EC-ABP Ambulatory BP System

Technical specification

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TECHNICAL SPECIFICATIONS OF AMBULATORY BLOOD PRESSURE SYSTEM

BP measurement method	Oscillometric with step deflation, Disatolic values correspond to Phase 5 Korotkoff Sounds
BP measurement range	20 – 280 mmHg (max inflation 300 mmHg)
Pressure Transducer Accuracy	± 3 mmHg
Pulse Rate Range	30 – 240 BPM (Beats Per Minute)
Pulse Rate Accuracy	± 2% or ±3 BPM, whichever is greater
Calibration	The device should be verified on a yearly interval.
Safety Systems	Max. inflation pressure is limited to 300 mmHg; Auto safety release valve for power failure. Maximum cuff inflation time is limited to 75 seconds. Duration of blood pressure reading is limited to 130 seconds.
Data Connector	Mini USB B type connector
Min. Power supply	2 x 1.2 V AA rechargeable batteries of minimum 2500 mAh capacity or 2 x 1.5V AA high quality alkaline batteries
Size	Approx. 125 x 70 x 33 mm
Weight	Approx. 250g (incl. Batteries)
Screen	No screen
Clinical Accuracy	Meets accuracy requirements of ANSI/AAMI SP10:2002(R)2008, EN1060-4:2004 and ISO 81060-2:2009.
Patient button	Yes
Storage Card	built-in 2GB (uSD), more than 4000 measurement
Interval settings	10 - 90 min (adjustable in 1 minute intervals)
Recording Period (hours)	8-336 hours (~ 72 h on one set of batteries)

AMBULATORY BLOOD PRESSURE SOFTWARE FUNCTIONS

• Start new recording from the PC using wireless connection	• Adjustable BP measurement frequency (awake, asleep, special time)	• Visualization of evaluated record on PC
• Store the Indication and medication of the patient	• Awake, Asleep and special time	• Adjustable max cuff pressure
• BP measurement after start	• Total, Asleep, Awake systole-diastole charts	• HR, MAP, Systole, Diastole graphs
• Total, Asleep, Awake systole-diastole-MAP histograms	• Systole against HR scatter	• Diastole against HR scatter
• Diastole against Systole scatter	• Statistics view	• Hyperbaric Impact Systole
• Hyperbaric Impact Diastole	• AASI	• Diurnal Index Systole
• Diurnal Index Diastole	• Dipper status	• Morning Surge
• Battery stats	• Adjustable parameters for analysis	• Comparison view
• Adult and Pediatric mode	• Circadian index	

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BASIC FUNCTIONS OF SOFTWARE

DATABASE FUNCTIONS		
• Common database for all Labtech system	• Record recycle bin function	• Search records
• Acquire Patient ID from barcode reader	• System log	• Local database, Network database: Microsoft SQL Server database, SQLite database
• Acquire Patient ID using magnetic card reader	• Filter records	• Different date format
• Medical record for patients	• Import – export records	• Password protected software starting
• Access control	• Import – export records by date	
BASIC FUNCTIONS		
• Automatic update of the software	• Normal and MSI install	• Full screen mode
• HIS integrations: GDT, DICOM MODALITY WORKLIST, Cardiospy SDK	• Two display mode	• Email function
• FTP integration		
PRINT AND EXPORT FUNCTIONS		
• Report printing and exporting	• Automatic print	• Selectable reports
• Color and Black and white reports	• Contrast settings	• Resizable resolution
• Customizable company logo	• Automatic diagnosis	• Custom report
• Adjustable paper speed and amplitude	• Import /Export settings	

SOFTWARE MINIMUM CONFIGURATION

Processor	minimum: Intel® Core™ i3 recommended: Intel® Core™ i5 or better (Sandy Bridge or newer architecture)
RAM	minimum: 4 GB; recommended: 8 GB
Graphics card	DirectX 10 compatible, min. 128 MB video memory
Display	minimum: min. 1280x800 resolution recommended: 22” monitor 1920 x 1080 resolution (Full HD)
HDD	500 GB (SATA II or newer recommended)
Interface	1 USB port for the EC-2H/3H/12H/ABP recorder 1 USB port for the USB-02 key 1 USB port for the printer
Printer	Laser (printing speed: 15-20 page/min, color printer recommended)
Operating system	Windows 7, Windows 8, Windows 8.1, Windows 10 (32-bit or 64-bit versions)

*Windows XP is no longer supported by Microsoft. Labtech provides only limited support for previously installed systems.

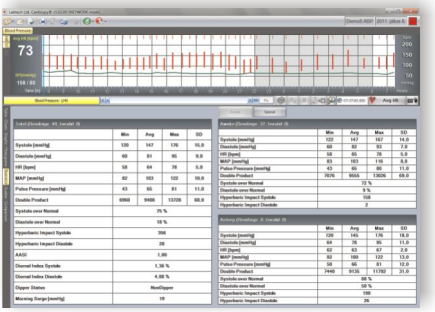
EC-ABP AMBULATORY BLOOD PRESSURE SYSTEM

- Small size, compact built
- Stores 250 BP measurements, up to 48 hours
- Interval settings: 10, 15, 30, 45, 60, 90 min.
- Option for patient event BP measurements
- Oscillometric method with step deflation
- Rechargeable batteries for economic operation
- Automatic analysis for precise diagnosis
- Digital signal storage in the solid state memory
- Precise systole and diastole values
- Values displayed in tables, pie charts, graphs, histograms
- Various editing and printing possibilities
- Simple, user-friendly interface
- Validations: BHS (A/A), ESH, ANSI/AAMI SP10:2002

EC-ABP

The EC-ABP is a member of the PC based ECG Holter product family. The diagnostic device operates with rechargeable or alkaline batteries, being suitable for 48-hour BP monitoring with up to 250 BP readings, using oscillometric technology. It is a clinically validated technology in all three internationally recognized standards (BHS, ESH and ANSI). The device computes accurate and comprehensive systolic and diastolic readings, heart rate, mean arterial pressure, BP load and pulse pressure. It provides report generation, editing, and data export-import functions. The integrated software can be operated in a network environment with a common database for the entire ECG Holter product family. The software is available with a wide range of languages to choose from.

Charts view



Statistics view

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Holter and ABP Accessories

Article Nr.	Products	Compatible with					
		EC-ABP	EC-3H/ABP	EC-2H	EC-3H	EC-12H	
ACC-CLAMP-01	**Cable clamp**	✗	✗	✓	✓	✓	
BAG-0012H-01	**Recorder bag (EC-2-3-12H V5/V6, attachable to patient's waistbelt)**	✗	✗	✓	✓	✓	
BAG-0012H-04	**Recorder bag (EC-2-3-12H V5/V6, attachable to patient's neck)**	✗	✗	✓	✓	✓	
BAG-3HABP-02	**Recorder bag (EC-ABP V5, EC-3H/ABP V5, attachable to patient's waistbelt)**	✓	✓	✗	✗	✗	
BAT-00000-01	**1.2V Rechargeable batteries (AAA)**	✗	✗	✓	✓	✓	
BAT-00000-02	**1.2V Rechargeable batteries (AA)**	✓	✓	✗	✗	✗	
BEL-00000-01	**Waist belt (160 x 3,7 cm)**	✓	✓	✗	✗	✗	
BEL-00000-02	**Shoulder strap**	✓	✓	✗	✗	✗	
CAB-00USB-01	**Extension cable for USB-02**	✓	✓	✓	✓	✓	
CAB-00USB-02	**Data transfer cable (USB A- USB miniB)**	✓	✗	✗	✗	✗	
CAS-00000-01	**Case for holding the systems**	✓	✓	✓	✓	✓	
CAS-00000-02	**Case for holding the recorders - New**	✗	✗	✓	✓	✓	
CAS-00000-03	**Case for holding the systems - New**	✓	✓	✓	✓	✓	
CHA-0002X-01	**Battery charger MINI Eneloop**	✗	✗	✓	✓	✓	
CHA-0004X-03	**Battery charger MAXI / Eneloop pro Power Set (with 4 pieces 2500 mAh, maxE, AA batteries)**	✓	✓	✗	✗	✗	
CUF-0ANCH-05	**Anchor clips for BP cuff**	✓	✓	✗	✗	✗	
ELE-00000-01	**Single-use ECG electrodes (1 pack /50 pcs)**	✗	✓	✓	✓	✓	
USR-00000-01	**Installation and Update Guide**	✓	✓	✓	✓	✓	
USR-00000-02	**User manual for holter recorders**	✗	✓	✓	✓	✓	
USR-00000-03	**User manual for ABP recorders**	✓	✗	✗	✗	✗	

Holter and ABP Spare Parts

Article Nr.	Products	Compatible with					
		EC-ABP	EC-3H/ABP	EC-2H	EC-3H	EC-12H	
ACC-0SWCD-02	**USB flash drive installer**	✓	✓	✓	✓	✓	
CAB-00L01-05	**1 CH bipolar patient cable (HDMI-Snap, 80cm)**	✗	✗	✓	✓	✓	
CAB-00L02-06	**2 CH bipolar patient cable (HDMI-Snap, 45cm)**	✗	✗	✓	✓	✓	
CAB-00L02-05	**2 CH bipolar patient cable (HDMI-Snap, 80cm)**	✗	✗	✓	✓	✓	
CAB-00L03-06	**3 CH bipolar patient cable (HDMI-Snap, 45cm)**	✗	✓	✗	✓	✓	
CAB-00L03-05	**3 CH bipolar patient cable (HDMI-Snap, 80cm)**	✗	✓	✗	✓	✓	
CAB-00L12-05	**12 CH standard patient cable (HDMI-Snap connector)**	✗	✗	✗	✗	✓	
CAB-00LNE-06	**NEHB patient cable (HDMI-Snap, 45cm)**	✗	✗	✗	✓	✓	
CAB-00LNE-07	**NEHB patient cable (HDMI-Snap, 80cm)**	✗	✗	✗	✓	✓	
CAB-00REC-06	**Data transfer cable (USB A - HDMI)**	✗	✓	✓	✓	✓	
CUF-00LOC-21	**BP cuff, Small Adult (17-25cm)**	✓	✓	✗	✗	✗	
CUF-00LOC-31	**BP cuff, Adult (23-33cm)**	✓	✓	✗	✗	✗	
CUF-00LOC-41	**BP cuff, Large Adult (31-40cm)**	✓	✓	✗	✗	✗	
CUF-00LOC-51	**BP cuff, Thigh (38-50cm)**	✓	✓	✗	✗	✗	

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QUALITY AND EFFICIENCY SINCE 1990

DEVELOPMENT AND MANUFACTURE PC-BASED ECG SYSTEMS

Ambulatory Blood Pressure Monitor

Cardiospy® User Manual

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Quality certifications

The CE mark indicates that the product meets the essential requirements of European Council Directive 93/42/EEC concerning medical devices.

