Inner Balance Assessment

Using Methods of the Heart Rate Variability Analysis

Practical Use Manual

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1. Introduction

For the past decades methods of the heart rate variability (HRV) analysis have become one of the most popular means of assessment of the autonomic nervous system (ANS) function because of their simple and very informative nature.

At this time there are well-defined standards and methodologies of using methods of HRV analysis, created special normative databases and criteria of assessment of various HRV parameters with regard to their comparison with normative ranges.

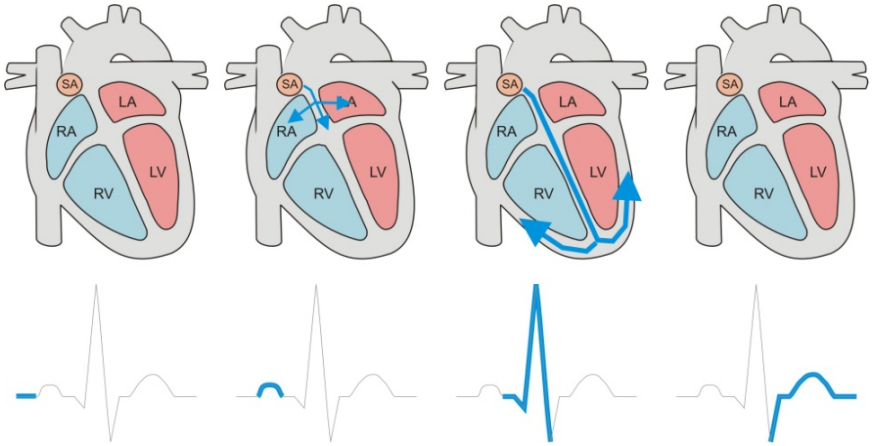
At the same time it is very important to point out that there is a tendency in specific cases to over-exaggerate diagnostic value of the assessment of results of HRV analysis when professionals attempt to use these results to make conclusions about presence or absence of certain diseases.

The above mentioned indicates that there is a need to better describe capabilities and limitations of the methods of HRV analysis.

This document is aimed to outline recommendation on how to practically use methods of HRV analysis with regard to the assessment of the autonomic nervous system function provided by Biocom Inner Balance Scan 2.0.

2. Physiological Background

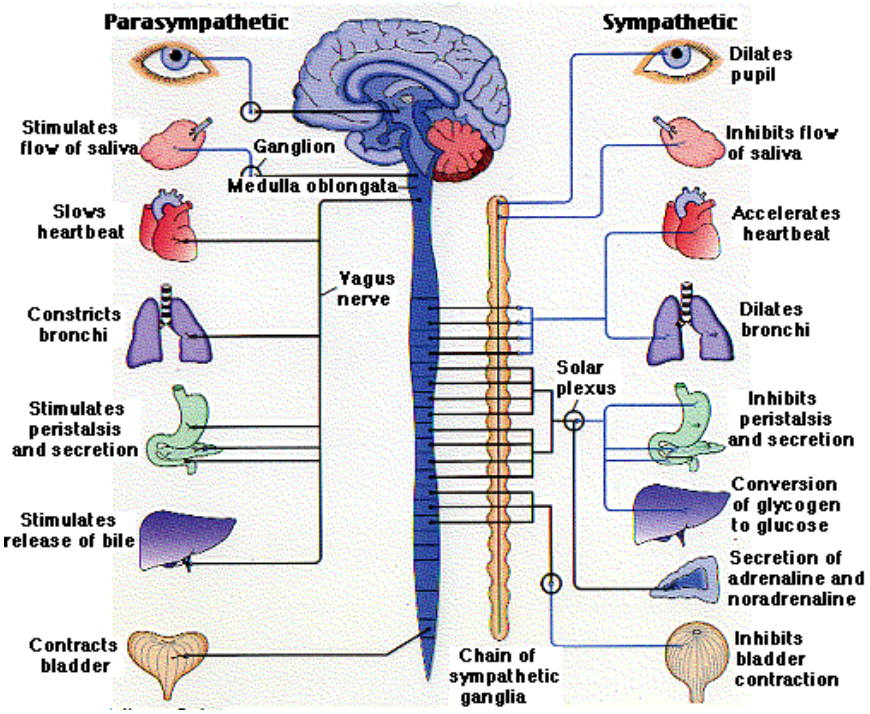
The origin of heartbeat is located in a right atrium wall of the heart, where a group of specialized cells forms so-called “sine node” that continuously generates electrical impulses spreading all over the heart muscle through specialized pathways and causing well-synchronized heart muscle contraction leading to its proper blood pumping.



The sine node generates around 100 – 120 heartbeats per minute at rest. However, healthy individuals have resting heart rate (HR) is usually much lower – around 60 – 70 beats per minute. This is due to continuous control of the autonomic nervous system (ANS) over the sine node activity.

The autonomic nervous system is a part of our nervous system responsible for non-voluntary control of our internal organs and systems like heart, lungs, intestines, glands, etc. 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.

For many organs increased stimulation of the sympathetic nervous system causes increase in their function, e.g. rising HR, increased heart stroke volume, adrenal secretion, etc. In contrast, increased stimulation of the parasympathetic nervous system inhibits their function. However for some other organs the effect of stimulation of the sympathetic and parasympathetic nervous system causes an opposed effect.



These specific effects serve our body as a very effective mechanism of survival by engaging in either stress (“fight or flight”) or relaxation (“rest and digest”) response.

Proper function of the autonomic nervous system is vital for maintaining the body in good health. Any factors affecting its function cause regulatory imbalance in the body. Repeated and prolonged negative influence of such factors may lead to persistent functional dysadaptation and development of various health conditions. This fact determines a high importance of having means to assess current body’s autonomic function and degree of its failure when it occurs.

The simplest way to assess the autonomic function is to measure heart rate and perform its special analysis as described below.

A heart response time to the sympathetic stimulation is relatively slow. Upon stimulation of the sympathetic nervous system it takes about 5 seconds to start increasing HR and almost 30 seconds to reach its peak level.

