The easy way to help in Quality System Requirements in Medicine The New Challenge

EIS SYSTEM

MONITORING

BIOFEEDBACK
Manufacturer and Developer Information

L.D TECHNOLOGY
USA
ISO 13485
SOFTMED TECHNOLOGY
EUROPE DISTRIBUTION

Training support
training.ldteck@gmail.com

Technical support
Support.ldteck@gmail.com
Intended Use and indications of the EIS SYSTEM.

MONITORING DEVICE

Early monitoring and visualization of treatment or lifestyle change

Adjunct to conventional diagnosis of ADHD children

Lifestyle: nutrition and sport
Indicators of the EIS SYSTEM

For each organ measured:
Estimation of Physiological tissue and microcirculation parameters:
Intra and interstitial pH, tissue oxygenation delivery and capillary & interstitial pressure

In general:
Interstitial Acid base balance
Interstitial hormonal balance
Interstitial ionograms

Applicable age > 5 years old
• The interpretation of the EIS System requires medical knowledge in the areas of physiology and physiopathology, adequate references, the subject’s clinical context, and a list of variables which can modify the results. The results interpretation is the responsibility of the health care professional.

• The EIS System does not replace or endorse any existing medical examination.

• This device is not intended to be used for diagnosis.
The EIS device delivers far less electrical energy than many other common biomedical devices.

Specifically, 84.5 milliJoules (mJ; or 0.0845 J) of electrical energy pass into the body, distributed across different anatomical regions, in the 110 seconds of active scanning during an EIS examination.

Expressed as electrical power (electrical power is defined as Watts [W]) -- One Watt = 1 Joule/s) -- the EIS device operates at 0.00077 W.

To put this figure in perspective, compare the 0.00077 W to a standard incandescent light bulb using 60 W of electrical power. The light bulb draws nearly seventy eight thousand (78,000) times more energy than the EIS device.
Contraindications

Contraindications are situations making it impossible to take an accurate EIS measurement/scan, and/or to make a correct interpretation of the data gathered.

- Dermatological lesions in contact with the electrodes or excessive perspiration
- Presence of defibrillators, cardiac pacemakers, patients connected to electronic life support devices, or any implanted electronic device
- People unable to be scanned while seated or standing
- Metal pins or prostheses at the level of the extremities or the joints
- Pregnant women ([6 months-plus] the effects on the fetus, as well as accuracy of readings are unknown)
- Absence of one or more limbs
BACKGROUND OF THE DEVICE
The EIS System
Uses the technique of bioelectrical impedance

Bioelectrical Impedance Measurements (BIM)
A non-invasive technology where a diminutive electrical current is applied to the body via a surface electrode, and the electricity that passes through the body is detected at other surface electrodes placed elsewhere on the body.

A drop in voltage occurs as the current encounters A.C. impedance (D.C. resistance) inherent in the fluids and tissues through which it passes, as it courses through the body’s physiological compartments.\(^{(1)}(3)\)

These compartments include the bloodstream, the intracellular space, the lymphatic system, the interstitial space, and others\(^{(3)}(4)\); providing indirect data about the physical and chemical properties of the compartments.

Total body water 60%  
Extra cellular water 20%  
Interstitial fluid 16%
"The Biological Impedance Analyzer resistance readings were extremely stable. They exhibited virtually no change within the five measurements when the electrodes were kept in place. The accuracy of the measurement of resistance was checked using 250, 400, 500 and 750 ohm precision resistors. The measured resistance did not deviate from the expected values by more than ± 2%."

No other non-invasive methods for sampling interstitial fluid is currently available.

The composition of interstitial fluid, which constitutes the environment of the cells and is regulated by body homeostasis, has previously been measured by the suction blister or liquid paraffin techniques, or by implantation of a perforated capsule or wick. The results of these investigations showed the following items:

1. Interstitial fluid differs from whole blood by the absence of red blood cells, and it differs from blood plasma in that there are far fewer proteins. The absence of haemoglobin and poor level of proteins which are the main buffers of the blood system explains a more acid interstitial pH(7.33)

2. The capillary pressure is determinate by the Hydrostatic and osmotic or oncotic pressure balance between the interstitial fluid and the microcirculation.