Labtech Ltd. also operates a quality system certified to ISO 13485:2016. Made in Hungary by Labtech Ltd.

We wish you success in the use of our ABPM System!

Release date: 11-08-2011
Revision date: 10-05-2024
Version number: v6.2

If you have any questions, ideas, partnership suggestions please contact us.

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1 Introduction

Dear Customer,

Thank you for purchasing our Ambulatory Blood Pressure Monitor System. We sincerely hope that our product will help you with your diagnostic and therapeutic work. To be able to use ABPM System and computer program appropriately, please read the manuals carefully. A basic knowledge of computers and Windows-based applications is required. We appreciate any comment you might have on the use of the System. Please, turn to us with confidence: our colleagues and representatives will be pleased to help you.

What is an Ambulatory Blood Pressure Monitor (ABPM)?

The Ambulatory Blood Pressure Monitor is a non-invasive Oscillometric Blood Pressure Monitor, which is capable of recording up to 1.000 measurements.

How to use ABP monitoring?

The ABP monitor is worn by the patient, and records ambulatory blood pressure during normal daily activities. After it has been recorded for the desired period of time, the readings are downloaded to a computer for analysis.

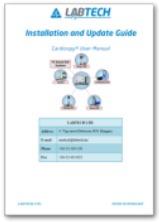
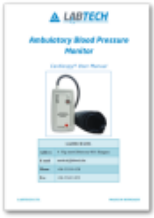
2 Preparations

NOTE: BEFORE STARTING TO USE THE ABPM SYSTEM YOU ARE EXPECTED TO FOLLOW **INSTALLATION AND UPDATE GUIDE**OFLABTECH LTD., WHICH PROVIDES GUIDANCE ON THE INSTALLATION OF THE SYSTEM.

2.1 List of accessories

Please check contents of the case for listed items and accessories before you start using the ABPM System.

Code No.	Specification	Qa.	EC-ABP	Picture
CAS-00000-03	Case for holding the systems	1	x	
DEV-0USBA-02	USB-02/A Bluetooth Interface Unit	1	x	
ACC-0SWCD-02	USB flash drive installer	1	x	
DEV-00ABP-05	EC-ABP recorder unit (BT)	1	x	
CHA-0004X-03	Battery charger MAXI / Eneloop pro Power Set (with 4 pieces 2500 mAh, maxE, AA batteries)	1	x	

Code No.	Specification	Qa.	EC-ABP	Picture
CAB-00USB-01	Extension cable for USB-02	1	x	
CAB-00USB-02	USB data transfer cable (USB A- USB Mini)	1	x	
USR-00000-01	Installation and Update Guide	1	x	
USR-00000-03	User Manual for ABP recorders	1	x	
BAG-3HABP-02	Recorder bag (EC-ABP V5, EC-3H/ABP V5, attachable to patient's waist belt)	1	x	
BEL-00000-01	Waist belt	1	x	

Code No.	Specification	Qa.	EC-ABP	Picture
CUF-00LOC-31	BP cuff, Adult (23-33cm)	1	x	

***The manufacturer maintains the right to change at any time.**

****The accessories highlighted in grey in the chart will be given as accessories for the recorders as well.**

NOTE: PLEASE REFER TO THE CODE NUMBER ABOVE WHEN PLACING AN ORDER.

2.2 Principles of Operation

This device is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult patient's systolic and diastolic blood pressures over an extended period of time.

The Ambulatory Blood Pressure Monitor unit is worn by the patient either in a waist belt or shoulder strap and is connected to a traditional cuff around the non-dominant upper arm. The cuff is inflated automatically at intervals that can be programmed via the software. Blood pressure is measured by oscillometric method, which senses the cessation of pressure waves in the artery when occluded by pressure in the cuff. Measurement of the frequency of the pressure waves also enables heart rate to be measured.

Symbols:

This equipment meets the requirements of Directive 93/42/EEC Annex II (excluding section 4).

Do not dispose of this product and batteries as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment(WEEE).

MDD IIa

MDD classification IIa. EMC class B. EMC group 1.

Bluetooth Wireless Communication Technology Not ionizing radiation – Device including Bluetooth based RF transmitter.

Pay special attention to the part, marked with the exclamation mark.

CF type side of patient

Year of manufacture

Manufacturer

Operating instruction

2.3 Warnings and contraindications to using ABPM system

General warnings:

DO NOT immerse the recorder in any fluid, or attempt to clean the unit with any liquid detergents or cleaning agents. This may cause an electrical hazard.

DO NOT disassemble the recorder case– doingso automatically invalidates the warranty. Using a component different from that supplied may result in measurement error.

DO NOTuse the recorder in the presence of flammable anaesthetics and oxygen rich environment.

DO NOT use recorders in strong heat or in strong electrostatic field.

DO NOT use the recorder if it has failed its diagnostic self-test, or if it displays greater than zero pressure with no cuff attached. The values displayed by such a unit may be inaccurate.

DO NOT use on neonates, on patients known to be susceptible to bruising, and do not attach the cuff to a limb being used for IV infusions.

The ABPM System is designed for external and non-invasive blood-pressure monitoring on the arm. The cuffs can be placed on intact skin-surface only.

The patient should be instructed on proper and safe removal of the cuff, in case it fails to deflate within 3 minutes.

Avoid compression or restriction of pressure tubes.

⚠Possible Adverse Reactions:

Allergic Exanthema (symptomatic eruption) in the area of the cuff Urticaria (allergic reaction including raised edematous patches of skin or mucous membranes and intense itching) caused by the fabric material of the cuff.

Petechia (a minute reddish or purplish spot containing blood that appears in the skin).

Rumple-Leede phenomenon (multiple petechia) on the forearm.

Idiopathic thrombocytopenia (spontaneous persistent decrease in the number of platelets associated with hemorrhagic conditions).

Phlebitis (inflammation of a vein).

⚠Environmental conditions of storage and operation

Temperature-range: -10-50ºC
Relative humidity: 10-95% non-condensing
Air pressure-range: 700-1060 hPa

Opening the enclosure by unauthorized person may invalidate warranty. Modification of the ME equipment can only be performed by the manufacturer. In case of problems contact a professional repair shop.

3 Main functions

3.1 Main parts of the ABP Monitor

Front view

Rear view

3.2 Signs and alarms of ABP

The recorder contains a single RGB LED which with you can indicate several colours and hues.

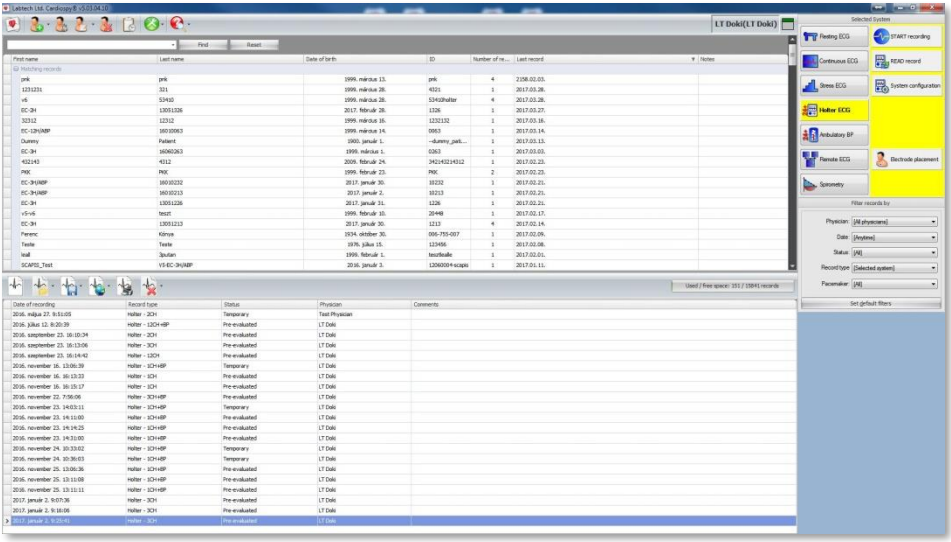
Light signal	Description	What should we do?
The LED light is red.	Hardware error.	After detecting the hardware error the devicewaits a few seconds and restarts automatically. If it does not then you need to restart the recorder byreplacing the batteries. If the problem still occurs it requires repairing.
The LED is red and flashing.	The battery has run out.	Battery exchange is required.
The LED light is green.	The recorder connects to the PC through the USB data transfer cable and it works properly.	-
Thegreen LED light flashes quickly.	The recorder connects to the PC through the USB data transfer cable and there is data transfer between the PC and the recorder. The rhythm of the flashing is synchronized with the rhythm of data transfer.	-
The green LED seldom flashes	The recorder is ready to start recording (doesn't contain any unread records, the self-test and initialization was	-

Light signal	Description	What should we do?
	successfully completed).	
The yellow LED flashes.	The device is recording.	-
Thecrimson LED flashes	The recorder contains unread record.	You need to read the last record from the recorder, otherwise you cannot start the next record and the device won't turn on the Bluetoothmodule.
The Blue LED seldom flashes	There is Bluetooth connection between the PC and recorder.	-
The Blue LED flashes quickly	There is data transfer between the PC and recorder.	-

The recorders include a buzzer which can operate in different frequencies. By this the recorders are able to indicate the different statuses and errors.

Sound signal	Tone	Description
One high-pitched short beep	•	Event button is pressed on the recorder or on the PC (Start/Stop BP).
One short beep in deep voice	o	The device was removed from the USB.
One high-pitched long beep	●	Start of recording.
		Stop of recording.
The recorder beeps for some seconds on a high-pitched voice.		Hardware error.
Two high-pitched short beep	••	Cannot start recording (no patient data).
		Event button is pressed, but there is no function related to pushing the button in the current state of the recorder (for example: the recorder connects to the USB).
Two short beep in deep voice	oo	The device has been connected to USB.
Two short beep with rising melody	o•	Bluetooth connection has been created.
Two short beep with descending melody	•o	Bluetooth connection has beenbroken.
Three high-pitched short beep	•••	After the battery was put in the initialization, self-test was successfully completed.
Four high-pitched short beep	••••	Discharged battery.

3.3 Database management interface



The database management interface enables us to add physicians and patients by name and ID number (e.g., social security number), which can be sorted and filtered according to different criteria. The interface also offers a search option by name or ID. The database management interface displays the list of patients and the pertaining number of records. Here we can view previous records and start new recordings as well.

