The Clinical Effects Of A Fermented Cellulose Antioxidant On Oxidative Stress And Free Radical Production Within Physiological Parameters

Purpose: The purpose of this clinical pilot study is to evaluate the efficacy, palatability and consumer acceptance of a new "Soft Gel" nutritional product. If the study reveals substantial scientific evidence, this evidence can be utilized as proof to many of the thoughts, claims and remarks regarding this "Soft Gel" nutritional product. Additionally, the intent of this study is to observe and record the level of tolerance and/or associated difficulties in the consumption of this product. Finally, the findings from this study may be utilized to enhance consideration of additional applications and pertinent secondary applications and studies.

Preparation: Prior to the onset of the clinical trial a number of factors were determined. These included:

1. Determining the number of clinical participants (N=10)
2. Determining the length of the trial (90-days)
3. Determining the correct dosage to be consumed by each member of the clinical trial (15 Capsules per day broken down throughout the day)
4. Creating a clinical participant information sheet (This would explain to each participant exactly what they need to do each day and what would be expected of them each month and at the end of the study)
5. Creating a clinical participant release form relinquishing liability as well as allowing their personal information to be utilized in discussions and possible publications of the clinical trial results
6. Creating a comprehensive clinical questionnaire.
    a. This clinical questionnaire will allow for the subjective assessment of such factors as:
        i. Secondary or deleterious affects
        ii. Alterations in energy levels
        iii. Alterations in digestion function
        iv. General overall mood shifts
        v. Alterations in pain levels or inflammatory issues

Scientific Procedure:

1. A base number of clinical participants will be selected (N). (N =10)
2. At day (0) each participant was asked asked to complete
    a. Clinical participant information data sheet

   b. Clinical participant release form
   c. Comprehensive clinical questionnaire
3. At day (0) each participant underwent a battery of assessment tests including
   a. BTA analysis (Utilization of saliva and urine which provides rH2 factors denoted as oxidative stress determined at a specific physiological pH)
   b. Postural hypotension screening
   c. Indikan test
   d. Urine dipstick analysis
   e. HRV (Heart Rate Variability assessment)
   f. Weight assessment.
   g. DDFAO Analysis which includes measurements of specific free radicals)
4. Upon completion of all tests each clinical participant was given a direction sheet specifying
   a. The amount of Soft Gel to be consumed
   b. The best time of the day that this product should be consumed
   c. Specifics regarding nutritional supplement utilization (Participants stopped all additional nutritional support as we did not want or were unable to calculate the variances due to possible interactions or secondary affects)
   d. Dietary restrictions and considerations (No dietary alterations were recommended as they may alter the outcome of the study and create doubt as to which procedure is offering the greatest results)
   e. When their next appointment was scheduled
   f. Necessary preparations required for future testing
5. At day (30) each participant was asked to complete
   a. Comprehensive clinical questionnaire
6. At day (30) each participant underwent a battery of assessment tests including
   a. BTA analysis (Utilization of saliva and urine which provides rH2 factors denoted as oxidative stress determined at a specific physiological pH)
   b. Postural hypotension screening
   c. Indikan test
   d. Urine dipstick analysis
   e. HRV (Heart Rate Variability assessment)
   f. Weight assessment.
   g. DDFAO Analysis which includes measurements of specific free radicals)
7. Upon completion of all tests each clinical participant was given a direction sheet specifying

   a. When their next appointment was scheduled
   b. Necessary preparations required for future testing
8. At day (60) each participant was asked to complete
   a. Comprehensive clinical questionnaire
9. At day (60) each participant underwent a battery of assessment test including
   a. BTA analysis (Utilization of saliva and urine which provides rH2 factors denoted as oxidative stress determined at a specific physiological pH)
   b. Postural hypotension screening
   c. Indikan test
   d. Urine dipstick analysis
   e. HRV (Heart Rate Variability assessment)
   f. Weight assessment.
   g. DDFAO Analysis which includes measurements of specific free radicals)
10. Upon completion of all tests each clinical participant was given a direction sheet specifying
   a. When their next appointment was scheduled
   b. Necessary preparations required for future testing
11. At day (90) each participant was asked to complete
   a. Comprehensive clinical questionnaire
12. At day (90) each participant underwent a battery of assessment tests including
   a. BTA analysis (Utilization of saliva and urine which provides rH2 factors denoted as oxidative stress determined at a specific physiological pH)
   b. Postural hypotension screening
   c. Indikan test
   d. Urine dipstick analysis
   e. HRV (Heart Rate Variability assessment)
   f. Weight assessment.
   g. DDFAO Analysis which includes measurements of specific free radicals)

Testing Discussion:

Numerous modalities and testing procedures were incorporated into this study; however, two primary sets of data were collected from the BTA-S2000 and the DDFAO. Therefore it is essential to discuss these two devices in detail.

BIOLOGICAL TERRAIN (BTA Testing)

Life and health as we know it today are changing dramatically. Never before in the history of man and womankind has the human organism had to deal with such an overwhelming degree of stress, illness, abuse and neglect. The depletion and degradation of vital resources, the exposure to new viral and bacterial strains, pollution, petrochemicals, allergens, free radicals, excessive electromagnetic radiation, additives and chronic environmental and mental stress are all giving rise to a vast array of new health challenges and degenerative conditions.[1] These modern-day ailments are necessitating new and expanded forms of health care assessment, evaluation and treatment. Some practitioners are continuing to cling to the old standard forms of health care. Others are focusing their attentions and energies on becoming more and more specialized and illness-oriented. Large numbers of alternative and allopathic physicians and health care providers both in North America and abroad, however, are beginning to move beyond the old paradigms into an expanded and revolutionary approach to medicine and health care called **Biological Terrain Assessment.** This rapidly emerging field of science is providing them and their patients with valuable information and answers to their health care concerns. These solutions are supporting and restoring their patients' bodies and protecting them from the harmful effects of the stress and strains of modern day living.

Biological Terrain has its beginnings in Europe and is based largely on the clinical research of a noted professor named Louis Claude Vincent. [2,3] Professor Vincent discovered that the key to healing the body was not found merely in administering drugs. Rather, he believed that the key was found in the biochemistry of the body. His belief, based on a lifetime of gathering and evaluating human clinical data, was that the building blocks of life, the elements, amino acids, enzymes, molecules and atoms found within the bodily fluids (the blood, urine and saliva), provided vital data about the way that the body was actually functioning. By monitoring the subtle yet powerful values of pH (acidity and alkalinity), oxidation-reduction potential or redox (the electron potential and enzymatic activity) and resistivity (molecular ion movement) of these bodily fluids and making changes at a biochemical level, health and vitality could be re-established within the body that could help it to naturally combat illness and disease. [4]

Although Biological Terrain Assessment requires a thorough understanding of chemistry, biochemistry, physiology and clinical nutrition, its philosophies and parameters are very basic. For example, in order to gain an overall working understanding of Biological Terrain, it can be very helpful to take a look at the process of growing food. Those who have lived on a farm or have had the wonderful opportunity to plant and care for a vegetable garden have probably come to deepen their respect, knowledge and appreciation for the earth and the process of growth. They have discovered that planting a field or a garden is not just a matter of planting a seed and harvesting healthy food several months later. It involves knowledge of the chemistry of the soil, the nature of the seeds, proper control and measurement of nutrients and fertilizing materials and assurance of adequate amounts of water and sunshine. It also requires an understanding of particular insects, molds, weeds and fungi and what their presence indicates. When the soil is rich and filled with nutrients and minerals, the farmer or gardener can be assured that the seeds that are planted will yield food filled with vitality. He or she can also be assured that such care and awareness of the soil's vitality and on-going monitoring of its enrichment minimizes or prevents the occurrences of molds, destructive plant microorganisms, fungi and insect invasions. Biological Terrain Assessment, like raising a healthy garden, necessitates a thorough and comprehensive understanding of the chemistry of the human body. When the patient's body chemistry is balanced and maintained with a healthy diet and proper vitamin and mineral supplementation as well as adequate amounts of exercise and rest, the body, like the garden, can remain strong and healthy. It can also nourish a vibrant immune system that can protect and sustain it. However, if the body is fed a diet that lacks adequate vitamins, minerals and nutrients or is processed and chemical-laden, much like the typical American diet, the body experiences illness and is unable to maintain or sustain a strong immune system. Likewise, if the body is exposed to improper amounts of rest or exercise or excessive levels of stress, the body becomes more susceptible to illness. Just as a neglected crop fails to produce healthy foods and becomes highly susceptible to elemental breakdown and destruction, so, too, the human body fails to produce vitality and wellness and becomes increasingly susceptible to illness, stress, fatigue and chronic degeneration. In our world these inadequacies and excesses are currently altering the biochemistry of the human body to such a degree that wellness and vitality are becoming the exception rather than the rule.

While many fields of medicine and science examine, isolate or treat one particular part or system of the body, Biological Terrain practitioners clinically monitor the entire internal biochemical environment of the body. The goal is to gain a deeper understanding of the in-depth elements within the patient's chemistry and prescribe the exact forms of treatment to help

their patients regain and maintain a healthy internal biochemical environment. Doing so at a chemical level can then, in time, translate vitality and health to every cell, tissue, organ and gland within the patient's body. Biological Terrain practitioners honor the principle that every human body is unique and as such, every ailment must be treated specifically. Even individuals that seem to have similar conditions such as arthritis or pre-menstrual syndrome may display biochemistries that are very different and subsequently require very different forms of treatment.

Many patients who initially undergo Biological Terrain Assessment come into their practitioner's office with reports of "normal" laboratory values and yet display illness both objectively and subjectively. After analyzing their bodily fluids for pH, redox and resistivity, important data begins to emerge. This information helps the practitioner and the patient uncover the underlying cause of their imbalance or illness. Often very subtle yet potent influences are at work within the patient's biochemical system which can include but are not limited to parasites, viruses, fungi, pollutants, xenobiotics (environmental poisons), invasive micro-organisms, free-radicals, lack of adequate vitamins and minerals, lack of available oxygen and the inability of the body to excrete carbon dioxide. Most standard laboratory tests are not equipped to detect or measure these elements and as a result, many patients remain sick and their doctors confused and unable to accurately ascertain their patient's clinical condition.

In order to evaluate an individual's Biological Terrain or internal biochemical environment, a practitioner analyzes urine, venous blood and saliva. [5] In most instances, these tests are conducted in a clinical in-office assessment procedure. This test requires that a patient undergo a 12-14 hour fasting period. They are advised to avoid the use of toothpaste, mouthwashes or lipstick that can change the chemistry of the mouth. They must also obtain and bring into the office their first morning urine. Upon the patient's arrival in the office, a small venous blood sample (0.5 ml) is drawn and a small amount of saliva (0.5 ml) is obtained. [6] The urine, blood and saliva are then analyzed by a computerized device called a BTA S-2000. This device uses a specialized multi-element microelectrodes to determine the pH, resistivity and redox values of the fluids. The nine scientific values obtained by the BTA S-2000 are then analyzed and plotted by the instrument's computer software onto a report. This data is then assessed by the practitioner and used as a teaching guide to share with the patient. Although the testing procedure does not diagnose any specific pathology or disease states, it does serve as an analytical guide post that tremendously aids in the overall evaluation of the patient. Any health care provider will instantly detect the value given from this information and implement its content along with his/her standard evaluation procedures. They will also revel in its in-office status and rely on its quick and accurate values to guide them into ordering more specific and focused laboratory tests. Regardless of

the type of patients that a practitioner is testing or the modalities that the practitioner chooses to implement for therapy, this scientific assessment, coupled with a deep appreciation for the underlying Biological Terrain is a worthy investment; An investment in time and commitment which is required to comprehend and appreciate a complete understanding of the biochemistry and physiology that define the revolutionary assessment of the "Biological Terrain."

pH

One of the primary values in the assessment of the Biological Terrain is "pH." pH is an analytical measurement which represents the activity and potential energetics found within the hydrogen ion. [7] All bio-chemistry texts relate the discussion and evaluation of pH with the life-sustaining fluid of water. No living species on this planet can survive without water, nor for that matter can one single living cell. The chemistry of our bodies is considered to be analogues to the chemistry of water. When it dissociates or breaks apart water will form ions. These ions are known as hydrogen and hydroxide. This dissociation can be understood by examining the equation: [8,9,10,11]

$$H_2O \longrightarrow H^+ + OH^-$$

As this equation illustrates, water will separate into its basic elemental components. This separation process is known as dissociation or the rate of dissociation. The rate in which water dissociates into its base elements is equal to 1×10^{-14} moles per litre. This occurs under specific definable parameters such as constant temperature of 22^o C and constant atmospheric pressure of 1ATM. Based on mathematical representation of negative cologrithyms, the concentration of the hydrogen ions is much more easily expressed in terms of whole numbers. Therefore, pH is in fact related to the hydrogen ion concentration and can be represented by the equation: [12,13]

$$pH = \log \frac{1}{H^+ \text{ Conc.}} = - \log H^+ \text{ concentration}$$

When expressed in these terms, the concentrations of the hydrogen ion can be placed on a scale ranging from theoretical 0 to 14.14. Upon further and more comprehensive examination of the equation above, it must be noted that **as the hydrogen ion concentration *increases*, the resulting pH *decreases.* This consequence creates what is termed as an <u>acidosis</u>. Similarly, as the hydrogen ion concentration *decreases*, the resulting pH *increases.* This consequence creates what is termed as an <u>alkalosis</u>**. [14]

The words acidosis and alkalosis are meant to refer to the relative concentrations of either an abundance of an acid to a base or an abundance of a base to an acid. Now that we know what creates an acid or a base we must more fully comprehend their definitions.

An **acid** is a molecule or ion that can function as a **proton donor**.
A **base** is a molecule or ion that can function as a **proton acceptor**. [15]

More definitively stated, an acid is an ion or molecule that can furnish a hydrogen ion (H^+) to a solution. This is viewed as HCL ionizes in water to form hydrogen ions (H^+) and chloride ions (CL^-) and therefore is the acid known as hydrochloric acid. The hydrochloric acid has donated a proton (the H^+ ion) to the solution. Other vital acids that function in a powerful biological capacity are carbonic acid, acetic acid, uric acid, phosphoric acid and nitric acid.

Similarly viewed, a base is an ion or molecule that will combine with hydrogen ions (H^+) and remove them from the solution. An example of this is the bicarbonate ion (HCO_3^-) which combines with a hydrogen ion (H^+) and forms the new compound known as carbonic acid (H_2CO_3). The bicarbonate ion has accepted a proton from the solution and is therefore responding as a base. Other vital bases that function in a powerful biological capacity are sodium bicarbonate, sodium phosphate, special inter-cellular proteins and even hemoglobin in the blood. [16]

The most important aspect concerning acid and base physiology and their relative concentrations is that they help to maintain a definitive biochemical balance within the body. Through the balance created by the concentrations of these compounds, proper and biologically compatible pH levels are sustained. These levels are very precise and must be carefully guarded and perpetuated in order that cellular function and chemical reactions within the body can occur. Without this delicate balance of pH within the body, life as we know it today would not exist. A number of vital pH measurements for the body have been accurately determined in the following chart. [17]

Tissue or Fluid	**pH**
Saliva	6.0-7.0
Gastric secretion	1.0-3.5
Pancreatic secretion	8.0-8.3
Bile	7.8
Small Intestinal secretion	7.5-8.0
Urine	4.5-8.0
Arterial blood	7.4-7.45
Capillary blood	7.35-7.4

Venous blood	7.3-7.35

As is demonstrated from the chart above, pH must fall within a very narrow band in order for proper biochemical function to occur. If the pH values fall outside the ranges described either cellular function diminishes or death to the organism will ensue. Therefore, it is critical that the body regulate and maintain all of these varying pH measurements in order to not only function effectively but more importantly, to survive. Consequently, the body has created numerous elaborate and complex systems that carefully monitor and then control any aberrant acid/alkaline deviations. The systems designed to correct these fluctuations are known as the ***acid-base buffer systems***. [18]

A buffer is a solution containing two or more chemical compounds that prevent significant alterations in pH regardless of whether an acid or a base is added to the solution. The buffer systems that are the most active and therefore the most critical are the bicarbonate/carbon dioxide system, the extracellular system (which is mainly comprised of the relative concentration of phosphate), the intercellular system (which relies on the buffering integrity of the intercellular proteins and in the hemoglobin within the erythrocyte) and the bone. Although this intricate web of powerful buffers is very complex and effective, variances in the pH of many of the more significant bodily fluids do often occur. The body is constantly being bombarded by acids, both from an internal metabolic production perspective as well as from exogenous sources. It is this on-going onslaught of acids that begins to wear on the efficiency of the biological buffers as well as deplete the necessary components that allow for proper buffer functioning. [19]

Acids are produced by the body as a normal function of cellular metabolism. These acids are greatly increased during times of stress as well as through factors that stimulate the sympathetic nervous system. Exercise also increases the rate and concentration of indigenous acids. Even with all of these many various forms contributing to the problem, the largest culprit in the excess acid production arena comes from the oxidation of fats, carbohydrates and proteins. [20]

In a normal 70kg male, the metabolism and oxidation of dietary foodstuffs produces a wide array of chemical components that acutely impact the acid-base condition. When insulin is present and the tissues are adequately perfused with oxygen, cellular oxidation of carbohydrates and fats produces an excessive quantity of CO_2. This massive production of CO_2 is potentially toxic and stressful on the organism as a whole. Depending on the ability and the level of efficiency of the respiratory system, some CO_2, (although usually only a trace amount), will be vented out through the lungs. The remaining concentration of CO_2 will combine with H_2O and produce a volatile acid known as carbonic acid (H_2CO_3).

Concentrations of carbonic acid are not only difficult for the body to store, but in fact must be readily converted into their base components for immediate removal or they will be stored for later removal from the body. The body will breakdown the carbonic acid into a hydrogen ion and a bicarbonate ion as illustrated: [21,22,23]

$$H_2CO_3 \longrightarrow H^+ + HCO_3^-$$

This breakdown allows for a higher level of efficiency to aid in the removal of this excess acid production. A portion of the newly formed hydrogen ions will be removed by the body through normal renal physiology. However, as the kidneys are excreting the acid out through the renal tubules they are concurrently reabsorbing the bicarbonate ion. The reabsorption of the bicarbonate ion is vital, for without this compensatory mechanism the loss of this valuable ion would be similar to the addition of greater amounts of acids. Unfortunately, when the bicarbonate ion is reabsorbed, it greatly influences and thereby increases its own concentration in the plasma. This increased bicarbonate concentration can easily lead to an increase in the very stable iso-electric pH of the blood. Therefore, as the renal tubules are collecting, condensing and ridding the body of the excess acids, they are also allowing for the continual reabsorption of the base. This reabsorption will directly effect the plasma pH. When the body is saturated with acids and the kidneys are able to continue their vital role in the removal of these acids, the body will thereby prevent the occurrence of a metabolic acidosis. However, the biological systems are compensatorily creating a plasma alkalemia. [24]

If under these circumstances the body fails to produce adequate levels of insulin, or if it is functioning in a varying state of hypoxia, then oxidation of these fats and carbohydrates takes on a different outcome. When either of these two scenarios occur, the body will produce large quantities of nonvolatile acids, namely lactic acid and beta-hydroxybutyric acid. The process in which the body manipulates and attempts to store or dispose of these nonvolatile acids is identical to the procedures utilized in exchanging acids that are produced through the oxidation and metabolism of protein.

The oxidation of amino acids forms the nonvolatile compounds of sulfuric acid, hydrochloric acid, nitric acid and phosphoric acid. These acids are all poisonous and destructive to the body. Therefore, the body must eliminate or store the less harmful constituents of these acids as quickly as possible. Through a simple chemical reaction these acids are successfully neutralized by a family of complex mineral compounds. When these mineral compounds react with the toxic acids they produce a product that is either no longer poisonous to the body or is readily and safely stored. [25]

The family of mineral compounds that are so successful in the neutralization of these acids is known as the ***carbonic salts***. These salts are often marked in chemistry texts as $X\text{-}CO_3$. The X represents any one of the four alkaline elements Na, Ca, K or Mg. When carbonic salts meet with strong acids such as sulfuric acid, phosphoric acid, hydrochloric acid, lactic acid or acetic acid, the alkaline minerals that are bound to the carbonate leave the salt and recombine with the acids to make a new less detrimental salt.

An example of this type of reaction would be: [26]

$$X\text{-}CO_3 + H_2SO_4 \longrightarrow X\text{-}SO_4 + H_2O + CO_2.$$

In this example, the toxic, highly dissociated sulfuric acid combines with the carbonic salt to form a less poisonous sulfuric salt, water and an additional molecule of carbon dioxide. The new product, the carbonic salt, can more readily be excreted through the kidneys than its earlier predecessor. While this process is effective, the entire premise is predicated on two key factors. First, that there are adequate numbers of readily available organic minerals to provide the initial creation of the carbonic salt. Secondly, that the production of additional levels of carbon dioxide can be eliminated by the body through the already overburdened respiratory system. Unfortunately, both of these assumptions are not always the case. Often times organic mineral concentrations are depleted from the body and the respiratory system is virtually incapable of ridding the system of greater concentrations of CO_2. Either of these scenarios will force the renal tubules to once again collect, condense and rid the body of this excess acid production and once again cause the reabsorption of the critical bicarbonate ion. This reabsorption of the bicarbonate ion has the great potential of adversely affecting the delicate balance of the plasma pH. When the kidneys are overstressed in their attempts to stay relatively current with the increased acid load, the blood is also stressed attempting to maintain homeostasis with respect to pH. The stress placed upon the blood will often create a shifting of the pH values further into the alkaline range. These stressors playing out continually over many months and years can create far-reaching distortions within the entire physiological climate. [27]

In the final analysis, the typical American adult consumes over 150meq/day of both volatile and nonvolatile acids. This large and excessive dietary acid consumption coupled with diminishing tissue stores of alkaline minerals, complicated by excessive simple sugar intake and compounded by an inability to adequately saturate the tissue with oxygen, all spells excess overburdening of the surrounding interstitial cells with acids. When the body reaches a point where its ability to remove the excess acids are overcome by the acids both produced and consumed, the body must resort to storing the

acids within. In its initial stages, the body will always store the acids in a region that represents the least amount of biological threat to the species. This area is the interstitial cells or the matrix. When this area becomes saturated, the body will begin to store these acids anywhere it can.[28] Unfortunately, the other storage places are not nearly as benign. As the intercellular space becomes loaded with acids, the cellular metabolism, respiration and ultimately cellular integrity are all greatly compromised. When all of these changes occur on a cellular level, the cell has become diseased and pathology is most certain to follow.

When the pH of a cell is altered, the normal enzymes utilized by or produced from the cell are also affected. Science has documented that enzyme kinetics is greatly dependent upon pH and temperature to maintain enzymatic integrity. [29] When the pH is altered even slightly, the overall enzyme function of many associated systems will also be detrimentally effected. The far-reaching influence of the pH alterations can be felt in the digestive system, the immune system and even in the lymphatic system. With this abbreviated approach to the understanding of the biochemistry and physiology reactions, it becomes increasingly apparent that a simple but accurate assessment of the varying fluid pH levels can give valuable information. This information can include endogenous and exogenous acid and alkaline production, physiological stress placed on varying organs and systems of the body, compensatory accomplishments and ultimately, enzyme kinetics.

Metabolic Production Of Nonvolatile And Volatile Acids From The Diet

Food Source	Acid Produced	Quantity (mEq/day)
Carbohydrates & Fats	Volatile Acids	20 mEq/day
Amino Acids:		
a. Sulfur-containing	H_2SO_4	
b. Cationic	HCL }	100 mEq/day
c. Antionic	HCO_3	
Phosphate	$H_2PO_4^-$	30 mEq/day
	TotalAcidsConsumed:	150mEq/day

OXIDATION-REDUCTION/REDOX

During the 1920's, biological medicine scientists and chemists began to discover that the monitoring and assessment of the movement of

electrons or electron potential of bodily fluids was as critical in the biochemical equation of Biological Terrain as pH. [30] Therefore, the second factor in the assessment of the Biological Terrain is called the ***oxidation-reduction potential.*** This analysis is predicated on the understanding that all chemical reactions are dependent upon the ability of electrons to attract or repel one another. [31] Before one can fully understand the dynamic role that these electrons play in the chemical reactions of molecules, an in-depth look at the basic structure and function of molecules and atoms would be prudent.

All life is composed of ***molecules***. Molecules are made up of tiny particles known as ***atoms***. An atom consists of a positively charged nucleus that is surrounded by one or more negatively charged particles called ***electrons***. The positive charges must equal the negative charges so that the atom can maintain electrical neutrality. The majority of the atom's mass is found in the nucleus. The mass of an electron, in comparison, is only 1/1836 the mass of the smallest and lightest of all the nuclei. The nucleus of an atom contains both ***protons*** and ***neutrons*****.** Protons and neutrons have masses that are almost equal but they differ in charges. A neutron lacks a charge while a proton has a positive charge that exactly balances the negative charge of a single attached electron.

When two atoms are close enough to combine and react chemically and form chemical bonds, it is the electron that determines or "sees" the incoming reagent and determines the chemical compatibility. The electrons in the outer most shell of one atom analyze the electrons in the outer most shell of the other atom and an instantaneous determination is made in accordance to binding congruity. It is therefore the electron that is the key to the reactability and chemical behavior of all atoms. Neither the neutron or the proton can rival the significance of this tiny negatively charged particle. [32]

In order to determine the chemical cohesiveness of an atomic or molecular compound, a monitoring device can be placed within the reaction confines of a solution. This device is often times a metal electrode and is arranged in a solution containing a reversible oxidation-reduction system. The primary focus of the electrode is to detect the system's ability to gain or lose electrons until it has reached a state of equilibrium. **A heterogeneous complex that will <u>donate</u> electrons is considered to be a <u>reducing</u> system while a heterogeneous complex that will <u>accept</u> electrons is considered to be an <u>oxidizing</u> system.** In living tissue, oxidation-reduction systems can be divided into two separate types: [33,34,35,36]

1) Those in which the oxidized and reduced forms differ solely in the number of electrons, e.g. in which a change in valence of an element has occurred and

2) Those in which "hydrogen transfer" occurs.

These two reaction possibilities can either occur simultaneously or consecutively. [37]

When a metal electrode is placed into a solution containing a reversible oxidation-reduction system, the electrode will analytically measure the oxidation-reduction potential or the **ORP**. [38] **The ORP is a relative measurement which determines the tendency for a reaction to occur. It is measured in the electrical value of milli-volts (mV) and is most often represented by the letter E.** [39]

Reduced substance $\longrightarrow$ Oxidized substance + electron = E

If E is +, the reaction has a greater tendency to occur in the direction that the arrow is drawn and hence favors the oxidized state. If, however, E is -, the reaction has a greater tendency to occur in the direction opposite to the way the arrow is drawn and hence will favor the reduced state. Examples of this would include:

$Na \longrightarrow Na^+ + e^-$ E = + 2.71 mV

$Ag \longrightarrow Ag^+ + e^-$ E = - .80 mV

In the first reaction, E is a positive number. The reaction, therefore, will favor the products which are in the oxidized state.

In the second reaction, E is a negative number. The reaction will favor the reactants which are in the reduced state.

The entire purpose for oxidation and reduction to occur is found in two very simple but extremely powerful premises:

1) To create high cellular energy in the form of ATP

2) To oxidize or burn up invading pollutants, xenobiotics and some species of micro-organisms[40,41]

These two premises are so significant that without them our life as we know it would cease to exist. ATP energy is the high cellular energy that runs each and every cell of our body. Without the adequate production of ATP, our bodies would rapidly run out of the fuel that enables them to work. When our cells stop functioning, so do our bodies. Many forms of diseases as well as many conditions that manifest themselves by creating fatigue in the host are inhibitors or depleters of ATP.[42] The ability of our cells to oxidize invading pollutants, xenobiotics and some species of micro-

organisms is paramount to survival in the contaminated polluted world that we live in. If the oxidation-reduction reaction were not able to burn up these contaminants then with the first exposure of our bodies to these factors, cellular integrity would most certainly be compromised. This would ultimately lead to death. It therefore becomes increasingly obvious to understand not only whether or not an oxidation-reduction reaction is occurring or will occur, but to fully appreciate the significance of the relative concentration of electrons.

When a life-sustaining fluid like blood is loaded with electrons and therefore has a negative E value, the potential for potent life-giving chemical reactions to occur is very great. However, when the blood becomes depleted of these essential life-providing electrons and the E value becomes more positive, the potential energetics of the fluid have been spent. To more completely comprehend what the change in the E value has on the energy of the fluid or cell, one must begin to think in terms of potential and kinetic energy. A fluid that has a positive E value has just spent all of its kinetic energy and accordingly is void of all potential energy. The fluid or cells that make up this entity are incapable on their own to create a chemical reaction. Conversely, a fluid that has a negative E value has a warehouse of available kinetic energy and therefore a very high potential energy. This fluid is able to donate its electrons and prime the system to create a chemical reaction. [43]

Understanding the value of E can easily provide tangible analytical evidence of the potential energetics and life-sustaining properties of a fluid. However, in a true biological system, E is replaced by a factor called rH_2. rH_2 is considered to represent the partial pressure of hydrogen that is exerted on the cathode. It is calculated from the Nernst equation: [44]

$$E = E^0 + 2.3 \frac{RT}{F} \log \frac{(\text{oxidants})}{(\text{reductants})}$$

E = oxidation-reduction potential in millivolts

E^0 = the standard potential occurring when all activities are equal

R = the gas constant

T = temperature in degrees Kelvin

F = Faradays constant or the number of electrons reacting

In a biological system the new equation becomes:

$$E = E^0 + 2.3 \frac{RT}{(H^+)} \log$$

F rH_2

If you solve the equation for rH_2 and factor in the concentration of the hydrogen ion (pH), the resultant is an oxidation-reduction potential calculated in respect for a true biological system. Since rH_2 is a relative factor representing partial pressure, it is denoted in the terms of bar. The scale for rH_2 ranges from 0 - 42, where 0 corresponds to the maximal hydrogen partial pressure of 1 bar and 42 corresponds to the minimal hydrogen pressure of 1×10^{-42} bar. The balance point of the rH_2 scale where the concentration of reductants is equal to the concentration of oxidants is 28. **Any rH2 value determined below 28 represents a reduced state while any rH2 value above 28 represents an oxidized state.** [45,46]

The measurable and definable scale of rH_2 allows the astute practitioner immediate access to the electron potential of the three major fluids of the body. In this easy and straightforward test, high versus low potential energy can be determined. This provides a window into the full biochemical make-up of the patient. In today's world where harmful oxidative stress comes from so many varying sources, the ability to quickly and precisely determine the extent of the damage created from the stress is a tool that each and every practitioner should have at their immediate disposal. Through the assessment of the rH_2, the underlying cause of the bio-chemical imbalance becomes even more readily available and assessable.

