimulation to be continuous (C), running according to the cycled program (N), or timed, running the cycled program for 15 or 30 minutes (Figure 9). If the timing control is set to 15 or 30, the device will shut down after the therapy time has elapsed. To restart the device, you must turn the intensity controls off and then on again. If the timing control is set to C or N, the device will continue until the intensity controls are shut off.

NOTE: Changing the timing control setting during therapy resets the timing to zero.

ON Time Setting Control/Preprogrammed Regimen Selection

The ON Time Setting Control allows the on times to be set at approximately 2.5, 5, 10, 15, 20, 25, 30 or 50 seconds when the cycling mode switch is set to S or A (Figure 10).

The ON time setting control is inactive if the timing control is set to continuous (C) or the cycling mode switch is set to preprogrammed regimen (P).

When the cycling mode switch is set to preprogrammed regimen (P), the ON time control allows you to choose among eight preprogrammed regimens. (See the "Preprogrammed Regimens" section.)

NOTE: When using preprogrammed regimen, ON time is predetermined within the regimen; OFF time is variable.

OFF Time Setting Control

The OFF Time Setting Control determines how long the stimulation will be off (Figure 10). The OFF time may be set to 0, 5, 10, 15, 20, 25, 30 or 50 seconds. When the cycling mode switch is set to alternate (A), channel 2's ON time will equal channel 1's OFF time if ON time ≥ OFF time. This also applies to preprogrammed regimens that use alternate timing, such as C and O.

The OFF time setting control is inactive if the timing control is set to continuous (C).

1. This device has a high amplitude shutdown feature which causes a no output situation. If the user attempts to increase the amplitude too quickly from OFF to ON or attempts to change the battery without turning the device OFF. To remedy this situation turn the device OFF and restart it.

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Clinical Information **FOCUS™ NMS**

NOTE: OFF time must be greater than ON time if the alternate (A) mode is selected to prevent channel 2 from curtailing its cycling mode.

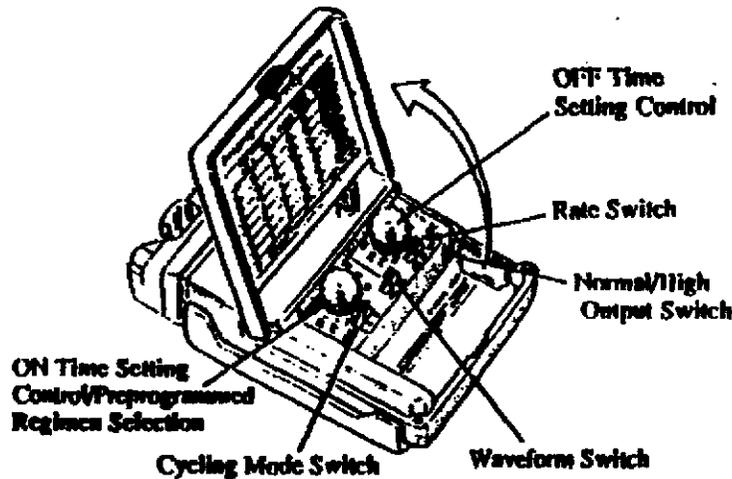


Figure 10. The ON and OFF time setting controls, cycling mode switch, waveform switch, rate switch and normal/high output switch are located under the front panel cover.

Cycling Mode Switch

The Cycling Mode Switch can be set to have the stimulation delivered on both channels synchronously (S) or alternating (A) (Figure 10). (See the "How ON and OFF Time is Determined" section.) This switch also allows the preprogrammed regimens (P) to be used. (See the "Preprogrammed Regimens" section.)

The cycling mode switch is inactive if the timing control is set to continuous (C).

FOCUS™ NMS **Clinical Information**

Waveform Switch

The Waveform Switch allows the pulse to be set as balanced asymmetrical biphasic or symmetrical biphasic (Figure 10).

NOTE: As a safety feature, changing the waveform switch setting while either channel is on will NOT change the waveform output.

To change the waveform, turn both intensity controls off, change the waveform switch position, and then turn the device back on.

Rate Switch

The Rate Switch allows the rate to be set at 25, 35 or 50 pps (Figure 10). The rate switch is inactive when the cycling mode is set to preprogrammed regimen (P), except when using regimen 11.

Normal/High Output Switch

Inside the battery compartment, on the upper right side, is a two position switch that allows the upper limit of the intensity to be adjusted from 60 mA (normal) to 100 mA (high output) (Figure 10). This is the Normal/High Output Switch.

Preprogrammed Regimens

When the cycling mode switch is set to preprogrammed regimen (P), the device enters the preprogrammed regimen mode. This allows the clinician to choose between eight preprogrammed regimens as shown in Table 1.

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Clinical Information

EXCUSSM NMS

Table 1. On the inside of the panel cover is the code identification table, as shown.

Preprogrammed Regimens

	Rate (pps)	Waveform	OFF time	Comments
A	12	9	35	Asym
B	12	5	45	Asym
C	10	10	60	Asym
D	4	4	30	Asym
E	10	10	60	Synchronous
F	5	5	30	Synchronous
G	5	5	35	Asym

(Channel 1 only) (Parameter Not Mandatory)
 - Parameter Not Mandatory
 (Parameter Not Mandatory)

The ON time setting control becomes the preprogrammed regimen selector when the cycling mode switch is set to P. The letter codes used in Table 1 correspond to the codes on the control. Table 2 gives the parameters for each of the regimens.

Table 2. The parameters for each of the regimens.

Regimen	Channel 1 (seconds)		Channel 2 (seconds)		Rate (pps)	Waveform (1)	OFF time	Comments	Mode		
	Up	ON Down	Up	ON Down							
A	3	12	2	7	9	1	35	SR	no set	Ch2 starts 3 s after Ch1	AMES
B	2	12	1	2	5	1	45	SR	no set	Ch2 starts 3 s after Ch1	AMES
C	3	10	2	3	10	2	60	SR	no set	channel alternate	TENS
D	2	4	2	1	4	2	30	AR	no set	Ch2 starts 2 s after Ch1	AMES
E	3	10	3	3	10	3	60	SB	no set	channel synchronous	TENS
F	3	5	2	3	5	2	35	AR	no set	channel synchronous	AMES
G	3	5	2	3	5	2	35	AR	no set	channel alternate	AMES
P	NA		NA				no set	(2)	NA	Ch1 triggered by remote switch	AMES

(1) AR = asymmetric of biphasic; SB = symmetric of biphasic (recommended setting)
 (2) waveform switch determines asymmetric of biphasic or symmetric of biphasic waveform for channel 1; channel 2 is the opposite of the selected waveform

EXCUSSM NMS

Clinical Information

Timing Control

Continuous (C)

When the timing control is in the Continuous (C) position, the remote switch can be used to turn the device on and off. All switches, except the rate and waveform switches, are inactive.

Normal Operation (N), Cycling Mode A or S

The cycling regimen will start from the beginning of ON time whenever the:

- power is turned on
- cycling mode is changed between A and S
- ON or OFF times are changed
- rate is changed
- timing control selection is changed
- waveform position is changed
- remote switch is turned on

Changing the remote switch operation will start/stop the device.

Normal Operation (N), Cycling Mode P

The preprogrammed regimen will start from the beginning of ON time whenever the:

- device is turned on
- OFF time is changed
- timing control selection is changed
- cycling mode is changed
- remote switch is turned on
- waveform position is changed
- selected regimen is changed

Changing the remote switch operation will start/stop the device.

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Clinical Information **FOCUS™ NMS**

15 or 30 Minute Positions

The device operates on its cycled programming, just as if the timing control is in the Normal operation (N) position, except:

- the device will run for 15 or 30 minutes and then turn off
- the remote switch is inoperative

Although the remote switch is inoperative, turning the remote switch on will reset the timing to zero, causing the therapy session to start over again.

Remote Switch

If the timing control is set at C or N, the Remote Switch can be used to turn the device on and off. If the timing control is set at 15 or 30, the remote switch is inactive. However, changing the remote switch position to ON will restart the therapy session.

The remote switch is also used in the preprogrammed regimen H to control which channel is active. When the remote switch is activated, the stimulation is delivered through channel 1.

Electrode Placement

When using NMS for the first time on a patient, set the timing control to Continuous (C). The stimulation will be sent through both channels constantly, allowing you to determine the best electrode placement and intensity setting.

Patients react differently to different electrodes. If a patient develops skin irritation, try a different electrode or electrode preparation.

When the electrodes have been placed, set the ON time, OFF time, cycling mode, rate, and waveform to the desired settings and then set the timing control to Normal operation (N). For timed therapy sessions, use the 15 minute or 30 minute setting.

FOCUS™ NMS **Technical Information**

Technical Information

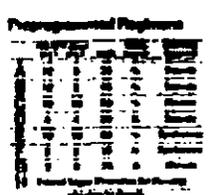
Physical Characteristics

Standard Conditions	23 °C ± 5 °C, 1000 Ohm load, 9.0 ± 3 percent supply voltage
Intensity	
Normal Output asymmetrical biphasic	0 to 60 mA
Normal Output symmetrical biphasic	0 to ± 60 mA (each phase)
High Output balanced asymmetrical biphasic	0 to 100 mA
High Output balanced symmetrical biphasic	0 to ± 100 mA (each phase)
Pulse Width	300 µs at 50% peak amplitude (Figures A and B)
Waveform	
balanced asymmetrical biphasic	zero net charge (Figures A, B, C, D, E)
symmetrical biphasic	zero net charge 0.8 ms delay between pulses (Figures A, D)
Maximum Charge per Pulse	40 µC into 500 Ohm load
Maximum Absolute Average Current	10 mA
Rate	25, 35, 50 Hz (Figure C)
Timing Control	continuous (C), normal operation (N), 15 min, 30 min
Output Isolation	> 10 ¹¹ Ohms
Remote Control Switch	normally closed (output is off)

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Technical Information **FIXUS™ NMS**

Conventional Cycling Modes	synchronous (S), alternating (A)
ON Time	2.5, 5, 10, 15, 20, 25, 30, 50 s
OFF Time	0, 5, 10, 15, 20, 25, 30, 50 s
Ramp Time	2 s up, 2 s down
Preprogrammed Regimens	<p>Preprogrammed Regimens</p> 
Cycling Modes	
S	Ch2 simultaneous with Ch1
A	Ch2 follows Ch1
P	Preprogrammed regimen format: ramp up (s), ON time (s), ramp down (s); channel cycling; rate (Hz)
A	Ch1 3, 12, 2; Ch2 2, 9, 1; Ch2 starts 3 s after Ch1; 35 Hz
B	Ch1 2, 12, 1; Ch2 2, 5, 1; Ch2 starts 5 s after Ch1; 45 Hz
C	both channels 3, 10, 2; channels alternate; 80 Hz
D	both channels 2, 4, 2; Ch2 starts 2 s after Ch1; 30 Hz
E	both channels 3, 10, 3; synchronous; 80 Hz

Ch2 ON time = Ch1 OFF time if ON time ≥ OFF time.
OFF time starts at end of ramp down. Ch2 ramp up starts at the beginning of
Ch1 ramp down time.

FIXUS™ NMS **Technical Information**

F	both channels 5, 5, 1.6; synchronous; 35 Hz
G	both channels 5, 5, 1.6; channels alternate; 35 Hz
H	n.a., n.a., n.a.; Ch2 on when Ch1 off; rate as selected; Ch1 waveform as selected; Ch2 waveform opposite; Ch1 triggered by remote switch

Power Information
Power source 9-volt alkaline battery

Low Voltage Indicator Threshold	6.0 V
Power Down Threshold	5.6 V
Power Up Threshold	5.6 V
LVI Flashing Rate	0.5 Hz

Expected Battery Life
Continuous mode, 60 mA setting,
asymmetrical biphasic, 35 Hz 8.0 hrs
Synchronous cycled mode,
5 s ON, 5 s OFF,
60 mA setting,
asymmetrical biphasic, 35 Hz 15.0 hrs

Mechanical Specifications
Dimensions (H x W x D) 9.1 cm x 6.35 cm x 2.1 cm
(3.6" x 2.5" x 0.83")

Weight 130 g (4.6 oz)

Environmental Conditions
Operational Temperature 0 °C to 50 °C
Storage Temperature -25 °C to 85 °C
Humidity (maximum) 90% at 40 °C

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Waveforms

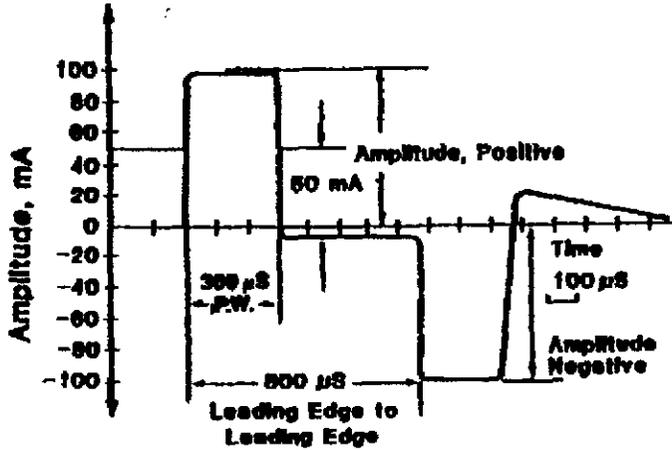


Figure A. Symmetrical Biphasic Waveform
Output current into 1K Ohm resistive load; maximum setting.

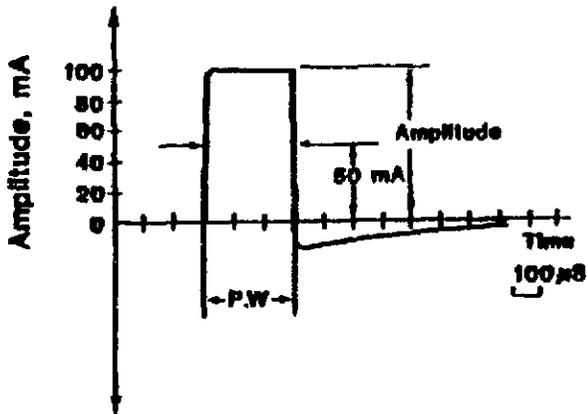


Figure B. Asymmetrical Biphasic Waveform (Balanced)
Output current into 1K Ohm resistive load; maximum setting.

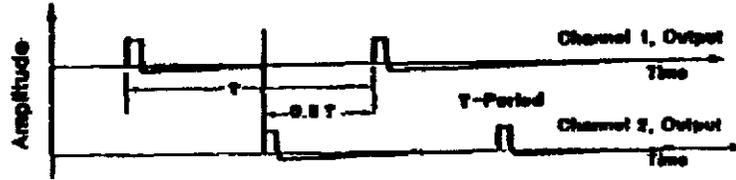


Figure C. Output Stimuli Relationship Between the Channels

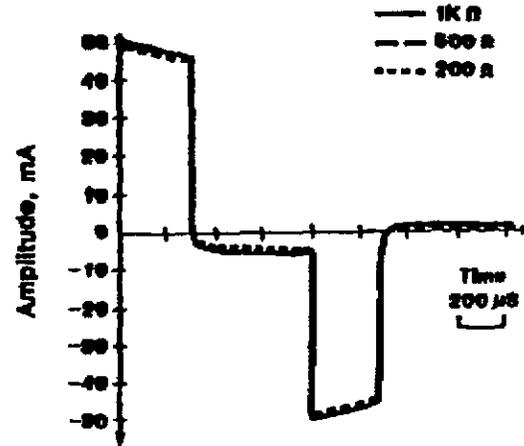


Figure D. Output Currents into AAMI Loads at 50% of Maximum Intensity Setting

Technical Information

FOCUS™ NMS

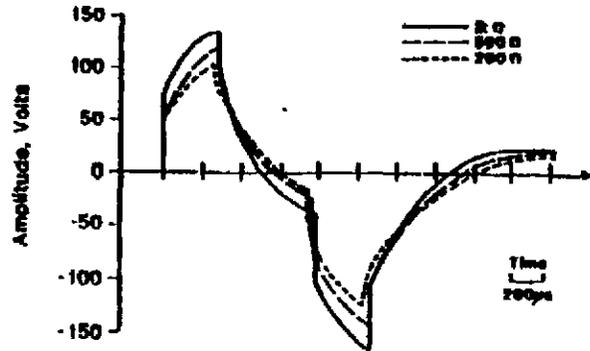


Figure E. Output Voltage into AAMI Loads at 50% of Maximum Intensity Setting

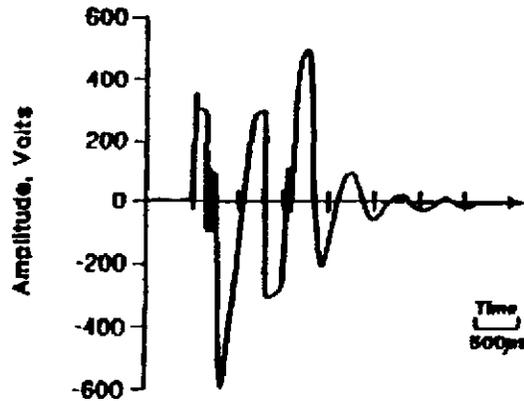


Figure F. Open Circuit, Half Intensity

Limited Warranty and Disclaimer

I. Warning

While, in the opinion of Empl, Inc. ("Empl"), the use of the FOCUS Neuromuscular Stimulation ("NMS") System (the "Product") has met with some success in the treatment of neuromuscular dysfunctions, Empl makes no warranties to the purchaser as to the effectiveness of the Product.

II. Warranty

A. Empl warrants to the initial purchaser ("Purchaser") (and to no other person) that the Product (with the exclusion of accessories such as chargers, rechargeable batteries, electrodes, lead wires, tape adhesive patches and electrode cream) and the component parts thereof, distributed or manufactured by Empl, shall be free from defects in workmanship and materials for three years after the date of purchase (the "Warranty Period").

B. Accessories including, but not limited to, chargers, rechargeable batteries, electrodes, lead wires, tape adhesive patches and electrode cream are excluded from the Warranty and are sold "AS IS" because their structure is such that they may be easily damaged before or during use.

III. Limitations of Liabilities and Disclaimer of Warranties

A. Empl's sole obligation in the case of any breach of its warranties set forth in Paragraph II(A) above, shall be, at Empl's option, to repair or replace the Product without charge to Purchaser or to refund the purchase price of the Product. In order to recover under this Warranty, Purchaser must send Empl written notice of the defect (setting forth the problem in reasonable detail) prior to expiration of the Warranty Period and within 30 days of discovery of the defect. Upon Empl's written request and authorization, Purchaser shall return the Product to Empl, freight and insurance prepaid, for inspection. Notice and return shipment shall be sent to Empl at 1275 Grey Fox Road, St. Paul, Minnesota 55112. Purchaser may request shipment approval by calling Empl Warranty Repair Department on its toll free number 1-800-328-2536. Empl will not be responsible for damage due to improper packaging or shipment. If Empl determines in its sole reasonable discretion that the Product contains defective workmanship or materials, Empl will refund to the Purchaser the purchase price for the defective Product or return the repaired Product or a replacement thereof to Purchaser, freight and insurance prepaid, as soon as

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reasonably possible following receipt of the Product by Empl. If Empl determines in its sole reasonable discretion that the Product does not contain defective workmanship or materials, Empl will return the Product to the Purchaser, freight and insurance billed to the Purchaser.

D. This Warranty is voided immediately as to any Product which has been repaired or modified by any person other than authorized employees or agents of Empl or which has been subjected to misuse, abuse, negligence, damage in transit, accident or neglect.

C. EXCEPT AS PROVIDED IN PARAGRAPH II(A), THE PRODUCT IS BEING SOLD ON AN "AS IS" BASIS, ALL ACCESSORIES ARE SOLD "AS IS", AND THE ENTIRE RISK AS TO THE QUALITY AND PERFORMANCE OF THE PRODUCT IS WITH PURCHASER. THE WARRANTY PROVIDED IN PARAGRAPH II(A) IS INTENDED SOLELY FOR THE BENEFIT OF THE INITIAL PURCHASER AND EMPL DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. PROVIDED, HOWEVER, THAT NOTWITHSTANDING THE FOREGOING SENTENCE, IN THE EVENT AN IMPLIED WARRANTY IS DETERMINED TO EXIST, THE PERIOD FOR PERFORMANCE BY EMPL THEREUNDER SHALL BE LIMITED TO THE LIFETIME OF THE INITIAL PURCHASER. NO EMPLOYEE, REPRESENTATIVE OR AGENT OF EMPL HAS ANY AUTHORITY TO BIND EMPL TO ANY AFFIRMATION, REPRESENTATION OR WARRANTY EXCEPT AS STATED IN THIS WRITTEN WARRANTY POLICY.

(This Warranty give Purchaser specific legal rights and Purchaser may also have other rights which vary from state to state. Some states do not allow limitations of how long an implied warranty lasts, so the above limitation may not apply to Purchaser.)

D. EMPL SHALL NOT BE LIABLE TO ANY PERSON FOR ANY DIRECT, INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, LOST PROFITS OR MEDICAL EXPENSES CAUSED BY ANY DEFECT, FAILURE, MALFUNCTION OR OTHERWISE OF THE PRODUCT, REGARDLESS OF THE FORM IN WHICH ANY LEGAL OR EQUITABLE ACTION MAY BE BROUGHT AGAINST EMPL (E.G., CONTRACT, NEGLIGENCE OR OTHERWISE). THE REMEDY PROVIDED IN PARAGRAPH II(A) HEREOF SHALL CONSTITUTE PURCHASER'S SOLE REMEDY. IN NO EVENT SHALL EMPL'S LIABILITY UNDER ANY CAUSE OF ACTION RELATING TO THE PRODUCT EXCEED THE PURCHASE PRICE OF THE PRODUCT.

(This Warranty give Purchaser specific legal rights and Purchaser may also have other rights which vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages so the above limitation may not apply to you.)

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APPENDIX E

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For best results with footswitch:

- Proper evaluation of weight bearing status is critical to determining best position for switch in shoe.
- Secure switch to shoe with tape.
- If stimulation program is not adequately controlled by the switch, try turning the switch upside-down in shoe to increase sensitivity.
- If insole of shoe is soft, taping a flat, hard surface (e.g., a quarter) under the switch will improve performance.

**FOCUS™
REMOTE SWITCH
FOR NMS
APPLICATIONS**

REMOTE HANDSWITCH

196710

REMOTE FOOTSWITCH

196887

Empl.

Empl, Inc.
1278 Gray Fox Road
St. Paul, Minnesota 55112
612-436-6600; 800-326-2638

360163 Rev B

Empl.

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INSTRUCTIONS

FOR FOCUS NMS REMOTE HANDSWITCH

Plug remote handswitch into connector located midway down the side of device.

Note: Make adjustments to amplitude only when stimulation is present.

When timing control (on top of FOCUS) is in the C position and amplitude control(s) is at desired level, output will be inhibited until the button is depressed. Continuous stimulation will occur at selected amplitude, rate and waveform when the button is depressed.

When timing control is in the N position, depressing the button will start the cycling program (including ramps) at the selected amplitude, rate and waveform and continue until the button is released. If a preprogrammed regimen is used, rate is preset and waveform is set manually.

When using preprogrammed regimen H, output on channels 1 and 2 alternate at the selected amplitude and rate when the button is depressed (channel 1 output) and released (channel 2 output.) Waveform on channel 1 is set by the waveform switch; channel 2 will produce the opposite waveform.

FOR FOCUS NMS REMOTE FOOTSWITCH

Plug remote footswitch into connector located midway down the side of device.

Note: Make adjustments to amplitude only when stimulation is present.

Place switch on the insole of the patient's shoe. While pressure (weight) is applied to the footswitch, stimulation will be inhibited. When weight is lifted off the switch, stimulation is initiated immediately. Output will cease when weight is reapplied to the footswitch.

When timing control (on top of FOCUS) is in the C position and amplitude control(s) is at desired level, output will be inhibited until weight is taken off the footswitch. Continuous stimulation will occur at selected amplitude, rate and waveform when pressure (weight) is lifted off.

When timing control is in the N position, taking weight off the switch will start the cycling program (including ramps) at the selected amplitude, rate and waveform, and continue until weight is reapplied. If a preprogrammed regimen is used, rate is preset and waveform is set manually.

When using preprogrammed regimen H, output on channels 1 and 2 alternate at the selected amplitude and rate when weight is released (channel 1 output) and reapplied (channel 2 output.) Waveform on channel 1 is set by the waveform switch; channel 2 will produce the opposite waveform.

CAUTION: Use of a footswitch may be inappropriate for some patients. A gait assist device may be contraindicated for patients with stance instability. Use only under the supervision of your clinician.

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APPENDIX F

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NeuroAid®

Self-Adhering Non-Sterile Reusable Electrodes for Neuromuscular and TENS Stimulation

1" x 6" 2/pack 56907794

- Large 1" x 6" Full Surface Stimulation
- Simple-To-Use Pin Connectors
- Needs No Tape Patches
- Reusable For Even Greater Cost-Effectiveness
- Trimmable For Best Placement

Empi.

Instructions for use

Caution: Be sure device is turned OFF before applying electrodes.

Application/Reapplication

1. Wash area with mild soap and water and dry prior to application.
2. Remove electrodes from pouch and insert lead wire connector pin into end of each electrode.
3. Peel electrodes from liner beginning at corner. Retain pouch and liner for electrode storage.
4. Apply electrode to stimulation site and hold in place for 10 seconds while applying slight pressure.

Note: Water content of the gel affects adhesion of these electrodes. For less adhesion or if gel has become soft and pliable — dry electrodes by exposing gel surface to air. For more adhesion, add a small amount of water to gel surface. Allow gel to absorb the water and become tacky before applying electrode to skin. Amount of moisture or time of drying required will vary according to skin type and climate.

Removal

1. Beginning at one corner, gently peel electrode from skin in direction of hair growth.
2. Grasp lead wire connector and withdraw from electrode. Do not pull directly on lead wire.

Storage

1. If electrode is too moist or dry, see Note above.
2. Place electrode on release liner and place in pouch. Reseal pouch and store at room temperature. Electrodes can be stored in refrigerator during warm weather.

Caution: If skin irritation, unusual sensation or pain develops during stimulation, remove electrodes and discontinue use. Consult your clinician.

Manufactured in U.S.A. for: Empi, Inc.
1275 Grey Fox Road
St. Paul, Minnesota 55112 USA
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home contact us practitioner login



combining medical technology
with physiology to optimise health

The Choice of Professionals

Why the Fenzian Treatment System™?

- Non-invasive technique
- Wide-range of clinical applications in mainstream medicine
- Enhances existing clinical and surgical treatments
- Maintenance vs. "Salvage" Medicine
- Cost Effective - meets the demands of increasing healthcare costs
- Individualised healthcare – treatment matches patient not label



News Headlines	Current Events
<p><u>Lois Pope Spinal Injuries Unit Pilot Study - 17/04/2003</u> 'Testing the Fenzian device on direct pain pathways'</p> <p><u>Northwick Park Pilot Study - 17/04/2003</u> 'The Fenzian Treatment System used to treat PMS.'</p>	

Fenzian Site Features

- The Fenzian System Educational Programme
- Find a Practitioner
- How to Apply
- Sports Medicine

News and Information

- Case Studies
- Newsletter
- Press Room
- Events
- FAQs

The Fenzian Success

The Fenzian Treatment System™ is an innovative development of electrical impulse techniques. Designed & built in the UK the treatment uses the latest microchip technology. The reliability of the "state-of-art" handheld device is matched only by its clinical efficiency.

Clinical Evidence

Over the last seven years this electrical impulse system has treated more than 1000 cases. This has already resulted in an independent retrospective analysis of 500 patients. The results are extremely encouraging and are to be published in mainstream medical literature. Medical evaluations and pilot studies are currently being conducted in the NHS.



The Clinical Team

Dr James Colthurst, MBBS; BSc; MBA; MFHom; FRCS heads the Fenzian Clinical Team. Dr Colthurst has extensive experience of electrical nerve impulse techniques. He is supported by Dr Antony Ashe, a London based general practitioner. Pam Giddings is the Training Manager responsible

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for the Fenzian Educational Programme™. Pam was a senior nurse and trainer in the UK National Health Service.

Government Sponsored

The Fenzian Treatment System™ - via its parent company - recently received a Smart Award from the Department of Trade and Industry. The grant was awarded after matching strict criteria for eligibility. The Fenzian system has undergone extensive investigation conducted by DTI appointed technology and medical experts.

 **Print this page**

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PATIENT MANUAL

**Bionicare® Stimulator
Model BIO-1000™**

**CAUTION:
FEDERAL LAW RESTRICTS THIS
DEVICE TO SALE BY OR ON
THE ORDER OF A PHYSICIAN**

**READ ALL INSTRUCTIONS PRIOR
TO USING THIS DEVICE**

Murray Electronics
260 Schilling Circle, Hunt Valley, MD 21031
(410) 771-0380 (Extension 231)

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PRESCRIBING INFORMATION

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

Indications

The Bionicare Stimulator System, Model BIO-1000 is indicated for use in relief of signs and symptoms of osteoarthritis of the knee based on scientific evidence from a multi-center, prospective, parallel, double-blinded, randomized, placebo device controlled clinical study that demonstrated significant improvement in the patient's self evaluation of pain and the physician's global evaluation of the active device treated knee. X

Contraindications

- Do not use the Bionicare Stimulator for any electrode placement that applies current to the carotid sinus (neck) region.
- Do not use the Bionicare Stimulator on patients who have a demand-type cardiac pacemaker.
- Do not use the Bionicare Stimulator for any electrode placement that causes current to flow transcranially (through the head).
- Do not use the Bionicare Stimulator whenever pain syndromes are undiagnosed, until etiology is established.

Warnings

- The safety of the Bionicare Stimulator for use during pregnancy or birth has not been established
- The Bionicare Stimulator is not effective for pain of central origin. (This includes headache.)
- The Bionicare Stimulator is a prescription device that should be used only under the continued supervision of a physician.
- The Bionicare Stimulator device has no curative value.
- The Bionicare Stimulator provides a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as protective mechanism.
- The user must keep the Bionicare Stimulator out of the reach of children.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when the Bionicare Stimulator is in use.
- The Bionicare Stimulator has not been tested for the potential effects of strong environmental magnetic or electric fields (electromagnetic interference). Such fields may interfere with the proper operation of the device. Therefore, discontinue using the device in any area where it does not appear to function normally.

Precautions

- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.

Adverse Reactions

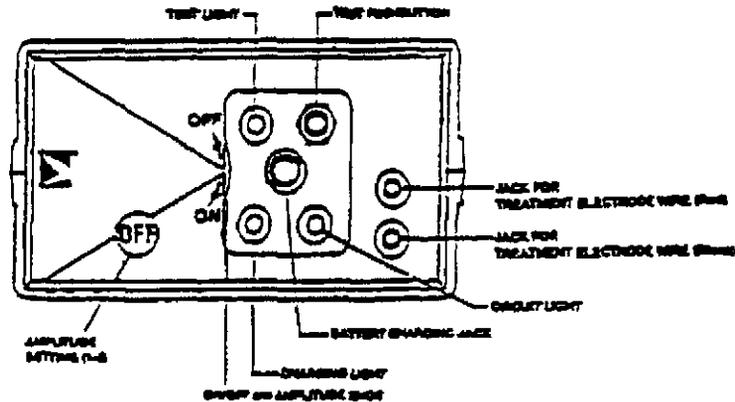
- Skin irritation and electrode burns are potential adverse reactions/patients with skin irritation should be monitored.

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STIMULATOR

Function

The stimulator produces a pulsed electrical signal with the negative electrode at the treatment site. It is portable, cordless, battery operated and rechargeable.



Features

On/off/amplitude - The amplitude knob turns the unit on, off, and sets the appropriate amplitude. Full rotation counter-clockwise turns the stimulator off. (Read "OFF" in the circular window at the lower left of the front panel.) Clockwise rotation of the knob turns the unit on to display the amplitude setting 1, 2, 3, 4...8. Eight is the highest amplitude setting (the greatest energy output.) The amplitude is set to a comfortable level as described by your physician. Be sure the unit remains "OFF" until electrodes are secured. Turn unit to "OFF" before recharging batteries or when stimulator is not in use to avoid electrical hazards.

Test Light - The test light will come on momentarily when both the test pushbutton is pressed and the amplitude knob has been turned on in the range of 2-½ through 8. The operator is then able to "see" and note the presence of the output from the stimulator within its voltage range. If the light does not come on within this range, refer to recharging section below. The test light becomes dim and goes out as the amplitude knob is adjusted below 2-½, thus indicating a decreasing amplitude range. If, however, the light does not diminish below 2-½, the unit is out of calibration and should not be used.

The amplitude setting will vary between patients based on their individual tolerances and the specific recommendations of your physician. Turn off the stimulator after each use.

Circuit Light - The circuit light comes on automatically to indicate the presence of current when the stimulator is operating with the electrodes in place on the knee and thigh.

Battery charging jack/charging light/charging - The stimulator operates on rechargeable batteries that are self contained within the stimulator. The batteries may be recharged hundreds of times. The batteries should be recharged for fourteen hours when the stimulator is first received, when it has been stored for longer than two weeks or after at least eight hours of cumulative stimulator use. Best charging occurs at room temperatures between 50° and 100° F.

Recharging BEFORE at least 8 cumulative hours of use may require increasingly higher amplitude settings for the test light to be activated.

Prior to starting the charge, turn the stimulator off. With the small plug from the battery charger fully inserted into the battery charging jack on the stimulator, plug the main charger body into an appropriate wall outlet (120 Volts/60 Hertz). The charging light will come on indicating that the unit is in the battery charging mode. DO NOT plug charger into the wall outlet first. DO NOT use the stimulator for treatment when the charger is connected.

If the charging light fails to operate, move the charger to another wall outlet and observe the charging light. Disconnect the charger when the charging light fails to operate and return it to the factory for repair or replacement.

Do **NOT** use the stimulator for treatment purposes when the battery charger is connected.
Do **NOT** use other chargers with the stimulator.

Care and Cleaning

The case of the stimulator may be cleaned with a cloth and cotton swab. Do not use liquids for cleaning; the stimulator is not waterproof. The stimulator should not be opened because it has no operator serviceable components. The stimulator should be turned "OFF" when not in use. Always store in a clean, dry place between 0° and 110° F.

SPECIFICATIONS - MODEL BIO-1000	
Output Voltage	0-12 volts, spike shaped pulses (nominally constant voltage)
Output Frequency	100 Hertz
Polarity	Negative electrical signal at the treatment electrode.
Electrical Requirements	Portable-cordless operation with self-contained 12 volt rechargeable nickel-cadmium battery pack (battery charger supplied with the stimulator operates on 120 volt/60 Hz input). DO NOT use other chargers with the stimulator.
Dimensions	13.2 cm x 8.5 cm x 4.5 cm
Weight	450 grams (includes battery)
Knee Electrode (cathode)	16 cm x 11 cm silver coated nylon fabric
Thigh Electrode (anode)	17 cm x 10 cm stainless steel fabric

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OPERATION

Operation Instructions: Each patient operator should read and become completely familiar with all of the instructions in the Patient Manual prior to using the Bionicare Stimulator. Special attention should be given to the sections on "CONTRAINDICATIONS", "WARNINGS", "PRECAUTIONS" AND "ADVERSE REACTIONS" listed on page 2. It is recommended that you become familiar with the capabilities of the stimulator by determining your comfort tolerance for voltage amplitude during your physician visit. Treatment times and amplitude setting procedure will be specified by your physician. This is a prescription device and must not be used by others.

Battery Charging: The stimulator contains rechargeable nickel-cadmium batteries that should be fully charged when the stimulator is first used and after each 8 to 10 hours of use to assure proper function. Additionally, the stimulator batteries must be charged for 10 to 14 hours prior to using the stimulator when it has been stored or not used for an extended period. The test light is used to confirm that the stimulator is ready for use after charging the batteries by following the procedures under Features-Test Light. Using the stimulator when the batteries are not fully charged will reduce the maximum available output amplitude until the stimulator is recharged.

Stimulator Preparation: The stimulator must be disconnected from the battery charger and must remain turned off until the following electrode placement procedure has been completed.

Electrode Placement - Stimulator Use: Special sets of electrodes are supplied to treat the knee. Your physician will instruct you in the application of electrode gel and the placement and use of these electrodes on your knee and leg (thigh). DO NOT use these electrodes for any other treatment or location. Refer to the diagram of "ELECTRODE POSITION FOR KNEE TREATMENT" on page 7.

The amplitude control should be set to the "OFF" position prior to placing the electrodes on your knee and thigh. After the gel and electrodes are in place and all connections and adjustments have been checked, the amplitude control is turned on and slowly adjusted to your tolerance and level of comfort as specified by your physician.

The factors for tolerance and level of comfort will vary among patients and over time for a single patient. It is therefore important that the above procedure be carefully repeated for each treatment. You should never be subjected to any discomfort. Your physician will instruct you on the specifics of your individual setting for the voltage amplitude as well as the number of hours for your daily treatments. You should discontinue your treatment and consult your physician if there is any adverse change in your condition or if any new condition develops. The stimulator should be turned off after each treatment.

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SKIN CARE

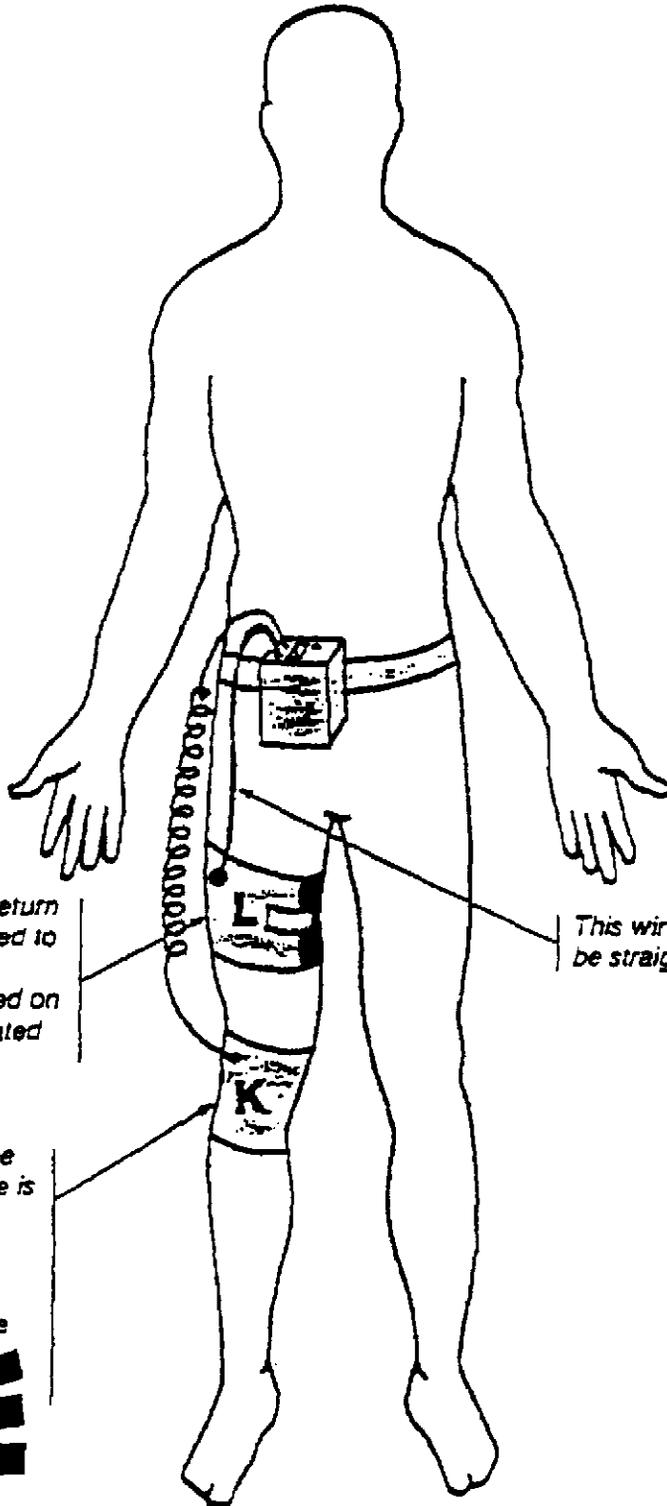
It is recommended that the area of skin on the knee and thigh where the electrodes are placed be thoroughly washed with water and a mild soap and dried prior to applying electrode gel and the electrodes. When the treatment is complete turn the stimulator off and immediately remove the electrodes. Do not leave the electrodes on between treatments. At the end of each treatment clean the skin with water and mild soap. Your physician may suggest a protective skin preparation for use between treatments. If you develop a rash or skin irritation discontinue your treatments and contact your physician. Resume treatment when the rash has disappeared and on the advice of your physician.

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Bionicare Bio1000

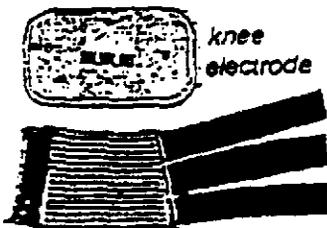
ELECTRODE POSITION FOR KNEE TREATMENT



The RED snap on the return electrode wire is attached to leg electrode (L). This electrode must be placed on the same leg as the treated knee.

This wire with red snap may be straight or coiled.

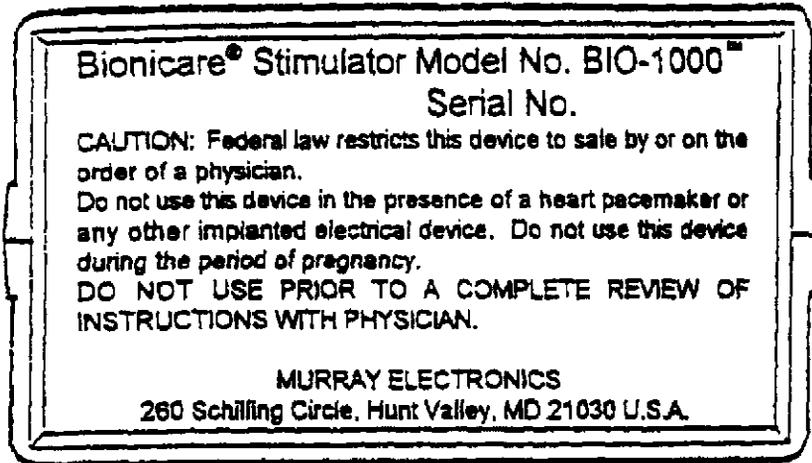
The BLACK snap on the treatment electrode wire is attached to the knee electrode (K).



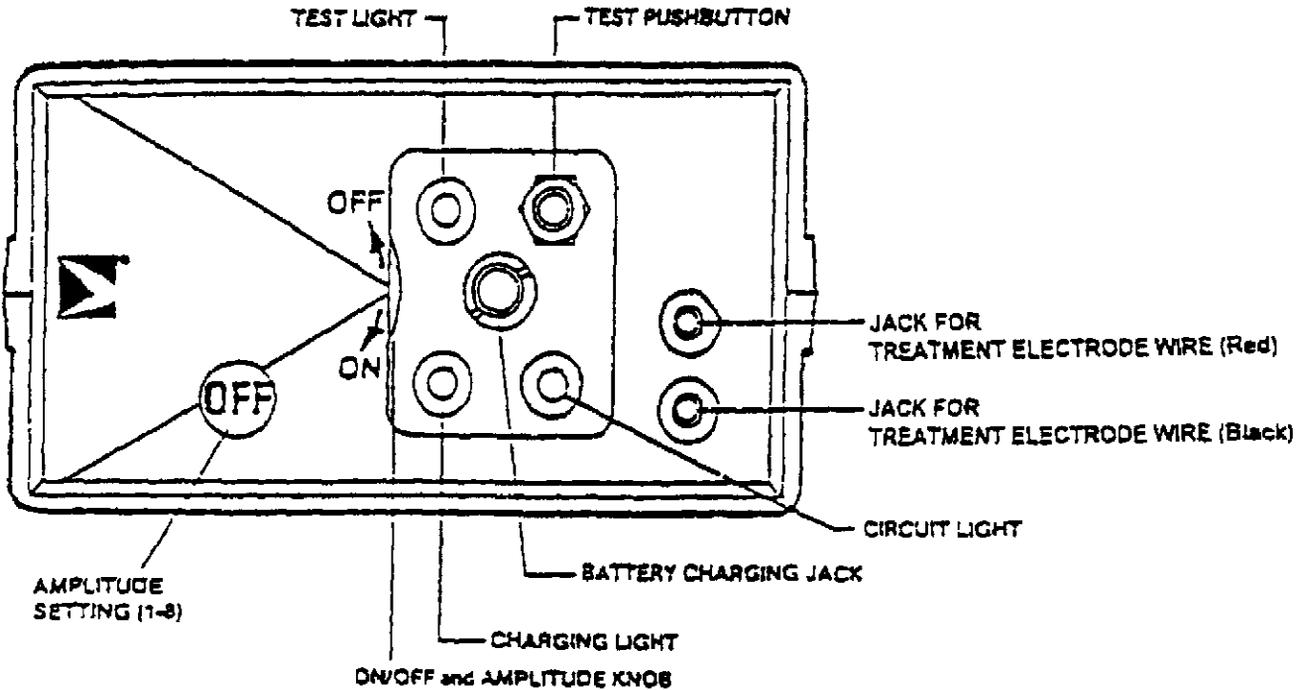
Adjustable knee strap holds knee electrode in place.

Electrodes approximate scale

BACK PANEL



FRONT CONTROL PANEL



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ACCESSORIES LIST

BIONICARE® STIMULATOR, MODEL BIO-1000™

<u>PART DESCRIPTION</u>	<u>PART NUMBER</u>
Knee Treatment Electrode	1000-005
Knee Treatment Electrode Wire	1000-006
Leg Return Electrode	1000-007
Leg Return Electrode Wire	1000-008
Holding Strap, Small	1000-009
Electrode Gel	1000-011
Battery Charger	1000-012
Patient Manual	1000-013

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SERVICE

Instructions for returning the stimulator and/or accessories can be obtained by writing to Murray Electronics, 260 Schilling Circle, Hunt Valley, MD 21030 U.S.A., telephone (410) 771-0380 (Extension 231).

The serial number, model number and a description of the problem should be included along with your name, address, and telephone number. This stimulator contains no user serviceable parts and must be returned to Murray Electronics or its representatives for service, repair or calibration at its factory.

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NOTES

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MODEL NUMBER	<u>BIO-1000</u>
SERIAL NUMBER	_____
DATE	_____
NAME	_____

(Retain this manual)

REORDER PATIENT MANUAL
PART NUMBER 1000-013

FORM 031897

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PHYSICIAN INFORMATION MANUAL

**Bionicare[®] Stimulator
Model BIO-1000[™]**

**CAUTION:
FEDERAL LAW RESTRICTS THIS
DEVICE TO SALE BY OR ON
THE ORDER OF A PHYSICIAN**

Murray Electronics
260 Schilling Circle, Hunt Valley, MD 21031
(410) 771-0380 (Extension 231)

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PRESCRIBING INFORMATION

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

Indications

The Bionicare Stimulator System, Model BIO-1000 is indicated for use in relief of signs and symptoms of osteoarthritis of the knee based on scientific evidence from a multi-center, prospective, parallel, double-blinded, randomized, placebo device controlled clinical study that demonstrated significant improvement in the patient's self evaluation of pain and the physician's global evaluation of the active device treated knee.

Contraindications

- Do not use the Bionicare Stimulator for any electrode placement that applies current to the carotid sinus (neck) region.
- Do not use the Bionicare Stimulator on patients who have a demand-type cardiac pacemaker.
- Do not use the Bionicare Stimulator for any electrode placement that causes current to flow transcerebrally (through the head).
- Do not use the Bionicare Stimulator whenever pain syndromes are undiagnosed, until etiology is established.

Warnings

- The safety of the Bionicare Stimulator for use during pregnancy or birth has not been established
- The Bionicare Stimulator is not effective for pain of central origin. (This includes headache.)
- The Bionicare Stimulator is a prescription device that should be used only under the continued supervision of a physician.
- The Bionicare Stimulator device has no curative value.
- The Bionicare Stimulator provides a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as protective mechanism.
- The user must keep the Bionicare Stimulator out of the reach of children.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when the Bionicare Stimulator is in use.
- The Bionicare Stimulator has not been tested for the potential effects of strong environmental magnetic or electric fields (electromagnetic interference). Such fields may interfere with the proper operation of the device. Therefore, discontinue using the device in any area where it does not appear to function normally.

Precautions

- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.

Adverse Reactions

- Skin irritation and electrode burns are potential adverse reactions/patients with skin irritation should be monitored.

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CLINICAL STUDY SUMMARY

Clinical Study of the Bionicare Stimulator System, Model BIO-1000, Used to Treat Osteoarthritis of the Knee:

Study Design/Patient Selection: Patients with osteoarthritis of the knee were enrolled in a multi-center, prospective, parallel, double-blinded, randomized, placebo device controlled clinical study to test the safety and effectiveness of the Bionicare Stimulator System, Model BIO-1000 as it is used to treat the signs and symptoms of osteoarthritis. All study subjects were required to be over the age of 20 years, to meet the inclusion and exclusion criteria described below and to sign the informed consent form for the study. Background, stable NSAID therapy was permitted as long as patients remained symptomatic despite such therapy.

Inclusion Criteria: The diagnosis of osteoarthritis was confirmed by fulfillment of the following criteria: (1) pain in the involved knee that was aggravated by activity and relieved by rest; (2) morning stiffness upon rising or after disuse; (3) at least one physical finding of joint crepitus, tenderness upon motion, swelling, or decreased range of motion; (4) the presence of at least one of the following radiological findings in the involved knee: narrowing of the joint space of either the medial or lateral compartment on standing anteroposterior radiograph, subchondral bony sclerosis, or osteophyte formation.

Exclusion Criteria: Patients were excluded from the study for other conditions, such as aseptic necrosis of the femoral condyle, juxtaarticular Paget's disease, chondrocalcinosis, hemochromatosis, ochronosis, hemophilic arthropathy, inflammatory arthropathy (such as rheumatoid arthritis, ankylosing spondylitis, or psoriatic arthritis), infectious arthritis, Charcot's knee joint, villonodular tenosynovitis, and synovial chondromatosis. Patients with heart pacemakers or other implanted electrical devices; patients who were pregnant; patients who were nursing; and patients who were immediately post-surgical were excluded from the study.

Study Period: The study interval was eight weeks, the first two weeks served as a pretreatment baseline period during which the patient was seen twice by the investigator to obtain baseline measurements and data. Patients were randomized to receive an active device or an identical appearing placebo device that was used for the next four weeks. Safety and efficacy data was recorded for each weekly visit during this period and also at the first, second and twentieth post treatment weeks. The primary reason for these follow-up visits was to look for post-treatment adverse reactions.

Study Device: The study device, the Bionicare Stimulator System, Model BIO-1000, is a portable battery operated stimulator with a 0-12 volt regulated output producing monophasic spike-shaped pulses (exponential time decay) repeating at a fixed frequency of 100 Hertz. The output of the stimulator is non-invasively coupled to the skin surface using conductive electrode gel and electrodes applied to the knee and thigh. Patients were instructed to activate the stimulator by pressing a setup switch while adjusting the output amplitude upward until an electrical sensation was just felt and then reducing this slightly until the sensation disappeared. The placebo device operated the same except that the output was disconnected automatically after the setup procedure. The patients were instructed to use the stimulator daily for six to ten hours for the duration of the study period. Compliance was monitored with a tamper-proof concealed timer that was read by the investigator and recorded on each weekly study visit form.

Efficacy Assessments: Clinical data for efficacy assessments was recorded on separate physician and patient evaluation forms at each scheduled study visit as described above. The primary outcome measures in this osteoarthritis study that included the physician's global evaluation of the treated knee, the patient's evaluation of pain in the treated knee and the patient's evaluation of function of the treated knee were each recorded on standard horizontal visual analog scales. The secondary measures included joint tenderness and swelling recorded on Likert scales, circumference of the knee, range of motion (flexion and extension), morning stiffness, an activities of daily living score and 50 foot walking time.

Statistical Procedures: Comparisons of demographic characteristics such as age, weight, height, body mass index, sex and baseline disease status between the active and placebo treatment groups and among centers were performed using standard statistical procedures

For outcome measures, scores from the two baseline visits were averaged to derive a baseline score. In addition to raw scores collected at weekly visits, improvement in scores from the baseline and percent improvement from the baseline were determined for each of the four weeks under Bionicare treatment.

The treatment effect for continuous outcome measures was assessed using mixed linear models¹ incorporating repeated measures of the outcome measures corresponding to the four weeks of Bionicare treatment. Discrete outcome measures such as those recorded on Likert scales were

¹ Recommended by the FDA document "Discussion for Designing Clinical Programs for Developing Drugs, Devices or Biological Products Intended for the Treatment of Rheumatoid Arthritis" that was issued on July 23, 1996 following the Rheumatoid Arthritis Outcome Measures Workshop which took place on March 27, 1996, and also used by FDA as the standard statistical procedure for analyzing repeated measured clinical data including the FDA's analysis of PMA data submitted by two companies whose osteoarthritis treatment devices were reviewed at the Orthopaedic and Rehabilitation Device panel meeting on November 20-21, 1996.

analyzed using Generalized Estimating Equations (GEE) that incorporated repeated measures.

For clinical evaluation, three important subgroups were defined in addition to the traditional intent-to-treat population as follows:

- Group A: Intent-to-treat, full patient population.
- Group B: Completers, those who completed the treatment period.
- Group C: Time compliant completers - those completers who used the device at least six hours daily per protocol.
- Group D: Stable NSAIDs completers - those completers who maintained the constant level of background NSAIDs throughout the study.

Two sided t-tests were used in testing the treatment main effect. A p-value of 0.05 or less was considered significant.

Results: Seventy-eight patients that fulfilled the entry criteria and signed informed consent at five study centers were randomized to receive either an active device (N=41) or a placebo device (N=37). Those patients who did not complete the study included two on the active device (1 mild rash, 1 unrelated asthma) and four on the placebo device (2 found the study was too much trouble, 1 mild rash, 1 did not return). No significant difference was found for the dropout rate between the active and placebo device groups (p=0.33). There were no significant baseline differences for demographics, osteoarthritis outcome measures and concomitant medication use between the active and the placebo groups, and this was consistent for all four study groups.

Results - Clinical Outcome Measures: The results of the analysis for the clinical outcome measures are provided for the seventy-eight patients in Group A, and the seventy-two completers in Group B. The results also include the subgroup of fifty-three time compliant completers in Group C, and the subgroup of sixty-one stable NSAIDs completers in Group D.

Significant findings in favor of the active Bionicare[®] treatment were consistently found in two of the three primary clinical outcome measures for each of the four study groups described above. These outcomes that demonstrated effectiveness of the Bionicare[®] Stimulator were the physician's global evaluation of the treated knee and the patient's evaluation of pain in the treated knee, measured in the raw visual analog scales, the improvement from the baseline and the percent improvement from the baseline. The improvement in the patient's evaluation of function of the treated knee was not statistically significant. The following four tables summarize the findings for the primary outcome measures.

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**Table 1. Efficacy Analysis of Primary Outcome Measures
Group A: Intent-to-Treat (N=78)**

Primary Outcome Measure	Week	Raw VAS Scores			Improvement from Baseline			% Improvement		
		AE	Pla	p	AE	Pla	p	AE	Pla	p
Physician's Global Evaluation - Treated Knee (VAS)	Base	5.68	5.55	0.023*	-	-	0.023*	-	-	0.055
	3	4.34	4.35		1.34	1.11		22.00	18.11	
	4	3.90	4.32		1.83	1.14		29.28	17.14	
	5	3.50	4.15		2.25	1.33		38.06	22.97	
	6	3.73	4.13		2.14	1.37		35.09	24.43	
Patient's Evaluation of Pain - Treated Knee (VAS)	Base	6.21	6.03	0.033*	-	-	0.033*	-	-	0.004*
	3	4.90	5.00		1.30	0.95		20.96	11.82	
	4	4.69	4.66		1.59	1.29		25.05	18.85	
	5	4.53	4.91		1.75	1.20		29.45	16.64	
	6	4.36	4.73		1.99	1.25		31.01	19.52	
Patient's Evaluation of Function - Treated Knee (VAS)	Base	6.07	6.35	0.178	-	-	0.178	-	-	0.152
	3	4.66	4.82		1.41	1.35		21.88	22.30	
	4	4.67	4.72		1.46	1.45		23.46	20.57	
	5	4.48	4.79		1.68	1.42		26.79	20.40	
	6	4.40	4.58		1.76	1.67		27.80	24.98	

*statistically significant, p-value based on the t-test

**Table 2. Efficacy Analysis of Primary Outcome Measures
Group B: Completers (N=72)**

Primary Outcome Measure	Week	Raw VAS Scores			Improvement from Baseline			% Improvement		
		AE	Pla	p	AE	Pla	p	AE	Pla	p
Physician's Global Evaluation - Treated Knee (VAS)	Base	5.79	5.48	0.008*	-	-	0.008*	-	-	0.021*
	3	4.41	4.42		1.38	1.05		22.27	16.84	
	4	3.89	4.36		1.88	1.11		30.05	16.45	
	5	3.51	4.15		2.28	1.33		38.40	22.97	
	6	3.73	4.13		2.14	1.37		35.09	24.43	
Patient's Evaluation of Pain - Treated Knee (VAS)	Base	6.33	5.98	0.037*	-	-	0.037*	-	-	0.007*
	3	5.05	5.03		1.28	0.95		19.66	11.57	
	4	4.76	4.80		1.58	1.17		24.41	16.39	
	5	4.59	4.91		1.74	1.20		28.92	16.64	
	6	4.36	4.73		1.99	1.25		31.01	19.52	
Patient's Evaluation of Function - Treated Knee (VAS)	Base	6.22	6.33	0.177	-	-	0.177	-	-	0.193
	3	4.76	4.91		1.46	1.30		22.27	21.22	
	4	4.74	4.68		1.46	1.53		22.95	21.84	
	5	4.54	4.79		1.68	1.42		26.38	20.40	
	6	4.40	4.58		1.76	1.67		27.80	24.98	

*statistically significant, p-value based on the t-test

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**Table 3. Efficacy Analysis of Primary Outcome Measures
Group C: Time Compliant Completers (N=53)**

Primary Outcome Measure	Week	Raw VAS Scores			Improvement from Baseline			% Improvement		
		Act	Pla	p	Act	Pla	p	Act	Pla	p
Physician's Global Evaluation - Treated Knee (VAS)	Base	5.80	5.06	<0.001*	-	-	<0.001*	-	-	<0.001*
	3	4.44	4.19		1.36	0.87		22.21	14.96	
	4	3.81	4.43		1.97	0.63		31.55	8.85	
	5	3.50	4.00		2.30	1.06		38.42	21.99	
	6	3.60	4.10		2.28	0.96		37.47	20.38	
Patient's Evaluation of Pain - Treated Knee (VAS)	Base	6.54	5.55	0.013*	-	-	0.013*	-	-	0.004*
	3	5.06	4.62		1.28	0.93		19.34	10.70	
	4	4.89	4.45		1.45	1.10		22.51	15.88	
	5	4.41	4.95		1.94	0.78		31.63	12.52	
	6	4.15	4.55		2.22	1.00		34.13	16.49	
Patient's Evaluation of Function - Treated Knee (VAS)	Base	6.20	6.14	0.029	-	-	0.029	-	-	0.062
	3	4.84	4.62		1.35	1.34		20.52	22.03	
	4	4.68	4.88		1.49	1.06		23.32	15.24	
	5	4.41	4.90		1.79	1.04		27.83	16.82	
	6	4.77	4.55		1.86	1.46		30.40	23.57	

*statistically significant, p-value based on the t-test

**Table 4. Efficacy Analysis of Primary Outcome Measures
Group D: Stable NSAIDs Completers (N=61)**

Primary Outcome Measure	Week	Raw VAS Scores			Improvement from Baseline			% Improvement		
		Act	Pla	p	Act	Pla	p	Act	Pla	p
Physician's Global Evaluation - Treated Knee (VAS)	Base	5.75	5.23	0.007*	-	-	0.007*	-	-	0.060
	3	4.50	4.33		1.25	0.90		20.03	15.80	
	4	3.94	4.13		1.79	1.08		28.12	17.60	
	5	3.50	3.96		2.25	1.27		37.13	25.66	
	6	3.70	3.96		2.12	1.27		34.44	23.34	
Patient's Evaluation of Pain - Treated Knee (VAS)	Base	6.24	5.97	0.002*	-	-	0.002*	-	-	<0.001*
	3	5.03	5.04		1.21	0.94		18.44	12.41	
	4	4.75	4.76		1.49	1.21		23.19	17.82	
	5	4.44	5.15		1.79	0.97		29.19	14.08	
	6	4.14	4.81		2.11	1.16		32.21	16.91	
Patient's Evaluation of Function - Treated Knee (VAS)	Base	6.13	6.23	0.015*	-	-	0.015*	-	-	0.023*
	3	4.88	4.93		1.25	1.25		19.20	20.43	
	4	4.64	4.61		1.47	1.58		22.69	23.17	
	5	4.41	4.96		1.72	1.21		26.41	17.32	
	6	4.77	4.63		1.84	1.60		28.74	22.41	

*statistically significant, p-value based on the t-test

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The analysis of the secondary efficacy measures that included joint tenderness and swelling (Likert scales), circumference of the knee, range of motion (flexion and extension), morning stiffness, an activities of daily living score and 50 foot walking time did not reveal any consistently significant trends. There were favorable trends for the active device group for morning stiffness of the treated knee, knee tenderness and knee circumference. The results for knee swelling, knee flexion and knee extension did not demonstrate any apparent trends. Unfavorable but not statistically significant trends were observed for the activities of daily living (ADL) score and 50 foot walking time, the two outcome measures that involved multiple joints. A single joint treatment modality such as the Bionicare stimulator would not be expected to be effective in this case since both outcome measures involved a number of untreated joints that included the opposite knee, the hips, the ankles and the feet.

Adverse Event Analysis: There were no reports of unanticipated adverse events for patients in this study. Prior to commencing the study it was anticipated that skin rash was the only known potential side effect and the patients consent form included a statement to that effect. It has been widely documented in the literature that this type of skin rash is the consequence of extended skin contact with electrode gel. In the study of osteoarthritis of the knee, about 39% of the active patients and 27% of the placebo patients reported transient skin rashes. The slightly higher rate in the active group was not significantly different than that of the placebo group and this can be explained by the fact that the active group demonstrated more time use of the device, thus longer skin contact with the electrode gel.

The duration of the rashes ranged from a few days to a few weeks. The severity of the rash was mild and the rash disappeared after patients changed to a different type of electrode gel and/or temporarily stopped the treatment. Two patients prematurely terminated the study as the result of rash.

Conclusion: The findings of this multi-center, prospective, parallel, double-blinded, randomized, placebo device controlled study demonstrate that the Bionicare Stimulator when used daily is safe and effective in the treatment of the signs and symptoms of osteoarthritis of the knee. These findings are:

Safety: There were no reports of unanticipated adverse effects in this study. As anticipated, skin rash appeared in both the active and placebo device group, 39% and 27% respectively. The rash was transient and completely resolved after stopping or changing the electrode gel. The rash appears to be due to the sustained use of the electrode gel. The observed frequency of skin reactions

reported herein appear similar to those reported in the literature for studies of TENS and muscle stimulator devices using comparable gels. Propylene glycol, a common ingredient in approved gels, is a skin irritant that may be in part the cause of these reactions.

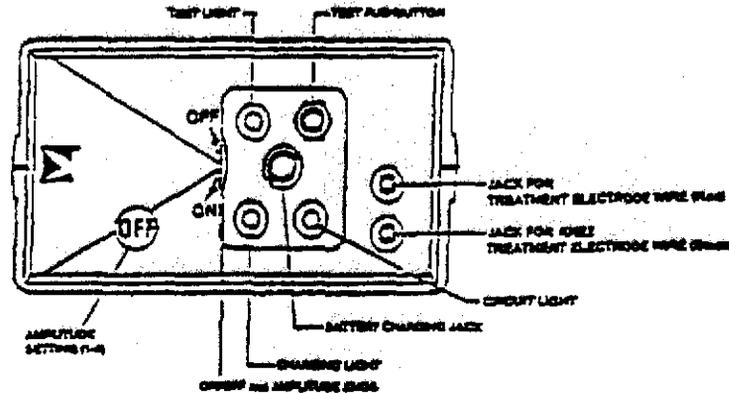
Effectiveness: Daily treatment with the Bionicare stimulator resulted in a clinically relevant and statistically significant reduction in the signs and symptoms in the knees of patients affected by osteoarthritis. The repeated measures analysis of the primary clinical outcome data collected in this study demonstrates significant improvements in the Bionicare active device group compared to the placebo device group for the physician's global evaluation of the treated knee and the patient's evaluation of pain in the treated knee. The significant improvements for these clinical outcomes are demonstrated both in terms of the absolute change and their percentage of change.

Indication: The Bionicare Stimulator, Model BIO-1000, is indicated for use in relief of signs and symptoms of osteoarthritis of the knee based on scientific evidence from a multi-center, prospective, parallel, double-blinded, randomized, placebo device controlled clinical study that demonstrated significant improvement in the patient's self evaluation of pain and the physician's global evaluation of the active device treated knee.

BIONICARE STIMULATOR

Function

The stimulator produces a pulsed electrical signal with the negative electrode at the treatment site. It is portable, cordless, battery operated and rechargeable.



Features

On/off/amplitude - The amplitude knob turns the unit on, off, and sets the electrical output to the selected amplitude. Full rotation counter-clockwise turns the stimulator off. (Read "OFF" in the circular window at the lower left of the front panel.) Clockwise rotation of the knob turns the unit on to display the amplitude setting 1, 2, 3, 4...8. Eight is the highest amplitude setting (the greatest energy output.) Be sure the unit remains "OFF" until electrodes are secured. Turn unit to "OFF" before recharging batteries or when stimulator is not in use to avoid electrical hazards.

Test Light - The test light will come on momentarily when both the test pushbutton is pressed and the amplitude knob has been turned on in the range of 2-1/2 through 8. The operator is then able to "see" and note the presence of the output from the stimulator within its voltage range. If the light does not come on within this range, refer to recharging section below. The test light becomes dim and goes out as the amplitude knob is adjusted below 2-1/2, thus indicating a decreasing amplitude range. If, however, the light does not diminish below 2-1/2, the unit is out of calibration and should not be used.

Circuit Light - The circuit light comes on automatically to indicate the presence of current when the stimulator is operating with the electrodes in place on the knee and thigh.

Battery charging jack/charging light/charging - The stimulator operates on rechargeable batteries that are self contained within the stimulator. The batteries may be recharged

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hundreds of times. The batteries should be recharged for fourteen hours when the stimulator is first received, when it has been stored for longer than two weeks or after at least eight hours of cumulative stimulator use. Best charging occurs at room temperatures between 50° and 100° F.

Recharging BEFORE at least 8 cumulative hours of use may require increasingly higher amplitude settings for the test light to be activated.

Prior to starting the charge, turn the stimulator off. With the small plug from the battery charger fully inserted into the battery charging jack on the stimulator, plug the main charger body into an appropriate wall outlet (120 Volts/60 Hertz). The charging light will come on indicating that the unit is in the battery charging mode. DO NOT plug charger into the wall outlet first. DO NOT use the stimulator for treatment when the charger is connected.

If the charging light fails to operate, move the charger to another wall outlet and observe the charging light. Disconnect the charger when the charging light fails to operate and return it to the factory for repair or replacement.

<p>Do <u>NOT</u> use the stimulator for treatment purposes when the battery charger is connected. Do <u>NOT</u> use other chargers with the stimulator.</p>

Care and Cleaning

The case of the stimulator may be cleaned with a cloth and cotton swab. Do not use liquids for cleaning; the stimulator is not waterproof. The stimulator should not be opened because it has no operator serviceable components. The stimulator should be turned "OFF" when not in use. Always store in a clean, dry place between 0° and 110° F.

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OPERATION

Introduction: Each patient should be instructed to read and become familiar with the information contained in the Patient Manual prior to using the Bionicare Stimulator. It is recommended that the physician discuss these instructions for using the Bionicare Stimulator and that this include the sections on "Contraindications", "Warnings", "Precautions" and "Adverse Reactions".

Battery Charging: The stimulator contains rechargeable nickel-cadmium batteries that should be fully charged when the stimulator is first used and after each 8 to 10 hours of use to assure proper function. Additionally, the stimulator batteries must be charged for 10 to 14 hours prior to using the stimulator when it has been stored or not used for an extended period. The test light is used to confirm that the stimulator is ready for use after charging the batteries by following the procedures under Features-Test Light. Using the stimulator when the batteries are not fully charged will reduce the maximum available output amplitude until the stimulator is recharged.

Stimulator Preparation: The stimulator must be disconnected from the battery charger and must remain turned off until the following electrode placement procedure has been completed.

Electrode Placement: The knee treatment electrode and thigh electrode are first prepared by applying electrode gel to the conductive surface of each electrode. The gelled knee treatment electrode is then placed over the front surface of the knee and held in place with the adjustable small hold strap. The gelled thigh electrode is placed on the middle of the thigh directly above the knee treatment electrode. Refer to the diagram of "Electrode Position for Knee Treatment" on page 16.

Stimulator Operation: The stimulator must remain turned off until the electrodes are in place and the color coded electrode wires have been connected to the stimulator. The red coded wire is connected to the thigh electrode and to the red coded output jack on the stimulator. The other wire is connected to the knee treatment electrode and the remaining output jack. The stimulator is turned on by rotating the amplitude control clockwise from the "OFF" position to "1". The output amplitude of the stimulator is slowly increased until a mild tingling sensation is felt from the electrical signal and then reduced slightly below this level. The recommended treatment time is six to ten hours each day.

The factors for tolerance and level of comfort will vary among patients and over time for a single patient. It is therefore important that the above procedure be carefully repeated for each treatment. The patient should never be subjected to any discomfort. The stimulator should be turned off after each treatment.

