# **Randomized Controlled Clinical Trial**

For The Evaluation Of

Product: The "Stirwand"

FINAL REPORT
SUBMITTED TO:
Quantum Age Water
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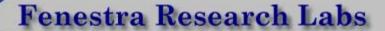
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Version 1.1

September 17, 2006

### **Randomized Controlled Clinical Trial**

For The Evaluation Of
Product: **The "Stirwand"**Final Report
Version 1.1

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# 1.0 Purpose

The purpose of this study was to test the effects of the "Stirwand" on parameters related to cellular hydration.

### 2.0 Study Overview

This was a 30-day 50-subject study. Each subject was to consume one-half their weight in ounces daily of purified water after being stirred with the **Stirwand** for 20-seconds just before drinking for the duration of this study. Twelve subjects from this study had blood draws to evaluate oxygen levels at baseline, at the second week mark, and on their final testing day of this study. All subjects tolerated this product well and there were no noted side effects for the duration of this study.

### 2.1 Water Amounts

Each subject was provided enough purified water for them to drink one-half of their weight in ounces daily.

### 2.2 Water Product

Each subject was instructed that they were only to consume their specific water product and under no circumstances were they to drink any other water product alone or in any water mixed product.

### 2.3 Contact Information

A contact phone number was provided each test subject so they could contact us for more water or a replacement "Stirwand" if they required any before there visit to the office.

# 2.4 Food Consumption

All subjects were instructed to make no changes to their daily food consumption in regards to the amount or the types of food they were consuming daily.

#### 2.5 "Stirwand"

Each subject was provided a "Stirwand" to take home with them for water technology use before drinking any water.

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**NOTE:** Compliance was monitored and maintained through bi-weekly phone calls.

# 3.0 Study Outline And Details

# 3.1 Purpose

To evaluate the "Stirwand", using scientifically proven methods of measuring hydration.

## 3.2 Study Type

\*Randomized Controlled Clinical Trial

## 3.3 Study Design

Evaluation, Randomized, \*\*Prospective Study (Data)

### 3.4 Official Title

A 30-Day, Randomized Control Clinical Study Evaluating the Hydration of purified water using the technology of the "Stirwand", according subjects with standard hydration measurements of hydration guidelines.

# 3.5 Further Study Details

Following an initial screening at the Visit 1 (week-0), subjects enter a 1 week baseline period (subjects are to refrain from taking any unnecessary OTC's, prescription drugs or natural products for the remainder of the study). Subjects who meet all inclusion and none of the exclusion criteria at the check at Visit 2 (week-1) will be provided; purified water, the "Stirwand", and protocol to follow for the duration of this study. Twelve randomized subjects have blood drawn for the purpose of measuring Oxygen Saturation through standard laboratory practices. The second evaluation on Visit 3 (week-3) was done following standard procedures and purified water was provided to the subjects for the remainder of this study. The same twelve

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randomized subjects had blood drawn for the purpose of measuring Oxygen Saturation through standard laboratory practices. Final evaluations of test subjects were done on visit 3 (week-2) of this study. The same twelve randomized subjects had blood drawn for the purpose of measuring Oxygen Saturation through standard laboratory practices.

- \*Randomized Controlled Clinical Trial (RCT): A prospective, analytical, experimental study using primary data generated in the clinical environment. Individuals similar at the beginning are randomly allocated to two or more treatment groups and the outcomes the groups are compared after sufficient follow-up time.
- \*\* Prospective Study (Data): Data collection and the events of interest occur after individuals are enrolled in a study. This prospective collection enables the use of more solid, consistent criteria and avoids the potential biases of retrospective recall. Prospective studies are limited to those conditions that occur relatively frequently and to studies with relatively short follow-up periods so that sufficient numbers of eligible individuals can be enrolled and followed within a reasonable period.

#### 4.0 Inclusion Criteria

### 4.1 Consent Form

Subjects who have signed a written informed consent consistent with required guidelines meet prior to participation in the trial.

### 4.2 Age and Gender

Subjects 18 years of age or older without any restriction to sex.

# 4.3 Optimal Wellness Test Indications

Subjects whose Optimal Wellness Test indicated they were at least 35% out of balance for standard Wellness in the Hydration and Toxicity indicators (in the red zone).

