

CLINICAL PROTOCOL # SAIRB-16-0010

Measuring the effects of the IonCleanse® by AMD on children with autism spectrum disorders

Sponsored by A Major Difference, Inc.

1. Study Synopsis

A Major Difference, Inc. (“AMD”)¹ in partnership the Therapy House, LLC,² have created an investigational study looking into the efficacy of using the IonCleanse® by AMD total body detoxification system for children with Autism Spectrum Disorders (“ASD”). The study is a prospective study that will be using a currently marketed product in treatment of symptoms of ASD in children. There will be no costs incurred by participants in the trial.

This study is planned and budgeted for 60 days and 30 children. Children who meet the inclusion criteria will be randomly selected either to receive the therapy (described next) or to be entered into the control group and receive no therapy. The group will be split evenly. For those receiving therapy, they will use the IonCleanse system for the recommended time and frequencies (based primarily on age). All participants will be evaluated pre and post by professional occupational therapists who will utilize the *Battelle Developmental Inventory, Second Edition*³ and the *Sensory Profile 2*⁴ as the measure for gauging effectiveness.

2. Background

AMD is the manufacturer and distributor of the IonCleanse® total body detoxification foot bath systems. AMD was founded in 2002 by Robert Moroney, and has sold over 13,000 units in 39 countries. With over 13 years of experience, AMD has learned how severely the planet and people are impacted by toxicity. With anecdotal and empirical evidence supporting our theories that children with ASD may benefit from detoxification and the use of our products, AMD entered the autism community in late 2014 promoting its IonCleanse system to parents of children on the spectrum.

In December of 2014, AMD was approached by The Thinking Moms’ Revolution to do a parent evaluation of the IonCleanse by AMD as it relates to children with ASD. The first of the 2-part study completed in April of 2015.⁵ This evaluation proved enormously successful and has paved the way for a wave of interest in the autism community.

In the summer of 2015, AMD was approached by Ronna Hochbein, the owner and lead therapist at Therapy House, LLC, to investigate a research project looking into the efficacy of the IonCleanse by AMD system for children with ASD as measured by professional testing standards, namely the Battelle 2 Kit mentioned above. This research will further advance AMD’s efforts in the autism community, and will provide a more scientific, unbiased testing method. With the help of Ronna and her practice, we hope to publish the results in trade publications which will greatly expand our reach into the practitioner market for ASD.

The study is considered under FDA regulations as non-significant risk clinical trial. The trial will comply with FDA regulations by having the approval of a qualified Institutional Review Board.

3. Objective of the Study

The purpose of the currently proposed research study is to determine the ability of the IonCleanse® Solo device by AMD total body detoxification system for children with Autism Spectrum Disorders (“ASD”). The goal is to show that symptoms of ASD can be improved as evaluated by acceptable diagnostic technique.

Specific Skill Symptoms to be evaluated are: (From the Battelle Developmental Inventory)

- Adaptive
 - Self Care
 - Personal Responsibility
- Personal-Social
 - Adult Interaction
 - Peer Interaction
 - Self Concept and Social Role
- Communication
 - Receptive Communication
 - Expressive Communication
- Motor
 - Gross Motor
 - Fine Motor
 - Perceptual Motor
- Cognitive
 - Attention and Memory
 - Reasoning and Academic Skills
 - Perception and Concepts

4. Subject Selection

Inclusion Criteria

Children (male or female) between the ages of 2 – 7 ys. 11 months.

Diagnosed symptom of ASD within 30 days of starting the trial.

Free from any current medical condition that would preclude the deionization procedure.

Exclusion Criteria

Child under the age of 2 or over the age of 8.

Child’s parent or guardian is unable to provide Informed Consent

Child is on any form of pharmacologic medication for treatment of ASD.

Any open wounds or signs of irritation on the feet at the time of therapy.