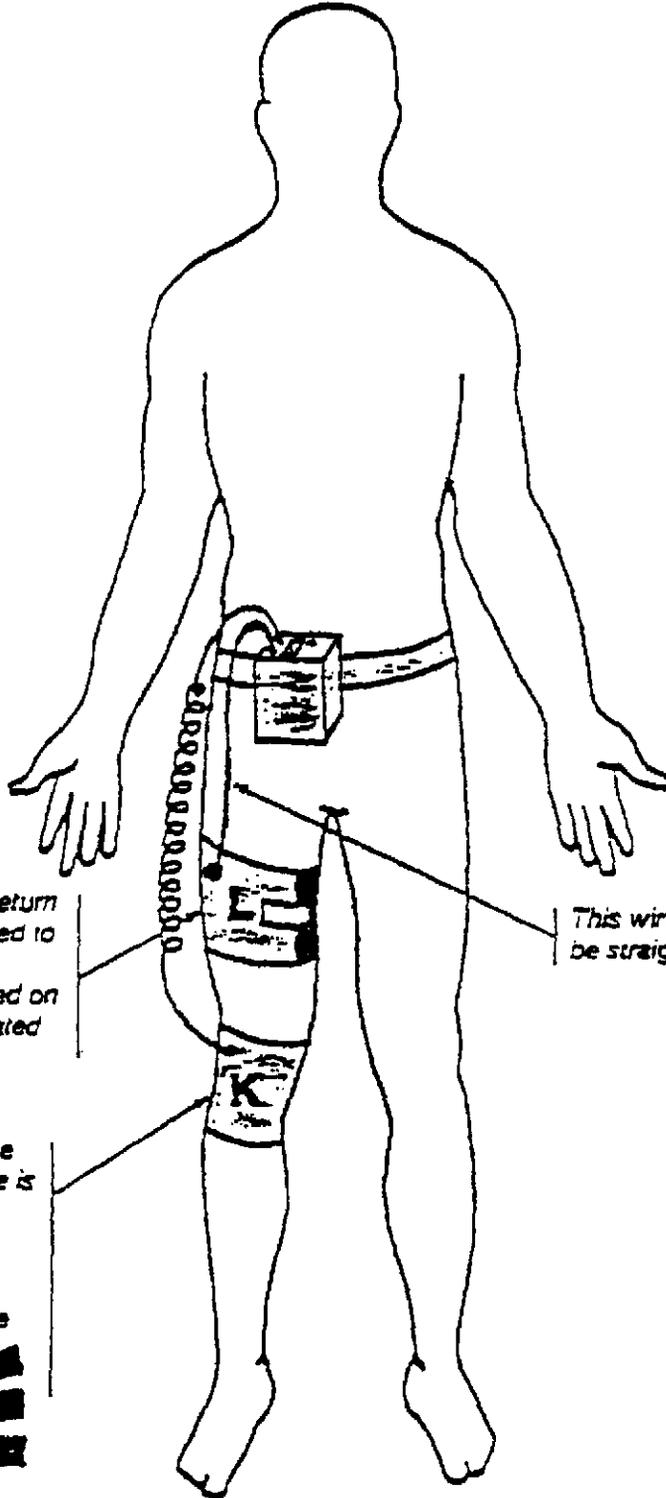
SKIN CARE

It is recommended that the area of skin on the knee and thigh where the electrodes are placed be thoroughly washed with water and a mild soap and dried prior to applying electrode gel and the electrodes. When the treatment is complete turn the stimulator off and immediately remove the electrodes. Do not leave the electrodes on between treatments. At the end of each treatment clean the skin with water and mild soap. The physician may suggest a protective skin preparation for use between treatments. If a rash or skin irritation develops discontinue treatments. Resume treatment when the rash has disappeared.

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Bionicare Bio1000

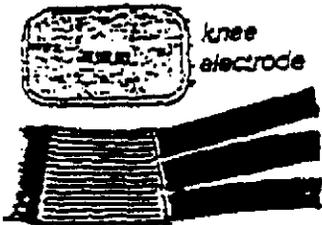
ELECTRODE POSITION FOR KNEE TREATMENT



The RED snap on the return electrode wire is attached to leg electrode (L). This electrode must be placed on the same leg as the treated knee.

This wire with red snap may be straight or coiled.

The BLACK snap on the treatment electrode wire is attached to the knee electrode (K).

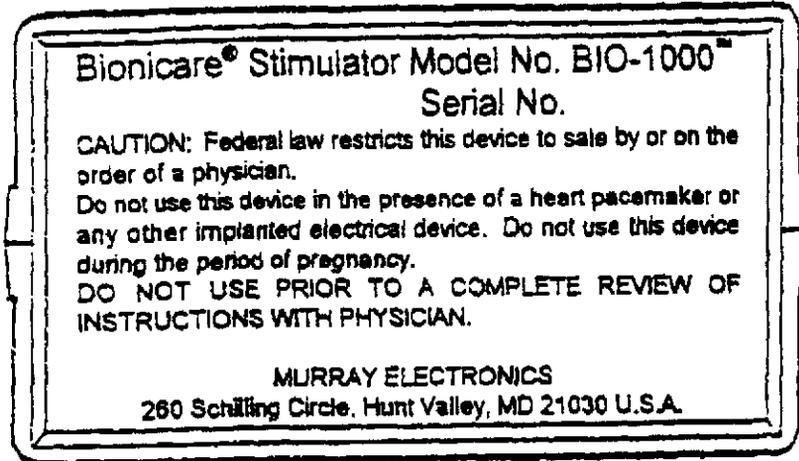


Adjustable knee strap holds knee electrode in place.

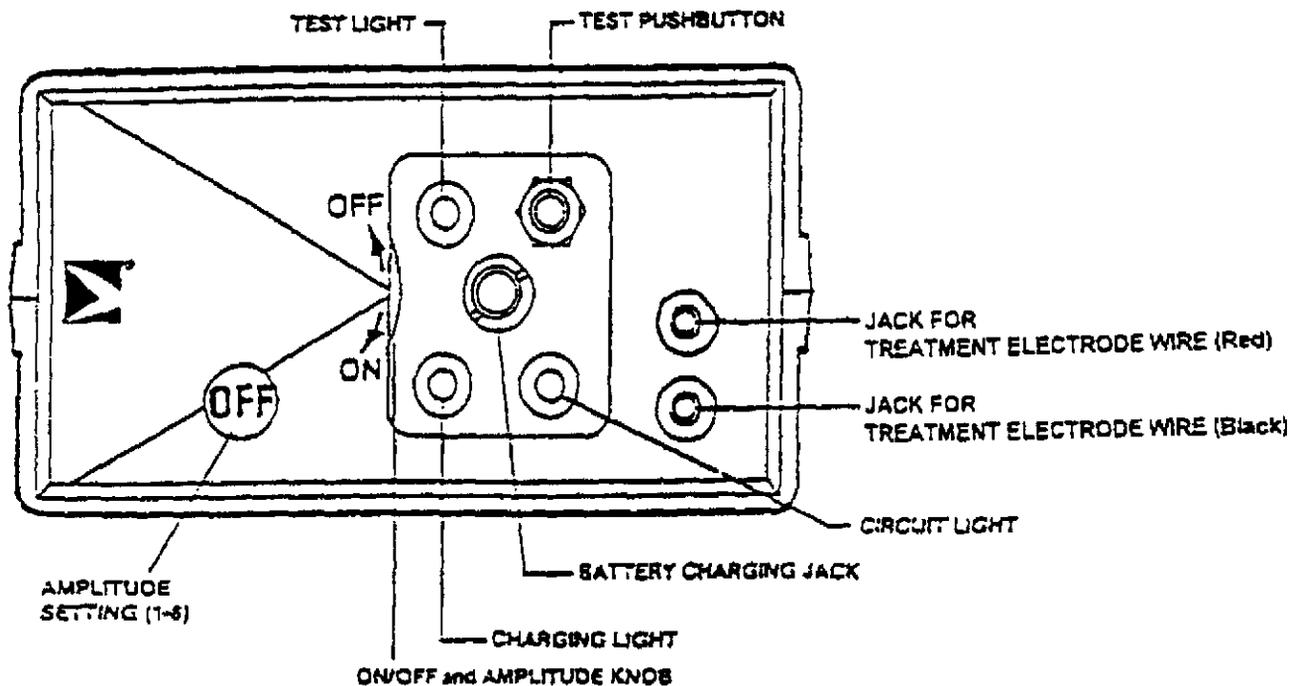
Electrodes approximate scale

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BACK PANEL



FRONT CONTROL PANEL



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SPECIFICATIONS: BIONICARE[®] STIMULATOR SYSTEM

MODEL BIO-1000

Output Voltage: 0-12 volts, spike shaped pulses (nominally constant voltage)

Output Frequency: 100 Hertz

Polarity: Negative electrical signal at the treatment electrode.

Electrical Requirements: Portable-cordless operation with self-contained 12 volt rechargeable nickel-cadmium battery pack (battery charger supplied with the stimulator operates on 120 volt/60 Hz input). DO NOT use other chargers with the stimulator.

Dimensions: 13.2 cm x 8.5 cm x 4.5 cm

Weight: 450 grams (includes battery)

Knee Electrode: 16 cm x 11 cm silver coated nylon fabric (surface area=176 cm²)

Thigh Electrode: 17 cm x 10 cm stainless steel fabric (surface area=170 cm²)

Knee Treatment Electrode Wire: 68 cm retracted length/244 cm extended length (Color coded black)

Leg Return Electrode Wire: 68 cm retracted length/244 cm extended length (Color coded red)

Electrode Gel: Parker Labs, Inc. Spectra 360 Electrode Gel or an electrically conductive equivalent medium intended for use with TENS electrodes.

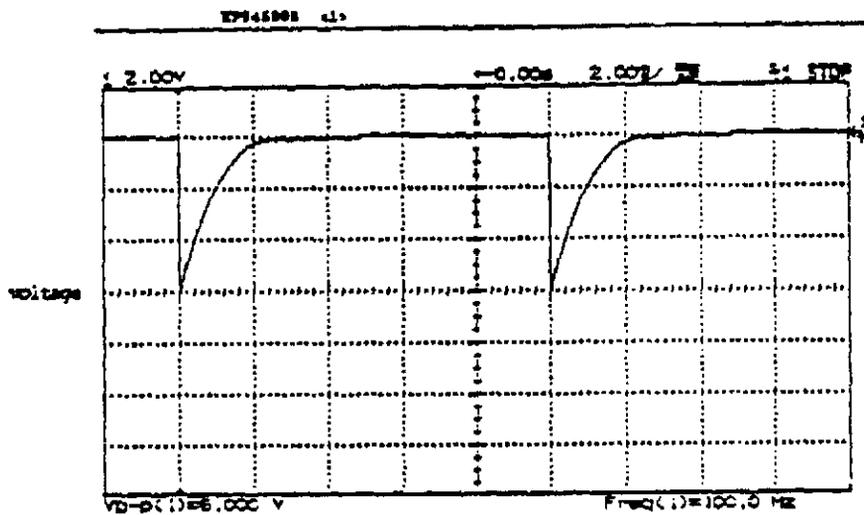
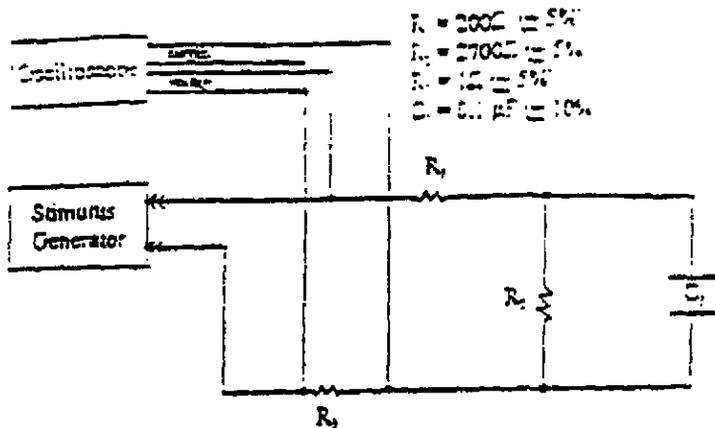
STANDARDS

ANSI/AAMI NS4-1985

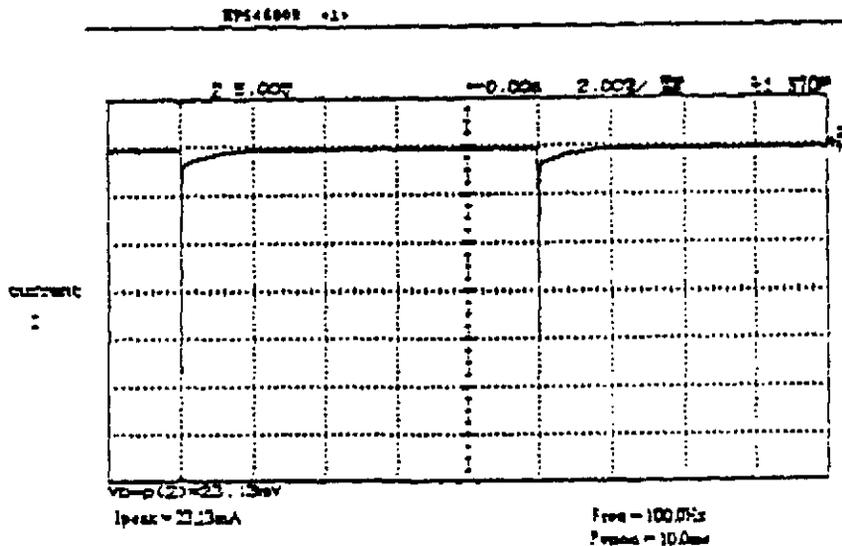
Output Waveforms:

The graphical representations of the output signal provided on the following pages show both voltage and current waveforms at the midpoint value of the adjustable output amplitude based on the standard test procedures of the American National Standard for Transcutaneous Electrical Nerve Stimulators, ANSI/AAMI NS4-1985 that are included in sections 3.1.2.1 (8) a-c and 4.1.2 of the standard.

105 62
105
331



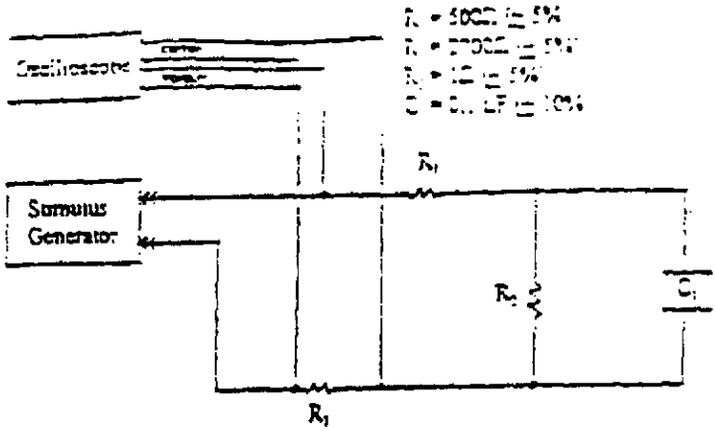
Test condition: Battery = 11.5V,
 $R_1 = 200 \text{ ohms}$.



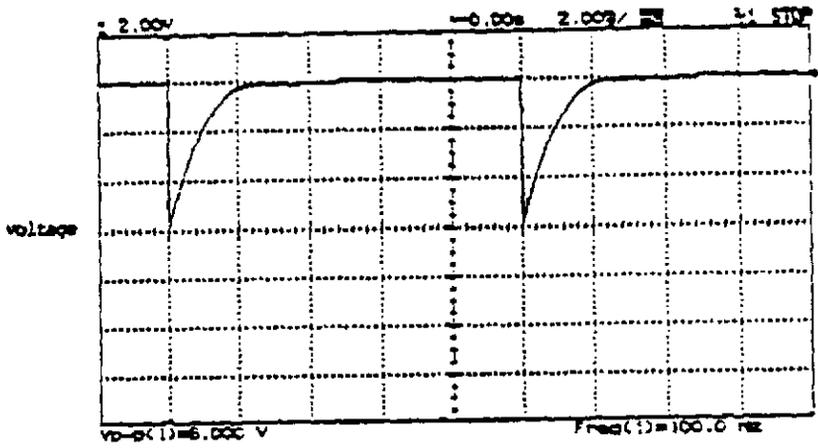
Test condition: 6V peak stimulator output (battery = 11.5V),
 $R_1 = 200 \text{ ohms}$.

106 63

102
 332

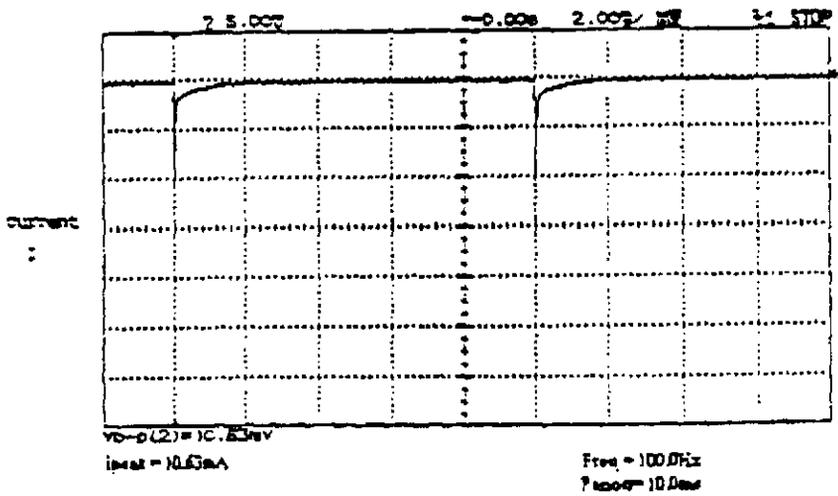


EP54600 <1>



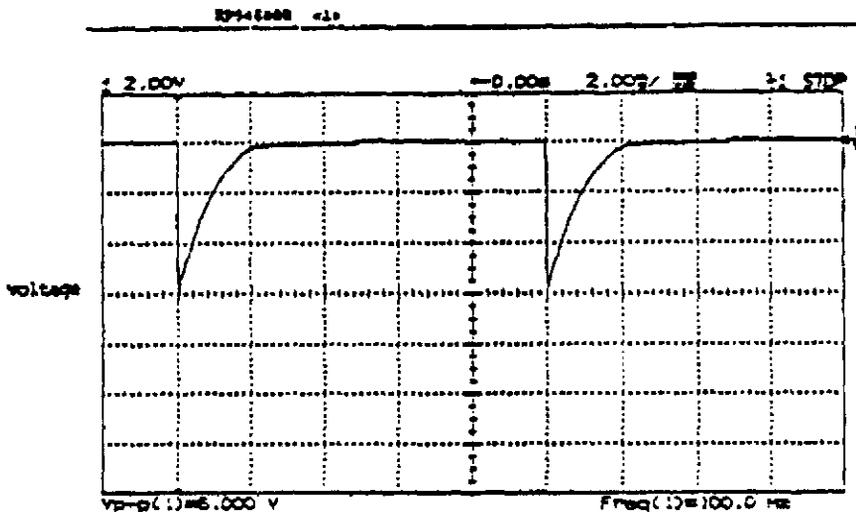
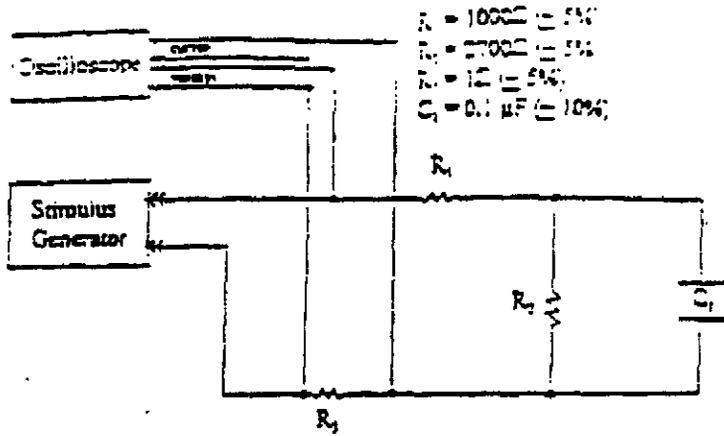
Test condition: Battery = 12.5V, R1 = 500 ohms.

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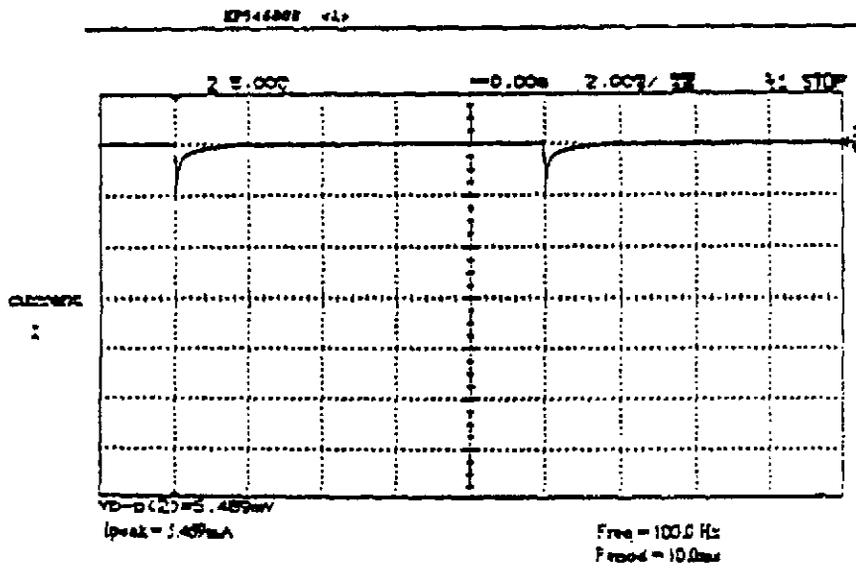


Test condition: 5V peak stimulus output (battery = 12.5V), R1 = 500 ohms.

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64
107
333



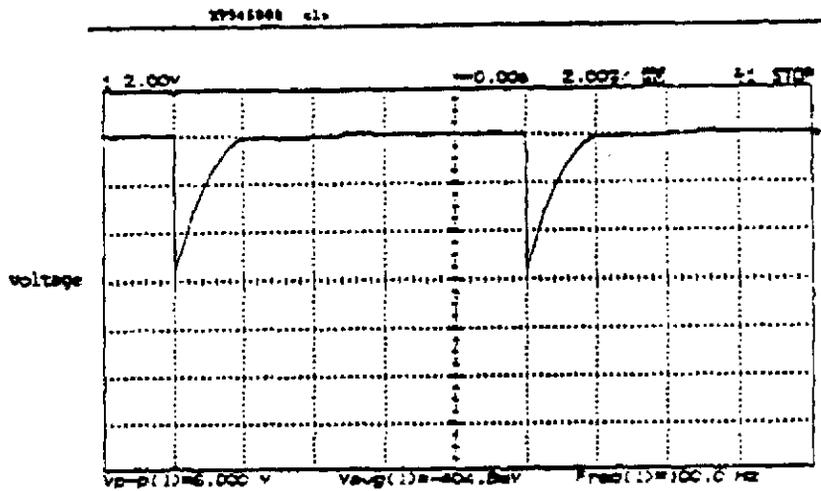
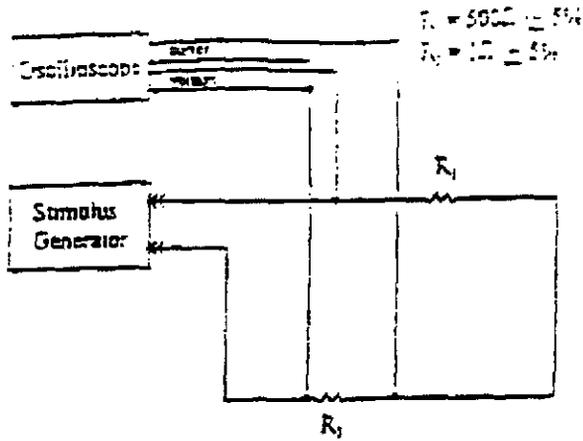
Test condition: Battery = 12.5V.
 $R_L = 1000 \text{ ohms}$.



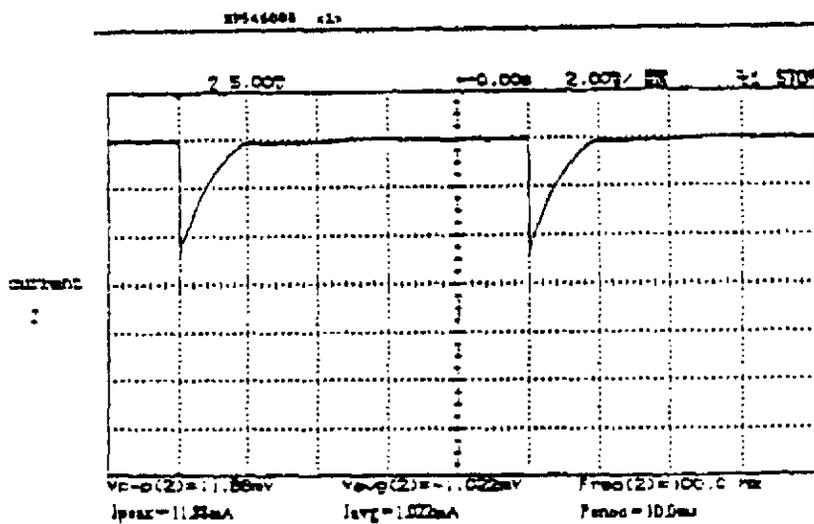
Test condition: 6V peak stimulator output (battery = 12.5V).
 $R_L = 1000 \text{ ohms}$.

108

108



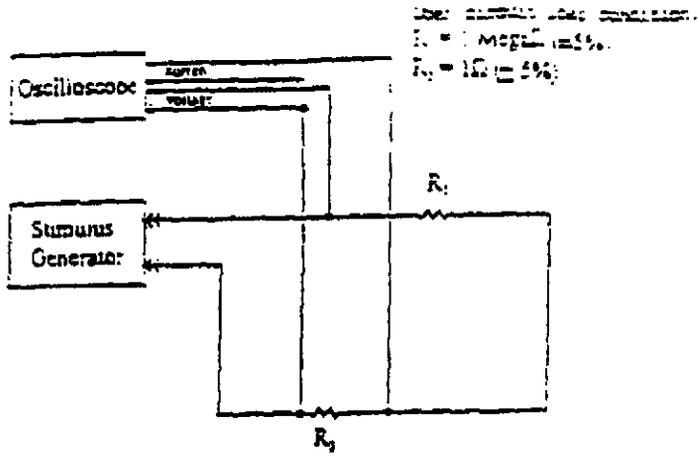
Test condition: Battery = 12.5V.
 50 ohm pure resistive load at output.



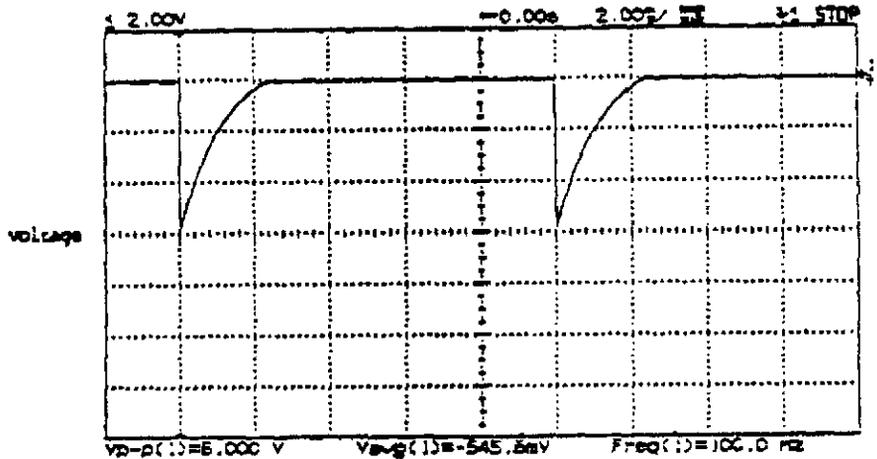
Test condition: 6V peak sinusoidal output (battery = 12.5V).
 50 ohm pure resistive load at output.

10466

109

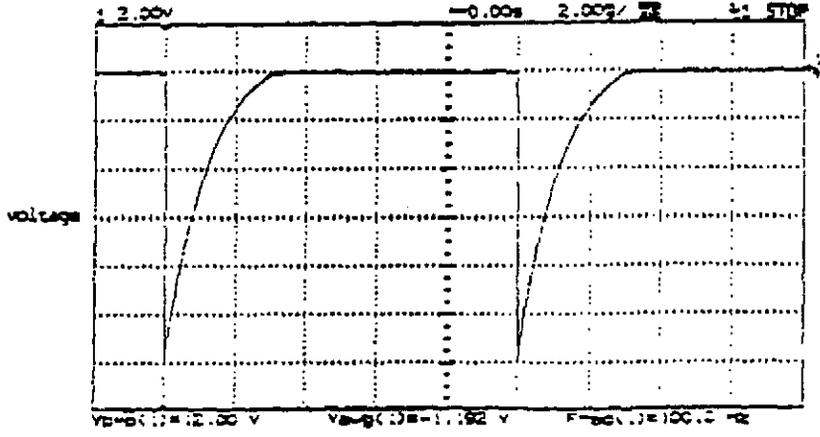


8754600 <1>



Test condition: Open circuit load condition:
 Battery = 12.5V
 1 MEG ohm pure resistive load at output.

8754600 <1>



Test condition: Open circuit load condition -
 Maximum resistor output (battery = 12.5V).
 1 MEG ohm pure resistive load at output.

110

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110

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ACCESSORIES LIST

BIONICARE® STIMULATOR, MODEL BIO-1000™

<u>PART DESCRIPTION</u>	<u>PART NUMBER</u>
Knee Treatment Electrode	1000-005
Knee Treatment Electrode Wire	1000-006
Leg Return Electrode	1000-007
Leg Return Electrode Wire	1000-008
Holding Strap, Small	1000-009
Electrode Gel	1000-011
Battery Charger	1000-012
Patient Manual	1000-013

111 65 111
337

SERVICE

Instructions for returning the stimulator and/or accessories can be obtained by writing to Murray Electronics, 260 Schilling Circle, Hunt Valley, MD 21030 U.S.A., telephone (410) 771-0380 (Extension 231).

The serial number, model number and a description of the problem should be included along with your name, address, and telephone number. This stimulator contains no user serviceable parts and must be returned to Murray Electronics or its representatives for service, repair or calibration at its factory.

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338

NOTES

113 70 113
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PACKAGE LABELING

**BIONICARE® STIMULATOR SYSTEM
MODEL BIO-1000**

**MURRAY ELECTRONICS
260 SCHILLING CIRCLE
HUNT VALLEY, MD 21031**

**TELEPHONE NO. 410 771-0380 ext. 231
FAX NO. 410 771-5576**

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

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Indications

NMES devices are indicated for:

- Relaxation of muscle spasm
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
- Maintaining or increasing range of motion.

TENS devices are indicated for:

- Symptomatic relief and management of chronic, intractable pain.
- Adjunctive treatment for post-surgical and post-trauma acute pain.

External functional muscle stimulation (FES) is indicated for:

- Stimulating muscles in the leg and ankle of partially paralyzed patients to provide flexion of foot and thus improve the patient's gait.



Contraindications

NMES/TENS treatments should not be used if the patient has any of the following conditions:

- Demand-type implanted cardiac pacemaker or defibrillator.
- Transcerebral electrode placements.
- Transthoracic electrode placements.
- Electrode placements over the carotid sinus (neck) region as this may cause changes in blood pressure. In addition, when the electrodes are placed across the throat or in the mouth, laryngeal or pharyngeal spasms may occur causing difficulty in breathing.

NMES treatments are also contraindicated if the patient has any of the following conditions:

- Electrode placements over malignant tumors.
- Electrode placements over areas in which symptoms of existing thrombosis, phlebitis, or varicose veins are present. These symptoms include swollen, infected, or inflamed areas or skin eruptions.

TENS treatments are also contraindicated if the patient has the following condition:

- Undiagnosed pain (until the etiology is established).

FES treatments are contraindicated for:

- Assisting paraplegic patients into the stance phase (standing).



Warnings

Review the following warnings before initiating treatment:

- **Pregnancy** - The safety of NMES/TENS devices for use during pregnancy or delivery has not been established.
- **Symptomatic Treatment** - TENS is a symptomatic treatment and, as such, may suppress the sensation of pain that would otherwise serve as a protective mechanism.
- **Central Pain** - TENS is not effective for pain of central origin.
- **Non-curative** - TENS has no known curative value for the conditions for which it is indicated.

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- **Medical Supervision** - This device should only be used under the medical supervision of a physician or a medical practitioner to whom the patient is referred by the physician. This is a prescription device and should not be given to other individuals.
- **Children** - Keep out of the reach of children.
- **Electromagnetic Radiation** - The lead wires and electrodes should be removed before using industrial, scientific or medical equipment (Group 2 ISM) that intentionally generates high frequency or high energy electromagnetic radiation. Operation in close proximity (e.g. < 3m) to this equipment may startle the user by producing output instability or improper operation of the stimulator. Simultaneous connection to the user may result in burns and possible damage to the stimulator. Examples of Group 2 ISM Equipment are: radio-frequency (rf) induction heating, cutting or welding equipment and short-wave/microwave therapy and diagnostic equipment such as diathermy, surgical electrocautery units.
- **External Defibrillators** - Remove the electrodes before defibrillation signals are applied. Defibrillation of a person wearing a this device can damage the device whether it is turned on or off. Under some circumstances there can be risk of burns under the electrode sites during the defibrillation. To eliminate any risk, remove the electrodes before defibrillation signals are applied.
- **Wall Sockets** - Do not plug lead wires into AC power outlets such as wall sockets or line cord receptacles under any circumstances. Doing so could result in severe shock or burns whether or not the lead wires are attached to the stimulator.
- **Patient Monitoring Equipment** - This device may interfere with the intended operation of electronic monitoring (ECG) equipment or alarms if the stimulator is simultaneously connected to the patient being monitored. However, the operation of this device will not be affected by the use of electronic patient monitoring equipment.
- **Safety and Efficacy** - The safety and efficacy of NMES/TENS depends on the proper use and handling of the device and accessories. If used improperly, NMES/TENS has a potentially hazardous electrical output. It must be used only as prescribed. Electrode or lead wire burns may result from misuse. Electrodes and lead wires should be securely fastened to prevent inadvertent disconnection or burns resulting from the metal portion of the lead wire touching the skin while the device is connected and operating. Electrodes and lead wires will eventually wear out. Check accessories regularly for signs of wear, and replace if needed.
- **Chronic Stimulation** - The effects of long-term chronic electrical stimulation are unknown.



Precautions

Review the following precautions:

- **Prescribed Conditions** - NMES/TENS therapy should not be used for conditions other than those for which the device is prescribed. If there are any changes in an existing condition, or if a new condition develops, the patient should consult a clinician.
- **Patient Selection** - The efficacy of TENS therapy is highly dependent upon patient selection by a person qualified in the management and treatment of pain.
- **Drugs or Mental State** - Treatment outcome will be influenced by the patient's psychological state and use of drugs.

53 052

- **Heart Patients** - Use caution in applying electrical stimulation to persons suspected of having heart disease. More clinical data is needed to show that such persons will not experience adverse results
- **Hemorrhage** - Use caution in applying electrical stimulation to persons with history of, or potential for, hemorrhage.
- **Menstruation** - Use caution in applying electrical stimulation over the abdomen during menstruation.
- **Epilepsy** - Use caution in applying electrical stimulation to persons suspected of having epilepsy. More clinical data is needed to show that such a person will not experience adverse results.
- **Recent Surgery** - Do not use NMES following recent surgery where muscle contraction may disrupt the healing process.
- **Adverse Reactions** - Patients who react negatively to the stimulation sensation after an adequate trial period or who find stimulation intolerable should not undergo further NMES/TENS treatment.
- **Sensory Deprivation** - Due to the risk of adverse skin reactions, electrodes should not be placed on areas of skin with reduced response to normal sensory stimuli.
- **Skin Irritation** - Skin irritation, hypersensitivity and burns beneath electrodes have been reported with the use of NMES/TENS. Electrodes should not be left in place for long periods of time without checking or cleaning the skin underneath them. Electrode sites should be rotated with long term use when possible. **DO NOT CONTINUE STIMULATION OVER IRRITATED SKIN.** Consult a clinician if any skin irritation or reaction develops at the electrode sites following use of the stimulator. The clinician may recommend a different type of electrode.
- **Operating Machinery** - Do not operate hazardous equipment such as automobiles or power tools while using this device. Abrupt changes in sensation can occur during use of this device which could startle the patient and create a hazard.
- **Cellular (Wireless) Telephones and Two-Way Radios** - Avoid operation in close proximity (e.g. < 1m) to transmitting cellular (wireless) telephones or two-way radios. This equipment may produce instability in the stimulator output. Sudden, unexpected changes in output could startle the patient and create a hazard.
- **Water Immersion** - Do not use in the bath or shower. The stimulator should not be submerged in water or other liquids as this may startle the patient and possibly damage the stimulator. If the device should become accidentally immersed in water, do not attempt to use immediately afterward. Remove the battery and allow the excess water to drain away. Air dry the device thoroughly for at least 48 hours at room temperature before attempting to operate it.
- **Heat and Cold** - The use of heat or cold producing devices, such as electric heating blankets, heating pads or ice packs, may impair the performance of the electrode or alter the patient's circulation and increase the risk of injury to the patient.
- **Sleep** - Do not use while sleeping because the lead wires or the electrodes may become disconnected.
- **Electrodes, Conductive Gels and Lead Wires** - Do not use electrodes, conductive gels, lead wires or accessories other than those supplied with the system or recommended by Empi. The safety of other products has not been established, and their use could result in injury to the patient.

54 053

- **Batteries - Do not carry batteries in a pocket, purse or any other place where the terminals could become short-circuited, e.g. by way of a coin or paper clip. Intense heat could be generated and injury may result.**



Adverse Reactions

- **Skin irritation and burns beneath the electrodes have been reported with the use of TENS.**

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APPENDIX D

**SUBSTANTIAL EQUIVALENCE
MATRIX**

SUBSTANTIAL EQUIVALENCE MATRIX

	InterX 5000	Fenzian Treatment System	EMPI Focus 795	Bionicare Bio-1000
510k Reference	(Proposed Device)	K041575	K951951	K971437
Indications for Use	<p>symptomatic relief and management of chronic, intractable pain</p> <p>adjunctive treatment in the management of post-surgical and post-traumatic pain</p> <p>relaxing muscle spasms</p> <p>increasing local blood circulation</p> <p>immediate post surgical stimulation of calf muscles to prevent venous thrombosis</p> <p>muscle reeducation</p> <p>maintaining or increasing range of motion</p> <p>preventing or retarding disuse atrophy</p>	<p>symptomatic relief and management of chronic, intractable pain</p> <p>adjunctive treatment in the management of post-surgical and post-traumatic pain</p>	<p>symptomatic relief and management of chronic, intractable pain</p> <p>adjunctive treatment in the management of post-surgical and post-traumatic pain</p> <p>relaxing muscle spasms</p> <p>increasing local blood circulation</p> <p>immediate post surgical stimulation of calf muscles to prevent venous thrombosis</p> <p>muscle reeducation</p> <p>maintaining or increasing range of motion</p> <p>preventing or retarding disuse atrophy</p>	<p>symptomatic relief and management of chronic, intractable pain</p> <p>adjunctive treatment in the management of post-surgical and post-traumatic pain</p>
Output Channels	1	1	2	1
Power Source	Battery, 9V alkaline, disposable	Battery, 9V	Battery, 9V	Battery, 12V mAH, internal nickel cadmium rechargeable
Weight	6 oz.	04. kg exc. battery	145 gm with battery	235 gm exc. battery
Dimensions	7 x 2.5 x 1.5 inches	7 x 7 x 2"	3.7 x 2.5 x 0.84"	13.2 x 8.5 x 4.5 cm
Electrodes	Stainless Steel	Stainless Steel	Snapcase Brand	
Waveform	Damped biphasic	Biphasic	Symmetrical biphasic	Monophasic spike-pulse
Maximum Output Voltages	40V @ 500 ohms 175V @ 2k ohms 450V @ 10k ohms	88V @ 500 ohms 306V @ 2k ohms 650V @ 10k ohms	+100V @ 1k ohm	0-12V peak
Maximum Output Current	80 mA @ 500-ohms 87.5 mA @ 2k-ohms	46 milliamps @ 500 ohms 16.8 milliamps @ 2k ohms	0-60 mA (normal) 0-100 mA (high)	0-24 mA peak @ 500 ohms 0-2 mA average @ 500 ohms

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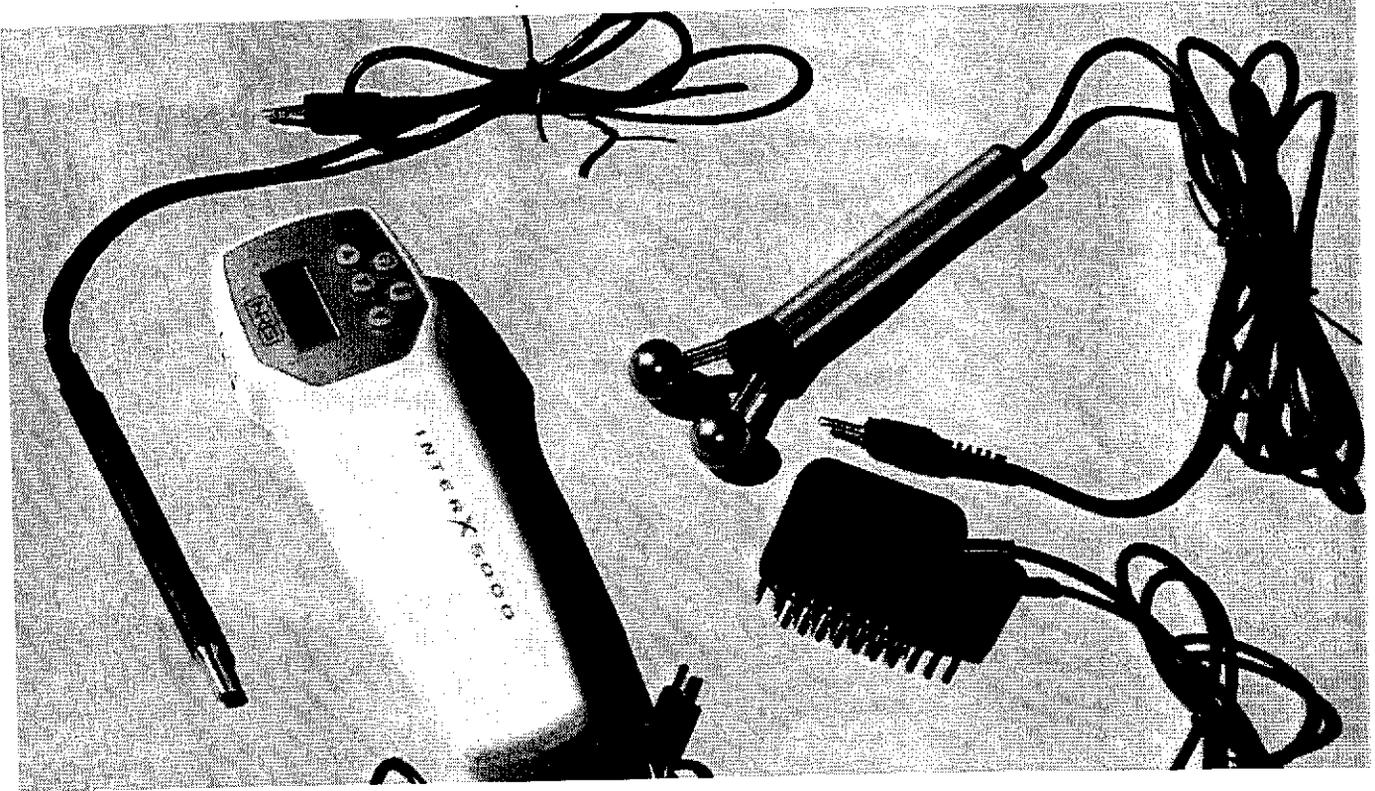
	(b)(4)
Pulse Width	
Frequency	
Net Charge	
Max. Phase Charge	
Max. Current Density² (mA/cm²)	
Avg. Power Density² (W/cm²)	
Burst Mode	
- Pulses/burst	
- Bursts/second	
- Burst duration	
Max. Delivered Current	
Range Load of Impedance	
Controller	
Housing	
Maximum Patient Leakage Current	
Maximum Charge per Pulse	

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APPENDIX E

**DRAWINGS, PHOTOS, AND
SCHEMATICS**





APPENDIX F

PERFORMANCE TESTING

Neuro Research Group, Inc.

Title	InterX5000 Test Report
Date	October 20th, 2004 th

Specification #	VV012-B
Page Number	1 of 22

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Neuro Research Group, Inc.

Title	InterX5000 Test Report
Date	October 20th, 2004 th

Specification #	VV012-B
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1. PURPOSE

This document describes the results and conclusions of testing performed to establish an outline of the electrical performance of the InterX5000 for comparison to published test data for similar devices. Testing was conducted according to test protocol VV013. Performance factors such as electrical stimulation waveform, voltage, current, charge transfer, energy and frequency were analyzed. Test data was also analyzed to verify that the InterX5000 complies with the safety and efficacy provisions of Guidance for TENS 510(K) content (FDA).

2. BACKGROUND

TENS and neuro-stimulation devices provide the means to stimulate nerves and the contraction of muscles. Nerve stimulation has been shown to provide pain relief and muscle stimulation has been shown to reduce muscle atrophy and improve muscle tone. The InterX5000 combines elements of muscle and nerve stimulation devices into one device.

3. REFERENCES

Guidance for TENS 510(K) content CDRH, 1998

4. MATERIAL/EQUIPMENT

Devices under test:

Device	Description	Serial Number
InterX5000	Pre-production device	001

Additional Equipment

Tektronix 360 Digital Oscilloscope with GPIB option

Resistive Load Fixtures

Adjustable Laboratory Power Supply

Personal Computer

LabVIEW v.7.1 software

LabVIEW VISA software

LabVIEW GPIB driver software

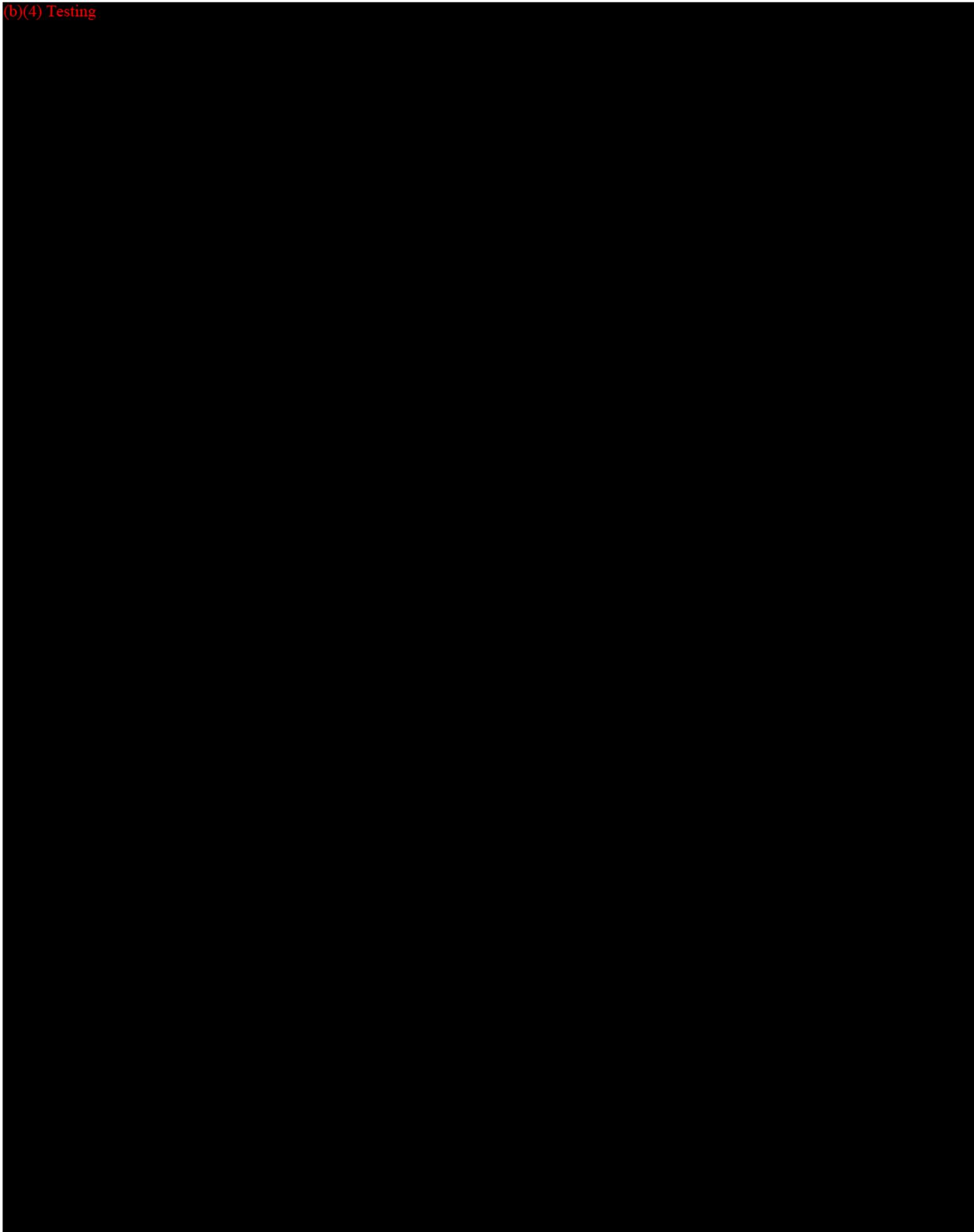
LabVIEW GPIB Interface

LabVIEW Scope capture waveform.vi

5. PROCEDURE

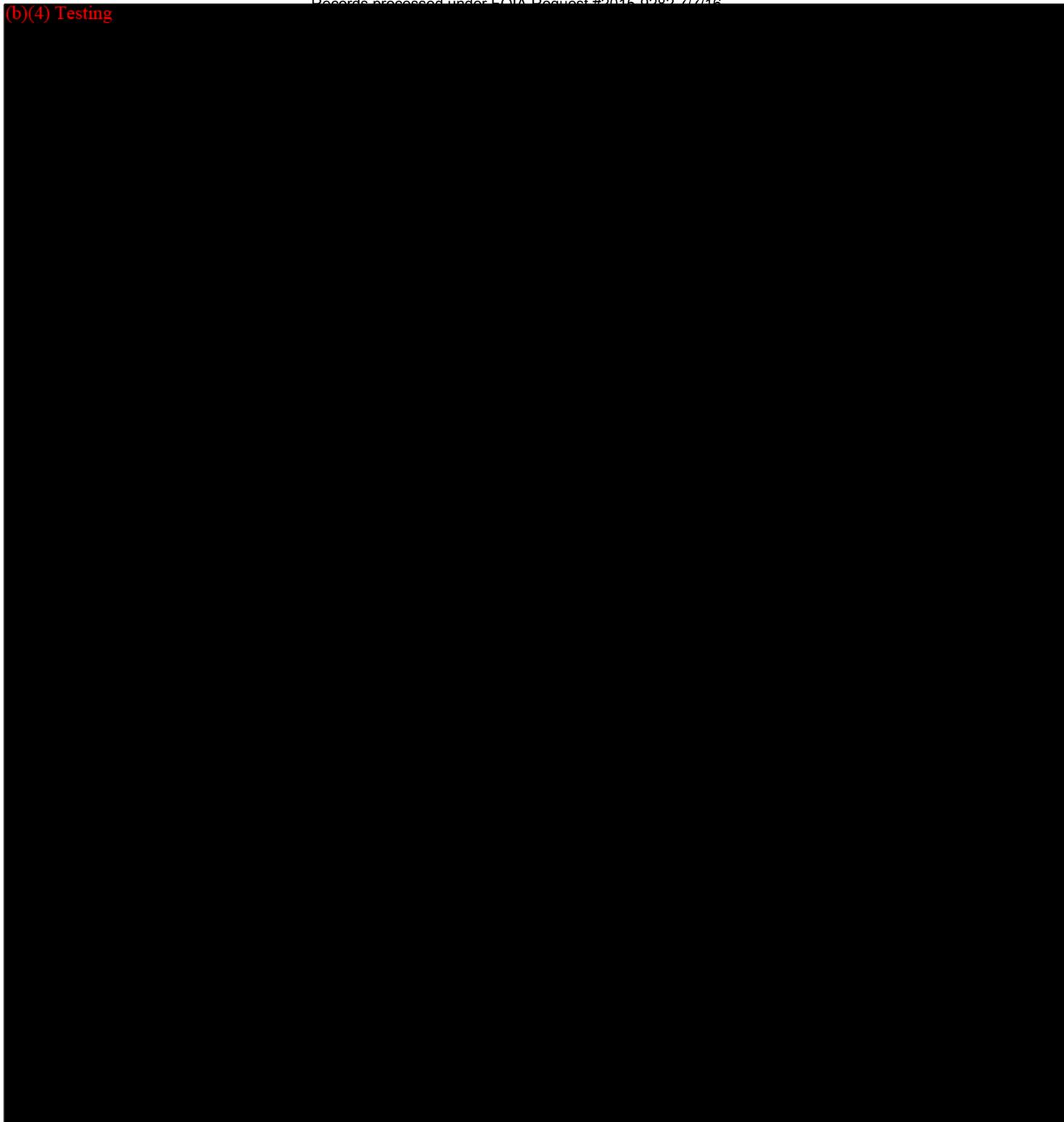
Testing was conducted as proscribed in test protocol VV013.

(b)(4) Testing



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(b)(4) Testing



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

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Neuro Research Group, Inc.

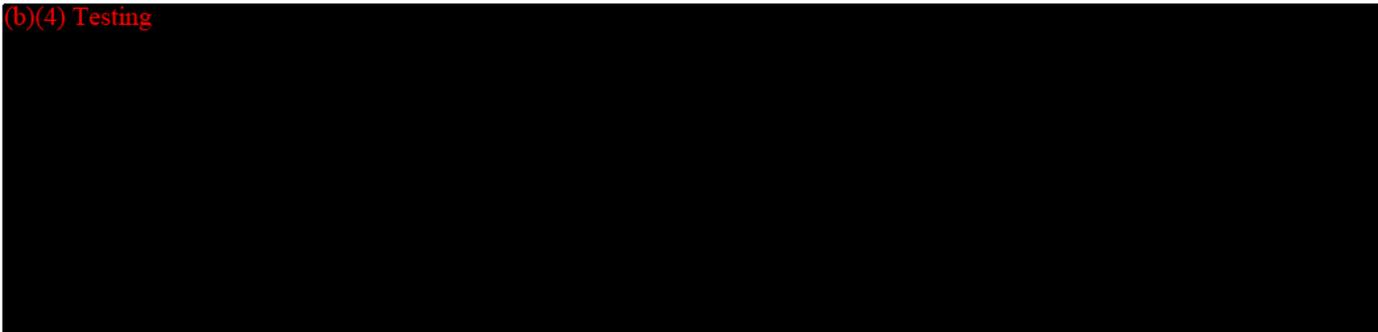
Title	InterX5000 Test Report
Date	October 20th, 2004 th

Specification #	VV012-B
Page Number	5 of 22

Test Case	(b)(4) Testing
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Table 2 – “General waveform description”

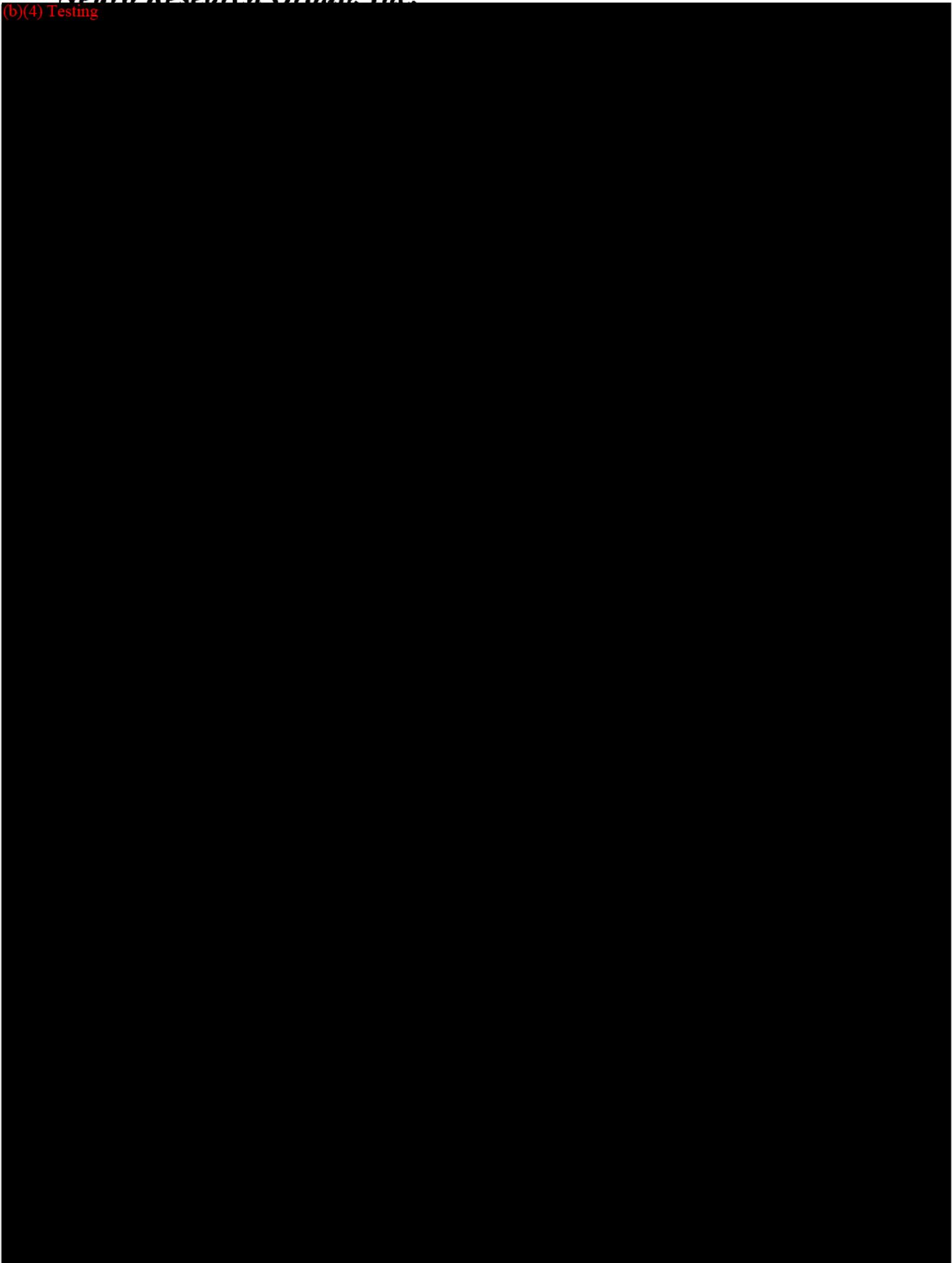
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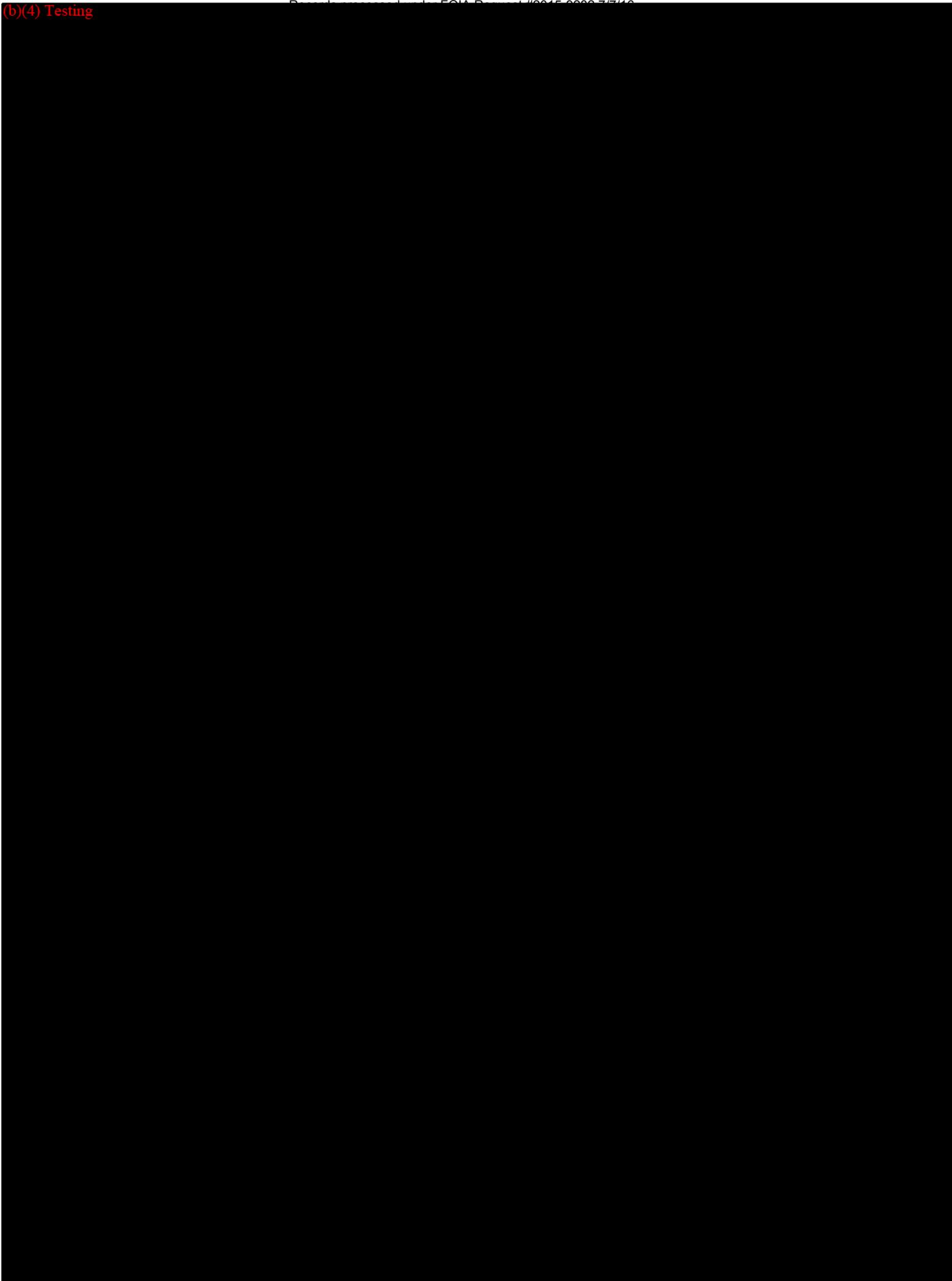
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Neuro Research Group, Inc.

