CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

TITLE:	A single site, 6 week, randomized, double-blind, placebo controlled trial to study the tolerability, safety and efficacy of a daily fixed dose of Alpha-Stim® AID, a Microcurrent and Cranial Electrotherapy Stimulation (CES) devise, in adult patients from 21-65 years of age with Major Depression Disorder (MDD), followed by a 2 week open extension phase
PROTOCOL NO.:	PR101 ASPIRE® Protocol #520160224
SPONSOR:	Electromedical Products International, Inc.
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SITE(S):	Advanced Psychotherapeutics 1047 Vista Park Drive, Suite A Forest, Virginia 24551 United States
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Please read this form carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. If there are any words or information that you do not understand, the study doctor or study staff will explain them to you. Reading this form and talking to the study doctor or study staff may help you decide whether to participate or not. If you decide to take part in the research study, you must sign the end of this form. Before you have anything done for this research study, you must sign this form.

"You" in the form refers to subjects eligible to understand the purpose of the study and hence to be able to give consent for participating in the study.

INTRODUCTION TO THE RESEARCH STUDY

You are being asked to take part in this research study because you are a physically healthy adult. This research study involves the use of the Alpha-Stim® AID microcurrent and cranial electrotherapy stimulator (Alpha-Stim® AID stimulator) (manufactured by Electromedical Products International, Inc.).
Alpha-Stim® AID stimulator has been cleared by the FDA for anxiety, depression, insomnia and pain. Alpha-Stim® AID stimulator can only be bought with a doctor's prescription.

Your participation is entirely voluntary.

Purpose of THE research STUDY

This study's primary objective is to look at the effect on the safety and tolerability of Alpha-Stim® AID stimulator (manufactured by Electromedical Products International, Inc.) in adult patients with Major Depression Disorder (MDD) compared to sham (no active treatment with the stimulator).

The purpose of this study is to:

a) Investigate the effects of the short-term treatment of Alpha-Stim® AID stimulator on mood measures in adult patients with Major Depression Disorder (MDD).

b) To evaluate the safety and tolerability of short-term treatment with Alpha-Stim® AID (Alpha-Stim® AID stimulator).

c) To evaluate the impact of an open phase in which all study subjects have treatment with the Alpha-Stim® AID stimulator.

INFORMATION ABOUT THE STUDY

If you agree to participate in this research study, you will be randomly (by chance, like flipping a coin) assigned to either Group 1 or 2. You will continue whatever medication you use that has been evaluated as acceptable by the study doctor:

Group 1:
6 wks. Alpha-Stim® AID stimulator will be used one hour daily, followed by 6 weeks of daily one-hour active treatments.

Group 2:
6 wks. Sham Alpha-Stim® AID stimulator will be used one hour daily, followed by 6 weeks of daily one-hour active treatments.

The use of Alpha-Stim® AID stimulator will be started on Study Visit 2.
Daily one-hour Alpha-Stim® AID stimulator treatments using ear clip electrodes with active current set at a fixed level of 100 µA 0.5 Hertz will be used for active Alpha-Stim® AID stimulator treatment group for 6 weeks. For the sham group, the Alpha-Stim® AID stimulator's ear clips will not emit electricity. All other procedures will be the same for the sham group as the active Alpha-Stim® AID stimulator group. The first and last treatment session will take place at the research study office. At the end of the study, you will be offered to use an unlocked active Alpha-Stim® device for treatment for six weeks.

You will have a 1 in 2 chance (50%) of getting the active Alpha-Stim® AID stimulator. Neither you nor the study doctor/study staff will know whether you will be on active or sham Alpha-Stim® AID stimulator. At the end of the study, you will be offered to use an unlocked active Alpha-Stim® device for treatment for six weeks.

Your participation may last about 6 weeks and will include 3 study visits and at least one Study Screening Visit. You may be asked to come to the study site for additional study visits if the study doctor feels it is necessary. A total of 141 subjects will be recruited.