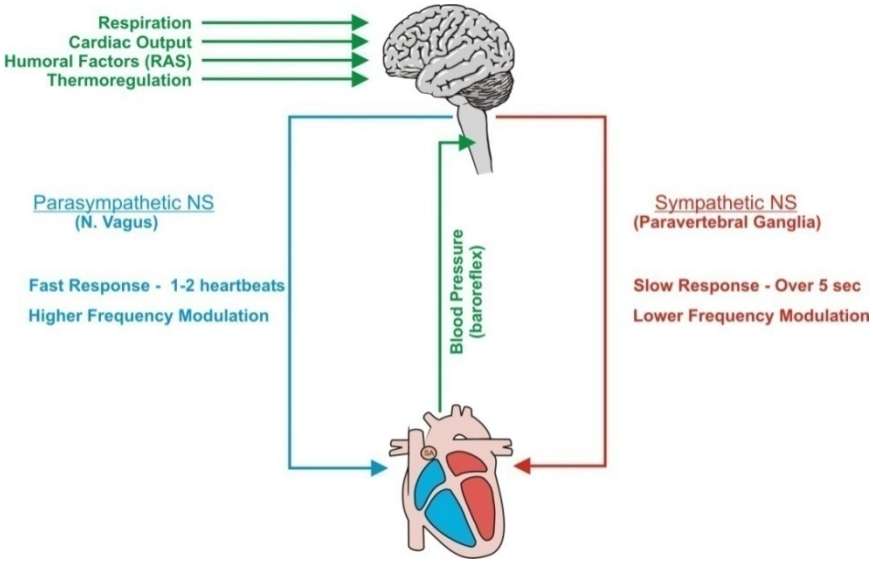
A heart response to the parasympathetic stimulation is almost instantaneous. Depending on actual phase of heart cycle, it takes just 1 or 2 heartbeats before heart slows down to its minimum level proportional to the level of stimulation.

At rest, both sympathetic and parasympathetic systems are active with moderate parasympathetic dominance. The actual balance between them is constantly changing maintaining an optimum body function.

There are various physiological factors affecting the autonomic regulation of heart rate: respiration, thermoregulation, hormonal regulation, blood pressure, cardiac output, etc. One of the most important factors is blood pressure. There are special cells in the heart and large blood vessels that sense blood pressure level and send afferent stimulation to the central structures of the ANS that control HR and blood vessel tonus forming a continuous feedback to maintain an optimal level of the blood pressure. This mechanism is also called baroreflex. It increases HR when blood pressure drops and vice versa and thus maintains a short-term stable blood supply to the vital organs.

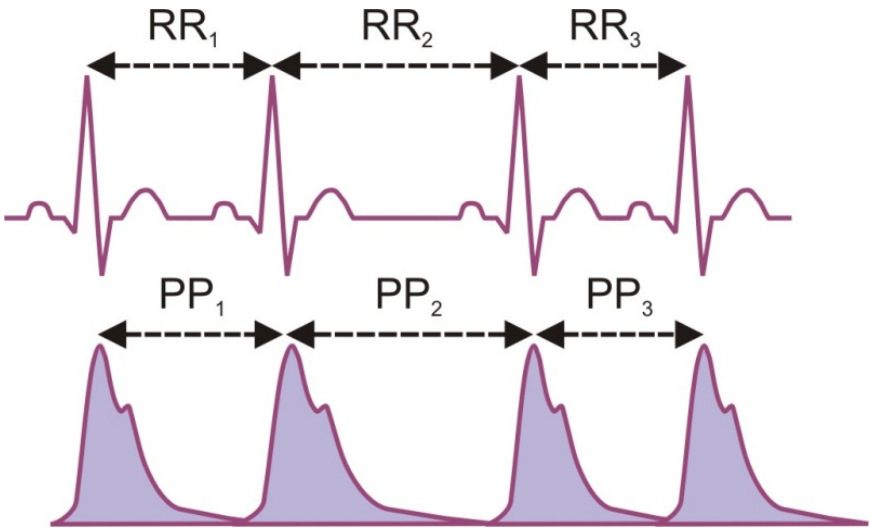
One of the best ways to assess the autonomic function is to analyze minute changes in heart rate, which are caused by many factors including regulatory influence of the autonomic nervous system.

A special method of analysis can be applied to recorded heart rate readings. It is called Heart Rate Variability (HRV) analysis. The HRV analysis is a powerful, very accurate, reliable, reproducible, yet simple to do.



3. HRV Equipment

The source information for HRV analysis is continuous beat-by-beat (not averaged) recording of heartbeat intervals. There are many ways to measure and record those intervals. However two such methods are found to be the most appropriate for this.



Electrocardiograph (ECG or EKG) is considered as the best way to measure heartbeat intervals. ECG is an electrical signal reflecting minute changes in the electrical field generated by heart muscle cells. It is measured by a special electronic device with conductive electrodes placed on chest around heart area or limbs. ECG signal has a very specific and robust waveform simple to detect and analyze. Cardiac rhythm (sequence of heartbeat intervals) derived from ECG is the best way to detect normal heartbeats as well as all sorts of ectopic heartbeats, which must be excluded from the HRV analysis.

Pulse wave is another way of measuring heartbeat intervals. It is a simple and least invasive method of measurement based on photoplethysmograph (PPG). PPG is a signal reflecting changes in a blood flow in tiny blood vessels typically spotted in fingertips or earlobes. Typical PPG sensor emits infrared light towards the skin area of an earlobe or finger. The blood passing this area through numerous tiny vessels absorbs certain portion of that light while remaining light is detected by a special photocell. The amount of absorbed light is proportional to the amount of blood passing by. Since the blood flow is not constant due to pulsations caused by heartbeats the sensor generates a very specific waveform reflecting those changes in blood flow. This waveform is usually called as a pulse wave. This waveform can be processed by a special algorithm to derive beat-by-beat heartbeat intervals.

Multiple research studies have shown that HRV parameters obtained from beat-by-beat analysis of heartbeat intervals derived from ECG and PPG signals have a very strong correlation (about 98%) and

therefore both methods of recording can be used for assessment of the autonomic nervous system function.

The Inner Balance Scan utilizes HRM-02 pulse wave sensor.

4. Assessment of the Inner Balance

4.1. Test Overview

Inner balance assessment is based on evaluation of the functional state of both sympathetic and parasympathetic branches of the autonomic nervous system.

This test is based on the short-term HRV analysis of resting heart rate recordings of 5 minutes long. Such recordings are assumed to be done at a steady-state physiological condition and should be properly standardized to produce comparable results.

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, the autonomic assessment and specifically its sympathetic and parasympathetic branches can be done based on frequency-domain analysis of HRV data. For this purpose the heartbeat intervals should be properly calculated and any abnormal heartbeats found.

4.2. Cardiac Rhythm Data Recording

A new inner balance test should be done after fasting for at least 2 hours.

The recording must be performed in comfortably sitting relaxed position limiting body movements.

If patient feels physically tired due to coming to examination room, allow him/her to have a rest for 10-15 minutes before testing.

It is important to eliminate any factors which can cause emotional arousals. There is no need to specially train patients on how to be tested. However it is important to brief patient on what the test is and what to do during the test. This will help to lower patient's alertness and anxiety and establish good communication with technical personnel performing the test.

After placing a sensor (or electrodes) and starting the software (refer to the software User's Manual) the patient should be given the following instruction:

This test will last for 5 minutes. Please remain sitting relaxed and having idle thoughts. Limit your body movements. Try not to talk without a real need. If you need to swallow, do it but not very often.