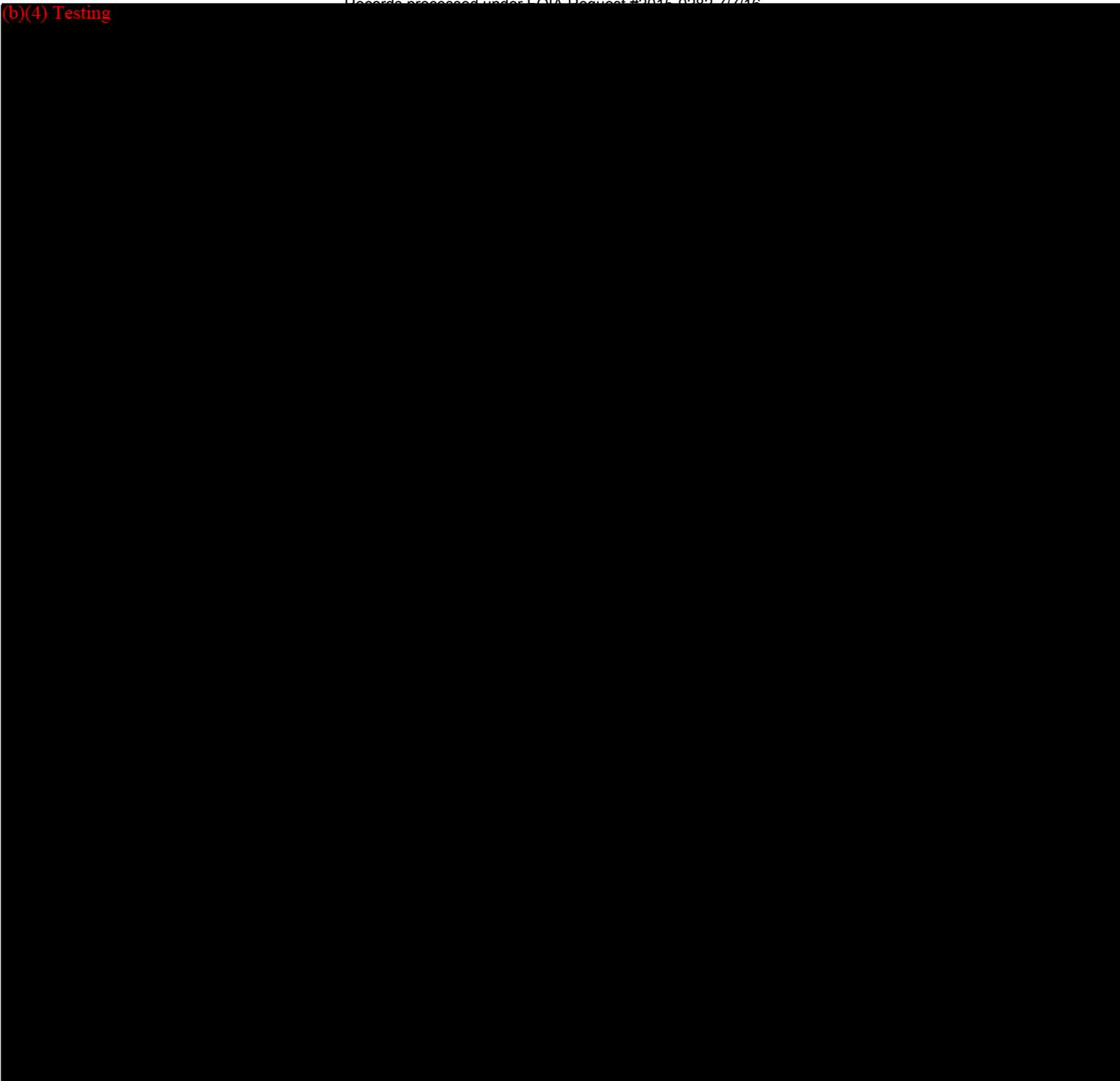
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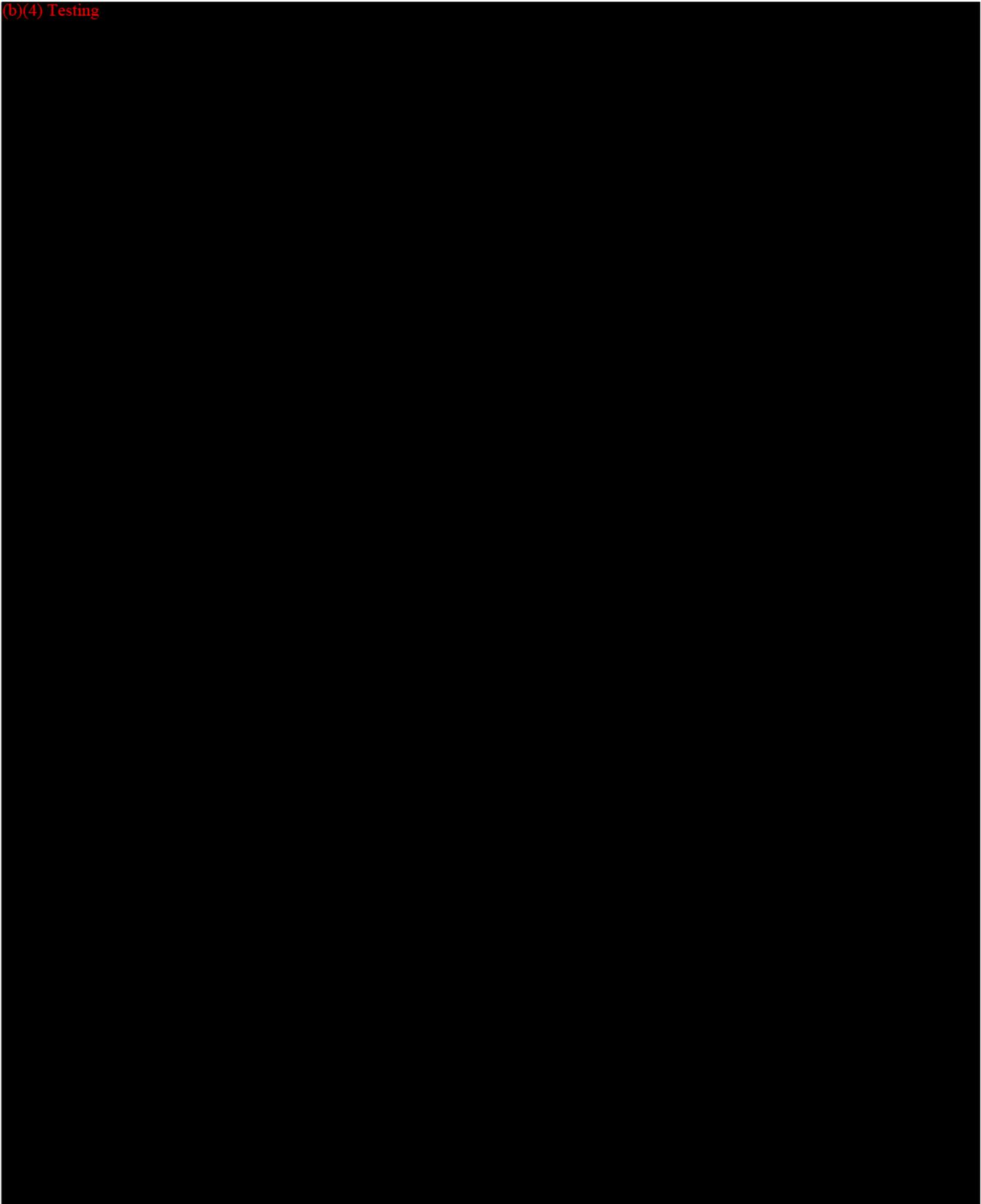


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(b)(4) Testing

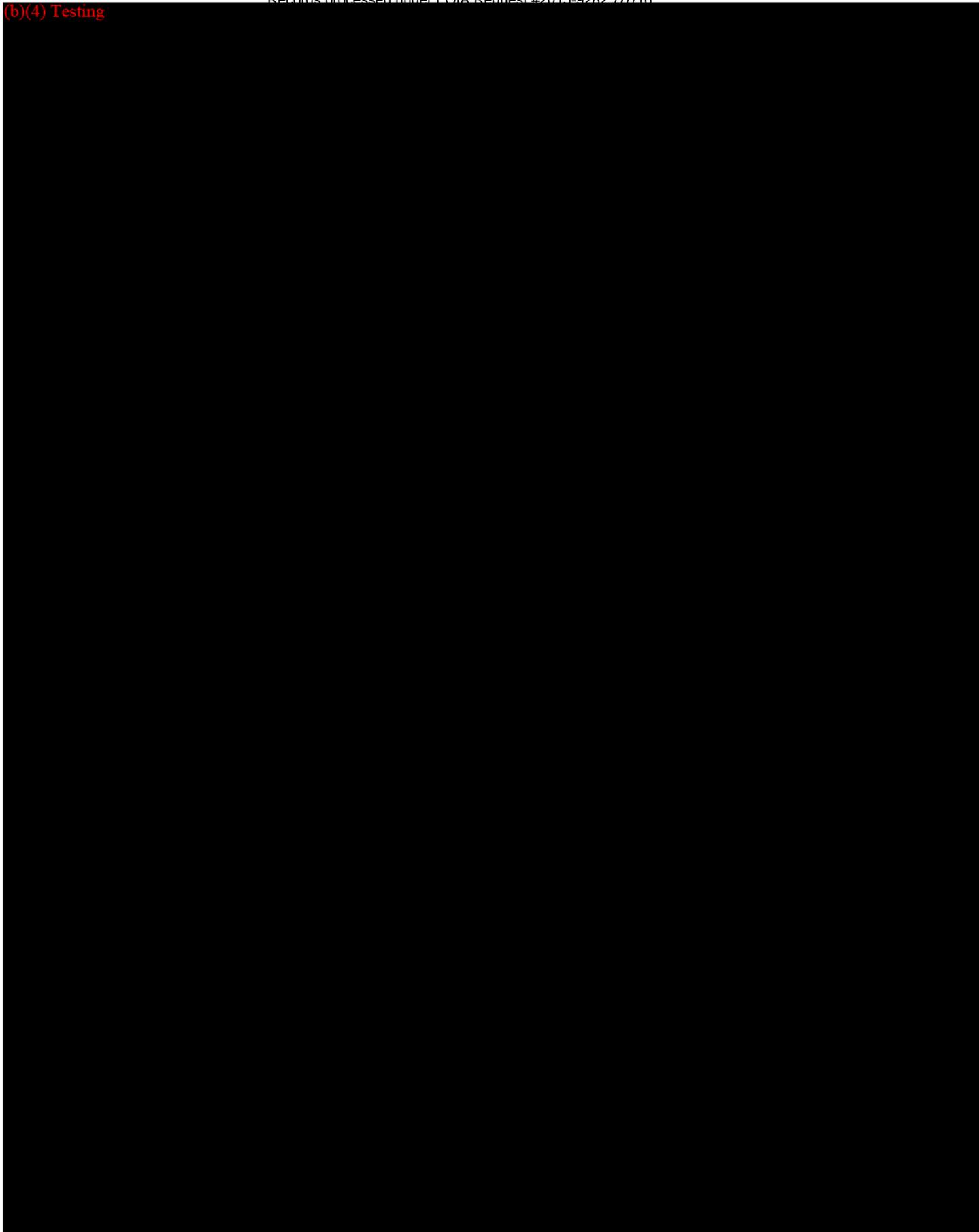


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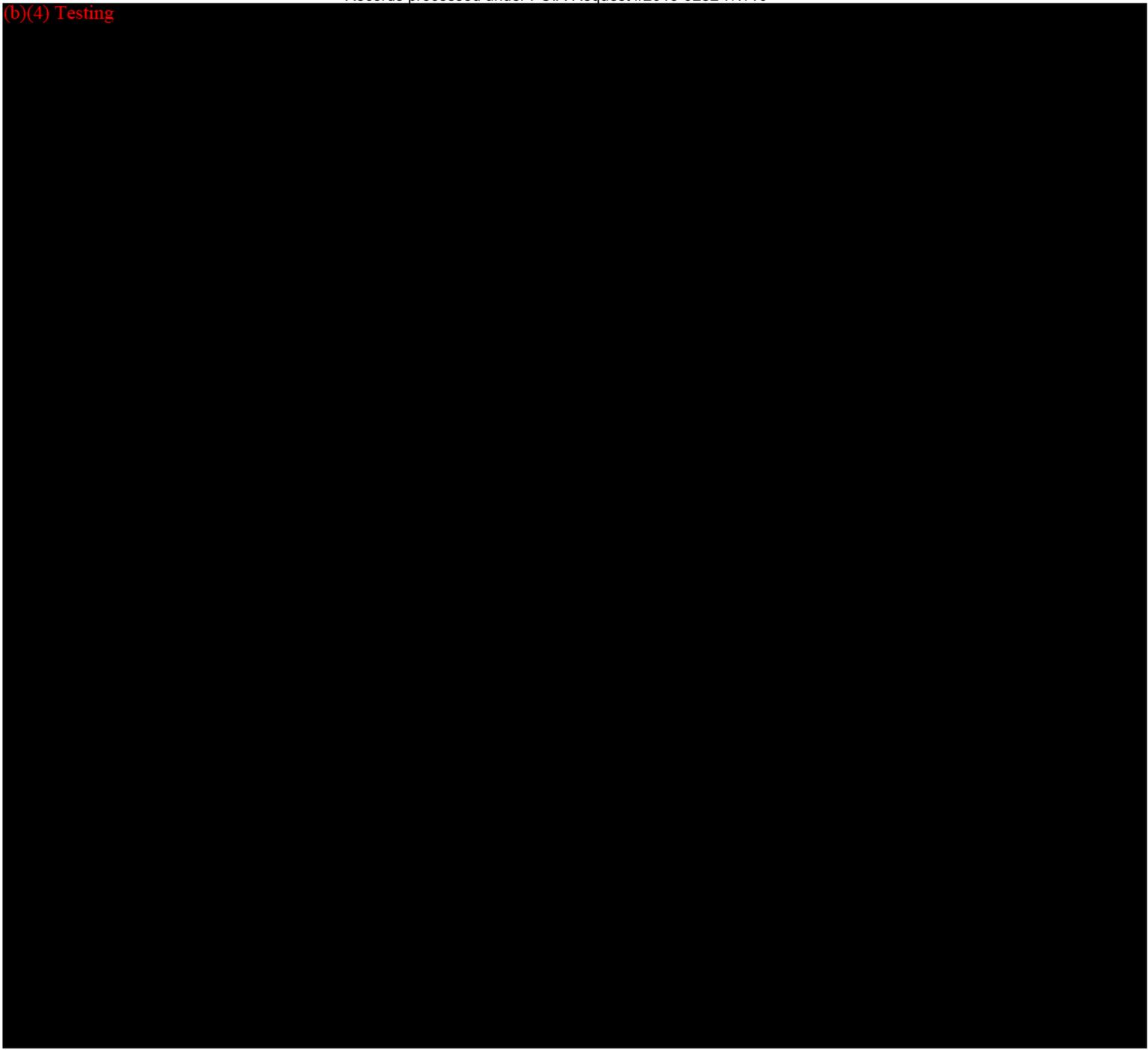
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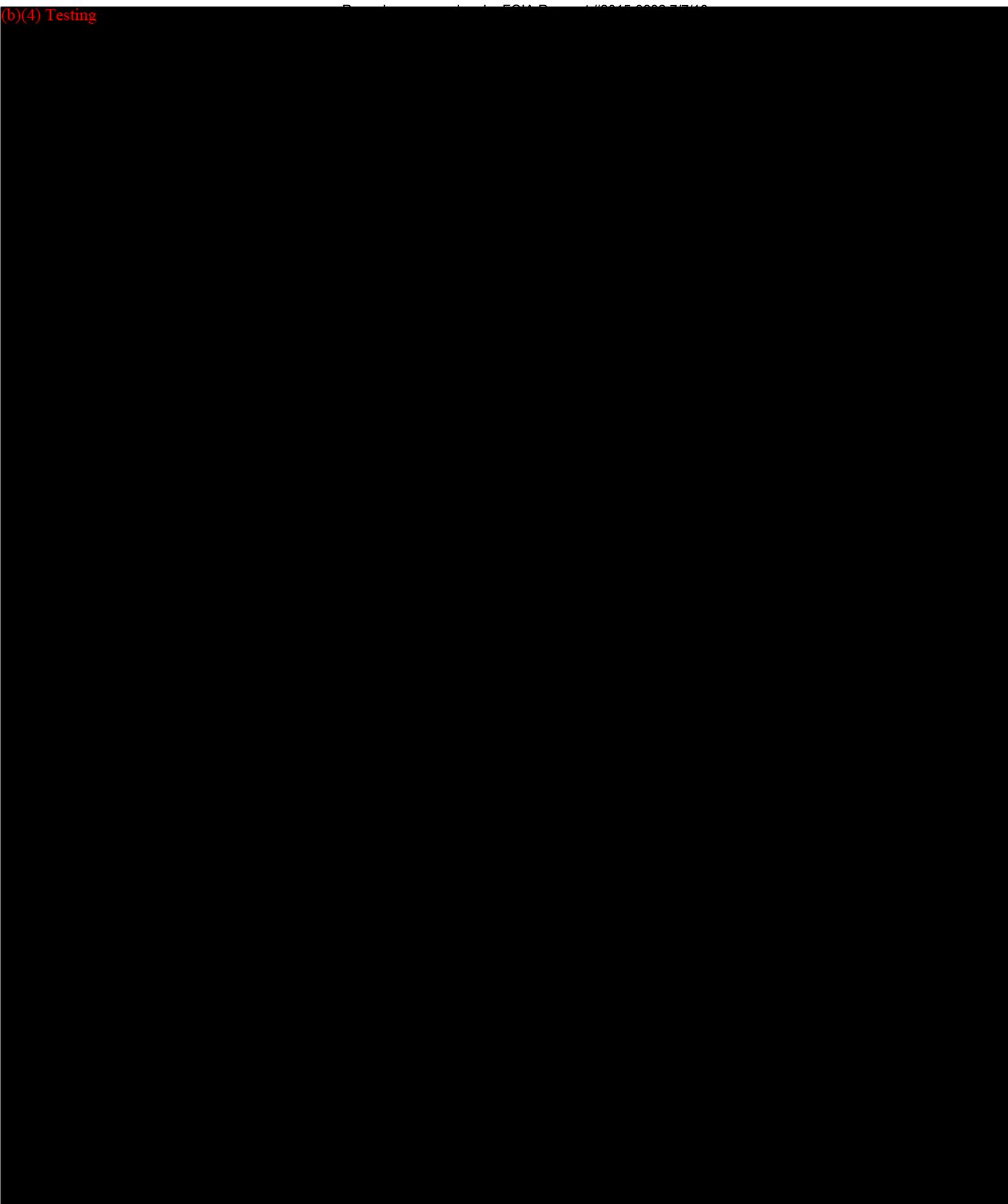
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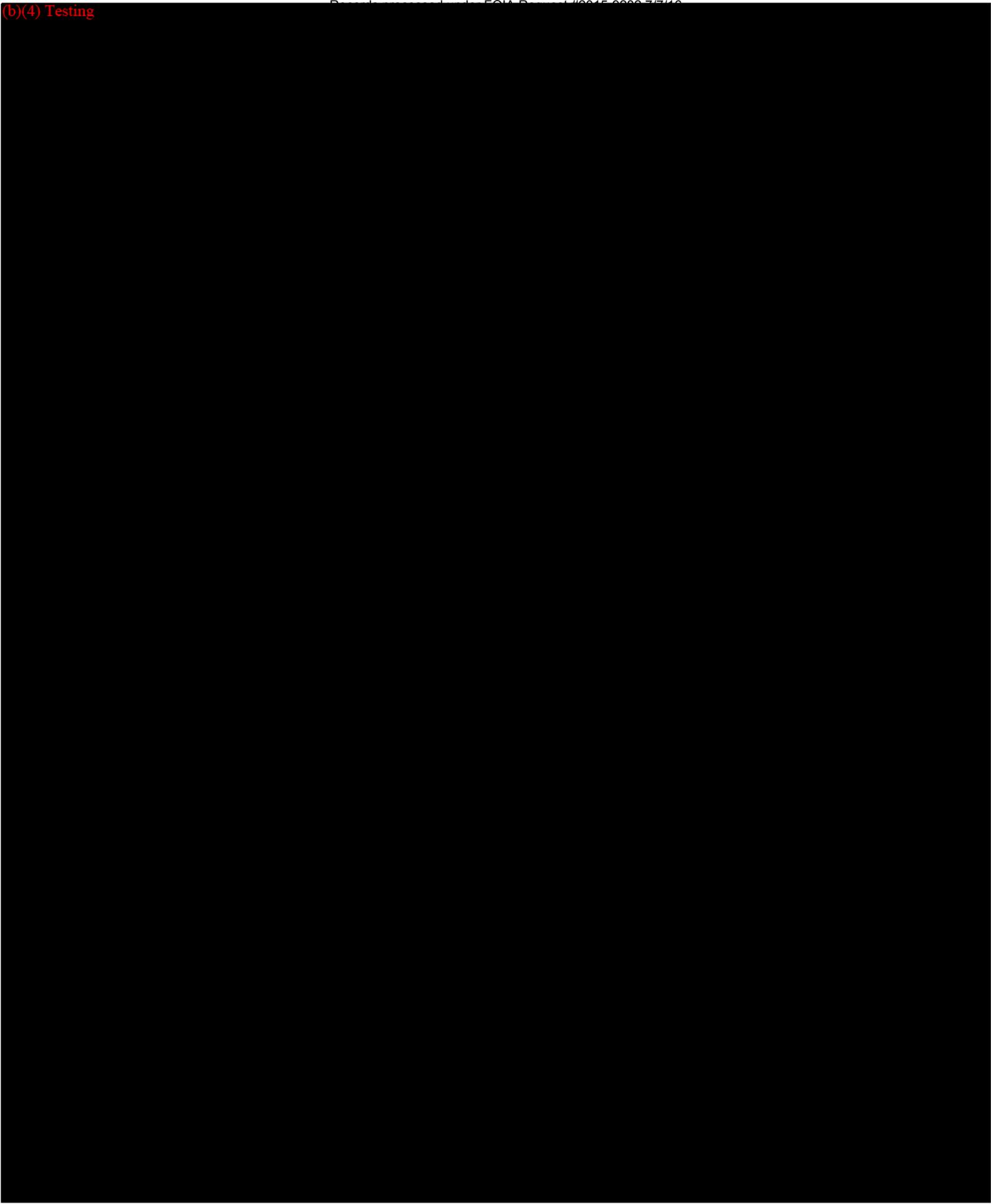


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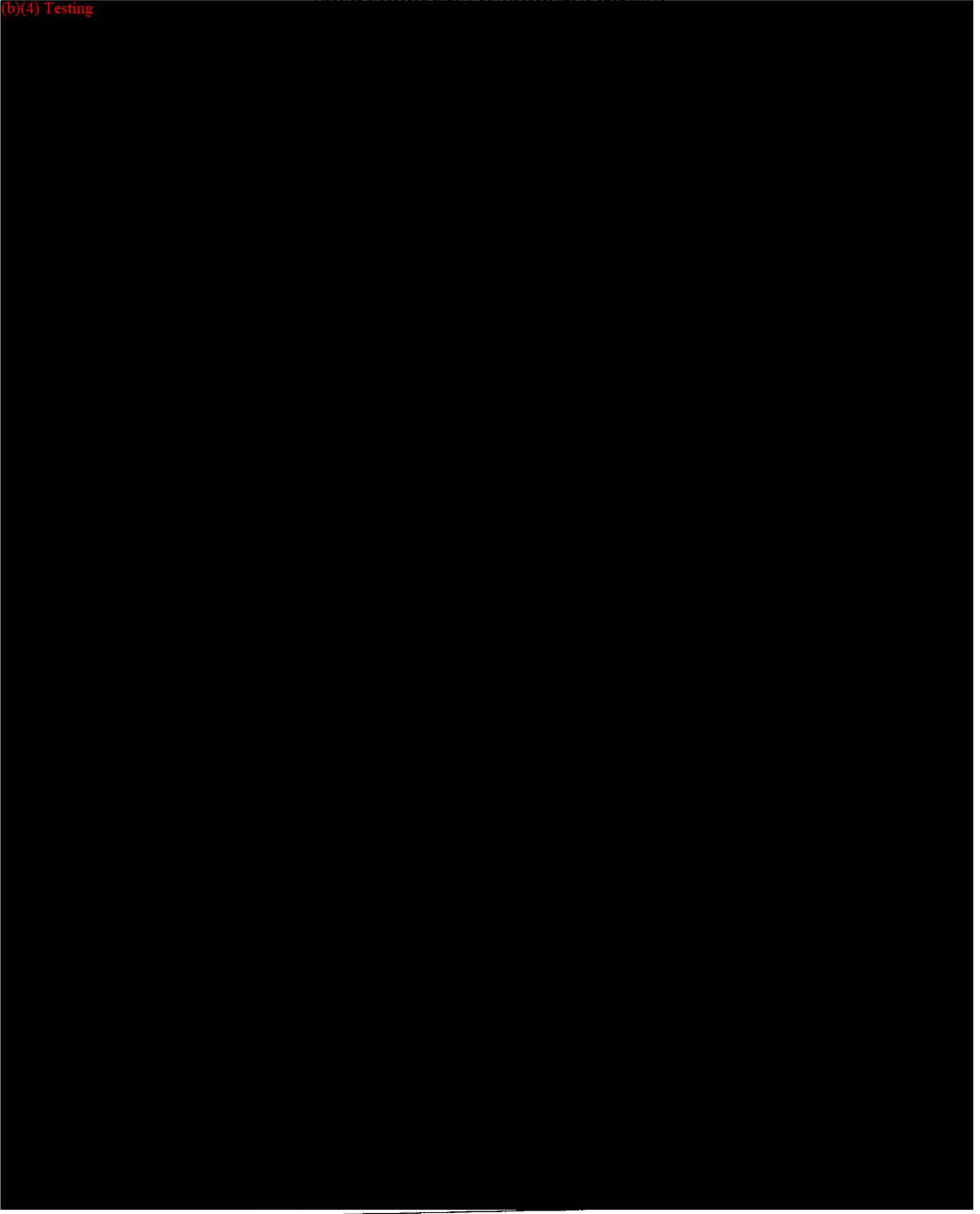
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APPENDIX G

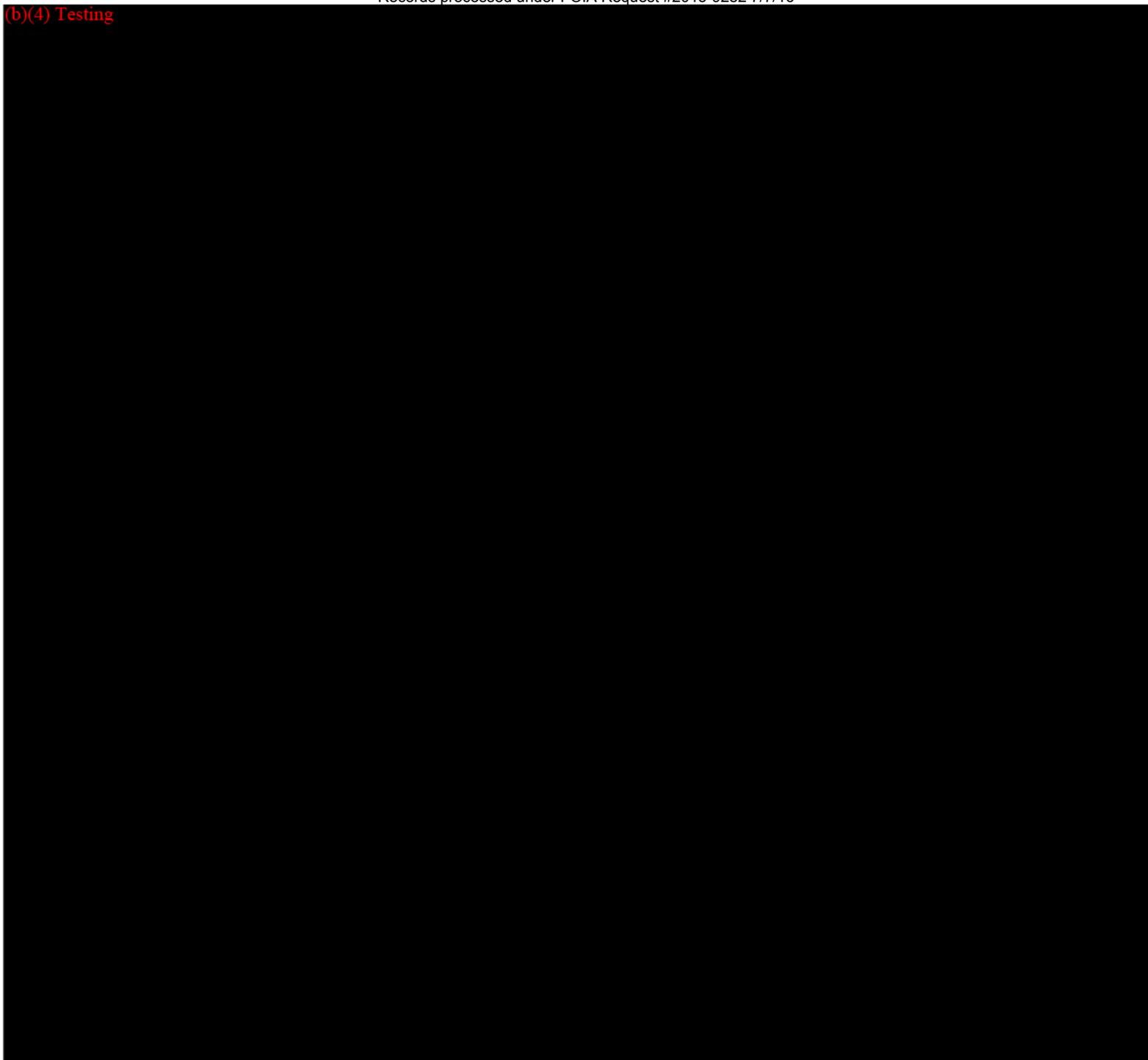
**ELECTRICAL SAFETY AND EMC
DATA**

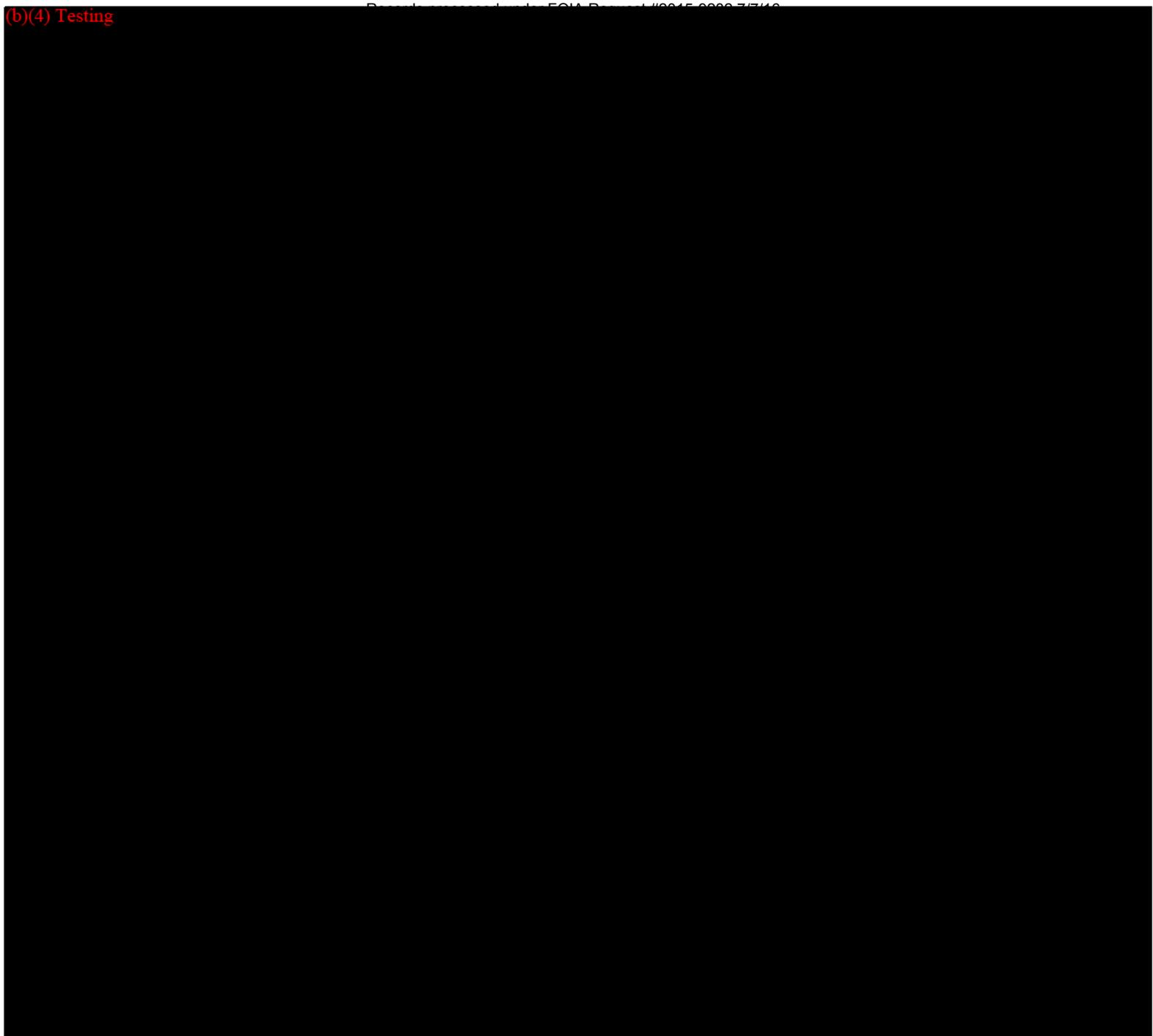


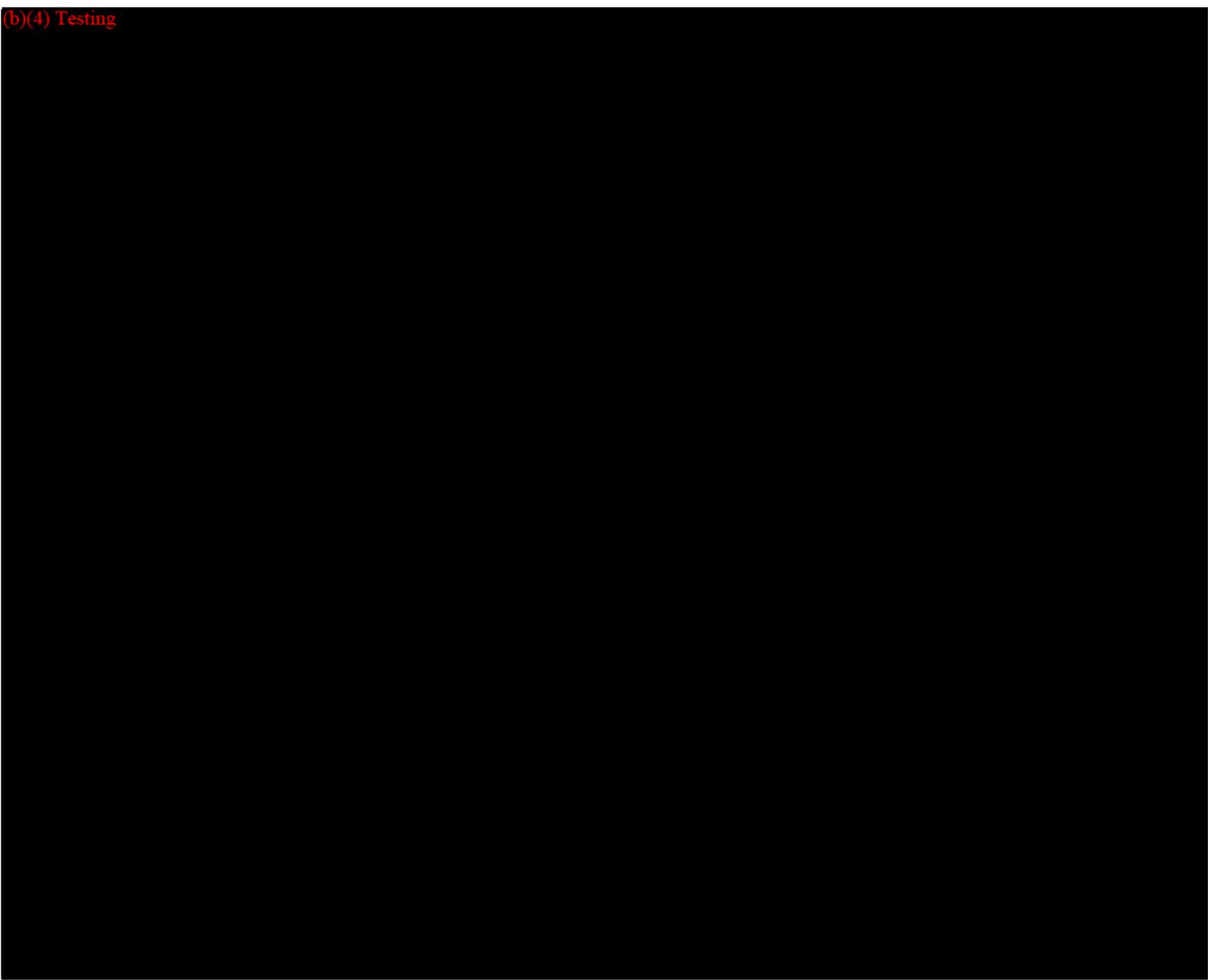
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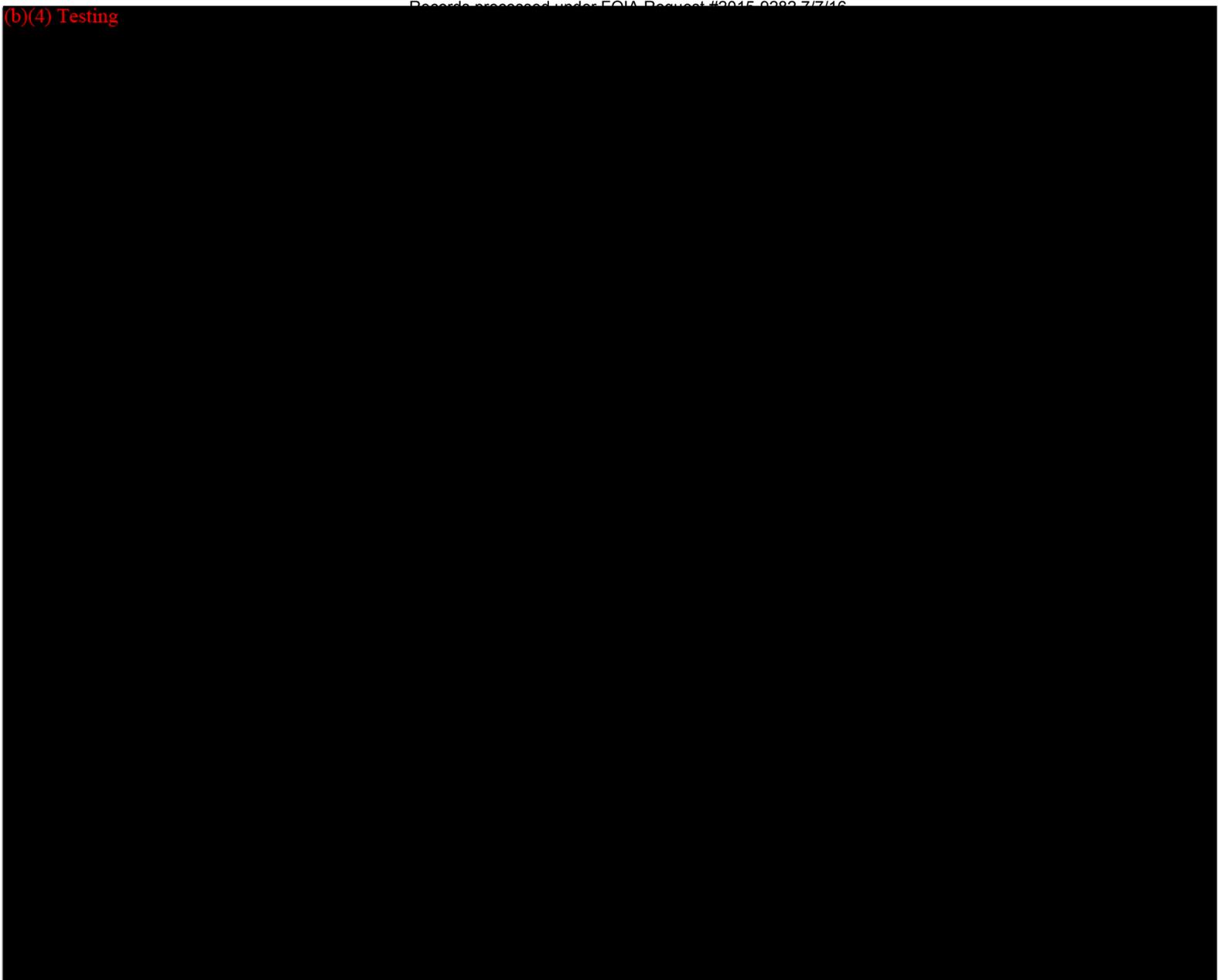


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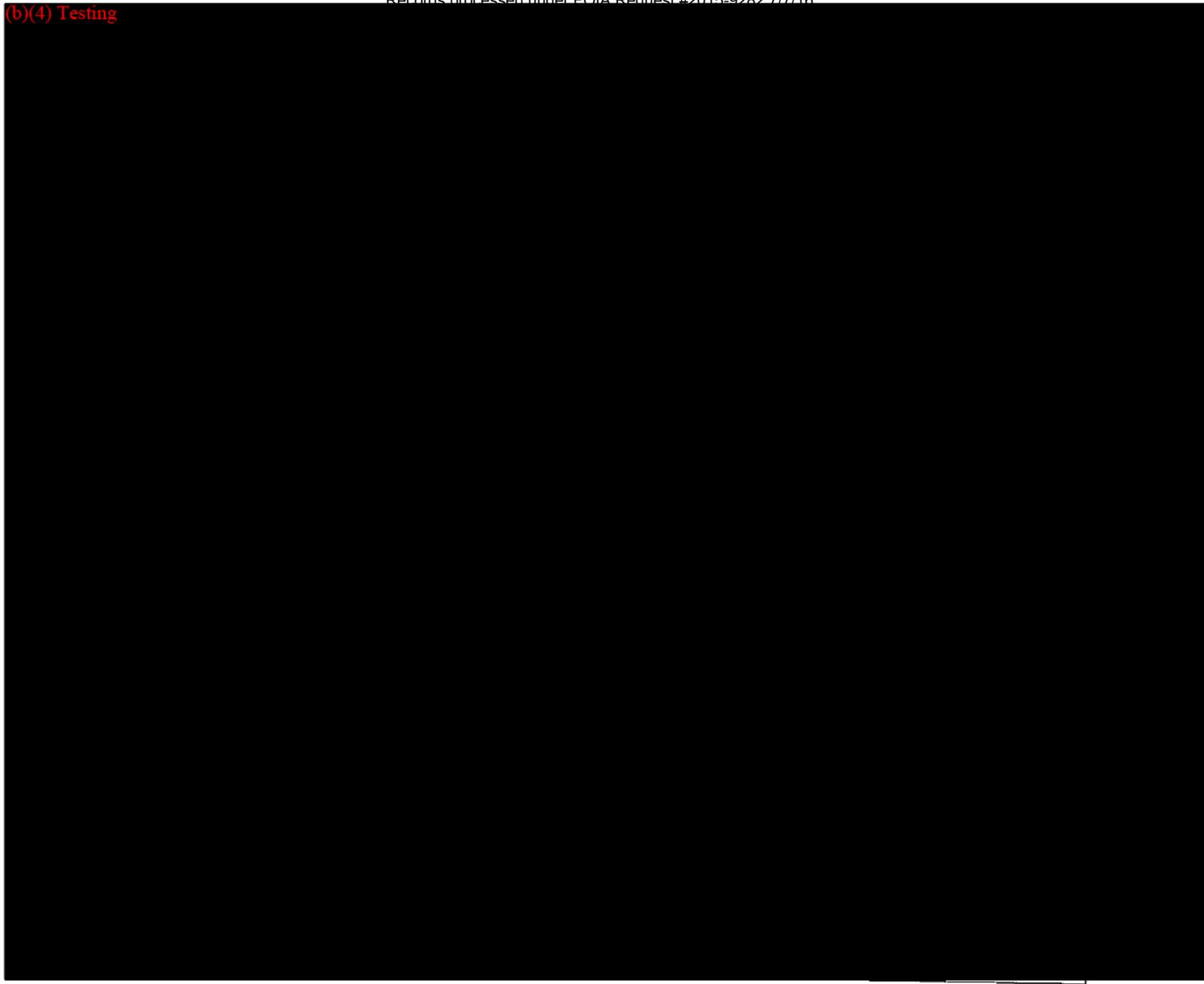






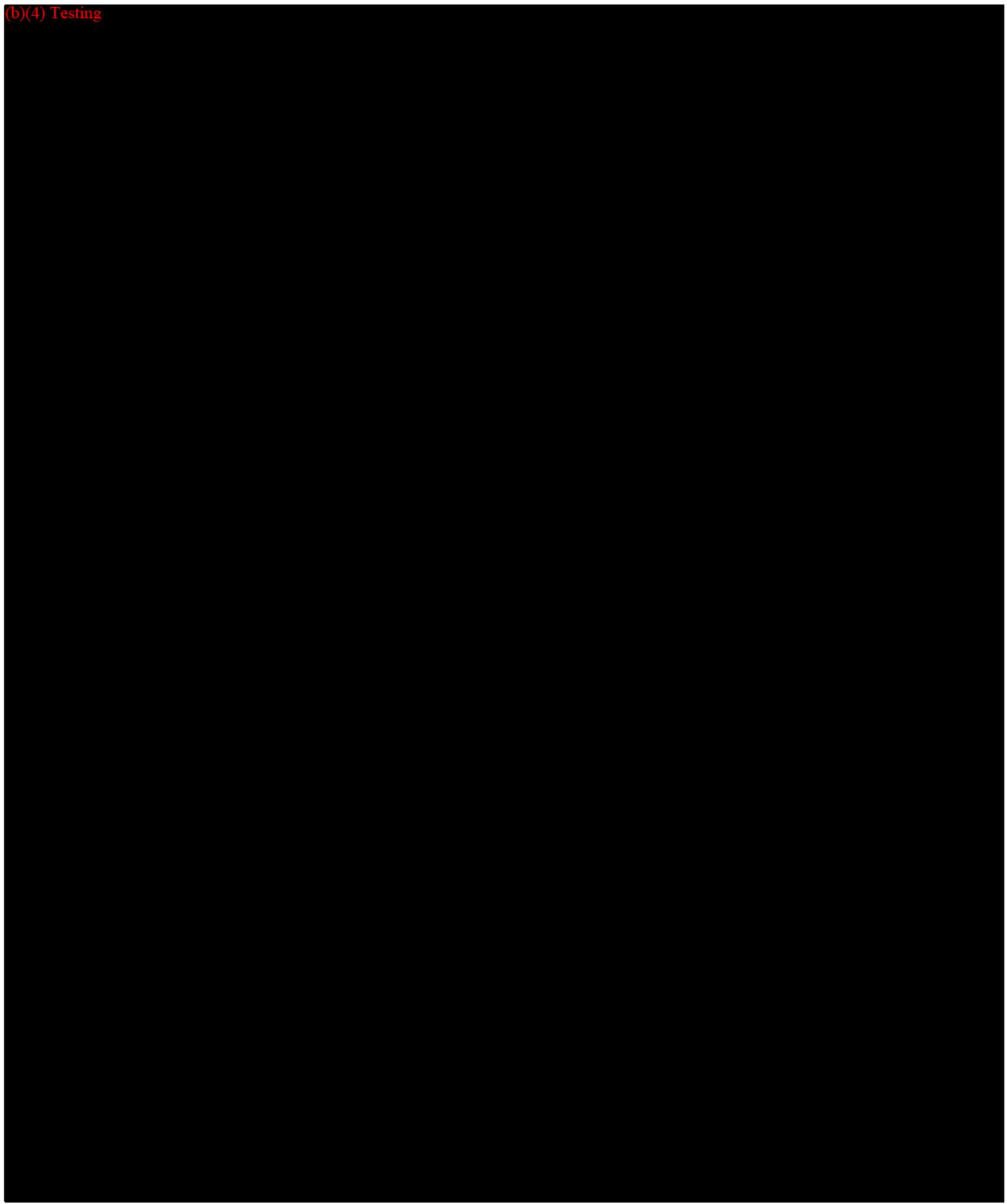


(b)(4) Testing

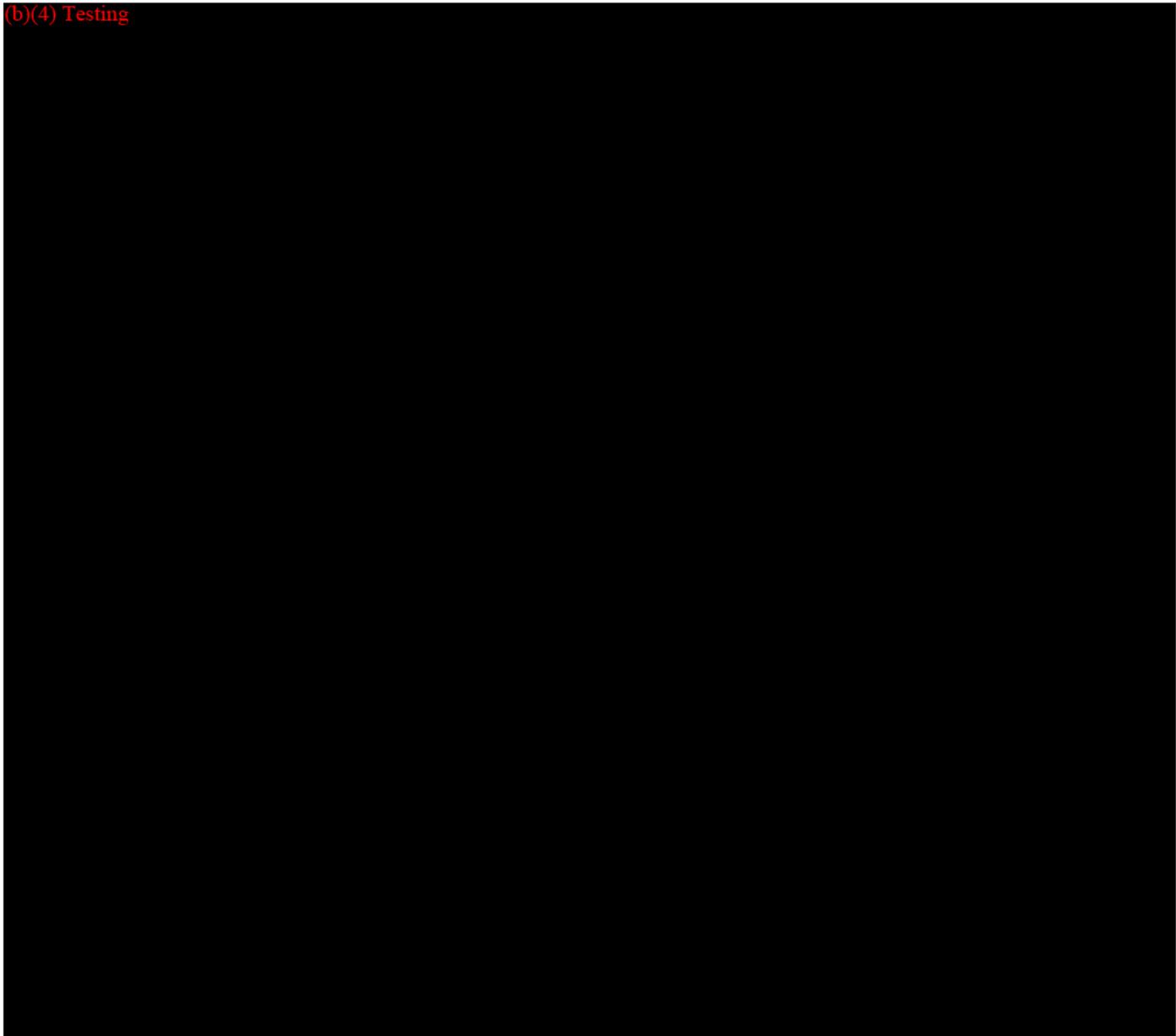


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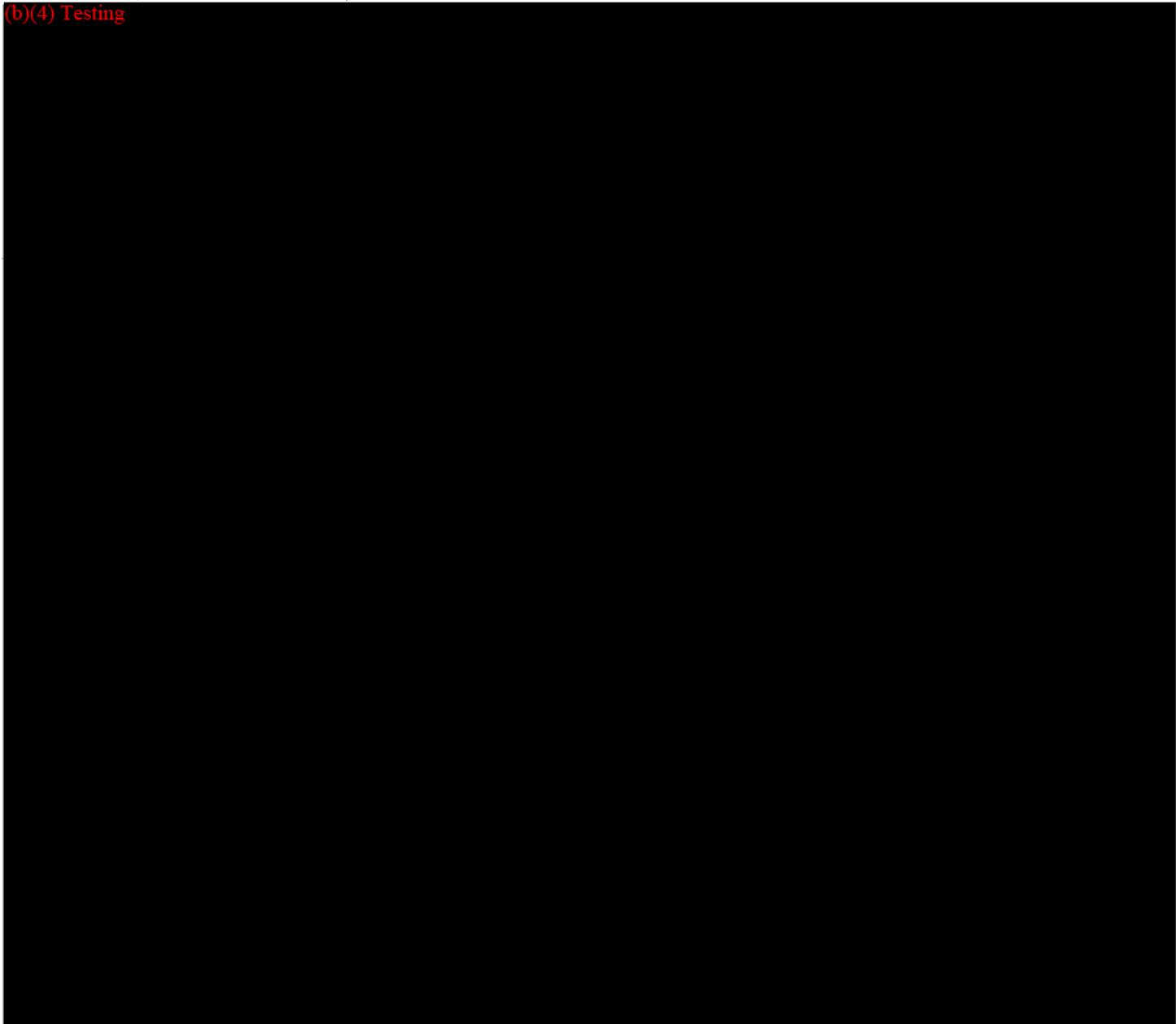




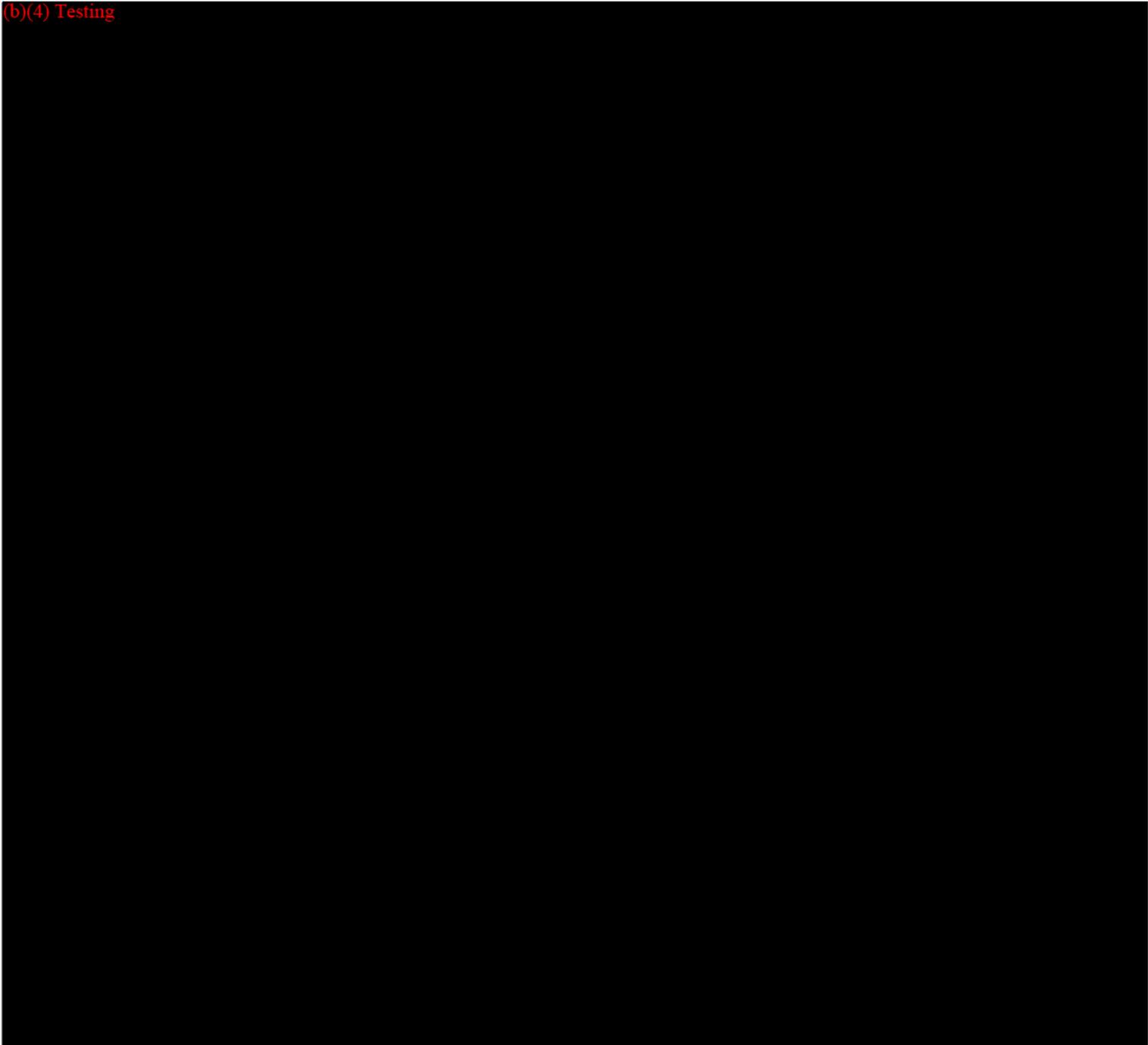
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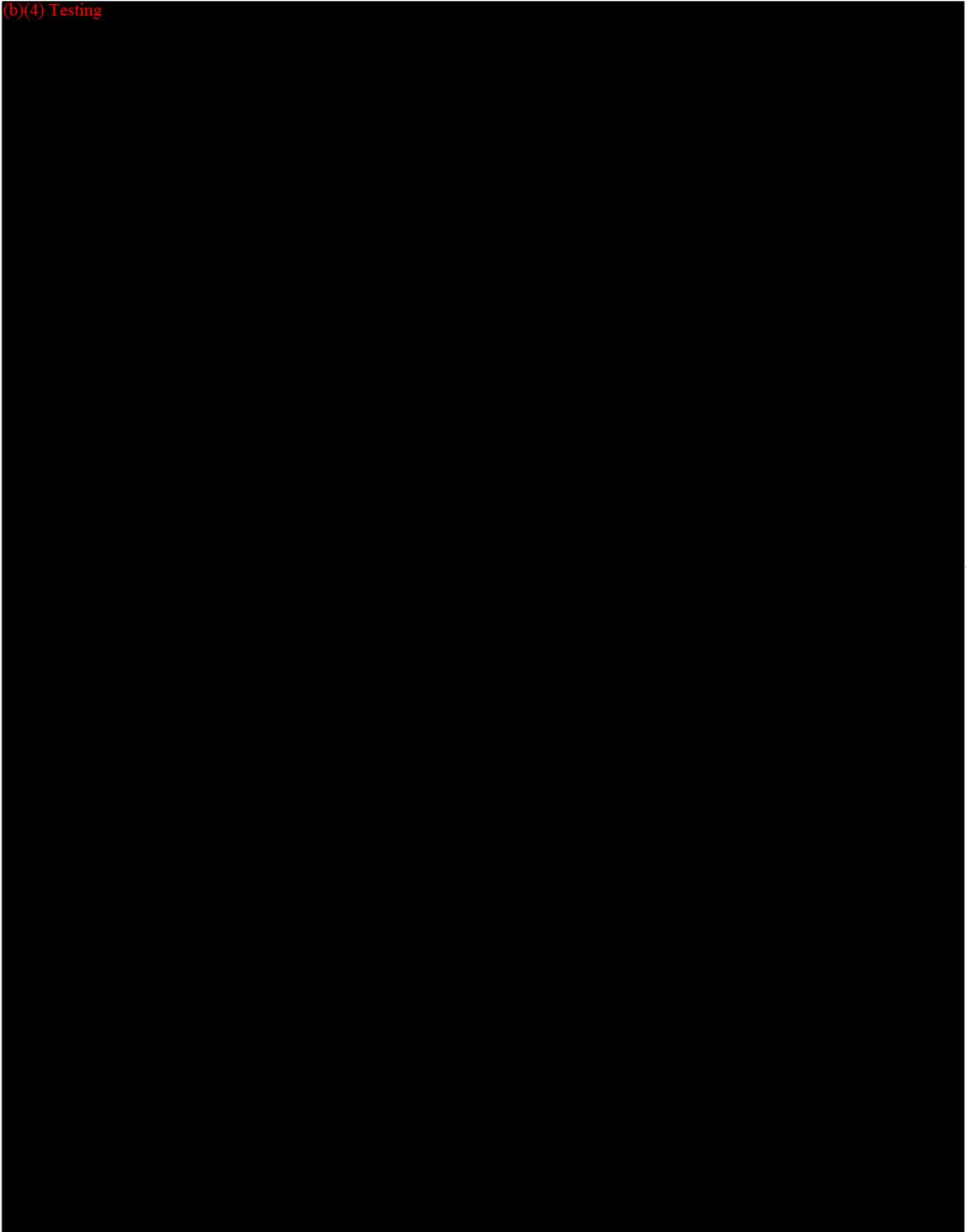
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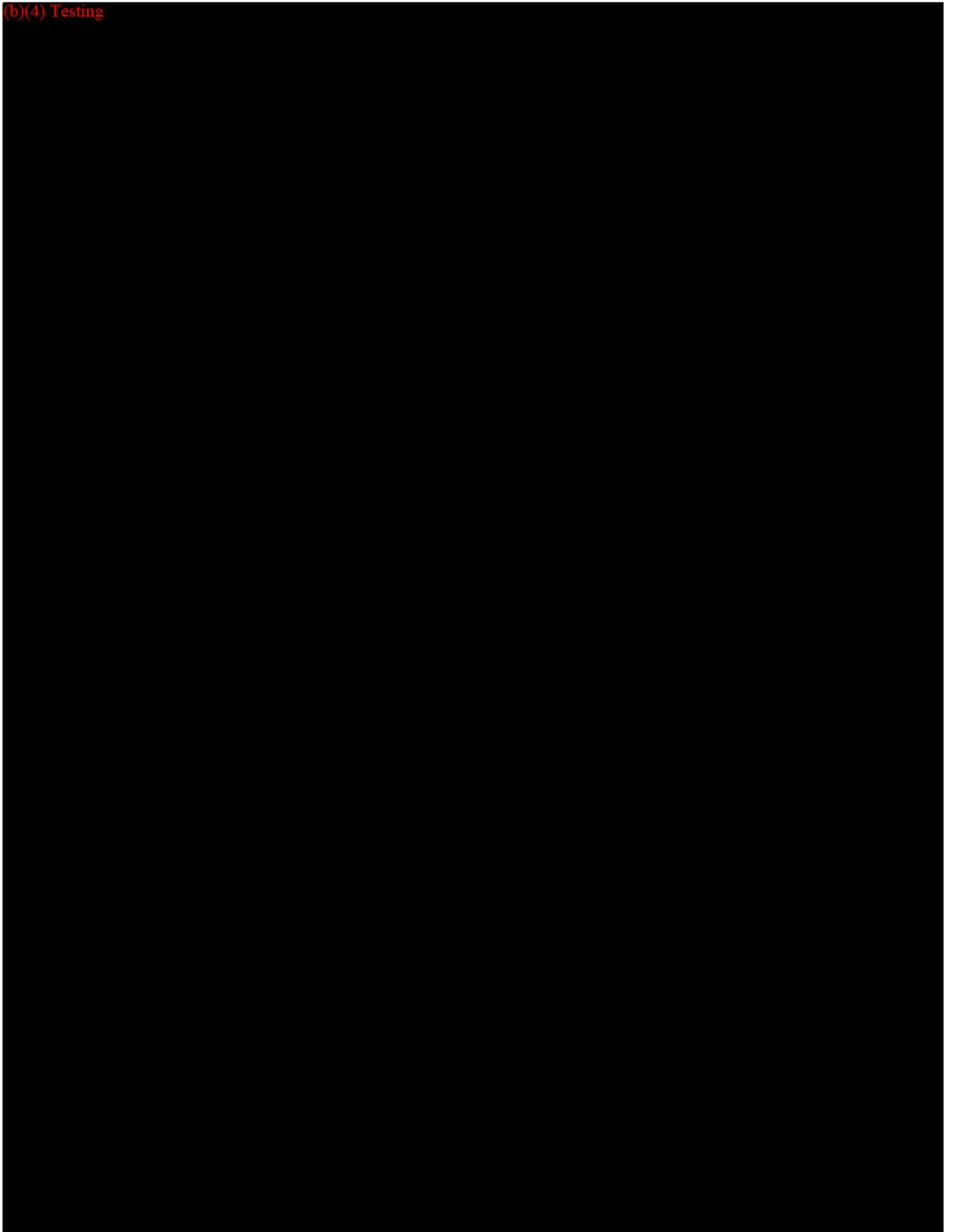
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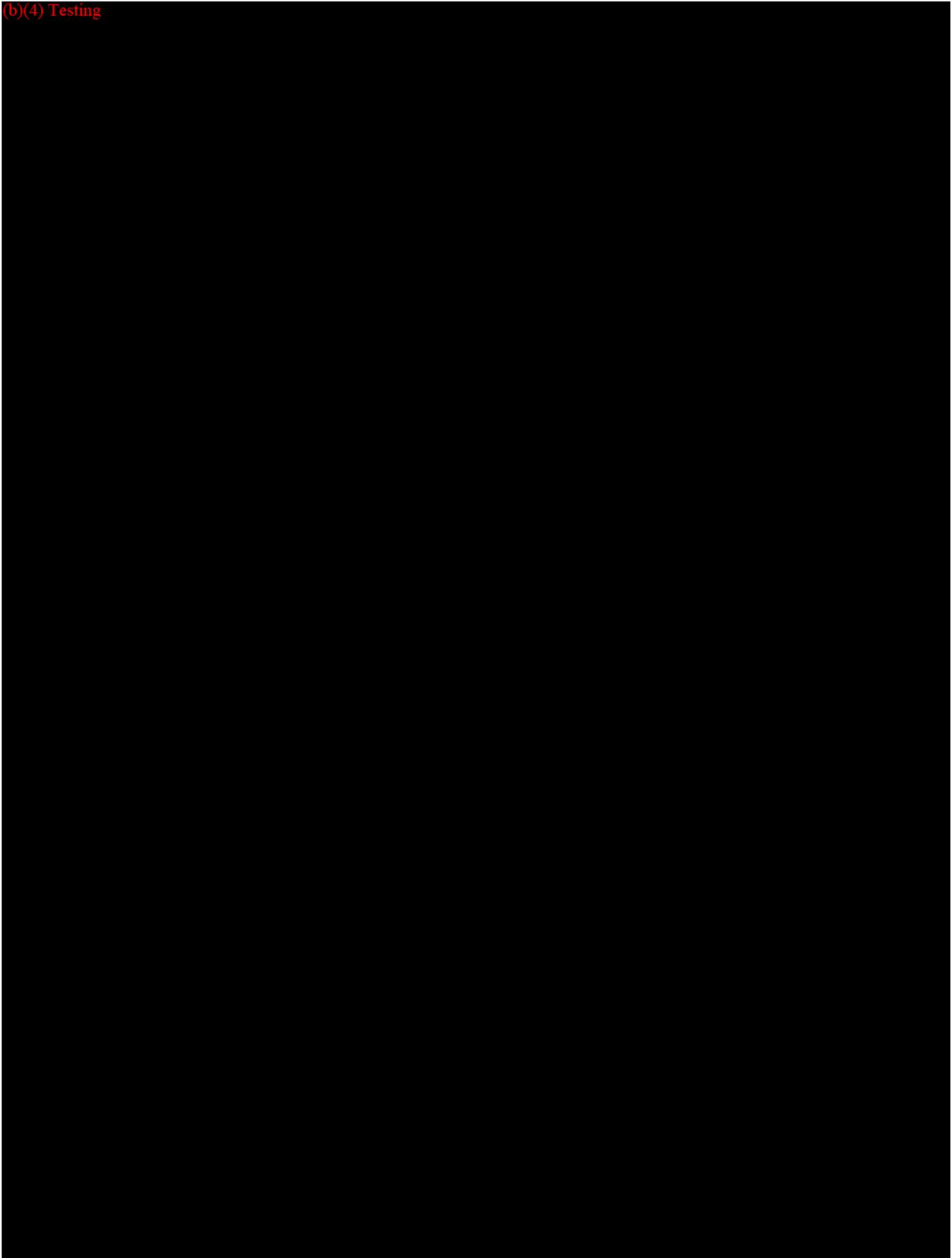
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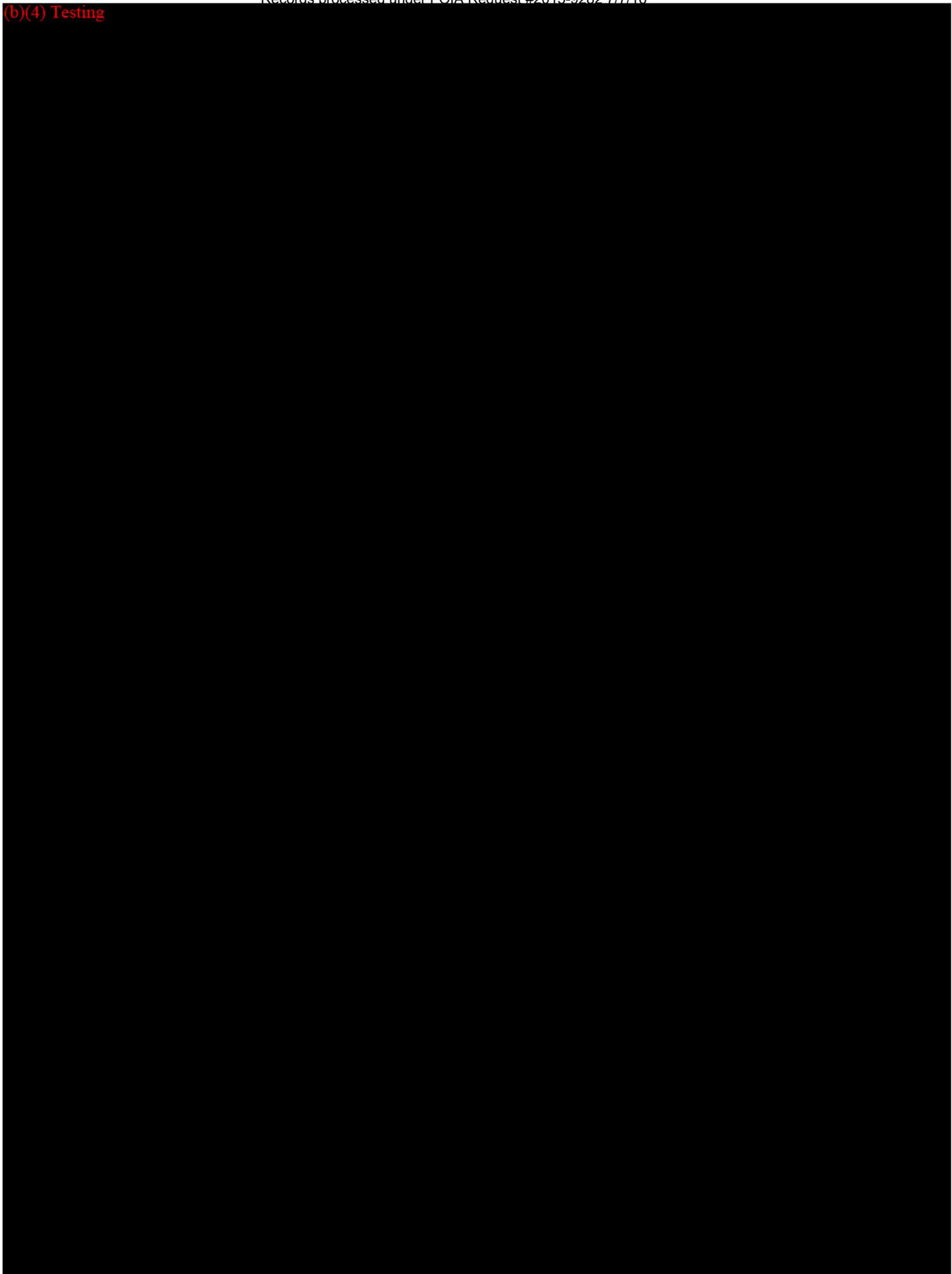
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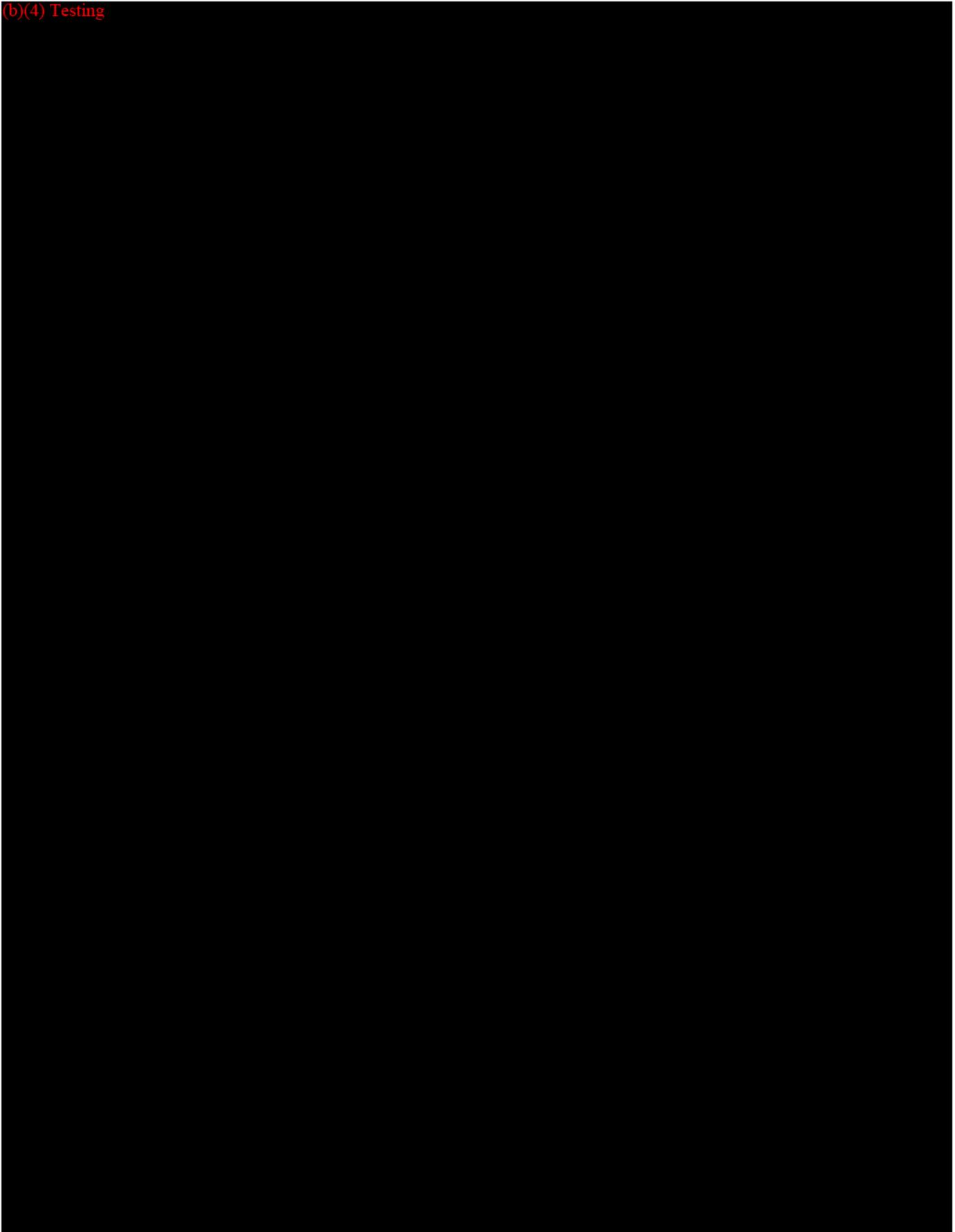
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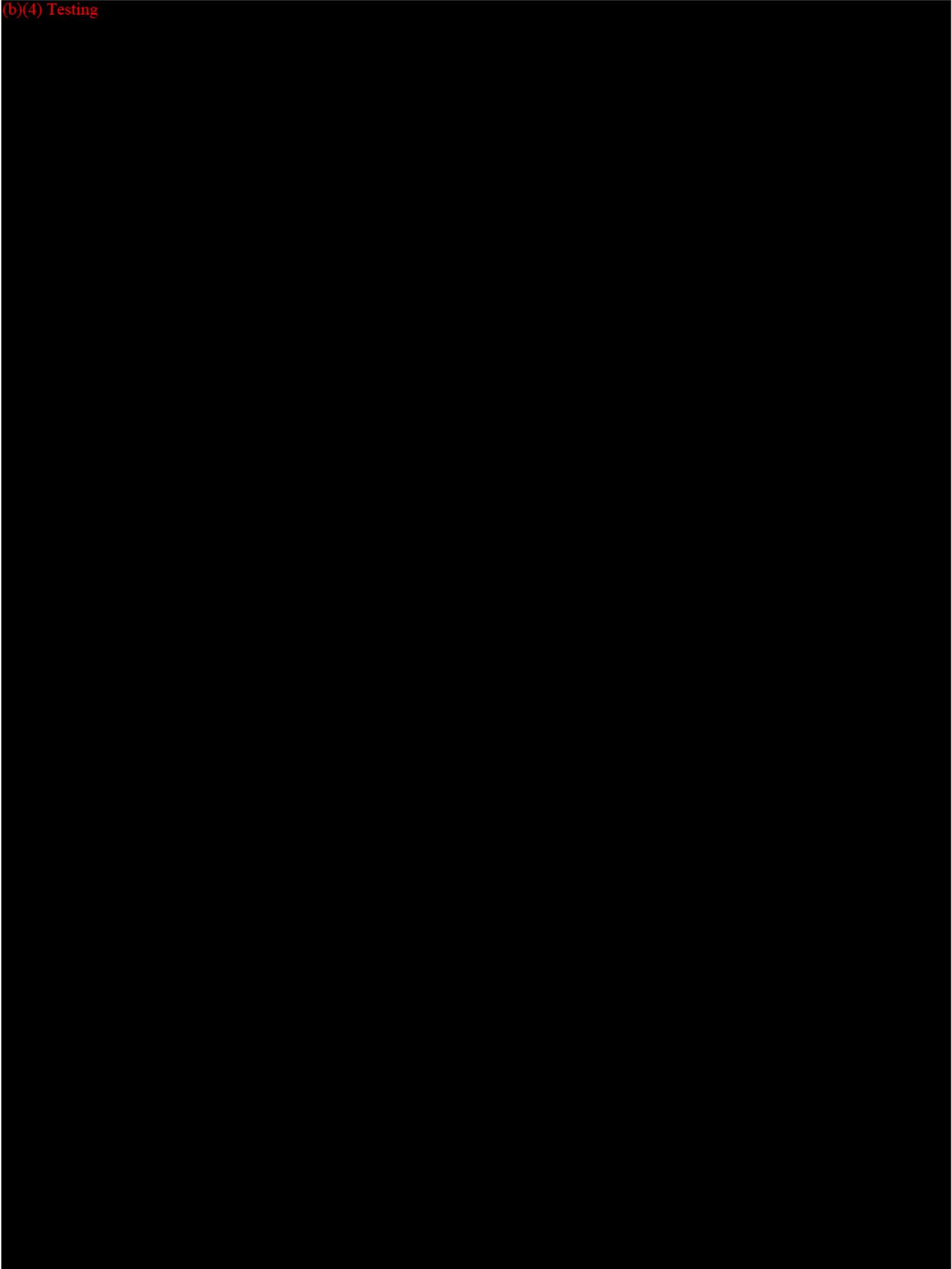
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(b)(4) Testing

