



CARDIOVASCULAR AND AUTONOMOUS NEUROPATHY ANALYZING SYSTEMS

- **3/6/12 channel ECG** with complete analysis
- Systems including **blood pressure measuring** and **Holter options**
- **Devices extended with neuropathy modules** (Sympathetic and parasympathetic tests)
- **Automated test management** and evaluation, preparation and immediate printing of medical reports
- **Adult and child** versions
- **Portable** (battery operated) **and installed analyzers**









Cardiovascular and autonomous neuropathy analyzing systems

Our **cardiovascular and neuropathy analyzing systems** provide comprehensive, quick and efficient support for making the proper diagnosis. The different types assist the users in a wide range of medical facilities. Our devices can be used from general practitioner's offices through outpatient clinics up to large clinics and hospitals; but even under totally unusual circumstances e.g. next to a sport field. So, everyone can find the most suitable device in our portfolio. The systems are available in installed and portable (battery-operated) forms, and in versions for examination of adults or children. The different systems are based on the same software background, so that users need not learn new skills when they change or upgrade their existing version. Extension of the configuration is done primarily in the software with

only minimal involvement of hardware parts. The management of measured and evaluated data, allowing access to well-known data acquisition systems, contributes to effectiveness.

The measuring and analyzing software uses Windows, the most popular OS, promoting easy learning and application. This significantly simplifies recording of the patients' personal data; storage, export, and printing of the corresponding measurement results; and the usage of the software in general.

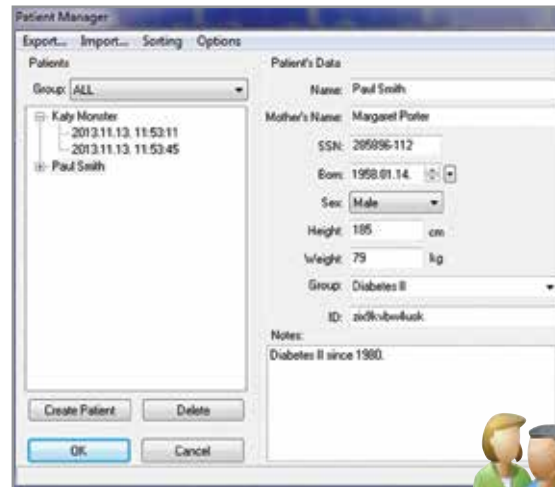
The configuration options of the system allow a more extensive exploration of side effects as well as recognition of susceptibility to further illnesses which cannot (yet) be detected by other diagnostic devices.

SYSTEMS	INSTALLED version	PORTABLE (battery operated) version
<p>CARDIOSYS^{BASIC} functions:</p> <ul style="list-style-type: none"> • 12 channels ECG monitoring and recording • Online ECG analysis and medical report printing • Full offline ECG analysis <p>Available versions:</p> <p>CAR-01-IA: installed, adult CAR-01-IC: installed, child CAR-01-PA: portable, adult CAR-01-PC: portable, child</p>		
<p>CARDIOSYS^{PLUS} functions:</p> <ul style="list-style-type: none"> • 12 channels ECG monitoring and recording • Online ECG analysis and medical report printing • Full offline ECG analysis • NIBP measuring and Holter function <p>Available versions:</p> <p>CAR-02-IA: installed, adult CAR-02-IC: installed, child CAR-02-PA: portable, adult CAR-02-PC: portable, child</p>		
<p>CARDIOSYS^{EXTRA} functions:</p> <ul style="list-style-type: none"> • 12 channels ECG monitoring and recording • Online ECG analysis and medical report printing • Full offline ECG analysis • NIBP measuring and Holter function • Autonomous neuropathy tests <p>Available versions:</p> <p>CAR-03-IA: installed, adult CAR-03-IC: installed, child CAR-03-PA: portable, adult CAR-03-PC: portable, child</p>		
<p>EWING TESTER functions:</p> <ul style="list-style-type: none"> • 3 channels ECG monitoring and recording • Online ECG analysis and medical report printing • ECG analysis by cycle or averaged • NIBP measuring function • Autonomous neuropathy tests <p>Available versions:</p> <p>ESP-01-IA: installed, adult ESP-01-IC: installed, child ESP-01-PA: portable, adult ESP-01-PC: portable, child</p>		