RESISTIVITY

The third and final parameter that defines the Biological Terrain is "resistivity." Of all of the three values, resistivity, which is represented by the small letter ***r,*** is perhaps the easiest to understand and integrate. Resistivity is a simple measurement of the fluid's ability to conduct an electrical current. [47] In actuality, resistivity is inversely proportional to the more common electrical testing parameter of conductivity. By first understanding the value of conductivity and then applying this understanding to the relationship between itself and resistivity, the ability to comprehend its full and diverse possibilities is immediately brought to light. Electrically speaking, conductivity is the ability of an electrical current to pass through a given medium. If the electrical current can easily and readily flow through the solution, in this case, one of the fluids of the body, then the conductivity is considered to be very high. However, if an electrical current has a great difficulty in passing through a solution, then the solution is said to have very poor electrical conductivity. The factor that dictates whether or not a solution is electrically conductive or not is dependent upon the relative concentration of electrically conductive biological ions. In the body, these ions are present in the form of mineral salts. Mineral salts are very

electrically conductive and when their presence is substantial, the ability of an electrical current to flow through the solution is tangible. **As the relative concentration of mineral salts increases, the ability to conduct an electrical current also increases and therefore the conductivity is elevated. Conversely, as the relative concentration of mineral salts decreases, the ability to conduct an electrical current also decreases and therefore, the conductivity is diminished.**

Recall that the relationship between electrical conductivity and electrical resistivity is inversely proportional. Therefore, **as the mineral content increases, the conductivity increases and the resistivity decreases.** Conversely, **as the mineral content decreases, the conductivity decreases and the resistivity increases.** Resistivity is a simple and relative measurement of the concentration of electrically conductive ions in solution. It is referred to and stated in the electrical scale in terms of ***ohms cm***. The simplicity in comprehending and testing for this last parameter is by no means a suitable representation of its relative significance. Resistivity values of the three biological fluids are a definitive analytical evaluation that imparts a great deal of information. [48]

As is found in any biological system, a balance or homeostasis must be maintained in order that maximum function is perpetuated. A set concentration of conductive ions, e.g. mineral salts, is essential to allow the body the ability to carry out its many complex and diverse chemical reactions. If the concentration of these mineral salts deviates from a normal and acceptable range then the underlying bio-chemical function is greatly effected. Mineral salts are designed to exist in relatively small and balanced concentrations in both the saliva and blood. Conversely, the mineral salts are ideally designed to flow freely through the excretable urine. This process assures that the kidneys are adequately removing excess minerals from the body and that the influx of essential conductive ions remains competent and stable. If the body loses too many minerals through the urine, then the biological function of all of the remaining systems of the body will be greatly effected. Conversely, if the body does not remove the mineral salts in sufficient enough concentrations, then the body will also become toxic and the underlying function will suffer. Osmotic gradients, cellular integrity, chemical reactivity and proper neurological function are all dependent on proper balance and elimination/retention of mineral salts.

A plethora of material has been written on the relative importance of minerals and the dynamic roles that they serve in the integrity and function of the body. [49,50,51] Through this last parameter of resistivity, indications of blood purification, kidney excretion, enzymatic concentration, dietary factors and alkaline reserve potential can all easily be inferred. Therefore, the overall value and significance of the assessment of the parameter defined as resistivity is not only crucial in determining many valuable biological

functions, but must be considered on equal ground with the factors of pH and rH_2.

SUMMARY

There exists a strong inter-relationship of the values of pH, rH2 and resistivity. One of these factors alone is not adequate, two factors together are more valuable, but only the three parameters of pH, rH_2 and r can successfully and completely define the Biological Terrain. In a world of at least three dimensions, finding a point in space can not be defined by only one component. In fact, in such a model, three direction or mapping points must be labeled. Most often these three points are referred to as the X, Y and Z coordinates. In a three-dimensional human body one should not expect the laws of physics to apply any differently. Therefore, in order to clinically monitor and evaluate the overall bio-chemical function and plot the Biological Terrain the three independent values must be utilized. Valuable information can be ascertained with one or two values, but all three parameters are necessary to obtain an in-depth comprehensive assessment of the terrain. The three analytical scientific factors not only provide the practitioner with invaluable information separately, but when all three factors are mathematically joined together the database multiplies exponentially.

Strong and highly emphasized words of guidance need to be imparted in relationship to the assessment of the three factors that define the Biological Terrain. While the information they impart can aid in the ascertainment of many valuable biological and chemical occurrences within the body, they **DO NOT** diagnose any specific pathology or disease states. They are 100% analytical guide posts or road signs that tremendously aid in the overall evaluation of the patient. They allow the practitioner to document a starting point or reference point to determine if the methodology chosen for therapeutic purposes is appropriate. They also give the practitioner a teaching guide to share with the patient, thus allowing the patient to take an active role in his or her health care. Finally, they provide the practitioner with immediate, easily ascertained in-office information that is irreplaceable in helping to determine the need for additional specific laboratory assays.

As any practitioner begins to work with and evaluate the Biological Terrain, he or she will understand that never before in the history of medicine has one simple test provided such a strong base of active and tangible information. The assessment of the Biological Terrain is a tool that can be easily and effectively implemented into any type of practice. The foundation for all of the factors is straight-forward basic biology and chemistry and will stand up to the highest levels of scrutiny and inspection.

Our way of life and our level of health are changing rapidly and dramatically. It is vitally important that today's health care providers take quantum leaps in their understanding, appreciation and treatment of these new health challenges. It is also extremely important that they are prepared and equipped to provide their patients with the information and strategies to deal with these expanding and at times, overwhelming health concerns. The study and practice of Biological Terrain is the medicine of the future and the field of science that is now fully equipped to meet these needs and address these clinical challenges. It is an extremely valuable field of science that necessitates strong degrees of knowledge, respect and appreciation for not only the chemistry of the body but more importantly, for the underlying forces of nature that control and dictate the body's internal environment. It is also a field of science and study that can enable both the allopathic and the alternative health care professions to not only clinically validate and monitor these subtle yet powerful forces of nature, but even more importantly, verify the effectiveness of their therapeutic protocols. Welcome to the fascinating and expansive world of Biological Terrain.

REFERENCES

[1] Advancement in Clinical Nutrition, 1994 Seminar Series, Health Comm, Inc., Gig Harbor, Washington.

[2] Roujon, L., Theory and Practice of the Bio-Electronic "Vincent", SIEB, 1975.

[3] Elmau, H., Bioelectronic according to Vincent and Acid-Base-Household in Theory and Practice, Haug Verlag, Heidelberg, 1985.

[4] Roujon, L., Theory and Practice of the Bio-Electronic "Vincent", SIEB, 1975.

[5] Gyorgyi, A., Bioelectronics, New York, New York, 1968.

[6] Elmau, H., Bioelectronic according to Vincent and Acid-Base-Household in Theory and Practice, Haug Verlag, heidelberg, 1985.

[7] Stryer, L., Biochemistry, W. H.Freeman and Company, New York, New York, 1988.

[8] Whang, S., Reverse Aging - Scientific Health Methods: Easier and More Effective than Diet and Exercise, Siloam Enterprise, Inc., Englewood Cliffs, New Jersey, 1994.

[9] Wingate, P., Gifford, C., and Treays, R., Essential Science, EDC Publishing, Tulsa, Oklahoma.

[10] Baroody, T., Alkalize or Die, Eclectic Press, Waynesville, NC., 1991.

[11] Aihara, H., Acid & Alkaline, George Ohsawa Macrobiotic Foundation, Oroville, California, 1986.

[12] Stryer, L., Biochemistry, W. H. Freeman and Company, New York, New York, 1988.

[13] Sander, F.F., Acid-Base-Household, Hippokrates Verlag, Stuttgart, 1985.

[14] Guyton, A., Textbook of Medical Physiology 8th Edition, W. B. Saunders Co., Philadelphia, Pennsylvania, 1991.

[15] Stryer, L., Biochemistry, W. H. Freeman and Company, New York, New York, 1988.
[16] Guyton, A., Textbook of Medical Physiology 8th Edition, W. B. Saunders Co., Philadelphia, Pennsylvania, 1991.
[17] Guyton, A., Textbook of Medical Physiology 8th Edition, W. B. Saunders Co., Philadelphia, Pennsylvania, 1991.
[18] Gilbert, H.F., Basic Concepts in Biochemistry, A Student's Survival Guide, McGraw-Hill, Inc., New York, New York, 1992.
[19] Guyton, A., Textbook of Medical Physiology 8th Edition, W. B. Saunders Co., Philadelphia, Pennsylvania, 1991.
[20] Gilbert, H.F., Basic Concepts in Biochemistry, A Student's Survival Guide, McGraw-Hill, Inc., New York, New York, 1992.
[21] Gilbert, H.F., Basic Concepts in Biochemistry, A Student's Survival Guide, McGraw-Hill, Inc., New York, New York, 1992.
[22] Champe, P.C. and Harvey, R.A., Biochemistry, 2nd edition, Lippincott's Illustrated Reviews, J. B. Lippincott Company, Philadelphia, Pennsylvania, 1994.
[23] Guyton, A., Textbook of Medical Physiology 8th Edition, W. B. Saunders Co., Philadelphia, Pennsylvania, 1991.
[24] Koeppen, B.M., Stanton, B.A., Renal Physiology, Mosby Year Book, St. Louis, Missouri, 1992.
[25] Guyton, A., Textbook of Medical Physiology 8th Edition, W. B. Saunders Co., Philadelphia, Pennsylvania, 1991.
[26] Aihara, H., Acid & Alkaline, George Ohsawa Macrobiotic Foundation, Oroville, California, 1986.
[27] Koeppen, B.M., Stanton, B.A., Renal Physiology, Mosby Year Book, St. Louis, Missouri, 1992.
[28] Pischinger, A., Matrix and Matrix Regulation, Basis for a Holistic Theory in Medicine, Haug International, 1991.
[29] Guyton, A., Textbook of Medical Physiology 8th Edition, W. B. Saunders Co., Philadelphia, Pennsylvania, 1991.
[30] Hanke, M., and Tuta, J., Studies on Oxidation-Reduction Potential of Blood, J. Biol. Chem., 78:36, 1928.
[31] Ziegler, E., The Redox Potential of the Blood In Vivo and In Vitro, Charles C. Thomas Publisher, Springfield, Illinois, 1960.
[32] Talbot, M., The Holographic Universe, Harper Perennial, New York, New York, 1991.
[33] Zerfas, L.G., and Dixon, M., An Improved Cell for Measurements of Oxidation-Reduction Potential, Bio-Chem. J., 34,365,1940.
[34] Cherry, R.H., The Measurement of Direct Potentials Originating in Circuits of High Resistance, Trans. Electrochem. Soc., 72, 33, 1937.
[35] Carter, D., Phillips, A., and Silver, J., Measurement of Oxidation-Reduction Potentials and pH of Tissues, J. Physiol., 129:33, 1955.

[36] Carter, D., Phillips, A., and Silver, J., Apparatus and Technique for Measurement of Oxidation-Reduction Potentials, pH and Oxygen Tension in Vivo, Proc. Roy. Soc. (Biol.), 146:289, 1957.
[37] Gyorgyi, A., Bioelectronics, New York, New York, 1968.
[38] Ingold, W., Redox Measurement, Principles and Problems, INGOLD, Urdorf, Switzerland, 1982.
[39] Hanke, M., and Tuta, J., Studies on Oxidation-Reduction Potential of Blood, J. Biol. Chem., 78:36, 1928.
[40] Clark, W. M., Oxidation Reduction Potentials of Organic Systems, The Williams & Wilkins Company, Baltimore, Maryland, 1960.
[41] Ziegler, E., The Redox Potential of the Blood In Vivo and In Vitro, Charles C. Thomas Publisher, Springfield, Illinois, 1960.
[42] Cheney, P.R., Entero-Hepatic Resuscitation in Patients with Chronic Fatigue Syndrome: A Pyramid of Nutritional Therapy, The CFIDS Chronicle, Fall:1, 1993.
[43] Clark, W. M., Oxidation Reduction Potentials of Organic Systems, The Williams & Wilkins Company, Baltimore, Maryland, 1960.
[44] Nernst, W., Theoretical Chemistry, 4th ed., Translated by R.A. Lehfeldt, Macmillan and Co., Ltd. London.
[45] Kollath, W., Regulators of Life - From the Nature of the Redox-Systems, Karl F. Haug Verlag, Heidelberg, 1968.
[46] Roujon, L., Theory and Practice of the Bio-Electronic "Vincent", SIEB, 1975.
[47] Wingate, P., Gifford, C., and Treays, R., Essential Science, EDC Publishing, Tulsa, Oklahoma.
[48] Stryer, L., Biochemistry, W. H. Freeman and Company, New York, New York, 1988.
[49] Pheiffer, C.C., Zinc and Other Micro-Nutrients, Keats Publishing, Inc., New Canaan, Connecticut, 1978.
[50] Kirshmann, J.D. and Dunne, L.J., Nutritional Almanac, 2nd Edition, McGraw-Hill Book Company, New York, New York, 1984
[51] Wilson, L., Nutritional Balancing and Hair Mineral Analysis, L. D. Wilson Consultants, Inc., Scottsdale, Arizona, 1992.

Understanding the Redox (rH_2) Measurement of the Biological Terrain (BTA Testing)

The measurement and assessment of pH in the biological field is well defined and documented.[1,2] It is known and accepted that enzyme kinetics as determined by the Michaelis-Menton equation for the determination of maximum enzyme velocity is pH dependent.[3] Maximum enzyme velocity and kinetics are also substrate concentration and temperature dependent as well. Science has clearly demonstrated that assessing and comprehending the factor of pH is a crucial aspect of understanding the biochemistry and physiology of the human body.[4,5]

In contrast, the discernment and dynamic implications of oxidation-reduction (redox) potential is only now coming to the forefront of modern medicine. Even though this field of science has been evaluated and scrutinized since 1928, it has not received the attention or dedication that pH has afforded.[6] There are many leading authorities who believe that redox potential is even more significant than pH in understanding biological actions and interactions.[7,8] In fact, one leading authority has stated that "in both living and non-living nature, oxidation and reduction reactions are more important than acid and base reactions."[9]

It is, therefore, essential that the full significance of redox potential and its encompassing influence on disease be well understood. Redox potential even now is already being viewed by marine biologists as the key factor in sustaining the quality of aquatic life. Its measurement enables scientists to secure the success of sexual reproduction and longevity in aquatic lifeforms.[10,11] The complete understanding of redox potential, the rH_2 factor and how these values effect human chemistry and physiology must also be researched and established.

According to an assemblage of well respected researchers and authors, oxidative stress is the key factor in many symptoms and disease states e.g., CFIDS, FMS (fibromyalgia syndrome), IBS (irritable bowel syndrome), alterations in nucleic acid sequences which may lead to cancers, environmental sensitivities, accelerated biological aging, food allergies, Leaky Gut Syndrome, energy deficiency, fatigue, sleep disturbances, immune dysregulation, cardiac problems, ocular problems, liver problems, kidney problems and pancreatic-based problems just to name a few.[12, 13,14] It seems that oxidative stress and the far reaching effects that this biochemical occurrence embraces, can now be directly or indirectly attributed to almost all of life's ailments and physiological dysfunctions.

Dr. Helmut Sies was paramount in categorizing all of these conditions under one united and comprehensive definition. He concluded that any shift in the redox potential toward increased oxidation of cellular macromolecules demonstrated oxidative stress. He further believed that this shift in redox potential could be measured and could provide vital information concerning the progression and degree of cellular damage. [15]

Mitochondrial damage, concentration of reactive oxygen species, anaerobic metabolism, derailment of the oxidative phosphorylation-electron transport chain and production of free radicals are all the results of oxidative stress and redox potential. [16] Therefore, in order to fully comprehend the extent of aberrant cellular function manifested in the conditions stated above, a viable working knowledge of redox potential must be established.

Redox potential is perhaps best described as a representation of overall electron activity. It must be clarified that in the truest state of physics, free electrons do not actually exist in aqueous solutions. They exist in a homogeneous blend and are often times being transferred from one atom or ion to another. [17] In a broader sense, redox potential could be considered as a measurement of the ease with which a substance either absorbs or releases electrons. [18] This donation or acceptance of electrons is correctly termed oxidation and reduction. Simply stated, oxidation is the loss of electrons and/or hydrogen atoms and/or the gain of oxygen. Reduction is the gain of electrons and/or hydrogen atoms and/or the loss of oxygen. [19]

The determination of redox potential is a potentiometric measurement. Within micro-limits, no actual current flows through the sample solution during this measurement process.[20,21] This limitation guarantees that no changes in the solution's chemical composition occur due to electrolysis. This also guarantees that undesirable electrode surface polarization is minimized. During the formation of the redox potential measurement, electrons either flow from the sensing electrode device to the redox system or vice-versa. This separation of electrical charge causes a potential to accumulate on the metal surface of the electrode. This potential represents the propensity of an aqueous solution to gain or lose electrons and is measured in millivolts. [22]

There are two (2) different types of redox reactions:

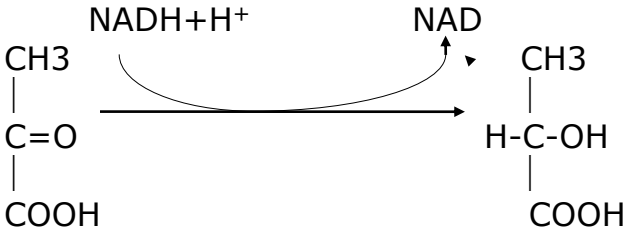
Example #1)

$$2Fe^{+3} + 2I^{-} \longrightarrow 2Fe^{+2} + I_2$$

This is an example of a reaction in which electron movement occurs due to alterations in ionic valences. In this reaction iron which begins in the ferric

state (Fe^{+3}) gains an electron and is reduced to the ferrous state (Fe^{+2}). Simultaneously, iodine in the -1 state loses an electron and is oxidized to atomic iodine. This reaction represents the "typical" form of a redox reaction. This type of redox reaction occurs most frequently outside the physical body. [23]

Example #2)



This is an example of a redox reaction that occurs without the visible exchange of electrons. Instead, the redox reaction transpires as a result of the exchange of hydrogen atoms. This occurs at the expense of NADH + H^+ being converted into NAD and liberating 2H's. These 2H's are then picked up by pyruvate which subsequently causes a conversion to lactate. In this reaction there are no visible exchanges of electrons or valence states as is demonstrated in example #1. Nevertheless, a complete redox reaction has occurred. In this example NADH + H^+ had been oxidized to become NAD. Subsequently, pyruvate has been reduced to become lactate. While the first example occurs more frequently outside the human body, the second example predominates inside the human body. Most redox reactions that are seen inside the human body occur not as an exchange of electrons that cause valence alterations, but instead as a production of energy rich reducing agents, in the form of NADH + H^+ or $FADH_2$. [24]

All redox reactions, whether they are similar to example #1 or #2, conform to Nernst's law which states:

$$\mathbf{E = E^0 + 2.3 \frac{RT}{nF} \ln \frac{(ox)}{(red)}}$$ [25]

In this equation:

E = redox potential in millivolts
E^0 = the standard electrode potential when all activity is equal to unity
R = the gas constant or 8.314 J/^{0}mol
T = absolute temperature
n = number of electrons involved in the reaction
F = Faraday's constant or 96000 coulombs

When an exchange of hydrogen atoms does not occur, the redox reaction is considered pH **independent**.[26,27] (See example #1) When hydrogen atoms play a key role in the redox reaction, it is pH **dependent**. (See example #2) The relative concentration of hydrogen ions will, in fact, play a significant role in the overall **E** or redox potential. [28] An analysis of these stated scientific facts clearly document that redox reactions that occur inside the body which are dependent upon the transference or exchange of hydrogen atoms are completely dependent upon changes and adjustments in relative pH conditions. Redox reactions which are independent of the transference or exchange of hydrogen atoms are completely independent from changes and adjustments in relative pH conditions. This vital fact can be demonstrated when Nernst's equation is solved with direct reference to the relative exchange of hydrogen atoms. To solve Nernst's equation under these parameters it is essential to understand the following reaction expressed by the equation:

$$\mathbf{H_2} \longrightarrow \mathbf{2H^+ + 2e^-}$$

In this equation, atomic hydrogen dissociates into hydrogen ions and simultaneously liberates electrons. This reaction is termed the "universal reference reaction" because it represents the basis of all universal life.[29] Therefore, when solving Nernst's equation utilizing the "universal reference reaction" it becomes:

$$\mathbf{E = E^0 + 2.3 \frac{RT}{n F} \ln \frac{(H^+)}{(H_2)}}$$

When expressed in this form, the log of the hydrogen ion concentration (H^+) is equal to the pH. However, because the molecular hydrogen concentration (H_2) is not a measurement that can be evaluated in terms of concentration like pH, it must instead be measured in terms of partial pressure. This mode of measurement is essential since H_2 at room temperature or greater, e.g. body temperature, is in a gaseous state. A gas is easily defined in terms of partial pressure and is represented by the symbol r. The partial pressure of molecular hydrogen is therefore represented by the symbol rH_2 and is measured in terms of atmospheric pressure known as "bar". [30, 31]

The defining and usage of rH_2 was first noted in print by Dr. W. Clark. Dr. Clark's original intention for inventing this factor was to prove that **E** of a biological system was independent of pH. Unfortunately, this discovery did not prove his hypothesis, but instead further documented that a biological,

or as he stated, "an organic system" is fully dependent upon variances in the hydrogen ion concentration or pH. [32,33]

Therefore, when **E** of a biological fluid is electronically measured, this value alone does not fully represent the internal state of electron donors and electron acceptors. Instead a true and accurate value must take into account the specific pH of the biological fluid in question. [34,35] Only by utilizing the Nernst equation and electronically measuring the **E** value and pH, the most accurate representation of redox, in an active biological solution or rH_2 can be derived. This derived value represents the standard by which all redox reactions existing within a biological solution must be measured.

In the advancing field of Biological Terrain Assessment, the evaluation of rH_2 must be considered.[36,37,38] This factor serves as an excellent source of evaluating the relative condition of oxidative stress. When rH_2 is utilized in relationship to the biological fluids of blood, saliva and urine, valuable scientific data can be ascertained in relationship to the degree and concentration of cellular oxidative stress. This objective information can aid in the assessment of many cellular and mitochondrial functions which have been directly associated with many diverse sub-pathological and pathological conditions. [39]

The optimal values of pH for biological solutions is a well documented and understood science. Guyton Textbook of Medical Physiology clearly states and references the optimal ranges for blood, saliva and urine. [40] However, until now the optimal values for rH_2 have not been as easily accessible and verifiable. Up to this time, the rH_2 values that have been referenced as optimal were values that were compiled by the French hydrologist and professor Louis Claude Vincent. [41] Almost 40 years ago, Professor Vincent compiled the optimal values by testing a large base sample of athletes in the French Alps. He considered these individuals to be representative of optimally healthy individuals and therefore assumed that the mathematical average of their readings should represent the optimal factors. While testing a large sample population of subjects has a definitive place in determining laboratory values, the electrical and necessary mathematical calculations were not fully understood and known at that time. The required electrical equipment of that era to test **E**, commonly experienced a phenomena that is even present in today's advanced technologies. This phenomena is known as electrode "poisoning." [42]

Electrode poisoning is a generic, modern term for a deleterious alteration in the platinum surface of a redox electrode. When a redox electrode is placed in an oxidizing solution, chemical adsorption of oxygen occurs which causes a monomolecular oxide layer. This layer serves as an oxidation reserve

which tends to maintain the electrode potential at an elevated level even when the redox potential of the sample solution has diminished resulting in slow, sluggish response times. This effect is even more noticeable when dilute biological solutions are being tested. A similar scenario is created when the redox electrode is placed in a reducing solution. This time, however, chemical adsorption of hydrogen and not oxygen is encountered. The monomolecular reduced layer that is generated from a reducing solution creates the same ultimate effect on the electrode that the oxide layer created only the opposite. Whereby this newly formed layer creates slow sluggish responses, it now diminishes the electrode potential even when the redox potential of the sample solution has increased. Like the monomolecular oxide layer, the monomolecular reduced layer is sensitive to dilute biological solutions.[43,44] Since the phenomena of electrode poisoning was not readily understood until recently, the probability that Professor Vincent encountered this factor or was even aware of its existence, is quite obtuse.

In addition to the electrode poisoning, additional factors need to be closely scrutinized before acceptance of Professor Vincent's values are generalized. The second factor that deserves investigation is temperature compensation of biological samples. While in its purest physical chemistry definition, **E** is not dependent upon variations in temperature, rH_2 is dependent. [45] A simple review of the Nernst equation clearly demonstrates the profound effects that varying temperature samples will have on the resultant rH_2 value. When testing biological fluids, it is almost impossible to guarantee that fluids that were drawn at different times and having varying durations of exposure to room temperature will have identical temperature readings. This fact dictates why it is essential to electronically and mathematically compensate for any variances that may occur in temperature from sample to sample during the actual testing process. While the overall significance that variances in temperature have on alterations in the resulting rH_2 factors are relatively small in comparison to the electrodes poisoning effect, they do never-the-less exist and should be considered. Not only do these temperature factors have a role to play in rH_2 derivation, but no where in the literature did Professor Vincent even acknowledge their existence. These factors create further credibility gaps which serve to allow additional query of Professor Vincents' rH_2 optimal values.

The final concern in relation to the precision and accuracy of the optimal rH_2 values is in the theoretical understanding of redox potential. By pure definition, "every redox reaction must have an oxidant and a reductant."[46] "There has to be oxidation to have reduction!" These simple but accurate scientific statements outline the parameters that must be adhered to under "ideal" situations. In other words, the variance in electron concentration

from a given reaction should have a net gain or loss of zero. When one substance has donated a hydrogen atom, carrying with it the electron, another substance will accept the hydrogen atom and the corresponding carried electron.[47] Therefore under "ideal" parameters and viewing the rH_2 value as approaching perfect chemical laws, the current optimal values as determined from the works of Professor Vincent can not be considered. When you solve the Nernst equation for the biological solutions of blood, saliva and urine and you consider all of the significant factual scientific information that is available today, a slight variance from Professor Vincent's values become apparent. The blood, which according to Professor Vincent has an ideal rH_2 of 22 should now more accurately be considered as 21.7. The saliva, which according to Professor Vincent also had a rH_2 of 22, now becomes 20.0. And the urine, which according to Professor Vincent had a rH_2 of 24, now becomes 20.6.

It is therefore imperative for all students evaluating Biological Terrain to use these values as ideal parameters and should not anticipate the return of the patients' values to these exact points. These specific factors are intended to serve as reference points and must be utilized as such. They clearly represent "ideal" optimal factors that unlike most standardized laboratory values have not been mathematically adjusted to compensate for the deteriorating health of the population. It is certainly possible, if deemed appropriate, to accurately and scientifically analyze with precise electronic equipment, a mass population and mathematically compute the mean rH_2 values. These new derived values would then become the new optimal values that all biological standards would be referenced against. But truthfully, why we would want to have those values that represent the true state of unwellness of our population?

We must remember that the assessment of the rH_2 factor in the Biological Terrain does not actually diagnose a condition.[48] Its truest wealth of value is attained from the scientific determination of relative and comparative states of oxidative stress only. Therefore, it makes more sense to understand that the statistical mean is insignificant when we consider the concept of scientific optimal value. The true evaluation of the rH_2 factor should therefore center around the degree of variance that the sample displays from the optimal value and the direction that the chosen therapy moves the biological fluid. These simple but profound examples exemplify the raw, easily attainable, purely scientific data that the assessment of the Biological Terrain can offer.

Upon reviewing the current literature, it becomes apparent that through the observation and assessment of variations in the rH_2 factor, the degree and extent of cellular oxidative stress could be determined. Within these factors lie the potential key in regulating biological tissue aging as well as solving

the mystery of countless disease and pathological conditions. Many authors, scientists and practicing physicians already recognize the significant inherent role that oxidative stress has in the realm of current medicine. However, it is time to unveil the core definition and understanding of this paradigm and fully grasp its most basic meaning. Oxidative stress is related to a shift in the redox potential toward increased oxidation of cellular macromolecules. By fully embracing this current awareness, testing for the body's **E** value and solving the rH_2 factor, it becomes evident that a simple, accurate assessment of the cellular oxidative stress level is readily accessible. The utilization of this technology is freely available to every practitioner today. However, one must first have a thorough comprehension of redox potential to fully understand the premise of Biological Terrain and its significance. The study of Biological Terrain is not only a gift from the past, but also represents a key to the successful health of our present and our future.

The precision and accuracy afforded us by modern-day technological advancements is enabling us to obtain more scientific research data than ever before in history. It is our responsibility as scientists and practitioners to embrace these expanded discoveries and shift our old health paradigms. This will enable us to accurately access and monitor the expanding health needs of our patients. Given the overall circumstances of his era and the relative state of biochemistry and electronics, the work that Professor Vincent accomplished was truly nothing short of extraordinary. Today, with the aid of modern technology and current perspectives on physics and chemistry, I have been able to not only improve on his foundation, but document the entire process as well. My truest heart felt thank-you is therefore extended to a mentor that I have never had the opportunity to meet, Professor Louis Claude Vincent!

REFERENCES

[1] Aihara, H., Acid an Alkaline, George Ohsawa Macrobiotic Foundation, 1511 Robinson Street, Oroville, California 95965, Fifth Edition 1986.
[2] Wingate, P., Gifford, C., Treays, R., Essential Science, EDC Publishing, 10302 E. 55th Place, Tulsa, Oklahoma 74146, 1995.
[3] Stryer, L., Biochemistry, W.H. Freeman Co., New York, New York, 1988.
[4] Aickn, C.C., Intracellular pH Regulation by Vertebrate Muscle, Annu. Rev. Physiol., 48:349, 1986.
[5] Seldin, D.W., Giebisch, G., The Regualation of Acid-Base Balance, Raven Press, New York, New York, 1989.
[6] Hanke, M., Tuta, J., Studies on Oxidation-Reduction Potential of Blood, J. Biol. Chem., 78:36, 1928.

[7] Carter, D., Philips, A., Silver, J., Measurement of Oxidation-Reduction Potentials and pH of Tissues, J. Physiol., 129:33, 1955.
[8] Ingold, W., Redox Measurement, Principles and Problems, Ingold Messtechnik AG, CH-89002 Urdorf, Switzerland, 1982.
[9] Clark, W. M., Oxidation-Reduction Potentials of Organic Systems, Williams & Wilkins Company, Baltimore, Maryland, 1960.
[10] Chapelle, F.H., Lovley, D.R., Rates of Microbial Metabolism in Deep Coastal Plan Aquifers, Applied Environmental Microbiology, v.56, p1865-1874.
[11] Gorby, Y.A., Lovley, D.R., Electron Transport Mechanisms in the Dissimilatory Fe (III) - Reducing Microorganism, Applied Environmental Microbiology, v.57, p867-870.
[12] Grisham, M.B., Reactive Oxygen Metabolism, Reactive Metabolites of Oxygen and Nitrogen and Medicine, Armstrong printing, Austin, Texas, 4-19.
[13] Halliwell, B., Gutteridge, J.M., Free Radicals in Biology and Medicine, Claverder Press, second edition, Oxford, England, 1991:31-34.
[14] Bandy, B., Davison, A.J., Mitochondrial Mutations May Increase Oxidative Stress: Implications for Carcinogenesis and Aging?, Free Radical Biology and Medicine, 1990, 8:523-39.
[15] Sies, H., Strategies of Antioxidant Defense, Eur J. Biochem, 1993;215(2):213-219.
[16] Bland, J., New Perspectives In Nutritional Therapies, HealthComm, Inc., Gig Harbor, Washington, 1996.
[17] Ingold, W, Redox Measurement Principles and Problems, INGOLD, Urdorf, Switzerland, 1982.
[18] Stryer, L., Biochemistry, 3rd Edition, W. H. Freeman and Company, New York, New York, 1981.
[19] Stryer, L., Biochemistry, 3rd Edition, W. H. Freeman and Company, New York, New York, 1981.
[20] Clark, W.M., Oxidation-Reduction Potentials of Organic Systems, The Williams & Wilkins Company, Baltimore, Maryland, 1960.
[21] Harbury, H.A., A Potentiometric Investigation of the Horse -Radish Peroxidase System, Dissertation, Johns Hopkins University, 1953.
[22] Ingold, C.K., Structure and Mechanism in Organic Chemistry, Cornell University Press, 1953.
[23] Clark, W.M., Oxidation-Reduction Potentials of Organic Systems, The Williams & Wilkins Company, Baltimore, Maryland, 1960.
[24] Stryer, L., Biochemistry, 3rd Edition, W. H. Freeman and Company, New York, New York, 1981.
[25] Nernst, W., Theoretical Chemistry, 4th ed., Translated by R. A. Lehfeldt, 1904.
[26] Carter, D., Phillips, A., and Silver, J., Measurement of Oxidation-Reduction Potentials and pH of Tissues, J. Physiol., 129:33, 1955.