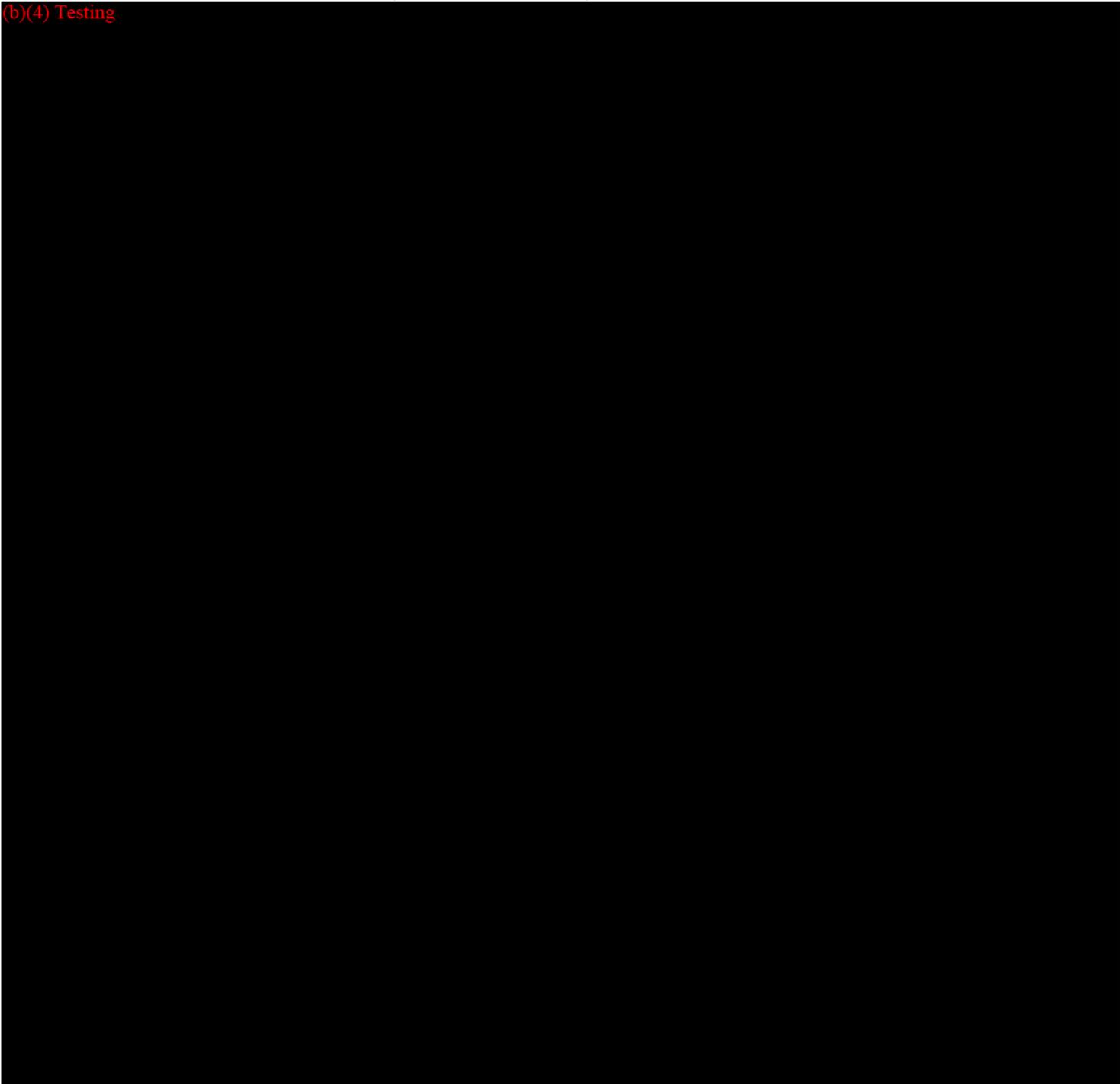


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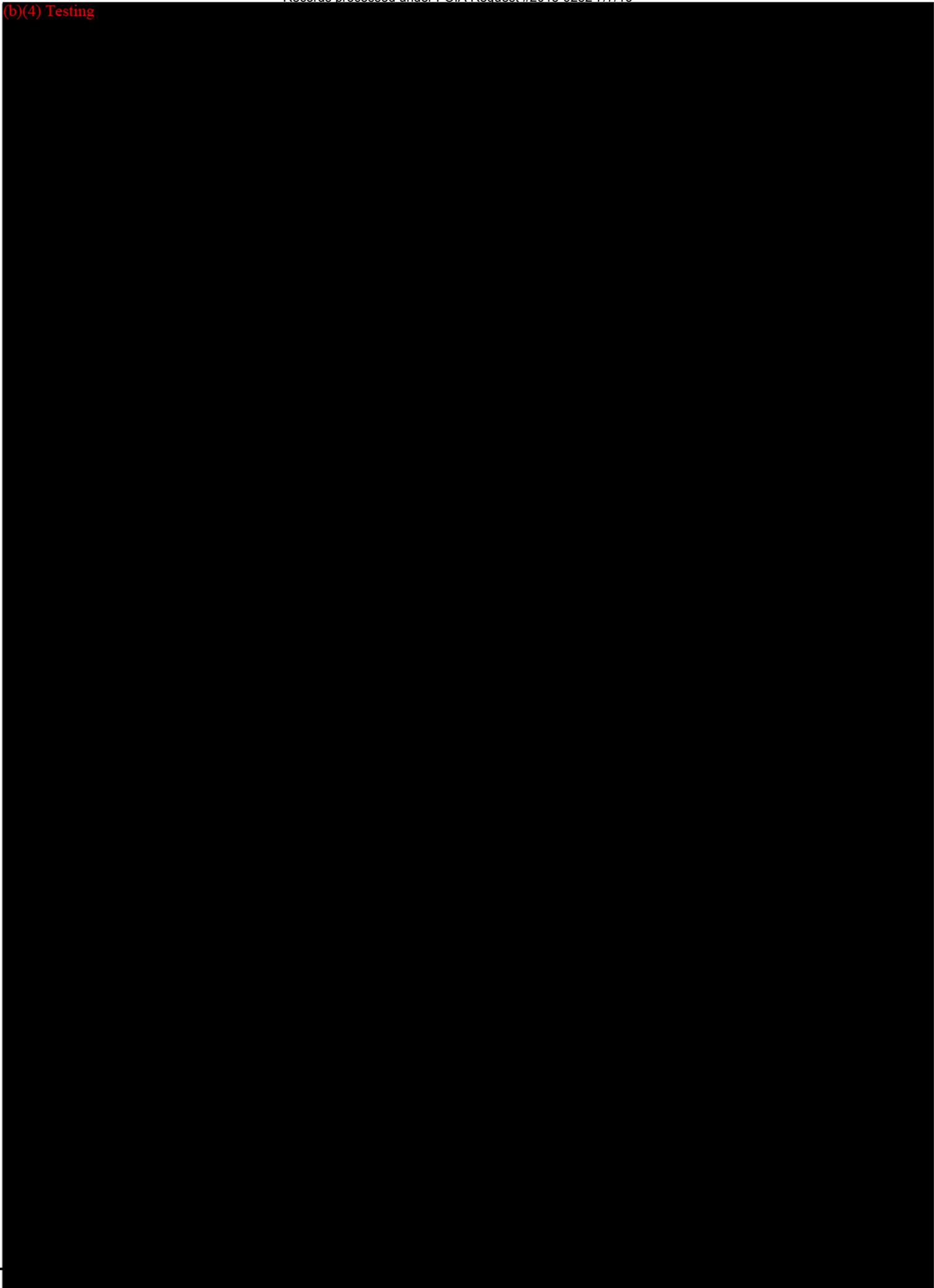


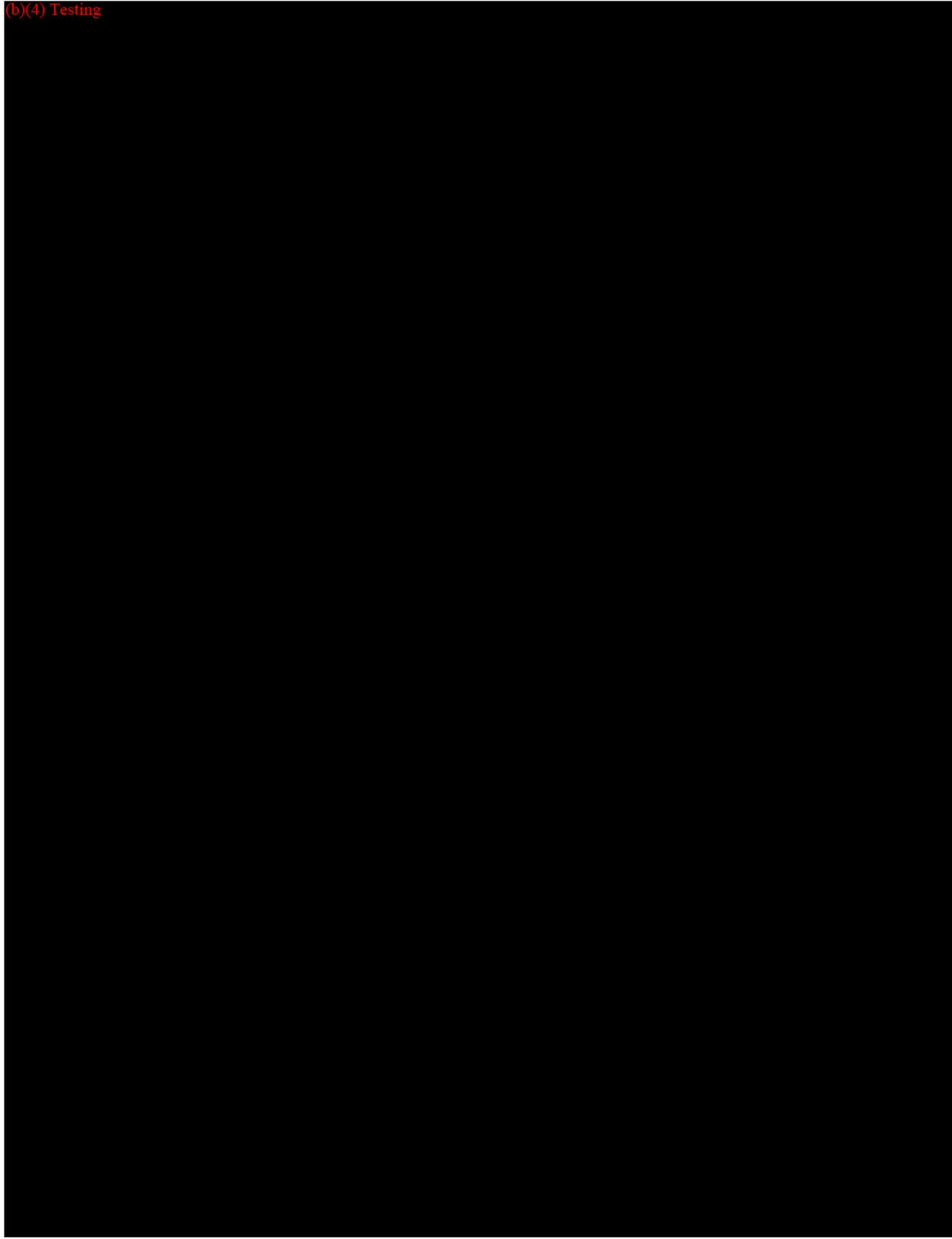
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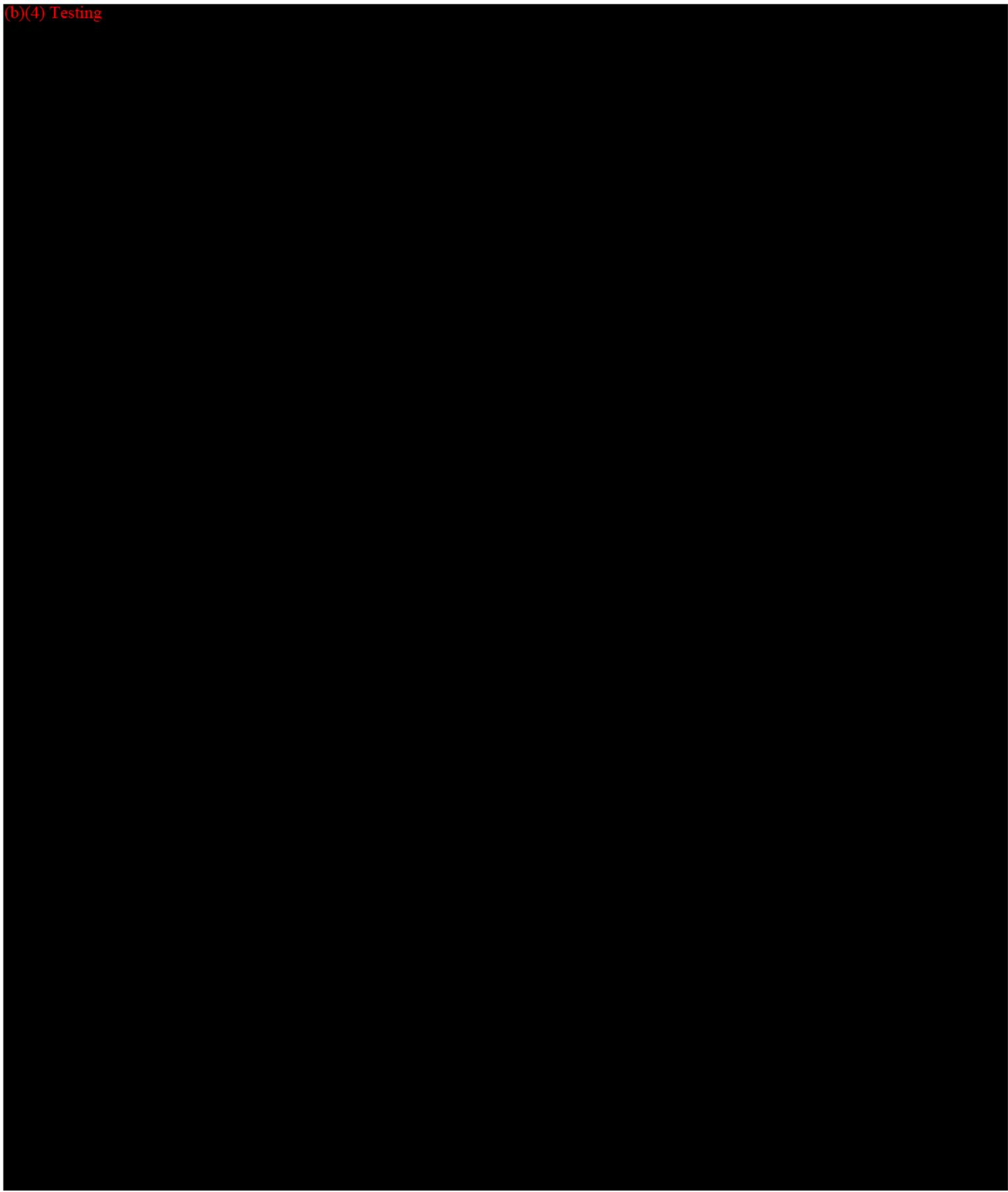
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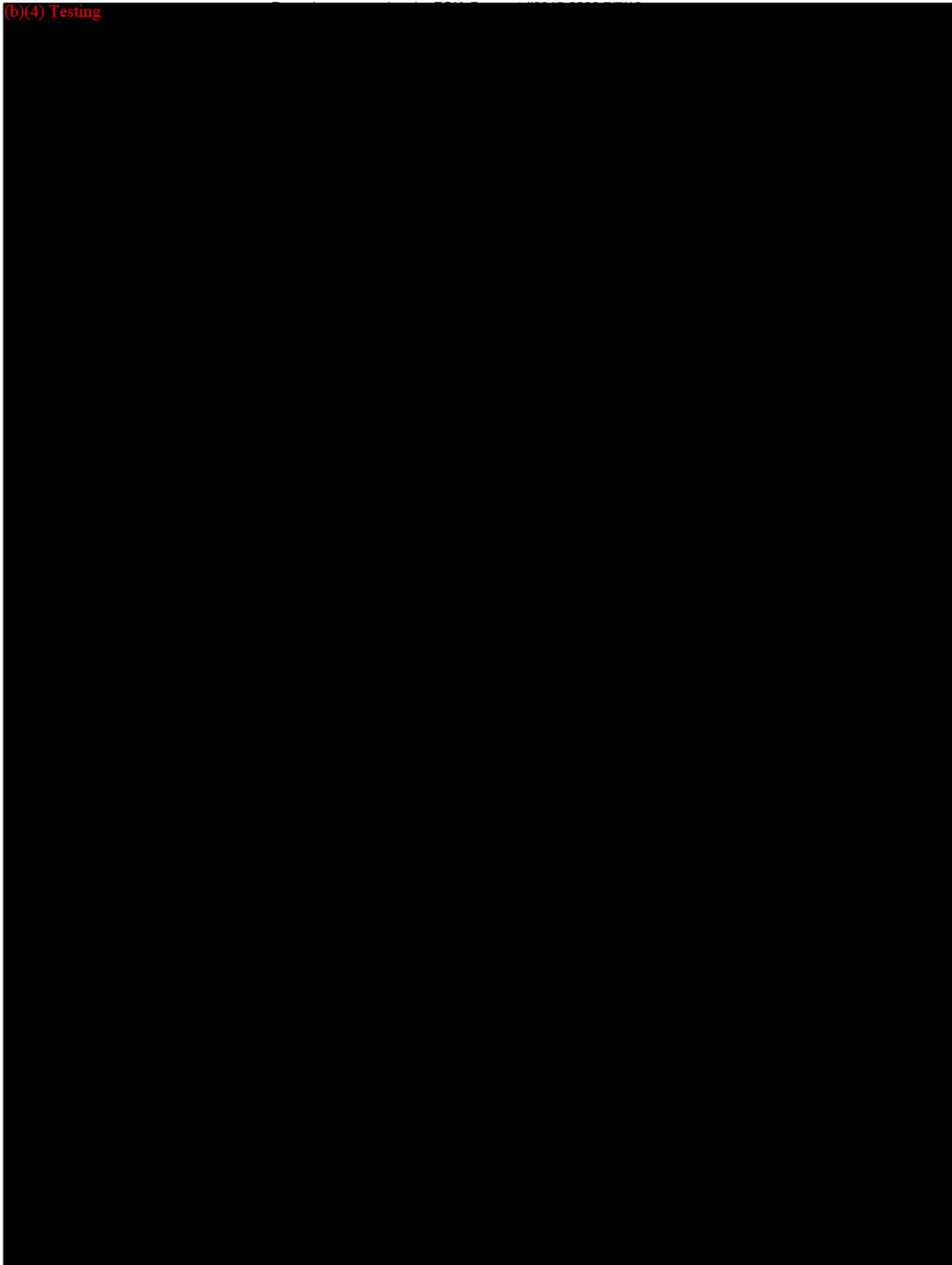


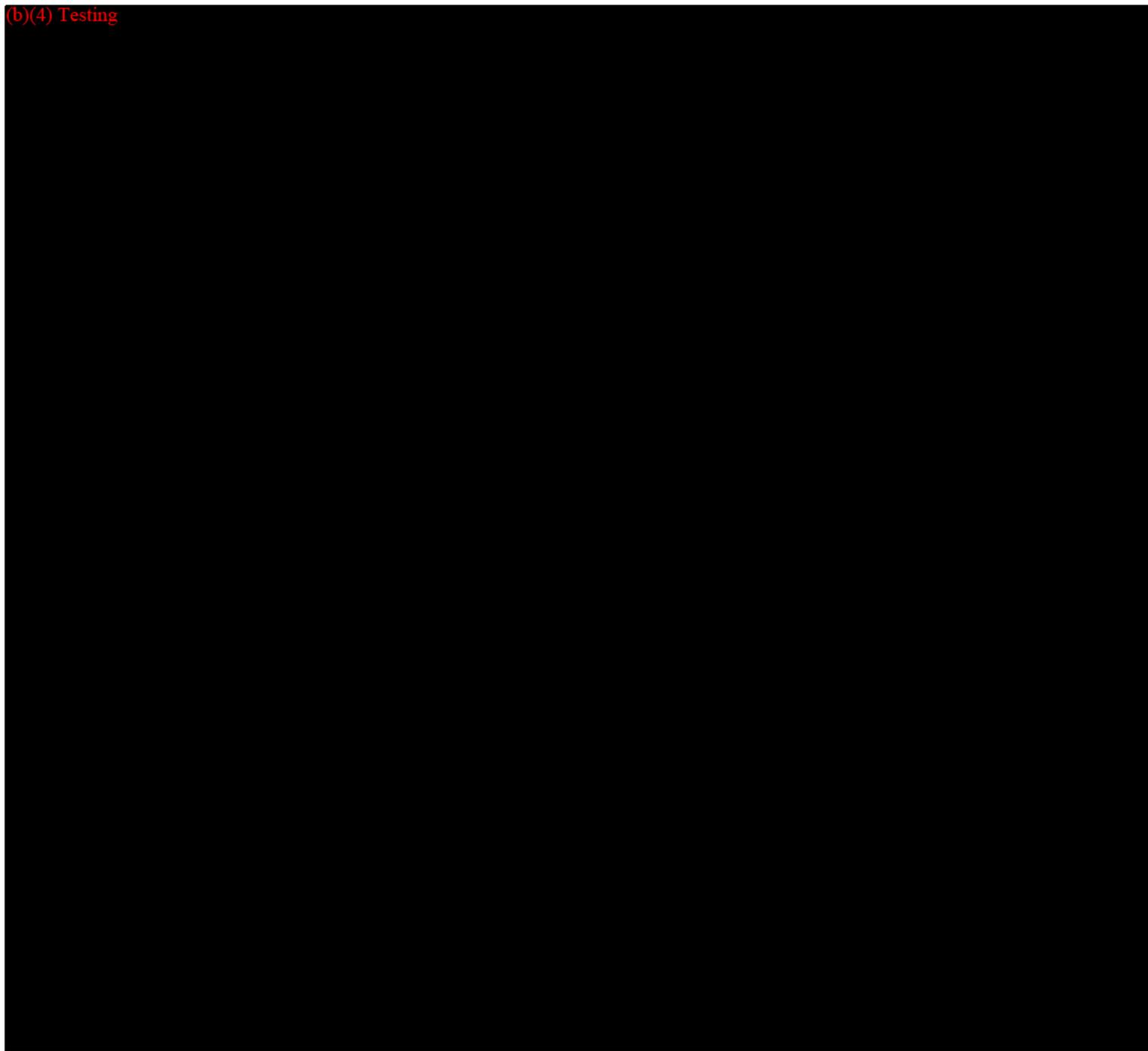
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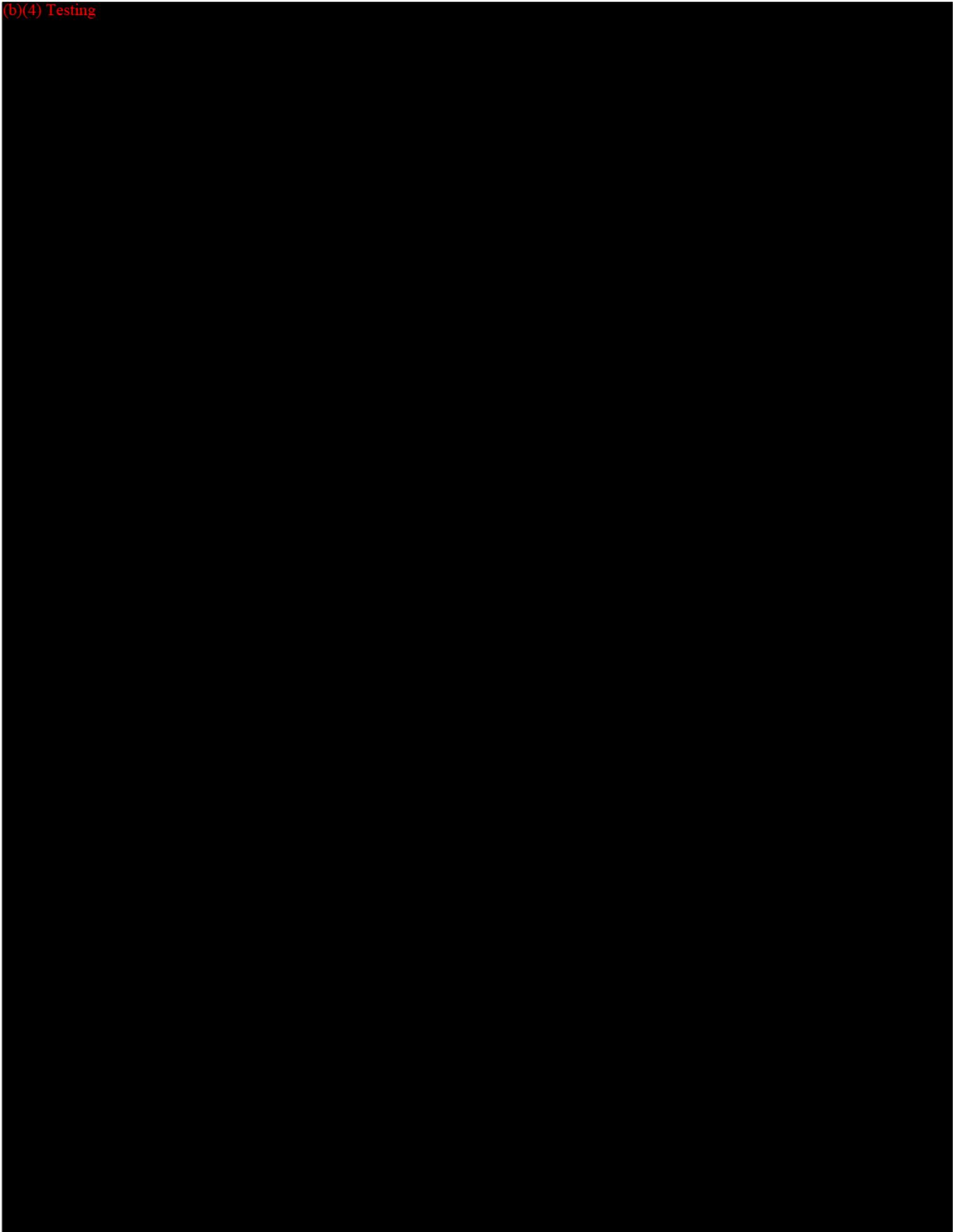


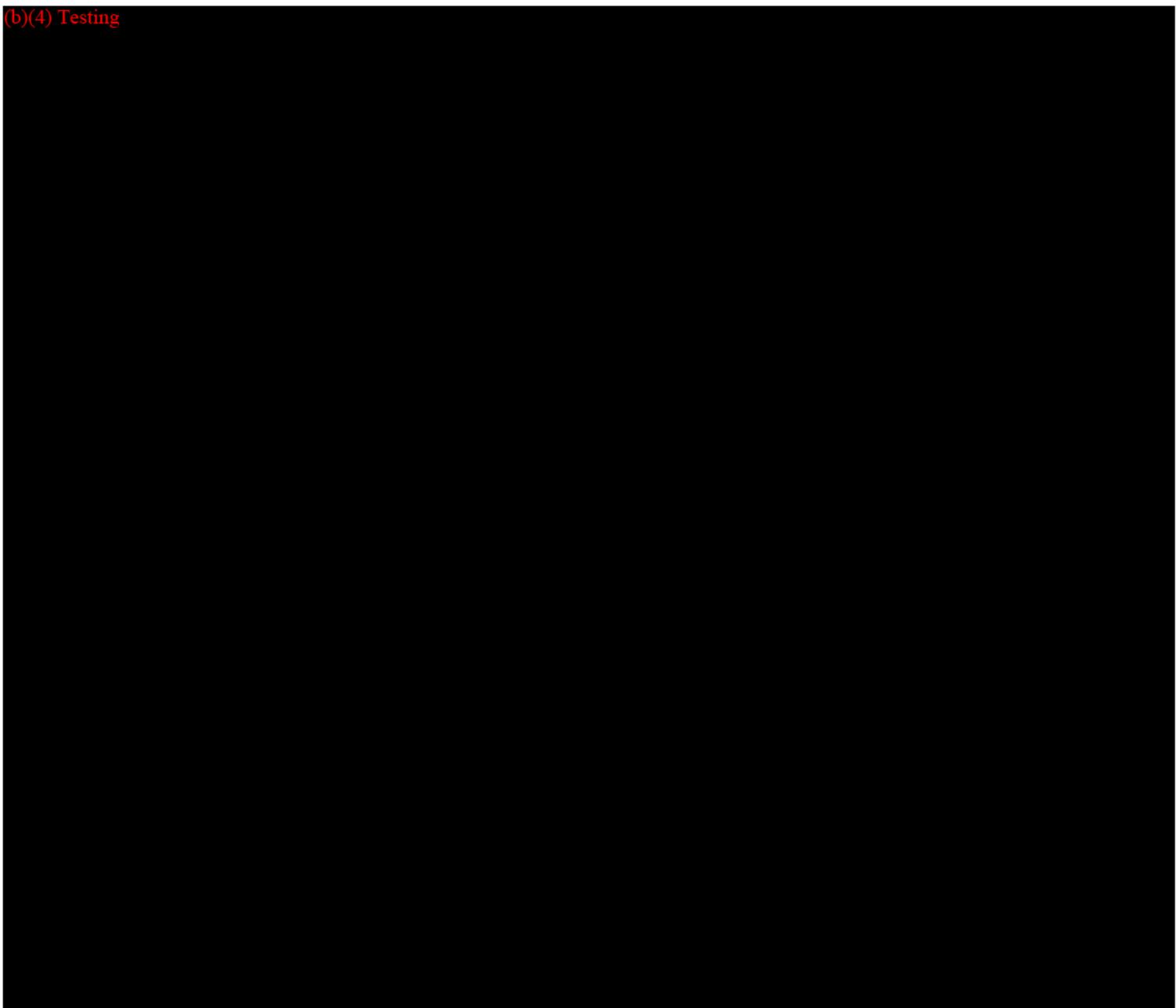


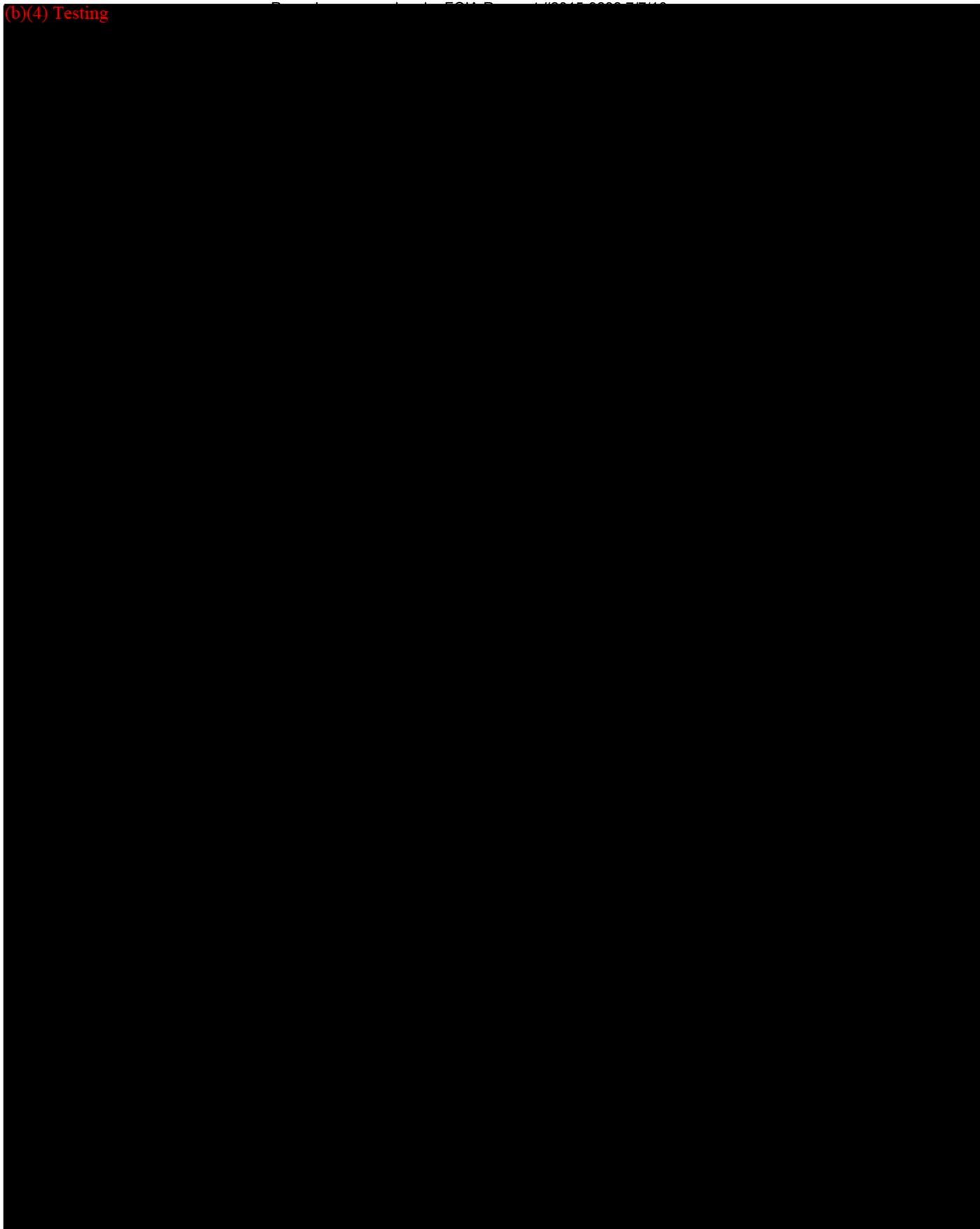




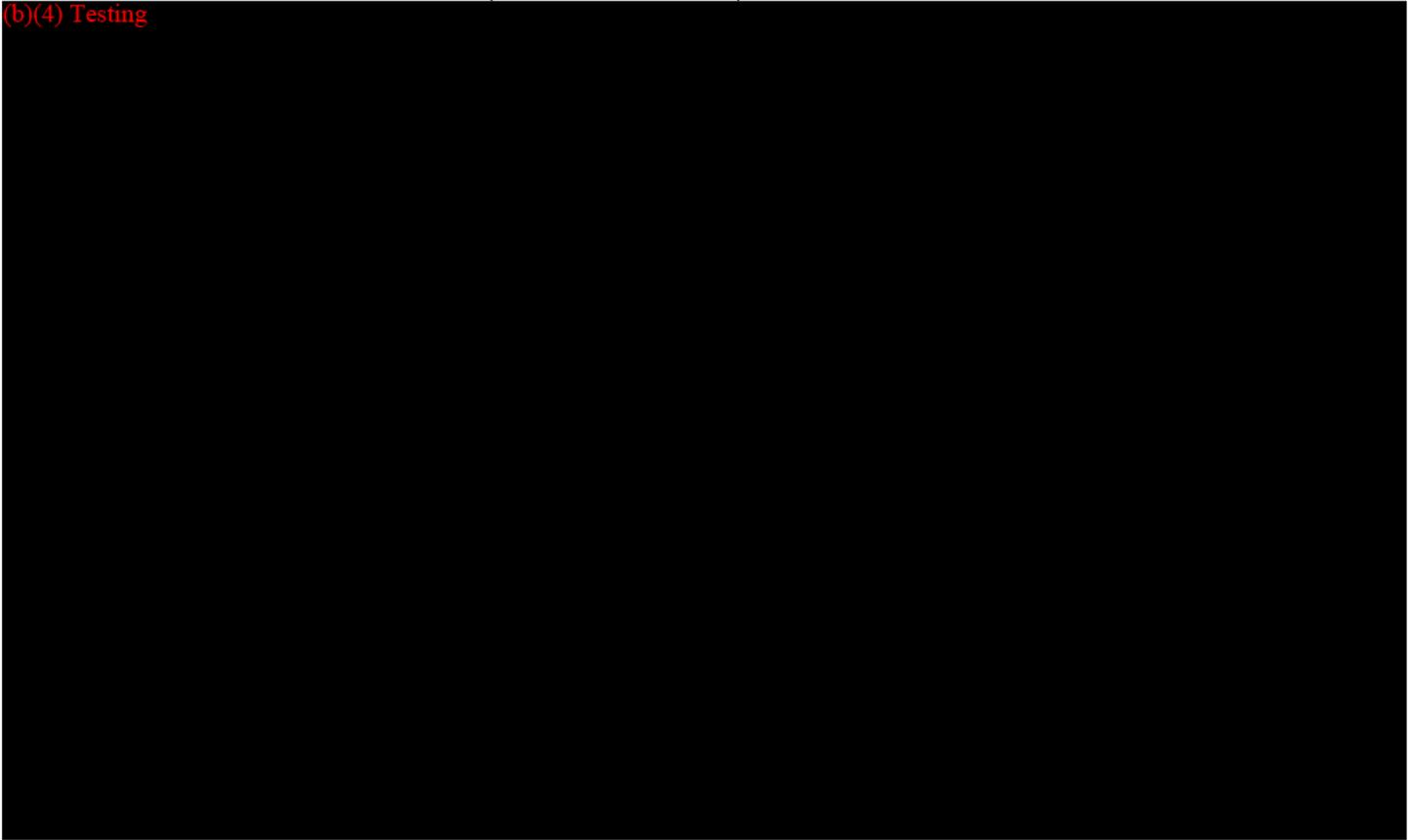


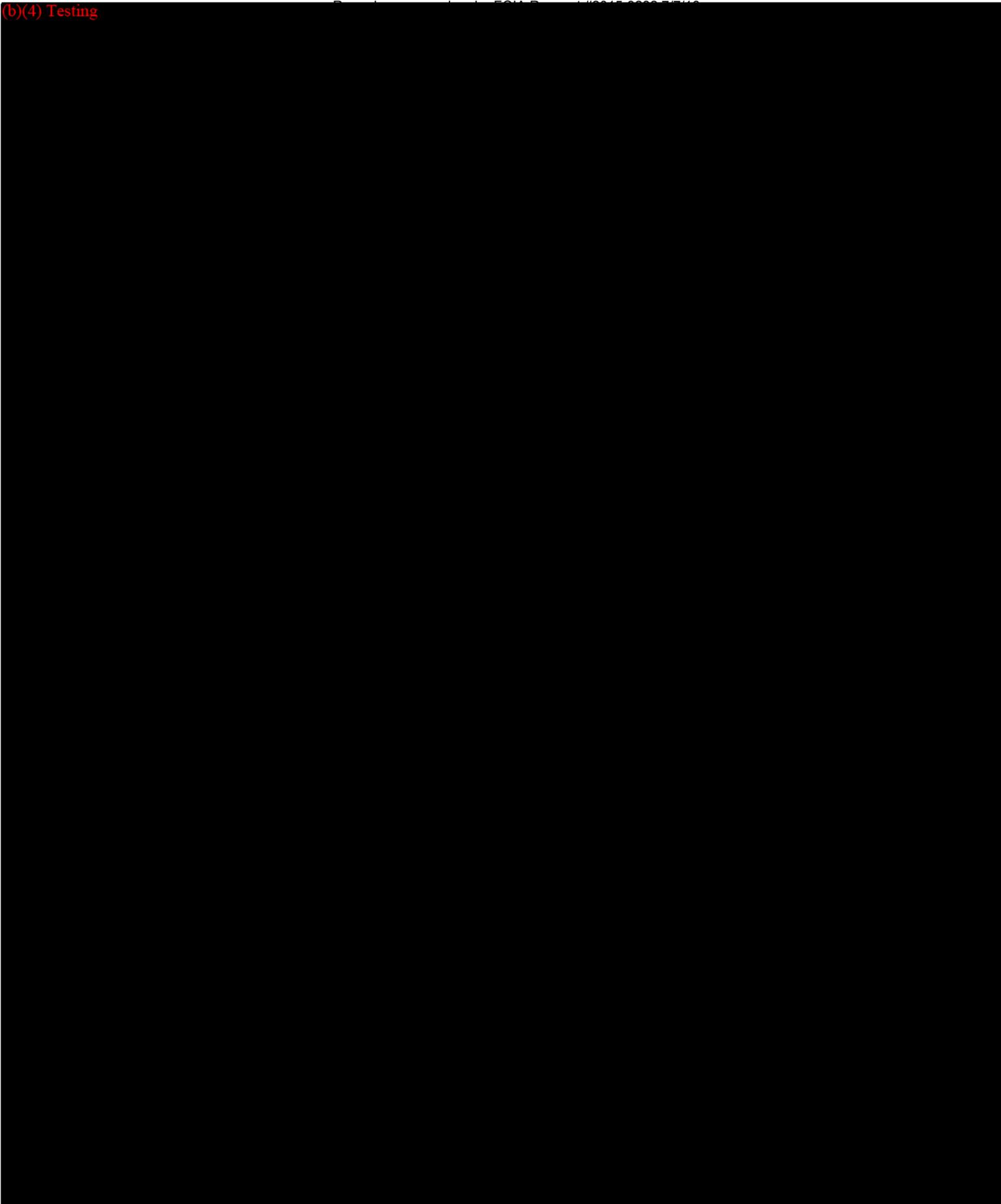




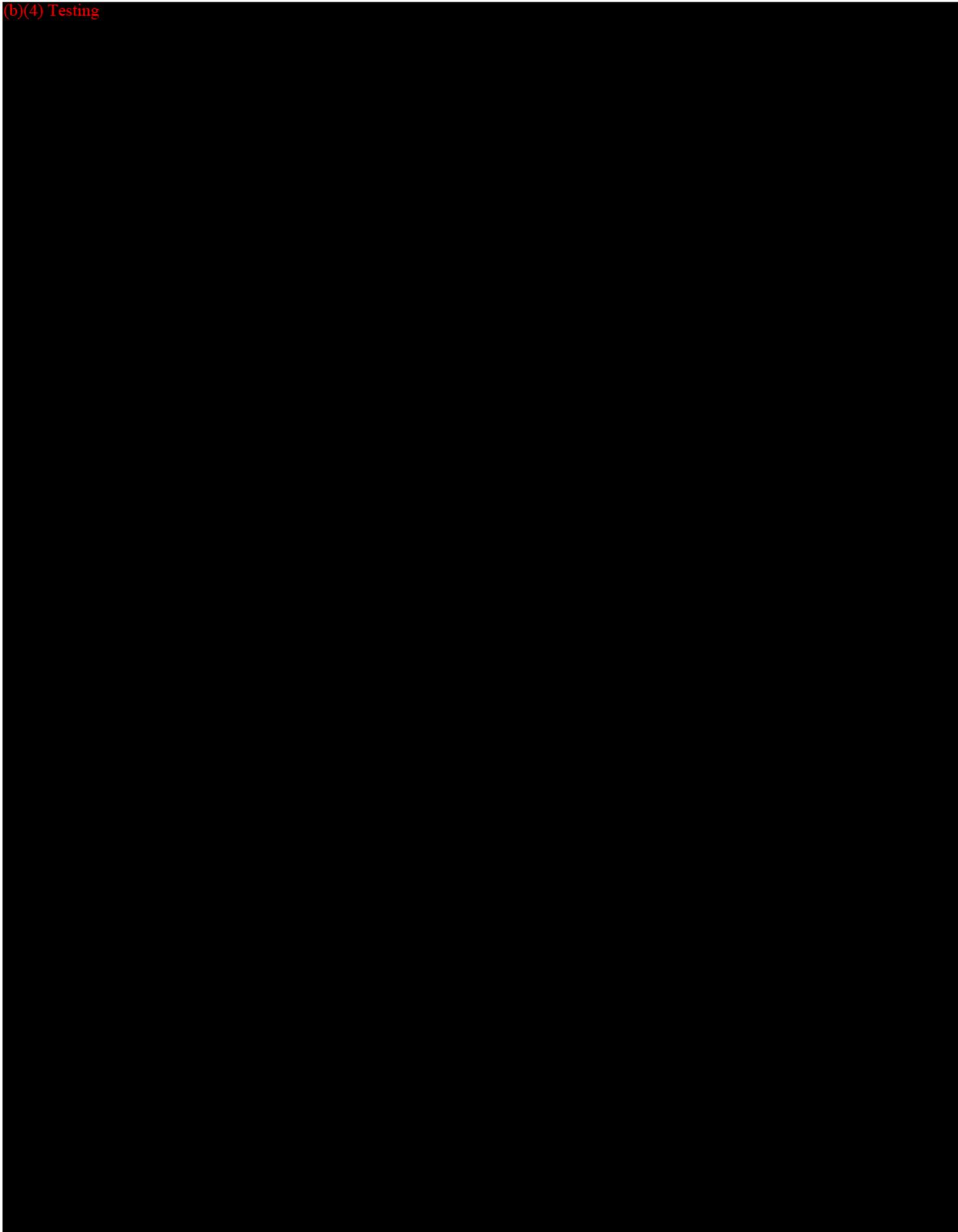


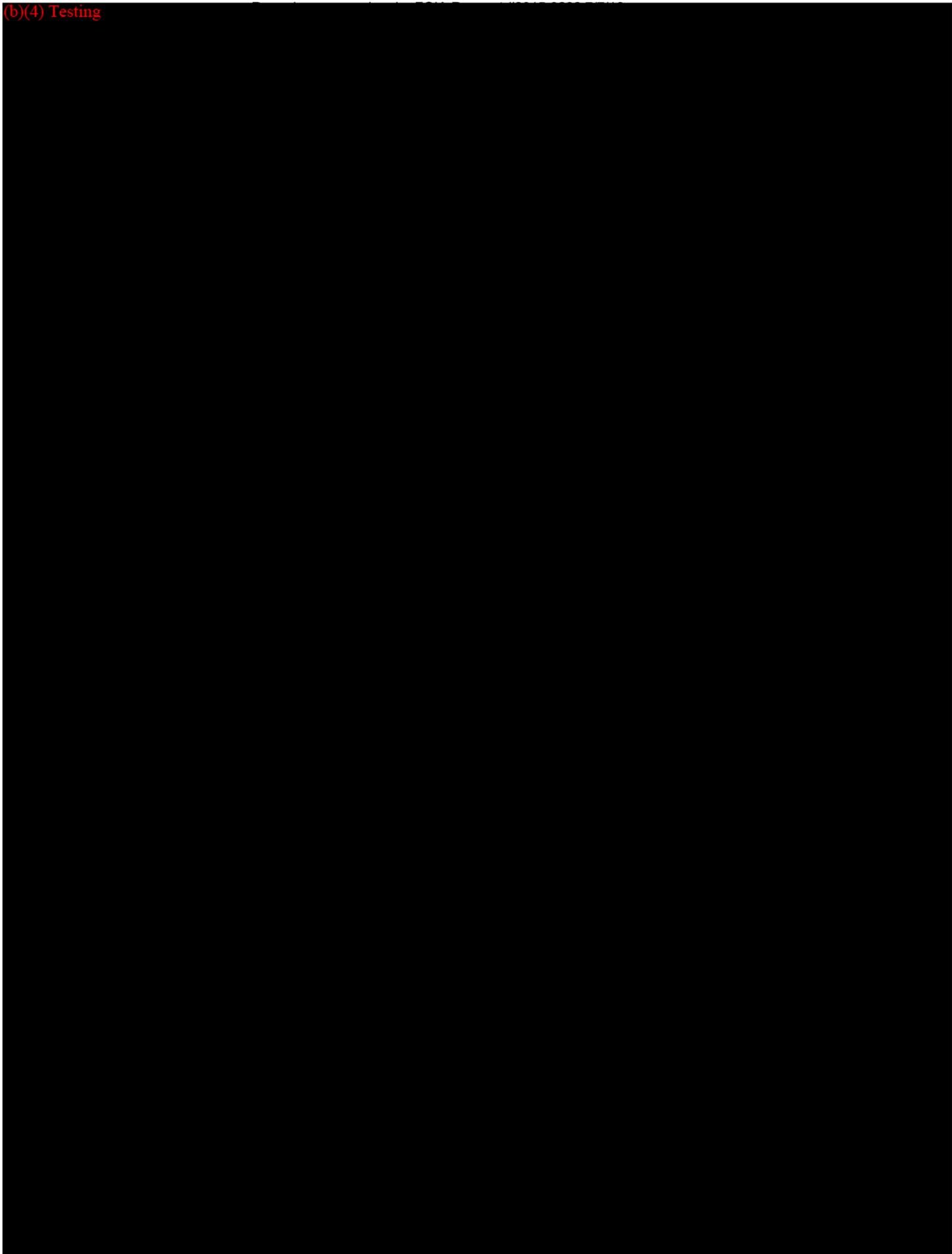
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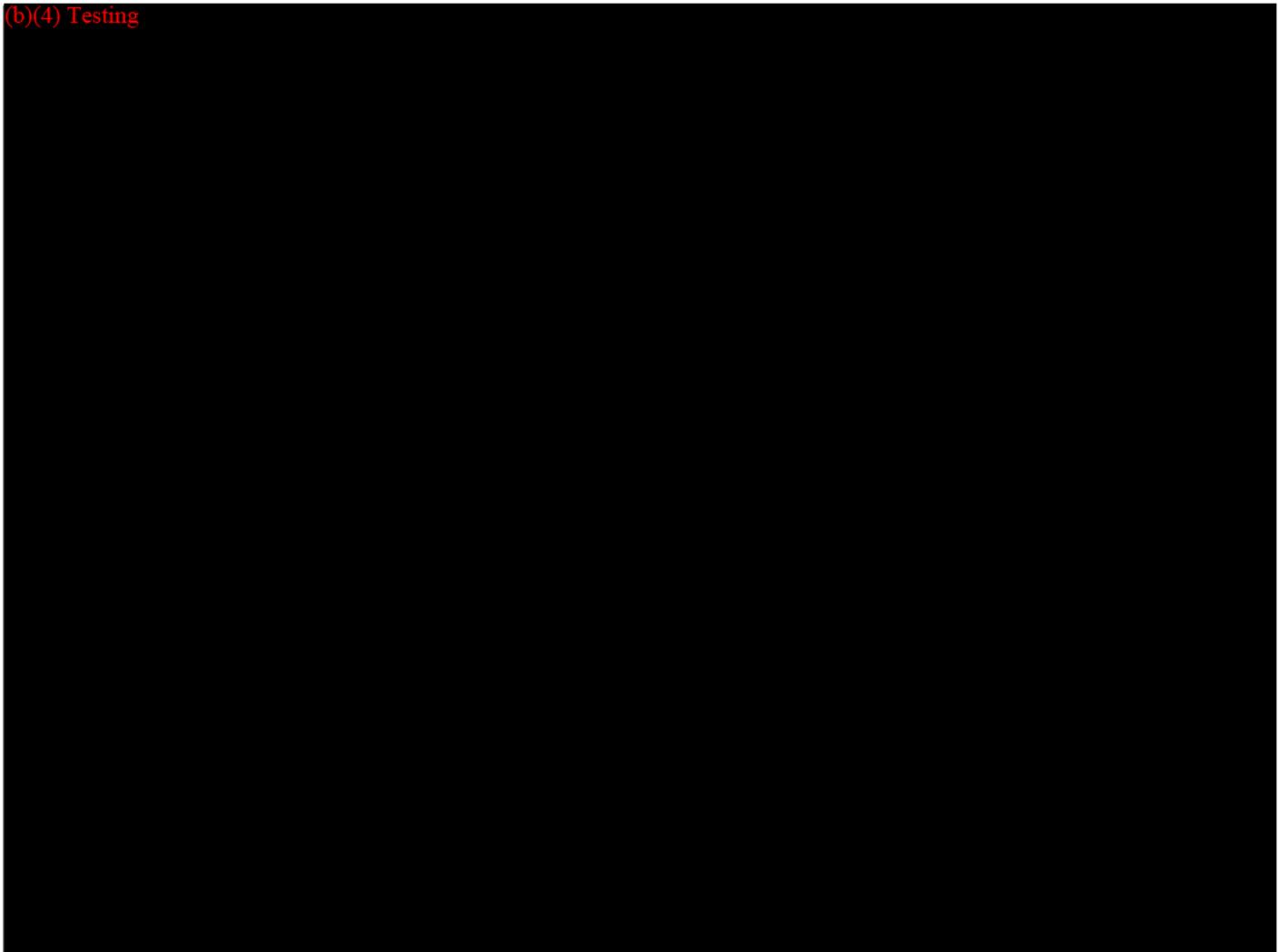


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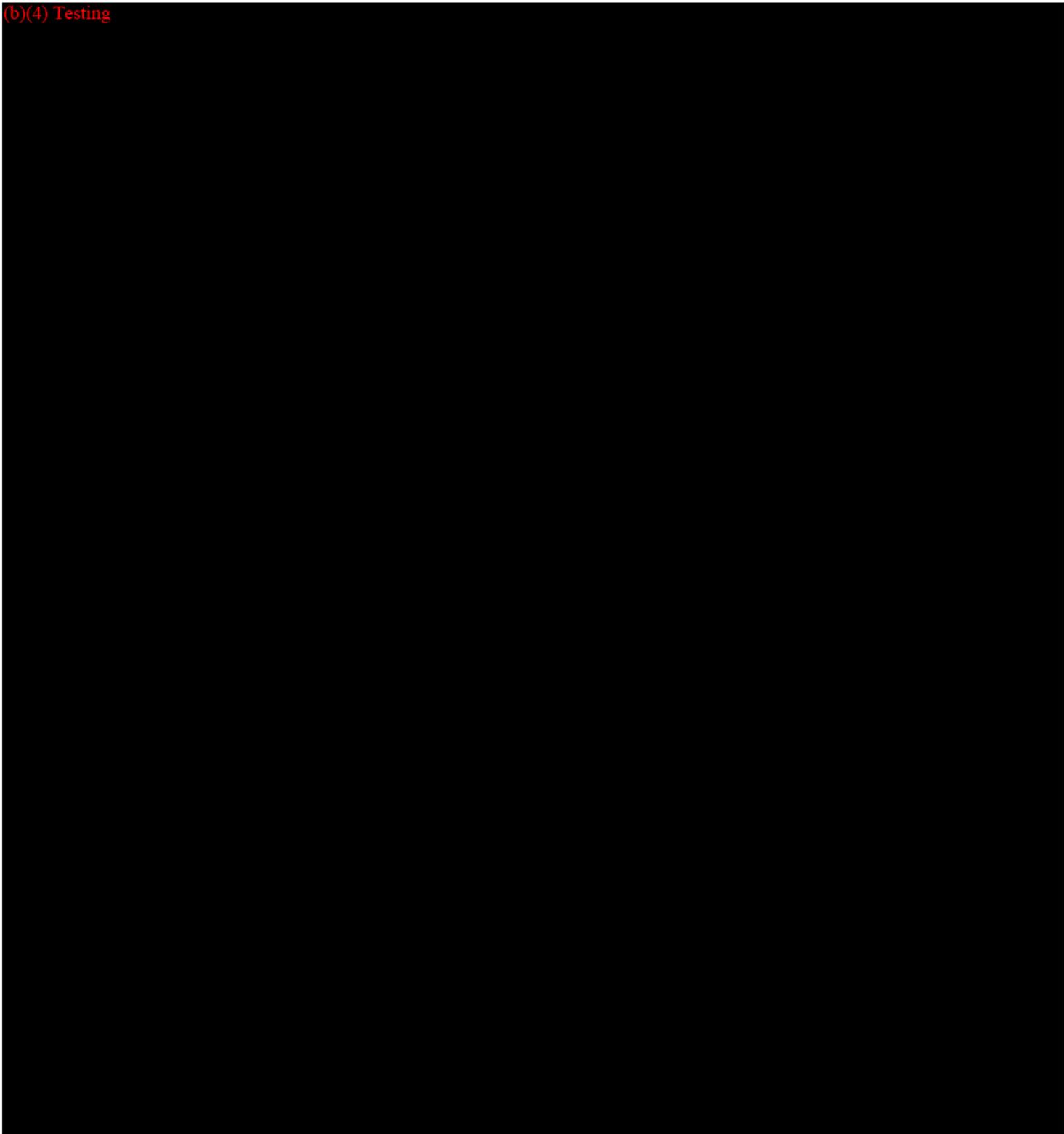




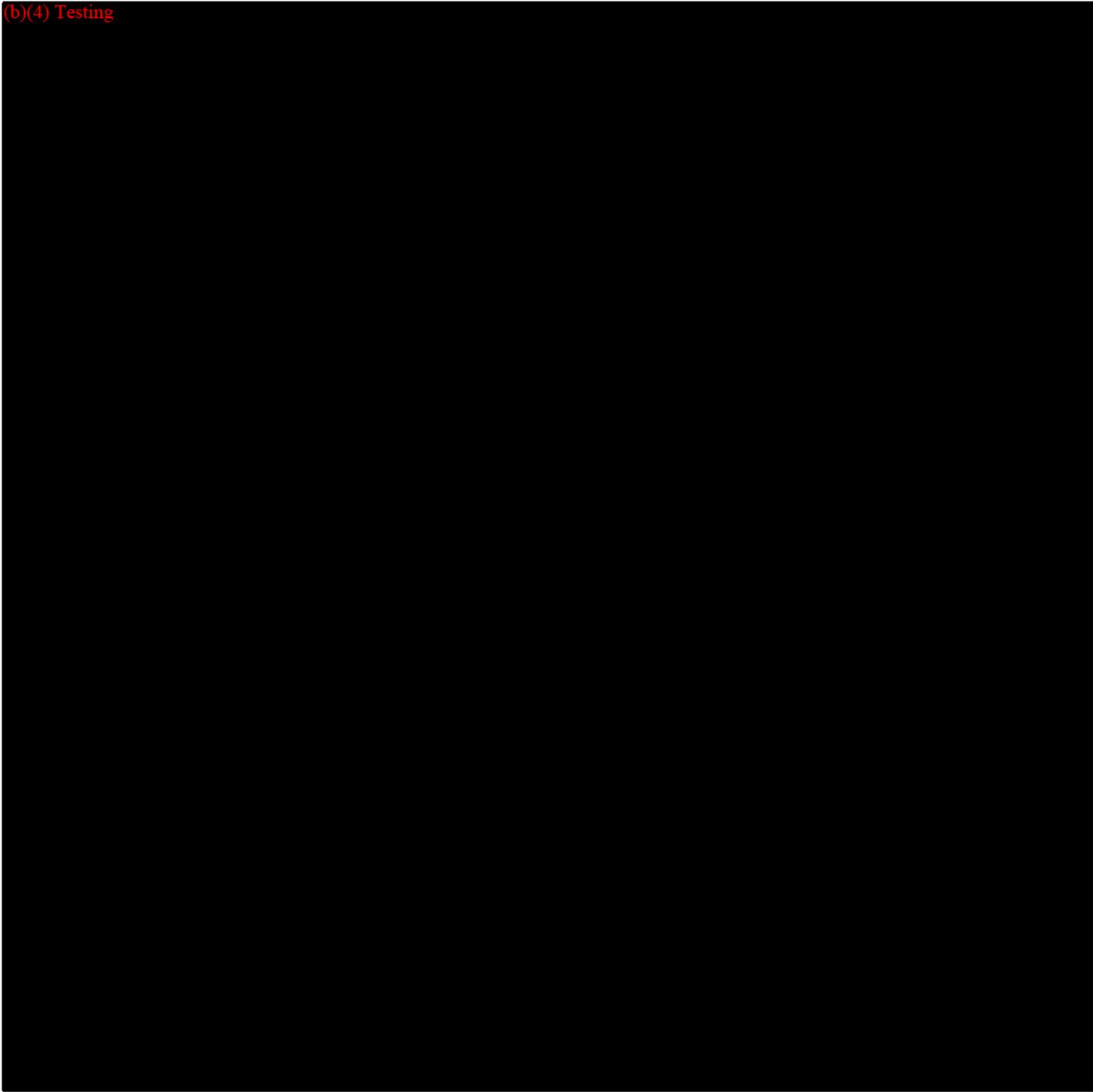
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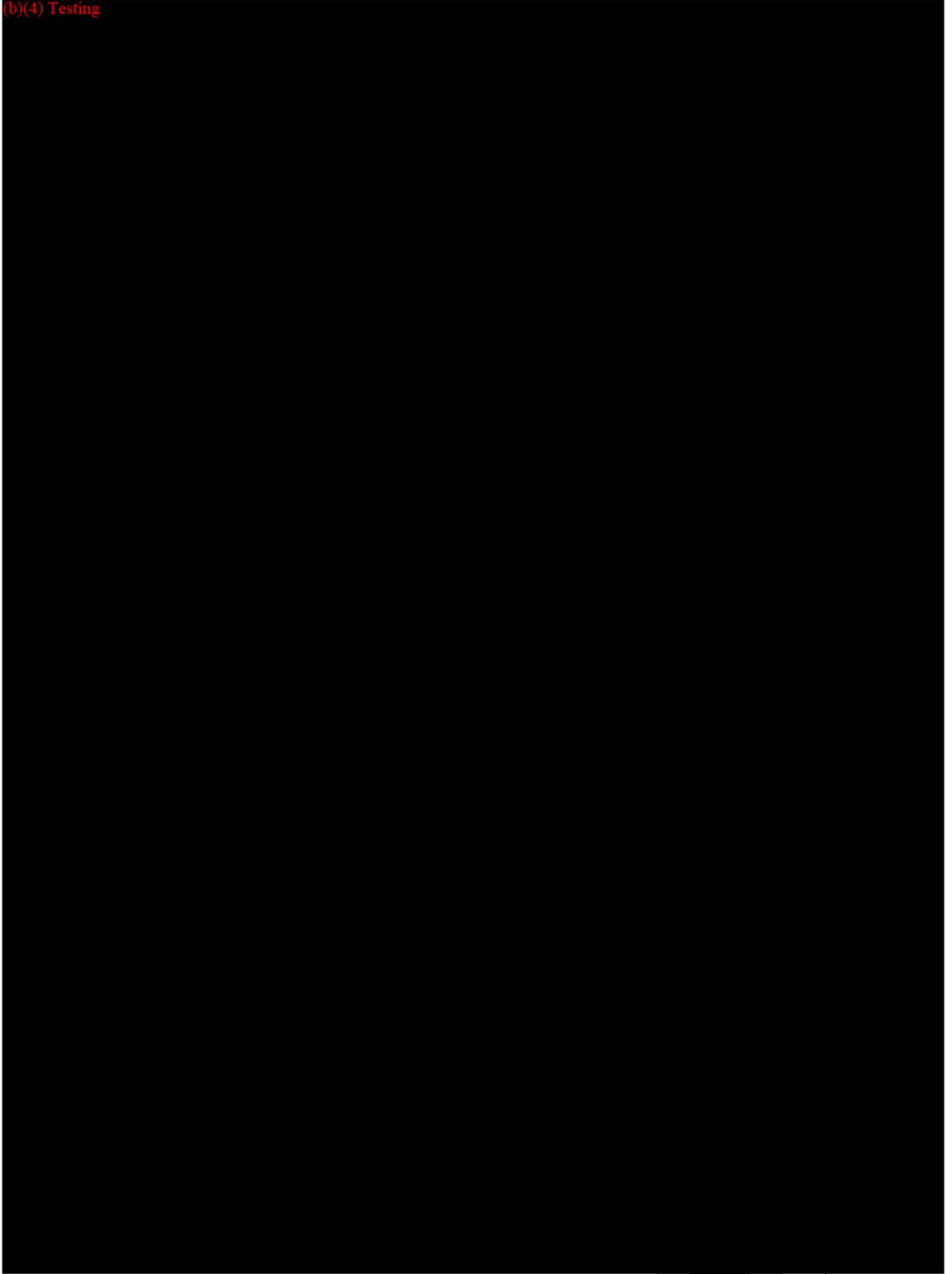
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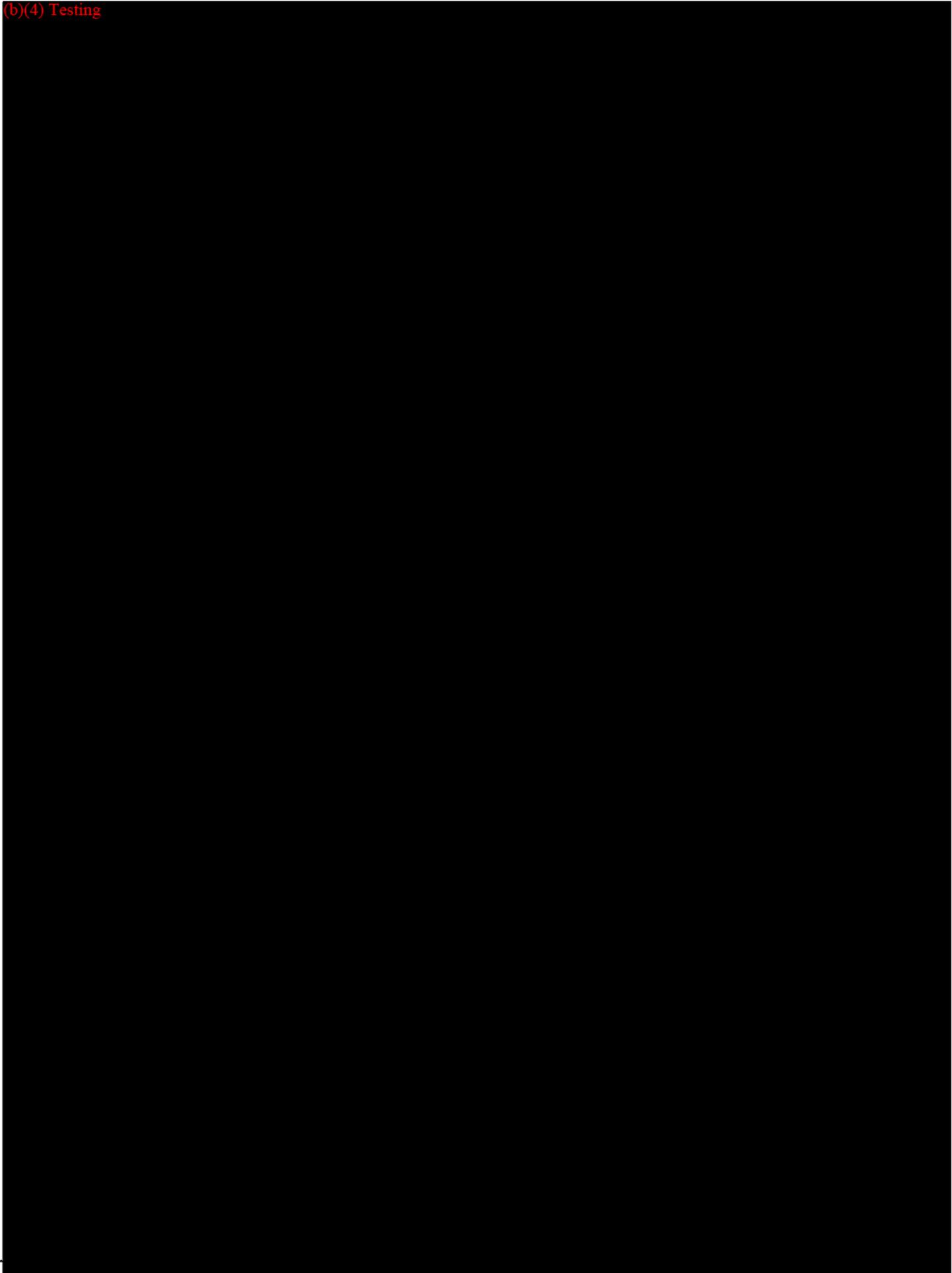
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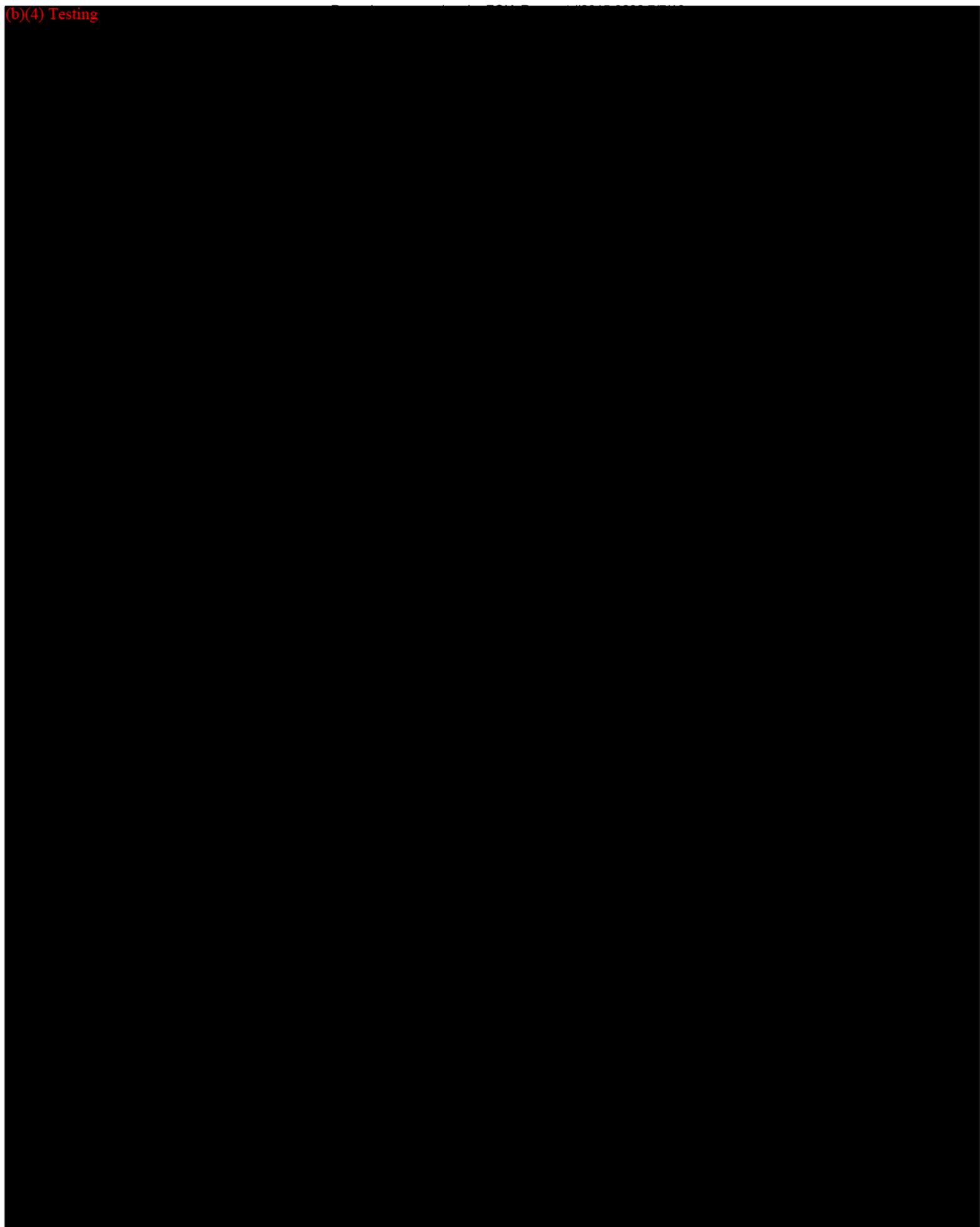