PATIENT MANAGEMENT

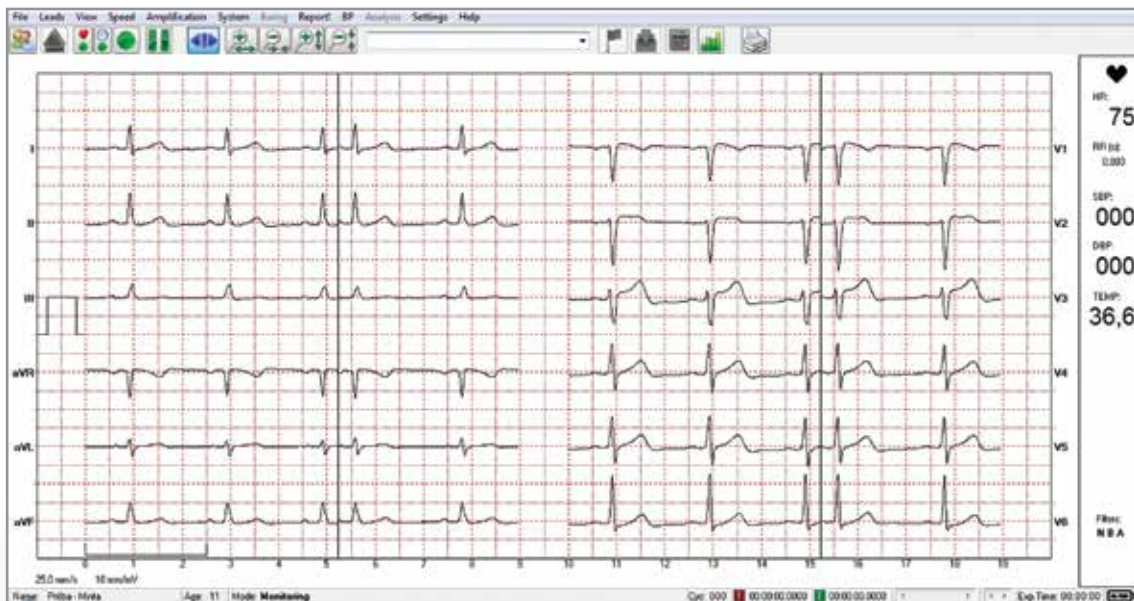
The patient manager panel is quickly available using the shortcut. In the panel, data of a new patient can be registered, or a previously registered patient can be chosen. The identification code for each patient is automatically generated by the software.

Besides recording of the personal data, further documentation (weight and height, creating patients groups, data export and import, storage of further important information related to the patients and the tests done) and reloading of older records can be executed here. At archiving the patients' personal data, protection of personal data has been considered.



ECG MONITORING AND RECORDING

Control functions are available from the shortcut icons located above the monitoring field and in the drop-down menus. Furthermore some of the functions (e.g.: recording 10sec or 20sec ECG, printing, etc.) can be controlled using keyboard shortcuts.



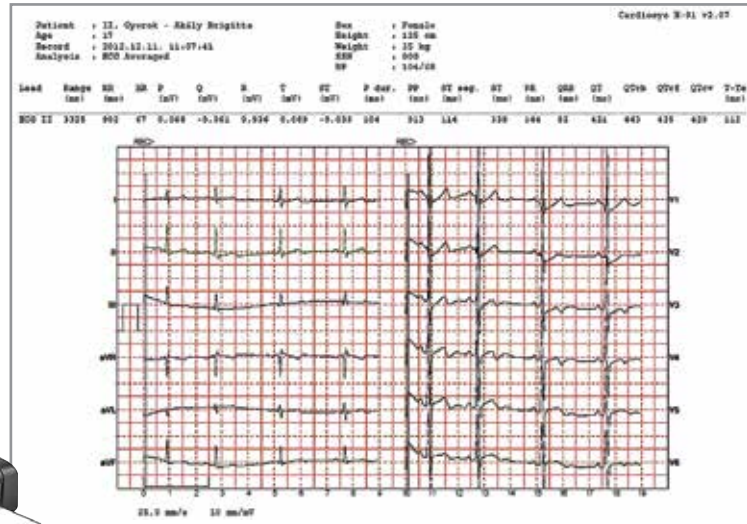
For example:

- Continuous recording,
- Time- or heart cycle-based recording,
- Setting the speed of display,
- Setting the amplification,
- Splitting the monitoring field,
- Recording notes and markers
- Setting trigger level and filters,
- Analysis function.