4.3. Data Quality Check

It is very important to make sure that the quality of data recording is sufficient before it is interpreted.

One of the important issues when measuring PPG is absence of any abnormal (irregular or dubious) heartbeats. Only heartbeats originated in a sine node are considered as normal (regular) heartbeats so the intervals measured between such heartbeats can be processed to obtain HRV data.

Whether there are irregular heartbeats or any signal distortions caused by movement or electrical noise which could be recognized as heartbeats, they must be excluded from analysis. There are various sophisticated statistical algorithms detecting such abnormal heartbeats filtering improper heartbeats out.

The Inner Balance Scan implements a special algorithm of data quality checking during the test. If it detects any type of rhythm disturbances occurred due to irregular heartbeats or movement artifacts, the test will be interrupted because it would have no value for further data analysis.

4.4. Test Results

Once the test is recorded the following HRV parameters are calculated by the software.

The Inner Balance Scan was designed as a **very simple tool** for assessment of the autonomic function. Therefore it uses a simplified terminology. The chart below shows relationship between terms used in the software and commonly known scientific terms reflecting HRV parameters.

A power spectrum analysis is applied to a 5-min sequence of normal heartbeat intervals. The following frequency-domain parameters are calculated:

Parameter	Unit	Description	Term Used	Physiological Meaning
TP	ms^2/Hz	**Total Power** – a power spectrum of RR intervals calculated for a frequency range from 0.0033 Hz to 0.4 Hz.	**Regulatory Effort**	Regulatory effort reflects current status of all regulatory systems, such as activity of the autonomic nervous system, hormones, etc. contributing in maintaining your body inner balance.

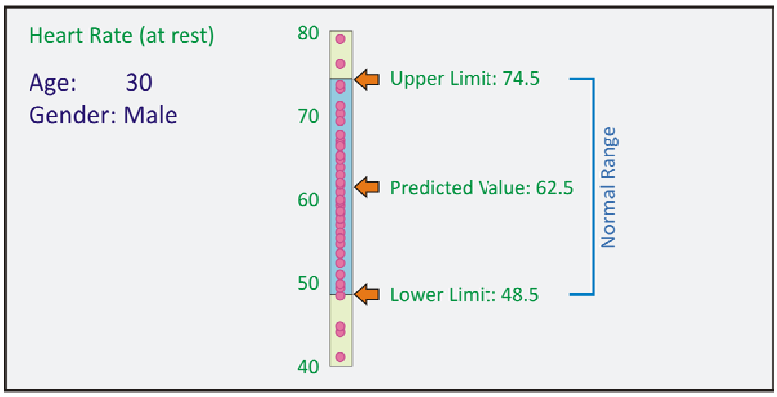
Parameter	Unit	Description	Term Used	Physiological Meaning
LF	ms^2/Hz	**Low Frequency** - a power spectrum of RR intervals calculated for a frequency range from 0.04 Hz to 0.15 Hz.	**Stimulating Activity**	Stimulating activity reflects the state of the sympathetic branch of the autonomic nervous system responsible for "fight or flight" response of the body when various internal or external factors require body to immediately activate its physical and mental performance. The analogy of its operation is car acceleration.
HF	ms^2/Hz	**High Frequency** - a power spectrum of RR intervals calculated for a frequency range from 0.04 Hz to 0.15 Hz.	**Calming Activity**	Calming activity reflects the state of the parasympathetic branch of the autonomic nervous system responsible for quieting the body to bring it back to normal condition after any physical or mental stimulation caused by internal or external factors. The analogy of its operation is braking car.

4.5. Evaluation of the Inner Balance Test Results

To make a conclusion on the test results actual readings of calculated HRV parameters are compared with their respective normal ranges specific to patient's age and gender. These normal ranges are taken from a normative database built in a special clinical study on a large pool of clinically validated healthy subjects.

Normal range is a range of values of certain HRV parameter representing statistical distribution of this parameter values in a large population of healthy individuals of selected age and gender. For instance, the logarithmic value of HF (ms^2/Hz) lies in range between 2.5 and 6.6 for males between 30 and 40 years old. Evidently comparing the actual value of evaluated parameter with its normative range gives only a ballpark assessment of its status.

The most appropriate way to assess the autonomic nervous system function is to use so-called predicted values defining normal values of specific HRV parameters, which we expect to obtain from a tested individual if we assume that this individual is healthy. Predicted value is a statistically most probable value of the parameter predicted based on correlation between this parameter values, age and gender of healthy individuals. Predicted values are calculated by the formulae created based on a special study obtained reading s from a large population of healthy subjects of different ages and gender.



The following example explains how to compare actual and predicted values of a specific HRV parameter and shows the problems which may arise when doing that.

Example. A 48 years old male was tested with an autonomic balance test. The test results showed an HF parameter value of 3.1 on logarithmic scale of ms^2/Hz. A predicted value for 48 years old males is 4.03. Evidently the HF parameter is noticeably lower than its predicted value. But what does this mean? Is this decrease significant and thus can be considered as abnormal or is it still normal? The answer to this could be given if we can find statistically significant boundaries of a certain range of values considered as a normal range for this parameter.

One of the widely used approaches is determining a normal range based on criteria of statistical distribution of measured parameter values in healthy subjects. Typically normal range is considered within 95% of the interval of confidence in both directions. This range would fit 95% of all readings obtained from healthy subjects of the selected population.

It is important to mention that there is a borderline zone (or conditional norm) in near proximity to the borders of the normal range. Actual readings falling into this zone have higher risk to be abnormal ones.

The above illustration shows how the predicted value and normal range are defined in the normative database. All test results of the healthy subjects tested in a special epidemiologic study were analyzed by separate gender and age groups. For example, all test results of all males of age 30 were put in one group. Predicted values for each HRV parameter were calculated as described above. Then all parameter values (in this example – mean heart rate) were grouped around the predicted values. 5% of the values most deviating from the predicted value are considered as outlying (outside of the normal range). The rest 95% of all values define the normal range. The Heart Rhythm Scanner considers 15% of the most

deviating values among those falling into 95% range as borderline range. Only remaining 80% of all values forms a true normal range.

For the subject described in this example a lower borderline level of HF parameter is 2.64. Thus the value shown in the example above falls into a borderline zone.

When using the Inner Balance Scan to monitor the dynamics of changes in the autonomic regulatory function or to evaluate the effects of specific factors on this function an important question is usually asked – if the changes in a measured parameter are considered significant or are result of normal variation of the random process. This question is answered based on assessment of the reproducibility and repeatability of the measured parameter.

Reproducibility is a variance of a parameter being repeatedly measured in the same subject within a limited time frame. Repeatability reflects natural variance of a specific parameter in the same subject observed during a long period of time (several weeks).