WHAT WILL HAPPEN DURING THE STUDY

Study Screening Visit (Visit 1)

If you decide to participate in this study and qualify for the study based on being a medically stable, healthy adult between the ages of 18-65 with symptoms of depression, you will be asked to sign this informed consent. Then you will have some tests done (screening procedures) to see if you can continue in the study. If you are on antidepressants, you will continue to take them.

This screening process could take up to 1 hour to complete and usually results in the immediate entry into the study as Study Visit 2. Otherwise there is a two-week allowance for the screening process. During the screening phase, the following procedures will occur:

- You will be asked about your medical and mental health history, including what medicines you are currently taking as well as OTC (nonprescription) medications and supplements.
- You must be between 18 and 65 years old.
- As we are looking for medically healthy subjects, if you have had such events as a recent heart attack, heart problems, cancer, hepatitis or stroke, we want to let you know you will not be allowed in the study.
- The psychiatric diagnosis of Major Depressive Disorder will be verified using the MINI
- You will be assessed on a depression scale (HAM-D)
- You will be asked about suicidal behavior.
- You will be asked if you have any unusual physical symptoms.
- Fertile females will be asked if they are pregnant
- You will be asked if you are abusing drugs or alcohol.

You should tell the study doctor about all of the medicines and supplements that you are taking. This will help the study doctor to find out whether the medicine(s)/supplements you take qualify you for the study.

Once you have signed the form, you will continue or return to the study site for Study Visits 2 through 4. If the study doctor feels it is necessary, more study visits can be scheduled. If you wish to continue in this study, you will be given the Alpha-Stim® AID stimulator on Study Visit 2. The first treatment of the Alpha-Stim® AID stimulator will be given to you while at the study site during Study Visit 1 or 2. All other treatments will be given at home. It will be important to use the Alpha-Stim® AID stimulator exactly as instructed by the study doctor.

Study Visit 2: Day 1, (up to 14 days after screening)

If you qualify and wish to continue with this study, you can formally enter the study. If not on the same day of screening, the following procedures will occur:

- Your general health will be assessed
- You will be asked about any medicines you have been taking.
- Fertile females will be asked if they are pregnant or planning on becoming pregnant in the next 2 months.
- You will be reassessed on a depression scale using the HAM-D
- You will be asked if you are abusing drugs or alcohol.

You will be given Alpha-Stim® AID stimulator. You will be asked to keep a record of the use of Alpha-Stim® AID stimulator each day by using the stimulator for an hour and documenting the time and day you used the stimulator.

- You will get a telephone call from the study site a few days after Study Visit 2 to make sure that you are not having any problems with the stimulator nor having any untoward effects or worsening of your depressive symptoms.

NOTE; Study Visits 3, 4 (weeks 3, 6)

List of questionnaires and rating scales to be used in all subsequent visits:

1. HAM-D (17-item Hamilton Depressive Rating scale)
2. Columbia Suicide Screening Questionnaire
3. SCL-90: Symptom Checklist-90 items

Study Visit 3 (week 3), the following procedures will occur:

- A detailed list of physical symptoms will be asked
- You will be asked about any other medicines you have been taking.
- You will be asked about any problems or illnesses you have had.
- Your mental status will be assessed for depression and suicidal ideation.
- Fertile females will be asked if they are pregnant
- You will be asked if you are abusing drugs or alcohol.
- Note that on Study Visit 3, you will not use the Alpha-Stim® AID stimulator at home before the visit. Instead you will bring the Alpha-Stim® AID stimulator to the clinic and show the personnel how you use it to document how you are using the stimulator.

Study Visit 4 (week 6)

This is the last study visit which will be on week 6. The following procedures will occur:

- You will be asked about any other medicines you have been taking.
- You will be asked how Alpha-Stim® AID stimulator affects your various body functions using a detailed list of physical symptoms.
- Your mental status will be assessed for depression and suicidal behavior
- You will be asked about any problems or illnesses you have had during this time.
- Fertile females will be asked if they are pregnant

- You will be asked if you are abusing drugs or alcohol.