3.4 Toolbar

The toolbar contains different buttons which provide access to the most often used functions in the software.

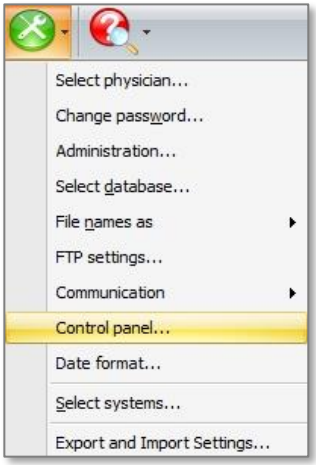
New patient: Here you can add new patients to the list. Patient's first and last names, date of birth and patient IDs are fields which need to be filled in. The software allows only unique patient IDs to be entered into the database, which is the reason why it is recommended to use this field for entering the social security number of each patient (or any other code which uniquely identifies a person). Entering address, weight and height is optional when registering a patient.

Modify: Patient data can be edited by clicking on the Modify button. The interface allows every field to be edited except patient ID (social security number)

Medical record: This function gives a summary about the medical record. This summary can be edited and we can also add explanations and observations.

Delete: Click on the Delete button for deleting patients. When patient is deleted, all of its corresponding records are deleted as well. After deleting, there is only one way to restore data. If the "Move deleted records to recycle bin" option is turned on (Settings/Administration/Settings) you can restore the deleted record from the "Record recycle bin". We suggest you to turn this function before you start using the software to prevent data loss.

3.4.1 Settings:

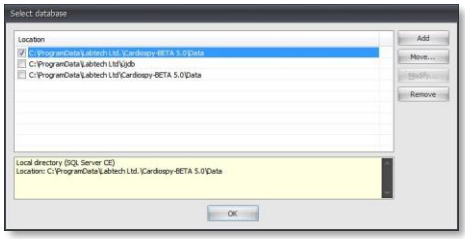


- **Select physician:** In this menu the physician, who is performing the current test, can login to the software and also select to view the records of other physicians whose records are not password protected.

- **Change password:** By selecting this option, the physician, who is performing the current test, can change his/her password.

- **Administration:** Here, we can manage the users and also the security settings and administrator rights can be set under this menu point. Further information on modifying user authorization can be found in **Cardiospy Installation and Update Guide.**

- **Select database:** In this menu, you can choose to create a new database or to use a different one. These databases operate independently of each other, so a patient who is created in one of them does not appear in another. The software always uses the database set for the previous operation.



Clicking on the "Add" button creates a new database.

If you need to work with a different one, then select it and click on "OK".

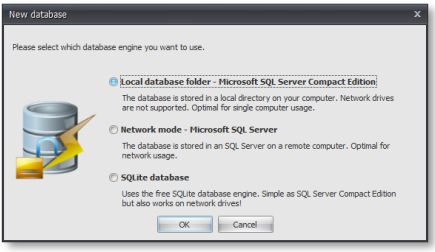
You can move a database to a different location with the "Move..." function.If the "Move…" operation is interrupted all the files will be restored in the original folder.

There are three possible ways to create a database:

Local database

Network mode - Microsoft SQL Server

SQLite database



Local database:

The database is stored in a local directory on your computer. Network drives are not supported.

It is optimal for single computer usage. Select the directory for the database and it is ready.

Network mode - Microsoft SQL Server:

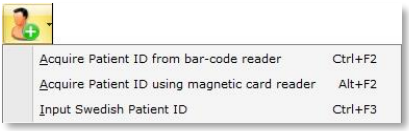
Please ask for help from your administrator.

SQLite database:

You can find its description in the **Cardiospy Installation and Update Guide**.

- File names as: Theorder of first and last name can be set in this menu.

- Input devices: Barcode readers and magnetic card readers can be set here.



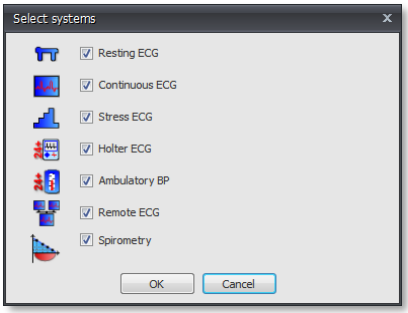
- FTP settings: You can find its description in the **Cardiospy Installation and Update Guide**.

- Communication: You are able to communicate through HL7 between Cardiospy and external software. To setup this, ask your local distributor and administrator.

- Select systems:

Here, you can enable / disable systems that you want / do not want to use.

You can activate or deactivate a system by ticking or un-ticking the checkbox next to the name of it.



3.4.2 Help

- Installation and update guide: The guide on software installation and system configuration also contains a description of the software update process.

- User manual: First of all, choose the system in the Select systems panel. Once you click on User manual button, the user manual of the currently selected system will appear.

- What's new: The novelties of the current software version can be found in this file.

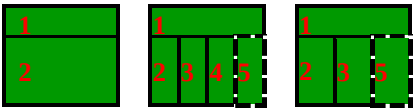
- Languages: The software offers a choice of several languages, from which you can select the one you wish to work in.

- Multilanguage translator: With this function, the user is able to translate each term which appears in the software into the desired language. A password is necessary to enter this menu point. In case you would like to use this function, ask your distributor for the password.

- About: Information about the software version, the operating system and the copyrights can be found here.

- Device Connection Status Indicator: This indicator shows thecurrent connection status of the devices (the USB-02 interface, the ECG recorder, the blood pressure monitor and the stress device).

The Device Connection Status Indicator has three types: the first one is used with the Holter, ABP and Resting Test systems. The second type is used with the Stress Test systems, and the third type with the Continuous ECG systems.



1. Status of Bluetooth or direct connection

2. Status of connection with Holter ECG recorder /ABP recorder / Resting ECG recorder / Test ECG recorder

3. Status of connection with blood pressure monitor

4. Status of connection with loading machine

5. Status of connection with Pulse Oximeter (this section is only available when Pulse Oximeter is activated under System Configuration menu).

Colour codes for the ECG Devices Connection Status Window:

Green - The device is properly connected

Yellow - Manual operation, the device is not connected to the computer

Red – No connection with the device

Grey – No connection is needed for recording

3.4.3 Records toolbar

This is a toolbar for managing existing records.

Load record: Opens the selected record from the list. Once the record is open we can edit, analyze or print it.

- Import: There are three methods to import records:

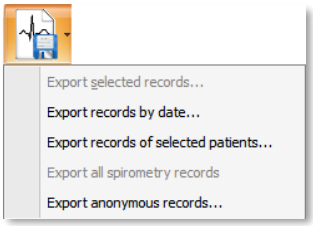
Import records: With this function we can import records from a directory of our choice.

Import records by date: You can import records from an existing folder within a date interval.

Import sample data: It is only working if you have the installation DVD inserted into the PC. This function will import demo records from it into your database.

The imported records are automatically saved into the current database.

- Export: In this menu point we can save the current record to an existing folder of our choice. This directory can also be on a network drive or on a portable drive (e.g., USB stick).



There are five methods to export records:

Export selected records: If you have single or multiple records selected, then you can export them with this function.

Export records by date: You can export records to an existing folder within a date interval.

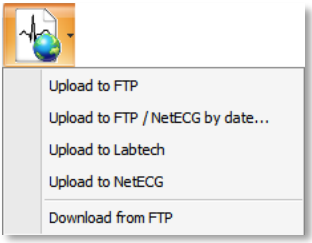
Export records of selected patients: If you have a single or multiple patients selected, then you can export all of their records at once.

Export all spirometry records: With this function, you are able to export spirometry records.

Export anonymous records: You can export records without the personal data of the patient.

- FTP - upload and download:

To set an FTP server, please check **Cardiospy Installation and Update Guide**.



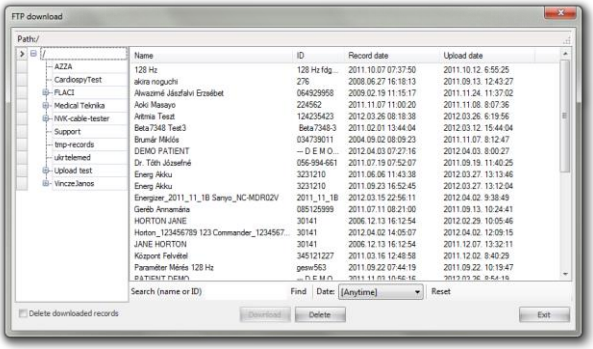
Upload to FTP: We can select multiple records from a single patient and upload them to the currently connected FTP server.

Upload to FTPby date: You can upload records within a date interval.

Upload to Labtech: In case you have any problem with the records, then you can upload them to the Labtech server.

Furthermore, you have the possibility to automatically upload records to FTP. You can enable it in the "System configuration" / "Settings" menu.

Download from FTP: We can download records from the currently connected FTP server. You can select multiple records to download at the same time.



- Print rest records by date: You are able to print every Rest record of the selected physician within a date interval.

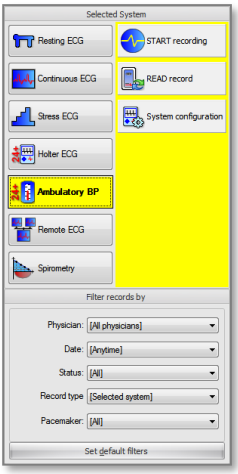
- Delete records:

Delete selected record: This buttons deletes every selected record from the database. You can only restore them from the record recycle bin (if it is enabled in the settings). You can enable it in the Administration / Settings by set "Move deleted records to recycle bin" to "Yes".

Delete records by date: It deletes every record within a date interval.

Delete all records: It deletes every record.

3.4.4 Selected System



Here you can select the ECG systems you wish to use, configure systems, add new recorders before you start recording. You can also start Demo recording in this field. Please keep in mind that a demo recording can only be started if the USB-02 device is not connected to the PC.

3.4.5 Filters

This field provides a few filters which enable the filtering of records by different criteria.

You can filter records by:

- **Physician:** You can filter the database to show records made by the selected physician only.

- **Date:** When this filter is used, you can only see the records that were made today / in the last 2 days / in the last 7 days / this month / this year.

- **Status:** You can filter records by their current status (Temporary, Pre-evaluated, Evaluated, Approved).