HRV parameters significantly depend on current condition of the subject at a time of testing. Thus it is virtually impossible to obtain absolutely identical readings measured at different moments. This means that the reproducibility and repeatability of the test cannot be 100%. High level of reproducibility and repeatability means only qualitative similarity of any two test results obtained from the same individual at substantially similar conditions of both subject and testing environment. When comparing test results, keep in mind that the autonomic nervous system is fairly sensitive to many internal and external factors including various genetically predetermined and transitory factors, health condition, etc.

4.6. Making an Assessment Conclusion on the Inner Balance Test

The Inner Balance Scan makes assessment of the regulatory function of the autonomic nervous system which includes the following parts:

Inner Balance	A condition of the autonomic nervous system, which attempts to achieve equilibrium between its stimulating and calming activities.
Regulatory Effort	Overall activity of the autonomic nervous system in functional regulation of the human organism.
Well-Being	A self-assessment of overall feelings obtained from the subject prior to testing.

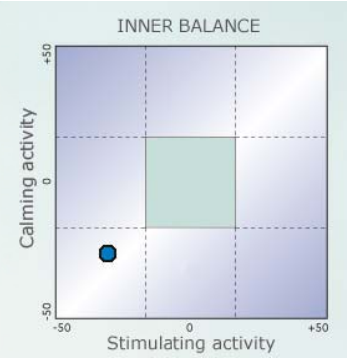
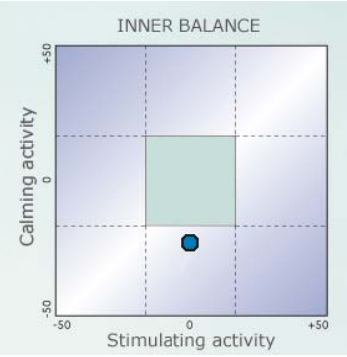
4.6.1. Inner Balance

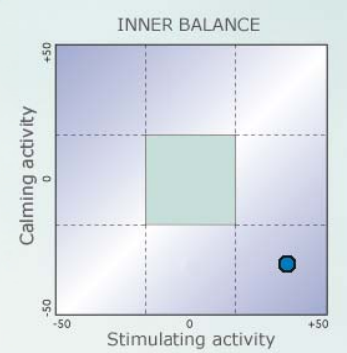
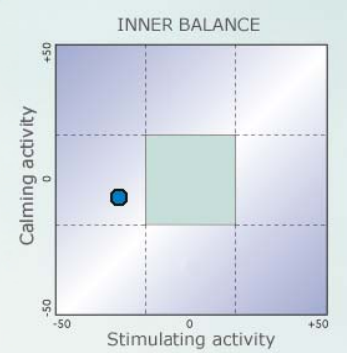
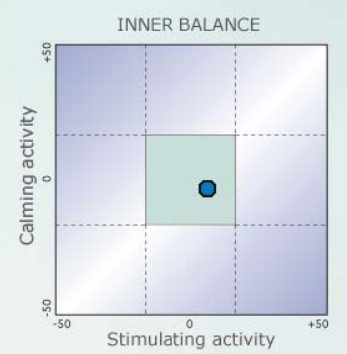
There are three main types of the inner balance conditions:

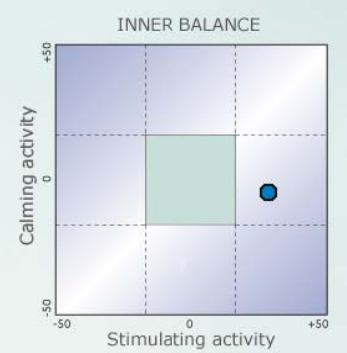
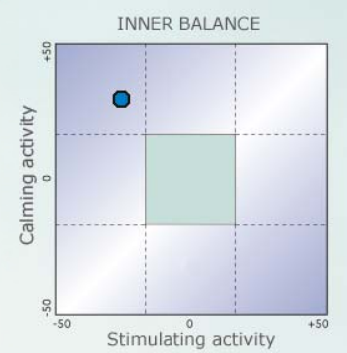
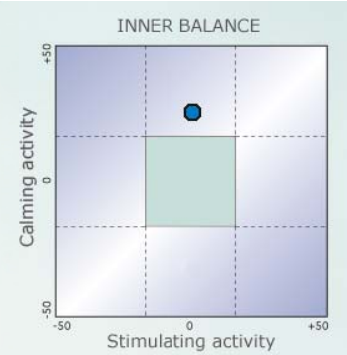
1. **Predominant state of calming activity** – typical for a state of relaxation.
2. **Predominant state of stimulating activity** – typical for a state of stress.
3. **State of inner balance** – typical for a normal balanced state.

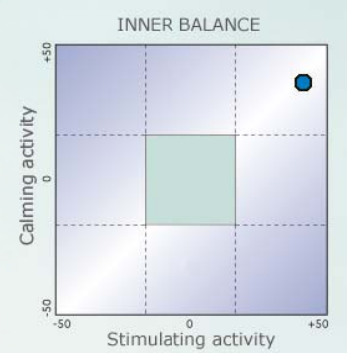
Each of these three categories may have three different levels of the autonomic tonus: **low**, **normal** or **high**.

Below is a detailed description of all 9 possible combinations of these two variables:

	Calming Activity	Stimulating Activity	Test Interpretation	
1	**Low**	**Low**		**Total autonomic dystonia**. Both stimulating and calming activity are below their normal ranges. ***This may be due to the effect of accelerated aging, significant physical or mental fatigue or possible presence of any chronic health condition that affects body's ability to maintain inner balance.***
2	**Low**	**Normal**		**Vagal dystonia.** The body's regulatory system is out of balance: calming activity is below its normal range while stimulating activity appears to be normal. ***This may be due to presence of chronic stress or health condition that substantially suppresses calming activity.***

	Calming Activity	Stimulating Activity	Test Interpretation	
3	**Low**	**High**		**Severe stress response.** The body's regulatory system is extremely out of balance: calming activity is substantially below its normal range while stimulating activity is above normal. ***This may be due to extreme and acute physical or mental stress or acute health problem such as infection, intoxication, etc.***
4	**Normal**	**Low**		**Sympathetic dystonia**. The body's regulatory system is out of balance: stimulating activity is substantially below its normal range while calming activity appears to be normal. ***This may be due to aging, presence chronic fatigue or health condition that substantially weakens stimulating activity.***
5	**Normal**	**Normal**		**Autonomic normotonia**. The body's regulatory system is in good balance: both stimulating and calming activities are within their normal ranges. ***This is an indication of achieving the inner balance, good health and optimum performance.***