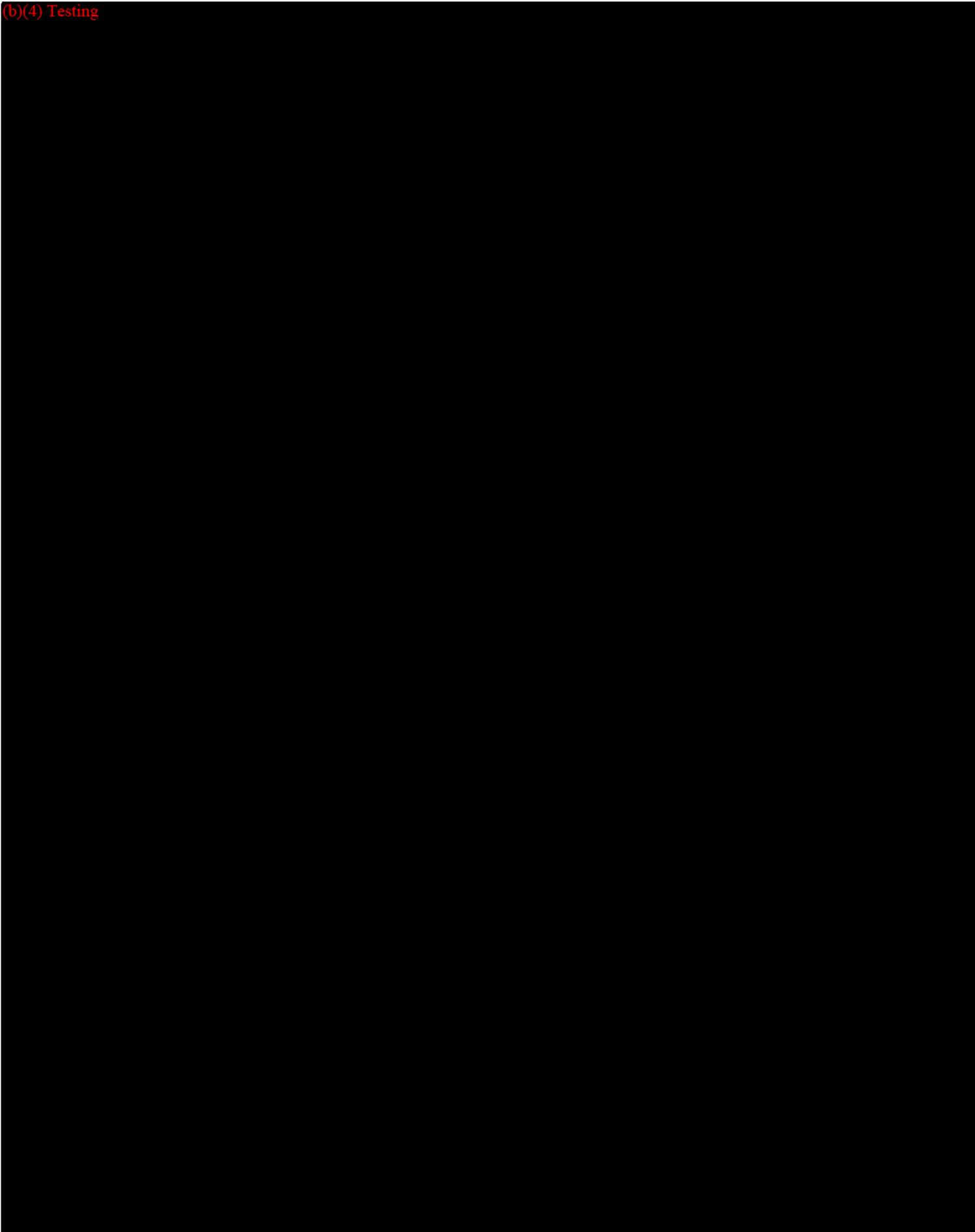
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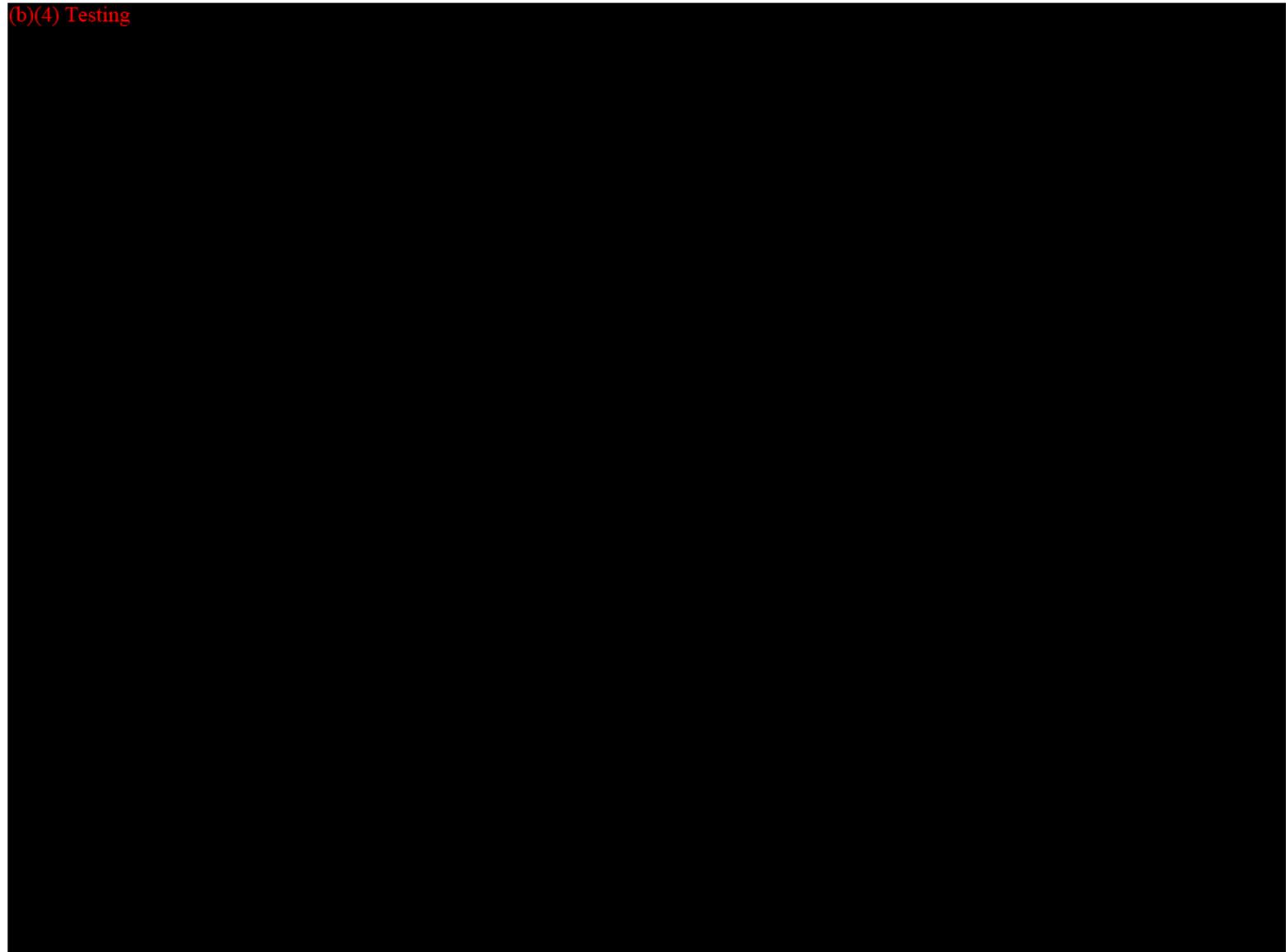


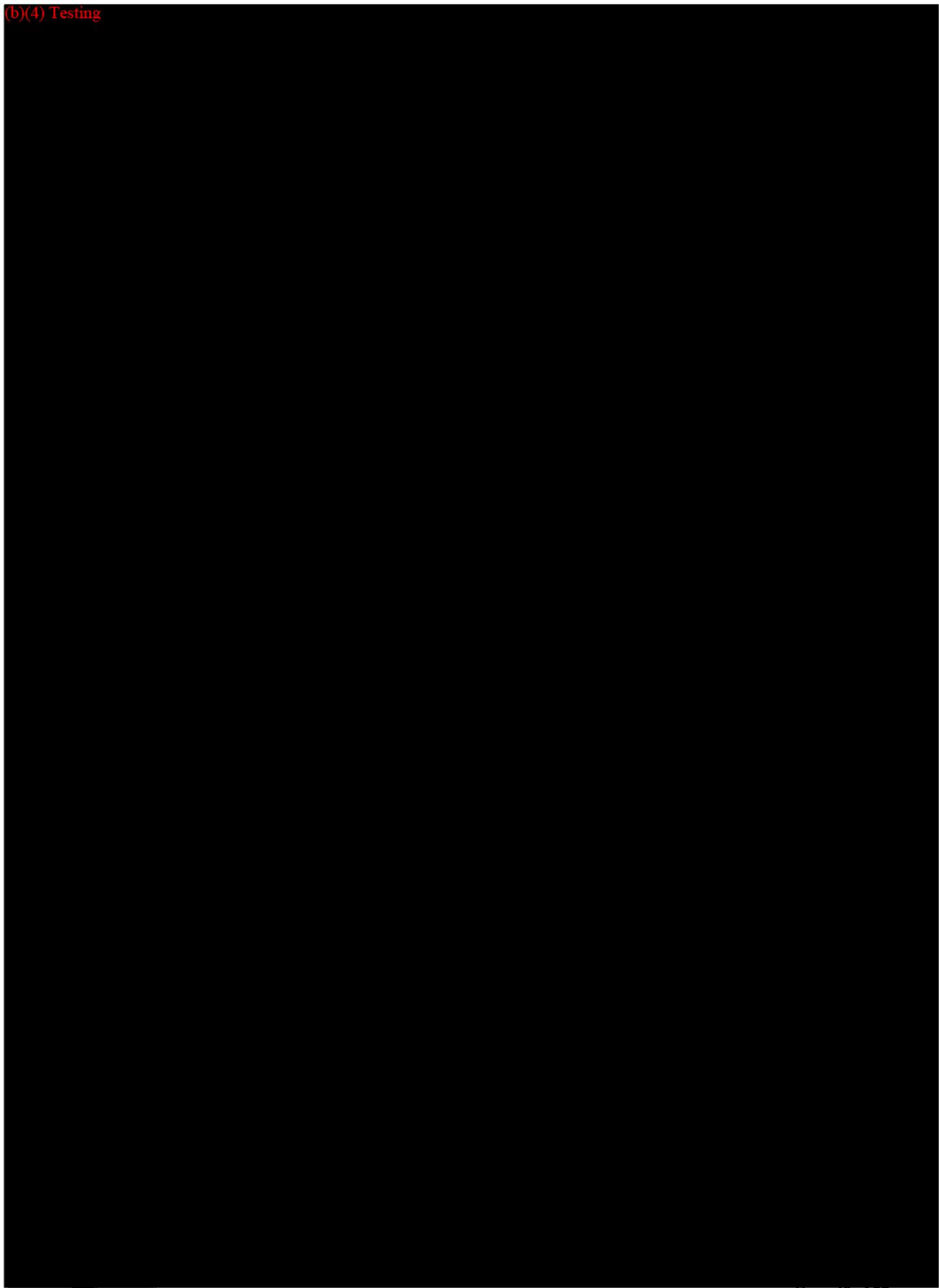
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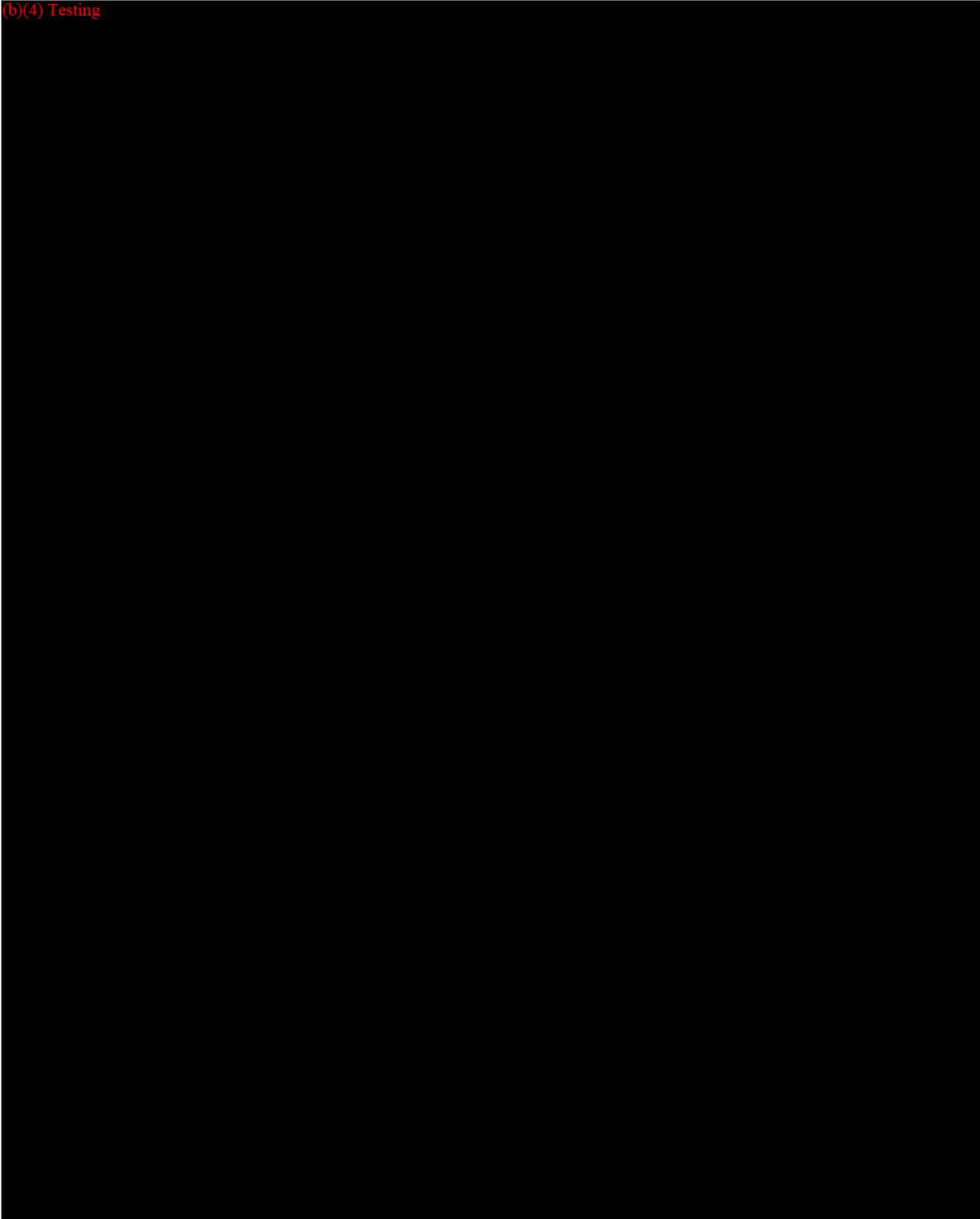




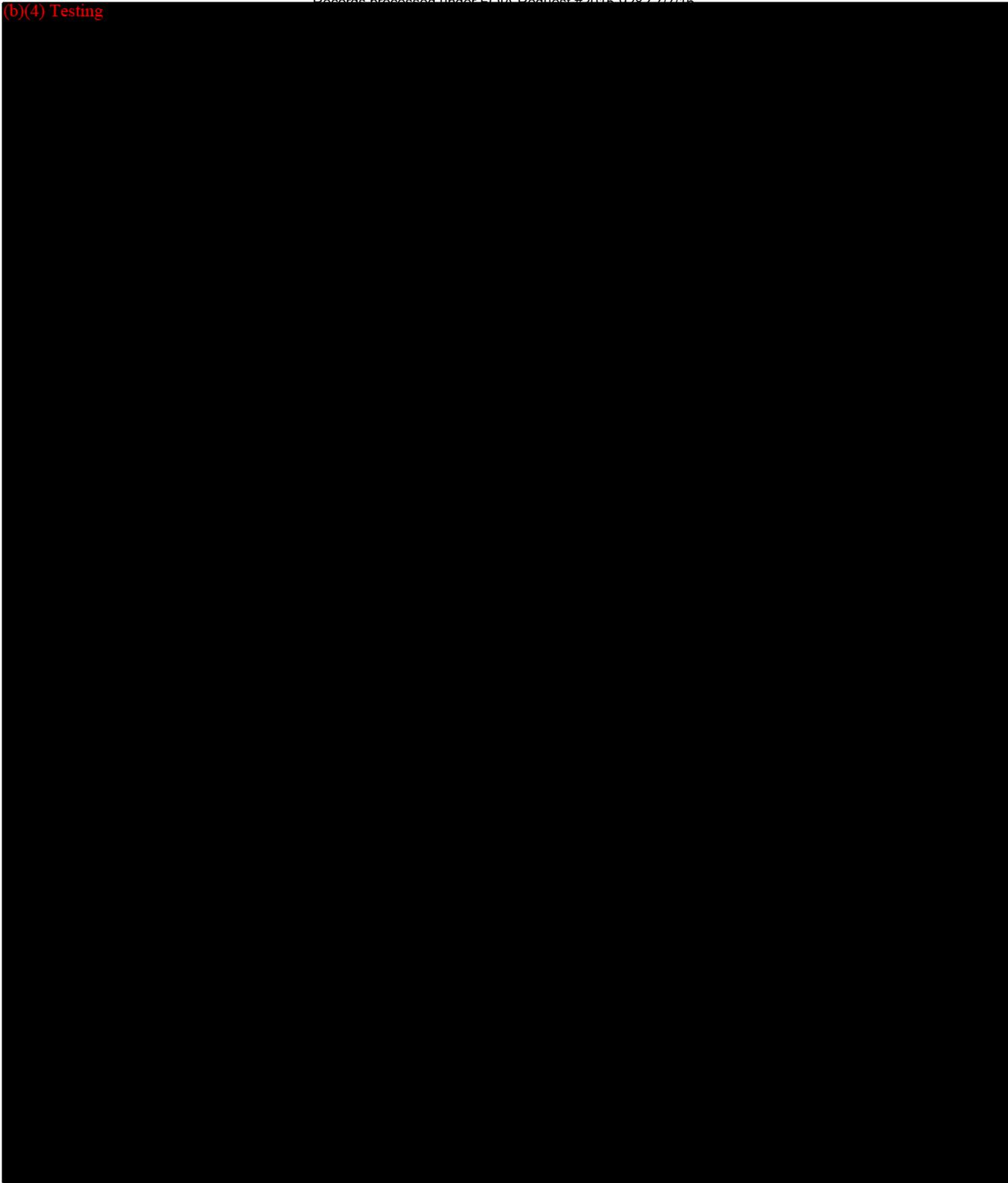




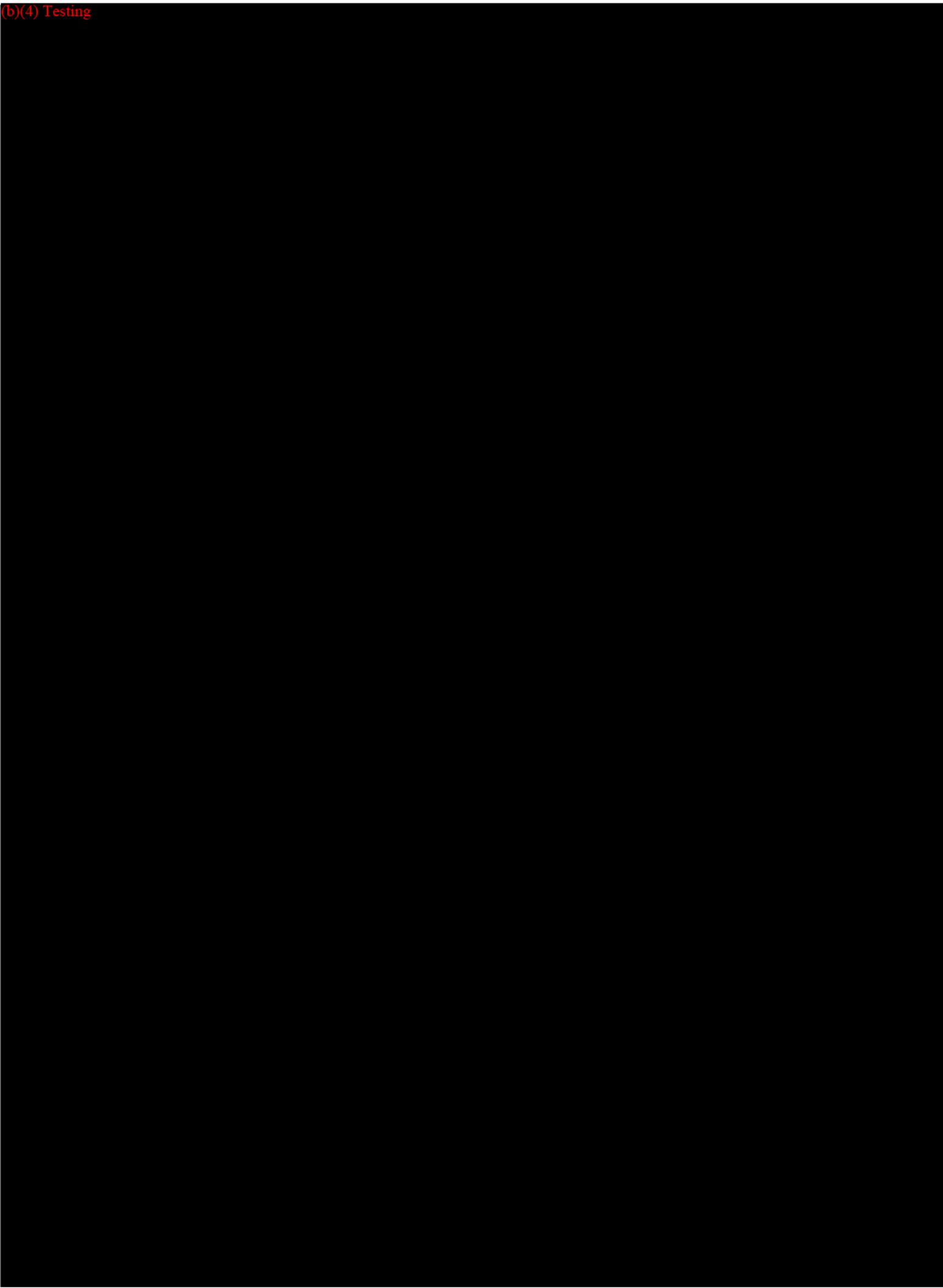
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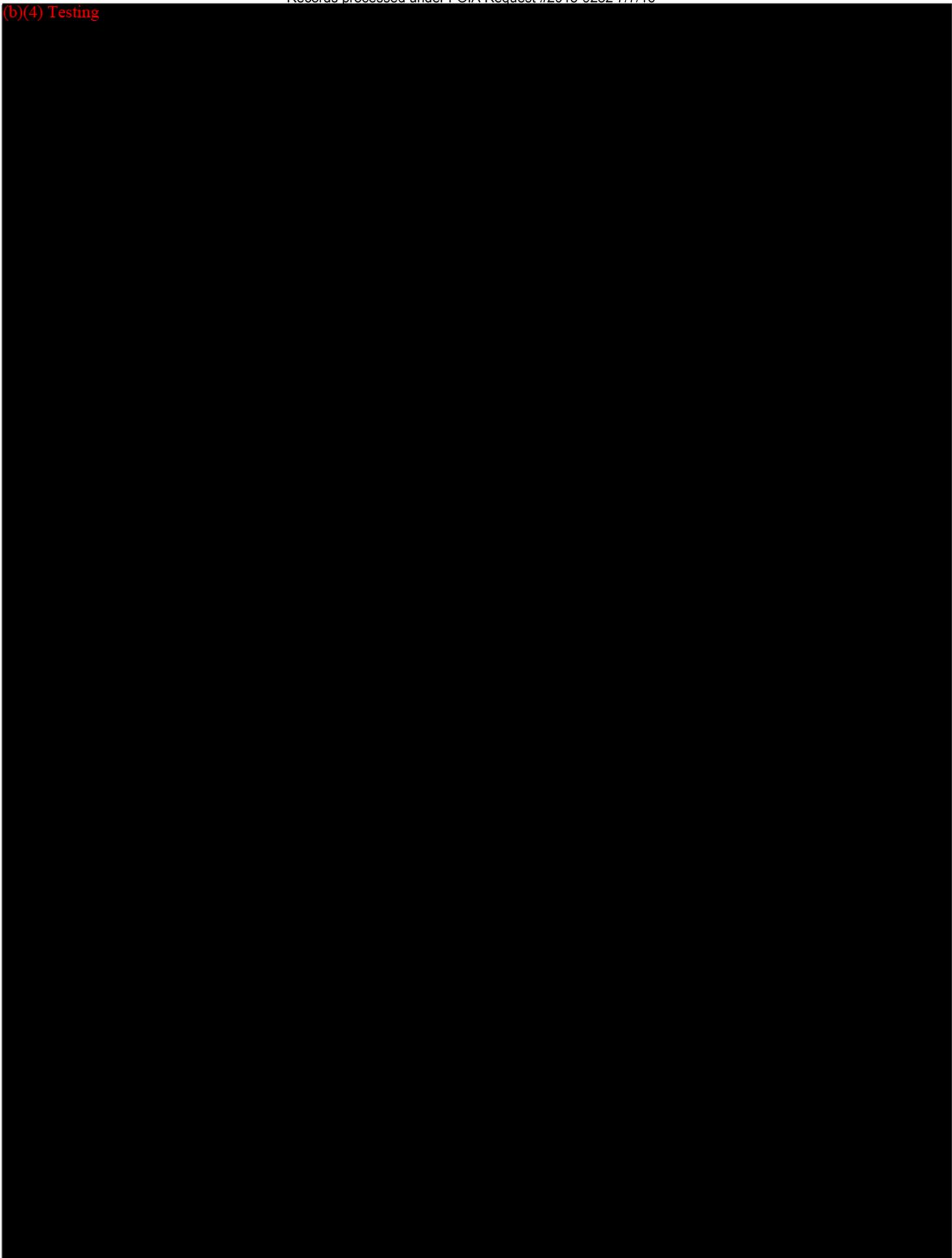
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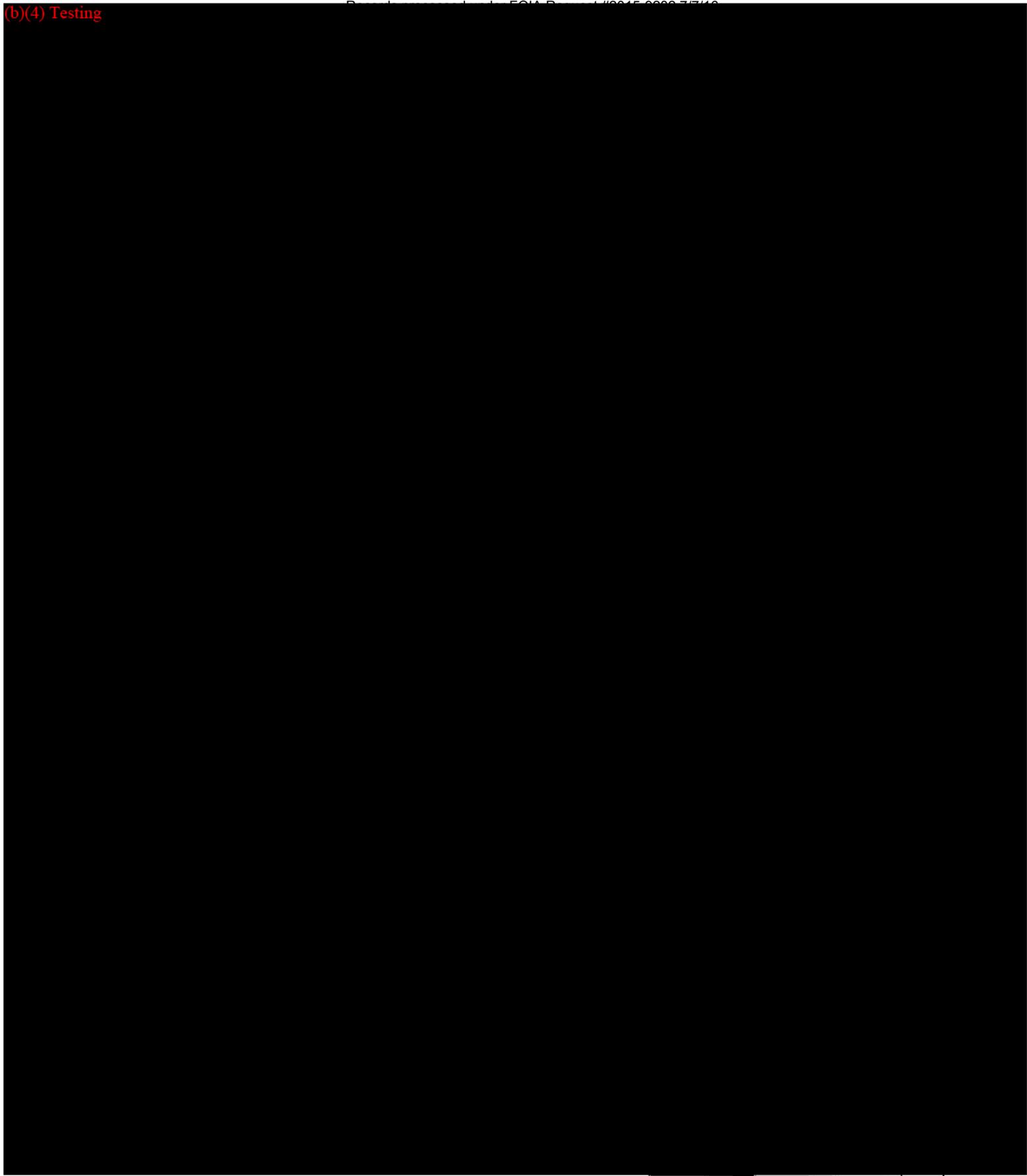


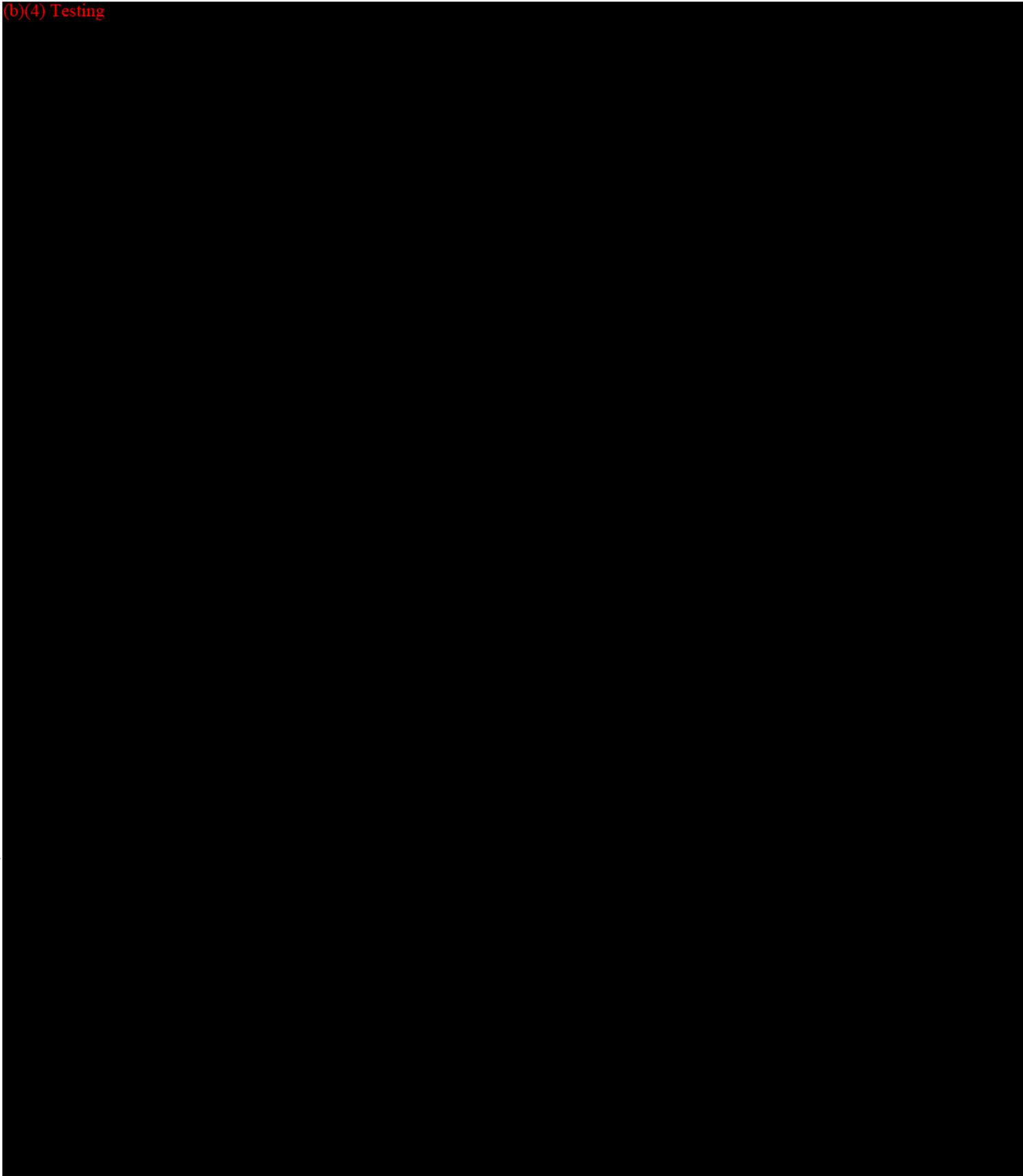
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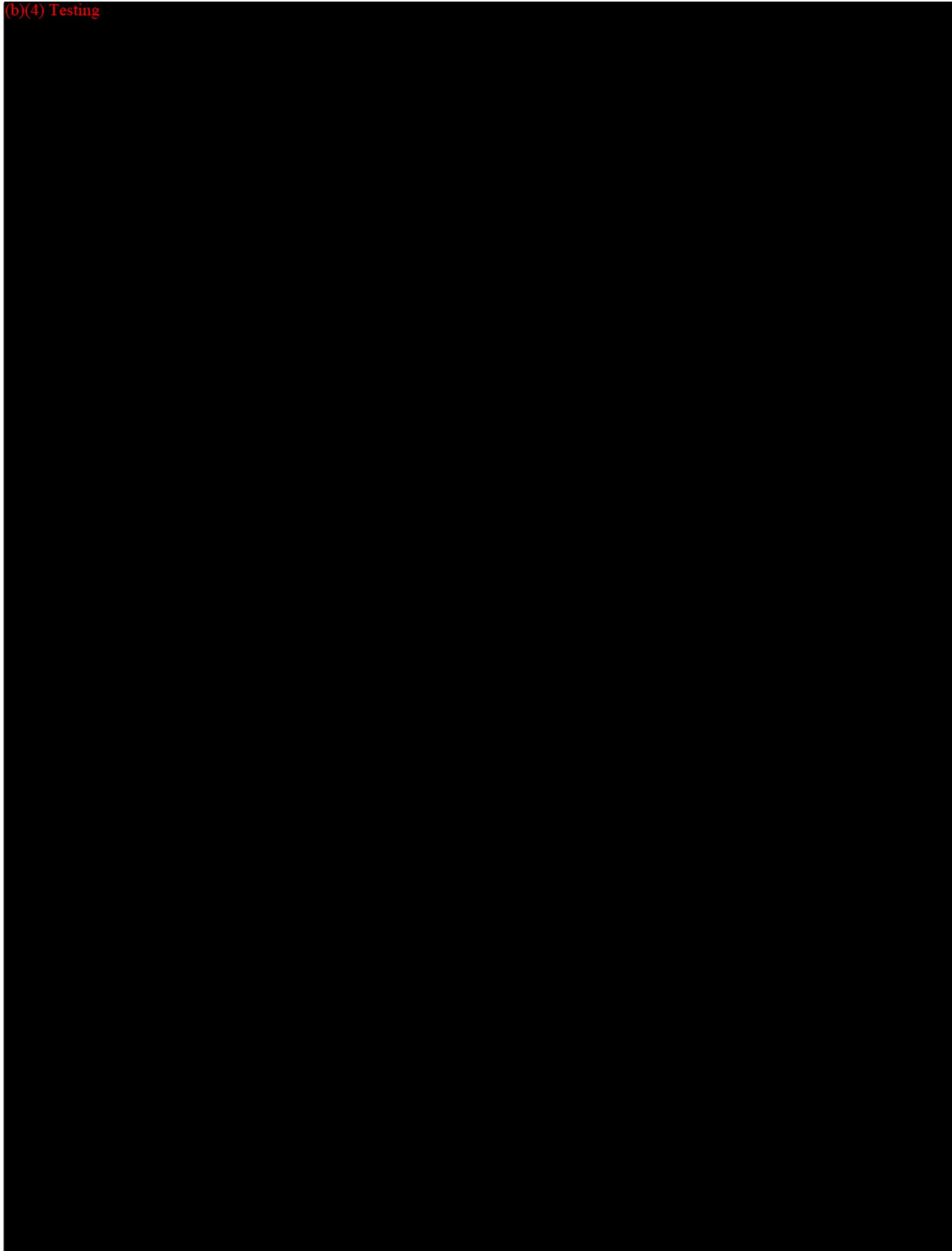


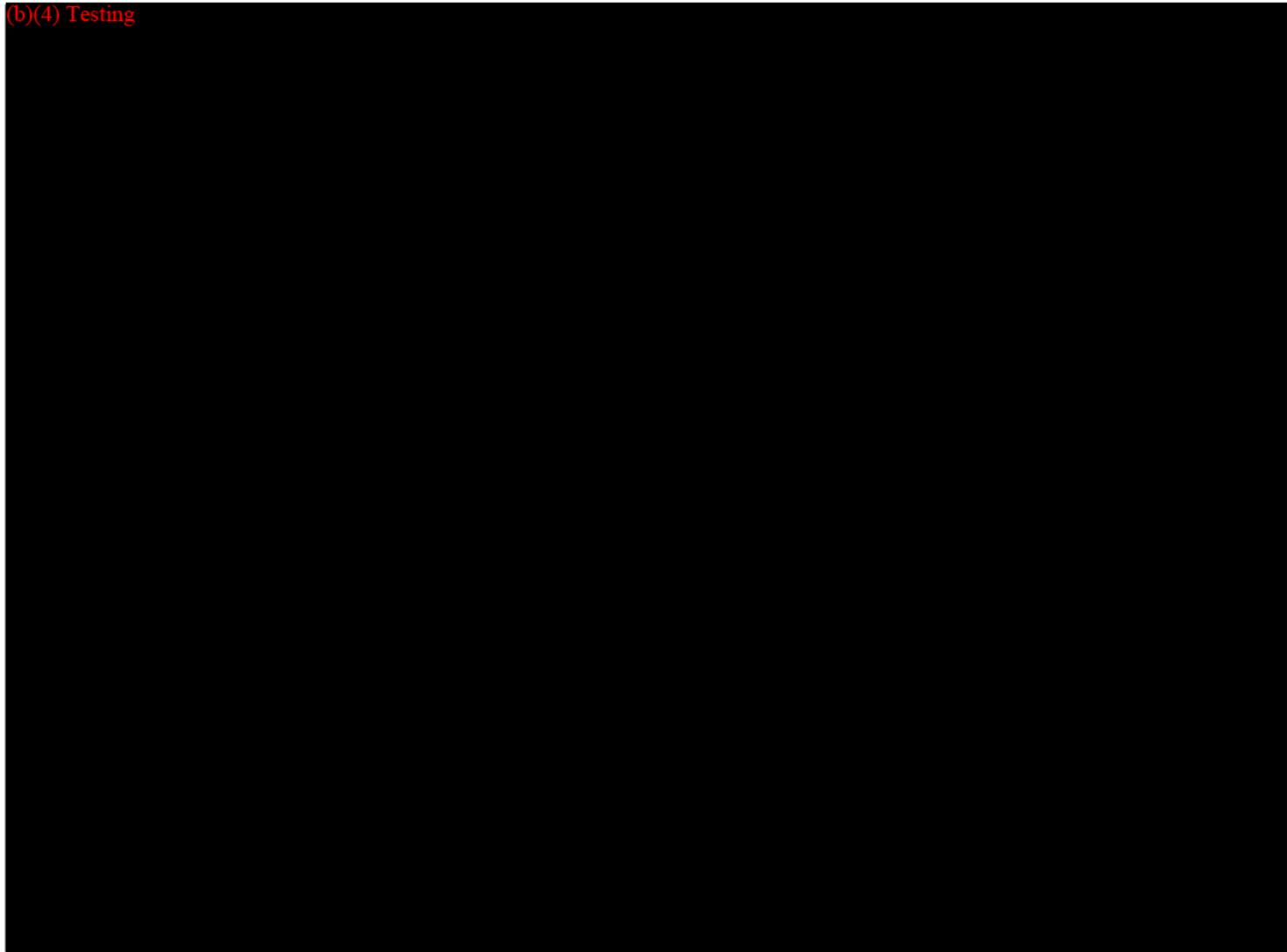
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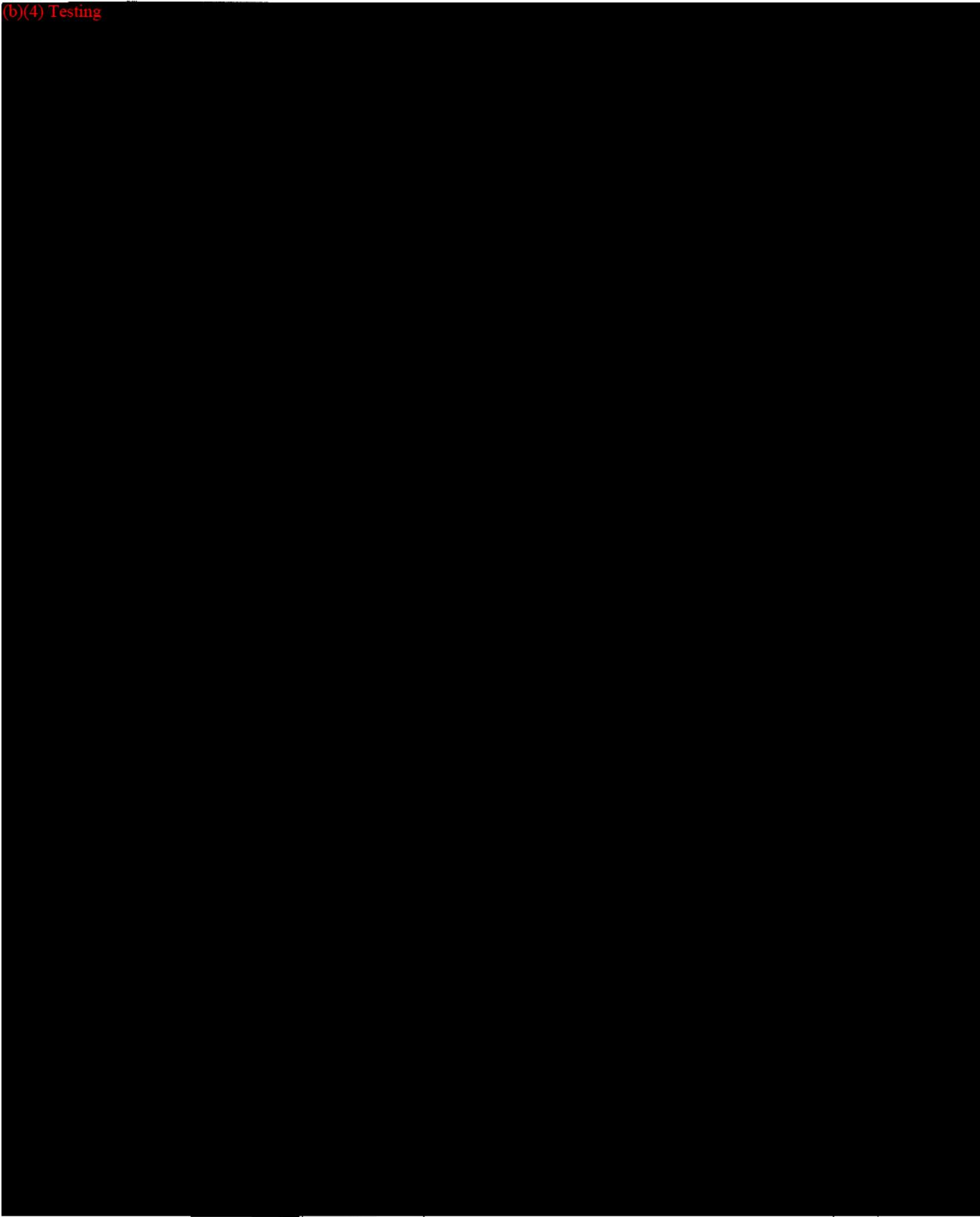




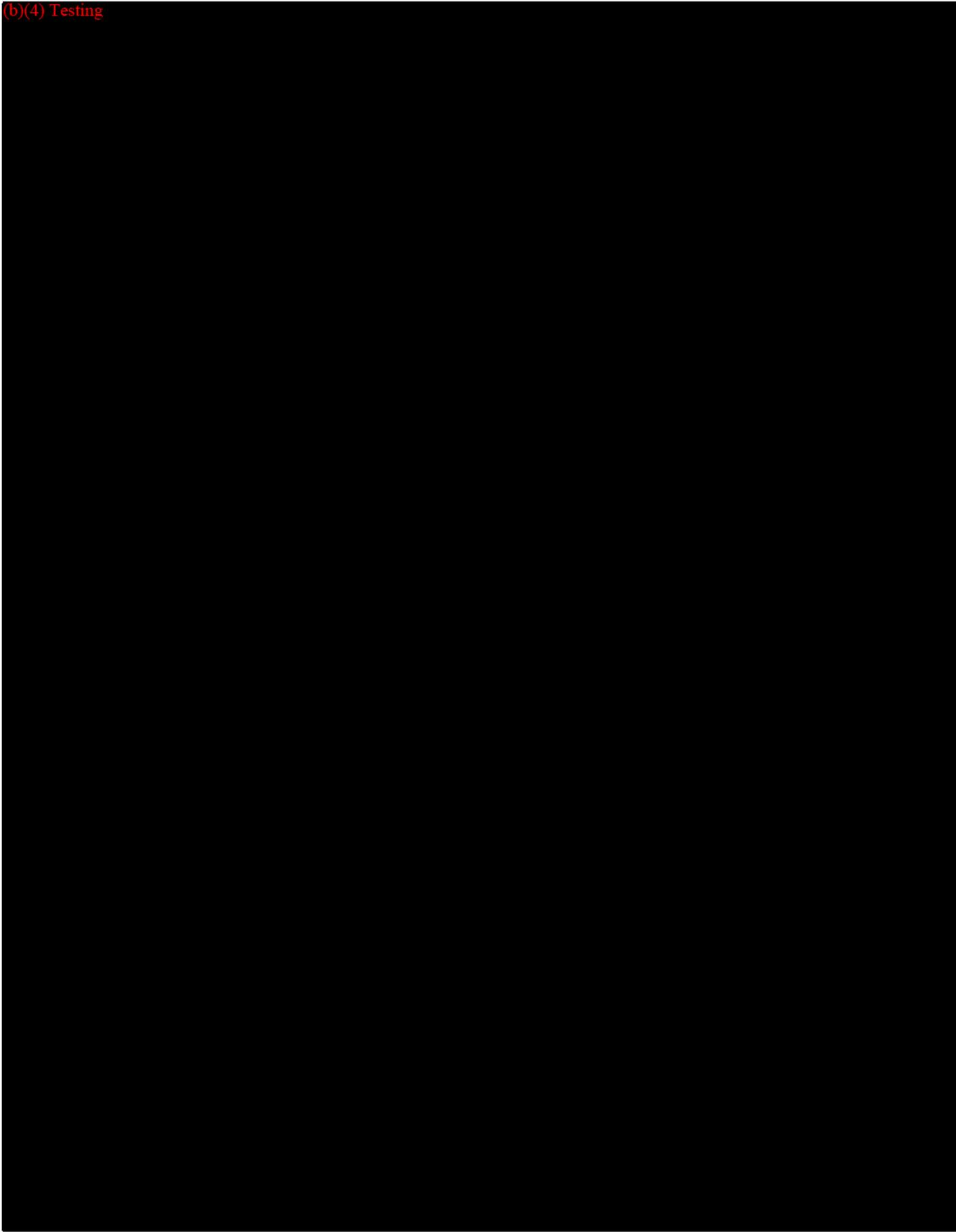




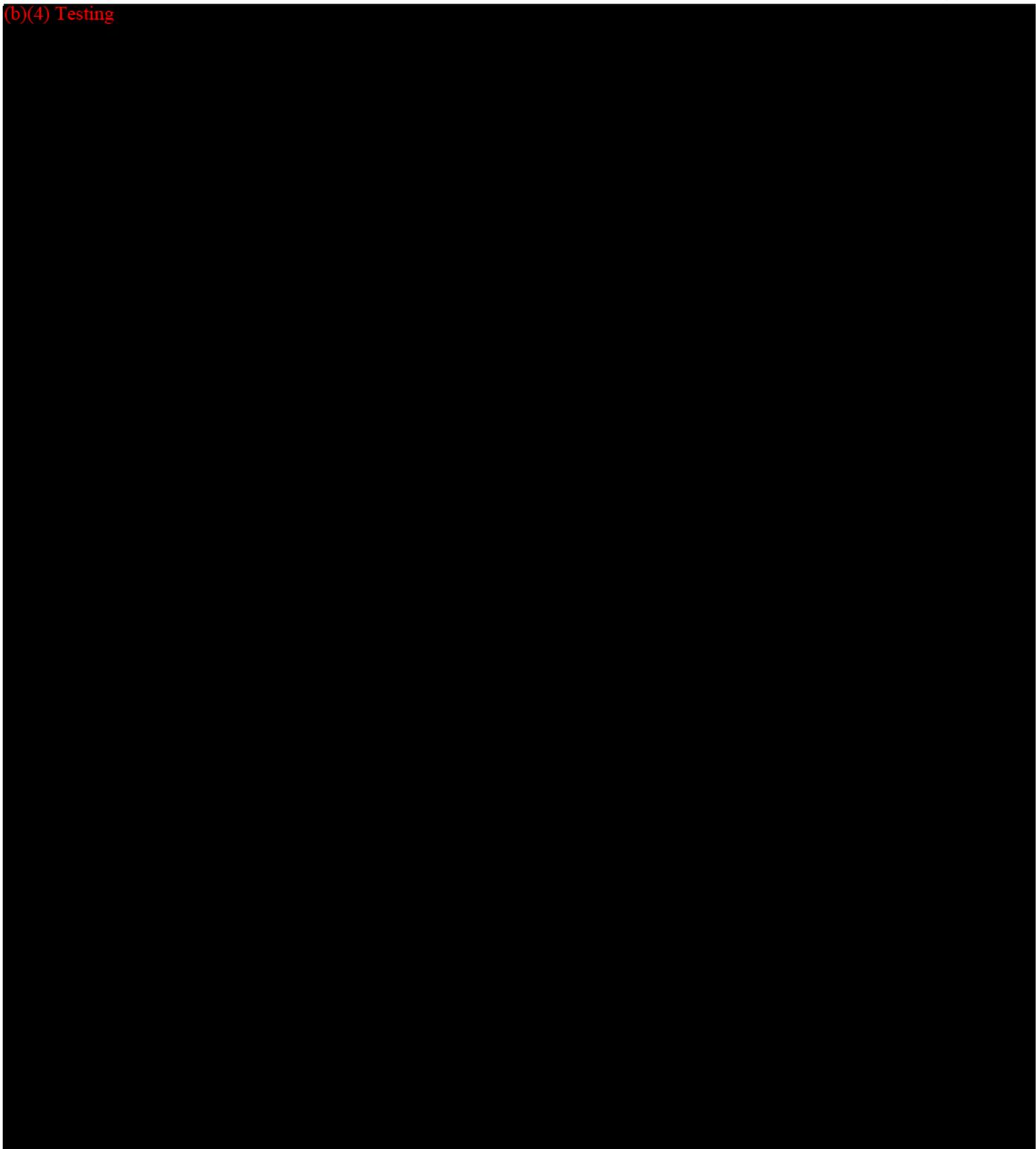
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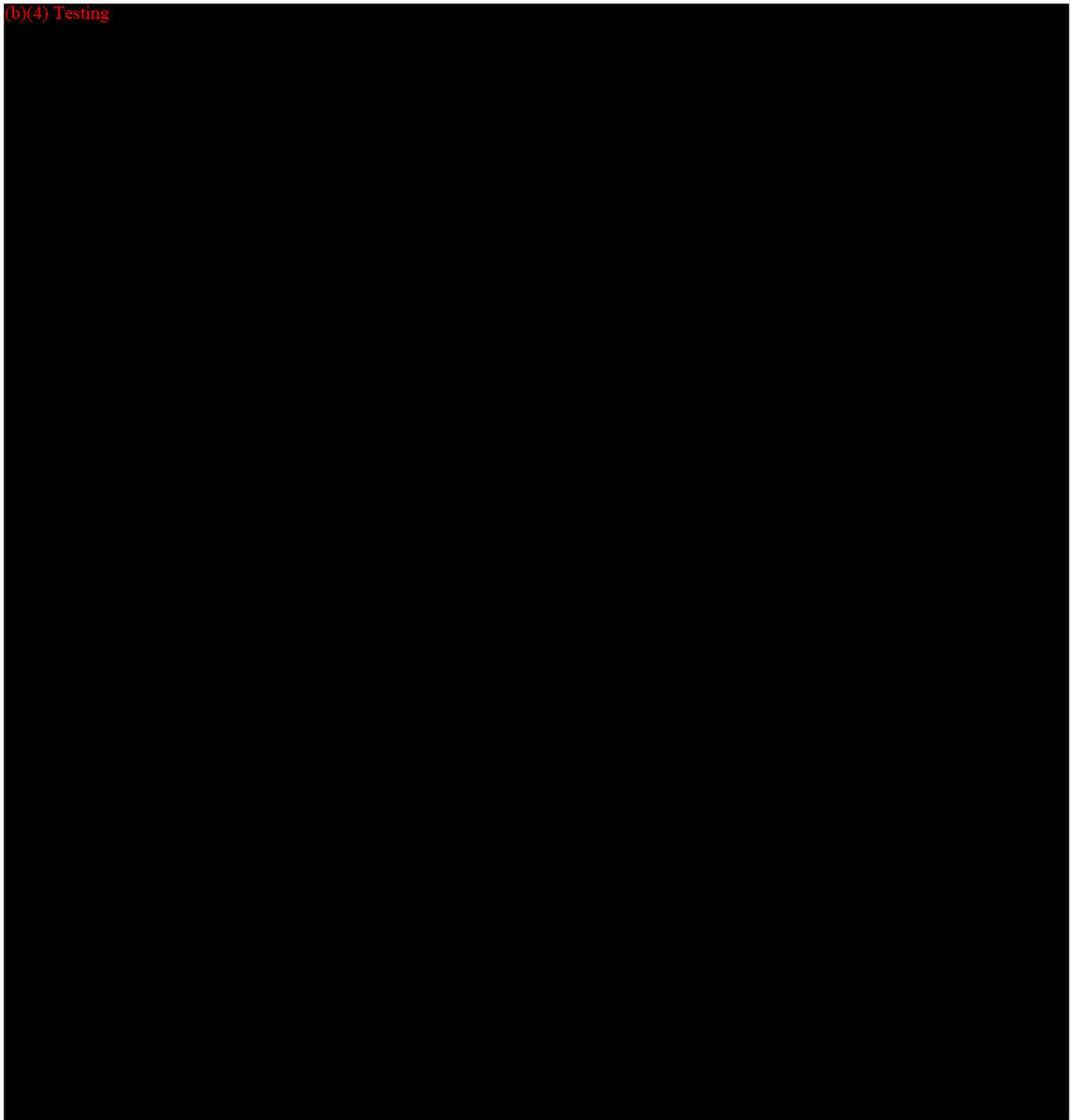


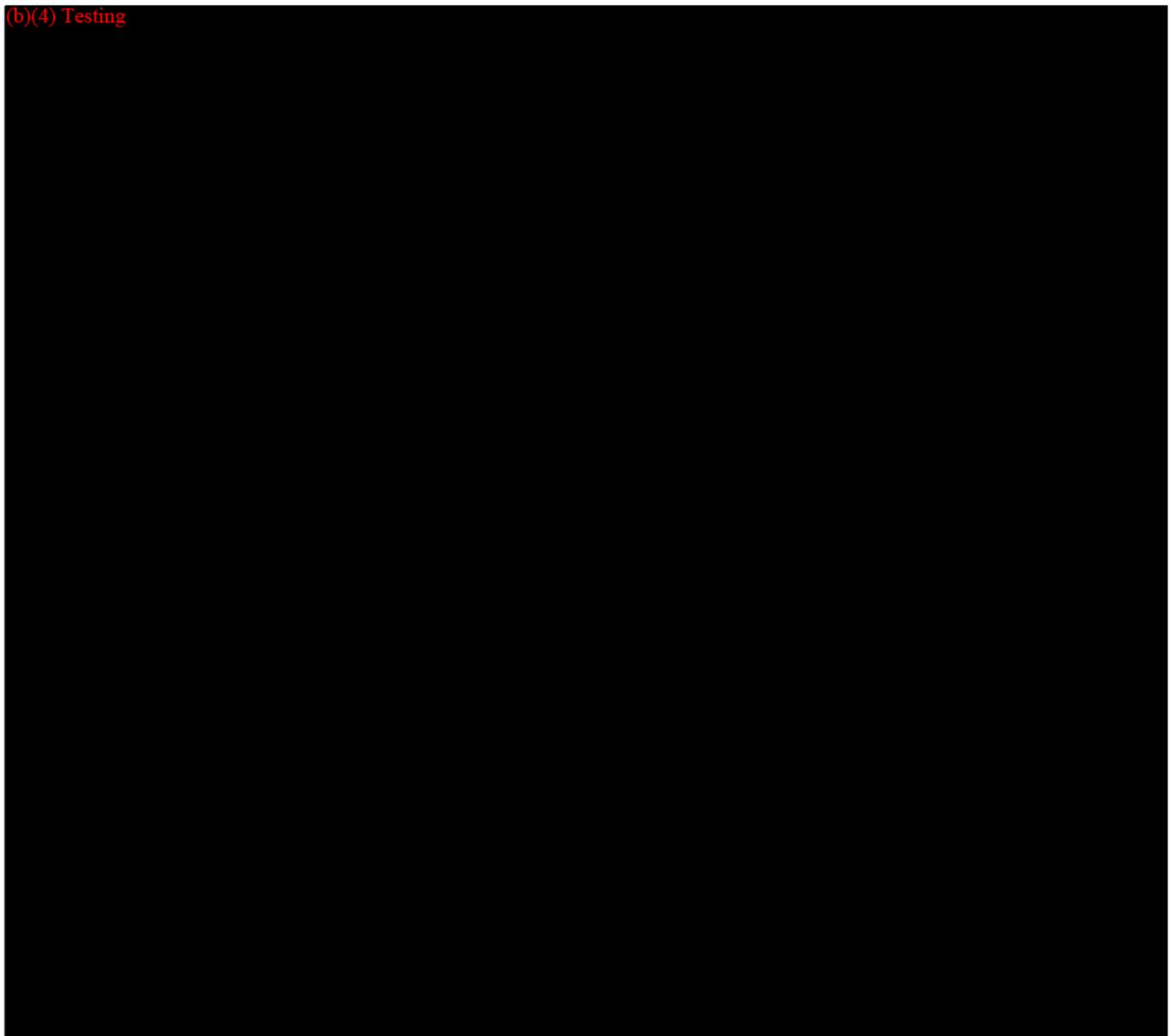
(b)(4) Testing



(b)(4) Testing







ENGINEERING TEST REPORT

NUMBER: 4L0504EEU1

ON

Model No.(s):
InterX 5000

IN ACCORDANCE WITH:
EN60601-1-2: 2001 FOR CLASS B

TESTED FOR:
Neuro Resource Group
2200 Chemsearch Blvd., Suite 108
Irving, TX 75062

TESTED BY:
Nemko Dallas, Inc.
802 N. Kealy
Lewisville, Texas 75057-3136

APPROVED BY:



David Light, Lab Resource Manager

DATE:

10/8/04

APPENDIX H

SOFTWARE DOCUMENTATION

Document No: NRG-0002 Revision: 1.0 Date: 9/13/04	InterX 5000 Software Requirements Specification	Page 1 of 10
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InterX 5000

Software Requirements Specification

Rev 1.0

September 13, 2004



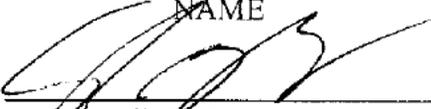
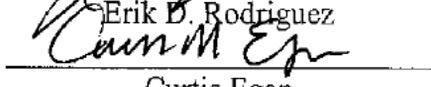
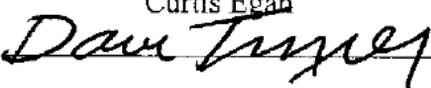
Prepared for:
Neuro Resource Group, Inc.
12222 Merit Drive, Suite 955
Dallas, TX 75251

Document No.: NRG-0003 Revision: 1.0 Date: 9/16/04	InterX 5000 Software Test Procedures	Page 1 of 15
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InterX 5000 Software Test Procedures

Rev 1.0

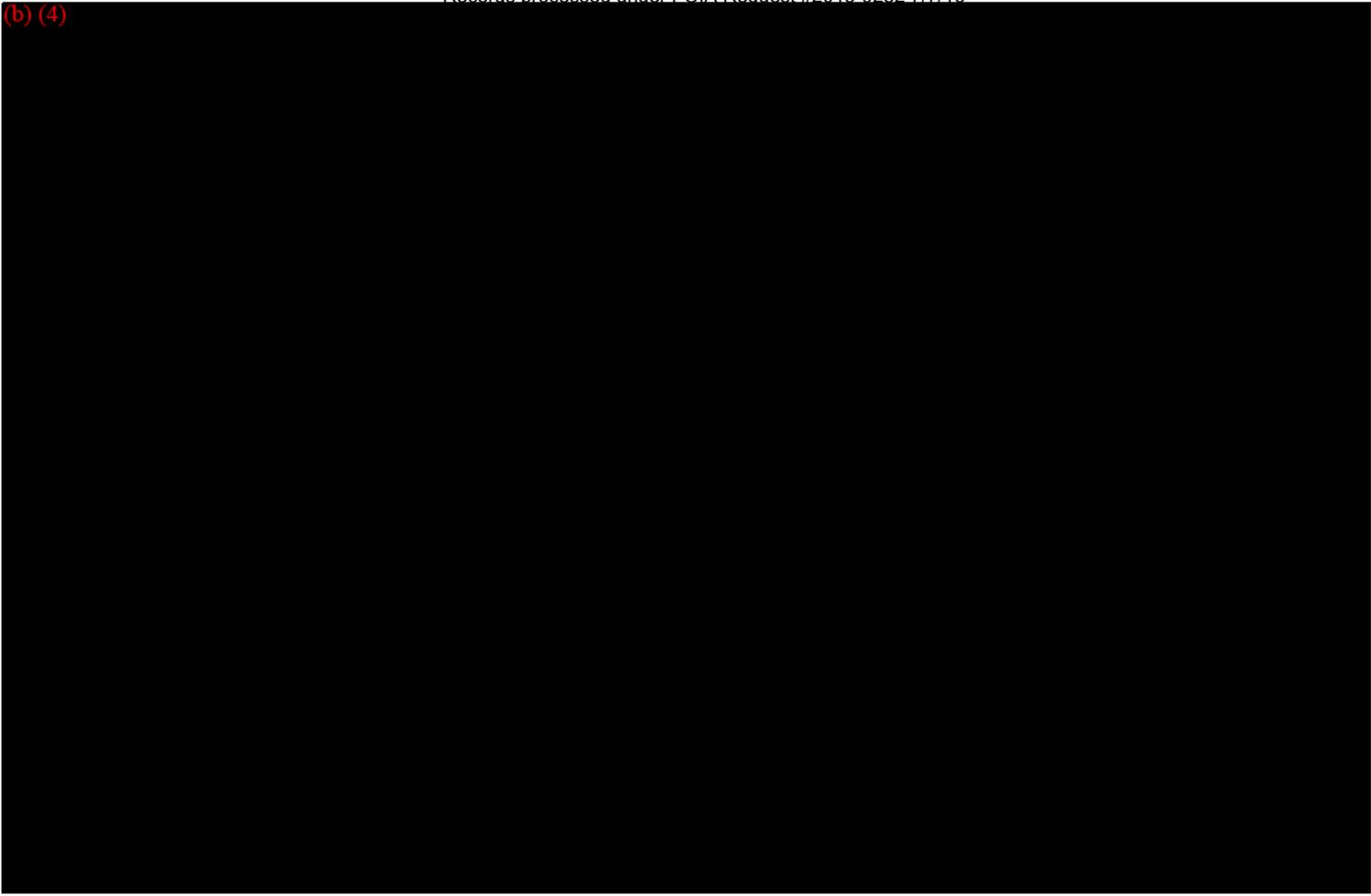
September 16, 2004

	NAME	DATE
PREPARED BY:	 Erik D. Rodriguez	<u>10/4/04</u>
REVIEWED BY:	 Curtis Egan	<u>10/4/04</u>
APPROVED BY:		<u>10/8/04</u>

Prepared by:
(b)(4)

Prepared for:
Neuro Resource Group, Inc.
12222 Merit Drive, Suite 955
Dallas, TX 75251

(b) (4)



Neuro Resoure Group, Inc.

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

495

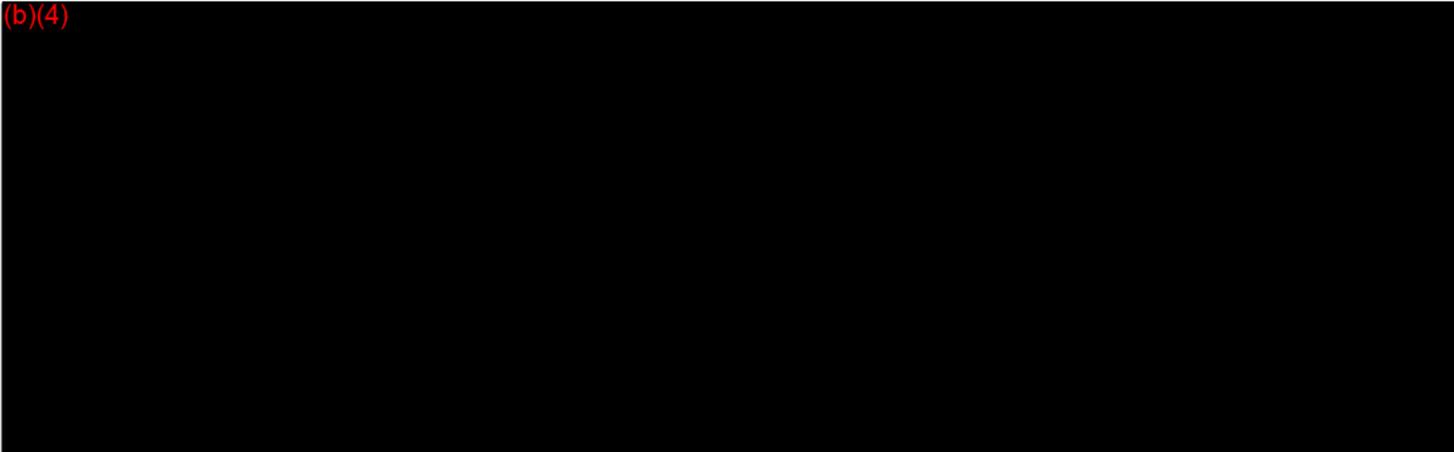
Revision: 1.0 Date: 10/4/04	InterX 5000 Software Test Report	Page 1 of 4
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InterX 5000 Software Test Report

Revision 1.0

October 4, 2004

(b)(4)



(b)(4) Software Verification



Prepared for:
Neuro Resource Group, Inc.
12222 Merit Drive, Suite 955
Dallas, TX 75251



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) T. Stevens / J. Rossi

Subject: 510(k) Number K042912/S'

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices N/A
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
 No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

673 882.5890 Class II

Review: [Signature] R20B 5/17/05
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 5/17/05
(Division Director) (Date)

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?	✓	
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes? <i>N/A</i>		
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?	✓	✓
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

MEMO RECORD

DATE: May 17, 2005


FROM: Theodore R. Stevens, Biomedical Engineer, HFZ-410
TO: The Record, K042912
SUBJECT: Neuro Resource Group InterX5000

Common Name: Transcutaneous Electrical nerve Stimulator

Trade Name: InterX5000

Classification: 21 CFR §882.5950

Class: II

Product Code: GZJ

510(k) summary 510(k) statement

Truth/Accuracy statement

Indications for Use: *"The InterX5000 is indicated for symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain."*

This device is for prescription use.

Contact/Telephone number: Krista Oakes

Tel: 972-665-1800

Fax: 972-665-1814

Claimed equivalent devices: K041575 – Fenzian Treatment System

K951951 – EMPI Focus 795

K870947 – Dynatron 500 Electrical Muscle Stimulator

K883911 – Electro Acuscope

Recommendation: Substantially equivalent.

Basis of Recommendation:

Intended Use: See "Indications for Use" above. The indications for use are identical to those for the Fenzian system cleared under K041575. Note that previously-included electrical muscle stimulator indications have been removed.

Device Description:

Physical: The InterX 5000 is handheld, and consists of a small handheld device in a unibody plastic case. The main electrodes are two concentric, rectangular stainless steel surfaces. The electrodes are placed directly on the unbroken skin and do not use any conductive material or gel. The unit has an LCD display.

Overall, the layout of the unit is very similar to that of the Fenzian unit cleared under K041575.

Electrical Output: The waveform is a high amplitude, short-duration bi-polar pulse. It appears identical to that for the cleared Fenzian device. The output varies according to changes in skin impedance, as with all TENS devices. With this device, the sponsor has made claims for the "interactive" nature of their device. This is similar to the case with the Electro-Acuscope cleared under K832442, which claims a feedback type function that monitors conductance during stimulation to ensure proper stimulus is delivered.

Accessories: 3 accessories are available: a remote concentric probe ("acuprobe"), dual ball probe, and comb probe. Similar probes are included as part of the Electro-acuscope predicate. As initially described, these accessories have a non-compliant 3.5mm stereo plug for attachment to the device. The submitter was informed that this does not conform to the mandator patients lead standard at 12 CFR part 898, which requires compliance with IEC 60601-1 56.3(c). Maximum current and power density have been reported with the smallest surface area electrodes, and are within values for cleared predicates. On May 17, 2005 the sponsor provided drawings of a compliant connector they will use.

Labeling:

NOTE: Supplemental information dated May 11, 2005 provides statements modifying the contents of the instruction manual submitted in the April 14, 2005 amendment. With the most recent modifications, the labeling does not appear to introduce unsupported new intended uses that would preclude clearance under 510(k).

The labeling includes all of the contraindications, precautions and warnings associated with TENS devices, as well as prescription use statements.

The InterX5000 provides an LCD screen which displays skin impedance measurements in the context of "DIAG" and "DOSE" readings. Note that the claims previously made for the DIAG and DOSE functions have been toned down, and are now more descriptive in nature. These give readings of skin impedance and change in impedance, which the practitioner can use in their assessment during treatment. Other cleared devices such as the Electro-Acuscope and Fenzian have indicators of skin impedance, some of which can be pre-set for specific values.

Recommendation: I believe that with the most recent modifications to the labeling, sufficient information has been provided to find the InterX5000 to be substantially equivalent to predicate TENS devices. However, if the sponsor were to revert to making claims for the ability of the device to locate treatment points, to make claims of indications other than the qualified pain indication above, or to claim an ability of the device to determine adequacy of treatment based on its measurements, then that would go beyond this clearance.