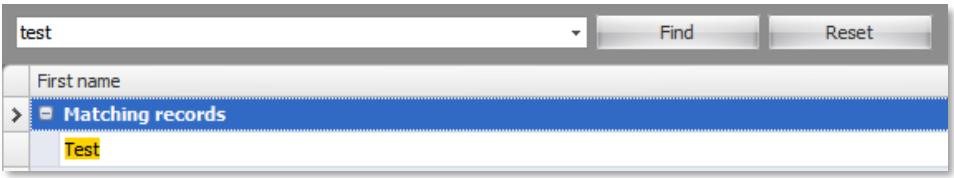
- **Record type**: You can filter records by device types.

- **Pacemaker:** You are able to filter records with or without pacemaker.

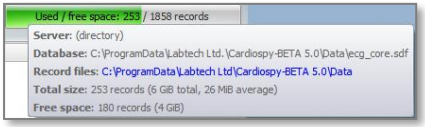
By default, no filter is enabled, the database shows every records.

3.4.6 Search

In this search-bar you can filter patients by typing characters that matches any of the patient's personal data.



3.4.7 Database information



Hover the mouse over the disk space info bar between the patient and record list and a small field appears which contains general information about the database, such as access path, number and size of records contained, etc.

3.5 How to start a new recording?

3.5.1 Patient preparation

3.5.1.1 *Attach the cuff to the patient's arm*

It is important to select the cuff size that is appropriate for the diameter of the patient's upper arm.

The cuff may be worn over a thin shirt, without compromising accuracy or performance. However, it is recommended that the cuff be secured using the cuff anchor.

Ensure the air hose from the monitor to the cuff is not compressed, crimped or damaged.

⚠ Please remember that using the wrong cuff size may result in inaccurate readings.

3.5.1.2 *Attach the adhesive cuff anchor*

With the patient cable draped over the patient's shoulder, attach an adhesive cuff anchor to the snap on the hose of the cuff bladder.

Do not remove the adhesive backing of the cuff anchor at this time.

3.5.2 New Recording

First of all, you have to connect the device to the PC, the software will read the record (that was made at the final measurement) in from the device automatically and open the record viewer.

You can read about how to read a record in the CHAPTER 3.6. You can start recording only from the database screen.

If you already have your device(s) registered in the list of the recorders, then you can start to work with it/them.

BEFORE STARTING A NEW RECORDING, YOU HAVE TO READ THE PREVIOUS RECORD FROM THE DEVICE

You can start a new recording in three possible ways:

- *Via Bluetooth*: By this way, you can start a test BP measurement, then start the recording from the PC, while the recorder is already attached to the patient. The patient data is automatically programmed to the device.

- *Via USB cable:*This way you do not have the ability to start a test BP measurement, but it makes the process quicker. You have to start the recording by pushing the "Event button" on the device for 3 seconds after programming the patient data to it.

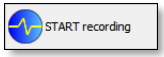
- *Without prespecified patient data:*This method is used in big hospitals where you have to start recording as quickly as possible. This way you do not have to go through the patient data programming process at the start. You can start recording by pushing the "Event button" on the device for 3 seconds. You have to register the patient while reading the record from the device.

3.5.2.1 *Start recording via Bluetooth*

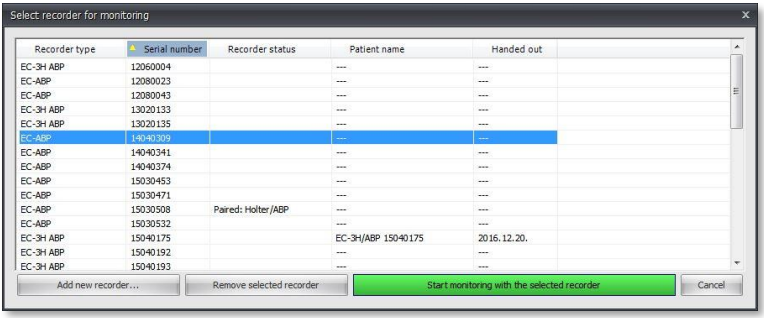
To start a new recording via Bluetooth connection, please follow these steps:

1. Make sure the USB-02 dongle is connected to the PC and working properly.

2. Make sure the Ambulatory BP system is selected at the Selected System menu.
3. The device **must not be connected** to the PC.
4. Add or Select a patient who you want to examine.
5. At the Selected System / Ambulatory BP menu, click on "START recording".



6. Select the device from the list with the proper serial number and then click on the "Start monitoring with the selected recorder" button.



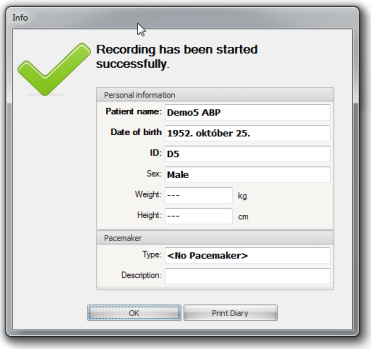
7. In the next window, you can set the measuring parameters for the recording. For further information about the "Holter Monitoring Settings" window, please checkCHAPTER 3.5.3. After you are done with the settings, click on the "Start monitoring" button.

8. Here, you can start a test BP measurement by clicking on the "Start BP" button.

9. From this point, you can continue the process two ways:

a. Start the recording from the software:

1. If you are satisfied with the result, you can start the recording by clicking on the "YES, START recording" button.
2. After you have started the recording successfully, a new window will pop up in which you can print the patient diary.



3. If the device is started to recording successfully, then the LED on it should flash in yellow colour and you can hear one high-pitched long beep.

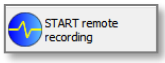
a. Start recording remotly from the device:

1. If you want to continue this way, then click on the „Cancel" button.
2. Hold the "Event button" on the recorder for 3 seconds to start recording.
3. If the device is started to recording successfully, then the LED on it should flash in yellow colour and you can hear one high-pitched long beep.

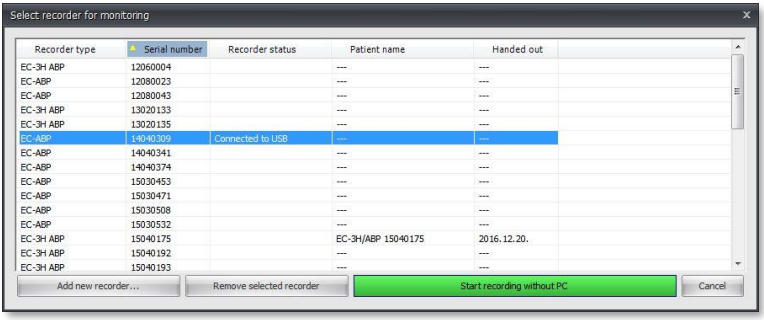
Please check CHAPTER 3.6about how to read a record.

3.5.2.2 *Start recording via USB cable*

1. Make sure the Ambulatory BP system is selected at the Selected System menu.
2. The device **must be connected** to the PC.
3. Add or Select a patient who you want to examine.
4. At the Selected System / Ambulatory BP, click on "START remote recording".



5. Select the device from the list with the proper serial number and then click on the "Start recording without PC" button.



6. In the next window, you can set the measuring parameters for the recording. For further information about the "Holter Monitoring Settings" window, please check CHAPTER 3.5.3. After you are done with the settings, click on the "Start recording" button.

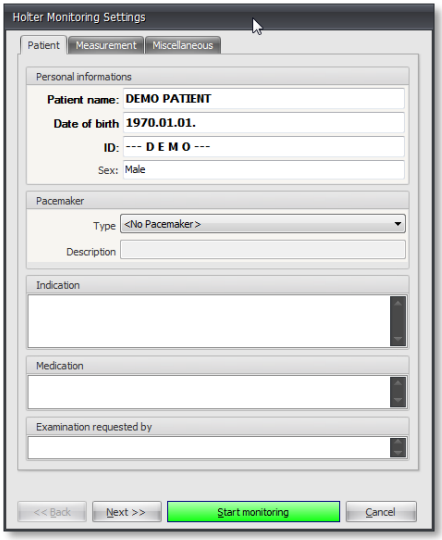
7. After the successful programming, a new window will pop up in which you can print the patient diary.
8. Hold the "Event button" on the recorder for 3 seconds to start recording.
9. If the device is started to recording successfully, then the LED on it should flash in yellow colour and you can hear one high-pitched long beep.

10. Please checkCHAPTER 3.6about how to read a record.

3.5.2.3 *Start recording without prespecified patient data*

1. To make this work, you have to enable an option in the Settings / Control Panel / Reading and recording settings. Tick the checkbox next to the "Enable Holter recording without prespecified patient data" text and then click "OK".
2. Connect the device you wish to use to the PC.
   a. If you have not worked with this device before, please follow the instructions in CHAPTER 3.5.2.1 or CHAPTER 3.5.2.2 and then start this process over from point 2/b.
   b. If it has a record in it, the Cardiospy will read it first. This way the software will automatically be programmed as a "dummy patient" with the last measuring settings.For further information about the "Holter Monitoring Settings" window, please check CHAPTER 3.5.3.
3. Disconnect the device from the PC.
4. Hold the "Event button" on the recorder for 3 seconds to start recording.
5. If the device is started to recording successfully, then the LED on it should flash in yellow colour and you can hear one high-pitched long beep.
6. Please check CHAPTER 3.6 about how to read a record.

3.5.3 Measurement settings



Patient tab: When starting a new recording, there is an opportunity in the software to enter the name of the doctor who requested the examination, the medication and the symptoms of the patient. The information will be stored if you read it on a PC.

At the **Measurement tab** you can find the settings of the awake period that you can also modify after the record was read. You can also set the frequency of the BP measurement the maximum pressure of the cuff and right after the output of the recorder it is able to measure.

Miscellaneous tab: Here you can disable to load the record after reading (on by default).

3.5.4 Informing patient about batteries and further instructions

Note that the patient can safely change the batteries at any time.The recording will continue until the device runs out of memory or connected to the PC for reading.

Please also provide the following instructions to your patient:

- The patient can mark events (e.g. exercising, feeling pain or nausea, etc.) by the "Event button", so the doctor can measure the ECG and BP values at these times.
- The patient can stop a BP measurement in progress by pressing the Event button. Starting a BP measurement is also possible at any time with this button.
- When the pressure in the cuff increases, the patient should avoid excess movement. Let the instrumented arm hang loosely, slightly away from the body. Avoid flexing the muscles or moving the hand and fingers of the instrumented arm.
- While sleeping, the patient should make sure that the hose is not crimped.
- Inform the patient on how and when to fill out the patient diary.
- If the device or cuff causes extreme pain or pain not normally associated with blood pressure measurement, the patient should remove the cuff and stop the measuring.