ONLINE ECG ANALYSIS AND REPORT PREPARATION

After recording, the system calculates automatically the following parameters averaged from five cycles of the recorded curves:

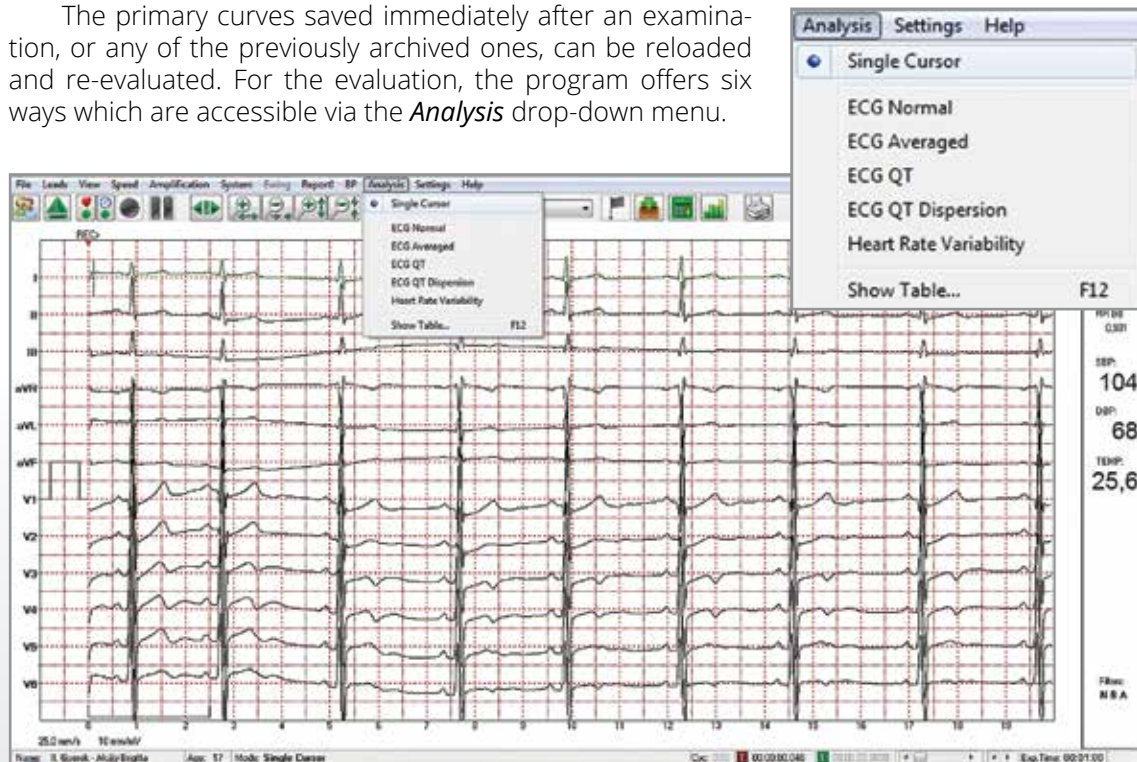
- RR (ms)
- HR (bpm)
- P duration (ms)
- PP (ms)
- ST segment (ms)
- ST interval (ms)
- PR interval (ms)
- QRS (ms)
- QT (ms)
- QTcb (ms)
- QTcf (ms)
- QTcv (ms)
- T-Te (ms)

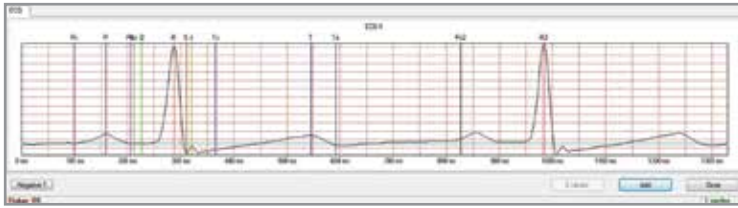


The calculated parameters are recorded in a table and can be printed out in a format shown on the right, together with the corresponding primary curves and personal data of the patient, clicking on the *Print* icon.