3. The volume of the interstitial fluid is closely related to the containing sodium pool

Carbonic anhydrase

Hb

CO2

HCO3

Cl-

Na+

K+

ATP

Volume

HCO3

O2

VO2

H+ H+ H+

Hb

CO2

ATP

Hydrostatic pressure

Osmotic pressure

Viscosity

Interstitial ACIDOSIS
Effect of intercapillary distance on relation between oxygen delivery and consumption when delivery is reduced by hypoxia (a fall in Pao2), reduced flow (stagnant), and anaemia (fall in haemoglobin concentration).


Copyright © 1998, British Medical Journal
Raicu et al., 2000
Modeling and localization of the organs

Mathematical principles:
Direct methods
Inverse problems

Electro Interstitial Scan
E.I.S
• The E.I.S device allows a modeling of the human body.

• What is modeling?

• Modeling is not the same imagery conventionally used in medicine. The approach is more like that of a physicist. We reduce the diversity and complexity of the bodily functions by an appropriate choice of assumptions and measurements.

• We choose for EIS modeling the following parameter: the conductivity of interstitial fluid
Modeling
Electro Interstitial Scan
E.I.S

CHRONOAMPEROMETRY
Cottrell equation
\[ i = nFAC_c \sqrt{\frac{D}{\pi t}} \]

\[ C_c = \frac{i}{nFA \sqrt{\frac{D}{\pi t}}} \]
## Corresponding Values of human body compartments

<table>
<thead>
<tr>
<th>Biochemical constants</th>
<th>Venous blood</th>
<th>Arterial blood</th>
<th>Capillary blood</th>
<th>Intracellular fluid</th>
<th>Interstitial fluid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na+ mEq/l</td>
<td>130</td>
<td>137</td>
<td>135</td>
<td>10</td>
<td>130</td>
</tr>
<tr>
<td>K+ mEq/l</td>
<td>3.2</td>
<td>3.5</td>
<td>4</td>
<td>140</td>
<td>3.17</td>
</tr>
<tr>
<td>Ca++ mEq/l</td>
<td>2.5</td>
<td>2.2</td>
<td>2.3</td>
<td>0.0001</td>
<td>1.55</td>
</tr>
<tr>
<td>Mg mEq/l</td>
<td>0.64</td>
<td>0.62</td>
<td>0.60</td>
<td>58</td>
<td>0.50</td>
</tr>
<tr>
<td>Cl- mEq/l</td>
<td>104</td>
<td>101</td>
<td>103</td>
<td>4</td>
<td>106</td>
</tr>
<tr>
<td>HCO₂ mEq/l</td>
<td>22</td>
<td>24</td>
<td>23</td>
<td>10</td>
<td>24</td>
</tr>
<tr>
<td>P mEq/l</td>
<td>2.5</td>
<td>2.3</td>
<td>2</td>
<td>75</td>
<td>0.70</td>
</tr>
<tr>
<td>SO₄ mEq/l</td>
<td>0.8</td>
<td>0.6</td>
<td>0.5</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Glycemia mg/dl</td>
<td>1</td>
<td>1</td>
<td>1.01</td>
<td>0.20</td>
<td>0.90</td>
</tr>
<tr>
<td>Cholesterol mg/dl</td>
<td>0.65</td>
<td>0.630</td>
<td>0.676</td>
<td>0.2</td>
<td>0.188</td>
</tr>
<tr>
<td>pO₂ mmHg</td>
<td>80</td>
<td>90</td>
<td>89</td>
<td>20</td>
<td>87.2</td>
</tr>
<tr>
<td>pCO₂ mmHg</td>
<td>46</td>
<td>40</td>
<td>42</td>
<td>50</td>
<td>46</td>
</tr>
<tr>
<td>pH</td>
<td>7.35</td>
<td>7.4</td>
<td>7.38</td>
<td>7.0</td>
<td>7.33</td>
</tr>
<tr>
<td>Proteins gm/dl</td>
<td>72</td>
<td>74</td>
<td>73.7</td>
<td>68</td>
<td>20.6</td>
</tr>
</tbody>
</table>