3.6 How to read a record?

The recording stops automatically if the device runs out of memory or connected to the PC for reading.

During recording it is possible to replace flat batteries. The recording will continue.

It is advisable to remove the batteries first and then the cables from the electrodes.

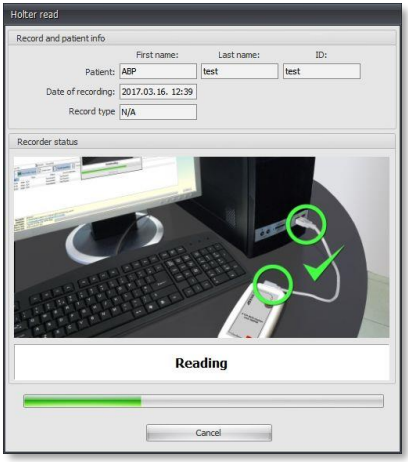
For reading a record, please follow the steps below:

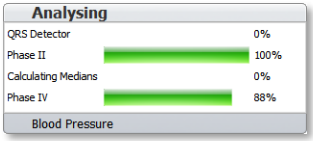
3.6.1 In case of normal records (via USB cable or Bluetooth)

1. Take off the recorder-case from the patient, remove the batteries and then remove the cuff from him/her.

For faster reading process, please place fully charged batteries into the device before you connect it to the PC.

2. Start the Cardiospy program on the computer. Then select the Ambulatory BP system.
3. Connect the recorder to the USB reader cable. The reading will start automatically (by default).
4. After the software finished with the reading, the "Record viewer" window will appear where you can analyze and evaluate the record.
5. If the automatic analyzing is enabled (see CHAPTER 4.2.6.4), an analyzing process will be performed.





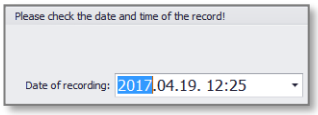
6. Now you can start to examine and edit the record. See CHAPTER 4.

3.6.2 In case you have started the recording without prespecified patient data

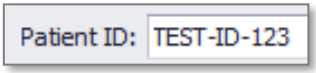
1. Take off the recorder-case from the patient, remove the batteries and then remove the cuff from him/her.

For faster reading process, please place fully charged batteries into the device before you connect it to the PC.

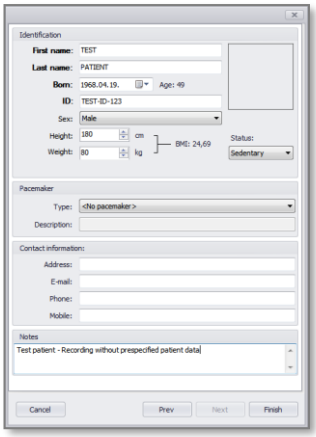
2. Start the Cardiospy program on the computer. Then select the Holter system.
3. Connect the recorder to the USB reader cable. The reading will start automatically (by default).
4. Since the recorder was started without prespecified patient data, thus you have to fill the personal data at the beginning of the reading process in a pop-up window.



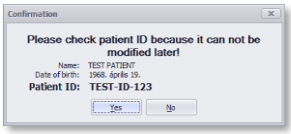
5. Since the recording was started without any PC connection, you have to verify the date and time when the recording was started.



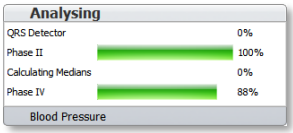
6. Click “Next” and then type the ID of the patient.
7. Click “Next” again and then fill the personal data of the patient.



8. Click “Finish”. A confirmation window will pop up.



9. After the software finished with the reading, the “Record viewer” window will appear where you can analyze and evaluate the record.

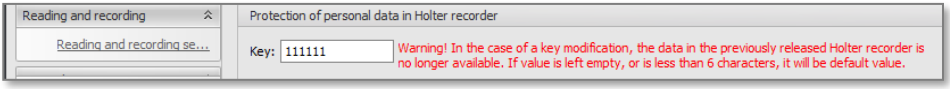


10. If the automatic analyzing is enabled (see CHAPTER 4.2.6.4), an analyzing process will be performed.
11. Now you can start to examine and edit the record. See CHAPTER 4.

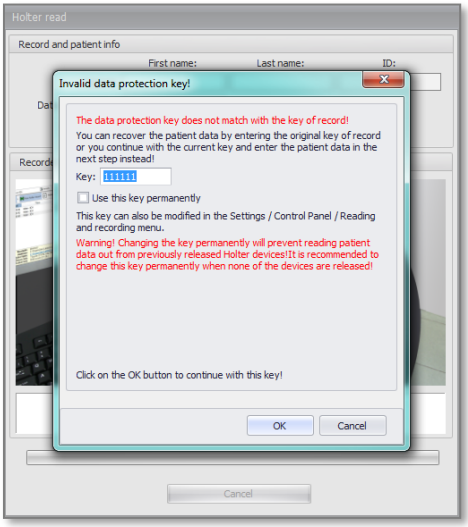
3.6.3 Patient data protection

From 25 May 2018, a new General Data Protection Regulation (GDPR) was enforced. For this reason, our analysing software (Cardiospy) was improved to meet the necessary expectations. Since every Holter record contains patient data in order to be able to recover it at the reading phase, the data must be encoded to prevent it to be used by unauthorized persons.

The encoding works based on an encoding key, which is automatically created at the first usage of Cardiospy (6 digits random number), but it can be modified in the Settings / Control panel / Reading and recording menu.



To sum the above, you can only recover the original patient data from a record, if you are using the same encoding key in your software (that same key which was used for starting the recording), otherwise, you will get a pop-up window, that your key is invalid and you will be prompted to enter the patient data manually.



As you can see, the current key - "111111" - is invalid, because the record was started on another computer, where the code was different from "111111".

You can continue to read the record by clicking on the OK button, but as it was mentioned above, you will be prompted to enter the patient data manually. Works the same way as the method used in CHAPTER 3.6.2.

You can only recover the original patient data, if you enter the original key into the "Key" field. If you modify its value, you have the opportunity to decide if you want to use the new key permanently or to just use it once and leave the current key in your settings. To save the new key permanently, tick the "Use this key permanently" checkbox!

If you have successfully entered the original data and you click on the OK button, then the record will be read with the original patient data automatically - without re-entering it. Cancelling this window will stop the reading process.

It is **always recommended to save your key**, so in that case you have to move your Cardiospy to another PC, you will still be able to read your pending records without any inconvenience.

However, it is especially necessary to know the function of this key when you are using the recorders on multiple computers:

- Start recording on a PC, then read the record on another PC.
- Star recording on multiple PCs, then read them on a single or on multiple computers.

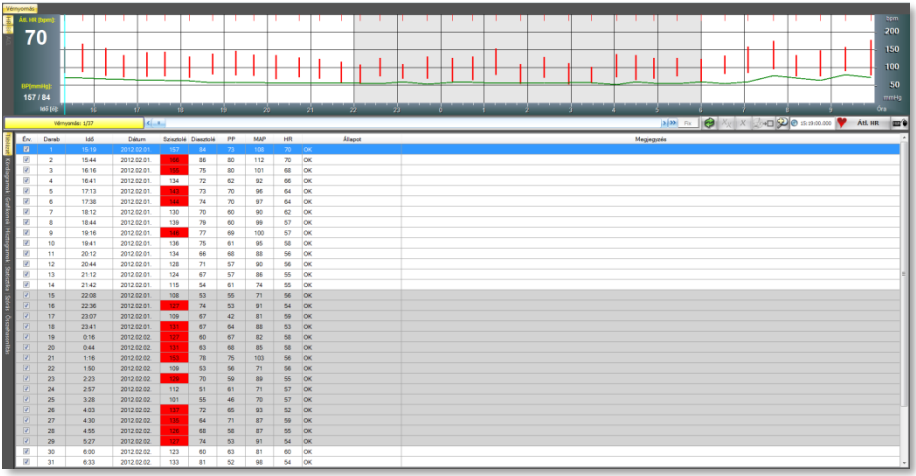
In that case where you are using multiple computers in a system, you will have to set the same protection key for every computer (in Cardiospy) to be able to read the records with the original patient data.

The data protection key itself only affect recorders where the patient data is actually stored on the device: **EC-ABP, EC-2-3-12H, EC-3H/ABP**.

4 Analysis with Cardiospy software

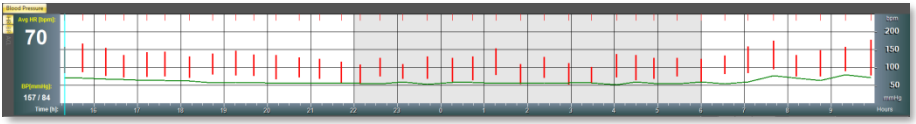
4.1 Views

This chapter provides information on the functions of the Cardiospy software regarding Blood Pressure analysis.



4.1.1 HR, BP graph

The graph presents Heart Rate and Blood Pressure measured by the ABPM device.

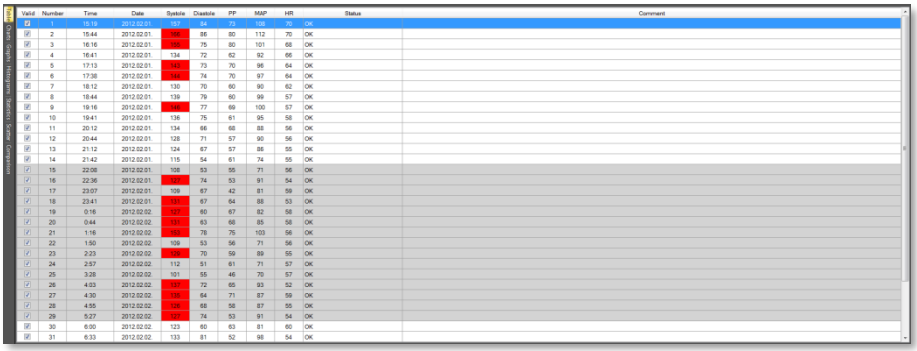


The green line is showing the Heart Rate and the red marks are showing the BP measurements.

4.1.2 Table

The table displays all the BP results in a chronological order. We can validate / invalidate each result by ticking / unticking the relevant checkbox in the column marked “Valid”.