### 4.4 Protocol

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Subjects who were able to follow the protocol as designed by Quantum Age Water and Fenestra Research labs.

### 5.0 Exclusion Criteria

- Subjects with a history of serious diseases or illness diagnosed at this time.
- Subjects with known moderate or severe renal insufficiency.
- Subjects with a recent history (i.e., 6 months or less prior to Visit 1) of myocardial infarction.
- Subjects who regularly use oxygen therapy.
- Subjects with known active tuberculosis.
- Subjects with a history of cancer within the last 5 years.
- Subjects with treated basal cell carcinoma are allowed.
- Subjects who have undergone thoracotomy with pulmonary resection.
- Subjects who are currently in a pulmonary rehabilitation program or who have completed a pulmonary rehabilitation program in the 6 weeks prior to the screening visit.
- Subjects on any current medications that are diuretics, cardiac stimulants, or any other prescribed or non-prescribed medication that may alter testing results.

### **6.0** Measurement of Parameters

During this test the flowing parameters were measured using standardized equipment:

- Heart rate
- Blood pressure
- Respiration
- Pulse
- Oxygen saturation
- \*Optimal Wellness Test
- \*\* 12-Subjects have blood draws for Oxygen saturation

### 6.1 \*Optimal Wellness Test

Provides Analysis of:

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Test	Urine	Saliva
рН	X	X
rH2 (oxidation and reduction)	X	X
r (resistivity)	X	X
C (conductivity)	X	Х
Nitrate	X	
Ammonia	X	
Brix (refractometry)	Χ	
Specific Gravity	X	X
Oxidative Stress	X	Χ
Cellular Respiration	X	Х
Renal Balance	X	X
Hepatic Balance	X	X
Digestion	X	X
Hydration	X	X
Toxicity	X	Χ
Adrenal Balance	X	X

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Protein digestion	X	X
Carbohydrate digestion	Χ	X
Blood Sugar Balance	X	X
Anabolic State	X	X
Catabolic State	X	X
Surface Tension	Χ	X
Surface Tension	Х	Х

## 6.2 Parameters Provided by Optimal Wellness Test

# 6.3 Hydration

There are four **Optimal Wellness Test** parameters used to determine overall hydration:

Conductance

Resistivity

Surface Tension

Specific Gravity

This involves a proprietary mathematical formula based on the four parameters (Conductivity, Resistivity, Surface Tension, and Specific Gravity) to determine whether or not a person is moving towards or is within the wellness range. The more a person is outside the range for hydration Wellness the more dehydrated they are considered to be.

To measure the four components for cellular hydration computation it is vital to analyze saliva, and urine samples from the body.

The foundation of evaluating the electrical properties in the **Optimal Wellness Test** technology is the basic formula C = R/V, which is Ohm's Law. Through the interplay of voltage

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with both Conductivity and Resistivity some basic knowledge about intra and extra cellular hydration can be accessed. Conductivity is related to intracellular hydration and Resistivity is related to extra cellular hydration. With the fluid samples obtained from each person in the Quantum Age Water Study these parameters can be measured and evaluated.

Specific Gravity and Surface Tension pertain more to chemical content but still relate to electrical properties of the body. Surface tension is directly related to inward molecular attraction, with the obvious implication that if solids are suspended properly via molecular combinations with H20 then the fluids of the body will have lower surface tension. Specific gravity of any given bodily fluid reveals the content of solids in solution, with higher and higher concentrations of solids –both intra and extra cellular – raising the specific gravity number as a possible indicator of dehydration.

# 6.4 Conductivity

Conductivity is a measurement of the amount and quality of electrical current in the body. Salts are electrolytes and they are responsible for the electrical conduction of information in the body. Conductivity is the measurement of the quantity of current flow within the biological specimen and is an indicator of osmotic pressure, heat loss, and fluid balance. If the current in the body is too high or too low there will be symptoms of degeneration of the body. Osmotic pressure comes in to play also here.

# 6.5 Resistivity

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Resistivity reflects the flow of ions across cellular membranes.