5. Study Procedure

Study participants will receive treatments with IonCleanse Solo device using the parameters defined in the User's Manual for the system. The water temperature will be 80-90 degrees Fahrenheit

The treatment will be given as follows:

A therapy schedule of Monday, Tuesday, Thursday, Friday will be used. Session times would be based on age:

Age 2-4: 20 minute sessions

Age 5-7 yrs 11 months: 30 minute sessions

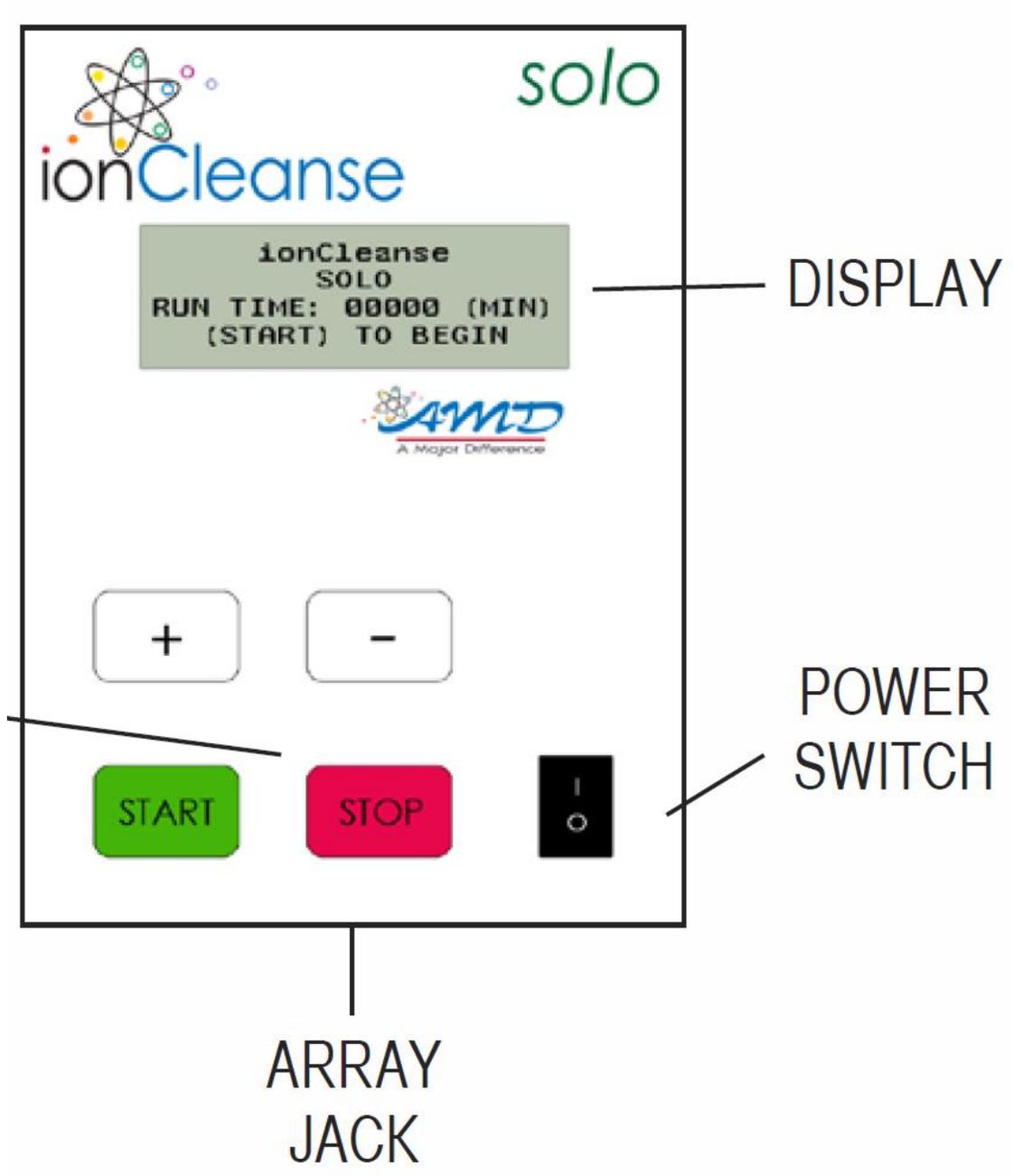
Study Device.