	Calming Activity	Stimulating Activity	Test Interpretation	
6	**Normal**	**High**		**Stress response**. The body's regulatory system is out of balance: stimulating activity is above its normal range while calming activity appears to be normal. ***This may be due to substantial physical or mental stress or acute health problem.***
7	**High**	**Low**		**Severe sympathetic dystonia**. The body's regulatory system is extremely out of balance: stimulating activity is below its normal range while calming activity is above normal. ***This is not a very typical state indicating very deep relaxation condition, or substantial effect of any factors suppressing ability to stimulate the body.***
8	**High**	**Normal**		**Relaxation response.** The body's regulatory system is out of balance: calming activity is above its normal range while stimulating activity appears to be normal. ***This may be due achieving mentally / physically restful condition, relaxation.***

	Calming Activity	Stimulating Activity	Test Interpretation	
9	**High**	**High**		**Total autonomic hypertonia**. The body's regulatory system is in balance: both stimulating and calming activities are above their normal ranges. ***If poor data quality problem due to substantial heartbeat irregularity or movement artifacts is ruled out, this condition is typical for healthy individuals or athletes being in a very active state of body regulation.*** ***If this pattern systematically appears in the report, it is recommended to check if you are getting clean pulse wave signal and heart rate graphs.***

4.6.2. Regulatory Effort

There are three main types of the regulatory effort conditions:

	Regulatory Effort	Test Interpretation
1	**Depleted**	The strength of overall regulatory capabilities is below its normal range. ***This may be due to the effect of aging, physical or mental fatigue, possible presence of any chronic health condition that affects autonomic regulation.***
2	**Optimal**	The strength of overall regulatory capabilities is in normal range. ***This is an indication of healthy regulatory performance.***

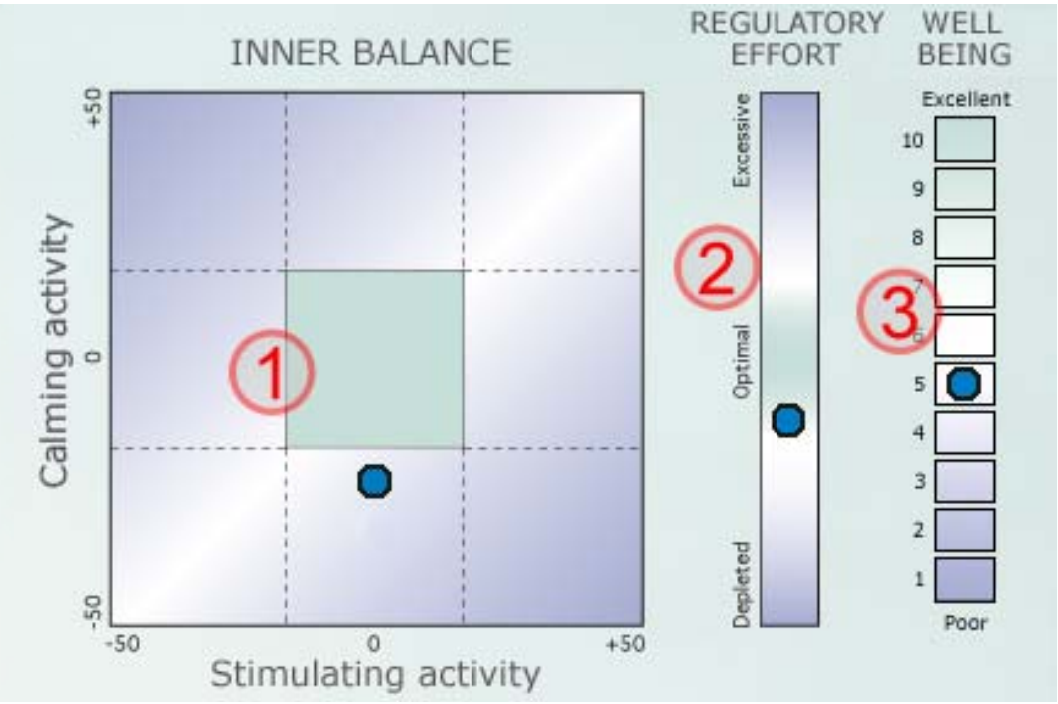
	Regulatory Effort	Test Interpretation
3	**Excessive**	The strength of overall regulatory capabilities exceeds normal range. ***If poor data quality problem due to substantial heartbeat irregularity or movement artifacts is ruled out, this condition is typical for healthy individuals or athletes being in a very active state of body regulation.*** ***If this pattern systematically appears in the report, it is recommended to check if you are getting clean pulse wave signal and heart rate graphs.***

4.6.3. Typical Examples

Below are a few typical samples of the autonomic assessments.

Case 1: Vagal Dystonia

Patient – J.O., 48 years old male. The following picture shows his inner balance assessment report.



Pay attention to the following moments:

1) The INNER BALANCE diagram (left segment of the report page) shows a resulting "dot" located in the middle bottom segment, which corresponds to a normal stimulating (sympathetic) activity level and abnormally low calming (parasympathetic) activity level.

2) The REGULATORY EFFORT bar (center segment of the report page) shows a resulting "dot" located slightly below the normal range.

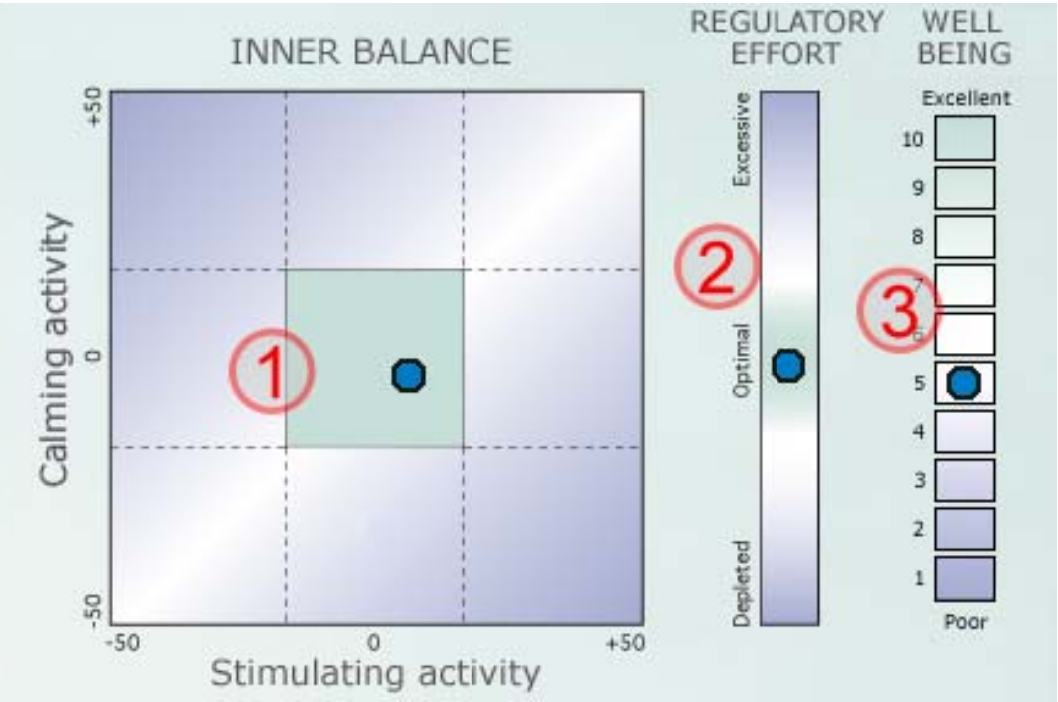
3) The WELL-BEING bar (right segment of the report page) shows a resulting "dot" located in segment 5 of the self-evaluation scale meaning that the subject's personal feeling is about average.