The resistivity is the measurement of the relative concentrations of minerals contained within the tested sample. The slight difference in the concentration of minerals found in the plasma vs. the amount found inside the cells creates a voltage gradient called the membrane potential. Therefore, resistivity is a direct reflection of the body's ability to conduct electrical currents.

### 6.6 Surface Tension

The surface tension of fluids in the body can be compared through technological analysis with that of pure water. Higher surface tension implies a decreased capacity for cellular permeability for any given fluid.

Surface tension of a fluid can be defined as inward molecular attraction forces, which must be overcome to increase the surface area. Surface tension is the energy required to increase the surface area of a liquid by a unit amount.

In water the intermolecular hydrogen bonds are involved in the inward attraction forces. The surface tension of water at 20 degrees centigrade is  $7.29 \times 10^{-2}$  J/m<sup>2</sup>.

# 6.7 Specific Gravity

Mathematically specific gravity is similar to density. Specific gravity is defined as density of a substance divided by the density of water. Since the units will cancel out in any computation it simply means that the only difference between specific gravity and density is that the there are no

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units associated with specific gravity, as is the case with density.

With bodily fluids, density is a function of the types and amounts of solids found in solution. The more there is of substances in solution that are heavier than water, the higher the density will be. With dehydration, whether it is intra or extra cellular, the density of fluids will be higher because the water content goes down as the solids go up. The converse is true for increased hydration.

#### 7.0 Other Indicators

# 7.1 pH

The pH is a measurement of the concentration of hydrogen ions within the various body fluids. The lower the pH, the more acidic the solution; conversely, the higher the pH, the more alkaline the solution is. The pH is measured on a logarithmic scale, meaning that for each charge of one pH unit, there is a tenfold change in the concentration of H+ ions in the fluids.

The normal range for venous blood is 7.30 to 7.35. This slightly alkaline pH is due to the reservoir of bicarbonate ions in the blood that act as physiologic buffers and maintain the normal pH range. The perfect number for fasting urine and saliva is 6.4. These fluids tend to be more acid due to the removal of acid that is taking place in these body fluids.

# 7.2 ORP (Oxidation-Reduction Potential)

The oxidation-Reduction potential is a true value. It is the actual measure of the fluids millivolt (mV) potential, the measurement of the fluid's ability to donate or accept

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electrons. The higher the ORP, the more reduced intermediates are in the specimen, meaning the fluid is active, charged, and has the ability to create energy. When the fluid is oxidized, the fluid has lost its capacity to create energy.

## 7.3 Oxidative Stress (rH2)

Oxidation is the combination of oxygen with other elements. In physiological terms, oxidation is defined as the gain of an oxygen molecule or the loss of a hydrogen particle (electron), during cellular respiration. Through a complex series of reactions (ATP cycle), the energy source for all biochemical processes in the body, energy is ultimately produced. This step-by-step removal of pairs of electrons from a substrate is the means by which food is converted into cellular energy. The end result of cellular respiration is the creation of energy (ATP), carbon dioxide, water and metabolic isolates.

The rH2 value is a derived measurement. It is a calculation from the OPR (oxidation-reduction), the pH and the temperature of the fluid. The normal for urine is 22.5-24.5 and for saliva 21.5-23.5

### 7.4 Brix

The refractometer is an instrument that is used to relate the amount of refractive light in a liquid or a dissolved solid. The unit of measurement that the refractometer uses is called degrees Brix. The Brix number represents the amount of potential energy available. This potential energy is in the form of heat (calories), electro-magnetic attraction, conductivity, and matter.

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If the Brix number falls below 1.2 the oxygen levels in the blood may be decreased and the body will not circulate enough oxygen. If the Brix number falls above 5.49 the oxygen levels may be higher than it needs to be, resulting in calcium absorption problems. This number being brought within range will often have the largest effect on your client's state of well-being!

### 7.5 Urea numbers- Nitrate and Ammonium

Both of these numbers influence the electromagnetic picture of the body fluids. Together they determine the amount of energy being lost from the system. Nitrate and ammonium are related to digestion, and they provide a look at the amount of usable energy being produced by digestion. The chemical reaction that takes place between food and digestive enzymes is vital to Wellness. The correct balance of water, calcium, and oxygen in the body is necessary for usable energy to be the result.