You will be asked if you want to take part in the active phase of the research study. In this phase all study participants receive active Alpha-Stim® AID stimulator to use at home for an additional 6 weeks.

NOTE; Study Visits 5, 6 (weeks 9, 12)

List of questionnaires and rating scales to be used in all subsequent visits:

1. HAM-D (17-item Hamilton Depressive Rating scale)
2. Columbia Suicide Screening Questionnaire
3. SCL-90: Symptom Checklist-90 items

Study Visit 5 (week 3 of active treatment phase), the following procedures will occur:

- A detailed list of physical symptoms will be asked
- You will be asked about any other medicines you have been taking.
- You will be asked about any problems or illnesses you have had.
- Your mental status will be assessed for depression and suicidal ideation.
- Fertile females will be asked if they are pregnant
- You will be asked if you are abusing drugs or alcohol.
- Note that on Study Visit 5, you will not use the Alpha-Stim® AID stimulator at home before the visit. Instead you will bring the Alpha-Stim® AID stimulator to the clinic and show the personnel how you use it to document how you are using the stimulator.

Study Visit 6 (week 6 of active treatment phase)

This is the last study visit which will be on week 12. The following procedures will occur:

- You will be asked about any other medicines you have been taking.
- You will be asked how Alpha-Stim® AID stimulator affects your various body functions using a detailed list of physical symptoms.
- Your mental status will be assessed for depression and suicidal behavior
- You will be asked about any problems or illnesses you have had during this time.
- Fertile females will be asked if they are pregnant
- You will be asked if you are abusing drugs or alcohol.

ALL EQUIPMENT MUST BE RETURNED TO THE STUDY DOCTOR. YOU WILL THEN HAND IN THE ALPHA-STIM® AID MICROCURRENT AND CRANIAL ELECTROTHERAPY STIMULATOR. IF THE STUDY DOCTOR IS NOT YOUR MENTAL HEALTH CARE PROVIDER YOU WILL BE ASKED TO RETURN TO YOUR REGULAR MENTAL HEALTH CARE PROVIDER TO CONTINUE YOUR TREATMENT FOR YOUR DEPRESSION.

YOUR ROLE IN THE STUDY

Your responsibilities as a study subject include the following:

- Provide truthful information about your medical history and current conditions. This includes drug use and pregnancies.

- Tell the study doctor about any problems you have during the study.
- Use Alpha-Stim® AID stimulator as directed by the study doctor and study staff.
- Do not take any medicines (including over-the counter medicines and supplements) without first talking to your study doctor about it.
- Do not share Alpha-Stim® AID stimulator with anyone else. Keep the Alpha-Stim® AID stimulator out of the reach of children and persons of limited capacity to read or understand.
- You should not operate dangerous machinery, including an automobile, until you are certain that the Alpha-Stim® AID stimulator does not affect you adversely.
- Inform the study doctor if you have been in a research study in the last 30 days or are in another research study at that time.

RISKS OF THE STUDY

Risks of Alpha-Stim® AID stimulator

During studies of adults the side effects reported were mild, transient and uncommon. No serious adverse events have been reported during the 39 years that Alpha-Stim® stimulators have been on the market.

The most common adverse events (less than 1 %) were non-serious:

- skin irritation at the site of the electrodes,
- dizziness,
- headache.

Both dizziness and headache frequently occur when the current is set too high for the individual and these symptoms tend to disappear when the current is decreased. One report of leg pain was found to be caused by a pinched nerve and not the Alpha-Stim® stimulator treatment.

While it is unlikely that Alpha-Stim® AID stimulator will interact with over-the-counter medications, we cannot predict how Alpha-Stim® AID stimulator will interact with such medicines so please let us know of any changes in what you take. Inform us immediately if you experience unusual side effects.

Risk of Questionnaires

The evaluations and questionnaires used in this study include questions which are personal and which ask specifically about your mood. This may make you feel uncomfortable or upset.