All these facts are typical signs of the presence of chronic stress or health condition that substantially suppresses calming activity.

Thus the assessment conclusion shown on this report page corresponds to the **Type 2** of the autonomic balance condition shown in the table above.

Case 2: Autonomic Normotonia

Patient – M.F., 58 years old male. The following picture shows his inner balance assessment report.



Pay attention to the following moments:

1) The INNER BALANCE diagram (left segment of the report page) shows a resulting "dot" located in the center segment, which corresponds to a normal stimulating (sympathetic) activity level and normal calming (parasympathetic) activity level.

2) The REGULATORY EFFORT bar (center segment of the report page) shows a resulting "dot" located within the normal range.

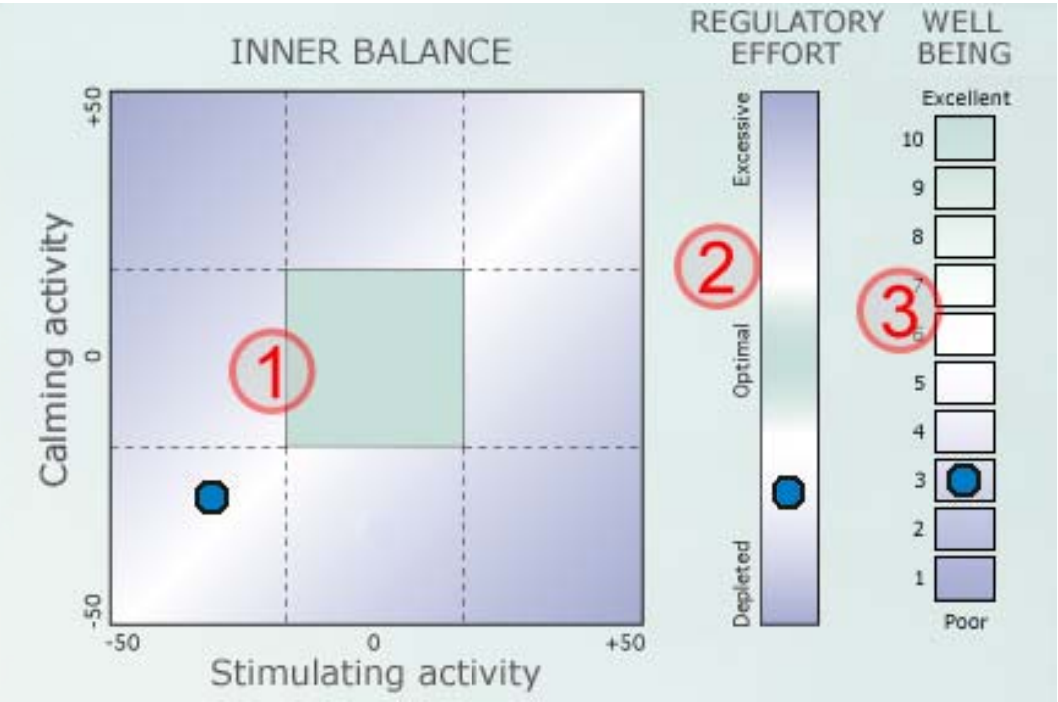
3) The WELL-BEING bar (right segment of the report page) shows a resulting "dot" located in segment 5 of the self-evaluation scale meaning that the subject's personal feeling is about average.

Although the subject's personal feeling does not look great the test shows that his body has achieved the inner balance, which is a sign of good health and optimum performance.

Thus the assessment conclusion shown on this report page corresponds to the **Type 5** of the autonomic balance condition shown in the table above.

Case 3: Total Autonomic Dystonia

Patient – S.V., 54 years old female. The following picture shows her inner balance assessment report.



Pay attention to the following moments:

1) The INNER BALANCE diagram (left segment of the report page) shows a resulting “dot” located in the bottom left segment, which corresponds to an abnormally low stimulating (sympathetic) activity level and abnormally low calming (parasympathetic) activity level.

2) The REGULATORY EFFORT bar (center segment of the report page) shows a resulting “dot” located substantially below the normal range.

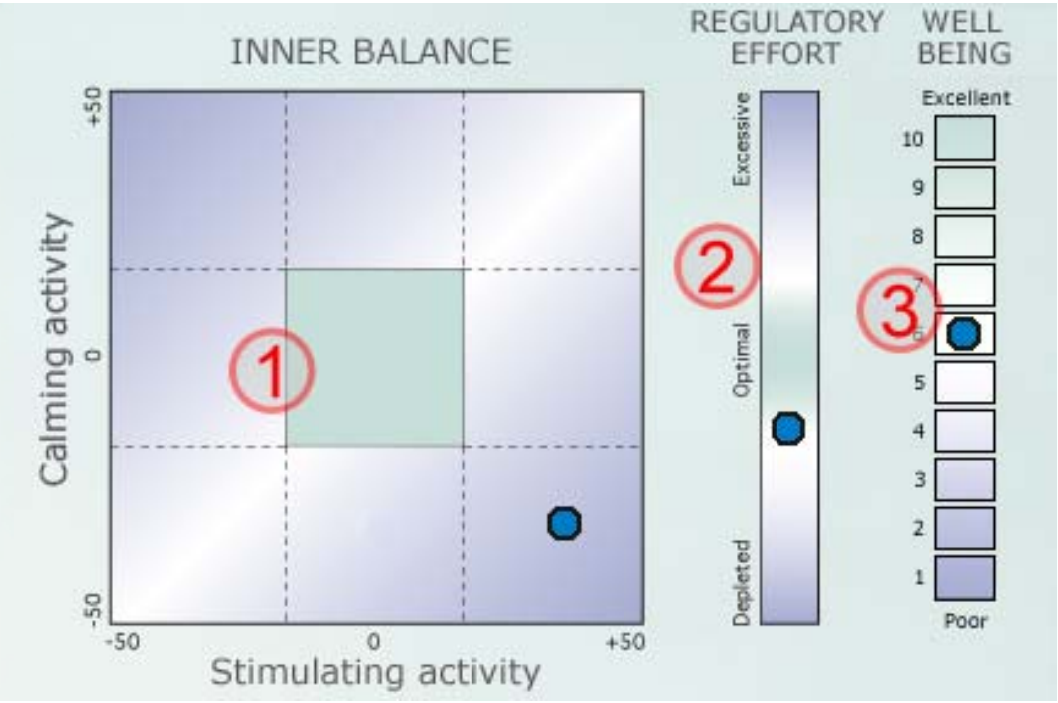
3) The WELL-BEING bar (right segment of the report page) shows a resulting “dot” located in segment 3 of the self-evaluation scale meaning that the subject’s personal feeling is not good.