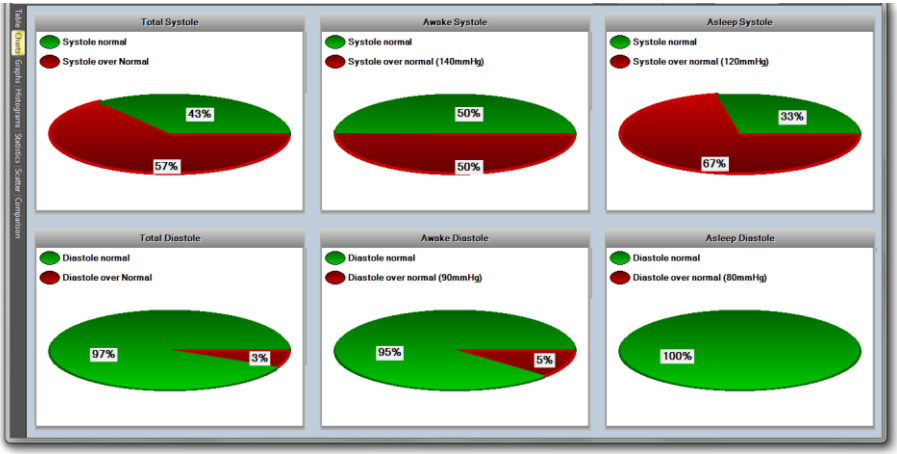
We can add short remarks to each measurement in the Comment column (double click).



Valid	Number	Time	Date	Systole	Diastole	PP	MAP	HR	Status	Comment
☑	1	15:19	2012.02.01.	157	84	73	108	70	OK	
☑	2	15:44	2012.02.01.	166	86	80	112	70	OK	
☑	3	16:16	2012.02.01.	150	75	80	101	68	OK	
☑	4	16:41	2012.02.01.	134	72	62	92	66	OK	
☑	5	17:13	2012.02.01.	143	73	70	96	64	OK	
☑	6	17:38	2012.02.01.	144	74	70	97	64	OK	
☑	7	18:12	2012.02.01.	130	70	60	90	62	OK	
☑	8	18:44	2012.02.01.	139	79	60	99	57	OK	
☑	9	19:16	2012.02.01.	146	77	69	100	57	OK	
☑	10	19:41	2012.02.01.	136	75	61	95	58	OK	
☑	11	20:12	2012.02.01.	134	66	68	88	56	OK	
☑	12	20:44	2012.02.01.	128	71	57	90	56	OK	
☑	13	21:12	2012.02.01.	124	67	57	86	55	OK	
☑	14	21:42	2012.02.01.	115	54	61	74	55	OK	
☑	15	22:08	2012.02.01.	108	53	55	71	56	OK	
☑	16	22:36	2012.02.01.	145	74	53	91	54	OK	
☑	17	23:07	2012.02.01.	109	67	42	81	59	OK	
☑	18	23:41	2012.02.01.	131	67	64	88	53	OK	
☑	19	0:16	2012.02.02.	127	60	67	82	58	OK	
☑	20	0:44	2012.02.02.	131	63	68	85	58	OK	
☑	21	1:16	2012.02.02.	153	78	75	103	56	OK	
☑	22	1:50	2012.02.02.	109	53	56	71	56	OK	
☑	23	2:23	2012.02.02.	132	70	59	89	55	OK	
☑	24	2:57	2012.02.02.	112	51	61	71	57	OK	
☑	25	3:28	2012.02.02.	101	55	46	70	57	OK	
☑	26	4:03	2012.02.02.	137	72	65	93	52	OK	
☑	27	4:30	2012.02.02.	135	64	71	87	59	OK	
☑	28	4:55	2012.02.02.	126	68	58	87	55	OK	
☑	29	5:27	2012.02.02.	127	74	53	91	54	OK	
☑	30	6:00	2012.02.02.	123	60	63	81	60	OK	
☑	31	6:33	2012.02.02.	133	81	52	98	54	OK	

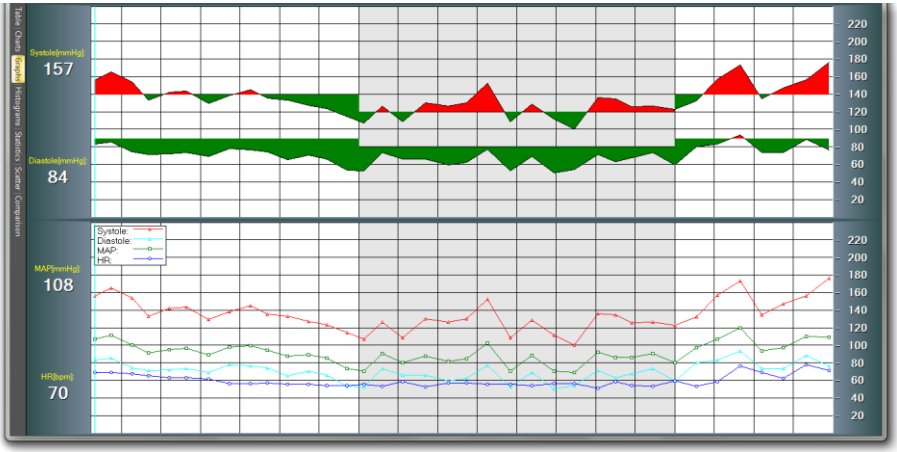
4.1.3 Charts

The software represents systole and diastole values in the form of pie-charts.



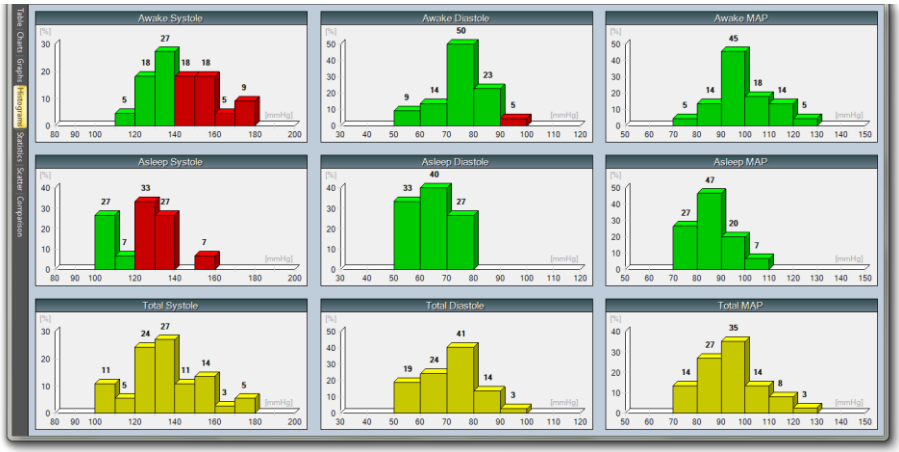
4.1.4 Graphs

The software shows BP burdens in the upper graph, while in the second graph Systole, Diastole, MAP and HR values are displayed.



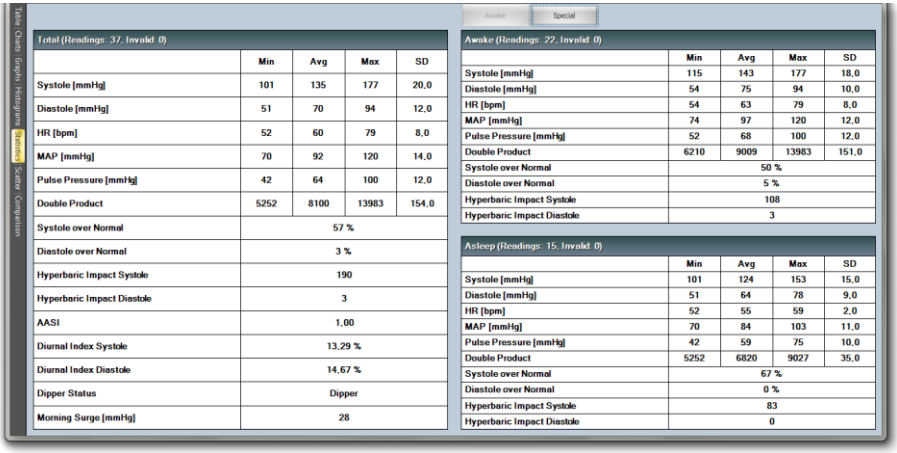
4.1.5 Histograms

In this part Systole, Diastole and Map values are represented in the form of histograms.



4.1.6 Statistics

Statistical parameters calculated from the validated Blood Pressure and Heart Rate values are shown in a table format.



Total (Readings: 37, Invalid: 0)

	Min	Avg	Max	SD
Systole [mmHg]	101	135	177	20,0
Diastole [mmHg]	51	70	94	12,0
HR [bpm]	52	60	79	8,0
MAP [mmHg]	70	92	120	14,0
Pulse Pressure [mmHg]	42	64	100	12,0
Double Product	5252	8100	13983	154,0
Systole over Normal	57 %			
Diastole over Normal	3 %			
Hyperbaric Impact Systole	190			
Hyperbaric Impact Diastole	3			
AASI	1,00			
Diurnal Index Systole	13,29 %			
Diurnal Index Diastole	14,67 %			
Dipper Status	Dipper			
Morning Surge [mmHg]	28			

Awake (Readings: 22, Invalid: 0)

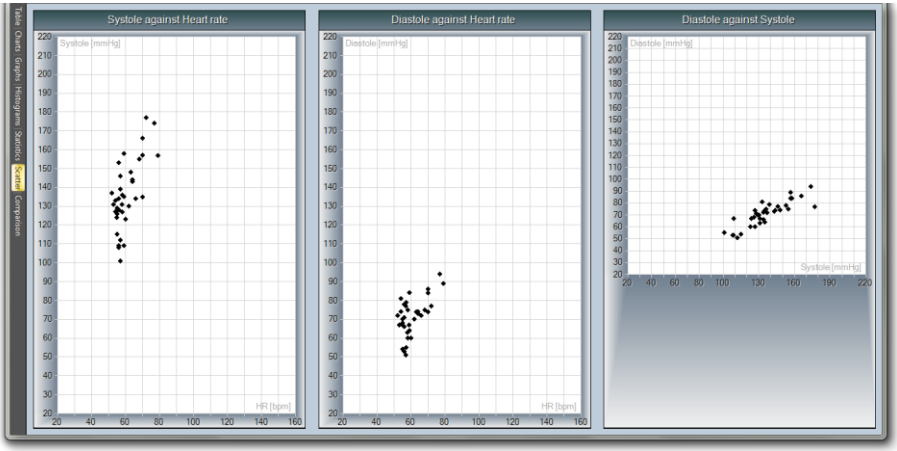
	Min	Avg	Max	SD
Systole [mmHg]	115	143	177	18,0
Diastole [mmHg]	54	75	94	10,0
HR [bpm]	54	63	79	8,0
MAP [mmHg]	74	97	120	12,0
Pulse Pressure [mmHg]	52	68	100	12,0
Double Product	6210	9009	13983	151,0
Systole over Normal	50 %			
Diastole over Normal	5 %			
Hyperbaric Impact Systole	108			
Hyperbaric Impact Diastole	3			

Asleep (Readings: 15, Invalid: 0)

	Min	Avg	Max	SD
Systole [mmHg]	101	124	153	15,0
Diastole [mmHg]	51	64	78	9,0
HR [bpm]	52	55	59	2,0
MAP [mmHg]	70	84	103	11,0
Pulse Pressure [mmHg]	42	59	75	10,0
Double Product	5252	6820	9027	35,0
Systole over Normal	67 %			
Diastole over Normal	0 %			
Hyperbaric Impact Systole	83			
Hyperbaric Impact Diastole	0			

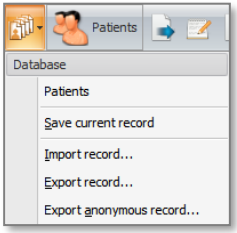
4.1.7 Scatter

In this function, the cohesive systole-HR, diastole-HR and Systole-Diastole points are displayed.