[27] Carter, D., Phillips, A., and Silver, J, Apparatus and Technique for Measurement of Oxidation-Reduction Potentials, pH and Oxygen Tension *in vito*, Proc. Roy. Soc. (Biol.), 146:289, 1957.
[28] Clark, W.M., Oxidation-Reduction Potentials of Organic Systems, The Williams & Wilkins Company, Baltimore, Maryland, 1960.
[29] Ziegler, E., The Redox Potential of the Blood in Vivo and in Vitro Its Measurement and Significance, Charles C. Thomas Publisher, Springfield, Illinois, 1960.
[30] Cohen, B., et.al. See Studies on Oxidation-Reduction.
[31] Zerfas, L. G. and Dixon, M., An Improved Cell for Measurements of Oxidation-Reduction Potential, Bio-chem. J., 34, 365.
[32] Clark, W., Oxidation-Reduction Potentials of Organic Systems, Baltimore, Maryland, Williams & Wilkins, 1960.
[33] Clark, W.M., Oxidation-Reduction Potentials of Organic Systems, The Williams & Wilkins Company, Baltimore, Maryland, 1960.
[34] Carter, D., Phillips, A., and Silver, J., Measurement of Oxidation-Reduction Potentials and pH of Tissues, J. Physiol., 129:33, 1955.
[35] Hesselink, T.L., Free Radical Chemistry.
[36] Elmau, H., Bioelectronic according to Vincent and Acid-Base-Household in Theory and Practice, Haug Verlag, Heidelberg, 1985.
[37] Kollath, W., Regulators of Life - from the Nature of the Redox-systems, Karl F. Haug Verlag, Heidelberg, 1968.
[38] Roujon, L., Theory and Practice of the Bio-Electronic "Vincent", SIBEV, 1975.
[39] Elmau, H., Bioelectronic according to Vincent and Acid-Base-Household in Theory and Practice, Haug Verlag, Heidelberg, 1985.
[40] Guyton, A., Textbook of Medical Physiology, W. B. Saunders Company, Philadelphia, Pennsylvania, 1991
[41] Roujon, L., Theory and Practice of the Bio-Electronic "Vincent", SIBEV, 1975.
[42] Anson, F.C. and Lingane, J.J., Chemical Evidence for Oxide Films on Platinum Electrometric Electrodes, J. Am. Chem. Soc., 79, 4901.
[43] Clark, W.M., Oxidation-Reduction Potentials of Organic Systems, The Williams & Wilkins Company, Baltimore, Maryland, 1960.
[44] Ingold, W, Redox Measurement Principles and Problems, Redox Measurement, Urdorf, Switzerland, 1982.
[45] Clark, W.M., Oxidation-Reduction Potentials of Organic Systems, The Williams & Wilkins Company, Baltimore, Maryland, 1960.
[46] Stryer, L., Biochemistry, 3rd Edition, W. H. Freeman and Company, New York, New York, 1981.
[47] Levine, S.A., Parris. M.K., Antioxidant Adaptation - Its Role in Free Radical Pathology, Allergy Research Group,1994.
[48] Greenberg, R.C., Biological Terrain Assessment, Townsend Letter, Oct/Nov, 1996

DDFAO:

Low chrono-amperometry voltage whole body:

Development of the technique and application to the vascular field

KEY WORDS: PRECLINIC ATHEROME, TRACKING, ELECTROCHEMICAL CONDUCTANCE, LAW OF COTTRELL

Whole body low voltage chronoamperometry: technical implementation and application to preclinical vascular disease

KEY-WORDS (Index medicus): PRECLINICAL ATHEROMA, EPIDEMIOLOGICAL SCREENING, ELECTROCHEMICAL CONDUCTANCE, COTTRELL LAW

Jean Pierre OLIVIER, Yann HEMERY, Franck REVEL, Jacques MONSÉGU

SUMMARY

The volume of the populations at risk athero-thrombotic, the late clinical expression of asymptomatic chronic lesions, the need for making carry the effort of prevention on the subjects at the risk encourage to seek diagnostic techniques appropriate to the tracking of mass: simplicity of implementation, weak cost, reliability.

The techniques of impedancemetry available use a AC current which, by nature, generates durable artefacts with the interface skin electrode. The new technique that we use is a chrono-amperometry with weak voltage, exploited by algorithms allowing the taking into account of various modes of conductance starting from 6 symmetrical cutaneous electrodes (head, arm, foot). The collection of the signals by the nurse takes one minute. The result is a radiate flow chart with 22 rays carrying each one the value of conductance in the direction relating to the axis of the body in the frontal plan. Characteristics specific [Sp] and equipped with a positive predictive value [Vp+] high, adapted to the tracking of a chronic vascular pathological state, are observed in a group of 53 hypertensive: Sp 91%, Vp+ 89%; in a group of 37 subjects carrying arterial plates and/or calcifications: Sp 95%, Vp+ 96%. Sensitivity being able to reach 75% for the risk athero-thrombotic.

The physical nature of the conductance on a whole organization scale brings into play, in a concomitant way: in the proximity of the electrode, electrochemical phenomena described by the law of Cottrell; in the space extended between two electrodes, a conduction described by an approximation of the law of Ohm.

Simple to implement, not very expensive, reproducible, innovative, chrono-amperometry whole body can become a decisive instrument of stratification in tracking on a large athero-thrombotic scale of the risk.

SUMMARY

High incidence and costs off atherothrombotic diseases, late clinical complications off asymptomatic chronic arterial wall lesions, and the necessity to provide has better prevention among the population subject to risk factors lead to promote diagnosis tools suitable for broad screening. Such tools should Be easy to utilize, low cost and applicable. Available impedancemetry technical uses alternate electric power, which intrinsically generates artefacts At the skin electrode interfaces. Technical The new we uses is has low voltage chronoamperometry, based one algorhythms integrating different off modes conductance, have measured from 6 symmetric skin electrodes located one head, hands, feet. The supplements recording by children's nurse does not last more than 1 minute. Results appear one A 22 radii diagram face planes, the magnitude off the conductance being transferred one each radius. Technical diagnosis performance off the was evaluated through specificity (Sp) and positive predictive been worth (Vp+), which were respectively: in A 53 hypertensive group, 91 and 89%; in A 37 atheroma group (arterial plates end/gold calcifications) 95 and 96%. Sensitivity was 62% and 75%.

Physical basis off conductance in total organism includes simultaneously: surrounding the electrode, electrochemical modifications according Cottrell law; through the inter electrodes space, properties approximated by Ohm law.

Easy to uses, low cost, reproducible, innovative, whole body chronoamperometry may appear have year appropriate stratification tool in broad atherothrombotic risk populations screening

The raised incidence, the exorbitant costs and the epidemiologic prospects established as regards athero-thrombotic affections result in developing more than ever the conduits of prevention. The athéromateuse disease knows a long clinical pre phase (before the infarction, before the cerebral

accident), itself fractionnable according to whether it exteriorizes identifiable vascular lesions by imagery (plates, calcifications), or not (disease still confined at the molecular level then cellular). In this context of public health, the development of a tool for tracking simple to use, able to sort, at low cost, the asymptomatic subjects carrying vascular anomalies will infra clinical can contribute to the effectiveness of the prevention policies [1].

The passive electric properties of useful living tissue for the diagnosis are exploited: the thoracic impedance for obtaining the cardiac flow in is an example [2]. On the other hand, the conductance, explored well at the cellular level, was hardly measured on the whole body. It is the technique which we used, by testing the assumption that the athero-thrombotic disease induced, well before it is expressed clinically, of the measurable modifications of conductance at the level whole body.

PHYSICAL PRINCIPLES

With the macroscopic level, the passive electric properties of living tissue were studied primarily in terms of impedance (quotient of the tension by the intensity) [3]. The current applied is in general a high frequency, variable AC current between 50 μA and 700 μA. the impedancemetry is however of limited range: the fabrics constituting an electrolytic medium in which conduction is ensured by ionic carriers, the setting in contact of a metal electrode and an electrolyte generates an impedance with the interface, often called wrongly “impedance of polarization”. Coming to fit directly in the measuring circuit, this impedance disturbs measurement. This is why, in spite of the important literature devoted to this subject, the techniques of impedancemetry are very delicate to use.

Giving up the AC current, we tried out a measurement technique of conductance (opposite of electric resistance) total between various points of the body in D.C. current of weak voltage, and physiologically in lower part of any rheobase. If one frees oneself thus from the capacitive effect on the level of each electrode, one does not escape the local electrochemical effects around the electrode These phenomena were studied in electrochemistry, in particular by the technique of chrono-amperometry which uses a level of continuous tension and measurement the resulting current between the two electrodes [4].

In D.C. current, of the 3 possible electrochemical behaviors: stationary (not of transformation of the ionic medium), temporal (transformation) and transient, (intermediary between the two first) this last alone is largely observed. It obeys the law of Cottrell: initially stationary the passage of the current evolves/moves like the reverse of the square root of time

[5].

With the level whole body, in D.C. current, the passage of the current depends on the tension applied and the resistance of the circuit made up itself 1) of the contact areas skin electrode; 2) of the solution of electrolytes contained in the cutaneous envelope. The most significant part of

resistance is that of the contacts. It varies according to the metal of electrode, the pressure, the local hydration.

METHODS

Technique and equipment

Equipment uses a topographic technology of impedancemetry applied to diagnostic ends [EZScan®]. Rapid and noninvasive, the examination of the patient is carried out by applying 6 electrodes symmetrically to the face (Ag/Ag Cl), to the hands and the feet (Cu). Each electrode is alternatively receiving and transmitting of a D.C. current of weak voltage. One chooses 22 modes of measurements of current on the thirty possible ones.

An electronic device of precision, able to treat signals of a few microamperes, collects the samples of the current passing between each pair of electrodes. Several consecutive sweepings make it possible to check the quality and the coherence of measurements by algorithms owners. Each measurement of current is the result of an average of 255 samples taken during 3 seconds. The dynamics of measurement is done on a scale of to 0 to 100.

Once validated, the data are transformed and standardized before being analyzed thanks to an expert system coupled to topological data bases. The topology of the results makes it possible to locate the state of the patient on an ergonomic chart.

Expression of the results

The measured physical parameter is the electrochemical conductance, expressed in micro mho [µS]. The actual values go from 0,1 to 10 µS. the results are presented on a radiate scale in the frontal plan: each ray has a space correspondence. One sees visu thus a second parameter: spatial of the conductances. This one is not equal in all the directions. This observation makes it possible to postulate that the local conductance and within the electrolytic element whole body is not isotropic. This anisotropy can have a significance. []

Methods of analysis

The checking of the law of normality in the distribution of the data on the unit of the population was operated 1) per classification of the values, which makes it possible to be ensured of the form in S of the curves, 2) by the following checks: average close to the normal, spaces interquartile symmetrical around the normal, classification of 66%, 95%, 99% of the values contained respectively between - 1 and 1, +2 and - 2, + 3 and - 3 standard deviation. We note well that all the variables used follow a normal law.

Correlations between parameters, ways of measurements: test of Spearman to the risk of 1% and 5% to qualify the level of correlation enters the ways of measurements and between the ways of measurements and the parameters such as the age, the size, the weight, the IMC and the factors of risk.

Exploration of the data for the groups patient/not patient: technique of the decision trees reduced to the ways of not correlated measurements, to lead to under relevant groups, very strong specificity. The comparison of the evolution of the correlations between measurements according to groups' patient/not patient also brought interesting elements.

Diagnostic performance: each sub-group is evaluated of predictive sensitivity, specificity, values positive and negative (VP+, VP-). These sub-groups, disjoined enough, could be amalgamated, in order to improve the total sensitivity of the tests while keeping a strong specificity. The evaluation of the confidence interval was made to 95% for the VP+ and VP- (1,96 ^{X} root [p * (1-p)/N] - p being the estimated proportion, N being the sample size).

The analyzes are led remotely place of collection, in the total ignorance of the medical files, without individual mention in the computer files.

Physiological value of the signal

We checked physical stability and the reproducibility of measurements. Each recording of the conductances at each patient comprises 4 identical measurements repeated during the meeting. A defect of stability of the parameter, factor of exclusion, was observed at less than 3% of the subjects.

In addition, a matrix of correlation between the 22 ways of measurements of conductance on the totality of the patients was established. []

Certain ways, showing rates of correlation ≥ 0,9, are particularly reliable: positive anodes foot, head positive, hand positive. These observations allow a minimum of three dimensions of analysis independent on the respective levels of these groups of ways, systematically applied in the search for diagnostic rules by decision trees.

Degree of independence of the signal

The signal is highly reproducible. Is it independent of current parameters used in pathology? The matrix of correlation between age, size, weight, index of body mass, numbers factors of risk shows that these factors do not contract any significant correlation with the conductances. []

RESULTS

Population of study: ***The principal group*** is composed of 96 patients (16 women), of average age 56 years (19 to 85 years). The number of factors of risk of vascular disease individual is of 1,76±1,42. Arterial hypertension is present at 50% of the patients; the coronary disease at 37%; an objective demonstration of athérome peripheral (associate or not with the coronary disease) at 37%. The proportion of diabetics is 13%.

Complementary group: in order to try to clarify the observations made on the first group, a group complementary to 28 indiscriminés patients was the subject of measurement of conductance before and after test of effort.

Hypertensive patients

The diagnosis of hypertension rests on a medical history of noncomplicated HTA going back at least to several months. One compares 53 hypertensive patients (67 ± 17 years) and 43 normotendus (47 ± 21 years) the conductance is independent of the factor "age".

The projection of the conductances on the axes of measurements not correlated that are the electrodes hands on a side and the electrodes hands/feet in addition, makes it possible to identify groups of different patients, with electrochemical conductance higher or lower than the normal. But especially, the anisotropy of the conductance in the whole body makes it possible to identify electrodes + and – more specifically "speaking" at the hypertensive one. [. 1]

Diagnostic performance of our technique: a sensitivity of about 60%, only to measures of electrochemical conductance, represents a remarkable result. The very strong specificity of measurement involves an excellent positive predictive value. On the whole: the distribution of the electrochemical anisotropy of conductance distinguishes 3 populations the hypertensive ones: to characteristic conductance enters the feet; to weak conductance enters the hands; with weak conductance between hand face. It is difficult, in the current state, to establish a link between these electroanalytic observations and the physiopathological forms of arterial hypertension.

Patients carrying chronic athero-thrombotic disease

One compares a population of 37 patients introducing a chronic athero-thrombotic disease, 69 ± 11 years (diagnosis by imagery), and a population of 59 subjects without athérome identified, 50 ± 21 years.

The distribution of anisotropy is different from that of the hypertensive patients. It implies combinations MGMD and PGPD on a side and MGMD and MDFG in addition. The analysis adapted to the characteristics of electrodes in this population provides a performance diagnoses high. [Tab.2]

The specificity of 95% for a sensitivity of 75% is all the more remarkable as it is not a question here of patients having obligatorily a clinical history, but only mention of athéromateuses plates or calcifications on examinations of imagery led to systematic title. In the same way, the positive predictive value of 96% making it possible to affirm the absence of infraclinic lesions offers a tool adapted to tracking.

Test of effort

28 patients (57 ± 16 years) consecutive, and indiscriminés with regard to the indication of the test of effort, had a measurement of conductance before and after this examination. There is not any connection between the values of conductance and the physical parameters of the test of effort (blood pressure, heart rate, total work) or the possible modifications of the electrocardiogram.

The comparison before/after effort makes it possible to make 2 types of observations: the topography of the anisotropy is modified by the effort: the raised conductances go towards the cephalic electrodes, the conductances undervalued towards the electrodes of foot. [4]

To try to include/understand this singularity, we applied, a posteriori and as a blind man, the model of anisotropy observed in the preceding group of athéromateux patients, on the subjects subjected to test of effort: according to this model, 12 patients are identified with probability of athéromateuse disease, at 16 subjects it is improbable. The patients with strong probability of atherothrombotic disease present a less deviation of anisotropy of electrochemical conductance after effort (in fatty feature) that subjects with weak probability. [] No univocal explanation can be brought to this observation.

DISCUSSION

The passive conduction of the electrical current in living tissue caused its old work, around the comprehension of the cutaneous genesis of the electrocardiographic signal [6]. Carried out in AC current, of measurements of body resistance values of about 2.000 Ω (ordinary contacts) gave to

500 Ω (goods contacts of great surface), grease having a resistance from 100 to 1000 times larger than blood, that of the muscles and full parenchymas being about 500Ω. to explain the reproducibility of the electrocardiogram, the globality of the body seemed comparable to the filled up regular shape of a homogeneous conducting liquid.
The properties of conductance are used like a tool for indication to functions varied by the fish [7]: emission and reception of electric signals make it possible many species to identify the presence of congeneric (high conductance) within the marine environment (weaker conductance).

The aim in view here is that of the identification of the subjects presenting a athérome preclinic, early tracking being a deciding factor of effectiveness. Extended to broad populations, the prevention of the athero-thrombotic diseases has to take a decisive importance in the years which come. Still is necessary it that it rests on a powerful diagnostic tool, of weak cost, technically usable by little trained personnel: three conditions to which our method satisfies.

On the fundamental level, the electrical current lower than the rheobase applied to the cutaneous coating of a living organism knows a conduction dependant on the characteristics of the current itself and properties of the organization.

In this case, the current constantly remains extracellular: the D.C. current does not cross the lipidic cellular barriers because of their very important capacitive effect which blocks the circulation of the electric charges. Its passage induces 2 principal phenomena:

- in the direct proximity of the electrodes, in the local interstitial medium, the electrochemical phenomena are prevalent. It are an especially function of the times, asymmetrical, and described well by the law of Cottrell (see appendix). They result in an amplification of the conductance, which we measured in the fork from 0,1 to 10 µS. the most important substrate of this phenomenon is probably ion $^{HCO3-}$ [. 3] [8];

- between the zones of proximity prone to these electrochemical phenomena, the conductance of the whole body obeys the law of Ohm at first approximation, independently of the factor time, and symmetrical when the two poles are reversed. This approximation is founded on the homogeneity of the concentration in Na+ ions and $^{HCO3-}$ in particular, but our measurements show that the laws of passage of the current are certainly more complex, and that the conductance whole body is strongly anisotropic.

In a more speculative way, at any spark gasp, the electrochemical activity within the interstitial solution can be influenced by the behavior of the same cells they since one locally unbalances the potential differences and the concentrations between this medium and the interior of the cells. The passage of the current can thus induce membrane modifications (channels ionic) or extra-membrane (proteins of connection).

Our working hypothesis is founded on the possibility of detecting by a physical process the clinical pre athéromateuse disease. The level in is certainly molecular then cellular, but the extension within a great part or totality of the arterial walls as suggests it molecular biology [9], makes a macroscopic phenomenon of scale of it, extended to the whole body, attested by the

measurement the thickness intima/media on the level of various arterial segments. It is difficult, in the current state, to precisely attach our observations to elaborate modelings of conduction of the interior medium [10]. In spite of the imperfect knowledge of the physics of conduction of the current in the alive mediums, measurements which we made show in fine a performance diagnoses high.

CONCLUSION

The predictibility of which has occurred in a given time of a vascular accident starting from the only usual factors of risk is all the more weak as the subject is young. A strategy of public health aiming at identifying the subjects carrying marks of pre athéromateuse disease clinical, all the more effective as the subject is young, should thus comprise, in addition to the identification of these factors of risk, a vascular imagery. If the results of our work are confirmed, a measure of conductance of the whole body, of a harmlessness total, easy to implement, of a weak cost, and without equivalent today, could be proposed in tracking of first intention, possibly upstream of the medical intervention.

APPENDIX

Electroanalytic methods:

The electroanalytic methods use the property of certain chemical substances (materials or solutions) to be able to exchange electrons with an electronic driver, which is often a metal solid (gold, platinum, palladium, copper, money….), through a solid ionic medium or liquid. The electronic conducting medium is called electrode. The capacity of a chemical species to exchange electrons, with another species or an electrode, is called the electroactivity, the incapacity names indifference, one uses also the inert adjective.

A electroanalytic method consists, either to impose a potential difference electric, or to run an imposed current (one can never make both simultaneously if one seeks a certain duration of observable experiment…), between two electrodes plunged in a gaseous medium or liquid or solid containing the substance to be analyzed, only or with others.

The great specificity of electrochemistry compared to other fields of physical measurements, it is the capacity to transform the species chemically. This advantage can be made profitable to produce species all while analyzing them, such as for example species at short lifespan or to analyze traces of substances in a medium by accumulating the product of their transformation. On the level of the electrode a constant of balance depends exponentially on the energy of

activation of the reaction. *The law of Nernst* establishes a linear dependence of the energy of activation with the difference between the potential of the electrode and the normal potential of the redox cell, via the coefficient **- *nF*/*RT.Deux*** great classes of methods is thus used, those with current imposed (like the impedancemetry in medicine) or those on imposed potential as the chrono-amperometry which we will further describe [11].

The impedancemetry is a electroanalytic method imposing a current modulated by a sinusoid of frequency given (which one can vary) and measuring the component of the potential at the same frequency. The comparison between the potential and the current (using an amplifier with synchronous detection) makes it possible to calculate the differential impedance or the admittance (conductance complexes) differential. Exploration in frequency constitutes the spectroscopy of impedance.

Chrono-amperometry consists in imposing a jump of potential starting from the potential of balance (running no one) up to a fixed value, to which can be carried out the reaction to the electrode, and to measure the current according to time. According to the reversibility of the transfer of load, the evolution of the concentrations to the electrode will follow that of the potential more or less: Perfectly, i.e. with an of the same jump forms, in the case of total reversibility, with delay when the reversibility is limited. The abrupt variation of potential also causes to charge or discharge the double layer, which results in an additional current. In liquid medium, time characteristic of load/discharge is generally lower (a few 10 ms) than time characteristic of the transfer of matter (some S), with the result that there is to take into account the current only beyond the initial moments.
When the transfer of load is completely reversible, the prediction of the response while running is very simple. The concentration on the site of initial species A follows an evolution in level (jump). The current is proportional to the temporal derivative p-ième (p = mode of transfer of matter) of the concentrations. Thus in the stationary mode one also obtains a jump of current, in the transitory mode after a peak limited by the instrumentation, the decrease is done according to a law in T power minus a half, which one indicates by the term of **law of Cottrell**. Finally in temporal mode, the theoretical answer is a "distribution of Dirac", i.e. a null function for any value of T safe for $t=0$ where it is infinite. This theoretical answer is never observed in practice for the reasons previously called upon of instrumental limitation or simply because a reversibility of transfer of load is never sufficient to admit infinitely fast variations of flow of matter or current.

The concept of limited reversibility means that there are conditions (potential, speed of transfer of matter, etc) beyond whose the transfer of load becomes irreversible. The rule of an operation of the less favorable mechanism in the event of irreversibility is checked: It is noted that the irreversibility of the transfer of load leads to currents weaker than in the reversible mode. The case of the temporal mode, in spite of appearances, does not escape this rule since theoretically the reversible current is infinite at the time of the jump. []

All these currents are proportional to the concentration in the ionic medium considered of the électroactive chemical species.

Electric law of conduction in inhomogenous medium

According to Kanai and Meijer [4] the membrane of the cell behaving like a capacity, the low frequency current does not penetrate in the intracellular medium. The high frequency power goes, to be on to him through the membrane of the cell, it thus will be present at the same time in the intracellular medium and the extracellular medium. What results in a formula of total impedance having the following form:

$$Z = \left(\frac{R_e}{R_e + R_i} \right) * \left(R_i + \frac{R_e}{1 + (j * \omega * C_M * (R_e + R_i))^{\alpha}} \right)$$

where *Re* represents extracellular resistance, *IH* total intracellular resistance, ω the pulsation, α the phase and *CM the* equivalent capacity. The techniques of traditional impedancemetry thus uses the high ones and low frequencies to try to distinguish the share from the water included/understood in the cells of those out of the cells.

For the D.C. current we thus have a very particular electric conduction which depends very appreciably on the cellular density of crossed fabrics. Many research tasks are carried out on this subject in particular on the level it brain to locate with precision the phenomena detected by imagery IRM, the treatment of ischaemias and others traumas and the delivery of the therapeutic agents.

Known models of propagation in inhomogenous medium like the models of archie [12] are regularly used. In particular the relation between the conductivity of solvent and apparent conductivity [10]:

$$\sigma eff = \sigma solv.(1-p)^{1/(1-La)} = (1-p)^{m}$$

p being the volume occupied by the cells; m being the factor of cementing which takes for value 3/2 for a sphere 2 for ellipsoids transversely and 1 for ellipsoids in the direction of the current.

However these models appear summary and largely insufficient to explain the differences in effective conductivity. Recent work [13] shows that this type of law does not apply also simply and calls into question the models of archie. Other complex concepts like the viscosity and the

difference of the sizes of cells are probably to take into account to evaluate the conductance of these complex mediums.

Bibliography

[1] C SIMON A, LEVENSON J. - Could the identification off subclinical atherosclerosis offer year alternative to the farmhouse drug off hyperchloesterolemia? *Atherosclerosis*, 1994, *105*, 245-249

[2] BRUCE D., SPIESS Mr. D., MUHAMMAD A. *and Al* - Comparison off bioimpedance versus thermodilution cardiac output during cardiac surgery: Evaluation off has second-generation bioimpedance device. *Newspaper off Cardiothoracic and Vascular Anaesthetized,* 2001,15*,* 567-573

[3] KYLE U.G., BOSAEUSI., DELORENZO A.D. and Al - Bioelectrical impedance analysis - share I: review off principles and methods. *Clinical Nutrition*, 2004, *23*, 1226-1243

[4] KANAI, K SAKAMOTO, Mr. HAENO - Electrical measurement off fluid distribution in human legacy: estimate off extra and intra-cellular linen fluid volume. *The Newspaper off Microwave Power* 1983, *18*, 233-243

[5] AUDEBERT P. - *Electrochemistry: Concepts with the applications*. (Dunod Edict.) 2005

[6] BLONDEAU Mr., HILTGEN Mr. - *Electrocardiography clinical*. (Masson Edict) 1980

[7] SCHMIDT-NIELSEN K. - *Animal Physiology,* (CambridgeUniversityClose Edict) 1998

[8] PITTS RF - *Physiology of the kidney and the interior medium*. (Masson Edict) 1973

[9] LIBBY P. - Ignition in atherosclerosis. *Nature*, 2002, *420*, 987-1002

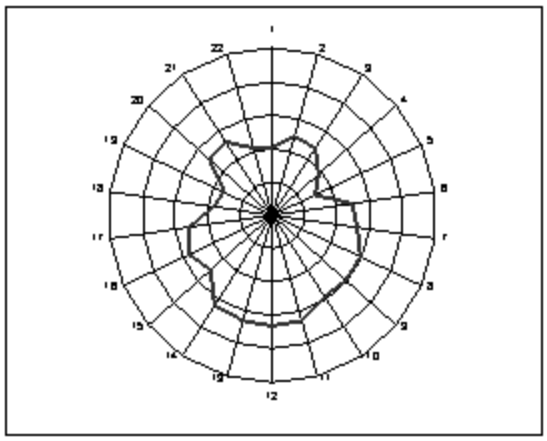
[10] PETERS Mr. J, HENDRIKS MR., STINSTRA J.G. - The passivates cd. conductivity off human tissues described by concealments in solution. *Bioelectrochemistry,* 2001, *53*, 155-160

[11] GEDDES L.A., BAKER L.E. - The specific resistance off biological material — has compendium off dated for the biomedical engineer and physiologist. *Med. Biol. Eng.* 1967, *5*. 271–293.

[12] ARCHIE G.E. - The electrical resistivity log have year aid in determining nap tank characteristics. *Trans. Amndt Inst. Min. Metal. Eng.*1942, *146*, 55–62.

[13] KUME-KICK J., MAZEL T., VORÍSEK I. and Al - Independence off extracellular tortuosity and volume fraction during osmotic challenge in rat neocortex. *Newspaper off Physiology*, 2002, *542.2*, 515-527

FIGURES AND TABLES

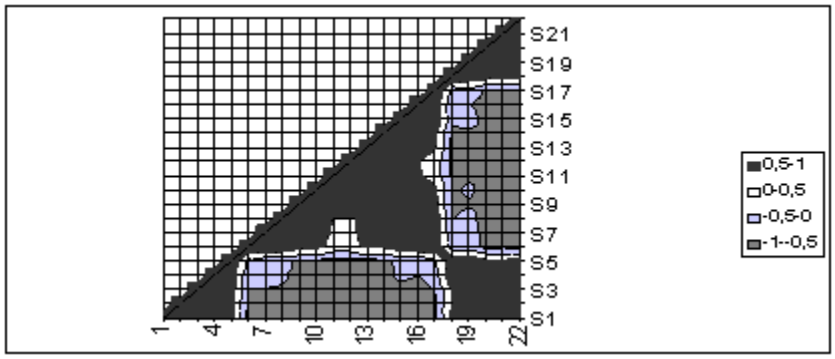


N°	
1	FG FD
2	FG MANDELEVIUM
3	FG MG
4	MG FD
5	MG FG
6	MG MANDELEVIUM
7	MG PG
8	MG PD
9	PG MG
10	PG MANDELEVIUM
11	PG PD
12	PD PG
13	PD MG
14	PD MANDELEVIUM
15	MANDELEVIUM PG
16	MANDELEVIUM PD
17	MANDELEVIUM MG
18	MANDELEVIUM FD
19	MANDELEVIUM FG
20	FD MANDELEVIUM
21	FD MG
22	FD FG

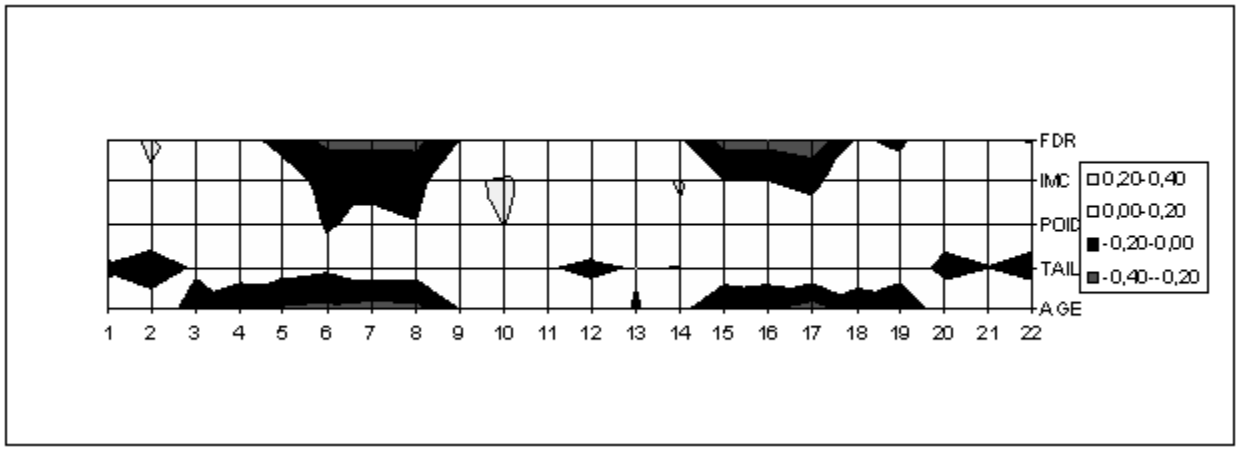
1: spatial of "derivations"

(F face; M hand; P left foot D right and G). The image

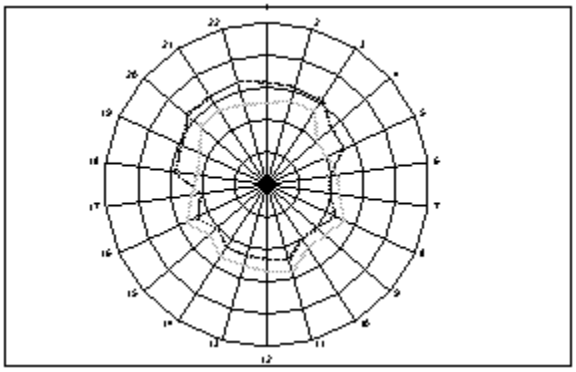
Characteristic is built by junction of the values of conductance related to each axis.