The IonCleanse Solo by AMD's proprietary and patented technology results in only biocompatible electrical frequencies entering the water. Biocompatible frequencies elicit a relaxation response in the body. Concurrently, the electrical frequencies create an ionic field that cleanses and purifies through the power of ions. The IonCleanse process ionizes the water, as H₂O is split into OH⁻ and H⁺ ions. These ions attract and neutralize oppositely charged toxins.

The IonCleanse by AMD has been on the market since 2002. There have been no reported adverse effects in using the IonCleanse. All components are medical-grade quality, and the proprietary design ensures that the user will never be exposed to dangerous electrical frequencies. The IonCleanse by AMD complies with CE and FCC safety requirements and has received clearances from these authorities.

IonCleanse Control Panel



Study Design

This will be a prospective randomized clinical trial involving 30 children. Children with symptoms of ASD who meet the inclusion criteria, upon obtaining informed consent, will be entered into the trial. Each patient will be randomized to a test group which will receive the deionization procedure, and a control group which will receive a foot bath with no deionizing used.

Of the 30+ participants, 50% will be randomly selected to receive the IonCleanse by AMD sessions, and 50% will be part of the control group that will receive no therapy. Pre and post evaluations will be performed for all 30 participants, and the evaluators will be blind as to which children received treatment and which did not. The parents of the children and the children cannot be blinded as they will observe the water which may change color during actual therapy. The blinding of the evaluators as to the therapy/no therapy should be sufficient to assure a valid conclusion. Each patient will have total of 32 treatments. The pre-evaluation testing will be done within 7 days of beginning therapy and post-evaluation will be completed with 7 days of the last treatment

After 60 days, success will be considered a significant reduction in ASD symptoms as determined by a repeat of the entry requirements assessment and a comparison of the treated patients to the control patients. For purposes of this study a greater than 25% overall reduction ASD symptoms will be clinically significant.

Patient Recruitment.

Current patients at the study site who appear to meet the inclusion criteria will be offered an opportunity to participate in the study. In addition, the Internet may be used to recruit patients using accepted internet sites for recruiting patients to clinical trials

Scope

Sample Size	30 children
Control Group	50% will receive therapy, 50% will not receive therapy
Ages	2 years through 7 years 11 months
Diagnosis	Autism Spectrum Disorder
Evaluation Methods	Battelle Developmental Inventory 2 nd Edition Sensory Profile 2
Therapy	IonCleanse by AMD
Session Times	15-30 minutes (determined by age)
Session Frequency	4 times/week
Time Frame	60 days
Evaluators	TBD – Therapists from Therapy House, LLC

Study Dates

Start Date	TBD pending IRB Approval.
Conclusion	60 days after the study begins

Control Group & Participation

Participants will receive the therapy and the pre and post evaluations at no charge. Participants who fulfill their obligations will have access to their child's test results following the conclusion of the study. Participants who drop out will not receive their child's test results. No other compensation will be granted.

6. Risk/Safety Information –

There are no expected risks of study related procedures that are not considered standard of care

7. Monitoring/Reporting of AE/SAE –

The sponsor will monitor AEs and SAEs. A serious adverse event (SAE) for purposes of this study is defined as any untoward medical occurrence that:

1. Results in death,
2. Is life-threatening
3. Requires inpatient hospitalization or causes prolongation of existing hospitalization
4. Results in persistent or significant disability/incapacity,
5. Is a congenital anomaly/birth defect, or
6. Requires intervention to prevent permanent impairment or damage.

Because of the non-significant risk aspect of the study it is not anticipated that any safety events will occur. However, if a safety event occurs, safety events they will be collected from the subjects; and the sponsor will receive reports of collected safety events

8. Study Oversight

It is not anticipated that the study would need to be prematurely terminated. If however such conditions that would seem to indicate potential harm to the patients could occur, the study site in consultation with the sponsor will prematurely terminate the study.