Reproductive Risks

Women Who Can Get Pregnant or Are Breastfeeding

If you are a fertile woman, the study doctor will ask to see if you might be having a baby. You should not have unprotected sex during your participation in this study. If you have sex, you must use birth control to be in the study. You must use birth control during the study and for **at least 30 days following the last use of the Alpha-Stim® AID stimulator**.

Your study doctor will talk to you about birth control, and answer any questions you might have. While there is no evidence that Alpha-Stim® AID stimulator's use should be contraindicated in pregnancy, it is unknown whether the use of Alpha-Stim® AID stimulator can be harmful to an unborn baby, or to babies who are breastfeeding. If you think you might be having a baby or miss a period, tell the study doctor right away. If you get pregnant during the study, you will be asked to stop the study. You may be asked for information about the pregnancy and the outcome of your pregnancy.

Unknown Risks

You might have side effects or discomforts that are not listed in this form. Some side effects may not be known yet. New ones could happen to you. Tell the study doctor or study staff right away if you have any significant problems.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

You do not need to take part in this research study as participation is totally voluntary. This research study is to collect data and is not to provide treatment for your depression. If you do not wish to take part in this research study, there are numerous alternative treatments available to treat your depression. These include psychotherapy, change in lifestyle, support groups, medication and the use of devices such as the Alpha-Stim® AID stimulator. Please discuss these options with your study doctor or your primary care physician before deciding to participate in this research.

POTENTIAL BENEFITS OF PARTICIPATING IN THE STUDY

You may or may not receive any benefit from being in the study. It is possible that you may get better, stay the same, or get worse. If you take part in this study, the characteristics of Alpha-Stim® AID stimulator in depression will be better known and may help people with depression in the future.

COSTS OF PARTICIPATING IN THE STUDY

The study device and all tests, procedures and visits required by the study are provided at no cost to you by the sponsor, Electromedical Products International, Inc., who pays for them.

YOUR PAYMENT FOR BEING IN THE STUDY

You will receive $30 for each session for a maximum of $180 for being in this study. You will be paid at the end of each study visit. If you do not finish the study, you will only be paid for the visits you completed. Upon completion you will be given a $30 voucher, included as part of the $180.

STUDY INVESTIGATOR PAYMENT

In this study, Electromedical Products International, Inc. is paying for the studies, as well as the study doctor and study staff for their work.

COMPENSATION FOR INJURY

If you become ill or are hurt while you are in the study, get the medical care that you need right away.

If you are injured as a direct result of being part of this study, the study doctor will provide usual mental health care. If this occurs, you will not have to pay medical expenses beyond those normally covered by your insurance. No additional financial help will be given.

You still have the right to make a claim through the legal system even if you sign this form, accept medical care, or accept payment for medical expenses.

CONFIDENTIALITY OF PERSONAL INFORMATION

Records created by a doctor or hospital as parts of medical care are called medical records. Records created by a research study are called research records. The records that will be collected, used, and shared for this study may include your research record, supporting information from your medical records, results of tests (laboratory, diagnostic or other), and observations made during your participation in the research study.

As part of this study, the study doctor and staff will record health information about you that contains your name and other personal identifiers. Authorized representatives Electromedical Products International, Inc., Aspire IRB (the Research Ethics Review Board that reviews this study), the Food and Drug Administration (FDA) and other US governmental agencies, and possibly governmental agencies of other countries, will be given access to these records on request and may copy them. Copies of the study records that do not include your name but may be traced back to you may be given to study sites, Aspire IRB and laboratories working with the sponsor on this study. The sponsor may send a copy of the records to the FDA or other regulatory agencies such as governmental agencies in other countries.

Absolute confidentiality cannot be promised because information needs to be shared as described above. However, information will be collected and shared following professional standards of confidentiality.

Information and results from this study may be presented at meetings or published in journals. Your name, and information that can easily be traced back to you, will not be included in presentations and publications.