Theodore R. Stevens

I concur.
S. Rhodes 5/17

**"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING
DOCUMENTATION**

K042912

Reviewer: Theodore R. Stevens

Division/Branch: DGRND/REDB

Device Name: InterX5000

Product To Which Compared (510(K) Number If Known): K041575 – Fenzian Treatment System; K801459, K832442, K883911 – Electro Acuscope

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

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PREVIOUS PAGE AS NEEDED

1. Explain why not a device: NOT APPLICABLE
2. Explain why not subject to 510(k): NOT APPLICABLE
3. How does the new indication differ from the predicate device's indication: *N/A*
4. Explain why there is or is not a new effect or safety or effectiveness issue: *NA*
5. Describe the new technological characteristics: *N/A*
6. Explain how new characteristics could or could not affect safety or effectiveness: *NA*
7. Explain how descriptive characteristics are not precise enough: *N/A*
8. Explain new types of safety or effectiveness questions raised or why the questions are not new: *NA*
9. Explain why existing scientific methods can not be used: *N/A*
10. Explain what performance data is needed: *NA*
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: *NA*

Indications for Use

510(k) # (if known): K042912

Device Name: InterX5000

Indications for Use:

The InterX5000 is indicated for symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain.

Prescription Use x
(21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(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)



NEURO RESOURCE GROUP

510(k) Summary

Submitter Information:

Contact:

Krista Oakes

Tel: 972-665-1810

Fax: 972-665-1814

Date Prepared:

May 17, 2005

Product Name & Classification:

Classification Regulation: 882.5950

Panel: Neurology

Product Code: GZJ

Trade Name(s): InterX5000

Predicate Device:

K041575 – Fenzian Treatment System

K951951 – EMPI Focus 795

K883911 – Electro Acuscope

Description:

The InterX 5000 consists of a small handheld device in a plastic case. It is powered by one nine-volt alkaline battery. On the upper face of the machine there are two LED's, an LCD display and 5 control buttons. The underside of the machine contains two metal surfaces that form the poles of a treatment electrode. The electrodes are placed directly on the unbroken skin and do not use any conductive material or gel.

On the side of the machine is one socket that connects the main unit to an optional external electrode accessory. The device's electrodes are disabled when the optional external electrode accessory is attached. The optional external electrode accessories only serve as an extension and allow the user to apply treatment in areas which may not be accessible by the main unit electrodes. None of the three electrode accessories intended for use with the InterX 5000 have any active electrical components.

The waveform is a high amplitude, short-duration bi-polar pulse (circuitry in the device integrates time and dosage delivered). A digital display monitors the skin impedance in relation to the starting point, enabling the operator to track changes in the tissues being treated and make appropriate adjustments to the output characteristics if necessary. This interaction and human adjustment continues throughout the length of the InterX treatment.

Intended Use:

The InterX5000 is indicated for:

- symptomatic relief and management of chronic, intractable pain
- adjunctive treatment in the management of post-surgical and post-traumatic pain

Comparison to Predicate Devices:

510k Reference	InterX 5000 (Proposed Device)	Fenzian Treatment System K041575	EMPI Focus 795 K951951
Indications for Use	<p>symptomatic relief and management of chronic, intractable pain</p> <p>adjunctive treatment in the management of post-surgical and post-traumatic pain</p>	<p>symptomatic relief and management of chronic, intractable pain</p> <p>adjunctive treatment in the management of post-surgical and post-traumatic pain</p>	<p>symptomatic relief and management of chronic, intractable pain</p> <p>adjunctive treatment in the management of post-surgical and post-traumatic pain</p> <p>relaxing muscle spasms</p> <p>increasing local blood circulation</p> <p>immediate post surgical stimulation of calf muscles to prevent venous thrombosis</p> <p>muscle reeducation</p> <p>maintaining or increasing range of motion</p> <p>preventing or retarding disuse atrophy</p>
Output Channels	1	1	2
Power Source	Battery, 9V alkaline, disposable	Battery, 9V	Battery, 9V
Weight	6 oz.	04. kg exc. battery	145 gm with battery
Dimensions	7 x 2.5 x 1.5 inches	7 x 7 x 2"	3.7 x 2.5 x 0.84"
Electrodes	Stainless Steel	Stainless Steel	Snapease Brand
Waveform	Damped biphasic	Biphasic	Symmetrical biphasic
Maximum Output Voltages	40V @ 500 ohms 175V @ 2k ohms 450V @ 10k ohms	88V @ 500 ohms 306V @ 2k ohms 650V @ 10k ohms	+100V @ 1k ohm
Maximum Output Current	80 mA @ 500-ohms 87.5 mA @ 2k-ohms 45 mA @ 10k-ohms	46 milliamps @ 500 ohms 16.8 milliamps @ 2k ohms 8.0 milliamps @ 10k ohms	0-60 mA (normal) 0-100 mA (high)
Pulse Width	10 – 500 µS	498 µS	300 µS of peak amplitude
Frequency	15.3 - 351 Hz	15-350 Hz	25, 30, 35, 45, 50, 80 pps
Net Charge	3.9 µC @ 500-ohms	1.16 µC @ 500 ohms	30 µC
Max. Phase Charge	14.8 µC @ 500 ohms	10.6 µC @ 500 ohms	40 µC @ 500 ohms
Max. Current Density ² (mA/cm ²)	52 mA/cm ² @ 2 K ohms	27.7 mA/cm ² @ 500 ohms	3.11 mA/cm ² @ 500 ohms
Avg. Power Density ²	0.024 W/cm ² @ 500 ohms	0.177 W/cm ² @ 500 ohms	0.187 W/cm ² @ 500 ohms

(W/cm ²)	(b)(4)		
Burst Mode			
- Pulses/burst		1-8	Unknown
- Bursts/second		15-2800	
- Burst duration		1-5 seconds	
Max. Delivered Current		< 7.0 mA	<10 mA
Range Load of Impedance		500-1000 ohms	Unknown
Controller		Microprocessor	Microprocessor
Housing		ABS	ABS
Maximum Patient Leakage Current		<100µA	<100µA
Maximum Charge per Pulse		37.5 µC @ 500 ohms	Unknown

Performance Data & Conclusions:

Performance bench testing was conducted to characterize the electrical performance of the InterX5000 as compared to published data of predicate devices.

14

Stevens, Ted

From: Krista Oakes [kristao@nrg-unlimited.com]
Sent: Tuesday, May 17, 2005 10:08 AM
To: Stevens, Ted
Cc: Provost, Miriam; HSR@CDRH.FDA.GOV; Rhodes, Stephen; Tommy Thompson; davet@nrg-unlimited.com; Martyn Abbott; john.manthei@lw.com
Subject: RE: Response to K042912

Hi, Ted –

As it turns out, we were able to get a drawing together more quickly than I thought, but thanks for making the inquiry.

Please find attached electronic copies of the proposed engineering drawing and the revised Summary. If these look good to you, I will forward in hard copy to the Document Mail Center, along with the information emailed to you last week.

I think we're seeing the finish line approaching! I think we have now addressed all of the outstanding issues, but please let me know if there is anything else we need to do to wrap this up.

Thanks –
Krista Oakes

From: Stevens, Ted [mailto:TRS@CDRH.FDA.GOV]
Sent: Monday, May 16, 2005 12:34 PM
To: 'Krista Oakes'
Subject: RE: Response to K042912

I will ask the head of our 510(k) staff if a statement would be sufficient.

-----Original Message-----

From: Krista Oakes [mailto:koakes@amicasolutions.com]
Sent: Monday, May 16, 2005 1:31 PM
To: 'Stevens, Ted'; davet@nrg-unlimited.com
Cc: 'Rhodes, Stephen'
Subject: RE: Response to K042912

Thanks - I will review the summary and respond as soon as possible.

(b)(4)



Regards,
Krista Oakes

From: Stevens, Ted [mailto:TRS@CDRH.FDA.GOV]
Sent: Monday, May 16, 2005 12:25 PM
To: 'Krista Oakes'; davet@nrg-unlimited.com
Cc: Rhodes, Stephen
Subject: RE: Response to K042912
Importance: High

Thanks for getting the attachments to me electronically so we can work interactively. There were some items in the 510(k) summary which I do not think are appropriate based on the current indications and labeling. I have attached a version with my edits in "tracked changes" with what I think we can easily accept.

5/17/2005

We also need to resolve the accessory plug issue ASAP. We can't clear the device as it stands now (b)(4) (b)(4).

-----Original Message-----

From: Krista Oakes [mailto:koakes@amicasolutions.com]
Sent: Tuesday, May 10, 2005 4:38 PM
To: 'Stevens, Ted'
Subject: RE: Response to K042912

Attached are the updated Indications for Use form and 510(k) summary. Hard copies will also be sent to the Document Mail Center.

Regards,
Krista Oakes

From: Stevens, Ted [mailto:TRS@CDRH.FDA.GOV]
Sent: Tuesday, May 10, 2005 8:59 AM
To: 'Krista Oakes'
Cc: Rhodes, Stephen; Provost, Miriam
Subject: RE: Response to K042912

Thank you for your response. Can you please provide a new "Indications for Use" form and 510(k) Summary that reflect the current indications?

I have scheduled the call for 4:30 pm Eastern Daylight time tomorrow, Wednesday May 11. Please let me know if this time works for you.

-----Original Message-----

From: Krista Oakes [mailto:koakes@amicasolutions.com]
Sent: Monday, May 09, 2005 9:00 PM
To: 'Stevens, Ted'
Cc: 'Rhodes, Stephen'; 'Provost, Miriam'; 'Tommy Thompson'; Tommy Thompson; john.manthei@lw.com; davet@nrg-unlimited.com; 'Martyn Abbott'; HSR@CDRH.FDA.GOV; 'Weinstein, Les S'
Subject: RE: Response to K042912

Dear Mr. Stevens:

Please find attached our response to your email of May 6. Please advise at your earliest convenience regarding a time for Wednesday's call.

Regards,

Krista Oakes
Vice President, Regulatory Affairs
Neuro Resource Group

From: Stevens, Ted [mailto:TRS@CDRH.FDA.GOV]
Sent: Monday, May 09, 2005 3:10 PM
To: Krista Oakes
Cc: Rhodes, Stephen; Provost, Miriam
Subject: RE: Response to K042912

Ms. Oakes: Thank you for taking our phone call today. I'm pleased that you received the email I sent after not reaching you by phone last week. You indicated that you didn't think you needed any clarification on any of the points raised, but if that changes, don't hesitate to contact me by phone or email.

We look forward to your email response, which you thought would be sent tonight or Tuesday. As you requested, we are planning to set up a follow-up telephone call on Wednesday, after we review what you send.

5/17/2005

Ted Stevens
Chief, Restorative Devices Branch
Division of General, Restorative & Neurological Devices
Office of Device Evaluation
(301) 594-1296 x147

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-----Original Message-----

From: Stevens, Ted
Sent: Friday, May 06, 2005 1:40 PM
To: 'kristao@nrg-unlimited.com'
Cc: Rhodes, Stephen; Provost, Miriam
Subject: Response to K042912

I have completed my review of the information you provided subsequent to our meeting. Unfortunately, the information you provided does not address the specific concerns we asked you to. If you can provide information which adequately addresses our previous concerns by Thursday, May 12, I can continue review without putting the document on hold.

In particular:

1. Accessory probes: (b)(4)

(b)(4)

(b)(4)

2. Current density: (b)(4)

3. Indications: (b)(4)

(b)(4)

4. TENS (b)(4)

(b)(4)

(b)(4)

(b)(4)

Please feel free to contact me by telephone or email if you need clarification of any of these requests.

Ted Stevens
Chief, Restorative Devices Branch
Division of General, Restorative & Neurological Devices
Office of Device Evaluation
(301) 594-1296 x147

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5/17/2005

19

Stevens, Ted

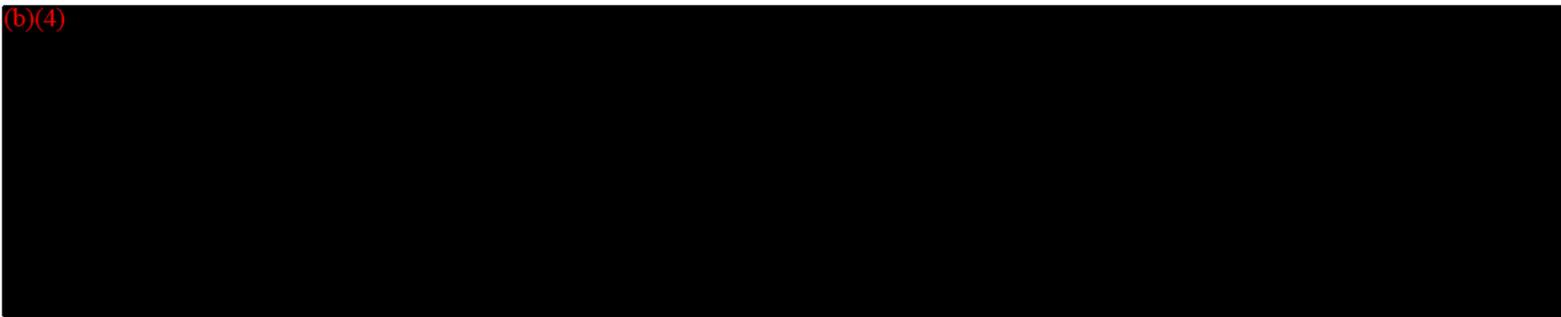
From: Stevens, Ted
Sent: Friday, May 13, 2005 5:12 PM
To: 'Dave Turner'
Cc: Krista Oakes; Tommy Thompson; tommyt@nrg-unlimited.com; Rhodes, Stephen; Provost, Miriam
Subject: RE: Web Site

Thank you for the website citation..

To re-cap, my interactions with our experts in the Office of Compliance confirm that the performance standard **does** apply to these hand-held probes, even though they are not affixed or adhered to the patient. There is a specific exception for the active probes for high-frequency electrosurgical equipment under 60601-2-2, but that applies only to high-frequency electrosurgical equipment.

There are several ways to move forward from here.

(b)(4)



T. Stevens
Chief, Restorative Devices Branch
Division of General, Restorative & Neurological Devices
Office of Device Evaluation
(301) 594-1296 x147

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-----Original Message-----

From: Dave Turner [<mailto:dturner@nrg-unlimited.com>]
Sent: Friday, May 13, 2005 3:52 PM
To: Stevens, Ted
Cc: Krista Oakes; Tommy Thompson; tommyt@nrg-unlimited.com
Subject: Web Site

Thank you for the phone call today. Although disappointing, we appreciate your efforts. We will let you know Monday the direction we plan to take.

Below is the web site I was referring to on our call. Please refer to the accessories section to see all of the cable connections which have similar connectors to ours.

<http://www.advbiomed.com/>

Sincerely,

5/16/2005

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

20

Dave Turner
Neuro Resource Group, Inc.
1100 Jupiter Rd., Ste 190
Plano, TX 75074

Phone: (972) 665-1810

Cell: (214) 725-1166

Fax: (972) 665-1814

E-mail: DaveT@nrg-unlimited.com

Stevens, Ted

From: Silberberg, Jeffrey L.
Sent: Friday, May 13, 2005 1:51 PM
To: Stevens, Ted; Berthold, Kent A.; Rodriguez, Gladys; Ulatowski, Tim
Cc: Foreman, Christy; Provost, Miriam; Rhodes, Stephen
Subject: RE: Patient Lead Standard

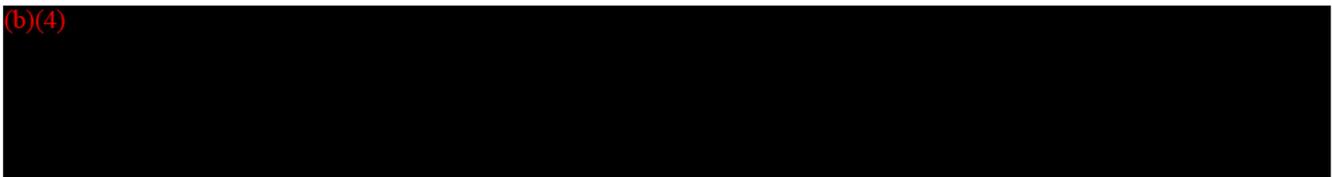
Yes. I'm not sure what you mean by "only". Provision for variance or exemption was intentionally included in the reg.

Jeff

-----Original Message-----

From: Stevens, Ted
Sent: Friday, May 13, 2005 1:42 PM
To: Silberberg, Jeffrey L.; Berthold, Kent A.; Rodriguez, Gladys; Ulatowski, Tim
Cc: Foreman, Christy; Provost, Miriam; Rhodes, Stephen
Subject: RE: Patient Lead Standard

(b)(4)



-----Original Message-----

From: Silberberg, Jeffrey L.
Sent: Friday, May 13, 2005 12:57 PM
To: Berthold, Kent A.; Stevens, Ted; Rodriguez, Gladys; Ulatowski, Tim
Cc: Foreman, Christy; Provost, Miriam; Rhodes, Stephen
Subject: RE: Patient Lead Standard

(b)(4)



Jeff

-----Original Message-----

From: Berthold, Kent A.
Sent: Friday, May 13, 2005 11:20 AM
To: Stevens, Ted; Rodriguez, Gladys; Ulatowski, Tim
Cc: Foreman, Christy; Silberberg, Jeffrey L.; Provost, Miriam; Rhodes, Stephen
Subject: RE: Patient Lead Standard

The standard applies to TENS devices. I would need to see an illustration of the device and its electrode lead wires to determine whether this specific TENS device needs to comply with this standard. Most TENS devices must pass the three tests described in the standard. Please contact me by telephone so we can discuss further. Thank you.

-----Original Message-----

From: Stevens, Ted
Sent: Friday, May 13, 2005 11:03 AM
To: Stevens, Ted; Rodriguez, Gladys; Ulatowski, Tim
Cc: Foreman, Christy; Berthold, Kent A.; Silberberg, Jeffrey L.; Provost, Miriam; Rhodes, Stephen
Subject: RE: Patient Lead Standard

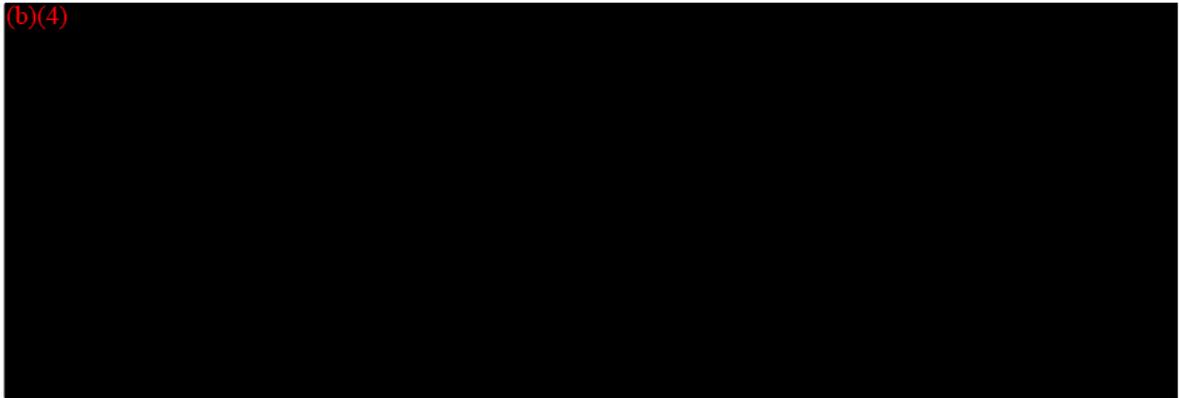
(b)(4)



-----Original Message-----

From: Stevens, Ted
Sent: Friday, May 13, 2005 10:59 AM
To: Rodriguez, Gladys; Ulatowski, Tim
Cc: Foreman, Christy; Berthold, Kent A.; Silberberg, Jeffrey L.; Provost, Miriam; Rhodes, Stephen
Subject: RE: Patient Lead Standard
Importance: High

(b)(4)



Any insight would be greatly appreciated!

-----Original Message-----

From: Rodriguez, Gladys
Sent: Friday, May 13, 2005 10:36 AM
To: Ulatowski, Tim; Stevens, Ted
Cc: Foreman, Christy; Berthold, Kent A.; Silberberg, Jeffrey L.
Subject: RE: Patient Lead Standard

Kent Berthold handles Patient cable and leads issues in compliance. I will ask him to chime in. Jeff Silberberg in OSEL was also involved in the promulgation of the performance standard and the development of the field test method.

Gladys Rodriguez
Director
Division of Enforcement B
Office of Compliance
Center for Devices and Radiological Health
Food and Drug Administration
Telephone number: 1-240-276-0120
Fax number: 1-240-276-0129
E-mail: gladys.rodriguez@fda.hhs.gov

-----Original Message-----

From: Ulatowski, Tim
Sent: Friday, May 13, 2005 10:29 AM
To: Stevens, Ted
Cc: Rodriguez, Gladys; Foreman, Christy
Subject: RE: Patient Lead Standard

Beats me. Let's see what others say.

-----Original Message-----

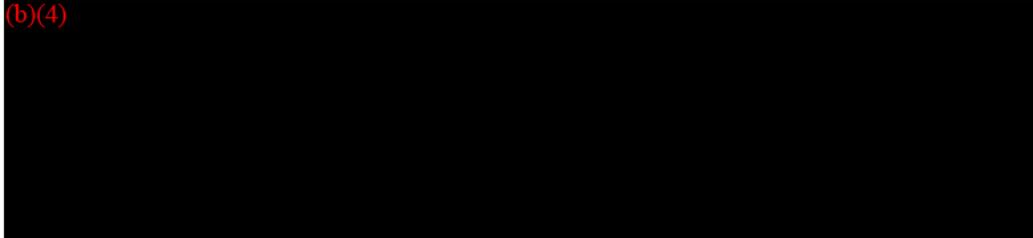
From: Stevens, Ted
Sent: Thursday, May 12, 2005 1:24 PM
To: Ulatowski, Tim

Subject: Patient Lead Standard
Importance: High

Who is the center guru on the lead standard (21 CFR 898), now that Stewart Crumpler is gone? His is the only contact name I can find on the various lead guidance documents.

This is quite time sensitive, since the 510(k) is coming due.

(b)(4)



Ted Stevens << File: NRG letter 56.3c.pdf >>
Chief, Restorative Devices Branch
Division of General, Restorative & Neurological Devices
Office of Device Evaluation
(301) 594-1296 x147

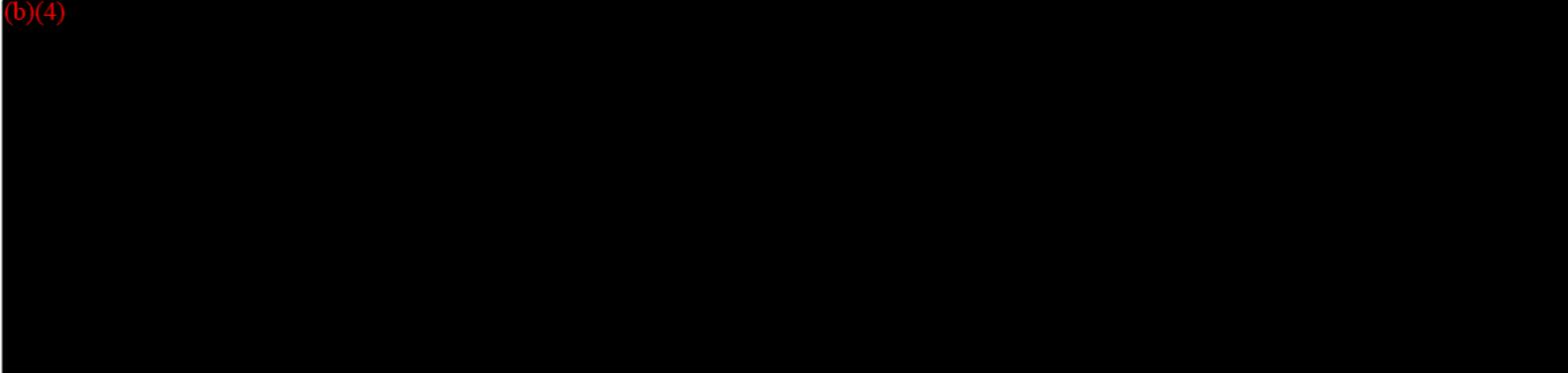
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Stevens, Ted

From: Krista Oakes [kristao@nrg-unlimited.com]
Sent: Thursday, May 12, 2005 12:43 AM
To: Stevens, Ted; Provost, Miriam; Rhodes, Stephen; Tommy Thompson; Tommy Thompson; davet@nrg-unlimited.com; Martyn Abbott; john.manthei@lw.com
Subject: K042912

Dear Mr. Stevens,

(b)(4)



Regards,

Krista Oakes
Vice President, Regulatory Affairs

5/12/2005



NEURO RESOURCE GROUP

May 11, 2005

Document Mail Center (HFZ401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 USA
Attn: Ted Stevens

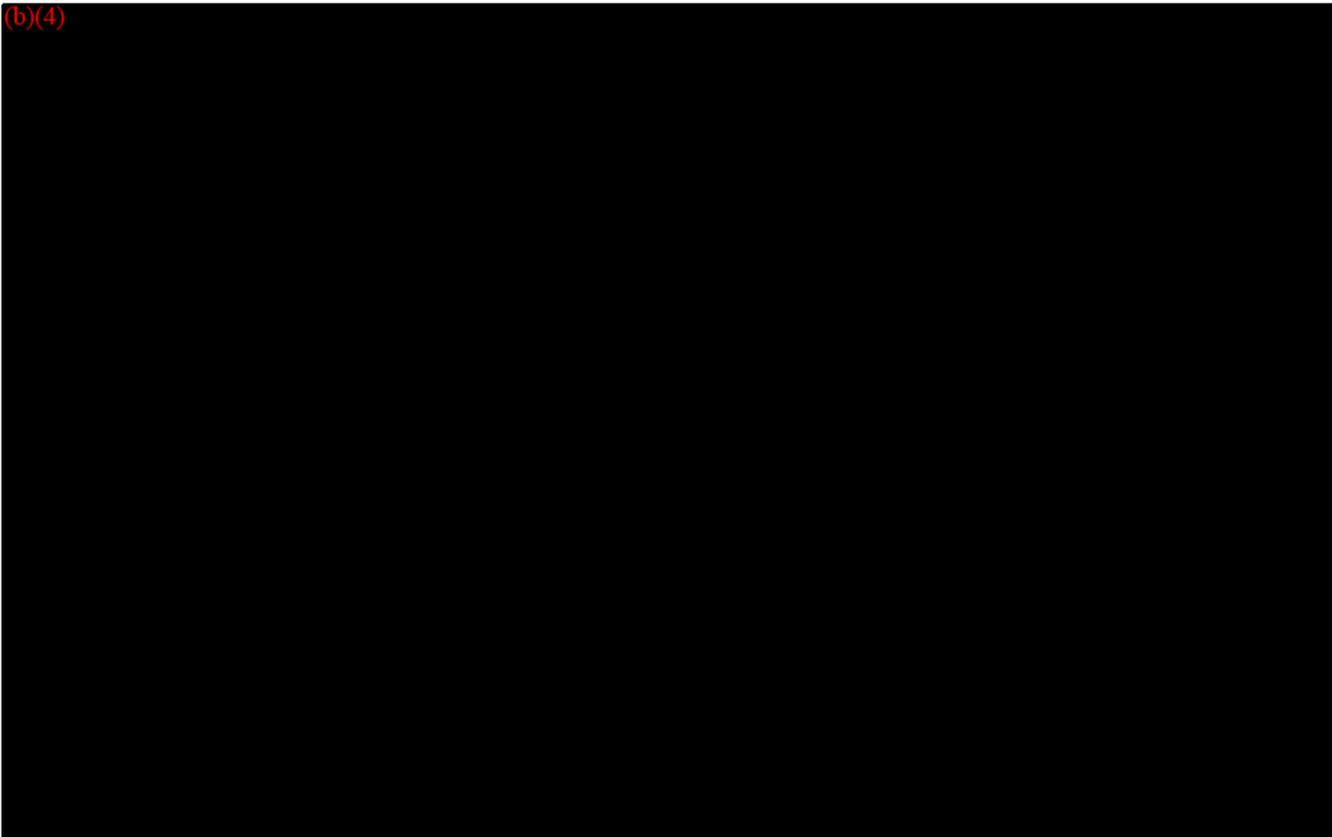
Re: K042912 – Supplemental Information

Dear Mr. Stevens:

Please find below our response to your email questions received on Friday, May 6, and pursuant to our telephone conversation today:

1. Accessory probes: As previously noted, the connectors for your accessory probes cannot meet the required patient lead standard (21 CFR Part 898). IEC 601-1 53.c (sic) requires that:

(b)(4)

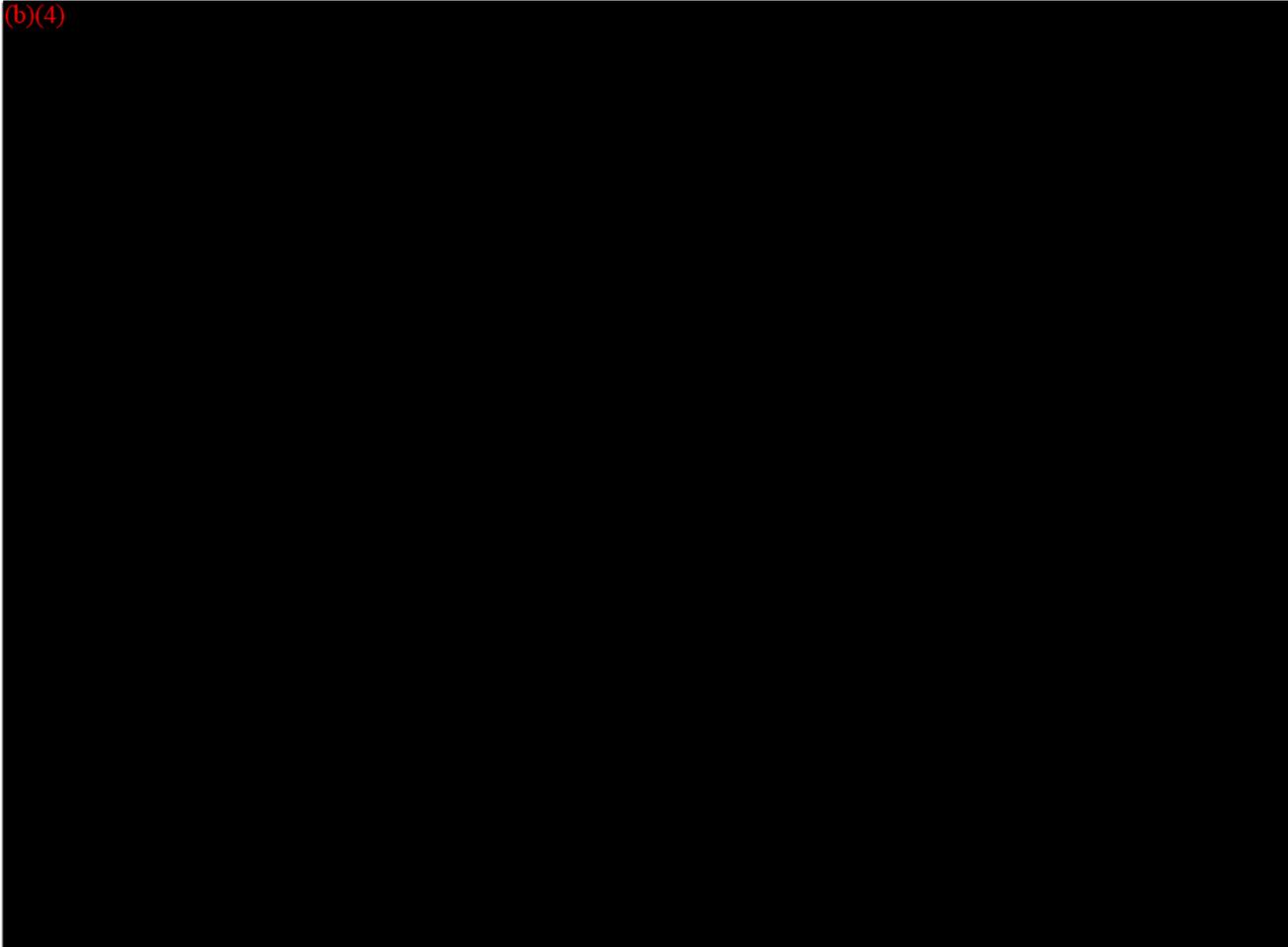


K042912 Additional Information

May 11, 2005

Page 2 of 5

(b)(4)



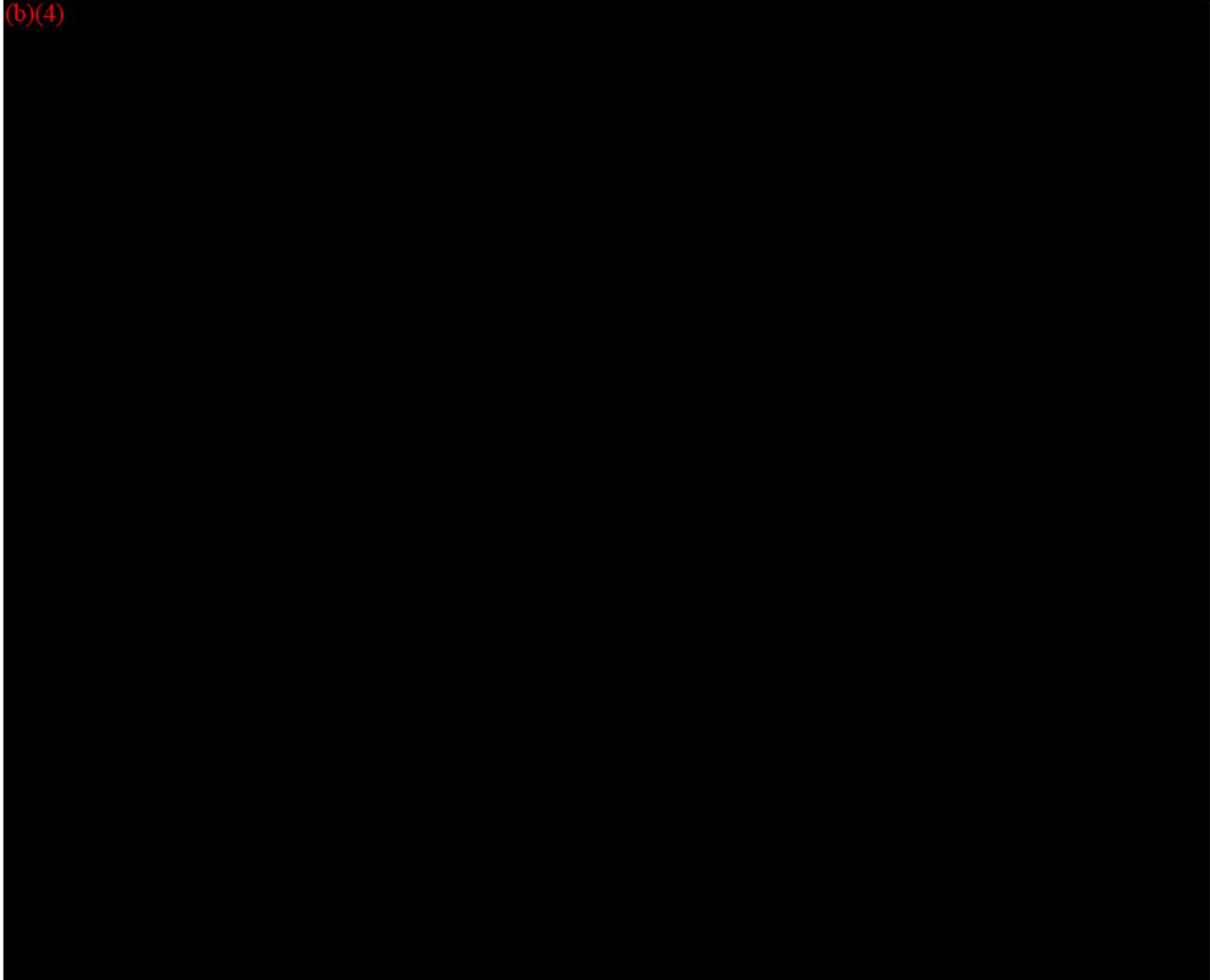
2. Current density: (b)(4)



The following numbers are “worst case”, absolute maximums based on maximum frequency, lowest impedance presented by the probes and maximum amplitude. We also calculated the two numbers for the comb probe using only two lines:

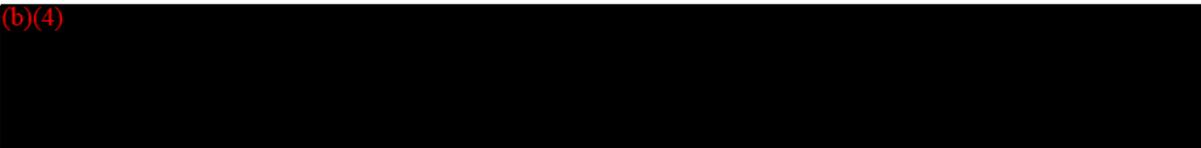
AcuProbe	Comb Probe	
351.219118	(b)(4)	
383.275704		

(b)(4)



3. Indications: You have included electrical muscle stimulator (EMS) indications for the InterX 5000 (relaxing muscle spasms, increasing local blood circulation, immediate postsurgical stimulation of calf muscles to prevent venous thrombosis, muscle reeducation, maintaining or increasing range of motion, prevention or retardation of disuse atrophy). You have not identified a predicate device for these indications that has similar technological characteristics. Please either remove the EMS indications, or identify a valid predicate device with equivalent output and electrode configuration, or provide supporting clinical data for each indication.

(b)(4)



4. TENS-type Claims/labeling: (b)(4)



K042912 Additional Information

May 11, 2005

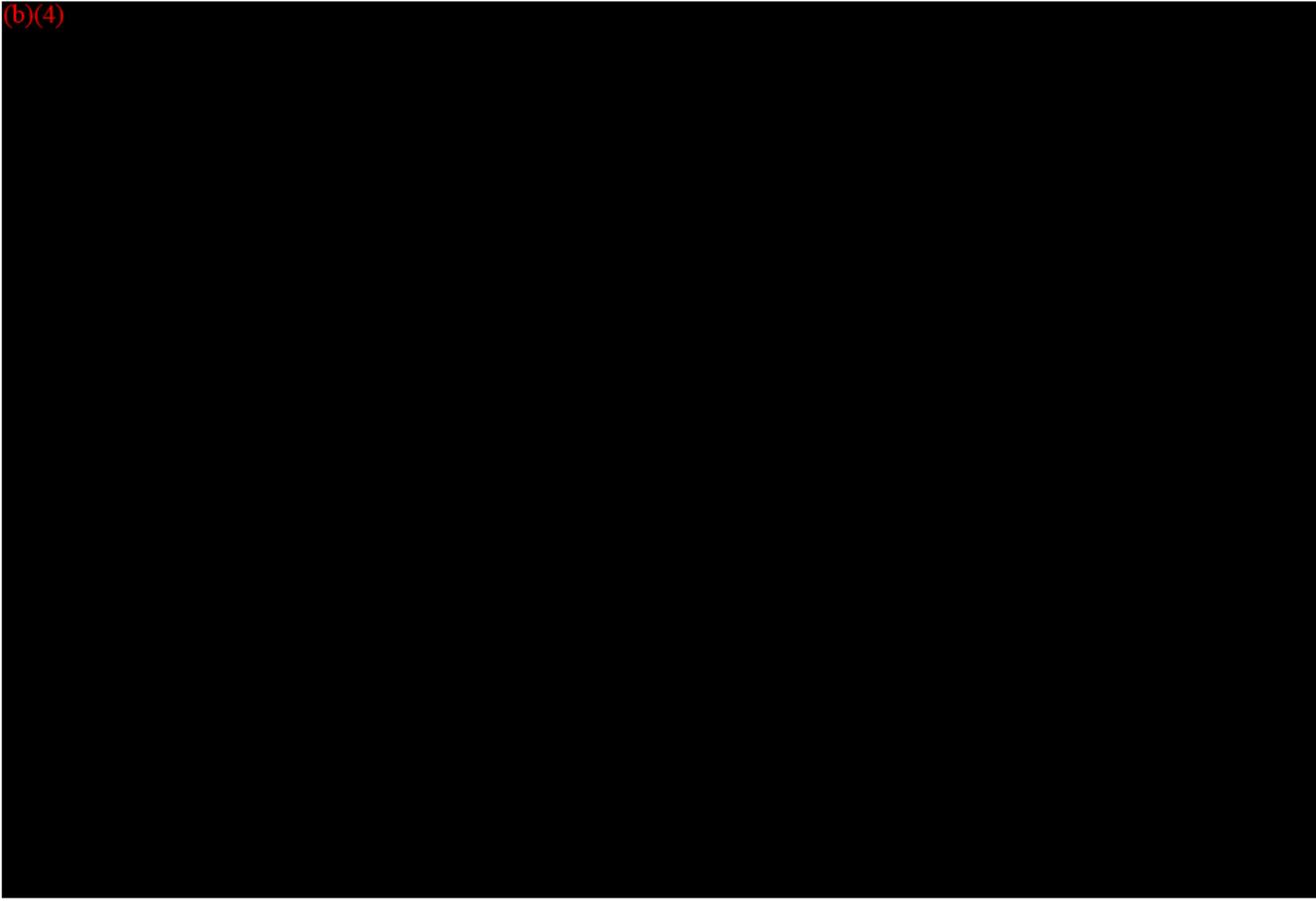
Page 4 of 5

(b)(4)

A horizontal black redaction bar covering a line of text.

Your labeling continues to include many statements that have not been supported. Please either remove them or provide valid scientific evidence to support each. Examples:

(b)(4)

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(b)(4)

A large rectangular black redaction box covering the bottom portion of the page's content.

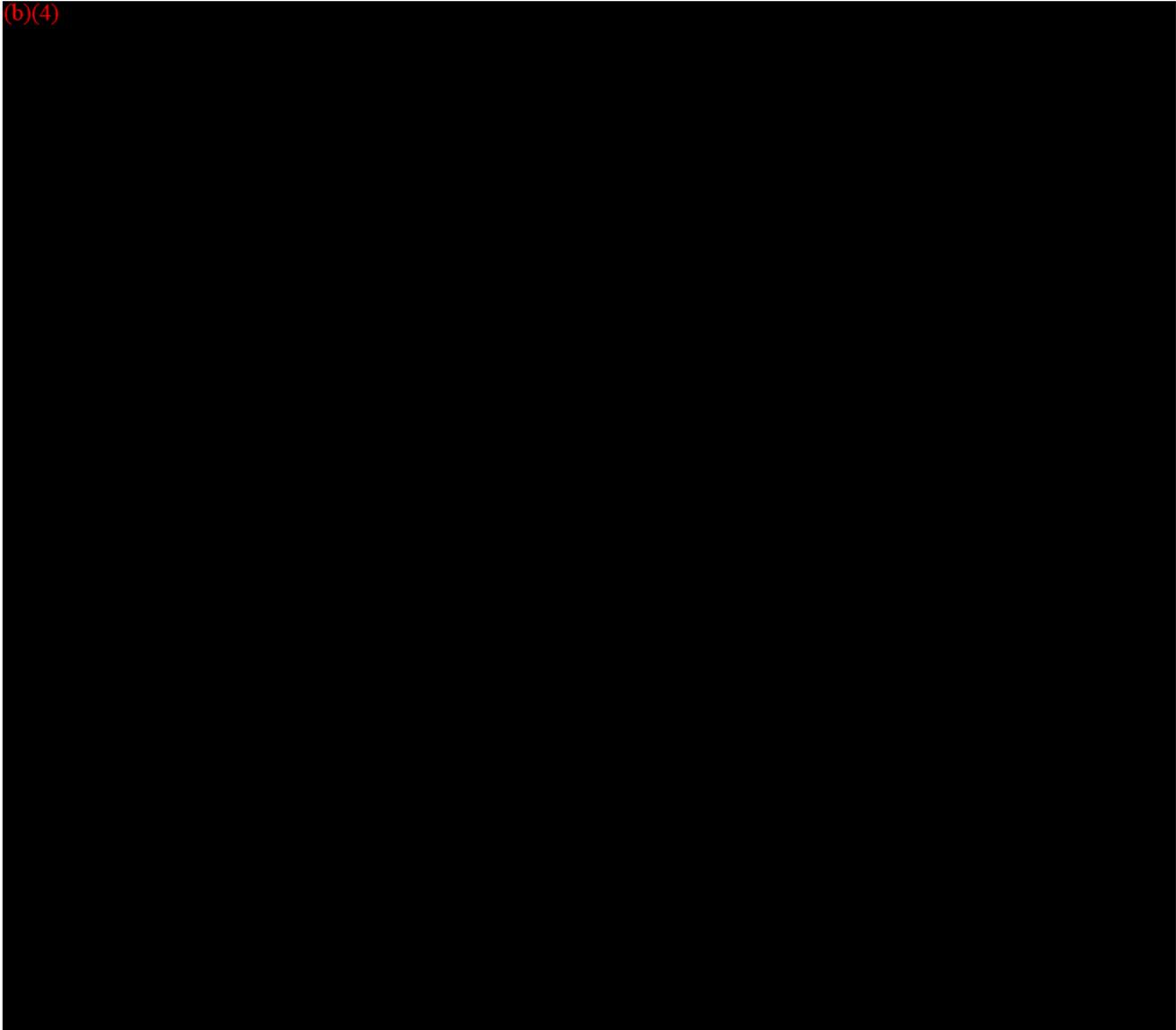
Our firm has determined that this statement is not necessary, and will remove it.

K042912 Additional Information

May 11, 2005

Page 5 of 5

(b)(4)



We believe that this information reflects our most recent discussions, and would be sufficient to support an SE determination. We appreciate having had the opportunity to discuss these items with CDRH in today's telephone meeting, and look forward to your review and reply.

Sincerely,

Krista Oakes
Vice President, Regulatory Affairs

/attachment: NEMKO letter



May 11, 2005

Mr. Dave Turner
Neuro Resource Group, Inc.
1100 Jupiter Rd., Ste 190
Plano, TX 75074

Subject: Acceptance of patient cables / probes according to IEC 60601-1, Clause 56.3(c)

Dear Mr. Turner,

Thank you for your telephone call today.

This letter is to confirm our acceptance of the patient cables/probes in the Nemko test report, Ref. No. 30293.

We stated this clause as "N" (not applicable) due to the intended nature of use of the patient cables/probes.

In reviewing Clause 56.3(c) and the associated rationale in Annex A.2, it is our opinion that since these patient cables/probes are not "attached" to the patient and they must be held in place by a trained care giver, there is no risk of the hazards implied by this clause and rationale. We therefore considered this clause as "N" (not applicable).

Should you have any questions, please do not hesitate to contact us.

Regards,

Grant Schmidbauer
General Manager
Nemko USA, Inc.
San Diego, CA

phone call 5/9/05 3:45

company is emailing response Monday, Tuesday

Stevens, Ted

From: Stevens, Ted
Sent: Friday, May 06, 2005 1:40 PM
To: 'kristao@nrg-unlimited.com' 9728495167
Cc: Rhodes, Stephen; Provost, Miriam
Subject: Response to K042912

I have completed my review of the information you provided subsequent to our meeting. Unfortunately, the information you provided does not address the specific concerns we asked you to. If you can provide information which adequately addresses our previous concerns by Thursday, May 12, I can continue review without putting the document on hold.

In particular:

(b)(4)

(b)(4)

(b)(4)

2. Current density: (b)(4)

3. Indications: (b)(4)

4. TENS-type Claims/labeling: In our meeting and telecon, we detailed our concerns with the new intended uses introduced by claims associated (b)(4)

(b)(4)

MEMO RECORD

DATE: May 6, 2005

FROM: Theodore R. Stevens, Supervisory Biomedical Engineer, HFZ-410

TO: The Record, K042912/S1

SUBJECT: NRG InterX5000 review of additional information supplied

The information they provided after the meeting still has statements about the device determining "optimal placement of the device", "interactive nature of the device is key to the effectiveness";

(b)(4)



(b)(4)



RECOMMENDATION: Request sponsor to correct deficiencies outlined above.

f) *Fixing of wiring*

(b)(4)

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*See rationale for 56.1

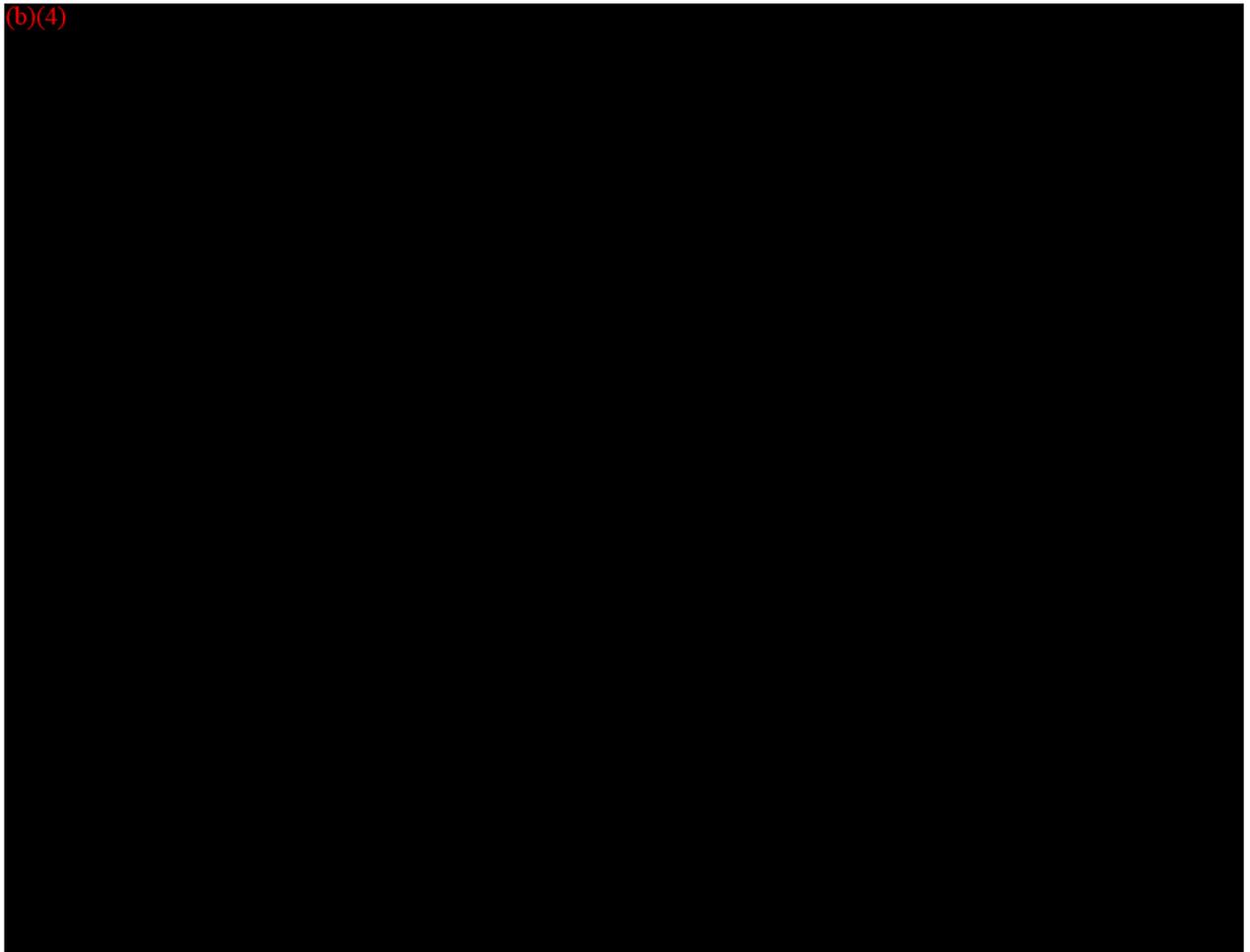
56.2 *Screws and nuts*

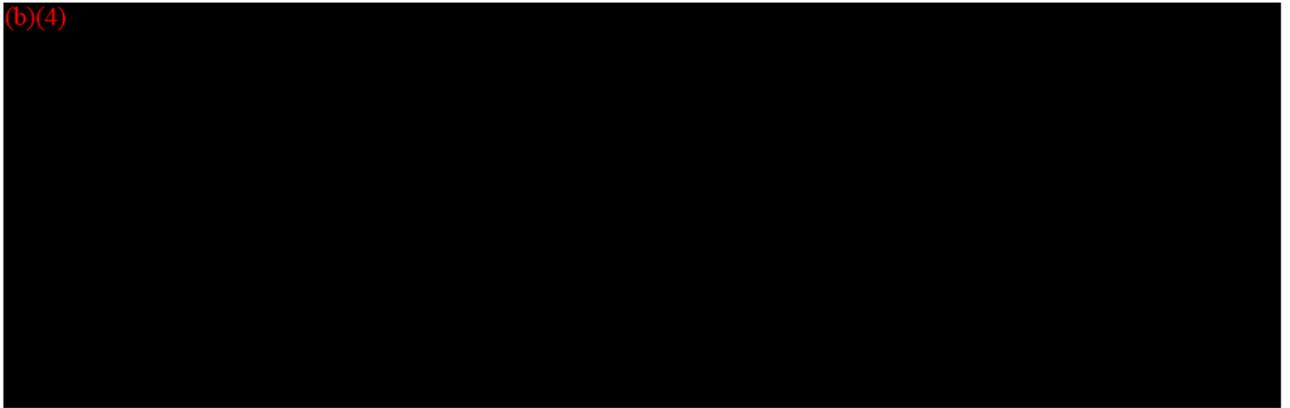
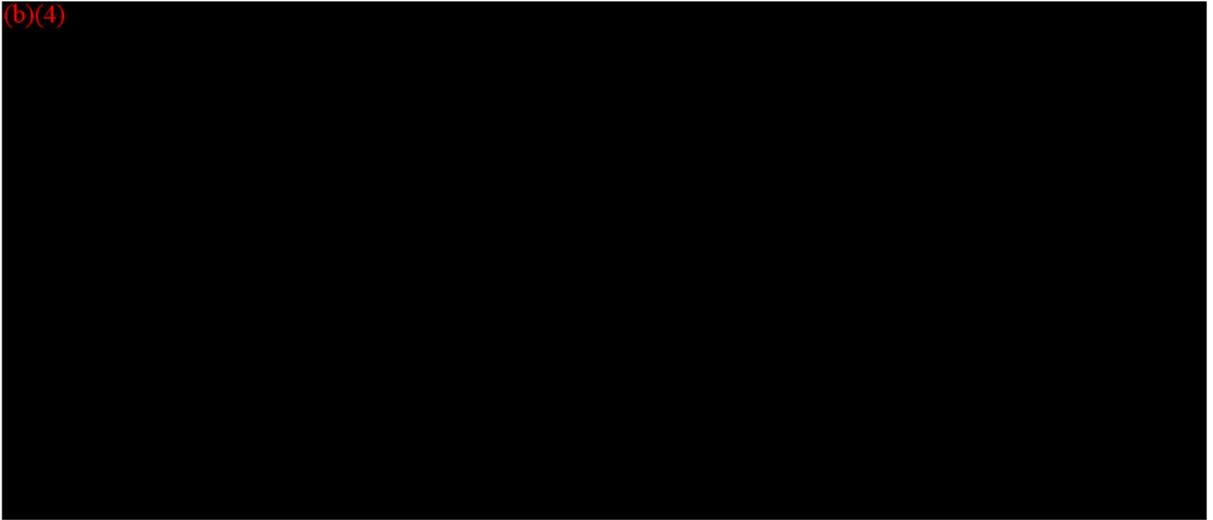
Not used.

56.3 *Connections – General*

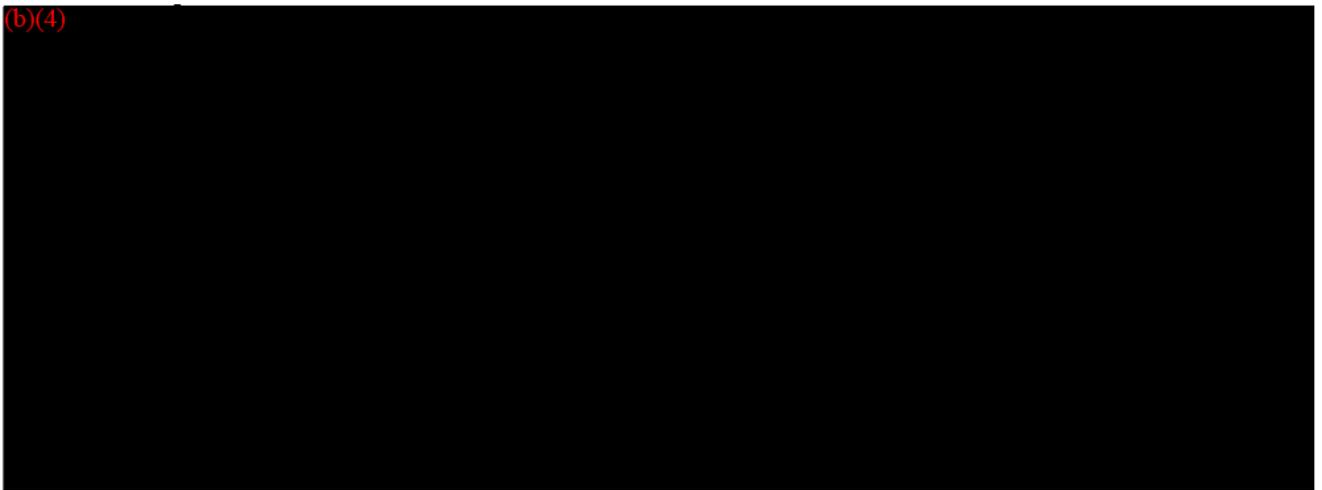
For connections and connectors in the MAINS PART see Sub-clauses 57.2 and 57.5.

(b)(4)

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56.4 *Connections of capacitors



Sub-clause

(b)(4)



interlocking device or an additional safety control.

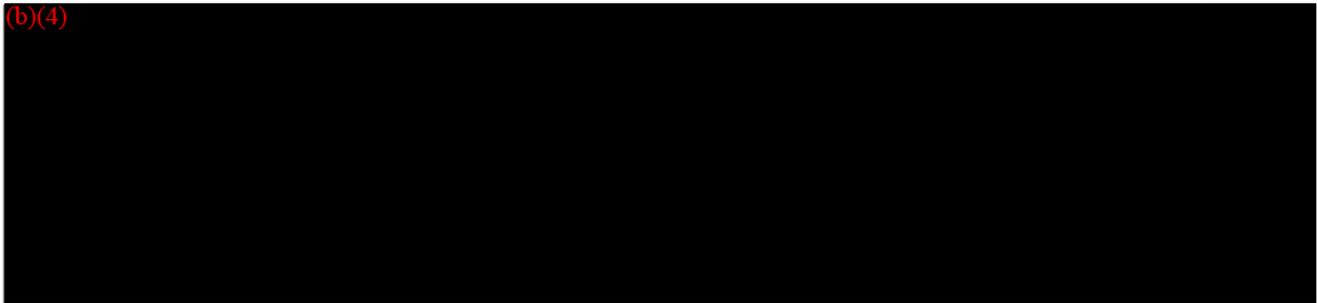
Sub-clause

(b)(4)



Subclause

(b)(4)



(b)(4)



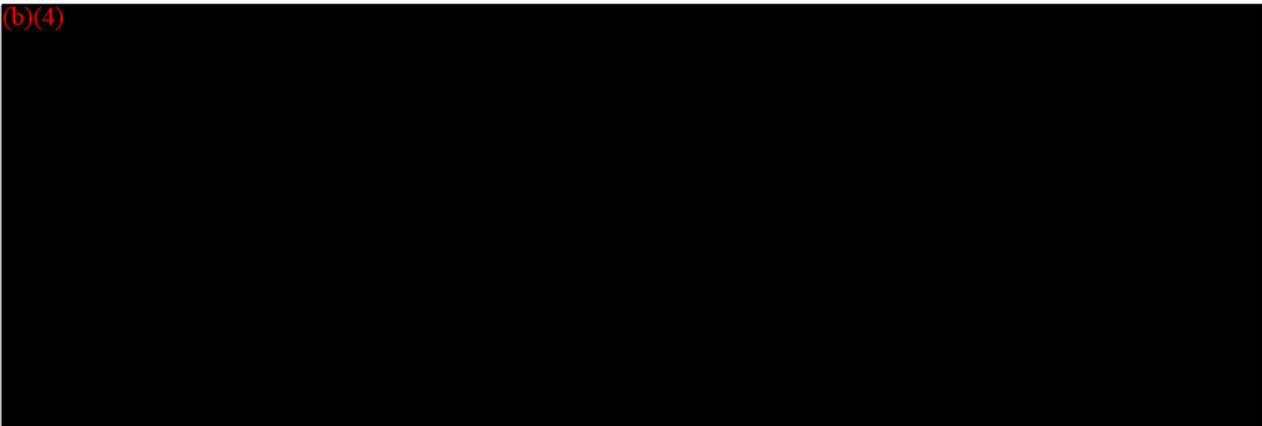
Sub-clause

56.4 (b)(4) [redacted]

Subclause

56.7 c)

(b)(4)





NEURO RESOURCE GROUP

May 9, 2005

Document Mail Center (HFZ401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 USA
Attn: Ted Stevens

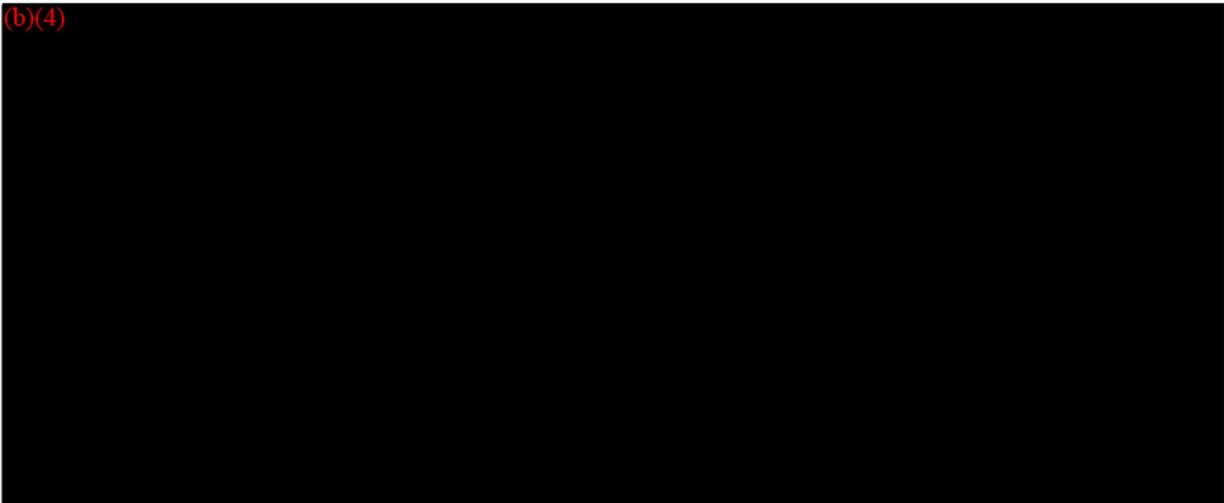
Re: K042912 – Supplemental Information

Dear Mr. Stevens:

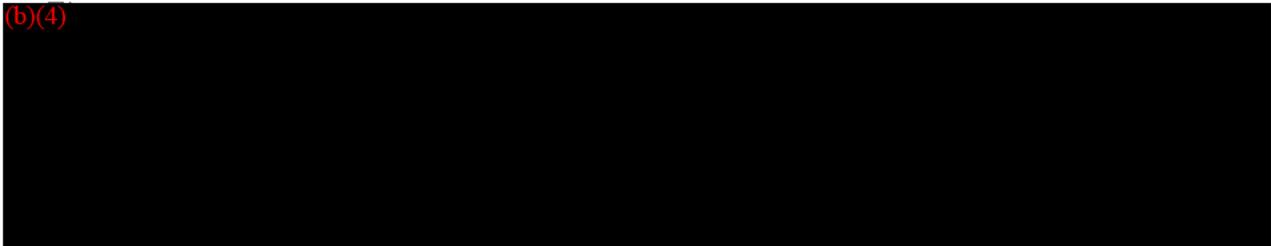
Please find below our response to your email questions received on Friday, May 6.

1. Accessory probes: As previously noted, the connectors for your accessory probes cannot meet the required patient lead standard (21 CFR Part 898). IEC 601-1 53.c (sic) requires that:

(b)(4)

A large rectangular area of the document is completely redacted with a solid black fill. The redaction covers the majority of the page's content.

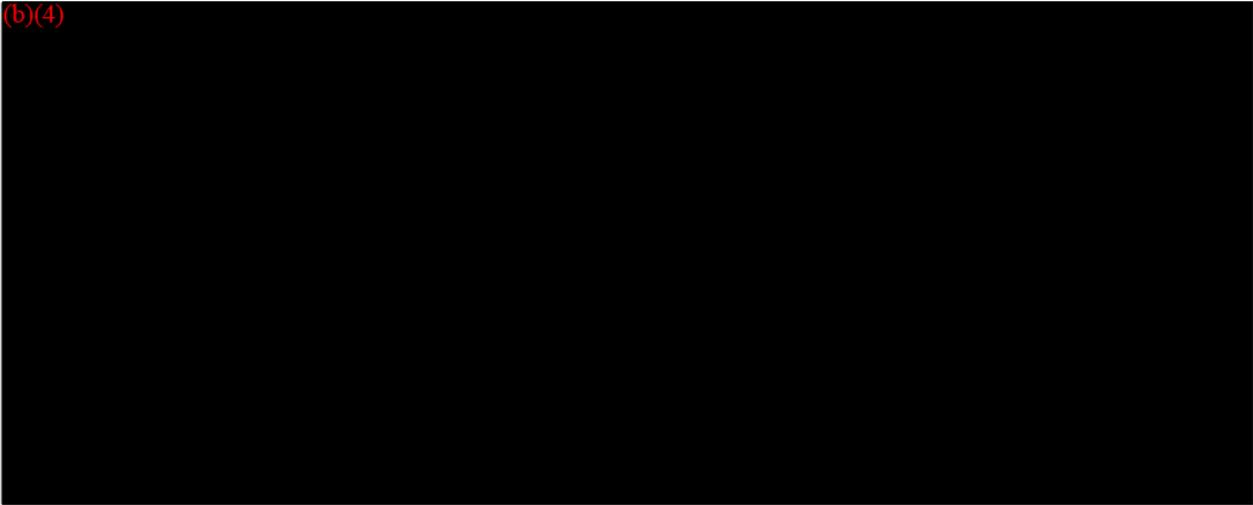
(b)(4)

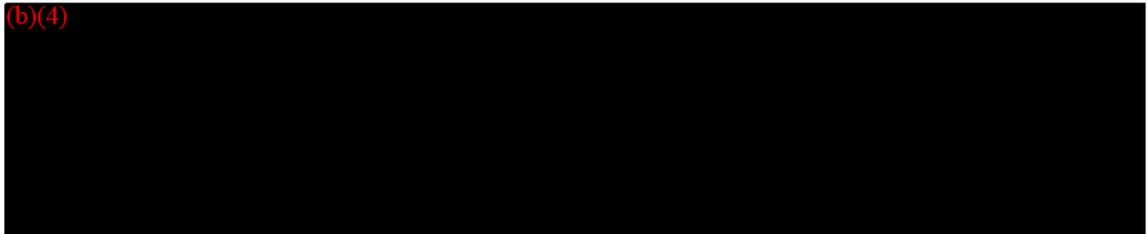
A second large rectangular area of the document is completely redacted with a solid black fill, located below the first redacted area.

1100 Jupiter Road, Suite 190 Plano, TX 75074 972-665-1810

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

(b)(4)



1. (b)(4)
 - 2.
 - 3.
 - 4.
 - 5.
- 

The risk of this multi-fault condition occurring, even inadvertently, is extremely remote with this device.

Prior to our firm's technology transfer in 2004, this device has been successfully used in Russia for over 20 years, and worldwide for at least seven years (including use by lay persons) with no reported cases of accidental electrical shock.

Our firm has previously identified similar accessory electrodes being marketed under K883911, Electro Acuscope, by Biomedical Design Instruments (now Advanced Biomedical Technologies – www.advbiomed.com). These accessory electrodes use the identical type of connector used in our device. A search of the MAUDE database has revealed no reported Medical Device Reports relating to accidental electrical shock (indeed, no reports were found for this device at all) since 1988. Based on this history and our own risk assessment activities, we believe that the accessory probes are safe.

Our firm requests that CDRH proceed with a determination of substantial equivalence based on the independent laboratory's findings as well as the historical safety of this device and predicate accessory probes marketed under K883911.

2. Current density: (b)(4)



(b)(4)

The representatives of our firm who attended the April 7 meeting have a different recollection of this discussion, and are concerned that a misunderstanding of this device still exists, despite our best efforts to describe its operation. As explained in our meeting, this product does not block pain like products used in spinal cord stimulation, but rather works over time to reduce pain. In all cases, the product is used under the condition where the patient is feeling the "first level of discomfort". In fact, during the procedure, it is common that the therapist is requested to turn *down* the output, because the sensation becomes too strong. It is clear that the patient would feel an elevated output and either jerk away or (if self-treating) remove the electrode from their skin. The suggestion that our device would desensitize the patient to "breakthrough pain" reflects a continued misunderstanding.

We also believe it is important to remind CDRH that unlike traditional TENS devices, which are attached in a fixed location to the patient, our device remains unfixed and is freely brushed across the treatment area by either the patient or their healthcare practitioner, where feedback from the patient relative to levels of discomfort is an important indicator of both location, stimulation setting, and treatment length.

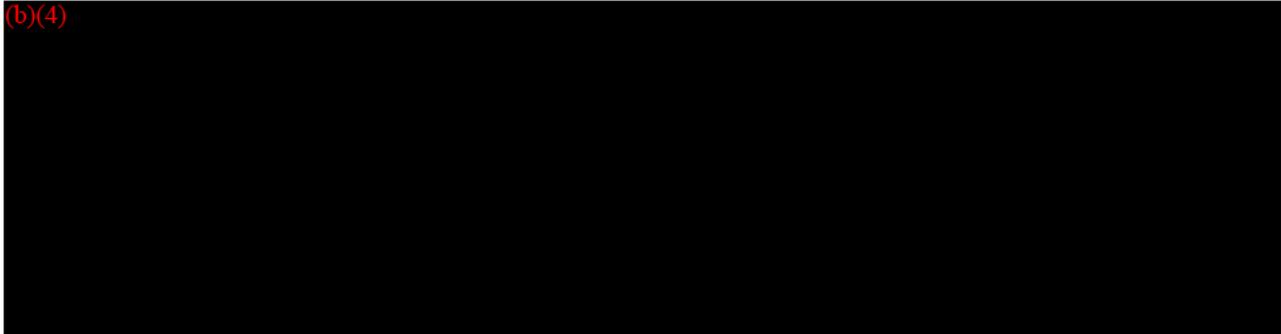
With regard to the comb probe, and as discussed in our April 7 meeting, the comb probe consists of electrodes arranged in a concentric pattern similar to the integrated electrodes on the main unit of the InterX5000. The "outside" electrodes are one polarity, and the "inside" circle of electrodes has the other polarity. This design prevents the user from inadvertently making contact with only two tines of opposing polarity. As such, testing a single pair of electrodes on the comb probe would not be practical or provide useful data for evaluating this device.