All these facts are typical signs of the effect of accelerated aging, significant physical or mental fatigue or possible presence of any chronic health condition that affects body’s ability to maintain inner balance.

Thus the assessment conclusion shown on this report page corresponds to the **Type 1** of the autonomic balance condition shown in the table above.

Case 4: Severe Stress Response.

Patient – A.S., 49 years old female. The following picture shows her inner balance assessment report.



Pay attention to the following moments:

1) The INNER BALANCE diagram (left segment of the report page) shows a resulting "dot" located in the bottom right segment, which corresponds to an abnormally high stimulating (sympathetic) activity level and abnormally low calming (parasympathetic) activity level.

2) The REGULATORY EFFORT bar (center segment of the report page) shows a resulting "dot" located slightly below the normal range.

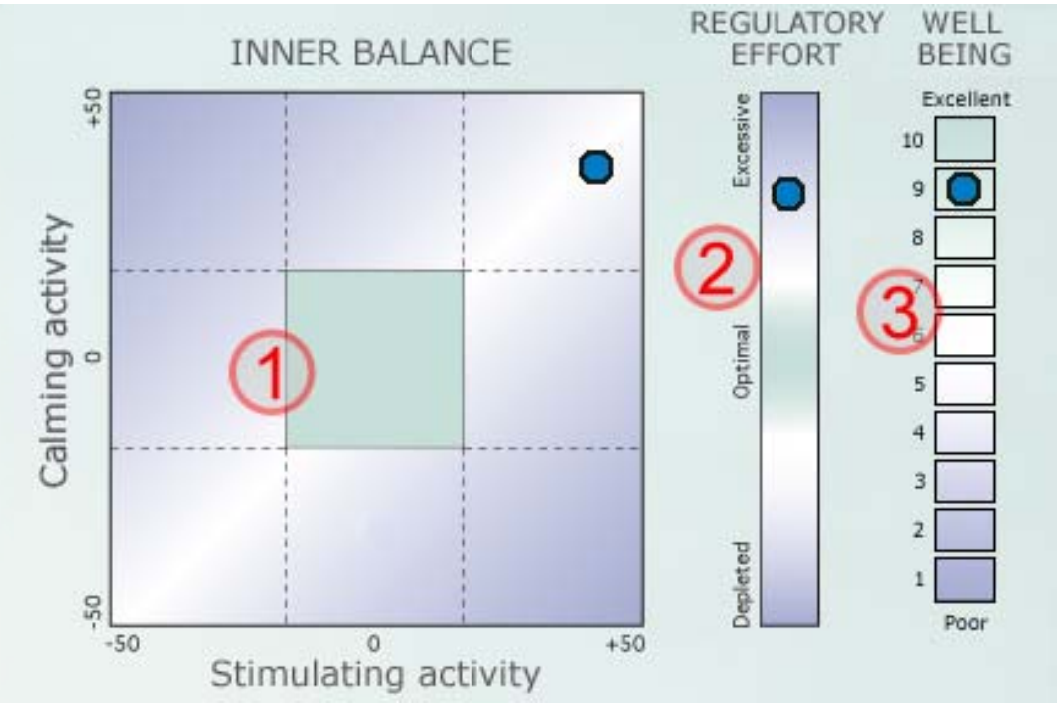
3) The WELL-BEING bar (right segment of the report page) shows a resulting "dot" located in segment 6 of the self-evaluation scale meaning that the subject's personal feeling is average.

All these facts are typical signs of extreme and acute physical or mental stress or acute health problem such as infection, intoxication, etc.

Thus the assessment conclusion shown on this report page corresponds to the **Type 3** of the autonomic balance condition shown in the table above.

Case 5: Total Autonomic Hypertonia

Patient – J.P., 20 years old male. The following picture shows his inner balance assessment report.



Pay attention to the following moments:

1) The INNER BALANCE diagram (left segment of the report page) shows a resulting "dot" located in the bottom right segment, which corresponds to a very high stimulating (sympathetic) activity level and very high calming (parasympathetic) activity level.

2) The REGULATORY EFFORT bar (center segment of the report page) shows a resulting "dot" located significantly above the normal range.

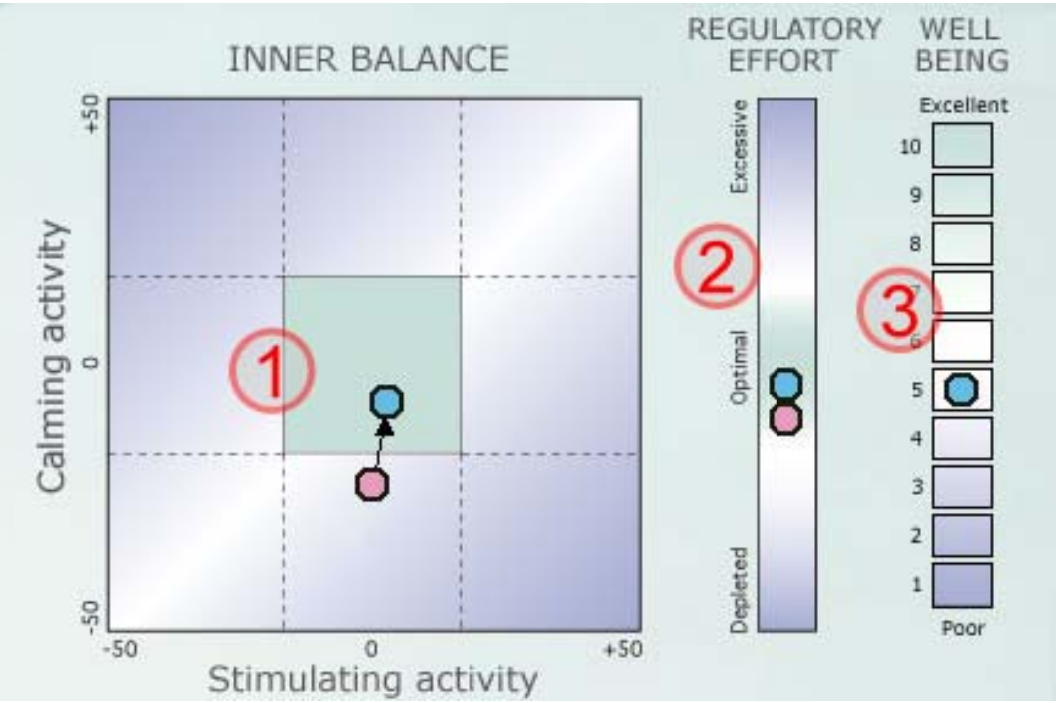
3) The WELL-BEING bar (right segment of the report page) shows a resulting "dot" located in segment 9 of the self-evaluation scale meaning that the subject's personal feeling is very good.