Tissue parameters and microcirculation on the modeling

Electro Interstitial Scan
E.I.S
<table>
<thead>
<tr>
<th></th>
<th>Values</th>
<th>Norms</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>il</td>
<td>3.66</td>
<td>10.2 - 23.2</td>
<td>µA</td>
</tr>
<tr>
<td>iR</td>
<td>366.00</td>
<td>58.0 - 130.0</td>
<td>KOhm</td>
</tr>
<tr>
<td>iC</td>
<td>2.73</td>
<td>7.7 - 17.2</td>
<td></td>
</tr>
<tr>
<td>ipH</td>
<td>7.271</td>
<td>7.31 - 7.35</td>
<td></td>
</tr>
<tr>
<td>icpH</td>
<td>7.099</td>
<td>7.00 - 7.04</td>
<td></td>
</tr>
<tr>
<td>tVO2</td>
<td>44.1</td>
<td>48 - 52</td>
<td></td>
</tr>
<tr>
<td>tO2</td>
<td>70.3</td>
<td>78 - 82</td>
<td></td>
</tr>
<tr>
<td>tCO2</td>
<td>40.1</td>
<td>44 - 48</td>
<td></td>
</tr>
<tr>
<td>ATP</td>
<td>35.2</td>
<td>45 - 55</td>
<td></td>
</tr>
<tr>
<td>A.C.H Pressure</td>
<td>29.1</td>
<td>33 - 37</td>
<td>mm/Hg</td>
</tr>
<tr>
<td>blood viscosity</td>
<td>3.4</td>
<td>4 - 5</td>
<td>%</td>
</tr>
<tr>
<td>I Oncotic forces</td>
<td>3.6</td>
<td>2.8 - 3.2</td>
<td>mm/Hg</td>
</tr>
<tr>
<td>iWater content</td>
<td>13.1</td>
<td>15 - 17</td>
<td>mm/Hg</td>
</tr>
</tbody>
</table>

Chronic inflammation
Frontal lobe area of the right cortex

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Values</th>
<th>Norms</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>IL</td>
<td>43.70</td>
<td>5.32 - 6.36</td>
<td>μA</td>
</tr>
<tr>
<td>IR</td>
<td>30.20</td>
<td>246-294</td>
<td>KOhm</td>
</tr>
<tr>
<td>IC</td>
<td>33.11</td>
<td>3.4 - 4.1</td>
<td>S.m.</td>
</tr>
<tr>
<td>ipH</td>
<td>7.368</td>
<td>7.31 - 7.35</td>
<td>I.U.</td>
</tr>
<tr>
<td>icpH</td>
<td>6.982</td>
<td>7.00 - 7.04</td>
<td>I.U.</td>
</tr>
<tr>
<td>KVO2</td>
<td>53.8</td>
<td>48-52</td>
<td>%</td>
</tr>
<tr>
<td>tO2</td>
<td>78.4</td>
<td>82-86</td>
<td>mm/Hg</td>
</tr>
<tr>
<td>tCO2</td>
<td>43.8</td>
<td>38-42</td>
<td>mm/Hg</td>
</tr>
<tr>
<td>ATP</td>
<td>59.5</td>
<td>44-45</td>
<td>%</td>
</tr>
<tr>
<td>Microcirculation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>blood pressure</td>
<td>13.9</td>
<td>11-13</td>
<td>cm/Hg</td>
</tr>
<tr>
<td>blood viscosity</td>
<td>5.4</td>
<td>4-5</td>
<td>10-4Pa/s</td>
</tr>
<tr>
<td>interstitial viscosity</td>
<td>1.2</td>
<td>1.4-1.8</td>
<td>10-4Pa/s</td>
</tr>
<tr>
<td>IWater content</td>
<td>17.9</td>
<td>15-17</td>
<td>%</td>
</tr>
</tbody>
</table>

Neuronal excitability: Increased
[41] Left cardiac ventricle

Patient: BILL
Age: 54
Visit: 23.1.2007 10:58

Left cardiac ventricle

<table>
<thead>
<tr>
<th>Value</th>
<th>Units</th>
<th>Norms</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>il</td>
<td>µA</td>
<td>17.6 ± 2.1</td>
<td>46.50</td>
</tr>
<tr>
<td>iR</td>
<td>KOhm</td>
<td>65-74.4</td>
<td>28.50</td>
</tr>
<tr>
<td>IC</td>
<td>W</td>
<td>13.4 - 15.8</td>
<td>34.97</td>
</tr>
<tr>
<td>iOhm</td>
<td>µW</td>
<td>7.31-7.35</td>
<td>7.371</td>
</tr>
<tr>
<td>tiO2</td>
<td>min</td>
<td>4.0-4.2</td>
<td>54.1</td>
</tr>
<tr>
<td>tiD2</td>
<td>%</td>
<td>62-66</td>
<td>77.6</td>
</tr>
<tr>
<td>tiCO2</td>
<td>%</td>
<td>36.42</td>
<td>44.1</td>
</tr>
<tr>
<td>ATP</td>
<td>%</td>
<td>44.46</td>
<td>60.2</td>
</tr>
<tr>
<td>Microcirculation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood pressure</td>
<td>mm/Hg</td>
<td>11.13</td>
<td>14.0</td>
</tr>
<tr>
<td>Blood viscosity</td>
<td>mm/Hg</td>
<td>4.5</td>
<td>5.4</td>
</tr>
<tr>
<td>Interstitial viscosity</td>
<td>%</td>
<td>1.4-1.8</td>
<td>1.2</td>
</tr>
<tr>
<td>Water content</td>
<td>%</td>
<td>15.17</td>
<td>18.0</td>
</tr>
</tbody>
</table>