Our firm believes that it has provided appropriate current density data that best represents the actual use conditions of the device. We would caution that providing other data as requested would be misleading in this context, particularly when there appears to be continued misunderstanding of how the device operates. We maintain that the current density data provided earlier is a more accurate description of the device under actual use conditions. Furthermore, as described earlier, this device has a history of use for many years in various countries including Russia, Europe, and Asia (including use by lay persons). Our review of available literature regarding this technology, as well as the clinical history of our own medical staff (with over 7 years of experienced clinical use of this device) has revealed no known incidents of adverse events relating to this device (including use of this device by lay persons).

We believe that further discussion by telephone may be necessary between our firm and CDRH to ensure a proper understanding of the operation of our device, and the appropriateness of the current density data provided.

3. Indications: (b)(4)

(b)(4)

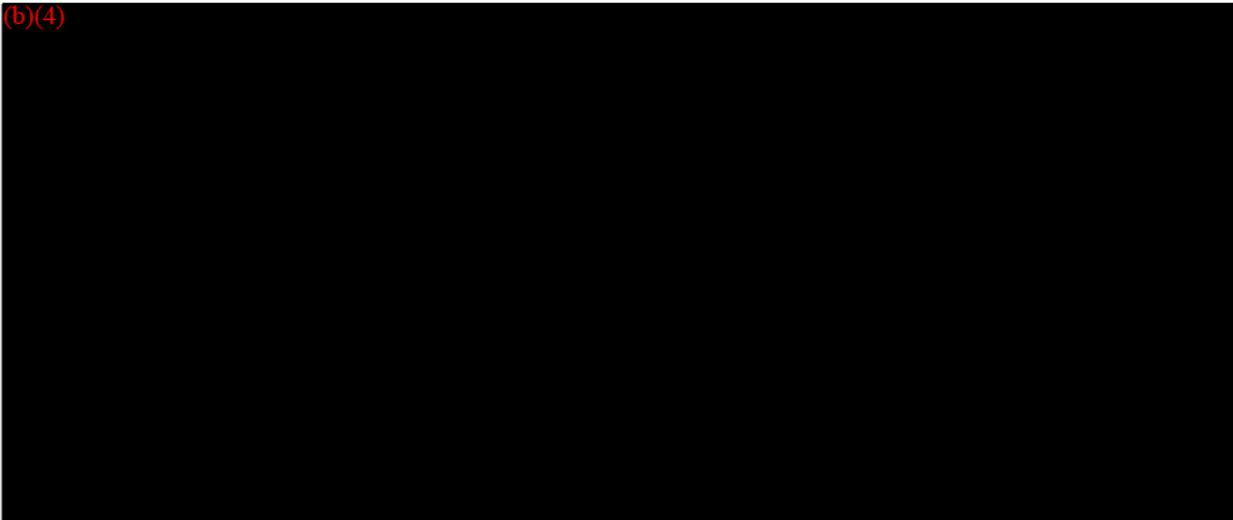


4. TENS-type Claims/labeling: (b)(4)



Your labeling continues to include many statements that have not been supported. Please either remove them or provide valid scientific evidence to support each. Examples:

(b)(4)



Our firm is surprised that there continues to be a misunderstanding of our device, despite what we believed were important clarifications achieved during our April 7 meeting.

Our firm has not introduced any “new intended uses” with this device, and is concerned about the continued reference to “new intended uses”. Specifically, as compared to its predicate devices, our device is similar in its labeling with regard to physiological purpose, conditions or diseases to be treated, type of user, parts of the body involved, frequency of use, indications, contraindications, cautions, and warnings. With the exception of the added EMS claims, which have been addressed in #3 above, our labeling contains all appropriate statements prescribed in FDA’s guidance document for TENS devices.

The differences between our device and the described technology in our predicate devices are the discussion of interactivity and the use of DIAG and DOSE features to provide optional information that may assist the user in determining location and treatment length. The DIAG and DOSE features as described in our labeling represent instructions for use, not new claims or intended uses.

With regard to DOSE and DIAG, our firm maintains that these informational features are based on established principles described by predicate devices. As discussed in our meeting, and as provided in the additional information submitted by our firm in February, established predicate device labeling describes the recommended means for determination of treatment location and treatment length based on certain observed feedback cues (including visual or tactical signs of tissue reaction indicating impedance levels). The predicate device labeling describes various theories of operation and acknowledges patient variability and trial-and-error approaches needed for effective use. We attempted to explain in our meeting that our device simply displays relative impedance information in the DOSE and DIAG displays that may be (optionally) used by the practitioner to accomplish the same objectives described by the predicate device. In the labeling revisions submitted by our firm on April 13, our firm was careful to include statements that these readings provide impedance information, and that the recommended protocol is not intended as a substitute for the practitioner's own evaluation and judgment relative to individual patient placement and length of treatment.

DIAG mode function

DIAG does not in and of itself determine treatment location. DIAG mode displays a relative measure of impedance, (acknowledged as acceptable to CDRH), which information may be used as an input to help in determining "treatment location by the user". In summary, DIAG is simply an optional feature that provides information to the user, and does not perform any diagnostic function, nor does it represent a new claim or intended use.

DOSE mode function

The DOSE function does not in and of itself determine treatment duration. DOSE mode displays a relative measure of the changes in skin impedance, and signals to the operator that the first aspect of the treatment has been successfully completed. This information may be used as an input to help the user determine length of treatment in any single treated location (not the overall treatment duration for the patient). In summary, DOSE is simply an optional feature that provides information to the user, and does not represent a new claim or intended use.

Interactive definition

As repeatedly explained throughout our discussions with CDRH, the output of our product changes with skin impedance although it is not active feedback; it is feedback by way of circuit design. The InterX 5000 responds to changes to skin impedance on an instantaneous basis providing an "interactive response to skin impedance changes".

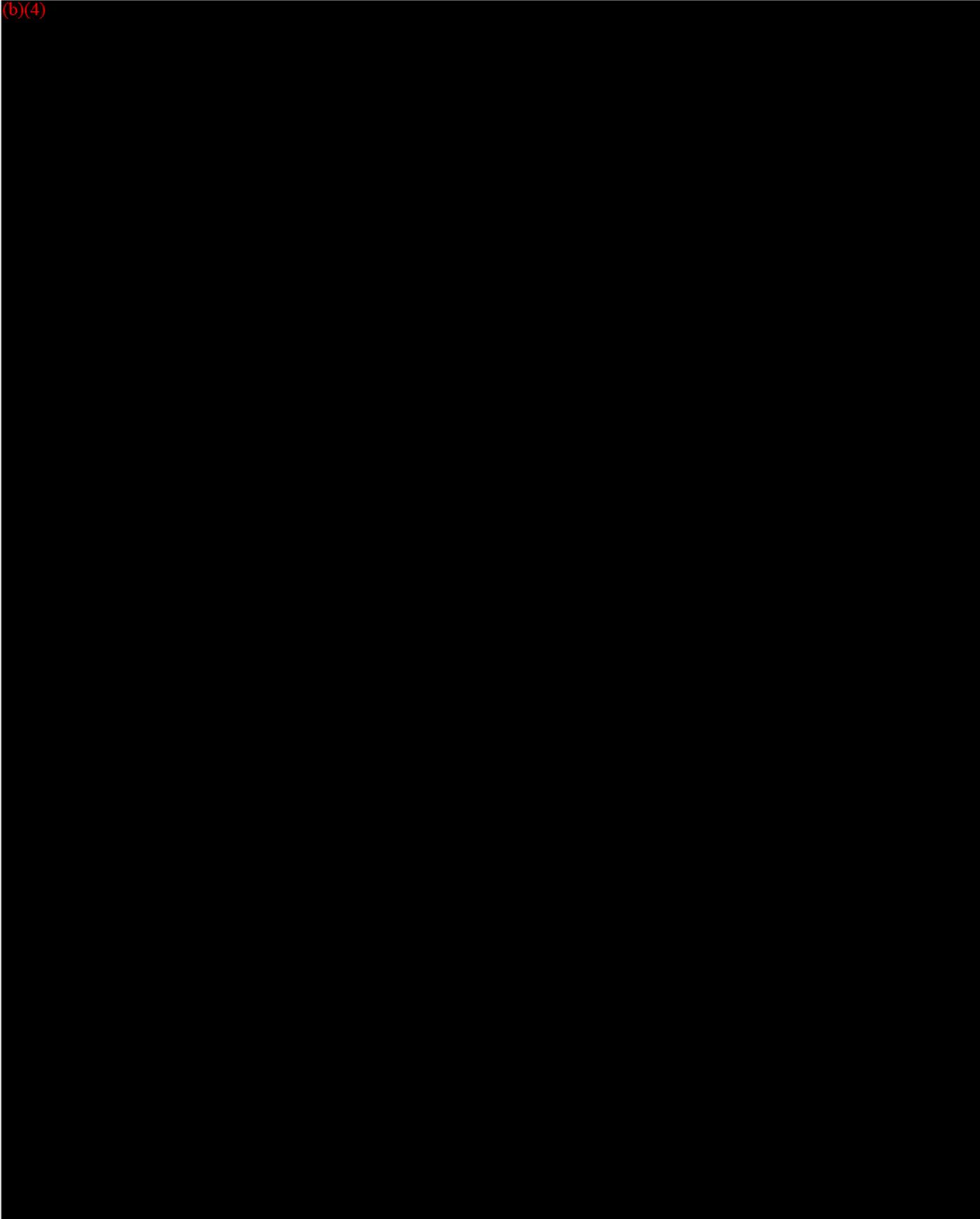
Based on our understanding of the April 7 meeting, our firm submitted labeling changes that we believe are consistent with the supported claims of our device. It is our understanding that CDRH only evaluates claims and intended use/indications for use, and does not "approve" labeling (including instructions for use) in the context of a 510(k) premarket notification. Nevertheless, our firm will change its labeling further to address each of the cited areas of concern as follows:

K042912 Additional Information

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Page 6 of 7

(b)(4)



K042912 Additional Information

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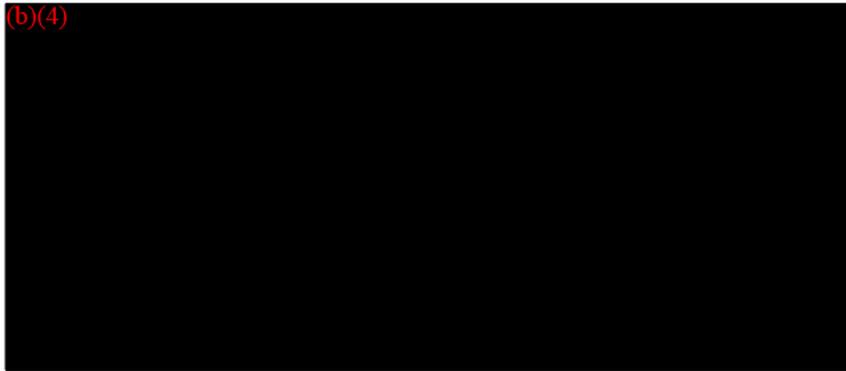
(b)(4)



Sincerely,

Krista Oakes
Vice President, Regulatory Affairs

Electrode
Dimensions in mm



TENS Comparison Chart

	<u>Fenzian Treatment System</u>	<u>Fenzian Treatment System</u>	<u>EMPI Focus 795</u>	<u>Guidance and KAB</u>	<u>ANSI/AAMI NS4 1985</u>
510(k)	K041575	K033932 (original NSE)	K951951		
Output Channels	1, alternating	1, alternating	2, simultaneous		
Regulated Voltage	Yes	Yes	yes		
Waveform	Biphasic	Biphasic	Symmetrical biphasic		
Wave shape	AC spike				
Maximum Output Voltages	88V @500 Ω 306V @2 kΩ 650 V @10 kΩ	30V @500 Ω 83V @2 kΩ 112 V @10 kΩ	± 100 V @ 1 kΩ		
Maximum Output Current mA	46 mA @500 Ω	0.019 mA 0.027 mA @2 kΩ 0.032 mA @10 kΩ	0 to 60 mA (normal) 0 to 100 mA (high)	>30 mA @500 Ω	>500 μA < 10 mA
Pulse Width	498 μsec	24 μsec	300 μsec		
Frequency	15 – 350 Hz	15 – 350 Hz	25 to 80 Hz	20 to 50 Hz**	
Net Charge***	1.16 μC @ 500 Ω	*	30 μC		
Max. Phase Charge***	10.6 μC @ 500 Ω	*	40 μC @ 500 Ω	6 - 14 μC for biphasic	≥7μC @ 500 Ω <75μC @ 500 Ω
Max. Current Density @ 500 Ω	27.7 mA/cm ²	0.02 mA/cm ²	3.11 mA/cm ²	> 1mA/cm ²	
Max Power Density @ 500 Ω	0.177 W/ cm ²	0.094 W/ cm ²	0.187 W/ cm ²	<0.25 W/ cm ²	
Burst Mode					
Pulses per burst	1 to 8	1 to 8			
Bursts per second	15 to 2800	15 to 2800			
Burst duration	1 to 5 seconds	1 to 5 seconds		>1 second	
Time on	1 to 5 seconds	1 to 5 seconds	2.5 to 50 seconds	≥1 second	
Off Time	1 second	1 second	0 to 50 seconds	≥1 second	
Max delivered current	<7.0 mA	<7.0 mA	<10 mA		

*Although in the original NSE submission the sponsor calculated the Charge per phase to be between 10 and 20 μC, the maximum current and pulse width do not support this range.

**(>100 Hz -> muscle fatigue)

*** Net charge is calculated by (average positive current x pulse width – average negative current x pulse width)
Maximum charge per phase is calculated average positive current x pulse

$$Q_{net} = I(\text{positive} - \text{negative})dt = 0.0212 \text{ Amp} * 498 \mu\text{sec} - 0.0125 \text{ Amp} * 758 \mu\text{sec} = 1.16 \mu\text{C}$$

$$Q_{max \text{ phase}} = I dt = 0.0212 \text{ Amp} * 498 \mu\text{sec} = 10.6 \mu\text{C}$$

k041575 fenzian treatment system tens (second attempt) 7/12/04

15

2/4

45

510 K PRIMARY REVIEW MEMORANDUM

DEVICE NAME:..... **INTERX 5000**
COMMON NAME:..... **TRANSCUTANEOUS ELECTRICAL NERVE**
STIMULATOR
CONTACT..... **KRISTA OAKES**
APPLICANT:..... **NEURO RESOURCE GROUP, INC.**
PHONE/ FAX:..... **(972)-438-5202 / (972)-401-9161**

UPDATE RESPONSES OF Feb 16, 2005 and Feb. 17 2005

Note: In our meeting of March 2, 2005 FDA management agreed that the period of response would be "approximately 60 days". I was told yesterday (4/5/2005) that FDA management was meeting with the company on April 6, 2005 and that I should complete my memorandum by April 7, 2005 am. I was also told that the management involved already had a pre-meeting regarding this meeting; however, I was not informed of the management's objectives regarding the 4/7 meeting with the sponsor. I was not invited to attend this meeting. It took me several weeks to order files from the microfiche archives. Based on my current work-flow, I need more time to finish my review. I also need policy clarifications from the management as indicated below in the "recommendations" rubric before I can make a final recommendation

- Q1. I explained why we needed a new predicate for the feedback function of the Sponsor's device.**
- a) I asked the Sponsor to describe the feedback mechanism fully**
 - b) I asked the sponsor to provide a suitable predicate.**
 - c) I asked the sponsor to provide supporting clinical data**
 - d) I asked the sponsor to support claims made in the software documentation provided**

- A. The sponsor has provided an argument as to why the EMPI focus is a valid predicate. In fact, the sponsor has been repeatedly advised on the telephone and in the letter that the EMMPI Focus is a valid predicate, but that the differences between their device and the EMPI focus (no use of electrode gel, different electrical characteristics, different electrode configuration, different expected skin impedance levels, different instructions for use) are such that a higher level of evidence is needed to fill in the gaps between their device and the EMPI focus than a more similar device. The FENZIAN system is electrically more similar to their device and is a closer predicate, because it uses a similar electrode configuration and does not use electrolytic gel. It is further noted that the electrical characteristic curves provided for the INTERX 5000 demonstrate load currents of 0.2- 1.2 mAmps. This is characteristic microcurrent device. This also contradicts their comparative table which recites a maximum output current of 80 mA. The EMPI focus uses conductive

gel, and as thus is expected to deliver the reported 40-100 mA needed for pain relief during normal use.

I am further confused by the inherent contradiction in the sponsor's argument that the EMPI focus is the closest predicate, when in fact they have stated elsewhere that their impedance feedback function is closest to the ELECTRO ACCUSCOPE (K883911). It has become apparent on the telephone that the sponsor wishes to piece together electrical characteristics of different devices in order to arrive at a "predicate". While we routinely use multiple devices as predicates for different functions of a device, these predicates are disparate enough that electrical characteristics cannot be combined in a piecemeal manner. The sponsor should decide which predicate they are relying on as the closest predicate, should provide a comparative chart for that predicate is complete, and should explain how their device is substantially equivalent. They should compare their output waveforms to the outputs of the predicate for which they are relying. If relying on a different predicate for the attachments, the sponsor should show that the electrical characteristics of those attachments are equivalent.

Currently, I have been provided with a comparative chart which compares this device to the FENZIAN SYSTEM, the EMPI FOCUS, and the BIONICARE BIO-1000. The INTERX 5000 is significantly different from the EMPI FOCUS because the EMPI focus uses traditional large area electrodes with electrolytic gel. The EMPI Focus (b)(4) (b)(4) This has been a point of contention between the reviewer and the office, since it is inconsistent. The sponsor should explain this discrepancy and update the comparative chart accordingly.

The sponsor has claimed that I stated that the use of impedance feedback is "unprecedented". In fact, I explained that there was no precedent of record for the sponsor's particular feedback function. The sponsor has supplied a supporting article (Lennox et al.) for the use of impedance feedback with microcurrent therapy in treating fibrosis in head and neck cancer patients. This article is irrelevant to the sponsor's 510(k) since we have no TENS device cleared for treating fibrosis for head and neck cancer patients. This would require a new 510(k) with supporting clinical data.

The sponsor argues that constant current TENS devices are impedance feedback functions. Constant current sources are ubiquitous both in the TENS community and in other applications and are not generally considered feedback functions to my knowledge. Sponsor has specific claims related to the concept that their device senses changes in feedback and adjusts output accordingly. In fact, the sponsor has added a resonating circuit to their device which has a characteristic frequency (1-10kHz) which will depend on the impedance of the electrodes. This is discussed in further detail below.

Although it is poorly explained in the sponsor's response, I have been able to piece together from our telephone conversations and considering the sponsor's response

that they appear to refer to two types of "feedback". One type of feedback is a change in oscillation frequency between 1-10 ohms when applied to the patient's skin. Note that predicate tens clearances provided do not describe ANY resonant oscillation frequency. This means that the waveform is different in the INTERX 5000 than the predicates with respect to pulse shape. Furthermore, the sponsor describes this as a "constant energy" source. From this description I understand that the pulse keeps on oscillating until a predetermined amount of energy has been delivered.

The second type of feedback appears to be in the display of two numbers related to impedance seen by the electrodes. One variable displayed is related to initial impedance (units unknown), and the second is related to "ongoing impedance". Based on this ratio, the clinician is instructed to change the treatment time:

$X=Y$ "body needs more treatment in that area"

$X>Y$ "low dynamic change and body needs attention"

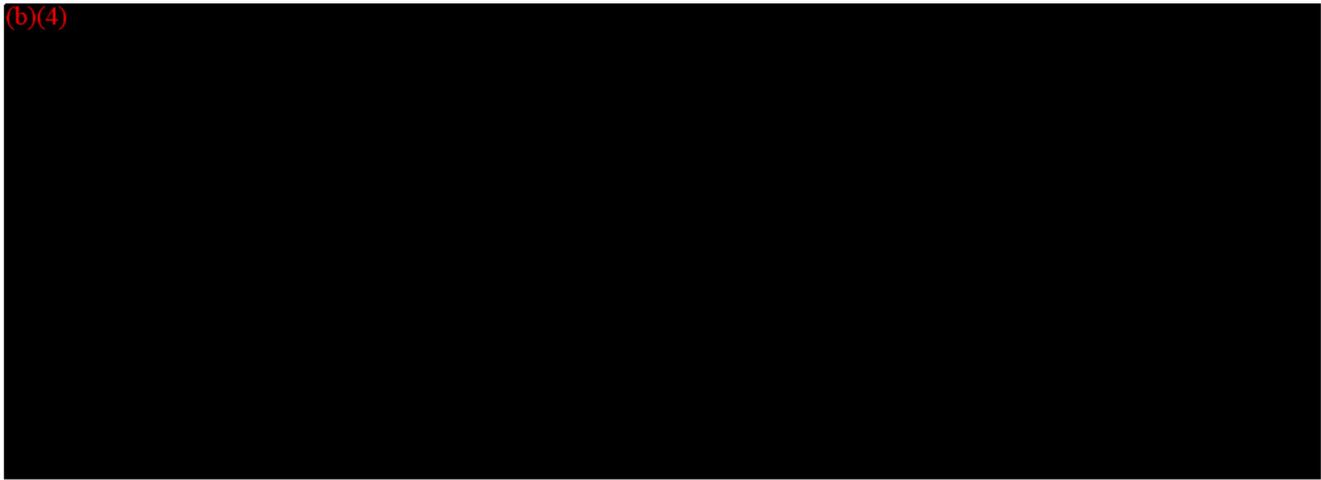
$X<Y$ "dynamic change and body has satisfactory response"

From this limited description it is clear that the clinician is instructed to deliver sufficient microcurrent therapy to cause a change in skin impedance. I am unaware of a TENS device that functions in this respect. The closest predicate of record appears to be K883911 which appears to have an alarm sound when a preset skin resistance is reached.

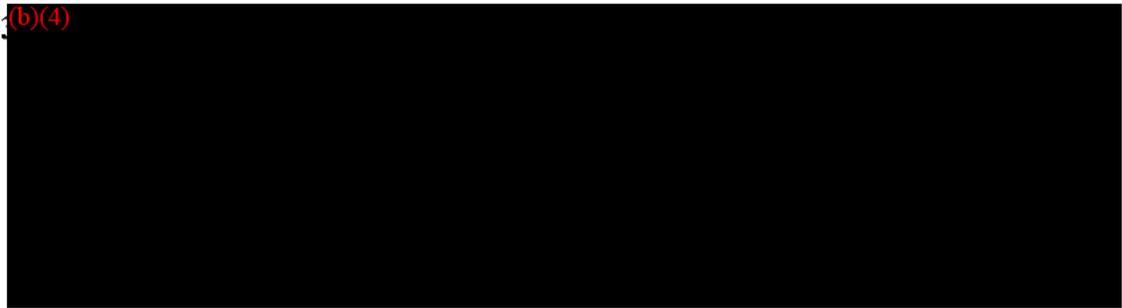
2) (b)(4)



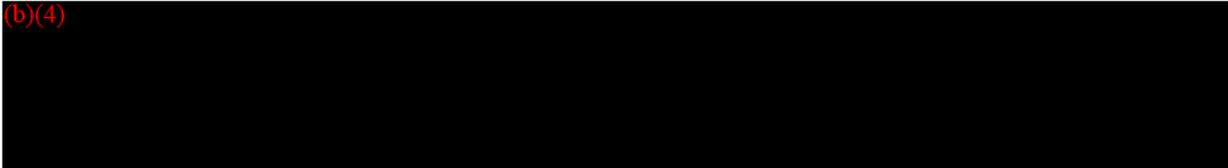
(b)(4)



(b)(4)

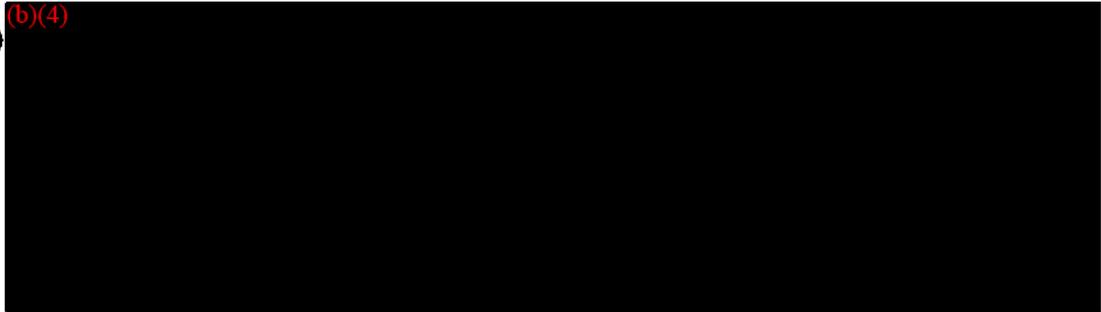


(b)(4)



4)

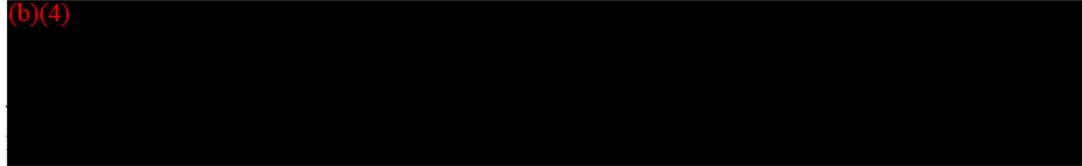
(b)(4)



Sponsor argues that this information was not requested in the predicate. The refusal of the sponsor to address this issue is inadequate for me to make a finding of substantial equivalence of this device.

5)

(b)(4)



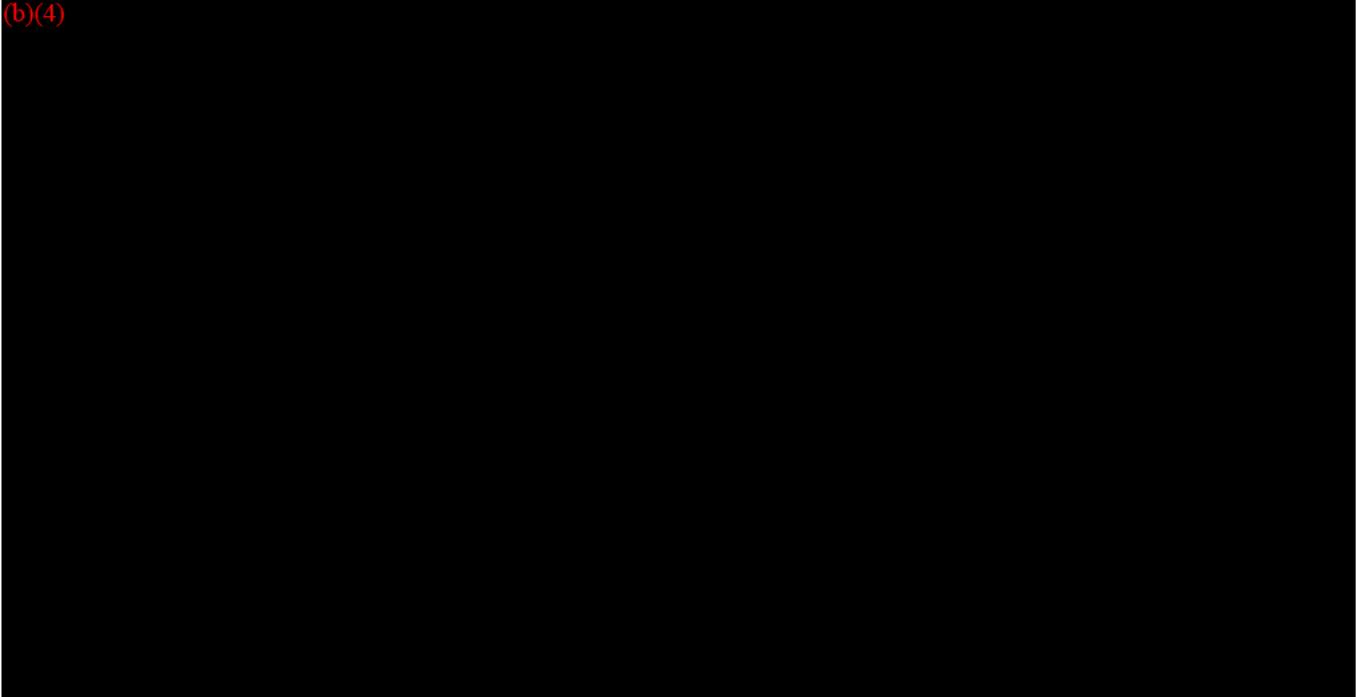
Sponsor has provided the number of K883911 which has a point probe and a ball probe. Sponsor has not provided a predicate for the comb electrode. Because a comparative chart has not been provided regarding the electrical output of K883911, I do not know if the accessories are used with similar output in the and in the same way. Sponsor should provide an actual comparative chart to K883911 with similar information to that asked for the other predicates. Sponsor should demonstrated that the probe outputs are the same and used in the same way.

Sponsor should be requested to provide more specific instructions for use regarding the comb electrode and provide clinical data supporting the use for pain relief. The comb electrode is designed to be used on the head, and TENS devices are contraindicated for trans-cerebral use. The sponsor's argument has been that the micro currents remain superficial. Absent clinical data, I do not have access to the animal/ clinical/ or bench-top data supporting this assertion. Sponsor should provide data (bench-top animal or clinical) demonstrating that the currents remain superficial to the head.

6) **As suggested in FDA'S TENS guidance (<http://www.fda.gov/cdrh/ode/300.html>), please address your integrated electrode specifications in a side-by-side comparison with a predicate device. This comparison should include a complete characterization of the geometrical properties of the electrodes, as well as evidence of material biocompatibility. This comparison should specifically address how changes to electrode shape would affect safety and/or effectiveness of your device relative to the predicate used.**

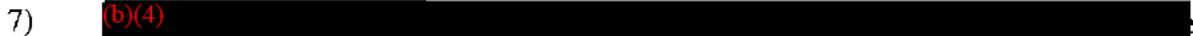
The sponsor has not compared the geometrical properties of their electrodes to the predicate in a scientific manner. I do not see how Sponsor has answered the question. Their response contains assertions of equivalence, but not diagrams and pictures in support of their assertions. Sponsor should provide an answer to this question which does not avoid the request for information.

(b)(4)



7)

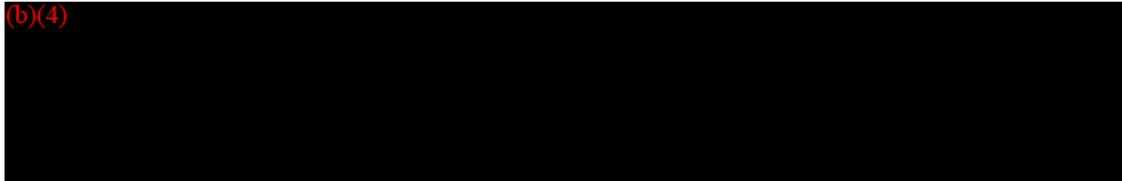
(b)(4)




Sponsor stated that they passed IEC 60601-1 and 60601-1-2 without deviations. I have no further questions.

8)

(b)(4)



Sponsor states that the electrode would perform like the ACCU probe if only an inner and outer tine were in contact with the skin. The sponsor has not performed the analysis as requested. The predicate tens electrodes were generally contraindicated for trans-cerebral use. The sponsor should update the charts provided as specified above.

There is a point that I do not understand. The sponsor has referred in their electrical report to the ACCU probe. It is unknown if this is the main electrode. The electrical data requested by the telephone was principally requested for the main electrode and comb accessory.

The probe accessory has been identified by several names such as "pencil" probe and "point-type" probe". If the ACCU probe is an accessory, the electrical information previously requested should be submitted for the regular electrode.

(b)(4)



The sponsor's response should be supported by bench top or clinical data. The sponsor stated merely that current rests on the surface of the head.

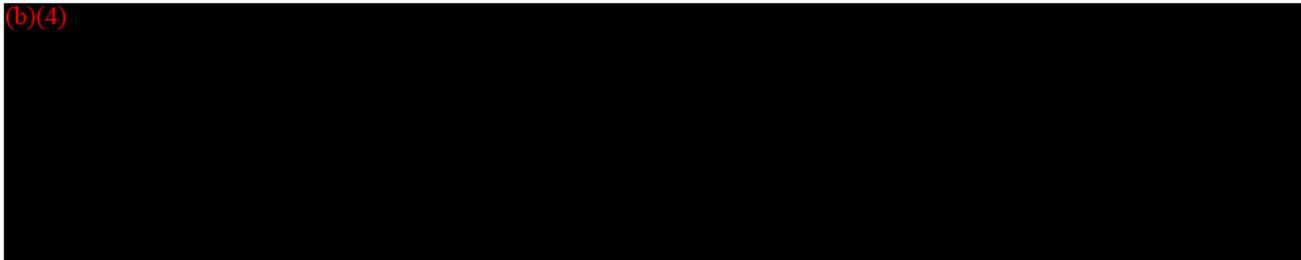
10)

(b)(4)

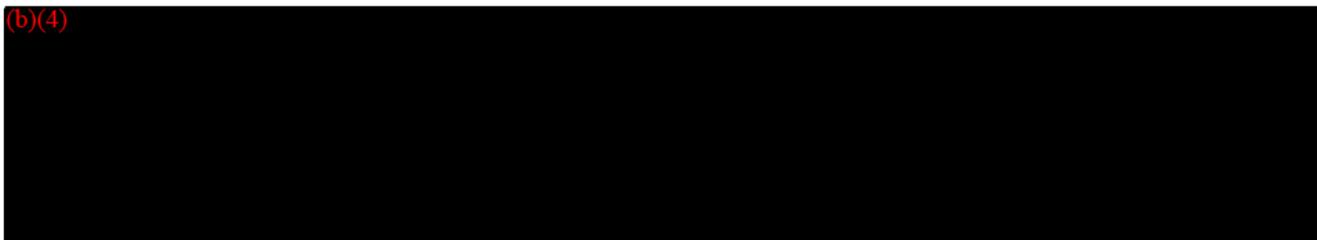


Sponsor states that they have all of the warnings, precautions etc. contained in the Guidance Documents referenced.

(b)(4)



(b)(4)



- 12) **We are concerned that the labeling you have provided for the predicate Fenzian system is from their European site. Although this labeling is accessible via the Internet, the European labeling is not regulated by the FDA, and is therefore not cleared labeling for the FENZIAN system in the United States. Please be aware that the FENZIAN system can only be used as a predicate based on the device description and labeling that they have provided to the FDA.**

Sponsor is aware that they have supplied labeling for the unapproved device.

13) (b)(4) [Redacted]

(b)(4) [Redacted]

14) **We were unable to locate an architectural design chart and hazard analysis for the software. Please provide these documents, or please indicate where they have been previously provided.**

The Sponsor has provided this information.

RECOMMENDATION

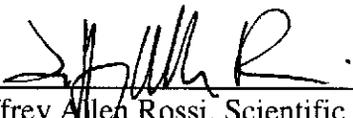
(b)(4) [Redacted]

Furthermore, we do not have a predicate for the comb electrode. Predicate TENS devices are consistently contraindicated for trans-cerebral use. There is only a "theory" regarding why charges would remain superficial in this instance. This should be supported by data.

If the office's policy is not to require a demonstration of effectiveness to find microcurrent devices substantially equivalent, then this device could be relabeled as a TENS device by removing the DIAG and ZERO functions and any reference thereto, and have the company positively assert that they will not advertise the product as effective for the proposed TENS indications. Otherwise, sponsor should provide clinical data supporting the DOSE and ZERO functions. Sponsor should further provide clinical data for the comb electrode regardless of the office policy regarding these devices. Finally, all of the items discussed above in my narrative report should be provided regardless of the office's policy as described above.

I am requesting a written decision regarding the offices policy on these devices in order to make a firm recommendation.

Finally, I am concerned about the off-label use of this device, since it appears to be designed for something other than TENS indications. Note that the article provided in support of this device recites microcurrent therapy for treatment of fibrosis in head and neck cancer patients. I am concerned that this device will be used in lieu of more proven therapies for off-label indications. This has not been a consideration in determining substantial equivalence to TENS devices, but it may explain why I am having so much difficulty putting the sponsor's responses into the TENS paradigm (*i.e.*, perhaps the DOSE and ZERO functions are not designed for TENS indications).


 Jeffrey Allen Rossi, Scientific Reviewer 4/6/2005
 General Surgical Devices Branch Date

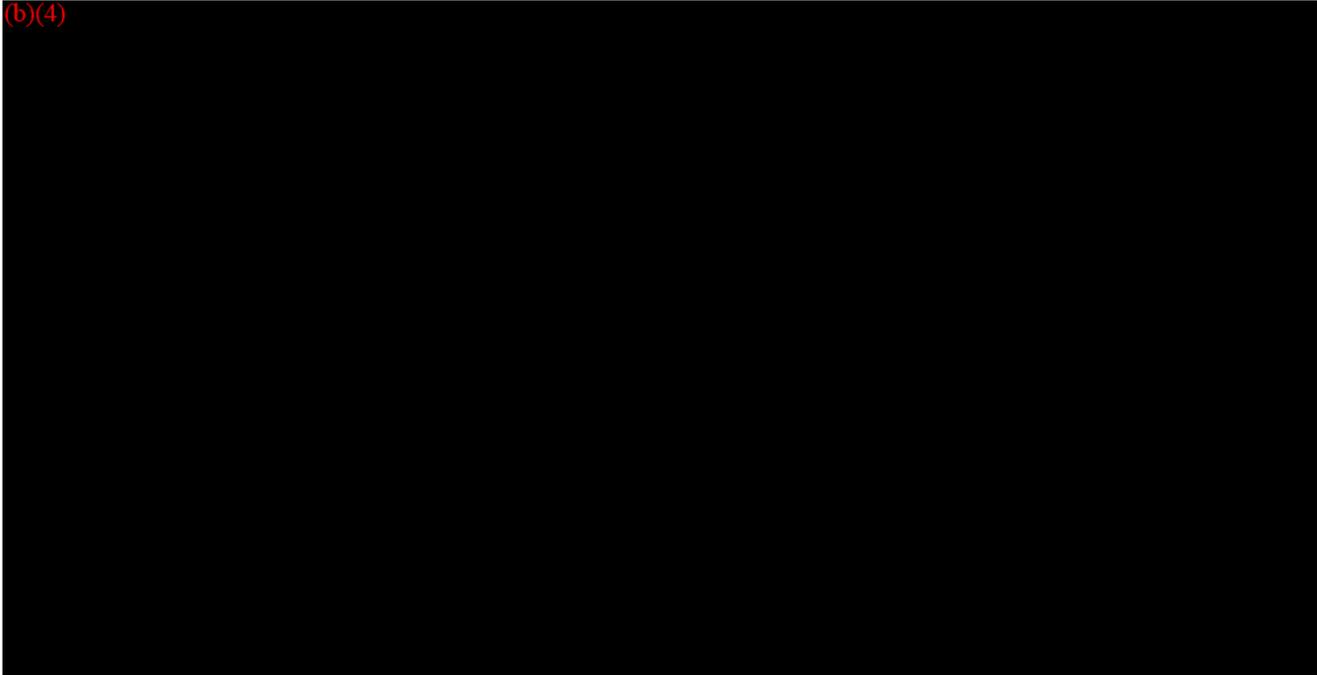
 Ted Stevens Date
 Chief, Restorative Devices Branch/ Concur

DEVICE DESCRIPTION

The INTERX5000 is an electrical impulse generator intended for superficial use which is claimed equivalent to a Transcutaneous Electrical Nerve Stimulator (TENS) and Electro-muscular Stimulator (EMS). The device is a battery-operated unibody design, with integrated

electrodes, which weighs 6 oz. The device is designed to be held in contact with a treatment site, and the length of time needed for treatment is said to vary between a few seconds and over 10 minutes. The device is intended to be used with **no electrolytic gel**, as the **concentric electrodes** would short out in the presence of conductive gel. Skin must be dry according to the instructions for use.

(b)(4)



INDICATIONS FOR USE

See comparative chart, below for the actual indications for use as listed in the IFU statement. These are TENS/ EMS indications for use which have been associated with multitudinous FDA cleared TENS/ EMS devices.

Although the indications for use recite TENS and EMS indications, the software documentation describes a basic treatment mode for use in the following ways, which suggest indications beyond traditional EMS/ TENS cleared indications.

- a. In the presence of clearly defined local symptoms (?)
- b. For achieving functional changes in organs/ systems (?)
- c. When large surfaces are being treated
- d. To localize symptoms (?)
- e. To save time when looking for asymmetry (?)
- f. To avoid a healing crisis (?)

¹ In the strictest sense, biofeedback processes are usually associated with a user making an effort through voluntary control of a body function. It could be debated whether this is a biofeedback device *per se* depending on the definition used for "biofeedback device". 21 CFR 882.5050 defines a biofeedback device as "an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters."

² I use the Sponsor's wording of impedance (resistance plus capacitance) to be consistent with the device specification, even though it appears that only skin resistance is actually measured

g. To optimize the action time (?)

These additional indications are not clearly explained by the Sponsor in the documentation provided to the office.

PREDICATE COMPARISON

The device cites several predicates, the most relevant of which is the FENZIAN SYSTEM (K951951), which is also a hand-held electrical stimulator with integral concentric electrodes intended to be used **without electrolytic gel**. The FENZINAN system 510(k) describes an impedance measurement, but does not describe a feedback mechanism by which output is modulated (either automatically or by user intervention) to the feedback.

The EMPI FOCUS 795 (K951951) and the BIONICARE BIO-1000, cited by the Applicant in the technical description, are both designed to be used with **large surface electrodes** and **electrolytic gel**, and therefore are not a valid comparison (for reasons set in further detail below).

TABLE 1: Comparison of the INTERX-5000 with the predicate FENZIAN treatment system

Parameter	InterX 5000	Fenzian Treatment System (K041975)	Comments
Indications for Use	Symptomatic relief of chronic, intractable pain Adjunctive treatment in the management of post-traumatic and post surgical pain Relaxing muscle spasms Increasing local blood circulation Immediate post surgical stimulation of calf muscles to prevent venous thrombosis Muscle reeducation Maintaining or increasing ROM Preventing or retarding disuse atrophy	Symptomatic relief of chronic, intractable pain Adjunctive treatment in the management of post-traumatic and post surgical pain	<i>EMS indications not supported by a valid predicate. Sponsor should provide clinical data to support the EMS indications, in addition to further data supporting the TENS indications as described below</i>
Waveform	Asymmetrical biphasic near balanced the first phase is a pulse wave with a decay, the second phase is a truncated impulse function, while the predicate is an impulse function in the second phase	Similar—visual inspection of 510(k) showed that the wave has the same general shape, a square wave with a decay followed by an impulse)	
Electrodes	Integrated stainless steel for use without conductive gel	Integrated stainless steel for use without conductive gel	
Max Output Voltage (V)	40@500 ohms 175@ 2 k ohms 450@ 10k ohms	88@500 ohms 306@ 2 k ohms 650@ 10k ohms	
Maximum Output	80@500 ohms 87.5@ 2 k ohms	46@500 ohms 16.8@ 2 k ohms	<i>Maximum output current for the predicate does not</i>

Current (mA)	(b)(4)	8.0@ 10k ohms	<i>make sense. The maximum voltage is higher in the Fenzian system, but the maximum current is reported lower. This violates ohms law. (V=IR)</i>
Pulse width (μ s)	(b)(4)	498	<i>Treatment effect of variable pulse width is unknown</i>
Frequency (Hz)	(b)(4)	15-350	
Net Charge (μ C)	(b)(4)	1.16	
Maximum Charge per Phase (μ C)	(b)(4)	10.6	<i>Maximum charge per phase is higher, but the waveform is similar and the voltage is reported lower—needs explanation</i>
Max Current Density (mA/cm ²)	(b)(4)	27.7	
Average Power Density (W/cm ²)	(b)(4)	0.177	
Burst Mode Pulses/ burst Bursts/ sec Burst Duration	(b)(4)	1-8 15-2800 1-5 s	<i>It is unknown how you can have 15-2800 bursts per second with a duration of 1-5 seconds. This seems electrically impossible</i>
Max delivered current (mA)	(b)(4)	<7.0	<i>Maximum delivered current appears to be an instantaneous current compared to an average current. This is an invalid comparison</i>
Range Impedance Load (ohms)	(b)(4)	500-1000	<i>This is not understood as to what this value represents. Both devices drop off substantially after 2 k ohms</i>
Max Charge/ pulse (μ C)	(b)(4)	37.5 @500 ohms	

COMMENTS

I have seen no scientific data in this 510(k) or predicate 510(k)'s of record suggesting that the electrode configuration used would be effective for TENS treatment. Specifically

- ◇ The absence of electrolytic gel would seem to create impedance values that would result in little or no current being delivered;
- ◇ The electrode configuration would not seem to allow either adequate spacing or surface area to provide an electrical pathway capable of affecting nerves (TENS) or capable of muscle contraction (EMS);
- ◇ The integration of the electrode into the unibody design would make it impractical to maintain consistent force on the site, thus further diminishing effectiveness.

Therefore, I do not see any scientific evidence for believing that this device could be effective as a TENS device according to traditional modes of operation.

The predicate FENZIAN system was cleared as a TENS device, and **does not use electrolytic gel**. The FENZIAN system (K041575) was also compared to the EMPI FOCUS K951951 cited in this 510(k). The 510(k) review memorandum for the FENZIAN system makes no mention of how the performance of the FENZIAN system was assessed clinically with respect to the 1) unibody design, 2) electrode configuration, or 3) lack of conductive gel. Clinical data was not requested nor provided for the FENZIAN system. The concern is that with such a configuration, without electrolytic gel and without clinical data to review, it is not understood how the FENZIAN was established substantially equivalent under 21 CFR 807.100 for TENS treatment to devices that use gel and traditional adhesive electrodes. Therefore, this makes a technical comparison of the differences between the INTERX5000 and the FENZIAN SYSTEM difficult, since it is unknown which range of technical parameters should be presumed effective, and how changing those parameters would affect the device effectiveness.

Despite apparent problems with assessing the relative safety and effectiveness to the predicate device, there remain significant differences between the INTERX5000 and the FENZIAN system. The predicate FENZIAN SYSTEM did not employ an impedance feedback system. Sponsor seems to confirm this by stating “the INTERX 50000 is **unique** in the way it is designed to continuously modify its output as it senses changes in tissue properties. In comparison to other types of currently available electro-stimulation devices, the INTERX5000 is **unique** in the way that it works interactively with the body, by modifying its signal in response to the changing impedance of the tissue in contact with its electrodes”—page 6 of Sponsors submission.

The fundamental differences between the FENZIAN system and the INTERX5000 are as noted above in the comments section of **TABLE 1**, and the lack of a predicate description of an impedance feedback mechanism. The INTERX5000 also includes several electrode attachments (ball electrodes, comb electrode, and probe) which seem unsuited for TENS treatment because they have a small surface area and no electrolytic gel, and for which no scientific basis in the predicate or in literature has been provided. The instructions for use describe a treatment dose function which senses impedance and indicates treatment is complete based on the impedance detection function in the device description above. Sponsor states that the time required for treatment with the INTERX5000 may vary from a few seconds to over 10 minutes. This is not the treatment time associated with traditional TENS treatments, which typically last from 20-40 minutes.

For reasons described above, there is a lack of predicate for this device, and a lack of clinical data which demonstrates the differences between this device and the closest predicate cited (FENZAN SYSTEM K041975).

Q2. We believe the closest predicate you have cited is the FENZIAN SYSTEM (K041575). The other predicates cited, the EMPI FOCUS

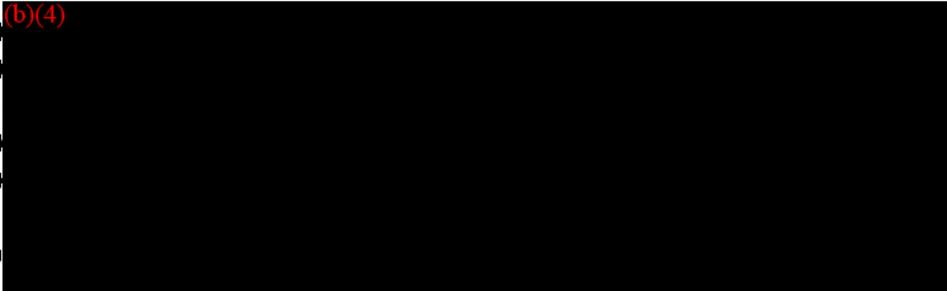
K951951, and the BIONICARE BIO-1000 (K971437) employ a significantly different electrode configuration and employ electrolytic gel, such that a technical comparison between your device and these devices without supporting clinical data could not show equivalence. Despite similarities between the INTERX5000 and the FENZIAN system, none of the predicates you used in your comparison employ a feedback mechanism (impedance) to modify the device output (with or without user intervention), and no predicate has been provided for the “dose” function of your device. Please provide the following to justify the effectiveness of your design for TENS/ EMS indications:

- 10) Please describe the impedance feedback mechanism fully [including the transfer function which relates impedance (input) to amplitude (output)]. Specifically, please explain in detail what is meant by “the INTERX 50000 is unique in the way it is designed to continuously modify its output as it senses changes in tissue properties... [by working] interactively with the body... modifying its signal in response to the changing impedance of the tissue in contact with its electrodes”—page 6 and “The device emits a damped, biphasic small electrical pulse which changes damping shape and amplitude as it encounters changes in tissue impedance”—description page 7; and
- 11) please provide a suitable predicate with an impedance feedback function used in the same manner as your device, including the described method of locating the treatment site and “dose” function or
- 12) please provide clinical data which supports use of your device for all of the TENS/ EMS indications sought specifically using the impedance feedback as instructed, including the method employed of locating the treatment site and “Dose” function.

The clinical data and/ or predicate cited as outlined above should *explicitly* address the intended uses listed in your labeling (labeling includes any descriptive material provided to the office). Specifically, it should address the following indications listed in your software review:

- a)
- b)
- c)
- d)
- e)
- f)
- g)

(b)(4)



Q3.

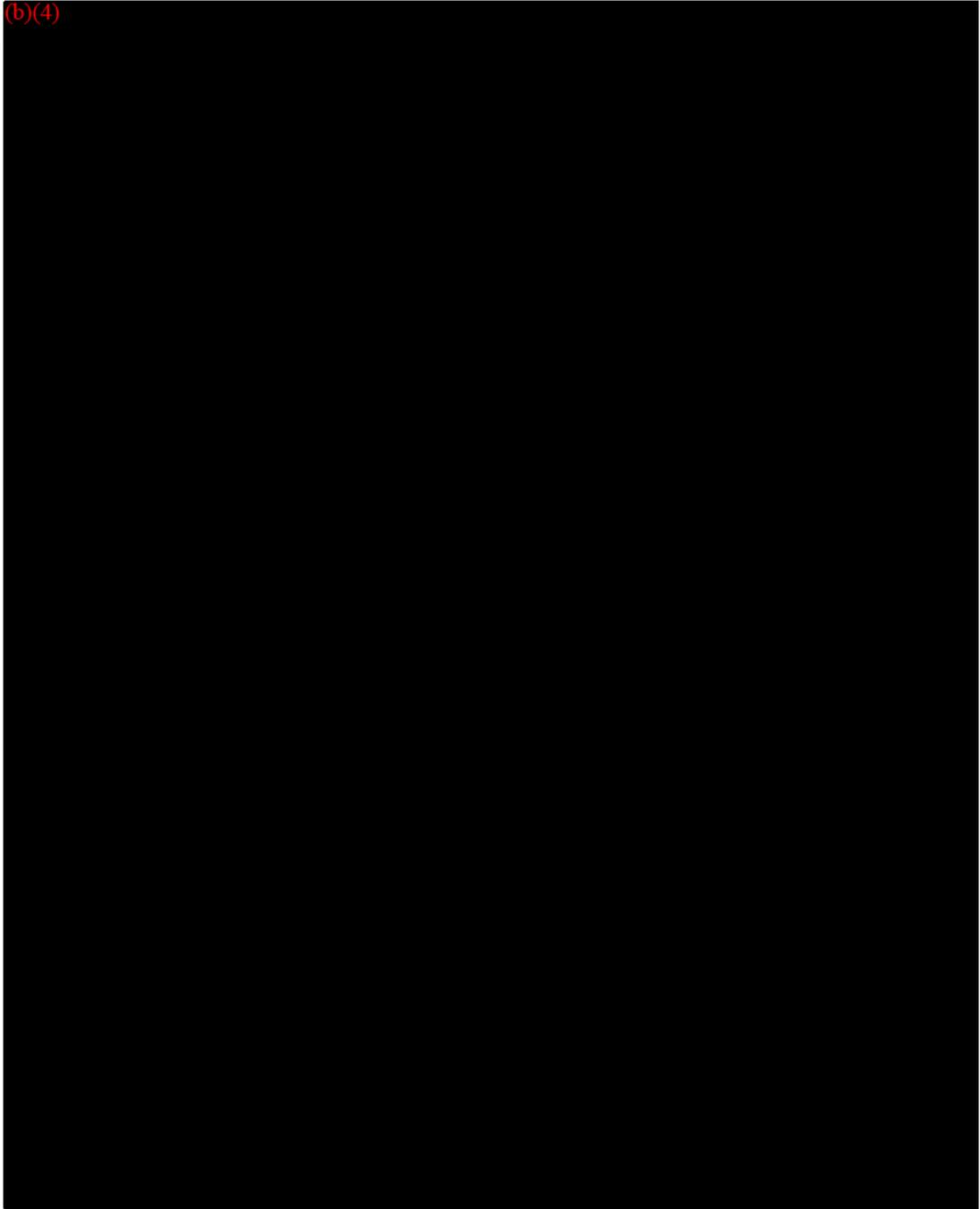
(b)(4)

Q4.

Q5.

Q6.

Q7.



ELECTRICAL SAFETY

The Sponsor has provided a fairly extensive test protocol to confirm device specifications as listed in the comparative chart correspond to device output. The Sponsor has further provided electrical output waveforms.

The Sponsor has provided a draft test report to IEC 60601-1 and IEC 60601-1-2, which is unsigned by the person(s) conducting the study.

Q8.

Q9.

Q10.

LABELING

The labeling appears to include all the warnings, cautions, and precautions listed for TENS and EMS device in the Guidance Document.

Q11.

Q12. (b)(4)

Q13.

LEAD WIRE GUIDANCE

A visual inspection of the photos provided of the accessory electrodes suggests that they do not meet lead wire guidance.

Q14. (b)(4)

Sponsor stated that this is covered in 56.3 of the NEMKO test report. The report stated that “plugs for connection of patient circuit cannot be connected to other outlets—None provided”—page 42 of 57. A visual inspection of the accessories leaves me with a concern for the contacting parts. Sponsor should please explicitly provide a clarification from NEMKO that they were unable to connect those connectors into an outlet. The connectors should be designed, for example, with a protective outer piece of plastic which prevents them from being connected to a mains outlets.

SOFTWARE

The Sponsor has supplied a software requirements specification, a functional test plan, traceability matrix between requirements and testing, and version information. This appears to be in sufficient detail. This is in addition to the extensive output testing they performed on the design. I did not uncover an architectural design chart or a hazard analysis.

Q15. (b)(4)

CONSULT HISTORY

I brought this device to “510(k) rounds” and asked all of the TENS/ EMS reviewers to attend on 12/8/04. In addition to the following management personnel {i.e., T. Stevens (Branch Chief), M. Melkerson (Deputy Director), N Ogden (Branch Chief—biofeedback devices)}, A Ferriter (reviewer) and M. Eudy (reviewer) were in attendance. I expressed concern that the FENZIAN system was cleared as a TENS device, for reasons I listed in my memorandum. Specifically, I expressed concern that the electrode configuration and lack of use of electrolytic gel would make this device ineffective at TENS, and that the labeling that I found on the web for the FENZIAN system (European site) suggested that it was not a TENS either. I was told by M. Melkerson that unless there were serious adverse event reports that the office would not consider rescinding the FENZIAN system, and that it was a valid predicate. I was further told by M. Melkerson if the Sponsor could show technical equivalence to the FENZIAN system that that would be a valid comparison. M. EUDY indicated that even before the FENZIAN system he had supervised clearance of a handheld system with concentric electrodes that **did not use electrolytic gel**. I have not been shown a clearance number or device name for this product, though. T. Stevens and A Ferriter suggested that the device could be found non-substantially equivalent based on the feedback function alone. While I agreed, I also agreed with M. Melkerson that it would be fair to give a Sponsor to address my concerns with clinical data or a new predicate. I expressed concern with meeting the MEDUFMA deadline of 90 days, because I do not even know what to ask in terms of a complete set of questions to the Sponsor. I do not know the extent of the differences between the Sponsor’s device and the predicate without clarification to the questions above. I asked for advice on this. M. Melkerson seemed to agree that my questions could not be “complete” so to speak until I got this additional information, and suggested that a hold would still be proper. I further expressed concern that in response to my questions, the Sponsor may change the device description which would make a substantially equivalent determination difficult in the 90 day time-frame.

RECOMMENDATION:..... AI (hold for information bolded above)
 PRODUCT CODE:..... **84GZJ, 89IPF**

CLASS:..... II

4/6/2005

Jeffrey Allen Rossi, Scientific Reviewer Date
General Surgical Devices Branch

Ted Stevens Date
Chief, Restorative Devices Branch/ Concur

Memorandum of Meeting Minutes

Sponsor: Neuro Resource Group	
Device Name: InterX5000	
Meeting Date: March 2, 2005	
Meeting Time and Location: 4-5:00 p.m., Teleconference	
Application Number (if applicable): K042912/S001	
Purpose of Meeting: To discuss Sponsor's response to FDA's request for clinical data.	
FDA	Attendees
Jeff Rossi, Lead Reviewer, REDB, DGRND	Krista Oakes, VP Regulatory Affairs
Ayanna Hill, Project Manager, PRSB, DGRND	John Manthei, Consulting Lawyer
Ted Stevens, Branch Chief, REDB, DGRND	Dave Turner, Chief Operating Officer
Mark Melkerson, Deputy Director, DGRND	Martyn Abbott, Engineering Director
Celia Witten, Division Director, DGRND	
Les Weinstein, Ombudsman, CDRH	
Discussion Points	
<ul style="list-style-type: none"> Sponsor's 2/15/05 response to FDA's 12/17/04 request for additional information. 	
Points of Concurrence/Recommendations	
<ul style="list-style-type: none"> The InterX5000 submission presents new technological parameters (i.e., dose & DIAG; accessory electrodes; output parameters, and impedance loads) for which clinical data and/or a detailed, side-by-side comparison to previously cleared 510(k)'s is required to determine the safety and effectiveness of this product. European labeling may not be used for comparison to support new technology. If new technological features may not be found in predicate devices, these features may be removed; changes in labeling will not adequately justify the use of these features. 	
Unresolved issues:	
<ul style="list-style-type: none"> (b)(4) 	
Next Steps:	
<ul style="list-style-type: none"> Sponsor will forward the submission number of the predicate with an impedance function. Once the FDA review of the 2/15/05 response is complete and determine whether another additional information (AI) request will be made. If additional information is needed, the Sponsor will be contacted to schedule a teleconference. The FDA review will complete in approximately 60 days after the receipt of the Sponsor's 2/15/05 response. 	
Minutes prepared by: Ayanna Hill <i>Ayanna Hill</i>	
Lead Reviewer: Jeff Rossi	
Branch Chief: Ted Stevens	
Deputy Director: Mark Melkerson	

Attachment: (Jeff Rossi) I asked the company if they had found a predicate comb electrode. The company indicated that they were unaware of a predicate comb electrode. I told the company that because we were unaware of a predicate comb electrode and that the sponsor supplied no clinical data, that they may not have an adequate basis for establishing safety and effectiveness for this accessory for the proposed indications ("relief of chronic intractable pain, etc.)

Rossi, Jeffrey

From: Rossi, Jeffrey
Sent: Wednesday, February 16, 2005 9:46 AM
To: Stevens, Ted
Cc: Witten, Celia; Weinstein, Les S
Subject: RE: K042912

Tracking:

Recipient	Read
Stevens, Ted	Read: 2/16/2005 9:50 AM
Witten, Celia	
Weinstein, Les S	

Hi Ted,

You showed me a copy of the company's appeal letter, but did not leave it for me to respond. Since I have not been formally presented with the company's appeal letter either in hard copy or e-mail, I cannot respond formally. However, I saw numerous comments in the letter which referred to things I allegedly stated to the company which I did not state to the company, and references to me which are false. My review memorandum contains the information which was conveyed to the company, and is complete.

If presented with a copy of the company's appeal, I will respond line by line to the items which are not true.

Thanks,

Jeffrey Allen Rossi, MSEE
Electrical Engineer - Reviewer
FDA/ Office of Device Evaluation
Rockville, MD
301-594-1307

-----Original Message-----

From: Stevens, Ted
Sent: Friday, February 11, 2005 7:50 AM
To: Rossi, Jeffrey; Ferriter, Ann M; Hinckley, Stephen M.
Subject: FW: K042912

I will need to talk to each of you about the Fenzian clearance to try to answer the questions this company is raising regarding the review of their own device.

-----Original Message-----

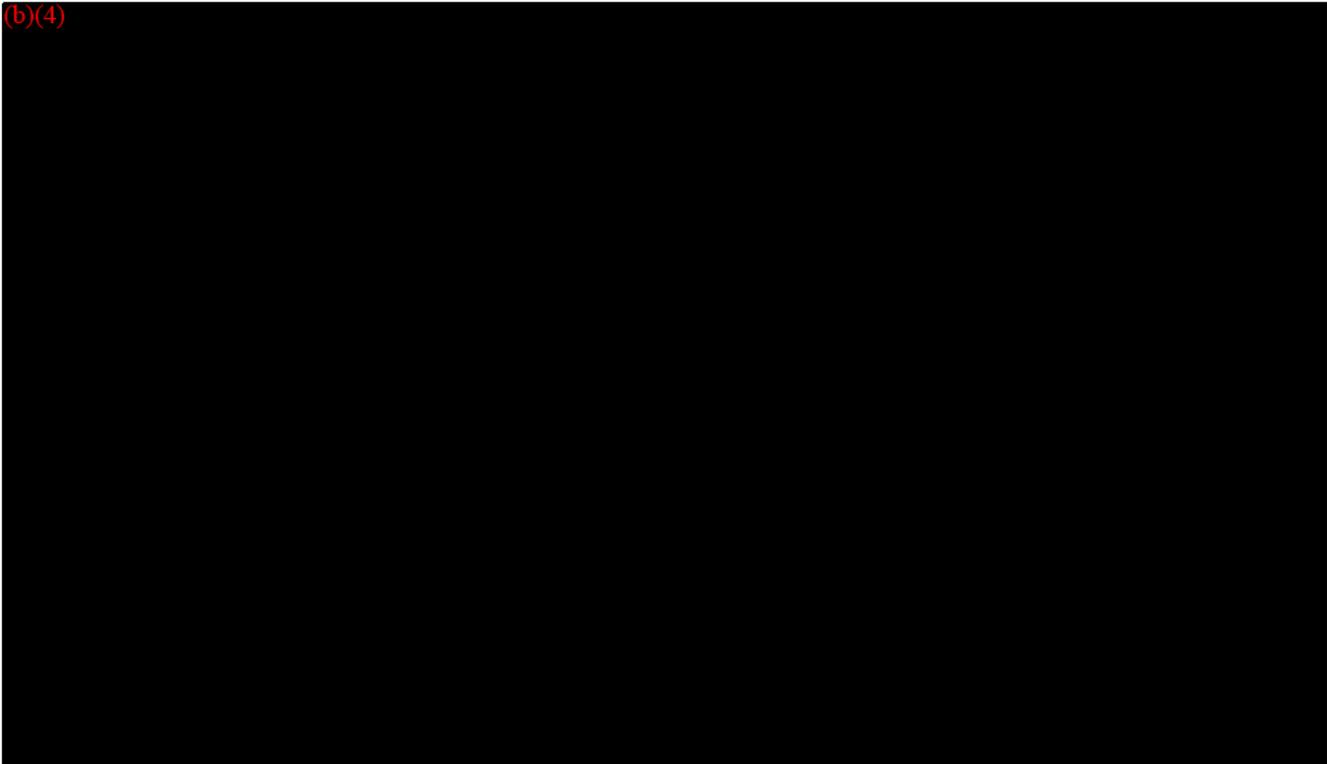
From: Krista Oakes [mailto:koakes@amicasolutions.com]
Sent: Thursday, February 10, 2005 6:01 PM
To: theodore.stevens@fda.hhs.gov; TRS@CDRH.FDA.GOV
Cc: 'Weinstein, Les S'
Subject: K042912

Dear Mr. Stevens:

As a reminder, our firm has raised serious questions regarding a "least burdensome" and "level playing field" approach to addressing the additional information requested by our 510k reviewer with regard to K042912, citing among other things, the approach described in the recently cleared Fenzian System's Summary of Safety and Effectiveness. During our phone meeting of January 19, you attempted to explain differences in these approaches by speculating about possible information that could be in the Fenzian System premarket notification, which may not be represented in the Summary of Safety and Effectiveness. However, since you were not familiar with the actual Fenzian System premarket notification, you agreed to conduct a review. Clearly, this information is essential to determining appropriate and least burdensome responses to the questions raised by our 510k reviewer. If the Summary of Safety and Effectiveness of K041575 is indeed representative of the information used as a basis for their SE determination, then this will materially impact the type and specificity of data that would be required for our device.

As discussed with Les Weinstein this afternoon, I have identified specific questions regarding the Fenzian System premarket notification, which may be helpful in narrowing its review in the interest of bringing this to a faster resolution:

1. (b)(4)
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.



I will call you early next week as a follow up to this email. Meanwhile, please do not hesitate to contact me if you have any further questions or comments regarding this request.

Regards,

Krista Oakes
Neuro Resource Group
972-849-5167

510 K PRIMARY REVIEW MEMORANDUM

DEVICE NAME:.....**INTERX 5000**
 COMMON NAME:.....**TRANSCUTANEOUS ELECTRICAL NERVE
STIMULATOR**
 CONTACT.....**KRISTA OAKES**
 APPLICANT:.....**NEURO RESOURCE GROUP, INC.**
 PHONE/ FAX:.....**(972)-438-5202 / (972)-401-9161**

DEVICE DESCRIPTION

The INTERX5000 is an electrical impulse generator intended for superficial use which is claimed equivalent to a Transcutaneous Electrical Nerve Stimulator (TENS) and Electro-muscular Stimulator (EMS). The device is a battery-operated unibody design, with integrated electrodes, which weighs 6 oz. The device is designed to be held in contact with a treatment site, and the length of time needed for treatment is said to vary between a few seconds and over 10 minutes. The device is intended to be used with **no electrolytic gel**, as the **concentric electrodes** would short out in the presence of conductive gel. Skin must be dry according to the instructions for use.

Although the device claims TENS and EMS indications, and is compared to TENS/ EMS devices, the device is described by the Sponsor as a type of biofeedback device¹ (“biofeedback process... enabling the operator to track changes and make appropriate adjustments if necessary”—page 7 of 12; “a digital display monitors the biofeedback process”—Summary of Safety & Effectiveness). Two types of feedback are described. First, the device output is modulated as a function of impedance² (resistance) measurements by modifying pulse amplitude and shape. The second type of feedback is the recommended dose, which is determined by measuring changes in skin impedance (resistance) as follows: 1) An initial impedance measurement is made to help “focus” treatment. 2) Subsequently, the device modifies output parameters over time in response to changes in tissue impedance. 3) Initial impedance X and ongoing impedance Y are evaluated in the following manner:

- “X=Y indicates no dynamic change (?) and the body needs more treatment”
 - “X>Y indicates that there is no dynamic change and the body still needs... attention”
 - “X<Y indicates that the body has responded satisfactorily to the treatment”
- (TREATMENT ENDS)

¹ In the strictest sense, biofeedback processes are usually associated with a user making an effort through voluntary control of a body function. It could be debated whether this is a biofeedback device *per se* depending on the definition used for “biofeedback device”. 21 CFR 882.5050 defines a biofeedback device as “an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient’s physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters.”

² I use the Sponsor’s wording of impedance (resistance plus capacitance) to be consistent with the device specification, even though it appears that only skin resistance is actually measured

INDICATIONS FOR USE

See comparative chart, below for the actual indications for use as listed in the IFU statement. These are TENS/ EMS indications for use which have been associated with multitudinous FDA cleared TENS/ EMS devices.

Although the indications for use recite TENS and EMS indications, the software documentation describes a basic treatment mode for use in the following ways, which suggest indications beyond traditional EMS/ TENS cleared indications.

- a. In the presence of clearly defined local symptoms (?)
- b. For achieving functional changes in organs/ systems (?)
- c. When large surfaces are being treated
- d. To localize symptoms (?)
- e. To save time when looking for asymmetry (?)
- f. To avoid a healing crisis (?)
- g. To optimize the action time (?)

These additional indications are not clearly explained by the Sponsor in the documentation provided to the office.

PREDICATE COMPARISON

The device cites several predicates, the most relevant of which is the FENZIAN SYSTEM (K951951), which is also a hand-held electrical stimulator with integral concentric electrodes intended to be used **without electrolytic gel**. The FENZINAN system 510(k) describes an impedance measurement, but does not describe a feedback mechanism by which output is modulated (either automatically or by user intervention) to the feedback.

The EMPI FOCUS 795 (K951951) and the BIONICARE BIO-1000, cited by the Applicant in the technical description, are both designed to be used with **large surface electrodes** and **electrolytic gel**, and therefore are not a valid comparison (for reasons set in further detail below).

TABLE 1: Comparison of the INTERX-5000 with the predicate FENZIAN treatment system

Parameter	InterX 5000	Fenzian Treatment System (K041975)	Comments
Indications for Use	Symptomatic relief of chronic, intractable pain Adjunctive treatment in the management of post-traumatic and post surgical pain Relaxing muscle spasms Increasing local blood circulation Immediate post surgical stimulation of calf muscles to	Symptomatic relief of chronic, intractable pain Adjunctive treatment in the management of post-traumatic and post surgical pain	<i>EMS indications not supported by a valid predicate. Sponsor should provide clinical data to support the EMS indications, in addition to further data supporting the TENS indications as described below</i>

	prevent venous thrombosis Muscle reeducation Maintaining or increasing ROM Preventing or retarding disuse atrophy		
Waveform	Asymmetrical biphasic near balanced the first phase is a pulse wave with a decay, the second phase is a truncated impulse function, while the predicate is an impulse function in the second phase	Similar—visual inspection of 510(k) showed that the wave has the same general shape, a square wave with a decay followed by an impulse)	
Electrodes	Integrated stainless steel for use without conductive gel	Integrated stainless steel for use without conductive gel	
Max Output Voltage (V)	40@500 ohms 175@ 2 k ohms 450@ 10k ohms	88@500 ohms 306@ 2 k ohms 650@ 10k ohms	
Maximum Output Current (mA)	80@500 ohms 87.5@ 2 k ohms 45@ 10k ohms	46@500 ohms 16.8@ 2 k ohms 8.0@ 10k ohms	<i>Maximum output current for the predicate does not make sense. The maximum voltage is higher in the Fenzi system, but the maximum current is reported lower. This violates ohms law. (V=IR)</i>
Pulse width (μs)	10-500	498	<i>Treatment effect of variable pulse width is unknown</i>
Frequency (Hz)	15.3-351	15-350	
Net Charge (μC)	3.9	1.16	
Maximum Charge per Phase (μC)	14.8	10.6	<i>Maximum charge per phase is higher, but the waveform is similar and the voltage is reported lower—needs explanation</i>
Max Current Density (mA/cm ²)	52	27.7	
Average Power Density (W/cm ²)	0.024	0.177	
Burst Mode Pulses/ burst Bursts/ sec Burst Duration	2-8 59.3 0.22-15.2 ms	1-8 15-2800 1-5 s	<i>It is unknown how you can have 15-2800 bursts per second with a duration of 1-5 seconds. This seems electrically impossible</i>
Max delivered current (mA)	87.5	<7.0	<i>Maximum delivered current appears to be an instantaneous current compared to an average current. This is an invalid comparison</i>
Range Impedance Load (ohms)	500-10000	500-1000	<i>This is not understood as to what this value represents. Both devices drop off substantially after 2 k ohms</i>
Max Charge/ pulse	25.6 @500 ohms	37.5 @500 ohms	

(μ C)			
------------	--	--	--

COMMENTS

I have seen no scientific data in this 510(k) or predicate 510(k)'s of record suggesting that the electrode configuration used would be effective for TENS treatment. Specifically

- ◇ The absence of electrolytic gel would seem to create impedance values that would result in little or no current being delivered;
- ◇ The electrode configuration would not seem to allow either adequate spacing or surface area to provide an electrical pathway capable of affecting nerves (TENS) or capable of muscle contraction (EMS);
- ◇ The integration of the electrode into the unibody design would make it impractical to maintain consistent force on the site, thus further diminishing effectiveness.