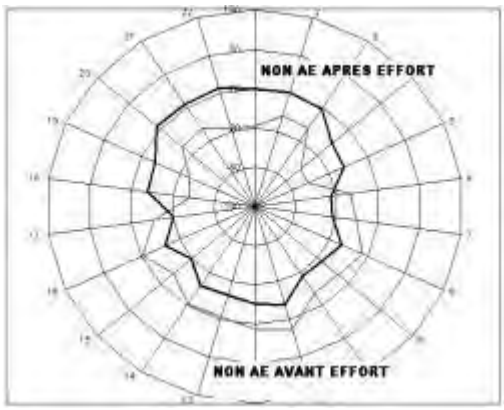
2: stamp correlation of 22 “derivations” on the totality of measurements: it objectifies the reliability of the data.

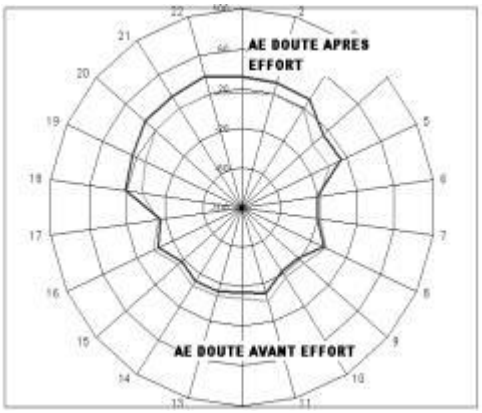


3: Stamp correlations between the descriptive characteristics of studied subjects (FDR: factors of cardiovascular risk; IMC: index of body mass P/T ²): they are independent of the values of conductance.

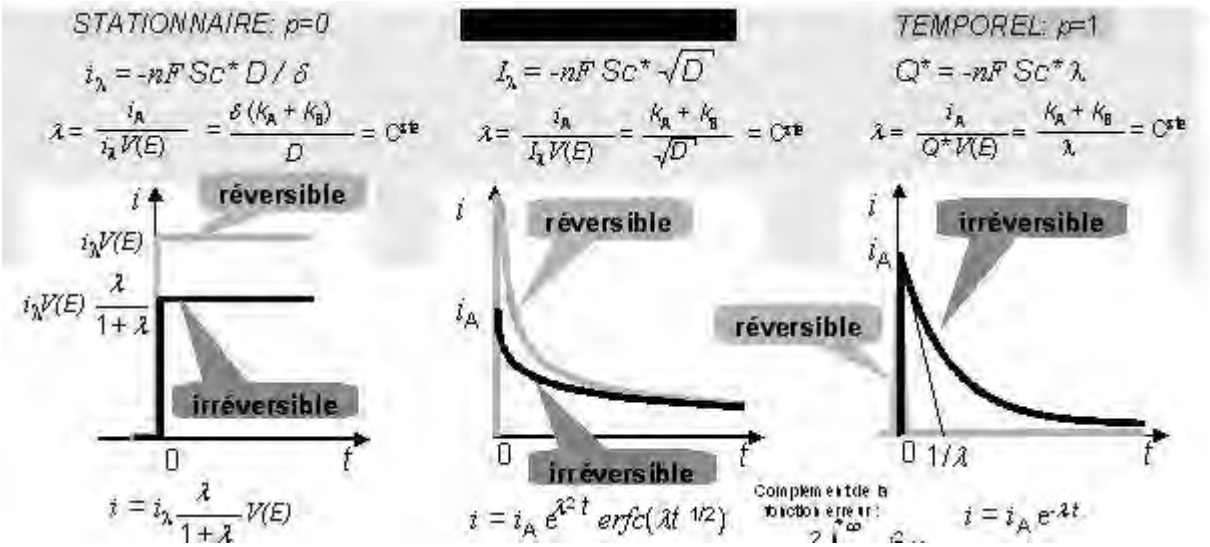


4: After effort (milked fatty), the conductances are increased in the direction of the cephalic electrodes.





5: The application of the law of anisotropy of conductance before and after test of effort formally distinguishes the patients with weak probability (NOT AE) of the patients with strong probability (AE DOUBTS) of athérome.



: 3 modes of behaviors of the interior medium in the proximity of the electrode.

HYPERTENSIVE	identified sick	identified not patient	totals		
hypertensive	33	20	53	**62%**	sensitivity
normotendu	4	39	43	**91%**	specificity
	89%	**66%**			
	VP+	VP-			
"+/- with the risk of 5%"	10,01%	12,08%			

. 1: diagnostic performance in the group of hypertensive patients (VP: predictive value)

ATHEROMATEUX	Diagnosis Nonathéromateux	Diagnosis athéromateux	totals		
ABSENCE ATHÉROME	44	15	59	**75%**	sensitivity
PRESENCE ATHÉROME	2	35	37	**95%**	specificity
	96%	**70%**			
	VP+	VP-			
"+/- with the risk of	**6%**	**13%**			

5%”					

Tab.2: diagnostic performance in the group of athéromateux patients (VP: predictive value)

Interstitium	concentration mmol/L	molar conductibility ms * m ² * mol-1	conductance µS/m
Cl	114	7,64	8,71E-01
HCO3-	30	5,46	1,64E-01
Na+	144	5	7,20E-01
H+	0,07	35	2,45E-03

Tab.3: Ionic composition and conductance of the interior medium (ms, µS = milli and micro Siemens). According to [8].

1[1]Military hospital of the Valley of Grace, Service of Cardiology, 75230 Paris Cedex 05

Drawn-with-share: Jean Pierre OLIVIER, with the address above

1. What is DDFAO ?

DDFAO has been invented in France and is an awkward French acronym to designate the first “Computer-Aided Screening and Functional Diagnosis” non-invasive investigation tool for the entire human body.

DDFAO is an imaging medical device but, unlike conventional scanners or MRI, which are expensive imaging devices looking for any possible lesion in the body and therefore require extensive computer power in order not to miss any detail, DDFAO is looking for the functional state of the different organs and systems of the human body.

2. What are the principles behind DDFAO ?

Unlike ENT or EAV devices (ElectroAcupuncture according to Voll), which might appear similar at first glance, DDFAO is NOT relying on a lengthy process of manually locating tiny

measuring points on the acupuncture meridians throughout the body in order to evaluate 'bio-energy flows'.

DDFAO is a true medical device which reliably measures bio-electroimpedances by mean of 6 convenient large flat pods and determines accurately body parameters like pH and blood pressures, thanks to its highly integrated electronic circuitry.

DDFAO's integrated expert-like patented technology is also able to interpret these data by applying the neurophysiology principles and to propose automatically its own analysis of the patient's risks in less than 3 minutes (measuring time included), instead of simply printing out the measurements results as a set of raw data which require significant time of a trained person for the analysis!

Unlike Body Composition Analyzers, devices of similar appearance which also measure bio-electroimpedances but determine only characteristics of the body like good and bad fat, weight of the bones, percentage of water…, with no further analysis, even for the most sophisticated ones, DDFAO expert-like system is able to deliver a full analytical report on the detailed functioning of the complete body with organs and systems (down to the hormones), along with quantifying the risks for pathologies, giving recommendations for conventional examinations, and suggestions for therapies.

3. How does DDFAO work?

DDFAO is measuring the human body's electrical activity, actually using the same principles which are behind the well-known EEG and ECG, but instead of focusing on brain or heart activities, DDFAO applies the technique to the entire body, to record an ElectroSomatoGram (ESG).

DDFAO is simply sending a harmless low DC-voltage (1.28V) to the patient's body, by the mean of 6 electrodes in contact with his skin: two on his feet, two on his hands and two on his foreheads. By sequentially applying the positive polarity on each one of these electrodes while every other one is sequentially receiving the negative polarity, DDFAO initiates a migration of H+ and HC03- ions in the different tissues traversed, thus creating a very low DC-current which is measured on each of the 22 branches under analysis.

The bio-electroimpedance of each branch is then simply calculated by the application of Ohm's Law and recorded as the ESG. Of course, each branch is composed of many organs and tissues but DDFAO's patented cross-analysis algorithms allow to calculate the bio-electroimpedance of more than 69 different volumes (organs and surrounding tissues) in the human body and ultimately to determine the pH of each one of these volumes, whose pH is representative of their alkalosis or acidosis state, which is significative of trends or pathologies, according to the importance of this pH value.

The correlation between an organ's bio-electroimpedance and its pH or blood pressure is not new: it was actually proved by numerous electro-physiological researches that started as early as

the middle of the 19th century (E. Du Bois Reymond, 1857). But at that time, this experimental work had no applicable usage in common practice because it would take way too long to manually make all the measurements and calculations needed to make a proper diagnosis: only the modern understanding of the neuro-physiology principles and the affordable and extensive power of today's computers allowed fast calculations and the neurophysiology systems to be modelized into DDFAO.

4. What is unique about DDFAO technology?

DDFAO is not representing these data on a hard-to-read list of numbers or hard-to-interpret graphics, but in a similar way that the data collected by mean of ultrasounds are displayed after calculations in an echography, DDFAO generates several reconstituted color graphic images in its unique easy-to-read yet comprehensive way.

DDFAO's unique power does not stop with its quick measurement time and easy-to-read colorful screenshots : DDFAO's embedded expert-like system instantaneously proposes to the doctor its own analysis of the risks related to the current condition of the patient, suggesting possible complementary conventional examinations and actions related to several possible therapies.

This is made possible by DDFAO's embedded expert-like system which integrates the neurophysiology models describing the way the different systems regulate the human body in order to maintain it in a well-balanced state (like the sympathic, parasympathic, endocrine, immune, central nervous systems, …) with the active links between each one of their elements, which lead to pinpointing the discrepancies between the expected behaviors of the different elements of the body and their actual states, revealed by the measurements.

DDFAO is not intended to replace doctors but is an easy-to-use investigation tool designed to help the doctor to quickly spot the disorders of a patient. It remains under the doctor's full responsibility to filter the relevant information according to his patient's knowledge and historical record and deliver the final diagnosis –even if the input of the patient's clinical context details will filter DDFAO's proposed automatic analysis of risks for an even more accurate diagnosis.

5. Why another diagnosis tool?

In the old days, when the engine of your car was exhibiting some noisy or smelly sign of disorder, you had to refer it to a specialist: a skilled old-timer in a garage would appropriately stick his screw-driver on some specific spots of the running engine before delivering his sober diagnosis. Even though this looked magic, it worked most of the time, as long as you can find them… Since they universally tend to disappear these days, the modern car industry has come-up with new diagnosis tools which allow young mechanical engineers to deliver a timely and accurate functional diagnosis after hooking-up a computer-based analyzing tool to the engine – with no magic.

Each year, the medical industry is presenting new medical devices focusing on different pathologies, but very few medical devices like DDFAO are addressing the needs of the general practitioner to ease his search of the origin of his patient's problem with a global approach, taking all systems into consideration, and shortening the time needed for his analysis work, not requesting laboratory examinations to start with.

Interestingly enough, outside of the surgical block where the patient's functional state is monitored in detail, no medical device before DDFAO was addressing the needs of the functional medicine in the private doctor's office or as initial check-up for screening purposes in school or in public hospitals, enabling quick locating of the origin of a problem, not just looking for symptoms to be treated.

As an example, an ECG will not provide a functional state of the heart. It is an 'instant picture' that may help to spot a problem in the heart, but one can have a good ECG and… an infraction one hour later! It is actually requiring an arteriography to get the functional state of the heart but it is a heavy and costly examination. Like an arteriography, DDFAO will help the doctor to narrow the scope of the search and quickly evaluate the functioning of his patient's heart and cardiovascular system –in 2 minutes, right in his office. If needed, the doctor will then suggest conventional examinations to his patient, to identify precisely a possible lesion.

6. What are the applications of DDFAO ?

Screening and early detection

By pinpointing any discrepancy between the expected values measured in the different areas of the body which are linked together through the different body's regulation systems modelized into DDFAO, all disorders in the organs and systems are highlighted, suggesting sensitivity to possible future pathologies and actions to be taken even before external symptoms have yet appeared. The operator-independent simple and quick procedure allows a high throughput for quick screening of large batches of population under scrutiny.

Functional diagnosis

DDFAO expert-like system analyzes the possible risks related to the current alkalosis or acidosis state of the organs and tissues of the patient, suggesting conventional examinations to assert the patient's condition. DDFAO allows the doctor to look for the origin of a problem, not just treat the external symptoms.

It is to be noted that, like in a normal medical practice, knowing the clinical context of a patient is of a particular importance, since DDFAO is not looking for lesions. If the body is used to function with a particular lesion with no harm, DDFAO will not show a disorder. Similarly, if a treatment is appropriate and suppress the initial disorder, DDFAO will only show that, as a result of the good treatment, the body returned in an homeostatic (i.e. well balanced) state.

Treatment follow-up

Dynamic comparisons between the patient's functional states, as recorded during two different visits. The values are instantly compared and DDFAO will pinpoint all the areas which have come closer to the homeostatic state, also highlighting the areas where the disorders have increased, allowing the doctor to take immediate corrective actions, before new external symptoms even appeared. Ultimately, DDFAO will allow asserting the return to the homeostatic state of a patient, thus indicating if the treatment must be continued even when the external symptoms have disappeared.

7. Who is using DDFAO?

Private doctors
As an easy-to-amortize diagnosis tool in their office, DDFAO will save time in getting a quick initial check-up for the new patients, narrowing the scope of the search with conventional examinations, then in appreciating the prescribed treatment's benefits or side-effects, and finally asserting the complete functional recovery of the patient, once the external symptoms have disappeared. DDFAO's suggestions for different therapies also help specialists (homeopaths, nutritionists, acupunctures, ear-therapists, osteopaths, etc…) to quickly determine where to apply the appropriate treatment.

Private clinics
With its multi-doctor hierarchical organization, DDFAO as an organizational tool will enable each department to keep track of their own patients' records and monitor all department activities –each one benefiting of DDFAO powerful features. All DDFAO devices may be linked on the clinic's local network, share the same database and centralize the analysis and the printouts.

Public hospitals
Above all features and benefits, with its high throughput and operator-independency, DDFAO will also help to quickly route the incoming patients to the relevant department. Additionally, some research work can be performed with DDFAO's detailed measurements values available any time at finger's request.

'Flying doctors'
With its comprehensive yet systemic approach, DDFAO is ideal for remote 'on-the-move' screening and diagnosis in villages, in the absence of nearby examinations laboratories.

Non-Governmental-Organizations
With its high throughput, DDFAO is ideal to realize large scale a quick screening and a statistical analysis of the concerned groups of population.

'Tele-doctors'
With its extremely simplified procedure and being totally operator-independent, DDFAO is especially designed for the 'telemedicine', where any low-skilled operator can remotely make the measurements at the patient's site and transmit the data using telephone, email (or even SMS), to the doctor in charge of the analysis and allow him to issue the diagnosis with no displacement.

‘Alternative doctors’
Thanks to its exclusive screens for instant ‘Before’ and ‘After’ comparisons, DDFAO will help them to explain and demonstrate the efficiency of their treatments.

Healthcare centers & Gyms
With is ease-of-use, DDFAO can not only measure their customers improvements but also detect their risks early and prevently direct them to further conventional examinations.

Sports doctors
With its simplified interface and quick diagnosis time, by visualizing the levels of stress and oxygenation at muscle level, as well as the athlete's psychological condition, DDFAO will determine the ultimate treatment or massage for sport teams or individuals during the preparation and just before or after a competition (pain-relief, stress, …).

Health products suppliers
Thanks to its exclusive screens for instant ‘Before’ and ‘After’ comparisons, DDFAO will help them to convince skeptical prospects of the efficiency of their products, from herbal supplements to FIR and NanoTechnology products.

All-of-the-above will use DDFAO’s unique colorful imaging interface as an efficient communication tool to help the patients to understand their own functioning and personal needs, and evaluate the adequation of the proposed treatment with their own personal metabolism.

8. What are the benefits of DDFAO?

- Non-invasive method of investigation, for the full body at the same time;

- Operator independency, thanks to its large flat pods and smart scanning technique that extracts the patient’s own metabolism parameters;

- Offload the doctor’s workload: no need for highly trained operators and the analysis can be made at a different time or remotely;

- Quick and fast: narrow the scope of the search for the origin of a problem, with its own analysis of risks proposed;

- Evaluate treatment efficiency and possible side-effects;

- Save costs (less time, less lab examinations, less visits);

- Hi-Tech communication tool for the doctor;

- Easy to understand education tool for the patient;

- Communication and sharing of the results (print, email,);

- Ease of use, with its acclaimed 'at your finger-tip' user-interface;

- Low-cost per diagnosis;

- Organization of the work: DDFAO conveniently keeps track of all the patient's data and visits measurements in its easy-to-retrieve folder organization;

- Time saving (think of it as if 69 blood pressure measurements were conducted at the same time on 69 different places of the body... if this was only possible !) ;

- Embedded statistics and maintenance tools.

9. What is the accuracy of DDFAO?

Clinical tests in public hospitals exhibit a high degree of accuracy against conventional examinations. Depending on pathologies, DDFAO achieves 73% to 89% accuracy- the lower 73% being for healthy patients…, while cancer detection averages at 80%.

As a reference, the well-known conventional mammography is achieving an accuracy of no more than 65 % to 75%.

10. What are the indications for DDFAO?

General medicine
As a complementary investigation tool to the clinical observation, DDFAO will determine:

- whether homeostasis is respected and if it is not, suggest further conventional examinations,
- the cause and origin of the functional diseases,
- the functional complications of lesions,
- assert the complete curing of all diseases.

Gynaecology
By visualising the psychoneuro-endocrino-immune connection DDFAO can help:

- to understand the causes of hypo-fertility or sterility,
- to monitor difficult pregnancies.

Cardiology
The inflammatory region revealed by the DDFAO can help:

- to evaluate the cardiovascular risk,
- to initiate action to prevent the pathology,
- to monitor the treatment of cardiovascular diseases,
- to treat aggravating factors (cortisol, sympathetic system, psychology, immunity).

ENT

- Distinguish between allergy and chronic inflammation,
- To monitor treatments.

Surgery

- Estimate the body's recovery potential before surgery and thereby reduce the risk of neucosomial diseases,
- reduce stress before surgery,
- Improve healing.

Anti-age medicine

The ESG provides a view of inflammation and tissue ischemia which significantly increases entropy.

Endocrinology

Visualize the psychoneuro-endocrino-immune connection and monitor the replacement therapy.

Psychology and psychiatry

Visualize the psychoneuro-endocrino-immune connection and acquire a greater understanding of the origin of psychiatric pathologies or behaviour.

Nutritionists

Visualize the psychoneuro-endocrino-immune connection and acquire a greater understanding of the origin of obesity or anorexia.

Oncology

- Determine the combination of oxydizing stress and alkalosis state, which promotes genetic damage responsible for initiating cancer, and introduce prevention at this stage,
- view the dysfunction caused by the cancerous lesion and restore homeostasis to improve prognosis,
- Therapeutic monitoring.

Gastro-enterology

Visualize the psychoneuro-endocrino-immune connection and acquire a greater understanding of the origin of digestive problems (constipation, mucosal hyper-permeability ….)

Sports medicine

Practicing a sport at a high level requires an optimal state of homeostatic balance: visualizing the levels of stress and oxygenation at muscle level, as well as the athlete's psychological condition will influence his or her performance.

Dermatology

Skin diseases often have psychological, endocrine, immune system, allergic or hepatic origins… Visualization of the psychoneuro-endocrino-immune connection is used to determine the origin of pathologies and appropriate treatment.

Pain-relief medicine
Practicing neuro-functional auricular acupuncture helps to reduce almost all types of pain. Several hospitals relieve cancer sufferers using this method and publication proves that this technique has given results where morphine was ineffective.

Homeopathy
Homeopathy acts without drugs, using the transmission of low frequency electromagnetic waves. DDFAO which records the bio-conductivity is well-suited to recommend the most suitable homeopathic or bio-electronic treatment.

Acupuncture
Acupuncture, empirically created by Chinese doctors 5000 years ago, is used to restore the body's balance (yin /yang), which neurophysiologists call homeostasis. It is precisely these variations in balance and connections which are spotted by DDFAO which displays the different meridians and their electrical values, taking chrono-biology into account, without using subjective methods such as pulse-taking or the condition of the tongue.

11. What are the contra-indications for DDFAO ?

Even though a non-invasive method of diagnosis, since DDFAO is measuring very small electrical currents, its use is not recommended in the following cases (since no specific studies have been conducted so far):

Pacemakers
While DDFAO will not harm the health of a patient with a pacemaker, it is possible that the pacemaker may disturb the measured values.

Pregnancy
While DDFAO will not harm the health of the pregnant woman nor her baby, but it is anticipated that the presence of the baby may disturb DDFAO’s neurophysiology models and results.

Dermatological lesions
While patients do not feel DDFAO’s harmless low-voltage current, dermatological lesions in contact with electrodes may induce some ‘burnt’ feelings.

12. Is DDFAO applicable to all types of skins?

All human bodies are functioning according to the same neurophysiology principles throughout the world, so DDFAO does not need to be adjusted for working in different parts of the world.

The skin is the interface between the body and DDFAO for its low DC-current measurements and the only parameters of concern for DDFAO are the patient’s sex, age, height and weight.

13. What is the time required for a diagnosis with DDFAO?

Thanks to its highly integrated electronics and expert-like embedded system, DDFAO allows making a diagnosis in less than 3 minutes:

- Patient's data recording (the first time): 1 minute
- Patient's clinical context (average): 1/2 minute
- Measurements: 2 minutes
- Automated Analysis of risks: instantenous
- Interpretation: depending on the patient's situation, as usual…

No extra time is to be added to the normal doctor's practice if the measurements can be made by an assistant, while the patients are in the waiting room (masked time).

14. What is the cost associated to each DDFAO diagnosis?

Only 2 new adhesive forehead electrodes are needed for each new patient (+ electricity!). A simple wipe-out with a moisturized tissue will help to maintain the hands and feet electrodes in healthy condition for the next patient.

As said before, no extra time is to be added to the normal doctor's practice if the measurements can be made by an assistant, while the patients are in the waiting room (masked time).

15. How does DDFAO protect its investment value?

Upgrades are simply made by downloading a compressed file (ZIP format) from Internet, which is automatically uncompressed and installed – adding new features to DDFAO whenever they become available.

16. Which agency approvals were granted to DDFAO?

- CE 0459 for medical devices in Europe
- CSA in Canada
- SDA in China
- FDA is in progress for the USA

17. What is the DDFAO range of products?

<u>DDFAO-PRO</u>

A ruggedized version specially designed for heavy usage in clinics and hospitals, integrating all electrical pods and cables in a stand with industrial-grade PC and hi-definition color touch-screen LCD.

DDFAO-TOP (new)
A completely integrated system with industrial-grade PC and hi-definition color touch-screen LCD, for doctors in their office, healthcare centers, etc…

DDFAO Mobile
A small Box and its set of 6 electrical pods and cables which connect to the USB port of a notebook computer (not included), for doctors on the move.

Special versions focusing in refining the diagnosis for specific pathologies are under development:
- Early Breast Cancer Detection
  - Early Prostate Cancer Detection;
  - Functional Cardio Vascular check-up.

Stay tuned on www.ms-tek.com for their official announcements!

18. Where DDFAO can be found at work?

In two years, around 1000 DDFAO devices have been already deployed mainly throughout Europe and are currently in use at private doctors' offices, private clinics, public hospitals and some health shops in:

- France
- Russia
- Greece
- Turkey
- Italy
- Spain
- Portugal
- Germany
- Roumania
- Holland
- UK
- Hong Kong
- China
- Korea
- Canada
- USA
- Mexico

HRV:

Short-term HRV analysis and assessment of the autonomic regulation:

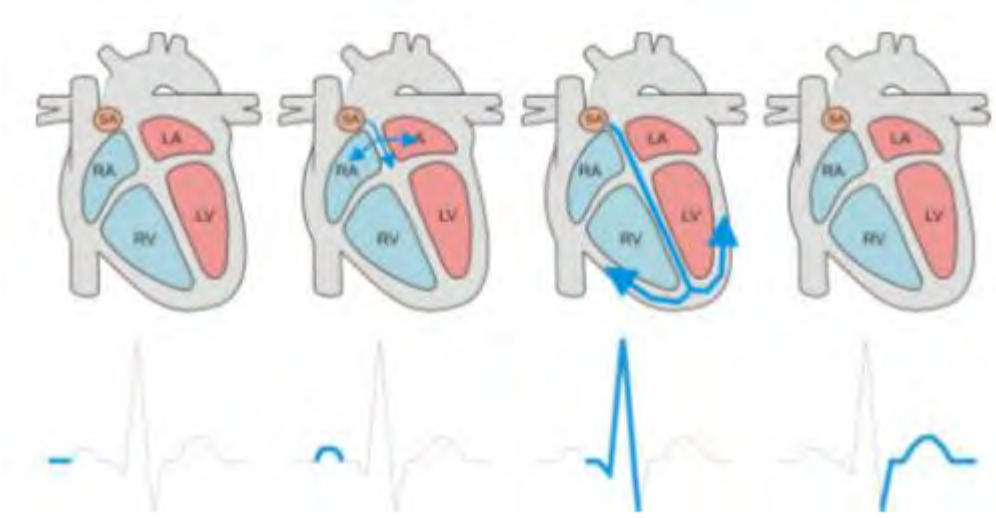
It is believed that **Heart Rate Variability** (HRV) will become as common as pulse, blood pressure or temperature in patient charts in the near future. In the last ten years more than 2000 published articles have been written about HRV. HRV has been used as a screening tool in many disease processes. Various medical disciplines are looking at HRV. In diabetes and heart disease it has been proven to be predictive of the likelihood of future events. In 1996, a special task force was formed between the US and European Physiological associations to outline current finds on HRV and set specific standards on using HRV in medical science and future practice. Since then a steady stream of new information and value continues to come out of HRV research.

It all started in 1966 when a variation in the beat-to-beat intervals between heartbeats was noticed. Initially all recording devices were averaging heart rate data stream trying to get rid of any rapid HR fluctuations. Then there were very specific patterns in such fluctuations were noticed that had links to certain conditions way before any clinical symptoms appeared.

Physiological Basics of HRV

The origin of heartbeat is located in a sino-atrial (SA) node of the heart, where a group of specialized cells continuously generates an electrical impulse spreading all over the heart muscle through specialized pathways and creating process of heart muscle contraction well synchronized between both atriums and ventricles. The SA node generates such impulses about 100-120 times per minute at rest. However in healthy individual resting heart rate (HR) would never be that high. This is due to continuous control of the **autonomic nervous system** (ANS) over the output of SA node activity, which net regulatory effect gives real HR. In healthy subject at rest it is ranging between 50 and 70 beats per minute.

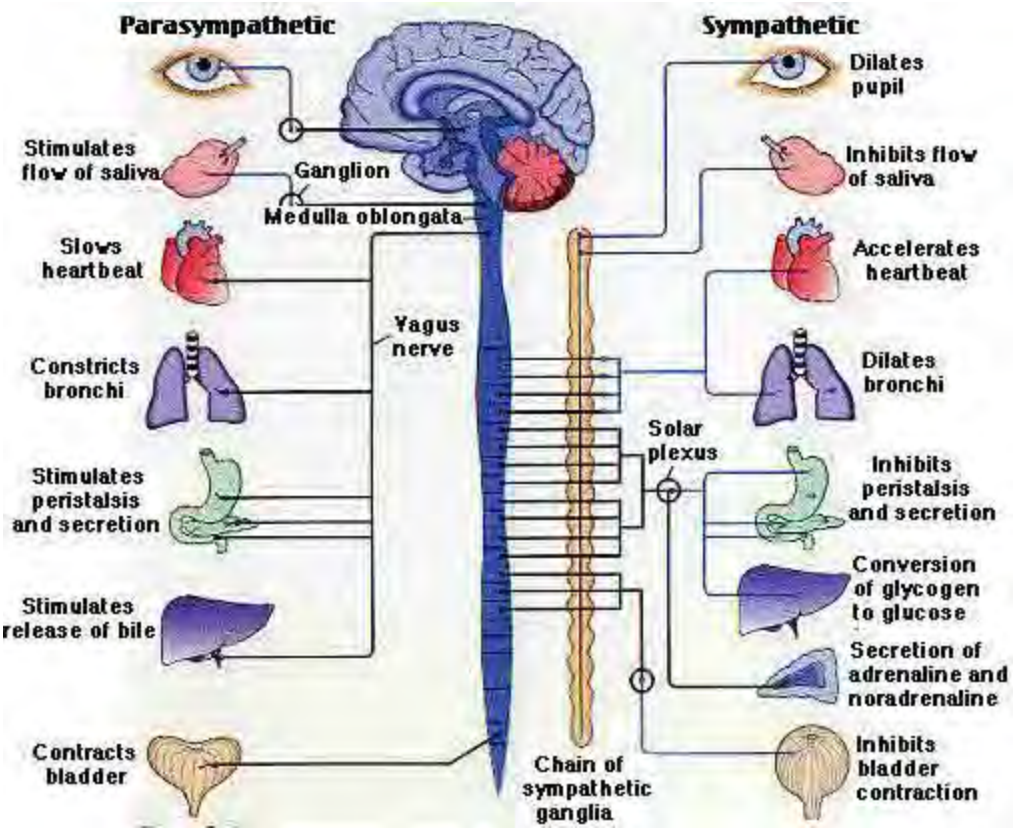
Schematic explanation of RA, LA, RV, LV parameters and their visualization on Heart Rate



Autonomic nervous system. The autonomic nervous system is a part of the nervous system that non-voluntarily controls all organs and systems of the body. As the other part of nervous system ANS has its central (nuclei located in brain stem) and peripheral components (afferent and efferent fibers and peripheral ganglia) accessing all internal organs. There are two branches of the autonomic nervous system - sympathetic and parasympathetic (vagal) nervous systems that always work as antagonists in their effect on target organs.