Volume Increased
Contractility Increased
Cardiac rate frequency: AR
Nutritional and micro nutritional program
Analysis

Body composition

BMI

Brain Analysis

Risk

Acid base balance
Clinical Application

Electro Interstitial Scan

E.I.S
EIS System: May be a solution for help quality system requirements in medicine
Positioning of the EIS in the Quality System Requirements

- Control
- Corrective actions
- Risk management/
  Patient' compliance
- Patient' needs
  Consultation
- Supplementary
  examinations
- Treatments
- Diagnostics
- EIS SYSTEM

ADHD
LS
Why a quality system with the EIS System

For the patient: Understanding of the treatment and goal of the treatment

For the practitioner: Early visualization of the therapies and early possibility of corrective action

Because a disease treatment requires drug, sometime surgery and always lifestyle change

Because, the major diseases cannot be treated by lifestyle change or alternative medicine.
Benefits of the quality system in medicine

For the patient: Visualization / motivation/ Trust

For the practitioner:
Organization, save time
Better understanding of the intended use and side effects of the treatments used
Corrective actions that the patient can understand
Patient’ compliance
Referrals
Income increased
How do we make a difference?
Transfer of information

DATA

DATA Processing
Quality system in medicine

Increase understanding
Higher level of expertise
Faster
Add to data acquisition ‘computer by calculation and statistical analysis
Better Results
Save time
Additional income

Visualization
Improve understanding
Compliance
Control or monitoring of the therapies
Therapeutic follow up

Electro Interstitial Scan
E.I.S
Effect of oxygenation (20 minutes).

You can see the effect on the digestive system (vasodilatation) and in the brain (neuronal excitability increased).
Effect of antibiotics therapy (treatment for Escherichia coli after 1 week)

You can see the vasodilatation of organs and reduction of infection.

Effect of antidepressant (IRSS after 45 days)

The neuronal excitability became normal.
Follow up of thyroid treatment

TSH 9 before treatment

dose 80µg
Follow up of thyroid treatment 2

dose 120µg  
dose 100µg
Hormonal assessment and follow-up over the course of one 1 year. The doses prescribed can be adjusted until satisfactory stabilization is reached.
Effect of chemotherapy (after 1 week). You can see in Davenport Diagram before the treatment (metabolic acidosis) and after the treatment (metabolic alkalosis).

Effect of hypotensor and anti-aggregate drugs (after one month).

In Davenport Diagram before the treatment (metabolic alkalosis) and after treatment (metabolic acidosis) results are obvious.
Effect of auriculopuncture on the catecholamine after 10 minutes (Right ear: Cosmonaut, O’, SPM points)
Effect of Homeopathy after 20 minutes: Nux Vomica 6X
Effect of Homeopathy after 20 minutes: Nux Vomica 6X

AFTER

BEFORE
Biofeedback Effect EIS for reduce the stress (9 minutes)
SPORT

AFTER

BEFORE
Effect of one egg by day in the diet for a strict vegetarian (result after 6 weeks)
Time necessary for follow-up and visualization of the treatment:

- Chiropractic, Auricular acupuncture, somatic acupuncture, homeopathy, frequencies: 5 minutes
- Plant therapy, micro nutrition, *trace elements, nutrition*: 6 weeks

Allopathic treatments:

- Antibiotics: 3 days
- Hypotensive therapies: 3 weeks
- Antiagregants: 3 weeks
- Anticoagulant: 24 hours
- Diuretics: 3 weeks
- Antidepressants: SSRI: 45 days
- Surgery: 24 hours
- Chemotherapy: 1 week