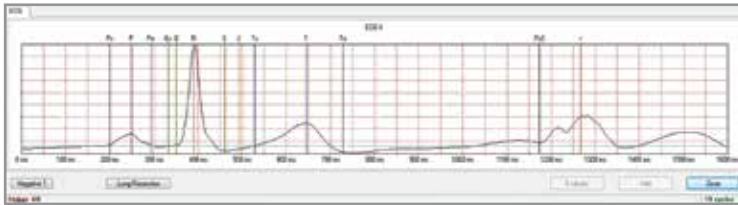
OFFLINE ECG ANALYSIS

The primary curves saved immediately after an examination, or any of the previously archived ones, can be reloaded and re-evaluated. For the evaluation, the program offers six ways which are accessible via the *Analysis* drop-down menu.

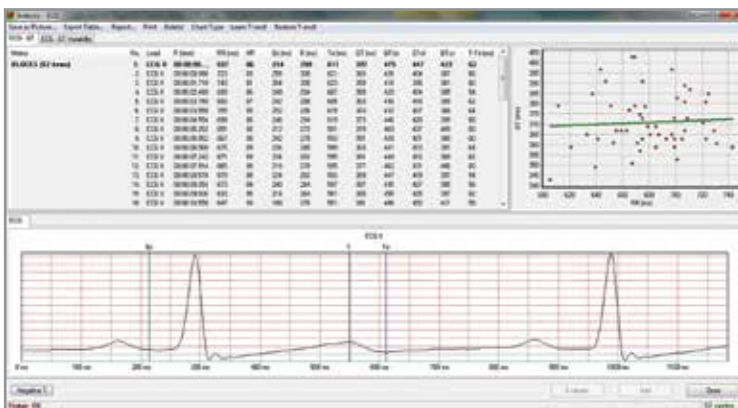




Cycle-based ECG analysis with automatic evaluation of the parameters.

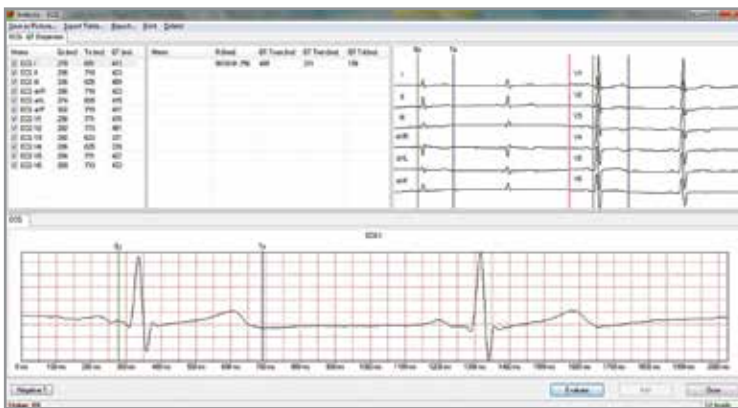


Averaged ECG analysis from cycles selected by the user with automatic evaluation of the parameters.

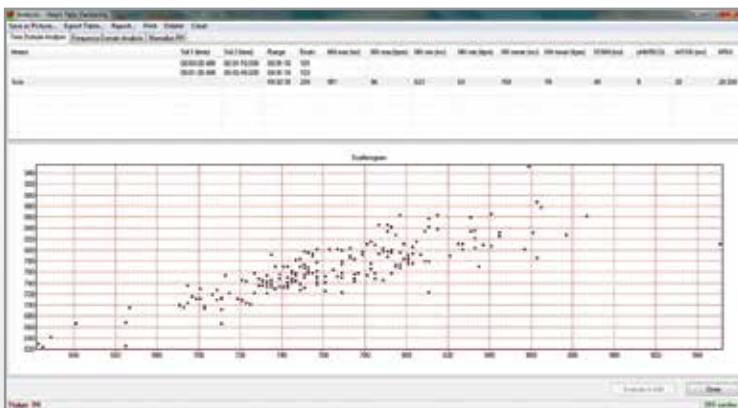


ECG QT evaluation:

- QT or QTc, depending on RR or HR (user-selected),
- **QT variability (QTv)** evaluation from at least 32 cycles.