For your safety, the study doctor can provide a note to take to your regular care provider notifying that you are in this study if the study doctor is not your regular care provider. Please discuss any concerns about this with the study doctor.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT THE STUDY

You can ask questions about this form or the study at any time. You may have questions about the research study, a research related injury, or payment during the study. You may have other questions.

Feel free to contact the study doctor or study staff with any questions, complaints or concerns at any time during the study. Their telephone number is printed on the first page of this form.

If you have any questions or complaints about your rights as a research subject, you should contact Timothy Barlcay, Ph.D. and Aspire IRB at your earliest convenience.

You may also contact the Study Subject Adviser if you are considering taking part or discontinuing in this research study and have questions about your rights.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 1-877-366-5414 (toll-free), email@aspire-irb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Although Aspire IRB has approved the information provided in this informed consent form and has granted approval for the investigator to conduct the study this does not mean Aspire has approved your being part of the study. You need to read the information in this informed consent form for yourself and decide whether or not you want to be in this study.

VOLUNTARY PARTICIPATION

Entering a research study is voluntary. Anyone who is asked to be in a research study can say no. No one has to become a research subject. There will be no penalty or loss of benefits to which you are otherwise entitled. No doctor can discriminate against you or treat you differently if you choose not to be in a research study.

If you start a research study, you may stop at any time. There will be no penalty or loss of benefits to which you are otherwise entitled. You do not need to give a reason. If you stop, it is in your best interest to tell the study staff and follow any instructions that they may give you.

The sponsor and the study doctor may stop the research or stop your participation in it at any time. This may be done for any reason (for example, if you need additional medicine, if you do not follow the study plan, if you experience a study-related injury, or for administrative reasons) and this termination does not require your agreement.

NEW INFORMATION ABOUT THE STUDY

The information in this form reflects what is known about the research study at the time it is signed. If any new information is discovered during the research study that may affect whether you want to continue to take part, you will be informed.

STATEMENT OF CONSENT

I have read this form. I know that this is a research study. I have been told about the risks and potential benefits of participating in the study. I have asked all the questions I have about the study and have received answers to my questions. I know that I am free to withdraw from the study at any time without any penalties or loss of benefits.

I will notify the study doctor, the study staff if I choose to stop the study so that my stopping will be done in the best way so as to not harm my health. I will be given a signed and dated copy of this form to keep. By signing this consent form, I am not giving up any of my legal rights.

I agree to participate in this research study.

_____ ____/____/____
Signature of Subject Date: MO/DAY/YR

_____
Printed Name of Subject

CERTIFICATION OF THE PERSON WHO EXPLAINED THE ICF
I have explained the details and the goals of the above study. I have given enough time and have provided a calm place to allow reading of the ICF to the subject who has signed this form. Opportunities were given to ask questions and to hear the answers about the nature, risks and benefits of participating in this research study. I understand that the subject understands the commitments that are required to participate and the subject is in agreement.

_____
Signature of the Person Explaining Consent

_____
Printed Name of the Person Explaining Consent

_____
Signature of the Principle Investigator (if not the Person Explaining Consent)

_____
Printed Name of the Principle Investigator (if not the Person Explaining Consent)

HIPAA AUTHORIZATION AGREEMENT
Permission to Review, Use and Release Information about You for Protocol PR101

INTRODUCTION

You are being asked to read, review, and sign this authorization agreement as a result of a federal law on the privacy of identifiable health information. The law is called the federal Health Insurance Portability and Accountability Act (HIPAA). It requires that research subjects get written notification about the collection, use and disclosure (sharing) of health information that can identify them. In addition, it requires researchers (like the study doctor) to ask research subjects for permission to use and disclose identifiable health information for the purpose of this research study.

Signing this authorization agreement authorizes the study doctor and study staff to collect health information that can identify you and to use and disclose this information to the parties specifically named in this authorization agreement.

EXPLANATION OF AUTHORIZATION

Information used and disclosed may include the entire research record, supporting information from your medical records, results of laboratory, diagnostic, or other tests, and clinical and research observations made during your participation in the research study.