Sympathetic nervous system. For most organs including heart the sympathetic nervous system stimulates organ's functioning. An increase in sympathetic stimulation causes increase in HR, stroke volume, systemic vasoconstriction, etc. The heart response time to sympathetic stimulation is relatively slow. It takes about 5 seconds to increase HR after actual onset of sympathetic stimulation and almost 30 seconds to reach its peak steady level.

Schema explaining how parasympathetic and
sympathetic nervous systems inhibit functioning organs

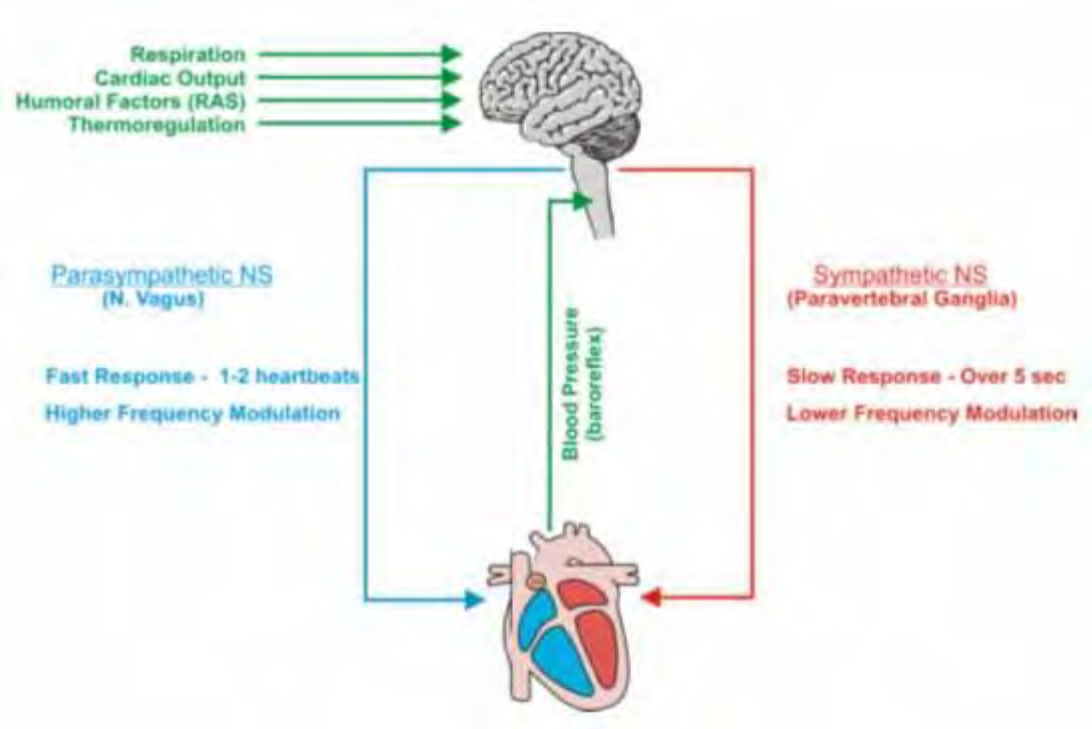


Parasympathetic nervous system. In contrast, the parasympathetic nervous system inhibits functioning of those organs. An increase in parasympathetic stimulation causes decrease in HR, stroke volume, systemic vasodilatation, etc. The heart response time to parasympathetic stimulation is almost instantaneous. Depending on actual phase of heart cycle it takes just 1 or 2 heartbeats before heart slows down to its minimum proportional to the level of stimulation.

At rest both sympathetic and parasympathetic systems are active with parasympathetic dominance. The actual balance between them is constantly changing in attempt to achieve optimum considering all internal and external stimuli.

There are various factors affecting autonomic regulation of the heart, including but not limited to respiration, thermoregulation, humoral regulation (rennin-angiotensin system), blood pressure, cardiac output, etc. One of the most important factors is blood pressure. There are special baroreceptive cells in the hear and large blood vessels that sense blood pressure level and send afferent stimulation to central structures of the ANS that control HR and blood vessel tonus primarily through sympathetic and somewhat parasympathetic systems forming continuous feedback dedicated to maintain systemic blood pressure. This mechanism is also called baroreflex, which increases HR when blood pressure decreases and vice versa. This mechanism is also targeted to maintain optimal cardiac output.

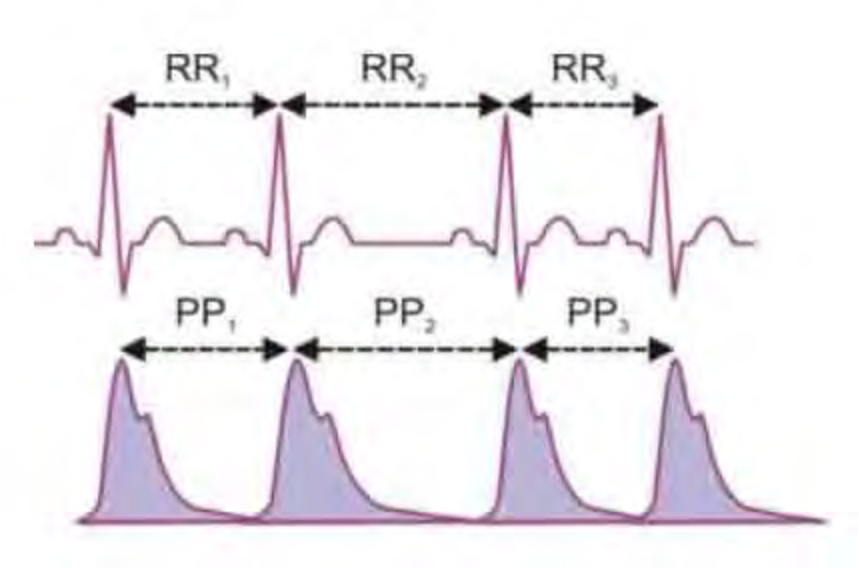
Schema showing the baroreflex functionality



HRV Analysis

The **heart rate variability analysis** is a powerful tool in assessment of the autonomic function. It is accurate, reliable, reproducible, yet simple to measure and process. The source information for HRV is a continuous beat-by-beat measurement of interbeat intervals. The electrocardiograph (ECG or EKG) is considered as the best way to measure interbeat intervals. ECG is an electrical signal measured with special conductive electrodes placed on chest around heart area or limbs. It reflects minute changes in electrical field generated by heart muscle cells originating from its SA node. ECG signal has a very specific and robust waveform simple to detect and analyze. Because of that cardiac rhythm derived from ECG is the best way to detect not only true sinus rhythm but **all types of ectopic heartbeats**, which must be excluded from consideration of **HRV analysis**.

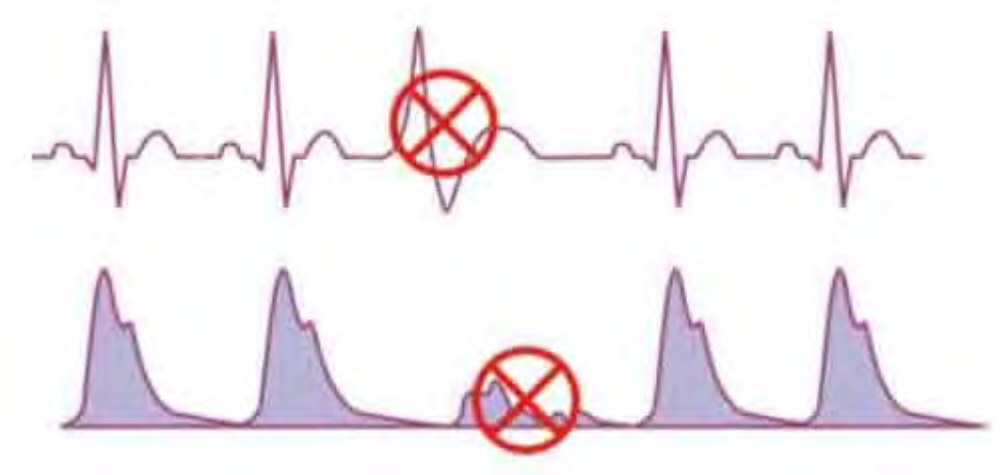
Schema showing the baroreflex functionality



Pulse wave measurement. The other approach to measure cardiac intervals is a measurement of pulse wave. It is less invasive and simple method of measurement based on photoplethysmograph. PPG is a signal reflecting changes in a blood flow detected when infrared light is emitted towards microcirculatory blood vessels. Depending on blood flow volume certain portion of that light is absorbed letting other part to pass or be reflected. An optical sensor detects a quantity of light passed (or reflected from) the blood flow producing a waveform identifying pulse wave. Such waveform can also be processed to derive beat-by-beat interbeat intervals. Although PPG gives the summary information reflecting both cardiac and blood vessel components of HRV, some research studies showed a significantly high correlation between interbeat interval data measured by both ECG and PPG in short-term steady-state recordings.

One of the important issues when measuring either ECG or PPG is the **absence of abnormal heartbeat** used in interval detection. Only heartbeats originated in SA node can be processed to obtain HRV data. Whether there are ectopic heartbeats (PVCs or other types of extrasystolic heartbeats) or various movement artifacts on ECG (or PPG) considered as heartbeats, they must be excluded from consideration. There are various statistically-based algorithms of detection of such abnormal heartbeats that minimize chances to get contaminated HR recordings. Nevertheless, for the sake of **accuracy in HRV analysis** it is important to be able to visually verify all heartbeats automatically found, remove abnormal ones and include missing. The **Heart Rhythm Scanner** has an automatic detection of such movement artifacts and also gives the possibility to manually correct it.

Example of an abnormal heartbeats



HRV Response to Controlled Autonomic Stimulation

There are several techniques that allow for autonomic assessment by means of applying certain stimuli that evoke specific responses of either branch of the autonomic nervous system.

Paced Breathing Test

The reflex arc associated with breathing evokes a specific response in heart rate variability. It was first described by Genovely and Pfeifer:

Tidal volume expands the lungs, which activates stretch receptors in the lung, chest wall and heart chambers. The activated sensors stimulate the afferent nerve (vagus nerve). The central processing unit located in the brainstem (the nucleus solitarius) processes information and then decreases parasympathetic tone and/or increases sympathetic tone by sending the appropriate impulses down the efferent vagus and cervical-thoracic-sympathetic nerves, respectively. This information terminates in end-organ (the heart), which responds with an increase in heart rate. Because the reflex arc associated with the R-R variation test is reasonably well known, interpretation of test results is easier to determine than those of the reflex arcs, which are poorly described and understood (such as gastric emptying) or to reflex arcs that are more complicated.

This end-organ response is used in assessment of the autonomic function with the test method described by Wheeler and Watkins in 1973:

With this method, the subject sits quietly while his heart rate is recorded on an ECG. He is then asked to breathe deeply and regularly at a rate of six breaths per minute (5 seconds in, 5 seconds out) for one minute, while the ECG record is continued. The longest and shortest R-R intervals during each breathing cycle are measured from the ECG and converted to beats per minute.

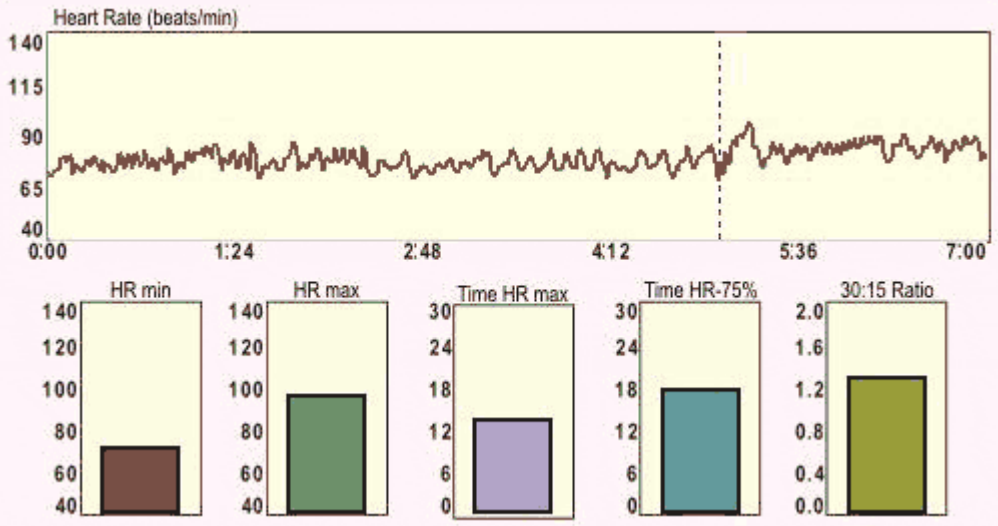
The heart rate variability in this test may be presented in the following parameters: Expiratory/Inspiratory Index (E/I), Standard Deviation, Mean Variance of R-R, etc.

Orthostatic Test

The cardiovascular response to the act of changing a posture from supine to standing was used as an indication of the autonomic function in diabetics for a long time. It is one of several tests described by Ewing that have certain clinical value because they are simple, non-invasive, easy-to-use, reproducible and have clear difference between normal and abnormal results.

During the test, the patient rises from a supine to a standing position. Normally this causes an immediate increase in heart rate and reaches its maximum level at about 15th heartbeat after beginning to stand. It is followed by a relative bradycardia that reaches its maximum around 30th heartbeat. The phenomena can be quantified as 30:15 ratio, which is the ratio of the longest R-R interval around 30th heartbeat to the shortest interval around 15th heartbeat.

Example of an Orthostatic Test report in Heart Rhythm Scanner SE



Bennet, Hosking and Hampton et al. h ave studied the relationship between changes in HR and blood pressure caused by standing to demonstrate its value in assessment of the autonomic effect on cardiovascular system in diabetics. They showed a complex interaction between sympathetic and parasympathetic systems and found that parasympathetic dysfunction is typically more dramatic than damage to sympathetic system. The posture test is considered as of highest value when it is performed along with other tests like paced breathing and Valsalva maneuver. The orthostatic test can be performed in Heart Rhythm Scanner Special Edition.

Valsalva Maneuver

The Valsalva maneuver was first described by Antonio M. Valsalva in 1707. In 1860 Einbrodt showed that Valsalva maneuver demonstrated “the integrity of the vagus nerves to the heart” – an acceleration of the heart rate during expiratory effort and slowing it down after it. Later Valsalva maneuver has become so well-known that wouldn’t require its explanation. The formal Valsalva maneuver definition was described by Hamilton et al. in 1943:

In practice the maneuver can be standardized by asking the seated subject to blow into a mouthpiece attached to a manometer to a pressure of 40 mm Hg for 15 seconds, while a continuous heart rate record is made with ECG. The result can then be simply calculated by measuring with a ruler the longest R-R interval after strain (representing the maximal bradycardia) and dividing it by the shortest R-R interval during strain (representing maximal tachycardia). This gives "Valsalva Ratio".

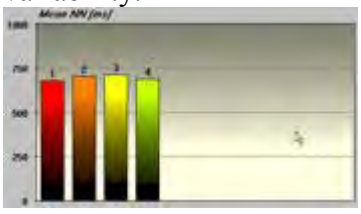
Methods of HRV Analysis

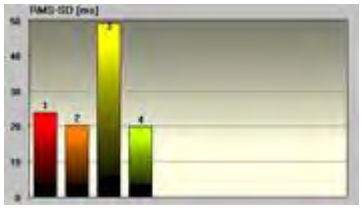
Short-term HRV analysis requires much shorter recordings - typically 5-min long. However such recordings are assumed to be done at steady-state physiological condition and should be properly standardized to produce comparable data. Typically such measurements should be done in either supine or comfortably sitting relaxed position, limiting body movements, conversations, any mental activities.

According to the standards set forth by the Task Force of the **European Society of Cardiology and North American Society of Pacing and Electrophysiology** in 1996, there are two methods of analysis of HRV data: time-domain and frequency-domain analysis. In either method, the interbeat intervals should be properly calculated and any abnormal heartbeats found.

Time-Domain HRV

Time-domain measures are the simplest parameters to be calculated. Before such calculation all abnormal heartbeats and artifacts must be removed from consideration. The following time-domain parameters can be calculated for both long-term and short-term recordings: Mean HR, SDNN and RMS-SD. Some extra parameters can be calculated specifically for long-term recordings. The time-domain parameters are associated mostly with overall variability of HR over the time of recording, except RMS-SD, which is associated with fast (parasympathetic) variability.



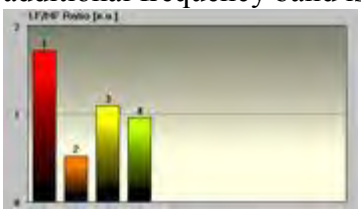


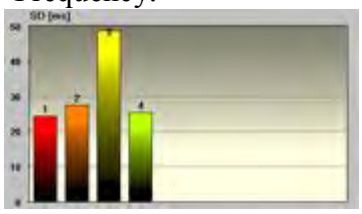
The example screenshots above were taken from Heart Rhythm Scanner which is the one of the Heart Rate Variability Systems available on the market today.

Frequency-Domain HRV

Frequency-domain measures pertain to HR variability at certain frequency ranges associated with specific physiological processes. Before frequency-domain analysis is performed, all abnormal heartbeats and artifacts must be detected and removed, then cardiotachogram

(sequence of RR intervals) must be re-sampled to make it as if it is a regularly sampled signal. A standard spectral analysis routine is applied to such modified recording and the following parameters evaluated on 5-min time interval: Total Power (TP), High Frequency (HF), Low Frequency (LF) and Very Low Frequency (VLF). When long-term data is evaluated an additional frequency band is derived - Ultra Low Frequency.





The HF power spectrum is evaluated in the range from 0.15 to 0.4 Hz. This band reflects parasympathetic (vagal) tone and fluctuations caused by spontaneous respiration known as respiratory sinus arrhythmia.

The LF power spectrum is evaluated in the range from 0.04 to 0.15 Hz. This band can reflect both sympathetic and parasympathetic tone.

The VLF power spectrum is evaluated in the range from 0.0033 to 0.04 Hz. The physiological meaning of this band is most disputable. With longer recordings it is considered representing sympathetic tone as well as slower humoral and thermoregulatory effects. There are some findings that in shorter recordings VLF has fair representation of various negative emotions, worries, rumination etc.

The TP is a net effect of all possible physiological mechanisms contributing in HR variability that can be detected in 5-min recordings, however sympathetic tone is considered as a primary contributor.

The LF/HF Ratio is used to indicate balance between sympathetic and parasympathetic tone. A decrease in this score might indicate either increase in parasympathetic or decrease in sympathetic tone. It must be considered together with absolute values of both LF and HF to determine what factor contributes in autonomic disbalance.

The frequency domain analysis is traditionally performed by means of Fast Fourier Transformation (FFT). This method is simple in calculation but for fair representation of all frequency-domain HRV scores at least 5-min data should be collected. FFT assumes that time series represents a steady-state process. Because of that all data recordings should be conducted at highly stable standardized conditions, when no other factors other than current autonomic tone contributes in HRV. One of the most serious disadvantages of that is its insensitivity to rapid transitory processes, which often possess very valuable information about how physiology or certain pathological processes behave dynamically.

Some most recent studies implemented an **alternative way to estimate power spectrum of HRV**. It is based on auto-regression methods. One of its major advantages is that it doesn't require to have analyzed data series to be in steady state. Thus any HRV data can be analyzed and fair HRV information still derived. Such analysis can be also performed on relatively shorter time intervals (less than 5 minutes) without missing meaningful HRV information. Finally this

method is sensitive to rapid changes in HR properly showing tiny changes in autonomic balance. The drawback of this approach is a necessity to perform massive calculations to find best order of auto-regression model.

Normative Data Sets

From clinical perspective it is important not only to evaluate all HRV scores but be able to assess such HRV data, whether they are normal or not and how to interpret such data. It is known that HRV scores are age-dependent. Most of scores decrease with age. For better HRV data assessment special sets of reference ranges for each HRV parameter were created. Such ranges are based on statistics derived from HR data measured in a number of healthy individuals of different ages under standardized conditions. Such norms are considered as a reference point and cannot be used for any diagnostic purpose.

References

1. A Measurement of Electrocardiography and Photoplethesmography in Obese Children. C. V. Russoniello, V. Pougtachev, E. Zhirnov and M. T. Mahar. Applied Psychophysiology and Biofeedback: Volume 35, Issue 3 (2010), Pages 257-259.

Read abstract...

2. A randomized controlled trial of a controlled breathing protocol on heart rate variability following myocardial infarction or coronary artery bypass graft surgery. Adams J, Julian P, Hubbard M, Hartman J, Baugh S, Segrest W, Russell J, McDonnell J, and Wheelan K. Clin Rehabil. 2009 Sep;23(9):782-9. Epub 2009 Jun 8.

Read abstract...

3. EEG, HRV and Psychological Correlates while Playing Bejeweled II: A Randomized Controlled Study. Carmen V Russoniello; Kevin O'Brien; Jennifer M Parks. Studies in Health Technology and Informatics. Volume 144, 2009.

Read abstract...

4. EEG, HRV and Psychological Correlates while Playing Bejeweled II: A Randomized Controlled Study. Carmen V Russoniello; Kevin O'Brien; Jennifer M Parks. Studies Journal of CyberTherapy and Rehabilitation, Volume 2, Issue 1, 2009.

Read abstract...

5. Sympathetic and parasympathetic responses to specific diversified adjustments to chiropractic vertebral subluxations of the cervical and thoracic spine. Arlene Welcha and Ralph Booneb. J Chiropr Med. 2008 September; 7(3): 86–93.

Read abstract...

6. Turo (Qi Dance) Training Attenuates Psychological Symptoms and Sympathetic Activation Induced by Mental Stress in Healthy Women. Hwa-Jin Lee, Younbyoung Chae, Hi-Joon Park, Dae-Hyun Hahm, Kyungeh An and Hyejung Lee. eCAM. Nov, 2007.

Read abstract...

7. Effect of Chiropractic Care on Heart Rate Variability and Pain in Multisite Clinical Study. John Zhang, MD, Ph.D, Douglas Dean, Ph.D, Dennis Nosco, Ph.D, Dennis Stratholopus, DC, and Minas Floros, DC. Journal of Manipulative and Physiological Therapeutics. May 2006. Vol. 29, N4. p.267-274.

Read abstract...

8. An Internet-Based Athlete Assessment, Analysis, Intervention and Database Center: Your Personal

Sport Psychology Consultant. Dr. Roland A. Carlstedt, Ph.D. July, 2005.

Read abstract...

9. Heart Rate Variability in Verifying Treatment Efficacy of Thought Field Therapy.Robert L Bray, Ph.D., LCSW, CTS, TFTdx and Monica Pignotti, MSW, CSW. 2005.

Read abstract...

10. The Healing Codes Proves it can lower Stress Levels according to Heart Rate Variability testing. By Inland Empire Boot Camp. December, 2005.

Read abstract...

11. A Randomized Controlled Trial of a Controlled Breathing Protocol on Heart Rate Variability following Myocardial Infraction or Coronary Artery Bypass Graft Surgery. Jenny L. Adams PhD, Peter Julian MA, Matthew Hubbard MS, Julie Hartman MS, Sallie Baugh BA, CLC, Wendy Segrest MS, Jenny Russell NP, Kevin Wheelan MD. Journal of Cardiopulmonary Rehabilitation. October, 2005.

Read abstract...

12. Tapping the healer within. Roger Callahan, Ph.D, Richard Trubo. 2001. McGraw-Hill, 240p.

Read abstract...

13. High Impact Hypnosis. Lawrence Leyton. Positive Health, February 2001.

Read abstract...

14. Heart Rate Variability as an Outcome Measure for Thought Field Therapy in Clinical Practice.

Monica Pignotti, Mark Steinberg, Ph.D. Journal of Clinical Psychology. October 2001. p.1193-1206.

Read abstract...

15. The Impact of Thought Field Therapy on Heart Rate Variability (HRV) Roger Callahan, Ph.D, Journal of Clinical Psychology. October 2001.

Read abstract...

16. Thought Field Therapy clinical applications: Utilization in an HMO in behavioral medicine and behavioral health services. Caroline Sakai, David Paperny, Marvin Mathews, Greg Tanida, Geri Boyd, Alan Simons, Charlene Yamamoto, Carolyn Mau, Lynn Nutter Journal of Clinical Psychology. August 2001.

Read abstract...

17. Resonant Frequency Biofeedback Training to Increase Cardiac Variability: Rationale and for Training. Paul M. Lehrer, Evgeny Vaschillo, Bronya Vaschill. Applied Psychophysiology and Biofeedback. September 2000. Vol.25, N3, p.177-191.

Read abstract...

Associated Forms and Testing Criteria:

Participant Consent Agreement (FCA Softgel)

I, _____ have read all of the attached information and fully understand what is expected of me during the next ninety-day period of time. I will do my best to comply with the regulations and procedures of this study and know that my consistency and accuracy in following these directions is paramount in determining the validity of the study.

I further understand that the purpose of this study is for research and educational purposes only. The testing that I will receive will not diagnose any metabolic condition or disease, but instead is used strictly to monitor and validate any alterations that occur in my body's biochemistry. The nutritional product that I will consume (Fermented Cellulose Antioxidant or FCA) is perfectly safe, healthy and free of any dangerous chemicals as determined by the FDA and will be provided to me absolutely free of charge.

Lastly, I agree to hold all parties connected with this research project free from any liability or tort proceedings either currently or any time in the future.

_____ _____

Name Date

Welcome (FCA Softgel Participants)

Dear Friend,

Thank-you for deciding to participate in our exciting research and educational study. It is through dedication and commitment like yours that complimentary, safe and natural therapies are now becoming more and more recognized as effective alternatives to drugs and surgery. After all, what could be safer and more natural than an all-natural anti-oxidant nutritional supplement?

The softgel that you are going to be consuming is a specially produced product that has been created to act as a very powerful anti-oxidant. This anti-oxidant is designed to control the production of damaging free radicals that participate in inflammation and premature aging. If free radical production is elevated due to stress or diseases or even exposure to certain environmental factors, the body will rapidly age and deteriorate. If however, this process can be mitigated so that the body can maintain a balance between anti-oxidants and oxidants, these deleterious detrimental changes will remain balanced and in check.

While the supplement you will be consuming has undergone extensive scientific and medical testing and research in Japan, limited data is available from the United States. It is for this reason that we are putting together this enjoyable and what we believe to be beneficial study, to scientifically prove the potential healing benefits of this product. Countless individuals around the world are currently consuming this specially prepared anti-oxidant, so we are confident that there should be absolutely no adverse side effects from its consumption. However, if you experience any negative health signs or symptoms please contact me immediately.

Attached is a short list of requirements that must be adhered to in order to complete the study. Please review the list and if you have any difficulties with any of the conditions, let us know immediately.

Thank-you once again for taking your time and committing your energy to not only an increase in health for yourself, but in helping us get the word out of this remarkable scientific discovery.

90-day Study Protocol (FCA Softgel)

On day (0) you will be asked to undergo a series of tests. These tests include:

BTA S-2000 test. This test requires a small sample of blood, saliva and urine. These samples must be collected after you have undergone a 12-14 hour fast period. Additional information is available on the attached sheet.

BIA (Bio-Impedance Analysis)
Postural hypotension screening
Indikan test
Weight assessment
Urine dipstick analysis
HRV (Heart Rate Variability assessment)
DDFAO Analysis (Which includes a measurement of specific free radicals)

A short questionnaire will be required to be completed. The questions will be centered on any primary complaints or health problems that you are currently experiencing and the intensity in which you are experiencing them.

Following the test you will be given a 1-month supply of specially prepared FCA softgel. This product should be stored in a cool dry place away from large electro-magnetic producing appliances (microwave, television, out of direct sunlight etc.

The product labeled "FCA Softgel" must be consumed at a rate of 15 capsules per day. If this amount is too great for your digestive system or creates any stress, you are to notify me immediately.

After you have been consuming this product for a period of (30) days, a second series of identical tests will be performed. This test will need to be prepared for in the same fashion as the original test at day (0). An updated symptom questionnaire will also be given to you for written verification concerning alterations in your health concerns.

Following the comprehensive tests, you will continue to consume the specially prepared water labeled "FCA Softgel" in the exact same dose of 15 capsules per day as you did prior to the testing.

After you have been consuming the product for a period of (30) additional days, or for a total of (60) days, a third series of identical tests will be performed. This test will need to be prepared for in the same fashion as the original test at day (0) and day (30). An updated symptom questionnaire will

also be given to you for written verification concerning alterations in your health concerns.

Following the comprehensive tests, you will continue to consume the specially prepared product labeled “FCA Softgel” in the exact same dose of 15 capsules per day as you did prior to the testing.

After you have been consuming the product for a period of (30) additional days, or for a total of (90) days, a forth series of identical tests will be performed. This test will need to be prepared for in the same fashion as the original test at day (0) day (30) and day (60). An updated symptom questionnaire will also be given to you for written verification concerning alterations in your health concerns. This final questionnaire will give you the ability to summarize your feelings on all aspects of the study

The final results of the test may be published in professional medical journals. Your name and identity will not be included and will be kept strictly confidential. A copy of this publication will be made available to you to see how the entire group fared during the study.

Participant Information (FCA Softgel)
(Day-0)

Name_____ Date_____

Age_____ Sex_____

Weight_____ Height _____

Amount of product to be consumed daily :(15) capsules

My primary area of health concern is
_____
_____
_____
_____

I am currently taking prescription medication: Yes No
If Yes, please list
_____
_____

If pain is associated with my primary health concern, I would grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would grade it: 0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

Participant Information (FCA Softgel)
(Day-30)

Name_____ Date____

Weight _____

I have been absolutely faithful in consuming the specified volume of FCA Softgel capsules: Yes No

If pain is associated with my primary health concern, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function _____
_____
_____

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage _____
_____
_____

Participant Information (FCA Softgel)
(Day-60)

Name_____ Date____

Weight _____

I have been absolutely faithful in consuming the specified volume of FCA Softgel capsules: Yes No

If pain is associated with my primary health concern, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function _____
_____
_____

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage _____
_____
_____

Participant Information(FCA Softgel)
(Day-90)

Name_____ Date____

Weight _____

I have been absolutely faithful in consuming the specified volume of FCA Softgel capsules: Yes No

If pain is associated with my primary health concern, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function

_____

_____

Additional comments on the overall effects of this product on your health and well being _____

_____

If I was consuming prescription medications at the onset of this study, I have changed my frequency or
dosage_____

Rules and Regulations

The rules and regulations of this study are very few and very simple, but must be adhered to exactly. Variances from these will result in data that will not offer true scientific documentation of the efficacy of the selected FCA Softgel capsules on your health and well-being.

This product must be consumed in the exact specified quantity each and every day.

No significant alteration in your normal diet can be allowed. Simply stated, what you are currently eating on a daily basis must remain relatively unchanged during the duration of this study.

No alteration in vitamins, minerals, herbs or homeopathic remedies will be allowed. Therefore during this entire 90-day period you must continue taking everything that you are taking at day-0 without any alterations.