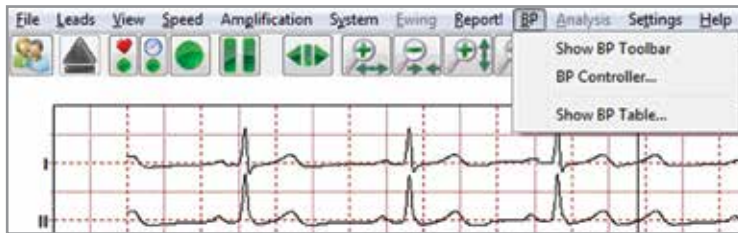
QTd (dispersion) determination from 12 leads and one cycle.



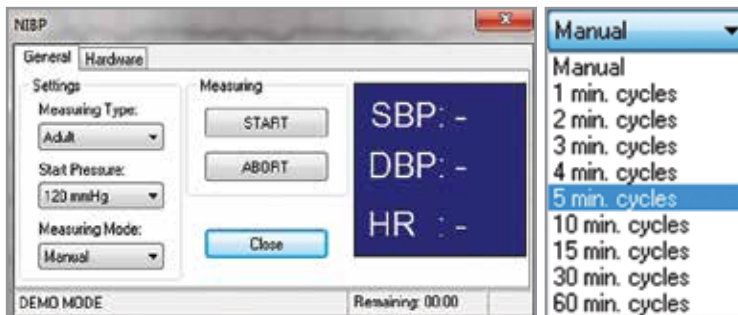
HRV (heart rate variability) determination by time and frequency range analysis.

NIBP MEASURING AND HOLTER FUNCTIONS

The **CARDIOSYS^{BASIC}** system improved with blood pressure measuring (NIBP) option (called **CARDIOSYS^{PLUS}** or **CARDIOSYS^{EXTRA}**) provides the possibility to examine cardiac effects and vascular responses at the same time (beyond the previously mentioned functions).



Measuring is activated by connecting the *non-invasive* blood pressure measurement hardware belonging to the system.



In the BP control panel, the user can choose between two options. The program is able to make measurements one-by-one at the user's command (**Manual mode**) or automatically in previously set intervals (**Holter mode**).

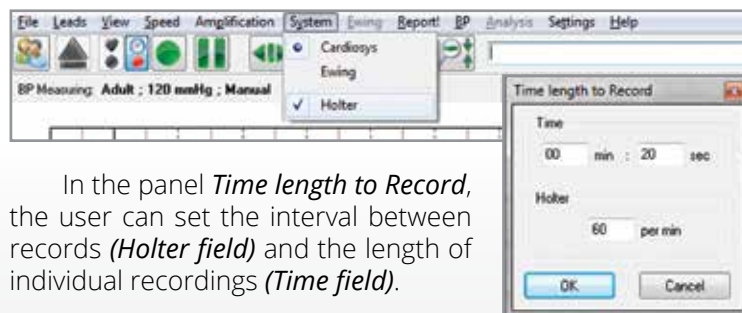
MANUAL MODE

Measurement can be started at any time by invoking **BP toolbar** in the monitoring field. The results can be printed out immediately, together with the ECG curve and its evaluated parameters.

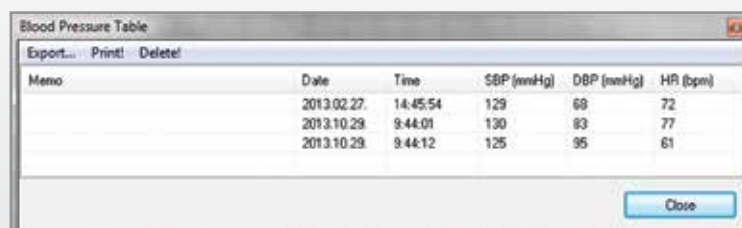


HOLTER MODE

This function is available from the **System** drop-down menu by choosing **Holter**. In Holter mode, ECG curves and blood pressure values (NIBP) are stored automatically.



In the panel **Time length to Record**, the user can set the interval between records (**Holter field**) and the length of individual recordings (**Time field**).