4.2 Toolbar

4.2.1 Database



From this menu, you can go back to the patient database, save the current record (it is recommended if you have made changes in it), import and export record (even anonymously).

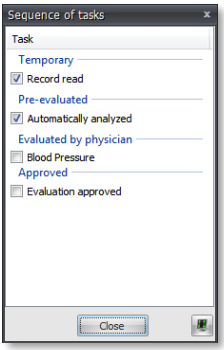
You can go back to the patient database more quickly with this button.

4.2.2 Report

By selecting the Report menu a text box appears in which you can write remarks. When pressing the 'Import Automatic Report' button both patient's data and the automatic report of the program will be copied to this page. If you have filled the Indication and the Medication box when you set up the measurement settings then the content of the symptoms and medication fields will be imported to the report, as well. The doctor's name will be imported to every report's letterhead.

In the Print View, you will see the content of the Report as a new sheet "Report".

4.2.3 Sequence of tasks



In this menu, you can follow through the whole operation from reading in to the approving of the evaluated record.

When you have finished examining the Blood Pressure measurements, you can tick the checkbox next to its name to mark the record as "Evaluated".

After you finished with the evaluating, you can mark the record as "approved", so it cannot be edited from then, until you untick the checkbox next to it.

4.2.4 Print

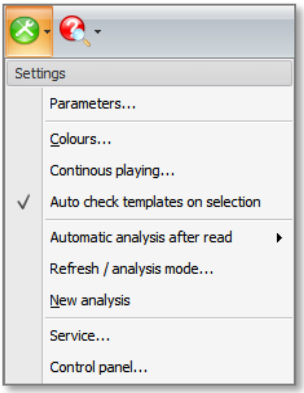
In this menu we can go through all the reports prepared by the software and print them separately.

4.2.5 Export

In this menu we can go through all the reports prepared by the software and export them separately (JPG, BMP, PDF, etc).

You can learn more about print / export and its settings in CHAPTER 5.

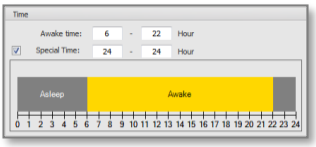
4.2.6 Settings



In this menu it is possible to set the various parameters of the program, such as parameters relevant to the analysis, colours of the screen, graphs to be displayed in the Main/Events menu, etc.

4.2.6.1 *Parameters...*

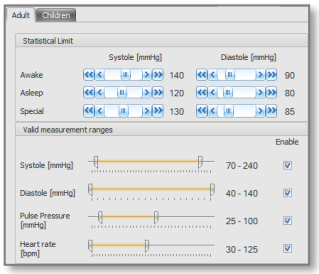
Time:



Here, you can change the “Awake” and the “Special time”. E.g. you can set when the patient was asleep if you set the parameters of the “Awake” time to the beginning and the end of the sleeping period.

Blood Pressure:

Here we can set parameters used for statistical calculations and measurement ranges used for automatic pre-filtering. Limits for children and adults can be adjusted separately.



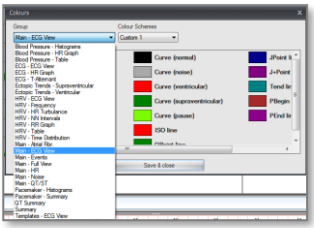
<u>Statistical Limit:</u>

You can set the normal systole and diastole limits in every interval separately (awake, asleep and special). If the patient’s result exceeds this limit the software indicates that it is in a high range (with red colour).

<u>Valid measurement ranges:</u>

The program’s analysis accepts BP values within these ranges. If the results of certain measurements are outside of this range the software takes the measurements out of the evaluation and marks them as invalid.

4.2.6.2 *Colours...*

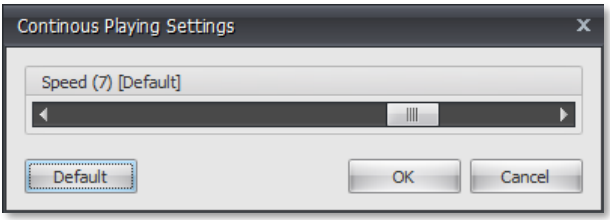


In this window, you can create your own custom colour schemes for the Cardiospy's looking or you can use the default ones. The default schemes cannot be modified.

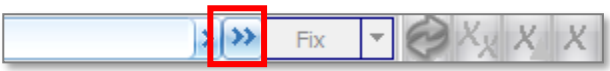
You can set the colour of the windows and menus separately by any way you want, since you can change almost every element of the software (like curves, background, ruler, QRS mark, etc.)

4.2.6.3 *Continuous playing...*

It is possible to modify the speed of continuous playing of the Holter ECG records. Setting>continuous playing menu>select the proper speed from 1 to 9.



You can play the record with this button next to the scrollbar at the middle of the screen.



4.2.6.4 *Automatic analyzing after read*

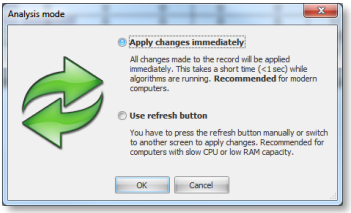
There are 3 options that you can set here: "Never", "Ask every time" and "Always".

Never: If you read in a record from the device, then it will be stored in the database, but the software is leaving it unfiltered and the analyzing process will not be performed.

Ask every time: If you read in a record from the device, then a prompt window will pop up every time about if you want to perform the analyzing process or not.

Always: This is the default option. The software will always perform the analyzing process.

4.2.6.5 *Refresh / Analysis mode...*



Apply changes immediately: The software runs the automatic analysis every time we edit the record, this way we'll see the results on the screen immediately. This function is only recommended for modern and fast computers.

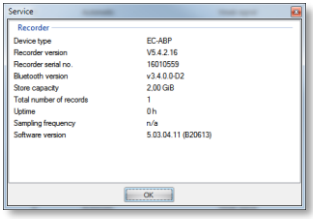
Use refresh button: The software does not run the automatic analysis each time the record is edited, the analysis only runs when the user presses the refresh button or change the screen. It is recommended for computers with slow CPU or insufficient RAM. Refresh button can be found in the middle of the screen, next to the horizontal slide.

4.2.6.6 *New analysis*

With this menu point, you can run a new analyzing process. It is useful when you have a record that was not analyzed before, you have updated the Cardiospy from an old version recently or you want to start the measuring from the start.

BE CAREFUL, THE NEW ANALYZIS WILL DELETE ALL OF YOUR PREVIOUS CHANGES THAT YOU HAVE MADE MANUALLY!

4.2.6.7 *Service*



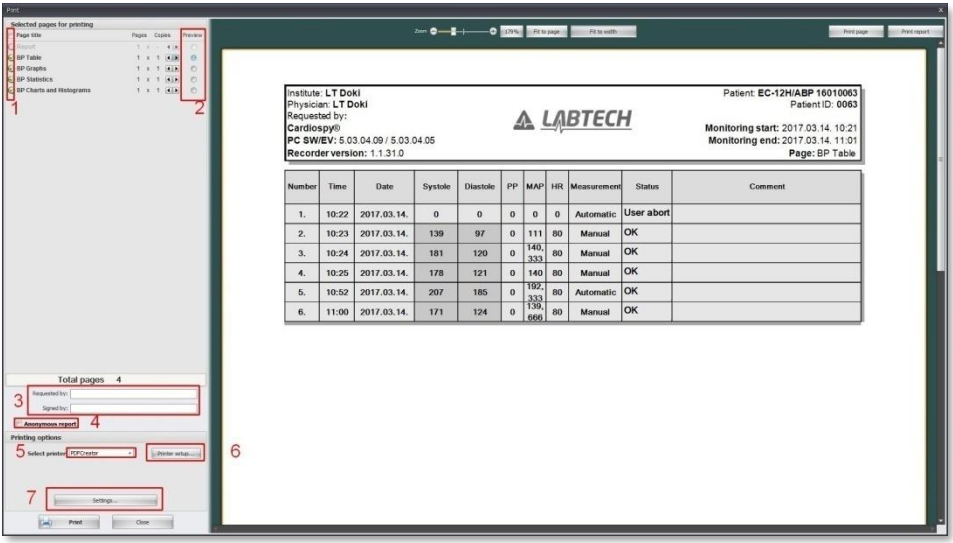
In this window, you can see information about the device that was used for the current record. You can see the device type, recorder version, recorder serial number, Bluetooth module version, story capacity, total number of records that was made with the device, uptime (total time of usage), previously defined sampling frequency and the current software version (if you have made the current record in an older version of Cardiospy, you will see its version number as well).

4.2.6.8 *Control panel...*

You can also open the Control panel, just like at the main screen (patient database). You can read more about the control panel in the **Cardiospy Installation and Update Guide**.