As part of this study, the study doctor and staff will record health information about you that contains your name and other items/characteristics (e.g. age and gender) that can be used to identify you. The health information identifying you will remain in the research records indefinitely. In addition, the records may be kept indefinitely. Authorized representatives of Electromedical Products International, Inc., Aspire Independent Review Board (a Research Ethics Review Board that reviews this study), the Food and Drug Administration (FDA) and other US governmental agencies, and possibly governmental agencies of other countries, will be given access to these records on request and may copy them. Copies of the study records that do not include your name but may be traced back to you may be given to Electromedical Products International, Inc., and laboratories working with the sponsor on this study. The sponsor may send a copy of the records to the FDA or other regulatory agencies such as governmental agencies in other countries. By signing this form, you are authorizing this use and disclosure.

Because of the need to release information to these and other parties, absolute confidentiality cannot be guaranteed. After its release, information that can identify you may no longer be protected by federal privacy rules. However, information will be collected and shared following professional standards of confidentiality.

This Authorization is valid once it is signed and dated by you. This Authorization has no expiration date, unless governed by state law, which requires a specific date of expiration. If state law applies, the authorization will expire December 31, 2054.

Information and results from this study may be presented at meetings or published in journals. Your name, and information that can easily be traced back to you, will not be included in presentations and publications.

SUSPENSION OF YOUR RIGHT TO ACCESS PERSONAL INFORMATION

Your research records may be used to make health care decisions about you. Under federal privacy rules you have a right to inspect and obtain a copy of your personal health information, including personal health information maintained in the study records. However, the right to inspect and obtain your personal health information in the study records will be suspended during the study to keep from spoiling the study results. Your right of access to the study records will be reinstated after the research is completed.

If there is a medical need during your participation, study records may be made available to you, or to medical professionals who are caring for you, as needed for your care.

VOLUNTARY PARTICIPATION

Your authorization to use and disclose your identifiable health information for the purpose of this research study is voluntary. If you decide not to sign this authorization, it will not affect your healthcare payment or enrollment in any health plans or affect your eligibility for benefits. However, if you do not provide your written authorization for the use and disclosure of your identifiable health information, you cannot participate in this research study.

In addition, your participation in the overall research study is entirely voluntary. You may refuse to participate or may quit at any time during the study. All you have to do is tell the study doctor.

If you decide to stop participating in the research study, you may also end your authorization allowing the researchers to collect, use and disclose any additional health information that could identify you. To end your authorization, you must notify the study doctor of your decision in writing. If you end your authorization, no new health information that can identify you will be gathered from you or your existing medical records. However, information that is in your study records at the time that your authorization is ended cannot be removed.

You may freely ask questions about this authorization agreement now or at any time. If anything causes you concern, or you have questions you may contact the study doctor or study staff at the telephone number printed on the first page of this form.

STATEMENT OF AUTHORIZATION

I have read this authorization agreement and its contents were explained. My questions have been answered. I voluntarily authorize study staff to collect, use and disclose my health information as specified in this authorization agreement. I will receive a signed and dated copy of this authorization agreement for my records. By signing this authorization agreement, I am not giving up any of my legal rights.

_____ ____/____/____
Signature of Subject Date: MO/DAY/YR

_____
Printed Name of Subject

CERTIFICATION OF THE PERSON WHO EXPLAINED THE HIPPA FORM

I have explained the details and the goals of the authorization. I have given enough time and have provided a calm place to allow reading of the HIPAA form to the subject who has signed this authorization. Opportunities were given to ask questions and to hear the answers about the nature of this authorization. I understand that the subject understands and gives informed authorization.

_____
Signature of the Person Explaining Consent

_____
Printed Name of the Person Explaining Consent

_____
Signature of the Principle Investigator (if not the Person Explaining Consent)

_____
Printed Name of the Principle Investigator (if not the Person Explaining Consent)