The measured blood pressure values are, together with the time of recording, automatically stored in a table. The results can be printed out at any time, or can be exported in a format suitable for spreadsheet programs.

AUTONOMOUS NEUROPATHY EXAMINATION

The **CARDIOSYS^{BASIC}** system improved with the blood pressure measurer (NIBP) and the autonomous neuropathy option (called **CARDIOSYS^{EXTRA}**) provides the possibility to examine the vascular and neuropathic answers occurring in parallel with the cardiac effects.

By means of the system, Ewing's reflex tests examining the cardiovascular autonomic nervous system functions can be performed with automatic test management and analysis.

Parasympathetic functions:

- Heart rate response to deep inspiration and expiration,
- Heart rate response to Valsalva maneuver,
- 30:15 ratio: heart rate response upon standing up.



Sympathetic functions:

- Decrease in systolic blood pressure upon standing up,
- Handgrip strength test: rise in diastolic blood pressure upon sustained tension of hand muscles.

The tests are configured in the Protocol board. Beside the basic protocols found in the literature, the users will have the possibility to add and use further protocols which have been applied successfully at the examination facility, or modify any of the protocols according to their needs.

The system gives assistance in performing the **sympathetic** and **parasympathetic** tests by written instructions and audible signals. Automatic management and evaluation (Score value) of the test significantly increases the throughput of patient care and results in higher cost-efficiency.

In the **Valsalva maneuver**, the patient has to perform exhalation for 15 seconds at a pressure of 40 mmHg. Heart rate response is given by the ratio of the longest RR distance after, and the shortest RR distance during the maneuver.

In examining the heart rate response to six **deep inspirations and expirations** per minute, the difference between the maximal and minimal heart rate can be measured.



30:15 ratio: After lying as given in the protocol, the patient will stand up and remain standing. From the continuously recorded ECG curves, ratio of the RR distance of the 30th and 15th (or nearby) cycles following standing up can be calculated.

Exhale/handgrip measurer



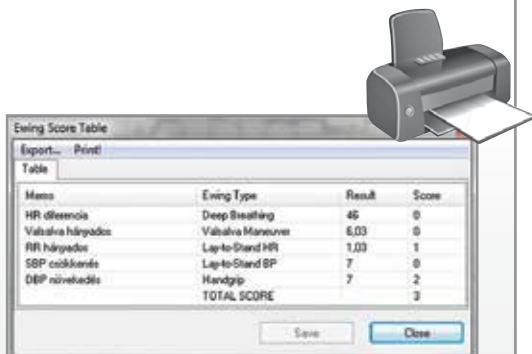
Decrease in systolic blood pressure upon standing up:
 Changes in systolic blood pressure upon standing up can be examined using the same measurement configuration by including blood pressure measurement.



In **Handgrip strength test**, the patient will grip the rubber pump and exert at first as much strength as he/she can do, then will maintain squeezing with 70% lower strength for 3 minutes. During the test, rise in diastolic blood pressure is measured.



The basic report shown below will be filled in automatically with the evaluated results from the summary **Ewing Score Board**. Users can also edit the documents according to their preferences.



HEADER

Name	: Kate Smith	SSN code	: 111222333
Date of birth	: 1949.07.26.	Mother's name	: Andrea Bibott
Weight	: 88 kg	Height	: 170 cm
Date	: 09/05/2014		
Doctor	: John Wallner, dr.		

Autonom cardialis neuropathia
 (Based on the cardiovascular reflex test determined by Ewing)

	Normal Limit	Abnormal	Result	Score
SIGNS OF PARASYMPATHETIC DAMAGES				
<i>Resting Heart Rate</i>				
QT _{cb} averaged ECG cycle:			444	
QT _{cb} RRmin ECG cycle:			501	
QT _{cb} RRmax ECG cycle:			417	
HR min:			59	
HR max:			78	
<i>Deep breath test:</i>	≥ 15	11 - 14	≤ 10	4
<i>Valsalva-maneuver:</i>	≥ 1,21	1,11 - 1,20	≤ 1,10	1,25
<i>Lying-to-standing (30:15):</i>	≥ 1,04	1,01 - 1,03	≤ 1,00	0,91
SIGNS OF SYMPATHETIC DAMAGES				
<i>Orthostatic BP changes:</i>	< 10	11 - 29	≥ 30	0
<i>Handgrip:</i>	> 16	11 - 15	≤ 10	0
Total SCORE value:	< 3	3 - 5	> 6	6
<i>HRVi triangular index:</i>		23,000		