5 Print and export

5.1.1 Parts of the Print view

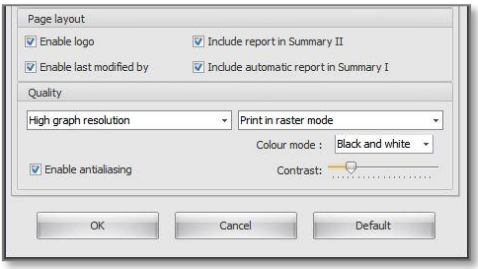


Number	Time	Date	Systole	Diastole	PP	MAP	HR	Measurement	Status	Comment
1.	10:22	2017.03.14.	0	0	0	0	0	Automatic	User abort	
2.	10:23	2017.03.14.	139	97	0	111	80	Manual	OK	
3.	10:24	2017.03.14.	181	120	0	140, 333	80	Manual	OK	
4.	10:25	2017.03.14.	178	121	0	140	80	Manual	OK	
5.	10:52	2017.03.14.	207	185	0	192, 333	80	Automatic	OK	
6.	11:00	2017.03.14.	171	124	0	139, 666	80	Manual	OK	

1. You can select the pages for printing by tick or untick the checkboxes next to the name of the pages.
2. You are able switch between the pages that you want to see with the radio buttons next to the name of the pages.
3. It is possible to type in the name of the doctor who is requested the examination and who signed the report.
4. With this checkbox you can hide the personal data of the examined patient, making the report anonymous.
5. Here you can select the printer you want to use from the list. First you have to set the printer in Windows to be able to choose it from here.
6. General printer settings. Number of copies, orientation, etc.
7. Print view settings. More in the next chapter.

5.1.2 Print view settings

General tab (only ABP related options)**:**



1. Enable logo: You can hide the logo from the header of the report.
2. Enable last modified by: If you have the "Report" page available, then you can make it visible or you can even hide it from the page.
3. Quality: You can set the quality of the printing to low or high graph resolution. You can set to print in raster or vectorgraphics mode.

"The major difference is that raster image pixels do not retain their appearance as size increases - when you blow a photograph up, it becomes blurry for this reason. Vector images do retain appearance regardless of size, since the mathematical formulas dictate how the image is rendered."

4. Colour mode: You can print in coloured and in black and white mode.

6 Calculation and Evaluation methods

6.1 General calculation methods

Pulse Pressure: $PPi = Sys_i - Dia_i$

Medium Arterial Pressure:

$$MAP_i = Dia_i + \frac{(Sys_i - Dia_i)}{3}$$

Diurnal Index: $\frac{Data_{(Awake,mean)} - Data_{(Asleep,mean)}}{Data_{(Awake,mean)}}$

Where Data: Sys, Dia.

Hyperbaric Impact: $24 * \frac{\Sigma_{(i=1)}^{N}(Data_i - Norm_i) * Time_i}{\Sigma_{(i=1)}^{N} Time_i}$

where $Data_i$: Sys_i, Dia_i

$Norm_i$ = the normal value related to the measurement (in Settings)

$Time_i$ =the represented time of the measurement

$$Time_i = \frac{(T_i - T_{i-1}) + (T_{i+1} - T_i)}{2}$$

where T_i = the time of the measurement

Double Product:

Double Product=Sys*HR

Dipper Status:

$$Dipper[\%] = 100 * \left(1 - \frac{Sys_{Asleep,mean}}{Sys_{Awake,mean}}\right)$$

Meaning:

Dipper	Dipper Status
< 0	Reverse Dipper
0-10%	Non-Dipper
10-20%	Dipper
>20%	Extreme Dipper

6.2 Morning Surge

Morning Surge is medically defined as the difference in systolic blood pressure during the first two hours after awakening and the lowest level recorded during the day. The greater the difference the more likely is the risk of stroke.

(Article Source: http://EzineArticles.com/3086388)

AASI (Ambulatory Arterial Stiffness Index)

AASI=1-Slope

where Slope = Diastole – Systole graph (Scatter) steepness of the regressive line.

6.3 Standard Interpretation

AHA

Learn what's considered normal, as recommended by the American Heart Association.

BLOOD PRESSURE CATEGORY	SYSTOLIC mm Hg (upper number)		DIASTOLIC mm Hg (lower number)
NORMAL	LESS THAN 120	and	LESS THAN 80
ELEVATED	120 – 129	and	LESS THAN 80
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 1	130 – 139	or	80 – 89
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 2	140 OR HIGHER	or	90 OR HIGHER
HYPERTENSIVE CRISIS (consult your doctor immediately)	HIGHER THAN 180	and/or	HIGHER THAN 120

NICE

Box 1. Hypertension stages

Stage 1 hypertension
Clinic blood pressure ≥140/90 mmHg and subsequent ambulatory blood pressure monitoring (ABPM) or home blood pressure monitoring (HBPM) average blood pressure ≥135/85 mmHg

Stage 2 hypertension
Clinic blood pressure ≥160/100 mmHg and subsequent ABPM or HBPM average blood pressure ≥150/95 mmHg

Severe hypertension
Clinic systolic blood pressure ≥180 mmHg, or clinic diastolic blood pressure ≥110 mmHg

ESC

Table 2.1 Classification of clinic blood pressure levels in adults

Diagnostic category*	Systolic (mmHg)		Diastolic (mmHg)
Optimal	<120	and	<80
Normal	120–129	and/or	80–84
High-normal	130–139	and/or	85–89
Grade 1 (mild) hypertension	140–159	and/or	90–99
Grade 2 (moderate) hypertension	160–179	and/or	100–109
Grade 3 (severe) hypertension	≥180	and/or	≥110
Isolated systolic hypertension	>140	and	<90

*When a patient's systolic and diastolic blood pressure levels fall into different categories, the higher diagnostic category and recommended actions apply.

Method of measurement	Systolic (mmHg)		Diastolic (mmHg)
Clinic blood pressure	≥140	and/ or	≥90
ABPM daytime (awake)	≥135	and/ or	≥85
ABPM night-time (asleep)	≥120	and/ or	≥70
ABPM over 24 hours	≥130	and/ or	≥80
HBPM	≥135	and/ or	≥85

ABPM, ambulatory blood pressure monitoring; HBPM, home blood pressure monitoring

7 Troubleshooting and maintenance

7.1 Sending a bug report

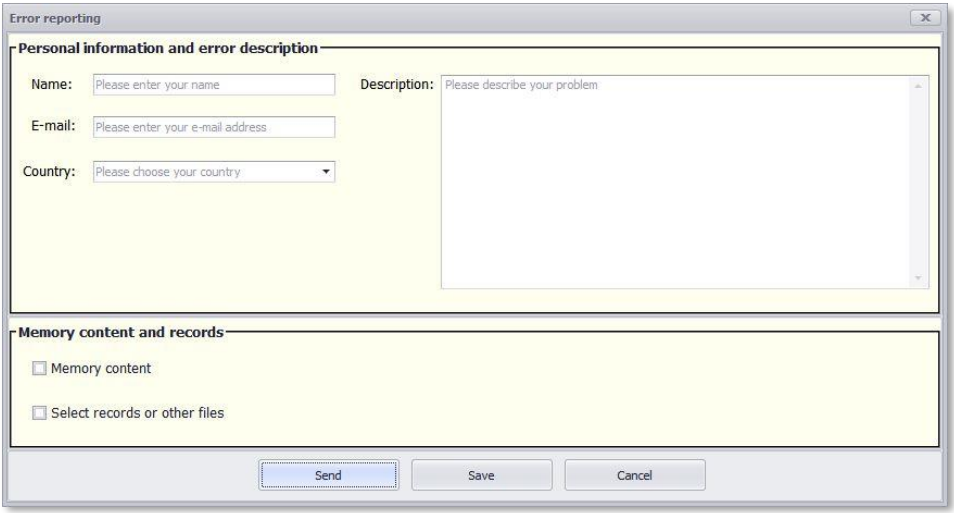
Creating Blackbox:

After the installation you can find a Generate black box shortcut under the Start Menu / Labtech / Cardiospy/. You can also reach this window from the Cardiospy, if you go into the Help / Bug report... menu.

Please fill the description based on your experiences with as much info as possible.

If you are ready to send us the bug report, then you can do it two ways.

1. If you click on the "Send" button, then the bug report will be automatically registered in our Issue Tracking System (Jira).
2. If you chose to save the blackbox file, please send it to our e-mail address. (develop@labtech.hu)



If you have problem with the recorder (you cannot read in for example), then connect the device to the PC and tick the "Memory content" checkbox.

If you exported the record files that you have problem with, you can attach them to the bug report by ticking the "Select records or other files" (like screenshots).

You can make screenshot withthe Print Screen button, then import it to Paint with CTRL+Vand save the file. The screenshots are important in that case you got an error message or to show in the record where you have problem with it.

7.2 Calibration and maintenance

7.2.1 Calibration

Calibration of the ABPM (blood pressure) has to be carried out from time to time as prescribed by the relevant standards. To ensure calibration is performed according to the relevant standards, please return the device to Labtech Ltd. where we will perform calibration free of charge.

The accuracy of controls is assured by using long lasting parts and techniques that are able to preserve their accuracy during the life cycle of the product.

7.2.2 Maintenance

Inspect every cable, pneumatic hose and the monitor case for cracks or fraying before each measurement. Do not use the monitor in case it shows any sign of damage.

The case of the recorder unit may be cleaned or washed if necessary. Do not immerse the monitor in any fluid, or attempt to clean with liquid detergents, cleaning agents, or solvents.

The quality of the batteries declines with time: it is recommended to switch to new ones after 6 months of usage.

Cleaningof the device

Do not dip the device in liquid, for cleaning the device use moistened wipes with a moderate acting (not aggressive) disinfectant or cleaning agent. Liquid getting inside of the device can cause electric failures!

Cleaning of the Blood Pressure cuff

First, remove the rubber tube and to clean the textile cuff.

Wipe or wash the cuff with moistened wipes with a moderate acting (not aggressive) and temperature (max. 30 °C) disinfectant or cleaning agent.Dry on room temperature.

8 Technical specifications

BP measurement method:	Oscillometric with step deflation, Diastolic values correspond to Phase 5 Korotkoff Sounds
BP measurement range:	25 – 260 mmHg (max inflate 300 mmHg)
Pressure TransducerAccuracy:	± 3 mmHg
Pulse Rate Range:	30 – 220 BPM (Beats Per Minute)
Pulse Rate Accuracy:	± 2% or ±3 BPM, whichever is greater
Calibration:	The device should be verified on a yearly interval.
Safety Systems:	Max. inflation pressure is limited to 300 mmHg; Auto safety release valve for power failure. Maximum cuff inflation time is limited to 75 seconds. Duration of blood pressure reading is limited to 130 seconds.
Data Connector:	Mini USBmini-B type connector
Min. Power supply:	2 x 1.2 V AA rechargeable batteries of minimum 2500 mAh capacity or 2 x 1.5V AA high quality alkaline batteries
Size:	Approx. 125 x 70 x 33 mm
Weight:	Approx. 250 g (incl. Batteries)
Clinical Accuracy:	Meets accuracy requirements of ANSI/AAMI SP10:2002(R)2008, EN1060-4:2004 and ISO 81060-2:2009.