All these facts are typical signs of a condition typical for healthy individuals or athletes being in a very active state of body regulation.

Thus the assessment conclusion shown on this report page corresponds to the **Type 9** of the autonomic balance condition shown in the table above.

Case 6: Effect of normalization of the autonomic function

Patient – A.S., 38 years old female. The following picture shows her inner balance assessment before and after chiropractic adjustment.



The Inner Balance Scan was used for patient testing in the PRE/POST mode. Two 5-min assessments were conducted before and after a chiropractic adjustment procedure to mitigate pain in the cervical segment of the spinal cord.

Pay attention to the following moments:

1) The INNER BALANCE diagram (left segment of the report page) shows a resulting pink “dot” reflecting a condition before the adjustment procedure located in the middle bottom segment, which corresponds to a normal stimulating (sympathetic) activity level and abnormally low calming (parasympathetic) activity level. Another blue dot reflecting a condition after the adjustment procedure is located in the center segment, which corresponds to a normal stimulating (sympathetic) activity level and normal calming (parasympathetic) activity level. Thus there was a shift of the inner balance from the vagal dystonia to the autonomic normononia.

2) The REGULATORY EFFORT bar (center segment of the report page) shows a shift of the resulting “dot” from slightly below the normal range (pink) to the normal range (blue).

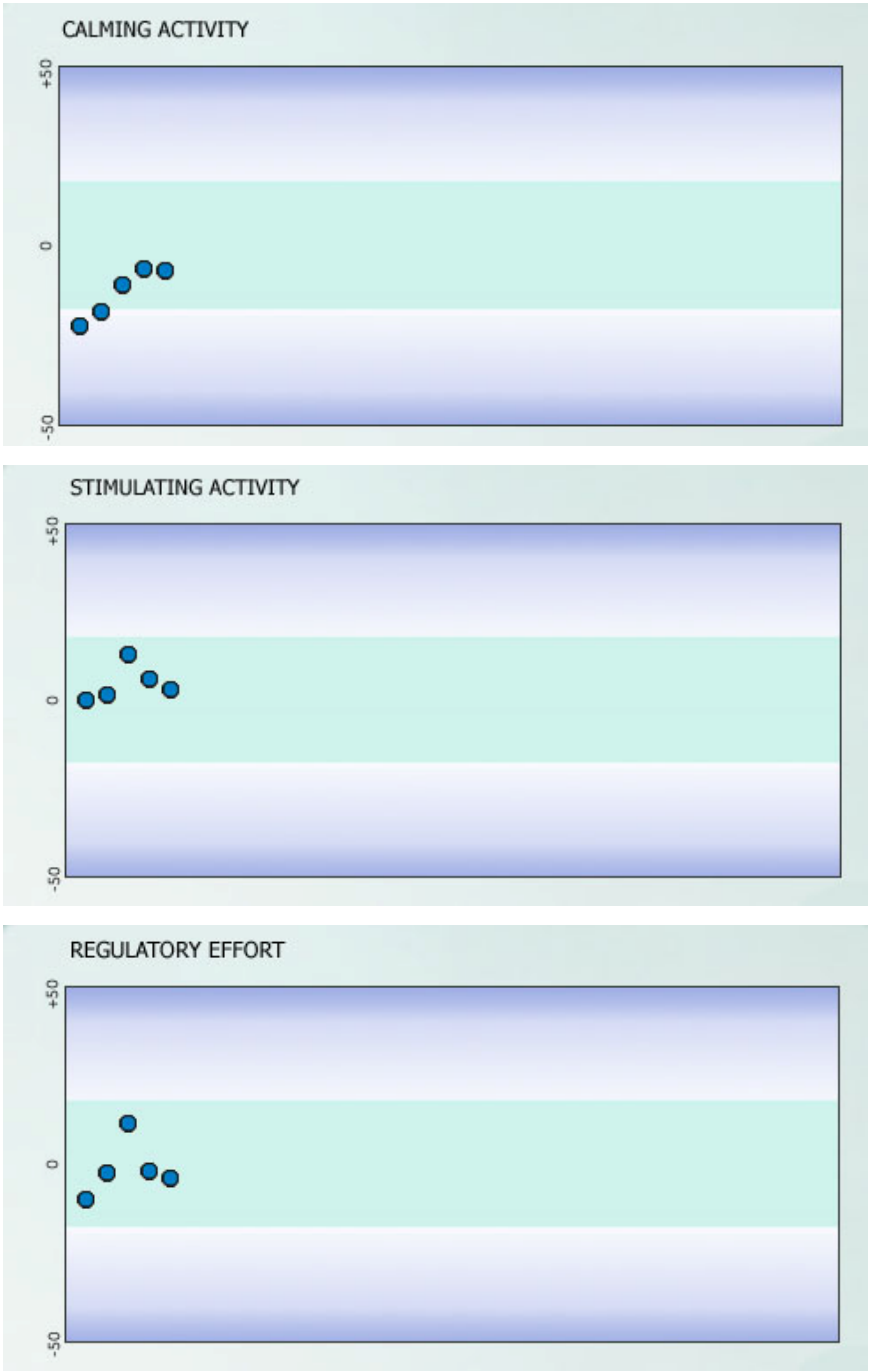
3) The WELL-BEING bar (right segment of the report page) shows a resulting “dot” located in segment 5 of the self-evaluation scale meaning that the subject’s personal feeling is about average before and after the procedure (the blue dot overlaps pink one).

All these facts indicate that the adjustment procedure helped to normalize an autonomic functional state, which was typical for chronic conditions like chronic dull pain in the spinal cord.

5. Assessment History

The Inner Balance Scan system keeps records of all assessment of each kind and gives ability to review entire history of assessments of a patient and thus evaluate the effect of administered treatment.

The following picture shows the history of the autonomic assessments of the patient - N.P., 48 years old female.



This chart clearly shows positive effects of a special diet and exercise program prescribed to the patient as a part of her treatment of hypertension and obesity. Particularly the following tendencies can be seen:

1. Calming activity is progressively increasing, which means that body's restorative regulatory function is getting stronger.
2. Stimulating activity has slightly increased and remains within its normal range.
3. Regulatory effort reflecting overall regulatory activity of the body has slightly increased and remains within its normal rage.