Diagnosis, therapeutic proposals:

Budapest, 09/05/2014

Signature/PH

OPTIONALLY AVAILABLE TROLLEYS



"Sitting" instrument trolley
56cm x 49cm x 75cm
(width x depth x height)

In case of customer request, special, custom designed and manufactured trolleys can be provided in addition to the measuring and analyzing systems, making the use of our systems even more convenient.

Different trolleys are available for examinations carried out in sitting or in standing. The users can choose from these according to their preferences, and can work with the tests further on under circumstances customary for that examination site.

The trolleys have drawers, shelves and further compartments (the equipments in the picture do not belong to the trolley), so the user can find a proper trolley for all types of devices. The storage of accessories and documents will be managed as well.

All our trolleys have four good-quality wheels, for easy motion. Therefore, the whole system can easily be pushed aside after the daily work to a less crowded part of the office and will not unnecessarily occupy any space at the examination bed.

"Standing" instrument trolley
(56cm x 50cm x 155cm)
(width x depth x height)



HOW OUR SYSTEM HELPS WITH YOUR WORK

These products are comprehensive **HEART ELECTROPHYSIOLOGICAL (ECG) MEASURING AND ANALYZING SYSTEMS** which can be rapidly and effectively used in the clinical practice, and in general or sports medicine. The main advantage of the system is that, due to the possibilities given by the software, the acute and chronic pathological changes caused by arrhythmia can be profoundly evaluated using the traditional electrode arrangement (nine leads). As an example, the etiology of “sudden cardiac death” – one of the main and serious problems of our age – the development of which can be investigated with the available systems complicatedly and only partially.

“Sudden cardiac death” is a common cause of death in the developed countries. In most of the cases, no observable structural heart disease can be verified in its background, and it can occur in apparently healthy people as well. In younger individuals, “sudden cardiac death” is often caused by hereditary diseases resulting in arrhythmias, such as the congenital long QT syndrome (LQTS) leading to disorders in the repolarization of heart muscle. Phenotype is highly variable in patients with LQTS, and the individual susceptibility to arrhythmias can be completely different also in patients having the same LQT mutation. In patients carrying subclinical LQT mutation and having normal length of QT interval measured by conventional ECG technique, life-threatening arrhythmias or “sudden cardiac death” can occur due to drugs or dietary factors which prolong cardiac repolarization. Currently it is a major problem in the clinical practice to estimate the risk of and predict the incidence of life-threatening arrhythmias.

Furthermore, it would be of primary importance to assess the arrhythmogenic (proarrhythmic) risk as a side effect of drugs currently under development. However, the existing methods, focusing mainly on the prolongation of repolarization and on the potential inhibitory effects on the IKr current, cannot give reliable data.

The concept of repolarization reserve was formed in relation to the above mentioned problems and its predictive value has been proven experimentally. According to this concept, if the repolarizing function of one ionic current in the heart muscle decreases due to congenital or acquired causes, it will not necessarily result in clinically observ-

able prolongation of repolarization and in arrhythmia (merely in decreased repolarization reserve), since the other ionic currents are able to compensate for the missing function. However, if repolarization is further inhibited (even mildly, e.g. by non-cardiovascular drugs or by dietary factors), significant prolongation of the QT interval and severe ventricular arrhythmias can occur, which can cause “sudden cardiac death”.

In the recent years, the use of a new ECG parameter has been proposed as a more reliable predictor of proarrhythmic risk and for the investigation of repolarization reserve. This is the beat-to-beat measurement of QT interval variability, characterizing the instability of cardiac repolarization, which can be numerically defined as short-term variability of the QT interval. The increment of short-term variability was better correlated with the incidence of serious ventricular arrhythmias occurring later than the conventional ECG parameters, both under preclinical and clinical circumstances.