In preparation for the BTA S-2000 test being administered during the study at day-0, day-30, day-60 and day-90, the following pre-test procedure must be strictly adhered to:
Fast for 12-14 hours prior to the test. In order to do so, please complete your dinner the evening prior to your test no later than 5:00-6:00p.m. After dinner brush your teeth and refrain from eating or drinking anything until after your test.

Refrain from using any toothpaste, mouthwashes or lipstick. These substances can change the chemistry of your mouth.
On the morning of the test, obtain a sample of your first morning urine. Some individuals may have to get up during the night or early morning to urinate. If this happens to you at 4:00a.m. or later, collect this urine in the specimen cup.

Discussion on FCA Softgel Capsules:

Product: Fermented Cellulose Antioxidant

The Fermented Cellulose Antioxidant product is an invention of Dr. Kokichi Hanaoka, a Membrane Scientist and a leading expert on functional electrolyzed water. A history on the FCA is provided. The product is a highly-effective antioxidant.

Forward

It has been considered that our planet earth was born 4.6 billion years ago. The significant difference between the modern age and a period in time, 4.6 billion years ago was the lack of oxygen. Nitrogen, hydrogen, methane, ammonia, sulfuric hydrogen and vaporized steam existed in that atmosphere. Not only did ultraviolet ray of shorter wave length in addition to visible light and infrared ray exist but radioactive ray fell to the earth's surface. During this time, the earth was rich in high potential energy.

On the other hand, photochemical reactions occurred due to this strong energy creating amino acids, nucleic acids and other saccharides. As a result, these processes may have created some living things. After that, it is presumed that simple organic molecules made biological polymers through peptides, nucleotides and polysaccharides. Some living things appeared on earth through these evolutions 30 billion years ago.

During that period, ultraviolet rays which had a strong level of energy fell to earth. The earth was not a safe place for living things. At the time, oxygen did not exist and the main components in the atmosphere were nitrogen, carbon dioxide and vaporized steam. Therefore, living things during that period subsisted in the sea without oxygen. They could obtain energy from the fermentation system without the aspiration system. They did not require oxygen.

After a long period of time, plants in the sea propagated well while the concentration of oxygen gradually increased on earth. Ozone was produced and the ozone layer was formed approximately 30 kilometers from the earth's surface. With the presence of the ozone layer, ultraviolet rays emanating from the sun were cut and the Anaerobes could not subsist under the condition of a hyper oxygen state. Instead of these anaerobes, aerobes appeared having the prevention system for oxygen toxins.

Most of the present day living things on earth are aerobes. Since oxygen is a toxin, it is a toxin to aerobes. Reactive oxygen species are considered as both important roles of being a toxin and being a component of a protective system.

Recently, medical studies have developed the mechanism of how disease occur. They have clarified that Reactive Oxygen Species are related to the onset of most disease. On the other hand, antioxidants against R.O.S. have been studied among a number of researchers. If effective antioxidants were available it will be an important means for the prevention of disease.

The FCA has been studied since 1975 as an effective antioxidant. Scientific reports of FCA will be illustrated.

What is Fermented Cellulose Antioxidant

Herbivorous animals have different feed from omnivorous animals. Herbivorous animals have special digestive systems of cellulose. Generally speaking, herbivorous animals can digest cellulose in its appendix for obtaining required energy with glycogen. Omnivorous animals cannot digest cellulose in its appendix. They obtain their energy from protein-based material than from cellulose-based material. Although humans belong to the herbivorous animal family, they have changed their digestive system. Because they are not able to digest cellulose materials in their appendix, they do not have any enzymes for cellulose digestion. As a side note, it is reported that an individual who had their appendix removed has a decreased level of immunity compared with individuals who retain their appendix. Therefore us humans have lost the function of cellulose digestion in our bodies. It is thought that the processes of fermentation of cellulose are very important to the human body not only for the decomposition of cellulose but also for other significant enzymatic products.

The Fermented Cellulose Antioxidant is a very strong antioxidant t product brought about by an extended fermentation process which is carried out by a specialized fermentation process. After 10,000 hours of fermentation, the Fermented Cellulose Antioxidant has been able to attain a very strong SOD-like antioxidant property.

This is the basic feature of the Fermented Cellulose Antioxidant.

Physicochemical Properties of Fermented Cellulose Antioxidant

Main Ingredient: Fermented Cellulose soluble in water

Molecular Weight: 20,000~70,000 and greater than 500,000 as shown in Figures 3 and 4.

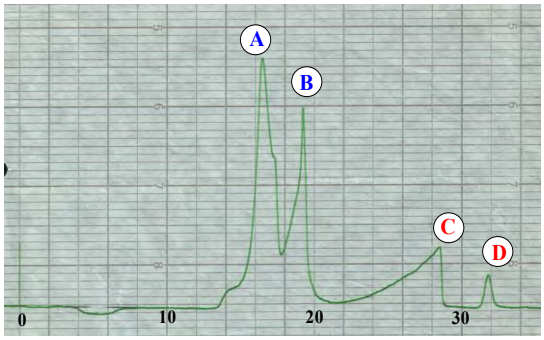
Solubility: Soluble in water but insoluble in organic solvent such as acetone and ethanol.

State: Powder, liquid or paste.

Color: Brown

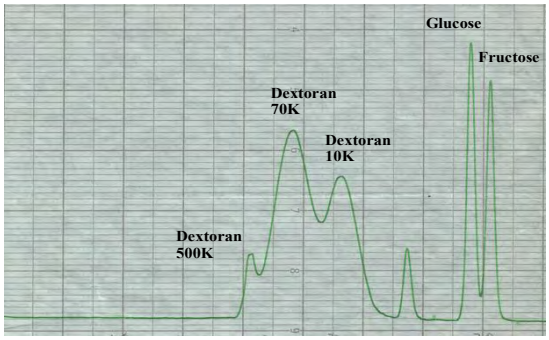
Heating: Boils at 100°C

Figure 3



Time = minutes

Figure 4



Time = minutes

Molecular weight of FCA by gel permeation Chromatography **Molecular Weight of Dextoran (Standard)**
A: 500,000 B:70,000 C: glucose D: fructose

Toxicity of Fermented Cellulose Antioxidant

1. Acute Toxicity Test

Method:	Litchfield-Wilcoxon	
Dosage:	Oral ingestion	
Mice:	ICR	
	Male:	20,000 mg/Kg (an impossibility in dosing)
	Female:	20,000 mg/Kg (an impossibility in dosing)
Rats-Spraque		
Dawley:	Male:	20,000 mg/Kg (an impossibility in dosing)
	Female:	20,000 mg/Kg (an impossibility in dosing)

2. Sub-Acute Toxicity Test

Dosage Period:	30 days
Dosage:	Oral ingestion
Amount of Dosage:	100, 500, 2,000 mg/Kg (mixture with food)
Rats:	All 12 rats were normal

3. Teratogenicity Test

Mice Count:	24 mice
Amount of Dosage:	70, 200, 500 mg/Kg per day
Dosage Period:	Pregnancy of 6~17 days
	Dissection conducted 18 days after the start of the pregnancy.
Results:	No negative effects noted in the mother or embryo.

What Is An Antioxidant

Antioxidant vitamins and enzymes such as superoxide dismutase, catalse and glutathione peroxidase are considered to function as scavengers and to provide protection against reactive oxygen species, including free radicals, which can damage or cause the death of cells.

Reactive oxygen species, including free radicals, are reactive molecules. A Free Radical is any molecule, which contains one or more unpaired electrons, and includes superoxide anions ($O2^{-\cdot}$), hydroxyl radicals (·OH), hydroperoxyl radicals (·OOH), nitrogen monoxide radicals (NO·) and

hydrogen peroxide molecules (H_2O_2). Oxygen atom has two lone paired electrons in its electrical shell. Figure (1) shows electrons in the most outside shell of oxygen.

Figure 1

Oxygen atom | Superoxide anion radical | Hydroxyl Radical

The toxin of Reactive Oxygen Species comes from lone paired electrons in the oxygen atom.

SOD, Superoxide Dismutase is the most important enzyme for living things on earth. SOD and its dismutation effect, especially through the superoxide anion radical, was discovered in 1968 by Dr. Irwin Fridvich, an American biochemist at Duke University. Almost all living things have SOD in their bodies for protecting damage from reactive oxygen species including radicals. Generally, SOD has three kinds of metals which are Zn, Mn, Fe and Cu. Figure (2) will illustrate the reactions of SOD.

Figure 2

$$SOD\text{-}Cu^{2+}\ (Fe^{3+}, Mn^{3+}) + O_2^{-\cdot} \rightarrow SOD\text{-}Cu^{1+}\ (Fe^{2+}, Mn^{2+}) + O_2$$

$$SOD\text{-}Cu^{1+}\ (Fe^{2+}, Mn^{2+}) + O_2 + 2H^+ \rightarrow SOD\text{-}Cu^{2+}\ (Fe^{3+}, Mn^{3+}) + H_2O_2$$

As illustrated, the reaction of dismutation is the transport of electrons. If a supplement has a strong antioxidant effect for radicals, the transport of electrons between the antioxidant and the radical will be strong.

Among radicals, ·OH (Hydroxyl Radical) is the most toxic radical. This ·OH can cause cell injury or cell death in our bodies. The most important life style is to make a balanced stated with the radicals that are in our bodies. As long as we live on this planet, we cannot avoid receiving radicals produced due to the radiation from the sun. We are able to take in high amounts of antioxidants through our food consumption. As we know, antioxidants play a role of scavenging remained radicals in our bodies.

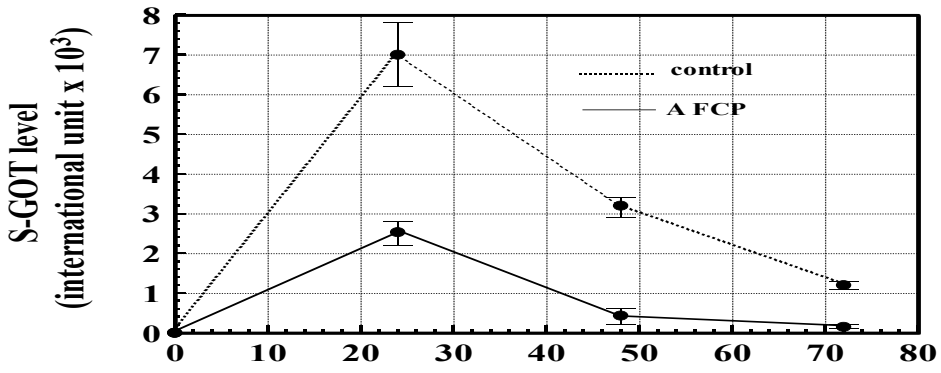
What we have outlined above is what we refer to as antioxidants.

Biological Effects of Fermented Cellulose Antioxidant for Liver Function Using Rats

Although liver cells are easily attached by free radicals such as superoxide anion free radicals, a number of enzymes of antioxidant protect damages from free radicals. Generally, carbon tetrachloride is used for the examination of acute hepatitis using mice or rats.

1. Figure (5) illustrates the difference in recovery period between the FCA and the control medium (no dosage provided). The illustration shows the result of S-GOT level with time after 20 U 1/Kg of carbon tetrachloride administration and 100 mg/Kg of FCA to the mice. S-GOT levels of the group provided with the FCA dosage compared to the control group (no dosage provided) was very low.

Figure 5

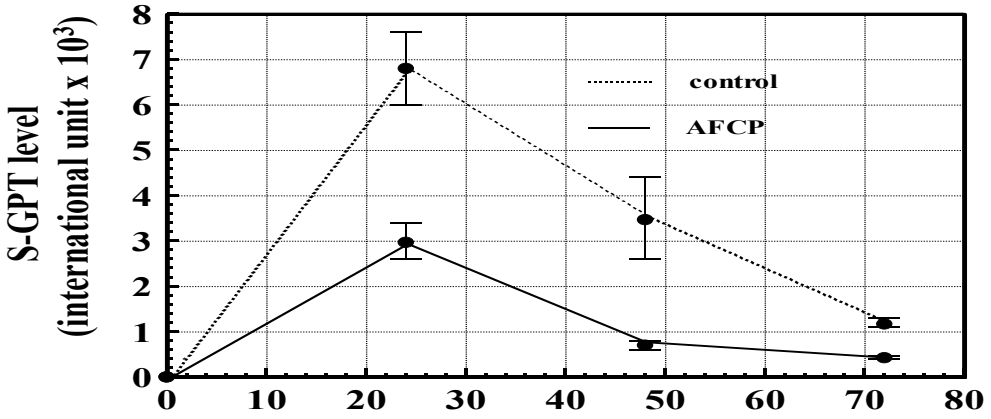


Time after tetrachloride administration in hours. (AFCP = FCA)

2. Figure (6) illustrates the difference in recovery between the FCA and the control medium (no dosage provided). The illustration shows the result of S-GPT level with time after 20 U 1/Kg of carbon tetrachloride administration and 100 mg/Kg of FCA to the mice. S-GPT levels of the group provided with the FCA dosage compared to the control group (no dosage provided) was very low.

AFCP2

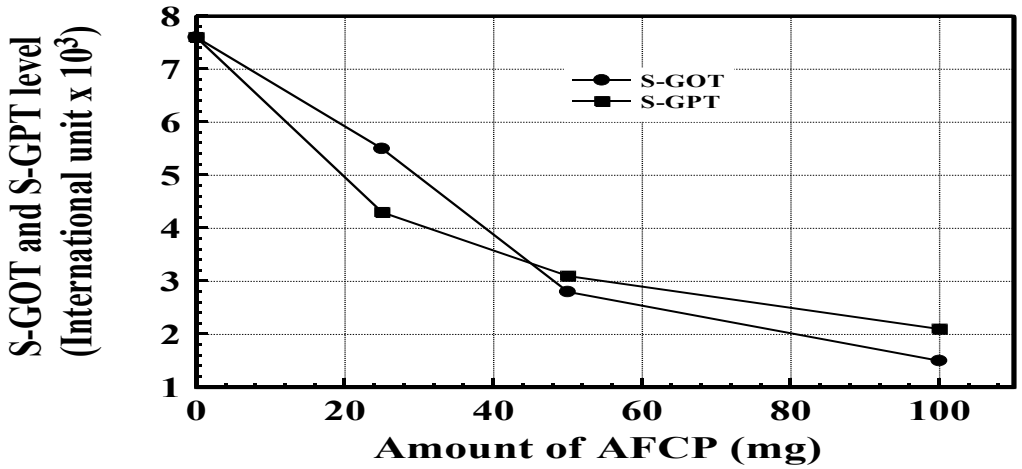
Figure 6



Time after tetrachloride administration in hours. (AFCP = FCA)

3. Figure (7) illustrates the relationship between the S-GOT and the S-GPT levels, and the amount of FCA. Figure (7) shows results of the relationship between S-GOT and S-GPT, and the amount of FCA, 0 to 100 mg at 24 hours after 20 U l/Kg of carbon tetrachloride administration. It will be seen that the efficiency of FCA depends upon the amount of FCA.

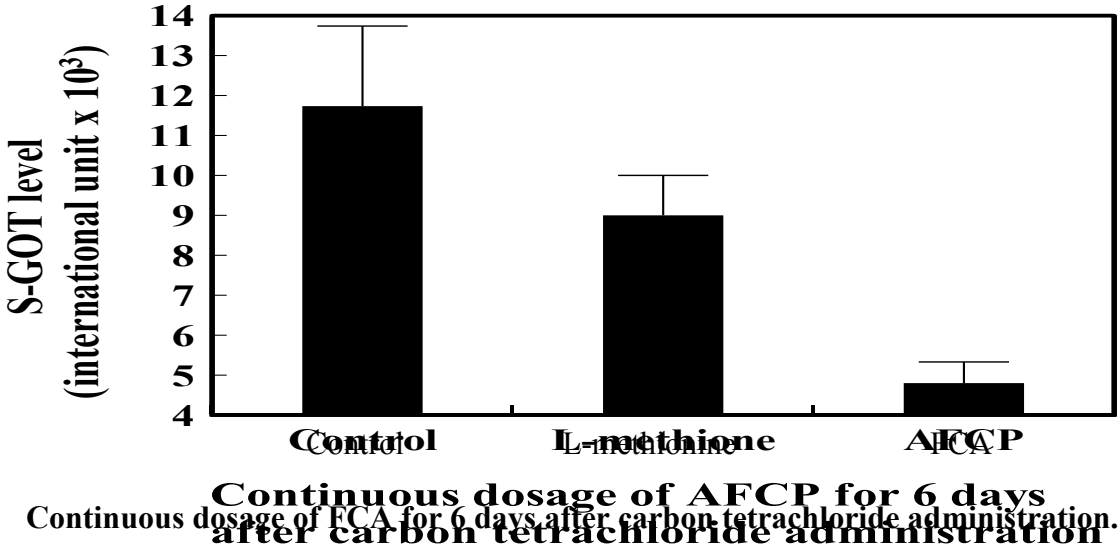
Figure 7



The amount of FCA in mg 24 hours after carbon tetrachloride administration

4. Figure (8) illustrates the result of the S-GOT level of the FCA, L-methionine and the control medium (no dosage provided) with the continuous dosage of FCA for 6 days after 20 U l/Kg of carbon tetrachloride administration as shown in Figure (8). Generally, L-methionine can be used for medications for the liver. As shown in the illustration, the FCA had the lowest level of S-GOT and twice the efficiency was shown when compared to L-methionine.

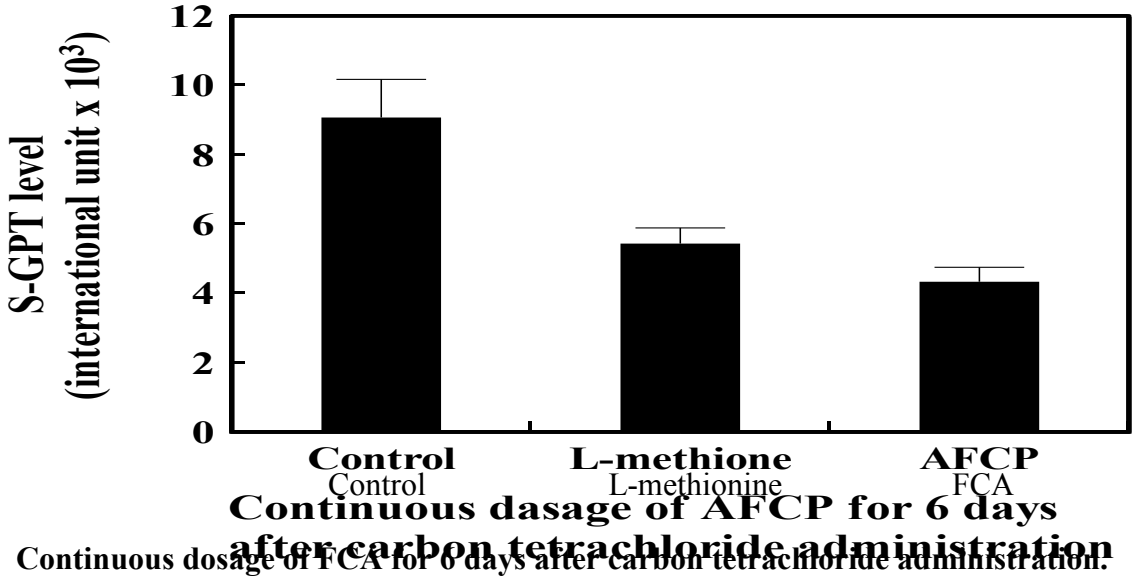
Figure 8



Continuous dosage of FCA for 6 days after carbon tetrachloride administration.

5. Figure (9) illustrates the result of the S-GPT level of the FCA, L-methionine and the control medium (no dosage provided) with the continuous dosage of the FCA for 6 days after 20 U 1/Kg of carbon tetrachloride administration as shown in Figure (9). Generally, L-methionine can be used for medications for the liver. As shown in the illustration, the FCA had the lowest level of S-GPT and the difference of efficiency between the FCA and L-methionine was not clearly evident.

Figure 9

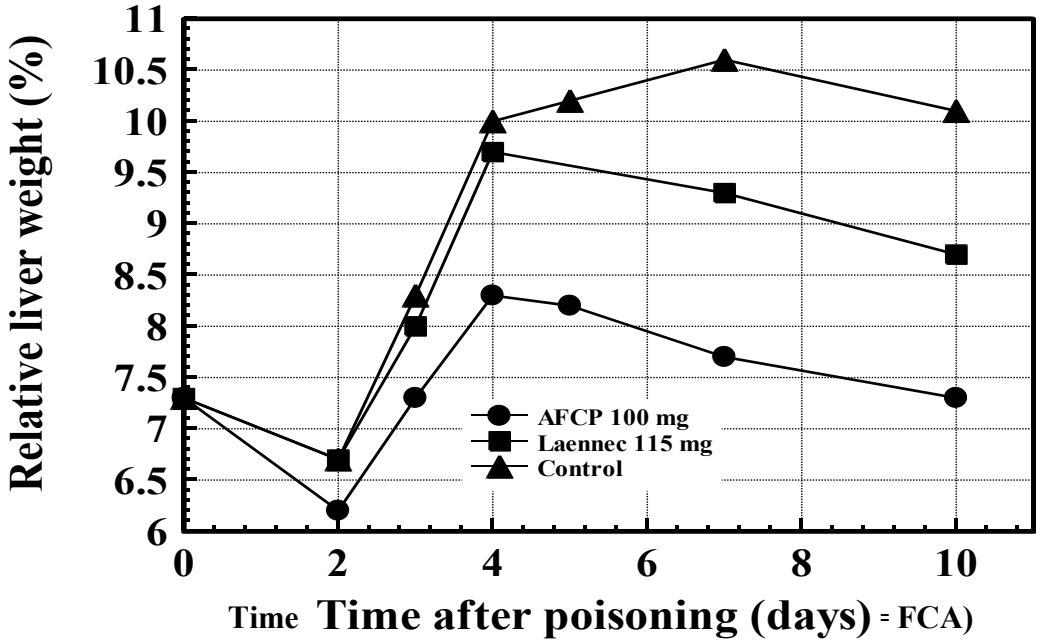


Continuous dosage of FCA for 6 days after carbon tetrachloride administration.

AFCP6

6. Figure (10) illustrates the effect of Laennec and the FCA of the relative weight of the liver in carbon tetrachloride intoxicated mice. The relative liver weight treated by FCA was the lowest among laennec and the control. In general terms, the relative weight increases in a damaged liver. If the system of protection from liver damage is in place the relative weight of the liver will be lower.

Figure 10



Effect of laennec and AFCP on relative liver weight in carbon tetrachloride intoxicated mice

Relevant effect of Laennec and FCA on liver weight in carbon tetrachloride intoxicated mice.

The liver is a very important organ in our body. Sometimes the liver is referred to as a chemical factory which produces not only enzymes but also energy such as glycogen. FCA is the antioxidant with a high level of SOD-like, Catalase-like and Glutathion peroxidase-like element. Recent science is indicating how most diseases evolve from damage caused by reactive oxygen species including free radicals. Therefore, a disease is a phenomenon derived from the state of electrons. If we can control these electrons with supplements or food sources, it would be the most natural method.

FCA is a very natural and safe product as was indicated in the toxicity tests outlined earlier. The reason as to why carbon tetrachloride was used for acute hepatitis was based on the premise that carbon tetrachloride will produce strong radicals and inert enzymes as indicated below.

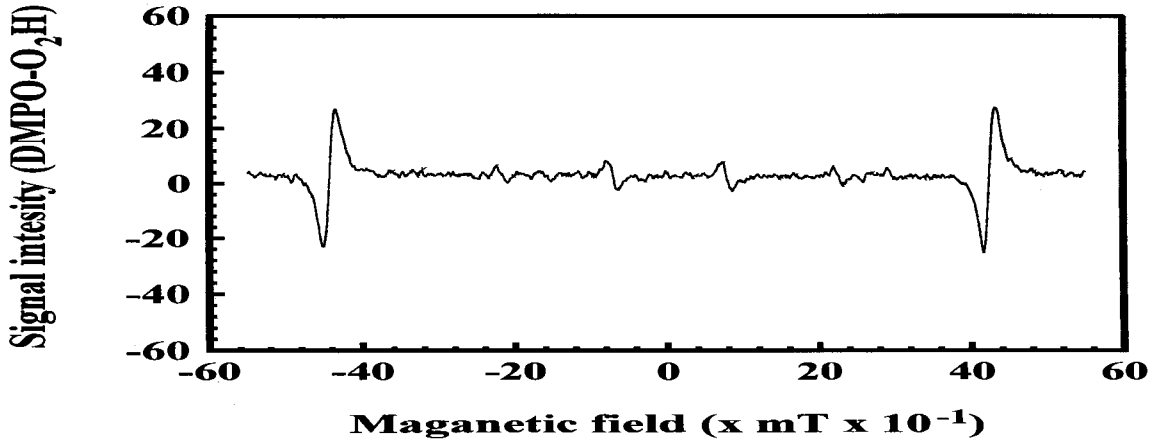
$E_{aq}^- + CCl_4 \rightarrow CCl_3^{\cdot} + Cl^-$
$CCl_3^{\cdot} + O_2 \rightarrow CCl_3O_2^{\cdot}$
$CCl_3O_2^{\cdot} + \text{Enzyme} \rightarrow \text{Inert}$
$CCl_3O_2^{\cdot} + GSH \rightarrow \text{Inert}$

Antioxidant Effect of FCA by Electron Resonance Spectrometer (ESR)

Super oxide anion radicals which are typical radicals are dismutated by the enzyme called SOD (superoxide dismutase). The function of SOD is shown as the redox reaction of transit metal such as Mn, Zn, Cu and Fe. ESR can detect electron spin states as signal intensity using spin trapping reagents. Radicals have lone paired electron in the most outside shell as shown in Figure (1).

Figure (11) shows the result of the control of signal intensity which is produced by the hypoxanthine-xanthine oxidase system. In general terms, the signal patterns in Figure (11) show results of superoxide anion radicals using DMPO (5,5-dimethyl-1-pyrroline-oxide) of a spin

This is the result of ESR spectro analysis for superoxide radicals with AFCP.



Magnetic field (x0.1 mT)

Figure (12) shows the result of the signal intensity of 2.48 g/l of FCA which will not show the signal pattern of the superoxide anion radicals.

Figure 12

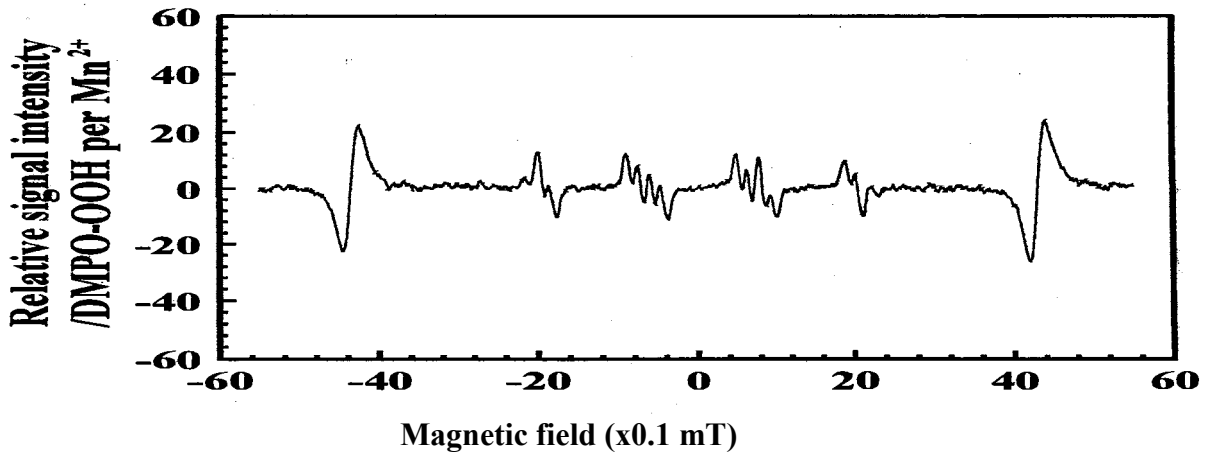


Figure (13) shows the result of signal intensity of hydroxyl radicals which will be produced by Fenton's reaction. Fenton's reaction will be used for producing hydroxyl radicals using H_2O_2 and $FeSO_4$.

Signal intensity of pure water by ESR using Fenton' reaction

Figure 13

Signal intensity of pure water by ESR using Fenton's reaction

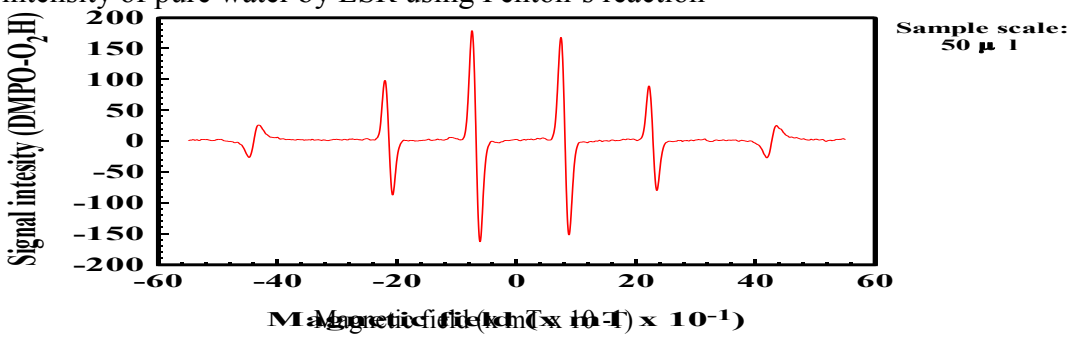
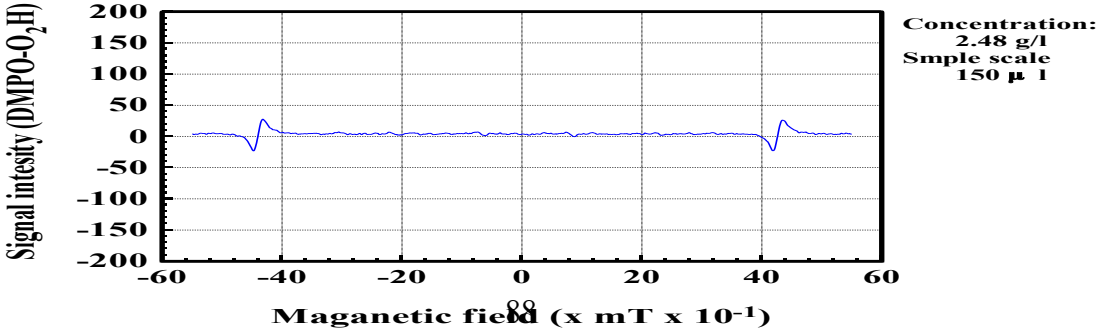


Figure (14) shows the result of signal intensity of hydroxyl radicals when using 2.48 g/l of FCA. It will indicate that the FCA possesses a strong ability to eliminate not only the superoxide anion radicals but also the hydroxyl radicals.

Figure 14

Signal intensity of FCA by ESR

Signal intensity of AFCP by ESR



Magnetic field (x mT x 10 -1)

Therefore, FCA has the role of a strong antioxidant performing similar functions as SOD, Catalase and Glutathione peroxidase which are known to be oxidation reduction enzymes. These are very important enzymes in our bodies.

In summary, the FCA provides its benefits in the following areas.

1. The safety factor of FCA is very significant against toxicity.
2. The elimination ability of FCA against superoxide anion radicals and hydroxyl radicals are very significant.
3. FCA is a natural product from rice plants.