The nitrate and ammonium particles are the result of poor digestion. For the liver to make energy the liver incites the urea cycle to occur. The body cannot use amino acids that have not been digested properly. Another cause of ammonium production is bacterial metabolism in the intestinal lumen. This released ammonium is absorbed and transported to the liver. The liver treats the nitrates and ammoniums as toxins because the poor digestion has rendered the byproduct unusable. This unusable material is converted into urea and stored in the body. Urea can only be stored for 72 hours before it becomes toxic, at that time the urea is broken down to urea salts of Nitrate and Ammonium Nitrogen. The numbers for perfect digestion are 3 nitrate and 3 for ammonium.

# 7.6 Toxicity

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Toxicity is an assessment of what the body is containing too much of causing a toxic relationship between the substance and the cellular body. Here we have several different mathematical representations of ammoniums, nitrates, salts, oxygen, urea's and other toxic materials that may be present in the body. Significant changes in toxicity have not been observed in studies less then three months in duration.

## 7.7 Protein Digestion

The importance of protease enzymes is directly related to protein digestion. Proteases refer to a group of enzymes whose catalytic function is to hydrolyze (breakdown) proteins.

Proteolytic enzymes are vital in digestion as they breakdown the peptide bonds in the protein to liberate the amino acids required by the body.

Enzymes break down undigested protein, cellular debris, and toxins in the blood, sparing the immune system this task. This measurement of protein digestion is a strong indicator of how well the cellular body can handle and destroy attacks on the body. One of the ways that acidity is created is through the digestion of protein. Therefore a protease deficiency results in alkaline excess in the blood.

# 7.8 Carbohydrate Digestion

Many of the vital chemical reactions that take place in the cell require energy, which is derived from the oxidation of the glucose within the cell. Measuring and evaluating carbohydrate metabolism provides you with a thorough look at the cellular functions, limitations and possible shortcomings of the body.

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## 7.9 Cellular Respiration

The series of metabolic processes by which living cells produce energy through the oxidation of organic substances. This measurement provides us a look at the most efficient way for cells to produce energy stored in food. Cellular respiration is a catabolic pathway for the production of adenosine triphosphate (ATP), a high-energy molecule, necessary for working cells. We provide a mathematical measurement of the bodies' ability to produce energy and predict how that ability can be enhanced as well as increase its efficiency.

# 7.10 Renal (Kidney) Balance

This calculation is a measurement of the kidneys ability to excrete istes products and the ability of the body to maintain the electrolyte balance. The proprietary measurement of fluids provides us a look at the function of and clues to rebalancing the kidneys. Hydration plays a significant roll in normalizing kidney function. Considerable changes in kidney function have not been seen in studies less than three months.

# 7.11 Hepatic (Liver) Balance

This measurement provides a look at the ability of the liver to impart its normal functions. Each day the liver is required to make millions of chemical reactions occur for necessary body functions. The pH plays an important roll in the ability of the liver to perform its functions because enzymes, hormones and many of the livers other chemicals are pH dependant for their strength and ability to provide

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reactions. The liver requires body fluids to be flowing and not stagnant to maintain normal functions. Changes in liver balance have not been seen in studies less than threemonths in duration.

#### 8.0 CONCLUSION

Significant changes were seen in the hydration and Oxygen saturation indicators. No other indicators had significant changes during the duration of this study.

### 8.1 CLINICAL DATA

Clinical data was collected and analyzed using analytical mathematical based standard science as described in the document. These analytical measurements concluded that overall average hydration increases were 23.5% for these subjects from their baseline numbers to their final numbers during this study. The 50-subjects overall Oxygen saturation increase was 9.4% for these subjects from their baseline numbers to their final numbers during this study. The 12-subjects who had blood draws during the length of this study saw an increase from their baseline numbers of blood Oxygen saturation for their third and fifth week testing on **averaging** of 9.82%.

### 8.2 Color Zone Indicators For Hydration

The color zone indicators for hydration, which were all in the red zone at the baseline of this study, all shifted more positively into the yellow and green zones by the final week of this study. This is a very powerful indicator as it measures and evaluates the body's cellular hydration levels.

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