The **NIBP MEASUREMENTS** (both in manual or Holter mode) offer outstanding benefits for examination of patients. In manual mode, blood pressure measurement can be carried out simultaneously with the cardiac examination of the patient. The measurement results are stored together and can be printed out at the same time. This way, examination requires significantly less time, and archiving the data helps with follow-up of patients. Thanks to archiving the data, measurement results are continuously available, and additionally, can be post-evaluated at any time. In resting Holter mode, guarding function is included in the system. This function can be advantageously used in, e.g., observation of athletes after doing exercise, observation of patients after catheter interventions, and mobile guarding in polyclinics.

CARDIOVASCULAR AUTONOMIC NEUROPATHY (CAN) often occurs in patients with diabetes, liver disease, autoimmune disease, in regular alcohol consumers, but can also occur in people suffering from metabolic syndrome. The importance of CAN is based on the complications threatening the quality of life and life expectancy of the patients. CAN is the most commonly examined form of autonomic nervous system dysfunctions, which is explained – beyond its clinical importance – by the easily performable and reproducible

testing methods. The involvement of the autonomic nervous system may also affect cardiac electrical activity, including ventricular repolarization. Its signs may also manifest as pathological changes of the surface ECG QT interval. Variable degree of damage in the adrenergic innervation of the myocardium results in the inhomogeneity of sympathetic influence, which can lead to inhomogeneous QT prolongation. Inhomogeneous prolongation of the QT interval, that is, of ventricular repolarization, may predispose to ventricular tachyarrhythmias. Increased QT dispersion is – besides silent myocardial infarction – an important risk factor of sudden cardiac death which can be traced back to malignant ventricular arrhythmia and is common in diabetic patients.

Assessment of the autonomic nervous system functions can be done most easily by the reproducible and properly standardized cardiovascular reflex tests (CRTs) described by Ewing. The examination is based on analysis of the ECG and blood pressure values recorded continuously during the reflex tests. One group of the reflex tests (orthostatic hypotension, handgrip strength test) mainly investigates sympathetic nervous system functions, while others (heart rate response to deep inspiration and expiration, Valsalva maneuver, 30:15 ratio) characterizes the functioning of the parasympathetic nervous system.

The importance of examining autonomic neuropathy has been generally recognized by now. Widespread application of this method was hampered because the methods of registration and evaluation of data were time-consuming. Our company has solved this problem successfully by automating the management of the examination at software level, and enabling simultaneous evaluation of data. Quick and easily identifiable data management provided by the software offers new ways in following-up patients with chronic diseases. Furthermore, this system can be perfectly applied in prevention, since cost-effectiveness and shorter examination time makes it suitable for health status surveys in large populations.

TECHNICAL DATA

ECG module

Program run on Windows-based 64-bit OS

Standard 12 channel ECG recording

Screen speed: 5, 10, 25 or 50mm/sec

Amplitude display: 5, 10, 20 or 50mm/mV

Each input is defibrillator proof

12-lead monitoring: real-time ECG curve monitoring and recording or review of stored records

Manual and automatic mode

Continuous ECG monitoring with heart rate display

Baseline drift correction

AC power noise filtering algorithm (50/60Hz)

Muscle motion (tremble, tremor) filtering algorithm

Digital sampling

Sampling frequency: 1000 sample/sec/channel

BP module

Configuration and measurement controlled by the software

Suitable for blood pressure measurement of infants, children and adults

Oscillometric measurement

Maximal cuff pressure is 300mm Hg for adults and 150mm Hg for infants

Real-time measuring, recording, or reviewing the stored data

Pressure measuring ranges for adults: systolic pressure 25-280mm Hg, diastolic pressure 10-220mm Hg

Pressure measuring ranges for infants: systolic pressure 20-150mm Hg, diastolic pressure 5-110mm Hg

Manual and automatic mode

Measurement frequency in automatic mode: 1, 2, 3, 4, 5, 10, 15, 30, 60, 90 min

Ewing module

Pressure sensor to perform measurements of neuropathy

Measuring range: 0-200mm Hg

Manual and automatic mode

Installed systems

Adapter-powered operation with 5kV isolation

4GB system memory

3D graphical support

2GHz processor

Full alphanumeric keyboard for data input and mouse to move the cursor

Portable systems

Portable, battery-powered device

USB connection to the computer providing a 5kV communication isolation

Modern Li-ion battery power supply

Operation time: 12hours

Built-in automatic battery charger