Data Collection:

Client # 1
Visit # 1
Date: 8/30/10
Age: 53
Sex: F
Weight: 149
Height: 5' 9"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Breast Cancer

Data: BTA

	pH	rH2	r
Blood	7.49	28.2	214
Saliva	6.76	29.6	253
Urine	6.50	24.0	76

Data: BCA
Resistance: 646.2
Reactance: 74.9
Phase Angle: 6.2

Data: Indole Analysis
Indole was present at a: +3

Data: Orthostatic Hypotension
Supine: 134/72
Standing: 144/76

Data: Urine Dipstick analysis
Specific Gravity: 1.010
pH: 6.5
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 4.1
Sympathetic Regulation: 3.6
Tension Index: 2.2

Data: DDFAO
ONOOH (Peroxynitrous Acid): 80
NO (nitrogen oxide): 60
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):80
OH- (Hydroxyl radical): 80

Data: Questionnaire
If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..**8**…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7…..**8**…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

Client # 1
Visit # 2
Date: 9/22/10
Age: 53
Sex: F
Weight: 149
Height: 5'9"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Breast Cancer

Data: BTA	pH	rH2	r
Blood	7.44	27.9	218
Saliva	6.69	29.2	257
Urine	6.32	22.0	71

Data: BCA
Resistance: 691.4
Reactance: 71.3
Phase Angle: 6.6

Data: Indole Analysis
Indole was present at a: +3

Data: Orthostatic Hypotension
Supine: 128/76
Standing: 140/73

Data: Urine Dipstick analysis
Specific Gravity: 1.030
pH: 6.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 2.2
Sympathetic Regulation: 5.1
Tension Index: 8.6

Data: DDFAO
ONOOH (Peroxynitrous Acid): 60
NO (nitrogen oxide): 60
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):40
OH- (Hydroxyl radical): 60

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..**7**…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..**7**…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **A little less pain**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 1
Visit # 3
Date: 10/23/10
Age: 53
Sex: F
Weight: 147
Height: 5'9"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Breast Cancer

Data: BTA

	pH	rH2	r
Blood	7.49	25.3	233
Saliva	6.88	28.1	241
Urine	6.37	21.6	63

Data: BCA
Resistance: 610.4
Reactance: 77.6
Phase Angle: 5.9

Data: Indole Analysis
Indole was present at a: +2

Data: Orthostatic Hypotension
Supine: 141/69
Standing: 147/78

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 6.5
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 3.4
Sympathetic Regulation: 2.1
Tension Index: 6.6

Data: DDFAO
ONOOH (Peroxynitrous Acid): 20
NO (nitrogen oxide): 80
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):10
OH- (Hydroxyl radical): 20

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..**4**…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..**4**…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **I just feel better with less pain**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 1
Visit # 4
Date: 11/24/10
Age: 53
Sex: F
Weight: 146
Height: 5'9"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Breast Cancer

Data: BTA

	pH	rH2	r
Blood	7.44	23.9	225
Saliva	6.76	24.1	189
Urine	6.10	20.5	72

Data: BCA
Resistance: 680.0
Reactance: 72.7
Phase Angle: 6.1

Data: Indole Analysis
Indole was present at a: +3

Data: Orthostatic Hypotension
Supine: 152/73
Standing: 162/81

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 6.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 4.8
Sympathetic Regulation: 3.6
Tension Index: 7.6

Data: DDFAO
ONOOH (Peroxynitrous Acid): 10
NO (nitrogen oxide): 40
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):0
OH- (Hydroxyl radical): 20

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..**3**…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..**3**…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **I still feel so much better**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Additional comments on the overall effects of this product on your health and wellbeing: **I love this product and would love to continue to use it!**

Client # 2
Visit # 1
Date: 8/20/10
Age: 59
Sex: M
Weight: 205
Height: 6'2"
Type of nutritional supplement consumed: FCA Soft Gel

Total amount of product consumed daily: 15 capsules
Primary Dx: Hydrocephalus

Data: BTA

	pH	rH2	r
Blood	7.50	27.6	169
Saliva	7.21	27.9	148
Urine	6.29	23.2	53

Data: BCA
Resistance: 472.7
Reactance: 54.7
Phase Angle: 6.6

Data: Indole Analysis
Indole was present at a: +3

Data: Orthostatic Hypotension
Supine: 121/82
Standing: 117/91

Data: Urine Dipstick analysis
Specific Gravity: 1.010
pH: 6
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 10.9
Sympathetic Regulation:1.4
Tension Index: 6.2

Data: DDFAO
ONOOH (Peroxynitrous Acid): 60
NO (nitrogen oxide): 80
H2O2 (Hydrogen Pyroxide): 80
O2- (Oxygen free radical):60
OH- (Hydroxyl radical): 80

Data: Questionnaire
If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..**3**…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..**2**…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

Client # 2
Visit # 2
Date: 9/22/10
Age: 59
Sex: M
Weight: 212
Height: 6'2"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Hydrocephalous

Data: BTA

	pH	rH2	r
Blood	7.52	24.6	154
Saliva	7.29	28.2	156
Urine	5.86	20.7	57

Data: BCA
Resistance: 465.8
Reactance: 56.2
Phase Angle: 6.9

Data: Indole Analysis
Indole was present at a: +4

Data: Orthostatic Hypotension
Supine: 131/91
Standing: 132/96

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 6
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 12.3
Sympathetic Regulation: 6.1
Tension Index: 14.4

Data: DDFAO
ONOOH (Peroxynitrous Acid): 10
NO (nitrogen oxide): 0
H2O2 (Hydrogen Pyroxide): 20
O2- (Oxygen free radical):20
OH- (Hydroxyl radical): 20

Data: Questionnaire

I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..**3**…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..**3**…..4…..5…..6…..7…..8…..9…..10

(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **Very little**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 2
Visit # 3
Date: 10/22/10
Age: 59
Sex: M
Weight: 208
Height: 6'2"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Hydrocephalus

Data: BTA

	pH	rH2	r
Blood	7.56	24.8	168
Saliva	7.36	27.1	144
Urine	5.91	19.3	41

Data: BCA
Resistance: 505.5
Reactance: 60.0
Phase Angle: 6.8

Data: Indole Analysis
Indole was present at a: +3

Data: Orthostatic Hypotension
Supine: 121/82
Standing: 117/97

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 6
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 5.3
Sympathetic Regulation: 3.1
Tension Index: 12.2

Data: DDFAO
ONOOH (Peroxynitrous Acid):0
NO (nitrogen oxide):0
H2O2 (Hydrogen Pyroxide):0
O2- (Oxygen free radical):0
OH- (Hydroxyl radical): 0

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No
If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..**3**…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..**3**…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **Very little**
If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 2
Visit # 4
Date: 11/21/10
Age: 59
Sex: M
Weight: 203
Height: 6'2"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Hydrocephalus

Data: BTA

	pH	rH2	r
Blood	7.51	24.6	172
Saliva	6.96	25.8	151
Urine	5.88	19.9	48

Data: BCA
Resistance: 465.8
Reactance: 56.2
Phase Angle: 6.8

Data: Indole Analysis
Indole was present at a: +3

Data: Orthostatic Hypotension
Supine: 132/84
Standing: 122/76

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 6
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 3.6
Sympathetic Regulation: 0.8
Tension Index: 8.2

Data: DDFAO
ONOOH (Peroxynitrous Acid):0
NO (nitrogen oxide):10
H2O2 (Hydrogen Pyroxide):0
O2- (Oxygen free radical):0
OH- (Hydroxyl radical): 10

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..**3**…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)
If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..**3**…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **I feel a little bit better overall, perhaps less episodes of dizziness**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Additional comments on the overall effects of this product on your health and wellbeing: **I would like to continue taking this product. While I am not absolutely certain, I think it is helping me**

Client # 3
Visit # 1
Date: 8/26/10
Age: 61
Sex: M
Weight: 178
Height: 5'10"

Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Rheumatoid Arthritis

Data: BTA

	pH	rH2	r
Blood	7.55	27.2	138
Saliva	6.52	28.6	149
Urine	6.48	23.2	151

Data: BCA
Resistance: 652.4
Reactance: 57.3
Phase Angle: 5.2

Data: Indole Analysis
Indole was present at a: 0

Data: Orthostatic Hypotension
Supine: 160/83
Standing: 132/90

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 6
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 5.6
Sympathetic Regulation: 8.7
Tension Index: 3.3
Data: DDFAO
ONOOH (Peroxynitrous Acid):80
NO (nitrogen oxide): 80
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):80
OH- (Hydroxyl radical): 80

Data: Questionnaire

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..**9**…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7…..8…..**9**…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

Client # 3
Visit # 2
Date: 9/23/10
Age: 61
Sex: M
Weight: 178
Height: 5'10"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Rheumatoid Arthritis

Data: BTA

	pH	rH2	r
Blood	7.58	27.8	133
Saliva	6.61	26.6	147
Urine	6.32	24.3	132

Data: BCA
Resistance: 652.2
Reactance: 59.3
Phase Angle: 5.2

Data: Indole Analysis
Indole was present at a: 0

Data: Orthostatic Hypotension
Supine: 154/86
Standing: 149/89

Data: Urine Dipstick analysis
Specific Gravity: 1.030
pH: 6
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones:
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 2.4
Sympathetic Regulation: 2.0
Tension Index: 16.0

Data: DDFAO
ONOOH (Peroxynitrous Acid):80
NO (nitrogen oxide): 80
H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical):60
OH- (Hydroxyl radical):80

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..**9**…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7…..8…..**9**…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **None**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **No change in my medications**

Client # 3
Visit # 3
Date: 10/22/10
Age: 61
Sex: M
Weight: 178
Height: 5'10"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Rheumatoid Arthritis

Data: BTA

	pH	rH2	r
Blood	7.52	26.9	141
Saliva	6.79	26.2	155
Urine	7.11	24.1	97

Data: BCA
Resistance: 654.2
Reactance: 56.7
Phase Angle: 5.0

Data: Indole Analysis
Indole was present at a: 0

Data: Orthostatic Hypotension
Supine: 166/87
Standing: 154/89

Data: Urine Dipstick analysis
Specific Gravity: 1.030
pH: 6
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Regulation: 8.2
Sympathetic Regulation: 2.1
Tension Index: 14.2

Data: DDFAO
ONOOH (Peroxynitrous Acid):60
NO (nitrogen oxide): 60
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):60
OH- (Hydroxyl radical): 60

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No
If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..**9**…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7…..8…..**9**…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **Very Little**
If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **No change in my medication**

Client # 3
Visit # 4
Date: 11/23/10
Age: 69
Sex: M
Weight: 178
Height: 5'10"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Rheumatoid Arthritis

Data: BTA

	pH	rH2	r
Blood	7.58	25.8	148
Saliva	6.32	25.9	162
Urine	6.91	23.6	92

Data: BCA
Resistance: 657.2
Reactance: 51.1
Phase Angle: 4.9

Data: Indole Analysis
Indole was present at a: 0

Data: Orthostatic Hypotension
Supine: 171/88
Standing: 167/92

Data: Urine Dipstick analysis
Specific Gravity: 1.030
pH: 6
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 9.6
Sympathetic Regulation: 4.7
Tension Index: 16.2

Data: DDFAO
ONOOH (Peroxynitrous Acid):40
NO (nitrogen oxide): 60
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):20
OH- (Hydroxyl radical): 60

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..**7**…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7…..**8**…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **My pain is less and I can do a little more**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **No change in medication**

Additional comments on the overall effects of this product on your health and wellbeing: **The product just seemed like it may be working, I am sorry that the study is over! I would like to keep taking this product!**

Client # 4
Visit # 1
Date: 8/31/10
Age: 54
Sex: F
Weight: 166
Height: 5'9"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Breast Cancer

Data: BTA

	pH	rH2	r
Blood	7.46	27.7	196
Saliva	6.49	29.2	185
Urine	5.12	28.5	76

Data: BCA
Resistance: 491.9
Reactance: 55.6
Phase Angle: 6.4

Data: Indole Analysis
Indole was present at a: 3

Data: Orthostatic Hypotension
Supine: 108/75
Standing: 114/80

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 5
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: En
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 6.3
Sympathetic Regulation: 2.4
Tension Index: 14.7

Data: DDFAO
ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 40
H2O2 (Hydrogen Pyroxide): 60
O2- (Oxygen free radical): 40
OH- (Hydroxyl radical): 40

Data: Questionnaire

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..**4**…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..**2**…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 4
Visit # 2
Date: 9/21/10
Age: 54
Sex: F
Weight: 166
Height: 5'9"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Breast Cancer

Data: BTA

	pH	rH2	r
Blood	7.32	26.2	187
Saliva	6.88	28.5	176
Urine	5.51	22.6	68

Data: BCA
Resistance: 491.9
Reactance: 55.5
Phase Angle: 6.4

Data: Indole Analysis
Indole was present at a: 3

Data: Orthostatic Hypotension
Supine: 112/82
Standing: 134/89

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 5.0
Leukocytes: EN

Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 5.4
Sympathetic Regulation: 3.6
Tension Index: 15.3

Data: DDFAO
ONOOH (Peroxynitrous Acid): 60
NO (nitrogen oxide):40
H2O2 (Hydrogen Pyroxide):40
O2- (Oxygen free radical):20
OH- (Hydroxyl radical): 40

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..**4**…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..**2**…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **Very Little**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 4
Visit # 3
Date: 10/27/10
Age: 54
Sex: F
Weight: 156
Height: 5'9"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Breast Cancer

Data: BTA

	pH	rH2	r
Blood	7.35	25.1	182
Saliva	6.77	26.3	167
Urine	5.42	20.3	65

Data: BCA
Resistance: 493.1
Reactance: 52.5
Phase Angle: 6.1

Data: Indole Analysis
Indole was present at a: 3

Data: Orthostatic Hypotension
Supine: 117/70
Standing: 115/82

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 5.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 5.8
Sympathetic Regulation: 6.2
Tension Index: 18.9

Data: DDFAO
ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide):20
H2O2 (Hydrogen Pyroxide):40
O2- (Oxygen free radical):10
OH- (Hydroxyl radical): 20

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..**2**…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..**2**…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **I do feel a little better**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 4
Visit # 4
Date: 11/24/10
Age: 54
Sex: F
Weight: 168
Height: 5'9"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Breast Cancer

Data: BTA

	pH	rH2	r
Blood	7.42	24.9	189
Saliva	6.81	25.8	176
Urine	5.45	20.2	69

Data: BCA
Resistance: 497.1
Reactance: 50.5
Phase Angle: 5.3

Data: Indole Analysis
Indole was present at a: 4

Data: Orthostatic Hypotension
Supine: 121/87
Standing: 118/80

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 5.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 3.1
Sympathetic Regulation: 8.6
Tension Index: 14.4

Data: DDFAO
ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide):10
H2O2 (Hydrogen Pyroxide):20
O2- (Oxygen free radical):10
OH- (Hydroxyl radical): 10

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..**2**…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..**2**…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **I feel more energy and hurt slightly less**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Additional comments on the overall effects of this product on your health and wellbeing: **I am not completely certain, but I really would like to continue taking this product. I feel it has helped me significantly on some level!**

Client # 5
Visit # 1
Date: 8/31/10
Age: 73
Sex: M
Weight: 176
Height: 5'8"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Prostate Cancer

Data: BTA

	pH	rH2	r
Blood	7.55	28.2	186
Saliva	7.17	27.6	183
Urine	5.57	20.3	58

Data: BCA
Resistance: 491.7
Reactance: 58.6
Phase Angle: 6.8

Data: Indole Analysis
Indole was present at a: 2

Data: Orthostatic Hypotension
Supine: 144/90
Standing: 166/95

Data: Urine Dipstick analysis
Specific Gravity: 1.030
pH: 6.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 9.7
Sympathetic Regulation: 2.8
Tension Index: 1.9

Data: DDFAO
ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 80
H2O2 (Hydrogen Pyroxide): 80
O2- (Oxygen free radical): 80
OH- (Hydroxyl radical): 60

Data: Questionnaire
If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..**4**…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..**1**…..2…..3…..4…..5…..6…..7…..8…..9…..10

(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)
If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage:

Client # 5
Visit # 2
Date: 9/30/10
Age: 73
Sex: M
Weight: 176
Height: 5'8"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Prostate Cancer

Data: BTA

	pH	rH2	r
Blood	7.58	27.9	192
Saliva	7.02	26.4	206
Urine	5.36	20.8	73

Data: BCA
Resistance: 468.2
Reactance: 55.2
Phase Angle: 6.7

Data: Indole Analysis
Indole was present at a: 2

Data: Orthostatic Hypotension
Supine: 145/96
Standing: 153/90

Data: Urine Dipstick analysis
Specific Gravity: 1.030
pH: 6.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN

Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 0.1
Sympathetic Regulation: 2.1
Tension Index: 16.7

Data: DDFAO
ONOOH (Peroxynitrous Acid): 60
NO (nitrogen oxide): 60
H2O2 (Hydrogen Pyroxide): 80
O2- (Oxygen free radical): 20
OH- (Hydroxyl radical): 60

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..**3**…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..**2**…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **NO changes**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 5
Visit # 3
Date: 10/27/10
Age: 73
Sex: M
Weight: 179

Height: 5'8"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Prostate Cancer

Data: BTA

	pH	rH2	r
Blood	7.42	28.2	207
Saliva	7.23	26.4	132
Urine	5.81	19.3	110

Data: BCA
Resistance: 462.4
Reactance: 55.8
Phase Angle: 6.9

Data: Indole Analysis
Indole was present at a: 2

Data: Orthostatic Hypotension
Supine: 152/87
Standing: 145/91

Data: Urine Dipstick analysis
Specific Gravity: 1.030
pH: 6.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 2.8
Sympathetic Regulation: 5.6
Tension Index: 16.2

Data: DDFAO
ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 60
H2O2 (Hydrogen Pyroxide): 20
O2- (Oxygen free radical): 10
OH- (Hydroxyl radical): 40
Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: **0**…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **I feel really good, no pain, no discomfort and I seem to be urinating better.**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 5
Visit # 4
Date: 11/23/10
Age: 73
Sex: M
Weight: 172
Height: 5'8"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Prostate Cancer

Data: BTA

	pH	rH2	r
Blood	7.39	27.0	212
Saliva	7.42	25.9	167
Urine	5.97	19.1	83

Data: BCA
Resistance: 497.2
Reactance: 57.3
Phase Angle: 5.9

Data: Indole Analysis
Indole was present at a: 2

Data: Orthostatic Hypotension
Supine: 140/85
Standing: 133/87

Data: Urine Dipstick analysis
Specific Gravity: 1.030
pH: 5.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 2.8
Sympathetic Regulation: 9.2
Tension Index: 16.7

Data: DDFAO
ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 20
H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical): 10
OH- (Hydroxyl radical): 20

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: **0**…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **No change in last 30-days**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Additional comments on the overall effects of this product on your health and wellbeing: **About 2-months into taking the product, my entire system changed. Pain went away, urination improved and I just feel better all day long. I want to keep taking this product!**

Client #6
Visit # 1
Date: 8/17/10
Age: 61
Sex: F
Weight: 130
Height: 5'6"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Hepatitis C

Data: BTA

	pH	rH2	r
Blood	7.52	28.3	157
Saliva	7.48	29.6	192
Urine	5.74	21.0	71

Data: BCA

Resistance: 667.0
Reactance: 67.0
Phase Angle: 5.7

Data: Indole Analysis

Indole was present at a: 3

Data: Orthostatic Hypotension
Supine: 99/66
Standing: 103/72

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 5.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 1.5
Sympathetic Regulation: 0.6
Tension Index: 10.2

Data: DDFAO
ONOOH (Peroxynitrous Acid):20
NO (nitrogen oxide): 20
H2O2 (Hydrogen Pyroxide): 80
O2- (Oxygen free radical): 60
OH- (Hydroxyl radical): 20

Data: Questionnaire
If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7….**.8**…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 6
Visit # 2
Date: 9/20/10
Age: 61
Sex: F
Weight: 130
Height: 5'6"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Hepatitis C

Data: BTA

	pH	rH2	r
Blood	7.58	30.1	138
Saliva	7.40	30.3	212
Urine	5.62	24.2	63

Data: BCA
Resistance: 725.0
Reactance: 61.8
Phase Angle: 4.9

Data: Indole Analysis
Indole was present at a: 3

Data: Orthostatic Hypotension
Supine: 98/66
Standing: 100/69

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 5.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 2.1
Sympathetic Regulation: 6.8
Tension Index: 12.2

Data: DDFAO
ONOOH (Peroxynitrous Acid):40
NO (nitrogen oxide): 20
H2O2 (Hydrogen Pyroxide): 80
O2- (Oxygen free radical): 60
OH- (Hydroxyl radical): 40

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7…..**8**…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **No Change**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 6
Visit # 3
Date: 10/27/10
Age: 61
Sex: F
Weight: 130
Height: 5'6"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Hepatitis C

Data: BTA

	pH	rH2	r
Blood	7.41	27.3	171
Saliva	7.22	26.1	262
Urine	5.36	20.5	79

Data: BCA
Resistance: 643.8
Reactance: 58.2
Phase Angle: 5.2

Data: Indole Analysis
Indole was present at a: 3

Data: Orthostatic Hypotension
Supine: 117/70
Standing: 115/82

Data: Urine Dipstick analysis
Specific Gravity: 1.030
pH: 5.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 2.3
Sympathetic Regulation: 1.5
Tension Index: 10.2

Data: DDFAO
ONOOH (Peroxynitrous Acid):20
NO (nitrogen oxide): 10
H2O2 (Hydrogen Pyroxide): 60
O2- (Oxygen free radical): 60
OH- (Hydroxyl radical): 40

Data: Questionnaire

I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7…..**8**…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **No change**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 6
Visit # 4
Date: 11/21/10
Age: 62
Sex: F
Weight: 126
Height: 5'6"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Hepatitis C

Data: BTA

	pH	rH2	r
Blood	7.48	26.7	183
Saliva	7.18	24.8	189
Urine	5.85	19.3	63

Data: BCA
Resistance: 652.0
Reactance: 64.0
Phase Angle: 5.6

Data: Indole Analysis
Indole was present at a: 1

Data: Orthostatic Hypotension
Supine: 105/80
Standing: 99/78

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 5.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 3.2
Sympathetic Regulation: 2.7
Tension Index: 10.1

Data: DDFAO
ONOOH (Peroxynitrous Acid):10
NO (nitrogen oxide): 10
H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical): 20
OH- (Hydroxyl radical): 20

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..**2**…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **I feel so much better. I have more energy and feel more alive. I can do things around the house and just feel GREAT**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Additional comments on the overall effects of this product on your health and wellbeing: **I did not think this product was going to work, but the last couple of weeks, I really started to notice a big difference in my energy and overall fatigue level. Where can I buy more?**

Client # 7
Visit # 1
Date: 8/17/10
Age: 62
Sex: M
Weight: 175
Height: 5'10"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Prostate Cancer

Data: BTA

	pH	rH2	r
Blood	7.52	27.2	148
Saliva	6.74	24.8	173
Urine	5.25	19.0	71

Data: BCA
Resistance: 424.5
Reactance: 46.1
Phase Angle: 6.2

Data: Indole Analysis
Indole was present at a: 0

Data: Orthostatic Hypotension
Supine: 126/73
Standing: 146/83

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 5.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 3.9
Sympathetic Regulation: 5.3
Tension Index: 2.5

Data: DDFAO
ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 40
H2O2 (Hydrogen Pyroxide): 40
O2- (Oxygen free radical): 40
OH- (Hydroxyl radical): 40

Data: Questionnaire
If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: **0**…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 7
Visit # 2
Date: 9/20/10
Age: 62
Sex: M

Weight: 175
Height: 5'10"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Prostate Cancer

Data: BTA

	pH	rH2	r
Blood	7.50	26.8	141
Saliva	7.21	25.7	165
Urine	5.88	19.2	68

Data: BCA
Resistance: 456.7
Reactance: 49.1
Phase Angle: 6.1

Data: Indole Analysis
Indole was present at a: 0

Data: Orthostatic Hypotension
Supine: 118/73
Standing: 131/82

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 5.0
Leukocytes: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 2.8
Sympathetic Regulation: 3.4
Tension Index: 4.5

Data: DDFAO
ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 40
H2O2 (Hydrogen Pyroxide): 40
O2- (Oxygen free radical): 40
OH- (Hydroxyl radical): 40
Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: **0**…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **Feel fine, no change noted**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 7
Visit # 3
Date: 10/29/10
Age: 62
Sex: M
Weight: 175
Height: 5'10"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Prostate Cancer

Data: BTA

	pH	rH2	r
Blood	7.48	26.4	135
Saliva	7.31	25.1	151
Urine	5.45	18.9	86

Data: BCA
Resistance: 477.9
Reactance: 50.3
Phase Angle: 5.8

Data: Indole Analysis
Indole was present at a: 0

Data: Orthostatic Hypotension
Supine: 128/76
Standing: 134/81

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 5.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 3.0
Sympathetic Regulation: 4.9
Tension Index: 4.1

Data: DDFAO
ONOOH (Peroxynitrous Acid): 20
NO (nitrogen oxide): 40
H2O2 (Hydrogen Pyroxide): 40
O2- (Oxygen free radical): 10
OH- (Hydroxyl radical): 40

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: **0**…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **No changes, still feel fine**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 7
Visit # 4
Date: 12/1/10
Age: 62
Sex: M
Weight: 175
Height: 5'10"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Prostate Cancer

Data: BTA

	pH	rH2	r
Blood	7.41	25.9	142
Saliva	7.27	24.7	149
Urine	5.88	19.1	73

Data: BCA
Resistance: 414.9
Reactance: 48.6
Phase Angle: 6.0

Data: Indole Analysis
Indole was present at a: 0

Data: Orthostatic Hypotension
Supine: 123/72
Standing: 132/98

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 5.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 2.3
Sympathetic Regulation: 4.1
Tension Index: 5.5

Data: DDFAO
ONOOH (Peroxynitrous Acid): 10
NO (nitrogen oxide): 20
H2O2 (Hydrogen Pyroxide): 40
O2- (Oxygen free radical): 0
OH- (Hydroxyl radical): 20

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: **0**…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **No changes, still feel great**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Additional comments on the overall effects of this product on your health and wellbeing: **I would like to continue to take this product. Although I have not felt any changes, I am lucky and felt fine to begin with.**

Client # 8
Visit # 1
Date: 8/24/10
Age: 50
Sex: F
Weight: 123
Height: 5'5"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Rheumatoid Arthritis

Data: BTA

	pH	rH2	r
Blood	7.55	28.4	163
Saliva	7.34	28.7	203
Urine	6.29	23.2	86

Data: BCA
Resistance: 720.0
Reactance: 72.0
Phase Angle: 5.7
Data: Indole Analysis

Indole was present at a: 2

Data: Orthostatic Hypotension
Supine: 142/96
Standing: 147/102

Data: Urine Dipstick analysis
Specific Gravity: 1.015
pH: 6.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 1.8
Sympathetic Regulation: 6.0
Tension Index: 8.3

Data: DDFAO
ONOOH (Peroxynitrous Acid):80
NO (nitrogen oxide):80
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical): 80
OH- (Hydroxyl radical): 60

Data: Questionnaire

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..**8**…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7…..8…..**9**…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **No changes**

Client # 8
Visit # 2
Date: 9/21/10
Age: 50
Sex: F
Weight: 123
Height: 5'5"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Rheumatoid Arthritis

Data: BTA	pH	rH2	r
Blood	7.46	28.1	141
Saliva	7.41	27.9	182
Urine	6.88	22.6	91

Data: BCA
Resistance: 611.0
Reactance: 60.0
Phase Angle: 5.6

Data: Indole Analysis
Indole was present at a: 2

Data: Orthostatic Hypotension
Supine: 159/103
Standing: 172/106

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 6.0
Leukocytes: pos
Nitrate: pos
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 1.1
Sympathetic Regulation: 3.1
Tension Index: 8.7

Data: DDFAO
ONOOH (Peroxynitrous Acid): 80
NO (nitrogen oxide): 60
H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical):40
OH- (Hydroxyl radical): 60

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..**8**…..9…..10

(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..4…..5…..6…..7…..8…..**9**…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **I have not seen any changes yet**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **No change in medication**

Client # 8
Visit # 3
Date: 10/20/10
Age: 50
Sex: F
Weight: 123
Height: 5'5"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Rheumatoid Arthritis

Data: BTA

	pH	rH2	r
Blood	7.44	26.6	146
Saliva	7.36	26.4	212
Urine	5.85	20.1	63

Data: BCA
Resistance: 683.2
Reactance: 68.0
Phase Angle: 5.5

Data: Indole Analysis
Indole was present at a: 2

Data: Orthostatic Hypotension
Supine: 155/100
Standing: 147/96

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 6.00
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 4.2
Sympathetic Regulation: 10.6
Tension Index: 12.5

Data: DDFAO
ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 20
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):20
OH- (Hydroxyl radical): 20

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..**6**…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..4…..5…..**6**…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **The pain in my hands, fingers and wrists is so much better. I can button my own clothes and do more things for myself.**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **No changes**

Client # 8
Visit # 4
Date: 11/20/10
Age: 50
Sex: F
Weight: 123
Height: 5'5"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Rheumatoid Arthritis

Data: BTA

	pH	rH2	r
Blood	7.38	24.8	166
Saliva	7.09	25.7	203
Urine	5.36	19.3	27

Data: BCA
Resistance: 718.6
Reactance: 75.2
Phase Angle: 5.5

Data: Indole Analysis
Indole was present at a: 2

Data: Orthostatic Hypotension
Supine: 161/102
Standing: 150/76

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 5.0
Leukocytes: EN
Nitrate: EN
Protein: EN

Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 3.1
Sympathetic Regulation: 8.5
Tension Index: 2.9

Data: DDFAO
ONOOH (Peroxynitrous Acid): 20
NO (nitrogen oxide): 0
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):10
OH- (Hydroxyl radical): 10

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..**5**…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..2…..3…..**4**…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)
During the last 30 days I have noticed these changes in my body or its' function: **My hands continue to improve and now my elbows and knees are also starting to feel better.**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **No changes**

Additional comments on the overall effects of this product on your health and wellbeing: **I know this product has helped me a great deal. I want to continue taking this product. How do I purchase more?**

Client # 9
Visit # 1
Date: 8/27/10
Age: 53
Sex: F
Weight: 118
Height: 5'6"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Lupus

Data: BTA

	pH	rH2	r
Blood	7.55	28.8	147
Saliva	7.16	27.5	172
Urine	6.87	25.5	111

Data: BCA
Resistance: 683.3
Reactance: 17.1
Phase Angle: 5.9

Data: Indole Analysis
Indole was present at a: 4

Data: Orthostatic Hypotension
Supine: 146/78
Standing: 131/82

Data: Urine Dipstick analysis
Specific Gravity: 1.040
pH: 6.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 3.1
Sympathetic Regulation: 7.6
Tension Index: 10.1

Data: DDFAO
ONOOH (Peroxynitrous Acid): 80
NO (nitrogen oxide): 80
H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical): 60
OH- (Hydroxyl radical): 80

Data: Questionnaire

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..**4**…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..**2**…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 9
Visit # 2
Date: 9/23/10
Age: 53
Sex: F
Weight: 118
Height: 5'6"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Lupus