Therefore, I do not see any scientific evidence for believing that this device could be effective as a TENS device according to traditional modes of operation.

The predicate FENZIAN system was cleared as a TENS device, and **does not use electrolytic gel**. The FENZIAN system (K041575) was also compared to the EMPI FOCUS K951951 cited in this 510(k). The 510(k) review memorandum for the FENZIAN system makes no mention of how the performance of the FENZIAN system was assessed clinically with respect to the 1) unibody design, 2) electrode configuration, or 3) lack of conductive gel. Clinical data was not requested nor provided for the FENZIAN system. The concern is that with such a configuration, without electrolytic gel and without clinical data to review, it is not understood how the FENZIAN was established substantially equivalent under 21 CFR 807.100 for TENS treatment to devices that use gel and traditional adhesive electrodes. Therefore, this makes a technical comparison of the differences between the INTERX5000 and the FENZIAN SYSTEM difficult, since it is unknown which range of technical parameters should be presumed effective, and how changing those parameters would affect the device effectiveness.

Despite apparent problems with assessing the relative safety and effectiveness to the predicate device, there remain significant differences between the INTERX5000 and the FENZIAN system. The predicate FENZIAN SYSTEM did not employ an impedance feedback system. Sponsor seems to confirm this by stating "the INTERX 50000 is **unique** in the way it is designed to continuously modify its output as it senses changes in tissue properties. In comparison to other types of currently available electro-stimulation devices, the INTERX5000 is **unique** in the way that it works interactively with the body, by modifying its signal in response to the changing impedance of the tissue in contact with its electrodes"—page 6 of Sponsors submission.

The fundamental differences between the FENZIAN system and the INTERX5000 are as noted above in the comments section of **TABLE 1**, and the lack of a predicate description of an impedance feedback mechanism. The INTERX5000 also includes several electrode attachments (ball electrodes, comb electrode, and probe) which seem unsuited for TENS treatment because they have a small surface area and no electrolytic gel, and for which no scientific basis in the

(b)(4)

10/14/2004 P. 5/9

predicate or in literature has been provided. The instructions for use describe a treatment dose function which senses impedance and indicates treatment is complete based on the impedance detection function in the device description above. Sponsor states that the time required for treatment with the INTERX5000 may vary from a few seconds to over 10 minutes. This is not the treatment time associated with traditional TENS treatments, which typically last from 20-40 minutes.

For reasons described above, there is a lack of predicate for this device, and a lack of clinical data which demonstrates the differences between this device and the closest predicate cited (FENZAN SYSTEM K041975).

1)

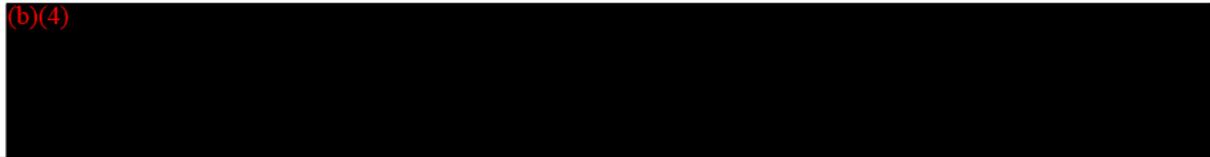
(b)(4)

The clinical data and/ or predicate cited as outlined above should *explicitly* address the intended uses listed in your labeling (labeling includes any descriptive material provided to the office). Specifically, it should address the following indications listed in your software review:

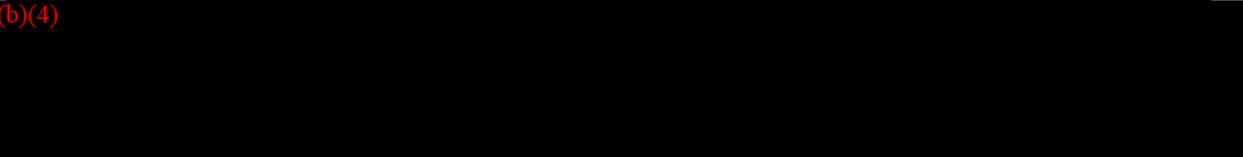
- a)
- b)
- c)
- d)
- e)
- f)
- g)



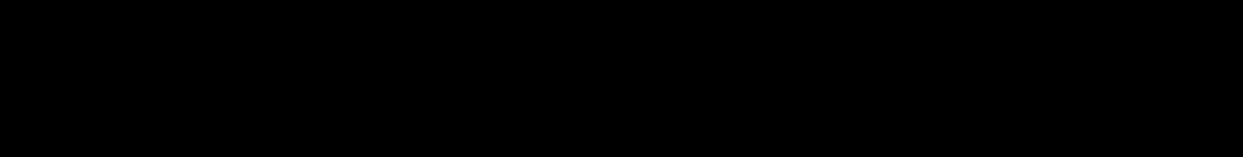
2)



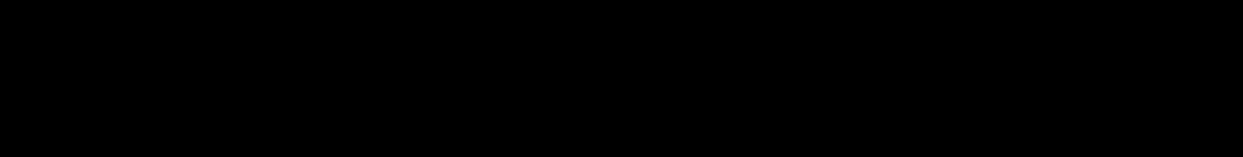
3)



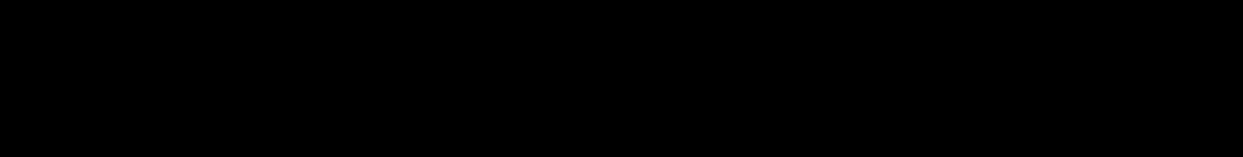
4)



5)



6)



ELECTRICAL SAFETY

The Sponsor has provided a fairly extensive test protocol to confirm device specifications as listed in the comparative chart correspond to device output. The Sponsor has further provided electrical output waveforms.

The Sponsor has provided a draft test report to IEC 60601-1 and IEC 60601-1-2, which is unsigned by the person(s) conducting the study.

7) (b)(4)

8)

9)

LABELING

The labeling appears to include all the warnings, cautions, and precautions listed for TENS and EMS device in the Guidance Document.

10) Please confirm that you have included all of the warnings, cautions, and precautions listed for power muscle stimulators as specified in both Guidance Documents for TENS devices and Powered Muscle Stimulators. Please be advised that further recommendations regarding labeling for your device cannot be made until you provide a more suitable predicate and/ or clinical data as described above. Please insure that the labeling is consistent with TENS indications for use, and that the instructions for use are consistent with a predicate and or clinical data provided in response to question N^o1 above.

11) Although you state that the term "Diag" is derived from Russian usage, and the device is not intended to diagnose any disease or condition (page 3 of the Software Requirements Specification), we are concerned that the use of the abbreviation DIAG implies a diagnosis. Please redesign your device user interface to use

terminology which is consistent with your device description, specifically, terminology which does not use "diag" or "diagnosis".

- 12) We are concerned that the labeling you have provided for the predicate Fenjian system is from their European site. Although this labeling is accessible via the Internet, the European labeling is not regulated by the FDA, and is therefore not cleared labeling for the FENZIAN system in the United States. Please be aware that the FENZIAN system can only be used as a predicate based on the device description and labeling that they have provided to the FDA.
-

LEAD WIRE GUIDANCE

A visual inspection of the photos provided of the accessory electrodes suggests that they do not meet lead wire guidance.

- 13) We are concerned that your accessory lead wires appear from the photographs provided to be common 3.5 stereo phono plug connectors, and that they could be inserted in a US electrical outlet and/ or another powered equipment receptacle. We encourage you to redesign the accessory electrodes to include connectors with a safety mechanism to prevent accidental connection to power receptacles. At any rate you must demonstrate that the lead wires meet 21 CFR 898, which set mandatory performance standards for electrode leadwire connections, and require them to be designed to prohibit accidental insertion into a power receptacle.
-

SOFTWARE

The Sponsor has supplied a software requirements specification, a functional test plan, traceability matrix between requirements and testing, and version information. This appears to be in sufficient detail. This is in addition to the extensive output testing they performed on the design. I did not uncover an architectural design chart or a hazard analysis.

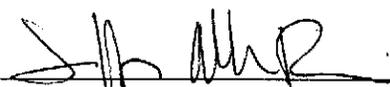
- 14) We were unable to locate an architectural design chart and hazard analysis for the software. Please provide these documents, or please indicate where they have been previously provided.

CONSULT HISTORY

I brought this device to "510(k) rounds" and asked all of the TENS/ EMS reviewers to attend on 12/8/04. In addition to the following management personnel {i.e., T. Stevens (Branch

Chief), M. Melkerson (Deputy Director), N Ogden (Branch Chief—biofeedback devices)}, A Ferriter (reviewer) and M. Eudy (reviewer) were in attendance. I expressed concern that the FENZIAN system was cleared as a TENS device, for reasons I listed in my memorandum. Specifically, I expressed concern that the electrode configuration and lack of use of electrolytic gel would make this device ineffective at TENS, and that the labeling that I found on the web for the FENZIAN system (European site) suggested that it was not a TENS either. I was told by M. Melkerson that unless there were serious adverse event reports that the office would not consider rescinding the FENZIAN system, and that it was a valid predicate. I was further told by M. Melkerson if the Sponsor could show technical equivalence to the FENZIAN system that that would be a valid comparison. M. EUDY indicated that even before the FENZIAN system he had supervised clearance of a handheld system with concentric electrodes that did not use electrolytic gel. I have not been shown a clearance number or device name for this product, though. T. Stevens and A Ferriter suggested that the device could be found non-substantially equivalent based on the feedback function alone. While I agreed, I also agreed with M. Melkerson that it would be fair to give a Sponsor to address my concerns with clinical data or a new predicate. I expressed concern with meeting the MEDUFMA deadline of 90 days, because I do not even know what to ask in terms of a complete set of questions to the Sponsor. I do not know the extent of the differences between the Sponsor's device and the predicate without clarification to the questions above. I asked for advice on this. M. Melkerson seemed to agree that my questions could not be "complete" so to speak until I got this additional information, and suggested that a hold would still be proper. I further expressed concern that in response to my questions, the Sponsor may change the device description which would make a substantially equivalent determination difficult in the 90 day time-frame.

RECOMMENDATION: AI (hold for information bolded above)
 PRODUCT CODE: **84GZJ, 89IPF**
 CLASS: II


 _____ 12/14/2004
 Jeffrey Allen Rossi, Scientific Reviewer Date
 General Surgical Devices Branch

 Ted Stevens Date
 Chief, Restorative Devices Branch/ Concur

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) J. Rossi

Subject: 510(k) Number K 042912

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
 No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

625, 1PF
Review: [Signature] RCOB 12/17/04
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	
4. If, not, has POS been notified?	N/A	
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	N/A	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.	N/A	

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 16, 2005

NEURO RESOURCE GROUP, INC.
2220 CHEMSEARCH BLVD.
SUITE 108
IRVING, TX 75062
ATTN: KRISTA OAKES

510(k) Number: K042912
Product: INTERX5000

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health



NEURO RESOURCE GROUP

K042912/S1

VIA OVERNIGHT MAIL

February 15, 2005

Document Mail Center (HFZ401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

FDA/CDRH/OCE/DID
2005 FEB 16 PM 10:26

Re: K042912 – Additional Information

This response is provided in response to additional information requested by CDRH in a fax dated December 17.

As discussed in subsequent communications with CDRH, including a telephone meeting with Mr. Jeff Rossi and Mr. Ted Stevens, our primary interest is in determining the least burdensome approach for bringing this device to market. In particular, we note that the fax of December 17 contains specific requests and/or suggestions relating to: 1) the provision of clinical data to support substantial equivalence, 2) the redesign of our device, and 3) the marketing of our device without its accessory probes. We believe that our device, as compared to predicates, raises no new safety or effectiveness concerns, as established through a less burdensome approach, and we have provided additional information accordingly.

Our response is organized according to the fourteen issues raised in the December 17 fax, stating the issue/question raised by CDRH and following with our response.

A timely review of this information, and immediate feedback/interaction to ensure timely resolution of any remaining open issues, is very much appreciated.

Regards,

Krista Oakes
Vice President, Regulatory Affairs

SK 26

2220 Chemsearch Blvd Suite 108 Irving, Texas 75062 972-438-5202

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(b)(4)

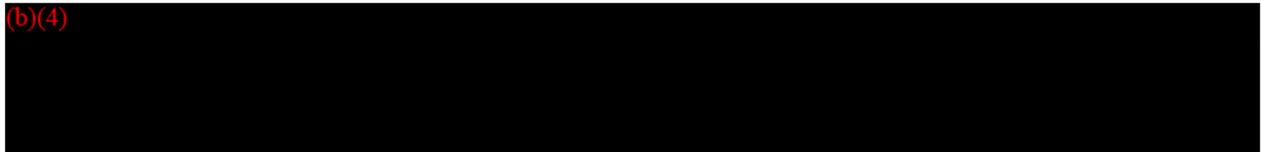


a) (b)(4)

b)

c)

(b)(4)



a) (b)(4)

b)

c)

d)

e)

f)

g)

Our response to this item is comprised of several components:

1. Validity of predicate devices
2. Precedence for "impedance feedback"
3. Accurate source for indications for use
4. Technical discussion of InterX5000

K042912 Additional Information

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Validity of Predicate Devices

Our firm believes that it has appropriately selected predicate devices that establish the substantial equivalence of our device.

Specifically with regard to the EMPI Focus, the fax document dated 12/17/04 states that the technical differences between the InterX5000 and the EMPI Focus are “such that a technical comparison...without supporting clinical data could not show equivalence.” Specifically cited were the differences in electrode configuration and the use of electrolytic gel. However, the same cited technical differences exist between the Fenzian System and the EMPI Focus. Yet, the EMPI Focus is the only predicate device identified in the Fenzian System (K041575) Summary of Safety and Effectiveness. Our 510k submission, and the identification of the EMPI Focus as a predicate for the InterX5000 device, was based on this recent precedent, as well as our belief that any technological differences between the InterX5000 device and predicates identified in the 510k do not raise new issues of safety or effectiveness.

Our firm has requested clarification and parity in the standards applied for the acceptance of a predicate device and the specificity of data required to establish substantial equivalence. Specifically, in a January 19 telephone meeting between our firm, Jeff Rossi, and Ted Stevens, our firm requested, and was promised, clarification and assistance in understanding the basis for substantial equivalence between the Fenzian System and the EMPI Focus, so that a similar approach may be used with our device to bridge the same technological differences. To date, this clarification and assistance has not been received by our firm.

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Precedence for Impedance Feedback

In our telephone discussion with Jeff Rossi on December 17, Mr. Rossi indicated that claims of impedance feedback were “unprecedented”.

Our firm believes that impedance feedback describes the way the device works, not a new “claim” or indication for use. Please refer to our Indications for Use Statement (Appendix B of our premarket notification), which contains the indications for which we intend to market the device.

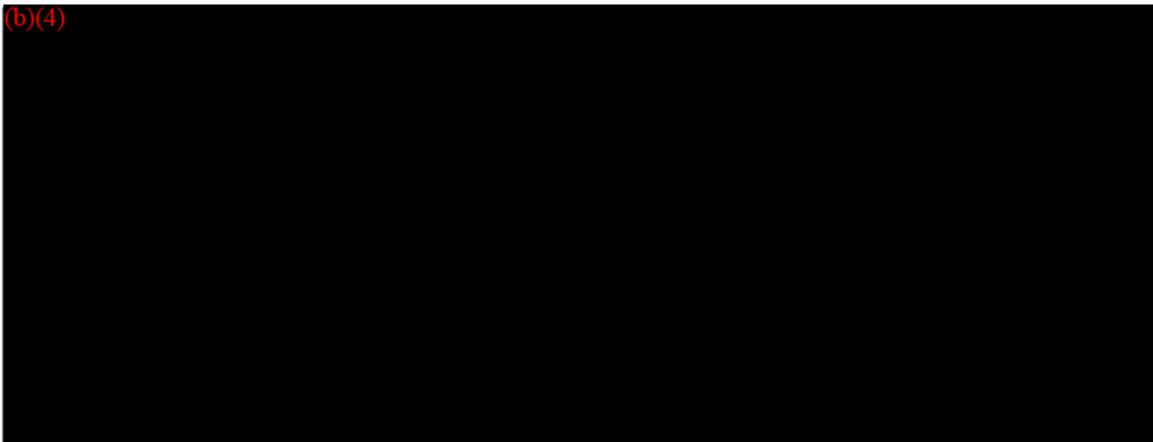
Our firm also believes that there is precedence for the modulation of device output based on impedance feedback. The following discussion was included in a published 2002 study of an impedance-controlled TENS device for treating range of motion limitations in head and neck cancer patients:

“It is well known that the body’s impedance changes when electrical current passes through it. The more sophisticated devices contain circuitry that monitors impedance and adjusts the output current to compensate for changes.” (Lennox A.J., Shafer J.P., *et al.* Pilot study of impedance-controlled microcurrent therapy for managing radiation-induced fibrosis in head-and-neck cancer patients. *Int J Radiat Oncol Biol Phys* 2002;54:23-24.)

A copy of this document is attached to this response (Attachment 1). The subject device in this article is the Electro Acuscope, by Biomedical Design Instruments (now Advanced Biomedical Technologies – www.advbiomed.com). This device was cleared under K883911.

Similarly, existing TENS devices typically operate by controlling either the voltage or the current applied to the stimulation electrodes. The InterX5000 behaves in a similar manner to a constant current device over a significant portion of operation. Every constant current TENS (by definition) has some kind of feedback mechanism between impedance and voltage that enables the device to keep the current constant. This is described in the textbook, *Clinical Transcutaneous Electrical Nerve Stimulation*, (Mannheimer, Jeffrey S. and Lampe, Gerald N., Philadelphia: Davis, c1984):

(b)(4)



Bibliography information and excerpts from this book are also included in Attachment 1 to this response.

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Source of Indications for Use

Our firm wishes to clarify that the intended use and indications for use for the InterX5000 are set forth in our Appendix C Labeling and in the Appendix B Statement of Indications for Use.

In the fax document dated 12/17/04, several references are made to information contained in the Appendix H Software Documentation, suggesting that this is a source of product claims. Please be advised that the software documentation was prepared by a third party consultant (Certified Software Solutions) who performed the software validation work for our device. At the time this validation was performed, our firm had not yet developed product labeling, so we provided Certified Software Solutions with labeling for a similar device, which had information adequate to proceed with their software validation work. As a result, some excerpts from that labeling were restated in their documentation. However, while the documentation is adequate for describing software validation, it was never intended to supplant our stated intended use/indications for use contained in the sources cited above.

Our firm has re-reviewed our software validation documentation in order to confirm that the descriptive information in the software validation documents was not material to the functionality of the software for validation purposes, and that the validation testing performed remains adequate despite subsequent differences in the described clinical implications of the software functionality when we completed our labeling.

Our intent is to market this device solely for the uses and indications set forth in Appendices B and C of our premarket notification.

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Technical Discussion of InterX5000

The fax document dated 12/17/04 asks for a description of the technological features of the InterX5000 device. As detailed below, our firm believes that these features do not raise new issues of safety or effectiveness.

Electrode Impedance

(b)(4)



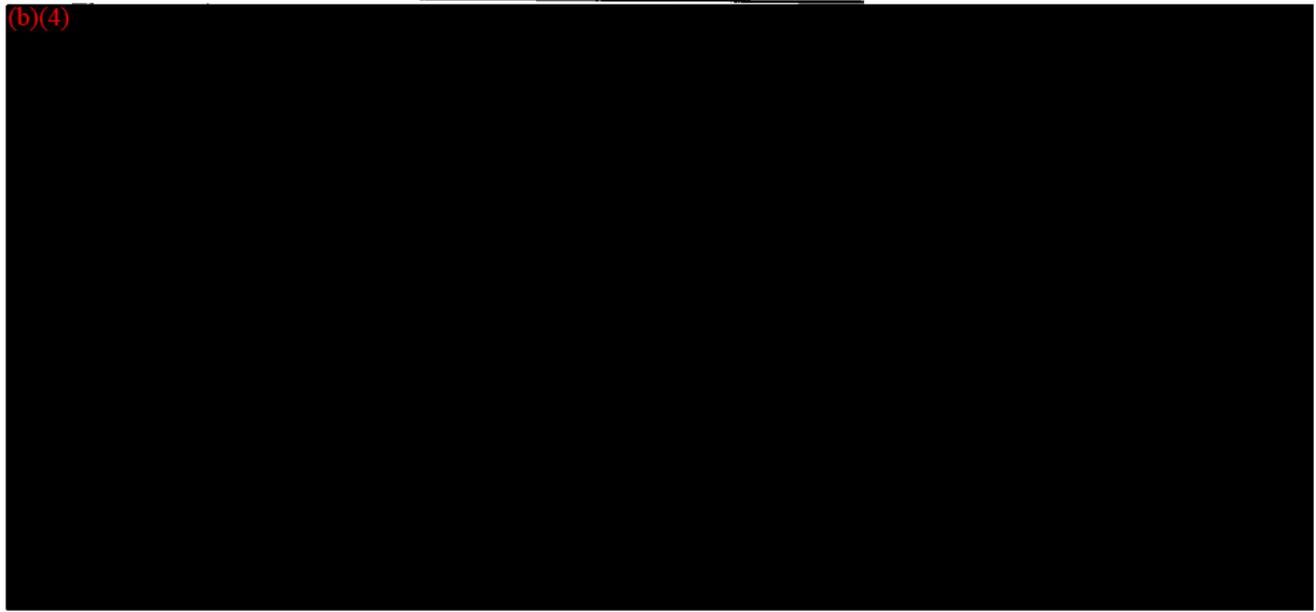
... maximum output voltage across the electrodes is limited by an internal voltage clamp.

(b)(4)



Interactive Elements of InterX 5000

(b)(4)



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Stimulation voltage and current versus load

(b)(4)

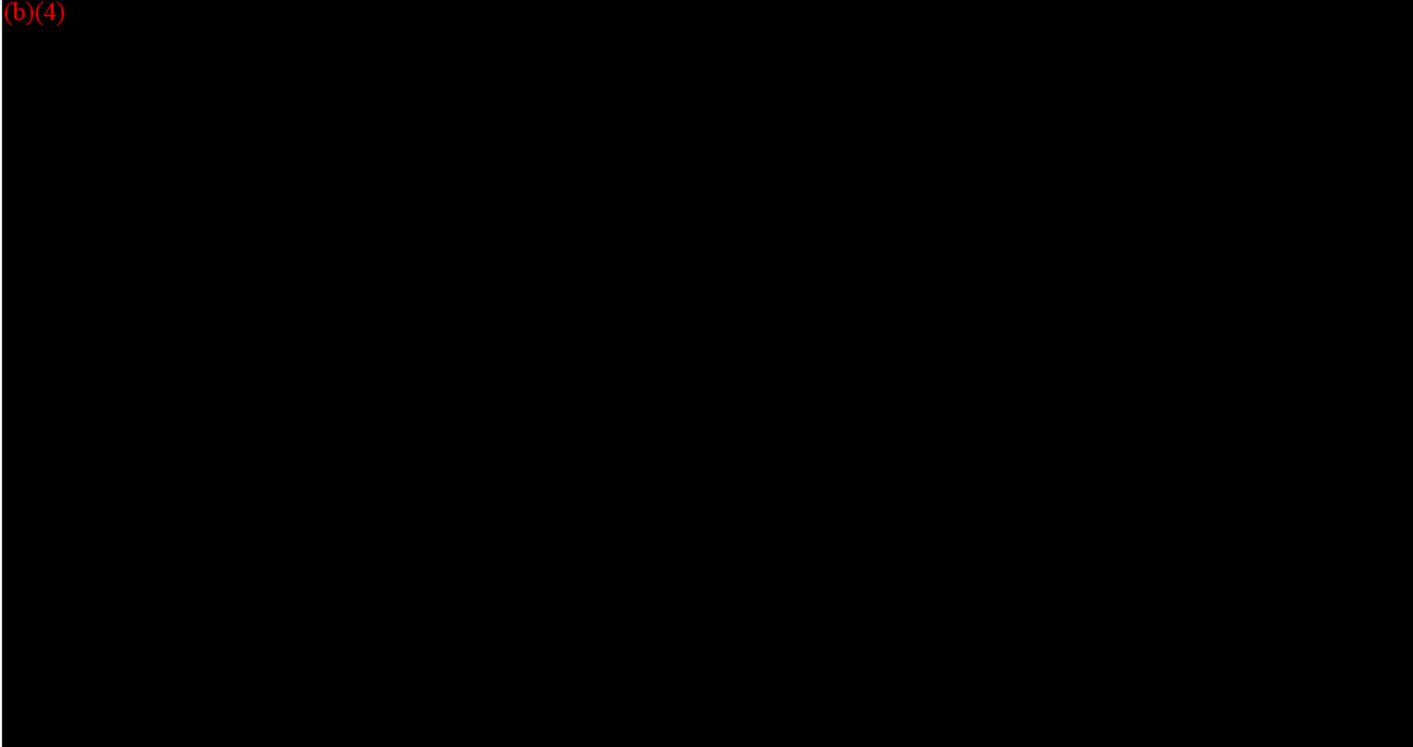
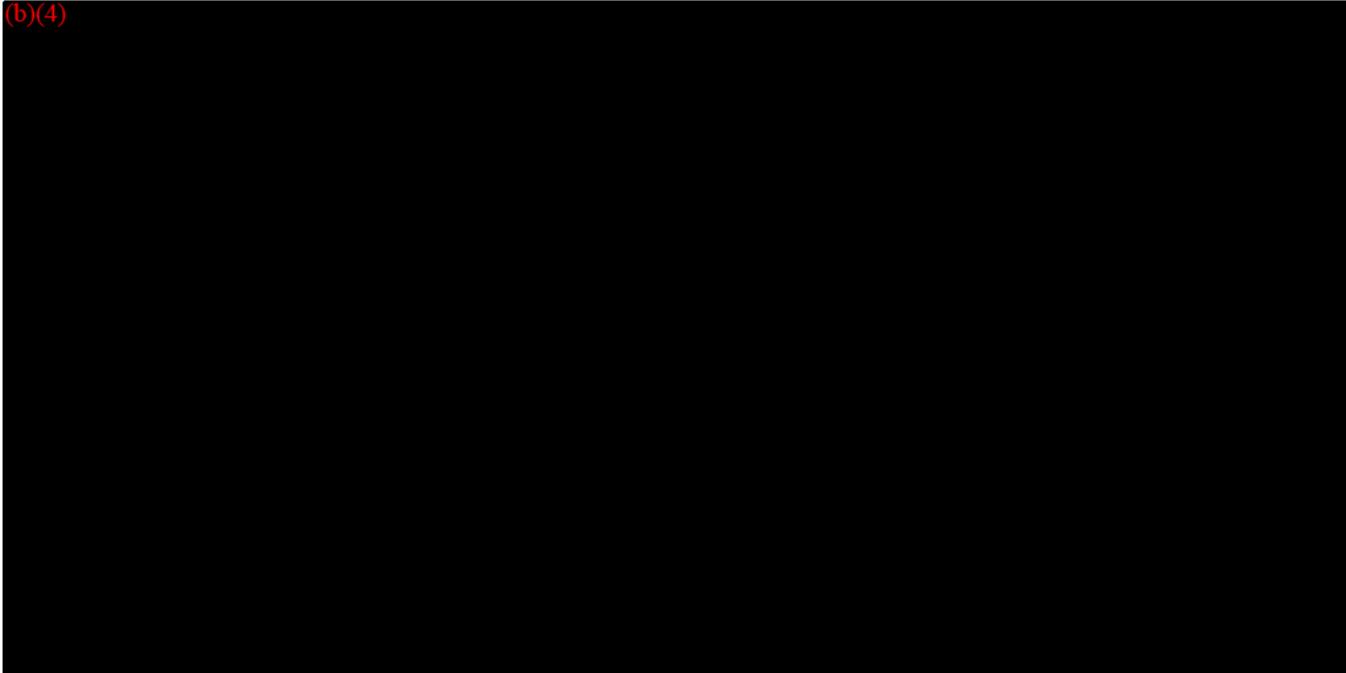


Figure 1 Peak stimulation voltage and current as a function of load resistance

(b)(4)



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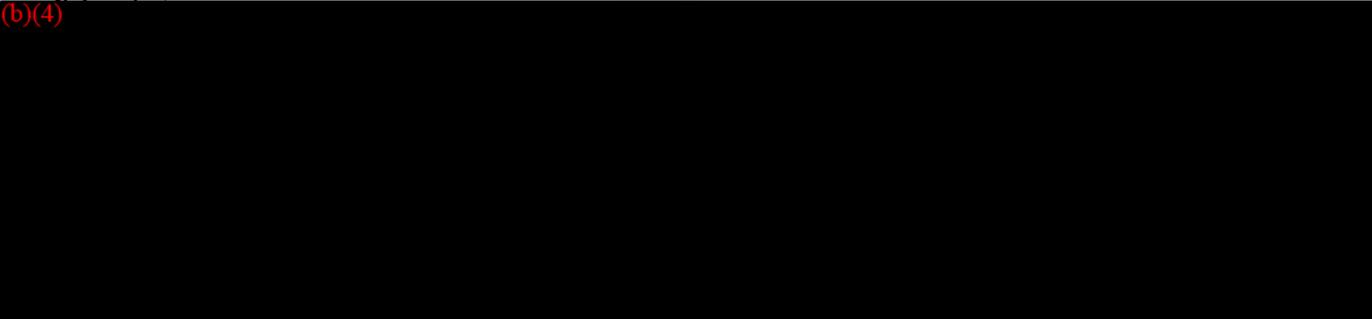
Page 8 of 28

(b)(4)

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Burst Mode

(b)(4)

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Burst Mode

(b)(4)

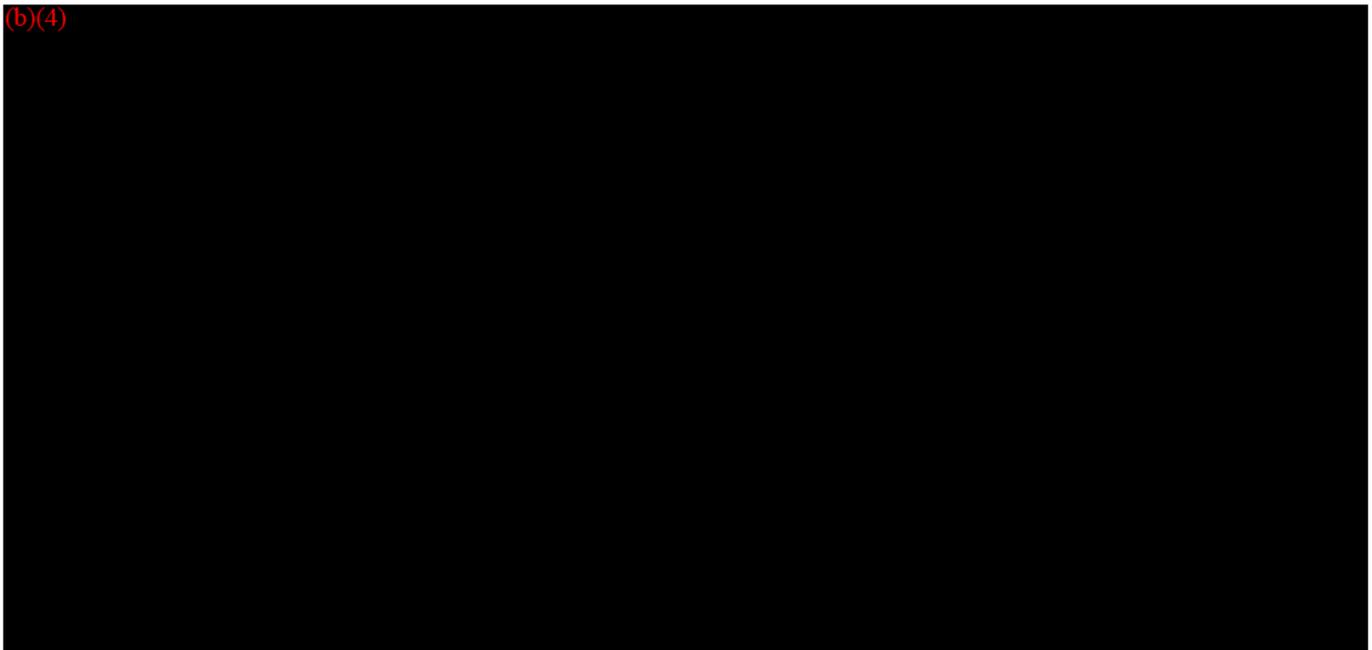
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Figure 2 Burst Mode showing an intensity of 2 and minimum pulse spacing

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Burst Mode

(b)(4)

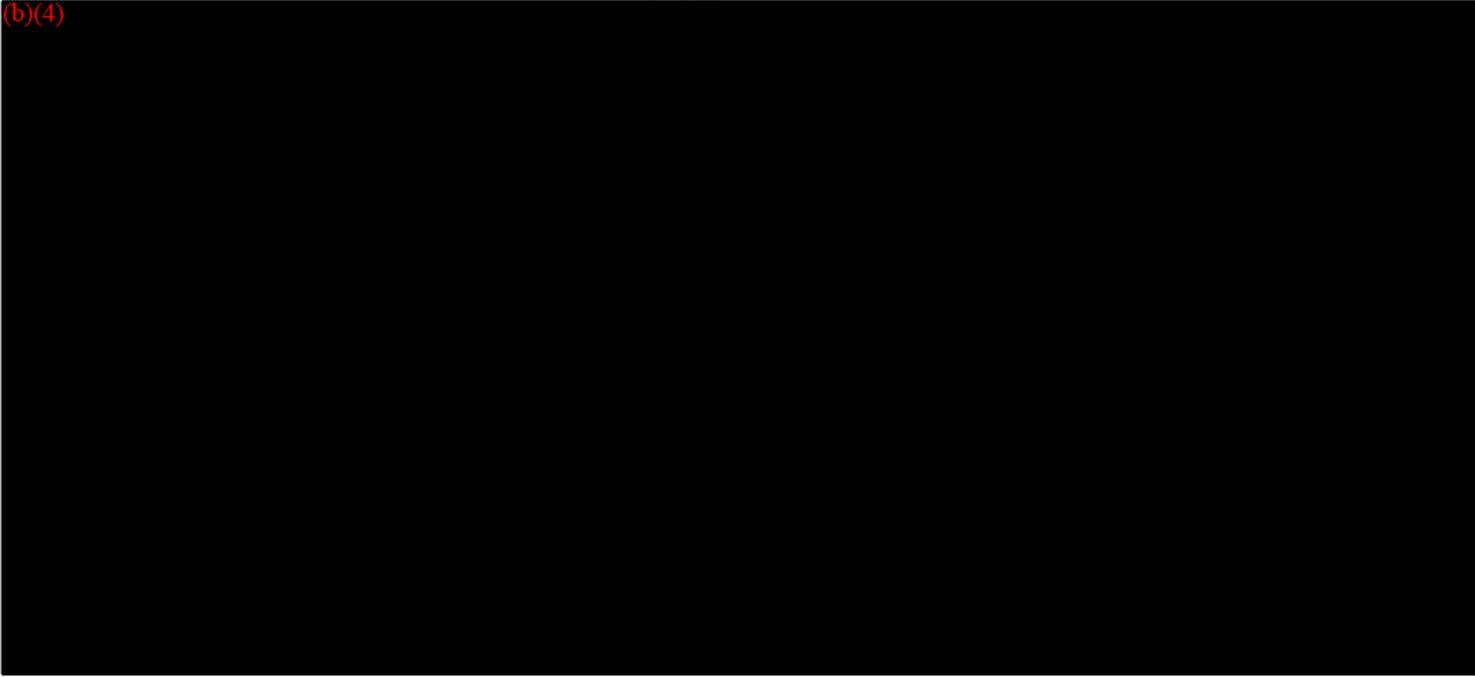


Figure 3 Burst Mode showing an intensity of 4 and minimum pulse spacing

(b)(4)

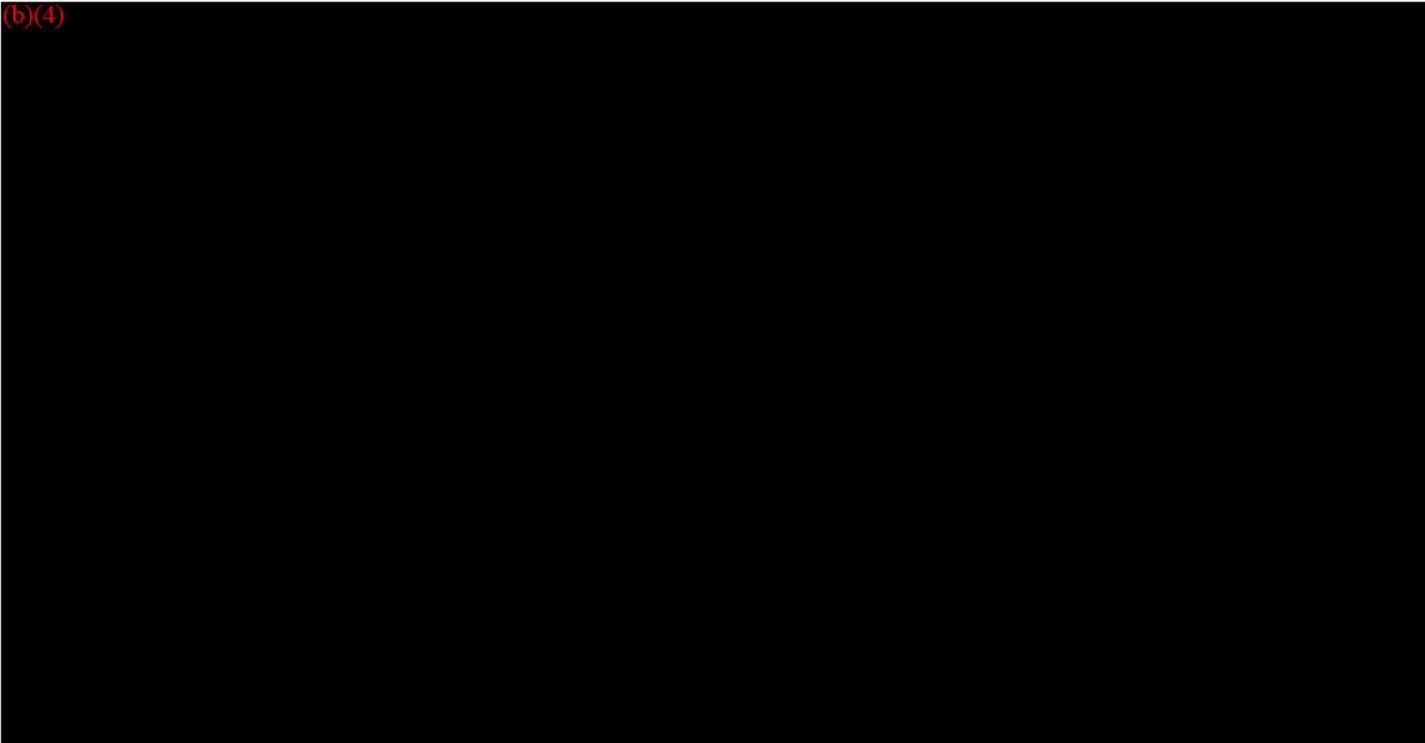


Figure 4 Burst Mode showing an intensity of 8 and minimum pulse spacing

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(b)(4)

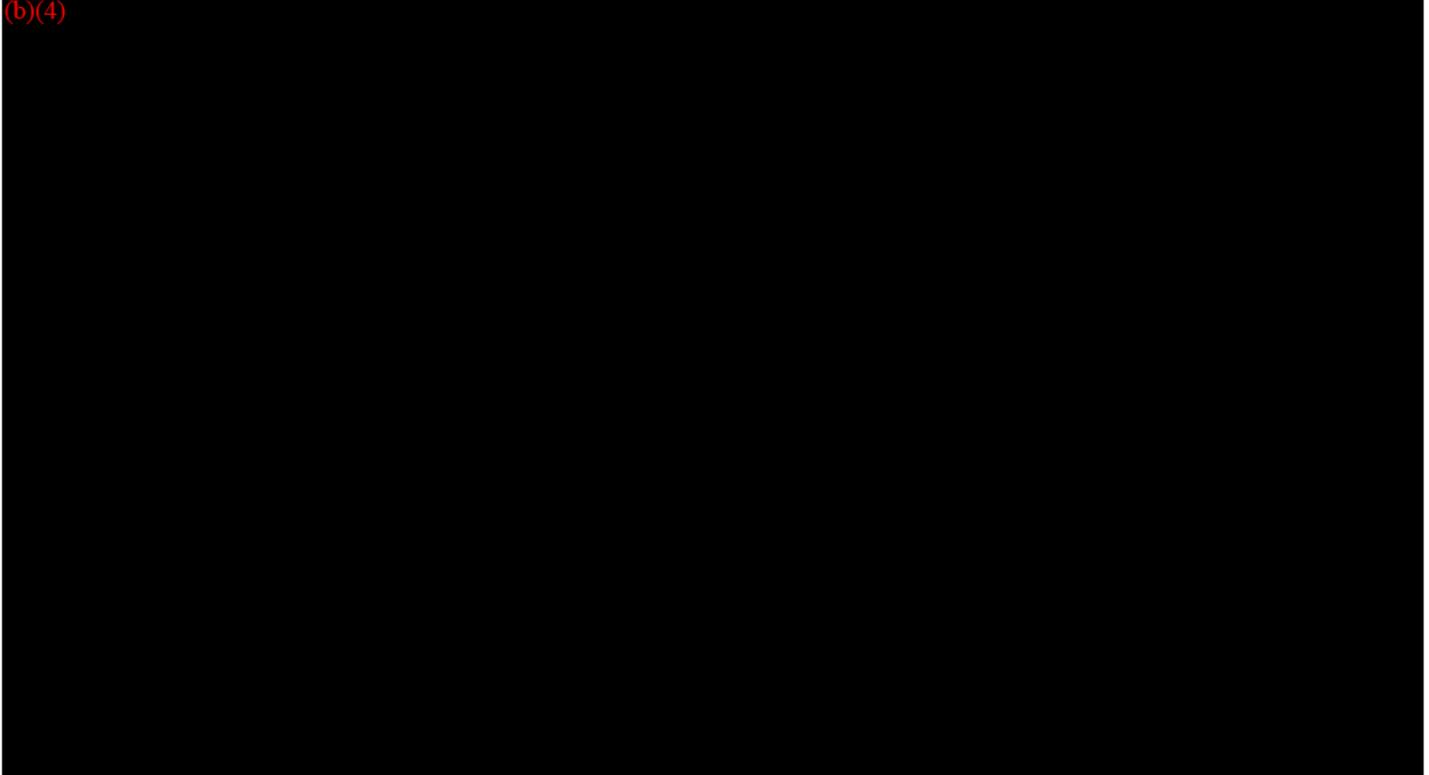


Figure 5 Burst Mode showing an intensity of 8 and maximum pulse spacing

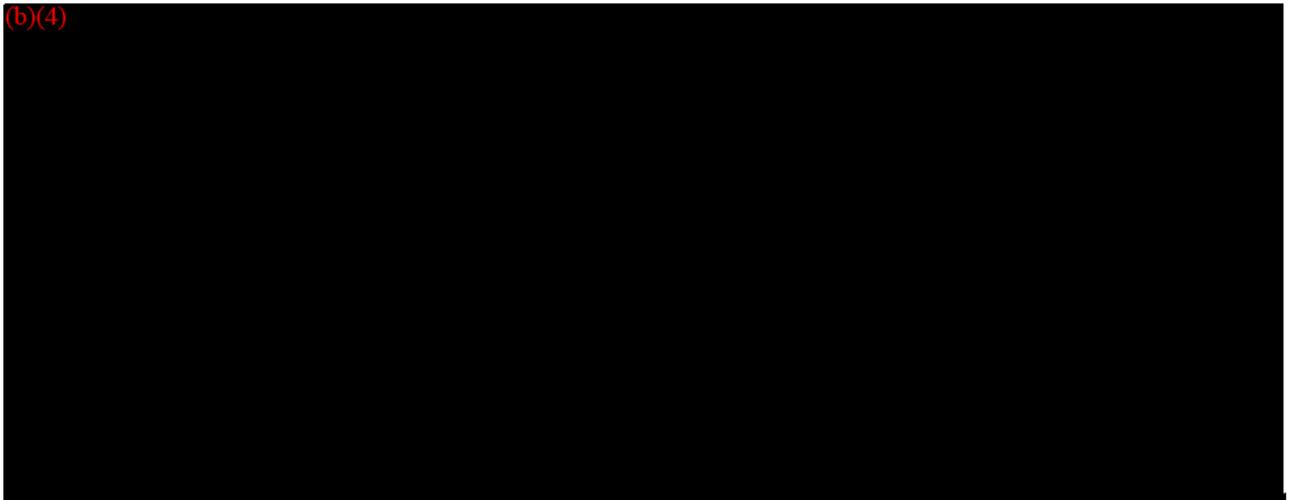
Theory of Operation

(b)(4)



Figure 6 InterX 5000 System Block Diagram

(b)(4)



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(b)(4)

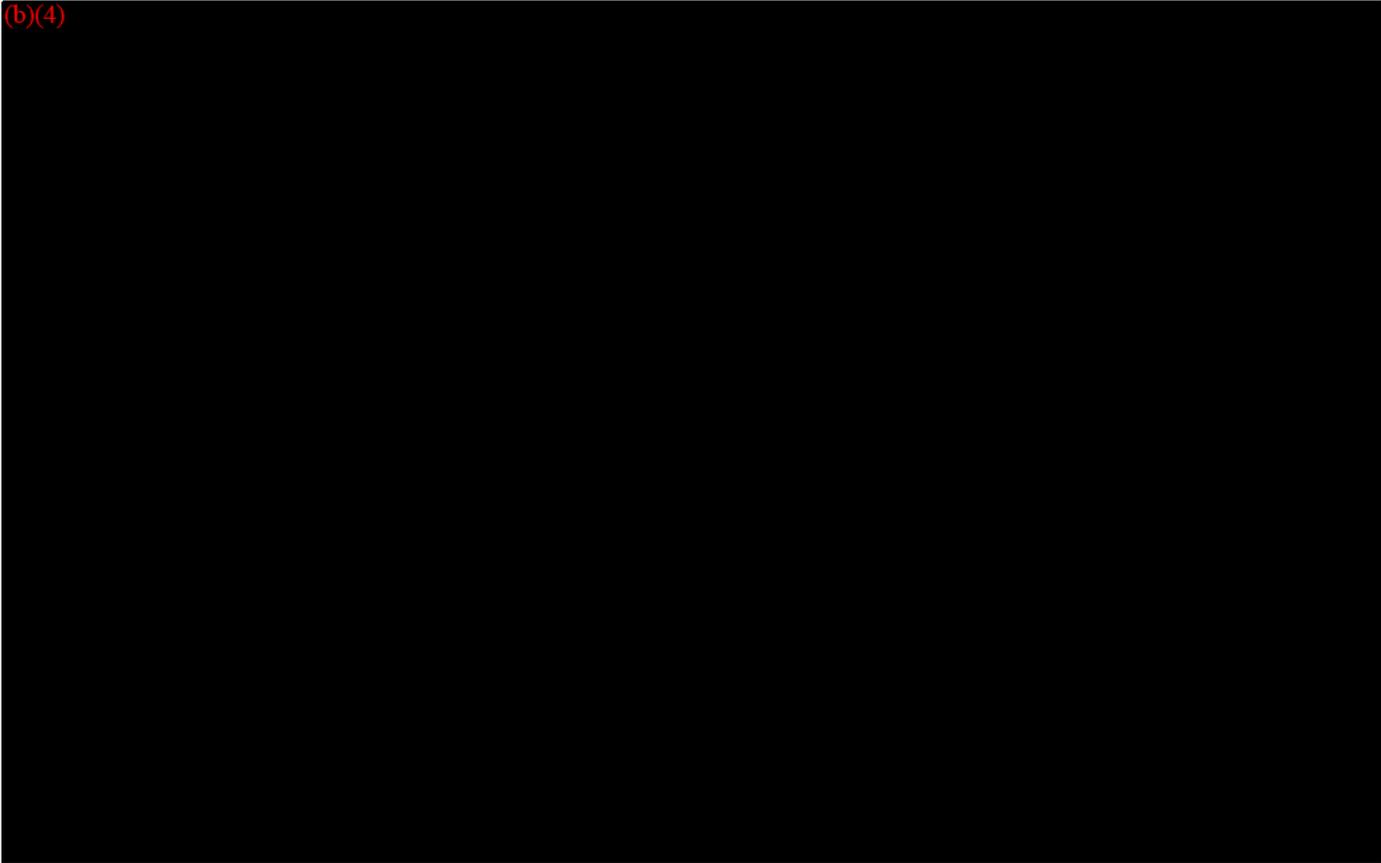


Figure 7 Stimulation voltage with no load

(b)(4)



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(b)(4)

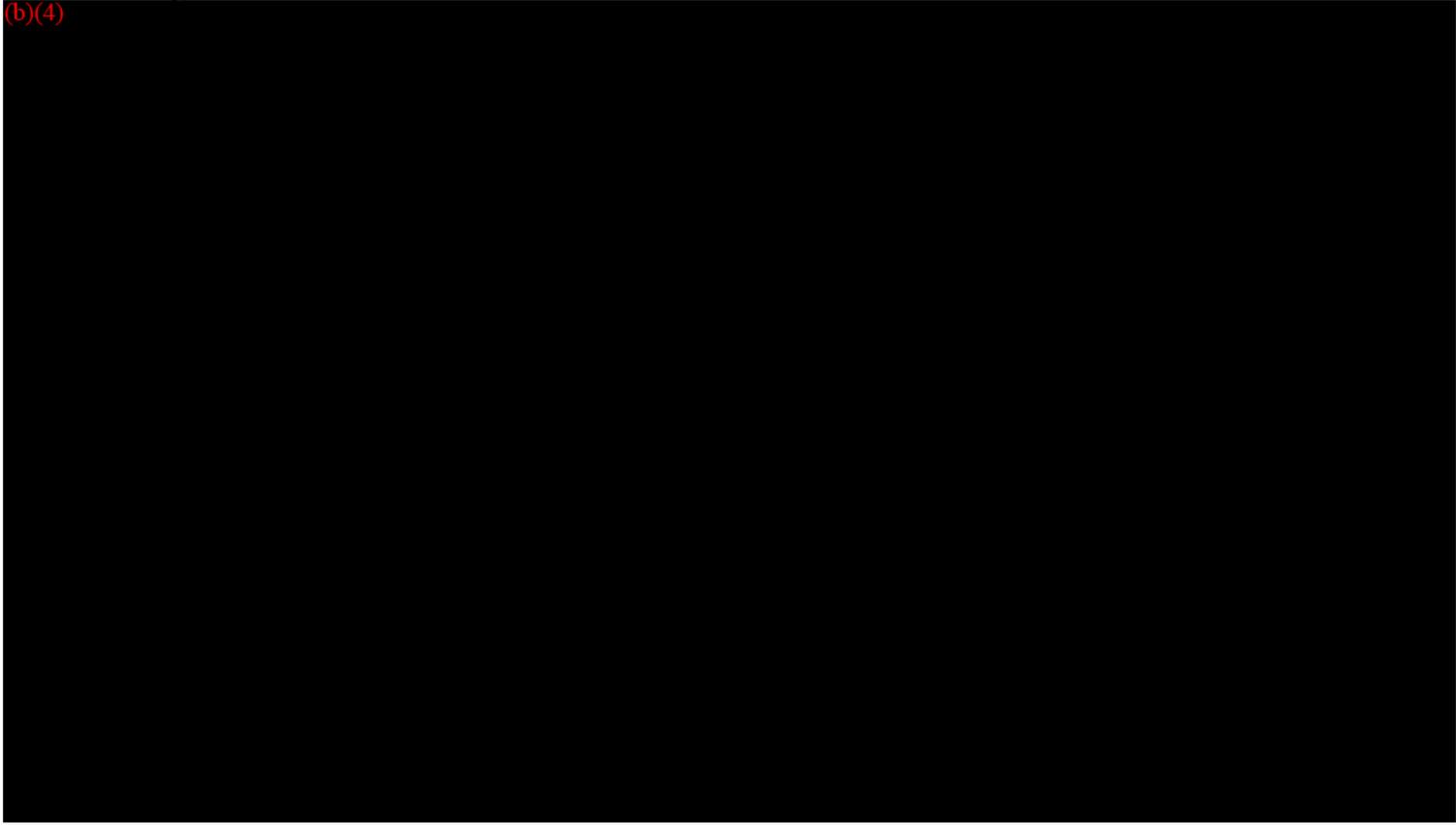


Figure 8 Stimulation voltage with dynamic load

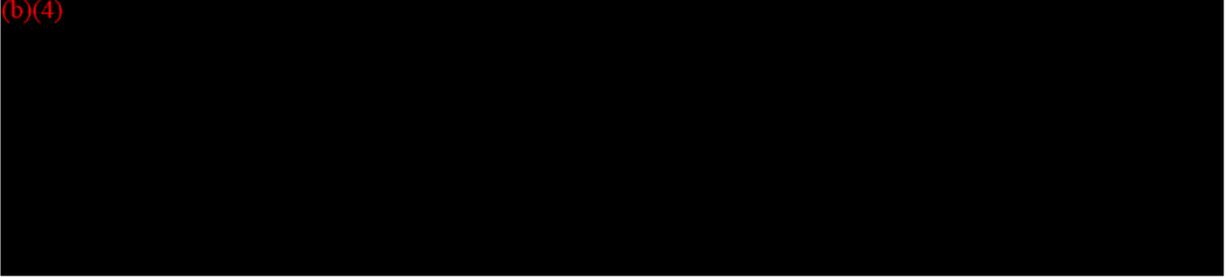
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- 2) Please justify the effectiveness of the suggested treatment times of "a few seconds to ten minutes", when typical TENS devices are used for considerably longer times to achieve results (20-40 minutes).

(b)(4)

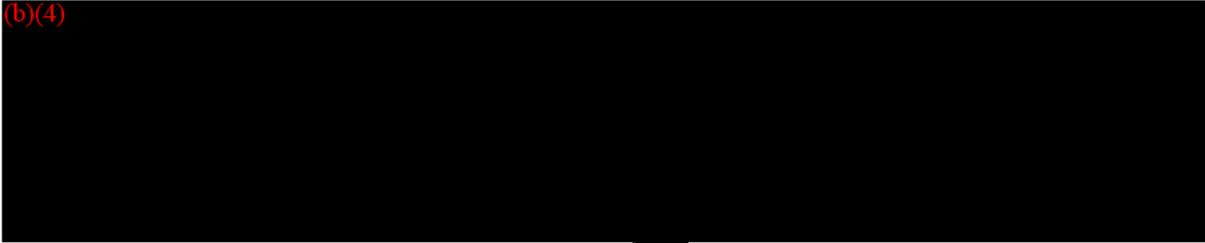


K042912 Additional Information

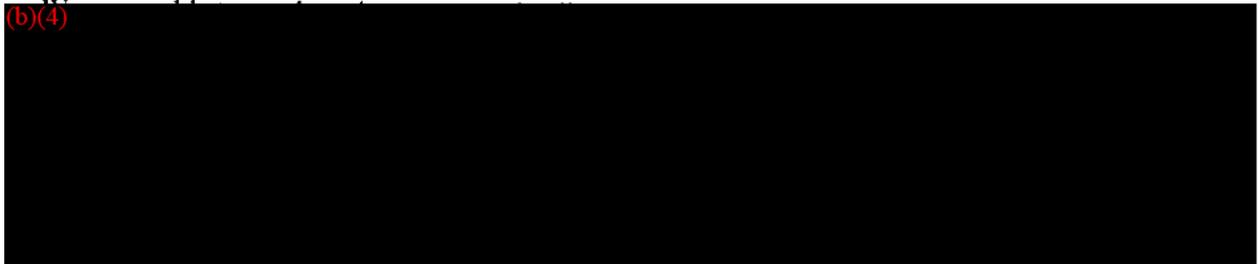
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3) (b)(4)

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(b)(4)

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4) (b)(4)



We believe that clinical data is unnecessary to establish the safety and effectiveness of these parameters of our device. As demonstrated in our comparison chart these specifications fall within the ranges of currently marketed TENS devices.

We also believe that this level of specificity has not been required in previous premarket notifications in order to establish substantial equivalence. For example, in the Fenzian System (K041575) Summary of Safety and Effectiveness the following comparison was made between the Fenzian System and the EMPI Focus 795 (the predicate device to which the Fenzian System was found equivalent):

Feature/Characteristic	Fenzian Treatment System	EMPI – Focus 795, Published Specs
Maximum Output Voltages	88 V @ 500 ohms 306 V @ 2 k ohms 650 V @ 10 k ohms	+/- 100V @ 1 k ohm
Maximum Output Current	46 milliamps @ 500 ohms 16.8 milliamps @ 2 k ohms 8.0 milliamps @ 10 k ohms	0-60 mA (normal) 0-100 mA (high)
Maximum Charge per Pulse	37.5 µC@500 ohms	Unknown
Burst/sec.	15-2800	Unknown
Burst duration	1-5 seconds	Unknown

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- 5) *The accessory electrodes provided with your device (comb, ball, probe) lack a predicate comparison and must be specifically addressed. If no predicate electrode for use for TENS/EMS is uncovered, their use for these indications must be supported with clinical data.*

Our firm has identified similar accessory electrodes being marketed under K883911, Electro Acuscope, by Biomedical Design Instruments (now Advanced Biomedical Technologies – www.advbiomed.com).

	InterX5000 Remote Electrodes	Electro Acuscope Remote Electrodes (K883911)
Electrode Area	18.8 – 46.8 mm ²	0.25" – 1"
Electrode Configurations	Ball probe Point-specific probe Comb probe	Point-specific probe Handheld metal bar Double roller probe Y probe
Material	Stainless Steel	Stainless Steel/Brass
Electrolytic Gel Needed	No	No

Electro Acuscope labeling is attached to this response (Attachment 2).

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- 6) *As suggested in FDA's TENS guidance, please address your integrated electrode specifications in a side-by-side comparison with a predicate device. This comparison should include a complete characterization of the geometrical properties of the electrodes, as well as evidence of material biocompatibility. This comparison should specifically address how changes to electrode shape would affect safety and/or effectiveness of your device relative to the predicate used.*

The InterX 5000 has a set of built-in electrodes that are similar in shape and size to the Fenzian System electrodes. This allows treatment to be given by moving the electrodes over the skin of the patient.

Three other external electrodes are designed to work with the device. These electrodes may be plugged into the device, at which time the built-in electrodes are disabled. All the electrodes operate in a similar manner, the primary difference being the size and shape of the electrode pair. Changing the size and shape of the electrodes allows treatment in different body locations. The comb probe is used primarily in areas that are covered in hair. The Acu probe is used where more precise positioning is required. The ball probe is intended for treating curved surfaces of the body.

Below is information regarding our electrodes, based on FDA's TENS guidance document requirements for "Electrodes and Conductive Media (Gel)":

A.

(b)(4)

B.

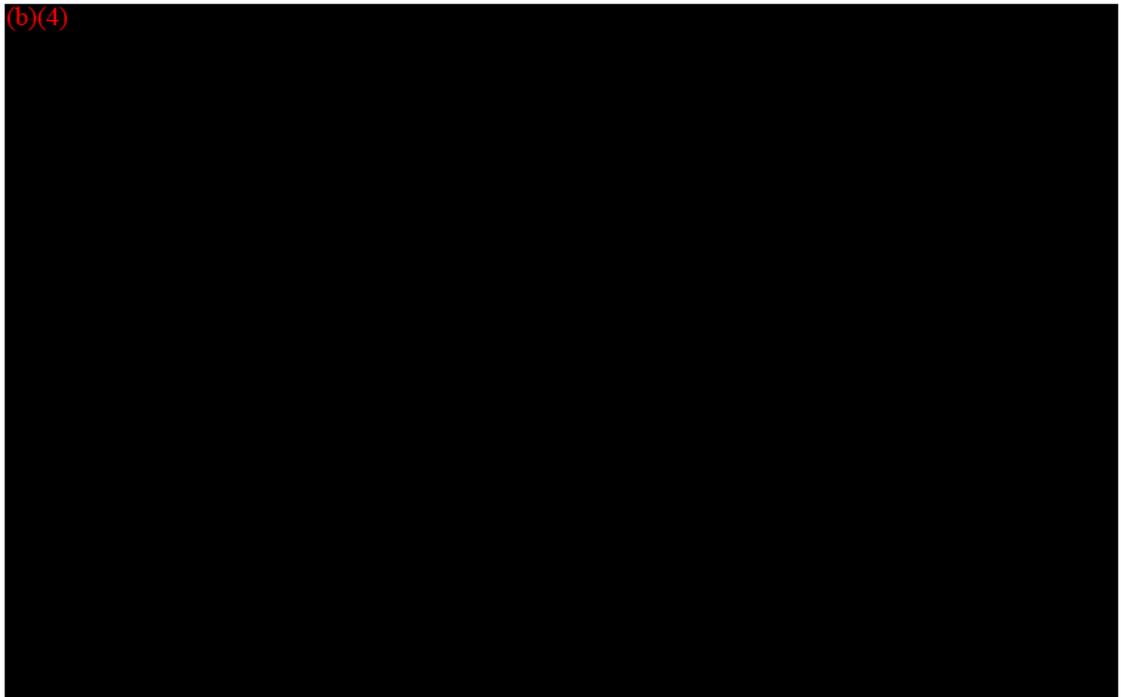
C.

D.

K042912 Additional Information

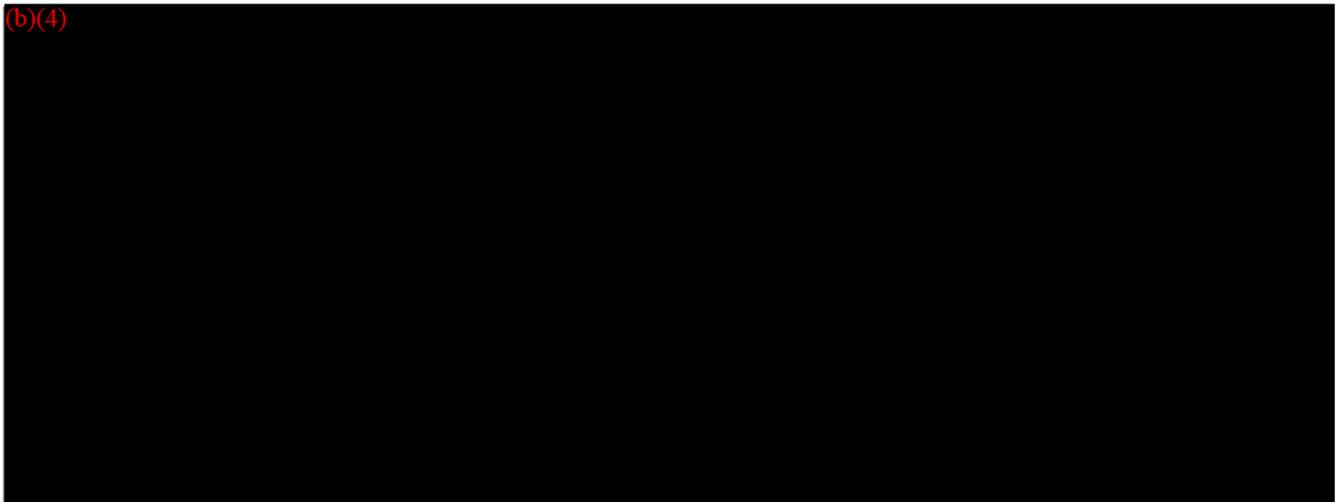
February 15, 2005

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	Max current density (mA/cm ²) in actual use	Max power density (mW/cm ²) in actual use	Inner Electrode Area (mm ²)	Outer Electrode Area (mm ²)	Total Electrode Area (mm ²)
Acu probe	(b)(4)				
Comb probe	(b)(4)				
	(b)(4)				
Note: Comb probe inner electrode has 10 tines, the outer electrode has 16 tines					

Table 1 External Probe Electrode Summary Chart



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- 7) *You have provided a draft test report to IEC 60601-1 and IEC 60601-1-2. Please specify whether the final test report has been completed. If there are no change, it is sufficient to so state. However, if there are pending modifications to the device that will be made in order for the device to pass, please specify these changes in detail.*

The final test report to IEC 60601-1 and IEC 60601-1-2 has been received, and no device modifications were necessary. Additionally, our firm has also received CSA approval for our device.

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8) (b)(4) [Redacted]

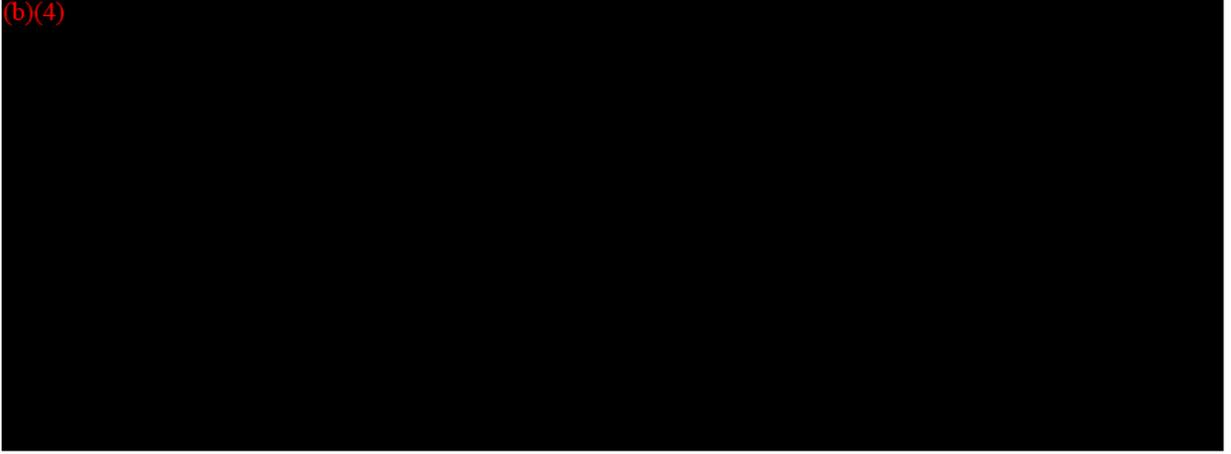
(b)(4) [Redacted]

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(b)(4)



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10) Please confirm that you have included all of the warnings, cautions, and precautions listed for power muscle stimulators as specified in both guidance documents for TENS devices and Powered Muscle Stimulators. Please be advised that further recommendations regarding labeling for your device cannot be made until you provide a more suitable predicate and/or clinical data as described above. Please insure that the labeling is consistent with TENS indications for use, and that the instructions for use are consistent with a predicate and/or clinical data provided in response to question # 1 above.

Our device labeling has incorporated the applicable statements from TENS and Powered Muscle Stimulator guidance documents.

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(b)(4)

11)



Our firm believes that redesigning the device is not a “least burdensome” resolution. The device user interface does include a screen that reads “DIAG”, when it is operated in a secondary and optional mode. The purpose of this mode is to assist the practitioner in determining the optimal placement of the device. Our device labeling makes no statements or implications that the device is intended to diagnose any disease or condition. Our firm believes that an appropriate, least-burdensome approach to this issue would be to modify our labeling to specifically and proactively state that the device does not diagnose any disease or condition, and that the “DIAG” reading is a symbol for this secondary mode of operation.

Specifically, our firm will add the following statement to our labeling where “DIAG” is discussed:

Important: The InterX5000 is not intended to diagnose any medical condition. The “DIAG” mode functions only to assist the practitioner in determining optimal placement of the device.

K042912 Additional Information

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12) We are concerned that the labeling you have provided for the predicate Fenzian System is from their European site. Although this labeling is accessible via the Internet, the European labeling is not regulated by the FDA and is therefore not cleared labeling for the Fenzian System in the United States. Please be aware that the Fenzian System can only be used as a predicate based on the device description and labeling that they have provided to the FDA.

It is our understanding, based on our telephone conversation of 12/17/04, that no additional information is required in response to this item.

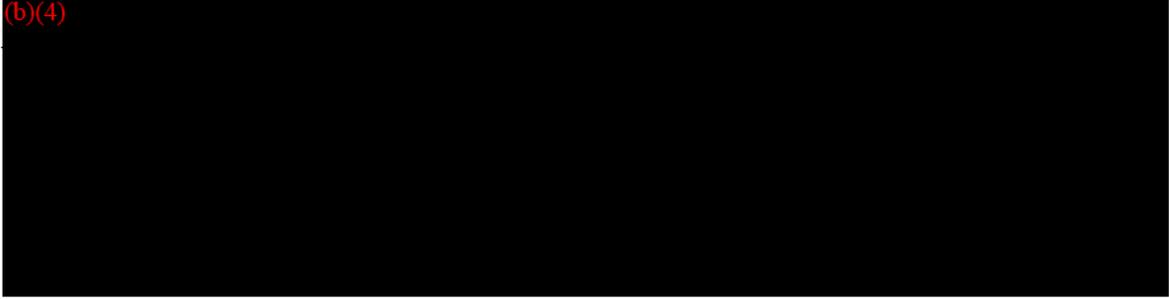
K042912 Additional Information

February 15, 2005

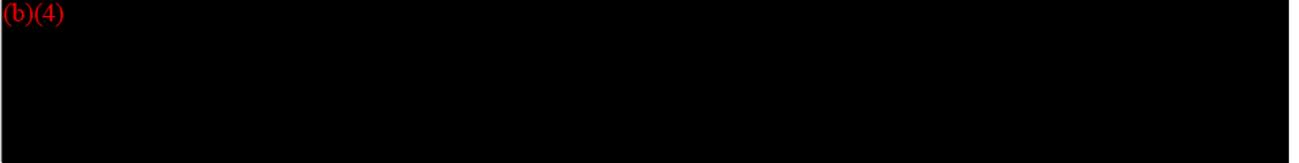
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14) We were unable to locate an architectural design chart and hazard analysis for the software. Please provide these documents, or please indicate where they have been previously provided.

It appears that these were inadvertently excluded from the submission. Our Risk Analysis document, which includes a Safety Architecture Summary, is attached to this response (Attachment 3).

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ATTACHMENTS

1. Article and book excerpt
2. Electro-Acuscope Labeling
3. Risk Analysis