Clinical application of medical device "Symona 111"

«Integral Monitoring System «Symona 111» (hereinafter – the System or Symona) is a diagnostic hardware and a software complex for non-invasive measurement of physiological indicators of the central and peripheral hemodynamics, respiration functions, body temperature, brain activity and metabolism status.

The main design elements involve computer and electronic measuring unit featuring nine monitoring channels:

1. Plethysmograph,
2. Electrocardiograph,
3. Photoplethysmograph + Pulsoximeter,
4. Non-invasive blood pressure monitor,
5. Body temperature monitor (2 channels)
6. Electroencephalograph,
7. Gas Module (CO2 + O2),
8. Breathing mechanics module,
9. Metabolimeter.

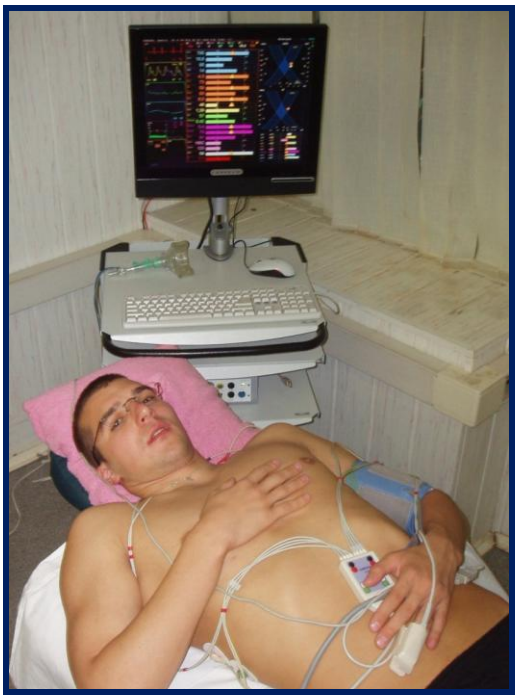
As many as 123 indicators and their trends are monitored using 17 graphic charts.

The System is assembled in two versions: as a stationary instrument (mounted on a trolley, weight 92 kg) and as a mobile device (featuring laptop, no trolley, weight 10 kg).

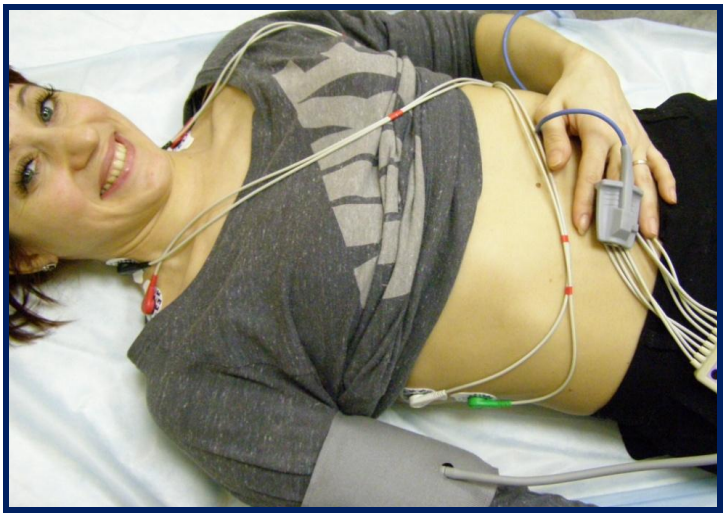
It is the only device in the world in which the original design and the computer program band the diagnostics of all three vital systems: cardiovascular system, system of breathing and nervous system (central and vegetative). Definitely the functioning of these three vital systems determines the general human health level and life expectancy. Symona provides system approach to diagnostics the whole body as a single biological unit.

For out-patients the System is used for early diagnostics of latent disorders in the three vital systems: cardiovascular system, respiratory system and nervous system (central and vegetative).

The System is mounted on a trolley



Mobile model of the System
(featuring laptop, no trolley)



The System diagnoses subclinical cardiac and respiratory failure and enables to choose exactly the right treatment, being guided by the dynamics of the relevant indicators.

The System diagnoses initial symptoms of hypertension, shows its roots and prompts to the doctor the algorithm of treatment.