The study will continually be made available for monitoring, auditing, IRB review and regulatory inspection by providing direct access to study related source data

9. Data Management

Data from the study will be collected at the study site, and provided to sponsor for data analysis. A simple analysis comparing pre procedure symptoms with post procedure symptoms will be performed, and a statically difference in measurement will be considered a success.

10. IRB Review/Ethics/Informed Consent

The protocol, informed consent document and relevant supporting information will be submitted to the IRB for review and must be approved before the study is initiated. In addition, any subject recruitment materials must be approved by the IRB prior to being used. This study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practice and applicable regulatory requirements. The study must be conducted in accordance with the regulations of the United States Food and Drug Administration (FDA) as described in 21 CFR 50 and 812 , applicable laws and the IRB requirements.

The Sponsor will submit any change to the protocol to the IRB for review and approval before implementation. A protocol change intended to eliminate an apparent immediate hazard to subjects may be implemented immediately provided the FDA and the reviewing IRB are notified within 10 working days.

It is the responsibility of the investigator to provide each subject with full and adequate verbal and written information using the IRB approved informed consent document, including the objective and procedures of the study and the possible risks involved before inclusion in the study. Informed consent must be obtained prior to performing any study-related procedures. A copy of **the signed informed consent must be given to the study subject.**

Patient Assent to be treated is required in studies involving children. In this study the IRB has been asked to waive this requirement due to the young age of the children to be included in the study (2 years through 7 years 11 months) and their medical diagnosis of Autism Spectrum Disorder. The sponsor does not believe the children would be capable of providing assent for the study.

11. Confidentiality

- a) Records identifying the subjects will be maintained by the sponsor and kept confidential.
- b) The United States Food and Drug Administration may inspect all records related to the study
- c) A study monitor, auditor, IRB and/or other regulatory authorities will have access to study-related medical records;
- d) Study-related records identifying the subject will be kept confidential and, to the extent permitted by applicable laws and/or regulations will not be made publicly available;
- e) If any results of the study are published, the subject's identity will remain confidential

12. Intended Use of the Data –

The expected end use of the data collected will be to demonstrate an effective treatment of symptoms of Autism Spectrum Disorders. This data may be presented for publication, and could be provided to FDA as part of the process to obtain approval to market the device for treatment of symptoms of Autism Spectrum Disorders.

13 Qualifications and Experience

Therapy House

Ronna Hochbein, Principal Investigator, is the owner and lead therapist has practiced OT for 22 years in the areas of hand therapy, neurology and pediatrics with the past 15 in early intervention as a therapist and evaluator. She graduated Magna Cum Laude from the University of Pittsburgh. She is the author of *Come What May, A Comprehensive Guide to Traditional and Non-Traditional Treatments for the Autism Spectrum* and lectures nationally on sensory processing and has guest lectured at the college level. She is a medical writer for The Age of Autism digital journal. Therapy House will be a fieldwork placement for Duquesne University in the upcoming year. She is also eligible to sit for the Certified Hand Therapy Exam.

Ronna is the parent of a young adult on the spectrum, and was research advisor for NY Times Best Seller's Jodi Picoult's autism book *House Rules*. She is certified in Therapeutic Listening, Advanced Listening and Level 1 Samonas Sound Therapy. She is a TACA Mentor, a biomed support group leader for ABOARD and knowledgeable of the casein free gluten free diet and all biomedical treatments for sensory processing, biochemistry and autism.

Therapy House employs 15 professional therapists who offer Occupational, Speech, Developmental, and Physical Therapy services.

References

¹ A Major Difference – www.amajordifference.com

² Therapy House, LLC – www.therapyhousellc.com

³ Battelle Developmental Inventory, 2nd Edition – www.riversidepublishing.com/products/bdi2/details.html

⁴ Sensory Profile 2 - <http://www.pearsonclinical.com/therapy/products/100000822/sensory-profile-2.html>

⁵ TMR Study - <http://thinkingmomsrevolution.com/the-thinking-moms-revolution-study-ioncleanse-by-amd-treatment-effectiveness-for-asd/>