Data: BTA

	pH	rH2	r
Blood	7.48	26.2	132
Saliva	7.02	27.8	191
Urine	6.93	22.1	134

Data: BCA
Resistance: 663.0
Reactance: 72.7
Phase Angle: 6.3

Data: Indole Analysis
Indole was present at a: 4

Data: Orthostatic Hypotension
Supine: 151/80
Standing: 143/89

Data: Urine Dipstick analysis
Specific Gravity: 1.040
pH: 7.0
Leukocytes: pos
Nitrate: pos
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 3.6
Sympathetic Regulation: 6.5
Tension Index: 12.1

Data: DDFAO
ONOOH (Peroxynitrous Acid): 80
NO (nitrogen oxide): 80
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical): 40
OH- (Hydroxyl radical): 80

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..**4**…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..**2**…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **Have not noticed anything different**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 9
Visit # 3
Date: 10/26/10
Age: 53
Sex: F
Weight: 118
Height: 5'6"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Lupus

Data: BTA

	pH	rH2	r
Blood	7.51	26.6	167
Saliva	7.34	24.1	232
Urine	6.67	20.2	146

Data: BCA
Resistance: 646.7
Reactance: 64.1
Phase Angle: 5.7

Data: Indole Analysis
Indole was present at a: 4

Data: Orthostatic Hypotension
Supine: 139/76
Standing: 127/82

Data: Urine Dipstick analysis
Specific Gravity: 1.040
pH: 7.0

Leukocytes: pos
Nitrate: pos
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 1.1
Sympathetic Regulation: 6.3
Tension Index: 12.2

Data: DDFAO
ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 20
H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical): 60
OH- (Hydroxyl radical): 40

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..**4**…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..**2**…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **Have not felt any changes**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 9
Visit # 4
Date: 11/21/10
Age: 53
Sex: F
Weight: 118
Height: 5'6"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Lupus

Data: BTA

	pH	rH2	r
Blood	7.39	25.5	139
Saliva	6.99	26.3	184
Urine	6.56	20.9	141

Data: BCA
Resistance: 674.6
Reactance: 73.2
Phase Angle: 5.8

Data: Indole Analysis
Indole was present at a: 4

Data: Orthostatic Hypotension
Supine: 151/88
Standing: 147/92

Data: Urine Dipstick analysis
Specific Gravity: 1.040
pH: 7.0
Leukocytes: pos
Nitrate: pos
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 2.1
Sympathetic Regulation: 6.6
Tension Index: 14.7

Data: DDFAO
ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 10
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical): 0
OH- (Hydroxyl radical): 10

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..**2**…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: 0…..1…..**2**…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **Just starting to notice a little less pain and a little more movement in my joints**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Additional comments on the overall effects of this product on your health and wellbeing: **I believe this product is now working for me. It has taken a while and I have swallowed a lot of pills. I would like to continue taking this product**

Client # 10
Visit # 1
Date: 8/25/10
Age: 59
Sex: M

Weight: 235
Height: 6'6"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Lung Cancer

Data: BTA

	pH	rH2	r
Blood	7.51	29.9	139
Saliva	6.72	29.7	156
Urine	5.38	23.5	48

Data: BCA
Resistance: 477.6
Reactance: 58.4
Phase Angle: 7.0

Data: Indole Analysis
Indole was present at a: 5

Data: Orthostatic Hypotension
Supine: 113/71
Standing: 119/81

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 6.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: pos
Blood: EN

Data: HRV
Vagal Regulation: 4.2
Sympathetic Regulation: 3.5
Tension Index: 6.1

Data: DDFAO
ONOOH (Peroxynitrous Acid): 60
NO (nitrogen oxide): 40
H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical): 40
OH- (Hydroxyl radical):40

Data: Questionnaire
If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: **0**…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client #10
Visit # 2
Date: 9/23/10
Age: 59
Sex: M
Weight: 235
Height: 6'6"
Type of nutritional supplement consumed: FCA Soft Gel
Total amount of product consumed daily: 15 capsules
Primary Dx: Lung Cancer

Data: BTA

	pH	rH2	r
Blood	7.44	28.4	136
Saliva	6.68	30.4	164
Urine	5.32	22.9	45

Data: BCA
Resistance: 474.6
Reactance: 55.3
Phase Angle: 6.6

Data: Indole Analysis
Indole was present at a: 5

Data: Orthostatic Hypotension
Supine: 121/83
Standing: 115/78

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 5.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: pos
Blood: EN

Data: HRV
Vagal Regulation: 3.2
Sympathetic Regulation: 4.1
Tension Index: 5.5

Data: DDFAO
ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 40
H2O2 (Hydrogen Pyroxide): 20
O2- (Oxygen free radical): 40
OH- (Hydroxyl radical): 40

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: **0**…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10

(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **No changes**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 10
Visit # 3
Date: 10/21/10
Age: 59
Sex: M
Weight: 235
Height: 6'6"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Lung Cancer

Data: BTA

	pH	rH2	r
Blood	7.42	27.4	142
Saliva	6.55	25.5	154
Urine	5.45	21.9	47

Data: BCA
Resistance: 473.2
Reactance: 56.6
Phase Angle: 6.8

Data: Indole Analysis
Indole was present at a: 5

Data: Orthostatic Hypotension
Supine: 128/86
Standing: 117/74

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 5.0
Leukocytes: EN
Nitrate: EN

Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: pos
Bilirubin: EN
Blood: EN

Data: HRV
Vagal Regulation: 4.1
Sympathetic Regulation: 3.3
Tension Index: 2.1

Data: DDFAO
ONOOH (Peroxynitrous Acid): 20
NO (nitrogen oxide): 20
H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical): 20
OH- (Hydroxyl radical): 20

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: **0**…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **No changes**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Client # 10
Visit # 4
Date: 11/25/10
Age: 59

Sex: M
Weight: 235
Height: 6'6"
Type of nutritional product consumed: FCA Soft Gel
Total amount of product consumed daily: 15 Capsules
Primary Dx: Lung Cancer

Data: BTA

	pH	rH2	r
Blood	7.48	25.6	158
Saliva	6.83	23.8	162
Urine	5.52	21.5	49

Data: BCA
Resistance: 475.2
Reactance: 57.6
Phase Angle: 6.2

Data: Indole Analysis
Indole was present at a: 5

Data: Orthostatic Hypotension
Supine: 115/74
Standing: 110/65

Data: Urine Dipstick analysis
Specific Gravity: 1.020
pH: 5.0
Leukocytes: EN
Nitrate: EN
Protein: EN
Glucose: EN
Ketones: EN
Urobilinogen: EN
Bilirubin: pos
Blood: EN

Data: HRV
Vagal Regulation: 2.8
Sympathetic Regulation: 5.0
Tension Index: 1.3

Data: DDFAO
ONOOH (Peroxynitrous Acid): 0
NO (nitrogen oxide): 10
H2O2 (Hydrogen Pyroxide): 20
O2- (Oxygen free radical): 10
OH- (Hydroxyl radical): 20

Data: Questionnaire
I have been absolutely faithful in consuming the specified capsules of FCA Soft Gel: **Yes** No

If pain is associated with my primary health concern, I would now grade it:
0…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents a complete absence of pain and discomfort and 10 represents the worst pain imaginable)

If my primary health concern interferes with my daily activity, I would now grade it: **0**…..1…..2…..3…..4…..5…..6…..7…..8…..9…..10
(0 represents no interference with normal daily activity and 10 represents a complete inability to perform any activities due to the primary health concern)

During the last 30 days I have noticed these changes in my body or its' function: **Very little, but maybe more energy and more stamina**

If I was consuming prescription medications at the onset of this study, I have changed my frequency or dosage: **NA**

Additional comments on the overall effects of this product on your health and wellbeing: **I would like to continue taking the product as it seems it has helped a little bit during these last 30-days or so**

Data Analysis: Data has been isolated to values that appear to have been affected by the FCA Soft Gel product, primarily values that represent oxidative stress through elevated free radicals or redox potential.

Evaluation of data obtained from BTA testing:

Client #1, Visit #1:

	pH	rH2	r
Blood	7.49	28.2	214
Saliva	6.76	29.6	253
Urine	6.50	24.0	76

Client #1, Visit #2:

	pH	rH2	r
Blood	7.44	27.9	218
Saliva	6.69	29.2	257
Urine	6.32	22.0	71

Client #1, Visit #3:

	pH	rH2	r
Blood	7.49	25.3	233
Saliva	6.88	28.1	241
Urine	6.37	21.6	63

Client #1, Visit #4:

	pH	rH2	r
Blood	7.44	23.9	225
Saliva	6.76	24.1	189
Urine	6.10	20.5	72

Calculated changes in rH2 values for Client #1:

Blood	4.3 (decreased value, decreased ORP)
Saliva	5.5 (decreased value, decreased ORP)
Urine	3.5 (decreased value, decreased ORP)

Client #2, Visit #1:

	pH	rH2	r
Blood	7.50	27.6	169
Saliva	7.21	27.9	148
Urine	6.29	23.2	53

Client #2, Visit #2:

	pH	rH2	r
Blood	7.52	24.6	154
Saliva	7.29	28.2	156
Urine	5.86	20.7	57

Client #2, Visit #3:

	pH	rH2	r
Blood	7.56	24.8	168
Saliva	7.36	27.1	144
Urine	5.91	19.3	41

Client #2, Visit #4:

	pH	rH2	r
Blood	7.51	24.6	172
Saliva	6.96	25.8	151
Urine	5.88	19.9	48

Calculated changes in rH2 values for Client #2:

Blood	3 (decreased value, decreased ORP)
Saliva	2.1 (decreased value, decreased ORP)
Urine	3.3 (decreased value, decreased ORP)

Client #3, Visit #1:

	pH	rH2	r
Blood	7.55	27.2	138
Saliva	6.52	28.6	149
Urine	6.48	23.2	151

Client #3, Visit #2:

	pH	rH2	r
Blood	7.58	27.8	133
Saliva	6.61	26.6	147
Urine	6.32	24.3	132

Client #3, Visit #3:

	pH	rH2	r
Blood	7.52	26.9	141
Saliva	6.79	26.2	155
Urine	7.11	24.1	97

Client #3, Visit #4:

	pH	rH2	r
Blood	7.58	25.8	148
Saliva	6.32	25.9	162
Urine	6.91	23.6	92

Calculated changes in rH2 values for Client #3:

Blood	1.4 (decreased value, decreased ORP)
Saliva	2.7 (decreased value, decreased ORP)
Urine	0.4 (increased value, increased ORP)

Client #4, Visit #1:

	pH	rH2	r
Blood	7.46	27.7	196
Saliva	6.49	29.2	185
Urine	5.12	28.5	76

Client #4, Visit #2:

	pH	rH2	r
Blood	7.32	26.2	187
Saliva	6.88	28.5	176
Urine	5.51	22.6	68

Client #4, Visit #3:

	pH	rH2	r
Blood	7.35	25.1	182
Saliva	6.77	26.3	167
Urine	5.42	20.3	65

Client #4, Visit #4:

	pH	rH2	r
Blood	7.42	24.9	189
Saliva	6.81	25.8	176
Urine	5.45	20.2	69

Calculated changes in rH2 values for Client #4:

Blood	2.8 (decreased value, decreased ORP)
Saliva	3.4 (decreased value, decreased ORP)
Urine	8.3 (decreased value, decreased ORP)

Client #5, Visit #1:

	pH	rH2	r
Blood	7.55	28.2	186
Saliva	7.17	27.6	183
Urine	5.57	20.3	58

Client #5, Visit #2:

	pH	rH2	r
Blood	7.58	27.9	192
Saliva	7.02	26.4	206
Urine	5.36	20.8	73

Client #5, Visit #3:

	pH	rH2	r
Blood	7.42	28.2	207
Saliva	7.23	26.4	132
Urine	5.81	19.3	110

Client #5, Visit #4:

	pH	rH2	r
Blood	7.39	27.0	212
Saliva	7.42	25.9	167
Urine	5.97	19.1	83

Calculated changes in rH2 values for Client #5:

Blood	1.2 (decreased value, decreased ORP)
Saliva	1.7 (decreased value, decreased ORP)
Urine	1.2 (decreased value, decreased ORP)

Client #6, Visit #1:

	pH	rH2	r
Blood	7.52	28.3	157
Saliva	7.48	29.6	192
Urine	5.74	21.0	71

Client #6, Visit #2:

	pH	rH2	r
Blood	7.58	30.1	138
Saliva	7.40	30.3	212
Urine	5.62	24.2	63

Client #6, Visit #3:

	pH	rH2	r
Blood	7.41	27.3	171
Saliva	7.22	26.1	262
Urine	5.36	20.5	79

Client #6, Visit #4:

	pH	rH2	r
Blood	7.48	26.7	183
Saliva	7.18	24.8	189
Urine	5.85	19.3	63

Calculated changes in rH2 values for Client #6:

Blood	1.6 (decreased value, decreased ORP)
Saliva	4.8 (decreased value, decreased ORP)
Urine	1.7 (decreased value, decreased ORP)

Client #7, Visit #1:

	pH	rH2	r
Blood	7.52	27.2	148
Saliva	6.74	24.8	173
Urine	5.25	19.0	71

Client #7, Visit #2:

	pH	rH2	r
Blood	7.50	26.8	141
Saliva	7.21	25.7	165
Urine	5.88	19.2	68

Client #7, Visit #3:

	pH	rH2	r
Blood	7.48	26.4	135
Saliva	7.31	25.1	151
Urine	5.45	18.9	86

Client #7, Visit #4:

	pH	rH2	r
Blood	7.41	25.9	142
Saliva	7.27	24.7	149
Urine	5.88	19.1	73

Calculated changes in rH2 values for Client #7:

Blood	1.3 (decreased value, decreased ORP)
Saliva	0.1 (decreased value, decreased ORP)
Urine	0.1 (increased value, increased ORP)

Client #8, Visit #1:

	pH	rH2	r
Blood	7.55	28.4	163
Saliva	7.34	28.7	203
Urine	6.29	23.2	86

Client #8, Visit #2:

	pH	rH2	r
Blood	7.46	28.1	141
Saliva	7.41	27.9	182
Urine	6.88	22.6	91

Client #8, Visit #3:

	pH	rH2	r
Blood	7.44	26.6	146
Saliva	7.36	26.4	212
Urine	5.85	20.1	63

Client #8, Visit #4:

	pH	rH2	r
Blood	7.38	24.8	166
Saliva	7.09	25.7	203
Urine	5.36	19.3	27

Calculated changes in rH2 values for Client #8:

Blood	3.6 (decreased value, decreased ORP)
Saliva	3.0 (decreased value, decreased ORP)
Urine	3.9 (decreased value, decreased ORP)

Client #9, Visit #1:

	pH	rH2	r
Blood	7.55	28.8	147
Saliva	7.16	27.5	172
Urine	6.87	25.5	111

Client #9, Visit #2:

	pH	rH2	r
Blood	7.48	26.2	132
Saliva	7.02	27.8	191
Urine	6.93	22.1	134

Client #9, Visit #3:

	pH	rH2	r
Blood	7.51	26.6	167
Saliva	7.34	24.1	232
Urine	6.67	20.2	146

Client #9, Visit #4:

	pH	rH2	r
Blood	7.39	25.5	139
Saliva	6.99	26.3	184
Urine	6.56	20.9	141

Calculated changes in rH2 values for Client #9:

Blood	3.3 (decreased value, decreased ORP)
Saliva	1.0 (decreased value, decreased ORP)
Urine	4.6 (decreased value, decreased ORP)

Client #10, Visit #1:

	pH	rH2	r
Blood	7.51	29.9	139
Saliva	6.72	29.7	156
Urine	5.38	23.5	48

Client #10, Visit #2:

	pH	rH2	r
Blood	7.44	28.4	136
Saliva	6.68	30.4	164
Urine	5.32	22.9	45

Client #10, Visit #3:

	pH	rH2	r
Blood	7.42	27.4	142
Saliva	6.55	25.5	154
Urine	5.45	21.9	47

Client #10, Visit #4:

	pH	rH2	r
Blood	7.48	25.6	158
Saliva	6.83	23.8	162
Urine	5.52	21.5	49

Calculated changes in rH2 values for Client #10:

Blood	4.3 (decreased value, decreased ORP)
Saliva	5.9 (decreased value, decreased ORP)
Urine	1.9 (decreased value, decreased ORP)

Mean calculated values for variances in rH2 for all 10 clients:

Blood	2.68 (decreased value, decreased ORP)
Saliva	3.02 (decreased value, decreased ORP)
Urine	1.9 (decreased value, decreased ORP)

Evaluation of data obtained from DDFAO testing:

Client #1, Visit #1:

ONOOH (Peroxynitrous Acid): 80
NO (nitrogen oxide): 60
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):80
OH- (Hydroxyl radical): 80

Client #1, Visit #2:

ONOOH (Peroxynitrous Acid): 60
NO (nitrogen oxide): 60
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):40
OH- (Hydroxyl radical): 60

Client #1, Visit #3:

ONOOH (Peroxynitrous Acid): 20
NO (nitrogen oxide): 80
H2O2 (Hydrogen Pyroxide): 0

O2- (Oxygen free radical):10
OH- (Hydroxyl radical): 20

Client #1, Visit #4:

ONOOH (Peroxynitrous Acid): 10
NO (nitrogen oxide): 40
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):0
OH- (Hydroxyl radical): 20

Calculated changes in DDFAO values for Client #1:

ONOOH (Peroxynitrous Acid): 70 (decreased presence)
NO (nitrogen oxide): 20 (decreased presence)
H2O2 (Hydrogen Pyroxide): 0 (no net change)
O2- (Oxygen free radical):80 (decreased presence)
OH- (Hydroxyl radical): 60 (decreased presence)

Client #2, Visit #1:

ONOOH (Peroxynitrous Acid): 60
NO (nitrogen oxide): 80
H2O2 (Hydrogen Pyroxide): 80
O2- (Oxygen free radical):60
OH- (Hydroxyl radical): 80

Client #2, Visit #2:

ONOOH (Peroxynitrous Acid): 10
NO (nitrogen oxide): 0
H2O2 (Hydrogen Pyroxide): 20
O2- (Oxygen free radical):20
OH- (Hydroxyl radical): 20

Client #2, Visit #3:

ONOOH (Peroxynitrous Acid):0
NO (nitrogen oxide):0
H2O2 (Hydrogen Pyroxide):0
O2- (Oxygen free radical):0
OH- (Hydroxyl radical): 0

Client #2, Visit #4:

ONOOH (Peroxynitrous Acid):0
NO (nitrogen oxide):10
H2O2 (Hydrogen Pyroxide):0
O2- (Oxygen free radical):0
OH- (Hydroxyl radical): 10

Calculated changes in DDFAO values for Client #2:

ONOOH (Peroxynitrous Acid): 60 (decreased presence)
NO (nitrogen oxide): 70 (decreased presence)
H2O2 (Hydrogen Pyroxide): 80 (decreased presence)
O2- (Oxygen free radical):60 (decreased presence)
OH- (Hydroxyl radical): 70 (decreased presence)

Client #3, Visit #1:

ONOOH (Peroxynitrous Acid):80
NO (nitrogen oxide): 80
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):80
OH- (Hydroxyl radical): 80

Client #3, Visit #2:

ONOOH (Peroxynitrous Acid):80
NO (nitrogen oxide): 80
H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical):60
OH- (Hydroxyl radical):80

Client #3, Visit #3:

ONOOH (Peroxynitrous Acid):60
NO (nitrogen oxide): 60
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):60
OH- (Hydroxyl radical): 60

Client #3, Visit #4:

ONOOH (Peroxynitrous Acid):40
NO (nitrogen oxide): 60
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):20
OH- (Hydroxyl radical): 60

Calculated changes in DDFAO values for Client #3:

ONOOH (Peroxynitrous Acid): 40 (decreased presence)
NO (nitrogen oxide): 20 (decreased presence)
H2O2 (Hydrogen Pyroxide): 0 (no net change)
O2- (Oxygen free radical):60 (decreased presence)
OH- (Hydroxyl radical): 20 (decreased presence)

Client #4, Visit #1:

ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 40
H2O2 (Hydrogen Pyroxide): 60
O2- (Oxygen free radical): 40
OH- (Hydroxyl radical): 40

Client #4, Visit #2:

ONOOH (Peroxynitrous Acid): 60
NO (nitrogen oxide):40
H2O2 (Hydrogen Pyroxide):40
O2- (Oxygen free radical):20
OH- (Hydroxyl radical): 40

Client #4, Visit #3:

ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide):20
H2O2 (Hydrogen Pyroxide):40
O2- (Oxygen free radical):10
OH- (Hydroxyl radical): 20

Client #4, Visit #4:

ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide):10

H2O2 (Hydrogen Pyroxide):20
O2- (Oxygen free radical):10
OH- (Hydroxyl radical): 10

Calculated changes in DDFAO values for Client #4:

ONOOH (Peroxynitrous Acid): 0 (no net change)
NO (nitrogen oxide): 30 (decreased presence)
H2O2 (Hydrogen Pyroxide): 40 (decreased presence)
O2- (Oxygen free radical):30 (decreased presence)
OH- (Hydroxyl radical): 30 (decreased presence)

Client #5, Visit #1:

ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 80
H2O2 (Hydrogen Pyroxide): 80
O2- (Oxygen free radical): 80
OH- (Hydroxyl radical): 60

Client #5, Visit #2:

ONOOH (Peroxynitrous Acid): 60
NO (nitrogen oxide): 60
H2O2 (Hydrogen Pyroxide): 80
O2- (Oxygen free radical): 20
OH- (Hydroxyl radical): 60

Client #5, Visit #3:

ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 60
H2O2 (Hydrogen Pyroxide): 20
O2- (Oxygen free radical): 10
OH- (Hydroxyl radical): 40

Client #5, Visit #4:

ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 20
H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical): 10
OH- (Hydroxyl radical): 20

Calculated changes in DDFAO values for Client #5:

ONOOH (Peroxynitrous Acid): 0 (no net change)
NO (nitrogen oxide): 60 (decreased presence)
H2O2 (Hydrogen Pyroxide): 70 (decreased presence)
O2- (Oxygen free radical):70 (decreased presence)
OH- (Hydroxyl radical): 40 (decreased presence)

Client #6, Visit #1:

ONOOH (Peroxynitrous Acid):20
NO (nitrogen oxide): 20
H2O2 (Hydrogen Pyroxide): 80
O2- (Oxygen free radical): 60
OH- (Hydroxyl radical): 20

Client #6, Visit #2:

ONOOH (Peroxynitrous Acid):40
NO (nitrogen oxide): 20
H2O2 (Hydrogen Pyroxide): 80
O2- (Oxygen free radical): 60
OH- (Hydroxyl radical): 40

Client #6, Visit #3:

ONOOH (Peroxynitrous Acid):20
NO (nitrogen oxide): 10
H2O2 (Hydrogen Pyroxide): 60
O2- (Oxygen free radical): 60
OH- (Hydroxyl radical): 40

Client #6, Visit #4:

ONOOH (Peroxynitrous Acid):10
NO (nitrogen oxide): 10
H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical): 20
OH- (Hydroxyl radical): 20

Calculated changes in DDFAO values for Client #6:

ONOOH (Peroxynitrous Acid): 10 (decreased presence))

NO (nitrogen oxide): 10 (decreased presence)
H2O2 (Hydrogen Pyroxide): 70 (decreased presence)
O2- (Oxygen free radical):40 (decreased presence)
OH- (Hydroxyl radical): 0 (no net change)

Client #7, Visit #1:

ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 40
H2O2 (Hydrogen Pyroxide): 40
O2- (Oxygen free radical): 40
OH- (Hydroxyl radical): 40

Client #7, Visit #2:

ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 40
H2O2 (Hydrogen Pyroxide): 40
O2- (Oxygen free radical): 40
OH- (Hydroxyl radical): 40

Client #7, Visit #3:

ONOOH (Peroxynitrous Acid): 20
NO (nitrogen oxide): 40
H2O2 (Hydrogen Pyroxide): 40
O2- (Oxygen free radical): 10
OH- (Hydroxyl radical): 40

Client #7, Visit #4:

ONOOH (Peroxynitrous Acid): 10
NO (nitrogen oxide): 20
H2O2 (Hydrogen Pyroxide): 40
O2- (Oxygen free radical): 0
OH- (Hydroxyl radical): 20

Calculated changes in DDFAO values for Client #7:

ONOOH (Peroxynitrous Acid): 30 (decreased presence))
NO (nitrogen oxide): 20 (decreased presence)
H2O2 (Hydrogen Pyroxide): 0 (no net change)
O2- (Oxygen free radical):40 (decreased presence)
OH- (Hydroxyl radical): 20 (decreased presence)

Client #8, Visit #1:

ONOOH (Peroxynitrous Acid):80
NO (nitrogen oxide):80
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical): 80
OH- (Hydroxyl radical): 60

Client #8, Visit #2:

ONOOH (Peroxynitrous Acid): 80
NO (nitrogen oxide): 60
H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical):40
OH- (Hydroxyl radical): 60

Client #8, Visit #3:

ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 20
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):20
OH- (Hydroxyl radical): 20

Client #8, Visit #4:

ONOOH (Peroxynitrous Acid): 20
NO (nitrogen oxide): 0
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical):10
OH- (Hydroxyl radical): 10

Calculated changes in DDFAO values for Client #8:

ONOOH (Peroxynitrous Acid): 60 (decreased presence))
NO (nitrogen oxide): 80 (decreased presence)
H2O2 (Hydrogen Pyroxide): 0 (no net change)
O2- (Oxygen free radical):70 (decreased presence)
OH- (Hydroxyl radical): 50 (decreased presence)

Client #9, Visit #1:

ONOOH (Peroxynitrous Acid): 80
NO (nitrogen oxide): 80

H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical): 60
OH- (Hydroxyl radical): 80

Client #9, Visit #2:

ONOOH (Peroxynitrous Acid): 80
NO (nitrogen oxide): 80
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical): 40
OH- (Hydroxyl radical): 80

Client #9, Visit #3:

ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 20
H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical): 60
OH- (Hydroxyl radical): 40

Client #9, Visit #4:

ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 10
H2O2 (Hydrogen Pyroxide): 0
O2- (Oxygen free radical): 0
OH- (Hydroxyl radical): 10

Calculated changes in DDFAO values for Client #9:

ONOOH (Peroxynitrous Acid): 40 (decreased presence))
NO (nitrogen oxide): 70 (decreased presence)
H2O2 (Hydrogen Pyroxide): 10 (decreased presence)
O2- (Oxygen free radical):60 (decreased presence)
OH- (Hydroxyl radical): 70 (decreased presence)

Client #10, Visit #1:

ONOOH (Peroxynitrous Acid): 60
NO (nitrogen oxide): 40
H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical): 40
OH- (Hydroxyl radical):40

Client #10, Visit #2:

ONOOH (Peroxynitrous Acid): 40
NO (nitrogen oxide): 40
H2O2 (Hydrogen Pyroxide): 20
O2- (Oxygen free radical): 40
OH- (Hydroxyl radical): 40

Client #10, Visit #3:

ONOOH (Peroxynitrous Acid): 20
NO (nitrogen oxide): 20
H2O2 (Hydrogen Pyroxide): 10
O2- (Oxygen free radical): 20
OH- (Hydroxyl radical): 20

Client #10, Visit #4:

ONOOH (Peroxynitrous Acid): 0
NO (nitrogen oxide): 10
H2O2 (Hydrogen Pyroxide): 20
O2- (Oxygen free radical): 10
OH- (Hydroxyl radical): 20
Calculated changes in DDFAO values for Client #10:

ONOOH (Peroxynitrous Acid): 60 (decreased presence))
NO (nitrogen oxide): 30 (decreased presence)
H2O2 (Hydrogen Pyroxide): 10 (Increased presence)
O2- (Oxygen free radical):30 (decreased presence)
OH- (Hydroxyl radical): 20 (decreased presence)

Mean calculated values for variances in free radical concentration for all 10 clients:

ONOOH (Peroxynitrous Acid): 37 (decreased presence))
NO (nitrogen oxide): 41 (decreased presence)
H2O2 (Hydrogen Pyroxide): 26 (decreased presence)
O2- (Oxygen free radical):54 (decreased presence)
OH- (Hydroxyl radical): 38 (decreased presence)

Data Analysis Discusssion:

The testing of all (10) clients clearly demonstrated that the oxidative stress as detected through ORP calculated with representation of normal physiological pH values determined by rH2 dropped after administration of the Softgel FCA product:

Blood	2.68 (decreased value, decreased ORP)
Saliva	3.02 (decreased value, decreased ORP)
Urine	1.9 (decreased value, decreased ORP)

Of similar readings the relative concentration of specific free radical components found in the body all decreased significantly:

ONOOH (Peroxynitrous Acid): 37 (decreased presence))
NO (nitrogen oxide): 41 (decreased presence)
H2O2 (Hydrogen Pyroxide): 26 (decreased presence)
O2- (Oxygen free radical):54 (decreased presence)
OH- (Hydroxyl radical): 38 (decreased presence)

Conclusion: Based on the premise stated at the onset of this document, (The purpose of this clinical pilot study is to evaluate the efficacy, palatability and consumer acceptance of a new "Soft Gel" nutritional product. If the study reveals substantial scientific evidence, this evidence can be utilized as proof to many of the thoughts, claims and remarks regarding this "Soft Gel" nutritional product. Additionally, the intent of this study is to observe and record the level of tolerance and/or associated difficulties in the consumption of this product. Finally, the findings from this study may be utilized to enhance consideration of additional applications and pertinent secondary applications and studies.) The study has clearly demonstrated that the product was first and foremost well-tolerated. In fact all ten out of ten participants found it to be easy to swallow and even though the dosage they consumed were very high, the product never created any secondary issues including stomach upset, nausea, vomiting, headaches or mood alterations. Therefore, it is completely reasonable to state that the product was extremely well-tolerated. Additionally, all (10) test subjects liked the product enough to question their ability to purchase the product from their own pocket. Each one stated in their own words on the final subjective questionnaire that they would like to continue using this product. This statement alone says volumes about the potential marketing and sales of this product in the future.

Of even greater significance were the compelling numbers that demonstrated from two different technologies that this product functions as a potent anti-oxidant. Both the DDFAO and the BTA clearly and decisively demonstrated that the administration of this natural nutritional supplement created significant changes in the ORP or free radical concentrations. Anti-oxidant therapy has been proven to be so very effective in lowering protein cross-linkage, alterations in telomere lengths and contributing to degeneration and premature aging. If this product can work well in lowering these stressors, the practical applications are unlimited.

Of course further research should be considered comparing the effectiveness of this product against known anti-oxidants like Vitamin C, Vitamin E, reduced glutathione and N-acetyl-cycteine. However, this short study with a limited clientele has clearly demonstrated that this product has an amazing capacity to lower oxidative stress and therefore have a significant role to play in nutritional support therapy and perhaps beyond.

Certainly a study entailing a cross-section of ten participants is undoubtedly limited in its comprehensive scope and breadth. However, considering the magnitude of significant changes experienced with the participants both from a subjective as well as an objective perspective, Softgel FCA has amazing potential as an excellent source of anti-oxidant, a limiter of

oxidative stress and perhaps even as a source to lower the pain experienced from many severe degenerative diseases, as this seems to have been one additional positive reaction from the consumption of this product.

In conclusion this product has met and even exceeded expectations for anti-oxidant capacity and for overall noticeable improvement in individuals suffering from severe degenerative diseases.