Symona compares the physiological performance indicators of these vital systems with the individual medical normal values considering weight, height, gender, age and body temperature of a patient. In addition, when re-examined, the System compares the latest values of patient indicators with their previous data, noting the smallest changes towards improvement or deterioration during any disease stage or during the recovery period. It allows the doctor to assess the efficiency of treatment very early and to correct it promptly. For example, it is possible to track the impact of different modes of hemodialysis or other medical activity (inhalations of Xenon+Oxygen or Helium+Oxygen gas mixtures) to the status of all vital systems.

Such approach providing initial diagnostics and objective monitoring of treatment allows optimizing therapy, shortening the period of sickness and to accelerate the recovery. Ultimately, this leads to productive and long life.

Using the System opened an entirely new branch of medicine called **“diagnostics healthy person"**. The System can define **the health level** of children (over 1 year of age), adults and old people based on the analysis of four integral indicators which show the work of all vital systems (cardiovascular, respiratory and nervous):

DO_2I – Index Oxygen Delivery (ml/min/m2). It characterizes the intensity of the aerobic metabolic processes. In a healthy person the normal rate is 600±100. Sick people have this indicator less than 500.

IB – Integral Balance Deviation (%). It characterizes the level of cardio-pulmonary system functioning. The normal rate for a healthy person is 0±100. IB for well-trained athletes can reach 300-700. Sick people have the reduced IB less than minus 100.

CR – Cardiac Reserve (conventional unit). It characterizes the existing reserves of the heart functioning. The normal rate is 5±1 for a healthy person. CR can reach up to 11 for well trained athletes. At any diseases or at the general exhaustion the CR is reduced and is spent on the recovery of the body. The higher the CR is the greater the endurance and the stronger the ability to perform a large amount of work. The lower the CR is, the worse the functional state of organism. In sick people the CP is less than four.

AR – Adaptive Reserve (conventional unit). It characterizes the level of reserves of the body to perform physical (sports) and mental activity. The normal rate is 500±100 for a healthy person. AR in elite athletes can reach 1200-1500. In sick people AR is less than 400.

All these indicators are very dynamic and they objectively reflect positive and negative effects of any carried out therapy. It allows the doctor to assess the impact of treatment very early and to correct it promptly.

In outpatient practice for diagnostics of level of health is urgently required to evaluate surgery and anesthesia risk for patients preparing for major surgery. With poor (low) levels of health the System shows the physiological parameters which are the most deviated from normal values. This allows improving the health status before surgery with the help of precisely chosen treatment the aim of which is to normalize the indicators. This ultimately will reduce the risk of the surgical intervention and facilitate recovery in the post surgery period.

Application of the System in pregnant women opens a whole new field of medicine. Repeated examination of women throughout all months of pregnancy allows with early stage to notice any undesirable deteriorations of vital systems and to start their correction initially. The monitoring throughout the pregnancy term allows to significantly ease the process itself and to avoid heavy late toxicosis of pregnant women, and also leads to proper embryofetal development and healthy childbirth.

The same four integrated indicators mentioned above are used for diagnostics of the functional state of the organism (FSO) of the athlete, which corresponds to the level of his physical fitness.

In sport medicine the System is used for the following:

- Diagnostics physical shape;
- Selection in national teams, assessment of the level of physical shape before signing the contract (football, diving, horse or camel riding);
- Screening for children to determine their abilities for sports exercising;
- Rapid diagnostics overtraining;
- Optimization of individual plans of training and competition;
- Evaluation of the training loads (sufficiency, redundancy);
- Control of medical treatment and trauma prevention;
- Control of rest and rehabilitation phase;
- Control of impact of medicines and food additives.

Application of the System for in-patients

Monitoring
of adult functional state
in intensive care unit

Monitoring
of child functional state
in intensive care unit

For in-patients the System is used for all categories of patients during intensive care, pregnancy monitoring, during all kinds of surgery providing comprehensive information on the health status and pathology associated with the following:

- various types of shock (traumatic, burn, toxic-allergic, hemorrhagic, septic, cardiologic);
- acute respiratory syndrome;
- unstable hemodynamic;
- artificial lung ventilation;
- hemodialysis and plasmapheresis;
- gestational toxicosis;
- cardiac distress;
- resistant hypertension.

The System is designed for short and long term patient monitoring during transportation, in day care clinics and in various departments of the hospitals.

The System can be used to monitor both adults and children.